“A SINGLE BLINDED RANDOMISED CONTROLLED TRIAL, TO INVESTIGATE THE CLINICAL EFFECTIVENESS OF PRE-FORMED SEMI-RIGID FOOT ORTHOSES, ON PAIN, QUALITY OF LIFE AND THE DYNAMICS OF GAIT OF PATIENTS DIAGNOSED WITH JUVENILE IDIOPATHIC ARTHRITIS (JIA)”.

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ABSTRACT

Introduction - Currently there is limited evidence supporting podiatric treatment of children with JIA. The foot orthoses (FOs) prescribed to JIA children so far appeared to be very expensive and required long time to manufacture before the fitting. This randomised controlled trial (RCT) aimed to determine whether pre-formed FOs that can be prescribed at chair side, impacted on pain, quality of life (primary outcomes) and/or gait-parameters (secondary outcomes) in children affected by JIA.

Methods - The study took place at the Gait Analysis laboratory at Queen Margaret University – Edinburgh and at the TORT Centre, Ninewells Hospital-Dundee. Children with JIA were diagnosed according to the ILAR criteria. Intervention was blinded to the patients. The trial group received Slimflex-plus FOs, with the addition of chair side corrections and the control FOs supplied were made with leather board (1mm thick) only. Both FOs had the same black EVA top cover. Primary outcomes were investigated using validated questionnaires (VAS, CHAQ and PedsQL). Tekscan™ equipment (F-Scan™ and HR Walkway®) measured secondary outcomes in-shoe pressure and force data with and without FOs intervention. Multiple foot strikes and repetitive gait patterns were compared pre and post-treatment. Primary and secondary outcome measures were recorded at baseline, 3rd and 6th month's period.

Results - Sixty children were recruited; 48.3% (n=29) control and 51.7% (n=31) active treatment group. Within the control group 20.7% (n=6) of patients were male. Within the active treatment group, 29% (n=9) subjects were male. Age ranged between 5 to 18 years, median age for the control group was 11 (range=12.90) and for the trial group were 11.50 (range=12.11). In order to attribute any effect solely on the FOs intervention, details of changes of medication and/or new joint injections were recorded during the trial. In the control group 65.5% (n=19) were considered to be prescribed with stable medications. Similarly, amongst children receiving active treatment 74.2% (n=23) were deemed to be taking stable medications. Overall, 99.4% (n=179/180) appointments were completed, only one subject did not attend the 6 month session. Significant improvement was identified in the primary outcomes favouring active treatment with regards to pain and quality of life measures: VAS ($p<0.05$); CHAQ ($p<0.05$); PedsQL paediatric-generic ($p<0.05$) Peds paediatric rheumatology ($p<0.05$); PedsQL parent-generic ($p<0.05$); PedsQL parent-rheumatology ($p<0.05$). In all these quality of life tools where $p<0.05$, clinical significance was also obtained. Significant differences were also identified between the groups for gait time, stance time, total plantar surface, heel contact, midfoot, 5th metatarsal head and distal phalanx.

Discussion - The results strongly suggest that FOs are effective in improving pain, quality of life and most gait parameters in JIA children. FOs can be customised at chair-side so JIA children can receive immediate podiatric benefit from the same day of the biomechanical assessment. Compliancy rate proved to be extremely high confirming that the podiatric treatment is well accepted by JIA children.

Conclusion - Primary and secondary outcome's results, strongly support the use of FOs in the treatment of JIA children, which highlights the important role of the podiatrists within the multidisciplinary team in paediatric rheumatology.

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Grazie

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Chapter 1: Introduction

In this thesis the clinical management of children who present with Juvenile Idiopathic Arthritis (JIA) in the lower limbs were researched. At present, there are no guidelines available for practitioners to effectively treat children diagnosed with JIA with the use of FOs. This randomised controlled trial (RCT), carried out with patients recruited in Scotland, (Edinburgh Royal Hospital for Sick Children, and Ninewells Hospital - Dundee) were investigated the effectiveness of foot orthoses (FOs) in reducing pain and improving the quality of life for JIA children. FOs have been widely used by podiatrists to treat different pathologies in adults and children. The use of pre-formed semi-rigid FOs may represent a cost effective option, available for practitioners within the NHS and private practice. In addition, off-the-shelf devices can easily be customised by the podiatrist with the appropriate use of corrections and special materials, to improve the patient's foot functional need. These types of FOs are becoming more and more popular compared to the Plaster of Paris (POP) custom-made FOs, because there is no need of special laboratories and machines to complete the manufacturing process. All the equipment required for manufacturing a custom-made FOs are often not available due to financial restrictions, limited space and/or health and safety issues. The time required to manufacture a custom-made FOs is significantly longer compared to the off the shelf device. Recent studies in adults and children which investigated the differences between off-the-shelf and custom-made FOs, have shown a similar efficacy in improving pain levels and biomechanical pathologies. The limited research available at present in JIA podiatric management reported that the custom-made FOs used for the trials was very expensive and that it took almost two months before the fitting appointment was made. In contrast, pre-formed semi-rigid FOs have the significant advantage that they can be supplied to the children on the same day as the initial biomechanical assessment. It can be argued, that if fitting appointments are postponed for long periods of time, it could have a negative effect on the condition of joints and may increase the pain suffered by JIA children. As a result, the multidisciplinary team follows an early treatment approach in an attempt to minimise long term deformities. Therefore, the prescription of off-the-shelf FOs would be in line with the mentioned approach to current treatment.

1.1. Juvenile Idiopathic Arthritis

JIA is the most common chronic rheumatic disease in childhood and adolescence and may cause short-term and long-term disability (Ravelli and Martini 2007). According to a Cochrane review, JIA can be diagnosed in children up to the age of 18 years (Takken et al. 2008). In the UK specifically, the prevalence is approximately 0.65 per 1000 children (Manners and Bower 2002) with a more general worldwide incidence of between 0.07 and 4.01 per 1000 every year (Hendry et al. 2008; Karmazyn et al. 2007). Previous research which investigated controlled quantitative gait analysis in JIA recorded significant differences compared to healthy children in recorded kinematics and temporal data (Brostrom et al. 2007). Evidence from two-cross sectional studies highlights that children with arthritis are physically less active compared to healthy children (Takken et al. 2008).

The provision of health care to JIA has been reported to be particularly challenging (Hazel et al. 2010; McDonagh 2007). Significant advances have been made lately with regards to new treatments, medications and research. A multidisciplinary approach to treat young arthritic patients has been reported to be necessary by Hazel et al. (2010). As in most clinical cases, successful outcomes with symptomatic children often depend on the single practitioner's ability to communicate effectively with the child and the parent. However, different therapists involved with the care of arthritic children should all be part of a united team, working together and communicating constructively to reach the best care for the patient (Hazel et al. 2010). Initially the main aim for the multidisciplinary team should be to relieve pain and discomfort, to reduce joint inflammation, to promote function and prevent deformities. With regards to long term care the focus should then concentrate on encouraging normal growth and development, while reducing possible side effects related to the disease and its treatment (Szer et al 2006).

Short and long term interventions are extremely important aspects, FOs may help in the reduction of pain, promote better joint alignment and function that could diminish the risk in developing deformities; additionally, through better bone and joint alignment FOs effect may contribute to normal growth and development.

Multidisciplinary team work may encourage JIA children to cope independently thorough the difficult transition into adult life and enable them to achieve their true potential in life (McDonagh 2007). It can be argued that in most of these publications, podiatrists are not considered to be part of multidisciplinary paediatric team. None of the authors referenced above considered or questioned what might be the benefits that podiatrists could bring into the multidisciplinary team. Sadly, this may be related to the lack of recognised evidence to support podiatric intervention available at present. This multicentre RCT will provide new research on the possible benefit and the potential role of podiatrists within the paediatric rheumatology teams.

1.2. Lower Limb Problems in JIA

The joints in the lower limbs are the most commonly affected in JIA children (Szer et al 2006). It is extremely important for practitioners to thoroughly examine these joint conditions, as symptomatic joints may result in antalgic gait (Hendry et al. 2008). It often happens that painful joints may generate compensation in children's walking during the normal gait cycle. This could have an impact on normal ambulation and possibly change the time mechanics of initial contact phase, mid-stance and/or propulsion phase. As the child may experience pain from a young age, abnormal walking habits may be adopted unconsciously to prevent pain (Thomson and Volpe 2001). A descriptive study of foot problems with 144 JIA children reported that ankle joint limitation was frequently diagnosed, although unrelated to the specific JIA subgroup (Spraul and Koenning 1994). Podiatrists could intervene at the early stage of the pathology with corrective FOs and specific exercises to prevent and improve abnormal biomechanics. However, podopaediatric care is currently limited within NHS paediatric hospitals.

If the hip becomes affected, it may results in a position of flexion and excessive internal rotation (Bresnahan 2002). This may be exacerbated if the child has not been mobile during the active phase of the disease; therefore, fixed flexion deformities may become noticeable during walking. During biomechanical assessments, practitioners are also likely to find weaknesses at the hip muscles as a result of reduction of activity level (Thomson and Volpe 2001). The lack of extension movement directly affects the child's normal stride. The presence of active disease in the lower limbs results in

overall joint limitation, an increase of double support time to minimise active joint demand, and reduced walking speed and step length (Hartmann et al. 2010; Hendry et al. 2008). The recent clinical study carried out by Hartmann et al. 2010 also reported that the JIA children tend to present with a 'crouch-like gait' with distinctive hyper-flexion in the hip and at the knee joint. In addition, significant reduction in ankle plantar flexion was found in the 36 subjects recruited in this study. The study concluded that physiotherapy and sports therapy intervention may be recommended, and that further studies are necessary to advance JIA clinical management. Even in the recent publications by Hartmann et al. 2010, the input that a podiatrist could bring to the care of JIA children is not even considered or mentioned as an alternative option. This fact confirms that podiatrists need to prove the importance of their clinical skills and use current research to develop and justify their role within the paediatric rheumatology team.

If the knees are involved with active disease, flexion abnormalities may be diagnosed. Nowadays if a joint is inflamed and painful, the child is encouraged to remain as active as possible to prevent muscle strength reduction and prolonged antalgic gait (Thomson and Volpe 2001). In addition, in JIA children apropulsive gait is often seen, usually related to metatarsalgia (inflammation of metatarsal heads), which can possibly have a negative impact on the amount of dorsiflexion at the ankle joint and reduce calf muscle power and flexibility (Thomson and Volpe 2001). Podiatrists are able to diagnose and effectively treat metatarsalgia by using deflecting-cushioning materials and other orthotic devices (Durham 2007). It can be argued that according to Durham (2007) patients diagnosed with metatarsalgia should be referred directly to podiatrists as soon as the symptoms appear, rather than waiting for a prolonged period of time which may lead to an increase in pain and further complications.

Leg length discrepancy may occur as a result of growth or enthesitis issues and it is not uncommon in JIA children (Simon et al. 1981). In this quite dated study, it has been reported that particularly JIA oligoarthritis patients are more likely to develop lower limb asymmetry. In the early stages of the disease, the affected leg is usually longer. As a natural compensation to prevent scoliosis and tilted hip, the child tends to flex the knee and force it into a valgus position. Usually the subtalar joint (STJ) excessively pronates on the longer leg in attempt to compensate the limb asymmetry. Without

treatment, these positions may become fixed (Simon, Whiffen and Shapiro 1981). Practitioners should always check the presence of asymmetry in length of limbs, as it can result in flexion deformity and pain in the foot, ankle, knee and/or hip level (Szer et al 2006).

JIA patients may have a lower aerobic capacity. This appears to be directly related to foot impairments, including joint pain, stiffness and deformities that can alter walking patterns; therefore, sharply reducing physical activities compared to healthy children (Broström et al. 2002). This study may favour and justify the intervention by the podiatrist to improve gait related issues, although it does not explain specifically what type of devices can be effective to improve biomechanical pathologies. In a more recent publication by Hendry et al. 2008, it appears that foot problems are common in JIA, with a prevalence of over 90%. DMARD[1] and biological therapies are often prescribed to control active joint disease and pain. In addition, JIA children with gait abnormalities and active foot disease were referred directly for podopaediatrics care (Hendry et al. 2008). It can be argued that encouraging results for the role of podiatrists within JIA children were outlined in this small survey; on the other hand, only 10% of the audited patients received podiatry foot care intervention in the previous 12 months.

Finally, the authors also reported that multidisciplinary intervention should be required in the paediatric rheumatology team and that more research is needed to prove the valuable input for podiatric intervention (Hendry et al. 2008). This thesis will investigate the use of FOs with its effects on symptoms and gait in JIA children with problems in the lower limbs.

1.3. Foot Orthoses in JIA

Foot orthoses (FOs) have been used for many years by podiatrists to improve gait abnormalities and prevent deformities (Evans 2003; Landorf and Keenan 2000; Selby-Silverstein et al. 2001). In children, FOs have been found to improve parameters of gait; however, little research has been carried out on subjects with JIA (Sullivan 1999).

DMARD: Disease-modifying anti-rheumatic drug.

Currently there are no guidelines available for podiatrists to treat JIA children with the use of FOs. At present, only one article was found which investigated foot orthotic management in JIA (Powell et al 2005). The authors investigated the efficacy of custom orthotics in improving pain and functional status in children with JIA. However, the custom made orthoses tested in this small study are very expensive and require specialised laboratory equipment and materials to dispense.

In the survey published by Hendry et al. 2008, seven of the ten children audited were diagnosed with polyarticular JIA. After biomechanical assessment, STJ pain, pes-planovalgus and digital pathologies were diagnosed. Participants were provided with footwear advice, orthotic therapy, silicone digital-splints, and strengthening exercises. The podiatry care was aimed at correcting biomechanical problems and improving pain by using customised FOs, splints and exercises. Final results showed that the overall clinical management of JIA appeared to be 'good', however, foot related problems and abnormal gait patterns unfortunately still persisted in some participants (Hendry et al. 2008). This negative feedback on the podiatric intervention may be attributed to the different casting techniques and orthotic manufacturers. In addition, each child had to wait between one and two months for their fitting, which may have had a negative effect on their gait and prolonged symptoms. Current podiatry practice aims to intervene as early as possible to reduce the risk of damages and developing deformities; hence, delay in supply of FOs does not comply with the methods reported in the survey published by Hendry et al. (2008). The results in this survey also showed that review appointments were carried out between one and six months from the fitting appointment. It can be argued that the review gap may be too long because the podiatrist should usually follow the progress of the patient more regularly. Finally the author reported that more extensive research is required to justify the role of FOs in the field of paediatric rheumatology (Hendry et al. 2008).

Higher cost custom-made FOs requires longer time for the manufacturing process compared to off-the-shelf devices. Time and costs are extremely important issues that have been taken into consideration in this RCT. These much cheaper pre-formed semi-rigid FOs will be prescribed to the recruited JIA children on the day of the initial visit. During the initial consultation, chair side modifications will also be applied to the trial

patients in order to customise the devices to the individual biomechanical needs. This thesis will explore the feasibility of FOs intervention in JIA.

1.4. Research Problem and Hypotheses

1.4.1. Research Problem

Modern modular foot-orthoses systems allow an integration of the cost and efficiency benefits afforded by the use of pre-formed semi-rigid FOs components, while simultaneously allowing a high degree of individualisation of prescription. Such systems, while popular, still remain unproven. Recent studies in paediatric rheumatology have made a contribution in developing guidelines with regards to pharmacological intervention in arthritic children. In addition, specific drug therapy protocols have been published to effectively help general practitioners, physiotherapists and ophthalmologists to successfully treat children with JIA patients (BSPAR 2006; Hull 2001; NICE guidelines 2002). A Cochrane systematic review on treatment of pes planus, highlighted that children with JIA were excluded as a group from most of the studies (Ashford et al. 2005).

At present little evidence exists for the podiatric management of children affected by this disabling pathology, especially for orthotic management. This thesis will provide evidence to support the use of readily available off-the-shelf FOs in treating JIA children.

1.4.2. Research Question

How effective is the podiatric intervention using pre-formed semi-rigid FOs in improving pain level and quality of life in JIA children?

1.4.3. Research Aim

The aim of this study is to investigate the effectiveness of commonly prescribed pre-formed semi-rigid FOs in children diagnosed with JIA.

1.4.4. Research Objectives

1. To evaluate the current literature with regards to the effectiveness of pre-formed semi-rigid FOs in JIA children.
2. To carry out a survey to investigate if podiatrists are likely to treat JIA children in Scotland and to determine what devices are most likely to be prescribed.
3. To determine the effects of pre-formed semi-rigid FOs on pain in paediatric rheumatology globally.
4. To study the effects of pre-formed semi-rigid FOs on quality of life in paediatric rheumatology using the PedsQL™ Paediatric (inventory) - version 4.0 for children and parents.
5. To study the effects of pre-formed semi-rigid FOs on quality of life in paediatric rheumatology using the PedsQL™ Rheumatology Module – version 3.0 for children and parents.
6. To investigate the effects of pre-formed semi-rigid FOs using the child health assessment questionnaire (CHAQ).
7. To analyse the quantitative kinematic and kinetic parameters when barefoot, with shoes, and with shoes with orthoses.

1.4.5. Hypotheses

1. FOs reduces global pain using VAS on children diagnosed with JIA.
2. FOs improves quality of life in paediatric rheumatology using the PedsQL™ Paediatric (inventory) - version 4.0 for children and parents.
3. FOs improves quality of life in paediatric rheumatology using the PedsQL™ Rheumatology Module – version 3.0 for children and parents.
4. FOs improves quality of life in using the child health assessment questionnaire (CHAQ).

1.5. Outline of the Thesis

1.5.1. Chapter 2: Critical Appraisal

This chapter will provide up-to-date evidence on epidemiology, aetiology, pathology and clinical features in the lower limbs (hip, knee, foot) in JIA children. In addition, the current treatment of JIA will be presented, as well as details of normal and pathological gait in JIA will be explained. Furthermore, comparison between custom made and off-the-shelf devices used will be provided. Finally, a comprehensive literature review on the questionnaires used to investigate pain and quality of life will be available for the reader.

1.5.2. Chapter 3: Methods – Instrumentation & Pre-Tests

This section will present the methods used to record plantar foot pressure measurements during gait analysis with JIA children. Also in this chapter calibration details and repeatability and reproducibility studies will be provided on the HR Walkway™ and the F-Scan® systems.

1.5.3. Chapter 4: Methods – Randomised Controlled Study

This chapter will provide information about the research procedures such as recruitment, inclusion exclusion criteria, justifications of methods and the type of podiatric interventions provided for the RCT study. Finally, data collection and statistical method adopted will be presented.

1.5.4. Chapter 5: Results

In this chapter, results will be presented for both control and trial groups. Data analysis on patient's demographics, pharmaceutical intervention and joint symptoms will be reported. Then statistical analysis will be carried out in order to explore data obtained from the VAS, CHAQ and PedsQL questionnaires. Finally, secondary outcomes parameters results will be presented.

1.5.5. Chapter 6: Discussion

This chapter will discuss the findings related to primary and secondary outcomes in relation to published work and practice. Also the strengths and the limitations of the study will be discussed.

1.5.6. Chapter 7: Conclusions

This last chapter will summarise the main findings emerging from this thesis and highlight the role for podiatrists with regards to FOs management in JIA and the potential role in the paediatric rheumatology team.

1.6. Definition and Abbreviation

1.6.1. Definition

Occasionally different researchers may not have uniform terminology; therefore, it may arise in controversial interpretation of literature and/or results in this thesis. To avoid any misinterpretation of the content of this extensive study, please find below a list of terms used with their related meanings:

- **Rearfoot:**

  In this thesis, rearfoot refers to the posterior part of the foot. In some publications authors describe it as the 'hind foot'.

1.6.2. Abbreviation

(-PP): Peak Pressure Values
(-PTI): Pressure Time Integral
CHAQ: Child Health Assessment Questionnaire
FOs: Foot Orthoses
ILAR: International League of Associations for Rheumatology
JIA: Juvenile Idiopathic Arthritis

JRA: Juvenile Rheumatoid Arthritis (term no longer in use, still present in some American publications)

PedsQL: Paediatric quality of life tool, divided into Generic & Rheumatology Module

PRINTO: Paediatric Rheumatology International Trials Organisation

RA: Rheumatoid Arthritis

VAS: Visual Analogue Scale

'*' means p-value < 0.05

'**' means p-value < 0.01

Chapter 2: Critical Appraisal

2.1. Epidemiology

In children JIA is diagnosed up to 18 years of age (Takken et al. 2008). Studies conducted in developed countries have reported a prevalence for JIA of between 0.16 and 1.13 individuals per 1000 and it appears to be more common in girls with a female to male ratio of 3 to 2 (Yang 2008). Other researchers report that prevalence varies between 16 and 150 per 100 000 (Szer et al 2006). An epidemiological study on JIA carried out in the Nordic countries reported an incidence on 15/100,000 children/year (Berntson et al. 2003). Specifically in the UK the prevalence is approximately 0.65 per 1000 children (Manners and Bower 2002) with a more general worldwide incidence of between 0.07 and 4.01 per 1000 every year (Hendry et al. 2008; Karmazyn et al. 2007). It can be argued that the prevalence of this disease is underestimated (Ravelli and Martini 2007). According to NICE guidelines (2002) JIA is a relatively rare disease, with an estimated incidence in the UK of 0.1 per 1000 children, equivalent to 1000 new cases per year. The prevalence is in the order of 1 per 1000 children, so about 10,000 children in the UK are currently affected (NICE 2002). Finally, it appears that different authors seems to report quite different prevalence and incidence data.

In 2003 a longitudinal, prospective, population based study with JIA patients involved twenty doctors in Iceland, Norway, Sweden, Denmark, and Finland. Data collection included the incidence of cases reported over a period of 1.5 years, beginning July 1, 1997. This study showed that in the whole group of 315 patients, the incidence rate was 15 per 100,000 children / year (Berntson et al. 2003). On the other hand, a more dated community-based survey carried out in Australia outlines the prevalence of 400 per 100 000 of school children (Manners and Diepeveen 1996). The authors also claim that worldwide the number of undiagnosed children with JIA may be much higher than the cases actually diagnosed so far (Manners and Bower 2002; Manners and Diepeveen 1996).

Finally, the progression of knowledge in paediatric rheumatology and the development of new technologies should help in reducing the number of misdiagnosed children,

which will allow earlier intervention and hopefully this will lead to better JIA outcomes.

2.2. Aetiology of JIA

The causes of juvenile idiopathic arthritis are still not clearly understood but appear to be related to both genetic and environmental factors (Cassidy and Petty 2005). The term idiopathic stands for unknown cause. In this disease, the immune system mistakenly targets the synovium, the tissue that lines the inside of the joint. In autoimmune diseases, the immune system fails to distinguish between self-antigens and foreign antigens. As a result, an immune system response is generated against some self-antigens, resulting in tissue damage. The synovium often reacts by producing excess fluid (synovial fluid), which may lead to swelling, pain and stiffness. This autoimmune disease can be difficult to control because the inflammation process can often spread to the surrounding tissues, eventually damaging cartilage and bone. Many immunological abnormalities, such as the inflammatory synovitis in JIA, are similar to that seen in adult rheumatoid arthritis (Szer et al 2006). The synovium may present with hyperplasia of the lining layer and an infiltration of the sub-lining layer with mononuclear cells, including T cells, B cells, macrophages, dendritic cells, and plasma cells (Gregorio et al. 2007; Wedderburn et al. 2000). The inflammatory process leads to pannus formation[2], with cartilage and bone erosions mediated by degenerative enzymes, such as metalloproteinase (Hashkes and Laxer 2005). Even though the true cause of this autoimmune disease have not been yet fully clarified, the next section will explain in more detail the pathology and the different clinical features that practitioners are likely to encounter during a biomechanical assessment.

[2] Pannus: fluid and immune system cells that accumulate in the synovium. It usually appears as thickened synovial tissue. It produces harmful enzymes that destroy nearby cartilage, aggravating the area and attracting more inflammatory white cells; thereby perpetuating the degeneration process within the joint.

2.3. Pathology of JIA

JIA is the most common chronic rheumatic disease in childhood and adolescence and it may cause short-term and long-term disability (Ravelli and Martini 2007). JIA children can develop symptoms in many areas of the body, especially extremities (hands and feet) but inflammation can often occur also in the eyes (uveitis) which may lead to visual impairments (BSPAR 2006).

Juvenile idiopathic arthritis is a term that describes different clinical subgroups. Each subgroup presents with unique clinical signs, symptoms and in some cases unique genetic background (Ravelli and Martini 2007). In order to successfully treat children affected by JIA, multidisciplinary effort is often required. As previously mentioned, the International League of Associations for Rheumatology (ILAR) recently proposed a new classification system in an attempt to reduce the international differences in defining and diagnosing JIA. This relatively new classification system includes seven JIA subtypes:

1. **Systemic Arthritis**

   Arthritis with, or anticipated by, daily fever for at least 2 weeks' duration; that must be recorded for at least 3 days, and must coincide with one or more of the following:

   - Evanescent, non-fixed, erythematosus rash.
   - Generalised enlargement of lymph node.
   - Splenomegaly and/or Hepatomegaly
   - Serositis.

     Exclusion: a,b,c,d *(see below)*

   This subgroup is usually equally found in boys and girls, and it does not appear to have a preferential age at onset. In order to diagnose this subtype of JIA, children present with quotidian fever for at least 2 weeks. In addition, one or more of the following conditions must be encountered: typical evanescent, non-fixed

erythematosus rash, hepatomegaly or splenomegaly, generalised lymphoadenopathy or serositis. Abdominal discomfort and myalgias can be frequent during high peak fever. Systemic arthritis is usually found to be symmetrical and polyarticular (Ravelli and Martini 2007). Laboratory tests highlight the presence of leucocytosis, a very high erythrocyte sedimentation rate (ESR), C-reactive protein concentration and thrombocytosis. Anaemia is often diagnosed along with systemic arthritis which is usually different and more severe than adult rheumatoid arthritis (RA). These subgroups are rarely diagnosed in adults and are usually are defined as Still's disease. Approximately 5-8% of patients within this subgroup develop a life-threatening complication known as macrophage activation syndrome (Ravelli et al. 2005). This syndrome can be recognised by a sudden onset of fever, pancytopenia, hepatosplenomegaly, liver complication and coagulopathy with haemorrhagic signs. Laboratory investigation shows raised triglyceride concentration, low sodium concentration and high concentration of ferratin (Ravelli 2002). Early recognition and intervention of macrophage activation syndrome could improve outcomes.

2. **Oligoarthritis**

Arthritis is diagnosed in 1-4 joints during the first 6 months of the disease. This group is subdivided in

- ***Persistent Oligoarthritis:*** upset no more than four joints throughout the course of the disease.
- ***Extended Oligoarthritis:*** upset a total of more than four joints after the first 6 months of disease

Exclusion: a,b,c,d,e *(see below)*

This subgroup is characterised by arthritic changes that affect four or less joints during the initial six months of the disease. This form of arthritis features asymmetric and early onset (usually before six years old) arthritis. Oligoarthritis mainly affects the knees and ankle joints. Symptoms include pain, stiffness and/or swelling in the joints (Brescia 2008). This disease appears to occur more often in females, with a high frequency of positive ANAs (Antinuclear Antibodies).

Children that present with oligoarthritis are likely to encounter iridocyclitis[3] and this can affect up 30% of patients. The onset of iridocyclitis (also called uveitis or iritis) may be totally asymptomatic and one or both eyes can be affected. Most patients are diagnosed with iridocyclitis during the first 5-7 years after onset. Children should be screened periodically by ophthalmologists (Brescia 2008; Ravelli and Martini 2007). These groups are rarely present in adults; however, iridocyclitis is commonly encountered with some HLA alleles. In addition ANAs is found in up to 70-80% of children (Ravelli and Martini 2007). According to the ILAR classification, the oligoarthritis group is subdivided into:

a) **Persistent Oligoarthritis:** if no additional joints are affected over a period of time, it is called persistent Oligoarthritis. This condition is a milder version of the disease.

b) **Extended Oligoarthritis:** if more than four joints are involved after the first 6 months of disease. This subgroup represents the same disease, however, the outcome can be more severe. High sedimentation rate results would indicate the presence of this subtype, which would usually involve the upper limb joint also (Curtis and Rea 2007; Hull 2001; Thomson et al. 2002).

3. **Rheumatoid – Factor-Positive Polyarthritis:**

- Arthritis affecting five or more joints during the first 6 months of disease; tests for RF is positive.
  Exclusion: a,b,c,e *(see below)*

According to the ILAR classification, this subtype of JIA affects five or more joints during the first six months of the disease and IgM RF[4] is found in a blood test on at least two occasions, more than three months apart. Young girls are more commonly diagnosed with this phenotype than young boys and usually children present with symmetric Polyarthritis. Symptoms include swelling or pain of small

[3] Iridocyclitis: a chronic, non-granulomatous, anterior uveitis that involve the iris and the ciliar part of the eyes. It has the potential to cause severe visual impairment and be present with or without active joint symptoms.
[4] IgM RF Immunoglobulin M Rheumatoid Factor

joints such as hands and feet. Occasionally ankles, knees, hips and neck are reported to be painful as well (Brescia 2008; Miller 2008; Ravelli and Martini 2007). Children may present with high fevers, skin rashes, and internal organ impairment such as of the heart, spleen or liver. This subtype appears to count for 20% of all JIA children (Miller 2008). Rheumatoid nodules frequently appear within the first year of the disease in anatomical areas, such as elbows and forearms (Ravelli and Martini 2007).

4. **Rheumatoid-Factor-Negative Polyarthritis:**

- Arthritis affecting five or more joints during the first 6 months of disease; tests for RF is negative.
  Exclusion: a,b,c,d,e *(see below)*

This subgroup is diagnosed when arthritic changes occur in five or more joints during the first six months of the disease in the absence of IgM RF. This subtype is less defined compared to the previous subtype, however, it is the most heterogeneous subtype (Szer et al 2006). According to Ravelli and Martini (2007), three different subtypes can be distinguished: the first one appears to be very similar to the early onset of oligoarticular JIA, with the exception that the number of joints affected over the past first six months. The second phenotype is a form that closely resembles the adult onset RF negative RA with the difference that it features symmetric synovitis of large and small joints in school age children. ANAs results are negative and increased values of ESR[5] are often found. The third subgroup is known as dry synovitis, which does not appear to have swelling of joints; however, children are likely to present with flexion contraction and slightly raised ESR values. Outcomes are generally negative with poor response to treatments and the deterioration of joints.

[5] ESR: Erythrocyte Sedimentation Rate. It is the rate at which red blood cells precipitate in a period of 1 hour.

5. **Enthesitis Related Arthritis**:

- Arthritis and Enthesitis or
- Arthritis and Enthesitis with at least 2 of the following:
  - Sacroiliac joint tenderness and/or inflammatory lumbo-sacral pain.
  - Presence of HLA B27
  - Onset of arthritis in a male after the age of 6 years.
  - Ankylosing Spondylitis, Enthesitis Related Arthritis, and Sacro-iliitis with inflammatory bowel disease, Reiter's syndrome or acute anterior uveitis in a first-degree relative.

  Exclusion: a,d,e *(see below)*

This subgroup is predominantly diagnosed in males after the age of six years who present with enthesitis and arthritis signs. Evidence shows that children with enthesitis-related arthritis are prone to have HLA-B27[6] positive (Szer et al 2006). Children usually report symptoms at the calcaneal insertion of the Achilles tendon, plantar fascia and tarsal area. With the progression of the disease, sacroiliac and spinal joint may become symptomatic as well, resulting in signs similar of ankylosing spondylitis. It is generally accepted that this subgroup mainly affects the lower limbs and that pain is often remitting and mild. Approximately 50% of children have four or fewer joints affected during the entire course of the disease. ILAR classification for enthesitis-related arthritis has recently been criticised because reactive arthritis and psoriatic arthritis are not seen as part of juvenile spondylo-arthritides, and arthritis of inflammatory bowel disease is confined to being only a descriptor of the disease (Burgos-Vargas et al. 2002; Burgos-Vargas 2002).

6. **Psoriatic Arthritis:**

- Arthritis and Psoriasis or
- Arthritis and at least 2 of the following

[6] HLA-B27 is a blood test to look for specific protein found on the surface of white blood cells. The protein is called human leukocyte antigen B27 (HLA-B27). HLAs are proteins that help the body's immune system tell the difference between its own cells and foreign, harmful substances (Medline Plus 2007).

- Dactylitis
- Nail Pitting or Onycholysis
- Psoriasis in a first degree relative

Exclusion: b,c,d,e *(see below)*

According to ILAR classification, in order to diagnose this JIA subgroup the simultaneous presence of arthritis and psoriatic rash need to be present. If only the psoriatic rash is not present, two of the following conditions need to be diagnosed: nail pitting, dactylitis[7] and family history of psoriasis in a first-degree relative (Ravelli and Martini 2007; Thomson et al. 2002). Few controversial opinions have been expressed regarding this specific subgroup, clinical and laboratory evidence questioned the appropriateness of its inclusion in this classification (Martini 2003; Petty 1994). Most children present also with: early onset of the disease, asymmetric oligoarthritis, iridocyclitis and ANAs positive. This features are very similar to the oligoarthritis subgroup, however, the main difference is that children with psoriatic arthritis have a greater chance of developing dactylitis and arthritic changes in small and large joints compared to oligoarthritis patients. Finally the prognosis of psoriatic arthritis, as defined according to ILAR classification, is not yet being established (Ravelli and Martini 2007).

7. Undifferentiated Arthritis:

- Arthritis that does not fulfil inclusion criteria for any category, or that is excluded by fulfilling criteria for more than one category.

According to ILAR criteria, it does not represent a separate subgroup. It has been introduced to include all children who do not satisfy the previous inclusion criteria for any subgroups or who can be identified in more than one subgroup. The evidence based reports shows that in some cases, children with definite diagnosis could wrongly be included in this subgroup (Burgos-Vargas 2002; Tsitsami et al.

[7] Dactylitis: swelling of one or more fingers that extend beyond the joint margins.

2003). Following the suggestion of revision of exclusion criteria, few changes were made and incorporated into the second revision of the ILAR criteria (Burgos-Vargas 2002; Petty 1994; Petty 2001; Tsitsami et al. 2003).

Exclusion Criteria for the Classification of JIA

a. Psoriasis in the patient or a first-degree relative
b. Arthritis in an HLA B27 positive male with arthritis onset after 6 years of age
c. Ankylosing spondylitis, enthesitis-related arthritis, sacro-iliitis with inflammatory bowel disease, Reiter's syndrome, acute anterior uveitis in a first-degree relative.
d. Presence of IgM rheumatoid factor on at least two occasions more than 3 months apart.
e. Presence of Systemic Arthritis.

The rational for classifying JIA children in different groups is to distinguish patients with certain physical manifestations from those without, which lead to better final diagnosis. The main reason why ILAR classification system has been adopted is to make a clinical distinction between different characteristics of every group with common arthritis diagnosis (Petty et al. 2004). The seven distinct groups are united under the umbrella term JIA in which the manifestation of arthritis begins before the age of 16 years. In order to thoroughly diagnose JIA, clinical features (number of joint affected, psoriasis, enthesis and family history of psoriasis or B27- related disease) and laboratory tests (rheumatoid factors, HLA B27) are used as diagnostic evidence. In addition, having a well-recognised classification, which is widely used also internationally, helps paediatric-rheumatology researchers to improve and facilitate the understanding of JIA (Petty et al. 2004).

With regards to prognosis and outcome, recent studies highlight inconsistent and conflicting results which are mainly linked to the subgroup of JIA. Research carried out over the past 10 years shows that only 40-60% of children had inactive disease or clinical remission at follow-up (Oen 2002; Ravelli 2004). A study conducted on 437 JIA children over a period of four years, reported that only 6% of patients had clinical remission of symptoms for at least 5 years (Wallace et al. 2005). It has been reported

that greater severity, extension of arthritis onset and symmetrical disease are common outcomes in JIA children (Ravelli and Martini 2003) although the long term prognosis of JIA still remains uncertain (Wallace et al. 2004).

2.4. Clinical features in the lower limb in JIA

2.4.1. The Hip in JIA

During a biomechanical examination the podiatrist may be likely to encounter flexion deformities of the hip which may have a direct effect in increasing lumbar lordosis as a compensation effect for the hip extension is commonly associated with JIA. Increased lumbar lordosis may become very noticeable with typical protrusion of the buttocks, which could be recognised by the practitioner as the initial signs of unrecognised arthritis at the hip (Szer et al 2006).

The British Journal of Radiology reported a publication that highlights the role of MRI scans in the evaluation of hip joint disease in JIA children (Argyropoulou et al. 2002). The results collected from 28 pathological children, reported that MRI scans are able to reveal early joint involvement and evaluate in detail the extent of the active joint disease. The hip is not a superficial joint, the clinical evaluation for active inflammation may be challenging and imaging can be effective in the evaluation of hip joint involvement in JIA. MRI has been used to evaluate the whole articulation surface and provide accurate details of the synovium, cartilages and bones. This study, suggested that MRI of the hip is a valuable method of assessment of patients with JIA (Argyropoulou et al. 2002). A more recent study published by Nistala et al. (2007) compared the diagnostic performance of clinical assessments against MRI in arthritic hip in 34 JIA children. The results highlight the role of MRI when there is clinical uncertainty between active and damaged hips. However the authors concluded that clinical and laboratory findings are inadequate diagnostic tools for the assessment of hip arthritis when compared with MRI as the gold standard (Nistala et al. 2007). It can be argued that, even if MRI scan seemed to be effective in diagnosing possible arthritis at the hip in JIA, some hospitals may find this option not always cost effective. On the other hand, if MRI scan may be taken at an early stage of the disease, it can be seen as

a valid investigative tool to encourage early diagnosis of the disease and immediate pharmaceutical and physical intervention.

Finally in order to provide accurate clinical features during the hip examination, strength tests of the hip adductor, abductor, flexors and extensor should be performed at the same time (Szer et al 2006). The clinician should refer back to the muscle strength grading chart and record the finding in the clinical records. The patient must be positioned against gravity at all time prior to carry out the tests[8] (Brown et al. 2007).

2.4.2. The Knee in JIA

The knee appears to be one of the most commonly affected joints in JIA and extension and flexion limitations are often observed (Cakmak and Bolukbas 2005). Children who suffer from arthritis in the knee often exhibit a unilateral involvement which may lead to atrophy of the quadriceps muscle of the symptomatic leg. Muscle weakness and reduction in strength have been reported to have a negative impact on the level of physical activity in children with JIA (Lelieveld et al. 2008). Podiatrists are able to recognise the typical signs of antalgic gaits, therefore, prompt biomechanical and physical therapy intervention may be proven valuable to help JIA children to reduce knee pain.

The knee in JIA may appear to have either localized or generalised swelling. In the first instance, fluid may be accumulated inside one or more bursae of the knee (pre-patellar, suprapatellar, infrapatellar, pes anserine, or gastrocnemious-semimembranous – 'Baker cyst'). In the second instance the fluid may be found within the joint itself or extended into the surrounding soft tissues as well. The suprapatellar bursa tends to be linked with the articular synovial space and it seems to be the most common bursa that becomes swollen and painful in arthritic children. Similarly the Baker Cyst directly

[8] Muscle strength grading chart (Brown, Hislop, and Montgomery 2007):

Muscle Gradations	Description
5 or normal	Complete range of motion against gravity with full resistance
4 or good	Complete range of motion against gravity but not full resistance
3 or fair	Full range of motion against gravity but no resistance
2 or poor	No joint motion against gravity but complete motion when gravity eliminated
1 or trace	Evidence of some muscle contractility but no motion at all
0 or zero	No evidence of contractility

communicates with the joint creating a synovial pouch behind the knee (Szer et al 2006).

Patients with patellofemoral pain syndrome may present with anterior knee pain that typically occurs with activity and often worsens when they are descending steps or hills. It can also be triggered by prolonged sitting and knee hypermobility (Cutbill et al. 1997; Fulkerson 2002; Junh 1999). Clinically, an uneven sensation during extension and flexion may be noticeable. Pain is often reproduced by palpating the medial under-surface portion of the patella while contracting the quadriceps muscle (Szer et al 2006). In addition, the clinician often performs the test commonly called 'patella apprehension test'. According to Ahmad et al (2009), the moving patellar apprehension test is an accurate physical examination technique which if performed and interpreted correctly, is highly sensitive and specific for patellar instability (Ahmad et al. 2009). It can be argued that if carried out in children with JIA this test may be too invasive.

Research on JIA children proved that full extension and 110° flexion are required to sit down and stand up from a chair. If these angles and the strength of the quadriceps are maintained, the child will have a better chance of preserving a correct function of the knees (Cakmak and Bolukbas 2005).

2.4.3. The Foot in JIA

Foot and ankle problems are often diagnosed but relatively neglected manifestation of JIA (Foster et al. 2007; Hendry et al. 2009; Rothschild 1999).

In a retrospective study of 100 children diagnosed with oligoarthritis, overgrowth of the involved extremity occurred in children who developed the disease before the age of 9 with most having overgrowth before the age of 5 which never exceeded 3 cm. The JIA children who developed the disease after the age of 9, however, had rapid premature epiphyseal plate closure resulting in shortening of the limb affected by arthritis (Simon, Whiffen and Shapiro 1981). JIA is a diagnosis of exclusion (Haber et al. 2010). Additional causes of ankle and foot pain that must be considered are: trauma, infection, toxic synovitis, malignant or benign bone lesion, overgrowth and other systemic

rheumatologic diseases. Clinical observation of the associated warmth and redness of a joint is also important (Ilowite et al. 1992). Pain and stiffness is usually worse in the mornings and then it tends to improve with movement and activity, and worsens with inactivity.

In normal conditions, JIA children usually exhibit 20° of dorsiflexion, 50° of plantar flexion (Szer et al 2006). Some small outpunching of synovium may be appreciated around the ankle along with tenosynovitis[9]. Tenosynovitis most often occurs on the extensor sheaths over the dorsum of foot and the peroneus longus and brevis tendons around the lateral malleoli (Haber et al. 2010). Clinically, posterior tibial tendonitis is often present and maybe tender on palpation. According to a research carried out by Rothschild (1999) on JIA children, inflammation can occur in the forefoot, rearfoot, and ankle. Results showed that inflammation at the ankle was found in 51% to 59%, subtalar joint (STJ) in 1% to 13% and finally metatarso-phalangeal joint 49% to 68% respectively (Rothschild 1999).

Another clinical feature used to confirm the diagnoses is joint fluid content. Joint aspiration and synovial fluid examination are useful to rule out other causes of arthritis. The white blood cell (WBC) count can be beneficial in helping to distinguish JIA from an infected joint. Usually, a WBC count greater than 40,000 (cell/mm^3) is associated with infectious arthritis. Patients with JIA may have a much higher WBC (Haber et al. 2010). A recent comparative study on synovial fluid component identified specific proteins which could act as criteria to prevent disease extension and may help to identify children who are at higher risk for recurrent inflammation and progression of JIA disease (Gibson et al. 2009).

Rearfoot and Midfoot Pathology in JIA

Biomechanical pathologies of the foot have been diagnosed directly associated with synovitis of the ankle and rearfoot joints, which has been found in up to 40% of JIA

[9] Tenosynovitis: inflammation of the lining of the sheath that surrounds a tendon. The cause of the inflammation may be unknown, or it may result from: infection, injury, overuse, strain

children across all different 7 JIA subtypes and particularly in 81% of children with systemic onset JIA (Ferrari 1998; Hendry et al. 2008).

Ferrari et al. (2008) reported that varus or valgus rearfoot position is likely to be diagnosed in JIA children; in addition, external factors such as ground reaction forces, knee and hip positions may have a direct effect on the rearfoot. The valgus foot position may be expected to be seen more frequently since the paediatric foot is typically pronated (Ferrari 1998).

On examination swelling at the rearfoot joint may be present. Palpation of the calcaneum may be symptomatic at the insertion point of the Achilles tendon and origin at the plantar fascia (Cassidy and Petty 2001; Szer et al 2006). Significant excessive pronation of the foot is a frequent finding in JIA patients which mostly occurs when synovitis stretches the capsule and ligaments of the STJ and talo-navicular joints and increases calcaneal pressure (Haber et al. 2010). In contrast, a small study conducted by Fairburn et al. (2002) subdivided the 15 JIA children that took part in the study in an attempt to identify clinical pattern during gait analysis. Significant stiffness of the STJ was diagnosed in two children. It must be noticed that this study concluded that despite the initial clinical observations it was not always possible to predict the resultant gait pattern particularly because of the small sample size (Fairburn et al. 2002). In addition, varus deformity can also occur because of synovitis, usually as a compensatory mechanism during ambulation to prevent excessive pressure on the metatarso-phalangeal and STJ (Haber et al. 2010).

According to Szer et. al (2006), in ‘normal’ circumstances JIA children usually appear to have 5° STJ eversion and 5° of STJ inversion at close kinetic chain. Generally at open kinetic chain 2/3 of supination and 1/3 of pronation. However, few studies are yet available on the degree of STJ ROM that should be expected in JIA children. Hendry et al. (2008) reported that 7 of the 10 pilot participants referred were diagnosed with polyarticular JIA and presented a pes-planovalgus foot posture and/or lesser toe deformities, with limited ROM and symptomatic STJ.

On some occasions, children seen at both hospitals in Edinburgh and Dundee, reported discomfort at the metatarsal heads particularly after activity. The arthritic forefoot, which consists of the inter-phalangeal and metatarso-phalangeal joints, creates deforming biomechanical forces that can act on the rearfoot, ankle and ultimately the rest of the body. Clinically the inter-phalangeal or metatarso-phalangeal joint may induce clawing of the toes. In addition to clawing, the inter-phalangeal joints may become dislocated (Melvin and Atwood 1989). Pain and swelling may lead to muscle contractions and eventual phalangeal joint flexion deformities may occur, which could present with the typical hallux valgus or hallux rigidus shape (Haber et al. 2010; Melvin and Atwood 1989).

Szer et al. (2006) report that, clinically the ROM of forefoot abduction and adduction should be respectively 10° and 20°. Conversely, from the images on the Szer et al (2006) textbook, inversion and eversion of forefoot are illustrated instead, which may be misleading for the reader. A possible printing mistake may have occurred. On the other hand, plantar-flexion and dorsiflexion measurements, respectively 45° and 70°-90°, seemed be correctly shown from the Szer et al. (2006) textbook.

During data collection few JIA participants were diagnosed with forefoot varus (FV). This pathology is defined as a static, osseous deformity of the forefoot, where the plane of the metatarsal heads is supinated in relation to the rearfoot, when the STJ is kept into neutral position (Valmassi 1996). The FV is thought to induce increased pronation of the STJ and mid-tarsal joints during midstance phase, in order to allow the medial metatarsals to gain ground contact. This may cause excessive internal rotation of most of the structures of the foot towards its medial side, increasing the tibio-calcaneal angle and pronation. Instead of being a rigid lever during propulsion phase, the forefoot may become a mobile structure generating larger compressive and shear forces transmitted to the surrounding soft tissues (Alonso-Vazquez et al. 2009). All these changes may lead to negative effects on the rest of the foot and to the more proximal joints of the lower limb, which will all have to account for these FV modifications. Patient diagnosed with FV are more likely to complain lower limb pain, swelling, tiredness as

well as problems of balance and coordination impartment (Alonso-Vazquez et al. 2009; Valmassi 1996).

MRI is very useful clinical diagnostic tool particularly used to identify the extension of the synovitis at the talo-navicular joint (Cassidy and Petty 2005). More evidence is required to fully establish clear clinical features of forefoot in JIA which may help clinicians with the clinical management.

2.5. Current Treatment JIA

JIA multidisciplinary management is a vast expanding area of paediatric care in need of research. The goal of JIA treatment is to achieve remission of disease; a combination of pharmacological interventions, physical and occupational therapy, and psychosocial support is required (Wallace 2006). This thesis will help to support the role of podiatric intervention and to encourage other professions to turn to podiatry for cost effective and non-invasive treatment for JIA. The unclear aetiology for rheumatic disease and the paucity of randomised controlled trials leaves practitioners with little evidence upon which to base clinical management (Wallace et al. 2005). However, even if drugs that are able to cure the disease are not available yet, over the past few decades prognosis has improved significantly. New therapies are now available to effectively intervene from lesser to more severe forms of JIA (Magni-Manzoni et al. 2003). The main focus should be to reach complete control of the disease, to maintain the physical and psychological integrity of the child and to prevent any long-term damage into adulthood (Ravelli and Martini 2007). As a result more paediatric rheumatologists are now shifting the method of tackling the disease, from ‘chasing failure approach’ (gradually adding medications according to the symptoms) to a more aggressive medical-pharmaceutical intervention.

2.5.1. Pharmaceutical intervention

Many children that took part to this RCT study were under some sort of pharmaceutical intervention, which was regularly monitored by the rheumatology nurses and consultants. All recruited JIA children had to meet inclusion and exclusion criteria which also related to drugs administration guidelines (please see section 4.2.3 – 4.2.4. for more details). Throughout the clinical trial, pharmaceutical intervention was recorded and cross-checked with parents and clinical records. Any changes in the drug dosage were recorded and monitored over the six months period in order to avoid any misleading interpretation of results. In order to fully understand the methodology adopted to carry out this research project, it is important to provide the reader with more details on what is the current approach adopted by paediatric rheumatology consultants to prescribe drugs and to achieve remission of the disease and symptoms. The following section will discuss in details the pharmaceutical intervention starting from less to more powerful drugs.

Non-steroidal anti-inflammatory drugs (NSAIDs)

Most children newly diagnosed with JIA start with administration of non-steroidal anti-inflammatory drugs (NSAIDs). Just a few NSAIDs are licensed for use in children. The most commonly used include Naproxen, Ibuprofen, Meloxicam and Indometacin. NSAIDs block the COX[10] enzymes and reduce prostaglandins production[11] throughout the body. As a consequence, on-going inflammation, pain, and fever are reduced. In certain conditions like arthritis, two weeks are required before the full benefit of this drug takes effect. NSAIDs tend to be well tolerated and side-effects are less common than in adults with RA (Ravelli and Martini 2007). Less commonly used, Meloxicam[12], an inhibitor of both COX1 and COX2, has proven to be effective and safe (Ruperto et al. 2005). The short and long-term safety and efficacy of meloxicam oral suspension has proven to be comparable with the safety and efficacy of naproxen in the treatment

[10] Cyclooxygenase (COX) is an enzyme is responsible for formation of important biological mediators called prostanoids. Pharmacological inhibition of *COX* can provide relief from the symptoms of inflammation and pain.
[11] Prostaglandins are a family of chemicals that are produced by the cells of the body and have several important functions. They promote inflammation, pain, and fever support the blood clotting function of platelets; and protect the lining of the stomach from the damaging effects of acid.
[12] Meloxicam is a non-steroidal anti-inflammatory drug with analgesic and fever reducer effects.

of oligoarthritis and polyarthritis JIA. The once-daily administration of Meloxicam oral suspension might represent an improvement in the treatment of JIA (Ruperto et al. 2005).

Disease-Modifying Antirheumatic Drugs

JIA treatment includes medications that reduce the progression of joint damage. These types of drugs are called disease-modifying antirheumatic drugs (DMARDs), and they are an important part of an overall treatment plan. Disease-modifying drugs act on the immune system to slow the progression of arthritis. A patient starting a course of DMARDs may take up to 6 months for the drugs to evoke a full response; these drugs are viewed as slow-acting (Pisetsky 1995).

It is not exactly understood how DMARDs work. DMARDs appear to decrease some inflammation though they are not categorized as anti-inflammatory drugs. They are unlike NSAIDs since they do not decrease prostaglandin production, do not directly relieve pain, nor reduce fever. In effect, DMARDs slow the disease process by modifying the immune system in some way. Studies have shown DMARDs to be very effective drugs, with rarely observed serious side effects. Frequent laboratory monitoring helps control the risk of side effects. Once thought to be a short-term treatment, DMARDs are now regarded as a long-term solution to controlling symptoms (Pisetsky 1995).

Methotrexate

Methotrexate belongs to the DMARDs group of drugs. Methotrexate is an antimetabolite, cytotoxic and immunosuppressant administered in the treatment of JIA, rheumatoid arthritis, juvenile dermatomyositis, vasculitis, uveitis and some cases of systemic lupus erythematosus, localised scleroderma and sarcoidosis (BSPAR 2007). The BSPAR[13] reports that Methotrexate is not licensed for use in childhood; however, it is extensively used in medical practice following positive clinical trials results. The published guideline confirms Methotrexate as the first line disease modifying anti-

[13] BSPAR: British Society for Paediatric and Adolescent Rheumatology

rheumatic drug for JIA. Methotrexate may take up to 6-12 weeks to become effective after commencing treatment or a dose increase (BSPAR 2007). The efficacy of 10 mg/m^2 per week of this drug was first established in a well-known controlled trial in 1992 carried out with 127 children (mean age, 10.1 years) who presented JIA for a mean duration of 5.1 years. The favourable findings from this quite dated RCT study, were very encouraging news at the time for clinicians who faced difficulties in managing a child's disease that had previously failed to respond adequately to non-steroidal drugs (Giannini et al. 1992).

Methotrexate is not a cure for JIA but has been proven to help to control the condition by reducing the symptoms and the need for other medicines (BSPAR 2010). When prescribed at higher dosages, methotrexate is a cytotoxic drug, which indicates that it can be destructive to cells and can be used for some forms of cancer. Methotrexate is usually administered once per week either by tablet, medicine or injection. Injections are recommended if a higher dose is required or if tablets induce sickness. It is important that pregnancy be avoided, because methotrexate may cause damage to the unborn child (BSPAR 2010). The Royal College of Nursing published extended guidelines for Paediatric Rheumatology Specialist Nurses, with the intention to provide clinical guidance to JIA children and their parents (RCN 2004).

The Paediatric Rheumatology International Trials Organization (PRINTO) conducted an extensive randomised trial involving 20 countries with the aim to evaluate the efficacy and safety of Methotrexate at an intermediate dosage (15 mg/m2/week) versus a higher dosage (30 mg/m^2/ week) in patients with polyarticular-course JIA whose condition failed to improve while receiving a standard dosage of methotrexate. This multicentre centre trial on 595 patients (followed up for 6 months) concluded that that the level of efficacy of methotrexate in JIA is achieved with parenteral administration[14] of 15 mg/m2 per week and that a further increase in dosage is not directly linked with any additional therapeutic benefit (BSPAR 2007; Ruperto et al. 2004). According to NICE guideline (2002) the DMARD of choice is methotrexate, administered orally or parenterally. The overall response rate to oral methotrexate in polyarticular-course JIA

[14] Parenteral: indicate medication that are administered by injecting a drug directly into a vein (intravenous), muscle (intramuscular), artery (intra-arterial), abdominal cavity (intra-peritoneal), heart (intra-cardiac) or into the fatty tissue beneath the skin (subcutaneous).

is estimated to be 85% in the short term. The evidence base for the effectiveness of alternative drug therapies is poor and no particular therapy stands out as the first choice once methotrexate has failed (NICE 2002).

Biologics

Hashkes and Laxer (2006) strongly state that even if many advances in the treatment of JIA, there is still a lack of evidence for treatment of several disease subtypes. The authors claimed that clinical management plan needs to be specifically adapted, based on the different JIA groups (Hashkes and Laxer 2005). The biologic therapies (etanercept, infliximab, adalimumab, anakinra, abatacept and rituximab) represent one of the latest pharmaceutical options available to treat more difficult cases of JIA. These types of drugs have been proven to be effective in treating inflammatory arthritis (Wallace 2006). The role of biologic therapies in patients with inflammatory joint disease is an evolving area which has significant clinical implications for clinicians. The term 'biologic' indicates a type of treatments created in live cell (biologically active systems). In biologics for inflammatory arthritis, the antibodies or proteins were initially designed to target or disable specific pro-inflammatory cytokines. The first biologic therapies to be developed targeted the pro-inflammatory cytokines tumour necrosis factor alpha (anti-TNFα[15]) and interleukin 1[16] (IL-1receptor agonist). Their use in children however, may generate special problems in JIA children, including the increased risk of infections (especially varicella), how or when to carry out standard immunizations and developmental issues at the central nervous system. The cases of reactivated tuberculosis have been particularly difficult; so all children should have a documented negative TB skin test before starting any biologic therapy. Wallace et al. (2006) reported that flare of disease occurred in most patients (treated for less than 1 year) within 1 month of discontinuing etanercept (longer for infliximab). It can be

[15] TNF: (tumour necrosis factor) is one of many natural inflammatory mediators that can cause disease when it is not regulated. Anti-TNFα therapy for arthritis may generate suppression of inflammatory disease processes and improve clinical results. The aim in anti-TNFα therapy in arthritis patients is to control excess TNF, while limiting associated risks.

[16] Interleukin-1: (IL-1) refers to a group of three polypeptides (interleukin-1 alpha (IL-1α), interleukin-1 beta (IL-1ß) and interleukin-1 receptor antagonist (IL-1Ra)) that play a central role in the regulation of immune and inflammatory responses. Both IL-1α and IL-1β are produced by macrophages, monocytes, fibroblasts and dendritic cells. They form an important part of the inflammatory response of the body against infection.

argued that there is inconsistent evidence of patients with JIA successfully stopping etanercept without flare of disease (Wallace 2006).

According to the guidelines published by the Royal College of Nursing Rheumatology (2009), to date, almost 1.5 million patients have been treated worldwide with anti-tumour necrosis factor alpha (known as anti-TNFα, anti-TNFs or TNF inhibitors). The resultant large volume of research into anti-TNFα therapies initially showed evidence of the safety and efficacy of these therapies for treating RA, but more recently further research also supports its uses for other conditions, such as psoriatic arthritis (PsA) and ankylosing spondylitis (AS) and other long term conditions (RCN 2009). Finally the introduction of biological medications has provided a very important new therapeutic option for the treatment of patients with juvenile idiopathic arthritis, who are resistant to conventional antirheumatic agents (Ravelli and Martini 2007).

The National Institute for Clinical Excellence (NICE) has published in 2002 extended guideline on the use of etanercept for the treatment of JIA. Etanercept is a recombinant human TNF receptor fusion protein that acts competitively to inhibit the binding of TNF to its cell-surface receptor (NICE 2002). Etanercept is licensed for the treatment of active polyarticular-course JIA in children aged from 4 to 17 years old who have responded unsuccessfully, or who are reported to be intolerant to methotrexate. Etanercept is supplied as a twice-weekly subcutaneous injection and may be administered for an indefinite period of time. However, once a child with JIA has had 2 disease-free years, it is common clinical practice for drug treatment to be stopped, even if evidence shows that 30% of children would be expected to manifest symptoms again (NICE 2002).

In the document published by NICE (2002) it appears that only a consultant who regularly treats children and young people with JIA and who manages specialised paediatric rheumatology clinics should prescribe etanercept. In addition, the clinic should have specially trained nurses who regularly teach children and parents how to administer etanercept. Both paediatric rheumatology departments involved in the multicentre trial, where the recruitment of JIA children took place, met the standard set out by NICE (2002). The paediatric rheumatologist consultants and specialist

rheumatology nurses worked closely with children and parents to monitor the pharmaceutical progress of many more aspects directly related to JIA care.

2.5.2. Physiotherapy and Occupation Therapy

Physiotherapy (PT) and occupational therapy (OT) provide valuable support and complement pharmaceutical intervention for treating JIA. Both at the Royal Edinburgh for Sick Children and Ninewells Hospital, PTs and OTs are actively working alongside the consultants and the specialised rheumatology nurses. Treatment of JIA includes education, medical treatment, physical therapy, and occupational therapy (Cakmak and Bolukbas 2005). A multidisciplinary approach is necessary for the successful treatment of JIA. The authors do not mention a possible involvement of podiatrists in the care of JIA. However, they support the participation of paediatric rheumatologists, physiatrists, therapists, psychologists, and dieticians (Cakmak and Bolukbas 2005). It can be argued that suppressing the inflammation is often insufficient to return the child to normal functioning (Malleson 1997). JIA children may develop painful deformities at the joints, not due to damaged joints, but due to inadequate treatment given to the soft tissue contractures that may appear as a consequence of having a painful, swollen joint. Therefore, in the treatment of JIA it is important to involve PTs and OTs occupational therapists in order to commence the appropriate rehabilitation programme in time (Malleson 1997).

PTs and OTs clinical intervention should occur at early stages of the disease, soon after a diagnosis of JIA has been made and pharmacological intervention has started. Treatment should include: assessment and management of pain and functional restriction, reduction of disability using age-appropriate techniques to maintain optimal function, evaluation and teaching of coping skills to improve self-efficacy, education programme to improve compliance and finally providing regular support and referral to the required member of the rheumatology team (Kutcha and Davidson 2006; Szer et al 2006).

In some instances, parents may be inclined to excessively protect their children and limit their activities level, which can affect the proper development of the child's

personality and prevent them from gaining adequate self-confidence and self-esteem. When appropriate, psychological support can be provided (Ravelli and Martini 2007). Children may have problems with teasing at school, bullying, or feeling isolated during sports activities. The therapist's role should include monitoring and assessing the need for any equipment required to enhance physical independency.

The precise roles of PTs and OTs may vary between countries and hospitals. However, in the early stages of the disease, pain is usually the first manifestation that alerts the family to look for medical support. PTs and OTs should encourage the family to supervise the child's functional limitation, both at school and at home, and directly engage in the treatment management by monitoring whether the child complies with the prescribed exercises. Evidence shows that when the family and the child are given the appropriate assistance and support, the level of anxiety decreases. "Adherence" is now the preferred term in the literature, replacing the term "compliance". The term adherence better reflects a more active role for patients in consenting to and following prescribed treatments (Rapoff 2006). The review published by Rapoff and Lindsley (2007) highlighted the difficulties that PTs and OTs usually have to face when coping with JIA treatment. An adherence questionnaire was distributed to 37 parents of children with JIA. The children involved were given medications and range-of-motion exercises, splints, or both. Negative reactions to medications were reported by 43% of parents. On the other hand, parents noted more problems (60%) with prescribed exercises. Children appeared to be complaining, refusing to do the exercises and crying. This review may help to better understand the difficult challenges that PTs and OTs have to face on a daily basis in encouraging self-management JIA (Rapoff and Lindsley 2007).

In conclusion PTs and OTs face a difficult task in treating JIA children. Prolonged physical and psychological support is required and often adherence in treatment can be difficult. Although podiatry does not yet appear to be a valuable part of the multidisciplinary team, certainly PTs and OTs already have an established clinical role in paediatric rheumatology.

2.6. Normal Gait Cycle

It is extremely important for podopaediatrics to be aware of what is a 'normal gait', to be able to diagnose possible pathologies in children's ambulation. The development of an adult-like gait is a constant maturation closely linked with the nervous system, muscle and bone growth. In addition, Volpe (2001) emphasised the idea that the child is not a 'mini adult'. Many parents are often concerned about their children's walking style from noticeable wide base of gait, significant bowed leg, and out-toeing. Most of the developmental milestones in growth should occur by 4-5 years of age (Sutherland 1997; Thomson and Volpe 2001). As a result, the minimum age inclusion criteria, for the recruitment of JIA children in this RCT, were set to start from 5 years old.

Not many clinical trials have been conducted yet to develop models for normal paediatric gait compared to adults, however, Smith et al. (2008) lately carried out a comparison study using three-dimensional foot and ankle motion analysis with 10 children vs. 40 adults. The authors stated that the rearfoot is referenced to the tibia and exhibit three main rockers in the sagittal plane: initially the ankle rocker occurs at heel contact during the first 5% of the gait cycle. The second rocker corresponds to a prolonged dorsiflexion of the rearfoot relative to the tibia. The remaining 15% of stance phase represents the forefoot rocker in which the rearfoot is no longer weight bearing due to gastroc-soleus muscle contraction activity. During the swing phase, ground clearance is obtained thanks to dorsiflexion of the foot and prepares for heel strike. In addition to this quite generalised summary of sagittal motion of a child gait, Smith et al. (2008) reported that STJ eversion during loading is on average of 4° and that STJ inversion instead occurs in late stance and continues through push-off. With regards to the sagittal motion of the forefoot, three dimensional data showed that it remains surprisingly stationary with respect to the rearfoot. Conversely, the forefoot appeared to pronates and abduct mostly at early and midswing phase. Even if there were limited number of subjects who took part in this comparative study, the technology used allowed data analysis of the hallux. In the sagittal plane, the hallux dorsiflexed on average of 35° during propulsion phase, which can be justified by the smaller strides that children have compared to an adult gait (Smith et al. 2008). On the other hand, it can be argued that many children tend to walk on forefoot, especially early walkers, which may exacerbate hallux dorsiflexion ROM (Thomson and Volpe 2001).

After 4 years-of-age the changes in velocity, cadence and step length in normal children are generally attributed to limb length growth (Sutherland 1997). Walking velocity is indicated by stride frequency and stride length. In normal children's gait, the right and left step lengths are approximately equal amongst each other. Force plate recording in children between 2 and 7 years-of-age highlighted an increase of vertical force curve during the mid-stance phase. Particularly in subjects of 4 years and older, similar gait patterns to adults were recorded, such as the moments of forces [17] and power curves of hip, knee and ankle movement. However, there are significant differences in magnitude between children and adult, suggesting that the youngest children use their hip flexor and extensor muscles more than their ankle plantar flexors for power generation (Sutherland 1997).

As normal children develop, cadence appeared to decrease while walking velocity and step length increases. Important contributor factors in the development of a more adult gait is the increase of limb length and higher limb stability, proven by increased duration of single-limb stance (Sutherland et al. 1980). It can be argued that this well-known publication, still often referenced in many paediatric textbooks, may be one of the first publications that enhanced the knowledge of paediatric gait analysis. However, the clinical relevance of this publication may be debatable as there are no specifications on the criteria used to differentiate children who were considered to be normal rather than abnormal. If more than one clinician was involved in the recruitment process, details on what was used to distinguish 'normal' from 'abnormal' children gait during biomechanical examination should have been reported. This important detail may have significantly skewed the results published. In addition, the authors failed to mention if the patients had lower limb injuries or operation prior to the study; or indeed if there were specific inclusion or exclusion criteria at all. No details are reported on the level of children symptoms present prior the recordings. Furthermore, even if the 186 subjects appeared to be completely asymptomatic, it does not necessarily indicate that the children did not present with biomechanical abnormalities which could have influenced the results. The reader is not informed if the recordings were carried out more than once with the same children at a given interval of time, as this useful data

[17] Moment: it indicate a tendency to produce motion

could have proven reliability and repeatability level of the equipment used and the chief investigator/s skills.

An important component of paediatric gait analysis is the availability of age-matched normative databases (Chester et al. 2007). Difficulties in comparing children's gait analysis data with what is normal may be attributable to disparities in marker sets, data processing techniques, and consistency of clinicians. Other differences arise from advances in computer technology, which have significantly improved motion analysis systems and data processing capability over the last 10 years. To prove this statement, a recent study conducted by Chester, Tingley and Biden (2007) compared a modern gait database to the historical San Diego database, using statistical classifiers developed by Tingley et al. (2002). In this recent research, gait analysis was performed on 60 children aged between 1–13 years (Sutherland et al. 1988; Tingley et al. 2002). A six-camera Vicon 512 motion analysis system and two force plates were chosen to record temporal-spatial, kinematic, and kinetic parameters during ambulation. Results indicated significant differences in sagittal angle data between the two databases and the reasons for these disparities were particularly attributed to technological advances and data processing techniques (data smoothing, sampling, and joint angle approximations).

Not many publications are available at present that fully describe what to expect in a normal child's gait. However, it can be noticed that at 7 years old children's cadence appears to be higher compared to adult gait, as well as walking velocity and pelvic rotation and hip joint rotation. Cadence results show an average of 140 steps per minute by the age of 7 years old, with mean velocity of 1.14 m/s. Typically adults instead appear to walk 1.46 m/s in males and 1.30 m/s for female (Sutherland et al. 1980; Volpe 2001). Generally children exhibit greater hip abductor during the swing phase, the step length increase as the limb is lengthening, which matches with the decrease in cadence noticeable with normal growth pattern. Tibialis anterior activity recorded with electromyography (EMG) showed that normal children have a prolonged stance phase compared to adults. In addition, paediatric gait could exhibit recurrent foot drop during swing phase and almost absence of heel strike, more common in very early walkers (Sutherland 1997; Volpe 2001).

In conclusion, all the studies discussed above are encouraging evidence that there is a need for clinicians to distinguish what is normal from abnormal. Being fully aware of what to expect during normal paediatric gait analysis at different ages, may be the key to base a more successful clinical management. It is more difficult to observe children's gait and make a concrete observation when compared to adults; however, many steps forward have been made in technology, from three dimensional systems to digital plantar pressure software, which significantly aid clinicians in establishing the appropriate treatment for children. It can be argued that the results obtained from quite dated publications may be difficult to relate completely to studies carried out using modern technology.

2.7. Pathological Gait in JIA

Children diagnosed with JIA may suffer from lower limb pain that may lead to posture and movement modifications and may cause muscular imbalance with a reduced range of motion in the affected joints. JIA impairs joint function and may result in significant physical handicap (Hafner et al. 1998). Previous research investigating controlled quantitative gait analysis in JIA highlighted significant alterations compared to healthy children in recorded kinematics and temporal data (Brostrom et al. 2007). Evidence from two cross-sectional studies highlights that children with arthritis are physically less active compared to healthy children (Takken et al. 2008). A recent study indicated that foot problems are common in JIA, with a prevalence of over 90%. It appears that, even if DMARDs, biological therapy and podiatry foot care are often used as a treatment, foot related issues and disability still persist in some JIA patients (Hendry et al. 2008). Foot impairments, including joint pain, stiffness and deformity can alter walking patterns, therefore sharply reducing physical activities when compared to healthy children. As a result children with JIA may have a lower aerobic capacity (Broström et al. 2002). Joint pain and inflammation trigger a vicious cycle that often ends in joint damage and fixed deformities (Hartmann et al. 2010). Physical activity (PA) is increasingly considered an important part of treatment for JIA patients in order to maintain joint function, to encourage normal growth and development, and to prevent a number of chronic diseases (Cassidy and Petty 2005; Hartmann et al. 2010; Rey-Lopez et al. 2008).

Hartmann et al. (2010) conducted a very informative comparative study with 36 JIA patients (with symmetrical polyarticular joint involvement of the lower extremities) and 20 healthy controls children which showed statistically significant differences. This study, published by the International Journal of Paediatrics, focused on the differences in kinematic, kinetic, and spatio-temporal parameters with 3D gait analysis. The authors aimed to quantify the differences in gait and to provide data for more detailed sport activities recommendations. Six infrared cameras (120 Hz) (Vicon,MX3) and one 3D ground reaction force plate (1080 Hz) allowed the recording of high resolution data which highlighted reduced walking speed and step length in JIA children. Arthritic children also appeared to have strongly anterior tilted pelvis, reduced maximum hip extension, reduced knee extension during single support phase and reduced plantar flexion in push off. The toeing off phase of gait seemed to be slower compared to healthy children. Additionally, the reduced push off motion recorded at the ankle was confirmed by lower peaks in ankle moment and power. It is reported that the gait of JIA-patients can be defined as a crouch-like gait with hyper-flexion in hip and knee joints and reduced plantar flexion in the ankle. The authors concluded that PA, stretching and strengthening the flexor and extensor muscles would be recommendable; and that more research is necessary to optimize recommendations for sporting activities. It can be argued that results may have been slightly skewed by the unequal number of subjects present in the control group (only 20) and also that within the control group 17 children were female and only 3 were male. In this retrospective study, data collection was carried out over 3 years, as part of routine procedures to individualise physiotherapy intervention. The reader should have been informed if more than one data collector was involved during this extended recruitment time. The authors should have provided details on the clinicians who were involved in data collection and particularly more information should have been written on the technique adopted in placing 3D markers. The reader is uninformed if the methods carried out were repeatable and reproducible over time. Furthermore, no details were provided about whether the JIA group were taking drugs and if data recorded were repeated more than once per session, which could have provided more accurate results. If the data would have been recorded over a longer period of time (for example 2 data collection session over 1 week interval) results would have shown that both groups

exhibited the same gait pattern and consequently confirmed the conclusion made by the authors.

Similarly, a study conducted by Brostrom et al. (2002) compared gait in JIA with a control group. This time the number of subjects in each group was more balanced (15 JIA and 14 control group). In this study published in the 'Scandinavian Journal of Rheumatology' all JIA subjects presented with lower limb involvement, with disease onset ranging from 1 to 10 years. This group was divided into two groups based upon whether the arthritis was affecting one leg (no= 4) or bilateral involvement (no=11) and classified also as oligo and polyarticular arthritis (respectively no=7 and no=8). Light-beams were used to record walking velocity and pain level was recorded with VAS. Two force plates allowed ground reaction forces to be recorded and foot-switches were used to obtain temporal parameters. The pilot study was conducted to prove that the mat did not affect the ground reaction forces recorded. Unlike the previous research mentioned by Hartmann et al. (2010), in this study ten walking trials were recorded with each subject, 5 trials with laboratory built foot-switches on both feet, and the remaining 5 without. Each foot switch was made of two rounded plastic coated 35mm diameter, which was attached with double-sided tape at the heel pad and underneath the 3rd metatarsal head. The first switch aimed to record heel strike and the latter toeing off; a complete walking trial was recorded if the child's right and left foot made a clean contact with the force plate. The authors reported that mean velocity for the children with JIA was significantly reduced when compared to the healthy controls. Peak vertical forces appeared to be different because the control group showed more pronounced heel strike and push-off. The smaller unilateral disease involvement group presented a tendency to have shorter single leg support than the control group. Results showed that the children who had higher VAS score exhibited slower walking speed and also bilateral disease involvement (Broström et al. 2002). On the other hand, it can be noticed that pain scores may be debatable as the reader is not informed if the patients were under medication that could have influenced the pain level hence the walking speed. It may have been more sensible to involve JIA children with stable pharmaceutical administration over a prolonged period of time. As previously reported in this thesis, certain medication may take up to 6 months to be fully effective.

Alternately, if the course of medication has been changed, the authors should have mentioned it in the result session. It can be argued that only applying a 35 mm sensor underneath the 3rd head to record propulsion phase may be not enough especially if the child present certain foot deformities as a compensation for abnormal gait. Also if the children presented with ankle or forefoot equinus, the time in which the forefoot would be in contact with the ground may occur very quickly but for a prolonged period of time when compared, for example, to pes planus. The list of compensation mechanisms that can occur in abnormal JIA gait may be quite long, therefore the single application of a sensor only underneath the 3rd metatarsal head, may be deemed to be insufficient.

As mentioned by Fairburn et al. (2002) it can be challenging to identify the range of gait deviations associated with JIA using only simple clinical observations. In this prospective study of 23 children with gait abnormalities referred for biomechanical assessment over a three year period, the 'Novel Pedar' in-shoe plantar pressure measurement system was utilised to record gait. During recruitment, 8 out of 23 children were excluded due to other diseases or neurological complications; the remaining 15 children had JIA with predominantly symmetrical polyarticular joint disease. The authors created clinical groupings based on the extent of joint restriction: minimal (group A, no= 7), and moderate–severe (with supinatory foot deformity (group B, no=6), or with pronatory foot deformity (group C, no=2). Gait analysis enabled classification of each subject into one of four gait patterns: either near normal (pattern I) or one of three adaptive patterns defined by the predominant abnormality—lower limb pain (pattern II), lower limb deformity (pattern III), or a combination of pain and deformity (pattern IV). All the subjects with gait patterns I and II were found in clinical group A. Both subjects from clinical group C exhibited gait pattern III. All subjects from clinical group B and the remainder from group A exhibited a mixture of gait patterns III and IV. Not surprisingly, the initial clinical observations did not always allow correct prediction of gait patterns. Conversely, scientific gait analysis allowed a clear distinction to be made between primary and secondary gait deviations, and accurate targeting of physiotherapy and orthotic management to best suit each child. The authors also recognised that a larger sample size of prospective quantitative analysis is required to provide more significant findings (Fairburn et al. 2002). Unlike platform systems, the use of plantar pressure FOs allows the collection and analysis of

data from a number of steps, while walking in shoes with or without orthoses. Plantar pressure data are commonly displayed as peak pressures produced during gait. However, some clinicians may object that the Pedar system may be too expensive, especially when dealing with paediatric gait where many Pedar insoles are required for each shoe size. In addition, the thickness of the Pedar insole is 2.2 mm which is much thicker than the F-Scan system only 0.15 mm; it can be argued that additional thickness may be perceived as intrusive or uncomfortable inside the child's shoe especially if data is recorded with an orthotic inside the shoe.

In the survey conducted by Hendry et al. (2008) gait abnormalities, deformity or abnormal foot biomechanics, and/or active foot disease were the main reasons for referral of JIA to the specialist podiatrist. Footwear advice, orthotic therapy and silicone digital splints and intrinsic muscle-strengthening exercises were used in 7 children assessed in this survey. The authors reported that lower limb pathology, foot deformity, and pain may inevitably lead to altered gait function (Hendry et al. 2008). Therefore, the use of orthoses was deemed to be an effective, non-invasive intervention that aimed to correct gait patterns. Children performed simple walking trials at a self-selected cadence. Gait was recorded using Gait-RITE, CIR-Systems. During the data collection the recorded variables included walking speed (m/s), double-support time (s) and step length (m). Walking speed ranged from 0.84–1.38 m/s, with a median of 1.09 m/s. The median double-support time was 0.2s, ranging from 0.1–0.3s. This survey concluded that primarily flexion and flexion/valgus deformity at the knee and ankle, can lead to pathological gait patterns.

In the thesis published by Broström (2004) difficulties are reported to take several 3D recording trials especially because JIA children often are in poor physical condition. Arthitic children may also present issues during gait analysis recording as they have to strike specifically on the force plate with only one foot at the time. This knowledge, together with children shorter strides, may not truly reflect the natural walking style during gait analysis. The clinical implication reported is that JIA gait may present with loss of power in plantar flexor and dorsiflexor muscle during walking, which directly affect heel strike and propulsion phase. JIA disease can influence strength muscle function at the ankle joint by 40% - 50% The weakened lower limb muscles can not only impair ambulation patterns, but also directly affect walking speed. The authur also

concluded that gait analysis is a proper and clinically relevant tool to establish and quantify joint movement with JIA (Broström 2004).

In order to gain a better understanding of pathological gait, it is important also to focus on the movement of the trunk and centre of mass (CoM). In order to maintain a static position, the CoM must remain in balance over the base of support; and the vertical projection onto the ground is often related to the centre of gravity (CoG). The change in CoM motion during gait represents the overall result of joint and segment movements on the forward progression, and is of importance when describing pathological gait (Winter 1995). A comparison study carried out by Broström (2007) investigated these issues further, by recording with 6-camera 3D motion analysis system between JIA and healthy subjects, and the direct effects of intra-articular cortico-steroid treatment were evaluated. Seventeen children between 5 and 16 years of age (mean 11.4, SD 2.9 years, 14 females, and 3 males) with JIA and twenty-one healthy subjects between 5 and 14 years of age (mean 10.4, SD 2.5 and 10 female, 11 male) were recruited. The patients with JIA were treated and injected with methylprednisolone acetate[18]. The treatment policy for the study was to inject joints that are active (with synovitis) at the time of evaluation. Results showed that children with JIA appeared to have more posterior tilt in the trunk, in contrast to the general clinical perception (Brostrom et al. 2007). Data analyses also showed that CoM was more posterior and off-centred (medio-laterally) relative to the pelvis, which could have been directly related to pain level. According to the authors, whether the pain at the hips can lead to a compensatory mechanism in gait, resulting to a reduction of hip abductor moment should still be investigated further. However, such a mechanism may lead to greater medio-lateral CoM motion within the pelvis (Brostrom et al. 2007; Gutierrez et al. 2003). Several other factors may influence the CoM movement, for example gender differences, particularly female have more frontal plane pelvic motion during gait compared to males, however, further evidence needs to be carried out specifically in JIA (Smith et al. 2002). Finally, Broström (2007)'s results could have several implications in clinical practice. By understanding how children with JIA compensate for pain at the hip level, ultimately it may be possible to plan better physical treatment to improve their gait and correlate the use of functional FOs to aid the improvement of biomechanics.

[18] Depo-medrol™.

In conclusion, it is encouraging to observe that level of research interest in gait in JIA. More research still has to be conducted to define the pathological JIA gait clearly, with the aim of facilitating clinicians to intervene effectively and promptly in improving gait patterns.

2.8. Foot Orthoses in JIA

As previously mentioned, foot orthoses (FOs) have been used for many years with the aim of improving symptoms, preventing deformity and enhancing patient's performance (Landorf and Keenan 2000). In children, FOs has been found to improve parameters of gait and posture; however, little research has been carried out on subjects with JIA (Evans 2003; Landorf and Keenan 2000; Marie 2005; Powell et al 2005; Selby-Silverstein, Hillstrom and Palisano 2001; Sullivan 1999; Szer et al 2006). In the well-known publication carried out by Cakmak and Bolukbas (2005) the use of FOs has been reported to be an effective option during the physical rehabilitation of JIA (Cakmak and Bolukbas 2005). Similarly Harry et al. (2004) in the journal of 'Foot & Ankle Surgery' published an extensive clinical practice guideline for diagnosis and treatment of paediatric flatfoot. The use of orthosis is recommended with this common paediatric pathology, also as pre and post-surgical intervention; in addition, follow-up appointments are suggested in order to assess the prescription made over a period of time (Harris et al. 2004).

A number of theories have been suggested to explain how FOs works. It appears that the STJ has a direct effect on the range and direction of motion of joints both proximal and distal to it. Therefore, in order to prescribe functional orthotics, it is important to establish the STJ neutral position. As stated by Root et al (1971) "the neutral position of the STJ is that position of the joint in which the foot is neither pronated nor supinated" (Root et al. 1971). Hence, orthotic aims to maintain ankle and foot joints into neutral position during close kinetic chain. Podiatrists must have a thorough knowledge of the biomechanics of the lower limbs and an understanding of how to manufacture and modify FOs (Valmassi 1996). In addition, a child's foot is much more flexible compared to adults with RA; therefore, when FOs is supplied, improvement of joint alignment is expected to be found with subsequent higher benefit in the long term

(Marie 2005). There is no clear explanation on how FOs has a direct effect on foot pain. There are many theories such as resisting or facilitating motion (Nigg et al. 1998; Novick and Kelley 1990; Stacoff et al. 2000) reduction and redistribution of plantar pressure (Cornwall and McPoil 1997; Novick et al. 1993; Redmond et al. 2000) altered muscle activity (Nawoczenski and Ludewig 1999) and enhanced proprioception (Nawoczenski and Janisse 2004). Many researchers have been investigating to find a conclusive answer to this (Landorf and Keenan 2000) however, failing so far to reach particular theoretical model. A systematic Cochrane review on effect of FOs, concluded that it is possible that FOs have different mechanisms for different types of foot pain (Hawke et al. 2008).

In 2009, NICE published an expended review on the management of rheumatoid arthritis in adults, which specified that 'FOs should be available for all people with RA if indicated' (NICE 2009). No such recommendation has been mentioned in JIA suggesting that more research, investigating the effect of FOs in JIA, is needed.

2.8.1. Custom Made FOs

The 'Cochrane Database of Systematic Reviews' in 2009 issued an extensive publication with the aim of evaluating randomised controlled trials and controlled clinical trials on the effectiveness of custom foot orthoses for different types of foot pain. The authors independently selected eleven trials involving 1332 subjects: five trials evaluated custom-made foot orthoses to treat plantar fasciitis (691 participants); three for foot symptoms in rheumatoid arthritis (231 participants); and one each for foot pain in pes cavus (154 participants), hallux valgus (209 participants) and JIA (47 participants) (Hawke et al. 2008). The authors reported that custom-made foot orthoses appeared to be significantly effective in the treatment of painful pes cavus, rearfoot pain in rheumatoid arthritis and foot pain in JIA and painful hallux valgus; however, surgery was even more effective for hallux valgus and non-customised foot orthoses appeared just as effective for JIA but the analysis may have lacked sufficient power to detect a difference in effect. It is unclear if custom-made foot orthoses were effective for plantar fasciitis or metatarso-phalangeal joint pain in rheumatoid arthritis. According to this Cochrane review, after 3 months, a custom-made foot orthoses improves foot pain by 11 more points on a scale of 0 to 100 (possibly as many as 19

points or as few as 3 points). This difference is also significant in JIA patients. Finally, custom-made foot orthoses were a safe intervention in all studies. It can be argued that different types of foot pain were analysed individually in each trial; therefore, a generalised conclusion regarding the effectiveness of custom-made foot device for the treatment of foot pain should not be drawn and all results cannot be grouped into a single 'level of evidence'.

Broström (2004), published the 'Patient Education and Foot Disability in JIA'. The main focus of this work was to investigate the outcomes of an education program for parent and children living with JIA and the use of custom-made FOs. The effect of FOs was evaluated in 48 JIA children / adolescent. Two consecutive capacity tests were carried out by the child. Randomly in one test the child was wearing the FOs and in the other test without FOs. All tests were observed and scored by the same physical therapist who was not made aware whether the child was wearing the FOs or not (Marie 2005). With regard to the outcome related to the foot position with FOs, pain after standing, jumping and climbing the stairs was significantly lower ($p<0.05$), and balanced improved as well ($p<0.05$) when the child was wearing an FOs. Results highlighted no significant differences in the subgroup with planovalgus pathologies: in contrast, the cavo-varus subgroup presented with significant differences in pain level after standing ($p<0.01$), walking speed ($p<0.05$) and running ($p<0.01$) in favour of the FOs group. These results can be seen as an encouraging indication that at least in Sweden, podiatric intervention is considered as part of the treatment of JIA within the paediatric rheumatology team and also that custom-made FOs can be useful particularly in cavo-varus patients and with oligo and polyarthritis JIA (Marie 2005). The author acknowledges that in the study one limitation could have been the lack of a control group for the evaluation of the educational program. Furthermore, the high dropout rate amongst those recruited was not expected. Marie (2005) fails to provide the reader with specific details about several questions. What method was used to take the casting (neutral or relax calcaneal stance at open or close kinetic chain)? Who was involved in the manufacturing process of the FOs (was it only one technician or more?) How long did the child have to wait before the fitting? What cost was involved in the manufacture of the FOs. Was there a review appointment arranged after fitting or not? Additionally, when the physical therapist observed and scored the children's activity test, with and without the FOs, the reader is not informed if the child wore different shoes or not. This

might be seen as a possible limitation, as the condition of footwear could have skewed the observation made by the data collector. Each child involved in the gait observation should have received the same shoes to limit variables in the final gait score. Finally the author failed to mention if the symptomatic children were under specific medication for JIA which, as previously mentioned, could have significantly changed the final pain level score, causing the reader to believe that pain reduction was solely attributed to the custom-made FOs intervention.

2.8.2. Off the Shelf FOs

A recent publication revealed that the government had released figures, which stated that the Northwest Health service is due to record a £230m surplus in its expenditure (Malone 2008a). It has been indicated that a number of factors have contributed to the savings made in the past year. One of them appears to be the more frequent use of affordable and cost-effective pre-formed orthotics, which have increased in use and become more commonly prescribed by podiatrists (Malone 2008a). The vast range of off-the-shelf devices eliminates the need for custom made orthotics. The off the shelf products can be customised to suit individual requirement by simply adding extrinsic correction. The convenience of prefabricated devices allows the NHS to manage time more effectively, by seeing additional patients. Finally, by eliminating orthotic manufacturing and laboratory cost, the NHS has been able to increase the savings and improve time management (Malone, 2008). These encouraging figures are expected to be welcomed in this difficult economic climate especially by NHS podiatry managers and also by many patients who are treated privately. The ideal scenario would imply that off-the-shelf devices have an equal if not better effect compared to the custom-made FOs. However, it can be argued that this interesting press release may be biased as it is written by Malone (2008) who also works for Algeos, who supplies these FOs. Thus more robust research is required.

Despite a lack of podiatric evidence in using pre-formed semi rigid FOs in JIA, few studies have been conducted in RA but still more well designed multicentre trials of satisfactory statistical power are needed (Korda and Bàlint 2004). A biomechanical evaluation of foot pressure and loading force during gait in RA patients with and

without foot orthosis has been conducted by Li et al. (2000). In this study, 12 female RA patients with foot pain in walking, and 8 healthy women without foot pain were matched for age. Foot pressures and loading forces with and without orthoses were measured using the F-Scan system. The pressure distributions and loading forces were standardised by body weight and compared. The FOs were made of pre-formed mouldable materials, mostly polyethylene foam rubber which encourage shock absorption and aim to support deformities (Li et al. 2000). Interestingly, in the methodology section, it is specified that one only orthotist was in charge of the fitting, supervising the correct use of FOs by the participants throughout the whole period of the study. Using the 0.15mm thick F-Scan insole, dynamic foot pressure was recorded with and without the off-the-shelf FOs. During recording the FOs used with RA patients provided significant pressure reduction (3.00 +/- 0.38 g/cm^2) compared to the control group (3.29 +/- 0.29 g/cm^2) ($p<0.001$). Similar redistribution of plantar pressures and loading forces were found between the two groups but the RA patients had a greater change at the stance phase of gait ($p<0.0001$). The authors concluded that the off-the-shelf mouldable FOs produce greater pressure and loading force relief and redistribution of pressure in RA patients compared to normal subjects (Li et al. 2000). It can be argued although the methodology adopted was fairly accurate; the sample size may be too small. The results would have possibly proved more significant if Li et al. (2000) recruited all RA participants instead. Then, they could have randomly subdivided the RA patients into two equal groups and investigated the effectiveness of off-the-shelf devices against a control group.

In the study conducted by Dixon and McNally (2008) 22 participants were asked to run barefoot at 3.83 m/s (±5%) over an RS scan foot-scan (0.5 m length) pressure plate (500 Hz). The influence of the prescribed orthoses on lower extremity kinematics and pressure beneath the shoe was assessed by collection of data for 10 running trials with a neutral shoe and 10 trials with the addition of an orthotic device. All devices were constructed from moulded EVA, with a base of 60 Shore A[19] and top layer 40 Shore A. Three off-the-shelf FOs' shells were available for the participant who took part in the study: high, normal and low arch. The 3 types of orthotic shell were determined directly by the software using the arch index values developed in 1987 by Cavanagh

[19] 'Shore A' scale: is used for testing soft Elastomer (rubbers) and other soft polymers.

and Rodgers, which are considered the precursor of gait analysis (Cavanagh and Rodgers 1987; Dixon and McNally 2008; McCrory et al. 1997). Dynamic arch index values were calculated for the entire foot contact, minus toes. Less than 21% midfoot contact area was classified as high arch, between 21% and 28% as normal and greater than 28% as low arch. Modifications were added to the preformed shell as required according to the participant. Initial and peak angles were determined for rearfoot inversion–eversion, lower leg internal rotation, ankle dorsi-plantar flexion, knee flexion and rearfoot eversion velocity. Furthermore, the relative pressure on the lateral side to medial side of the shoe (pressure balance) was determined by dividing the foot into areas of medial and lateral heel and five metatarsals. The moulded off-the-shelf FOs recording showed significant reduction in peak eversion and in eversion velocity and a significant increase in the initial inversion angle ($p<0.05$). The 'Exeter Biomechanics Research Team' concluded that the devices used in this study successfully helped to decrease the peak eversion and the eversion velocity by encouraging the foot to operate in a more inverted position throughout the running recordings. Finally, this research confirmed that the pressure plate aids in establishing orthotic effect (Dixon and McNally 2008).

2.8.3. Comparative Studies

The only comparative article which investigates FOs in JIA has been compiled by Powell et al. (2005). The authors used a quasi-experimental method in a prospective, randomised, single blinded study which addressed the use of custom made orthoses in the management of JIA. In the study, the speed of ambulation, self-rated activity, functional ability level and pain, all showed significant improvements compared to off-the-shelf cushioning inserts or supportive athletic shoes (Powell et al 2005). Forty children were recruited to the study which was then subdivided into three subgroups, receiving: a) custom-made semi-rigid foot orthotics with shock absorbing posts (n= 15), b) off-the-shelf flat neoprene shoe inserts (n= 12), or c) supportive athletic shoes with a medial longitudinal arch support and shock absorbing soles (n= 13). This study has been included in a Cochrane Systematic Review that focused on the potential of relieving foot pain within three months, by using custom made FOs (Hawke et al. 2008). However, the study compared custom-made functional devices against non-

functional off the shelf cushioning devices only. It would have been better to compare the effectiveness of expensive custom-made functional devices (costing approximately between £132- £232[20]) against cheaper off-the-shelf preformed functional orthotics. Such a study would have shown whether it is the casting methods that yield clinical benefit against similar but more cost effective off-the-shelf prescription. If the research proved that it is the functional prescription rather than the type of device that generates clinical benefit, then, the actual saving for the NHS would be significant. Furthermore, being a quasi-experimental study, it does not provide any comparison with a control group. A randomised control trial would have been a more robust design.

Recent publications claimed that more podiatrists commonly utilise prefabricated orthotics when patients cannot afford custom devices (Losito 2006). However, it is seen as unethical when a practitioner selects a treatment based on his or her perception of a patient's ability to afford the treatment. Such judgments should be evidence-based on the effects of types of orthotics and this highlights the need for more research into the effectiveness of pre-formed orthotics.

Recently Redmond et al (2009) published an interesting study which compared the mechanical properties between customised orthotic and off-the-shelf. This cross-over randomised clinical trial investigated 15 patients diagnosed with flat-feet. All patients recruited were asymptomatic and they were between 18 and 45 years old. The study was carried out in Australia in 2002/2003 (at University of Western Sydney). In addition, one of the inclusion criteria was a relax calcaneal value higher than 5° valgus. Gait analysis was carried out using Pedar in-shoe plantar pressure system only on the right foot following the manufacturer's instruction. Data were collected following a specific standardised protocol which included details such as speed, cadence, shoes, distance and timing. Results highlighted the forces and force time integrals in the midfoot and forefoot between the customised and off-the-shelf FOs (Redmond et al. 2009). In conclusion, this cross-over randomised clinical trial showed that almost no changes in loading were detected between the two types of devices.

[20] Which is the equivalent of $200–$350 as it was reported in the Powel et al. (2005) paper.

Redmond, Landorf and Keenan (2009) proved no statistical significant results were found on the customised FOs over the effect of semi-rigid prefabricated orthoses to justify the much higher cost involved for the devices obtained by using plaster of paris (POP) casting. It can be argued that the financial difference always has represented a big issue for the practitioner when prescribing an orthotic. This study is one of many studies conducted to try to prove that the "gold standard" of customised FOs no longer exist; and that very similar, if not better results, can be obtained with off the shelf semirigid orthotic. However, this study presents few issues that might have influenced the final results: firstly the number of patients may be too small to be draw significant conclusions, it may be argued that only 15 participants is not sufficient to produce a robust evidence based on a randomised clinical trial, even if it was a cross-over study. In addition, the age group may not be truly representative of the active population present nowadays. Secondly the author did not clearly specify what type of flatfoot the asymptomatic patients had. Some practitioners may argue that pes planus may present with true rear foot valgus or varus, fully, partially or not compensated. No indications on forefoot condition were reported as well.

In the paper published by Redmond, Landorf and Keenan (2009) the reader is not informed if the subjects recruited presented with soft tissue flattening or instead it was due to any possible tarsal coalition. However, some practitioners may believe that one of the main criteria used to establish whether or not a prescription is successful, is to evaluate clinical improvement. Improvement of pain is generally accepted to be the primary outcome for any trial that compared the use of different devices. Therefore, even if only 15 subjects took part in the study, if all of them reported improvement of symptoms, that could have been significant evidence in favour of prescribing off-the-shelf FOs compared to POP. The authors reported that all participants met the inclusion criteria of a relaxed calcaneal stance position of > 5° valgus. Unfortunately it is not specified how this procedure was carried out. Results may be affected according to the technique used to collect STJ ROM at close kinetic position. In addition, the reader is not aware if these measurements were collected by the same podiatrist or not. It can be argued that the more people who are involved in the collection of STJ measurement, the more variables and errors may be introduced into the cross-over trial. Under the section of orthosis type, it is specified that only one technician from the 'The Orthotic Lab Pty Ltd' was involved in the manufacturing process. The customised devices were

'modified Root' type orthosis, posted to the neutral calcaneal stance position. Materials used were carefully described (4mm white 'semi-flex' polypropylene shell, heel posts were made from 450kgm^3 EVA[21] and thin vinyl top layer was added as cover). On the other hand, the prefabricated devices were a commercially available brand (Cast and Foot Adjusted Orthoses®) supplied by the same laboratory (The Orthotic Laboratory Pty Ltd) and already had 4° varus rearfoot post. The materials used, length and heel cup height were the same used for the customised devices and the prefabricated orthoses which certainly helped data analysis comparison (Redmond, Landorf and Keenan 2009). Interestingly, one of the authors of this research, Landor KB, is a Deputy Editor of Journal of Foot and Ankle Research in which the study was published. Finally, no disclaimer was written regarding any conflict of interest in promoting one particular product sold directly by the same Australian orthotic company.

As previously mentioned, in this current economic situation financial cuts are made across all sectors, even within the health care system. It appears to be clear that there is a general drive from clinicians to prove whether or not the cheaper option can be equally if not better effective than the more expensive options for podiatric intervention. Another recent publication carried out by Cho et al. (2009) investigated the effects of shoes with FOs in patients with rheumatoid arthritis and the differences in terms of type of FOs and anatomical location of foot pathology. This single-blinded randomised controlled trial recruited participants from the outpatients of the physical medicine and rehabilitation clinic at a university hospital in Seoul. Forty-two patients with RA foot lesions (all female, with mean age 49.1 ±11.6 years old) were randomly divided into two different orthotic intervention groups. The anatomical locations of the foot lesions were recorded. The participants were provided with an extra deep forefoot-rocketed shoe and either a custom-made semi-rigid FOs or a ready-made simple soft FOs. Participant was asked to wear the FOs for at least 3 hours a day over six months. Similar to previous mentioned studies, primary outcome measures were foot pain detected by using VAS scores and Foot Function Index (FFI). Secondary outcome measures were erythrocyte sedimentation rate and C-reactive protein levels in blood, amounts of medications and active joint counts (Cho et al. 2009). These were checked at baseline and post intervention. Unexpectedly, 8 women dropped out at follow-up

[21] EVA= ethyl vinyl acetate

after six months of treatment. At six-month follow-ups, VAS scores and total Foot Function Index scores had decreased significantly in both groups versus baseline but intergroup comparison showed no significant differences in view of the type of FOs and anatomical locations of foot pathology. The authors concluded that they were unable to highlight differences between the types of FOs in terms of their clinical effects in the two groups, but both groups presented signs of significant improvement.

It can be argued that Cho et al (2009) should have recruited a more mixed population of patients, not only female. In addition, some clinicians may disagree with the review appointment being made 6 months after the initial fitting, which could be deemed to be too long a gap, especially for the RCT, as many variables could have been introduced within the study in between this long period of time. Fitting issues, inadequate use of the FOs, wearing wrong shoes or not wearing the FOs at all could have been possible variables that require more frequent check-up as part of clinical management, in order to avoid wrong interpretation of results. Not surprisingly the dropout rate was quite high for this RCT.

The relative merit of customised versus prefabricated foot orthoses continues to be the subject of passionate debate between podiatrists (Menz 2009). Even if there is currently insufficient evidence to establish the best devices to use, more and more research literature suggests that prefabricated foot orthoses may produce equivalent clinical outcomes to customised foot orthoses for certain conditions. Prescription guidelines for customised FOs need to be developed, by so doing the hypothesised benefits of these devices would be thoroughly evaluated (Menz 2009). The clinical satisfaction to reduce wide range of chronic pain with FOs when all other treatments have failed, is an extremely positive clinical experience (Landorf and Keenan 2000). Research in podiatry often are criticised because the results obtained can be directly attributed to the different methodologies used by the authors and by the controversial quality of the research often available (Landorf and Keenan 2000). Menz (2009) concluded that in the future, further research may indeed reveal that there are specific subgroups of patients and conditions that respond more favourably to particular types of customised orthoses compared to prefabricated orthoses or vice-versa.

2.9. Pain and Quality of Life:

As previously mentioned, the primary clinical outcome in this thesis will focus on the effects of pre-formed semirigid FOs on pain using the widely recognised VAS and other quality of life tools, particularly the CHAQ and the PedsQL™ (generic paediatric module and paediatric rheumatology module). It has been proven that parents and children have different perceptions of pain levels and pain coping strategies (Sawyer et al. 2004).

2.9.1. VAS

VAS is a psychometric response scale which can be used in questionnaires and it measures a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured (Grant et al. 1999). For example, with respect to the amount of pain that a patient feels, VAS ranges from none to the highest pain imaginable. From the subject's point of view this spectrum appears continuous ± their individual pain; it does not have a categorization of none, mild, moderate and severe would instead suggest. VAS was devised to capture an idea of an underlying continuum sensation (Gould et al. 2001). Practically VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end, as illustrated in Figure 2.9.1.1. The parent is asked to mark on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in millimetres from the left hand end of the line to the point that the patient marks (Gould et al. 2001; Grant et al. 1999).

Figure 2.9.1.1: Example of VAS, 100mm long, used to record pain level.

The VAS has been found to be a sufficiently reliable and cost-effective tool to detect pain (Bijur et al. 2001; Chapman and Kirby-Turner 2002; Schanberg et al. 1997). Pain is considered to be the most common primary outcome that measures the effectiveness of a specific treatment; VAS is used not only in prospective clinical studies but also in RCTs (Grant et al. 1999; Hendry et al. 2008; Hendry et al. 2009; Powell et al 2005). Furthermore a recent study conducted by Lam et al.(2004) concluded that the VAS

was the best pain investigating tool to differentiate between patients and controls age 5 years old or older (Lam et al. 2004).

A recent investigation compared JIA children with the healthy population, specifically on the associations between physical activity and disease-related factors. This cross-sectional study evaluated the overall well-being of participants by using a VAS. Final results obtained also by using VAS helped to conclude that interventions by paediatric rheumatologists are suggested to improve physical activity levels in patients with JIA (Lelieveld et al. 2008).

2.9.2. CHAQ

The CHAQ is a widely used tool to investigate quality of life in children. It has been validated for children between the ages of 1 and 19 years, contains 30 questions grouped into 8 domains: dressing, arising, eating, walking, hygiene, reach, grip, and daily activities. A scale of 0 to 3 assesses the level of difficulty in performing the tasks (0 = no difficulty, 1 = some difficulty, 2 = much difficulty, and 3 = unable to do). The highest score of a question in a domain determines the overall score for that domain. In order to calculate the final score, the highest scores of every domain are summarized and divided by eight (eight domains). Possible scores range from 0 to 3.0 (Geerdink et al. 2009).

Also the CHAQ has been shown to be a valid and sensitive tool in the evaluation of functional outcomes in children with chronic arthritis and it has been used to measure improvement of the pathology in many clinical trials (American College of Rheumatology 2009). In order to provide further data regarding quality of life in children with JIA, CHAQ will be used for this study. In the UK a study was carried out on 440 children using the British version of the CHAQ, 219 patients with JIA (17% systemic onset, 41% polyarticular onset, 33% extended oligoarticular subtype, and 9% persistent oligoarticular subtype) and 221 healthy patients. The UK-CHAQ proved to be able to discriminate between healthy subjects and JIA patients. In addition, in this well-known study conducted at the Institute of Child Health, University College in London the reliability and validity of the CHAQ for functional, physical and psychosocial assessments of children with JIA was confirmed as well (Nugent et al.

2001). A bigger study was carried out in 32 different countries amongst all the members of the Paediatric Rheumatology International Trials Organisation (PRINTO). This research, founded by European Union, analysed the health-related quality of life of 6,644 subjects. The study evaluated 3,235 children with JIA (20% systemic onset, 33% polyarticular onset, 17% extended oligoarticular subtype, and 30% persistent oligoarticular subtype) against 3,409 healthy children. The results supported using CHAQ as a valid and reliable tool for different socio-economic and socio-demographic conditions of JIA children of countries that took part in the study (Ruperto et al. 2001). In a more dated study carried out in Italy at the Rheumatology Department Milan University, 96 patients with JIA were evaluated; both male and female, ranging from 3 to 19 years (mean age 9.9). The questionnaire was completed by parents if the children were younger than 8 years old (23 subjects) and by the children themselves in the remaining subjects. Children with systemic or polyarticular onset had higher scores compared to those with pauciarticular onset. Significant statistical difference was found in the disability index value between children with different subgroups of the pathology. The CHAQ proved to have a positive reproducibility rate in test-retest over a two-week period. In addition, positive correlations were reported in between child and parent scores, as well as internal reliably and discriminant validity (Fantini et al. 1995).

It has been reported that in order to obtain complete systematic monitoring of disease activity in all JIA patients, the CHAQ should be completed by every patient at every outpatient paediatric rheumatology clinic visit (Sawyer et al. 2004). In order to encourage parents and their JIA children to complete the CHAQ at each visit, a few clinicians started using digital computerised version of the CHAQ within routine paediatric rheumatology visits (Geerdink et al. 2009). The score of the digital CHAQ is calculated automatically by the software, avoiding possible human errors, and it is available electronically to the clinicians during the patient's consultation. In the study carried out by Geerdink et al. (2009) security measures were applied, data were protected by passwords and saved on the hard disk; finally, prints were kept in the patient's paper file. This recent study on 51 JIA children, confirmed the reliability of the CHAQ also under the user-friendly digital option, which was completed systematically at the outpatient paediatric rheumatology clinic during each routine visit (Geerdink et al. 2009).

2.9.3. PedsQL

Health-related quality of life (HRQOL) measurements have become an important health outcome in clinical trials, clinical practice and in improvement of clinical management (Fayers and Machin 2000). The PedsQL™ measurement model is a modular approach to measuring health-related quality of life (HRQOL) in healthy children and adolescents and those with acute and chronic health conditions. The PedsQL™ integrates both generic core scales and disease-specific modules into one measurement system. Evidence reports reliability and validity of PedQL™ 4.0 Generic Core Scale and PedQL™ 3.0 Rheumatology Module in paediatric Rheumatology (Varni et al 2004; Varni et al. 2002; Varni et al. 2003).

Scores near 0 indicate poorer physical functioning and scores near 100 indicate better physical functioning. The parent and child must complete the questionnaires independently from one another. In case of some difficulties in understanding the question, the data collector must not interpret the sentence; instead, it is advised to repeat the item to them verbatim. The child and/or the parent have the option of not answering a question if they truly do not understand the question.

In the study conducted by Varni et al. (2002) the 4 PedsQL™ 4.0 Generic Core Scales (physical, emotional, social, and school functioning) and the 5 PedsQL™ 3.0 Rheumatology Module scales (pain and hurt, daily activities, treatment, worry, and communication) were administered to 231 children and 244 parents recruited from a paediatric Rheumatology clinic. Results showed that internal consistency reliability (α) for the PedsQL™ Generic Core total scale score (α= 0.91 for child self-report, α= 0.93 for parent proxy report), physical health summary score (α= 0.87 for child self-report, α= 0.89 for parent proxy report), and psychosocial health summary score (α= 0.86 for child self-report, α= 0.90 for parent proxy report) were acceptable for group comparisons. Specifically with regards to the 'Rheumatology Module' scales also demonstrated reliability for group comparisons (α= 0.75–0.86 for child self-report, α= 0.82–0.91 for parent proxy report). The PedsQL™ proved to be able to distinguish between healthy children and children with rheumatic diseases as a group. Overall, the

results demonstrate excellent reliability, validity and responsiveness of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Rheumatology Module in paediatric Rheumatology (Varni et al. 2002). It can be argued that the same person who carried out the research is the actual licensor of the PedQL™ tool.

In the study conducted from Powel et al. (2005) on the use of the custom-made FOs, PedsQL™ was used as well, however, because the intervention used in this research was primarily physical, as opposed to psychosocial: the child self-report and parent proxy-report physical functioning subscales were the only subscales recorded in this study (Powell et al 2005). It should be noticed that the PedsQL™ Physical Functioning Scale includes items not necessarily related to foot functioning; therefore, because of the nature of this scale, it may be misleading. It can be argued that in the study conducted by Powell et al. (2005) the authors failed to consider the overall impact that orthotics could potentially have on the quality of life of JIA children. Instead, they only focused on the results obtained by physical functioning subscale. As pain level and quality of life represent the primary outcome, the authors should have investigated the correlation between different subscales within the PedsQL. Results could have highlighted a repeatable trend between improvements of physical functioning level, directly linked with improvements of social, emotional and school functioning. Some paediatric clinicians may also state that by providing more quality of life data on the effect of prescribing FOs, the role of podiatrists may improve within the multidisciplinary team in paediatric rheumatology.

While a PedsQL™ Rheumatology Module does exist (Varni et al. 2002) it was not considered during data collection in the trial conducted by Powel et al. (2005). Results obtained with the PedsQL™ showed that the orthotic group was the only group to show significant improvement in paired t tests. Interestingly in the orthotic group the PedsQL™ score showed more than twice the 5 points considered to be the clinically important score to indicate significant changes or differences (Powell et al 2005; Varni et al. 2002). Finally, the correlation between the child self-report and parent proxy-report was positive and significant at baseline and at follow up as well (Powell et al 2005).

Interestingly, a study was conducted by sending mail survey between February and March 2001. The questionnaire was sent to 20,031 families with children ages 2–16 years throughout the state of California, amongst all new applicants to the 'State's Children's Health Insurance Program' (SCHIP). This information may indicate that many insurance companies, particularly in America, are looking for valid tools that can be used regularly to monitor the HRQOL. The results demonstrate the feasibility, reliability, and validity of the PedsQL 4.0 as a paediatric population health outcome. Finally the author concluded that evaluating paediatric HRQOL may be also a valid option to establish the health outcomes of SCHIP (Varni et al. 2003).

Chapter 3: Methods – Instrumentation & Pre-Tests

3.1. Survey

3.1.1. Introduction

In order to decide which pre-formed semi-rigid FOs had to be used for the RCT on pain, quality of life and the dynamics of gait of patients diagnosed with JIA, a survey was carried in Scotland.

3.1.2. Aim

The aim of the survey was to investigate the type of treatment that symptomatic JIA children received within NHS podiatry departments in Scotland.

3.1.3. Justification

Currently there is limited evidence supporting podiatric treatment of children and particularly JIA patients. This survey was an opportunity to compare similarities and differences on podopaediatric clinical management within the NHS sector. Only after the survey was completed, it became possible to decide which was the most commonly prescribed FOs amongst the podopaediatric clinics in Scotland, and to choose what type of FOs would have been adopted for the RCT research.

3.1.4. Ethics

Ethical approval was obtained from the QMU Ethics Committee. All podopaediatrics specialists were entitled not to participate in the survey without giving any reasons. All podopaediatrics specialists were able to speak with an independent person, who knew about the project but was not directly involved in it. In order to maintain anonymity, all podopaediatric specialists contacted at the NHS clinics in Scotland were given a survey number at the beginning of the study. A sheet containing the podopaediatric assigned

survey number and contact details were held in a locked filing cabinet at QMU. This was destroyed at the end of the study.

3.1.5. Results

A template letter was sent out to each podopaediatric specialist's clinic across Scotland by hard-copy or electronically (appendix II). The survey was designed considering the limited time available for a practitioner to spend on completing the survey. The questionnaire took no longer than five minutes to be completed. The JIA survey was constructed to investigate specifically which FOs were most commonly prescribed for the clinical management of JIA patients. Practitioners were asked: firstly, if they treated JIA patients within their NHS clinics; secondly, what types of FOs were normally prescribed (palliative custom made, functional custom made, palliative off the shelf or functional off the shelf FOs). Lastly, if they prescribed off the shelf FOs, which type and brand of FOs did they normally supply for JIA patients? Two weeks deadline were given to each practitioner and the majority of podopaediatrics specialists replied by email. In total 11 NHS podopaediatrics clinics were contacted, 8 of them replied to the survey. Practitioners were suitable if they positively answered to the question "have you treated JIA children before?" As shown in the table below, 5 out of 11 practitioners previously treated JIA children with FOs. The remaining 6 podiatrists were not suitable for the survey as they never treated JIA children.

Survey Practitioner Number	Did they replay?	Was it suitable?
1	No	No
2	**Yes**	No
3	**Yes**	No
4	No	No
5	No	No
6	**Yes**	**Yes**
7	**Yes**	**Yes**
8	**Yes**	**Yes**
9	**Yes**	**Yes**
10	**Yes**	No
11	**Yes**	**Yes**

Table 3.1.5.1: Survey results. Practioners that replied with a positive answer, were highlighted in green

According to table 3.1.5.1 the survey practitioner number 6, appeared to use palliative custom made, functional custom made and functional off the shelf FOs. Survey

practitioner number 7 reported to prescribe palliative custom made FOs, functional custom made as well as functional off the shelf FOs. Survey practitioner number 8 did not use palliative custom made and palliative off the shelf; instead, usually prescribes functional custom made and functional off the shelf. On the other hand, survey practitioner number 9, treated JIA patients mainly using functional off the shelf devices only. Finally, survey practitioner number 11, appeared to use the same devices as survey practitioner number 8. Table 3.1.5.2 also showed that none of the podopaediatrics specialists used palliative off the shelf devices but instead results highlighted that every podopaediatric specialists prescribed functional off the shelf devices.

According to the results obtained in table 3.1.5.2, the most commonly used pre-formed semi-rigid foot orthoses device appeared to be the Interpod range (three practitioners currently use these types of devices). The Slimflex (1st Phase) and 'Vasyli' were reported to be prescribed both by two practitioners as well.

Survey No.	Palliative Custom made	Functional custom made	Palliative Off-the-shelf	Functional Off-the-shelf	Additional Notes
6	Yes	Yes	No	Yes	Green Vasyli full length if some form of control, as well as shock absorption is required.
7	Yes	Yes	No	Yes	Interpod Range
8	No	Yes	No	Yes	Mostly Interpod flex, Slimflex Plus
9	No	No	No	Yes	Formthotics, or Interpod
11	No	Yes	No	Yes	Vasyli VOL. Algeos 1st Phase, Slim Flex with adaptations.

Table 3.1.5.2: survey results from the suitable practitioners, on what type of devices were used to treat JIA children.

These devices were easily available on the market, and could be bought directly online. At the time of the survey, these devices were available for the following foot sizes:

Interpod Range

Control Tech Soft - ¾ Length	Available from size 2 till 12
Control Tech Full Length -(low arch 4°, moderate arch 6°, high arch 8°):	Available from size 3 till 10
Interpod For Kids - ¾ Length - Moderate Arch (6°):	Available from size Child 9 till 2
Interpod For Kids - Soft - Full Length - Low Arch (4°):	Available from size Child 10 till 2

Table 3.1.5.3 Interpod Range and available foot size details

Slimflex	
Basic Green Slimflex	Available from size 3 till 14
Slimflex PLUS FOs	Available from size 8 (Childs) till adult 12
Slimflex Plastic FOs	Available from size 3 till 12

Table 3.1.5.4: Slimflex Range and available foot size details

Vasyli	
Vasyli Custom Full Length (6°) (Low – Medium - High Density).	Available from size Kid 12 till adult 14½
Vasyli Custom Regular ¾ Length (6°) (Low – Medium - High Density).	Available from size Kid 12 till adult 14½

Table 3.1.5.5: Vasyli Range and available foot size details

3.1.6. Discussion

Each NHS podiatry clinic was managed independently, and have limited budget available to provide FOs to their patients. In most cases podiatrist's clinical management was restricted by a specific number of FOs that could have been supplied each month to patients. This may be considered as unethical, as all JIA patients should be entitled to the same level of care, independently from monthly availability of FOs. This issue may be considered as a limitation in providing the appropriate level of care, and a restriction to cure patients symptoms based on the limited budget available.

Realistically this is a problem that all medical sectors have to face. The limited resources available have always been and always will be one on the most difficult challenges that NHS has to face. It is well known that the main aim for NHS is to

provide high standard level of care at competitive and cost effective prices. For this reason, this JIA study required to have results from the survey, in order to establish what FOs were provided across different trusts in Scotland.

According to the results obtained by the JIA survey, the most common form of pre-formed semi-rigid FOs appeared to be: Interpod, Slimflex and Vasyli. However, not all these three pre-formed semi-rigid FOs were particularly cost effective for NHS. In addition, different NHS local trusts had different financial resources specifically dedicated for FOs prescriptions. As previously mentioned, it could be argued, that it may be unethical that certain JIA children may be prescribed more effective and costly FOs compared to other children that were born in less fortunate areas of Scotland where the podiatry resources were, instead, very limited.

All podopaediatrics specialists seemed in favour of using functional pre-formed semi-rigid FOs, on the other hand, none actually used palliative off the shelf FOs. These data indicated that all practitioners believed that the gait of JIA children should be treated; and consequently it could be concluded that one of the key issues to improve JIA symptoms was to intervene on the biomechanics of the JIA children. It could be argued that, if this option was the most common clinical management adopted by most podopaediatrics specialists in Scotland, the possible positive results of the JIA multicentre study may be welcomed amongst practitioners, as the possible new evidence to be adopted for the podiatric treatment of JIA patients.

In addition, at the time of the study, it had to be taken into consideration that not all devices previously mentioned, could have been purchased at all foot sizes. This factor could be seen as a possible limitation in some of those products, as practitioners could experience difficulties during clinical management. In many occasions, podiatrists may have to decide the type of FOs based on the foot size availability and not of its efficacy.

In order to standardise the type of FOs prescribed to the JIA study, the same brand of devices had to be prescribed to all patients that took part to the study. Finally, at the time of the survey, the Slimflex Plus appeared to be the most commonly prescribed FOs amongst clinicians in Scotland, which was available in all foot sizes (full range from child to adult). The Slimflex Plus could be easily adjusted and customised to meet

the biomechanical requirements for the patients. Podiatrists could supply the Slimflex Plus at chair-side to the patients, with the addition of extrinsic corrections and different materials.

3.1.7. Conclusion

This JIA survey provided useful information regarding the podiatric clinical management for JIA, currently in placed in different NHS trust across Scotland. The results obtained from this survey showed that not all podopaediatrics specialists' clinics treated JIA patients; and that each clinic had different podiatric approaches. Some practitioners were more prone in using palliative and/or functional customised FOs; other podopaediatrics specialists relayed more on functional off the shelf FOs. In most cases the decision of devices was made on a basis of the resources available. With regards to pre-formed semi-rigid FOs, it appeared that the most commonly used were: Interpod range, Slimflex and Vasyli orthotics. However, the only FOs brand that was more cost effective and available in all sizes was Slimflex Plus. For these two main reasons, the JIA study was conducted using Slimflex Plus as a type of FOs that could be modified at chair-side and customised according to the different biomechanical requirement of the patients.

3.2. Plantar Foot Pressure Measurement

Over the past two decades, measurement of pressure under the foot has generated vast interest amongst clinicians and researchers, particularly in the fields of diabetes, orthopaedics, sports science, rheumatology and podopaediatrics. During biomechanical

assessment of the lower limbs, podiatrists are able to diagnose pathologies related to abnormal loading of plantar pressure. Recordings obtained from a plantar pressure measurement represent valuable information for physical therapists in the analysis and management of adult and paediatric gait, which comprise a wide variety of foot and lower-extremity disorders. Orthotic devices are frequently prescribed as a conservative and non-invasive treatment of lower extremity injury. Gait analysis is defined as the systematic study of human motion using the eye and the brain of observers, aided by the use of technology that allows the investigation of movements, mechanics, and muscle activity (Whittle 2010). The increasing number of publications studying gait confirms the role of using a plantar foot pressure system to analyse foot parameters pre-post treatment (Dixon and McNally 2008).

One of the pioneers of gait analysis is considered to be Aristotle (384-322 a.c.) with '*De Motu Animalium'* (the Gait of Animals). Aristotle claimed that 'everything that is in motion has been initiated by forces; as the world is not infinite, the original forces must have been originated by static entity'. This statement indicates the effect applied to an object which determines movement, is directly linked to the ground reaction forces applied to human motion, which is remarkable considering the historical period in which this philosopher developed his concepts (Bragagnolo 2000). Much later, in 1680, Giovanni Alfonso Borelli also called his last publication '*De Motu Animalium'* which became his most famous work. Unfortunately the professor in mathematics, who was born in Naples, passed away before his work became widely recognised (Davidson 2003). According to the author, Mr Borelli is often referred to as the 'father' of biomechanics. In his attempt to describe the first concepts of biomechanics, Borelli worked to analyse in detail movements such as running and jumping, using mechanical principles upon muscle contraction and mathematical role movements. Finally, Borelli also focused on providing valuable explanations for issues such as muscle fatigue and organ secretion and he also tried to clarify the concept of pain (Davidson 2003).

With the advance of photography, it became possible to record different sequences of images which displayed animal and human motion, which had been difficult to observe with the naked eye. The coetaneous Eadweard Muybridge (9/4/1830-8/5/1904) and Etienne-Jules Marey (5/4/1830-21/5/1904) are considered to be the precursors of this new science in the early 1900s. In 1877 Leland Stanford hired these pioneers of

biomechanics to demonstrate that during the trotting gait of horses, all four limbs were off the ground at one point. According to Solnit (2003) an electronic shutter was developed to prove this theory. In 1878, Muybridge connected approximately a dozen cameras to record the gait of a horse sequentially. While light exposures at that time were often several minutes long, the 12 exposures occurred over about 30sec. A highly contrasting, light background was used to enhance the images taken. The photos taken were numbered which allowed him to obtain time and spacing information. Stanford ultimately recorded the evidence which demonstrated that horse's feet left the ground during a trot. Therefore with the aid of photography a sequence of the horse 'gallop' gait was revealed for the very first time to the world. Before this discovery, the gallop was wrongly depicted in paintings (Solnit 2003). According to the book "River of Shadows" published by Solnit (2003), the motion analysis breakthroughs developed by the two pioneers of biomechanics were as follows: the development of an electronic automatically triggered shutter; advances in the development of plates to capture movement on an image in less time than anyone had accomplished previously; recording of sequential images that could be added together to represent an animated motion cycle (such as a gait cycle) instead of single isolated moment (Solnit 2003).

In the 1980s, significant developments occurred in gait analysis to a point at which the data collected became a valuable tool for the development of treatment protocols in orthopaedic surgery (Sutherland 2002; Sutherland 2005). The force that the human applies to the ground is recognised to be equally matched by the reaction of the ground. For centuries philosophers made this type of deductions from animal or human movements by simply observing their paw or foot prints. The precursor of this concept was the English physicist Isaac Newton (1643 – 1727) who formulated that ''for every force applied there is an equal and opposite reaction'' (Motte 2007). Sutherland (2005) wrote an extensive review on the evolution of clinical gait analysis in which he underlined that the pressures applied by the body through the foot to the ground are vector forces. The world's first three-component (pneumatic) force plate, which was called the ''Trottoire Dynamique'', was developed by Georges Demeny and Etienne-Jules Marey along with Jules Amar, who was a rehabilitation doctor working with amputees during and after the First World War in France (Braune 1992). In 1938 the first device capable of measuring the ground reaction in three planes was developed by Dr. Elftman: it consisted of an upper and a lower platform suspended with calibrated

springs that measured the ground reaction forces and separated them into different components (Elftman 1938; Sutherland 2005).

Plantar pressures can be measured using a variety of instruments, including: force-sensing resistors (FSRs), hydro-cells, microcapsules, projection devices, pedoscopes, capacitance transducers, as well as by critical light deflection (Orlin and McPoil 2000). Pressure systems measure vertical force in different anatomical parts of the foot and they provide data regarding the effects of various podiatric interventions, including use of footwear, use of foot orthoses, gait training, and surgical management. In contrast, although the force platform provides valuable data regarding both the vertical and shear components of the ground reaction force, it provides limited information on how the plantar surface of the foot is loaded with respect to the supporting surface during ambulation (Cavanagh et al. 1992; Duckworth et al. 1985). Ankle sagittal plane motion may be described as the '3 rockers'. The first rocker refers to the moment when the rearfoot has contact with the terrain after initial contact. The second rocker starts when the tibia move forward over the foot whist at midstance, Finally, the third rocker occurs during propulsion phase when the heel rises and the load is transferred to the forefoot (Perry and Burnfield 2010). It is important to be aware of the different phases that occur during gait in order to give meaning to the extended data that modern gait analysis software are able to provide at present.

3.2.1. Barefoot measurements

During the past two decades new technology has led to the development of new clinical systems applicable for the evaluation of foot pressure, step dynamics and postural disturbances. Lately, capturing and recording gait data has become much easier than ever before confirming the efficacy of treatment protocols and therapeutic regimens. Barefoot measurement is becoming more and more popular amongst podiatrists as it represents a valuable educational tool for patients with different pathologies and it can

be used for numerous research purposes. Regular barefoot screenings could help podiatrists to identify high pressure aspect of the foot that may help to prevent the incidence of ulcers and/or pressure sores. The data recorded allows the identification of precise areas of concern and the implementation of the clinical management by podiatrists.

One of the first barefoot measurement systems was called the 'projection device'. This type of device consists of a rubber mat which was filled with ink and then covered with paper. When plantar pressure is applied to the mat by the patient, the ink is deposited on the paper at the locations of highest pressure because all the layers of the mat are more compressed by the applied load. In 1947, Harris and Beath first reported using this type of device when attempting to classify the foot structure of 3619 Canadian soldiers (Stamm 1950). From this extensive survey, the authors concluded that even though it was not possible to reassess and compare the data obtained more than once, soldiers who presented with cavus feet with clawing toes were initially found without any disabling pathologies that would stop them from starting training. However, during intensive training, the conditions of those soldiers rapidly worsened compared to others without cavus foot (Stamm 1950). The mat type of projection device appeared to be suitable for a qualitative description of the pattern of plantar pressure, but this type of device cannot be used to quantify the magnitude of plantar pressures (Orlin and McPoil 2000).

Depending on the dimension of the barefoot analysis system, single or multiple foot strikes can be captured to observe gait abnormalities. For example, multiple foot strikes recorded on a HR Walkway (Tekscan) allows recording of cadence (steps per min), the velocity (metres per second), the gait time and the gait distance. Depending on the resolution of the sensels and their sizes, it is possible to display foot pressure and forces curve over time, extremely useful for the podiatrist to assist in the orthotic prescriptions and alterations. The foot recordings may be segmented in different parts (for example: heel, mid-foot, toes etc.) in order to allow the podiatrist to study details on foot functional behaviour in adult and paediatric patients. Therefore, it is possibly to quantify high pressure points in different anatomical areas of the plantar surface. Also a comparison between left and right foot is also possible which would help to investigate if any asymmetrical patterns are present. In clinical scenarios, using barefoot

measurements is intended to provide the patients with direct and tangible visual feedback, which may help the patient's compliancy and may improve clinical outcomes.

Most digital mat systems available on the market at present allow obtaining static and dynamic recordings instantly and are displayed frame by frame to identify pressure profile discrepancies. Podiatrists who are equipped with this modern technology can present foot images to their patients to compare pre-orthotic and post-orthotic intervention, sway pattern improvements, pre-surgical and postsurgical patterns and pre and post-manipulative adjustments. Hughes et al. (1991) reported that diabetic patients with neuropathy could be at risk of plantar ulceration when walking multiple barefoot steps on the digital platforms. In addition, patients with neurological impairment may have difficulty targeting the platform because of proprioception and coordination problems (Cavanagh and Ulbrecht 1991).

One of the advantages of the barefoot analysis system is that the pressure sensors are always positioned parallel to the supporting surface to provide a 'true' vertical force measurements (Orlin and McPoil 2000). Digital platforms enable collection of data without the influence of footwear; recording can be achieved very quickly without wires or data-boxes attached to the subject, which may indirectly influence normal ambulation.

On the other hand, it can be argued that some clinicians are not in favour of using barefoot analysis because it indirectly induces the patients to target the plate instead of focusing on walking naturally. Long platform is able to record high quality data which are significantly more expensive, and which require more space, not always available in private practice. Other thick platforms, unless are embedded in the floor, may appear slightly raised surface and might influence normal gait.

The HR walkway system is a reasonably easy system to use and it does not require too long to become familiar with the different options available. The foot segmentation option can be applied to calculate toe-in or toe-out angle and to compare the line of progression. Calculation of values for step and gait time, distance, velocity, and cadence can be investigated. In addition, individual data for the left and right foot with

regard to the gait cycle, step-stride parameters, and symmetry scores can be obtained. The new updated Walkway software (version 7.0) features additional options (ie: Human Table Icon) that generate tables and provide clear visual display of gait parameters by using the.

The use of the Tekscan digital mat has been reported by the Journal of the American Podiatric Medical Association in a publication written by Clough (2005) in which new methods of identification of functional hallux limitus were discussed. The Tekscan barefoot analysis data provides useful information for the researchers to develop adequate clinical management. The VAS score showed a significant improvement of pain level from 8/10 to 2/10. Even if this was only one clinical case, the software was able to aid in the podiatric prescription and quantify precisely the shifts in plantar pressure.

A comparative technical assessment was carried out in Rome with the aim of investigating the appropriateness of different plantar pressure measurement devices (Giacomozzi 2010). After extended static pressure tests using a special customised pneumatic bladder, results showed the high accuracy of the Matscan from Tekscan and highly linear behaviour up to 800 KPa. This independent researcher also reported that after dedicated calibration, the resistive Matscan proved to have high correlation under sinusoidal loading[22], and high precision in COP[23] estimation (Giacomozzi 2010).

Recently the 'Journal for Foot and Ankle Research' published a paper written by Zammit (2010) in which the reliability of the Tekscan Matscan-system for the measurement of plantar forces and pressures during barefoot level walking in healthy adults were investigated. This system is widely available to podiatrists and to researchers; however, according to the author's knowledge, apart from the actual manufacturers, no independent clinical trials to date had investigated the reliability of the Tekscan Matscan. The author used the 2 step approach which involves striking the platform on the 2nd step once a constant speed has been reached, and it appeared to reproduce plantar force and pressure data that is reflective of foot function during gait.

[22] Sinusoidal loading: in the form of a wave, represent one whose amplitude varies in proportion to the sine of some variable (such as forces or time).
[23] COP= centre of pressure

Zammit (2010) particularly investigated the maximum force, peak pressure and average pressure variables from each recording obtained. In addition, 7 regions of the foot were investigated: heel, midfoot, 3rd-5th metatarso-phalangeal joint, 2nd metatarso-phalangeal joint, 1st metatarso-phalangeal joint, hallux and the lesser toes. Results showed that the system displayed moderate to good reliability of mean and median calculations for all the 3 analysed variables (rearfoot, midfoot and forefoot) and across all 7 regions of plantar pressure. It can be argued that there are few limitations to be considered while interpreting these values which will be taken into account for the research presented in this thesis. Firstly, in this study the subjects recruited were mostly young (mean age was 28.2), therefore, conclusions cannot necessarily be generalised to other older clinical populations. Secondly, it can be noticed that unlike the Novel EMED® system, which allowed uploading an automatic mask during data analysis of each recording, the Tekscan Matscan® instead, requires a mask to be manually constructed and applied over each recordings. However, it must be outlined that the standardised mask can be modified, positioned and saved independently from different foot sizes and with reference to multiple anatomical landmarks analysed (for example: rearfoot, midfoot and forefoot). Some podiatrists may argue that that even if the mask template for each patient can be saved and re-uploaded for the subsequent trials, there could be some potential margin for error. In particular with the Zammit (2010) research, even if the smaller system Tekscan Matscan® is portable and more convenient to move in different clinical environments, it only captures 1 barefoot measurement of either the left or right foot at the time each trial. This limitation will not apply to the HR walkway as multiple foot strike can be captured over the 1.97m platform and, thanks to the new version of the software (7.0) masking different anatomical portions of the foot, it has become easier and allows more precise extrapolation of data.

In 2003 the journal of 'Foot and Ankle International' published a study in which great focus was given to the changes to the Achilles tendon (AT) as a result of surgical medialising-calcaneal-osteotomy (MCO). The researchers studied different proposed surgical techniques using the Tekscan HR Mat plantar changes on 14 fresh-frozen cadaver legs. No specifications were provided on what were the resolution and the dimension of the Tekscan system. With the aid of a specially designed frame, perpendicular axial loading (100 lbs) of each specimen was applied in neutral and at

15° dorsiflexion (Hadfield et al. 2003). The 3 trials were recorded, each in neutral and dorsiflexed positions, in order to study Achilles tendon length alteration and to monitor plantar foot pressure parameters. The authors reports that the findings may indicate that the Achilles tendon could have an effect on the inversion of the forefoot without undergoing a significant elongation of its fibres in any of the regions tested (Hadfield et al. 2003). Not many details were provided on how the pressure applied by the frame was constantly monitored to be at 100 lbs applied directly on the proximal area of the frozen cadaver's tibia. It can be argued that at room temperature, the flesh condition may change rapidly making the soft tissue softer and more flexible. Therefore, unless each specimen recording was taken at the same room temperature, with the same exposure to heat, the final foot pressure recording values may be skewed. In addition, the reader is not informed if the tibia's cadaver used had similar length and if there were any inclusion or exclusion criteria to select the specimens. However, even if the procedure adopted in this study may be debatable, the HR Mat enabled Hadfield (2003) to record valuable details for data analysis. Interestingly, during the gait analysis the foot was subdivided into 7 segments, coincidentally the same parameters investigated by Zammit (2010). In the RCT study discussed in this thesis, the same parameters will be analysed in order to confirm the need to analyse these anatomical areas of the foot, as supported by previous clinical evidence (Hadfield et al. 2003; Zammit et al. 2010).
It is important to underline that the development of a barefoot analysis system also helps to develop veterinary research proposals. Research suggests that up to 30% of cats may suffer from osteoarthritis, with the incidence rising to 90% in cats older than 12 years of age, and the elbow joint becoming frequently symptomatic (Hardie et al. 2002). Lascelles (2006) investigated dog biomechanics using 7100 HR walkway system (precisely the same resolution of the equipment available at Queen Margaret University). Data recorded using the HR walkway, revealed that short-term postoperative morbidity may be reduced in dogs that undergo arthroscopic joint surgery compared to the traditional open arthrotomy technique (Lascelles et al. 2006).

The HR Walkway has also been used by Lascelles (2007) to investigate kinetic evaluation of normal walking and jumping in cats as well. The primary outcome of this research was to determine whether kinetic data could be recorded from client-owned cats while walking and jumping. The secondary outcome was to determine whether the kinetic parameters of peak vertical force (PVF) and vertical impulse (VI) were

significantly different across all 4 limbs (Lascelles et al. 2007). Tekscan results indicated that there were no significant differences between the PVF or VI of the left and right limbs, but both parameters were significantly greater for the forelimbs than the hind limbs ($p<0.01$) for the walking data. The author concluded that results obtained proved that the system is sensitive enough to detect postoperative lameness, and may make it possible to assess post-operative analgesia (Lascelles et al. 2007).

To date few studies have been conducted to provide comparative data from normal to pathological paediatric gait. An HR Mat (Tekscan) has often been used to provide a single capture of the foot strike during barefoot analysis (Riad et al. 2007). However, the evidence is scarce at present with regard to recording children's multiple barefoot strike using the HR Walkway.

3.2.2. In shoe measurement

Similarly to barefoot measurement, in-shoe plantar pressure measurement has the potential to play a crucial role in the screening, treatment and orthotic management of patients who are at risk of, or are suffering from lower limbs pathologies (Cavanagh, Hewitt and Perry 1992). In the past only few gait analysis laboratories were able to carry out in-shoes data collection. Instead, at present this is no longer the case because many commercially available systems for measuring in-shoe plantar pressure (ie: Pedar insole system, F-Scan system, and Musgrave footprint system) are able to offer a higher degree of portability compared to long platforms. Therefore, podiatrists are now able to carry out in-shoe recording in different indoor and outdoor environments and in multiple clinic sites. Compared to the platform system, the use of plantar pressure insoles allows the collection and analysis of data from multiple steps, while walking in shoes with or without orthoses. Finally, plantar pressure data can be displayed as peak pressures produced during gait (Fairburn et al. 2002).

The use of microcapsules represented one of the first significant steps to provide a cost-effective tool to clinicians to gain in-shoe plantar pressures data. It consisted of small dye-filled capsules sandwiched between 2 layers of thin foam, which were inserted in the patient's shoes. As the patient walked, the capsules would break when pressure was

applied, causing the dye to be released into the foam layers. The release of the dye would stain the foam and provide an impression of the areas on the plantar surface of the foot with the highest pressures. However, podiatrists were unable to quantify the precise amount of pressure applied in a particular anatomical area. In addition, this system often provided a faulty reading as the microcapsules often fractured when inserted in the shoes (Orlin and McPoil 2000). Another system, technologically more advanced, consisted of the Force-Sensing Resistors (FSR). The FSR is a very thin layered device with metal patterns printed on 2 Mylar sheets[24], with a conductive polymer layer placed between the 2 sheets (Cavanagh, Hewitt and Perry 1992). The conductive layer reduces resistance to the flow of electrons as the pressure between the Mylar layers increases. This pressure between the Mylar layers causes the resistance to decrease. The output of the devices using the sensor technology can be expressed either by force or by pressure. A company originally called 'Tekscan' (originally from Boston, USA) uses the FSR technology in a matrix array for different applications from dentistry to the car industry. With regard to biomechanics, this company has developed an in-shoe measurement insole that is commercially available under the trade name F-Scan™ system (Orlin and McPoil 2000). The F-Scan™ in-shoe technology will be discussed in detail in the next section of this chapter as it has been adopted in the JIA study.

In the research carried out by Fairburn et al. (2002), gait analysis measurements were performed also using the novel Pedar in-shoe system (Novel GmbH, Munich, Germany). The standard Novel-Pedar in-shoe pressure measurement system consists of an insole pair (with all optional European sizes from 24 to 45), connected to a lightweight belt unit worn around the waist, linked with special wires to a PC (Fairburn et al. 2002). The Pedar system can be connected with a synchronised digital video camera, allowing the simultaneous display of 2D and 3D data. In addition, step selection, force-time integrals and comparison for pre/post difference picture can be quickly obtained by the software. The Pedar system can be purchased along with an air pressure device called 'Trublu®' used to obtained accurate calibration of the insoles. With the aid of the Trublu® calibration device, all sensors of the Pedar® system are calibrated individually using high air pressure which occurred automatically by the

[24] Mylar sheet: polyester films, exceptionally flexible, strong and durable. They have a high tensile, tear and impact strength. They remain tough and flexible at temperatures ranging from -70°c to 150°c. Widely used for different engineering purposes

software. It can be argued that in clinical scenario and during research trails, the necessity of having to link the Trublu® calibration device to the software at every single time prior to data collection may be deemed to be time consuming. Furthermore, all the equipment required (Pedar®, Trublu® and air compressor) not only may be too pricy for some clinicians but also it occupies lots of space, not always feasible for every private practice or hospital room.

Finally, some podiatrists may debate that the thickness of the Pedar (1.9mm) is too much, especially in narrow shoes or when orthotic devices are inserted. At first, Pedar thickness does not seem problematic but when compared to F-Scan™ digital insole (0.15mm) it appears clear that other systems are significantly thinner. Furthermore, the number of total sensors present and their resolution are extremely important details that should to be taken into consideration when deciding what system can be used, especially in research. For example, in the Pedar® the total numbers of sensors are 99 compared to 960 sensing elements in the F-Scan™. Instead, the pressure range in the Pedar® goes from 15 to 600 KPa, compared to the F-Scan™ that goes from 125 to 862 KPa (Tekscan 2010).

The significant advantage of taking in-shoe measurements is to capture multiple footsteps data from both feet at the same time and record foot functional behaviours directly inside the shoe. Unlike to what occurs while using platform measurements, during in-shoe recording the patient can walk more naturally instead of targeting a plate on the floor, which could potentially alter normal ambulation. In contrast, the natural walking style of a patient may be altered by the presence of wires and data boxes attached to the waist. However, few systems recently developed are equipped with wireless connection, eliminating any possible issues related to wires connecting insole and data box. Dependent on the quality of the sensors of the digital insole, certain areas of the foot may be missed during recording under the influence of the shoe. In addition, the different materials used with the digital insole (for example: rigid type), could have a direct effect on the recordings and may alter the data, resulting in false interpretation of results.

Some clinicians may argue that one of the disadvantages of using the in-shoes system is that when corrective orthotics are placed into the shoe, the depth of the shoe and

thickness of the digital insole may affect pressure. Some surfaces can be slippery therefore recording may be affected. Certain skills are required by the podiatrist when inserting the patient's foot inside the shoes without creating uneven surfaces on the digital insole; a particularly difficult task to be carried out thoroughly when dealing with symptomatic children using very small shoes. Some clinicians may fail to ensure that the digital insole is placed correctly on top of the orthotics, with the unfortunate results of bending the sensors and altering the direction of forces.

The F-scan in-shoe pressure measurement system provided objective quantifiable and reliable measures to study different types of pathologies (Ahroni, Boyko, and Forsberg 1998b; Chen and Bates 2000; Joanne et al. 2007; Luo et al. 1998; Nicolopoulos and Barnett 1998; Randolph et al. 2000; Rash and Quesada 1997).

F-scan system allows a high degree of portability of the system in different clinical settings, and it can be utilised to investigate in-shoe foot behaviours with multiple pathologies. The Diabetic Foot Journal published the study conducted by Joanne (2007) in which custom-made total contact FOs and prefabricated functional diabetic FOs efficacy were compared (Joanne et al. 2007). According to Cochrane systemic reviews, reducing plantar mechanical pressure is one of the most important clinical interventions required to encourage the healing process, particularly in neuropathic feet (Grimm et al. 2004; Spencer 2008). Recent evidence also confirms that there is a direct links between peak plantar pressure and the development of neuropathic foot ulcers. Thus, FOs designed to reduce elevated plantar pressure are prescribed to prevent ulceration in diabetes patients (Bus et al. 2004; Spencer 2008). In the comparison clinical case study carried out by Joanne (2007) on diabetic patients it was possible to prove that F-scan in-shoe pressure measurement systems, have the great potential to instantly identify and optimise off-loading interventions which would reduce the patient's risk of ulceration (Joanne et al. 2007). The author investigated 5 pre-selected foot outcome measures: peak plantar pressure, total plantar contact area, rate of forefoot load, forefoot pressure time integral, duration of metatarsal region load as a percentage of stances. Finally it was concluded that thanks to the data obtained by the Tekscan software the prefabricated functional FOs appeared to offer a successful alternative to the more costly custom-made FOs. This comparative study also highlighted the importance of

considering foot biomechanics to effectively prescribe load-reducing FOs in ulcer prevention and management (Joanne et al. 2007).

In clinical practice, it is fairly common to find practitioners who have different opinion regarding the choices of in-shoes system that should be used with patients. For example, Cavanagh (1992) published a review in which the F-scan system was heavily criticised for not providing accurate and reliable results. This author, instead, favoured the use of the Pedar system as more precised equipment used for in-shoe measurements (Cavanagh, Hewitt and Perry 1992). Regardless of clinical preference, a few years later Rash (1997) carried out a comparative study between Pedar and F-scan system which revealed no significant difference in the ability to measure uniform absolute pressure (Rash and Quesada 1997). In addition, it was suggested that F-scan is more accurate than the Pedar over a longer period of time and by the same patient (Rash and Quesada 1997). It has to be said that since the time that this fairly dated publication was written, both systems have evolved in technology and improved the resolution of their sensel.

In shoe analysis systems, such as F-scan appear to have generated a lot of interest amongst biomechanical researchers in the late 90's. The 'Journal of Rehabilitation Research and Development' published an interesting study conducted by Dr Luo (1998) in which validation of F-Scan pressure sensor system was investigated. This study performed a quantitative validation using a servo-hydraulic material test system[25] that was able to exert compression forces on the entire FOs sensor and on each single cell. The FOs sensor was positioned between 2 layers of plastizote (6.4mm), backed by 2 layers of 12.7mm thick aluminium plates. Constant pressure was applied to the whole surface of the F-scan sensor by the MTS machine. The researcher tested the application of uniform pressure by moving the F-scan insole in different positions inside the compressor, showing no changes in the sensor output contours. Due to the heat generated within the electric circuit and insulation by the foam, the sensor temperature could have increased, leading to output voltage variations. Therefore, temperature changes were monitored with the aid of a digital thermometer and a thermo-sensor needle placed near the central region of the F-Scan insole sensor. Evaluation of the linearity and homogeneity of cell response was performed at five static loading levels.

[25] MTS 810, MTS Systems Corporation, Minneapolis, MN

Several tests at different temperatures were carried out in order to monitor sensor response in hot and cold environments. It can be argued that in the clinical scenario, prior to using the F-scan on a patient, the sensor would almost never be exposed to 45°. Therefore, although it is important to be aware that at certain temperatures the sensitivity of the F-scan may change, equally it should never occur that patients are exposed to these overwhelming temperatures during gait analysis. During this research, the F-scan was tested with different materials (softer and harder) to investigate how the sensor would react if placed over static pressure (for a period of 120 sec) and over dynamic pressure (1 sec). This study concluded that factors that should be considered while using F-scan are: contact surface, loading conditions, and temperature changes. Additionally, re-examination of the F-Scan sensor system is also necessary whenever it is upgraded. Finally the results indicated that the sensor is adequate for determination of pressure distribution under contact conditions with soft materials (Luo, Berglund and An 1998).

Encouraging evidence on the reliability of the F-scan is also provided by Ahroni (1998). This prospective study, which was made available by the journal of 'foot and ankle international', highlights that for elderly patients with diabetes who were wearing their own shoes and were tested over two days with different FOs, the F-Scan insole system proved to be a reliable system to measure in-shoe parameters. In each of the 51 subjects recruited from a cohort of 977 diabetic veterans with risk factors for foot ulceration and amputation, high pressure and peak pressure was investigated particularly on the forefoot and particularly underneath the metatarsal head, which represent the anatomical areas with a higher incidence of developing ulcers (Ahroni, Boyko and Forsberg 1998b). Finally, from this quite dated research, carried out in Seattle, Washington, not only was it possible to confirm the reliability of the F-scan system, but also it was proven that this in-shoe technology could significantly prevent the creation of ulcers underneath exposed metatarsal heads, which may lead to amputations.

Another comparison study published by the 'Physiotherapy Theory and Practice Journal' investigated the F-Scan in-shoe system with the AMTI[26] force-plate system in

[26] AMTI = Advanced Medical Technologies, Inc

measuring vertical ground reaction force during gait. According to the author, the AMTI served as the 'gold standard' for comparison with the F-Scan system (Chen and Bates 2000). For this study, 2 force-plates were placed on two separate aluminium supports, which were firmly inserted into the concrete foundation within the floor of the gait laboratory. The force-plates were placed to allow 2 consecutive steps during the data collection (Chen and Bates 2000). The F-scan and the AMTI were adopted to simultaneously record the self-selected walking pace of 30 healthy adults. Participant presented the following characteristics: 27.7 ± 2.9 years; weight 80.1 ± 14.9 kg; height 181.3 ± 5.6 cm). As shown the age range might be deemed to be insufficient to represent the entire population as well as the fact that only males were recruited in this study. All subjects were volunteers from the university student body. The criteria adopted allowed the selection of participants who were free of injury and having no lower extremity deformities. All subjects were right leg dominant as established by their kicking leg preference. Furthermore, due to limited availability of shoes and F-scan sensors, all volunteers had to have a foot size between 9 and 11 (Chen and Bates 2000). All subjects wore standard laboratory shoes provided by the investigators to avoid introducing additional variables in the in-shoe recordings. In this interesting paper, it is specified that one biomechanical specialist was in charge of pre-screening each individual subject in order to exclude those with noticeable abnormalities or pathological gait patterns. Prior to using the F-scan system, static STJ measurements were obtained at close kinetic chain using a gravitational goniometer.

Chen (2000) calculated the STJ values 3 times at each trial, and then averaged the values to monitor if the participant met the inclusion and exclusion criteria. Therefore, individuals with more than 5° of ankle valgus or varus were excluded from participation. Data analysis revealed no statistical differences between the 2 systems ($p>0.05$). Curve correlation showed higher correlations for the 21–90% interval of the support phase (midstance) compared to the initial (heel strike) and a brief period before toe-off. These results may indicate that the F-Scan insole system is a useful system to measure the vertical GRF during ambulation. However, according to this research particular attention should be given in the interpretation of pressure and force data particularly during the initial 21% and final 10% of the support phase of walking (Chen and Bates 2000). The reader should be reminded that in this comparative study, in which a very limited part of the population was investigated; because only males in the

age range of 25 to 30 years were involved in the study. Some clinicians may argue that having only 3 FOs sizes available may be considered as a possible limitation to thoroughly test the full potentials of the system. In addition, podiatrists may argue that right footed subjects should not necessarily have been recruited in the study; also, the reader is not informed about the type of shoes used for all the recording, which may have directly caused the F-scan system to fail to produce valid data at heel strike and toeing-off. Finally, the author failed to provide valuable details on the type of criteria used by the biomechanical specialist to include or exclude participants. For example, it is not mentioned in the text if the initial gait observations were made with subjects walking with shoes: some participants could have appeared to have a sound biomechanics because they could have been previously fitted with functional devices in their shoes. Subsequently, the F-scan recordings were taken without the orthotics; therefore results obtained could have been completely skewed, particularly if such a small population was involved.

From the Archives of Physical Medicine and Rehabilitation, it is possible to evaluate another study conducted by Randolph (2000) in which the reliability of measurements of pressures applied on the foot during walking F-scan system was investigated. This study was conducted in the gait laboratory of the department of Physical Medicine and Rehabilitation of the New York Medical College, in which 10 healthy subjects were, studied (2 men, 8 women, age 30 to 59 years, mean age of 46 years). The insoles were cut to fit the entire sole of the foot and then placed in the shoes. Final results indicated no significant difference between the 4 F-scan insoles tested in this small study. The pressure data obtained by this in-shoe measurement system appeared to be sufficiently reliable to be used for the podiatric management.

Not many in-shoe measurements publications have been yet carried out by authors who have expertise in the rheumatology field. Interestingly, Woodburn (1996) and Li (2000) drew two completely opposite conclusions with regard to the use of the F-scan system. The former claimed that the F-Scan system lacks durability and suffers from significant calibration errors. In addition, few limitations related to the physical characteristics and capabilities of the sensor of the system were disclosed. For example: the material used for making the FOs did not help its durability; the author frequently experienced creasing in the heel region which caused to permanent damage and strain to connected wires and ultimately led to sensor failure. The sensors were found to be flexible in two

directions but not simultaneously and therefore they did not adapt well to the curved surfaces of the FOs inserted. Woodburn (1996) challenged the ability of the upper pressure range of the sensor (1250 KPa) which may be inadequate for use in some patient groups who experience very high plantar pressures, particularly neuropathic diabetics with plantar ulceration. The podiatrist involved at the rheumatology department of the Huddersfield Royal Infirmary, concluded his publication by reporting that despite an initial positive impression of the system, F-Scan is not entirely suitable for accurate and repeatable in-shoe pressure measurements. Nevertheless, Woodburn still values the F-scan, reporting that useful information can be gained where the user understands and takes account of the limitations of the system.

On the other hand, Li (2000) used the F-Scan system with RA patients who were wearing FOs. The Chinese researcher raised the question whether FOs would have an effect on the foot pressures distribution and forces during gait. Biomechanical changes were investigated on 12 female RA patients and compared with 8 healthy female participants. FO is commonly prescribed to patient affected by this disabling autoimmune pathology, however, at the time of the publication little was known about the biomechanical effects of in-shoe foot orthoses (Janisse 1998; Li et al. 2000). Gait Analysis was recorded using the F-Scan software (version 3.623) and analysed with subjects walking in-shoe with or without foot orthoses. Each recording was carried out wearing commercial sport socks and a constant room temperature of 20° was maintained. Sensors were adjusted to fit shoe size and calibration of the F-Scan was carried out prior to each measurement using subjects' body weights in a single-limb support model (standing calibration).

Although this research provided positive results of the use of the F-scan system, it can be argued that using brand new sensors with each patient represents a very accurate way to record data; however, it is feasible only with such a small population of patients recruited. Furthermore, in real clinical scenarios, due to financial issues, it might be difficult to reproduce the same methodology carried out by Li (2000). The reader is not informed about what types of shoes were used during the data recording. On the paper it is illustrated a common gymnastic shoe; however, the author simply reported that patients walked with ‘their shoes’, which could have potentially skewed the final results. Finally, some podiatrists may argue that it would have been more appropriate to

recruit a more mixed gender population, rather than only female. However, most importantly, if the recordings were repeated more than once with each patient, at a certain interval (for example: 6 weeks or 3 months), it would have been possible also to verify the effectiveness in pain relief and gait improvement over a period of time.

3.3. Equipment

3.3.1. Tekscan computer requirement

During the entire data collection process the same equipment has been used both for the repeatability and reproducibility study and for the RCT in JIA children: HR Walkway and F-scan system. In this chapter details of the equipment will be provided. Most of the gait recording has been carried out at Queen Margaret University Gait Laboratory; however, part of this multicentre research project has also been carried out in Dundee at the TORT centre in Ninewells Hospital.

In order to utilise the equipment, two laptops have been provided by Queen Margaret University in which HR Walkway (software version 7.0) and F-scan (software version: 6.30) were installed. According to the manual provided by the manufacturer, the Tekscan system must meet or exceed certain requirements. The suggested minimum computer requirements (desktop or laptop) for all Tekscan Systems are: Intel Pentium 600 MHz or higher processor 1 with 128 MB RAM (512 MB RAM recommended); 1 GB hard drive and 1 CD ROM drive; Windows 2000 (SP4), XP (SP2), Vista7 operating system (32-bit versions only).

3.3.2. The HR Walkway™

As reported by the Tekscan, the HR Walkway system provides static and dynamic gait data and barefoot pressure and force measurements over several steps using a low profile floor walkway (Figure 3.3.2.1).

Figure 3.3.2.1:HR Walkway

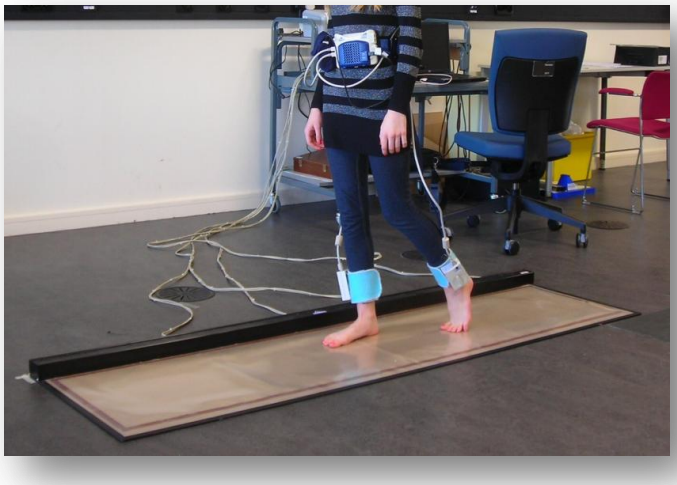


Figure 3.3.2.2: patient walking on HR Walkway

The barefoot analysis system used for this paediatric rheumatology research has 4 sensels per cm^2. It was possible to carry out the calibration process by application of a known and controlled force. According to Tekscan (2010) the sampling rate of the #7101QL model is 60 Hz and the pressure range goes from 1-862 kPa, which is quite remarkable considering that the floor mat thickness is only 5 mm (Figure 3.3.2.1, Figure 3.3.2.3). Multiple foot strike was made possible as the High Resolution Walkway is 1956 mm long and 442 mm wide platform and counts for a total number of

33,408 of high resolution sensing elements.

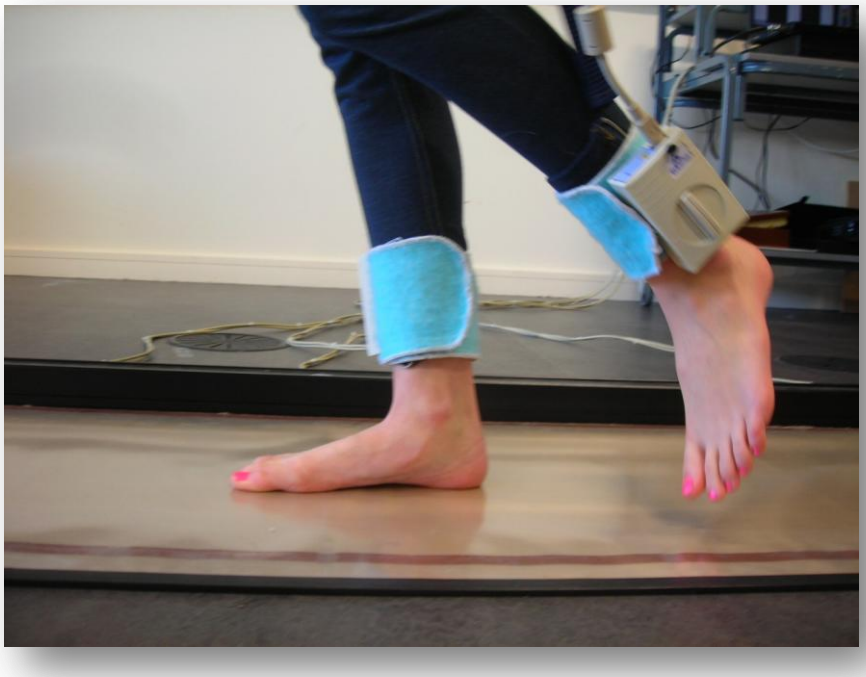
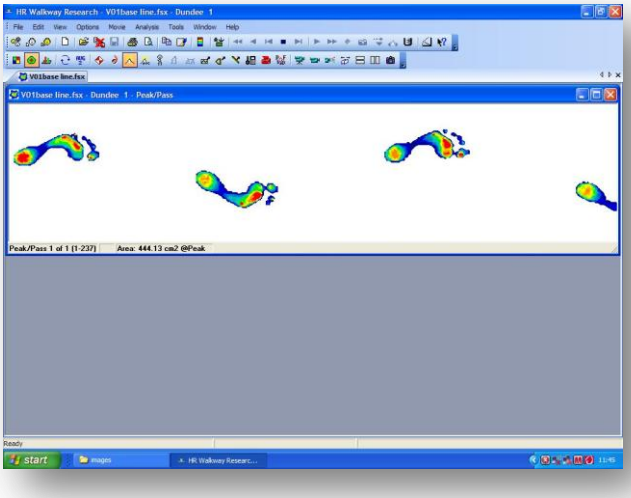


Figure 3.3.2.3: close up on patient walking on HR Walkway with the F-Scan ankle cuff on.

As previously mentioned the sequence of recording was randomly decided with each participant Figure 3.3.2.4. However, each participant was asked to familiarise with the platform by walking on it at least twice.

Figure 3.3.2.4: recording icon

Figure 3.3.2.5: example of barefoot recording



At the countdown of 3, the patient was asked to start walking at the desired speed. At the same time on the white screen the recorded button was selected. When a gait 'movie' is being recorded, the left side of the Real-time Status Bar displays the "Rec. Frame", which is the "frame count "of the recording in progress. If

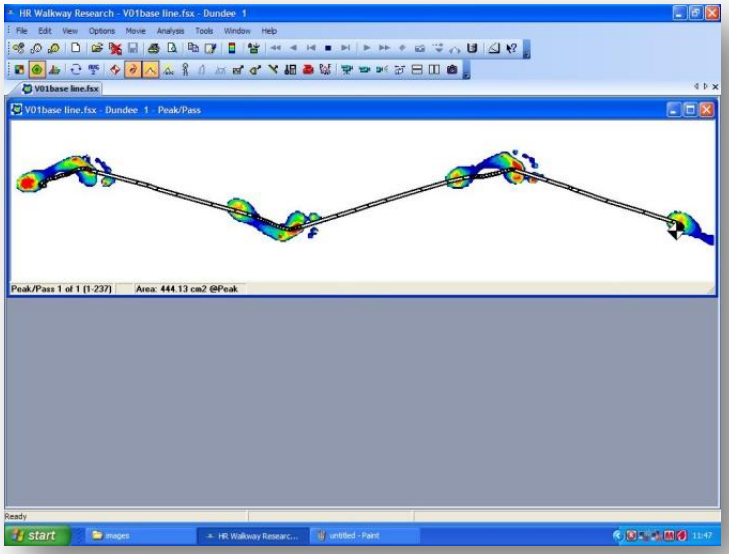


Figure 3.3.2.7: centre of trajectory option shown on HR Walkway recording

the practitioner prefers to initiate the recording using the keyboard, it is possible to start and to stop recording using the following buttons: F2 and F4 respectively. It is possible to select the icon forward or backward. In addition, CoF trajectory (Figure 3.3.2.5,Figure 3.3.2.6, Figure 3.3.2.7) and movie speed can be selected as well.

Figure 3.3.2.6: human icon

With Walkway software (version 7.0) it is possible to obtain an automatic calculation of gait parameters and presented it in tables. The so called 'Human Table Icon' (Figure 3.3.2.6) also it allows for the generation of a gait table between more than one recording at one time (Figure 3.3.2.8).

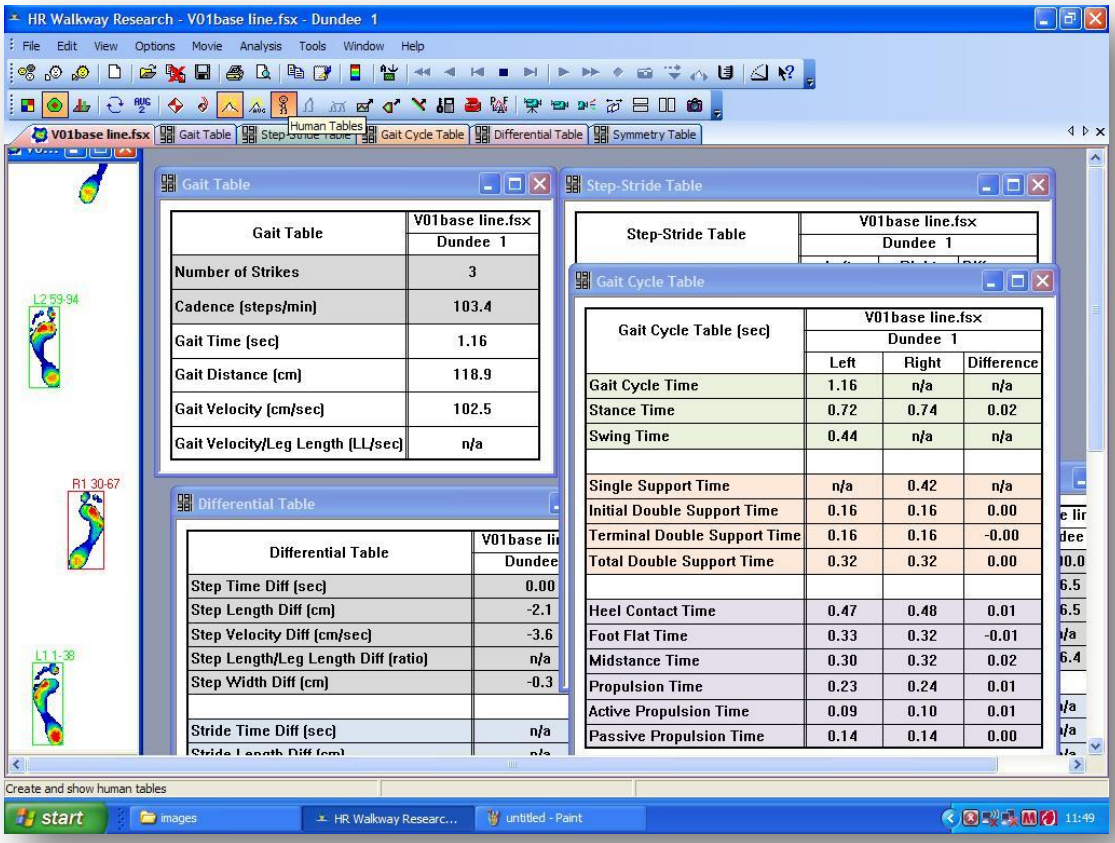


Figure 3.3.2.8: example of gait table generated by the human icon

3.3.3. F-Scan® Mobile

This system enables to quantify forces, and multiple pressure parameters. The F-scan insoles are extremely thin (0.15 mm) and the high resolution F-Scan sensor ensures accurate data is captured. The F-scan 3000E was used for this research project: according to the manufacturer the pressure ranges from 345 to 862 kPa, and each F-scan insole comprises a total of 954 sensing elements (3.9 sensel in each cm^2). Each F-scan insole has the specification directly imprinted on its surface (Figure 3.3.3.1) which is useful to keep

Figure 3.3.3.1: specification of the F-scan insole

monitoring the type of F-scan used in each data recording (Figure 3.3.3.3).

Figure 3.3.3.3: a pair F-scan insole used in the study

Figure 3.3.3.2: example on how the F-scan insole was divided into separate folders

For the RCT all recordings have been carried out using the 3000E model of F-scan. The software also is able to analyse specific areas of plantar foot pressure and the centre of force trajectory. The F-scan 3000E is able to be trimmed to size and fitted to virtually all foot sizes from very small to very big feet (Figure 3.3.3.2). With respect to the trial, the smallest foot size cut was 9 child's size and the oldest recruited patients had size 10 adult (Figure 3.3.3.4).

Figure 3.3.3.4: display of different pairs of F-scan insole used in the study

Each sensor was trimmed to fit shoe size, checked to see if it was suitable for the shoes and subsequently divided into pairs in individual transparent envelopes each containing size details. In order to avoid any damage at the sensel, the manufacturer suggests paying particular care in cutting the insole: normal scissors were used to trim the white outline of the insole; the sensel had to be cut precisely in between the columns according to the size intended to be prepared. The sensel could be ruined too, if the connection points (silver dots) were cut through. Depending on the degree of damage of the sensel, the F-scan insole may not be able to transmit the voltage changes to the F-scan mobile unit (Figure 3.3.3.5 and Figure 3.3.3.6).

Figure 3.3.3.5: how to trim the F-scan insole

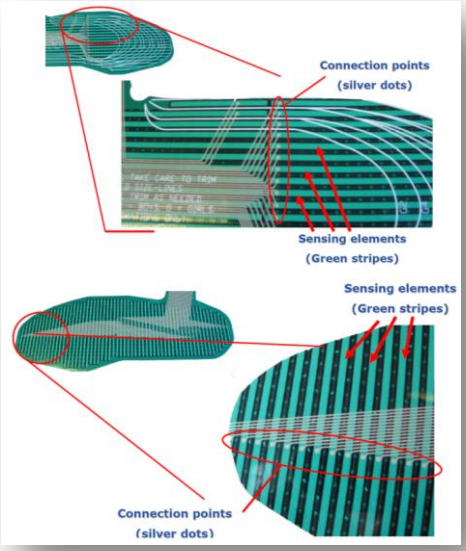


Figure 3.3.3.6: F-scan connection points and sensel elements

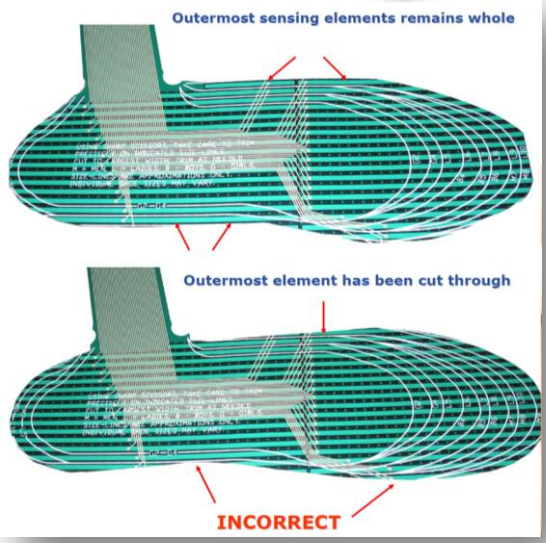


Figure 3.3.3.7: incorrect example of how to trim F-scan insole

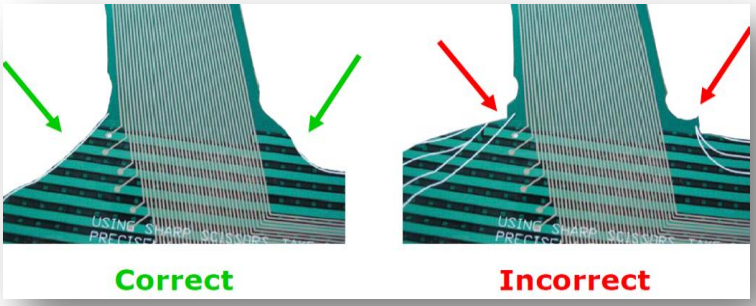


Figure 3.3.3.8: correct and incorrect technique of cutting the F-scan

In some instances, if just one sensor was damaged, it was possible to notice 'drop out traces' appearing on the screen prior the recording, causing the sensor to read a lower total force (Figure 3.3.3.7, Figure 3.3.3.8 and Figure 3.3.3.9).

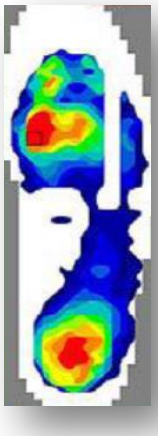


Figure 3.3.3.9: drop out traces

The F-scan system has the great advantage that it is completely portable; therefore, data can be recorded in different locations (Figure 3.3.3.10), hence suitable for a multicentre trial.

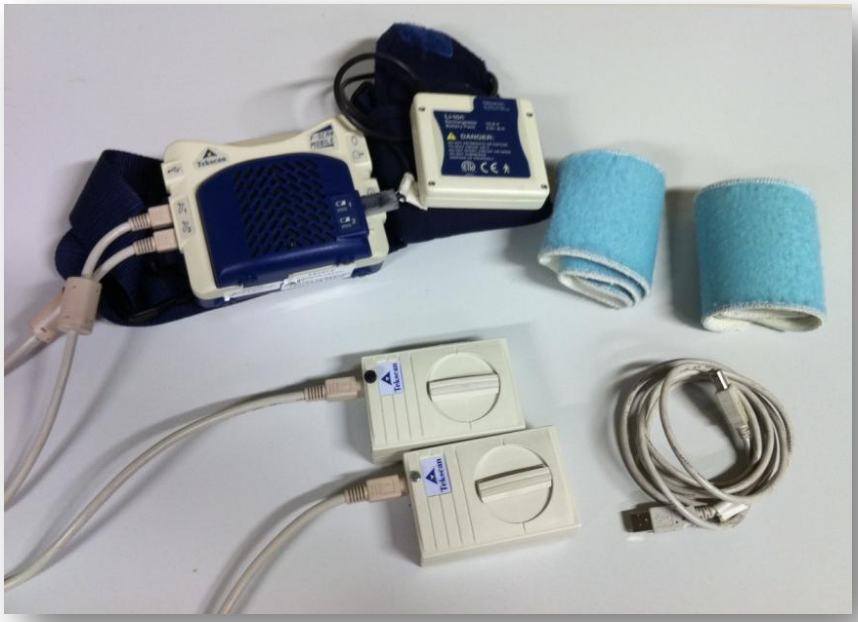


Figure 3.3.3.10: F-scan mobile unit with battery, cable, ankle cuff and strapping

As shown in Figure 3.3.3.10, the F-scan consists of the F-scan mobile unit, attached to an adjustable belt that is clicked around the patient's waist. Strapped on the belt, the F-scan battery is placed inside a pocket which supplies power to the F-scan mobile through a small cable inserted directly into the unit. On the opposite side of the F-scan unit, 2 cables are connected in portal 1 and portal 2, which link the unit to the ankle cuff. It is important to make sure that the cables are firmly inserted into the ankle cuff as any possible interference or excessive stress applied to the cable may stop the transmission of the signal to the F-scan unit. The F-scan insole can be used on either side, there is no different between left and right (Figure 3.3.3.11).

There is a narrow connection within the ankle cuff, which must be used to insert the F-scan insole. It is important to verify that every time, the F-scan insole is introduced completely into the narrow connection, otherwise no signal will be transmitted to the

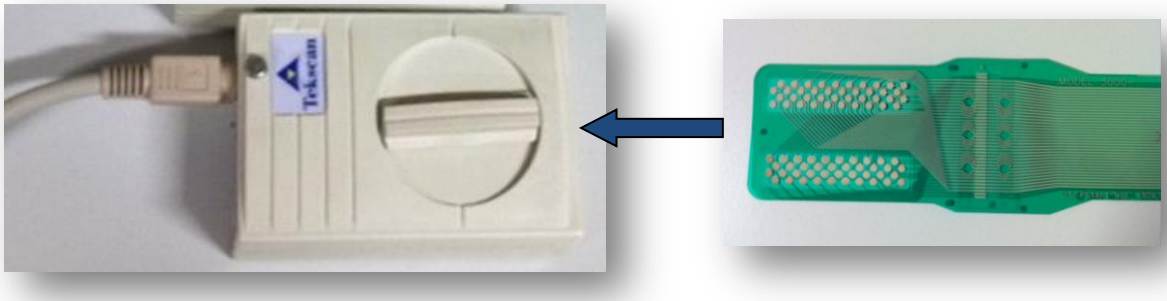


Figure 3.3.3.11: F-scan ankle cuff and the connecting sensors

software, which will automatically inform about the faulty connection. The circular switch must be turned by 90° in order to secure and lock the F-scan insole inside the ankle cuff.

The shoes were chosen on the basis of finding a suitable brand which had the same features from child sizes to adult sizes (Figure 3.3.3.12). Furthermore, by using the same shoes style with every child, it would have also limited the variables during data recording related to the condition of the shoes.

Figure 3.3.3.12: Clarks shoes

Each participant was able to wear Clark shoes and to have the F-scan insole trimmed to fit each shoe size. Each F-scan insole presented with an additional lamination layer made of vinyl which provide an additional reinforcement to the sensor. The laminated F-scan insole is slightly thicker (no details of thickness are provided by the manufacturer) but less prone to cracks along the traces, which can be particularly useful for high impact sports, research or extended data collection. On some occasions, additional tape can be applied to the sensor neck for reinforcement and to avoid unwanted sensor movement during recordings of running.

The manufacturer suggests that, when subjects have smaller feet, the edge of the sensor should be trimmed to fit and sit precisely on the insole. The best way to assure the optimum contact is to visually observe whether or not the sensor covers and sits on the full area of the inner sole of the footwear, and that the weight of the foot is going entirely through the active region of the sensor applied on the FOs (Figure 3.3.3.13).

Figure 3.3.3.13: correct (left) and incorrect (right) position of the F-scan insole

The sensel in the insoles reacts and respond to compression force, which results in small changes of voltage. The change in voltage of each sensel is registered and directly correlated to a known calibration load (force), and then converted to a force (having an engineering unit such as kilograms (kg). By having force measured and a known area, the pressure (kg/cm^2) can be calculated automatically by the software and displayed on the screen. The subject's weight is needed when performing the calibration. Therefore, it is always convenient to remember to weigh the subject and record this detail for later reference. Once the patient is wearing the F-scan belt, linked to the battery and with the F-scan insole inside the shoes (with the circular switch turned into locked position), the last stage is to insert the wire that connect the USB entry of the laptop with the F-scan mobile unit. Once the connection has been made, the F-scan mobile unit can be switched on. The laptop will recognise the F-scan mobile unit and only at this stage the software can be successfully launched (Figure 3.3.3.14).

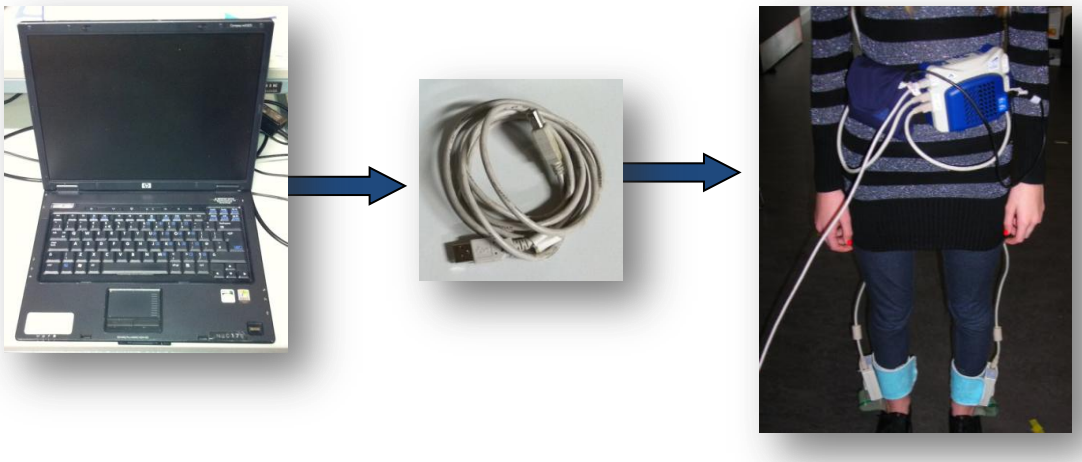


Figure 3.3.3.14: illustration on how to connect the laptop to the F-scan mobile unit

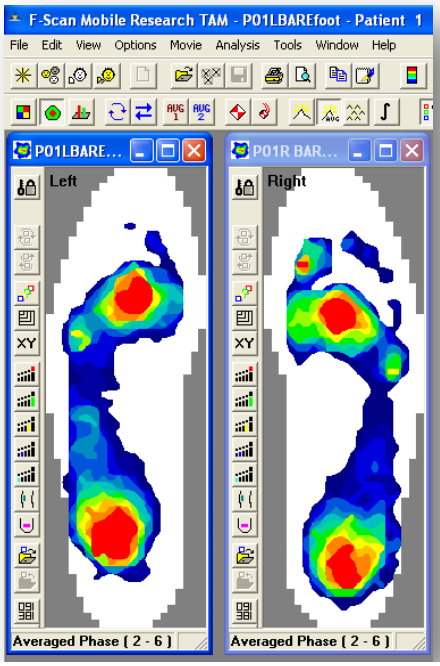


Figure 3.3.3.15: example of F-Scan recording

The F-scan Mobile research software available was version 6.30. The process for entering patient's details was exactly the same as for the HR Walkway (Figure 3.3.3.15).

The recording button was pressed at the start of the recording and then re-pressed to indicate the finish of the recording. The F-scan mobile was then connected to the cable and the data were downloaded in the programme and saved for future analysis.

The F-scan software allows multiple displays of all the stances recorded and the force versus time graph is also shown on the screen (Figure 3.3.3.16).

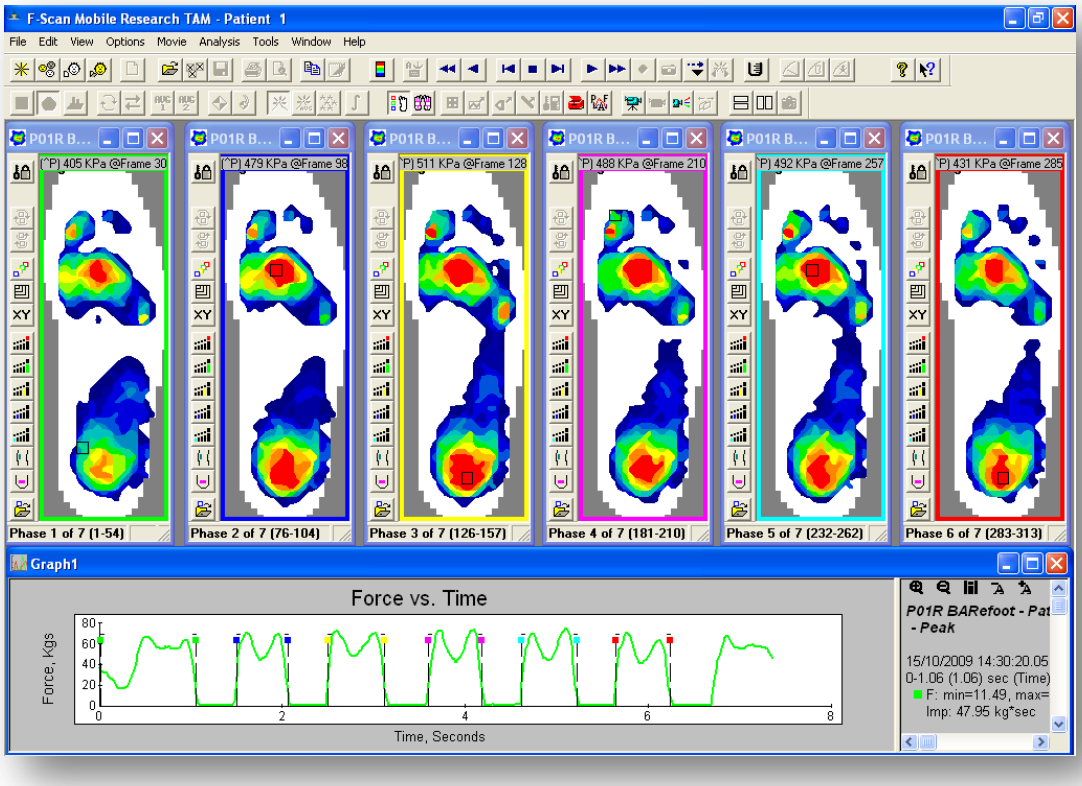


Figure 3.3.3.16: example of multiple phase recording's display with force vs time graph

3.4. Repeatability and Reproducibility Study

3.4.1. Aim

The aim of this study is to test the repeatability and reproducibility of the F-Scan and the HR Walkway in the gait of healthy children.

3.4.2. Objective

- To determine the repeatability of F-Scan® and HR Walkway™ in healthy children".
- To determine the reproducibility of F-Scan® and HR Walkway™ in healthy children".

3.4.3. Calibration

Calibration of the HR Walkway™

Calibration procedure was carried out following the instruction provided by the manual. Calibration should be performed before each new patient session, and when a new sensor is used. Calibration should take no longer than 2 min. The subject had to stand as still as possible in order to perform the calibration procedure. From the calibration tool bar it is possible to access to the step calibration option which consist in applying only 1 foot on the platform at the time.

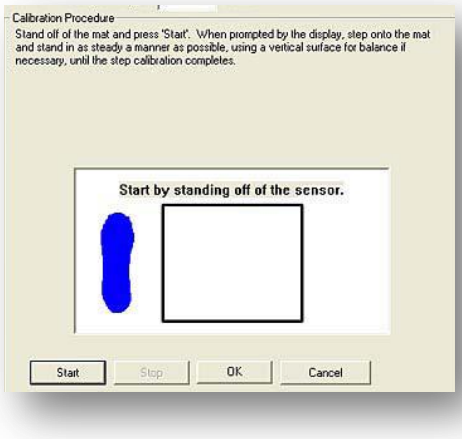


Figure 3.4.3.1: Calibration procedure window

If successful the calibration test should last no more than 4-5 sec. If the patient fail to stand on one foot or struggles to stand still for 4-5 sec, then the software would immediately inform the user that the calibration has been 'unsuccessful'; therefore, the test has to be performed again (Figure 3.4.3.1). When finished, the 'Calibration' can be saved or delete.

Calibration of the F-Scan

Calibration is the method by which the raw digital output of the sensor is converted to actual pressure units, such as "PSI" or "kPa". Step calibration procedures merely require that the patient stand completely still on the sensor (one foot at a time) for a moment. Calibration should be performed before each new patient session, and when a new sensor is used. Proper calibration of the sensors is critical to obtaining accurate pressure readings with the system. Two options of calibration are available:

Step Calibration: to initiate the step calibration, the subject must stand entirely with one foot on the platform. After few seconds, the computer instructs the subject to shift the weight onto the other and stand on one foot for 5 to 10 seconds (Figure 3.4.3.2 and Figure 3.4.3.3). This procedure is then repeated with the other foot. Calibration is then saved for left and right foot (Tekscan 2008).

Figure 3.4.3.2: step calibration icon

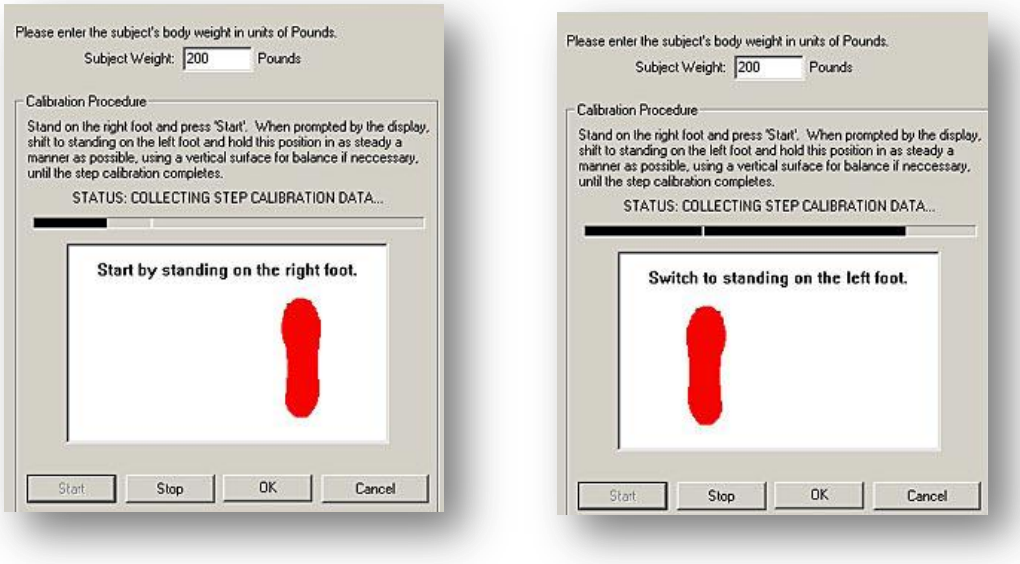


Figure 3.4.3.3: step calibration procedure for left foot

Walk Calibration: At the beginning of a trial, or series of trials, the user enters the patient's weight, and the patient walks (Figure 3.4.3.4).

Figure 3.4.3.4: walk calibration icon

The computer analyses walking data, and calculates a linear relation between raw counts and engineering units. Walk calibration is accomplished for the left and right foot together. Walk calibration is done automatically after the trial of interest is recorded. In addition, the manufacturer reports that walk calibration will not function well for subjects who are standing still, jogging or running. Also, during data recording, issues may arise if high heel impact forces and large propulsive forces from the toe and forefoot cause the sensor to measure force significantly higher than the inserted body weight. For the studies reported in this thesis, the walk calibration method was chosen because more suitable for the type of recordings taken and the age population considered in the trial. (Figure 3.4.3.5).

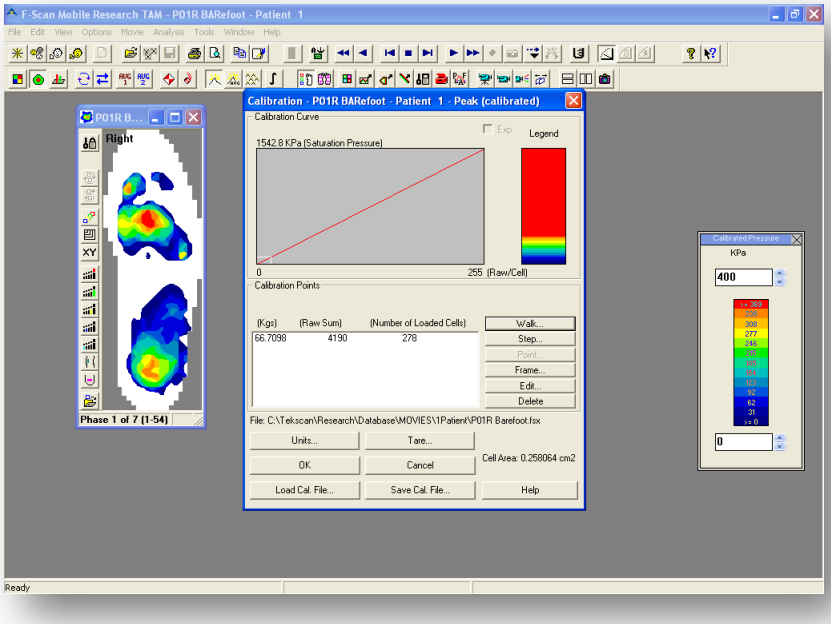


Figure 3.4.3.5: walking calibration successfully completed

3.4.4. Method

Healthy children recruited for the study took part in non-invasive clinical assessments. The Ethics Committee at Queen Margaret University granted the approval for this

repeatability and reproducibility study. The recording of study data took approximately 30 min per session. Each patient received verbal and written information regarding the study. A total of 30 healthy patients were recruited ranging between 5 to 18 years of age. Those participants willing to take part in the study were asked to attend the Gait Laboratory at Queen Margaret University for data collection at baseline and one week later. Risk assessment of the gait laboratories was carried out prior data collection. All participants to the study were able to withdraw from the study at any time without giving any reasons. All subjects were given an opportunity to speak with an independent person, who knew about the project but was not directly involved in it.

On the day of the appointment, informed consent was obtained from the parents or carer (appendix XVI). Height and weight were measured in order to calculate each participant's BMI and health status. Each subject was given a standardised shoe wear to verify shoe size before the start of gait recording; the equivalent F-scan insole size was used without socks. All information collected during the study was strictly confidential and anonymous; details were safely locked in a metal filing cabinet placed within a restricted personal area of the university.

Inclusion Criteria:

- All subjects with no lower extremity joint involvement ranging from 5 to 18 years old.
- Ability to walk a minimum of 15 metres without assistive devices.
- No medication.

Exclusion Criteria:

- Inability to walk barefoot or shod.
- Concomitant musculoskeletal disease, central or peripheral nerve disease and endocrine disorders, especially Diabetes Mellitus.
- Previous foot surgery.
- Currently using foot orthosis.

In each appointment, the sequence of data recording was completely randomised in order to avoid any possible influence from the data collector. Especially when dealing with young children, the level of attention and tiredness can vary significantly. Therefore, F-scan and HR Walkway recording were randomly selected following the order generated by the computer programme.

Each visit was completed in between 30 to 45 min each, depending upon the age of the participant. Usually, the younger the patient the longer was the meeting: however, the data collection never exceeded 45min. The equipment was set up prior to the start of data collection. The F-Scan insoles were accurately trimmed according to the instruction provided by the manufacturer.

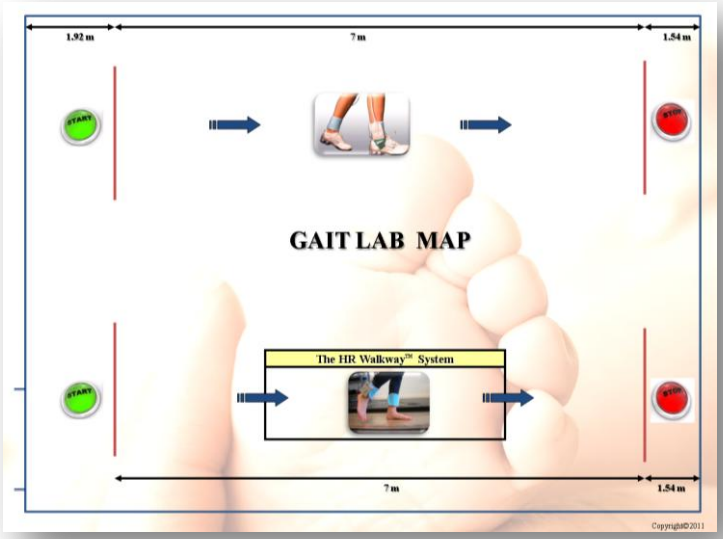


Figure 3.4.4.1: gait lab map. Indicating where the HR Walkway was placed and where the F-Scan recordings were carried out. The overall distance for the F-Scan recording (shod and with insole) was 7 metres.

All equipment was set up as explained on section 3.3 and calibration was carried out and saved (Figure 3.4.4.2). In order to familiarise with the equipment, each patient performed 2 walks along the length of the lab prior to starting the recording. Every patient was recorded walking from one end

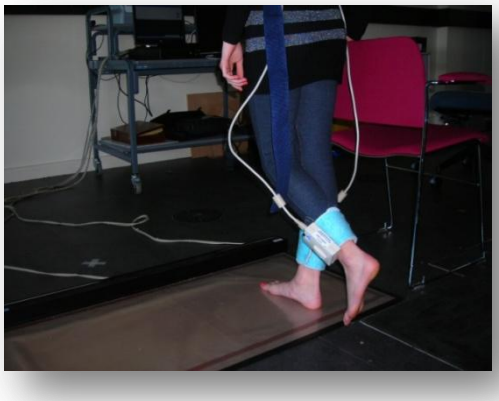


Figure 3.4.4.2: HR Walkway standing calibration with patient while wearing the F-Scan mobile unit

of the lab and stopped after 7 metres. The starting and the finishing point were defined by a tape attached to the floor. The tape was never removed for the whole duration of the data collection, allowing patients to have the gait recorded for the same distance at each appointment. Because of dealing with quite young children, the same chair was used by all participants to help them maintain balance. The subject was constantly monitored in order to recognise any possible mistakes which might be related to excessive weight applied on the chair.

It is important to notice that each patient was calibrated on the Walkway platform while simultaneously wearing the F-scan belt, the connecting wires, the battery and finally the ankle cuff. The rationale behind this procedure was to avoid any possible introduction of variables within the recordings and to account for possible gait changes which may be related to wearing the F-scan belt during in-shoes analysis. Therefore, each participant walked the 7 metres length of the gait analysis lab, while wearing the 1.7 kgs extra weight at barefoot, in-shoe barefoot and in-shoes with insole. Each patient was asked to familiarise themselves with walking barefoot on the platform prior to starting the recording; two trials were carried out before recording. Once the patients felt comfortable and ready, at the count of 3 the recording started. A total of 3 recordings were taken and saved with their anonymous code name.

The same procedure was repeated at a 1 week interval following the randomisation order decided by the software. Participants were advised to wear similar clothes for the following week's data collection, in order to limit and control the variables that could affect the final results. All data were safely stored in the computer, protected by password, and access to the computer at the gait analysis laboratory was allowed only to a restricted number of researchers. Each participant's hard copy records are safely kept in a locked cabinet within the Podiatry department at Queen Margaret University.

3.4.5. Data Analysis

Foot Mapping

Recent research into child and adult gait provided useful evidence based on the analysis of different parameters of plantar foot pressure (Broström et al. 2002; Dixon and McNally 2008; Fairburn et al. 2002; Hadfield et al. 2003; Hendry et al. 2009). According to Hadfield et. al (2003), the mapping of the foot for plantar pressure was divided into seven separate regions (1^{st}, 2^{nd}, 3^{rd} till 5^{th} metatarsal head, medial and lateral portion of the midfoot, and medial and lateral portion of the heel): toe regions were completely excluded from consideration as, according to the authors, these regions were negligible to non-existent (Hadfield et al. 2003).

Thanks to the technology available using the Tekscan equipment, it was possible to implement plantar pressure mapping investigation using previous clinical evidence as guidance for data analysis. Each foot recording was mapped into 10 different plantar foot regions with both the F-Scan and HR Walkway (Figure 3.4.5.1, Figure 3.4.5.2.) Please find below all the parameters investigated:

- **F-Scan**
    - Total contact (left and right)
    - Heel (left and right)
    - Midfoot (left and right)
    - Forefoot (left and right)
    - 5^{th} met. head (left and right)
    - 3^{rd} to 4^{th} met head (left and right)
    - 2^{nd} met head (left and right)
    - 1^{st} met head (left and right)
    - Lesser toes (left and right)
    - 1^{st} Distal phalanx. (left and right)

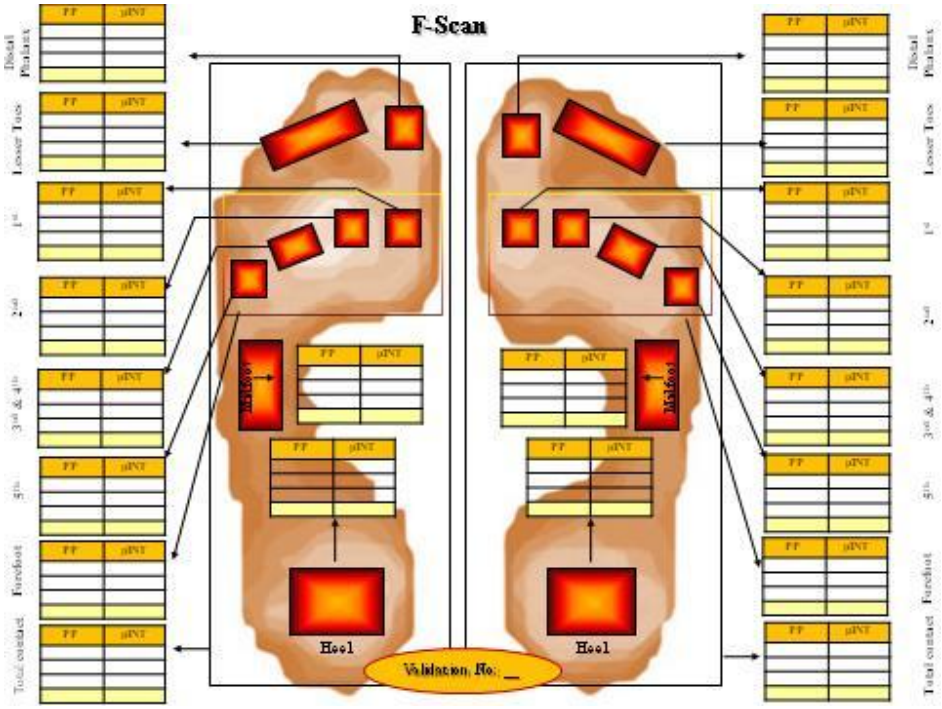


Figure 3.4.5.1: F-Scan plantar pressure template

- **HR Walkway**
  - Total contact (left and right)
  - Heel (left and right)
  - Midfoot (left and right)
  - Forefoot (left and right)
  - 5^{th} met. head (left and right)
  - 3^{rd} to 4^{th} met head (left and right)
  - 2^{nd} met head (left and right)
  - 1^{st} met head (left and right)
  - Lesser toes (left and right)
  - 1^{st} Distal phalanx. (left and right)

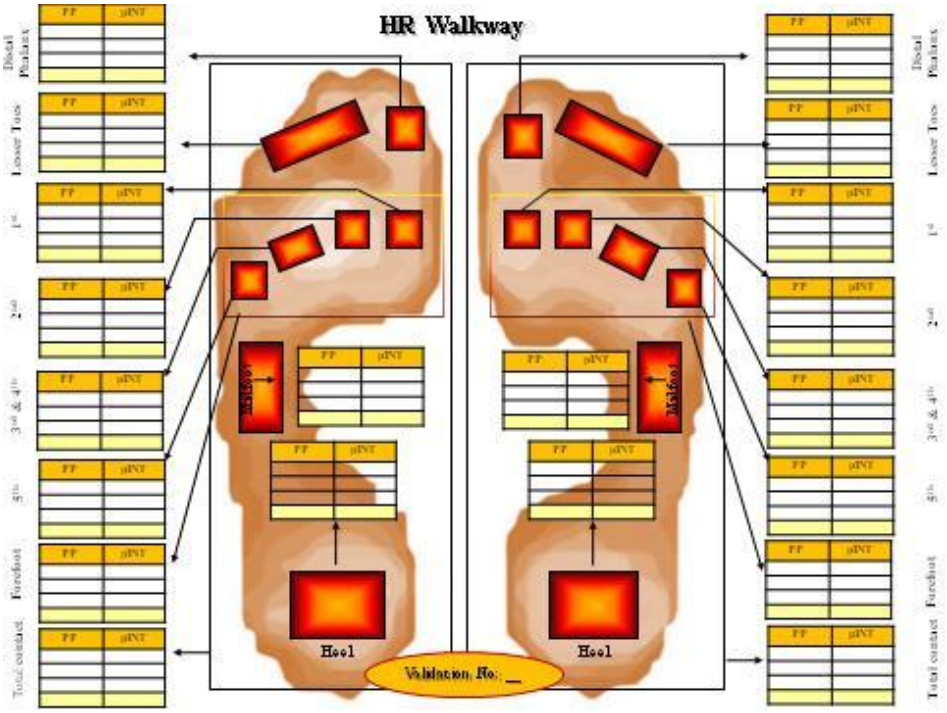


Figure 3.4.5.2: HR Walkway plantar pressure mapping template

Additionally, the HR Walkway software (version 7) allowed also the investigation of the following parameters:

- Gait Time (sec)
- Gait Velocity (cm/sec)
- Stance Time (sec)

The PP Box approach was used during data analysis and consisted in isolating the anatomical part of the foot involved. From each of the 10 anatomical portions of the plantar surface of the foot, the PP Box approach allowed the investigation of:

- Peak Pressure (identifies a specific area where there is the highest amount of pressure) – peak pressure versus time - (PP).
- Pressure Time Integral (relationship between the amount of pressure that is applied throughout a period of time) - (PTI)

BMI Calculation

The children's BMI score and health status were calculated according to the 'Scottish Intercollegiate Guidelines Network (SIGN). This national clinical guideline (no. 115) provides extended details with regards to the 'Management of Obesity'. By consulting the 'Annex no.10' it is possible to plot the 'childhood BMI centile chart' for boys and girls up to the age of 20 years old. The same SIGN guideline will be used to identify the obesity rate for the 60 JIA children who took part in the RCT study as well.

Repeatability and Reproducibility Analysis

According to Portney and Watkins (2000), the ICC[27] is an important statistical test that must be used in clinical research when comparing data. Furthermore, the authors report that the inter-rater values are considered to be: 'good' when ICC is above 0.75; 'moderate' when ICC value is between 0.5 and 0.75; finally 'poor' is considered to be present if ICC values are below than 0.5 (Portney and Watkins 2000). Similarly, a much older publication made by Fleiss (1986), which investigated the design and analysis of the experiments, reports that if the ICC values are above 0.75 is deemed to be 'excellent'. Any ICC values obtained between 0.4 and 0.75 are considered to be 'fair-to-good. Finally, any ICC value below 0.4 is deemed to be 'poor' (Fleiss 1986). As reported in the results section, the association between temporal and kinematic data was mostly excellent with healthy children. As Portney and Watkins (2000) is the most recent publication and the score-classification is stricter, it was chosen for this study.

In order to test for repeatability of the F-scan and HR walkway, comparison of the data within each visit was carried out. Each recording occurred consecutively, within the same environment, using the same shoe size, utilising the same equipment and the same distance was travelled by the participants (7 metres). In addition, in each visit the recordings were carried out within a period of maximum 5 minutes. The same randomised procedure took place at baseline and at one week intervals. The repeatability tests of all parameters investigated, were considered individually between the 3 recordings at baseline and between the 3 recordings taken at week 1 (Figure 3.3.5.3, Figure 3.3.5.4).

[27] ICC: intraclass correlation coefficient.

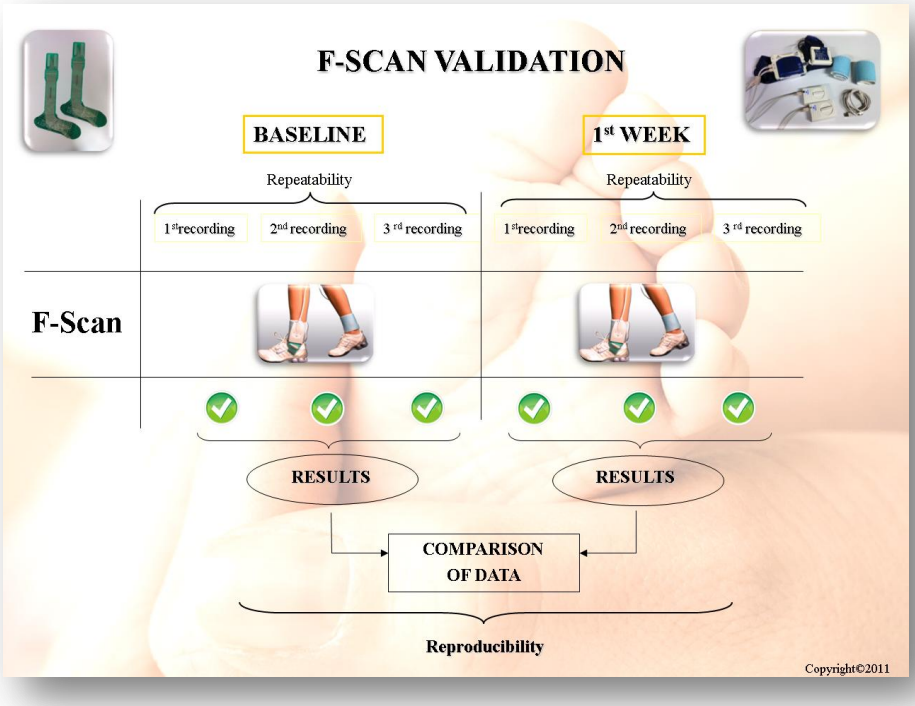


Figure 3.4.5.3: F-scan repeatability and reproducibility procedure

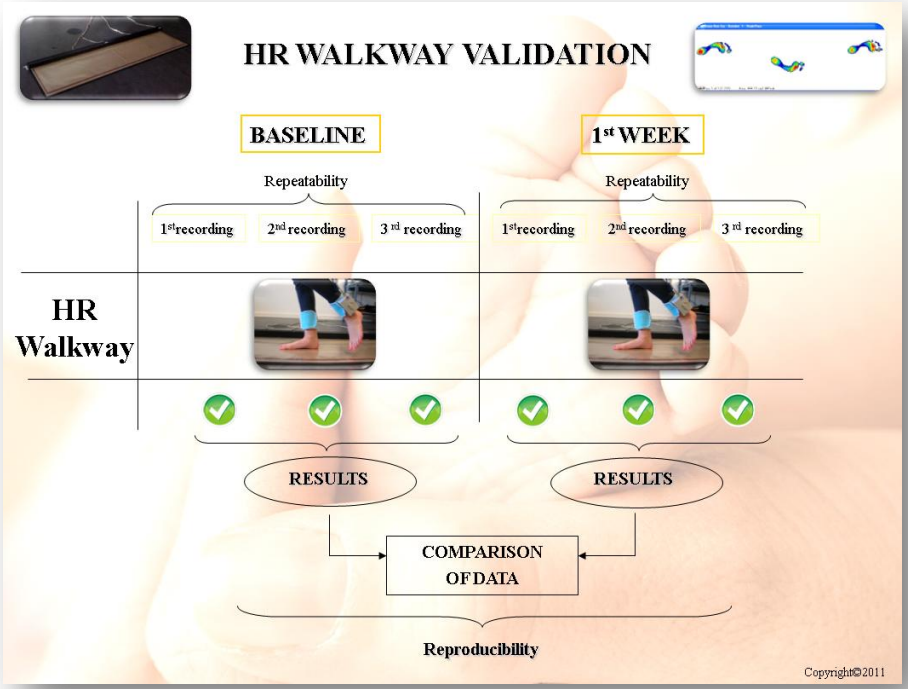


Figure 3.4.5.4: HR Walkway repeatability and reproducibility n procedure

With regards to the reproducibility of the equipment, a comparison of the recorded data obtained between baseline and week 1 was carried out with F-Scan and HR Walkway (Figure 3.3.5.3, Figure 3.3.5.4). In order to acquire the data for the reproducibility study between baseline and one week intervals, the average was made of the 3 recordings taken at baseline, and an average of the values gathered at one week later. Therefore, the two averaged values were compared and ICC data analysis was carried out. The same data analysis procedure was repeated for each of the 10 anatomical areas investigated of the foot.

Finally, data analysis was carried out during the study using the SPSS Statistics software (version: 17.0) and Microsoft Office Excel (2007). Data analysis mostly involved quantitative interpretation of parameters of gait. All raw data were initially inserted into excel spread sheets and subsequently exported into SPSS for statistical analysis.

3.4.6. Results

All 30 healthy patients recruited, attended the Motion Analysis Laboratory at Queen Margaret University at baseline and at 1 week intervals. Overall, 53.3% (n=16) were female and 46.7% (n=14) were male. Mean age was 13.3 years (SD 4.5), with a age-range of 5 to 18.6 years. According to the BMI score, the health status of each participant showed that 6.7% (n=2) were underweight, 73.3% (n=22) subjects were healthy; 13.3% (n=4) were overweight and finally 6.7% (n=2) were obese. Health status of the subjects remained unaltered between baseline and week 1 interval.

F-Scan Repeatability

During data analysis of the PP, positive results were obtained from using the F-Scan equipment at baseline (Table 3.4.6.1). In all 10 anatomical areas investigated it was possible to observe ‘good’ ICC values for left, right and both feet. Similarly, after 1 week, the same ‘good’ ICC results were gathered in all anatomical areas with the exception of the right foot for the ‘lesser toes’ at week1 which scored ‘moderate’ ICC values. Therefore, results confirmed the high repeatability values obtained when PP was investigated when using the F-Scan system (Table 3.4.6.1)

Table 3.4.6.1: ICC repeatability results for F-scan regarding PP at baseline and at week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Repeatability of F-Scan						
Peak Pressure Values						
	Baseline			**Week 1**		
Anatomical Area	**Left**	**Right**	**Both**	**Left**	**Right**	**Both**
Total	0.933	0.970	0.960	0.972	0.940	0.961
Heel	0.833	0.976	0.952	0.946	0.920	0.936
Midfoot	0.879	0.885	0.879	0.909	0.858	0.883
Forefoot	0.952	0.974	0.964	0.973	0.951	0.966
5^{th}	0.953	0.872	0.924	0.896	0.945	0.917
3^{rd}-4^{th}	0.947	0.952	0.949	0.941	0.945	0.943
2^{nd}	0.961	0.963	0.962	0.980	0.947	0.971
1^{st}	0.937	0.978	0.964	0.944	0.935	0.942
Lesser Toes	0.858	0.857	0.856	0.893	0.716*	0.807
Distal Phalanx	0.951	0.920	0.938	0.955	0.917	0.933

The PTI values at baseline of the left, right and both feet showed that 'good' ICC scores were found for all anatomical areas (Table 3.4.6.2). The analysis carried out one week later confirmed the 'good' ICC score in all parameters. Finally, also when PTI analysis was carried out, the ICC appeared to be highly repeatable for most anatomical area investigated (Table 3.4.6.2)

Table 3.4.6.2: ICC repeatability results for F-scan regarding PTI at baseline and at week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Repeatability of F-Scan						
Pressure Time Integral						
	Baseline			**Week 1**		
Anatomical Area	**Left**	**Right**	**Both**	**Left**	**Right**	**Both**
Total	0.959	0.924	0.947	0.943	0.951	0.928
Heel	0.856	0.786	0.827	0.933	0.830	0.893
Midfoot	0.846	0.761	0.809	0.836	0.847	0.838
Forefoot	0.970	0.904	0.950	0.954	0.832	0.917
5^{th}	0.885	0.915	0.897	0.884	0.899	0.889
3^{rd}-4^{th}	0.926	0.936	0.930	0.914	0.914	0.914
2^{nd}	0.937	0.963	0.952	0.970	0.898	0.954
1^{st}	0.889	0.910	0.901	0.929	0.871	0.913
Lesser Toes	0.674*	0.860	0.728*	0.763	0.675*	0.717*
Distal Phalanx	0.938	0.767	0.900	0.889	0.825	0.857

F-Scan Reproducibility

The PP reproducibility scores were investigated in all 10 anatomical areas while using the F-Scan system. 'good' ICC values were reported from the PP reproducibility for all anatomical areas (Table 3.3.6.3).

Table 3.4.6.3: ICC reproducibility results for F-scan regarding PP at baseline and at week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Reproducibility of F-Scan			
Peak Pressure Values			
Anatomical Area	**Left**	**Right**	**Both**
Total	0.845	0.860	0.825
Heel	0.803	0.801	0.704
Midfoot	0.961	0.823	0.901
Forefoot	0.896	0.872	0.894
5^{th}	0.857	0.676	0.780
3^{rd}-4^{th}	0.778	0.836	0.803
2^{nd}	0.805	0.779	0.895
1^{st}	0.846	0.939	0.857
Lesser Toes	0.917	0.787	0.816
Distal Phalanx	0.900	0.782	0.831

As shown below on Table 3.4.6.4, with regards to the reproducibility of the F-Scan (PTI values) 'good' ICC results were found on most of the parameters investigated. Instead, 'moderate' ICC results were discovered on the left foot at 3^{rd}-4^{th}, and 'both' for the 3^{rd}-4^{th} and lesser toes (Table 3.4.6.4).

Table 3.4.6.4: ICC reproducibility results for F-scan regarding PTI at baseline and at week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Reproducibility of F-Scan			
Pressure Integral			
Anatomical Area	**Left**	**Right**	**Both**
Total	0.853	0.850	0.638
Heel	0.839	0.714	0.746
Midfoot	0.889	0.804	0.784
Forefoot	0.787	0.783	0.781
5^{th}	0.832	0.710	0.773
3^{rd}-4^{th}	0.653*	0.786	0.705*
2^{nd}	0.915	0.758	0.835
1^{st}	0.888	0.838	0.833
Lesser Toes	0.787	0.777	0.733*
Distal Phalanx	0.827	0.765	0.755

The trend of reproducibility ICC results for PP and PTI appear to show highly repeatable and reproducible ICC scores.

HR Walkway repeatability

With regards to the repeatability values obtained with HR Walkway system, it was possible to investigate the ICC results between the left, right foot and both feet accounted together. With regards to the PP repeatability results obtained at baseline with the HR Walkway, 'good' ICC results were highlighted in most anatomical areas investigated for the left, right and both feet accounted together (Table 3.3.6.5). The only exception was noted for the heel (left, right and 'both' feet) which showed 'moderate' ICC repeatability. Similarly, one week later, 'moderate' ICC scores were only found on the left at the midfoot, and on the right for the heel. All remaining anatomical areas investigated at week 1, appeared to have 'good' PP repeatability scores (Table 3.3.6.5). Overall the PP for the HR Walkway showed highly repeatability values.

Table 3.4.6.5: ICC repeatability results for HR Walkway regarding PP at baseline and at week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Repeatability of HR Walkway						
Peak Pressure versus Time						
	Baseline			**Week 1**		
Anatomical Area	**Left**	**Right**	**Both**	**Left**	**Right**	**Both**
Total	0.755	0.754	0.752	0.787	0.798	0.790
Heel	0.725*	0.673*	0.701*	0.764	0.673*	0.754
Midfoot	0.906	0.804	0.856	0.638*	0.920	0.766
Forefoot	0.904	0.914	0.908	0.929	0.917	0.923
5^{th}	0.893	0.937	0.917	0.917	0.925	0.921
3^{rd}-4^{th}	0.887	0.920	0.902	0.891	0.900	0.893
2^{nd}	0.959	0.933	0.943	0.942	0.937	0.939
1^{st}	0.787	0.842	0.815	0.927	0.918	0.923
Lesser Toes	0.877	0.875	0.876	0.670*	0.901	0.790
Distal Phalanx	0.849	0.846	0.847	0.892	0.895	0.893

With regards to the PTI repeatability results obtained at baseline with the HR Walkway, 'good' ICC values were observed in most of anatomical areas for the left, right and 'both' feet (Table 3.4.6.6). The only exceptions recorded was the 'moderate' ICC values at baseline identified on the left at the heel, on the right at total contact, heel and lesser toes; and finally on 'both' feet at heel and distal phalanx.

As shown on Table 3.4.6.6, when repeatability analysis was carried out one week later, most anatomical areas presented with 'good' ICC results. 'Moderate' ICC results were noted only on the left foot at total contact, 5^{th} met head and lesser toes; on the right at total contact, and on 'both' feet for the lesser toes and distal phalanx. Overall, the PTI repeatability measurements revealed highly repeatable values both at baseline and at week 1 interval.

Table 3.4.6.6: ICC repeatability results for HR Walkway regarding PTI at baseline and at week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Repeatability of HR Walkway						
Pressure Time Integral						
	Baseline			**Week 1**		
Anatomical Area	**Left**	**Right**	**Both**	**Left**	**Right**	**Both**
Total	0.817	0.710*	0.757	0.705*	0.525*	0.810
Heel	0.573*	0.657*	0.585*	0.816	0.866	0.807
Midfoot	0.791	0.888	0.846	0.884	0.916	0.859
Forefoot	0.879	0.917	0.896	0.949	0.784	0.865
5^{th}	0.778	0.908	0.842	0.540*	0.936	0.892
3^{rd}-4^{th}	0.877	0.888	0.881	0.900	0.905	0.884
2^{nd}	0.936	0.883	0.909	0.957	0.899	0.888
1^{st}	0.783	0.859	0.823	0.809	0.930	0.786
Lesser Toes	0.826	0.710*	0.760	0.704*	0.881	0.695*
Distal Phalanx	0.699	0.789	0.745*	0.860	0.853	0.732*

Additional gait parameters were investigated with the 30 healthy children while using the HR Walkway system. ICC tests revealed 'good' values for the cadence at baseline and 'moderate' values at week 1 (Table 3.4.6.7). With regards to gait time, distance and velocity parameters, ICC appeared to be 'good' both at baseline and week 1.

Table 3.4.6.7: ICC repeatability results: cadence, gait time, distance and velocity at baseline and week 1. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Repeatability of HR Walkway		
Parameters	**Baseline**	**Week 1**
Cadence	0.815	0.727*
Gait Time	0.975	0.900
Distance	0.961	0.900
Velocity	0.819	0.880

On the other hand, 'moderate' ICC values were found at baseline and week 1 for left, right and 'both' feet at heel contact, foot flat, midstance and propulsion time. 'Moderate' ICC was also noted on right and 'both' feet for the stance time parameters at week 1. The remaining parameters scored 'good' ICC values both at baseline and week 1 (Table 3.4.6.8).

Table 3.4.6.8: ICC repeatability results for peak pressure, stance time, heel contact time, foot flat time, midstance time and propulsion time. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Repeatability of HR Walkway						
	Baseline			Week 1		
Parameters	Left	Right	Both	Left	Right	Both
Peak Pressure	0.860	0.768	0.816	0.766	0.814	0.789
Stance Time	0.833	0.768	0.795	0.765	0.609*	0.653*
Heel Contact Time	0.714*	0.699*	0.703*	0.648*	0.559*	0.609*
Foot Flat Time	0.648*	0.559*	0.616*	0.524*	0.481*	0.508*
Midstance Time	0.680*	0.541*	0.611*	0.795	0.525*	0.643*
Propulsion Time	0.703*	0.769	0.741*	0.681*	0.574*	0.616*

As shown on Table 3.4.6.7 and Table 3.4.6.8, positive results were obtained while using the HR Walkway. The highly repeatable measurements gathered during the repeatability and reproducibility study may indicate that the equipment was able to collect repeatable data at baseline and at week 1.

HR Walkway Reproducibility

The Table 3.4.6.9 showed data related to the PP reproducibility of the HR Walkway for left, right and 'both' feet. Also in this scenario, 'poor' ICC results were not found for any of the 10 anatomical areas investigated. On the other hand, most of the PP parameters showed 'good' ICC scores for left, right and 'both' feet. As shown on Table 3.4.6.9 few anatomical areas appeared to have 'moderate' ICC results. For example: on the left foot at the heel, midfoot, 3rd-4th and 1st met head; for the right at the total contact, heel and midfoot; and finally for 'both' at the total contact, heel, midfoot, 3rd-4th and 1st met head. Overall these reproducibility data for PP were able to confirm that over a period of 1 week interval the HR walkway system was able to reproduce reliable data.

Table 3.4.6.9: ICC reproducibility results for HR Walkway regarding PP. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Reproducibility of HR Walkway			
Peak Pressure Values			
Anatomical Area	**Left**	**Right**	**Both**
Total	0.754	0.697*	0.722*
Heel	0.635*	0.701*	0.655*
Midfoot	0.682*	0.743*	0.709*
Forefoot	0.871	0.864	0.865
5th	0.812	0.790	0.796
3rd-4th	0.713*	0.764	0.733*
2nd	0.910	0.844	0.876
1st	0.681*	0.779	0.724*
Lesser Toes	0.819	0.884	0.855
Distal Phalanx	0.806	0.754	0.776

With regards to reproducibility of PTI, left, right and 'both' feet were investigated while using the HR Walkway system. As shown on Table 3.4.6.10 'good' reproducible ICC values were identified for most of the anatomical areas. The only few exceptions were shown with 'moderate' ICC score for the left at heel, lesser toes, distal phalanx; and for 'both' heel and distal phalanx. Overall, the PTI reproducibility ICC score indicated that although some parameters were moderate, most of anatomical areas showed a very positive ICC score between baseline and one week interval.

Table 3.4.6.10: ICC reproducibility results for HR Walkway regarding PTI. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Reproducibility of HR Walkway			
Pressure Integral			
Anatomical Area	**Left**	**Right**	**Both**
Total	0.848	0.938	0.923
Heel	0.711*	0.773	0.726*
Midfoot	0.877	0.820	0.845
Forefoot	0.939	0.949	0.943
5th	0.840	0.895	0.867
3rd-4th	0.840	0.774	0.809
2nd	0.894	0.918	0.903
1st	0.893	0.844	0.866
Lesser Toes	0.719*	0.835	0.783
Distal Phalanx	0.614*	0.756	0.696*

With the HR Walkway system it was possible to investigate the level of reproducibility of cadence, gait time, distance and velocity. 'Moderate' ICC score was found for cadence and velocity of the healthy children. As shown on Table 3.4.6.11 and the remaining gait time and distance parameters appeared to have a 'good' ICC score.

Table 3.4.6.11: ICC reproducibility results for HR Walkway regarding Cadence, Gait Time, Distance, Velocity. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Reproducibility of HR Walkway	
Parameters	**ICC**
Cadence	0.700*
Gait Time	0.914
Distance	0.831
Velocity	0.733*

Finally, Table 3.4.6.12 highlights that there is 'good' ICC level for most parameters investigated on the left, right and 'both' feet. 'Moderate' ICC values were found at stance time on the right and for 'both' feet; at foot flat for left and 'both' feet and finally at midstance for 'both' feet (Table 3.4.6.12).

Table 3.4.6.12: ICC reproducibility results for HR Walkway regarding Peak Pressure, Stance Time, Heel Contact Time, Foot Flat Time, Midstance Time and Propulsion Time. ** means 'poor'; * means 'moderate'; 'none' means 'good'. Poor ICC<0.5; Moderate ICC between 0.5-0.75; Good >0.75.

Reproducibility of HR Walkway			
Pressure Integral			
Parameters	**Left**	**Right**	**Both**
Peak Pressure	0.801	0.762	0.779
Stance Time	0.752	0.709*	0.727*
Heel Contact Time	0.789	0.818	0.799
Foot Flat Time	0.646*	0.848	0.737*
Midstance Time	0.782	0.848	0.570*
Propulsion Time	0.787	0.798	0.791

3.4.7. Discussion

Reproducibility and repeatability tests are frequently carried out in research. Intra-class correlation coefficient (ICC) appears to be the statistical test adopted to calculate the level of repeatability and reproducibility when quantitative measurements are carried out (Li Lu and Nawar 2007). The ICC also describes how strongly units in the same group resemble one another. Bland and Altman in 1996 published a paper on the BMJ[28] in which they underlined that when the number of investigated parameters are the same for each participant, one way analysis of variance can be used when calculating the ICC (Bland and Altman 1996). Therefore, ICC tests were used to investigate repeatability and reproducibility values within this study. Additionally, in order to interpret ICC results, the Portney and Watkins (2000) score-classification was used in this validity study, as it is one of the most recent evidence available in this field and it follows on the previous founding reported by Fleiss (1986). Additionally the work carried out by these authors has been published by the 'Foundation of in Clinical Research' journal, which is a recognised provider of updated clinical evidence.

According to Tekscan (2010) it is important to carry out the calibration procedure prior to start any recording. The F-scan equipment (overall 1.7kg) was added to the subject's original weight. The walking calibration was chosen because is the most clinically effective, as it is automatic (Tekscan 2010). Furthermore, it is faster and helpful to increase the number of subjects that can be seen within busy clinical environments and it allows more trials to be performed. Walking calibration may be beneficial for those subjects who cannot stand on one foot for ten seconds (Tekscan 2008). As advised by the manufacturer, calibration must be repeated till the software recognised the success of the procedure. If a child reported soreness while standing on a single leg stance, the 'stand calibration' would have been very difficult to carry out successfully with every participant. The continued failure to obtain a suitable standing calibration, could have affected the over-all length of time for each visit; as a result, each data collection could have been significantly longer. It can be argued that some children may become unhappy to spend too long time for each appointment and they may have started to adopt an altered gait because bored, tired or possibly in pain.

[28] BMJ: British Medical Journal

According to the F-scan manufacturer, it would have been possible for the patient to wear thin socks during recordings. However, the cushioning of the thick socks may increase pressure in regions that would otherwise exhibited low pressure values, and possibly skew the final results. It can be argued that unless every recording was carried out using the same type of socks, then data comparison might prove to be difficult. During this research project, for practicality reasons, it was decided not to wear socks during data recording. When dealing with children, multiple socks per each size must be available for each recording, and constant monitoring of the wearing patterns of the socks must be carried out to avoid recording issues. In addition, possible health-related problems could arise from using the same socks more than once between patients, which may have led to a risk of contagious dermatological pathologies between patients. The insoles were whipped with a surface disinfectant between subjects as an infection control measure.

All lamination layers were removed from the F-Scan insole. As no running or long distance recordings were investigated in this study, it was decided to utilise the F-scan sensors alone. Additionally, the vinyl layer increases the rigidity of the insole, which potentially could have affected the ability of the sensors to adapt to the counter of the shoes and potentially skew the results. Particular care was dedicated in positioning the sensor correctly. If the F-Scan sensors were not precisely placed underneath the subject's foot, plantar pressure data might have been quite poor. Furthermore, if the sensor were trimmed too much, some plantar foot pressure data would have been excluded during recording. On the other hand, if the F-scan insoles were too big or large for the shoes in which they were inserted, some vertical forces may have be transmitted through the sidewall of the footwear.

Few studies have been previously carried out to test the repeatability and reproducibility of the F-Scan system reporting positive results in using the sensors for research and clinical applications (Chen and Bates 2000; Luo, Berglund and An 1998; Randolph et al. 2000). However, none of the publications available have yet investigated PP and PTI in 10 anatomical parameters.

Data obtained showed that the repeatability study presented mostly with 'good' ICC score. However, Chen and Bates (2000) reported that caution should be exercised when

interpreting the pressure data during the initial 21% and final 10% of the support of walking (Chen and Bates 2000).

Most of the parameters investigated with the F-Scan system showed ‘good’ ICC score particularly for the repeatability study. On the other hand, ‘moderate’ ICC score was shown more frequently during the reproducibility study. These validity results may indicated that the F-scan system can be used with healthy children and potentially adopted to identify pathological gait as well.

According to Tekscan (2010) calibration procedure of the HR Walkway system must be carry out prior to any recordings as well. The step-calibration procedure is available for the HR Walkway system and it was carried out according to the indication provided by the manufacturer. Tekscan (2010), suggested that subjects should have enough room to walk two full steps before reaching the platform. Furthermore, in order to accept the recording the subject should have enough space for two full steps after walking off the mat. If the subject failed to follow these indications, the recording was discharged and a new trial was taken.

Compared to other barefoot analysis system, the HR Walkway not only is able to provide high resolution recordings, but it also allows multiple steps recordings. This option is particularly useful when dealing with young children because in some instances up to 4 or 5 steps were recorded at the same time, which helped avoiding targeting errors during gait.

Data analysis reported that during the repeatability and reproducibility test no ‘poor’ ICC results were obtained. It can be argued that some of the ‘moderate’ ICC results may be obtained due to human error that may occur during the data extrapolation process. In addition, if the participant wore different clothes between the two data collections, it could have influenced some gait parameters. Young children may exhibit low attention span particularly if the appointments were made early in the morning or late in the afternoon after a long day at school. All these possible factors should be taken into account when interpreting the results obtained with the F-scan and HR Walkway.

The process for data analysis and for extrapolating all the parameters had to be done manually which resulted to be quite lengthy. An average of 2 hours for each patient was required for data analysis for F-Scan and HR Walkway together and additional time necessary for ICC statistical analysis. It can be argued that modern technology should be able to carry out the extrapolation process automatically, which may help in reducing human error, and allow practitioners to spend more time to implement podiatric clinical management and patient education.

Finally, an overall positive trend can be highlighted with most results showing a 'good' ICC score in this study which indicate that the HR Walkway may be suitable for future clinical investigation on healthy children and potentially also for pathological gait.

3.4.8. Conclusion

The results suggested that the repeatability and reproducibility study showed 'good' ICC scores in most of the parameters investigated with the HR Walkway system. Similarly, with regards to the F-Scan, the repeatability study showed 'good' ICC scores in most of the parameters investigated and few 'moderate' ICC values were recorded for the reproducibility tests. Compliancy amongst the children was really positive and none of the participants dropped from the study. These encouraging results will be taken into account for the progression of the randomised controlled trial on the effect of FOs in children diagnosed with Juvenile Idiopathic Arthritis (JIA) using the HR walkway and F-Scan system.

Chapter 4: Methods – Randomised Controlled Study

4.1. Ethics

Ethical approval was granted by QMU ethics committee, NHS Lothian and Tayside. Risk assessment of the gait laboratories was carried out prior to commencing the data collection. Research liability was covered by QMU.

All participants were able to withdraw from the study at any time without giving any reasons. All subjects were free to speak with an independent person, who knew about the project but was not directly involved in the research. Anonymity was maintained throughout the whole duration of the research, all subjects are given a study number and their identity kept confidential for the whole duration of the study and even after.

4.2. Research Procedures

4.2.1. Patient Recruitment

Prior to the RCT study, all equipment was tested (see chapter 3.4). The recruitment process occurred at the Paediatric Rheumatology Department of the Royal Edinburgh Hospital for Sick Children, and Ninewells Hospital (Dundee). The Rheumatology consultants provided significant help in identifying the potential candidates to the research project. In order for patients to be accepted, they had to meet the study criteria. Firstly, the patient had to be diagnosed with JIA according to the ILAR[29] criteria. All details related to the ILAR criteria and the details of each of the 7 subtypes of JIA were highlighted in section 2.3 of this thesis. In addition, subjects had to meet the other inclusion and exclusion criteria which are underlined in section 4.2.3 and 4.2.4.

The initial approach to the patient and their parent / carer occurred during the routine appointment in the paediatric hospitals. The patients and their parents were introduced to the researcher by the paediatric rheumatology consultants. The recruitment process for this multicentre study began by providing verbal information about the study. If the patient and their parents / carers appeared interested, then an information sheet was

[29] The ILAR criteria are already been used to classified JIA within the paediatric hospitals.

supplied. Information sheets for children were divided according to the age range (5 years old, 6 to 10 years old, 11 to 15 years old and 16 to 18 years old) as advised by the NHS ethical committee. This division was proposed to allow a better understanding of the details of the research for subjects of a different age. Thus the language was adapted and the use of pictures and/or diagrams was introduced to explain details of the project. All parents / carers received the same information sheet with extended details of the project.

Following the order in which each patient was met during the recruitment day, a phone call was made 1 week after the initial meeting in order to give enough time for the participant and their parents to think about their volunteered participation in the study. Those patients not interested in taking part in the study were classified as 'not suitable'. For those patients willing to participate in the study, an appointment was organised. If the patient was initially seen at the Paediatric Rheumatology Department of the Royal Edinburgh Hospital for Sick Children, the child was invited to attend the Gait Analysis laboratory at QMU. On the other hand, if the patient was met at Ninewells Hospital (Dundee) the appointment was made to attend the T.O.R.T. centre[30] in Dundee. Once the parent or carer agreed to take part in the study, the anonymous code was given to the patient. Two copies of the consent form were signed, one was given to the patient to be kept for their own records, and the other one was inserted into the medical file of the participant. Only once the consent form was signed could the data collection process begin.

4.2.2. Patients

This randomised controlled study involved male and female children ranging in age from 5 to 18 years old. Children younger than 5 years old were not able to take part in the study due to possible difficulties in following the instruction necessary to obtain gait analysis data, to maintain attention span for the whole duration of the study and to fully comprehend the questionnaire supplied for the quality of life. In addition, the belt used for the in-shoe analysis system available for the research would have not fitted the waist circumference of a child younger than 5 years old. On the other hand, participants older than 18 years old would have been too old according to the ILAR criteria;

[30] Department of Orthopaedic and Trauma Surgery, Medical School, University of Dundee.

therefore, they could no longer be diagnosed with JIA pathology. Additionally, in Edinburgh, patients of more than 18 years of age are referred from the paediatric hospital to the adult rheumatology department at the Western General Hospital in Edinburgh. Similarly these changes from paediatric to adult department also occurred at Ninewells.

The data collection took approximately one hour for the initial assessment at baseline and then usually 45 mins for the two follow-up appointments at 3rd and 6th month intervals. Participants will be asked to attend for data collection at baseline, 3 months and 6 months intervals.

4.2.3. Inclusion Criteria

- Diagnosed with JIA according to ILAR criteria.
- All subjects with lower extremity joint involvement with disease onset ranging from 5 to 18 years old.
- Previous failure of orthotic management, where the patient has not worn any FOs for a period of at least 3 months.
- Ability to walk a minimum of 15 metres without assistive devices.
- Six months after start of DMARD therapy.

4.2.4. Exclusion Criteria

- Inability to walk barefoot or shod.
- Concomitant musculoskeletal disease, central or peripheral nerve disease and endocrine disorders, especially Diabetes Mellitus.
- Previous foot surgery.
- Currently using foot orthosis.
- Where supply of orthotics are contraindicated:
    - Less than 12 degrees at subtalar joint
    - Fully compensated ankle equinus
    - Osseous anomaly noted in the lower limbs and/or vertebrae during the physical evaluation.
    - Inappropriate footwear for fitting orthoses.

4.2.1. Justification for Methods

Evidence-based medicine (EBM) or evidence-based practice (EBP) aims to apply the highest available evidence obtained from the scientific method to clinical decision making (Timmermans and Mauck 2005). Researchers should be focusing on establishing the strength of evidence of the risks and benefits of treatments (including lack of treatment) and diagnostic test (Elstein 2004). The quality of research can range from meta-analyses and systematic reviews of double-blind, placebo-controlled clinical trials at the top end, descending towards 'conventional wisdom' at the bottom. The systematic review of published studies is a method used for researching different type of treatments mostly in the medical field. The Cochrane is one of the best-known organisations for systematic reviews. Once all the best evidence is assessed, treatment can be classified as "likely to be beneficial", "likely to be harmful", or "evidence did not support either benefit or harm" (Cochrane 2011).

NHS and the Oxford Centre for Evidence-based Medicine uses a system with categories labelled A, B, C, and D which clearly suggests the levels of evidence (LOE) according to the study designs and critical appraisal of prevention, diagnosis, prognosis, therapy, and harm studies:

- Level A: Consistent Randomised Controlled Clinical Trial, cohort study,
- Level B: Consistent Retrospective Cohort, Exploratory Cohort, Ecological Study, Outcomes Research, case-control study; or extrapolations from level A studies.
- Level C: Case-series study or extrapolations from level B studies.
- Level D: Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles (CEBM 2009).

It can be argued that it is widely recognised that the most powerful type of experimental study is the randomized controlled trial (Altman 1996; CEBM 2009; Chan 2003; Stolberg et al. 2004). The randomised controlled trial is one of the simplest but most powerful tools of research. The RCT can be described as a study in which people are allocated at random to receive one of several clinical interventions that may have an effect on their health status (Vader 1998). RCT are also often described in

terms of whether they evaluate the efficacy or effectiveness of an intervention. Efficacy refers to interventions carried out under ideal circumstances, whereas effectiveness investigates the effects of an intervention under similar conditions those found in daily practice (Stolberg, Norman and Trop 2004).

According to Altman, a RCT is the best way to compare the effectiveness of different interventions, and to allow valid inferences of cause and effect. As in all studies, RCT may also be open to bias if carried out badly. Therefore, it is essential that RCT are reported adequately and that the readers should not have to wonder what was probably done during the research, because they should be told explicitly (Altman 1996).

According to Chan (2003), in order to successfully complete a RCT, it is important to dedicate 35% of time in planning the methodology that will be used throughout the whole duration of the research. The author mentioned that the designing stage is the foundation of the project itself, and it should be focused on a few aspects, such as: defining the primary and the secondary outcomes; the study population; inclusion and exclusion criteria and the sample size. Chan (2003) reported that 50 % of time should be dedicated to the conduct of the study (data capture, database design and data entry) and finally, the remaining 15% of time should be occupied in statistical analysis (Chan 2003).

The design of an RCT is based on having a control group which receives no treatment and in theory should result in no improvement over the study period. In contrast, the trial group should exhibit the effect of the new intervention, which may be positive or negative. The trial group intervention is then statistically compared against no treatment. In addition, by introducing the randomisation, all possible systematic bias involuntarily introduced during the data collection stage, should be eliminated because it is equally accounted for in both groups. After having evaluated the different types of methodologies that could have been adopted for this JIA study, the RCT design was chosen. With this type of methodology no direct influence from the data collector and external variables could have skewed the final results of this study.

The randomised sequence was chronologically followed for each patient recruited in order to avoid any mistakes or bias influence in the selection of the groups. The patient

and the parent / carer was not told to which group the subject belonged till the end of the whole data collection process for all 60 JIA children.

The sequence for the randomisation in the controlled and trial group was obtained for each individual motion analysis centre before the recruitment of patients began, to avoid any possible indirect influence or bias decision by patients, doctors or researcher. The block randomisation was chosen as the most suitable for the type of the RCT trial because according to the power calculation obtained, it was possible to have an estimate of what was the required number of patients that needed to be recruited in order to produce robust evidence based from this RCT study. According to the power calculation (section 4.4.4) the recommended number was 60 JIA patients in total; however, although it was an ambitious number of patients to achieve in such short period of time available to complete the PhD project, it was not possible to predict how many patients would have agreed to take part to the RCT or how many children would have met all the criteria required. For this reason, the randomisation was organised in blocks of 10 each time, therefore, randomly 5 patients in the controlled and 5 in the trial group. Once 10 patients successfully agreed to take part in the study, then the new randomised block of 10 was utilised till all 60 patients were recruited. In contrast, if a non-blocked randomised list of 60 patients was decided prior to commencing the study and only few patients actually were recruited, it could have generated a significantly unequal number of patients in either the controlled or trial group.

As previously mentioned, the primary outcome data have been collected by using the questionnaires for quality of life. In order to avoid any bias results the order that all questionnaires were completed, were randomly assigned to the patients and their parents / carer. It can be argued that the attention span might be different according to the age of the participants. In order to account for any influence in answering the questionnaires if the younger children became tired or bored while completing the forms, all questionnaires were randomised. Each child randomly received 2 questionnaires divided according to the age range: the PedsQL Paediatric module (version 4.0) and the PedsQL Rheumatology module (version 3.0).

Similarly, the parents/cares randomly received the VAS, CHAQ and PedsQL questionnaires. It is important to highlight that, in order to avoid introduction of

variables during data collection, only the parent/carer was allowed to complete the questionnaires.

4.2.2. Intervention

Either for the control group and the trial group, every patient was recommended to wear the FOs gradually to gently get used to the new sensation of wearing an FOs inside the shoes. At the end of the first data collection appointment, every child was given plenty of time to walk to check the comfort of the FOs with all the shoes that were brought on the day. Each patient was told that, after the initial stage of gently breaking in, the FOs had to be worn daily in all shoes for 6 months. Each child was given a demonstration of how to insert the FOs inside the shoes and how to remove them without damaging the materials. Each participant was asked to demonstrate to the data collector if she/he was able to insert and remove the FOs correctly. If the patient was really young, for example 5 years old, also the parent / carer was asked to demonstrate their ability to appropriately fit the FOs inside their child's shoes.

Control Group

The control FOs, or placebo FOs was supplied to patients who were randomly included in the control group. The control FOs was made of leather board (1mm), grey poron (1mm), and black EVA (0.75mm) as covering. This thin inner sole did not have any sort of biomechanical support, nor had it any effect on the distribution of pressure, as it was completely flat. In addition, the placebo FOs did not present with any intrinsic or extrinsic correction underneath the STJ (Figure 4.2.2.1).

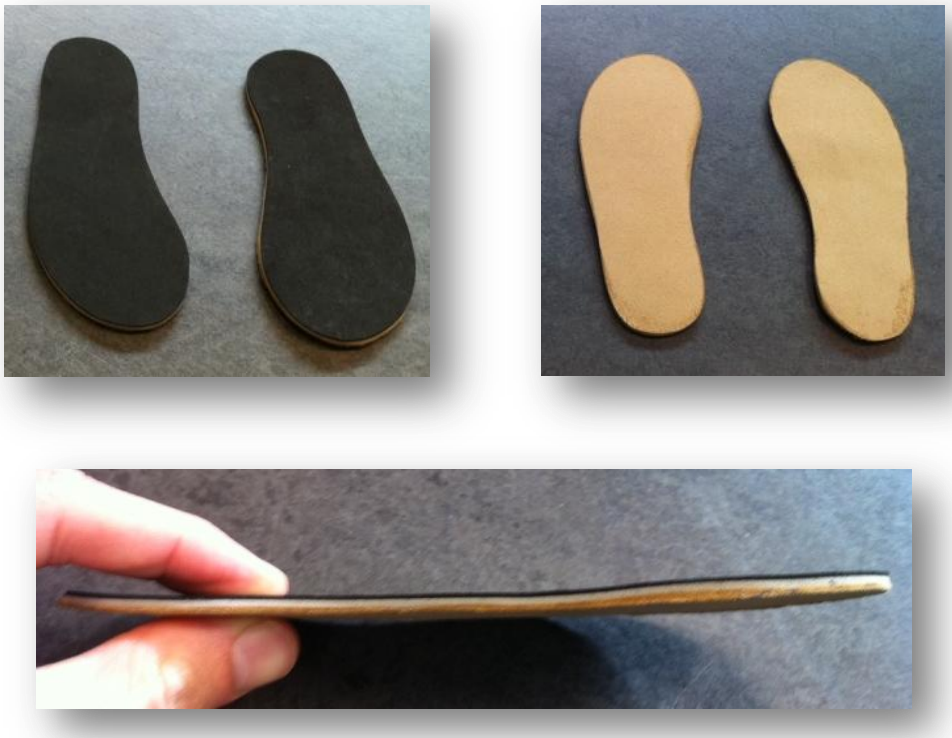


Figure 4.2.2.1: control FOs: frontal - plantar – medial view. No corrections were added in the control FOs, made with 1mm leather board, 1mm poron and black EVA (0.75mm - exactly the same top cover as the trial FOs.

The use of black EVA as the covering material and the leather-board as a base, allowed for gathering of a dynamic impression over the 6 months of the trial. This aspect is extremely important, because it allowed the data collector to monitor if the control patient wore the prescribed FOs for the whole duration of the trial, as requested. Both materials would quickly adapt to the dynamic behaviour of the plantar aspect of the foot at closed kinetic chain. If the FOs was worn correctly and on a daily basis, the data collector would have been able to observe that the leather-board bent to the shape of the foot for the pressure exerted under the rearfoot and forefoot. Additionally, during gait, the plantar aspect of the leather board in contact with the shoes would change to a darker colour. The black EVA instead, was in direct contact with the child's foot, and it allowed monitoring of the dynamic impression of the foot. The dynamic impression produced was able to provide useful information to the data collector with regards to the degree of usage of the placebo FOs. If worn on a daily basis the dynamic impression on the placebo FOs would have been very noticeable at 3rd month's interval and significantly more visible by the end of the study. At each individual follow-up appointment, the data collector monitored the condition of the placebo FOs to check if

the FOs had actually been worn by the patient. All patients appeared to be very compliant with the instruction given as noted by the dynamic impression.

Trial Group

With regards to the trial group, the children who were randomly introduced into this group received the pre-formed semi-rigid FOs. The 'Slimflex' FOs were used as an off-the-shelf device and subsequently customised with chair side modifications (Figure 4.2.2.2). Slimflex plus is the same shape as the original green Slimflex but instead it is more rigid and supportive. This is due to the royal blue ¾ length EVA material incorporated as an under-layer, which acts as a hard stabiliser and provides increased support for greater functional control. As reported by the manufacturer (Algeos) the Slimflex plus can also be used with wedges and components to create a chair-side custom functional device if required (Algeos 2011). Slimflex plus is widely available in UK sizes for children 8-13 and adults 1½-12.

In order to reproduce the exact same aesthetical appearance as the control FOs, grey poron (1mm) and black EVA (0.75mm) was used as well to cover the trial FOs. Furthermore, depending on the type of correction applied to the trial patient, the black EVA also allowed the correction applied on the surface of the device to be masked.

Figure 4.2.2.2 : trial FOs: frontal - plantar - medial view. In this particular case 5°antipronatory wedge were extrinsically added underneath the heel to improve STJ excessive pronation - 1mm poron and black EVA (0.75mm) - exactly the same top cover as the control FOs.

The off the shelf FOs also allowed a high degree of prescription underneath the surface of the device. For example, it was possible to add extrinsic antipronatory wedges to improve the STJ alignment. In order to apply the appropriate correction to maintain the STJ in neutral position, 5° or 3.5° high density EVA antipronatory wedges were mostly used or combined together to further correct biomechanical joint alignments. Depending on each child's prescription, heel raises, antipronatory wedges and cushioning material like poron (1mm, 3mm, and 6mm) were utilised. Corrections were applied at the rear-foot and/or forefoot as well. Forefoot cushioning, kinetic wedges, PMP (plantar metatarsal padding), metatarsal bars, or deflection of metatarsal pressure could have been easily and quickly obtained by simply altering the pre-formed semi-rigid FOs. In some cases, particularly with female patients, it was noticed that restricted foot wear was used on a daily basis (for example: ballerina or narrow school shoes) and the FOs' fitting was more challenging.

The off the shelf FOs, not only allowed the podiatrist to achieve a high degree of freedom of prescription with the trial patient, but also helped the clinician to check how the FOs responded in improving the JIA child biomechanics. In order to report and attribute the positive or negative effect of the trial FOs, it was necessary to check if the patient actually wore the FOs for 6 months period of time. Equally to the control FOs, the covering material of the FOs significantly helped in providing details with regards to usage of the device. By looking at the plantar surface of the FOs in contact with the shoes, the researcher was able to check if patients had worn the FOs by noticing the condition of the extrinsic correction. For example, if the trial patient wore the FOs daily, the edge of the antipronatory correction would start to show signs of wear and become more rounded. On other occasions, if a kinetic wedge was created underneath the 1st metatarsal head, it was possible to observe the effect of the plantar-flexion of the 1st ray into the cut-out, showing the suitability of the forefoot correction prescribed by the podiatrist. In addition, the forefoot portion of the FOs in contact with the shoe is completely white. Therefore, the data collector was able to record how much the FOs was worn by monitoring the gradual change of colour at 3 month and 6 month interval. For obvious reasons, a darker colour was interpreted as a good sign of usage of the FOs.

During both follow-up appointments, the data collector monitored if the corrections were still in good condition and especially if they were at the same position as initially prescribed. It must be underlined that the data collector precisely recorded every single correction added to the FOs with each trial patient. This precaution was adopted from the start of the data collection in case the patient or the parent/carer decided to make unexpected self-modifications to the devices supplied. No instances were recorded of self-modification of the FOs; however, it seemed an important detail to check to avoid alteration of results and to prevent the introduction of a new and unknown variable during data analysis.

Finally it can be argued that the use of the trial FOs reflects current podiatric practice within NHS and private clinics. Many podiatrists on a daily basis utilised cost-effective pre-formed semi-rigid FOs with the addition of customised correction to specifically suit different biomechanical lower limbs pathologies (Malone 2008b). As previously

mentioned, this podiatric intervention has not yet been tested and proven with JIA children.

4.3. Data Collection

4.3.1. Data Collection

Figure 4.3.1.1: height measurement tool used with every patient

The researcher obtained details of the medication of the patient and past medical history from the medical records of the paediatric hospital, which was accessed only after the patient agreed to take part in the study. On the day of the visit at QMU or TORT centre, the data collector thoroughly recorded if the patients were prescribed with any new medications. Details of the dosage were recorded and monitored at each individual follow-up appointment.

Subsequently, height and weight details were recorded in order to calculate the BMI values and the health status according to the SIGN (2010). Each patient was asked to remove shoes and socks and jackets. The same height scale and weight balance was used for the duration of the data collection, at both gait analysis centres (Figure 4.3.1.1 and Figure 4.3.1.2).

Figure 4.3.1.2: balance used to measure weight with all patients and the plinth used for off weight baring biomechanical examination

At this stage, the patient was asked to sit on the provided plinth and a biomechanical assessment of the lower limb joint was carried out. Examination of joints at open and close kinetic chain was carried out. After bisecting the calcaneus, a line at the back of the heel was drawn. STJ measurements were then taken of relax and neutral calcaneal

stance positions and recorded on the study data research sheet at baseline, 3rd month and 6th month interval. The STJ measurements were taken three times each visit in both feet, and then averaged in order to monitor the intra-tester repeatability. Diagnosis was made according to the biomechanical findings, which usually did not take longer than 30 min. The degrees of correction required to maintain the STJ into neutral was tested and reliability analysis was carried out. The ICC score indicated 'excellent' repeatability results for the control and the trial group.

On examination the most commonly symptomatic joints in the lower limbs appeared to be: the hip, medial aspect of the knee, patella-tibia tendon, tibial tuberosity, tibialis-posterior tendon, achilles tendon, ankle joint, STJ, dorsal aspect of the midtarsal joint (talo-navicular and calcaneo-cuboid joint) and metatarsal heads. It was not possible to statistically calculate the most commonly affected joints.

The questionnaires used to record quality of life score (VAS, CHAQ, PedsQL) were randomly supplied to the patient and the parent / carer. In order to avoid any confusion, the patient's code was written on the top right corner of the questionnaires with details regarding baseline, 3rd month or 6th month appointment date. The data collector informed them that each questionnaire had to be completed independently, and that no communication was allowed between the child and the parent / carer. In this way the scores obtained were not influenced by other people and exactly the same instructions were repeated at all follow up appointments. Questionnaires had to be completed following the order provided by the data collector. Each sheet had a brief instructions section that helped to show how to fill in the questionnaire. For any clarification, the data collector was available to help or explain what had to be done. According to the instruction provided by PedsQL system, if the child was 7 years old or younger, the data collector had to read out the questions and circle the answer provided. During the 5 minutes normally required for completion of the questionnaire, the data collector observed the suitability of the shoes and checked the fitting of the FOs inside the shoes. Any modification or adjustment of the FOs would have been made at this stage, prior to the gait analysis.

Figure 4.3.1.3: control and trial FOs

Each subject received a pair of standardised Clark's shoes (Figure 3.3.3.12) and the suitability of the FOs inside the shoe was verified before the start of gait recording. Once the Clark's shoes size was chosen, the equivalent F-scan insole (already pre-cut) was selected. The order in which the equipment was used was rigorously followed according to the randomised sequence of what gait analysis system had to be used with each patient. For example, one of the combination or randomised sequence might have been: 1st= HR Walkway; 2nd= in-shoe (with device); 3rd= in-shoe (without device). With each of the gait equipment used, 3 recordings were taken and saved.

The equipment was set up and calibrated as explained in section 3.3. Each recording was saved in the patient's folder, using the anonymous code. The data recording was successfully completed usually within 20-25 min. Under normal circumstances, it occurred that the quickest visits were with older JIA children. In some occasions, especially with 5 year old children, it took slightly longer to convey the instructions and in some cases they were reassured by the parents/carer while walking. In addition, with regards to the F-scan, in every recording the data collector was responsible for initiating and terminating the recording by pressing the recording button of the F-scan mobile unit. Two rehearsal trials were undertaken prior to the recording, to allow the subject to familiarise themselves with walking while using the equipment; usually 2 walks of 7 metres each appeared to be sufficient. Each recording occurred consecutively, within the same environment, using the same shoe size[31], utilising the same equipment; the calibration made on the day was uploaded, and finally, the same distance was travelled by the participant (7 m). During the follow-up appointments, the

[31] During the trial the shoe size was monitored and only one child within the control group showed an increase in foot size within the 6 months. Same prescription one size longer was then supplied to the patient.

data collector always checked the condition of the devices supplied, both control inner sole and the trial FOs (Figure 4.3.1.3). If the data collector, by observing the signs gathered by the condition of the material, realised that the FOs had not been used as requested, the patient was no longer suitable for the study and no further data would be recorded using the questionnaires and the gait analysis systems (Figure 4.3.1.4).

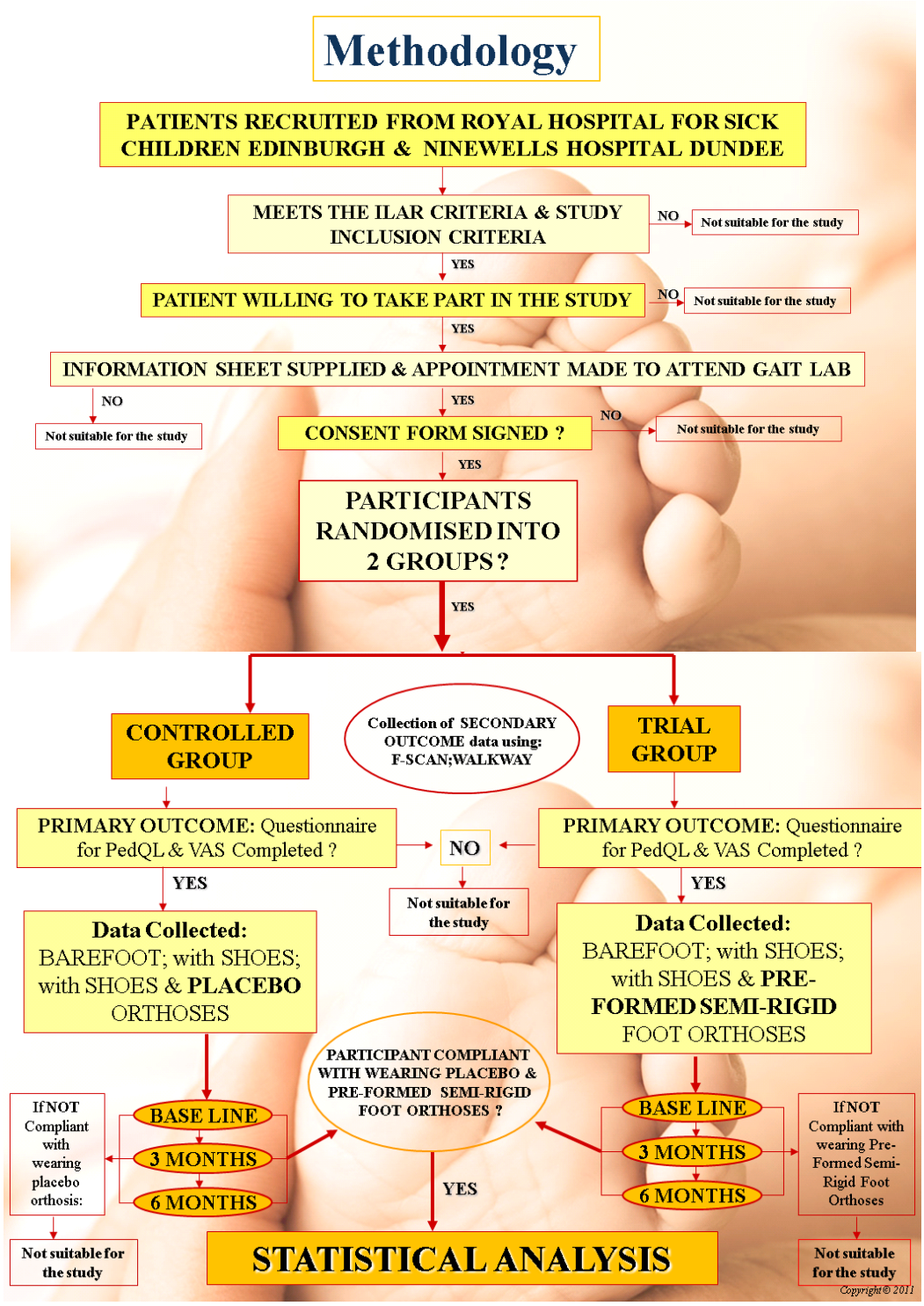


Figure 4.3.1.4: RCT methodology diagram

During each appointment, pharmaceutical changes were recorded and monitored over the 6 months period of time. Further information was gathered from patients and from medical records regarding possible steroid injections changes that may have occurred during the six months. If any modifications, of medication or steroid injection was noted during the study period, that patient was classified as not stable, because any possible interference with the treatment could have influenced the final primary outcome results.

4.3.2. Data Process

Pain Questionnaires: VAS

The VAS scores completed by the parent were extrapolated by using a simple ruler. Data at baseline, 3rd month and 6th month interval were recorded into a table and kept inside the patient's medical records. It can be argued that in order to provide a clinical significance of the data obtained, it is essential to investigate previous VAS papers suggesting clinically significant difference for VAS scores. According to Kelly (1998), in adult patients the minimum clinically significant difference in VAS pain scores was found to be 9 mm. Differences of less than this amount, even if statistically significant, are unlikely to be of clinical significance (Kelly 1998). With regard to children, a small study reported that the minimum clinically significant difference in VAS pain score for 73 children aged range from 8 to 15 years, to be 10 mm with 95% confidence interval 7 to 12 mm (Powell et al. 2001). More specifically for paediatric rheumatology, a study carried out with 533 paediatric rheumatology patients in Toronto looked at establishing the minimal change on pain using the VAS measured at 2 consecutive visits to a clinic. The authors stated that for future studies, the results should aim for a minimum reduction in pain score of 0.82 cm on a 10-cm VAS in order to achieve clinical improvement in quality of life with children affected by rheumatic disease (Dhanani et al. 2002). In this study a difference in VAS scores of 0.82cm was taken as clinically significant.

Quality of Life Questionnaires: CHAQ

The CHAQ scores were obtained according to the instruction provided by the juvenile dermatomyositis research centre. The CHAQ scoring consists in looking at the section ticked by the parent of the JIA participants: each of the eight sections is scored for the highest value ticked in its own section. 'Zero' was the score associated for 'without any difficulties' or 'not applicable'. One was recorded for 'with some difficulties' answer. Two for 'with much difficulty' and finally, three for 'unable to do'. Subsequently, the section which referred to the 'help required' had to be observed (ie: AIDS, DEVICEs etc.). If any of these were ticked, the correspondent section had to be looked at: if that section score was a 'zero' or a 'one', then the score had to be increased to a 'two'. If that section already scored a 'two', then the score remained as a 'two'. Then, if that section scored a 'three' then the score remained as a 'three'. Finally, all the scores had to be added together and divided by 'eight' in order to obtain the CHAQ score.

Little evidence is available with regards to the minimal clinically important differences (MCID) with the CHAQ score. Interestingly, in 2005 the Journal of Rheumatology released a publication in which claimed that the MCID for improvement of the CHAQ was -0.188 at most, while the MCID for worsening was at most +0.125 (Brunner et al. 2005). Similarly, Dempster et al. (2001) claimed that clinicians, as well as researchers should aim for a minimum improvement of 0.13 in the CHAQ score when treating paediatric patients with arthritis (Dempster et al. 2001). In this study a minimum improvement in the CHAQ score of 0.13 was taken as a clinically significant difference.

Quality of Life Questionnaires: PedsQL

The Peds quality of life score was equally calculated for the generic module (version 4.0) and rheumatology module (version 3.0). According to Mapi Research Trust Centre, the scores are transformed on a scale from 0 to 100. Items are 'reversely scored' and 'linearly transformed' to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. If more than 50% of the items in the scale are missing, the scale scores should not be computed. The mean score can be calculated by simply summing the

items over the number of items answered. According to the author there is not a total score (Mapi 2008). All the scores gathered were transcribed from the questionnaire into another form in order to have a hard copy form with all the scores. Subsequently, data were transposed into the excel spread sheets.

According to Varni et al. (2003), a 4.4 points change in the Total Scale Score for child self-report represents a minimal clinically meaningful difference. Similarly, a 4.5 change in the Total Scale Score for parent is deemed to be a minimal clinically meaningful difference. In this study a minimum improvement in the PedsQL total score of 4.4 points was considered as a clinically significant difference.

4.4. Statistical Methods

4.4.1. Data Analysis

All data collected during the study from baseline, 3 months and 6 months will be carried out using Shapiro Wilks test to check for normality. Where the variable presents ordinal data, the appropriate non-parametric test will be used. A series of between and within group analyses will be carried out. Most of the data were not parametric therefore data tend not fit a normal distribution curve. If results were parametric, it can be argued that results may have been stronger as parametric methods make more assumptions than non-parametric methods, such as normality (Corder and Foreman 2009). However, the not parametric data obtained in this research do not rely on assumptions that the data are drawn from a given probability distribution.

4.4.2. Comparison between controlled Group and Trial Group

In order to test the hypothesis the controlled group was compared with the trial group. Pair wise statistical analysis was carried out using an unpaired t-test or Mann Whitney U test, depending on the distribution of the data.

4.4.3. Within each individual Group Analysis

In order to investigate the relationships between the groups at baseline, 3 months and 6 months, a repeated measures ANOVA was carried out for parametric data where

sphericity exist; or a Friedman test where non-parametric and/or no-sphericity exists. Pair wise statistical analysis was carried out using a paired t-test or Wilcoxon's test, depending on the distribution of the data.

4.4.4. Power Calculation

For a 5% 2-sided t-test with α=0.05 and power 80% for a RCT design with baseline and 2 post-intervention observations, and a moderate effect size, it was estimated that a total of 46 subjects would be required (23 controls and 23 trial) (Noordzij et. al 2010; Cohen 1988). The study was overpowered to an estimated 30 subjects per group to allow for dropouts during the 6 months data collection period.

Depending of what parameters were investigated, different tests were carried out. Please find below details of what tests was adopted for the primary and secondary outcome:

4.4.5. Primary Outcomes:

VAS scores were tested for normality and appropriate parametric and non-parametric tests were carried out to test if normality assumptions were met or not. With regards to the CHAQ and the PedsQL scores, they are considered to be a non-parametric ordinal data. Data were compared amongst the control and the trial group. When 2 groups were compared (ie: baseline – 3rd month; or 3rd month – 6th month; or baseline – 6th month), the following test may be chosen. If paired group design, then Shapiro-Wilks test will be carried out, if $p>0.05$ data is parametric and pair t-test is run; if $p<0.05$ data is not-parametric and Wilcoxon test will be chosen. If un-paired group design, then Shapiro-Wilks test will be carried out, if $p>0.05$ data is parametric an un-paired t-test is used; if $p<0.05$ data is not-parametric and Mann Whitney test will be chosen.

In statistical analysis p-value is commonly accepted at 0.05; this value is indicative that there is less than 5% chance of achieving results by chance assuming that the null hypothesis (Ho) is true. It appears that 5% is an arbitrary significance level that should not be too high to avoid many Type I errors (assuming an effect where there is not one), but equally not too low to exclude too many Type II errors (assuming there is not

an effect where there is one). Bonferroni adjustments has been previously employed in research to reduce Type I errors (for example: rejecting Ho when Ho is true) when multiple tests are conducted for pair-wise comparison. It consists of modifying the p-value by the number of tests that has been carried out. Bonferroni procedures appear to raise few issues, and there is no formal consensus for when it should be used, even among statisticians (Moran 2003; Nakagawa 2004; Perneger 1998). The same authors also state that Bonferroni adjustments do not guarantee a "prudent" interpretation of results because it provides a correct answer to a largely irrelevant question. Type I errors cannot decrease without inflating type II errors; and type II errors are no less false than type I errors (Moran 2003).

Perneger (1998) in the BMJ raised the question that in biomedical research if Bonferroni adjustments will become routinely adopted, cynical researchers would 'slice their results like salami' publishing one p-value at the time to avoid criticism from reviewers, which will results in lower quality of evidence base and wasting time, energy and public money.

Additionally, the extensive use of Bonferroni procedures may increase the tendency of researchers not to present non-significant results, because presentation of more tests with non-significant data may make previously 'significant' results 'non-significant' under Bonferroni procedures (Nakagawa 2004). Similarly, also Moran (2003) mentioned that the irony of the sequential Bonferroni correction (and multiple tests in general) is that as a researcher performs more detailed work, the chances of finding significant results declines dramatically. The best approach that should be adopted, appears to be that researchers should simply report accurately the methodology and effect size along with exact p-values; and discuss in details the possible interpretations of each result, allowing the reader to independently reach a conclusion without the unclear support of Bonferroni test (Nakagawa 2004; Perneger 1998).

In this RCT, the conclusion made by these authors will be taken into account in reporting the findings and all p-values will be clearly expressed in each of the multiple statistical tests that will be carried out. As this study is a pragmatic study in which many primary and secondary variables have not yet been explored together in JIA children, the reader will be informed in details about the statistical test carried out. This

may help the reader to make a final informed decision to whether accept or reject the conclusion made in this multicenter study. Thus Bonferroni adjustments where not carried out because of the reasons expressed in this chapter. However, as many details as possible will be provided to allow the reader to make an inform decision to accept or reject the results acquired from this multicenter study.

4.4.6. Secondary Outcomes

With regards to the secondary outcomes, although more variables were investigated, the same statistical method as the primary outcome were utilised. Gait analysis data was compared within and between the control group and within the trial group with F-scan (with insole and shod) and HR walkway.

Parameters investigated during Gait Analysis		
F-Scan	**HR Walkway**	**Human Icon**
Total contact (left and right)	Total contact (left and right)	Gait Time (sec)
Heel (left and right)	Heel (left and right)	Gait Velocity (cm/sec)
Midfoot (left and right)	Midfoot (left and right)	Stance Time (sec) (left and right)
Forefoot (left and right)	Forefoot (left and right)	
5^{th} met. head (left and right)	5^{th} met. head (left and right)	
3^{rd} to 4^{th} met head (left and right)	3^{rd} to 4^{th} met head (left and right)	
2^{nd} met head (left and right)	2^{nd} met head (left and right)	
1^{st} met head (left and right)	1^{st} met head (left and right)	
Lesser toes (left and right)	Lesser toes (left and right)	
1^{st} Distal phalanx. (left and right)	1^{st} Distal phalanx. (left and right)	

Table 4.4.6.1: Parameters investigated during Gait Analysis while using the F-Scan (with insole and shod) and HR Walkway.

Chapter 5: Results

5.1. Patient Demographics

With regard to patient demographics, 60 JIA patients took part in this RCT study. According to the descriptive results, 48.3% (n=29) of children received the control FOs, and the remaining 51.7% (n=31) were fitted with the trial pre-formed semi-rigid foot orthosis. Overall, 99.4% (n=179/180) of the planned JIA data collection visits were sucessfully completed. As part of this multicentre study 78.3% (n=47) patients were recruited from the NHS Royal Hospital for Sick Children in Edinburgh, and the remaining 21.7% (n=13) JIA children were seen at the NHS Ninewells Hospitals in Dundee.

5.1.1. Age

Age ranged between 5 to 18 years, mean age for the control group was 11.17(SD3.51) and for the trial group were 10.64 (SD3.84). With regards to the control group, the minimum age was 5 and max was 17.9; similarly in the trial group minimum age was 5 and maximum was 17.11 (Table 5.1.1.1).

Table 5.1.1.1: descriptive statistics for age (year) for the control and trial group

Age (year)		
	Control	**Trial**
Mean (SD)	11.17 (3.51)	10.64 (3.84)
Minimum	5	5
Maximum	17.9	17.11

5.1.2. Gender

Particularly within the control group, only 20.7% (n=6) of patients were male and 79.3% (n=23) were female. Similarly, within the trial group, 29% (n=9) subjects were male and the remaining 71% (n=22) were female.

5.1.3. Shoes size

Descriptive statistics highlighted that the mean value for shoes size was 35.55(SD3.88) (UK size=3) for the control group, similarly 35.14(SD4.54) (UK size=3) (Table 5.1.3.1). In both groups the minimum and the maximum shoe size was 28 (UK=10 child) and 44.5 (UK=10 adult).

Table 5.1.3.1: descriptive statistics at baseline for shoe size (control and trial group); European and UK sizes

Shoe Size European & (UK) at baseline		
	Control	**Trial**
Mean (SD)	35.55(3.88) (UK=3)	35.14(4.54) (UK=3)
Minimum	28 (UK=10 child)	28 (UK=10 child)
Maximum	44.50 (UK=10 adult)	44.50 (UK=10 adult)

5.1.4. Height

With regard to height, at baseline the control group showed a mean of 142.07cm (SD17.94), minimum and maximum value of 107.20cm and 175.80cm respectively. Similarly, the trial group presented with a mean height of 140.39cm (SD22.17), minimum height of 103.30cm and maximum of 178.00cm (Table 5.1.4.1).

Table 5.1.4.1: descriptive statistics at baseline for height (control and trial group)

Height (cm) at baseline		
	Control	**Trial**
Mean (SD)	142.07(17.94)	140.39(22.17)
Minimum	107.20	103.30
Maximum	175.80	178.00

5.1.5. Weight

With respect to weight recorded at baseline (Table 5.1.5.1), the control group presented with the mean weight of 38.97kg (SD18.04); minimum weight of only 19kg and the maximum of 98kg. On the other hand, the trial group appeared to have a mean value of 42.07kg (SD23.41), and similarly the minimum weight was of only 15kg and the maximum reaching 121kg.

Table 5.1.5.1: descriptive statistics at baseline for weight (control and trial group)

Weight (kg) at baseline		
	Control	**Trial**
Mean (SD)	38.97(18.04)	42.07(23.41)
Minimum	19	15
Maximum	98	121

5.1.6. BMI & Health Status

The BMI results showed that at baseline the control group's mean value was 18.29 (SD 4.05), minimum value of 12.90, maximum value of 31.70. Similarly the trial group presented with mean values of 19.70 (SD5.91), minimum BMI value of 12.30 and maximum of 38.20 (Table 5.1.6.1).

Table 5.1.6.1: descriptive statistics for BMI values at baseline (control and trial group)

BMI at baseline		
	Control	**Trial**
Mean (SD)	18.29(4.05)	19.70(5.91)
Minimum	12.90	12.30
Maximum	31.70	38.20

Healthy status results were divided in 4 categories: underweight; healthy; over weight; and obese. Each of these nominal data, shown in the table below (Table 5.1.6.2), is divided between control and trial group. According to the descriptive statistics within the control group 6.9% (n=2) were deemed to be underweight, 75.9% (n=22) healthy, 13.8% (n=4) overweight and finally 3.4% (n=1) obese. Similarly, the health status for the trial group appeared to have 6.5% (n=2) of the children considered to be underweight, 74.2% (n=23) healthy, only 3.2% (n=1) overweight, but with 16.1% (n=5) obese. Thus for health status and BMI there was a similar distribution between the groups.

Table 5.1.6.2: descriptive statistics at baseline for health status

Health Status at baseline		
	Control	**Trial**
Underweight	6.9% (n=2)	6.5% (n=2)
Healthy	75.9% (n=22)	74.2% (n=23)
Overweight	13.8% (n=4)	3.2% (n=1)
Obese	3.4% (n=1)	16.1% (n=5)
Total	100% (n=29)	100% (n=31)

5.2. Pharmacological Intervention

In order to attribute any effect solely on the FOs intervention, details of changes of medication and/or new joint injections were recorded during the trial. The 'stable' patients were considered those children that did not change medication, drug's dosage or did not received injections during the whole period of the study. On the other hand, those JIA children who changed the medications, dosage and/or received new injections within the 6 months were classified as 'not stable'. According to the data obtained within the control group 65.5% (n=19) seemed to be stable and the remaining 34.5% (n=10) were proven to be unstable. Similarly, within the trial group 74.2% (n=23) were on stable medication and 25.8% (n=8) were unstable (Table 5.1.6.1).

Table 5.1.6.1: descriptive statistics on the medication status (control and trial patients)

Medication Status		
	Control	**Trial**
Stable	65.5% (n=19)	74.2% (n=23)
Not Stable	34.5% (n=10)	25.8% (n=8)

5.3. Quality of Life Questionnaires

5.3.1. VAS

Control Group (VAS)

According to the descriptive statistics within the control group there was only 1 missing recording at 6th month due to patient D9 that failed to attend the last appointment. Hence, the same missing data will not be found in all other tools adopted to investigate quality of life. Median score was 6.5 at baseline, 3.6 at 3rd month and 4.65 at 6th month. It is possible to notice a stable trend by the end of 6 months (Table 5.3.1.1, Figure 5.3.1.1).

Table 5.3.1.1: descriptive statistics on VAS data at baseline, 3rd month and 6th month (control and trial patients)

VAS						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median (IQR)	6.5(50.5)	3.6(34)	4.65(46.75)	14(31)	5(24)	4(19)

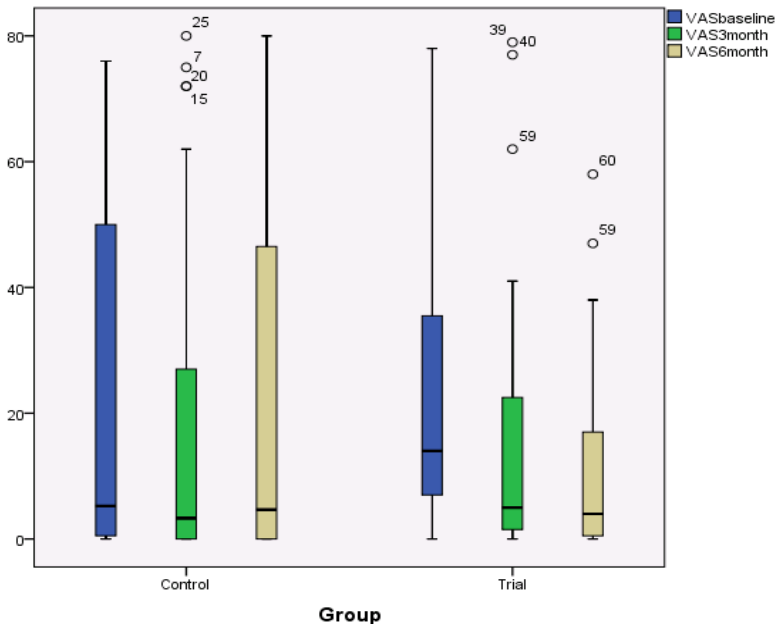


Figure 5.3.1.1: descriptive statistics on VAS data at baseline, 3rd month and 6th month (control and trial patients)

Data are NOT parametric; therefore, Friedman's test was carried out. As shown on Table 5.3.1.2 there is no statistical difference for the control group.

Table 5.3.1.2: details of the Friedman test on VAS data at baseline, 3rd month and 6th month (control and trial patients). From this table onward all values indicating p<0.05 will be followed by * and p<0.01 by **.

Friedman Test – VAS score (baseline, 3rd month & 6th month)		
	Control	**Trial**
p-value	**p=0.708**	**p=0.000****
Stable	**p=1.000**	**p=0.000****
Non Stable	**p=0.439**	**p=0.066**

Furthermore, data were compared within two intervals each time (baseline with 3rd month; 3rd month with 6th month; and baseline with 6 month). As data are not parametric and paired, Wilcoxon's test was carried out. Table 5.3.1.3 highlights that the p>0.05 for all the intervals within the control group, which indicates a non-statistical difference amongst all intervals. Also when only the stable group is considered separately the same results are obtained. This suggests that there were no statistical difference in pain score when any of the interval where compared for the control group.

Table 5.3.1.3: details of the Wilcoxon's test on VAS data (control and trial patients); * means p<0.05, ** means p<0.01.

Wilcoxon's Test – VAS Score			
		Control	**Trial**
Baseline – 3rd month		**p=0.615**	**p=0.003****
3rd month – 6th month		**p=0.286**	**p=0.055**
Baseline – 6th month		**p=0.808**	**p=0.000****
Stable	**Baseline – 3rd month**	**p=0.779**	**p=0.044***
	3rd month – 6th month	**p=0.443**	**p=0.034***
	Baseline – 6th month	**p=0.875**	**p=0.000****
Not Stable	**Baseline – 3rd month**	**p=0.813**	**p=0.018****
	3rd month – 6th month	**p=0.553**	**p=0.866**
	Baseline – 6th month	**p=0.515**	**p=0.090**

Trial Group (VAS)

Median score was 14 at baseline, 5 at 3rd month and 4 at 6th month (Table 5.3.1.1). According to the descriptive statistics (median values) the 8mm difference required to

achieve clinical significance within the appointments was found by the end of the 6 months. As shown on Table 5.3.1.2 there is statistical difference over the 6 month period of time. Also when only the stable group is considered separately the same results are obtained. However, no statistical difference was found for the non-stable medication group.

Table 5.3.1.3 highlights that: statistical difference was found at baseline-3rd month ($p<0.05$); and at baseline-6thmonth ($p<0.01$); but not at 3rdmonth-6thmonth.interval ($p>0.05$). Finally, when only the stable group is considered separately the same results are obtained with an additional significance difference also within the 3rd month and 6th month interval. Therefore, it is possible to notice of improvement of pain of the 6 months period (Figure 5.3.1.1).

Comparison between the Control and the Trial Group (VAS)

According to the Shapiro-Wilks Test $p<0.01$**, hence data are not parametric for both the control and the trial group at baseline- 3rd month- 6th month. In order to test if there were statistical difference between the control and trial group at baseline, Mann Whitney Test was carried out; the results showed that at the start of the trial $p>0.05$; therefore there was no statistical difference (Table 5.3.1.4). On the other hand, statistical significance was obtained between the groups at: baseline-3rdmonth, 3rd month-6th month, and baseline-6thmonth. When the groups were split according the to medication status, statistical difference was noted at 3rdmonth-6th month and baseline-6thmonth interval.

The same statistical test used to investigate primary outcomes will be carried out for all other parameters.

Table 5.3.1.4: details of the Mann Whitney Test carried out on VAS data between control and trial patients at baseline; and the difference of data between: the baseline-3rd month (B-3rd), 3rd month-6thmonth (3rd-6th), and baseline-6thmonth (B-6th). IQR is indicative of the inter quartile range (75%-25%). * means p<0.05, ** means p<0.01.

VAS - Mann Whitney Test				
	BASELINE	**DIFFERENCE**		
		B-3rd	**3rd-6th**	**B-6th**
p-value **control: Median (IQR)** **trial: Median (IQR)**	**p=0.221** 6.5(50.5) 14(31)	**p=0.030*** 0(-0.5) 5(8)	**p=0.002**** 0(-5) 1(6)	**p=0.029*** 0(0.25) 8(19)
Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.586** 4(62) 13(21)	**p=0.145** 0(0) 2(6)	**p=0.002**** 0(-5) 1(10)	**p=0.025*** 0(-2) 8(11)
Not Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.101** 6.75(20.5) 35.5(47.25)	**p=0.260** 1.45(1.75) 10.5(19.25)	**p=0.197** 0(-5.75) 1(-1.25)	**p=0.655** 2(3.5) 14(20.75)

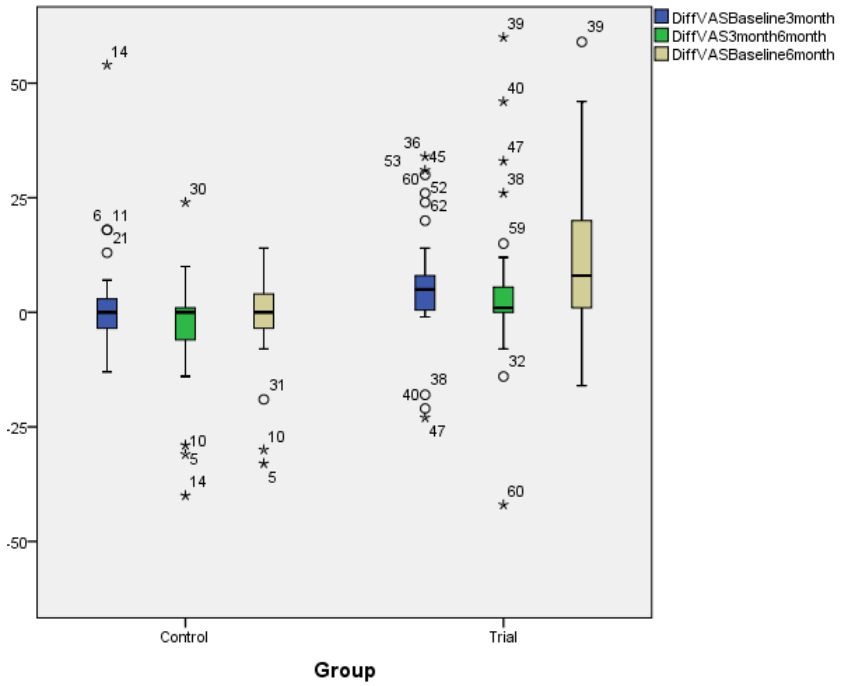


Figure 5.3.1.2: VAS data between control and trial patients that indicates the significant difference between baseline-3rd month (B-3rd), 3rd month-6thmonth (3rd-6th), and baseline-6thmonth (B-6th).

5.3.2. CHAQ

Control Group (CHAQ)

With regards to median values at baseline was 0.13, 0 at 3rd month, and 0.13 at 6th month. It is possible to notice a stable trend all over the 6 months (Table 5.3.2.1, Figure 5.3.2.1).

Table 5.3.2.1: descriptive statistics on CHAQ data at baseline, 3rd month and 6th month (control and trial patients).

CHAQ						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median (IQR)	0.13 (1.125)	0 (0.94)	0.13 (0.5)	0.38 (0.75)	0.25 (0.875)	0.13 (0.625)

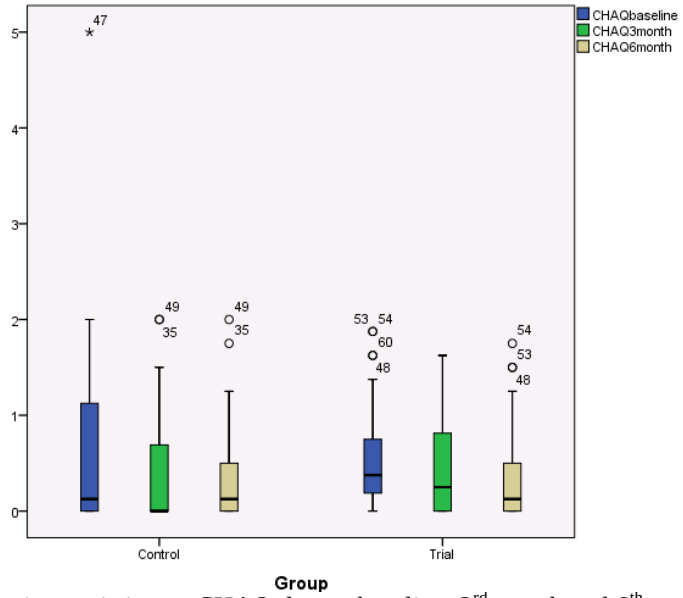
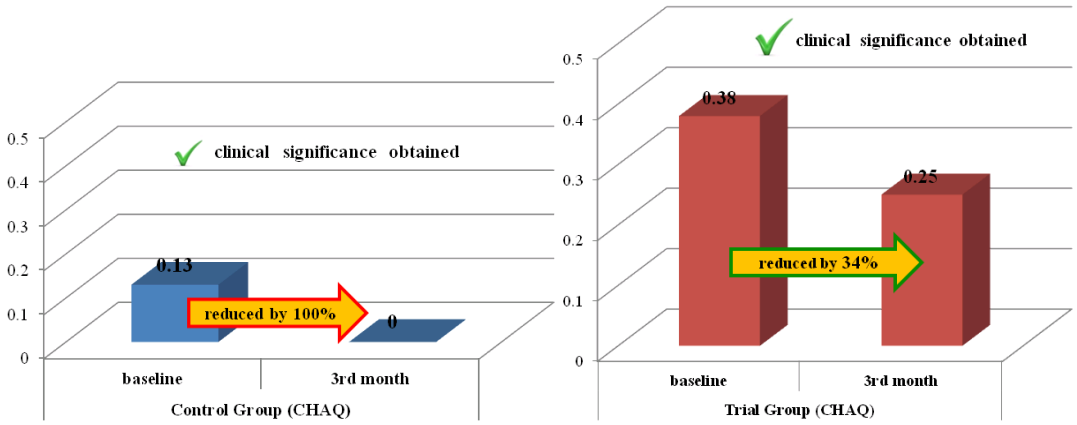


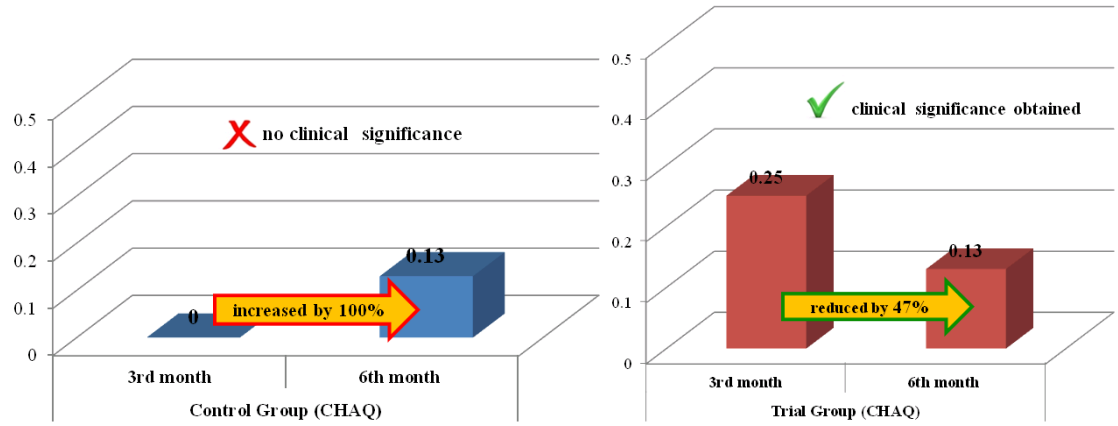
Figure 5.3.2.1 descriptive statistics on CHAQ data at baseline, 3rd month and 6th month (control and trial patients)

As shown in the table below, CHAQ clinical significance for the control group is obtained only for the baseline-3rdmonth interval. The remaining intervals did not achieve clinical significance (Figure 5.3.2.2).

Baseline - 3rd month interval (control and trial group)



3rd month - 6th month interval (control and trial group)



Baseline – 6th month interval (control and trial group)

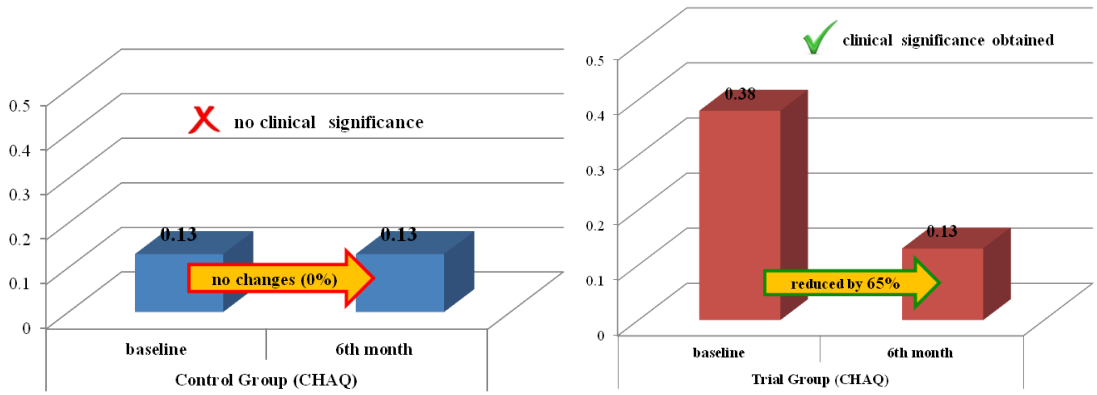


Figure 5.3.2.2: Clinical significance calculations for the CHAQ scores. The median value for clinical significance improvement for the control group (blue) and the trial group (red) was calculated of at least 30% difference. If the median value for the 3rd month or 6th month was reduced of 30%, then clinical significance was achieved.

As shown on Table 5.3.2.2 the Friedman test indicates that $p<0.01$; hence there is statistical difference for the control group. Also when only the stable group is considered separately the same results are obtained. Unstable group is also significant at $p<0.05$ which is acceptable for this study.

Table 5.3.2.2: details of the Friedman test on CHAQ data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test – CHAQ score (baseline, 3rd month & 6th month)		
	Control	**Trial**
p-value	**p=0.000****	**p=0.000****
Stable	**p=0.006****	**p=0.000****
Non Stable	**p=0.024***	**p=0.215**

Table 5.3.2.3 highlights that the $p<0.05$* of the control group at baseline-3rdmonth and baseline-6thmonth, but $p>0.05$ at 3rd month-6th month interval. When the stable group is considered separately the results slightly change and no significant changes occur at both 3rdmonth-6thmonth and baseline-6th month. The CHAQ data suggests by the end of the 6 month statistical changes occurred for the control group. Finally, the CHAQ scores show a trend of small improvement within baseline-3rd month; however, the scores worsen by the end of the study for the control group.

Table 5.3.2.3: details of the Wilcoxon's test on CHAQ data (control and trial patients). * means p<0.05, ** means p<0.01.

CHAQ - Wilcoxon's Test			
		Control	**Trial**
Baseline – 3rd month		**p=0.002****	**p=0.015***
3rd month – 6th month		**p=0.718**	**p=0.027***
Baseline – 6th month		**p=0.004****	**p=0.060***
Stable	**Baseline – 3rd month**	**p=0.001****	**p=0.009****
	3rd month – 6th month	**p=0.717**	**p=0.021***
	Baseline – 6th month	**p=0.029***	**p=0.001****
Not Stable	**Baseline – 3rd month**	**p=0.068***	**p=0.673****
	3rd month – 6th month	**p=0.180**	**p=0.546**
	Baseline – 6th month	**p=0.068**	**p=0.053**

Trial Group (CHAQ)

As shown on Table 5.3.2.1 median values at baseline were 0.38, at 3rd month 0.25, and at 6th month 0.13 (Table 5.3.2.1). As shown on Table 5.3.2.2 the Friedman test confirms that p<0.01**, hence there is a statistical difference. Also when only the stable group is considered separately the same results are obtained. Wilcoxon's test shows that there is statistical difference (p<0.01) only during the 3rd month-6th month interval. However, when only the stable group is considered separately, an improvement trend is found, and statistical difference is achieved also between baseline-6th month intervals (p<0.01**) (Table 5.3.2.3).

According to the descriptive statistics (median values) the 30% difference required to achieve clinical significance within the appointments was found all intervals. These positive results provides a further confirmation on how the CHAQ system was able to record improvements in the quality of life for those JIA children who worn the FOs.

Comparison between the Control and the Trial Group (CHAQ)

As shown in Table 5.3.2.4 results highlighted that p>0.05; therefore, there was no statistical difference between the groups at baseline. In addition, at baseline when the groups were split according the medication status, equally no statistical difference was noted (p>0.05). No significance was found between the control group at Baseline-3rdmonth, 3rdmonth-6thmonth and baseline-6thmonth.On the other hand, the CHAQ scores indicate that statistical difference is found for the stable group between baseline and 6th month interval; which also is reflected the positive trend shown by the clinical significance improvement for the trial group only.

Table 5.3.2.4: details of the Mann Whitney Test carried out on CHAQ data between control and trial patients. * means p<0.05, ** means p<0.01.

CHAQ - Mann Whitney Test				
	BASELINE	**DIFFERENCE**		
		B-3rd	**3rd-6th**	**B-6th**
p-value **control: Median (IQR)** **trial: Median (IQR)**	**p=0.247** 0.125(1.31) 0.375(0.625)	**p=0.575** 0(0.128) 0.13(0.25)	**p=0.136** 0(0) 0.123(0.25)	**p=0.066** 0.125(0.125) 0.125(0.375)
Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.586** 0.13(1) 0.375(0.5)	**p=0.425** 0.12(0.125) 0.125(0.375)	**p=0.103** 0(-0.138) 0.125(0.25)	**p=0.031*** 0.125(0.125) 0.125(0.5)
Not Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.101** 0.313(1.53) 0.50(1.69)	**p=0.744** 0(0.16) 0.063(0.03)	**p=0.711** 0(0.313) 0.63(-0.44)	**p=0.924** 0(0.564) 0.125(0.281)

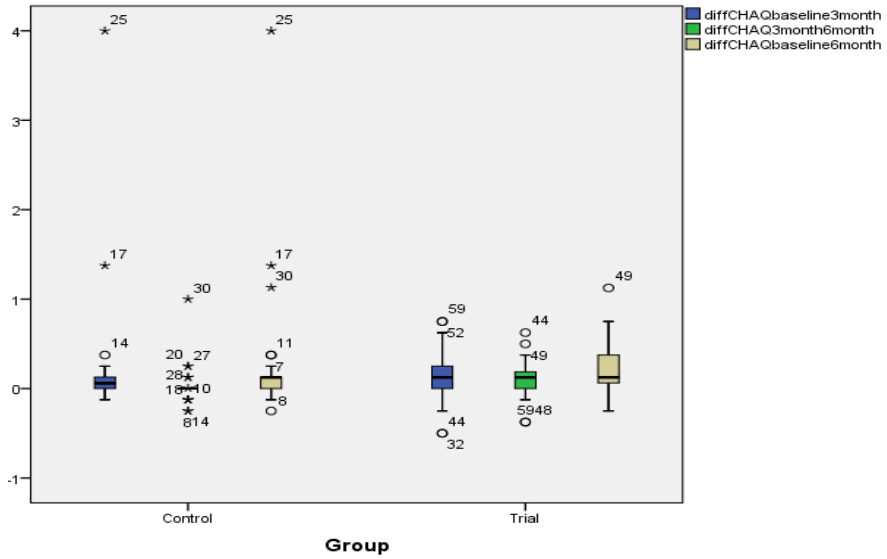


Figure 5.3.2.3: details of the Mann Whitney Test carried out on CHAQ data between control and trial patients.

5.3.3. PedsQL Paediatric Generic module (version 4.0)

Control Group (PedsQL Peadiatric Generic)

The median values at baseline were 86.10, 85 at 3rd month, and 87.10 at 6th month. It is possible to notice a stable trend of the control group data throughout the 6 months period of time (Figure 5.3.3.1, Table 5.3.3.1).

Table 5.3.3.1: : descriptive statistics on PedsQL Paediatric Generic data at baseline, 3rd month and 6th month (control and trial patients).

PedsQL Paediatric Generic (version: 4)						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median (IQR)	86.1(26.48)	85(26.8)	87.11(27.15)	77.2(28.77)	83.91(16.72)	85.22(13.44)

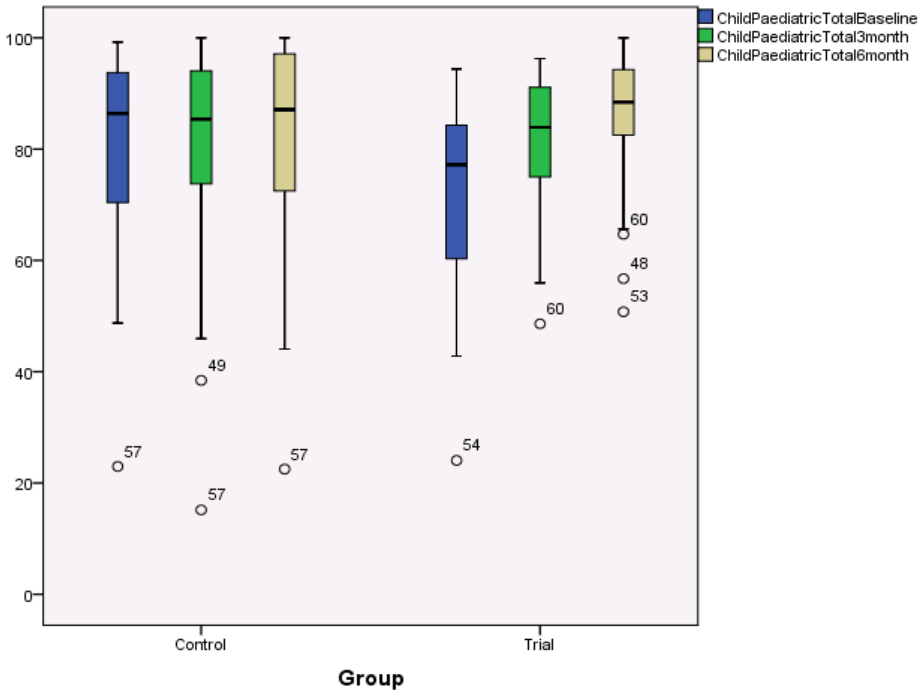


Figure 5.3.3.1: descriptive statistics on PedsQL Paediatric Generic data at baseline, 3rd month and 6th month (control and trial patients).

As shown on Table 5.3.3.2 the Friedman test indicates that p>0.05; hence there is no statistical difference within the control group. Also when the stable group is considered separately the same results are obtained.

Table 5.3.3.2: details of the Friedman test on PedsQL Paediatric Generic data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test – PedsQL Paediatric Generic (baseline, 3rd month & 6th month)		
	Control	Trial
p-value	p=0.488	p=0.000**
Stable	p=-0.486	p=0.000**
Non Stable	p=0.832	p=0.093

Table 5.3.3.3 highlights that the p>0.05 in all 3 intervals from the control group. Equally, when the stable and not-stable group is considered separately the results do not change and no statistical significance was recorded. This suggests that there were no statistical difference in PedsQL paediatric generic module in any of the intervals considered for the control group.

Table 5.3.3.3: details of the Wilcoxon's test on PedsQL Paediatric Generic data (control and trial patients). * means p<0.05, ** means p<0.01.

PedsQL Paediatric Generic - Wilcoxon's Test			
		Control	Trial
Baseline – 3rd month		p=0.503	p=0.000**
3rd month – 6th month		p=0.182	p=0.015*
Baseline – 6th month		p=0.265	p=0.000**
Stable	Baseline – 3rd month	p=0.433	p=0.003**
	3rd month – 6th month	p=0.298	p=0.009**
	Baseline – 6th month	p=0.460	p=0.000**
Not Stable	Baseline – 3rd month	p=0.799	p=0.036*
	3rd month – 6th month	p=0.374	p=0.779
	Baseline – 6th month	p=0.515	p=0.025*

Trial Group (PedsQL Peadiatric Generic)

Median values at baseline were 77.2, at 3rd month 83.91, and at 6th month 84.22 (Table 5.3.3.1). According to the descriptive statistics (median values) the 5 points difference required to achieve clinical significance within the appointments was found.

As shown on Table 5.3.3.2 the Friedman test displayed a $p<0.01^{**}$ hence there is statistical difference. Also when only the stable group is considered separately the same result is obtained. According to the results clinical significance is obtained within the baseline-3rdmonth and baseline-6thmonth.

As shown on Table 5.3.3.3 Wilcoxon's test shows that there is statistical difference during baseline-3rd month ($p<0.05^{*}$); 3rd month-6th month ($p<0.05^{*}$); and baseline-6thmonth ($p<0.01^{**}$) interval. Furthermore, when only the stable group is considered separately, statistical difference is also achieved within all intervals.

Finally, there is a clear trend that indicates the improvement of quality of life score for the trial group.

Comparison between the Control and the Trial Group (PedsQL Peadiatric Generic)

Results highlighted that at the start of the trial $p>0.05$; therefore, no statistical difference was found (Table 5.3.3.4, Figure 5.3.3.2). In addition, when the stable groups were analysed at baseline no statistical difference was noted ($p>0.05$). When the difference in score between the intervals were analysed, the trend indicated a significance difference between the groups particularly at baseline-3rdmonth and baseline-6thmonth, and clinical significance was attained for the same intervals. The same trend was attained for the stable trial group.

Table 5.3.3.4: details of the Mann Whitney Test carried out on PedsQL Paediatric Generic data. * means p<0.05, ** means p<0.01.Note that the negative values are indicative of an improvement and the positive PedsQL scores shows a reduction in the quality of life of the patient.

PedsQL Generic Paediatric - Mann Whitney Test				
	BASELINE	**DIFFERENCE**		
		B-3rd	**3rd-6th**	**B-6th**
p-value **control: Median (IQR)** **trial: Median (IQR)**	**p=0.058** 86(26.49) 77.19(28.77)	**p=0.001**** -0.31(-8.75) -5.31(-10.78)	**p=0.549** -1.33(-8.24) -1.56(-5.94)	**p=0.000**** -0.235(-4.3) -8.91(-22.18)
Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.150** 83.13(19.69) 82.19(13.59)	**p=0.004**** 0.31(-8.59) -5.31(16.25)	**p=0.537** -1.91(-8.47) -1.56(-7.81)	**p=0.003**** 0.24(-5.54) -10(-22.64)
Not Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.274** 86.57(45.12) 62.74(42.77)	**p=0.076** -2.03(-12.42) -5.17(-12.42)	**p=0.790** -0.625(-8.55) 0.7(-8.5)	**p=0.083** 0.39(-4.23) 0.53(-22.54)

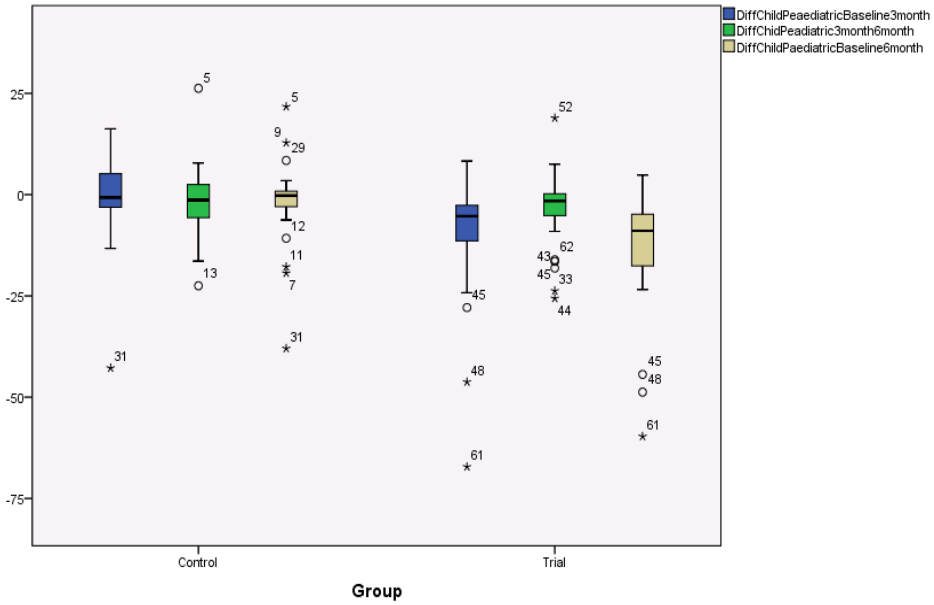


Figure 5.3.3.2: details of the Mann Whitney Test carried out on PedsQL Paediatric Generic data between control and trial patients.

5.3.4. PedsQL Paediatric Rheumatology module (version 3.0)

Control Group (PedsQL Peadiatric Rheumatology)

The median values at baseline was 78.63, 78.69 at 3rd month, and 83.63 at 6th month. It is possible to notice a stable trend by the end of 6 months (Table 5.3.4.1, Figure 5.3.4.1).

Table 5.3.4.1: descriptive statistics on PedsQL Paediatric Rheumatology data at baseline, 3rd month and 6th month (control and trial patients)

PedsQL Paediatric Rheumatology module (version 3.0)						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median(IQR)	78.63(18.65)	78.69(20.48)	83.63(27.14)	72.60(29.43)	81.72(20.49)	89.67(17.92)

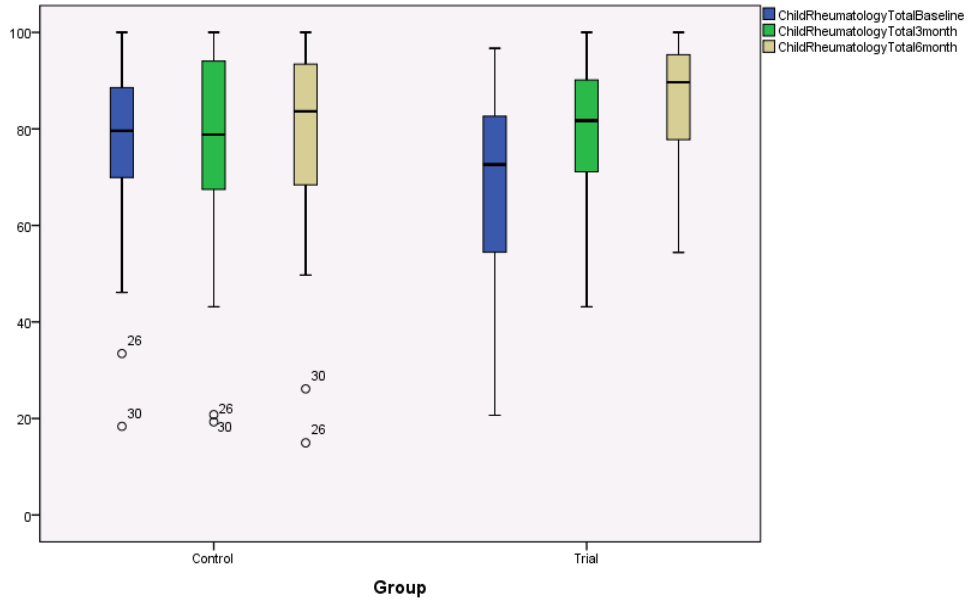


Figure 5.3.4.1: descriptive statistics on PedsQL Paediatric Rheumatology data at baseline, 3rd month and 6th month (control and trial patients).

As shown on Table 5.3.4.2 the Friedman test indicates that p>0.05; hence, there is no statistical difference within the control group. Also when only the stable group is considered separately the same results are obtained.

Table 5.3.4.2: details of the Friedman test on PedsQL Paediatric Rheumatology module data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test PedsQL Paediatric Rheumatology module (version 3.0) - (baseline, 3rd month & 6th month)		
	Control	**Trial**
p-value	**p=0.178**	**p=0.000****
Stable	**p=0.302**	**p=0.000****
Non Stable	**p=0.232**	**p=0.034***

Table 5.3.4.3 highlights that the p>0.05 in all 3 intervals for the control group. Equally, when the stable and not-stable group is considered separately the results do not change and no statistical significance was recorded. This suggests that there were no statistical difference in the PedsQL Paediatric Rheumatology module for the control group.

Table 5.3.4.3: details of the Wilcoxon's test on PedsQL Paediatric Rheumatology data (control and trial patients). * means p<0.05, ** means p<0.01.

PedsQL Paediatric Rheumatology module - Wilcoxon's Test			
		Control	**Trial**
Baseline – 3rd month		**p=0.882**	**p=0.001****
3rd month – 6th month		**p=0.276**	**p=0.007****
Baseline – 6th month		**p=0.131**	**p=0.000****
Stable	**Baseline – 3rd month**	**p=0.571**	**p=0.011***
	3rd month – 6th month	**p=0.079**	**p=0.001****
	Baseline – 6th month	**p=0.098**	**p=0.000****
Not Stable	**Baseline – 3rd month**	**p=0.646**	**p=0.025***
	3rd month – 6th month	**p=0.767**	**p=0.674**
	Baseline – 6th month	**p=0.575**	**p=0.017***

Trial Group (PedsQL Peadiatric Rheumatology)

Median values at baseline 72.60, at 3rd month 81.72 and at 6th month 89.67 (Table 5.3.4.1). According to the descriptive statistics (median values) the 5 points difference required to achieve clinical significance within the appointments was found.

As shown on Table 5.3.4.2 the Friedman test displayed a p<0.01** hence there is statistical difference within the trial group compared to the control group. Also when only the stable group is considered separately the same result is obtained. As shown on Table 5.3.4.3 Wilcoxon's test shows that there is statistical difference during baseline-3rd month (p<0.01**); 3rd month-6th month (p<0.05*); and baseline-6thmonth (p<0.01**) interval. Furthermore, when only the stable group is considered separately, statistical difference is also achieved within all intervals. Finally, a positive trend of improvement was found for the trial group and according to the results, clinical significance was obtained within the baseline-3rdmonth and baseline-6thmonth.

Comparison between the Control and the Trial Group (PedsQL Peadiatric Rheumatology)

At baseline with PedsQL Paediatric Rheumatology module, and no statistical difference was found. As shown in Table 5.3.4.4 and Figure 5.3.4.2, results highlighted that p>0.05 only between 3rdmonth-6thmonth; however, p<0.001** was found at baseline-3rdmonth and baseline-6thmonth intervalls. In addition, when the groups were split according the medication status, the same results were found (p<0.001**). The trend indicates significant difference between the groups particularly between the baseline-3rd month and baseline-6thmonths.

Table 5.3.4.4: details of the Mann Whitney Test carried out on PedsQL Paediatric Rheumatology data between control and trial patients. * means p<0.05, ** means p<0.01.

PedsQL Paediatric Rheumatology - Mann Whitney Test				
	BASELINE	**DIFFERENCE**		
		B-3rd	**3rd-6th**	**B-6th**
p-value **control: Median (IQR)** **trial: Median (IQR)**	**p=0.101** 78.63(18.65) 72.6(29.45)	**p=0.001**** 0(-0.5) 5(8)	**p=0.167** -0.18(12.77) -2.86(11.56)	**p=0.000**** -1.5(7.92) -9.05(-24.62)
Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.161** 77.69(17.39) 75.37(29.45)	**p=0.002**** -0.51(13.23) -9.11(10.17)	**p=0.189** -2.5(11.77) -7.2(14.33)	**p=0.000**** -2.27(9.09) -10.10(23.83)
Not Stable **control: Median (IQR)** **trial: Median (IQR)**	**p=0.286** 79.6(30.29) 62.71(47.06)	**p=0.183** -4.64(21.11) -9.04(21.86)	**p=0.859** 2.41(12.81) 1.07(10)	**p=0.091** -0.69(10.33) -5.6(26.37)

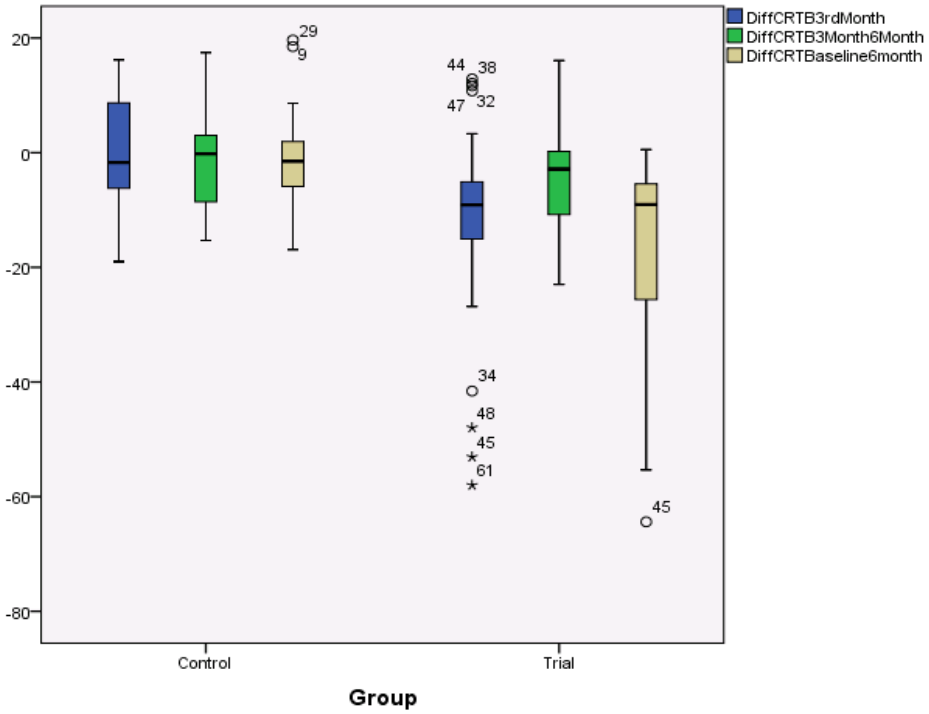


Figure 5.3.4.2: details of the Mann Whitney Test carried out on PedsQL Paediatric Rheumatology data between control and trial patients

5.3.5. PedsQL Parent Generic module (version 4.0)

Control Group (PedsQL Parent Generic)

The median values at baseline was 75, 87.81 at 3rd month, and 86.72 at 6th month. It is possible to notice an improvement within the baseline and 3rd month; however, within the 3rd month and 6th month interval for the control group, a stable trend was found (Table 5.3.5.1, Figure 5.3.5.1).

Table 5.3.5.1: descriptive statistics on PedsQL Parent Generic data at baseline, 3rd month and 6th month (control and trial patients).

PedsQL Parent Generic module (version 4.0)						
	CONTROL			**TRIAL**		
	Baseline	**3rd month**	**6th month**	**Baseline**	**3rd month**	**6th month**
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median (IQR)	75(38.05)	87.81(40.23)	86.72(33.16)	65.31(27.03)	79.85(21.88)	84.70(19.53)

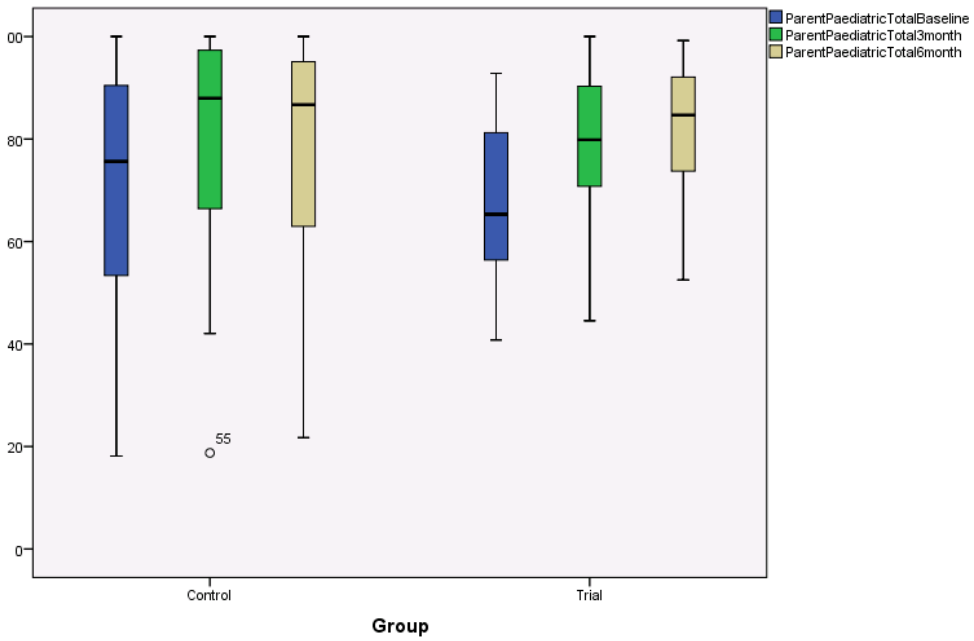


Figure 5.3.5.1: descriptive statistics on PedsQL Parent Generic data at baseline, 3rd month and 6th month (control and trial patients).

As shown on Table 5.3.5.2 the Friedman test indicate that p<0.01**; hence, there is statistical difference within the control groups. Instead, when only the stable group is considered separately the statistical significance is obtained for the stable group (p<0.01**) but not for the not-stable group (p>0.05).

Table 5.3.5.2: details of the Friedman test on PedsQL Parent Generic data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test PedsQL Parent Generic module (version 4.0) - (baseline, 3rd month & 6th month)		
	Control	**Trial**
p-value	**p=0.000****	**p=0.000****
Stable	**p=0.000****	**p=0.000****
Non Stable	**p=0.567**	**p=0.034***

Table 5.3.5.3 highlights that the p<0.05* at baseline-3rd month and baseline-6th month; in contrast, p>0.05 for the 3rdmonth-6thmonth interval for the control group. Equally, when the stable is considered separately the results did not change; therefore, the data are indicative that there was statistical difference in PedsQL Parent Generic module for the control group. On the other hand, when not stable group is analysed, a different trend appeared because all intervals appeared to be p>0.05, therefore, no statistical significance was recorded for the control group.

Table 5.3.5.3: details of the Wilcoxon's test on PedsQL Parent Generic data (control and trial patients). * means p<0.05, ** means p<0.01.

PedsQL Parent Generic module (version 4.0) - Wilcoxon's Test			
		Control	**Trial**
Baseline – 3rd month		**p=0.004****	**p=0.001****
3rd month – 6th month		**p=0.032***	**p=0.071**
Baseline – 6th month		**p=0.004****	**p=0.000****
Stable	**Baseline – 3rd month**	**p=0.002****	**p=0.004****
	3rd month – 6th month	**p=0.733**	**p=0.107**
	Baseline – 6th month	**p=0.01****	**p=0.000****
Not Stable	**Baseline – 3rd month**	**p=0.508**	**p=0.093**
	3rd month – 6th month	**p=0.263**	**p=0.400**
	Baseline – 6th month	**p=0.859**	**p=0.017***

Trial Group (PedsQL Parent Generic)

Median values at baseline were 65.31, at 3rd month 79.85, and at 6th month 84.70 (Table 5.3.5.1). According to the descriptive statistics (median values) the 5 points

difference required to achieve clinical significance within the appointments was found. As shown on Table 5.3.5.2 the Friedman test displayed a p<0.01** hence there is statistical difference within the trial group compared to the control group. Also when only the stable group is considered separately the same result was obtained. As shown on Table 5.3.5.3 Wilcoxon's test shows that there is statistical difference during baseline-3rdmonth (p<0.01**); and baseline-6thmonth (p<0.01**) interval; instead during 3rdmonth-6thmonth interval (p>0.05) which indicates no statistical difference. Furthermore, when also the stable group is considered, results remained the same. Finally, according to the results clinical significance is obtained within the baseline-3rdmonth and baselin-6thmonth. Therefore, a positive trend towards improvement was found particularly between the baseline-3rdmonth and baseline-6thmonth interval for the trial group.

Comparison between the Control and the Trial Group (PedsQL Parent Generic)

As shown in Table 5.3.5.4 at the start of the trial, results highlighted that p>0.05; therefore, there was no statistical difference. In addition, when the groups were split according the medication status, equally no statistical difference was noted (p>0.05) (Table 5.3.5.4, Figure 5.3.5.2). Overall the data show a positive trend of clinical and statistical significance difference between the groups particularly between the baseline-6th months.

Table 5.3.5.4: details of the Mann Whitney Test carried out on PedsQL Parent Generic data between control and trial patients. * means p<0.05, ** means p<0.01.

PedsQL Parent Generic module (version 4.0) - Mann Whitney Test				
	BASELINE	DIFFERENCE		
		B-3rd	3rd – 6th	B – 6th
p-value control: Median (IQR) trial: Median (IQR)	**p=0.473** 75(38.05) 65.31(27.03)	**p=0.473** -7.66(17.5) -8.75(19.85)	**p=0.053** 0.000(1.85) -3.75(5.79)	**p=0.047*** -3.91(13.29) -10.94(14.26)
Stable control: Median (IQR) trial: Median (IQR)	**p=0.622** 75(37.54) 65(18.6)	**p=1.00** -9.53(14.38) -8.90(22.65)	**p=0.145** 0.00(2.03) -3.75(5.79)	**p=0.264** -6.88(13.84) -11.69(15.61)
Not Stable control: Median (IQR) trial: Median (IQR)	**p=0.573** 77.11(44.96) 70.79(37.41)	**p=0.328** -1.88(17.42) -7.19(10.74)	**p=0.286** -0.00(3.99) -1.64(15.65)	**p=0.062** -0.16(16.83) -8.73(6.33)

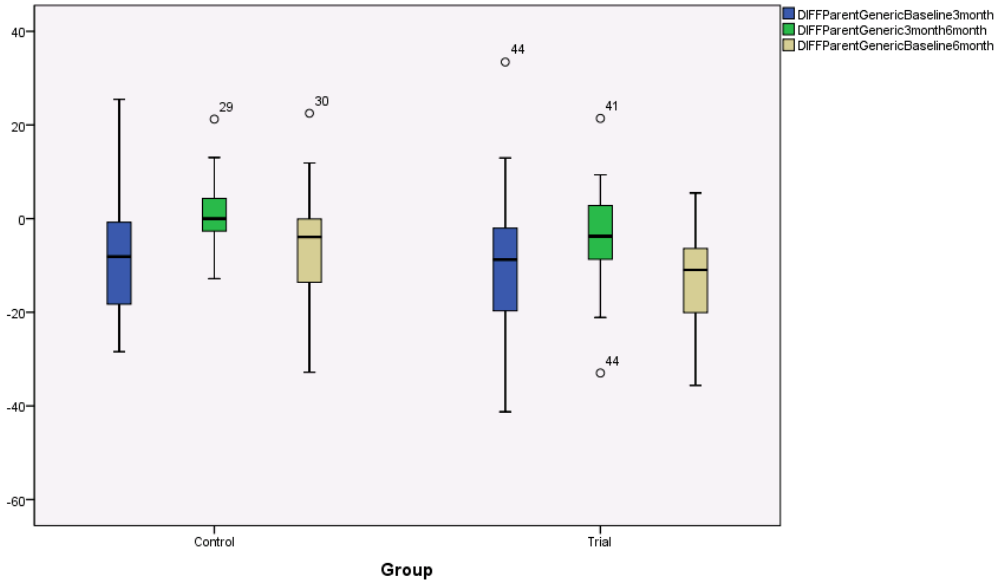


Figure 5.3.5.2: details of the Mann Whitney Test carried out on PedsQL Parent Generic data between control and trial patients

5.3.6. PedsQL Parent Rheumatology module (version 3.0)

Control Group (PedsQL Parent Rheumatology)

The median values at baseline was 78.04, 83.60 at 3rd month, and 84.47 at 6th month. It is possible to notice a stable trend by the end of the 6 months (Table 5.3.6.1, Figure 5.3.6.1).

Table 5.3.6.1: descriptive statistics on PedsQL Parent Rheumatology data at baseline, 3rd month and 6th month (control and trial patients).

PedsQL Parent Rheumatology module (version 3.0)						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median(IQR)	78.04(40.58)	83.60(34.03)	84.47(35.58)	62.52(33.89)	79.00(27.95)	83.70(31.5)

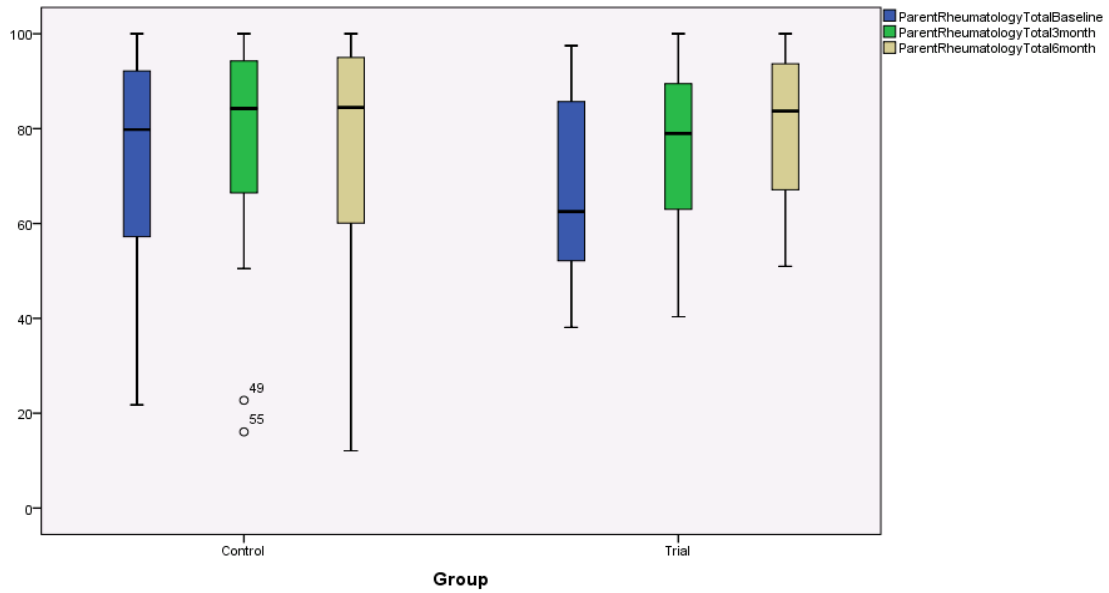


Figure 5.3.6.1: descriptive statistics on PedsQL Parent Generic data at baseline, 3rd month and 6th month (control and trial patients).

As shown on Table 5.3.6.2 the Friedman test indicates that p>0.05, hence there is no statistical difference within the control group. Equally, when only the stable and the not-stable group is considered separately, statistical significance is not achieved (p>0.05).

Table 5.3.6.2: details of the Friedman test on PedsQL Parent Rheumatology data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test PedsQL Parent Rheumatology (version 3.0) - (baseline, 3rd month & 6th month)		
	Control	**Trial**
p-value	**p=0.081**	**p=0.000****
Stable	**p=0.133**	**p=0.000****
Non Stable	**p=0.387**	**p=0.368**

Table 5.3.6.3 highlights that the p<0.05* only at baseline-3rd month interval. On the other hand, 3rdmonth-6thmonth and baseline-6th month did not prove to be statistically different (p>0.05). Equally, when the stable group is considered separately the results did not change; instead, when the stable group is analysed all intervals appeared to be p>0.05, therefore, no statistical significance was recorded for the control group.

Table 5.3.6.3: details of the Wilcoxon's test on PedsQL Parent Rheumatology data (control and trial patients). * means p<0.05, ** means p<0.01.

PedsQL Parent Rheumatology module (version 3.0) - Wilcoxon's Test			
		Control	**Trial**
Baseline – 3rd month		**p=0.019***	**p=0.002****
3rd month – 6th month		**p=0.738**	**p=0.044***
Baseline – 6th month		**p=0.064**	**p=0.000****
Stable	**Baseline – 3rd month**	**p=0.035***	**p=0.04***
	3rd month – 6th month	**p=0.433**	**p=0.046***
	Baseline – 6th month	**p=0.068**	**p=0.000****
Not Stable	**Baseline – 3rd month**	**p=0.333**	**p=0.327**
	3rd month – 6th month	**p=0.515**	**p=0.499**
	Baseline – 6th month	**p=0.575**	**p=0.069**

5.4.6.2 Trial Group (PedsQL Parent Rheumatology)

Median values at baseline were 62.52, at 3rd month 79.00, and at 6th month 83.70 (Table 5.3.6.1). According to the descriptive statistics (median values) the 5 points difference required to achieve clinical significance within the appointments were found.

As shown on Table 5.3.6.2 the Friedman test displayed a p<0.01** hence there is statistical difference within the trial group. Also when only the stable group is considered separately the same result was obtained. As shown on Table 5.3.6.3 Wilcoxon's test shows that there is statistical difference during baseline-3rdmonth (p<0.05*), 3rdmonth-6thmonth and within baseline-6thmonth (p<0.01**) intervals. When the trial-stable group was considered, statistical difference was attained across the all intervals (baseline-3rdmonth, p<0.05*; 3rdmonth-6thmonth, p<0.05*; baseline-6thmonth, p<0.01**). Finally, according to the results clinical significance is obtained within the baseline-3rdmonth and baseline-6thmonth. Therefore, the trend that emerged from data analysis, indicate a progressive improvement of the PedsQL Parent Rheumatology module over the 6 months for the trial group.

5.4.6.3 Comparison between the Control and the Trial Group (PedsQL Parent Rheumatology)

As shown in Table 5.3.6.4 at the start of the trial, results highlighted that p>0.05; therefore there was no statistical difference. In addition, at baseline when the groups were split according to the medication status, equally no statistical difference was noted (p>0.05). Statistical significance was obtained between the groups at baseline-6thmonth interval, also for the stable medication group. Finally, the trend also shows that clinical significance was found with a greater improvement in scores for the trial group at the baseline-6thmonth comparison.

Table 5.3.6.4: details of the Mann Whitney Test carried out on PedsQL Parent Rheumatology data between control and trial patients. * means p<0.05, ** means p<0.01.

PedsQL Parent Rheumatology module (version 4.0) - Mann Whitney Test				
	BASELINE	DIFFERENCE		
		B-3rd	3rd – 6th	B – 6th
p-value control: Median (IQR) trial: Median (IQR)	**p=0.371** 78.04(40.57) 62.52(33.89)	**p=0.124** -2.08(13.98) -7.6(17.74)	**p=0.137** 0.00(7.52) -1.51(9.57)	**p=0.020*** -1.48(16.47) -11.37(14.5)
Stable control: Median (IQR) trial: Median (IQR)	**p=0.318** 81.55(43.49) 62.52(32.86)	**p=0.136** -1.00(13.53) -7.84(20.62)	**p=0.258** 0.00(8.57) -1.51(6.67)	**p=0.040*** -3.24(14.93) -13.93(21.54)
Not Stable control: Median (IQR) trial: Median (IQR)	**p=0.722** 65.46(41.67) 59.07(45.52)	**p=0.594** -2.17(11.63) -2.81(13.83)	**p=0.351** 0.96(11.98) -2.56(15.82)	**p=0.722** 1.28(15.86) -8.93(16.35)

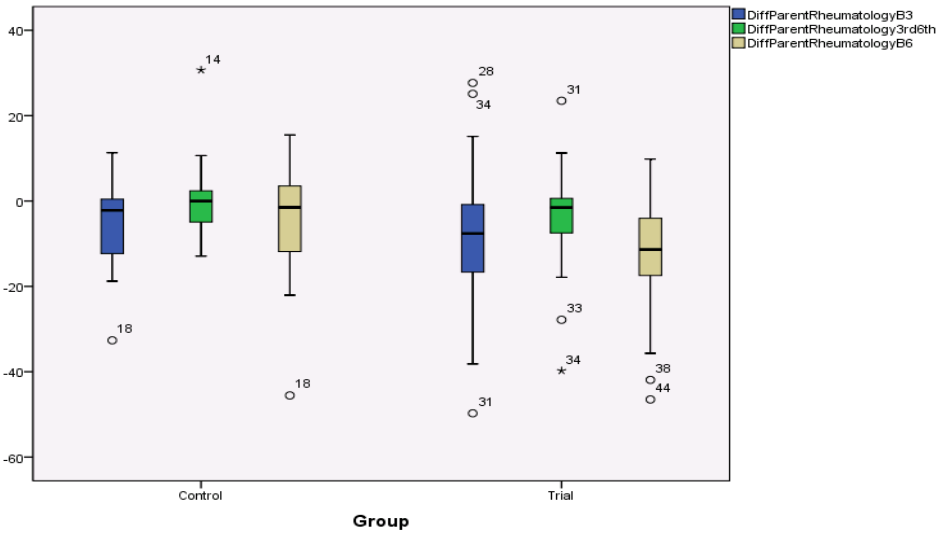


Figure 5.3.6.2: box plot of the Mann Whitney Test carried out on the difference of PedsQL Parent Rheumatology data between control and trial patients.

5.3.7. Summary of Primary Outcomes

In order to allow the reader to have a clear understanding of the primary outcome results presented in the previous chapters, a summary of the major findings obtained with regards to the 'Pain' and 'Quality of Life Questionnaire' are displayed in table 5.3.6.5.

Table 5.3.7.1: this concise table shows the primary outcome results comparison between the trial and the control group (baseline-3rdmonth; 3rdmonth-6thmonth; baseline-6thmonth). Green background indicates that statistical significant difference was obtained (* means p<0.05; ** means p<0.01; p<0.001 means p=0.000). Red background shows that statistical significant difference was not obtained (p>0.05).

Primary Outcome Results comparison between groups (Mann Whitney U-Test)			
	Baseline - 3rdmonth	**3rdmonth – 6thmonth**	**Baseline – 6thmonth**
VAS	**p=0.03***	**p=0.002****	**p=0.029***
stable	**p=0.145**	**p=0.002****	**p=0.025***
CHAQ	**p=0.575**	**p=0.136**	**p=0.066**
stable	**p=0.425**	**p=0.103**	**p=0.031***
PedsQL child rheumatology	**p=0.001****	**p=0.167**	**p<0.001**
Stable	**p=0.002****	**p=0.189**	**p<0.001**
PedsQL child generic	**p=0.001****	**p=0.0549**	**p<0.001**
stable	**p=0.004****	**p=0.537**	**p=0.003****
PedsQL parent rheumatology	**p=0.124**	**p=0.137**	**p=0.020***
stable	**p=0.136**	**p=0.258**	**p=0.040***
PedsQL parent generic	**p=0.473**	**p=0.053**	**p=0.047***
stable	**p=0.100**	**p=0.145**	**p=0.264**

5.4. Gait Analysis

In this chapter the following anagrams related to specific parameters will be used:

- Peak Pressure (identifies a specific area where there is the highest amount of pressure) – peak pressure versus time = (-PP). It can also be defined as the average value of the maximum pressure from each step recorded over the analysed foot region.
- Pressure Time Integral (relationship between the amount of pressure that is applied throughout a period of time) = (-PTI). It is also defined as the amount of load maintained through a specific area over the time taken to complete a particular phase of gait.

5.4.1. Gait Time (sec)

Control Group (Gait Time)

According to the descriptive statistics within the control group there was only 1 missing recording at 6th month due to patient D9 that did not complete the last data collection appointment. Hence, the same missing data will not be found in all other parameters investigated as secondary outcomes.

Table 5.4.1.1: descriptive statistics on Gait Time data at baseline, 3rd month and 6th month (control and trial patients)

Gait Time (sec)						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median (IQR)	1.11(0.33)	1.13(0.47)	1.11(0.54)	1.17(0.32)	1.17(0.34)	1.04(0.27)

Data are NOT parametric; therefore, Friedman's test was carried out. Data were split to allow comparison within the control and the trial groups. These gait time data are, paired and 3 groups (baseline, 3rd month, 6th month) were tested. As shown on Table 5.4.1.2 the Friedman test shows that $p>0.05$, therefore, no significance difference is

obtained within the control group. Also when only the stable group is considered separately the same results are obtained. It is possible to notice a stable trend over a period of 6 months.

Table 5.4.1.2: details of the Friedman test on Gait time data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test - Gait time (sec) - (baseline, 3rd month & 6th month)		
	Control	Trial
p-value	p=0.623	p=0.019*
Stable	p=0.646	p=0.025*
Non Stable	p=0.926	p=0.607

Furthermore, gait time data were compared within two intervals each time (baseline with 3rd month; 3rd month with 6th month; and baseline with 6 month). As data are not parametric and paired, Wilcoxon's test was carried out. Table 5.4.1.3 highlighted that the p>0.05 in all 3 intervals for the control group. Equally, when the stable and not-stable group is considered separately the results did not change and no statistical significance was recorded.

Table 5.4.1.3: details of the Wilcoxon's test on Gait Time data (control and trial patients). * means p<0.05, ** means p<0.01.

Gait Time (sec) - Wilcoxon's Test			
		Control	Trial
Baseline – 3rd month		p=0.917	p=0.877
3rd month – 6th month		p=0.761	p=0.005**
Baseline – 6th month		p=0.487	p=0.006**
Stable	Baseline – 3rd month	p=0.811	p=0.638
	3rd month – 6th month	p=0.670	p=0.009**
	Baseline – 6th month	p=0.420	p=0.012*
Not Stable	Baseline – 3rd month	p=0.799	p=0.674
	3rd month – 6th month	p=0.767	p=0.362
	Baseline – 6th month	p=0.878	p=0.293

Trial Group (Gait time)

As shown on Table 5.4.1.1 the descriptive statistics within the trial group all appointments were carried out over the whole duration of the trial, and no missing data was recorded (Table 5.4.1.1). As shown on Table 5.4.1.2 the Friedman test displayed a $p<0.05$*, hence there is statistical difference within the trial group compared to the control group. Also when only the stable group is considered separately the same result is obtained. In addition, data were compared within two time intervals (baseline with 3rd month; 3rd month with 6th month; and baseline with 6 month). As data are not parametric and paired, Wilcoxon's test was carried out. As shown on Table 5.4.1.3 Wilcoxon's test shows that there is no statistical difference during baseline-3rd month ($p>0.05$); on the other hand, significant difference was detected at 3rd month-6th month ($p<0.05$*); and baseline-6thmonth ($p<0.05$*) interval. Furthermore, when only the stable group was considered separately, the same results were obtained. Finally, it appears that there is a positive trend for the gait time of the trial group only.

Comparison between the Control and the Trial Group (Gait time)

According to the Shapiro-Wilks Test $p<0.05$* hence data are not parametric for both control and trial group at baseline,3rd month and 6th month. Mann Whitney Test was carried out in order to test statistical difference between the control and trial group at baseline at the start of the trial. As shown in Table 5.4.1.4 results highlighted that $p>0.05$; therefore there was no statistical difference. In addition, when the groups were split according the statibility status, equally the same trend was found and no statistical difference was noted ($p>0.05$).

The same statistical test used to investigate secondary outcomes, will be carried out for all other parameters.

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Table 5.4.1.4: details of the Mann Whitney Test carried out on Gait Time data between control and trial patients. * means p<0.05, ** means p<0.01.

Gait Time (sec) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
p-value	p=0.391	p=0.615	p=0.902
Stable	p=0.810	p=0.742	p=0.060
Not stable	p=0.274	p=0.203	p=0.929

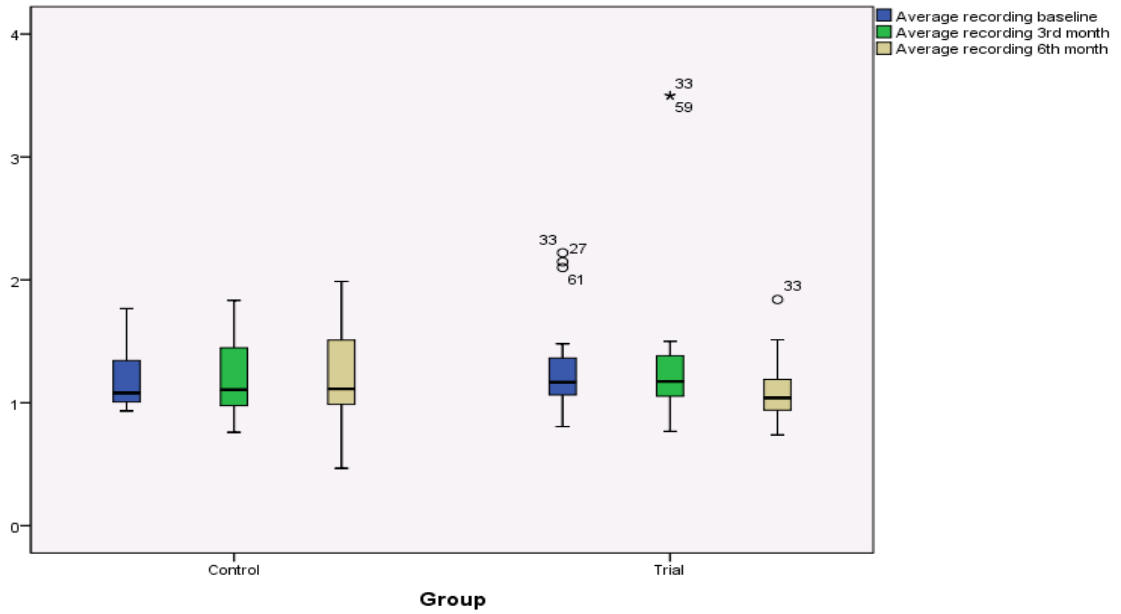


Figure 5.4.1.1: boxplot carried out on Gait Time average data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.2. Gait Velocity (cm/sec)

Control Group (Gait Velocity)

According to Table 5.4.2.1 it is possible to notice a stable trend for the velocity median values over the 6 months for the control group.

Table 5.4.2.1: descriptive statistics on Gait Velocity data at baseline, 3rd month and 6th month (control and trial patients)

Gait Velocity (cm/sec)						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	29	29	28	31	31	31
Missing	0	0	1	0	0	0
Median (IQR)	114.77(22.22)	114.6(22.22)	117.87(24.4)	111.43(12.04)	108.1(24.76)	116.9(19.7)

As shown on Table 5.4.2.2 the Friedman test shows that p>0.05, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained.

Table 5.4.2.2: details of the Friedman test on Gait Velocity data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test Gait Velocity (cm/sec) - (baseline, 3rd month & 6th month)		
	Control	Trial
p-value	p=0.565	p=0.62
Stable	p=0.607	p=0.265
Non Stable	p=0.905	p=0.008**

Table 5.4.2.3 highlighted that the p>0.05 in all 3 intervals for the control group. Equally, when the stable and not-stable group is considered separately the results did not change and no statistical significance was recorded.

Table 5.4.2.3: details of the Wilcoxon's test on Gait Velocity data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Gait Velocity (cm/sec) - Wilcoxon's Test			
		Control	**Trial**
Baseline – 3rd month		**p=0.510**	**p=0.769**
3rd month – 6th month		**p=0.194**	**p=0.006****
Baseline – 6th month		**p=0.716**	**p=0.004****
Stable	**Baseline – 3rd month**	**p=0.748**	**p=0.523**
	3rd month – 6th month	**p=0.170**	**p=0.136**
	Baseline – 6th month	**p=0.420**	**p=0.007****
Not Stable	**Baseline – 3rd month**	**p=0.445**	**p=0.123**
	3rd month – 6th month	**p=0.721**	**p=0.012***
	Baseline – 6th month	**p=0.575**	**p=0.263**

Trial Group (Gait Velocity)

Median values at baseline were 111.43, at 3rd month 108.10, and at 6th month 116.90 (Table 5.4.2.1). As shown on Table 5.4.2.2 the Friedman test displayed a p>0.05 hence there is no statistical difference within the trial group compared to the control group. Also when only the stable group is considered separately the same result is obtained. However, within the non-stable group significance difference was found (p<0.05*). As shown on Table 5.4.2.3 Wilcoxon's test shows that there is no statistical difference during baseline-3rd month (p>0.05). In contrast a sharp increase of velocity occurred within the 3rd month-6th month (p<0.05*); and baseline-6thmonth (p<0.05*) interval. These values indicate an improvement of walking velocity within the JIA children that were wearing the FOs although the recording was carried out barefoot on the HR-Walkway. Furthermore, when only the stable group was considered separately, results showed a significance difference within the baseline-6thmonth interval (p<0.05*). Therefore there is a positive trend indicating the faster walking speed within the trial JIA patients only by 6 months.

Comparison between the Control and the Trial Group (Gait Velocity)

As shown in Table 5.4.2.4 at the start of the trial results highlighted that p>0.05; therefore, there was no statistical difference. In addition, when the groups were split according the medication status, the same trend were highlighted and equally no statistical difference was noted (p>0.05) between the groups.

Table 5.4.2.4: details of the Mann Whitney Test carried out on Gait Velocity data between control and trial patients. * means p<0.05, ** means p<0.01.

Gait Velocity (cm/sec) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
p-value	**p=0.129**	**p=0.464**	**p=0.832**
Stable	**p=0.456**	**p=0.587**	**p=0.511**
Not stable	**p=0.101**	**p=0.021**	**p=0.408**

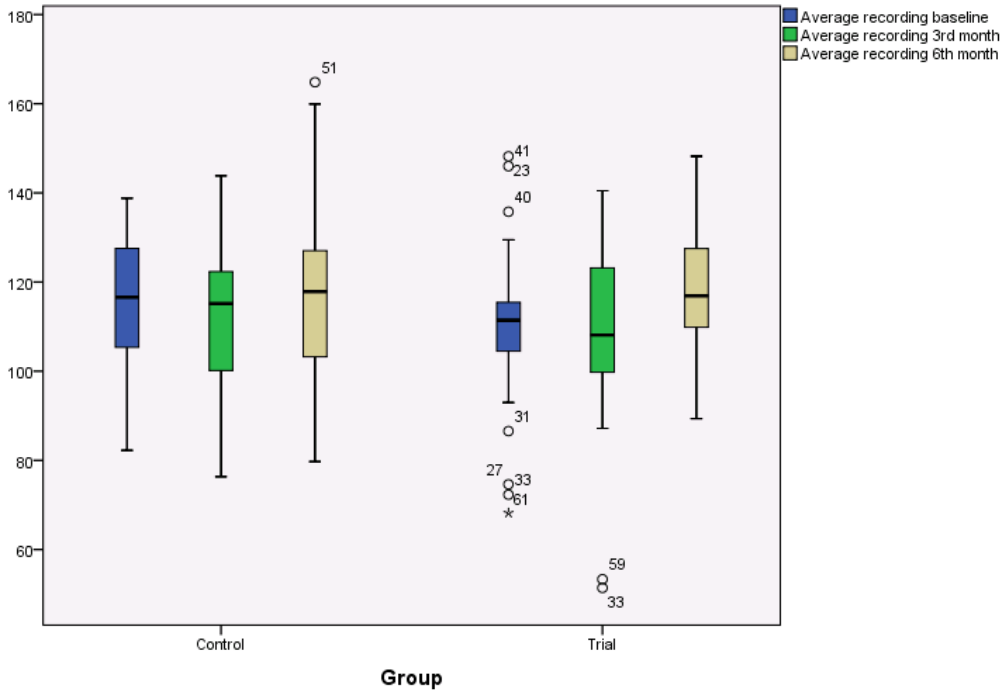


Figure 5.4.2.1: boxplot carried out on Velocity average data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.3. Stance Time (sec)

Control Group (Stance Time)

The median values at baseline was 0.60, 0.60 at 3rd month, and 0.61 at 6th month, It is possible to notice a stable trend for the control group throughout the 6 months (Table 5.4.3.1).

Table 5.4.3.1: descriptive statistics on Stance Time data at baseline, 3rd month and 6th month (control and trial patients).

Stance Time (sec)						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	0.6(0.08)	0.6(0.09)	0.6(0.1)	0.6(0.11)	0.6(0.01)	0.58(0.09)

As shown on Table 5.4.3.2 the Friedman test shows that p>0.05, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained.

Table 5.4.3.2: details of the Friedman test on Stance Time data at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Friedman Test - Stance Time (sec) - (baseline, 3rd month & 6th month)		
	Control	Trial
p-value	p=0.60	p=0.049*
Stable	p=0.993	p=0.041*
Non Stable	p=0.208	p=0.350

Table 5.4.3.3 highlighted that the p>0.05 in all 3 intervals for the control group. Equally, when the stable and not-stable group is considered separately the results did not change and no statistical significance was recorded.

Table 5.4.3.3: details of the Wilcoxon's test on Stance Time data (control and trial patients). * means p<0.05, ** means p<0.01.

Stance Time (sec) - Wilcoxon's Test			
		Control	**Trial**
Baseline – 3rd month		**p=0.297**	**p=0.173**
3rd month – 6th month		**p=0.612**	**p=0.469**
Baseline – 6th month		**p=0.132**	**p=0.005****
Stable	**Baseline – 3rd month**	**p=0.82**	**p=0.078**
	3rd month – 6th month	**p=0.922**	**p=0.753**
	Baseline – 6th month	**p=0.844**	**p=0.002****
Not Stable	**Baseline – 3rd month**	**p=0.144**	**p=0.691**
	3rd month – 6th month	**p=0.295**	**p=0.306**
	Baseline – 6th month	**p=0.033***	**p=0.776**

Trial Group (Stance Time)

Median values at baseline were 0.60, at 3rd month 0.60, and at 6th month 0.58 (Table 5.4.3.1). As shown on (Table 5.4.3.2) the Friedman test displayed a p<0.05* hence there is statistical difference within the trial group compared to the control group. Also when only the stable group is considered separately the same result is obtained. However, within the non-stable group significance difference was not found (p>0.05).

As shown on (Table 5.4.3.3) Wilcoxon's test shows that there is no statistical difference during baseline-3rd month (p>0.05) and 3rdmonth-6thmonth (p>0.05); in contrast, significance difference was found within baseline-6thmonth (p<0.05*) interval. Furthermore, when only the stable group was considered separately, results confirmed the same results in favour of the trial group (p<0.05*). Finally there is a positive trend for the trial group, particularly highlighted for the baseline-6thmonth interval.

Comparison between the Control and the Trial Group (Stance Time)

As shown in Table 5.4.3.4 at the start of the trial, results highlighted that p>0.05; therefore there was no statistical difference. In addition, when the groups were split according the statibility status, equally no statistical difference was noted (p>0.05)

(Table 5.4.3.4). It is possible to notice a fairly stable trend when data are compared between the groups. However, particularly for the non-stable group, statistical significance is attained; and there is a clear tendency towards significance difference also for the stable group (p=0.055) by the end of 6 months. Potentially if data were collected again after 9 months, statistical significance might have been achieved between the groups.

Table 5.4.3.4: details of the Mann Whitney Test carried out on Stance Time data between control and trial patients. * means p<0.05, ** means p<0.01.

Stance Time (sec) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
p-value	**p=0.193**	**p=0.941**	**p=0.168**
Stable	**p=0.925**	**p=0.217**	**p=0.055**
Not stable	**p=0.025***	**p=0.04***	**p=0.048***

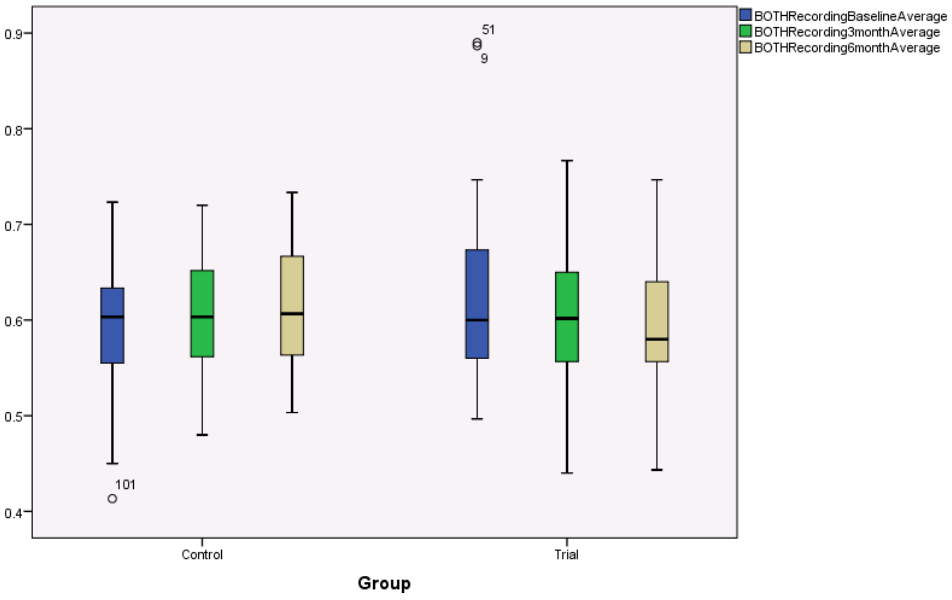


Figure 5.4.3.1: boxplot carried out on Stance Time average data between control and trial patients at baseline, 3rd month and 6th month interval

5.4.4. Total Contact

Total - Peak Pressure Values - (t-PP)

Control Group (t-PP)

With regards to F-scan (shod): median value at baseline was 456.83, 534.67 at 3rd month, and 561.50 at 6th month (Table 5.4.4.1).

Table 5.4.4.1: descriptive statistics on Total – PP (F-Scan shod) data at baseline, 3rd month and 6th month (control and trial patients).

Total – Peak Pressure Values (t-PP) - F-Scan-Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	456.83(308.91)	534.67(391.17)	561.5(291.08)	498.33(390.75)	514.5(383.33)	569.67(443.66)

With regards to F-scan With Insole: median value at baseline was 498, 501.33 at 3rd month, and 518.83 at 6th month (Table 5.4.4.2).

Table 5.4.4.2: descriptive statistics on Total – PP (F-scan with insole) data at baseline, 3rd month and 6th month (control and trial patients)

Total – Peak Pressure Values (t-PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	498(367.58)	501.33(299.91)	518.33(337)	341.33(286.59)	335.83(261.92)	339.67(273.5)

With regards to HR Walkway: median value at baseline was 461.50, 453.67 at 3rd month, and 491 at 6th month (Table 5.4.43). Overall, it is possible to notice a stable trend for the control group over the 6 months period of time.

Table 5.4.4.3: descriptive statistics on Total – PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Total – Peak Pressure Values (t-PP) - HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	461.5(190.84)	453.67(184.91)	491(262)	452.83(235.84)	448.83(230.5)	436.83(210.09)

Friedman test shows that most p>0.05, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. The only p<0.05* was found from the F-scan-Barefoot (also for the not stable group) (Table 5.4.4.4).

Table 5.4.4.4: details of the Friedman test on Total – PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Total - Peak Pressure Values (t-PP)-Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.033	p=0.584
Stable	p=0.411	p=0.438
Not stable	p=0.026*	p=0.444
F-Scan – With Insoles	p=0.140	p=0.026*
Stable	p=0.378	p=0.337
Not stable	p=0.350	p=0.013*
HR Walkway	p=0.943	p=0.258
Stable	p=0.697	p=0.754
Not stable	p=0.610	p=0.144

Table 5.4.4.5 highlighted that all intervals are not significantly different for the control group (p>0.05). Equally, when the stable group is considered separately the results showed p>0.05, therefore, no statistical significance was recorded. The only p<0.05* was found from not-stable group of the F-scan-Barefoot & With Insole for baseline-3rdmonth interval; and for the stable group of HR Walkway baseline-3rdmonth only (p<0.05*). This suggests that there were no statistical difference in the t-PP for the control group (Table 5.4.4.5).

Table 5.4.4.5: details of the Wilcoxon's test on Total-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Total - Peak Pressure Values (t-PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan - Shod			
Baseline – 3rd month		**p=0.009****	**p=0.345**
3rd month – 6th month		**p=0.448**	**p=0.406**
Baseline – 6th month		**p=0.091**	**p=0.127**
Stable	Baseline – 3rd month	**p=0.249**	**p=0.942**
	3rd month – 6th month	**p=0.863**	**p=0.064**
	Baseline – 6th month	**p=0.145**	**p=0.157**
Not Stable	Baseline – 3rd month	**p=0.337**	**p=0.056**
	3rd month – 6th month	**p=0.337**	**p=0.109**
	Baseline – 6th month	**p=0.337**	**p=0.679**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.172**	**p=0.126**
3rd month – 6th month		**p=0.552**	**p=0.986**
Baseline – 6th month		**p=0.100**	**p=0.249**
Stable	Baseline – 3rd month	**p=0.271**	**p=0.596**
	3rd month – 6th month	**p=0.802**	**p=0.806**
	Baseline – 6th month	**p=0.432**	**p=0.569**
Not Stable	Baseline – 3rd month	**p=0.391**	**p=0.011***
	3rd month – 6th month	**p=0.502**	**p=0.712**
	Baseline – 6th month	**p=0.100**	**p=0.121**
HR Walkway			
Baseline – 3rd month		**p=0.748**	**p=0.236**
3rd month – 6th month		**p=0.407**	**p=0.459**
Baseline – 6th month		**p=0.259**	**p=0.713**
Stable	Baseline – 3rd month	**p=0.307**	**p=0.952**
	3rd month – 6th month	**p=0.777**	**p=0.650**
	Baseline – 6th month	**p=0.535**	**p=0.926**
Not Stable	Baseline – 3rd month	**p=0.263**	**p=0.035***
	3rd month – 6th month	**p=0.171**	**p=0.535**
	Baseline – 6th month	**p=0.279**	**p=0.352**

Trial Group (t-PP)

As shown on Table 5.4.4.1, the descriptive statistics within the trial group of the F-scan (shod), the median values at baseline were 498.33, at 3rd month 514.50, and at 6th

month 569.67 (Table 5.4.4.1). With regards to F-scan with insole, descriptive statistics showed: median values at baseline were 341.33, at 3rd month 335.83, and at 6th month 337.67 (Table 5.4.4.2). With regards to HR Walkway, descriptive statistics showed: median values at baseline were 452.83, at 3rd month 448.83, and at 6th month 436.83 (Table 5.4.4.3).

As shown on Table 5.4.4.4 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. A statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$).

As shown on Table 5.4.4.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$). It is possible to notice a stable trend for the t-PP for the within the trial group data over the 6 months.

Comparison between the Control and the Trial Group (t-PP)

As shown in Table 5.4.4.6 results highlighted that $p<0.05$* between control and trial patient when investigation were carried out with the F-scan while wearing the insole. In addition, no statistical difference was noted ($p>0.05$) with the F-Scan at barefoot and with HR Walkway ($p>0.05$). This suggests that there is a clear trend towards changes that happens between the control and the trial group only when t-PP data are compared with the F-Scan with insole, indicating the positive effect that FOs may have on JIA total plantar pressure.

Table 5.4.4.6: details of the Mann Whitney Test carried out on Total-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Total - Peak Pressure Values (t-PP) -Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.183	p=0.927	p=0.411
Stable	p=0.253	p=0.515	p=0.313
Not stable	p=0.203	p=0.311	p=0.093
F-Scan – With Insoles	p=0.090	p=0.000**	p=0.001**
Stable	p=0.222	p=0.011*	p=0.026*
Not stable	p=0.223	p=0.01**	p=0.004**
HR Walkway	p=0.958	p=0.610	p=0.622
Stable	p=0.836	p=0.811	p=0.598
Not stable	p=0.610	p=0.104	p=0.08

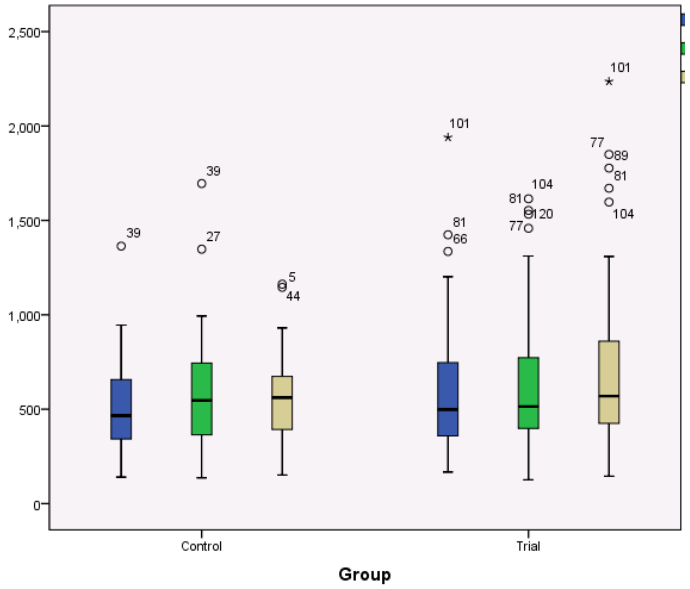


Figure 5.4.4.1: boxplot carried out on F-Scan Shod - Total PP data between control and trial patients at baseline (blue), 3rd month (green) and 6th month (yellow).

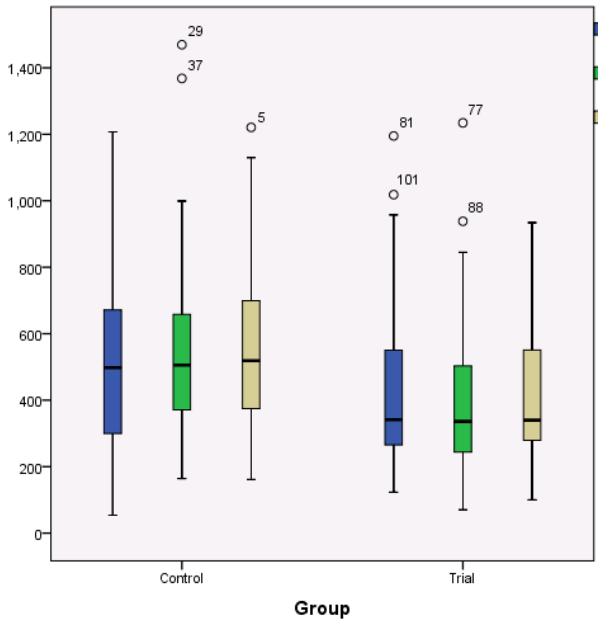


Figure 5.4.4.2: boxplot carried out on F-Scan with insole - Total PP data between control and trial patients at baseline, 3rd month and 6th month interval

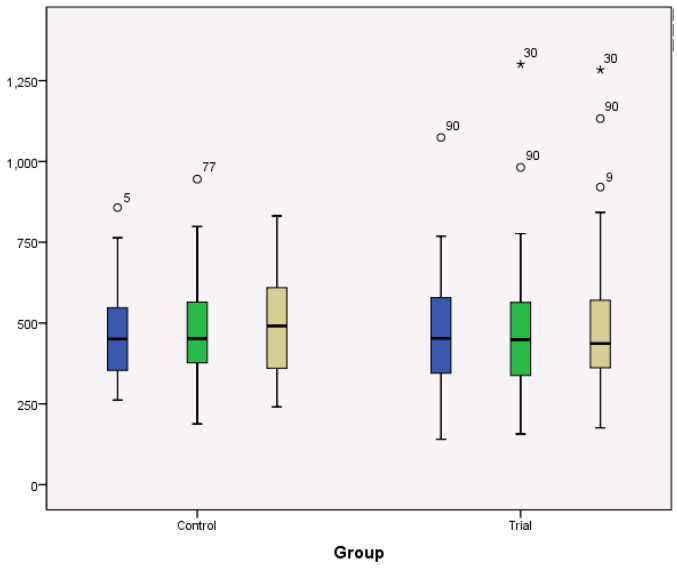


Figure 5.4.4.3: boxplot carried out on HR Walkway - Total PP data between control and trial patients at baseline, 3rd month and 6th month interval

Total - Pressure Time Integral (t-PTI)

Control Group (t-PTI)

With regards to F-scan shod: median value at baseline was 80.72, 98.72 at 3rd month and 89.80 at 6th month (Table 5.4.4.7).

Table 5.4.4.7: descriptive statistics on Total – PTI (F-Scan-shod) data at baseline, 3rd month and 6th month (control and trial patients).

Total - Pressure Time Integral - (t-PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	80.72(59.07)	98.72(47.91)	89.80(44.17)	87(64.33)	81.59(68.88)	89.54(55.42)

With regards to F-scan With Insole: median value at baseline was 73.88(166.10), 90.94(134.74) at 3rd month, and 85.50(139.03) at 6th month (Table 5.4.4.8).

Table 5.4.4.8: descriptive statistics on Total – PTI (F-Scan-with insole) data at baseline, 3rd month and 6th month (control and trial patients).

Total - Pressure Time Integral - (t-PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	73.38(58.5)	90.94(48.03)	85.50(55.95)	67.66(50.46)	61.91(44.23)	71.75(53.22)

With regards to HR Walkway the median value at baseline was 58.78, 54.82 at 3rd month, and 87.28 at 6th month (Table 5.4.4.9). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.4.9: descriptive statistics on Total – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Total - Pressure Time Integral - (t-PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	58.78(18.01)	54.82(17.11)	57.28(19.12)	55.06(24.88)	56.78(26.83)	53.66(24.41)

As shown on (Table 5.4.4.10) the Friedman test shows p>0.05 in all cases, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. The only p<0.05* was found from the HR Walkway, also when stable group was considered separately. Hence, a stable trend over the period of 6 months was noted particularly with the F-Scan equipment.

Table 5.4.4.10: details of the Friedman test on Total –PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rdmonth and 6thmonth (control and trial patients). * means p<0.05, ** means p<0.01.

Total - Pressure Time Integral - (t-PTI) - Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.067	p=0.824
Stable	p=0.358	p=0.859
Not stable	p=0.116	p=0.210
F-Scan – With Insoles	p=0.143	p=0.926
Stable	p=0.205	p=0.844
Not stable	p=0.449	p=0.269
HR Walkway	p=0.048*	p=0.668
Stable	p=0.920	p=0.859
Not stable	p=0.000**	p=0.646

Table 5.4.4.11 highlighted that all intervals are not significantly different (p>0.05). Equally, when the stable group is considered separately the results showed p>0.05, therefore, no statistical significance was recorded with F-scan shod, F-scan with insole and HR Walkway system for the control group.

Table 5.4.4.11: details of the Wilcoxon's test on Total-PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Total - Pressure Time Integral - (t-PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan - Shod			
Baseline – 3rd month		**p=0.086**	**p=0.364**
3rd month – 6th month		**p=0.993**	**p=0.535**
Baseline – 6th month		**p=0.131**	**p=0.158**
Stable	Baseline – 3rd month	**p=0.215**	**p=0.797**
	3rd month – 6th month	**p=0.850**	**p=0.441**
	Baseline – 6th month	**p=0.371**	**p=0.474**
Not Stable	Baseline – 3rd month	**p=0.263**	**p=0.163**
	3rd month – 6th month	**p=0.737**	**p=0.642**
	Baseline – 6th month	**p=0.167**	**p=0.148**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.160**	**p=0.930**
3rd month – 6th month		**p=0.935**	**p=0.311**
Baseline – 6th month		**p=0.234**	**p=0.229**
Stable	Baseline – 3rd month	**p=0.162**	**p=0.756**
	3rd month – 6th month	**p=0.470**	**p=0.650**
	Baseline – 6th month	**p=0.388**	**p=0.312**
Not Stable	Baseline – 3rd month	**p=0.737**	**p=0.717**
	3rd month – 6th month	**p=0.204**	**p=0.088**
	Baseline – 6th month	**p=0.411**	**p=0.569**
HR Walkway			
Baseline – 3rd month		**p=0.055**	**p=0.682**
3rd month – 6th month		**p=0.052**	**p=0.572**
Baseline – 6th month		**p=0.250**	**p=0.952**
Stable	Baseline – 3rd month	**p=0.528**	**p=0.866**
	3rd month – 6th month	**p=0.975**	**p=0.797**
	Baseline – 6th month	**p=0.950**	**p=0.488**
Not Stable	Baseline – 3rd month	**p=0.028**	**p=0.278**
	3rd month – 6th month	**p=0.000****	**p=0.121**
	Baseline – 6th month	**p=0.017***	**p=0.215**

Trial Group (t-PTI)

As shown on Table 5.4.4.7 within the trial group of the F-scan shod median value at baseline was 87, 81.59 at 3rd month, and 89.54 at 6th month (Table 5.4.4.7). The F-scan with insole, median value at baseline was 67.66, 61.91 at 3rd month, and 71.75 at 6th month (Table 5.4.4.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 55.06, 56.78 at 3rd month and 53.66 at 6th month (Table 5.4.4.9).

As shown on Table 5.4.4.10 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$).

As shown on Table 5.4.4.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$).

Comparison between the Control and the Trial Group (t-PTI)

As shown in Table 5.4.4.12 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at 3rd month ($p<0.01$**) and 6th month ($p<0.05$*). In addition, no statistical difference was noted ($p>0.05$) with the F-Scan at barefoot and with HR Walkway ($p>0.05$). This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to t-PTI when the FOs are used particularly at 3rd month and 6th month intervals.

Table 5.4.4.12: details of the Mann Whitney Test carried out on Total-PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Total - Pressure Time Integral - (t-PTI) -Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.532	p=0.306	p=0.923
Stable	p=0.332	p=0.590	p=0.637
Not stable	p=0.545	p=0.324	p=0.373
F-Scan – With Insoles	p=0.098	p=0.000**	p=0.028**
Stable	p=0.178	p=0.003**	p=0.137
Not stable	p=0.0220	p=0.018*	p=0.03*
HR Walkway	p=0.416	p=0.838	p=0.354
Stable	p=0.355	p=0.879	p=0.674
Not stable	p=0.799	p=0.924	p=0.181

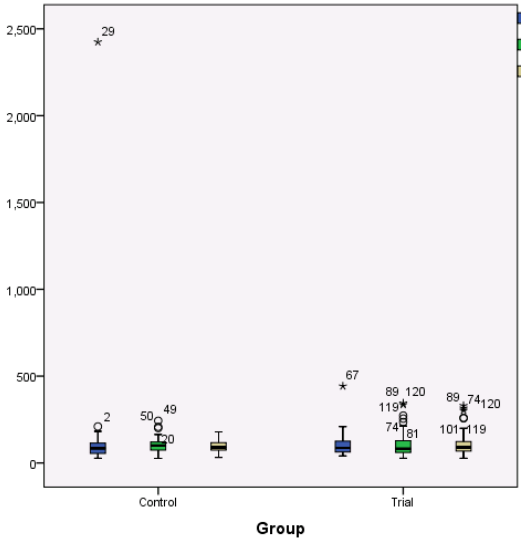


Figure 5.4.4.4: boxplot carried out on F-Scan Shod - Total PTI data between control and trial patients at baseline, 3rd month and 6th month.

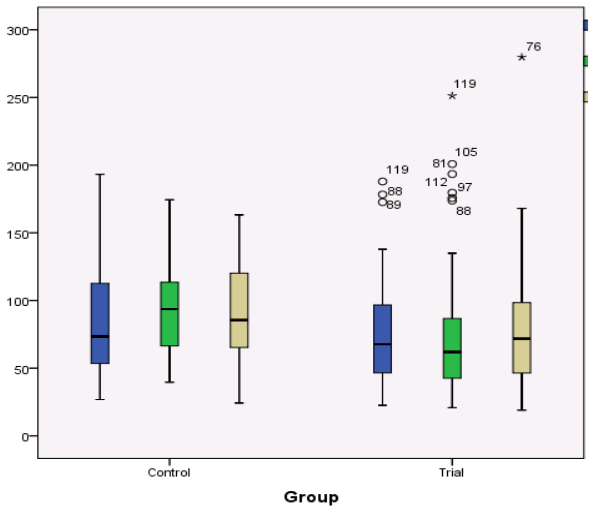


Figure 5.4.4.5: boxplot carried out on F-Scan with insole - Total PTI data between control and trial patients at baseline, 3rd month and 6th month interval

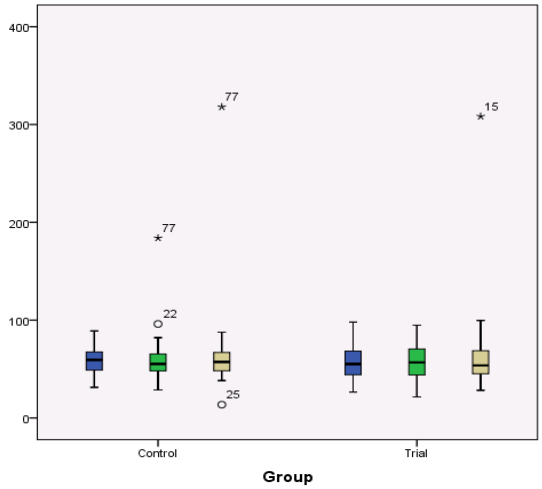


Figure 5.4.4.6: boxplot carried out on HR Walkway – Total PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.5. Heel Contact

Control Group (h-PP)

With regards to F-scan shod: median value at baseline was 386.83, 386.33 at 3rd month and 353.50 at 6th month. It is possible to notice a stable trend over the period of 6 months for the control group (Table 5.4.5.1).

Table 5.4.5.1:descriptive statistics on Heel – PP (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Heel – Peak Pressure Values - (hPP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	386.83(191.17)	386.33(219.58)	353.50(237.91)	333.83(290.67)	373.83(300.42)	371.33(291.84)

With regards to F-scan with Insole: median value at baseline was 355.17, 375.67 at 3rd month, and 350.17 at 6th month (Table 5.4.5.2).

Table 5.4.5.2: descriptive statistics on Heel– PP (F-Scan with insole) data at baseline, 3rd month and 6th month (control and trial patients).

Heel – Peak Pressure Values - (hPP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	355.17(220)	375.67(202.17)	350.17(221.08)	202.50(204.41)	252.33(142.33)	229.67(151.25)

With regards to HR Walkway the median value at baseline was 349, 367.73 at 3rd month and 366.50 at 6th month (Table 5.4.5.3). It is possible to notice a stable trend over the period of 6 months for the h-PP using the in-shoe and barefoot equipment for the control group.

Table 5.4.5.3:descriptive statistics on Heel– PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients)

Heel – Peak Pressure Values - (hPP)– HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	349(143.91)	367.73(137.67)	366.50(150.41)	378.83(180.92)	345.67(154)	359(147.58)

On Table 5.4.5.4 Friedman test shows $p>0.05$ in all cases, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. It is possible to notice a stable trend over the period of 6 months.

Table 5.4.5.4: details of the Friedman test on Heel – PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Heel – Peak Pressure Values - (hPP)–- Friedman Test (baseline, 3rd month & 6th month)		
	Control	**Trial**
F-Scan - Shod	**p=0.592**	**p=0.972**
Stable	**p=0.863**	**p=0.761**
Not stable	**p=0.549**	**p=0.646**
F-Scan – With Insoles	**p=0.482**	**p=0.972**
Stable	**p=0.313**	**p=0.165**
Not stable	**p=0.100**	**p=0.717**
HR Walkway	**p=0.107**	**p=0.781**
Stable	**p=0.068**	**p=0.510**
Not stable	**p=0.110**	**p=0.740**

Table 5.4.5.5 highlighted that all intervals are not significantly different for the control group (p>0.05). Equally, when the stable group is considered separately the results showed p>0.05, therefore, no statistical significance was recorded with F-scan shod, F-scan with insole and HR Walkway system for the control group.

Table 5.4.5.5: details of the Wilcoxon's test on Heel-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Heel – Peak Pressure Values - (hPP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.294**	**p=0.797**
3rd month – 6th month		**p=0.616**	**p=0.360**
Baseline – 6th month		**p=0.308**	**p=0.766**
Stable	Baseline – 3rd month	**p=0.690**	**p=0.935**
	3rd month – 6th month	**p=0.962**	**p=0.261**
	Baseline – 6th month	**p=0.783**	**p=0.416**
Not Stable	Baseline – 3rd month	**p=0.247**	**p=0.438**
	3rd month – 6th month	**p=0.478**	**p=0.959**
	Baseline – 6th month	**p=0.167**	**p=0.379**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.583**	**p=0.625**
3rd month – 6th month		**p=0.585**	**p=0.933**
Baseline – 6th month		**p=0.636**	**p=0.733**
Stable	Baseline – 3rd month	**p=0.583**	**p=0.810**
	3rd month – 6th month	**p=0.397**	**p=0.883**
	Baseline – 6th month	**p=0.467**	**p=0.731**
Not Stable	Baseline – 3rd month	**p=0.940**	**p=0.532**
	3rd month – 6th month	**p=0.852**	**p=0.918**
	Baseline – 6th month	**p=0.926**	**p=0.918**
HR Walkway			
Baseline – 3rd month		**p=0.693**	**p=0.343**
3rd month – 6th month		**p=0.233**	**p=0.182**
Baseline – 6th month		**p=0.278**	**p=0.743**
Stable	Baseline – 3rd month	**p=0.133**	**p=0.258**
	3rd month – 6th month	**p=0.789**	**p=0.159**
	Baseline – 6th month	**p=0.278**	**p=0.743**
Not Stable	Baseline – 3rd month	**p=0.126**	**p=0.865**
	3rd month – 6th month	**p=0.053**	**p=0.836**
	Baseline – 6th month	**p=0.575**	**p=0.642**

Trial Group (h-PP)

As shown on Table 5.4.5.1 within the trial group of the F-scan shod median value at baseline was 333.83, 373.83 at 3rd month, and 371.33 at 6th month (Table 5.4.5.1).

With regards to F-scan with insole, the median value at baseline was 202.50, 252.33 at 3rd month, and 229.67 at 6th month (Table 5.4.5.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 378.83, 345.67 at 3rd month and 359 at 6th month (Table 5.4.5.3). It is possible to notice a stable trend over the period of 6 months for the trial group with all equipment used.

As shown on (Table 5.4.5.4) the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$).

As shown on (Table 5.4.5.5) Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all intervals considered with the stable-groups ($p>0.05$). Hence a stable trend over the period of 6 months for the trial group was attained.

Comparison between the Control and the Trial Group (h-PP)

As shown in Table 5.4.5.6 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at baseline ($p<0.01$**), 3rd month ($p<0.01$**), and 6th month ($p<0.01$**). In addition, statistical difference was noted also when the stable group was considered separately. Interestinlgy no statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$). This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to h-PP at baseline, 3rd month and 6th month only when FOs were introduced in the JIA shoes.

Table 5.4.5.6: details of the Mann Whitney Test carried out on Heel-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Heel – Peak Pressure Values - (hPP) -Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.848	p=0.638	p=0.728
Stable	p=0.857	p=0.911	p=0.823
Not stable	p=0.504	p=0.373	p=0.408
F-Scan – With Insoles	p=0.000**	p=0.000**	p=0.000**
Stable	p=0.001**	p=0.001**	p=0.002**
Not stable	p=0.005**	p=0.001**	p=0.002**
HR Walkway	p=0.898	p=0.272	p=0.676
Stable	p=0.098	p=0.914	p=0.258
Not stable	p=0.036	p=0.075	p=0.022*

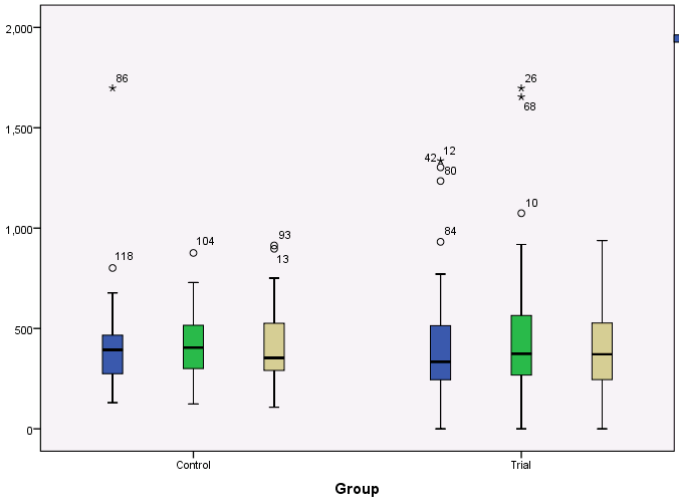


Figure 5.4.5.1: boxplot carried out on F-Scan Shod – Heel - PP data between control and trial patients at baseline, 3rd month and 6th month.

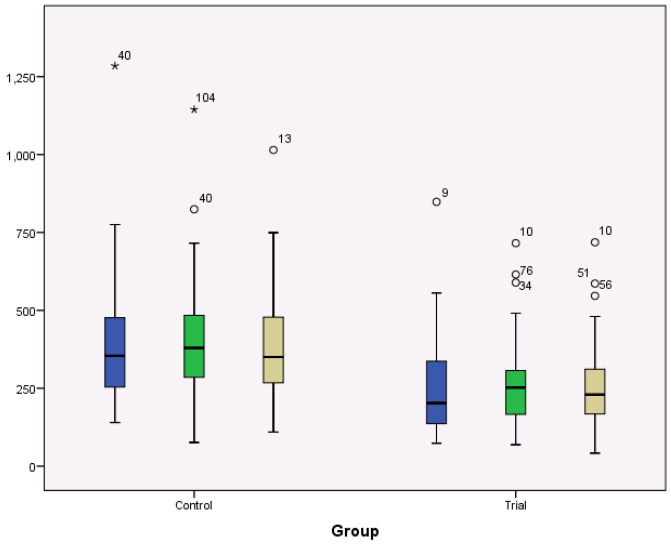


Figure 5.4.5.2: boxplot carried out on F-Scan with insole - Heel PP data between control and trial patients at baseline, 3rd month and 6th month interval.

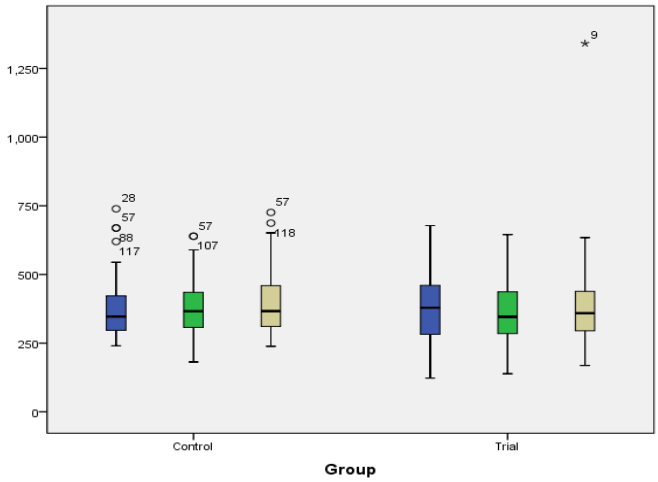


Figure 5.4.5.3: boxplot carried out on HR Walkway - Heel PP data between control and trial patients at baseline, 3rd month and 6th month interval.

Heel - Pressure Time Integral - (h-PTI)

Control Group (h-PTI)

With regards to F-scan shod: median value at baseline was 51.18, 63.86 at 3rd month and 49.70 at 6th month (Table 5.4.5.7).

Table 5.4.5.7: descriptive statistics on Heel – PTI (F-Scan shod) data at baseline, 3rd month and 6th month (control and trial patients)

Heel – Pressure Time Integral (h-PTI) - F-Scan Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	51.18(42.43)	63.86(38.53)	49.70(32.87)	59.8(39.87)	58.33(38.99)	51.09(36.07)

With regards to F-scan With Insole: median value at baseline was 53.76, 63.30 at 3rd month, and 54.16 at 6th month (Table 5.4.5.8).

Table 5.4.5.8: descriptive statistics on Heel – PTI (With Insole) data at baseline, 3rd month and 6th month (control and trial patients)

Heel – Pressure Time Integral - (h-PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	53.76(41.51)	63.30(39.59)	54.16(33.52)	38.67(43.16)	40.14(30.86)	36.51(32.16)

With regards to HR Walkway the median value at baseline was 34.42, 35.10 at 3rd month and 34.60 at 6th month (Table 5.4.5.9). It is possible to notice a stable trend over the period of 6 months for the control group with all the equipment used.

Table 5.4.5.9: descriptive statistics on Heel – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Heel – Pressure Time Integral (h-PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	34.42	35.10	34.60	34.49(19.04)	35.31(20.17)	33.14(15.58)

As shown on Table 5.4.5.10 the Friedman test shows $p>0.05$ in all cases, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. Hence, a stable trend appeared to be recorded over the 6 months period of time for the control group.

Table 5.4.5.10: details of the Friedman test on Heel – PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Heel – Pressure Time Integral (h PTI) – Friedman Test (baseline, 3rd month & 6th month)		
	Control	**Trial**
F-Scan - Shod	**p=0.325**	**p=0.454**
Stable	**p=0.256**	**p=0.290**
Not stable	**p=0.247**	**p=0.939**
F-Scan – With Insoles	**p=0.049***	**p=0.461**
Stable	**p=0.058**	**p=0.196**
Not stable	**p=0.165**	**p=0.829**
HR Walkway	**p=0.313**	**p=0.607**
Stable	**p=0.973**	**p=0.457**
Not stable	**p=0.079**	**p=0.068**

Table 5.4.5.11 highlighted that all intervals are not significantly different (p>0.05). Equally, when the stable group is considered separately the results showed p>0.05, therefore, no statistical significance was recorded with F-scan shod, F-scan with insole and HR Walkway system. In all intervals, a stable trend for the h-PTI seemed to be found using the Tekscan equipment.

Table 5.4.5.11: details of the Wilcoxon's test on Heel-PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Heel – Pressure Time Integral (h-PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.270**	**p=0.549**
3rd month – 6th month		**p=0.054**	**p=0.358**
Baseline – 6th month		**p=0.304**	**p=0.154**
Stable	Baseline – 3rd month	**p=0.902**	**p=0.604**
	3rd month – 6th month	**p=0.192**	**p=0.232**
	Baseline – 6th month	**p=0.099**	**p=0.188**
Not Stable	Baseline – 3rd month	**p=0.062**	**p=0.836**
	3rd month – 6th month	**p=0.167**	**p=0.796**
	Baseline – 6th month	**p=0.654**	**p=0.605**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.151**	**p=0.563**
3rd month – 6th month		**p=0.032***	**p=0.451**
Baseline – 6th month		**p=0.590**	**p=0.542**
Stable	Baseline – 3rd month	**p=0.470**	**p=0.679**
	3rd month – 6th month	**p=0.029***	**p=0.391**
	Baseline – 6th month	**p=0.369**	**p=0.397**
Not Stable	Baseline – 3rd month	**p=0.100**	**p=0.679**
	3rd month – 6th month	**p=0.478**	**p=0.1**
	Baseline – 6th month	**p=0.709**	**p=0.756**
HR Walkway			
Baseline – 3rd month		**p=0.464**	**p=0.744**
3rd month – 6th month		**p=0.384**	**p=0.434**
Baseline – 6th month		**p=0.3**	**p=0.554**
Stable	Baseline – 3rd month	**p=0.971**	**p=0.181**
	3rd month – 6th month	**p=0.850**	**p=0.857**
	Baseline – 6th month	**p=0.937**	**p=0.236**
Not Stable	Baseline – 3rd month	**p=0.135**	**p=0.049***
	3rd month – 6th month	**p=0.077**	**p=0.234**
	Baseline – 6th month	**p=0.048***	**p=0.379**

Trial Group (h-PTI)

As shown on Table 5.4.5.7 within the trial group of the F-scan shod median value at baseline was 59.80, 58.33 at 3rd month, and 51.09 at 6th month (Table 5.4.5.7). With

regards to F-scan with insole, the median value at baseline was 38.67, 40.14 at 3rd month, and 36.51 at 6th month (Table 5.4.5.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 34.49, 35.31 at 3rd month and 33.14 at 6th month (Table 5.4.5.9). It is possible to notice a quite stable trend over the period of 6 months for the trial group h-PTI.

As shown on Table 5.4.5.10 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$). As shown on Table 5.4.5.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$). It is possible to notice a stable trend over the period of 6 months for the trial group.

Comparison between the Control and the Trial Group (h-PTI)

As shown in Table 5.4.5.12 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at baseline ($p<0.05$*), 3rd month ($p<0.01$**), and 6th month ($p<0.05$*). In addition, statistical difference was noted also when the stable group was considered separately on the 3rd month-6thmonth interval. No statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$). These data suggest that there is a clear trend toward changes that happen between the control and the trial group with regards to h-PTI at baseline, 3rd month and 6th month only when FOs were worn.

Table 5.4.5.12: details of the Mann Whitney Test carried out on Heel-PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Heel – Presurre Integral (h-PTI) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.103**	**p=0.103**	**p=0.103**
Stable	**p=0.103**	**p=0.103**	**p=0.103**
Not stable	**p=0.103**	**p=0.103**	**p=0.103**
F-Scan – With Insoles	**p=0.026***	**p=0.006****	**p=0.028***
Stable	**p=0.123**	**p=0.021***	**p=0.438**
Not stable	**p=0.567**	**p=0.171**	**p=0.464**
HR Walkway	**p=0.646**	**p=0.649**	**p=0.276**
Stable	**p=0.939**	**p=0.541**	**p=0.823**
Not stable	**p=0.265**	**p=0.1**	**p=0.024**

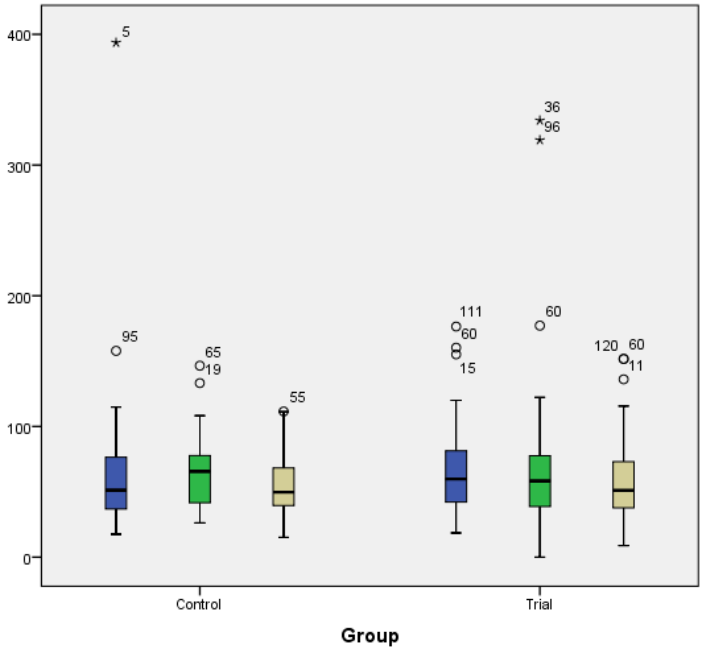


Figure 5.4.5.4: boxplot carried out on F-Scan Shod - Heel PTI data between control and trial patients at baseline, 3rd month and 6th month.

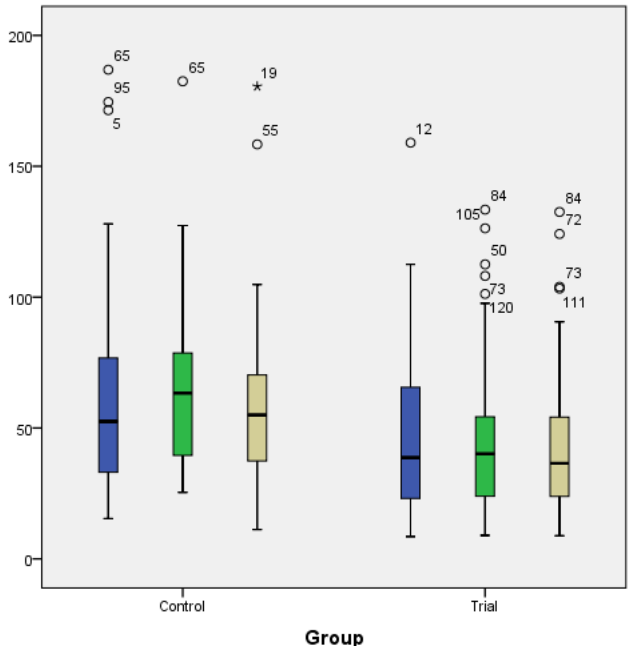


Figure 5.4.5.5: boxplot carried out on F-Scan with insole - Heel PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

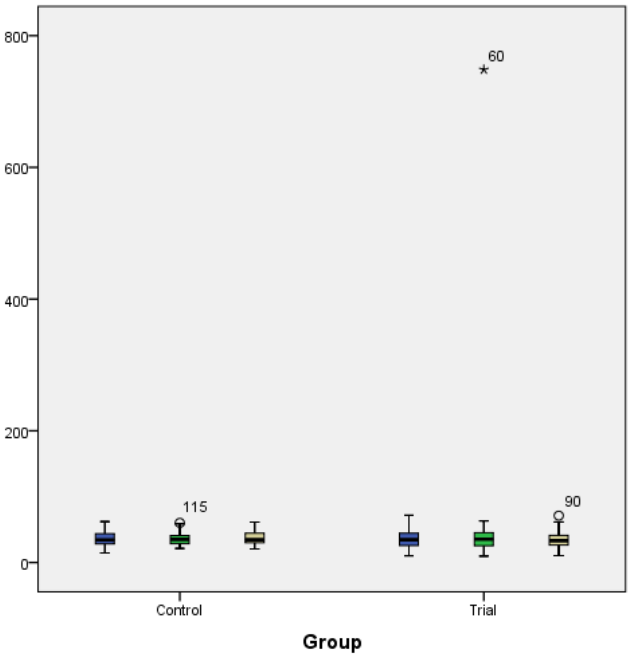


Figure 5.4.5.6: boxplot carried out on HR Walkway – Heel PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.6. Midfoot – contact

Midfoot - Peak Pressure Values- (m-PP)

Control Group (m-PP)

With regards to F-scan shod: median value at baseline was 108.33, 99.33 at 3rd month and 90.83 at 6th month.

Table 5.4.6.1: descriptive statistics on Midfoot – PP (F-Scan shod) data at baseline, 3rd month and 6th month (control and trial patients).

Midfoot – Peak Pressure Values - (m-PP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	108.33(85.75)	99.33(89.83)	90.83(122.75)	93.67(85.09)	106.67(108.33)	112(114.17)

With regards to F-scan With Insole: median value at baseline was 98.5, 99.83 at 3rd month, and 111.50 at 6th month (Table 5.4.6.2).

Table 5.4.6.2: descriptive statistics on Midfoot – PP (F-Scan-With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Midfoot – Peak Pressure Values - (m-PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	98.5(106.33)	99.83(130.75)	111.5(123.17)	126.5(100.42)	139.83(130.33)	142(96.75)

With regards to HR Walkway the median value at baseline was 88.50, 84.50 at 3rd month and 86.67 at 6th month (Table 5.4.6.3). It is possible to notice a stable trend over the period of 6 months with some reduction of m-PP values particularly for the F-Scan (shod) for the control group (Table 5.4.6.1).

Table 5.4.6.3: descriptive statistics on Midfoot – PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients)

Midfoot – Peak Pressure Values - (m-PP)– HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	88.5(52.05)	84.5(55.41)	86.67(52.59)	77(59.83)	81.5(62.58)	73.5(59.17)

As shown on Table 5.4.6.4 the Friedman test shows p>0.05 in all cases; therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained.

Table 5.4.6.4: details of the Friedman test on Midfoot – PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Midfoot – Peak Pressure Values - (m-PP) Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.376	p=0.266
Stable	p=0.067	p=0.147
Not stable	p=0.731	p=0.087
F-Scan – With Insoles	p=0.343	p=0.972
Stable	p=0.010*	p=0.751
Not stable	p=0.204	p=0.229
HR Walkway	p=0.188	p=0.072
Stable	p=0.368	p=0.114
Not stable	p=0.462	p=0.444

Table 5.4.6.5 highlighted that all intervals are not significantly different (p>0.05). Equally, when the stable group is considered separately the results showed p>0.05, therefore, no statistical significance was recorded with F-scan shod, F-scan with insole and HR Walkway system. This suggests that there is no statistical difference in m-PP for the control group.

Table 5.4.6.5: details of the Wilcoxon's test on Midfoot- PP data with F-Scan shod , F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Midfoot – Peak Pressure Values - (mPP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.978**	**p=0.633**
3rd month – 6th month		**p=0.341**	**p=0.361**
Baseline – 6th month		**p=0.446**	**p=0.056**
Stable	Baseline – 3rd month	**p=0.453**	**p=0.116**
	3rd month – 6th month	**p=0.027**	**p=0.707**
	Baseline – 6th month	**p=0.199**	**p=0.022**
Not Stable	Baseline – 3rd month	**p=0.255**	**p=0.205**
	3rd month – 6th month	**p=0.124**	**p=0.408**
	Baseline – 6th month	**p=0.629**	**p=0.958**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.698**	**p=0.464**
3rd month – 6th month		**p=0.478**	**p=0.980**
Baseline – 6th month		**p=0.682**	**p=0.624**
Stable	Baseline – 3rd month	**p=0.074**	**p=0.140**
	3rd month – 6th month	**p=0.131**	**p=0.604**
	Baseline – 6th month	**p=0.581**	**p=0.477**
Not Stable	Baseline – 3rd month	**p=0.088**	**p=0.473**
	3rd month – 6th month	**p=0.210**	**p=0.438**
	Baseline – 6th month	**p=0.981**	**p=0.717**
HR Walkway			
Baseline – 3rd month		**p=0.123**	**p=0.443**
3rd month – 6th month		**p=0.288**	**p=0.017***
Baseline – 6th month		**p=0.851**	**p=0.355**
Stable	Baseline – 3rd month	**p=0.232**	**p=0.419**
	3rd month – 6th month	**p=0.724**	**p=0.027***
	Baseline – 6th month	**p=0.950**	**p=0.391**
Not Stable	Baseline – 3rd month	**p=0.322**	**p=0.796**
	3rd month – 6th month	**p=0.212**	**p=0.352**
	Baseline – 6th month	**p=0.985**	**p=0.756**

Trial Group (m-PP)

Table 5.4.6.1 within the trial group of the F-scan shod median value at baseline was 93.67, 106.67 at 3rd month, and 112 at 6th month (Table 5.4.6.1). With regards to F-scan

with insole median value at baseline was 126.50, 139.83 at 3rd month, and 142 at 6th month (Table 5.4.6.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 77, 81.50 at 3rd month and 73.50 at 6th month (Table 5.4.6.3). Hence, it is possible to notice a quite stable trend over the period of 6 months for the F-scan (shod) and HR Walkway, however, descriptive statistics indicated an increase of m-PP with the F-Scan (with insole) data were collected (Table 5.4.6.1).

As shown on Table 5.4.6.4, the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$).

As shown on Table 5.4.6.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all intervals considered with the stable-groups ($p>0.05$). It is possible to observe a stable trend within the trial group when the equipment was adopted for investigation over the period of 6 months (Table 5.4.6.1).

Comparison between the Control and the Trial Group (m-PP)

As shown in Table 5.4.6.6 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at baseline ($p<0.01$**), 3rd month ($p<0.01$**), and 6th month ($p<0.01$**). In addition, statistical difference was noted also when the stable group was considered separately. Interestinlgy, no statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$). These data are indicative of the significant peak pressure changes that occur at the midfoot only when the FOs are introduced in the JIA shoes (Table 5.4.6.6).

Table 5.4.6.6: details of the Mann Whitney Test carried out on Midfoot-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Midfoot – Peak Pressure Values - (mPP) -Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.803**	**p=0.438**	**p=0.267**
Stable	**p=0.818**	**p=0.502**	**p=0.184**
Not stable	**p=0.726**	**p=0.702**	**p=0.861**
F-Scan – With Insoles	**p=0.013***	**p=0.017***	**p=0.044***
Stable	**p=0.004****	**p=0.009****	**p=0.006****
Not stable	**p=0.962**	**p=0.949**	**p=0.524**
HR Walkway	**p=0.316**	**p=0.614**	**p=0.292**
Stable	**p=0.624**	**p=0.362**	**p=0.466**
Not stable	**p=0.390**	**p=0.667**	**p=0.545**

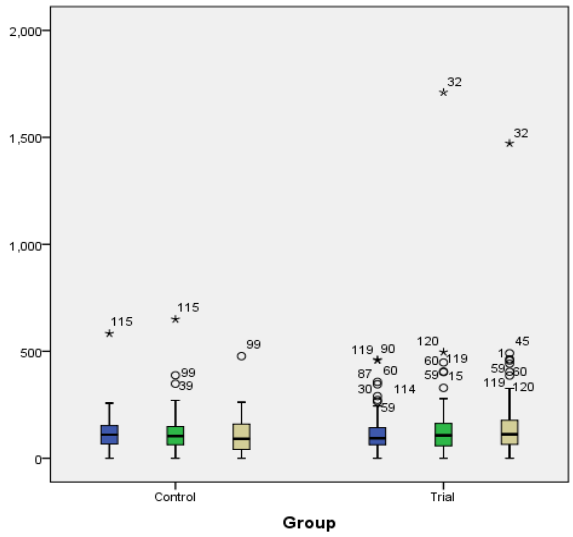


Figure 5.4.6.1: boxplot carried out on F-Scan Shod - Midfoot PP data between control and trial patients at baseline, 3rd month and 6th month.

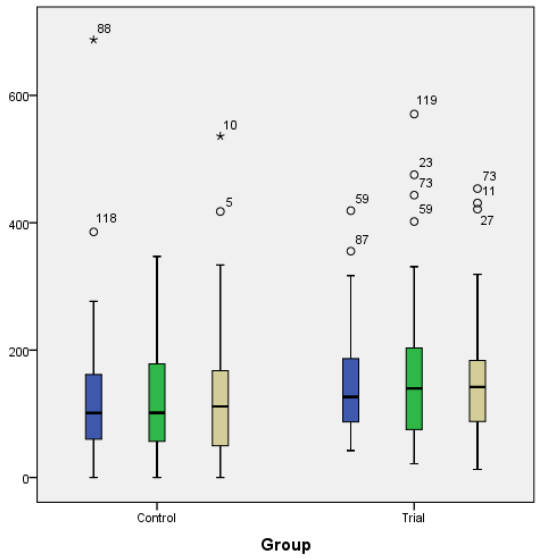


Figure 5.4.6.2: boxplot carried out on F-Scan with Insole - Midfoot PP data between control and trial patients at baseline, 3rd month and 6th month.

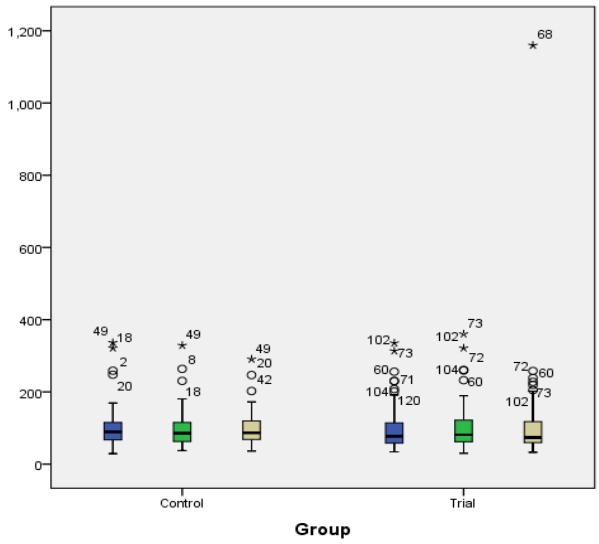


Figure 5.4.6.3: boxplot carried out on HR Walkway – Midfoot PP data between control and trial patients at baseline, 3rd month and 6th month interval.

Midfoot - Pressure Time Integral (m-PTI)

Control Group (m-PTI)

With regards to F-scan shod: median value at baseline was 24.44, 23.41 at 3rd month and 23.54 at 6th month (Table 5.4.6.7).

Table 5.4.6.7: descriptive statistics on Midfoot – PTI (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Midfoot – Pressure Time Integral (m-PTI) - F-Scan – Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	24.44(22.18)	23.41(26.39)	23.54(34.56)	26.80(22.36)	22.72(24.61)	30.39(27.61)

With regards to F-scan with Insole: median value at baseline was 22.98, 25.65 at 3rd month, and 25.83 at 6th month (Table 5.4.6.8).

Table 5.4.6.8: descriptive statistics on Midfoot–PTI (with insole) data at baseline, 3rd month and 6th month (control and trial patients).

Midfoot – Pressure Time Integral (m-PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	22.98(29.55)	25.65(34.92)	25.83(24.76)	32.23(26.66)	34.43(31.03)	33.61(27.41)

With regards to HR Walkway the median value at baseline was 15.33, 13.41 at 3rd month and 16.34 at 6th month (Table 5.4.6.9). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.6.9: descriptive statistics on Midfoot – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Midfoot – Pressure Time Integral (m-PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	15.33(9.18)	13.41(6.44)	16.34(9.54)	14.78(10.61)	14.14(13.2)	13.72(10.33)

As shown on (Table 5.4.6.10) Friedman test shows $p>0.05$ in all cases, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. The only interval where significance difference was met was for the control group of the F-scan with insole, similarly from the correspondent stable group $p<0.05$*.

Table 5.4.6.10: details of the Friedman test on Midfoot– PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Midfoot – Pressure Time Integral (m-PTI); Friedman Test (baseline, 3rd month & 6th month)		
	Control	**Trial**
F-Scan - Shod	**p=0.203**	**p=0.130**
Stable	**p=0.007****	**p=0.225**
Not stable	**p=0.390**	**p=0.174**
F-Scan – With Insoles	**p=0.043***	**p=0.582**
Stable	**p=0.020***	**p=0.931**
Not stable	**p=0.327**	**p=0.304**
HR Walkway	**p=0.072**	**p=0.064**
Stable	**p=0.358**	**p=0.109**
Not stable	**p=0.074**	**p=0.269**

Table 5.4.6.11 highlighted that all intervals are not significantly different (p>0.05). Interestingly, in the stable control group of the F-scan (shoes and with insole) and the HR Walkway, significant changes were found (p>0.05). It is possible to notice a stable trend over the period of 6 months for the control group particularly for the F-Scan shod and the HR Walkway. Also in this case, it is possible to notice a stable trend over the period of 6 months for the control group, with the exception of 3rd month-6thmonth interval with the F-Scan (shod & with insole) and HR Walkway.

Table 5.4.6.11: : details of the Wilcoxon's test on Total-PT data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Midfoot – Pressure Time Integral - (m-PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.539**	**p=0.488**
3rd month – 6th month		**p=0.159**	**p=0.083**
Baseline – 6th month		**p=0.672**	**p=0.261**
Stable	Baseline – 3rd month	**p=0.959**	**p=0.819**
	3rd month – 6th month	**p=0.012***	**p=0.073**
	Baseline – 6th month	**p=0.054**	**p=0.118**
Not Stable	Baseline – 3rd month	**p=0.407**	**p=0.352**
	3rd month – 6th month	**p=0.407**	**p=0.796**
	Baseline – 6th month	**p=0.177**	**p=0.717**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.727**	**p=0.860**
3rd month – 6th month		**p=0.179**	**p=0.464**
Baseline – 6th month		**p=0.150**	**p=0.493**
Stable	Baseline – 3rd month	**p=0.453**	**p=0.448**
	3rd month – 6th month	**p=0.004****	**p=0.474**
	Baseline – 6th month	**p=0.054**	**p=0.835**
Not Stable	Baseline – 3rd month	**p=0.062**	**p=0.334**
	3rd month – 6th month	**p=0.149**	**p=0.326**
	Baseline – 6th month	**p=0.868**	**p=0.352**
HR Walkway			
Baseline – 3rd month		**p=0.082**	**p=0.804**
3rd month – 6th month		**p=0.011***	**p=0.056**
Baseline – 6th month		**p=0.585**	**p=0.097**
Stable	Baseline – 3rd month	**p=0.057**	**p=0.546**
	3rd month – 6th month	**p=0.140**	**p=0.254**
	Baseline – 6th month	**p=0.765**	**p=0.223**
Not Stable	Baseline – 3rd month	**p=0.881**	**p=0.605**
	3rd month – 6th month	**p=0.028**	**p=0.07**
	Baseline – 6th month	**p=0.179**	**p=0.196**

Trial Group (m-PTI)

As shown on Table 5.4.6.7 within the trial group of the F-scan shod the median value at baseline was 26.80, 22.72 at 3rd month, and 30.39 at 6th month (Table 5.4.6.7). With

regards to F-scan with insole, median value at baseline was 32.23, 34.43 at 3rd month, and 33.61 at 6th month (Table 5.4.6.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 14.78, 14.14 at 3rd month and 13.72 at 6th month (Table 5.4.6.9). Therefore, it is possible to notice how the m-PTI was higher only when the F-Scan system was used with the FOs inside the shoes, suggesting that PTI increased only for the trial groups.

As shown on Table 5.4.6.10 Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$).

As shown on Table 5.4.6.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all intervals considered with the stable-groups ($p>0.05$). This suggests that there were no statistical differences in m-PTI over a period of the 6 month for the trial group, possibly indicating that FOs did not modify and retained its original prescription for the whole duration of the study.

Comparison between the Control and the Trial Group (m-PTI)

As shown in Table 5.4.6.12 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at baseline ($p<0.05$*), 3rd month ($p<0.05$*), and 6th month ($p<0.05$*). In addition, statistical difference was noted also when the stable group was considered separately. No statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$). Therefore, a clear trend was found between the control and the trial FOs only when orthotics were worn, which lasted for all the intervals investigated.

Table 5.4.6.12: details of the Mann Whitney Test carried out on -PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Midfoot – Pressure Time Integral - (m-PTI) -Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.925**	**p=0.744**	**p=0.245**
Stable	**p=0.935**	**p=0.935**	**p=0.096**
Not stable	**p=0.824**	**p=0.873**	**p=0.787**
F-Scan – With Insoles	**p=0.015***	**p=0.028***	**p=0.012***
Stable	**p=0.012***	**p=0.012***	**p=0.002****
Not stable	**p=0.726**	**p=0.774**	**p=0.702**
HR Walkway	**p=0.542**	**p=0.644**	**p=0.308**
Stable	**p=0.523**	**p=0.634**	**p=0.525**
Not stable	**p=0.545**	**p=0.975**	**p=0.588**

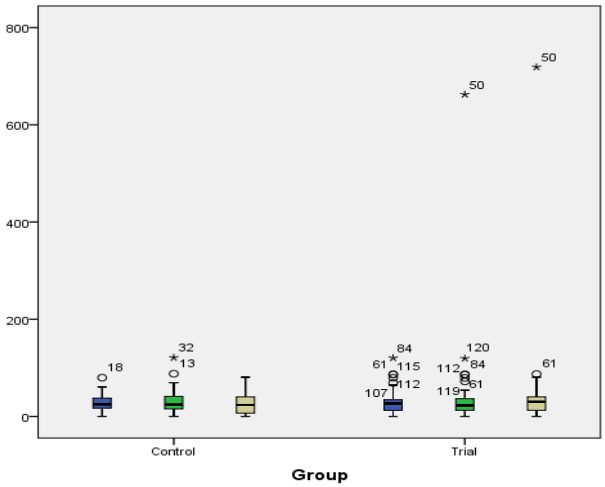


Figure 5.4.6.4: boxplot carried out on F-Scan Shod – Midfoot PTI data between control and trial patients at baseline, 3rd month and 6th month.

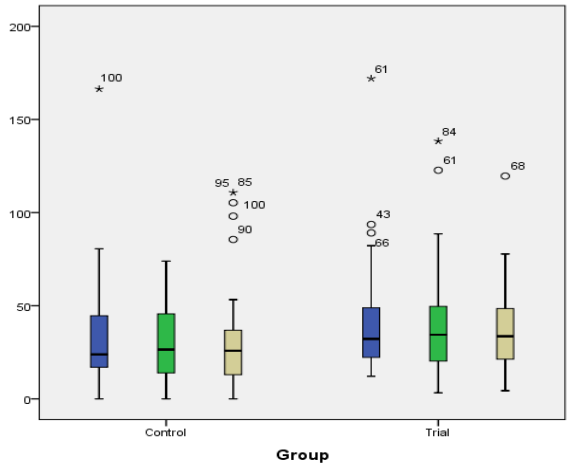


Figure 5.4.6.5: boxplot carried out on F-Scan with insole - Midfoot PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

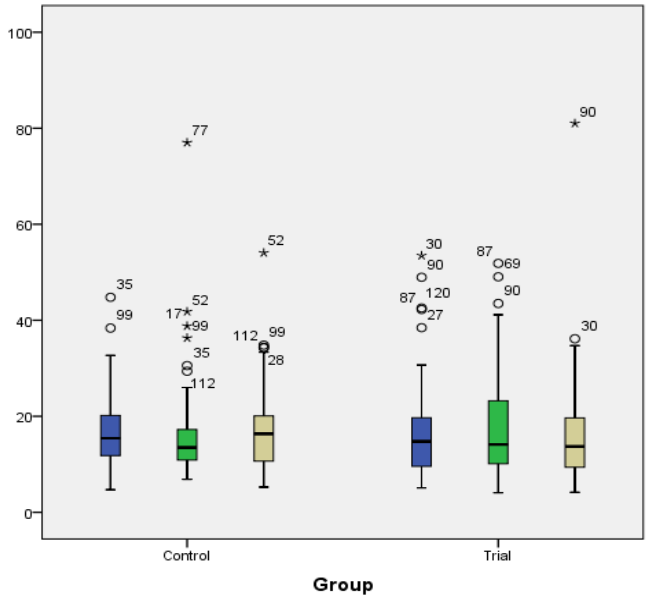


Figure 5.4.6.6: boxplot carried out on HR Walkway – Midfoot PTI data between control and trial patients at baseline, 3rd month and 6th month interval

5.4.7. Forefoot – Contact

Forefoot - Peak Pressure Values- (f-PP)

Control Group (f-PP)

With regards to F-scan shod: median value at baseline was 372, 411.50 at 3rd month and 402 at 6th month (Table 5.4.7.1).

Table 5.4.7.1: descriptive statistics on Forefoot – PP (F-Scan-Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Forefoot – Peak Pressure Values - (f-PP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	372(270.42)	421.5(340.5)	402(345.42)	381.33(338.5)	385.67(373.33)	380(319.17)

With regards to F-scan With Insole: median value at baseline was 333.83, 369.83 at 3rd month, and 389.17 at 6th month (Table 5.4.7.2).

Table 5.4.7.2: descriptive statistics on Forefoot – PP (With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Forefoot – Peak Pressure Values - (f-PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	333.83(301.16)	369.83(277.42)	389.17(278.59)	258.17(267.66)	284(290.5)	340.83(253.25)

With regards to HR Walkway median value at baseline was 305.17, 300.67 at 3rd month and 307 at 6th month (Table 5.4.7.3). It is possible to notice a stable trend over the period of 6 months for the control group. It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.7.3: descriptive statistics on Forefoot – PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Forefoot – Peak Pressure Values - (f-PP)– HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	305.17(197.91)	300.67(241.5)	307(220.59)	349.10(191.67)	354.13(195.84)	367.93(213.42)

As shown as Table 5.4.7.4 the Friedman test shows p>0.05 in all cases; therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.7.4: details of the Friedman test on Midfoot– PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Forefoot – Peak Pressure Values (f-PP) Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.059	p=0.412
Stable	p=0.163	p=0.393
Not stable	p=0.026	p=0.829
F-Scan – With Insoles	p=0.225	p=0.903
Stable	p=0.249	p=0.570
Not stable	p=0.157	p=0.229
HR Walkway	p=0.066	p=0.736
Stable	p=0.121	p=0.633
Not stable	p=0.024	p=0.646

Table 5.4.7.5 highlighted that with HR Walkway and the F-scan (shod and with insole) were not significantly different (p>0.05) for the control group. Same results were obtained with the control-stable group. No statistical significance was recorded with any other interval with the F-scan with insole and HR Walkway system. This suggests that there were no statistical difference in m-PP for the control group.

Table 5.4.7.5: details of the Wilcoxon's test on Forefoot-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Forefoot – Peak Pressure Values - (m-PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.011**	**p=0.091**
3rd month – 6th month		**p=0.775**	**p=0.671**
Baseline – 6th month		**p=0.02**	**p=0.146**
Stable	Baseline – 3rd month	**p=0.031**	**p=0.174**
	3rd month – 6th month	**p=0.30**	**p=0.756**
	Baseline – 6th month	**p=0.265**	**p=0.145**
Not Stable	Baseline – 3rd month	**p=0.218**	**p=0.234**
	3rd month – 6th month	**p=0.126**	**p=0.569**
	Baseline – 6th month	**p=0.019**	**p=0.717**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.226**	**p=0.832**
3rd month – 6th month		**p=0.616**	**p=0.221**
Baseline – 6th month		**p=0.125**	**p=0.603**
Stable	Baseline – 3rd month	**p=0.065**	**p=0.604**
	3rd month – 6th month	**p=0.561**	**p=0.258**
	Baseline – 6th month	**p=0.282**	**p=0.135**
Not Stable	Baseline – 3rd month	**p=0.681**	**p=0.069**
	3rd month – 6th month	**p=0.057**	**p=0.569**
	Baseline – 6th month	**p=0.322**	**p=0.109**
HR Walkway			
Baseline – 3rd month		**p=0.430**	**p=0.723**
3rd month – 6th month		**p=0.355**	**p=0.430**
Baseline – 6th month		**p=0.103**	**p=0.197**
Stable	Baseline – 3rd month	**p=0.048**	**p=0.223**
	3rd month – 6th month	**p=0.888**	**p=0.275**
	Baseline – 6th month	**p=0.245**	**p=0.105**
Not Stable	Baseline – 3rd month	**p=0.156**	**p=0.255**
	3rd month – 6th month	**p=0.078**	**p=0.816**
	Baseline – 6th month	**p=0.211**	**p=0.918**

Trial Group (f-PP)

As shown on Table 5.4.7.1 within the trial group of the F-scan shod the median value at baseline was 381.33, 385.67 at 3rd month, and 380 at 6th month (Table 5.4.7.1). With

regards to F-scan with insole, median value at baseline was 258.17, 284 at 3rd month, and 340.83 at 6th month (Table 5.4.7.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 349.10, 354.13 at 3rd month and 367.93 at 6th month (Table 5.4.7.3). These data suggests that the median m-PP values appeared to be lower than without the FOs and HR Walkway.

As shown on Table 5.4.7.4 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$). As shown on Table 5.4.7.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$). It is possible to notice a stable trend over the period of 6 months within the trial group.

Comparison between the Control and the Trial Group (f-PP)

As shown in Table 5.4.7.6 results highlighted that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan (shod and with insole) and HR walkway ($p>0.05$) over 6 months period of time. This suggests that there is not a clear trend toward changes that happen between the control and the trial group with regards to m-PP.

Table 5.4.7.6: details of the Mann Whitney Test carried out on Forefoot-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

Forefoot – Peak Pressure Values - (mPP) -Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.211	p=0.590	p=0.755
Stable	p=0.124	p=0.386	p=0.427
Not stable	p=0.975	p=0.849	p=0.567
F-Scan – With Insoles	p=0.241	p=0.054	p=0.063
Stable	p=0.458	p=0.153	p=0.329
Not stable	p=0.464	p=0.181	p=0.052
HR Walkway	p=0.688	p=0.869	p=0.831
Stable	p=0.829	p=0.808	p=0.772
Not stable	p=0.937	p=0.975	p=0.279

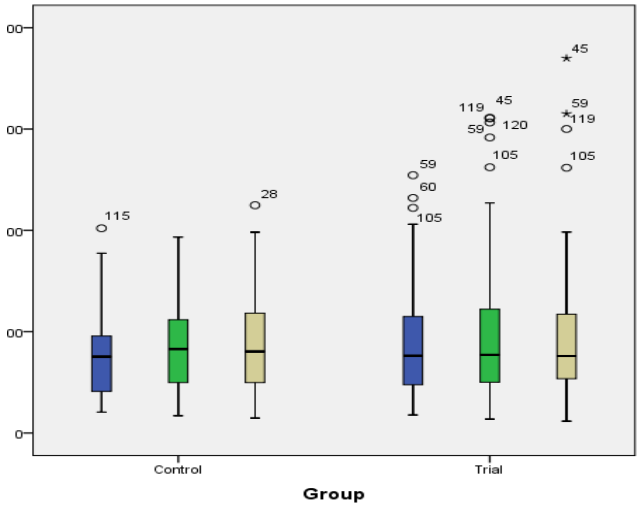


Figure 5.4.7.1: boxplot carried out on F-Scan Shod – Forefoot PP data between control and trial patients at baseline, 3rd month and 6th month.

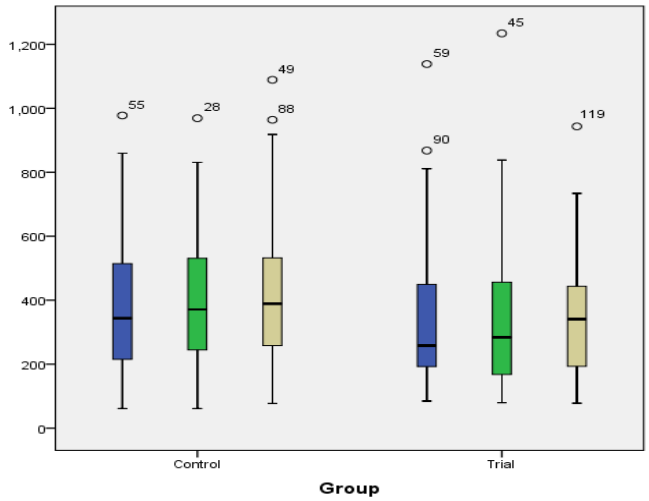


Figure 5.4.7.2: boxplot carried out on F-Scan with insole - Forefoot PP data between control and trial patients at baseline, 3rd month and 6th month interval.

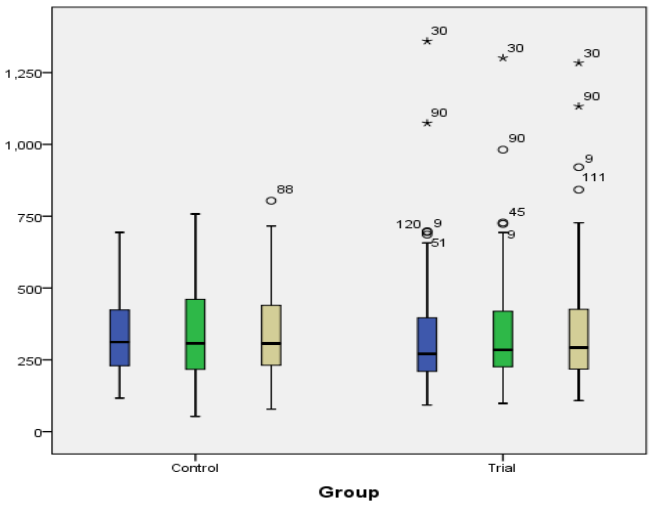


Figure 5.4.7.3: boxplot carried out on HR Walkway - Forefoot PP data between control and trial patients at baseline, 3rd month and 6th month interval.

Forefoot - Pressure Time Integral (f-PTI)

Control Group (f-PTI)

With regards to F-scan shod: median value at baseline was 54.19, 64.51 at 3rd month and 58.45 at 6th month for the control group (Table 5.4.7.7).

Table 5.4.7.7: descriptive statistics on Forefoot – PTI (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Forefoot – Pressure Time Integral (f-PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	54.19(33.06)	64.51(41.26)	58.45(45.23)	50.86(37.56)	60.76(44.26)	61.73(36.47)

With regards to F-scan With Insole: median value at baseline was 55.10, 69.31 at 3rd month, and 62.39 at 6th month (Table 5.4.7.8).

Table 5.4.7.8: descriptive statistics on Forefoot – PTI (With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Forefoot – Pressure Time Integral (f-PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	55.10(34.29)	69.31(41.11)	62.39(31.55)	47.54(35.26)	49.43(35.66)	53.26(40.04)

With regards to HR Walkway the median value at baseline was 42.06, 40 at 3rd month and 40.08 at 6th month (Table 5.4.7.9). It is possible to notice a stable trend over the period within the 6 months period of time for the control group.

Table 5.4.7.9: descriptive statistics on Forefoot – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Forefoot – Pressure Time Integral (f-PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	42.06(20.51)	40(22.87)	40.08(21.16)	34.7(28.45)	38.35(28.66)	35.99(24.55)

As shown on Table 5.4.7.10 the Friedman test shows p>0.05 in all cases, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained. The only interval where significance difference was met was for the control-stable group of the F-scan with insole.

Table 5.4.7.10: details of the Friedman test on Forefoot – PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Forefoot – Pressure Time Integral (f-PTI) –- Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.516	p=0.308
Stable	p=0.558	p=0.323
Not stable	p=0.074	p=0.829
F-Scan – With Insoles	p=0.235	p=0.819
Stable	p=0.008**	p=0.984
Not stable	p=0.212	p=0.556
HR Walkway	p=0.143	p=0.865
Stable	p=0.459	p=0.662
Not stable	p=0.004	p=0.779

Table 5.4.7.11 highlighted that all intervals are not significantly different (p>0.05) for the control group. Interestingly, in the stable control group of the f-scan (with insole) at baseline-3rdmonth interval, significant changes was found (p<0.05). Overall, it is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.7.11: details of the Wilcoxon's test on Forefoot- PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Forefoot – Pressure Time Integral - (f-PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.105**	**p=0.127**
3rd month – 6th month		**p=0.630**	**p=0.422**
Baseline – 6th month		**p=0.088**	**p=0.422**
Stable	Baseline – 3rd month	**p=0.106**	**p=0.157**
	3rd month – 6th month	**p=0.087**	**p=0.642**
	Baseline – 6th month	**p=0.509**	**p=0.403**
Not Stable	Baseline – 3rd month	**p=0.627**	**p=0.679**
	3rd month – 6th month	**p=0.073**	**p=0.501**
	Baseline – 6th month	**p=0.030***	**p=0.959**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.200**	**p=0.90**
3rd month – 6th month		**p=0.636**	**p=0.508**
Baseline – 6th month		**p=0.436**	**p=0.900**
Stable	Baseline – 3rd month	**p=0.042***	**p=0.823**
	3rd month – 6th month	**p=0.053**	**p=0.866**
	Baseline – 6th month	**p=0.981**	**p=0.439**
Not Stable	Baseline – 3rd month	**p=0.478**	**p=0.955**
	3rd month – 6th month	**p=0.04***	**p=0.379**
	Baseline – 6th month	**p=0.263**	**p=0.088**
HR Walkway			
Baseline – 3rd month		**p=0.359**	**p=0.880**
3rd month – 6th month		**p=0.052**	**p=0.577**
Baseline – 6th month		**p=0.405**	**p=0.530**
Stable	Baseline – 3rd month	**p=0.617**	**p=0.409**
	3rd month – 6th month	**p=0.981**	**p=0.523**
	Baseline – 6th month	**p=0.900**	**p=0.589**
Not Stable	Baseline – 3rd month	**p=0.067**	**p=0.379**
	3rd month – 6th month	**p=0.001****	**p=0.796**
	Baseline – 6th month	**p=0.086**	**p=0.642**

Trial Group (f-PTI)

As shown on Table 5.4.7.7 within the trial group of the F-scan shod the median value at baseline was 50.86, 60.76 at 3rd month, and 61.73 at 6th month (Table 5.4.7.7). With

regards to F-scan with insole, median value at baseline was 47.54, 49.43 at 3rd month, and 53.26 at 6th month (Table 5.4.7.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 34.70, 38.35 at 3rd month and 35.99 at 6th month (Table 5.4.7.9). It is possible to notice a stable trend over the period of 6 months for the trial group.

Friedman's test was carried out; as shown on Table 5.4.7.10 the Friedman test displayed a p>0.05; hence, there is no statistical difference within the trial group. Statistical difference was not obtained (p>0.05) when stable group is considered separately. The non-stable group was found to be not significance difference (p>0.05). As shown on Table 5.4.7.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all intervals considered with the stable-groups (p>0.05). It is possible to notice a stable-trend over the period of 6 months for the trial group with regards to f-PTI.

Comparison between the Control and the Trial Group (f-PTI)

Results highlighted that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan (shod – p>0.05; and with insole – p>0.05) and with the HR Walkway (p>0.05). In addition, no statistical difference was noted also when the stable group was considered separately. This suggests that there is a stable trend toward no changes that happen between the control and the trial group with regards to f-PTI.

Table 5.4.7.12: details of the Mann Whitney Test carried out on Forefoot -PT with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Forefoot – Peak Pressure Values- (f-PTI) -Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.446	p=0.813	p=0.914
Stable	p=0.529	p=0.850	p=0.501
Not stable	p=0.774	p=0.633	p=0.524
F-Scan – With Insoles	p=0.289	p=0.087	p=0.141
Stable	p=0.189	p=0.051	p=0.416
Not stable	p=0.924	p=0.899	p=0.111
HR Walkway	p=0.753	p=0.725	p=0.521
Stable	p=0.374	p=0.822	p=0.524
Not stable	p=0.464	p=0.408	p=0.975

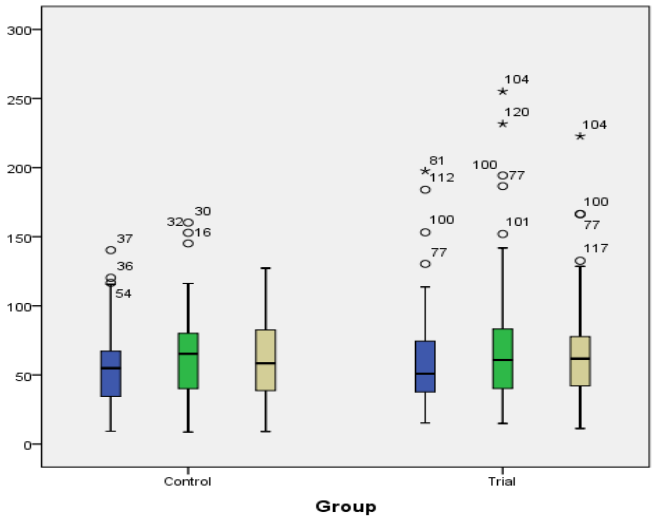


Figure 5.4.7.4: boxplot carried out on F-Scan Shod – Forefoot PTI data between control and trial patients at baseline, 3rd month and 6th month.

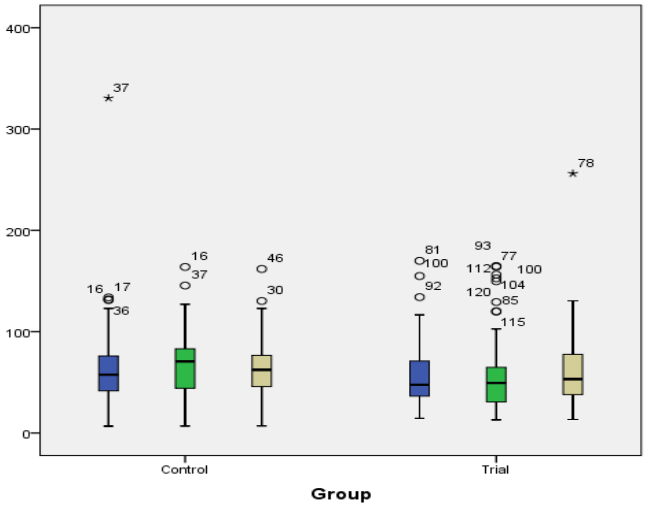


Figure 5.4.7.5: boxplot carried out on F-Scan with insole - Forefoot PTI data between control and trial patients at baseline, 3rd month and 6th month interval

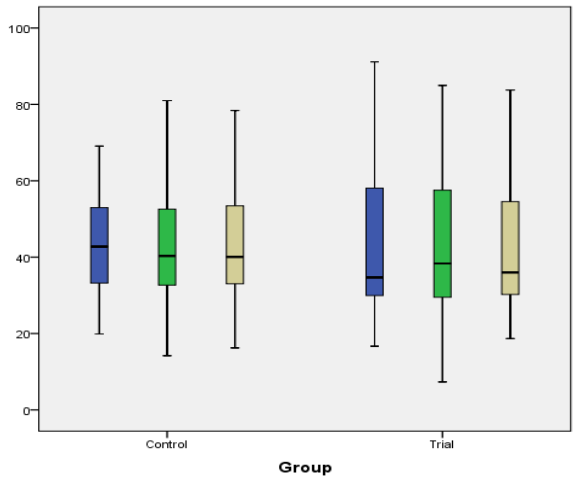


Figure 5.4.7.6: boxplot carried out on HR Walkway – Forefoot PTI data between control and trial patients at baseline, 3rd month and 6th month interval

5.4.8. 5th Metatarsal Head Contact

5th - Peak Pressure Values- (5th -PP)

Control Group (5th- PP)

With regards to F-scan shod: median value at baseline was 158.5, 163 at 3rd month and 170 at 6th month (Table 5.4.8.1).

Table 5.4.8.1: descriptive statistics on 5th – PP (F-Scan-Shod) data at baseline, 3rd month and 6th month (control and trial patients).

5th Met. Head – Peak Pressure Values (5th-PP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	158.5(182.92)	163(172.42)	170(129.25)	162.33(142.58)	138.83(111.83)	173.05(166.74)

With regards to F-scan with insole: median value at baseline was 172.33, 187.17at 3rd month, and 198.83 at 6th month (Table 5.4.8.2).

Table 5.4.8.2: descriptive statistics on 5th – PP (With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

5th Met. Head – Peak Pressure Values - (5th PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	172.33(171.67)	187.17(182)	198.83(150.67)	115.67(72.33)	149.83(82)	139(121.25)

With regards to HR Walkway the median value at baseline was 130, 115.5 at 3rd month and 121.33 at 6th month (Table 5.4.8.3). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.8.3: descriptive statistics on 5th– PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

5th Met. Head – Peak Pressure Values (5th-PP) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	130(62.91)	115.5(84.5)	121.33(92)	123.5(101.58)	121.17(102.91)	122.17(107.58)

As shown on Table 5.4.8.4 the Friedman test shows p>0.05 in all intervals; therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained.

Table 5.4.8.4: details of the Friedman test on 5th PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

5th Met Head – Peak Pressure Values (5th PP) Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.607	p=0.117
Stable	p=0.303	p=0.024*
Not stable	p=0.287	p=0.144
F-Scan – With Insoles	p=0.754	p=0.092
Stable	p=0.378	p=0.138
Not stable	p=0.819	p=0.538
HR Walkway	p=0.336	p=0.988
Stable	p=0.353	p=0.671
Not stable	p=0.610	p=0.210

Table 5.4.8.5 highlighted there is no statistical difference within the control groups. The only significant results was recorded within the stable group was found for the 3rdmonth-6th month interval (p<0.05*). No statistical significance was recorded with any other interval with the F-scan with insole and HR Walkway system. Therefore, it is possible to notice a stable trend over the period of 6 months.

Table 5.4.8.5: details of the Wilcoxon's test on 5th-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

5th Met. Head – Peak Pressure Values (5th PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.569**	**p=0.702**
3rd month – 6th month		**p=0.645**	**p=0.074**
Baseline – 6th month		**p=0.613**	**p=0.061**
Stable	Baseline – 3rd month	**p=0.151**	**p=0.067**
	3rd month – 6th month	**p=0.036***	**p=0.190**
	Baseline – 6th month	**p=0.962**	**p=0.025***
Not Stable	Baseline – 3rd month	**p=0.255**	**p=0.034***
	3rd month – 6th month	**p=0.044***	**p=0.234**
	Baseline – 6th month	**p=0.360**	**p=0.877**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.874**	**p=0.123**
3rd month – 6th month		**p=0.766**	**p=0.325**
Baseline – 6th month		**p=0.910**	**p=0.068**
Stable	Baseline – 3rd month	**p=0.722**	**p=0.097**
	3rd month – 6th month	**p=0.122**	**p=0.422**
	Baseline – 6th month	**p=0.664**	**p=0.100**
Not Stable	Baseline – 3rd month	**p=0.502**	**p=0.865**
	3rd month – 6th month	**p=0.156**	**p=0.717**
	Baseline – 6th month	**p=0.765**	**p=0.501**
HR Walkway			
Baseline – 3rd month		**p=0.277**	**p=0.599**
3rd month – 6th month		**p=0.179**	**p=0.989**
Baseline – 6th month		**p=0.633**	**p=0.757**
Stable	Baseline – 3rd month	**p=0.237**	**p=0.516**
	3rd month – 6th month	**p=0.519**	**p=0.768**
	Baseline – 6th month	**p=0.347**	**p=0.498**
Not Stable	Baseline – 3rd month	**p=0.779**	**p=0.056**
	3rd month – 6th month	**p=0.184**	**p=0.717**
	Baseline – 6th month	**p=0.709**	**p=0.079**

Trial Group (5th – PP)

As shown on Table 5.4.8.1 within the trial group of the F-scan shod the median value at baseline was 162.33, 138.83 at 3rd month, and 173 at 6th month (Table 5.4.8.1). With

regards to F-scan with insole, the median value at baseline was 115.67, 149.83 at 3rd month, and 139 at 6th month (Table 5.4.8.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 123.5, 121.17 at 3rd month and 122.17 at 6th month (Table 5.4.8.3). It is possible to notice a stable trend over the period of 6 months within the trial group; however, the F-scan with insole clearly recorded a lower 5th-PP compared to the F-scan (shod) measurements. As shown on Table 5.4.8.4 the Friedman test displayed a $p>0.05$ for all intervals; hence, with the only exception for the F-Scan (shod) for the stable-trial group ($p<0.05$*). As shown on Table 5.4.8.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$). This suggests that overall there were no statistical difference in 5thPP for the trial group

Comparison between the Control and the Trial Group (5th-PP)

As shown in Table 5.4.8.6 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at baseline ($p<0.01$**), 3rd month ($p<0.05$*), and 6th month ($p<0.05$*). In addition, statistical difference was noted also when the stable group was considered,particularly at baseline ($p<0.05$*) and 3rd month ($p<0.05$*). On the other hand, no statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$). This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to 5thPP, indicating the positive effect applied by the FOs in JIA.

Table 5.4.8.6: details of the Mann Whitney Test carried out on 5th- PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

5th Met. Head – Peak Pressure Values - (5th-PP) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.799**	**p=0.35**	**p=0.981**
Stable	**p=0.975**	**p=0.587**	**p=0.181**
Not stable	**p=0.886**	**p=0.111**	**p=0.086**
F-Scan – With Insoles	**p=0.002****	**p=0.021***	**p=0.030***
Stable	**p=0.009****	**p=0.039***	**p=0.249**
Not stable	**p=0.07**	**p=0.181**	**p=0.048***
HR Walkway	**p=0.609**	**p=0.850**	**p=0.712**
Stable	**p=0.550**	**p=0.699**	**p=0.970**
Not stable	**p=0.937**	**p=0.750**	**p=0.599**

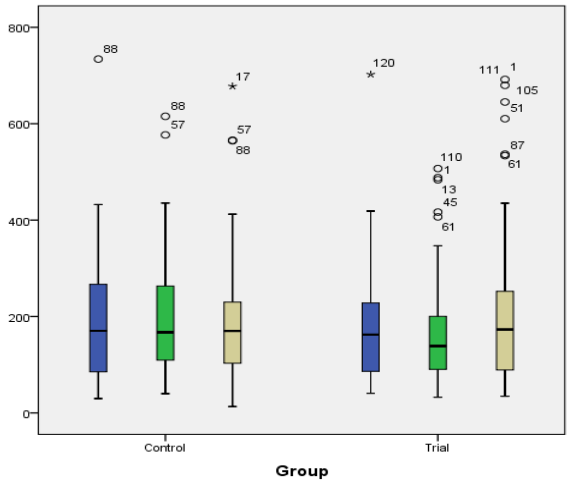


Figure 5.4.8.1: boxplot carried out on F-Scan Shod – 5th met .head PP data between control and trial patients at baseline, 3rd month and 6th month.

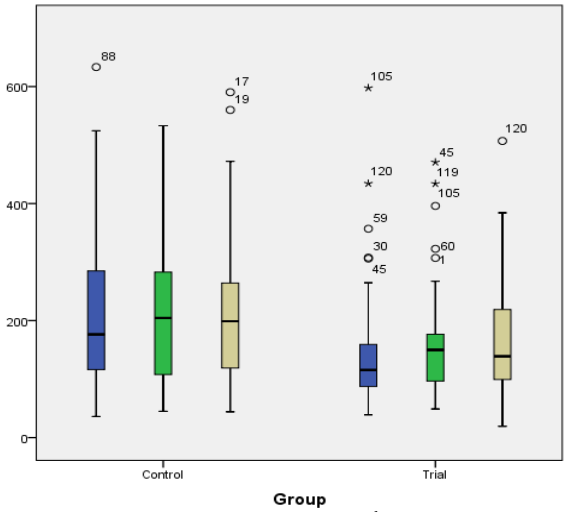


Figure 5.4.8.2: boxplot carried out on F-Scan with insole - 5th met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval

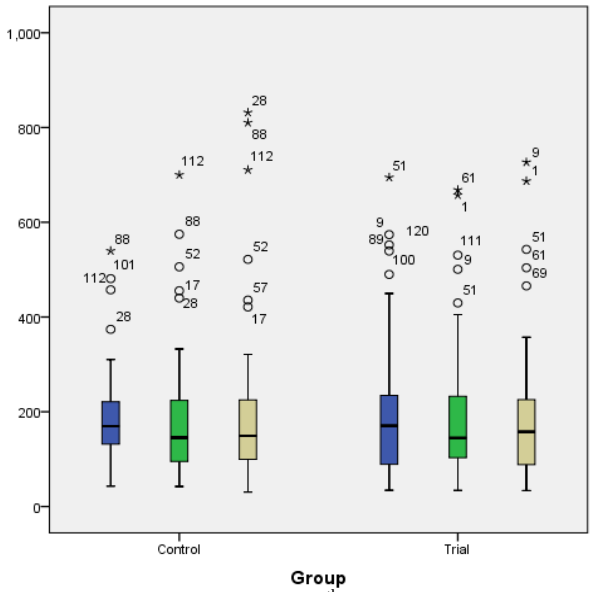


Figure 5.4.8.3: boxplot carried out on HR Walkway – 5th met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval.

5th - Pressure Time Integral (5th -PTI)

Control Group (5th –PTI)

With regards to F-scan shod: median value at baseline was 42.90, 45.06 at 3rd month and 38.14 at 6th month (Table 5.4.8.7).

Table 5.4.8.7: descriptive statistics on 5th –PTI (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

5th Met. Head – Pressure Time Integral (5th- PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	42.90(40.83)	45.06(44.77)	38.14(43.98)	36.79(35.45)	40.35(31.98)	42.61(59.08)

With regards to F-scan With Insole: median value at baseline was 52.91, 42.70 at 3rd month, and 46.78 at 6th month (Table 5.4.8.8).

Table 5.4.8.8: descriptive statistics on 5th – PTI (F-Scan- with insole) data at baseline, 3rd month and 6th month (control and trial patients).

5th Met. Head – Pressure Time Integral (5th - PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	52.91(53.31)	42.70(49.65)	46.78(50.42)	35.23(26)	38.09(23.85)	38.78(30.43)

With regards to HR Walkway the median value at baseline was 33.82, 32.88 at 3rd month and 35.14 at 6th month (Table 5.4.8.9). It is possible to notice a stable trend over the period of 6 months.

Table 5.4.8.9: descriptive statistics on 5th – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

5th Met. Head – Pressure Time Integral (5th-PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	33.82(20.93)	32.88(17.97)	35.14(25.24)	33.57(29.58)	34.83(32.9)	32.17(31.9)

As shown on Table 5.4.8.10 the Friedman test shows p>0.05 in all cases for the control group. Therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained (p>0.05) with the only exception for the non-stable group (p<0.05*).

Table 5.4.8.10: details of the Friedman test on 5th -PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

5th Met. Head – Pressure Time Integral (5th-PTI) - Friedman Test (baseline, 3rd month & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.882	p=0.637
Stable	p=0.303	p=0.094
Not stable	p=0.026*	p=0.028*
F-Scan – With Insoles	p=0.793	p=0.949
Stable	p=0.558	p=0.770
Not stable	p=0.819	p=0.314
HR Walkway	p=0.115	p=0.351
Stable	p=0.184	p=0.142
Not stable	p=0.706	p=0.444

Table 5.4.8.11 highlighted that most intervals are not significantly different (p>0.05). During the interval within 3rdmonth-6thmonth for the stable control group of the F-Scan (shod) and the HR Walkway, significant changes were found (p<0.05*). This suggests that there were no statistical difference in 5th PTI.

Table 5.4.8.11: details of the Wilcoxon's test on 5th- PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

5th Met. Head – Pressure Time Integral (5th-PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.935**	**p=0.936**
3rd month – 6th month		**p=0.707**	**p=0.083**
Baseline – 6th month		**p=0.858**	**p=0.206**
Stable	Baseline – 3rd month	**p=0.404**	**p=0.102**
	3rd month – 6th month	**p=0.04***	**p=0.249**
	Baseline – 6th month	**p=0.162**	**p=0.061**
Not Stable	Baseline – 3rd month	**p=0.332**	**p=0.004****
	3rd month – 6th month	**p=0.021**	**p=0.163**
	Baseline – 6th month	**p=0.100**	**p=0.379**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.277**	**p=0.877**
3rd month – 6th month		**p=0.607**	**p=0.919**
Baseline – 6th month		**p=0.374**	**p=0.455**
Stable	Baseline – 3rd month	**p=0.658**	**p=0.502**
	3rd month – 6th month	**p=0.093**	**p=0.611**
	Baseline – 6th month	**p=0.285**	**p=0.428**
Not Stable	Baseline – 3rd month	**p=0.279**	**p=0.112**
	3rd month – 6th month	**p=0.191**	**p=0.179**
	Baseline – 6th month	**p=0.940**	**p=0.796**
HR Walkway			
Baseline – 3rd month		**p=0.607**	**p=0.952**
3rd month – 6th month		**p=0.038***	**p=0.276**
Baseline – 6th month		**p=0.378**	**p=0.208**
Stable	Baseline – 3rd month	**p=0.286**	**p=0.650**
	3rd month – 6th month	**p=0.198**	**p=0.581**
	Baseline – 6th month	**p=0.900**	**p=0.978**
Not Stable	Baseline – 3rd month	**p=0.627**	**p=0.379**
	3rd month – 6th month	**p=0.100**	**p=0.234**
	Baseline – 6th month	**p=0.100**	**p=0.015**

Trial Group (5th – PTI)

As shown on Table 5.4.8.7 within the trial group of the F-scan shod the median value at baseline was 36.79, 40.35 at 3rd month, and 42.61 at 6th month (Table 5.4.8.7). With

regards to F-scan with insole, the median value at baseline was 35.23, 38.09 at 3rd month, and 38.78 at 6th month (Table 5.4.8.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 33.57, 34.83 at 3rd month and 32.17 at 6th month (Table 5.4.8.9). It is possible to notice a stable trend over the period of 6 months but lower compared to the control group.

As shown on Table 5.4.8.10 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$). As shown on Table 5.4.8.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all intervals considered with the stable-groups ($p>0.05$).

Comparison between the Control and the Trial Group (5th – PTI)

As shown in Table 5.4.8.12 highlighted that there is statistical difference between control and trial patients when investigation were carried out only with the F-scan (with insole) particularly at baseline recordings ($p<0.05$*). In addition, statistical difference was noted as well when the stable group was analysed separately at baseline. This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to 5th-PTI particularly at baseline, however, these changed were not attained at 3rdmonth and 6thmonth.

Table 5.4.8.12: details of the Mann Whitney Test carried out on 5th-PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

5th Met. Head – Pressure Time Integral (5th-PTI) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.581	p=0.386	p=0.996
Stable	p=0.679	p=0.693	p=0.167
Not stable	p=0.975	p=0.104	p=0.065
F-Scan – With Insoles	p=0.016*	p=0.093	p=0.071
Stable	p=0.015*	p=0.138	p=0.232
Not stable	p=0.390	p=0.426	p=0.203
HR Walkway	p=0.671	p=0.549	p=0.397
Stable	p=0.350	p=0.693	p=0.581
Not stable	p=0.633	p=0.545	p=0.610

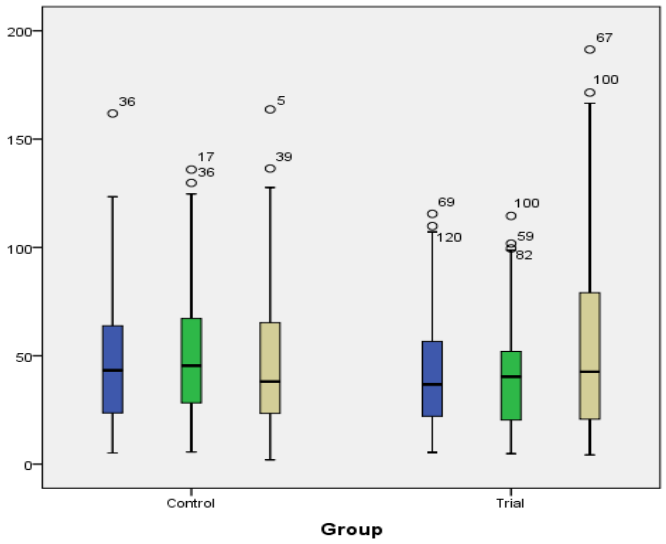


Figure 5.4.8.4: boxplot carried out on F-Scan Shod - PTI data between control and trial patients at baseline, 3rd month and 6th month.

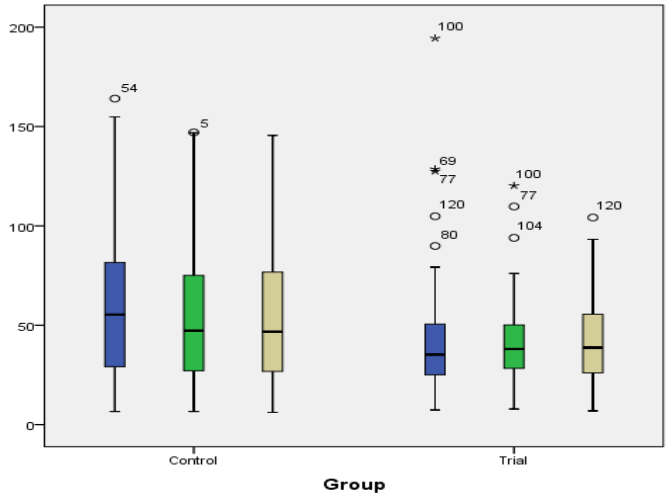


Figure 5.4.8.5: boxplot carried out on F-Scan with insole - 5th met. head PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

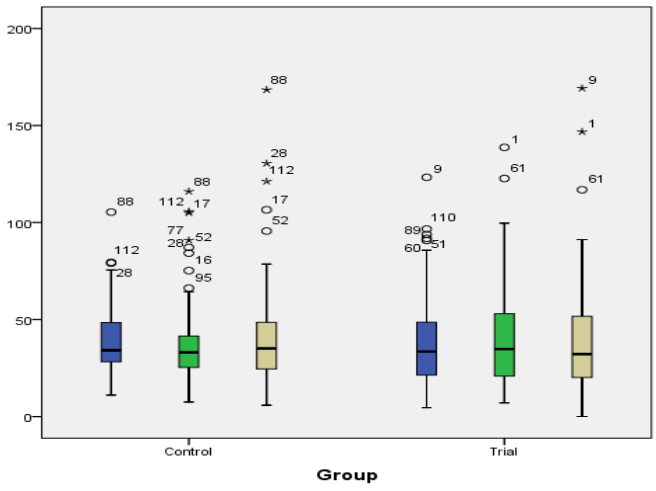


Figure 5.4.8.6: boxplot carried out on HR Walkway – 5th met. head PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.9. 3rd / 4th – Metatarsal Head – Contact

3rd / 4th - Peak Pressure Values- (3rd/4th -PP)

Control Group (3rd/4th – PP)

With regards to F-scan shod: the median value at baseline was 249.83, 299.50 at 3rd month and 263.17 at 6th month (Table 5.4.9.1).

Table 5.4.9.1: descriptive statistics on 3rd/4th – PP (F-Scan-shod) data at baseline, 3rd month and 6th month (control and trial patients).

3rd/4th Met. Head – Peak Pressure Values (3rd/4th -PP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	249.83(220.17)	299.5(326.34)	263.17(265.75)	268.67(248.17)	285.33(311.75)	280.87(162.58)

With regards to F-scan With Insole: the median value at baseline was 249.50, 289.83 at 3rd month, and 295.50 at 6th month (Table 5.4.9.2).

Table 5.4.9.2: descriptive statistics on 3rd/4th – PP (F-Scan-With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

3rd/4th Met. Head – Peak Pressure Values - (3rd/4th PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	249.5(272.92)	289.83(225.92)	295.50(251.33)	197(221.16)	197.67(171.59)	232.5(171.91)

With regards to HR Walkway the median value at baseline was 199.83, 196.33 at 3rd month and 187 at 6th month (Table 5.4.9.3). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.9.3: descriptive statistics on 3rd/4th – PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

3rd/4th Met. Head – Peak Pressure Values (3rd/4th- PP) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	199.83(134.67)	196.33(136.83)	187(147.91)	183.5(133.66)	201.67(111.33)	199.67(98.42)

As shown on Table 5.4.9.4 the Friedman test shows p<0.05* for the F-scan (shod) also for the stable group (p<0.05*). Instead, in all other cases, no significance difference is obtained within the control group for the F-scan (with insole) and HR Walkway (p>0.05).

Table 5.4.9.4: details of the Friedman test on 3rd/4th - PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

3rd/4th Met Head – Peak Pressure Values (3rd/4th PP) Friedman Test (baseline, 3rd & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.005**	p=0.500
Stable	p=0.008**	p=0.544
Not stable	p=0.247	p=0.829
F-Scan – With Insoles	p=0.272	p=0.819
Stable	p=0.184	p=0.570
Not stable	p=0.449	p=0.403
HR Walkway	p=0.659	p=0.551
Stable	p=0.499	p=0.551
Not stable	p=0.009**	p=0.939

Table 5.4.9.5 highlighted there is no statistical difference within the control groups. The only significant results was recorded within the baseline-3rdmonth interval (p<0.05*) also for the stable group. No statistical significance was recorded with any other interval with the F-scan with insole and HR Walkway system (p>0.05). It is possible to notice a stable trend over the period of 6 months for the control group, excluding the F-scan (shod) at baseline.

Table 5.4.9.5: details of the Wilcoxon's test on 3rd/4th- PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

3rd/4th Met. Head – Peak Pressure Values (3rd/4th PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.002****	**p=0.239**
3rd month – 6th month		**p=0.302**	**p=0.776**
Baseline – 6th month		**p=0.066**	**p=0.472**
Stable	Baseline – 3rd month	**p=0.009****	**p=0.186**
	3rd month – 6th month	**p=0.056**	**p=0.917**
	Baseline – 6th month	**p=0.326**	**p=0.170**
Not Stable	Baseline – 3rd month	**p=0.108**	**p=0.796**
	3rd month – 6th month	**p=0.550**	**p=0.438**
	Baseline – 6th month	**p=0.086**	**p=0.326**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.580**	**p=0.796**
3rd month – 6th month		**p=0.732**	**p=0.232**
Baseline – 6th month		**p=0.136**	**p=0.689**
Stable	Baseline – 3rd month	**p=0.567**	**p=0.801**
	3rd month – 6th month	**p=0.802**	**p=0.095**
	Baseline – 6th month	**p=0.093**	**p=0.265**
Not Stable	Baseline – 3rd month	**p=0.852**	**p=0.910**
	3rd month – 6th month	**p=0.332**	**p=0.605**
	Baseline – 6th month	**p=0.601**	**p=0.196**
HR Walkway			
Baseline – 3rd month		**p=0.807**	**p=0.710**
3rd month – 6th month		**p=0.463**	**p=0.997**
Baseline – 6th month		**p=0.899**	**p=0.258**
Stable	Baseline – 3rd month	**p=0.303**	**p=0.299**
	3rd month – 6th month	**p=0.338**	**p=0.697**
	Baseline – 6th month	**p=0.649**	**p=0.109**
Not Stable	Baseline – 3rd month	**p=0.067**	**p=0.352**
	3rd month – 6th month	**p=0.027***	**p=0.642**
	Baseline – 6th month	**p=0.723**	**p=0.717**

Trial Group (3rd/4th – PP)

As shown on Table 5.4.9.1 within the trial group of the F-scan shod the median value at baseline was 268.67, 285.33 at 3rd month, and 280.87 at 6th month (Table 5.4.9.1). With

regards to F-scan with insole, the median value at baseline was 197, 197.67 at 3rd month, and 232.5 at 6th month (Table 5.4.9.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 183.5, 201.67 at 3rd month and 199.67 at 6th month (Table 5.4.9.3). It is possible to notice a stable trend over the period of 6 months for the trial group. As shown on Table 5.4.9.4 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. As shown on Table 5.4.9.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$).

Comparison between the Control and the Trial Group ($3^{rd}/4^{th}$ – PP)

As shown in Table 5.4.9.6 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at 3rd month ($p<0.05$*), and 6th month ($p<0.05$*). No statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$) in any of the intervals investigated. This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to $3^{rd}/4^{th}$-PP that become particularly evident after 3 and 6 months after initial supply of the FOs.

Table 5.4.9.6: details of the Mann Whitney Test carried out on $3^{rd}/4^{th}$-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

$3^{rd}/4^{th}$ Met. Head – Peak Pressure Values - ($3^{rd}/4^{th}$ -PP) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.157**	**p=0.931**	**p=0.983**
Stable	**p=0.095**	**p=0.719**	**p=0.340**
Not stable	**p=0.702**	**p=0.836**	**p=0.340**
F-Scan – With Insoles	**p=0.355**	**p=0.031***	**p=0.046***
Stable	**p=0.683**	**p=0.067**	**p=0.144**
Not stable	**p=0.524**	**p=0.279**	**p=0.086**
HR Walkway	**p=0.478**	**p=0.952**	**p=0.867**
Stable	**p=0.448**	**p=0.875**	**p=0.914**
Not stable	**p=0.911**	**p=0.924**	**p=0.750**

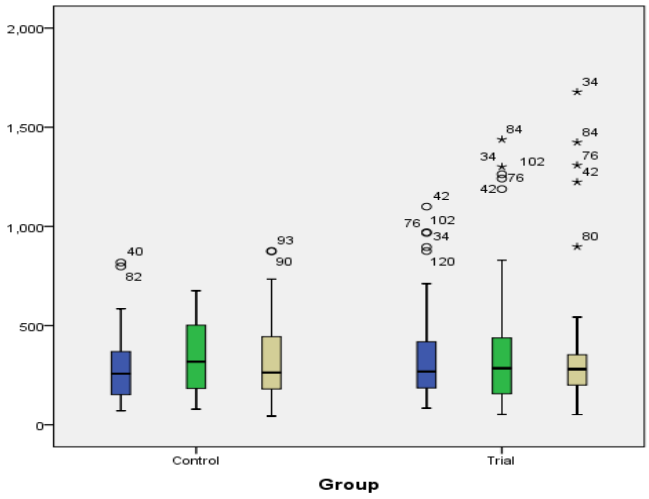


Figure 5.4.9.1: boxplot carried out on F-Scan Shod – 3rd-4th met. head PP data between control and trial patients at baseline, 3rd month and 6th month.

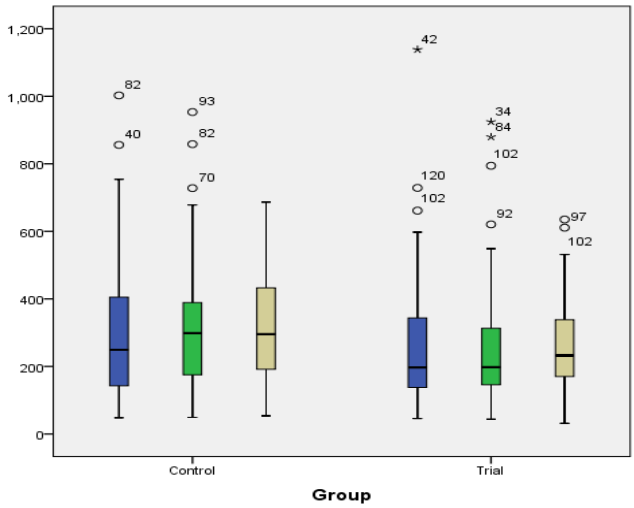


Figure 5.4.9.2: boxplot carried out on F-Scan with insole - 3rd-4th met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval.

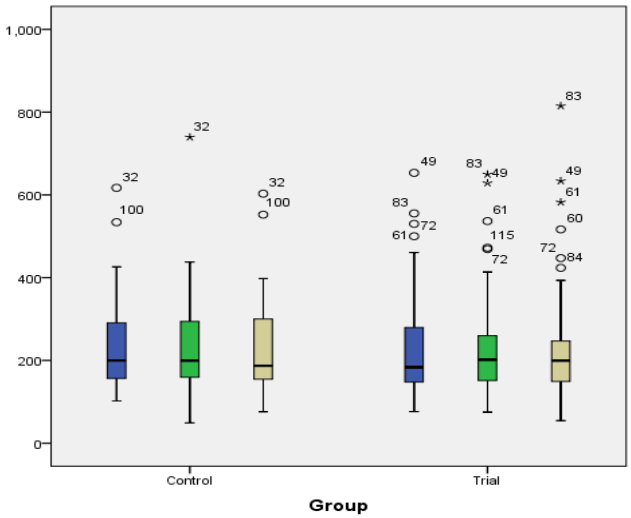


Figure 5.4.9.3: boxplot carried out on HR Walkway - 3rd-4th met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval.

3rd / 4th - Pressure Time Integral (3rd/4th -PTI)

Control Group (3rd/4th – PTI)

With regards to F-scan shod: the median value at baseline was 53.30, 71.81 at 3rd month and 59.98 at 6th month (Table 5.4.9.7).

Table 5.4.9.7: descriptive statistics on 3rd/4th – PTI (F-Scan-Shod) data at baseline, 3rd month and 6th month (control and trial patients).

3rd/4th Met. Head – Pressure Time Integral (3rd/4th - PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	53.30(55.48)	71.81(63.78)	59.98(55.91)	56.69(42.84)	55.97(66.96)	62.79(50.5)

With regards to F-scan With Insole: the median value at baseline was 60.42, 66.25 at 3rd month, and 68.86 at 6th month (Table 5.4.9.8).

Table 5.4.9.8: descriptive statistics on 3rd/4th – PTI (F-Scan-With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

3rd/4th Met. Head – Pressure Time Integral (3rd/4th- PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	60.42(54.81)	66.25(55.44)	68.86(50.31)	49.94(39.19)	50.29(43.66)	54.79(44.2)

With regards to HR Walkway the median value at baseline was 46.93(83.55), 44.74(173.91) at 3rd month and 47.88(80.25) at 6th month (Table 5.4.9.9). It is possible to notice a stable trend over the period of 6 month for the control group.

Table 5.4.9.9: descriptive statistics on 3rd/4th – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

3rd/4th Met. Head – Pressure Time Integral (3rd/4th -PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	46.93(30.96)	44.74(37.49)	47.88(32.21)	41.14(45.04)	43.77(39.07)	42.21(37.73)

As shown on Table 5.4.9.10 the Friedman test shows p>0.05 in all cases, therefore, no significance difference is obtained within the control group. Also when only the stable group is considered separately the same results are obtained (p>0.05). The only exception occurred with the F-Scan (shod) (p<0.05*).

Table 5.4.9.10: details of the Friedman test on 3rd/4th– PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

3rd/4th Met. Head – Pressure Time Integral (3rd/4th -PTI) - Friedman		
	Control	Trial
F-Scan - Shod	p=0.032*	p=0.551
Stable	p=0.057	p=0.323
Not stable	p=0.142	p=0.829
F-Scan – With Insoles	p=0.687	p=0.533
Stable	p=0.358	p=0.822
Not stable	p=0.705	p=0.269
HR Walkway	p=0.109	p=0.598
Stable	p=0.717	p=0.494
Not stable	p=0.022	p=0.939

Table 5.4.9.11 highlighted that most intervals are not significantly different (p>0.05). Significant changes were only found with F-Scan (Shod) at baseline-3rdmonth (p<0.05*) also for its correspondent stable group only (p<0.05*). During the interval within 3rdmonth-6thmonth for the stable control group of the F-Scan (shod) and the HR Walkway, significant changes were found (p<0.05*). It is possible to notice a quite unclear trend over the period of 6 months for the 3rd/4th PTI.

Table 5.4.9.11: details of the Wilcoxon's test on Total-PT data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

3rd/4th Met. Head – Pressure Time Integral (3rd/4th -PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.018**	**p=0.858**
3rd month – 6th month		**p=0.296**	**p=0.597**
Baseline – 6th month		**p=0.066**	**p=0.285**
Stable	Baseline – 3rd month	**p=0.020***	**p=0.806**
	3rd month – 6th month	**p=0.021***	**p=0.650**
	Baseline – 6th month	**p=0.172**	**p=0.096**
Not Stable	Baseline – 3rd month	**p=0.601**	**p=0.438**
	3rd month – 6th month	**p=0.247**	**p=0.796**
	Baseline – 6th month	**p=0.135**	**p=0.605**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.719**	**p=0.558**
3rd month – 6th month		**p=0.304**	**p=0.980**
Baseline – 6th month		**p=0.660**	**p=0.592**
Stable	Baseline – 3rd month	**p=0.280**	**p=0.883**
	3rd month – 6th month	**p=0.167**	**p=0.909**
	Baseline – 6th month	**p=0.10**	**p=0.978**
Not Stable	Baseline – 3rd month	**p=0.411**	**p=0.109**
	3rd month – 6th month	**p=0.852**	**p=0.836**
	Baseline – 6th month	**p=0.526**	**p=0.352**
HR Walkway			
Baseline – 3rd month		**p=0.580**	**p=0.809**
3rd month – 6th month		**p=0.190**	**p=0.638**
Baseline – 6th month		**p=0.310**	**p=0.875**
Stable	Baseline – 3rd month	**p=0.500**	**p=0.650**
	3rd month – 6th month	**p=1.00**	**p=0.578**
	Baseline – 6th month	**p=0.881**	**p=0.674**
Not Stable	Baseline – 3rd month	**p=0.940**	**p=0.877**
	3rd month – 6th month	**p=0.023***	**p=0.959**
	Baseline – 6th month	**p=0.117**	**p=0.278**

Trial Group (3rd/4th – PTI)

As shown on Table 5.4.9.7 within the trial group of the F-scan shod all appointments were carried out over the whole duration of the trial, and no missing data was recorded:

the median value at baseline was 56.69, 55.97 at 3rd month, and 62.79 at 6th month (Table 5.4.9.7). With regards to F-scan with insole, the median value at baseline was 49.94, 50.29 at 3rd month, and 54.79 at 6th month (Table 5.4.9.8). With regards to HR Walkway, the median value at baseline was 41.14, 43.77 at 3rd month and 42.21 at 6th month (Table 5.4.9.9). It is possible to notice a stable trend over the period of 6 months for the trial group.

As shown on Table 5.4.9.10 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. Statistical difference was not obtained ($p>0.05$) when stable group is considered separately. The non-stable group was found to be not significance difference ($p>0.05$). As shown on Table 5.4.9.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all intervals considered with the stable-groups ($p>0.05$). It is possible to notice a stable trend over the period of 6 months.

Comparison between the Control and the Trial Group ($3^{rd}/4^{th}$ – PTI)

Mann Whitney Test highlighted that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan (shod & with insole). Statistical difference was noted at 3rd month only with the stable F-scan (with insole) group. This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to $3^{rd}/4^{th}$-PTI.

Table 5.4.9.12: details of the Mann Whitney Test carried out on $3^{rd}/4^{th}$ – PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

$3^{rd}/4^{th}$ Met. Head – Pressure Time Integral ($3^{rd}/4^{th}$ -PTI) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.146**	**p=0.731**	**p=0.755**
Stable	**p=0.189**	**p=0.703**	**p=0.385**
Not stable	**p=0.390**	**p=0.975**	**p=0.504**
F-Scan – With Insoles	**p=0.248**	**p=0.052**	**p=0.174**
Stable	**p=0.336**	**p=0.033***	**p=0.161**
Not stable	**p=0.874**	**p=0.726**	**p=0.774**
HR Walkway	**p=0.672**	**p=0.996**	**p=0.592**
Stable	**p=0.259**	**p=0.450**	**p=0.372**
Not stable	**p=0.408**	**p=0.226**	**p=0.524**

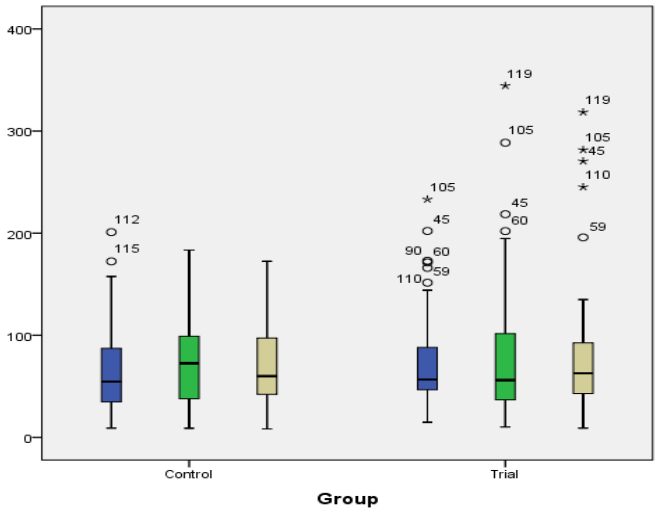


Figure 5.4.9.4: boxplot carried out on F-Scan Shod – 3rd-4th month PTI data between control and trial patients at baseline, 3rd month and 6th month.

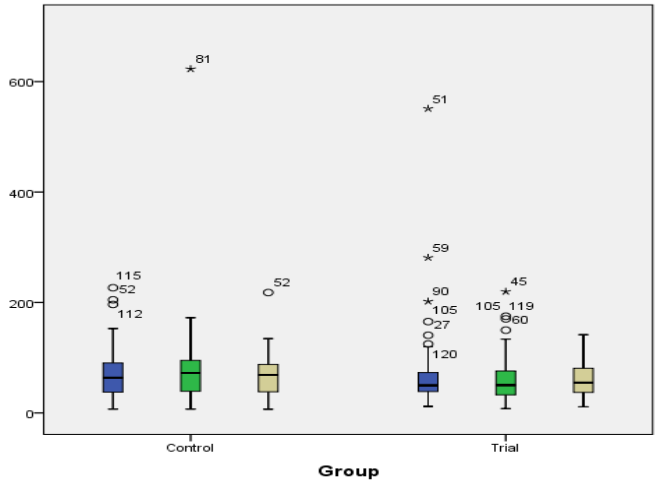


Figure 5.4.9.5: boxplot carried out on F-Scan with insole - 3rd-4th month PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

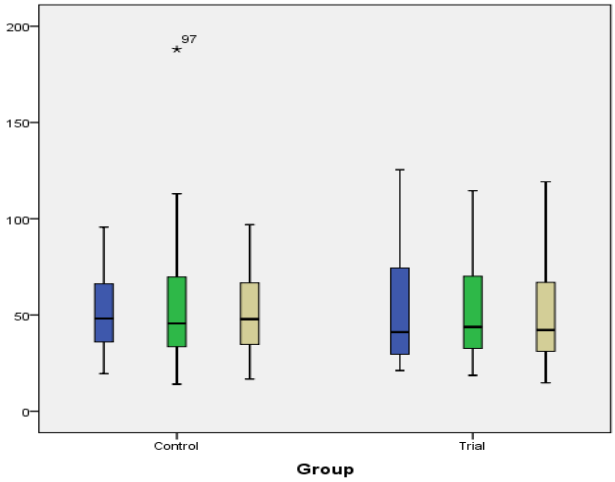


Figure 5.4.9.6: boxplot carried out on HR Walkway – Total PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.10. 2nd Metatarsal Head – Contact

2nd - Peak Pressure Values- (2nd -PP)

Control Group (2nd –PP)

With regards to F-scan shod: the median (IQR) value at baseline was 223.17, 286 at 3rd month and 302 at 6th month (Table 5.4.10.1).

Table 5.4.10.1: descriptive statistics on 2nd – PP (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients)

2nd Met. Head – Peak Pressure Values (2nd -PP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	223.17(264.09)	286(315.16)	302(384.33)	302.17(278.83)	314.5(372.58)	320.5(335.92)

With regards to F-scan With Insole: median value at baseline was 237, 288.67 at 3rd month, and 332.17 at 6th month (Table 5.4.10.2).

Table 5.4.10.2: descriptive statistics on 2nd – PP(F-Scan With Insole) data at baseline, 3rd month and 6th month (control and trial patients)

2nd Met. Head – Peak Pressure Values- (2nd PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	237(269.5)	288.67(249.5)	332.17(286.59)	221.17(228.75)	246.83(189.67)	230.83(229.92)

With regards to HR Walkway the median value at baseline was 226.5, 208 at 3rd month and 218 at 6th month (Table 5.4.10.3). It is possible to notice a stable trend over the period of 6 months for the control group for the HR Walkway measurements only. Instead, the F-scan (insole and shod) measurements did not seem to have a stable trend.

Table 5.4.10.3: descriptive statistics on 2nd – PP(HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients)

2nd Met. Head – Peak Pressure Values(2nd- PP) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	226.5(166.75)	208(182.59)	218(179.16)	221.83(151.17)	221.67(170.58)	222.17(193)

As shown on Table 5.4.10.4 the Friedman test shows p<0.05* for the F-scan Shod (p<0.05*). Instead, in all other cases, no significance difference is obtained within the control group for the F-scan with insole (p>0.05), and HR Walkway (p>0.05).

Table 5.4.10.4: details of the Friedman test on 2nd – PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

2nd Met Head – Peak Pressure Values (2nd PP) Friedman Test (baseline, 3rd & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.013*	p=0.675
Stable	p=0.307	p=0.457
Not stable	p=0.004**	p=0.814
F-Scan – With Insoles	p=0.019*	p=0.904
Stable	p=0.205	p=0.266
Not stable	p=0.019*	p=0.110
HR Walkway	p=0.241	p=0.432
Stable	p=0.823	p=0.544
Not stable	p=0.004**	p=0.779

Table 5.4.10.5 highlighted there is statistical difference within the control groups with F-scan (shod) at baseline-3rdmonth (p<0.05*) and baseline-6th month; with F-Scan (with insole) at baseline-6th month (p<0.05*); and HR Walkway at 3rdmonth-6thmonth. It is possible to notice a not stable trend over the period of 6 months for the control group.

Table 5.4.10.5: details of the Wilcoxon's test on 2nd-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

2nd Met. Head – Peak Pressure Values(2nd PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.039***	**p=0.191**
3rd month – 6th month		**p=0.340**	**p=0.860**
Baseline – 6th month		**p=0.008****	**p=0.430**
Stable	Baseline – 3rd month	**p=0.107**	**p=0.08**
	3rd month – 6th month	**p=0.414**	**p=0.996**
	Baseline – 6th month	**p=0.213**	**p=0.345**
Not Stable	Baseline – 3rd month	**p=0.232**	**p=0.335**
	3rd month – 6th month	**p=0.017***	**p=0.865**
	Baseline – 6th month	**p=0.009****	**p=0.959**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.267**	**p=0.318**
3rd month – 6th month		**p=0.091**	**p=0.705**
Baseline – 6th month		**p=0.021***	**p=0.274**
Stable	Baseline – 3rd month	**p=0.049**	**p=0.160**
	3rd month – 6th month	**p=0.962**	**p=0.474**
	Baseline – 6th month	**p=0.153**	**p=0.042**
Not Stable	Baseline – 3rd month	**p=0.313**	**p=0244**
	3rd month – 6th month	**p=0.02***	**p=0.605**
	Baseline – 6th month	**p=0.048***	**p=0.098**
HR Walkway			
Baseline – 3rd month		**p=0.159**	**p=0.195**
3rd month – 6th month		**p=0.025***	**p=0.983**
Baseline – 6th month		**p=0.899**	**p=0.121**
Stable	Baseline – 3rd month	**p=0.425**	**p=0.353**
	3rd month – 6th month	**p=0.771**	**p=0.694**
	Baseline – 6th month	**p=0.753**	**p=0.221**
Not Stable	Baseline – 3rd month	**p=0.002****	**p=0.379**
	3rd month – 6th month	**p=0.002****	**p=0.501**
	Baseline – 6th month	**p=0.478**	**p=0.326**

Trial Group (2nd – PP)

As shown on Table 5.4.10.1 within the trial group of the F-scan shod the median value at baseline was 302.27, 314.5 at 3rd month, and 320.5 at 6th month (Table 5.4.10.1).

With regards to F-scan with insole, the median value at baseline was 221.17, 246.83 at 3rd month, and 230.83 at 6th month (Table 5.4.10.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 221.83, 221.67 at 3rd month and 222.17 at 6th month (Table 5.4.10.3). It is possible to notice a stable trend over the period of 6 months for the trial group. Also the values of the F-Scan (with insole) clearly appeared lower than those with F-Scan (shod).

As shown on Table 5.4.10.4 the Friedman test displayed a $p>0.05$, hence there is no statistical difference within the trial group compared to the control group. As shown on Table 5.4.10.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$). It is possible to notice a stable trend over the period of 6 months for the trial group.

Comparison between the Control and the Trial Group (2nd – PP)

As shown in Table 5.4.10.6 results highlighted that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at 6th month ($p<0.05$*). No statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$) in any of the intervals investigated. This suggests that only at 6th month with the F-Scan (with insole) there is a clear trend towards changes that happen between the control and the trial group with regards to 2nd-PP.

Table 5.4.10.6: details of the Mann Whitney Test carried out on 2nd-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

2nd Met. Head – Peak Pressure Values - (2nd -PP) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.062	p=0.289	p=0.620
Stable	p=0.078	p=0.199	p=0.313
Not stable	p=0.514	p=0.975	p=0.975
F-Scan – With Insoles	p=0.401	p=0.291	p=0.017*
Stable	p=0.673	p=0.429	p=0.154
Not stable	p=0.514	p=0.426	p=0.042
HR Walkway	p=0.891	p=0.306	p=0.465
Stable	p=0.826	p=0.500	p=0.357
Not stable	p=0.667	p=0.265	p=0.899

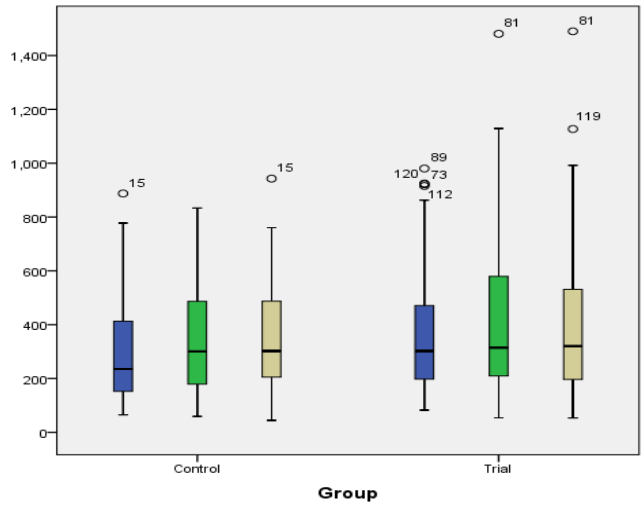


Figure 5.4.10.1: boxplot carried out on F-Scan Shod – 2nd met. head PP data between control and trial patients at baseline, 3rd month and 6th month.

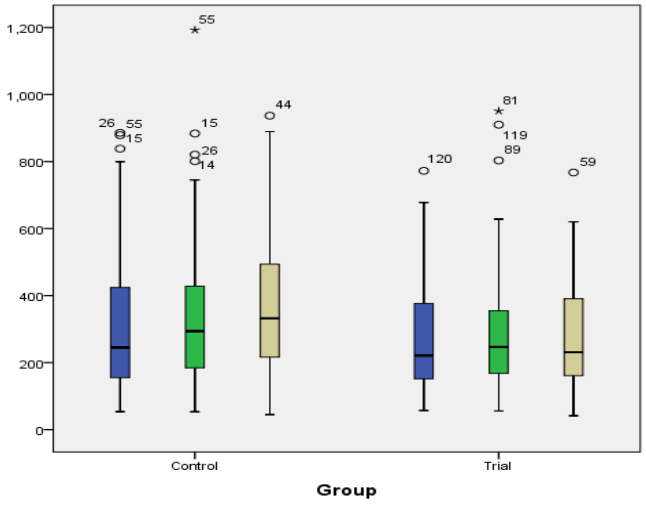


Figure 5.4.10.2: boxplot carried out on F-Scan with insole – 2nd met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval

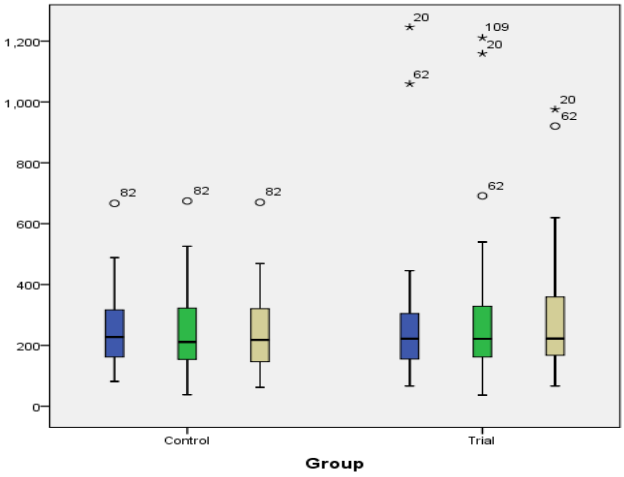


Figure 5.4.10.3: boxplot carried out on HR Walkway – 2nd met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval.

2nd - Pressure Time Integral (2nd -PTI)

Control Group (2nd – PTI)

With regards to F-scan shod: the median value at baseline was 49.77, 70.59 at 3rd month and 63.69 at 6th month (Table 5.4.10.7).

Table 5.4.10.7: descriptive statistics on 2nd – PTI (F-Scan-Shod) data at baseline, 3rd month and 6th month (control and trial patients).

2nd Met. Head – Pressure Time Integral (2nd - PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	49.77(64.18)	70.59(63.2)	63.69(68.45)	63.03(49.71)	56.34(75.09)	65.13(59.47)

With regards to F-scan With Insole: the median value at baseline was 58.03, 60.61 at 3rd month, and 72.07 at 6th month (Table 5.4.10.8).

Table 5.4.10.8: descriptive statistics on 2nd– PTI (F-Scan-with insole) data at baseline, 3rd month and 6th month (control and trial patients)

2nd Met. Head – Pressure Time Integral (2nd- PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	58.03(57.11)	60.61(59.68)	72.07(62.59)	48.93(50.8)	53.96(56.29)	49.37(56.29)

With regards to HR Walkway the median value at baseline was 55.85, 49.75 at 3rd month and 52.91 at 6th month (Table 5.4.10.9). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.10.9: descriptive statistics on 2nd – PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

2nd Met. Head – Pressure Time Integral (2nd -PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	55.85(38.63)	49.75(38.17)	52.91(30.01)	49.24(36.43)	53.63(42.14)	45.83(38.14)

As shown on Table 5.4.10.10 the Friedman test shows p<0.05* only for the HR Walkway (also for the stable group). The rest of the tests showed p>0.05. It is possible to notice a stable trend over the period of 6 months for the control group with the exception of HR Walkaway data.

Table 5.4.10.10: details of the Friedman test on 2nd– PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

2nd Met. Head – Pressure Time Integral (2nd -PTI) - Friedman		
	Control	Trial
F-Scan - Shod	p=0.793	p=0.686
Stable	p=0.823	p=0.344
Not stable	p=0.142	p=0.459
F-Scan – With Insoles	p=0.302	p=0.713
Stable	p=0.697	p=0.393
Not stable	p=0.605	p=0.039*
HR Walkway	p=0.047*	p=0.736
Stable	p=0.697	p=0.706
Not stable	p=0.008**	p=0.829

Table 5.4.10.11 highlighted that most intervals are not significantly different (p>0.05). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.10.11: details of the Wilcoxon's test on 2nd-PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

2nd Met. Head – Pressure Time Integral (2nd -PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.898**	**p=0.499**
3rd month – 6th month		**p=0.732**	**p=0.432**
Baseline – 6th month		**p=0.260**	**p=0.611**
Stable	Baseline – 3rd month	**p=0.833**	**p=0.223**
	3rd month – 6th month	**p=0.346**	**p=0.461**
	Baseline – 6th month	**p=0.789**	**p=0.317**
Not Stable	Baseline – 3rd month	**p=0.881**	**p=0.326**
	3rd month – 6th month	**p=0.044**	**p=0.776**
	Baseline – 6th month	**p=0.100**	**p=0.501**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.985**	**p=0.919**
3rd month – 6th month		**p=0.253**	**p=0.975**
Baseline – 6th month		**p=0.195**	**p=0.646**
Stable	Baseline – 3rd month	**p=0.380**	**p=0.192**
	3rd month – 6th month	**p=0.530**	**p=0.823**
	Baseline – 6th month	**p=0.802**	**p=0.552**
Not Stable	Baseline – 3rd month	**p=0.296**	**p=0.010***
	3rd month – 6th month	**p=0.003****	**p=0.717**
	Baseline – 6th month	**p=0.037***	**p=0.056**
HR Walkway			
Baseline – 3rd month		**p=0.089**	**p=0.558**
3rd month – 6th month		**p=0.06**	**p=0.558**
Baseline – 6th month		**p=0.100**	**p=0.558**
Stable	Baseline – 3rd month	**p=0.788**	**p=0.756**
	3rd month – 6th month	**p=0.499**	**p=0.523**
	Baseline – 6th month	**p=0.671**	**p=0.596**
Not Stable	Baseline – 3rd month	**p=0.008****	**p=0.756**
	3rd month – 6th month	**p=0.028***	**p=0.877**
	Baseline – 6th month	**p=0.411**	**p=0.836**

Trial Group (2nd – PTI)

As shown on Table 5.4.10.7 within the trial group of the F-scan shod the median value at baseline was 63.03, 66.34 at 3rd month, and 66.34 at 6th month (Table 5.4.10.7). With

regards to F-scan with insole, the median value at baseline was 48.93, 53.96 at 3rd month, and 49.37 at 6th month (Table 5.4.10.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 49.24, 53.63 at 3rd month and 45.83 at 6th month (Table 5.4.10.9). It is possible to notice a stable trend over the period of 6 months for the trial group which is lower than the control groups.

The Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group. Wilcoxon's test highlighted no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$).

Comparison between the Control and the Trial Group (2nd – PTI)

As shown in Table 5.4.10.12 results showed that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at 6th month ($p<0.05$*). No statistical difference was discovered while using F-scan shod and HR walkway ($p>0.05$) in any of the intervals investigated. This suggests that only at 6th month with F-Scan (with insole) there is a clear trend toward changes that happen between the control and the trial group with regards to 2nd-PTI.

Table 5.4.10.12: details of the Mann Whitney Test carried out on 2nd -PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

2nd Met. Head – Pressure Time Integral (2nd-PTI) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.673**	**p=0.221**	**p=0.586**
Stable	**p=0.120**	**p=0.327**	**p=0.274**
Not stable	**p=0.340**	**p=0.408**	**p=0.633**
F-Scan – With Insoles	**p=0.495**	**p=0.380**	**p=0.035***
Stable	**p=0.369**	**p=0.424**	**p=0.167**
Not stable	**p=0.874**	**p=0.588**	**p=0.111**
HR Walkway	**p=0.807**	**p=0.219**	**p=0.836**
Stable	**p=0.925**	**p=0.514**	**p=0.572**
Not stable	**p=0.484**	**p=0.152**	**p=0.656**

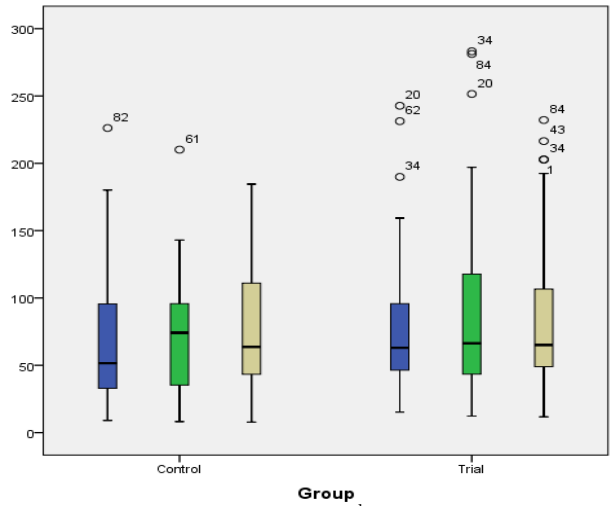


Figure 5.4.10.4: boxplot carried out on F-Scan Shod – 2nd met. head PTI data between control and trial patients at baseline, 3rd month and 6th month.

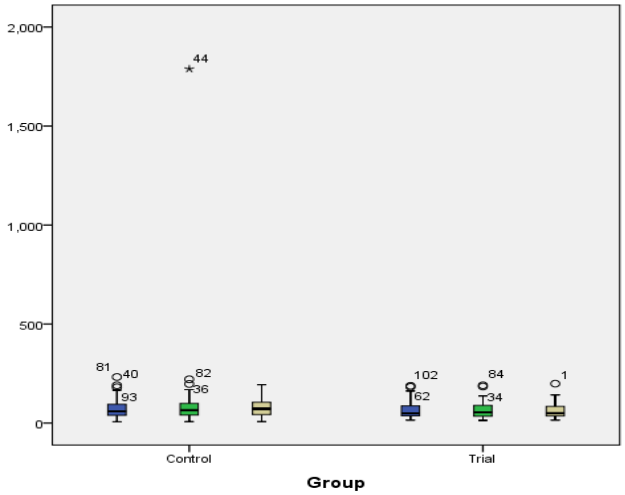


Figure 5.4.10.5: boxplot carried out on F-Scan with insole – 2nd met. head PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

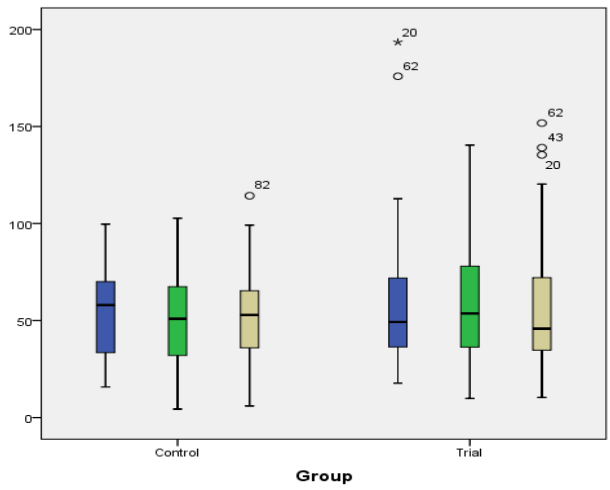


Figure 5.4.10.6: boxplot carried out on HR Walkway – 2nd met. head PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.11. 1st metatarsal head - Contact

1st - Peak Pressure Values- (1st -PP)

Control Group (1st – PP)

With regards to F-scan shod: the median value at baseline was 166, 188 at 3rd month and 172.83 at 6th month (Table 5.4.11.1).

Table 5.4.11.1: descriptive statistics on 1st – PP (F-Scan -Shod) data at baseline, 3rd month and 6th month (control and trial patients).

1st Met. Head – Peak Pressure Values (1st -PP) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	166(151.42)	188(152.66)	172.83(135.42)	176.33(184.67)	202.17(198.83)	186.67(174.41)

With regards to F-scan With Insole: the median value at baseline was 178.5, 163 at 3rd month, and 198 at 6th month (Table 5.4.11.2).

Table 5.4.11.2: descriptive statistics on 1st – PP (F-Scan – with insole) data at baseline, 3rd month and 6th month (control and trial patients).

1st Met. Head – Peak Pressure Values (1st -PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	178.5(154.16)	163(155.79)	198(149.33)	143.5(107.25)	161.5(168.75)	155.67(146.66)

With regards to HR Walkway the median value at baseline was 160.67, 158.83 at 3rd month and 161.33 at 6th month (Table 5.4.11.3). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.11.3: descriptive statistics on 1st – PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients)

1st Met. Head – Peak Pressure Values (1st- PP) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	160.67(121.08)	158.83(94.41)	161.33(107.92)	138.5(96.5)	152.17(96.92)	162.5(93.25)

The Friedman test showed p>0.05 for the F-scan Shod. No significance difference is obtained within the control group for the F-scan with insole (p>0.05), and HR Walkway (p>0.05) (Table 5.4.11.4). Similarly, it is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.11.4: details of the Friedman test on 1st – PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

1st Met Head – Peak Pressure Values (1st-PP) Friedman Test (baseline, 3rd & 6th month)		
	Control	Trial
F-Scan - Shod	p=0.206	p=0.216
Stable	p=0.477	p=0.333
Not stable	p=0.387	p=0.646
F-Scan – With Insoles	p=0.427	p=0.308
Stable	p=0.856	p=0.931
Not stable	p=0.350	p=0.047*
HR Walkway	p=0.982	p=0.543
Stable	p=0.459	p=0.142
Not stable	p=0.754	p=0.505

Table 5.4.11.5 highlighted that there is no statistical difference within the control groups with F-scan (shod & with insole) and HR Walkway in all intervals.

Table 5.4.11.5: details of the Wilcoxon's test on 1st-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

1st Met. Head – Peak Pressure Values (1st- PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.441**	**p=0.141**
3rd month – 6th month		**p=0.509**	**p=0.608**
Baseline – 6th month		**p=0.087**	**p=0.288**
Stable	Baseline – 3rd month	**p=0.432**	**p=0.382**
	3rd month – 6th month	**p=0.588**	**p=0.631**
	Baseline – 6th month	**p=0.189**	**p=0.307**
Not Stable	Baseline – 3rd month	**p=0.970**	**p=0.148**
	3rd month – 6th month	**p=0.737**	**p=0.877**
	Baseline – 6th month	**p=0.232**	**p=0.679**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.293**	**p=0.318**
3rd month – 6th month		**p=0.135**	**p=0.902**
Baseline – 6th month		**p=0.479**	**p=0.546**
Stable	Baseline – 3rd month	**p=0.863**	**p=0.917**
	3rd month – 6th month	**p=0.638**	**p=0.991**
	Baseline – 6th month	**p=0.707**	**p=0.795**
Not Stable	Baseline – 3rd month	**p=0.126**	**p=0.030***
	3rd month – 6th month	**p=0.052**	**p=0.836**
	Baseline – 6th month	**p=0.455**	**p=0.134**
HR Walkway			
Baseline – 3rd month		**p=0.777**	**p=0.530**
3rd month – 6th month		**p=0.769**	**p=0.405**
Baseline – 6th month		**p=0.760**	**p=0.102**
Stable	Baseline – 3rd month	**p=0.557**	**p=0.302**
	3rd month – 6th month	**p=0.777**	**p=0.764**
	Baseline – 6th month	**p=0.311**	**p=0.317**
Not Stable	Baseline – 3rd month	**p=0.126**	**p=0.569**
	3rd month – 6th month	**p=0.911**	**p=0.334**
	Baseline – 6th month	**p=0.490**	**p=0.098**

Trial Group (1st – PP)

As shown on Table 5.4.11.1 within the trial group of the F-scan shod the median value at baseline was 176.33, 202.17 at 3rd month, and 186.67 at 6th month (Table 5.4.11.1).

With regards to F-scan with insole, the median value at baseline was 143.5, 161.5 at 3rd month, and 155.67 at 6th month (Table 5.4.11.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 138.5, 152.17 at 3rd month and 162.5 at 6th month (Table 5.4.11.3). It is possible to notice a stable trend over the period of 6 months and also F-Scan (with insole) data appeared to be lower than the F-Scan (shod).

Friedman's test was carried out; as shown on Table 5.4.11.4 the Friedman test displayed a $p>0.05$, hence there is no statistical difference within the trial group. As shown on Table 5.4.11.5 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$).

Comparison between the Control and the Trial Group (1st – PP)

As shown in Table 5.4.11.6 results highlighted that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan shod ($p>0.05$) and with insole ($p>0.05$) and HR walkway ($p>0.05$). This suggests that there is a stable trend toward changes that happen between the control and the trial group with regards to 1st-PP.

Table 5.4.11.6: details of the Mann Whitney Test carried out on Heel-PT with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

1st Met. Head – Peak Pressure Values- (1st -PP) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.200	p=0.223	p=0.417
Stable	p=0.136	p=0.202	p=0.254
Not stable	p=0.886	p=0.899	p=0.726
F-Scan – With Insoles	p=0.578	p=0.881	p=0.298
Stable	p=0.341	p=0.787	p=0.562
Not stable	p=0.656	p=0.762	p=0.152
HR Walkway	p=0.329	p=0.830	p=0.872
Stable	p=0.489	p=0.875	p=0.877
Not stable	p=0.494	p=0.824	p=0.656

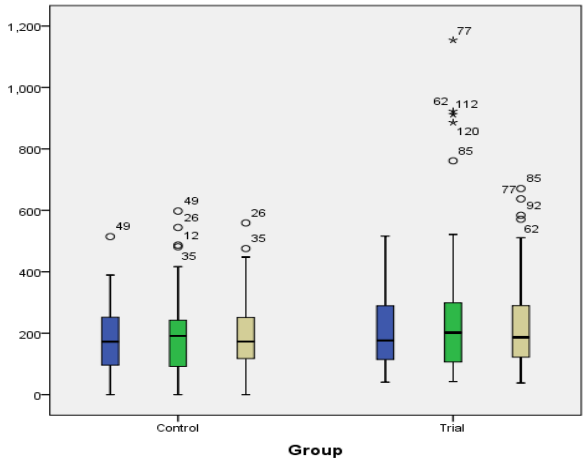


Figure 5.4.11.1: boxplot carried out on F-Scan Shod -1st met. head PP data between control and trial patients at baseline, 3rd month and 6th month.

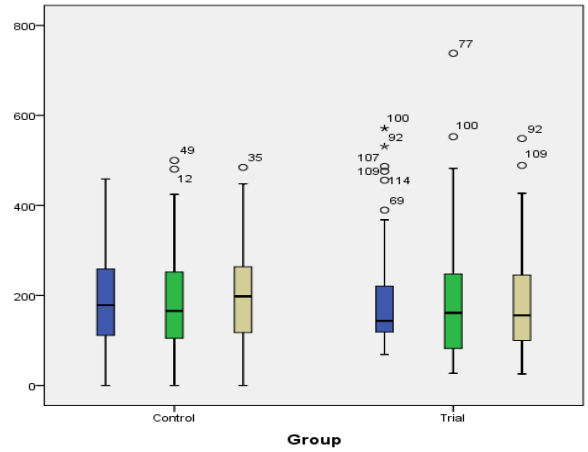


Figure 5.4.11.2: boxplot carried out on F-Scan with insole - 1st met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval.

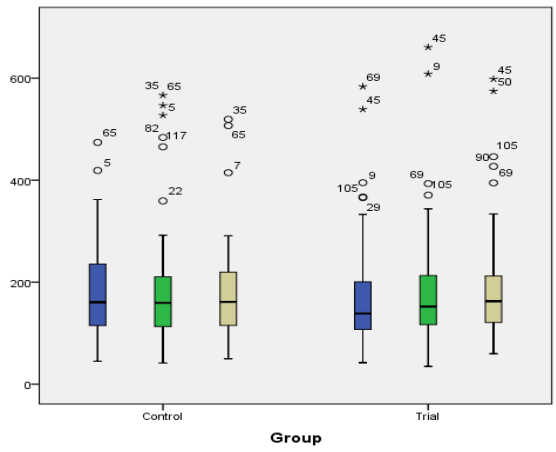


Figure 5.4.11.3: boxplot carried out on HR Walkway – 1st met. head PP data between control and trial patients at baseline, 3rd month and 6th month interval.

1st - Pressure Time Integral (1st -PTI)

Control Group (1st PTI)

With regards to F-scan shod: the median value at baseline was 40.55, 33.53 at 3rd month and 34.53 at 6th month (Table 5.4.11.7).

Table 5.4.11.7: descriptive statistics on 1st PTI (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

1st Met. Head – Pressure Time Integral (1st - PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	40.55(37.98)	33.53(36.61)	34.53(28.68)	37.73(57.17)	39.76(126.07)	32.24(83.37)

With regards to F-scan With Insole: the median value at baseline was 39.7, 36.92 at 3rd month, and 39.90 at 6th month (Table 5.4.11.8).

Table 5.4.11.8: descriptive statistics on 1st PTI (F-Scan-With Insole) data at baseline, 3rd month and 6th month (control and trial patients)

1st Met. Head – Pressure Time Integral (1st- PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	39.70(33.69)	36.92(36.22)	39.90(25.43)	33.67(34.2)	35.74(41.14)	28.92(30.37)

With regards to HR Walkway the median value at baseline was 40.39, 35.89 at 3rd month and 38.88 at 6th month (Table 5.4.11.9). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.11.9: descriptive statistics on 1st PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

1st Met. Head – Pressure Time Integral (1st -PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	40.39(24..82)	35.89(22.47)	38.88(24.93)	30.41(22.94)	35.29(22.74)	36.79(20.73)

As shown on Table 5.4.11.10 the Friedman test shows p>0.05 for the F-scan (shod and with insole) and HR Walkway (also for the stable group). It is possible to notice a stable trend over the period of 6 months.

Table 5.4.11.10: details of the Friedman test on 1st PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

1st Met. Head –Pressure Time Integral (1st-PTI) - Friedman		
	Control	Trial
F-Scan - Shod	p=0.945	p=0.500
Stable	p=0.913	p=0.266
Not stable	p=0.638	p=0.646
F-Scan – With Insoles	p=0.549	p=0.198
Stable	p=0.795	p=0.274
Not stable	p=0.086	p=0.276
HR Walkway	p=0.244	p=0.713
Stable	p=0.920	p=0.937
Not stable	p=0.011*	p=0.472

Wilcoxon's test was carried out which highlighted no statistical difference within the intervals (p>0.05) (Table 5.4.11.11).

Table 5.4.11.11: details of the Wilcoxon's test on 1st-PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

1st Met. Head – Pressure Time Integral (1st -PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.940**	**p=0.542**
3rd month – 6th month		**p=0.574**	**p=0.175**
Baseline – 6th month		**p=0.418**	**p=0.925**
Stable	Baseline – 3rd month	**p=0.935**	**p=1.00**
	3rd month – 6th month	**p=0.936**	**p=0.120**
	Baseline – 6th month	**p=0.837**	**p=0.857**
Not Stable	Baseline – 3rd month	**p=0.737**	**p=0.088**
	3rd month – 6th month	**p=0.232**	**p=1.00**
	Baseline – 6th month	**p=0.218**	**p=0.877**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.206**	**p=0.623**
3rd month – 6th month		**p=0.990**	**p=0.508**
Baseline – 6th month		**p=0.210**	**p=0.078**
Stable	Baseline – 3rd month	**p=0.765**	**p=0.987**
	3rd month – 6th month	**p=0.256**	**p=0.277**
	Baseline – 6th month	**p=0.367**	**p=0.160**
Not Stable	Baseline – 3rd month	**p=0.014***	**p=0.256**
	3rd month – 6th month	**p=0.145**	**p=0.501**
	Baseline – 6th month	**p=0.296**	**p=0.326**
HR Walkway			
Baseline – 3rd month		**p=0.410**	**p=0.611**
3rd month – 6th month		**p=0.195**	**p=0.626**
Baseline – 6th month		**p=0.546**	**p=0.266**
Stable	Baseline – 3rd month	**p=0.597**	**p=0.530**
	3rd month – 6th month	**p=0.888**	**p=0.874**
	Baseline – 6th month	**p=0.530**	**p=0.658**
Not Stable	Baseline – 3rd month	**p=0.023***	**p=0.877**
	3rd month – 6th month	**p=0.044***	**p=0.438**
	Baseline – 6th month	**p=0.852**	**p=0.134**

Trial Group (1st PTI)

As shown on Table 5.4.11.7 within the trial group of the F-scan the median value at baseline was 37.73, 39.76 at 3rd month, and 32.24 at 6th month (Table 5.4.11.7). With

regards to F-scan with insole, the median value at baseline was 33.67, 35.74 at 3rd month, and 28.92 at 6th month (Table 5.4.11.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 30.41, 35.29 at 3rd month and 36.79 at 6th month (Table 5.4.11.9). It is possible to notice a stable trend over the period of 6 months for the trial group.

As shown on Table 5.4.11.10 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group. As shown on Table 5.4.11.11 Wilcoxon's test shows that there is no statistical difference during all three intervals, as well as with all interval considered with the stable-groups ($p>0.05$).

Comparison between the Control and the Trial Group (1st PTI)

As shown in Table 5.4.11.12 results showed that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole or shod or HR Walkway ($p>0.05$) in any of the intervals investigated. This suggests that there are no significant changes between the control and the trial group with regards to 1st-PTI.

Table 5.4.11.12: details of the Mann Whitney Test carried out on 1st-PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

1st Met. Head – Pressure Time Integral (1st-PTI) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.355	p=0.311	p=0.609
Stable	p=0.323	p=0.369	p=0.654
Not stable	p=1.0	p=0.750	p=0.874
F-Scan – With Insoles	p=0.208	p=0.610	p=0.119
Stable	p=0.153	p=0.243	p=0.114
Not stable	p=0.849	p=0.588	p=0.679
HR Walkway	p=0.242	p=0.753	p=0.312
Stable	p=0.199	p=0.355	p=0.131
Not stable	p=0.726	p=0.567	p=0.949

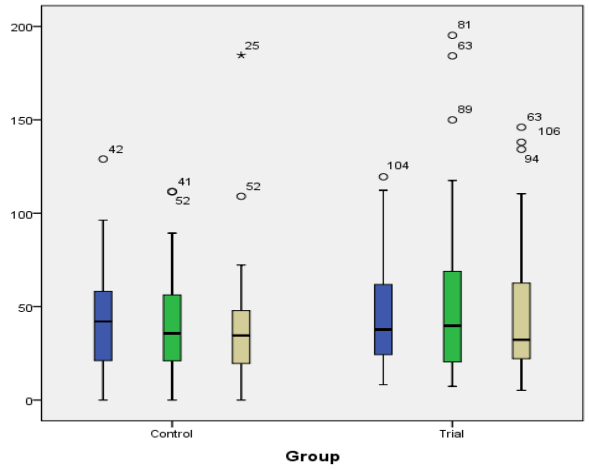


Figure 5.4.11.4: boxplot carried out on F-Scan Shod – 1st met. head PTI data between control and trial patients at baseline, 3rd month and 6th month.

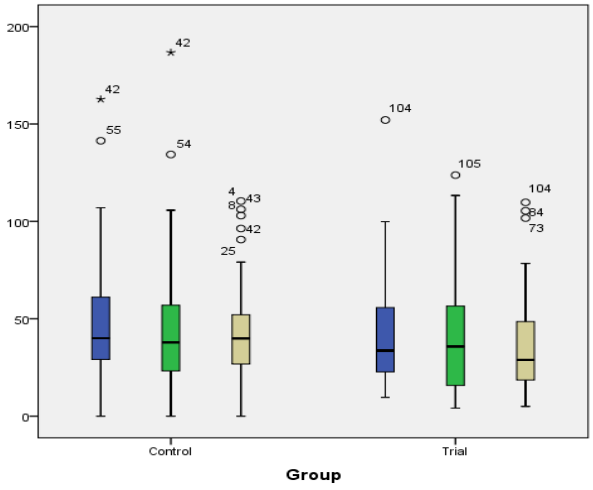
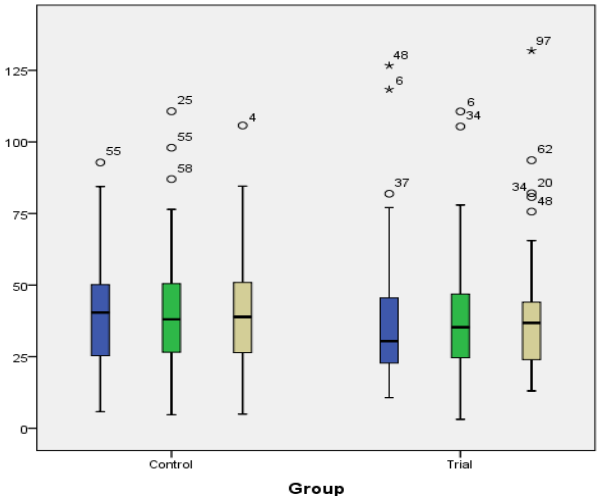


Figure 5.4.11.5: boxplot carried out on F-Scan with insole - 1st met. head PTI data between control and trial patients at baseline, 3rd month and 6th month interval.



boxplot carried out on HR Walkway – 1st met. head PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.12. Lesser Toes contact

Lesser Toes - Peak Pressure Values- (lt -PP)

Control Group (lt-PP)

With regards to F-scan shod: the median value at baseline was 170.67, 147.5 at 3rd month and 163.67 at 6th month (Table 5.4.12.1).

Table 5.4.12.1: descriptive statistics on lt – PP (F-Scan- Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Lesser Toes – Peak Pressure (lt - PP) - F-Scan – Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	170.67(135.34)	147.5(147.75)	163.67(143.25)	149.17(140.09)	159.67(153.33)	179.83(151.5)

With regards to F-scan With Insole: the median value at baseline was 170.67, 174.17 at 3rd month, and 167.33 at 6th month (Table 5.4.12.2).

Table 5.4.12.2: descriptive statistics on lt – PP (F-Scan with Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Lesser Toes – Peak Pressure Values (lt- PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	170.67(136.58)	174.17(146)	167.33(161.58)	155.83(161.16)	140.5(206.17)	182.67(139.67)

With regards to HR Walkway the median value at baseline was 120.67, 116.33 at 3rd month and 122.83 at 6th month (Table 5.4.12.3). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.12.3: descriptive statistics on lt–PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Lesser Toes – Peak Pressure Values (lt -PP) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	120.67(59.58)	116.33(46.17)	122.83(60.34)	120(73.5)	111.17(88.34)	114.83(87.59)

As shown on Table 5.4.12.4 the Friedman test shows p>0.05 for the F-scan (shod and with insole) and HR Walkway (also for the stable group). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.12.4: details of the Friedman test on lt–PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Lesser Toes – Peak Pressure Values (lt-PP) - Friedman		
	Control	Trial
F-Scan - Shod	p=0.221	p=0.258
Stable	p=0.239	p=0.146
Not stable	p=0.522	p=0.175
F-Scan – With Insoles	p=0.432	p=0.643
Stable	p=0.142	p=0.671
Not stable	p=0.538	p=0.646
HR Walkway	p=0.149	p=0.659
Stable	p=0.071	p=0.817
Not stable	p=0.513	p=0.444

Table 5.4.12.5 highlighted that the within intervals are not significantly different (p>0.05) with the exception of F-Scan (with insole) and HR Walkway for the 3rdmonth-6thmonth interval.

Table 5.4.12.5: details of the Wilcoxon's test on lt-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Lesser Toes – Peak Pressure vs. Time (lt-PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.192**	**p=0.780**
3rd month – 6th month		**p=0.854**	**p=0.059**
Baseline – 6th month		**p=0.436**	**p=0.076**
Stable	Baseline – 3rd month	**p=0.232**	**p=0.110**
	3rd month – 6th month	**p=0.974**	**p=0.029**
	Baseline – 6th month	**p=0.502**	**p=0.434**
Not Stable	Baseline – 3rd month	**p=0.575**	**p=0.056**
	3rd month – 6th month	**p=0.737**	**p=0.836**
	Baseline – 6th month	**p=0.852**	**p=0.039**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.361**	**p=0.930**
3rd month – 6th month		**p=0.301**	**p=0.906**
Baseline – 6th month		**p=0.943**	**p=0.894**
Stable	Baseline – 3rd month	**p=0.261**	**p=0.930**
	3rd month – 6th month	**p=0.031***	**p=0.608**
	Baseline – 6th month	**p=0.725**	**p=0.913**
Not Stable	Baseline – 3rd month	**p=0.968**	**p=0.679**
	3rd month – 6th month	**p=0.411**	**p=0.535**
	Baseline – 6th month	**p=0.575**	**p=0.679**
HR Walkway			
Baseline – 3rd month		**p=0.874**	**p=0.266**
3rd month – 6th month		**p=0.052**	**p=0.436**
Baseline – 6th month		**p=0.114**	**p=0.217**
Stable	Baseline – 3rd month	**p=0.936**	**p=0.261**
	3rd month – 6th month	**p=0.037***	**p=0.735**
	Baseline – 6th month	**p=0.161**	**p=0.619**
Not Stable	Baseline – 3rd month	**p=0.709**	**p=0.642**
	3rd month – 6th month	**p=0.679**	**p=0.352**
	Baseline – 6th month	**p=0.502**	**p=0.121**

Trial Group (lt-PP)

As shown on Table 5.4.12.1 within the trial group of the F-scan shod the median value at baseline was 149.17, 159.67 at 3rd month, and 179.83 at 6th month (Table 5.4.12.1). With regards to the F-scan with insole, the median value at baseline was 155.83, 140.5 at 3rd month, and 182.67 at 6th month (Table 5.4.12.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 120, 111.17 at 3rd month and 114.83 at 6th month (Table 5.4.12.3). It is possible to notice a stable trend over the period of 6 months for the trial group.

As shown on Table 5.4.12.4 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group. As shown on Table 5.4.12.5 Wilcoxon's test shows that there is no statistical difference during all three intervals ($p>0.05$). The only interval that was $p<0.05$* was with stable-F-Scan (shod) during the 3rdmonth-6thmonth.

Comparison between the Control and the Trial Group (lt-PP)

As shown in Table 5.4.12.6 results showed that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole or shod or HR walkway ($p>0.05$) in any of the intervals investigated. This suggests that there is a stable trend between the control and the trial group with regards to t-PTI.

Table 5.4.12.6: details of the Mann Whitney Test carried out on lt-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

Lesser Toes – Peak Pressure Values(lt-PP) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.558	p=0.585	p=0.785
Stable	p=0.183	p=0.918	p=0.452
Not stable	p=0.192	p=0.226	p=0.504
F-Scan – With Insoles	p=0.969	p=0.316	p=0.927
Stable	p=0.364	p=0.939	p=0.156
Not stable	p=0.072	p=0.026*	p=0.092
HR Walkway	p=0.875	p=0.891	p=0.555
Stable	p=0.406	p=0.421	p=0.769
Not stable	p=0.077	p=0.356	p=0.484

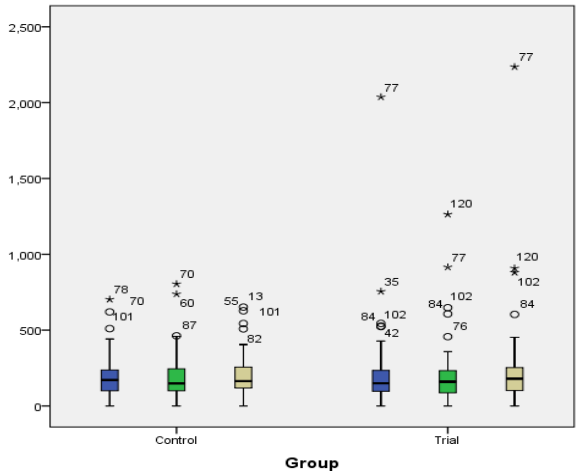


Figure 5.4.12.1: boxplot carried out on F-Scan shod – Lesser Toe PP data between control and trial patients at baseline, 3rd month and 6th month.

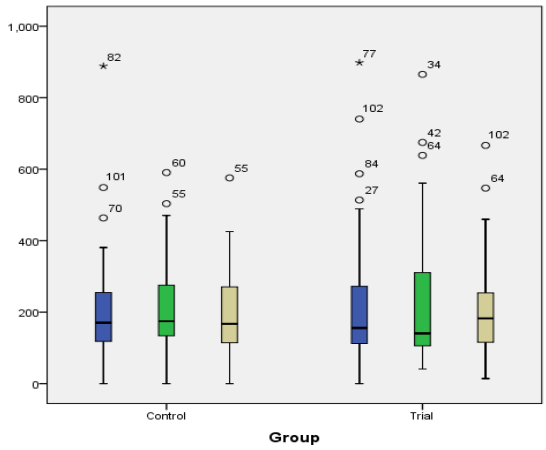


Figure 5.4.12.2: boxplot carried out on F-Scan with insole - Lesser Toe PP data between control and trial patients at baseline, 3rd month and 6th month interval.

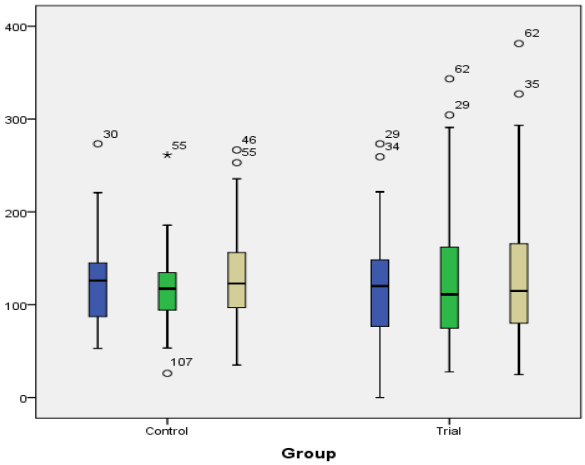


Figure 5.4.12.3: boxplot carried out on HR Walkway – Lesser Toe PP data between control and trial patients at baseline, 3rd month and 6th month interval.

Lesser Toes - Pressure Time Integral (lt-PTI)

Control Group (lt-PTI)

With regards to F-scan shod: the median value at baseline was 26.26, 26.16 at 3rd month and 28.22 at 6th month (Table 5.4.12.7).

Table 5.4.12.7: descriptive statistics on lt-PTI (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Lesser Toes – Pressure Time Integral (lt - PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	26.26(27.42)	26.16(33.22)	28.22(26.01)	27.78(20.18)	25.89(25.89)	32.74(28.95)

With regards to F-scan With Insole: the median value at baseline was 29.4, 30.65 at 3rd month, and 31.7 at 6th month (Table 5.4.12.8).

Table 5.4.12.8: descriptive statistics on lt-PTI (F-Scan With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Lesser Toes –Pressure Time Integral (lt-PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	29.4(27.97)	30.65(24.78)	31.7(21.88)	32.22(38.07)	30.39(37.94)	32.08(35.6)

With regards to HR Walkway the median value at baseline was 14.34, 13.72 at 3rd month and 15.62 at 6th month (Table 5.4.12.9). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.12.9: descriptive statistics on lt-PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Lesser Toes – Pressure Time Integral (lt -PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	14.34(11.74)	13.72(11.94)	15.62(14.37)	16.48(14.23)	15.9(14.3)	15.68(13.4)

As shown on Table 5.4.12.10 the Friedman test shows p>0.05 for the F-scan (shod and with insole) and HR Walkway (also for the stable group). It is possible to notice a stable trend over the period of 6 months within the control group.

Table 5.4.12.10: details of the Friedman test on lt– PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Lesser Toes – Pressure Time Integral (lt-PTI) - Friedman		
	Control	Trial
F-Scan - Shod	p=0.683	p=0.285
Stable	p=0.972	p=0.642
Not stable	p=0.449	p=0.294
F-Scan – With Insoles	p=0.612	p=0.504
Stable	p=0.293	p=0.428
Not stable	p=0.705	p=0.895
HR Walkway	p=0.104	p=0.230
Stable	p=0.111	p=0.205
Not stable	p=0.522	p=0.939

Table 5.4.12.11 highlighted that all results are not significantly different (p>0.05). The only significant interval was found with the HR Walkway at 3rdmonth-6thmonth interval, also for the stable-HR Walkway.

Table 5.4.12.11: details of the Wilcoxon's test on lt-PTI data with F-Scan Shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Lesser Toes – Pressure Time Integral (lt-PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.528**	**p=0.487**
3rd month – 6th month		**p=0.535**	**p=0.088**
Baseline – 6th month		**p=0.993**	**p=0.143**
Stable	Baseline – 3rd month	**p=0.934**	**p=0.340**
	3rd month – 6th month	**p=0.844**	**p=0.234**
	Baseline – 6th month	**p=0.857**	**p=0.674**
Not Stable	Baseline – 3rd month	**p=0.332**	**p=0.826**
	3rd month – 6th month	**p=0.126**	**p=0.255**
	Baseline – 6th month	**p=0.654**	**p=0.030***
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.772**	**p=0.906**
3rd month – 6th month		**p=0.675**	**p=0.549**
Baseline – 6th month		**p=0.615**	**p=0.510**
Stable	Baseline – 3rd month	**p=0.874**	**p=0.635**
	3rd month – 6th month	**p=0.232**	**p=0.379**
	Baseline – 6th month	**p=0.318**	**p=0.353**
Not Stable	Baseline – 3rd month	**p=0.852**	**p=0.427**
	3rd month – 6th month	**p=0.433**	**p=0.796**
	Baseline – 6th month	**p=0.575**	**p=0.756**
HR Walkway			
Baseline – 3rd month		**p=0.994**	**p=0.723**
3rd month – 6th month		**p=0.021***	**p=0.162**
Baseline – 6th month		**p=0.112**	**p=0.246**
Stable	Baseline – 3rd month	**p=0.761**	**p=0.611**
	3rd month – 6th month	**p=0.009****	**p=0.074**
	Baseline – 6th month	**p=0.102**	**p=0.117**
Not Stable	Baseline – 3rd month	**p=0.478**	**p=0.836**
	3rd month – 6th month	**p=0.654**	**p=0.836**
	Baseline – 6th month	**p=0.654**	**p=0.796**

Trial Group (lt-PTI)

As shown on Table 5.4.12.7 within the trial group of the F-scan shod the median value at baseline was 27.78, 25.89 at 3rd month, and 32.74 at 6th month (Table 5.4.12.7). With regards to F-scan with insole, the median value at baseline was 32.22, 30.39 at 3rd month, and 32.08 at 6th month (Table 5.4.12.8). With regards to HR Walkway,

descriptive statistics showed: median value at baseline was 16.48, 15.9 at 3rd month and 15.68 at 6th month (Table 5.4.12.9). As shown on Table 5.4.12.10 the Friedman test displayed a p>0.05 hence there is no statistical difference within the trial group. As shown on Table 5.4.12.11 Wilcoxon's test shows that there is no statistical difference during all three intervals (p>0.05). The only interval that was p<0.05* was with stable-F-Scan (shod) during the 3rdmonth-6thmonth.

Comparison between the Control and the Trial Group (lt-PTI)

As shown in Table 5.4.12.12 results indicated that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole or shod or HR walkway (p>0.05) in any of the intervals investigated. This suggests that no significant changes between the control and the trial group with regards to lt-PTI.

Table 5.4.12.12: details of the Mann Whitney Test carried out on lt-PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means p<0.05, ** means p<0.01.

Lesser Toes –Pressure Integral (lt-PTI) - Mann Whitney Test			
	Baseline	**3rd Month**	**6th Month**
F-Scan - Shod	**p=0.443**	**p=0.517**	**p=0.258**
Stable	**p=0.183**	**p=0.918**	**p=0.452**
Not stable	**p=0.192**	**p=0.226**	**p=0.504**
F-Scan – With Insoles	**p=0.544**	**p=0.618**	**p=0.635**
Stable	**p=0.336**	**p=0.218**	**p=0.270**
Not stable	**p=0.588**	**p=0.226**	**p=0.203**
HR Walkway	**p=0.815**	**p=0.663**	**p=0.225**
Stable	**p=0.723**	**p=0.653**	**p=0.098**
Not stable	**p=0.949**	**p=1.00**	**p=0.679**

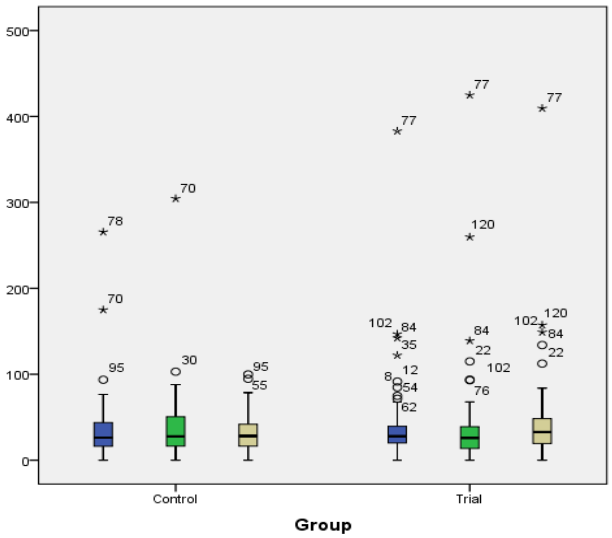


Figure 5.4.12.4: boxplot carried out on F-Scan Shod – Lesser Toes PTI data between control and trial patients at baseline, 3rd month and 6th month.

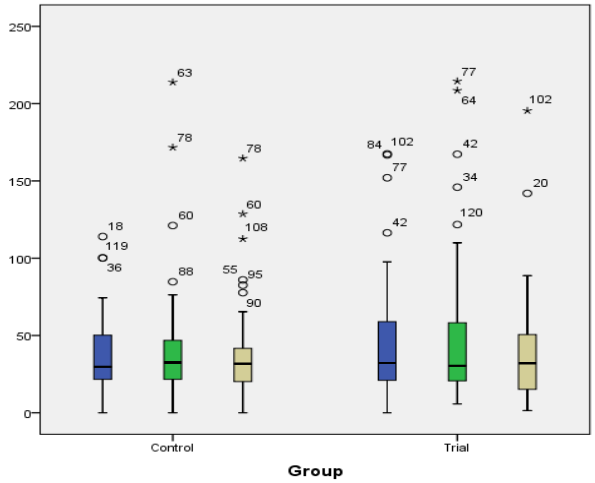


Figure 5.4.12.5: boxplot carried out on F-Scan with insole – Lesser Toes PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

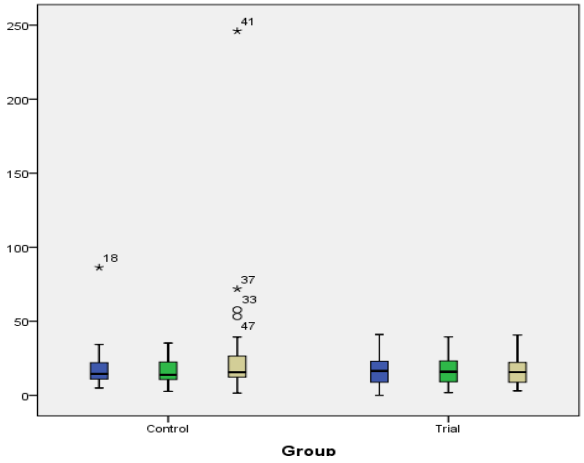


Figure 5.4.12.6: boxplot carried out on HR Walkway – Lesser Toes PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.13. Distal Phalanx of the 1st toe

Distal Phalanx of the 1st toe - Peak Pressure Values- (dp -PP)

Control Group (dp-PP)

With regards to F-scan shod: the median value at baseline was 280.33, 254.5 at 3rd month and 301.33 at 6th month (Table 5.4.13.1).

Table 5.4.13.1: descriptive statistics on dp– PP (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients).

Distal Phalanx of the 1st toe – Peak Pressure Values (dp-PP) F-Scan-Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	280.33(275.42)	254.50(326.83)	301.33(321.66)	204.83(275.83)	235.33(286)	220.67(330.75)

With regards to F-scan With Insole: the median value at baseline was 308.17, 282 at 3rd month, and 340.33 at 6th month (Table 5.4.13.2).

Table 5.4.13.2: descriptive statistics on dp– PP (F-Scan With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Distal Phalanx of the 1st toe – Peak Pressure Values(dp-PP) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median (IQR)	308.17(275.33)	282(223)	340.33(320.5)	244.50(184.08)	260.83(234.59)	261.33(213.09)

With regards to HR Walkway the median value at baseline was 285.67, 296.17 at 3rd month and 300.67 at 6th month (Table 5.4.13.3). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.13.3: descriptive statistics on dp– PP (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Distal Phalanx of the 1st toe – Peak Pressure (dp-PP) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	285.67(127.09)	296.17(166.08)	300.67(243.92)	241.17(221.75)	254.83(209.75)	251.33(250.33)

As shown on Table 5.4.13.4 the Friedman test shows p>0.05 for the F-scan (shod and with insole) and HR Walkway (also for the stable group). The only case where p<0.05* was found with stable and not-stable F-Scan (shod).

Table 5.4.13.4: details of the Friedman test on dp– PP data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Distal Phalanx of the 1st toe – Peak Pressure Values (dp-PP) - Friedman		
	Control	Trial
F-Scan - Shod	**p=0.615**	**p=0.401**
Stable	**p=0.021***	**p=0.346**
Not stable	**p=0.020**	**p=0.895**
F-Scan – With Insoles	**p=0.640**	**p=0.457**
Stable	**p=0.697**	**p=0.366**
Not stable	**p=0.861**	**p=0.538**
HR Walkway	**p=0.982**	**p=0.126**
Stable	**p=0.459**	**p=0.393**
Not stable	**p=0.341**	**p=0.055**

Wilcoxon's test was carried out and Table 5.4.13.5 highlighted that the only significant difference was found at the stable-F-scan (shod) at 3rdmonth-6thmonth (p<0.05*).

Table 5.4.13.5: details of the Wilcoxon's test on dp-PP data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Distal Phalanx of the 1st toe – Peak Pressure Values (dp-PP) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.858**	**p=0.240**
3rd month – 6th month		**p=0.493**	**p=0.325**
Baseline – 6th month		**p=0.227**	**p=0.062**
Stable	Baseline – 3rd month	**p=0.055**	**p=0.561**
	3rd month – 6th month	**p=0.017***	**p=0.565**
	Baseline – 6th month	**p=0.203**	**p=0.181**
Not Stable	Baseline – 3rd month	**p=0.006****	**p=0.179**
	3rd month – 6th month	**p=0.028***	**p=0.352**
	Baseline – 6th month	**p=0.852**	**p=0.173**
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.588**	**p=0.551**
3rd month – 6th month		**p=0.538**	**p=0.341**
Baseline – 6th month		**p=0.348**	**p=0.680**
Stable	Baseline – 3rd month	**p=0.310**	**p=0.172**
	3rd month – 6th month	**p=0.519**	**p=0.160**
	Baseline – 6th month	**p=0.561**	**p=0.804**
Not Stable	Baseline – 3rd month	**p=0.467**	**p=0.140**
	3rd month – 6th month	**p=0.837**	**p=0.569**
	Baseline – 6th month	**p=0.502**	**p=0.717**
HR Walkway			
Baseline – 3rd month		**p=0.859**	**p=0.262**
3rd month – 6th month		**p=0.673**	**p=0.615**
Baseline – 6th month		**p=0.732**	**p=0.077**
Stable	Baseline – 3rd month	**p=0.839**	**p=0.581**
	3rd month – 6th month	**p=0.217**	**p=0.500**
	Baseline – 6th month	**p=0.480**	**p=0.808**
Not Stable	Baseline – 3rd month	**p=0.323**	**p=0.605**
	3rd month – 6th month	**p=0.488**	**p=0.027***
	Baseline – 6th month	**p=0.523**	**p=0.026**

Trial Group (dp-PP)

As shown on Table 5.4.13.1 within the trial group of the F-scan shod the median value at baseline was 204.83, 235.33 at 3rd month, and 220.67 at 6th month (Table 5.4.13.1). With regards to F-scan with insole, the median value at baseline was 244.50, 260.83 at 3rd month, and 261.33 at 6th month (Table 5.4.13.2). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 241.17, 254.83 at 3rd month and 251.33 at 6th month Table 5.4.13.3. It is possible to notice a stable trend over the period of 6 months for the trial group. As shown on Table 5.4.13.4 the Friedman test displayed a $p>0.05$ hence there is no statistical difference within the trial group compared to the control group. As shown on Table 5.4.13.5 Wilcoxon's test shows that there is no statistical difference during all three intervals ($p>0.05$).

Comparison between the Control and the Trial Group (dp-PP)

As shown in table 5.4.13.6 results showed that there is statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole at baseline ($p<0.05$*) and at 6th month; which mirrowed the results when the stable group was considered separately. The 3rd month value was $p=0.059$ hence just not significant. In addition, HR Walkway appeared to have $p<0.05$* at baseline only. This suggests that there is a clear trend toward changes that happen between the control and the trial group with regards to dp-PP.

Table 5.4.13.6: details of the Mann Whitney Test carried out on dp-PP with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

Distal Phalanx of the 1st toe – Peak Pressure Values (dp-PP) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.082	p=0.349	p=0.146
Stable	p=0.100	p=0.733	p=0.093
Not stable	p=0.588	p=0.308	p=0.799
F-Scan – With Insoles	p=0.009*	p=0.059	p=0.021*
Stable	p=0.011*	p=0.188	p=0.030*
Not stable	p=0.308	p=0.07	p=0.373
HR Walkway	p=0.019*	p=0.107	p=0.247
Stable	p=0.199	p=0.608	p=0.390
Not stable	p=0.008**	p=0.016*	p=0.356

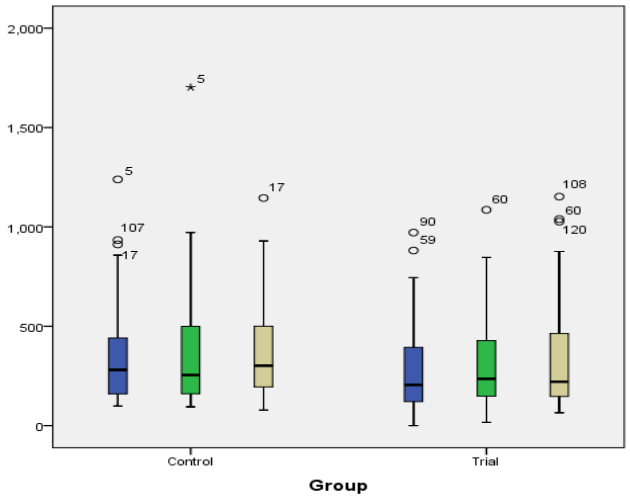


Figure 5.4.13.1: boxplot carried out on F-Scan Shod – Distal Phalanx of the 1st toe, PP data between control and trial patients at baseline, 3rd month and 6th month.

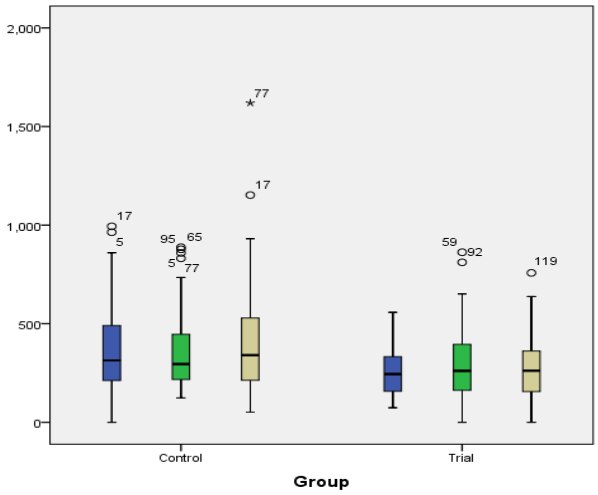


Figure 5.4.13.2: boxplot carried out on F-Scan with insole – Distal Phalanx of the 1st toe, PP data between control and trial patients at baseline, 3rd month and 6th month interval

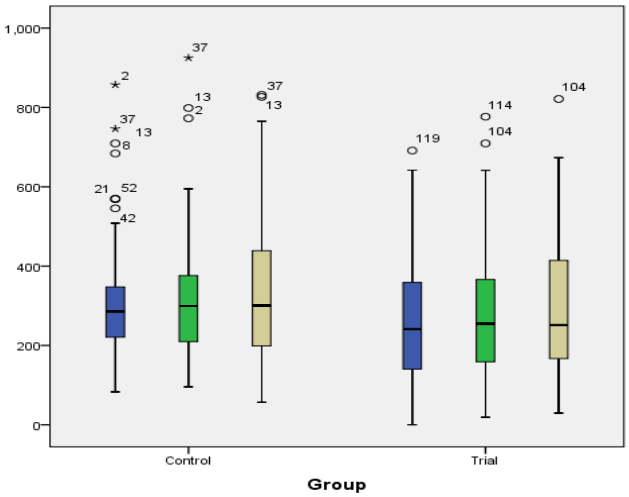


Figure 5.4.13.3: boxplot carried out on HR Walkway - Distal Phalanx of the 1st toe, PP data between control and trial patients at baseline, 3rd month and 6th month interval

Distal Phalanx of the 1st toe - Pressure Time Integral (dp-PTI)

Control Group (dp-PTI)

With regards to F-scan shod: the median value at baseline was 40.42, 35.73 at 3rd month and 38.83 at 6th month (Table 5.4.13.7).

Table 5.4.13.7: descriptive statistics on dp –PTI (F-Scan Shod) data at baseline, 3rd month and 6th month (control and trial patients)

Distal Phalanx of the 1st toe – Pressure Time Integral (dp - PTI) - F-Scan - Shod						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	40.42(47.59)	35.73(42.49)	38.83(52.4)	29.81(45.3)	34.58(46.19)	36.59(41.92)

With regards to F-scan With Insole: the median value at baseline was 45.99, 49.05 at 3rd month, and 41.89 at 6th month (Table 5.4.13.8).

Table 5.4.13.8: descriptive statistics on dp –PTI (F-Scan-With Insole) data at baseline, 3rd month and 6th month (control and trial patients).

Distal Phalanx of the 1st toe – Pressure Time Integral (dp- PTI) - F-Scan – With Insole						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	45.99(32.2)	49.05(46.21)	41.89(33.51)	40.17(35.13)	40.18(45.47)	37.01(36.1)

With regards to HR Walkway the median value at baseline was 29.72, 29.71 at 3rd month and 26.17 at 6th month (Table 5.4.13.9). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.13.9: descriptive statistics on dp –PTI (HR Walkway) data at baseline, 3rd month and 6th month (control and trial patients).

Distal Phalanx of the 1st toe – Pressure Time Integral (dp -PTI) – HR Walkway						
	CONTROL			TRIAL		
	Baseline	3rd month	6th month	Baseline	3rd month	6th month
Valid	58	58	56	62	62	62
Missing	0	0	2	0	0	0
Median(IQR)	29.72(15.01)	29.71(19.52)	26.17(20.35)	24.01(21.38)	25.46(19.28)	26.81(19.54)

As shown on Table 5.4.13.10 the Friedman test shows p>0.05 for the F-scan (shod and with insole) and HR Walkway (also for the stable group). It is possible to notice a stable trend over the period of 6 months for the control group.

Table 5.4.13.10: details of the Friedman test on distal phalanx of the 1st toe – PTI data with F-Scan shod, F-Scan with Insole and HR Walkway at baseline, 3rd month and 6th month (control and trial patients). * means p<0.05, ** means p<0.01.

Distal Phalanx of the 1st toe – Pressure Time Integral (dp - PTI) - Friedman		
	Control	Trial
F-Scan - Shod	p=1.00	p=0.142
Stable	p=0.080	p=0.323
Not stable	p=0.011*	p=0.305
F-Scan – With Insoles	p=0.417	p=0.119
Stable	p=0.338	p=0.119
Not stable	p=0.705	p=0.717
HR Walkway	p=0.417	p=0.454
Stable	p=0.358	p=0.180
Not stable	p=0.861	p=0.570

Wilcoxon's test was carried out and Table 5.4.13.11 highlighted that statistical difference was found for stable-F-Scan (shod) at baseline-3rdmonth (p<0.05*), 3rdmonth-6thmonth (p<0.05*).

Table 5.4.13.11: details of the Wilcoxon's test on dp-PTI data with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients). * means p<0.05, ** means p<0.01.

Distal Phalanx of the 1st toe – Pressure Time Integral (dp - PTI) - Wilcoxon's Test			
		Control	**Trial**
F-Scan – Shod			
Baseline – 3rd month		**p=0.528**	**p=0.364**
3rd month – 6th month		**p=0.714**	**p=0.435**
Baseline – 6th month		**p=0.763**	**p=0.042***
Stable	Baseline – 3rd month	**p=0.026***	**p=0.831**
	3rd month – 6th month	**p=0.035***	**p=0.909**
	Baseline – 6th month	**p=0.900**	**p=0.258**
Not Stable	Baseline – 3rd month	**p=0.037**	**p=0.163**
	3rd month – 6th month	**p=0.030***	**p=0.148**
	Baseline – 6th month	**p=0.627**	**p=0.039***
F-Scan – With Insoles			
Baseline – 3rd month		**p=0.702**	**p=0.258**
3rd month – 6th month		**p=0.443**	**p=0.069**
Baseline – 6th month		**p=0.562**	**p=0.511**
Stable	Baseline – 3rd month	**p=0.800**	**p=0.112**
	3rd month – 6th month	**p=0.379**	**p=0.019***
	Baseline – 6th month	**p=0.480**	**p=0.656**
Not Stable	Baseline – 3rd month	**p=0.765**	**p=0.570**
	3rd month – 6th month	**p=0.823**	**p=0.642**
	Baseline – 6th month	**p=0.737**	**p=0.535**
HR Walkway			
Baseline – 3rd month		**p=0.523**	**p=0.891**
3rd month – 6th month		**p=0.415**	**p=0.872**
Baseline – 6th month		**p=0.392**	**p=0.955**
Stable	Baseline – 3rd month	**p=0.567**	**p=0.698**
	3rd month – 6th month	**p=0.838**	**p=0.444**
	Baseline – 6th month	**p=0.405**	**p=0.608**
Not Stable	Baseline – 3rd month	**p=0.881**	**p=0.535**
	3rd month – 6th month	**p=0.263**	**p=0.379**
	Baseline – 6th month	**p=0.681**	**p=0.352**

Trial Group (dp-PTI)

As shown on Table 5.4.13.7 within the trial group of the F-scan shod the median value at baseline was 29.81, 34.58 at 3rd month, and 36.59 at 6th month (Table 5.4.13.7). With regards to F-scan with insole, the median value at baseline was 40.17, 40.18 at 3rd

month, and 37.01 at 6th month (Table 5.4.13.8). With regards to HR Walkway, descriptive statistics showed: median value at baseline was 24.01, 25.46 at 3rd month and 26.81 at 6th month (Table 5.4.13.9). It is possible to notice a stable trend over the period of 6 months for the trial group.

As shown on Table 5.4.13.10 the Friedman test displayed a $p>0.05$ hence there is no statistical difference. As shown on Table 5.4.13.11, Wilcoxon's test shows that there is statistical difference only during F-Scan (shod) during the baseline-6thmonth interval; and for F-Scan (with insole) at 3rdmonth-6thmonth ($p<0.05$*).

Comparison between the Control and the Trial Group (dp-PTI)

As shown in Table 5.4.13.12 results showed that there is no statistical difference between control and trial patients when investigation were carried out with the F-scan while wearing the insole or shod or HR walkway ($p>0.05$) in any of the intervals investigated. The only scenario where $p<0.05$* was found with the stable-F-Scan (with insole). This suggests that there is not a clear trend toward changes that happen between the control and the trial group with regards to dp-PTI.

Table 5.4.13.12: details of the Mann Whitney Test carried out on dp-PTI with F-Scan Shod, F-Scan with insole and HR Walkway data between control and trial patients. * means $p<0.05$, ** means $p<0.01$.

Distal Phalanx of the 1st toe – Pressure Integral (dp-PTI) - Mann Whitney Test			
	Baseline	3rd Month	6th Month
F-Scan - Shod	p=0.057	p=0.434	p=0.597
Stable	p=0.088	p=0.596	p=0.239
Not stable	p=0.226	p=0.545	p=0.679
F-Scan – With Insoles	p=0.159	p=0.303	p=0.419
Stable	p=0.040*	p=0.254	p=0.365
Not stable	p=0.849	p=0.588	p=0.656
HR Walkway	p=0.175	p=0.313	p=0.490
Stable	p=0.203	p=0.590	p=0.449
Not stable	p=0.445	p=0.380	p=0.924

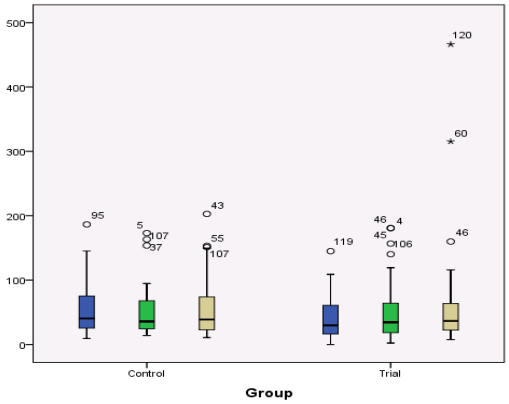


Figure 5.4.13.4: boxplot carried out on F-Scan Shod – Distal Phalanx of the 1st toe PTI data between control and trial patients at baseline, 3rd month and 6th month.

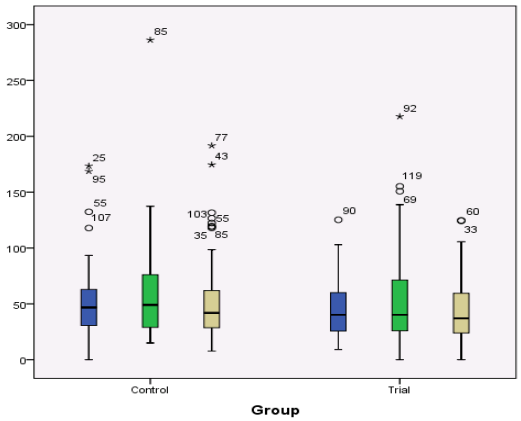


Figure 5.4.13.5: boxplot carried out on F-Scan with insole - Distal Phalanx of the 1st toe PTI data between control and trial patients at baseline, 3rd month and 6th month interval.

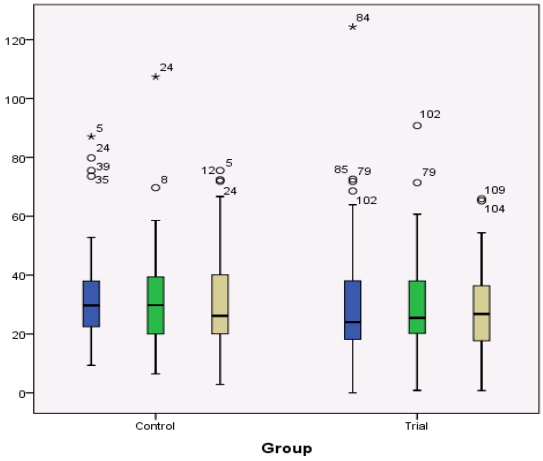


Figure 5.4.13.6: boxplot carried out on HR Walkway – Distal Phalanx of the 1st toe, data between control and trial patients at baseline, 3rd month and 6th month interval.

5.4.14. Summary of Plantar Pressure Mapping Outcomes

In order to allow the reader to have a clear understanding of the vast plantar pressure mapping outcome results, a summary of the major findings are displayed in table 5.4.14.1.

Table 5.4.14.1: this concise table shows the plantar pressure mapping outcome (PP and PTI) results comparison between the trial and the control group (baseline, 3rdmonth, 6th month). Green background indicates that statistical significant difference was obtained (* means p<0.05; ** means p<0.01; p<0.001 means p=0.000). Red background shows that statistical significant difference was not obtained (p>0.05).

Secondary Outcome Results comparison between groups (Mann Whitney U-Test)				
		Baseline	**3rd month**	**6th month**
Total	**PP**	**p=0.090**	**p<0.001**	**p<0.001**
	PTI	**p=0.098**	**p<0.001**	**p=0.028****
Heel	**PP**	**p<0.001**	**p<0.001**	**p<0.001**
	PTI	**p=0.026****	**p=0.006****	**p=0.028***
Midfoot	**PP**	**p=0.013****	**p=0.017***	**p=0.044***
	PTI	**p=0.015****	**p=0.028***	**p=0.012***
Forefoot	**PP**	**p=0.241**	**p=0.054**	**p=0.063**
	PTI	**p=0.289**	**p=0.087**	**p=0.141**
5th met. head	**PP**	**p=0.002****	**p=0.021***	**p=0.030***
	PTI	**p=0.016***	**p=0.093**	**p=0.071**
3rd – 4th met. head	**PP**	**p=0.355**	**p=0.031**	**p=0.046**
	PTI	**p=0.248**	**p=0.052**	**p=0.174**
2nd met. head	**PP**	**p=0.401**	**p=0.291**	**p=0.017***
	PTI	**p=0.495**	**p=0.380**	**p=0.035***
1st met. head	**PP**	**p=0.578**	**p=0.881**	**p=0.298**
	PTI	**p=0.208**	**p=0.610**	**p=0.119**
Lesser Toes	**PP**	**p=0.969**	**p=0.316**	**p=0.927**
	PTI	**p=0.544**	**p=0.618**	**p=0.635**
Hallux	**PP**	**p=0.009****	**p=0.059**	**p=0.021***
	PTI	**p=0.159**	**p=0.303**	**p=0.419**

Chapter 6: Discussion

6.1. Patient Demographics

According to a Cochrane review reported by Takken et al. (2008), JIA can be diagnosed in children up to the age of 18; this evidence was used to set the maximum age limit for this RCT. During the recruitment process some parents with children younger than 5 years old, showed interest in this study. In these occasions, the parents were told that according to the inclusion criteria, 5 years old was the minimum age, however, as it occurred with patient E31 & E32 when the child was old enough, the parents were recalled and they agreed to participate in the study. It can be argued that some parents recognised the importance of early podiatric intervention and they were keen to take part to the study.

As a result of using the block randomisation, the number of patients that received the control FOs was similar with respect to the trial patients. With regards to multicentre recruitment more patients were recruited in Edinburgh as the paediatric rheumatology department run clinics on a weekly basis, compared to the monthly clinics at Ninewells Hospital.

Attrition was very low with all participants, except with only one patient that failed to complete the last appointment for unknown reasons. In this study the ratio of female and male was 3:1. This fact may reflect the ratio described by Yang (2008) where the overall number of female with JIA was proportionally higher compared to male.

It was noted how the shoe size rarely changed over the 6 months period of time, which allowed to repeat the recordings by using the same shoe and FOs. In only one case within the control group where the FOs size became too small, the patient was informed to contact the data collector and a larger FOs size with the same prescription was supplied back to the patient. It was important to closely monitor shoe sizes as the fitting of the FOs may vary, possibly compromising comfort and effectiveness.

Undergrowth (possibly induced by premature fusion of epiphyseal plates) and overgrowth (possibly linked to inflammation or indirect increased of vascularisation

and release of growth factor) are typical signs of JIA (Szer et al 2006). Similar height levels were recorded in both groups during the trial. Due to symptomatic joints in the lower limb, JIA children may have more difficulties to exercise on a regular basis; and the chances to increase weight might be higher compared to healthy children (Broström et al. 2002; Broström 2004; Lelieveld et al. 2008; Thomson and Volpe 2001). However, as mentioned by these authors the general approach to treat JIA symptoms is to encourage movement and activity level; therefore, constant monitoring from the multi-disciplinary paediatric rheumatology team should be carried out (Kutcha and Davidson 2006; Szer et al 2006).

6.2. Pharmacological Intervention

Since the beginning of the recruitment process it was noticed how most of the candidates for the study were taking different types of drugs. Some of the JIA children have been taking drugs such as Methotrexate or Etanercept for many years. The overall number of potential participants that were not taking medications appeared very small since the beginning of the data collection stage. Therefore, in order to fully attribute any possible changes in pain level and quality of life, one of the important aspects of this study was to keep an updated record of medication changes. The medications prescribed to JIA children aimed to reduce the progression of the joint damage since early stages of the disease, which reflected the philosophy of prescribing FOs during the initial biomechanical consultations. Podiatric management may be able to provide immediate relief, instead the DMARDs drugs may take up to 6 months before fully exhibit their full response (Pisetsky 1995).

Additionally, despite the conclusion made by Pisetsky (1995), in the study carried out by Powel et al. (2005) the inclusion criteria section stated that JIA children must have stable medication for only one month prior to entry the study. This study was carried out without monitoring the progression of pharmacological changes over a period of time, nor accounting them within the data analysis. These limitations were highlighted by the author. According to the survey carried out by Hendry et. al (2008) their findings had to be taken with caution as it was difficult to closely monitor the intensive pharmacological intervention that their patients received.

By subdividing the groups into ‘stable’ and ‘not stable’ group it was possible to monitor the drug therapy changes within the patients and to observe if the increase or decrease of pain and quality of life can be attribute solely to the FOs intervention over the trial period. The methodological approach adopted in this RCT allowed accounting for pharmaceutical issues that may have had an impact on the final results.

Additionally, in this RCT steroid injection details were recorded. It appeared that steroid injection was frequently considered as part of the early intervention treatment when joints may flare up and start becoming symptomatic. If a patient would have received an injection in the lower limbs at any time during the 6 months period it would

have been recorded and during statistical analysis the participant would have been considered as ‘non stable’ participant. In this JIA study, more importance was given to the results attained by the ‘stable’ group results, compared to the ‘non-stable’; because it was possible to precisely attribute and isolate data achieved solely by the FOs intervention.

Few patients were included into the ‘not stable’; overall, the number of ‘stable’ patients remained the vast majority of the cases. Statistical tests for quality of life and gait analysis were carried out using SPSS by splitting the data and accounting for all these variables which may have indirectly affected the results.

This pragmatic study truly reflected real on-going JIA clinical care; therefore, it was extremely important during the data collection to carefully monitor the pharmacological interventional supplied by the consultant and by the other members of the multidisciplinary team. By adopting this thorough methodology the true effects of the FOs intervention was possible to be recorded.

Finally, data analysis showed that by splitting the groups into ‘stable’ and ‘not stable’, statistical significance changed within few parameters that were investigated. This fact confirmed the importance of accounting for ‘stable’ and ‘not stable’ groups, which significantly helped obtaining results that were purely reflecting the podiatric intervention adopted during the RCT investigation.

6.3. Symptomatic Joints

In normal circumstances the JIA child should be able to adduct the hip across the midline of the body by 20° and abducted laterally from the midline by 45°. When supine on the plinth, the JIA child should be able to flex the hip to the chest, at least of 135° and on prone position the extension of the hip should reach 30°. During extension test of the hip, the practitioner should ensure that the child does not compensate with the lower spine, as this may provide faulty results; therefore, it is advisable to apply a gentle pressure on the buttocks while lifting the leg. In addition, the internal and external rotation test of the hip should provide useful feedback on whether active disease is present or not at the femoral head (Szer et al 2006).

All biomechanical tests mentioned above were carried out prior to data recording with JIA children at the Motion Analysis Laboratory at Queen Margaret University and Ninewells Hospital. Each child was examined at open (on a provided plinth) and at close kinetic chain. Any possible joint deformities, limitation of ROM were recorded in the patient data sheet.

As it was noticed during the recruitment visits with the paediatric rheumatology consultants, examination on the knee usually commences with palpation of the bursae and out-pocketing of the knee joint. With the RCT patients recruited in both hospitals who complained of knee pain, it was challenging to distinguish simple fluid from synovial thickening, because both may be noticeable at the same time. In a more severe arthritic knee, the excessive fluids make the patella very movable and ‘bouncy’ after being pushed distally. Szer et al (2006) recommend that the patella ROM should be tested independently from the rest of the knee in order to distinguish different types of pathologies. In contrast, a study carried out by Forslind et al (1997) reported that physical examination may have low reliability in the assessment of disease activity because different examiners may report different subjective findings (Forslind et al. 1997). Antalgic gait due to knee flexion issues, must be rapidly recognised and treated by the clinician (Cakmak and Bolukbas 2005).

Conventional radiographs is adopted as initial radiologic evaluation and assessment of disease progression in JIA, which may have a limited application in early arthritis because they are not able to highlight inflamed synovium, cartilage destruction, and early bone erosions, all of which are recognised with magnetic resonance (MR) imaging (Forslind et al. 1997). Similarly, a more recent study conducted on 30 JIA children who presented active arthritis at the knees, concluded that MR imaging may potentially aid therapeutic decisions, particularly at early stages of the disease process, by helping the clinician in the quantification of synovitis, and cartilage and bone destruction which are not evident on conventional radiographs (Gylys-Morin et al. 2001).

Another clinical feature diagnosed in many recruited children in the study was 'patellofemoral syndrome', which can be defined as retropatellar or peripatellar pain resulting from physical and biochemical changes in the patellofemoral joint. This condition is different from chondromalacia, which is the fraying and damage to the underlying patellar cartilage. In order to fully test the ROM of the knee, children should be placed in a supine position. The paediatric clinician should bear in mind that 'one of the most obvious facts about grownups, is that they have forgotten what it is like to be a child" (Randall 1965). Therefore, in order to gain trust it is important to make the child feel comfortable and to spend some time to get to know the patient during the consultation (Thomson and Volpe 2001). If arthritis is not present, the knee should be flexed till the heel touches the buttock and may be extended slightly beyond neutral. During the biomechanical consultations for this RCT, it was often noticed that JIA children had knee hypermobility.

Physical therapists should prescribe strengthening exercise for medial quadriceps and straight leg rises with the foot abducted by 45°. These exercises should be repeated 25 to 30 times. In addition, if leg length discrepancy (LLD) is diagnosed, correction is required. Night splints should be worn in case flexion contractures begin to develop. According to a recent study of medical treatment of JIA, intra-articular corticosteroid injections (especially triamcinolone hexace-tonide (Zulian et al. 2004)) is effective for most patients presenting with flexion contractures or leg length discrepancies (Hashkes and Laxer 2005) Finally, the activities that should be recommended to improve knee

pain are swimming, ascending and descending stairs, and kicking a ball (Cakmak and Bolukbas 2005; Emery et al. 1995).

During this RCT study, biomechanical assessment was carried out with each participant, and foot and ankle pain was often reported by the children. An important step that should be made in order to improve clinical outcomes is to recognise inflammatory joint at early stage of the disease (Haber et al. 2010; Tattersall and Rangaraj 2008). The optimal management is highly variable in each JIA patient; some of the articles available only offer recommendations because the actual treatment should be customised to meet the conditions of each patient (Haber et al. 2010). In order to maintain function and to minimize deformities, early recognition of the disease and application of effective JIA therapy are vital (Haber et al. 2010). The podopaediatric intervention should focus on the examination on the affected and the unaffected joints; tests should be carried out with particular care on: joints, bones, insertion of tendons, ligaments ROM and strength.

If pathologies are diagnosed as a direct compensation for antalgic gait, is it is advised that treatment should be focused to address the pain, rather than the deviation itself (Fairburn et al. 2002). These authors clearly support the idea that pain relief is the primary JIA treatment outcome, which reflects the main aim of this doctoral thesis.

During data collection it was not possible to statistically quantify how long the symptoms have been present in different joints or tendons. A quite significant proportion of patients, particularly for the youngest children, could not recall with precision when the pain started. In some occasions the parents mentioned the child complained of pain in a particular joint but on examination the child showed no clinical signs of pathology. In addition, depending on the different arthritic flare up episodes, certain children before starting the data collection reported that some joints may became suddenly painful and acute, and other joints instead remained more stabled. Another fact that did not allow an accurate account of symptomatic joints was related to poly-arthritic JIA children. Some of them could not always remember exactly the history of symptomatic joints within the lower limbs, particularly in the toes, making it difficult to provide exact number. It can be argued that these are typical autoimmune symptoms patterns in JIA children that cannot be controlled and most of all it is

difficult to report them with statistical precision. Finally, even if the precise number of symptomatic joint was not statistically reported, it was still possible to intervene and provide podiatric care to the trial group.

6.4. Subtalar Joint (STJ)

In order to test repeatability skills from the data collector, the STJ ROM for each child recruited in this doctorial project, have been recorded three times in each visit and in each of the two follow up appointments (3rd month and 6th months). The ankle joint allows dorsiflexion and plantar flexion of the foot, therefore, the loss of dorsiflexion ROM due to synovitis, can have a direct effect on the level of ambulation and eventually on the level of activity and resistance (Rothschild 1999). The loss of plantar flexion, although less common, can occur in children and can lead to abnormal gait. In the survey carried out by Hendry et al. (2008) gait abnormalities, foot pathologies and/or active foot disease were outlined to be the most common reasons for referral to the specialist podiatrist.

During data collection it was noted that children diagnosed with extended oligo- or polyarticular-onset JIA underwent multiple intra-articular corticosteroid injections at six month intervals, with the ankles and STJ commonly injected (Hendry et al. 2008). For this particular reason accurate details of joint injections were recorded and subsequently labelled as not-stable. Hashkes and Ronald (2008) recently reported that potential non-medical treatment for JIA could involve the use of orthotics as they are often used for ankle or subtalar arthritis or for foot deformities in order to reduce pain during ambulation and to improve gait. The authors also mention that arch support could be used for flatfoot, and to minimize pressure on metatarsal heads, thus preventing the formation of callus or subluxations of the toes (Hashkes and Ronald 2008). This thesis may provide evidence to confirm the assumptions made by Hashkes and Ronald (2008).

The ICC results confirmed the reliability of the STJ measurements taken in each of the data collection. These are important aspects as the prescription of the pre-formed semi-rigid FOs highly depend on the correction added on the rearfoot to improve STJ alignments. According to Portney and Watkins (2000) the ICC results obtained in both groups STJ measurements can be considered as ‘excellent’. In addition, both groups presented with similar STJ features. None of the patients presented with less than 4° of eversion when measuring the difference between relax-calcaneal-stance-position

(RCSP) and the neutral-calcaneal-stance-position (NCSP). Additionally, none of the JIA children presented with STJ ROM of less than 12°, which may be considered to be an insufficient ROM required for functional FOs prescription. No changes of FOs rear-foot prescription were made during the 6 month trial. In conclusion, the RCSP and the NCSP measurements proved to be highly repeatable (appendix II).

6.5. Pain and Quality of Life Questionnaires

In this chapter, primary and secondary outcomes results will be discussed in details. As mentioned in the chapter 4.4, within and between data analysis were carried out to provide extended details of the different parameters investigated.

Because of the nature of this pragmatic research, many primary and secondary variables have not yet been explored before in JIA children; therefore the reader will be informed in details about the clinical implication and the links between the different outcomes variables.

It is important to underline that Bonferroni adjustments were not utilised for the different reasons expressed in chapter 4.4.5. Within the statisticians community there is no clear consensus about the use of this type of adjustment which is proven to dramatically increase Type II errors (Perneger 1998). As new experimental studies are performed, the chances of finding significant results decline radically. Type I errors cannot decrease without inflating type II errors; and type II errors are deemed to be no less false than type I errors (Moran 2003). The use of Bonferroni procedures further reduces power, increasing a Type II error to unacceptable levels. Moran (2003) explained that if for example a researcher has 10 single tests in a table achieving with five of them statistical significance at p=0.049, with the use of Bonferroni correction, the maximum p-value to reject the first null-hypothesis is 0.005. Therefore, none would fall below that level; hence the researcher is forced to fail to reject all null hypotheses. Furthermore, Bonferroni adjustment possibly contributes to publication bias and obstructing the advance of the research field (Nakagawa 2004). P-values, although useful, are not more important than effect sizes and do not substitute the quality interpretation of recognised reviewers. Very few institutions would keep investing time and money in a research where significant finding are altered by the not correct use of a p-value adjustment test (Moran 2003).

In the BMJ, Dr Perneger (1998) used the following example to explain why researchers should immediately discourage the use of Bonferroni adjustment: in a case of a doctor who orders 20 different laboratory tests for a patient, only to be told that some are

abnormal, without further details. Thus, Bonferroni adjustments provide an answer to a largely irrelevant question. Also, with the use of Bonferroni in experimental research, an effective treatment will highly risk to be no better than a simple placebo. Therefore, Bonferroni adjustment does not guarantee a prudent interpretation of clinical results (Perneger 1998).

The same author also indicates that, if Bonferroni adjustment will routinely be used, cynical researchers would 'slice their results like salami', publishing one p-value at a time to escape the fret of the reviewers, which will end up in wasting time, energy and public money. Furthermore, meta-analysis would 'go out of business', since a pooled analysis would reject retrospectively all original discoveries by adding more tests to be adjusted for. According to Dr Perneger (1998) journals would have to create a new section names "p-value updates," in which p-values of previously published papers would be corrected for newly published tests, based on the same study, and so on. This is clearly an unsustainable scenario in any research field.

Finally, the best approach that should be adopted, it appears to be that researcher should simply report accurately the details of the methodology and the effect size, along with the exact p-values. Furthermore, the author/s should discuss in details the possible interpretations of each result, allowing the reader to independently reach a conclusion without the unclear support of Bonferroni test (Nakagawa 2004; Perneger 1998).

6.5.1. VAS

In the field of pain research, the method often adopted for the quantification of pain severity and relief is VAS. The VAS is easy to use, the results are reproducible, and it can be applied in a variety of practice settings (Powell, Kelly and Williams 2001). Very little time is required to describe individual pain level and the subjects should feel better understood, less vulnerable and more cared for (Chapman and Kirby-Turner 2002).

With regards to paediatric rheumatology, the VAS system has been successfully used to monitor and evaluate the pain level and improvements over a period of time whilst using prescribed FOs in JIA children (Marie 2005; Powell et al 2005). Recent studies conducted on acute pain with 96 patients provided 432 paired measures which highlighted the high repeatability level of the VAS (Bijur et al. 2001). As reported by the study presented by Dhanani et al. (2002) with 533 paediatric rheumatology patients, an 8mm difference in the VAS score is indicative of clinical difference (Dhanani et al. 2002).

During the RCT, an evaluation of pain level at baseline was conducted to identify if any discrepancies were present amongst the two groups. The same results at baseline were recorded when the medication status was considered separately in the statistical test.

The improvement on pain level recorded by the parents suggested that FOs had a positive effect on JIA children. Pain improvement was statistically significant only for the trial group between baseline-3rdmonth, 3rdmonth-6thmonth and baseline-6thmonth intervals. These encouraging findings may indicate that FOs were able to reduce pain level in JIA children by the 3 months with further reduction in pain by 6 months. In addition, these results reflected the findings reported by Dhanani et al. (2002), because between the baseline and the 6th month interval, 8mm difference was found for the trial group only. Another indication that FOs had a positive clinical effect upon improving the pain level in JIA children was that for the stable medication group, 8mm difference was found at baseline-6thmonth interval. These results appear to show the similar positive conclusions presented by Powell et al. (2005); however, this JIA study was able to involve a much greater number of participants and pain improvement was compared between a control and an active treatment group, providing a more robust evidence base.

Finally, VAS appeared to be an easy, quick and effective tool for the investigation of pain in JIA children, and it will be useful to adopt this for future studies in paediatric rheumatology. The clinical implications of these findings, outline in the result section, are that children with JIA who are prescribed FOs with chair-side modifications should

experience a decrease in lower limb pain by three months. The trend showed that the trial group experienced reduction of symptoms for the whole duration of the study.

6.5.2. CHAQ

All JIA children recruited at the 'Royal Edinburgh Hospital for Sick Children' and 'Ninewells Hospital, Dundee' regularly received the CHAQ questionnaire before their paediatric rheumatology consultation. The 30 questions, grouped into 8 domains, are assessed in a scale range from 0 to 3 (Geerdink et al. 2009). This questionnaire has been described as easy to administer and very well accepted by the patients and their parents. PRINTO cross-culturally adapted and evaluated the original English versions of the CHAQ in 32 different countries. The translated versions appear to be reliable and valid tools for the functional, physical and psycho-social assessment of children with JIA and can be easily used in routine clinical practice and in clinical trials (Ruperto et al. 2001). However, few issues have been reported about the CHAQ, particularly with regard to being able to distinguish accurately age with the variation of items in assessing chronic rheumatic diseases in children (Pouchot et al. 2004). Baring in mind these issues, CHAQ was handed out to the parents and all questions were always completed. It can be argued that compared to the PedsQL, the CHAQ does not account for the different age of the patients, which may have had an influence on the overall results obtained.

Within the groups, CHAQ appeared to have recorded significant differences within both the control and the trial group, even when the stable group was analysed on its own. These results suggest that within the groups changes occurred during the whole duration of the trial. The median of the control group started at 0.13 (baseline), then 0 (3^{rd} month) and 0.13 (6^{th} month); therefore, no major changes occurred for the control group during the study. On the other hand, the trial group showed a more positive trend towards quality of life improvement, 0.38 (baseline), 0.25 (3^{rd} month) 0.13 (6^{th} month). Additionally, clinical significance was found for the trial group at baseline-3^{rd}month, 3^{rd}month-6^{th}month, and baseline-6^{th}month; indicating a positive trend of improvement of quality of life for the JIA children who worn the FOs during the whole period of the trial.

With regards to the comparison between the groups, the CHAQ results showed significant difference only for the stable-trial group at baseline-6^{th}month, which

reflected the data obtained for the VAS. Therefore, data indicated improvement for the stable-trial group only; however, changes were not significant between baseline-3rdmonth and 3rdmonth-6thmonth.

Although positive results emerged from the analysis of the CHAQ data, it is important to be mindful of the observations made by Pouchot et al. (2004) in which he expressed issues from the CHAQ system in detecting the age variation, particularly when investigating chronic rheumatic diseases in children. Furthermore, although the CHAQ is a widely used and well validated tool in paediatric rheumatology, it appears to be fairly insensitive to score changes. It is important not to over interpret the CHAQ score in isolation, but instead it is advisable to compare the trend of data in conjunction with other quality of life tools.

Finally, the data gathered may indicate that parents observed an improvement in their children's quality of life between the stable-trial groups. CHAQ data reflect the trend highlighted by the other tools adopted to investigate the pain and quality of life of JIA children. CHAQ is currently used on a regular basis during routine appointments within the paediatric rheumatology team at Edinburgh Royal Hospital for Sick Children and Ninewells Hospital (Dundee); it is important to notice that during the study nobody failed to complete the questionnaire or struggled to understand the questions. The clinical implications of the findings obtained with the CHAQ are that stable-children with JIA, who are prescribed FOs, should experience an improvement of quality of life within 6 months.

6.5.3. PedsQL Paediatric Generic module (version 4.0)

This quality of life tool is completed directly by children and represents a valuable system to detect paediatric generic activities. PedsQL is designed to gather independent ratings from children and parents describing problems with children's physical, emotional, social and school functioning (Sawyer et al. 2004). The generic core scale consists of 23 items, if more than 50% of the items in the scale are missing, the scale scores should not be computed (Varni et al. 2002); during this study all questionnaires were always fully completed and the questions were divided according to the age of the patient. Previous studies carried out on 5991 children ages 5–16 confirmed the reliability of this questionnaire's feasibility, reliability, and validity of the PedsQL 4.0 as a paediatric population health outcome (Varni et al. 2003). On the basis of these positive results, PedsQL 4.0 was provided to the JIA children during data collection.

The results gathered in this RCT were very encouraging; PedsQL (paediatric generic) showed similar score level between the control and trial group at baseline indicating that both groups started with similar score levels. Statistical difference was observed for the trial group and stable-trial only; and it manifested in each of the intervals investigated during the study. The PedsQL (paediatric generic) was able to be answered by all the recruited children without issues. The younger age group was helped by the data collector who read out the questions.

Analysis between the groups showed that statistical and clinical significance was attained for the trial group and stable-trial group only. The minimum 5 points difference between intervals determined if clinical significance was attained (Varni et al. 2002). Therefore, it appeared that the introduction of FOs as the only additional treatment intervention seemed to have an immediate positive effect on the quality of life of the children already within 3 months. Additionally, it appeared that the sharpest improvements occurred between baseline-6thmonth intervals; on the other hand, no particular changes were noted between the 3rd-month-6thmonth intervals. These results reflected the positive trend showed by Powell et al. (2005). However, during that study the only PedsQL score which contributed to the final conclusion was the physical functioning subscale. Instead, in this RCT all subscales (physical, emotional, social and

school functioning) were analysed and counted together to provide better overall conclusions on the quality of life impact that FOs have on the JIA children.

Finally, the PedsQL (paediatric generic) questions independently answered by the children, suggested that for those JIA patients who received the FOs there is a trend of immediate clinical improvement of their quality of life compared to the control group.

6.5.4. PedsQL Paediatric Rheumatology module (version 3.0

According to Varni et al. (2002) this particular module (version 3.0) was designed to measure paediatric rheumatology–specific issues, which have been increasingly adopted for clinical trials, clinical practice and health care research. Evidence-based confirmed the reliability, validity and responsiveness of the PedsQL 3.0 Rheumatology. The responsiveness of the PedsQL in paediatric rheumatology was proven through patient changing score over time as a result of a clinical intervention (Varni et al. 2002). According to Powell et al (2005), while a PedsQL Rheumatology Module does exist, it was not used in their trial. Instead, only the Physical Functioning Subscale of the PedsQL 4.0 was used for their investigation of JIA quality of life using expensive custom made FOs (Powell et al 2005). It can be argued that the remaining subscales of the PedsQL (emotional, social, therapeutic and school functioning) would have provided additional evidence to monitor the impact of FOs specifically in JIA quality of life.

In the RCT the results acquired directly by the patients themselves, showed a similar score level between the control and trial group at baseline, indicating that both groups commenced the trial from a similar score level.

Median values indicated no change within the control group over 6th months; in contrast, the median values of the trial group started at 72.60, and then a sharp increase followed till 81.72 at the 3rd month and at 6th month were 89.67. The positive results obtained by Varni et al (2002) reflected the findings within the trial group attained for the whole duration of the study even when the stable group was considered separately. Statistical significance was not found within the control group.

During data comparison between the groups, statistical significance was obtained particularly at baseline-3rdmonth and baseline-6thmonth, indicating that the improvement of JIA quality of life was recorded for the trial group in only 3 months and it was maintained for the whole duration of the trial. These positive outcomes are particularly important for this multicenter study, as the questions which were asked evaluated typical daily issues expressed by JIA children. The trial and stable-trial group

also showed a significant clinical improvement over the baseline-3rdmonth and baseline-6thmonth. Also in this PedQL (paediatric rheumatology module), if five points difference were recorded between each data collection, clinical significance was attained (Varni et al. 2002). Results showed that the difference at baseline-6thmonth interval was 9.05 for the trial group, and 10.10 for the stable-group. Therefore, clinical significance was acquired with more than twice the minimum score required.

These encouraging results may suggest that PedsQL 3.0 was able to be completed by all participants without problems and that only the trial group appeared to report an improvement with regard to common issues related to paediatric rheumatology. These results reflect the positive trend previously identified by the PedsQL 4.0, and may provide new clinical evidence suggesting an improvement in quality of life already by 3 months when using the FOs.

6.5.5. PedsQL Parent Generic module (version 4.0)

This particular PedsQL module (version 4.0) allows investigation of quality of life of patients from the parent's point of view. According to the author of PedsQL, during each data collection parents have to complete the questionnaires independently, without consulting the child. Additionally, as happens with all other tools to investigate quality of life, exactly the same parent was asked to fill in the questionnaire. Failing to do so could have introduced reporting errors within the study which might have influenced the final results. In order to monitor any communication between parents and child, the data collector was always present to guarantee the appropriate procedure for completion.

In a recent study, when the PedsQL 4.0 Generic Core Scales were administered to 1,629 parents, the results indicated that the questionnaires were reliable for group comparisons also from the parent's point of view (Varni et al. 2002). It can be argued that to accurately evaluate the quality of life of JIA children, clinicians should consider as many sources of information as possible. Sawyer et al. (2004) reported some dissimilarity in the final PedsQL data obtained from parents and children. This fact underlines how important it is for practitioners to compare questionnaire results from both children and their parents. Additionally, it can be argued that clinicians should receive adequate training to develop the required skills to assess children (Sawyer et al. 2004). On the other hand, a more extended study based of PedsQL (parent generic) involved 10241 families which demonstrated the feasibility and measurement properties of this quality of life tool for parents (Varni et al. 2003).

The results obtained from this JIA study reflected the conclusion made by Varni et al. (2002 and 2003). Firstly, the PedsQL Parent Generic module score in both groups started at similar levels. Over the course of the study, it appeared that statistical difference between the groups was acquired only at baseline-6thmonth in favour of the trial group. However, the same trend was not noted when the stable-trial group was considered on its own, suggesting that for those children who had stable medications, parent did not appear to notice any significant changes in their children's quality of life.

Clinical significance for the PedsQL Parent module was achieved if five points difference were recorded between each data collection (Varni et al. 2002); however, Varni et al. (2003) concluded that minimal clinical significance for the parent can also be achieved with 4.5 points difference. During the RCT study, 5 points was deemed to be the more appropriate difference to be considered between the intervals, also to maintain the same role applied to the children data analysis and to allow an easier data comparison. During baseline-6thmonth interval, clinical significance was found only for the trial group (10.94) and not for the control group (3.91). It can be argued that, no significant changes were recorded during the first 3 months of the trial, and only after 6 months, that parents appeared to record improvement in the quality of life of the active-treatment group. On the other hand, as the questions asked of the parent were not specific to the child pathology, this evidence provides further confirmation that the PedsQL (parent generic) is suitable to establish a generic parental impression of their child's quality of life.

Finally, all parents were able to successfully complete the questionnaire supplied. The results obtained in this RCT provide similar findings to the Paediatric Generic Module (version 4.0), reflecting the conclusion made by Varni et al. (2002), suggesting that the perception of the child's improvement is perceived correctly by their parents but it took up to 6 months before it became significant.

6.5.6. PedsQL Parent Rheumatology module (version 3.0)

The PedsQL Parent Rheumatology Module (version 3.0) was randomly handed to the parents; the feedback received was usually very positive as the questions were specifically related to the issues often experienced on a daily basis by their JIA children. All questionnaires were completed by the same parent over the 6 months period of time in order to limit the introduction of reporting errors that could have affected the final results. This methodological approach was not adopted in the study from Powell et al. (2005), or at least the author failed to specify this important detail.

Varni et al. (2002) confirmed reliability, validity, and responsiveness of the PedsQL 3.0 Rheumatology Module in paediatric rheumatology with a population of 231 children and their parents. Recent evidence underlined the importance for clinicians in obtaining specific information about children's quality of life and pain from both parents and children (Sawyer et al. 2004).

Initially, the PedsQL (Parent Rheumatology Module) initial score in both groups started at similar levels, confirming that the perception of the quality of life was not different between the groups. Within the control group, median values were mostly stable and parents did not seem to report any significance changes over the whole study period. On the other hand, the parents of the active treatment group showed a sharp increase in the median values, starting from 62.52, then 79.00 at 3rd month and finally reaching 83.70 at 6th month. Data highlighted significance improvement within all intervals considered, even when the stable-trial group was considered independently.

According to the data gathered from the comparison of the two groups, it appeared that clinical significance was found in both trial and stable-trial group at baseline-6thmonth interval with more than twice the minimum score required. The clinical implications of these findings are very positive, as the paediatric rheumatology questions answered by the parents match with the perception expressed by the JIA children, providing further evidence that FOs may have contributed to this positive final outcome. Furthermore, the results reflect the reliability and responsiveness of the PedsQL 3.0 Rheumatology Module previously investigated by other researchers (Sawyer et al. 2004; Varni et al.

2003). This additional evidence may help in the future to extend the use of the PedsQL in paediatric rheumatology.

On the other hand, it worth noticing that although there was a positive trend already between baseline-3rdmonth and 3rdmonth-6thmonth, it was not substantial enough to acquire statistical significance. These findings may suggest that it takes up to 6 months for parents to identify improvements in their JIA child's conditions; whereas the PedsQL (paediatric rheumatology) showed significant improvement for the trial group already after 3 months. These results may reflect previous observations made by other studies where few dissimilar data were recorded between parent and child data (Sawyer et al. 2004). Possible reasons for these slower parental observations may be related to lack of communication between the child and the parent; or that the observed changes only become noticeable in the longer term, whilst children report improvements earlier since they are in less pain by already 3 month.

In conclusion, the PedsQL (parent rheumatology) scores suggest the FOs intervention to have had a positive impact in improving the quality of life of JIA children; results match the overall trend expressed by the parents and their child. However, the parent seemed to require more time to recognise quality of life improvements when compared to their children.

6.6. Gait Analysis

Motion analysis laboratories measure aspects relating to human locomotion as part of clinical practice or research (Sutherland 2005). However, the applications of gait analysis to humans with different pathologies such as Cerebral Palsy, Parkinson's disease, and neuromuscular disorders only started in the 1970s. With the advances of technology, video gait camera systems allowed researchers to obtain and record gait on pathological and healthy patients with significant reduction in costs and time (Sutherland 2002).

With the aid of barefoot and in-shoe measurements technology, it has also been possible to diagnose recurrent foot pathologies in JIA children such as planus-valgus, pes cavus, hallux valgus, forefoot adduction and claw or hammer toes (Truckenbrodt et al. 1994). Research has suggested that barefoot pressure data from at least 3 to 5 steps are required and multiple barefoot walking trials across the platforms is needed during research data collection (Hughes et al. 1991). For these reasons, all JIA children involved in the RCT study were recorded using a 1.956m length HR Walkway, as well for the F-Scan, allowing for multiple steps recordings.

Recent publications suggest that on some occasions certain recordings were excluded and repeated if they appeared incorrect, or if the subject stopped on the mat during walking, or if the patient did not keep walking past the mat for more than two steps (Zammit, Menz and Munteanu 2010). Additionally, 3 trials seemed to be commonly used during paediatric gait analysis, as this number of trials has previously been proven to be sufficient in an analysis of force and pressure data (Hughes et al. 1991; van der Leeden et al. 2004).

Hadfield et al. (2003) reported that the Tekscan software was able to evaluate the plantar pressure changes which occurred in the Achilles tendon after the medialising-calcaneal-osteotomy (MCO). The data also revealed that average pressure over the 1st and 2nd metatarsal heads decreased significantly after MCO surgical intervention. At the same time there was a significant increase in average pressure over the medial and

lateral aspect of the heel post-operation. This publication also confirmed the ability of the Tekscan system to detect forefoot pressure changes.

Randolph (2000) concluded that the use of F-scan could benefit podiatrists for orthotic prescription to assist in pain relief and to improve excessive pressure on the foot, which could lead to foot ulceration (Randolph et al. 2000). Unlike other previous authors mentioned in this chapter, Randolph (2000) stated what he believed to be the disadvantages related to the F-scan system. Firstly, he referred to its high cost, which at the time of that study was $25 per each individual digital insole. Secondly, according to the author the time needed to interpret and analyse the data was deemed to be too lengthy, and it initially required training in order to carry out appropriate gait analysis.

Similarly, Li et al (2000) tested the F-Scan with his participants walking in their shoes at a comfortable speed. Measurements were recorded 3 times for at least 3 consecutive footsteps. The same methodology was adopted in this JIA study. Li et al. (2000) reported that brand new F-scan sensors were used for each new subject enrolled in the research. The peak pressure over the entire foot was investigated as well as the hind-foot, the midfoot, the forefoot; comparisons between the 2 groups were evaluated. Results revealed that FOs prescribed to the RA patients proved to reduce peak pressure more when compared to those of the control group. The RA group particularly showed greater reduction of pressure during the stance phase of gait ($p<0.01$). The author concluded that thanks to the F-scan system it was possible to prove the efficacy of FOs with RA patients (Li et al. 2000). It can be argued that, although the F-scan sensors might be quite costly, they seemed to be very durable over a period of time, particularly when dealing with children, and also the continuous software updates over the years made data analysis process much easier and quicker.

According to Joanne (2007) approximately 6 to 7 consecutive steps should be recorded per trial at a sampling frequency of 50 Hz. The podiatrist should normally disregard the first and last step in order to exclude the effects of gait acceleration and deceleration (Joanne et al. 2007). The indications highlighted by this author were taken into consideration during the data collection stage of this study.

In conclusion, the previous studies carried out in gait analysis using Tekscan equipment, proved to be valuable clinical evidence that allows the construction of a robust and repeatable methodology for this pragmatic paediatric study. These guidelines were adopted for each gait analysis recording carried out with JIA children at the motion analysis lab in Queen Margaret University and the TORT centre.

6.6.1. Gait Time (sec)

Gait time represents an important parameter that was investigated during this RCT study using the HR Walkway. It indicates the time from the first contact of the first step to the time of first contact of the last step registered on the walkway (Tekscan 2010). Currently this outcome measure is not often used in literature to report Tekscan gait analysis findings, particularly in children. One of the possible reasons may be because it is only recently that this parameter can be easily obtained from the new Tekscan software (version 7.0).

Previous veterinary research recorded gait time in dogs. It appeared that the walkway system can be effectively used for comparison of the walking gait time and that the pressure-sensing walkway is a simple method for the acquisition of a temporal-spatial parameter (Jongmin et al. 2011). It can be argued that, although veterinary research is an extremely important field, more evidence base is needed to support the role of investigating gait time, particularly in children.

Firstly, gait time comparison in this RCT showed that both groups started with similar values, confirming that no statistical difference was present between the groups at baseline. As gait time is a parameter that few instruments of gait-software can automatically gather, it was important for this study to monitor the level of repeatability of the Tekscan between each data recording. As shown in Appendix XIX, the ICC results measured over the three recordings taken in each data collection confirmed a high degree of repeatability and reproducibility. Precisely, the ICC can be defined as ‘good’ in both control and trial groups, even when the stable group was considered separately.

Data analysis (Friedman test) highlighted that statistical difference was found within the trial and stable-trial group, which was not obtained for the control group. Wilcoxon’s test reflected the same results, with the only exception being that the initial interval (baseline-3rdmonth) did not show statistical difference. In contrast, results showed a sharp increase for the trial group within 3rdmonth-6thmonth and baseline-6thmonth. The same trend was confirmed once again when the stable-trial group was

considered independently. Furthermore, median values allow the researcher to verify how the control group values were really stable (baseline 1.10, 3rd month 1.13, 6th month 1.11); instead, in the trial group a reduction in gait time was recorded at 6thmonth (baseline 1.17, 3rd month 1.17, 6th month 1.04).

On the contrary, the between group comparison analysis did not appear to show any significant results. However, even if statistically it was not significant, the stable-trial group showed a positive trend towards improvement (p=0.060). It can be argued that if more patients were involved in the study or if there would have been the opportunity to monitor gait time changes for example at 9th month, possibly more significant results might have been identified from the children that received FOs intervention. As the recordings were carried out at barefoot, the results may suggest that the benefit of the treatment is reported mostly when the FOs are worn. Therefore, clinician should underline to the JIA children, that gait time can improve, primarily is FOs are worn regularly.

Finally, this new evidence suggests that gait time improvement was found within the group that received FOs; however, it takes up to 6 months before they become significant. In conclusion, even if a trend toward gait time reduction was noted, it was not sufficient to achieve statistical significance. The results suggest that the effect of the podiatric intervention is recorded mostly if the FOs are worn. Hopefully these data can contribute to strengthen and add new knowledge on paediatric gait time.

6.6.2. Gait Velocity (cm/sec)

Gait velocity is a parameter that is commonly investigated in paediatric rheumatology patients (Broström et al. 2002; Hartmann et al. 2010; Powell et al 2005; Szer et al 2006). A study of twenty-three pre-pubertal children, aged between 5 and 11 years old suggested that JIA had significantly less participation in organised sports (Henderson et al. 1995). JIA children were found to have a walking velocity significantly lower than healthy children: therefore clinicians should encourage JIA children to participate in regular physical activities in order to prevent reduced fitness level (Broström et al. 2002; Broström 2004). The study investigated 14 juvenile chronic arthritis, and 15 healthy children. With the aid of a light-beam which triggered the recording, a second light beam was placed 5 metres away which stopped the timer. The walking velocity of arthritic children appeared to be 1.06 m/s, whereas healthy children seemed to be 1.28m/s (Broström 2004).

During this RCT study velocity was investigated on the JIA children with the aid of HR Walkway software. Initial gait velocity data showed that both groups started with similar values, confirming that no statistical difference was present between the groups at baseline. As well as for the gait time recordings, a repeatability test was carried out within each data collection, and the ICC values confirmed that the HR Walkway was able to record ‘good’ values (appendix XIX).

Powell et al. (2005) reported that speed of ambulation was recorded using a stopwatch, and that 3 attempts were timed and an average speed of ambulation was recorded. From that publication, the reader is not informed about the repeatability skills of the data collector; additionally, the reaction time from each child may vary considerably depending on the age and the extension of the pathology. Instead, in our RCT study, gait velocity measurements were initiated by the software as soon as the heel came into contact with the digital platform. With a known length of the HR walkway and the contact time, speed of ambulation was automatically calculated. On the basis of the repeatability data obtained (appendix XIX), it can be argued that this methodology may be better than that of a manual stopwatch.

During the RCT study, the results have shown that there is a significant improvement in walking speed within the trial group either at 3rd month-6thmonth and baseline-6thmonth intervals, compared to the control group. In addition, the stable-trial group was analysed separately and significant difference was found only within the baseline-6thmonth interval. Results indicated that FOs have significantly contributed to improve walking speed of JIA children who wore FOs. However, changes did not occur immediately and the sharpest improvements were noted at 6th month interval. On the other hand, when both groups were compared with each other, no significant changes were attained.

It can be argued that these results reflect partially the conclusion made by Powell et al. (2005), as FOs appear to have a positive impact on the walking velocity of JIA children, with the considerable difference that in our RCT children received the chair side FOs on the same day. Customisation of the FOs was much more cost-effective compared to the POP custom made supplied by Powell et al (2005).

Finally, it can be argued that podopaediatrics could play an important role within the paediatric rheumatology team and contribute to children's ability to become more active. Podiatrists could potentially help the multidisciplinary team by providing cost-effective and non-invasive intervention to arthritic children. Although no significant results were noticed between the groups, the active treatment group appeared to increase their speed of ambulation and one of the reasons may be because the trial and the stable-trial reported a reduction of pain and better quality of life level by the end of the study.

6.6.3. Stance Time (sec)

The stance phase of the normal gait cycle begins with the strike of the heel on the ground and ends with toe-off at the beginning of the swing phase of gait; therefore, it represents the interval in which the foot is on the ground (60% of the gait cycle). The stance phase is commonly subdivided through different actions that occurred during ambulation: heel strike to foot-flat, foot flat through mid-stance, midstance to heel off, and finally from heel off to toe off (Valmassi 1996).

It can be argued that as JIA children appear to walk slower than healthy children (Broström et al. 2002), their percentage stance time will be higher compared to what is deemed to be 'normal'. During rehabilitation, clinicians should encourage JIA children to maintain a good physical activity level (Szer et al 2006). One of the aims of FOs intervention is to reduce the stance time of JIA and to encourage a more propulsive gait. If the swing phase time increases, the JIA child will exhibits less double leg support (Valmassi 1996).

Stance time was calculated automatically by the HR Walkway software (version 7.0) and it provided values for the left and the right foot, however, as previously shown (Table 5.4.3.1), results were expressed by evaluating both feet accounted together. Results showed that both groups started with similar values in between both groups. With regards to the repeatability and reproducibility data, all recordings acquired were 'good' (appendix XIX).

Data analysis demonstrated that there is a trend of reducing the stance time only within the trial and stable-trial group. Furthermore, there is evidence that particularly within the trial and stable-trial group at baseline-6thmonth interval, statistical significant changes were recorded; indicating that the trial JIA children spend less time during stance phase. These results confirm the conclusion made by Valmassi (1996), in which, along with the improvement of symptoms, patients may exhibit reduction of stance time and potentially become more propulsive.

During data comparison between the control and the trial group, no significant difference was found. However, the stable-trial group presented a clear trend towards

improvement of the stance time values between the baseline-6thmonth interval (p=0.055). The not-stable trial group presented with significant difference between the groups in all the intervals investigated, suggesting a reduction in stance time compared to the control group.

In conclusion, these data suggest that FOs may have a direct effect in reducing the stance time in JIA children within the trial group. Potentially if the study were to be conducted for a longer period of time, results might have been even more significant when compared to the control group.

6.6.4. Total Contact

The Total contact area was identified by using the PP box available from the Tekscan software. With the aid of the PP box, peak pressure values were recorded to quantify the area where there is the highest amount of pressure. Hadfield et al. (2004) investigated the plantar foot pressure subdividing the foot into seven different regions using the HR Walkway; however, they failed to provide an overall result considering the total-foot contact. In contrast, Ahrony et al. (1998) proved the importance of investigating the PP on the 'whole' foot contact parameter. Their study was conducted using the F-Scan insole and the whole foot contact provided 'good' reliability for measurements of PP with their patients. The t-PP represents a very important parameter investigated in this RCT, as it provides new evidence on plantar pressure measurement with JIA children.

Statistical difference was obtained between the groups only when F-Scan t-PP and t-PTI measurements were taken with the FOs inside the shoes. On the other hand, the t-PP and t-PTI data analysed for the HR Walkway and F-Scan-shod showed no difference between the groups. These results suggested a positive trend that the functional FOs adopted for this study were compared against no-corrective device, and that the Tekscan software was able to record the changes between the control and the trial FOs. These secondary outcome measures matched with the primary outcomes as the reduction of t-PP and t-PTI reflects the improvement of quality of life and reduction of pain for the trial group only. It can be argued that possible errors could have occurred during the recording process. In order to monitor any mistakes during data collection, repeatability tests were conducted in each of the 3 appointments made with the participants. The data acquired was demonstrated to have a 'moderate' and mostly 'good' ICC score. These results may help to underline the reliability of the data acquired in this study, and add strength to the methodology adopted.

In conclusion, the FOs appeared to significantly reduced t-PP and t-PTI values within and between the trial groups only. This positive trend of reduction of t-PP and t-PTI match with the improvement of quality of life and reduction of pain level only to the trial group.

6.6.5. Heel Contact

Previous studies focused on quantifying the differences in gait between JIA patients and healthy controls. JIA patients showed reduced plantar flexion in push off motion (Hartmann et al. 2010). The authors mentioned that the 3D-gait analysis showed that the patient group suffered from malposition that can be attributed to movement restrictions. The main differences compared to controls lay in reduced hip extension, reduced knee extension, and reduced plantar flexion with a passive and decelerated push off of the ankle. At present there are no guidelines on how to improve the misalignment on some of those joints that may create muscle restriction. Hartmann et al. (2010) cautiously recommended mild strengthening exercise to reduce inflammation. However, it can be argued that if inflammation is present on the calcaneum, heel strike phase may be affected and possible antalgic gait may be adopted by the patients. Additionally, the joint malposition may be improved by simple podiatric intervention that may aim to readdress STJ alignment.

In fact the results acquired in our RCT while using the F-scan with insole, confirmed that FOs supplied to the JIA children played a central role in reducing h-PP compared to the control FOs (Table 5.4.5.2). From the data acquired it appeared that FOs with chair-side modifications may aid in improving shock absorption at heel strike. Additionally, as reported in Table 5.4.5.8 also h-PTI values for the trial FOs are much lower compared when compared to the control FOs. These data reflect the aim of the study carried out by Hartmann et al. (2010); however, in this RCT it was possible to provide positive conclusions by utilising other cost-effective treatment solutions which may have a direct link in improving primary outcomes.

Another study investigated the reliability of measure applied in different areas of the foot; one of these was the heel (Randolph et al. 2000). The healthy subjects were recruited to check if the F-scan insole was able to provide reliable h-PP values that could have been used in podiatric management for patients with diabetes. Their study concluded that the F-scan insoles are sufficiently reliable to provide PP values. Few considerations can be highlighted from this study: firstly, the author provided further confirmations on the importance of investigating only the heel area separately from the

rest of the foot. Secondly, it gives updated evidence that h-PP data are valuable data that need to be acquired with at-risk patients. On the other hand, the number of patients recruited is limited and they failed to provide details on the h-PTI. However, Zammit et al. (2010), demonstrated 'moderate' to 'good' h-PP MatScan reliability, but no details are provided with regard to h-PTI. It can be argued that particularly when diabetes patients are investigated, the treatment goal is to reduce the h-PTI in order to minimise the effect of pressure and time of loading (Tekscan 2008).

As shown in Appendix XIX, the ICC scores gathered with JIA children for the repeatability and reproducibility study of h-PP and h-PTI within each data recording showed that most data had 'moderate' and 'good' values. This data carried out alongside the RCT, may add new evidence on the reliability level of the Tekscan equipment and add strength to the methodology of the study.

Statistical difference was obtained between the groups at baseline, 3rdmonth and 6thmonth only when F-Scan with insole was used and when h-PP measurements were taken with the FOs inside the shoes. Also stable-trial group for the h-PP reflected the same trend. The values for the h-PTI show significant difference between the groups when FOs measurements were carried out. The h-PP and h-PTI data for the HR Walkway and F-Scan-shod, showed no difference between the groups. This positive trend suggests that h-PP and h-PTI values are lower compared to the control group. The results are indicative of the fact that FOs contribute in the redistribution of pressure also from the heel area. It appears that the positive effects of the FOs are noted immediately, also for the stable-group, since the first recording using the F-Scan system. These secondary outcome measures reflects with the primary outcomes as the reduction of heel plantar pressure values, shows an improvement of quality of life and reduction of pain for the trial group only. These results matched with the conclusion made by Li et al. (2000), where heel plantar pressure values were reduced after the FOs prescription on adults affected by RA.

All patients' shoes were checked for suitability to fit FOs at each appointment. The chief investigator provided indications to the parents and the patients in how to recognise suitable foot wear.

In conclusion, previous evidence base confirmed the importance in investigating h-PP and h-PTI which was used as guidance during this data analysis. The FOs prescribed to the JIA children appeared to significantly reduce h-PP compared to the control FOs; which may contribute to improve symptoms and the overall quality of life on the active treatment group only. These positive results on reduction of h-PP and h-PTI with the use FOs are recorded immediately and reflect the early intervention approach considered by other members of the paediatric rheumatology team; and most importantly it appears to benefit the JIA children.

6.6.6. Midfoot contact

Previous research conducted on adults diagnosed with RA confirmed that when F-Scan in-shoe analysis is carried out using FOs, the m-PP appear to be higher (Li et al. 2000). Additionally, the authors indicated that the FOs can have a cushioning effect and may significantly help in redistributing the plantar pressures. The RA gait recordings displayed a significant reduction in heel and forefoot peak pressure, and it seemed that one of the main reasons was related to the fact that the PP underneath the midfoot became greater. The gait analysis data reflected that the FOs supplied were perceived to be comfortable and reduced foot pain during walking (Li et al. 2000). This evidence supports the need to map the midfoot section of the foot during gait analysis and additionally that m-PP is a common parameter that is investigated to relate secondary to primary outcome measures. It can be argued that only 12 symptomatic and 8 healthy patients were recruited for their study, and the population of subjects were not solely women of the same age. The reader is not informed if the participants were randomised and m-PTI was not investigated. The methodology might have been more robust if: more patients with different age group were involved in the trial; and finally if only symptomatic RA patients were randomly compared against a control or a trial FOs.

Unlikely to the Li et al. (2000) our RCT provided both m-PP and m-PTI. The results suggested that when a comparison between the groups was carried out, statistical significance was acquired in all intervals for m-PP and m-PTI, also for the stable group. Therefore, with this parameter too, the FOs supplied to the trial JIA children, appeared to have immediate effects since the baseline recordings, and it lasted for up to 6 months. Data reflected the findings made by Li et al. (2000) because higher m-PP values were shown only for the trial group (Table 5.4.6.2 and Table 5.4.6.8). In contrast, the recording made with HR Walkway and F-Scan Shod did not presented any significant changes. Only the data acquired with the F-Scan (with insole) for the trial group, clearly show a trend in which the midfoot values are much higher compared to the control group. These results may suggest that redistributing the plantar pressures only occur when FOs are worn for the trial group.

According to the repeatability and reproducibility study carried out prior to the RCT, the results reflected the conclusion previously made by Randolph et al. (2000) and Zammit et al. (2010) in which they reported that the F-Scan and MatScan systems generally demonstrated 'moderate' to 'good' ICC score level in reporting m-PP. As shown in the appendix XIX, the ICC score appeared to be mostly 'good' either for the m-PP and for m-PTI. This additional evidence based on the repeatability and reproducibility of the Tekscan may be useful for future gait analysis studies in podopaediatric.

In conclusion, results seemed to suggest that in the stable-trial and trial group the m-PP and the m-PTI were significantly higher than the control group. Therefore, indicating that the FOs aid in redistributing plantar foot pressure as the midfoot makes contact with the insole. In the foot without the insole, the medial arch usually does not make contact, hence the low pressure was found in the control subjects who wore the placebo insole. These data reflect previous findings made by other authors, previously described, who investigated the effect of FOs. It can be argued that these secondary outcomes mirror the improvement of symptoms exhibited only by the JIA children who were part of the trial group.

6.6.7. Forefoot contact

Plantar pressure examination can be used by the clinicians in the evaluation and management of adult and paediatric patients' gait (Cakmak and Bolukbas 2005; Orlin and McPoil 2000). Particularly with JIA gait, it appears that due to juvenile arthritic foot pain at push-off, the ground reaction forces may be lower compared to healthy chidren (Broström et al. 2002). The forefoot is a parameter commonly investigated while using the Tekscan equipment (Hadfield et al. 2003; Joanne et al. 2007; Luo, Berglund and An 1998; Randolph et al. 2000; Riad et al. 2007). On the basis of this extensive evidence base in adult and paediatric gait, during our RCT each recording carried out with the JIA children was analysed considering the PP and PTI at the forefoot.

With regards to the clinical management of JIA forefoot pain, often cushioning material, such as poron, was utilised with the aim to reduce the f-PP . As shown on Table 5.4.7.2, the values obtained with the F-Scan (with insole) for the trial group only were found to be lower compared to the control insole; in contrary, no changes for the HR Walkway and F-Scan (shod) were noticed. Therefore, the FOs appear to be able to reduce forefoot PP and PTI by shifting some of the load to the midfoot and increasing the m-PP and m-PTI. However, the comparison between the groups did not show significant differences for f-PP and f-PTI. Particularly for the f-PP, a positive trend was found at 3rd month (p=0.054) and at 6thmonth (p=0.063); but it was not enough to achieve a statistical significant difference between the groups. It can be argued that one possible reason to explain these results is that only a few children presented with forefoot pain and pathologies: hence less corrections were applied on the forefoot of the FOs. Therefore when the control and the trial FOs were statistically compared on the forefoot, no particular differences were attained. Furthermore, as most of the young female participants wore very narrow fitting shoes, it was important to customise the FOs and reduce as much as possible the thickness of the FOs in the forefoot. A very thick FOs may have constricted the forefoot and subsequently incease the forefoot pressure.

According to Randolph et al. (2000), the forefoot pressure data obtained by the Tekscan system are reliable in use for clinical management. These results reflected our findings

gathered during the repeatability and reproducibility study carried out alongside the RCT (Appendix XIX). The ICC score revealed that most of the f-PP and f-PTI were 'good' with the F-Scan (shod and with insole) and HR Walkway. These results may suggest the positive repeatability level of the Tekscan equipment utilised in the study and may provide new evidence in the field of paediatric rheumatology.

In conclusion, the f-PP and f-PTI results suggested that no significant difference was recorded between the trial and the control group. Overall, with the aid of cushioning materials and chair-side modifications applied on the FOs, the f-PP and f-PTI appeared to be reduced for the trial group only. It is important to remember that the forefoot corrections were less frequently applied compared to rear-foot adjustments, as they might have constricted the forefoot inside narrow fitting children's shoes. Finally, the forefoot results comprised the 5^{th}, 4^{th}-3^{rd}, 2^{nd} and 1^{st} metatarsal heads. The results of each of these parameters will be further explained in this chapter.

6.6.8. 5th metatarsal head contact

Skin callus and bursae are often observed at the metatarso-phalangeal joints as a natural protective mechanism, but over a period of time they may become symptomatic. These observations were highlighted by Woodburn and Helliwell already in 1996 by using in-shoes analysis systems on RA patients. Most of the publications only focus on the peak pressure of the rearfoot, midfoot and forefoot, but exclude investigation of the metatarsals. Tsung et al. (2004) are among the few authors that investigated both 5th-PP and 5th-PTI. They managed to map the forefoot in different anatomical areas using the F-Scan insole (shod and with insole). They analysed the different effect that FOs have in redistributing the pressure in diabetes patients against the healthy population. Although a very small number of participants took part in the trial (6 diabetes and 8 healthy), this study provided additional evidence on the importance of investigating the metatarsal heads, not only for extrapolating peak pressure data, but also for Pressure Time Integral values (Tsung et al. 2004). It can be argued that at present most of the literature available on investigation of 5th metatarsal pressure, is focussed primarily on diabetic patients (Joanne et al. 2007), and the evidence as yet available on JIA children are limited. Our RCT will be able to provide new evidence on the importance of identifying the effect of FOs on 5th metatarsal pressure.

According to the results, statistical significance was attained when comparison between the groups was carried out for 5th-PP (at baseline, 3rd month and 6th month) and 5th-PTI (at baseline). These findings indicate that the FOs contributed in the reduction of 5th-PP and 5th-PTI compared to the control FOs. Furthermore, changes were recorded only when the FOs were used by the JIA children, immediately after the initial data collection and did not vary for at least 6 months. The clinical implication of these results suggest that FOs have an immediate effect for symptomatic JIA children in reducing peak pressure and Pressure Time Integral over the 5th metatarsal (Table 5.4.8.2, Table 5.4.8.8), therefore reflecting the trend of reduction of pain highlighted in the primary outcome measures. It can be argued that if less pain is experienced during walking or running, the JIA children might be more encouraged to be active and take part in sport activities.

The reliability of the 5th metatarsal-head has been extensively tested, and most of the publications concluded that the Tekscan equipment is able to provide 'moderate' to 'good' ICC scores (Ahroni, Boyko, and Forsberg 1998a; Hadfield et al. 2003; Zammit, Menz and Munteanu 2010). According to the appendix XIX, the repeatability study of the 5th-PP and 5th-PTI conducted in parallel with the RCT, reflected the same conclusions as the authors previously mentioned.

Finally, the investigation on the 5th metatarsal head revealed that FOs have a significant effect when compared between the control FOs. The reduction of the 5th-PP and 5th-PTI not only were repeatable and reproducible over the whole duration of the study, but they may have directly contributed in improving the quality of life and reducing the symptoms from the JIA children. These findings could potentially be considered by the paediatric rheumatology team and the cost-effective inputs that podopaediatrics could bring into the care of JIA children may be welcome.

6.6.9. 3rd / 4th metatarsal head contact

The 3rd and the 4th metatarsal heads are gait parameters that have been analysed separately from each other or together with the other metatarsals. For example, Tsung et al. (2004), considered the 3rd met-head together with the 2nd met-head; Hadfield et al. (2003) and Zammit et al. (2010) instead looked at 3rd to 5th met-head; and finally Paton et al. (2007) managed to individually investigate each metatarsal head. Therefore, on the basis of the previous publications, during this RCT different tests were carried out to evaluate the most suitable methodology that should have been adopted during data analysis. The plantar recordings were carried out on children age ranged 5 to 18 years old, and the feet dimension varied significantly. During data analysis it appeared that with the smallest foot sizes it was more difficult to accurately position the PP-boxes on the correct anatomical position. It can be argued that the PP-boxes have a limit in sizes, and on some occasions it was not enough to accurately isolate very small 3rd and 4th metatarsal heads. Therefore, in order to reduce measurement errors and wrongly distinguish small children metatarsals, the 3rd and 4th met-heads were accounted together.

During data analysis, particular care was adopted in monitoring the ICC of the measurements made with these smaller anatomical areas; however, as shown in appendix XIX, the ICC scores for the 3rd-4th PP and 3rd-4th PTI were mostly 'good'. These findings confirmed that the methodology adopted was reliable. It can be argued that these latest findings may be used as possible guidance for future paediatric gait analysis.

Results indicated that the 3rd/4thPP and 3rd/4thPTI values of the F-Scan (shod) and HR Walkway did not vary between the control and the trial groups; however, from Table 5.4.9.2 and Table 5.4.9.8 it appeared that FOs facilitated the reduction of 3rd/4thPP and 3rd/4thPTI. During F-Scan (with insole) data analyses, statistical tests seemed to suggest that for 3rd/4thPP significant difference was recorded between the groups at 3rd month and 6th month. The clinical implications of these data indicate that changes in 3rd/4thPP does not occur immediately; however, it is sustained for at least 6 months. Compared to previous rearfoot and midfoot PP parameters, the forefoot changes seem to take longer before becoming significant. In addition, statistical significance between the groups for

the 3rd/4thPTI, was only recorded for the stable F-Scan (with insole) at 3rd month. Therefore, no clear patterns of improvement were highlighted.

It is important to remember that forefoot corrections were less frequently used in comparison to rearfoot adjustments, as fewer JIA children appeared with forefoot pathologies, but also, because if the FOs were too bulky, comfort and fitting could have been affected. As shown from the descriptive tables previously mentioned, it can be argued that rearfoot correction and the use of appropriate materials aided in improving redistribution of pressure and reduction of PP and PTI.

Finally, due to the small shoe sizes of some participant and sizing limitation of the PP boxes, 3rd and 4th metatarsals were accounted together. The results confirmed the repeatability and reproducibility of the data carried out and highlighted the positive effect that FOs has in comparison to the control FOs; which may be linked to the improvement of quality of life and reduction of pain experienced only by the trial group.

6.6.10. 2nd metatarsal head

As the 2nd met-head appears to be the most weight bearing metatarsal in the foot (Clough 2005), the Tekscan equipment allowed the investigation of the effect of FOs in JIA children in this particular anatomical area. The colour grading option available from the Tekscan software allowed easy identification of 2nd metatarsal head from the gait recording compared to the adjacent 1st met-head. Previous authors recognised the importance in isolating the 2nd met-head during plantar mapping of the foot in order to specifically analyse and compare the differences that occur when podiatric intervention is applied (Ahroni, Boyko and Forsberg 1998a; Hadfield et al. 2003; Zammit, Menz and Munteanu 2010). Riad et al. (2007) instead, mapped the forefoot into medial and lateral aspect, and did not extrapolate 2ndPP and 2ndPTI. Similarly, Randolph et al. (2000) examined the forefoot as a whole; and finally, Powell et al. (2005) failed to make any plantar pressure recording on the forefoot.

The JIA results showed that only for the trial group, 2ndPP and 2ndPTI were much reduced since baseline, compared to the control group; indicating that the FOs aid in redistributing pressure and reducing the time spent over this particular anatomical area (Table 5.4.10.2 and Table 5.4.10.8). Furthermore, only with F-Scan (with insole) recordings, statistical difference was noticed for 2ndPP and 2ndPTI between the groups 6th month interval. The clinical implication of these results may reflect the trend previously described for the 3rd-4thPP and PTI, in which FOs seems to have a slower effect of forefoot parameters compared to the immediate changes that were recorded since baseline on the rear-foot. Another factor that might have influenced these final results is that few forefoot corrections were applied underneath the 2nd met-head simply because it was not necessary and also the data collector had to be mindful of possible fitting issues, particularly with young female subjects. It can be argued that this pragmatic study also provided new evidence in how to approach podopaediatric clinical management, in which caring for fitting issues proved to increase compliancy.

As previously mentioned, in order to monitor if the JIA children regularly wore the FOs prescribed, both control and trial FOs were covered with black 0.75cm EVA material; the signs of dynamic impression demonstrated compliance, and were typically shown

underneath the 2nd met-head, which also helped to establish the degree of durability of the materials over the 6 months.

With regards to the repeatability of the recording taken, our results reflected the conclusion made by Ahori et al. (1998) and Zammit et al. (2010). The ICC scores emerged during each data collection session using the Tekscan equipment appeared to be mostly ‘good’.

Finally, it appears that the FOs provided significant reduction of 2ndPP and 2ndPTI; however, these changes may require a few months before showing any effect, and are not as immediate as those made by the rearfoot correction. However, the data collected suggested a very high level of reliability and may contribute to build a wider knowledge on gait analysis of the 2nd metatarsal head.

6.6.11. 1st metatarsal head contact

During data analysis using the Tekscan software, the 1st met-head appeared to be the easiest metatarsal head to identify. Apart from Riad et al. (2007) who subdivided the plantar foot pressure into medial and lateral forefoot areas; most of the gait publications available at present investigated the 1st met-head during mapping of the foot (Ahroni, Boyko and Forsberg 1998a; Hadfield et al. 2003; Paton et al. 2007; Redmond, Landorf and Keenan 2009; Tsung et al. 2004; Zammit, Menz and Munteanu 2010). The authors mostly reported details about the 1stPP; in contrary, information regarding the 1stPTI is less frequently available. Only Redmond, Landorf and Keenan (2009) presented their results including 1stPTI. This RCT focussed also on 1stPTI, and it may add new evidence for the importance of this parameter particularly in paediatric gait.

As shown from Figure 5.4.11.2 and Figure 5.4.11.5, no major changes occurred between the groups in all the intervals investigated. The reduction of 1stPP and 1stPTI was noted particularly for the children who wore the customised FOs; however it was not sufficient to distinguish it from the control group. Therefore, it appeared that no statistical difference was recorded between the groups for both 1stPP and 1stPTI. It can be argued that as for previous parameters mentioned, the narrow fitting shoes led to minimise the type of forefoot corrections. Although, kinetics wedges were often prescribed in the trial group, which would have implied a reduction of thickness underneath the 1st met-head, the masking of these areas using the PP box prove that no significant changes were attained.

The statistical tests carried out within the groups suggest that no changes occurred over the 6 months of the study. These results indicate that the control and trial FOs used did not undergo significant modifications during the whole duration of the trial; therefore they might be suitable for future podiatric studies where comparison of different FOs is investigated.

During the repeatability and reproducibility study carried out in parallel with the RCT, it emerged that 1stPP and 1stPTI mostly displayed ‘good’ ICC values. It can be argued that with this parameter also, the repeatability results for the 1stPP and 1stPTI reflected the positive conclusion made by Ahori et al. (1998) and Zammit et al. (2010). This

evidence hopes to add further strength to this study and provide new information for future studies in paediatric gait.

In conclusion, the technique of mapping the 1stmet-head has been extensively used in previous studies, but only few papers focussed on 1stPP and 1stPTI together. The results did not show any significant difference between the trial and the control groups.

6.6.12. Lesser Toes contact

Investigation of the lesser toes is less frequently carried out in gait analysis compared to other forefoot parameters; some authors completely excluded this parameter from plantar mapping of the foot (Ahroni, Boyko and Forsberg 1998a; Chen and Bates 2000; Hadfield et al. 2003; Paton et al. 2007; Randolph et al. 2000; Tsung et al. 2004). In other studies the lesser toes data were defined but not included in the final analysis of the results (Redmond, Landorf and Keenan 2009). On the other hand, Zammit et al. (2010) described the 'good' ICC scores obtained from the lesser toes data obtained during the repeatability tests. Finally, Clough (2005) also utilised Tekscan equipment to investigate the implications of functional hallux limitus for lesser-metatarsal overload. It can be argued that particularly in the paediatric field, fewer publications are yet available which provide details on how the lesser toes parameter changes with podiatric intervention. The equipment available for this study allowed focusing also on this parameter contributing to the evidence base.

During the repeatability and reproducibility study, the ICC scores for the lesser toes appeared to be mostly 'good' (Appendix XIX).

Results seem to suggest that no statistical difference is recorded between the trial and the control group, indicating that the FOs did not appear to have clinically any significant effect on the lt-PP and lt-PTI. Additionally, no major changes occurred within each group over the 6 months of the study. From the descriptive statistics (Table 5.4.12.3 and Table 5.4.12.9) it emerged that during barefoot analysis on the HR Walkway, the lt-PP and lt-PTI appeared to be lower than the F-Scan (shod and with insole) recordings. Finally, the results suggest that no statistical difference for the lesser toes is obtained when FOs are introduced on the JIA children.

6.6.13. Distal Phalanx of the 1st toe

The distal phalanx is the last parameter that was investigated during plantar foot mapping in this RCT. This anatomical part was extensively studied by previous authors using in-shoes and barefoot Tekscan systems (Ahroni, Boyko and Forsberg 1998a; Clough 2005; Hadfield et al. 2003; Tsung et al. 2004; Zammit, Menz and Munteanu 2010). These authors focussed mostly on detecting peak pressure changes at the distal phalanx of the 1st toe, and rarely mentioned the Pressure Time Integral values. It can be argued that it is useful to gather information on for how long pressure is applied over a period of time, as it might convey useful details with regards to paediatric propulsion phase of gait. Generally, suitable children shoes are designed with an inbuilt rocker sole in the forefoot increasing contact with the toes; therefore it is important to compared plantar pressure changes with and without FOs. On the basis of these previous publications dp-PP and dp-PTI was investigated with JIA children during in-shoes and barefoot analysis. According to the results gathered using the Tekscan equipment, it appears that statistical difference was obtained for F-scan (with insole) between the groups for the dp-PP at baseline and at 6th months, but not for 3rd month interval p=0.059, although showing a positive trend towards significance as well. With regards to dp-PTI the stable-baseline was the only interval that appeared to achieve significant difference, hence the changes that the FOs had on pressure over a period of time were not too dissimilar compared to the control group.

From the descriptive statistics (Table 5.4.13.2, Table 5.4.13.8) with F-Scan (with insole) it was possible to notice that the control group data are generally higher compared to the trial group for the dp-PP and dp-PTI, suggesting that FOs help in reducing and redistributing some of the plantar pressure also from the distal phalanx of the 1st toe. However, within the trial group only, the dp-PP increased over the months and the dp-PTI decreased. This trend indicates that the trial patients became more propulsive than before, hence higher dp-PP; however, as they became faster, because less symptomatic, the time spent on distal phalanx of the 1st toe (dp-PTI) is reduced. On the basis of these findings, if the propulsion stage of the active treatment group is significantly different from the control group, it could be associated with the reduction of symptoms and improvement of quality of life of the trial patients. If the propulsion

phase is improved, better ambulation may occur as a result and the JIA children may exhibit a faster walking speed.

From a clinical perspective, if JIA children can be more propulsive and walk faster by simply wearing customised FOs, this increased level of activity may be reflected in an improved quality of life level.

Distal phalanx of the 1st toe, analysis has been often investigated in adult and diabetic patients and less frequently in paediatric. Therefore, these findings may prove helpful in adding new evidence within paediatric rheumatology. The repeatability test has been previously carried out for the distal phalanx of the 1st toe. Ahroni et al. (1998) used ICC to demonstrate the level of reliability of dp-PP which appeared to be 'good'. Furthermore, Zammit et al. (2010) concluded that the ICC score of the Tekscan-mat system was 'moderate-good' also for the distal phalanx. According to the results attained in this RCT both dp-PP and dp-PTI were mostly 'good'.

In conclusion, many authors proved the importance of investigating the distal phalanx of the 1st toe, most of them only focused on adult and diabetics and little evidence is yet available on distal phalanx on paediatric plantar pressure. A significant difference was highlighted between the groups, indicating a more propulsive gait for the trial group only. The positive repeatability values obtained may add strength to the findings. Finally, from a clinical point of view, the JIA children appeared to have an improved function of the distal phalanx and match with a faster ambulation data recorded only for the trial participants; therefore, this reflects the improved quality of life results for the trial children living with rheumatoid arthritis.

6.7. Strengths of the Study

This study has several strength points that contributed to the overall quality of the research:

- **RCT -** firstly, this research has been conducted as a randomised control trial, with single blinded patient intervention. This methodology allowed the investigation of the effect of the FOs supplied to the trial group against a control group. Therefore, the improvements in the trial group could be attributed solely to the treatment FOs and not a placebo effect.

- **Multicentre -** the benefits of multicenter trials from different geographic regions, allowed accessing a larger participant pool and permitted to compare results among centers; all of which may add strength to the study. The possibility of recruiting patients who lived in different parts of the country allowed the obtaining of results that may have better reflected the overall paediatric rheumatology conditions in Scotland and how they responded with FOs intervention.

- **Attrition rate –** In this study, overall 239/240 visits were successfully completed. Specifically for the JIA trial, only one visit was not completed (6^{th} month interval). However, the results gathered from that patient (at baseline and 3^{rd} month) still contributed towards the final data analysis. This very low attrition rate was one of the strengths of this study.

- **Repeatability and reproducibility of the equipment –** according to the results attained, the tools used to investigate pain, quality of life and gait parameter showed 'good' ICC scores. This fact could be considered as a significant strength of this research because it gives more credibility to the results obtained. In addition, this study not only produced new evidence base with regards to podiatric intervention with JIA patients, but also added new evidence of the level of repeatability and reproducibility of the Tekscan equipment for future podiatric/biomechanical studies in children.

- **Tekscan sensor type, resolution and sampling rate** – the in-shoe and the barefoot Tekscan systems both used the same type of sensors of equal resolution, this

allowed for F-scan and HR-Walkway measurements to be compared together. In addition, the sampling rate used was the same for the HR Walkway and F-Scan used in this study.

- **Medications –** during data analysis it was possible to distinguish between the stable and the non-stable medication group; this allowed for any positive effect to be solely attributed to the FOs intervention and not to the medication changes.

- **Standardised shoes –** by making sure that standardised shoes were worn for each data collection, no shoe construction variability errors were introduced during the gait recordings. Therefore, no effect can be attributed to wearing different shoe types during data collection.

- **FOs –** the FOs prescribed were customised according to the biomechanical needs of the patient and supplied immediately on the initial appointment. This reflected the needs of current clinical practice in JIA of early treatment with an immediate supply of customised FOs at the first biomechanical visit, rather than waiting many weeks for a fitting appointment.

6.8. Potential Limitation

- **Blinding –** a double or triple blind methodology would have been more robust**,** compared to a single-blinded randomised control trial.

- **FOs durability –** the effect of FOs was studied for a period of 6 months with each patient. Should this time frame have been extended further, it would have been possible to monitor the effectiveness of the FOs over, for example, one or two years. In this way, tests on the durability of the material could have been recorded. As a result, it would have been possible to provide extended guidelines for podopaediatrics specialists with regards to FOs replacement. Additionally, long term pain and quality of life outcomes could have been measured beyond 6 months.

- **Instrumentation and pre-test -** more detailed investigation could have been carried out to effectively validate the equipment used**.** This study conducted on healthy children was carried out with the intent to establish the level of repeatability and reproducibility of the equipment used; however, many researchers previously highlighted the level of validity of the Tekscan equipment. The extensive evidence already attained so far, were taken into account during this trial.

- **Children shoes –** during the data collection, female patients were found to be wearing very narrow school shoes. As the FOs had to be worn on a daily basis for a period of six months, it was of paramount importance that the FOs were comfortable. In some occasions, the supplied forefoot corrections could have had a positive effect on JIA gait. However, additional forefoot wedges were not often prescribed due to fitting issues. If more forefoot corrections were added onto the FOs, more significant changes in the forefoot parameters could have been recorded between the control and the trial group. However, this was a pragmatic study, reflecting real life clinical management which on the other hand is strength.

6.9. Future Research

The findings obtained from the present study suggested the need for a robust methodology such as randomised controlled trial to investigate primary and secondary outcome in JIA children.

Further research is needed into the effects of FOs for a longer period of time. In this study the FOs were tested for a period of 6 months; it would be interesting to monitor how long the materials used are able to last and to retain the correction applied. With these additional data, podiatrists would be able to have further indications on how frequently FOs must be reviewed. In addition, as the child foot-size keeps growing, adjustments and substitution with a bigger pairs of FOs maybe required, ensuring that the child remains asymptomatic.

Future research is required to compare the clinical outcomes from different types of FOs to treat JIA children. With more research it would be possible to establish the clinical effect of: different materials, different orthotics brands, and to test new customised FOs modifications suitable in JIA patients.

In order to gather more robust results, it would also be beneficial to recruit a bigger number of patients from more paediatric rheumatology hospitals in UK and abroad. With the involvements of multicentre clinical trials in different countries, further analysis and data comparison will be carried out to establish the clinical impact of the podiatry intervention with symptomatic JIA children.

During the time considered for data collection, improved JIA health-status were recorded for the trial group only. Although statistical analysis was not carried out, the BMI data seemed to suggest that, as the trial JIA group was in less pain and with improved quality of life, more activity level could have had a direct impact in reducing weight in JIA children. This encouraging trend could generate collaboration with nutritional and physiotherapy departments to tackle the ever growing issues of obesity in children and JIA. Therefore, this multidisciplinary approach could really provide new cost-effective and not-invasive treatment options for obesity in children and adolescent; and attract more private and public funding to meet these targets.

Further investments to promote research in podopaediatric will contribute to the development of more robust evidence and international guidelines, which will strengthen the role of podiatrists and the profession within the multidisciplinary paediatric rheumatology team.

Chapter 7: Conclusion

The primary findings from this research are that FOs significantly reduce pain and improve quality of life of JIA children already in the 3 months since FOs are supplied. This also suggests that patients provided with cost-effective customised FOs may experience some quick improvements in their lower limbs symptoms, compared to the children who received the control FOs, which had no correction. It can be argued that these results strongly suggest how podiatric intervention can be carried out directly on the same day of the initial assessment. Furthermore, more JIA children showed a high level of compliancy. Therefore, if the FOs are regularly worn, there is a higher chance that the corrections applied to improve lower limb biomechanics, will be of benefit.

With regards to the secondary outcomes, this pragmatic study was able to provide extensive details in paediatric gait and plantar pressure analysis, using modern technology to investigate Peak Pressure and Pressure Time Integral changes at in-shoe (with-insole and shod) and barefoot analysis. Significant difference was attained between the groups for the gait time, gait velocity, stance time, total plantar surface, heel contact, midfoot, 5^{th} – 3^{rd}/4^{th} – 2^{nd} metatarsal heads and the distal phalanx of the 1^{st} toe. On the basis of the positive findings, all the control JIA patients were contacted again as soon as the final results were gathered, and they were offered the option to be supplied with the trial FOs.

According to the results obtained in this RCT, the tools used to investigate primary outcomes and the Tekscan equipment adopted for the secondary outcomes, appeared to have scored mostly ‘good’ and ‘excellent’ ICC scores. Therefore, this study may be helpful for future research who intend adopting the similar methodology.

The clinical implications of these results are that practitioners should encourage JIA children to wear the FOs regularly for at least 6 months. Practitioners should also emphasise to their patients that redistribution of pressure and shock absorption occurs only if the device are worn regularly. Therefore, in order to encourage compliancy the practitioners need to ensure that FOs are comfortable and that appropriate modifications are utilised to aid in the reduction of foot pain.

The significant results obtained from this pragmatic study, strongly support the use of FOs in the treatment of JIA children, which highlights the central role of the podiatrists within the multidisciplinary team in paediatric rheumatology; and hopes to raise the profile of podiatrists working within paediatric hospitals and private practices.

Appendices

Appendix I: Symptomatic Joints

On examination the most commonly symptomatic joints in the lower limbs appeared to be: the hip, medial aspect of the knee, patella-tibia tendon, tibial tuberosity, tibialis-posterior tendon, achilles tendon, ankle joint, STJ, dorsal aspect of the midtarsal joint (talo-navicular and calcaneo-cuboid joint) and metatarsal heads. It was not possible to statistically calculate the most commonly affected joints.

Subtalar Joint (STJ)

Intra-test repeatability for STJ measurements

All STJ measurements taken during each appointment were analysed throughout the 6 months trial period. The data obtained from every patient in each of the three appointments were compared in order to investigate the repeatability skills of the data collector. As only D9 (control group) missed the last of the 3 appointments, only 2 measurements were missed (left & right of the 6th month). Therefore, within the control group 96.6% (n=56/58) of the measurements were completed. Instead, within the trial group 100% (n=62) STJ measurements were successfully carried out.

Table 6.6.13.1: percentages of STJ measurements obtained (control and trial patients)

STJ measurements		
	Control	**Trial**
Valid	96.6% (n=56)	100% (n=62)
Excluded	3.4% (n=2)	0% (n=0)
Total	100% (n=58)	100% (n=62)

In order to measure the reliability of the data recorded, both groups were split and ICC statistical test was carried out. With regard to the control group the ICC values = 0.950, and for the trial group ICC = 0.947. As previously explained in both cases ‘excellent’ ICC score were obtained.

Table 6.6.13.2: details of the ICC score obtained from the STJ measurements at baseline (control and trial patients)

ICC - STJ measurements at baseline		
	Control	**Trial**
ICC score	0.950	0.947
Interpretation	'excellent'	'excellent'

STJ measurements for JIA subjects

According to descriptive statistics all STJ data were collected at baseline, 58 for the control and 62 for the trial group; no missing data were reported. The overall degrees of correction required to maintain the STJ into neutral position in the control group was 8.14° (SD2.01), 0.73, minimum 5° and maximum was 14°. Similarly, within the trial group the mean value was 7.27° (SD1.63), minimum STJ was 5° and maximum 12°.

Table 6.6.13.3: descriptive statistics of the STJ measurements at baseline (control and trial patients)

STJ at Baseline		
	Control	**Trial**
Valid	58	62
Missing	0	0
Mean (SD)	8.14°(2.01)	7.27°(1.63)
Minimum	5°	5°
Maximum	14°	12°

Appendix II: Juvenile Idiopathic Arthritic FOs Survey

Queen Margaret University
EDINBURGH

Juvenile Idiopathic Arthritic FOs Survey

	Yes	No
Do you treat Juvenile Idiopathic Arthritis (JIA) patients?	☐	☐
What FOs do you normally prescribe to JIA:		
Palliative Custom made	☐	☐
Function custom made	☐	☐
Palliative Off-the-shelf	☐	☐
Functional Off-the-shelf	☐	☐
Other:		
If you prescribe Off-the-Shelf FOs, which type and brand of FOs do you normally prescribe for JIA patients?		

Andrea Coda Chief investigator PhD researcher in Paediatric Rheumatology BSc (Hons) MChS HPC Registered Podiatrist	Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 acoda@qmu.ac.uk

Appendix III: Liability insurance scheme

MARSH

MARSH MERCER KROLL
GUY CARPENTER OLIVER WYMAN

Marsh Ltd
Glasgow
Postal Address:
PO Box 3262
Norwich, NR7 7BH
0141 304 4386 Fax 0141 221 5409
Tommy.Masterson@marsh.com
www.marsh.co.uk

31st July 2008

Subject:
To Whom It May Concern

Dear Sirs

EVIDENCE OF INSURANCE – QUEEN MARGARET UNIVERSITY

We are writing to confirm that we act as Insurance Brokers to the above client and that we have arranged liability insurance on their behalf as detailed below:

EMPLOYERS LIABILITY

INSURER	Royal & Sun Alliance
POLICY NUMBER	RTT153481
PERIOD OF INSURANCE	1st August 2008 – 31st July 2009 both days inclusive
LIMIT OF LIABILITY	£10,000,000

PUBLIC/PRODUCTS LIABILITY

INSURER	Royal & Sun Alliance
POLICY NUMBER	RTT153481
PERIOD OF INSURANCE	1st August 2008 – 31st July 2009 both days inclusive
LIMIT OF LIABILITY	£10,000,000 any one occurrence unlimited in the period of insurance for Public Liability and in the aggregate in the period of insurance for Products Liability

EXCESS EMPLOYERS LIABILITY

INSURER	ACE Insurance
POLICY NUMBER	UKCASO01497108
PERIOD OF INSURANCE	1st August 2008 – 31st July 2009 both days inclusive
LIMIT OF LIABILITY	£15,000,000 in excess of £10,000,000 (insured by Royal & Sun Alliance) any one occurrence

Registered in England Number: 1507274, Registered Office: 1 Tower Place West Tower Place London EC3R 5BU
Marsh Ltd is authorised and regulated by the Financial Services Authority.
Marsh Ltd conducts its general insurance activities on terms that are set out in the document "Our Business Principles and Practices". This may be viewed on our website http://www.marsh.co.uk/aboutMarsh/principles.html

MMC Marsh & McLennan Companies

EXCESS PUBLIC/PRODUCTS LIABILITY

INSURER	ACE Insurance
POLICY NUMBER	UKCASO01497108
PERIOD OF INSURANCE	1st August 2008 – 31st July 2009 both days inclusive
LIMIT OF LIABILITY	£10,000,000 in excess of £10,000,000 (insured by Royal & SunAlliance) any one occurrence unlimited in the Period of Insurance for Public Liability and in the aggregate in the Period of Insurance for Product Liability

PROFESSIONAL INDEMNITY

INSURER	Royal & Sun Alliance
POLICY NUMBER	RKK415215
PERIOD OF INSURANCE	1st August 2008 – 31st July 2009 both days inclusive
LIMIT OF LIABILITY	£3,000,000 each and every claim and in the aggregate

Standard policy terms, conditions and exceptions apply to all policies.

This letter is issued as a matter of information only and confers no rights upon the recipient of this letter other than those provided by the policy. This letter does not amend, extend or alter the coverage afforded by the policy or policies as described herein.

Notwithstanding any requirement, term or condition of any contract or other document with respect to which this letter may be issued or pertain, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions or exclusions of such policy (policies). Limits shown may have been reduced by paid claims.

If you should require any further information on the above please do not hesitate to contact us.

Yours sincerely

Tommy Masterson
Client Adviser

Appendix IV: ILAR Classification

Study No: (to be completed by chief investigator only)

Queen Margaret University
EDINBURGH

CLASSIFICATION FOR POTENTIAL CANDIDATES

	Yes	No
ILAR CLASSIFICATION **If one of the following applied, tick yes:** • Systemic Arthritis • Oligoarthritis • Rheumatoid- Factor-Positive Polyarthritis • Rheumatoid- Factor-Negative Polyarthritis • Enthesitis-Related Arthritis • Psoriatic Arthritis • Undifferentiated Arthritis	☐	☐
INCLUSION CRITERIA		
Diagnosed with JIA according to ILAR criteria	☐	☐
All subjects with lower extremity joint involvement with disease onset ranging from 5 to 18 years old.	☐	☐
Ability to walk a minimum 15 meters without assistive devices	☐	☐
Ability to walk barefoot or shod	☐	☐
No concomitant musculoskeletal disease, central or peripheral nerve disease and endocrine disorders, especially Diabetes Mellitus	☐	☐
No previous foot surgery	☐	☐
No foot osseous anomaly noted during the physical evaluation	☐	☐
Six months since DMARD therapy	☐	☐
No contraindications in prescription of insole	☐	☐

If all the above boxes are ticked "Yes", then patient is suitable to be invited to participate in the study.

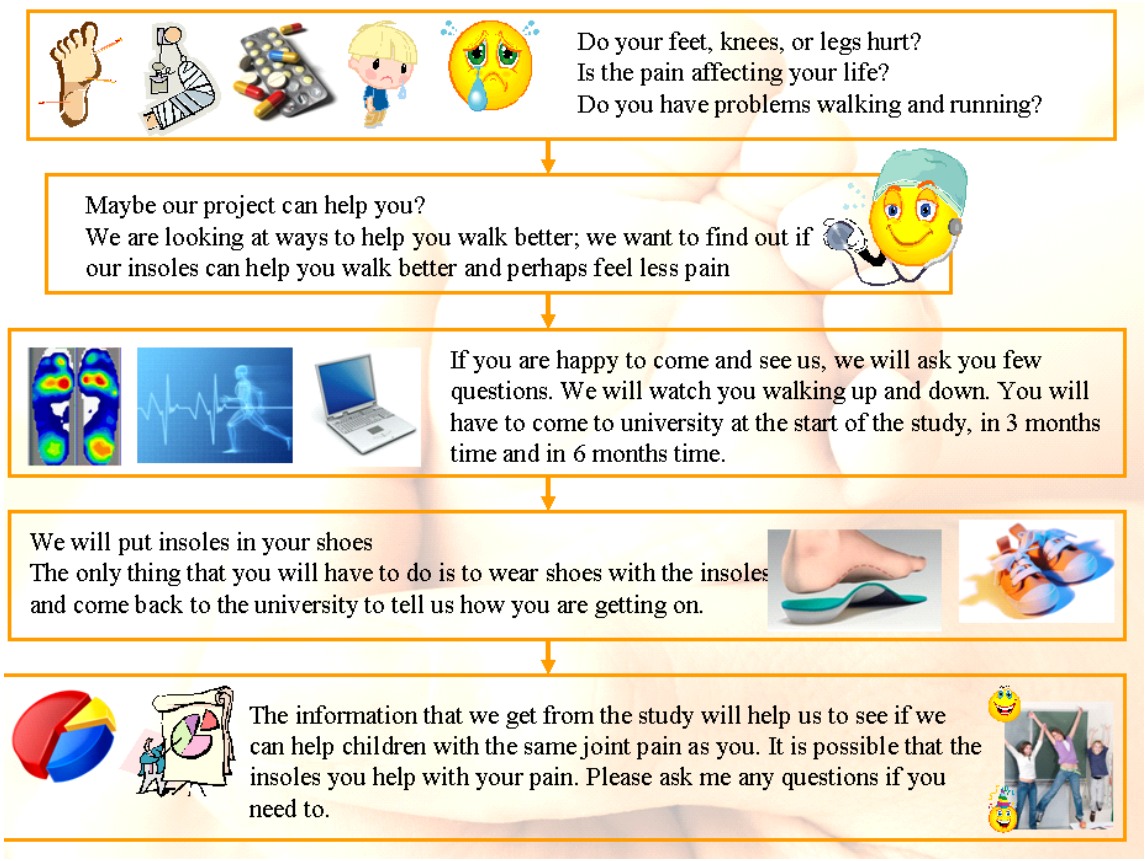
Appendix V: Information sheet for participants up to 5 year old

Queen Margaret University
EDINBURGH

Andrea Coda : (PhD Researcher ~ BSc MChS HPC Registered Podiatrist)
Dr. J. Davidson - Consultant Paediatric Rheumatologist, Royal Hospital for Sick Children, Edinburgh.
Dr. P. Fowlie - Consultant Paediatrician & Clinical Director, Ninewells Hospital.
Dr. J. Walsh - Consultant Paediatric Rheumatology, Royal Hospital for Sick Children, Edinburgh.
Dr. Tom Carline - Second Supervisor, Queen Margaret University.
Dr. Derek Santos - Director of Study, Queen Margaret University.

The following information sheet it is intended to be shown and explained to the child by their parent/ guardian.

Contact details of the Chief Researcher Mr Andrea Coda Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 acoda@qmu.ac.uk	Contact details of the independent adviser Mrs Lynne Flynn Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 lflynn@qmu.ac.uk



Appendix VI: Information sheets for potential participants from 6 to 10 years old

Queen Margaret University
EDINBURGH

Andrea Coda: (PhD Researcher ~ BSc MChS HPC Registered Podiatrist)

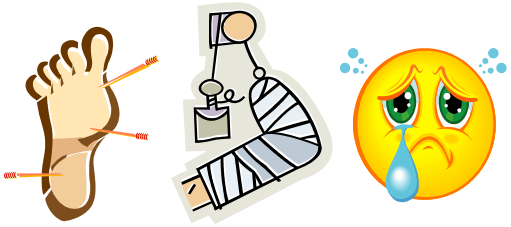
Dr. J. Davidson - Consultant Paediatric Rheumatologist, Royal Hospital for Sick Children, Edinburgh.
Dr. P. Fowlie - Consultant Paediatrician & Clinical Director, Ninewells Hospital.
Dr. J. Walsh - Consultant Paediatric Rheumatology, Royal Hospital for Sick Children, Edinburgh.
Dr. Tom Carline - Second Supervisor, Queen Margaret University.
Dr. Derek Santos - Director of Study, Queen Margaret University.

The following information sheet it is intended to be shown and explained to the child by their parent/ guardian.

Study Title
"The effect of FOs in children with joint pain"

The purpose of the study

FOs are worn in shoes to reduce foot, knee and leg pain. Not many people have studied the effect of FOs in children with painful joints. We want to find out if our FOs can help you walk better.



Why have you been chosen?

You have been chosen because you have painful joints.

Do I have to take part?

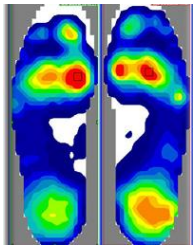
It is up to you. Please take part if you want to. If at any point you are not happy, then tell us and you can stop without any problems.

What will happen if I decide to take part?

If you are happy to take part we will give you FOs. You will have 50% chance of receiving a basic FOs or a corrective FOs.
We will put the FOs in your shoes that you wear every day. You will have to do 2 things:

1st thing: you will have to answer few questions about joint pain (about 15 min).

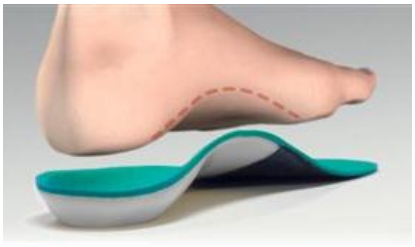
2nd thing: you will have to walk up and down in a room (barefoot, with shoes and with FOs in the shoes).



You will have to come to see us 3 times (at the start of the study, in 3 months' time and in 6 months' time).
In total you will have to stay no longer than 1 hour. You will be free to stop at any time and you will not have to say why.

What do I have to do?

The only thing that you have to do is to use the FOs when you wear your shoes and come back to university to tell me how you are getting on.



What are the possible disadvantages and risks of taking part?
We believe that this is a safe clinical assessment. The researcher is not aware of any risks.
What are the possible benefits of taking part?

You will receive a pair of FOs which may help your joint pain. The information that we get from the study will help us to see if we can help children with the same joint pain that you have.

What if something goes wrong?
We do not expect anything to go wrong while wearing the FOs.

Will my taking part in this study be kept confidential?
Yes always. Please let me know if you want me to tell your doctor about you taking part to this research.

Thank you for taking time to read this information sheet. If you have any questions, please call Mr Andrea Coda.

Contact details of the Chief Researcher Mr Andrea Coda Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 acoda@qmu.ac.uk	Contact details of the independent adviser Mrs Lynne Flynn Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 lflynn@qmu.ac.uk

Appendix VII: Information sheet for potential participants from 11 to 15 years old

Queen Margaret University
EDINBURGH

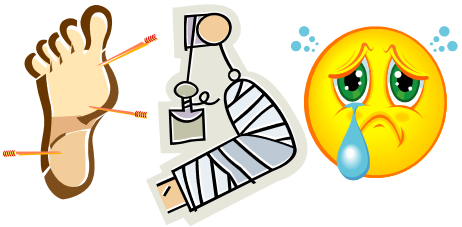
Andrea Coda : (PhD Researcher ~ BSc MChS HPC Registered Podiatrist)

Dr. J. Davidson - Consultant Paediatric Rheumatologist, Royal Hospital for Sick Children, Edinburgh.
Dr. P. Fowlie - Consultant Paediatrician & Clinical Director, Ninewells Hospital.
Dr. J. Walsh - Consultant Paediatric Rheumatology, Royal Hospital for Sick Children, Edinburgh.
Dr. Tom Carline - Second Supervisor, Queen Margaret University.
Dr. Derek Santos - Director of Study, Queen Margaret University.

Study Title
"An investigation of clinical effectiveness of foot FOs on pain; quality of life and gait of young patients with arthritis".

You have been invited to take part in this research study. Before you decide it is important for you to understand what this research is all about. Please read this information carefully. If there is anything that is not clear or you would like more information please contact us at the telephone number below.

The purpose of the study



FOs which are worn in shoes can help to reduce foot, knee and leg pain and allow you to walk better. Unfortunately there is not a lot of research in children with joint pain. We want to study if FOs help reduce joint pain in children.

Why have you been chosen?

You have been chosen because you have painful joints.

Do I have to take part?

It is up to you to decide whether or not you would like to take part. You do not need to give a reason if you decide not to take part in the study. If you decide to take part you are free to stop at any time without giving a reason.

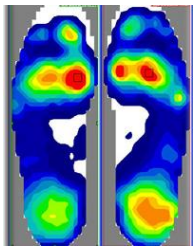
What will happen if I decide to take part?

If you agree to take part in the study you will be provided with a pair of new FOs which are to be worn inside your shoes all the time. You will have 50% chance of receiving a basic FOs or a corrective FOs If you agree to participate in the study, you will be asked to provide your height, weight and age. You will then be asked to do two things.

1st task: we will ask you a few questions about your joint pain (about 15 min).

2nd task: you will have to walk up and down in a room (barefoot, with shoes and with insoles in the shoes) for about 30min.

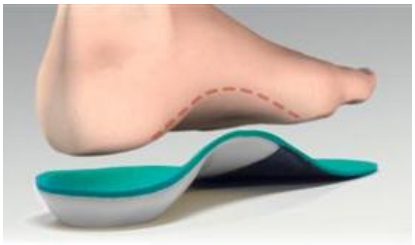




You will have to come to see us 3 times (at the start of the study, in 3 months time and in 6 months' time). In total you will have to stay no longer than 1 hour. You will be free to stop at any time and you will not have to say why.

The researcher is not aware of any risks associated with these procedures.

What do I have to do?




The only thing that you have to do is to come to university and while wearing the FOs.

What are the possible disadvantages and risks of taking part?

We believe that this is safe clinical assessment. The researcher is not aware of any risks.

What are the possible benefits of taking part?

We cannot promise that the FOs will help you but they may reduce your joint pain. The information that we will obtain from the study will help us to identify if we can help future children with the same joint pain that you have. It is intended that this information will be used by clinicians to help decide if prefabricated FOs are effective, and therefore used more frequently for helping patients with your condition.

What if something goes wrong?

You are being asked to take part in non-invasive clinical assessment and it is unlikely that anything will go wrong.

Will my taking part in this study be kept confidential?

All information that is collected about you will be kept strictly confidential. Any information about you which leaves the premises will have your name and address removed so that you cannot be recognised or identified. Please let me know if you want me to tell your doctor about you taking part in this research.

What will happen to the results of the research study?

The results of the research will be published some months after the study has been completed. You will not be identified in any of the reports or medical publications and all data will only be kept until the study is completed.

Thank you for taking time to read this information sheet. If you have any questions, please call Mr Andrea Coda.

Contact details of the Chief Researcher	Contact details of the independent adviser
Mr Andrea Coda Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 acoda@qmu.ac.uk	Mrs. Lynne Flynn Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 lflynn@qmu.ac.uk

Appendix VIII: Information sheet for potential participants from 16 to 18 years old and parents/ guardians

Queen Margaret University
EDINBURGH

Andrea Coda : (PhD Researcher ~ BSc MChS HPC Registered Podiatrist)

Dr. J. Davidson - Consultant Paediatric Rheumatologist, Royal Hospital for Sick Children, Edinburgh.
Dr. P. Fowlie - Consultant Paediatrician & Clinical Director, Ninewells Hospital.
Dr. J. Walsh - Consultant Paediatric Rheumatology, Royal Hospital for Sick Children, Edinburgh.
Dr. Tom Carline - Second Supervisor, Queen Margaret University.
Dr. Derek Santos - Director of Study, Queen Margaret University.

Study Title
"A randomised control trial to investigate the clinical effectiveness of pre-formed semi-rigid foot orthoses, on pain, quality of life and the dynamics of gait of patients diagnosed with Juvenile Idiopathic Arthritis (JIA)"

You have been invited to take part in this research study. Before you decide if you would like to take part it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read the following information carefully and to discuss it with others if you wish. If there is anything that is not clear or you would like more information please contact the chief investigator at the telephone number below. Take time to decide whether or not you would like to take part.

The purpose of the study

Orthoses are specialised FOs which are worn in shoes to reduce foot pain and allow a more comfortable walk. Unfortunately few studies have been conducted on children with Juvenile Idiopathic Arthritis. The purpose of this study is to investigate the effectiveness of prefabricated FOs in children with JIA.

Why have you been chosen?

You have been chosen because you have been diagnosed with Juvenile Idiopathic Arthritis by your doctor according to ILAR criteria (International League of Association for Rheumatology). You have also been chosen because you do not suffer from any disease other than Juvenile Idiopathic Arthritis and because the disease is affecting joints in your lower limb.

Do I have to take part?

It is up to you to decide whether or not you would like to take part. You do not need to give a reason if you decide not to take part in the study. If you decide to take part you

will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are free to withdraw from the study at any time without giving a reason.

What will happen if I decide to take part?

If you agree to take part in the study you will be provided with a pair of new FOs which are to be worn inside your shoes. Following a "wearing in" period of approximately one week, the FOs should be worn in your shoes all of the time. The purpose of these FOs is to reduce pain that you may be experiencing in your lower limbs due to your arthritis. You will have 50% chance of receiving a control FOs or a study FOs. If you agree to participate in the study, you will be asked to provide your height, weight and age. You will then be asked to perform two different tasks.

1st task: you will be asked to complete 3 questionnaires that should not take longer than 15 minutes to complete. The questionnaire contains questions regarding your pain, foot function and your daily activities.

2nd task: you will be asked to walk along a walkway at your chosen speed approximately 9 times. You will walk barefoot, with shoes (these will be provided) and with a pair of FOs in the shoes.

If you decide to take part in the study, you will be asked to attend the gait laboratory for data collection on 3 separate occasions (at the start of the study, 3 months later, and then 3 months after that).

The researcher is not aware of any risks associated with these procedures. The whole procedure should take no longer than 60 minutes. You will be free to withdraw from the study at any stage and you will not have to give a reason.

What do I have to do?

The only things that you have to do are report to the gait laboratory and undertake the procedures outlined above. There are no other requirements.

What are the possible disadvantages and risks of taking part?
The study involves a simple and safe clinical assessment. The researcher is not aware of any risks.

What are the possible benefits of taking part?

The benefit of taking part is that you will receive a pair of FOs which may help reduce lower limb pain which you maybe experiencing due to your JIA. The information that we will obtain from the study will help us to identify if we can help children with the same joint pain that you have.
It is intended that this information will be used to provide clinicians with useful evidence about whether prefabricated FOs are effective, and whether they will be used more frequently to help patients with your condition.

What if something goes wrong?

You are being asked to take part in a non-invasive clinical assessment and it is unlikely that anything will go wrong. However, a risk assessment of the laboratory has been carried out and Queen Margaret University has a liability insurance scheme for compensation as a result of harm caused due to negligence on the part of the researcher in connection with the above mentioned study.

Will my taking part in this study be kept confidential?

All information which is collected about you will be kept strictly confidential. Any information about you which leaves the premises will have your name and address removed so that you cannot be recognised or identified. Please let me know if would like your General Practitioner (GP) to be informed about you taking part to this study.

What will happen to the results of the research study?

The results of the research will be published some months after the study has been completed. The results will be published as research papers in scientific journals and will also be available as part of a research thesis at the Queen Margaret University Library. You will not be identified in any of the reports or publications and all data will only be kept until the study and all associated works are completed.

Who is organizing and funding the research?

Mr Andrea Coda, a research student based at the Queen Margaret University Edinburgh, is conducting this study. Queen Margaret University funds the study as a PhD research degree. Mr Andrea Coda is a BSc (Hons) MChS HPC Registered Podiatrist.

Will my General Practitioner (GP) be informed if I decide to take part in the study?

If you decide to take part in the study then your General Practitioner (GP) will only be informed of your participation if you want them to be informed. On the consent form there is a box you can tick if you wish to give permission for you GP to be informed that you are taking part in the study.

Thank you for taking time to read this information sheet. If you have any questions please do not hesitate to contact Mr Andrea Coda during office hours.

If you would like to contact an independent person, who knows about this project but is not involved in it, you are welcome to contact Mrs. Lynne Flynn. Her contact details are given below.

If you have read and understood this information sheet and you would like to be a participant in the study, please see the consent form.

Appendix IX: Consent form

Queen Margaret University
EDINBURGH

CONSENT FORM

Study No: (to be completed by chief investigator only)

"A randomised control trial to investigate the clinical effectiveness of pre-formed semi-rigid foot orthoses, on pain, quality of life and the dynamics of gait of patients diagnosed with Juvenile Idiopathic Arthritis (JIA)"

Name of PhD researcher: Andrea Coda

Please initial box

- I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected ☐
- I agree to participate in this study. ☐
- I give my permission for my General Practitioner (GP) to be informed of my participation in this study. ☐

Name of participant: _____

Name of parent/guardian: _____

Signature of parent/guardian: _____

Signature of researcher: _____

Date: _____

Contact details:
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1 copy for participant and 1 copy for chief investigator

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Appendix X: Participant Medical History, Medication, CHA Scores

Queen Margaret University
EDINBURGH

Study No.

MEDICAL HISTORY	
Age at onset	
Date of onset	
Sub-type of JIA	
Joint(s) Affected	
Symptoms	

MEDICATIONS		
Drug Name	Dosage	Frequency
Joint Injection (please circle)	Yes / No	
If Yes, please specify: Date: Which Joint was injected:		

CHA SCORES:	Date:	Score:

Appendix XI: Participant details (Base Line, 3 month, 6 month)

Study No.

Baseline	
D.O.B.	
Date:	
Shoe Size	
Weight	
Height	
BMI	
3 Month	
Date:	
Shoe Size	
Weight	
Height	
BMI	
6 Month	
Date:	
Shoe Size	
Weight	
Height	
BMI	

Appendix XII: Quality of Life Scores (Base Line, 3 month, 6 month)

Study No.

Baseline Scores	**Date:**
Child PedQL Score (Generic)	
Child PedQL Score (Rheumatology)	
Parents PedQL Score (Generic)	
Parents PedQL Score (Rheumatology)	
CHAQ	
3 Months Scores	**Date:**
Child PedQL Score (Generic)	
Child PedQL Score (Rheumatology)	
Parents PedQL Score (Generic)	
Parents PedQL Score (Rheumatology)	
CHAQ	
6 Months Scores	**Date:**
Child PedQL Score (Generic)	
Child PedQL Score (Rheumatology)	
Parents PedQL Score (Generic)	
Parents PedQL Score (Rheumatology)	
CHAQ	

Note: Higher Scores Indicate lower problems.

ID#_____

Date:_____

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YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers	☺	😐	☹

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

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Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PHYSICAL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to walk	0	2	4
2. Is it hard for you to run	0	2	4
3. Is it hard for you to play sports or exercise	0	2	4
4. Is it hard for you to pick up big things	0	2	4
5. Is it hard for you to take a bath or shower	0	2	4
6. Is it hard for you to do chores (like pick up your toys)	0	2	4
7. Do you have hurts or aches (*Where?*_____)	0	2	4
8. Do you ever feel too tired to play	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

EMOTIONAL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Do you feel scared	0	2	4
2. Do you feel sad	0	2	4
3. Do you feel mad	0	2	4
4. Do you have trouble sleeping	0	2	4
5. Do you worry about what will happen to you	0	2	4

SOCIAL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to get along with other kids	0	2	4
2. Do other kids say they do not want to play with you	0	2	4
3. Do other kids tease you	0	2	4
4. Can other kids do things that you cannot do	0	2	4
5. Is it hard for you to keep up when you play with other kids	0	2	4

SCHOOL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to pay attention in school	0	2	4
2. Do you forget things	0	2	4
3. Is it hard to keep up with schoolwork	0	2	4
4. Do you miss school because of not feeling good	0	2	4
5. Do you miss school because you have to go to the doctor's or hospital	0	2	4

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How much of a problem is this for you?

Not at all	Sometimes	A lot
☺	😐	☹

ID# _____

Date: _____

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PARENT REPORT for **YOUNG CHILDREN** (ages **5-7**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has your child had with …*

PHYSICAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores, like picking up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with school activities	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

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PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has your child had with ...*

PHYSICAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

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CHILD REPORT (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you ...*

About My Health and Activities *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

About My Feelings *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

How I Get Along with Others *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

About School *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

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PARENT REPORT for **TEENS** (ages **13-18**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

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*In the past **ONE month**, how much of a **problem** has your teen had with ...*

PHYSICAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other teens	0	1	2	3	4
2. Other teens not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other teens	0	1	2	3	4
4. Not able to do things that other teens his or her age can do	0	1	2	3	4
5. Keeping up with other teens	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

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Date: _____

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Pediatric Quality of Life Inventory

Version 4.0

TEEN REPORT (ages **13-18**)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

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*In the past **ONE month**, how much of a **problem** has this been for you ...*

About My Health and Activities *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

About My Feelings *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

How I Get Along with Others *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other teens	0	1	2	3	4
2. Other teens do not want to be my friend	0	1	2	3	4
3. Other teens tease me	0	1	2	3	4
4. I cannot do things that other teens my age can do	0	1	2	3	4
5. It is hard to keep up with my peers	0	1	2	3	4

About School *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

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Date:_____

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Rheumatology Module

Version 3.0

PARENT REPORT for **YOUNG CHILDREN** (ages **5-7**)

DIRECTIONS

Children with a rheumatic illness sometimes have special problems. On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has your child had with ...*

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PAIN AND HURT *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Aches in joints and/or muscles	0	1	2	3	4
2. Having a lot of pain	0	1	2	3	4
3. Trouble sleeping because of pain or aching in joints and/or muscles	0	1	2	3	4
4. Feeling stiff in the morning or when he/she sits too long	0	1	2	3	4

DAILY ACTIVITIES *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Difficulty turning on water faucets	0	1	2	3	4
2. Difficulty turning door handles	0	1	2	3	4
3. Trouble eating with a fork and spoon	0	1	2	3	4
4. Difficulty writing or drawing with a pen or pencil	0	1	2	3	4
5. Difficulty carrying school books	0	1	2	3	4

TREATMENT *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Medicines making him/her feel sick	0	1	2	3	4
2. Physical therapy or daily exercise causing pain	0	1	2	3	4
3. Getting anxious about having blood drawn	0	1	2	3	4
4. Getting anxious about having needle sticks/shots	0	1	2	3	4
5. Getting anxious about going to the doctor	0	1	2	3	4

WORRY *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Worrying about side effects from medicines	0	1	2	3	4
2. Worrying about whether or not medicines are working	0	1	2	3	4
3. Worrying about his/her illness	0	1	2	3	4

COMMUNICATION *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Difficulty telling the doctors and nurses how he/she feels	0	1	2	3	4
2. Difficulty asking the doctors or nurses questions	0	1	2	3	4
3. Difficulty explaining his/her illness to other people	0	1	2	3	4

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Date: _____

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YOUNG CHILD REPORT (ages **5-7**)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is <u>not at all</u> a problem for you, point to the smiling face

If it is <u>sometimes</u> a problem for you, point to the middle face

If it is a problem for you <u>a lot</u>, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers	☺	😐	☹

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

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Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PAIN AND HURT *(problems with…)*	Not at all	Some-times	A lot
1. Do you ache or hurt in your joints and/or muscles	0	2	4
2. Do you hurt a lot	0	2	4
3. Do you have trouble sleeping because of pain or aching in your joints and/or muscles	0	2	4
4. Do you feel stiff in the morning or when you sit too long	0	2	4

DAILY ACTIVITIES *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to turn on water faucets	0	2	4
2. Is it hard for you to turn door handles	0	2	4
3. Do you have trouble eating with a fork and spoon	0	2	4
4. Is it hard for you to write or draw with a pen or pencil	0	2	4
5. Do you have trouble carrying your school books	0	2	4

TREATMENT *(problems with…)*	Not at all	Some-times	A lot
1. Do your medicines make you feel sick	0	2	4
2. Does your physical therapy or daily exercise hurt	0	2	4
3. Do you get scared when you have to have blood tests	0	2	4
4. Do you get scared about having needle sticks/shots	0	2	4
5. Do you get scared when you have to go to the doctor	0	2	4

WORRY *(problems with…)*	Not at all	Some-times	A lot
1. Do you worry about side effects from medicines	0	2	4
2. Do you worry about whether or not your medicines are working	0	2	4
3. Do you worry about your illness	0	2	4

COMMUNICATION *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to tell the doctors and nurses how you feel	0	2	4
2. Is it hard for you to ask the doctors and nurses questions	0	2	4
3. Is it hard for you to explain your illness to other people	0	2	4

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How much of a problem is this for you?

Not at all ☺ Sometimes 😐 A lot ☹

ID# _____

Date: _____

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Rheumatology Module

Version 3.0

CHILD REPORT (ages **8-12**)

DIRECTIONS

Children with a rheumatic illness sometimes have special problems. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you …*

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PAIN AND HURT *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I ache or hurt in my joints and/or muscles	0	1	2	3	4
2. I hurt a lot	0	1	2	3	4
3. I have trouble sleeping because of pain or aching in my joints and/or muscles	0	1	2	3	4
4. I feel stiff in the morning or when I sit too long	0	1	2	3	4

DAILY ACTIVITIES *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to turn on water faucets	0	1	2	3	4
2. It is hard to turn door handles	0	1	2	3	4
3. I have trouble eating with a fork and knife	0	1	2	3	4
4. It is hard to write or draw with a pen or pencil	0	1	2	3	4
5. I have trouble carrying my school books	0	1	2	3	4

TREATMENT *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. My medicines make me feel sick	0	1	2	3	4
2. My physical therapy or daily exercise hurts	0	1	2	3	4
3. It is hard to be responsible for my medicines or physical therapy	0	1	2	3	4
4. It is hard to manage my illness	0	1	2	3	4
5. I get scared when I have to have blood drawn	0	1	2	3	4
6. I get scared about having needle sticks/shots	0	1	2	3	4
7. I get scared when I have to go the doctor	0	1	2	3	4

WORRY *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I worry about the side effects from medicines	0	1	2	3	4
2. I worry about whether or not my medicines are working	0	1	2	3	4
3. I worry about my illness	0	1	2	3	4

COMMUNICATION *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4

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ID#_____

Date:_____

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Rheumatology Module

Version 3.0

PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

Children with a rheumatic illness sometimes have special problems. On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has your child had with ...*

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PAIN AND HURT *(problems with...)*	Never	Almost Never	Sometimes	Often	Almost Always
1. Aches in joints and/or muscles	0	1	2	3	4
2. Having a lot of pain	0	1	2	3	4
3. Trouble sleeping because of pain or aching in joints and/or muscles	0	1	2	3	4
4. Feeling stiff in the morning or when he/she sits too long	0	1	2	3	4

DAILY ACTIVITIES *(problems with...)*	Never	Almost Never	Sometimes	Often	Almost Always
1. Difficulty turning on water faucets	0	1	2	3	4
2. Difficulty turning door handles	0	1	2	3	4
3. Trouble eating with a fork and knife	0	1	2	3	4
4. Difficulty writing or drawing with a pen or pencil	0	1	2	3	4
5. Difficulty carrying school books	0	1	2	3	4

TREATMENT *(problems with...)*	Never	Almost Never	Sometimes	Often	Almost Always
1. Medicines making him or her feel sick	0	1	2	3	4
2. Physical therapy or daily exercise causing pain	0	1	2	3	4
3. Difficulty being responsible for medicines or physical therapy	0	1	2	3	4
4. Difficulty managing his/her illness	0	1	2	3	4
5. Getting anxious about having blood drawn	0	1	2	3	4
6. Getting anxious about having needle sticks/shots	0	1	2	3	4
7. Getting anxious about going to the doctor	0	1	2	3	4

WORRY *(problems with...)*	Never	Almost Never	Sometimes	Often	Almost Always
1. Worrying about side effects from medicines	0	1	2	3	4
2. Worrying about whether or not medicines are working	0	1	2	3	4
3. Worrying about his/her illness	0	1	2	3	4

COMMUNICATION *(problems with...)*	Never	Almost Never	Sometimes	Often	Almost Always
1. Difficulty telling the doctors and nurses how he/she feels	0	1	2	3	4
2. Difficulty asking the doctors or nurses questions	0	1	2	3	4
3. Difficulty explaining his/her illness to other people	0	1	2	3	4

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Rheumatology Module

Version 3.0

TEEN REPORT (ages **13-18**)

DIRECTIONS

Teens with a rheumatic illness sometimes have special problems. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

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*In the past **ONE month**, how much of a **problem** has this been for you ...*

PAIN AND HURT *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I ache or hurt in my joints and/or muscles	0	1	2	3	4
2. I hurt a lot	0	1	2	3	4
3. I have trouble sleeping because of pain or aching in my joints and/or muscles	0	1	2	3	4
4. I feel stiff in the morning or when I sit too long	0	1	2	3	4

DAILY ACTIVITIES *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to turn on water faucets	0	1	2	3	4
2. It is hard to turn door handles	0	1	2	3	4
3. I have trouble eating with a fork and knife	0	1	2	3	4
4. It is hard to write or draw with a pen or pencil	0	1	2	3	4
5. I have trouble carrying my school books	0	1	2	3	4

TREATMENT *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. My medicines make me feel sick	0	1	2	3	4
2. My physical therapy or daily exercise hurts	0	1	2	3	4
3. It is hard to be responsible for my medicines or physical therapy	0	1	2	3	4
4. It is hard to manage my illness	0	1	2	3	4
5. I get scared when I have to have blood tests	0	1	2	3	4
6. I get scared about having needle sticks/shots	0	1	2	3	4
7. I get scared when I have to go the doctor	0	1	2	3	4

WORRY *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. I worry about the side effects from medicines	0	1	2	3	4
2. I worry about whether or not my medicines are working	0	1	2	3	4
3. I worry about my illness	0	1	2	3	4

COMMUNICATION *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4

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Date:_____

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Rheumatology Module

Version 3.0

PARENT REPORT for **TEENS** (ages **13-18**)

DIRECTIONS

Children with a rheumatic illness sometimes have special problems. On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has your teen had with ...*

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PAIN AND HURT *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Aches in joints and/or muscles	0	1	2	3	4
2. Having a lot of pain	0	1	2	3	4
3. Trouble sleeping because of pain or aching in joints and/or muscles	0	1	2	3	4
4. Feeling stiff in the morning or when he/she sits too long	0	1	2	3	4

DAILY ACTIVITIES *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Difficulty turning on water faucets	0	1	2	3	4
2. Difficulty turning door handles	0	1	2	3	4
3. Trouble eating with a fork and knife	0	1	2	3	4
4. Difficulty writing or drawing with a pen or pencil	0	1	2	3	4
5. Difficulty carrying school books	0	1	2	3	4

TREATMENT *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Medicines making him/her feel sick	0	1	2	3	4
2. Physical therapy or daily exercise causing pain	0	1	2	3	4
3. Difficulty being responsible for medicines or physical therapy	0	1	2	3	4
4. Difficulty managing his/her illness	0	1	2	3	4
5. Getting anxious about having blood drawn	0	1	2	3	4
6. Getting anxious about having needle sticks/shots	0	1	2	3	4
7. Getting anxious about going to the doctor	0	1	2	3	4

WORRY *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Worrying about side effects from medicines	0	1	2	3	4
2. Worrying about whether or not medicines are working	0	1	2	3	4
3. Worrying about his/her illness	0	1	2	3	4

COMMUNICATION *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Difficulty telling the doctors and nurses how he/she feels	0	1	2	3	4
2. Difficulty asking the doctors or nurses questions	0	1	2	3	4
3. Difficulty explaining his/her illness to other people	0	1	2	3	4

Peds ULS 3.0 - Parent (13-18) Rheumatology 03/00
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Appendix XIII: CHAQ Questionnaire

CHILDHOOD HEALTH ASSESSMENT QUESTIONNAIRE

1990 © Original version Singh G et al. 1998 © Cross-cultural version Woo P, Murray P, Nugent J

We are interested in learning how your child's illness affects his/her ability to function in daily life. Please feel free to add any comments on the back of this page. In the following questions, please tick the one response which best describes his/her usual activities OVER THE PAST WEEK. ONLY NOTE THOSE DIFFICULTIES OR LIMITATIONS WHICH ARE DUE TO ILLNESS. If most children at your child's age are not expected to do a certain activity, please mark it as 'not applicable'. For example, if your child has difficulty in doing a certain activity or is unable to do it because he/she is too young, but not because he/she is RESTRICTED BY ILLNESS, please mark it as 'not applicable'.

	Without ANY Difficulty	With SOME difficulty	With MUCH difficulty	UNABLE to do	Not applicable
DRESSING & PERSONAL CARE					
Is your child able to:					
- Dress, including tying shoelaces and doing buttons?	☐	☐	☐	☐	☐
- Shampoo his/her hair?	☐	☐	☐	☐	☐
- Remove socks?	☐	☐	☐	☐	☐
- Cut fingernails?	☐	☐	☐	☐	☐
GETTING UP					
Is your child able to:					
- stand up from a low chair or floor?	☐	☐	☐	☐	☐
- Get in and out of bed ?	☐	☐	☐	☐	☐
EATING					
Is your child able to:					
- Cut his/her own meat?	☐	☐	☐	☐	☐
- Lift a cup or glass to mouth?	☐	☐	☐	☐	☐
- Open a new cereal box?	☐	☐	☐	☐	☐
WALKING					
Is your child able to					
- Walk outside on flat ground?	☐	☐	☐	☐	☐
- Climb up five steps?	☐	☐	☐	☐	☐

*** Please tick any AIDS or DEVICES that your child usually uses for any of the above activities:**

Devices used for dressing (button hook, zip pull, long-handled shoe horn, etc.)	☐		
Walking stick	☐		
Walking frame	☐	Built up pencil or special utensils	☐
Crutches	☐	Special or built up chair	☐
Wheelchair	☐	Other _____	☐

*** Please tick any categories for which your child usually needs help from another person BECAUSE OF PAIN OR ILLNESS:**

Dressing and personal care	☐	Eating	☐
Getting up	☐	Walking	☐

	Without ANY Difficulty	With SOME Difficulty	With MUCH Difficulty	UNABLE To do	Not Applicable
HYGIENE					
Is your child able to					
- Wash and dry your entire body?	☐	☐	☐	☐	☐
- Take a bath (get in and get out)?	☐	☐	☐	☐	☐
- Get on and off the toilet or potty?	☐	☐	☐	☐	☐
- Brush teeth?	☐	☐	☐	☐	☐
- Comb/brush hair?	☐	☐	☐	☐	☐
REACH					
Is your child able to:					
- Reach and get down a heavy object such as a large game or books from just above his/her head?	☐	☐	☐	☐	☐
- Bend down to pick up clothing or a piece of paper from the floor?	☐	☐	☐	☐	☐
- Pull on a jumper over his/her head?	☐	☐	☐	☐	☐
- Turn neck to look back over shoulder?	☐	☐	☐	☐	☐
GRIP					
Is your child able to:					
- Write or scribble with pen or pencil?	☐	☐	☐	☐	☐
- Open car doors?	☐	☐	☐	☐	☐
- Open jars, which have been	☐	☐	☐	☐	☐
- previously opened?					
Turn taps on and off?	☐	☐	☐	☐	☐
- Push open a door when you have to turn a door knob?	☐	☐	☐	☐	☐
ACTIVITIES					
Is your child able to:					
- Run errands and shop?	☐	☐	☐	☐	☐
- Get in and out of a car, toy car or school bus?	☐	☐	☐	☐	☐
- Ride bike or tricycle?	☐	☐	☐	☐	☐
- Do household chores (eg. Wash dishes, take out rubbish, hovering)	☐	☐	☐	☐	☐
- Run?	☐	☐	☐	☐	☐

*** Please tick any AIDS or DEVICES that your child usually uses for any of the above activities:**

Raised toilet seat	☐	Bath rail	☐
Bath seat	☐	Long-handled appliances for reach	☐
Jar opener (for jars previously opened)	☐	Long-handled appliances in bathroom	☐

*** Please tick any categories for which your child usually needs help from another person BECAUSE OF ILLNESS:**

Hygiene	☐	Gripping and opening things	☐
Reach	☐	Errands and chores	☐

PAIN : We are also interested in learning whether or not your child has been affected by pain because of his or her illness. How much pain do you think your child has had <u>IN THE PAST WEEK</u>? Place a mark on the line below, to indicate the severity of the pain

No pain 0 ——————————— 100 Very severe pain

GENERAL EVALUATION: Considering all the ways that arthritis affects your child, rate how he/she is doing doing by placing a single mark on the line below.

Very well 0 ——————————— 100 Very poor

Appendix XIV: CHAQ Scoring

CHAQ scoring

Each of the eight sections are scored
for the highest value tick in its own section.

zero for "without any difficulty" or "not applicable"
one for "with some difficulty"
two for "with much difficulty"
three for "unable to do"

Then look at the section that refers to help required by AIDS/ DEVICES or ANOTHER PERSON.

If any of these are ticked please look at the section that the comment refers to.

If that section scored a zero or a one then increase it to a two.
If that section scored a two leave it as a two.
If that section scored a three leave it as a three.

Add the eight totals and divide that total by eight= CHAQ

JUVENILE DERMATOMYOSITIS RESEARCH CENTRE
INSTITUTE OF CHILD HEALTH
RHEUMATOLOGY UNIT, GROUND FLOOR, PHILIP ULLMANN WING
30 GUILFORD STREET, LONDON, WC1N 1EH

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REGIONAL CONSULTANT: JOYCE DAVIDSON
TEL: 0151 252 5221 *Email:* JOYCE.DAVIDSON@RLCH-TR.NWEST.NHS.UK

Appendix XV: Information Sheet for Participants to the Repeatability and Reproducibility Study

Andrea Coda - QMU Podiatry PhD Student QMU Edinburgh
Dr. Tom Carline - Second Supervisor, Queen Margaret University.
Dr. Derek Santos - Director of Study, Queen Margaret University.

Information Sheet for Potential Participants to the Repeatability and Reproducibility Study.

Study Title:

"A study to test the Repeatability and Reproducibility of the F-Scan® and the HR Walkway™ in the gait of healthy children".

You have been invited to take part in this research study. Before you decide if you would like to take part it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read the following information carefully and to discuss it with others if you wish. If there is anything that is not clear or you would like more information please contact the chief investigator Mr. Andrea Coda at the number below. Take time to decide whether or not you would like to take part.

The purpose of the study
Orthoses are specialised FOs which are worn in shoes to reduce foot pain and allow a more comfortable walk. Unfortunately few studies have been conducted on children. The purpose of this study is to investigate that modern in-shoes (F-Scan) and barefoot analysis system (HR Walkway) are able to provide repeatable and reproducible data, useful for clinical practice and research.

Why have you been chosen?

You have been chosen because you are a healthy subject, with no history of lower limb impairments and you are age ranging between 5 and 18 years old.

Do I have to take part?
It is up to you to decide whether or not you would like to take part. You do not need to give a reason if you decide not to take part in the study. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are free to withdraw from the study at any time without giving a reason.

What will happen if I decide to take part?
If you agree to take part in the study you will be asked to attend the Gait Laboratory at Queen Margaret University. If you agree to participate in the study, you will be asked

to provide your height, weight and age. You will be asked to walk along a walkway at your chosen speed approximately 9 times. You will be asked to walk barefoot and with shoes.

.

If you decide to take part to the study, you will be asked to attend the gait laboratory for data collection on 2 separate occasions (one week intervals between the 1st and the 2nd data collection). The researcher is not aware of any risks associated with these procedures. You will be asked to wear shorts and t-shirt. The whole procedure should take no longer than one hour. You will be free to withdraw from the study at any stage and you would not have to give a reason.

What do I have to do?

The only things that you have to do are: report to the gait laboratory and undertake the procedures outlined above. There is no other requirement.

What are the possible disadvantages and risks of taking part?

The study involves simple and safe clinical assessments. The researcher is not aware of any risks. The Chief investigator, Mr Andrea Coda, has obtained enhanced disclosure of Scotland and he is a HPC registered Podiatrist.

What are the possible benefits of taking part?

The information that we will be able to collect will help us to identify if the equipment is repeatable and reproducible; and if the chief investigator (Mr Andrea Coda) will be able to record all the data required for a future bigger study on children affected by JIA (Juvenile Idiopathic Arthritis). It is intended that this information will be used to provide clinicians with useful evidence with regards to gait analysis and FOs prescription with symptomatic JIA children.

What if something goes wrong?

You are being asked to take part in non-invasive clinical assessments and it is unlikely that anything will go wrong. However, a risk assessment of the laboratory has been carried out and Queen Margaret University has a liability insurance scheme for compensation as a result of harm caused due to negligence on the part of the researcher in connection with the above mentioned study.

Will my taking part in this study be kept confidential?

All information which is collected about you will be kept strictly confidential. Any information about you which leaves the premises will have your name and address removed so that you cannot be recognised or identified.

What will happen to the result of the research study?

The results of this study will be collected, analysed and will allow to begin the bigger study on JIA children. The results will be published as research papers in scientific journals and will also be available as part of a research thesis at the Queen Margaret University Library. You will not be identified in any of the reports or medical

publications and all data will only be kept until the study and all associated works are completed.

Who is organizing and funding the research?
Mr Andrea Coda, a research student based at the Queen Margaret University Edinburgh, is conducting this study. Queen Margaret University funds the study as a PhD research degree. Mr Andrea Coda is a BSc (Hons) MChS HPC Registered Podiatrist.

Will my General Practitioner (GP) be informed if I decide to take part in the study?
If you decide to take part in the study then your General Practitioner (GP) will only be informed of your participation if you want them to be informed. On the consent form there is a box you can tick if you wish to give permission for you GP to be informed that you are taking part in the study.

Thank you for taking the time to read this information sheet. If you have any questions please do not hesitate to contact Mr Andrea Coda during office hours.
If you would like to contact an independent person, who knows about this project but is not involved in it, you are welcome to contact Mrs Lynne Flynn. Her contact details are given below. If you have read and understood this information sheet and you would like to be a participant in the study, please see the consent form.

Contact details of the Chief Researcher Mr. Andrea Coda Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 acoda@qmu.ac.uk	Contact details of the independent adviser Mrs. Lynne Flynn Podiatry School of Health Sciences Queen Margaret University Drive, Musselburgh EH21 6UU Tel: +44 (0)131 474 0000 lflynn@qmu.ac.uk

Appendix XVI: Consent Form for Repeatability and Reproducibility Study

Queen Margaret University
EDINBURGH

Consent Form

Study No: (to be completed by chief investigator only)

"A study to test the Repeatability and Reproducibility of the F-Scan® and the HR Walkway™ in the gait of healthy children".

Name of PhD researcher: Andrea Coda
Please initial box

I confirm that I have read and understood the information sheet dated for the above study and have had the opportunity to ask questions ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected ☐

I agree to participate in this study. ☐

Name of participant: _____

Name of parent/guardian: _____

Signature of parent/guardian: _____

Signature of researcher: _____

Date: _____
Contact details:
Andrea Coda
PhD Research Student
Email: acoda@qmu.ac.uk
Phone: +44 (0)131 474 0000

1 copy for participant and 1 copy for chief investigator

Appendix XVII: Contact details for Repeatability and Reproducibility Study Participants

Queen Margaret University
EDINBURGH

CONTACT DETAILS

Study No.	
First Name	
Surname	
D.O.B.	
Address	**Postcode:**
Tel.	
Mobile	
Email	

Appendix XVIII: Repeatability and Reproducibility Study Participant's details (Base Line, 1 week later)

Queen Margaret University
EDINBURGH

Study No.

Baseline	
D.O.B.	
Date:	
Shoe Size	
Weight	
Height	
BMI	
1 Week Later	
Date:	
Shoe Size	
Weight	
Height	
BMI	

Appendix XIX: ICC Scores

ICC - Gait Time

Details of ICC values on Gait Time obtained with the HR Walkway (control and trial patients)

ICC – Gait Time (sec) - HR-Walkway			
ICC		**Control**	**Trial**
Baseline (1^{st}-2^{nd} -3^{rd})		0.856	0.796
3^{rd} month (1^{st}-2^{nd} -3^{rd})		0.793	0.658
6^{th} month (1^{st}-2^{nd} -3^{rd})		0.871	0.632
Stable (1^{st}-2^{nd} -3^{rd})	**Baseline**	0.934	0.773
	3^{rd} month	0.793	0.902
	6^{th} month	0.818	0.654
Not Stable (1^{st}-2^{nd} -3^{rd})	**Baseline**	0.486	0.878
	3^{rd} month	0.902	0.493
	6^{th} month	0.926	0.589

Control Group

The ICC values from the cadence for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection. With regards to the control group the ICC value was 0.856 at baseline, 0.793 at 3rd month, and 0.871 at 6th month. Results showed that with regards to the stable-control group, ICC score was 0.934 at baseline, 0.793 at 3^{rd} month and 0.818 at 6^{th} month. Instead, the not-stable control group appeared that the ICC score was 0.486 at baseline, 0.902 at 3^{rd} month and 0.926 at 6^{th} month.

Trial Group

With regards to repeatability within the trial group the ICC value was 0.796 at baseline, 0.658 at 3^{rd} month, and finally 0.632 at 6^{th} month. Similarly, stable-trial ICC score was 0.773 at baseline, 0.902 at 3^{rd} month, and 0.654 at 6^{th} month. The not stable-trial group was 0.878 at baseline, 0.493 at 3^{rd} month and 0.589 at 6^{th} month.

ICC - Gait Velocity

Details of ICC values on Velocity obtained with the HR Walkway (control and trial patients)

ICC – Gait Velocity (cm/sec) - HR-Walkway			
ICC		**Control**	**Trial**
Baseline (1^{st}-2^{nd} -3^{rd})		0.822	0.810
3rd month (1^{st}-2^{nd} -3^{rd})		0.838	0.724
6th month (1^{st}-2^{nd} -3^{rd})		0.908	0.735
Stable (1^{st}-2^{nd} -3^{rd})	**Baseline**	0.834	0.795
	3rd month	0.847	0.816
	6th month	0.834	0.795
Not Stable (1^{st}-2^{nd} -3^{rd})	**Baseline**	0.748	0.870
	3rd month	0.819	0.478
	6th month	0.748	0.870

Control Group

The ICC values from the gait velocity for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection. With regards to the control group the ICC value was 0.822 at baseline, 0.838 at 3rd month, and 0.908 at 6th month. Results showed that with regards to the stable-control group, ICC score was 0.834 at baseline, 0.847 at 3rd month and 0.834 at 6th month. Instead, the not-stable control group appeared that the ICC score was 0.748 at baseline, 0.819 at 3rd month and 0.748 at 6th month.

Trial Group

With regards to repeatability within the trial group the ICC value was 0.810 at baseline, 0.724 at 3rd month, and finally 0.735 at 6th month. Similarly, stable-trial ICC score was 0.795 at baseline, 0.816 at 3rd month, and 0.795 at 6th month. The not stable-trial group was 0.870 at baseline, 0.478 at 3rd month and 0.870 at 6th month.

ICC - Stance Time

Details of ICC values on Cadence obtained with the HR Walkway (control and trial patients).

ICC – Stance Time (sec) - HR-Walkway			
ICC		**Control**	**Trial**
Baseline (1^{st}-2^{nd} -3^{rd})		0.786	0.694
3^{rd} month (1^{st}-2^{nd} -3^{rd})		0.733	0.692
6^{th} month (1^{st}-2^{nd} -3^{rd})		0.672	0.719
Stable (1^{st}-2^{nd} -3^{rd})	**Baseline**	0.736	0.676
	3^{rd} month	0.772	0.721
	6^{th} month	0.698	0.679
Not Stable (1^{st}-2^{nd} -3^{rd})	**Baseline**	0.795	0.811
	3^{rd} month	0.497	0.624
	6^{th} month	0.592	0.829

Control Group

The ICC values from the stance time, for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection. With regards to the control group the ICC value was 0.786 at baseline, 0.733 at 3rd month, and 0.672 at 6th month. Results showed that with regards to the stable-control group, ICC score was 0.736 at baseline, 0.772 at 3^{rd} month and 0.698 at 6^{th} month. Instead, the not-stable control group appeared that the ICC score was 0.795 at baseline, 0.497 at 3^{rd} month and 0.592 at 6^{th} month.

Trial Group

With regards to repeatability within the trial group the ICC value was 0.694 at baseline, 0.692 at 3^{rd} month, and finally 0.719 at 6^{th} month. Similarly, stable-trial ICC score was 0.676 at baseline, 0.721 at 3^{rd} month, and 0.679 at 6^{th} month. The not stable-trial group was 0.811 at baseline, 0.624 at 3^{rd} month and 0.829 at 6^{th} month.

ICC - Total - Peak Pressure Values - (t-PP)

Details of ICC values on Total -PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC - Total - Peak Pressure Values (t-PP)			
		Control	Trial
F-Scan - Shod	Baseline	0.824	0.862
	3rd month	0.832	0.774
	6th month	0.776	0.536
F-Scan – With Insoles	Baseline	0.877	0.766
	3rd month	0.493	0.891
	6th month	0.871	0.799
HR Walkway	Baseline	0.765	0.750
	3rd month	0.705	0.765
	6th month	0.799	0.865

Control Group - Peak Pressure Values (t-PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (barefoot and with insole) and with HR Walkway. With regards to the control group of F-scan barefoot, the ICC value was 0.824 at baseline, 0.832 at 3rd month, and 0.776 at 6th month. Results with F-scan insole showed that ICC score was 0.877 at baseline, 0.493 at 3rd month and 0.871 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.765 at baseline, 0.705 at 3rd month and 0.799 at 6th month.

Trial Group - Peak Pressure Values (t-PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan barefoot was 0.862 at baseline, 0.774 at 3rd month, and finally 0.536 at 6th month. Similarly, F-scan with insole ICC score was 0.766 at baseline, 0.891 at 3rd month, and 0.799 at 6th month. Finally the HR Walkway group was 0.750 at baseline, 0.765 at 3rd month and 0.865 at 6th month.

ICC - Total - Pressure Time Integral - (PTI)

Details of ICC values on Total -PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC - Total - Pressure Time Integral - (PTI)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.620	0.627
	3rd month	0.785	0.805
	6th month	0.738	0.793
F-Scan – With Insoles	**Baseline**	0.790	0.858
	3rd month	0.760	0.783
	6th month	0.803	0.322
HR Walkway	**Baseline**	0.585	0.880
	3rd month	0.699	0.527
	6th month	0.902	0.910

Control Group - Pressure Time Integral - (PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.620 at baseline, 0.785 at 3rd month, and 0.738 at 6th month. Results with F-scan with insole showed that ICC score was 0.790 at baseline, 0.760 at 3rd month and 0.803 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.585 at baseline, 0.699 at 3rd month and 0.902 at 6th month.

Trial Group - Pressure Time Integral - (PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.627 at baseline, 0.805 at 3rd month, and finally 0.793 at 6th month. Similarly, F-scan with insole ICC score was 0.858 at baseline, 0.783 at 3rd month, and 0.322 at 6th month. Finally the HR Walkway group was 0.880 at baseline, 0.527 at 3rd month and 0.910 at 6th month.

ICC - Heel – Peak Pressure Values - (hPP)

Details of ICC values on Heel -PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC - Heel – Peak Pressure Values - (hPP)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.782	0.819
	3rd month	0.658	0.806
	6th month	0.756	0.867
F-Scan – With Insoles	**Baseline**	0.885	0.880
	3rd month	0.841	0.772
	6th month	0.807	0.786
HR Walkway	**Baseline**	0.684	0.687
	3rd month	0.711	0.736
	6th month	0.721	0.723

Control Group Peak Pressure Values - (hPP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.782 at baseline, 0.658 at 3rd month, and 0.756 at 6th month. Results with F-scan with insole showed that ICC score was 0.885 at baseline, 0.841 at 3rd month and 0.807 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.684 at baseline, 0.711 at 3rd month and 0.721 at 6th month.

Trial Group Peak Pressure Values - (hPP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.819 at baseline, 0.806 at 3rd month, and finally 0.867 at 6th month. Similarly, F-scan with insole ICC score was 0.880 at baseline, 0.772 at 3rd month, and 0.786 at 6th month. Finally, the HR Walkway group was 0.687 at baseline, 0.736 at 3rd month and 0.723 at 6th month.

ICC - Heel –Pressure Time Integral (h-PTI)

Details of ICC values on Heel -PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC - Heel –Pressure Time Integral (h-PTI)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.862	0.634
	3rd month	0.518	0.713
	6th month	0.533	0.612
F-Scan – With Insoles	**Baseline**	0.703	0.763
	3rd month	0.690	0.769
	6th month	0.594	0.636
HR Walkway	**Baseline**	0.533	0.612
	3rd month	0.703	0.763
	6th month	0.690	0.769

Control Group - Pressure Time Integral (h-PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.862 at baseline, 0.518 at 3rd month, and 0.533 at 6th month. Results with F-scan with insole showed that ICC score was 0.703 at baseline, 0.690 at 3rd month and 0.594 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.533 at baseline, 0.703 at 3rd month and 0.690 at 6th month.

Trial Group - Pressure Time Integral (h-PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.634 at baseline, 0.713 at 3rd month, and finally 0.612 at 6th month. Similarly, F-scan with insole ICC score was 0.763 at baseline, 0.769 at 3rd month, and 0.636 at 6th month. Finally, the HR Walkway group was 0.612 at baseline, 0.763 at 3rd month and 0.769 at 6th month.

ICC - Midfoot – Peak Pressure Values - (m-PP)

Details of ICC values on Midfoot -PP obtained with F-Scan shod; F-Scan with insole and HR Walkway (control and trial patients).

ICC - Midfoot – Peak Pressure Values - (m-PP)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.800	0.760
	3rd month	0.813	0.745
	6th month	0.668	0.776
F-Scan – With Insoles	**Baseline**	0.885	0.607
	3rd month	0.720	0.639
	6th month	0.864	0.451
HR Walkway	**Baseline**	0.702	0.704
	3rd month	0.684	0.661
	6th month	0.673	0.739

Control Group -Peak Pressure Values - (m-PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.800 at baseline, 0.813 at 3rd month, and 0.668 at 6th month. Results with F-scan with insole showed that ICC score was 0.885 at baseline, 0.720 at 3rd month and 0.864 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.702 at baseline, 0.684 at 3rd month and 0.675 at 6th month.

Trial Group -Peak Pressure Values - (m-PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.760 at baseline, 0.745 at 3rd month, and finally 0.776 at 6th month. Similarly, F-scan with insole ICC score was 0.687 at baseline, 0.639 at 3rd month, and 0.451 at 6th month. Finally, the HR Walkway group was 0.704 at baseline, 0.661 at 3rd month and 0.739 at 6th month.

ICC - Midfoot – Pressure Time Integral (m-PTI)

Details of ICC values on Midfoot -PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC - Midfoot – Pressure Time Integral (m-PTI)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.743	0.749
	3rd month	0.664	0.742
	6th month	0.708	0.951
F-Scan – With Insoles	**Baseline**	0.877	0.778
	3rd month	0.849	0.724
	6th month	0.913	0.654
HR Walkway	**Baseline**	0.727	0.797
	3rd month	0.412	0.842
	6th month	0.568	0.880

Control Group - Pressure Time Integral (m-PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.743 at baseline, 0.664 at 3rd month, and 0.708 at 6th month. Results with F-scan with insole showed that ICC score was 0.877 at baseline, 0.849 at 3rd month and 0.913 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.727 at baseline, 0.412 at 3rd month and 0.568 at 6th month.

Trial Group - Pressure Time Integral (m-PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.749 at baseline, 0.742 at 3rd month, and finally 0.951 at 6th month. Similarly, F-scan with insole ICC score was 0.778 at baseline, 0.724 at 3rd month, and 0.654 at 6th month. Finally, the HR Walkway group was 0.797 at baseline, 0.842 at 3rd month and 0.880 at 6th month.

ICC - Forefoot – Peak Pressure Values - (f-PP)

Details of ICC values on Forefoot – PP obtained with F-Scan shod F-Scan with insole and HR Walkway (control and trial patients).

ICC - Forefoot – Peak Pressure Values - (f-PP)			
		Control	Trial
F-Scan - Shod	Baseline	0.898	0.927
	3rd month	0.832	0.860
	6th month	0.893	0.881
F-Scan – With Insoles	Baseline	0.840	0.832
	3rd month	0.839	0.856
	6th month	0.847	0.862
HR Walkway	Baseline	0.840	0.855
	3rd month	0.839	0.891
	6th month	0.801	0.895

Control Group - Peak Pressure Values - (f-PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.898 at baseline, 0.832 at 3rd month, and 0.893 at 6th month. Results with F-scan with insole showed that ICC score was 0.840 at baseline, 0.839 at 3rd month and 0.847 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.840 at baseline, 0.839 at 3rd month and 0.801 at 6th month.

Trial Group - Peak Pressure Values - (f-PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.927 at baseline, 0.860 at 3rd month, and finally 0.881 at 6th month. Similarly, F-scan with insole ICC score was 0.832 at baseline, 0.856 at 3rd month, and 0.862 at 6th month. Finally, the HR Walkway group was 0.855 at baseline, 0.891 at 3rd month and 0.895 at 6th month.

ICC - Forefoot – Pressure Time Integral (m-PTI)

Details of ICC values on Total -PT obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC - Forefoot – Pressure Time Integral (m-PTI)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.858	0.845
	3rd month	0.766	0.816
	6th month	0.693	0.828
F-Scan – With Insoles	**Baseline**	0.895	0.836
	3rd month	0.706	0.780
	6th month	0.780	0.767
HR Walkway	**Baseline**	0.713	0.859
	3rd month	0.866	0.905
	6th month	0.823	0.883

Control Group Pressure Time Integral (m-PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.858 at baseline, 0.766 at 3rd month, and 0.693 at 6th month. Results with F-scan with insole showed that ICC score was 0.895 at baseline, 0.706 at 3rd month and 0.780 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.713 at baseline, 0.866 at 3rd month and 0.823 at 6th month.

Trial Group Pressure Time Integral (m-PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.845 at baseline, 0.816 at 3rd month, and finally 0.828 at 6th month. Similarly, F-scan with insole ICC score was 0.836 at baseline, 0.780 at 3rd month, and 0.767 at 6th month. Finally, the HR Walkway group was 0.859 at baseline, 0.905 at 3rd month and 0.883 at 6th month.

ICC – 5th Met Head – Peak Pressure Values (5th PP)

Details of ICC values on 5th -PT obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 5th Met Head – Peak Pressure Values (5th PP)			
		Control	Trial
F-Scan - Shod	Baseline	0.71	0.71
	3rd month	0.679	0.591
	6th month	0.659	0.725
F-Scan – With Insoles	Baseline	0.715	0.755
	3rd month	0.735	0.577
	6th month	0.73	0.805
HR Walkway	Baseline	0.638	0.7888
	3rd month	0.769	0.691
	6th month	0.848	0.817

Control Group - Peak Pressure Values (5th PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.71 at baseline, 0.679 at 3rd month, and 0.659 at 6th month. Results with F-scan with insole showed that ICC score was 0.715 at baseline, 0.735 at 3rd month and 0.73 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.638 at baseline, 0.769 at 3rd month and 0.848 at 6th month.

Trial Group - Peak Pressure Values (5th PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.71 at baseline, 0.591 at 3rd month, and finally 0.725 at 6th month. Similarly, F-scan with insole ICC score was 0.755 at baseline, 0.577 at 3rd month, and 0.805 at 6th month. Finally, the HR Walkway group was 0.788 at baseline, 0.691 at 3rd month and 0.817 at 6th month.

ICC – 5th Met Head – Pressure Time Integral (5th-PTI)

Details of ICC values on 5th -PT obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 5th Met Head – Pressure Time Integral (5th-PTI)			
		Control	Trial
F-Scan - Shod	Baseline	0.711	0.691
	3rd month	0.619	0.492
	6th month	0.659	0.621
F-Scan – With Insoles	Baseline	0.712	0.786
	3rd month	0.777	0.614
	6th month	0.788	0.660
HR Walkway	Baseline	0.736	0.846
	3rd month	0.773	0.767
	6th month	0.801	0.879

Control Group - Pressure Time Integral (5th -PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.711 at baseline, 0.619 at 3rd month, and 0.659 at 6th month. Results with F-scan with insole showed that ICC score was 0.712 at baseline, 0.777 at 3rd month and 0.788 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.736 at baseline, 0.773 at 3rd month and 0.801 at 6th month.

Trial Group - Pressure Time Integral (5th -PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.691 at baseline, 0.492 at 3rd month, and finally 0.621 at 6th month. Similarly, F-scan with insole ICC score was 0.786 at baseline, 0.614 at 3rd month, and 0.660 at 6th month. Finally, the HR Walkway group was 0.846 at baseline, 0.767 at 3rd month and 0.879 at 6th month.

ICC – 3rd/4th Met Head – Peak Pressure Values (3rd/4th PP)

Details of ICC values on 3rd/4th -PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients)

ICC – 3rd/4th Met Head – Peak Pressure Values (3rd/4th PP)			
		Control	Trial
F-Scan - Shod	Baseline	0.857	0.830
	3rd month	0.882	0.801
	6th month	0.832	0.862
F-Scan – With Insoles	Baseline	0.881	0.828
	3rd month	0.806	0.877
	6th month	0.816	0.802
HR Walkway	Baseline	0.808	0.821
	3rd month	0.870	0.865
	6th month	0.835	0.812

Control Group - Peak Pressure Values (3rd/4th PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.857 at baseline, 0.882 at 3rd month, and 0.832 at 6th month. Results with F-scan with insole showed that ICC score was 0.881 at baseline, 0.806 at 3rd month and 0.816 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.808 at baseline, 0.870 at 3rd month and 0.835 at 6th month.

Trial Group - Peak Pressure Values (3rd/4th PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.830 at baseline, 0.801 at 3rd month, and finally 0.862 at 6th month. Similarly, F-scan with insole ICC score was 0.828 at baseline, 0.877 at 3rd month, and 0.802 at 6th month. Finally, the HR Walkway group was 0.821 at baseline, 0.865 at 3rd month and 0.812 at 6th month.

ICC – 3rd/4th Met Head – Pressure Time Integral (3rd/4th - PTI)

Details of ICC values on 3rd/4th- PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 3rd/4th Met Head – Pressure Time Integral (3rd/4th -PTI)			
		Control	Trial
F-Scan - Shod	Baseline	0.888	0.823
	3rd month	0.799	0.793
	6th month	0.737	0.900
F-Scan – With Insoles	Baseline	0.887	0.959
	3rd month	0.810	0.857
	6th month	0.857	0.740
HR Walkway	Baseline	0.802	0.895
	3rd month	0.805	0.842
	6th month	0.812	0.848

Control Group - Pressure Time Integral (3rd/4th -PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.888 at baseline, 0.799 at 3rd month, and 0.737 at 6th month. Results with F-scan with insole showed that ICC score was 0.887 at baseline, 0.810 at 3rd month and 0.857 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.802 at baseline, 0.805 at 3rd month and 0.812 at 6th month.

Trial Group - Pressure Time Integral (3rd/4th -PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.823 at baseline, 0.793 at 3rd month, and finally 0.9 at 6th month. Similarly, F-scan with insole ICC score was 0.959 at baseline, 0.887 at 3rd month, and 0.740 at 6th month. Finally, the HR Walkway group was 0.895 at baseline, 0.842 at 3rd month and 0.848 at 6th month.

ICC – 2nd Met Head – Peak Pressure Values (2nd PP)

Details of ICC values on 2nd -PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 2nd Met Head – Peak Pressure Values(2nd PP)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.923	0.908
	3rd month	0.895	0.881
	6th month	0.867	0.829
F-Scan – With Insoles	**Baseline**	0.915	0.758
	3rd month	0.864	0.873
	6th month	0.867	0.848
HR Walkway	**Baseline**	0.860	0.940
	3rd month	0.825	0.453
	6th month	0.878	0.851

Control Group - Peak Pressure Values(2nd PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.923 at baseline, 0.895 at 3rd month, and 0.867 at 6th month. Results with F-scan with insole showed that ICC score was 0.915 at baseline, 0.864 at 3rd month and 0.867 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.860 at baseline, 0.825 at 3rd month and 0.878 at 6th month.

Trial Group - Peak Pressure Values(2nd PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.908 at baseline, 0.881 at 3rd month, and finally 0.829 at 6th month. Similarly, F-scan with insole ICC score was 0.758 at baseline, 0.873 at 3rd month, and 0.848 at 6th month. Finally, the HR Walkway group was 0.940 at baseline, 0.453 at 3rd month and 0.851 at 6th month.

ICC – 2nd Met Head – Pressure Time Integral (2nd -PTI)

Details of ICC values on 2nd –PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 2nd Met Head – Pressure Time Integral (2nd -PTI)			
		Control	Trial
F-Scan - Shod	Baseline	0.880	0.830
	3rd month	0.846	0.816
	6th month	0.791	0.794
F-Scan – With Insoles	Baseline	0.911	0.783
	3rd month	0.946	0.853
	6th month	0.791	0.794
HR Walkway	Baseline	0.799	0.872
	3rd month	0.805	0.856
	6th month	0.805	0.856

Control Group - Pressure Time Integral (2nd -PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.880 at baseline, 0.846 at 3rd month, and 0.791 at 6th month. Results with F-scan with insole showed that ICC score was 0.911 at baseline, 0.946 at 3rd month and 0.791 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.799 at baseline, 0.805 at 3rd month and 0.805 at 6th month.

Trial Group - Pressure Time Integral (2nd -PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.830 at baseline, 0.816 at 3rd month, and finally 0.794 at 6th month. Similarly, F-scan with insole ICC score was 0.783 at baseline, 0.853 at 3rd month, and 0.794 at 6th month. Finally, the HR Walkway group was 0.872 at baseline, 0.856 at 3rd month and 0.856 at 6th month.

ICC – 1st Met Head – Peak Pressure Values(1st- PP)

Details of ICC values on 1st - PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 1st Met Head – Peak Pressure Values(1st- PP)			
		Control	Trial
F-Scan - Shod	Baseline	0.794	0.719
	3rd month	0.757	0.780
	6th month	0.618	0.694
F-Scan – With Insoles	Baseline	0.725	0.760
	3rd month	0.802	0.712
	6th month	0.755	0.777
HR Walkway	Baseline	0.681	0.737
	3rd month	0.708	0.734
	6th month	0.630	0.654

Control Group Peak Pressure Values (1st- PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.794 at baseline, 0.757 at 3rd month, and 0.618 at 6th month. Results with F-scan with insole showed that ICC score was 0.725 at baseline, 0.802 at 3rd month and 0.755 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.681 at baseline, 0.708 at 3rd month and 0.630 at 6th month.

Trial Group - Peak Pressure Values (1st- PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.719 at baseline, 0.780 at 3rd month, and finally 0.694 at 6th month. Similarly, F-scan with insole ICC score was 0.760 at baseline, 0.712 at 3rd month, and 0.777 at 6th month. Finally, the HR Walkway group was 0.737 at baseline, 0.734 at 3rd month and 0.654 at 6th month.

ICC – 1st Met Head – Pressure Time Integral (1st-PTI)

Details of ICC values on 1st PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – 1st Met Head – Pressure Time Integral (1st-PTI)			
		Control	Trial
F-Scan - Shod	Baseline	0.714	0.645
	3rd month	0.665	0.705
	6th month	0.790	0.734
F-Scan – With Insoles	Baseline	0.695	0.713
	3rd month	0.831	0.746
	6th month	0.682	0.698
HR Walkway	Baseline	0.678	0.695
	3rd month	0.684	0.647
	6th month	0.540	0.683

Control - Pressure Time Integral (1st-PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.714 at baseline, 0.665 at 3rd month, and 0.790 at 6th month. Results with F-scan with insole showed that ICC score was 0.695 at baseline, 0.831 at 3rd month and 0.682 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.678 at baseline, 0.684 at 3rd month and 0.540 at 6th month.

Trial Group - Pressure Time Integral (1st-PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.645 at baseline, 0.705 at 3rd month, and finally 0.734 at 6th month. Similarly, F-scan with insole ICC score was 0.713 at baseline, 0.46 at 3rd month, and 0.698 at 6th month. Finally, the HR Walkway group was 0.695 at baseline, 0.647 at 3rd month and 0.683 at 6th month.

ICC – Lesser Toes – Peak Pressure (lt-PP)

Details of ICC values on lt -PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – Lesser Toes – Peak Pressure (lt-PP)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.747	0.839
	3rd month	0.715	0.835
	6th month	0.662	0.766
F-Scan – With Insoles	**Baseline**	0.733	0.810
	3rd month	0.768	0.824
	6th month	0.618	0.742
HR Walkway	**Baseline**	0.577	0.810
	3rd month	0.602	0.737
	6th month	0.379	0.701

Control Group - Peak Pressure (lt-PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.747 at baseline, 0.715 at 3rd month, and 0.662 at 6th month. Results with F-scan with insole showed that ICC score was 0.733 at baseline, 0.768 at 3rd month and 0.618 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.577 at baseline, 0.602 at 3rd month and 0.379 at 6th month.

Trial Group - Peak Pressure (lt-PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.839 at baseline, 0.835 at 3rd month, and finally 0.766 at 6th month. Similarly, F-scan with insole ICC score was 0.810 at baseline, 0.824 at 3rd month, and 0.742 at 6th month. Finally, the HR Walkway group was 0.810 at baseline, 0.737 at 3rd month and 0.701 at 6th month.

ICC – Lesser Toes – Pressure Time Integral (lt-PTI)

Details of ICC values on lt –PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – Lesser Toes – Pressure Time Integral (lt-PTI)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.820	0.788
	3rd month	0.757	0.800
	6th month	0.503	0.865
F-Scan – With Insoles	**Baseline**	0.630	0.769
	3rd month	0.308	0.829
	6th month	0.644	0.868
HR Walkway	**Baseline**	0.155	0.635
	3rd month	0.571	0.577
	6th month	0.310	0.666

Control Group - Pressure Time Integral (lt-PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.820 at baseline, 0.757 at 3rd month, and 0.503 at 6th month. Results with F-scan with insole showed that ICC score was 0.630 at baseline, 0.308 at 3rd month and 0.644 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.155 at baseline, 0.571 at 3rd month and 0.31 at 6th month.

Trial Group - Pressure Time Integral (lt-PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.788 at baseline, 0.800 at 3rd month, and finally 0.865 at 6th month. Similarly, F-scan with insole ICC score was 0.769 at baseline, 0.829 at 3rd month, and 0.868 at 6th month. Finally, the HR Walkway group was 0.635 at baseline, 0.577 at 3rd month and 0.666 at 6th month.

ICC – Lesser Toes – Peak Pressure (dp-PP)

Details of ICC values on dp-PP obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – Lesser Toes – Peak Pressure (dp-PP)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.786	0.779
	3rd month	0.809	0.740
	6th month	0.752	0.836
F-Scan – With Insoles	**Baseline**	0.796	0.638
	3rd month	0.774	0.830
	6th month	0.750	0.709
HR Walkway	**Baseline**	0.773	0.783
	3rd month	0.777	0.781
	6th month	0.829	0.805

Control Group -Peak Pressure (dp-PP)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.786 at baseline, 0.809 at 3rd month, and 0.752 at 6th month. Results with F-scan with insole showed that ICC score was 0.796 at baseline, 0.774 at 3rd month and 0.750 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.773 at baseline, 0.777 at 3rd month and 0.829 at 6th month.

Trial Group - Peak Pressure (dp-PP)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.779 at baseline, 0.740 at 3rd month, and finally 0.836 at 6th month. Similarly, F-scan with insole ICC score was 0.638 at baseline, 0.830 at 3rd month, and 0.709 at 6th month. Finally, the HR Walkway group was 0.783 at baseline, 0.781 at 3rd month and 0.805 at 6th month.

ICC – Distal Phalanx – Pressure Time Integral (lt-PTI)

Details of ICC values on dp -PTI obtained with F-Scan shod, F-Scan with insole and HR Walkway (control and trial patients).

ICC – Distal Phalanx – Pressure Time Integral (lt-PTI)			
		Control	**Trial**
F-Scan - Shod	**Baseline**	0.744	0.731
	3rd month	0.783	0.738
	6th month	0.683	0.768
F-Scan – With Insoles	**Baseline**	0.701	0.576
	3rd month	0.746	0.696
	6th month	0.751	0.708
HR Walkway	**Baseline**	0.751	0.310
	3rd month	0.698	0.688
	6th month	0.789	0.558

Control Group - Pressure Time Integral (lt-PTI)

The ICC values for the control group appeared to be repeatable amongst the three recordings that regularly were taken in each data collection with F-scan (shod and with insole) and with HR Walkway. With regards to the control group of F-scan shod, the ICC value was 0.744 at baseline, 0.783 at 3rd month, and 0.683 at 6th month. Results with F-scan with insole showed that ICC score was 0.701 at baseline, 0.746 at 3rd month and 0.751 at 6th month. Instead, the HR Walkway appeared that the ICC score was 0.751 at baseline, 0.698 at 3rd month and 0.789 at 6th month.

Trial Group - Pressure Time Integral (lt-PTI)

With regards to repeatability within the trial group the ICC value showed the following results: F-scan shod was 0.731 at baseline, 0.738 at 3rd month, and finally 0.768 at 6th month. Similarly, F-scan with insole ICC score was 0.576 at baseline, 0.696 at 3rd month, and 0.708 at 6th month. Finally, the HR Walkway group was 0.310 at baseline, 0.688 at 3rd month and 0.558 at 6th month.

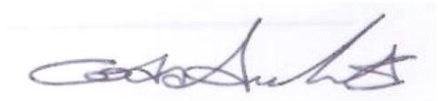
Published Material

Statement of original authorship

The work submitted in this thesis is original. The work contained in this thesis has not been previously submitted to meet the requirements for an award at this or any other higher education institution.

To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

All research procedures reported in this thesis received the approval of NHS and University Committee.



Andrea Coda

Date: 13th of March 2013

Publications, Presentations & Awards

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos *"Foot Orthoses in Juvenile Idiopathic Arthritis (JIA).* Educational (Lecture and Workshop) Biomechanics Track. 2013 World Congress of Podiatry, Rome. October 18th 2013.

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2012). *Multicentre RCT in Juvenile Idiopathic Arthritis to investigate pain and quality of life using foot orthoses*. Abstract Publication. British Society for Paediatric and Adolescent Rheumatology. John McIntyre Conference Centre, Edinburgh, 27th September 2012.

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2011). *Pre-Formed Orthoses in Juvenile Idiopathic Arthritis: results from an RCT*. Abstract Publication. British Society of Rheumatology, 2/5/2012, SECC exhibition centre, Glasgow. Print ISSN 1462-0324; online ISSN 1462-0332, Oxford University Press.

- Coda, A; T. Carline; D. Santos (2012). *"*Repeatability and Reproducibility *of the Tekscan HR-Walkway system in healthy children".* 10th Staffordshire Conference on Clinical Biomechanics (SCCB), Stoke on Trent, Staffordshire University 20/4/2012

- Coda, A; T. Carline; D. Santos (2012). *"Can In-shoe and Barefoot Analysis be helpful in podopaediatric?"* Tekscan® Foot Pressure Educational Seminars & Workshops**.** Stoke on Trent, Staffordshire University. 19/4/2012

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2011): *"Pre-formed orthoses in Juvenile Idiopathic Arthritis [JIA] - a multi-centre single blinded randomised control trial".* Submitted to 'Research Arthritis UK' on 30/11/2011.

- Coda, A; T. Carline; D. Santos (2011): *"Pre-formed orthoses in Juvenile Idiopathic Arthritis [JIA]: preliminary results from an RCT".* Research Seminar, Queen Margaret University. November 2011.

- Coda, A; T. Carline; D. Santos (2011): *"The role of podiatrists within the paediatric rheumatology team".* Presentation for Queen Margaret University's 4th Annual Doctoral Research Student Conference, awarded for best presentation.

- Coda, A; T. Carline; D. Santos (2011): *"Repeatability and Reproducibility of the Tekscan HR-Walkway system in healthy children".* Waiting to be published.

- Coda, A; T. Carline; D. Santos (2011): *"Repeatability and Reproducibility of the Tekscan F-Scan system in healthy children".* Waiting to be published.

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2011). *"Pre-formed orthoses in Juvenile Idiopathic Arthritis [JIA]: preliminary results from an RCT"*. Research paper presentation; 1st International Symposia Conference of Lower Limb Sports and Surgical Medicine". Planned for 29th September 2011. Athens, Greece. (Postponed - date TBC).

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2011). *"Pre-formed orthoses in Juvenile Idiopathic Arthritis [JIA]: preliminary results from an RCT"*. Research paper presentation; Foot & Ankle Scotland - 3rd annual meeting. 25th September 2011, the Royal College of Surgeons of Edinburgh, UK. Awarded for best presentation.

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2011). *"A RCT to investigate the clinical effectiveness of pre-formed semi-rigid foot orthoses, on pain, quality of life and the dynamics of gait of patients diagnosed with Juvenile Idiopathic Arthritis (JIA)".* Research paper presentation; Podiatry Practice Development Group; Erskine Hospital, 20th of May 2011; Erskine- UK.

- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2011). *"Investigation of Pre-formed orthoses from an RCT with Juvenile Idiopathic Arthritis [JIA]*.Research paper presentation; The Society of Chiropodist and Podiatrists – Northern Ireland Branch; Annual Conference, 6th May 2011; Armagh – Northern Ireland - UK.

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- Coda, A; J. Davidson; P. Fowlie; J. Walsh; T. Carline; D. Santos (2010). Poster presentation in: PhD Association & Graduate School Conference, 2nd Annual conference: Real World Research. 25th November 2010. Queen Margaret University, Edinburgh, UK.

- Coda, A; T. Carline; D. Santos (2010). *"The role of podiatrists within the paediatric rheumatology team"*; 17th June 2010. Paediatric Rheumatology Team Meeting. Royal Hospital for Sick Children, Edinburgh.

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