THE EFFECT OF LEG LENGTHENING SURGERY ON MUSCLE FUNCTION : IMPLICATIONS FOR REHABILITATION.

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Abstract

Limb length discrepancy is a common orthopaedic problem, frequently requiring surgical intervention. This thesis is concerned with one method of limb equalisation, leg lengthening surgery. It investigates the effect of leg lengthening surgery on the muscle function and rehabilitation of patients.

Qualitative research methodologies demonstrated that there is considerable uncertainty about the best physiotherapy management of patients treated by the Ilizarov method. There is little evidence-based research into the rehabilitation of patients treated by this method of surgery.
A clinical cohort study was conducted which examined different aspects of rehabilitation. These included the effects of leg lengthening surgery on joint range of motion, muscle strength and on the ability to perform functional activities.

The study of the effect of surgery on joint range of motion highlighted the need for repeatable measurement techniques. It found that there was a significant loss of joint range of motion in the latent period prior to distraction of the bones starting. Factors that influenced loss of joint range in the subjects included in this study included the rate of lengthening, the age and the diagnosis of the patient. A mathematical model was developed to assist in predicting the loss of joint range, at the pre-operative examination.
The ability to perform functional activities and the effect on muscle strength were investigated and found to recover for up to 2 years following surgery and the removal of the Ilizarov fixator. Muscle strength recovered to within 5% of the baseline value by 2 years. This emphasises the need for a prolonged period of rehabilitation for patients treated by this method of surgery.

Finally a Delphi survey was conducted to produce Clinical Guidelines about the physiotherapy management of patients treated by the Ilizarov method.

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SECTION ONE

CHAPTER 1 – INTRODUCTION.

1.1 Introduction

Discrepancy in limb lengths (*anisomelia)* is a common orthopaedic problem arising from either shortening or overgrowth of one or more of the bones in the limb. The incidence of leg length inequality greater than 2 cm affects at least 1 in 1000 (Guichet et al 1991). These discrepancies may be congenital, or acquired, for instance, due to infection, after growth plate injuries or due to non-union of fractures.

The early work of the pioneering Russian surgeon Gavriel Ilizarov (1921-1992) has led to an increasing use of the principles of distraction osteogenesis, the formation of new bone by applied tension, to treat a wide range of orthopaedic conditions. The Ilizarov apparatus can be applied to utilise the three dimensional properties of the fixator enabling bones to be lengthened or widened; angular or rotational deformities to be corrected; fractures to be immobilised or segments of bone to be transported. These actions may be performed individually, sequentially or simultaneously, giving a system that is infinitely adjustable (Newschander & Dunst 1989, Aronson 1997).

This has made the generation of new bone at appropriate sites a technique that is used by orthopaedic surgeons in this country, across Europe and the USA as well as in Russia. It is particularly useful in the field of limb length discrepancy. Thus surgeons may use the technique of distraction histogenesis to form new tissues and equalise the length of the short limb.

Research to date, has focussed on the biological mechanisms of new bone formation in distraction osteogenesis. However, the role of the soft tissues in these procedures remains comparatively poorly understood. Operations to correct limb length discrepancies are associated with numerous complications including muscle contractures, joint stiffness, muscle weakness and subluxation of joints (Green 1990, Paley 1990, Holm et al 1995, Maffuli et al 1995). These are thought to arise because of difficulty of soft tissues, particularly muscle and nerve, to adapt to imposed changes in length. It is known from animal studies that different tissues have differing optimal rates of distraction in order to achieve histogenesis of tissues (Simpson et al 1995). This offers one explanation for the soft tissue

complications that occur. These soft tissue changes present an enormous challenge to physiotherapists involved in the rehabilitation of Ilizarov patients. Whilst most authors recognise the importance of the post-operative care of patients undergoing distraction osteogenesis, particularly limb lengthening procedures; relatively little is published about the rehabilitation and physiotherapy treatment of patients treated by these techniques. Information about the efficacy of rehabilitation of patients treated by the Ilizarov method, relating to the effectiveness of interventions is sparse. The limited published work that is available tends to rely upon expert opinion concerning what are effective strategies for rehabilitation, rather than being based on observational or evidence-based clinical studies (Simard et al 1992, Folkerts et al 1992, Coglianese et al 1993).

The trend in the health service is increasingly towards evidence-based healthcare, defined as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients' (Sackett et al 1996). Hierarchies of the strength of scientific evidence exist, based on the validity of different methodologies, and the extent to which they can reduce the likelihood of erroneous conclusions being reached. These place systematic reviews and multiple well-designed randomised controlled trials (RCT) as the most valid, and expert opinion and descriptive studies as the least (Moore et al 1995). The evidence-base of approaches to the physiotherapy treatment of Ilizarov patients needs to be strengthened. The rehabilitation of these patients is inter-dependent on many other decisions made within the multidisciplinary team. However, the patient group treated in any centre tends to be small in number and varied in both the original pathology and the goals of the surgical intervention. Thus Ilizarov patients may not be well suited to a RCT approach and many believe that the RCT is inappropriate in many areas of rehabilitation and therapy research (Andrews 1991, Gladman 1991). Therefore, this study was planned using a clinical cohort design rather than a randomised controlled trail.

1.2 Aims of Thesis

a) To identify the current treatment methods, experiences and problems faced by physiotherapists treating patients with an Ilizarov fixator in the United Kingdom.

b) To identify the factors that contribute to the development of soft tissue contractures, specifically loss of joint range of motion, in lower limb lengthening.

c) To investigate whether there is an assessment measure that has predictive validity in respect of which patients will develop soft tissue complications.

d) To investigate the effect of limb lengthening surgery on muscle function, specifically power, strength and the ability to perform normal functional activities using a longitudinal clinical study.

e) To produce clinical guidelines for the rehabilitation of patients with an Ilizarov fixator using a Delphi Survey technique and the results of the clinical longitudinal studies.

f) To suggest future research and research methodologies, to establish the effectiveness of physiotherapy approaches.

CHAPTER 2 – BACKGROUND

2.1 Leg Length Discrepancy

Leg length discrepancy represents a significant orthopaedic problem affecting a single bone or a whole limb (Figueiredo et al 1993, Stanitski 1996). It is generally accepted that limb length discrepancies of greater than 2 cm require action to compensate for the inequality (Kenwright & Albinana 1991). Patients with 2 cm of discrepancy may have some minor functional problems, but they can usually compensate for these by using a small wedge inside the shoe or a shoe raise. Shoe raises can correct the leg length discrepancy and restore mechanical forces to normal. However, they tend to be poorly accepted by patients who are resistant to wearing them and non-compliance results in no effective treatment. More than 2cm difference in leg length results in both cosmetic and functional concerns due to postural imbalance whilst standing, as well as an uneven gait. Heel cord contractures, scoliosis, degenerative joint disease and low back pain may arise as a result (Mier & Brower 1994). Once the discrepancy is over 4 cm it usually requires surgical correction (Winquist 1986).

Surgical correction of leg length discrepancies by lengthening using distraction osteogenesis and external fixation is being performed increasingly more frequently in the United Kingdom for a variety of orthopaedic conditions. In 1993 only 19 surgeons were performing the surgery at their hospitals, by 1999 this had risen to 86 surgeons in 73 hospitals (Graham 2000). In the past poliomyelitis was the most common cause of limb length inequality but this is now uncommon. Today marked limb length differences may result from congenital or developmental abnormalities, or from growth arrest of the physes due to trauma or infection. Non-union or malunion of fractures are often treated by orthopaedic procedures that produce a limb length inequality in order to eradicate the infected or dead bone. Any of these presenting conditions may lead to treatment by external fixation using the principles of distraction histogenesis. Leg lengthening is a complex procedure with a high complication rate but can produce excellent and dramatic results.

Limb shortening is a simpler and safer option that has less effect on the quadriceps mechanism and allows a relatively fast return to normal function. It may be performed as an open or closed procedure, removing a segment of bone and collapsing the limb to shorten the leg. In children arresting the growth plate at the epiphysis will produce limb shortening.
A final option is to combine lengthening and shortening and this is usually performed for patients with a discrepancy in excess of 10 cm.
To summarise, the options for the surgical correction of leg length inequality are :

a) Lengthening the short limb
b) Shortening the long limb by removing a segment of bone
c) In children, surgical growth arrest of the long limb (epiphysiodesis)
d) A combination of the above

This thesis focuses on correction of limb length discrepancy by lengthening the short limb.

2.2 Principles of Limb Lengthening

Limb lengthening is based upon the knowledge that bone will regenerate in the gap of an osteotomised bone. Under certain biological and mechanical conditions bone can be carefully divided and the two bone ends separated in a controlled manner to allow new bone to be generated in the gap that is created, a process known as *distraction osteogenesis*. This occurs naturally under certain conditions, for example, the bone growth at the perimeter of the growth plate is the result of traction forces from the surrounding attached periosteum (Tetsworth & Paley 1995). Surgeons can use mechanical distraction to reproduce and accelerate this natural phenomenon and exploit it to address a range of clinical problems including limb length discrepancy. The first widely used technique to achieve limb lengthening was the Wagner method (Wagner 1978). This utilised a transverse mid shaft osteotomy, intraoperative lengthening of 1 cm and post-operative distraction of 1.0-1.5 cm / day. This is now known to result in less

osteogenesis than the methods that are currently used such as the Ilizarov fixator or modern unilateral fixators.

Ilizarov (1989a,b) and others (Aronson et al 1989, Delloye 1990) have demonstrated that under appropriate conditions distraction osteogenesis produces intramembranous ossification. Ilizarov (1990) states that certain mechanical and biological factors are essential for osteogenesis:

a) Maximum preservation of extraosseous and medullary blood supply.
b) Stable external fixation.
c) A delay period prior to distraction of between 5 and 10 days.
d) A distraction rate of 1 mm per day in small frequent steps.
e) A period of stable fixation after the correction is completed (consolidation).
f) Physiological use of the elongating limb.

2.2.1 Preservation of Extraosseous and Medullary Blood Supply

Optimal bone formation occurs when the bone is divided but the periosteum and endosteum are left intact, i.e. a corticotomy in which bone is cut with minimal damage to the surrounding soft tissues. Alho et al (1982) and Ilizarov (1989a,b) demonstrated that the endosteum and periosteum participated in the filling of the distraction gap after osteotomy. They described a central area of growth, the interzone, where most of the regenerate bone forms. Kojimoto et al (1988) suggested that preservation of the periosteum is vital if regenerate bone is to form. However, this research was conducted on immature rabbits and may not apply to humans. Endosteal preservation is less important as it recovers quickly, the endosteum can be completely transected with no apparent effect on the quality of the regenerate bone (Delloye et al 1990,Tetsworth & Paley 1995).

Most papers suggest that metaphyseal osteotomy is preferable to diaphyseal. It has greater osteogenic potential as the blood flow and transverse diameter are greatest at the metaphysis. Metaphyseal corticotomies produce regenerate of better quality, which unite more rapidly than those performed in the diaphysis (Aronson 1994, Fischgrund et al 1994, Schwartsman 1992). However, some clinical studies have

suggested that it is easier to get fixation favourable to osteogenesis using a diaphyseal osteotomy (Steen et al 1990).

2.2.2 Stable External Fixation.

Ilizarov emphasised that stability of the external fixation is important for successful bone formation. One of the most important parameters in determining the mechanical stiffness of the fixator is the axial stiffness. This was demonstrated by Ilizarov (1989 a,b, 1991) who divided dogs into five groups according to the degree of stability of the fixation during distraction. He found a relationship between the level of osteogenic activity and the level of axial stability. Unstable fixation led to cartilage and fibrous tissue formation whilst stable fixation led to direct bone formation within the distraction zone. Aronson et al (1988) found that regenerate bone formation improved with more rigid fixation. The effects of bending and shear forces are not clear, although shear stresses at the osteotomy site are thought to hinder bone formation (Sproul & Price 1992b).

2.2.3 Delay Before Distraction.

The osteotomy is followed by a latent period of several days when the site is left undisturbed in an anatomically reduced position. This latent period allows the inflammatory phase of fracture healing to subside and distraction to commence during the reparative phase when early osteogenesis normally occurs (Tetsworth & Paley 1995). White & Kenwright (1990, 1991) demonstrated the importance of a delay before distraction, comparing immediate distraction with a delay of 7 days. They found that experimental osteotomies subjected to immediate distraction resulted in the production of a small volume of callus with deficient vascularity. When a delay period was added the response was altered, leading to increased callus and rich capillary ingrowth either side of the growth zone. This showed a delay period enhanced bone healing in an animal model. The authors acknowledge that there are doubts about their choice of outcome measure, as they measured callus from radiographs, a method with known limitations.

Possible explanations for these results are that immediate distraction may inhibit the recruitment of osteogenic precursor cells from surrounding tissues. The lack of stability associated with immediate and repeated traction may inhibit the local repair of damaged blood vessels (Mulholland & Pritchard 1959).

Tetsworth & Paley (1995) state that the age of the patient and the quality of the osteotomy will effect the latency period. The older the patient the longer the latent period is likely to be. In children a delay of three days may be sufficient but in adults 5-10 days is normal. Osteotomies that have produced significant vascular trauma to the periosteum or endosteum will require a longer latent period than those that are minimally traumatic. Clinical studies reveal considerable variation in the length of the latent period between different authors and with different methods of fixation; Kawamura et al (1968) waits 4 days, Ilizarov (1989) 7 days and De Bastiani (1987) 10-15 days. Morphological studies by Schwartsman (1992) have suggested that the optimum period of delay is 7 to 10 days.

2.2.4 Rate Of Distraction

It is well recognised that bone is a mechanically sensitive tissue and that the magnitude, direction, and timing of the applied load are all critical factors in influencing osteogenesis (Kenwright & Goodship 1989). If distraction is too slow then premature union of the osteotomy site may occur. If distraction is too rapid cartilage formation and an enchondral sequence may result.
Ilizarov (1989b) investigated the influence of changing the rate and rhythm of distraction using a canine model. He combined different rates of distraction (0.5mm, 1.0 mm or 2.0 mm /day) and rhythms (1 step, 4 steps, 60 steps / day). He observed that distraction at a rate of 0.5 mm / day in 4 steps often led to premature consolidation of the regenerating bone, whilst with a distraction rate of 2.0 mm / day a large proportion of the regenerate zone was filled with fibrous connective tissue. The best bone formation occurred with a rate of 1.0 mm / day in 4 steps, or using electrical auto-lengthening at 0.017 mm every 24 minutes. Li et al (1997) used a rabbit model to investigate the optimum rate of distraction. He found that the proliferation of osteoprogenitor cells during distraction osteogenesis was

affected by the rate of distraction. The rate of cell proliferation was found to increase as the rate of lengthening increased from 0.3mm to 0.7 mm / day. However, at rates of over 0.7 mm / day there was no further increase in cell proliferation and 0.7 mm / day appeared optimal for cell proliferation and histological characteristics.

A rate of 0.25 mm, four times a day is the most commonly used regimen in the clinical setting as this uses the rate at which Ilizarov found best bone formation occurred, in a manner that is acceptable to the patients' undergoing correction. This may be decreased in situations where the bone is less vascular, such as dense cortical bone. In general, bone forms more slowly in adults who require slower distraction rates than children. During deformity correction the surgeon must vary the rate of distraction to avoid premature consolidation at the apex, whilst not exceeding the potential for ingrowth of the vascular supply at the base of the opening wedge at the lengthening site (Aronson 1988). Frequent intervals of distraction may be better in allowing soft tissue relaxation due to the viscoelastic behaviour of collagenous tissues and this may decrease the incidence of soft tissue complications associated with distraction osteogenesis (Leong et al 1979). However, as yet the evidence for this is not strong and more needs to be known about visco-elastic behaviour.

2.2.5 Period Of Consolidation after Lengthening

The consolidation period is the time following distraction during which the regenerate bone matures and establishes cortices as the bone is remodelled. This period of neocorticalisation is necessary for the regenerate bone to increase its strength prior to removal of the external fixator (Ilizarov 1989, Aronson 1994a). Consolidation of the regenerate can be accelerated by dynamic loading of the new bone, dynamisation of the fixator, or slight compression of the regenerate bone (Haminishi et al 1994). Once the regenerate has formed a complete cortex on three sides, as viewed on three orthogonal x-ray views the fixator may be removed (Green 1991).

2.2.6 Physiological Use Of The Elongating Limb.

Ilizarov (1989,1990) advocated maximal use of the elongating limb in as functional a way as possible during the period of fixation. Repetitive axial compression and distraction forces such as occurs in walking have been shown to stimulate bone formation. This has been demonstrated by Sarmiento (1972) and Meadows et al (1990) in rat studies and in canine models. Goodship & Kenwright (1985) applied repetitive axial loading to sheep tibiae after osteotomy and external fixation. Cyclic loading with 0.5 and 1 mm of displacement cycled every two seconds increased osteotomy healing significantly compared to a control group in doses as small as 17 minutes per day.

2.3 Lengthening by Distraction Osteogenesis

Once the bone ends are separated Tetsworth & Paley (1995) describe the four stages of distraction osteogenesis (Figure 2-1):

i) The lengthening phase; longitudinally orientated trabeculae form either side of the bone gap with a central fibrous zone.

ii) The consolidation phase; the new bone is allowed to mature and ossification of the central fibrous interzone begins.

iii) The corticalisation phase, during which the cortices around the bone forms; when there is sufficient neocorticalisation for the bone to be united, the fixator may be safely removed.

iv) Recanalisation; the medullary canal is remodelled and the new cortex is formed.

Figure 2-1: Stages of distraction osteogenesis.(From Paley et al 1991)

Following corticotomy, there is a short latent period before the bone ends are gradually distracted. The distraction period continues throughout the period when gradual, controlled mechanical distraction forces are applied. Bone forms from intramembranous ossification. The gap is initially filled with haematoma and fibrous exudate. Within a few days this is invaded by immature connective tissue fibroblast-like cells, and vascular channels appear. A central zone of longitudinally orientated type-1collagen fibres are laid down. Columns of bone spicules form about these fibres forming micro columns of bone (trabeculae) that are predominantly orientated parallel to the distraction force. They emanate from each corticotomy surface and span the vascularised region terminating in a central fibrous interzone, typically 4 to 8 mm wide. Detailed examination of the fibrous interzone shows spindle-shaped cells, which appear to gradually differentiate into osteoblasts, that then produce mineralised osteoid. At the junction of the fibrous interzone and the new trabeculae, collagen is visible. Cuboidal osteoblasts line the outer surface of each new trabeculum along its entire length. The trabeculae are conical in shape, with a narrow tip 7μm to 10μm wide and a broader base 150μm to 200μm in diameter (Aronson 1994, Schenk 1994) (Figure 2-2). The columns of new bone are eventually interconnected transversely, forming a honeycomb appearance on microscopy (Aronson 1997).

At the end of the distraction period, fibrocartilage is interposed between the bone ends and the ossified or sclerotic zone and this is where the collagen fibres end.

The gap begins to consolidate, columns of bone bridge the collagen interface and rapid bone modelling occurs. There is thickening of the trabeculae at the periphery of the tube of regenerating bone marking the start of neocorticalisation.

Figure 2-2: Distraction Osteogenesis (Reproduced from Sproul & Price 1992b)

During the consolidation phase bone eventually grows across the fibrous interzone, the regenerate matures and neocorticalisation continues as the bone is remodelled (Ilizarov 1989 a,b, Aronson 1994, Schenk 1994, Tetsworth & Paley 1995).

The cortices of the bone ends become thinner and osteopenic and by 4 weeks after distraction new bone is laid down in the central growth zone (Alho et al 1982, Aronson 1988, Delloye et al 1990, Tajana et al 1989). The content of the new bone includes water 15%, lipid 5%, calcium 25%, phosphate 12% and collagen 24%. These are found in approximately the same ratios as in normal bone (Aronson 1994). Corticalisation occurs at 4-6 months post-distraction.

Remodelling of the bone continues for up to a year or more (Sproul & Price 1992).

The progression of healing from the central zone of collagenous growth to the more peripheral columns of mineralised bone results in a distinctive x-ray appearance. The regenerate bone has longitudinal striations, clearly defined lateral margins, a central radiolucent growth zone and a cylindrical appearance (Ilizarov 1989, Kojimoto et al 1988). Once matured the regenerate bone is indistinguishable from host bone (Aronson 1988, Ilizarov 1990). This is unlike the new bone seen in fracture healing, in which there is a disorganised collagen network of bone and where the bone often does not recover its normal contour (Tetsworth & Paley 1995).

2.4 METHODS OF EXTERNAL FIXATION

The above sections have described distraction osteogenesis to achieve limb lengthening using the Ilizarov method. This method may be applied using a variety of different methods of external fixation, not just the Ilizarov fixator. There are two main types of external fixator; circular and unilateral. The main differences relate to their physical appearances and the placement of the fixation elements in one (linear) or more than one (circular) planes (Caja et al 1995).

2.4.1 Circular Fixators

Ilizarov pioneered the circular or ring fixator. It uses a combination of rings that surround the limb that are interconnected by threaded rods. Tensioned Kirschener wires pierce the bone and are tightly attached to the rings. Thus the bone segments are held in a stable position by tensioned wires within an external scaffold of rings and threaded rods. The rings may be made of stainless steel or carbon fibre. Alternatively, half-pins which are screwed into the bone are used to reduce the transfixation of musculotendinous structures (Coglianese et al 1993). This basic design is altered by the surgeon, depending upon the goals of surgery. It is very adaptable and can be modified to suit different situations and types of deformity. It produces suitable conditions for bone regeneration and allows the management

of complications arising during treatment by supplementing the basic frame with additional components (Aronson 1997) (Figure 2-3).

The major disadvantages of the Ilizarov fixator are that it is time consuming and difficult to apply and requires a lot of post operative management. It is also bulky and less convenient for the patient to wear than a unilateral fixator (Sproul & Price 1992a).

Figure 2-3: Ilizarov fixator

2.4.2 Unilateral Fixators.

Wagner (1978) developed a unilateral or rigid cantilever frame in the 1960s, which proved to result in good bone formation. In 1977 DeBastiani developed a rigid unilateral fixator with a telescopic component that could be used for dynamic bone loading. This system of cantilever fixation is axially more rigid than the ring fixator and biomechanically offers stiffness to bending forces in the plane of the fixator, but less rigidity perpendicular to the plane of the fixator. The cantilever design imparts eccentric loads on the bone and may result in angulation of the lengthened segment (Aronson 1989, Simpson et al 1997). The device devised by DeBastini, the Orthofix fixator, has evolved into 3 basic models, the Orthofix external fixator, the Orthofix lengthener and the Orthofix slide

lengthener. The Orthofix external fixator has adjustable locking ball joints at either end, facilitating a 35° arc of motion, which allows for angular correction at the osteotomy site. The friction locks of the ball joints can slip during lengthening and so the Orthofix Lengthener model tends to be used for this function (Figure 2-4). The Lengthener model does not have any ball joints and requires precision when being applied. The third version is a segmental slide lengthener, which again requires precision when being applied, but is versatile in allowing closer pin placement, a longer range of distraction and the ability segmentally to transport bone (Chao 1988, Sproul & Price 1992). (Figure 2-4). The fixator may be dynamised in the consolidation phase and axial micromovement is present during gait (DeBastini 1984).

In a study comparing the biomechanical properties of the main types of unilateral fixator, Gardener et al (1997) found that all were subject to fatigue and that plastic or slip failure of frames may occur prematurely during routine weight-bearing and frame fatigue may affect long-term interfragmentary stability. Biomechanically, unilateral fixators result in stiffness to bending forces only in the plane of the fixator. This necessitates that care is taken to choose the most appropriate fixator that will withstand the stresses placed upon it during any surgery and subsequent distraction or correction of alignment.

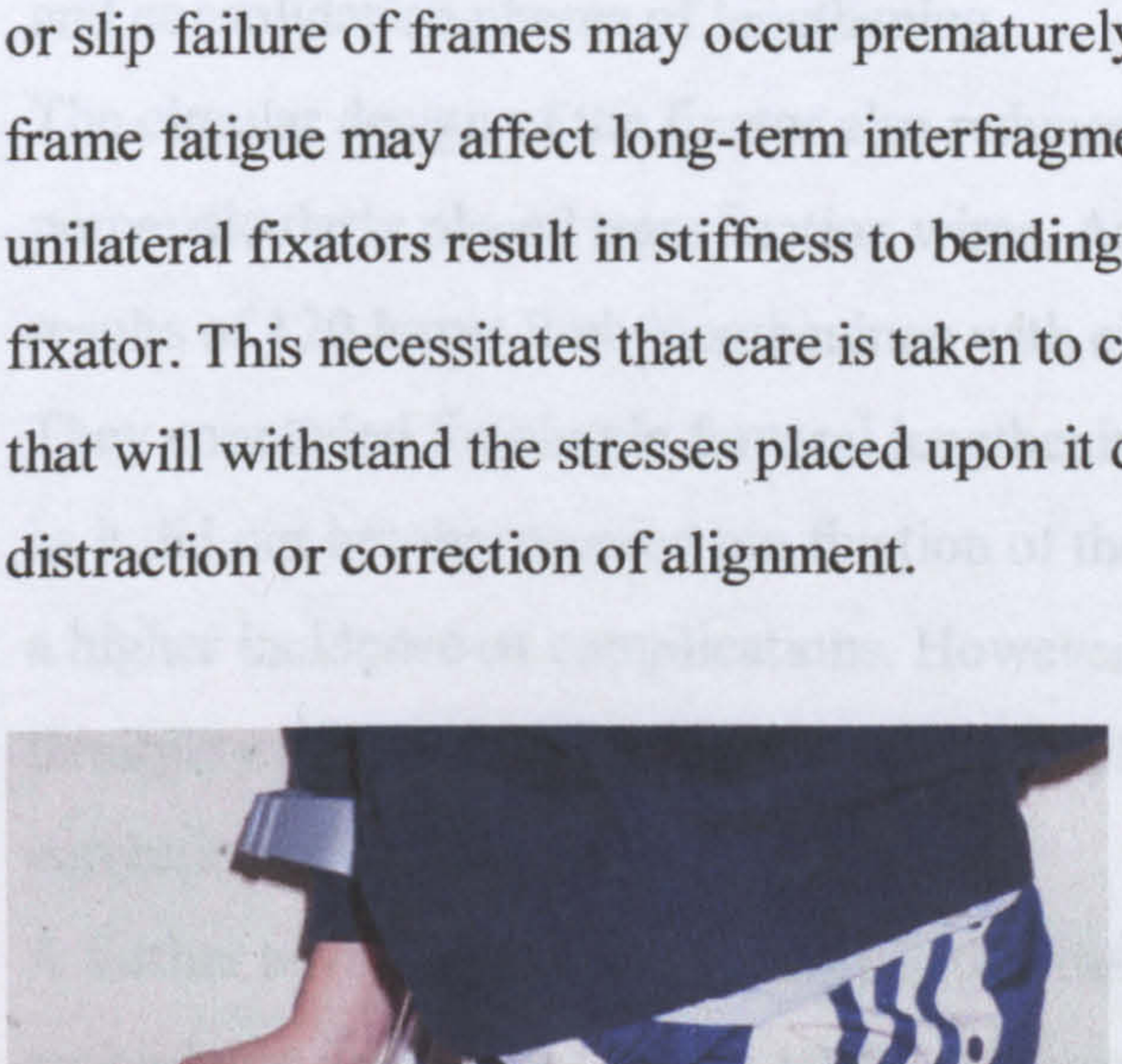


Figure 2-4: Orthofix fixator.

2.5 Advantages and Disadvantages of the circular Vs unilateral Fixators.

The main points are summarised in Table 2-1. Clinically, both unilateral and circular fixators can be used to produce excellent bone formation (Aronson 1997). Biomechanical analysis of the different types of fixator shows that the Ilizarov fixator has a stiffness in axial loading that is equal or less than other common types of fixator (Fleming et al 1989, Paley 1990a, Kummer 1989). This decreased axial stiffness allows cyclic loading of the bone during weight bearing which has been shown to enhance fracture healing (Chao 1988, Gasser et al 1990). Sproul & Price (1992) describe this decreased axial stiffness as a trampoline effect allowing axial compression and distraction with weight bearing throughout the distraction and consolidation phases of lengthening.

The circular design of the fixator also reduces lateral bending by the use of the perpendicularly placed transfixation wires. Amaya et al (1990) compared their results of 120 lower limb lengthenings with either circular or Orthofix fixators. They concluded for simple femoral lengthenings unilateral fixation was preferred as it did not involve crossed pin fixation of the thigh, which may result in pain and a higher incidence of complications. However, ring fixation offered more flexibility and scope when carrying out complex realignment of bone and correction of multiplanar deformities.

A further advantage of ring fixators is that they allow gradual correction of multiplanar deformities (Paley 1990). Aronson (1997) states that as a general rule monolateral fixators may not be as well suited as ring fixators for the mechanical correction of deformities with angulation or rotation or those that need more than two sites of treatment.

Unilateral fixators allow limb lengthening but not the correction of spatial deformities (Korzinek et al 1992), although some of the newer versions allow angular correction. Their main advantage is their ease of application and their convenience for the patient. Amaya et al (1990) concluded that unilateral fixation is preferable for femoral lengthenings reducing the pain and complications associated with crossed-pin fixation of the thigh.

TRAIT	CIRCULAR FIXATOR	UNILATERAL FIXATOR
Bone formation	Excellent	Excellent
Transfixation of soft tissues	More, thigh and lower leg	vastus lateralis
Correction of angular and rotational deformity	Acutely or gradually	Possible on some patients
Pin-site problems	Moderate	Moderate
Ease of patient management	Bulky to wear. Distraction more complicated	Less bulky Easier to distract.
Operative technique	Technically demanding Time consuming	Less technically demanding Less time consuming.
Maintenance of alignment.	Good.	Good with non-ball joint devices.
Postoperative management	Time consuming adjustments to frame design	Less time consuming
Expense	Expensive	Cheaper

Table 2-1: Comparison of circular and unilateral fixators.

In clinical practice a choice is often made on a patient by patient basis about whether unilateral or circular fixation is to be used. In lengthenings involving the entire limb a hybrid system may be used with a unilateral fixator on the femur and a circular fixator on the tibia. The different types of fixator have implications for the physiotherapy management of patients. The circular fixator tends to have a higher incidence of transfixation of soft tissues and is bulkier, impeding the mobility of the patient to a greater extent. The unilateral fixators tend to transfix the vastus lateralis, but overall impede the movement of patients to a lesser extent. It is possible that the choice of type of fixator may have implications for the

physiotherapy management of patients and could be a significant co-variate in determining recovery.

2.6 Clinical Indices Used in Distraction Osteogenesis.

During distraction osteogenesis factors may be manipulated to achieve the goals of surgery. The rate of lengthening and the total amount of lengthening may be adjusted in accordance with how well the patient is tolerating the procedure. If the bone starts to prematurely unite the rate of lengthening may need to be increased and thus the total length will be achieved more quickly than if the standard protocol is used. Likewise, the time that the frame is on the limb will be affected by the amount that the bone is being lengthened, by the need for further corrections of alignment and by the speed of new bone formation and healing. Thus the limbs of two patients being lengthened by the same amount of new bone, may have differing treatment regimens and have different lengths of time within the fixator. These variables are incorporated into clinical indices that allow comparisons between different treatment regimens to be made. In reports of clinical results these clinical indices, reflecting the differences in the rate of lengthening and duration of fixation are often cited. These have been defined by Tsuchiya et al (1997) and Aronson (1997), amongst others. (Table 2-2)

Healing Index External Fixation Index	The total duration of treatment (days)divided by the length of new bone generated (cm).
Lengthening Index Distraction Index	The duration of distraction (days) divided by the length of new bone generated (cm).
Maturation Index	The duration of external fixation, measured from completion of distraction to the removal of external fixation, divided by the length of new bone generated (cm).

Table 2-2: Clinical Indices

CHAPTER 3 – LITERATURE REVIEW

3.1 Complications of Limb Lengthening

The process of limb lengthening is fraught with numerous complications, many of which have still to be resolved (Paley 1990, DeBastiani et al 1987, Mosca 1986). The impact of these complications on a successful outcome has long been recognised. Compere (1936) divided complications into three groups, overstretching, interference with the blood supply and insufficient stabilisation of the fragments.

Lack of adaptability of muscles, tendons, blood vessels and nerves of the lengthened limb segment have all been identified as problems that may lead to joint contractures or subluxation or fracture of the bone (Aldegheri et al 1989, Cattaneo 1986, DeBastiani et al 1987, Ganel & Blankstein 1987, Paley 1990, Simpson et al 1995). Early authors all emphasised the importance of soft tissue releases and/or tendon lengthenings to reduce the forces that occur during the distraction phase of lengthening (Codivilla 1905, Putti 1921, Kawamura et al 1968). The range of complications that were described included angulation, non-union, delayed union, refracture of the lengthened segment, osteomyelitis, traumatic arthritis, limitation of joint range, necrosis of bone or skin and displacement of the fibula head or malleoli (Compere 1936, Sproul & Price 1992a).

The more modern techniques using callostasis, or distraction of callus, such as the Ilizarov or Orthofix external fixators are much less prone to complications, allowing planned goals of treatment to be achieved in most cases. These methods have solved many of the problems that arose with bone healing but there is still a considerable range of potential problems remaining. Paley (1990) developed a scheme for categorising complications experienced during lengthening into problems, obstacles or true complications. A problem is defined as an expected potential difficulty that is resolved by the end of the treatment period by non-operative means, an obstacle as an expected potential difficulty that arises during the treatment period that is resolved by operative means. Complications are described as any local or systemic intraoperative or perioperative complication or

a difficulty that compromise the end result. Paley (1990) reported an incidence of 35 problems (minor complications) and 28 complications in a series of 46 lengthenings.

Sproul & Price (1992a) proposed a simpler classification of complications into either major or minor.

Major complications:

1. Bone or joint infection.
2. Permanent loss of functional joint range of motion.
3. Arthritis.
4. Subluxation / dislocation of the knee or hip joints.
5. Delayed or non-union of bone.
6. Residual limb length inequality.
7. Malalignment of the anatomical limb axis greater than 5 degrees.
8. Migration of the lateral malleolus in a proximal direction.
9. Vascular or nerve injury through either stretch or pin penetration.
10. Chronic oedema.
11. Decreased muscle strength.
12. Poor limb function (worse than would have resulted from amputation).

Minor complications:

1. Pin site inflammation / infections.
2. Pin loosening.
3. Premature consolidation of the distraction site.
4. Temporary malalignment of the anatomical axis.
5. Temporary neuropraxia.

The complications that are of the most interest from the rehabilitation professional's point of view are those that arise from poor adaptation of the soft tissues to distraction. This limited adaptation of soft tissue may be directly responsible for such complications as:

- Loss of functional joint range of motion
- Subluxation / dislocation of the hip or knee joints
- Decreased muscle strength
- Poor limb function
- Migration of the lateral malleolus in a proximal direction

and indirectly for such complications as:

- Oedema
- Malalignment of the anatomical axis of the limb
- Vascular or nerve damage

3.2 Effect of limb lengthening on joint range of motion

The reported incidence of muscle contractures and joint stiffness varies considerably from 5% by Mezhenina (1984) to 92% by Tjernstrom et al (1994) Several authors have described the joint complications that they noted in their series of patients. Faber et al (1991) reported transient restriction in joint motion in almost all patients undergoing limb lengthening, serious restriction of motion in 27 out of 46 and permanent limitation of the joint range in 9 out of 46 lengthenings. This is a very high reported complication rate compared to other authors, however it may be explained partly by semantic factors about the definition of a complication. Karger et al (1994) also reported that all patients had transient restriction of movement.

Tjernstrom et al (1994) reported on 53 lengthening operations using three different styles of frame: Hoffman, Orthofix and Ilizarov. They found restrictions of joint motion during 49 of the lengthenings and that the contractures appeared after varying periods of time and had an unpredictable onset. Approximately one third of their patients still had some restriction of joint mobility at follow-up, which they postulated meant that most patients regain their range of motion within six months of frame removal. They suggested that surgical intervention might be needed if range has not returned by that time and that transfixation of the quadriceps muscle by the wires was one of the major causes of restriction of movement. There was no correlation with the pre-operative range of motion and the development of post-operative joint limitation.

Aldegheri (1989, 1999) reported substantial lengthenings of over 30% of original bone length in achondroplastics without soft tissue complications. This is possibly because of the marked elasticity in the soft tissues, tortuous nerves and vessels and lax joints typical of achondroplasia (Saleh and Burton 1991). Knee flexion contractures occur less often and may predispose to knee subluxation. Fixed flexion deformity increases the transverse component of the force vector of the hamstrings, allowing them to work unopposed to pull the tibia posteriorly on the femoral condyles (Jones 1985, Barker et al 2001a, Paley 1990).

There are problems in comparing the rate of joint complications across these different series of patients. All patients were reviewed retrospectively where there were inevitably problems with bias and the accuracy and interpretation of the patient records. There are also problems with semantics and the definition of a complication. Some would consider that there are complications that are intrinsic to the lengthening procedure and cannot be avoided e.g. transient joint stiffness and pin site infection, whilst other complications e.g. joint subluxation, permanent joint restriction and nerve damage are extrinsic and should be avoided (Wagner 1978, Coleman 1978). Thus the differences in reported soft tissue complications may be due as much to different systems of evaluation, as to genuine differences in the rate of complications.

3.3 Effect of lengthening on muscle

Distraction histogenesis, the process of subjecting the soft tissues to distraction in order to stimulate the growth of new tissues, occurs as a natural phenomenon, for example, in the 900-fold increase in the size of the female uterus during pregnancy. Although different tissues react in different ways they all involve two predominant mechanisms: reorganisation of collagen in response to stretch and neohistogenesis (Tetsworth & Paley 1995). Whilst the factors that affect the ability of the bone to lengthen are well established i.e. osteotomy, a latent period

and the rate and frequency of distraction, those effecting the ability of the soft tissues to accommodate to changes in bone length are not so clearly understood.

3.3.1 Changes to muscle morphology.

Ilizarov (1989a) proposed that gradual traction on living tissues creates stresses that stimulate and maintain the regeneration and active growth of the tissue. He called this phenomenon "The Law of Tension-Stress" and claimed that soft tissues react to distraction by developing the characteristics of embryonic tissue (Ilizarov 1989 a,b, 1990). Ilizarov and his fellow researchers performed much of the pivotal basic scientific research into the effect of lengthening on the tissues. Using metal clips to mark the length change in different parts of the distracted muscle and fascia in a canine limb, they found that with up to 20% lengthening of the bone, the new tissue was distributed along the total length of the muscle and fascia. In lengthenings of over 20 % they found that the muscle and fascia tended to lengthen most at the corticotomy site. Ilizarov stated that under experimental conditions parts of the distracted muscle developed an identical appearance ultrastructurally as embryonic muscle tissue. He suggested that this was because the muscle tissue was demonstrating a proliferative response to an increase in length (Ilizarov 1989b). However, Ilizarov failed to evaluate this postulated proliferative response and although it is reported that up to 500 animals were studied, no details of how many ultrastructural surveys were undertaken or statistical analysis is given. The published electron microscope pictures of the lengthened muscle do not provide definite evidence of the generation of new muscle tissue as Ilizarov claims (Chirkova 1981).

They also reported an increase in the number of fibroblasts during distraction and an increase in the contact areas between them with dense junctions in many places. They reported that the fibroblasts were type II collagenoblasts, i.e. cells typical of embryonic connective tissue. The increased activity in the tissue was reflected by a number of other changes including hypertrophy of the Golgi complex, enlargement of mitochondria, cytoskeletal microfilaments and the rough endoplasmic reticulum. As a result of his studies Ilizarov thought that, like bone, soft tissues responded to tension-stress distraction by forming new tissue, not by

simply stretching (Ilizarov 1991). He likened this to the tension-stress that is an important stimulatory force for the development of limb buds in embryogenesis (Milichenko 1974).

Ilizarov considered that myoblasts were formed under the conditions of tension-stress and fused into myotubes. He also studied the response of the connective tissue elements of muscle to lengthening and reported that the orientation of the collagen fibres became parallel to the tension -stress force vector (Ilizarov 1989b). He states that the muscle, nerve, vessels and skin undergo myogenesis, axonogenesis, vascogenesis and dermatogenesis respectively. Unfortunately, good scientific evidence for his theories is not presented and, therefore, there remains a question as to whether myogenesis does occur during lengthening. Many of Ilizarov's results could be explained by a damage and repair process.

3.3.2 Other Morphological Studies.

Yasui et al (1991) used metal wires to mark the fascia of the antero-lateral muscle of growing Japanese White rabbits prior to lengthening the tibia with an external fixator. They found that elongation occurs throughout the substance of the muscle and not just at the site of the osteotomy. However, there are some questions about their methodology as the wire markers were only placed in the fascia or epimysium and so would not reflect the adaptability of the muscle belly to lengthening.

Calandrello (1975) used a canine model to demonstrate that lengthening produced a series of microscopic ruptures of the myofibrils, which later regenerated.

Kyberd et al (1994) distracted rabbit tibiae by 20 %. They found evidence of muscle damage including the presence of internal nuclei, necrosis, thickening of the perimysial connective tissue and enlargement of muscle fibres. Likewise Lee et al (1993) found histopathological changes such as endomysial fibrosis and internalisation of nuclei after 20 % lengthenings, which may suggest irreversible muscle damage.

Kawamura et al (1968) showed that biochemical abnormalities can occur under experimental conditions in the presence of only a 10 % increase in limb length. They reported that the levels of the muscle enzyme creatine phosphokinase,

involved in energy storage, rose by between 5-10 times their normal values after one stage lengthening of 10% of the length of the tibia. This is thought to occur due to an actively increased metabolism or it may simply represent intravascular release of enzymes as a result of muscle fibre damage. Whilst this study does not reflect the clinical picture where the lengthening is achieved more gradually it does indicate that damage can occur to the muscle in lengthenings of only 10%. These studies demonstrate that muscle responds to stretch initially by stretching without cell proliferation, followed by a mixed cellular response with further stretching. Changes to the muscle morphology occur with distraction of more than 10% of the original limb length, however, these may only be temporary.

3.3.3 Studies of the proliferative response of muscle

Ilizarov (1989a,b) showed that under experimental conditions parts of the distracted muscle develop the same appearance as seen in embryonic tissue, which suggests that there is a proliferative response of muscle tissue with adaptation to an increase in length. Simpson et al (1995) lengthened the tibiae of New Zealand white rabbits in twice daily increments. They found that new contractile tissue formed during lengthening but that damage to muscle fibres occurred at rates of distraction as low as 1 mm/day. There was proliferation of fibrous tissue between the muscle fibres at distraction rates of over 1 mm/day. Schumacher et al (1994) lengthened the tibia of New Zealand white rabbits and compared them to a control group. The nuclei of the tibialis anterior muscle in the proliferative phase was evaluated and found to demonstrate a significant increase in the weight of the lengthened muscle and in the number of proliferating cell nuclei compared to a control group. This response was observed only during the lengthening period and ceased when the lengthening was stopped. The authors concluded that muscle cell proliferation occurred only during the distraction phase of limb lengthening and agreed with Ilizarov (1989a) that stretch was the major stimulus for longitudinal muscle growth.

3.3.4 Degenerative response to lengthening.

Shen & Aronson (1993) lengthened adult rat tibiae by 20 %. They found that this caused acute stiffness in the gastrocnemius muscle, which they attributed to an increase in endomysial and perimysial fibrosis, a change that they considered irreversible. However, another explanation for this finding would be that the bone had lengthened but that the muscle had not grown and was effectively short. Simpson et al (1993) studied the effect of lengthening rabbit tibiae at rates of greater than 0.7 mm/day and found that this led to changes usually found in muscle damage such as whorled fibres and centralisation of nuclei. The length/passive tension curves of these muscles demonstrated that there was a relative increase in muscle stiffness. They postulate that this may lead to the antagonist group using more energy to produce range of movement and reduced efficiency.

3.3.5 Functional Vs Structural Adaptation To Lengthening.

Matano et al (1994) studied the adaptation of the extensor digitorum lateralis muscle in 21 Japanese White rabbits who had undergone osteotomy of the radius and ulna, followed by immediate lengthening of 3.5 mm. The rabbits were divided into five groups which were sacrificed at 0, 2, 5, 9, and 14 days after surgery. The lengths of the sarcomeres of the extensor digitorum lateralis muscle of the fifth digit were measured in a standardised wrist and elbow position using a light diffraction technique. The sarcomeres initially stretched to 3.51μm after distraction of the bone but became shorter with the passage of time. On the 9th day post-operatively the length was 3.10 μm, which was similar to the length of the unstretched muscle. These results indicated structural adaptation of the muscle to a new length and could explain why the efficiency of muscle function is maintained after limb lengthening. Other authors have reported these stretch-induced changes in sarcomere length in studies of immobilised limbs (Williams & Goldspink 1973,1976,1978, Tabary et al 1972).

Conversely, Williams et al (1994) lengthened rabbit tibiae by 20 % using different rates of distraction. They found that irrespective of the rate of distraction, the muscle belly length was significantly longer than in the control limb. At lower rates of distraction this could be accounted for by an increase in the serial sarcomeres with no change to the sarcomere length. At higher rates of distraction fewer sarcomeres were added, sarcomere length was significantly increased and the muscle showed evidence of atrophy and damage.

Simpson et al (1995) reported that muscle responded most favourably to rates of distraction that are below those commonly used in prolific bone formation. Up to a distraction rate of 1 mm/day the muscle showed active muscle function, however, the compliance of the muscle was only normal with a distraction rate of 0.4 mm/day. At higher rates of distraction there was evidence of dysfunction of the tibialis anterior muscle with alterations to the active and passive length / tension curves of the stretched muscle. The results indicate that muscle responds more slowly to the lengthening regimen than does the supporting bone.

3.4 Rehabilitation.

There is little published material on the rehabilitation of patients with Ilizarov fixators. The early experience in the use of Ilizarov was at the Kurgan All-Union Centre for Restorative Traumatology in Kurgan, Siberia in the former Soviet Union. Ilizarov (1997) states that it is essential to involve patients in up to 6 hours of active therapy a day to improve circulation and to prevent soft tissue complications developing. None of Ilizarov's reports in English language journals report the details of the functional outcome of the patients treated by his method. Furthermore, none of his literature documents the effectiveness of interventions used to prevent soft tissue restrictions in limb lengthening using distraction osteogenesis. Though Ilizarov reported that weight bearing and range of motion are central to the rehabilitation of patients being treated by his method, no details on how best to do this appear in the literature, nor are criteria for rehabilitation progress proposed. The little that is known about the treatment in Kurgan is described by Coglianese et al (1992) and shows the use of exercise classes for 6 hours a day. Photographs from these classes show patients walking with crutches

or in a gym lined up in columns and rows, standing and practising weight shifting onto the operative side.

Bagnoli (1990) in his writings on the use of the Ilizarov method for fracture fixation shows a patient performing sit to stand exercises at a rail to facilitate functional loading. The patient progressed to standing in parallel bars, where weight-shifting exercises were performed later followed by forwards and backwards stepping. There appear to be no graduated treatment goals and no justification for why 6 hours a day of functional loading exercises were given. The patients all remained resident at the centre for the entire duration of their treatment with the Ilizarov frame, which meant that they were in-patients for periods of many months or even years.

Within a Western model of healthcare treating patients as in-patients for a protracted time would be neither practicable or cost effective and is unlikely to be acceptable to Western patients.

Korzinek & Barbarossa (1992) states that the postoperative period extends from before surgery to the complete resocialisation of the patient and will be associated with numerous complications and problems. They state that the physiotherapists' commitment and the patient's compliance are equally important in preventing and solving these problems.

Green (1990, 1991) states that active and passive physiotherapy as well as constant stretching of tightening tissues with either strategically placed elastic bands or a dynamic splint form the basis of the post operative management of every patient having a limb lengthened. He states that at least 2 or 3 hours a day should be devoted to stretching exercises and that the greater the proposed lengthening, the more hours each day that must be devoted to passive stretching. Intensive "hands-on" physiotherapy is considered essential to prevent the contractures and joint subluxations associated with limb elongation. Other important factors are thought to include night positioning and ambulation (Simard et al 1993, Coglianese et al 1992). Paley (1990) describes that persistent non-improving muscle contractures require tendon lengthening. Conversely, Ilizarov (1989,1990) considered the best method to prevent soft tissue contractures was to improve the adaptation of the muscle and tendon by stretching and walking.

Functional weight bearing exercise is cited as an important feature of all treatment programmes for Ilizarov patients. Green (1990) states that physiotherapy is the key to a successful application of the Ilizarov method. Walking and functional loading are essential for ossification of the regenerate bone, and stretching and preserving range of motion are the keys to preventing contractures, subluxation and dislocations of the joints. He thinks that a natural rhythmic walking pattern is probably more important than the actual amount of weight on the limb at the beginning of the rehabilitation programme and that with time the patient must progressively increase the load on the limb (Green 1991).

Physiotherapy treatment continues throughout the period of distraction, the consolidation period and after the frame has been removed. The patient should avoid contact activities until the bone has formed complete cortex on all sides and a new marrow canal is apparent on x-ray views taken in multiple views (Green 1991).

The literature highlights the fact that use of the Ilizarov fixator is fraught with numerous difficulties including soft tissue complications. These complications present an enormous challenge to physiotherapists involved in the rehabilitation of the patients. There is little published material about the physiotherapy treatment of patients with the Ilizarov, no prospective studies in the area of Ilizarov rehabilitation and no papers published that cite evidence-based practice.

There is clearly a need to use the research process to gain the appropriate evidence that will enable an evidence-based approach to physiotherapy treatment to be implemented. Although descriptions of physiotherapy regimens in North America have been published (Simard et al 1992, Green 1990,1991, Coglianese et al 1993, Folkerts et al 1992), these do not reflect practice in this country due to differences in methods of funding and the allocation of health care resources. Clinical experience would suggest that a variety of approaches and regimes are used to rehabilitate Ilizarov patients. However, these regimes seem to be consultant led rather than based upon rehabilitation principles, and the most effective treatment regimen remains unclear.

3.5 Summary

- The literature on the complications of limb lengthening, effect on muscle and rehabilitation of patients after limb reconstruction surgery reports that, despite many advances in both the surgical and medical management of the patient, complication rates remain high.

- Many of the complications are due to difficulties of the soft tissues adapting to imposed changes of length as the bone is lengthened.

- The muscle undergoes both structural and functional adaptation to lengthening.

- There was a paucity of information about the rehabilitation of patients following limb reconstruction surgery, the only articles being descriptions of the regimes at different hospitals.

CHAPTER 4 – SURVEY OF U.K. PHYSIOTHERAPY PRACTICE

4.1 Introduction

UK physiotherapists are increasingly finding themselves treating patients with an Ilizarov fixator. Use has escalated over the last few years. In 1993 only 19 surgeons were performing the surgery at their hospitals, by 1999 this had risen to 86 surgeons in 73 hospitals (Graham 2000). In an attempt to examine the variation in practice in treating patients with the Ilizarov fixator and to determine standard treatment protocols, a nation-wide UK survey of physiotherapists was designed.

4.2 Purpose

The objective of this survey was to: -

- identify the current physiotherapeutic practice for patients treated with an Ilizarov fixator and to examine the variation in methods of treatment and difficulties experienced.
- to address the uncertainty that exists about the best methods of physiotherapy treatment for the rehabilitation of patients treated by the Ilizarov method.
- identify complications that were of particular interest to physiotherapists in their rehabilitation of these patients.
- establish a database of information on current Ilizarov treatment, which would be used later in the development of clinical guidelines.

4.3 Method

A questionnaire was designed consisting of open and closed questions. The closed questions sought to obtain numerical data about the numbers of physiotherapists who were familiar with the Ilizarov method, the numbers and types of patients seen and the degree of difficulty presented by specific problems that are likely to

be encountered. In some questions respondents were asked to grade their response utilising a rating scale (Oppenheim 1992, Fink & Kosecoff 1985). The open questions asked about subjects such as treatment objectives, methods of treatment and criteria for discharge. There was also space at the end of the questionnaire in which respondents were asked to add any other information about their experience of treating patients with the Ilizarov fixator that they felt was relevant. A copy of the questionnaire is enclosed in Appendix 1.

The questionnaire was pilot tested by 12 physiotherapists working at four NHS clinics. To establish internal validity, physiotherapists who completed the pilot questionnaire were asked to complete it for a second time, two weeks later. Subsequently minor changes were made to the questionnaire, mostly to the syntax used in some of the questions.

400 questionnaires were distributed by post using physiotherapists selected in two ways. First, a list of the centres that had purchased the most Ilizarov apparatus was obtained from the manufacturer, and the physiotherapy departments of these centres were sent a questionnaire. Second, members of three Special Interest Groups (SIGs) of the Chartered Society of Physiotherapy were mailed a questionnaire and a covering letter explaining the purpose of the study. The SIGs used were the Association of Orthopaedic Chartered Physiotherapists (AOCP), Association of Chartered Physiotherapists in Independent Hospitals (ACPIH) and the Association of Paediatric Chartered Physiotherapists (APCP). This sampling method was used as the aim was to sample physiotherapists who had experience of using the Ilizarov method, rather than to sample physiotherapists as a whole. The sample was intended to be representative of the range of physiotherapists likely to treat patients with an Ilizarov fixator. The letter asked the physiotherapist to complete and return the questionnaire or to designate the most appropriate person in their department to do so. They were informed that all information would be confidential. A self-addressed envelope was enclosed with the questionnaire for return to the audit department at St Peter's Hospital, Chertsey. The respondents were asked to return their questionnaire even if they had never treated a patient with an Ilizarov fixator in order to gain insight into how common it is for physiotherapists to treat this condition. If no response had been received after four weeks a reminder letter was sent.

4.4 Data analysis

The survey was exploratory, generating nominal level data, which was analysed using relative frequency tables (Fink 1985). Further analysis was performed using a method of content analysis in which responses were converted to relative frequencies and expressed as a percentage (Holsti 1969). The analysis examined possible differences between physiotherapists based at the specialist hospitals and those treating small numbers of patients with an Ilizarov fixator.

4.5 Results

Four hundred questionnaires were distributed and 274 returned, giving a response rate of 68.5%. Of these, only 28 % (n= 76) of the respondents indicated that they had treated a patient with an Ilizarov fixator. The remaining questionnaires were returned by physiotherapists who had no Ilizarov experience, all of whom had been sampled via the SIGs. Subsequent data analysis only included the 76 respondents who had experience of treating patients with the Ilizarov method.

4.5.1 Results from respondents with experience of the Ilizarov method.

In this sample 20 (26%) of the respondents worked in specialist centres, 26 (34%) had treated patients with Ilizarov fixators on both upper and lower limbs and 50 (66%) had only treated lower limb patients.

Physiotherapists treating these patients worked in a variety of settings; 31 (41%) were specialist orthopaedic physiotherapists, 19 (25%) paediatric, 13 (17%) community and 13 (17%) outpatient physiotherapists (Figure 4-1).

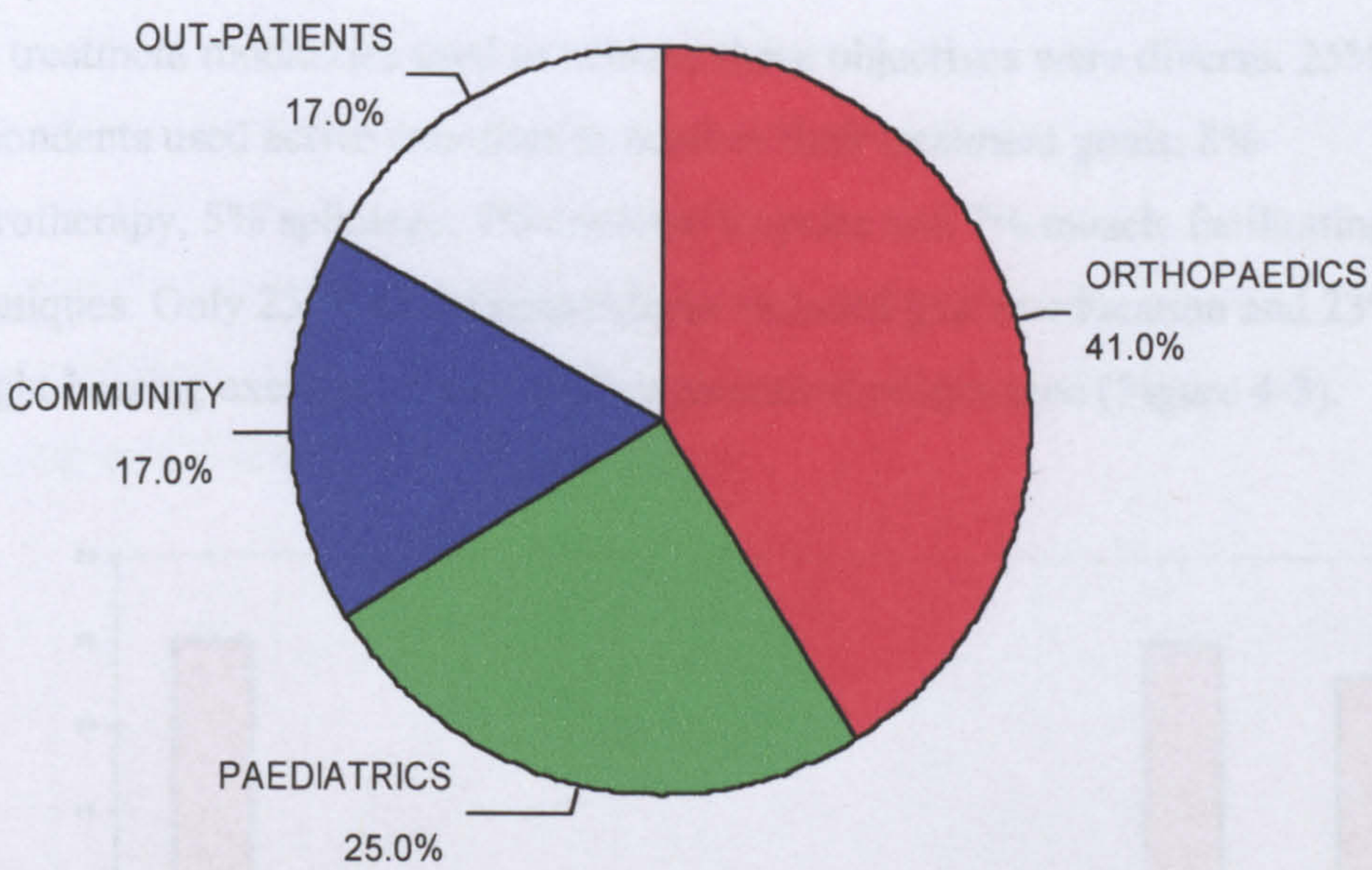


Figure 4-1: Working place of respondents

There was little agreement about the main objectives of treatment, with 35% of respondents listing their principal treatment objective as maintaining joint range of motion and 15% citing promoting weight bearing activity and functional use of the limb. Other objectives were pain control, increasing muscle strength, maintaining mobility and teaching independence in activities of daily living (Figure 4-2).

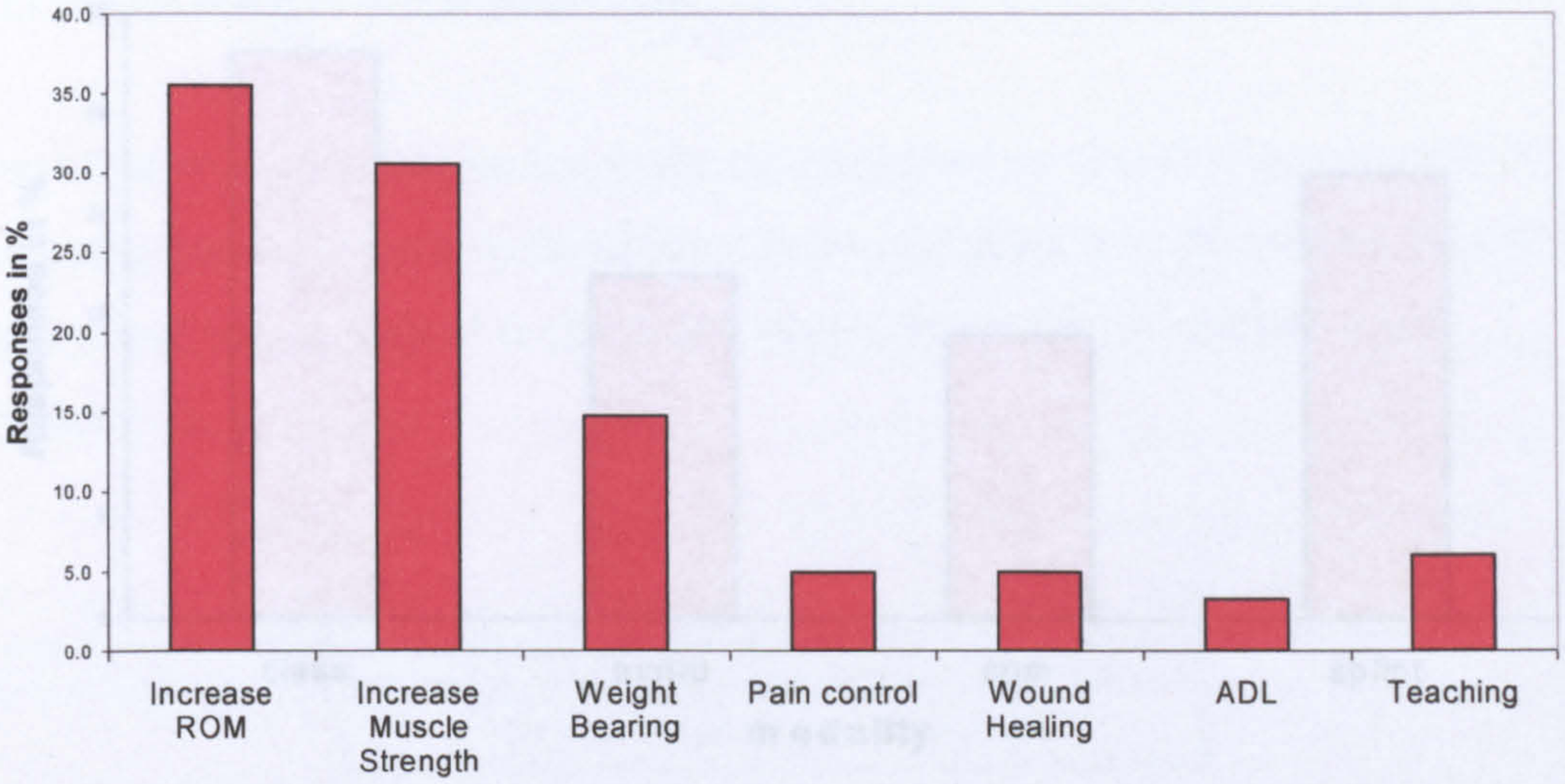


Figure 4-2: Main Treatment Objectives

The treatment modalities used to achieve these objectives were diverse. 25% of respondents used active exercises to achieve their treatment goals; 8% hydrotherapy, 5% splintage, 7% exercise bicycles and 7% muscle facilitating techniques. Only 25 % of the respondents included gait re-education and 23% weight bearing exercise as part of their treatment programme (Figure 4-3).

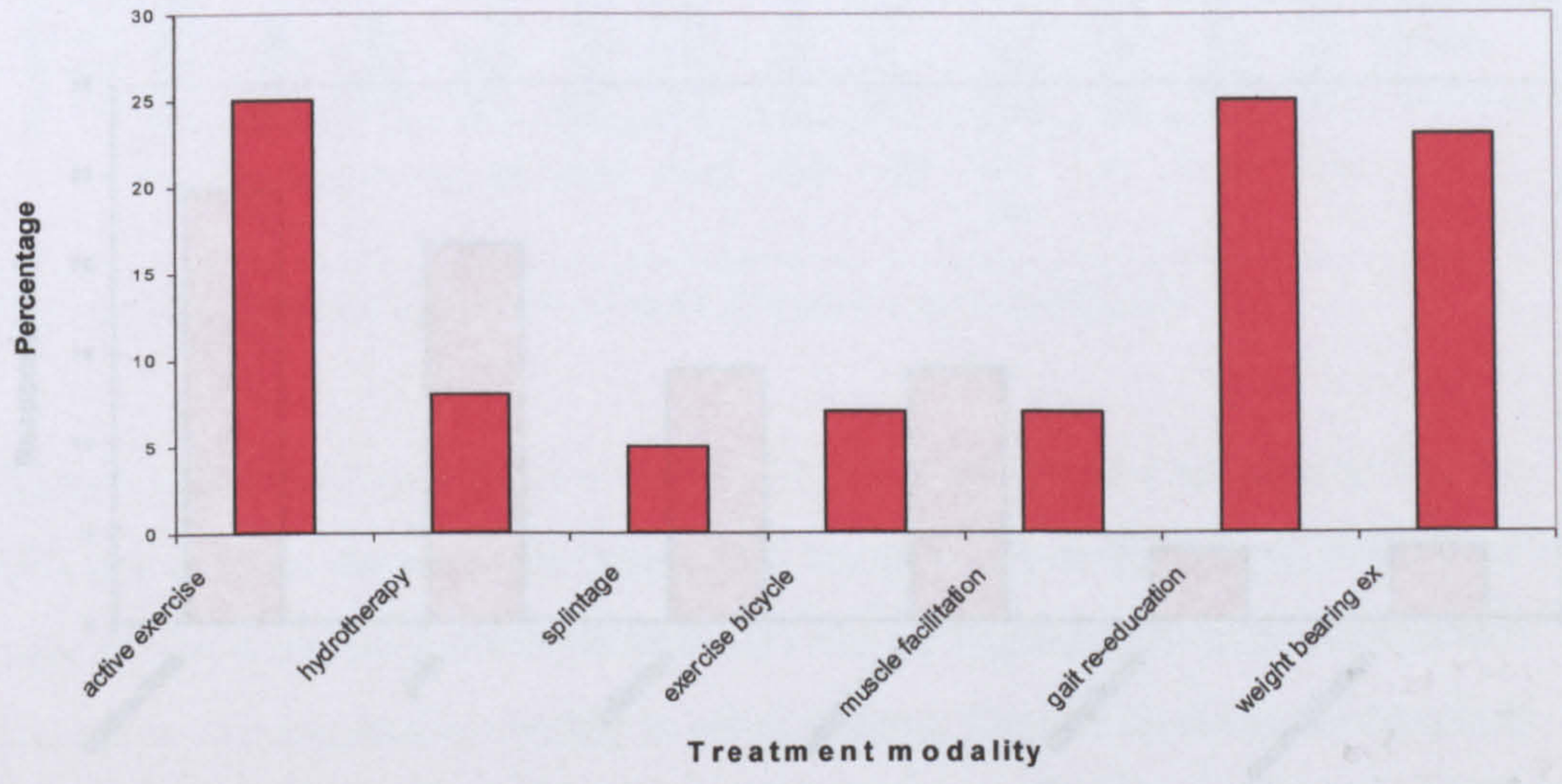


Figure 4-3: Treatment modalities used

In the centres where more than 50 patients a year were treated, 28% used a class or gym setting, 17% hydrotherapy, 14% continuous passive motion machines and 22% splintage (Figure 4-4).

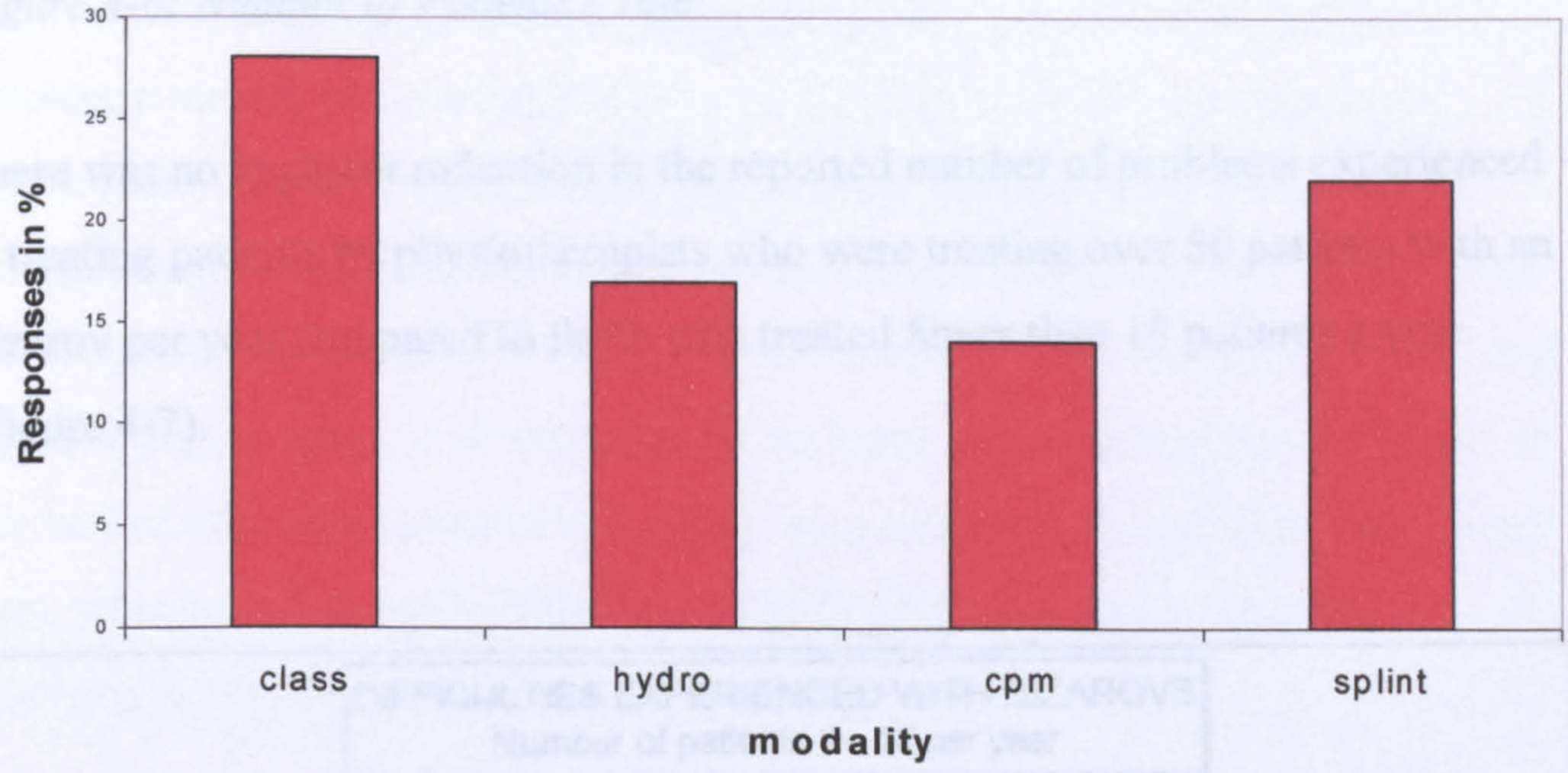


Figure 4-4: Modalities used in specialist centres

Despite the complex nature of the treatment required by this group of patients, only 53 (69%) of the respondents were working as part of a multidisciplinary team, defined as working in liaison with a surgeon and one other discipline e.g. nurse, occupational therapist, psychologist.

The main problems experienced were: soft tissue contractures reported by 24% of the respondents, pain 21%, infection 14%, weight bearing 14%, and patient compliance 4% (Figure 4-5).

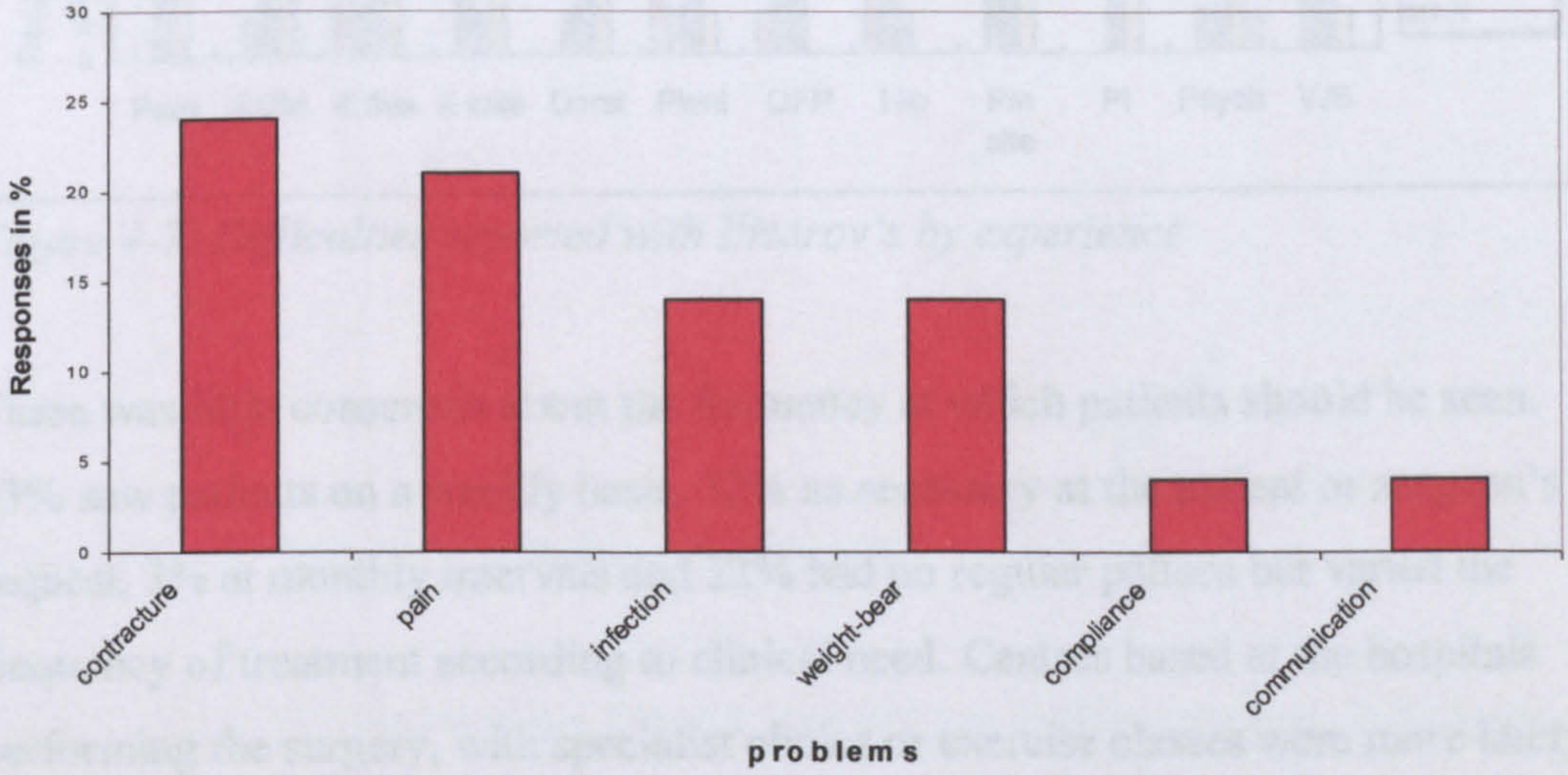


Figure 4-5: Problems experienced

Fifty-two (68%) of the physiotherapists treated fewer than 10 patients with an Ilizarov a year, 17 (22%), 10-50 patients per year and 7 (10%), more than 50 patients per year (Figure 4-6).

Figure 4-6: Number of Patients / Year

There was no apparent reduction in the reported number of problems experienced in treating patients by physiotherapists who were treating over 50 patients with an Ilizarov per year compared to those who treated fewer than 10 patients a year (Figure 4-7).

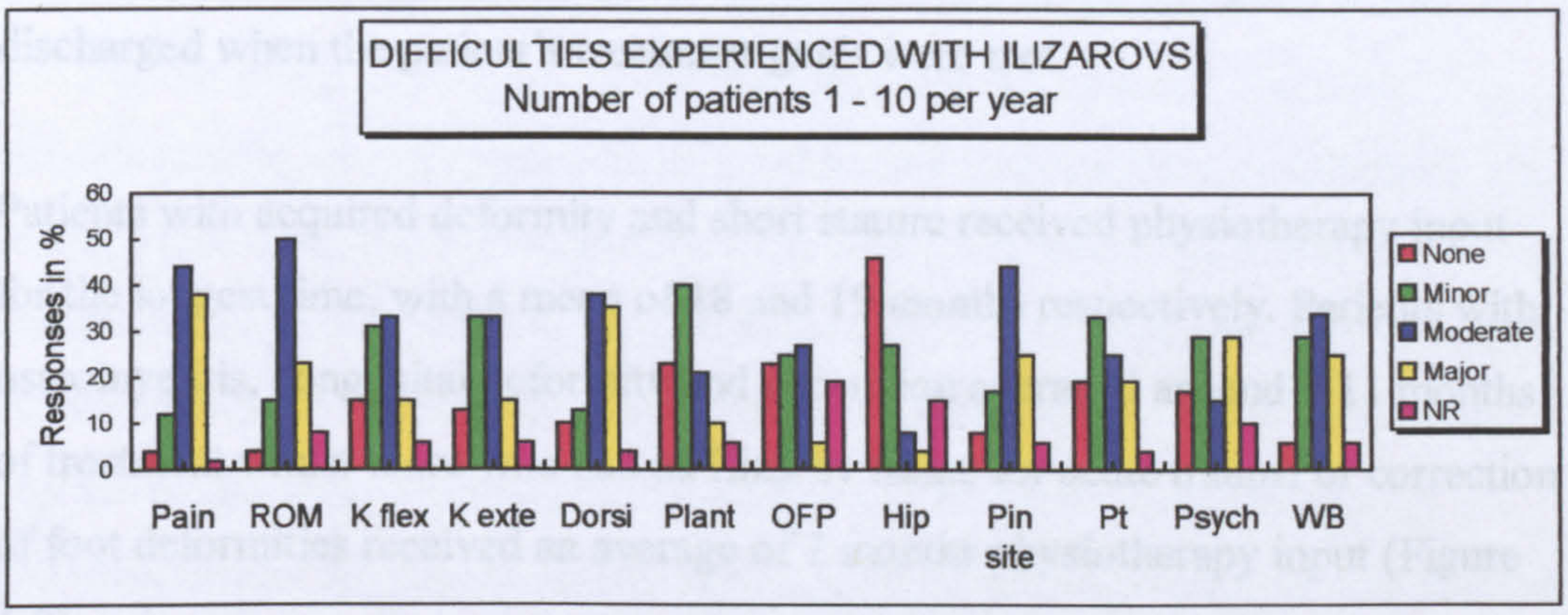


Figure 4-7: Difficulties reported with Ilizarov's by experience

There was little consensus about the frequency at which patients should be seen. 43% saw patients on a weekly basis, 32% as necessary at the patient or surgeon's request, 3% at monthly intervals and 22% had no regular pattern but varied the frequency of treatment according to clinical need. Centres based at the hospitals performing the surgery, with specialist clinics or exercise classes were more likely to see their patients on a weekly basis throughout the time period that they were wearing a fixator. Paediatric patients mostly received their treatment at a combination of community and hospital based physiotherapy services. However,

60% of those who received their physiotherapy in a school setting received no treatment outside of term time.

Again there was little agreement about the stated criteria for discharge from physiotherapy treatment. Thirty-five percent discharged patients when they were mobile, 8% when the patient had improved muscle strength and 8% at the time of frame removal. A range of other criteria included when the patient was happy, at the end of treatment (unspecified), when the patient was independent and when pain was controlled and wounds healed. Only 5% stated that the patient was discharged when the patient's treatment goals were met.

Patients with acquired deformity and short stature received physiotherapy input for the longest time, with a mean of 18 and 19 months respectively. Patients with osteomyelitis, congenital deformity and non-union averaged around 9-11 months of treatment whilst those who had an Ilizarov frame for acute trauma or correction of foot deformities received an average of 7 months physiotherapy input (Figure 4-8).

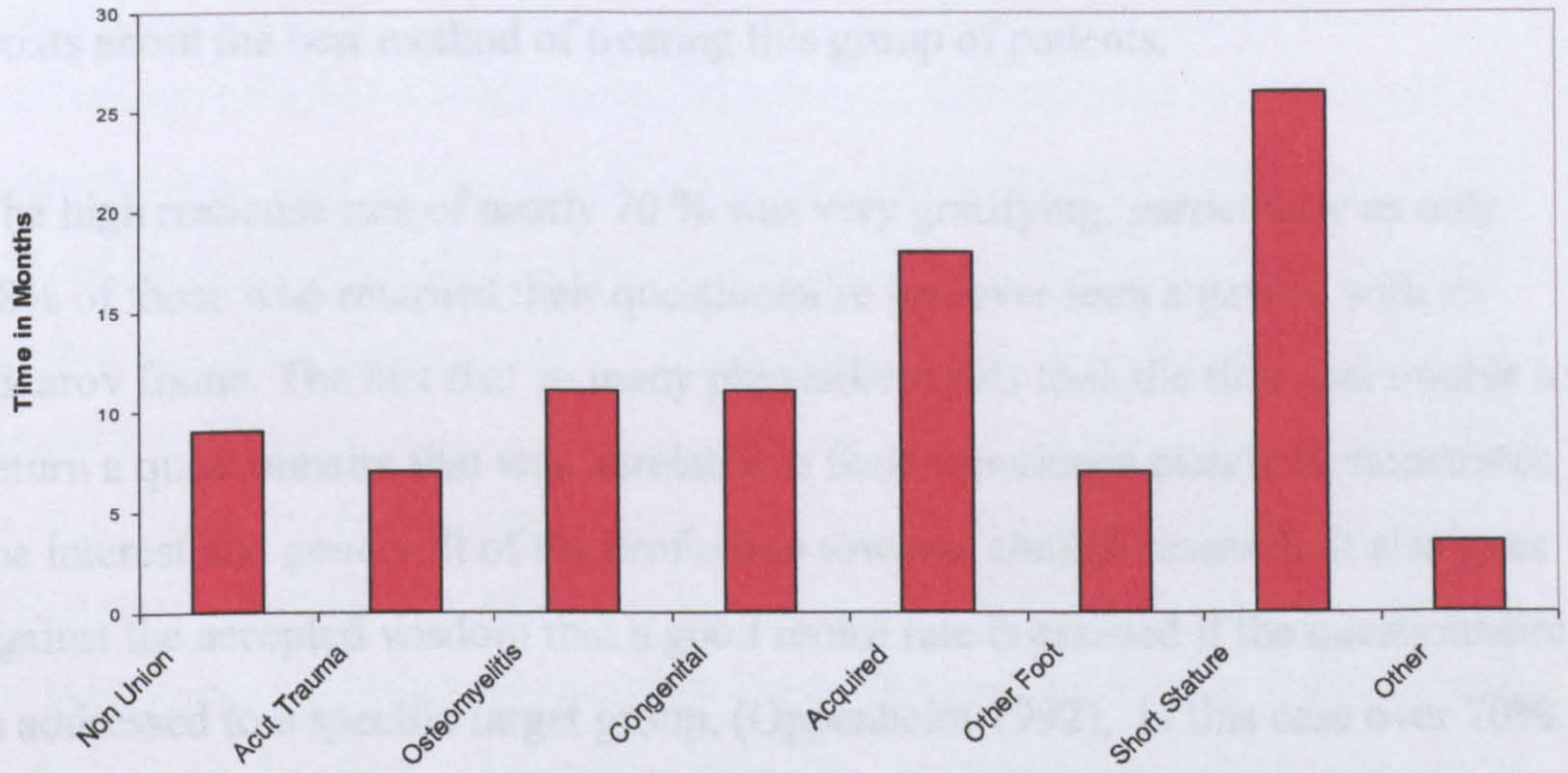


Figure 4-8 - Length of Treatment with Diagnosis

30% (n=23) of physiotherapists felt that they did not receive adequate information from the referring centre. 80% (n=60) felt that there was a need for more information and more clearly defined protocols of care for these patients. 11% (n=9) suggested that a clinical pathway for the treatment of patients with the Ilizarov should be developed. Additional comments reflected concerns in the areas of communication, clear leadership of the patient's care and ensuring patient

compliance. Others reported difficulties in persuading local services that out-patient treatment may be needed for many months, even after the frame was removed, particularly in days of limited resources and sometimes set time periods for patients to receive treatment.

4.6 Discussion

The survey emphasised the variety of treatment approaches that were utilised in treating this group of patients. Whilst the argument can be made that these patients require no more than normal good quality orthopaedic physiotherapy, the length of the treatment period and the likelihood of experiencing soft tissue complications make them a group that require special attention and further study. An assessment of the efficacy of treatment procedures is needed, as is research into the rehabilitation of this group of patients. The results from this survey demonstrate that the physiotherapy treatment of this group of patients was diverse and varied considerably in its quantity, focus and the modalities used. Uncertainty exists about the best method of treating this group of patients.

The high response rate of nearly 70 % was very gratifying, particularly as only 28% of those who returned their questionnaire had ever seen a patient with an Ilizarov frame. The fact that so many physiotherapists took the time and trouble to return a questionnaire that was unrelated to their experience clearly demonstrates the interest and good will of the profession towards clinical research. It also goes against the accepted wisdom that a good return rate is assisted if the questionnaire is addressed to a specific target group, (Oppenheim 1992), in this case over 70% of the respondents were outside the target group and yet a very acceptable response rate was achieved.

The majority of physiotherapists who returned the questionnaire who had experience of treating Ilizarov patients were orthopaedic physiotherapists, followed by paediatric, community and out-patient specialists. Whilst this is what would be expected from a predominantly orthopaedic procedure, the results may also have been influenced by the method used to distribute the questionnaires. The

targeting of the SIGs for orthopaedics and paediatrics may have ensured a disproportionately high return rate from these specialities as opposed to the physiotherapy population as a whole. This may have biased the results towards those treating more complex patients rather than those working in areas such as trauma.

The treatment objectives that were cited by the majority of the respondents were expected i.e. increasing joint range, muscle strength and mobility, but there was a number of people whose main treatment objectives were pain control, wound healing and promoting psychological acceptance of the frame. These were surprising as they reflect areas, which are more usually dealt with by members of other specialist groups such as nurses, rather than by physiotherapists. It is possible that this reflects the influence of working in multi-disciplinary teams.

There was a wide range of modalities used to achieve the treatment goals. The treatment methods used seemed to reflect the objectives of treatment cited, with an emphasis on active and passive exercises, gait re-education and muscle facilitating techniques. Other treatment methods utilised were ice therapy, hydrotherapy, exercise bike/pedals, continuous passive motion machines (CPM) and splinting. Interestingly, no-one reported using electrical stimulation, despite the fact that this is widely used by physiotherapists in both the United States of America and at the centre at Kurgan in Russia. There is also a good rationale for its' use, based on the work into electrical stimulation and sarcomere length of Williams et al (1986). In America neuromuscular electric stimulation is used in the post-operative period for muscle re-education and facilitation. Folkerts et al (1992) report that during femoral lengthening the quadriceps muscle appears to respond particularly well to electrical stimulation. In Russia the primary aim of electrotherapy is pain relief and a variety of electrical modalities are routinely used to achieve this goal.

The patients who were treated at centres where more than 50 patients per year were seen, received their treatment in a specialist exercise class or gym session. They were also more likely to be treated by methods such as hydrotherapy, CPM, splinting and footwear modifications than those treated in centres with fewer

patients. This possibly reflected the greater resources available in the specialist centres. Obviously, without a large number of referrals it is not an efficient use of the physiotherapists' time to organise a specialist class.

The class situation is similar to the treatment setting used at the large centres in Russia and the USA. In Kurgan patients receive much of their treatment in the class setting, spending many hours a day practising functional weight-bearing activities in the gymnasium. Outpatients at Mt Washington Pediatric Hospital, receive one hour of hydrotherapy and two hours of therapeutic exercise, functional activities and gait training, five days a week (Folkerts et al 1992). Other centres use a programme of one to two hours of treatment, three to five times a week complemented by a home exercise programme of one to two hours a day. The time devoted to out-patient physiotherapy in these American practices is much longer than can be provided by most out-patient departments in this country and reflects differences in funding, medical insurance and the way in which these complex orthopaedic procedures are costed.

A number of physiotherapists cited difficulties gaining access to the hydrotherapy pool for their patients due to either worries about hygiene or consultant preference. The prevalence of pin site infections around the wires makes many infection control advisors reluctant to allow patients with the Ilizarov fixator into the hydrotherapy pool. However, those departments who regularly use hydrotherapy for their patients with fixators report few problems with either pin sites or pool hygiene.

The main problems reported in treating patients with the Ilizarov were diverse. Some respondents cited predominantly physiotherapy-related problems such as joint contractures, lack of weight bearing and muscle weakness. The work of Ilizarov places much emphasis on the need for functional weight bearing as early in the post-operative period as possible. Patients have difficulty in weight bearing effectively due to the surgical procedure, pain and the physical constraints of the fixator. Insufficient weight-bearing and a lack of proprioceptive input compromise gait quality, thus activities that encourage weight bearing and weight-shifting in standing are encouraged. There are some surgeons who delay weight bearing activities until later in the rehabilitation period, believing that there is a greater likelihood of contractures developing if the patient bears weight through the limb.

In these cases attention is focused on maintenance of joint range and static muscle exercises rather than Ilizarov's more functional approach.
A significant number of respondents mentioned problems such as pin site infections, pain and patient compliance, reflecting the complex nature of managing these patients, where problems such as untreated pin site infections and poorly controlled pain can significantly impede the successful implementation of a physiotherapy programme. Interestingly, when the problems of pain and range of motion were rated for the difficulties that they presented, there was no marked difference between the responses of those who treated less than 10 Ilizarov patients a year and those who treated in excess of 50 patients per year. One might expect that the more experienced physiotherapists would have fewer problems due to having gained greater experience of treating these patients. However, it may be that the more experienced physiotherapists see a greater number of complex patients or they have greater insight into the range of problems that can occur in the management of these patients, and this might account for the high level of difficulties reported. It must also be remembered that experience does not necessarily correlate with expertise.

There was no consensus about the frequency of treatment. Whilst 40 % of physiotherapists treated patients on a weekly basis, 30 % only treated on a P.R.N. (as necessary) basis and the rest had no set criteria for the frequency of treatment provided. The patients who were seen by centres treating more than 50 patients a year were more likely to be seen every week, particularly if they were attending an out-patient exercise class. This again contrasts with the practice in other countries where treatment is more intensive, particularly in the out-patient period and daily treatment sessions of several hours are the norm. It was of interest that in the paediatric patients a number received their treatment from a physiotherapist based at the school, a service that was restricted to term time only. This potentially leaves patients with an extended period without treatment during school holidays and is a factor that should be considered when planning the timing of surgery on children.

Patients received physiotherapy treatment for an extended time period with an average treatment period of 6 months (0-24). Patients who underwent limb

reconstruction procedures with the Ilizarov for short stature, acquired deformity, congenital deformity and osteomyelitis received physiotherapy for the longest and those whose underlying pathology was foot deformity or acute trauma the shortest. The wide range of responses to the question about discharge criteria reflects the lack of a clear protocol of care or care pathway for this group of patients and the considerable variation that exists in physiotherapists treatment goals. It was disappointing that only 5% of the respondents linked the discharge of their patients to the achievement of pre-set treatment goals.

Finally, the survey did highlight the desire among the respondents for further information about the subject and the problems of feeling isolated and vulnerable when treating cases of such a complex nature. A number of respondents expressed the desire for better guidance on the rehabilitation of this group of patients. This was particularly noticeable amongst those physiotherapists treating less than 10 patients a year, 70% of whom requested further information.

4.7 Summary

The main purpose of the survey was to identify current rehabilitation protocols for patients with an Ilizarov fixator. It was found that:

- Few centres used a defined treatment protocol for their patients but preferred to treat them on an individual basis.

- The level of problems treating these patients was high, irrespective of where they were treated.

- The biggest problem faced by physiotherapists was in the management of progressive soft tissue contractures.

- 80% of physiotherapists felt that more information about the rehabilitation of patients with an Ilizarov fixator was needed and that clinical guidelines would be beneficial.

- There remains considerable uncertainty about the clinical management of patients receiving physiotherapy during treatment by the Ilizarov method.

CHAPTER 5 - PRODUCTION OF CLINICAL GUIDELINES.

5.1 Introduction

There is an increasing awareness of the need for clinical guidelines in order to ensure that health professionals practise in accordance with the best available research evidence. They are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field et al 1992). Thomas et al (1999) reviewed the use of clinical guidelines in nursing and professions allied to medicine as part of the Cochrane Collaboration and found that guideline-driven care can be effective in changing the process and outcome of care. Guidelines have been in existence since Hippocrates day, when aphorisms such as the familiar "the most desperate cases need the most desperate remedies" were used (Lloyd 1978). Ideally, clinical guidelines are evidence-based, the process starting with a precise definition of the clinical condition(s) to which they are to be applied. A systematic review of the published literature is undertaken and the strength of the evidence gathered and categorised into different levels depending on the quality of the studies. Thus more weight is given to evidence drawn from a well-designed randomised control trial than to that of an uncontrolled study or consensus (Baker 1997).

However, in areas where there are insufficient clinically controlled trials and published information is inadequate or non-existent, the information is often best synthesised by a consensus method. This provides a means of harnessing the insights of appropriate experts to produce guidelines based upon the extent to which experts agree about an issue (Jones & Hunter 1995).

The consensus methods that are most commonly used are the consensus development conference, the expert panel and the Delphi process. The method using a consensus development conference requires extensive resources and is usually used in large, nationally funded programmes (Perry 1987). Expert panels use a highly structured meeting to gather information from a small number of experts about a given issue. The meeting is facilitated by a credible expert, or neutral non-expert, who ensures that each participant contributes one idea about the topic under discussion. The group then discusses and ranks each idea, the

results are summarised and the expert panel discuss and re-rank in light of the discussion. This method has been used extensively in health care research (Lemmer 1998, Scott & Black 1991). The method can be dominated by one or more participants, but this can be avoided by appropriate intervention by the chairperson. It requires that all experts be able to attend one or more meetings and thus may be expensive in terms of time and resources.

The Delphi process takes its name from Greek mythology. Apollo, the God of light and rationality, acquired sanctuary at the temple complex at Delphi after slaying the Python monster. The resident priestess, or oracle at the temple, Pythia, made prophecies about the future and was famous for her skills of interpretation and foresight (Everett 1993, Sumsion 1998).

The classic Delphi technique is used for canvassing opinion and for structured decision-making and forecasting. It is a multiple iterative survey technique that enables anonymous, systematic refinement of expert opinion with the aim of arriving at a combined or consensual position (Helmer 1967). Bowles (1999) and Jones & Hunter (1995) suggest that the Delphi technique is likely to be most relevant to aspects of medical practice which are poorly supported by other research findings. The Delphi technique is widely used in nursing and allied health fields. It has been cited in at least 1,000 published research papers and in over 300 projects in the nursing and allied health literature in the last 15 years (McKenna 1994, Bowles 1999). It has previously been used to produce physiotherapy treatment programmes (Enloe et al 1996).

The Delphi technique uses a postal questionnaire and was chosen as the main method to produce the guidelines for the physiotherapy treatment of the Ilizarov patient. The information gained by this method was subsequently developed using a meeting of an expert panel.

5.2 Purpose

5.2.1 The Need For Guidelines

The survey of current physiotherapy practice reported in Chapter 4 showed considerable variation in the physiotherapy management of patients with an Ilizarov fixator and suggested the need for guidelines for the physiotherapy management of these patients (Barker et al 1999). The guidelines are particularly aimed at assisting the physiotherapist, working away from the major limb reconstruction centres, who has little experience of treating this group of patients. This decision was made as the survey showed that physiotherapists treating less than 10 patients/ year were most likely to request further information about the physiotherapy management of patients.

5.2.2 Objectives of the guidelines

- To provide a comprehensive clinical guideline document with recommendations about the physiotherapy treatment of patients with an Ilizarov external fixator, that would represent the "standard" management of this patient group.

- They should encompass the wide variety of patients and conditions treated by the Ilizarov fixator, adults and paediatrics, trauma and elective surgery.

- They should apply to frames on the lower limb and humerus.

- They should provide physiotherapists with a starting point for the treatment of these patients, but are not intended to be exhaustive or prescriptive.

- Where it exists the guidelines should provide evidence to support the recommended guidelines for practice.

- To clarify the uncertainties that exist about the best physiotherapy management of patients.

5.3 Method

5.3.1 Clinical Guideline Steering Group

A group was brought together to reflect the expert opinion required to prepare these guidelines. The guideline steering group consisted of two physiotherapists, two consultant orthopaedic surgeons and a member of a clinical audit department. The physiotherapists were experienced in the use of the Ilizarov fixator and were members of the AOCP (Association of Orthopaedic Chartered Physiotherapists), the surgeons were members of the BLRS (British Limb Reconstruction Society), an affiliated society of the British Orthopaedic Association. The role of the steering group was to decide the subject for study and to frame the questions for the first questionnaire and to decide when sufficient information had been elicited to form the guidelines.

The survey data reported in Chapter 4 was used as the method of selecting physiotherapists to form the group of experts to participate in the Delphi process (Barker et al 1999). Those physiotherapists who had responded that they treated more than 50 patients per year were invited to participate as group members.

5.3.2 Expert Group Membership

The expert group membership was made up of experienced clinicians from the major centres carrying out limb reconstruction surgery in the United Kingdom. The interpretation of the term expert has been subject to considerable variation (Walker & Selfe 1996) and the question of how an expert is defined is largely unresolved (McKenna 1994). Beech (1999) defines experts as individuals with knowledge of a particular area. In this research the steering group defined experts as those treating more than 50 patients with the Ilizarov per year for more than 2 years. It was felt that this definition would ensure that experts had sufficient breadth and depth of experience to make a valuable contribution to the group and would not be swayed by impressions gained from specific individual cases. Specialists in the areas of paediatrics, adults, trauma and specialist elective surgery were included. The group number was set at 12, reflecting the number of physiotherapists who were considered to have treated enough patients on a regular

basis to have developed the necessary expertise. Where several physiotherapists from one centre had the necessary expertise only one representative from a centre was included, in order that the panel would not be weighted towards any one centre. However, that centre could produce their responses to the questionnaires using information from other physiotherapists in the centre. Members of the steering group were not included in the expert group.

5.3.3 Development of the guidelines – process.

In order to investigate how much information about the physiotherapy management was in the public domain a review of relevant literature was conducted. This used the databases EMBASE, CINAHL, MEDLINE and the Cochrane Library. The search strategy used the keywords *Ilizarov* in conjunction with *rehabilitation, physiotherapy, physical therapy* and *clinical guidelines.* Evidence from 1980 - August 1999 was considered, earlier papers were not considered as little Ilizarov surgery occurred in the U.K. prior to this date. Any relevant literature identified by the search was read by the steering group and weighted for the strength of its evidence base (Guyatt et al 1995) using the following levels:-

I Systematic review and randomised controlled trial

II Clinical trial and or observational paper

III Respected, expert opinion by consensus method.

No systematic reviews or RCTs were found and only one observational paper (Herzenberg et al 1994). Five papers were found that anecdotally described physiotherapy treatment of patients with the Ilizarov technique (Simard et al 1992, Coglianese et al 1993, Folkerts et al 1992, Green 1990,1991). The paper by Herzenberg et al (1994) was graded as level II, the others were rejected as not reaching the required standard of evidence. The information contained in the Herzenberg paper was incorporated into the guidelines.

Therefore, a Delphi survey was performed using the experts identified from the survey to form the consensus panel. It used a postal questionnaire to elicit and refine expert opinion in a systematic manner.

A plan of the study design is shown in Figure 5-1.

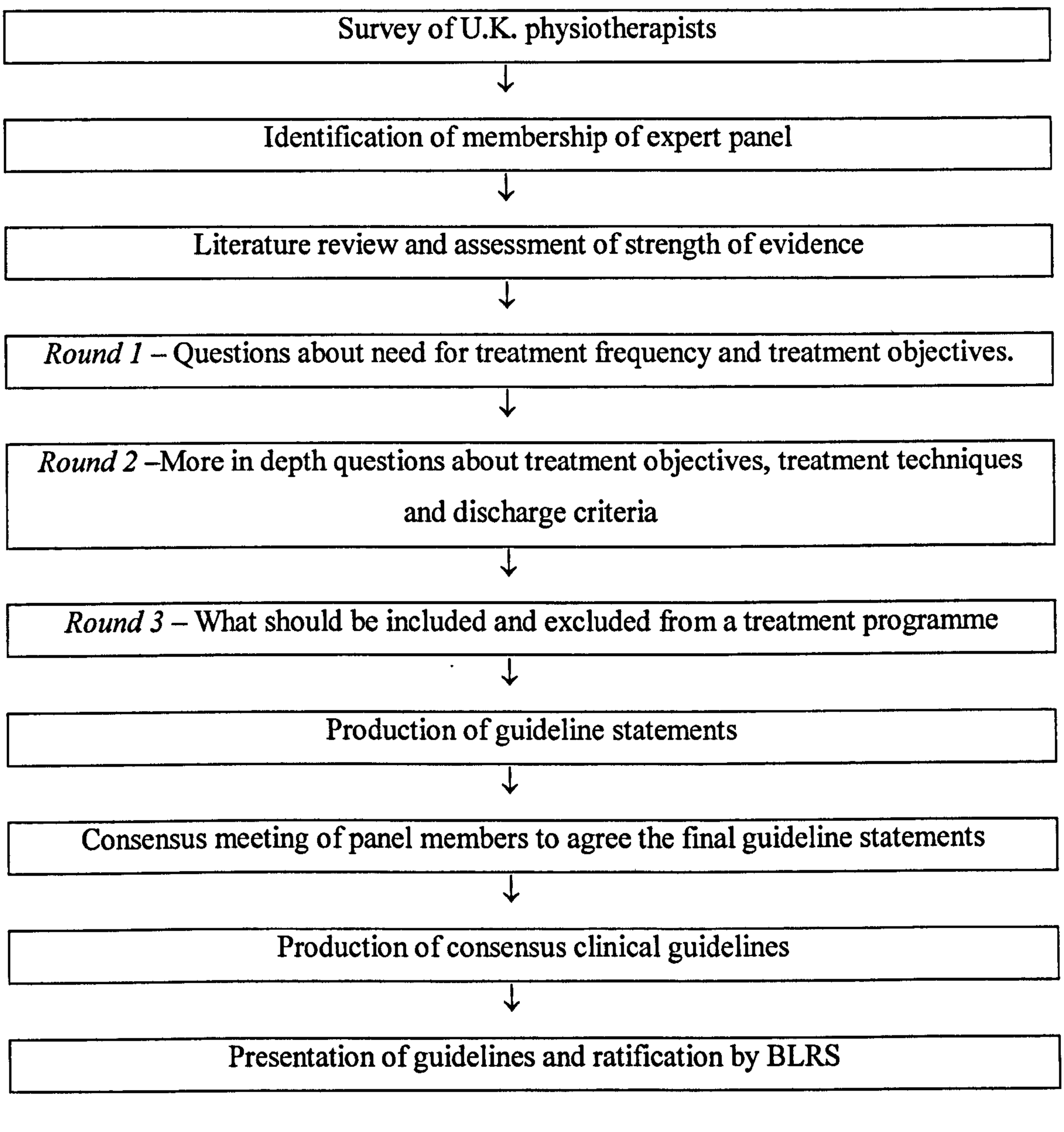


Figure 5-1: Plan of method

Participants were asked to give an answer to the questions that was applicable to the fixator used in all of its common methods, (adult and paediatric, elective and trauma), rather than focussing on their own particular area of clinical expertise. They were also asked to respond, ignoring confounding factors such as staffing

levels or consultant-mandated protocols, in order to produce what they felt was an ideal, but realistic, treatment programme.

The first round questionnaire was written by the steering group and asked broad open-ended questions about the need for physiotherapy intervention, the frequency of treatment and treatment objectives that participants believed should be used when treating patients with an Ilizarov fixator. Participants were invited to add any additional suggestions or comments that they felt were important. The questionnaires are contained in Appendix 2, 3 & 4.

Following Round 1, the steering group summarised the participants' responses and if 80% of the experts mentioned an item it was included in the draft guidelines. There is no standard threshold for consensus (Walker & Selfe 1996). Enloe et al (1996) set their threshold at 50%, Boyce et al (1993) at 66% and Williams & Webb (1994) at 70%. The study by Enloe et al (1996) was the most similar in subject matter to the current study. They found 80% consensus for treatment categories in developing their treatment programmes. Accordingly a consensus level of 80% was chosen for this study. If consensus did not reach 80% but exceeded 50%, the topic was explored further in the next round. The level of 50% for further exploration was selected based on the reports of Enloe (1996) and Williams & Webb (1994).

The subsequent rounds built on the response from the previous rounds and explored issues in more depth and refined the opinions elicited. Round 2 fed back the group responses from Round 1 and explored in greater depth the treatment objectives and treatment techniques as well as looking at discharge criteria. Round 3 fed back the responses from the previous round and concentrated on what the basic essential elements were that should be included in a physiotherapy programme at the pre-operative, in-patient, out-patient and post frame removal stages of treatment.

At each stage the criteria for inclusion was set at 80% agreement.

After 3 rounds of questionnaires the issues that the steering group felt were relevant had been explored. Draft statements for inclusion in the guidelines were formulated and a draft copy of the guidelines produced. All panel members were

invited to a consensus meeting at which each member individually voted on their level of agreement with each statement. Each member completed a 9-point linear rating scale to indicate their level of agreement with each statement. 9 indicated complete agreement, 1 indicated complete disagreement (Figure 5-2). A 9-point scale was chosen as some authors have suggested that this best reflects the strength of agreement (Jones & Hunter 1995).

Figure 5-2: 9 point linear rating scale

5.4 Results

In Rounds 1,2,and 3 all the participants returned their questionnaires. For the consensus meeting 9 out of the original 12 attended and the others completed their agreement with the statements by post.

The results of the questionnaires have been summated and tabulated to show both the agreed text for the guidelines and the level of agreement that existed for that statement. Two levels of agreement were calculated, firstly, how strongly the panel agreed with the guideline statements and secondly, how strongly the panel agreed with each other that a statement should be included in the final guideline document. The mean and median score for each statement was calculated to give an indication of how strongly the panel members agreed with each of the guideline statements. The level of agreement between panel members was shown by the measures of dispersion using standard deviation (Jones et al 1992). The level of agreement calculated by Kappa was also used to provide a measure of dispersion and to show the level of certainty about how strongly the panel as a whole agreed with the inclusion of a guideline statement (Siegel & Castellan 1988, Fleiss 1981, Haley & Osberg 1989).

At the panel meeting if a median score of at least 5 was not reached the item was excluded from the guidelines, items that exceeded this were formulated into guidelines ordered according to the stage of treatment.

5.4.1 (A) Pre-operative Phase

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
1	All patients with an Ilizarov fixator should receive physiotherapy treatment	9	9	0	1	III
2	All patients should be seen pre-operatively	8.9	9	0.3	.82	III
3	Patients should be taught a pre-operative stretching programme	7.3	8	1.7	.52	III
4	Patients where a femoral frame is planned should routinely be taught how to stretch the following muscle groups, in order of priority :-					
	Quadriceps	8.8	9	0.4	.82	III
	Hamstrings	8.5	9	0.7	.46	
	Hip flexors	8.8	9	0.4	.52	
	Tensor Fascia Lata / iliotibial band	8.4	9	1.8	.38	
	Hip Adductors	8.6	9	0.7	.52	
5	Patients where a tibial frame is planned should routinely be taught how to stretch the following muscle groups , in order of priority :-					
	Gastrocnemius / Soleus	9	9	0	1	
	Toe Flexors	7.6	9	2.8	.46	III
	Hamstrings	7.4	9	2.3	.47	
	Tibialis Posterior	7.9	9	2.3	.52	
	Tibialis Anterior	6.1	7	3.3	.29	
	Quadriceps	6.3	7	3.0	.29	
6	Patients where a combined femoral and tibial frame is planned should be taught to stretch all of the above.	8.6	9	0.7	1	III

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
7	Patients where an upper limb frame (humeral) is planned should routinely be taught to stretch the following muscle groups, in order of priority :-					
	Biceps	8.1	9	1.4	.46	III
	Triceps	7.9	9	1.8	.38	
	Shoulder Rotators	6.3	7	2.4	.47	
	Wrist Extensors	6.5	8	3.4	.52	

5.4.2 (B) In –Patient Phase

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
1	Treatment should start on the first post-operative day	8.4	9	1.3	.69	III
2	Treatment sessions should be twice daily	8.2	9	1.1	.37	II
3	The objectives of treatment are :-					
	Maintain joint range of motion	8.8	9	0.6	.83	
	Maintain muscle power	9	9	0	1	
	Maintain muscle length	8.8	9	0.9	1	
	Maintain functional independence	9	9	0	1	
	Minimise contractures	9	9	0	1	III
	Ensure adequate analgesia is given prior to treatment	9	9	0	1	
	Be aware of psychological problems and provide appropriate support	9	9	0	1	
	Educate patients / carers in a home exercise programme	9	9	0	1	
	Educate patients / carers about importance and correct use of splints.	9	9	0	1	
4	The following most commonly used techniques should be used :-					
	Active ROM exercises	8.3	9	2.6	1	
	Active assisted ROM exercises	7.2	9	3.5	.69	
	Passive ROM exercises	7.4	9	3.5	.83	
	Weight Bearing exercises	7.4	9	3.5	.83	III
	Gait re-education	9	9	0	1	
	Soft tissue stretches	7.5	9	3.5	1	
	Hydrotherapy	6.4	8	3.2	.45	
	Proprioceptive Neuromuscular Facilitation (PNF)	5.3	5	3.4	.38	

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
5	In the latent phase prior to frame adjustment patients should be taught ROM and strengthening exercises and continue with a stretching programme	8.8	9	0.4	.83	III
6	Prior to their discharge from hospital the patient should be able to carry out the following activities:-					
	Transfer safely from bed to standing	9	9	0	1	
	Transfer safely from sitting to standing	9	9	0	1	
	Mobilise with an appropriate aid	6.9	9	2.8	.70	III
	Weight bear as appropriate for the individuals condition	8.5	9	1.5	.60	
	Go safely up and down stairs	9	9	0	1	
	Have reasonable amount of ROM	9	9	0	.60	
	Correctly apply appropriate splintage	9	9	0	1	
	Understand home exercise programme and the need for any out-patient treatment					
	Know how to adjust / maintain frame	9	9	0	1	
	Know how to perform pin site care	9	9	0	1	III
	Understand the need for functional use of the limb	8.8	9	0.4	1	
		9	9	0	.70	

5.4.3 (C) EXERCISES

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
1	Patients with a femoral frame should routinely be taught ROM exercises for :-					
	Knee extension	8.6	9	0.9	.83	
	Hip extension	8.9	9	0.3	.83	
	Knee flexion	8.8	9	0.4	.70	III
	Hip abduction	8.6	9	0.8	.56	
	Hip flexion	8.9	9	0.3	.59	
2	Patients with a femoral frame should routinely be taught the following strengthening exercises:-					
	Hip extensors	8.7	9	0.7	.60	
	Hip abductors	8.6	9	0.7	.51	
	Quadriceps	8.8	9	0.4	.70	III
	Hamstrings	8.8	9	0.5	.60	
	Back Extensors	6.5	7	2.7	.31	
	Abdominals	6.7	7.5	2.7	.29	
3	Patients with a tibial frame should routinely be taught ROM exercises for:-					
	Knee extension	9	9	0	1	
	Ankle dorsiflexion	8.8	9	0.4	1	
	Knee flexion	9	9	0	.83	III
	Toe flexion	8.5	9	1	.60	
	Ankle plantarflexion	8.5	9	1	.60	
	Toe extension	9	9	0	.47	

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
4	Patients with a tibial frame should routinely be taught strengthening exercises for the following groups:-					
	Ankle dorsiflexors	8.8	9	0.6	.83	III
	Quadriceps	8.1	9	1.4	.83	
	Hamstrings	8.9	9	0.3	.83	
	Tibialis Anterior	8.2	9	2.6	.38	
5	Patients with a combined femoral and tibial frame should perform all of the above exercises	8.8	9	0.6	.83	III
6	Patients with an upper limb (humeral) frame should routinely be taught ROM exercises for :-					
	Elbow extension	8.8	9	0.5	.70	III
	Elbow flexion	8.3	9	0.9	.60	
	Shoulder (Gleno-humeral and Scapulo-thoracic) joints	8.6	9	0.7	.60	III
	Radio-ulnar joints	8.8	9	0.60	.56	
	Cervical spine	8.7	9	.7	.44	
7	Patients with an upper limb (humeral) frame should routinely be taught strengthening exercises for the following groups:-					
	Elbow extensors	8.5	9	1.2	.83	
	Elbow flexors	8.6	9	1.2	.68	
	Pronators	8.5	9	0.9	.60	III
	Supinators	8.2	9	1.3	.45	
	Shoulder abductors	8.5	9	1.2	.60	
	Shoulder extensors	8.5	9	1.2	.56	
	Shoulder girdle musculature	8.6	9	1.2	.21	

5.4.4 (D) Out-Patient Phase

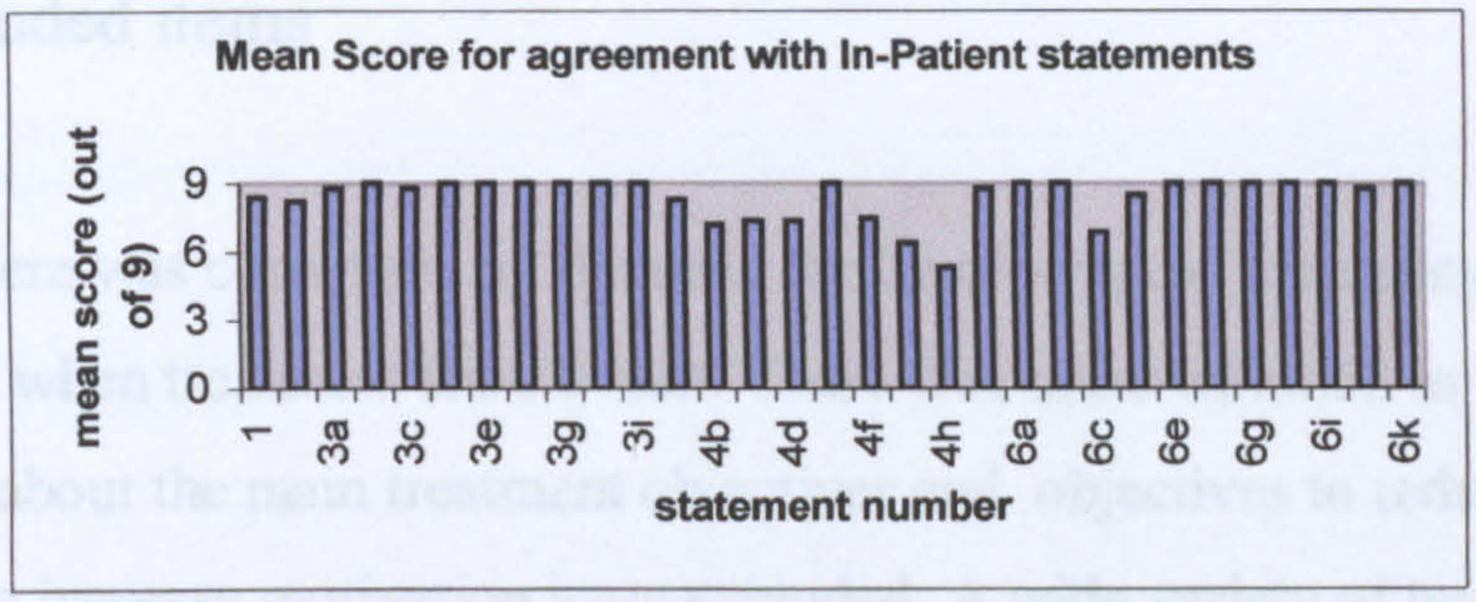
	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
1	During the period of frame adjustment / lengthening all patients should receive out-patient physiotherapy	8.7	9	0.9	.83	III
2	Out-patient treatment should start within 5 days of the patients' discharge from hospital	7.7	8	1.7	.83	III
3	During the period of frame adjustment many problems may begin to occur, frequent monitoring is needed and treatment may need to be increased	8.8	9	0.5	.60	III
4	The following problems will require an increase in the frequency of out-patient treatment :-					
	Moderate / major loss of ROM	9	9	0	1	
	Difficulty in weight bearing	8.9	9	0.3	1	III
	Increase in soft tissue tension	9	9	0	1	
	Poor compliance with out-patient physiotherapy / home exercise programme	8.9	9	0.3	.83	

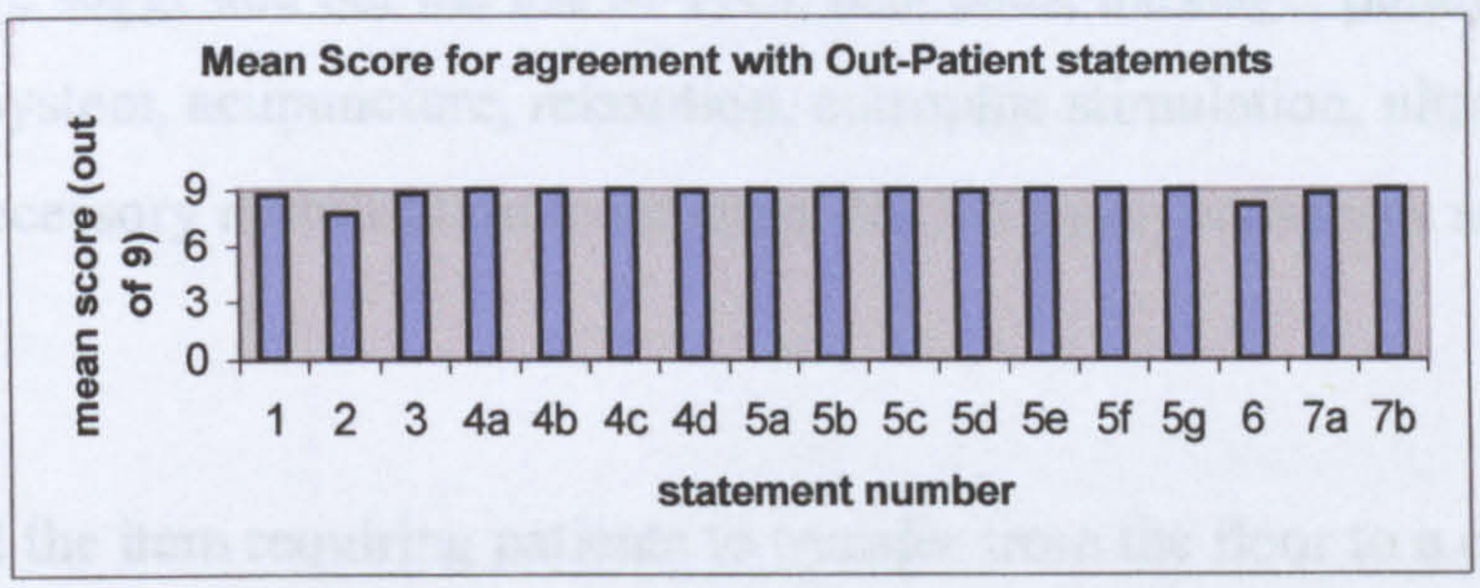
	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
5	The following problems should be looked for and will require referral back to the referring centre:-					
	Joint subluxation	9	9	0	1	
	Loss of sensation	9	9	0	1	
	Loss of EHL	9	9	0	1	
	Neurogenic pain	8.9	9	0.3	1	III
	Pin / wire breakage or problems with the frame	9	9	0	1	
	Sudden increase in pain on weight bearing	9	9	0	1	
	Severe pin site infection	9	9	0	.83	
6	Loss of range of motion is common during the period of frame adjustment	8.2	9	1.8	.56	II
7	During the period of frame adjustment optimum functional abilities should be encouraged using weight bearing activities and gait re-education.	8.8	9	0.4	.71	III
	Functional use of the upper limb should be encouraged	9	9	0	1	

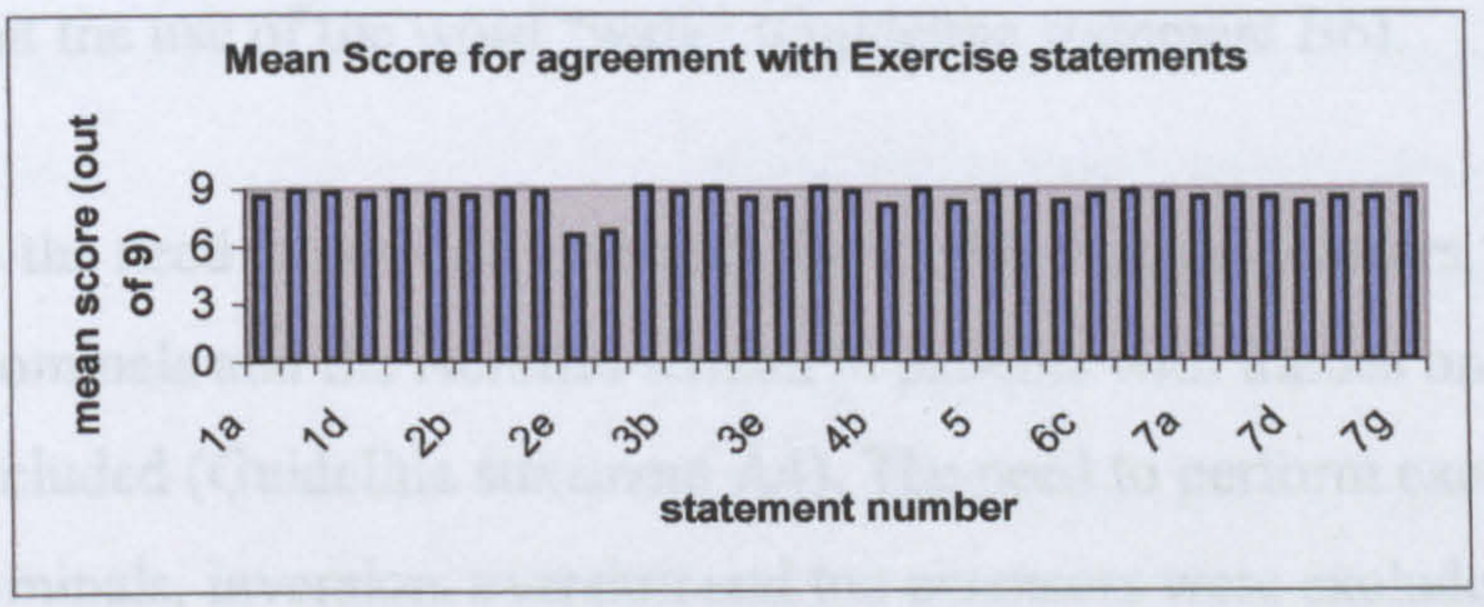
5.4.5 (E) Consolidation Phase / Post frame removal

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
1	During the consolidation phase the emphasis of treatment is on regaining any loss of range of movement and increasing functional activities. In the lower limb weight bearing should be maximised	8.9	9	0.3	1	III
2	During the consolidation phase of treatment patients should continue with progressive strengthening exercises using resistance, body weight and functional activities	9	9	0	1	II
3	During the consolidation phase activities should focus on the following areas :-					
	Lower limb					
	Full weight bearing activities	9	9	0	1	
	Single stance activities	9	9	0	1	
	Proprioception	9	9	0	1	
	Sport	8.8	9	0.5	.70	III
	Cardio-vascular fitness	8.9	9	0.5	.83	
	Increasing endurance	8.9	9	0.4	.83	
	Upper limb					
	Functional activities	9	9	0	1	
	Full use of arm	8.9	9	0.3	.83	
	Throwing and catching	8.9	9	0.3	.83	III
	Fine dexterity	9	9	0	1	
4	Treatment in a class or group setting is desirable where possible, but not essential	8.2	9	1.6	.65	III

	Guideline Statement	***Mean***	***Median***	***SD***	***Kappa***	***Type of evidence***
5	Patients should not be discharged until the following criteria have been fulfilled:-					
	Maximal ROM has been achieved	9	9	0	.83	
	Maximal weight bearing is occurring	9	9	0	.83	III
	Maximal function has been attained	9	9	0	.70	
	Optimal gait has been achieved	9	9	0	.83	
6	Great care should be taken after frame removal as the regenerate bone or fracture site is at risk from deforming forces and there is the potential for fracture.	9	9	0	1	II
	Advice should be sought from the referring centre about each individual case and the strength of union / risk of fracture.	9	9	0	1	







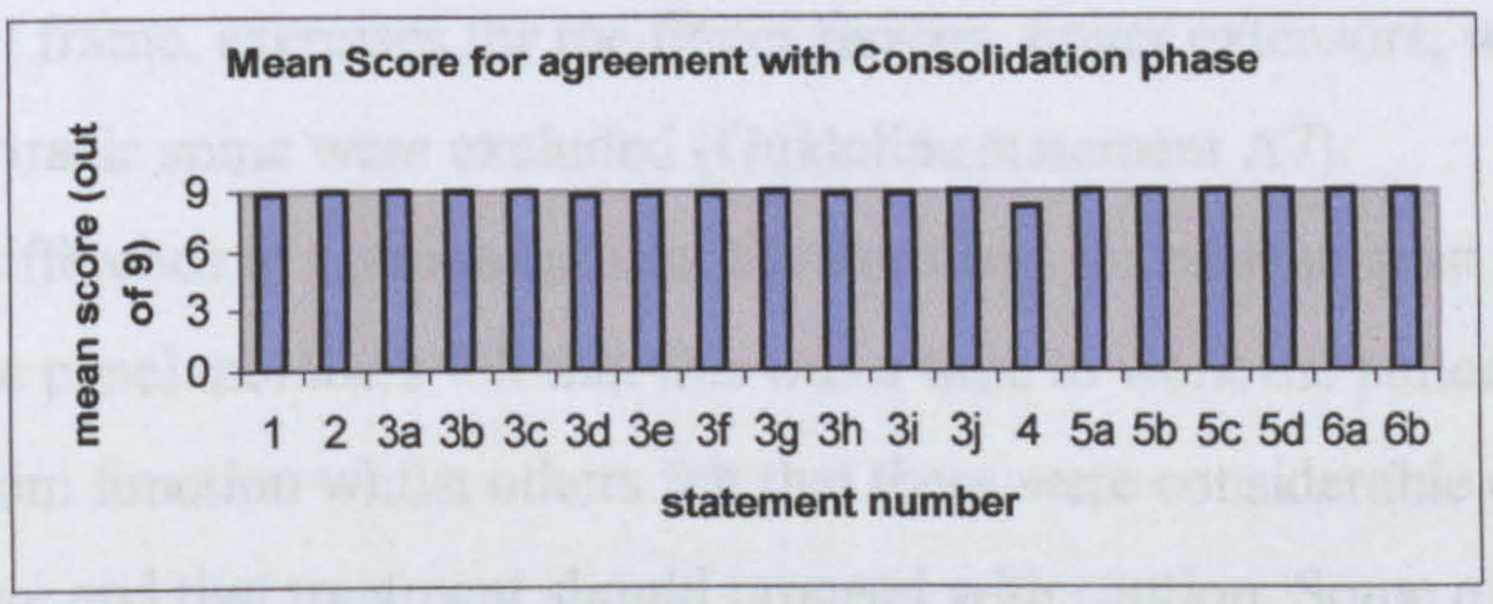


Figure 5-3: Mean Agreement with guideline statements

5.4.6 Excluded items

In Round 1 there was consensus on the need for treatment, the frequency of treatment and when treatment should start. There was some variation in the panels' ideas about the main treatment objectives and objectives to reduce oedema and to increase motivation were excluded. A wide variety of treatment modalities were suggested but the use of TNS, heat pads, massage, pulleys, slings, A-V impulse system, acupuncture, relaxation, eutrophic stimulation, ultrasound, weights and accessory mobilisation techniques did not reach consensus and were excluded.

From Round 2 the item requiring patients to transfer from the floor to a chair prior to discharge was excluded and the wording for going up and down stairs was changed to omit the use of the word "walk" (Guideline statement B6).

From Round 3 the need to perform exercises for the hip internal rotators, back extensors, abdominals and the Achilles tendon in patients with frames on the femur were excluded (Guideline statement A4). The need to perform exercises for the back, abdominals, inversion, eversion and toe extensors were excluded for patients undergoing treatment of the tibia (Guideline statement A5). For patients with a humeral frame, exercises for the finger flexors, finger extensors, wrist flexors and thoracic spine were excluded (Guideline statement A7).
The greatest difference in opinion came at the exercises for patients post frame removal. Some panel members felt that this was a time to work the patient hard to regain maximum function whilst others felt that there were considerable dangers of early fracture and that treatment should proceed with caution. Some of the panel members were worried that the guidelines were too prescriptive and wanted to add an introduction to state that the guidelines were not intended to be exhaustive and that other treatment modalities beyond those suggested might be appropriate. There was also a wish for a statement advising that the guidelines should be adapted to the differing clinical needs of each individual patient and were intended as a starting point only. This was included in the final version of

the guidelines. The main areas of uncertainty where the consensus of the panel was weakest are summarised in Table 5-1.

Phase of treatment	***Uncertainty remains about the need to include the following items:***
Pre-operative stretching	Femoral frames - hamstrings, Ilio-tibial band. Tibial frames – toe flexors, hamstrings, quadriceps and tibialis anterior. Humeral frames – biceps, triceps and shoulder rotators.
In-Patient Phase	Treatment twice daily Treatment using hydrotherapy and Proprioceptive Neuromuscular Facilitation.
Exercises - Range of Motion (ROM) and Strengthening.	Femoral frames – back extensors and abdominal muscle strengthening. Tibial frames – tibialis anterior strengthening. Humeral frames – ROM exercises for cervical spine and strengthening of the shoulder girdle musculature.

Table 5-1 Areas of weak consensus where uncertainty remains.

The completed clinical guideline document is enclosed in the publications folder.

5.5 Discussion

The survey described in Chapter 4 has shown considerable variation in the physiotherapy management of patients with an Ilizarov fixator (Barker et al 1999). However, amongst the panel there was a good degree of agreement and in most cases consensus was attained. This variation is possibly explained by the difference in the respondents between the two groups. The survey research was based upon the opinions of physiotherapists with varying levels of experience of treating patients with the Ilizarov fixator, whilst the expert panel all had an established, and similar, level of experience. The variety of conditions treated by an Ilizarov frame means that there will, inevitably be different treatment approaches for a baby undergoing correction of a congenital condition and an adult trauma patient. However, in his writings Ilizarov is clear that all share the same basic principles of distraction histogenesis and a similar approach to rehabilitation (Ilizarov 1989, 1991, 1997).

For successful results it is advocated that the limb must be used in a physiological manner and that the limb should be functionally loaded (Ilizarov 1989, Green 1991, Ilizarov 1997). This has been a basic principle taught to physiotherapists involved in the treatment of patients with an Ilizarov fixator. However, amongst the panel there was felt to be a need to modify this basic tenet with the recognition that it is not practicable or desirable in all circumstances. It was felt that there was little therapeutic benefit in striving to make babies weight bear through a frame, instead rehabilitation efforts should concentrate on the child using the limb to achieve activities appropriate to that child's developmental milestones. Likewise, there was felt the need to recognise the fact that in fracture management with the Ilizarov fixator, there is sometimes a need for a period of non-weight bearing or partial weight bearing status. During this period functional loading of the limb would not be encouraged, for example, in the initial weeks after fixation of an intra-articular fracture.

The only reported treatment protocols that have been published originate from North America (Folkerts et al 1992, Simard et al 1992, Coglianese et al 1993). These articles all describe the treatment approach taken at the authors' individual centres for the rehabilitation of Ilizarov patients. However, all focus on patients who are undergoing limb lengthening and do not address the differing needs of trauma patients. This omission results in the physiotherapist reading the literature gaining the impression that maximal weight bearing is desirable in all circumstances. It also biases the treatment direction towards preventing those complications particularly associated with limb lengthening. The panel felt the need to address this issue and include caveats to highlight the needs of patients undergoing treatment by the Ilizarov method for reasons other than limb lengthening. The different circumstances faced by trauma and elective patients were also highlighted in the section on the pre-operative management of patients. Whilst all of the panel felt that pre-operative preparation of the patient was desirable, it is obviously not always practicable in the trauma environment.

The final version of the guidelines included only statements that had been derived by a consensus of 80% in rounds 1-3 and had a median score of 5 or more. In addition to the mean, median and standard deviation, the kappa value was calculated for each statement as suggested by Altman 1991, Siegel & Castellan 1988 and Fleiss 1981. However, this only takes into account the number of times that raters agree with each other. It does not reflect the extent of agreement with the statement, thus if all 12 raters scored 9/9 with a statement it would have a kappa value of 1, the value would also be 1 if they all scored their level of agreement as 5/9. Landis & Koch (1977) suggest that a kappa value of < 0.20 reflects poor agreement, 0.21-0.40 fair agreement, 0.41-0.60 moderate agreement, 0.61-0.80 good agreement and 0.81-1.0 very good agreement. It was apparent that in some cases the kappa value was low whilst the mean and median scores were high, reflecting a strong level of agreement by the panel members with the statement, but weaker consensus about the exact score given to the statement. The kappa values may have been higher if the panel had been given less choice on the scale of agreement using a 5 or 7 point scale rather than the 9 point scale chosen. However, by using the method detailed here, the level of uncertainty amongst the panel about the best physiotherapy management was more clearly highlighted.

The consensus system identified those modalities that were felt to be most likely to achieve the goals of treatment. A large number of treatment modalities were suggested, totalling 42 different techniques. However, only 8 met the inclusion criterion of 80% and were included in the draft statements at the consensus meeting. Other exercises that did not achieve consensus may well be of value and achieve similar outcomes and are possibly useful methods for treating individual patients. The exclusion of so many treatment modalities may be due to the consensus method used. It has been argued that the Delphi technique forces consensus and is weakened by not allowing panel members to discuss issues (Sackman 1975). It is probable that had individual panel members discussed the advantages and disadvantages of different treatment techniques, more might have been included. Other weaknesses of the Delphi technique are that the researcher does not know the rationale behind responses (Jeffrey et al 1995) and respondents have no opportunity to elaborate on their views (Goodman 1987, Walker & Selfe 1996). It is possible that more treatment modalities would have been included if respondents had argued their case for their inclusion.

A further concern about the use of the Delphi technique is that the anonymity afforded, whilst protecting panel members from peer pressure, may result in a lack of accountability (Goodman 1987). This issue was addressed by only recruiting to the panel members with a specific interest in the subject area, who were experienced in their field. They were informed prior to agreeing to take part the expected time commitment and the need to participate through until the final guidelines were drafted.

The decision to move to an expert panel approach for the last stage was partly pragmatic. Previous research has suggested that the optimum number of rounds is two or three, after which participants become fatigued and are slower to respond to each round (Bond & Bond 1982, Walker & Selfe 1996, Maxwell 1995). Initially respondents returned their questionnaires within 30 days, but the speed of return decreased as the process continued. Beretta (1996) estimated that each round of the Delphi may take between 45-56 days. It was felt that a meeting of the expert panel would enable the final round to be completed with less delay, as well as having advantages in allowing the panel to meet each other, and that it would

increase the panels' sense of ownership of the guidelines. It was certainly evident that the move to a consensus panel meeting to rate agreement with the draft guideline statements resulted in a lively exchange of ideas and a high level of consensus when individual statements were rated.

Through this consensus exercise a standard treatment programme for patients with an Ilizarov fixator was developed (Barker & Burns 2000, 2001a). It provides clinicians with valuable information about the rehabilitation of these patients, based upon the expert opinion of clinicians from a variety of geographical and clinical areas. Consensus was achieved on the core elements that should be included in a treatment programme for this group of patients, whilst recognising the potential benefits of other treatment approaches. The need to match individual patient needs to specifically tailored exercises or treatment techniques is recognised and the caveat issued that the guidelines should not stifle the imagination or scope of the treating physiotherapist (Barker & Burns 2001a). The guidelines have been presented to and adopted by the British Limb Reconstruction Society.

5.6 Summary

- This chapter describes how the Delphi technique was used to produce clinical guidelines for the management of patients treated by the Ilizarov method.

- There is a paucity of published research material regarding the physical rehabilitation of Ilizarov patients, thus a consensus method of information gathering was chosen.

- An expert panel of 12 clinical physiotherapists used the Delphi technique to produce draft guideline statements.

- There was consensus on basic tenets of treatment, but considerable variety of opinion about treatment modalities.

- A second consensus technique, the expert conference, was used to formulate these into guidelines and to rate for strength of agreement amongst the panel members.

- The guidelines are designed to be applicable to the range of uses of the Ilizarov fixator, trauma and elective, adult and paediatric.

- The final version of the guidelines was agreed by all members of the panel and has been adopted by the British limb Reconstruction Society.

SECTION TWO

Rationale for Clinical Studies.

The review of the literature showed that there was little published material about the rehabilitation of patients treated by the Ilizarov method. This lack of material led to qualitative research strategies being used to explore the level of knowledge about physiotherapy management.

The survey of current physiotherapy practice, (Chapter 4), showed that there was considerable uncertainty about the clinical management of patients receiving physiotherapy during treatment by the Ilizarov method.

In an attempt tofulfil the wish of 70% of the survey respondents for more information, evidence-based guidelines were generated based upon expert opinion and existing sources of information (Chapter 5). The guidelines also showed that there was uncertainty about the best physiotherapy management, particularly regarding strengthening exercises.

Range of Motion

The survey (Chapter 4) showed that the most frequent treatment objective set by physiotherapists was to increase the range of joint motion. The main problem that respondents cited was with soft tissue contractures leading to loss of joint range. Loss of joint range of motion has been also been cited as a problem in much of the literature about the surgical management of patients by the Ilizarov method (Green 1990, 1991, Paley 1990, Stanitski 1995), and in the reports about physiotherapy treatment (Coglianese et al 1993, Folkerts et al 1992, Simard et al 1992).

The work of Herzenberg et al (1994) reported the effect of lengthening the femur on knee range of motion in a retrospective study.

No reports were found that reported joint range of motion in detail, for patients having tibial lengthening or combined femoral and tibial lengthenings.

The combination of the survey results reporting that maintaining range of motion during and after treatment by the Ilizarov method, and the lack of published

reports about joint range of motion, led to the decision to study this area further via a longitudinal clinical cohort study.

Functional Outcome

The majority of reports about the results of surgery with the Ilizarov method have concentrated on results in terms of how much length was achieved, the alignment of the limb and the time to achieve union. The quantity of work on rehabilitation is considerably less.

The restoration of function, being fundamental to rehabiliation, led to the inclusion of the effect of limb lengthening surgery on function being included in the longitudinal clinical study.

Muscle Strength

The survey showed that the second most frequent treatment objective set by physiotherapists was to increase muscle strength.

A review of the literature showed that some authors had found that muscle strength was impaired following limb lengthening surgery and that this was a long lasting effect (Maffulli & Fixsen 1995, Kaljumae et al 1995). However, this finding was not universal and Holm et al (1995) found that muscle strength recovered after limb lengthening, but that it took more than 2 years for full recovery to occur. Thus there is uncertainty from the literature, about the duration of changes in muscle strength after surgery. This was selected for further study in the longitudinal clinical study.

CHAPTER 6 - MEASUREMENT OF JOINT RANGE OF MOTION IN PATIENTS WITH AN ILIZAROV FIXATOR.

6.1 Introduction

Range of motion measurements of the knee are taken many times over the patient's treatment period to monitor the progress of lower limb reconstruction, and are an important factor in clinical decision making about the rate and regimen of lengthening. (Herzenberg et al 1994, Paley et al 1997, Bowen et al 1993). These measurements need to be precise and accurate. Therefore, before commencing the data collection of range of motion it was important that a reliable method of measurement was found.

6.1.1 Measurement Reliability

Reliability of joint measurement refers to the amount of agreement between successive measurements of the same joint. There are two types of reliability that are of interest: intra-tester and inter-tester. Intra-tester reliability refers to the amount of agreement between measurements of the same joint by the same tester. Inter-tester reliability refers to the amount of agreement between measurements of the same joint by different testers (Norkin & White 1995).
Papers have been published on the reliability of goniometer measurements in other conditions (Watkins et al 1991, Gogia et al 1987, Rothstein et al 1983) and experience shows that both the position of the limb and the alignment of the goniometer are important (Norkin & White 1995). When a patient is wearing an Ilizarov external fixator it is difficult to measure knee range of motion accurately as the fixator obscures anatomical bony landmarks and the transfixation wires often make it impossible to place the goniometer on the surface of the limb. Because of these problems in the clinical setting the goniometer tends to be either held parallel to the limb or an attempt is made to introduce the goniometer between the frame and the surface of the limb. Alternatively, the measurements are taken from a fixed point on the fixator frame. These methods present the possibility of increasing measurement error and decreasing the reliability of the

measurements of range of motion. Therefore, a prototype goniometer was designed to overcome these difficulties (Figure 6-1).
The inter and intra-tester repeatability of three protocols of goniometer measurements of the knee in patients wearing an Ilizarov external fixator were examined to establish the repeatability of the measurements of joint range of motion in a clinic based setting.

6.2 Method

6.2.1 Subjects

Subjects for this study were patients undergoing limb lengthening with the Ilizarov external fixator who attended either the out-patient clinic at the Nuffield Orthopaedic Centre NHS Trust, Oxford or St Peter's Hospital NHS Trust, Chertsey. Patients were included in the study if they had fixators on both the femur and tibia and if they were able to attend the clinic on a weekly basis.

6.2.2 Testers

All testers were qualified physiotherapists with at least three years experience post qualification. They worked in the field of orthopaedic rehabilitation and were familiar with measuring joint range. The 13 physiotherapists had a mean of 9 years experience (Range 4-19years, S.D. 4.9).

6.2.3 Equipment

Measurements of knee range were taken using:

1) A standard clear plastic 360 ° universal goniometer (UG) marked in one degree increments referenced against anatomical landmarks.

2) A standard clear plastic 360 ° universal goniometer marked in one degree increments referenced against fixed points on the Ilizarov frame – frame referenced (FR).

3) A modified clear plastic 360 ° universal goniometer – prototype goniometer. This had extending pins positioned perpendicular to the arms and fulcrum of the goniometer. This was referenced against anatomical landmarks – (PG).

The prototype goniometer had extending perpendicular pins added to the arms of a standard goniometer. It was hypothesised that this would allow consistent placement relative to the limb (Figure 6-1). Without the use of extending pins the tester had to hold the goniometer parallel to the limb, resting it outside the Ilizarov frame. This led to inaccuracies in both placement and reading the scale.

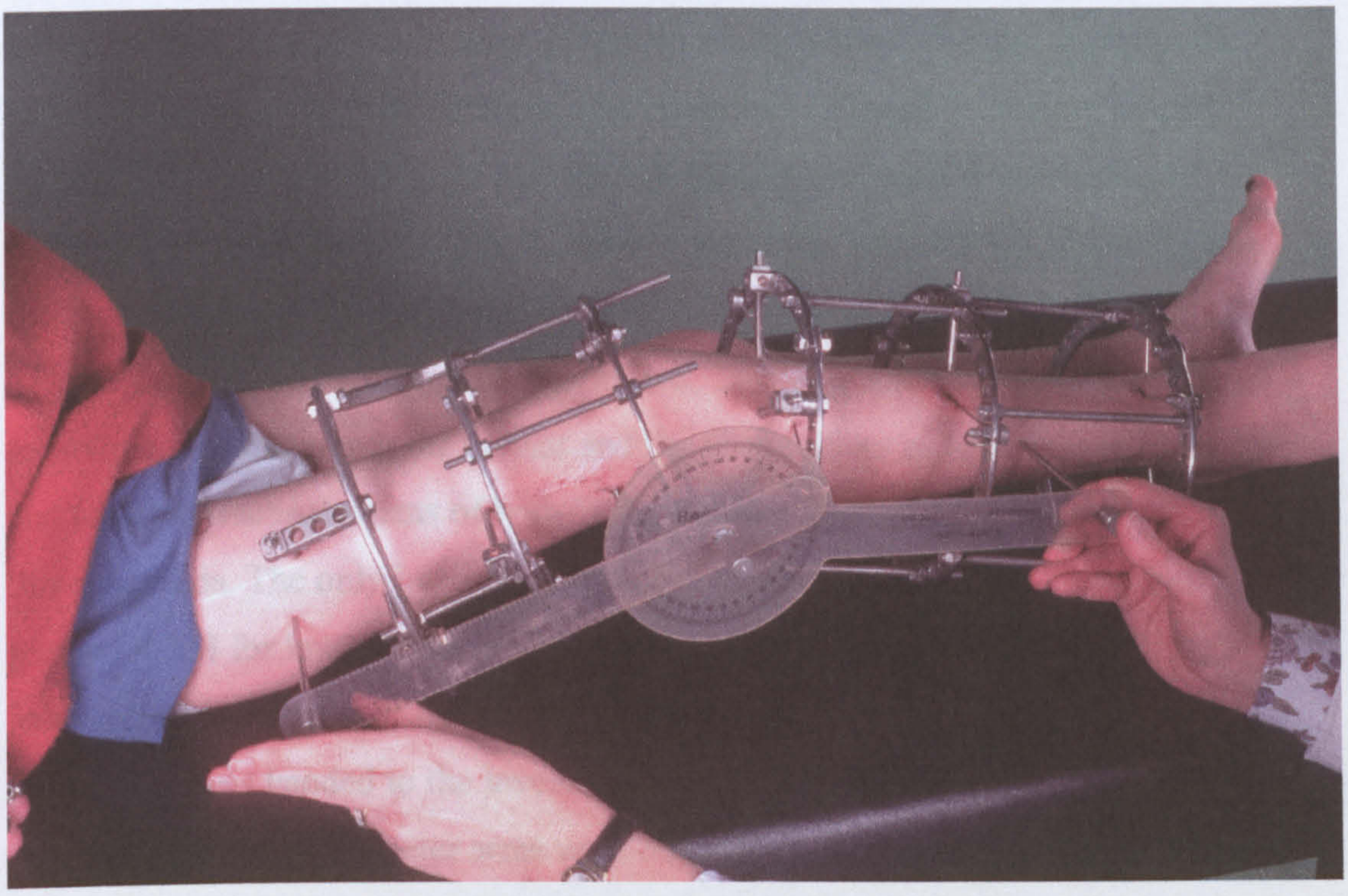


Figure 6-1: Prototype goniometer.

Each of the goniometers was calibrated prior to commencing the study by measuring a series of angles drawn using a protractor. The goniometers all measured the angles accurately. After setting the angle of the goniometer it was handed to a recorder to read the range of motion. This ensured that the testers did not recall the measurements that they had taken.

6.2.4 Procedure

The design replicated the clinical situation in which sequential measurements of range of motion are often performed by different clinicians. In the clinic measurements may be taken by any of the clinicians present; patients will not necessarily see the same therapist twice, and not all patients are measured by the same therapists. In order to try to replicate this and to minimise any biases, such as learning effects or physiotherapist-patient interaction, the study was designed to randomly assign therapists to patients. This used two levels of randomisation; first the physiotherapists were assigned into sets of random pairs i.e. 25 pairs. The investigator then used a computer generated random-allocation list to assign the subject to a pair of testers. Thus each therapist was assigned to random pairings and only measured in the same pair for one subject, and each tester measured three or four subjects. For example, tester 5 measured subjects 4,6,18 and 21 and measured as part of the pairings 4 & 5, 5 & 6, 5 & 10 and 5 & 13. Passive range of knee flexion and extension was measured. Each tester used their own preferred technique for positioning the patient and the goniometers as in the clinic situation, and took two measurements of both knee flexion and extension with each of the three methods. The only instruction that they were given was to measure full passive ROM for knee flexion and extension. On completion of each measurement when the arms had been aligned to the tester's satisfaction, the goniometer was handed to the investigator who recorded the value. After each measurement the goniometer arms were returned to the zero degree position and the subject's limb was repositioned in its starting position. Once the first tester had completed taking their two pairs of measurements, the second therapist took the measurements in the same order as the first therapist.

6.3 Data Analysis

The concept of reliability is complex and different statistical methods can be used to demonstrate aspects of reliability (Bruton et al 2000). An interclass correlation coefficient (ICC) which reflects both systematic error and random differences in test scores is generally accepted as the preferable method of quantifying reliability (Guyatt et al 1987). This along with the Bland and Altman agreement test (1986) allows useful interpretation of the data and gives a level of reliability that can indicate if differences between tests are clinically acceptable. Neither test alone provides sufficient information and it is recommended that both are used in reliability studies (Rankin & Stokes 1998, Chinn 1991).

The range of motion for each method of measurement was summarised as the measurement of flexion – extension. Two sources of variation were examined intra- and inter-tester. The assumption was made that inter-subject variation was not a significant source of variation. This assumption was checked by secondary analysis of the prototype goniometer method.

6.3.1 Intra Tester Variation

Statistical analysis was performed using Bland and Altman's method of assessing reliability (Bland & Altman 1986) and by the Intraclass Correlation (Shrout & Fleiss 1979, Bland & Altman 1996)). The Intra-class correlation coefficient (ICC) is a single index calculated using variance estimates obtained through the ANOVA method and thus reflects both degrees of consistency and agreement among ratings. However, it tends to give a high level of agreement in cases where the between – subjects variance is large and it does not give an indication of the magnitude of disagreement between measurements. The Bland & Altman method indicates a range of error and any bias in measurements. It also presents the data in a way that is easily interpreted visually. Bland & Altman plots of the difference between the first and second measurements versus the mean of the two measurements were constructed for intra-tester and inter-tester reliability for each of the three methods of measurement. Further analysis of inter and intra subject

variation was performed on the results of the modified goniometer method looking for variation between repeatability of measurements taken on the different subjects and by the different testers.

6.3.2 Inter-Tester Variation

The mean difference between the measurements made by the first and second tester, the standard deviations and the coefficients of variation was calculated and plots of mean difference versus mean constructed. The between testers variance was assessed using a visual plot of the differences in the ranges measured versus individual testers for each repeated measure. The intraclass correlation was calculated using the method described by Bland & Altman (1996).

6.4 Results.

6.4.1 Subjects

There were 16 male and 9 female subjects with a mean age of 32 years (range 9-52). The mean time from surgery was 8 months (range 1-26).

6.4.2 Intra-tester Reliability

The mean differences between repeated measures and standard deviations for the different methods are shown in Table 6-1.
Bland & Altman plots of the difference in range versus the mean range are shown in Figure 6-2.
The mean difference between repeated measures was smallest for measures taken with the prototype goniometer (PG), followed by the universal goniometer (UG) and greatest using the universal goniometer referencing against the frame (FR).
The repeatability calculated using coefficient of variation was best for the prototype goniometer (PG).
Calculations of reliability according to Bland & Altman method and ICC are shown in Tables 6.1 and 6.2.

The error standard deviation was much smaller for the measures taken with the prototype goniometer (PG).

6.4.3 Inter-tester Reliability

The results are shown in Tables 6.1 and 6.2 and the plots of mean difference versus the mean in Figure 6-2.

The inter-tester results were similar to the intra-tester results with the mean difference between the testers being smallest for the prototype goniometer (PG). The coefficient of variation was best for the PG method and the error standard deviation was smallest for the PG measurements. The plots of mean difference versus mean show that the spread of the data was much smaller on the plot for the PG method.

There was no trend in the data, showing that the size of the measurement error did not increase or decrease with the total range of motion.

6.4.4 Inter and Intra Subject Variation

The data was investigated to see if any of the subjects were more difficult to measure than others. The differences between repeated measures were plotted against individual subjects to test this question and any subject where the repeated measures demonstrated a large difference was investigated (Figure 6-3). The figure shows that there was no variation in the reliability of the measurements taken on the different subjects, with the exception of subject 10.

In the analysis of the intra-tester reliability the assumption was made that variance between testers was not a problem. To test if this assumption was valid, plots were drawn of the differences between the repeated measures and the different testers. Figure 6-4 shows the difference in the measurements taken by each tester, indicating that there were no testers who were much more, or less, accurate than the others.

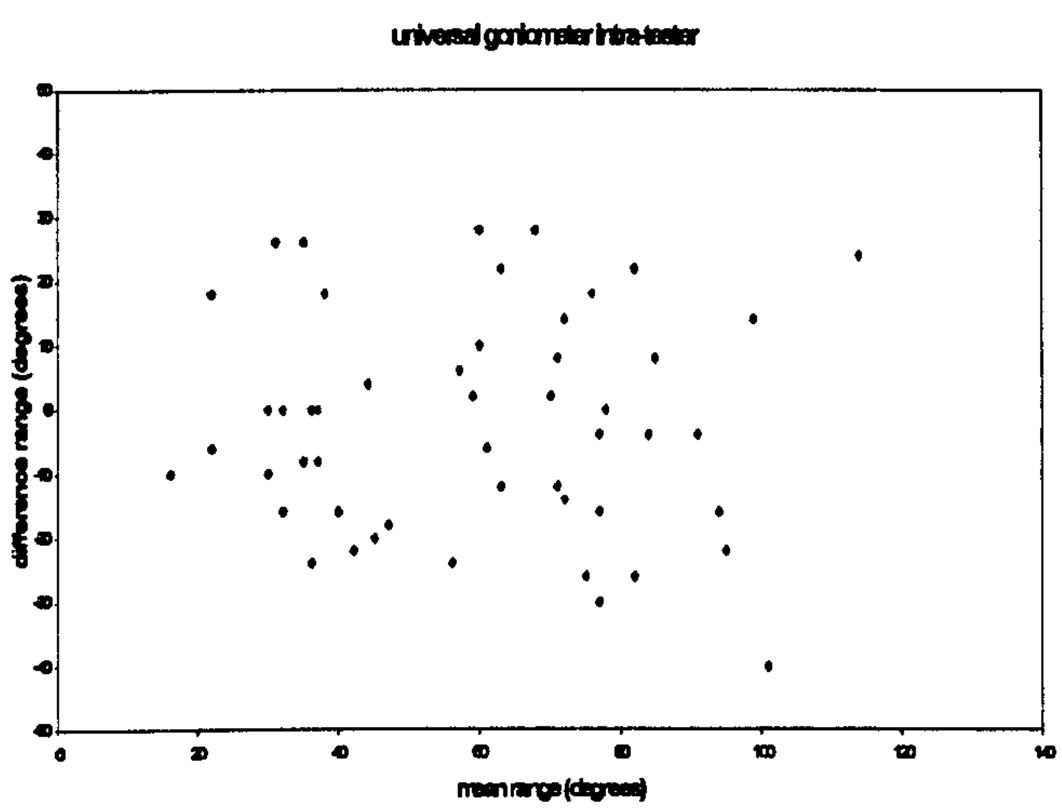
Interactions between subjects and testers were searched for manually by examining those cases where either testers or subjects showed outliers on the data plots against the raw data. No suggestion of any such interaction was found.

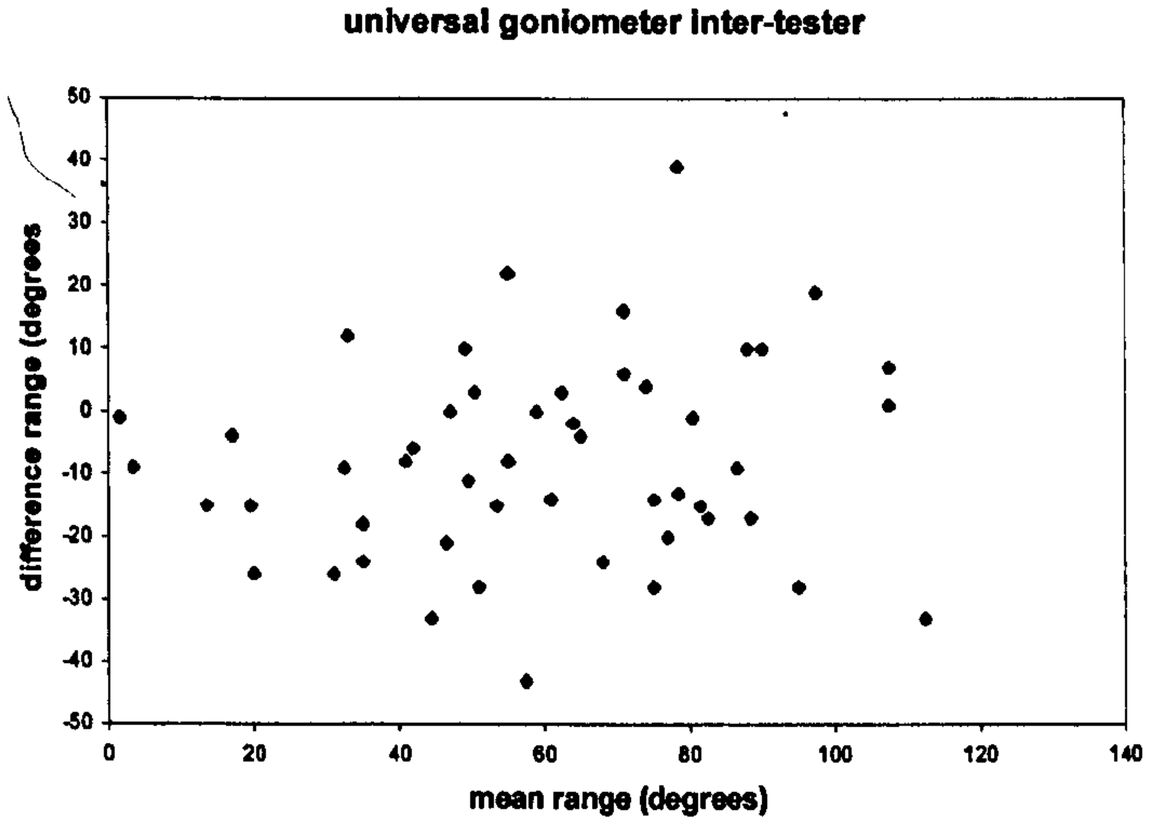
Method		Mean difference (degrees) Difference	Std. Deviation Difference	Std.Error Difference	95% C.I.for mean difference	Reliability Coefficient	95% limits agreement (degrees)
U.G.	Inter-rater	7.94	16.09	2.27	-3.36,12.51	32.18	-40.12, 24.24
U.G.	Intra-rater	0.48	13.9	1.96	-4.43, 3.47	27.8	-28.29, 27.33
F.R.	Inter-rater	3.92	16.3	2.3	-0.71, 8.55	32.6	-28.69, 36.53
F.R.	Intra-rater	2.32	17.2	2.43	-7.20, 2.57	34.4	-36.72, 32.08
P.G.	Inter-rater	0.34	10.48	1.48	-3.31, 2.64	20.96	-21.30, 20.62
P.G.	Intra-rater	1.44	8.36	1.18	-0.9, 3.81	16.72	-15.28, 18.16

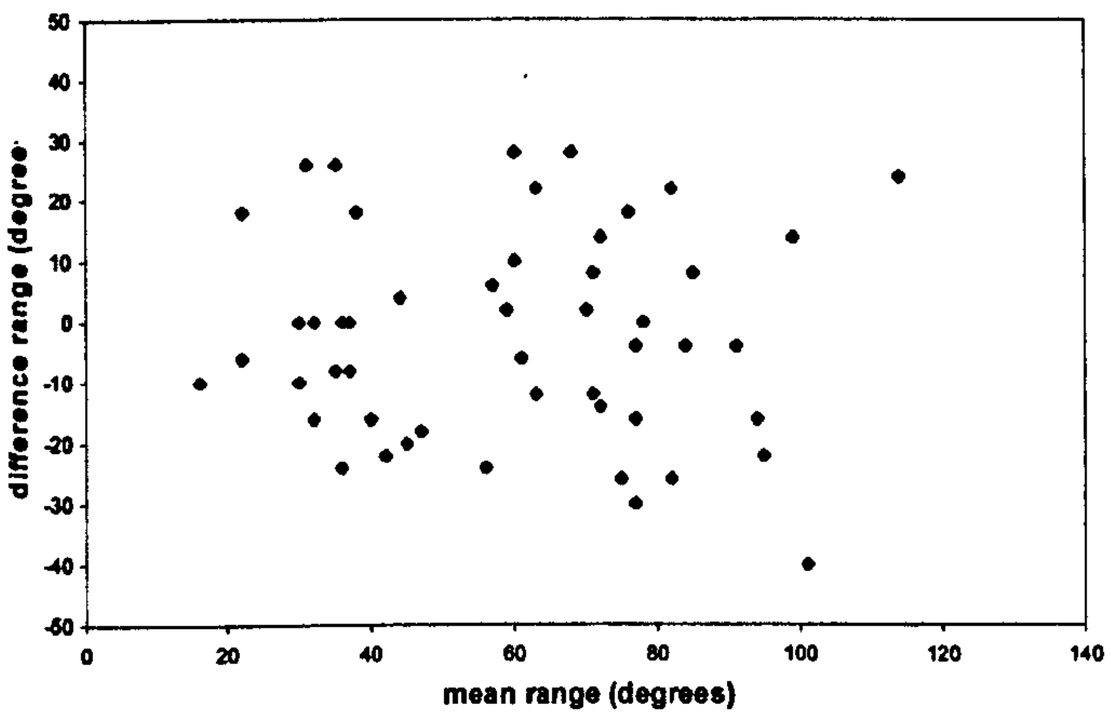
Table 6-1.Results for Bland and Altman method of inter and intra tester repeatability.

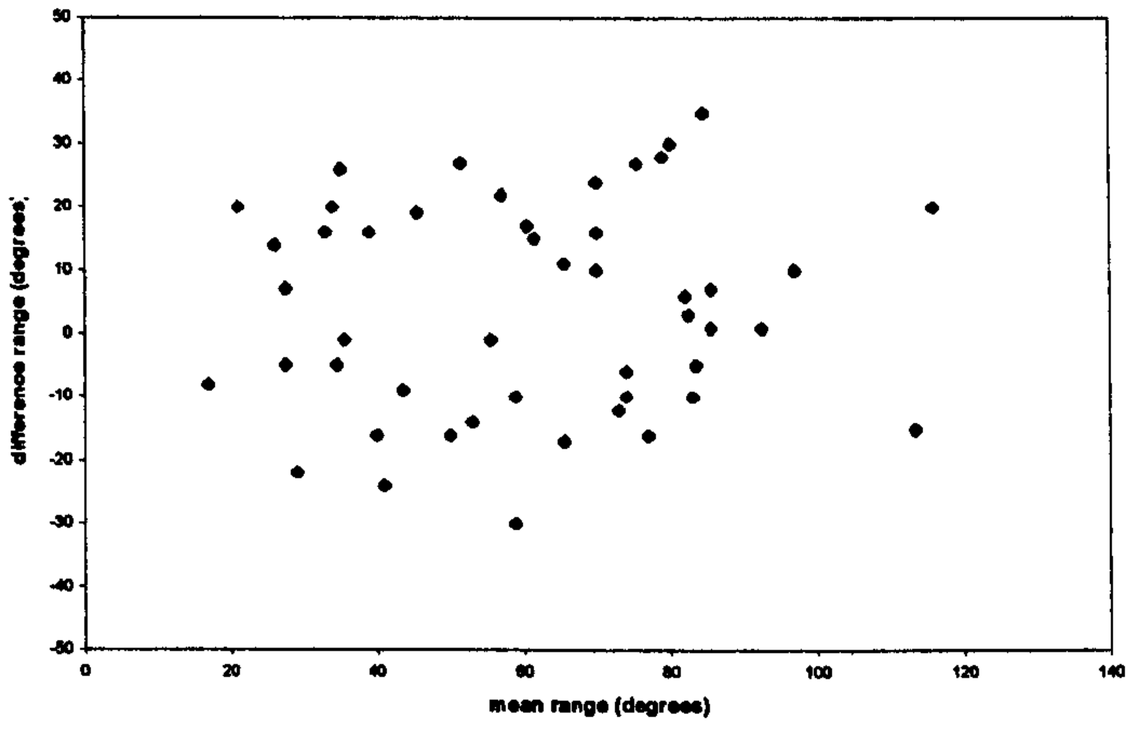
Method	Sum Squares Between Subjects	Sum Squares Within Subjects	Total Sum of Squares	I.C.C
U.G. Inter-rater	384.16	64168.88	64553.04	0.98
U.G. Intra- rater	5.76	78783.24	78789.00	0.99
F.R. Inter-rater	1576.09	77691.70	79267.79	0.96
F.R. Intra-rater	134.56	64010.28	64144.84	0.99
P.G. Inter-rater	2.89	47864.42	47867.31	0.99
P.G. Intra-rater	51.84	47862.2	47914.04	0.99

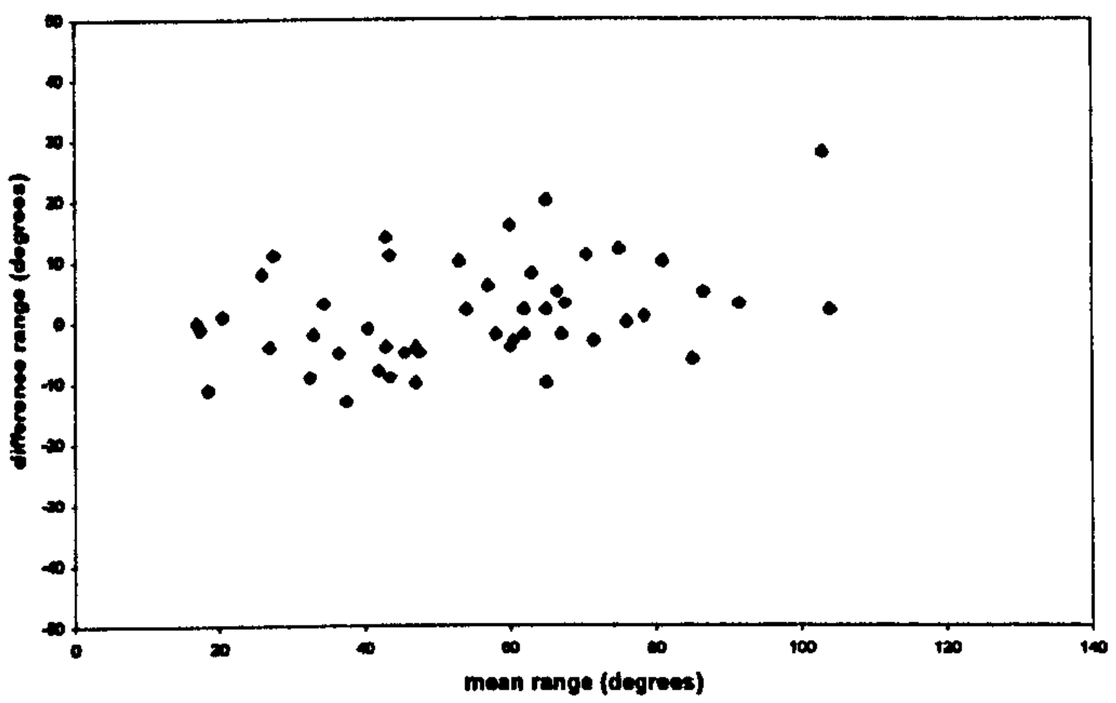
Table 6-2. Inter and Intra-rater repeatability using Intraclass Correlation Coefficients.











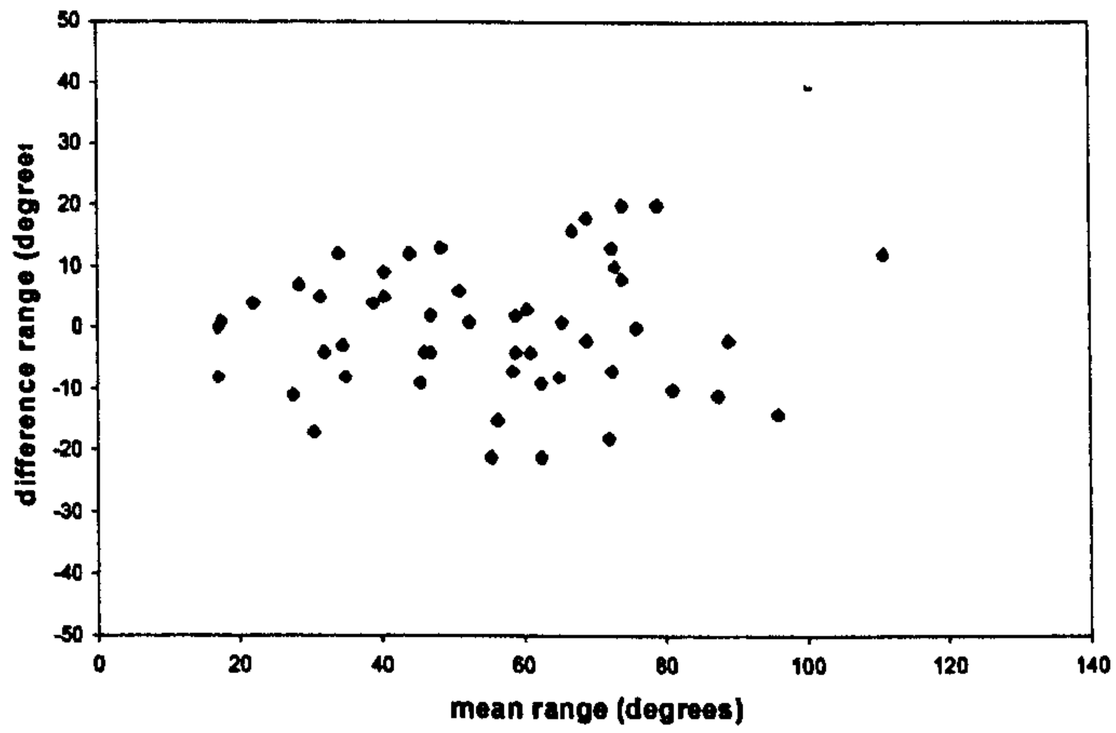


Figure 6-2: Bland & Altman plots

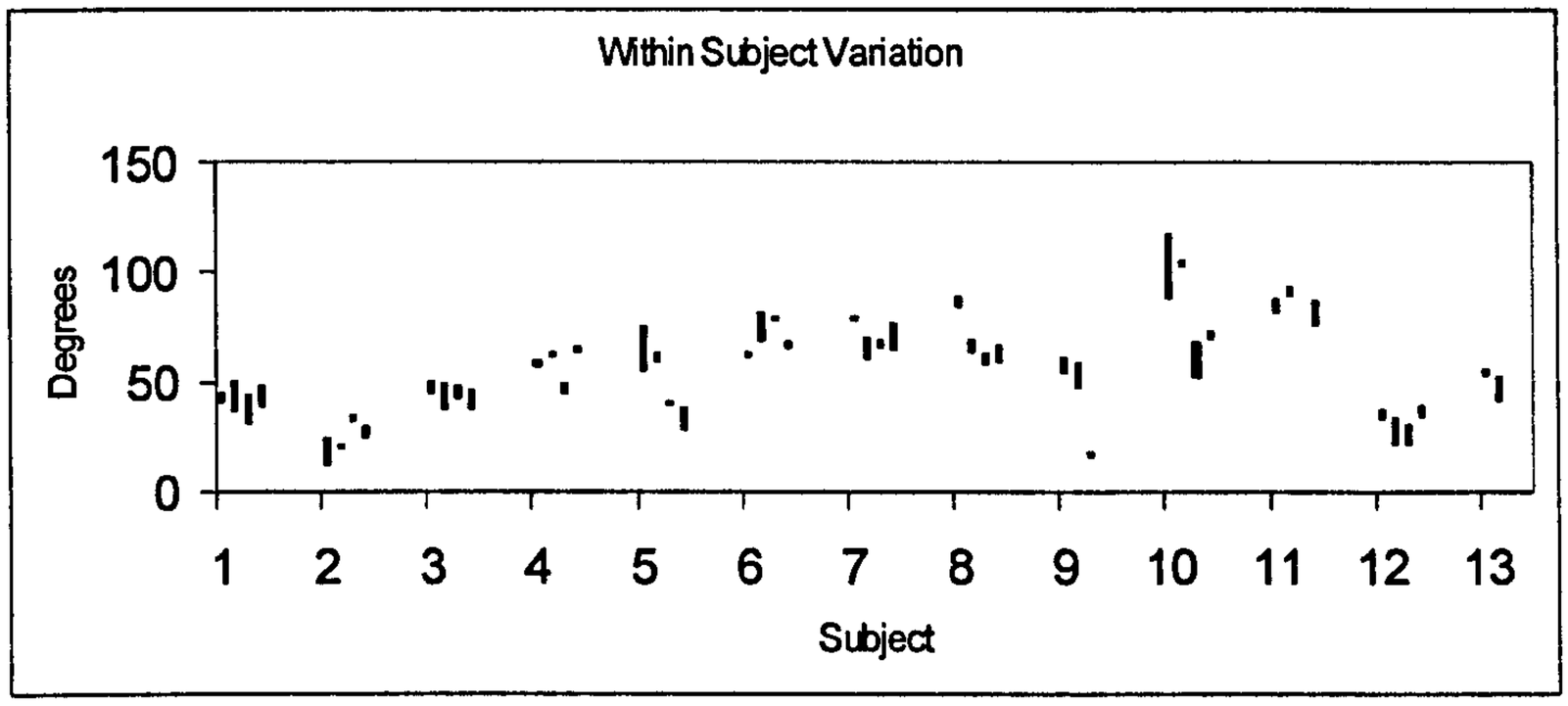


Figure 6-3. Variation between subjects.

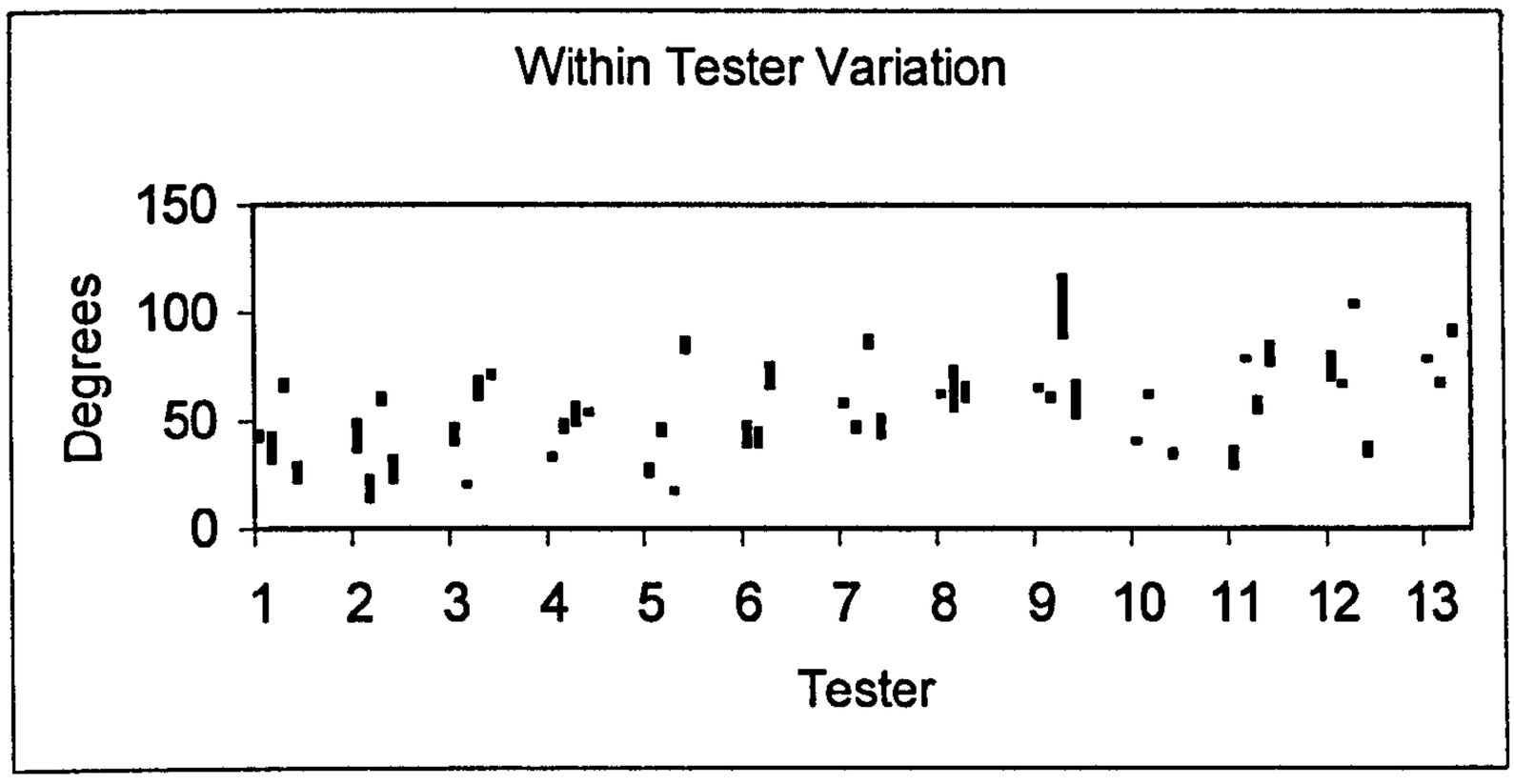


Figure 6-4.Variation between testers.

6.5 Discussion

There is a need to demonstrate that clinical measurements are accurate and reliable. This study showed that reliability is enhanced by the use of a prototype goniometer (PG) when taking measurements in this group of patients. The level of reliability on this sample of patients was higher than that cited by other investigators (Watkins et al 1991). In keeping with other studies, we found that the intra-tester reliability was greater than inter-tester reliability in all three methods of measurement (Watkins et al 1991, Rothstein et al 1983, Norkin & White 1995, Elkstrand et al 1982).

It is probable that the reliability of the (PG) method of measurement was greater than by the other method because the design of the goniometer removed some of the obstacles encountered with the use of the conventional universal goniometer. The modified universal goniometer (PG) had protruding pins enabling consistent placement to be made without interference from the frame. It also enabled the tester to place the goniometer in a position directly parallel to the long axes of the bones allowing clear visualisation of the joint angle.

Potential weaknesses of the study and additional sources of error for all the methods were that the positioning of the patients was not standardised between testers, although it was standardised within testers. It has been suggested that the position of the patient significantly contributes to the measurement error in measurements of passive knee extension (Watkins et al 1991), although this finding is not confirmed by other investigators (Rothstein et al 1983). Errors may also have occurred in identifying the anatomical landmarks by the testers, lack of consistency in technique by the testers, pain or fatigue in the subjects and error by the recorder in reading the goniometer. However, these sources of error are likely to be present irrespective of the method of measurement that was used and represent the true clinic based situation.

The analysis of the data was complicated as there was a complex data set with many possible sources of interaction and it was difficult to exclude these with complete confidence. Bland & Altman's method of assessing reliability was chosen as it was felt to be the best method of comparing agreement between the

methods of clinical measurement, avoiding the errors in interpretation that can arise from the use of correlation coefficients (ICC). ICC is the ratio of between subject's variance to the sum of error variance and subject variance. If the between subjects variance is high, that is, the data comes from a heterogeneous sample, then the reliability will inevitably be high. ICC is also difficult to interpret clinically, as it gives no indication of the magnitude of disagreement between measurements. However, ICC has the advantage of being easy to understand and is useful when multiple sets of observations are taken (Bruton et al 2000). In accordance with the suggestions of Rankin & Stoke (1998) and Bruton et al (2000) both the intra-class correlation coefficient and Bland & Altman's method were calculated.

The results presented here show that high levels of ICC were achieved with all methods of measurement with values varying between 0.96 and 0.99. These figures taken alone, would suggest good reliability with all methods. However, as there was a large degree of heterogeneity within the sample, these figures are likely to be falsely inflated. The reliability measured by the Bland & Altman method are thought to be more reliable in this sample.

It is difficult to separate all the components of variation that occur in the clinical setting, but it was felt that the assumptions made in the data analysis were robust. The level of reliability achieved with the prototype goniometer was considered sufficient for the purposes of use in the longitudinal study of range of motion. The prototype goniometer had a 95% confidence interval for differences between measurements of 4° for intra-rater testers and 6° for inter-tester raters. In clinical practice measurement error of less than 5° at the knee joint is considered acceptable (Gogia et al 1987, Watkins et al 1991). It is unlikely that a decision to alter a patients management would be based upon a difference between two measurements of less than 5°. This method was also felt to be more reliable than that used in other studies (Herzenberg et al 1994).

6.6 Summary

- The repeatability of range of motion measurements taken using a universal goniometer was not acceptable in patients with an Ilizarov external fixator in situ.

- Repeatability was enhanced when a prototype goniometer, designed to overcome some of the problems of the fixator, was used.

- The repeatability attained with the prototype goniometer was acceptable for the purposes of the proposed longitudinal study of range of motion.

CHAPTER 7 -LONGITUDINAL CLINICAL STUDY OF THE EFFECT ON JOINT RANGE OF MOTION OF LIMB LENGTHENING.

7.1 Introduction

The literature review and survey of physiotherapists have highlighted that maintaining joint range of motion is a major problem in the physiotherapy management of patients treated by the Ilizarov method.

Contractures are thought to occur due to an inadequate lengthening response of the muscle to the tension generated within the muscles, when the bone ends are distracted (Simpson et al 1993,1995; Paley 1990, Green 1991). An imbalance develops between the strength of the flexors and extensors and the most powerful muscle tends to overpower its opposing muscle group. Thus in lengthening the tibia, the triceps surae muscles offer the greatest resistance, tending to flex the knee and plantarflex the ankle, whereas in lengthening the femur the hamstrings tend to flex the knee causing flexion contractures. Muscles that cross two joints are most commonly involved in contractures.

Characteristic patterns of contractures thus develop (Paley 1990, Eldridge 1991, Green 1991):

Hip joint : Flexion / Adduction.
Knee joint : Flexion
Ankle joint : Plantarflexion (Equinus)

Joint contractures may seriously compromise the success of the entire leg lengthening procedure since an equalised, (but almost completely stiff) limb is functionally almost as insufficient as a limb with considerable length inequality. Prevention of loss of joint range is thus of major importance (Korzinek 1992). Paley (1990) suggests that if the total lengthening is less than 10% of the original bone length, then lengthening rarely causes soft tissue contractures. It is more likely during lengthening of the femur than the tibia, as a result of quadriceps

transfixation. Knee extension contraction is common during lengthening and is well tolerated, allowing ambulation.

In lengthening the tibia, the problem of developing an equinus deformity is common (Eldridge 1991, Green 1991, Paley 1990). Patients undergoing treatment by the Ilizarov method for lengthening or malunuion often have compromised function of the gastrocnemius-soleus-Achilles tendon complex prior to surgery. Further tension placed upon this structure by lengthening the underlying bone may impose stresses that the soft tissues cannot adapt to and pull the heel into an equinus position. The avoidance of equinus is one of the principal goals of physiotherapy treatment (Stanitski 1996, Lehman 1991, Nakamura 1996, Coglianese 1993, Simard 1992).

It may be concluded therefore that the maintenance of joint range of motion is a major concern in limb lengthening programmes. However, despite an abundance of references to these problems, literature searches only revealed one study that documented the changes in joint range of motion. This was conducted by a retrospective review of the patients' medical records (Herzenberg 1994).
The Herzenberg study is of great interest, but has some inherent flaws, as it used a retrospective chart review of 25 patients undergoing isolated femoral lengthening. The criteria for inclusion was that the charts should include a pre-operative measurement of knee ROM, at least three measurements of ROM during the period of external fixation and three measurements after the frame had been removed. The data was normalised and expressed as a percentage of the treatment time to allow comparison of patients with differing treatment times and amounts of lengthening. Missing measurements were interpolated statistically to provide a smoothed temporal sequence. The author analysed worst flexion in the fixator and final follow up compared to the pre-operative measurement. Herzenberg et al acknowledged that there were flaws in the study as the data was gathered retrospectively, making it difficult to link loss of ROM with other clinical indices, such as the rate of lengthening at the time of any loss of range. There were also problems as the measurements of joint range were made by multiple observers and recorded in the medical notes. The observers used a standard goniometer and

thus there may have been errors introduced both by the use of multiple observers and in the reliability of the measurement instrument.
The documentation of the pattern and recovery of joint range of motion in patients' undergoing limb lengthening has yet to be reported on a cohort of patients followed prospectively through the course of their treatment programme using a reliable measurement system.

7.2 Purpose

The aim was to prospectively follow the loss of joint range of motion and its subsequent recovery; in patients' undergoing either lengthening of the femur, lengthening of the tibia or simultaneous ipsilateral lengthening of both the femur and the tibia. It aimed:

1) To identify factors that influence the loss of range of motion (ROM) and the final outcome i.e. the difference from the pre-operative measurement and at 12 months after frame removal.

2) To determine whether modifications could be made to the current methods of managing the patients to prevent the loss of joint movement.

This information could be used in formulating physiotherapy treatment programmes, particularly in preventing the loss of joint range of motion.

7.3 Patients and Methods

Patients undergoing lengthening in this period were invited to participate in the study, for which Ethics Committee approval had been obtained (NAPREC. N97.014.), in accordance with the Royal College of Physicians guidelines. All patients, or their legal guardians, gave informed consent.

The types of fixator used were Ilizarov circular fixator in 40 cases, Orthofix unilateral fixator in 13 cases and a combination of the Orthofix on the femur and

Ilizarov on the tibia in 12 cases. (Ilizarov Smith & Nephew, Memphis, Tennessee. Limb Reconstruction System, Orthofix, Verona, Italy).
All of the patients were encouraged to perform a regular physiotherapy programme consisting of a balanced programme of stretching, mobilising and strengthening exercises twice a day. Patients were also advised to attend for out-patient physiotherapy twice a week, where this was practicable.

All patients had the range of motion of knee flexion and extension measured pre-operatively. The patients received their surgery when a corticotomy was made to create a lengthening site and the external fixator was applied. This was followed by a latent period of 5-7 days before starting to distract the bone ends.
Measurements were taken at the end of the latent period and at weekly intervals throughout the period of active frame adjustment, when actual limb lengthening or correction of alignment was occurring. Patients undergoing tibial, or combined femoral and tibial lengthening also had ankle dorsiflexion measured. Once the final correction had been achieved joint range was measured at the time of frame removal and at six months and one year post-frame removal. The patients were measured using from a starting position of half supine lying measuring active range of motion, taking measurements of knee flexion and extension. Ankle dorsiflexion was measured using a universal goniometer from a starting position of sitting with the knee flexed and the tibia stabilised to prevent knee motion and hip rotation. The same person took all measurements (Norkin 1995).
The patients' x-rays were examined for evidence of posterior subluxation of the knee. A line was drawn along the long axes of the femur and the tibia and the point of intersection noted. If this point was posterior to the normal axis of rotation of the knee joint, a posterior subluxation of the tibia was diagnosed and this was included in the factorial analysis.

7.3.1 Data Analysis.

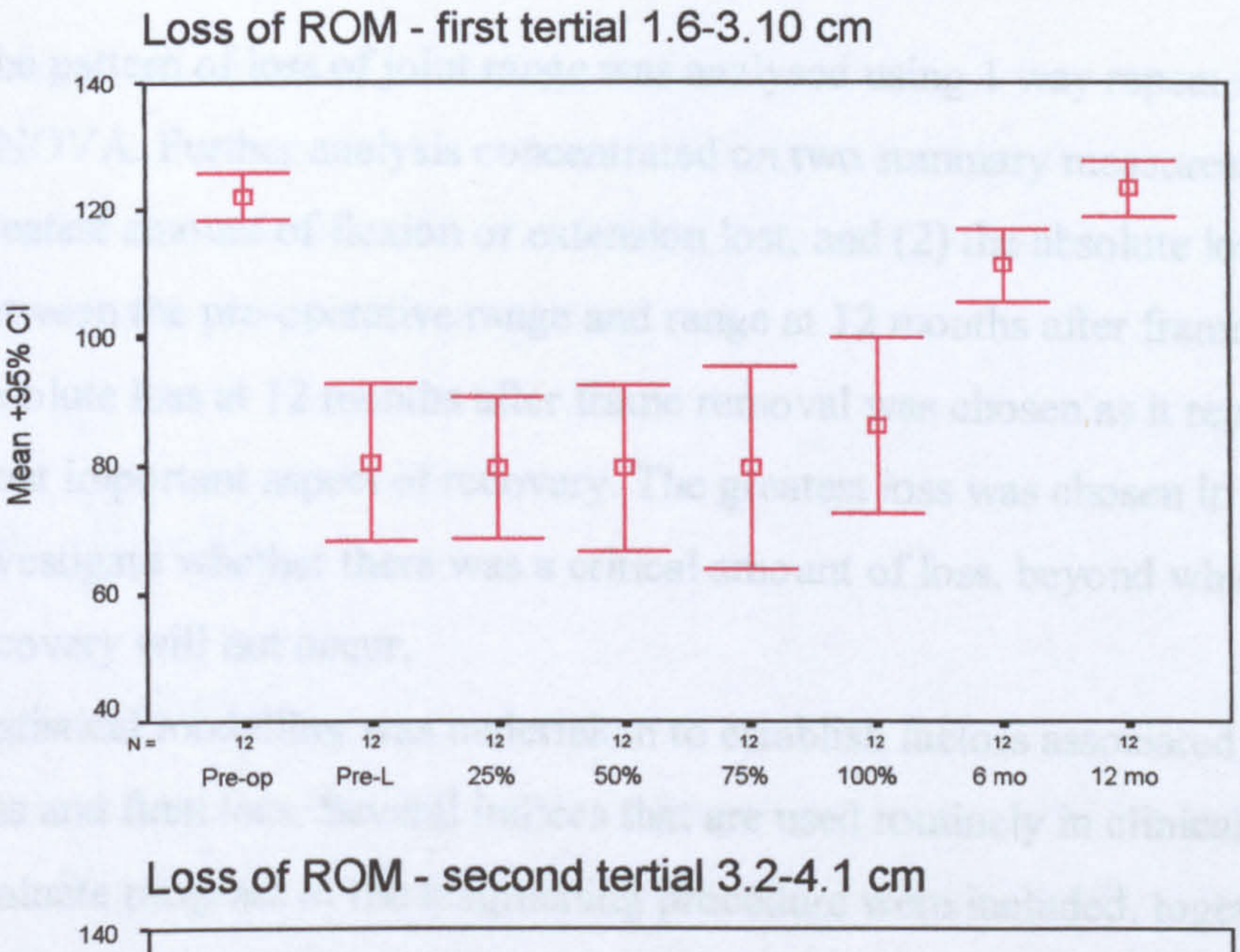
Data was analysed using the statistical package SPSS Version 7.5.

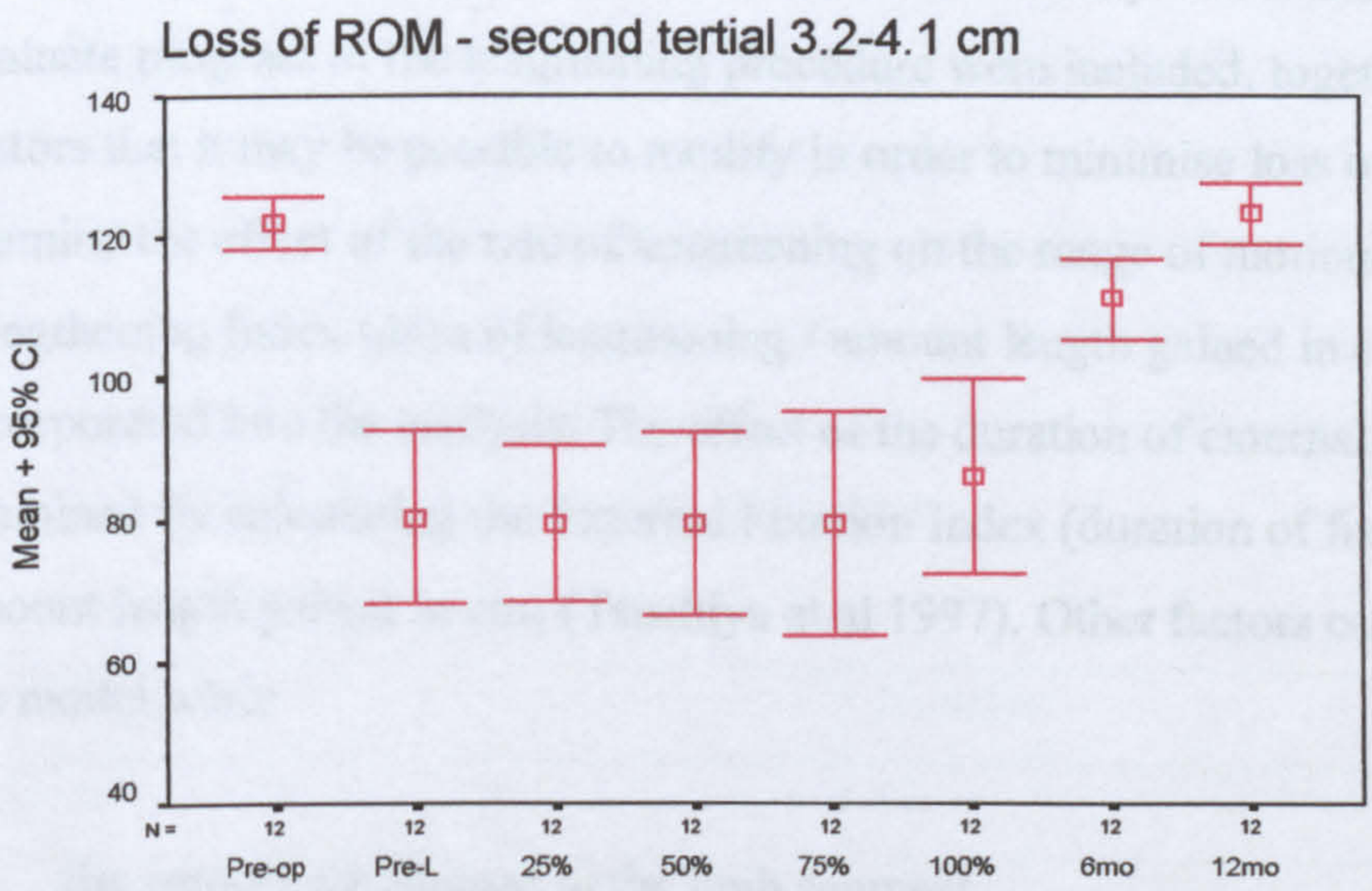
Standardisation of data

Patients had varying numbers of data points depending upon the time period over which frame adjustments were being carried out. Therefore, the statistical advice was that the data should be standardised. The approaches that could be used were to express the temporal sequence of range of motion as a percentage of the treatment time, or as a percentage of the total length that had been gained in the bone. These approaches attempt to standardise the data set, as patients who had lengthened by the greatest amounts had far more data points than those who had lengthened by a smaller amount. In order to make direct comparisons between patients standardisation of the data was needed. As one of the primary sources of interest was to identify the stage at which ROM was lost it was thought appropriate to model the data based on the percentage of the total lengthening. Thus data was analysed pre-operatively, prior to commencing frame adjustment, and at 25%, 50%, 75% and 100% of the total length of new bone formed whilst in the fixator. It was also recorded just prior to frame removal and at six and twelve months after frame removal. This allowed standardised comparisons to be made for patients who were lengthened by different amounts and at different rates. In an ideal world, comparisons would only be made between patients who had lengthened the same amount. However, to do this would have resulted in tiny sample sizes, as it is not possible to collect sufficiently large numbers of limb lengthening patients in a prospective study without using a multi-centre approach. An attempt was made to try and increase the sample size by also recruiting patients from St Peter's Hospital, Chertsey. Unfortunately, this only added 10 tibial lengthening patients to the sample.

Confirmation of validity of method

To confirm that this method of analysis was valid, the data for the patients undergoing femoral lengthening was further analysed by dividing the data into tertials based upon the amount of length gained in the femur. This more detailed analysis is presented in Figure 7-1. It demonstrates that the method of normalising the data was acceptable as a similar pattern of loss is seen in all three groups irrespective of the amount of lengthening.





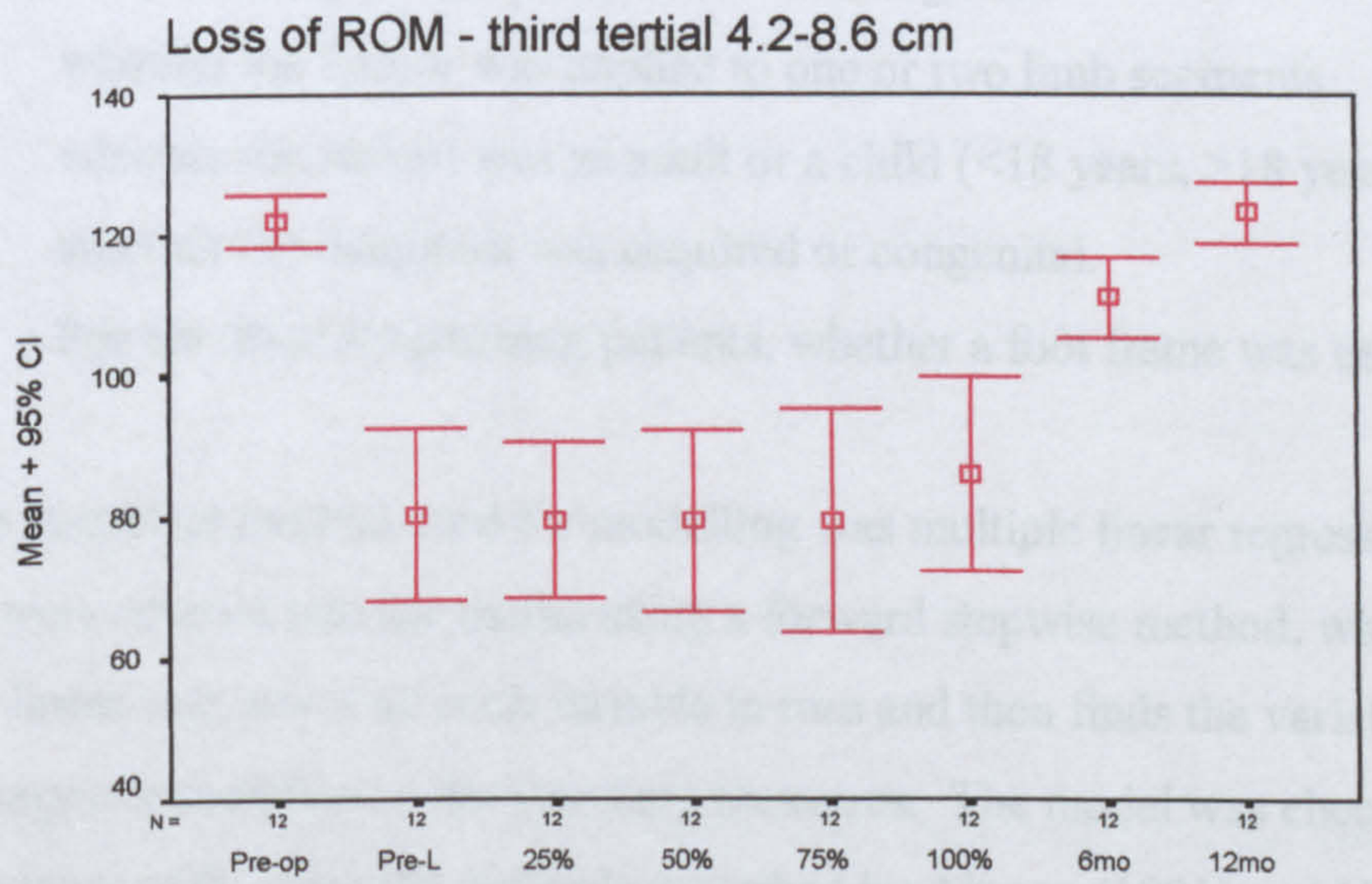


Figure 7-1: Analysis of loss of knee flexion by tertials

The pattern of loss of joint range was analysed using 1 way repeated measures ANOVA. Further analysis concentrated on two summary measures, (1) the greatest amount of flexion or extension lost, and (2) the absolute loss of range between the pre-operative range and range at 12 months after frame removal. The absolute loss at 12 months after frame removal was chosen as it represented the most important aspect of recovery. The greatest loss was chosen in order to investigate whether there was a critical amount of loss, beyond which full recovery will not occur.

Statistical modelling was undertaken to establish factors associated with greatest loss and final loss. Several indices that are used routinely in clinical practice to evaluate progress of the lengthening procedure were included, together with factors that it may be possible to modify in order to minimise loss of range. To examine the effect of the rate of lengthening on the range of motion, the Lengthening Index (days of lengthening / amount length gained in cm) was incorporated into the analysis. The effect of the duration of external fixation was examined by calculating the External Fixation Index (duration of fixation in days / amount length gained in cm) (Tsuchiya et al 1997). Other factors considered in the model were:

a) the amount lengthened in the limb segment
b) the percentage lengthening of the limb segment
c) whether the fixator was applied to one or two limb segments
d) whether the patient was an adult or a child (<18 years, >18 years)
e) whether the diagnosis was acquired or congenital.
f) For the tibial lengthening patients, whether a foot frame was used.

The statistical method used for modelling was multiple linear regression. Factors a-f were entered into the model using a forward stepwise method, which carries out linear regression on each variable in turn and then finds the variables with the strongest association to the summary measures. The model was checked for goodness of fit using the methods described by Altman (1991) and Verrans (1987).

Division of sample by surgical procedure

In order to decrease the heterogeneity that existed within the sample, the data was analysed with the data split into 3 groups. These were based upon the limb segment(s) undergoing lengthening.

7.4 Results.

7.4.1 Subjects

65 consecutive patients who were undergoing either isolated femoral lengthening (n = 18), simultaneous femoral and tibial lengthening (n = 17), or isolated tibial lengthening (n= 30) were studied over a two year period commencing in January 1997. There were 46 male patients and 19 female patients, ranging in age from 4 - 56 years (mean 22). 43 of the patients were adult at the time of surgery and 22 children. 33 were receiving surgery for an acquired leg length discrepancy and 32 for congenital or other deformities (see Table 7-1).

DIAGNOSIS	*Number*
Mal-union	12
Non-union	21
Childhood osteomyelitis	3
Ollier's Disease	5
Proximal Focal Femoral Deficiency	6
Hemiatrophy, hypoplasia	5
Fibula hemimelia	6
Hypophosphatemic rickets	1
Achondroplasia	6

Table 7-1 : Patients' Diagnosis.

The results are presented in three separate sections relating to the limb segment that has been lengthened. Thus the results for lengthening the femur are presented first, followed by the results of simultaneous lengthening of the femur and tibia and finally the results of lengthening the tibia are presented.

7.4.2 FEMUR ONLY

The results are summarised in Tables 7-2 & 7-3.

Variable	***Mean***	***Range***
Gain in length in femur	4cm	2 – 9 cm
Percentage increase	10 %	4 – 18 %
Time in external fixation	127 days	37 – 257 days
Lengthening Index	16 d/cm	6 - 27 d/cm
External Fixation Index	32 d/cm	13 – 83 d/cm
Final Difference knee flexion	1°	-5 , 15°
Final Difference knee extension	0°	-6 , 2°
Maximum loss knee flexion	41°	10 - 90°
Maximum loss knee extension	7°	0 - 30°

Table 7-2: Summary of femoral lengthening.

Knee Flexion

The pattern of knee flexion is shown in Figure 7-2 and Table 7-3.

	Mean flexion and Standard Deviation (degrees)	Decrease in flexion from pre-op + SD (degrees)	F value	Significance Of change from baseline.
Pre-op	120 (10.9)			
Pre-Lengthening	86 (22.7)	34 (21.8)	11.07	.001
25%	86 (20.5)	34 (17.8)	48.75	.000
50%	89 (24.3)	31 (20.5)	7.18	.014
75%	85 (28.3)	35 (23.7)	7.97	.014
100%	89 (27.3)	31 (21.3)	25.4	.000
6 month	109 (18.1)	11 (11.4)	2.66	.097
12 month	120 (12.7)	0 (3.7)	.118	.821

Table 7-3: Loss and Recovery of knee flexion (femur)

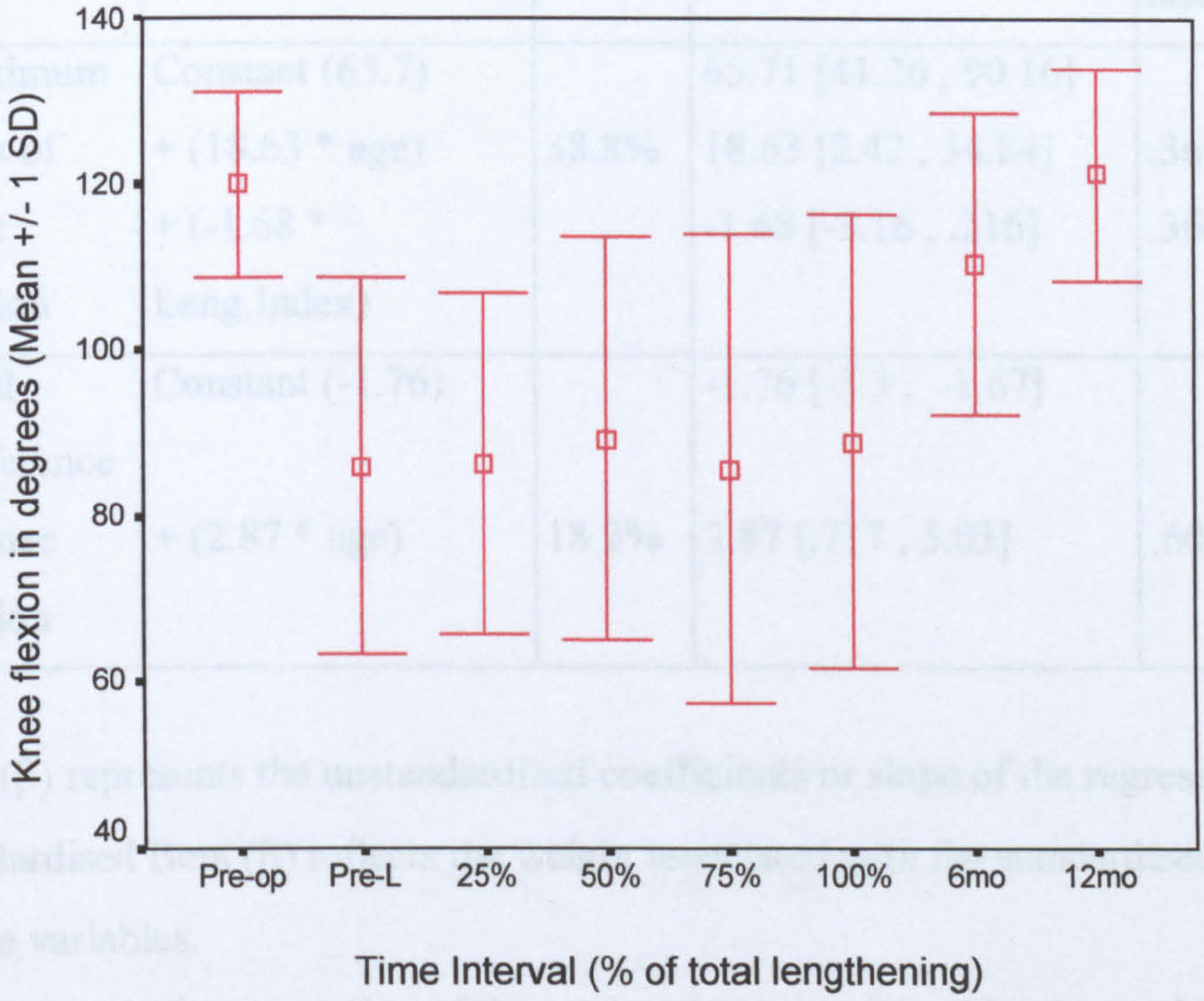


Figure 7-2: Loss and recovery of knee flexion (femur)

Surprisingly, the largest amount of loss of knee flexion occurred early. There was a significant decrease in knee flexion in the latent period prior to distraction starting, with a mean decrease of 33.8° ($p<0.001$). Range continued to be lost until maximum range was lost towards the end of lengthening, it then recovered from that point. Recovery of flexion occurred soon after the frame was removed and continued for 12 months post frame removal. Of the 18 patients, 11 regained their pre-operative ROM, 6 increased their ROM and 1 lost ROM. Three patients lost range so that their knee flexion was ≤ 40°. One patient did not regain his pre-operative range and had a final loss of 10°.

The analysis of the factors influencing the loss of range is shown in Table 7-4. Age and lengthening index were both important in predicting maximum loss of flexion. Children lost more flexion than adults, and those who were lengthened more rapidly were more likely to lose knee flexion. No other factors were statistically significant.

	Prediction Equation	R^2	***β [95% CI]***	***Standardised β***	***Sign.***
Maximum Loss of knee flexion	Constant (65.7) + (18.63 * age) + (-1.68 * Leng.Index)	38.8%	65.71 [41.26 , 90.16] 18.63 [2.42 , 34.84] -1.68 [-3.16 , .216]	 .365 .364	0.000 0.026 0.026
Final Difference of knee flexion	Constant (-1.76) + (2.87 * age)	18.2%	-1.76 [-3.3 , -1.67] 2.87 [.717 , 5.03]	 .603	0.027 0.011

Beta (β) represents the unstandardised coefficients or slope of the regression lines.

Standardised Beta (β) reflects the weight associated with the standardised scores on the variables.

R^2 represents the proportion of the total variation explained by the model.

Table 7-4: Results of forwards stepwise regression modelling to predict loss of knee range (degrees) and final difference (degrees).

KNEE EXTENSION

The pattern of loss and recovery are shown in Figure 7-3. Pre-operatively the mean knee extension was 0° with patients losing an average of 4° in the latent period and a maximum of 5° by the end of lengthening. These changes were not statistically or clinically significant. Most patients retained full extension throughout the procedure but 5 lost range, with the greatest loss being 30°. All patients regained full extension during the follow up period and there were no significant differences between the pre-operative and final values for knee extension. No factors influencing loss of knee extension were identified.

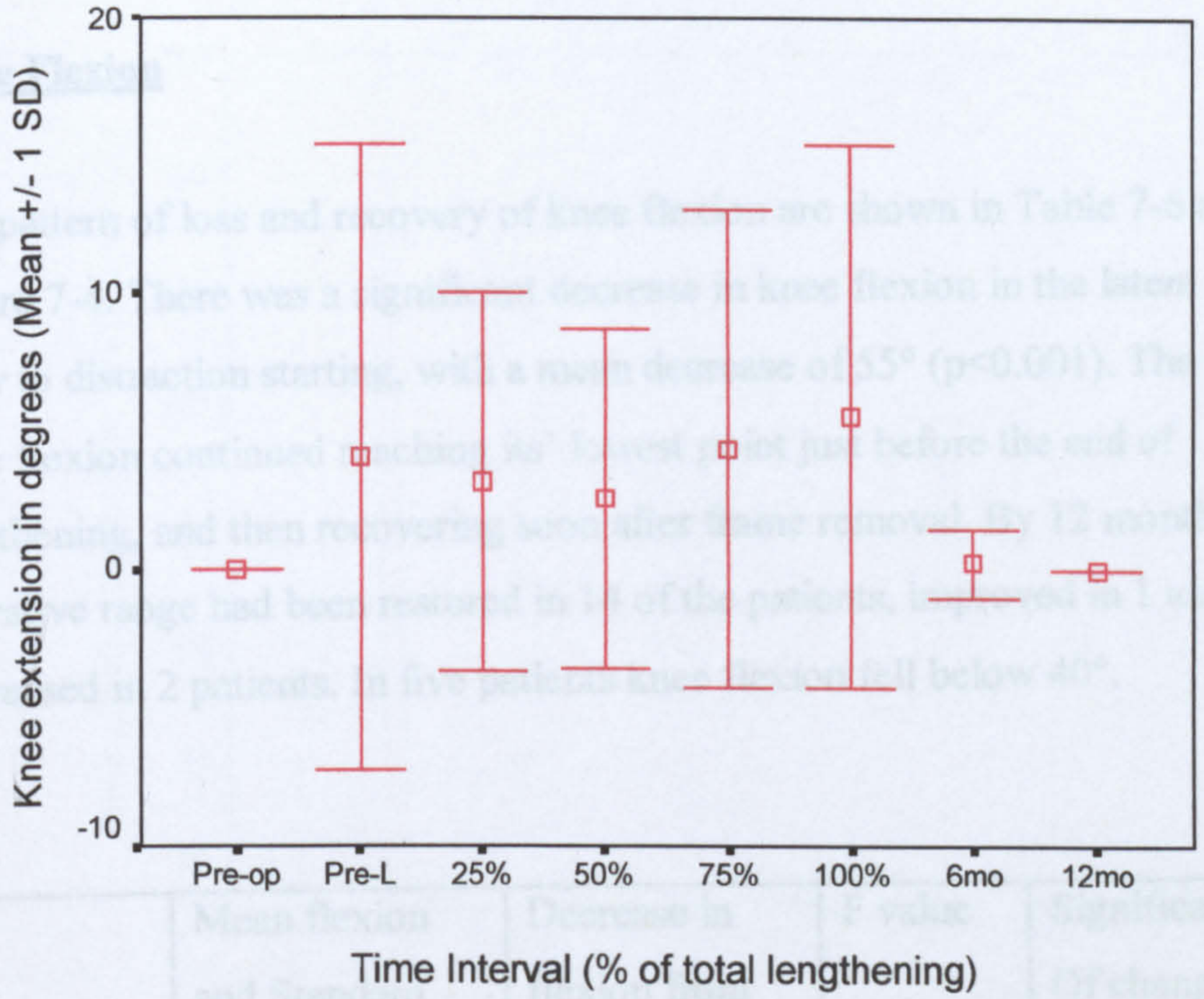


Figure 7-3: Loss and recovery knee extension (femur)

RESULTS SIMULTANEOUS FEMORAL & TIBIAL LENGTHENING.

The results are summarised in Table 7-5.

Variable	***Mean***	*Range*
Gain in length in femur	3.6cm	2.3 – 4.75 cm
Percentage increase	14 %	5 – 25 %
Gain in length in tibia	3.6 cm	2.3 - 5.8 cm
Time in external fixation	217 days	138 – 318 days
Lengthening Index	9 d/cm	6 - 17 d/cm
External Fixation Index	32 d/cm	17 – 60 d/cm
Final Difference knee flexion	1°	-5 – 10°
Final Difference knee extension	0°	0 – 0°
Final Difference ankle dorsiflexion	3°	0 - 35°
Maximum loss knee flexion	68°	35 – 105°
Maximum loss knee extension	13°	0 – 55°
Maximum loss ankle dorsiflexion	5°	-30 – 40°

Table 7-5 Summary of lengthening femur and tibia.

Knee Flexion

The pattern of loss and recovery of knee flexion are shown in Table 7-6 and Figure 7-4. There was a significant decrease in knee flexion in the latent period prior to distraction starting, with a mean decrease of 55° ($p<0.001$). The loss of knee flexion continued reaching its' lowest point just before the end of lengthening, and then recovering soon after frame removal. By 12 months the pre-operative range had been restored in 14 of the patients, improved in 1 and was still decreased in 2 patients. In five patients knee flexion fell below 40°.

	Mean flexion and Standard Deviation (degrees)	Decrease in flexion from pre-op value and Standard Deviation (degrees)	F value	Significance Of change from baseline.
Pre-op	127 (8.11)			
Pre-Length.	71 (21.1)	56 (20.7)	24.8	0.000
25%	69 (20.3)	58 (19.6)	127	0.000
50%	63 (25.2)	64 (23.7)	18.6	0.001
75%	64 (26.7)	63 (24.9)	9.2	0.008
100%	70 (28.5)	57 (26.6)	38.3	0.000
6 mo	106 (17.3)	21 (16.1)	.6	0.440
12 mo	126 (8.45)	1 (4.6)	26.8	0.846

Table 7-6: Knee Flexion Loss and Recovery Anova – Femur and Tibia

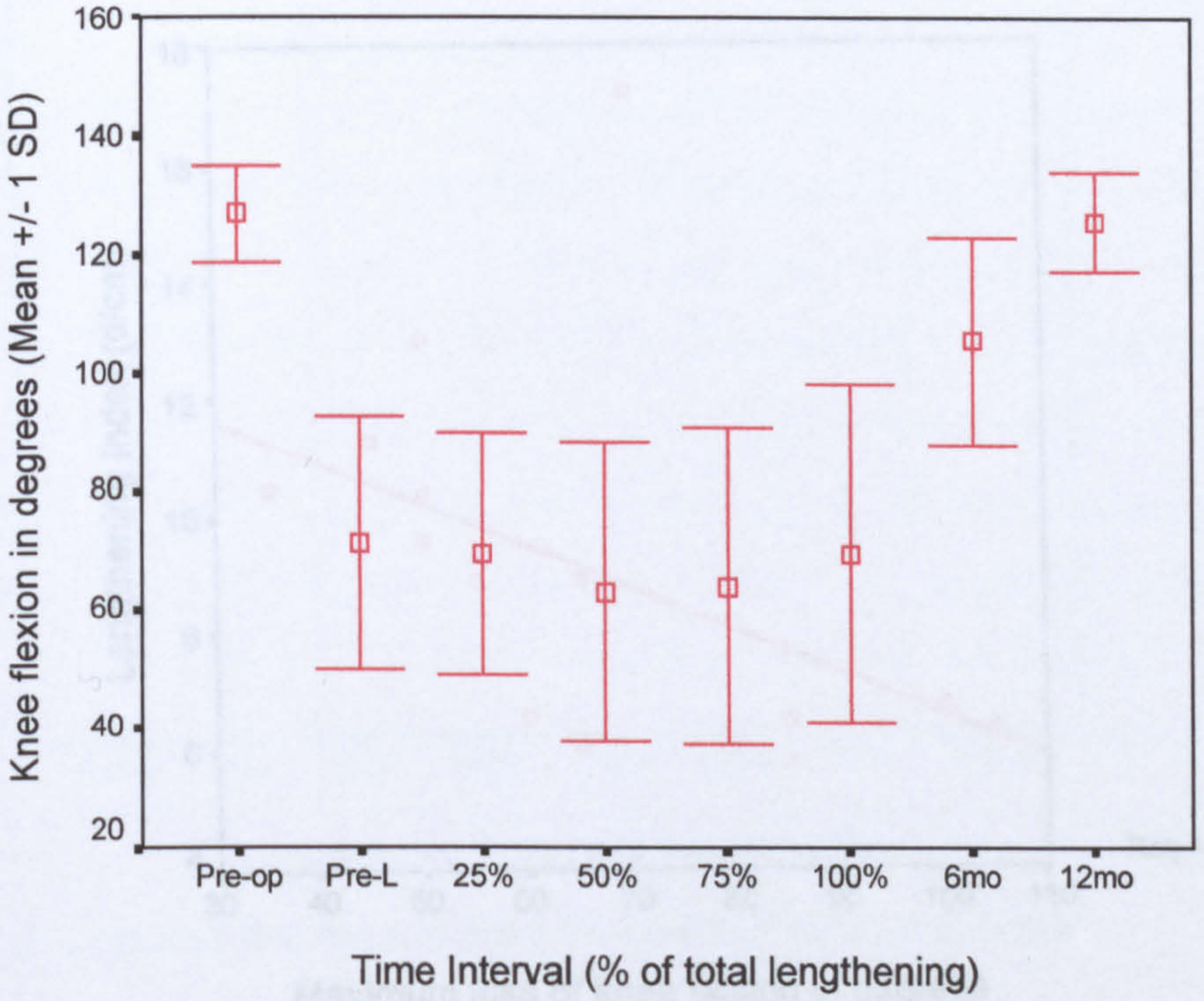


Figure 7-4 Knee Flexion Loss and Recovery – Femur and Tibia

Analysis of the factors influencing loss of range are shown in Table 7-7. The only factor that was predictive of maximum loss of range was the lengthening index (Figure 7-5). Those patients who lengthened more rapidly were more likely to lose flexion, losing 4° of flexion for each unit of the lengthening index. None of the factors tested were predictive of a final difference between the pre-operative and final follow up values.

Outcome measure	*Prediction Equation*	R^2	*ß [95% C.I.]*	*Stand ß*	*Sign.*
Maximum loss of knee flexion	Constant (100.9) + 3.6*Lengthening Index	26.3 %	3.6 [-.286 – 7]	.512	0.03

Table 7-7: Forwards stepwise regression modelling to predict loss of knee range(f+t)

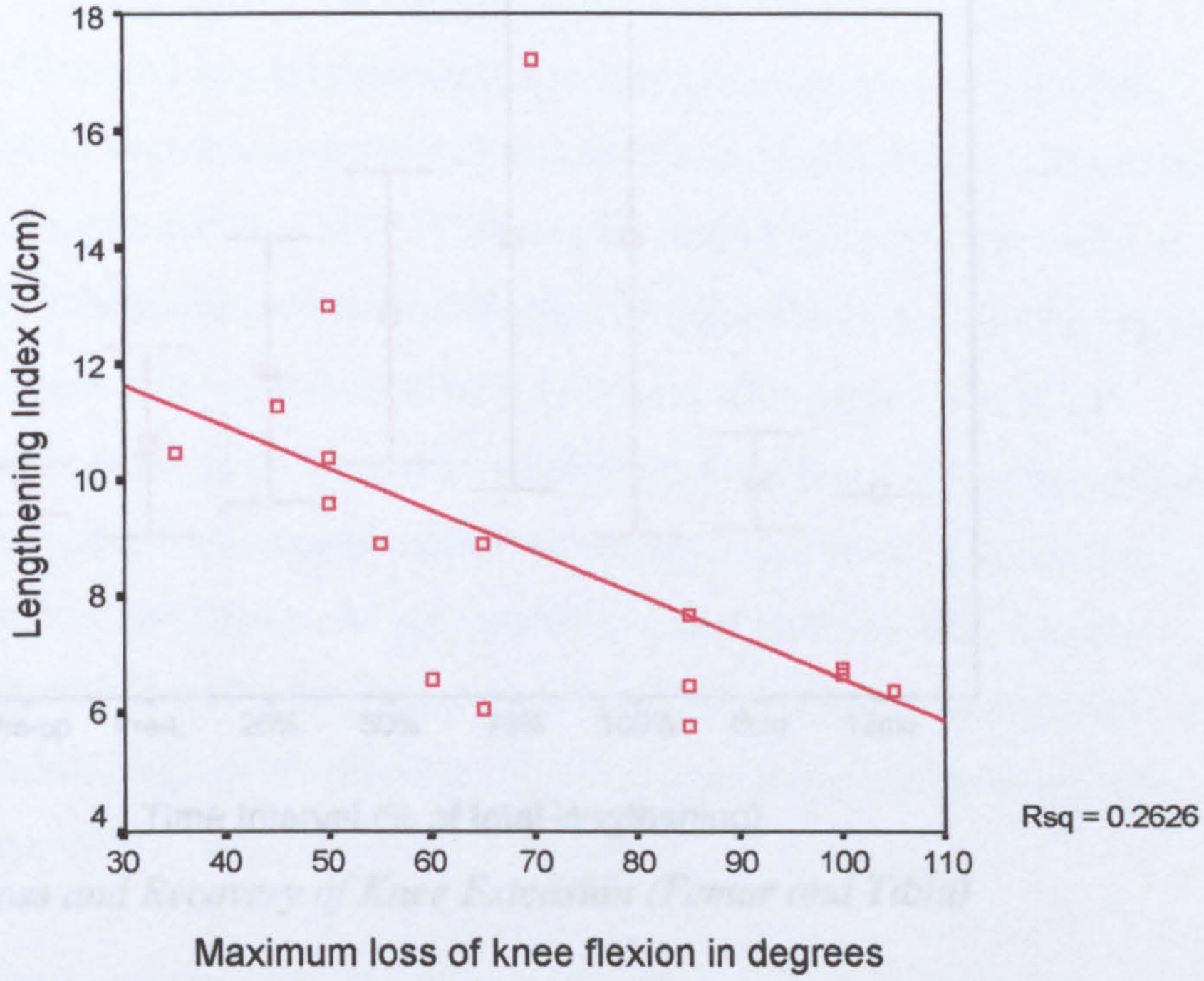


Figure 7-5: Loss of knee flexion versus Lengthening Index showing relationship between increased loss of flexion at higher rates of lengthening.

Knee extension

Pre-operatively the mean knee extension was 0° with patients losing an average of 2.5° in the latent period prior to distraction and losing a mean maximum of 13° ($p < 0.009$) by the end of lengthening. (Figure 7-6) Most patients lost a small amount of extension throughout the procedure, with the greatest loss being 55°. All patients regained full extension during the follow up period and there were no significant differences between the pre-operative and final post-operative values for knee extension. There were no factors that could be identified that influenced either the final difference or the maximum loss of knee extension. Two patients developed early knee subluxation as indicated by a lateral x-ray. Both of these patients had a fixed flexion deformity of more than 40°. (Figure 7-7)

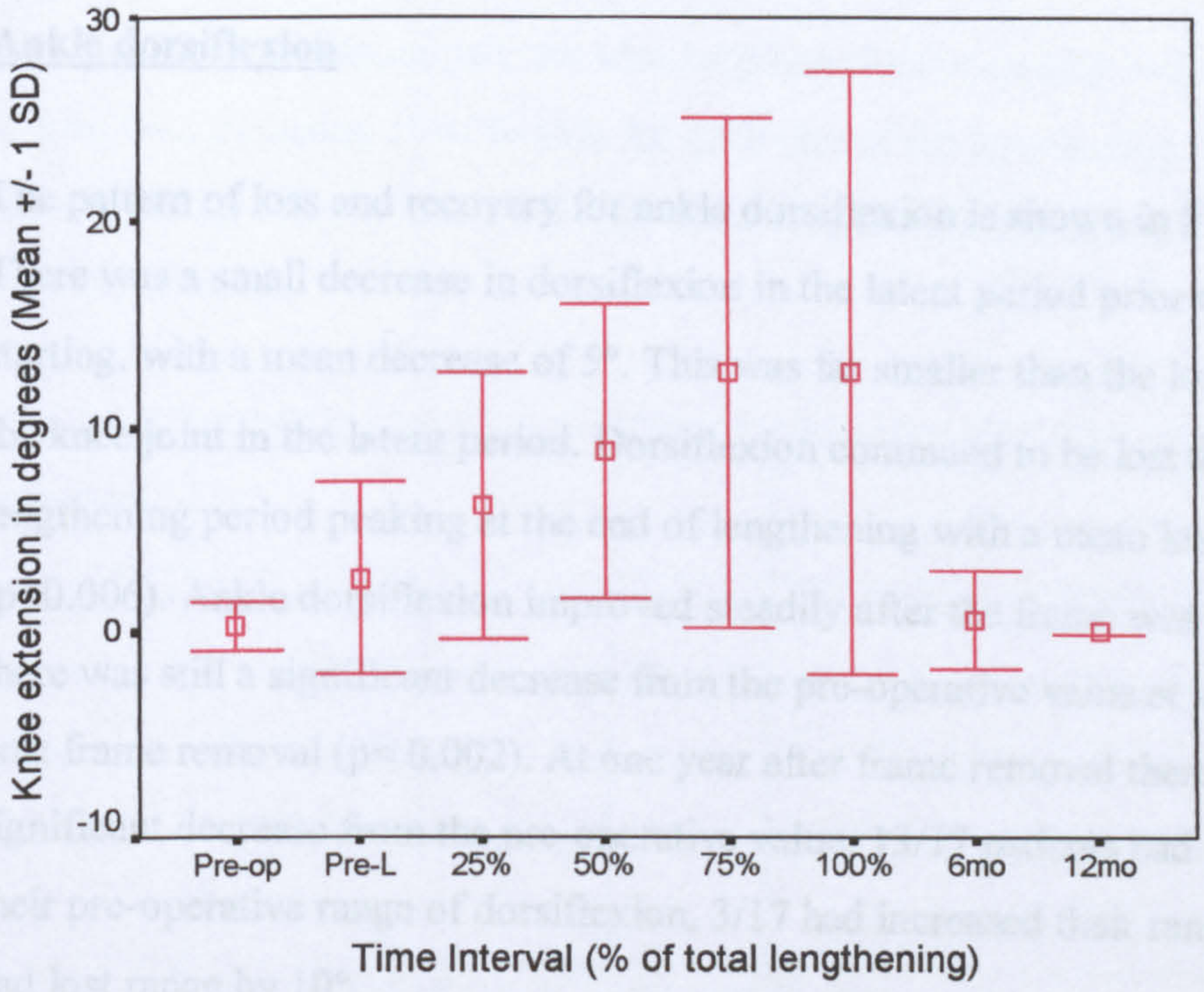
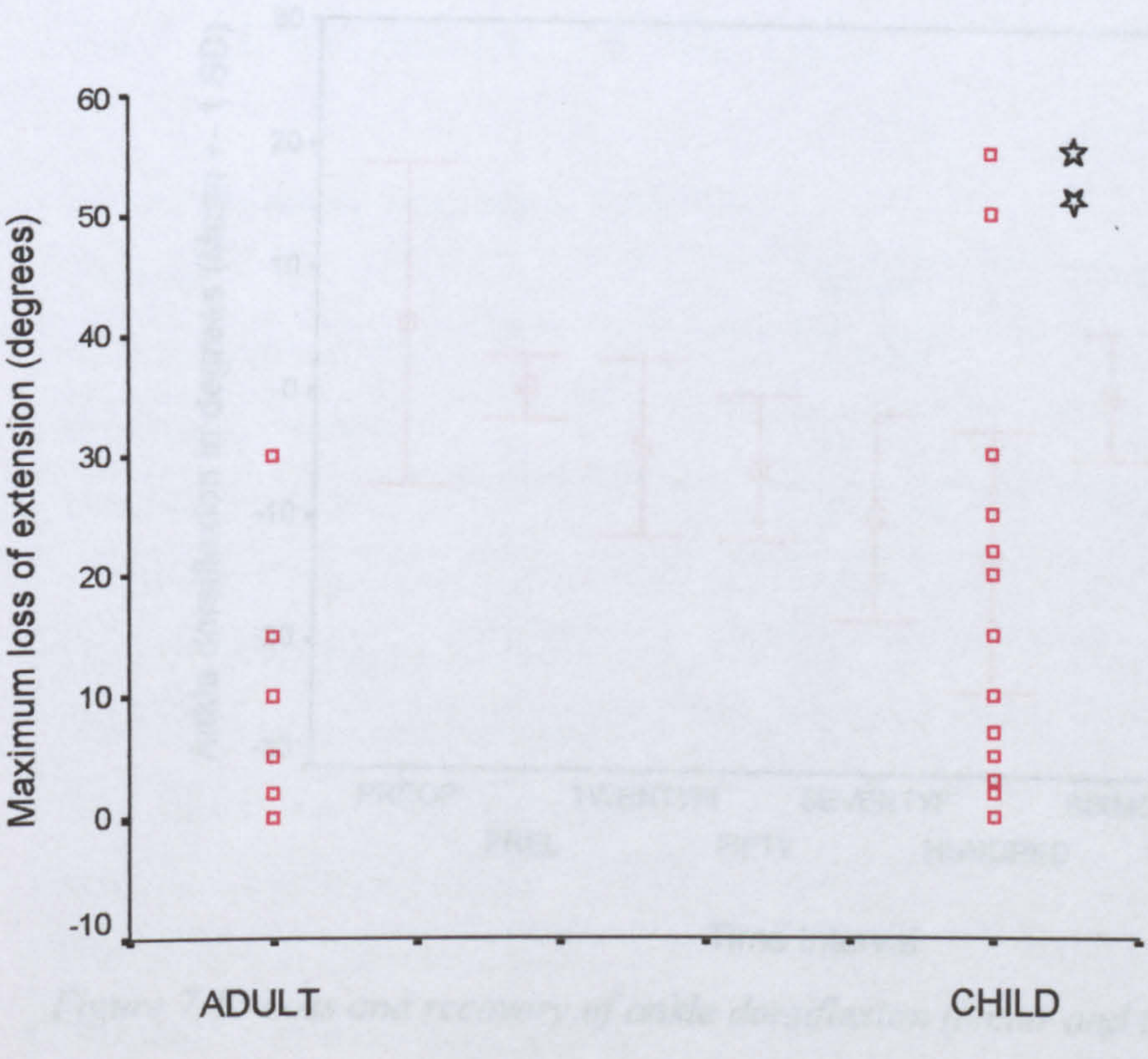


Figure 7-6: Loss and Recovery of Knee Extension (Femur and Tibia)



✡ **Cases with knee subluxation**

Figure 7-7: Loss of knee extension (FFD) and subluxation. (Femur and Tibia)

Ankle dorsiflexion

The pattern of loss and recovery for ankle dorsiflexion is shown in Figure 7-8. There was a small decrease in dorsiflexion in the latent period prior to distraction starting, with a mean decrease of 5°. This was far smaller than the losses seen at the knee joint in the latent period. Dorsiflexion continued to be lost throughout the lengthening period peaking at the end of lengthening with a mean loss of 18° ($p<0.006$). Ankle dorsiflexion improved steadily after the frame was removed but there was still a significant decrease from the pre-operative value at six months post frame removal ($p< 0.002$). At one year after frame removal there was no significant decrease from the pre-operative value. 13/17 patients had regained their pre-operative range of dorsiflexion, 3/17 had increased their range and one had lost range by 10°.

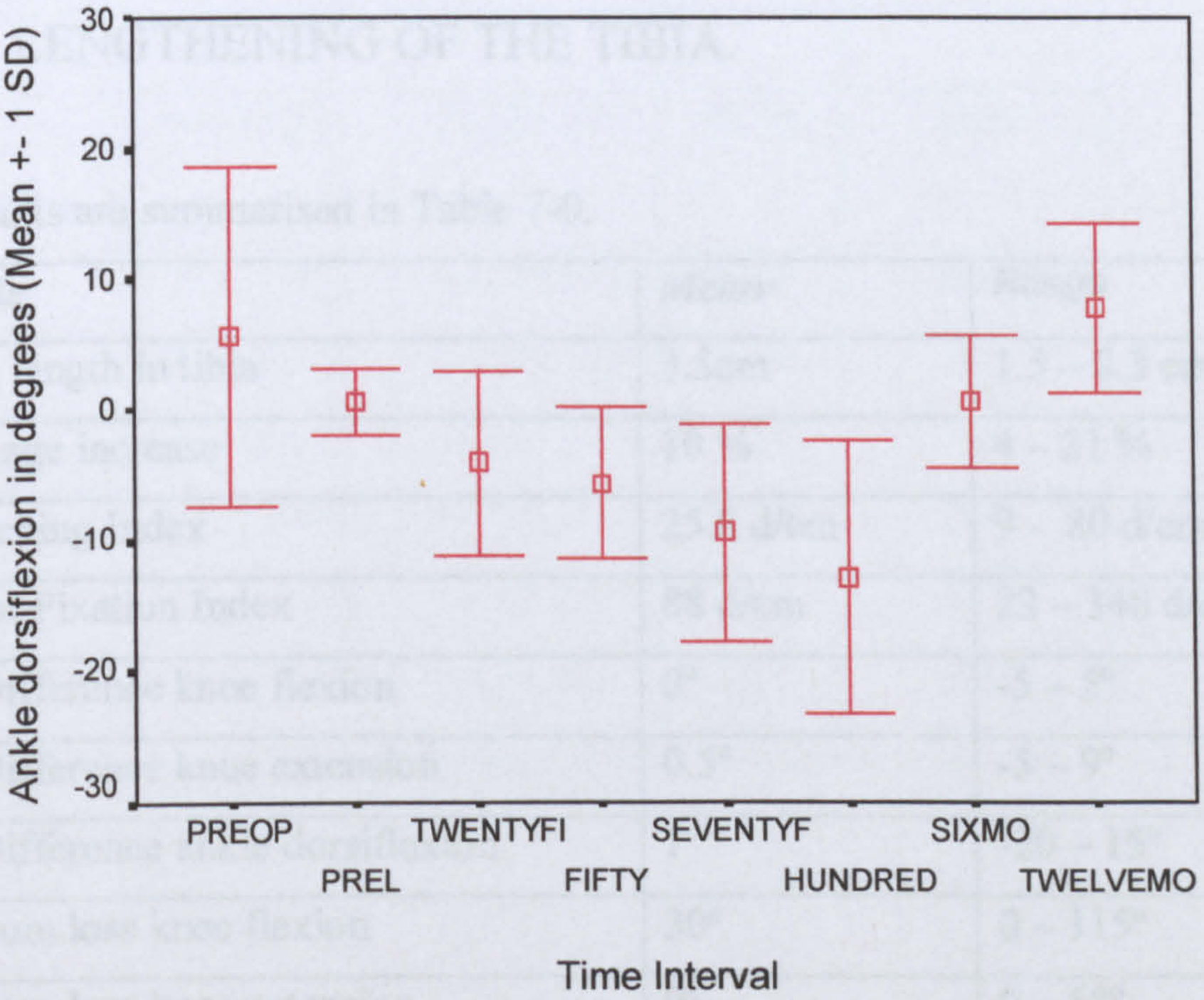


Figure 7-8: Loss and recovery of ankle dorsiflexion (femur and tibia)

The analysis of the factors influencing loss of range are shown in Table 7-8. The main factor that was predictive of the final loss of dorsiflexion was the presence of a foot frame in the frame construct. The rate of lengthening was a lesser factor. Those patients who had a foot frame were understandably protected from losing

dorsiflexion whilst those patients who lengthened more rapidly were more likely to lose flexion, losing 1° of flexion for each unit of the lengthening index. No factors were predictive of a final difference between the pre-operative and final follow up values.

Outcome measure	***Prediction Equation***	***R^2***	***ß [95% C.I.]***	***Stand ß***	***Sign.***
Maximum loss of dorsi-flexion	Constant (-7.6)	92.1%	-7.6 [-12.89 , -2.50]		.007
	+ (-33.27 * presence of a foot frame)		-33.27 [-39.67 , -26.77]	-.877	.000
	+ (.88 * Lengthening Index)		.88 [.314 – 1.44]	.267	.005

Table 7-8 Regression Analysis of Ankle dorsiflexion.

7.4.3 LENGTHENING OF THE TIBIA.

The results are summarised in Table 7-9.

Variable	*Mean*	***Range***
Gain in length in tibia	3.5cm	1.5 – 8.3 cm
Percentage increase	10 %	4 – 21 %
Lengthening Index	25.8 d/cm	9 - 80 d/cm
External Fixation Index	88 d/cm	22 – 340 d/cm
Final Difference knee flexion	0°	-5 – 5°
Final Difference knee extension	0.5°	-5 – 9°
Final Difference ankle dorsiflexion	1°	-20 – 15°
Maximum loss knee flexion	30°	0 – 115°
Maximum loss knee extension	9°	0 – 58°
Maximum loss ankle dorsiflexion	15°	-30 – 30°

Table 7-9: Summary of lengthening of tibia

Knee Range of Motion

The pattern of knee flexion and extension during and after lengthening is shown in Figures 7-9 & 7-10 and Tables 7-10 & 7-11.

There is a steady loss of knee extension throughout the lengthening period peaking at the 75% point of lengthening. Thereafter there is recovery of knee extension until at both 6 months and at the final review 12 months after frame removal knee extension has recovered to the pre-operative value.

	Mean flexion and Standard Deviation (degrees)	Decrease in flexion from pre-op + SD (degrees)	F value	Significance of change from baseline.
Pre-op	125 (17.73)			
Pre-lengthening	94 (18.21)	31 (25.67)	42.66	.000
25%	92 (17.85)	33 (25.04)	64.05	.000
50%	93 (19.11)	32 (24.73)	13.96	.001
75%	94 (20.51)	31 (25.54)	2.44	.129
100%	98 (19.68)	27 (23.37)	17.21	.000
6 mo	121 (15.76)	4 (8.19)	6.45	.017
12 mo	126 (15.60)	-1 (5.08)	.779	.385

Table 7-10: Loss and recovery of knee flexion (Tibial lengthening).

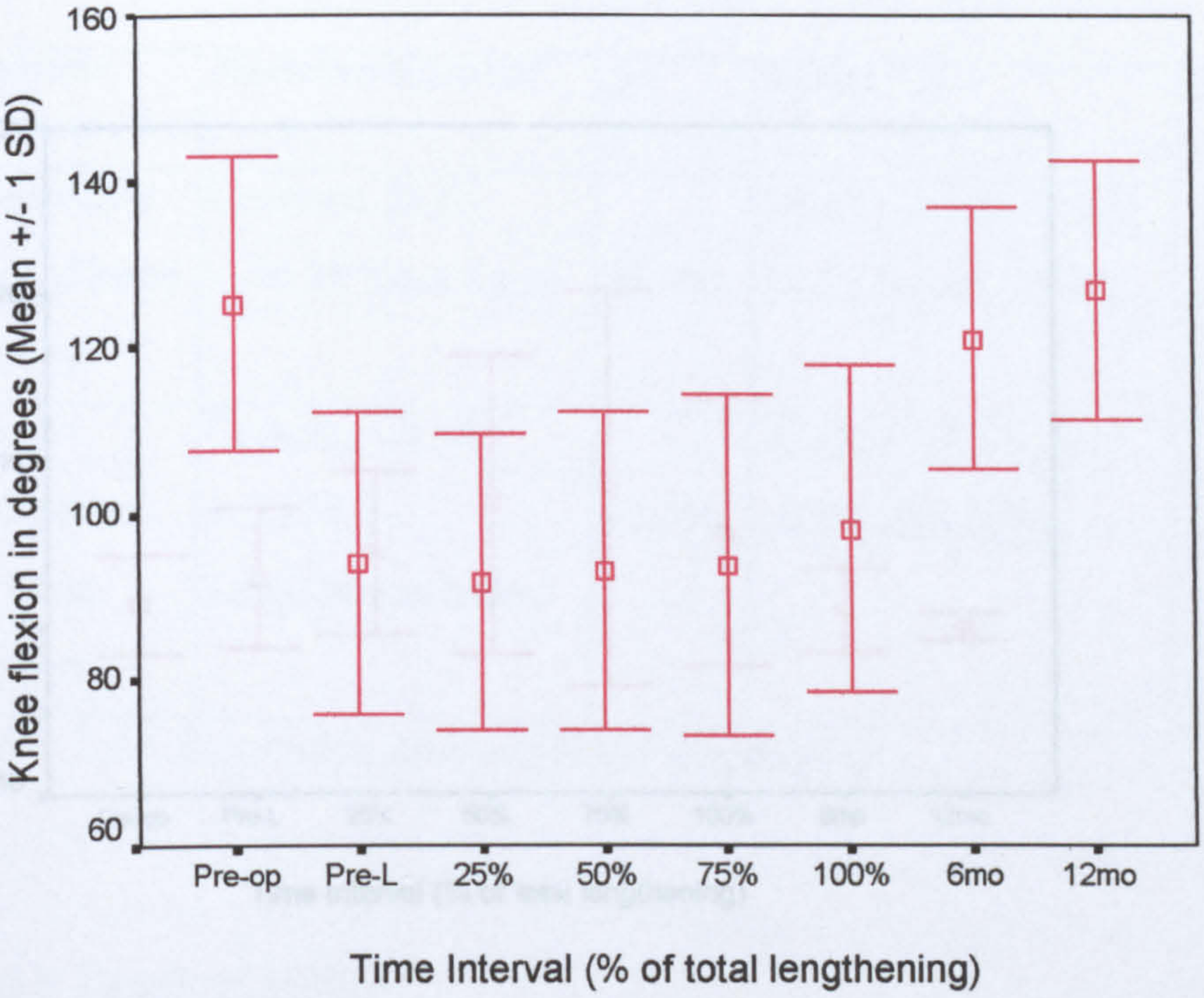


Figure 7-9: Loss and recovery of knee flexion (tibia)

	Mean extension + SD (degrees)	Mean decrease in extension +SD from pre-op (degrees)	F value	Significance of change from baseline.
Pre-op	1.5 (3.02)			
Pre-lengthening	3 (4.17)	1.5 (4.40)	4.70	0.39
25%	4.5 (4.88)	3 (5.55)	14.19	0.001
50%	7 (8.90)	5.5 (9.79)	.918	0.346
75%	8.00 (11.87)	6.5 (12.39)	5.67	0.024
100%	6 (7.95)	4.5 (8.05)	4.18	0.050
6 mo	1 (2.53)	0.5 (2.79)	.019	0.890
12 mo	3.5 (.865)	2 (2.78)	.029	0.865

Table 7-11: Loss and recovery of knee extension (Tibial lengthening)

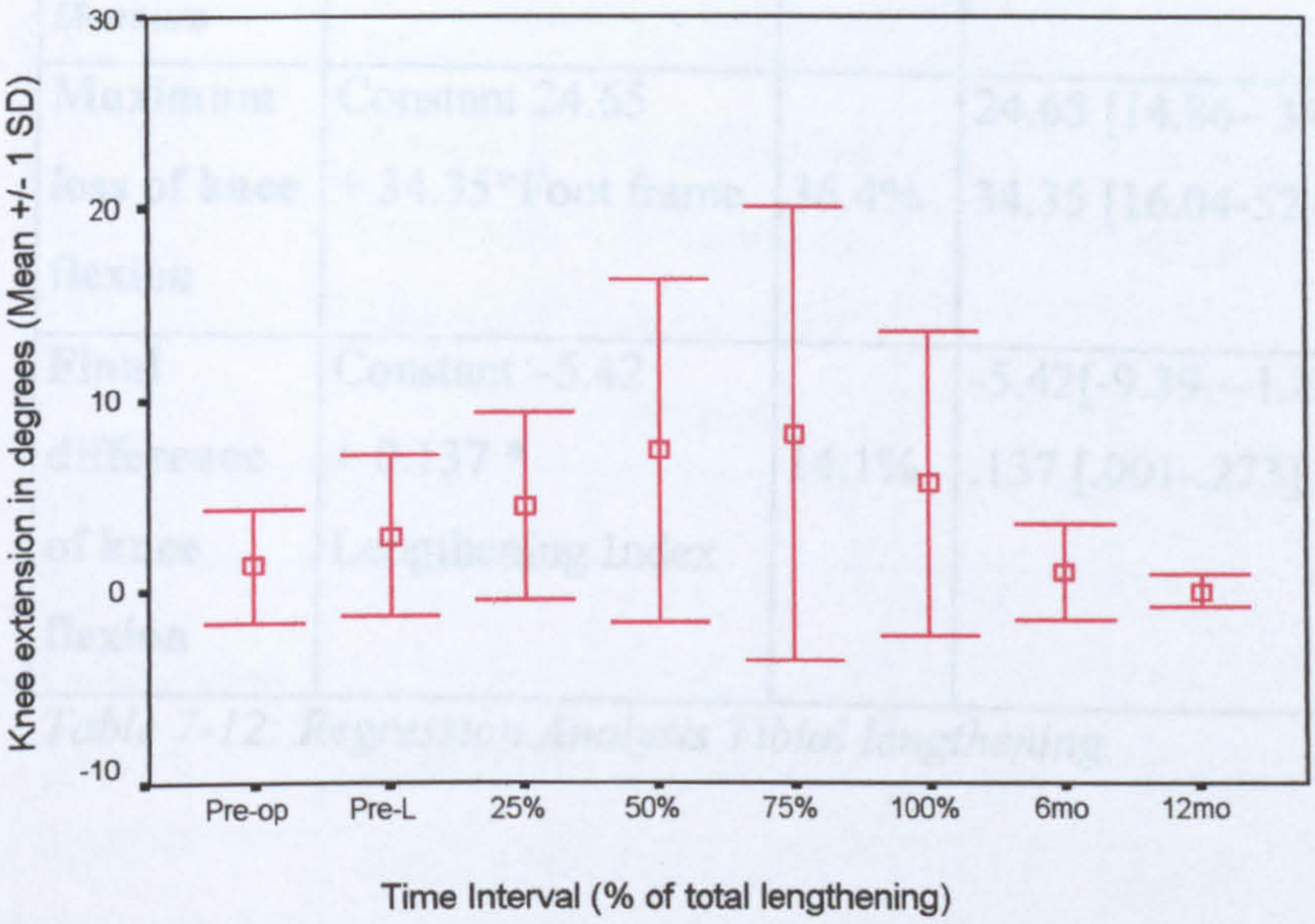


Figure 7-10: Loss and recovery knee extension (Tibial lengthening)

Interestingly, whilst there was a steady loss of extension resulting in fixed flexion deformity of the knee during lengthening, there was also a simultaneous loss of the ability to fully flex the knee. The ability to fully flex the knee fell noticeably in the latent period prior limb lengthening occurring and continued to fall slowly until it reached a maximum towards the end of the lengthening process at the 75% point. Recovery occurred soon after frame removal with 97% of recovery occurring by 6 months and the full pre-operative range restored by twelve months after frame removal.

Of the 30 patients undergoing tibial lengthening 28 (93.3%) regained their pre-operative ROM for knee flexion and all regained their pre-operative range of knee extension. Of the two patients who had not regained their knee flexion at 12 months, both had regained their pre-operative range by 18 months.

The analysis of the factors influencing the loss of range is shown in Table 7-12. Maximum loss of knee flexion was associated with the presence of a frame construct that included a foot frame. Final loss of knee flexion was associated with the Lengthening Index; those who were lengthened more rapidly, were more likely to lose knee flexion. No factors were identified for the loss of knee extension or ankle dorsiflexion.

Outcome Measure	*Prediction Equation*	R^2	*ß [95% C.I.]*	*Stand. ß*	*Sign.*
Maximum loss of knee flexion	Constant 24.65 + 34.35*Foot frame	36.4%	24.65 [14.86– 34.43] 34.35 [16.04-52.65]	.603	.001
Final difference of knee flexion	Constant –5.42 + 0.137 * Lengthening Index	14.1%	-5.42[-9.39—1.46] .137 [.001-.273]	.376	.05

Table 7-12: Regression Analysis Tibial lengthening.

Ankle Range of Motion.

The pattern of loss and recovery of ankle dorsiflexion is shown in Figure 7-11 and Table 7-13.

Pre-operatively the mean ankle dorsiflexion was 4° (S.D. 10.17) with patients losing an average of 3.5° in the latent period and losing a maximum of 12.8° ($p< 0.001$) by the end of lengthening. There was a gradual recovery of dorsiflexion following frame removal and the final difference between the dorsiflexion at 12 months post frame removal and pre-operatively was not statistically significant ($p<0.126$). However, 9 patients (30%) had a loss of dorsiflexion on review at 12 months, 7 of 5° and 2 of 15°. 17 patients (56.5%) retained their pre-operative range of dorsiflexion and 4 (13.5%) increased their range of motion.

Most patients retained full plantarflexion and all regained their full range by the final review.

	Mean dorsiflex-ion + SD (degrees)	***Decrease in dorsiflexion from pre-op value +SD (degrees)***	***F value***	***Significance of change from baseline.***
Pre-op	4 (10.17)			
Pre-lengthening	.5 (7.04)	3.5 (6.5)	4.37	0.045
25%	-2 (7.14)	6 (7.91)	64.07	0.000
50%	-6 (10.45)	10 (11.74)	10.32	0.003
75%	-8 (10.87)	12 (10.15)	3.33	0.078
100%	-8 (11.60)	13 (10.96)	19.59	0.000
6 mo	-.5 (7.98)	4.5 (7.82)	1.15	0.292
12 mo	3.5 (9.11)	0.5 (6.99)	2.48	0.126

Table 7-13: Loss and Recovery of ankle dorsiflexion (Tibal lengthening)

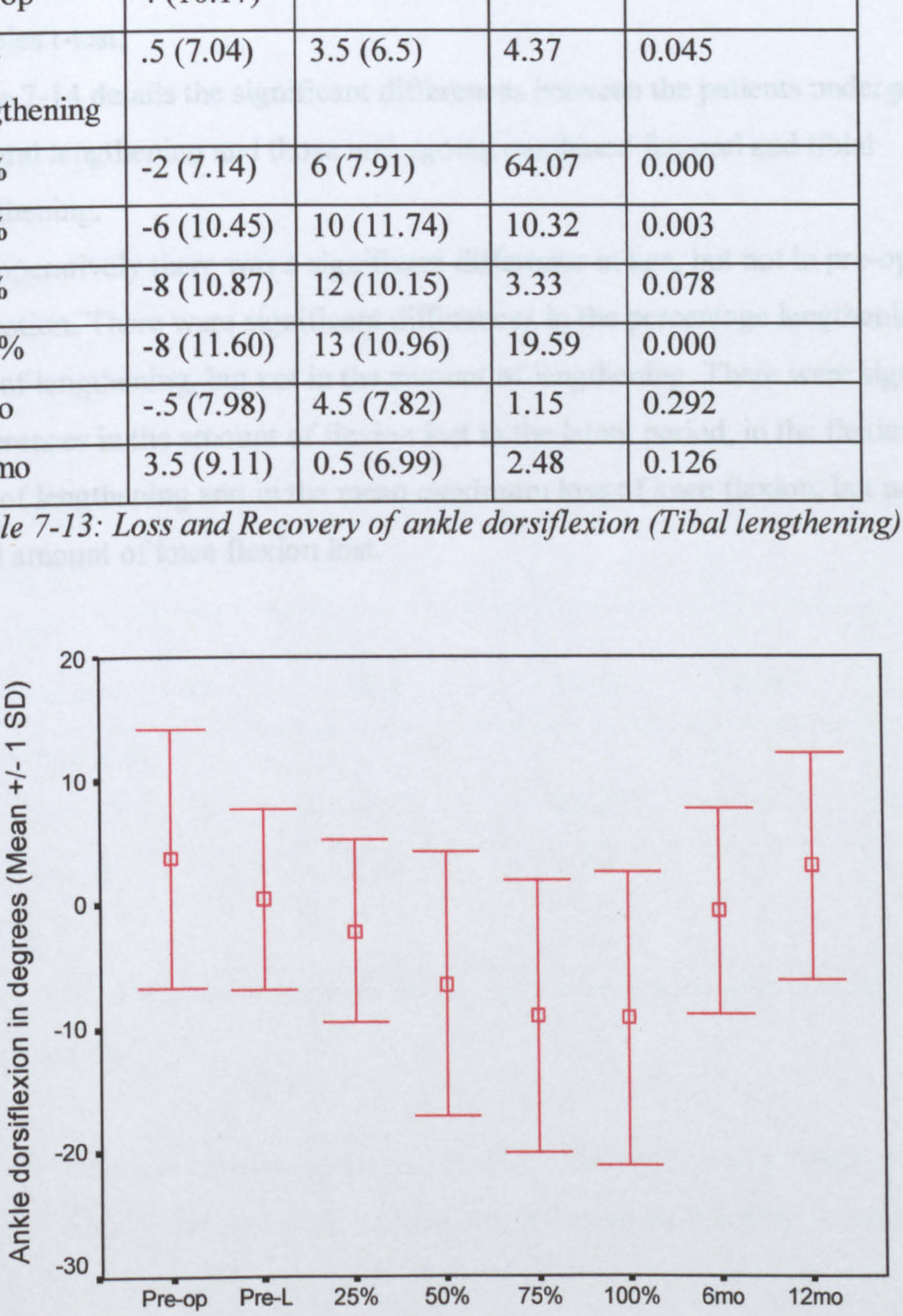


Figure 7-11: Loss and recovery of ankle dorsiflexion (Tibial lengthening).

7.4.4 Comparison between the three surgical groups

The method chosen to deal with the heterogeneity of the sample was to analyse the group separately according to the bone being lengthened. In order to confirm whether this decreased heterogeneity, the groups were compared to each other and any significant differences either at baseline or in the final result noted.
Comparisons were made between one group and another using an independent samples t-test.
Table 7-14 details the significant differences between the patients undergoing femoral lengthening and those undergoing combined femoral and tibial lengthening.
Pre-operatively there was a significant difference in age, but not in pre-op range of motion. There were significant differences in the percentage lengthening and rate of lengthening, but not in the amount of lengthening. There were significant differences in the amount of flexion lost in the latent period, in the flexion at the end of lengthening and in the mean maximum loss of knee flexion, but not in the final amount of knee flexion lost.

Variable	***Femur (Mean)***	***Femur & Tibia (Mean)***	***Mean difference***	***t- value***	***Significance (p-value)***
Age (Years)	26.6	9.17	17.5	5.69	0.000
Length gained in femur (cm)	4.36	3.65	0.71	1.376	n.s.
Percentage lengthening (%)	9.81	13.85	4.03	2.38	0.02
Lengthening Index	15.8	8.9	6.9	4.61	0.000
External Fixation Index	32.0	32.7	0.72	0.153	n.s.
Pre-op knee flexion (°)	120	127	7	2.15	n.s
Pre-L knee flexion (°)	86.11	71.47	14.6	1.97	0.05
End of lengthening (°)	89.1	69.7	19.46	2.06	0.04
Maximum loss of flexion (°)	41.1	68.2	27.12	3.6	0.001
Final loss of flexion (°)	-1.1	0.58	1.69	3.6	n.s.

Table 7-14: Differences between femur and femur & tibia group by independent samples t-test.

The difference at baseline and in the results between the group undergoing simultaneous femur and tibia lengthening and tibial lengthening are shown in Table 7-15.

Variable	***Tibia (Mean)***	***Femur & Tibia (Mean)***	***Mean difference***	***t- value***	***Significance (p-value)***
Age (Years)	28.2	9.17	19	5.86	0.000
Length gained in tibia (cm)	3.48	4.47	0.99	1.31	n.s.
Percentage lengthening (%)	9.7	14.92	5.18	3.86	0.000
Lengthening Index	25.86	8.9	16.9	4.9	0.000
External Fixation Index	88.04	32.7	55.3	3.65	0.001
Pre-op dorsi-flexion (°)	4.23	5.62	1.39	0.40	n.s
Pre-L dorsi-flexion (°)	0.5	0.62	0.12	0.06	n.s
End of lengthening (°)	3.5	7.8	4.31	1.67	n.s.
Maximum loss of dorsi-flexion (°)	14.6	20	5.32	1.23	n.s.
Final loss of dorsiflexion (°)	0.73	2.18	1.45	1.2	n.s.

Table 7-15: Differences between tibia and femur & tibia group by independent samples t-test.

Table 7-15 details the significant differences between the patients undergoing tibial lengthening and those undergoing combined femoral and tibial lengthening. Pre-operatively there was a significant difference in age, but not in pre-op range of motion. There were significant differences in the percentage lengthening, the rate of lengthening and in the duration of fixation, but not in the amount of lengthening. There were no significant differences in the amount of knee flexion or dorsiflexion lost during or at the end of lengthening.

7.5 Discussion

It is well documented that joint and muscle contractures continue to provide the clinician with a significant problem during limb lengthening (Paley 1988,1990, Green 1991, Hezenberg 1994, Simard 1992, Coglianese 1993).

Muscle has been shown to generate new tissue in response to lengthening (Simpson 1995). However, in order to give the stimulus to the muscle to grow it is essential to retain full ROM, as it is only at the extremes of motion that the muscle is stretched and put under tension. Tension on the muscle is considered to be the principal stimulating mechanism for muscle regeneration (Paley 1990). This study highlighted that significant decreases in knee flexion occur early in the programme before lengthening has started, in both isolated femoral lengthening and in simultaneous femoral and tibial lengthening. Thus these patients will not be stimulating the muscle to grow in the early stages of lengthening and it may be beneficial to concentrate physiotherapy on the early post-operative phase to prevent this early loss of joint range.

Whilst it is thought that tension stimulates muscle histogenesis, it also leads to muscle contractures if the connective tissue element of the muscle has not adapted fully. Early loss of range in the latent period cannot be attributed to muscle tension. The surgical technique that was used in the study aimed to minimise tethering of the soft tissues by checking for tethering by means of putting the joint through its full range with the transfixation wires and external fixation pins in situ. Whilst some decrease from the pre-operative range of knee flexion is likely due to the physical constraints imposed by the fixators, the loss observed was greater than that which is likely to be due to pure physical limitations. Yasui et al (1997)

suggest that loss of knee flexion immediately after the operation is due to irritation of the iliotibial tract by the distal femoral pins. Other explanations for this early loss of range are insufficient patient analgesia in the immediate post-operative phase, apprehension about moving and poor psychological acceptance of the frame by the patients. The further loss in ROM, which was greatest towards the end of the lengthening phase, is most likely attributable to the tension on the tissues (Simpson 1995, Kyberd 1994, Leong 1979, Wolfson 1990).

Whilst some authors state that physiotherapy and stretching programmes must be completed for six hours per day to avoid contractures (Paley 1990, Green 1990) this may be impossible for many patients to integrate into their lives. The amount of physiotherapy received by most of our patients fell far short of the 6 hours of physiotherapy and functional loading advocated by Ilizarov. The physiotherapy given in the early stages of rehabilitation i.e. during the latent period and for the first 2 days of lengthening was standardised as the patients were in hospital. Subsequently patients were referred for out-patient treatment close to their homes and there was greater variability in the amount of physiotherapy each received.

In those patients undergoing simultaneous femoral and tibial lengthenings the frames on the femur and tibia were not linked and thus movement of the knee joint was unconstrained other than by soft tissue opposition. Regression analysis showed that lengthening one bone or more than one bone simultaneously had no effect on the loss of knee flexion range. Bowen et al (1993) carried out simultaneous ipsilateral femoral and tibial lengthening using the Wagner method of limb lengthening, and reported a high rate of knee subluxation in 3 out of 10 cases, whereas Curran et al (1999) utilised the Ilizarov device with linked frames throughout the lengthening process. They reported no cases of subluxation, but two of the patients developed an extension contracture of the knee that required a quadricepsplasty.

In our series of 17 simultaneous femoral and tibial lengthenings, 2 patients showed signs of subluxation during lengthening and were treated by slowing down the rate of lengthening, linking the frames and correcting the alignment of the two bones. It is possible that fewer problems were experienced with subluxation than have been reported by other authors, despite using unconstrained frames, due to the fact that the total length we aimed for in these patients was

smaller, averaging 6.9 cm (3.9 – 9.0). This is considerably less than that achieved by Curran who averaged 11 cm (7.8-18.5). Both the patients who subluxed regained full range of knee flexion without any further surgical procedures. Fixed flexion deformity of the knee increases the transverse component of the force vector of the hamstrings and increases the risk of subluxation of the knee. These results support the view that if loss of extension exceeds 40°, lengthening should be temporarily halted until range is regained, or stopped if recovery does not occur.

Of the 35 patients in the study who had the femur lengthened, all but three regained or improved their pre-operative ROM. None of the patients lost more than 10° flexion, this amount of loss of knee flexion is not sufficient to have an impact on functional abilities (Kettlekamp 1970, Rowe 2000, Laubenthal 1972). This incidence of permanent loss of full joint range is similar to that reported by other authors. Paley (1997) reported that 77% of his cases regained movement within a month but that 1/32 cases had restriction beyond 2 years and Yun (2000) reported 2/35 late contractures beyond 2 year follow up. Stanitski (1995) reported that 16/28 patients undergoing femoral lengthening were unable to flex the knee beyond 45° during lengthening. This resolved in all but 4 patients, two of whom recovered gradually over the course of 18 months, one had a manipulation under anaesthesia and one had a quadricepsplasty.

The analysis of the patients undergoing femoral lengthening found a relationship between the rate of lengthening as represented by the lengthening index (days of lengthening / amount of lengthening) and the likelihood of a significant decrease in the range of knee flexion. Other factors that had an influence on the loss of knee flexion were whether the patient was an adult or a child, children tolerating the procedure less well than adults. The reasons for this are not known. The children were operated on for congenital deformities, which are reported to have a higher complication rate (Stanitski 1995). The children were still growing and so were naturally lengthening their muscles as well as the imposed increases in length created by the surgery. In addition, in the children, lengthening was producing a genuine increase in the limb length whereas, in the adults most of whom had a mal-union or non-union, the limb was being restored to a length that

it had already achieved prior to injury. These differences could account for the greater loss of ROM in the children compared to the adults.

In the patients in whom the tibia was lengthened there were problems in maintaining range of motion at both the knee and the ankle. Except in those cases where the loss of range of motion at the ankle had been controlled by the use of a foot frame or a heel wire, there was a tendency for range to be maintained at one joint and lost at the other. Regression analysis showed that those patients who had the ankle range controlled by a foot frame were most likely to lose range of motion at the knee. However, in the patients that lost range at the knee, this was a temporary disability and in all cases full range of knee motion was eventually regained, within 12 months in 28/30 cases and within 18 months in the remaining two cases, without any change in the range of motion at the ankle.

In those cases where a foot frame or heel wires were used the range of ankle dorsiflexion was more likely to return to the pre-operative value. A significant number of the patients undergoing tibial lengthening lost dorsiflexion and exhibited signs of an equinus contracture. This failed to completely resolve after the frame had been removed and some patients were left with a permanent loss of dorsiflexion.

Other authors have also reported difficulties in maintaining dorsiflexion during tibial lengthening, Noonan (1998) reported that in 147 tibiae that were lengthened, 50% had to undergo subsequent lengthening of the Achilles tendon to restore ankle motion and 8 cases (5.5%) had severe contracture or subluxation of the knee joint. Stanitski (1996) reports that 3/62 (5%) of operations to lengthen the tibia resulted in persistent equinus contractures that required Achilles tendon lengthening or posterior ankle capsulotomies to restore a plantargrade foot position. In her series, 12 (20%) of the limbs had prolonged ankle stiffness which had resolved in 9 of the cases by the final review 18 months – 5 years after surgery. In our series of patients 9 (30%) had failed to regain their pre-operative range of dorsiflexion. Importantly, most patients (93%) could get the foot to a neutral or plantargrade position, thus meaning that they could achieve an adequate functional gait pattern after surgery. 1/30 (3.3%) went on to have a lengthening of the Achilles tendon which restored the pre-operative range but one patient was left

with a 10° equinus contracture, impairing the ability to walk with a normal heel-toe gait pattern (Rose and Gamble 1994, Hill 1995, Crosbie 1999).

The failure of patients to achieve active dorsiflexion beyond the neutral position is clinically significant. Perry (1992) states that as the arcs of normal ankle motion are small, yet functionally critical to either progression or stability, in some situations a 5° error is clinically significant. In normal gait, dorsiflexion beyond the neutral occurs in the mid-stance and terminal stance phases when propulsive forces are being applied to the foot, at least 10° dorsiflexion is used to roll over one's forefoot for a full stride in the last stages of stance (Root 1977). If there is decreased dorsiflexion the heel strike phase may also be reduced, decreasing the momentum for progression and the knee flexion contribution to shock absorption. These effects are particularly noted when the patient walks fast, runs, walks on slopes or on uneven ground (Perry 1992). Thus the loss of dorsiflexion observed, whilst small, is clinically significant in terms of the patients' optimum function.

A number of authors have indicated the need to maintain the range of motion at the ankle throughout the course of the lengthening programme. They advocate physiotherapy, splinting or a combination of these as the most effective methods of achieving this (Paley 1990, Green 1991, Simard 1992, Coglianese 1993, Folkerts 1992, Burton 1991). Lehman (1991) recommended a physiotherapy programme of stretching the soleus-gastrocnemius-Achilles tendon complex reinforced by splints applied to keep the foot in a plantargrade position. He also advocates prophylactic use of heel wires or a foot frame in all cases where the child is too young to co-operate with physiotherapy, where lengthening will exceed 5-6 cm and where there is pre-existing damage to the soleus-gastrocnemius complex. Nakamura et al (1996) compared tibial lengthenings in patients with achondroplasia treated by either physiotherapy or splintage. He reported that physiotherapy on its own for 15 minutes a day was ineffective at preventing equinus contractures even when the patient could walk. Conversely, use of an orthosis for a minimum of 16 hours a day prevented equinus in patients undergoing up to 50% lengthenings. Caution needs to be applied when interpreting this result as patients with achondroplasia have a different soft tissue response to lengthening than other patient groups. In the present study a combined

approach of out-patient physiotherapy twice a week, a stretching programme carried out at home and use of a lightweight, removable orthosis to maintain the foot in a neutral position was used.

There are very few studies that have studied the effect of lengthening on range of motion. Indeed, it is only in the paper by Herzenberg (1994) that range of motion has been specifically studied. Other studies have looked at the results of leg lengthening procedures as a whole and include range of motion as one aspect of their results (Stanitski 1995, Paley 1988, Yasui 1997, Noonan 1998). In conducting this study, the reliability of the measurement technique has been enhanced and for the first time range of motion has been studied prospectively throughout the entire time course of the leg lengthening process. The results obtained build on those of Herzenberg for femoral lengthenings, and present longitudinal data for simultaneous femoral and tibial lengthening and for tibial lengthening for the first time. The results are of particular importance to physiotherapists as they identify the need for intensive physiotherapy in the latent phase prior to distraction starting. This has not been identified in the previous reports on the physiotherapy management of patients undergoing limb lengthening (Simard 1992, Green 1990, 1991, Folkerts 1992, Coglianese 1993).

The lack of homogeneity amongst the group presents a problem in generalising the results. The method of dividing the sample into three according to the limb(s) lengthened improved heterogeneity, although there was still variation between the groups. The most significant differences at baseline were of age, those in the combined femur and tibia group were much younger than those in the other two groups, and more likely to be receiving surgery due to a congenital condition. The results of lengthening showed that whilst there were differences between the groups in the amount of range they lost during lengthening, these differences were not present at the final review.

7.6 Summary

- Lengthening of the femur resulted in loss of range of motion at the knee joint. This was less severe in patients lengthened at a slower rate ($p<0.05$).

- A major decrease in range early in the programme before distraction had started was observed, indicating that factors other than muscle tension may be responsible for early loss of joint range. This stresses the need for meticulous surgical technique and intensive physiotherapy treatment at this stage of the programme.

- A fixed flexion deformity at the knee of more than 40° was associated with increased risk of posterior subluxation. This indicates the importance of maintaining knee extension as well as knee flexion. It is suggested that lengthening is halted if more than 40° FFD occurs.

- Lengthening of the tibia resulted in a permanent loss of dorsiflexion in a small number of patients, whilst there was no permanent loss of knee range of motion. It is suggested that rehabilitation efforts are concentrated on all joints, but specifically at maintaining the ankle joint in at least a neutral position.

- Patients who had a heel wire or foot frame were less likely to sustain any permanent loss of dorsiflexion, but did temporarily lose knee flexion. It is suggested that the use of such frame constructs is considered prophylactically in patients undergoing substantial lengthening of the tibia.

CHAPTER 8 - PREDICTING THE LOSS OF KNEE FLEXION USING INHERENT MUSCLE LENGTH

8.1 Introduction

In studying the patients' loss of range of motion during lengthening, an impression was gained that there were some patients whose tissues were able to tolerate limb lengthening better than others. It was postulated that this might be due to a difference in the inherent flexibility or suppleness of the patients. It is recognised that achondroplastic patients are much better able to tolerate imposed changes of length and may be lengthened by as much as 50% of the original limb length (Ganel 1979, Atar 1991,Yasui 1997, Saleh 1991). This is thought to be because of the marked elasticity in the soft tissue composition of achondroplastic patients (Burton 1991). In contrast the tissues of patients with LLD from other congenital conditions are said to be difficult to lengthen and there is a high complication rate when lengthening these patients. Stanitski (1995) reported an incidence of transient knee joint stiffness of 47% in those patients with LLD compared to 8% in those patients with short stature during femoral lengthening. Loss of knee movement is a recognised problem during limb lengthening, but the amount lost is variable between patients and the factors associated with it are not clearly identified (Herzenberg 1994). Some authors have related loss of range to the total amount of lengthening, or to the percentage lengthening. These figures do not take into account the width of the limb and its effect on the various muscles nor the inherent passive compliance of the soft tissues.

It is hypothesised that variations in the inherent muscle length of patients may be a factor in determining which patients lose range of motion during limb reconstruction procedures.

8.2 Purpose

To investigate if the amount of joint range that is lost during limb lengthening might be affected by the inherent passive compliance and length of the patients' soft tissues.

8.3 Method

Patients were selected retrospectively from the original cohort of 35 patients who had undergone lengthening of the femur or femur and tibia All those patients who had complete x-ray records of both an AP and lateral x-ray of the hip and knee joints and a scanogram were included in the study. Those patients in whom the data was incomplete or where the x-ray views were unclear were excluded.
A mathematical model was developed to calculate the inherent length of the quadriceps and hamstrings based upon anthropometric data derived from x-rays and scanograms.

The 'spare' length of the muscle was then calculated and this compared with the loss of knee flexion that the patient had experienced whilst undergoing limb lengthening surgery. The 'spare' length of the muscle was defined as the difference in the length of the muscle at its longest position at one extreme of the arc of movement of the knee joint, minus the length in its shortest position at the other extreme of joint position.
The total amount of knee flexion lost was calculated by subtracting the pre-op knee flexion from the worst knee flexion during lengthening.

Lateral x-rays of the knee were used to measure the radius of curvature of the femoral condyles and this was taken as the distance of the extensor mechanism from the centre of rotation of the knee. The position of attachment of the quadriceps and patella tendon was taken to be the mid-point of the patella.
The patella increases the distance of the extensor mechanism from the centre of the knee, but as it runs in a groove on the femur, the radius of the condyles was taken as the distance of the quadriceps tendon from the centre of rotation.

Magnetic Resonance Imaging scans of the hip and cross-sectional anatomy textbooks demonstrated that the hamstrings tendons lie at a distance from the femoral head approximately equal to the radius of the femoral head. As the edge of the femoral head is 1 radius from the centre of rotation of the hip, the hamstrings distance from the centre of rotation of the joint was calculated to be equal to the diameter of the femoral head. For spherical femoral heads this could be measured on the Antero-Posterior scanogram views of the hips, using a femoral head gauge.

The difference in length between the lengthened and shortened position of the quadriceps and hamstrings muscles was calculated by:

1. Measuring the range of movement of the knee and hip joints respectively.

2. Estimating the distance of the muscle / tendon from the centre of rotation of the joint.

3. Measuring the arc of movement of the hamstrings at the hip by recording the Straight Leg Raise.

For each patient the 'spare' length of the quadriceps and hamstrings was calculated using the formulae:-

$$\text{Spare Length Quadriceps} = 2\,\Pi \text{ radius femoral condyles} * \frac{\text{pre-op knee flexion}}{360°}$$

$$\text{Spare Length Hamstrings} = 2\,\Pi\,(2 \text{ radius head femur}) * \frac{\text{Straight Leg Raise}}{360°}$$

The range of movement of the knee was measured using a universal goniometer and recorded in degrees (Norkin and White 1995). The arc of movement of the hamstrings at the hip was measured by carrying out a Straight Leg Raise test. The patient was tested in supine lying with the trunk, shoulders and hips in a neutral

position. The tester kept the knee in extension by holding above the knee and raised the leg, supporting it at the ankle whilst moving it in a sagittal plane, until the patient complained of pain. The contra-lateral leg was fixed into a neutral position to control for movement at the lumbar spine. The angle from the neutral leg position in supine lying was measured using a long arm goniometer, measuring to the nearest 5° (Grieve 1994).

8.4 Data Analysis

Data was analysed using the statistical package SPSS 7.5. Stepwise linear regression modelling was performed to identify any factors that were associated with a loss of knee flexion during lengthening. Correlations between variables were calculated by a Spearmans rank correlation test and plotted as scatterplots.

8.5 Results

28 of the patients who had undergone limb lengthening surgery of the femur were studied. A summary of the patients in this sample is detailed in Table 8-1.

DIAGNOSIS	Number	Sex	Age (Mean & S.D.)
Mal-union	8	1♂, 4♀	25.2 (4.54)
Non-union	5	8♂	34.3 (11.42)
Childhood osteomyelitis	3	1♂, 2♀	11 (2)
Ollier's Disease	3	2♂, 1♀	7.6 (3.05)
PFFD	4	2♂, 2♀	7.5 (1.97)
Hemiatrophy, hypoplasia	4	1♂, 3♀	12 (4.9)
Achondroplasia	1	1♂	9.5

Table 8-1: Subjects diagnosis and age

The mean loss of knee flexion during limb lengthening was 51° (range 10 – 100, SD 24.31).

Pre-operatively the mean knee flexion was 125° (range 95 – 140, SD 11.43)

The mean pre-operative SLR was 75° (range 65 –80, SD 3.95).

The mean spare length of the quadriceps was 4.6 cm (range 2.6 – 7.0; SD 12.14)

The mean spare length of the hamstrings was 5.7 cm (range 2.9 – 7.8; SD 13.94)

There was a strong association between the loss of knee flexion and the spare length of the quadriceps (Spearman's rho = 0.627, p = 0.01) shown in Figure 8-1, those patients with less spare length being more likely to lose knee flexion.

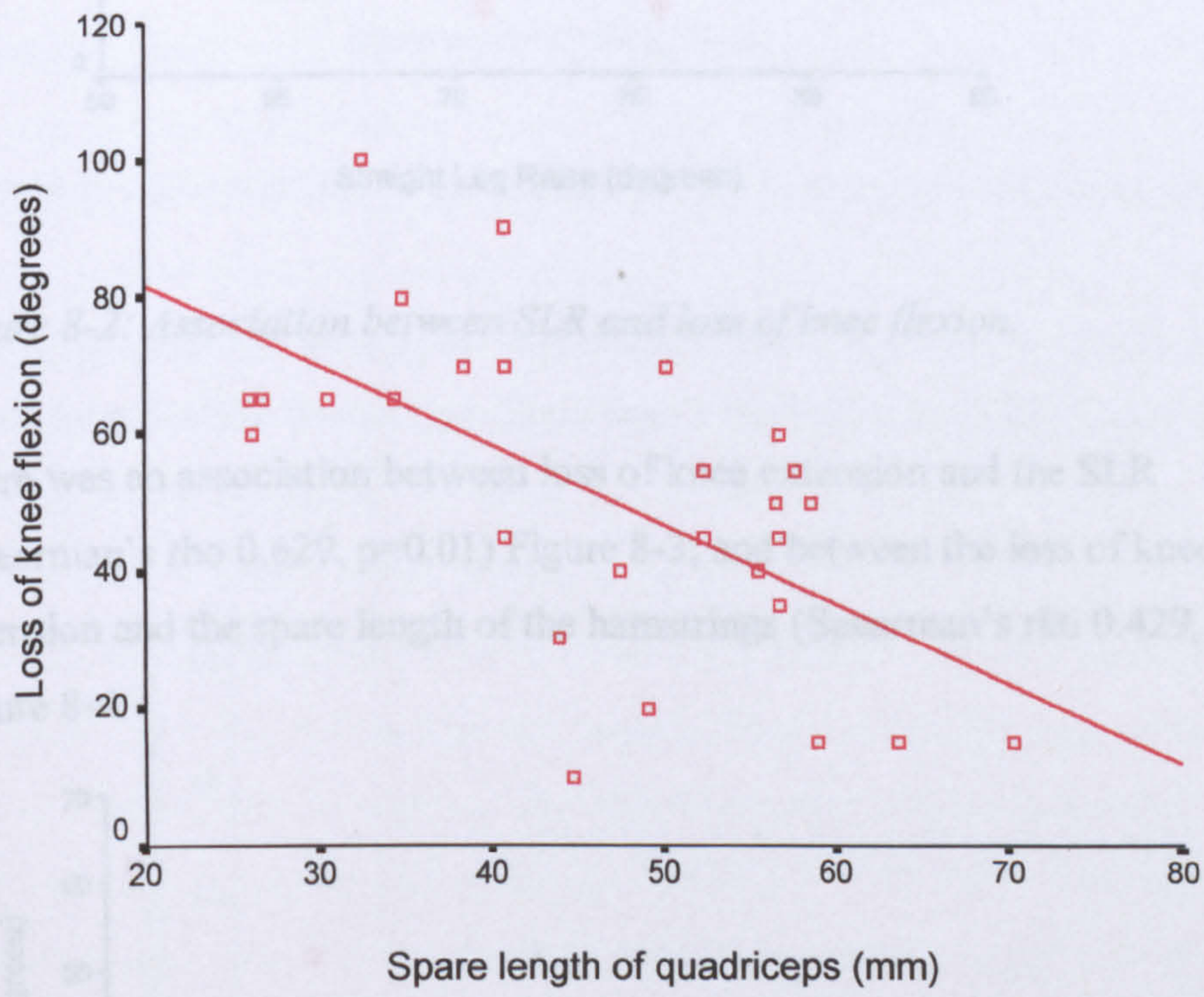


Figure 8-1: Association between spare length of quadriceps and loss of knee flexion.

There was an association between the loss of knee flexion and the pre-operative SLR (Spearman's rho 0.503, p = 0.01), Figure 8-2.

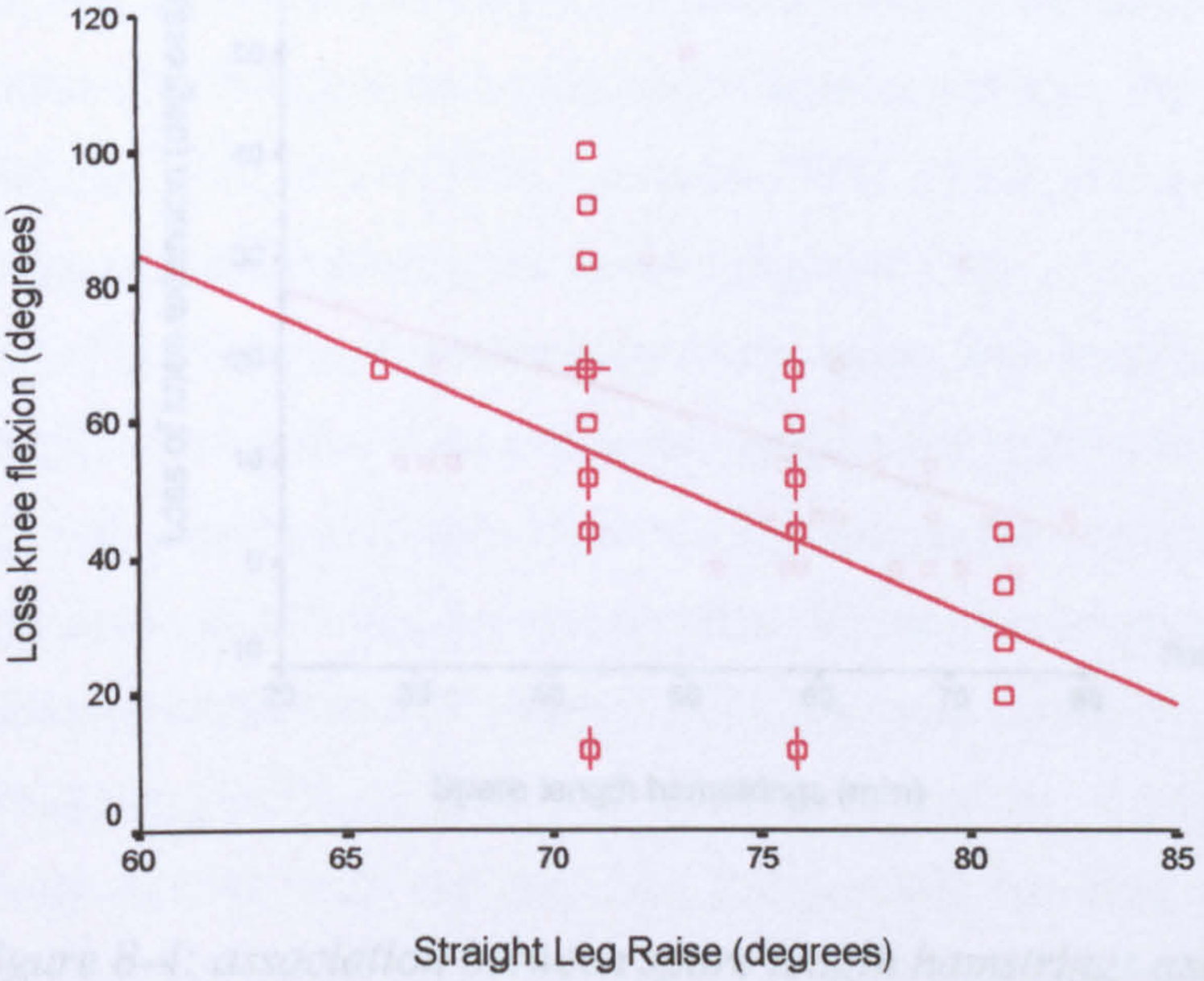


Figure 8-2: Association between SLR and loss of knee flexion.

There was an association between loss of knee extension and the SLR (Spearman's rho 0.629, p=0.01) Figure 8-3; and between the loss of knee extension and the spare length of the hamstrings (Spearman's rho 0.429, p=0.05) Figure 8-4.

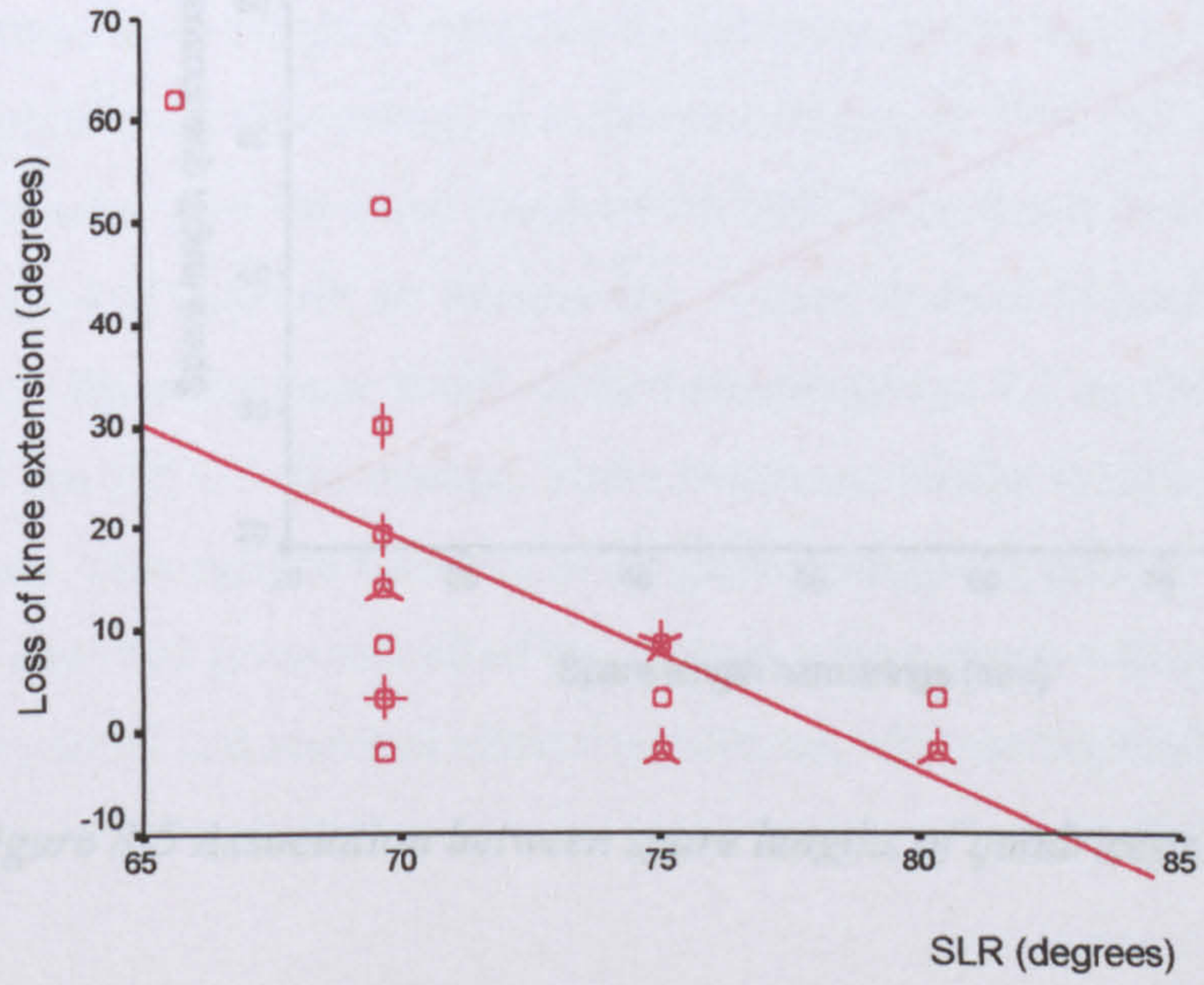


Figure 8-3 Association between loss of knee extension and SLR..

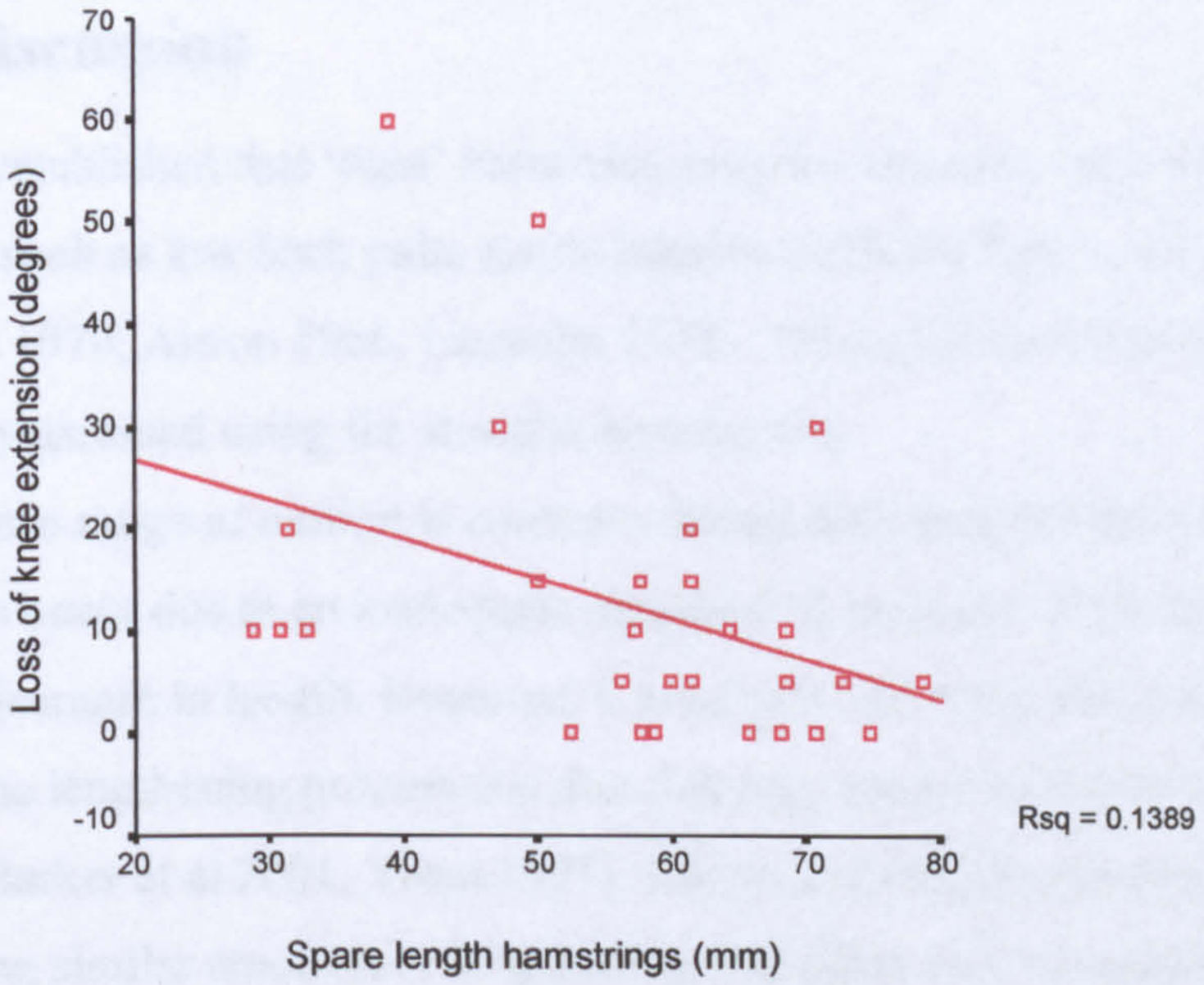


Figure 8-4: association between spare length hamstrings and loss of extension.

There was a strong association between the spare length of the quadriceps and the spare length of the hamstrings (Spearman's rho 0.631, $p < 0.01$) Figure 8-5.

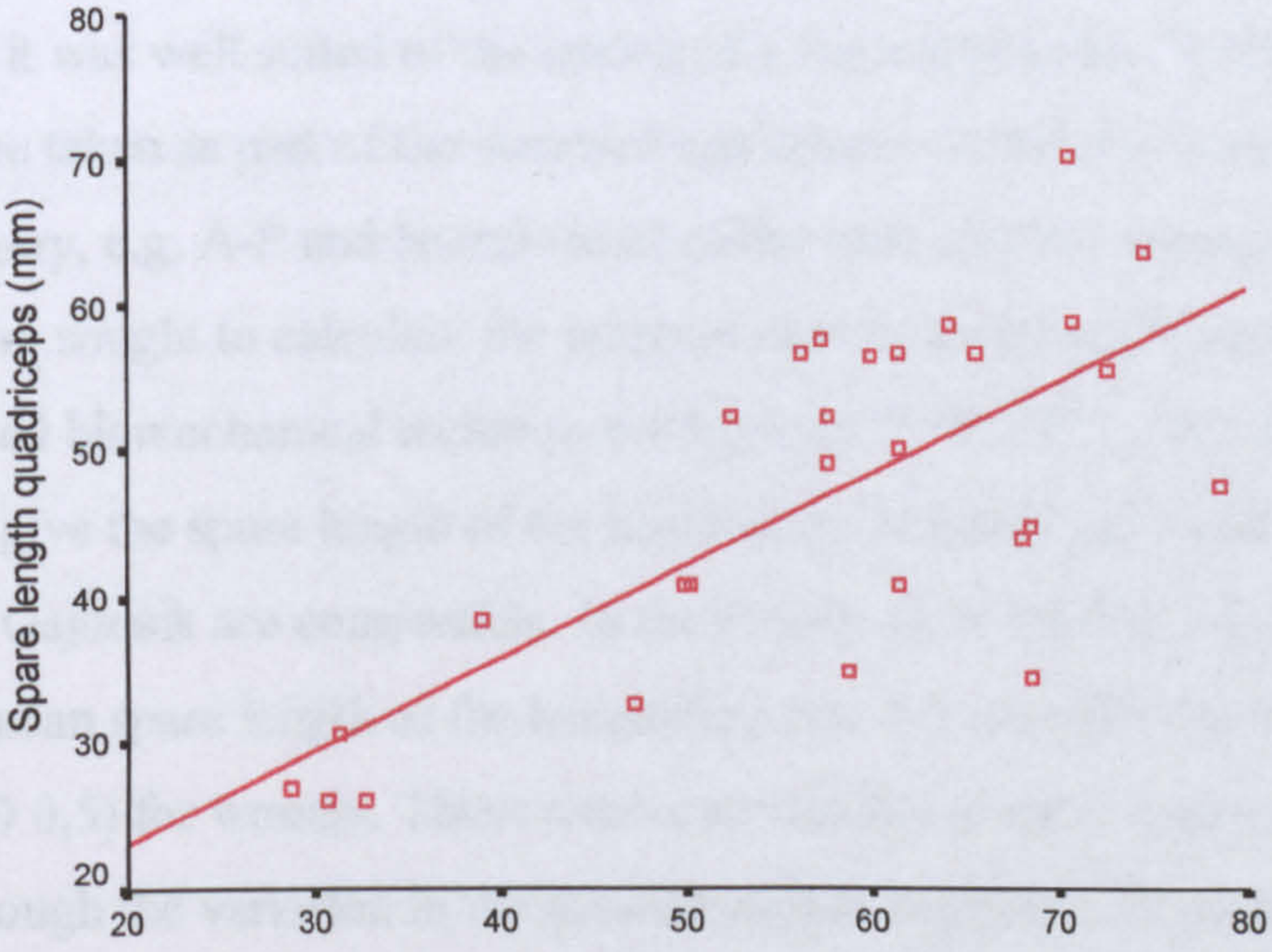


Figure 8-5 Association between spare lengths of quadriceps and hamstrings

8.6 Discussion

It is well established that 'tight' hamstring muscles are associated with clinical problems such as low back pain, sports injuries and knee ligament injury (Nicholas 1970, Alston 1966, Liemohn 1978). The tightness of the hamstrings is commonly assessed using the straight leg raise test.

Loss of knee range of motion is common during limb lengthening surgery, and is thought to occur due to an inadequate lengthening response of the muscles to an imposed increase in length. However, it is known that many patients lose range early in the lengthening process and that this may not be attributable to muscle tension (Barker et al 2001, Yasui 1997). Likewise similarly sized patients undergoing similar amounts of lengthening will often vary considerably in the amount of knee range that they lose. It is possible that there are fundamental differences in the patients that may account for this variable response and which might assist in predicting which patients will be at risk of developing muscle contractures during the lengthening programme.

The method of calculating the spare length or compliance of the muscle was simple but it was well suited to the setting of a leg length clinic. It only utilises x-rays that are taken as part of the standard assessment of patients undergoing limb length surgery, e.g. A-P and lateral views of the knee and the scanogram. Other authors have sought to calculate the inherent muscle length using more sophisticated biomechanical techniques (Gajdosik 1990,1991). The calculations derived to give the spare length of the muscles by this technique and by the method of Gajdosik are comparable. In their study of 30 healthy adults aged 21-37 years the mean spare length of the hamstrings was 4.2 cm (SD 0.6) for men and 3.7 cm (SD 0.5) for women. These results are similar to those derived in this study, although the variation in the present sample is greater. However, this is to be expected given that all of the subjects were patients with a range of both congenital and acquired clinical conditions, whereas Gajdosik used subjects from a student population.

It was not possible to draw any conclusions about the difference in inherent muscle length due to different causes of LLD. In this sample of patients there

were only two who underwent lengthening of the femur for short stature. It was not possible, therefore, to perform any analysis to confirm the hypothesis that achondroplastic patients have muscles with greater inherent length and more compliant soft tissues than other patient groups.

The association between the loss of knee flexion and both the inherent muscle length of the quadriceps and the pre-operative value of SLR was interesting and may well indicate that there are some patients whose tissues are better suited to tolerating imposed increases in length. The literature reports considerable variation in the reliability of the SLR test (Dixon 2000, Urban 1986). However, this issue was addressed by adhering to a strict measurement protocol that included standardised neck, trunk, hip and knee positions.

It was not immediately obvious why loss of knee flexion should be associated with a smaller range of SLR, it is most likely to be due to the strong correlation between the spare lengths of both the quadriceps and hamstring muscles. Loss of knee extension was also correlated with the pre-operative SLR, although correlation with the spare length of the hamstrings did not reach statistical significance.

8.7 Conclusions

It is suggested that the SLR of the patient is added to the clinical examination of all patients prior to surgery as this may forewarn the surgeon that a patient is at risk of developing problems in maintaining full range of motion at the knee.

8.8 Summary

- The possible link between loss of joint range of motion and the inherent length of the quadriceps and hamstrings was investigated.

- A simple mathematical model was developed based upon anthropometric data derived from x-rays and scanograms. Although simple, it was well suited to the clinic setting.

- The spare length of the muscles was calculated and regression modelling used to identify any factors associated with loss of knee range of motion.

- A positive association was found between loss of knee flexion and the spare length of the quadriceps and between loss of knee extension and the spare length of the hamstrings.

- There was a positive association between loss of knee extension and the pre-operative SLR test.

- The association between the loss of joint range and the spare length of the muscle indicates that there are some patients whose tissues are better suited to tolerating imposed changes in length.

- Due to small numbers it was not possible to draw any conclusions about the relative amounts of compliance in the soft tissues of different diagnostic groups.

- The use of the SLR test pre-operatively is recommended.

CHAPTER 9 - FUNCTIONAL OUTCOME MEASURES.

9.1 Introduction

Rehabilitation is defined as the *" restoration of the individual to the fullest level of function"* (Hasselkus 1989). It is one of the major goals of physiotherapy treatment. It is, however, an area that receives little attention in the published literature, where comments on function tend to be based on reports of patient satisfaction, or on the surgeon's opinion, rather than on critical study.
The majority of previous evaluations of outcome after Ilizarov reconstruction have concentrated on musculoskeletal measures rather than looking at the overall functional result or using patient-orientated health questionnaires. Few studies exist that address this important aspect of recovery (Ghoneem et al 1996) and only one has been conducted on the adult population (McKee et al 1998).

Using musculoskeletal indices such as range of motion or x-ray appearance may not accurately reflect changes in physical disability. Young et al (1995) quote the example that despite radiographic curve correction in children with spina bifida, walking ability may decrease (Mazur et al 1986). In limb lengthening a leg that has been equalised, but that has lost a significant amount of range of motion or strength may be more disabling to the patient than the original leg length discrepancy. Thus, although musculoskeletal indices may be useful they have limitations, and activity based physical function measures are arguably the most useful outcomes of orthopaedic interventions.

From a clinical perspective physical function may be evaluated by simple clinical measures, by physiological measures such as a timed walking test or by questionnaire (Davis et al 1996). The ability of the patient to perform their normal physical activities is one of the most important determinants of outcome after surgical intervention. A huge number of tests exist that measure physical performance ranging from simple measures based on observation to sophisticated exercise physiology or biomechanically based tests.
From a clinical perspective there is a need for simple physical measures that are quick to complete and that require minimal apparatus, in order that their use can

easily be replicated in other centres and in the clinical setting. Performance tests fit these criteria; in these a person is asked to perform a specified activity which is evaluated in an objective manner using a pre-determined method such as counting of repetitions or timing the activity. The measures are reported to have good discriminatory and evaluative validity as they are scaled continuously and standardised, which enhances test-re-test reliability (Guralnik et al 1989). Three performance measures were selected:-

1. Walking speed
2. Stair climbing
3. Sit to stand.

Walking speed represents one of the most fundamental functional activities and, in studies in older people, is well correlated to general health status, the ability to function in activities of daily living (Cress et al 1995) and to muscle strength (Bassey et al 1992).

The speed of walking is also an important indicator of a person's ability to function in society. For example, crossing a pelican crossing requires that someone can walk at a speed of 1.2m/s, in order to cross during the safe zone afforded by the traffic signals (Walsh et al 1998). It is a measure with good repeatability that can be performed with minimal equipment and that uses an activity familiar to the subjects being tested (Howe et al 1995, Kwoh et al 1997).

The ability to stand up from a chair (sit to stand) has been shown to give an indirect measure of leg strength (Hughes et al 1996, Bohannon et al 1995,1998). It also replicates an important activity of every day life (Lamb et al 1995) and gives a useful indication about the subject's balance and proprioception. Howe et al (1995) examined the variability of both walking speed and sit-to-stand in osteoarthritic subjects and concluded that they could confidently be applied as sequential measures in the clinical setting.

Stair climbing has been shown to correlate well with both walking speed and sit to stand (Lamb et al 1995, Tinetti et al 1997, Madsen et al 2000). It has been used as an outcome measure in many studies interested in lower limb function such as

studies after hip fracture and joint replacement (Tinetti et al 1997, Walsh et al 1998, Rogind et al 1998).

In addition to the performance measures it is important to explore patients' perceptions of their health, as these are recognised as being important outcome measures in evaluating the effectiveness of surgical treatment (Long et al 1996, Davis et al 1999). Indeed, current standards for good practice require evaluation of patients' perceptions of their own health (Rineberg 1990). In order to increase the breadth of the physical activities that can be assessed beyond the scope of the 3 objective timed tests, the use of a self reported questionnaire about physical activity was incorporated into the study protocol.

There are a number of questionnaires designed to elicit information about patients' physical ability. Some questionnaires are disease specific e.g. Oswestry Disability Index (low back pain), others are generic and may be applied to any population e.g. SF-36, Nottingham Health Profile. However, most of these questionnaires are not solely designed to investigate physical functioning alone, but assess physical function as a sub-component of more global health measures including aspects of emotional or social functioning and quality of life.
The Toronto Extremity Salvage Score (TESS) evaluates a single domain, physical disability, based on patients' reports of their function. There are two versions covering upper and lower limb activities; the lower limb version was used in this study. It is applicable to a heterogeneous population being sensitive to change across a range of levels of disability. The questionnaire has good reported validity and repeatability when used with musculoskeletal tumour patients (Davis et al 1996, 1999). It also meets the recommended goal for patient rated questionnaires, of being self completed in 5 to 15 minutes (McHorney & Tarlov 1995).
It was considered important to include both types of measurements, objective and questionnaire, in the study. One evaluates function in a controlled environment under a specific set of conditions, allowing objective measures to be gathered; whereas the patient reported assessments reveal the limitations that the patients had been experiencing when carrying out everyday activities in their own environments.

9.2 Purpose

The aim was to study the baseline functional abilities of the patients prior to surgery and to follow their subsequent recovery up to 2 years after the completion of limb reconstruction surgery i.e. when the external fixator was removed.

The objectives were to explore the relationship between range of motion and function, and to gain a better understanding of whether these two variables may be used interchangeably.

A secondary aim was to determine if there was one measure of function that was optimal in this group of patients, that could be recommended for use in clinical practice.

9.3 Method and Measures.

The same consecutive 65 patients as detailed in Chapter 7 (7.3.2) were studied. The effect of limb reconstruction surgery on patients' ability to perform functional activities was measured in two ways. Three simple performance measures were used:

1) Walking speed over a 20m course (m/s)
2) Ability to rise from a seated position (Number of times able to sit-to-stand in 60s)
3) Ability to climb stairs (Number of stairs climbed in 60s).

Secondly, a questionnaire measuring functional outcome, the Toronto Extremity Salvage Score (TESS) was used (Appendix 5).
All of the physical outcome measures were administered to the patients on the day before surgery, and at 6, 12 and 24 months after the external fixator had been removed from their limb. Data was not collected during the period when the frame

was on, as the physical bulk of the frame would impede movement and affect the performance of the tests.

Walking Speed

The time taken to walk a 20 metre course was measured over a marked course. Subjects stood with both feet on the start line and were asked to walk around a cone positioned 9.5 metres away and to return to the start line, this position of the cone allowed for a 0.5m turn around the cone. The tests were conducted in a gymnasium with a non-slip floor. Subjects were instructed to walk at their normal comfortable pace and the speed was recorded using a digital hand-held stopwatch. Timing was from the time the subject crossed the start line, until they stepped over the finish line (Figure 9-1). The speed of walking was calculated by dividing the distance by the time taken and recorded in metres/second.

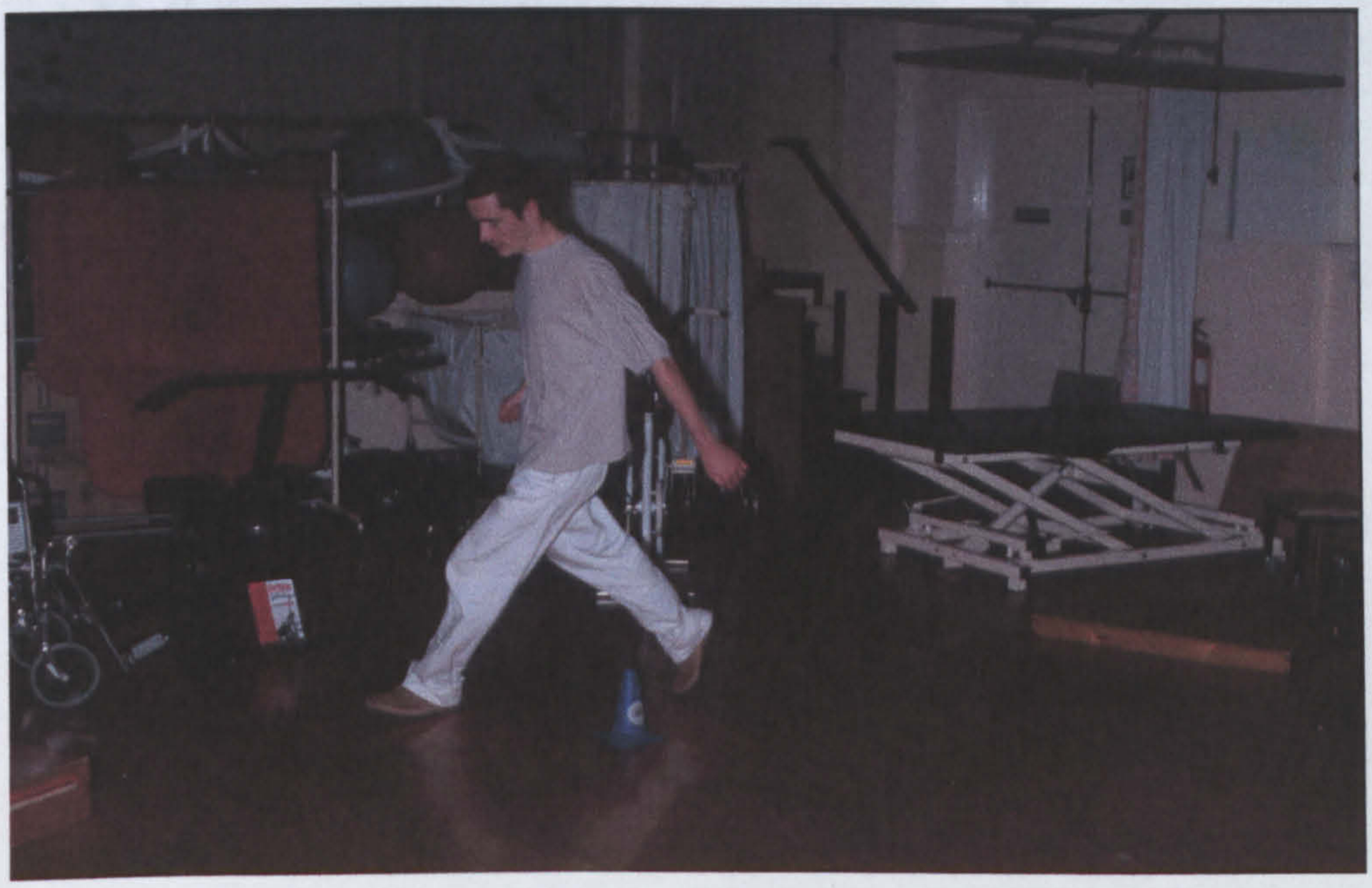


Figure 9-1: Timed walking test.

Stair Climbing

Subjects climbed a staircase with 7 steps up and 6 steps down, each of 19cm depth. They were asked to climb the stairs in the manner in which they felt comfortable and that they would normally use. The staircase required the subjects

to turn at the top before descending. The number of stairs that they ascended and descended in 60 seconds was recorded, using a stopwatch. Use of banisters was also recorded (Figure 9-2).

Figure 9-2 Timed stair climbing.

Sit to Stand

Subjects were seated in a chair with the seat 49 cm from the ground (British Standard Height) and with their feet placed flat on the floor in front of them. Patients were asked to fold their arms and keeping their arms folded, on the command 'go' they were asked to stand upright to a position with their knees straight, and then sit back down immediately. They were asked to do this repeatedly as fast as possible until asked to stop. They were asked not to use their hands to push down on the chair or their thighs, if they could not stand up without use of the arms, this use was recorded. The number of times that each subject rose and returned to the starting position in 60 seconds was recorded. (Figure 9-3).

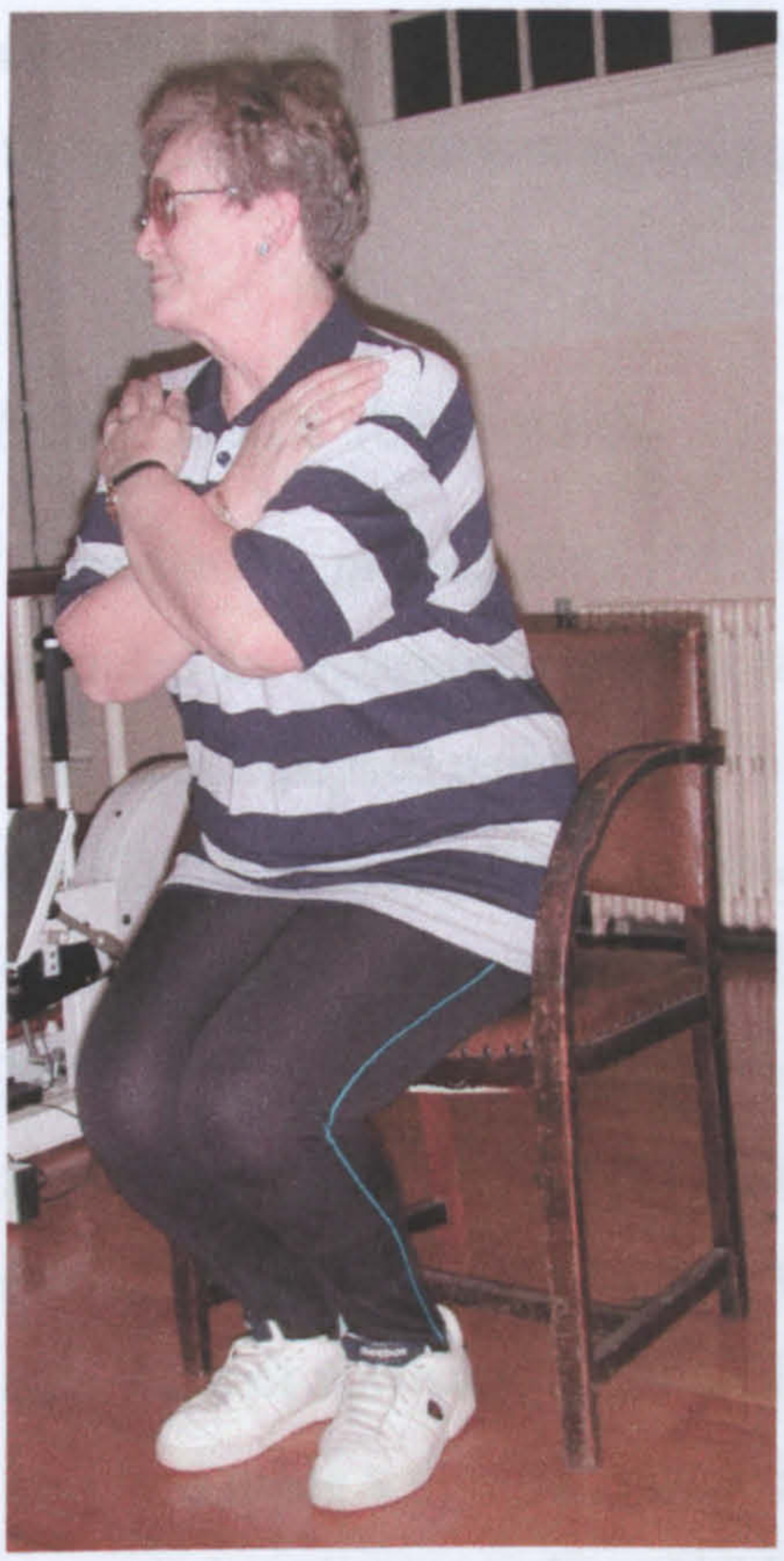


Figure 9-3: Sit to stand

TESS Questionnaire

The TESS questionnaire was chosen as it has previously been tested on a sarcoma population, who had similar characteristics to the study population in terms of age range, part of body affected and magnitude of surgery. The questionnaire has a major advantage over many more general questionnaires as it is produced in both a lower and upper limb version, and so can be specific to the affected area. It is also specific to the assessment of physical disability.

It is self administered with patients rating 30 questions on a 5 point Likert – type scale ranging from "not at all difficult" to "impossible to do". If the activity is not part of patients' normal activities it is marked "not applicable". The score is an aggregation of the items and possible scores range from 0-100. Thus the scoring of the questionnaire can cope with missing questions, if an activity mentioned would normally not be attempted by a patient. The patient was given the questionnaire to fill in at the pre-operative baseline assessment. They were asked to complete it by themselves without referring to relatives who might be

accompanying them, or to anyone else who might be present such as nursing staff. Subsequent questionnaires were completed during clinic visits. (Appendix 5)

9.4 Data Analysis

There was no missing data. All of the patients could complete the timed tests and attended for measurement at all four of the measurement sessions.

Data was analysed using SPSS Version 7.5. At baseline, tests of normality using the Kolmogorov-Smirnov statistic with Lilliefors correction were applied, this tests for normality based on the absolute value of the maximum difference between the observed cumulative distribution and that expected based on the assumption of normality. If the significance level is small, then the assumption of normality is unreasonable and a normal distribution does not exist. The baseline data was not normally distributed (Table 9-1), thus within subject changes were analysed using a non-parametric statistical test, the Wilcoxon matched-pairs test. Associations between the variables were tested using a Spearmans Rank Correlation Coefficient.

9.5 Results

VARIABLE	*STATISTIC*	*SIGNIFICANCE*
TIMED WALK (m/s)	0.106	0.066
SIT TO STAND (No. in 60 seconds)	0.082	0.200
STAIRS (No. in 60 seconds)	0.143	0.002
TESS (%)	0.182	0.000

Table 9-1: Kolmogorov-Smirnov tests for normality at baseline.

9.5.1 Walking Speed.

The effect of surgery on walking speed and the recovery post surgery are shown in Tables 9-2 and in Figure 9-4.

Time Interval	***Mean walking speed (m/s)***	***Median Walking Speed (m/s)***	***Range***	***Standard Deviation***	***Z value***	***Sign. of change from baseline***
Pre-op	1.13	1.16	.62 – 1.5	.20		
Six months	1.17	1.2	.60 – 1.54	.18	-2.21	0.027
One year	1.24	1.29	.71 – 1.65	.17	-6.77	0.000
Two years	1.27	1.27	.89 – 1.64	.15	-6.93	0.000

Table 9-2: Change in walking speed n = 65.

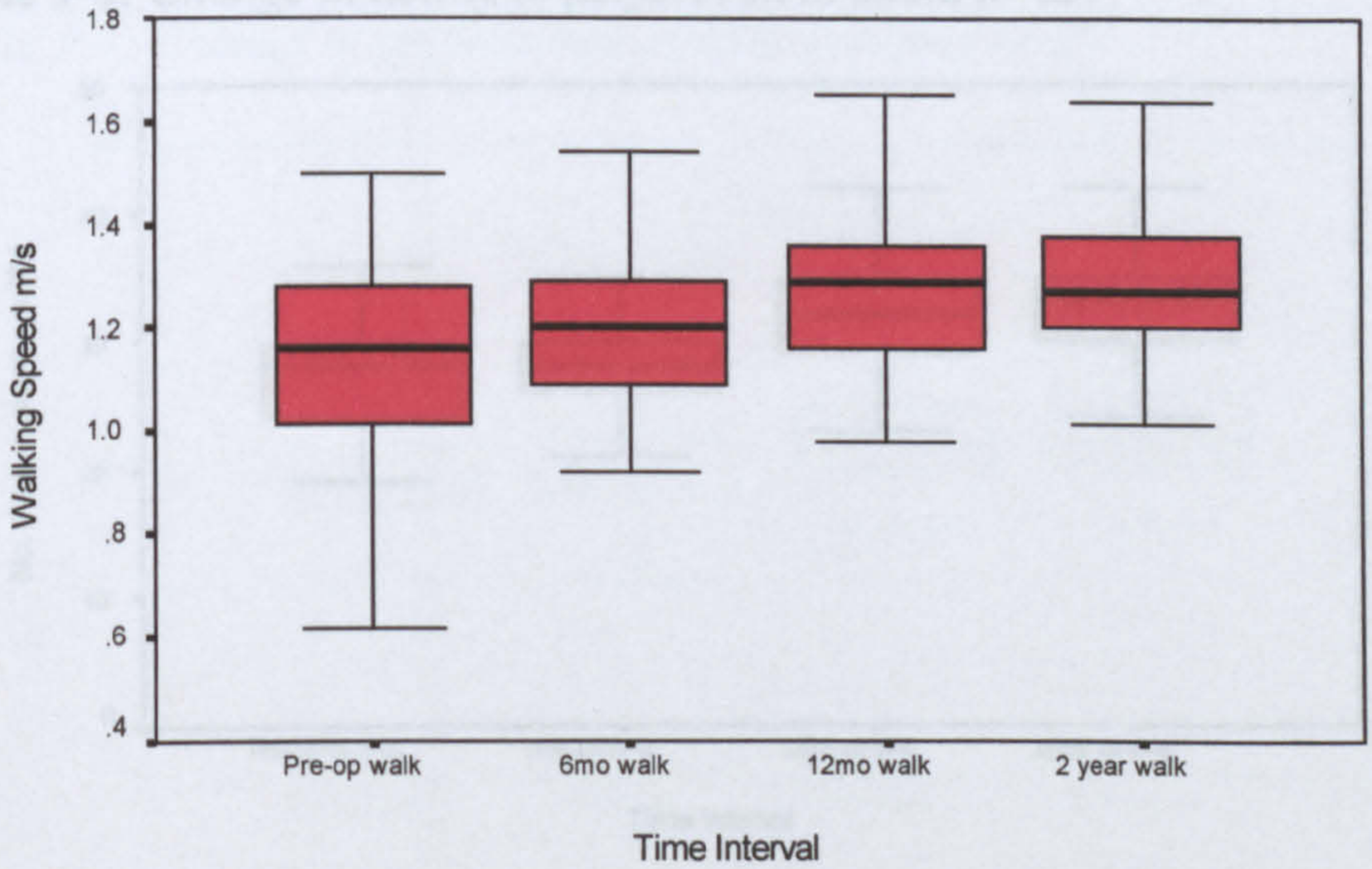


Figure 9-4: Boxplot of change in walking speed showing median (bar), upper and lower quartiles (limits of box) and whiskers (smallest and largest values not categorised as outliers) N=65.

There was only a small increase in walking speed during the first six months after surgery, which did not reach statistical significance. Thereafter, the improvements in walking speed at one and two years after surgery, compared to the baseline score, were greater and statistically significant.

9.5.2 Sit to stand.

The effect of surgery on sit to stand and the recovery post surgery are shown in Tables 9-3 and in Figure 9-5.

Time Interval	***Mean No. Sit to stand.***	***Median No. Sit to stand.***	***Range***	***Standard Deviation***	***Z value***	***Sign. of change from baseline***
Pre-op	27.2	28	12-41	5.17		
Six month	27.8	28	10-37	4.77	-1.06	0.289
One year	31.6	32	14-42	4.80	-6.89	0.000
Two years	32.3	33	14-43	5.01	-6.96	0.000

Table 9-3: Change in ability to perform sit to stand n=65.

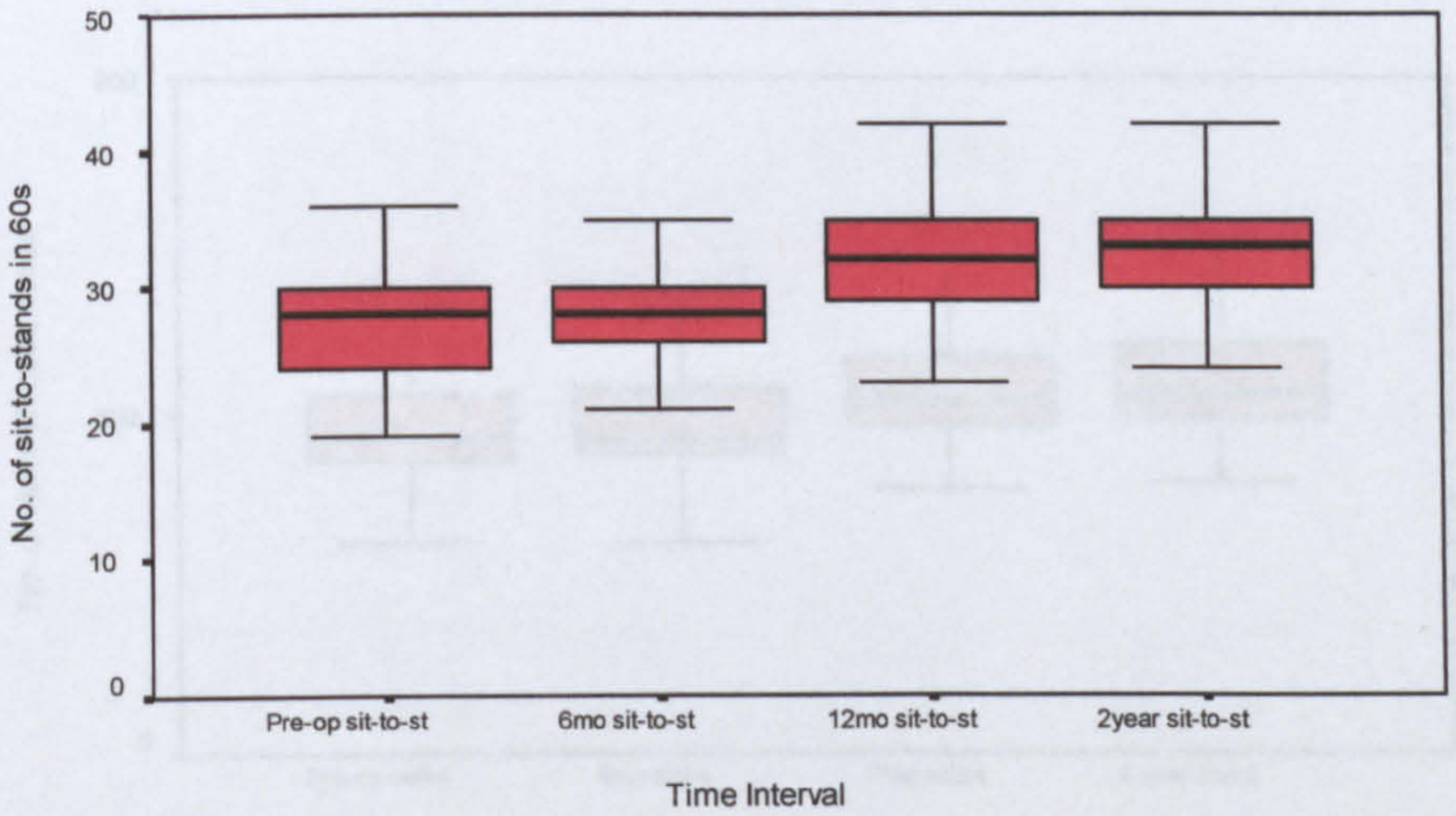


Figure 9-5: Boxplot of change in sit-to-stand showing median (bar), upper and lower quartiles (limits of box) and whiskers (smallest and largest values not categorised as outliers) N=65.

There was no statistical improvement in the patients' ability to perform a sit to stand test between baseline and six months after frame removal. However, by one year this had improved significantly, and on average subjects could complete 4.4 more sit to stands.

9.5.3 Stair Climbing

The effect of surgery on stair climbing and the recovery post surgery are shown in Table 9-4 and in Figure 9-6.

Time Interval	***Mean No. Stairs.***	***Median No. Stairs.***	***Range***	***Standard Deviation***	***Z value***	***Sign. of change from baseline***
Pre-op	95	93	17-163	27.8		
Six month	97	93	14-152	24.9	-0.76	0.446
One year	107	104	28-161	23.5	-6.52	0.00
Two years	110	106	28-164	24.2	-6.58	0.00

Table 9-4: Change in performance of stair climbing n=65.

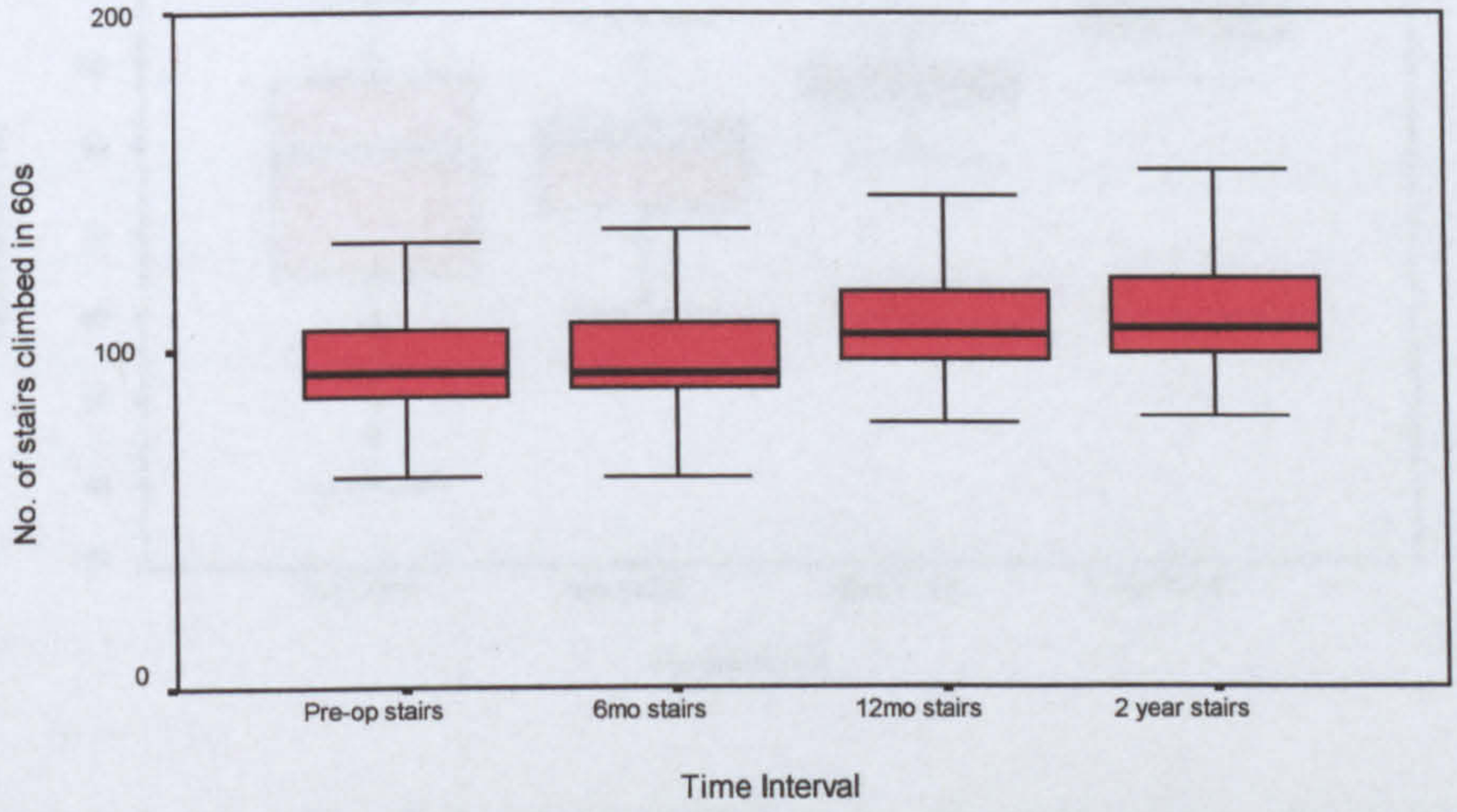


Figure 9-6: Boxplot of change in stair climbing showing median (bar), upper and lower quartiles (limits of box) and whiskers (smallest and largest values not categorised as outliers) N=65.

There was no statistical improvement in the patients' ability to climb stairs between baseline and six months after frame removal. However, by one year this had improved significantly, and on average subjects could climb 15 more stairs.

9.5.4 TESS Questionnaire

The effect of surgery on reported TESS score and the recovery post surgery are shown in Table 9-5 and in Figure 9-7.

Time Interval	***Mean TESS scores.***	***Median TESS score***	***Range***	***Standard Deviation***	***Z value***	***Sign. of change from baseline***
Pre-op	74	79	39-97	16.25		
Six month	76	80	43-94	10.18	-.422	0.673
One year	86	86	74-94	4.58	-4.68	0.000
Two years	93	94	84-100	3.84	-6.90	0.000

Table 9-5: Change in TESS score n=65.

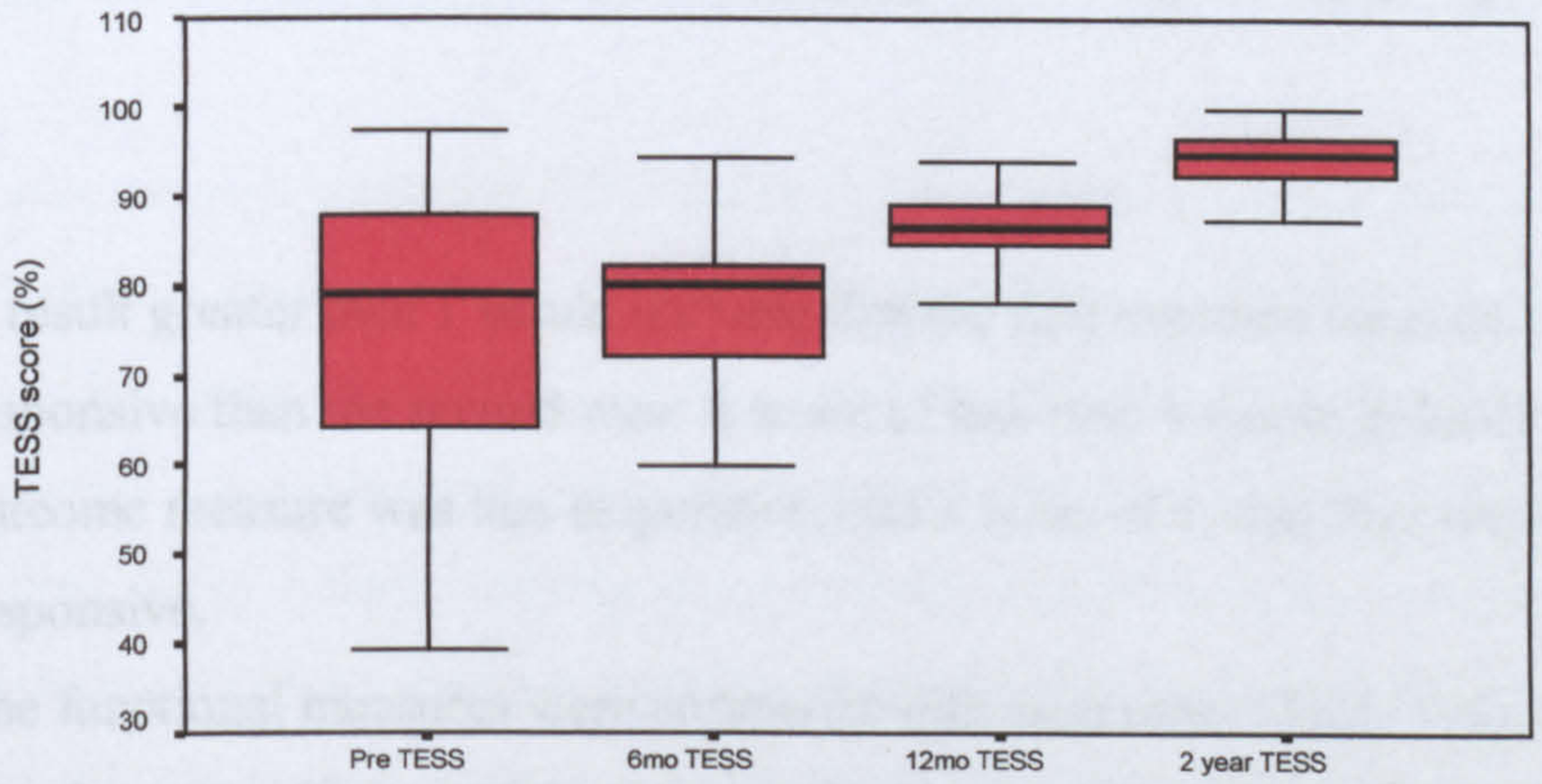


Figure 9-7: Boxplot of change in TESS score showing median (bar), upper and lower quartiles (limits of box) and whiskers (smallest and largest values not categorised as outliers) N=65.

There was no statistical improvement in the patients' TESS score between baseline and six months after frame removal. However, by one year this had improved significantly, and on average subjects had improved by 19 percentage points.

9.5.5 Comparison between functional measures.

Subjects, on average, improved on all of the mean functional measures. To allow comparison between the 4 different functional scores the relative efficiency of the measures was calculated. The relative efficiency was calculated according to Barr et al (1994) using the z statistics derived from the Wilcoxon sign rank test at baseline and final review at two years. As the data was not normally distributed this method of calculation based on non-parametric statistics provides a more conservative estimate of statistical significance than would be obtained by other methods of calculating effectiveness such as effect sizes (Kazis et al 1989). The formula used was: -

$$\text{Relative efficiency (Functional Measure 1 versus Functional Measure 2)} = \left(\frac{Z\,Fm1}{Z\,Fm2} \right)^2$$

A result greater than 1 would indicate that the first outcome measure was more responsive than the second was. A score of less than 1 would indicate that the first outcome measure was less responsive, and a score of 1, that they were equally responsive.

The functional measures were compared with each other (Table 9-6). Sit to stand was the most efficient of the functional outcome measures and stair climbing the least efficient.

Measure	***Sit to stand***	***Walking speed***	***Stair Climbing***	***TESS***
Sit to stand	1	1.008	1.118	1.017
Walking speed		1	1.109	1.008
Stair Climbing			1	.909
TESS				1

Table 9-6: Relative Efficiency of outcome measures

9.5.6 Association between patient-reported and observed outcome measures.

The association between the self-reported function scores (TESS) at baseline and the observed functional activities was explored. This found poor correlation between the variables, with only one significant correlation between pre-op TESS and pre-op sit to stand (Table 9-7)

	Walking Speed	***Sit-to-Stand***	***Stairs***	***TESS***
Walking Speed	1	.418	.537	/
Sit-to-Stand	.418	1	.636	.351
Stairs	.534	.636	1	/
TESS	/	.351	/	1

Table 9-7 Significant correlations between functional measures at P<0.01 level.

It was surprising that the TESS questionnaire did not correlate more strongly with the other outcome measures. To explore this further, the association between specific questions in TESS and the objective performance variables was tested using the chi- square test. Sit to stand was compared with the question about getting out of a chair, walking speed with the questions about walking indoors and outdoors and stair climbing with the questions about going up and down stairs. The functional performance scores were divided into tertials (Table 9-8) and compared to the TESS score for individual questions (Table 9-9).

	First Tertial	***Second Tertial***	***Third Tertial***
Walking speed (m/s)	0.62 – 1.08 n = 21	1.09 – 1.22 n = 21	1.23 – 1.50 n = 23
Sit to stand (No. in 60s)	< 25 n = 21	26 – 29 n = 25	30 – 41 n = 19
Stairs (No. in 60s)	17 – 87 n = 20	88 – 98 n = 24	99 – 163 n = 21

Table 9-8: Division of data into tertials.

Significance was set at the P<0.05 level. This showed an association between the TESS questions about stair climbing and the performance of stair climbing, but not for the other variables.

Variable compared	***chi-square***	***df***	***Significance***	***Spearman's***	***Significance***
Walking speed and Q. walking indoors	6.52	4	0.170	0.123	0.335
Walking speed and Q. walking outside	4.80	6	0.605	-0.06	0.607
Stair climbing and Q. going upstairs	23.38	6	0.000*	0.542	0.000*
Stair climbing and Q. going downstairs	25.50	6	0.000*	0.345	0.005*
Sit to stand and Q. out of a chair	7.72	6	0.102	0.263	0.040

Table 9-9 Associations between individual TESS questions and functional measures.

It was unexpected that there were such poor associations between the individual TESS questions and their related activities. One possible explanation for this might be the age of the patient, as the study of range of motion in chapter 7 demonstrated a difference between the adults and children in the sample. The children were also more functionally impaired than the adults at baseline, having a mean TESS score of 68.94 compared with 85.86 for adults. Therefore, the data was explored further to investigate whether the adults and children in the study answered the questions differently (Tables 9-10 & 9-11).

Variable compared	***Chi-square***	***Df***	***Significance***	***Spearman's***	***Significance***
Walking speed & Q. walk inside	9.65	4	0.039*	0.533	0.003*
Walking speed & Q.walk outside	5.32	6	0.549	0.218	0.255
Stair climbing & Q. upstairs	19.88	6	0.002*	0.640	0.000*
Stair climbing & Q.downstairs	14.41	6	0.021*	0.425	0.025*
Sit to stand & Q. out of a chair	6.72	6	0.165	0.410	0.031*

Table 9-10: Associations between individual questions and functional measure (Adults).

Variable compared	***chi-square***	***Df***	***Significance***	***Spearman's***	***Significance***
Walking speed &Q. walk indoor	2.39	2	0.345	0.300	0.204
Walking speed & Q. walking outside	2.43	4	0.690	0.060	0.805
Stair climbing & Q. upstairs	11.30	6	0.057*	0.571	0.006*
Stair climbing & Q.downstairs	13.91	6	0.025*	0.457	0.019*
Sit to stand and Q. out of a chair	4.64	2	0.117	0.069	0.758

Table 9-11: Associations between individual questions and functional measures (Children).

The adult data showed much better associations between the questionnaire and objective data, with positive associations on all variables except walking outdoors. Conversely, when the data for the children was analysed in the same way there was only a positive association for stair climbing.

9.5.7 Timing of maximum recovery.

The amount of recovery of the outcome measures between six months and one year, and between one and two years was explored to establish at what point in the rehabilitation programme the most progress is made, and at what point patients may be deemed to have made their maximum achievable recovery.

On all the outcome measures the differences in score between the six month and one year measurements and between one and two years were significant at the $p<0.001$ level (Wilcoxon's signed rank test of differences) see Table 9-12.

OUTCOME MEASURE & TIME INTERVAL	***Z SCORE***	***SIGNIFICANCE***
Walking Speed		
Pre-op - six months	2.2	0.027
Six months – one year	6.7	0.000*
One year - two years	4.5	0.000*
Sit to Stand		
Pre-op - six months	1.06	0.289
Six months – one year	6.69	0.000*
One year - two years	4.28	0.000*
Stairs		
Pre-op – six months	0.76	0.446
Six months – one year	6.67	0.000*
One year - two years	5.7	0.000*
TESS		
Pre-op – six months	0.42	0.673
Six months - one year	6.65	0.000*
One year - two years	7.01	0.000*

**significant at P<0.001 Level.*

Table 9-12: Timing of Recovery.

Thus it can be seen that all outcome measures show a significant improvement between one and two years. Recovery was slowest in the early stages after frame removal when most patients had regained their pre-operative score, but had not improved upon it. In the period between six months after frame removal and one year a highly significant improvement in function on all measures was seen and this continued in the period between one and two years (Figure 9-8).

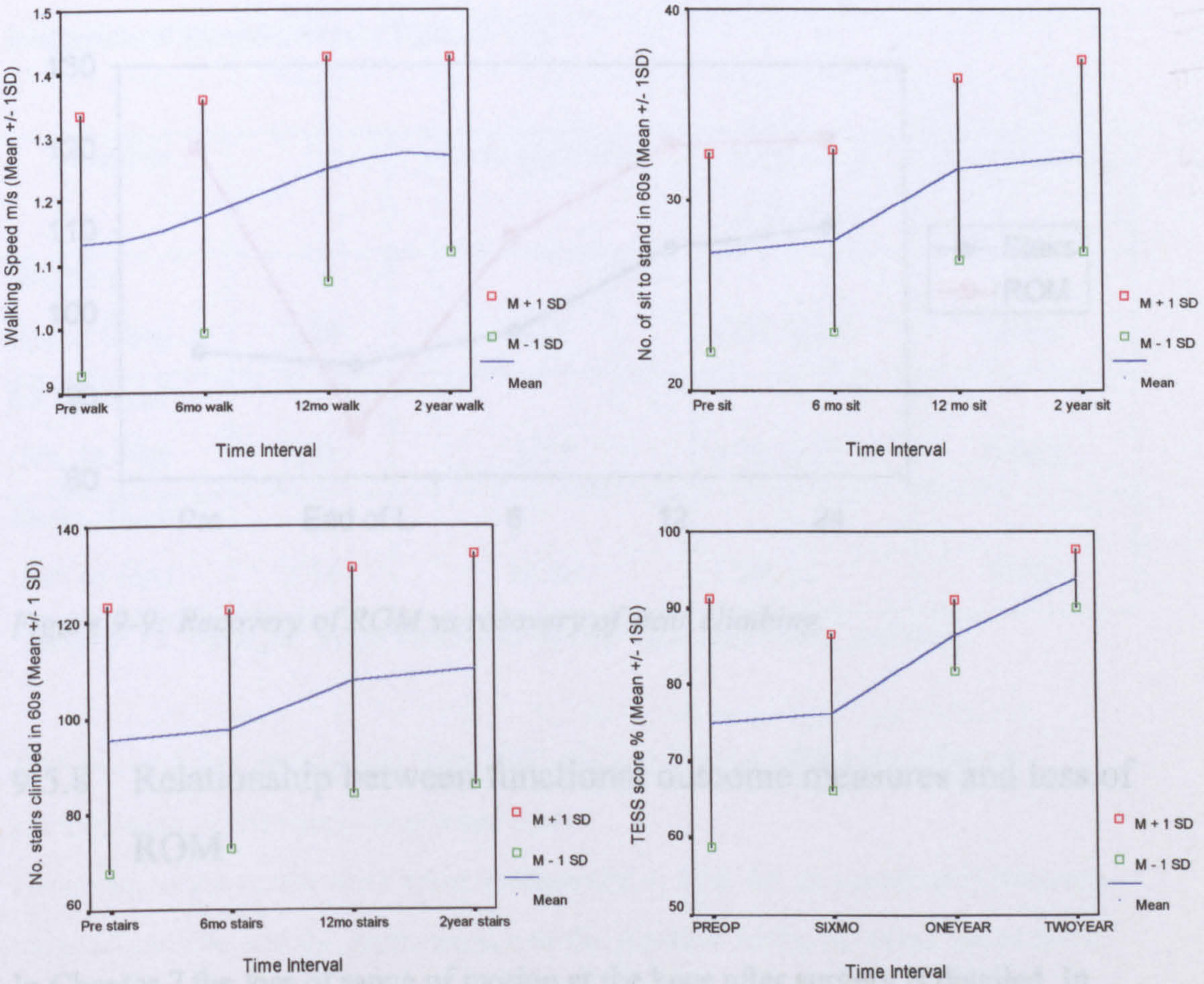


Figure 9-8: Timing of recovery

The timing of recovery was compared to that of range of motion (Figure 9-9). Figure 9-8 had demonstrated that a similar pattern of recovery was seen for all the functional measures. Therefore, one of these measures, stair climbing, was selected to compare with range of motion. This showed that most recovery of ROM had occurred by six months. Conversely, most recovery of stair climbing occurred between 6 and 12 months.

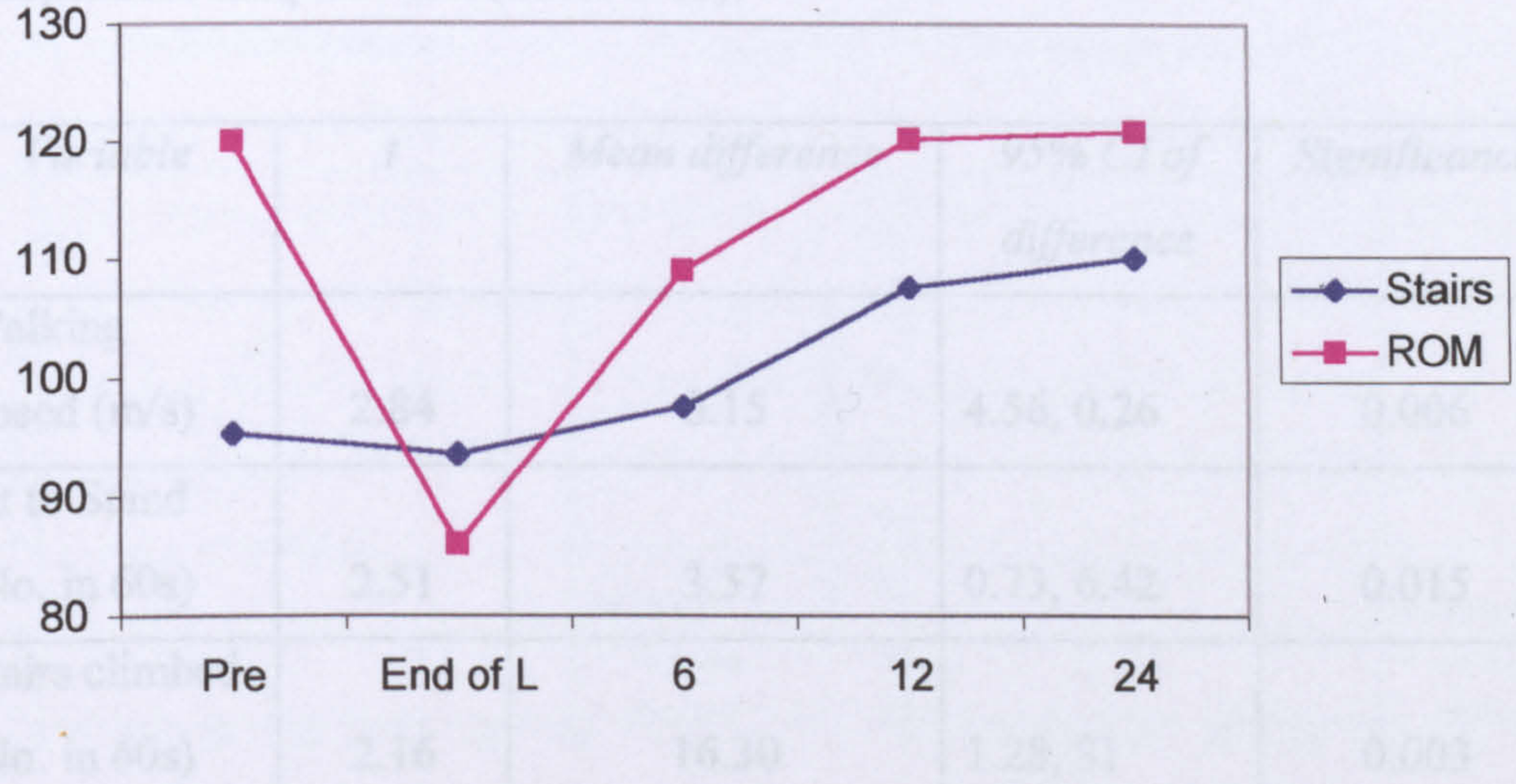


Figure 9-9: Recovery of ROM vs recovery of stair climbing.

9.5.8 Relationship between functional outcome measures and loss of ROM

In Chapter 7 the loss of range of motion at the knee after surgery is detailed. In order to investigate any association between range of motion and the performance of functional activities the relationship between loss of range of motion and the performance of the timed functional activities was investigated. Loss of knee range of motion was categorised as being greater or less than 100°. This figure was chosen based on the work of Rowe et al (2000), Laubenthal et al (1972), Andriacchi et al (1980) and Kettlekamp et al (1970) who cite the amount of knee flexion required for such activities as stair climbing, walking and rising from a chair.

Badley et al (1984) have investigated whether there is a threshold of loss of knee ROM in patients with arthritis, that affects their ability to perform activities of daily living. They reported that a threshold of 85° was associated with sit to stand and 110° with stair climbing. They suggested that these thresholds could be regarded as representing the critical limiting ranges for performance.

Differences between the performance of those subjects with < 100° knee flexion and those with >100° knee flexion after frame removal were investigated using an independent samples t-test (Table 9-13).

Variable	*t*	*Mean difference*	*95% CI of difference*	*Significance*
Walking Speed (m/s)	2.84	0.15	4.56, 0.26	0.006
Sit to Stand (No. in 60s)	2.51	3.57	0.73, 6.42	0.015
Stairs climbed (No. in 60s)	2.16	16.30	1.28, 31	0.003

Table 9-13: t-test for ROM threshold of 100° and functional activities

This showed that having less than 100° of knee flexion adversely affected performance of the timed functional tests.
However, when scatterplots were constructed to look for an association between range of motion and the performance of the physical tasks, no linear association between these variables was found (Figure 9-10) .

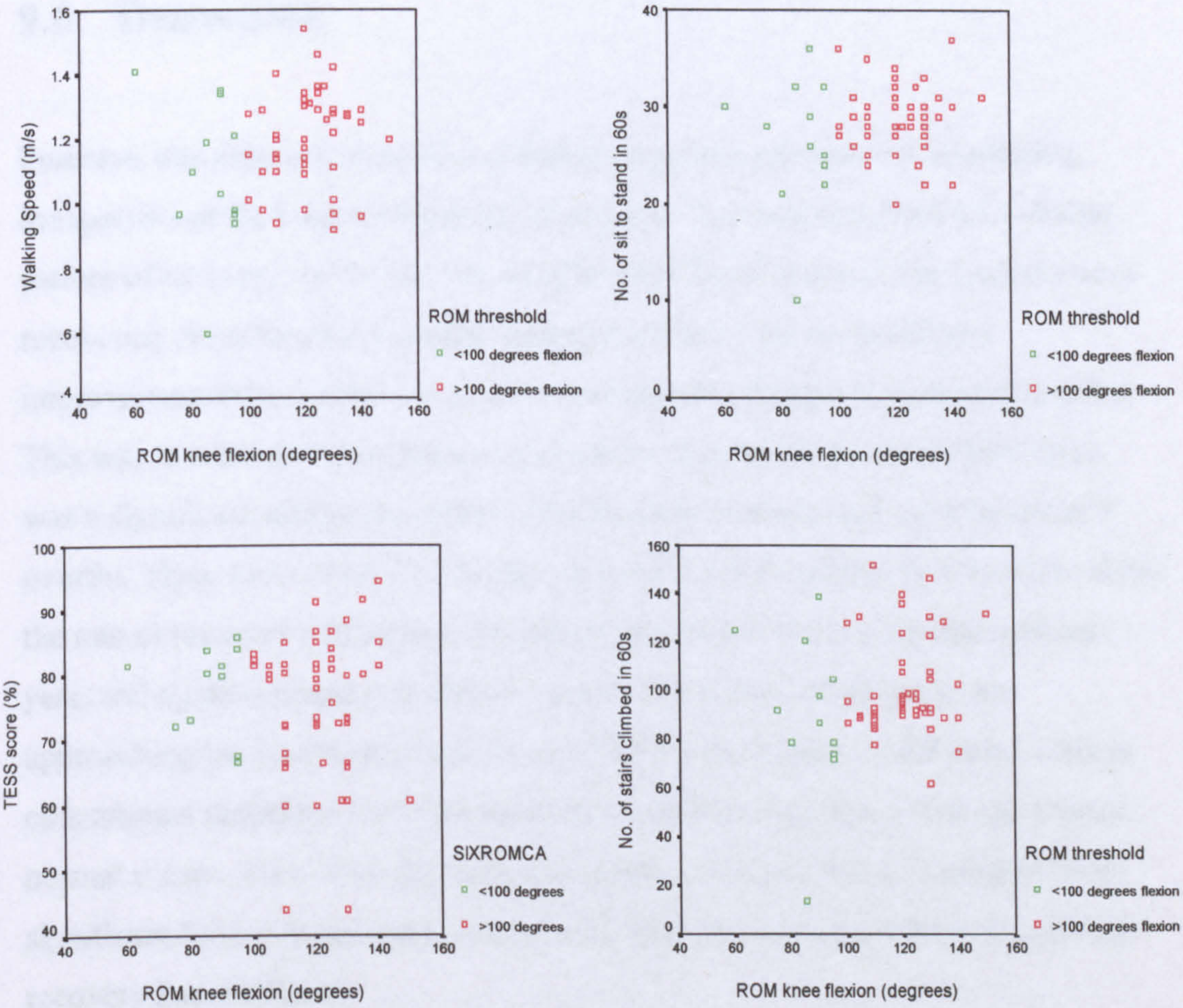


Figure 9-10: Scatterplots showing correlation between ROM and function

9.6 Discussion

Function was assessed using four different measures recorded on all patients, irrespective of their age or the goals of surgery. The measures showed a similar pattern of recovery. In the first six months after frame removal, the patients were recovering from the effects of the surgery and there was no significant improvement between the scores at six months after frame removal and baseline. This was in contrast to the pattern of recovery of range of motion, where there was a significant difference between the baseline measure and the measure at 6 months. Thus, most recovery of range of motion was complete by 6 months whilst the rate of recovery of function was much greater between six months and one year, and again between one and two years. The scores at two years are approaching the maximum score for the TESS and on many of the cases without concomitant disability, the other outcome measures were near to the age related normal values. Thus it would seem reasonable to assume that it is unlikely that significant further improvement will occur after the two year follow up and that recovery has stabilised.

The findings about the time taken for recovery to occur are important as many studies that are conducted prospectively have a shorter follow up than the two years after frame removal used in this study (Ramaker et al 2000). It is also of note as the survey of physiotherapy practice showed that 20% of physiotherapists discharged their patients when they have regained range of motion and a further 8% discharged them at the time of frame removal (Barker et al 1999).
The significant improvements demonstrated on all functional outcome measures between one and two years has important implications for the length of follow-up incorporated into any future study design and for clinical practice.

The association with knee range of motion is interesting. Those patients who had less knee flexion demonstrated a poorer performance on the functional tests. This is possibly accentuated by the fact that the functional tests of sit to stand and stair climbing are activities that require a good range of knee flexion.Rowe et al (2000)

found that a sample of 20 elderly subjects used a maximum of 99° to sit and stand from a standard height chair, 103° from a low chair and 93° to climb stairs. Thus the importance of a good range of knee flexion in performing functional tasks is evident, indeed Rowe et al (2000) suggest that the minimum goal for rehabilitation programmes should be 110° for patients to have sufficient knee motion for normal everyday activities.

Responsiveness to change is recognised as an important characteristic of measurement distinct from reliability and validity in that it measures the efficiency with which the measure detects clinical change (Guyatt et al 1987, Lachs 1993). It would be useful to be able to pin-point one outcome measure to recommend in the evaluation of outcome in this patient population.

All of the measures were sensitive to change, but there was considerable variation within the patient population. Most variability was found in the baseline measurements of stair climbing and sit to stand. However, this may be explained by flaws in the design of the testing procedure. All the subjects were tested using a standardised protocol and standardised equipment. Thus the height of the tread of the stairs and the chair height were standard sizes, based upon adult anthropometric data and were not scaled down for the children in the subject sample. The wide range of ages and sizes in the sample could account for the large variation in these outcome measures. There was less variation on the measures for walking speed and TESS. Overall, the sit to stand test showed the greatest responsiveness to change over time and this test is recommended if only one objective outcome measure is to be used. Although, it did not perform so well on the measure of responsiveness to change, the use of the TESS questionnaire is also recommended, as it gives patient–derived data and adds depth to the measurement of functional ability.

It is recognised that for an outcome measure to be responsive the scores should be evenly distributed about the middle score, and there should be no floor or ceiling effects, whereby patients can decline or improve beyond the measurement range (Wade 1992). The advantages of the three measures of functional activities based upon timed tests is that they are less influenced by such restrictions and are capable of encompassing a range of abilities. The TESS score is liable to be

subject to such an effect. The data was examined to look at the possible influence of floor and ceiling effects (Table 9-5). Pre-operatively all of the subjects scored significantly higher than the baseline score of 0. At the final review the mean score was near to the ceiling of 100 (mean 93.8); but only one patient scored the maximum score. In this population TESS meets the recommendation of McHorney & Tarlov (1995) that floor and ceiling scores should occur in less than 15% of subjects. Thus the outcome measures chosen were suitable in being able to detect change across a range of functional ability.

Calculation of relative efficiency is a recognised method of comparing the responsiveness to change of different measures (Liang 1985, 1995). Responsiveness is defined as the ability of an instrument to measure a clinically meaningful or important change in a clinical state (Liang 1995). They derive a single 'signal to noise' estimate for each measure. If the variability in the scores between subjects (the signal) is much greater than the variability within subjects (the noise), an instrument will be deemed responsive (Guyatt et al 1995a). The use of responsiveness analysis enabled one functional test, sit-to-stand; to be identified as most likely to detect clinical change and its use is recommended as an outcome measure in clinical practice. This test could be further improved by using anthropometric tables to adjust the height of the chair to the individual subject's body size.

There was a good association between the different physical outcome measures as has been observed by other authors (Bassey et al 1992, Howe et al 1995, Madsen et al 2000, Tinetti et al 1997). However, there was weaker agreement between the physical outcome measures and the total TESS score. The further exploration of the association between the objective physical measures and the individual TESS questions that relate to that activity, showed a poor correlation when applied to the whole sample. The difference in the results between adults and children when they were analysed separately would imply that the adult and children in the sample were answering the questionnaire in a different way. Although the authors of the TESS have successfully used the questionnaire on subjects as young as 12 years, 21 of this sample were below that age. Measurement of paediatric function has specific problems, such as the impact of growth and development, which few

scales address (Young et al 1995). Young identified 13 generic scales that may be used to assess physical function in children but made no recommendations about which was the most appropriate. It would appear from the results reported that the TESS questionnaire needs further evaluation for children below the age of 12 years.

The TESS questionnaire was chosen because a self- reported measure of function was wanted, as it is known that abilities in a clinical setting do not reflect abilities in the community (Haworth et al 1979, Sheikh et al 1979). It is known that there may be error associated with proxy report (Sprangers et al 1992, Dorevitch et al 1992) and it is likely that despite asking subjects to complete the questionnaire without assistance, the younger children's questionnaires may have been completed with parental assistance. In retrospect, the use of a more specific paediatric function questionnaire suitable for orthopaedics, such as the POSNA (Daltroy et al 1998) should also have been used for the children in the sample. In this analysis the TESS has not yet been shown to be suitable in the younger age group, nor could they complete it unaided.

The association between the self-reported and observed outcome measures was not as strong as may have been expected when both purport to measure the same dimension of physical function. Overall there are many reasons why the level of agreement between the observed outcome measures and the self-reported questionnaire measures was not stronger. Clinical observation measures may restrict the generalisability of the information beyond the clinical setting. Other explanations for the weak associations may be that the observed outcomes were all timed activities in which subjects were trying to score as highly as possible in a given time period. It is possible that many subjects would rate themselves as having no difficulty in carrying out an activity when they can perform that activity at a self paced optimum speed, yet their score may be poor when the activity is observed and scored against the clock. Satisfaction with the ability to perform an activity may not be related to time.

It is possible that the correlation between observed and self-rated activities would have been improved, if the observed activities had been scored on a basis of the quality of the movement, e.g. use of hands to assist in rising, use of walking aids, reciprocal pattern in stair climbing, rather than being done against the clock. The

TESS questionnaire does not specifically ask about the need to use aids to complete activities. Other studies have also shown a poor correlation between self -evaluation and observed performance (Wijlhizen et al 1999, Cress et al 1995, Reuben et al 1995). Another explanation may be differing self-efficacy beliefs amongst the subjects where a subject's confidence in their abilities (self-efficacy) might impact on their physical performance and self-completed questionnaire as reported by Rejeski et al (1996,1998).

The World Health Organisation (1990) has defined health as '*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'*. The choice of the TESS questionnaire excludes studying the effect of the procedure on social or mental well being. However, because of the nature of orthopaedic interventions, the physical function component of a patient's status is the most likely to be affected and thus the study focused on this particular aspect of health. Other authors have investigated the psychological and social impact of the Ilizarov method on patients (Ramaker et al 2000, Ghoneem et al 1996, Hrutkay et al 1990).

9.7 Summary

- All patients demonstrated a statistically significant improvement in their ability to perform functional activities following limb reconstruction surgery, continuing to improve for up to 2 years after frame removal.

- Knee flexion <100° was associated with poorer performance on the timed functional tests.

- All outcome measures were responsive to change in this population, but sit to stand showed the greatest responsiveness of the observed measures.

- The timed tests were responsive to change but did not consistently correlate well with observed measures. An observed measure that relied less on the speed that an activity was completed in, and more on the quality of movement might have correlated better with the self reported measure.

- The TESS self reported questionnaire was responsive to change, but did not correlate well to observed activities in the sub sample of the children in the group.

- The use of TESS in patients under the age of 12 years may not be appropriate, specifically designed paediatric measure of physical function such as the POSNA should be used and compared to the TESS.

- The use of TESS and sit to stand are recommended for adult patients.

- The use of a paediatric self reported measure and stair climbing are recommended for children. Further work needs to be done looking at incorporating size-related stair and chair measures into the testing protocol.

CHAPTER 10 - MUSCLE STRENGTH AFTER LIMB RECONSTRUCTION SURGERY

10.1 Clinical Studies of Muscle Function after Limb Lengthening.

A further important aspect of function is muscle strength. The effect of limb lengthening on muscle strength has been investigated but the results are inconclusive. Cattaneo (1986) and Shurov (1972) found that electromyographic changes occurred in the muscle after limb lengthening and that these were seen for a prolonged period of time before reverting to normal, despite normal histopathology. In 15 patients undergoing lengthening of 5 cm at a rate of 1.5 - 2.0 mm per day biopsies were taken at different times after the start of distraction. They found that dystrophic changes in parts of the muscle fibres occurred and that electromyographic changes were the last to return to normal after histomorphology and anatomy had been restored.

Young et al (1993) reported that prolonged muscle weakness is a feature of limb lengthening. The aetiology of this may be either neuropathic or myopathic. They studied six patients undergoing tibial lengthening with nerve conduction studies. All six demonstrated abnormalities in the deep peroneal muscle response, and in five there was an abnormal superficial peroneal sensory response.

Maffulli and Fixsen (1995) studied seven patients with congenital femoral hypoplasia who underwent lengthening of the femur. They measured the maximum, isometric voluntary contraction strength of the knee extensors for each leg pre-operatively and at six monthly intervals for 2 years, starting from 2 months after the fixator was removed. Changes in muscle strength were positively correlated with the increase in limb size in both the lengthened and the normal limb. They found that the normal limb was always stronger, even when standardised anthropometric estimates of the thigh muscle and bone cross sectional areas were calculated. Although limb length was equalised by the end of the procedure, the functional characteristics of the lengthened limb remained impaired for a significant time past the two- year follow up period of the study.

Kaljumae et al (1995) performed surface electromyography on seven patients, who had undergone between 11 and 24 % lengthening of the femur, 6-15 years after surgery, when the patients had made a complete recovery clinically. Electromyograms were made during sustained (thirty seconds) isometric extension of the knee, at an angle of 30°, while a load equal to 15 % of body weight was applied to the leg just proximal to the ankle. The average circumference of the thigh was smaller, the motor-unit recruitment of the muscles was slower and the fatigability was greater on the involved side compared with the uninvolved side. Vastus medialis exhibited greater fatigability and slower motor-unit recruitment than the rectus femoris or the vastus lateralis. There was a correlation between muscle fatigability and the preoperative limb length discrepancy and the percentage of lengthening. The percentage of lengthening correlated with the extent of motor unit recruitment. The authors concluded that the amount of damage to neuromuscular tissue varies according to the extent of the lengthening of the femur. Of all the knee extensors, the vastus medialis was the most affected. This study revealed that limb-lengthening surgery has a long-lasting effect on muscle, a finding in agreement with the reports by Kawamura (1968), Sofield (1958) and Macnicol (1982).

Conversely, Holm et al (1995) performed isokinetic testing of muscle strength of the quadriceps and hamstrings in 9 patients undergoing bilateral femoral lengthening for short stature. They measured the peak torque produced by the quadriceps and hamstrings at 60°/sec (measuring strength) and the total work of the muscles (measuring endurance). The median femoral lengthening was 17 %. Measurements were taken pre-operatively and between 2-3.5 years postoperatively. In all of the patients except one, who was measured at two years, there were only small changes in muscle strength. This may indicate that it takes over two years after the completion of limb lengthening surgery for muscle strength to be restored.

Thus, there is some uncertainty about the length of time that a decrease in strength following limb lengthening lasts, and whether these changes are permanent. The individual studies are difficult to compare as each uses a different patient

population and there are considerable variations in the amount lengthened and in the regimens used.

10.2 Purpose

This study sought to document the loss and return of strength following limb lengthening, in the clinical cohort of patients.

It was hypothesised that patients would not have regained their pre-operative strength two years after frame removal.

10.3 Measurement of muscle strength.

Amundsen (1990) states that muscle weakness almost always contributes to the problem of patients with movement disorders. He considers that the logical sequence for assessing the skeletal muscle strength component of movement is to first assess activities of daily living (ADL), then carry out simple performance tests followed by muscle strength testing. Techniques for measuring muscle strength vary from simple observations of ADL to sophisticated computerised systems. Isometric, isokinetic and power measurements have all been used to measure lower limb muscle function (Robertson 1998). For this study two methods of measurement were chosen, isokinetic dynamometry and measurement of extensor power.

10.3.1 Isokinetic dynamometry.

Isokinetic dynamometry may be used as an objective measure of muscle strength, a method that has been used by other researchers as an outcome measure (Holm 1995, Winquist 1985). Several devices are available e.g. Cybex, Biodex, Kin-Com. The device used in this study was a Kin-Com 125 machine (Chatanooga Group Ltd). The repeatability of this machine has been assessed previously and found to be satisfactory (Farrell and Richards 1986, Harding et al 1988). Isokinetic dynamometry has the advantage over isometric testing of allowing strength to be tested through range and both concentrically and eccentrically (Amundsen 1990).

10.3.2 Leg Extensor Power

Another useful measure of lower limb performance is leg extensor power (LEP). The ability of muscle to perform work over short periods may be defined as explosive power and be measured by the leg extensor power rig. It measures explosive power in a manner that minimises impact and excessive postural demands. The measures of explosive force obtained correlate to other measures such as a single jump. Bassey et al (1990a) also report significant correlations between LEP and ramp running and stair climbing. It is suggested that measures of maximal LEP are of more relevance to function than maximal strength measures, as the motion replicates movement patterns which are a common component of such tasks as walking and climbing stairs. It has good test-retest repeatability and in an elderly population agreed with other measures of performance such as sit to stand, stair climbing and walking (Bassey et al 1990,1992, Lamb et al 1995).

10.4 Method

10.4.1 Subjects

Measures of muscle strength were only completed on the adult subjects in the cohort undergoing femoral lengthening. Some of the children were physically too small to fit the testing equipment or had difficulty following instructions. The additional burden of undergoing muscle strength testing, at a time when they were subject to intensive medical examination and undergoing major surgery, was also considered to be too onerous for the children. Therefore, of the original patient cohort of 35 patients described in Chapter 7, 17 subjects were available for testing. One of these was not suitable as they presented with unstable non-union of the leg and had non-weight bearing status. 16 patients successfully completed the testing protocol being measured by both methods pre-operatively and at 6,12 and 24 months after the removal of the external fixator. The subjects are described in Table 10-1.

DIAGNOSIS	*Number*	*Sex*	*Age (Mean & S.D.)*
Mal-union	7	1♂, 6♀	31 (12.3)
Non-union	5	5♂	28 (3.8)
Childhood osteomyelitis	1	1♂	13
Hemiatrophy, hypoplasia	3	2♂, 1♀	15 (2.6)

Table 10-1: Description of subjects

All patients were tested on the Kin-Com 125 isokinetic dynamometer, following a set protocol that measured peak isokinetic torque of the knee flexors and extensors, during concentric muscle activity. Measurements were taken pre-operatively and at 6, 12, and 24 months post-operatively at an angular velocity of 60°/second. The range of motion for the knee was set between 0-90° flexion. Patients were positioned in the seat so that the axis of the knee joint was aligned with the axis of rotation of the machine. Patients were stabilised within the seat using straps to secure the pelvis, thigh and ankle and with their arms held in a relaxed position. Both legs were tested, the un-operated first. The patient warmed up on a cycle ergometer and was familiarised with the equipment prior to data capture (Figure 10-1). Standardised verbal commands were given with strong encouragement to produce a maximum effort.

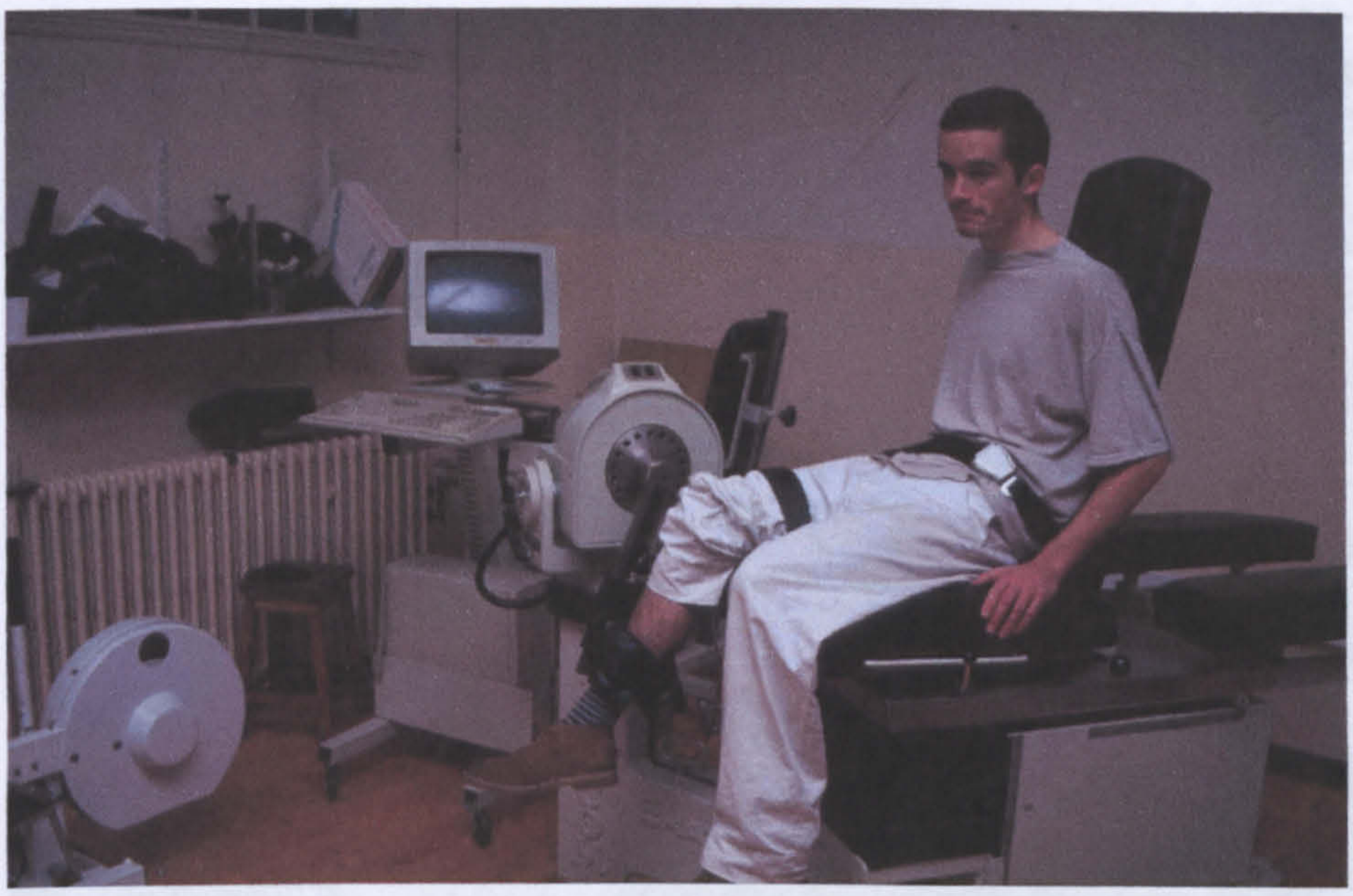


Figure 10-1: Kin-Com Isokinetic Dynamometer.

10.4.2 Measure of Leg Extensor Power.

Patients were measured using the Leg Extensor Power Rig (Bio-Med International, Nottingham). It consists of a seat and a footplate connected through a lever and chain to a flywheel. The subjects were seated in an upright position settled against the back of the seat. The seat position was determined by comfortable extension of the knee, in conjunction with full depression of the foot pedal varying with subjects' leg length (Figure 10-2). The subject rested their free foot on the floor and were asked to make 2-3 submaximal practice pushes, then 5 maximal efforts were requested. Strong verbal encouragement was given after the instruction to "push the footplate down as hard and as fast as possible". There was a rest period of 20s between efforts. After each attempt the force produced was displayed in Watts as a numeric display and recorded. The highest recorded power output was used. Both legs were measured. Body weight was recorded using a set of calibrated bathroom scales. Power was divided by body weight in Kg to give the measure of LEP (Watts/kg).

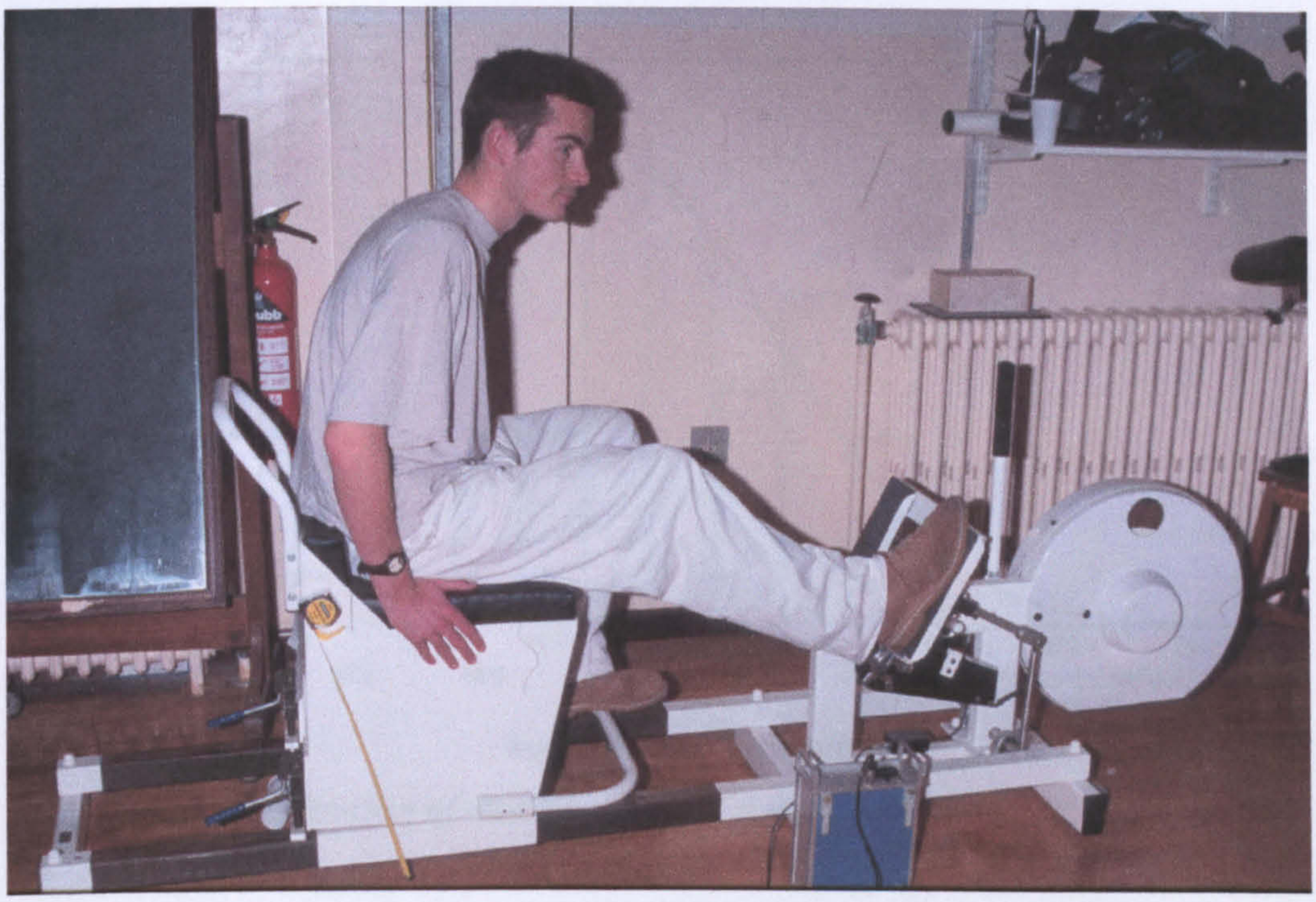


Figure 10-2: Leg Extensor Power Rig.

10.5 Data Analysis

The data was tested for normality, and where normally distributed, differences in the mean values were analysed with the Student t-test for paired data. For the data that was not normally distributed the Wilcoxon matched-pairs test was used.

10.6 Results

10.6.1 Isokinetic Dynamometry

Concentric isokinetic torque data was found to be normally distributed with a Kolmogorov-Smirnov statistic of 0.134, significance 0.200 (Figure 10-3).

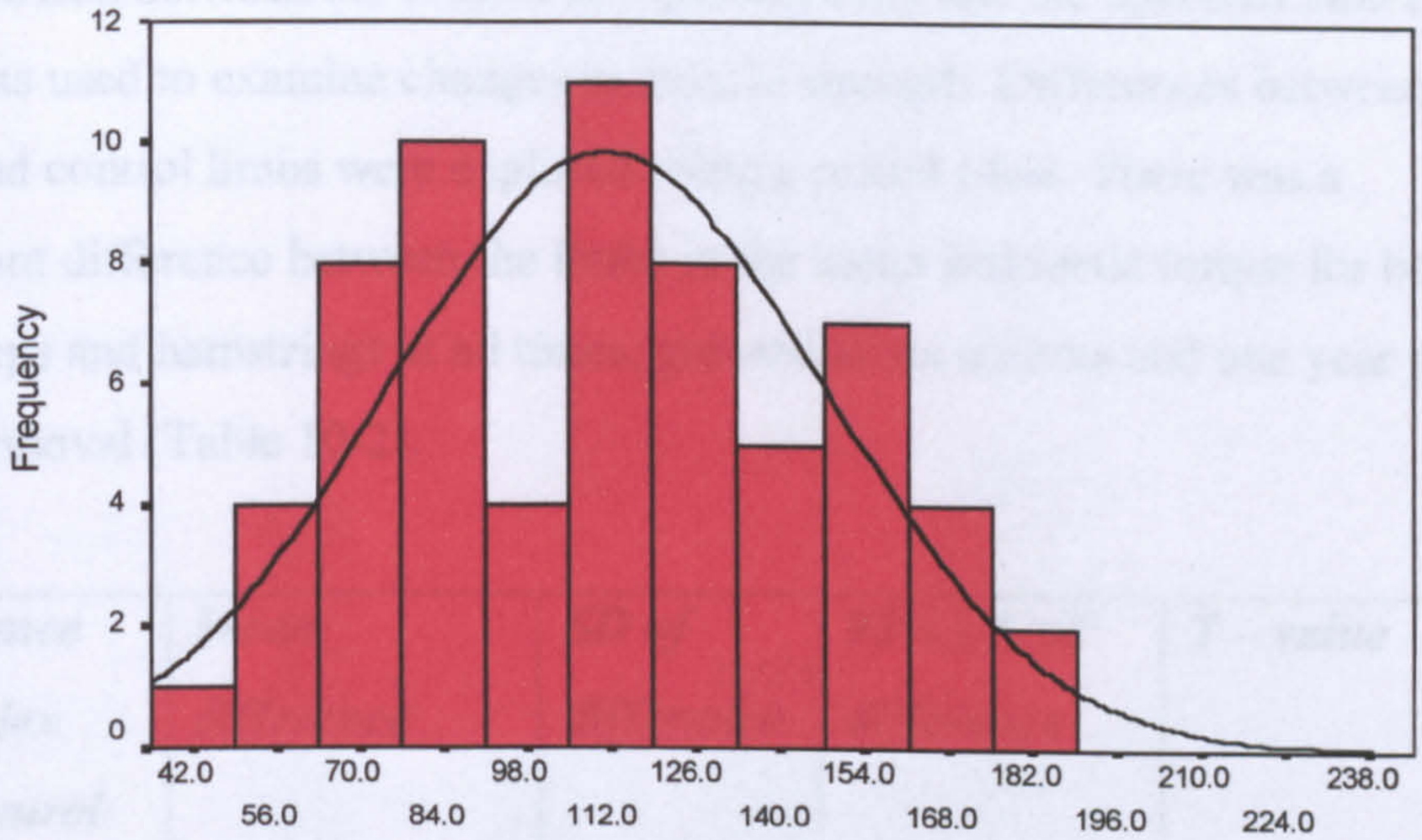


Figure 10-3 Distribution of muscle strength data.

A significant decrease in both quadriceps and hamstring torque was seen during lengthening and at 6 months after frame removal (Figure 10-4).

From six months onwards torque recovered until there was a percentage increase in the mean concentric torque values between the pre-operative and final values of 3% for quadriceps and 9.4% for hamstrings.

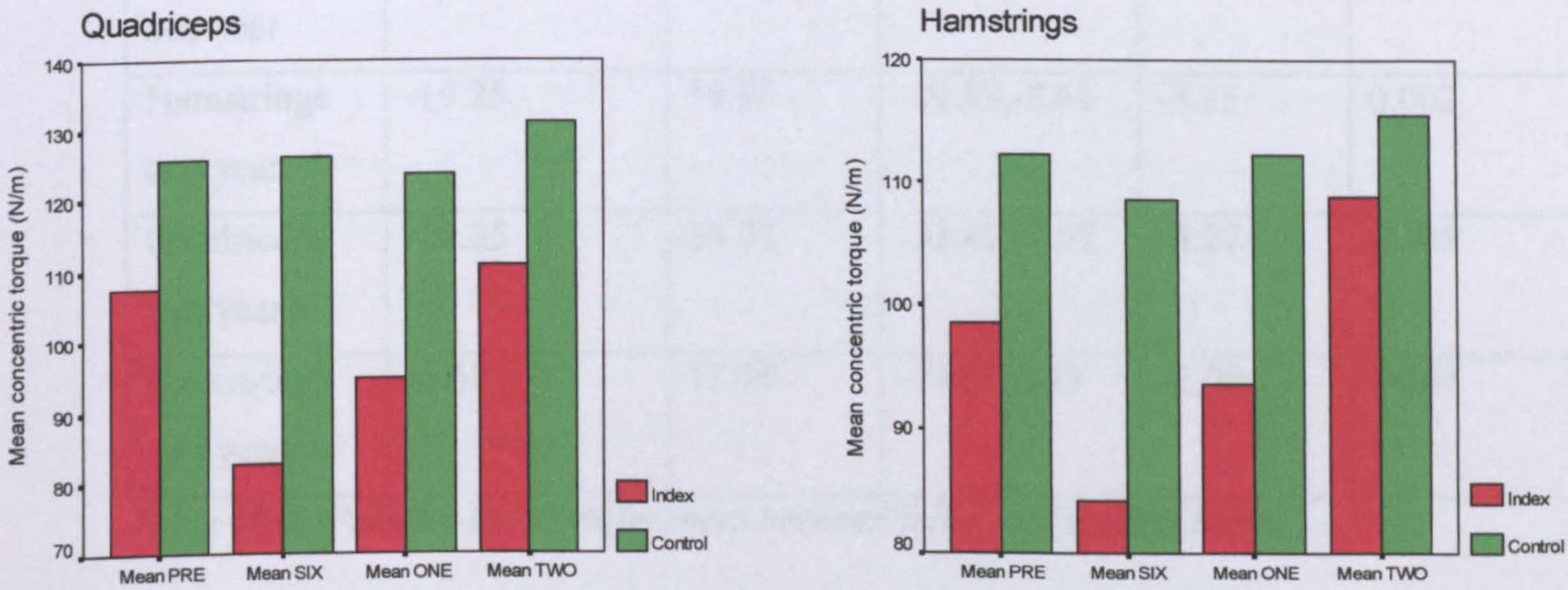


Figure 10-4:Changes over time in isokinetic muscle torque comparing index & control.

A comparison between the control un-operated limb and the operated limb (index limb) was used to examine changes in muscle strength. Differences between the index and control limbs were explored using a paired t-test. There was a significant difference between the limbs in the mean isokinetic torque for both quadriceps and hamstrings at all times, greatest at six months and one year post frame removal (Table 10-2).

Difference b/w index and control	***Mean difference***	***SD of difference***	***95% CI of difference***	***T – value***	***Significance***
Quadriceps pre-op	-16.81	36.65	-36.34,2.72	-1.83	0.086
Hamstrings pre-op	-13.75	29.30	-29.36,1.86	-1.87	0.080
Quadriceps six months	-44.81	29.54	-60.55,-29.07	-6.06	0.000
Hamstrings six months	-25.56	21.08	-36.79,-14.32	-4.85	0.000
Quadriceps one year	-29.56	26.25	-43.55,-15.57	-4.50	0.000
Hamstrings one year	-19.25	19.95	-29.88,-8.61	-3.85	0.002
Quadriceps two years	-20.25	24.72	-33.42,-7.07	-3.27	0.005
Hamstrings two years	-6.68	13.36	-13.80,0.43	-2.00	0.064

Table 10-2: Paired t-test of differences between index and control limbs.

Pre-operatively the difference between the limbs was not significant ($P < 0.08$). Thereafter, the differences between the limbs was greater with the differences being significant at the $p<0.005$ level for both quadriceps and hamstrings at six months and one year and for quadriceps at two years. The difference for hamstrings at two years was less ($p<0.1$). The muscles on the operated side were

weaker throughout. Figure 10-5 shows the changes in control / index limb torque over time.

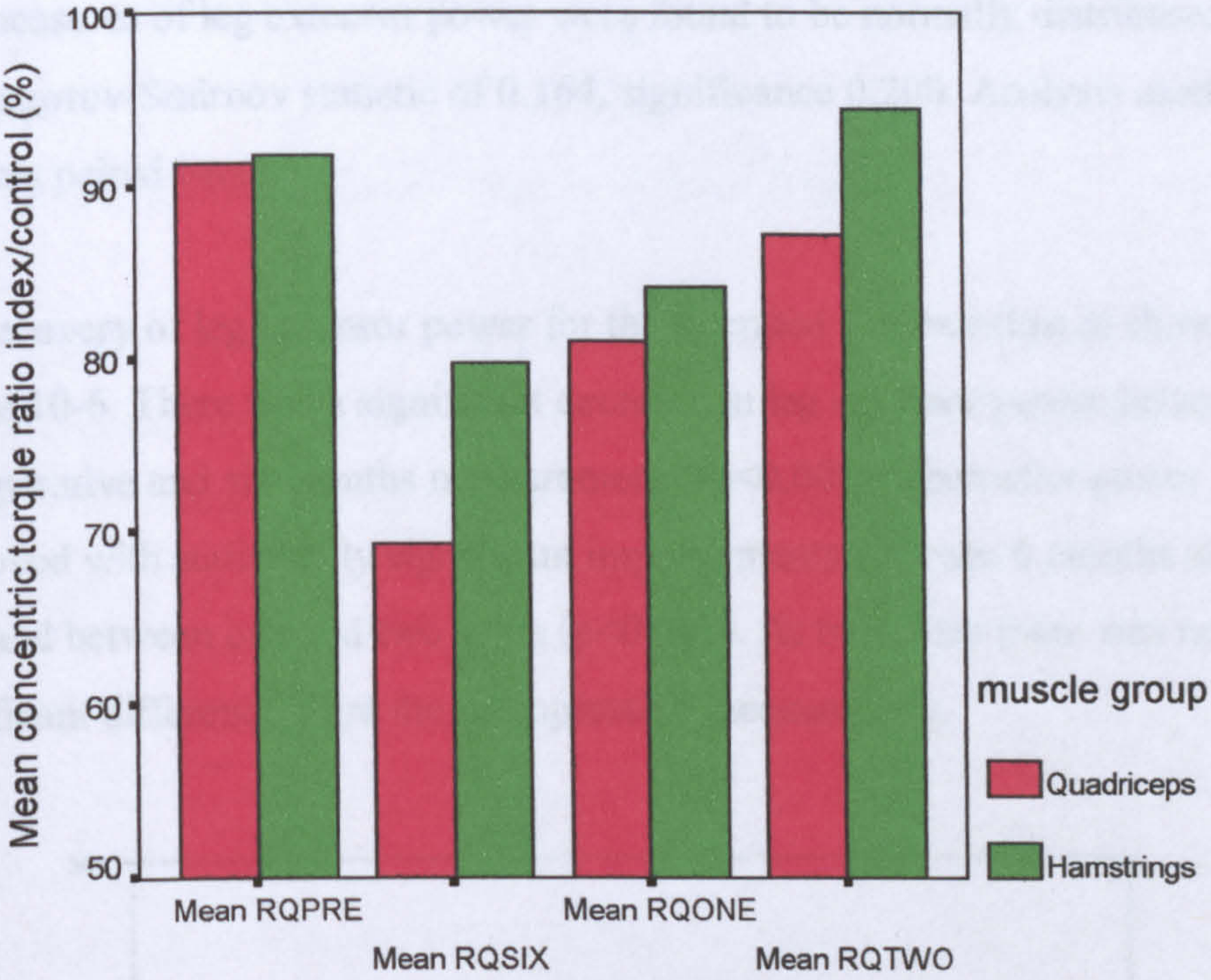


Figure 10-5: Changes in control/index limb torque over time.

A significant decrease in index/control torque ratio for quadriceps was found between pre-op and six months post frame removal ($p<0.01$). This improved at one and two years, but remained decreased compared to the pre-operative value. The decrease in index/control torque for hamstrings between pre-op and six months was less marked and did not reach statistical significance ($p<0.121$). The index/torque ratio for hamstrings was found to significantly increase from one to two years post frame removal ($p<0.008$).

The difference between the control and index limb at final review was a decrease of 15.5% for the quadriceps and an increase of 5.8% for the hamstrings.

10.6.2 Leg Extensor Power

The measures of leg extensor power were found to be normally distributed, with a Kolmogorov-Smirnov statistic of 0.164, significance 0.200. Analysis used students paired t-tests.

The recovery of leg extensor power for the operated leg over time is shown in Figure 10-6. There was a significant decrease in leg extensor power between the pre-operative and six months measurements ($p<0.001$). Thereafter power improved with statistically significant improvements between 6 months and one year and between one and two years ($p<0.001$). At two years there was no significant difference from the pre-operative measurement.

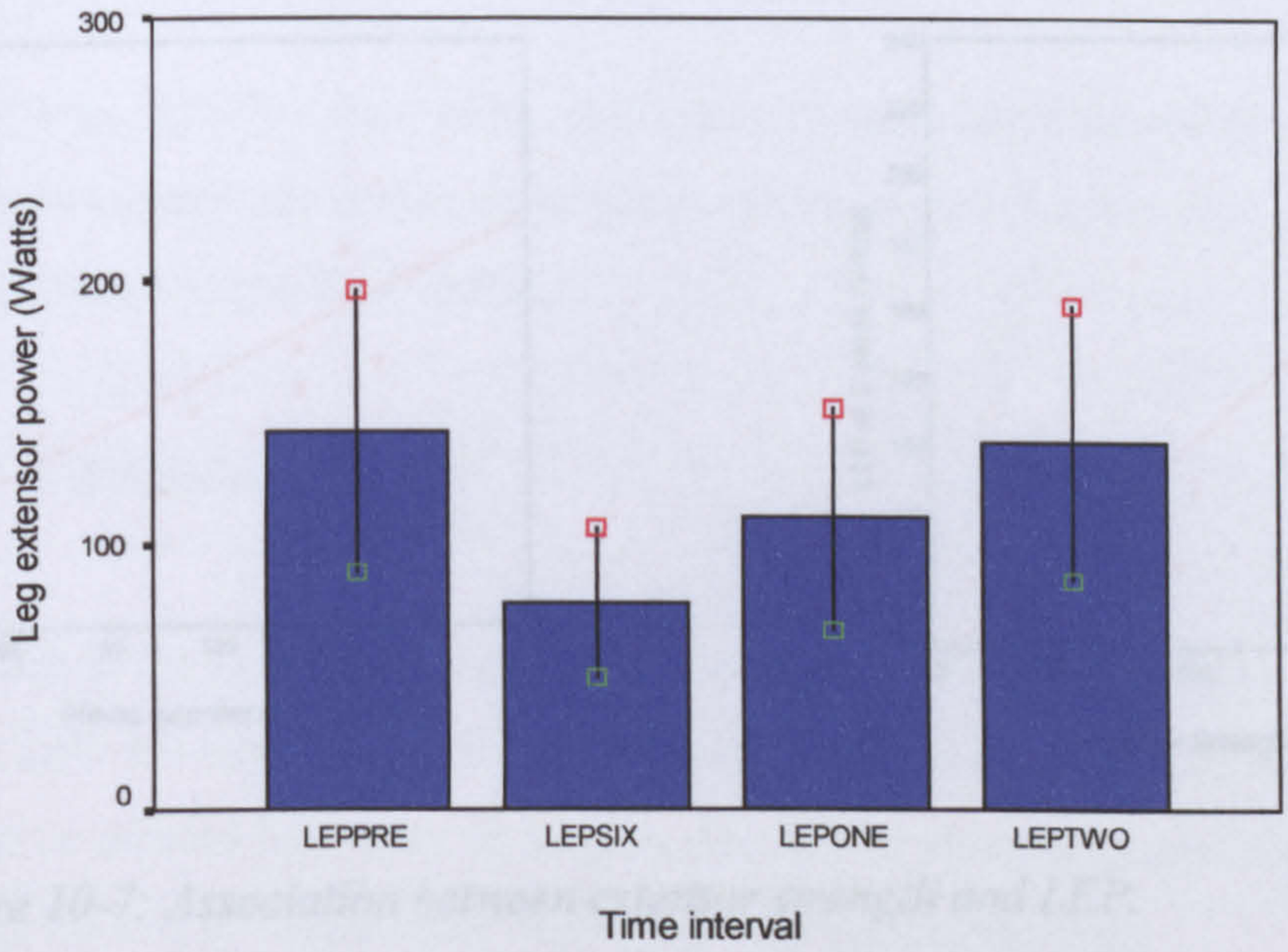


Figure 10-6 Changes over time in leg extensor power.

Measures of LEP were summarised as relative power i.e. absolute power divided by body weight, as this index has greater functional relevance and to allow comparison with other studies (Table 10-3).

	Mean Power (Watts/kg)	***Range***	***SD***
Pre-op	1.93	1.19 – 3.87	.65
Six Months	1.11	0.61 – 2.96	.55
One Year	1.57	0.91 – 4.65	.87
Two Years	1.96	1.16 – 5.37	.98

Table 10-3: Leg extensor power relative to body weight.

The strength of association for the measurements of concentric quadriceps strength and extensor power were found to correlate well, both pre-operatively (0.858, $p<0.01$) and at two years (0.851, $p<0.01$) Figure 10-7.

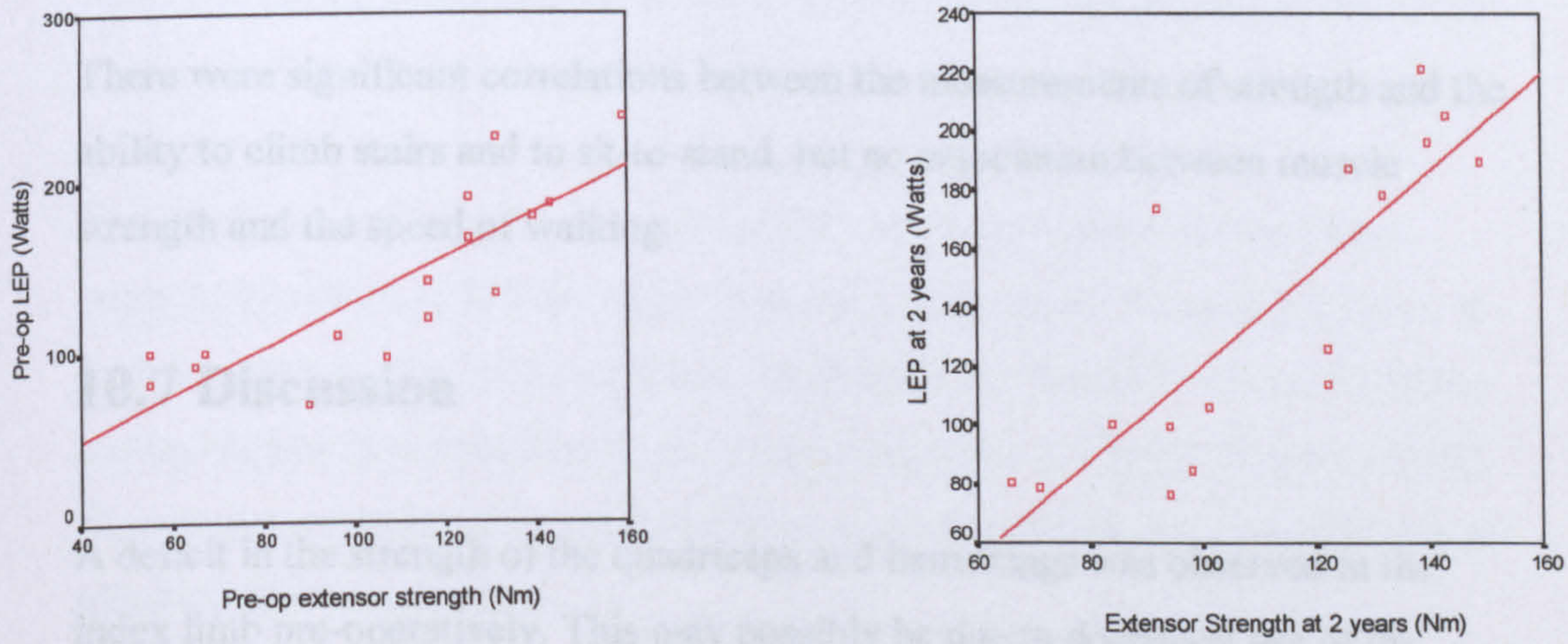


Figure 10-7: Association between extensor strength and LEP.

The strength of association between the muscle strength measurements and the other functional outcome measures was explored using Spearman's Rank correlation for the pre-operative data (Table 10-4).

	Pre-op Extensor strength (Nm)	***Pre-op LEP (W/kg)***	***Pre-op Stairs (No.in 60s)***	***Pre-op Sit-to-stand (No.in 60s)***	***Pre-op walking speed (m/s)***
Pre-op LEP (W/kg)	.858*		.779*	.774*	
Pre-op Extensor strength (Nm)		.858*	.737*	.770*	

*Correlation significant at 0.01 level.

Table 10-4: Correlations between muscle strength and function data

There were significant correlations between the measurements of strength and the ability to climb stairs and to sit-to-stand, but no association between muscle strength and the speed of walking.

10.7 Discussion

A deficit in the strength of the quadriceps and hamstrings was observed in the index limb pre-operatively. This may possibly be due to decreased use of the shorter or injured limb prior to surgery, to reduced physiological challenge to the shorter limb or to the patients' favouring their unaffected limb.

Quadriceps strength decreased more than hamstrings strength and at the final measure, two years after frame removal, quadriceps strength had just returned to the pre-operative value. The percentage difference between the operated and control limb was 15.5%, within the normal values of 0-24% quoted by Young et al (1984).

The return of muscle strength after lengthening, although very small, agrees with the reported findings of Kaljumae (1995) and Maffulli (1995). The failure of this

study to show an increase on the pre-operative value for quadriceps may well reflect an inadequate follow up time. It is of note that the one patient in Holm's cohort who did not regain their pre-operative peak torque value was the one with the shortest follow-up of just 2 years. The results presented here suggest that recovery can occur within two years. Holm suggested that it took more than two years for muscle strength to recover after limb lengthening. However, the patients in this sample were lengthened by a mean of 9.77 % compared to the mean 17% lengthening reported by Holm, which may explain why recovery appears to have occurred within two years after frame removal.

The effect of surgery on power was very similar to that of extensor strength. At 2 years post frame removal LEP had almost returned to the pre-operative value with just a 2.7 % decrease from the pre-operative value for LEP. For the concentric quadriceps score the difference between the pre-operative and 2-year values was 3%. Thus it can be seen that both measures of muscle strength and power correlate well. The testing procedure for the LEP is much simpler taking an average of 20 minutes per patient compared with 45-60 minutes for testing by the isokinetic dynamometer.

The mean values for LEP were only slightly lower than those reported for a normal population of 312 Watts for men and 173 Watts for women. However, at final review a number of patients had not attained the threshold value of 2 Watts per kg suggested as necessary to climb stairs (Activity & Health Research 1992). Despite not exceeding this threshold, there were no patients who had difficulty in climbing the stairs unaided.

Simpson and Kenwright (2000) cite an incidence of fracture in the early period after frame removal of 9.4%. It was this risk that precluded testing this cohort of patients at a time period earlier than six months post frame removal. However, as the LEP rig produces forces that are similar to those found in every day activities and the generation of force is along the long axis of the bone, the risk to the regenerate bone may be lessened. It is also advantageous as it is a closed kinetic chain exercise, that is one that is weight bearing, with the movement occurring at several joints and the distal segment fixed to a supporting surface. These are believed by many authors to be safer and more functional than open kinetic chain

exercises (Fitzgerald 1997, Kibler 2000). Thus it may be a safer method of testing muscle function than isokinetic dynamometry, which produces torque and is performed as an open kinetic chain exercise. Open chain exercises are usually non-weight bearing with movement occurring at a single segment and the distal segment free to move. The positive correlation between the measurements of LEP and concentric quadriceps concur with the findings of other authors (Robertson et al 1998) and Bassey et al (1992).

Bassey et al (1992) and Lamb et al (1995) report a strong association between LEP and other functional measures, although their studies were cross-sectional in design, not longitudinal. In this study a good correlation was found between LEP and stair climbing and sit to stand, but no association was found between LEP and walking speed. This is possibly because subjects were asked to walk the 20-metre course at a pace at which they felt comfortable, whereas the other activities represented the maximum performance possible in 60 seconds. It may also be affected by the fact that the walking speed in this population was towards the upper end of the normal range. Some authors have suggested that the relationship between walking speed and strength is curvilinear and that as strength increases, gains in walking speed become smaller (Buchner 1996, Ferrucci 1997, Lamb 1995). The patients in this cohort were appreciably stronger than the elderly subjects used in these studies, and this may account for the failure to find a significant association between these variables.

The activities of stair climbing and sit to stand are also more dependent on quadriceps strength than walking, which may explain their closer relationship to both LEP and concentric extensor strength.

10.8 Summary

- Concentric quadriceps muscle strength was decreased at 6 months post frame removal, but improved throughout the study period until it was within 3% of the pre-operative value at two years.

- The concentric data for hamstrings showed a similar pattern but the amount of the decrease in strength was much less.

- At all times the muscles on the operated side were weaker.

- The measurements of LEP showed a significant decrease in power in the first 6 months, which recovered over the two years, until the decrease in LEP was, on average, less than 3% of the pre-operative value.

- There was a strong correlation between the measures of LEP and concentric quadriceps torque.

- The functional activities of stair climbing and sit to stand correlated well with both LEP and quadriceps strength.

- Interestingly, there was no correlation between the measures of muscle function and walking speed, despite this being a finding in most other studies.

- As the LEP has good reliability and correlates well to concentric quadriceps measures its use is recommended particularly as it is quicker and easier to perform and potentially less hazardous to this type of patient.

CHAPTER 11 - FINAL SUMMARY AND DISCUSSION

11.1 Synopsis of study and findings.

One of the primary aims of this thesis was to investigate what is known about the current physiotherapy management of patients treated by the Ilizarov method. A review of the literature revealed that there were no published papers about rehabilitation that were evidence-based; all relied on descriptions of case studies or expert opinion.

Following a survey of current practice in the U.K. the research concentrated specifically on the effect of surgery on joint range of motion, muscle strength and on the ability to perform functional activities. This was investigated by conducting a longitudinal study on 65 patients, who formed a clinical cohort and who were studied prospectively from pre-operatively until 2 years after their frame had been removed.

The lack of published material led to qualitative research strategies being used to explore the level of knowledge about physiotherapy management. The information obtained was used to establish the areas for more detailed examination in the clinical study. The survey showed that there was considerable uncertainty about the clinical management of patients receiving physiotherapy during treatment by the Ilizarov method. Using the clinical study and existing sources of information, evidence-based guidelines were generated based upon expert opinion, to address this uncertainty, and the wish of 80% of the survey respondents for more information.

It was established that existing measurement tools were not reliable at measuring range of motion in patients wearing an Ilizarov fixator. An objective measurement tool was designed, constructed and assessed for repeatability and validity. The repeatability attained with the prototype goniometer was acceptable for the purposes of measuring range of motion during a clinic-based longitudinal study. Changes in range of motion of the knee and ankle during surgical lengthening of the femur, tibia or lengthening of both these bones were documented. These

showed a major decrease in range early in the programme during the latent period before distraction had started. This loss was greater than that reported by Herzenberg (1994) or Yasui (1997), who attributed loss of range to tension in the soft tissues. Fixed flexion of the knee exceeding 40° was associated with an increased risk of posterior subluxation of the knee, although this finding was based on small numbers. Lengthening of the tibia was associated with a permanent loss of dorsiflexion in a small number of patients, whilst loss of knee range in these patients was temporary and recovered fully.

The thesis aimed to identify whether there was an assessment measure that had predictive validity in respect of which patients would develop soft tissue complications. A simple, theoretical model was developed based upon anthropometric measurements of bone length and width, straight leg raise test (SLR) and range of motion of the knee. This suggested that incorporating the SLR test into the pre-operative assessment might be useful in warning the surgeon of potential difficulties with the soft tissues during lengthening.

Statistically significant improvements in the patients' ability to perform functional activities were observed following limb lengthening surgery. Function continued to improve until 2 years after frame removal. Function was linked to range of motion, those patients with < 100° of knee flexion performing less well at the timed functional tests. The use of a self reported questionnaire (TESS) was piloted for this patient population and found to be sensitive to change in subjects over the age of 12 years old, but not in younger patients. These functional outcomes were particularly important, as surgeons tend to report their results using indices such as state of union, limb length and alignment. Patients have a different perspective, being more interested in function and cosmesis (Saleh 1997). Other authors (McKee 1998, Saleh 1997) have used different functional questionnaires such as the SF-36 and Nottingham Health Profile, and the most appropriate functional questionnaire for this patient population has yet to be established. The use of the TESS by other researchers in this area may now be considered for adult patients.

Muscle strength deteriorated after limb reconstruction surgery, recovering to close to the pre-operative value by two years after frame removal. At all times the

operated side remained weaker than the control limb. Improvements in muscle strength were associated with improvements in function.

11.2 Significance of Findings.

This research is thought to contribute to the field of study in several ways. Firstly, a reliable objective measure of range of motion has been developed for patients with an Ilizarov fixator. This is important, as other studies of joint range have used methods that are less reliable for this patient population (Herzenberg 1994). The objective of identifying which factors contribute to the development of soft tissue complications was partially achieved. The association between pre-operative SLR, inherent length of the muscles and loss of joint motion is interesting but must be interpreted with caution due to the small numbers of patients involved. Likewise the significance of the loss of knee flexion in the latent period, the influence of the rate of lengthening and the differences noted between the results in adults and children should all be interpreted with caution, until replicated by study of a larger clinical cohort. The small number of subjects limited the number of factors that could be entered into the analysis of loss of joint range. As the outcome of limb reconstruction surgery is dependent upon many factors, more work is required to explicate and detail the causes of variation in outcome.

In an area where no evidence-based literature existed this study has added to the evidence-base available using both observational clinical studies and consensus techniques. The production of clinical guidelines is a significant step towards future research, providing a base line programme upon which future research may be based.

11.3 Clinical Relevance

The observations about the loss of range of motion have emphasised the need for physiotherapy efforts to be concentrated on regaining knee flexion in the early stages of rehabilitation, before distraction of the bone commences. The importance of maintaining range of motion if muscle is to be stimulated to regenerate has been highlighted. Likewise, the need to avoid the risk of posterior subluxation of the knee, by pausing the lengthening programme if > 40° fixed flexion of the knee develops is demonstrated, concurring with the clinical suggestions of Paley (1994) and Herzenberg (1994). The interplay between loss of knee flexion and ankle dorsiflexion in patients undergoing lengthening of the tibia is emphasised and suggestions made about the priority that should be given between these joints.

The lengthy time course of the involvement of physiotherapists with patients treated by the Ilizarov method is demonstrated both in the results of the survey of clinical practice and those of the clinical studies. It is important that physiotherapy is not stopped too early. Physiotherapists should be aware that whilst most recovery of lost range of motion will occur in the first 6 months after frame removal, muscle strength and function does not achieve maximal recovery until at least 2 years after frame removal.

The publication of clinical guidelines for the physiotherapy management of Ilizarov patients addresses a need for information that was identified in the early stages of the research. It will hopefully contribute to improving the consistency of rehabilitation across the country.

Patient care is likely to benefit from improved outcome assessment. This work has stressed the importance of objective and subjective measures in evaluating surgical intervention. The study has also highlighted the imbalance between the research into rehabilitation compared to the surgical management of patients.

11.4 Study Limitations

11.4.1 Sample Size

One of the main limitations of the study is the small sample size used. Machin et al (1997) state that if too few subjects are involved, the study is devalued because realistic medical improvements are unlikely to be distinguished from chance variation. For the main body of the trial 65 patients were used, but for some aspects such as measuring muscle strength the numbers were low and only 16 patients were studied.

The specialist nature of the surgery means that patient numbers are perforce small. All patients who underwent limb reconstruction surgery involving a net increase in limb length, at the Nuffield Orthopaedic Centre from January 1997 onwards were invited to participate in the research. The only exceptions were overseas patients, who would not be available for follow-up. Of all eligible patients over 90% consented to be included in the study. The small numbers included in the study of muscle strength was caused by the decision to exclude children from the testing, both because of difficulties in the reliability of measurements obtained, and because of the additional and unacceptable burden it was felt to place upon them.

Sample size calculations were performed based on the chance of detecting a clinically and statistically significant change in ROM and in muscle strength based upon the method of Altman (1991). The calculations are appended in Appendix 6. These calculations suggest that a sample size of 65 will detect a clinically relevant difference of 10°, with a significance level at 0.05 and the power at 0.80.

For the study of muscle strength a clinically relevant difference of 25 Nm was used. This would require sample sizes of 75 and 55 if the power and significance levels were set as before. With the sample size of 16 that was used, the power of the study is very small at 0.33.

The calculation of sample size makes the assumption that the sample uses continuous data and is split into 2 independent groups.
The small numbers involved in this research mean that care must be exercised in interpreting the results.

11.4.2 Study Design

Another potential criticism of the research is the choice of study design. The design was chosen as cohort studies are recommended where exposure is likely to be rare (Hennekens 1987, Bland 2000). By choosing to follow a clinical cohort the design was essentially a before-after trial with each subject serving as his or her own control. Thus the temptation exists to interpret all results as causally related. For each patient to effectively act as their own control assumptions had to be made about the patient population. In this study the assumption was made that on each occasion that measurements were recorded, the patient would make a maximal effort. This was facilitated by giving the same instructions and the same degree of encouragement at each session. The assumption was also made that the changes observed were attributable to the surgical intervention and not to other factors. Thus loss and recovery of joint range or muscle strength were attributed to the surgery and not to a natural deterioration or improvement in the patient over time. This assumption fails to allow for other explanations, such as the fact that as a number of the cohort were children they would naturally change in their abilities as they grew. It also fails to consider the impact of any physiotherapy treatment that the patients may have received. Nonetheless, the surgical intervention was felt to be so dramatic in its effect that it was safe to attribute most of any observed changes to the surgery and not to other factors.

Most authors would recommend the use of a control group to counteract the problems of patients acting as their own controls and circumspection is advised for investigators using patients as their own controls. However, as potential numbers were small and the time course of the intervention lengthy, it was not possible to ethically withhold treatment from patients in order to create a control group. The lack of any control group or randomisation, even though due to

practical and ethical reasons, means that conclusions arising from the research must be cautious (Andersen 1990).

11.4.3 Heterogeneity of Sample

The patients were heterogeneous in their characteristics, varying in age, cause of leg length discrepancy and chosen treatment technique. It is not ideal study design to have a heterogeneous sample, especially when the sample size is small. However, the advantage of the sample used is that it is truly representative of the population of the limb reconstruction clinic. Attempts were made to deal with the heterogeneity of the sample by dividing the total sample into 3 groups for analysis of range of motion, based upon the site of the surgical procedure. This increased the homogeneity of the sample. The analysis of the differences between the three groups presented in section 7.4.4 demonstrated that the homogeneity of the sample was increased by analysing the patients in this way.

11.5 Significance of Adding to the Evidence-Base.

Evidence-based medicine is defined as the integration of best research evidence with clinical expertise and patient values (Sackett et al 2000). This may be synthesised into clinical guidelines or " systematically developed statements to assist practitioner and patient decisions about appropriate health care" (Sackett et al 2000). Currently there is wide variation in clinical practice by physiotherapists, resulting from differences in individuals skills, knowledge, experience and ability, and from the different resources and philosophies in the environment within which they work (Bury 1998). Sir Michael Peckham, then Director of Research and Development for the NHS stated in 1991 that " *strongly held views based upon belief rather than sound information still exert too much influence in health care. In some instances the relevant knowledge is available but is not being used, in other situations additional knowledge needs to be generated from reliable sources*" (Department of Health 1991).

It was evident that there was little information in the public domain about the physiotherapy management of Ilizarov patients and that there was a need to try to generate and document knowledge in this area. The lack of supporting evidence derived from research for much physiotherapy practice is a recognised problem (Appleby et al 1995). Observations from clinical practice can be used to develop theories and ideas, which can then be evaluated in a systematic way.

This study has made a contribution towards providing evidence-based information. At present the strength of the information generated falls into category II, based upon Guyatt's hierarchy (Guyatt et al 1995).

This study contains baseline data that reports a cohort of patients, pragmatically treated by the physiotherapy protocols used at the hospitals where the research was conducted. Further work with other centres would be needed to strengthen the evidence-base. Furthermore, as yet no work exists that evaluates the efficacy of specific rehabilitation interventions.

11.6 Future Work.

Some of the implications for future research have been discussed in the relevant sections of the thesis. The studies are based upon a small sample and rely upon the clinical practice at one centre. The observations from this study need to be replicated by a larger multi-centre trial. The observed loss of range in the latent period, the link to the rate of lengthening and the time-dependant recovery curves are all worthy of further investigation, with an increased sample size to improve the results' validity.

The clinical guidelines that were produced should be evaluated to see if they do change clinical practice. Grimshaw and Russell (1993) conducted a systematic review of the effect of clinical guidelines on medical practice. They reported that

55 of 59 studies detected significant improvements in the process of care while 9 of 11 studies demonstrated significant improvement in patient outcomes. It would be interesting to assess the impact of the Ilizarov physiotherapy guidelines.

The use of a multi-centre approach to generate the consensus guidelines has enabled links to be forged that could be built upon to conduct such a multi-centre study in the future. With larger numbers and a multi-centre approach it would also be possible to compare the efficacy of different treatment regimes by a randomised controlled trial design, although this would obviously be costly in terms of such resources as time, money and personnel. The emphasis of these studies should be on demonstrable, sustained improvements in the patients' functional abilities. In conclusion, any research that furthers our understanding of how surgical reconstruction and subsequent rehabilitation improves function will contribute to the goal of providing the optimum treatment for this patient group.

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APPENDICES

Appendix No	Title	Referenced in section
1	Survey Questionnaire	4.3
2	Clinical Guidelines – Part 1	5.3.3
3	Clinical Guidelines – Part 2	5.3.3
4	Clinical Guidelines – Part 3	5.3.3
5	TESS questionnaire	9.3
6	Sample size calculation	11.4.1

ILIZAROV QUESTIONNAIRE

Q1 What is your Main clinical area of work?

Orthopaedics ☐

Paediatrics ☐

Community ☐

Other (please specify)

☐

4 5 6 7 8

Q2 How many patients wearing an Ilizarov frame do you treat per year?

☐☐☐

Q3 Were any of these upper limb?

Yes ☐

No ☐

Q4 Do you see Ilizarov patients (Please tick all that apply).

Pre-Operatively ☐

In-patients ☐

Out-patients ☐

Q5 Do you receive adequate information from the referring centre??

Yes ☐

No ☐

Q6 What is the main reason for the patients that you see wearing an Ilizarov frame (tick all that apply?)

	Adult	Child
Non Union	☐	☐
Acute trauma	☐	☐
Osteomyelitis	☐	☐
Congenital deformities	☐	☐
Acquired deformities	☐	☐
Foot deformities including Talipes	☐	☐
Short Stature	☐	☐
Other	☐	☐

Q7 If you feel able please state the most common group

☐

1 2 3 4 5 6 7 8

Q8 What are your main treatment objectives?

1 2 3 4 5 6 7 8 9 10

Q9 What treatment methods do you usually use?

1 2 3 4 5 6 7 8 9 10

Q10 How often do you see these patients?

Weekly ☐ Monthly ☐

PRN ☐ Other ☐

Q11 On average how long do you keep the patients on treatment?

Months ☐☐

Q12 What are your criteria for discharge?

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

Q13 Do you have involvement with / or use the following (tick all that apply).

Special class / group work ☐
Gymnasium ☐
Hydrotherapy ☐
Continuous passive motion ☐
Splinting ☐
Footwear modifications ☐

Q14 Do you work as part of a multidisciplinary team Yes ☐ No ☐

Q15 List in order of priority the 3 main problems that you have experienced in treating these patients:

1

1 2 3 4 5 6 7 8 9 10

2

11 12 13 14 15 16 17 18 19 20

3

21 22 23 24 25 26 27 28 29 30

Q16 Please mark the following in terms of difficulties that they present to you treating your patients.

	NONE	MINOR	MODERATE	MAJOR
Pain	☐	☐	☐	☐
Range of knee flexion	☐	☐	☐	☐
Loss of knee extension	☐	☐	☐	☐
Loss of dorsiflexion	☐	☐	☐	☐
Loss of plantarflexion	☐	☐	☐	☐
Other foot problems	☐	☐	☐	☐
Hip contractures	☐	☐	☐	☐
Pin site infections	☐	☐	☐	☐
Patient compliance	☐	☐	☐	☐
Psychological problems	☐	☐	☐	☐
Weight bearing	☐	☐	☐	☐

Q17 Is more information specific to the treatment of Ilizarov patients required?

Yes ☐ No ☐

PAEDIATRICS ONLY

Q18 Did the patient have a wheelchair?

Yes ☐

No ☐

Q19 If YES, who supplied it?

1 2 3 4 5 6 7 8 9 10

Q20 Was patient treated in:

- Hospital ☐
- School ☐
- Community ☐
- Other ☐
- Combination of the above ☐

Q21 If treatment was at school, was treatment only given during term time?

- Yes ☐
- No ☐

Q22 Did the patient appear to understand the treatment and adjustments to the frame needed?

- Yes ☐
- No ☐

Q23 Did the patient attend school?

- Yes ☐
- No ☐
- N/A ☐

Q24 If YES, was there a delay in getting back to school?

- Yes ☐
- No ☐

Q25 What was the reason for the delay in getting back to school?

1	2	3	4	5	6	7	8	9	10

Q26 Please feel free to add any other information about your experience of treating Ilizarov patients that you think is relevant.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Karen Barker, Nuffield Orthopaedic Centre, Oxford.

Mary Burns, St Peter's Hospital.

Research Physiotherapists

TREATMENT OF ILIZAROV PATIENTS

Please comment on each of the questions below, making any points that you feel are relevant and commenting as fully as possible. If you prefer you may wish to split your answers for different groups e.g. trauma, elective, paediatric. Please comment based on the optimum treatment you would like (not based on actual staff, resource etc.)

1. Should all Ilizarov patients be treated?

INPATIENTS

2. Ideally, at what frequency should treatment be given?

3. When should treatment start?

4. What are the main treatment objectives?

5. What treatment techniques do you use?

6. What involvement do you have with splints, footwear, aids etc.

7. What should a patient be able to do before they are discharged?

OUTPATIENTS

8. Should all patients receive Out Patient treatment?

9. Ideally, at what frequency should out patient treatment be given?

10. When should Out Patient treatment start?

11. What are your main treatment objectives?

12. What treatment techniques do you use?

13. What involvement do you have with splints, footwear, aids etc.?

14. How long do you think patients should receive treatment for?

15. Should patients attend a special class?

16. What are your discharge criteria?

Please return your questionnaire in the envelope provided by Thursday 15 July 1999 at the latest.

Thank you.

TREATMENT OF ILIZAROV PATIENTS (PART 2)

1. Using the scale provided, please rate how important you consider each of the following treatment objectives.

Objective	Not at all important	Fairly important	Important	Very Important	Essential
Increase joint range	☐	☐	☐	☐	☐
Increase muscle power	☐	☐	☐	☐	☐
Increase muscle length	☐	☐	☐	☐	☐
Increase functional independence	☐	☐	☐	☐	☐
Compliance with regime / motivation	☐	☐	☐	☐	☐
Increase weight bearing	☐	☐	☐	☐	☐
Reduce oedema	☐	☐	☐	☐	☐
Reduce positional problems	☐	☐	☐	☐	☐
Reduce contractures	☐	☐	☐	☐	☐
Reduce psychological problems	☐	☐	☐	☐	☐
Educate on management of scar tissue	☐	☐	☐	☐	☐
On frame management	☐	☐	☐	☐	☐
On pain control	☐	☐	☐	☐	☐
On gait	☐	☐	☐	☐	☐
On use of splinting	☐	☐	☐	☐	☐
To monitor progress	☐	☐	☐	☐	☐

2. How often do you use the following treatments?

Technique	Never	Occasionally	Usually	Always
Active range of movement	☐	☐	☐	☐
Passive range of movement	☐	☐	☐	☐
Active assisted range of movement	☐	☐	☐	☐
Soft tissue stretches	☐	☐	☐	☐
Gravity / frame assisted	☐	☐	☐	☐
Positioning	☐	☐	☐	☐
Pulley	☐	☐	☐	☐
Sliding boards	☐	☐	☐	☐
Isometrics	☐	☐	☐	☐
Strengthening	☐	☐	☐	☐
PNF	☐	☐	☐	☐
Weight bearing	☐	☐	☐	☐
Proprioception	☐	☐	☐	☐
Gait	☐	☐	☐	☐
Hydro	☐	☐	☐	☐
TNS	☐	☐	☐	☐
Heat pads	☐	☐	☐	☐
Massage	☐	☐	☐	☐
Splinting	☐	☐	☐	☐
Acupuncture	☐	☐	☐	☐
Eutrophic stimulation	☐	☐	☐	☐
Ultrasound	☐	☐	☐	☐
Rehab groups	☐	☐	☐	☐
Information booklets	☐	☐	☐	☐

3. How beneficial do you consider the following techniques to be?

Technique	Not at all	Fairly	Beneficial	Very	Essential
Active range of movement	☐	☐	☐	☐	☐
Passive range of movement	☐	☐	☐	☐	☐
Active assisted range of movement	☐	☐	☐	☐	☐
Soft tissue stretches	☐	☐	☐	☐	☐
Gravity / frame assisted	☐	☐	☐	☐	☐
Positioning	☐	☐	☐	☐	☐
Pulley	☐	☐	☐	☐	☐
Sliding boards	☐	☐	☐	☐	☐
Isometrics	☐	☐	☐	☐	☐
Strengthening	☐	☐	☐	☐	☐
PNF	☐	☐	☐	☐	☐
Weight bearing	☐	☐	☐	☐	☐
Proprioception	☐	☐	☐	☐	☐
Gait	☐	☐	☐	☐	☐
Hydro	☐	☐	☐	☐	☐
TNS	☐	☐	☐	☐	☐
Heat pads	☐	☐	☐	☐	☐
Massage	☐	☐	☐	☐	☐
Splinting	☐	☐	☐	☐	☐
Acupuncture	☐	☐	☐	☐	☐
Eutrophic stimulation	☐	☐	☐	☐	☐
Ultrasound	☐	☐	☐	☐	☐
Rehab groups	☐	☐	☐	☐	☐
Information booklets	☐	☐	☐	☐	☐

4. Which of the following should a patient be able to do before they are discharged? (Tick as many as you feel apply).

Transfer
Bed to standing
Floor to standing
Bed to chair

Mobilise
Mobilise with appropriate walking aid
Mobilise with appropriate
Weight bear (as appropriate)
Pinsite care
Have a maximum range of movement and muscle power
Have passive and active range of movement
Apply appropriate splint

5. Ideally, at what frequency should out patient treatment be given? Please tick the most appropriate one from each section.

A No problem group
Weekly ☐
Fortnightly ☐
Monthly ☐
With clinic appointment ☐
SOS ☐

B During Lengthening / Active Frame Adjustment
Daily ☐
2 – 3 x per week ☐
Weekly ☐
Fortnightly ☐
Monthly ☐

C Minor / Moderate Problems
(Please give examples of what you consider these to be and what you would define as minor / appropriate)

Daily ☐
2 – 3 x per week ☐
Weekly ☐
Fortnightly ☐

D Major Problems

(Please give examples of what you consider these to be and what you would define as major)

Daily	☐
2 – 3 x per week	☐
Weekly	☐
Fortnightly	☐

6. When should Out Patient treatment start?

< 3 days	☐
3 – 5 days	☐
Within 7 days	☐
Within 14 days	☐

7. What treatment techniques do you use in Out Patients, in addition to those listed in question 2?

8. How long do you think patients should receive treatment for?

a) Until condition has plateaud	☐
b) Until frame is removed	☐
c) After frame removal	☐

9. How important do you consider the following discharge criteria?

Technique	Not at all important	Fairly important	Important	Very Important	Essential
Outcomes achieved	☐	☐	☐	☐	☐
Frame off	☐	☐	☐	☐	☐
Max / plateau function	☐	☐	☐	☐	☐
Full ROM	☐	☐	☐	☐	☐
Full muscle power	☐	☐	☐	☐	☐
No longer lengthening	☐	☐	☐	☐	☐
Discharged by surgeon	☐	☐	☐	☐	☐
Full WB	☐	☐	☐	☐	☐
Minimal gait alteration	☐	☐	☐	☐	☐
Psyshologically / able to cope without contact from Physio	☐	☐	☐	☐	☐

Please would you indicate (delete as applicable) whether you think you will be able to attend the meeting in Oxford on 3 December 1999.

Your Name(s)

YES, I / we shall be able to attend on 3 December 1999

NO, I / we shall not be able to attend on 3 December 1999

Thank you once again for completing our questionnaire

Please would you return your completed 2nd questionnaire (and the 1st one if you have not yet done so) in the envelope provided by
10 September 1999.

TREATMENT OF ILIZAROV PATIENTS (PART 3)

This third questionnaire builds on the previous rounds of questions but requires more detailed answers. This will be the final round before the draft guidelines are drawn up. The draft guidelines will be presented at the consensus meeting in Oxford on 3 December 1999. For those who are unable to attend the meeting, the draft will be sent to you, for your comments, in advance.

AIM OF QUESTIONNAIRE

To arrive at precise muscle groups, joints focused on at each stage for an average patient presuming they have the normal range of complications, compliance etc.

Question 1
Would you consider the following to be:

Minor / Moderate Problem

	YES	NO
Minor pin site infection	☐	☐
Wire breakage	☐	☐
Mod loss of ROM	☐	☐
Difficulty weightbearing	☐	☐

Major Problem

	YES	NO
Joint subluxation	☐	☐
Loss of ROM requiring hospitalisation	☐	☐
Nerve / vascular injury	☐	☐

Question 2

Phase One

Do you teach patients a pre-op stretching programme? ☐ Yes ☐ No

If so list the muscles that you teach patients to stretch in order of priority.

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Phase Two

What treatment do you give in the immediate post op phase prior to starting frame adjustment whilst the patient is an in-patient?

List of ROM exercises (in order of Priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Strengthening / stretching exercises (in order of priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Transfers / Functional activity

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Others

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Phase three

What treatment do you give in the period of activity lengthening / frame adjustment?

List of ROM exercises (in order of Priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Strengthening / stretching exercises (in order of priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Transfers / Functional activity

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Others

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Phase four

Treatment in consolidation phase / after frame adjustments complete.

List of ROM exercises (in order of Priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Strengthening / stretching exercises (in order of priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Transfers / Functional activity

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Others

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Phase Five

Treatment after frame / splintage removal

List of ROM exercises (in order of Priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Strengthening / stretching exercises (in order of priority)

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Transfers / Functional activity

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Others

a) Femoral frame

b) Tibial frame

c) Combined femoral and tibial frame

d) Upper limb frame

Thank you for completing this final questionnaire.

Please return it in the envelope provided to arrive no later than

Monday 8 November 1999.

The following questions ask about your ability to perform activities that are common to everyday life. Considering the amount of difficulty you have performing the activity due to the current problem you are having with your leg, please answer the questions by choosing the answer that best describes your ability to do the activity **over the past week.**

1 PUTTING ON A PAIR OF TROUSERS IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

2 PUTTING ON SHOES IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

3 PUTTING ON SOCKS OR STOCKINGS IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

4 SHOWERING IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

5 LIGHT HOUSEHOLD CHORES eg tidying and dusting are:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

6 GARDENING AND OUTDOOR WORK ARE:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

7 PREPARING AND SERVING MEALS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

8 GOING SHOPPING IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

9 HEAVY HOUSEHOLD CHORES eg Vacuuming and moving furniture:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

10 GETTING IN AND OUT OF THE BATH IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

11 GETTING OUT OF BED IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

12 RISING FROM A CHAIR IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

13 KNEELING IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

14 BENDING TO PICK SOMETHING UP FROM THE FLOOR IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

15 WALKING UPSTAIRS IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

16 WALKING DOWNSTAIRS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

17 DRIVING A CAR IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

18 WALKING WITHIN THE HOUSE IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

19 WALKING OUTDOORS IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

20 SITTING IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

21 WALKING UP OR DOWN HILLS OR A SLOPE IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

22 STANDING UPRIGHT IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

23 GETTING UP FROM KNEELING IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

24 GETTING IN AND OUT OF A CAR IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

25 PARTICIPATING IN SEXUAL ACTIVITIES IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

26 COMPLETING MY USUAL ACTIVITIES AT WORK (OR HOME IF A HOUSEWIFE) IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

27 WORKING MY USUAL NUMBER OF HOURS IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

28 TAKING PART IN MY USUAL LEISURE ACTIVITIES IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

29 SOCIALISING WITH FRIENDS AND FAMILY IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

30 PARTICIPATING IN MY USUAL SPORTING ACTIVITIES IS:

1	☐	Impossible to do
2	☐	Extremely difficult to do
3	☐	Moderately difficult
4	☐	A little bit difficult
5	☐	Not at all difficult
99	☐	This task is not applicable for me

Sample size calculations

This used the values for :

1. clinically relevant difference (δ)
2. standard deviation of the difference (*s*)
3. the significance level (α - 2 sided)
4. the power (1-β)

The Standardised difference was calculated : δ / *s*

Using Altman's nomogram a straight line was 'drawn' from the value for the standardised difference scale to the power scale at the 0.9 and 0.8 power levels and the sample size equivelent to a significance level of 0.05 was read off.

Range of Motion

Clinically relevant difference = 10°.
Pre-op SD = 14.09.
10 / 14.09 = 0.709.
If draw line between 0.709 and 0.9 power at significance level of 0.05
N = 80.
If draw line between 0.709 and 0.8 power at significance level 0.05
N = 64.

Muscle Strength

Clinically relevant difference = 25 Nm.
Pre-op SD = 32.82
25/32.82 = 0.76.
If draw line between 0.76 and 0.9 power at significance level of 0.05
N = 75.
If draw line between 0.76 and 0.8 power at significance level of 0.05
N = 55.
With a sample size of 16 the power of the study is 0.33.

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