A SINGLE CENTRE RANDOMISED CONTROLLED TRIAL OF THE TWIN BLOCK AND BUTTON & BEAD APPLIANCES IN CLASS II MALOCCLUSIONS

by

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Abstract

Aim: To determine if there is a clinical difference in the rate of overjet reduction using a Twin Block appliance or a Button & Bead appliance.

Method: A single centre, two-arm parallel, randomised controlled trial with a 1:1 allocation ratio was conducted. Sixty four patients (28 male, 36 female) between the age of 10 and 14 were recruited and randomly allocated to the Twin Block or Button & Bead group for functional appliance treatment. Treatment was provided in the orthodontic department at Birmingham Dental Hospital. Baseline, follow up and end of functional appliance treatment occlusal measurements and standard orthodontic records were taken. The primary outcome measure was the rate of overjet reduction. Secondary outcome measures included change in PAR, patient dropout and cost effectiveness of the appliances.

Results: Twenty four patients in the Twin Block group and twenty three patients in the Button & Bead group completed their assigned appliance treatment successfully. The remaining participants failed to complete their assigned appliance treatment either due to poor compliance, lack of efficacy or withdrawn consent. There was no statistically significant difference (0.1mm/month, p=0.517) in the rate of overjet reduction using a Twin Block (0.7-1.0mm/month 95% CI) or Button & Bead appliance (0.7-1.2mm/month 95% CI). There was a statistically significant difference between baseline and post-functional PAR scores in both groups. There were a high proportion of breakages in both groups. In the Twin Block group, the acrylic and clasps on the lower appliance were most likely to break whereas in the Button & Bead group, the acrylic and bead on the upper appliance were most likely to break.

Conclusion: There were no differences in the rate of overjet reduction and occlusal outcomes between both appliances.

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LITERATURE REVIEW

1.1 Class II division 1 malocclusion

1.1.1 Introduction

The American Association of Orthodontists (AAO) Glossary defines orthodontics and dentofacial orthopaedics as the dental specialty involved in 'the diagnosis, prevention, interception, guidance and correction of mal-relationships of the developing or mature orofacial structures'(AAO, 2017). Alternatively, the British Standards Institute (BSI) defines orthodontics as the 'branch of dentistry concerned with the study of craniofacial growth and development, and the treatment or prevention of malocclusions and other dentofacial anomalies' (BSI, 2010). Both these definitions encompass the concept that the field of orthodontics is concerned with more than just the straightening of teeth; contrary to what the etymology of the word orthodontics would suggest.

In order to diagnose, prevent and treat malocclusions, one must understand the notion of an ideal occlusion, which we should aim to achieve. Angle (1899) was one of the first to attempt to describe an ideal occlusion as illustrated by the images below:

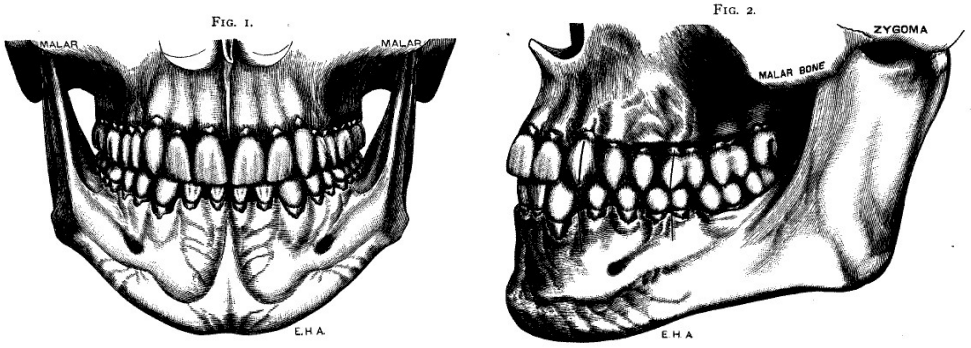

Figure 1: Ideal occlusion (Angle, 1899)

He felt that the anteroposterior position of the first permanent molars in relation to each other was fundamental to occlusion. With this in mind, he postulated that 'in normal occlusion the mesiobuccal cusp of the upper first molar is received in the sulcus between the mesial and distal buccal cusps of the lower'. This was his basis for diagnosing and classifying malocclusion.

Andrews (1972) through his reflections and clinical expertise recognised the deficiencies of describing a normal occlusion purely on the basis of the molar relationship. Over four years, he collected 120 models of teeth that had not been treated orthodontically which he believed exhibited a normal occlusion. He analysed the crowns of these teeth and compared his findings with 1,150 treated cases to validate the features of a normal occlusion that he had proposed. He termed these 'the six keys to normal occlusion' and they are now widely accepted as the static occlusal outcome that should be achieved with successful orthodontic treatment.

Andrews (1972) described the six keys as follows:

(I) '*Molar relationship*. The distal surface of the distobuccal cusp of the upper first permanent molar made contact and occluded with the mesial surface of the mesiobuccal cusp of the lower second molar. The mesiobuccal cusp of the upper first permanent molar fell within the groove between the mesial and middle buccal cusps of the lower first permanent molar.'

(II) '*Crown angulation, the mesiodistal "tip"*. The gingival portion of the long axis of each crown was distal to the incisal portion, varying with the individual tooth type.' This means that all crowns should be mesially tipped.

(III) '*Crown inclination (labiolingual or buccolingual inclination)*.' This is often stated as crown torque where positive refers to buccal/labial crown torque and negative refers to lingual crown torque. Upper and lower incisors had to have sufficient positive crown torque enough to prevent their overeruption and enable posterior teeth to interdigitate appropriately. Upper and lower posterior teeth (from the canines backwards) had to be negatively crown torqued at varying levels for each tooth.

(IV) '*Rotations.*' Rotated teeth take up more space in the arch therefore there should be no rotations.

(V) '*Spaces*.' There should be tight contacts with no spaces.

(VI) '*Occlusal plane.*' There should be a flat or slight curve of Spee.

In recent years, there has been an increased focus on determining what constitutes a normal dynamic occlusion. Although it is beyond the scope of this literature review to explore this concept further, it is important to be aware of the notion of a functional or dynamic occlusion.

Malocclusion has been defined as 'an appreciable deviation from the ideal that may be considered aesthetically or functionally unsatisfactory' (Cobourne and DiBiase, 2016). Angle (1899) classified malocclusion into Class I, Class II Division 1, Class II Division 2 and Class III (with further subdivisions in Class II and III categories) primarily based on molar relationships. Angle (1899) defined a Class II Division 1 malocclusion as one where the anteroposterior relationship of the teeth in both jaws was abnormal with 'all the lower teeth occluding distal to normal… characterised by a narrowing of the upper arch, lengthened and protruding upper incisors, accompanied by abnormal function of the lips and some form of nasal obstruction and mouth-breathing.' Nearly a century later, the British Standards Institute classified malocclusion using the same major categories but created definitions based on the

incisor relationship. BSI (1983) defined a Class II Division 1 malocclusion as “the lower incisor edges lie posterior to the cingulum plateau of the upper incisors. There is an increase in overjet and the upper central incisors are usually proclined.”

1.1.2 Prevalence and aetiology

The prevalence of Class II Division 1 malocclusions varies between 12.5-49% depending on the race and age of the populations studied (Todd and Lader, 1991, Thilander et al., 2001, Lauc, 2003, Josefsson et al., 2007, Perillo et al., 2010, Proffit et al., 1998).

The aetiology of a malocclusion can be determined by considering skeletal, soft tissue, dental and other factors. Skeletal factors can be considered in three planes: anteroposterior, vertical and transverse. Skeletal or dental base relationships, which refer to the anteroposterior position of the maxilla and mandible in relation to each other, can be described as Class I, II or III. This assessment is made primarily on clinical assessment although cephalometric radiographs may also be used. A Class I skeletal relationship is one where the mandible is related normally (roughly 2mm posterior) to the maxilla. A Class II skeletal relationship is where the mandible is retruded relative to the maxilla (mandibular retrognathia), or the maxilla is protruded relative to the mandible (maxillary prognathia) or a there is a combination of both. Conversely, a Class III skeletal relationship is where the mandible is protruded relative to the maxilla (mandibular prognathia), or the maxilla is retruded relative to the mandible (maxillary retrognathia) or a combination of both.

Hopkin et al. (1968) demonstrated the influence of skeletal factors, in particular cranial base dimensions, on the development of dental Class II and III malocclusions. A longer cranial base results in a prognathic maxilla and conversely an increased cranial base angle results in

mandibular retrognathia – both of which could contribute to the development of a class II malocclusion. A Class II Division 1 incisor relationship is frequently observed in individuals with a Class II skeletal relationship (Mitchell et al., 2013). McNamara (1981) carried out a cephalometric study of 277 children between the age of 8 and 10 and reported that a retrognathic mandible was 'the most commonly occurring factor contributing to Class II malocclusion.' Class II malocclusions can also present in hypodivergent, average or hyperdivergent skeletal relationships.

Soft tissue position is inherently dependent on the underlying skeletal pattern. Incompetent lips are often seen in patients with a Class II skeletal pattern, and where the lower lip gets trapped behind the upper incisors, it causes proclination of the upper incisors. Rarely, a strong lower lip may result in retroclination of the lower incisors and a Class II Division 1 malocclusion with increased overjet.

Dental factors such as crowding in the upper anterior segment, retained deciduous incisors and ectopic labial eruption of permanent incisors, and dental trauma can lead to an increased overjet and a Class II Division 1 malocclusion. Periodontally involved teeth with reduced alveolar support may also be proclined and spaced resulting in a Class II Division 1 malocclusion.

Other factors such as a digit sucking habit can also be responsible for the development of Class II Division 1 incisor relationship (independent of the underlying skeletal pattern) due to the proclination of upper incisors and retroclination of lower incisors.

1.1.3 Management of children and young adolescents

The management of Class II Division 1 malocclusions in children and young adolescents can be broadly divided into two major categories: orthodontic camouflage and growth modification. Orthognathic treatment is not an option in these age groups as maxillary and largely mandibular growth are still incomplete.

The decision to treat by orthodontic camouflage or growth modification is predominantly dependent on the extent of the class II skeletal pattern and consequently the patient's facial appearance. In principle, children and young adolescents with a Class II Division 1 incisor relationship on a mild Class II skeletal base or Class I/Class III skeletal base are likely to be treated with a camouflage approach. However, if there is significant crowding, a severe overjet or any other factor that is likely to increase anchorage requirements in the fixed appliance phase of treatment, a growth modification technique may also be used in such cases.

Children and young adolescents with a Class II Division 1 incisor relationship on a moderate to severe skeletal II base are more likely to be treated using growth modification techniques such as a functional appliance or an extra-oral appliance.

1.2 Functional appliances

1.2.1 Introduction and history

A functional appliance is defined as one that engages upper and lower teeth and works mainly by posturing the lower jaw away from its normal position (Isaacson et al., 1990). The first functional appliances were introduced in the late 1800s and early 1900s. Norman Kingsley in

1879 is credited with the use of a removable appliance which encouraged anterior positioning of the lower jaw and this appears to have initiated the development of various designs of functional appliances (Wahl, 2006). Some of the more widely used eponymous appliances created over the next 100 years included the Andresen activator, the Herbst appliance, the Bimler appliance, Fränkel's function regulator and Balter's bionator (Wahl, 2006).

1.2.2 Classification and types

The simplest way of classifying functional appliances is by describing whether they are fixed or removable in nature. Functional appliances can also be classified by the type of malocclusion they are designed to treat, that is Class II or III.

Ireland and McDonald (2003) classified functional appliances based on how soft tissue and muscular forces are used:

a) Myotonic – Appliances such as the Harvold activator are proposed to rely on forces developed from 'elastic recoil within the stretched soft tissues'. This means that these appliances when worn, open the bite considerably to generate the forces from a passive muscle stretch.
b) Myodynamic – Appliances such as Clark's Twin Block, Andresen's activator and the bionator are proposed to rely on forces developed from the reflex contraction of masticatory muscles stimulated whilst the appliance is worn.

Proffit et al. (2013) classified functional appliances into four groups based on how they were held in the mouth and the type of components:

a) passive tooth-borne e.g. Balter's bionator and the Herbst appliance

b) active tooth-borne e.g. Clark's Twin Block appliance

c) tissue-borne e.g. Frankel's function regulator

d) hybrid

1.2.3 Timing of treatment

Several management strategies exist for children and young adolescents with a Class II Division 1 incisor relationship. If it is decided that a growth modification approach will be used to treat the malocclusion, the question then becomes when is the optimal time to carry out the treatment. Correction of a class II malocclusion can be commenced early, that is before the age of 10 years or during early adolescence when the patient is in the late mixed dentition / early permanent dentition and the pubertal growth spurt is likely to begin. If correction is commenced early, this results in the need for a two-phase treatment, which involves functional appliance treatment in the first phase (age 7-10 years) followed by fixed appliances (± functional appliances) as an adolescent (age 11-16 years). If correction is started in early adolescence only one phase of treatment is required starting with a functional appliance and transitioning to fixed appliances (age 11-16 years).

Early two phase treatment

Randomised controlled trials conducted by Keeling et al. (1998), Tulloch et al. (2004) and O'Brien et al. (2009) sought to answer the question: Are there any benefits in a two phase treatment? O'Brien et al. (2009) conducted a multi-centre randomised controlled trial (RCT) in National Health Service (NHS) hospital orthodontic departments across the United Kingdom to overcome some of the limitations associated with previous studies. The aim of the trial was to compare the 'effectiveness' of orthodontic treatment for class II malocclusions

with a minimum 7mm overjet between those patients that received early two-phase treatment and those patients that received adolescent one phase treatment. The functional appliance of choice in the trial was a modified Clark's Twin Block. The study included 174 patients with 73 patients in the adolescent one phase group completing treatment and 54 patients in the early two-phase group completing treatment. A further 13 patients in the early two-phase group accepted their occlusion after the early Twin Block functional appliance treatment. The study concluded that there were no differences between the two groups when considering the patients' skeletal pattern and self-esteem. However, when overall treatment was accounted for, the patients in the early two-phase treatment had significantly higher number of attendances (with associated time and monetary costs) and poorer end Peer Assessment Rating (PAR) scores compared to the patients who had adolescent one phase treatment.

The findings from the aforementioned studies were collated in a Cochrane systematic review by Thiruvenkatachari et al. (2013). The meta-analysis revealed that there was a statistically significant difference in overjet, ANB and PAR score at the end of early functional appliance treatment compared to no treatment. Thiruvenkatachari et al. (2013) also confirmed that when the overjet, ANB, PAR and self-concept score were compared at the end of treatment for one phase and two-phase management, there were no differences. However, receiving early treatment, reduced the risk of incisor trauma (Thiruvenkatachari et al., 2015).

Adolescent one phase treatment

The alternative to early treatment for a Class II Division 1 malocclusion with increased overjet is to treat the patient in the late mixed / early permanent dentition using functional or fixed appliances or a combination of the two. Treatment is best carried out when the patient is

undergoing peak skeletal growth (pubertal growth spurt) although it can be difficult to predict when this will occur for an individual patient.

The various ways in which this stage of skeletal development can be assessed include serial measurements in standing height, development of secondary sexual characteristics and radiographic interpretation of certain bones such as cervical vertebrae, and the hand and wrist. Chronological age and dental development do not always correlate well with the stages of skeletal development and therefore the aforementioned factors may need to be assessed to aid in the timing of orthodontic intervention (Flores-Mir et al., 2004).

1.2.4 Mode of action

Since the use of functional appliances, there has been much controversy about whether they truly produce orthopaedic change. It is now widely accepted that the majority of correction of a Class II Division 1 malocclusion occurs by dento-alveolar change in combination with a small proportion of skeletal change. O'Brien et al. (2003a) reported that 27% of the overjet improvement could be attributed to skeletal change and 73% to dento-alveolar change, and 59% of the molar correction could be attributed to dento-alveolar change.

Three studies with slightly varied methodologies and non-RCT designs have been conducted to determine the treatment effects of the Twin Block appliance. Mills and McCulloch (1998), Lund and Sandler (1998) and Trenouth (2000) reported a significant increase in SNB and consequently reduction in ANB, an increase in mandibular length (ranging from 2.4mm to 4.2mm), reduction in overjet by a combination of upper incisor retroclination (ranging from 2.5 degrees to 14.4 degrees) and lower incisor proclination (ranging from 1.1 degrees to 7.9 degrees) and partial correction of Class II buccal segments by mild upper molar distalisation

and lower molars moving anterior and superior in patients treated with Twin Blocks compared to untreated controls.

Furthermore, a systematic review and meta-analysis by Nucera et al. (2016) concluded that 'removable functional appliances in class II growing patients have a slight inhibitory effect on the sagittal growth of the maxilla in the short term, but they do not seem to affect rotation of the maxillary plane.' The meta-analysis concludes a mean difference in treatment effect with functional appliances of -0.61 degrees per year for SNA and -0.61mm per year for anterior maxillary displacement when compared to untreated controls. This supports the theory that one of the ways in which functional appliances work is by restraining maxillary growth, although this is likely to be of minimal clinical significance.

A prospective study by Chintakanon et al. (2000) comparing hard and soft tissue changes of the temporomandibular joint (TMJ) in 40 children undergoing Twin Block functional appliance treatment to untreated controls over a 6 month period showed that 'the condyle occupied a more anterior position in the glenoid fossa' in the Twin Block group. The study was however unable to confirm whether remodelling within the TMJ had taken place to explain this change. It is still not clear whether alveolar remodelling of various aspects of the TMJ and change in the position of the condyle are elements involved in explaining how functional appliances work.

1.2.5 Twin Block

The Twin Block functional appliance was developed in 1977 and described by Clark (1982). It was conceived using the design principles of Pierre Robin's monobloc and Schwarz's

double plate. The Twin Block is a myodynamic and tooth-borne functional appliance, which can be passive or active depending on the components.

The Twin Block has a separate upper and lower removable appliance. The original Twin Block had bite blocks that met at 45º. 'The upper appliance is retained by modified double arrowhead clasps usually spanning two buccal teeth. The clasps incorporating a coiled tube for extra-oral traction… a mid-line expansion screw and a labial bow extending from the mesial of the upper first permanent molars'. 'The lower appliance is retained by peripheral clasping, depending on which teeth have erupted. In the permanent dentition retention is obtained by interdental clasps spanning two teeth in the incisor and in the premolar region… a reversed U-loop is placed lingual to the lower central incisors for intermaxillary traction' (Clark, 1982).

Since the original design of the Twin Block, several modifications have been made (Clark, 2010). The modified Twin Block appliance will generally have no tube for extra-oral traction, no upper labial bow, usually has Adams clasps on the posterior dentition for retention and steeper inclined bite planes. A randomised controlled trial by Yaqoob et al. (2012) comparing Twin Block functional appliance treatment with and without a maxillary labial bow showed that the presence of this component had no bearing on rate of overjet reduction or on skeletal or dento-alveolar changes. Various methods of achieving retention in the lower incisor region include the use of Southend clasps, acrylated and standard labial bows, ball ended clasps and incisor capping.

The Twin Block can also be modified during treatment to increase the amount of mandibular advancement that can be achieved. This is particularly useful for large overjets where patients may not be able to posture in an edge-to-edge position at the start of functional appliance

treatment. Banks et al. (2004) conducted a large randomised controlled trial to compare maximum versus incremental mandibular advancement (2 millimetres every 6 weeks with an advancement screw) of Twin Block functional appliances and found no benefit of incremental advancement over maximum advancement.

The Twin Block is the most commonly used functional appliance to correct Class II malocclusions in the UK (Chadwick et al., 1998). The advantages of the Twin Block compared to other functional appliances include that it is removable which provides the scope for better maintenance of oral hygiene, it can be designed to incorporate various auxillary features to start correcting different aspects of a malocclusion, it can be easily adjusted and activated, it is tolerated better by patients compared to bulkier 'monobloc' type appliances, it can be designed aesthetically to improve patient acceptance, it interferes less with speech once the patient has adapted to it and they require potentially less chair side time.

1.2.6 Button & Bead

A simple class II corrector known as the Button & Bead appliance has been described by Spary and Little (2015). This corrector consists of a separate upper and lower appliance. Both appliances are in essence vacuum or pressure formed splints. The upper appliance has a plastic or composite bead on the distopalatal cusps of the first permanent molars and is relieved labially on the incisors to allow placement of attachments. Sometimes a second splint is made with the bead on the mesiopalatal cusps of the first permanent molars to enable further anteroposterior activation of the mandible. The lower appliance has a flat occlusal table posteriorly which stops at the distal surface of the first permanent molar. 'The patient has to posture the mandible forwards until the bead drops down the distal surface of the

thickened table on the lower appliance, producing a class I molar relationship' (Spary and Little, 2015). Attachments are bonded to the upper incisors and lower first permanent molars to enable placement of intermaxillary class II elastics. These attachments can be orthodontic brackets or buttons composed of various materials including metal, ceramic and composite. Anecdotally, this appliance has been successful in reducing overjets in a short time frame in several patients. However, there is no scientific evidence to my knowledge to confirm this.

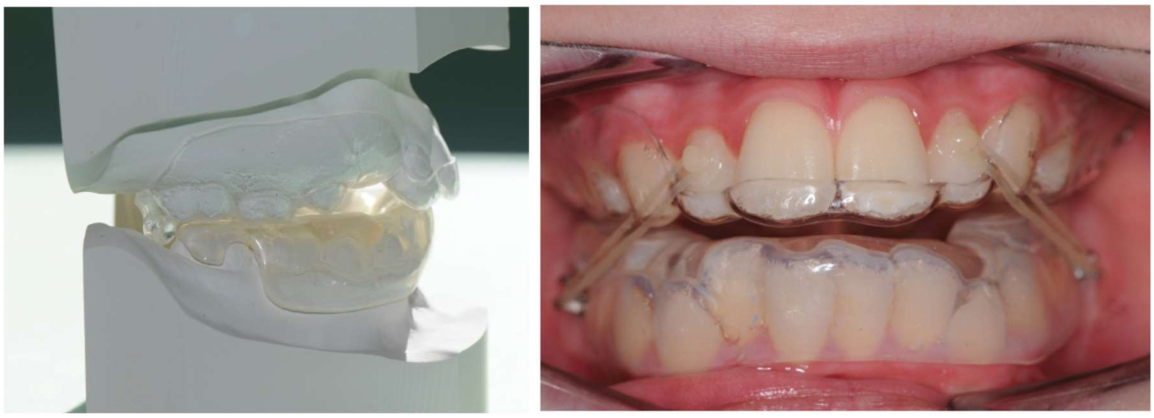

Figure 2: Button & Bead appliance

1.2.7 Monitoring progress of functional appliance treatment

Prior to commencing functional appliance treatment, baseline records including dental study casts, a lateral cephalogram and clinical measurements are taken. The clinical measurements, which include overjet, overbite, canine and molar relationships, centrelines, crossbites and lateral open bites are all taken with the mandible in retruded contact position. Manipulation of the mandible into its retruded contact position is usually achieved by using techniques borrowed from our prosthodontic colleagues. The only exception to this is the maximum protruded overjet, which is taken from the most anterior excursion of the mandible.

These clinical measurements should be recorded at each subsequent visit after the functional appliance is fitted in order to help monitor treatment progress. An indication of successful progress with functional appliance treatment in an individual will include signs of wear and adaptation to the appliance and a serial reduction in overjet that matches an increase in maximum protruded overjet. Removable functional appliances rely on patient cooperation and compliance. The failure to comply with and complete functional appliance treatment ranges from 6.7% to 33.6% (Clark, 2010).

When nearing the end of functional appliance treatment, the appliance may be left out of the mouth for a period of 48-72 hours before clinical measurements are taken to eliminate the habitual forward posturing the patient will inevitably have developed.

1.2.8 Transition from functional to fixed appliances

Class II correction achieved by functional appliances can be preserved in many ways. Fleming et al. (2007) described three principle approaches to this: over-correction, reinforcing anchorage with headgear (particularly where there is a maxillary aetiology to the malocclusion) and maintenance of a postured bite. Maintenance of a postured bite can be obtained through ‘part-time functional appliance wear, use of fixed functional appliance, use of an upper removable appliance with an inclined bite plane and early use of class II elastics’.

1.3 Peer Assessment Rating (PAR) index

1.3.1 Introduction

The PAR index was developed and introduced by Richmond et al. (1992a). One of the reasons for developing this index was the need for 'a quantitative objective method of measuring malocclusion and efficacy of treatment' (Richmond et al., 1992a). The purpose of developing this index was to be able to numerically score various features of a malocclusion on a dental study model and the summation of these scores would provide a total. This total represents the extent of deviation from 'normal alignment and occlusion' (Richmond et al., 1992a). In order to ensure the PAR index was reliable and valid, a weighted PAR score was developed. The figure below shows the traits of a malocclusion scored by PAR and how they are weighted. Contact point displacements are scored in the anterior segments and fit of the buccal occlusion is assessed and scored in all three planes. Overjet, overbite and centrelines are scored and given higher weighting compared to the other traits.

PAR SCORING SHEET

Name

CASE NUMBER		**Pre-Treatment**		**Date**												**UN-WEIGHTED TOTAL**	**WEIGHTED TOTAL**
PAR COMPONENTS		**RIGHT**													**LEFT**		
Upper anterior segments		3-2		2-1		1-1		1-2		2-3							X1
Lower anterior segments		3-2		2-1		1-1		1-2		2-3							X1
Buccal occlusion		Antero-posterior				Right				Left							X1
		Transverse				Right				Left							X1
		Vertical				Right				Left							X1
Overjet		Positive				Negative											X6
Overbite		Overbite				Openbite											X2
Centre line																	X4
														TOTAL			

CASE NUMBER		**Post-Treatment**		**Date**												**UN-WEIGHTED TOTAL**	**WEIGHTED TOTAL**
PAR COMPONENTS		**RIGHT**													**LEFT**		
Upper anterior segments		3-2		2-1		1-1		1-2		2-3							X1
Lower anterior segments		3-2		2-1		1-1		1-2		2-3							X1
Buccal occlusion		Antero-posterior				Right				Left							X1
		Transverse				Right				Left							X1
		Vertical				Right				Left							X1
Overjet		Positive				Negative											X6
Overbite		Overbite				Openbite											X2
Centre line																	X4
														TOTAL			

ASSESSMENT OF OUTCOME

PAR SCORE		**IMPROVEMENT**	
Change in PAR score		Greatly improved	
% change in PAR score		Improved	
		Worse or no different	

Figure 3: PAR scoring sheet

The ability to give a numerical representation to malocclusion at a particular time point naturally lends itself to comparison of these totals before and after orthodontic treatment for a

set of dental study models. In their second article, Richmond et al. (1992b) discussed how the weighted PAR index scores could be used to assess treatment outcomes and together with a nomogram (Figure 4) the level of improvement of a malocclusion. Improvements in weighted PAR scores can be evaluated by looking at the actual reduction in scores or the percentage reduction. From this study, it was determined that "at least 30 per cent reduction was needed for a case to be judged 'improved' and a change in score usually of 22 to bring about a change judged to be 'greatly improved'." (Richmond et al., 1992b)

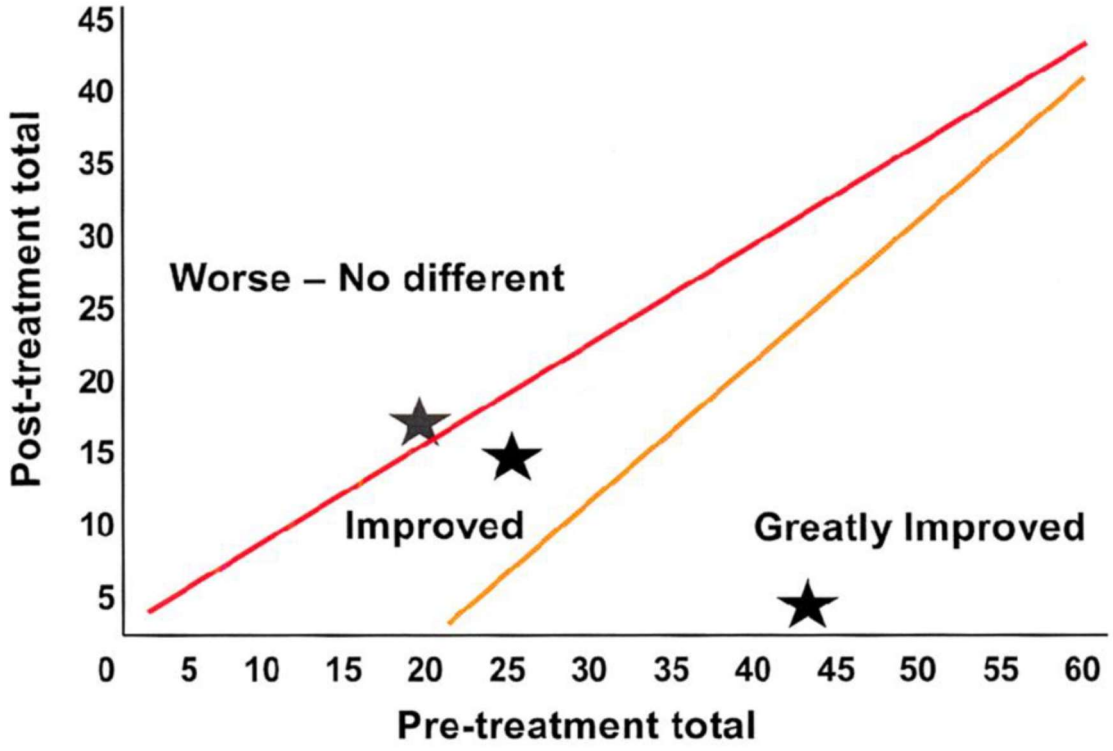

Figure 4: The PAR nomogram

1.3.2 PAR index critique

The PAR index is a valid and reliable tool and weighted PAR scores have been widely adopted as an objective, numerical assessment of a malocclusion. Richmond et al. (1992a)

reported intra and inter-examiner reliability with intraclass correlation coefficient (ICC) ≥ 91. Similar figures for intra and inter-examiner reliability for PAR scores have been reported by Mayers et al. (2005). The PAR score is heavily weighted towards overjet, centrelines and overbite all of which have aesthetic and functional implications and therefore of most importance to patients as well. Weighted PAR scores can be easily interpreted and analysed making the index useful for research and audit purposes. Since the PAR score is calculated on dental study casts, it has the added advantage of not requiring the patient to be present when conducting analyses.

However, PAR scoring dental study casts can be time consuming. The index can also be misleading with regard to the complexity of a malocclusion/treatment provided. For example, well-aligned arches with an impacted maxillary permanent canine and retained deciduous canine will score very low both before and after orthodontic treatment (if the permanent canine is aligned) and potentially even show worsening of the score despite a positive outcome. Furthermore, the PAR index does not take into account pre-treatment malocclusions and therefore whether the weighting of the overjet, overbite and centrelines is appropriate. The index also does not consider patient experiences and whether functional benefit and long term stability have been achieved. This makes it difficult to use the index on its own as a measure of quality of care provided. Lastly, the PAR index does not consider whether there have been other adverse outcomes of treatment such as decalcification and root resorption.

1.4 Aims of the study

The aim of the present study was to determine whether there was any clinical difference in the rate of overjet reduction using a Twin Block appliance or a Button & Bead appliance. A

clinically significant difference between the two appliances would be important for determining how future orthodontic care for growing patients with class II malocclusions is managed.

The primary objective of this study was to compare the time taken for overjet reduction between the Twin Block and Button & Bead appliances.

The secondary objectives of this study were:

- To compare the Button & Bead and Twin Block appliances dento-occlusal outcomes as measured by the PAR index.
- To compare patient compliance with the Button & Bead and Twin Block appliances and identify causes for failure.
- To compare the health economics of the Button & Bead and Twin Block appliances (cost of appliances, number of visits, number and cost of repairs and/or replacements).

The null hypothesis was there is no difference in the time taken to reduce the overjet between the Twin Block appliance and the Button & Bead appliance.

Chapter 2

PATIENTS AND METHODS

Ethical approval for this study was obtained from the West Midlands – South Birmingham Research Ethics Committee (REC Reference: 17/WM/0158, IRAS project ID: 219179). Local National Health Service (NHS) Research and Development (R&D) approval was obtained from Birmingham Community Healthcare (BCHC) NHS Foundation Trust. The University of Birmingham agreed to act as a Sponsor for this project (Sponsor Reference: RG_16-204).

2.1 Trial design

The study was conducted as a prospective, single centre, two-arm parallel, randomised controlled trial with a 1:1 allocation ratio.

2.2 Participants

Patients for this trial were recruited from existing treatment waiting lists and new patient consultation clinics. Patients were screened and if they fitted the eligibility criteria, they were invited to participate in the study. An invitation letter (Appendix I), participant information leaflet and parent information leaflet (Appendix II) were given to the patient and their parent/guardian. Appropriate consent and assent (Appendix III) for participation in the research study were obtained from the carer and patient respectively prior to enrolment in the trial. Baseline records (dental study casts, clinical photographs, appropriate x-rays, occlusal measurements, standing height and weight) were then collected. After fit of the appliances and provision of information leaflets for the appliances (Appendix IV), patients in both

groups were seen every 4 weeks. Occlusal measurements (overjet, overbite, canine relationship, molar relationship, centrelines, maximum protruded overjet), standing height, number of hours of reported wear of appliance and any breakages / loss of appliance was recorded at each of these visits until the functional appliance phase of treatment was complete (Appendix V).

Patients were deemed to have completed the functional appliance phase of treatment when the overjet was reduced to below 4mm. At this point the functional appliance was withdrawn for 48-72 hours and occlusal measurements recorded again to reduce the habitual postural element in the measurements. If the overjet increased, the patient was instructed to return to wearing the appliances 24 hours a day as directed previously until the overjet was reduced to below 4mm again.

At the end of functional appliance treatment, further records (dental study casts, clinical photographs, a lateral cephalogram x-ray, occlusal measurements, standing height and weight) were taken. The dental study casts enabled the PAR scores to be calculated. Transition to fixed appliances was carried out in one of two ways:

a. Reduction of functional appliance wear to part-time (usually night only wear) for those assigned to the Twin Block group.
b. Use of an upper removable appliance with a steep inclined bite plane to maintain postured bite, a midline screw for expansion as needed and Adams' cribs for retention for those assigned to the Button and Bead group.

2.2.1 Eligibility criteria

Inclusion criteria:

- Overjet greater than 7mm
- Age 10 – 14 years inclusive
- English speaking
- No previous orthodontic treatment or mid-arch extractions
- Patient suitable for orthodontic treatment in terms of dental health and oral hygiene, as judged by the treating clinician

Exclusion criteria:

- Patients with craniofacial syndromes/cleft lip and palate
- Allergy to any material used in appliance manufacture

2.2.2 Trial setting

The trial was undertaken in the Orthodontic Department at Birmingham Dental Hospital, United Kingdom, a secondary/tertiary NHS hospital setting. Orthodontic treatment was provided by consultants and specialty registrars.

2.3 Interventions

Twin Block

The clinical intervention for patients in this group was a modified Clark's Twin Block. Retention for the appliances was obtained from Adams' clasps on the first premolars and first permanent molars with additional anterior retention in the lower appliance using an acrylated labial bow. A midline screw was also incorporated into the upper appliance to enable maxillary expansion if necessary. Approximately 7-8mm of protrusion was registered using standard clinical practice and bite blocks of 7-8mm with 70 degree incline were used. Patients were instructed to wear the appliances for 24 hours a day, except during tooth brushing and contact / water sports, but including whilst eating.

Button & Bead

The clinical intervention for patients in this group was a Button & Bead appliance. As described previously, it consisted of a vacuum formed upper appliance constructed from a vacuum form blank with a 4mm plastic bead placed on the disto-palatal cusp of the first permanent molars and a second upper appliance with the bead on the mesio-palatal cusps of the first permanent molars (Centrilux vacuum/ pressure forming material, clear rigid 1.50mm thick: WHW Plastics, Therm road, Cleveland Street, Hull HU8 7BF tel 01482 329154 www.whwplastics.com). This was trimmed to a retainer shape with half coverage of the labial surface of the upper incisors, to allow for buttons or brackets to be bonded on the upper lateral / central incisors. If the maxillary second permanent molars had erupted, the appliance would provide occlusal coverage to prevent over-eruption. The lower appliance was a vacuum formed retainer from 0.030 inch / 0.75mm Essix ACE material, with clear acrylic added to form thin posterior bite-planes and extended to the distal aspect of the lower first permanent

molar. The lower appliance was relieved around the buccal surface of the first permanent molar to allow for attachment of buttons or molar tubes.

Composite buttons were placed on the buccal surface of the upper lateral / central incisors and metal buttons or molar tubes on the lower first permanent molars. This allowed for attachment of Class II inter-maxillary elastics (Orange 6.4mm 4.5oz elastics; TP Orthodontics). Patients were instructed to wear the appliance, with concurrent use of the elastics, for 24 hours per day, except during tooth brushing and contact / water sports, but including whilst eating.

2.4 Outcomes

Primary outcome measure

The primary outcome measure was the rate of overjet reduction. Occlusal measurements taken at baseline and at the end of functional appliance treatment were used to calculate this. The time taken for overjet reduction was calculated using the date on which the appliance was fitted and the date on which active functional appliance treatment was completed.

Secondary outcome measures

- Change in PAR (measured as a percentage and actual PAR score)
- Drop-out rate (measured as a percentage)
- Cost of appliances, number of visits, number and cost of repairs/replacement of appliances

2.5 Sample size calculation

The sample size calculation was based on preliminary audit data of 28 patients showing a mean time of treatment to overjet reduction of 8.5 months with a standard deviation of 4.2 months. Assuming a reduction in treatment time by 4 months with the Button & Bead appliance compared to the Twin Block appliance (deemed clinically important), a sample size of 24 patients in each group would be required. In order to account for attrition bias (due to dropouts and incomplete data in each group), the sample was set at 32 patients in each group. Power was set at 90% and the significance level was set at 0.05.

A patient was classified as noncompliant for both treatment groups if the patient refused to wear the appliance, if he or she broke or damaged the appliance on 3 or more occasions, or persistently failed to attend for follow-up appointments. If the overjet was not reduced by at least 10% after 9 months it was likely to be due to the patient not wearing the appliance and that patient was considered to be non-compliant. In such a situation, the treatment plan was reviewed by the clinician and alternative options discussed with the participant and their parent / guardian and the patient was then excluded from the study.

2.6 Randomisation

Randomisation was by block randomisation with variable block size stratified for gender created by the statistician using a computer generated sequence. Allocation was concealed and study data was collected and managed with the assistance of a secure, web-based application Research Electronic Data Capture (REDCap) tool hosted at University of Birmingham (Harris et al., 2009). Participants were enrolled by treating clinicians who confirmed eligibility. Once eligibility criteria had been confirmed and all baseline assessments were completed and

entered onto REDCap, the assigned co-investigator (Dr Kotecha) was contacted to assign the intervention by accessing the REDCap application.

Due to the nature of the study, it was not possible to blind the patient or the treating clinician to the study group. A PAR calibrated examiner was used to measure PAR scores on anonymised models, blinding them to the appliance the patient had received.

2.7 Statistical analysis

The rate of overjet reduction was tested for normality using a Shapiro-Wilkes test and confirmed as normally distributed ($p=0.171$). Therefore, a two-sample t-test was used to test the null hypothesis that there are no differences in the mean rates of overjet reduction between the two appliances.

The baseline and post-functional PAR scores were tested for normality using a Shapiro-Wilkes test and confirmed as normally distributed ($p=0.105$ and $p=0.522$ respectively). Therefore, a two sample t-test was used to test whether there were differences in baseline and post-functional PAR scores within and between both appliances.

Chapter 3

RESULTS

3.1 Participant flow

The CONSORT flow diagram below shows the flow of patients through the trial.

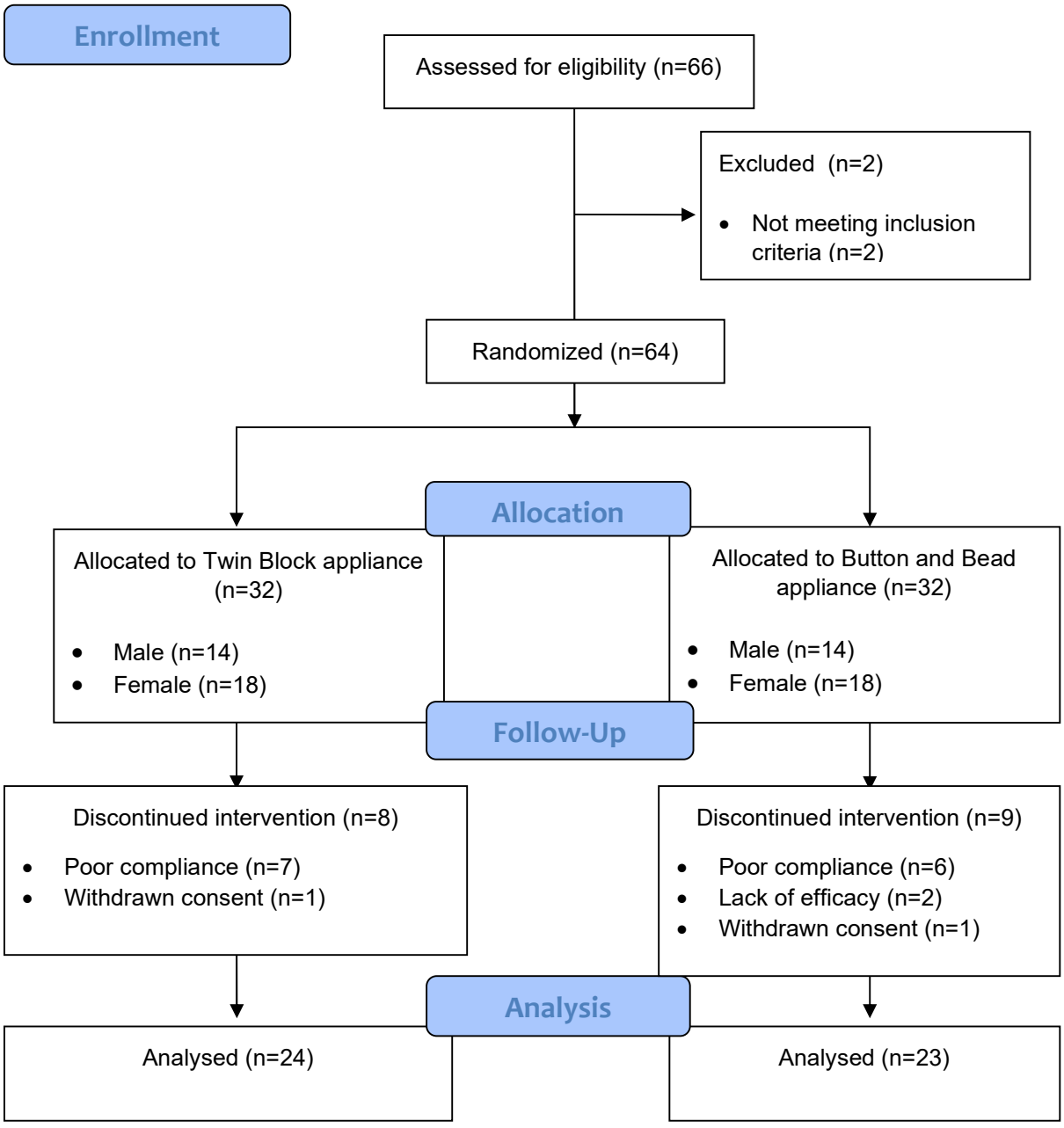

Figure 5: CONSORT flow diagram

3.2 Recruitment

Patient recruitment commenced in July 2017 and was completed in January 2018. Patients were followed up until completion of their assigned functional appliance treatment.

3.3 Baseline data

Table 3.1 shows the baseline gender distribution, age, pre-treatment overjet, maximum protrusion and standing height for the patients who completed their assigned functional appliance treatment in the Twin Block and Button & Bead groups.

	Twin Block (TB) group	Button & Bead (BB) group
Male	12	9
Female	12	14

	Twin Block (TB) group		Button & Bead (BB) group	
	Mean	SD	Mean	SD
Age (Years)	12.3	1.2	12.1	1.1
Overjet (mm)	10.8	2.2	10.9	1.5
Maximum protrusion (mm)	0.8	1.9	1.1	2.3
Height (cm)	158.5	7.5	158.9	9.6

Table 3.1: Baseline combined data for patients who completed their assigned functional appliance treatment in both groups.

Table 3.2 shows the mean, SD and 95% confidence intervals for the pre-treatment overjet of patients who completed their assigned functional appliance treatment. The pre-treatment overjet was similar in both the TB (10.8 ± 2.2mm) and BB group (10.9 ± 1.5mm).

	n	Mean (mm)	SD (mm)	95% Confidence Interval (mm)	
				Lower limit	Upper limit
Males					
TB group	12	10.8	2.0	9.6	12.1
BB group	9	11.4	1.9	10.0	12.9
Females					
TB group	12	10.9	2.5	9.3	12.5
BB group	14	10.5	1.2	9.8	11.2
Combined					
TB group	24	10.8	2.2	9.9	11.8
BB group	23	10.9	1.5	10.2	11.5

Table 3.2: Pre-treatment overjet (mm) for patients who completed their assigned functional appliance treatment.

3.4 Outcomes

3.4.1 Changes in overjet as a result of functional appliance treatment

Table 3.3 shows the final post-treatment overjet for patients that completed functional appliance treatment. The end point for functional appliance treatment in both groups was

deemed as overjet < 4mm. However, if patients presented with broken or lost appliances and the buccal segments were corrected, they were then transitioned into the next phase of treatment. Therefore, the post-treatment overjet was slightly higher than would be expected but similar in both the TB (3.9 ± 1.2mm) and the BB group (4.2 ± 1.3mm).

	n	Mean (mm)	SD (mm)	95% Confidence Interval (mm)	
				Lower limit	Upper limit
Males					
TB group	12	4.2	1.4	3.4	5.1
BB group	9	4.5	1.3	3.5	5.5
Females					
TB group	12	3.6	1.0	3.0	4.2
BB group	14	4.0	1.3	3.2	4.7
Combined					
TB group	24	3.9	1.2	3.4	4.4
BB group	23	4.2	1.3	3.6	4.7

Table 3.3: Post-treatment overjet for patients who completed their assigned functional appliance treatment.

Following a paired Students t-test it was shown that both the Twin Block and the Button & Bead appliance produced a statistically significant reduction (p=0.001) in overjet in males and females, Table 3.4. Each appliance produced a similar amount of overjet reduction ranging from 6.5 ± 0.8mm to 7.3 ± 2.1mm. The 95% confidence for the pre-treatment and post-

treatment overjet changes were similar for both genders in the Twin Block and Button & Bead appliance groups.

	Pre – treatment		Post - treatment		Pre treatment - Post treatment				
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)	Mean difference (mm)	SD (mm)	95% Confidence Interval for the difference (mm)		p-value
							Lower	Upper	
Males									
TB	10.8	2.0	4.2	1.4	6.6	2.2	5.2	8.0	0.001*
BB	11.4	1.9	4.5	1.3	6.9	1.9	5.5	8.4	0.001*
Females									
TB	10.9	2.5	3.6	1.0	7.3	2.1	5.9	8.6	0.001*
BB	10.5	1.2	4.0	1.3	6.5	0.8	6.1	7.0	0.001*

TB = Twin Block
BB = Button & Bead
* Results of a paired Students *t*-test

Table 3.4: Pre and Post-treatment overjet for patients who completed their assigned functional appliance treatment detailing the changes.

3.4.2 Duration of functional appliance treatment

Table 3.5 shows that the duration of treatment using the Twin Block appliance combining the Male and Female group was 300 days ± 121 days and for the Button & Bead appliance was 260 days ± 107 days. Even though the mean difference in treatment duration was 40 days between the appliances the large 95% confidence interval for the difference (-27 to 108 days) highlights the variability of the response.

	Twin Block (TB)		Button & Bead (BB)					
	Mean (Days)	SD (Days)	Mean (Days)	SD (Days)	Mean Difference (TB-BB) (Days)	95% Confidence Interval for the difference (Days)		p-value
						Lower	Upper	
Male	293	126	272	83	21	-80	122	0.699
Females	307	122	253	123	55	-44	154	0.263
Combined	300	121	260	107	40	-27	108	0.236

Table 3.5: Duration of treatment using the Twin Block appliance and the Button & Bead appliance.

3.4.3 Rate of overjet reduction

The rate of overjet reduction (mm/month) for patients who completed their assigned functional appliance treatment is shown in Table 3.6. The results of a two-sample *t* test showed there was no statistically significant difference in the rate of overjet reduction between a Twin Block appliance and a Button & Bead (0.1mm/month) appliance in males (p=0.926) and in females (p

= 0.457). Given there was no difference in the rate of overjet reduction between males and females, the two groups were combined and following a two-sample t test, the results showed there was no statistically significant difference (0.1 mm/month) in the rate of overjet reduction using a Twin Block or Button & Bead appliance (p = 0.517).

	n	Mean (mm/ month)	SD (mm/ month)	95% Confidence Interval (mm/month)		p-value
				Lower limit	Upper limit	
Males						
TB group	12	0.9	0.5	0.6	1.1	
BB group	9	0.8	0.4	0.6	1.1	
Difference (TB-BB)		0.1		-0.4	0.4	0.926
Females						
TB group	12	0.9	0.5	0.6	1.1	
BB group	14	1.0	0.6	0.7	1.4	
Difference (TB-BB)		-0.1		-0.6	0.3	0.457
Combined						
TB group	24	0.9	0.5	0.7	1.0	
BB group	23	0.9	0.5	0.7	1.2	
Difference (TB-BB)		-0.1		-0.4	0.2	0.517

Table 3.6: Rate of overjet reduction (mm/month) for patients who completed their assigned functional appliance treatment.

Therefore, the null hypothesis that there is no difference in the time taken to reduce the overjet with the Twin Block appliance as compared to the Button & Bead appliance was accepted.

3.4.4 Peer Assessment Rating (PAR) scores

PAR scores were calculated by a blinded, calibrated examiner using baseline and post-functional study models for all patients that completed their assigned functional appliance treatment Table 3.7. PAR scores were not calculated if the study models were missing or damaged. Twenty-six PAR scores (13 baseline and 13 post-functional) were repeated by the examiner to ensure consistency of measurement. Intra-rater reliability was assessed using intraclass correlation coefficient (ICC). The ICC was 0.94 (95% CI 0.87-0.97) suggesting excellent reliability in the measurement of PAR scores.

	Twin Block (n = 22)		Button & Bead (n = 18)		Mean differences	p-value
	Mean	SD	Mean	SD		
Baseline PAR score	35.9	7.8	34.9	6.4	1.0	0.659
Post-functional PAR score	25.2	11.7	23.1	10.7	2.1	0.556
PAR score reduction	11.0	11.6	12.8	7.3	-1.8	0.575
PAR % reduction	29.6	31.1	37.4	22.9	-7.8	0.380

Table 3.7: Changes in PAR scores as a result of treatment.

Two-sample t tests showed there were no statistically significant differences (p = 0.659) between the Twin Block group and Button & Bead group in baseline PAR scores (1.0), post-

functional PAR scores (2.1, p = 0.556), PAR score reduction (-1.8, p = 0 .575) and PAR percentage reduction (-7.8, p = 0.38).

Paired t tests showed there were statistically significant differences between the post-functional and baseline PAR scores in the Twin Block (-10.7, p<0.001) and Button & Bead (-11.8, p<0.001) groups.

3.4.5 Patient dropout

Sixty-four patients were randomised and allocated on a 1:1 basis to the Twin Block and Button & Bead groups. In the Twin Block group, the appliance treatment was discontinued in 8 patients. One patient withdrew consent and the other 7 were due to poor compliance. In the Button & Bead group, treatment was discontinued in 9 patients. One patient withdrew consent and 6 patients were deemed to have poor compliance. The remaining 2 patients reported wearing the appliance as directed and there were signs of wear but seemed not to respond to treatment suggesting lack of efficacy.

The Twin Block group had a 25% dropout rate and the Button & Bead group had a 28.1% dropout rate. The combined mean total dropout rate was 26.6%.

3.4.6 Cost effectiveness

There were a total of 279 follow-up visits (of patients who completed their assigned functional appliance treatment); 137 follow-up visits for patients in the Button & Bead group and 142 follow-up visits in the Twin Block group. This equates to on average, 6 follow-up visits per patient in both groups.

There were 3 instances of patients losing the Button & Bead appliance, but no patients lost Twin Block appliances, Table 3.8. In 76 out of 279 follow-up visits (27%), an appliance breakage was identified. 63% of these breakages (n = 48) were in the Button & Bead group and 27% were in the Twin Block group (28). In the Button & Bead group, 29 out of the 48 breakages required a remake of the appliance, 16 required a repair and 1 did not require either a repair or remake. In the Twin Block group, 9 out of the 28 breakages required a remake of the appliance, 15 required a repair and 4 required neither a repair nor remake.

No instances of significant harm or adverse effects was reported with either appliance.

	No. of follow up visits	No. of times appliance lost	No. of times appliance broken	No. of repairs	No. of remakes
Twin Block group	142	0	28	15	9
Button & Bead group	137	3	48	16	29
Total	279	3	76	31	38

Table 3.8: Number of follow up visits, lost appliances and breakages. Number of appliances repaired / remade.

Table 3.9 shows that the lower appliance was more likely to be broken in the Twin Block group (86%) whereas in the Button & Bead group it was more likely to be the upper appliance

that was broken (79%). The majority of breakages in both groups were in the acrylic component of the appliances.

These appliances were made in the laboratory within Birmingham Dental Hospital. An arbitrary charge is assigned to the appliances when billing the orthodontic department. However, if these appliances were to be made in a commercial laboratory, the average charges for the Twin Block appliance and Button & Bead appliance are likely to be around £100 and £75 respectively. This is reflective of the time taken to manufacture the appliances and the material costs involved.

	No. of follow up visits	No. of times appliance broken	Appliance broken			Broken component				
			Upper	Lower	Both	Acrylic	Clasp	Labial bow	Bracket	Button
Twin Block group	142	28	3	24	1	21	11	1	N/A	N/A
Button & Bead group	137	48	38	8	2	34	N/A	N/A	4	10
Total	279	76	41	32	3	55	11	1	4	10

Table 3.9: Number and type of appliance breakages.

Chapter 4

DISCUSSION

This study was part of a larger study on the same group of patients with the aim of conducting a randomised controlled trial to determine whether there were any differences between two functional appliances to correct class II malocclusions. The design of this study was modelled on similarly conducted randomised controlled trials by O'Brien et al. (2003a), O'Brien et al. (2003b). In addition to the dental, skeletal and psychosocial effects studied in these trials, our current study also investigated the 3D soft tissue effects of these appliances.

This part of the study primarily investigated the clinical and dental effects including the rate of overjet reduction, occlusal outcomes using the PAR index and simple cost effectiveness measures. Although this discussion will focus on this, it is important to understand the context of the wider study under which these findings should be interpreted.

Baseline data between the two groups was comparable and confirmed that the randomisation, which was of variable block size and stratified for gender worked as intended. As mentioned previously, the ideal time to carry out functional appliance treatment is during an individual's pubertal growth spurt but predicting this is difficult and does not correlate well with chronological age. We therefore chose a slightly larger age range (10-14 years) for the inclusion criteria, similar to studies by Lund and Sandler (1998) and Yaqoob et al. (2012), compared to the studies by Campbell et al. (2020) and O'Brien et al. (2003b) (11-14 years). The other patient inclusion and exclusion criteria were similar to the study by O'Brien et al. (2003b).

The Twin Block appliance was chosen as the functional appliance to which the intervention (Button & Bead appliance) would be compared as it is the most commonly used functional appliance in the UK (Chadwick et al., 1998). Therefore, it may be argued that there may be some bias in the level of experience clinicians may have with both appliances and hence this may affect the results of the study. The functional appliance treatment in this study was provided by consultants who were equally familiar with both appliances and registrars at the same early stage in their orthodontic training supervised by these consultants.

The findings of this study shows that there is no difference between the rate of overjet reduction between the Twin Block appliance (95% CI 0.7-1.0 mm/month) and the Button & Bead appliance (95% CI 0.7-1.2 mm/month). Both appliances were equally successful in reducing the overjet on average by roughly 7mm. This is similar to the findings by Lund and Sandler (1998) who reported a mean overjet reduction of 7.5mm. These findings need to be interpreted together with the skeletal, cephalometric and soft tissue effects to quantify and validate the extent to which this was as a result of dento-alveolar or skeletal change. The study into the cephalometric effects of both these appliances revealed that there was statistically and clinically significant increased upper incisor retroclination in the Button & Bead group compared to the Twin Block group. Furthermore, the Twin Block group showed a statistically significant increase in mandibular skeletal variables such as mandibular length, mandibular base position and SNB. No difference in the change in lower incisor inclination between the two appliances was found (-0.9°, p=0.372). Therefore it may be argued that the majority of overjet reduction in the Button & Bead group is through dento-alveolar tipping of the upper and lower incisors whereas it is likely to be more of a combination of skeletal and dento-alveolar change in the Twin Block group. The soft tissue changes in the anteroposterior direction reinforced the skeletal changes with statistically and clinically significant retraction

of the upper lip in the Button & Bead group and statistically and clinically significant greater horizontal anterior movement of the chin in the Twin Block group (1.9mm, p= 0.001). In addition to this, there were statistically and clinically significant greater vertical changes noted in the Button & Bead group with particular reference to the upper lip, lower lip and chin. Although a direct causal link cannot be made between these findings and the mode of treatment, one can postulate that these dental, skeletal and soft tissue changes may be expected from the use of an appliance that is heavily reliant on the use of class II intermaxillary elastics.

In order to account for patient dropout and incomplete data, 64 patients were recruited to the trial with 48 patients needed for the study to be adequately powered for the primary outcome measure. Although only 47 patients completed their assigned functional appliance treatment successfully (24 in the Twin Block group and 23 in the Button & Bead group) and the sample size was not met, the results are unlikely to be affected by one more patient completing Button & Bead appliance treatment. Ideally, an intention to treat analysis would be conducted to account for this attrition bias but it is beyond the scope of this thesis to do so. Missing or damaged study models has also resulted in further attrition in the PAR data. The overall patient dropout (failure to complete treatment) rate in this study is 26.6% (28.1% in Button and Bead group and 25% in Twin Block group). This was lower than the dropout rate reported for the Twin Block group (33.6%) in the study by O'Brien et al. (2003b) but more than that reported in the Herbst group (12.9%) in the same study and more than that reported in the Twin Block group (16%) in the study by O'Brien et al. (2003a). A recent study by Campbell et al. (2020) had a similar overall attrition of 26.7%.

The method error (intra-examiner reliability) in our study assessed using ICC was 0.94. This shows excellent reliability of the PAR index and adds to the body of evidence already available on the high reliability of this index with ICC > 0.94 reported by Buchanan et al. (1993), DeGuzman et al. (1995) and Mayers et al. (2005). There were statistically significant differences between baseline and post-functional PAR scores in both groups suggesting an improvement in occlusal outcomes. O'Brien et al. (2003a) reported a mean PAR score percentage reduction of 42% (SD = 29.3) in the group treated with a Twin Block compared to a mean PAR score reduction percentage of 29.6% (SD = 31.1) in the Twin Block group and 37.4% (SD = 22.9) in the Button & Bead group in our study. The post-functional study models for our study were taken as soon as the functional appliance treatment was deemed to have been completed successfully whereas the data collection in the study by O'Brien et al. (2003a) was conducted at 15 months from fit of the appliance by which point one would expect on average a 12 month phase of functional appliance treatment and 3 months of transition to be complete. This may account for the apparently better improvement in occlusal outcome. It is difficult to compare PAR score reduction percentage with other studies as final PAR scores have been reported at the point at which both functional and subsequent fixed appliance treatment has been completed. However, a very recent study by Campbell et al. (2020) reported a mean PAR score reduction of 17.1 in their Twin Block group and 15.0 in their Fränkel II group compared to 11.0 in our Twin Block group and 12.8 in our Button & Bead group. Although, both of our groups had a lower PAR score reduction, this study has not reported the variance of these mean PAR score reductions and therefore it is difficult to make any meaningful comparisons with our data. There were no statistically significant differences found between both groups in our study with regard to baseline PAR scores, post-functional PAR scores, PAR score reduction and PAR percentage reduction.

Patients that completed their assigned functional appliance treatment were seen for 6 follow up visits on average. Although we set out with idealistic aims to follow these patients up every 4 weeks, it is likely that we reviewed them closer to every 6 weeks due to various logistical issues. This is confirmed by the mean treatment duration (and standard deviation) of 300 days (± 121 days) and 260 days (± 107 days) in the Twin Block and Button & Bead groups respectively. This amounts to an average 8-10 months of functional appliance treatment. The mean difference of 40 days between the two groups was not found to be statistically significant (p=0.236). The number of regular visits during the functional phase in the study by O'Brien et al. (2003b) for the Twin Block group was similar to our study (5.63) with time in months slightly higher than our study (11.22 ± 1.64 months). A recent study also reported slightly longer treatment duration in the functional appliance phase of treatment with a mean of 376 days (± 101 days) in the Fränkel II group and 340 days (± 102 days) in the Twin Block group (Campbell et al., 2020). There may be various reasons for these differences but a better overview can be gained by comparing overall treatment time rather than just the duration of the functional appliance phase of treatment. The patients in our study will be followed up until any subsequent fixed appliance treatment has been completed. It is only after this data has been gathered that we will be able to make valuable comparisons on the clinical, morphologic and psychosocial effects of these appliances within and between studies.

An appliance breakage was identified at 27% of follow up visits. The majority of these breakages were in the Button & Bead group. There were also 3 instances of loss of the Button & Bead appliance reported with none in the Twin Block group. The Button & Bead appliance is made from a clear material which may explain why these appliances were misplaced or lost compared to the Twin Block appliance which was made with metal clasps and pink acrylic.

There were several repairs and remakes of both appliances. We tried to minimise disruption to the patients and carers as much as possible by attempting to repair or remake appliances on the same day. However, this may not be realistic where there is no on-site laboratory. In the Twin Block group, the acrylic or a clasp on the lower appliance was more likely to fracture as would be expected from clinical experience. In the Button & Bead group, the acrylic and particularly the bead on the upper splint was most likely to fracture. The other breakages in this group were in relation to fractured brackets and buttons to which class II elastics would have been placed. The upper splint in a Button & Bead appliance is made with a thinner material akin to a vacuum or pressure formed removable retainer and therefore may be more prone to fracture particularly from occlusal and functional forces. There is likely to have been a learning curve for the laboratory technicians in making the Button & Bead appliance and this may also have contributed to appliance breakages. A higher percentage of breakages in the Button & Bead group compared to the Twin Block group may be attributed to the aforementioned reasons particularly in light of the fact that the Button & Bead appliance has both fixed and removable components. Contrary to this, only a handful of breakages were reported by Campbell et al. (2020).

A detailed cost effectiveness analysis was not carried out for this study. Based on an assumption that these appliances are made in a commercial laboratory with a turnaround time, the costs per appliance during an average course of treatment are likely to be similar as the Button & Bead appliance is cheaper to manufacture but broke more often compared to the Twin Block appliance. However, the Button & Bead appliance is likely to impact more on the time of the clinician and patients/carers due to the higher frequency of breakages.

As a randomised controlled trial conducted in a single centre, the findings can be used to comment on the efficacy of the Button & Bead appliance. There is no difference in the rate of overjet reduction between the Twin Block and Button & Bead appliances. Therefore, other factors such as clinical experience and patient preference need to be taken into account when making an evidence-based decision to use the Button & Bead appliance. The trial was conducted in a multi-ethnic patient group within a secondary care NHS hospital setting in the United Kingdom and the results of this study can be generalised to a similar population. In order to determine the effectiveness of these appliances and improve the external validity of this study, one must consider a multi-centre trial in various settings, which was unfortunately not feasible in the limited time available for this study. As mentioned previously, we also need to await completion of the fixed appliance phase of treatment for both groups of patients in this study before definitive conclusions can be made.

Chapter 5

CONCLUSIONS

From this study, the following conclusions can be made:

1. Treatment with the Twin Block and Button & Bead appliances resulted in a clinically significant reduction in overjet (ranging from 6.5 ± 0.8mm to 7.3 ± 2.1mm respectively).
2. There is no statistically or clinically significant difference in the rate of overjet reduction (0.1mm/month, p=0.517) between a Twin Block functional appliance and Button & Bead appliance.
3. There are no statistically or clinically significant gender related differences in the rate of overjet reduction between a Twin Block or Button & Bead appliance (0.1mm/month, p=0.926 in males and 0.1mm/month, p=0.457 in females).
4. There are statistically significant differences between post-functional and baseline PAR scores in both Twin Block (-10.7, $p<0.001$) and Button & Bead groups (-11.8, $p<0.001$).
5. There are no statistically significant differences in occlusal outcomes (using the PAR index as a measure) between the Twin Block and Button & Bead groups (-1.8, p = 0 .575).
6. There was a similar but high dropout (failure to complete treatment) rate between the Twin Block (25%) and Button & Bead (28.1%) groups. This was mainly attributed to poor compliance.
7. There was a higher percentage of breakages in the Button & Bead (35%) group compared to the Twin Block (20%) group.

8. The acrylic and clasps on a lower Twin Block were the most likely breakages in the Twin Block group whereas the acrylic and beads on an upper Button & Bead splint were most likely to fracture in the Button & Bead group.
9. No significant harm or adverse effects were reported in either group.

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Appendix I

IRAS Number: 219179
Version 1.3 26/05/2017

UNIVERSITY OF BIRMINGHAM

Invitation letter to participants

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

Dear Participant,

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

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

All the information is enclosed with this letter. You do not have to take part if you do not wish to do so and this will not affect your care at Birmingham Dental Hospital. However, we hope that you will choose to take part and help us to provide the best treatment for our patients.

Yours Sincerely,

Sheena Kotecha
Consultant Orthodontist

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

Birmingham Community Healthcare NHS
NHS Foundation Trust

Appendix II

Participant Information Sheet for Children
Version 1.7 15/06/2017 IRAS Number: 219179

UNIVERSITY OF BIRMINGHAM

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

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

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

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

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

Why are we doing this study?

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

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

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

Are there any risks I should know about?

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

Why am I being asked to take part?

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

What will happen to me if I take part?

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

As part of either treatment, you will have:

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

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

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

What happens when the study is finished?

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

What if there is a problem or something goes wrong?

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

Confidentiality

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

UNIVERSITY OF BIRMINGHAM

Parent Information Sheet

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

UNIVERSITY OF BIRMINGHAM

Why are we doing this study?

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

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

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

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

Are there any risks associated with this treatment?

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

Your child has been invited to take part in this study

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

What is involved in this study?

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

As part of either treatment, your child will have:

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

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

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

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

UNIVERSITY OF BIRMINGHAM

More information about taking part

What happens following completion of the study?

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

What if there is a problem or something goes wrong?

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

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.

Appendix III

IRAS Number: 219179
Version 1.5 15/06/2017

UNIVERSITY OF BIRMINGHAM

Children's Assent Form

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.

Birmingham Community Healthcare NHS
NHS Foundation Trust

IRAS Number: 219179
Version 1.5 15/06/2017

UNIVERSITY OF BIRMINGHAM

Print Name: _____ Job title: _____

Sign: _____ Date: _____

UNIVERSITY OF BIRMINGHAM

Parental Consent Form

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 1.7 dated 15.06.2017 provided to me for the above study. ☐

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

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

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

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

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

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

Print name: _____ Relationship: _____

Sign: _____ Date: _____

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

Birmingham Community Healthcare NHS
NHS Foundation Trust

IRAS Number: 219179
Version 1.4 15/06/2017

UNIVERSITY OF BIRMINGHAM

Name of person taking consent:

Print Name: _____ Job title: _____

Sign: _____ Date: _____

Appendix IV

IRAS 219179
V 1.2 21/03/2017

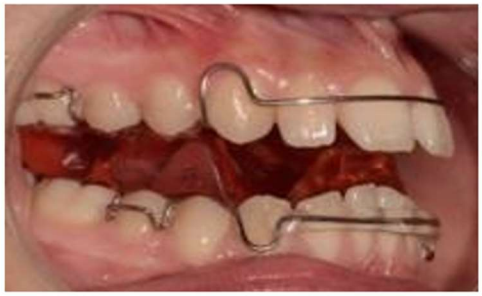
UNIVERSITY OF BIRMINGHAM

PATIENT INFORMATION LEAFLET:

TWIN BLOCK APPLIANCE

What is Twin Block brace?

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



Important rules:

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

Will it be painful?

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

How else will it affect me?

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

Can I eat normally?

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

How do I clean the brace?

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

When can I remove the brace?

- For cleaning
- When playing sports or swimming

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

How long will the treatment take?

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

How often do I need an appointment?

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

What if my brace breaks?

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

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IRAS 219179
V 1.2 19/03/2017

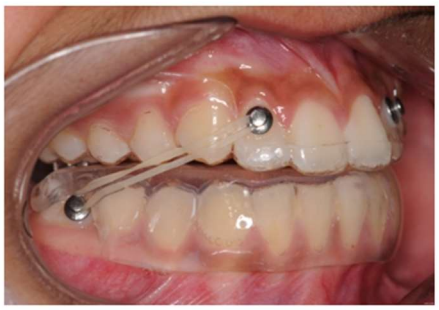
UNIVERSITY OF BIRMINGHAM

PATIENT INFORMATION LEAFLET:

BUTTON & BEAD APPLIANCE

What is Button and Bead brace?

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



Important rules:

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

Will it be painful?

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

How else will it affect me?

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

Can I eat normally?

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

How do I clean the brace?

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

When can I remove the brace?

- For cleaning
- When playing sports or swimming

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

How long will the treatment take?

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

How often do I need an appointment?

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

What if my brace breaks?

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

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Appendix V

Unique patient ID:
IRAS No: 219179
Version 1.5 16/03/2017

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Button and bead trial case report form

Date	Time point B/M/U/T/E (See overleaf)	OJ	OB	R Molar	R canine	L canine	L molar	Centrelines	OJ at maximum protrusion	Height of patient (cm)	Reported appliance wear (hrs)	Appliance damaged?

Please record details of appliance damage/breakage:

Date	Loss/damage (give details)	Outcome – repaired/remade

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Details of adverse event/serious adverse event:

Date	Event	Outcome

Key for time points
B = begin treatment start
M = Mid treatment review
U = Unscheduled appointment
T = end of full-time wear and start of transition period
E = end of functional appliance wear – progress to phase II

Was treatment completed? If not reason for non-compliance	
Date functional fitted	
Date of transition	
Transition Method	
Total time in full-time appliance wear (months)	
Total number of visits with functional (including unscheduled)	
Total number of visits with functional (excluding unscheduled)	
Adverse effects (please detail)	

Start PAR	
End of functional PAR	
End of treatment PAR	
Extractions needed (please state)	
Date of debond	
Total number of visits in phase II (excluding unscheduled appointments)	
Total number of visits including functional	