Cephalometric Evaluation of Skeletal and Dentoalveolar Effects of Twin-Block Appliance and van Beek Headgear-Activator (vBHGA) in the Correction of Class II Malocclusion

By

Rohan S. Kirtane

A Thesis submitted to
the Faculty of Graduate Studies of
The University of Manitoba
in partial fulfilment of the requirements for the degree of

MASTER OF SCIENCE

Department of Preventive Dental Science
Faculty of Dentistry
Division of Orthodontics
University of Manitoba
Winnipeg, Manitoba

Abstract

Objective: To evaluate the cephalometric skeletal and dentoalveolar short-term effects of Twin Block (TB) and van Beek Headgear Activator (vBHGA) appliances, in the correction of skeletal Class II malocclusion (ANB≥5) in growing patients as determined by the CVM method, in comparison with a growing untreated control.

Materials and Methods: Pre (T1) and post-functional appliance (T2) lateral cephalograms were retrospectively obtained for the vBHGA (n=46), TB (n=45), and control (n=45) groups. The groups were also stratified into horizontal or vertical using Jarabak ratio values. A customized cephalometric analysis and superimposition-based measurements were performed. Analysis of Covariance (ANCOVA) regression models at the 5% level of significance were used.

Results: Both appliances equally improved the jaw relationship. For vBHGA, they were: ANB (1.59^0; p=0.00) and Harvold Difference (2.51mm; p<0.0001) and for TB, they were ANB: 1.70^0; p=0.01, Wits: 3.59mm; p<0.001 and Harvold Difference: 2.65mm; p<0.0001). While this mostly occurred due to forward positioning of the mandible (SNB: 0.96^0; p=0.01) for TB; maxillary restriction with counterclockwise rotation of the palatal plane (SNA: 1.59^0; p=0.00 and PP-SN: 0.18^0; p=0.64) was seen with vBHGA. Dentoalvelolar changes were more pronounced with TB. Only U1-SN^0, U1-NA^0, and U1-PP^0 values were affected by the growth pattern. The TB horizontal growers experienced more maxillary incisor retroclination than their vBHGA counterparts (U1/NA^0: 3.62^0; p=0.0067) The overbite reduced more in the TB group (OB: 1.83mm; p<0.001), but this was due to greater relative intrusion of the lower incisors as they proclined (0.80mm; p=0.05).

Conclusions: Both appliances were effective to correct skeletal Class II malocclusions in growing

patients regardless of growth pattern. The mechanism by which this occurred differed between the groups and can be used in favor of specific patients’ needs.

Dedication

I dedicate this work to my wife Rajasi, daughter Navya, my parents, parents in-laws, my sister and brother-in-law and my late grandparents (Gurunath and Shanta Kulkarni) for their endless love, belief in my dreams, encouragement and faith. I will be forever indebted to Dr.William Wiltshire, who gave me this golden opportunity to pursue one of the most challenging and rewarding true specialties in dentistry and for his leadership, good counsel and good faith. He not only taught me Orthodontics, but to be a better and kind human being.

Acknowledgements

The authors are grateful for the Dr. Gerald Niznick College of Dentistry Endowment Fund that assisted with the costs associated with this study

A sincere thank you to:

Dr.Fabio Pinheiro for giving me an opportunity to undertake this study, and encouraging me to come out of my comfort zone to reach my goals and that promoted critical thinking.

Dr.William Wiltshire, for making my dream, of becoming an Orthodontist, come true for his unflinching support during my entire residency, for being fair and kind, and for allowing me to use records from his twenty-five years of the use of the van Beek Headgear-Activator (vBHGA) functional appliance at the University of Manitoba, Graduate Orthodontic Program.

Dr.Adnan Shah, for guidance and support throughout my Residency and this project.

Dr.Robert Drummond, for his selfless help throughout my Residency, and troubleshooting my research project despite not being on my advisory committee. I will be forever grateful to you.

Dr.Badri Thiruvenkatachari, for providing the sample of Twin-Block (TB) patients, and continually advising on innumerable occasions.

Brenden Dufault, for his outstanding statistical analysis, and professional work ethic.

Barbara Brinker, at Dolphin imaging and management solutions.

Sean Curry, at the AAOF legacy foundation.

Sandra and Egon Munoz, for helping me find and collect records from the archives of patient records at the Graduate Orthodontic Clinic.

Dr.Santhosh Jayachandran, for his guidance and encouragement.

Dr.Matt Kotyk, for allowing me to build on his original sample of the vBHGA.

My Family, without whom, I would not be where I am today.

AAOF legacy foundation: *"This study was made possible by use of material from the Burlington Growth Centre, Faculty of Dentistry, University of Toronto, which was supported by funds provided by Grant (1) (No. 605-7-299) National Health Grant (Canada), (data collection); (2) Province of Ontario Grant PR 33 (duplicating) and (3) the Varsity Fund (for housing and collection)".*

Table of Contents

List of Tables

List of Figures

Chapter 1

Introduction

Every practicing orthodontist is involved with the correction of Class II malocclusions since they constitute a significant percentage of the cases they see in their practices (Tulloch et al, 1990). Myriad ways to treat them have been investigated and published (Proffit et al, 2012). Some attempt to correct the underlying skeletal imbalance through restraint of maxillary growth by extraoral traction (EOT), others attempt growth modification with use of functional appliances for mandibular advancement, and the rest choose dental camouflage of the jaw discrepancy or orthognathic surgery.

The technique chosen should be directed toward the true etiology of the malocclusion (McNamara, 1981). The most common diagnostic finding in Class II malocclusion is mandibular skeletal retrusion (Pancherz, 1997; McNamara, 1981;).

A wide range of functional appliances aimed to stimulate mandibular growth by forward posturing of the mandible is available to correct this type of skeletal and occlusal disharmony (Pangrazio-Kulbersh et al, 2003; McNamara et al, 2001;).

The Twin-Block (TB) appliance is one of the most widely used removable functional appliances. It is constructed in two separate parts: the upper and lower appliances. Forward positioning of the mandible is achieved by incorporating buccal blocks with interlocking inclined planes of approximately 70^{o}, with the lower block engaging in front of the upper block (Clark, 1982).

The van Beek Headgear-Activator (vBHGA) is also a removable functional appliance. Forward positioning of the mandible is achieved by its monobloc structure with a thick (8-10 mm) posterior bite plane, long and deep lingual flanges in the lower base, labial coverage of the upper and lower anterior teeth and a short and rigid outer bow at the level of the maxillary canines. Differently from the TB, it is combined with a high pull headgear (van Beek, 1984, 1982).

Systematic review of the literature has repeatedly shown the TB to be clinically effective and efficient in increasing the total mandibular length (Co-Gn and Co-Pg), ramus height (Ar-Go) and the mandibular body length (Go-Gn) when treated during the peak of mandibular growth and for a sufficient duration (Ehsani et al, 2015; Cozza et al, 2006; Chen et al, 2002). Hence, TB has probably become the gold-standard of the removable functional appliances (Ehsani et al, 2015; Cozza et al, 2006; Chen et al, 2002; Chadwick et al, 1998).

Among the dentoalveolar changes, TB causes eruption of mandibular molars, eruption and distalization of the maxillary molars, retrusion and retroclination of the maxillary incisors and protrusion and proclination of the mandibular incisors causing clockwise rotation of the mandible (Ehsani et al, 2015). So, despite the increased mandibular length, its facial impact is reduced by the simultaneous increase in the face height, which is not desirable in the correction of the convex profile in class II faces (Ehsani et al, 2015).

vBHGA, on the other hand, has been reported to produce true intrusion of the maxillary incisors, thereby favoring the treatment of deep overbites, which is commonly encountered in Class II malocclusions (van Beek, 1984, 1982). Due to presence of its thick bite blocks in excess of the freeway space on the posterior teeth, it has the "bite-block" effect and prevents the upper and lower molar extrusion, thus preventing the increase in the face height and translating the increase in mandibular length to increased horizontal projection of the chin, hence improving facial profile (Dermaut et al, 1992; van Beek, 1984, 1982).

Therefore, vBHGA appears to be an effective appliance for Class II malocclusions with a steep mandibular plane angle (MPA), deep overbite and over-extruded maxillary incisors causing a gummy smile (Dermaut et al, 1992).

To date, numerous studies (Varlik et al, 2008; Jena et al, 2006; Sidlauskas, 2005; O'Brien et al, 2003a; Mills & McCulloch, 2000, 1998; Toth & McNamara, 1999; Illing et al, 1998; Morris et al, 1998; Lund & Sandler, 1998) have been conducted on the effects of the TB appliance and only a handful (Phan, 2006; Dermaut et al, 1992; van Beek, 1984, 1982) on the vBHGA. They have been researched in isolation, with no studies comparing the effectiveness and possible indications of the two appliances, especially in relation to the growth pattern (Horizontal or Vertical). Therefore, this study aims to compare the skeletal and dentoalveolar effects of the TB and vBHGA as well as assess their indication in relation to growth pattern.

Chapter 2

Literature Review

2.1 Prevalence of Class II Malocclusion

Phase 1 of the National Health and Nutrition Estimates Survey III (NHANES III) conducted in the United States (US) between 1988 and 1991 provided estimates of malocclusion in the US population (Proffit et al, 1998). Overjet of more than 5mm, suggestive of Class II malocclusion, occurs in 23% of children, 15% of youths, and 13% of adults (Proffit et al, 1998) making Class II malocclusions one of the most common orthodontic problems (Proffit et al, 1998).

2.2 Etiology of Class II Malocclusion

The development of Class II malocclusion is a complex multifactorial process and arises due to both skeletal and dental abnormalities (Proffit & Fields, 2012). These abnormalities do not follow a simple Mendelian inheritance, but rather result from a close interaction between genetics and environment (epigenetics) during growth and development of both the jaws and the dentition; the etiology of Class II malocclusion lies at this junction. Determining the etiology, is the critical step to provide the most appropriate treatment (Proffit & Fields, 2012).

Craniofacial growth appears to be genetically controlled, and the polygenetic inheritance of Class II malocclusion has been established in the literature (Nakasima et al, 1982; Harris, 1975), particularly in relation to mandibular retrognathia. A study (Nakasima et al, 1982) compared craniofacial morphologic correlations between 96 Class II patients, 104 Class III patients, and their parents. Lateral and frontal cephalograms were obtained for the patients and their parents. Correlation coefficients were calculated for various cephalometric measurements. The authors found significant differences between the Class II and III groups, but high correlation coefficients between parents and their offspring within each group. Therefore, they concluded that a strong familial tendency exists for the development of Class II malocclusion.

Various environmental and physiological factors are also known to contribute to Class II malocclusion. Children with nasopharyngeal obstruction associated with enlarged adenoids have been shown to have longer faces and smaller mandibles when compared to controls (Linder-Aronson, 1970). Harvold et al (1981) studied the effects of oral respiration on craniofacial development of primates. When nasal respiration was blocked in primates using silicone plugs, the investigators noted that they developed an open mouth posture and subsequently showed a more vertical growth pattern and greater tendency toward Class II malocclusion, likely due to backward rotation of the mandible. Similar findings were noted by Melsen et al (1987) when they compared mouth breathing patients to nasal breathers. Melsen et al (1979) studied the effects of swallowing pattern on malocclusion. They found that children who exhibited a swallowing pattern with tooth contact had a significantly lower prevalence of vertical and sagittal discrepancies compared to children with other swallowing patterns. It is also known that individuals with decreased masticatory muscle function have a tendency toward a vertical growth pattern, Class II malocclusion, and anterior open bite (Kiliaridis, 2006). However, it has been shown that the bite forces are the same for normal and long-faced children, implying that the loss of bite force and the difference in muscle fiber type may develop with, as opposed to causing, a malocclusion (Proffit & Fields, 1983). Prolonged non-nutritive digit sucking has also been known to contribute to malocclusion, depending on the type, frequency, intensity and duration. Melsen et al (1979) found that prolonged thumb sucking results in maxillary constriction, clockwise rotation of the mandible and subsequent Class II malocclusion. Finally, children who constantly exhibit posture with head extension (raised position of the head in relation to cervical column) are more likely to present with vertical growth patterns and Class II malocclusion (Solow & Sonnesen, 1998). Therefore, it seems that environmental adaptations and physiological functions, in addition to genetics, play an important role in the development of Class II malocclusion.

There is conflicting evidence on the contribution of the two skeletal units (maxilla and mandible) in the etiology of Class II malocclusions. A study (Johnston, 1998) on the development of occlusion from the mixed-dentition stage showed that mandibular excess during the pubertal growth spurt and control of the mesial movement of maxillary molars during the differential mandibular growth is sufficient to end up with a Class I occlusal relationship.

A study on the long-term skeletal and dental outcomes of completed cases treated with the edgewise technique successfully showed that the mandible does reach its predetermined genetic potential if the right environment is created for it by controlling the vertical dimension which involves the anchoring of the maxillary molars, thereby preventing them from extruding and mesializing (Bayirli et al, 2013).

Studies using treated cases with the Alexander Discipline from the "Room of Truth" at Baylor University has shown stable corrections of skeletal Class II malocclusions in growing children, by restricting the growth of the maxilla with a cervical facebow (Council on Scientific Affairs, 2005; Elms et al, 1996a, 1996b).

Contrastingly, the mandible is implicated as being underdeveloped or small in Class II malocclusions in several (Bishara, 2006; Baccetti et al, 1997; McNamara, 1981) cephalometric studies that aimed to characterize the key features of Class II malocclusion. In one of those studies (Bishara, 2006), it was observed that a Class II division 1 malocclusion may be characterized by the anterior position of the skeletal maxilla and/or maxillary teeth relative to the cranium, a posterior position of the mandible and/or mandibular teeth, an underdeveloped mandible, or a combination of these factors. Another study (McNamara, 1981) reviewed previous publications and investigated the frequency of occurrence of key components in children with Angle Class II malocclusion. Lateral cephalograms of 277 children aged 8-10 with Class II malocclusion were evaluated and the characteristics contributing to the malocclusion in each patient were recorded. It was found that the maxilla exhibited a neutral position in most cases and true skeletal protrusion was only present in a small percentage of the patients. When not neutrally located, the maxilla was found to be in a retruded position more often than a protruded position. The study (McNamara, 1981) found that mandibular skeletal retrusion was the single most common characteristic the studied sample. From these findings, it was suggested that treatment to alter the amount and direction of mandibular growth may be more appropriate than those directed at restricting maxillary development.

The early identification of patients with significant Class II malocclusion would definitely be helpful in considering the applicability of early intervention. In a study (Varrela, 1998) which investigated the early developmental traits in Class II malocclusion, it was concluded that the first skeletal signs of Class II malocclusion are a narrow maxilla and reduced sagittal mandibular growth; other skeletal features may develop as secondary adaptations.

Baccetti et al (1997) also studied the early dentofacial characteristics of Class II malocclusion from the primary through the mixed dentition. They found that in the transition to the mixed dentition, Class II features were either maintained or became more prominent. They also reported that significant mandibular retrusion and size deficiency were present in the deciduous dentition in Class II patients. Compared to the Class I control sample, the Class II group cephalometrically showed greater maxillary growth increments and smaller mandibular increments as well as greater downward and backward rotation of the mandible. The authors concluded that clinical signs of

Class II malocclusion, both skeletal and dental, are evident in the primary dentition and persist into the mixed dentition.

2.3 Growth in Individuals with Class II Malocclusion

Growth differences in patients with Class II malocclusion compared to Class I subjects are important to consider. The Bioprogressive philosophy and one school of clinicians and educators believe that growth of the skeletal units is identical in Class I and Class II malocclusions. The mandible can and does reach its pre-determined genetic potential when the environment is provided for its growth by restraining the maxilla and unlocking the mandible in the sagittal, vertical and transverse dimensions (Bayirli et al, 2013; Council on Scientific Affairs, 2005; Johnston, 1998; Ricketts, 1998; Elms, 1996a, 1996b).

The other school of thought has a different take on this subject. A study (Stahl et al, 2008) compared the craniofacial growth changes in 17 untreated subjects with Class II division 1 malocclusion to 17 subjects with normal occlusion from the pre-pubertal through post-pubertal stages of development. The cervical vertebral maturation (CVM) method (Baccetti et al, 2005) was used as a biological indicator of skeletal maturity. The study (Stahl et al, 2008) showed that craniofacial growth in individuals with Class II malocclusion is similar to growth in those with normal occlusion at most developmental stages. The only exception being the significantly smaller increments in mandibular length during the growth spurt (cervical stage 3-4) in Class II subjects. As a result, when compared to long-term (cervical stage 1-6), Class II patients showed less mandibular growth than Class I subjects. The authors concluded that Class II skeletal disharmony does not spontaneously self-correct with growth. It can also be inferred from the study that the best time to attempt to stimulate mandibular growth in Class II patients would be during the growth spurt (cervical stage 3-4) since this is when mandibular growth significantly lags behind in these patients compared to those with normal occlusion.

These conclusions had already been drawn in a longitudinal study (Buschang & Martins, 1998) of 99 Class I and II subjects. The authors found that anteroposterior relationships (measured as horizontal distance from ANS to pogonion) usually improved during childhood, but worsened during adolescence. Difference in the horizontal growth of the mandible when comparing Class I and II subjects was the primary reason. This study also supports the idea that Class II malocclusion does not self-correct over time and appropriate intervention is necessary.

2.4 Psychosocial Impact of Increased Overjet and Protruded Incisors

Even though malocclusion is not a disease state, the benefits of Orthodontic treatment should be considered in terms of both the social and mental well-being of an individual.

Facial appearance is critical for an individual's social status. Attractive children are seen to make stronger first impressions, have higher intelligence quotient (I.Q.), being more sociable, and receiving more positive treatment (Hunt et al, 2005; Shaw et al, 1980).

Certain occlusal traits, such as increased overjet, appear to make a child more susceptible to teasing and bullying, which can have a profound impact on self-esteem and lead to long term health and social problems (Seehra et al, 2011). Interceptive orthodontic treatment to reduce overjet reduced bullying by 78% in one study (Seehra et al, 2013).

More recently, there has been greater focus on the potential impact that malocclusions can have on quality of life (QOL) for affected individuals. This is a difficult relationship to define, but in terms of health it is based on an individual's experience of pain or discomfort, physical function, psychology and social function. Certain occlusal traits, such as increased overjet and dental spacing, appear to have some negative impact for children and their families (Johal et al, 2007). Other studies (Al-Omari et al, 2014; Al-Bitar et al, 2013) on bullying have found a significant relationship between bullying and dentofacial features and negative effects on oral health-relation quality of life (OHRQOL). Teeth were the first target of bullying followed by strength and weight. The three most commonly reported dentofacial features targeted by bullies were spacing between the teeth or missing teeth, shape and color of the teeth, and prominent maxillary anterior teeth (Al-Bitar et al, 2013). It was reported (Badran, 2010) that patients who had received orthodontic treatment displayed greater self-esteem than those who did not. It was also shown that dissatisfaction with dental appearance had a strong predictive effect on self-esteem. Higher levels of self-esteem were reported in Korean girls following fixed orthodontic treatment compared to an untreated control group (Jung, 2010). On the other hand, longitudinal studies have demonstrated little objective evidence to support the assumption that orthodontic treatment can improve long-term psychological health of the individual (Benson, 2015; Kenealy et al, 2007).

Besides the negative psychosocial impact, increased overjet is a risk factor for trauma to the upper incisors (Järvinen, 1978). Correction of the incisor relationship will theoretically reduce the vulnerability of these teeth to damage following trauma. Although most incidences of trauma occur soon after eruption of the permanent incisors and prior to the age when orthodontics is usually started, the literature supports the early correction of Class II division 1 incisor relationship to reduce the later incidence of trauma (Batista et al, 2018).

2.5 Mandibular Growth and Maturational Indices

Arne Bjork's 1963 longitudinal radiographic cephalometric study of facial growth in children using the implant method (where metallic implants were placed in the jaws of growing children and used as fixed reference points) found a strong correlation between the pubertal growth spurt peak height velocity (PHV) and the peak mandibular growth rate (Bjork, 1963). In 1982, Leonard Fishman of the Eastman Dental Center in Rochester, NY, described the hand-wrist radiographic evaluation and the skeletal maturity indices (SMI) to assess general skeletal maturity (Fishman, 1982). Recently, the Cervical Vertebral Maturation (CVM) method (Baccetti et al, 2005), based on the analysis of the second through fourth cervical vertebrae in a lateral cephalometric radiograph, thus avoiding additional radiation exposure, has become a practical and useful maturational index. Identification of skeletal maturational indicators allows the clinician to detect the optimal time to start mandibular deficiency treatment with functional orthopedics. The CVM method has been validated as a reliable indicator of mandibular skeletal maturity by correlating it to the hand-wrist method (Wong et al, 2009; Grave & Townsend, 2003).

2.6 CVM Method of Differentiating Pre-peak from Post-peak Growth Phases

The six stages of CVM can be divided into stages before the peak: (CS1-2), at peak (CS3-4) and stages after the peak: (CS 5-6). Detection of CS2 indicates that growth spurt is approaching. Peak in mandibular growth occurs at CS 3-4. Active growth is virtually complete at the CS6 stage. The following description is according to the method described by Baccetti (Baccetti et al, 2005).

Cervical Stage 1 (CS1)

- Inferior borders of C2, C3, C4 are flat.
- The bodies of C3 and C4 are trapezoid in shape.
- The peak in mandibular growth will occur on average 2 years after this stage.

Cervical Stage 2 (CS2)

- A concavity is present at the inferior border of C2.
- The bodies of C3 and C4 are still trapezoid in shape.
- The peak in mandibular growth will occur on average 1 year after this stage.

Cervical Stage 3 (CS3)

- Distinct concavities are present in the inferior borders of C2 and C3.
- The bodies of C3 and C4 are rectangular horizontal or trapezoid in shape.
- The peak in mandibular growth will occur during the year after this stage.

Cervical Stage 4 (CS4)

- Distinct concavities are present in the inferior borders of C2, C3, and C4.
- The vertebral bodies of C3 and C4 are rectangular horizontal in shape.
- The peak in mandibular growth has already occurred within 1-2 years before this stage.

Cervical Stage 5 (CS5)

- Concavities are present at the lower borders of C2, C3 and C4.
- The bodies of C3 and C4 are square in shape.
- The peak in mandibular growth has ended at least 1 year before this stage.

Cervical Stage 6 (CS6)

- Deep concavities are seen in the inferior borders of C2, C3, and C4.
- The bodies of C3 and C4 are rectangular vertical in shape.
- The peak in mandibular growth has ended at least 2 years before this stage.

2.7 Molecular Basis for Functional Jaw Orthopedics

The efficacy of functional appliance treatment of mandibular deficiencies strongly depends on the biological responsiveness of the condylar cartilage which is dependent on the mandibular growth rate (Baccetti et al, 2000). Molecular mediators, chiefly the Indian Hedgehog (Ihh) and SOX-9 were found (Al-kalaly et al, 2009; Rabie & Al-Kalaly, 2008; Dai & Rabie, 2008; Shen et al, 2006; Shum et al, 2004; Leung et al, 2004; Rabie et al, 2004a, 2004b, 2003a, 2003b, 2003c, 2003d, 2003e, 2002a, 2002b, 2001; Chayanupatkul, 2003) to translate mechanical forces delivered through functional advancement of the mandible into cellular responses in the condylar cartilage leading to growth.

It was proved in animal studies that, firstly, there is a minimum threshold of advancement needed to elicit a biologic response in the condylar cartilage (Rabie & Al-Kalaly, 2008). Secondly, the method of advancement (stepwise versus maximum advancement) matters (Wey et al, 2007). And lastly, the duration of advancement is what creates stability of the newly formed bone in the condyle. The "emergency" Type 3 collagen needs adequate time to convert into solid type 1 collagen (Chayanupatkul, 2003).

2.8 History of Class II Treatment and Functional Appliances

At the beginning of the 20th century, extraoral forces were applied to the maxilla with headgear for the correction of Class II malocclusion. This therapeutic method was a reflection of the belief that prevailed during that era that the majority of skeletal Class II malocclusions are caused by the protrusion of the maxilla (Mills & McCulloch, 1998).

However, subsequent studies indicated that the incidence of Class II division 1 malocclusion resulting from the protrusion of the maxilla does not exceed 20% of the total cases of Class II malocclusion, and the majority of these cases are significantly caused by mandibular retrusion, which prompted many researchers to use functional appliances that stimulate the growth of the mandible for the treatment of skeletal Class II malocclusion (Pancherz et al, 1997; McNamara, 1981) via protraction of the condyles out of the glenoid fossa in order to stimulate cartilaginous growth on the condylar head within the Temporomandibular joint (TMJ).

Many researchers have developed various functional appliances, starting with the Monoblock developed by Robin (Wahl, 2006), followed by the Activator developed by Andresen and Haupl

(Wahl, 2006), modified activators by Harvold (Vargervik & Harvold, 1985) and Woodside (Woodside et al, 1987), the Bionator developed by Wilhelm Balters (Eirew, 1981), and the Function Regulator developed by Rolf Frankel (Proffit & Fields, 2012; Fränkel, 1980) These can be combined with extra-oral traction with a high-pull headgear such as the van Beek Headgear-Activator (vBHGA) (van Beek, 1984) or the Teuscher activator (Teuscher, 1978).

All the activator variations described above are monobloc appliances generally to be worn at night. William Clark developed the Twin Block appliance which should be used full-time. He invented it fortuitously to treat one of his young patients who had suffered an avulsion of one of his maxillary central incisors and had the need to keep the mandible advanced to keep the lower lip from putting pressure on the replanted tooth (Clark, 1988). He may also have been inspired by the Removable Double Plate Appliance developed by Martin Schwarz in the 1950s, which was later referred to as the Bite-Jumping Appliance (BJA). It incorporates guide bars in a maxillary plate, which are guided by an inclined plane in a mandibular plate. This articulation leads the mandible forward when occlusion occurs (Lisson & Tränkmann, 2002). The Twin Block (TB) also consists of upper and lower removable appliances, but its bite blocks are composed of bite ramps set at about 70 degrees. When occluding, the lower block bites in front of the upper to posture the mandible forwards. Although the Twin Block appliance is robust, it is well tolerated and has become very popular in the UK (Clark, 1988, 1982).

The Twin Block is one of the most widely used and researched removable functional appliances to correct Class II dentoskeletal disharmony. It was found to be the preferred functional appliance in the United Kingdom; more than 75% of British Orthodontic Society members claimed it is their first choice (Chadwick et al, 1998).

2.9 Dental and Skeletal Effects of Functional Orthopedic Appliances

A systematic review of the literature to assess the effectiveness and efficiency of functional orthopedic appliances in general in enhancing mandibular growth in Class II subjects have been carried out previously (Chen et al, 2002). The authors focused on randomized controlled trials (RCTs) done between 1966 to 1999, but were followed by others (Cozza et al, 2006) who added longitudinal prospective and retrospective controlled clinical trials (CCTs) to broaden the scientific information on the treatment effects of functional orthopedic appliances.

The CCTs and retrospective studies that were analyzed showed that the supplementary mandibular growth (Co-Gn or Co-Pg) induced by functional appliances was clinically significant (> 2mm) in 2/3rd of their samples compared to untreated Class II samples (Cozza et al, 2006) when treated during the peak pubertal growth spurt and for an adequate duration. The correction is through forward mandibular posturing and vertical opening of the bite through extrusion of the molars, which helps to reduce the deep overbite. A millimeter of vertical increase in the lower anterior face height (LAFH) camouflages a millimeter of increased mandibular length, so the horizontal chin projection at pogonion might not be evident despite the mandibular growth (Clark, 1988).

There are interesting findings from the RCTs (Tulloch et al, 2004; O'Brien et al, 2003a; Keeling et al, 1998) that were done over the years in terms of the gains in mandibular lengths with phase 1 early (pre-adolescent) treatment using functional appliances followed by a second phase of comprehensive orthodontic treatment using fixed-appliances during adolescence compared to one-phase treatment using fixed-appliances during the adolescent growth spurt.

An RCT was conducted in North Carolina (Tulloch et al, 2004) between 1988 and 2001 with children randomly assigned to a combination headgear, modified Bionator or to an untreated control group. All three groups had an average starting age of 9.4 years. Phase 1 treatment consisted of 15 months of treatment. The ANB and overjet reduction in the short term was similar for both groups, but with different mechanics. The headgear restricted the maxilla, while the bionator advanced the mandible (3.69mm). However, these promising changes waned during the second phase of full-fixed orthodontic therapy when compared to untreated controls and there was no difference between the early pre-adolescent treatment group and the group treated during adolescence (Tulloch et al, 2004). It must be noted here that some patients were started as early as 7 years, which may have been too young and too pre-pubertal.

A similar trend was seen and reported with the RCT at the University of Florida (Keeling et al, 1998). The results of the study reported significant enhancement of mandibular growth with either a Bionator or Headgear in 9-10 year olds, compared to the control group, but the follow-up study describing long term results for early treatment of Class II malocclusions stated that there was no difference in mandibular growth between the early treated group and the group treated during adolescence (Dolce et al, 2007).

The RCT done in the UK (O'Brien et al, 2003a) was a multicenter one and was conducted between 1997 and 2000 with 174 children, aged 8-10 years, randomly assigned to a TB treatment and an untreated phase 1 control group. The study reported successful correction of overjet and molar relationship, but it was mainly with dentoalveolar changes and only a small contribution from the skeletal changes. The results did not report a clinically significant change in the total mandibular length (1.55mm increase in the Co-Gn or Co-Pg) with the TB. This study was however done in the pre-pubertal growth phase, and perhaps more mandibular growth could have been obtained had it been conducted during the growth spurt. When this cohort was followed up after completion of the second phase of comprehensive orthodontic treatment, the skeletal gains were further lost when compared to untreated controls (O'Brien et al, 2009).

Another RCT (Jakobsson, 1967) published over fifty years ago, reported similar outcomes from wearing the activator at the average age of 8.5 years, which is prior to the adolescent growth spurt. The supplementary increase in the total mandibular length (Co-Gn or Co-Pg) was barely 0.7mm, exactly the same amount recorded elsewhere (Nelson, 1993), although the latter failed to report an appraisal of the skeletal maturity.

There is unanimous agreement in the literature (Marşan, 2007; Tulloch et al, 2004; O'Brien et al, 2003a, 2003b; Keeling et al, 1998; Altenburger & Ingervall, 1998;) regarding the dentoalveolar changes with functional appliances which include retroclination and retrusion of the upper incisors, proclination and protrusion of the lower incisors, distalization/distal tipping of the maxillary molars and mesialization of the mandibular molars. The deep-bite improvement is due to eruption of the buccal segments.

A robust retention plan to maintain the skeletal and dentoalvelolar changes must be a critical part of the management of early correction of Class II malocclusions (Wiltshire & Tsang, 2006).

RCTs on the effects of functional appliances prescribed at the pubertal growth spurt are few and far between. There have been a few studies (Santamaría-Villegas et al, 2017; Marsico, 2011; Antonarakis & Kiliaridis, 2007) evaluating the effect of different functional appliances, including the extra-oral traction (EOT) alone (Pirttiniemi et al, 2005; Tulloch et al, 1997), activators (Illing et al, 1998; Tulloch et al, 1997; Courtney et al, 1996; Kjellberg et al, 1995), headgear-activator (HGA) combination appliances (Sari et al, 2003; Uçüncü et al, 2001; Illing et al, 1998) and the TB (O'Brien et al, 2003b; Illing et al, 1998; Lund & Sandler, 1998;) amongst others used during early adolescence as assumed by the chronologic age reported in the studies. The conclusions from these studies were that these various appliances have most of their skeletal effect on one of the two jaws: it is the mandible for TB, activators and HGA; while it is the maxilla for EOT. The only functional appliance that showed mandibular and maxillary effect was the TB (Illing et al, 1998). The skeletal effects of such appliances were statistically significant, but not clinically significant. A Cochrane review (Batista et al, 2018) that compared ANB and overjet (OJ) correction in an early two-phase treatment group versus a one-phase adolescent treatment group, concluded that the only benefit of early treatment is reduced incidence of incisal trauma. An RCT (O'Brien et al, 2003b) comparing the TB with the Herbst appliances in growing (aged 11-14 years) patients with established Class II division 1 malocclusions did not find any skeletal or dentoalveolar differences between the two appliances.

The study by Antonarakis & Kiliaridis (2007) reviewed the short-term anteroposterior treatment effects of functional appliances and extra-oral traction on Class II malocclusion in growing patients with an age range of 9.2 years to 12.5 years. The TB favored improvement in SNB (1.53^0; $p<0.0001$), ANB (2.61^0; $p<0.00001$) and the OJ (6.45mm; $p<0.00001$). There was a statistically insignificant improvement in the SNA values (1.03^0; $p=0.02$). The activators showed an improvement in SNB (0.66^0; $p=0.04$), ANB (0.92^0; $p<0.00001$) and OJ (3.88mm; $p<0.00001$). The EOT group favored improvement in SNA (1.01^0; $p<0.00001$) and ANB (1.38^0; $p<0.00001$). The combination group (functional appliance and EOT) showed improvement in SNB (1.05^0; $p<0.00001$), ANB (1.8^0; $p<0.0001$) and OJ (4.37mm; $p<0.00001$).

A systematic review (Marsico et al, 2011) on the effectiveness of functional appliances on short term mandibular growth analyzed four studies with age ranging from 8.5 years to 11.6 years. One study (O'Brien et al, 2003a)[22] reported CVM stages as their skeletal maturity indicator, and the other (Tulloch et al, 1997) reported hand-wrist radiographic stage. The results showed a statistically significant increase in the mandibular length (1.79mm; $p=0.0001$).

Another systematic review and meta-analysis (Santamaría-Villegas et al, 2017) on the effect of functional appliances on mandibular length in patients with Class II with retrognathism, showed an average increase of 1.53mm (CI 95% 1.15- 1.92) mandibular length as compared to untreated controls. TB showed an increase of 1.80mm (CI 95% 0.87-2.73).

2.10 Dental and Skeletal Effects of the Twin Block

The effects of the TB are well established in the literature. The systematic review and meta-analysis of the short-term treatment effects produced by the TB appliance provides the most useful clinically relevant information (Ehsani et al, 2015). The included studies (Varlik, 2008; Jena et al, 2006; Sidlauskas, 2005; O'Brien et al, 2003a; Baccetti et al, 2000; Mills & McCulloch, 2000, 1998; Toth & McNamara, 1999; Illing et al, 1998; Morris et al, 1998; Lund & Sandler et al, 1998) have used a combination of linear and angular measurements to quantify mandibular dimension, its sagittal position and the incisors position. The skeletal findings from the meta-analysis (Ehsani, et al, 2015) suggest a minor restriction in growth of the maxilla, which may be masked by anterior remodeling of the A-point, slight projection of the mandible forward, increase in the mandibular body length and increase in the lower anterior face height, depending on the manipulation of the appliance. This vertical component of change masks the anterior projection of the chin. At the dental level (Ehsani, et al, 2015), significant reduction in the upper incisor proclination regardless of the presence or absence of the labial bow, and increase in the lower incisor proclination, regardless of whether there was a labial bow present or the incisors were capped with acrylic, is manifested. The upper molars distalized and the lower molars mesialized. The dental changes were perceived by the patient as the most significant change. No clinically consistent findings in the lip position were found because the standard deviations for these measurements were large and large variations in individual responses were seen.

Although an increase in mandibular length is normally observed with the TB, it is usually mild regardless of whether the appliance is worn during pre (CS1-2)- or pubertal (CS3-4) growth stages (Santamaría-Villegas et al, 2017; Marsico et al, 2011; Antonarakis & Kiliaridis, 2007; Tulloch et al, 2004; O'Brien et al, 2003a; Keeling et al, 1998; Jakobsson, 1967). Some authors (O'Brien et al, 2009; Tulloch et al, 1990) argue that most of the studies that have reported significant skeletal improvements with functional appliances were retrospective in nature and therefore exposed to selection bias, resulting in overestimated treatment effects.

The literature (Antonarakis & Kiliaridis, 2007; Cozza et al, 2006; Illing et al, 1998; Lund & Sandler, 1998) has supported and hailed the TB as the most effective functional appliance that acts on the mandible.

2.11 Drawback of Removable Functional Appliances and Comparison of TB to Herbst Appliance

The main drawback of the functional appliances is that they are removable and hence compliance can be problematic (Illing et al, 1998). Therefore, fixed appliances have been developed for Class II correction to improve the outcomes and success of treatment.

Amongst the fixed functional appliances, the Herbst appliance is the most commonly used (Pancherz, 1979). The short term effects with it are restraint of maxillary growth and enhanced mandibular growth (Pancherz, 1982, 1979). The improvement in occlusal relationship is equally skeletal and dental. Overjet reduction is commonly achieved in 6-8 months. It can also be combined with a headgear (Wieslander, 1993).

Schaefer at al (2004) compared the treatment effects of the TB and Herbst appliances. They found that molar relationship and sagittal jaw discrepancy correction were greater for TB appliance. O'Brien at al (2003b) also reported similar dental and skeletal effects. These authors suggested that Herbst appliance, being a non-compliant appliance, could be a good treatment alternative for treating adolescents with Class II division 1 malocclusions than a TB. However, neither of the two studies (Schaefer et al, 2004; O'Brien at al, 2003b) included an untreated control group. A prospective clinical study, a decade later therefore included a control group (Baysal & Uysal, 2014), which reported that the TB group mainly showed mandibular skeletal changes. While the Herbst group, in addition to skeletal changes, showed maxillary arch distalization and greater mandibular incisor protrusion that helped with Class II correction. The Herbst appliance may be especially useful in skeletal Class II patients with maxillary dentoalveolar protrusion and mandibular dentoalveolar retrusion, whereas TB appliance may be preferred for skeletal mandibular retrognathic patients (Baysal & Uysal, 2014).

On comparing the different functional appliances for their efficiency (supplementary mandibular elongation divided by the number of months in treatment), the Herbst appliance showed the highest coefficient of efficiency (0.28mm per month) followed by the TB (0.23 mm per month), making them the most effective functional appliances in the fixed and removable category respectively (Cozza et al, 2006).

2.12 Dental and Skeletal Effects of the van Beek Headgear Activator (vBHGA)

Dermaut at al (1992) evaluated the vBHGA dental and skeletal effects in 78 patients with severe class II malocclusions. It was found to be an effective treatment modality to correct Class II Division I malocclusions; treatment effects included minor mandibular growth stimulation, no maxillary orthopedic effect, decreased overjet and overbite by means of intrusion and retroclination of the upper incisors.

Altenburger & Ingervall (1998) compared the first phase treatment effects of the vBHGA, the Herren activator, and an activator-headgear combination. The overjet reduction in the vBHGA group was primarily achieved by a combination of skeletal and dentoalveolar effects: mandibular prognathism increased, maxillary incisors retroclined and the mandibular incisors proclined. Maxillary skeletal effects were statistically insignificant. The authors noted that the vBHGA had superior incisor control compared to the other appliances studied.

Two other studies (Phan et al, 2006; Bendeus, 2002) on the vBHGA concluded that the appliance was efficient in improving the jaw relationships in young patients with mild-to-moderate skeletal Class II malocclusions with increased overjet by means of restraint of maxillary sagittal growth combined with normal mandibular growth. One of them (Phan et al, 2006) then compared the treatment effects of the vBHGA to the Herbst-Andreson Activator (HAA) and concluded that maxillary prognathism decreased with the vBHGA treatment while mandibular prognathism increased with the HAA treatment. Furthermore, the vBHGA subject group was divided into good and poor responders based on overjet reduction of >4mm. The good responders displayed significant posterior development of condylion, maxillary molar distalization, maxillary incisor retrusion, mandibular incisor protrusion and mandibular molar mesialization.

vBHGA and its mode of advancement was studied in a couple of studies (Hägg et al, 2008; Wey et al, 2007). These studies investigated step-wise advancement (5mm advancement every 3 months and ending with edge-edge bite) versus maximum jumping with the vBHGA in patients with skeletal Class II malocclusions. The skeletal contribution to the overjet reduction in the step-wise group was 70% compared to 59% in the maximum jumping group.

Lastly, a Master's thesis (Kotyk, 2017) on vBHGA concluded that the vBHGA appliance treatment produced skeletal and dental Class II correction via restraint of maxillary anterior growth, increased mandibular anterior growth, counter clockwise palatal plane rotation, retroclination and retraction of the upper incisors, and proclination and protrusion of the lower incisors resulting in reduced overjet and overbite. The favorable skeletal and dental changes from vBHGA treatment were maintained after the completion of the second treatment phase (Kotyk, 2017).

2.13 Comparison of vBHGA and Other Functional Appliances

vBHGA has been compared to other activator varieties and headgear activator combinations (Altenburger & Ingervall, 1998). The appliance was studied in 39 children, aged 9-13 years (mean age of 11 years) and compared to the Herren activator and with the combination headgear-activator. Lateral cephalometric radiographs, taken at the start (T1) and at the end of 9-months of treatment (T2) when a Class 1 molar relationship was achieved, were analyzed. The improvements seen were in the total mandibular length (Co-Pg 1.9mm; $p<0.0001$), OJ (4.7mm; $p<0.0001$) and of the molar relationship (3.6mm; $p<0.001$). The results were achieved with a skeletal mandibular response (SNB 0.80; $p<0.001$) with a moderate maxillary response (SNA 0.5^{0}; $p<0.0001$). In regards to the dentoalvelolar changes, the maxillary incisors retroclined (U1-PP 5.9^{0}; $p<0.0001$), but remained unchanged vertically (0.2mm; $p>0.05$) and the mandibular incisors proclined (IMPA 2.4^{0}; $p<0.0001$). The maxillary molars distalized (0.9mm; $p>0.05$) and extruded (0.8mm; $p>0.05$). In addition, there was a statistically insignificant clockwise rotation of the palatal plane (PP-SN 0.4^{0}; $p=0.05$).

The vBHGA has also been compared with other headgear activator therapy in high-angle cases (Uçüncü et al, 2001). One such study consisted of 32 patients with a high-angle (MPA >38^{0}) Class II Division 1 malocclusion treated with a modified Teuscher (n=12) and a vBHGA (n=10) with a mean age of 12 and 11.8 years respectively. These treatment groups were compared to an untreated control group (n=10) with a mean age of 11.5 years. The results for vBHGA showed increased skeletal mandibular growth (SNB 0.78^{0}; $p<0.05$) and improvement of the A-P skeletal intermaxillary relationship (ANB 1.57^{0}; $p<0.05$). There was a statistically insignificant maxillary restriction (SNA 0.64^0; p>0.05) and a statistically insignificant increase in the LAFH (1.37mm; p>0.05) as compared to the untreated controls.

A study has compared the long term effects of the vBHGA with the Herbst appliance (Phan et al, 2006). It comprised of 16 male patients with a mean age of 11.6 years and 12.6 years in the HGA and the Herbst respectively. Lateral cephalograms taken at the start of treatment and at 6, 12 and 24 months of treatment were analyzed. It reported maxillary growth restriction with the vBHGA (SNA 1^0; p=0.0052) and mandibular growth with the Herbst appliance (SNB 2^0; p=0.001).

2.14 Response of Vertical and Horizontal Growers to Functional Appliances

Functional appliances work by a combination of skeletal and dentoalveolar effects. Skeletal changes include forward mandibular displacement/growth and maxillary restraint. Dentoalveolar changes include retrusion and retroclination of maxillary incisors, protrusion and proclination of mandibular incisors, distalization and eruption of maxillary molars and mesialization and eruption of the mandibular molars in the correction of class II jaw relationship, molar relationship and the deep overbite (Southard et al, 2013). Extrusion of the molar causes a clockwise rotation of the mandible, increasing the lower anterior face height (LAFH) and the convexity of the face. In horizontal growers, it is favorable, but in the vertical growers, due to decreased bite forces (Proffit & Fields, 1983), extrusion of molars occurs more readily, causing clockwise mandibular rotation, and negating the horizontal chin projection (Dermaut et al, 1992). Therefore, it is critical that the sagittal and vertical descent of the maxilla be controlled if backward rotation of the mandible is undesirable.

vBHGA has been studied in relation to different growth patterns (Dermaut et al, 1992). Dermaut et al, in their study of 78 severe Class II subjects, stratified them into hyperdivergent and hypodivergent based on the mandibular plane angle (MPA) and the Jarabak's ratio measurements.

They found no differences in the variables investigated, except the inclination of the maxillary incisors, which was more pronounced in the overall group (U1-PP 5.5^0; p<0.005), but not in the two stratified sub-groups (2.4^0; p<0.0005). Although undesirable, extrusion of the mandibular molars (0.9mm; p<0.05) and a subsequent increase in the LAFH (0.7mm; p>0.05) was found in the vertical vBHGA growers as compared to untreated controls.

vBHGA has also been compared with other headgear activator therapy in high-angle cases (Uçüncü et al, 2001). In this study, vBHGA was compared to the modified Teuscher appliance in the high-angle subjects. An untreated control group was used to account for normal growth. It was shown that although both appliances increased the LAFH and the MPA, the increase in the LAFH is controlled more in the vBHGA group (1.28mm; p<0.05) as compared to the Teuscher group (2.16mm; p<0.05).

The effect of functional appliances in patients with increased vertical dimensions has been studied by Freeman et al (2007) in their study of treatment effects of the bionator and high-pull facebow combination. The records of 24 subjects with high-angle consecutively treated with the protocol were examined and compared with matched sample of untreated controls from the University of Michigan Growth Study. Lateral cephalograms at the start (T1), end of functional appliance phase (T2) and after end of full-fixed orthodontics (T3) were analyzed. The age at T1 was 9.1 years, 11.9 years at T2, 14.7 years T3. From T1 to T2, the treated group showed increased total mandibular length (Co-Gn 2.2mm; p<0.05), but the maxillary/mandibular differential in the treated group increased compared to the control group (2.2mm; p<0.01). There was a statistically significant increase in the LAFH (1.3mm; p<0.05). OJ reduced more in the treatment group compared to the control group (0.9mm; p<0.05) as did the molar relationship (1.5mm; p<0.01). Due to the capping of the mandibular incisors, they retroclined more in the treatment group compared to the control group (3.7^0; $p<0.01$). Mandibular molars extruded more in the treatment group compared to the control group (1mm; $p<0.05$).

Increase in LAFH with accompanying clockwise rotation of the mandible is seen in both growth patterns with the use of functional appliances. However, it is less pronounced in the horizontal growers as compared to the vertical growers. Addition of EOT in the vertical growers can provide modest control of this dimension.

2.15 Indications of vBHGA and TB

Extra-oral traction through the high-pull headgear in the vBHGA provides the sagittal and vertical control of the maxilla, needed in vertical growers, if maximum chin projection is to be achieved with the supplementary mandibular growth and prevention of the clockwise mandibular rotation. Therefore, vBHGA is indicated in the vertical growers to control the LAFH (Dermaut et al, 1992), while TB by allowing molar extrusion is indicated in the horizontal growers with a deep bite tendency (Clark, 1982).

Thus, although both the vBHGA and TB have shown to produce similar improvements in the A-P skeletal jaw relationships, it differs in their mechanism of action, by influencing one of the two jaws. Hence, their indications in clinical use will depend on the specific patient morphology, including their LAFH, growth pattern, A-P chin projection, and OB. Both appliances have been studied in isolation; TB more than the vBHGA, but there has been no study comparing one with the other, especially in relation to the growth pattern of the patient (horizontal or vertical). Hence this present study attempted to fill this void in the literature.

Chapter 3

Purpose and Hypothesis

3.1 Purpose of the Study

The purpose of this retrospective study was to evaluate the pertinent short-term skeletal and dentoalveolar cephalometric changes when correcting a skeletal Class II malocclusion with growth modification therapy with the Twin-Block (TB) and the van Beek Headgear Activator (vBHGA) appliances. An untreated control group of the Burlington Growth Center, Ontario, Canada, was also included.

3.2 Hypothesis

This study intends to test the following null hypotheses:

- $H_{01:}$ That there are no statistically significant skeletal and dentoalvelolar changes when comparing TB, vBGHGA and an untreated control, in the correction of skeletal Class II malocclusion.
- $H_{02:}$ That the growth pattern of the patients does not influence on the skeletal and dentoalveolar changes in any of the groups studied.

Chapter 4

Materials and Methods

4.1 Ethics

This study was approved by the University of Manitoba (U of M) Bannatyne Campus Health Research Ethics Board (HREB) on November 13, 2019 (Ethics #:HS23301 (H2019:400) (Appendix 1).

4.2 Sample Size Calculation

It was decided to prioritize skeletal parameters measuring the antero-posterior growth and position of the mandible. For the skeletal parameter SNB, using the systematic review on TB (Cozza et al, 2006), the mean difference was found to be 1.2^0 (SD= 2^0). The mean difference between TB and vBHGA was expected to be at least double (2.4^0) to be clinically significant. Therefore, considering a standard deviation (SD) of $2^{0,}$ a power of the test of 80%, a 2-sided test, and 5% level of significance, the number of patients required was 44.

For the skeletal parameter Co-Gn, the mean difference for TB was found to be 2.0mm (σ 0.5mm) (Cozza et al, 2006). To be clinically significant, it was decided that the mean difference for vBHGA should be at least the double (4mm) that of TB. Considering a σ of 0.5mm, the calculation of sample size was unreliable, requiring just one patient. Hence, it was decided to raise the σ to 2.0mm, and the required number of patients was only 16.

Therefore, the sample size calculations showed that a number of 44 patients should be appropriate.

4.3 Sample Groups

The three groups (vBHGA, TB and Control) were submitted to the same inclusion and exclusion criteria as listed below.

The following inclusion criteria were applied:

1. Skeletal Class II indicated by ANB angle value $>5^0$
2. Available T1 and T2 cephalometric radiographs of acceptable quality
3. Treatment with either TB or vBHGA, except for the control group

The subjects were excluded using the following exclusion criteria:

1. Missing teeth (excluding 3rd molars)
2. Craniofacial anomalies
3. Medical condition or prescription medication that may affect growth
4. Lack of compliance whenever documented in the charts

4.4 Study Groups

This study comprised three groups (vBHGA, TB and Control) whose characteristics are provided below.

4.4.1 van Beek Headgear Activator (vBHGA) Group

The vBHGA group included patients treated consecutively at the University of Manitoba Graduate Orthodontic Clinic, from 1996 to 2020. All subjects were treated by the Graduate Orthodontic Residents under the supervision of a single instructor. A thick construction wax bite was first fabricated to be approximately 8-10mm in height and to allow for a minimum of 6mm mandibular protrusion or to an edge-edge bite with coincident upper and lower dental midlines, as described and proposed by van Beek (1984, 1982). (photo of the prototype vBHGA shown in Figure 4.1). A deep mandibular impression with alginate is made so the activator flanges can extend deep into the lingual vestibule. Patients were fitted with a high-pull headgear strap with a short and thick outer bow which is bent up so that the line of action of force passes either through or above the center of resistance of the maxillary incisors. Eight ounces (240 gram) of force was prescribed for the first month to let the patients become accustomed to the appliance, followed by 16 oz (500 gram) force per side subsequently. Patients were instructed to wear the appliance 12-14 hours a day, starting after supper and throughout the night, 7 days per week. Patient compliance, appliance fit including the long lingual flanges and headgear force levels were checked at each appointment and adjusted as needed. Overjet and reverse overjet were measured in millimeters at each appointment with a periodontal probe with millimetric (mm) markings. The occlusal and lingual indentations on the acrylic bite-block were trimmed flat in the second appointment for three reasons. Firstly, to break the occlusal pattern and the proprioceptive reflexes and allow the mandible to posture forward without any interferences. Secondly, to allow eruption of the upper and lower molars. Lastly, it also prevents the clockwise rotation of the maxilla and the maxillary teeth due to the distal force of the activator passing below the center of resistance of the maxilla (van Beek, 1984).[9] The labial coverage of the upper incisors is to provide torque control, and that of the lower incisors is to prevents its proclination (van Beek, 1984).[9] The observation period ended when molars were over-corrected to Angle's super Class I relationship and/or the incisors were in an edge-edge relationship, whichever was earlier. The mean duration of vBHGA treatment was 8.6 months. Patients transitioned to night-time wear afterwards until all permanent teeth erupted and they were ready for phase 2 with full-fixed orthodontics.

Of the total patients, 20 subjects who did not meet the inclusion criteria were excluded due to poor compliance wearing the vBHGA compliance was documented in the subjects' treatment charts. The final sample that met the inclusion criteria comprised of 46 subjects (20 males and 26 females), all of which completed the vBHGA treatment. The demographic information is shown in Table 4.1.

Lateral Cephalometric radiographs were taken before the start of treatment (T1) and at the end of the vBHGA phase of treatment (T2) for each subject.

Figure 4.1: vBHGA

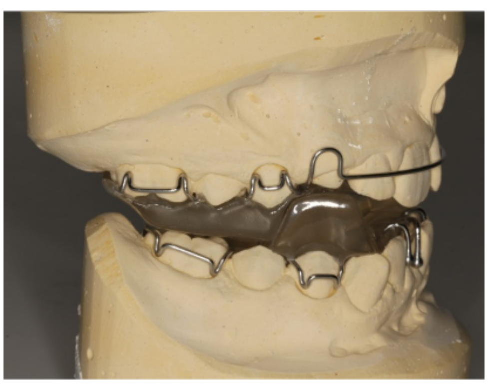
4.4.2 Twin-Block (TB) Group

The second group of patients was a sample of patients from a database of various university teaching hospitals spread across England (UK), treated with the Twin-Block (TB) appliance from 2010 and 2016. Fifteen patients treated with TB with the same protocol in the University of Manitoba Graduate Orthodontic Clinic were also included to meet the sample size as determined by the sample size calculation. Each subject had a construction wax-bite made to an edge-edge bite with the upper and lower dental midlines coincident. The height of the wax-bite was not critical. The TB appliance was then fabricated in the commercial dental laboratory in the UK and the in-house Orthodontic laboratory at the University of Manitoba, Graduate Orthodontic Department. The TB appliance consisted of upper and lower removable appliances with bite blocks composed of bite ramps set at about 70 degrees (prototype of the TB appliance shown in Figure 4.2). When occluding, the lower block bites in front of the upper to posture the mandible forward. It consisted of a labial bow and Adam's clasps on the first premolars and first molars for retention. The subjects were instructed to wear the appliance full-time (24 hours) except when eating and oral hygiene. Compliance was monitored at each appointment and necessary trimming to the acrylic made to allow eruption of the upper and lower molars. The phase 1 treatment ended when molars were over-corrected to Angle's super Class I relationship and/or the incisors were in an edge-edge relationship, whichever was earlier. The mean duration of phase 1 TB treatment was 9 months. Patients transitioned to night-time wear until all permanent teeth erupted and they were ready for full-fixed orthodontics.

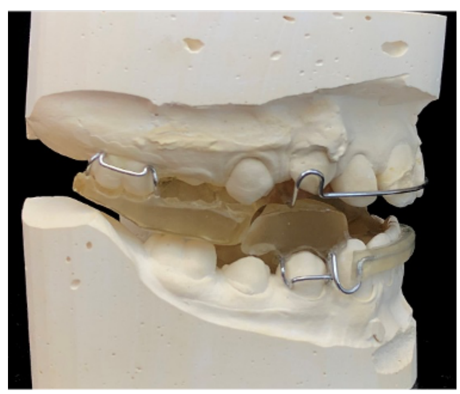
Of the total UK pool of patients, nine subjects were excluded because they did not have T2 cephalometric radiographs. The final sample group that met the inclusion criteria comprised of 45 subjects (19 males and 26 females), all of which completed the first phase of TB treatment. The demographic information is shown in Table 4.1.

Lateral Cephalometric radiographs were taken before the start of treatment (T1) and at the end of the TB phase of treatment (T2) for each subject.

Figure 4.2



UK TB



Manitoba TB

4.4.3 Control Group

A sample of 45 untreated Class II subjects served as the control group. These were chosen from the archives of the Burlington Growth Center that was established in 1952 at the University of Toronto, Ontario, Canada. All the subjects were of Northern European descent and at the beginning of the study, were living in Burlington, part of the Greater Toronto Area, Ontario, Canada. They were matched with the treatment subjects based on the ANB angle >5^0. Although there was an attempt to match the T1 and T2 CVM stages of the treatment groups, this was not entirely possible due to the unavailability of such records in this historical control database after applying the inclusion criteria based on the ANB angle.

4.5 Demographic Details of the Three Groups

- The detailed characteristics of the three groups are shown in Table 4.1. The majority of subjects in the TB and vBHGA groups were female (n=26 in each; 57.77% and 56.52% respectively), while the control group was predominantly comprised of male subjects (n = 31; 68.88%). At T1, TB and vBHGA groups had a similar distribution of subjects in pre-peak, peak and post-peak stages, with approximately half in pre- and the other half in post-peak stages (Table 4.1). The majority of the control subjects were in the pre-peak stage (Table 4.1). The groups were sub-divided into horizontal (H) and vertical (V) growers, based on their Jarabak's ratio values (Valiathan et al, 2001). All three groups had more horizontal than horizontal growers (68.9%, 60.9% and 55.6% in the TB, vBHGA and control groups, respectively). Stratification into ***horizontal or vertical growers*** was based on the ratio of their posterior face height (Sella-Gonion) to the anterior face height (Nasion-Menton) (%)- which ***ultimately determines the horizontal chin projection- AKA Jarabak's Ratio***[21]

- Ratio <62% = vertical growers
- Ratio >65% = horizontal growers

Normal (mesocephalic growers) were merged with the horizontal group, since it is the vertical growers that pose a clinical challenge during Class II correction due to their poor response to mandibular advancement

Table 4.1: Demographic data for the three study groups

Group	(n)	Sex (n/%)		CVM* Stage (n/%)						Growth Pattern (n/%)	
		Male	Female	Pre-peak (CS1-2)		Peak (CS3-4)		Post-peak (CS5-6)		Horizontal	Vertical
				T1	T2	T1	T2	T1	T2		
TB	45	19/42.2	26/57.8	24/52.3	8/18	20/45.4	33/73	1/2.3	4/9	31/68.9	14/31.1
vBHGA	46	20/43.5	26/56.5	23/50	11/24	23/50	31/67	0/0	7/9	28/60.9	18/39.1
Control	45	31/68.9	14/31.1	34/75	5/11	11/25	40/89	0/0	0/0	25/55.6	20/44.4

*CVM: Cervical Vertebral Maturation; CS: Cervical Stage

4.6 Data Collection

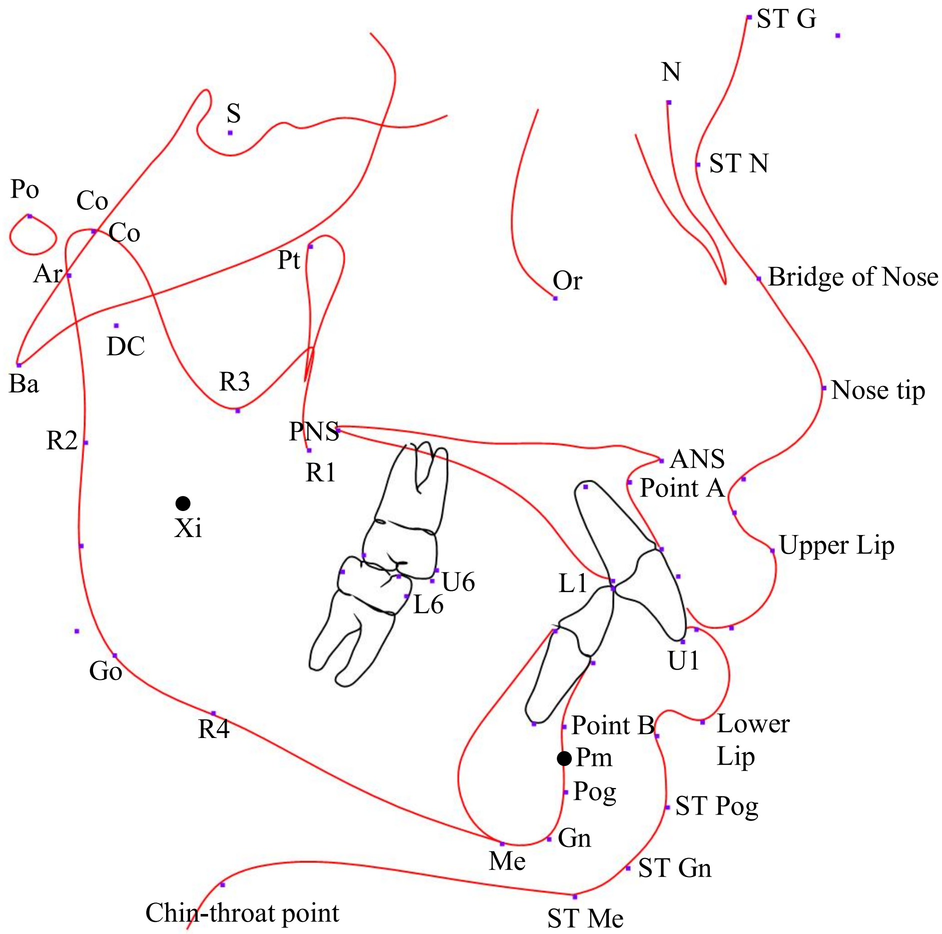
The T1 and T2 lateral cephalometric x-rays were imported into a commercial software (Dolphin Digital Imaging System version 11.9, Chatsworth, CA, USA). For the Twin-Block (TB) and the Van Beek (vBHGA) samples, the magnification of the radiographs was accounted for using the known ruler measurements that were captured on the cephalograms. The magnification of 9.84% from the Burlington growth center were corrected to 0% by dividing the known ruler measurements by (1- 9.84/100) and using that value as the new ruler length before tracing the radiograph on Dolphin.

All images were given an independent numerical code in order to de-identify patient's personal information and maintain their confidentiality. A master list that contained the original information was linked to the numerical code and was kept locked in a secure location in room D411 in the dentistry building at 780 Bannatyne Ave, Winnipeg, R3E 0W2, Manitoba, Canada.

Each radiograph was digitally traced by identification of each of the cephalometric landmarks according to the definitions in Table 4.2. The custom cephalometric analysis included a combination of variables selected from Steiner's (1953), Jarabak's (Valiathan et al, 2001; Jarabak, 1972), Rickett's (1981) and McNamara's (1984) analyses. The description of such variables can be found in Table 4.3.

Maxillary and mandibular regional superimpositions were performed by the method proposed by Ricketts (1981) in order to evaluate sagittal and vertical dentoalveolar changes of the incisal edges of the upper and lower central incisors (U1/L1's) and the mesio-buccal cusps of the upper and lower first molars (U6/L6's). The maxillary regional superimpositions were performed at ANS-PNS registering at ANS. The mandibular regional superimpositions were performed at the corpus axis, registering at Protuberance menti (Pm) (Ricketts, 1981). Once superimposed, the horizontal and vertical changes of the U1/L1 and U6/L6 were measured in millimeters (mm) from the x and y coordinates of the reference points (U1/L1 incisal edge and U6/L6 mesiobuccal cusp tip) using the commercial software (Dolphin Digital Imaging System version 11.9, Chatsworth, CA, USA). For the sagittal/horizontal movements, the x-axis values were used. A positive (+ve) number implies forward movement and a negative (-ve) number implies backward movement of Upper and Lower teeth. For the vertical movements, the y-axis values were used. A positive (+ve) number implies intrusion of upper teeth and extrusion of lower teeth, while a negative (-ve) number implies extrusion for upper teeth and intrusion of lower teeth.

Overall and regional cephalometric superimpositions of cases illustrating most of the changes encountered in each group are presented in the results chapter (Figures 4.5.1- 4.5.9). The maxillary skeletal superimposition was done at Ba-Na, registering at Na whereas the mandibular skeletal superimposition at Ba-Na registering at CC point (center of cranium). In order to depict the dentoalveolar changes, the same regional superimposition methods described in the previous paragraph was followed.



Cephalometric landmarks used for the study

4.7 Reliability of Measurements

The principal investigator (R.K.) carried out all tracings and measurements, including CVM assessment. In order to demonstrate how reproducible these measurements are, it was decided to also measure the inter-rater reliability. A second investigator (S.M.) was a radiologist with large experience in tracing cephalometric radiographs. In order to measure the intra-rater reliability (repeatability), both traced 30% of the sample that was randomly selected four weeks later after completion of the initial measurements. Inter- and intra-rater reliability assessments were performed based on intra-class correlation coefficient (ICC) tests and the values interpreted according to the method suggested by Fleiss et al (1979).

4.8 Definition of Cephalometric Landmarks and Analyses

A cephalometric landmark is a distinguishable point on a radiograph that represents the location of an anatomical structure, either hard or soft tissue. Constructed landmarks, however, are not true anatomic structures, but are formed by the intersection of lines. Cephalometric planes or lines are drawn by connecting various landmarks. The landmarks and planes are then used for numerical determination of cephalometric measurements. The measurements will vary based on the specific cephalometric analysis utilized. In this study, and as described in Table 4.2, landmarks from the Steiner's (1953), Ricketts' (1981) and McNamara's (1984) analyses were used. The cephalometric measurements used in this study are described in Table 4.3.

Table 4.2: Description of cephalometric landmarks (Jacobson, 2006)

Landmark	Description
Skeletal	
A-point (Subspinale, ss)	Deepest, most posterior midline point on the curvature between the ANS and prosthion.
Anterior nasal spine (ANS)	Tip of the bony anterior nasal spine at the inferior margin of the piriform aperture, in the midsagittal plane.
B-point (Point B, Supramentale, sm)	Deepest most posterior midline point on the bony curvature of the anterior mandible, between infradentale and pogonion.
Basion (Ba)	Most anterior inferior point on the margin of the foramen magnum, in the midsagittal plane. Located on the inferior border of the basilar part of the occipital bone to its posterior limit, superior to the dens of the axis.
Condylion (Co)	Most superior posterior point on the head of the mandibular condyle.
Center of Cranium (CC)	Cephalometric landmark formed by the intersection of the two lines Ba-N and Pt-Gn
Glabella (G)	Most prominent point of the anterior contour of the frontal bone in the midsagittal plane.
Gnathion (Gn)	Most anterior inferior point on the bony chin in the midsagittal plane. A constructed landmark by using the mid-point between the anterior (pogonion) and inferior (menton) points of the bony chin.
Gonion (Go)	Most posterior inferior point on the outline of the angle of the mandible. Constructed by bisecting the angle formed by the

	intersection of the mandibular plane and the ramal plane and by extending the bisector through the mandibular border.
Menton (Me)	Most inferior point of the mandibular symphysis, in the midsagittal plane.
Nasion (N, Na)	Intersection of the internasal and frontonasal sutures, in the midsagittal plane.
Orbitale (Or, O)	Lowest point on the inferior orbital margin.
Pogonion (Pog, P, Pg)	Most anterior point on the contour of the bony chin, in the midsagittal plane.
Porion (Po)	Most superior point of the outline of the external auditory meatus.
Posterior nasal spine (PNS)	Most posterior point on the bony hard palate in the midsagittal plane; the meeting point between the inferior and the superior surfaces of the bony hard palate (nasal floor) at its posterior aspect. Located by extending the anterior wall of the pterygopalatine fossa inferiorly, until it intersects the floor of the nose.
Prosthion (Pr, Superior prosthion, Supradentale)	The most inferior anterior point on the maxillary alveolar process, between the central incisors.
Protruberance menti (Pm) or suprapogonion	Most superoposterior point on mandibular symphysis changes from concave to convex.
R1	The deepest point on the curve of the anterior border of the ramus, one half the distance between the inferior and superior curves.
R2	A point located on the posterior border of the ramus of the mandible, directly opposite to R1

R3	A point located at the center and most inferior aspect of the sigmoid notch of the ramus of the mandible.
R4	A point on the lower border of the mandible, directly inferior to the center of the sigmoid notch of the ramus
Sella (S)	The geometric center of the pituitary fossa (sella turcica).
Xi-Point	The geometric center of the mandibular ramus
Soft Tissue	
Lower Lip	Most anterior point on the curve of the lower lip.
Soft tissue A-point (ST A-point)	Most concave point between subnasale and the anterior point of the upper lip.
Soft tissue B-point (ST B-point)	Most concave point between the lower lip and the soft tissue chin.
Soft tissue Gnathion (ST Gn)	The midpoint between the most anterior and inferior points of the soft tissue chin in the midsagittal plane.
Soft tissue Menton (ST Me)	The most inferior point of the soft tissue chin.
Soft tissue Nasion (ST N)	Soft tissue profile's most concave point where the bridge of the nose meets the frontal bone.
Soft tissue Pogonion (ST Pog)	Point on the anterior curve of the soft tissue chin.
Tip of nose (pronasale)	Point of the most anterior curve of the nose.
Upper Lip	Most anterior point on the curve of the upper lip.
Dentoalveolar	
Distal U6	Most distal surface of the upper first molar crown.

Distal L6	Most distal surface of the lower first molar crown.
L1 root	Root apex of the lower central incisors.
L1 tip	Tip of the lower central incisors.
L6 occlusal	Mesial-buccal cusp tip of the mandibular first molar.
Mesial U6	Most mesial surface of the upper first molar crown.
Mesial L6	Most mesial surface of the lower first molar crown.
U1 root	Root apex of the upper central incisors.
U1 tip	Incisal tip of the upper central incisors.
U6 occlusal	Mesial-buccal cusp tip of the maxillary first molar.

Table 4.3: Description of cephalometric measurements (Jacobson, 2006, 1975)

Measurement	Landmarks Involved	Description
Cranial Base		
Ba-S-N, °	Ba, S, N	The inferior angle formed by the Ba-S and S-N lines. Angular measurement of the cranial base.
Maxillary Skeletal		
SNA, °	S, N, A-point	The inferior posterior angle formed by the intersection of lines S-N and N-A. Assessment of the anteroposterior position of the maxilla with respect to the cranial base.
A-Na Perp, mm	A-point, N, Po, Or	The linear distance between nasion-perpendicular (to Frankfort Horizontal plane) and Point A. Frankfort Horizontal (FH) is the Po-Or line. Assessment of the anteroposterior position of the maxilla.
Co-A, mm	Co, A-point	The linear distance from condylion to A-point. Measurement for the length of the maxilla.
Co-ANS	Co, ANS Point	The linear distance from condylion to ANS-point. Measurement of the unit length of the maxilla for the Harvold Difference measurement
Mandibular Skeletal		
SNB, °	S, N, B-point	The inferior posterior angle formed by the intersection of lines S-N and N-B. Assessment of the anteroposterior position of the mandible in relation to the cranial base.

Pg-Na Perp, mm	Pog, N, Po, Or	The linear distance between nasion-perpendicular (to FH) and pogonion. Assessment of the anteroposterior position of the mandible.
Co-Gn, mm	Co, Gn	The linear distance between condylion and gnathion. Measurement for the length of the mandible.
Co-Pg	Co, Pg	The linear distance between condylion and Pogonion. Measurement of the unit length of the mandible for the Harvold difference measurement.
Ar-Go, mm	Co, Go	The linear distance between articulare and gonion. Measurement for the length of the mandibular ramus.
Inter-maxillary		
ANB, °	A-point, N, B-point	The difference between the SNA and SNB angles. Evaluates the anteroposterior relationship between the maxillary and mandibular skeletal bases.
Wits, mm	A-point, B-point, U6/L6 occlusal	Perpendicular lines to the functional occlusal plane are drawn from A-point and B-point. The linear distance between the two points of intersection along the occlusal plane gives the measurement. An evaluation of the anteroposterior relationship between the maxilla and mandible.
Harvold Difference, mm	Co, pogonion, ANS	The linear distance between condylion and ANS subtracted from the linear distance between condylion and

		pogonion. Measurement of the difference in length of the maxilla and mandible.
Convexity, mm	N, A-point, Pog	Linear distance between A-point and the N-Pog line. Measurement of the anteroposterior relationship between the maxilla and mandible.
Vertical Skeletal		
PP, °	S, Na, ANS, PNS	The posterior angle formed by the palatal plane (anterior nasal spine and posterior nasal spine) and the SN plane. Measurement of the steepness of the palatal plane.
FMA, °	Po, Or, Go, Me	The anterior-inferior angle formed by the Frankfort Horizontal plane and the Mandibular line (gonion-menton). Assessment of the steepness of the mandibular plane; indicator of mandibular growth direction.
MPA, °	S, N, Go, Me	The anterior-inferior angle formed by the S-N line and the Go-Me line. Assessment of the steepness of the mandibular plane relative to the cranial base; indicator of growth pattern.
Y-axis, °	N, S, Gn	The anterior-inferior angle formed by the S-N line and the Gn-S line. Assessment of the direction of mandibular growth.
LAFH, mm	ANS, Me	The linear distance from Menton to ANS. The linear measurement gives an indication of the growth pattern.

Jarabak's Ratio (PFH:AFH) X 100	S, Go, Na, Me	The ratio between posterior face height and the anterior face height multiplied by 100. Indication of the growth pattern (Horizontal or Vertical).
Maxillary Dentoalveolar		
U1-NA, mm	Na, A-point, U1-tip	The linear distance between the NA line and the U1 tip. Assessment of the anteroposterior position of the maxillary incisors.
U1-NA, °	Na, U1 tip, U1 root	The angle formed by the long axis of the maxillary central incisor and the NA line. An assessment of the angulation of the maxillary incisors.
U1-PP, ^{0}	PP, U1 tip, U1 root	The angle formed by the long axis of the maxillary central incisor and the palatal plane (PP). An assessment of the angulation of the maxillary incisors.
U1-SN, °	S, N, U1 tip, U1 root	The posterior-inferior angle formed by the long axis of the maxillary central incisor and the S-N line. An assessment of the angulation of the maxillary incisors.
Mandibular Dentoalveolar		
L1-APo, mm	L1 tip, A-point, Pog	The linear distance from the incisal edge of the mandibular central incisor to the A-Pog line. An assessment of the anteroposterior position of the mandibular incisors.
L1-NB, mm	L1 tip, N, B-point	The linear distance from the incisal edge of the mandibular central incisor to the NB line. An assessment of the anteroposterior position of the mandibular incisors.

L1-NB, ⁰	L1 tip, L1 root tip, N, B-point	The angle formed by the long axis of the mandibular central incisor and the NB line. An assessment of the angulation of the mandibular incisors.
IMPA, °	Go, Me, L1 tip, L1 root	The posterior-superior angle between the long axis of the mandibular central incisor and the mandibular plane (Go-Me). An assessment of the angulation of the mandibular incisors.
Interdental		
OJ, mm	U1/L1 tip, U6/L6 occlusal	The distance between the incisal edges of the upper and lower central incisors measured along the occlusal plane (line from horizontal bisection of U6/L6 occlusal and U1/L1 tip).
OB, mm	U1/L1 tip, U6/L6 occlusal	The vertical distance between the incisal edges of the upper and lower central incisors measured perpendicular to the occlusal plane.
U1/L1, °	U1/L1 tip, U1/L1 root,	The interincisal angle, which is the posterior angle formed at the intersection of the long axes of the maxillary and mandibular central incisors.
Molar relation, mm	Distal U6/L6 U6/L6 occlusal, U1/L1 tip	The distance from between the distal crown convexities of the upper and lower permanent first molars, measured along the occlusal plane. Positive value denotes mesial position of upper molar relative to lower molar and vice versa.
Soft Tissue		

U lip to E-plane, mm	Tip of nose, ST Pg, Upper lip	Linear distance from the upper lip to a line connecting the tip of the nose and the most anterior point of the soft tissue chin (ST Pg). An assessment of the position of the upper lip relative to the esthetic plane (E-plane).
L lip to E-plane, mm	Tip of nose, ST Pg, Lower lip	Linear distance from the lower lip to a line connecting the tip of the nose and the most anterior point of the soft tissue chin (ST Pg). An assessment of the position of the lower lip relative to the esthetic plane (E-plane).

4.7 Statistical Analysis

Although the sample size calculation was based on a meaningful mean difference, standard deviation, power of test and level of significance, the simultaneous interaction of different cephalometric variables, six CVM stages, three groups, two types of growth pattern within each group, and two time points (T1 and T2) called for the utilization of Analysis of Covariance (ANCOVA) regression models. The statistically significant differences encountered and the regression graphs both indicated an increased power and that model residues had met distribution assumption, being approximately normal, something that was confirmed by residue Q-plots and histograms. Descriptive statistics (mean and SD) and treatment effect were calculated for all possible pairwise comparisons (TB vs. Control, vBHGA vs. Control, and TB vs. vBHGA) (Tables 5.2. and 5.3). For each measurement, T2-T1 difference is the dependent variable and it is regressed upon the treatment group and the growth pattern, which are the main variables of interest (covariates). Using the baseline value as a covariate/predictor of the treatment effect leads to increased explanatory power and hence increased statistical power. Significant interactions in relation to growth pattern was observed for only three variables, namely: U1-SN^0, U1-NA^0, and

U1-PP^0 (Table 5.4). Imbalance between the groups with regards to CVM values at T2 were adjusted for, but the results remained unchanged given that CVM was found not to be frequently associated with the outcome. To guard against a large number of false positives, the *p*-value was adjusted to be more stringent and to have a limited overall false discovery rate. R^2 values were reported to denote the percent of variation in the T2 value of a variable explained by the predictors. It was fairly high for the most part due to the strong correlation between T1 and T2 values. The sagittal and vertical changes of U1/L1's and U6/L6's were analyzed using the regional superimposition method proposed by Ricketts (1981), and that is why only difference (T2-T1) values were provided (Table 5.5). In this case, as T1 values were not used as covariates, the R^2 values were low (Table 5.5).

Chapter 5

Results

5.1 Treatment Group

The sample characteristics of the three groups, Twin-Block (TB), van Beek Headgear Activator (vBHGA) and the Control Groups, are shown in Table 5.1. The sample size calculation was performed for an adequate power size and demanded 45 subjects in each group. The TB group had one extra subject (n =46) due to availability of records. The final sample group that met the inclusion criteria was comprised of 46 subjects in the TB group, and 45 subjects each in the vBHGA and the control groups. The majority of subjects in the TB and vBHGA groups were female (n =26 in each; 57.77% and 56.52% respectively), while the control group was predominantly comprised of male subjects (n = 31; 68.88%). TB and vBHGA groups had almost equal distribution of subjects in pre-peak (n=24; 52.3% and n=23; 50 % respectively) and peak pubertal (n=20; 45.4 % and n=23; 50% respectively) growth stages as determined by the CVM method suggested by Baccetti et al (2005), while 75% (n=34) of the control subjects were pre-peak and 25% (n=11) were in the pubertal growth peak. Only 2.3% (n=1) of the TB subjects were past their growth spurt. There were no subjects past their peak growth spurt in the other two groups. The groups were sub-divided into horizontal (H) and vertical (V) growers, based on their Jarabak's ratio values (Siriwat & Jarabak, 1985). All three groups had more horizontal than vertical growers (68.9%, 60.9% and 55.6% in the TB, vBHGA and control groups, respectively).

5.1.1 Assessment of Skeletal Maturity

The cervical vertebral maturation (CVM) index as outlined by Baccetti et al (2005)[46] was used for this study. The subjects were divided into pre-peak, peak and post-peak stages. The distribution for the three groups is outlined in Table 5.1. The skeletal, dentoalveolar and soft-tissue cephalometric data at T1 and T2 are represented in Tables 5.2 and 5.3. The cephalometric variables that were significantly affected by the growth pattern (Horizontal or Vertical) are listed in Table 5.4. The changes in the upper and lower incisors (U1/L1) and the upper and lower first molars (U6/L6) in the vertical and horizontal planes as derived from the regional superimpositions proposed by Ricketts (1981) are represented in Table 5.5.

Table 5.1: Demographic data

Group	(n)	Sex (n/%)		CVM* Stage (n/%)						Growth Pattern (n/%)	
		Male	Female	Pre-peak (CS1-2)		Peak (CS3-4)		Post-peak (CS5-6)		Horizontal	Vertical
				T1	T2	T1	T2	T1	T2		
TB	45	19/42.2	26/57.8	24/52.3	8/18	20/45.4	33/73	1/2.3	4/9	31/68.9	14/31.1
vBHGA	46	20/43.5	26/56.5	23/50	11/24	23/50	31/67	0/0	7/9	28/60.9	18/39.1
Control	45	31/68.9	14/31.1	34/75	5/11	11/25	40/89	0/0	0/0	25/55.6	20/44.4

TB: Twin-Block; vBHGA: van Beek Headgear Activator; Control: Untreated Class II subjects

5.2 Skeletal Treatment Effect of Twin-Block (TB) Versus Control group

The treatment effect of the TB appliance is shown in the first-row figures of the Tables 5.2, 5.3 5.4 and 5.5. These are in comparison to the effect seen in untreated controls. The variables that showed statistically significant ($p<0.05$) treatment effect are mentioned below.

In comparison with the control, the TB group showed an increase in skeletal mandibular growth (SNB:0.96^0; $p=0.01$). The inter-maxillary skeletal parameters which showed improvement towards Class I were ANB ($1.7^{0;}$ $p<0.001$), Wits (3.59mm; $p<0.001$) and Harvold Difference (2.65mm; $p<0.001$). The pattern of growth (FMA:1.34^0; $p=0.01$, MPA: 1.13^0; $p= 0.0076$ and PP-SN: 1.27^0; $p=0.0014$) all showed an increase towards the vertical growth direction.

5.3 Skeletal Treatment Effect of van Beek Headgear Activator (vBHGA) Versus Control Group

The treatment effect of the vBHGA appliance is shown in the second-row figures of the Tables 5.2, 5.3 5.4 and 5.5. These are in comparison to the effect seen in untreated controls. The variables that showed statistically significant ($p<0.05$) treatment effect are mentioned below. The vBHGA group showed significant maxillary growth restriction (SNA: 1.59^0; p=0.00) and a reduction in the inter-maxillary (ANB: 1.59^0; p=0.00 and Harvold difference: 2.51mm $p<0.0001$) values. It showed an increased skeletal mandibular growth (Go-Pg: 3.04mm; p=0.0022) as well as the ramus height (Ar-Go: 2.44mm; p=0.02). The only growth pattern variable that showed an increase in its value was the PP-MP (1.27^0; p=0.0053).

5.4 Skeletal Treatment Effect of TB Versus vBHGA

The treatment effect of the TB in comparison to the vBHGA appliance is shown in the third-row figures of the Tables 5.2, 5.3, 5.4 and 5.5. The variables that showed statistically significant ($p<0.05$) treatment effect are mentioned below. Although the TB group showed a reduction in the skeletal maxillary parameters (SNA: 0.83^0; p=0.05; Co-A: -2.45mm; p=0.00 and Co-ANS: -2.38mm; p=0.00), the improvement in one of the skeletal mandibular parameter (SNB: 1.34^0; p=0.0004) was greater than in the vBHGA group. A greater reduction in the SNA value (-1.59^0; p=0.00) was observed in the vBHGA group whose skeletal mandibular parameters (Co-Gn: 1.89mm; p=0.04, Co-Pg: 2.07mm; p=0.01 and Go-Pg: 1.60mm; p=0.0065) also showed signs of improvement. The TB group showed increased reduction in the inter-maxillary parameter (Wits: 3mm; p=<0.0001) as compared to the vBHGA group, although no statistically significant difference was found for ANB. The pattern of growth increased in the vertical direction more in TB than in the vBHGA (FMA: 1.23^0; p=0.02) and the palatal plane showed a clockwise rotation

(PP-SN: 1.45^0; p=0.0002) in contrast to the counter-clockwise rotation in the vBHGA group. The growth pattern became less vertical according to the PP-MP values (-1.08^0; p=0.01).

Table 5.2: Skeletal cephalometric data at T1 and T2

Variable	TB (n= 45) Mean (SD)		vBHGA (n=46) Mean (SD)		Control (n=45) Mean (SD)		Treatment effect Mean (SD)	*p value	R^2
	T1	***T2***	***T1***	***T2***	***T1***	***T2***	***TB-control vBHGA-control TB-vBHGA***		
FH-SN^0	8.12 (3.49)	8.11 (2.98)	9.44 (2.89)	10.07 (2.52)	7.57 (3.06)	7.84 (3.61)	0.10 (0.86, 1.07) 1.22 (0.23, 2.21) -1.12 (-2.08, -0.15)	0.83 0.01* 0.02*	0.50
SNA^0	83.58 (4.65)	82.68 (4.04)	81.81 (4.09)	80.44 (3.77)	82.94 (4.57)	82.89 (4.37)	-0.75 (-1.6, 0.09) -1.59 (-2.44, -0.74) 0.83 (-0.01, 1.68)	0.07 0.00* 0.05*	0.77
SNB^0	76.60 (3.83)	78.09 (3.67)	75.67 (3.51)	75.95 (3.44)	77.72 (4.00)	77.99 (3.83)	0.96 (0.20, 1.72) 0.38 (-1.15, 0.38) 1.34 (0.61, 2.08)	0.01* 0.32 0.0004*	0.78
ANB^0	6.96 (2.32)	4.59 (2.37)	6.15 (2.24)	4.48 (2.38)	5.21 (2.14)	4.89 (2.10)	-1.70 (-2.31, -1.09) -1.16 (-1.74, -0.58) -0.53 (-1.11, 0.04)	<0.001* 0.00* 0.07	0.64
Wits (mm)	6.24 (2.55)	1.27 (2.95)	4.78 (2.22)	3.36 (2.53)	1.78 (2.26)	2.08 (2.42)	-3.59 (-4.77, -2.41) -0.59 (-1.63, 0.45) -3.00 (-3.95, -2.04)	<0.0001* 0.26 <0.0001*	0.37
A-NPg (mm)	5.26 (2.67)	3.54 (2.91)	4.62 (2.51)	3.13 (2.90)	2.49 (1.44)	2.33 (1.57)	-1.35 (-2.00, -0.69) -1.18 (-1.79, -0.56) -0.16 (-0.74, 0.40)	<0.0001* 0.0002* 0.56	0.72
A-Na-perp (mm)	1.50 (3.94)	0.72 (3.55)	1.16 (3.07)	0.48 (3.56)	0.28 (2.40)	0.45 (2.96)	-0.68 (-1.63, 0.26) -0.66 (-1.59, 0.27) -0.02 (-0.95, 0.91)	0.15 0.16 0.96	0.56
Pg-Na-perp (mm)	-7.06 (6.66)	-5.26 (7.28)	-6.67 (5.96)	-5.14 (6.46)	-4.21 (3.94)	-3.55 (4.98)	0.86 (-0.75, 2.48) 0.63 (-0.94, 2.21) 0.22 (-1.32, 1.78)	0.29 0.42 0.77	0.66
Co-A (mm)	81.49 (8.75)	80.66 (8.20)	81.73 (6.45)	83.28 (8.10)	57.80 (4.27)	59.82 (4.96)	-1.89 (-4.25, 0.45) 0.55 (-1.81, 2.92) -2.45 (-3.78, -1.11)	0.11 0.64 0.00*	0.93
Co-ANS (mm)	83.85 (8.76)	83.70 (8.40)	84.07 (6.09)	86.22 (8.40)	59.85 (4.43)	61.66 (5.25)	-1.61 (-4.27, 1.04) 0.77 (-1.91, 3.45) -2.38 (-3.86, -0.90)	0.23 0.57 0.00*	0.93
Co-Gn (mm)	104.91 (10.82)	108.87 (10.93)	106.22 (7.04)	111.99 (9.44)	76.87 (5.84)	80.34 (6.88)	0.43 (-2.66, 3.53) 2.29 (-0.90, 5.48) -1.86 (-3.65, -0.06)	0.78 0.15 0.04*	0.93
Go-Pg (mm)	63.75 (7.73)	65.15 (7.32)	66.37 (6.10)	69.03 (6.65)	46.21 (3.49)	47.78 (3.73)	1.43 (-0.33, 3.20)	0.11	0.94

							3.04 (1.11, 4.96) -1.60 (-2.75, -0.45)	0.0022* 0.0065	
Ar-Go (mm)	45.30 (6.86)	47.52 (7.22)	41.57 (4.95)	44.44 (5.63)	30.86 (3.29)	33.04 (4.32)	2.38 (-0.08, 4.84) 2.44 (0.32, 4.57) -0.06 (-1.72, 1.58)	0.05* 0.02* 0.93	0.80
Co-Pg (mm)	97.58 (9.81)	101.20 (9.65)	100.38 (7.12)	106.03 (9.65)	71.58 (5.44)	74.78 (6.22)	0.52 (-2.41, 3.47) 2.60 (-0.56, 5.76) -2.07 (-3.80, -0.33)	0.72 0.10 0.01*	0.93
Harvold difference (mm)	13.71 (3.85)	17.51 (4.24)	16.31 (3.08)	19.81 (4.02)	11.72 (2.84)	13.11 (3.47)	2.65 (1.57, 3.73) 2.51 (1.32, 3.71) 0.13 (-0.95, 1.22)	<0.0001* <0.0001* 0.81	0.73
FMA^0	24.02 (6.08)	24.94 (6.49)	23.65 (5.91)	23.38 (5.69)	25.57 (5.08)	25.04 (5.26)	1.34 (0.28, 2.40) 0.10 (0.95, 1.16) 1.23 (0.18, 2.28)	0.01* 0.84 0.02*	0.81
MPA^0	32.15 (6.06)	33.06 (6.36)	33.10 (6.05)	33.45 (5.92)	33.15 (5.62)	32.90 (5.60)	1.13 (0.30, 1.96) 0.60 (-0.21, 1.42) 0.52 (-0.29, 1.34)	0.0076 0.14 0.20	0.89
Y-Axis^0	67.78 (4.22)	67.96 (4.23)	68.61 (4.38)	68.96 (4.29)	66.23 (3.84)	66.44 (3.65)	0.18 (-0.51, 0.87) 0.42 (-0.26, 1.12) -0.24 (-0.91, 0.41)	0.60 0.22 0.46	0.85
PP-SN^0	-0.64 (3.51)	0.33 (3.12)	0.33 (3.14)	-0.36 (2.95)	-2.2 (3.45)	-2.12 (3.36)	1.27 (0.49, 2.04) -0.18 (-0.97, 0.59) 1.45 (0.71, 2.20)	0.0014* 0.64 0.0002*	0.71
PP-MP^0	25.80 (6.47)	25.72 (6.83)	25.77 (5.20)	26.81 (5.42)	28.35 (5.28)	28.03 (5.43)	0.19 (-0.69, 1.08) 1.27 (0.38, 2.16) -1.08 (-1.95, -0.20)	0.66 0.0053* 0.01*	0.87
Ba-Na-Pt-Gn (Facial Axis)^0	0.03 (5.29)	0.08 (5.35)	-2.14 (5.03)	-2.10 (5.24)	0.17 (4.02)	0.07 (4.13)	0.18 (-0.62, 1.00) 0.07 (-0.75, 0.90) 0.11 (-0.70, 0.93)	0.64 0.86 0.77	0.85
LAFH (mm)	59.16 (8.20)	61.52 (8.29)	62.38 (4.92)	65.05 (6.01)	43.41 (4.13)	45.08 (4.32)	1.12 (-0.56, 2.82) 1.52 (-0.34, 3.39) -0.39 (-1.53, 0.74)	0.19 0.11 0.49	0.94
Jarabak Ratio (%)	66.29 (4.59)	66.38 (4.71)	65.26 (4.85)	65.21 (4.52)	64.68 (4.75)	65.22 (4.66)	-0.28 (-1.06, 0.50) -0.53 (-1.30, 0.24) 0.25 (-0.52, 1.02)	0.48 0.17 0.52	0.84
SN-Ba^0	131.90 (5.74)	132.45 (6.24)	131.09 (3.75)	132.08 (4.27)	128.2 (4.58)	128.64 (5.11)	1.11 (-0.47, 2.71) 1.26 (-0.27, 2.81) -0.14 (-1.65, 1.35)	0.16 0.10 0.84	0.58

*p-value: significant if ≤ 0.05; #variables reported in degrees

5.5 Dentoalveolar and Soft-tissue Treatment Effect of Twin-Block (TB) Versus Control Group

As per measurements reported in Table 5.3, there was no difference in the retrusion of the U1's (upper incisors) in the TB group as compared to the control group (U1-NA: 0.48mm; p=0.20). The L1's (lower incisors) proclined and protruded more in the TB group compared to the control group (L1-NB^0: 5.89^0; p<0.0001 and IMPA: 3.92^0; p<0.0001, L1-NB: 1.63mm; p<0.0001 and L1-APog: 2.97; p<0.0001). The overjet (OJ) and the overbite (OB) in the TB group reduced more than in the control group (OJ: 2.29mm; p<0.0001 and OB: 1.86mm; p<0.001). Molar correction in the TB group was more compared to the control group (molar relation: 4.24mm; p<0.0001).

As per measurements reported in Table 5.4, the U1's retroclined more in the vertical TB (TB-V) growers compared to the vertical control growers (Ctrl-V) as per the U1-NA^0 and U1-SN^0 measurements (U1-NA^0: 3.68^0; p=0.03 and U1-SN^0: 4.99^0; p=0.0091).

As per the measurements reported in Table 5.5, there was no difference between TB and control groups in terms of U1 extrusion (0.52mm; p=0.07). The U1's retruded more in the TB group compared to the control group (2.05mm; p=0.0001). There was no difference between the TB and control groups in terms of U6 extrusion (0.52mm; p=0.20). The U6's distalized more in the TB group compared to the control group (1.26mm; p=0.04). The L1's intruded and protruded more in the TB group compared to the control group (1.23mm; p=0.0044 and 1.27mm; p<0.0001) respectively. The L6's extruded equally in the TB group compared to the control group (0.74mm; p=0.19). The L6's mesialized equally in the TB group compared to the control group (0.70; p=0.09). The upper lips in the TB group retruded more compared to the control group (Upper lip-E-line: 1.8mm; p<0.0001) (Table 5.3). Lower lips in the TB group retruded equally to the control group (Lower lip-E-line: 0.10mm; p=0.81) (Table 5.3).

5.6 Dentoalveolar and Soft-tissue Effect of van Beek Headgear Activator (vBHGA) Versus Control Group

As per measurements reported in Table 5.3, there was no difference in the retrusion of the U1's in the vBHGA group as compared to the control group (U1-qNA: 0.55mm; p=0.18). The L1's proclined and protruded more in the vBHGA group compared to the control (L1-NB^0: 2.04^0; p=0.03, IMPA: 1.99^0; p=0.02, L1-NB: 1.09mm; p=0.0002, and L1-APog: 2.01mm; p<0.0001). There was no difference in the OJ and OB reduction between vBHGA and the control groups (OJ: 0.64mm; p=0.24 and OB: 0.02mm; p=0.94). There was more molar correction in the vBHGA group was more compared to the control group (molar relation: 1.50mm; p=0.0075).

As per measurements reported in Table 5.4, the U1's retroclined more in the horizontal vBHGA (vB-H) growers compared to the horizontal control growers (Ctrl-H) as per the U1-NA^0 measurements (U1-NA^0: 3.00^0; p=0.03). The U1's also retroclined more in the vertical vBHGA (vB-V) growers compared to the vertical control growers (Ctrl-V) as per the U1-NA^0, U1-SN^0 and U1-PP^0 measurements (U1-NA^0: 3.26^0; p=0.04, U1-SN^0: 4.96^0; p=0.005 and U1-PP^0: 4.47^0; p=0.01).

As per the measurements reported in Table 5.5, the U1's intruded and retruded in the vBHGA group compared to the control group (0.21mm; p=0.01, and 3mm; p<0.0001). The U6's extruded equally in the vBHGA and the control groups (0.36mm; p=0.37), but the U6 distalized more in the vBHGA group compared to the control group (1.37mm; p=0.03). There was no difference in the L1 position in the vertical plane between the vBHGA and the control groups (0.43mm; p=0.30), while L1's protruded more in the vBHGA group compared to the control group (0.85mm; p=0.0019). The L6's extruded equally in the vBHGA group compared to the control group (0.01mm; p=0.98), but the L6's mesialized more in the vBHGA group compared to the control group (0.85mm; p=0.04). The upper lip retruded more in the vBHGA group compared to the control group (Upper lip-E-line: 0.84mm; p=0.03) (Table 5.3). There was no difference between the vBHGA and control groups in terms of lower lips (Lower lip-E-line: 0.20mm; p=0.64) (Table 5.3).

5.7 Dentoalveolar and Soft-tissue Effect of TB Versus vBHGA (Note for Fabio: Re-read)

As per measurements reported in Table 5.3, the U1's retruded more in the TB group than in the vBHGA group (U1-NA: 1.04mm; p=0.00). The L1's proclined and protruded more in the TB group compared to the vBHGA group (L1-NB^{0}: 3.84^{0}; p<0.0001, IMPA: 1.92^{0}; p=0.02, L1-NB: 0.54mm; p=0.04 and L1/APog: 0.96mm; p=0.00). The OJ and OB in the TB group reduced more than the vBHGA group (OJ: 1.65mm; p<0.0001 and OB: 1.83mm; p<0.001). There was more molar correction in the TB group compared to the vBHGA group (molar relation: 2.74mm; p<0.001).

As per the measurements reported in Table 5.4, the U1's retroclined more in the horizontal TB growers (TB-H) compared to the horizontal vBHGA growers (vB-H) as per the U1-NA^{0} measurements (U1-NA^{0} 3.62^{0}; p=0.0067).

As per the measurements reported in Table 5.5, the U1's extruded more in the TB group compared to the vBHGA group (0.73mm; p=0.01). There was no difference between TB and vBHGA groups in terms of U1 retrusion (0.95mm; p=0.06). The U6 extruded equally in TB and vBHGA groups (0.15mm; p=0.70). The U6 distalized equally in TB and vBHGA groups (0.10mm; p=0.86). The L1's intruded more in the TB group compared to the vBHGA group (0.80mm; p=0.05). There was no difference in the TB and vBHGA groups in terms of the L1's protrusion (0.41mm; p=0.12). The L6's extruded equally in the TB group compared to the vBHGA group (0.73mm; p=0.20). The L6's mesialized equally between TB and vBHGA groups (0.15mm; p=0.71). The upper lip retruded more in the TB group compared to the vBHGA group (Upper lip-E-line: 1.03mm; $p=0.00$) (Table 5.3). Lower lips retruded equally in the TB and vBHGA groups (Lower lip-E-line: 0.30mm; $p=0.48$) (Table 5.3).

Table 5.3: Dentoalveolar and soft-tissue cephalometric data at T1 and T2

Variable	**TB (n= 45) Mean (SD)**		**vBHGA (n=46) Mean (SD)**		**Control (n=45) Mean (SD)**		**Treatment effect Mean (SD)**	***p value**	**R^2**
	T1	***T2***	***T1***	***T2***	***T1***	***T2***	***TB-control*** ***vBHGA-control*** ***TB-vBHGA***		
U1-NA (mm)	3.73 (3.46)	2.76 (2.54)	6.08 (3.38)	5.20 (2.80)	1.60 (1.98)	1.92 (2.02)	-0.48 (-1.23, 0.26) -0.55 (-0.27, 1.39) -1.04 (-1.78, -0.30)	0.20 0.18 0.00*	0.64
L1-NB^0	22.04 (7.77)	29.29 (7.73)	26.51 (6.29)	28.90 (6.39)	22.89 (6.77)	24.04 (6.54)	5.89 (4.06, 7.72) 2.04 (0.19, 3.89) 3.84 (1.97, 5.71)	<0.0001* 0.03* <0.0001*	0.65
IMPA^0	93.28 (7.71)	98.20 (7.41)	97.75 (6.49)	99.50 (5.77)	92.00 (7.05)	93.12 (7.13)	3.92 (2.24, 5.60) 1.99 (0.24, 3.75) 1.92 (0.19, 3.65)	<0.0001* 0.02* 0.02*	0.70
L1-NB (mm)	4.06 (2.84)	5.84 (3.01)	5.46 (3.00)	6.65 (3.38)	3.01 (1.61)	3.20 (1.56)	1.63 (1.09, 2.18) 1.09 (0.52, 1.66) 0.54 (0.00, 1.08)	<0.0001* 0.0002* 0.04*	0.83
L1-APog (mm)	-0.43 (2.76)	2.82 (3.01)	0.98 (2.83)	3.08 (3.08)	0.52 (1.85)	0.67 (1.61)	2.97 (2.31, 3.64) 2.01 (1.36, 2.67) 0.96 (0.28, 1.63)	<0.0001* <0.0001* 0.00*	0.70
U1-L1^0	126.58 (15.25)	125.36(10.57)	121.38 (10.48)	122.34(9.59)	132.76 (11.78)	131.0 (11.93)	-1.50 (-4.47, 1.46) -1.17 (-4.25, 1.89) -0.32 (-3.24, 2.59)	0.31 0.44 0.82	0.63
Overjet (mm)	8.47 (2.65)	2.97 (2.18)	8.97 (2.70)	4.81 (2.03)	3.35 (1.59)	3.35 (1.83)	-2.29 (-3.33, -1.26) -0.64 (-1.71, 0.43) -1.65 (-2.42, -0.89)	<0.0001* 0.24 <0.0001*	0.30
Overbite (mm)	4.00 (2.13)	1.13 (2.35)	4.46 (2.20)	3.19 (2.06)	2.02 (1.64)	1.90 (1.72)	-1.86 (-2.64, -1.07) -0.02 (-0.84, 0.78) -1.83 (-2.56, -1.10)	<0.001* 0.94 <0.001*	0.40
Molar Relation (mm)#	1.40 (1.70)	-3.63 (3.14)	2.11 (1.32)	-0.41 (2.19)	-0.17 (1.27)	-0.16 (1.40)	-4.24 (-5.25, -3.23) -1.50 (-2.59, -0.40) -2.74 (-3.68, -1.80)	<0.0001* 0.0075* <0.0001*	0.40
U-lip-E-Line (mm)	-0.21 (2.25)	-2.75 (2.71)	1.40 (2.77)	-0.40 (2.89)	-1.52 (1.71)	-1.88 (1.77)	-1.88 (-2.61, -1.14) -0.84 (-1.64, -0.05) -1.03 (-1.76, -0.30)	<0.0001* 0.03* 0.00*	0.61
L-lip-E-Line (mm)	-0.31 (2.79)	-0.77 (2.92)	1.47 (3.57)	1.05 (4.11)	-0.70 (1.76)	-0.86 (1.84)	-0.10 (-0.94, 0.74) 0.20 (-0.67, 1.08) -0.30 (-1.17, -0.55)	0.81 0.64 0.48	0.61

*p-value: significant if ≤ 0.05; #Molar Relation: +ve value indicates mesial position of U6 in relation to L6; -ve value indicates distal position of U6 in relation to L6

Table 5.4: Cephalometric variables that were statistically significant based on the growth pattern (Horizontal or Vertical)

Variable		TB (n= 45) (31H; 68.9% and 14V; 31.1%) Mean (SD)		vBHGA (n=46) (28H; 60.9% and 18V; 39.1%) Mean (SD)		Control (n=45) 25H; 55.6% and 20V; 44.4%) Mean (SD)		Treatment effect Mean (SD)	*p value	R^2
		T1	***T2***	***T1***	***T2***	***T1***	***T2***	***TB-H/Ctrl-H*** ***TB-V/Ctrl-V*** ***vB-H/Ctrl-H*** ***vB-V/Ctrl-V*** ***TB-H/vB-H*** ***TB-V/vB-V***		
U1-NA^0	H	24.63 (12.70)	21.33 (6.68)	25.92 (9.16)	25.67 (7.42)	17.05 (8.78)	17.74 (9.05)	-0.62 (-3.39,2.14) -3.68 (-7.16,-0.20)	0.65 0.03*	0.58
	V	23.88 (7.79)	20.55 (7.47)	25.93 (8.37)	22.11 (6.68)	21.71 (7.18)	23.04 (6)	-3.00 (0.14,5.86) -3.26 (-6.53,-0.00) -3.62 (-6.22,-1.02) -0.41 (-3.97,3.13)	0.03* 0.04* 0.0067* 0.81	
U1-SN^0	H	109.29 (12.87)	104.90 (6.23)	109.28 (8.96)	107.44 (7.08)	101.85 (9.02)	102.36 (9.42)	-1.61 (-4.57,1.35) -4.99 (-8.73,-1.26)	0.28 0.0091*	0.54
	V	105.03 (6.08)	100.23 (8.75)	105.39 (7.78)	100.47 (5.75)	102.36 (7.79)	103.74 (8.09)	0.92 (-2.10,3.96) -4.96 (-8.44,-1.47) -2.54 (-5.33,0.24) -0.41 (-3.97,3.13)	0.54 0.0056* 0.07 0.98	
U1-PP^0	H	114.85 (12.83	111.53 (6.42)	115.28 (8.75)	113.14 (7.33)	105.82 (8.37)	106.56 (9.23)	0.07 (-3.03,3.18) -3.00 (-6.88,0.87)	0.96 0.12	0.49
	V	113.15 (7.85)	109.14 (10.16)	114.79 (7.10)	108.57 (5.20)	108.17 (6.53)	109.45 (6.34)	1.44 (-1.74,4.63) -4.47 (-8.12, -0.82) -1.37 (-4.24,1.50) 1.46 (-2.46,5.40)	0.37 0.01* 0.34 0.46	

*p-value: significant if ≤ 0.05; vB: van Beek Headgear Activator, TB: Twin-Block; Ctrl: Control; H: Horizontal grower and V: Vertical grower

Table 5.5: Changes in the U1/L1 and U6/L6 positions in the vertical and sagittal planes according to the Ricketts (1981) regional maxillary and mandibular cephalometric superimpositions

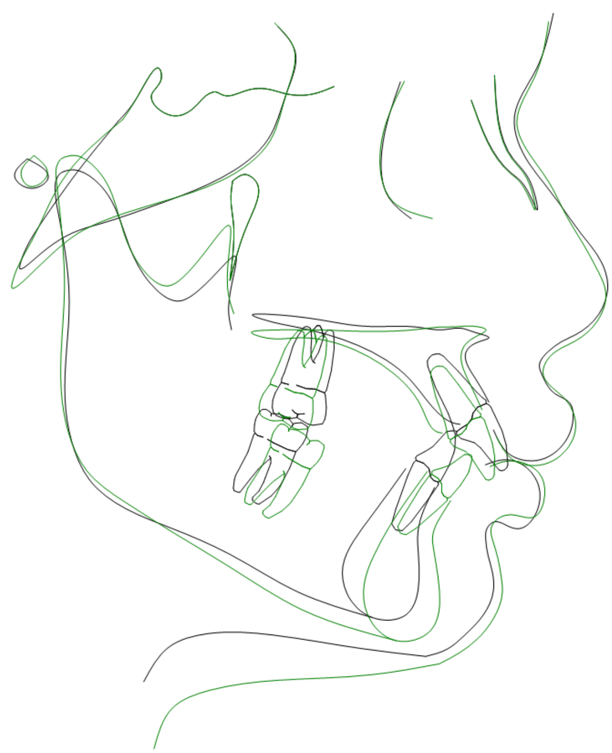
Variable	TB (n= 45) Mean (SD)	vBHGA (n=46) Mean (SD)	Control (n=45) Mean (SD)	Treatment effect Mean (SD)	*p value	R^2
	T1-T2	***T1-T2***	***T1-T2***	***TB-control*** ***vBHGA-control*** ***TB-vBHGA***		
U1-Vertical	-1.00 (1.47)	-0.27 (1.33)	-0.48 (1.26)	-0.52 (-1.09, 0.04) 0.21 (-0.35, 0.77) -0.73 (-1.30, -0.16)	0.07 0.01* 0.01*	0.05
U1-Horizontal	-1.59 (2.98)	-2.54 (2.21)	0.46 (1.98)	-2.05 (-3.07, 1.03) -3.00 (-4.01, -1.99) 0.95 (0.05, 1.95)	0.0001* <0.0001* 0.06	0.21
U6 Vertical	-0.47 (2.27)	-0.63 (2.01)	-0.99 (1.43)	0.52 (-0.29, 1.33) 0.36 (-0.43, 1.17) 0.15 (-0.65, 0.96)	0.20 0.37 0.70	0.01
U6-Horizontal	-0.75 (2.95)	-0.85 (3.54)	0.51 (2.40)	-1.26 (-2.52, -0.01) -1.37 (-2.61, -0.12) 0.10 (-1.13, 1.34)	0.04* 0.03* 0.86	0.06
L1-vertical	-0.60 (2.17)	0.20 (2.43)	0.63 (1.21)	-1.23 (-2.07, -0.39) -0.43 (-1.26, 0.40) -0.80 (-1.63, 0.02)	0.0044* 0.30 0.05*	0.07
L1-Horizontal	1.34 (1.42)	0.92 (1.50)	0.06 (0.83)	1.27 (0.73, 1.82) 0.85 (0.32, 1.39) 0.41 (-0.12, 0.95)	<0.0001* 0.0019* 0.12	0.15
L6-Vertical	1.02 (1.27)	0.28 (4.15)	0.27 (1.78)	0.74 (-0.39, 1.88) 0.01 (-1.11, 1.14) 0.73 (-0.39, 1.86)	0.19 0.98 0.20	0.01
L6-Horizontal	0.93 (2.26)	1.09 (2.09)	0.23 (1.63)	0.70 (-0.12, 1.54) 0.85 (0.03, 1.68) -0.15 (-0.97, 0.67)	0.09 0.04* 0.71	0.07

*p-value: significant if ≤ 0.05 TB: Twin Block; vBHGA: van Beek Headgear Activator; #: Values in millimeters (mm); U1: Maxillary central incisor; U6: maxillary 1st molar; L1: Mandibular central incisor; L6: Mandibular 1st molar; Maxillary superimposition: ANS-PNS at ANS; mandibular superimposition: corpus axis at Pm (Protuberance menti); Horizontal: +ve value: mesial/forward movement of U/L teeth; -ve value: distal/backward movement of U/L teeth; Vertical: +ve: Intrusion of upper and extrusion of lower teeth; -ve value: Extrusion of upper and intrusion of lower teeth.

5.8 Sample Superimpositions for the Treatment and Control Groups

Sample superimpositions of each treatment group and the control group are shown in Figures 5.1 through 5.9. These represent the general trend of the skeletal and dentoalvelolar changes seen with each of the two treatment modalities and the control group

Figure 5.1: Cranial base (Sella-Nasion at Sella) superimposition of a patient in the vBHGA group at T1 (black) and T2 (green)



Figures 5.2: Cranial base (Sella-Nasion at Sella) superimposition of a patient in the TB group at T1 (black) and T2 (green)

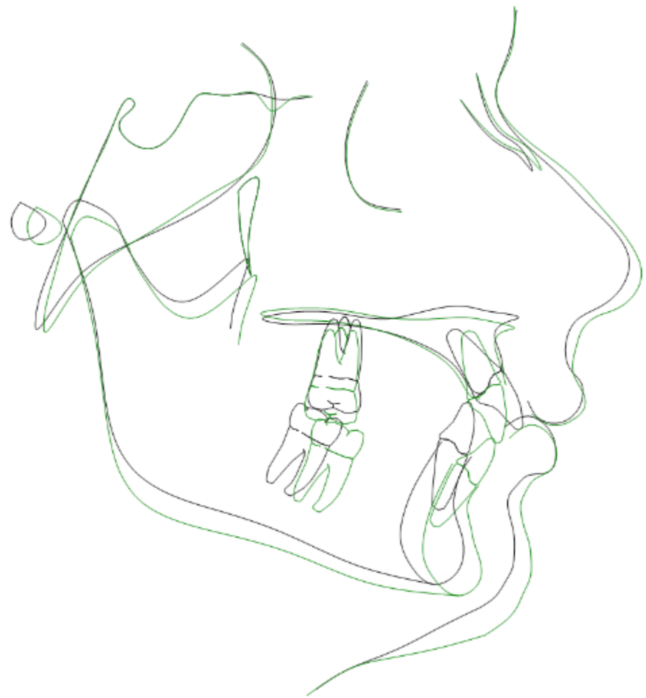


Figure 5.3: Sample cranial base (Sella-Nasion at Sella) superimposition of a patient in the control group at T1 (black) and T2 (green)

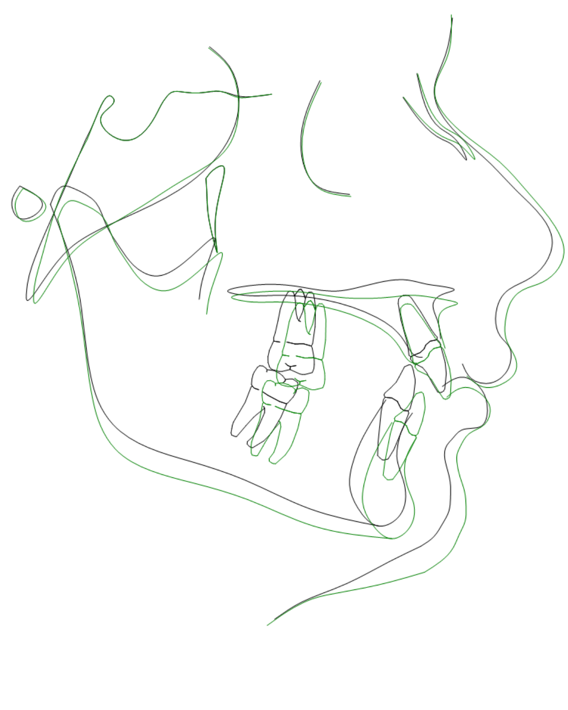


Figure 5.4: Maxillary (Ba-Na at Na) and mandibular (Ba-Na at CC - Center of Cranium) superimpositions to evaluate skeletal changes in the vBHGA group; T1 (black), T2 (green)

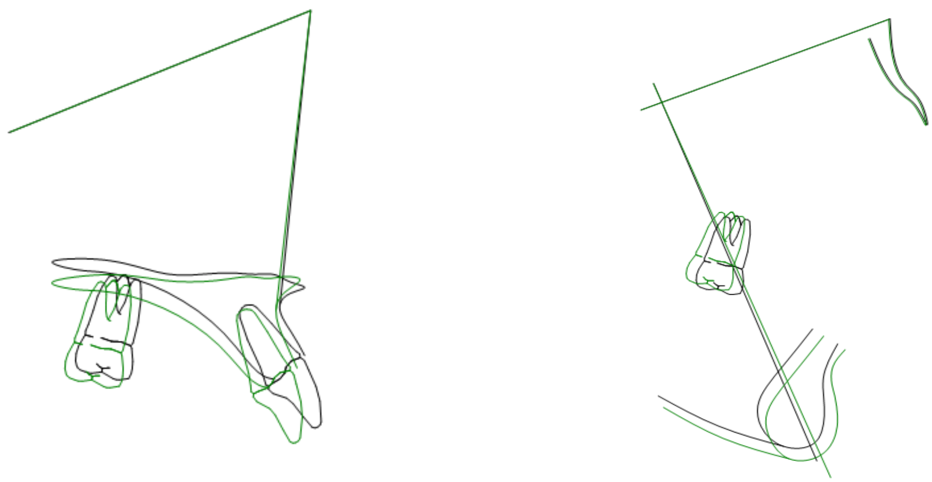


Figure 5.5: Maxillary (Ba-Na at Na) and mandibular (Ba-Na at CC - Center of Cranium) superimpositions to evaluate skeletal changes in the TB group; T1 (black), T2 (green)

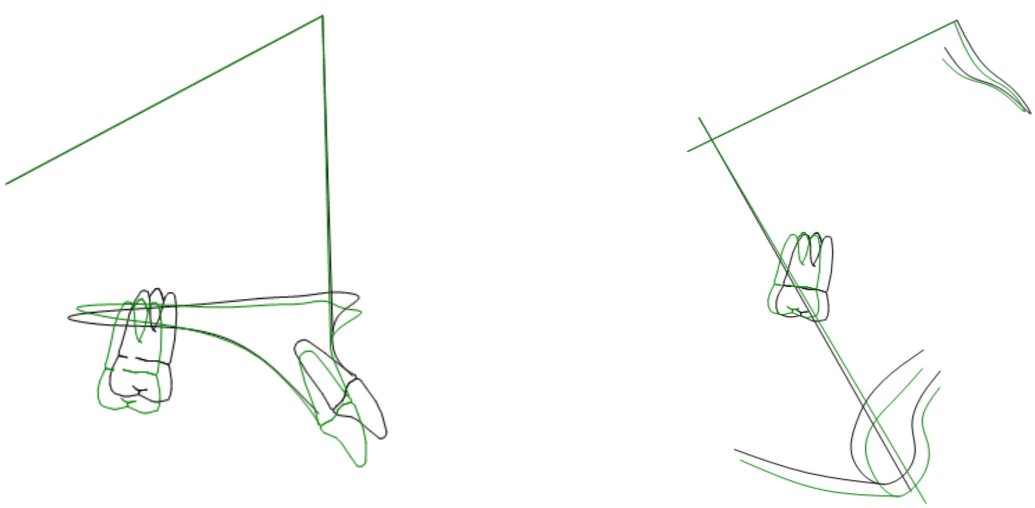


Figure 5.6: Maxillary (Ba-Na at Na) and mandibular (Ba-Na at CC - Center of Cranium) superimpositions to evaluate skeletal changes in the control group; T1 (black), T2 (green)

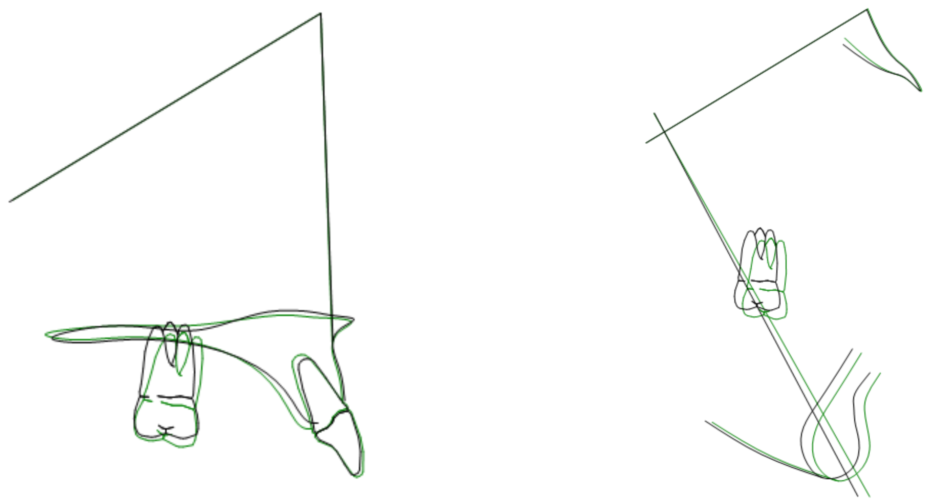


Figure 5.7: Maxillary (ANS-PNS at ANS) and mandibular superimposition (Corpus axis at Pm - Protuberance menti) to evaluate dentoalveolar changes in the vBHGA group; T1 (black), T2 (green)

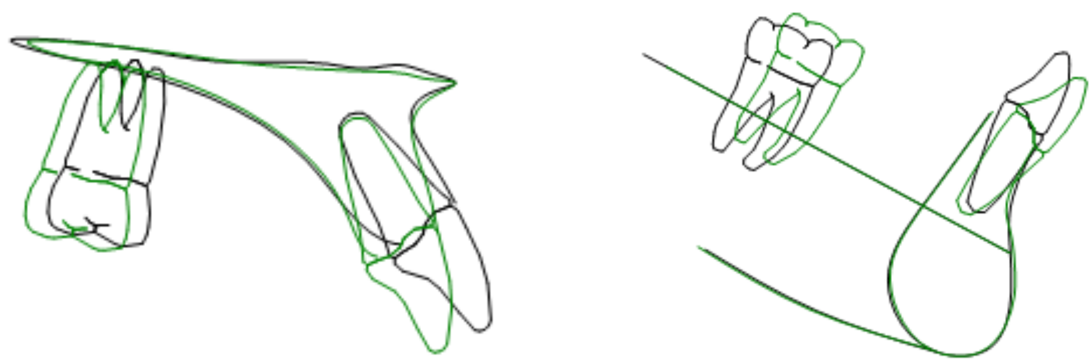


Figure 5.8: Maxillary (ANS-PNS at ANS) and mandibular superimposition (Corpus axis at Pm - Protuberance menti) to evaluate dentoalveolar changes in the TB group; T1 (black), T2 (green)

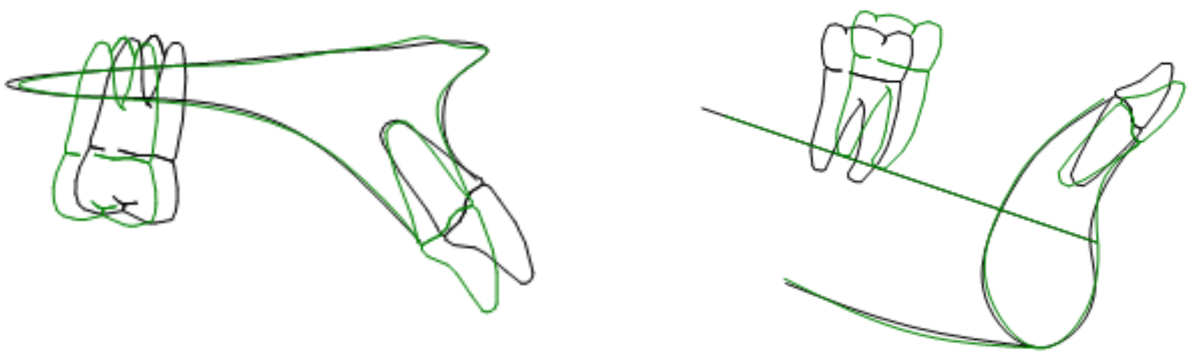
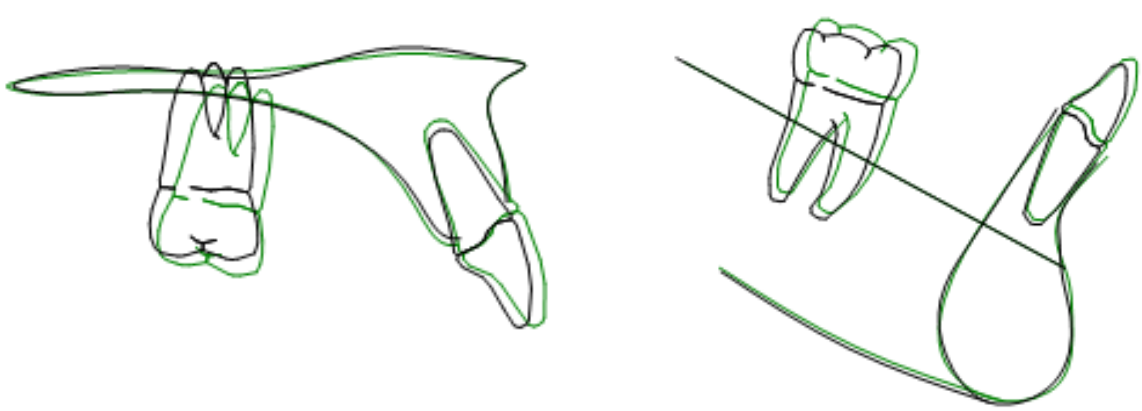


Figure 5.9: Maxillary (ANS-PNS at ANS) and mandibular superimposition (Corpus axis at Pm - Protuberance menti) to evaluate dentoalveolar changes in the control group; T1 (black), T2 (green)



5.9 Reliability

The Intraclass Correlation (ICC) values for intra- and inter-rater reliability are shown in Table 5.6. ICC agreement values can be poor (<0.40), fair to good (0.40-0.75) or excellent (>0.75), according to the method suggested by Fleiss (1999). All intra-rater ICC values showed excellent agreement, except fair-good agreement for the Ar-Go measurement. All inter-rater ICC values indicated an excellent level of agreement. There were no poor agreements. The CVM stages also indicated excellent agreement for both inter and intra-rater reliability. Based on these results, it seems appropriate to state that there was an overall good reproducibility of nearly all involved cephalometric measurements.

Table 5.6: Intra and inter-rater agreement

Cephalometric Variable	Inter-rater reliability (*ICC)	Intra-rater reliability (*ICC)
FH-SN	0.76	0.78
SNA	0.79	0.77
SNB	0.88	0.88
ANB	0.81	0.83
Wits	0.89	0.92
A-NPog	0.83	0.83
A-NA-perp	0.76	0.80
Pg-NA-perp	0.87	0.83
Co-A	0.90	0.84
Co-Gn	0.91	0.81
Go-Pg	0.91	0.83
Ar-Go	0.79	0.66
Co-ANS	0.91	0.81
Co-Pg	0.92	0.83
Harvold Difference	0.81	0.86
FMA	0.84	0.87
MPA	0.86	0.89
Y-Axis	0.91	0.93
PP-SN	0.81	0.82
PP-MP	0.90	0.85
Ba-Na/Pt-Gn	0.92	0.89
LFH	0.95	0.85
Jarabak Ratio	0.78	0.85
SN-Ba	0.89	0.86
U1-SN	0.82	0.86
U1-NA	0.86	0.82
U1-PP	0.89	0.90
U1-NA (mm)	0.83	0.89
L1-NB	0.94	0.91
IMPA	0.91	0.85
L1-NB (mm)	0.94	0.91
L1-APog	0.90	0.88
U1-L1	0.86	0.82
Overjet (OJ)	0.98	0.96
Overbite (OB)	0.90	0.93
Molar Relation	0.89	0.91
Upper Lip- E- line	0.96	0.95
Lower Lip- E- line	0.96	0.96
CVM	0.92	0.94
Average	0.87	0.88

*ICC Intra-Class Coefficient

Chapter 6

Discussion and Conclusion

The present study compared the skeletal and dentoalveolar effects of the Twin-Block (TB) appliance and the van Beek Headgear Activator (vBHGA) in the correction of Class II malocclusions in growing subjects. It also assessed the influence from growth pattern (Horizontal or Vertical) on dental and skeletal interarch relationships. CVM stages as described by Baccetti et al (2005) was used as the skeletal maturity index, as chronologic age can sometimes be unreliable for assessing craniofacial growth (Proffit & Fields, 2012).

In summary, although both appliances similarly improved the intermaxillary relationship (ANB angle), each predominantly targeted a specific apical base. The TB mainly positioned the mandible forward (SNB) whereas the vBHGA restricted the maxilla (SNA), with counterclockwise rotation of the palatal plane (PP-SN) (Table 5.2). The literature has indeed supported greater effect on the maxilla with the vBHGA (Phan et al, 2006) and on the mandible with the TB (Cozza et al, 2006). Dentoalveolar compensations were larger in the TB group resulting in greater reduction of the overjet (OJ) and overbite (OB) (Tables 5.3 and 5.5). The growth pattern (normal/horizontal and vertical) did not influence on the results, except for the inclination of the maxillary incisors (Table 5.4). For these reasons, the first and third null hypotheses, that there would be no difference between the two appliances in terms of skeletal changes and no influence from the growth pattern", were partially accepted. The second hypothesis, that there would be no difference in terms of dentoalveolar changes, was rejected.

6.1 Intergroup Baseline Differences

Firstly, at T1, both TB and vBHGA groups had an equal distribution of subjects in pre-peak (CS 1-2) and peak (CS 3-4) stages, but the TB group had one subject in the post-peak stage (CS 5-6) (Table 5.1). Since CS stages cannot always accurately predict the peak in mandibular growth (Ball et al, 2011) and secondary sexual characteristics do not always correlate with the CS stages (Santiago et al, 2012), it was decided to include that one subject in the sample. Also, as observed by O'Brien et al (2003b) when comparing the TB and the Herbst appliances, the statistical model showed that CVM stages did not have a significant influence on the treatment effects. It is important to bear in mind that individuals whose vertebral maturation lies between CS5 and CS6 still have some growth remaining. In contrast, the control group, that fit the inclusion criteria of ANB angle $>5^0$, had more subjects in the pre-peak stage (Table 5.1) due to limited availability of the historical archives. Although including such historical control was as best as it could get, it limited the assessment on how much these appliances could stimulate changes beyond natural growth. However, the main purpose of this study was to compare the two appliances, what was achieved in its entirety. Both experimental groups experienced changes that favored the class II correction.

Females predominantly comprised the TB and vBHGA groups whereas males, the control group. Developmentally, females mature earlier than males, and this unbalanced sex distribution could have overestimated the treatment effects with the two appliances. Including similar number of males and females and/or increasing the sample size would have resulted in a more balanced ratio, but this is not always achievable with retrospective studies and would require a broader multicenter collaboration. In addition, the control group started out with reduced overjet (OJ= 3.35mm) as compared to the TB (8.47mm) and the vBHGA (8.97mm) groups. Although such reduced baseline overjet in the control group limited the comparisons in regards to dentoalveolar compensations, it did not limit the comparisons related to skeletal changes since the control group had a comparable baseline ANB angle. Regardless, it is important to point out that the current study mainly focused on comparing the two appliances, for which there was a similar representation of males and females as well as comparable overjets.

6.2 Growth Pattern Assessment

Jarabak's ratio was used to stratify the samples into horizontal or vertical growers. Rather than less specific angular measurements such as the MPA, FMA ant the Y-Axis, Jarabak's ratio accounts for the proportion between the anterior and the posterior face heights. Although normal growers are also included in the Jarabak's ratio analysis, it was decided to dichotomize the sample into horizontal and vertical subgroups by merging the horizontal and normal growers. This was done because the vertical growers are the ones who actually pose a clinical challenge during Class II correction due to their poor response to mandibular advancement, something that does not occur with normal and horizontal growers (Freeman et al, 2007). Our sample had more horizontal than vertical growers in all three groups, thereby making them comparable in terms of growth pattern.

6.3 Mandibular Changes

Neither appliance superseded normal mandibular growth as compared to the controls (Co-Pg, Co-Gn) (Table 5.2), which was similar to the findings of Tümer and Gültan (1999), who studied the TB, and Phan at al (2006), who studied the vBHGA.

According to the SNB angle, the mandibles in the TB group were advanced 1.22^0 more than in the control group. This was similar to what was reported in a meta-analysis (Antonarakis & Kiliardis, 2007) that studied the treatment effects of various functional appliances, which showed an increase of 1.53^0 for the SNB value in comparison to the control. There was no statistically significant difference between the vBHGA and the control groups (Table 5.2), which was similar to the findings of Bendeus et al (2002), who studied the growth and treatment changes with the vBHGA.

TB performed better than vBHGA in increasing the SNB angle value (treatment effect = 1.34^0) despite the greater mandibular growth with vBHGA (Co-Pg and Co-Gn) (Table 5.2). Although not statistically significant when seen in isolation (Table 5.2), this conundrum probably occurred due to the following cumulative effects: 1. increase in the Jarabak's ratio in the TB group while a decrease was observed in the vBHGA group (treatment effect = 0.25), and 2. slightly larger increase in the lower anterior face height (LAFH) with the vBHGA (treatment effect = 0.39). Although such effects were small, their combination might have favored a more forward positioning of B-point in the TB group. The TB group experienced a 2.36 mm increase in LAFH, slightly less than the 2.7 mm reported by Illing et al (1998). Variations like this normally occur in direct proportion to the magnitude of mandibular advancement as well as both the amount and the type of correction of the curve of Spee before advancing, whichever can differ among clinicians. The LAFH increased 2.67 mm with the vBHGA in spite of the high pull headgear. The counterclockwise rotation of the maxilla experienced by the patients treated with the vBHGA might have contributed to this. Marşan (2007) reported a similar increase of 2.6 mm in her study on the vBHGA. There may be other factors involved that could explain why TB showed more forward positioning of the mandible despite a larger increase in Co-Gn and Co-Pg with the vBHGA. In a cephalometric study, it is sometimes not possible to fully understand discrepancies between the effective length of an apical base and its spatial position given that intramatrix rotation, as described by Bjork (1963), can only be assessed accurately with implants.

A more forward mandibular positioning with the TB can also be assumed to have occurred due to a muscular posturing of the mandible. This would need to be confirmed by guiding the mandible in centric relation, but such information is not always available in a retrospective study as it would rely on chart annotations. In a prospective study design, weaning the patients off from the functional appliance for 12 months so that type 3 collagen can convert into type 1 collagen (Chayanupatkul, 2003) could be another way of checking for muscular posturing before taking the T2 cephalometric radiograph. This, however, would be clinically undesirable as initiation of fixed appliances and thereby the mechanics to camouflage any anteroposterior relapse would be delayed. Understanding why this would have predominantly occurred with the TB appliance would require a close look at the two different protocols.

6.4 Maxillary Changes

The vBHGA appliance performed better than the control and TB groups in reducing the SNA angle value (treatment effects = 1.59^0 and 0.83, respectively) (Table 5.2). The T2-T1 difference with the vBHGA in comparison to the control was 1.32^0. This was in agreement with previous investigations (Marşan, 2007; Dermaut, 1992) on the vBHGA appliance where orthopedic maxillary restriction was observed as a reduction in the SNA angle value between 1^0 and 2^0 when compared to respective controls.

There was no difference, however, between the two appliances in regards to A-Na-perp, which is a relevant measurement given that the Frankfort horizontal plane was considered an appropriate reference to assess the position of the jaws (Ellis & McNamara, 1988). On the other hand, the difficulty in reliably reproducing porion can make such values (FH-SN, A-Na-perp, Pog-Na-perp and FMA) less accurate (Raju & Naidu, 2012). Whatever was the reason, the fact is that the expected larger impact of vBHGA on maxillary growth could not be observed in all the pertinent measurements of this study. Another way to indirectly validate that the vBHGA group might have been somehow efficient in reducing the forward growth of the maxilla lies on the fact that its Co-

A and Co-ANS increased more than in the TB group, what should lead to a more pronounced forward positioning of the maxilla, something that did not occur. A possible explanation for this could be the counterclockwise rotation of the maxilla with the vBHGA appliance, what might have reduced the expression of its antero-posterior restrictive effect on the maxilla. In fact, the PP-SN clearly reduced with vBHGA and increased with TB (treatment effect = 1.45), the difference between the appliances being statistically significant. The line of action of the short and rigid outer-bow of the high-pull headgear in the vBHGA appliance near the maxillary canine might have passed above the center of resistance (CR) of the maxilla, causing the palatal plane to rotate in the counterclockwise direction, a maneuver aimed at reducing the gingival display, which is one of the indications of this appliance (van Beek, 1984).

Maxillary restriction shall be expected with any intermaxillary functional appliance whose primary goal is to stimulate mandibular growth. This is because of the distal vector of force that gets passed on to the maxilla through the forcers of occlusion as these appliances are worn (van Beek, 1984). Although SNA and A-Na-perp also were reduced in the TB group, such reduction was not statistically different than what was observed in the control group (Table 5.2). Lund and Sandler (1998) also observed a non-statistically significant restraint of the maxilla with the TB. Only one measurement (A-NPog) in the TB group showed some antero-posterior restriction of the maxilla (treatment effect = 1.35) in comparison to the control group. It is important to bear in mind that A-NPog can sometimes be unreliable because pogonion might have moved forward.

6.5 Intermaxillary Relationship

Although the TB group experienced more ANB reduction (mean T2-T1: 2.37^0) than the vBHGA group (mean T2-T1: 1.67^0), the difference was not statistically significant (Table 5.2). Such amount of ANB reduction was in agreement with the results of the meta-analysis published by

Antonarakis & Kiliaridis[10] and the study by Altenburger & Ingervall (1998), which assessed the short-term effects of the TB and vBHGA, respectively. Previous studies (Bendeus et al, 2002; Lund & Sandler, 1998) on the TB appliance found ANB reductions between 2^0 and 2.3^0 when compared to controls, which was similar to that found in the present study, which was 2.05^0. The mean T2-T1 change in the control group was only 0.32^0, being statistically less than that observed with both appliances (Table 5.2). Despite the larger frequency of pre-peak patients in the control group and larger frequency of peak patients in both treatment groups at T1 (Table 5.1), it is appropriate to state that both appliances were able to reduce the intermaxillary discrepancy in comparison to the control. This is because the literature has demonstrated lack of significant Class II self-correction with normal growth (Baccetti et al, 2009). From a clinical viewpoint, the 2.37^0 ANB reduction with TB sounds more clinically relevant than the 1.67^0 reduction with vBHGA. It was postulated previously that angular measurement changes of 1^0 or more are considered clinically significant (Aelbers & Dermaut, 1996). It is also important to be reminded that the mechanisms by which such reduction was achieved differed between the appliances, with more intervention on the maxilla with the vBHGA and on the mandible with TB. This calls the attention to the fact that it is not the amount of ANB reduction that is important when deciding between these two appliances, but also which apical base will need to be addressed. The literature also supports more mandibular effects with the TB[10] and greater maxillary changes with the headgear-activators (Antonarakis & Kiliardis, 2007).

The TB group statistically superseded the vBHGA and control groups in reducing the Wits value (Table 5.2). The mean T2-T1 reduction was 4.97 mm for the TB and 1.42 mm for the vBHGA. However, based on the low R^2 of 0.37, the regression equation did not seem to be capable of explaining 50% or more of the variation. As Wits seems to be more reliable than the ANB in vertically growing patients (Jacobson, 2003), and our sample had a higher frequency of horizontal/normal growers in all three groups (Table 5.1), this finding needs to be considered with caution.

6.6 Dentoalveolar Compensations Contributing to Correction of the OJ

In terms of dentoalveolar compensations, the TB superseded the vBHGA, with greater maxillary incisor retrusion (treatment effect U1-NA mm=1.04mm) (Table 5.3) and extrusion (treatment effect U1-vertical =0.73mm) (Table 5.4) as well as more pronounced mandibular incisor protrusion (treatment effect L1-NB mm and L1-APog mm = 0.54mm and 0.96mm respectively), proclination (treatment effect L1-NB^0=3.84^0 and IMPA=1.92^0) (Table 5.3) and relative intrusion (treatment effect L1-vertical =0.80mm) (Table 5.5), thereby producing a greater reduction in the OJ (treatment effect =1.65mm)and OB (treatment effect =1.83mm) (Table 5.3).

When taking growth pattern into account, the maxillary incisors retroclined more in the TB horizontal growers (treatment effect U1-NA^0 = 3.62) (Table 5.3). It is well known that such type of dentoalveolar compensation tends to occur in result of a reactionary distal vector of force acting on the maxillary incisors as the mandible is projected forward and maintained in such position for a long period of time. Such reactionary distal vector of force will certainly lie more horizontally in horizontal growers. The fact that this was only observed in the TB group corroborates this assumption since the addition of a vertical vector from the high-pull headgear in the vBHGA group might have created a less horizontal reactionary distal vector.

Although the literature suggests the use of vBHGA in vertical growers (Dermaut et al, 1992), perhaps the TB can be an equally suitable appliance for these patients. O'Brien et al (2003b), in their study comparing the TB with the Herbst appliance, corroborated this assumption based on the maxillo-mandibular plane angle (MMPA) as a measure of the vertical proportions.

Only TB showed a statistically significant reduction in the OJ (Table 5.3). However, the reduction of 4.16mm with the vBHGA cannot be overlooked. This probably occurred due to sample variation, hence the low R^2 value, indicating that the predictor variable did not precisely predict the response, and to the reduced baseline overjet (3.35mm) in the control group. Also, capping of the mandibular incisors in the vBHGA group might have also led to less dentoalveolar compensation. Altogether, this could have underestimated the effect of the vBHGA on the OJ reduction.

Molar correction towards Angle's Class I was more pronounced in the appliance groups than in the control (Table 5.3). When comparing both appliances, the TB group showed greater molar correction, probably in result of the more pronounced dentoalveolar compensations of the maxillary (U1-NA mm) and mandibular (L1-NB mm, L1-APog mm, L1-NB^0) incisors (Table 5.3).

6.7 Treatment Effect on the Soft Tissues

The upper lip retruded more in the TB group compared to the vBHGA group (Table 5.3). This could be due to the greater retrusion (treatment effect U1-NA mm 1.04mm) and retroclination (treatment effect U1-NA^0=3.62^0) of the maxillary incisors found in the TB group (Table 5.4).

There was no difference in the lower lip position between the two treatment groups despite the greater dentoalvelolar compensation in the mandibular dentition with the TB (L1-NB mm and L1-APog mm; L1/NB^0 and IMPA) (Table 5.3). This is in contrast to the findings by Morris et al (1998) wherein the upper lip remained stable and the lower lip protruded. This may be attributed to the inclusion of more horizontal growers in our study who also experienced more maxillary incisor retroclination (U1-NA^0) (Table 5.4). In addition, vertical growers present with low muscle tone (Kiliaridis, 2006), leading to more pronounced changes in the posture of the soft tissues in response to tooth movement. Moreover, response of the soft-tissues to functional appliance treatment can be highly variable, and individual variation might occur due to myotactic reflexes and soft-tissue viscoelasticity (Sharma & Lee, 2005; McDonagh et al, 2001).

6.8 Clinical Message

Treatment with the TB and vBHGA appliances resulted in a modest ANB reduction of 2.37^0 and 1.67^0, respectively. The TB ANB reduction seems to echo the conclusions of some RCTs (O'Brien et al, 2009; Dolce et al, 2007; Tulloch et al, 2004) that reported a reduction of approximately 2^0 with functional appliances at the end of 2-phase treatments. The clinical significance of 1^0 to 2^0 is indeed debatable, but considering that the ANB standard deviations at T2 were as large as 2^0 with both appliances (Table 5.2), one can assume that the outcome can also be highly variable. Such large variation with some individuals showing a significant above-average response has also been raised by previous authors (Wiltshire, 2006). This, together with other benefits from functional appliances, support the idea that the use of functional appliances is not in vain. There are several benefits from functional appliances. Firstly, the considerable reduction in OJ prevents trauma, improves self-esteem, eliminates lip traps and may decrease the duration of the second phase of treatment with fixed-appliances or clear aligner therapy (Thiruvenkatachari et al, 2015; O'Brien et al, 2009).

The current study showed that the ANB angle reduction was overall similar between the two appliances. The mechanism by which this occurred, however, consisted in a more forward positioning of the mandible with the TB and greater posterior positioning of the maxilla with the vBHGA appliance due to counterclockwise rotation. Dentoalveolar changes were more pronounced with the TB appliance, resulting in greater overbite and overjet reduction. Except for three dental cephalometric variables (U1-NA^0, U1-SN^0, and U1-PP^0), growth pattern did not seem to play an important role in determining the outcome with either appliance. Therefore, instead of growth pattern, mechanism of action and amount of dentoalveolar compensation seem to be the main parameters to guide the clinician when choosing between these two appliances. For instance, vertically or horizontally growing retrognathic patients with a large overjet could be prescribed a TB. By the same token, horizontally growing patients with a prognathic maxilla could be prescribed a vBHGA due to its peculiar orthopedic effect of rotating the maxilla counterclockwise. Due to its more pronounced dentoalveolar compensation in both the maxillary and mandibular dentitions, especially in the maxillary incisors of horizontal growers, the TB would be preferrable in patients with excessive overjet, retrognathic mandible, proclined maxillary incisors, and horizontal growth pattern.

6.9 Conclusions

Despite the expected limitations of a retrospective study, it was possible to draw the following conclusions:

1. Both the Twin-Block (TB) and the van Beek Headgear-Activator (vBHGA) appliances produced modest skeletal changes that favored the correction of the class II malocclusion. Notwithstanding the greater maxillary growth restriction with the TB, the maxilla was found to be more posteriorly positioned in the vBHGA group due to counterclockwise rotation. Despite greater increase in the effective length of the mandible with the vBHGA, the mandible in the TB group was found to be more anteriorly positioned.
2. Dentoalveolar compensations to correct the class II malocclusion was observed with both appliances, but was found to be more pronounced in individuals treated with the TB appliance who also experienced greater improvement in molar relationship and reduction in overjet and overbite.
3. Except for three upper incisor cephalometric measurements (U1-NA^0, U1-SN^0 and U1-PP^0),

growth pattern (vertical or horizontal) did not influence on the performance of the two appliances.

References

Aelbers, C. M., & Dermaut, L. R. (1996). Orthopedics in orthodontics: Part I, Fiction or reality--a review of the literature. *American Journal of Orthodontics and Dentofacial Orthopedics*, *110*(5), 513–519. https://doi.org/10.1016/s0889-5406(96)70058-6

Al-Bitar, Z. B., Al-Omari, I. K., Sonbol, H. N., Al-Ahmad, H. T., & Cunningham, S. J. (2013). Bullying among Jordanian schoolchildren, its effects on school performance, and the contribution of general physical and dentofacial features. *American Journal of Orthodontics and Dentofacial Orthopedics*, *144*(6), 872–878. https://doi.org/10.1016/j.ajodo.2013.08.016

Al-kalaly, A., Wu, C., Wong, R., & Rabie, A. B. (2009). The assessment of cell cycle genes in the rat mandibular condyle. *Archives of Oral Biology*, *54*(5), 470–478. https://doi.org/10.1016/j.archoralbio.2009.01.020

Al-Omari, I. K., Al-Bitar, Z. B., Sonbol, H. N., Al-Ahmad, H. T., Cunningham, S. J., & Al-Omiri, M. (2014). Impact of bullying due to dentofacial features on oral health-related quality of life. *American Journal of Orthodontics and Dentofacial Orthopedics*, *146*(6), 734–739. https://doi.org/10.1016/j.ajodo.2014.08.011

Altenburger, E., & Ingervall, B. (1998). The initial effects of the treatment of Class II, division 1 malocclusions with the van Beek activator compared with the effects of the Herren activator and an activator-headgear combination. *European Journal of Orthodontics*, *20*(4), 389–397. https://doi.org/10.1093/ejo/20.4.389

Antonarakis, G. S., & Kiliaridis, S. (2007). Short-term anteroposterior treatment effects of functional appliances and extraoral traction on class II malocclusion. A meta-analysis. *The Angle Orthodontist*, *77*(5), 907–914. https://doi.org/10.2319/061706-244

Baccetti, T., Stahl, F., & McNamara, J. A. (2009). Dentofacial growth changes in subjects with untreated Class II malocclusion from late puberty through young adulthood. *American Journal of Orthodontics and Dentofacial Orthopedics*, *135*(2), 148–154. https://doi.org/10.1016/j.ajodo.2007.03.033.

Baccetti, T., Franchi, L., & McNamara, J. A. (2005). The Cervical Vertebral Maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopedics. *Seminars in Orthodontics,*11(3), 119–129. https://doi.org/10.1053/j.sodo.2005.04.005

Baccetti, T., Franchi, L., Toth, L. R., & McNamara, J. A. (2000). Treatment timing for Twin-block therapy. *American Journal of Orthodontics and Dentofacial Orthopedics*, *118*(2), 159–170. https://doi.org/10.1067/mod.2000.105571

Baccetti, T., Franchi, L., McNamara, J. A., Jr, & Tollaro, I. (1997). Early dentofacial features of Class II malocclusion: a longitudinal study from the deciduous through the mixed dentition. *American Journal of Orthodontics and Dentofacial Orthopedics, 111*(5), 502–509. https://doi.org/10.1016/s0889-5406(97)70287-7

Badran, S. A. (2010). The effect of malocclusion and self-perceived aesthetics on the self-esteem of a sample of Jordanian adolescents. *European Journal of Orthodontics*, *32*(6), 638–644. https://doi.org/10.1093/ejo/cjq014

Ball, G., Woodside, D., Tompson, B., Hunter, W. S., & Posluns, J. (2011). Relationship between cervical vertebral maturation and mandibular growth. *American Journal of Orthodontics and Dentofacial Orthopedics*, *139*(5), e455–e461. https://doi.org/10.1016/j.ajodo.2010.01.035

Batista, K. B., Thiruvenkatachari, B., Harrison, J. E., & O'Brien, K. D. (2018). Orthodontic treatment for prominent upper front teeth (Class II malocclusion) in children and adolescents. *The Cochrane Database of Systematic Reviews*, *3*(3), CD003452. https://doi.org/10.1002/14651858.CD003452.pub4

Bayirli, B., Vaden, J. L., & Johnston, L. E., Jr (2013). Long-term mandibular skeletal and dental effects of standard edgewise treatment. *American Journal of Orthodontics and Dentofacial Orthopedics*, *144*(5), 682–690. https://doi.org/10.1016/j.ajodo.2013.07.008

Baysal, A., & Uysal, T. (2014). Dentoskeletal effects of Twin Block and Herbst appliances in patients with Class II division 1 mandibular retrognathy. *European Journal of Orthodontics*, *36*(2), 164–172. https://doi.org/10.1093/ejo/cjt013

Bendeus, M., Hägg, U., & Rabie, B. (2002). Growth and treatment changes in patients treated with a headgear-activator appliance. *American Journal of Orthodontics and Dentofacial Orthopedics, 121*(4), 376–384. https://doi.org/10.1067/mod.2002.122177

Benson, P. E., Da'as, T., Johal, A., Mandall, N. A., Williams, A. C., Baker, S. R., & Marshman, Z. (2015). Relationships between dental appearance, self-esteem, socio-economic status, and oral health-related quality of life in UK schoolchildren: A 3-year cohort study. *European Journal of Orthodontics*, *37*(5), 481–490. https://doi.org/10.1093/ejo/cju076

Bishara, S. E. (2006). Class II malocclusions: Diagnostic and clinical considerations with and without treatment. *Seminars in Orthodontics,* 12(1):11–24. https://doi.org/10.1053/j.sodo.2005.10.005

Bjork, A. (1963). Variations in the growth pattern of the human mandible: longitudinal radiographic study by the implant method. *Journal of dental research*, *42(1)Pt 2*, 400–411. https://doi.org/10.1177/00220345630420014701

Buschang, P. H., & Martins, J. (1998). Childhood and adolescent changes of skeletal relationships. *The Angle Orthodontist*, *68*(3), 199–208. https://doi.org/10.1043/0003-3219(1998)068<0199:CAACOS>2.3.CO;2

Chadwick, S. M., Banks, P., & Wright, J. L. (1998). The use of myofunctional appliances in the UK: a survey of British orthodontists. *Dental Update*, 25(7), 302–308.

Chayanupatkul, A. (2003). Temporomandibular response to early and late removal of bite-jumping devices. *European Journal of Orthodontics,* 25(5), 465–470. https://doi.org/10.1093/ejo/25.5.465

Chen, J. Y., Will, L. A., & Niederman, R. (2002). Analysis of efficacy of functional appliances on mandibular growth. *American Journal of Orthodontics and Dentofacial Orthopedics, 122*(5), 470–476. https://doi.org/10.1067/mod.2002.126730

Clark, W. J. (1988). The twin block technique. A functional orthopedic appliance system. *American Journal of Orthodontics and Dentofacial Orthopedics*, *93*(1), 1–18. https://doi.org/10.1016/0889-5406(88)90188-6

Clark, W. J. (1982). The twin block traction technique. *European Journal of Orthodontics,* 4(2), 129–138. https://doi.org/10.1093/ejo/4.2.129

Council on Scientific Affairs. (2005). Functional appliances and long-term effects on mandibular growth. *American Journal of Orthodontics and Dentofacial Orthopedics, 128*(3), 271–272. https://doi.org/10.1016/j.ajodo.2005.07.008

Courtney, M., Harkness, M., & Herbison, P. (1996). Maxillary and cranial base changes during treatment with functional appliances. *American Journal of Orthodontics and Dentofacial Orthopedics, 109*(6), 616–624. https://doi.org/10.1016/s0889-5406(96)70073-2

Cozza, P., Baccetti, T., Franchi, L., De Toffol, L., & McNamara, J. A. (2006). Mandibular changes produced by functional appliances in Class II malocclusion: a systematic review. *American Journal of Orthodontics and Dentofacial Orthopedics*, 129(5), 599.e1–e6. https://doi.org/10.1016/j.ajodo.2005.11.010

Dai, J., & Rabie, A. B. (2008). Gene therapy to enhance condylar growth using rAAV-VEGF. *The Angle Orthodontist*, *78*(1), 89–94. https://doi.org/10.2319/102606-441.1

Dermaut, L. R., van den Eynde, F., & de Pauw, G. (1992). Skeletal and dento-alveolar changes as a result of headgear activator therapy related to different vertical growth patterns. *European Journal of Orthodontics*, *14*(2), 140–146. https://doi.org/10.1093/ejo/14.2.140

Dolce, C., McGorray, S. P., Brazeau, L., King, G. J., & Wheeler, T. T. (2007). Timing of Class II treatment: skeletal changes comparing 1-phase and 2-phase treatment. *American Journal of Orthodontics and Dentofacial Orthopedics*, *132*(4), 481–489. https://doi.org/10.1016/j.ajodo.2005.08.046

Ehsani, S., Nebbe, B., Normando, D., Lagravere, M. O., & Flores-Mir, C. (2015). Short-term treatment effects produced by the Twin-block appliance: a systematic review and meta-analysis. *European Journal of Orthodontics*, 37(2), 170–176. https://doi.org/10.1093/ejo/cju030

Eirew, H. L. (1981). The bionator. *British Journal of Orthodontics*, *8*(1), 33–36.

https://doi.org/10.1179/bjo.8.1.33

Ellis, E., & McNamara, J. (1988). Cephalometric reference planes--sella nasion vs Frankfort horizontal. *The International Journal of Adult Orthodontics and Orthognathic Surgery*, *3*(2), 81–87.

Elms, T. N., Buschang, P. H., & Alexander, R. G. (1996a). Long-term stability of Class II, Division 1, nonextraction cervical face-bow therapy: II. Cephalometric analysis. *American Journal of Orthodontics and Dentofacial, 109*(4), 386–392. https://doi.org/10.1016/s0889-5406(96)70120-8

Elms, T. N., Buschang, P. H., & Alexander, R. G. (1996b). Long-term stability of Class II, Division 1, nonextraction cervical face-bow therapy: I. Model analysis. *American Journal of Orthodontics and Dentofacial Orthopedics, 109*(3), 271–276. https://doi.org/10.1016/s0889-5406(96)70150-6

Fishman, L. S. (1982). Radiographic evaluation of skeletal maturation. A clinically oriented method based on hand-wrist films. *The Angle Orthodontist*, *52*(2), 88–112. https://doi.org/10.1043/0003-3219(1982)052<0088:REOSM>2.0.CO;2

Fleiss, J. L. (1999). *The Design and Analysis of Clinical Experiments*. Wiley & Sons, Inc.

Fleiss, J. L., Slakter, M. J., Fischman, S. L., Park, M. H., & Chilton, N. W. (1979). Inter-examiner reliability in caries trials. *Journal of Dental Research*, *58*(2), 604–609. https://doi.org/10.1177/00220345790580021101

Fränkel, R. (1980). A functional approach to orofacial orthopaedics. *British Journal of Orthodontics*, *7*(1), 41–51. https://doi.org/10.1179/bjo.7.1.41

Freeman, C. S., McNamara, J. A., Jr, Baccetti, T., Franchi, L., & Graff, T. W. (2007).

Treatment effects of the bionator and high-pull facebow combination followed by fixed appliances in patients with increased vertical dimensions. *American Journal of Orthodontics and Dentofacial Orthopedics, 131*(2), 184–195. https://doi.org/10.1016/j.ajodo.2005.04.043

Grave, K., & Townsend, G. (2003). Cervical vertebral maturation as a predictor of the adolescent growth spurt. *Australian Orthodontic Journal,* 19(1), 25–32.

Hägg, U., Rabie, A. B., Bendeus, M., Wong, R. W., Wey, M. C., Du, X., & Peng, J. (2008). Condylar growth and mandibular positioning with stepwise vs maximum advancement. *American Journal of Orthodontics and Dentofacial Orthopedics, 134*(4), 525–536. https://doi.org/10.1016/j.ajodo.2006.09.064

Harris, J. E. (1975). Genetic factors in the growth of the head. Inheritance of the craniofacial complex and malocclusion. *Dental Clinics of North America*, *19*(1), 151–160.

Harvold, E. P., Tomer, B. S., Vargervik, K., & Chierici, G. (1981). Primate experiments on oral respiration. *American Journal of Orthodontics*, *79*(4), 359–372. https://doi.org/10.1016/0002-9416(81)90379-1

Hunt, O., Burden, D., Hepper, P., & Johnston, C. (2005). The psychosocial effects of cleft lip and palate: a systematic review. *European Journal of Orthodontics*, *27*(3), 274–285. https://doi.org/10.1093/ejo/cji004

Illing, H. M., Morris, D. O., & Lee, R. T. (1998). A prospective evaluation of Bass, Bionator and Twin Block appliances. Part I - The hard tissues. *European Journal of Orthodontics*, *20*(5), 501–516. https://doi.org/10.1093/ejo/20.5.501

Jacobson, A. (2006). *Radiographic Cephalometry: From Basics to 3-D Imaging.* (2nd ed.). Quintessence Publishing Co,Inc.

Jacobson A. (1975). The "Wits" appraisal of jaw disharmony. *American Journal of Orthodontics*, *67*(2), 125–138. https://doi.org/10.1016/0002-9416(75)90065-2

Jakobsson, S. O. (1967). Cephalometric evaluation of treatment effect on Class II, Division I malocclusions. *American Journal of Orthodontics*, *53*(6), 446–457. https://doi.org/10.1016/0002-9416(67)90005-x

Jarabak, J. R. (1972). *Technique and treatment with light-wire edgewise appliances*. C. V. Mosby Company.

Järvinen, S. (1978). Incisal overjet and traumatic injuries to upper permanent incisors. A retrospective study. *Acta Odontologica Scandinavica*, *36*(6), 359–362. https://doi.org/10.3109/00016357809029088

Jena, A. K., Duggal, R., & Parkash, H. (2006). Skeletal and dentoalveolar effects of Twin-block and bionator appliances in the treatment of Class II malocclusion: a comparative study. *American Journal of Orthodontics and Dentofacial Orthopedics*, *130*(5), 594–602. https://doi.org/10.1016/j.ajodo.2005.02.025

Johal, A., Cheung, M. Y., & Marcene, W. (2007). The impact of two different malocclusion traits on quality of life. *British Dental Journal*, *202*(2), E2. https://doi.org/10.1038/bdj.2007.33

Johnston, L. E. (1998). Growth and the Class II patient: rendering unto Caesar. *Seminars in Orthodontics*, *4*(1), 59–62. https://doi.org/10.1016/s1073-8746(98)80042-x

Jung, M. H. (2010). Evaluation of the effects of malocclusion and orthodontic treatment on self-esteem in an adolescent population. *American Journal of Orthodontics and Dentofacial*, *138*(2), 160–166. https://doi.org/10.1016/j.ajodo.2008.08.040

Keeling, S. D., Wheeler, T. T., King, G. J., Garvan, C. W., Cohen, D. A., Cabassa, S., McGorray, S. P., & Taylor, M. G. (1998). Anteroposterior skeletal and dental changes after early Class II treatment with bionators and headgear. *American Journal of Orthodontics and Dentofacial Orthopedics*, *113*(1), 40–50. https://doi.org/10.1016/S0889-5406(98)70275-6

Kenealy, P. M., Kingdon, A., Richmond, S., & Shaw, W. C. (2007). The Cardiff dental study: a 20-year critical evaluation of the psychological health gain from orthodontic treatment. *British Journal of Health Psychology*, *12*(Pt 1), 17–49. https://doi.org/10.1348/135910706X96896

Kiliaridis, S. (2006). The Importance of Masticatory Muscle Function in Dentofacial Growth. *Seminars in Orthodontics,* 12(2), 110–119.

Kjellberg, H., Kiliaridis, S., & Thilander, B. (1995). Dentofacial growth in orthodontically treated and untreated children with juvenile chronic arthritis (JCA). A comparison with Angle Class II division 1 subjects. *European Journal of Orthodontics*, *17*(5), 357–373. https://doi.org/10.1093/ejo/17.5.357

Kotyk, M. W. (2017). *Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances*. [Master’s thesis, University of Manitoba].

Leung, F. Y., Rabie, A. B., & Hägg, U. (2004). Neovascularization and bone formation in the condyle during stepwise mandibular advancement. *European Journal of*

Orthodontics, *26*(2), 137–141. https://doi.org/10.1093/ejo/26.2.137

Linder-Aronson, S. (1970). Adenoids. Their effect on mode of breathing and nasal airflow and their relationship to characteristics of the facial skeleton and the denition. A biometric, rhino-manometric and cephalometro-radiographic study on children with and without adenoids. *Acta Oto-laryngologica. Supplementum*, *265*, 1–132.

Lisson, J. A., & Tränkmann, J. (2002). Effects of angle Class II, division 1 treatment with jumping-the-bite appliances. A longitudinal study. *Journal of Orofacial Orthopedics*, *63*(1), 14–25. https://doi.org/10.1007/s00056-002-0048-y

Lund, D. I., & Sandler, P. J. (1998). The effects of Twin Blocks: a prospective controlled study. *American Journal of Orthodontics and Dentofacial Orthopedics*, *113*(1), 104–110. https://doi.org/10.1016/S0889-5406(98)70282-3

Marşan, G. (2007). Effects of activator and high-pull headgear combination therapy: skeletal, dentoalveolar, and soft tissue profile changes. *European Journal of Orthodontics*, *29*(2), 140–148. https://doi.org/10.1093/ejo/cjm003

Marsico, E., Gatto, E., Burrascano, M., Matarese, G., & Cordasco, G. (2011). Effectiveness of orthodontic treatment with functional appliances on mandibular growth in the short term. *American Journal of Orthodontics and Dentofacial Orthopedics*, *139*(1), 24–36. https://doi.org/10.1016/j.ajodo.2010.04.028

McDonagh, S., Moss, J. P., Goodwin, P., & Lee, R. T. (2001). A prospective optical surface scanning and cephalometric assessment of the effect of functional appliances on the soft tissues. *European Journal of Orthodontics*, *23*(2), 115–126. https://doi.org/10.1093/ejo/23.2.115

McNamara, J. A., Brudon, W. L., & Kokich, V. G. (2001). *Orthodontics and Dentofacial Orthopedics*. Needham Press.

McNamara, J. A. (1984). A method of cephalometric evaluation. *American Journal of Orthodontics*, *86*(6), 449–469. https://doi.org/10.1016/s0002-9416(84)90352-x

McNamara, J. A. (1981). Components of class II malocclusion in children 8-10 years of age. *The Angle Orthodontist,* 51(3). https://doi.org/10.1043/0003-3219(1981)051<0177:COCIMI>2.0.CO;2

Melsen, B., Attina, L., Santuari, M., & Attina, A. (1987). Relationships between swallowing pattern, mode of respiration, and development of malocclusion. *The Angle Orthodontist*, *57*(2), 113–120. https://doi.org/10.1043/0003-3219(1987)057<0113:RBSPMO>2.0.CO;2

Melsen, B., Stensgaard, K., & Pedersen, J. (1979). Sucking habits and their influence on swallowing pattern and prevalence of malocclusion. *European Journal of Orthodontics*, *1*(4), 271–280. https://doi.org/10.1093/ejo/1.4.271

Mills, C. M., & McCulloch, K. J. (2000). Posttreatment changes after successful correction of Class II malocclusions with the twin block appliance. *American Journal of Orthodontics and Dentofacial Orthopedics, 118*(1), 24–33. https://doi.org/10.1067/mod.2000.104902

Mills, C. M., & McCulloch, K. J. (1998). Treatment effects of the twin block appliance: a cephalometric study. *American Journal of Orthodontics and Dentofacial Orthopedics, 114*(1), 15–24. https://doi.org/10.1016/s0889-5406(98)70232-x

Morris, D. O., Illing, H. M., & Lee, R. T. (1998). A prospective evaluation of Bass, Bionator and Twin Block appliances. Part II--The soft tissues. *European Journal of Orthodontics*, *20*(6), 663–684. https://doi.org/10.1093/ejo/20.6.663

Nakasima, A., Ichinose, M., Nakata, S., & Takahama, Y. (1982). Hereditary factors in the craniofacial morphology of Angle's Class II and Class III malocclusions. *American Journal of Orthodontics*, *82*(2), 150–156. https://doi.org/10.1016/0002-9416(82)90493-6

Nelson, C., Harkness, M., & Herbison, P. (1993). Mandibular changes during functional appliance treatment. *American Journal of Orthodontics and Dentofacial Orthopedics, 104*(2), 153–161. https://doi.org/10.1016/S0889-5406(05)81005-4

O'Brien, K., Wright, J., Conboy, F., Appelbe, P., Davies, L., Connolly, I., Mitchell, L., Littlewood, S., Mandall, N., Lewis, D., Sandler, J., Hammond, M., Chadwick, S., O'Neill, J., McDade, C., Oskouei, M., Thiruvenkatachari, B., Read, M., Robinson, S., Birnie, D., … Worthington, H. (2009). Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: a multi-center, randomized, controlled trial. *American Journal of Orthodontics and Dentofacial Orthopedics, 135*(5), 573–579. https://doi.org/10.1016/j.ajodo.2007.10.042

O'Brien, K., Wright, J., Conboy, F., Sanjie, Y., Mandall, N., Chadwick, S., Connolly, I., Cook, P., Birnie, D., Hammond, M., Harradine, N., Lewis, D., McDade, C., Mitchell, L., Murray, A., O'Neill, J., Read, M., Robinson, S., Roberts-Harry, D., Sandler, J., … Shaw, I. (2003a). Effectiveness of early orthodontic treatment with the Twin-block appliance: a multicenter, randomized, controlled trial. Part 1: Dental and skeletal effects. *American Journal of Orthodontics and Dentofacial, 124*(3), 234–243. https://doi.org/10.1016/S0889540603003524

O'Brien, K., Wright, J., Conboy, F., Sanjie, Y., Mandall, N., Chadwick, S., Connolly, I., Cook, P., Birnie, D., Hammond, M., Harradine, N., Lewis, D., McDade, C., Mitchell, L., Murray, A., O'Neill, J., Read, M., Robinson, S., Roberts-Harry, D., Sandler, J., … Shaw, I. (2003b). Effectiveness of treatment for Class II malocclusion with the Herbst or twin-block appliances: a randomized, controlled trial. *American Journal of Orthodontics and Dentofacial Orthopedics, 124*(2), 128–137. https://doi.org/10.1016/s0889-5406(03)00345-7

Pancherz, H., Zieber, K., & Hoyer, B. (1997). Cephalometric characteristics of Class II division 1 and Class II division 2 malocclusions: A comparative study in children *The Angle Orthodontist*, 67(2),111-20. 1997;67(2):111–120. https://doi.org/10.1043/0003-3219(1997)067<0111:CCOCID>2.3.CO;2

Pancherz, H. (1982). The mechanism of Class II correction in Herbst appliance treatment. A cephalometric investigation. *American Journal of Orthodontics*, *82*(2), 104–113. https://doi.org/10.1016/0002-9416(82)90489-4

Pancherz, H. (1979). Treatment of class II malocclusions by jumping the bite with the Herbst appliance. A cephalometric investigation. *American Journal of Orthodontics*, *76*(4), 423–442. https://doi.org/10.1016/0002-9416(79)90227-6

Pangrazio-Kulbersh, V., Berger, J. L., Chermak, D. S., Kaczynski, R., Simon, E. S., & Haerian, A. (2003). Treatment effects of the mandibular anterior repositioning appliance on patients with Class II malocclusion. *American Journal of Orthodontics and Dentofacial Orthopedics,* 123(3), 286–295. https://doi.org/10.1067/mod.2003.8

Phan, K. L., Bendeus, M., Hägg, U., Hansen, K., & Rabie, A. B. (2006). Comparison of the headgear activator and Herbst appliance--effects and post-treatment changes. *European Journal of Orthodontics*, *28*(6), 594–604. https://doi.org/10.1093/ejo/cjl052

Pirttiniemi, P., Kantomaa, T., Mäntysaari, R., Pykäläinen, A., Krusinskiene, V., Laitala, T., & Karikko, J. (2005). The effects of early headgear treatment on dental arches and craniofacial morphology: an 8 year report of a randomized study. *European Journal of Orthodontics*, *27*(5), 429–436. https://doi.org/10.1093/ejo/cji025

Proffit, W. R., & Fields, H. W. (2012). *Contemporary Orthodontics.* (5th ed.). Elsevier Publishers.

Proffit, W. R., Fields, H. W., Jr, & Moray, L. J. (1998). Prevalence of malocclusion and orthodontic treatment need in the United States: estimates from the NHANES III survey. *The International Journal of Adult Orthodontics and Orthognathic Surgery*, *13*(2), 97–106.

Proffit, W. R., & Fields, H. W. (1983). Occlusal forces in normal- and long-face children. *Journal of Dental Research*, *62*(5), 571–574. https://doi.org/10.1177/00220345830620051301

Rabie, A. B., & Al-Kalaly, A. (2008). Does the degree of advancement during functional appliance therapy matter?. *European Journal of Orthodontics*, *30*(3), 274–282. https://doi.org/10.1093/ejo/cjm129

Rabie, A. B., Tang, G. H., & Hägg, U. (2004a). Cbfa1 couples chondrocytes maturation and endochondral ossification in rat mandibular condylar cartilage. *Archives of Oral Biology*, *49*(2), 109–118. https://doi.org/10.1016/j.archoralbio.2003.09.006

Rabie, A. B., Xiong, H., & Hägg, U. (2004b). Forward mandibular positioning enhances condylar adaptation in adult rats. *European Journal of Orthodontics*, *26*(4), 353–358. https://doi.org/10.1093/ejo/26.4.353

Rabie, A. B., She, T. T., & Hägg, U. (2003a). Functional appliance therapy accelerates and enhances condylar growth. *American Journal of Orthodontics and Dentofacial Orthopedics*, *123*(1), 40–48. https://doi.org/10.1067/mod.2003.45

Rabie, A. B., Wong, L., & Tsai, M. (2003b). Replicating mesenchymal cells in the condyle and the glenoid fossa during mandibular forward positioning. *American Journal of Orthodontics and Dentofacial Orthopedics, 123*(1), 49–57. https://doi.org/10.1067/mod.2003.46

Rabie, A. B., Wong, L., & Hägg, U. (2003c). Correlation of replicating cells and osteogenesis in the glenoid fossa during stepwise advancement. *American Journal of Orthodontics and Dentofacial Orthopedics, 123*(5), 521–526. https://doi.org/10.1067/mod.2003.S0889540602570335

Rabie, A. B., Tsai, M. J., Hägg, U., Du, X., & Chou, B. W. (2003d). The correlation of replicating cells and osteogenesis in the condyle during stepwise advancement. *The Angle Orthodontist*, *73*(4), 457–465. https://doi.org/10.1043/0003-3219(2003)073<0457:TCORCA>2.0.CO;2

Rabie, A. B., Tang, G. H., Xiong, H., & Hägg, U. (2003e). PTHrP regulates chondrocyte maturation in condylar cartilage. *Journal of Dental Research*, *82*(8), 627–631. https://doi.org/10.1177/154405910308200811

Rabie, A. B., Shum, L., & Chayanupatkul, A. (2002a). VEGF and bone formation in the glenoid fossa during forward mandibular positioning. *American Journal of Orthodontics and Dentofacial Orthopedics*, *122*(2), 202–209. https://doi.org/10.1067/mod.2002.125991

Rabie, A. B., & Hägg, U. (2002b). Factors regulating mandibular condylar growth. *American Journal of Orthodontics and Dentofacial Orthopedics*, *122*(4), 401–409. https://doi.org/10.1067/mod.2002.125713

Rabie, A. B., Zhao, Z., Shen, G., Hägg, E. U., Dr, O., & Robinson, W. (2001). Osteogenesis in the glenoid fossa in response to mandibular advancement. *American Journal of Orthodontics and Dentofacial Orthopedics*, *119*(4), 390–400. https://doi.org/10.1067/mod.2001.112875

Raju, D. S., & Naidu, D. L. (2012). Reliability and Reproducibility of Natural Head Position: A Cephalometric Study. *The Journal of Indian Orthodontic Society*, *46*(4):340–347.

Ricketts, R. M. (1998). The wisdom of the bioprogressive philosophy. *Seminars in Orthod*ontics, 4(4), 201–209. https://doi.org/10.1016/S1073-8746(98)80025-X

Ricketts, R. M. (1981). Perspectives in the clinical application of cephalometrics. The first fifty years. *The Angle Orthodontist*, *51*(2), 115–150. https://doi.org/10.1043/0003-3219(1981)051<0115:PITCAO>2.0.CO;2

Santamaría-Villegas, A., Manrique-Hernandez, R., Alvarez-Varela, E., & Restrepo-Serna, C. (2017). Effect of removable functional appliances on mandibular length in patients with class II with retrognathism: systematic review and meta-analysis. *BMC Oral Health*, 17(1), 52. https://doi.org/10.1186/s12903-017-0339-8

Santiago, R. C., de Miranda Costa, L. F., Vitral, R. W., Fraga, M. R., Bolognese, A. M., & Maia, L. C. (2012). Cervical vertebral maturation as a biologic indicator of skeletal maturity. *The Angle Orthodontist*, *82*(6), 1123–1131. https://doi.org/10.2319/103111-673.1

Sari, Z., Goyenc, Y., Doruk, C., & Usumez, S. (2003). Comparative evaluation of a new removable Jasper Jumper functional appliance vs an activator-headgear combination. *The Angle Orthodontist*, *73*(3), 286–293. https://doi.org/10.1043/0003-3219(2003)073<0286:CEOANR>2.0.CO;2

Schaefer, A. T., McNamara, J. A., Franchi, L., & Baccetti, T. (2004). A cephalometric comparison of treatment with the Twin-block and stainless steel crown Herbst appliances followed by fixed appliance therapy. *American Journal of Orthodontics and Dentofacial Orthopedics, 126*(1), 7–15. https://doi.org/10.1016/j.ajodo.2003.06.017

Seehra, J., Newton, J. T., & Dibiase, A. T. (2013). Interceptive orthodontic treatment in bullied adolescents and its impact on self-esteem and oral-health-related quality of life. *European Journal of Orthodontics*, *35*(5), 615–621. https://doi.org/10.1093/ejo/cjs051

Seehra, J., Fleming, P. S., Newton, T., & DiBiase, A. T. (2011). Bullying in orthodontic patients and its relationship to malocclusion,self-esteem and oral health-related quality of life. *Journal of Orthodontics*, *38*(4), 247–294. https://doi.org/10.1179/14653121141641

Shaw, W. C., Addy, M., & Ray, C. (1980). Dental and social effects of malocclusion and effectivenessof orthodontic treatment: a review. *Community Dentistry and Oral Epidemiology*, *8*(1), 36–45. https://doi.org/10.1111/j.1600-0528.1980.tb01252.x

Sharma, A. A., & Lee, R. T. (2005). Prospective clinical trial comparing the effects of conventional Twin-block and mini-block appliances: Part 2. Soft tissue changes. *American Journal of Orthodontics and Dentofacial Orthopedics*, *127*(4), 473–482. https://doi.org/10.1016/j.ajodo.2004.03.027

Shen, G., Zhao, Z., Kaluarachchi, K., & Bakr Rabie, A. (2006). Expression of type X collagen and capillary endothelium in condylar cartilage during osteogenic transition--a comparison between adaptive remodelling and natural growth. *European Journal of Orthodontics*, *28*(3), 210–216. https://doi.org/10.1093/ejo/cji123

Shum, L., Rabie, A. B., & Hägg, U. (2004). Vascular endothelial growth factor expression and bone formation in posterior glenoid fossa during stepwise mandibular advancement. *American Journal of Orthodontics and Dentofacial Orthopedics*, *125*(2), 185–190. https://doi.org/10.1016/j.ajodo.2002.12.002

Sidlauskas, A. (2005). The effects of the Twin-block appliance treatment on the skeletal and dentolaveolar changes in Class II Division 1 malocclusion. *Medicina (Kaunas, Lithuania)*, *41*(5), 392–400.

Siriwat, P. P., & Jarabak, J. R. (1985). Malocclusion and facial morphology is there a relationship? An epidemiologic study. *The Angle Orthodontist*, *55*(2), 127–138. https://doi.org/10.1043/0003-3219(1985)055<0127:MAFMIT>2.0.CO;2

Solow, B., & Sonnesen, L. (1998). Head posture and malocclusions. *European Journal of Orthodontics*, *20*(6), 685–693. https://doi.org/10.1093/ejo/20.6.685

Southard, T. E., Marshall, S. D., Allareddy. V., Uribe L. M., & Holton, N. E. (2013). An evidence-based comparison of headgear and functional appliance therapy for the correction of Class II malocclusions. *Seminars in Orthodontics,* 19(3), 174–195. https://doi.org/10.1053/j.sodo.2013.03.007

Stahl, F., Baccetti, T., Franchi, L., & McNamara, J. A. (2008). Longitudinal growth changes in untreated subjects with Class II Division 1 malocclusion. *American Journal of Orthodontics and Dentofacial Orthopedics, 134*(1), 125–137. https://doi.org/10.1016/j.ajodo.2006.06.028

Steiner, C. C. (1953). Cephalometrics for you and me. *American Journal of Orthodontics,* 39(10), 729–755. https://doi.org/10.1016/0002-9416(53)90082-7

Tang, G. H., Rabie, A. B., & Hägg, U. (2004). Indian hedgehog: a mechanotransduction mediator in condylar cartilage. *Journal of Dental Research*, *83*(5), 434–438. https://doi.org/10.1177/154405910408300516

Teuscher, U. (1978). A growth-related concept for skeletal class II treatment. *American Journal of Orthodontics*, *74*(3), 258–275. https://doi.org/10.1016/0002-9416(78)90202-6

Thiruvenkatachari, B., Harrison, J., Worthington, H., & O'Brien, K. (2015). Early orthodontic treatment for Class II malocclusion reduces the chance of incisal trauma: Results of a Cochrane systematic review. *American Journal of Orthodontics and Dentofacial Orthopedics*, *148*(1), 47–59. https://doi.org/10.1016/j.ajodo.2015.01.030

Toth, L. R., & McNamara, J. A. (1999). Treatment effects produced by the twin-block appliance and the FR-2 appliance of Fränkel compared with an untreated Class II sample. *American Journal of Orthodontics and Dentofacial Orthopedics, 116*(6), 597–609. https://doi.org/10.1016/s0889-5406(99)70193-9

Tulloch, J. F., Proffit, W. R., & Phillips, C. (2004). Outcomes in a 2-phase randomized clinical trial of early Class II treatment. *American Journal of Orthodontics and Dentofacial Orthopedics, 125*(6), 657–667. https://doi.org/10.1016/j.ajodo.2004.02.008

Tulloch, J. F., Phillips, C., Koch, G., & Proffit, W. R. (1997). The effect of early intervention on skeletal pattern in Class II malocclusion: a randomized clinical trial. *American Journal of Orthodontics and Dentofacial Orthopedics*, *111*(4), 391–400. https://doi.org/10.1016/s0889-5406(97)80021-2

Tulloch, J. F., Medland, W., & Tuncay, O. C. (1990). Methods used to evaluate growth modification in Class II malocclusion. *American Journal of Orthodontics and Dentofacial Orthopedics,* 98(4), 340–347. https://doi.org/10.1016/S0889-5406(05)81491-X

Tümer, N., & Gültan, A. S. (1999). Comparison of the effects of monoblock and twin-block appliances on the skeletal and dentoalveolar structures. *American Journal of Orthodontics and Dentofacial Orthopedics*, *116*(4), 460–468. https://doi.org/10.1016/s0889-5406(99)70233-7

Uçüncü, N., Türk, T., & Carels, C. (2001). Comparison of modified Teuscher and van Beek functional appliance therapies in high-angle cases. *Journal of Orofacial Orthopedics*, *62*(3), 224–237. https://doi.org/10.1007/pl00001930

Valiathan, M., Valiathan, A., & Ravinder, V. (2001). Jarabak Cephalometric Analysis Reborn. *Journal of Indian Orthodontic Society*, 34, 66-76. https://doi.org/10.1177/0974909820010302

van Beek, H. (1984). Combination headgear-activator. *Journal of Clinical Orthodontics*, 18(3), 185-189.

van Beek, H. (1982). Overjet correction by a combined headgear and activator. *European Journal of Orthodontics*, 4(4), 279–290. https://doi.org/10.1093/ejo/4.4.279

Vargervik, K., & Harvold, E. P. (1985). Response to activator treatment in Class II malocclusions. *American Journal of Orthodontics*, *88*(3), 242–251. https://doi.org/10.1016/s0002-9416(85)90219-2

Varlik, S. K., Gültan, A., & Tümer, N. (2008). Comparison of the effects of Twin Block and activator treatment on the soft tissue profile. *European Journal of Orthodontics*, *30*(2), 128–134. https://doi.org/10.1093/ejo/cjm121

Varrela, J. (1998). Early developmental traits in class II malocclusion. *Acta odontologica Scandinavica*, *56*(6), 375–377. https://doi.org/10.1080/000163598428356

Wahl, N. (2006). Orthodontics in 3 millennia. Chapter 9: functional appliances to midcentury. *American Journal of Orthodontics and Dentofacial Orthopedics, 129*(6), 829–833. https://doi.org/10.1016/j.ajodo.2006.03.019

Wey, M. C., Bendeus, M., Peng, L., Hägg, U., Rabie, A. B., & Robinson, W. (2007). Stepwise advancement versus maximum jumping with headgear activator. *European Journal of Orthodontics*, *29*(3), 283–293. https://doi.org/10.1093/ejo/cjm018

Wieslander, L. (1993). Long-term effect of treatment with the headgear-Herbst appliance in the early mixed dentition. Stability or relapse?. *American Journal of Orthodontics and Dentofacial Orthopedics, 104*(4), 319–329. https://doi.org/10.1016/S0889-5406(05)81328-9

Wiltshire, W. A., & Tsang, S. (2006). A modern rationale for orthopedics and orthopedic retention. *Seminars in Orthodontics,* 12(1), 60–66.

https://doi.org/10.1053/j.sodo.2005.10.010

Wong, R. W., Alkhal, H. A., & Rabie, A. B. (2009). Use of cervical vertebral maturation to determine skeletal age. *American Journal of Orthodontics and Dentofacial Orthopedics*, *136*(4), 484.e1–485. https://doi.org/10.1016/j.ajodo.2007.08.033

Woodside, D. G., Metaxas, A., & Altuna, G. (1987). The influence of functional appliance therapy on glenoid fossa remodeling. *American Journal of Orthodontics and Dentofacial Orthopedics, 92*(3), 181–198. https://doi.org/10.1016/0889-5406(87)90411-2

ORIGINAL ARTICLE

Cephalometric effects of Twin-Block and van Beek Headgear-Activator in the correction of Class II malocclusion

Rohan S. Kirtane,[a] Badri Thiruvenkatachari[b], William A. Wiltshire,[c] Adnan Shah[d], Fabio Henrique de S. L. Pinheiro[e]

[a] Graduate Orthodontic Resident, Department of Preventive Dental Sciences, Division of Orthodontics, Faculty of Dentistry, University of Manitoba, Canada [c]

[b] Professor in Orthodontics, Sree Balaji Dental College and Hospital, Bharath University, Chennai, India

[c] Full professor, Program Director and Department Head, Division of Orthodontics, University of Manitoba, Winnipeg, Canada

[d] Professor and Department Head, Dental Diagnostic and Surgical Sciences, Division Head, Oral and Maxillofacial Surgery, Faculty of Dentistry, University of Manitoba, Canada

[e] Assistant Professor, Department of Preventive Dental Sciences, Division of Orthodontics, Faculty of Dentistry, University of Manitoba, Canada (Corresponding Author)

Abstract

Introduction: The twin-Block (TB) and the van Beek Headgear-Activator (vBHGA) are both indicated for Class II patients with a retrognathic mandible. While the former is commonly prescribed for horizontally growing patients, the latter is usually recommended to those growing vertically. **Objective**: This study aimed to compare the skeletal, dentoalveolar and soft tissue short-term effects of TB and vBHGA in regards to growth pattern as determined according to Jarabak's ratio values. **Material and Methods**: Immediate pre-treatment (T1) and post-functional appliance (T2) lateral cephalometric radiographs were retrospectively obtained for vBHGA (n=46), TB (n=45), and untreated control (n=45) groups. The interaction of several variables at T1, T2 and T2-T1, as well as the resultant treatment effect, was analyzed using Analysis of Covariance

(ANCOVA) regression models at the 5% level of significance. **Results**: Except for a greater reduction in Wits (3.0mm; p<0.0001) in the TB group, no anteroposterior (A-P) skeletal difference was observed between the two appliances (ANB: 0.530; p=0.07, Harvold: 0.13mm; p=0.81). Both improved the A-P skeletal relationship (ANB and Harvold) in comparison to the control (p<0.05). While this mostly occurred due to forward positioning of the mandible with the TB (SNB: 0.960; p=0.01), maxillary restriction was the main mechanism with the vBHGA (SNA: 1.590; p=0.00). Dentoalvelolar compensations were more pronounced with the TB (IMPA: 1.92; p=0.02), leading to greater overbite and overjet correction. Only the inclination of the upper incisors showed interaction with growth pattern, with the TB horizontal growers experiencing more retroclination (U1-NA°: 3.620; p=0.0067). **Conclusions**: Both appliances produced similar modest A-P skeletal changes that, together with dentoalveolar compensations, were able to correct the Class II regardless of growth pattern.

Introduction

When correcting a skeletal Class II malocclusion, orthodontists need to choose between restraining the maxilla, advancing the mandible or a combination of both[1]. The chosen modality will depend on the true etiology of the malocclusion. The most common finding in Class II malocclusion is mandibular skeletal retrusion[2], hence a plethora of functional appliances to advance the mandible[3].

The TB has been extensively researched[5–11] and is one of the most widely used removable functional appliances[4]. Forward posturing of the mandible is achieved through upper and lower acrylic blocks that meet each other at an incline of 70°[12]. This appliance was originally designed to produce statistically significant short-term effects on the mandible during growing years[13], thereby increasing the total mandibular length and the SNB angle. Its modest skeletal changes and accompanying substantial dentoalveolar compensations usually result in overjet (OJ) reduction and increase in lower anterior face height (LAFH)[5,6], making it supposedly suitable for horizontal growers with retrognathia[14].

In contrast, the vBHGA is a less known removable functional appliance[15]. It is a monobloc activator with a thick (8-10mm) posterior bite block, long and deep lingual flanges, labial coverage of the upper and lower anterior teeth, and a short and rigid outer bow at the level of the upper canines, to which a high-pull headgear is attached[15]. It has been shown to produce statistically significant effects on the maxilla when used during growing years[16], decreasing the SNA angle. Besides dentoalveolar changes, the thick bite-block is thought to also control for any increase in the LAFH, thus ensuring to express the increase in mandibular length in the form of chin projection[17]. For this reason, the vBHGA is believed to be appropriate for vertical growers with retrognathia[14].

The efficacy of these two appliances has never been compared in relation to growth pattern (normal/horizontal or vertical), what could shed more light on their clinical indication. This study aims to compare their skeletal, dentoalveolar and soft tissue effects in growing individuals, taking the growth pattern into consideration. The null hypothesis was that there would be no difference between TB and vBHGA in the correction of skeletal Class II malocclusion, regardless of growth pattern.

MATERIAL AND METHODS

This retrospective study was approved under numbers HS23301 (H2019:400) and 14/WA/1258 (166813) by the local ethics committee of the universities of Manitoba, Canada, and Manchester, UK, respectively. It comprised three groups, namely TB, vBHGA, and untreated control, for which the inclusion criteria were CVM (cervical vertebral maturation) stage 1-5 according to Baccetti et al[19], acceptable compliance as per monthly chart notes, ANB>5^0, available T1 and T2 lateral cephalometric radiographs, and absence of craniofacial anomalies.

Based on a clinically significant intergroup difference of 2.0^0 (SD=2^0) in SNB and 2.0mm (SD=2mm) in Co-Gn as well as 80% power, α of 0.05, and a 2-tailed test, a total of 45 patients per group was recommended.

The vBHGA group comprised patients who were consecutively treated in the University of Manitoba, Canada, from 1996 to 2020 by orthodontic residents under the supervision of the same instructor. A thick construction wax bite approximately 8-10 mm in height with a minimum of 6mm mandibular protrusion was fabricated as described by van Beek[15] (Figure 1). A deep lower arch impression was made so the activator flanges could capture the lingual vestibule. A high-pull headgear strap was fitted to the short and rigid outer bow, which was bent up so that the line of action of force passed either through or above the center of resistance of the upper incisors. Eight ounces (240 grams) of force was prescribed per side for the first month, followed by 16 oz (500 gram) for the subsequent months. Patients were instructed to wear the appliance 14-16 hours a day, including nighttime, 7 days a week. Twenty individuals were excluded due to poor compliance. Due to availability of records, 46 subjects comprised the final vBHGA sample (Table I).

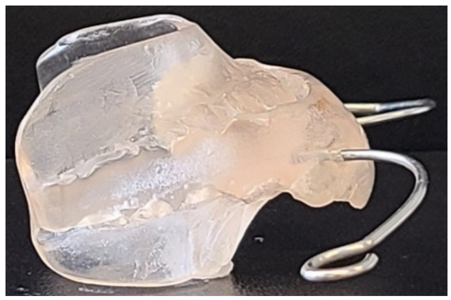


Figure 1. Van Beek Headgear-Activator (vBHGA) utilized in the study

In order to meet the sample size, the TB group comprised 30 individuals consecutively treated in various university teaching hospitals across England, United Kingdom, from 2010 to 2016, and 15 individuals treated by the same protocol in the University of Manitoba from 1996 to 2020. The construction wax-bite was 4-5mm in height with a minimum of 6mm mandibular protrusion. The appliance consisted of upper and lower removable plates with bite ramps set to interlock at about 70^{o} when occluding, with the lower block lying ahead of the upper to posture the mandible forward. It consisted of a labial bow, Adam's clasps on the first premolars and first molars as well as ball clasps in the lower incisor interproximal areas for retention (Figure 2). The subjects were instructed to wear the appliance full-time except for eating and tooth brushing. Nine were excluded due to lack of T2 cephalograms. The final sample consisted of 45 subjects.

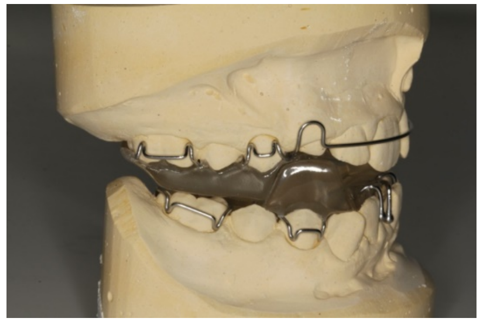


Figure 2. Twin-Block utilized in the study

In both groups, selective trimming of the acrylic was performed to allow eruption of the upper and lower molars. The functional appliance phase ended when molars were over-corrected to Angle's super Class I relationship and/or the incisors were in an edge-edge, whichever was earlier. Patients then transitioned to nighttime wear until eruption of all permanent teeth, after which they were considered ready for full-fixed orthodontics. The mean treatment duration was 8.6 months with the vBHGA and 9.1 months with the TB.

The control group comprised 45 untreated Class II subjects from the historical archives of the Burlington Growth Center at the University of Toronto, Canada. After applying the ANB angle ($>5^0$) inclusion criteria, it was not possible to match the groups according to CVM stage given the limitations of the database. In each group, the frequency of growth pattern (vertical and normal/horizontal) as well as the CVM stages at T1 and T2 can be found in Table I.

Table I: Sample demographic characteristics

Group	(n)	Sex (n/%)		CVM* Stage (n/%)						Growth Pattern (n/%)	
		Male	Female	Pre-peak (CVM 1-2)		Peak (CVM 3-4)		Post-peak (CVM 5-6)		Normal/ Horizontal	Vertical
				T1	T2	T1	T2	T1	T2		
TB	45	19/42.2	26/57.8	24/52.3	8/18	20/45.4	33/73	1/2.3	4/9	31/68.9	14/31.1
vBHGA	46	20/43.5	26/56.5	23/50	11/24	23/50	31/67	0/0	7/9	28/60.9	18/39.1
Control	45	31/68.9	14/31.1	34/75	5/11	11/25	40/89	0/0	0/0	25/55.6	20/44.4

*CVM: Cervical Vertebral Maturation; TB: Twin-Block; vBHGA: van Beek Headgear-Activator

All cephalometric radiographs were imported into a commercial software (Dolphin Digital Imaging System version 11.9, Chatsworth, CA, USA), corrected for magnification, and a custom analysis containing well known landmarks and reference planes from Steiner's[20], Ricketts'[21], McNamara's[22], and Jarabak's[18] analyses was generated (figure 3). This digital imaging system was also used to obtain regional maxillary and mandibular cephalometric superimpositions according to Ricketts[21] (Figure 4), and to measure in millimeters (mm) the horizontal and vertical changes of incisal edges (U1/L1's) as well as mesio-buccal cusps of first molars (U6/L6's) from the x and y coordinates set up by the software.

Figure 3: Cephalometric landmarks used to generate the custom cephalometric analysis used in the study

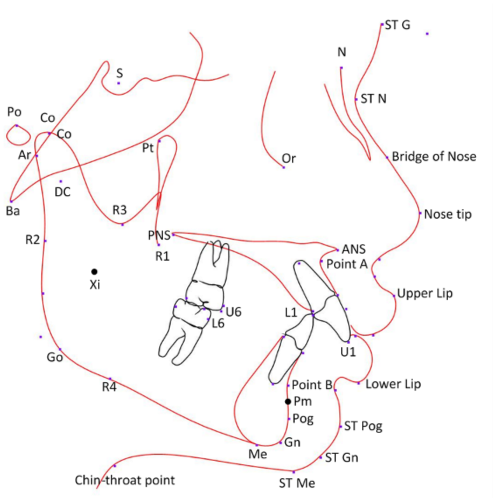
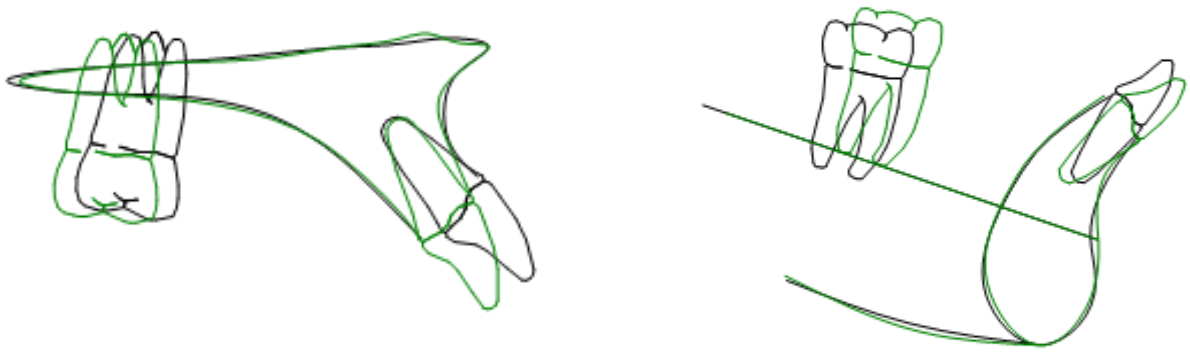


Figure 4: Regional maxillary (ANS-PNS at ANS) and mandibular (Corpus axis at Pm - Protuberance menti) superimpositions according to Ricketts to quantify horizontal and vertical dentoalveolar changes; T1 (black), T2 (green)



The principal investigator and a calibrated second investigator (Oral and Maxillofacial Radiologist) retraced 41 radiographs to assess the inter- and intra-rater reliability using the intraclass correlation coefficient (ICC) test whose values were interpreted according to the method suggested by Fleiss[23].

Statistical Analysis

All data analysis was performed using SPSS 10.0 (SPSS, Chicago, Ill). The simultaneous interaction of 38 cephalometric variables, six CVM stages, three groups, two types of growth pattern at T1, T2 and the T1-T2 difference required utilization of Analysis of Covariance (ANCOVA) regression models. The regression graphs indicated that model residues met distribution assumption, being approximately normal, something that was confirmed by residue Q-plots and histograms. Descriptive statistics (mean and SD) and treatment effect (T1-T2), which was the dependent variable regressed upon the covariates (treatment group and the growth pattern), were calculated. To guard against false positives, the *p*-value was adjusted to be more stringent and R^2 values were reported to denote the percent of variation in the T2 value of a variable explained by the predictors. Imbalance between the groups with regard to CVM stages at T2 were adjusted for, but the results remained unchanged.

RESULTS

Overall, R^2 values were found to be fairly high, denoting a strong correlation between T1 and T2 (tables III, IV, V and VI). All intra- and inter-rater ICC values demonstrated excellent agreement for all cephalometric variables and CVM stages, except for the intra-rater Ar-Go measurement whose agreement was fair to good (Table II).

Table II: Intra and inter-rater agreements

Cephalometric Variable	Inter-rater reliability (*ICC)	Intra-rater reliability (*ICC)
FH-SN	0.76	0.78
SNA	0.79	0.77
SNB	0.88	0.88
ANB	0.81	0.83
Wits	0.89	0.92

A-NPog	0.83	0.83
A-NA-perp	0.76	0.80
Pg-NA-perp	0.87	0.83
Co-A	0.90	0.84
Co-Gn	0.91	0.81
Go-Pg	0.91	0.83
Ar-Go	0.79	0.66
Co-ANS	0.91	0.81
Co-Pg	0.92	0.83
Harvold Difference	0.81	0.86
FMA	0.84	0.87
MPA	0.86	0.89
Y-Axis	0.91	0.93
PP-SN	0.81	0.82
PP-MP	0.90	0.85
Ba-Na/Pt-Gn	0.92	0.89
LFH	0.95	0.85
Jarabak Ratio	0.78	0.85
SN-Ba	0.89	0.86
U1-SN	0.82	0.86
U1-NA	0.86	0.82
U1-PP	0.89	0.90
U1-NA (mm)	0.83	0.89
L1-NB	0.94	0.91
IMPA	0.91	0.85
L1-NB (mm)	0.94	0.91
L1-APog	0.90	0.88
U1-L1	0.86	0.82
Overjet (OJ)	0.98	0.96
Overbite (OB)	0.90	0.93
Molar Relation	0.89	0.91
Upper Lip- E- line	0.96	0.95
Lower Lip- E- line	0.96	0.96
CVM	0.92	0.94
Average	0.87	0.88

*ICC Intra-Class Coefficient

Baseline Intergroup Differences

The TB and vBHGA groups had more females (n=26 in each; 57.77% and 56.52% respectively) while the control group had more males (n=31; 68.88%). All three groups had more normal/horizontal than vertical growers (68.9%, 60.9% and 55.6% respectively). At T1, the TB and vBHGA groups had almost an equal distribution of subjects in pre-peak (n=24;52.3%, and n=23;50%, respectively) and peak (n=20;45.4%, and n=23;50%, respectively) stages, while 75% (n=34) of the control group subjects were in the pre-peak stage and 25% (n=11) in the peak stage.

Only 2.3% (n=1) of the TB subjects was in the post-peak stage. Sample demographics of the three groups were shown in Table I.

Skeletal Changes

All skeletal changes can be seen in Table III.

Although both treatment groups did not supersede the control group in terms of mandibular length (Co-Gn and Co-Pg), the vBHGA mandibles grew more than in the TB group (Co-Gn: 1.86mm; p=0.04). Such growth was mostly observed in the anterior aspect of the mandible (Go-Pg: 3.04mm; p=0.0022) whereas there was no difference in regards to the posterior aspect (Ar-Go). Despite that, the spatial position of the mandible in relation to the cranial base (SNB angle) improved more in the TB group compared to the vBHGA group (1.34^0; p=0.0004).

Although the maxilla in the vBHGA group experienced more growth than in the TB group (Co-A: 2.45^0; p=0.00 and Co-ANS: 2.38^0; p=0.00), it projected less in the vBHGA group compared to the control (SNA: 1.59^0; p=0.00) and to the TB (SNA: 0.83^0; p=0.05) groups. The palatal plane rotated clockwise in the TB group and counterclockwise in the vBHGA group, being the difference statistically significant (SN-PP: 1.45, p=0.0002). In comparison to the control, the TB group experienced maxillary restriction according to A-NPog (-1.35mm; p<0.0001), but not according to SNA and A-Na-perp.

While both the TB and vBHGA groups showed comparable reductions in both the ANB angle (1.70^0; p<0.001, and 1.16^0; p=0.00, respectively) and the Harvold Difference values (2.65mm; p<0.0001 and 2.51mm; p<0.0001 respectively), the Wits value decreased more in the TB group (-3mm; p<0.0001).

There was no statistically significant difference between the two groups in terms of MPA and Y-axis, but FMA showed greater increase in the TB group (FMA: 1.34^0; p=0.01). Although not statistically significant, an increase in LAFH was observed in both groups, albeit less in the TB group. Also not statistically significant, the Jarabak ratio increased in the TB group and decreased in the vBHGA group.

Table III: Skeletal cephalometric data at T1 and T2

Variable	TB (n= 45) Mean (SD)		vBHGA (n=46) Mean (SD)		Control (n=45) Mean (SD)		Treat Mean
	T1	***T2***	***T1***	***T2***	***T1***	***T2***	***TB-co*** ***vBHG*** ***TB-vB***
FH-SN^0	8.12 (3.49)	8.11 (2.98)	9.44 (2.89)	10.07 (2.52)	7.57 (3.06)	7.84 (3.61)	0.10 (0 1.22 (0 -1.12 (
SNA^0	83.58 (4.65)	82.68 (4.04)	81.81 (4.09)	80.44 (3.77)	82.94 (4.57)	82.89 (4.37)	-0.75 (-1.59 (0.83 (-
SNB^0	76.60 (3.83)	78.09 (3.67)	75.67 (3.51)	75.95 (3.44)	77.72 (4.00)	77.99 (3.83)	0.96 (0 0.38 (- 1.34 (0
ANB^0	6.96 (2.32)	4.59 (2.37)	6.15 (2.24)	4.48 (2.38)	5.21 (2.14)	4.89 (2.10)	-1.70 (-1.16 (-0.53 (
Wits (mm)	6.24 (2.55)	1.27 (2.95)	4.78 (2.22)	3.36 (2.53)	1.78 (2.26)	2.08 (2.42)	-3.59 (-0.59 (-3.00 (
A-NPg (mm)	5.26 (2.67)	3.54 (2.91)	4.62 (2.51)	3.13 (2.90)	2.49 (1.44)	2.33 (1.57)	-1.35 (-1.18 (-0.16 (
A-Na-perp (mm)	1.50 (3.94)	0.72 (3.55)	1.16 (3.07)	0.48 (3.56)	0.28 (2.40)	0.45 (2.96)	-0.68 (-0.66 (-0.02 (
Pg-Na-perp (mm)	-7.06 (6.66)	-5.26 (7.28)	-6.67 (5.96)	-5.14 (6.46)	-4.21 (3.94)	-3.55 (4.98)	0.86 (- 0.63 (- 0.22 (-
Co-A (mm)	81.49 (8.75)	80.66 (8.20)	81.73 (6.45)	83.28 (8.10)	57.80 (4.27)	59.82 (4.96)	-1.89 (0.55 (- -2.45 (

Co-ANS (mm)	83.85 (8.76)	83.70 (8.40)	84.07 (6.09)	86.22 (8.40)	59.85 (4.43)	61.66 (5.25)	-1.61 (0.77 (- -2.38 (
Co-Gn (mm)	104.91 (10.82)	108.87 (10.93)	106.22 (7.04)	111.99 (9.44)	76.87 (5.84)	80.34 (6.88)	0.43 (- 2.29 (- -1.86 (
Go-Pg (mm)	63.75 (7.73)	65.15 (7.32)	66.37 (6.10)	69.03 (6.65)	46.21 (3.49)	47.78 (3.73)	1.43 (- 3.04 (1 -1.60 (
Ar-Go (mm)	45.30 (6.86)	47.52 (7.22)	41.57 (4.95)	44.44 (5.63)	30.86 (3.29)	33.04 (4.32)	2.38 (- 2.44 (0 -0.06 (
Co-Pg (mm)	97.58 (9.81)	101.20 (9.65)	100.38 (7.12)	106.03 (9.65)	71.58 (5.44)	74.78 (6.22)	0.52 (- 2.60 (- -2.07 (
Harvold difference (mm)	13.71 (3.85)	17.51 (4.24)	16.31 (3.08)	19.81 (4.02)	11.72 (2.84)	13.11 (3.47)	2.65 (1 2.51 (1 0.13 (-
FMA^0	24.02 (6.08)	24.94 (6.49)	23.65 (5.91)	23.38 (5.69)	25.57 (5.08)	25.04 (5.26)	1.34 (0 0.10 (0 1.23 (0
MPA^0	32.15 (6.06)	33.06 (6.36)	33.10 (6.05)	33.45 (5.92)	33.15 (5.62)	32.90 (5.60)	1.13 (0 0.60 (- 0.52 (-
Y-Axis^0	67.78 (4.22)	67.96 (4.23)	68.61 (4.38)	68.96 (4.29)	66.23 (3.84)	66.44 (3.65)	0.18 (- 0.42 (- -0.24 (
PP-SN^0	-0.64 (3.51)	0.33 (3.12)	0.33 (3.14)	-0.36 (2.95)	-2.2 (3.45)	-2.12 (3.36)	1.27 (0 -0.18 (1.45 (0
PP-MP^0	25.80 (6.47)	25.72 (6.83)	25.77 (5.20)	26.81 (5.42)	28.35 (5.28)	28.03 (5.43)	0.19 (- 1.27 (0 -1.08 (

Ba-Na-Pt-Gn (Facial Axis) ^{0}	0.03 (5.29)	0.08 (5.35)	-2.14 (5.03)	-2.10 (5.24)	0.17 (4.02)	0.07 (4.13)	0.18 (- 0.07 (- 0.11 (-
LAFH (mm)	59.16 (8.20)	61.52 (8.29)	62.38 (4.92)	65.05 (6.01)	43.41 (4.13)	45.08 (4.32)	1.12 (- 1.52 (- -0.39 (
Jarabak Ratio (%)	66.29 (4.59)	66.38 (4.71)	65.26 (4.85)	65.21 (4.52)	64.68 (4.75)	65.22 (4.66)	-0.28 (-0.53 (0.25 (-
SN-Ba ^{0}	131.90 (5.74)	132.45 (6.24)	131.09 (3.75)	132.08 (4.27)	128.2 (4.58)	128.64 (5.11)	1.11 (- 1.26 (- -0.14 (

*p-value: significant if ≤ 0.05

Dentoalveolar and Soft Tissue Changes

The dentoalveolar changes can be seen in Tables IV, V and VI.

More pronounced retrusion of the upper incisors (U1-NA: 1mm; p=0.00), increased proclination (L1-NB^0: 3.84^0; p<0.0001, IMPA: 1.92^0; p=0.02) and protrusion (L1-NB: 0.54mm; p=0.04, and L1-APog: 0.96mm; p=0.00) of the lower incisors as well as greater reduction in overjet (OJ: 1.65mm; p<0.0001) and overbite (OB: 1.83mm; p<0.001) were observed in the TB group in comparison to the vBHGA group. There was also greater molar correction in the TB group (molar relation: 2.74mm; p<0.001). The upper lip retruded more in the TB group compared to the vBHGA group (Upper lip-E-line: 1.03mm; p=0.00) whereas the lower lip retruded equally in both treatment groups (Lower lip-E-line: 0.30mm; p=0.48) (Table IV).

Table IV: Dentoalveolar and soft tissue cephalometric changes

Variable	TB (n= 45) Mean (SD)		vBHGA (n=46) Mean (SD)		Control (n=45) Mean (SD)	
	T1	***T2***	***T1***	***T2***	***T1***	***T2***
U1-NA (mm)	3.73 (3.46)	2.76 (2.54)	6.08 (3.38)	5.20 (2.80)	1.60 (1.98)	1.92 (2.02)
L1-NB^0	22.04 (7.77)	29.29 (7.73)	26.51 (6.29)	28.90 (6.39)	22.89 (6.77)	24.04 (6.54)
IMPA^0	93.28 (7.71)	98.20 (7.41)	97.75 (6.49)	99.50 (5.77)	92.00 (7.05)	93.12 (7.13)
L1-NB (mm)	4.06 (2.84)	5.84 (3.01)	5.46 (3.00)	6.65 (3.38)	3.01 (1.61)	3.20 (1.56)
L1-APog (mm)	-0.43 (2.76)	2.82 (3.01)	0.98 (2.83)	3.08 (3.08)	0.52 (1.85)	0.67 (1.61)
U1-L1^0	126.58 (15.25)	125.36(10.57)	121.38 (10.48)	122.34(9.59)	132.76 (11.78)	131.0 (11.93
Overjet (mm)	8.47 (2.65)	2.97 (2.18)	8.97 (2.70)	4.81 (2.03)	3.35 (1.59)	3.35 (1.83)
Overbite (mm)	4.00 (2.13)	1.13 (2.35)	4.46 (2.20)	3.19 (2.06)	2.02 (1.64)	1.90 (1.72)
Molar Relation (mm)#	1.40 (1.70)	-3.63 (3.14)	2.11 (1.32)	-0.41 (2.19)	-0.17 (1.27)	-0.16 (1.40)

U-lip-E-Line (mm)	-0.21 (2.25)	-2.75 (2.71)	1.40 (2.77)	-0.40 (2.89)	-1.52 (1.71)	-1.88 (1.77)
L-lip-E-Line (mm)	-0.31 (2.79)	-0.77 (2.92)	1.47 (3.57)	1.05 (4.11)	-0.70 (1.76)	-0.86 (1.84)

**p-value: significant if ≤ 0.05; U: upper; L: lower; #Molar Relation: +ve value indicates mesial position of U6
distal position of U6 in relation to L6

Based on the regional superimpositions, the lower incisors intruded (L1-vertical: 0.80mm; p=0.05) and the upper incisors extruded (U1-vertical: 0.73mm; p=0.01) more in the TB group. There was no difference between the treatment groups in terms of upper incisor retrusion (U1-Horizontal: 0.95mm; p=0.06) and lower incisor protrusion (L1-Horizontal: 0.41mm; p=0.12). The upper first molars extruded (U6-Vertical: 0.15mm; p=0.70) and distalized (U6-Horizontal: 0.10mm; p=0.86) equally in both treatment groups. The lower molars also extruded (L6-Vertical: 0.73mm; p=0.20) and mesialized (L6-Horizontal: 0.15mm; p=0.71) equally in in both treatment groups. (Table V). As T1 values were not used as covariates, the R^2 values in table V were very low.

Table V: Changes in the U1/L1 and U6/L6 positions in the vertical and sagittal planes according to Ricketts'[21] re
and mandibular (corpus axis at Pm -Protuberance menti) cephalometric superimpositions

Variable	TB (n= 45) Mean (SD)	vBHGA (n=46) Mean (SD)	Control (n=45) Mean (SD)	Treatment effect Mean (SD)	p value	R^2
	T1-T2	***T1-T2***	***T1-T2***	***TB-control*** ***vBHGA-control*** ***TB-vBHGA***		
U1-Vertical	-1.00 (1.47)	-0.27 (1.33)	-0.48 (1.26)	-0.52 (-1.09, 0.04) 0.21 (-0.35, 0.77) -0.73 (-1.30, -0.16)	0.07 0.01* 0.01*	0.0
U1-Horizontal	-1.59 (2.98)	-2.54 (2.21)	0.46 (1.98)	-2.05 (-3.07, 1.03) -3.00 (-4.01, -1.99) 0.95 (0.05, 1.95)	0.0001* <0.0001* 0.06	0.2
U6 Vertical	-0.47 (2.27)	-0.63 (2.01)	-0.99 (1.43)	0.52 (-0.29, 1.33) 0.36 (-0.43, 1.17) 0.15 (-0.65, 0.96)	0.20 0.37 0.70	0.0
U6-Horizontal	-0.75 (2.95)	-0.85 (3.54)	0.51 (2.40)	-1.26 (-2.52, -0.01) -1.37 (-2.61, -0.12) 0.10 (-1.13, 1.34)	0.04* 0.03* 0.86	0.0
L1-vertical	-0.60 (2.17)	0.20 (2.43)	0.63 (1.21)	-1.23 (-2.07, -0.39) -0.43 (-1.26, 0.40) -0.80 (-1.63, 0.02)	0.0044* 0.30 0.05*	0.0
L1-Horizontal	1.34 (1.42)	0.92 (1.50)	0.06 (0.83)	1.27 (0.73, 1.82) 0.85 (0.32, 1.39) 0.41 (-0.12, 0.95)	<0.0001* 0.0019* 0.12	0.1
L6-Vertical	1.02 (1.27)	0.28 (4.15)	0.27 (1.78)	0.74 (-0.39, 1.88) 0.01 (-1.11, 1.14) 0.73 (-0.39, 1.86)	0.19 0.98 0.20	0.0
L6-Horizontal	0.93 (2.26)	1.09 (2.09)	0.23 (1.63)	0.70 (-0.12, 1.54) 0.85 (0.03, 1.68) -0.15 (-0.97, 0.67)	0.09 0.04* 0.71	0.0

*p-value: significant if ≤ 0.05; TB: Twin Block; vBHGA: van Beek Headgear Activator; U1: Upper central incisor; U6: Upper 1st mola
molar; Horizontal: +ve value: mesial/forward movement; -ve value: distal/backward movement; Vertical: +ve: Intrusion of upper and e
of upper and intrusion of lower teeth.

Significant interactions in relation to growth pattern was observed for only three variables, namely U1-SN^0, U

retroclined more in the normal/horizontal TB growers (TB-H) than in the horizontal vBHGA growers (vB-H) (U1-N

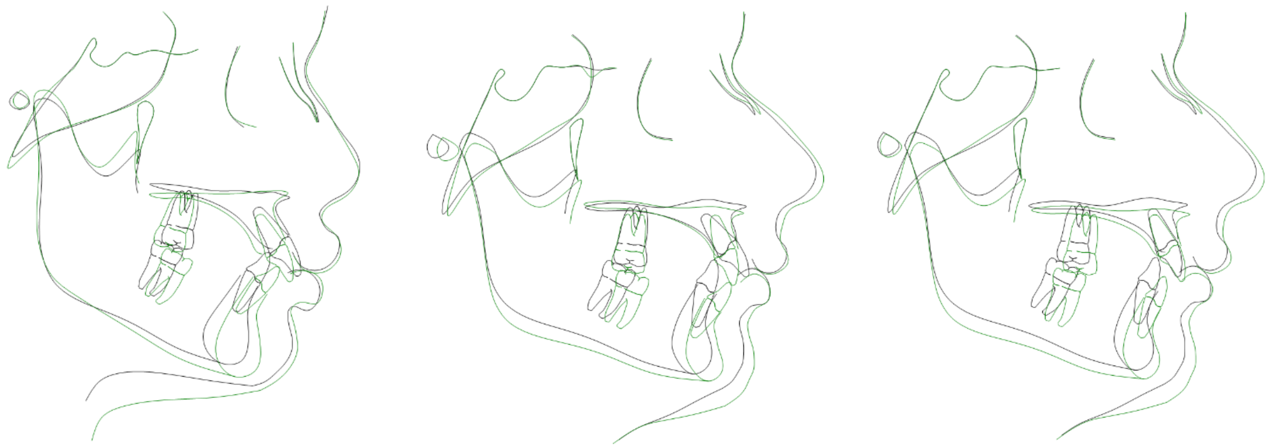
Table VI: Cephalometric variables that were statistically significant based on the growth pattern (Normal/Horizontal o

Variable		**TB (n= 45) (31H; 68.9% and 14V; 31.1%) Mean (SD)**		**vBHGA (n=46) (28H; 60.9% and 18V; 39.1%) Mean (SD)**		**Control (n=45) 25H; 55.6% and 20V; 44.4%) Mean (SD)**	
		T1	***T2***	***T1***	***T2***	***T1***	***T2***
U1-NA^0	H	24.63 (12.70)	21.33 (6.68)	25.92 (9.16)	25.67 (7.42)	17.05 (8.78)	17.74 (9.05)
	V	23.88 (7.79)	20.55 (7.47)	25.93 (8.37)	22.11 (6.68)	21.71 (7.18)	23.04 (6)
U1-SN^0	H	109.29 (12.87)	104.90 (6.23)	109.28 (8.96)	107.44 (7.08)	101.85 (9.02)	102.36 (9.42)
	V	105.03 (6.08)	100.23 (8.75)	105.39 (7.78)	100.47 (5.75)	102.36 (7.79)	103.74 (8.09)
U1-PP^0	H	114.85 (12.83	111.53 (6.42)	115.28 (8.75)	113.14 (7.33)	105.82 (8.37)	106.56 (9.23)
	V	113.15 (7.85)	109.14 (10.16)	114.79 (7.10)	108.57 (5.20)	108.17 (6.53)	109.45 (6.34)

*p-value: significant if ≤ 0.05; vB/vBHGA: van Beek Headgear Activator, TB: Twin-Block; Ctrl: Control; H: Norma

Superimposition of T1 and T2 cephalometric tracings illustrating the trend observed in each group is shown in Figure 5.

Figure 5: T1 (black) and T2 (green) cranial base (Sella-Nasion at Sella) superimposition representative of each group



Twin-Block vBHGA Control

Discussion

The present cephalometric study compared the skeletal, dentoalveolar and soft tissue effects of the TB and the vBHGA appliances in the correction of Class II malocclusion in growing patients, taking into account the influence of growth pattern. CVM stages as described by Baccetti[19] were used in lieu of chronologic age to assess potential for skeletal growth[24].

Even though both appliances similarly improved the intermaxillary relationship (ANB angle), each predominantly targeted a specific apical base. The TB mainly positioned the mandible forward (SNB) whereas the vBHGA restricted the maxilla (SNA) (Table II). The literature supports greater effect on the maxilla with the vBHGA[16], and on the mandible with the TB[13]. Dentoalveolar compensations were more pronounced in the TB group resulting in greater reduction of the overjet (OJ) and overbite (OB) (Tables III and V). The growth pattern (normal/horizontal and vertical) did not influence on the results, except for the inclination of the maxillary incisors (Table IV). Therefore, the null hypotheses was rejected.

At T1, both treatment groups had an equal distribution of subjects in pre-peak (CS 1-2) and peak (CS 3-4) stages, but the TB group had one subject in the post-peak stage (CS 5-6) (Table I). Since CVM stages do not always accurately predict the peak in mandibular growth[25] and secondary sexual characteristics do not always correlate with the such stages[26], it was decided to include that one subject in the sample. Also, as observed by O'Brien et al[8] in their comparison between the TB and the Herbst appliances, the regression model showed that CVM stages did not have a significant influence on the treatment effects. It is also important to bear in mind that individuals whose vertebral maturation lies between CS5 and CS6 can still have some growth remaining.

It was not possible to fully match the control group in terms of CVM stage (table 1). Although inclusion of such historical control was as best as it could get, it limited the assessment on whether the appliances were able to stimulate changes beyond natural growth. Anyway, this was not the main goal of the study, but rather compare the two appliances and the influence of growth pattern.

Females predominantly comprised the TB and the vBHGA groups whereas males, the control group. Developmentally, females mature earlier than males, and this unbalanced sex distribution could have overestimated the treatment effects with the two appliances. This is a common limitation of retrospective studies, but the treatment groups were comparable at baseline, thus allowing to test the hypothesis.

The control group started with a more reduced overjet (3.35mm) as compared to the TB (8.47mm) and the vBHGA (8.97mm) groups. Although such more reduced overjet at baseline in the control group limited the comparison in regards to dentoalveolar compensations, it did not limit the comparisons related to skeletal changes. Again, it is important to point out that the current study mainly focused on the effects of the two appliance groups, in which there was a similar representation of males and females as well as comparable overjets.

Jarabak's ratio, which accounts for the proportion between the anterior and the posterior face heights, was used to stratify the samples into normal/horizontal and vertical growers. In order to avoid decreasing the statistical power, it was decided to merge the horizontal and normal growers because the vertical growers are the ones who actually pose a clinical challenge during Class II correction due to their poor response to mandibular advancement[27]. Our sample had more normal/horizontal than vertical growers in all three groups, thus making them reasonably comparable in terms of growth pattern.

Neither appliance superseded normal mandibular growth as compared to the control (Co-Pg, Co-Gn) (Table II). This finding was in agreement with Tumer and Gultan[28], who studied the TB appliance, and Rabie at al[16], who studied the vBHGA. According to the SNB angle, however, the mandibles in the TB group were advanced 1.22^0 more than in the control group. This was similar to what was reported in a meta-analysis[9] on the treatment effects of various functional appliances, which showed an increase of 1.53^0 in the SNB angle in comparison to a control. There was no statistically significant difference between the vBHGA and the control group (Table II), which was also reported in a previous vBHGA study[29].

The TB performed better than the vBHGA in increasing the SNB angle (treatment effect = 1.34^0) despite the greater mandibular growth with the vBHGA (Co-Pg and Co-Gn) (Table II). Despite the lack of statistical significance when analyzed in isolation, such conundrum probably occurred due to the combination of the following two factors: 1. increase in the Jarabak's ratio in the TB group while it decreased in the vBHGA group (treatment effect = 0.25), and 2. slightly larger increase in the lower anterior face height (LAFH) with the vBHGA (treatment effect = 0.39). The TB group experienced a 2.36 mm increase in the LAFH, slightly less than the 2.7 mm reported by Illing[5]. The LAFH increased 2.67 mm with the vBHGA in spite of the high pull headgear. This probably occurred because the force vector was directed at or above the center of resistance of the incisors, a maneuver aimed at reducing the gingival display, which is one of the indications of this appliance[34]. Although not statistically significant, a counterclockwise rotation of the maxilla was observed with the vBHGA appliance (table III). A similar increase of 2.6 mm with the vBHGA was also reported elsewhere[30]. There may be other factors to explain why the TB produced a more forward positioning of the mandible despite a larger increase in Co-Gn and Co-Pg with the vBHGA. In a two-dimensional cephalometric study, it is not possible to fully understand discrepancies between the effective length of an apical base and its spatial position given the intramatrix rotations reported by Bjork[31].

The more forwardly positioned mandibles in the TB group can also have occurred due to a muscular posture. This would need confirmation by guiding the mandible in centric relation, something usually unavailable or unreliable in a retrospective study. In a prospective study design, however, weaning the patients off from the functional appliance for 12 months so that type 3 collagen can convert into type 1 collagen[31] would also be clinically undesirable as it would delay camouflage of any anteroposterior relapse.

The vBHGA appliance performed better than the control and TB groups in reducing the SNA angle value (treatment effects = 1.59^0 and 0.83, respectively) (Table II). The T1-T2 difference with the vBHGA in comparison to the control was 1.32^0. This was in agreement with previous studies[17,30] on the vBHGA appliance where orthopedic maxillary restriction was observed as a reduction in the SNA angle between 1^0 and 2^0 when compared to respective controls. There was no difference, however, between the two appliances in regards to A-Na-perp, which is a relevant measurement given that the Frankfort horizontal plane was considered an appropriate reference to assess the position of the jaws[32]. On the other hand, the difficulty in reliably reproducing porion can make such values (FH-SN, A-Na-perp, Pog-Na-perp and FMA) less accurate[33]. Whatever the reason, the expected larger impact of vBHGA on maxillary growth could not be observed in all pertinent cephalometric measurements (table III). The assumption that the vBHGA group might have been more efficient in restraining the maxillary A-P position also lies on the fact that its Co-A and Co-ANS increased more than in the TB group, yet its maxilla did not displace anteriorly in the same proportion. A possible explanation for this could be the counterclockwise rotation of the maxilla with the vBHGA appliance, what might have reduced the expression of its antero-posterior restrictive effect on the maxilla. In fact, the PP-SN clearly reduced with vBHGA and increased with TB (treatment effect = 1.45), being the difference between the appliances statistically significant (table III).

Maxillary restriction shall be expected with any intermaxillary functional appliance, even when the primary goal is to stimulate mandibular growth. This is because of the occclusal reactionary distal vector of force against the maxilla while the appliance is in use[34]. Although SNA and A-Na-perp also were reduced in the TB group, such reduction was not statistically different than what was observed in the control group (Table II). Lund and Sandler[6] also observed a non-statistically significant restraint of the maxilla with the TB. Only one measurement (A-NPog) in the TB group indicated some antero-posterior restriction of the maxilla (treatment effect = 1.35) in comparison to the control group. It is important to bear in mind that A-NPog can sometimes be unreliable because pogonion might have moved forward.

Although the TB group experienced more ANB reduction (mean T2-T1: 2.37^0) than the vBHGA group (mean T2-T1: 1.67^0), the difference was not statistically significant (Table II). Such magnitude of ANB reduction was in agreement with the results of a meta-analysis[9] and a retrospective study[35] which assessed the short-term effects from TB and vBHGA, respectively. Previous studies[5,6] on the TB appliance found ANB reductions between 2^0 and 2.3^0 when compared to a control, which was similar to that found in the present study, which was 2.05^0. The mean T1-T2 change in the control group was only 0.32^0, being statistically less than that observed with both appliances (Table III), and in line with the literature[36] that demonstrated lack of Class II self-correction with normal growth. From a clinical viewpoint, the 2.37^0 ANB reduction with the TB sounds more clinically relevant than the 1.67^0 reduction with the vBHGA. It was previously postulated that angular changes of 1^0 or more should be considered clinically significant[14]. As the ANB reduction was achieved by each appliance through different mechanisms[9], it is not only the amount that matters, but also which apical base will need to be addressed.

The TB group statistically superseded the vBHGA and control groups in reducing the Wits value (Table II). The mean T1-T2 reduction was 4.97 mm with the TB and 1.42 mm with the vBHGA. However, based on the low R^2 of 0.37 (table III), the ,regression equation did not seem to explain 50% or more of the variation. As Wits seems to be more reliable than the ANB in vertically growing patients[37], and our sample had a higher frequency of horizontal/normal growers in all three groups (Table I), this finding needs to be considered with caution.

In terms of dentoalveolar compensations, the TB superseded the vBHGA, with greater maxillary incisor retrusion (treatment effect U1-NA mm=1.04mm) (Table III) and extrusion (treatment effect U1-vertical =0.73mm) (Table IV) as well as more pronounced mandibular incisor protrusion (treatment effect L1-NB mm and L1-APog mm = 0.54mm and 0.96mm respectively), proclination (treatment effect L1-NB^0=3.84^0 and IMPA=1.92^0) (Table III), and relative intrusion (treatment effect L1-vertical =0.80mm) (Table V), thereby producing a greater reduction in the OJ (treatment effect =1.65mm) and OB (treatment effect =1.83mm) (Table III).

When taking growth pattern into account, the maxillary incisors retroclined more in the TB normal/horizontal growers (treatment effect U1-NA^0 = 3.62) (Table III). It is well known that such type of dentoalveolar compensation tends to occur in result of a reactionary distal vector of force acting on the maxillary incisors as the mandible is projected forward and maintained in such position for a long period of time. Such reactionary distal vector of force will certainly lie more horizontally in normal/horizontal growers. The fact that this was only observed in the TB group corroborates this assumption since the addition of a vertical vector from the high-pull headgear in the vBHGA group might have created a less horizontal reactionary vector.

Despite the literature suggesting the use of vBHGA in vertical growers[17], perhaps the TB could be an equally suitable appliance for these patients. O'Brien et al[8] corroborated this assumption in their study comparing the TB with the Herbst appliance, in which the maxillo-mandibular plane angle (MMPA) was used as a measure of the vertical proportions.

Only the TB showed a statistically significant reduction in the OJ (Table III), but the reduction of 4.16mm with the vBHGA shall not be overlooked. This probably occurred due to sample variation, hence the low R^2 value, and to the reduced baseline overjet (3.35mm) in the control group. Also, capping of the mandibular incisors in the vBHGA group might have led to less dentoalveolar compensation. Altogether, these factors might have contributed to underestimated the effect of the vBHGA on the OJ.

Molar correction was more pronounced with the appliances than in the control group (Table III). When comparing both appliances, the TB group showed greater molar correction, probably in result of the more pronounced dentoalveolar compensations (U1-NA mm, L1-NB mm, L1-APog mm, and L1-NB^0) (Table III).

The upper lip retruded more in the TB group compared to the vBHGA group (Table III). This probably occurred due to the greater retrusion (U1-NA:1.04mm) and retroclination (U1-NA^0: 3.62^0) of the maxillary incisors in the TB group (Table IV). There was no difference in the lower lip position between the two treatment groups despite the greater dentoalvelolar compensation in the mandibular dentition of the TB group (L1-NB mm and L1-APog mm; L1/NB^0 and IMPA) (Table III). This is in contrast to a previous study[38] wherein the upper lip remained stable and the lower lip protruded. This may be attributed to the inclusion of more normal/horizontal growers in the current study as they experienced more maxillary incisor retroclination (U1-NA^0) (Table IV). In addition, vertical growers usually present a low muscle tone[39], leading to more pronounced changes in the posture of the soft tissues in response to tooth movement. Moreover, soft tissue response to functional appliances can be highly variable, and individual variation can occur due to myotactic reflexes and soft-tissue viscoelasticity[40,41].

In summary, treatment with the TB and the vBHGA appliances resulted in a modest ANB reduction of 2.37^0 and 1.67^0, respectively. The TB ANB reduction seemed to echo the conclusions of some RCT's[42-44] that reported a reduction of approximately 2^0 with functional appliances at the end of a 2-phase treatment. The clinical significance of 1^0 to 2^0 can be a matter of debate, but considering that the ANB standard deviations at T2 were as large as 2^0 with both appliances (Table III), one can assume that the outcome can highly vary. Large variations with some individuals showing a significant above-average response have also been cited elsewhere[45]. This, together with other benefits from functional appliances, support the idea that the use of functional appliances can be worthwhile. There are several benefits from functional appliances. Firstly, the considerable reduction in OJ prevents trauma, improves self-esteem, eliminates lip traps and may decrease the duration of the second phase of treatment with full-fixed appliances or clear aligner therapy[44,46]. This study also showed that rather than growth pattern, mechanism of action and amount of dentoalveolar compensation should be more influential when choosing between the two appliances. For instance, vertically or horizontally growing retrognathic patients with a large overjet could be prescribed a TB. On the other hand, normally/horizontally growing patients with a prognathic maxilla could be prescribed a vBHGA. Due to its more pronounced dentoalveolar compensation in both the maxillary and mandibular dentitions, especially in the maxillary incisors of horizontal growers, the TB would be preferable in patients with excessive overjet, retrognathic mandible, proclined maxillary incisors, and a normal/horizontal growth pattern.

Conclusions:

It was possible to draw the following conclusions:

4. Both the Twin-Block (TB) and the van Beek Headgear-Activator (vBHGA) produced modest skeletal changes that favored the correction of the class II malocclusion. Notwithstanding the greater growth restriction with the TB, the maxilla was found to be more posteriorly positioned in the vBHGA group due to counterclockwise rotation. Despite greater increase in the effective length of the mandible with the vBHGA, the mandible in the TB group was found to be more anteriorly positioned.
5. Dentoalveolar compensations were observed with both appliances, but were more pronounced in individuals treated with the TB, leading to greater improvement in molar relationship and reduction in overjet and overbite.
6. Except for three upper incisor cephalometric measurements (U1-NA^0, U1-SN^0 and U1-PP^0), growth pattern (vertical or normal/horizontal) did not influence on the performance of the two

appliances.

Acknowledgements:

The authors would like to thank Dr.Sunil Mutalik for retracing some of the cephalometric radiographs as part of the error of the method assessment. We are also grateful to the AAOF legacy foundation. *"This study was made possible by use of material from the Burlington Growth Centre, Faculty of Dentistry, University of Toronto, which was supported by funds provided by Grant (1) (No. 605-7-299) National Health Grant (Canada), (data collection); (2) Province of Ontario Grant PR 33 (duplicating) and (3) the Varsity Fund (for housing and collection)".*

References

1. Tulloch JFC, Medland W, Tuncay OC. Methods used to evaluate growth modification in Class II malocclusion. Am J Orthod Dentofac Orthop 1990;98(4):340–7.

2. McNamara JA. Components of class II malocclusion in children 8-10 years of age. Angle Orthod 1981;51(3).

3. Pangrazio-Kulbersh V, Berger JL, Chermak DS, Kaczynski R, Simon ES, Haerian A. Treatment effects of the mandibular anterior repositioning appliance on patients with Class II malocclusion. Am J Orthod Dentofac Orthop 2003;123(3):286–95.

4. Chadwick SM, Banks P, Wright JL. The use of myofunctional appliances in the UK: a survey of British orthodontists. Dent Update 1998;25(7):302-8.

5. Illing HM, Morris DO, Lee RT. A prospective evaluation of Bass, Bionator and Twin Block appliances. Part I - The hard tissues. Eur J Orthod 1998;20(5):501–16.

6. Lund DI, Sandler PJ. The effects of Twin Blocks: a prospective controlled study. Am J Orthod Dentofacial Orthop 1998;113(1):104–10.

7. O'Brien K, Wright J, Conboy F, et al. Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: A multi-center, randomized, controlled trial. Am J Orthod Dentofac Orthop 2009;135(5):573–9.

8. O'Brien K, Wright J, Conboy F, et al. Effectiveness of treatment for class II malocclusion with the Herbst or Twin-block appliances: A randomized, controlled trial. Am J Orthod Dentofac Orthop 2003;124(2):128–37.

9. Antonarakis GS, Kiliaridis S. Short-term anteroposterior treatment effects of functional appliances and extraoral traction on class II malocclusion: A meta-analysis. Angle Orthod

2007;77(5):907–14.

10. Marsico E, Gatto E, Burrascano M, Matarese G, Cordasco G. Effectiveness of orthodontic treatment with functional appliances on mandibular growth in the short term. Am J Orthod Dentofac Orthop 2011;139(1):24–36.

11. Santamaría-Villegas A, Manrique-Hernandez R, Alvarez-Varela E, Restrepo-Serna C. Effect of removable functional appliances on mandibular length in patients with class II with retrognathism: Systematic review and meta-analysis. BMC Oral Health 2017;17(1).

12. Clark WJ. The twin block traction technique. Eur J Orthod 1982;4(2):129–38.

13. Cozza P, Baccetti T, Franchi L, De Toffol L, McNamara JA. Mandibular changes produced by functional appliances in Class II malocclusion: A systematic review. Am J Orthod Dentofac Orthop 2006;129(5):599.e1-599.e12.

14. Aelbers CM, Dermaut LR. Orthopedics in orthodontics: Part I, Fiction or reality--a review of the literature. Am J Orthod Dentofacial Orthop 1996;110(5):513–9.

15. van Beek H. Overjet correction by a combined headgear and activator. Eur J Orthod 1982;4(4):279–90.

16. Phan KLD, Bendeus M, Hägg U, Hansen K, Rabie ABM. Comparison of the headgear activator and Herbst appliance - Effects and post-treatment changes. Eur J Orthod 2006;28(6):594–604.

17. Dermaut LR, Van Den Eynde F, De Pauw G. Skeletal and dento-alveolar changes as a result of headgear activator therapy related to different vertical growth patterns. Eur J Orthod 1992;14(2):140–6.

18. Jarabak JR. Technique and treatment with light-wire edgewise appliances. 2nd ed. St.

Louis: C.V Mosby Company; 1972.

19. Baccetti T, Franchi L, McNamara JA. The Cervical Vertebral Maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopedics. Semin Orthod 2005;11(3):119–29.

20. Steiner CC. Cephalometrics for you and me. Am J Orthod 1953;39(10):729–55.

21. Ricketts RM. Perspectives in the clinical application of cephalometrics. The first fifty years. Angle Orthod 1981;51(2):115–50.

22. McNamara JA. A method of cephalometric evaluation. Am J Orthod 1984;86(6):449–69.

23. Fleiss JL. The Design and Analysis of Clinical Experiments. New York: John Wiley & Sons, Inc; 1999.

24. Proffit W, Fields H. Contemporary Orthodontics. 5th ed. 5th ed. Canada: Elsevier; 2012.

25. Ball G, Woodside D, Tompson B, Hunter WS, Posluns J. Relationship between cervical vertebral maturation and mandibular growth. Am J Orthod Dentofac Orthop 2011;139(5).

26. Santiago RC, De Miranda Costa LF, Vitral RWF, Fraga MR, Bolognese AM, Maia LC. Cervical vertebral maturation as a biologic indicator of skeletal maturity: A systematic review. Angle Orthod 2012;82(6):1123–31.

27. Freeman CS, McNamara JA, Baccetti T, Franchi L, Graff TW. Treatment effects of the bionator and high-pull facebow combination followed by fixed appliances in patients with increased vertical dimensions. Am J Orthod Dentofac Orthop 2007;131(2):184–95.

28. Tümer N, Gültan AS. Comparison of the effects of monoblock and twin-block appliances on the skeletal and dentoalveolar structures. Am J Orthod Dentofacial Orthop 1999;116(4):460–8.

29. Bendeus M, Hägg U, Rabie B. Growth and treatment changes in patients treated with a headgear-activator appliance. Am J Orthod Dentofac Orthop 2002;121(4):376–84.

30. Marşan G. Effects of activator and high-pull headgear combination therapy: Skeletal, dentoalveolar, and soft tissue profile changes. Eur J Orthod 2007;29(2):140–8.

31. Bjork A. Variations in the growth pattern of the human mandible: longitudinal radiographic study by the implant method. J Dent Res 1963;42(1):400-11.

32. Ellis E, McNamara J. Cephalometric reference planes--sella nasion vs Frankfort horizontal. Int J Adult Orthodon Orthognath Surg 1988;3(2):81-7.

33. Raju DS, Naidu DL. Reliability and Reproducibility of Natural Head Position: A Cephalometric Study. J Indian Orthod Soc 2012;46:340–7.

34. van Beek H. Combination headgear-activator. J Clin Orthod 1984;18(3):185-9.

35. Altenburger E, Ingervall B. The initial effects of the treatment of Class II, division 1 malocclusions with the van Beek activator compared with the effects of the Herren activator and an activator-headgear combination. Eur J Orthod 1998;20(4):389–97.

36. Baccetti T, Stahl F, McNamara JA. Dentofacial growth changes in subjects with untreated Class II malocclusion from late puberty through young adulthood. Am J Orthod Dentofac Orthop 2009;135(2):148–54.

37. Jacobson A. The "Wits" appraisal of jaw disharmony. Am J Orthod Dentofac Orthop 2003;124(5):470–9.

38. Morris DO, Illing HM, Lee RT. A prospective evaluation of Bass, Bionator and Twin Block appliances. Part II - The soft tissues. Eur J Orthod 1998;20(6):663–84.

39. Kiliaridis S. The Importance of Masticatory Muscle Function in Dentofacial Growth. Semin Orthod 2006;12(2):110–9.

40. McDonagh S, Moss JP, Goodwin P, Lee RT. A prospective optical surface scanning and cephalometric assessment of the effect of functional appliances on the soft tissues. Eur J Orthod 2001;23(2):115–26.

41. Sharma AA, Lee RT. Prospective clinical trial comparing the effects of conventional Twin-block and mini-block appliances: Part 2. Soft tissue changes. Am J Orthod Dentofac Orthop 2005;127(4):473–82.

42. Tulloch JFC, Proffit WR, Phillips C. Outcomes in a 2-phase randomized clinical trial of early class II treatment. Am J Orthod Dentofac Orthop 2004;125(6):657–67.

43. Dolce C, McGorray SP, Brazeau L, King GJ, Wheeler TT. Timing of Class II treatment: Skeletal changes comparing 1-phase and 2-phase treatment. Am J Orthod Dentofac Orthop 2007;132(4):481–9.

44. O'Brien K, Wright J, Conboy F, et al. Early treatment for Class II Division 1 malocclusion with the Twin-block appliance: A multi-center, randomized, controlled trial. Am J Orthod Dentofac Orthop 2009;135(5):573–9.

45. Wiltshire WA, Tsang S. A modern rationale for orthopedics and orthopedic retention. Semin Orthod 2006;12(1):60–6.

46. Thiruvenkatachari B, Harrison J, Worthington H, O'Brien K. Early orthodontic treatment for Class II malocclusion reduces the chance of incisal trauma: Results of a Cochrane systematic review. Am J Orthod Dentofac Orthop 2015;148(1):47–59.

Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

NISCHR

Gwasanaeth Moeseg Ymchwil | RES | Research Ethics Service

WALES REC 7
PO Box 108
Building 1
Jobswell Road
St David's Park
Carmarthen SA31 3WY
(for sat nav/courier purposes SA31 3HB)

Telephone : 01267 225045
E-mail : sue.byng@wales.nhs.uk
Website : www.hra.nhs.uk

Dr Badri Thiruvenkatachari
NIHT Academic Clinical Lecturer in Orthodontics
University of Manchester
1.032 Coupland 3 Building
Higher Cambridge Street
Manchester
M15 6FH

4 December 2014

Dear Dr Thiruvenkatachari

Study title:	**A comparison of the results from a retrospective patient group and patients from a randomised controlled trial for the effectiveness of Twin Block functional appliance**
REC reference:	**14/WA/1258**
IRAS project ID:	**166813**

The Proportionate Review Sub-committee of the Wales REC 7 reviewed the above application on 03 December 2014.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Ms Sue Byng, .

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

GIG Cymru NHS Wales | Bwrdd Iechyd Addysgu Powys | Powys Teaching Health Board

Cynhelir Cydweithrediad Gwyddor Iechyd Academaidd y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd gan Fwrdd Addysgu Iechyd Powys

The National Institute for Social Care and Health Research Academic Health Science Collaboration is hosted by Powys Teaching Health Board

Ariennir gan Llywodraeth Cymru
Funded by Welsh Government

Research Ethics Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB R3E 0W3
T: 204 789 3255
F: 204 789 3414
bannreb@umanitoba.ca

University of Manitoba | Research Ethics and Compliance

HEALTH RESEARCH ETHICS BOARD (HREB)

CERTIFICATE OF ANNUAL APPROVAL

PRINCIPAL INVESTIGATOR: Rohan Kirtane	**INSTITUTION/DEPARTMENT:** U of M/Dentistry/Preventive Dental Sciences	**ETHICS #:** HS23301 (H2019:400)
HREB MEETING DATE (If applicable):	**APPROVAL DATE:** November 2, 2020	**EXPIRY DATE:** **November 13, 2021**
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. Fabio Pinheiro		

PROTOCOL NUMBER: NA	**PROJECT OR PROTOCOL TITLE:** Evaluation of the dental and skeletal effects of Twin-Block Appliance and the van Beek Headgear-Activator (vBHGA) in the correction of Class II malocclusion- A cephalometric analysis
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: University of Manitoba	

Submission Date of Investigator Documents: September 27, 2020	**HREB Receipt Date of Documents:** September 27, 2020

REVIEW CATEGORY OF ANNUAL REVIEW: **Full Board Review** ☐ **Delegated Review** ☒

THE FOLLOWING AMENDMENT(S) and DOCUMENTS ARE APPROVED FOR USE:

Document Name(If applicable)	Version(If applicable)	Date

Annual approval

*Annual approval implies that the most recent **HREB approved** versions of the protocol, Investigator Brochures, advertisements, letters of initial contact or questionnaires, and recruitment methods, etc. are approved.*

Consent and Assent Form(s):

CERTIFICATION

The University of Manitoba (UM) Health Research Board (HREB) has reviewed the annual study status report for the research study/project named on this ***Certificate of Annual Approval*** as per the category of review listed above and was found to be acceptable on ethical grounds for research involving human participants. Annual approval was granted by the Chair or Acting Chair, UM HREB, per the response to the conditions of approval outlined during the initial review (full board or delegated) of the annual study status report.

HREB ATTESTATION

The University of Manitoba (UM) Health Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba. In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in

Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

QUALITY ASSURANCE
The University of Manitoba Research Quality Management Office may request to review research documentation from this research study/project to demonstrate compliance with this approved protocol and the University of Manitoba Policy on the Ethics of Research Involving Humans.

CONFLICT OF INTEREST
Any Principal or Co-Investigators of this study who are members of the UMHREB did not participate in the review or voting of this study.

CONDITIONS OF APPROVAL:

1. The study is acceptable on scientific and ethical grounds for the ethics of human use only. ***For logistics of performing the study, approval must be sought from the relevant institution(s).***
2. This research study/project is to be conducted by the local principal investigator listed on this certificate of approval.
3. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to the research study/project, and for ensuring that the authorized research is carried out according to governing law.
4. **This approval is valid until the expiry date noted on this certificate of annual approval. A Bannatyne Campus Annual Study Status Report** must be submitted to the REB within 15-30 days of this expiry date.
5. Any changes of the protocol (including recruitment procedures, etc.), informed consent form(s) or documents must be reported to the HREB for consideration in advance of implementation of such changes on the **Bannatyne Campus Research Amendment Form.**
6. Adverse events and unanticipated problems must be reported to the REB as per Bannatyne Campus Research Boards Standard Operating procedures.
7. The UM HREB must be notified regarding discontinuation or study/project closure on the **Bannatyne Campus Final Study Status Report**.

[redacted]

Please quote the above Human Ethics Number on all correspondence.
Inquiries should be directed to the REB Secretary **Telephone:** (204) 789-3255/ **Fax:** (204) 789-3414