Comparison of 3D facial soft tissue changes following Twin-block and Button & Bead appliances: A single centre randomised clinical trial.

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A thesis submitted to the University of Birmingham for the degree of

MSc in Research

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October 2019

Abstract

Objectives

To determine if the horizontal advancement of soft tissue pogonion was statistically significantly different following treatment with a Twinblock appliance and Button & Bead appliance.

Method: Sixty-four children aged 10-14 years were recruited from the Birmingham Dental Hospital. Following randomization thirty-two patients were allocated to either the Twinblock or the Button & Bead appliance group. Records, including three-dimensional facial soft tissue images (3dMD), were taken at the start (T_0) and and at the end of functional appliance therapy (T_1).

Results: The overlying soft tissue changes followed the underlying skeletal and dental changes produced by the appliances. There were no statistically significant differences in upper lip movement between the two appliances. There was statistically significantly more anterior horizontal movement at pogonion (p=0.001) and B-point (p=0.012) in the Twinblock group compared to the Button & Bead group.

Conclusion: As a result of Twinblock treatment there were minimal changes in upper lip position. In the Button & Bead group there was some retraction and lengthening of the upper lip, this could be clinically significant (>2mm) and mainly in the philtrum region. The horizontal anterior movement of the soft tissue chin region was statistically and clinically significantly greater in the Twinblock group compared to the Button & Bead group. The Button & Bead appliance produced a clinically significant vertical increase in chin and lower lip compared to the Twinblock.

Acknowledgements

I would like to express my sincere gratitude to the following:

- Professor Balvinder Khambay for all his overall guidance and supervision.
- Miss Sheena Kotecha and Mr. Emile Habib for their ongoing clinical support and management of the trial patients.
- The trial team, in particular the nurses, for their hard work enabling me to complete my study.
- The patients and parents at Birmingham Dental Hospital for taking part in the study.
- My fellow MSc students for their support and sharing of results.

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CHAPTER 1

LITERATURE REVIEW

1. LITERATURE REVIEW

1.1 Introduction

1.1.1 Definition

The British Standards Institute classification for a class II division 1 incisor relationship is “the lower incisor tips lie posterior to the cingulum plateau of the upper incisors. The overjet is increased and the upper incisors are of average inclination or are proclined” (British Standards Institute, 1983).

1.2 Prevalence

Prominent upper front teeth are one of the commonest problems seen by orthodontists in the United Kingdom and affects about a quarter of 12-year-old children in the UK (Holmes, 1992) and has an incidence of 20% (Todd and Dodd, 1988).

1.3 Aetiology

The aetiology of any malocclusion can be divided into skeletal, dental, soft tissue and habits. The resulting malocclusion is generally a combination of the interaction of all three components as they are interdependent. As well as these local factors there is thought to be a strong genetic background to malocclusions (Mossey, 1999). The magnitude of the overjet will be influenced by the patient’s sex, age and soft tissue (Ferrario et al, 1997a; Blanchette et al., 1996; Foley and Duncan, 1997).

1.3.1 Skeletal

Class II malocclusions can be caused by skeletal factors affecting the mandible, maxilla, cranial base or a combination of all three (Hopkins et al., 1968; Proffit et al., 1998). Mandibular causes can result from a normally sized mandible, which is retrusive, and / or a small or hypoplastic mandible. Mandibular features include a reduced mandibular length when compared to controls (Stahl et al., 2008) and a backward and downward rotation of the mandible (Baccetti et al., 1997). The class II skeletal pattern may also be associated with maxillary prognathia (Rosenblum, 1995). Maxillary causes often relate to an increased cranial base angle as well as an increased anterior cranial base length (Björk,1950). Class II division 1 malocclusions can occur on any anterior-posterior skeletal pattern but the majority present on a class II skeletal pattern (76%), the remainder present on a class I (18%) and class III (6%) skeletal pattern (James, 1963). As well as anterior-posterior discrepancies, there may be associated vertical and transverse abnormities. The lower facial height is usually average or reduced (Hopkins et al., 1968) but there are large variations (Sidlauskas et al., 2006). Transversally, a narrow maxilla has also been noted which is thought to affect skeletal growth of the mandible (Mc Namara et al., 1980).

1.3.2 Dental

The dentition develops based on the soft tissue forces and balance from the lips, cheeks and tongue within the oral cavity, in a position of equilibrium (Proffit, 1978). The dental features associated with a class II malocclusion will obviously include an increased overjet. The extent of the overbite will depend on tongue function, underlying vertical skeletal pattern and the extent of the curve of Spee. The buccal segments are often class II but can be modified by local factors, for example early loss of primary molars. The presence or absence of posterior crossbites can also be dependent on local factors such as retained teeth and digit sucking (Hopkins et al., 1968). In addition, the anterior-posterior position of the mandible will have a potential effect on the transverse relationship due to the discrepancy in arch width. The upper arch can present with minimal crowding if the arch length has increased enough to accommodate the teeth, but again this will be dependent on local factors. In cases with a small retrusive mandible, crowding often occurs due to the reduced arch length (Howe et al., 1983).

1.3.3 Soft tissue

The overlying soft tissue position and morphology will be partly determined by the underlying skeletal pattern. In a normal situation the lower lip should cover the lower one third of the labial surface of the upper incisors and maintain their position. Given the mandibular retrusion, the lower lip is also often retrusive and this will typically result in a lower lip trap which will procline the upper incisors. A short upper lip, vertical maxillary excess and a posterior growth rotation of the mandible can result in incompetent lips (Ricketts, 1989a). During swallowing there is a need to establish an anterior oral seal and the tongue may come forward to contact the lower lip (Hopkins et al., 1968). This change in soft tissue equilibrium may affect the underlying dental positions and result in proclination of the upper labial segment. The lower lip can also act to retrocline the lower labial segment and increase the overjet especially if it is “strap-like” or hyperactive during function. In addition, the upper front teeth can procline due to a habit such as thumb sucking (Larsson, 1987).

1.4 Treatment Need

1.4.1 Function

Individuals with class II division 1 malocclusions usually have a mandibular deficiency, (Moss et al., 1994), a convex profile and a less prominent lower lip (Ferrario et al., 1995) and are commonly referred for treatment for aesthetic concerns (Dann et al., 1995). In addition to aesthetic concerns, Class II patients can suffer with functional difficulties such as mastication and achieving an oral seal (Singh and Clark, 2003).

1.4.2 Dental Trauma

The features associated with a class II malocclusion such as an increased overjet, incompetent lips and mouth breathing, increase the risk of dental trauma (Forsberg and Tedestam, 1993). Recent systematic reviews have reported, that based on the current quality of evidence there is an increased risk of incisal trauma as a result of an increased overjet. When front teeth protrude more than 3mm, the teeth are twice as likely to be traumatised (Nguyen et al., 1999). It has been suggested that early treatment of class II division 1 patients, using two-stage treatment, is more effective at reducing trauma than a single treatment modality in adolescence (Batista et al., 2018). The risk of dental trauma is associated with gender, age, lip incompetency and lip length. The odds of trauma are over 3.5 times more likely with a short upper lip (Yaman Dosdogru et al., 2017).

1.4.3 Psychological trauma / Quality of life

A class II profile and associated features can give patients an appearance that may be a target for teasing (Shaw et al., 1980) and bullying (Seehra, 2011) which impacts on their self-esteem (Tung and Kiyak, 1998) as well as the patient's quality of life (Johal et al., 2007). As well as reducing the risk of trauma, early treatment of the increased overjet has been reported to improve the individual's self-esteem and reduce "negative social experiences" (O'Brien et al., 2003). However, this was a relativity short-lived effect, and into adulthood the improved quality of life and psychological impact had little effect when compared to a non-treated group, who would have benefitted from treatment earlier (Shaw et al.,1980; Kenealy et al., 2007).

1.5 Treatment Options

The treatment options for a class II malocclusion include orthodontic growth modification, orthodontic camouflage or a combined orthodontic and orthognathic approach (Hopkins et al., 1968). The preferred option will depend on the aetiology of the malocclusion, accompanying features such as overbite, crowding, spacing and inclination of the incisors and other features.

1.5.1 Camouflage

Camouflage treatment reduces the overjet and aligns the teeth to achieve a stable occlusion but does not address the skeletal discrepancy. This relies on the upper incisors being proclined and amenable to tipping or bodily movement. Space requirements need to be met either utilising any space within the arch or space creation with extractions, distalisation or expansion. As space is required for relief of crowding and overjet reduction, in severely crowded arches full overjet reduction can be difficult. If bodily movement and space is required for overjet reduction this can be achieved with fixed orthodontic appliances and premolar extractions (Nayak et al., 2011). The overjet as well as other features such as the soft tissues are crucial in orthodontic treatment planning and can indicate or limit treatment (Ackerman and Proffit, 1997). The naso-labial angle needs to be assessed prior to treatment as there is an increase in the angle as a result of camouflage treatment (Kinzinger et al., 2009). For post-treatment stability the lower lip needs to cover the labial surface of the upper incisors.

1.5.2 Growth modification

Orthodontic growth modification treatment would ideally include a combination of maxillary restraint, enhanced mandibular growth, forward rotation of the mandible and correction of the incisor relationship. This can be achieved in part using a functional appliance such as a Twinblock. For the Twinblock to produce a positive effect the ideal features include; proclined upper incisors, mandibular retrusion, a growing patient and cessation of any habit (Burden et al., 1999). The use of a functional appliance encourages forward movement of the mandible (Rondeau, 1996) which helps the patient to achieve a lip seal and overall an improved facial appearance (Clark, 1988; McNamara et al., 1995). However, any increase in mandibular unit length is minimal (Kinzinger et al., 2009). Following this growth modification stage, a second phase of fixed appliances is advocated (Tulloch et al., 2004; Keeling et al., 1998).

1.5.3 Orthognathic Surgery

A surgical approach is considered if there is a severe skeletal component (ANB > 9^{o}) that cannot be treated with orthodontic treatment alone and therefore surgery is the only treatment option (Houston, 1989). In the situation where the patient has a profile concern and has reached full growth or development, orthodontic growth modification or orthodontic camouflage treatment to retrocline the upper incisors may not be suitable and a surgical approach maybe indicated. The process generally involves a course of fixed appliance treatment to correct the inclination of the upper and lower incisor relative to the maxilla and mandibular skeletal bases respectively. The greatest change in mandibular unit length and profile change occur as a result of surgery (Kinziger et al., 2009).

1.6 Definition of a functional appliance

A functional appliance uses the forces created from facial muscles and the periodontium to change the dental or skeletal relationship in a growing patient (Bishara et al., 1989). They can be fixed or removable (Ishaq et al., 2016).

1.6.1 Classification of functional appliances

There have been various classifications of functional appliances including:

- Myotonic and myodynamic (Graber and Neumann, 1984),
- Tooth borne and tissue borne (Proffit, 1986)

Myotonic appliances have a large mandibular opening and induce passive muscular stretching; for example the Harvold appliance (Houston et al., 1993). Myodynamic appliances have less than 5mm opening of the mandible and stimulate activity in the muscle, for example the Andreson appliance (Houston et al., 1993). Functional appliances can also be classified as tooth borne, such as the Twinblock or tissue borne, such as the Frankel appliance (Proffit et al., 1986).

In the United Kingdom, 99% of Orthodontists use some form of functional appliance. The most popular design (75%) is the Clark's Twinblock, which has also shown to have the best compliance (Chadwick et al., 1998). The main advantages of the Twinblock are its relatively simple design that enhances the muscles of mastication and its concurrent use with fixed appliances (Clark, 1982; Clark, 2002). A key disadvantage is that it is removable and therefore requires compliance and cooperation from the patient. Studies have shown treatment dropouts and discontinuation of up to 9-15% of children (Illing et al., 1998; Harradine and Gale, 2000).

1.7 Modes of action of functional appliances

Functional appliances reportedly treat a Class II skeletal pattern by altering the position of the mandible in both a vertical and anterior-posterior direction via condylar remodelling and growth. The majority of the evidence for the modes of action of functional appliances has been based on study models and lateral cephalogram (Carels and Van der Linden, 1987). There are several proposed mechanisms for the correction; restriction of maxillary growth, growth of the mandible (and condyle) and tipping of the incisors, in combination with orthopaedic change, to reduce the overjet (Bishara and Ziaja, 1989).

There is considerable debate as to whether functional appliances such as the Twinblock encourage mandibular growth or any other skeletal change. Numerous systematic reviews have been carried out showing inconclusive results but with minimal skeletal change (Cozza et al., 2006).

1.7.1 Maxilla

Orthopaedic maxillary restraint is thought to occur due to the distally directed forces produced by the upper component of the appliance. These changes, reported in early studies, should be viewed with caution due to small sample sizes, lack of control groups and variations and inconsistencies in the appliance design; making comparison between studies difficult (Forsberg and Odenrick, 1981; Pancherz, 1984; Vargervik and Harvold, 1985; Bishara and Ziaja, 1989; Mills and McCulloch, 1998).

Over the later years randomised clinical control studies have been undertaken to determine the effects of functional appliance treatment (Tulloch et al., 1997; O'Brien et al., 2003). These have been collated and analysed as a systematic review and meta-analysis assessing the short-term effectiveness of orthodontic treatment with functional appliances on maxillary growth (Nucera et al., 2016). The results of the meta-analysis showed that functional appliances statistically significantly inhibit sagittal growth in the maxilla with a reduction in SNA of -0.61° per year compared to controls. However, there was a high level of heterogeneity between the studies. Even though there were statistical differences, these small changes would not be clinically significant. In a recent systematic review, analysing previous systematic reviews on class II orthopaedic correction, changes in SNA of between -0.7° to -1.03° were reported (D'Anto et al., 2015). The evidence would therefore suggest that there is minimal maxillary restraint during functional appliance treatment and any change is not clinically significant.

1.7.2 Mandible

Skeletal growth of the mandible is thought to occur from forward posturing of the mandible with a functional appliance (Cozza et al., 2006). This provides a constant protrusive force, which in turn creates a proprioceptive response and stimulates mandibular growth (Clark, 1988). The initial studies on the effect of functional appliances on the mandible were demonstrated by animal studies, which showed mandibular growth was stimulated by posturing the mandible by up to 15% (McNamara, 1985; Bishara and Ziaja, 1989). Whether these findings are comparable to humans however is controversial as the use of continuous forces is not possible and therefore the results would be less profound (Bishara and Ziaja, 1989). Numerous studies undertaken since have shown differing results in humans (Cozza et al., 2006). Significant mandibular growth was shown with active functional appliance therapy compared to controls of 1.2mm per year (Clark, 2002; McNamara, 1985). Other studies found smaller changes of 1.1mm per year (Creekmore and Radney, 1983) and 0.7mm per year (Baumrind et al., 1983), which are unlikely to be clinically significant. These changes should be viewed with caution however, as comparison is difficult owing to small sample sizes and variation in appliance design.

More recently randomised control trials have been undertaken to determine the effects of functional appliance treatment on the mandible (O'Brien et al., 2003). Small mandibular changes were found of 1mm highlighting some skeletal change could occur. However, the majority of the class II correction and overjet reduction may be due to other factors (O'Brien et al., 2003; Tulloch et al., 1998; Keeling et al., 1998). Through systematic reviews and meta-analyses, the short-term effect of orthodontic treatment with functional appliances on mandibular growth has been debated. The results seem controversial with regard to a significant quantitative mandibular change (Cozza et al., 2006) and were inconclusive (Chen et al., 2002). Significant mandibular growth was reported in two thirds of the treatment group when compared with controls but this was not supported by the randomised control trials within the review (Cozza et al., 2006; Ishaq et al., 2016). Summarising the evidence from a systematic review of systematic reviews; there appears to be some evidence that SNB increases with a Twinblock appliance by 1.2 degrees (Ehsani et al., 2014) and other activators by 0.66 degrees (Antonarakis and Kiliaridis, 2007). Mandibular length increases with functional appliance treatment from 0.8mm - 4.7mm (Cozza et al., 2006). It was noted, that a key factor in obtaining mandibular growth (> 2mm) with functional appliances was ensuring treatment was undertaken during the pubertal growth spurt (D'Anto et al., 2015; Cozza et al., 2006; Petrovic et al., 1990; Perinetti et al., 2016).

The correction of a class II malocclusion requires forward movement of the mandible either through growth or position. Overall there is some evidence to support some mandibular growth / increased length following treatment with functional appliances but the clinical relevance of this change is questionable (D'Anto et al., 2015).

1.7.3 Muscles

The Twinblock postures the mandible forward causing a muscular imbalance described by McNamara as the "pterygoid response" and by a zone of tension created distal to the condyle (McNamara, 1980; Harvold, 1985). Bishara et al.

(1989) described the Twinblock as an appliance that alters the muscular arrangement to induce forces on the basal bone and dentition enabling orthopaedic change. The forces created in the muscles by posturing the mandible were transferred through the teeth and enabled mandibular growth and maxillary restraint (Graber and Neuman, 1984).

Previous experiments have shown an adaptive response with inclined bite planes (McNamara, 1980). There is an altered proprioceptive response in the neuromusculature leading to muscular changes and the dentoalveolar and skeletal changes adapt to support the muscular change and restore function. The downward and forward position of the mandible caused by the inclined bite planes of the Twinblock improves facial balance and soft tissue competence. Skeletal changes described by McNamara and Clark showed; a decreased ANB angle, increased lower facial height, reduced convex profile and increased mandibular length (McNamara, 1980; Clark, 1988).

1.7.4 Dental

There seems to be an overall consensus regarding the overjet correction after functional appliance treatment. O'Brien et al. (2003) describes how overjet correction was attributed to dento-alveolar and skeletal change affecting both the maxilla and the mandible. The amount of dento-alveolar change was greater than the skeletal change; indicating the changes as a result of Twinblock appliance treatment are mainly dento-alveolar (D'Anto et al., 2015; Thiruvenjatachari et al., 2013; Graber and Neuman, 1984; Pancherz, 1984; Ehsani et al., 2014). A class I occlusion was achieved by incisal tipping to reduce the overjet, of which 50% was maxillary retroclination and 20% mandibular proclination (Pancherz, 1984). Palatal tipping of the upper incisors aids overjet reduction and can be a result of either a labial bow on the labial surface of the maxillary incisors, the distal force created by the mandible or through achieving lip competency (Ireland and McDonald, 2003). Lower incisor proclination may not be desirable in all cases and not all studies support the theory that the lower incisors procline during active treatment (Ireland and McDonald, 2003; Nielsen, 1984). In addition to incisor changes, the maxillary molars tip distally and the lower molars mesially which also helps to correct the class II buccal segments (Fleming and Lee, 2016). This is however disputed by D'Anto et al. (2015) who found any molar movements to be small and reported insufficient evidence to support these molar movements with the use of a Twinblock appliance. The long-term stability of dento-alveolar change remains unknown (Antonarakis and Kiliaridis, 2007).

1.7.5 Soft tissue

There is limited evidence to determine the effects of functional appliance treatment on the facial soft tissue profile due to low quality studies and insufficient evidence (D’Anto et al., 2015). The soft tissue profile is thought to improve in association with the dento-alveolar and skeletal changes following functional appliance therapy (Clark, 1988). The soft tissues adapt to the new dento-alveolar relationship to provide an adequate oral seal for mastication and swallowing. In addition, the soft tissue changes are thought to improve facial balance and reduce facial convexity (Clark, 1988). Earlier studies reported that changes in the soft tissue profile and advancement of the lower lip are associated with the forward movement of the mandible and proclination of the lower incisors (Bishara and

Ziaja, 1989; Cozza et al., 2004; Morris et al., 1998). Significant advancement of soft tissue pogonion, soft tissue B-point, and an increase in labiomental angle was noted after functional appliance wear compared to controls (Varlik et al., 2008). Overall, advancement of the lower lip, forward movement of the chin and lengthening of the lip have been reported which reflect the underlying hard tissue treatment changes (Forsberg and Odenrick, 1981; Morris et al., 1998; Singh, 2002; Singh and Clark, 2003; Baysal and Uysal, 2013).

The results for the changes associated with the upper lip are however conflicting. Some studies suggest retraction of the lip is associated with retroclination of the upper incisors (Ramos et al., 2005; Kasai, 1998; Perkins and Stanley, 1993). Other studies showed no significant change in the upper lip position following functional appliance therapy (Morris et al., 1998; Lange et al., 1995). Studies have also reported a reduction in the facial convexity as well as an increase in the nasolabial angle of the treated subjects compared with controls (Morris et al., 1998; Battagel, 1990; Looi and Mills, 1986). These studies were based on cephalometric measurements with various sample sizes and differing evaluation methods and therefore care is required when comparing the results.

To date the majority of studies have reported profile cephalometeric changes based on a limited number of landmarks. Soft tissue changes based on conventional two-dimensional (2D) diagnostic methods may underestimate the actual clinical effect (D'Anto et al, 2015). The changes produced by functional appliances are three-dimensional (3D) in nature. The use of a single landmark to report the three-dimensional changes of an entire structure such as a lip, greatly underestimates complex 3D changes. Previous studies have reported changes in volume and surface area as a result of Twinblock appliance (Bourne et al., 2001; Salloum et al., 2017). A recent study using 3D stererophotogrammetry presented soft tissue changes following Twinblock treatment with displacements of single landmarks in the x, y and z-direction together with changes in their Euclidian distance (Salloum et al., 2017). To address the shortcomings of using a limited number of landmarks, more comprehensive analysis based on region meshes has been proposed (Cheung et al., 2016; Almukhtar et al., 2017). This process uses a generic mesh to establish anatomical correspondences between the pre and post intervention images, followed by selection of a region of interest, for example upper lip, lower lip and chin region. The 3D changes of the anatomical region can then be determined (Almukhtar et al., 2017). Differences in the Euclidian distances only quantify the magnitude of change, not the direction of change. Three-dimensional can only be assessed when the changes in the x, y and z-direction are analysed.

1.8 Three-dimensional (3D) imaging

Since the introduction of radiographs in 1895 by Professor Wilhelm Conrad Roentgen, a number of advancements have taken place for their use in Medicine and Dentistry. In 1931, Broadbent and Hofrath simultaneously reported the use of a standard method for taking a lateral cephalogram to reduce distortion (Broadbent, 1931; Hofrath, 1931). Cephalometric radiographs have been used to diagnose dental and skeletal malocclusions and evaluate facial growth; however, a number of limitations exist using conventional two-dimensional imaging (Bourne et al, 2001; Karatas and Toy, 2014). Viewing a three-dimensional object in profile can cause distortion due to displacement of structures either in a horizontal or vertical direction (perspective distortion), which is dependent on the film distance and the object (Nalcaci et al., 2010). In addition, analysing and superimposing lateral cephalograms is often difficult due to incorrect head positioning and in the presence of facial asymmetry (Burke and Beard, 1967). Finally, measurement errors often occur due to incorrect identification of landmarks (Baumrind and Frantz, 1971). Cephalometric radiographs record the hard and soft tissues in profile (2D); due to the 3D nature of facial soft tissues, 3D imaging and diagnosis are essential (Mihalik et al., 2003).

Three-dimensional imaging was first introduced in the 1900's, initially to analyse changes in maxillary growth (Singh and Savara, 1966) and since then has become an important tool for assessing soft tissues changes in orthodontics and maxillofacial surgery (Subramanyan and Dean, 1966). Through the collection of anatomical data via specialist equipment and computer processing, 3D images can be displayed on a 2D computer screen (Hajeer et al., 2004). 3D imaging is an important adjunct to treatment planning in orthodontics and orthognathic surgery as it aids assessment of the skeletal, dental and soft tissue relationship, which is important for profile hard and soft tissue evaluation pre and post treatment (Mavili et al., 2007).

1.9 Methods of capturing three-dimensional images

Three-dimensional image generation requires a number of stages. Modelling occurs initially where a frame is created out of triangle shapes. Using pixels, a surface can be added which is known as 'texture mapping'. The next stage requires addition of light and shade and the final stage requires the computer to convert the data into a 3D object (rendering) (Seeram, 1997). There are three 3D imaging approaches; slice imaging, projective imaging and volume imaging (Udupa and Herman, 1991). To measure objects either orthogonal or triangulation measurements are used. Orthogonal is used with CT scanners where the object is cut into slices where the x and y axes are measured directly on the layers and the z is quantified by the number of slices. Triangulation requires two images of the object from different views, which is used in stereophotogrammetry (Hajeer et al., 2004).

A number of imaging modalities have been reported including; volumetric scanning, Computerized Tomography (CT), Cone Bean Computerized Tomography (CBCT), Magnetic Resonance imaging (MRI) and surface scanning including 3D lasers and stereophotogrammetry (Herman, 2009; Scarfe et al., 2006; Ritman, 2004; Paddock and Eliceiri, 2014; Fechteler et al., 2007; Ras et al., 1996; Ferrario et al., 1996; Edelman et al., 2005).

1.9.1 Computerized Tomography (CT) scanning

CT scanning has been used for 3D imaging since the 1980's initially for craniofacial patients. Simulation software was then introduced and the use of 3DCT and MRI was published (Udupa and Herman, 1991). Since then, 3D imaging has continued to evolve, to analyse and manipulate facial structures (Hajeer et al., 2004). There are 2 main types of CT imaging technologies, these include fan beam and cone beam (Aboudara et al., 2003). Fan beam involves the patient being supine and the x-ray source rotates around the patient. The process is painless and creates multiple images of the patient's body (Aboudara et al., 2003). The disadvantages however are that they are expensive and involves high levels of radiation exposure, which is not appropriate for orthodontic treatment in general. The resolution of soft tissues can be limited, and metal objects can lead to artifacts (Svendsen et al., 1980). It is however useful for certain craniofacial deformities where 3D imaging of the soft and hard tissues can be invaluable (Westesson et al., 1987; Zilkha, 1982).

To overcome the cost and radiation exposure limitations of CT scanners, cone beam computerized tomography (CBCT) was introduced; which improved scan time and reduced the radiation dose (Kau et al., 2005; Halazonetis, 2005). With CBCT it is possible to view images in multiple planes and assess volumetric change (White, 2008). This provides important information for orthodontic treatment planning and diagnosis particularly for localization of impacted teeth and resorption, assessing root lengths and determining abnormal anatomy (Scarfe et al., 2006 and Harorli, 2006). Advantages of CBCT include reduced cost, dose reduction, time, 3D reconstruction and image processing. A CBCT emits 98% less radiation than conventional CT at approximately 36.9-50.3 microsievert. The CBCT x-ray source only requires one revolution and is therefore quicker and a less traumatic experience for the patient. The 3D data can be manipulated and software is available to process and provide measurements for orthodontic diagnosis and implant placement (Scarfe et al., 2006). Disadvantages of CBCT scanning however include sensitivity of the sensors, which can affect image quality, and the soft tissue texture is not captured. Any movement can cause blurring of the image (motion artefact) and the scanner is more expensive than conventional radiographic equipment (Scarfe et al., 2006). Virtual 3D models of images can be created for surgery, predictions of facial change after orthodontic treatment or orthognathic surgery can be visualized and image manipulation is available to determine hard and soft tissue outlines (White et al., 2010). CBCT images can also be superimposed to show growth modification and treatment outcomes following treatment, which is important to indicate post-operative stability (White et al., 2010). In addition, bone thickness and root positioning can be assessed for when placement of mini screws is required (Cevidanes et al., 2006).

1.9.2 Laser scanners

Laser scanners are an imaging modality which capture the air / object surface boundary and is a non-invasive technique for 3D imaging for orthodontics and orthognathic surgery (Hajeer et al., 2004). 3D laser scanning can be used to assess growth and treatment outcomes following nonsurgical and surgical treatment (Anung et al., 1995). Following technological advancements laser technology has improved and is now more user-friendly and more compact. Studies have reported an acceptable level of clinical accuracy of (1.9mm ± 0.8mm) (Kusnoto and Evans, 2002) and 1.1 ± 0.3mm (Marmulla et al., 2003) with the Minolta 700/900 devices. However, this technique does have some disadvantages including; image distortion, safety concerns regarding lasers, texture and landmark identification difficulties and a slow capture time (Halazonetis, 2005; Baumrind and Frantz, 1991). Kau et al. (2005) investigated the use of laser scanners to measure soft tissue morphology of 60 children using two Minolta Vivid 900 laser devices as a stereo-pair. The images were processed using modelling software and the shell deviations compared. The study concluded that the technique was reproducible and a valid method of assessing clinical or growth changes in children and despite previous criticisms of slow capture time showed good compliance with both the adults and children. The reliability and accuracy of an image is dependent on the capture device and subject compliance (Kau et al., 2005).

1.9.3 Structured light scanners

Structured light technique records the face in 3D without radiation (Underhill et al., 1988). A series of patterns is projected on to the subjects' face and as result of the underlying facial morphology are distorted. A camera captures these distorted patterns and using the appropriate software and the principle of triangulation creates a 3D image. To ensure high quality images however the face needs to be illuminated multiple times with various light patterns which increases the capture time (Nguyen et al., 2000). A single image does also not ensure a facial model from ear to ear, which could be a reason for the decreased use of this technique (Tuncay, 2001).

1.9.4 Stereophotogrammetry

Stereophotogrammetry is the process of obtaining three-dimensional co-ordinates from a stereoscopic pair of images. The technique was originally used for aerial photogrammetric measurements in the 1920’s, and then the opportunities and benefits of using a similar technique in the medical and dental fields were later reported (Hertzberg et al., 1947). Facial contours were mapped and used to quantify facial swelling (Thalmann-Degen, 1944). Stereophotogrammetry was first used in Orthodontics in 1944 by Thalmann-Degan who investigated facial changes following orthodontic treatment (Burke and Beard, 1967). Since then it has also found applications in orthognathic surgery, both in surgical prediction planning and assessment, as well as three-dimensional (3D) analysis of facial deformities (Ayoub et al., 1997; Ayoub et al., 2007; Shafi et al., 2013). The accuracy of 3D stereophotogrammetry imaging and identifying landmarks has been assessed and found to be valid for facial analysis (Khambay et al., 2008; Ayoub et al., 2003). The 3D coordinates of any facial landmark can be evaluated through stereophotogrammetry (Ras et al., 1996) thus enabling the calculation of facial change (Larheim, 2005).

Technological advances have improved capture speeds and image resolution enabling clinicians to evaluate and assess children and adult's facial topography in a more comprehensive and accurate way (Hajeer et al., 2004; Karatas and Toy, 2014; Maal et al., 2010). Stereophotogrammetry is considered an ideal tool for facial imaging due to the quality of the images produced with a short capture speed (2ms), whilst being noninvasive and safe for patients. Three-dimensional imaging allows assessment of the soft tissue shape, which is important for evaluation pre- and post-treatment. The Cartesian coordinates system, on which the principles of three-dimensional imaging are based, includes the x axis (horizontal), the y axis (vertical) and the z axis (depth). This coordinate system therefore represents three-dimensional space (Udupa and Herman, 1991).

Stereophotogrammetry creates a 3D image by triangulation and works on the principles of binocular vision, in a similar way to the human visual system

(Hertzberg et al., 1947). The commercially available stereophotogrammetry systems use two pairs of digital cameras (stereo-pairs). The system requires the synchronised cameras to be approximately 50cm apart with 2 different coplanar planes that converge at approximately 15 degrees (Larheim, 1995). The 3D model is created using specialised software that analyses the two images, provided by the cameras, to determine and compare corresponding points from each image. Based on a pre-capture calibration, which determines the intrinsic and extrinsic camera properties, the x, y and z co-ordinates of the corresponding points calculate a “range” model of the face. Several processes are undertaken to produce the 3D model which can be manipulated and viewed from different directions. Initially a mesh is created which is comprised of polygons. A surface of pixels can then be added (texture mapping) onto the model from ear to ear. Light and shade is used to improve the appearance and finally the computer renders the image into a photorealistic image (Seeram, 1997).

There are some disadvantages of using stereophotogrammetry, which include light specific conditions, specialist equipment and set up cost (van Loon et al., 2010). Care is also required as the process can be technique sensitive. Besides reflective and curved surfaces not always being well visualized; reflections, hair placement and postural changes of the patient, can all have an effect the accuracy of the image (Ferrario, 1996).

1.9.5 Magnetic Resonance Imaging (MRI)

Magnetic Resonance Imaging (MRI) has the highest resolution compared with other imaging techniques. It uses radio waves in a magnetic field to produce an image. It is radiation free and shows detailed resolution of hard and soft tissues (van Dijke et al., 1997). However, the equipment required is expensive, not readily available, has a long procedure time and is not suitable for claustrophobic patients or wearing braces as the metal can cause artifacts on the image (Vig, 1991; Mckee et al., 2002).

1.10 Assessment of soft tissue facial change

A number of studies have reported facial changes following orthodontic and/or surgical interventions using different imaging modalities. CT scans have been used to assess changes in hard and soft tissues as a result of surgery (McCance et al., 1992; McCance et al., 1993; Soncul and Bamber 1999). Laser scans have been used to assess soft tissue changes following dental extractions, functional appliances and orthognathic surgery (Morris et al., 1998). Stereophotogrammetry has been used to assess treatment outcome following Twinblock appliance therapy (Bourne et al., 2010) and following the surgical correction of Class III and class II malocclusions (Hajeer et al., 2002).

Numerous methods exist to assess and measure soft tissue changes following treatment which include landmark displacement (Berkowitz and Cuzzi, 1977), mesh analysis (Ferrario et al., 1998), inter-landmark angles and distance (Ras et al., 1996), millimetric maps (McCance et al., 1992; Morris et al., 1998), volumetric changes (Kobayashi et al., 1990; Motegi et al., 1999) and 3D Euclidean matrix (O’Grady and Antonyshyn, 1999; Montegi et al., 1999).

In summary recent systematic reviews and meta-analyses summarising the current evidence on soft tissue effects of functional appliances conclude that there is insufficient evidence to determine the effects of functional appliances on the soft tissue. The main reasons given were low quality studies and limited data (Ehsani et al., 2014). It is generally accepted that the use of non-invasive three-dimensional scanning is fundamentally more accurate in quantifying the soft tissue changes following functional appliance treatment (Flores-Mir and Major, 2006).

CHAPTER 2

AIMS & NULL HYPOTHESIS

2. AIMS & NULL HYPOTHESIS

2.1 Primary aim

To determine whether the soft tissue horizontal mandibular advancement produced by a Twinblock appliance is statistically significantly different to a Button & Bead appliance.

2.1.1 Outcome measure

Horizontal change in soft tissue pogonion point in millimeters (mm).

2.2 Null hypothesis

The null hypothesis is that there is no statistically significant difference in soft tissue horizontal mandibular advancement produced by a Twinblock appliance compared to a Button & Bead appliance, measured at soft tissue pogonion.

2.3 Secondary aims

1. Describe the upper lip changes between the Twinblock appliance and Button & Bead appliance as a result of treatment.
2. To determine whether the vertical mandibular advancement produced by a Twinblock is statistically significantly different to a Button & Bead appliance.

CHAPTER 3

MATERIALS AND METHODS

3. MATERIALS AND METHODS

3.1 Ethical approval

Ethical approval was sought and approved through the local Clinical Research Ethics Committee (REC reference number 219179). The University of Birmingham provided Research and Development approval.

3.2 Sample size calculation

A sample size calculation proposed a sample of 22 patients in each group to determine a clinically significant difference in soft tissue horizontal advancement at pogonion of 2mm (Jones et al., 2008) with a standard deviation of ±2.3mm (Morris et al., 1998) between the Button & Bead and Twinblock appliance, with a power of 90% and $\alpha=0.05$.

3.3 Patient recruitment

All patients were recruited from the Birmingham Dental Hospital waiting list and directly from Consultant New Patient Clinics.

Inclusion criteria

- Overjet > 7mm
- Age 10 to 14 years 11 months
- Dentally healthy
- No previous orthodontic treatment or premolar extractions

Exclusion Criteria

- No craniofacial syndrome (including cleft lip and palate patients)

- Unwilling to participate in study

3.4 Patient enrolment

For those patients that met the inclusion criteria, the aims, risks and benefits were explained at the first visit. A Participant Information Sheet (PIS) for parents and children were provided as well as an invitation letter into the trial, (Appendix I and II).

At the subsequent visit, informed consent was obtained from the parent and the child, (Appendix III and IV). The signed copy of the consent form was scanned into the medical notes. A copy was given to the family and the original document kept in the site file (SF).

Following enrolment into the trial, (when their eligibility was confirmed) the patients were registered onto an online trial database REDCap (Research Electronic Data Capture) where each patient was allocated a unique number (Harris et al., 2009).

Their willingness to continue in the trial was re-assessed at each visit and documented in the medical notes. Patient's notes were recoded contemporaneously throughout the treatment and the General Dental Practitioner (GDP) was informed of their participation.

Routine pre-treatment (T_0) clinical records were taken which included; upper and lower alginate impressions with a wax bite for study models, conventional clinical photographs, 3D stereophotogrammetry images (3dMD images), orthopantomogram (OPT) and lateral cephalogram radiographs.

3.5 Randomisation

Participants were then randomly allocated to one of the two functional appliances:

1. Twinblock group
2. Button & Bead group

The patients were randomised using block randomisation with variable block-size, computer-generated on REDCap. They were stratified according to gender, to account for the difference in timing of growth between the genders. Allocation concealment was carried out using REDCap.

3.6 Functional appliance design and construction

Following recruitment and randomization, upper and lower alginate impressions (ALGINoplast, Kulzer LLC) and a wax bite (ANUTEX toughened dental modelling wax, UK Associated Dental Products Limited, UK), in retruded contact position (RCP), were taken for each participant.

3.6.1 Twinblock appliance

Twinblock appliances were constructed using a modified Clarks design, Figure 3.1. Upper and lower appliances were retained with 0.7mm Adams clasps on the first permanent molars and first premolars. Additional retention in the lower labial segment was provided with an acrylated labial bow. The blocks were approximately 7mm high in the buccal segments and inclined at 70^{o}.

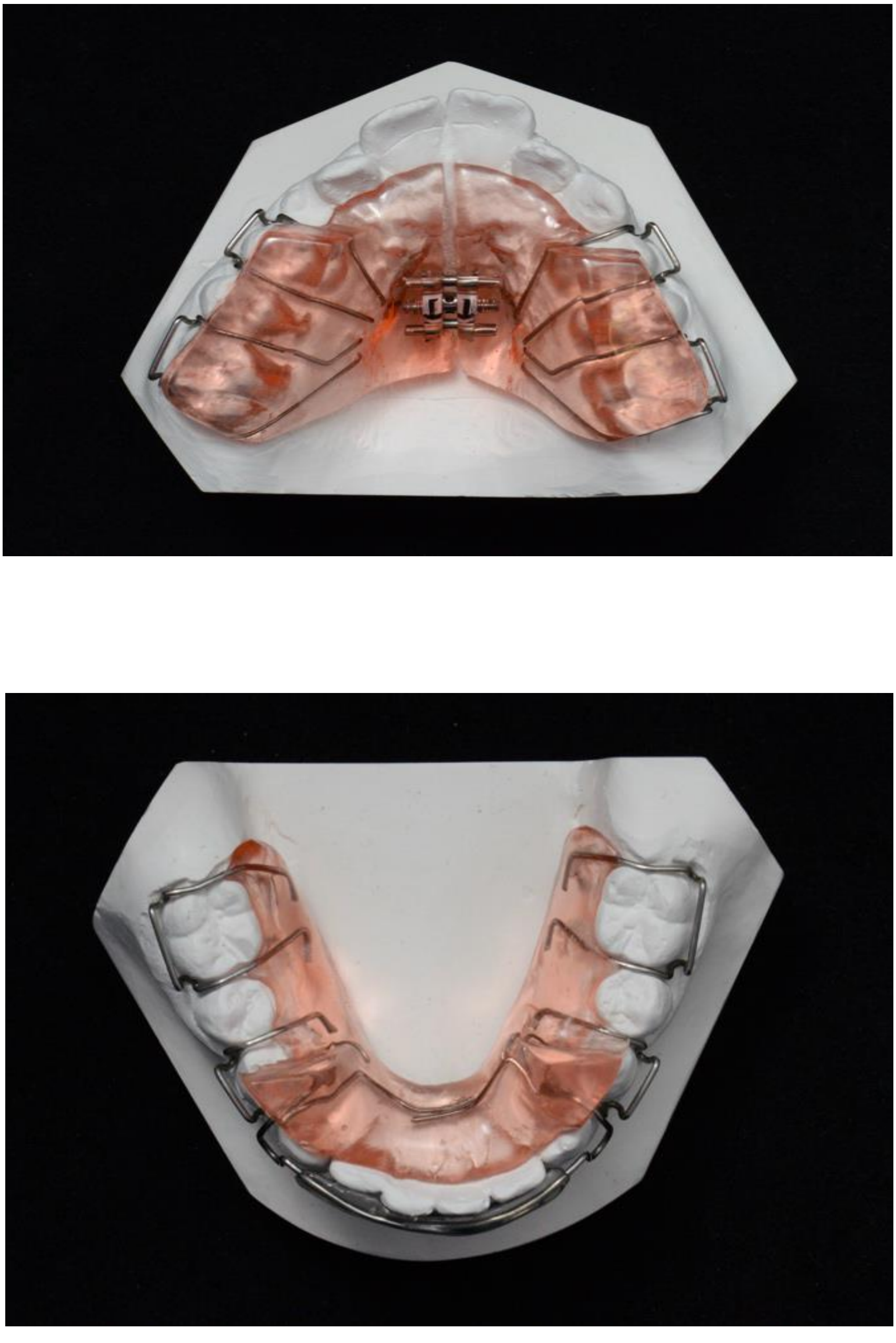

Figure 3.1 Design of upper and lower Twinblock used in the study

3.6.2 Button & Bead appliance

The Button & Bead appliance was a vacuum formed upper and lower appliance (Spary and Little, 2014). The upper appliance was constructed from 1.50mm thick Centrilux vacuum/ pressure forming material (DB Lab Supplies, Ryefield Way, West Yorkshire, UK) and the lower appliance from 0.75mm/0.030 inch Essix ACE material (Dentsply Limited, Weybridge, UK). Two upper splints were constructed, the first with a 4mm methyl methacrylate acrylic bead (Orthoresin, DeTrey Division, Dentsply Limited, Weybridge, UK) placed on the disto-palatal cusp (Splint 1) and a second splint with a 4mm acrylic bead on the mesial buccal cusp (Splint 2) of the upper first permanent molars. The upper appliance was trimmed to cover half of the labial surface of the upper incisors, Figure 3.2. The lower appliance was reduced on the buccal surface in the region of the lower first permanent molars to for button attachment. A continuous layer of clear methyl methacrylate acrylic was added to form thin (4mm) posterior bite-planes.

3.7 Clinical

The Twinblock and Button & Bead appliances were fitted 3 weeks after the impressions were taken. The participants were then reviewed every 4 weeks. With the exception of tooth-brushing, swimming and contact sports, patients were instructed to wear the appliance full time (24 hours a day) including whilst eating. If necessary, the midline expansion screw in the Twinblock was turned once per week to correct any transverse discrepancies.

Figure 3.2 Upper and lower Button & Bead design used in the study

In addition, for the Button & Bead appliance composite buttons were bonded on the labial surface of the upper lateral incisors and metal buttons (OrthoCare, Shipley, UK) on the buccal aspect of the lower first permanent molars. Class II inter-maxillary elastics (Orange 6.4mm 4.5oz elastics; TP Orthodontics, Leeds, UK) were placed from the composite buttons on the upper lateral incisors to the lower molars. Patients were instructed to wear the Button & Bead appliance with the class II elastics full time (24 hours a day) including when eating but except during tooth-brushing, contact sports and swimming.

3.8 Transition

Once the patient had achieved a class I incisor relationship with an overjet between 0-4mm, the appliance was withdrawn for 48 hours to assess any habitual posturing. At review, once it was confirmed that the incisors remained class I, functional treatment was deemed to be complete and patients entered a transition phase. Post treatment (T_1) study models, 3D stereophotogrammetry images, clinical measurements and a lateral cephalogram radiograph were repeated and changes assessed as part of the patient's routine care. The patient also completed a patient satisfaction survey and oral health questionnaire.

The Twinblock patients wore the same appliance during the transition period, whilst the Button & Bead patients were fitted with a "steep and deep appliance". The appliance was designed with 0.7mm Adams cribs on the upper first permanent molars and upper first premolars, a midline expansion screw, and steep and deep anterior bite plane. Following the 3-month transition period, patients were reassessed by the same Consultant in Orthodontics regarding the need for orthodontic extractions prior to progression onto fixed appliances.

3.9 IMAGING

3.9.1 Imaging system

For each patient pre (T_0) and post-treatment (T_1) 3D images were taken using a 3dMD trio system (3dMD Limited, Brentford, London, UK). The system had an ultrafast capture speed of 1.5 milliseconds and provided a 200º facial capture field from ear to ear. The system allowed extraction of x, y and z-coordinates from the 3D image as well as generating a 3D polygon surface mesh.

3.9.2 Calibration

Prior to image capture the 3dMD imaging system required calibration. Calibration was performed using the manufactures calibration target and according to the instructions. In summary the calibration target was captured in two different positions; the first with the calibration board orientated so that the 'T' was positioned upside down and in the middle of the field view of the three cameras. The second with the calibration board tilted back at an angle of 45º, Figure 3.3.

3.9.3 Patient imaging

Each patient was seated upright in front of the 3dMD system with their Frankfort Plane parallel to the floor. A headband ensured any hair was kept away from the face. Any jewelry (ear rings, studs, necklaces and piercing etc.) as well as clothing such as hats, coat, scarfs and headscarfs were removed to show the patients

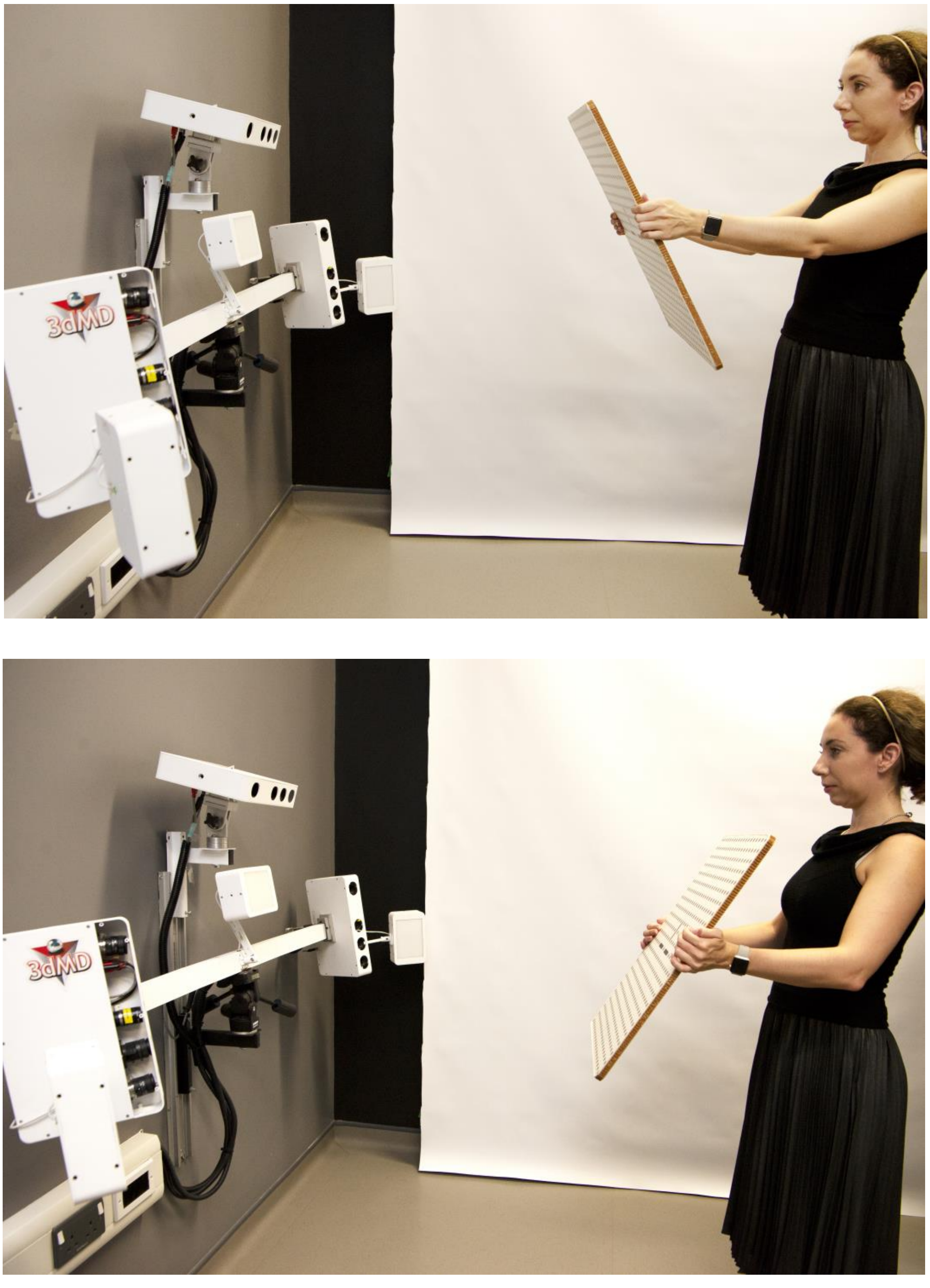

Figure 3.3 3dMD system calibration

forehead, ears and jaw line clearly. Immediately prior to capture patients were instructed to have a relaxed facial expression, with their lips in repose, to keep their eyes open and to bite on their back teeth, Figure 3.4.

Following each capture the 3D image was checked before the patient left. The image was reviewed to check there was no data missing. If grey patches or holes were encountered, the capture was repeated. The satisfactory 3D images were then saved in .OBJ (Wavefront) format for analysis.

3.9.4 Image analysis

Superimposition

For each patient the pre-treatment (T_0) 3dMD image was imported into Di3DView (Di3DView, Version 6.6, Dimensional Imaging Ltd, Glasgow, UK). The image was then re-oriented into a standardized position with the Frankfort Plane oriented parallel to the horizontal plane (axial) and the sagittal plane passing through soft tissue nasion, Figure 3.5. The post-treatment (T_1) 3dMD image was then aligned to the pre-treatment 3D image using rigid transformation. This was achieved by selecting 3 corresponding landmarks, common to both images, and using the "align tool" in the software. This process rotated and translated the post-treatment (source) image until it was aligned on the pre-treatment image (target) based on the 3 landmark pairs. The two images were then further aligned by selecting a stable "patch" on one image i.e. the forehead. Using the ICP algorithm within the software the two images were aligned so a "best-fit" of the two images based solely on the forehead patch. The pre-treatment image remained unchanged (target) and the post-treatment (source) image was moved. The post-treatment

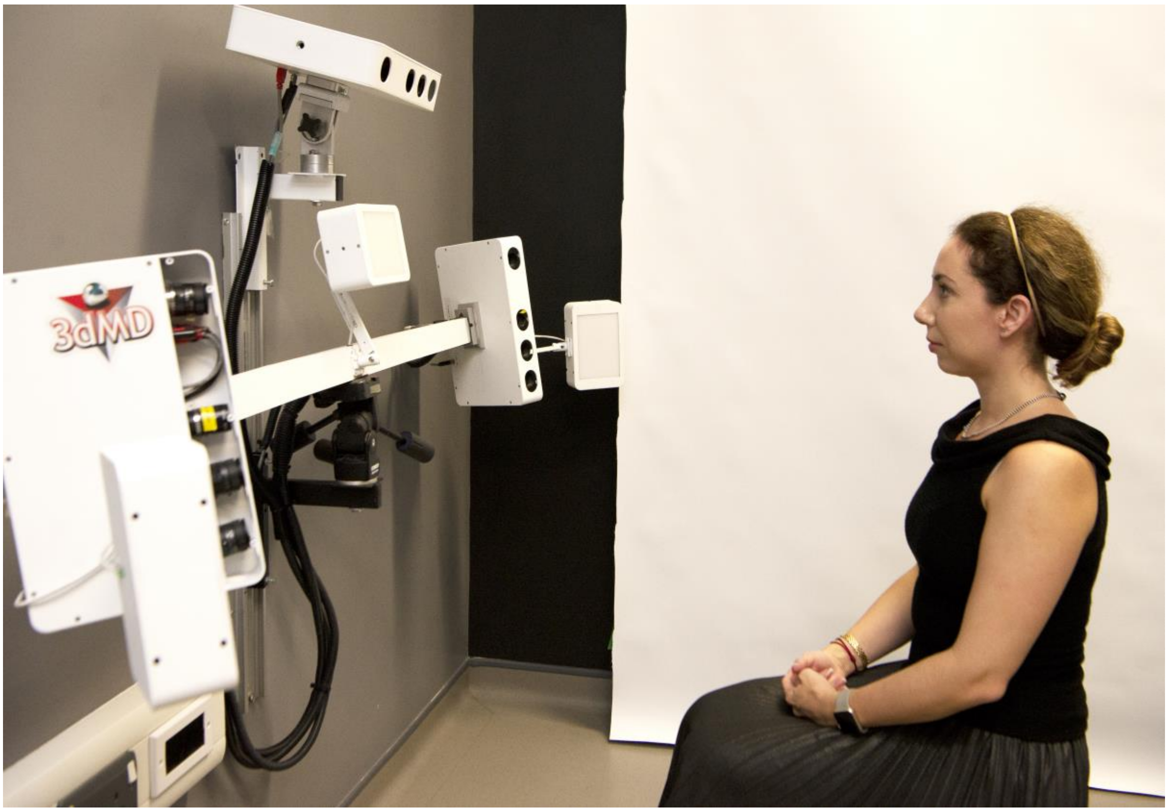

Figure 3.4 Patient positioned in front of 3dMD system.

Frankfort plane parallel to the floor

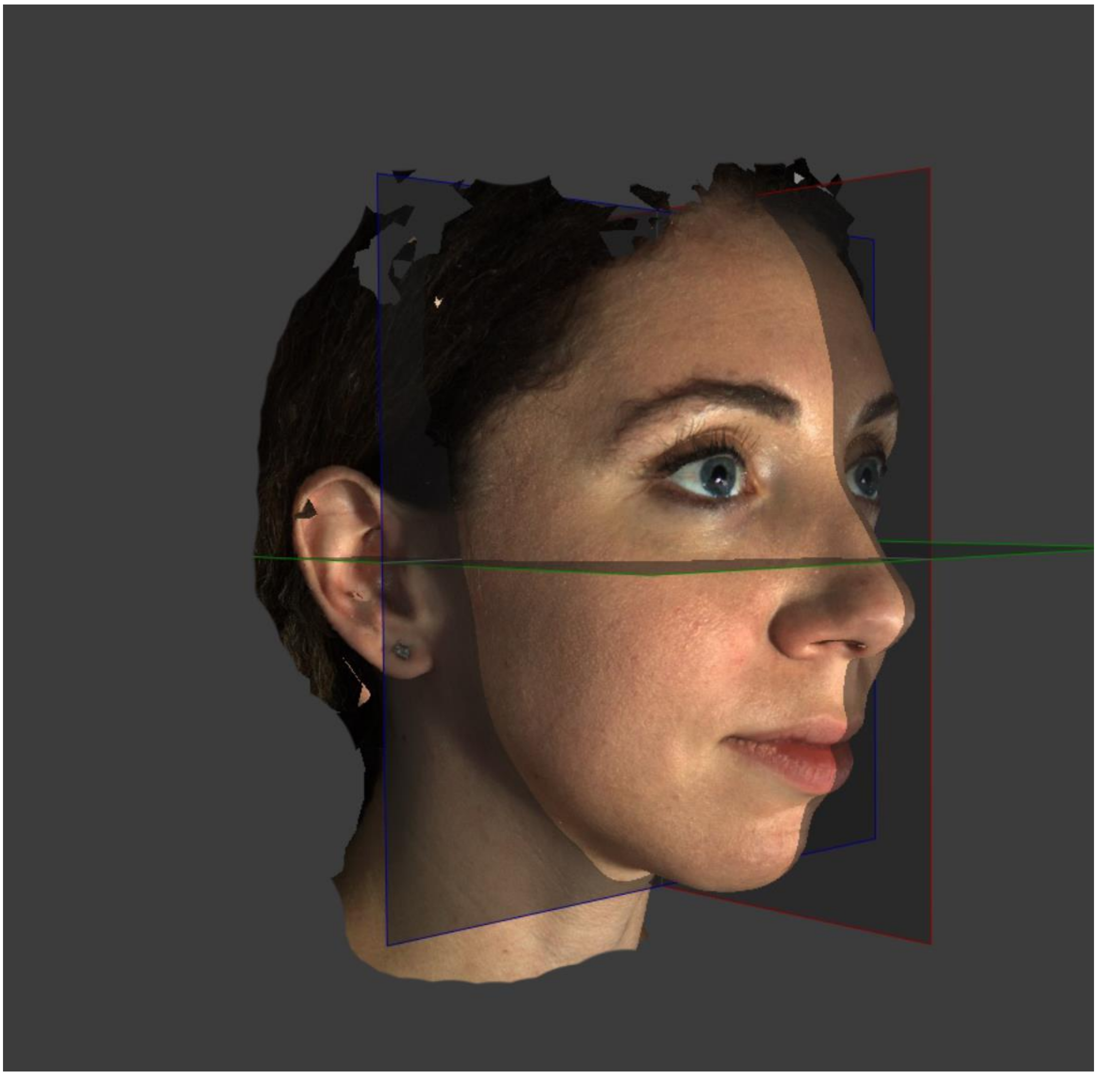

Figure 3.5 3dMD image re-orientated to Frankfort plane and sagittal plane

Passing through nasion

image was then re-saved in the new aligned position. When the two images were now re-imported into any 3D software they would automatically be aligned on the forehead.

Landmarking and co-ordinate extraction

For each patient the pre-treatment 3dMD image was imported into Di3DView. The software allowed three “windows” to be open simultaneously allowing the same image to be seen in 3 different orientations, Figure 3.6. Using the landmark tool it was possible to place a landmark on the image but to view it from the three different orientations to ensure accurate placement. In total 26 landmarks were placed on the pre-treatment. This was repeated for the post-treatment image, Figure 3.7 and Table 3.1. The x, y and z co-ordinates for each of the 26 landmarks, for each patients per-treatment and post-treatment 3dMD image, were saved.

3.10 Landmark error study

To determine the landmark accuracy, an error study was undertaken which involved selecting ten 3D images at random and placing the 24 landmarks on the image. This 3D landmark configuration was saved. The same ten 3D images were then re-landmarked 2 weeks later and the second 3D landmark configuration saved. The two 3D landmark configurations were loaded into MATLAB (MathWorks, Cambridge, UK) and the differences in Euclidian and x, y and z co-ordinates between the two were calculated.

Figure 3.6 DiView landmarking – 3 windows opened simultaneously

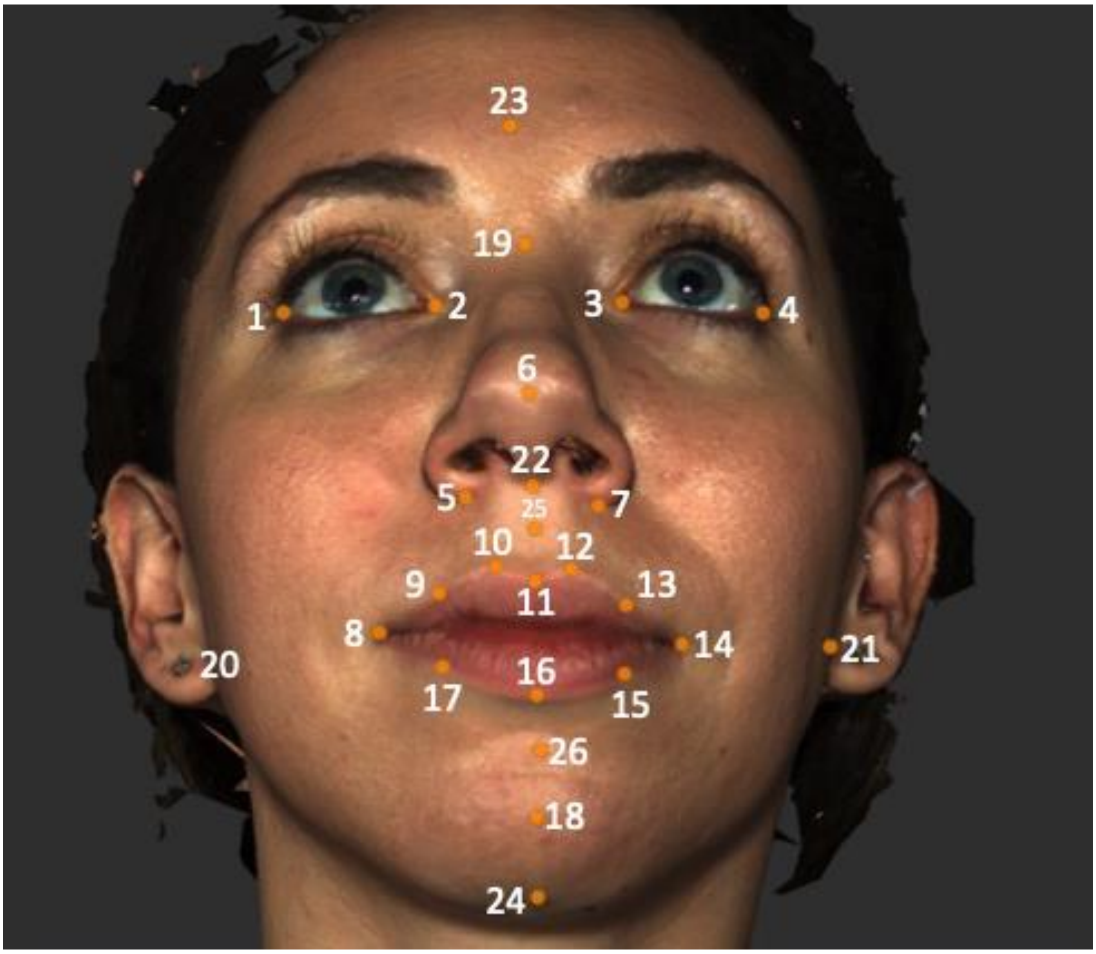

Figure 3.7 Twenty-six landmarks used during the study

Table 3.1 Soft tissue landmark definitions (From Cheung et al., 2016)

Landmark	Definition
Exocanthion*	Soft tissue point located on the fissure of the outer commissure of each eye
Endocanthion*	Soft tissue point located on the inner commissure of each eye fissure
Alar base*	The base of the nostril
Pronasale	The most protruded point of the tip of the nose identified in the lateral view (of the rest position of the head)
Chelion*	Right and left labial commissure
Crista philtre*	Point crossing the vermillion line and the elevated margin of the philtrum
Labrale superius	Midpoint of the vermillion border of the upper lip
Labrale inferius	Midpoint of the vermillion border of the lower lip
Midpoint between Crista Philtre and Chelion on the upper lip*	A point on the upper lip located Crista Philtre and Cheilion
Midpoint between Crista Philtre and Chelion on the lower lip*	A point on the lower lip located Crista Philtre and Cheilion
Pogonion	Most anterior midpoint of the chin
Nasion	Midpoint of the soft tissue at the level of the nasal root and the frontonasal suture
Tragus*	A landmark on the midpoint of the medial aspect (of the facial insertion) of the tragus
Subnasale	Nasolabial soft tissue midpoint between columella and upper lip
Glabella	The midpoint of the most prominent ridge between the eyebrows
Menton	The lowest median landmark on the inferior border on the mandible
A-point	The innermost point on the curve on the upper lip
B-point	The innermost point on the curve on the lower lip

*Indicate bilateral right and left landmarks

3.10.1 Conformed mesh generation

Based on (Chueng et al., 2015) each of the pre-treatment and post-treatment images were “conformed”. In summary this process used a “generic mesh” made up of 1214 landmarks. Using Di3DView it was possible to change the shape of the generic mesh to each of the patients pre- and post-treatment 3D images. Di3DView software uses the previously placed 26 landmarks on the patient’s image to deform the generic mesh, which has also been landmarked with the same 26 corresponding landmarks. This allows each of the 1214 landmarks to be used for analysis, Figure 3.8.

3.11 Measurements

3.11.1 Linear and angular measurements

The pre-treatment, post-treatment and changes in Euclidian linear distances and angular measurements for the Twinblock and Button & Bead appliance were measured using Di3DView. The linear and angular measurements chosen are shown in Table 3.2.

3.11.2 Changes in the x-direction and y-direction

The changes in the x- and y-direction of 12 landmarks were measured for the Twinblock and Button & Bead appliance using Di3DView. The chosen landmarks are shown in Table 3.3.

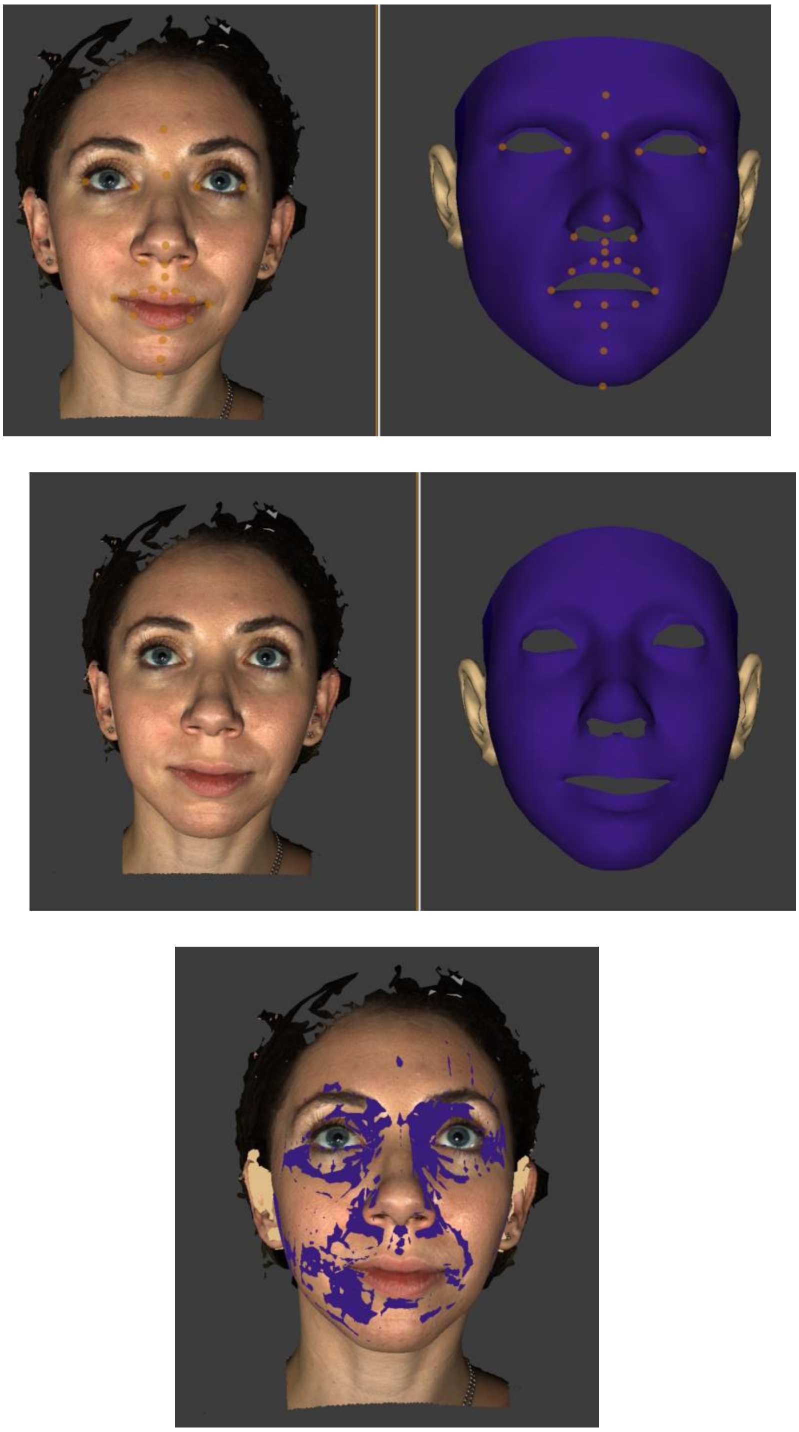

Figure 3.8 Conformation process

Top – 3dMD image & generic mesh
Middle – 3dMD image & conformed
Bottom – Superimposed 3dMD image & conformed to show mesh has the same shape.

Table 3.2 Soft tissue measurement definitions for angular and linear measurements

Soft tissue measurement	Definition
Upper Face Height	Distance from Glabella to Subnasale
Alar Base Width	Distance between right and left Alar base
Mouth width	Distance between right and left Cheilion
Upper lip length	Distance from Subnasale to Labrale superius
Lower lip length	Distance from Labrale inferius to B-point
Philtrum width	Distance between right and left Crista Philtre
Lower Anterior Face Height to Menton	Distance from Subnasale to Menton
Inter-labial distance	Distance between Labrale Inferius to Labrale Superius
Naso-labial angle	Pronasale to Subnasale to Labrale superius
Facial convexity	Angle between Nasion, Subnasale and Pogonion
Labio-mental angle	Angle between Labrale inferius, B-point and Pogonion

Table 3.3 Soft tissue landmarks used for changes in the x and y-direction

Pronasale	The most protruded point of the tip of the nose identified in the lateral view (of the rest position of the head)
Chelion*	Right and left labial commissure
Crista philtre*	Point crossing the vermillion line and the elevated margin of the philtrum
Labrale superius	Midpoint of the vermillion border of the upper lip
Labrale inferius	Midpoint of the vermillion border of the lower lip
Pogonion	Most anterior midpoint of the chin
Nasion	Midpoint of the soft tissue at the level of the nasal root and the frontonasal suture
Subnasale	Nasolabial soft tissue midpoint between columella and upper lip
Glabella	The midpoint of the most prominent ridge between the eyebrows
Menton	The lowest median landmark on the inferior border on the mandible
A-point	The innermost point on the curve on the upper lip
B-point	The innermost point on the curve on the lower lip

3.11.3 Changes in the Euclidian distance, x-direction and y-direction using the conformed mesh

Using in-house developed MATLAB software pre- and post-treatment changes in the Euclidian distance, x-direction and y-direction of a “chin patch”, of the Twinblock and Button & Bead appliance, were measured, Figure 3.9.

3.12 Statistical analysis

The data was tested for normality using the Shapiro-Wilk test and visual assessment of data. The data was also checked for outliers. Paired-samples *t*-tests were used to determine whether there were statistically significant mean differences between the upper lip and lower lip and chin regions before and after treatment, for each appliance. An independent-sample *t*-test was run to determine if there were differences between the upper lip and lower lip and chin regions before and after treatment between the appliances. In order to assess clinical significance a one- sample *t*-test was run to determine if the horizontal distance between the chin regions was greater than 2mm between the two appliances.

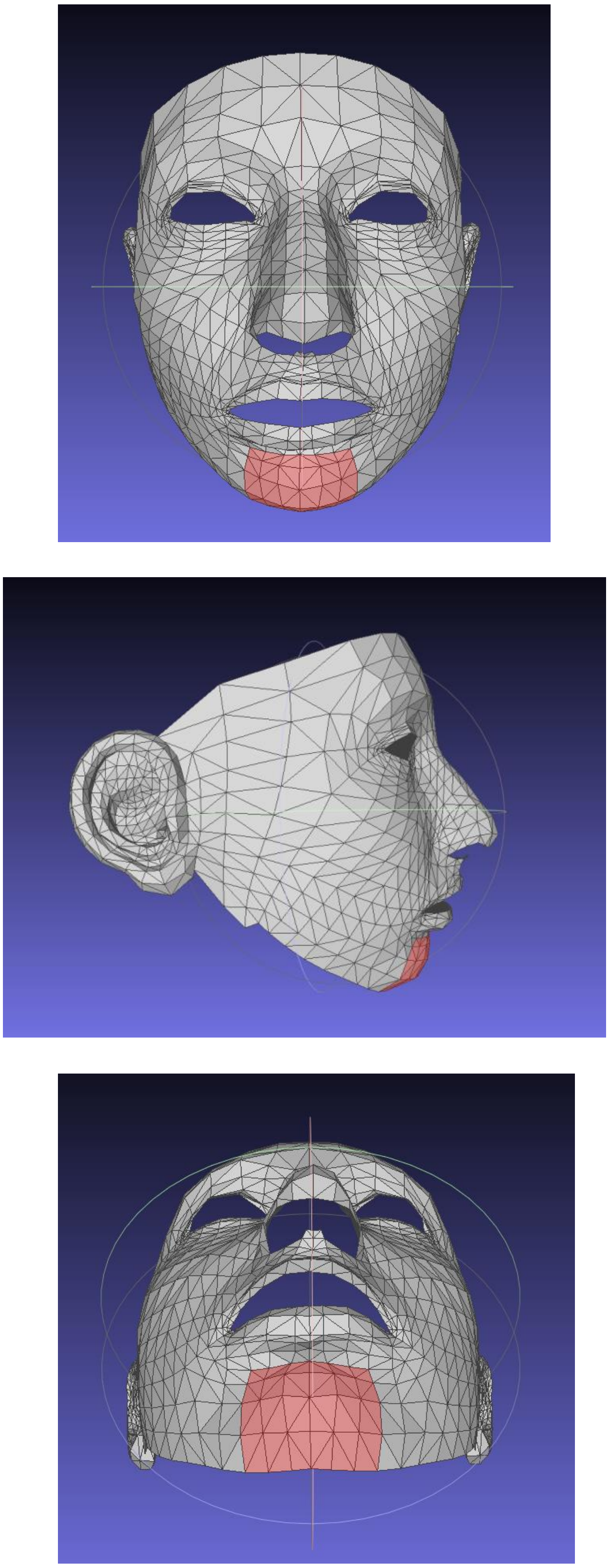

Figure 3.9 Chin patch used for analysis

CHAPTER 4

RESULTS

4. RESULTS

At the time of data analysis 44 patients had completed the trial, 17 dropped out and the remainder were still under treatment. 22 patients were enrolled into each arm of the study (25 Females and 19 Males) with an age range from 10-14 years old (Button & Bead group mean 12.1±1.2 years and Twinblock mean 12.4±1.2 years), Figure 4.1.

4.1 Error study

The results for the landmark placement error study are shown in Table 4.1. There were no random or systematic errors as all coefficients of reliability were above 90% and all p-values above p=0.05. The mean absolute landmark identification error was within ±0.5mm for all landmarks.

4.2 Linear and angular changes following Twinblock appliance treatment

Tables 4.2 and 4.3 show the pre-treatment and post-treatment mean linear and angular measurements for the Twinblock group. The mean differences in linear and angular soft tissue measurements following Twinblock appliance treatment are shown in Table 4.4. There were statistically significant increases in mean philtrum width (0.6±1.2mm), lower lip length (1.1±1.4mm), labio-mental fold angle (14.4±15.1^{o}), lower anterior face height (1.0±2.7mm) and facial convexity angles (5.1±2.8^{o}). The lower anterior face height and mouth width had 95% confidence intervals greater than 2mm, which would suggest these changes maybe clinically significant. In addition, there was a statistically significant reduction in the mean inter-labial distance (-1.7±3.4mm). The mean changes in the upper face height, alar base width, nasolabial angle, upper lip length and mouth width following were not statistically significant.

Figure 4.1 Flow diagram of patients in the study

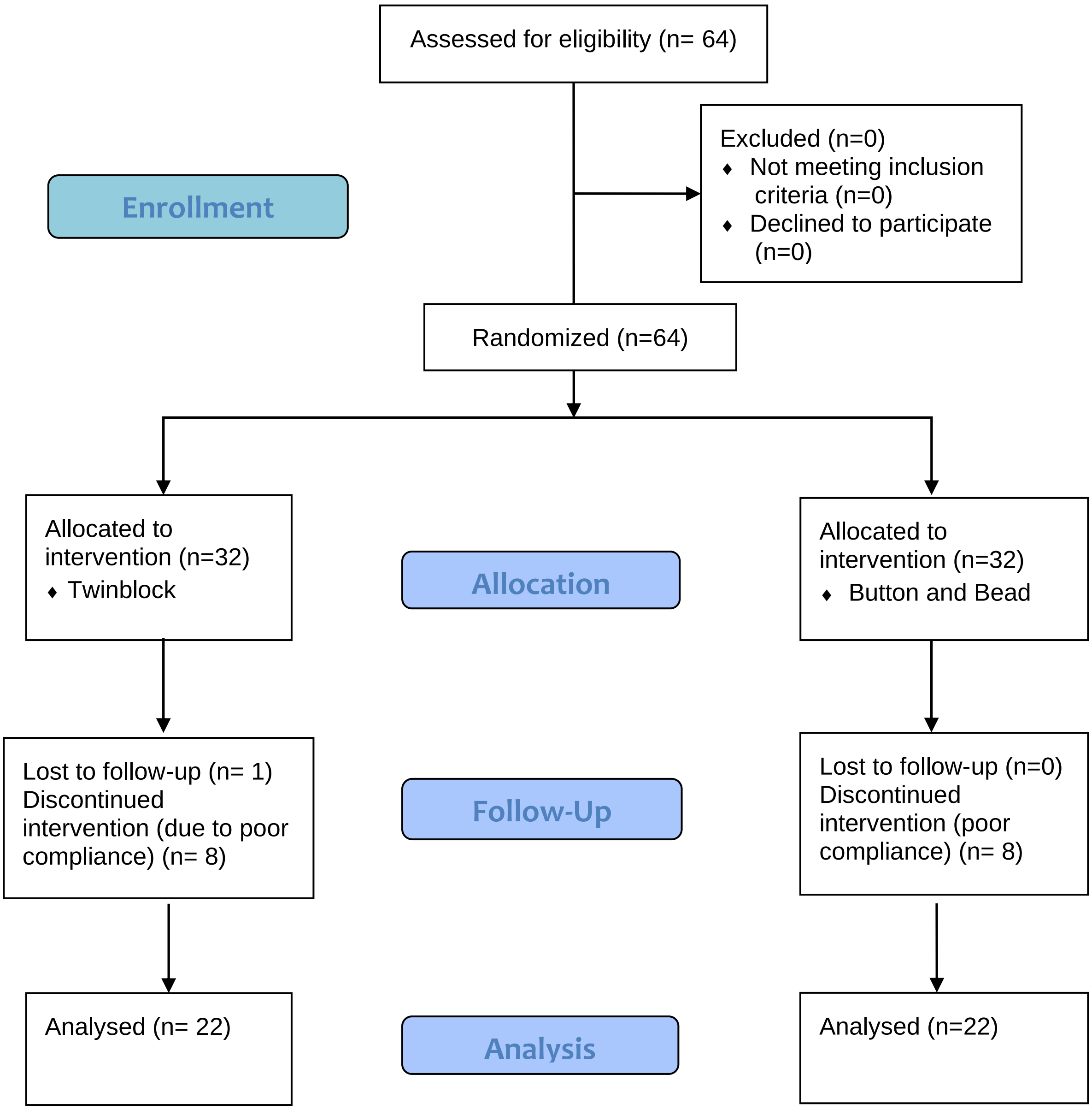

Table 4.1 Error study – Mean absolute error is the error of the measurement

Random error assessed using coefficients of reliability, Systematic error assessed using paired *t*-tests

	X-direction				Y-direction				Z-direction			
Landmark	Absolute Mean Difference (mm)	SD (mm)	Random error	Systematic error	Absolute Mean Difference (mm)	SD (mm)	Random error	Systematic error	Absolute Mean Difference (mm)	SD (mm)	Random error	Systematic error
Upper lip region												
R-alar	0.5	1.0	0.050	0.998	0.5	0.8	0.044	0.999	0.5	0.8	0.059	1.000
Prn	0.5	0.4	0.900	0.999	0.4	0.5	0.070	1.000	0.1	0.2	0.240	1.000
L-alar	0.5	0.5	0.494	0.998	0.5	0.5	0.065	1.000	0.4	0.4	0.957	1.000
A-point	0.3	0.3	0.255	1.000	0.4	0.4	0.340	1.000	0.1	0.1	0.625	1.000
Sn	0.2	0.2	0.439	1.000	0.5	0.6	0.148	1.000	0.1	0.2	0.371	1.000
R-Ch	0.4	0.4	0.524	0.999	0.4	0.4	0.054	1.000	0.2	0.2	0.058	1.000
R-Phil	0.1	0.3	0.929	1.000	0.1	0.1	0.873	1.000	0.1	0.1	0.339	1.000
Ls	0.1	0.2	0.919	1.000	0.3	0.4	0.593	1.000	0.1	0.1	0.886	1.000
L-Phil	0.4	0.6	0.712	0.999	0.2	0.3	0.823	1.000	0.1	0.1	0.425	1.000
L-Ch	0.4	0.4	0.867	0.999	0.2	0.3	0.193	1.000	0.1	0.2	0.491	1.000
Lower lip & chin region												
Li	0.2	0.2	0.823	1.000	0.5	0.5	0.069	1.000	0.5	0.6	0.051	1.000
Pog	0.4	0.4	0.278	0.999	0.5	0.7	0.953	0.999	0.1	0.1	0.782	1.000
Me	0.5	0.6	0.072	0.999	0.5	0.5	0.512	1.000	0.5	0.5	0.389	0.989
B-point	0.3	0.2	0.440	0.999	0.3	0.3	0.385	1.000	0.1	0.1	0.060	1.000

Table 4.2 Pre-treatment linear and angular soft tissue measurements for the Twinblock group at T_0

	Mean	SD	95% Confidence Interval	
			Lower	Upper
Upper Face Height	66.1	5.6	63.6	68.5
Alar Base Width	22.4	3.2	21.0	23.8
Mouth Width	46.0	3.0	44.7	47.3
Upper lip length	11.9	2.6	10.8	13.0
Lower lip length	8.4	1.5	7.7	9.0
Philtrum width	11.5	2.2	10.5	12.4
Lower Anterior Face height	64.0	5.7	61.5	66.6
Inter-labial distance	19.3	4.8	17.2	21.4
Naso-labial angle	125.0	11.6	119.8	130.2
N_Sn_Pog	155.2	5.2	152.9	157.6
N_Prn_Pog	126.7	5.3	124.4	129.0
Labio-mental angle	120.8	15.0	114.2	127.5

Table 4.3 Post-treatment linear and angular soft tissue measurements for the Twinblock group at T_1

	Mean	SD	95% Confidence Interval	
			Lower	Upper
Upper Face Height	66.1	5.6	63.6	68.6
Alar Base Width	22.5	2.7	21.3	23.6
Mouth Width	47.0	3.7	45.3	48.6
Upper lip length	9.5	2.0	8.6	10.4
Lower lip length	61.3	3.2	59.8	62.7
Philtrum width	12.0	2.3	11.0	13.0
Lower Anterior Face height	65.0	4.8	62.9	67.1
Inter-labial distance	17.6	4.0	15.9	19.4
Naso-labial angle	125.8	9.1	121.7	129.8
N_Sn_Pog	160.3	5.6	157.8	162.8
N_Prn_Pog	129.7	5.2	127.4	132.0
Labio-mental angle	135.2	12.6	129.6	140.8

Table 4.4 Differences in linear and angular soft tissue measurements for the Twinblock group ($T_1 - T_0$)

	Mean	SD	95% Confidence Interval		*p*-value
			Lower	Upper	
Upper Face Height	0.0	1.8	-0.8	0.8	0.946
Alar Base Width	0.1	1.8	-0.8	0.9	0.886
Mouth Width	1.0	3.0	-0.3	2.3	0.139
Upper lip length	0.4	1.6	-0.3	1.1	0.24
Lower lip length	1.1	1.4	0.5	1.7	0.001
Philtrum width	0.6	1.2	0.0	1.1	0.034
Lower Anterior Face height to Me	1.0	2.7	-0.2	2.2	0.110
Inter-labial distance	-1.7	3.4	-3.2	-0.2	0.031
Naso-labial angle	0.8	6.6	-2.2	3.7	0.591
N_Sn_Pog	5.1	2.8	3.8	6.3	0.001
N_Prn_Pog	3.0	2.0	2.1	3.8	0.001
Labio-mental angle	14.4	15.1	7.7	21.1	0.001

Paired *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

4.3 Changes in the x-direction for following Twinblock appliance treatment

The mean horizontal linear changes (x-direction) resulting from Twinblock treatment are shown in Table 4.5. There were minimal changes to the nasolabial region. There was a statistically significant mean decrease in A-point (-0.7±1.1mm) and left alare (0.7±1.1mm). The majority of statistically significant changes were seen in the lower lip and chin region; pogonion and menton moved forward 2.7±1.8mm and 2.6±3.8mm respectively. Labiale inferius also moved forward 2.6±2.1mm. The largest mean horizontal change was seen at B-point (3.3±2.2mm). Given these changes are above 2mm they could be regarded as clinically significant.

4.4 Changes in y-direction following Twinblock appliance treatment

Table 4.6 shows the mean vertical linear changes (y-direction) following Twinblock treatment. There were minimal changes to nasion, pronasale and labiale inferius. The majority of changes of the nasio-labial and mandibular soft tissues were negative indicating there was a statistically significant downward movement as a result of Twinblock treatment. With a 95% confidence interval greater than 2mm these may also be clinically significant. The nasolabial changes were greatest in the midline (labiale superius, -1.8±2.2mm) and reduced laterally towards right and left cheilion, -1.1±1.6mm and -1.2±2.0mm respectively. Larger movements were associated with the mandibular soft tissues, in particular B-point (-2.9±2.4mm) and pogonion (-2.7±2.3mm), with the greatest vertical change being seen at menton (-3.1±2.6mm). Again with 95% confidence intervals greater than 2mm, these changes could be clinically significant.

Table 4.5 Soft tissue changes in the X-direction produced following Twinblock treatment ($T_1 - T_0$)

	Mean	SD	95% Confidence Interval		*p*-value
			Lower	Upper	
R-Alare	-0.4	1.3	-1.0	0.2	0.185
Pronasle	0.5	1.2	-0.1	1.0	0.078
L-Alare	-0.7	1.1	-1.1	-0.2	0.008
R-Cheilion	-0.1	2.2	-1.1	0.9	0.836
R-Crista Philtri	-0.6	1.4	-1.2	0.1	0.083
Labiale Superius	-0.6	1.4	-1.2	0.0	0.056
L-Crista Philtri	-0.5	1.7	-1.3	0.2	0.150
L-Cheilion	-0.1	2.8	-1.3	1.2	0.894
Labiale Inferius	2.6	2.1	1.7	3.5	0.001
Pogonion	2.7	1.8	1.9	3.5	0.001
Nasion	0.0	1.0	-0.4	0.5	0.890
Subnasale	-0.5	1.3	-1.1	0.1	0.077
Glabella	0.2	0.8	-0.1	0.6	0.227
Menton	2.6	3.8	0.9	4.2	0.005
A-point	-0.7	1.1	-1.2	-0.2	0.007
B-point	3.3	2.2	2.3	4.2	0.001

Paired *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

-ve values indicate backward movement.

+ve values indicate forward movement.

Table 4.6 Soft tissue changes in the Y-direction produced following Twinblock treatment ($T_1 – T_0$)

	Mean	SD	95% Confidence Interval		*p*-value
			Lower	Upper	
R-Alare	-0.8	1.3	-1.4	-0.3	0.005
Pronasle	-0.9	2.2	-1.8	0.1	0.077
L-Alare	-0.8	1.3	-1.4	-0.2	0.015
R-Cheilion	-1.1	1.6	-1.8	-0.4	0.003
R-Crista Philtri	-1.3	2.2	-2.3	-0.3	0.010
Labiale Superius	-1.8	2.2	-2.8	-0.8	0.001
L-Crista Philtri	-1.6	2.3	-2.6	-0.5	0.005
L-Cheilion	-1.2	2.0	-2.1	-0.3	0.011
Labiale Inferius	-0.9	2.5	-2.1	0.2	0.100
Pogonion	-2.7	2.3	-3.8	-1.7	0.001
Nasion	0.3	1.6	-0.4	1.0	0.380
Subnasale	-1.2	1.4	-1.8	-0.5	0.001
Glabella	-0.9	1.7	-1.7	-0.2	0.015
Menton	-3.1	2.6	-4.3	-1.9	0.001
A-point	-1.0	1.6	-1.7	-0.3	0.010
B-point	-2.9	2.4	-4.0	-1.9	0.001

Paired *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

-ve values indicate downward movement.

+ve values indicate upward movement.

4.5 Linear and angular changes following Button & Bead appliance treatment

The pre-treatment and post-treatment soft tissue linear and angular measurements are shown in Table 4.7 and Table 4.8. The changes in linear and angular soft tissue measurements as a result of Button & Bead appliance treatment are shown in Table 4.9. There were statistically significant increases in the upper face height (1.4±2.6mm), labio-mental fold angle (10.6±14.0^{o}), lower lip length (1.3±2.4mm), lower anterior face height (3.0±4.5mm) and facial convexity angles (3.5±2.1^{o}). Changes in philtrum width, alar base width, upper lip length, mouth width, nasolabial angle and inter-labial distance were not statistically significant. The changes in lower lip length and lower face height could be considered clinically significant.

4.6 Changes in the x-direction following Button & Bead appliance treatment

Table 4.10 shows the mean horizontal linear (x-direction) changes following Button & Bead treatment. There were minimal changes in of glabella, nasion, menton, right and left alare and right and left chelion. There was a statistically significant retraction of the upper lip with labiale superius (-1.3±1.3mm), A-point (-0.9±0.9mm), right (1.3mm±1.4mm) and left (-1.3±1.1mm) crista philtri all moving posteriorly. Conversely, the lower lip at labiale inferius (1.6±2.5mm) and at B-point (1.7±1.7mm) moved forward; these changes were also statistically significant. There was a wide 95% confidence interval range for changes in Menton in the x-direction.

Table 4.7 Pre-treatment linear and angular soft tissue measurements for the Button & Bead group at T_0

	Mean	SD	95% Confidence Interval	
			Lower	Upper
Upper Face Height	62.0	3.5	60.4	63.5
Alar Base Width	22.0	3.2	20.5	23.4
Mouth Width	45.3	3.4	43.8	46.8
Upper lip length	12.1	2.1	11.1	13.0
Lower lip length	8.6	1.7	7.8	9.4
Philtrum width	11.0	2.1	10.1	11.9
Lower Anterior Face height	64.3	5.1	62.0	66.5
Inter-labial distance	18.5	3.9	16.8	20.3
Naso-labial angle	124.5	11.5	119.4	129.6
N_Sn_Pog	157.1	5.2	154.8	159.4
N_Prn_Pog	126.7	4.0	124.9	128.4
Labio-mental angle	130.0	13.7	124.0	136.1

Table 4.8 Post-treatment linear and angular soft tissue measurements for the Button & Bead group at T_1

	Mean	SD	95% Confidence Interval	
			Lower	Upper
Upper Face Height	63.3	2.8	62.1	64.6
Alar Base Width	21.5	2.8	20.3	22.8
Mouth Width	44.8	3.3	43.3	46.3
Upper lip length	12.8	2.0	11.9	13.7
Lower lip length	9.9	2.3	8.8	10.9
Philtrum width	11.0	2.0	10.1	11.9
Lower Anterior Face height	67.3	4.4	65.3	69.2
Inter-labial distance	17.7	4.0	15.9	19.4
Naso-labial angle	127.2	11.1	122.3	132.1
N_Sn_Pog	160.6	4.9	158.4	162.7
N_Prn_Pog	128.7	4.7	126.6	130.8
Labio-mental angle	140.6	8.7	136.8	144.5

Table 4.9 Differences in linear and angular soft tissue measurements for the Button & Bead group ($T_1 – T_0$)

	Mean	SD	95% Confidence Interval		*p*-value
			Lower	Upper	
Upper Face Height	1.4	2.6	0.2	2.5	0.024
Alar Base Width	-0.5	2.0	-1.4	0.4	0.298
Mouth Width	-0.5	1.9	-1.3	0.3	0.237
Upper lip length	0.7	1.7	0.0	1.4	0.065
Lower lip length	1.3	2.4	0.2	2.3	0.023
Philtrum width	0.0	1.5	-0.6	0.7	0.947
Lower Anterior Face height	3.0	4.5	1.0	5.0	0.005
Inter-labial distance	-0.9	4.0	-2.6	0.9	0.322
Naso-labial angle	2.7	7.3	-0.5	5.9	0.098
N_Sn_Pog	3.5	2.1	2.5	4.4	0.001
N_Prn_Pog	2.1	1.7	1.3	2.8	0.001
Labio-mental angle	10.6	14.0	4.4	16.8	0.002

Paired *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

Table 4.10 Soft tissue changes in the X-direction produced following Button & Bead treatment ($T_1 - T_0$)

	Mean	SD	95% Confidence Interval		*p*-value
			Lower	Upper	
R-Alare	-0.3	1.2	-0.8	0.2	0.208
Pronasle	0.4	0.6	0.1	0.7	0.005
L-Alare	-0.3	1.4	-0.9	0.4	0.373
R-Cheilion	-0.6	2.5	-1.7	0.5	0.282
R-Crista Philtri	-1.3	1.4	-1.9	-0.7	0.001
Labiale Superius	-1.3	1.3	-1.9	-0.7	0.001
L-Crista Philtri	-1.3	1.1	-1.8	-0.8	0.001
L-Cheilion	-0.8	2.6	-2.0	0.4	0.165
Labiale Inferius	1.6	2.5	0.5	2.7	0.005
Pogonion	0.8	1.9	-0.1	1.6	0.069
Nasion	-0.1	0.8	-0.4	0.3	0.674
Subnasale	-0.6	1.1	-1.1	-0.2	0.012
Glabella	0.1	0.7	-0.2	0.4	0.679
Menton	0.1	5.3	-2.2	2.5	0.916
A-point	-0.9	0.9	-1.3	-0.5	0.001
B-point	1.7	1.7	1.0	2.5	0.001

Paired *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

-ve values indicate backward movement.

+ve values indicate forward movement.

4.7 Changes in y-direction following Button & Bead appliance treatment

Table 4.11 shows the mean vertical linear (y-direction) changes following Button & Bead treatment. There was a minimal change at nasion and glabella but the remaining landmarks moved vertically downwards. The upper lip moved both clinically and statistically significantly downwards. There was more vertical change in the lower facial soft tissue than the nasolabial soft tissue. The largest changes were seen at labiale inferius (-2.3±3.6mm), pogonion (-3.9±3.5mm) and B-point (-4.2±3.0mm) and menton (-4.9±3.5mm).

4.8 Differences in linear and angular changes between the Twinblock and the Button & Bead appliances

Table 4.12 shows the mean differences in changes in linear and angular soft tissue measurements between the Twinblock and Button & Bead appliance. Even though there were differences between the Twinblock and Button & Bead appliance only the change in facial convexity (N-Sn-Pog) was statistically significantly greater in the Twinblock group (1.6º). However, differences in the lower anterior face height between the Button & Bead and Twinblock could be clinically significant.

4.9 Differences in horizontal changes (x-direction) between the Twinblock and the Button & Bead appliances

The mean horizontal linear (x-direction) differences for the changes following Twinblock treatment compared to the Button & Bead treatment are shown in Table 4.13. For the upper lip region there were no statistical differences between the two appliances but there was more upper lip retraction in the Button & Bead group.

Table 4.11 Soft tissue changes in the Y-direction produced following Button & Bead treatment ($T_1 - T_0$)

	Mean	SD	95% Confidence Interval		*p*-value
			Lower	Upper	
R-Alare	-1.1	1.0	-1.5	-0.6	0.001
Pronasle	-1.3	1.4	-1.9	-0.7	0.001
L-Alare	-1.1	1.2	-1.6	-0.6	0.001
R-Cheilion	-2.1	1.4	-2.7	-1.4	0.001
R-Crista Philtri	-2.2	1.9	-3.1	-1.4	0.001
Labiale Superius	-2.7	1.9	-3.5	-1.8	0.001
L-Crista Philtri	-2.4	1.9	-3.3	-1.6	0.001
L-Cheilion	-1.9	1.7	-2.6	-1.1	0.001
Labiale Inferius	-2.3	3.6	-3.9	-0.8	0.006
Pogonion	-3.9	3.5	-5.5	-2.4	0.001
Nasion	0.3	1.4	-0.3	1.0	0.276
Subnasale	-1.8	1.9	-2.6	-0.9	0.001
Glabella	-0.1	2.1	-1.1	0.8	0.764
Menton	-4.9	3.5	-6.4	-3.3	0.001
A-point	-1.9	1.5	-2.6	-1.2	0.001
B-point	-4.2	3.0	-5.5	-2.9	0.001

Paired *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

-ve values indicate downward movement.

+ve values indicate upward movement.

Table 4.12 Differences in linear and angular soft tissue measurements between the Button & Bead group and the Twinblock group (Twinblock – Button & Bead)

	Mean	95% Confidence Interval		*p*-value
		Lower	Upper	
Upper Face Height	-1.3	-2.7	0.0	0.057
Alar Base Width	0.5	-0.7	1.7	0.379
Mouth Width	1.5	-0.1	3.0	0.058
Upper lip length	-0.3	-1.3	0.7	0.569
Lower lip length	-0.2	-1.3	1.0	0.798
Philtrum width	0.6	-0.3	1.4	0.177
Lower Anterior Face height	-2.0	-4.3	0.2	0.076
Inter-labial distance	-0.8	-3.1	1.5	0.474
Naso-labial angle	-1.9	-6.1	2.3	0.364
N_Sn_Pog	1.6	0.1	3.1	0.043
N_Prn_Pog	0.9	-0.2	2.0	0.109
Labio-mental angle	3.8	-5.1	12.6	0.395

Two sample *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

Table 4.13 Differences in soft tissue changes in the X-direction produced between the Twinblock & Button & Bead appliance, (Twinblock – Button & Bead)

	Mean	95% Confidence Interval		*p*-value
		Lower	Upper	
R-Alare	-0.1	-0.8	0.7	0.859
Pronasle	0.1	-0.5	0.6	0.854
L-Alare	-0.4	-1.2	0.4	0.323
R-Cheilion	0.5	-0.9	1.9	0.491
R-Crista Philtri	0.8	-0.1	1.6	0.077
Labiale Superius	0.7	-0.1	1.5	0.083
L-Crista Philtri	0.7	-0.1	1.6	0.094
L-Cheilion	0.7	-0.9	2.4	0.379
Labiale Inferius	1.0	-0.4	2.4	0.164
Pogonion	1.9	0.8	3.1	0.001
Nasion	0.1	-0.4	0.6	0.712
Subnasale	0.1	-0.6	0.8	0.791
Glabella	0.2	-0.3	0.6	0.510
Menton	2.4	-0.4	5.3	0.090
A-point	0.2	-0.4	0.8	0.466
B-point	1.5	0.4	2.7	0.012

Two sample *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

For the mandibular soft tissues there was statistically significantly more anterior horizontal movement at pogonion (1.9mm) and B-point (1.5mm) in the Twinblock group compared to the Button & Bead group. In addition, there was also greater forward movement of labiale inferius (1.0mm) and menton (2.4mm), but these were not statistically significant. Even though the mean horizontal differences at menton was not statistically significant there was a wide 95% confidence interval (-0.4mm to 5.3mm).

4.10 Differences in vertical changes (y-direction) between the Twinblock and the Button & Bead appliances

Table 4.14 shows the mean differences in vertical linear (y-direction) changes produced the Twinblock and Button & Bead appliance. Both groups showed vertical movement of the upper lip and mandibular soft tissues following treatment. However generally there was a larger downward movement in the Button & Bead group, but this was not statistically significant. It is noteworthy that the 95% confidence intervals for the differences were over to 2mm or greater for many of the upper lip points and for labiale inferius (-0.5 to 3.3mm), pogonion (-0.6mm to 3.0mm), menton (-0.1mm to 3.6mm) and B-point (-0.4mm to 2.9mm).

4.11 Differences in horizontal distance between the chin regions following Twinblock and Button & Bead appliance treatment

The results of the one sample *t*-test confirmed that the absolute horizontal distance between the two chin patches was not statistically different to 2mm (p=0.068). In other words, the change is no different to 2mm. So, if a difference of

2mm is taken as being clinically significant the differences between the two appliances could be clinically significant in the x-direction.

Table 4.14 Differences in soft tissue changes in the Y-direction produced between the Twinblock & Button & Bead appliance, (Twinblock – Button & Bead)

	Mean	95% Confidence Interval		*p*-value
		Lower	Upper	
R-Alare	0.2	-0.5	0.9	0.517
Pronasle	0.4	-0.7	1.5	0.465
L-Alare	0.3	-0.4	1.1	0.375
R-Cheilion	1.0	0.0	1.9	0.04
R-Crista Philtri	0.9	-0.3	2.2	0.151
Labiale Superius	0.9	-0.4	2.1	0.17
L-Crista Philtri	0.8	-0.5	2.1	0.2
L-Cheilion	0.7	-0.5	1.8	0.246
Labiale Inferius	1.4	-0.5	3.3	0.137
Pogonion	1.2	-0.6	3.0	0.183
Nasion	0.0	-1.0	0.9	0.955
Subnasale	0.6	-0.4	1.6	0.254
Glabella	-0.8	-2.0	0.4	0.173
Menton	1.8	-0.1	3.6	0.062
A-point	1.0	0.0	1.9	0.046
B-point	1.3	-0.4	2.9	0.126

Two sample *t*-test to assess if the changes were statistically significant ($p<0.05$)

Values in RED are statistically significant.

CHAPTER 5

DISCUSSION

5. DISCUSSION

5.1 Discussion

This study was a randomised clinical controlled trial investigating differences between the Twinblock appliance and the Button & Bead appliance. Three main areas of interest were investigated; the rate of overjet reduction and compliance, the skeletal and dental differences and finally differences in facial soft tissue between the two appliances. This particular project investigated and reports the soft tissue effects and differences between the two appliances, but will also refer to the underlying skeletal and dental changes to fully explain the findings. So, any references to hard tissue changes were not directly measured by the author but were obtained from the results of the second project.

The study recruited 64 patients into the trial and was conducted at the Birmingham Dental Hospital and School. At the time of data analysis 44 patients had completed the trial with 17 dropping out and the remainder still under treatment. 22 patients were enrolled into each arm of the study with an age range from 10-14 years old (Button & Bead group mean 12.1 SD 1.2 years and Twinblock mean 12.4 SD 1.2 years). The inclusion criteria were similar to those of previous studies and block randomisation was used to reduce bias and produce two homogeneous groups.

Studies have shown that for children, treatment dropouts and discontinuation vary between 9% and 15% (Illing et al., 1998; Harradine and Gale, 2000). The Button and Bead appliance was developed in an attempt to improve compliance, as it was believed to be more aesthetic. In addition, it was thought to be more efficient by utilising fulltime class II elastic wear. This was supported by anecdotal evidence suggesting the Button and Bead appliance was more effective at reducing the overjet and was better tolerated by patients (Spary and Little, 2014).

To date the majority of studies have reported profile cephalometeric changes based on a limited number of landmarks. Soft tissue changes based on conventional (two dimensional) diagnostic methods are likely to underestimate the actual clinical effect (D'Anto et al., 2015). The changes produced by a functional appliance are three-dimensional in nature, for both the hard and soft tissues. It is therefore generally accepted that the use of non-invasive three-dimensional scanning is fundamentally more accurate in quantifying the soft tissue changes following functional appliance treatment (Flores-Mir and Major, 2006). Previous systematic reviews and meta-analysis summarising the effects of the facial soft tissue following functional appliance treatment are inconclusive given the low-quality studies and limited data (Ehsani et al., 2014). Therefore this study was partly undertaken to address deficiencies in the current knowledge base.

5.2 Soft tissue effects of the Twinblock appliance

Twinblock appliances were initially introduced with the aim of increasing mandibular length whilst restricting maxillary growth (Bishara and Ziaja, 1989). Numerous systematic reviews and meta-analysis have subsequently shown that this is not the case, and that growth is predominantly genetically pre-determined (Mossey, 1999; Perinetti et al., 2016; D'Anto et al., 2015). The majority of changes produced by the appliance are due to changes in upper and lower incisor inclinations and not skeletal change (Pancherz, 1984; D'Anto et al., 2015). Functional appliances are often suggested in Class II malocclusions with mandibular retrusion, with correction requiring forward movement of the mandible, either through growth or position (D'Anto et al., 2015).

In the present study, following Twinblock appliance treatment, the philtrum and corners of the mouth moved downwards by less than 2mm. These changes were not clinically significant, with all 95% confidence intervals being less than 2mm. However, there was a gradation of movement with most movement at the philtrum and less towards of the corner of the mouth. This may have been due to greater movement of the upper incisors, rather than changes more laterally in the canine and premolar region. Horizontally, there was a small amount of retrusion of labiale superius (-0.6mm) and soft tissue A-point (-0.7mm) these were clinically insignificant. These finding were similar to those reported by Morris et al. (1998) and Salloum et al. (2018). In the present study the mean upper incisors retroclination was 6.1±2.0^{o}.

The soft tissue overlying the bony chin moved horizontally (pogonion 2.7±1.8mm, menton 2.6±3.8mm) and vertically (pogonion 2.7±2.3mm, menton 3.1±2.6mm). In addition, soft tissue B-point also translated downwards and forward by a similar amount, 3.3±2.2mm and -2.9±2.4mm respectively, these were consistent with previous studies (Morris et al., 1988; Varlik et al., 2008; Salloum et al., 2018). This may have been predicted as the reported changes in mandibular length following Twinblock treatment are in the order of 3-4mm (Illing et al., 1998). Given that the overlying soft tissue at the chin region moves in a ratio of 1:0.9 hard to soft tissue ratio, it is not surprising that a 3mm forward change in the soft tiisue chin region is seen, as it mirrors the underlying skeletal change (Olate et al., 2016). In the present study there was a 4.1±2.3mm increase in mandibular unit length. Interestingly the lower lip at labiale inferius moved forward (2.6mm) the same amount as the chin. Based on the chin soft tissues changes following a mandibular advancement procedure in an orthognathic patient, this should have been less. A possible explanation for this observation may be that the lower lip is often retrusive in class II skeletal patterns and can result in incompetent lips together with a lip trap (Ricketts, 1968). Following Twinblock treatment the lower lip will "unroll" and together with the lower incisor proclination (6.2±3.3^{o} in the present study); the lower lip is pushed forward keeping pace with the soft tissue chin movement. These horizontal changes cannot be taken in isolation, as vertical changes in lower face height will also affect the lower lip. Interestingly, there was little change in the position of labial inferius following treatment but the lower lip increased in length and the inter-labial distance decreased. This could be as a result of lengthening of the upper lip with labiale superius moving downwards and in the lower with menton, pogonion and B-point moving downwards. The vertical soft tissue change associated with the Twinblock appliance resulted in B-point moving downward by -2.9mm and Menton by -3.1mm, which were similar findings to the 3mm increase in facial height shown by previous studies, interestingly the LAFH increased by 3.6±1.8mm in the present study (Morris et al, 1998, Clark, 2003 and McNamara et al., 1985).

5.2.1 Summary

In summary, the soft tissue changes produced by the Twinbock treatment were approximately equal downward and forward movement of the lower facial soft tissue with lengthening of the lower face. Interestingly the lower lip position did not change but there were clinically significant changes below the lower lip i.e. greater than 2mm. The upper lip lengthens more than it retracts and as a result the inter-labial distance decreases, but these changes may not be clinically significant. In other words a change of around 6º upper incisor retraction produces changes in the upper lip which may not be clinically significant.

5.3 Soft tissue effects of the Button & Bead appliance

The effects of the Button & Bead functional appliance on the upper lip were both retraction and lengthening, with approximately twice as much lengthening (2.7±1.9mm) than retraction (1.3±1.3mm). This could be clinically significant (greater than 2mm) in the larger population given the wide 95% confidence interval (-3.5mm to -1.8mm). The changes in upper lip position could have been due to either retroclination of the upper labial segment, retrusion of the maxilla, growth or a combination. The change was most likely due to incisal tipping as previous studies have shown 50% of overjet reduction was usually due to upper incisor retroclination (Pancherz, 1984). In a limited case series, using the Button & Bead appliance, the upper incisors retroclined 10º (Spary and Little 2015). This magnitude of retroclination was similar to the finding of the present study in which the upper incisors retroclined 11.2º. The upper lip changes were greater in the midline and lessened towards the corners of the mouth. This would suggest that there was a “tenting” effect with the upper incisors supporting the philtrum of the upper lip.

The lower facial soft tissues also changed as a result of Button & Bead treatment. Vertically, there was an increase in lower lip length (1.3±2.4mm) and lower anterior face height (3.0±4.5mm) with minimal change in inter-labial distance (-0.9mm±4mm). The majority of change was in the vertical direction with pogonion, B-point and menton moving inferiorly 4-5mm, in addition to the lower lip. This mirrored the skeletal vertical change of 3.6±1.5mm in LAFH.

Horizontally, there was little change in the chin position measured at menton (0.1±5.3mm) and pogonion (0.8±1.9mm) but more change as B-point (1.7±1.7mm) and labial inferius (1.6mm±2.5). Given that the two latter points are more closely related to the underlying dental and dento-alveolar structures this would suggest that there were also dental changes following Button & Bead treatment (5.3±3.6º in the present study). There could have been a horizontal mandibular change (2.6±1.9mm in the present study) but the effect could have been reduced by a backward rotation of the mandible that would explain the increase in face height with minimal change in AP correction. A possible explanation could have been the class II elastics extruding the lower molars causing a clockwise rotation of the mandible.

5.3.1 Summary

In summary, the soft tissue changes produced by Button & Bead treatment were mainly downward movement of the lower facial soft tissue with lengthening of the lower face. The lower lip position also moved down, together with the upper lip lengthening, there was minimal change in the inter-labial distance. The upper lip also retracts but more so in the midline (philtrum region) and less towards the corners of the mouth, these changes could be clinically significant. This may suggest a change of around 11º upper incisor retraction produces changes in the upper lip that are probably clinically significant.

5.4 Differences between the soft tissue following Twinblock and the Button & Bead appliance

There were few statistical differences between the Twinblock and Button & Bead appliances regarding soft tissue changes. This is probably expected, as their modes of action were similar.

Even though not statistically significant the Button & Bead appliance produced more retraction and downward movement of the upper lip. This would have been due to greater magnitude of retraction of the upper incisors following Button & Bead treatment (11.2º) compared to the Twinblock group (6.0º). For all the upper lip landmarks, in the x-direction, none of the 95% confidence intervals for the differences between the Twinblock and the Button & Bead were greater than 2mm and could therefore also be regarded as not being clinically significant in the wider population. However, based on the 95% confidence intervals there could be more than 2mm upper lip lengthening in the Button & Bead group, especially in the philtrum region.

The situation was different for the soft tissue changes in the lower face. Here there were statistical differences in the difference between pogonion and B-point, as well as the chin region, horizontally between the two appliances. There was more horizontal advancement of pogonion in the Twinblock group and the 95% confidence intervals for the differences were above 2mm suggesting this difference would be clinically significant. Vertically the mean soft tissue changes between the Twinblock and Button & Bead appliance were not statistically significantly different. However, the 95% confidence intervals for labial inferius, pogonion, menton and B-point were above 2mm. This suggests there may be a clinically significant downward movement of the chin and lower lip with the Button & Bead appliance chin compared to the Twinblock. This may have been due to the greater increase in mandibular length seen in the Twinblock group (4.1mm) compared to the Button & Bead (2.6mm).

5.5 Limitations of study

There are numerous limitations of the present study that should be taken into account. Care should be taken when interpreting the results as there was no untreated control group and therefore any changes in the soft tissue could have been as a result of growth rather than appliance wear. In addition the gender distribution was uneven between the groups and again could have influenced the results.

Given that the Button & Bead appliances was a new appliance to the Department, a manufacturing learning curve by the laboratory technicians and treating clinicians may have had an effect on the results. The Button & Bead appliance required the patient to wear the upper and lower appliances as well as the class II elastics. This may have been more demanding on the patient compared to the conventional Twinblock appliance treatment. The current literature suggests that even though the patients are instructed to wear the appliance fulltime, there is around 12 hours appliance wear in reality (Parekh et al., 2019). No such data exists for the Button & Bead appliance, but the duration of appliance wear would affect the findings.

The design of the Button & Bead appliance incorporated no midline screw, but in the Twinblock appliance was considered usual practice, and was used were clinically indicated. However this could have affected the results as there was no expansion undertaken in the Button & Bead appliance until in the transition phase.

Finally a per-protocol analysis was used in this study instead of an intention-to-treat analysis which may have also bias the result. Surprisingly the dropout rates were relatively high (17 drops outs) however both appliances had a similar number of patients discontinue treatment.

CHAPTER 6

CONCLUSIONS

6. CONCLUSIONS

6.1 Conclusions

1. The horizontal anterior movement of the soft tissue pogonion and the chin region was statistically and clinically significantly greater in the Twinblock group compared to the Button & Bead group.
2. As a result of Twinblock treatment there were minimal changes in upper lip position.
3. In the Button & Bead group there was some retraction and lengthening of the upper lip, this was clinically significant (above 2mm) and mainly in the philtrum region.
4. The Button & Bead appliance produced a clinically significant vertical increase in chin and lower lip compared to the Twinblock.

6.2 Null hypothesis

The null hypothesis was rejected as there was a statistically significant difference in horizontal mandibular advancement produced by a Twinblock compared to a Button & Bead appliance measured at soft tissue pogonion. In addition, this difference was clinically significant i.e. greater than 2mm.

CHAPTER 7

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APPENDICES

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. With your permission we will inform your dentist that you are taking part in this research.

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

IRAS No: 219179

UNIVERSITY OF BIRMINGHAM

Parent Information Sheet v1.7 15/06/2017

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.

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.

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against Birmingham Community Healthcare Trust but you may have to pay for legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). In addition, the University will cover non-negligent harm/payment of compensation in the event of harm.

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.

With your consent, your child's dentist will be informed that they are partaking in this trial.

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.

IRAS Number: 219179

UNIVERSITY OF BIRMINGHAM

Children's Assent Form v 1.5 15.6.2017

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. ☐
7. I am happy for my dentist to be told that I am taking part in this research ☐

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:

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.

IRAS Number: 219179

UNIVERSITY OF BIRMINGHAM

Parental Consent Form v1.2 28.3.2017

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 1.1 dated 2.11.2016 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. ☐

Name of parent/guardian/patient:

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

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.