CHANGES IN LOWER INCISOR INCLINATION FOLLOWING THE TREATMENT OF CLASS II MALOCCLUSIONS WITH THE TWIN-BLOCK AND BUTTON-AND-BEAD APPLIANCES: A SINGLE CENTRE RANDOMISED CONTROLLED TRIAL

BY

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ABSTRACT

AIM: To compare post-treatment changes in lower incisor inclination in patients with Class II division 1 malocclusions treated with the Twin-Block and Button-and-Bead appliances.

METHOD: A UK based, single centre, prospective, two-armed randomised controlled trial with a 1:1 allocation ratio was conducted at the Birmingham Dental Hospital between July 2017 and January 2018. A total of 64 participants (28 males and 36 females) were recruited to the study and participants were randomly allocated to one of the two arms of the study. The primary outcome measure was differences in changes in lower incisor inclination in patients treated with the Twin-Block and Button-and-Bead appliances. Secondary outcomes included differences in the changes in upper incisor inclination, the ANB angle, changes in the maxillary-mandibular planes angle (MMPA) and lower anterior face height (LAFH).

RESULTS: Treatment was successfully completed by 47 participants (21 males and 26 females). A total of 17 (27%) participants did not complete the intervention as planned. There was no statistically significant difference in the change in lower incisor inclination between the two appliances ($p=0.372$). The Button-and-Bead appliance resulted in a statistically significant greater degree of upper incisor retroclination whilst the Twin-Block appliance resulted in statistically significant greater reductions in the ANB angle. No statistically significant differences were found for MMPA and LAFH between the two appliances.

CONCLUSION: Both appliances were effective in the treatment of Class II division 1 malocclusions. The Twin-Block appliance appeared to result in a greater degree of skeletal change compared to the Button-and-Bead appliance, although these differences are unlikely to be of clinical significance. There was no difference in the degree of lower incisor proclination between the two appliances.

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LITERATURE REVIEW

1. LITERATURE REVIEW

1.1 Introduction

Orthodontics is the speciality of dentistry, which is concerned with the development and management of deviations in the positions of the teeth, jaws and face from the norm. A malocclusion is described when the position of the teeth deviates from what is considered to be the norm. A normal incisor relationship is described as a Class I incisor relationship in which the incisal edges of the lower incisors occlude with or just anterior to the cingulum plateau of the upper incisors (British Standards Institution, 1983). In a Class II malocclusion, the upper teeth are further forward than in a Class I relationship. This malocclusion is further divided into Class II division 1 and Class II division 2 malocclusions. In a Class II division 1 malocclusion, the incisal edges of the lower incisors occlude posterior to the cingulum plateau of the upper incisors and the upper incisors are either proclined or of average inclination. In a Class II division 2 malocclusion, the upper incisors are retroclined (British Standards Institution, 1983). Angle (1899) defined a Class II division 1 malocclusion in which the mesio-buccal cusp of the upper first permanent molar occludes anterior to the buccal groove of the lower first permanent molar and the overjet is increased (Angle, 1899).

1.2 Prevalence

A Class II malocclusion is one of the most commonly occurring malocclusions and affects around 25% of 12 year olds (Holmes, 1992). The prevalence of a Class II division 1 malocclusion amongst the Caucasian population is reported to be around 27% (Foster and Walpole Day, 1974). The prevalence of Class II malocclusions varies widely between racial groups, ranging from 16% amongst Afro-Caribbean individuals (Garner and Butt, 1985), to 22.5% amongst Caucasian individuals (Horowitz, 1970). The prevalence is reported to be 21.5% in Chinese and Latino populations (Lew et al., 1993, Silva and Kang, 2001).

1.3 Aetiology

The aetiology of a Class II division 1 malocclusion is multifactorial and can be divided into skeletal, soft tissue and dental factors. A complex multifactorial process involving both genetic and environmental factors is involved in the development of different malocclusions with suggestion of polygenic inheritance for Class II division 1 malocclusions (Mossey, 1999).

1.3.1 Skeletal pattern

Class II division 1 malocclusions are usually associated with a Class II skeletal pattern, where the mandible is further behind the maxilla compared to a Class I skeletal relationship. Class II skeletal patterns have been reported in 76% of cases with a Class II malocclusion. Retrusion of the mandible relative to the maxilla can occur due to a small or hypoplastic mandible, a normal sized mandible postured posteriorly, an obtuse cranial base angle or a combination of all three (Hopkin et al., 1968). Reduced mandibular length associated with a hypoplastic mandible has been attributed to reduced vertical condylion growth and less gonial modelling than in Class I patients (Jacob and Buschang, 2014). Sidlauskas et al. (2006) reported a retrognathic mandible in 60% and a prognathic maxilla in 55.8% of patients with a Class II skeletal pattern when assessing the cephalograms of 86 9-12 year olds (Sidlauskas et al., 2006). Conversely, a cross-sectional study, which assessed 277 lateral cephalograms of Class II malocclusions reported huge variation in the aetiological factors for Class II malocclusions amongst 8-10 year olds. The most commonly reported finding was a retrusive mandible. The position of the maxilla was found to be relatively neutral, and where there was an abnormality, the maxilla was more likely to be retrusive than protrusive. In the vertical dimension, both increased and reduced vertical dimensions have been reported (McNamara, 1981, Sidlauskas et al., 2006).

1.3.2 Soft tissues

The soft tissue positions in a Class II division 1 malocclusion are usually as a result of the skeletal pattern, both anterior-posteriorly and vertically. Ideally, the lower lip should cover the incisal third of the upper incisors at rest (Naini and Gill, 2008). With more severe Class II skeletal patterns or increased vertical proportions, the lips may be incompetent, in which case the upper incisors escape control of the lower lip and are proclined. A lower lip trap can also contribute to an increased overjet by further proclining the upper incisors. In cases of lip incompetence, individuals will attempt to achieve an anterior oral seal during swallowing either through circumoral muscular activity, forward posturing of the mandible, placing the tongue to the lower lip or placing the lower lip behind the upper incisors. The method of achieving an anterior oral seal can result in proclination of the upper incisors and retroclination of the lower incisors, contributing to an increased overjet (Mossey, 1999).

Prolonged thumb or digit sucking acts as an orthodontic force, which can alter the position of the developing dentition. The resulting Class II division 1 malocclusion occurs due to retroclination of the lower incisors and proclination of the upper incisors, contributing to spaced upper incisors and an increased overjet. Although the tongue and lips can allow for some self-correction, this is less likely to occur whilst the habit still persists (Curzon, 1974). The positioning of the digit also results in a localised anterior open bite, which may be asymmetric. Unilateral crossbites often occur as a result of the tongue occupying a lower position in the oral cavity. This leaves the buccinator muscle unopposed and together with the negative pressure generated during sucking, results in narrowing of the upper arch (Larsson, 1987). The severity of malocclusion that develops is dependent on the frequency, intensity and duration of the habit.

1.3.3 Dento-alveolar factors

A Class II division 1 incisor relationship may also occur as a result of crowding, in which lack of space results in displacement of the upper lateral incisors palatally, proclination of the upper central incisors and exacerbation of an overjet. In addition, upper arch crowding may not always be evident as an increase in the anterio-posterior arch dimension allows for accommodation of all the teeth with an increased overjet. Where there is an existing periodontal condition, there is less supporting alveolar bone and the upper incisors can escape control of the lower lip, resulting in a Class II division 1 malocclusion (Bernhardt et al., 2019).

1.3.4 Other causes

Rarer causes of a Class II division 1 malocclusion include juvenile rheumatoid arthritis affecting the temporomandibular joints before the age of 16 which restricts the growth of the mandible and can result in a severe Class II skeletal pattern (Synodinos and Polyzois, 2008). A similar skeletal pattern can be seen in cases of condylar fractures in growing children, with 5-10% of mandibular deficiencies being as a result of condylar trauma (Proffit et al., 1980). Individuals with sickle cell disease can also present with a Class II division 1 malocclusion as a result of maxillary bone marrow expansion in response to the reduced life span of red blood cells (Alves e Luna et al., 2014). This results in an increased overjet, spaced and proclined upper incisors and a deep bite. Several syndromes including Treacher Collins, Hemifacial Microsomia, Achondroplasia, Pierre Robin sequence and Moebius syndrome are also associated with a Class II division 1 malocclusion.

1.4 Need for treatment

The Index of Orthodontic Treatment Need (IOTN) is an index used in the National Health

Service (NHS) to assess eligibility for orthodontic treatment. According to the IOTN, patients with an overjet between 6.1mm and 9mm are classified as having a great need for treatment. Those with an overjet of greater than 9mm are classified as having a very great need for treatment (Brook and Shaw, 1989). The treatment of a Class II division 1 malocclusion is indicated for both dental health and psychosocial implications.

1.4.1 Trauma

A Class II division 1 malocclusion is associated with an increased incidence of dental trauma. Studies have shown that patients with an overjet of 6mm or more are four times more likely to sustain injuries to the upper incisors compared to those with a smaller overjet (Schatz et al., 2013). A systematic review published by Nguyen et al. (1999) analysed 11 different studies to assess the relationship between an increased overjet and traumatic dental injuries. It was reported that children with an overjet of greater than 3mm were twice as likely to sustain injuries to the anterior teeth when compared to those with an overjet of less than 3mm. The risk of injury increased with the increase in overjet (Nguyen et al., 1999).

1.4.2 Bullying

Seehra et al. (2011) reported an incidence of bullying of 12.8% amongst 10-14 year olds with untreated malocclusions (Seehra et al., 2011a). This incidence of bullying was associated with an increased overjet and increased overbite, features that are commonly associated with a Class II division 1 malocclusion. A study assessing the effects of interceptive orthodontics on bullied adolescents due to the presence of a malocclusion suggested that 71% of adolescents were no longer being bullied following commencement of their orthodontic treatment (Seehra et al., 2013). Adolescents being bullied due to the presence of a malocclusion reported a negative impact on their self-esteem and oral-health-related quality of life (OHRQoL) (Seehra et al., 2011b).

1.4.3 Psychosocial factors

Although the relationship between malocclusion and psychosocial health is complex, occlusal traits such as a large overjet have been reported to have a significant negative impact on the quality of life of children and their families (Johal et al., 2007). Helm et al. (1985) reported unfavourable self-perception amongst adolescents to be associated with an extreme overjet, deep bite and the presence of dental crowding (Helm et al., 1985). Other studies have reported improved self-esteem in individuals who have completed fixed appliance therapy, with less of a psychological and social impact on the daily performances of adolescents following completion of orthodontic treatment (Jung, 2010, Bernabe et al., 2008). Patients undergoing functional appliance therapy reported higher levels of self-esteem and positive childhood experiences when compared to a control group with no orthodontic treatment. Lower levels of negative experiences were also experienced by those receiving early treatment compared to the control group in the short term (O'Brien et al., 2003b). In contrast, although orthodontics improves dental appearance, longitudinal observational studies have shown that treatment does not directly improve overall body image or self-esteem, with no significant effect on psychological well-being following orthodontic treatment (Shaw et al., 2007). Variation in the literature is likely due to analysis of different data sets and population groups and the complex and multifactorial processes contributing to one’s self-esteem.

1.5 Treatment modalities

The treatment of a Class II division 1 malocclusion is influenced by a number of factors. Clinicians must consider the aetiological factors involved, severity of the malocclusion, the underlying skeletal pattern, patient age, patient compliance and patient preference. Additional considerations include factors such as dental crowding and tooth morphology. A thorough clinical examination with the aid of radiographs allows for accurate diagnosis and treatment planning on an individual basis. Treatment can be carried out at various different stages with a variety of appliances. Treatment modalities can be categorised as orthodontic camouflage, growth modification or orthognathic surgery.

1.5.1 Orthodontic camouflage

Orthodontic camouflage involves treatment of malocclusions with the use of either fixed appliances or removable appliances in order to mask the underlying skeletal discrepancy. As removable appliances are capable of only tipping movements, their use can be considered in well-aligned arches. With the use of a removable appliance, correction of a Class II division 1 malocclusion can be achieved by overbite reduction with a flat anterior bite plane allowing for posterior eruption of the molars and retroclination of the upper incisors with the use of an activated labial bow in order to reduce their proclination. Correction of a more severe overjet and crowding requires the use of fixed appliances, either on an extraction or non-extraction basis. Fixed appliances are capable of bodily retracting teeth; however, the movements achieved are limited by the amount of bone surrounding the upper incisors. Upper mid-arch extractions to create space for overjet reduction and relief of crowding are indicated, but can increase the nasio-labial angle, which is often aesthetically undesirable. Soft tissue and skeletal factors need to be considered and patients should be informed of the possible consequences of orthodontic camouflage (Kinzinger et al., 2009). Irrespective of the treatment modality, it is essential to ensure that the upper incisors are under the control of the lower lip at the end of treatment to maximise chances of stability (Verma and Chitra, 2019).

1.5.2. Growth modification

Growth modification utilises orthopaedic change in order to improve skeletal discrepancies and is considered to be best carried out in growing children or adolescents. In the mixed or early permanent dentition, where the mandible is deficient, growth modification can be of particular use in the treatment of Class II division 1 malocclusions, resulting in a reduction in the severity of the malocclusion or even complete resolution. The use of growth modification is not limited to anterior-posterior change but can also be beneficial for correcting transverse and vertical discrepancies. Examples of growth modification include functional appliances and the use of headgear.

Headgear is an extra oral orthodontic appliance, which utilises the cranio-facial bones in order to provide extra oral traction or anchorage in conjunction with a removable or fixed appliance. There are three directions of pull which can be achieved with headgear including high or occipital pull, straight or combi-pull and low or cervical pull. High pull headgear is usually indicated in cases with increased vertical dimensions, combi-pull is used to allow anterior-posterior control in cases of average vertical dimensions and low pull is used in patients with reduced vertical dimensions and deep over bites. Studies have shown distalisation of the maxillary molars and restraint on maxillary growth with extra-oral traction, which is beneficial in the treatment of Class II division 1 malocclusions (Tulloch et al., 1997, Henriques et al., 2015).

1.5.3 Orthognathic surgery

Treatment of Class II division 1 malocclusions can pose difficulties in cases of severe skeletal discrepancies and in adults where there is little or no growth potential. Orthognathic surgery can provide true correction of an underlying skeletal discrepancy whilst also aiding the treatment of vertical and traverse discrepancies and correction of any concurrent facial asymmetry. Surgical treatment involves a phase of pre-surgical orthodontics in which the teeth are decompensated into an ideal position for surgery. Surgical treatment involves repositioning of either the maxilla, mandible or a combination of both, followed by a short phase of post-surgical orthodontic treatment. Orthognathic surgery has a number of potential complications which include cranial nerve injury or numbness in up to 50% of cases, tempomandibular joint disorders or impairment, bleeding, auditory damage, infection, swelling and dento-alveolar complications (Jędrzejewski et al., 2015). Studies have reported a higher incidence of relapse as a result of condylar resorption when compared to non-surgical treatment in borderline Class II division 1 cases (Cassidy et al., 1993). Evidence suggests a greater risk of condylar resorption in female patients with mandibular deficiencies and a high mandibular planes angle (de Moraes et al., 2012).

A cephalometric study of 60 young adults with a Class II division 1 malocclusion compared camouflage orthodontics, growth modification and orthognathic surgery (Kinzinger et al., 2009). A reduction in overjet was seen despite the treatment modality, however, bony change and an increase in mandibular length were only evident in the surgical and functional appliance group. Although there is no single indicator for orthognathic surgery, Proffit et al. (1992) reported an indication for orthognathic surgery in patients with an overjet of more than 10mm, especially where mandibular length is less than 70mm (Proffit et al., 1992).

1.6 Functional appliances

A functional appliance is a removable or fixed appliance, which is usually used in growing individuals to treat Class II division 1 malocclusions. By allowing forward posturing of the mandible, it is thought that forces generated through stretching of striated muscles and soft tissues are transmitted to the dentition and skeletal structures. Despite being in use since the 1930s, their ability to truly "modify growth" is unclear and treatment often needs to be followed by a course of fixed appliance therapy. Although there is no universally accepted classification for functional appliances, they can be divided into either tooth or tissue borne, depending on where they derive their support and myotonic or myodynamic, depending on the mechanism of action and degree of soft tissue stretch induced by the appliance (Carels and van der Linden, 1987). Myotonic appliances rely on the elastic recoil within the stretched soft tissues in order to generate the forces that move the dentition, whereas myodynamic appliances, rely on the forces generated by the muscles of mastication in order to allow tooth movement.

Several different functional appliances have been developed for the treatment of Class II division 1 malocclusions. The more commonly used appliances include the Twin-Block, Herbst and Bionator appliances. The Bionator is a tooth-borne removable appliance constructed in one piece. It has been shown to be effective in overjet reduction and correction of Class II division 1 malocclusions through a combination of skeletal and dento-alveolar effects (Almeida et al., 2004). The Herbst appliance is a fixed functional appliance, which is used in conjunction with a fixed appliance. When compared to the Twin-Block appliance, a randomised controlled trial showed that the Herbst appliance was equally effective in treating Class II division 1 malocclusions, however, compliance was much greater, with a failure rate of 12.9% amongst the Herbst group and 33.6% amongst the Twin-Block group. Nevertheless, the Herbst appliance was more expensive to construct and the Herbst group required more unscheduled attendances due to a greater number of breakages (O'Brien et al., 2003c).

1.6.1 Twin-Block appliance

The Twin-Block is a type of tooth-borne, myodynamic, removable functional appliance, which was designed for the treatment of Class II division 1 malocclusions. The original appliance incorporated upper and lower inclined bite blocks in the premolar region, designed to lock together at a 45° angle, in order to create favorable occlusal forces by maintaining a forward displacement of the mandible (Clark, 1988).

Clark's original design allowed use of this appliance with orthopedic traction for the treatment of severe anterior-posterior and vertical skeletal discrepancies. It incorporated a Concorde facebow to allow for combination of extra oral traction with inter-maxillary traction, eliminating the unfavorable upward component of inter-maxillary traction (Clark, 1982). The original upper appliance consisted of clasps on the upper molars with incorporation of a coiled tube to allow traction to be applied. An upper labial bow allowed control of the upper labial segment with incorporation of a midline screw for transverse expansion in the maxilla to accommodate for the advancement of the mandible. In the lower arch, retention for the appliance was obtained with interdental ball ended clasps anteriorly and arrowhead clasps in the buccal segments (Clark, 1988).

A survey of British Orthodontists revealed that the Twin-Block appliance for treatment of Class II division 1 malocclusion was the most prescribed functional appliance, being preferred by 75% of British Orthodontists (Chadwick et al., 1998). Treatment with the Twin-Block appliance and other removable appliances is heavily reliant on patient compliance and cooperation. Failure of compliance with the Twin-Block appliance has been reported to be between 15% and 50% in the literature (Illing et al., 1998, Barton and Cook, 1997).

1.6.2 Modifications of the Twin-Block appliance

There have been various modifications of the Twin-Block appliance in order to allow different orthodontic effects. Screws can be incorporated into both the upper and lower appliances in order to allow expansion in the sagittal and transverse planes. The screw design can also allow separation of anterior and posterior expansion. Anterior screws with the addition of torqueing spurs can be of particular use in the case of retroclined upper incisors and the correction of Class II division 2 malocclusions with the Twin-Block appliance (Dyer et al., 2001). Magnetic Twin-Block appliances have been modified with either samarium and cobalt, or naeodymium and boron, to allow a magnetic force to posture the mandible forwards in the treatment of Class II patients (Wu et al., 2007). Reported advantages include force prediction, controlled anchorage and good patient compliance (Xu et al., 1999). A fixed Twin-Block appliance is designed with inclined bite blocks extended from a transpalatal arch in the upper and a lingual arch in the lower, allowing full time wear in patients with poor compliance (Gong et al., 2016). Reverse Twin-Blocks which are fabricated in the position of maximum possible retrusion of the mandible can be used for the early management of Class III malocclusions (Mittal et al., 2017).

1.6.3 Mode of action

The Twin-Block appliance allows for correction of Class II division 1 malocclusions through a combination of both skeletal and dento-alveolar effects. Suggested skeletal effects include an increase in mandibular length (Sidlauskas, 2005) and anterior relocation of the glenoid fossa, resulting in a forward positioning of the mandible (Bhattacharya et al., 2013). The restraint of maxillary growth has been debated, with systematic reviews suggesting no clinically significant effect of the Twin-Block appliance on maxillary growth (Ehsani et al., 2015, Jena et al., 2006). Despite several studies using the SNB angle to assess skeletal changes in the mandible, a systematic review including 22 studies concluded the SNB angle to be a poor indicator of mandibular growth. Changes in Pogonion (Pg) also occurred as a result of the increase in the lower face height following functional appliance therapy. Although 66% of the studies reported a significant elongation in total mandibular length, this was not reported in any of the 4 randomised controlled trials and most studies included were of medium quality (Cozza et al., 2006).

Dento-alveolar changes include retroclination of the upper incisors, proclination of the lower incisors, mesial tipping and eruption of the mandibular molars as well as distalisation or inhibition of mesial movement of the upper molars (Ehsani et al., 2015). Success of treatment is reliant on patient cooperation as well as timing treatment with periods of growth. Large variation in response to treatment amongst different individuals has been reported (Bishara and Ziaja, 1989).

A prospective controlled study by Lund and Sandler (1998) investigated the skeletal and dento-alveolar effects produced in patients treated with the Twin-Block appliance compared to an untreated control group. A total of 63 patients were recruited and randomised to either treatment with a modified version of Clark's Twin-Block or no treatment. The study found a statistically significant increase in mandibular length of 2.4mm, an increase in the vertical face height and an overall improvement in the Class II skeletal pattern in the treatment group through an increase in the SNB angle. Changes in the maxillary position were assessed using measurement of the SNA angle, with no evidence of any maxillary restraint in the treatment group. The mean overjet reduction was 7.5mm with significant proclination of the lower incisors and retroclination of the upper incisors during Twin-Block therapy. Statistically significant changes in the molar relationship were observed amongst the Twin-Block group, with evidence of small but significant upper molar distalisation and forward movement of the lower molars. A significant amount of lower molar eruption was also seen, aiding reduction in the overbite as well as an increase in the lower face height (Lund and Sandler, 1998).

Tulloch et al. (1997) compared the skeletal changes between patients undergoing growth modification in the form of headgear or functional appliances and those without growth modification. The trial consisted of three phases of treatment: early treatment in the mixed dentition (phase 1), treatment in the permanent dentition (phase 2) and retention following treatment (phase 3) over a period of 10 years. Stratified block randomisation was used to allocate 166 patients to one of the three groups for phase 1, with all cases being treated by one clinician. At 15 months, findings reported small but significant differences amongst the growth modification and control groups, with evidence of maxillary restraint in the headgear group and an increase in mandibular length and mandibular advancement in the functional appliance group. Despite the statistically significant results, wide variation was seen in all three groups, with some patients in the control group showing an improvement in the skeletal pattern despite having no treatment and others in the treatment group showing worsening of the skeletal pattern despite receiving treatment. A huge variation in growth, with or without treatment was seen (Tulloch et al., 1997).

A cephalometric study assessing the effects of the Twin-Block appliance utilised the Pancherz analysis to provide a comparison of treatment changes. Statistically significant changes were observed in the treatment group, with evidence of slight maxillary restraint using SNA as a measure and an increase in mandibular length in the form of ramus length. A statistically significant increase in the SNB was also seen amongst the treatment group. An increase in anterior and posterior facial height, upper molar distalisation and increased eruption of the lower molars were also observed in the Twin-Block group. The study attributed 50% of the change in the molar relationship as a result of skeletal changes and the other 50% being dento-alveolar. Although the results were promising, the study consisted of a small sample size of consecutively treated patients with no randomisation, making it difficult to draw conclusions regarding the long term effects of the Twin-Block appliance (Mills and McCulloch, 1998).

A randomised controlled trial conducted by O'Brien et al. (2003a) studied the effectiveness of early orthodontic treatment specifically with the Twin-Block appliance. This was a multicentre randomised controlled trial carried out in the United Kingdom. A total of 174 children between the ages of 8-10 years old were recruited and randomised to either a control group or treatment with the Twin-Block appliance using block stratification for gender and treatment centre. Outcomes measured were limited to the final anterior-posterior discrepancy using the Pancherz analysis, the final overjet and the final peer assessment rating (PAR). Through a combination of dento-alveolar and skeletal effects, early intervention with the Twin-Block appliance resulted in statistically significant reductions in overjet, correction of molar relationships and reduced the severity of the malocclusion. The study described 73% of the change in the overjet occurring as a result of dento-alveolar change with the remaining 27% being attributed to skeletal changes. With regards to changes in the molar relationships, 59% occurred as a result of dento-alveolar change and 41% due to skeletal changes. Statistically significant skeletal changes were found, but this amounted to only 1.9mm, which may not be clinically significant. The changes in the skeletal pattern were attributed to varying amounts of growth between individuals with the majority of the overjet reduction occurring as a result of dento-alveolar changes. Although some degree of favourable mandibular growth was seen in the Twin-Block appliance group, this was not thought to be clinically significant. A mild restraining effect on the maxilla was evident, however, this was attributed to possible retroclination of the upper incisors and remodelling of A point, rather than a true maxillary restraint effect (O'Brien et al., 2003a).

1.6.4 Timing of treatment

There is further controversy surrounding the timing of orthodontic treatment and the benefits of early treatment. Treatment can be carried out in two phases, with the first phase being carried out in the pre-adolescent years of 8-11 years old where treatment objectives are limited and focused around overjet and overbite reduction (Fulstow, 1968). The second phase of treatment is more definitive and usually carried out around the age of 12-15 years old once the permanent dentition is fully established (Dugoni, 1998). In Class II division 1 cases, the first phase of treatment often involves treatment in the form of growth modification to allow reduction of the overjet and some correction of the Class II skeletal discrepancy. This is then followed by a second phase of treatment involving fixed appliances.

The benefits of early Class II treatment were assessed in the second part of a series of studies by Tulloch et al. (1998). One hundred and forty seven of the 166 treated patients continued to a second phase of treatment, with treatment being carried out by 4 different clinicians. Preliminary results suggested very little benefit of early treatment with headgear or functional appliances, and although treatment time in fixed appliances was shorter if early treatment was carried out, the overall time in treatment was significantly longer. Only small differences in the anterior-posterior skeletal patterns were noted (Tulloch et al., 1998). This was later confirmed in the final follow up of the study, which concluded that although early treatment resulted in skeletal and dental differences when compared to the control group, these differences were not maintained following treatment in the permanent dentition. Early treatment did not appear to reduce the complexity of treatment in the second phase, with a similar number of patients going on to have dental extractions or surgery regardless of whether early treatment was received or not (Tulloch et al., 2004).

A 10 year follow up study by O’Brien et al. (2009) compared groups receiving early treatment in two stages at 8-9 years old or treatment in late adolescence in a single stage at an average age of 12.4 years. Whilst early treatment resulted in significant reductions in overjet, small skeletal changes and improved self-esteem of patients, in the long term, this resulted in increased treatment time, increased patient attendances and a higher overall treatment cost, with little overall benefit of early treatment (O'Brien et al., 2009). Although there is an increased burden on resources and time spent in treatment for patients, early treatment has been shown to reduce the incidence of trauma to the maxillary incisors. No other advantages in terms of treatment outcome and skeletal change have been found in the long term (Thiruvenkatachari et al., 2013). Careful patient and case selection is required in order to assess the benefits of early treatment of a Class II division 1 malocclusion for each individual.

1.6.5 Button-and-Bead appliance

The Button-and-Bead appliance is a hybrid appliance combining the use of mandibular advancement and Class II elastics. It has been reported to provide promising results in the treatment of Class II division 1 malocclusions (Spary and Little, 2015). The appliance was initially referred to as “a simple Class II corrector” and consists of upper and lower vacuum formed retainers with plastic beads in the upper first molar region and acrylic blocks in the lower molar region. Bonded attachments in the form of buttons, either metal or composite, are placed on the buccal aspects of the lower first molars and the upper lateral incisors and the patient is instructed to wear the appliance full time in combination with Class II elastics. The correction of Class II division 1 malocclusions with the use of Class II elastics occurs through dento-alveolar changes in the form of extrusion and mesialisation of the lower permanent molars, retroclination and extrusion of the maxillary incisors and proclination and intrusion of the mandibular incisors. The literature suggests an average period of 8.5 months for the correction of Class II discrepancies with the use of light forces on stabilised arches and excellent patient compliance (Janson et al., 2013).

Case reports published by Spary and Little (2015) reported two Class II division 1 cases treated with the Button-and-Bead appliance. The first reported a 7mm reduction in the overjet in just 3 months with fully corrected buccal segments. A second case combining the use of a sectional fixed appliance showed full overjet reduction and correction of buccal segments in just over 5 months. Its use has also been documented in a third case for the correction of a Class III malocclusion and a reverse overjet (Spary and Little, 2015). These case reports showed promising results with regards to overjet reduction and correction of the buccal segment relationship in Class II division 1 cases. Given the limited number of cases reports and evidence surrounding the appliance, further research is required regarding the skeletal and dental effects of the Button-and-Bead appliance as well as patient acceptance and satisfaction.

1.7 Growth

Certain orthodontic treatment modalities such as growth modification rely on periods of accelerated growth. It is therefore crucial to identify and monitor patients so that orthodontic interventions can be timed appropriately with the stage of growth. Hägg and Pancherz (1988) reported that patients treated during the pubertal peak experience twice the amount of sagittal condylar growth when compared to patients treated 3 years before or after this period (Hägg and Pancherz, 1988). Baccetti et al. (2000) investigated the timing of treatment with functional appliances assessing treatment outcomes at a mean age of 9 years old and 11 years old. Treatment with functional appliances was most effective at the onset or just after the pubertal peak as this resulted in the greatest skeletal contribution to the molar correction, large increments in mandibular and ramus length and a more posterior direction of mandibular growth (Baccetti et al., 2000).

Historically, hand wrist radiographs were utilised as a means of assessing skeletal maturation, however, their use can no longer be justified due to the excessive radiation involved (Hägg and Taranger, 1980). Other biological indicators include the standing height of the patient (Hunter, 1966), the stage of dental development, voice changes (Hägg and Taranger, 1980) and maturation of the cervical vertebrae (O'Reilly and Yanniello, 1988). Chronological age in males and females does not appear to represent the adolescent peak in skeletal maturation (Baccetti et al., 2006).

1.7.1 Hand wrist radiographs

Fishman (1982) developed an 11-grade system as a method of predicting the onset of the peak pubertal growth spurt using skeletal maturation indicators on hand-wrist radiographs (Fishman, 1982). Studies have shown that assessment of skeletal maturation using hand-wrist radiographs is indicative of the velocity of horizontal and vertical facial growth, however, correlations of mandibular and maxillary growth velocities with skeletal maturation are weaker (Flores-Mir et al., 2004). Verma et al. (2009) reported a statistically significant correlation between growth predictions from hand-wrist radiographs and increases in patient height. However, no correlation was found between the growth predictions and increases in mandibular length during the observation period (Verma et al., 2009). Similarly, a further study reported that growth predictions with hand-wrist radiographs did not give a predicable indication of remaining vertical growth of the mandibular ramus (Verma et al., 2012).

1.7.2 Standing height

In adolescents, most studies have reported the incremental peak in skeletal maturation of the maxilla and mandible to be in line with the growth peak in body height (Björk and Helm, 1967). Studies have suggested that growth of body height completes prior to growth of the face, with the pubertal peak velocity of facial growth occurring just after that of standing height (Nanda, 1955). Despite this, it appears that height proves to be the greatest indicator of skeletal maturation with studies showing that the anterior-posterior length of the mandible has the most consistent relationship with growth in height during adolescence (Hunter, 1966). Despite a secular trend for an increased growth velocity and early maturation for height over the 19th century, standing height and the age of menarche appears to be stabilising (Cole, 2003). There is a secular trend towards early maturation of the mandible, which appears to have accelerated in comparison to somatic growth (Patcas et al., 2017).

1.7.3 Cervical vertebral maturation

Cervical Vertebral Maturation (CVM) staging is a method, initially described by Lamparksi in 1972, used to assess skeletal maturation on lateral cephalograms, with applications for determining the peak of pubertal growth. This method consisted of 6 stages assessing the morphological features of the second to the sixth cervical vertebrae (Lamparski, 1972, Lamparski, 1975). Hassel and Farman (1995) later described the CVM staging method based on the assessment of the second to the fourth cervical vertebrae (Hassel and Farman, 1995). The use of this technique was popularised by Baccetti et al. (2002) (Baccetti et al., 2002, Baccetti et al., 2005). Stages 1 to 3 represent an accelerative phase of growth whilst stages 4 to 6 represent a decelerated phase of growth. The period between stage 3 and 4 represents the pubertal growth peak, which is key for growth modification to be effective (Petrovic et al., 1990). Hellsing (1991) described a strong correlation between the length of cervical vertebrae and the standing height of 8-11 year olds (Hellsing, 1991). The uses of the CVM method has been further documented by Franchi et al. (2000), describing its validity in determining skeletal maturations and identifying the pubertal peak in craniofacial growth (Franchi et al., 2000). Although CVM staging may be useful and avoids an additional radiographic exposure, other studies have shown poor inter-observer and intra-observer agreement (Gabriel et al., 2009), with some weaknesses arising from the difficulty in classifying the shape of the third and fourth cervical vertebrae, leading to poor reproducibility (Nestman et al., 2011).

1.8 Cephalometrics

Cephalometric analysis in orthodontics uses lateral cephalometric radiographs which are taken in a standardised position with equipment to ensure precise alignment of the X-ray beam, image receptor and the patient. With the identification of soft tissue and bony anatomical landmarks; the skeletal pattern, dental relationships and soft tissue patterns can be assessed. Cephalometric radiographs can also be used to assess and monitor growth and surgical changes and provide a useful diagnostic tool in research for comparison of treatment outcomes. Although used routinely in orthodontics, cephalometric radiographs are not always indicated and are used only to supplement the clinical findings which are key in diagnosis and treatment planning of Class II malocclusions (Rischen et al., 2013). Once key landmarks are identified, numerous cephalometric analyses can be applied to the radiographs. The Eastman analysis and Pancherz analysis will be discussed in further detail. Other popular analyses include those of Downs, Steiner, Tweed, Sassouni, Ricketts, Wits and McNamara.

1.8.1 Eastman analysis

The Eastman analysis was initially designed by Clifford Ballard at the Eastman Dental Hospital and was further developed by Richard Mills. The original Eastman analysis was divided into skeletal and dental components, with assessment of the anterior-posterior jaw relationship using SNA, SNB and ANB, the vertical components and dental relationships to give upper and lower incisor inclinations using the maxillary and mandibular planes (Mills, 1970). Variations in the position of Nasion (N) can alter cephalometric values for the SNA and SNB angles and the Mill's Eastman correction can be applied in order to account for the aberrant anterior-posterior position of Nasion (Mills, 1982).

1.8.2 Pancherz analysis

The Pancherz analysis aims to relate the changes in the occlusion to skeletal and dental changes in the maxilla and the mandible in the sagittal plane (Pancherz, 1982a, Pancherz, 1984). It is carried out in two parts, assessing the sagittal occlusal analysis (SO) (Pancherz, 1982a) and the vertical occlusal analysis (VO) (Pancherz, 1982b). The SO consists of 11 linear measurements and the VO consists of 6 linear measurements and 4 angular measurements (Wu et al., 2010). Once the occlusal line (OL) is identified using the disto-buccal cusp of the maxillary permanent first molar and the incisal tip of the most prominent central incisor, a line perpendicular (OLp) intersecting Sella (S) is drawn. All linear measurements are carried out perpendicular from OLp and parallel to OL. Pancherz' analysis allows comparison of several variables such as overjet, molar relationships, the position of the maxillary and mandibular bases, position of the condyle, mandibular length and the position of the maxillary and mandibular central incisors. With the superimposition or comparison of these variables, treatment changes in the sagittal and vertical plane can be assessed. The use of OL/OLp for such measurements allows an assessment of the changes in the skeletal and dental factors whilst using Sella which is a relatively stable and reproducible measure (Björk, 1968). Errors in the analysis can however, arise from variations and difficulties in identifying the occlusal line.

1.8.3 Other analyses

The Steiner analysis involves identification of the cranial base using Sella and Nasion and relates the maxilla and the mandible to the SN plane in order to provide values for skeletal relationships and dental relationships using the NA and NB lines to identify the position of the upper and lower incisors (Steiner, 1953). The Wits appraisal involves analysis of the maxilla and mandible independent of the cranial base and uses the functional occlusal plane to allow a linear assessment of the skeletal pattern (Jacobson, 1976). As with the Pancherz analysis, errors can arise in identification of the functional occlusal plane. The McNamara analysis uses the Frankfort plane and a perpendicular line drawn from Nasion in order to provide a horizontal and vertical axis. The analysis consists of assessment of skeletal and dento-alveloar components as well as assessment of the airway and measurement of pharyngeal widths for orthognathic cases (McNamara, 1984).

1.8.4 Cephalometric errors

Errors arising from cephalometric analyses can be due to variations in the way in which radiographs are obtained as well as the measurements and interpretation of cephalometric radiographs. One of the greatest errors is due to differences in tracing and landmark identification which varies from operator to operator, with errors arising in obtaining radiographs being relatively small (Houston et al., 1986). Errors can be classified as “errors of projection” which can occur due to the representation of a three-dimensional object on a two-dimensional film and “errors of identification” of points on the films used to draw measurements from. Studies have shown errors in landmark identification to be too large to ignore, with variation in accuracy between different landmarks and each point having its own envelope of error (Baumrind and Frantz, 1971). Certain points, for example Pogonion and Orbitale (Or), are more difficult to identify than others, with Sella being the most consistently and most precisely identified landmark (Schlicher et al., 2012).

Attempts can be made to reduce cephalometric errors. Landmark identification is thought to improve with operator experience, with a similar level of error amongst observers with the same training level (Proffit, 2013). Other studies have suggested that no more than 10 radiographs are traced at any given time in order to reduce operator fatigue and the use of high-resolution screens (Naoumova and Lindman, 2009). Tracing software programs with image enhancing tools can be used to aid landmark identification and tracing of radiographs (Mosleh et al., 2016). It is accepted that with a careful technique, tracing errors should be in the order of 0.5mm for linear measurements and 0.5° for angular measurements (Mitchell et al., 2013).

1.8.5 Conventional and digital cephalometrics

Conventional cephalometric analysis is carried out by overlaying acetate on radiographic films in order to allow point identification and subsequent angular and linear measurements. This is a time-consuming process with room for identification and measurement errors. With developments in orthodontics, there has been a move to digital films and the use of digital tracing software. Benefits of digital cephalometrics include the ability to adjust the contrast on digital films, allow superimpositions of films taken at different time points and time efficiency. McClure et al. (2005) showed a similar precision and identification of landmarks with direct digital images and conventional lateral cephalometric films (McClure et al., 2005). Other studies have also shown that both methods of conventional and digital cephalometric analysis are highly reliable with no clinically significant differences (Albarakati et al., 2012, Polat-Ozsoy et al., 2009). Digital tracing methods have been reported to be more user friendly and time saving (Celik et al., 2009).

1.9 Lower incisor proclination

The movement and position of the lower incisors before and after orthodontic treatment is an important factor in orthodontic treatment planning (Tweed, 1954). Lower incisor inclination is important with regards to stability post-treatment as well as periodontal health. Studies have suggested an increased risk of adverse periodontal health and gingival recession with excessive lower incisor proclination. Årtun and Krogststad (1987) reported a statistically significant increase in the clinical crown height and incidence of gingival recession amongst orthognathic patients with more than 10° of proclination during pre-surgical orthodontics when compared to patients with minimal change in lower incisor inclination (Årtun and Krogstad, 1987). A more prominent position of the mandibular incisors has also been associated with less keratinised gingiva (Dorfman, 1978). Conversely, other studies have reported no correlation between lower incisor proclination and the level of gingival recession with no worsening of pre-existing recession in children and adolescents despite an average proclination of the lower incisors by 8.9° (Ruf et al., 1998). There is huge variability in the gingival tissue architecture, thickness and tissue reactions between different individuals.

The position of the upper and lower incisors exists in a state of equilibrium between the forces exerted by the lips, tongue and cheeks as well the periodontal ligament (Ackerman and Proffit, 1997, Weinstein et al., 1963). The ability of soft tissues to adapt to the changes in arch widths and dimension is narrow and therefore, changes to arch form and incisor position should be treated with caution with regards to stability. Changes in the mandibular inter-canine width during orthodontic treatment have been shown to relapse to pre-treatment dimensions, indicating the need to maintain the inter-canine width and lower incisor position as close to the pre-treatment position as possible (Shapiro, 1974).

1.9.1 Functional appliance design and lower incisor proclination

Functional appliances can be designed with components to aid anterior retention. The most common forms of anterior retention include a labial bow (which may be acrylated), ball ended claps, a Southend clasp or lower incisal capping. Systematic reviews have shown significant proclination of the lower incisors despite the method of anterior retention used during Twin-Block therapy (Ehsani et al., 2015). Jena et al. (2006) reported a significant amount of lower incisor proclination in patients treated with either the Twin-Block (1.27mm) or the Bionator appliance (1.50mm), which was statistically significant when compared to the control group (retroclined 0.60mm). This was suggested to be as a result of a mesial force on the mandibular incisors following protrusion of the mandible (Jena et al., 2006).

A 3-year follow up study by Mills and McCulloch (2000) investigated the effects of the Twin-Block appliance in comparison to a control group. Twenty-six patients of the original 28 patients were assessed. The Twin-Block appliance used consisted of an acrylated labial bow in the lower appliance, with no anterior retention in the upper. The lower incisors in the treatment group proclined by a mean of 5.6^{o} compared to a mean of 1.7^{o} in the control group. This proclination relapsed by 1.5^{o} in the treatment group 3 years later, whereas a further 0.8 ^{o} proclination of the lower incisors was seen in the control group, contributing to a small 1mm increase in the overjet in the treatment group (Mills and McCulloch, 2000).

Trenouth (2000) reported 1.13° of lower incisor proclination in patients treated with the Twin-Block appliance with the use of a Southend clasp as a method of anterior retention in a prospective study (Trenouth, 2000). Supporting this initial finding, a randomised controlled trial consisting of a total of 52 patients compared the effect of two different types of Twin-Block appliances, one with and one without Southend clasps on the upper and lower incisors. Individuals were randomised using a computer-generated sequence, with all cases being treated by one of two operators. Results showed 3.0° of lower incisor proclination for the Southend group compared to 6.9° in the non-Southend group. This was found to be statistically significant. A statistically significant change in the ANB angle was also seen between the Southend group and non-Southend group, suggesting that reducing upper incisor retroclination and lower incisor proclination may result in greater skeletal changes (Trenouth and Desmond, 2012). Although a well conducted randomised controlled trial, the results need to be analysed with caution as the appliance in both groups also consisted of a passive labial bow on both the upper and lower appliances, which may have influenced the final inclinations of the incisors. Lund and Sandler (1998) reported 7.9° of lower incisor proclination in the Twin-Block group when using ball ended clasps as a method of anterior retention on the lower appliance in comparison to 0.29° of lower incisor proclination in the control group (Lund and Sandler, 1998). Other studies using lower anterior ball ended claps have reported lower incisor proclination ranging from 2.0° to 8.01° (Illing et al., 1998, Harradine and Gale, 2000, Parkin et al., 2001, Yaqoob et al., 2012, van der Plas et al., 2017). A summary of the values for lower incisors proclination and the method of anterior retention on the Twin-Block can be found in Table 1.1.

Table 1.1: A table to show the different values of lower incisor proclination using different methods of anterior retention using the Twin-Block appliance

Author	Lower anterior retention	Lower incisor proclination
Lund and Sandler (1998)	Ball-ended clasps	7.9 ^{o}
Illing et al. (1998)	Ball ended clasps	2.0 ^{o}
Mills and McCulloch (2000)	Acrylated labial bow	5.6 ^{o}
Harradine and Gale (2000)	Lower incisor capping	4.7 ^{o}
Parkin et al. (2001)	Ball-ended clasps	7.3 ^{o} (average of two groups)
Yaqoob et al. (2012)	Ball-ended clasps	4.98 ^{o} (average of two groups)
Trenouth and Desmond (2012)	South-end clasp	3.0 ^{o}
Trenouth and Desmond (2012)	Non South-end clasp	6.9 ^{o}
van der Plas et al. (2017)	Ball-ended claps	8.01 ^{o}
van der Plas et al. (2017)	Lower incisor capping	7.23 ^{o}

Lower incisor capping involves extending the lingual acrylic on the lower appliance to cover the lower incisor edges and 1-2mm of the labial surface of the lower incisors. This method of anterior retention was first introduced with an aim to reduce fractures and breakages of the lower appliance. Case reports have documented a higher incidence of caries and demineralisation with lower incisor capping in patients with poor oral hygiene and high sugar intake (Dixon et al., 2005). Case selection and pre-treatment planning is therefore key when considering incorporation of lower incisor capping into the Twin-Block appliance design. A retrospective study including 56 patients assessed treatment with the Twin-Block appliance using ball ended clasps compared to lower incisor capping as a method of lower anterior retention (van der Plas et al., 2017). The lower incisors proclined by 8.01^{o} in the ball end clasps group and 7.23^{o} in the group with lower incisor capping. No statistically significant differences were observed with respect to the ANB angle and lower incisor inclination between the two groups. Pre-treatment lower incisor inclination was found to be the only statistically significant predictor of post-treatment lower incisor inclination suggesting lower incisor capping does not have a significant inhibitory effect on lower incisor proclination. A previous study reported 4.7° of proclination of the lower incisors with the use of lower incisor capping, however, a different method of anterior retention was used in the upper appliance which may have affected the lower incisor inclination (Harradine and Gale, 2000). Further prospective randomised controlled are needed in this field to draw further conclusions regarding the effects of lower incisor capping on lower incisor inclination.

1.9.2 Measuring lower incisor proclination

The cephalometric radiograph is a key tool for assessing for lower incisor inclination. The lower border of the mandible is often used to assess the lower incisor position despite being subjected to remodelling in growing children (Jabbal et al., 2016). The lower incisor to mandibular plane (LIMP) is used, with the three most commonly used planes for the mandibular plane being Men-Go, Go-Gn and the tangent to the lower border of the mandible. Different analyses utilise different planes to assess LIMP. Jabbal et al. (2016) reported from a respective study, equally valid results for LIMP using all three planes with excellent agreement for growing patients. Growth and remodelling appeared to have little effect on the lower incisor inclination measurement (Jabbal et al., 2016).

1.9.3 Functional appliance design and upper incisor inclination

Harradine and Gale (2000) compared the use of anterior labial spurs and an upper labial bow on the Twin-Block appliance. Although there was no significant difference in lower incisor inclination, there was statically significant less retroclination of the upper incisors with the use of labial spurs resulting in 6.9° of retroclination compared 14.1° with the use of a labial bow. They found a greater subsequent change in the ANB angle, resulting in slightly more favourable growth in the group treated with labial spurs (Harradine and Gale, 2000). Parkin et al. (2001) reported a similar value of 6.9° of retroclination of the upper incisors with use of torqueing springs and 11° with the use of a labial bow, although this difference was not statistically significant (Parkin et al., 2001).

With the Twin-Block appliance, Lund and Sandler (1998) reported upper incisor retroclination to be 10.8° compared to only 2.5° by Mills and McCulloch (2000). This difference is likely to be as a result of incorporation of an upper labial bow by Lund and Sandler (Lund and Sandler, 1998, Mills and McCulloch, 2000). Conversely, a randomised controlled trial consisting of 60 patients assessed the effects of an upper anterior labial bow with the Twin-Block appliance. Patients were allocated to treatment with a Twin-Block appliance either with or without an upper labial bow. Results showed 10.1° of upper incisor retroclination with the use of a labial bow and 7.7° of upper incisor retroclination without a labial bow. There was no statistically significant difference in the rate of overjet reduction, degree of skeletal change, degree of maxillary incisor retroclination or patient compliance between both groups (Yaqoob et al., 2012). It has been suggested that omitting an upper labial bow allows for alteration of the anchorage balance between the maxillary and mandibular dentition, allowing for less lower incisor proclination (Lee et al., 2007). A summary of the values for upper incisor retroclination and the method of anterior retention with the Twin-Block appliance are demonstrated in Table 1.2.

Although retroclination of the upper incisors and proclination of the lower incisors can result in significant overjet reduction, this is not considered to be a treatment objective with functional appliances. Excessive tipping of the incisors can be unstable and may also limit the degree of overjet reduction as a result of skeletal change. There is a considerable amount of literature reporting varying values for lower incisor proclination during functional appliance therapy with no conclusive data on the ideal method of anterior retention. Further randomised controlled trials and systematic reviews are required to determine the ideal method of anterior retention when assessing changes in upper and lower incisor inclination during functional appliance therapy.

Table 1.2: A table to show the different values of upper incisor retroclination using different methods of anterior retention with the Twin-Block appliance

Author	**Upper anterior retention**	**Upper incisor retroclination**
Lund and Sandler (1998)	Anterior labial bow	10.8 ^{o}
Illing et al. (1998)	No anterior retention	9.1 ^{o}
Mills and McCulloch (2000)	No anterior retention	2.5 ^{o}
Harradine and Gale (2000)	Anterior labial spurs	6.9 ^{o}
Harradine and Gale (2000)	Anterior labial bow	14.1 ^{o}
Parkin et al. (2001)	Anterior torqueing springs	6.9 ^{o}
Parkin et al. (2001)	Anterior labial bow	11.0 ^{o}
Yaqoob et al. (2012)	No anterior retention	7.73 ^{o}
Yaqoob et al. (2012)	Anterior labial bow	10.13 ^{o}
Trenouth and Desmond (2012)	South-end clasp	6.1 ^{o}
Trenouth and Desmond (2012)	Non South-end clasp	12.0 ^{o}

1.10 Aims of the study

The aim of the present study is to investigate and compare post-treatment cephalometric changes in lower incisor inclination in patients with Class II division 1 malocclusions treated with the Twin-Block appliance and the Button-and-Bead appliance. Secondary aims are to compare differences in the changes in upper incisor inclination, the ANB angle, changes in the maxillary-mandibular planes angle (MMPA) and lower anterior face height (LAFH).

Primary null hypothesis:

- There is no difference in lower incisor inclination in the treatment of Class II division 1 malocclusions between the Twin-Block or Button-and-Bead appliances.

Secondary null hypotheses:

- There is no difference in upper incisor inclination in the treatment of Class II division 1 malocclusions between the Twin-Block or Button-and-Bead appliances.
- There is no difference in the change in the ANB angle in the treatment of Class II division 1 malocclusions between the Twin-Block or Button-and-Bead appliances.
- There is no difference in the MMPA and LAFH in the treatment of Class II division 1 malocclusions between the Twin-Block or Button-and-Bead appliances.

CHAPTER TWO:

METHOD

2. METHOD

2.1 Ethical approval

This research project was granted ethical approval by the Health Research Authority (HRA) in June 2017 (IRAS number: 219179, REC reference number: 17/WM/0158). Research and development approval was granted by the University of Birmingham.

2.2 Study participants

This was a UK based, single centre, prospective, two-armed randomised controlled trial with a 1:1 allocation ratio for assessing the changes in lower incisor inclination following the treatment of Class II malocclusions using the Twin-Block and Button-and-Bead appliances.

All participants were recruited from new patient assessment clinics at the Birmingham Dental Hospital between July 2017 and January 2018. Referrals to the new patient clinic included those from primary care general dental practitioners, orthodontic specialists and paediatric specialists. Recruitment was carried out by the lead research supervisor and four co-investigators, all of whom had completed or were undergoing orthodontic speciality training at the Birmingham Dental Hospital. Consecutive children attending new patient clinics who satisfied the inclusion criteria were invited to participate in the study. The criteria for inclusion in the study were:

- Overjet greater than 7mm
- Age 10 to 14 years old
- English-speaking patients
- No previous orthodontic treatment or mid-arch extractions
- Patient assessed as suitable for orthodontic treatment in terms of dental health and oral hygiene

The exclusion criteria were:

- Patients with craniofacial syndromes or cleft lip and palate
- Allergy to any material used in appliance manufacture
- History of previous orthodontic treatment or extractions
- Unwillingness to participate in the study

2.3 Sample size calculation

A sample size calculation proposed inclusion of 18 participants in each of the two groups in order to detect a minimum effect size of a 5^{o} difference in the change in lower incisor inclination between the Twin-Block and Button-and-Bead groups. The sample size calculation was based on a power of 90%, a statistical significance of 0.05 and a standard deviation of 4.4^{o} (Yaqoob et al., 2012). A 5^{o} difference in lower incisor inclination between the two group was deemed to be clinically significant (van der Plas et al., 2017). It was expected that some participants would not complete the study and provide incomplete data, therefore, 32 participants were recruited in each group, allowing for a 44% drop out rate.

2.4 Method

Once deemed suitable for treatment with a functional appliance, the study was verbally explained to the patient and their parents or legal guardian. Participants were invited to participate in the trial if the inclusion criteria were met and were given an information pack comprising of an invitation to participate in the study (Appendix 1), a parent information sheet (Appendix 2) and a child information sheet (Appendix 3). Further information leaflets on the Twin-Block appliance (Appendix 4) and the Button-and-Bead appliance (Appendix 5) were also provided.

2.4.1 Baseline records

Where both the patient and the parent or legal guardian agreed to the patient's participation in the study, a written consent form was completed with the patient (Appendix 6) and their parent or legal guardian (Appendix 7). Baseline records were collected as per the standard orthodontic protocol which included:

- Clinical examination including overjet and dental relationships recorded using the case report form (CRF) (Appendix 8)
- Study models
- Start radiographs (including a lateral cephalogram taken in the natural head position (NHP) and a dental panoramic tomograph (DPT))
- Extra-oral and intra-oral photographs with three-dimensional views (3dMD, Atlanta, GA, USA)

Participants were also required to complete the child oral health questionnaire (Appendix 9). Data on gender was collected to allow stratification and equal distribution of male and female participants across the two groups. Baseline records recorded using the CRF (Appendix 8) were inputted into the Research Electronic Data Capture (REDcap) application, a secure computer web application for managing databases and concealing allocation.

2.4.2 Randomisation

Subjects were allocated an identification number and randomly allocated to one of the two arms of the study, either treatment with a Twin-Block or the Button-and-Bead appliance. Computer-generated block randomisation stratified for gender was carried out using the REDcap software. Only chief investigators were able to access the allocation system and instruct randomisation of participants. Once randomised, co-investigators were able to view which group participants had been allocated to.

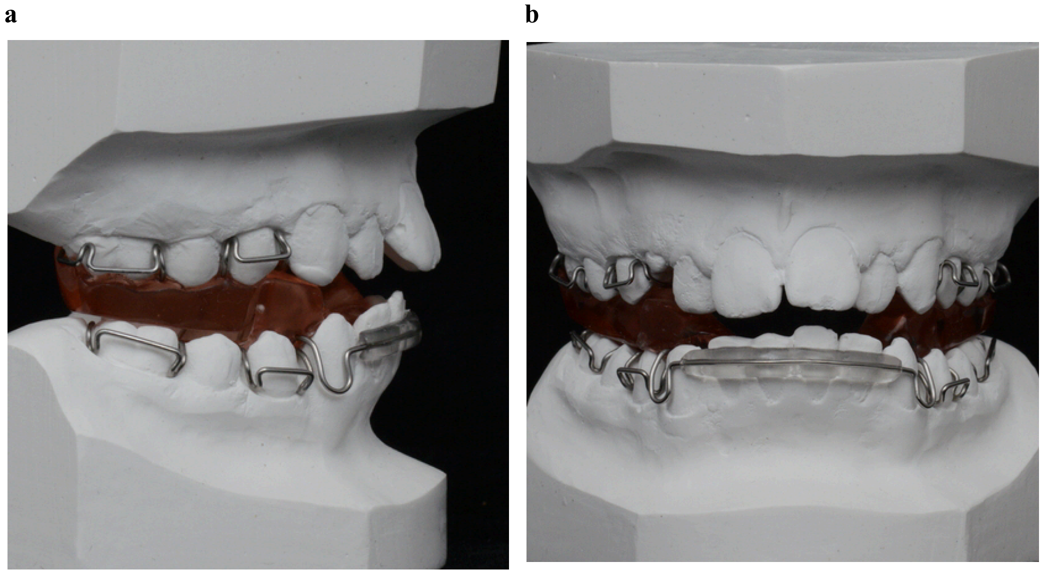
Patients and parents or legal guardians were informed regarding the participants allocation to either the Twin-Block appliance or the Button-and-Bead appliance. The appropriate appliance was then constructed given their continued willingness to participate in the study. The relevant information leaflet was provided to the participant on the wear and care of the appliance (Appendix 4, Appendix 5).

2.4.3 Design of appliances

The design of the appliance followed a standard protocol for all participants. Participants in both groups were instructed to wear the appliance full time, including eating and drinking with the exception of contact sports and brushing. Oral hygiene instruction and dietary advise was emphasised and participants were instructed to stop wearing the appliance and contact the orthodontic department urgently in the case of any breakages. All breakages were seen by a member of the research team.

A modified Clark's Twin-Block appliance was constructed as upper and lower removable appliances with Adam's claps on the maxillary and mandibular first permanent molars and premolars (with modifications for deciduous or missing teeth if required). A passive lower acrylated labial bow was incorporated for anterior retention, with no form of anterior retention in the upper appliance. A mid-line screw was incorporated in order to allow expansion in the upper arch if required. The appliance consisted of standard 70° inclined posterior bite blocks to allow forward posture of the mandible into an edge-to-edge incisor position. If an edge-to-edge incisor relationship could not be achieved, the appliance was constructed to achieve the maximum forward posture of the mandible. The design of the Twin-Block appliance used in the present study is illustrated in Figure 2.1.

Figure 2.1: The Twin-Block appliance with no upper anterior retention and a lower passive acrylated labial bow: a) Lateral view b) Frontal view



The Button-and-Bead Appliance was constructed as clear upper and lower vacuum formed appliances, with two upper appliances and one lower appliances using a vacuum formed blank (Centrilux vacuum/ pressure forming material, clear rigid 1.50mm thick: WHW Plastics, Therm road, Cleveland Street, Hull HU8 7BF tel 01482 329154 www.whwplastℱics.com) (Spary and Little, 2015). The first upper appliance consisted of an acrylic bead on the disto-palatal cusp of the maxillary first permanent molars and the second appliance consisted of an acrylic bead on the mesio-palatal cusp of the maxillary first permanent molars. The lower appliance consisted of occlusal acrylic blocks in the premolar region which were 4mm in height and designed to occlude with the upper appliance to produce Class I buccal segments. Composite buttons were bonded onto the buccal surface of the upper lateral incisors (or upper central incisors if the upper laterals were instanding or missing) and metal tubes on the buccal surface of the lower first permanent molars. The appliances were modified in these areas to allow placement of these attachments. Patients were instructed to wear the appliances with Class II elastics full time. Routinely, orange Class II elastics (¼", 4.5 Oz., TP Orthodontics Inc., Indiana, USA) were prescribed unless the elastics were being attached to the upper central incisors, in which case blue Class II elastics (¼", 3.5 Oz., TP Orthodontics Inc., Indiana, USA) were prescribed. The design of the Button-and-Bead appliance is illustrated in Figure 2.2.

Figure 2.2. The Button-and-Bead appliance with Class II elastics: a) Lateral view with metal buttons on upper laterals. b) Frontal view with composite buttons on upper laterals (used in the present study) (Source: Spary and Little, 2015)

a b

2.4.4 Follow-up of participants

Each participant was reviewed on a 4-weekly basis and the following parameters were recorded at each visit using the CRF (Appendix 9) and inputted electronically at each visit onto the REDcap application:

- Overjet
- Overbite
- Reverse overjet
- Right and left molar relationship
- Right and left canine relationship
- Upper and lower centre lines
- Reported hours of wear
- Height

- Breakages
- Willingness to continue in the trial

Once the overjet was deemed to have been satisfactorily reduced to less than 4mm, the participant was instructed to stop wearing the appliance for 48 hours in order to eliminate any postural element. Participants were reviewed again at 48 hours and the overjet was reassessed. Where the overjet had remained stable without signs of relapse, the participant was transitioned to either night time wear of the existing appliance in the Twin-Block group, or a steep and deep appliance for the Button-and-Bead group. The steep and deep appliance was an upper removable appliance constructed with Adam's clasps on the maxillary first permanent molars and premolars and a steep 70° inclined bite plane. A midline screw was incorporated if further expansion in the upper arch was deemed necessary. At the transition stage, further records were taken which included a lateral cephalogram, study models, extra-oral and intra-oral photographs with three-dimensional views. Participants were also asked to complete a second child oral health questionnaire and a patient satisfaction questionnaire. In cases in which the overjet relapsed following the 48-hour period, the participants were instructed to continue wearing their appliances on a full-time basis and reviewed on a 4-weekly basis until the overjet had been satisfactorily reduced.

2.4.5 Non-compliant patients

A patient was deemed to be non-compliant in either group if they refused to wear the appliance, failed to attend multiple appointments or presented with breakages on more than 3 occasions. Where the overjet had failed to reduce by at least 10% over a period of 9 months, the treatment plan was re-evaluated by the appropriate clinician due to the likelihood of non-compliance. Any adverse events were appropriately reported to the lead investigator.

2.5 Cephalometric analysis

Cephalograms were taken on one of two machines at the Birmingham Dental Hospital and therefore were adjusted for magnification errors to prevent discrepancies in linear and angular measurements (Rino Neto et al., 2013). The baseline (T_0) and post-functional (T_1) digital cephalograms were confidentially downloaded and stored on a secure computer database and labelled using the participants individual identification number, blinding the assessor from the intervention. All radiographs measurements were carried out by a single assessor. Cephalometric landmarks were identified digitally. The cephalometric landmarks and the cephalometric planes and measurements used in the present study are defined in Table 2.1 and Table 2.2 respectively.

The Pancherz analysis in combination with the Eastman analysis was used in order to perform the cephalometric analysis. The Pancherz analysis required identification of the occlusal line (OL) which is a horizontal line through incisal tip of the most prominent central incisor (is) and the disto-buccal cusp of the maxillary permanent first molar (Pancherz, 1982). A vertical line drawn perpendicular to OL through Sella (S) was used to provide occlusal line perpendicular (OLp), providing an X-Y Cartesian axis. The linear and angular measurements adapted from both analyses are illustrated in Figure 2.3 and Figure 2.4 respectively.

Table 2.1: Definition of cephalometric landmarks (Adapted from Ludlow et al., 2009, Sahitya et al., 2015)

Landmark	Abbreviation	Definition
A-point	A	Deepest point of the curve of the maxilla, between anterior nasal spine and the dental alveolus
Anterior nasal spine	ANS	Tip of the anterior nasal spine of the maxilla
B-point	B	Deepest point in the concavity along the anterior border of the mandibular symphysis
Condylion	Co	Most posterior superior point of the right condyle
Gonion	Go	The most convex point along the inferior border of the mandibular ramus
Incision superius	Is	The incisal tip of the most prominent maxillary incisor
Incision inferior	Ii	The incisal tip of the most prominent mandibular incisor
Maxillary incisor apex	UIA	Apex of the maxillary central incisor
Mandibular incisor apex	LIA	Apex of the mandibular central incisor
Menton	Me	Most inferior point of the mandibular symphysis
Nasion	N	Intersection of the internasal suture with the nasofrontal suture in the midsagittal plane
Pogonion	Pg	Most anterior point on the midsagittal symphysis
Posterior nasal spine	PNS	Tip of the posterior nasal spine
Sella	S	Centre of the pituitary fossa of the sphenoid bone

Table 2.2: Definition of cephalometric planes and measurements (Adapted from Wu et al., 2010, Pancherz, 1984)

Landmark	Abbreviation	Definition
Reference planes		
Sella-Nasion line	SN	A line from Sella to Nasion
Occlusal line	OL	A line tangent to the distobuccal cusp of the maxillary first molar to the incisal edge of the most prominent maxillary incisor
Occlusal line perpendicular	OLp	A line perpendicular to OL through Sella (S)
Maxillary plane	MxP	A line from ANS to PNS
Mandibular plane	MnP	A line from Gonion to Menton
Maxillary incisor	UI	Maxillary incisor tip to maxillary incisor apex
Mandibular incisor	LI	Mandibular incisor tip to mandibular incisor apex
Skeletal variables		
Maxillary base position (mm)	A/OLp	Position of the maxillary base measured from OLp
Mandibular base position (mm)	Pg/OLp	Position of the mandibular base measured from OLp
Condylar head position (mm)	Co/OLp	Position of the condyle measured from OLp
Mandibular length (mm)	Pg/OLp + Co/OLp	Length of the mandible
Sella—Nasion—A-point (°)	SNA	Angular measurement of maxillary base position relative to SN
Sella—Nasion—B-point (°)	SNB	Angular measurement of mandibular base position relative to SN
A-point—Nasion—B-point (°)	ANB	Angular relationship between the maxillary and mandibular bases
SN-Maxillary plane (°)	SN/MxP	Angle formed between the SN line and the maxillary plane
Maxillary mandibular planes angle (°)	MMPA	Angle formed between the maxillary and mandibular planes
Lower anterior face height (%)	LAFH	Lower anterior face height (ANS-Men) / Total anterior face height (N-Men) x 100

Dental variables		
Maxillary incisor position (mm)	Is/OLp	Position of the maxillary incisor relative to OLp
Mandibular incisor position (mm)	Ii/OLp	Position of the mandibular incisor relative to OLp
Maxillary incisor position to A-point (mm)	Is/OLp-A/OLp	Maxillary incisor position relative to the maxillary base position (mm)
Mandibular incisor position to Pgonion (mm)	Ii/OLp-Pg/OLp	Mandibular incisor position relative to the mandibular base position (mm)
Maxillary incisor inclination (°)	UI/MxP	Angle formed between the maxillary incisor and maxillary plane
Mandibular incisor inclination (°)	Li/MnP	Angle formed between the mandibular incisor and mandibular plane

Due to dento-alveolar changes, the occlusal line is subject to change following treatment with an appliance or growth. As per previous studies (O'Brien et al., 2003a), the occlusal line was identified on the pre-functional cephalogram and transferred to the post-functional cephalogram following superimposition of the two radiographs using the stable anatomical structures in the anterior cranial base (Björk, 1968).

Once the X-Y axis had been correctly identified and transferred onto the correct orientated post functional appliance radiographs, the cephalograms were traced digitally using a modified Pancherz analysis using Dolphin Imaging Software (Patterson Dental Supply, St. Paul, MN). All superimpositions and tracings were completed by a single operator on a single computer (display size: 27 inch, resolution: 1920 x 1080 pixels @ 60 Hz) in a dark room to improve detectability (Moshfeghi et al., 2015). A maximum of 10 radiographs were traced in a day to reduce chances of operator fatigue (Naoumova and Lindman, 2009). Values were obtained for lower incisor inclination at baseline (T0) and post-treatment (T1) along with upper incisor inclination, ANB angle, MMPA and lower anterior face height. Other variables measuring skeletal and dental parameters were also recorded. A random sample of 10% of the radiographs were re-superimposed and re-traced by the same operator to allow assessment of intra-examiner variability and reproducibility of the method.

Figure 2.3: Linear measurements carried out at (T0) and (T1)

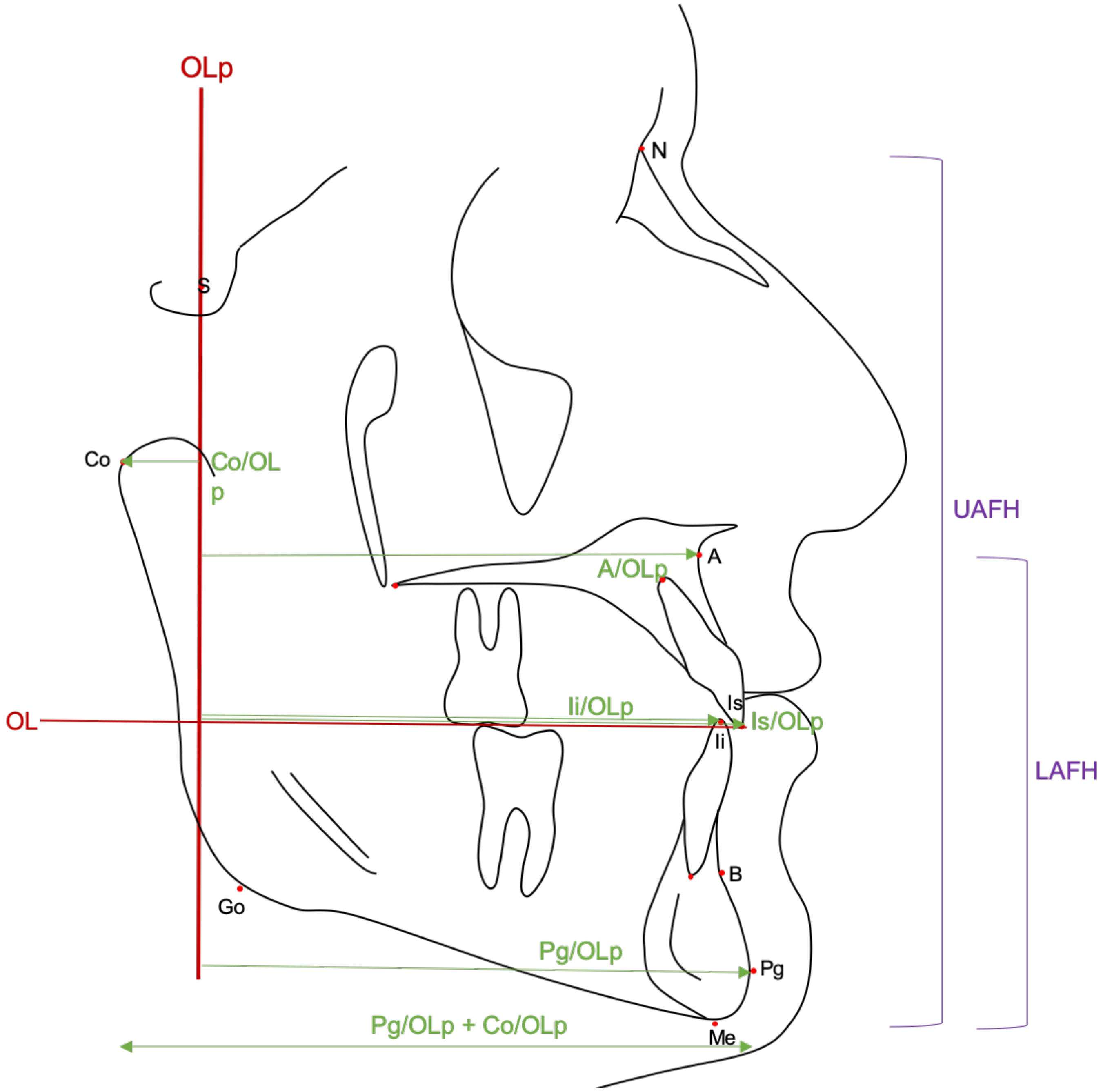
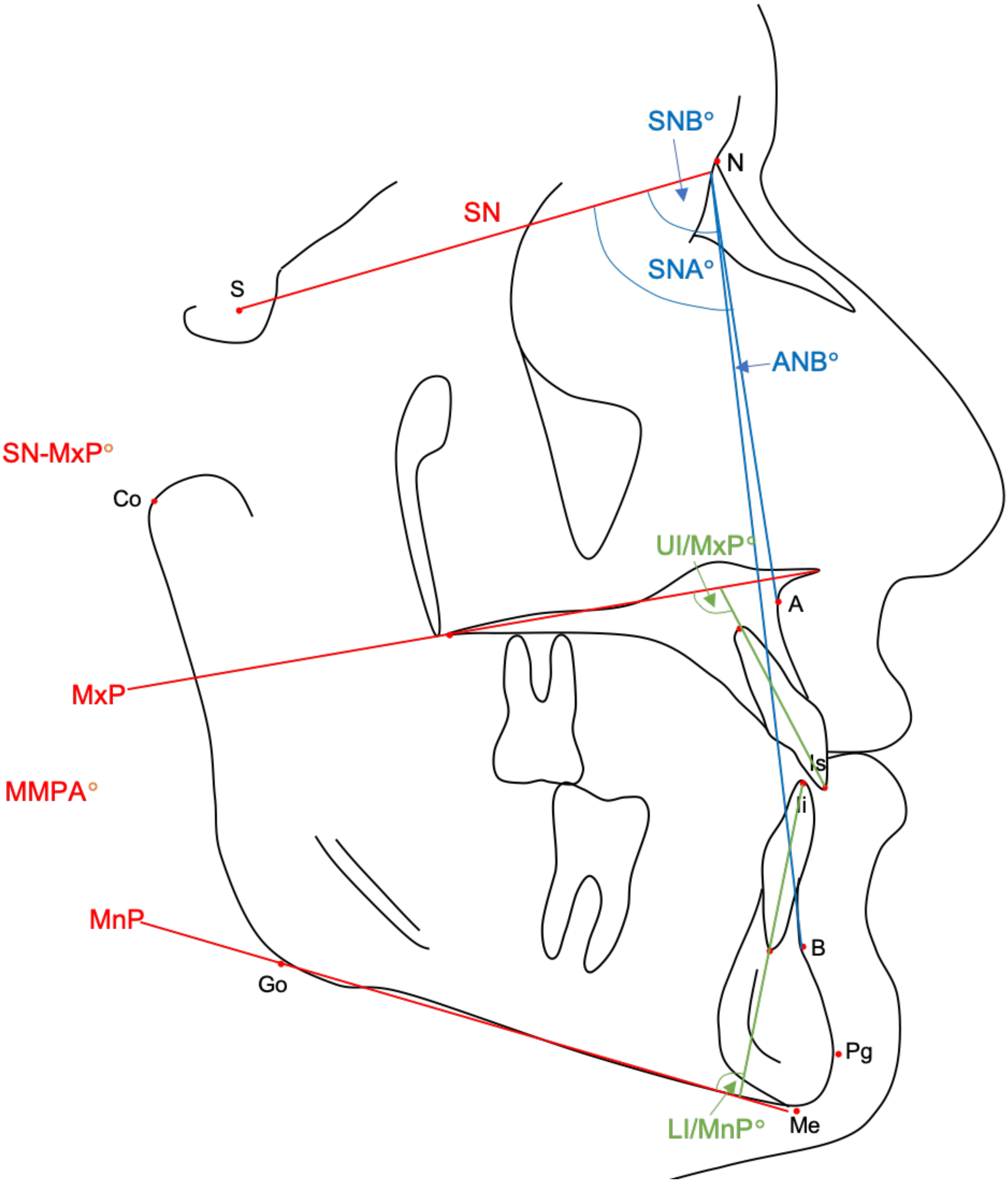


Figure 2.4: Angular measurements carried out at (T_0) and (T_1)



2.6 Statistical analysis

All data was inputted into a database (Microsoft Excel, 2016, Microsoft Corp, Seattle, USA) using the patients' unique identification numbers for analysis. Analysis of the data was conducted using the IBM Statistical Package for the Social Sciences (SPSS) software (IBM Corp. Released 2017, Version 25.0. Armonk, NY). Normality of the data and each of the variables was tested using Q-Q plots and the Shapiro-Wilks test. Parametric tests were utilised as the data was normally distributed.

Paired t-tests were used to assess the effects of the Twin-Block and Button-and-Bead appliances independently for skeletal and dental variables, including lower incisor inclination. Independent sample t-test were used to determine the differences between the effects of the Twin-Block and Button-and-Bead appliances for the skeletal and dental variables. All statistical tests conducted were two-tailed tests with a significance of $\alpha=0.05$. Systematic error was assessed using paired *t*-tests and random error was assessed by coefficients of reliability.

CHAPTER THREE:

RESULTS

3. RESULTS

3.1 Characteristics of the sample

Recruitment for the study began in July 2017 and was completed in January 2018. A total of 64 participants were screened and enrolled into the study. Computer-generated blocked randomisation stratified for gender was carried out using the REDcap software. Thirty-two participants (14 males and 18 females) were allocated to the Twin-Block group and 32 participants (14 males and 18 females) were allocated to the Button-and-Bead group. Of the 64 participants, all individuals received the allocated intervention. Treatment was successfully completed by 47 participants. A total of 17 (27%) participants did not complete the intervention as planned due to either poor compliance, withdrawal of consent or lack of efficacy of treatment. The failure rate for the Twin-Block appliance was 25% compared to 28% for the Button-and-Bead appliance. A per-protocol analysis was applied, as those who did not successfully complete their allocated intervention, did not undergo further radiographic examination. It was therefore not possible to carry out an intention-to-treat analysis for the purpose of the present study. A chart depicting the flow of participants through the study is illustrated in Figure 3.1.

The sample of participants completing the intervention included 21 males and 26 females with a mean age of 12.6 years (SD ±1.2) and mean start overjet of 10.9mm (SD ±1.9). In the Twin-Block group, 50% of the participants were male and 50% were female with a mean age of 12.7 years (SD ±1.2) and a mean start overjet of 10.9mm (SD ±2.2). In the Button-and-Bead group, 45% of participants were male and 55% were female with a mean age of 12.4 years (SD ±1.2) and a mean start overjet of 10.9mm (SD ±1.5). The demographics of the participants are demonstrated in Table 3.1

Figure 3.1: CONSORT 2010 Flow diagram to represent flow of participants through the trial

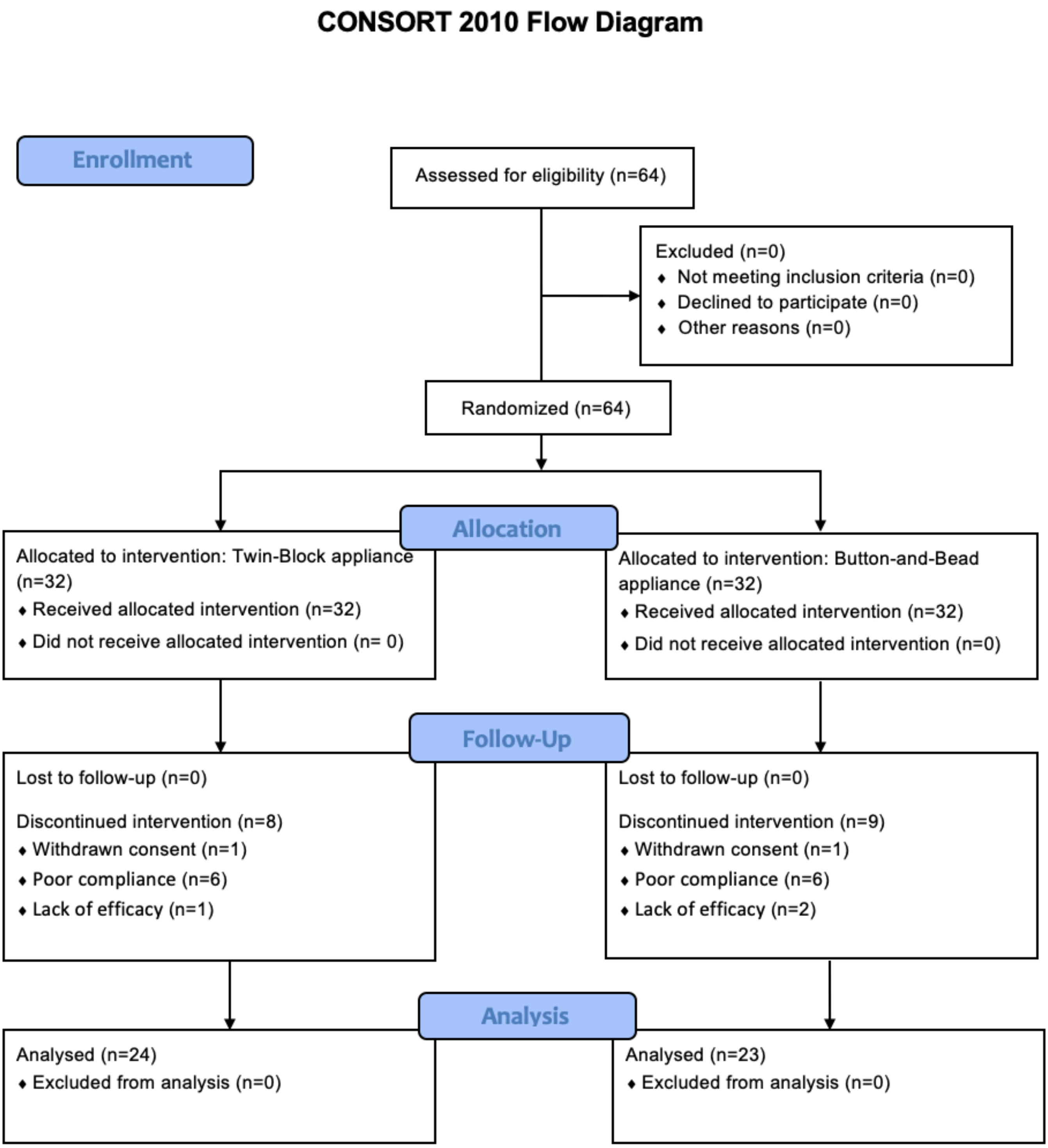


Table 3.1: Demographics of the participants

	Twin-Block group (n=24)	Button-and-Bead group (n=23)	Total (n=47)
Gender % (n)			
- Male	50% (12)	39% (9)	45% (21)
- Female	50% (12)	61% (14)	55% (26)
Age (years):			
- Mean (SD)	12.7 (1.2)	12.4 (1.2)	12.6 (1.2)
Start overjet (mm):			
- Mean (SD)	10.9 (2.2)	10.9 (1.5)	10.9 (1.9)

3.2 Error study

Measurements from a random sample of 10 radiographs (10% of the original sample) were repeated 3 months after data collection was completed. The selected radiographs were re-superimposed and re-traced in order to assess the reproducibility of the overall method. Systematic error was assessed using paired *t*-tests and random error was assessed by coefficients of reliability. No statistically significant systematic errors were observed as all *p*-values obtained were greater than 0.05. There was no statistically significant random error as all coefficients of reliability were above 90%. All angular measurements had an error of less than 1° and all linear measurements has an error of less than 0.5mm. The results of the error study are illustrated in Table 3.2.

Table 3.2: Intra-observer reliability demonstrated by *p*-vales and coefficient of reliability

	Mean	SD	Coefficient of reliability (Correlation)	*p*-value
Skeletal variables				
A/OLp (mm)	0.0	0.67	0.98	0.926
Pg/OLp (mm)	0.3	0.9	0.99	0.314
Co/OLp (mm)	-0.5	1.0	0.97	0.170
Pg/OLp + Co/OLp (mm)	-0.2	1.2	0.97	0.653
SNA (°)	0.2	1.0	0.96	0.578
SNB (°)	0.1	0.7	0.97	0.646
ANB (°)	0.1	0.4	0.98	0.570
SN/MxP (°)	0.1	1.3	0.90	0.747
MMPA (°)	-0.5	1.4	0.96	0.327
LAFH (%)	0.1	0.7	0.99	0.650
Dental Variables				
Is/OLp (mm)	0.4	0.9	0.97	0.185
Ii/OLp (mm)	0.2	0.8	0.99	0.365
Is/OLp-A/OLp (mm)	-0.3	0.6	0.93	0.136
Ii/OLp-Pg/OLp (mm)	0.2	0.4	0.98	0.125
UI/MxP (°)	-0.4	1.7	0.97	0.449
Li/MnP (°)	0.1	1.3	0.97	0.889

3.3 Skeletal and dental variables at baselines

Radiographic skeletal and dental variables at baseline were collected for each group using a combination of the Pancherz and Eastman analysis. The mean baseline values with the standard deviations for pre-treatment comparison between the two intervention groups are represented in Table 3.3. Normality of the data was tested using Q-Q plots and the Shapiro-Wilks Tests, with all variables following a normal distribution.

Table 3.3: Baseline comparison of skeletal and dental variables for the Twin-Block group and Button-and-Bead group (T_0)

	Twin-Block (n=24)		**Button-and-Bead (n=23)**	
	Mean	**SD**	**Mean**	**SD**
Skeletal variables				
A/OLp (mm)	71.2	4.4	70.6	4.3
Pg/OLp (mm)	70.1	4.9	70.6	5.2
Co/OLp (mm)	8.1	3.7	7.2	3.3
Pg/OLp + Co/OLp (mm)	78.2	5.3	77.8	4.9
SNA (°)	80.9	3.9	82.5	4.2
SNB (°)	74.4	3.7	76.8	4.2
ANB (°)	6.5	2.3	5.7	1.7
SN/MxP (°)	8.4	3.5	6.0	4.5
MMPA (°)	26.5	5.0	29.6	6.0
LAFH (%)	56.2	5.5	58.3	4.5
Dental Variables				
Is/OLp (mm)	80.9	4.8	80.9	4.7
Ii/OLp (mm)	69.4	5.3	69.7	5.2
Is/OLp-A/OLp (mm)	9.7	1.8	10.3	1.8
Ii/OLp-Pg/OLp (mm)	-0.7	3.7	-0.9	3.7
UI/MxP (°)	122.0	8.0	124.4	7.3
Li/MnP (°)	92.6	6.9	88.2	7.0

3.4 Effects of the Twin-Block appliance

The skeletal and dental effects of the Twin-Block appliance, with the mean values, standard deviations and 95% confidence intervals at baseline (T_0) and post-treatment (T_1) are listed in Table 3.4.

The data was analysed using paired *t*-tests. Mean changes in the variables along with the standard deviations, 95% confidence intervals and *p*-values are listed in Table 3.5. There were statistically significant changes in the position of the mandibular base (p=0.001), mandibular length (p=0.001), SNB angle (p=0.001), ANB angle (p=0.001), LAFH (p=0.001), maxillary incisor position (p=0.006) and inclination (p=0.001) and mandibular incisor position (p=0.001) and inclination (p=0.001) with the Twin-Block appliance. Effects on the maxillary base position (p=0.711), condylar head position (p=0.740), SNA angle (p=0.055), SN-MxP angle (p=0.254) and MMPA (p=0.748) where not statistically significant.

Table 3.4: Pancherz and Eastman analysis at baseline (T_0) and post-treatment (T_1) with the Twin-Block appliance

	Twin-Block (n=24)							
	T_0				T_1			
			95% Confidence Interval				95% Confidence Interval	
	Mean	SD	Lower limit	Upper limit	Mean	SD	Lower limit	Upper limit
Skeletal Variables								
A/OLp (mm)	71.2	4.4	69.4	73.1	71.3	4.2	69.6	73.1
Pg/OLp (mm)	70.1	4.9	68.0	72.2	74.2	5.5	71.9	76.6
Co/OLp (mm)	8.1	3.7	6.5	9.6	8.2	2.7	7.1	9.3
Pg/OLp + Co/OLp (mm)	78.2	5.3	75.9	80.4	82.5	5.2	80.2	84.7
SNA (°)	80.9	3.9	79.3	82.6	80.5	4.1	78.8	82.2
SNB (°)	74.4	3.7	72.8	76.0	76.8	4.0	75.1	78.5
ANB (°)	6.5	2.3	5.6	7.5	3.7	2.1	2.9	4.6
SN/MxP (°)	8.4	3.5	6.9	9.9	8.6	3.8	7.0	10.2
MMPA (°)	26.5	5.0	24.4	28.6	26.6	5.2	24.4	28.8
LAFH (%)	56.2	5.5	53.9	58.6	59.8	5.1	57.7	62.0
Dental Variables								
Is/OLp (mm)	80.9	4.8	78.9	83.0	79.7	5.2	77.5	81.8
Ii/OLp (mm)	69.4	5.3	67.2	71.6	75.4	5.7	73.0	77.8
Is/OLp-A/OLp (mm)	9.7	1.8	8.9	10.5	8.3	2.2	7.4	9.2
Ii/OLp-Pg/OLp (mm)	-0.7	3.7	-2.3	0.8	1.2	3.6	-0.4	2.7
UI/MxP (°)	122.0	8.0	118.7	125.4	115.9	6.3	113.2	118.6
Li/MnP (°)	92.6	6.9	89.6	95.5	98.8	8.6	95.1	102.4

Table 3.5: Changes in Pancherz and Eastman analysis for the Twin-Block group

	Twin-Block (n=24)				
			95% Confidence Interval		
	Mean	**SD**	**Lower limit**	**Upper limit**	***p*-value**
Skeletal variables					
A/OLp (mm)	0.1	1.2	-0.4	0.6	0.711
Pg/OLp (mm)	4.1	2.3	3.1	5.1	*0.001
Co/OLp (mm)	0.2	2.2	-0.8	1.1	0.740
Pg/OLp + Co/OLp (mm)	4.3	2.4	3.3	5.3	*0.001
SNA (°)	-0.5	1.1	-0.9	0.0	0.055
SNB (°)	2.4	1.1	1.9	2.8	*0.001
ANB (°)	-2.8	1.1	-3.3	-2.4	*0.001
SN/MxP (°)	0.2	1.0	-0.2	0.7	0.254
MMPA (°)	0.1	1.6	-0.6	0.8	0.748
LAFH (%)	3.6	1.8	2.8	4.4	*0.001
Dental Variables					
Is/OLp (mm)	-1.3	2.1	-2.2	-0.4	*0.006
Ii/OLp (mm)	6.0	2.0	5.2	6.9	*0.001
Is/OLp-A/OLp (mm)	-1.4	1.6	-2.1	-0.7	*0.001
Ii/OLp-Pg/OLp (mm)	1.9	1.1	1.4	2.4	*0.001
UI/MxP (°)	-6.1	5.0	-8.3	-4.0	*0.001
Li/MnP (°)	6.2	3.3	4.8	7.6	*0.001

**Statistically significant paired t-test*

3.5 Effects of the Button-and-Bead appliance

The skeletal and dental effects of the Button-and-Bead appliance, with the mean values, standard deviations and 95% confidence intervals at baseline (T_0) and post-treatment (T_1) are listed in Table 3.6. The data was analysed using paired *t*-tests. Mean changes in the variables along with the standard deviations, 95% confidence intervals and *p*-values are listed in Table 3.7. There were statistically significant changes in the position of the maxillary base (p=0.010), mandibular base (p=0.001), mandibular length (p=0.001), SNB angle (p=0.001), ANB angle (p=0.001), LAFH (p=0.001), maxillary incisor position (p=0.001) and inclination (p=0.001) and mandibular incisor position (p=0.001) and inclination (p=0.001) with the Button-and-Bead appliance. Effects on the condylar head position (p=0.859), SNA angle (p=0.495), SN-MxP angle (p=0.555) and MMPA (p=0.166) where not statistically significant.

Table 3.6 Pancherz and Eastman analysis at baseline (T_0) and post-treatment (T_1) with the Button-and-Bead appliance

	Button-and-Bead (n=23)							
	T_0				T_1			
			95% Confidence Interval				95% Confidence Interval	
	Mean	SD	Lower limit	Upper limit	Mean	SD	Lower limit	Upper limit
Skeletal variables								
A/OLp (mm)	70.6	4.3	68.7	72.4	71.2	4.6	69.2	73.2
Pg/OLp (mm)	70.6	5.2	68.4	72.9	73.2	4.9	71.1	75.3
Co/OLp (mm)	7.2	3.3	5.7	8.6	7.3	3.7	5.7	8.8
Pg/OLp + Co/OLp (mm)	77.8	4.9	75.7	79.9	80.4	5.3	78.2	82.7
SNA (°)	82.5	4.2	80.7	84.3	82.3	4.0	80.6	84.1
SNB (°)	76.8	4.2	75.0	78.6	78.0	4.1	76.2	79.7
ANB (°)	5.7	1.7	5.0	6.4	4.3	1.8	3.5	5.1
SN/MxP (°)	6.0	4.5	4.1	8.0	6.2	4.7	4.1	8.2
MMPA (°)	29.6	6.0	27.0	32.2	30.1	5.9	27.6	32.7
LAFH (%)	58.3	4.5	56.3	60.3	61.9	4.2	60.1	63.7
Dental Variables								
Is/OLp (mm)	80.9	4.7	78.9	83.0	78.2	5.0	76.1	80.4
Ii/OLp (mm)	69.7	5.2	67.5	72.0	74.2	5.0	72.0	76.3
Is/OLp-A/OLp (mm)	10.3	1.8	9.6	11.1	7.0	1.9	6.2	7.8
Ii/OLp-Pg/OLp (mm)	-0.9	3.7	-2.5	0.7	1.0	3.6	-0.6	2.6
UI/MxP (°)	124.4	7.3	121.2	127.6	113.2	5.9	110.7	115.8
Li/MnP (°)	88.2	7.0	85.1	91.2	93.5	6.8	90.5	96.4

Table 3.7: Changes in Pancherz and Eastman analysis for the Button-and-Bead group

	Button-and-Bead (n=23)				
			95% Confidence Interval		
	Mean	SD	Lower limit	Upper limit	*p*-value
Skeletal variables					
A/OLp (mm)	0.6	1.1	0.2	1.1	*0.010
Pg/OLp (mm)	2.5	2.4	1.5	3.6	*0.001
Co/OLp (mm)	0.1	2.2	-0.9	1.0	0.859
Pg/OLp + Co/OLp (mm)	2.6	1.9	1.8	3.4	*0.001
SNA (°)	-0.2	1.4	-0.8	0.4	0.495
SNB (°)	1.2	1.0	0.7	1.6	*0.001
ANB (°)	-1.4	1.2	-1.9	-0.9	*0.001
SN/MxP (°)	0.1	1.0	-0.3	0.6	0.555
MMPA (°)	0.5	1.6	-0.2	1.2	0.166
LAFH (%)	3.6	1.5	3.0	4.3	*0.001
Dental Variables					
Is/OLp (mm)	-2.7	1.5	-3.3	-2.1	*0.001
Ii/OLp (mm)	4.5	2.1	3.6	5.4	*0.001
Is/OLp-A/OLp (mm)	-3.3	1.1	-3.8	-2.9	*0.001
Ii/OLp-Pg/OLp (mm)	1.9	1.3	1.4	2.5	*0.001
UI/MxP (°)	-11.2	4.1	-13.0	-9.4	*0.001
Li/MnP (°)	5.3	3.6	3.7	6.8	*0.001

**Statistically significant paired t-test*

3.6 Differences between the effects of the Twin-Block and Button-and-Bead appliances

The mean differences between the effects of the Twin-Block and Button-and-Bead appliances were analysed using independent sample *t*-tests. The mean values, 95% confidence intervals and *p*-values for the differences between the two appliances are represented in Table 3.8.

Statistically significant differences between the two appliances were found for changes in the mandibular base position (p=0.027), mandibular length (p=0.013), SNB angle (p=0.001), ANB angle (p=0.001), maxillary incisor position (p=0.01), mandibular incisor position (p=0.001) and maxillary incisor inclination (p=0.001). The Twin-Block appliance appeared to result in a greater increase in the mandibular base position and mandibular length, with a greater increase in the SNB angle and reduction in the ANB angle when compared to the Button-and-Bead appliance. The Button-and-Bead appliance resulted in a greater amount of upper incisor retroclination when compared to the Twin-Block appliance. Differences in the maxillary base position (p=0.115), condylar head position (p=0.917), SNA angle (p=0.475), SN-MxP angle (p=0.689), MMPA (p=0.413), LAFH (p=0.979) and mandibular incisor inclination (p=0.372) between the two appliances were not statistically significant.

Table 3.8: Differences between the effect of the Twin-Block and Button-and-Bead appliances

	Differences between the Twin-Block and Button-and-Bead			
		95% Confidence Interval		
	Mean^	Lower limit	Upper limit	*p*-value
Skeletal variables				
A/OLp (mm)	0.5	-0.1	1.2	0.115
Pg/OLp (mm)	-1.6	-3.0	-0.2	*0.027
Co/OLp (mm)	-0.1	-1.4	1.2	0.917
Pg/OLp + Co/OLp (mm)	-1.6	-2.9	-0.4	*0.013
SNA (°)	0.3	-0.5	1.0	0.475
SNB (°)	-1.2	-1.8	-0.6	*0.001
ANB (°)	1.4	0.8	2.1	*0.001
SN/MxP (°)	-0.1	-0.7	0.5	0.689
MMPA (°)	0.4	-0.6	1.3	0.413
LAFH (%)	0.0	-1.0	1.0	0.979
Dental Variables				
Is/OLp (mm)	-1.4	-2.5	-0.4	*0.01
Ii/OLp (mm)	-1.6	-2.8	-0.4	*0.011
Is/OLp-A/OLp (mm)	-1.9	-2.8	-1.1	*0.001
Ii/OLp-Pg/OLp (mm)	0.0	-0.7	0.7	0.893
UI/MxP (°)	-5.1	-7.7	-2.4	*0.001
Li/MnP (°)	-0.9	-3.0	1.1	0.372

^Mean differences calculated as changes for Button-and-Bead appliance minus changes for Twin-Block appliance.

**Statistically significant independent t-test*

CHAPTER FOUR:

DISCUSSION

4. DISCUSSION

4.1 Discussion

A randomised controlled trial was conducted to investigate the changes in lower incisor inclination following the treatment of Class II malocclusions with the Twin-Block and Button-and-Bead appliances. As the Button-and-Bead appliance provides full occlusal coverage and acts as a rigid splint on the dentition, it was speculated that the Button-and-Bead appliance may result in less lower incisor proclination in comparison to the Twin-Block appliance. The study was a UK based, single centre, prospective, two-armed randomised controlled trial with a 1:1 allocation ratio carried out at the Birmingham Dental Hospital. Sixty-four patients were recruited into the study, with 32 patients allocated to the Twin-Block group and 32 patients being allocated to the Button-and-Bead group. Seventeen patients failed to complete the assigned treatment, resulting in inclusion of a total of 47 patients (21 males and 26 females) for the purpose of this study. The study was adequately powered at 90% in order to detect a minimum effect of a 5° difference in lower incisor proclination between the two groups. An intention to treat analysis was not possible as it was deemed unethical to carry out additional radiographic exposures where the patient did not complete the assigned intervention.

The age of participants included in this study ranged from 10-14 years old with a mean age of 12.6 years (SD ±1.2). All patients presented with an overjet >7mm with a mean overjet of 10.9mm (SD ±1.9). This is consistent with other functional appliance clinical trials conducted in the UK (Lee et al., 2013, O'Brien et al., 2009, Thiruvenkatachari et al., 2013, O'Brien et al., 2003a, Jones et al., 2008).

Randomisation was carried out using computer generated block randomisation stratified for gender to ensure equal distribution of male and female participants across the two intervention groups. Stratification according to gender was deemed necessary due differences in the onset and the peak, of the pubertal growth spurt between males and females, with the peak being between 12-14 years old in males and 10-12 years old in females (Tanner et al., 1976). Differences in outcomes for treatment and compliance with functional appliances between males and females have also been reported in previous studies (Schäfer et al., 2014).

4.2 Effects of the Twin-Block appliance

The skeletal effects of the Twin-Block appliance in the present study included an advancement in the mandibular base position by a mean of 4.1mm (SD ±2.3) and an increase in the mandibular length by a mean of 4.3mm (SD ±2.4). This figure is consistent with other studies reporting an increase in the mandibular length by a mean of 4.2mm (Mills and McCulloch, 1998). Statistically significant changes in the SNB angle were observed, with an increase in SNB by a mean of 2.4° (SD ±1.1) and a subsequent reduction in the ANB angle by a mean of 2.8° (SD ±1.1). This is consistent with previous studies suggesting a 1.9° increase in the SNB angle following treatment with the Twin-Block appliance (Mills and McCulloch, 1998). Although these figures are promising, it is difficult to ensure that there was no forward posturing of the mandible as a result of the lateral open bites seen following treatment with the Twin-Block appliance. It is generally well accepted that functional appliances do not result in clinically significant amounts of mandibular growth (O'Brien et al., 2009). The benefits of a using a Twin-Block appliance in those with deep overbites and reduced vertical proportions has been well documented. This is supported by statistically significant increases in the LAFH with the Twin-Block appliance seen in the present study as well as previous studies (Lund and Sandler, 1998, Mills and McCulloch, 1998). The effects of the Twin-Block appliance on the maxillary base position and the SNA angle were not statistically significant. A systematic review of randomised controlled trials also failed to demonstrate any maxillary restraint effect of the Twin-Block appliance (Ehsani et al., 2015). Where studies did report a small maxillary restraint effect, the Twin-Block included an upper labial bow which may have resulted in further upper incisor retroclination and remodelling of the A point, giving the impression of a maxillary restraint effect (O'Brien et al., 2003a).

Depending on the method of anterior retention, upper incisor retroclination and lower incisor proclination with the Twin-Block appliance has been reported to range from 2.5° to 14.1° (Mills and McCulloch, 2000) and 3.0° to 8.0° (Trenouth and Desmond, 2012, Lund and Sandler, 1998) respectively. Dental effects of the Twin-Block appliance in the present study included upper incisor retroclination by a mean of 6.1° (SD ±2.0) which is slightly less than studies reporting 7.7° of upper incisor retroclination with no upper anterior retention (Yaqoob et al., 2012). The lower incisors proclined by a mean of 6.2° (SD ±3.3) in the present study which is consistent with a previous study reporting 5.6° of lower incisor proclination with the Twin-Block appliance when designed with a lower acrylated labial bow (Mills and McCulloch, 2000). Linear changes in positions of the upper and lower incisors derived from the Pancherz analysis need to be interpreted with consideration of changes in the position of their relative dental bases. Accounting for changes in the maxillary and mandibular base positions, the maxillary incisors were retracted by 1.4mm (SD ±1.6) and the lower incisors were advanced by 1.9mm (SD ±1.1). In comparison to a randomised controlled trial utilising the Pancherz analysis to assess the effects of early treatment with the Twin-Block appliance, less upper incisor retraction and a similar degree of lower incisor advancement was observed (O'Brien et al., 2003a). The difference in the amount of upper incisor retraction is likely to be as a result of omission of an upper labial bow in this study, resulting in less upper incisor retraction.

4.3 Effects of the Button-and-Bead appliance

Skeletal effects of the Button-and-Bead appliance included a small but statistically significant effect on the maxillary base position giving the appearance of maxillary advancement by 0.6mm (SD ±1.1). This is unlikely to be of any clinical significance and is within the limits of tracing error. The observation may also be explained by dental changes such as upper incisor retroclination resulting in advancement of the root position and remodelling of A point. Effects on the SNA angle were not of statistical significance. Mandibular effects consisted of an increase in the mandibular length by a mean of 2.6mm (SD ±1.9) and advancement of the mandibular base position by a mean of 2.5mm (SD ±2.4). The mandibular changes are further supported by an increase in the SNB angle by a mean of 1.2° (SD ±1.0) and a reduction in the ANB angle by a mean of 1.4° (SD ±1.2). The Button-and-Bead appliance also resulted in an increase in the LAFH which is beneficial in the treatment of deep bite cases. The skeletal effects of the Button-and-Bead appliance on the mandible are consistent with other Class II correctors (Karacay et al., 2006).

Dental effects of the Button-and-Bead appliance included statistically and clinically significant effects on the incisor positions and inclinations. The upper incisors retroclined by mean of 11.2° (SD ±4.1) and the lower incisors proclined by a mean of 5.3° (SD ±3.6). The changes in incisor angulations are consistent with case reports describing the effects of the Button-and-Bead appliance with 10° of upper incisor retroclination and 4° of lower incisor proclination. Although both studies describe an identical appliance, the initial case reports analysed lateral cephalograms during the fixed appliance stage of treatment rather than at the end of the Class II correction phase, making comparisons difficult (Spary and Little, 2015). When considering the linear changes in the position of the incisors, the upper incisors were retracted by a mean 3.3mm (SD ±1.1) and the lower incisors were advanced by a mean 1.9mm (SD ±1.3). The amount lower incisor proclination in the present study was less than when compared to a retrospective study reporting 7.2° of lower incisor proclination with the use of a Twin-Block appliance with lower incisor capping (van der Plas et al., 2017). Differences in the amount of lower incisor proclination may occur as the Button-and-Bead appliance is designed to provide full occlusal coverage of the upper and lower dentitions compared to lower incisor capping which only covers the lower anterior labial segment.

4.4 Differences between the Twin-Block and Button-and-Bead appliances

Statistically significant differences between the Twin-Block and Button-and-Bead appliances were observed in this study for various skeletal and dental paramenters. The most significant differences were observed for changes in the mandibular length, mandibular base position, SNB angle, ANB angle and upper incisor position and inclination.

4.4.1 Skeletal changes

Treatment with the Twin-Block appliance resulted in statistically significantly greater advancement of the mandibular base and increase in mandibular length compared to treatment with the Button-and-Bead appliance. A difference of 2.0mm in the mandibular length between two interventions is considered clinically significant (Cozza et al., 2006). In the Twin-Block group, the increase in mandibular length was greater by a mean of 1.6mm (95% CI: -2.9 to -0.4) and the mandibular base advancement was greater by a mean of 1.6mm (95% CI: -3.0 to -0.2). Although a mean difference of 1.6mm in mandibular length between the two appliances is unlikely to be of any clinical significance, at the upper limit of the 95%

confidence interval, a 2.9mm greater increase in mandibular length with the Twin-Block would be a significant skeletal change. The Twin-Block appliance also resulted in a greater increase in the SNB angle by a mean of 1.2° (95% CI: -1.8 to -0.6) and a greater reduction in the ANB angle by a mean of 1.4° (95% CI: 0.8 to 2.1) compared to the Button-and-Bead appliance. The differences in the SNB and ANB angles between the two appliances were statistically significant, however, are unlikely to be of clinical significance.

Increases in the vertical dimension were seen with both the Twin-Block and Button-and-Bead appliances during Class II correction. Differences between the two appliances with regards to MMPA and LAFH were not statistically or clinically significant. Both appliances are therefore best utilised in cases with reduced vertical dimensions and deep overbites. Treatment needs to be undertaken with caution in those with increased vertical proportions due to a bite opening effect of both appliances. The Twin-Block appliance can be modified to allow the use of high-pull headgear in those with increased vertical proportions, although this requires excellent compliance and often is needed for the duration of the growth period (Lv et al., 2012). Currently, we are not aware of any modifications of the Button-and-Bead appliance for those with increased vertical proportions.

4.4.2 Upper incisor inclination

The Button-and-Bead appliance resulted in statistically significantly more upper incisor retroclination in comparison to the Twin-Block appliance. Despite the full occlusal coverage provided by the Button-and-Bead appliance, the upper incisors retroclined by a mean of 5.1° (95% CI: -7.7 to -2.4) greater than that with the Twin-Block appliance. The difference in upper incisor retroclination is both statistically and clinically significant (Yaqoob et al., 2012). The mechanism of upper incisor retroclination is likely the result of the attachment of inter-maxillary elastics directly to the upper incisors. The dento-alveolar effects of Class II elastics in the form of upper incisor retroclination and lower incisor proclination are well documented in the literature (Nelson et al., 1999). With the Button-and-Bead appliance, the upper splint covered only half of the labial surface of the upper incisors, which may have allowed for some flexibility in the upper splint and a greater degree of upper incisor retroclination. It is accepted that Class II correction should maximise skeletal changes, however, as with the Button-and-Bead appliance, studies have shown that 73% of overjet reduction occurs as a result of dento-alveolar changes in the form of upper incisor retroclination and lower incisor proclination (O'Brien et al., 2003a).

4.4.3 Lower incisor inclination

Studies have previously reported lower incisor proclination to be as low as 3.0° with a South-end clasp (Trenouth and Desmond, 2012) and 4.7° with lower incisor capping (Harradine and Gale, 2000) compared to lower incisor proclination as high as 8.0° with ball ended clasps (Lund and Sandler, 1998, van der Plas et al., 2017). In the present study, the mean difference in lower incisor proclination between the two appliances was 0.9º (95% CI: -3.0 to 1.1), which is not statistically or clinically significant. Despite the Button-and-Bead appliance acting as a rigid splint on the lower dentition, the amount of lower incisor proclination was not reduced. In line with other studies, full occlusal coverage of the dentition, as with lower incisor acrylic capping, does not reduce the amount of lower incisor proclination (van der Plas et al., 2017). A possible confounding factor for lower incisor inclination could be the use of inter-maxillary Class II elastics with the Button-and-Bead appliance. The use of inter-maxillary elastics has been shown to result in 3.8° of lower incisor proclination (Jones et al., 2008). Considering lower incisor capping is of limited beneift in reducing lower incisor proclination, use of incisal capping should be limited to careful case selection due to reports of a higher risk of decalcification and caries, especially on the incisal edges (Dixon et al., 2005).

4.5 Limitations

A high number of drop outs were experienced in this study with 27% of the originally recruited 64 participants failing to complete treatment with their allocated intervention. Although failure of compliance with the Twin-Block appliance has been reported to be anywhere between 15% (Illing et al., 1998) to 50% (Barton and Cook, 1997), a large randomised controlled trial assessing the effects of early treatment with the Twin-Block appliance reported a failure rate of 16% in the early treatment group (O'Brien et al., 2003a) and 0.01% in the adolescent treatment group (O'Brien et al., 2009) . A failure rate of 27% in the present study was considerably higher. A recent randomised controlled trial assessing part-time vs full-time wear of the Twin-Block appliance reported only 12.38 hours of wear of the Twin-Block appliance amongst those who were instructed to wear the appliance full time (Parekh et al., 2019). Variations in failure rates reported in the literature are likely due to differences in the data sets and the demographics of populations studied. The success of both the Twin-Block and Button-and-Bead appliances is heavily dependent on patient compliance as well as patient factors and perceptions. The use of apps or remainders may be utilised to improve patient compliance with treatment (El-Huni et al., 2019). There is currently no literature reporting compliance rates with the Button-and-Bead appliance or removable Class II correctors, however, the present study suggests that the failure rates for the Button-and-Bead appliance are similar to that of the Twin-Block appliance.

Missing data from participants who failed to complete the assigned intervention could not be accounted for by an intention-to-treat analysis as it was deemed unethical to carry out a radiographic exposure which was not clinically indicated. The last observation carried forward method was considered to be inappropriate for the present study as this would have provided a repetition of the baseline data as a further radiograph was only taken if the patient completed the functional appliance phase. A per-protocol analysis was therefore felt to be more appropriate. Due to ethical implications and the risks of ionising radiation, it would be difficult to conduct the study differently to allow a meaningful intention-to-treat analysis.

The Twin-Block appliance can be modified to incorporate a midline screw allowing for transverse maxillary expansion during correction of the sagittal relationship. The Twin-Block appliance can also be utilised during the transitioning phase of functional appliance therapy, reducing the need for an additional appliance. A limitation of the Button-and-Bead appliance includes the difficulty in transverse expansion of the maxillary dentition during sagittal correction. In this study, a second appliance in the form a steep and deep appliance was prescribed in the Button-and-Bead group to allow settling during transitioning as well as allowing for transverse maxillary expansion with the use of a midline screw where required. The Button-and-Bead therefore often requires a second appliance in the transition phase which requires additional time and has additional laboratory costs.

This study could be improved by designing the Twin-Block appliance with lower incisor capping instead of a lower acrylated labial bow. This modification would allow for a more direct comparison of the two appliances and their effects on the lower incisor inclination, reducing the number of confounding factors. Careful case selection of participants would be required due to the higher risk of decalcification associated with incisor capping or full occlusal coverage (Dixon et al., 2005).

The Button-and-Bead appliance acts an effective Class II corrector which is more discrete and has better aesthetics when compared to the Twin-Block appliance. It may be the appliance of choice in patients with a severe gag reflex as there is very little coverage of the palate in contrast to the Twin-Block appliance. The Button-and-Bead appliance may also be considered for Class II correction in non-growing patients or where the upper incisors are excessively proclined. Where skeletal change is desired in growing patients, the preferred appliance of choice remains the Twin-Block appliance.

The null hypothesis that there is no difference in the lower incisor inclination between Twin-Block appliance and Button-and-Bead appliance cannot be rejected.

CHAPTER FIVE:

CONCLUSION

5. CONCLUSION

There is no difference in the change in lower incisor inclination with treatment with the Twin-Block appliance and Button-and-Bead appliances for correction of Class II division 1 malocclusions.

When compared to the Button-and-Bead appliance, correction of a Class II division 1 malocclusion with the Twin-Block appliance resulted in a:

- Statistically significant greater increase in the mandibular length by 1.6mm
- Statistically significant greater advancement of the mandibular base position by 1.6mm
- Statistically significant greater increase in the SNB angle by 1.2°
- Statistically significant greater reduction in the ANB angle by 1.4°

Despite being statistically significant, the differences in the mandibular length, mandibular base position and the SNB and ANB angles are unlikely to be of any clinical significance.

When compared to the Twin-Block appliance, the Button-and-Bead appliance resulted in a:

- Statistically and clinically significant greater degree of upper incisor retroclination by 5.1°

Although both appliances were successful in correction of Class II division 1 malocclusions, the Twin-Block appliance appears to result in a greater degree of favourable skeletal change compared to the Button-and-Bead appliance. The Twin-Block appliance is therefore the appliance of choice in growing individuals where advancement of the mandible is desirable. The Button-and-Bead appliance is an effective Class II corrector and may be considered in non-growing adults as the effects of the appliance are largely dento-alveolar.

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APPENDICIES

Appendix 1: Invitation letter to participants

UNIVERSITY OF BIRMINGHAM

School of Dentistry

INVITATION LETTER TO PARTICIPANTS

Invitation to take part in research to assess the effectiveness of two different functional appliances (braces).

Dear Participant,

I am an orthodontic trainee/orthodontist at the Birmingham Dental Hospital. I am part of a team with the University of Birmingham who are undertaking research to compare two different orthodontic appliances for their effectiveness.

We are asking you to take part because you fit the criteria for our research. If you agree to take part, then you will receive treatment with one of the two brace types in this study. This will be chosen at random and therefore we cannot tell which of the two of braces you will be given. We will take measurements, photographs, x-rays and models, that would be part of your normal treatment. You do not have to have any extra appointments, but we will give you a questionnaire to complete at the beginning and the end of treatment and take some additional photos of your teeth.

All the information is enclosed with this letter. You do not have to take part if you do not wish to do so and this will not affect your care at Birmingham Dental Hospital.

Yours Sincerely,

Sheena Kotecha
Consultant Orthodontist

Institute of Clinical Sciences, School of Dentistry
5 Mill Pool Way, Edgbaston, Birmingham , B5 7EG United Kingdom
T: 0121 466 5544

Appendix 2: Parent information sheet

IRAS No 219179

UNIVERSITY OF BIRMINGHAM

Parent Information Sheet v1.6 09/06/2017

Effectiveness of class II treatment: A randomised controlled trial to compare the Twin Block and Button & Bead appliances

We would like to invite your child to take part in a research study.

- Before your child decides whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with others if you wish.
- Your child is free to decide whether or not to take part in this trial. If your child chooses not to take part, this will not affect the care your child gets from your orthodontist.
- Ask us if there is anything that is not clear or if you would like more information.

Important things that you need to know

- We want to find the best way to treat children whose upper teeth are further ahead of their lower teeth.
- We are testing the use of two different braces (Twin Block and Button & Bead) for correcting sticky out teeth.
- This study fits into the normal treatment, so there are no extra clinic visits or x-rays.
- Your child can stop taking part in the study at any time.

Contents

Why are we doing this study?

We want to find the best way to treat children whose upper teeth are further ahead of their lower teeth (class II with a large overjet). We use removable braces called 'functional appliances' to treat this problem in growing children. There are many different types of these appliances and we want to compare two of them.

What do I need to know about the appliances being used in this study?

The Twin Block appliance is most commonly used for treating this problem. The benefits of this appliance have been reported in previous studies. The Button & Bead appliance has been developed by one of our consultants (Mr. Spary). Although the Button & Bead appliance has not been used in a trial, it has been used successfully by clinicians at Birmingham Dental Hospital and Queen's Hospital, Burton. Both these appliances work by encouraging your child to position their lower jaw further forward than it would normally be.

The research team will monitor the progress of your child's treatment to ensure there are no differences in the success of the treatments.

Are there any risks associated with this treatment?

Both appliances carry a risk of decalcification of the teeth (white/brown marks) if good oral hygiene and appropriate diet is not followed. There may also be some pain and discomfort associated with the use of both these appliances, however, your orthodontist will explain how to manage these risks.

Your child has been invited to take part in this study

Your child has been invited to take part in this study because it has been identified that they have more than a 7mm gap between their top and bottom front teeth and are of the right age to potentially benefit from this treatment. Participation is entirely voluntary and your child's treatment will not be affected if your child decides not to participate. We would still recommend a functional appliance for your child.

What is involved in this study?

Once you and your child have verbally agreed to participate we will obtain written consent from you and your child. Your child will be randomly allocated to have either the Twin Block or Button & Bead appliance. Your child will be asked to complete a questionnaire at the start and end of your treatment which should not take long to complete.

As part of either treatment, your child will have:

1. Photographs, x-rays and impressions taken at the first and last visits
2. Simple measurements taken at each visit

These are part of the normal treatment process and taking part in this study will not require any extra clinic visits or x-rays than would be routinely necessary. We will be taking some additional photographs to allow us to check for white marks of the teeth and changes to the soft tissues. You may withdraw your child from the study at any time without consequence to the quality of care your child will receive. We will see your child every 4 weeks whilst they are wearing the functional appliance.

Most children go on to have fixed appliances ('train track braces') and retainers after completing the functional appliance treatment. Your child will be seen every 6-8 weeks during the fixed appliance phase of treatment. The study will end once they have the fixed braces taken off.

Thank you for reading so far – if you are still interested, please continue reading the rest of this leaflet.

UNIVERSITY OF BIRMINGHAM

More information about taking part

What happens following completion of the study?

The study team will not need to contact you or your child again however you would be able to speak to us at any time regarding the study if you wish.

What if there is a problem or something goes wrong?

If your child has any problems these will be seen to immediately. If you are worried about the treatment received or the way your child have been treated then you may contact the study team.

Confidentiality

All of the information that is collected regarding the participants, during the course of the research, will be kept strictly confidential. You will not be asked to provide any personal details. Information that has been provided will be anonymised.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. Approval for this study has been granted by the Health Research Authority (IRAS No: 219179)

Organisation and funding

This study is being funded by the University of Birmingham.

How to contact us

If you or your child has any questions you can ask the study team:

Sheena Kotecha Emile Habib	Paras Haria Lucy Dunsford	Chandni Patel

Email: bchnt.bbtrial@nhs.net(We will aim to answer your queries within 24 hours)

Department Tel: 0121 466 5038 (Monday to Friday, 9am – 4.30pm)

If you require further advice or have concerns, independent of the research team, then you may contact the Customer Services Team (formerly PALS) in the first instance.

Email: contact.bchc@nhs.net Tel: 0800 917 2855

Thank you for reading this – please ask if you have any questions.

Appendix 3: Participant information sheet for children

Participant Information Sheet for Children

Version 1.6 29/05/2017 IRAS Number: 219179

UNIVERSITY OF BIRMINGHAM

We invite you to take part in our research study titled:
"Effectiveness of class II treatment: A randomised controlled trial to compare the Twin Block and Button & Bead appliances"

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Discuss it with parents and friends if you wish.

You are free to decide whether or not to take part in this research. If you choose not to take part, this will not affect the care you get from your orthodontist.

Ask us if there is anything that is not clear or if you would like more information.

Why are we doing this study?

We want to find the best way to treat children whose upper teeth are much further ahead of their lower teeth. We use removable braces called 'functional appliances' to treat this problem in growing children. There are many different types of these appliances and we want to compare two of them.

What do I need to know about the appliances being used in this study?

The Twin Block brace is most commonly used for treating this problem. Studies have shown the benefits of this appliance. The Button & Bead brace has been developed by one of our consultants (Mr. Spary). Both these braces work by encouraging you to position your lower jaw forward.

Are there any risks I should know about?

Both treatments carry a risk of white/brown marks if you don't look after your teeth. There may also be some pain and discomfort but your orthodontist will tell you how to control this.

Why am I being asked to take part?

You have been asked to take part in this study because you have a gap between your top and bottom front teeth and are of the right age to potentially benefit from this treatment. Other children with a similar problem will also be asked to take part in this study.

What will happen to me if I take part?

If you agree to take part, you will be chosen by chance by a computer to wear either the Twin Block or Button & Bead brace. You will be asked to complete a questionnaire at the start and end of your treatment, which should not take long to complete.

As part of either treatment, you will have:

1. Photographs, x-rays and moulds taken at your first and last visits
2. Simple measurements taken at each visit

Taking part in this study will not require any extra appointments or x-rays but we may take some additional pictures of your teeth. You will be seen every 4 weeks by your orthodontist when you are wearing the appliance.

Most children will then go on to have fixed braces ('train track braces') and retainers. You will be seen every 6-8 weeks when you have a fixed brace. The study will end once you have the fixed braces taken off.

What happens when the study is finished?

The study team will not need to speak to you again however you would be able to speak to us at any time regarding the study if you wish.

What if there is a problem or something goes wrong?

If you have any problems or wish to complain, please let your parent or carer know.

Confidentiality

You will not need to provide any personal details. We will not give anyone the information you have provided.

Who is organising this research?

This research is organised and supported by the University of Birmingham.

Who has reviewed the study?

Before any research goes ahead it has to be checked by a group of people called the Research Ethics Committee. They make sure that the research is fair.

How to contact us

If you have any questions you can ask the study team:

Sheena Kotecha Emile Habib	Paras Haria Lucy Dunsford	Chandni Patel

bchnt.bbtrial@nhs.net (We will aim to answer your questions within 24 hours)

0121 466 5038 (Monday to Friday, 9am – 4.30pm)

Thank you for reading this – please ask any questions that you want to

Appendix 4: Twin-Block appliance patient information leaflet

IRAS 219179
V 1.2 21/03/2017

UNIVERSITY OF BIRMINGHAM

PATIENT INFORMATION LEAFLET:

TWIN BLOCK APPLIANCE

What is Twin Block brace?

- An upper and lower removable brace with acrylic blocks
- It aims to correct to reduce the gap between your top and bottom teeth

Important rules:

- If the brace is damaged, do not wear it
- Brush regularly after every meal
- Avoid sugar and fizzy drinks to prevent damage to your teeth

Will it be painful?

- You will experience some discomfort for the first few days which is likely to subside with time
- Take painkillers if necessary
- If there is an obvious area of soreness, please contact the department

How else will it affect me?

- Your speech may be different. Talking out loud with the brace will allow your speech to return to normal within a few days
- You may find you produce more saliva. This is expected and resolves very quickly

Can I eat normally?

- Follow the instructions given to you by the orthodontist
- It is advised to wear the appliance full-time, including eating

How do I clean the brace?

- Remove the brace for cleaning
- Clean your teeth at least 2 times a day with a fluoride toothpaste
- Clean your brace separately, with a soft tooth brush and warm soapy water

When can I remove the brace?

- For cleaning
- When playing sports or swimming

Ensure you store the brace in a protective box when not wearing. Any breakages are likely to prolong your treatment

How long will the treatment take?

- This will vary according to each individual
- On average, this first phase of treatment is expected to last 9-12 months
- You may then require a second phase of treatment with a different type of brace

How often do I need an appointment?

- You will need regular appointments for your brace to be adjusted
- It is importance to see your own dentist for regular check-ups throughout your treatment

What if my brace breaks?

- Ring up for an appointment as soon as possible on **0121 466 5044**
- Keep both parts of your brace safe

Birmingham Community Healthcare NHS
NHS Foundation Trust

Appendix 5: Button-and-Bead appliance patient information leaflet

IRAS 219179
V 1.2 19/03/2017

UNIVERSITY OF BIRMINGHAM

PATIENT INFORMATION LEAFLET:

BUTTON & BEAD APPLIANCE

What is Button and Bead brace?

- A top and bottom clear removable brace with fixed buttons on 4 teeth
- Your orthodontist will show you how to place the elastics on each side
- It is important for the brace to work to wear both the splints and the elastics together

Important rules:

- Never wear the elastics without the splints
- If the splint is damaged, do not wear your it or the elastics
- Brush regularly after every meal
- Avoid sugar and fizzy drinks to prevent damage to your teeth

Will it be painful?

- You will experience some discomfort for the first few days which is likely to subside with time
- Take painkillers if necessary
- If there is an obvious area of soreness, please contact the department

How else will it affect me?

- Your speech may be different. Talking out loud with the brace will allow your speech to return to normal within a few days
- You may find you produce more saliva. This is expected and resolves very quickly

Can I eat normally?

- Follow the instructions given to you by the orthodontist
- It is advised to wear the appliance full-time, including eating

How do I clean the brace?

- Remove the brace for cleaning
- Clean your teeth at least 2 times a day with a fluoride toothpaste
- Clean your brace separately, with a soft tooth brush and warm soapy water

When can I remove the brace?

- For cleaning
- When playing sports or swimming

Ensure you store the brace in a protective box when not wearing. Any breakages are likely to prolong your treatment

How long will the treatment take?

- This will vary according to each individual
- On average, this first phase of treatment is expected to last 9-12 months
- You may then require a second phase of treatment with a different type of brace

How often do I need an appointment?

- You will need regular appointments for your brace to be adjusted
- It is importance to see your own dentist for regular check-ups throughout your treatment

What if my brace breaks?

- Ring up for an appointment as soon as possible on **0121 466 5044**
- Keep both parts of your brace safe

Birmingham Community Healthcare NHS
NHS Foundation Trust

Appendix 6: Children's assent form

IRAS Number: 219179

UNIVERSITY OF BIRMINGHAM

Children's Assent Form v 1.4 26.5.2017

Effectiveness of class II treatment: A randomised controlled trial to compare the Twin Block and Button & Bead appliances

Research team: Chandni Patel, Paras Haria, Lucy Dunsford, Sheena Kotecha, David Spary

Please answer the following by placing your initials in the boxes below:

1. I have read (or had read to me) information about this project. ☐

2. I understand what this project is about. ☐

3. I have asked all the questions that I would like to. ☐

4. I have had my questions answered in a way that I understand them. ☐

5. I understand that I can stop taking part in this project at any time I wish. ☐

6. I am happy to take part in this project. ☐

You will have to attend appointments every 4 weeks as part of your orthodontic treatment.

If you have answered **no** to any questions and you **do not** want to take part, please **do not** sign your name.

If you **do** want to take part, please write your name and today's date:

Your name: ___________________________ Date: _____________________________

Name of Parent/Guardian: ___________________________

The doctor who explained this project to you needs to sign too:

Print Name: ______________________________ Job title: ______________________________

Sign: ______________________________ Date: ____________________________

When completed, provide a copy for the patient; and place a copy in research file which is in a locked office in Birmingham Dental Hospital.

Birmingham Community Healthcare NHS
NHS Foundation Trust

IRAS Number: 219179

Name of person taking consent:

Print Name: ____________________________ Job title: __________________________

Sign: ____________________________ Date: __________________________

When completed, provide a copy for the parent, one to be kept in a file in a locked office at Birmingham Dental Hospital.

Birmingham Community Healthcare NHS
NHS Foundation Trust

Appendix 7: Parental consent form

IRAS Number: 219179

UNIVERSITY OF BIRMINGHAM

Parental Consent Form v1.3 26.5.2017

Effectiveness of class II treatment: A randomised controlled trial to compare the Twin Block and Button & Bead appliances

Research team: Chandni Patel, Paras Haria, Lucy Dunsford, Sheena Kotecha, David Spary

Please read and initial each statement below if you are happy for your child to take part.

1. I confirm that I have read and understood the information sheet version 1.5 dated 29.05.2017 provided to me for the above study. ☐

2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

3. I understand that participation is voluntary and that I am free to withdraw him/her any time without giving any reason and without my or my child's treatment or legal rights being affected. ☐

4. I consent to my child taking part in the study. ☐

5. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my child's taking part in this research. I give permission for these individuals to have access to these records. ☐

6. I agree to my child's General Dental Practitioner being informed of his/her participation in the study. ☐

If you are happy for your child to take part in the study, please sign below:
Child's name: ________________________

Print name: ________________________ Relationship: ________________________

Sign: ________________________ Date: ________________________

When completed, provide a copy for the parent, one to be kept in a file in a locked office at Birmingham Dental Hospital.

Birmingham Community Healthcare NHS
NHS Foundation Trust

IRAS Number: 219179

Name of person taking consent:

Print Name: ____________________________ Job title: __________________________

Sign: ____________________________ Date: __________________________

When completed, provide a copy for the parent, one to be kept in a file in a locked office at Birmingham Dental Hospital.

Birmingham Community Healthcare NHS
NHS Foundation Trust

Appendix 8: Baseline recrods case report form (CRF)

Confidential

Baseline records

Record ID	______________________________
Date of visit	______________________________
Sex of child	○ Male ○ Female
DOB	______________________________
Age	______________________________
Overjet	______________________________ (in mm)
Overbite	○ Reduced ○ Average ○ Increased ○ AOB
Overbite	○ Complete ○ Incomplete
Right molar	○ I ○ II ○ III
Right molar extent	○ 1/4 ○ 1/2 ○ 3/4 ○ full
Right canine	○ I ○ II ○ III
Right canine extent	○ 1/4 ○ 1/2 ○ 3/4 ○ full
Left canine	○ I ○ II ○ III
Left canine extent	○ 1/4 ○ 1/2 ○ 3/4 ○ full
Left molar	○ I ○ II ○ III
Left molar extent	○ 1/4 ○ 1/2 ○ 3/4 ○ full
Upper centreline	○ Coincident ○ Non coincident
Lower centreline	○ Coincident ○ Non coincident
Overjet at maximum protrusion	______________________________ (in mm)

Height (in cm)	______________________ (in cm)
Weight (in kg)	______________________ (in kg)
BMI	______________________
Have upper and lower alginate impressions and wax bite been taken?	○ Yes ○ No
Has a protrusive bite been taken?	○ Yes ○ No
Is there a baseline OPG?	○ Yes ○ No
Has a baseline lateral cephalogram been taken in RCP?	○ Yes ○ No
Have baseline photos been taken?	○ Yes ○ No (3DMD, SOV10, SOV5 polarised)
Has the patient's GDP been sent the letter informing them of the patient's involvement in a research trial?	○ Yes ○ No
Has the QoL questionnaire been given to the patient?	○ Yes ○ No

Appendix 9: Child oral health questionnaire

Todays Date | |

CHILD ORAL HEALTH QUESTIONNAIRE

Hello,

Thanks for agreeing to help us with our study!

This study is being done so that there will be more understanding about problems children may have because of their **teeth, mouth, lips and jaws**. By answering the questions, you will help us learn more about young people's experiences.

PLEASE REMEMBER:

- Don't write your name on the questionnaire
- This is **not a test** and there are no right or wrong answers
- Answer as **honestly** as you can. Don't talk to anyone about the questions when you are answering them. Your answers are **private**; no one you know will see them
- Read each question **carefully** and think about your experiences in the **past 3 months** when you answer
- Before you answer, ask yourself**: "Does this happen to me because of problems with my teeth, mouth, lips and jaws?"**
- Put an ☒ in the box for the answer that is best for you

QUESTIONS ABOUT ORAL PROBLEMS

In the <u>past 3 months</u>, how often have you had:

1. Pain in your teeth, lips, jaws or mouth?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

2. Sores in your mouth?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

3. Bad breath?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

4. Food stuck in or between your teeth?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

In the <u>past 3 months</u>, because of your teeth, mouth, lips and jaws, how often has it been:

5. Taken longer than others to eat a meal?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

6. Difficult to bite or chew firm foods like apples, corn on the cob or steak?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

7. Difficult to say any words?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

8. Difficult to sleep?

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

QUESTIONS ABOUT FEELINGS

Have you had the feeling because of your teeth, mouth, lips and jaws?
If you felt this way for another reason, answer 'Never'.

In the past 3 months, how often have you:

9. Felt irritable or frustrated?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day

10. Felt shy or embarrassed?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day

In the past 3 months, because of your teeth, mouth, lips and jaws, how often have you:

11. Been concerned what other people think about your teeth, mouth, lips and jaws?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day

12. **Been upset?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

QUESTIONS ABOUT YOUR SPARE-TIME ACTIVITIES & BEING WITH OTHER PEOPLE

Have you had these experiences because of your teeth, mouth, lips and jaws? If it was for another reason, answer 'Never'.

In the past 3 months, how often have you:

13. **Avoided smiling or laughing when around other children?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

14. **Argued with other children or your family?**

- ❑ Never
- ❑ Once or twice
- ❑ Sometimes
- ❑ Often
- ❑ Everyday or almost every day

In the past 3 months, because of your teeth, mouth, lips and jaws, how often have:

15. Other children teased you or called you names?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day

16. You not wanted to speak or read out loud in class?

- ☐ Never
- ☐ Once or twice
- ☐ Sometimes
- ☐ Often
- ☐ Everyday or almost every day

This is the end of the questionnaire. Thank you for taking the time to complete it. Please return it your orthodontist.