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A COMPARATIVE CEPHALOMETRIC STUDY OF THE BIONATOR AND TWIN BLOCK APPLIANCES IN THE TREATMENT OF CLASS II MALOCCLUSION

by

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Submitted in partial fulfillment of the requirements for the degree of

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Abstract

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The purpose of this study was to determine whether there is a difference between the Bionator and Twin Block appliances in the treatment of class II malocclusion, with a focus on vertical and angular changes. Records from the office of a single orthodontist who treated with both appliances were obtained, and using discriminant analysis, a subsample of fifty-four Bionator and thirty-eight Twin Block subjects who were equally susceptible to either treatment modality was identified. Subjects were matched between the groups for gender, age at start of treatment, and treatment time resulting a group of thirty pairs of subjects.

Cephalometric analysis failed to show any overall difference in most measures between the Bionator and Twin

Block appliances. However, it was shown that the Bionator differed from the Twin Block in how it produced its class II correction. The Twin Block tends to affect the occlusal plane, moving it in a more clockwise direction, resulting in a greater Wits reduction. This may be of clinical significance although not statistically significant. Nonetheless, both appliances were efficient in correcting class II malocclusions in terms of overjet reduction, molar relationship improvement, and articulare change. Hence, the decision of whether to use a Bionator or Twin Block appliance is basically a patient management decision.

DEDICATION

To Mom, Dad, and Kai

For their love and support in helping make my dream of becoming an orthodontist a reality

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INTRODUCTION

Functional appliances, "a class of removable appliances which utilize the muscle action of the patient to produce orthodontic or orthopedic forces" (Graber 1993), have been used for skeletal correction since 1880, when Kingsley introduced the concept of "jumping" the bite (cited after Rakosi 1997). Functional appliances provide the orthodontist with an additional tool to fixed appliances in correcting among other discrepancies, class II malocclusion. They are categorized into fixed functional appliances such as the Herbst and Mara and removable functional appliances such as the Fränkel, Bionator, and Twin Block (McNamara and Brudon 2001). The latter two are primarily tooth-borne appliances compared to the Fränkel which is primarily tissue-borne.

Pangrazio-Kulbersh and Huge (2001) described the Bionator as one of the most popular functional appliances in the United States, especially during 1970s and 1980s when there was an overall increase in functional

appliance use. Faltin and colleagues (2002) discussed the Twin Block as the most popular clinical alternative to the Bionator. Treatment effects of both functional appliances have been well documented in the literature; these findings, however, have generally focused on changes in the horizontal dimension. Vertical changes, or the lack of them, can contribute greatly to the success or failure of class II correction. Hence, there is a need to evaluate changes in the vertical dimension. This study compares the treatment effects of the Bionator and Twin Block appliances in order to determine whether these appliances can be used interchangeably.

LITERATURE REVIEW

The Bionator Appliance

The Bionator appliance was developed by Wilhelm Balters in the early 1950s and is a modification of the activator appliance (as cited by Rakosi 1997). According to Balters (1964), the equilibrium between the tongue and the circumoral musculature was responsible for the position of the teeth in the transverse plane. In order to develop normally, he thought that functional space for the tongue was necessary with the circumoral musculature playing a lesser role. Hence, Balters' goal was to eliminate any imbalance of the tongue which might lead to abnormal growth. The Bionator was created for posturing the mandible forward anteriorly in order to allow for proper tongue posture, and to help with lip closure, enabling the patient adapt to a normal functional pattern.

The Design of the Bionator

Each Bionator needs to be designed based on an individual's unique malocclusion. Although one may read

of "standard" designs, this should be interpreted carefully as specific components may be added or removed depending on the requirements of the patient (Pangrazio-Kulbersh and Huge 2001). Balters (1964) described three main types of Bionators: a basic Bionator, one with tongue shields to correct open bites, and one to correct Class III malocclusions. Here, three main designs will be discussed: Bionators to open the bite, to close the bite, and to maintain the bite. In these designs, the main goal of the Bionator is to advance the mandible in a forward position.

The basic design of the Bionator is a horseshoe shaped acrylic plate with a maxillary palatal bar (Coffin spring) and a labial bow. The palatal bar has a posterior curve because it is intended to stimulate the dorsal surface of the tongue, allowing it to orient itself forward. It also aids in giving the appliance stability. The labial bow supports lip closure and helps in keeping the incisors upright. In the posterior region, the loops of the labial bow called buccinator loops keep the cheeks away from the teeth so that they are shielded from muscular influences. There is a lingual acrylic shield in the posterior region which is

also meant to prevent the tongue from affecting the teeth. With these buccal and lingual shields, selective tooth eruption through acrylic trimming can take place.

A Bionator used to open the bite has anterior capping of lower incisors for both retention and maintenance of their vertical and sagittal position (Pangrazio-Kulbersh and Huge 2001). There is interocclusal acrylic in the posterior area which when trimmed, allows for eruption.

A Bionator used to close the bite may or may not have anterior occlusal coverage depending the type of open bite the patient has (Pangrazio-Kulbersh and Huge 2001). If the open bite is of dentoalveolar origin, there would be no acrylic in the anterior region to allow for eruption of the upper and lower incisors. If the open bite is of skeletal origin with an acceptable smile line, there should be lower incisor acrylic coverage and upper incisor contact with this acrylic to prevent anterior incisor eruption. Facebow tubes can be added to the acrylic to facilitate headgear wear to aid in vertical control. A posterior bite block would be included in both types of Bionators used to close the bite.

A Bionator used to maintain the vertical dimension of the bite while repositioning the mandible forward has all the acrylic and wire parts of the anterior and posterior areas contacting the teeth (Pangrazio-Kulbersh and Huge 2001). This would allow the clinician maximum control of the vertical dimension of all the teeth.

The Effects of the Bionator

As the Bionator is a modified version of the Activator, which was originally developed by Andresen in 1908(as cited by Rakosi 1997), there is larger volume of research on Activators than Bionators. Bionator studies that examined treatment effects in the literature, as well as one two-part activator study, will be discussed (Table 1). Research by Illing and coworkers (1998) and Tümer and Gültan (1999) compared the Twin Block and Bionator appliances directly; their studies will be discussed in a separate section.

Horizontal Effects

Bolmgren and Moshiri (1986) examined twenty patients first treated with a Bionator, then with fixed appliances. They were compared to an untreated sample from the Michigan Growth Study and a group treated with fixed appliances only from the Rocky Mountain Data

TABLE 1.--Summary of the Literature on the Bionator.

AUTHOR	YEAR	TYPE OF STUDY	CONTROL GROUP	SIZE OF BIONATOR GROUP
De Almeida et al.	2002	Retrospective	Untreated class II patients	22
Tümer and Gültan	1999	Prospective	Untreated class II division 1 patients	13
Tulloch et al.	1998	Prospective	Untreated class II patients	53
Keeling et al.	1998	Prospective	Normative Growth Data; Matched	78
Illing et al.	1998	Prospective	Untreated class II division 1 patients	16
Courtney et al.; Nelson et al. (two-part study)	1996 1993	Prospective	Untreated class II patients	Activator Group of 12
Bolmgren and Moshiri	1986	Retrospective	Untreated patients from Michigan Growth Study and treated patients from Rocky Mountain Data	20

Systems Records. The average age at the start of Bionator treatment was 11.8 years for males and 11.1 years for females. The average treatment time with the Bionator was 12.7 months and with fixed appliances was 15.9 months. No statistically significant differences between groups were found with regards to the maxillary skeletal parameters. They did, however, find that the Bionator group demonstrated more uprighting of the maxillary incisors. The mandibular dental parameters did not show any significant difference for all four groups. They felt that because they made use of mandibular

incisor capping, there was good control against mandibular incisor flaring. The mandibular length increase of 5.05 mm after treatment with the Bionator was only slightly more than the mandibular length of the fixed appliance controls at 4.44 mm. Overall, they concluded that major changes were accomplished with whichever appliance was used first, regardless of whether it was the Bionator or fixed appliances. In interpreting their results, it is important to note that their sample size was small, there was no description of their sampling method and level of statistical significance used, nor was there data charts showing their actual numerical findings for the cephalometric parameters examined.

De Almeida and coworkers (2002) carried out a retrospective study comparing the Fränkel functional regulator-2 (FR-2) and Bionator with controls. They found there was lingual tipping of upper incisors and labial tipping of lower incisors in both appliances with greater changes in the tooth-borne Bionator than the tissue-borne Fränkel. One would then expect to find more skeletal change in the Fränkel than with the Bionator, however, the reverse was found. Also, with both

appliances, there was no significant restriction of maxillary growth (ANB change = 0°), perhaps because the average bite advancement of 5.0 mm was not large enough to see this headgear effect. The SNB change and effective mandibular length increase in the Bionator group was 1.4° and 4.9 mm respectively versus 0° and 3.0 mm in the control group.

In recent years, there have been large scale randomized clinical trials looking at early class II treatment with Bionators and headgears. Tulloch and colleagues (1997) conducted a randomized clinical trial, starting with 175 patients who met initial screening criteria and were assigned to either a Bionator, headgear, or control group. This study included strict inclusion criteria and treatment standardization. They found that the Bionator patients showed an increase in forward positioning of the mandible with an increase in mandibular unit length compared to the control group. The headgear patients similarly achieved a comparable class II correction to the Bionator patients, but this was through restriction of forward maxillary movement. Tulloch and colleagues did not discuss the vertical changes of the appliances they used.

Keeling and coinvestigators (1998) randomly assigned 249 subjects to either a Bionator, a headgear with biteplane, or a control group. This study employed strict inclusion criteria and blinded examiners to treatment group and stage. They studied the anteroposterior skeletal and dental changes with the Bionator and headgear, finding that there was correction of the class II molar relationships, reduced overjets and apical base discrepancies, and posterior maxillary tooth movement. Unlike Tulloch and colleagues (1997), Keeling and coinvestigators found that there was enhanced mandibular growth in both the Bionator and headgear groups. They also did not report on the vertical changes in their subjects.

In their two-part prospective study, Courtney and colleagues (1996) and Nelson and colleagues (1993) examined the treatment effects of the Harvold activator and Fränkel functional regulator to a control group after eighteen months of appliance wear. In the first part of the study, they examined mandibular changes and in the second part of the study, they examined maxillary changes. Their sample size was small with fifty total subjects in all three groups. They found that the

treatment effects of the two functional appliances were confined mainly to dentoalveolar structures. There was no orthopedic change in the maxilla which corroborates with the findings of Bolmgren and Moshiri (1986) and De Almeida and colleagues (2002). Most of the overjet correction came from tipping of the maxillary incisors lingually with both appliances. There were no horizontal or vertical effects on the maxillary molars. Nelson and colleagues found that the activator proclined the lower anteriors even though they were capped with acrylic. They also found an increase in the gonial angle and articulare-pogonion length. This was attributed to the condyles being positioned downward and forward from treatment. There was, however, no change in the size of the mandible with use of either functional appliance.

Vertical Effects

Bolmgren and Moshiri (1986) discussed that if the mandibular plane angle and anterior face height both increase in value, any actual mandibular growth will be masked by the pogonion moving down and back. In their study, they found more increase in anterior facial height and mandibular plane angle with the Bionator than with fixed appliances alone. De Almeida et al. (2002) found

increases in lower anterior face height in both the Bionator and control groups, but they were not statistically different. With lower posterior face height, there was a statistically greater increase in the Bionator group of 3.7 mm compared to the control group with 2.1 mm. The mandibular plane was not significantly changed in both groups, however there was a tendency for clockwise rotation of the maxillary plane with the Bionator group, although this did not affect the lower anterior face height.

Courtney and colleagues (1996) found that there was a larger increase in the total and lower anterior face height of the Harvold activator group compared to the Fränkel group. They, however, found no significant vertical change in maxillary molar eruption. Nelson and colleagues (1993) studied the mandibular changes in the same sample as Courtney and colleagues and found that there was an increase in anterior face height which was due to increased eruption of the mandibular molar.

The Timing of Treatment with the Bionator

Faltin and coworkers (2003) examined the effect of the Bionator on two groups of class II patients using cervical vertebrae maturation stages to determine if a

difference in skeletal maturation stage could affect treatment results. The early treated group had not entered their peak mandibular growth at the beginning of their therapy while the late treated group received Bionator therapy during the peak of their growth; also, there was an early and late control group. Both treatment groups received fixed appliance therapy after Bionator treatment and were examined six years after Bionator therapy was stopped. They found that the late treated group had greater long term improvement compared to the early treated group in overjet, -4.2 mm versus -1.6 mm, and mandibular lengthening, 5.1 mm versus 1.9 mm. They concluded that Bionator treatment is more stable and effective if started while the patient is still in the pubertal growth spurt.

Mamandras and Allen (1990) studied the mandibular response to the Bionator in forty patients. Twenty patients were successfully treated because of an arbitrary change of 3.5 mm or more in skeletal pogonion position and twenty patients were less successfully treated, having a change of 3.0 mm or less. Both groups were treated to a class I molar relationship dentally. They examined the cephalometric changes through a

customized analysis and found that both groups did not differ in pretreatment cephalometric values, but the larger advancement group did show a significant delay in mandibular growth compared to published mandibular size normative data. The smaller advancement group was not delayed compared to these norms. This might suggest that patients who have smaller jaws can greater benefit from Bionator treatment compared to those with normal sized mandibles. They concluded that the Bionator may help to eliminate growth retarding factors and create a favorable growth environment for those with significant mandibular growth delay. In addition, it is interesting to note that the average pretreatment ages of the males and females in the larger advancement group were 11.8 years and 10.11 years and in the smaller advancement group were 10.6 years and 10.3 years. The patients with larger advancements were older, corroborating with the findings of Faltin and coworkers (2003).

Retention and Post-Retention Effects of the Bionator

Keeling and colleagues (1998) in their randomized clinical trial followed their Bionator subjects for six months after the end of treatment with some of the patients under retention with the same appliance and the

other half unretained. There was also an additional six months post-retention follow up with the Bionator discontinued. They found that the skeletal changes were stable during retention and post-retention, but the dental movements relapsed. Their retention protocol of every-other night wear of the Bionator was not effective in preventing dental relapse. They surmise that a different retention protocol, such as nightly wear, or a longer retention period with the appliance could have helped prevent this relapse.

The Twin Block Appliance

The Twin Block appliance, developed by William Clark in 1977, is, as the name implies, a two-piece appliance which uses occlusal inclined planes to guide the mandible forward in order to correct the malocclusion. Clark (1997) refers to the philosophy of form following function, namely that skeletal form can be modified by functional therapy, as the biological basis for the first functional appliance designed by Kingsley and for his appliance. Clark sought to maximize the genetic potential of the growing face and dentition by guiding them towards an optimal pattern of development. He saw the force of dental occlusion as something that could be

directed to cause this change by being transmitted through the teeth to the supporting basal bone and stimulating bony remodeling.

The Design of the Twin Block Appliance

The Twin Block, like all appliances, needs to be designed according to the patient's specific malocclusion. There are numerous different Twin Block designs, but only Clark's design and common modifications will be described.

The Twin Block is composed of two retainer-like pieces. The maxillary part of the appliance is made up of thin palatal acrylic coverage with thick acrylic posterior bite blocks. There is often a midline screw to allow for palatal expansion for those who are maxillary transverse deficient. The maxillary part is held in place by the close fitting acrylic palate and clasps on the first premolars and molars. The location of the clasping is dictated by which teeth are present during appliance construction. Clark (2002) uses a combination of delta clasps on the molar and ball clasps for the premolars. The anterior part of the bite block terminates in an inclined plane at a 70° angle to the occlusal surface and is where the block of the mandibular

part functions against. The position of the inclined plane is mesial to the first permanent molars. Early in the development of this technique, Clark experimented with the location of the inclined plane, moving it to the area of the first premolars but found that there was less resultant functional force corresponding to a lesser treatment response.

The mandibular part of the appliance consists of a horseshoe shaped acrylic piece which is stopped mesial to the mandibular first molars to allow for their eruption. Close fitting acrylic and delta clasps on the premolars and ball clasps on the anteriors are used in Clark's design to hold the lower appliance in place. There is the posterior bite block acrylic which has a 70° angle to the occlusal surface inclined plane at its posterior termination, allowing contact against the upper block. This contact is what allows the mandibular functional protrusion to occur.

McNamara (2001) describes the use of a labial bow with acrylic similar to that of a spring retainer in his modification, although the incisor positions on the cast are not altered with the Twin Block. He explains that the incorporation of this labial bow helps control lower

incisor proclination during treatment. He also extends the acrylic to the lingual surface of the permanent molar region for more retention. Modifications made by other clinicians include incorporating a lower midline screw and anterior acrylic capping. Mills (1998) solders an elastic hook to the upper and lower delta clasps to allow vertical elastics to be worn at night so that the patient maintains the mandible closed in a protruded position during sleep.

Like the Bionator, the Twin Block can be designed to close anterior open bites. This design would cover all upper posterior teeth and provide occlusal rests for all lower posterior teeth. There could be a shield of acrylic extending to the cingulums of the upper and lower anterior teeth which helps in controlling tongue thrust habits, but there would need to be sufficient relief of the acrylic to allow the anterior teeth to erupt.

The Effects of the Twin Block Appliance

In recent years, as the Twin Block Appliance continues to gain popularity as a functional appliance, numerous research efforts have being aimed at elucidating its treatment effects (Table 2). Studies, both prospective and retrospective, have attempted to control

as many variables as possible. Some of these studies have concentrated solely on the effects of the Twin Block while others have compared the Twin Block to other functional appliances.

Table 2.--Summary of the Literature on the Twin Block.

AUTHOR	YEAR	TYPE OF STUDY	CONTROL GROUP	SIZE OF TWIN BLOCK GROUP
O'Brien et al.	2003	Prospective	Untreated class II division 1 patients	87
Trenouth	2000	Retrospective	Normative Growth Data; Matched	30
Toth and McNamara	1999	Retrospective	Michigan Growth Study; Matched	40
Tümer and Gültan	1999	Prospective	Untreated class II division 1 patients	13
Illing et al.	1998	Prospective	Untreated class II division 1 patients	16
Mills and McCulloch	1998	Retrospective	Burlington Growth Study; Matched	28
Lund and Sandler	1998	Prospective	Untreated class II division 1 patients	36

Horizontal Effects

O'Brien and colleagues (2003) dichotomized studies into those that evaluate the efficacy of treatment and those whose goal was to evaluate the effectiveness in treatment. They described that most studies, which are carried out in one center by one to four operators, look at "the provision of care under ideal conditions" and might not be relevant in actual orthodontic practices.

Their approach was to look at the effectiveness of treatment—"the provision of care under conditions that are more relevant to the setting under which the proposed care is routinely provided." Their randomized, controlled study carried this out by involving fourteen hospital-based orthodontists, each at a different center.

O'Brien's group (2003) divided 174 children, aged 8-10 years old, into a treatment or control group and collected cephalometric data on them at the start of the study and after fifteen months of Twin Block treatment. In their analysis, they found that they successfully reduced dental overjet, molar discrepancies and the severity of the malocclusion through dental and skeletal change. Skeletal change was responsible for 27% of overjet correction and 41% of molar change. This skeletal change amounted to 1.9 mm which, in their opinion, is not considered clinically significant even though it is statistically significant. Instead, they found that the most important changes from treatment were dentoalveolar. Their findings indicated a much smaller contribution of skeletal change than previous studies because they analyzed all patient records regardless of the outcome of treatment which likely diluted the size of

their treatment effect. Also, they mentioned that other studies used historical control groups which might not be as directly comparable to the respective study's sample. O'Brien and colleagues concluded that early treatment with a Twin Block did not change the class II skeletal pattern to a clinically significant degree.

Lund and Sandler (1998) conducted a prospective study with thirty-six subjects in the treatment group and twenty-seven subjects in the control group. The mean initial age was 12.4 years for treatment subjects and 12.1 years for control subjects. The average treatment time was 0.9 years. They found that most of the overjet correction was through dentoalveolar change and is consistent with O'Brien and coworkers' (2003) finding. The mean initial overjet was 8.2 mm with a mean overjet reduction of 7.5 mm, involving a net 10.8° maxillary incisor retroclination and 7.9° mandibular incisor proclination. Lund and Sandler found that the most noticeable skeletal change was an increase in SNB, statistically significant at 1.9°. Although small, in their view, this increase was very worthwhile. They could not find any significant maxillary skeletal restraint (SNA decreased 0.1°) although there was slight

distal movement of the upper molars helping in buccal segment correction. Lower molar eruption in an anterior and superior direction also contributed to the correction.

Trenouth (2000) conducted a retrospective Twin Block study, matching patients individually for age, sex, and treatment time with normative growth data derived from class I London school children. Trenouth studied thirty patients with an average age of 12 years 6 months. To see if treatment effects were clinically significant, he compared the changes to twice the method error. He found ANB reduced 2.6°, mainly due to a 2° increase in SNB. Trenouth concluded that the combination of maxillary incisor tipping (14.4°) and bodily correction of the dental base through ANB change resulted in the reduction of overjet by 7 mm or more. Still, the class II dental base relationship was not completely corrected to that of the class I controls.

Mills and McCulloch (1998) carried out a retrospective study on twenty-eight patients with twenty-eight untreated class II controls from the Burlington Growth Center. Average age of the treatment and control groups was 9 years 1 month and average treatment time was

fourteen months. The controls were matched with the treatment group for age, gender, and overbite. Pretreatment difference was found due to the Twin Block group having a more severe class II malocclusion than the controls prior to appliance wear. In the treatment group, overjet decreased an average of 5.6 mm with nearly two thirds of this accounted for by the forward growth of the mandible. The mandible increased by 6.5 mm in unit length in the treatment group compared to 2.3 mm in the control group. Two thirds of this 6.5 mm could be attributed to an increase in ramus height and one third to an increase in body length. Mills and McCulloch emphasized that functional appliances need to express growth in a horizontal direction to aid in skeletal correction.

In Mills and McCulloch's study (1998), lower incisors tipped 5.2° and 1.4° labially in the treatment and control groups respectively. In his treatment group, Trenouth (2000) found lower incisor tipping to be 1.1° and Lund and Sandler (1998) found it to be 7.9°. These differences demonstrate that the magnitude of dental treatment effects can vary depending on the design of the appliance. On the lower anterior segment, Mills and

McCulloch used an acrylic labial bow while Lund and Sandler used ball clasps. Trenouth used Southend clasps which he described as providing more rigid retention, hence resulting in the least lower incisor tipping. Appliance design can help explain some of the different treatment effects when comparing various studies.

Toth and McNamara (1999) compared the treatment effects of the Twin Block and the Fränkel functional regulator-2 (FR-2) appliance to an untreated class II sample. Forty patients were in each of the three groups. The Twin Block patients had an average age of 10 years 5 months, Fränkel patients were 10 years 2 months, and control patients were 9 years 11 months. With regards to mandibular skeletal measures, they found a significant increase in SNB in Twin Block patients, 1.6° compared to 0.3° in the controls and 0.6° in the FR-2 patients. They, however, found minimal maxillary skeletal effects from either appliance.

Often times, there is mention of the skeletal headgear effect of functional appliances—namely, that there is maxillary growth inhibition. Toth and McNamara (1999) discussed that if functional appliances are used in combination with extraoral force, there will likely be

a headgear effect; however, none of the Twin Block studies discussed used extraoral force.

Lund and Sandler (1998) did not find any skeletal headgear effect in their study while Mills and McCulloch (1998) found some headgear effect as evidenced by a 0.9° decrease in SNA.

The dental component of the headgear effect was more readily found in all of the Twin Block studies. Upper molars were distalized 1.6 mm in Mills and McCulloch's study (1998). Lund and Sandler (1998) also found slight distalization of the upper molars of 0.7 mm as did O'Brien and his group (2003) with 0.8 mm.

Vertical Effects

Clark (2002) intended that the Twin Block control maxillary molar eruption through acrylic occlusal coverage and enhance mandibular molar eruption through gradual acrylic removal. Through this eruption, deep bites could be corrected. Lund and Sandler (1998) found a significant amount of tipping of the labial segments in both arches but only examined the horizontal component and not the vertical component. They did address the question of maxillary molar control with the Twin Block, reporting that even though the maxillary first molar was

capped, there was some extrusion of the mesial contact point and distal tipping of the molar. Toth and McNamara (1999) also found that they were unable to control the vertical dimension of the maxillary first molar, with 0.6 mm of eruption. Mills and McCulloch (1998) found slight maxillary first molar intrusion of 0.4 mm.

Trenouth (2000) recognized that ANB could be influenced by factors other than dental changes, namely rotation of both jaws relative to the cranial base. He also measured the maxillary-mandibular plane angle and the angle of the cranial base but did not find any significant changes.

Toth and McNamara (1999) found that both the Twin Block and FR-2 produced increases in vertical facial measures with the most pronounced increase in the Twin Block patients. The mandibular plane angle and lower face height increased the most in the Twin Block group, however, there was no significant difference in facial axis angle or palatal plane angle in both groups. Most Twin Block studies focus primarily on horizontal changes and do not address vertical changes in much depth.

The Timing of Treatment with the Twin Block Appliance

Mills and McCulloch (2000) commented that although

many suggest growth modification should be attempted during the pubertal growth spurt, they chose to begin treatment earlier, at a mean age of 9 years 1 month. Their reasons were that earlier treatment might achieve more skeletal correction, Twin Blocks are easier to use when the deciduous molars are still stable because they can be used for clasping, and younger patients can generally adapt easier to the appliance than teenagers.

Baccetti and researchers (2000) examined the effect of the Twin Block on two groups of class II patients using the cervical vertebrae maturation stages to find if a difference in skeletal maturation stage could affect treatment results. At the start, the early treatment group belonged to stage one or two in cervical vertebrae maturation, meaning that it was before the onset of pubertal growth while the late treatment group belonged to stage three, four or five which corresponded to treatment during the growth spurt or shortly after its onset. They found that there was greater skeletal contribution to molar correction for the late group than the early group, 3.2 mm versus 2.5 mm. In addition, there was a larger increase in total mandibular length and ramus height and a more posterior direction of

condylar growth in the late group. Although their cephalometric study was short-term, they concluded that the optimal time for Twin Block treatment is during the growth spurt or shortly afterwards.

Retention and Post-Retention Effects with the Twin Block Appliance

Mills and McCulloch (2000) carried out a follow-up study on the sample they used in their initial Twin Block study. Of the twenty-eight patients from their first study, they were unable to contact two patients, leaving them with twenty-six patients. They retained their patients after having achieved a class I molar relationship with night time Twin Block wear for an average of eighteen months. This was followed by a post-retention period where there was no Twin Block wear for fourteen months. Their post-treatment follow-up cephalogram was taken at a mean age of 13 years 1 month (T3). Once again, they compared their patients with class II control subjects from the Burlington Growth Study. They found that there was a decline in growth of ramus height and forward maxillary growth from T2 (immediately after treatment) to T3 in the treatment group compared to the control group. There was some

uprighting of mandibular incisors, 1.5°, and some slight labial proclination of the maxillary incisors, 0.8°.

Although there was a reduction in mandibular growth rate after treatment, Mills and McCulloch concluded that the favorable skeletal change from active Twin Block treatment was maintained nearly three years later. They felt that because their patients finished at T2 or T3 with molars in occlusion, this posterior bite support could help explain why there was fairly normal, but somewhat diminished mandibular growth increments. Some studies have shown a dramatic decrease in mandibular growth increments in the retention and postretention follow-up years.

Comparison of the Bionator and Twin Block Appliances

Only two studies have directly compared the Bionator to the Twin Block. Tümer and Gültan (1999) prospectively compared thirteen patients treated with monoblock to thirteen patients treated with Twin Block and used an untreated control group which they matched according to age, sex, and vertical and sagittal skeletal and dental characteristics. Both treatment groups exhibited significant ANB decreases attributed mainly to SNB angle increases compared with the controls. A significant

increase in mandibular plane angle was found only in the Twin Block group. Tümer and Gültan believe than an increase in gonial angle helps explain this. Overbite was decreased significantly only in the Twin Block group. They attribute this to the significant increase in the height of the upper and lower posterior alveolar processes while in the monoblock group, they found significant change in the height of the lower alveolar process only. The Twin Block patients showed greater lower incisal proclination while in the monoblock group, upper incisors showed a greater degree of retrusion. Interincisal angle increased only in the monoblock group.

Illing and colleagues (1998) conducted a prospective clinical trial on forty-seven patients comparing the Bass, Bionator, and Twin Block appliances. The average ages prior to treatment were 12.5, 11.8 and 11.5 years respectively with 11.2 years for the controls. In this study, they found that the Bionator exhibited the greatest lower incisor proclination, 4°, and that both Twin Block and Bionator groups demonstrated significant retrusion of upper incisors (to the maxillary plane), -9.1° and -7.6° respectively. Their group also noted that Twin Block patients exhibited the least forward

movement of A point which they explain is due to a change in the inclination of the maxillary plane. This can also help explain why the reduction in maxillary-mandibular plane angle was the greatest in the Twin Block group, 1.5°. Illing and colleagues concluded that the Twin Block appliance was the most effective among the three appliances in producing sagittal and vertical changes.

Illing and colleagues' findings indicate that the Twin Block appliance would be preferential to the Bionator in class II treatment. Tümer and Gültan did not find one appliance to be more effective than the other. They did find that the Twin Block patients had a greater decrease in the degree of overbite, possibly meaning that the Twin Block was prone to greater change in the vertical dimension. These findings from both studies demonstrate that the comparision of vertical changes between the Bionator and Twin Block needs further investigation.

In both Tümer and Gültan (1999) and Illing's group (1998), the treatment effects were examined after treatment times of 10 months and 7 months respectively for the monoblock and Twin Block groups in the first study and 9 months in the second study. Their sample

sizes were twenty-six for two treatment groups in the first study and forty-seven for three treatment groups in the second study. Both treatment times and samples sizes were small in these studies. Longer treatment times and use of a larger sample size could increase the strength of the comparison.

Summary of the Literature

Based on literature, one can deduce that class II correction using either the Bionator or Twin Block is the resulting sum of many parts: maxillary and mandibular skeletal effects and maxillary and mandibular dental effects. These effects are expressed in both the horizontal and vertical dimensions. There appears to be ample data focusing on changes in the horizontal dimension while data addressing the vertical dimension is lacking.

STATEMENT OF THESIS

The Bionator and Twin Block appliances are both commonly used removable functional appliances in correcting class II malocclusion. Although both appliances require the patient to protrude the mandible forward, the appliances themselves are of different design. Can these differences in design affect how the class II malocclusion is corrected? Are both appliances equally viable clinical options in achieving the same clinical effects, or are there reasons to use one appliance over the other? Clinicians need information to help make unequivocal decisions in their appliance choice. The purpose of this study is to compare the skeletal and dentoalveolar treatment effects of the Bionator appliance to the Twin Block appliance. This research aims to provide orthodontists with evidence to help choose between the two appliances.

Hypotheses

The Twin Block appliance differs from the Bionator appliance in how class II correction is produced. The

Twin Block appliance produces:

1. Greater downward and less forward movement of A point.

2. Greater clockwise rotation of the palatal plane resulting in an increased lower anterior face height.

SUBJECTS AND METHODS

Sample

All patients whose records were used in this study were treated by a single, Board certified orthodontist. This experienced orthodontist began using the Twin Block appliance in 1992 in addition to the Bionator appliance for correcting class II malocclusion. He explained that post-1991, his main selection criteria for using the Twin Block instead of the Bionator was a stable dentition. This meant that patients chosen to receive Twin Block therapy were either younger, with a stable mixed dentition, or older, with a stable permanent dentition. The necessity for maxillary expansion was also considered, with patients needing more expansion likely receiving a Hyrax, then Bionator appliance versus a Twin Block with an expansion screw.

The treating orthodontist's inclusion criteria for using either functional appliance were an overjet greater than 7 mm and/or mandibular retrognathia. The patient may not have started off with a 7 mm overjet if there

were dental compensations. Inclusion criteria for this study were no prior treatment with another functional appliance, pre-treatment (T1) and post-treatment (T2) records, namely good quality, readable lateral cephalograms, and no extractions of permanent teeth prior to or during functional appliance treatment.

The researcher was given access to all of the orthodontist's charts and compiled those patients treated post-1991 with the Twin Block or Bionator. The sample needed to be selected from patients that were equally susceptible to either treatment modality in order to minimize susceptibility bias (Johnston et al. 1991). As mentioned previously, dental age and maxillary transverse dimension were biases in appliance selection. However, were there any other pretreatment variables which unknowingly influenced the orthodontist in his appliance selection? A list of eight possible variables was determined and tested with stepwise discriminant analysis: overjet, intermolar width, ANB angle, SN-MP angle, overbite, Wits, chronological age, and dental age.

The parent sample consisted of seventy-two Bionator patients and fifty-six Twin Block patients less three and two patients respectively who did not complete treatment

and return for T2 records. All patients, regardless of treatment outcome or compliance, were included in the parent sample. The pretreatment lateral cephalograms from each of these 123 subjects were hand traced using a 0.5 mm lead pencil and 0.003 inch matte acetate. ANB angle, SN-MP angle, overbite, and Wits were measured using a 3M orthodontic protractor and a Mitutoyo Digimatic electronic caliper. Overjet and intermolar width were measured directly off of the patient's pretreatment cast with the digital caliper. All measurements were made to the nearest one-tenth of a millimeter or degree. Chronological age was obtained from the patient's chart. Dental age was assessed using Schour and Massler's (1940) dental development chart.

All the data were analyzed using the stepwise discriminant analysis function in the Statistical Package for the Social Sciences (SPSS) software. Of the eight characteristics tested, a linear combination of two, dental age and Wits were found to significantly discriminate between the two groups. The equation used to calculate the discriminant scores was:

$$\text{Discriminant score} = 0.184\,(\text{Wits}) + 0.582\,(\text{Dental Age}) - 6.667$$

A discriminant score was calculated for each of the 123 subjects. Discriminant scores closer to zero indicate that the patient could have been treated with either appliance, while those with scores further away would more likely have been treated with one appliance than the other (Figure 1).

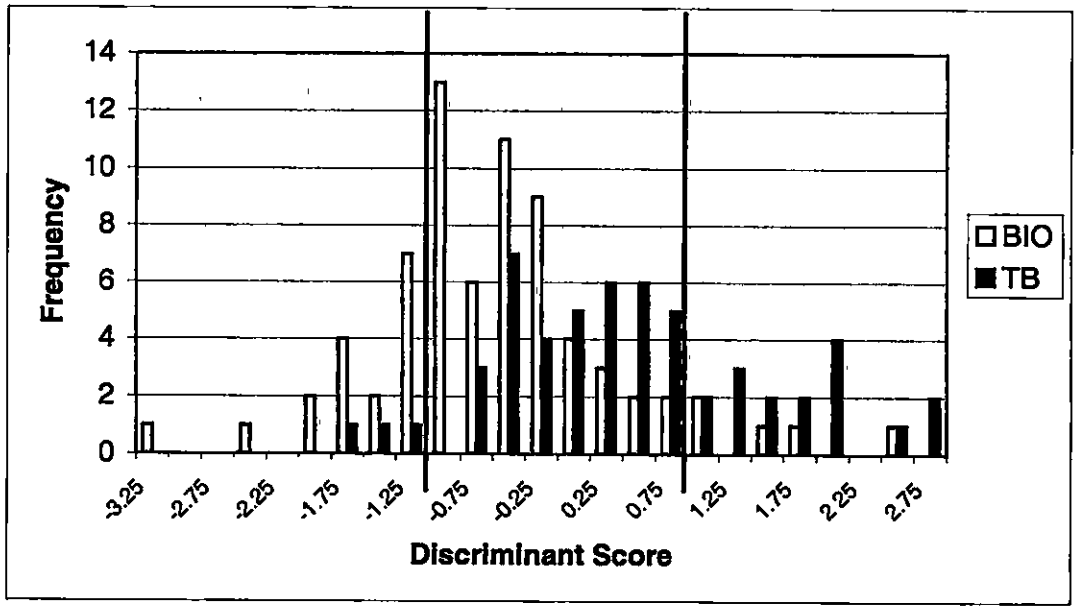


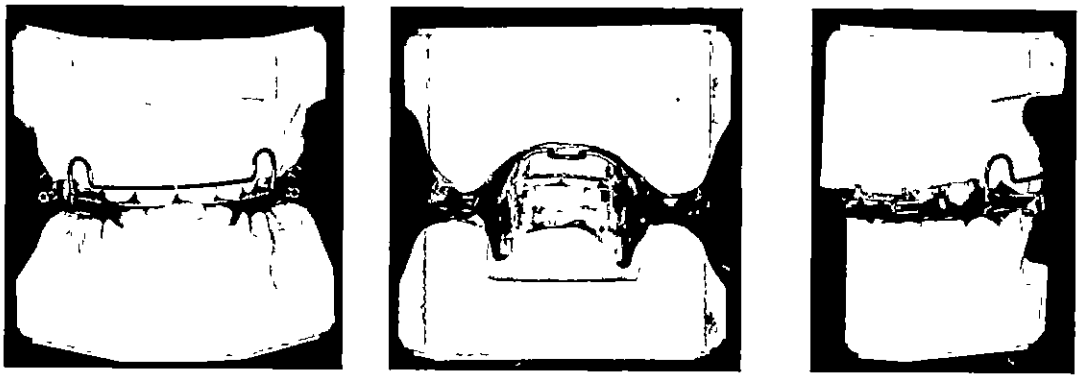
Figure 1. Bar graph of Frequency versus Discriminant Score of Bionator and Twin Block subjects, with lines representing the area between which the sample of patients was chosen.

A sample was chosen of those subjects in the equipoise of the distribution, with a discriminant score greater than -1.1 and lesser than 1.1 because this range

fell within one standard deviation of the mean. There were thirty-eight Twin Block and fifty-four Bionator patients within this range. At this point, subjects within each appliance group were matched for gender, then, as closely as possible, age at start of treatment, and finally treatment time. This resulted in a group of eighteen pairs of males and a group of twelve pairs of females for a total of sixty, all Caucasian. Thirty subjects as the sample size in each comparison group satisfies the Central Limit Theorem, allowing inferences to be made about the target population.

Bionator Appliance Treatment Protocol

The Bionator appliance design used for this study included a maxillary labial bow, flat plane acrylic over the maxillary anterior teeth and mandibular anterior acrylic capping of 3 mm with no relief, Adam's clasps for maxillary first molars, headgear tubes just occlusal or mesial to these molars, maxillary coffin spring, lingual protrusive bow contacting the lingual of the maxillary incisors, and an open palate (Figure 2). The mandible was advanced no more than 5 mm and the vertical opening between the incisors was approximately 1 mm. The bulk of the acrylic on the lingual was kept minimal for speech.



(A) (B) (C)

Figure 2. (A) Bionator appliance used in this study from frontal view. (B) Bionator appliance from lingual view. (C) Bionator appliance from side view.

The maxillary posterior teeth were capped while approximately 1 mm relief over the mandibular posterior teeth allowed for their eruption.

Bionator therapy was preceded with maxillary expansion using a Hyrax expander if insufficient maxillary transverse dimension following mandibular advancement was anticipated. If expansion was used, there was a minimum period of three months retention with the Hyrax stabilized. If maxillary incisors were retroclined and/or mandibular incisors were proclined, thus preventing enough overjet for mandibular advancement, a short duration of limited fixed appliance treatment was carried out prior to Bionator fabrication.

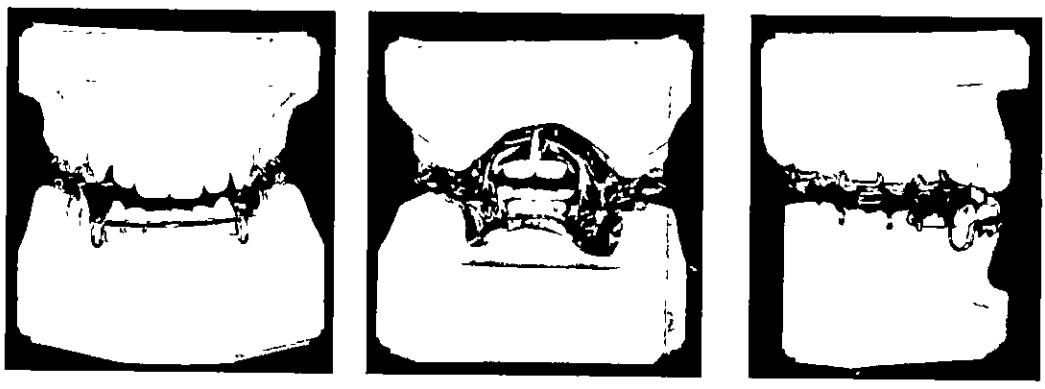
Patients were placed on a graduated wear schedule with the Bionator, wearing it one hour the first day, two hours the second day, three hours the third, then four hours each day for the rest of the first week. For the second week, the patient was instructed to wear the appliance for six to eight hours each day, adding night wear in the third week, and finally full time when confident. In some cases, high-pull headgear was used in conjunction with the Bionator. If used, it was added during the first appointment following appliance delivery when it could be certain that the patient was wearing the Bionator full time. Patients were also told to wear the headgear on a graduated schedule, wearing it for four hours during the first week, six to eight hours for the second week, and beginning night wear for the third week, ensuring there is at least fourteen hours of wear in a twenty-four hour period.

The Bionator was worn full time until the patient achieved maximal overjet correction. Sometimes, a second appliance was necessary, especially if the initial overjet greatly exceeded 5 mm as the mandible was advanced in a stepwise manner to maximize skeletal change

(Kumar et al. 1996). Retention was initially on an after school and night wear basis, then night wear only.

Twin Block Appliance Treatment Protocol

The Twin Block appliance design used for this study included a mandibular labial bow, maxillary and mandibular anterior acrylic capping, ball clasps between bicuspids, Adam's clasps for maxillary first molars, and headgear tubes occlusal or mesial to the first molars (Figure 3). A maxillary midline expansion screw may or may not be included in the upper part of the Twin Block depending on whether expansion was necessary. Clear acrylic was placed on the mandibular labial bow for added retention. The lower part of the Twin Block included



(A) (B) (C)

Figure 3. (A) Twin Block appliance used in this study from frontal view. (B) Twin Block appliance from lingual view. (C) Twin Block appliance from side view.

lingual extensions to help with retention. The mandible was advanced no more than 5 mm and the thickness of the acrylic interposing the molars was 4-5 mm thick in order to exceed freeway space so that patients did not override the anterior repositioning of the mandible.

Twin Block therapy was preceded by a short duration of limited fixed appliance treatment if maxillary incisors were retroclined and/or mandibular incisors were proclined, preventing enough overjet for mandibular advancement. Patients were placed on a graduated wear schedule similar to that of the Bionator. If necessary, the maxillary expansion screw was activated one turn per week until sufficient expansion was attained. High-pull headgear was used in conjunction to the Twin Block in certain cases. It was added during the first appointment following appliance delivery when it could be certain that the patient was wearing the Twin Block full time. Patients were also told to wear the headgear on a graduated schedule similar to that of the Bionator patients.

The Twin Block was worn full time until the patient achieved maximal overjet reduction. Acrylic was added to the lower block in order to carry out stepwise

advancement if necessary. Often times, a Bionator or a Twin Block support plate was used as a retainer unless it was an extended one-phase case where fixed appliances would follow immediately afterwards. Retention was initially on an after school and night wear basis, then night wear only.

Data Capture

All cephalometric tracings were completed by hand on the 120 lateral cephalograms at T1 and T2 (thirty T1 and T2 films in each appliance group). A 0.5 mm lead pencil was used on 0.003 inch matte acetate to trace all required hard and soft tissue landmarks. Seventeen hand identified landmarks were used to find a total twenty-seven measurements for each tracing (Figure 4). All landmarks used are listed in Appendix B.

All superimpositions were completed manually using the T1 and T2 cephalograms in order to demonstrate overall changes, changes within the maxilla, and changes within the mandible. Three fiduciary points were first marked on the T1 tracing, then transferred to the T2 tracing after the superimposition was carried out. As three different superimpositions were performed on each

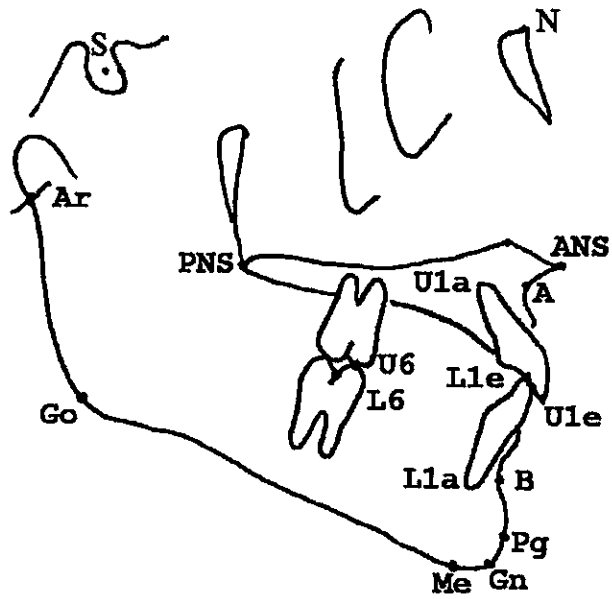


Figure 4. Seventeen landmarks used for Cephalometric analysis (See Appendix B for definitions).

set of T1-T2 tracings, three different sets of three fiduciary points were assigned to each superimposition. Each of the fifteen superimposition values were measured manually using the digital caliper and entered into Microsoft Excel for tabulation and statistical analysis.

The overall superimpositions were carried out using the anterior cranial base as the stable anatomical landmark. According to Elmajian (1959), the anterior cranial base, namely the ethmoid triad consisting of the

greater and lesser wings of the sphenoid bone, the superior aspect of the cribriform plate of the ethmoid bone, and the planum of the sphenoid bone are relatively unchanging after age seven. Whereas, sella and nasion remodel during growth, the ethmoid triad remains stable after age seven which is the time that most orthodontists render treatment. In addition to using the ethmoid triad, internal trabecular patterns within the ethmoid triad were used to help enhance the accuracy of the superimposition. An average occlusal plane was constructed bisecting the occlusal planes of the T1 and T2 tracings. Horizontal and vertical changes were measured parallel and perpendicular to this average overall occlusal plane. Using this overall superimposition, the direction and amount of maxillary skeletal change could be described.

The maxillary superimpositions were carried out using the method described by Doppel and colleagues (1994). The inferior third of the anterior and posterior outlines of the key ridge of the maxilla determine the anteroposterior orientation while a ratio of 1.5 to 1.0 of the inferior border of the orbit to the inferior portion of the palate determine the vertical orientation.

An average maxillary occlusal plane was constructed bisecting the maxillary occlusal planes of the T1 and T2 tracings. Horizontal and vertical changes were measured parallel and perpendicular to this average maxillary occlusal plane. Using this maxillary superimposition, dental changes within the maxilla could be described, as could changes in palatal plane.

The mandibular superimpositions were carried out based on Björk's findings (1963). Using implants, Björk found that the internal architecture of the inner aspect of the lingual symphysis, the inferior outline of the third molar crypt, and the inferior alveolar canal were stable landmarks. These landmarks were used for the mandibular superimposition. An average mandibular occlusal plane was constructed bisecting the mandibular occlusal planes of the T1 and T2 tracings. Horizontal and vertical changes were measured parallel and perpendicular to this average mandibular occlusal plane. Using this mandibular superimposition, dental changes within the mandible and mandibular lengthening could be described.

The 120 tracings were scanned into a digital format using an Epson Expression 1600 scanner. All tracings

were placed in the upper right hand corner of the scanner, adjacent to a calibration ruler taped to the transparency adapter, and scanned using Adobe Photoshop 6.0 at the following settings:

1. Document Source: Flatbed
2. Image Type: 24 bit color
3. Resolution: 150 dpi

Images were saved in a tagged image file format (tiff), then imported into the Case Western Reserve University Imaging Program in order to carry out the descriptive measurements. Each scanned tracing was calibrated with the program by identifying the two crosshairs 100 mm apart on the scanned ruler. The preidentified landmarks were then digitized allowing the generation of twenty-four descriptive measurements. The raw data were extracted into Microsoft Notepad, then pasted into Microsoft Excel spreadsheets for tabulation and statistical analysis.

Method of Error

Intra-operator error was examined by randomly selecting ten sets of lateral cephalograms, and then tracing, landmarking, scanning, and digitizing them again to recalculate the twenty-seven descriptive measurements.

The films were also superimposed and manually measured to obtain the fifteen superimposition values. These tracings were carried out four weeks after the original tracings were completed.

Statistics

Microsoft Excel software was used to tabulate and statistically analyze the imported data. Paired Student t-tests were carried out on twenty measurements which the researcher determined would best test the hypotheses. These measurements focus on examining angular and vertical changes and are a combination of descriptive and superimposition values. Descriptive measurements include Ar-A, Ar-Gn, ANB, Wits, SN-OP, SN-PP, SN-MP, SN-SPg, N-ANS, ANS-Me, and S-Go. Superimposition values include those from the overall superimposition—ANS vertical, A horizontal, B horizontal, and B vertical; those from the maxillary superimposition—upper incisor horizontal, upper incisor vertical, and upper molar vertical; and those from the mandibular superimposition—lower molar vertical and articulare. Statistical significance was set at $p < 0.05$, however, Bonferroni correction was used in testing the twenty variables in order to adjust for the numerous measurements. Hence $0.05/20$ gives $\alpha = 0.0025$.

Beta (β) and power were also examined. Beta represents the probability of committing a type II error, when there is a failure to reject a false null hypothesis (Daniel 1999). The power of a test, $1 - \beta$, then tells what the probability of rejecting a false null hypothesis is for given a sample size. Both beta and power were calculated by hand.

The intra-operator error was calculated on SPSS software using r, intra-class correlation coefficient. An $r < 0.75$ signifies weak intra-operator reliability.

RESULTS

The average age pre-treatment (T1) for the Twin Block group was 12.1 years and for the Bionator group was 12.0 years (Table 3). The average age post-treatment (T2) for the Twin Block group was 13.3 years and for the Bionator group was 13.2 years. Mean treatment time for both groups was 14.4 months.

Table 3.--Age Characteristics of Bionator and Twin Block Groups.

	Bionator group (n=30)		Twin Block group (n=30)	
	Mean	SD	Mean	SD
Age at T1 (years)	12.0	1.0	12.1	1.1
Age at T2 (years)	13.2	1.0	13.3	1.0

T1 films were taken an average of 0.5 years and 0.6 years prior to treatment for the Twin Block and Bionator groups respectively. T2 films were taken an average of 0.1 years after completing active functional appliance wear for both groups.

Table 4 presents twenty-seven pre-treatment (T1) descriptive cephalometric measurements for the Bionator and Twin Block treatment groups. All measurements between the two appliance groups showed similarity, with only two of them differing more than 1.5° or mm. These are U1-SN that differed 2.4°, with the Bionator group having upper incisors slightly more retroclined than the Twin Block group, and interincisal angle that was larger in the Bionator group by 5.4°.

Table 5 presents twenty-seven post-treatment (T2) descriptive cephalometric measurements for both appliances, once again showing similarity between them. All T2 measurements differed between the two appliances less than 1.8° or mm other than for interincisal angle which was larger for the Bionator group by 4.8°.

TABLE 4.--Means and Standard Deviations of Pretreatment (T1) Descriptive Cephalometric Measurements for Bionator and Twin Block Treatment Groups.

	BIONATOR		TWIN BLOCK	
	Mean	SD	Mean	SD
MAXILLARY SKELETAL				
SNA (°)	81.7	3.2	80.4	2.7
Ar-A (mm)	89.4	4.4	88.8	4.6
MANDIBULAR SKELETAL				
SNB (°)	75.8	2.7	75.1	2.9
Ar-Gn (mm)	104.2	6.0	103.7	5.4
Ar-Go (mm)	43.2	4.1	43.2	3.9
Go-Pg (mm)	74.1	5.2	73.8	4.2
Ar-SN (mm)	29.0	3.3	28.2	3.1
MAXILLA TO MANDIBLE				
ANB (°)	5.5	1.5	4.9	1.4
Wits (mm)	3.8	2.3	4.2	2.1
Ar/Gn-Ar/A(mm)	14.8	3.3	14.9	3.0
VERTICAL				
SN-OP (°)	18.1	3.1	17.0	3.3
SN-PP (°)	7.1	3.2	5.8	2.7
SN-MP (°)	32.3	3.9	32.3	4.7
SN-SPg (°)	64.3	2.4	65.1	2.5
N-ANS (mm)	52.6	3.2	51.2	3.3
ANS-Me (mm)	63.8	5.5	64.4	4.2
N-Me (mm)	116.5	6.9	115.6	5.9
Ar-Go-Gn (°)	123.8	5.5	123.8	4.4
S-Go (mm)	74.0	6.0	73.5	5.8
Post/Ant Facial Ht (%)	63.6	3.5	63.6	4.0
MAXILLARY DENTAL				
U1-SN (°)	101.8	6.1	104.2	7.0
MANDIBULAR DENTAL				
L1-A-Pg (°)	19.4	5.5	20.9	4.1
L1-MP (°)	96.2	5.0	97.2	5.0
INTERDENTAL				
OB (mm)	5.8	1.5	5.3	1.6
OJ(mm)	6.6	1.9	7.5	2.0
Interincisal (°)	133.8	12.7	128.4	9.9
Molar relationship (mm)	4.1	1.2	4.3	1.4

TABLE 5.--Means and Standard Deviations of Post-treatment (T2) Descriptive Cephalometric Measurements for Bionator and Twin Block Treatment Groups.

	BIONATOR		TWIN BLOCK	
	Mean	SD	Mean	SD
MAXILLARY SKELETAL				
SNA (°)	81.8	3.4	80.1	2.9
Ar-A (mm)	91.8	4.7	90.3	5.2
MANDIBULAR SKELETAL				
SNB (°)	76.6	2.8	75.9	2.6
Ar-Gn (mm)	110.0	7.3	109.2	6.1
Ar-Go (mm)	47.0	5.5	47.0	5.0
Go-Pg (mm)	76.9	5.4	76.2	4.4
Ar-SN (mm)	30.5	3.6	29.4	3.0
MAXILLA TO MANDIBLE				
ANB (°)	4.8	2.0	3.7	1.5
Wits (mm)	2.6	2.0	1.6	2.7
Ar/Gn-Ar/A(mm)	18.2	4.3	18.9	3.1
VERTICAL				
SN-OP (°)	18.3	4.3	18.7	3.9
SN-PP (°)	7.0	2.9	6.4	2.8
SN-MP (°)	32.4	5.0	33.1	5.0
SN-SPg (°)	65.1	2.6	65.8	2.3
N-ANS (mm)	54.8	3.6	53.6	3.0
ANS-Me (mm)	68.2	5.8	68.6	4.5
N-Me (mm)	123.1	7.3	122.3	6.2
Ar-Go-Gn (°)	123.8	5.5	124.1	5.2
S-Go (mm)	79.4	7.0	78.4	6.7
Post/Ant Facial Ht (%)	64.5	4.3	64.1	4.4
MAXILLARY DENTAL				
U1-SN (°)	98.3	4.9	99.3	4.7
MANDIBULAR DENTAL				
L1-A-Pg (°)	22.6	6.2	23.6	4.4
L1-MP (°)	97.8	5.5	98.0	4.4
INTERDENTAL				
OB (mm)	3.8	2.1	2.8	2.2
OJ(mm)	3.3	1.6	3.3	2.0
Interincisal (°)	136.6	11.3	131.8	8.0
Molar relationship (mm)	-0.3	2.1	-0.7	2.1

Differences (T2-T1) between post-treatment (T2) and pre-treatment (T1) descriptive cephalometric measurements for the Bionator and Twin Block groups are reported in Table 6. T2-T1 changes were extremely similar between both groups, varying no more than 1.5° or mm. There was good control of the mandibular plane angle, SN-MP, with 0.1° and 0.7° increase in the Bionator and Twin Block groups respectively. There was a greater reduction of the Wits measurement in the Twin Block group, at 2.5 mm versus the Bionator group at 1.2 mm. Table 7 shows that this would be significant at $p < 0.05$ but not at $p < 0.0025$. Overall, there was good class II molar correction of 4.4 mm and 4.9 mm and overjet reduction of 3.3 mm and 4.2 mm in the Bionator and Twin Block groups.

TABLE 6.--Means and Standard Deviations of Differences (T2-T1) between Post-treatment (T2) and Pre treatment(T1) Descriptive Cephalometric Measurements for Bionator and Twin Block Groups.

	BIONATOR		TWIN BLOCK	
	Mean	SD	Mean	SD
MAXILLARY SKELETAL				
SNA (°)	0.1	0.2	-0.3	0.2
Ar-A (mm)	2.4	0.3	1.6	0.7
MANDIBULAR SKELETAL				
SNB (°)	0.8	0.2	0.8	0.3
Ar-Gn (mm)	5.8	1.3	5.5	0.7
Ar-Go (mm)	3.9	1.4	3.8	1.1
Go-Pg (mm)	2.8	0.2	2.4	0.2
Ar-SN (mm)	1.4	0.3	1.2	0.1
MAXILLA TO MANDIBLE				
ANB (°)	-0.7	0.5	-1.2	0.1
Wits (mm)	-1.2	0.3	-2.6	0.5
Ar/Gn-Ar/A(mm)	3.4	1.0	3.9	0.1
VERTICAL				
SN-OP (°)	0.2	1.2	1.6	0.6
SN-PP (°)	-0.1	0.3	0.6	0.1
SN-MP (°)	0.1	1.0	0.7	0.3
SN-SPg (°)	0.8	0.2	0.7	0.2
N-ANS (mm)	2.2	0.4	2.5	0.3
ANS-Me (mm)	4.4	0.3	4.2	0.3
N-Me (mm)	6.6	0.4	6.7	0.3
Ar-Go-Gn (°)	0.0	0.1	0.2	0.8
S-Go (mm)	5.3	1.1	4.9	0.9
Post/Ant Facial Ht (%)	0.9	0.8	0.6	0.4
MAXILLARY DENTAL				
U1-SN (°)	-3.5	1.2	-5.0	2.3
MANDIBULAR DENTAL				
L1-A-Pg (°)	3.2	0.7	2.7	0.2
L1-MP (°)	1.6	0.5	0.8	0.7
INTERDENTAL				
OB (mm)	-2.0	0.6	-2.5	0.5
OJ(mm)	-3.3	0.3	-4.2	0.0
Interincisal (°)	2.8	1.4	3.4	1.9
Molar relationship (mm)	-4.4	0.9	-4.9	0.7

Increases were assigned a positive value and decreases a negative value.

Fifteen superimposition values between T2-T1 for Bionator and Twin Block are reported on Table 7. Superimposition values between the two appliance groups differed by less than 0.8 mm. In the overall superimposition, A point moved forward 1.9 mm and 1.5 mm while ANS moved downward 1.8 mm and 1.7 mm respectively in the Bionator and Twin Block groups. Hence there was a small amount of maxillary skeletal movement downward and forward in both groups. The intraclass correlation coefficient values included in this table were all greater than 0.75 other than A horizontal at 0.65 and PNS vertical at 0.72. These two measurements exhibited weak correlation.

Intraclass correlation coefficient values, listed in Tables 8 and 9, represent intra-operator error. Most coefficient values were greater than 0.75, signifying strong correlation except A horizontal with r = 0.65 and PNS vertical with r = 0.72.

TABLE 7.--Superimposition Means and Standard Deviations for Bionator and Twin Block Treatment Groups.

	BIONATOR		TWIN BLOCK	
	Mean	SD	Mean	SD
OVERALL				
ANS vertical	-1.8	1.4	-1.7	1.2
A horizontal	-1.9	1.4	-1.5	1.4
PNS vertical	-1.7	1.5	-1.7	1.3
B horizontal	3.1	1.8	3.5	2.3
B vertical	-5.6	2.8	-6.0	3.2
Pg horizontal	3.6	2.3	3.7	2.5
MAXILLA				
Upper 1 horizontal	0.9	3.0	0.8	2.2
Upper 1 vertical	-2.1	1.5	-1.8	1.4
Upper 6 horizontal	0.9	2.7	0.2	1.7
Upper 6 vertical	-1.8	1.7	-1.1	1.4
MANDIBLE				
Lower 1 horizontal	0.6	1.4	0.6	1.0
Lower 1 vertical	0.8	1.2	1.1	1.1
Lower 6 horizontal	1.1	1.3	1.8	1.0
Lower 6 vertical	2.5	1.1	1.7	1.2
Articulare	-6.3	2.1	-5.9	2.2

All measurements in millimeters. Change which improved a class II relationship in the horizontal direction was assigned a positive value as was upward change in the vertical direction, while change which worsened a class II relationship in the horizontal direction was assigned a negative value as was downward change in the vertical direction.

TABLE 8.--Intraclass Correlation Coefficient Values, r, for the Descriptive Measurements of Ten Sets of Randomly Selected Lateral Cephalograms.

	r
MAXILLARY SKELETAL	
SNA (°)	0.93
Ar-A (mm)	0.98
MANDIBULAR SKELETAL	
SNB (°)	0.96
Ar-Gn (mm)	0.99
Ar-Go (mm)	0.98
Go-Pg (mm)	0.98
Ar-SN (mm)	0.95
MAXILLA TO MANDIBLE	
ANB (°)	0.91
Wits (mm)	0.84
Ar/Gn-Ar/A(mm)	0.96
VERTICAL	
SN-OP (°)	0.89
SN-PP (°)	0.93
SN-MP (°)	0.96
SN-SPg (°)	0.93
N-ANS (mm)	0.97
ANS-Me (mm)	0.99
N-Me (mm)	0.99
Ar-Go-Gn (°)	0.94
S-Go (mm)	0.99
Post/Ant Facial Ht (%)	0.95
MAXILLARY DENTAL	
U1-SN (°)	0.90
MANDIBULAR DENTAL	
L1-A-Pg (°)	0.92
L1-MP (°)	0.91
INTERDENTAL	
OB (mm)	0.94
OJ(mm)	0.93
Interincisal (°)	0.99
Molar relationship (mm)	0.94

TABLE 9.--Intraclass Correlation Coefficient Values, r, for the Superimposition Measurements of Ten Sets of Randomly Selected Lateral Cephalograms.

	r
OVERALL	
ANS vertical	0.90
A horizontal	0.65
PNS vertical	0.72
B horizontal	0.91
B vertical	0.87
Pg horizontal	0.94
MAXILLA	
Upper 1 horizontal	0.84
Upper 1 vertical	0.87
Upper 6 horizontal	0.83
Upper 6 vertical	0.89
MANDIBLE	
Lower 1 horizontal	0.89
Lower 1 vertical	0.82
Lower 6 horizontal	0.90
Lower 6 vertical	0.83
Articulare	0.94

Paired two tail t-tests were performed on twenty selected measurements in order to test the hypothesis (Table 10). These twenty measurements included eleven descriptive and nine measurements from the superimposition. Of these nine superimposition measurements, four were from the overall superimposition, two were from the maxillary superimposition, and three were from the mandibular superimposition. None of the twenty measurements showed any significance at the $p <$

0.0025. At $p < 0.05$, two of the measurements, Wits and lower molar vertical position were significant.

TABLE 10.--Summary of Two Tailed Paired t-Tests of Twenty Measurements, From Both Descriptive and Superimposition Values, Comparing Changes in the Bionator and Twin Block Treatment Groups.

	BIONATOR		TWIN BLOCK			
	Mean	SD	Mean	SD	P-Value	Sig†
Ar-A (mm)	2.41	0.27	1.56	0.66	0.0661	NS
Ar-Gn (mm)	5.77	1.31	5.47	0.70	0.6073	NS
ANB (°)	-0.73	0.48	-1.17	0.04	0.2592	NS
Wits (mm)	-1.17	0.29	-2.52	0.53	0.0150	NS*
SN-OP (°)	0.23	1.18	1.63	0.64	0.1281	NS
SN-PP (°)	-0.10	0.33	0.57	0.09	0.1431	NS
SN-MP (°)	0.10	1.04	0.73	0.32	0.2708	NS
SN-SPg (°)	0.77	0.19	0.73	0.18	0.9384	NS
N-ANS (mm)	2.23	0.39	2.46	0.25	0.5370	NS
ANS-Me (mm)	4.37	0.35	4.21	0.32	0.7546	NS
S-Go (mm)	5.33	1.06	4.95	0.90	0.5464	NS
ANS vertical (mm)	-1.80	1.41	-1.72	1.24	0.8066	NS
A horizontal (mm)	-1.94	1.39	-1.53	1.43	0.2381	NS
B horizontal (mm)	3.13	1.76	3.54	2.29	0.4127	NS
B vertical (mm)	-5.59	2.81	-5.95	3.20	0.6381	NS
Upper 1 horizontal (mm)	0.95	2.96	0.83	2.22	0.8683	NS
Upper 1 vertical (mm)	-2.07	1.53	-1.84	1.39	0.4863	NS
Upper 6 vertical (mm)	-1.85	1.65	-1.11	1.44	0.0803	NS
Lower 6 vertical (mm)	2.46	1.06	1.65	1.17	0.0148	NS*
Articulare (mm)	-6.27	2.15	-5.92	2.22	0.5313	NS

Change which improved a class II relationship in the horizontal direction was assigned a positive value as was upward change in the vertical direction, while change which worsened a class II relationship in the horizontal direction was assigned a negative value as was downward change in the vertical direction.
†Statistical Significance determined at $p < 0.0025$ after Bonferroni Correction; NS = not significant.
*Significant at $p < 0.05$ level.

Beta values and the power of four measurements with the smallest p-values for the Bionator and Twin Block groups are shown in Table 11. The beta value for Wits was extremely small, meaning that it is unlikely a type II error has been committed. The power of the Wits measurement was very high at > 99.9%. The beta values for the lower molar vertical, Ar-A, and upper molar vertical measurements were extremely large, meaning that it is possible a type II error was committed. The power of these three measurements were very low at < 0.01%.

TABLE 11.--Beta values and Power of Four Measurements with the Smallest P-Value for the Bionator and Twin Block Treatment Groups.

	Beta value	Power
Lower 6 vertical	0.9999	<0.01%
Wits	0.0001	>99.99%
Ar-A	0.9999	<0.01%
Upper 6 vertical	0.9999	<0.01%

Critical value taken at $\alpha = 0.05$.

DISCUSSION

Numerous studies have been carried out between various functional appliances in order to help clinicians understand where the differences in treatment effect lie. Although there have been treatment effect studies on the Bionator and Twin Block appliances individually, there have not been many studies directly comparing the Bionator to the Twin Block appliance. All functional appliances work by positioning the mandible forward. Are there, however, specific dentoalveolar and skeletal changes that differ between the two? This study was designed in order to provide answers to this question.

Sample Selection

Of utmost importance in a retrospective cohort study is sample selection as many biases may be encountered. Consecutively treated patients who met the inclusion criteria were included in this study. All patients, not only "good" appliance wearers, were included avoiding selection bias. They were treated by a single, Board certified orthodontist which removes the problem of

proficiency bias (Johnston et al. 1991). However, because the treating orthodontist used both appliances in his practice at the same time, there was the problem of susceptibility bias. Patients might have been chosen to receive one appliance over the other because of a specific dentofacial characteristic meaning that patients in each treatment group would not be the same at the outset. Discriminant analysis was used to reduce susceptibility bias, helping in the selection of patients who were most similar prior to treatment. Following discriminant analysis, subjects were matched based on gender, age, and treatment time to obtain the final sample to ensure pretreatment equivalence between the two treatment groups.

A weakness of the sample was that the Bionator or Twin Block treatment may have been preceded by an earlier treatment. Some patients, especially the Bionator patients may have been first treated with a Hyrax expander while the Twin Block patients may have been treated with the palatal expansion screw on the upper part of their Twin Block during appliance therapy. In addition, some of both the Bionator and Twin Block patients may have had a short duration of limited fixed

appliances in order to decompensate the dentition to allow for maximum mandibular advancement. Finally, some of both appliance patients may have had high-pull headgear added to their functional appliance. Although earlier treatment information was culled out of the dental charts, separating the sample using this information was not feasible as it would have greatly diminished sample size.

Treatment Effects

Maxillary Skeletal Effects

The maxillary skeletal changes in the Bionator and Twin Block subjects in this study are similar to that of other studies (Bolmgren and Moshiri 1986; Lund and Sandler 1998; Toth and McNamara 1999; De Almeida et al. 2002). There was no orthopedic change in the maxilla as evidenced by the minor change in SNA of 0.1° and -0.3° in the Bionator and Twin Block groups. SNA change for the control group in Toth and McNamara's study was 0.3° and in De Almeida and coworkers' study was -0.2°.

Referring to the overall superimposition, A point was measured in the horizontal direction, showing slight forward movement of 1.9 mm in the Bionator and 1.5 mm in the Twin Block. Although there is no control data in

this study, it can be deduced from the other studies listed that there was no real headgear effect with both functional appliances.

Mandibular Skeletal Effects

Mandibular skeletal changes from the two appliances were almost identical with SNB change being 0.8° for both and articulare change being 6.3 mm and 5.9 mm for the Bionator and the Twin Block appliances respectively. The biological response of the mandible to either appliance is remarkably similar. Other researchers such as De Almeida and coworkers (2002) found a slightly larger SNB change of 1.4 mm for their Bionator subjects as did Lund and Sandler (1998) with an SNB change of 1.9 mm for their Twin Block subjects. SNB change in the control group in De Almeida and coworkers' study was 0.0° and in Lund and Sandler's study was 0.4°. Perhaps the non-homogenous combination of growth responders and non-responders diluted the magnitude of the mandibular change in this study.

Maxillary Dental Effects

The U1-SN measurement showed that the maxillary incisor retroclining 1.5° more at 5.0° in the Twin Block subjects compared to the Bionator subjects. However,

from the superimposition measurements of the changes of the maxillary incisal edge, both appliances were very similar, moving slightly forward and downward. An explanation for seeing more change in the Twin Block patients may be the effect of appliance design. Although both Bionator and Twin Block appliances in this study incorporated maxillary labial bows, the difference could lie in how the appliance is used. The force of the mandibular inclined plane against the maxillary inclined plane at the level of the occlusion in the Twin Block could possibly create more retroclination of the maxillary incisors since the force vector is acting well below the center of resistance of the maxilla, slightly inferior to orbitale according to mathematical modeling (Vanden Bulcke et al. 1987). The design of the Bionator is such that the patient protrudes the mandible forward distributing the force equally at the level of the occlusal plane, possibly avoiding this tendency towards greater maxillary incisal retroclination.

Mandibular Dental Effects

There was similar mandibular incisor forward horizontal displacement and extrusion with both appliances. The horizontal displacement was slight at

0.6 mm with both appliances, and extrusion was 0.8 mm and 1.1 mm for the Bionator and Twin Block appliances respectively despite there being acrylic coverage of the lower incisors with both appliances. The acrylic coverage of the lower incisors was in the form of capping in the Bionator and in the form of acrylic on a labial bow in addition to lingual coverage in the Twin Block.

Extrusion of the mandibular molars was greater with the Bionator at 2.46 mm than with the Twin Block at 1.65 mm. This difference of 0.81 mm was not statistically significant at $p < 0.0025$ but is significant at $p < 0.05$. The likely explanation for the difference is that there was no adjustment of the acrylic to allow for mandibular molar eruption in the Twin Block, while there was some adjustment in the Bionator. In the horizontal dimension, mandibular molars moved forward a similar amount in both appliance groups. Perhaps this could be explained by loss of E space in mixed dentition cases as forward mandibular molar movement is not likely to happen, especially with full time Twin Block wear.

Maxillomandibular, Rotational, and Vertical Effects

ANB and Wits measurements decreased in both appliance groups as expected, aiding in class II

correction. The change in ANB was greater in the Twin Block group, with a slightly larger difference of 0.5 mm than in the Bionator group. The difference in Wits reduction between the appliance groups was 1.4 mm, with the Twin Block group once again having a greater reduction in Wits value. This difference was not statistically significant at the Bonferroni correction level, but may still have meaning clinically.

A possible explanation for the difference in Wits value is the difference in angulation of the occlusal plane as the Wits measurement can be affected or changed by it. The difference in SN-OP was 1.5° greater in the Twin Block group and as seen in the schematic in Figure 5, this greater SN-OP value can increase Wits even though A and B points are in the same position.

The maxillomandibular differential (ArGn - ArA) was similar in both appliance groups showing 3.4 mm and 3.9 mm change in the Bionator and Twin Block groups. The class II correction measured is dependent on this differential of mandibular growth exceeding maxillary growth.

The vertical and rotational effects appeared to be quite similar between the two groups. All the angular

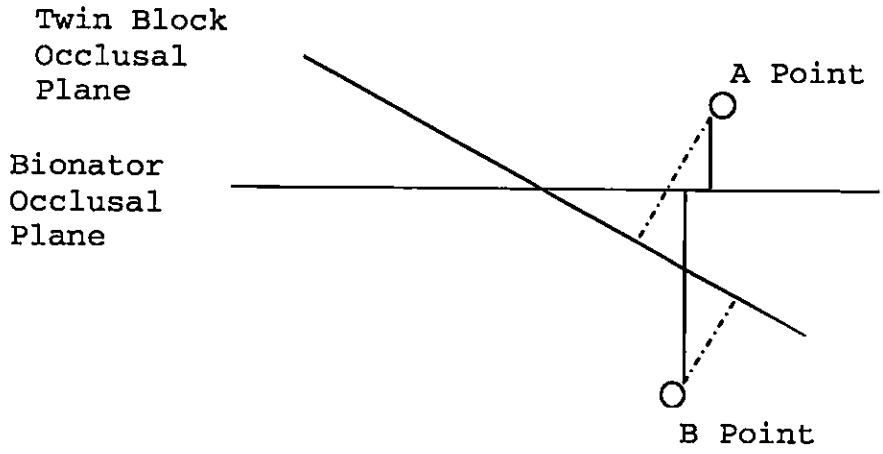


Figure 5. Schematic showing a possible explanation of how changes in occlusal plane angulation can affect the Wits value; the Twin Block sample had a greater change from T1 to T2 in the angle of the occlusal plane relative to SN than the Bionator sample leading to a greater Wits value.

measures such as SN-PP, SN-MP, and SN-SPg showed minimal differences. Although no significant differences were noted, it is of interest to mention that SN-PP was -0.1° for the Bionator group and 0.6° for the Twin Block group. The negative change in the Bionator shows that there is a tendency for this appliance to cause a counterclockwise palatal plane rotation while the Twin Block tends toward a clockwise palatal plane rotation. The SN-OP change was greater for the Twin Block patients, and once again, this change is in the clockwise direction.

The hypotheses of greater downward and less forward movement in A point and greater clockwise rotation of the palatal plane in Twin Block patients compared to Bionator patients were not accepted. The four measurements that clearly illustrate this are A horizontal and ANS vertical, from the overall superimposition, and SN-PP and ANS-Me, from the descriptive measurements. None of these measurements showed any statistical significance between the two appliance meaning that the rotational and vertical effects of the Bionator and Twin Block are not as different as initially believed.

Previous Comparable Studies

Previous studies carried out by Illing and colleagues (1998) and Tümer and Gültan (1999) attempted to study the Bionator and Twin Block appliances. Their sample sizes were much smaller than the sixty subjects in two appliance groups in this study, having twenty-six subjects in two appliance groups and Illing and colleagues having a total of forty-seven subjects in three appliance groups. In addition, both functional appliances groups were treated for an average time of 14.4 months in this study while in Tümer and Gültan's study, subjects were only treated for ten months with the

monoblock and seven months with the Twin Block. Illing and colleagues treated their subjects for nine months in each appliance group.

A longer treatment time would ensure more stable treatment results. Clark (2002) discussed his treatment timetable for the Twin Block was 6-9 months of active treatment and a support phase of 3-6 months during which time there is trimming of the blocks to allow premolars to erupt. The range in full-time recommended wear was 9-15 months. Afterwards, there is a retention stage of nine months where the appliance wear time is reduced. Appliances in this study were worn for an average of 14.4 months, placing it on the longer end of the wear spectrum. A longer treatment time would more likely show results with better reliability.

This study showed different findings to that of Illing and colleagues (1998). Most noticeably, they found that the Twin Block group showed the least forward movement of A point and greater maxillary incisor extrusion. This study did not find this, as A point moved forward and the maxillary incisors extruded a similar amount in both appliance groups. The actual appliance design of the Bionators in both studies was

very similar. In the Twin Block, the only major appliance design difference was that this study used a mandibular labial bow while ball hooks were used by Illing and colleagues, but this does not explain the differences in results.

Tümer and Gültan (1999) found an increase in gonial angle, corresponding with an increase in mandibular plane angle in the Twin Block group compared to the Bionator group. Dentally, their study found that the monoblock group demonstrated greater maxillary incisor retrusion while the Twin Block group showed greater mandibular incisor proclination. This study did not find significant differences in gonial angle or in maxillary and mandibular angulation between the two appliances. Dental treatment effects are fairly dependent on the design of the appliances. As Tümer and Gültan did not discuss the designs of their appliances, it is possible that appliance design might explain the difference in findings.

Clinical Implications

As discussed in the literature review, the effects of the Bionator and its predecessor the Activator are well known. Since the Twin Block was introduced in the

late 1970s, it has been gaining popularity. A fair amount of research has been carried out in recent years to elucidate its treatment effects. As orthodontists are always interested in using the newest and latest appliance, many have been quick to switch from the Bionator to the Twin Block (Faltin et al. 2003).

This study found no statistical difference on average in using the Twin Block over the Bionator appliance. Hence, based on this data, clinicians can choose to use either appliance. Individual variation amongst the sample and the small sample size may limit the data's application to the external population. As Baumrind (1987) discussed,

> "At best, all that…research can give us are grouped data concerning the usual outcome of apparently similar treatments performed…for apparently similar subjects. …there is real value to…statistics given that one realizes their limitations."

What is this "real value" which Baumrind mentions? It is that clinicians can use the information obtained from studies such as this to treat individual patients by using not only the mean, but also the standard deviation, range, confidence intervals around the mean, and other statistical measures from a large group of parameters.

There is large interpatient variability but these statistical measures can help in recognizing where the individual patient may lie compared to the sample group. While the mean of a parameter can only tell what is likely to happen to the patient, additional statistical information can tell what might possibly happen.

Although the small skeletal and dental changes seen between the Bionator and Twin Block in this study have no statistical significance, clinicians may consider them of clinical significance if they are looking at the range. For instance, one can consider the differences for ANS-Me, lower anterior face height, from T1-T2 for the two appliances (Table 8). The mean ANS-Me difference for the Bionator was 4.37 ± 0.04 mm, but the actual differences ranged from 1.07 to 7.73 mm while for the Twin Block, ANS-Me was 4.21 ± 0.32 mm yet the actual differences ranged from 0.54 to 10.36 mm. So, in looking at extreme values, one Bionator patient had an ANS-Me change of 1.07 mm while another Twin Block patient had a change of 10.36 mm. The difference between these two extreme values is 9.29 mm which is likely of significance to the treating clinician as their patient can lie anywhere in this 9.29 mm range.

Even though there was no significance between the two appliances when Bonferroni correction was used, there needs to be an understanding that Bonferroni correction is an ultraconservative way of examining the data. In looking at the beta values of four measurements with the smallest p-values (Table 11) and determining their power, it was found that at the current sample size, there is sufficient power to study only one of these four measurements, Wits. For the other three measurements, a larger sample size is necessary in order to detect any differences between the appliances. The likely explanation of why there was enough power to evaluate the Wits measurement is because there was not much variability for this measurement between all the subjects at T2 as the treating orthodontist stopped appliance wear when overjet was ideal. It is possible that there could still be a difference between appliances which was not detected in this study for the other three measurements because of the small differences between appliances and the great interpatient variability in their T2 values.

Future studies could include calculating the necessary sample size, then repeating this investigation. Also, one could study the Bionator and Twin Block

patients who were not in the equipoise of Figure 1 in order to characterize the specific dentoskeletal features that are unique to patients treated with each appliance.

CONCLUSION

Based on the results of this study, the decision of whether to use the Bionator or Twin Block is basically a patient management decision. Some clinicians feel that the Twin Block is more readily tolerated by the patient in terms of convenience in speech and mastication and may therefore choose to use it. Others might decide to use the Bionator because of familiarity with the appliance and stability in mixed or permanent dentition. There is yet a third group that could select an appliance based on a specific characteristics such as maxillary labial segment length, choosing the Twin Block for patients with a tendency towards decreased to average upper labial segment length, stable dentition, and/or need for mild palatal expansion. This group of clinicians would then choose the Bionator for use in patients in a transitional dentition and/or increased maxillary labial segment lengths, with or without anterior open bite. None of these clinicians would be incorrect based on the findings of this study.

This study failed to show any overall differences between the Bionator and Twin Block appliances in most horizontal, vertical, or rotational measures. However, the results of this study showed that the Bionator differed from the Twin Block in how it produced its class II correction. The Twin Block tends to affect the occlusal plane, moving it in a more clockwise direction, resulting in a greater Wits reduction. This may be of clinical significance although not statistically significant. Nonetheless, the results of this study showed that both the Bionator and the Twin Block functional appliances were efficient in correcting class II malocclusions in terms of reduction of overjet, improvement of molar relationship, and change at articulare.

APPENDICES

APPENDIX A.--Case Western Reserve University
Institutional Review Board Notice of Approval

Responsible Investigator: J. Martin Palomo
Department: Dental Clinic Ortho
IRB Protocol #: 20031007
Title: A Comparative Cephalometric Study of the Twin Block and Bionator Appliances in the Treatment of Class II Malocclusion

Approval Date: November 25, 2003
Continuing Review Deadline: November 10, 2004
Expiration Date: November 24, 2004

The Institutional Review Board (IRB) has APPROVED the above new protocol through the expedited review process.

It has been determined that this study involves no risk, and that the following vulnerable populations will be involved: minors.

As an investigator of human subjects, your responsibilities include the following:

1. Report all adverse events and unanticipated problems involving human subjects to the Office of Research Compliance (ORC) within three (3) days of your knowledge of the occurrence.
2. Provide the ORC with a complete Continuing Review form (available at the CWRU IRB Web Pages, or from the ORC) by the continuing review deadline noted above, and when the study is terminated.
3. Discontinue all work pertaining to this protocol if a continuing review approval is not finalized by the expiration date noted above.
4. Submit all proposed changes to the protocol to the ORC, and receive approval from the IRB, before implementation of the change.
5. Keep all research data and consent documents in your possession for at least three (3) years after the final close-out or publication, whichever comes last.

APPENDIX B.--Landmarks used for Cephalometric Analysis listed in alphabetical order with corresponding definitions.

ANS: Anterior Nasal Spine. The anterior tip of the bony process of the maxilla at the lower margin of the anterior nasal opening.

Ar: Articulare. The point at the junction of the posterior border of the ramus and the inferior border of the posterior cranial base (occipital bone).

Go: Gonion. The point on the curvature of the angle of the mandible located by bisecting the angle formed by lines tangent to the posterior ramus and the inferior border of the mandible.

Gn: Gnathion. The point located by taking the mid-point between the anterior (pogonion) and inferior (menton) points of the bony chin.

L1e: Lower Incisor Edge. The most incisal point on the crown of permanent mandibular central incisor.

L1a: Lower Incisor Apex. The root apex of the permanent mandibular central incisor.

L6: Lower Incisor. The buccal groove of the permanent mandibular first molar.

N: Nasion. The most anterior point on the frontonasal suture in the mid-sagittal plane.

Pg: Pogonion. The most anterior point on the chin.

A point: Subspinale. The most posterior midline point in the concavity between the anterior nasal spine and the prosthion (the most inferior point on the alveolar bone overlying the maxillary incisors).

B point: Supramentale. The most posterior midline point in the concavity of the mandible between the most superior point on the alveolar bone overlying the lower incisors (infradentale) and pogonion.

PNS: Posterior Nasal Spine. The posterior spine of the palatine bone constituting the hard palate.

S: Sella. The geometric center of pituitary fossa located by visual inspection.

U1e: Upper Incisor Edge. The incisal most point on the crown of the permanent maxillary central incisor.

U1a: Upper Incisor Apex. The apex of the maxillary central incisor root.

U6: Upper Molar. The midpoint of the mesiobuccal cusp of the permanent maxillary first molar at the cusp tip.

APPENDIX C.--Linear and Angular Measurements used with definitions listed in alphabetical order.

Descriptive Measurements

Maxillary Skeletal

Articulare to A-point. The linear measurement between articulare and A-point.

SNA: The angular measurement between the lines sella-nasion and nasion-A point.

Mandibular Skeletal

Articulare to Gonion. The linear measurement between articulare and gonion.

Articulare to Gnathion. The linear measurement between articulare and gnathion.

Articulare to SN. The linear measurement between articulare and the line between sella and nasion.

Gonion to Pogonion. The linear measurement between gonion and pogonion.

SNB. The angular measurement between the sella-nasion and nasion-B point.

Maxillary to Mandible

ANB. The angular measurement between A point-nasion and nasion-B point.

Maxillomandibular differential. The difference between the linear distances articulare-gnathion and articulare-A point.

Wits. The linear distance between the perpendicular projections of A point and B point to the occlusal plane.

Vertical

Ant Facial Height. The linear measurement between nasion and menton.

Facial Axis Angle. The angular measurement between sella-nasion and sella-pogonion.

Gonial angle. The measurement between articulare-gonion and gonion-gnathion.

Lower Facial Height. The linear measurement between anterior nasal spine and menton.

Post/Ant Facial Height. The posterior facial height (S-Go) divided by the anterior facial height (N-Me), multiplied by one hundred.

Posterior Facial Height. The linear measurement between sella and gonion.

SN to Mandibular Plane. The angular measurement between sella-nasion and gonion-menton.

SN to Occlusal Plane. The angular measurement between sella-nasion and occlusal plane.

SN to Palatal Plane. The angular measurement between the lines sella-nasion and anterior nasal spine-posterior nasal spine.

Upper Facial Height. The linear measurement between nasion and anterior nasal spine.

Maxillary Dental

Upper 1 to SN. The posterior inferior angle formed between the long axis of the maxillary central incisor and sella-nasion.

Mandibular Dental

Lower 1 to A-Pogonion. The linear measurement between the mandibular central incisor tip to the line between A-point and pogonion.

Lower 1 to Mandibular Plane. The posterior-superior angle between the long axis of the mandibular central incisor and gonion-menton.

Interdental

Interincisal Angle. The angular measurement between the long axis of maxillary central incisor and the long axis of the mandibular central incisor.

Molar relationship. The linear distance between the mesiobuccal groove of the mandibular first molar and the cusp tip of the maxillary first molar and parallel to the occlusal plane.

Overbite. The vertical measurement between the incisal edges of the maxillary and mandibular central incisors, perpendicular to the occlusal plane.

Overjet. The horizontal measurement between the incisal edges of the maxillary and mandibular central incisors, parallel to the occlusal plane.

Superimposition Measurements

Overall

A point. The change in the linear position of A-point between Time-1 and Time-2, measured parallel to the average occlusal plane.

ANS horizontal. The change in the linear position of anterior nasal spine between Time-1 and Time-2, measured parallel to the average occlusal plane.

ANS vertical. The change in the linear position of anterior nasal spine between Time-1 and Time-2, measured perpendicular to the average occlusal plane.

B point horizontal. The change in the linear position of B point between Time-1 and Time-2, measured parallel to the average occlusal plane.

B point vertical. The change in the linear position of B point between Time-1 and Time-2, measured perpendicular to the average occlusal plane.

Lower 1 horizontal. The change in the linear position of the incisal edge of the mandibular central incisor between Time-1 and Time-2, measured parallel to the average occlusal plane.

Lower 1 vertical. The change in the linear position of the incisal edge of the mandibular central incisor between Time-1 and Time-2, measured perpendicular to the average occlusal plane.

PNS horizontal. The change in the linear position of posterior nasal spine between Time-1 and Time-2, measured parallel to the average occlusal plane.

PNS vertical. The change in the linear position of posterior nasal spine between Time-1 and Time-2, measured perpendicular to the average occlusal plane.

Pogonion horizontal. The change in the linear position of pogonion between Time-1 and Time-2, measured parallel to the average occlusal plane.

Upper 1 horizontal. The change in the linear position of incisal edge of the maxillary central incisor between Time-1 and Time-2, measured parallel to the average occlusal plane.

Upper 1 vertical. The change in the linear position of incisal edge of the maxillary central incisor between Time-1 and Time-2, measured perpendicular to the average occlusal plane.

Upper 6 horizontal. The change in the linear position of mesiobuccal cusp tip of the maxillary first molar between Time-1 and Time-2, measured parallel to the average occlusal plane.

Upper 6 vertical. The change in the linear position of mesiobuccal cusp tip of the maxillary first molar between Time-1 and Time-2, measured perpendicular to the average occlusal plane.

Maxilla

Upper 1 horizontal. The change in the linear position of the incisal edge of the maxillary central incisor between Time-1 and Time-2, measured parallel to the average occlusal plane from the maxillary superimposition.

Upper 1 vertical. The change in the linear position of the incisal edge of the maxillary central incisor between Time-1 and Time-2, measured perpendicular to the average occlusal plane from the maxillary superimposition.

Upper 6 horizontal. The change in the linear position of mesiobuccal cusp tip of the maxillary first molar between Time-1 and Time-2, measured parallel to the average occlusal plane from the maxillary superimposition.

Upper 6 vertical. The change in the linear position of mesiobuccal cusp tip of the maxillary first molar between Time-1 and Time-2, measured perpendicular to the average occlusal plane from the maxillary superimposition.

Mandible

Articulare. The change in the linear position of articulare between Time-1 and Time 2.

B Point horizontal. The change in the linear position of B point between Time-1 and Time-2, measured parallel to the average occlusal plane from the mandibular superimposition.

Lower 1 horizontal. The change in the linear position of incisal edge of the mandibular central incisor between Time-1 and Time-2, measured parallel to the average occlusal plane from the mandibular superimposition.

Lower 1 vertical. The change in the linear position of incisal edge of the mandibular central incisor between Time-1 and Time-2, measured perpendicular to the average occlusal plane from the mandibular superimposition.

Lower 6 horizontal. The change in the linear position of the mesiobuccal groove of the mandibular first molar between Time-1 and Time-2, measured parallel to the average occlusal plane from the mandibular superimposition.

Lower 6 vertical. The change in the linear position of the mesiobuccal groove of the mandibular first molar between Time-1 and Time-2, measured perpendicular to the average occlusal plane from the mandibular superimposition.

Appendix D.--Range of Minimum and Maximum Values of Pretreatment (T1) Descriptive Cephalometric Measurements for Bionator and Twin Block Treatment Groups.

	BIONATOR		TWIN BLOCK	
	MIN	MAX	MIN	MAX
MAXILLARY SKELETAL				
SNA (°)	75.0	89.0	74.0	85.0
Ar-A (mm)	82.2	99.0	79.0	99.6
MANDIBULAR SKELETAL				
SNB (°)	71.0	80.0	67.0	80.0
Ar-Gn (mm)	92.6	116.8	92.7	116.4
Ar-Go (mm)	33.3	50.5	33.7	52.1
Go-Pg (mm)	61.7	85.3	63.9	81.3
Ar-SN (mm)	22.3	36.5	19.8	34.4
MAXILLA TO MANDIBLE				
ANB (°)	2.0	8.0	1.0	8.0
Wits (mm)	-0.5	7.9	0.5	9.1
Ar/Gn-Ar/A(mm)	9.5	22.8	10.1	22.4
VERTICAL				
SN-OP (°)	13.0	25.0	10.0	25.0
SN-PP (°)	1.0	13.0	1.0	14.0
SN-MP (°)	23.0	39.0	22.0	43.0
SN-SPg (°)	60.0	69.0	60.0	71.0
N-ANS (mm)	46.2	61.1	46.3	60.3
ANS-Me (mm)	54.2	71.7	56.7	75.9
N-Me (mm)	101.6	130.4	106.5	134.1
Ar-Go-Gn (°)	111.0	139.0	114.0	131.0
S-Go (mm)	59.6	86.0	62.2	83.5
Post/Ant Facial Ht (%)	58.0	73.0	53.8	73.7
MAXILLARY DENTAL				
U1-SN (°)	91.0	120.0	91.0	120.0
MANDIBULAR DENTAL				
L1-A-Pg (°)	7.0	34.0	12.0	32.0
L1-MP (°)	91.0	108.0	91.0	107.0
INTERDENTAL				
OB (mm)	1.3	10.5	1.3	9.4
OJ(mm)	2.4	10.6	4.5	11.8
Interincisal (°)	113.0	159.0	112.0	152.0
Molar relationship (mm)	2.3	6.8	2.1	8.1

Appendix E.--Range of Minimum and Maximum Values of Post-treatment (T2) Descriptive Cephalometric Measurements for Bionator and Twin Block Treatment Groups.

	BIONATOR		TWIN BLOCK	
	MIN	MAX	MIN	MAX
MAXILLARY SKELETAL				
SNA (°)	75.0	91.0	75.0	86.0
Ar-A (mm)	84.9	100.5	78.8	101.5
MANDIBULAR SKELETAL				
SNB (°)	72.0	82.0	69.0	81.0
Ar-Gn (mm)	94.7	128.6	97.3	123.9
Ar-Go (mm)	33.2	58.6	35.9	56.3
Go-Pg (mm)	66.4	90.1	66.4	84.0
Ar-SN (mm)	21.4	39.6	23.6	36.7
MAXILLA TO MANDIBLE				
ANB (°)	2.0	8.0	1.0	6.0
Wits (mm)	-1.1	8.3	-3.4	6.3
Ar/Gn-Ar/A(mm)	9.5	28.4	12.5	25.4
VERTICAL				
SN-OP (°)	9.0	29.0	12.0	28.0
SN-PP (°)	2.0	15.0	0.0	11.0
SN-MP (°)	19.0	41.0	26.0	45.0
SN-SPg (°)	60.0	71.0	60.0	71.0
N-ANS (mm)	47.6	62.2	47.8	61.2
ANS-Me (mm)	57.6	78.2	61.5	80.6
N-Me (mm)	111.9	138.1	113.7	141.7
Ar-Go-Gn (°)	109.0	135.0	113.0	134.0
S-Go (mm)	62.1	94.2	65.8	90.9
Post/Ant Facial Ht (%)	55.5	76.6	53.7	71.4
MAXILLARY DENTAL				
U1-SN (°)	92.0	111.0	93.0	115.0
MANDIBULAR DENTAL				
L1-A-Pg (°)	11.0	36.0	15.0	32.0
L1-MP (°)	92.0	116.0	91.0	106.0
INTERDENTAL				
OB (mm)	-0.1	8.0	-0.7	6.9
OJ(mm)	0.3	6.9	0.0	6.7
Interincisal (°)	111.0	161.0	111.0	145.0
Molar relationship (mm)	-4.5	3.1	-5.3	2.8

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