Change in Vertical Dimension of Class II, Div I Patients After Use of Cervical-
or High-Pull Headgear

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THESIS

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LIST OF ABBREVIATIONS

ANB  Angle formed from lines drawn from A point to Nasion and from B point to Nasion, with Nasion being the axis
ANS  Anterior nasal spine
Ar   Articulare
Ba   Basion
CHG  Referring to the group treated with cervical pull headgear
D    Difference
DF   Degrees of freedom
FH   Frankfort Horizontal
FMA  Angle formed from Frankfort Horizontal and mandibular plane
Gn   Gnathion
Go   Gonion
HPHG Referring to the group treated with high pull headgear
L6   Lower first molar
MP   Mandibular Plane
MPA  Mandibular plane angle
N    Nasion
OP   Occlusal Plane
PI   Principle investigator
PNS  Posterior nasal spine
Pog  Pogonion
PP   Palatal plane
SD   Standard deviation
SN   Sella – Nasion
T1   Time point 1 or pretreatment
T2   Time point 2 or after phase I treatment
U6   Upper first molar
SUMMARY

Growth modification through the use of headgear is a widely accepted treatment option in the treatment of class II malocclusions. It redirects the growth of the maxilla which allows the mandibular growth to catch up. Two types of headgear used by practitioners include high pull and cervical pull headgear. There is controversy in the literature regarding the type of headgear that best controls vertical changes of the growing child.

This retrospective study looked at cephalometric radiographs from two treatment groups. One treated with cervical pull headgear and the other with high pull headgear. The radiographs were taken before treatment and after the completion of phase I treatment to assess changes in the vertical dimension after treatment with headgear. Each treatment group was also compared to an untreated predicted growth model, based on each group’s mean age prior to treatment and mean treatment time, to compare changes in vertical dimension as result of phase I expansion treatment to untreated predicted growth. All subjects were growing patients with a class II skeletal pattern. Lateral cephalograms taken before treatment and after the completion of expansion and phase I treatment were traced using Dolphin Imaging, and these cephalometric tracings were used to analyze the changes in vertical dimension.

When the cervical pull and high pull groups were compared to each other, no difference was found at before treatment or after phase I treatment. When the cervical pull group was compared at initial and after phase I treatment it was found that there.
were significant differences for the variables convexity, convexity, facial axis, facial angle, occlusal plane, FMA, U6 to SN, posterior ramus height, palatal plane inclination, posterior facial height, U6 to PTV, and U6 to PP. When the high pull group was compared at the initial time point and after phase I treatment there was a significant difference for the variables palatal plane inclination, posterior facial height, U6 to PP, L6 to PP. When the amount of change over the course of treatment was compared between the two groups, statistically significant differences were found for the variables convexity, facial axis, facial angle, occlusal plane inclination, palatal plane inclination, and L6 to the mandibular plane.

Over the course of treatment both cervical pull headgear and high pull headgear were able to have effects on the growth of the subjects. When comparing the mean change in measurements from the initial radiograph to the radiograph taken after treatment, there were differences in the amount that each headgear affected the variables tested. These differences suggested that cervical pull headgear had more control over skeletal vertical measurements than high pull headgear.
1. INTRODUCTION

1.1 Background and Significance

It is common to treat a class II, division I malocclusion in a growing patient with headgear in order to alter the growth of the maxilla while the mandible is allowed to grow as normal. Two types of headgear that are commonly used are referred to as high pull headgear and cervical-pull headgear. There have been mixed opinions regarding which headgear design is better able to correct class II division I malocclusions and also control the vertical dimension of growth. Cervical pull headgear applies downward and backward force to the maxilla which redirects forward growth into downward growth. High pull headgear exerts a distal and upward force on the maxilla. (Merrifield, 1970).

Some have said that extrusion of teeth during use of cervical pull headgear creates a smile with excessive gingival display and that backward rotation of the mandible creates a worsened class II malocclusion due to an increase in the degree measurement of the angle made by the Frankfort horizontal plane and the mandibular plane (Merrifield, 1970). These comments lead some orthodontists to utilize high-pull headgear in order to treat this malocclusion without extrusion of the molars and subsequent negative changes in mandibular position. In the 1950’s, Ricketts stopped use of high-pull headgear in his practice because he felt he was observing the failure of high pull headgear to prevent vertical changes (Ricketts, 1997).

It is unknown the differences in the true effect that cervical pull and high pull headgear exert on the posterior vertical dimension and the reflex effect on the position
of the mandible of growing patients with a class II, division I malocclusion and a
hyperdivergent face typology.

1.2 Objectives

The goal of this study is to compare the effects that cervical pull and high pull
headgear have on the vertical dimension in class II, division I patients with
hyperdivergent face typology.

1.3 Hypothesis

There is no statistically significant mean difference in vertical dimension changes
between cervical pull headgear and high pull headgear during phase I treatment of
growing skeletal class II subjects.

There is no statistically significant mean difference in vertical dimension changes
after phase I treatment with cervical pull headgear when compared to normal growth
measurements.

There is no statistically significant mean difference in vertical dimension changes
after phase I treatment with high pull headgear when compared to normal growth
measurements.
2. LITERATURE REVIEW

2.1 Growth of the Human Mandible

Hellman, through measurements of living individuals with calipers, determined that the face grows forward in individuals, but that it changes in its relationship to the cranium according to one of three patterns of growth. The patterns are hyperdivergent, hypodivergent, and a more normal average between the two (Hellman, 1935). These patterns of growth can be expressed in terms of what happens to the mandibular plane angle as a child grows. Arne Bjork showed the lower border of the mandible rotating forward slightly in the majority of cases. In some cases it rotated forward a large amount and in an even smaller number of subjects it rotated backward. He said that the mandible can be thought of as an “unconstrained bone” and that it can change its inclination during growth several ways. Two determinations of the change in inclination are the direction of growth at the condyle and the axis of rotation. He split children into groups of forward rotators (the hypodivergent and normal growers) and backward rotators (the hyperdivergent growers). When forward rotation is observed, there is an underdevelopment of the anterior facial height and a more prominent development of the posterior facial height. In most cases the differences are minimal and normal growth is seen. Some cases result in a deep bite. When backward rotation is seen, there is an increase in anterior facial height with underdevelopment of the posterior facial height. This may result in a class II malocclusion and even an anterior open bite (Bjork, 1969). There is evidence that the rotation of the mandible is the result of a number of
contributing factors. One factor is the growth of the maxilla. Implant studies have shown that growth of the maxilla is in a downward and forward direction and it also displays a forward rotation which results in an increased vertical height at the posterior molar (Bjork and Skieller, 1972). This increase in height at the maxillary molars causes an interference with mandibular molars and a forward positioning of the mandible. Together these actions result in flattening of the occlusal plane (Fushima, 1996). It has even been suggested that the increase in vertical dimension in the posterior dentition and the forward repositioning of the mandible results in a stimulus for the condyle to grow to allow the mandible to function in a more functional position (Kim 2006). This agrees with Moss and Salentijn’s belief that the size and shape of the mandible is a direct result of the functional demands placed upon it. It is not the condylar growth that translates the mandible down and forward, it is more accurate to say that the growth of the condyle is determined by the functional demands of the oral system (Moss and Salentijn, 1971). When there are changes in the structure and therefore the function of the oral system, the growth of the condyle and mandible is affected. This has been shown in studies where occlusal function was altered in monkeys by placing a piece of plastic between the premolars. This altered occlusal function created an artificial axis point and was able to alter the growth of the mandible (Harvold, 1968).

2.2 Relationship between Class II Malocclusion and Occlusal Plane

Backward rotation is associated with a steep cant of the posterior occlusal plane and may actually be caused by the occlusal plane abnormalities (Fushima, 1996). Fifty cephalometric radiographs of adult females with a class II division I malocclusion were compared to radiographs taken of a similar group of women who had decent class I
occlusion. Since the occlusal plane cannot be accurately represented using one straight line, this study split it into the posterior occlusal plane and the anterior occlusal plane. The cant of each occlusal plane was measured from Frankfort Horizontal. It was found that the anterior occlusal plane in both groups were similar while the posterior occlusal plane and the difference between the anterior and posterior occlusal planes was significantly larger for the class II group. It was also discovered that a steep posterior occlusal plane is correlated with a steep mandibular plane and a small facial axis. It is strongly correlated to a small mandibular length and ramus height. These findings show that a lack of mandibular growth and backward rotation of the mandible is related to the angle of the posterior occlusal plane measured from Frankfort Horizontal. When the correlation between the posterior occlusal plane and the inclination of the teeth was measured it was found that there was a correlation between the cant of the posterior occlusal plane and the inclination of the maxillary molars. The steeper the posterior occlusal plane, the more distally inclined the molars would be (Fushima, 1996).

Further evidence can be found in a 2008 study by Tanaka and Sato. They gathered cephalometric radiographs from 102 untreated subjects at three time points. The 102 subjects were split into groups based on their malocclusion classification of class I, II, or III. They also split the conventional occlusal plane into anterior and posterior segments just as the previously mentioned study did. They found that in all three groups the occlusal plane tended to become more horizontal with growth. No significant difference between the groups was seen when the angle of the anterior occlusal plane or the conventional occlusal plane to Frankfort Horizontal was measured. They did find significant differences when the posterior occlusal plane was measured from Frankfort.
Class II malocclusions had steeper posterior occlusal planes than their class I or class III counterparts. Class III malocclusions showed an even flatter posterior occlusal plane than the other two groups. This shows that the cant of the posterior occlusal plane is closely related to development of class II, class I, or class III malocclusions (Tanaka, 2008).

When treating class II malocclusions, it is best to use techniques that work with growth and development to encourage correct mandibular adaptation and growth. Because of the trend of high angle class II malocclusions having a steep posterior occlusal plane and a short vertical height at the upper second molar, the ideal treatment would be to level the occlusal plane and extrude the upper molars (Kato, 2002). Many techniques exist for this type of treatment. One type is the use of headgear.

2.3 History of Headgear

The use of headgear dates back to 1892 when William Kingsley advocated the use of extraoral anchorage to obtain a class I molar relationship (Jeckel and Rakosi, 1991). It wasn’t until the 1950’s that Kloehn’s cervical pull headgear came into common use. Kloehn was influenced by the rise of cephalometry which allowed the clinician to finally see that class II correction was accomplished by moving the lower teeth forward without regard to their position on the apical base and without accomplishing any distal movement of the maxillary teeth. He believed that this was a source of relapse and instability. Instead, guiding the teeth into proper occlusion with the use of growth could lead to a much more stable result (Kloehn, 1953). Further evidence for the efficacy of headgear in the correction of class II malocclusions lies in studies which used serial
cephalometric radiographs to compare the changes that occur during class II growth and the changes that occur when extra oral anchorage is used. When class II children are allowed to grow without intervention, the upper dentition moves forward at a rate similar to the forward growth of the mandible. This means that class II correction does not happen by itself (Poulton, 1964). Two studies that looked at the position of the dentition and A point found that extra oral anchorage of both face bow and occipital pull types were able to decrease forward growth of both the upper first molar and A point when compared to a similar population of untreated subjects. This combined with mandibular growth aids in class II correction (Wieslander, 1963; Poulton, 1964)

2.4 Cervical Pull Headgear

Dr. Kloehn described in his 1953 paper, Force or Persuasion, the components of cervical pull headgear. It consisted of a facebow made of .050” steel wire coupled at the midline to a steel wire of .045”. The smaller wire was placed in buccal tubes extending from banded maxillary first molars. Elastic bands were placed on hooks at the end of the outer bow and extended to a strap around the cervical portion of the neck. The elastics placed between .75 to 1.5 pounds of pressure which was measured by a spring scale. Patients were instructed to wear the appliance 7 days a week for 10-12 hours per night. Tipping of the maxillary molars to the distal can be seen when the outer bow of the facebow is oriented in proximity to the lower border of the mandible. Movement of the molar roots to the distal can be seen when the outer bow is oriented above the dentition. When the clinician does not desire tipping of the maxillary molars, the outer and inner bow should be oriented in the same plane. This puts pressure on the molar at a right angle to its long axis and maintains the axial inclination (Kloehn, 1953).
Throughout his career, Robert M Ricketts has been a proponent of cervical pull headgear. He has been able to show downward and forward rotation of the occlusal plane while the palatal plane and the maxillary complex rotate in a clockwise direction. He was able to show control of extrusion of the upper molars. The soft tissue change was also favorable with the upper lip moving back with the maxillary complex and therefore preventing any excess gingival display in the anterior (Ricketts, 1973). The success that many practitioners have had with cervical pull headgear may be due to the ability of cervical pull headgear to place forces on the dentition that mimic natural growth as described earlier. It can cause an increase in height at the maxillary molar much like what happens during forward rotation of the maxilla. This increase in height produces an interference and subsequent movement of the mandible forward to maintain occlusal contacts (Fushima, 1996). Even though Dr. Kloehn and Dr. Ricketts showed success with this technique, there have been clinicians who doubt the efficacy of cervical pull headgear.

2.5 Mandibular Movement During Orthodontic Treatment

A 1954 study by Abraham Silverstein compared the boney profile of children who were class II division I and untreated controls. He found that much orthodontic treatment worked against the natural growth tendency which is to flatten the mandibular plane angle and the plane of occlusion in the majority of cases. Treatment could actually result in a more convex profile and more obtuse angles for the mandibular plane and the occlusal plane than what would have been expected if the child were allowed to grow as normal. There were problems with this study such as using class I patients as controls and the method of treatment being unclear. Still, this study suggested that
rotation of the mandible backward during orthodontic treatment was a possibility (Silverstein, 1954). Creekmore has also investigated movement of the mandible during orthodontic treatment. He looked at high angle children and compared the class II correction of these patients to a group with more moderate readings for the mandibular plane angle. It became clear to him that class II correction in high angle cases was more challenging than for moderate and low angle cases (Creekmore, 1967).

The force that the cervical pull facebow places on the dentition can result in extrusion of the upper molars. There are differing opinions on the effect that this extrusion has. Some believe it encourages the mandible to rotate forward (Fushima, 1996). Others believe the extrusion of the upper molars leads to a downward and backward rotation of the mandible to accommodate the upper teeth. This rotation of the mandible means that point B also moves down and back making ANB increase in value. This backward rotation and increase in ANB result in a facial profile that is not improved from the pretreatment profile. Opponents of the cervical pull facebow have also claimed to see severe relapse of class II cases, second molar impaction, ectopic eruption of second molars, over extrusion of the maxillary incisors, and torque issues in both maxillary and mandibular incisors. All of these things together have been called the “Kloehn reaction” (Merrifield and Cross, 1970). Some orthodontists who have seen the negative effects of cervical pull headgear advocate the use of high pull headgear.

2.6 High Pull Headgear

Schudy recognized that the vertical dimension is partially dependent on the height of the alveolar process at the molars and thought that excessive vertical growth
of the maxillary alveolar process in the posterior will negate growth at the condyles. This means instead of forward movement of pogonion, we will actually see it move down or down and back even when the mandible is growing at the condyles (Schudy, 1964). Schudy (Schudy, 1965) and Creekmore (Creekmore, 1967) came up with a design of high pull headgear which had the outer bow extending to the position of the maxillary first molars and elastic traction toward the top and back of the head. This design has been shown to exert a distal and upward force on the maxilla. It has been thought that these forces will inhibit extrusion of the upper first molars and therefore will allow full expression of growth at the condyle. Any backward rotation of the mandible will be avoided (Schudy, 1965) which is imperative in children exhibiting a medium to high mandibular plane angle (Pfeiffer and Grobety, 1975).

Dr. Shudy attempted to prove the superiority of the high pull headgear method on a sample of high MPA cases. He reported that forty-two percent of his cases showed an increase in MPA while sixty-four percent of controls treated by other practitioners showed an increase. The mandibular plane angle was the only vertical measurement reported (Schudy, 1965).

The direction of force of the high pull headgear is largely vertical and does not offer the same power to distilize the maxilla as cervical pull headgear (Baumrind, 1978). It tends to be a slower correction of the class II malocclusion and does little to prevent patterns of vertical facial growth. Cervical pull headgear is much more effective at correcting class II malocclusions and most of the negative effects of its use can be avoided by decreasing the extraoral force and only prescribing headgear for night time.
wear. This would give the occlusion and musculature time to rebound and recover (Ricketts, 1997).

2.7 Previous Studies

2.7.1 Other studies comparing cervical and high pull headgear

Due to the controversy surrounding the method of extraoral traction used, there have been several studies that have looked at changes that occur during treatment. Baumrind gathered subjects that had been treated with cervical pull headgear, high pull headgear, and a variety of other class II correction methods. It was found that all of the methods to correct class II malocclusion resulted in a very slight change in the mandibular plane angle when compared to untreated controls. In all of the methods, the natural tendency of the mandibular plane angle to decrease was inhibited, but there was not a significant difference between the means of any of the groups. The change in the mandibular plane angle measured by SN to Go-Gn was the only measurement taken and did not account for remodeling of the border of the mandible (Baumrind, 1978). A follow-up study was done that looked at more measurements and also the rate of change of those measurements which was calculated as total change over the time of the treatment. It was found that the group treated with cervical pull headgear had a statistically significant increase in total facial height when compared to the control and high pull groups. It was noted that children in the cervical pull group were treated over a longer period of time and were also a year and a half older than the other groups. Interestingly, the children treated with cervical traction also were found to have an increased rate of growth in ramus height (Baumrind, 1981). Studies on occlusion suggest that forward posturing of the mandible occurs when there is an interference in
the posterior (Harvold, 1968) and that the condyle has the ability to grow to adapt to the functional demands of the oral system (Moss and Salentijn, 1971).

Another study looked at two different treatment strategies for class II division I malocclusions. They attempted to treat one group with four first premolar extractions plus high pull headgear. The second group was treated without extractions and with cervical pull headgear. The decision to extract was based on vertical control alone, not on amount of crowding. Both groups were matched in terms of growth potential, age, and malocclusion. It was found that in the group treated with high-pull headgear and extractions there was dental movement due to extraction of premolars. There was no significant difference between the two groups when vertical measurements were compared. This shows that there is a limit to the amount that orthodontics alone can alter the vertical dimension (Gkantidis, 2011).

Burke and Jacobson did a similar study where they retrospectively looked at change in vertical dimension during and after treatment with cervical pull and high pull headgear. They found that cervical pull headgear causes extrusion of the upper molar, flattening of the occlusal plane and slight increase in mandibular plane angle. When they compared these to the high pull group and accounted for differences in treatment time, none of the measurements retained their statistical significance (Burke, 1992).

Another study to compare vertical changes in children treated with cervical pull or high pull headgear was done by Peter Brown D.D.S. in 1978. He found that cervical pull headgear extruded the upper molar and tipped both the maxilla and mandible down and backward. He also found that high pull headgear allowed extrusion of the lower molar.
Many of the other measurements that Dr. Brown made were reported as a difference between the two groups, but then he went on to say that the measurements did not amount to any statistical significance (Brown, 1978).

2.7.2 **Finite Element Studies**

One way to look at the forces placed on the skeletal structure is through analysis with a finite element model. Dry skulls at dental age 7 were outfitted with sensor nodes and then subjected to 1 kilogram of force directed at angles 25 degrees downward from, parallel to and 35 degrees above the palatal plane. The skulls were scanned using AutoCAD software to produce a three dimensional stress-strain model. It was found that displacement of the maxillary posteriorly happened with all three types as well as clockwise rotation of the maxilla. The rotation was the most pronounced for the cervical pull group and least pronounced for the high pull group. In all groups structures expanded laterally, similarly to what would be expected during rapid maxillary expansion. Different headgear types caused movement of bones around different centers of rotation. High pull headgear caused the maxillary and zygomatic complex to move around a center of rotation in the anterior, while cervical pull and straight pull headgear caused the center of rotation to lie in the posterior (Gautam, 2009).

2.7.3 **Implant Studies**

Implant studies are able to give us a clearer picture of the true skeletal changes taking place. A 1978 study by Birte Melsen used serial cephalograms with implants placed in the anterior nasal spine, symphysis, body of the mandible, and the ramus to determine the effects that cervical headgear had on the growing child. Two groups
received cervical headgear. One with the outer bow angled twenty degrees upward and the other with the outer bow angles twenty degrees downward from the inner bow. Dr. Melsen found that cervical headgear with the outer bow angled down, the distalization of the first molar was really a distal tipping of the crown. When the bow is angled upward, there is minimal tipping but the molars extrude more than in the other group. When either configuration is used both maxillary and mandibular prognathism are decreased. She mentioned that there was a large variation in the group and individual characteristics such as occlusal forces, occlusal contacts, functional demands, and variations in skeletal turnover might have a large effect on the treatment outcome. The study was continued with post-treatment cephs taken after the patients had finished growth as determined by a hand-wrist radiograph. The post-treatment ceps showed that the change in growth pattern inflicted by the cervical headgear is only temporary and that the growth of the maxillary catches up to the amount that would have been expected without treatment. The mandible also continues to grow forward and any backward rotation that happens during treatment is likely to reverse once treatment is discontinued (Melsen, 1978).

2.7.4 Effect of Cervical Headgear on Overbite

Due to information that suggests cervical headgear causes backward rotation of the mandible. A group sought out to test the effect of cervical headgear on patients with varying growth patterns with regard to overbite. They split patients into horizontal, neutral, and vertical growers based on the Y-axis measurement. They found that the differences produced in overbite between the groups was minimal and did not amount to statistical significance. They recommended for class II division I patients who had
good growth potential to be treated with cervical pull headgear regardless of the direction of growth (Godt, 2007).
3. METHODS

3.1 Study Design

Pre- and post- treatment cephalometric radiographs of children who have undergone class II division I correction with cervical-pull or high-pull headgear were scanned and uploaded into Dolphin Imaging™ 11.0 and calibrated using the ruler present in the radiograph. The transfer structures method by means of fiducials and anatomical best-fit structures was used to ensure the most accurate tracing possible and minimize landmark identification error. This was done by the Principle Investigator and also an orthodontic instructor who is experienced in using Dolphin Imaging cephalometric software. Intra- and inter-reliability was assessed and was found to be reliable. Fifteen cephalometric variables were analyzed as part of the study.

3.2 Setting

The study was carried out in the orthodontic department of the University of Illinois-Chicago using cephalometric radiographs taken at two locations, a private orthodontic office in Campinas Brazil for the cervical headgear sample and from UNESP Araraquara SP- Brazil for the high pull headgear sample. The scanned digital radiographs were kept on a password protected computer.

3.3 Sample

3.3.1 Inclusion Criteria

Females age 7-13 and males age 7-14

Caucasian
Class II, division I malocclusion with a convexity ≥ 4mm and facial axis of ≤ 90 degrees
Treated with cervical-pull or high-pull headgear and no other appliances
Cephalometric Radiographs taken before and after treatment
Mesofacial – dolicofacial head type with a Ricketts total facial height ≥ 57 degrees
Treatment time of 1-2.5 years

### 3.3.2 Exclusion Criteria

Any malocclusion other than class II, division I
Patients outside of the age range of 7-13 for females and 7-14 for males
Brachyfacial head type
Missing pre-treatment or post-treatment cephalometric films
Craniofacial anomalies that may impact cephalometric tracings

### 3.4 Anticipated Risks and Benefits

**Risks:** The anticipated risks for this study are minimal. Radiographs utilized by this study have already been taken and were only taken for the purpose of treatment of the malocclusion. No radiographs have been taken for research purposes. There is the risk of potential loss of confidentiality. Measures will be taken to reduce this risk. For example, minimal patient information will be obtained. All protected health information will be stripped of the sample radiographs before they leave the private orthodontic office where they are stored. All radiographs will be assigned a number. The number corresponding to patient identity will be kept at the private orthodontic office and will not
be made available to the PI. The only purpose of the number is to allow for re-filing after the radiographs are scanned.

**Benefits:** Subjects will not benefit directly. The patients involved in the study have already been treated for their malocclusion. The overall benefit would be to the general population if it is shown that one technique for using headgear is more beneficial than the other.

### 3.5 Selection Strategy and Characteristics of the Subjects

Radiographs were obtained from the private practice and hand delivered to UIC College of Dentistry stored on a flash drive. Approximately 30 subjects from each group were assessed for adherence to inclusion criteria. After subjects who did not conform to the inclusion criteria were eliminated, 19 were left in the high pull group and 22 were left in the cervical pull group. The samples provided were half male and half female. There was no statistical significance between groups with respect to age or treatment time. The high pull headgear sample was on average 9.4 years old at the start of treatment. The cervical headgear sample was on average 8.6 years old at the start of treatment. The treatment protocol 8-10 hours per day with 450g per side and the end of the outer bow positioned posterior to the position of the upper first molar and angled up from the inner bow by thirty degrees for the group treated with cervical pull headgear. The group who wore high pull headgear was instructed to wear the appliance full time with 500-550 grams per side, and the outer bow parallel with the inner bow, but with the angle of pull forty-five degrees up to the back of the head. The outer bow was also shorter than that of the cervical pull group so that the end was positioned anterior of the first molar.
3.5.1  **Uploading Radiographs**

For each subject a file was made in Dolphin Imaging™ 11.0. The first name was entered as an alphabetical code that was assigned to each radiograph. The last name was entered as the last name of the PI so it could be identified from other investigations. The age of each subject was known in years and months so the birthdate was added into the profile by counting backward from the date of the first radiograph. After the subject profile was completed, two time points were made for each subject. They were identified with the date of the X-ray along with either "Initial" or "Final". The images were then uploaded using the “Capture/Scan” function in Dolphin Imaging™.

3.5.2  **Image Calibration and Cephalometric Tracing**

After selecting the appropriate image, the “Digitize” function was used to begin tracing the image. Each radiograph was calibrated for size using the ruler visible in each image and the ruler 1 and ruler 2 points available when tracing the images. Sixty-seven points were traced. The landmarks and definitions can be found in table 1. This was done for each subject at both an initial and final time point.

To ensure the most accurate tracing and to minimize landmark identification error, the “transfer structure” function in Dolphin Imaging™ was used. The two cephalometric radiographs were viewed to determine which had the clearest structures. The one with the less clear structures was selected and once the image was being digitized, the “Overlay structures” function was used. This function allows the user to lay the tracing from the clearest radiograph over the less clear radiograph. The outlines of the structures can then be moved around so that they overlay the structures on the
cephalogram the best that they can be. Once all structures were transferred successfully, each radiograph was oriented so that the Frankfort Horizontal line was perpendicular to the true vertical. This was done for all subjects at the initial timepoint (T1) and after treatment (T2).
TABLE I

CEPHALOMETRIC LANDMARKS

<table>
<thead>
<tr>
<th>Landmark</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Porion (Po)</td>
<td>The most superiorly positioned point of the external auditory meatus.¹</td>
</tr>
<tr>
<td>Orbitale (Or)</td>
<td>The lowest point on the inferior rim of the orbit.¹</td>
</tr>
<tr>
<td>Nasion (N)</td>
<td>The most anterior point on the frontonasal suture in the midsagittal plane.¹</td>
</tr>
<tr>
<td>A Point (A)</td>
<td>The most posterior point in the concavity between ANS and the maxillary alveolar process.¹</td>
</tr>
<tr>
<td>B Point (B)</td>
<td>The most posterior point in the concavity between the chin and the mandibular alveolar process.¹</td>
</tr>
<tr>
<td>Anterior Nasal Spine (ANS)</td>
<td>The anterior tip of the nasal spine.¹</td>
</tr>
<tr>
<td>Posterior Nasal Spine (PNS)</td>
<td>The posterior spine of the palatine bone constituting the hard palate.¹</td>
</tr>
<tr>
<td>Pogonion</td>
<td>Most anterior point on the mid-sagittal symphysis.²</td>
</tr>
<tr>
<td>Basion (Ba)</td>
<td>The lowest point on the anterior rim of the foramen magnum.¹</td>
</tr>
<tr>
<td>Pt</td>
<td>Junction of the pterygomaxillary fissure and foramen rotundum.¹</td>
</tr>
<tr>
<td>Gnathion (Gn)</td>
<td>Point midway between pogonion and menton on the outline of the symphysis.¹</td>
</tr>
<tr>
<td>Menton (Me)</td>
<td>The lowest point on the symphyseal shadow of the mandible.¹</td>
</tr>
<tr>
<td>Gonion (Go)</td>
<td>A point at the intersection of the ramus and the mandibular plane (from Go-Gn).¹</td>
</tr>
<tr>
<td>CF</td>
<td>Point of intersection of the pterygoid vertical and the Frankfort horizontal plane.¹</td>
</tr>
<tr>
<td>Pm</td>
<td>The point at which the shape of the symphysis mentalis changes from convex to concave.¹</td>
</tr>
<tr>
<td>Xi</td>
<td>Located in the center of the rectangle created by R1, R2, R3, and R4 at the intersection of the diagonals.¹</td>
</tr>
<tr>
<td>Articulare (Ar)</td>
<td>Posterior border of the neck of the condyle.²</td>
</tr>
<tr>
<td>Upper 6 Occlusal</td>
<td>Mesiobuccal cusp tip of the upper first molar.²</td>
</tr>
<tr>
<td>Lower 6 Occlusal</td>
<td>Mesiobuccal cusp tip of the lower first molar.²</td>
</tr>
</tbody>
</table>

¹ = Jacobson.
² = Dolphin Imaging™ version 11.0.
3.5.3  **Intra- and Inter-reliability**

The PI was tested for intra-reliability by tracing ten cephalometric radiographs as described previously. The PI then traced the same ten radiographs two weeks later. All fifteen variables were tested for reliability using SPSS version 22.0

Inter-reliability was determined by comparing variables from ten radiographs traced by the PI to the same variables from radiographs traced by a faculty member of the University of Illinois at Chicago Department of Orthodontics. The statistical test used was the Pearson Correlation.

3.5.4  **Data Extraction**

A custom measurement table was created by using the “Custom Analysis Editor” in Dolphin Imaging™. Once clicking this function, each variable can be selected and added to the custom analysis. This was done for each of the following variables in table II. Once the custom analysis was made, the values for each of the variables were copied and pasted from Dolphin into Microsoft Excel for data analysis.
3.6 **Data Analysis and Statistics**

Based on the distribution of the raw data, the mean differences between initial and final measurements of each sample group and mean differences between the two sample groups were tested by parametric student t-test. Data was analyzed using SPSS version 22.0. The cut off of significance was \( \alpha = 0.05 \).
4. RESULTS

4.1 Normality

Descriptive statistics were computed for all the variables. The Shapiro-Wilk test showed that the majority of the variables in the study have a normal distribution. Independent t-tests and paired t-tests were performed.

4.2 Inter- and Intra-reliability Testing

All fourteen variables were tested for intra- and inter-reliability using the Pearson Correlation test. All variables showed a correlation higher than 0.80.

4.3 Independent Samples test between Cervical Headgear and High Pull Headgear

Pretreatment (T1)

At T1 all fifteen variables were tested using the independent samples test to see if there was a significant difference between the cervical pull group and the high pull group. The only variable that showed a significant difference between the two treatment groups was ramus height (Ar-Go) with the high pull headgear group having a 3.18mm higher mean (p-value = 0.021). One variable, facial angle (FH-NPo), displayed a borderline statistically significant mean difference with a p value at 0.055. The high pull group had on average 1.55 degrees higher facial angle. For the most part the independent t-tests showed similarity between the cervical headgear group and the high pull headgear group at the initial time point (T1).
Table II

INDEPENDENT SAMPLES TEST BETWEEN THE CERVICAL HEADGEAR AND HIGH PULL HEADGEAR GROUPS PRETREATMENT (T1)

<table>
<thead>
<tr>
<th>Groups</th>
<th>Cervical Pull N (22)</th>
<th>High Pull N (19)</th>
<th>Mean Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variables</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Maxillary Depth (FH-NA)*</td>
<td>92.16</td>
<td>3.45</td>
<td>93.09</td>
<td>2.48</td>
</tr>
<tr>
<td>Convexity (A-NPo) mm</td>
<td>6.90</td>
<td>2.88</td>
<td>6.40</td>
<td>2.08</td>
</tr>
<tr>
<td>Facial Axis (NaBa-PtGn)*</td>
<td>83.94</td>
<td>3.17</td>
<td>84.77</td>
<td>2.85</td>
</tr>
<tr>
<td>Facial Angle (FH-NPo)</td>
<td>84.93</td>
<td>2.62</td>
<td>86.48</td>
<td>2.36</td>
</tr>
<tr>
<td>Facial Height (NaBa-Xipm)*</td>
<td>63.55</td>
<td>4.08</td>
<td>63.87</td>
<td>3.29</td>
</tr>
<tr>
<td>Mandibular Arc °</td>
<td>28.50</td>
<td>4.68</td>
<td>27.58</td>
<td>5.14</td>
</tr>
<tr>
<td>Occlusal Plane (OP-FH)*</td>
<td>10.22</td>
<td>2.42</td>
<td>9.03</td>
<td>3.66</td>
</tr>
<tr>
<td>FMA (MP-FH)*</td>
<td>29.49</td>
<td>3.69</td>
<td>28.51</td>
<td>3.01</td>
</tr>
<tr>
<td>U6 to SN°</td>
<td>64.69</td>
<td>4.60</td>
<td>67.11</td>
<td>3.29</td>
</tr>
<tr>
<td>Ramus Height (Ar-Go)</td>
<td>36.51</td>
<td>4.31</td>
<td>39.69</td>
<td>4.17</td>
</tr>
<tr>
<td>Palatal Plane inclination ANS-PNS to FH)°</td>
<td>2.76</td>
<td>2.81</td>
<td>3.73</td>
<td>3.98</td>
</tr>
<tr>
<td>Posterior Facial Height (Go-CF) mm</td>
<td>54.05</td>
<td>5.23</td>
<td>56.44</td>
<td>4.68</td>
</tr>
<tr>
<td>U6 to PTV mm</td>
<td>12.62</td>
<td>3.22</td>
<td>13.03</td>
<td>3.26</td>
</tr>
<tr>
<td>U6 to PP mm</td>
<td>17.80</td>
<td>1.80</td>
<td>18.80</td>
<td>2.35</td>
</tr>
<tr>
<td>L6 to MP mm</td>
<td>31.98</td>
<td>2.42</td>
<td>31.60</td>
<td>3.15</td>
</tr>
</tbody>
</table>

* borderline significance
** p <0.05

4.4 Paired Samples t-test between Cervical Headgear Variables Pretreatment (T1) and After Treatment (T2)

The paired samples t-test was done to compare mean differences for the variables in the cervical-pull group between T1 and at T2. Eleven out of fifteen variables showed significant mean differences. They include the decrease in convexity, the
increase in facial axis, the increase in facial angle, the decrease in the inclination of the occlusal plane, the decrease in the FMA, increase in U6 to SN, increase in posterior ramus, increase in palatal plane inclination, increase in posterior facial height, increase in the distance of U6 to PTV and the extrusion of U6 to PP.

**TABLE III**

**PAIRED SAMPLES T-TEST OF CERVICAL PULL HEADGEAR VARIABLES PRETREATMENT (T1) AND AFTER PHASE I TREATMENT (T2)**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean Difference</th>
<th>SD</th>
<th>95% Confidence Interval of the Difference</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary Depth (FH-NA)°</td>
<td>-0.32</td>
<td>2.10</td>
<td>lower 1.25 - upper 0.61</td>
<td>21</td>
<td>0.485</td>
</tr>
<tr>
<td>Convexity (A-NPo) mm</td>
<td>-1.84</td>
<td>1.94</td>
<td>lower 2.70 - upper -0.98</td>
<td>21</td>
<td>0.000*</td>
</tr>
<tr>
<td>Facial Axis (NaBa-PtGn)°</td>
<td>1.04</td>
<td>1.74</td>
<td>lower 0.26 - upper 1.81</td>
<td>21</td>
<td>0.011*</td>
</tr>
<tr>
<td>Facial Angle (FH-NPo)</td>
<td>1.82</td>
<td>1.70</td>
<td>lower 1.06 - upper 2.57</td>
<td>21</td>
<td>0.000*</td>
</tr>
<tr>
<td>Facial Height°</td>
<td>-0.52</td>
<td>1.79</td>
<td>lower 1.31 - upper 0.27</td>
<td>21</td>
<td>0.184</td>
</tr>
<tr>
<td>Mandibular Arc °</td>
<td>0.70</td>
<td>3.73</td>
<td>lower 0.96 - upper 2.35</td>
<td>21</td>
<td>0.391</td>
</tr>
<tr>
<td>Occlusal Plane (OP-FH) °</td>
<td>-2.18</td>
<td>2.47</td>
<td>lower 3.27 - upper -1.09</td>
<td>21</td>
<td>0.000*</td>
</tr>
<tr>
<td>FMA (MP-FH) °</td>
<td>-1.13</td>
<td>1.69</td>
<td>lower 1.88 - upper -0.38</td>
<td>21</td>
<td>0.005*</td>
</tr>
<tr>
<td>U6 to SN°</td>
<td>3.20</td>
<td>4.66</td>
<td>lower 1.14 - upper 5.27</td>
<td>21</td>
<td>0.004*</td>
</tr>
<tr>
<td>Ramus Height (Ar-Go)</td>
<td>2.53</td>
<td>2.68</td>
<td>lower 1.34 - upper 3.72</td>
<td>21</td>
<td>0.000*</td>
</tr>
<tr>
<td>Palatal Plane inclination (ANS-PNS to FH) °</td>
<td>0.94</td>
<td>1.90</td>
<td>lower 0.09 - upper 1.78</td>
<td>21</td>
<td>0.031*</td>
</tr>
<tr>
<td>Posterior Facial Height (Go-CF) mm</td>
<td>2.20</td>
<td>2.70</td>
<td>lower 1.00 - upper 3.39</td>
<td>21</td>
<td>0.001*</td>
</tr>
<tr>
<td>U6 to PTV mm</td>
<td>1.64</td>
<td>2.82</td>
<td>lower 0.39 - upper 2.89</td>
<td>21</td>
<td>0.013*</td>
</tr>
<tr>
<td>U6 to PP mm</td>
<td>1.73</td>
<td>1.32</td>
<td>lower 1.15 - upper 2.32</td>
<td>21</td>
<td>0.000*</td>
</tr>
<tr>
<td>L6 to MP mm</td>
<td>-0.65</td>
<td>2.25</td>
<td>lower 1.65 - upper 0.35</td>
<td>21</td>
<td>0.190</td>
</tr>
</tbody>
</table>

*p<0.05
4.5 Paired Samples t-test between High Pull Headgear Variables Pretreatment (T1) and after Phase I Treatment (T2)

For high-pull headgear, the variables that showed a statistically significant difference included the decrease in palatal plane inclination, increase in posterior facial height, extrusion of upper 6 to PP, and extrusion of L6 to MP.

**TABLE IV**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean Difference</th>
<th>SD</th>
<th>95% Confidence Interval of the Difference</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary Depth (FH-NA) °</td>
<td>-0.54</td>
<td>1.54</td>
<td>-1.28 - 0.21</td>
<td>18</td>
<td>0.147</td>
</tr>
<tr>
<td>Convexity (A-NPo) mm</td>
<td>-0.51</td>
<td>1.41</td>
<td>-1.19 - 0.18</td>
<td>18</td>
<td>0.136</td>
</tr>
<tr>
<td>Facial Axis (NaBa-PtGn)°</td>
<td>0.00</td>
<td>1.14</td>
<td>-0.55 - 0.55</td>
<td>18</td>
<td>1.000</td>
</tr>
<tr>
<td>Facial Angle (FH-NPo)</td>
<td>0.21</td>
<td>1.10</td>
<td>-0.32 - 0.74</td>
<td>18</td>
<td>0.426</td>
</tr>
<tr>
<td>Facial Height</td>
<td>-0.23</td>
<td>1.35</td>
<td>-0.88 - 0.42</td>
<td>18</td>
<td>0.465</td>
</tr>
<tr>
<td>Mandibular Arc°</td>
<td>0.85</td>
<td>2.78</td>
<td>-0.49 - 2.19</td>
<td>18</td>
<td>0.198</td>
</tr>
<tr>
<td>Occlusal Plane (OP-FH)°</td>
<td>0.28</td>
<td>2.28</td>
<td>-0.81 - 1.38</td>
<td>18</td>
<td>0.593</td>
</tr>
<tr>
<td>FMA (MP-FH)°</td>
<td>-0.08</td>
<td>1.89</td>
<td>-1.00 - 0.82</td>
<td>18</td>
<td>0.838</td>
</tr>
<tr>
<td>U6 to SN°</td>
<td>1.33</td>
<td>3.30</td>
<td>-0.26 - 2.92</td>
<td>18</td>
<td>0.096</td>
</tr>
<tr>
<td>Ramus Height (Ar-Go)</td>
<td>0.95</td>
<td>2.81</td>
<td>-0.40 - 2.31</td>
<td>18</td>
<td>0.156</td>
</tr>
<tr>
<td>Palatal Plane inclination ANS-PNS to FH)°</td>
<td>-1.29</td>
<td>1.71</td>
<td>-2.12 - 0.47</td>
<td>18</td>
<td>0.004*</td>
</tr>
<tr>
<td>Posterior Facial Height (Go-CF) mm</td>
<td>1.74</td>
<td>2.00</td>
<td>0.77 - 2.70</td>
<td>18</td>
<td>0.001*</td>
</tr>
<tr>
<td>U6 to PTV mm</td>
<td>0.37</td>
<td>1.93</td>
<td>-0.55 - 1.30</td>
<td>18</td>
<td>0.409</td>
</tr>
<tr>
<td>U6 to PP mm</td>
<td>1.14</td>
<td>1.01</td>
<td>0.64 - 1.65</td>
<td>18</td>
<td>0.000*</td>
</tr>
<tr>
<td>L6 to MP mm</td>
<td>1.14</td>
<td>1.50</td>
<td>0.42 - 1.86</td>
<td>18</td>
<td>0.004*</td>
</tr>
</tbody>
</table>

*p<0.05
4.6 **Independent t-test between Cervical headgear and High Pull Headgear Groups**

**after Phase I Treatment (T2)**

At T2 there was no significant difference between the Cervical pull group and the High pull group for any of the fifteen variables tested.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups</th>
<th>Cervical Pull N=22</th>
<th>High Pull N=19</th>
<th>Mean Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxillary Depth (FH-NA)°</td>
<td></td>
<td>91.85</td>
<td>92.56</td>
<td>-0.71</td>
<td>0.493</td>
</tr>
<tr>
<td>Convexity (A-NPo) mm</td>
<td></td>
<td>5.06</td>
<td>5.89</td>
<td>-0.83</td>
<td>0.319</td>
</tr>
<tr>
<td>Facial Axis (NaBa-PtGn)°</td>
<td></td>
<td>84.98</td>
<td>84.77</td>
<td>0.20</td>
<td>0.827</td>
</tr>
<tr>
<td>Facial Angle (FH-NPo)</td>
<td></td>
<td>86.75</td>
<td>86.68</td>
<td>0.06</td>
<td>0.941</td>
</tr>
<tr>
<td>Facial Height</td>
<td></td>
<td>63.03</td>
<td>63.65</td>
<td>-0.62</td>
<td>0.600</td>
</tr>
<tr>
<td>Mandibular Arc°</td>
<td></td>
<td>29.19</td>
<td>28.43</td>
<td>0.76</td>
<td>0.634</td>
</tr>
<tr>
<td>Occlusal Plane (OP-FH)°</td>
<td></td>
<td>8.04</td>
<td>9.32</td>
<td>-1.27</td>
<td>0.194</td>
</tr>
<tr>
<td>FMA (MP-FH)°</td>
<td></td>
<td>28.36</td>
<td>28.42</td>
<td>-0.06</td>
<td>0.961</td>
</tr>
<tr>
<td>U6 to SN°</td>
<td></td>
<td>67.90</td>
<td>68.45</td>
<td>-0.55</td>
<td>0.694</td>
</tr>
<tr>
<td>Ramus Height (Ar-Go)</td>
<td></td>
<td>39.04</td>
<td>40.65</td>
<td>-1.61</td>
<td>0.270</td>
</tr>
<tr>
<td>Palatal Plane inclination (ANS-PNS to FH)°</td>
<td></td>
<td>3.70</td>
<td>2.43</td>
<td>1.26</td>
<td>0.213</td>
</tr>
<tr>
<td>Posterior Facial Height (Go-CF) mm</td>
<td></td>
<td>56.25</td>
<td>58.18</td>
<td>-1.93</td>
<td>0.200</td>
</tr>
<tr>
<td>U6 to PTV mm</td>
<td></td>
<td>14.26</td>
<td>13.40</td>
<td>0.86</td>
<td>0.457</td>
</tr>
<tr>
<td>U6 to PP mm</td>
<td></td>
<td>19.53</td>
<td>19.94</td>
<td>-0.41</td>
<td>0.579</td>
</tr>
<tr>
<td>L6 to MP mm</td>
<td></td>
<td>31.33</td>
<td>32.74</td>
<td>-1.41</td>
<td>0.079</td>
</tr>
</tbody>
</table>

*p<0.05

4.7 **The Change from the Initial (T1) to after Treatment(T2) in the Cervical Pull Group Compared to the Change from the Initial (T1) to after Treatment (T2) in the High Pull Group**

The mean value for each variable at T1 was subtracted from the T2 value. This produced the mean change in each variable. The mean change for each variable of the
cervical pull group was compared to the mean change for each variable of the high pull group. The variables that reached a statistical significance included the difference in convexity, facial axis, facial angle, occlusal plane inclination, palatal plane inclination, and the vertical distance of L6 to the mandibular plane. Convexity was reduced significantly more in the cervical group than the high pull group. Facial axis was increased by 1.04 degrees in the cervical group while there was no change (0.00 degrees) in the high pull group. Facial angle behaved the same with an increase of 1.82 degrees in the cervical pull group and very little change (0.21 degrees) in the high pull group. The occlusal plane flattened by 2.18 degrees in the cervical pull group and steepened by 0.28 degrees in the high pull group. The palatal plane inclination increased in the cervical group by 0.94 degrees while it flattened by 1.29 degrees in the high pull group. Finally in the cervical group the vertical distance of the lower first molar(L6) to the mandibular plane decreased by 0.65mm, meaning the molar intruded. In the high pull group the lower molar extruded 1.14mm.
### Table VI

THE CHANGE FROM PRETREATMENT (T1) TO AFTER PHASE I TREATMENT (T2) IN THE CERVICAL PULL GROUP COMPARED TO THE CHANGE FROM PRETREATMENT (T1) TO AFTER PHASE I TREATMENT (T2) IN THE HIGH PULL GROUP

<table>
<thead>
<tr>
<th>Variables</th>
<th>Cervical Pull N (22)</th>
<th>High Pull N (19)</th>
<th>Mean Difference</th>
<th>95% Confidence Interval of the Difference</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>D Maxillary Depth (FH-NA)°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>-0.32</td>
</tr>
<tr>
<td>D Convexity (A-NPo) mm</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>-1.84</td>
</tr>
<tr>
<td>D Facial Axis (NaBa-PtGn)°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>1.04</td>
</tr>
<tr>
<td>D Facial Angle (FH-NPo)</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>1.82</td>
</tr>
<tr>
<td>D Facial Height (NaBa-XiPm)°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>-0.52</td>
</tr>
<tr>
<td>D Mandibular Arc °</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>0.70</td>
</tr>
<tr>
<td>D Occlusal Plane (OP-FH)°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>-2.18</td>
</tr>
<tr>
<td>D FMA (MP-FH)°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>-1.13</td>
</tr>
<tr>
<td>D U6 to SN°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>3.20</td>
</tr>
<tr>
<td>D Ramus Height (Ar-Go)</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>2.53</td>
</tr>
<tr>
<td>D Palatal Plane inclination ANS-PNS to FH)°</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>0.94</td>
</tr>
<tr>
<td>D Posterior Facial Height (Go-CF) mm</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>2.20</td>
</tr>
<tr>
<td>D U6 to PTV mm</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>1.64</td>
</tr>
<tr>
<td>D U6 to PP mm</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>1.73</td>
</tr>
<tr>
<td>D L6 to MP mm</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>-0.65</td>
</tr>
</tbody>
</table>

*p<0.05

### 4.8 Comparison between the Cervical Headgear Group after Treatment (T2) and the Untreated Predicted Growth

The variables after treatment (T2) were compared to the expected values for those variables as produced from the Ricketts growth prediction programmed into Dolphin Imaging™. The variables which displayed a statistically significant change

...
from T1 to T2 which could be attributed to normal growth and not to the action of cervical pull headgear include the increase in facial axis, the increase in ramus height, and the increase in the distance from U6 to PTV. The variables which displayed statistical significance from T1 to T2 and also displayed a greater change than would be expected with normal growth include the increase in facial angle, the decrease in the angle of the occlusal plane to Frankfort Horizontal, and the decrease in the mandibular plane angle (FMA). The decrease in convexity displayed statistical significance from T1 to T2 and the value at T2 was also different than the expected growth value, however it was actually less of a decrease than would have been expected with normal growth of the subjects. Variables which did not show a difference from the initial cephalogram to the final cephalogram and also were not statistically different from normal growth at T2 included maxillary depth and mandibular arc.
### TABLE VII

**INDEPENDENT T-TEST BETWEEN THE CERVICAL HEADGEAR GROUP AFTER PHASE I TREATMENT (T2) AND THE UNTREATED PREDICTED GROWTH**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean Difference</th>
<th>SD</th>
<th>95% Confidence Interval of the Difference</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>lower</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>upper</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxillary Depth</td>
<td>-0.33</td>
<td>3.80</td>
<td>-2.02</td>
<td>1.35</td>
<td>21</td>
</tr>
<tr>
<td>Convexity</td>
<td>-1.83</td>
<td>2.61</td>
<td>-2.99</td>
<td>-0.67</td>
<td>21</td>
</tr>
<tr>
<td>Facial Axis</td>
<td>0.58</td>
<td>2.96</td>
<td>-0.73</td>
<td>1.89</td>
<td>21</td>
</tr>
<tr>
<td>Facial Angle</td>
<td>1.53</td>
<td>2.31</td>
<td>0.50</td>
<td>2.55</td>
<td>21</td>
</tr>
<tr>
<td>Mandibular arc</td>
<td>0.53</td>
<td>5.54</td>
<td>-1.93</td>
<td>2.99</td>
<td>21</td>
</tr>
<tr>
<td>Occlusal Plane</td>
<td>0.66</td>
<td>2.03</td>
<td>-3.66</td>
<td>-1.86</td>
<td>21</td>
</tr>
<tr>
<td>FMA</td>
<td>-1.88</td>
<td>3.60</td>
<td>-3.48</td>
<td>-0.29</td>
<td>21</td>
</tr>
<tr>
<td>Ramus Height</td>
<td>0.59</td>
<td>4.42</td>
<td>-1.37</td>
<td>2.55</td>
<td>21</td>
</tr>
<tr>
<td>U6 to PTV</td>
<td>-0.83</td>
<td>2.48</td>
<td>-1.93</td>
<td>0.27</td>
<td>21</td>
</tr>
</tbody>
</table>

*p<0.05

### 4.9 Comparison between the High Pull Headgear Group after Treatment (T2) and Untreated Predicted Growth

The values obtained from the cephalograms taken after treatment were compared to the values obtained from the Ricketts growth prediction as programmed in Dolphin Imaging™. Out of all of the variables, only the increase in the distance from U6 to PTV was significantly less than would have been expected with normal growth.
Table VIII

INDEPENDENT T-TEST BETWEEN HIGH PULL HEADGEAR GROUP AFTER PHASE I TREATMENT (T2) AND THE UNTREATED PREDICTED GROWTH

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean Difference</th>
<th>SD</th>
<th>95% Confidence Interval of the Difference</th>
<th>df</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>lower</td>
<td>higher</td>
<td></td>
</tr>
<tr>
<td>Maxillary Depth</td>
<td>-0.34</td>
<td>2.60</td>
<td>-1.58</td>
<td>.90</td>
<td>18</td>
</tr>
<tr>
<td>Convexity</td>
<td>-0.48</td>
<td>2.65</td>
<td>-1.75</td>
<td>0.80</td>
<td>18</td>
</tr>
<tr>
<td>Facial Axis</td>
<td>-0.13</td>
<td>2.95</td>
<td>-1.55</td>
<td>1.29</td>
<td>18</td>
</tr>
<tr>
<td>Facial Angle</td>
<td>0.15</td>
<td>2.93</td>
<td>-1.26</td>
<td>1.57</td>
<td>18</td>
</tr>
<tr>
<td>Mandibular arc</td>
<td>0.74</td>
<td>4.42</td>
<td>-1.39</td>
<td>2.87</td>
<td>18</td>
</tr>
<tr>
<td>Occlusal Plane</td>
<td>-.39</td>
<td>3.72</td>
<td>-2.19</td>
<td>1.40</td>
<td>18</td>
</tr>
<tr>
<td>FMA</td>
<td>-1.24</td>
<td>3.72</td>
<td>-3.03</td>
<td>0.55</td>
<td>18</td>
</tr>
<tr>
<td>Ramus Height</td>
<td>-1.48</td>
<td>4.77</td>
<td>-3.78</td>
<td>0.81</td>
<td>18</td>
</tr>
<tr>
<td>U6 to PTV</td>
<td>-2.46</td>
<td>4.39</td>
<td>-4.58</td>
<td>-0.34</td>
<td>18</td>
</tr>
</tbody>
</table>

*p<0.05
5. DISCUSSION

There is a lack of consistent evidence that describes the differences that cervical pull headgear and high pull headgear have on the dental and skeletal characteristics of a growing child, particularly a child who is growing with the tendency to see an increased anterior facial height and possibly backward mandibular rotation. This study was done in an attempt to find clear evidence that there is a difference in the mechanism of action of the two types of headgear and that one is able to produce a greater positive change in children with vertical growth tendencies.

5.1 Characteristics of the Cervical Headgear Group and High Pull Headgear Group at initial (T1)

The variable, ramus height, showed a statistically significant mean difference between the cervical-pull and high-pull treatment groups. The ramus height of the high-pull headgear group was on average 3.18mm greater than the cervical pull headgear group.

The variable facial angle showed a borderline statistically significant mean difference with high pull headgear having an average of 1.55 degrees greater facial angle. The greater the facial angle, the more protrusive the chin. This means the high pull group started out with the chin slightly more forward than the cervical pull group.

Other than the two variables which displayed a significant difference or a borderline significant difference, the two groups were similar. Due to this similarity we
were able to reasonably compare the outcomes of the two treatment techniques. Figure 1 shows the tracings for T1 compiled into an average.

**Figure 1** AVERAGE TRACING OF THE CERVIAL PULL GROUP AND HIGH PULL GROUP AT T1

5.2 Comparison of the Cervical Pull Group Pretreatment (T1) and After Phase I Treatment (T2)

Comparisons were made between T1 and T2 values for the group that received treatment with cervical -pull headgear in order to determine changes that happen over the course of treatment. Eleven out of fifteen variables showed significant difference
from T1 to T2. The average T2 values were then compared to a growth prediction obtained with the growth simulation feature of Dolphin Imaging. This allowed us to determine if the changes seen from T1 to T2 were due to the treatment mechanics, or if the changes were the result of normal growth.

5.2.1 Convexity

Convexity decreased from T1 to T2 by an average of 0.32mm. This means that the chin came forward so that the distance from point A to N-Po was decreased. This improves the facial profile. According to growth prediction of Ricketts, a child of 8-9 years old would be expected to decrease in their convexity 0.33mm per year, so this change in convexity was about half the expected change if the patient were to grow without influence (RMO Data services).

5.2.2 Facial Axis

Facial axis increased an average of 1.04 degrees. This means the chin came forward and profile was improved. It is important to mention that the facial axis indicates growth direction of the chin. A smaller than normal facial axis indicates a vertical grower, while a larger than normal facial axis indicates a horizontal grower (RMO Data services). Our sample population included only vertical growers. Without treatment the facial axis is expected to change only slightly with growth (Ricketts, 1961). This group of subjects who received cervical pull headgear displayed an increase in the angle of the facial axis. This could mean that the cervical pull headgear was able to produce a favorable change in the pattern of facial growth. It helped change vertical growers into more horizontal growers. This is a favorable, but curious finding since previous studies
have shown that it is not uncommon for the facial axis to decrease as the mandible swings back during orthodontic treatment (Ricketts, 1961). When the facial axis at T2 was compared to the expected value that was obtained from a two year growth prediction obtained through the Dolphin Imaging 11.0 growth simulation, the difference was not significant.

5.2.3 Facial Angle

Facial angle describes the A-P position of pogonion. Facial angle increased 1.82 degrees meaning the chin came forward. Pogonion came significantly more forward in our sample than would be expected due to normal growth. The expected amount of change over a three year period from 9 to 12 years old is one degree (RMO data services). This indicates that cervical headgear is capable of producing increases in Facial angle that are significantly greater than with no treatment. When the average value at T2 was compared with the Dolphin Imaging growth prediction, the significance remained with the T2 average being significantly greater than the two year growth prediction.

5.2.4 Occlusal Plane to Frankfort Horizontal

Occlusal Plane measured from FH decreased an average of 2.18 degrees. This indicates that the occlusal plane flattened. Cervical Pull headgear aids in the flattening of the occlusal plane which is a critical component to normal growth and development of the face. Other studies have found that the occlusal plane flattened more when cervical pull headgear was used versus high pull (Burke, 1992; Brown, 1978). They also found that this flattening of the occlusal plane was stable over time (Burke, 1992). When
compared with the two year growth prediction from Dolphin Imaging, it was found that this flattening of the occlusal plane was significantly more than would be expected with normal growth.

5.2.5 **Mandibular Plane**

The Mandibular plane angle decreased an average of 1.13 degrees over the course of treatment. When a patient is allowed to grow without interference, the mandibular plane is expected to decrease at a rate of 1 degree every three years (RMO Data services). In our sample the mandibular plane decreased over 1 degree in two years. This is more than would be expected without the mechanics of the cervical headgear. It is certainly more closing than would be expected during treatment. The closing of the MPA contradicts another study that showed the MPA increasing during treatment and closing once treatment was finished. Results were variable with this study with not all of the measurements for mandibular plane showing an increase and only one showing statistical significance (Burke, 1992). When compared to the Dolphin growth prediction for our sample, the value retained its significance.

5.2.6 **Inclination of Upper 6 to SN**

The angle produced when a line is drawn through the long axis of the upper 6 and intersected with SN produces an angle that indicates the inclination of the upper molar. The cervical pull headgear acted to upright the U6. It uprighted by an average of 3.20 degrees over the course of phase I treatment. This is an important step in correcting class II malocclusion due to the correlation between a distally inclined upper molar and a class II malocclusion (Fushima, 1996)
5.2.7 Ramus Height

Ramus height increased from T1 to T2 by an average of 2.53mm. While this increase in ramus height is favorable in correcting the class II malocclusion, it is not more than the increase that would be expected in this population over the course of two years. This is shown when the values from T2 was compared to the value given by the growth prediction was not significantly different.

5.2.8 Palatal Plane inclination

The angle between the palatal plane and Frankfort Horizontal increased an average of 0.94 degrees. These findings are similar to the finding by Brown that cervical face bow therapy puts forces on the maxilla that tip it downward in the anterior region thereby increasing the inclination of the palatal plane (Brown, 1978) and also similar to reports by Ricketts and Melsen that cervical headgear allows the maxilla to rotate in a clockwise manner (Ricketts, 1973; Melsen, 1978, Gautam, 2009). Other studies have shown decreases in palatal plane inclination, but not to the point of statistical significance (Burke, 1992).

5.2.9 Posterior Facial Height

Posterior facial height measured from Go-CF increased an average of 2.20mm. This is not surprising since the children included in this study are growing and also it is consistent with findings from other works that looked at growth of the mandible during treatment with cervical headgear (Burke, 1992)
5.2.10 **Upper 6 to PTV**

The distance of U6 to PTV increased an average of 1.64mm from T1 to T2. This is similar to what would be expected with growth and was confirmed to be not statistically different from the value that would have been expected is normal growth were to continue (Dolphin). On average the distance from the upper molar to PTV is the age of the patient plus 3mm. Therefore in a 9 year old the distance should be 12mm. It increases 1mm every year until growth ceases (Ricketts, 1961).

5.2.11 **Upper 6 to PP**

Upper 6 to palatal plane increased indicating that the cervical headgear acted to extrude the upper molar. This has been found in previous literature (Brown, 1978; Burke, 1992 and MelsEn 1978). Extrusion of the molar might be expected to cause backward rotation of the mandible (Shudy, 1965), but in these subjects, the extrusion of the molar did not adversely affect the position of the mandible. This is in agreement with Burke and Jacobson who also noted extrusion of the upper molar without changes in the mandibular position. They postulated that the extrusion of the upper molar was compensated for by the absence of change in the lower molar (Burke 1992). This could be what has happened in our sample since the measurement of L6 to the mandibular plane did not change significantly from T1 to T2.

5.2.12 **Lower 6 to MP**

The distance of the mesiobuccal cusp of the lower first mandibular molar to the mandibular plane did not change significantly from T1 to T2 in the CHG population. One explanation for this is that the extrusion of the upper 6 along with the musculature
helped hold the L6 in position. This agrees with previous studies (Burke, 1992; Brown, 1978).

Figure 2  AVERAGE TRACING OF THE CERVICAL PULL GROUP AT T1 AND T2
5.2.13 **Maxillary Depth**

The changes seen in maxillary depth were not significantly different from T1 to T2. The average value for T2 was not significantly different from the expected value obtained from the Dolphin Imaging growth prediction.

5.2.14 **Mandibular Arc**

Mandibular arc describes and predicts the nature of the growth of the mandible as it grows in a pattern that resembles a segment of a circle. The dimensions of this circle are determined by the shape of the mandible (Ricketts, 1972). The changes seen in Mandibular arc between T1 and T2 were not significantly different. The average value from T2 was not significantly different from the Dolphin Imaging growth prediction.

5.2.15 **Total Facial Height**

The changes seen in total facial height from T1 to T2 were not significant. The value for T2 was not significantly different from the value obtained from the Dolphin Imaging growth prediction. Even though these findings are not significant, it has implications in this study. Previous studies have recommended that cervical head gear not be used in vertical growers due to its tendency to increase the anterior facial height. In this study, the use of cervical headgear did not increase facial height which is favorable when treating vertically growing patients.

5.3 **Comparison of High Pull Headgear Group Pretreatment (T1) and After Phase I Treatment (T2)**

Comparisons were made between T1 and T2 values for the group that received treatment with high-pull headgear in order to determine changes that happen over the
course of treatment. Four out of fifteen variables showed significant difference from T1 to T2. The average T2 values were then compared to a growth prediction obtained with the growth simulation feature of Dolphin Imaging. This allowed us to determine if the changes seen from T1 to T2 were due to the treatment mechanics, or if the changes were the result of normal growth.

5.3.1 **Palatal Plane inclination**

The palatal plane decreased in steepness by 1.29 degrees. One explanation for this flattening of the palatal plane is that high pull headgear causes the maxillary complex to rotate around a center of rotation in the anterior portion of the maxilla while cervical pull headgear causes the maxilla to rotate around a center of rotation in the posterior portion of the maxilla. This is consistent with the findings of Gautam who looked at stresses applied to bone using dry skulls and the finite element model (Gautam, 2009).

5.3.2 **Posterior Facial Height**

Posterior facial height increased by 1.74mm over the course of treatment. Based on the Ricketts growth prediction programmed in the Dolphin Imaging software this change in posterior facial height is consistent with normal growth.

5.3.3 **U6 to Palatal Plane**

The distance of the upper first molar to the palatal plane increased by 1.14mm over the course of treatment. This means that U6 extruded. The proponents of high pull headgear claim that high pull headgear holds the position of the upper molar (Shudy, 1965). This was found to not be the case in our population.
5.3.4 **L6 to Mandibular Plane**

The distance of the lower first molar to the mandibular plane increased 1.14mm from T1 to T2. The agrees with the findings from Burke and Jacobson who also noted extrusion of L6 in the high pull sample, but not in the cervical sample (Burke, 1992).

5.3.5 **Additional Variables**

The other eleven variables did not show any significant difference between T1 and T2. Also, the values at T2 were not significantly different from the expected values obtained with the Dolphin Imaging growth prediction with one exception. The distance of U6 to PTV was significantly different than the growth prediction for this variable. The value at T2 was less than would be expected with normal growth. This suggests that high pull headgear acts to hold the anterior movement of the upper molar.
5.4 Comparison of High Pull Headgear and Cervical Pull Headgear after Phase I treatment (T2)

There were no statistically significant differences in skeletal or dental changes between the two groups over the course of treatment. The high pull headgear group on average was in treatment for 7 months longer than the cervical pull headgear group. The high pull group was also on average one year and one month older than the cervical pull group. This could indicate that changes seen in the cervical pull group occurred over a shorter span of time than for the high pull group. This is similar to the
findings from a 1992 paper by Burke and Jacobson. They compared vertical changes in subjects treated with cervical or high pull headgear. The only differences between the groups that were statistically significant were the extrusion of the maxillary molar and its inclination relative to SN.

Figure 4  AVERAGE TRACINGS OF THE CERVICAL PULL GROUP AND THE HIGH PULL GROUP AT T1 AND T2
5.5 Comparison between the change in variables of the Cervical Pull Group and the High Pull Group

Six out of fifteen variables showed statistical significance when the mean change from T1 to T2 was compared. The variables that displayed a significant difference included convexity, facial axis, facial angle, occlusal plane inclination, palatal plane inclination, and the vertical distance of L6 to the mandibular plane. Convexity is one of the measurements that indicates a class II skeletal relationship with a retrusive mandible. One of the primary goals of headgear wear is a reduction in convexity. Over the course of treatment the reduction in convexity was greater for the cervical pull group. This indicates that cervical pull headgear was more effective at reducing convexity than high pull headgear. Facial axis indicates growth direction of the chin. A smaller than normal facial axis indicates a vertical grower, while a larger than normal facial axis indicated a horizontal grower. Without intervention the facial axis is not expected to change much with growth. This lack of change in facial axis was consistent with the findings of the high pull group. Facial axis increased in the group treated with cervical pull headgear. This means that cervical pull headgear facilitated the conversion of our group from vertical growers to being less vertical in growth tendency. Facial angle also showed a significant difference in the changes from T1 to T2. Facial angle describes the anterior-posterior position of the chin. Cervical pull headgear produced a much greater forward movement of pogonion when compared to high pull headgear. The difference in the occlusal plane change was significant as well. Cervical pull headgear was able to flatten the occlusal plane. This is especially helpful to do in a growing child since class II malocclusions are strongly related to the steepness of the
posterior occlusal plane (Fushima, 1996; Kim, 2006). By flattening the occlusal plane and providing a fulcrum at the first molar (Harvold, 1968), the cervical pull headgear is acting to encourage growth at the condyle by forcing it to react to the needs of the oral system (Moss and Salentijn, 1971). Even though the tendency of cervical pull headgear was to flatten the occlusal plane, it was the opposite for the palatal plane. Cervical pull headgear produced a force that steepened the palatal plane while high pull headgear flattened the palatal plane. This is consistent with findings from other studies (Ricketts, 1973; Brown, 1978; Melson, 1978; Gautam, 2009). Finally, the last variable that displayed a significant difference in change from T1 to T2 between the groups was the lower first molar (L6) to the mandibular plane. Cervical pull headgear acted to intrude the lower first molar while high pull headgear allowed the lower first molar to extrude almost 1.5mm. This helps explain why high pull headgear was unable to produce favorable changes in the FMA, facial axis, and facial angle like cervical pull headgear produced. The extrusion of the lower molar prevented any favorable change that was expressed in the cervical pull headgear population.

On possible explanation for the difference in action of the two types of headgear is their direction of pull through the center of resistance of the maxilla. The placement of the center of resistance of the maxilla lies approximately at the pterygomaxillary fissure when cervical pull headgear is used. It lies further anterior at approximately at the premaxilla when high pull headgear is used (Gautam, 2009). This accounts for the steepening of the palatal plane when cervical pull headgear was used and flattening of the palatal plane when high pull headgear was used.
5.6 **Clinical Applicability**

Even though there is no standard of treatment concerning the choice to use cervical pull headgear or high pull headgear in a population with a class II, division I malocclusion and a vertical growth pattern, these findings suggest that cervical pull headgear may work with a mechanism of action that can help reduce vertical measurements and encourage forward movement of the mandible. This was demonstrated in the decrease in mandibular plane angle, the increase in facial angle and facial axis, and the flattening of the occlusal plane that is seen in the cervical headgear group versus the lack of changes in these measurements in the high pull headgear group. It was further demonstrated by the difference between the groups regarding the amount of change seen from the initial time point to the final time point for the variables convexity, facial angle, facial axis, occlusal plane, palatal plane, and L6 to mandibular plane. Cervical pull headgear was able to produce favorable changes such as the decrease in convexity, the increase in facial angle, the increase in facial axis, the flattening of the occlusal plane, and the inhibition of extrusion of the lower first molar. High pull headgear was only able to produce a significant change in the vertical distance of the lower first molar to the mandibular plane. In other words, it extruded.

5.7 **Strengths and Limitations of the Current Study**

Many studies look at the affect that headgear has on growing children, but few look at children who specifically have a vertical pattern of growth. The strength of this study was the strict inclusion criteria that narrowed down the type of subject to those with a vertical growth pattern. Also few previous studies have looked at facial angle and facial axis changes as a measure of headgear efficiency.
As with any study that looks at the effects of headgear, this study did not account for compliance on the part of the patient. It is unknown the true duration of headgear wear each night by each subject and no data was collected implying compliance. This was a limitation.

Also, the group categorization was known by the PI for the entire experiment. Strength of the study would be increased if the PI had been blinded to the treatment group status.
6. CONCLUSION

It seems that the two groups were similar at the start of treatment and therefore were suitable to be compared. Over the course of treatment both cervical pull headgear and high pull headgear were able to have effects on the growth of the subjects. When comparing the mean change in measurements from the initial radiograph to the radiograph taken after treatment, there were differences in the amount that each headgear affected the variables tested. These differences suggested that cervical pull headgear had more control over skeletal vertical measurements than high pull headgear.
CITED LITERATURE


APPENDIX A

Determination Notice

Research Activity Does Not Involve “Human Subjects”

November 25, 2013

Erin Dobbins, DMD
Orthodontics
801 S. Paulina Street
M/C 841
Chicago, IL 60612

Phone: (317) 727-6524 / Fax: (312) 996-0873

RE: Research Protocol # 2013-1148

“Change in the Vertical Dimension of Class II Division I Patients after use of either Cervical-pull or High-pull Headgear”

Sponsor: None

Dear Dr. Dobbins:

The above proposal was reviewed on November 24, 2013 by OPRS staff/members of IRB #2. From the information you have provided, the proposal does not appear to involve “human subjects” as defined in 45 CFR 46.102(f).

The specific definition of human subject under 45 CFR 46.102(f) is:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information.
Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

All the documents associated with this proposal will be kept on file in the OPRS and a copy of this letter is being provided to your Department Head for the department’s research files.

If you have any questions or need further help, please contact the OPRS office at (312) 996-1711 or me at (312) 355-2908. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Charles W. Hoehne, B.S., C.I.P.
Assistant Director
Office for the Protection of Research Subjects

cc: Carlotta A. Evans, Orthodontics, M/C 841
    Budi Kusnoto, Orthodontics, M/C 841
APPENDIX B

Dentistry Science Graduate Program Database Agreement
Dentistry School of Araraquara
University of São Paulo State – UNESP

DATABASE RELEASE AGREEMENT
Dentistry Science Graduate Program
University of São Paulo State - UNESP
School of Dentistry
Rua Humaitá, 1680
Bairro: Centro
14801-903 - Araraquara, SP
Pabx: (16) 3301-6300

Access to the Database
The Throug Class II Treatment database will be made available to researchers on a case-by-case basis. To receive a copy of the imagery and associated data, the requestor must sign this document and agree to observe the conditions listed in this document. In addition to other possible remedies, failure to observe these conditions may result in access being denied for any other portion of the database, loss of use of the database, and the possibility of being subject to civil litigation.

Conditions for use of the Database
In consideration for access to the Throug Class II Treatment Database, the researcher(s) agrees to the following conditions:
1. Signed permission may be granted for use of Class II Throug treatment data after consideration of a written request for the use of the records by the Dr. Ary dos Santos Pinto, professor of the Department of Orthodontics. To apply to use the database, a researcher must fill out a regulation form letter. This must be accompanied by a proposal which indicates the records, ages and sample sizes required, measurements to be recorded. Criteria to be considered for granting permission to use data are: the importance and feasibility of the proposed analysis, the competence of the investigator and overlap or relationship to other analyses currently being undertaken.

ARARQUARA DENTISTRY SCIENCE GRADUATE PROGRAM DATABASE RELEASE AGREEMENT
Persons wishing to use the Dentistry Science Graduate Program data should send a written proposal and the formal application for the use of the records to Prof. Ary Santos-Pinto at the above address.
2. The proposal should include a statement of the data required, the purpose for which it will be used, the names of the persons intending to use it and plans for publishing results.
3. The Dentistry Science Graduate Program data are made available to specific individuals to use for specific purposes only.
4. Permission to use the data expressly forbids its being passed on or disclosed to any individual not specified in paragraph 2.
5. The data provided may not be used for any but the originally stated purposes. Any change can only be agreed to after receipt of a new request and agreement. For example, if the initial data is incorporated into a new phase or additional studies, further approval is necessary.
6. Data from the files is the property of the Dentistry Science Graduate Program and not of any one individual researcher. Therefore, upon the completion of the project the raw non-digital and digital data as well as a summary or thesis of the work must be submitted to the Dentistry Science Graduate Program to be stored in a data bank and be available to other users.
7. Any derived data at the individual level, e.g., individual growth curves fitted by a user, are to be returned to the files of the Dentistry Science Graduate Program where they will become available to other users. They may not be copied for commercial purposes.
8. Each user must submit a detailed report on research progress and any relevant publications by the end of each year. The raw non-digital and digital data and six reprints of all publications or a copy of their thesis are to be forwarded to the Dentistry Science Graduate Program as soon as possible after receipt.
Conditions for Redistribution:

1. The Dentistry Science Graduate Program, in whole or in part, shall not be further distributed, published, reproduced, copied, or disseminated in any way or form whatsoever, including but not limited to digital images, negatives, electronic, paper, video, print, cable, or the Internet, whether for profit or not. This includes further distributing, copying or disseminating to a different facility or organizational unit within the requesting university, organization, or company.

2. Modification and Commercial Use: Without prior approval from the Dentistry Science Graduate Program, raw data from the Dentistry Science Graduate Program, in whole or in part, may not be modified or used for commercial purposes.

3. Warranties: The Dentistry Science Graduate Program makes no warranties of any kind - expressed or implied - including but not limited to warranties of fitness of purpose or of results obtained from Researcher's use of Dentistry Science Graduate Program Database.

4. Requests for the Dentistry Science Graduate Program Database: All requests regarding the Dentistry Science Graduate Program Database will be forwarded to Prof. Ary dos Santos-Pinto of the Dentistry Science Graduate Program Database.

5. Publication Requirements: Publication is encouraged, and appropriate recognition of the source of the data must be included in publications. Prior written approval must be obtained from the Dentistry Science Graduate Program for those seeking to include renderings from the Dentistry Science Graduate Program Database in reports, papers, and other documents. In no case should the facial images be used in a way that could cause the original subject humiliation, harassment, or mental anguish, or be perceived in a false light. Anyone utilizing the Dentistry Science Graduate Program Data has to supply Dentistry Science Graduate Program Library with a copy of the completed and approved thesis or four (4) copies of the published article.

6. Citation: All documents and papers that report on research that uses the Dentistry Science Graduate Program Database must acknowledge the use of the database by including the appropriate citation: "This study was made possible by use of data from the Dentistry Science Graduate Program, School of Dentistry, University of São Paulo State - UNESP".

7. Publications to University of São Paulo State – UNESP. A copy of all reports, papers, and other documents that are for public or general release that use Dentistry Science Graduate Program Database must be forwarded immediately upon release or publication to Prof. Ary Santos-Pinto.

8. Indemnification: Researcher agrees to release, indemnify, defend, and hold harmless the University of Toronto and its Board of Trustees, officers, employees, and agents, individually and collectively, from any and all losses, expenses, damages, demands, and/or claims based upon any such injury or damage (real or alleged) and shall pay all damages, claims, judgments or expenses resulting from Researcher's use of the Dentistry Science Graduate Program Database.

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[Page 2]

[BURLINGTON GROWTH CENTRE DATABASE RELEASE AGREEMENT]

9. No Assignment: Researcher may not assign this Agreement, nor may any rights under this Agreement be assigned or otherwise transferred to any third party, without the prior written consent of Prof. Ary Santos-Pinto from the Dentistry Science Graduate Program.

10. Equitable Relief: Researcher acknowledges and agrees that the Dentistry Science Graduate Program shall be entitled to seek injunctive relief to prevent an actual breach of this Agreement and enforce its terms. The Dentistry Science Graduate Program may pursue any other remedy to which it is entitled in law or in equity.

12. Term: The Dentistry Science Graduate Program may terminate access to the Dentistry Science Graduate Program database at any time, for any reason and at its sole discretion.

NAME (Erin E Dobbins) SIGNATURE DATE

NAME OF SUPERVISOR (Nelson D Oppermann) SIGNATURE DATE

UNIVERSITY OF ILLINOIS AT CHICAGO 801 S. PAULINA ST RM 131

ORGANIZATION AND ADDRESS (in capitals) CHICAGO, IL 60612 USA

EMAIL ADDRESS PHONE NUMBER
RESEARCH DESCRIPTION: (Please provide a brief description and attach your research proposal)

Changes in the Vertical Dimension of Class II Division I Patients after the application of different headgear tractions and its effects

BY
ERIN E. DOBBINS
B.S., Purdue University, 2005
D.M.D., University of Louisville School of Dentistry, 2012

THESIS
Submitted as partial fulfillment of the requirements for the degree of Master of Science in Oral Sciences in the Graduate College of the University of Illinois at Chicago, 2015

Chicago, Illinois

Defense Committee:
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