Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances

By

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Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances

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Objective: The purpose of this study was to retrospectively assess the long term dental and skeletal treatment and growth changes in growing patients with Class II malocclusions treated with the van Beek Headgear Activator (vBHGA) appliance followed by comprehensive fixed orthodontic appliance treatment.

Materials and Methods: A retrospective chart review was undertaken on 40 consecutively treated subjects who were then compared to matched growing untreated control subjects from the Burlington Growth Study and growth forecast simulations. Lateral cephalometric radiographs were used to determine dental, skeletal and growth changes between each treatment phase.

Results: Phase 1 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 favourable skeletal and dental changes from vBHGA treatment were maintained after the completion of the second treatment phase.

Conclusions: The vBHGA appliance was effective in correcting Class II malocclusions by producing favourable skeletal and dental treatment effects in both jaws that were maintained after the completion of phase 2 treatment, in stark contrast to published randomized clinical trials. Success with the vBHGA and potentially other growth modification appliances could be related to patient compliance, timing of the individual's growth spurt, length of phase 1 treatment, and continued orthopedic retention between the first and second phases of treatment.

Key Words: van Beek Headgear Activator; vBHGA; Class II; Functional appliance; Growth modification; Growth prediction

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CHAPTER 1

INTRODUCTION AND REVIEW OF THE LITERATURE

1.1 Introduction

A fundamental question in orthodontic diagnosis is: what is the origin of the dentofacial problem? Is it dental, dentoalveolar, skeletal, or a combination? The answer to this question leads to the type of treatment; does the patient require no treatment, regular orthodontic treatment (dentoalveolar intervention), orthopedic treatment, orthognathic surgical treatment or a combination of the various treatment types? While orthodontic treatment most frequently aims to correct dental irregularities and may be used to camouflage skeletal abnormalities, it must often be combined with dentofacial orthopedics or maxillofacial surgery to correct skeletal discrepancies, in addition to even periodontic and prosthodontic intervention to correct the myriad of potential malocclusions.

Class II malocclusions in children originate from deficient anterior mandibular growth and/or excessive anterior maxillary growth which often results in significant skeletal abnormalities. Treatment consists of either a single phase of full fixed orthodontic appliance treatment or a first phase of treatment with various types of removable or fixed functional appliances normally followed by a second phase with full fixed appliances. However, the value and timing of two phase orthopedic treatment with functional appliances compared to single phase treatment has been a subject of intense controversy in the literature.[1–4] Nonetheless, many studies suggest that functional appliances can be effective in correcting skeletal Class II discrepancies by restraining maxillary growth, promoting growth of the mandible with inter alia glenoid fossa remodeling, or a combination of both.[5–13]

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The headgear activator (HGA) described by van Beek[14] is a removable functional appliance consisting of a monoblock activator with a thick (8-10 mm) posterior bite plane, long and deep lingual wings in the lower base, labial coverage of the upper and lower anterior teeth, and a short outer bow at the level of the maxillary canines combined with high pull headgear. The appliance is designed to achieve orthopedic Class II correction via maxillary growth restriction and enhanced mandibular growth with vertical control.

1.2 Review of the Literature

1.2.1 Prevalence of Class II Malocclusion

Phase 1 of the National Health and Nutrition Estimates Survey III (NHANES III) conducted in the United States between 1988 and 1991 provided malocclusion estimates in the US population, with separate estimates for the major racial/ethnic groups.[15] While Angle's molar relationships were not evaluated directly, overjet, which can be measured more precisely during a clinical examination, was used to reflect Angle's Class II and Class III molar relationships. Overjet of 5mm or more, suggestive of Angle's Class II malocclusion, occurs in 23% of children, 15% of youths, and 13% of adults[15] making Class II malocclusion one of the most common orthodontic problems.

1.2.2 Psychosocial Impact

> "Nothing has a more pronounced effect on a person's outlook than his appearance, or if not his appearance itself, then at least his belief that it is or isn't attractive."
>
> Leo Tolstoy, Childhood, Boyhood, Youth[16]

Facial appearance has a significant effect on an individual's social status, attractive children compared to their unattractive counterparts are seen by others as making more favourable first impressions, having a higher level of intelligence, being more socially attractive with more positive social behaviour, and receiving more positive treatment.[17,18]

The literature evidence regarding the psychosocial benefits of orthodontic treatment is inconclusive. Two recent studies[19,20] on bullying among Jordanian children found a significant relationship between bullying and dentofacial features and negative effects on oral health-related quality of life. 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.[19] Victims of bullying reported playing absent from school and disliked school compared to non-bullied children.[19] Seehra and coworkers investigated UK adolescents and found an association between bullying and a Class II Division 1 incisor relationship with increased overjet and a high need for orthodontic treatment assessed using the aesthetic component (AC) of the Index of Orthodontic Treatment Need (IOTN).[21] In a follow-up study of bullied UK adolescents, Sheehra and coworkers found that interceptive orthodontic treatment reduced bullying due to malocclusion in 78% of study participants.[22] A recent study of Jordanian adolescents by Badran[23] concluded that respondents who had received orthodontic treatment displayed greater self-esteem than those who did not and dissatisfaction with dental appearance had a strong predictive effect on self-esteem. Jung reported higher levels of self-esteem in Korean girls after fixed orthodontic treatment compared to an untreated control group.[24] Conversely, several previous longitudinal studies comparing self-esteem before and after orthodontic treatment failed to find a correlation between orthodontic treatment and self-esteem.[25–27]

1.2.3 Mandibular Growth and Maturational Indices

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.[28] In 1982 Fishman published a refined hand-wrist radiographic evaluation method to assess general skeletal maturity.[29] Recently, the Cervical Vertebral Maturation (CVM) method,[30] based on the analysis of the second through fourth cervical vertebrae in a lateral cephalometric radiograph and thus avoiding additional radiographs, has developed into a useful maturational index. Identification of skeletal maturational indicators allows the clinician to detect the optimal time to start mandibular deficiency treatment with 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.[31] Rabie and coworkers have identified many of the cellular events, genes, mediators, and growth factors involved in condylar growth regulation.[32–50] Furthermore, Pancherz[51–54] and Rabie[55] have independently demonstrated that reactivation of condylar growth in adults is possible with forward repositioning of the mandible via the Herbst appliance.

1.2.4 Early Treatment Clinical Trials

The value and timing of two phase orthopedic treatment compared to single phase treatment remains controversial due to the disagreement between the results of nonrandomized and randomized investigations.[1–4,10,13,56,57]

In 1966, Marschner and Harris published a preliminary cephalometric study to investigate mandibular growth in a group of Class II malocclusions treated with an activator appliance and a control group of untreated Class II patients.[58] While the authors found a significantly higher mandibular growth rate in the experimental group during treatment compared to the control group, they cautioned that "if the appliance affects growth at all, it can only alter it within the confines of the individual's genetic growth potential."[58] The following year, Jakobsson published the first clinical trial to evaluate Class II malocclusions treated with either activator or headgear therapy compared to an untreated control group.[59] Sixty subjects between the ages of 8 to 9 years of age were divided into three groups consisting of headgear treatment, activator treatment and an untreated control group and compared by lateral head röntgenograms after 18 months. Both headgear and activator groups demonstrated posterior movement of the maxilla and distalization of the maxillary dentition, while the activator group also displayed mesial bodily movement of the mandibular incisors resulting in a significantly greater reduction in overjet with a concurrent descent of the mandible rather than clockwise rotation. Furthermore, activator treatment was observed to increase the gonial angle, in agreement with the observations of Marschner and Harris.[58] Jakobsson concluded that the results from his study could not support the hypothesis that activator treatment resulted in condylar growth or a more forward mandible position.[59]

Since the aforementioned early studies, hundreds of studies comparing two phase orthopedic treatment to single phase treatment for Class II malocclusions have been published.[60,61] Of these studies, a recent Cochrane systematic review[60,61] found the highest quality of evidence originated from three large-scale randomized clinical trials reported in several articles from Florida,[1,3,62–66] North Carolina,[2,25,67–74] and the United Kingdom.[4,75–77]

The Florida study[1,3,62–66] was a prospective longitudinal randomized clinical trial conducted between 1990 and 2000 with 261 subjects, aged 7 to 12 years, divided into a phase 1 Bionator treatment group (86 subjects), a phase 1 headgear/biteplane treatment group (95 subjects), and a phase 1 control group (80 subjects). All subjects were then treated with full orthodontic appliances in phase 2. At the end of phase 1, there were differences in the skeletal measurements between the treatment and control groups. The SNA angle increased in the bionator and control groups and decreased in the headgear/biteplane groups, the SNB angle increased in the Bionator and control groups and remained the same in the headgear/biteplane group, and the ANB angle decreased in the bionator and headgear/biteplane groups and was unchanged in the control group. The authors concluded that both appliances reduced the severity of the Class II skeletal discrepancy at the end of phase 1 treatment with a simultaneous reduction in peer assessment rating (PAR) scores in the two treatment groups. However, upon completion of phase 2, the skeletal measurements for all 3 groups were within 1º, thus the authors concluded that there was no detectable skeletal difference between 1-phase and 2-phase treatment by the end of full orthodontic treatment. The length of phase 2 treatment was found to be about 6 months faster in those who had a phase 1 treatment; however 2-phase total treatment time was significantly longer than 1-phase treatment.

The North Carolina study[2,25,67–74] was a randomized clinical trial conducted between 1988 and 2001 with children randomly assigned to combination headgear (52 subjects completed phase 1, 47 subjects completed phase 2), modified Bionator (53 subjects completed phase 1, 39 subjects completed phase 2) or to observation (control; 61 subjects completed phase 1, 51 subjects completed phase 2) groups. All three groups had an average starting patient age of 9.4 years. Phase 1 treatment consisted of 15 months of treatment by a single doctor without any retention followed by waiting for the permanent dentition and re-randomization for full orthodontic appliance phase 2 treatment. Of the 166 patients who completed phase 1 treatment, 4 subjects were judged to not need further treatment while 137 patients completed phase 2 of treatment. The authors reported that phase 1 treatment improved skeletal and dental characteristics in approximately 80% of patients relative to the untreated control group. Although both treatment groups had a similar reduction in Class II severity via a decrease in the ANB angle, the headgear group showed a restricted forward movement of the maxilla while the Bionator group showed a greater increase in the length of the mandible. However, the authors report that during phase 2 treatment the progress made during the phase 1 treatment in the headgear and bionator groups was lost and by the end of phase 2 there was no significant difference between any of the 3 groups. The authors also reported that, similar to the Florida study, the length of phase 2 treatment was shorter in patients who had phase 1 treatment; however 2-phase total treatment time was significantly longer than 1-phase treatment.

The United Kingdom study[4,75–77] was a multicenter randomized clinical trial conducted between 1997 and 2000 with 174 children, aged 8 to 10 years, randomly assigned to a Twin-block treatment group (89 subjects) and an untreated phase 1 control group (85 subjects). After 15 months of phase 1 treatment, the Twin-block group showed a reduction in overjet, correction of molar relationships, a reduction in the severity of the malocclusion via a reduced PAR score, increased self-concept and self-esteem, a reduction in negative social experiences, and profiles that were generally perceived as more attractive relative to the controls. The sagittal correction resulted primarily from dentoalveolar change with a lesser amount of favourable skeletal change. Of the 89 patients who completed early Twin-block treatment, 13 (approximately 15%) accepted their occlusion and declined further treatment while none of the subjects in the control group accepted their occlusion after the 15 month period. Nevertheless, after the completion of phase 2 treatment, the authors concluded that both groups displayed no differences in skeletal pattern, extraction rates, and self-esteem. However, patients in the early treatment group had more total appointments, fewer phase 2 appointments, longer total treatment times, incurred higher treatment costs, and had a significantly poorer final occlusion as assessed by means of higher PAR scores.

The conclusions from the Cochrane systematic review[60,61] were that early treatment resulted in a reduction in incisal trauma by 33% to 41% with no other long-term advantages to providing 2-phase treatment compared to 1-phase treatment in early adolescence. Nonetheless, short-term improvements in both self-esteem and severity of the malocclusion were observed in a majority of patients. It is important to keep in mind that large-scale randomized clinical trials have a risk of systemic bias resulting from the study design,[56] examples of this from the 3 large-scale studies include:

- The choice of early treatment appliance was not selected based on an individual patient's unique skeletal pattern, e.g. hyperdivergent or hypodivergent
- Patients meeting the study inclusion criteria and placed in a treatment group typically received treatment within a month of initial records irrespective of the timing of the their peak growth spurt
- The length of early treatment was standardized and not individualized to each specific patient and their response to treatment
- Upon completion of the early treatment phase, initiation of the second treatment phase was often delayed while waiting for eruption of all the permanent teeth with no retention protocol thereby allowing relapse to occur unimpeded

1.2.5 The van Beek Headgear Activator (vBHGA)

The van Beek headgear activator (vBHGA) was first described in 1982 by van Beek[14] with the evaluation of 40 consecutive patients between the ages of 9 to 14 years. The appliance consists of a combined high pull headgear and a monoblock acrylic activator; the activator has a thick posterior biteplane covering the lingual half of the occlusal surfaces, long and deep lingual wings in the lower base to maintain maximum mandibular protrusion, a thick and short strong outer bow for headgear attachment at the level of the maxillary canines, labial acrylic coverage of the mandibular incisors to minimize proclination, labial and lingual acrylic coverage of the maxillary incisors for torque control. All the patients had increased overjet and Class II dental malocclusion; the vBHGA treatment goals were to decrease the overjet, correct the Class II malocclusion, to level excessive Curve of Spee, and to control the lower anterior facial height. After establishing a Class I occlusion, fixed appliances were used to correct tooth irregularities if necessary. Overjet reduction occurred at an average rate of 1mm per month during the first six months, after which the rate decreased; this was primarily achieved by retroclination of the upper incisors, proclination of the lower incisors, and a significant increase in mandibular length which was noted in many, but not all, patients.

In 1992, Dermaut and coworkers[78] evaluated the vBHGA dental and skeletal effects in 78 patients with severe Class II malocclusions and compared treatment changes to two different control groups. The vBHGA was found to be an effective treatment modality to correct Class II Division 1 malocclusions; vBHGA treatment effects included minor growth stimulation of the mandible, no maxillary orthopedic effect, vertical control of the lower anterior facial height in subjects with hyperdivergent skeletal patterns, decreased overjet and overbite by means of intrusion and retroclination of the upper incisors.

In 1998, Altenburger and Ingervall[79] compared the first phase treatment effects of the vBHGA, the Herren activator, and an activator-headgear combination. The vBHGA treatment group consisted of 39 consecutively treated children between the ages of 8 years 9 months and

13 years 4 months, with a median age of 11 years, 4 months. The median overjet reduction of 4.7mm was primarily achieved by a combination of skeletal and dentoalveolar effects; mandibular prognathism increased, maxillary skeletal effects were insignificant, the maxillary incisors retroclined without intrusion, and the mandibular incisors proclined. The authors noted that the vBHGA had superior incisor control compared to the other appliances.

In 2002, Rabie and coworkers published the first[8] of five[8,9,11,80,81] investigations into growth and treatment effects of vBHGA treatment. 20 consecutively treated boys, whose average age at the start of treatment was 11.7 years, with mild-to-moderate Class II Division 1 malocclusions and hyperdivergent skeletal patterns were treated with the vBHGA for 12 months and followed-up after 24 months. Four of the subjects were then excluded due to poor compliance resulting in a treatment group of 16 subjects. The treatment effects included reduction in overjet by 2.8mm, restraint of maxillary forward growth by 1.1mm and reduction in SNA by 0.6º, improvement in jaw-base relationship by 1.8mm and reduction in ANB by 1.3º, improvement in molar relationship by 3.0mm, increase in mandibular length by 0.9mm and increase in SNB by 0.8º, and decreased overbite by 1.9mm. Post-treatment growth changes over 24 months included a further reduction in overjet by 1.1mm, forward maxillary growth of 2.3mm, forward mandibular growth of 4.1mm, jaw relationship improvement of 1.8mm, increase in mandibular length of 5.0mm, and a further decrease in overbite of 0.5mm. Rabie concluded[8] that the vBHGA 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 sagittal mandibular growth. Rabie and coworkers then compared[9] the treatment effects of the vBHGA from the same subject group to the Herbst appliance followed by the Andresen activator (HAA) and concluded that maxillary prognathism decreased with vBHGA treatment while mandibular prognathism increased with HAA treatment. Furthermore, the same vBHGA subject group was evenly divided into good responders (n = 8, 50%) and bad responders (n = 8, 50%) based on overjet reduction of ≥4mm.[80] While no significant dental movements were observed in the bad responders, the good responders displayed significant posterior development of condylion, maxillary incisor retrusion, maxillary molar distalization, mandibular incisor protrusion, and mandibular molar protrusion.[80]

Subsequently, Rabie and coworkers investigated the effect of stepwise advancement compared to maximum jumping with the vBHGA in patients with skeletal Class II malocclusions (age = 8-16 years, overjet ≥ 6mm, ANB ≥ 4º).[11,81] The stepwise advancement group (n = 24, mean age = 11.9 ± 1.2 years) was treated for a total of 13 months and had 4mm mandibular advancements every 3 months. The maximum jumping group (n = 31, mean age = 11.2 ± 1.5 years) was treated for a total of 15.4 months with reduced wear in the last 6.9 months. Both groups displayed a reduction in overjet and overbite, increased mandibular prognathism and lower facial height, increased mandibular plane angle, mandibular molar eruption, improved jaw base and molar relationships, and restraint of maxillary forward growth. While the mandibular incisors were unaffected in the stepwise advancement group, they protruded significantly in the maximum jumping group. Additionally, the stepwise advancement group showed a significantly more pronounced reduction in overbite, improvement in jaw base (ANB) and molar relationship. The skeletal contribution of the overjet reduction at the end of treatment was 70% in the stepwise advancement group and 59% in the maximum jumping group. The authors concluded that both modes of mandibular jumping enhanced mandibular growth with extended treatment time (orthopedic retention) being a crucial factor in maintaining the treatment effect.[11] Rabie and coworkers then compared the previous two treatment groups to a group treated with a headgear-

Herbst appliance with stepwise advancement and a matched control group.[81] While all three treatment groups demonstrated enhanced posterior and superior condylar growth after treatment, both vBHGA groups had more superior than posterior condylar growth and the vBHGA stepwise advancement group had a significantly greater effect on superior condylar growth than both other treatment groups.

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CHAPTER 2

PURPOSE AND HYPOTHESES

2.1 Purpose

The purpose of this study was to retrospectively assess the long term dental and skeletal treatment effects and growth changes in growing patients with Class II malocclusions treated with the vBHGA appliance, followed by full fixed orthodontic treatment. The treatment group will be compared to both a matched growing untreated control group from the Burlington Growth Study and growth forecast simulations. Numerous dental and skeletal parameters will be measured to determine dental and skeletal changes in the treatment group and to differentiate them from the dental and skeletal changes originating from growth. Treatment subgroups will be used to evaluate the dental and skeletal treatment effects and growth changes following completion of vBHGA treatment as well as the long term stability of treatment.

2.2 Hypotheses

Hypothesis #1:

Null: There are no statistically significant differences in the skeletal parameters following vBHGA treatment and full fixed orthodontic appliance treatment compared to both a matched untreated control group and growth forecast simulations.

Alternative: There are statistically significant differences in the skeletal parameters following vBHGA treatment and full fixed orthodontic appliance treatment compared to both a matched untreated control group and growth forecast simulations.

Hypothesis #2:

Null: There are no statistically significant differences in the dental parameters following vBHGA treatment and full fixed orthodontic appliance treatment compared to both a matched untreated control group and growth forecast simulations.

Alternative: There are statistically significant differences in the dental parameters following vBHGA treatment and full fixed orthodontic appliance treatment compared to both a matched untreated control group and growth forecast simulations.

Hypothesis #3:

Null: There are no statistically significant differences in the skeletal parameters following vBHGA treatment compared to both a matched untreated control group and growth forecast simulations.

Alternative: There are statistically significant differences in the skeletal parameters following vBHGA treatment compared to both a matched untreated control group and growth forecast simulations.

Hypothesis #4:

Null: There are no statistically significant differences in the dental parameters following vBHGA treatment compared to both a matched untreated control group and growth forecast simulations.

Alternative: There are statistically significant differences in the dental parameters following vBHGA treatment compared to both a matched untreated control group and growth forecast simulations.

CHAPTER 3

MATERIALS AND METHODS

3.1 Ethics

This study was approved by the University of Manitoba (U of M) Bannatyne Campus Health Research Ethics Board (HREB) on September 24, 2015 (Ethics #: H2015:277) (Appendix 1).

3.2 Sample Groups and Size

The treatment group included growing patients with Class II malocclusions treated consecutively in the U of M Graduate Orthodontic Clinic with a first phase of van Beek Headgear Activator (vBHGA) treatment in the late mixed to early permanent dentition under the supervision of one instructor (Dr. W.A. Wiltshire, Supervisor) followed by a second phase of comprehensive fixed orthodontic appliance treatment. If initiation of the second treatment phase was delayed while waiting for eruption of all the permanent teeth, patients were instructed to wear the vBHGA appliance at night time without the headgear strap until the start of the second treatment phase. The vBHGA appliance was prescribed when indicated during peak height velocity (PHV) for each individual patient. The subjects were all treated by graduate orthodontic residents of the U of M Graduate Orthodontic program. A construction wax bite was first fabricated to be approximately 8 to 10mm in height and with a minimum of 6mm of mandibular protrusion. Patients were fitted with a high pull headgear strap adjusted to 8 ounces (approximately 250 grams) of force per side for the first month of appliance wear to allow the patient to adjust to the appliance followed by an increase to 16 ounces (approximately 500 grams) of force per side after the first month of appliance wear. Patients were instructed to wear the appliance 12 to 14 hours per day, starting from after dinner and throughout the night, 7 days per week. Patient compliance, appliance fit and headgear force levels were checked at each appointment and adjusted as needed. The subjects were selected using the following inclusion criteria:

(1) Class II malocclusion with overjet greater than 4.5mm.

(2) Fair to good compliance with the vBHGA as documented in the subjects' treatment charts.

(3) No craniofacial anomalies.

Subjects were divided into groups based on having completed the first phase of vBHGA treatment with a progress (T1) lateral cephalometric radiograph taken and having completed the second phase of treatment with comprehensive fixed orthodontic appliances with a post-treatment (T2) lateral cephalometric radiograph taken. Additionally, a subgroup of the treatment group returned for a retention check (T3) where intra-oral and extra-oral photographs were taken to evaluate dental and soft tissue variables.

The control group with Class II malocclusions was chosen from the archives of the Burlington Growth Centre that was established in 1952 at the University of Toronto, Ontario, Canada. They were matched in gender, age, and craniofacial morphology with the treatment subjects. Each subject had a complete set of orthodontic records taken at 9, 12, 14, and 16 years of age. The records included a lateral cephalometric radiograph, set of plaster models, and medical and dental histories. All the subjects were of Northern European descent and at the beginning of the study, were living in the small town of Burlington, part of the Greater Toronto Area, Ontario, Canada.

3.3 Cephalometric Analysis

A total of 36 sagittal and vertical cephalometric parameters (section 3.4) were measured pretreatment (T0), after vBHGA treatment (T1), and post treatment (T2) in this study. Changes in overjet, overbite, canine and molar relationships, and soft tissue variables were evaluated at all time points by evaluation of the traced lateral cephalometric radiographs, plaster models, and intra-oral and extra-oral photographs.

The subjects in the treatment group had lateral cephalometric radiographs taken between 2000 and 2015 at the U of M Graduate Orthodontic Clinic (Winnipeg, Canada). Images taken between 2000 and 2008 were taken with an analogue Gendex® GX900 radiographic unit operated at 90 kVp/15 mA, 15 millisecond exposure, 15 cm film to object distance, and 150 cm source to object distance. Analogue (film) lateral cephalometric radiographs were scanned by a single operator with an Epson (Model Perfection V700 Photo) digital scanner (Seiko Epson Corporation, Japan) at 1200 dpi resolution and subjected to cephalometric analysis using Dolphin® Imaging version 11.8 (Dolphin Imaging & Management Solutions, Chatsworth CA, USA). Images taken between 2008 and 2015 were taken with a KODAK® 8000C Digital Panoramic and Cephalometric Extraoral Imaging System (Kodak, Rochester NY, USA) that was operated at 71 kVp/6.3-10 mA (child) or 73 kVp/10-12 mA (adult), depending on the patient's age and build. The images were captured using the Kodak® Orthodontic Imaging Software (Carestream Dental LLC, Rochester NY, USA) and exported into Dolphin® Imaging version 11.8 and digitally traced by identification of each of the cephalometric landmarks according to the definitions in section 3.4.1. All images were given an independent numerical code in order to de-identify patients' personal information and maintain patients' confidentiality. A master list that contained the original chart number linked to the numerical code was kept locked in a secure location.

The control group subjects' lateral cephalometric radiographs were all taken at a magnification of 9.84%, all images were exported into Dolphin® Imaging version 11.8 and digitally traced by identification of each of the cephalometric landmarks according to the definitions in section 3.4.1. All images were given an independent numerical code in order to de-identify patients' personal information and maintain patients' confidentiality. A master list that contained the original chart number linked to the numerical code was kept locked in a secure location.

Additionally, the pre-treatment (T0) lateral cephalometric radiographs of the treatment group subjects were used to construct lateral profile growth forecast simulations that incorporated craniofacial growth changes using the Ricketts norms that would occur during treatment (T1 and T2) with the treatment simulation feature in Dolphin® Imaging version 11.8 software. The growth forecast simulations are analogous to lateral cephalometric radiographs of the treatment subjects recorded at their progress (T1) and post-treatment (T2) ages if they had not undergone treatment. They serve as an additional control group for comparison of skeletal parameters.

3.4 Definitions

CVM Stage: Assessment of the stage of cervical vertebral maturation as an indicator of skeletal growth potential[1]

3.4.1 Cephalometric Landmarks

A point (A): Most posterior point in the anterior concavity of the maxillary alveolar process, between the anterior nasal spine and the dental alveolus

Anterior nasal spine (ANS): Tip of the anterior nasal spine, the most anterior superior point of the maxilla in the midsagittal plane

Articulare (Ar): Posterior border of the neck of the condyle

B point (B): Most posterior point in the concavity along the anterior border of the symphysis of the mandible, between pogonion and infradentale

Basion (Ba): Most inferior posterior point of the occipital bone at the anterior margin of the occipital foramen

Condylion (Co): Most posterior superior point of the condyle

Gnathion (Gn): Most inferior anterior point on the inferior border of the chin in the midsagittal plane, between pogonion and menton

Gonion (Go): Most convex point along the inferior border of the ramus

L1 root apex: Root apex of the lower central incisor

L1 tip (L1): Incisal tip of the lower central incisor

Menton (Me): Most inferior point of the symphysis of the mandible in the midsagittal plane

Nasion (N): Intersection of the internasal suture with the nasofrontal suture in the midsagittal plane

Orbitale (Or): Most inferior point on the infraorbital margin, midpoint between right and left margins

Protuberance menti (PM): Point on the anterior border of the symphysis of the mandible between B point and Pogonion where the curvature changes from concave to convex

Pogonion (Pog): Most anterior point on the midsagittal symphysis of the mandible

Porion (Po): Most superior point of the external auditory meatus

Posterior nasal spine (PNS): Tip of the posterior nasal spine, the point of intersection of palatum durum, palatum molle, and pterygopalatine fossa

Pt point (Pt): Intersection of the inferior border of the foramen rotundum with the posterior wall of the pterygomaxillary fissure

R1: Most concave point on the anterior border of the ramus, used to locate Xi point

R2: Most convex point on the posterior border of the ramus, used to locate Xi point

R3 (Sigmoid notch): Most inferior point of the sigmoid notch of the ramus, used to locate Xi point

R4: Point on the inferior border of the mandible, directly inferior to the center of the sigmoid notch of the ramus, used to locate Xi point

Sella (S): Center of the sella turcica or pituitary fossa of the sphenoid bone

U1 root apex: Root apex of the upper central incisor

U1 tip (U1): Incisal tip of the upper central incisor

Xi point (Xi): The geometric center of the ramus

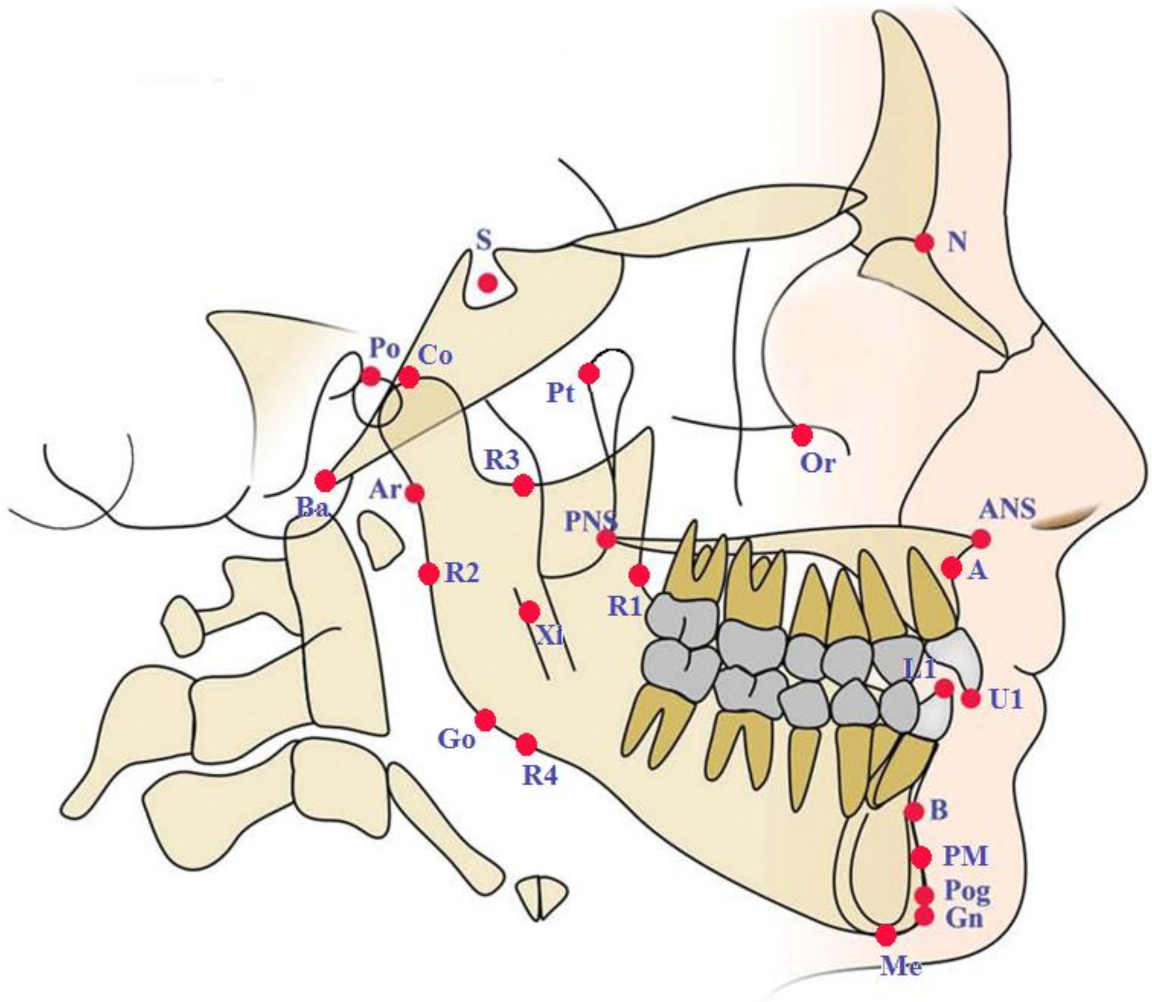

Figure 1. Cephalometric Landmarks (modified from Phulari 2013[2])

3.4.2 Cephalometric Linear Measurements

Overjet (mm): The horizontal distance between the incisal tips of the upper and lower incisors

Overbite (mm): The vertical distance between the incisal tips of the upper and lower incisors

Wits Appraisal (mm): The linear distance between AO and BO points

Harvold Mx Unit Length (mm): The linear distance between Co and ANS points

Harvold Md Unit Length (mm): The linear distance between Co and Pog points

Harvold Difference (mm) : The difference between the Mx and Md unit lengths (Md subtract Mx)

Md Body Length (mm): The linear distance between Go and Gn points

Md Corpus Length (mm): The linear distance between Xi and PM points

Md Ramus Height (mm): The linear distance between Ar and Go points

Convexity (mm): The linear distance from A point to the N-Pog plane; a measure of the sagittal position of the maxilla relative to the skull base and the chin

A-NPerp Distance (mm): The linear distance from A point to the N perpendicular (to the Frankfort Horizontal) line

Pog-NPerp Distance (mm): The linear distance from Pog point to the N perpendicular (to the Frankfort Horizontal) line

LFH (mm): The linear distance from ANS to Me point

U1-NA (mm) : The linear distance from the upper incisor incisal tip to the NA plane

U1-APog (mm): The linear distance from the upper incisor incisal tip to the A-Pog plane

L1-NB (mm): The linear distance from the lower incisor incisal tip to the NB plane

L1-APog (mm): The linear distance from the lower incisor incisal tip to the A-Pog plane

Pog-NB (mm): The linear distance from Pog point to the NB plane

U6-PTV (mm): The linear distance from the distal of the upper first molar crown to the Pterygoid vertical (PTV) line

3.4.3 Cephalometric Angular Measurements

SN-FH Angle (°): The angle between the SN and Frankfort Horizontal (P-Or) planes

SNA Angle(°): The angle between S, N and A points; a measure of the sagittal position of the maxillary basal bone relative to the anterior cranial base

SNB Angle (°): The angle between S, N and B points; a measure of the sagittal position of the mandibular basal bone relative to the anterior cranial base

ANB Angle (°): The angle between A, N and B points; a measure of the sagittal position of the maxillary basal bone relative to the mandibular basal bone

Facial Angle (°): The angle between the Frankfort Horizontal (P-Or) and Facial (N-Pog) planes; an indicator of the sagittal position of the mandible relative to the skull base

Saddle Angle (°): The angle between N, S and Ar points; a measure of the sagittal relationship of the anterior and posterior cranial bases

Gonial Angle (°): The angle between Ar, Go and Me points

MPA (°): The angle between the SN and Mandibular (Go-Gn) planes; an indicator of growth direction, vertical facial height and rotation of the mandible

FMA (°): The angle between the Frankfort Horizontal (P-Or) and Mandibular (Go-Gn) planes; an indicator of growth direction, vertical facial height and rotation of the mandible

FOP (°): The angle between the SN and Occlusal (point of occlusion between the maxillary and mandibular first molars to half of the overbite of the maxillary and mandibular incisors) planes; indicates the occlusal plane angle relative to the anterior cranial base

Y-axis (°): The angle between S, N and Gn points; a measure of the mandibular growth direction from the craniofacial complex

SN-PP (°): The angle between the SN and palatal (ANS-PNS) planes

PP-MP (°): The angle between the palatal (ANS-PNS) and mandibular (Go-Gn) planes

U1-SN (°): The angle between the upper incisor (U1 incisal tip-U1 root apex) and the SN plane

U1-PP (°): The angle between the upper incisor (U1 incisal tip-U1 root apex) and the Palatal plane (ANS-PNS)

U1-NA (°): The angle between the upper incisor (U1 incisal tip-U1 root apex) and the NA plane

U1-APog (°): The angle between the upper incisor (U1 incisal tip-U1 root apex) and the A-Pog plane

L1-NB (°): The angle between the lower incisor (L1 incisal tip-L1 root apex) and the NB plane

L1-APog (°): The angle between the lower incisor (L1 incisal tip-L1 root apex) and the A-Pog plane

L1-MPA (°): The angle between the lower incisor (L1 incisal tip-L1 root apex) and the Mandibular plane (Go-Gn)

U1-L1 (°): The angle between the upper incisor (U1 incisal tip-U1 root apex) and lower incisor (L1 incisal tip-L1 root apex)

3.5 Statistical Analysis

Descriptive statistics such as proportion, sample size, and chi-square were used to explain the results and correlation between predictor variables and outcome variables. T-test was used to see difference between means and regression analysis was used to see difference between condition and treatment by taking account the correlation between individual over the time. R-square and F-test were used to validate each regression model. The statistical package SAS 9.3 was used for all analyses.

3.6 References

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CHAPTER 4

RESULTS

4.1 Treatment Group

The final sample group that met the inclusion criteria was comprised of 40 subjects (20 females and 20 males), all of which completed the first phase of vBHGA treatment. The 17 subjects who did not meet the inclusion criteria were excluded due to poor compliance wearing the vBHGA appliance as documented in the subjects' treatment charts. At the time of the pre-treatment (T0) lateral cephalometric radiographs, the subjects' ages and CVM stages are listed in Table 1, and varied between 8-15 years and stages 1-4.

Table 1. Age and CVM stage statistics at pre-treatment (T0)

	Mean	**SD**	**Median**	**Minimum**	**Maximum**
Age	11.8	1.3	11.8	8.7	15.1
CVM	2.3	0.8	2	1	4

SD=standard deviation

One of the subjects was satisfied with the result of vBHGA treatment and declined further treatment. One subject accepted combined orthognathic surgical orthodontic treatment in the second treatment phase. This subject's pre-surgical lateral cephalometric radiograph was used as the post-treatment (T2) radiograph to assess their skeletal cephalometric parameters, but the subject's T2 dental parameters were not included in the group analysis. One subject had congenitally missing mandibular second premolars with retained mandibular primary second molars and the retained primary molars and upper second premolars were extracted in their second treatment phase. This subject's T2 dental cephalometric parameters were not included in the group analysis. The remaining 37 subjects underwent non-surgical, non-extraction treatment with fixed orthodontic appliances in the second treatment phase. Of the 40 subjects, 33 subjects (17 females, 16 males) had records taken after vBHGA treatment (T1), 34 subjects (17 females, 17 males) had completed the second phase of treatment and had post-treatment records taken (T2), and 14 subjects (7 females, 7 males) returned for a retention check where overjet and overbite were measured with a probe to the nearest half millimeter and intra-oral and extra-oral photographs were taken (T3). The treatment group had approximately equal numbers of female and male subjects at all time points and the entire sample was therefore considered to be gender neutral.

Statistics for the treatment time lengths between the time points are listed in Table 2. Total treatment was completed in an average of 32 months, of which, the average vBHGA treatment lasted 10 months. The retention follow-up period averaged 6.7 years and ranged from 2 to 11 years.

Table 2. Treatment time statistics between time points

	n	**Mean**	**SD**	**Median**	**Minimum**	**Maximum**
T0-T1 (months)	33	10	4	9	2	20
T1-T2 (months)	27	22	10	20	10	47
T0-T2 (months)	34	32	11	29	16	55
T2-T3 (years)	14	6.7	3.0	6.3	2.2	11.3

SD = standard deviation

Descriptive statistics for the treatment group's cephalometric variables at each of the three time points is provided in Appendix 2. The treatment group's mean cephalometric values at the three time points and the mean differences between each time point are shown in Table 3. The treatment group's dental relationship classifications at all the time points are shown in Table 4.

Table 3. Treatment group mean cephalometric values and mean differences between time points

	Means			Mean Differences		
Variable	**T0**	**T1**	**T2**	**T1-T0**	**T2-T1**	**T2-T0**
n	40	33	34	33	27	34
Overjet (mm)	9.1	4.9	3.3	-4.4	-1.7	-5.9
Overbite (mm)	4.6	3	1.3	-1.3	-1.9	-3.5
SN-FH (°)	10	10.1	9.7	-0.1	0.1	-0.2
SNA (°)	80.5	79.5	79.9	-0.8	-0.3	-0.9
SNB (°)	74.9	75.8	76.5	1.1	0.1	1.4
ANB (°)	5.7	3.7	3.4	-1.9	-0.4	-2.3
Wits (mm)	4.8	2.7	0.8	-2.1	-2.3	-4.2
Harvold Mx (mm)	85.5	86.6	90.4	1.9	1.3	3.7
Harvold Md (mm)	102.4	107.6	112.9	5.9	2.6	9.2
Harvold Diff (mm)	16.9	21	22.5	3.9	1.2	5.4
Md Body Length (mm)	74.4	77	80	3.1	1.5	4.8
Md Corpus Length (mm)	63.9	66.4	69.6	3.0	1.8	5.0
Md Ramus Height (mm)	44.3	47.4	50.8	3.6	2.3	6.3
Facial Angle (°)	86	87.2	87.6	1.0	0.4	1.3
Convexity (mm)	4.4	2.4	2	-1.9	-0.5	-2.3
A-NPerp (mm)	0.5	-0.4	-0.6	-1.0	-0.2	-1.2
Pog-NPerp (mm)	-7.4	-5.2	-5	1.6	0.5	2.0
Saddle Angle (°)	124.4	124.2	123.7	-0.1	0.3	-0.2
Gonial Angle (°)	123.5	122.1	122.2	-1.1	0.2	-1.1
MPA (°)	33.3	32.9	32.2	-0.5	0.3	-0.5
FMA (°)	23.3	22.8	22.5	-0.4	0.2	-0.2
FOP (°)	16.2	15.3	17.4	-0.9	3.0	1.6
Y-Axis (°)	68.9	68.6	68.5	-0.4	0.7	0.2
LFH (mm)	63.4	65.7	69.3	2.4	3.4	5.8
SN-PP (°)	1.6	-0.5	-0.2	-1.9	0.3	-1.7
PP-MP (°)	24.6	26.3	25.3	1.3	0.1	1.3
U1-SN (°)	106.4	104.9	104.8	-2.5	0.1	-1.3
U1-PP (°)	114.9	111.4	111.5	-4.4	0.3	-2.9
U1-NA (°)	25.8	25.4	25.1	-1.7	0.4	-0.3
U1-NA (mm)	6.4	6	5.3	-0.8	-0.2	-0.9
U1-APog (°)	35.3	30.4	29	-5.9	-0.7	-5.5
U1-APog (mm)	10.1	8.1	7	-2.3	-0.6	-2.8
L1-NB (°)	26.2	28.9	33.6	2.7	4.4	7.8

L1-NB (mm)	5.2	6.2	6.9	1.0	1.1	2.1
L1-APog (°)	22.4	27.6	33	5.0	5.1	10.8
L1-APog (mm)	0.8	3.1	3.7	2.2	1.2	3.3
L1-MPA (°)	98	100.1	105.2	2.1	4.0	7.0
U1-L1 (°)	122.3	122.1	118	0.9	-4.4	-5.3
Pog-NB (mm)	2.2	2.4	2.8	0.1	0.4	0.5
U6-PTV (mm)	14.4	15.2	17.6	0.5	2.2	2.8

Table 4. Treatment group Angle molar and canine relationship classifications at all time points

		C II					**C I**	**C III**				**Unerupted**
		1 1/2	1	3/4	1/2	1/4		1/4	1/2	3/4	1	
Right Molar	T0	1	20	11	8	0	0	0	0	0	0	0
	T1	0	2	1	6	5	13	3	2	0	0	0
	T2	0	0	0	1	3	24	3	1	0	0	0
	T3	0	0	0	1	0	12	0	1	0	0	0
Left Molar	T0	1	20	6	9	1	3	0	0	0	0	0
	T1	0	1	2	5	3	13	3	3	0	2	0
	T2	0	0	0	3	2	23	4	0	0	0	0
	T3	0	0	0	0	0	12	2	0	0	0	0
Right Canine	T0	0	8	17	10	0	1	0	0	0	0	4
	T1	0	1	3	9	9	9	0	0	1	0	0
	T2	0	0	0	0	24	8	0	0	0	0	0
	T3	0	0	0	1	6	6	0	1	0	0	0
Left Canine	T0	0	12	9	14	2	0	0	0	0	0	3
	T1	0	1	3	3	11	10	0	0	1	0	3
	T2	0	0	0	3	17	12	0	0	0	0	0
	T3	0	0	0	0	6	7	0	1	0	0	0

4.1.1 Phase 1 vBHGA Changes (T1-T0)

After phase 1, the treatment group showed a decrease in overjet (-4.4mm) and overbite (-1.3mm), restraint of maxillary anterior growth (SNA -0.8°, A-NPerp -1.0mm), increased mandibular anterior growth (SNB +1.1°, Pog-NPerp +1.6mm), improvement of jaw base and dental relationships (ANB -1.9°, Wits -2.1mm), increased mandibular lengths (body +3.1mm, corpus +3.0mm) and ramus height (+3.6mm), slight counter clockwise rotation of the mandible

(MPA -0.5°), counter clockwise rotation of the palatal plane(SN-PP -1.9°), increased lower anterior facial height (+2.4mm), retroclination (U1-SN -2.5°, U1-NA -1.7°) and retraction (U1-NA -0.8mm) of the upper incisors, and slight proclination (L1-NB +2.7°, L1-MPA +2.1°) and protrusion (L1-NB +1.0mm) of the lower incisors.

4.1.2 Phase 2 Treatment Changes (T2-T1)

After completion of phase 2 treatment, the treatment group showed a further decrease in overjet (-1.7mm) and overbite (-1.9mm), slight improvement of jaw base relationships (ANB -0.4°, Wits -2.1mm), further improvement of dental relationships, increased mandibular lengths (body +1.5mm, corpus +1.8mm) and ramus height (+2.3m), further increase in lower anterior facial height (+3.4mm), minimal change in the upper incisor angulation (U1-SN +0.1°, U1-NA +0.4°), and further proclination of the lower incisors (L1-NB +4.4°, L1-MPA +4.0°).

4.1.3 Total Treatment Changes (T2-T0)

After completing both phases of treatment, the treatment group showed a decrease in overjet (-5.9mm) and overbite (-3.5mm), restraint of maxillary anterior growth (ANB -0.9°, A-NPerp -1.2mm), increased mandibular anterior growth (SNB +1.4°, Pog-NPerp +2.0mm), improvement of jaw base and dental relationships (ANB -2.3°, Wits -4.2mm), increased mandibular lengths (body +4.8mm, corpus +5.0mm) and ramus height (+6.3mm), slight counter clockwise rotation of the mandible (MPA -0.5°), counter clockwise rotation of the palatal plane (SN-PP -1.7°), increased lower anterior facial height (+5.8mm), retroclination (U1-SN -1.3°) and retraction (U1-NA -0.9mm) of the upper incisors, and proclination (L1-NB +7.8°, L1-MPA +7.0°) and protrusion (L1-NB +2.1mm) of the lower incisors.

4.1.4 Retention Changes (T3-T2)

The treatment group's overjet and overbite values at the four time points and the mean differences between the time points are shown in Table 5.

Table 5. Treatment group mean overjet and overbite values and mean differences between time points

	Means			Mean Differences		
Variable	**T0**	**T2**	**T3**	**T2-T0**	**T3-T2**	**T3-T0**
n	40	34	14	34	14	14
Overjet (mm)	9.1	3.3	4.1	-5.9	1.4	-4.5
Overbite (mm)	4.6	1.3	2.9	-3.5	1.6	-2.7

There was an increase in both overjet (+1.4mm) and overbite (+1.6mm) in the retention period; however the overjet and overbite means in retention are both decreased compared to the pre-treatment (T0) values.

4.2 Treatment and Control Group Differences

Descriptive statistics for the control group's cephalometric variables at each of the three time points and the mean differences between each time point is provided in Appendix 3. The net treatment effects (the treatment group mean difference minus the control group mean difference) between each time point is shown in Table 6.

Table 6. Net treatment effects between time points: treatment group mean differences minus control group mean differences

	T1-T0 (n=33)				T2-T1 (n=27)				T2-T0 (n=34)			
Variable	**MD**	**SD**	**t Value**	**p Value**	**MD**	**SD**	**t Value**	**p Value**	**MD**	**SD**	**t Value**	**p Value**
Overjet (mm)	-4.4	2.2	-8.08	<0.0001	-2.0	1.8	-3.97	0.0002	-6.4	2.4	-11.08	<0.0001
Overbite (mm)	-1.0	1.6	-2.60	0.0115	-1.4	1.5	-3.48	0.0010	-2.8	1.9	-6.02	<0.0001
SN-FH (°)	0.2	1.5	0.42	0.6787	0.6	1.5	1.46	0.1504	0.7	1.8	1.59	0.1156
SNA (°)	-0.8	1.4	-2.14	0.0359	-0.7	1.3	-2.01	0.0493	-0.9	1.5	-2.64	0.0103
SNB (°)	0.9	0.9	3.93	0.0002	-0.3	0.9	-1.43	0.1600	0.7	1.2	2.24	0.0281
ANB (°)	-1.6	1.3	-5.03	<0.0001	-0.4	1.1	-1.17	0.2481	-1.6	1.5	-4.43	<0.0001
Wits (mm)	-2.6	1.9	-5.66	<0.0001	-3.2	2.1	-5.55	<0.0001	-5.4	2.7	-8.18	<0.0001
Harvold Mx (mm)	0.0	2.8	-0.04	0.9654	-0.4	2.7	-0.50	0.6178	0.4	3.4	-0.51	0.6141
Harvold Md (mm)	2.6	3.3	3.23	0.0020	-0.4	2.8	-0.58	0.5665	2.7	3.8	2.90	0.0050
Harvold Diff (mm)	2.6	2.4	4.44	<0.0001	-0.1	2.1	-0.13	0.8939	2.3	2.6	3.59	0.0006
Md Body Length (mm)	0.8	2.8	1.14	0.2567	-1.4	2.3	-2.30	0.0252	-0.6	3.2	-0.81	0.4207
Md Corpus Length (mm)	1.3	1.8	2.88	0.0054	-0.5	1.7	-1.18	0.2432	0.5	2.1	0.89	0.3749
Md Ramus Height (mm)	1.7	2.6	2.70	0.0088	-0.4	2.5	-0.59	0.5563	1.5	3.1	2.05	0.0444
Facial Angle (°)	0.8	1.6	1.99	0.0505	0.2	1.5	0.37	0.7114	1.1	1.8	2.43	0.0178
Convexity (mm)	-1.5	1.2	-4.98	<0.0001	-0.2	1.3	-0.54	0.5911	-1.5	1.5	-4.08	0.0001
A-NPerp (mm)	-0.6	1.9	-1.20	0.2348	0.0	1.9	-0.09	0.9309	-0.2	2.1	-0.37	0.7151
Pog-NPerp (mm)	1.6	3.0	2.17	0.0337	0.3	3.0	0.43	0.6706	2.2	3.5	2.61	0.0111
Saddle Angle (°)	-0.4	2.0	-0.76	0.4502	0.4	1.8	0.91	0.3692	-0.3	2.5	-0.51	0.6119
Gonial Angle (°)	-0.1	3.0	-0.19	0.8516	2.3	2.6	3.25	0.0020	2.2	3.4	2.65	0.0101
MPA (°)	-0.2	1.2	-0.57	0.5726	1.6	1.4	4.13	0.0001	1.1	1.6	2.92	0.0047
FMA (°)	-0.3	1.9	-0.69	0.4911	1.0	1.9	1.88	0.0663	0.4	2.2	0.74	0.4624
FOP (°)	0.5	2.2	0.86	0.3934	4.7	2.2	7.67	<0.0001	4.9	3.2	6.32	<0.0001
Y-Axis (°)	-0.5	0.9	-2.42	0.0185	1.1	0.9	4.32	<0.0001	0.4	1.2	1.30	0.1979
LFH (mm)	0.7	2.0	1.45	0.1515	1.4	2.5	2.08	0.0423	2.2	2.7	3.30	0.0016
SN-PP (°)	-2.2	1.4	-6.24	<0.0001	0.1	1.4	0.37	0.7124	-2.1	1.6	-5.31	<0.0001
PP-MP (°)	2.0	1.8	4.41	<0.0001	1.4	1.8	2.96	0.0046	3.2	1.9	6.83	<0.0001

U1-SN (°)	-3.3	5.6	-2.39	0.0200	-1.7	6.8	-0.89	0.3786	-4.3	8.2	-2.10	0.0397
U1-PP (°)	-5.5	5.8	-3.84	0.0003	-1.6	7.0	-0.81	0.4215	-6.3	8.1	-3.17	0.0023
U1-NA (°)	-2.5	5.9	-1.75	0.0852	-0.9	7.0	-0.48	0.6345	-3.2	8.2	-1.59	0.1179
U1-NA (mm)	-1.5	2.4	-2.49	0.0152	-0.4	2.0	-0.81	0.4231	-2.4	2.6	-3.68	0.0005
U1-APog (°)	-5.8	5.5	-4.29	<0.0001	-1.3	6.8	-0.67	0.5062	-6.2	8.2	-3.06	0.0032
U1-APog (mm)	-2.6	1.9	-5.59	<0.0001	-0.6	1.9	-1.14	0.2617	-3.5	2.3	-6.00	<0.0001
L1-NB (°)	2.4	2.8	3.50	0.0008	5.3	3.9	4.91	<0.0001	9.0	5.0	7.27	<0.0001
L1-NB (mm)	0.6	1.0	2.43	0.0181	1.2	1.2	3.69	0.0005	1.9	1.5	5.14	<0.0001
L1-APog (°)	4.0	3.3	5.01	<0.0001	5.3	4.0	4.77	<0.0001	10.3	5.0	8.33	<0.0001
L1-APog (mm)	1.9	1.4	5.57	<0.0001	1.5	1.6	3.45	0.0011	3.2	1.7	7.71	<0.0001
L1-MPA (°)	1.7	2.6	2.71	0.0087	4.1	4.0	3.66	0.0006	7.4	4.9	6.10	<0.0001
U1-L1 (°)	1.8	6.4	1.13	0.2606	-4.1	8.2	-1.80	0.0780	-4.1	9.4	-1.77	0.0813
Pog-NB (mm)	-0.3	0.6	-2.29	0.0256	-0.2	0.9	-0.96	0.3411	-0.4	0.9	-2.06	0.0436
U6-PTV (mm)	-1.2	1.6	-3.08	0.0031	0.2	1.7	0.53	0.5954	-0.4	1.9	-0.93	0.3549

MD = mean difference; SD = standard deviation

4.2.1 Net Phase 1 vBHGA Effects vs. Control (T1-T0)

The statistically significant (P<0.05) net phase 1 vBHGA treatment effects were a reduction in overjet (-4.4mm) and overbite (-1.0mm), restraint of maxillary anterior growth (SNA -0.8°), increased mandibular anterior growth (SNB +0.9°, Harvold Md +2.6mm, Pog-NPerp +1.6mm), improved jaw base relationships (ANB -1.6°, Wits -2.6mm), increased mandibular corpus length (+1.3mm) and ramus height (+1.7mm), counter clockwise rotation of the palatal plane (SN-PP -2.2°), retroclination (U1-SN -3.3°) and retraction (U1-NA -1.5mm) of the upper incisors, proclination (L1-NB +2.4°, L1-MPA +1.7°) and protrusion (L1-NB +0.6mm) of the lower incisors, and distalization of the maxillary first molar (U6-PTV -1.2mm). Non-statistically significant changes were found for the following cephalometric measurements: mandibular body length, saddle angle, gonial angle, mandibular plane angle, functional occlusal plane angle, lower anterior facial height, and interincisal angle.

4.2.2 Net Phase 2 Treatment Effects vs. Control (T2-T1)

The statistically significant (P<0.05) net phase 2 treatment effects were a further decrease in overjet (-2.0mm) and overbite (-1.4mm), continued restraint of maxillary anterior growth (SNA -0.7°), increased gonial angle (+2.3°), mandibular plane angle (+1.6°), and functional occlusal plane angle (+4.7°), increased lower anterior facial height (+1.4mm), and proclination (L1-NB +5.3°, L1-MPA +4.1°) and protrusion (L1-NB +1.2mm) of the lower incisors. Non-statistically significant changes were found for the following cephalometric measurements: mandibular sagittal position, jaw base relationship, mandibular corpus length and ramus height, saddle angle, palatal plane angle relative to the cranial base, upper incisor angulation and sagittal position, interincisal angle, and maxillary first molar sagittal position.

4.2.3 Net Total Treatment Effects vs. Control (T2-T0)

The statistically significant (P<0.05) net treatment effects were a reduction in overjet (-6.4mm) and overbite (-2.8mm), restraint of maxillary anterior growth (SNA -0.9°), increased mandibular anterior growth (SNB +0.7°, Harvold Md +2.7mm, Pog-NPerp +2.2mm), improved jaw base relationships (ANB -1.6°, Wits -5.4mm), increased mandibular ramus height (+1.5mm), increased gonial angle (+2.2°), mandibular plane angle (+1.1°), and functional occlusal plane angle (+4.9°), increased lower anterior facial height (+2.2mm), counter clockwise palatal plane rotation (SN-PP -2.1°), retroclination (U1-SN -4.3°) and retraction (U1-NA -2.4mm) of the upper incisors, and proclination (L1-NB +9.0°, L1-MPA +7.4°) and protrusion (L1-NB +1.9mm) of the lower incisors. The clinically valuable treatment effects included the reduction in overjet (-6.4mm), overbite (-2.8mm), and Wits appraisal (-5.4mm), upper incisor retroclination (U1-SN -4.3°, U1-NA -3.2°), and lower incisor proclination (L1-NB +9.0°, L1-MPA +7.4°). Non-statistically significant changes were found for the following cephalometric measurements: mandibular body and corpus lengths, saddle angle, interincisal angle, and maxillary first molar sagittal position.

4.3 Treatment and Growth Forecast Differences

Descriptive statistics for the growth forecast's cephalometric variables at each of the three time points and the mean differences between each time point is provided in Appendix 4. The net treatment effects (the treatment group mean difference minus the growth forecast group mean difference) between each time point is shown in Table 7.

Table 7. Net treatment effects between time points: treatment group mean differences minus growth forecast group mean differences

	T1-T0 (n=33)				T2-T1 (n=27)				T2-T0 (n=34)			
Variable	**MD**	**SD**	**t Value**	**p Value**	**MD**	**SD**	**t Value**	**p Value**	**MD**	**SD**	**t Value**	**p Value**
Overjet (mm)	-4.3	2.3	-7.97	<0.0001	-1.8	2.7	-2.64	0.0106	-5.9	2.9	-8.69	<0.0001
Overbite (mm)	-1.4	1.9	-3.08	0.0029	-1.5	2.5	-2.27	0.0271	-3.1	2.4	-5.31	<0.0001
SN-FH (°)	-0.3	1.0	-1.10	0.2758	0.1	1.4	0.34	0.7363	-0.4	1.4	-1.11	0.2703
SNA (°)	-1.0	2.2	-1.95	0.0547	0.1	2.4	0.15	0.8792	-0.8	1.9	-1.70	0.0942
SNB (°)	0.6	1.7	1.47	0.1447	0.2	1.8	0.49	0.6252	0.9	1.7	2.32	0.0231
ANB (°)	-1.6	1.6	-4.24	<0.0001	-0.1	1.7	-0.27	0.7854	-1.7	1.8	-4.08	0.0001
Wits (mm)	-1.4	2.2	-2.79	0.0069	-1.8	2.4	-2.91	0.0050	-3.0	2.3	-5.42	<0.0001
Harvold Mx (mm)	-0.5	3.9	-0.60	0.5505	-3.0	5.0	-2.34	0.0222	-3.1	4.6	-2.88	0.0053
Harvold Md (mm)	1.4	4.7	1.28	0.2051	-2.9	6.9	-1.67	0.1003	-0.8	5.6	-0.63	0.5320
Harvold Diff (mm)	2.0	2.7	3.15	0.0024	0.1	3.2	0.09	0.9289	2.3	2.9	3.38	0.0012
Md Body Length (mm)	0.1	3.9	0.08	0.9335	-1.9	4.5	-1.72	0.0909	-1.7	3.8	-1.92	0.0587
Md Corpus Length (mm)	0.0	3.7	0.00	0.9973	-1.8	4.7	-1.49	0.1399	-1.7	3.6	-2.00	0.0496
Md Ramus Height (mm)	2.3	3.2	3.11	0.0027	1.0	3.2	1.30	0.1971	3.7	2.8	5.56	<0.0001
Facial Angle (°)	0.3	1.6	0.85	0.4006	0.6	2.2	1.13	0.2619	0.9	2.0	1.89	0.0624
Convexity (mm)	-1.6	1.9	-3.63	0.0005	-0.6	2.2	-1.01	0.3169	-2.2	2.1	-4.44	<0.0001
A-NPerp (mm)	-1.4	2.2	-2.73	0.0079	0.2	2.0	0.43	0.6711	-1.2	1.7	-2.95	0.0043
Pog-NPerp (mm)	0.6	3.3	0.75	0.4576	1.5	4.4	1.33	0.1874	1.9	3.8	2.15	0.0346
Saddle Angle (°)	-1.6	2.8	-2.48	0.0153	-0.7	3.4	-0.82	0.4175	-2.8	3.3	-3.71	0.0004
Gonial Angle (°)	-1.7	3.2	-2.20	0.0313	-1.8	3.6	-1.96	0.0541	-3.6	3.3	-4.63	<0.0001
MPA (°)	-0.8	3.0	-1.19	0.2394	-0.9	3.2	-1.12	0.2669	-2.0	2.9	-2.90	0.0049
FMA (°)	-0.6	2.8	-0.85	0.4000	-1.0	3.4	-1.22	0.2265	-1.6	2.8	-2.47	0.0161
FOP (°)	-0.9	2.3	-1.69	0.0955	2.4	2.7	3.46	0.0010	1.0	2.8	1.59	0.1173
Y-Axis (°)	-0.6	2.2	-1.13	0.2617	0.4	2.3	0.62	0.5404	-0.4	2.0	-0.84	0.4045
LFH (mm)	-0.1	4.1	-0.14	0.8869	-0.1	5.7	-0.10	0.9243	-0.2	4.4	-0.23	0.8173
SN-PP (°)	-1.4	2.2	-2.60	0.0112	0.0	2.6	-0.06	0.9501	-1.5	1.8	-3.50	0.0008
PP-MP (°)	0.5	3.4	0.64	0.5265	-0.9	3.8	-0.90	0.3734	-0.4	3.4	-0.55	0.5863

U1-SN (°)	-2.2	6.8	-1.36	0.1780	1.0	7.8	0.48	0.6364	0.1	9.1	0.06	0.9505
U1-PP (°)	-3.5	7.7	-1.96	0.0540	1.0	8.5	0.45	0.6518	-1.2	8.8	-0.57	0.5686
U1-NA (°)	-1.1	7.8	-0.61	0.5430	0.9	8.5	0.41	0.6804	1.0	9.0	0.46	0.6446
U1-NA (mm)	-1.0	2.7	-1.51	0.1354	-0.5	3.0	-0.70	0.4848	-1.3	3.2	-1.70	0.0931
U1-APog (°)	-4.5	7.5	-2.57	0.0122	0.2	9.1	0.08	0.9332	-3.1	10.5	-1.23	0.2220
U1-APog (mm)	-2.5	2.4	-4.43	<0.0001	-0.9	3.4	-1.04	0.3035	-3.1	3.7	-3.52	0.0008
L1-NB (°)	2.6	4.2	2.59	0.0155	3.9	5.6	2.72	0.0084	7.2	5.2	5.82	<0.0001
L1-NB (mm)	0.9	1.7	2.18	0.0323	1.1	2.1	2.07	0.0424	2.0	1.8	4.68	<0.0001
L1-APog (°)	4.4	4.1	4.52	<0.0001	4.5	4.8	3.66	0.0005	9.6	4.8	8.45	<0.0001
L1-APog (mm)	1.9	1.9	4.26	<0.0001	1.0	2.3	1.72	0.0905	3.0	1.8	7.05	<0.0001
L1-MPA (°)	2.8	2.7	4.39	<0.0001	4.5	4.7	3.74	0.0004	8.4	5.3	6.61	<0.0001
U1-L1 (°)	0.2	8.7	0.10	0.9195	-4.7	10.5	-1.76	0.0837	-6.5	11.9	-2.28	0.0255
Pog-NB (mm)	0.0	1.1	0.15	0.8848	0.6	1.4	1.75	0.0856	0.7	1.4	2.15	0.0352
U6-PTV (mm)	-1.5	2.5	-2.62	0.0106	0.4	2.9	0.53	0.5997	-1.0	2.5	-1.69	0.0948

MD = mean difference; SD = standard deviation

4.3.1 Net Phase 1 vBHGA Effects vs. Growth Forecast (T1-T0)

The statistically significant (P<0.05) net phase 1 vBHGA treatment effects were a reduction in overjet (-4.3mm) and overbite (-1.4mm), restraint of maxillary anterior growth (A-NPerp -1.4mm), improved jaw relationships (ANB -1.6°, Wits -1.4mm), increased ramus height (+2.3mm), decreased saddle angle (-1.6°) and gonial angle (-1.7°), counter clockwise rotation of the palatal plane (SN-PP -1.4°), proclination (L1-NB +2.6°, L1-MPA +2.8°) and protrusion (L1-NB +0.9mm) of the lower incisors, and distalization of the maxillary first molar (U6-PTV -1.5mm). Non-statistically significant changes were found for the following cephalometric measurements: mandibular body and corpus lengths, mandibular plane angle, lower anterior facial height, upper incisor angulation, and interincisal angle.

4.3.2 Net Phase 2 Treatment Effects vs. Growth Forecast (T2-T1)

The statistically significant (P<0.05) net phase 2 treatment effects were a further decrease in overjet (-1.8mm) and overbite (-1.5mm), increased functional occlusal plane angle (+2.4°), and proclination (L1-NB +3.9°, L1-MPA +4.5°) and protrusion (L1-NB +3.9mm) of the lower incisors. Non-statistically significant changes were found for the following cephalometric measurements: jaw base relationships, mandibular body and corpus lengths, mandibular ramus height, saddle angle, gongial angle, mandibular plane angle, lower anterior facial height, palatal plane angle relative to the cranial base, upper incisor angulation and sagittal position, interincisal angle, and maxillary first molar sagittal position.

4.3.3 Net Total Treatment Effects vs. Growth Forecast (T2-T0)

The statistically significant (P<0.05) net treatment effects were a reduction in overjet (-5.9mm) and overbite (-3.1mm), restraint of maxillary anterior growth (A-NPerp -1.2mm), increased mandibular anterior growth (SNB +0.9°, Pog-NPerp +1.9mm), improved jaw base relationships (ANB -1.7°, Wits -3.0mm), increased ramus height (+3.7mm), decreased saddle angle (-2.8°) and gonial angle (-3.6°), counter clockwise rotation of the mandible (-2.0°) and palatal plane (SN-PP -1.5°), and proclination (L1-NB +7.2°, L1-MPA +8.4°) and protrusion (L1-NB +2.0mm) of the lower incisors. The clinically valuable treatment effects included the reduction in overjet (-5.9mm), overbite (-3.1mm), and Wits appraisal (-3.0mm), and lower incisor proclination (L1-NB +7.2°, L1-MPA +8.4°). Non-statistically significant changes were found for the following cephalometric measurements: mandibular body length, functional occlusal plane angle, lower anterior facial height, upper incisor angulation, and maxillary first molar sagittal position.

4.4 Reliability

The statistical package SAS 9.3 was used for all statistical analyses. The reliability of the cephalometric measurements were tested by investigating the errors in locating, superimposing, and measuring the changes of all landmarks. A sample size calculation was performed; to detect a mean square difference in the treatment and control groups of 2°, a sample size of 29 cases will be required from each treatment and control group with a significance level of 0.05 and 80% power. A sample size calculation was performed to determine the maximum number of patients required to determine the intra and inter-rater reliability. A maximum of 11 patients was required from each treatment and control group with a significance level of 0.05 and 80% power to have at least a 0.7 correlation between the two raters. Pretreatment (T0) and post treatment (T2) lateral cephalometric radiographs of 11 randomly selected patients from the treatment and control groups were retraced by a second operator (Virginie Provencal) and the principal investigator (Matthew Kotyk) at minimum 4 weeks after the initial tracing and analyzed to evaluate errors.

For all cephalometric variables, differences between the measurements recorded at the first and second tracings were compared for each subject before treatment and after the second phase of treatment. For intra-rater and inter-rater reliability, the Intraclass Correlation Coefficient test (ICC) values, which range from 0 (no agreement) to 1 (perfect agreement), were used to test the reliability of the two raters. ICC values between 0.75 and 1.00 are considered to be in excellent agreement, between 0.60 and 0.74 are considered to be in good agreement, between 0.40 and 0.59 are considered to be in fair agreement and less than 0.40 are considered to be in poor agreement.

4.4.1 Intra-rater Reliability

The intra-rater results showed a high consistency in the repeated measurements as shown in Table 8. All ICC values were greater or equal to 0.831 (average 0.929). Based on these results we are confident that the reproducibility of the cephalometric radiograph measurements are reliable within the 4 week time lapse period.

Table 8. Intraclass Correlation Coefficient (ICC) values for intra-rater and inter-rater reliability

	Intra-rater Reliability	**Inter-rater Reliability**
Variable	**Intraclass Correlation Coefficient**	**Intraclass Correlation Coefficient**
Overjet (mm)	0.987	0.997
Overbite (mm)	0.911	0.993
SN-FH (°)	0.934	0.997
SNA (°)	0.953	0.991
SNB (°)	0.981	0.994
ANB (°)	0.934	0.971
Wits (mm)	0.956	0.959
Harvold Mx (mm)	0.979	0.992
Harvold Md (mm)	0.938	0.997
Harvold Diff (mm)	0.885	0.986
Md Body Length (mm)	0.864	0.972
Md Corpus Length (mm)	0.893	0.977

Md Ramus Height (mm)	0.960	0.988
Facial Angle (°)	0.954	0.994
Convexity (mm)	0.972	0.981
A-NPerp (mm)	0.973	0.992
Pog-NPerp (mm)	0.971	0.994
Saddle Angle (°)	0.949	0.981
Gonial Angle (°)	0.935	0.961
MPA (°)	0.955	0.993
FMA (°)	0.990	0.990
FOP (°)	0.959	0.976
Y-Axis (°)	0.950	0.997
LFH (mm)	0.886	0.995
SN-PP (°)	0.900	0.983
PP-MP (°)	0.888	0.991
U1-SN (°)	0.863	0.997
U1-PP (°)	0.880	0.997
U1-NA (°)	0.831	0.997
U1-NA (mm)	0.858	0.983
U1-APog (°)	0.871	0.995
U1-APog (mm)	0.903	0.993
L1-NB (°)	0.963	0.994
L1-NB (mm)	0.950	0.993
L1-APog (°)	0.949	0.989
L1-APog (mm)	0.916	0.992
L1-MPA (°)	0.987	0.992
U1-L1 (°)	0.866	0.997
Pog-NB (mm)	0.967	0.986
U6-PTV (mm)	0.880	0.992

4.4.2 Inter-rater Reliability

The inter-rater results showed a high consistency in the repeated measurements as shown in Table 8. All ICC values were greater or equal to 0.959 (average 0.988). Based on these results we are confident that the reproducibility of the cephalometric radiograph measurements are reliable within the 4 week time lapse period.

CHAPTER 5

DISCUSSION

5.1 Discussion

In this retrospective study, a treatment group of consecutively treated growing patients with Class II malocclusions were treated with a first phase of vBHGA[1] treatment followed by a second phase of comprehensive fixed orthodontic appliance treatment. All the subjects in the treatment group had fair to good compliance with the vBHGA as documented in the subjects' treatment charts. A control group of matched untreated subjects from the archives of the Burlington Growth Centre and lateral profile growth forecast simulations constructed from the pre-treatment (T0) lateral cephalometric radiographs of the treatment group were used as controls. In this study, cephalometric analysis consisted of both linear and angular cephalometric variables. To differentiate growth changes from treatment changes, the mean difference of each control group was separately subtracted from the mean difference of the treatment group between the time points for each cephalometric variable. This removed changes in the cephalometric variables due to growth and revealed the cephalometric changes from orthodontic treatment.

The first vBHGA treatment phase had a mean duration of 10 months and a median duration of 9 months. This was beneficial as previous experimental results[2] in a rat model showed that premature completion of the functional appliance treatment prevents maturation of newly formed condylar bone and less bone is preserved, conversely extended functional appliance use allows maturation of newly formed condylar bone.

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The cephalometric changes observed in the treatment group after the first vBHGA treatment phase were consistent with findings in previous studies[3–5] including: reduction in overjet,[3–5] overbite,[3,4] restraint of maxillary anterior growth,[3–5] increased mandibular anterior growth,[3–5] improved jaw base and dental (including Angle molar classification) relationships,[3–5] increased mandibular lengths,[4] increased lower anterior facial height,[4] retroclination[3] and retraction[4,5] of the upper incisors, and minor proclination[3] and protrusion[5] of the lower incisors. Counter clockwise rotation of the palatal plane was observed in this study while no rotational change in the palatal plane[4] or clockwise rotation[3] were reported in previous investigations. This could be due to the manipulation of the extra oral force superior and anterior to the center of resistance of the maxilla. Additionally, minor mesialization of the maxillary first molar was observed in this study while minor distalization was observed in previous studies.[3–5] These findings are consistent with the vBHGA appliance design and the differential mandibular growth expected in growing adolescent patients.

The cephalometric changes observed in the treatment group during the second phase of treatment included mostly dental changes with minor skeletal changes; this was expected from fixed orthodontic appliance treatment and the differential mandibular growth in growing adolescent patients.

The cephalometric changes in the treatment group were consistent with the findings of the only other previous study[1] that examined patients after completion of both treatment phases including: reduction in overjet, improved jaw base relationship, increased mandibular length, increased lower anterior facial height, upper incisor retroclination, lower incisor proclination, and no change in occlusal plane angle. Counter clockwise rotation of the palatal plane was observed in this study and in a minority of cases in a previous study.[1] These findings are consistent with the vBHGA appliance design and fixed orthodontic appliance treatment with the differential mandibular growth expected in growing adolescent patients.

The net treatment effects observed in this study (relative to both the control and growth forecast groups) after the first vBHGA treatment phase were consistent with findings in previous studies[4,6,7] including: reduction in overjet,[4,6,7] overbite,[4,7] restraint of maxillary anterior growth,[4,6,7] increased mandibular anterior growth,[6] improved jaw base relationships,[4,7] retroclination[6] and retraction[7] of the upper incisors, and distalization of the maxillary first molar.[4] Proclination[6] and protrusion[4,7] of the lower incisors was observed in this and previous studies, however the proclination[6] and protrusion[4] were not found to be statistically significant in some of the previous investigations. Net upper incisor retroclination and lower incisor proclination was observed despite acrylic coverage of the labial surfaces of the upper and lower incisors; nevertheless, the magnitude of incisor inclination change would likely have been greater than that observed with less incisor acrylic coverage as observed in previous studies.[3] A non-statistically significant increase in functional occlusal plane angle was observed in this study while a statistically significant increase was found in a previous investigation.[7] Furthermore, a non-statistically significant increase in lower anterior facial height was observed in this study and one previous investigation[4] while a statistically significant increase was found in another earlier study.[7] More statistically significant net phase 1 skeletal treatment effects were observed relative to the control group compared to the growth forecast group, specifically restraint of maxillary anterior growth, increased mandibular anterior growth, and increased mandibular corpus length and ramus height.

The net treatment effects observed in this study (relative to both the control and growth forecast groups) during the second treatment phase consisted primarily of dental changes with minor skeletal changes; this was expected from fixed orthodontic appliance treatment. Although minor, more statistically significant net phase 2 skeletal treatment effects were observed relative to the control group compared to the growth forecast group, specifically continued restraint of maxillary anterior growth and increased lower anterior facial height.

The net total treatment effects observed in this study (relative to both the control and growth forecast groups) after the completion of both treatment phases included improved jaw base and dental relationships from a combination of both skeletal and dental treatment effects. These consisted of reduced overjet, overbite, restrained maxillary anterior growth, increased mandibular anterior growth, a significantly decreased Wits appraisal, increased ramus height, counter clockwise palatal plane rotation, retroclination and retraction of the upper incisors and proclination and protrusion of the lower incisors. While the net skeletal changes were minimal in the second phase of treatment, the net skeletal changes observed in the first treatment phase were maintained to the end of the second phase of treatment. This is in stark contrast to previous randomized clinical trials[8–28] which reported phase 1 treatment skeletal changes were not maintained by the end of phase 2 treatment. Possible explanations for the retained phase 1 skeletal treatment effects in this study likely originate from the level of compliance with the phase 1 vBHGA appliance (patients with poor compliance were excluded) and the timing of treatment; patients in this study were treated based on the timing of their individual peak growth spurts, the length of phase 1 treatment was individualized to each patient and their response to treatment, and the vBHGA appliance was used as a retainer between phases if initiation of the second treatment phase was delayed while waiting for eruption of all the permanent teeth. Intriguingly, the statistically significant net total skeletal treatment effects relative to the control group and the growth forecast group were similar, for instance: restraint of maxillary anterior growth, increased mandibular anterior growth, improved jaw base relationships, increased mandibular ramus height, and counter clockwise palatal plane rotation. The difference in net skeletal treatment effects between the control and growth forecast groups may have been due to the matched control group having a skeletal Class II (mandibular retrognathic) growth pattern while the Ricketts norms that were used to construct the lateral profile growth forecast simulations were based on a skeletal Class I growth pattern with more mandibular growth.

The observed increase in both overjet (mean = 1.4mm) and overbite (mean = 1.6mm) in the retention period is minor and not unexpected, especially given the extended length (mean = 6.7 year, median = 6.3 years) of the retention period. The magnitude of relapse was likely highly dependent on each individual patient's retainer wear compliance. However, the small amount of relapse in both overjet and overbite indicates that the skeletal changes produced in the first phase vBHGA treatment are highly stable long term.

Clinically recognizable net changes (Table 6) were noted between the treatment and control groups including reduction in overjet (-4.4mm after phase 1 and -6.4mm after phase 2) and overbite (-2.8mm after phase 2), upper incisor retroclination (U1-SN -3.3° after phase 1 and –4.3° after phase 2; U1-NA -2.5° after phase 1 and -3.2° after phase 2), lower incisor proclination (L1-NB +9.0° after phase 2; L1-MPA +7.4° after phase 2), as well as significant improvement in the Wits appraisal (-5.4mm after phase 2).

5.2 Error In The Study

The ability of this study to accurately and precisely reveal treatment changes and net treatment effects is determined by exact cephalometric landmark identification and obtaining cephalometric radiographs of high quality. Error in landmark identification caused by poor cephalometric radiograph quality and individual anatomic variation was a potential source of error in this study. Some cephalometric landmarks are more difficult than others to identify resulting in possible discrepancies in some cephalometric measurements.[29–31] The intra-rater and inter-rater reliability analysis suggested that there was a high level of reliability for all the cephalometric measurements.

The different sample populations may introduce selection bias; the treatment group was selected from graduate orthodontic program in a city that is ethnically diverse while the historical control group subjects were of Northern European descent. The type and severity of malocclusions have been shown to vary depending on the individual's ethnic background.[32] While the lateral profile growth forecast simulations constructed from the treatment groups' pre-treatment cephalometric radiographs were used, the Ricketts growth norms were based on a normal Class I skeletal growth pattern. Furthermore, while this study excluded subjects with poor vBHGA appliance compliance, the response to treatment even in compliant patients may vary.[5] These factors affect the capability of the findings of this study to be extrapolated to the global population.

5.3 Future Studies

The development of ultra low dose 3D cone beam computed tomography (CBCT) and 3D analysis software allowing volumetric measurements and superimpositions provides the potential for intriguing future research. CBCT scans taken 6 months prior to the start of treatment, prior to initiation of phase 1 treatment, after phase 1 treatment, after phase 2 treatment, and 6 months after the completion of phase 2 treatment could be taken for each subject. This would allow for the measurement of each individual subject's growth and allow each subject to serve as their own control by extrapolating their individual growth rates between time points. Furthermore, radiographic landmark identification issues could be reduced and 3D volumetric skeletal, dental, and airway measurements could be analyzed providing valuable insight into net treatment effects. This would provide orthodontists with clear evidence regarding the value of two phase orthopedic treatment with functional appliances when making treatment decisions.

5.4 Revisiting The Null Hypotheses

The null hypotheses for this study were:

1. There are no statistically significant differences in the skeletal parameters following vBHGA treatment and full fixed orthodontic appliance treatment compared to both a matched untreated control group and growth forecast simulations. This first hypothesis was rejected. Statistically significant mean skeletal changes from improved jaw base relationships and palatal plane rotation were observed.
2. There are no statistically significant differences in the dental parameters following vBHGA treatment and full fixed orthodontic appliance treatment compared to both a matched untreated control group and growth forecast simulations. This second hypothesis was rejected. Statistically significant mean dental changes from decreased overjet, overbite, and proclination and protraction of the lower incisors were observed.
3. There are no statistically significant differences in the skeletal parameters following vBHGA treatment compared to both a matched untreated control group and growth forecast simulations. This third hypothesis was rejected. Statistically significant mean skeletal changes from improved jaw base relationships and palatal plane rotation were observed.

4. There are no statistically significant differences in the dental parameters following vBHGA treatment compared to both a matched untreated control group and growth forecast simulations. This fourth hypothesis was rejected. Statistically significant mean dental changes from decreased overjet, overbite, proclination and protraction of the lower incisors, and distalization of the maxillary first molar were observed.

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CHAPTER 6

CONCLUSIONS

6.1 Conclusions

The conclusions from this study are:

1. The vBHGA appliance is an effective Class II treatment modality in compliant growing patients.

2. Skeletal and dental Class II correction with phase 1 vBHGA appliance treatment consisted of favourable skeletal and dental net treatment effects in growing patients.

3. vBHGA appliance treatment resulted in 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.

4. Favourable skeletal and dental changes from phase 1 treatment were maintained after the completion of the second phase of treatment, in stark contrast to published randomized clinical trials.

5. Minor relapse in both overjet and overbite was observed in the retention period indicating the skeletal changes produced in phase 1 vBHGA treatment are highly stable long term.

6. Success with the vBHGA and potentially other growth modification appliances could be related to patient compliance, timing of the individual's growth spurt, length of phase 1 treatment, and continued orthopedic retention between the first and second phases of treatment.

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JOURNAL ARTICLE

Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances

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ABSTRACT

Introduction: Class II malocclusions in children originate from deficient anterior mandibular growth and/or excessive anterior maxillary growth with treatment consisting of either a single phase of full fixed orthodontic appliance treatment or a first phase of functional appliance treatment followed by a second treatment phase with full fixed orthodontic appliances. The aim of this study was to assess the dental and skeletal treatment and growth changes in growing patients with Class II malocclusions treated with the van Beek Headgear Activator (vBHGA) appliance in phase 1 followed by phase 2 comprehensive fixed orthodontic appliance treatment.

Materials and Methods: A retrospective chart review was undertaken and compared to matched untreated control subjects from the Burlington Growth Study. Lateral cephalometric radiographs were used to determine dental, skeletal and growth changes between each treatment phase.

Results: Phase 1 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 favourable skeletal and dental changes from vBHGA treatment were maintained after the completion of the second treatment phase.

Conclusions: The vBHGA appliance was effective in correcting Class II malocclusions by producing favourable skeletal and dental treatment effects in both jaws that were maintained after the completion of phase 2 treatment, in stark contrast to published randomized clinical trials. Success with the vBHGA and potentially other growth modification appliances could be related to patient compliance, timing of the individual's growth spurt, length of phase 1 treatment, and continued orthopedic retention between the first and second phases of treatment.

INTRODUCTION

Class II malocclusions in children originate from deficient anterior mandibular growth and/or excessive anterior maxillary growth which often results in significant skeletal abnormalities. Treatment consists of either a single phase of full fixed orthodontic appliance treatment or a first phase of treatment with various types of removable or fixed functional appliances normally followed by a second phase with full fixed appliances. However, the value and timing of two phase orthopedic treatment with functional appliances, has been a subject of intense controversy in the literature.[1–4] Nonetheless, many studies suggest that functional appliances can be effective in correcting skeletal Class II discrepancies by restraining maxillary growth, promoting growth of the mandible with inter alia glenoid fossa remodeling, or a combination of both.[5–13] Furthermore, facial appearance has a significant effect on an individual's social status, attractive children compared to their unattractive counterparts are seen by others as making more favourable first impressions, having a higher level of intelligence, being more socially attractive with more positive social behaviour, and receiving more positive treatment.[14,15] Nevertheless, the literature evidence regarding the psychosocial benefits of orthodontic treatment is inconclusive.[19]

Many studies comparing two phase orthopedic treatment to single phase treatment for Class II malocclusions have been published.[20,21] Of these studies, a recent Cochrane systematic review[20,21] found the highest quality of evidence originated from three large-scale randomized clinical trials reported in several articles from Florida,[1,3,22–26] North Carolina,[2,27–35] and the United Kingdom.[4,36–38]

The Florida study,[1,3,22–26] a prospective longitudinal randomized clinical trial with 261 subjects, concluded that both Bionator and headgear/biteplane appliances reduced the severity of the Class II skeletal discrepancy at the end of phase 1 treatment. However, upon completion of phase 2, the skeletal measurements for all 3 groups (two treatment and one control group) were within 1º, thus the authors concluded that there was no detectable skeletal difference between 1-phase and 2-phase treatment by the end of full orthodontic treatment.

The North Carolina study,[2,27–35] a randomized clinical trial, reported that phase 1 treatment (either headgear or Bionator appliances) improved skeletal and dental characteristics in approximately 80% of patients relative to the untreated control group. However, the authors report that during phase 2 treatment the progress made during the phase 1 treatment in the headgear and bionator groups was lost and by the end of phase 2 there was no significant difference between the 2 treatment groups and the control group.

The United Kingdom study,[4,36–38] a multicenter randomized clinical trial, reported that after 15 months of phase 1 (Twin-block appliance) treatment, the treatment group group showed a reduction in overjet, correction of molar relationships, and a reduction in the severity of the malocclusion via a reduced PAR score. Nevertheless, after the completion of phase 2 treatment, the authors concluded that both groups displayed no differences in skeletal pattern and extraction rates.

The conclusions from the Cochrane systematic review[20,21] were that early treatment resulted in a reduction in incisal trauma by 33% to 41% with no other long-term advantages to providing 2-

phase treatment compared to 1-phase treatment in early adolescence. Nonetheless, short-term improvement in the severity of the malocclusion were observed in a majority of patients.

The van Beek headgear activator (vBHGA) was first described in 1982 by van Beek[39] and was found to be effective at correcting Class II malocclusions with control of the vertical dimension, after establishing a Class I malocclusion fixed appliances were used if necessary. Overjet reduction was primarily achieved by retroclination of the upper incisors, proclination of the lower incisors, and a significant increase in mandibular length which was noted in many, but not all patients.

In 1992, Dermaut and coworkers[40] evaluated the vBHGA dental and skeletal effects in severe Class II malocclusions and compared treatment changes to two different control groups. The vBHGA was found to be an effective treatment modality to correct Class II Division 1 malocclusions. Treatment effects included minor growth stimulation of the mandible, no maxillary orthopedic effect, vertical control of the lower anterior facial height in subjects with hyperdivergent skeletal patterns, decreased overjet and overbite by means of intrusion and retroclination of the upper incisors.

In 2002, Rabie and coworkers published the first[8] of five[8,9,11,41,42] investigations into growth and treatment effects of vBHGA treatment. Rabie concluded[8] that the vBHGA 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 sagittal mandibular growth. Rabie and coworkers then compared[9] the treatment effects of the vBHGA from the same subject group to the Herbst appliance followed by the Andresen activator (HAA) and concluded that maxillary prognathism decreased with vBHGA treatment while mandibular prognathism increased with HAA treatment. Furthermore, the same vBHGA subject group was evenly divided into good responders and bad responders based on overjet reduction.[41] While no significant dental movements were observed in the bad responders, the good responders displayed significant posterior development of condylion, maxillary incisor retrusion, maxillary molar distalization, mandibular incisor protrusion, and mandibular molar protrusion.[41]

Subsequently, Rabie and coworkers investigated the effect of stepwise advancement compared to maximum jumping with the vBHGA in patients with skeletal Class II malocclusions.[11,42] Both groups displayed a reduction in overjet and overbite, increased mandibular prognathism and lower facial height, increased mandibular plane angle, mandibular molar eruption, improved jaw base and molar relationships, and restraint of maxillary forward growth. While the mandibular incisors were unaffected in the stepwise advancement group, they protruded significantly in the maximum jumping group. Additionally, the stepwise advancement group showed a significantly more pronounced reduction in overbite, improvement in jaw base (ANB) and molar relationship. The skeletal contribution of the overjet reduction at the end of treatment was 70% in the stepwise advancement group and 59% in the maximum jumping group. The authors concluded that both modes of mandibular jumping enhanced mandibular growth with extended treatment time (orthopedic retention) being a crucial factor in maintaining the treatment effect.[11] Rabie and coworkers then compared the previous two treatment groups to a group treated with a headgear-Herbst appliance with stepwise advancement and a matched control group.[42] While all three treatment groups demonstrated enhanced posterior and superior condylar growth after treatment, both vBHGA groups had more superior than posterior condylar growth and the vBHGA stepwise advancement group had a significantly greater effect on superior condylar growth than both other treatment groups.

The purpose of this study was to retrospectively assess the long term dental and skeletal treatment effects and growth changes in growing patients with Class II malocclusions treated with the vBHGA appliance, followed by full fixed orthodontic treatment to evaluate whether our cohort of patients maintained the first phase orthopedic changes, which has been disputed by several randomized clinical trials.

MATERIALS AND METHODS

The treatment group included growing patients with Class II malocclusions treated consecutively in the University of Manitoba Graduate Orthodontic Clinic in Canada, with a first phase of van Beek Headgear Activator (vBHGA) treatment in the late mixed to early permanent dentition under the supervision of one instructor (Dr. W.A. Wiltshire) followed by a second phase of comprehensive fixed orthodontic appliance treatment. If initiation of the second treatment phase was delayed while waiting for eruption of all the permanent teeth, patients were instructed to wear the vBHGA appliance at night time without the headgear strap until the start of the second treatment phase. The vBHGA appliance was prescribed when indicated during peak height velocity (PHV) for each individual patient. A construction wax bite was first fabricated to be approximately 8 to 10mm in height and with a minimum of 6mm of mandibular protrusion. Patients were fitted with a high pull headgear strap adjusted to 8 ounces (approximately 250 grams) of force per side for the first month of appliance wear to allow the patient to adjust to the appliance followed by an increase to 16 ounces (approximately 500 grams) of force per side after the first month of appliance wear. Patients were instructed to wear the appliance 12 to 14 hours per day, starting from after dinner and throughout the night, 7 days per week. Patient compliance, appliance fit and headgear force levels were checked at each appointment and adjusted as needed. The subjects were selected using the following inclusion criteria:

(1) Class II malocclusion with overjet greater than 4.5mm.

(2) Fair to good compliance with the vBHGA as documented in the subjects' treatment charts.

(3) No craniofacial anomalies.

Subjects were divided into groups based on having completed the first phase of vBHGA treatment with a progress (T1) lateral cephalometric radiograph taken and having completed the second phase of treatment with comprehensive fixed orthodontic appliances with a post-treatment (T2) lateral cephalometric radiograph taken.

The control group consisted of untreated subjects with Class II malocclusions chosen from the archives of the Burlington Growth Centre that was established in 1952 at the University of Toronto, Ontario, Canada. They were matched in gender, age, and craniofacial morphology with the treatment subjects. Each subject had a complete set of orthodontic records taken at 9, 12, 14, and 16 years of age. The records included a lateral cephalometric radiograph, set of plaster models, and medical and dental histories. All the subjects were of Northern European descent and at the beginning of the study, were living in the small town of Burlington, part of the Greater Toronto Area, Ontario, Canada.

Lateral cephalometric radiographs were taken in maximum intercuspation at pretreatment (T0), after vBHGA treatment (T1), and post treatment (T2) and digitally traced and analyzed. The reliability of the cephalometric measurements was tested by investigating the errors in locating, superimposing, and measuring the changes of all landmarks. A sample size calculation was performed to determine the maximum number of patients required to determine the intra and inter-rater reliability. Pretreatment (T0) and post treatment (T2) lateral cephalometric radiographs of 11 randomly selected patients from the treatment and control groups were retraced by a second operator and the principal investigator at minimum 4 weeks after the initial tracing and analyzed to evaluate errors. For all cephalometric variables, differences between the measurements recorded at the first and second tracings were compared for each subject before treatment and after the second phase of treatment.

Statistical analysis

The statistical package SAS 9.3 was used for all analyses. T-test was used to see difference between means and regression analysis was used to see difference between condition and treatment by taking account the correlation between individual over the time. R-square and F-test were used to validate each regression model. A sample size calculation was performed; to detect a mean square difference in the treatment and control groups of 2°, a sample size of 29 cases was required from each treatment and control group with a significance level of 0.05 and 80% power. Another sample size calculation was performed to determine the intra and inter-rater reliability; a maximum of 11 patients was required from each of the treatment and control groups with a significance level of 0.05 and 80% power to have at least a 0.7 correlation between the two raters.

RESULTS

The final sample group that met the inclusion criteria was comprised of 40 subjects (20 females, 20 males), all of which completed the first phase of vBHGA treatment. The 17 subjects who did not meet the inclusion criteria were excluded due to poor compliance wearing the vBHGA appliance as documented in the subjects' treatment charts. At the time of the pre-treatment (T0) lateral cephalometric radiographs, the subjects' ages and CVM stages are listed in Table I, and varied between 8-15 years and stages 1-4. Total treatment was completed in an average of 32 months, of which, the average vBHGA treatment lasted 10 months and the average comprehensive fixed orthodontic appliance treatment lasted 22 months.

One of the subjects was satisfied with the result of vBHGA treatment and declined further treatment. One subject accepted combined orthognathic surgical orthodontic treatment in the second treatment phase. This subject's pre-surgical lateral cephalometric radiograph was used as the post-treatment (T2) radiograph to assess their skeletal cephalometric parameters, but the subject's T2 dental parameters were not included in the group analysis. One subject had congenitally missing mandibular second premolars with retained mandibular primary second molars and the retained primary molars and upper second premolars were extracted in their second treatment phase. This subject's T2 dental cephalometric parameters were not included in the group analysis. The remaining 37 subjects underwent non-surgical, non-extraction treatment with fixed orthodontic appliances in the second treatment phase. Of the 40 subjects, 33 subjects

(17 females, 16 males) had records taken after vBHGA treatment (T1), 34 subjects (17 females, 17 males) had completed the second phase of treatment and had post-treatment records taken (T2). The treatment group had approximately equal numbers of female and male subjects at all time points and the entire sample was therefore considered to be gender neutral. The treatment and control groups' mean cephalometric values at the three time points and the mean differences between each time point are shown in Table II.

Treatment Group Changes

During phase 1 (vBHGA appliance treatment) the treatment group showed a decrease in overjet (-4.4mm) and overbite (-1.3mm), restraint of maxillary anterior growth (SNA -0.8°, A-NPerp -1.0mm), increased mandibular anterior growth (SNB +1.1°, Pog-NPerp +1.6mm), improvement of jaw base relationships (ANB -1.9°, Wits -2.1mm), increased mandibular lengths (body +3.1mm, corpus +3.0mm) and ramus height (+3.6mm), slight counter clockwise rotation of the mandible (MPA -0.5°), counter clockwise rotation of the palatal plane (SN-PP -1.9°), increased lower anterior facial height (+2.4mm), retroclination (U1-SN -2.5°) and retraction (U1-NA -0.8mm) of the upper incisors, and slight proclination (L1-MPA +2.1°) and protrusion (L1-NB +1.0mm) of the lower incisors.

During phase 2 (full fixed appliance treatment) the treatment group showed a further decrease in overjet (-1.7mm) and overbite (-1.9mm), slight improvement of jaw base relationships (ANB -0.4°, Wits -2.3mm), increased mandibular lengths (body +1.5mm, corpus +1.8mm) and ramus height (+2.3mm), further increase in lower anterior facial height (+3.4mm), minimal change in the upper incisor angulation (U1-SN +0.1°), and further proclination (L1-MPA +4.0°) of the lower incisors.

Over both phases of treatment, the treatment group showed a decrease in overjet (-5.9mm) and overbite (-3.5mm), restraint of maxillary anterior growth (SNA -0.9°, A-NPerp -1.2mm), increased mandibular anterior growth (SNB +1.4°, Pog-NPerp +2.0mm), improvement of jaw base relationships (ANB -2.3°, Wits -4.2mm), increased mandibular lengths (body +4.8mm, corpus +5.0mm) and ramus height (+6.3mm), slight counter clockwise rotation of the mandible (MPA -0.5°), counter clockwise rotation of the palatal plane (SN-PP -1.7°), increased lower anterior facial height (+5.8mm), retroclination (U1-SN -1.3°) and retraction (U1-NA -0.9mm) of the upper incisors, and proclination (L1-MPA +7.0°) and protrusion (L1-NB +2.1mm) of the lower incisors.

Net Treatment Effects

The net treatment effects (the treatment group mean difference minus the control group mean difference) between each time point is shown in Table III. The statistically significant ($P<0.05$) net phase 1 vBHGA treatment effects were a reduction in overjet (-4.4mm), overbite (-1.0mm), restraint of maxillary anterior growth (SNA -0.8°), increased mandibular anterior growth (SNB +0.9°, Harvold Md +2.6mm, Pog-NPerp +1.6mm), improved jaw base relationships (ANB -1.6°, Wits -2.6mm), increased mandibular corpus length (+1.3mm) and ramus height (+1.7mm), counter clockwise rotation of the palatal plane (SN-PP -2.2°), retroclination (U1-SN -3.3°) and retraction (U1-NA -1.5mm) of the upper incisors, proclination (L1-MPA +1.7°) and protrusion

(L1-NB +0.6mm) of the lower incisors, and distalization of the maxillary first molar (U6-PTV -1.2mm).

The statistically significant net phase 2 treatment effects were a further decrease in overjet (-2.0mm) and overbite (-1.4mm), continued restraint of maxillary anterior growth (SNA -0.7°), increased gonial angle (+2.3°), mandibular plane angle (+1.6°), and functional occlusal plane angle (+4.7°), increased lower anterior facial height (+1.4mm), and proclination (L1-MPA +4.1°) and protrusion (L1-NB +1.2mm) of the lower incisors.

The statistically significant net total treatment effects were a reduction in overjet (-6.4mm) and overbite (-2.8mm), restraint of maxillary anterior growth (SNA -0.9°), increased mandibular anterior growth (SNB +0.7°, Harvold Md +2.7mm, Pog-NPerp +2.2mm), improved jaw base relationships (ANB -1.6°, Wits -5.4mm), increased mandibular ramus height (+1.5mm), increased gonial angle (+2.2°), mandibular plane angle (+1.1°), and functional occlusal plane angle (+4.9°), increased lower anterior facial height (+2.2mm), counter clockwise palatal plane rotation (SN-PP -2.1°), retroclination (U1-SN -4.3°) and retraction (U1-NA -2.4mm) of the upper incisors, and proclination (L1-MPA +7.4°) and protrusion (L1-NB +1.9mm) of the lower incisors. Clinically important net changes which manifested at T2 were: overjet reduction, overbite reduction, upper incisor retroclination and retraction, and lower incisor proclination and protrusion.

DISCUSSION

In this retrospective study, a treatment group of consecutively treated growing patients with Class II malocclusions was treated with a first phase of vBHGA[39] treatment followed by a second phase of comprehensive fixed orthodontic appliance treatment. All the subjects in the treatment group had fair to good compliance with the vBHGA as documented in the subjects' treatment charts. A control group of matched untreated subjects from the archives of the Burlington Growth Centre was used as controls. In this study, cephalometric analysis consisted of both linear and angular cephalometric variables. To differentiate growth changes from treatment changes the mean difference of each control group was separately subtracted from the mean difference of the treatment group between the time points for each cephalometric variable. This removed changes in the cephalometric variables due to growth and revealed the cephalometric changes from orthodontic treatment.

The cephalometric changes observed in the treatment group after the first vBHGA treatment phase were consistent with findings in previous studies[8,41,43] including: reduction in overjet,[8,41,43] overbite,[8,43] restraint of maxillary anterior growth,[8,41,43] increased mandibular anterior growth,[8,41,43] improved jaw base and dental relationships,[8,41,43] increased mandibular lengths,[8] increased lower anterior facial height,[8] retroclination[43] and retraction[8,41] of the upper incisors, and minor proclination[43] and protrusion[41] of the lower incisors. Counter clockwise rotation of the palatal plane was observed in this study while no rotational change in the palatal plane[8] or clockwise rotation[43] were reported in previous investigations. This could be due to the manipulation of the extra oral force superior and anterior to the center of resistance of the maxilla. Additionally, minor mesialization of the maxillary first molar was observed in this study while minor distalization was observed in previous studies.[8,41,43] The cephalometric changes observed in the treatment group during the second phase of treatment included mostly dental changes with minor skeletal changes. The cephalometric changes in the treatment group were consistent with the findings of the only other previous study[39] that examined patients after completion of both treatment phases including: reduction in overjet, improved jaw base relationship, increased mandibular length, increased lower anterior facial height, upper incisor retroclination, lower incisor proclination, and no change in occlusal plane angle. Counter clockwise rotation of the palatal plane was observed in this study and in a minority of cases in a previous study.[39] These findings are consistent with a first phase of vBHGA appliance treatment followed by a second phase of fixed orthodontic appliance treatment in a growing adolescent patient undergoing differential mandibular growth.

The net treatment effects observed in this study (relative to the control group) after the first vBHGA treatment phase were consistent with findings in previous studies[8,9,40] including: reduction in overjet,[8,9,40] overbite,[8,9] restraint of maxillary anterior growth,[8,9,40] increased mandibular anterior growth,[40] improved jaw base relationships,[8,9] retroclination[40] and retraction[9] of the upper incisors, and distalization of the maxillary first molar.[8] Proclination[40] and protrusion[8,9] of the lower incisors was observed in this and previous studies, however the proclination[40] and protrusion[8] were not found to be statistically significant in some of the previous investigations. Net upper incisor retroclination and lower incisor proclination was observed despite acrylic coverage of the labial surfaces of the upper and lower incisors; nevertheless, the magnitude of incisor inclination change would likely have been greater than that observed with less incisor acrylic coverage as observed in previous studies.[43] The net second phase treatment effects observed in this study consisted primarily of dental changes with minimal skeletal changes, as would be expected from fixed orthodontic appliance treatment. The dental changes included a further reduction in overjet, overbite, clockwise rotation of the functional occlusal plane, and proclination and protrusion of the lower incisors.

The net total treatment effects observed in this study included improved jaw base and dental relationships from a combination of both skeletal and dental treatment effects. These consisted of reduced overjet, overbite, restrained maxillary anterior growth, increased mandibular anterior growth, a significantly decreased Wits appraisal, increased ramus height, counter clockwise palatal plane rotation, retroclination and retraction of the upper incisors and proclination and protrusion of the lower incisors. While the net skeletal changes were minimal in the second phase of treatment, the net skeletal changes observed in the first treatment phase were maintained to the end of the second phase of treatment. This is in stark contrast with previous randomized clinical trials[1–4,22–38] which reported phase 1 treatment skeletal changes were not maintained by the end of phase 2 treatment. Possible explanations for the retained phase 1 skeletal treatment effects in this study likely originate from the level of compliance with the phase 1 vBHGA appliance (patients with poor compliance were excluded) and the timing of treatment; patients in this study were treated based on the timing of their individual peak growth spurts, the length of phase 1 treatment was individualized to each patient and their response to treatment, and the vBHGA appliance was used as a retainer between phases if initiation of the second treatment phase was delayed while waiting for eruption of all the permanent teeth.

CONCLUSIONS

The vBHGA appliance was found to be an effective Class II treatment modality in compliant growing patients. Phase 1 vBHGA treatment produced favourable skeletal and dental treatment effects in both jaws which were maintained after the completion of phase 2 treatment.

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TABLES

Table I. Age and CVM stage statistics at pre-treatment (T0)

	Mean	**SD**	**Median**	**Minimum**	**Maximum**
Age	11.8	1.3	11.8	8.7	15.1
CVM	2.3	0.8	2	1	4

SD=standard deviation

Table II. Comparison of treatment and control group cephalometric variables pre-treatment (T0, n=40), after the completion of the first treatment phase (T1, n=33), and after completion of the second treatment phase (T2, n=34).

	T0				**T1**				**T2**			
	vBHGA		**Control**		**vBHGA**		**Control**		**vBHGA**		**Control**	
Variables	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Overjet (mm)	9.1	2.6	5.6	2.5	4.9	2.1	5.3	2.4	3.3	1.5	5.9	2.3
Overbite (mm)	4.6	2.5	4.4	2.0	3.0	2.1	4.0	2.3	1.3	1.0	3.8	2.4
SN-FH (°)	10.0	2.5	6.7	3.1	10.1	2.5	6.2	4.1	9.7	2.8	5.5	3.5
SNA (°)	80.5	3.5	80.3	4.3	79.5	3.4	80.4	4.8	79.9	3.5	80.7	4.3
SNB (°)	74.9	2.9	75.3	3.7	75.8	3.2	75.8	4.1	76.5	3.3	76.5	3.8
ANB (°)	5.7	1.9	4.9	1.3	3.7	1.9	4.6	1.5	3.4	1.6	4.3	1.5
Wits (mm)	4.8	2.5	3.1	1.9	2.7	2.3	3.5	2.2	0.8	2.9	4.3	2.7
Harvold Mx (mm)	85.5	6.4	89.9	5.1	86.6	7.8	91.9	6.7	90.4	7.3	93.6	6.4
Harvold Md (mm)	102.4	7.7	107.4	7.6	107.6	9.2	111.0	8.9	112.9	8.4	114.0	9.0
Harvold Diff (mm)	16.9	3.4	17.5	3.9	21.0	3.9	19.1	4.3	22.5	3.7	20.4	4.4
Md Body Length (mm)	74.4	5.9	72.9	6.3	77.0	6.9	75.5	7.2	80.0	6.3	78.0	8.1
Md Corpus Length (mm)	63.9	5.4	63.6	5.2	66.4	6.3	65.7	5.6	69.6	5.5	68.1	6.1
Md Ramus Height (mm)	44.3	4.7	47.6	5.3	47.4	5.8	49.9	6.1	50.8	5.8	52.7	6.7
Facial Angle (°)	86.0	2.9	83.1	3.0	87.2	2.9	83.3	3.8	87.6	2.8	83.6	3.2
Convexity (mm)	4.4	2.3	3.7	1.6	2.4	2.5	3.5	1.8	2.0	2.4	2.8	1.6
A-NPerp (mm)	0.5	3.1	-3.1	3.3	-0.4	3.1	-3.5	4.3	-0.6	2.9	-3.9	4.0
Pog-NPerp (mm)	-7.4	5.4	-12.7	5.6	-5.2	5.5	-12.9	7.2	-5.0	5.8	-12.4	6.0
Saddle Angle (°)	124.4	4.9	125.1	4.8	124.2	4.6	124.9	5.1	123.7	4.4	125.0	5.3
Gonial Angle (°)	123.5	4.4	126.6	7.4	122.1	4.7	125.4	7.0	122.2	4.5	123.8	7.5
MPA (°)	33.3	5.4	32.9	5.5	32.9	6.2	32.5	6.0	32.2	6.0	30.6	5.7
FMA (°)	23.3	5.2	26.2	5.0	22.8	5.5	26.3	5.5	22.5	5.4	25.1	5.6

FOP (°)	16.2	4.5	17.4	4.1	15.3	5.2	16.0	4.4	17.4	4.9	13.6	3.6
Y-Axis (°)	68.9	4.1	68.3	3.8	68.6	4.4	68.5	4.0	68.5	4.6	67.7	3.7
LFH (mm)	63.4	4.7	63.1	5.2	65.7	5.4	65.2	5.9	69.3	6.5	66.2	6.1
SN-PP (°)	1.6	2.7	0.1	3.5	-0.5	2.8	0.2	3.8	-0.2	2.8	0.4	3.7
PP-MP (°)	24.6	4.9	26.5	6.0	26.3	5.7	26.1	5.9	25.3	5.2	23.9	6.0
U1-SN (°)	106.4	9.4	100.1	9.2	104.9	8.3	100.2	8.5	104.8	5.7	103.0	7.9
U1-PP (°)	114.9	8.9	107.2	8.9	111.4	7.7	107.4	8.4	111.5	4.3	110.5	7.6
U1-NA (°)	25.8	9.5	19.8	9.7	25.4	8.1	19.8	8.9	25.1	4.8	22.2	8.1
U1-NA (mm)	6.4	3.5	2.5	3.6	6.0	3.1	2.9	3.3	5.3	2.5	3.7	3.2
U1-APog (°)	35.3	9.5	27.9	8.9	30.4	7.4	27.1	7.9	29.0	4.8	27.9	7.4
U1-APog (mm)	10.1	3.6	5.7	3.6	8.1	3.4	5.8	3.3	7.0	3.1	6.0	3.0
L1-NB (°)	26.2	6.4	25.3	6.7	28.9	6.5	25.9	7.4	33.6	6.8	24.1	8.3
L1-NB (mm)	5.2	2.6	3.8	2.2	6.2	2.9	4.2	2.5	6.9	2.6	4.0	2.7
L1-APog (°)	22.4	5.4	22.1	6.0	27.6	5.0	23.2	6.3	33.0	5.4	22.6	7.6
L1-APog (mm)	0.8	2.8	0.0	2.4	3.1	3.0	0.3	2.7	3.7	2.9	0.1	3.1
L1-MPA (°)	98.0	6.2	97.1	6.6	100.1	6.1	97.6	7.3	105.2	6.1	97.0	8.4
U1-L1 (°)	122.3	11.8	130.0	12.6	122.1	10.2	129.7	11.1	118.0	7.6	129.4	10.9
Pog-NB (mm)	2.2	1.7	2.1	1.6	2.4	1.9	2.3	1.7	2.8	2.0	3.1	1.8
U6-PTV (mm)	14.4	3.5	14.9	3.7	15.2	3.8	16.6	4.0	17.6	3.2	18.4	4.4

SD=standard deviation

Table III. Net treatment effects during the first (T1-T0, n=33), second (T2-T1, n=27) and total (T2-T0, n=34) treatment phases: treatment group mean differences minus control group mean differences

	T1-T0		T2-T1		T2-T0	
Variables	**MD**	**SD**	**MD**	**SD**	**MD**	**SD**
Overjet (mm)	-4.4***	2.2	-2.0***	1.8	-6.4***	2.4
Overbite (mm)	-1.0*	1.6	-1.4**	1.5	-2.8***	1.9
SN-FH (°)	0.2	1.5	0.6	1.5	0.7	1.8
SNA (°)	-0.8*	1.4	-0.7*	1.3	-0.9*	1.5
SNB (°)	0.9***	0.9	-0.3	0.9	0.7*	1.2
ANB (°)	-1.6***	1.3	-0.4	1.1	-1.6***	1.5
Wits (mm)	-2.6***	1.9	-3.2***	2.1	-5.4***	2.7
Harvold Mx (mm)	0.0	2.8	-0.4	2.7	0.4	3.4
Harvold Md (mm)	2.6**	3.3	-0.4	2.8	2.7**	3.8
Harvold Diff (mm)	2.6***	2.4	-0.1	2.1	2.3***	2.6
Md Body Length (mm)	0.8	2.8	-1.4*	2.3	-0.6	3.2
Md Corpus Length (mm)	1.3**	1.8	-0.5	1.7	0.5	2.1
Md Ramus Height (mm)	1.7**	2.6	-0.4	2.5	1.5*	3.1
Facial Angle (°)	0.8	1.6	0.2	1.5	1.1*	1.8
Convexity (mm)	-1.5***	1.2	-0.2	1.3	-1.5***	1.5
A-NPerp (mm)	-0.6	1.9	0.0	1.9	-0.2	2.1
Pog-NPerp (mm)	1.6*	3.0	0.3	3.0	2.2*	3.5
Saddle Angle (°)	-0.4	2.0	0.4	1.8	-0.3	2.5
Gonial Angle (°)	-0.1	3.0	2.3**	2.6	2.2*	3.4
MPA (°)	-0.2	1.2	1.6***	1.4	1.1**	1.6
FMA (°)	-0.3	1.9	1.0	1.9	0.4	2.2
FOP (°)	0.5	2.2	4.7***	2.2	4.9***	3.2
Y-Axis (°)	-0.5*	0.9	1.1***	0.9	0.4	1.2
LFH (mm)	0.7	2.0	1.4*	2.5	2.2**	2.7
SN-PP (°)	-2.2***	1.4	0.1	1.4	-2.1***	1.6
PP-MP (°)	2.0***	1.8	1.4**	1.8	3.2***	1.9
U1-SN (°)	-3.3*	5.6	-1.7	6.8	-4.3*	8.2
U1-PP (°)	-5.5***	5.8	-1.6	7.0	-6.3**	8.1
U1-NA (°)	-2.5	5.9	-0.9	7.0	-3.2	8.2
U1-NA (mm)	-1.5*	2.4	-0.4	2.0	-2.4***	2.6
U1-APog (°)	-5.8***	5.5	-1.3	6.8	-6.2**	8.2
U1-APog (mm)	-2.6***	1.9	-0.6	1.9	-3.5***	2.3
L1-NB (°)	2.4***	2.8	5.3***	3.9	9.0***	5.0
L1-NB (mm)	0.6*	1.0	1.2***	1.2	1.9***	1.5

L1-APog (°)	4.0***	3.3	5.3***	4.0	10.3***	5.0
L1-APog (mm)	1.9***	1.4	1.5**	1.6	3.2***	1.7
L1-MPA (°)	1.7*	2.6	4.1***	4.0	7.4***	4.9
U1-L1 (°)	1.8	6.4	-4.1	8.2	-4.1	9.4
Pog-NB (mm)	-0.3*	0.6	-0.2	0.9	-0.4*	0.9
U6-PTV (mm)	-1.2**	1.6	0.2	1.7	-0.4	1.9

MD = mean difference; SD = standard deviation; *P<0.05; **P<0.01; ***P<0.001

Submission Confirmation for Inbox x

American Journal of Orthodontics 4:45 PM (17 hours ago)

to me

Dear Dr. Kotyk,

Your submission entitled "Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances" has been received by journal American Journal of Orthodontics & Dentofacial Orthopedics

You will be able to check on the progress of your paper by logging on to Elsevier Editorial Systems as an author. The URL is https://ees.elsevier.com/ajodo/.

Your manuscript will be given a reference number once an Editor has been assigned.

Thank you for submitting your work to this journal.

Kind regards,

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Manuscript submission: www.ees.elsevier.com/ajodo
Journal website: www.ajodo.org
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APPENDICES

Appendix 1: Approval of Study Protocol by University of Manitoba Bannatyne Campus Health Research Ethics Board (HREB)

UNIVERSITY OF MANITOBA | BANNATYNE CAMPUS
Research Ethics Board

P126 - 770 Bannatyne Avenue
Winnipeg, Manitoba
Canada R3E 0W3
Telephone 204-789-3255
Fax 204-789-3414

HEALTH RESEARCH ETHICS BOARD (HREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Delegated Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. Matthew Kotyk	U of M/Preventive Dental Sciences/Orthodontics	H2015:277 (HS18829)
APPROVAL DATE: September 24, 2015	**EXPIRY DATE:** September 24, 2016	
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. W. Wiltshire		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE;
NA	Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
June 30 and Sepembe 21, 2015	July 7 and September 21, 2015

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Revised REB Submission Form submitted September 21, 2015		
Consent and Assent Form(s):		
Other:		
Data Collection/Capture Sheet	V. 1.0	submitted June 30, 2015

CERTIFICATION
The above named research study/project has been reviewed in a ***delegated manner*** by the University of Manitoba (UM) Health Research Board (HREB) and was found to be acceptable on ethical grounds for research involving human participants. The study/project and documents listed above was granted final approval by the Chair or Acting Chair, UM HREB.

HREB ATTESTATION
The University of Manitoba (UM) 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.

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www.umanitoba.ca/faculties/medicine/ethics

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.

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 approval. A Bannatyne Campus Annual Study Status Report** must be submitted to the HREB 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 HREB 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**.

Sincerely,

[redacted]

John Arnett, PhD. C. Psych.
Chair, Health Research Ethics Board
Bannatyne Campus

- 2 -

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

P126-770 Bannatyne Avenue
Winnipeg, Manitoba
Canada, R3E 0W3
Telephone : 204-789-3255
Fax: 204-789-3414

UNIVERSITY OF MANITOBA | Research Ethics - Bannatyne
Office of the Vice-President (Research and International)

HEALTH RESEARCH ETHICS BOARD (HREB)

CERTIFICATE OF ANNUAL APPROVAL

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. Matthew Kotyk	U of M/Preventive Dental Sciences/ Orthodontics	HS18829 (H2015:277)
HREB MEETING DATE (If applicable):	**APPROVAL DATE:** September 6, 2016	**EXPIRY DATE:** **September 24, 2017**
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. W. Wiltshire		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE:
N/A	Dental, Skeletal and Growth Effects of Malocclusions Treated with the van Beek Headgear Activator and Comprehensive Fixed Orthodontic Appliances
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: N/A	

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
August 10, 2016	August 10, 2016

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.

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umanitoba.ca/research

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.

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**.

Sincerely,

[redacted]

John Arnett, PhD., C. Pysch.
Chair, Health Research Ethics Board
Bannatyne Campus

2

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

Appendix 2: Treatment Group Cephalometric Statistics

Table 9. Treatment group cephalometric descriptive statistics at T0 (n=40)

Variable	Mean	Std Dev	Median	Minimum	Maximum
Overjet (mm)	9.1	2.6	8.8	4.8	15.4
Overbite (mm)	4.6	2.5	5.1	-2.5	8.5
SN-FH (°)	10.0	2.5	9.8	3.8	15.2
SNA (°)	80.5	3.5	80.4	74.9	89.3
SNB (°)	74.9	2.9	74.5	69.1	82.8
ANB (°)	5.7	1.9	5.3	1.2	10.1
Wits (mm)	4.8	2.5	4.8	-0.2	10.0
Harvold Mx (mm)	85.5	6.4	85.9	71.5	100.6
Harvold Md (mm)	102.4	7.7	102.2	88.4	117.1
Harvold Diff (mm)	16.9	3.4	16.9	11.0	25.6
Md Body Length (mm)	74.4	5.9	74.2	64.7	84.8
Md Corpus Length (mm)	63.9	5.4	63.4	53.8	76.1
Md Ramus Height (mm)	44.3	4.7	43.5	35.9	54.2
Facial Angle (°)	86.0	2.9	85.8	79.5	92.2
Convexity (mm)	4.4	2.3	4.8	-0.6	9.3
A-NPerp (mm)	0.5	3.1	0.8	-5	6.5
Pog-NPerp (mm)	-7.4	5.4	-8.2	-19.3	4.4
Saddle Angle (°)	124.4	4.9	125.4	107.8	132.4
Gonial Angle (°)	123.5	4.4	122.8	114.6	134.0
MPA (°)	33.3	5.4	33.7	21.4	45.6
FMA (°)	23.3	5.2	23.4	12.2	36.2
FOP (°)	16.2	4.5	15.8	6.7	26.0
Y-Axis (°)	68.9	4.1	69.7	59.0	77.3
LFH (mm)	63.4	4.7	63.3	52.0	72.5
SN-PP (°)	1.6	2.7	1.3	-2.7	6.6
PP-MP (°)	24.6	4.9	24.4	13.1	37.9
U1-SN (°)	106.4	9.4	107.8	85.5	126.8
U1-PP (°)	114.9	8.9	115.1	91.6	132.9
U1-NA (°)	25.8	9.5	26.0	4.9	42.9
U1-NA (mm)	6.4	3.5	6.8	-0.5	14.5
U1-APog (°)	35.3	9.5	35.4	10.2	48.3
U1-APog (mm)	10.1	3.6	10.0	1.3	17.1
L1-NB (°)	26.2	6.4	26.0	12.5	46.0
L1-NB (mm)	5.2	2.6	5.1	0.5	14.5
L1-APog (°)	22.4	5.4	21.0	13.3	38.5
L1-APog (mm)	0.8	2.8	0.6	-3.2	8.9
L1-MPA (°)	98.0	6.2	98.4	85.2	114.3

U1-L1 (°)	122.3	11.8	120.1	97.4	153.2
Pog-NB (mm)	2.2	1.7	1.8	-1.0	6.4
U6-PTV (mm)	14.4	3.5	13.8	6.7	24.0

Table 10. Treatment group cephalometric descriptive statistics at T1 (n=33)

Variable	Mean	Std Dev	Median	Minimum	Maximum
Overjet (mm)	4.9	2.1	5.0	1.3	10.2
Overbite (mm)	3.0	2.1	3.5	-2.5	6.8
SN-FH (°)	10.1	2.5	10.2	3.8	14.6
SNA (°)	79.5	3.4	79.3	75.7	86.6
SNB (°)	75.8	3.2	75.6	70.4	83.0
ANB (°)	3.7	1.9	3.5	0.4	7.7
Wits (mm)	2.7	2.3	2.5	-1.6	8.1
Harvold Mx (mm)	86.6	7.8	86.1	73.0	104.9
Harvold Md (mm)	107.6	9.2	108.7	91.8	126.2
Harvold Diff (mm)	21.0	3.9	21.0	11.2	29.3
Md Body Length (mm)	77.0	6.9	76.8	66.9	92.5
Md Corpus Length (mm)	66.4	6.3	65.7	57.2	78.3
Md Ramus Height (mm)	47.4	5.8	46.8	37.2	65.3
Facial Angle (°)	87.2	2.9	86.6	81.3	92.8
Convexity (mm)	2.4	2.5	2.3	-3.0	7.0
A-NPerp (mm)	-0.4	3.1	-0.5	-6.8	5.4
Pog-NPerp (mm)	-5.2	5.5	-6.5	-16.3	5.8
Saddle Angle (°)	124.2	4.6	124.7	111.2	131.0
Gonial Angle (°)	122.1	4.7	122.2	113.1	131.2
MPA (°)	32.9	6.2	33.6	17.9	44.1
FMA (°)	22.8	5.5	23.3	10.8	34.1
FOP (°)	15.3	5.2	14.7	5.1	22.8
Y-Axis (°)	68.6	4.4	68.8	59.0	76.2
LFH (mm)	65.7	5.4	66.1	50.9	77.4
SN-PP (°)	-0.5	2.8	-1.4	-6.0	5.6
PP-MP (°)	26.3	5.7	26.7	9.5	39.3
U1-SN (°)	104.9	8.3	104.3	83.9	123.9
U1-PP (°)	111.4	7.7	111.8	91.7	128.9
U1-NA (°)	25.4	8.1	26.7	2.3	43.6
U1-NA (mm)	6.0	3.1	6.5	-0.4	14.6
U1-APog (°)	30.4	7.4	30.9	11.6	43.2
U1-APog (mm)	8.1	3.4	8.2	0.8	16.9
L1-NB (°)	28.9	6.5	28.8	16.2	51.3
L1-NB (mm)	6.2	2.9	5.9	1.2	16.6

L1-APog (°)	27.6	5.0	27.0	18.5	43.4
L1-APog (mm)	3.1	3.0	2.8	-2.6	13.0
L1-MPA (°)	100.1	6.1	100.4	90.2	118.5
U1-L1 (°)	122.1	10.2	120.2	93.3	144.9
Pog-NB (mm)	2.4	1.9	1.8	-1.3	7.7
U6-PTV (mm)	15.2	3.8	15.2	6.4	25.3

Table 11. Treatment group cephalometric descriptive statistics at T2 (n=34)

Variable	Mean	Std Dev	Median	Minimum	Maximum
Overjet (mm)	3.3	1.5	3.0	1.4	9.7
Overbite (mm)	1.3	1.0	1.4	-1.1	3.8
SN-FH (°)	9.7	2.8	9.7	4.0	15.5
SNA (°)	79.9	3.5	79.9	73.2	86.8
SNB (°)	76.5	3.3	76.4	69.3	83.7
ANB (°)	3.4	1.6	3.3	0.3	7.5
Wits (mm)	0.8	2.9	0.7	-3.9	10.2
Harvold Mx (mm)	90.4	7.3	90.1	78.4	109.3
Harvold Md (mm)	112.9	8.4	112.6	97.0	128.4
Harvold Diff (mm)	22.5	3.7	22.0	14.9	31.4
Md Body Length (mm)	80.0	6.3	80.3	68.1	96.1
Md Corpus Length (mm)	69.6	5.5	70.3	58.4	80.0
Md Ramus Height (mm)	50.8	5.8	50.4	41.3	63.4
Facial Angle (°)	87.6	2.8	87.3	82.8	93.2
Convexity (mm)	2.0	2.4	2.2	-4.3	6.1
A-NPerp (mm)	-0.6	2.9	-0.9	-7.1	5.5
Pog-NPerp (mm)	-5.0	5.8	-5.5	-16.0	6.7
Saddle Angle (°)	123.7	4.4	125.2	111.7	131.8
Gonial Angle (°)	122.2	4.5	121.6	112.3	130.8
MPA (°)	32.2	6.0	32.5	18.5	42.8
FMA (°)	22.5	5.4	22.0	11.9	32.1
FOP (°)	17.4	4.9	16.7	5.8	28.2
Y-Axis (°)	68.5	4.6	69.1	58.3	76.4
LFH (mm)	69.3	6.5	69.7	53.2	80.8
SN-PP (°)	-0.2	2.8	-0.7	-4.7	6.9
PP-MP (°)	25.3	5.2	26.0	11.2	35.7
U1-SN (°)	104.8	5.7	105.0	89.6	117.6
U1-PP (°)	111.5	4.3	111.2	101.4	120.4
U1-NA (°)	25.1	4.8	25.7	15.2	38.1
U1-NA (mm)	5.3	2.5	4.8	1.8	10.8
U1-APog (°)	29.0	4.8	29.5	19.3	37.3

U1-APog (mm)	7.0	3.1	6.5	0.1	13.9
L1-NB (°)	33.6	6.8	34.2	17.3	47.9
L1-NB (mm)	6.9	2.6	6.6	1.0	12.9
L1-APog (°)	33.0	5.4	34.1	21.5	46.0
L1-APog (mm)	3.7	2.9	3.3	-1.5	11.0
L1-MPA (°)	105.2	6.1	105.1	92.5	121.2
U1-L1 (°)	118.0	7.6	118.4	99.3	132.8
Pog-NB (mm)	2.8	2.0	2.8	-0.7	8.9
U6-PTV (mm)	17.6	3.2	18.1	10.5	25.5

Appendix 3: Control Group Cephalometric Statistics

Table 12. Control group cephalometric descriptive statistics at T0 (n=40)

Variable	Mean	Std Dev	Minimum	Maximum
Overjet (mm)	5.6	2.5	2.2	13.1
Overbite (mm)	4.4	2.0	0.6	7.7
SN-FH (°)	6.7	3.1	0.9	12.0
SNA (°)	80.3	4.3	71.4	89.6
SNB (°)	75.3	3.7	67.3	83.9
ANB (°)	4.9	1.3	2.7	7.3
Wits (mm)	3.1	1.9	-1.7	6.4
Harvold Mx (mm)	89.9	5.1	81.0	106.1
Harvold Md (mm)	107.4	7.6	97.8	125.9
Harvold Diff (mm)	17.5	3.9	11.2	27.3
Md Body Length (mm)	72.9	6.3	61.8	89.2
Md Corpus Length (mm)	63.6	5.2	54.9	76.0
Md Ramus Height (mm)	47.6	5.3	36.6	65.1
Facial Angle (°)	83.1	3.0	76.9	89.7
Convexity (mm)	3.7	1.6	0.2	7.6
A-NPerp (mm)	-3.1	3.3	-8.1	4.4
Pog-NPerp (mm)	-12.7	5.6	-26.4	-0.5
Saddle Angle (°)	125.1	4.8	113.6	136.8
Gonial Angle (°)	126.6	7.4	112.9	138.8
MPA (°)	32.9	5.5	22.7	42.6
FMA (°)	26.2	5.0	16.0	36.9
FOP (°)	17.4	4.1	8.7	25.8
Y-Axis (°)	68.3	3.8	60.8	76.5
LFH (mm)	63.1	5.2	54.2	76.0
SN-PP (°)	0.1	3.5	-9.7	5.7
PP-MP (°)	26.5	6.0	14.4	37.4
U1-SN (°)	100.1	9.2	84.4	121.8
U1-PP (°)	107.2	8.9	93.0	129.7
U1-NA (°)	19.8	9.7	2.1	40.4
U1-NA (mm)	2.5	3.6	-4.1	11.8
U1-APog (°)	27.9	8.9	11.1	48.3
U1-APog (mm)	5.7	3.6	-0.6	14.5
L1-NB (°)	25.3	6.7	9.3	36.3
L1-NB (mm)	3.8	2.2	-0.8	7.5
L1-APog (°)	22.1	6.0	8.5	30.4
L1-APog (mm)	0.0	2.4	-6.0	3.7
L1-MPA (°)	97.1	6.6	84.7	111.5

U1-L1 (°)	130.0	12.6	107.5	158.4
Pog-NB (mm)	2.1	1.6	-1.1	6.6
U6-PTV (mm)	14.9	3.7	7.1	24.9

Table 13. Control group cephalometric descriptive statistics at T1 (n=33)

Variable	Mean	Std Dev	Minimum	Maximum
Overjet (mm)	5.3	2.4	1.8	12.6
Overbite (mm)	4.0	2.3	0.0	7.7
SN-FH (°)	6.2	4.1	0.0	13.2
SNA (°)	80.4	4.8	71.4	92.5
SNB (°)	75.8	4.1	67.3	86.0
ANB (°)	4.6	1.5	1.4	6.8
Wits (mm)	3.5	2.2	-1.3	6.4
Harvold Mx (mm)	91.9	6.7	83.7	107.0
Harvold Md (mm)	111.0	8.9	99.5	134.9
Harvold Diff (mm)	19.1	4.3	12.2	27.9
Md Body Length (mm)	75.5	7.2	65.2	96.6
Md Corpus Length (mm)	65.7	5.6	58.6	81.7
Md Ramus Height (mm)	49.9	6.1	41.0	66.2
Facial Angle (°)	83.3	3.8	75.7	91.6
Convexity (mm)	3.5	1.8	0.0	7.7
A-NPerp (mm)	-3.5	4.3	-9.3	5.5
Pog-NPerp (mm)	-12.9	7.2	-27.8	2.9
Saddle Angle (°)	124.9	5.1	114.3	136.1
Gonial Angle (°)	125.4	7.0	114.6	137.7
MPA (°)	32.5	6.0	22.3	42.6
FMA (°)	26.3	5.5	17.1	36.3
FOP (°)	16.0	4.4	6.7	24.5
Y-Axis (°)	68.5	4.0	60.9	76.5
LFH (mm)	65.2	5.9	55.2	80.4
SN-PP (°)	0.2	3.8	-10.5	7.4
PP-MP (°)	26.1	5.9	14.0	36.4
U1-SN (°)	100.2	8.5	84.4	121.3
U1-PP (°)	107.4	8.4	93.0	129.7
U1-NA (°)	19.8	8.9	2.1	40.4
U1-NA (mm)	2.9	3.3	-4.1	11.8
U1-APog (°)	27.1	7.9	11.1	45.7
U1-APog (mm)	5.8	3.3	-0.6	13.7
L1-NB (°)	25.9	7.4	9.3	36.3
L1-NB (mm)	4.2	2.5	-1.1	8.2

L1-APog (°)	23.2	6.3	8.5	30.4
L1-APog (mm)	0.3	2.7	-6.0	4.3
L1-MPA (°)	97.6	7.3	84.7	111.5
U1-L1 (°)	129.7	11.1	107.6	158.4
Pog-NB (mm)	2.3	1.7	-1.0	5.8
U6-PTV (mm)	16.6	4.0	9.2	27.0

Table 14. Control group cephalometric descriptive statistics at T2 (n=34)

Variable	Mean	Std Dev	Minimum	Maximum
Overjet (mm)	5.9	2.3	1.9	10.2
Overbite (mm)	3.8	2.4	-0.8	7.3
SN-FH (°)	5.5	3.5	-0.5	13.2
SNA (°)	80.7	4.3	72.3	91.0
SNB (°)	76.5	3.8	68.0	86.6
ANB (°)	4.3	1.5	1.4	7.7
Wits (mm)	4.3	2.7	-1.1	8.2
Harvold Mx (mm)	93.6	6.4	85.1	106.8
Harvold Md (mm)	114.0	9.0	100.2	134.8
Harvold Diff (mm)	20.4	4.4	13.1	28.0
Md Body Length (mm)	78.0	8.1	65.2	98.9
Md Corpus Length (mm)	68.1	6.1	58.8	84.3
Md Ramus Height (mm)	52.7	6.7	44.8	70.2
Facial Angle (°)	83.6	3.2	78.2	90.8
Convexity (mm)	2.8	1.6	0.0	7.6
A-NPerp (mm)	-3.9	4.0	-10.3	4.0
Pog-NPerp (mm)	-12.4	6.0	-22.9	1.6
Saddle Angle (°)	125.0	5.3	113.5	134.1
Gonial Angle (°)	123.8	7.5	110.7	140.6
MPA (°)	30.6	5.7	19.6	40.8
FMA (°)	25.1	5.6	15.4	36.3
FOP (°)	13.6	3.6	3.8	19.7
Y-Axis (°)	67.7	3.7	59.0	75.4
LFH (mm)	66.2	6.1	57.1	79.5
SN-PP (°)	0.4	3.7	-9.8	5.8
PP-MP (°)	23.9	6.0	12.7	35.7
U1-SN (°)	103.0	7.9	90.5	119.3
U1-PP (°)	110.5	7.6	93.4	122.1
U1-NA (°)	22.2	8.1	4.7	35.3
U1-NA (mm)	3.7	3.2	-2.3	8.9
U1-APog (°)	27.9	7.4	15.9	41.5

U1-APog (mm)	6.0	3.0	-0.2	11.0
L1-NB (°)	24.1	8.3	6.3	33.8
L1-NB (mm)	4.0	2.7	-1.1	8.2
L1-APog (°)	22.6	7.6	7.3	32.5
L1-APog (mm)	0.1	3.1	-6.0	4.5
L1-MPA (°)	97.0	8.4	81.4	112.4
U1-L1 (°)	129.4	10.9	112.2	155.6
Pog-NB (mm)	3.1	1.8	-0.1	6.6
U6-PTV (mm)	18.4	4.4	10.2	29.1

Table 15. Control group mean cephalometric values and mean differences between time points

	Mean					
Variable	**T0**	**T1**	**T2**	**T1-T0**	**T2-T1**	**T2-T0**
n	40	33	34	33	27	34
Overjet (mm)	5.6	5.3	5.9	0.0	0.3	0.6
Overbite (mm)	4.4	4.0	3.8	-0.3	-0.4	-0.7
SN-FH (°)	6.7	6.2	5.5	-0.3	-0.5	-0.9
SNA (°)	80.3	80.4	80.7	0.0	0.4	0.0
SNB (°)	75.3	75.8	76.5	0.2	0.5	0.7
ANB (°)	4.9	4.6	4.3	-0.3	0.0	-0.7
Wits (mm)	3.1	3.5	4.3	0.5	0.9	1.2
Harvold Mx (mm)	89.9	91.9	93.6	2.0	1.7	3.3
Harvold Md (mm)	107.4	111.0	114.0	3.3	3.0	6.5
Harvold Diff (mm)	17.5	19.1	20.4	1.3	1.3	3.2
Md Body Length (mm)	72.9	75.5	78.0	2.4	2.9	5.5
Md Corpus Length (mm)	63.6	65.7	68.1	1.8	2.3	4.5
Md Ramus Height (mm)	47.6	49.9	52.7	1.9	2.7	4.8
Facial Angle (°)	83.1	83.3	83.6	0.2	0.2	0.2
Convexity (mm)	3.7	3.5	2.8	-0.3	-0.3	-0.9
A-NPerp (mm)	-3.1	-3.5	-3.9	-0.4	-0.1	-1.0
Pog-NPerp (mm)	-12.7	-12.9	-12.4	0.0	0.2	-0.2
Saddle Angle (°)	125.1	124.9	125.0	0.2	-0.1	0.1
Gonial Angle (°)	126.6	125.4	123.8	-1.0	-2.1	-3.2
MPA (°)	32.9	32.5	30.6	-0.4	-1.3	-1.6
FMA (°)	26.2	26.3	25.1	-0.1	-0.8	-0.6
FOP (°)	17.4	16.0	13.6	-1.3	-1.7	-3.3
Y-Axis (°)	68.3	68.5	67.7	0.1	-0.4	-0.2
LFH (mm)	63.1	65.2	66.2	1.7	2.0	3.6
SN-PP (°)	0.1	0.2	0.4	0.3	0.1	0.4
PP-MP (°)	26.5	26.1	23.9	-0.6	-1.4	-1.9

U1-SN (°)	100.1	100.2	103.0	0.8	1.7	3.0
U1-PP (°)	107.2	107.4	110.5	1.1	1.9	3.4
U1-NA (°)	19.8	19.8	22.2	0.9	1.3	2.9
U1-NA (mm)	2.5	2.9	3.7	0.7	0.2	1.5
U1-APog (°)	27.9	27.1	27.9	-0.1	0.6	0.7
U1-APog (mm)	5.7	5.8	6.0	0.3	0.0	0.6
L1-NB (°)	25.3	25.9	24.1	0.3	-0.9	-1.2
L1-NB (mm)	3.8	4.2	4.0	0.4	-0.1	0.2
L1-APog (°)	22.1	23.2	22.6	0.9	-0.2	0.5
L1-APog (mm)	0.0	0.3	0.1	0.3	-0.3	0.1
L1-MPA (°)	97.1	97.6	97.0	0.4	-0.1	-0.3
U1-L1 (°)	130.0	129.7	129.4	-0.8	-0.3	-1.2
Pog-NB (mm)	2.1	2.3	3.1	0.4	0.6	1.0
U6-PTV (mm)	14.9	16.6	18.4	1.7	1.9	3.3

Appendix 4: Growth Forecast Cephalometric Statistics

Table 16. Growth forecast cephalometric descriptive statistics at T1 (n=33)

Variable	Mean	Std Dev	Minimum	Maximum
Overjet (mm)	9.4	2.7	4.8	15.4
Overbite (mm)	4.3	2.5	-2.5	8.2
SN-FH (°)	10.3	2.5	3.9	15.0
SNA (°)	80.4	3.7	74.9	89.3
SNB (°)	74.9	3.0	69.4	82.9
ANB (°)	5.4	2.0	1.1	9.8
Wits (mm)	4.3	2.5	-0.4	9.5
Harvold Mx (mm)	87.0	6.5	74.4	103.2
Harvold Md (mm)	105.3	7.6	91.6	121.1
Harvold Diff (mm)	18.2	3.3	12.0	27.2
Md Body Length (mm)	76.3	6.1	66.8	87.4
Md Corpus Length (mm)	65.8	5.5	57.4	78.9
Md Ramus Height (mm)	45.0	4.7	37.0	54.1
Facial Angle (°)	86.4	2.8	79.8	92.2
Convexity (mm)	4.2	2.4	-0.6	9.3
A-NPerp (mm)	0.6	3.1	-4.7	6.5
Pog-NPerp (mm)	-6.9	5.3	-19.5	4.5
Saddle Angle (°)	125.9	5.2	109.1	133.8
Gonial Angle (°)	124.1	4.4	115.9	133.0
MPA (°)	34.0	5.7	22.3	46.1
FMA (°)	23.7	5.4	12.7	36.6
FOP (°)	16.5	4.7	6.9	26.2
Y-Axis (°)	69.4	4.2	59.2	77.6
LFH (mm)	65.6	4.8	54.2	75.6
SN-PP (°)	1.3	2.6	-2.4	6.5
PP-MP (°)	25.6	5.2	13.9	38.5
U1-SN (°)	107.1	9.6	85.0	126.6
U1-PP (°)	115.4	9.4	90.8	132.6
U1-NA (°)	26.7	9.5	4.2	42.6
U1-NA (mm)	7.0	3.6	-0.1	14.8
U1-APog (°)	35.6	9.7	9.2	47.9
U1-APog (mm)	10.7	3.7	1.5	17.3
L1-NB (°)	26.7	6.7	12.8	46.4
L1-NB (mm)	5.4	2.8	0.6	14.7
L1-APog (°)	23.2	5.6	14.2	38.6
L1-APog (mm)	1.2	2.9	-2.9	9.2
L1-MPA (°)	97.7	6.5	85.1	114.0

U1-L1 (°)	121.1	12.2	97.4	153.2
Pog-NB (mm)	2.2	1.8	-1.1	6.2
U6-PTV (mm)	16.2	3.6	8.0	25.8

Table 17. Growth forecast cephalometric descriptive statistics at T2 (n=34)

Variable	Mean	Std Dev	Minimum	Maximum
Overjet (mm)	9.2	2.6	4.8	15.4
Overbite (mm)	4.8	2.4	-2.5	8.5
SN-FH (°)	9.9	2.4	4.0	14.8
SNA (°)	80.7	3.5	75.0	89.3
SNB (°)	75.5	2.7	71.5	83.1
ANB (°)	5.3	1.8	0.9	8.0
Wits (mm)	4.0	2.8	-1.6	8.9
Harvold Mx (mm)	92.3	5.6	82.3	105.1
Harvold Md (mm)	112.0	6.9	96.5	124.0
Harvold Diff (mm)	19.7	3.6	13.5	28.7
Md Body Length (mm)	80.8	5.2	70.2	93.3
Md Corpus Length (mm)	70.3	5.1	62.9	81.7
Md Ramus Height (mm)	47.3	4.6	38.2	55.4
Facial Angle (°)	86.4	2.8	81.2	92.2
Convexity (mm)	4.4	2.3	-0.6	8.3
A-NPerp (mm)	0.6	3.2	-4.3	6.4
Pog-NPerp (mm)	-7.4	5.8	-18.9	4.7
Saddle Angle (°)	127.1	4.9	110.9	135.5
Gonial Angle (°)	125.2	4.3	117.5	135.1
MPA (°)	34.0	5.3	23.2	45.1
FMA (°)	24.2	4.9	13.0	32.9
FOP (°)	16.3	4.2	7.2	24.8
Y-Axis (°)	69.2	4.1	59.5	76.2
LFH (mm)	68.9	5.2	55.8	79.4
SN-PP (°)	1.3	2.8	-3.4	6.4
PP-MP (°)	25.6	4.6	14.4	36.0
U1-SN (°)	105.4	9.1	84.8	126.3
U1-PP (°)	113.6	8.9	90.4	132.2
U1-NA (°)	24.7	9.1	3.9	41.9
U1-NA (mm)	6.6	3.4	0.0	15.0
U1-APog (°)	33.4	9.2	8.8	46.5
U1-APog (mm)	10.4	3.3	1.9	17.2
L1-NB (°)	26.8	5.9	13.8	41.9
L1-NB (mm)	5.2	2.3	1.1	10.7

L1-APog (°)	23.4	5.5	15.1	39.6
L1-APog (mm)	1.0	2.6	-2.6	8.4
L1-MPA (°)	97.5	5.6	85.0	108.0
U1-L1 (°)	123.2	11.4	102.4	153.2
Pog-NB (mm)	2.0	1.8	-1.5	5.9
U6-PTV (mm)	18.2	4.0	10.9	27.6

Table 18. Growth forecast mean cephalometric values and mean differences between time points

	Mean					
Variable	**T0**	**T1**	**T2**	**T1-T0**	**T2-T1**	**T2-T0**
n	40	33	34	33	27	34
Overjet (mm)	9.1	9.4	9.2	-0.1	0.2	0.1
Overbite (mm)	4.6	4.3	4.8	0.1	-0.4	-0.4
SN-FH (°)	10.0	10.3	9.9	0.1	0.0	0.1
SNA (°)	80.5	80.4	80.7	0.2	-0.4	-0.1
SNB (°)	74.9	74.9	75.5	0.5	-0.1	0.5
ANB (°)	5.7	5.4	5.3	-0.3	-0.3	-0.6
Wits (mm)	4.8	4.3	4.0	-0.7	-0.6	-1.2
Harvold Mx (mm)	85.5	87.0	92.3	2.5	4.3	6.8
Harvold Md (mm)	102.4	105.3	112.0	4.5	5.4	10.0
Harvold Diff (mm)	16.9	18.2	19.7	2.0	1.2	3.2
Md Body Length (mm)	74.4	76.3	80.8	3.1	3.4	6.5
Md Corpus Length (mm)	63.9	65.8	70.3	3.0	3.6	6.7
Md Ramus Height (mm)	44.3	45.0	47.3	1.3	1.3	2.6
Facial Angle (°)	86.0	86.4	86.4	0.7	-0.2	0.4
Convexity (mm)	4.4	4.2	4.4	-0.2	0.1	-0.2
A-NPerp (mm)	0.5	0.6	0.6	0.4	-0.4	0.0
Pog-NPerp (mm)	-7.4	-6.9	-7.4	1.1	-0.9	0.2
Saddle Angle (°)	124.4	125.9	127.1	1.5	1.0	2.6
Gonial Angle (°)	123.5	124.1	125.2	0.6	1.9	2.5
MPA (°)	33.3	34.0	34.0	0.3	1.2	1.5
FMA (°)	23.3	23.7	24.2	0.2	1.2	1.4
FOP (°)	16.2	16.5	16.3	0.0	0.6	0.6
Y-Axis (°)	68.9	69.4	69.2	0.2	0.4	0.6
LFH (mm)	63.4	65.6	68.9	2.5	3.5	6.1
SN-PP (°)	1.6	1.3	1.3	-0.5	0.3	-0.3
PP-MP (°)	24.6	25.6	25.6	0.8	0.9	1.7
U1-SN (°)	106.4	107.1	105.4	-0.3	-0.9	-1.4
U1-PP (°)	114.9	115.4	113.6	-0.8	-0.7	-1.7
U1-NA (°)	25.8	26.7	24.7	-0.5	-0.5	-1.3

U1-NA (mm)	6.4	7.0	6.6	0.2	0.3	0.4
U1-APog (°)	35.3	35.6	33.4	-1.3	-0.9	-2.4
U1-APog (mm)	10.1	10.7	10.4	0.1	0.3	0.3
L1-NB (°)	26.2	26.7	26.8	0.1	0.5	0.6
L1-NB (mm)	5.2	5.4	5.2	0.1	0.0	0.1
L1-APog (°)	22.4	23.2	23.4	0.6	0.6	1.2
L1-APog (mm)	0.8	1.2	1.0	0.3	0.1	0.4
L1-MPA (°)	98.0	97.7	97.5	-0.7	-0.5	-1.3
U1-L1 (°)	122.3	121.1	123.2	0.7	0.3	1.3
Pog-NB (mm)	2.2	2.2	2.0	0.0	-0.2	-0.2
U6-PTV (mm)	14.4	16.2	18.2	2.0	1.8	3.8