University of Alberta

Skeletal and Dentoalveolar Effects of Class II Treatment Using a CrossBow Appliance Compared to an Untreated Control Group

by

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Dedications

This work is dedicated to everyone that helped me get this far, including, in no particular order:

- Paul Major
- Carlos Flores-Mir
- Jim Posluns
- Frank Pileiro
- Patrick Smith
- Gavin James
- Dennis Smith
- Duncan Higgins
- My immediate "Family Tree" – Grandpa Keith King, Big Brother Mike Ziglo, Little Brother Khaled Sharaf, and Granddaughter Jill Gordon
- My "actual" family for their love and support
- And my wife Megan. I wouldn't be here without you.

Abstract

Objective: The aim of this study was to determine the dental and skeletal effects of the CrossBow appliance as determined by linear and angular measurements on lateral cephalographs.

Methods: Lateral cephalographs were obtained of 30 untreated subjects from the Burlington Growth Study and of 67 consecutively-treated CrossBow subjects from a private orthodontic practice. A modified Pancherz Analysis was used to assess changes.

Results: Three of the angular (SNA, ANB, and L1-MP) and five of the linear variables (L1 minus Pg, OJ, U6 minus A, L6 minus Pg, and A-OLp) showed statistically significant changes in the direction of Class II malocclusion correction for the CrossBow-treated subject at the $\alpha=0.05$ level or better. These results where achieved in a mean of 4.54 months of CrossBow use.

Conclusion: The CrossBow appliance showed statistically significant changes in the direction of Class II correction for 8 of the 14 variables measured.

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Chapter 1

Introduction and Literature Review

1.1 Introduction

Studies have estimated that 15-20% of children will develop Angle Class II malocclusions[1]. The treatment of Class II malocclusions is one of the most popular areas of research in orthodontics, and certainly one of the most controversial. While some methods involve purely dental movements to align the dentition, such as a Pendulum appliance or Wilson's Bimetric Distalizing Arch, others aspire to correct the skeletal component of the problem. These include head-gear, which purports to restrict maxillary anterior growth. A wide range of functional appliances, also exist. These hold the mandible in a protruded position hoping to encourage its growth in this direction, while the reactive force from this protrusion is transmitted to the maxilla, theoretically producing "head-gear effect" in restraining the maxillary anterior growth. Recent long-term randomized control trials performed by Tulloch et al[2] have raised doubts as to the efficacy of both head-gear and functional appliance treatment in regards to their long-term skeletal changes. Orthodontists continue to seek for appliances that will treat Class II malocclusions quickly and predictably.

One such orthodontist is Duncan Higgins, currently practicing in Delta, British Columbia. He has recently developed a new appliance to correct Class II malocclusions called the CrossBow (abbreviated as "Xbow"). He has lectured on his appliance across North America, claiming fast treatment times (around 3-6 months in most cases) in which both maxillary 1st molar distalization and lower incisor proclination occur. Since studies show no significant skeletal effect in the long term, there is an argument that there is limited value in prolonged treatment attempting skeletal change that will only diminish later.

This paper is a study of Xbow treated patients compared to an untreated Control group so that the precise method and magnitude of Class II correction taking place can be evaluated.

1.2 Literature Review

1.2.1 Functional Appliance History

The term *functional appliance*, when used in orthodontics and dento-facial orthopedics, refers to both removable and fixed appliances designed to alter maxillary or mandibular position both sagittally and vertically.[1] The goal of these appliances is to encourage or possibly redirect growth in a favourable direction.

Early animal studies[3, 4]using functional appliance interventions showed increases in mandibular dimensions, but similar results have not been clearly demonstrated in human studies. Currently there is little doubt that measurable dental changes such as reduced overjet or molar Angle Class correction occur in a favorable manner with the continuous use of functional appliances. However, the degree of skeletal versus dentoalveolar change that underlie these treatment effects (especially in the long-term) have become a source of debate.[5-8]

Both removable and fixed functional appliances have been used for decades, with various forms coming in and out of popular use. While removable appliances such as activators, bionators, and twin-blocks are still widely used, fixed functional appliances have enjoyed a recent surge of use. Fixed functional appliances have the advantage of not relying on patient compliance because they are "fixed" in the mouth thus always working, and they can be used concurrently with full fixed appliances. One significant disadvantage is that they are more prone to breakage[9] than some of their removable counterparts. The most used and researched of these appliances is the Herbst appliance, re-introduced by Pancherz in the late 1970's.

1.2.2 Mandibular Growth

As mentioned, functional appliance use generally occurs around the time of the pubertal growth spurt. Research has shown that cranio-facial and mandibular growth spurts exist around this time as well[10, 11]. These same studies highlight that the mandible grows more during this time than the maxilla, and a general lessening of facial profile convexity is seen over the adolescent years. Since orthodontists generally treat patients during this crucial time-period, and treatment times typically range anywhere from 6-24 months[6, 12], an appreciable amount of growth will take place and be reflected in the post-treatment radiographs. Positive change, especially concerning mandibular skeletal measurements, would be anticipated, regardless if a functional appliance was used or not. Thus the need for comparisons to untreated control groups: so investigators can evaluate to what extent the changes seen are the work of the appliance, and not just the result of normal growth.

1.2.3 Herbst Appliance

The Herbst appliance (see Figures 1-1, 1-2, and 1-3) was originally developed by its name-sake in the early 1900s[13], and was re-introduced by Pancherz in the late 1970s[14] who has subsequently published much research on the Herbst[15-25]. Pancherz and his collaborators have been able to show stimulated condylar growth in Herbst patients[14, 16, 17, 26-29], as well as glenoid fossa remodeling [14, 24, 28, 30]. A systematic review[31] of the literature regarding TMJ-related changes with Herbst treatment found that the condylar changes produced were not clinically significant and that nature of glenoid fossa condylar remodeling, as well as disc position change, were not clearly established.

Both O'Brien et al[9] and Schaefer et al[32] published studies directly comparing Herbst treatment to Twin-Blocks. Schaefer found similar results at the end of treatment with both appliances, but noted that the twin-block appliance seemed to be more efficient in correcting molar relationship and sagittal maxillo-mandibular skeletal differences as well as showing greater elongation of the ramus. It should be noted that final measurements were taken after full fixed appliances were used. In O'Brien[9], consideration was also given to "psycho-social" effects, and showed that the patients with twin-blocks had less cooperation, and felt their appliance affected their eating and family relationships more than the Herbst group. The Herbst group had a slightly shorter treatment time (1.5-2.2 months shorter), but had more appointments over that time due to appliance breakage or debonding. They noted similar dental and skeletal results between the two groups.

There are variations in the exact Herbst appliance design, including the "original" banded version used by Pancherz[17, 18, 25, 33](Figure 1-1), an acrylic-splint Herbst (popularized by McNamara and colleagues[34-36](Figure 1-2), a "cast –splint" design[37-39](Figure 1-3), and a "crown" Herbst, which covers the entire molar, save for an opening on the occlusal to facilitate removal in some designs[32, 40, 41]. Burkhardt et al[42] found few differences between the acrylic-splinted and crown-Herbst designs.

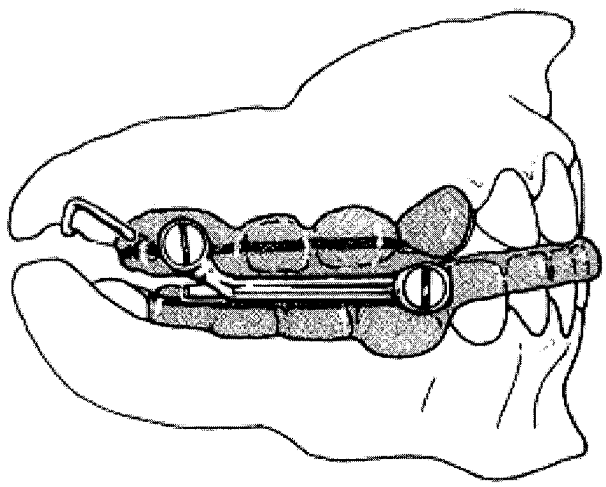


Figure 1-1, Acrylic Splint Herbst (image taken from Franchi, 1999[36]), lateral view

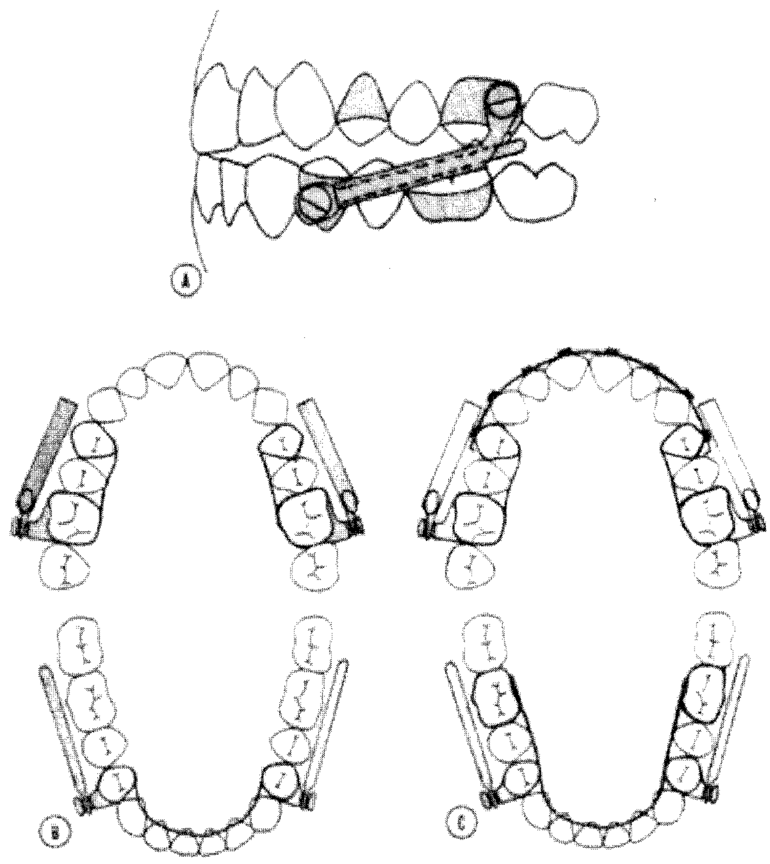


Figure 1-2, "Banded" Herbst appliance (image taken from Pancherz, 1985[24]). Top: lateral view. Bottom: Occlusal views, with (right) and without (left) increased anchorage

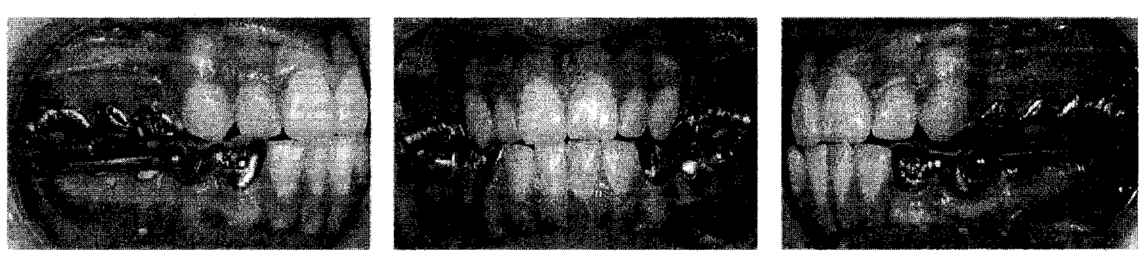


Figure 1-3, Intra-oral views of "cast-splint" Herbst appliance (image taken from O'Brien et al 2003[9])

Recently two systematic reviews have investigated the Herbst literature[43, 44]. The review of the acrylic-splint Herbst literature[44] ended up including three studies, none of which were randomized control trials. The other review[43] included only banded or crown Herbst appliance treatment. Again only three studies met the inclusion criteria, and two of those[16, 17] used the same patient samples but provided different measurements in each paper. Both systematic reviews focused only on short-term changes of both skeletal and dental variables, using both linear and angular measurements. Results were measured upon appliance removal. The finding of the two reviews were similar in that statistically significant changes were found regarding increased mandibular sagittal length, proclination of lower incisors, anterior movement of the lower molars and distal movement of the upper molars. Both also found no significant effect on maxillary skeletal position. The acrylic-splint study showed an increase in vertical height of the ramus and lower face height, while the other investigation had mixed results for these variables.

1.2.4 <u>Forsus Springs and Similar Appliances</u>

There are several appliances and devices which allow the patient to close in centric occlusion while still correcting a Class II problem. These appliances, which Ritto has termed "Flexible Fixed Functional Appliances (FFFA's)"[45] would thus include the Jasper Jumper (American Orthodontics, Sheboygan, WI), the Eureka Spring (Eureka Spring Co, San Luis Obispo, CA), and the Forsus Flat Nitinol Spring (3M Unitek, Monrovia, CA), among others. These could be categorized as non-protrusive inter-arch Class II correctors. There are no published studies on the Forsus FRD ("Fatigue Resistant Device") (3M Unitek, Monrovia, CA), although case report and technology description-style articles do exist[46-48]. The Forsus Flat Nitinol Spring has been the subject of at least two studies[49, 50], while only one clinical trial exists for the Eureka Spring[51]. The appliances are shown in Figures 1-4, 1-5, and 1-6 below.

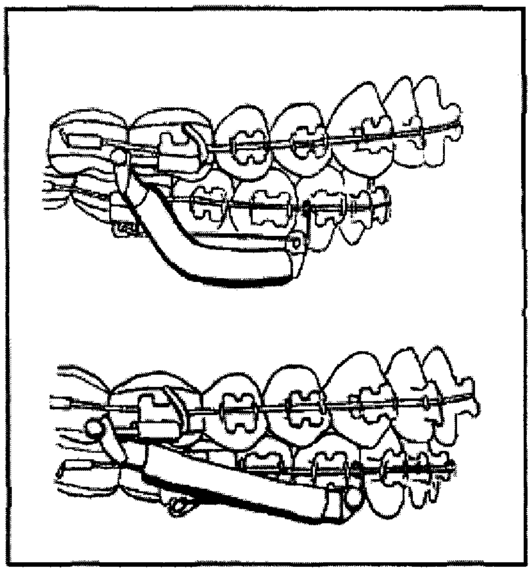


Figure 1-4, Jasper Jumper, pictured with mandible in centric occlusion (top) and protruded to relieve spring pressure (bottom) (image taken from Covell 1999[52])

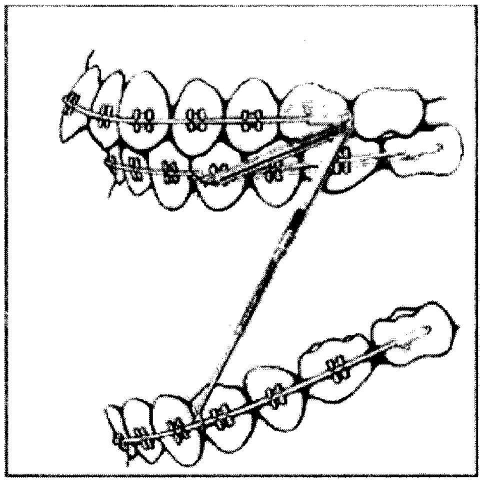


Figure 1-5, Eureka Spring, shown in open and closed position (image taken from Stromeyer 2002[51])

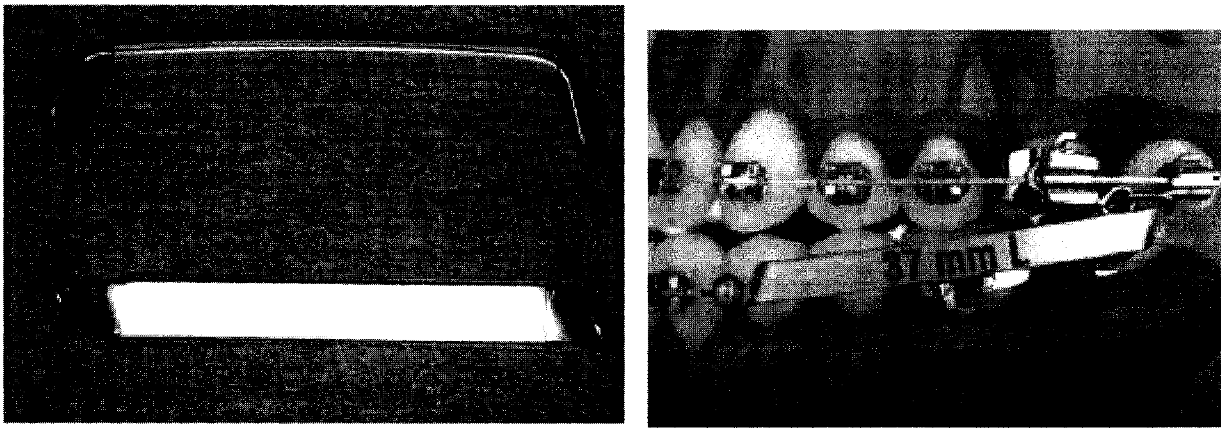


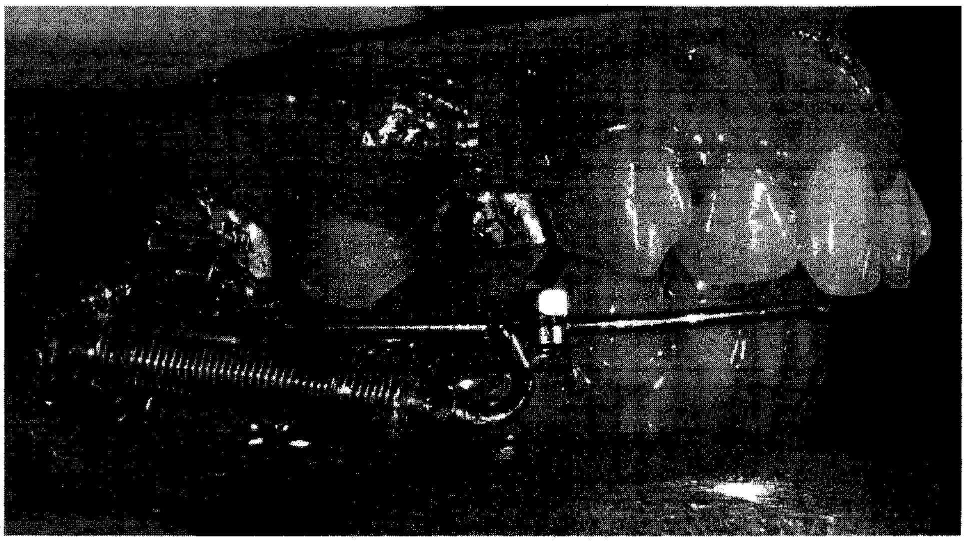
Figure 1-6, Forsus Flat Nitinol Springs, prior to insertion (left) and inserted on a typodont (right) (images taken from Heinig 2001[50](right) and http://solutions.3m.com/wps/portal/3M/en_US/orthodontics/Unitek/solutions/class-II/Forsus-spring (left))

By far the most studied of these appliances is the Jasper Jumper, which has been the subject of at least seven clinical trials[49, 52-57]. Mean treatment times to obtain either Class I or "over-corrected Class I" molar relationships ranged from 4 to 6 months. Generally, all three appliances showed similar results, which is not surprising given the similar mode of action. The two most interesting studies include one by Weiland et al. that compares Jasper Jumpers to an activator and an activator-headgear combination[57] and another by Karacay et al[49] which directly compared the Jasper Jumper and Forsus Flat Nitinol Springs to an untreated Control group. In the Karacay et al. study[49], their results showed very similar treatment effects for both appliances, with the only statistically significant differences between the two shown in change in ANB angle, with Forsus showing a greater reduction by 1.2 degrees (but interestingly no difference versus the Jasper Jumper was found in changes regarding SNA or SNB), and Jasper Jumpers showing a greater increase in S-Go distance (by 1.4mm) out of a total of 38 measurements. With the Weiland et al study[57], they found that the Jasper Jumpers corrected to a molar Class I relationship within 6 months of treatment, while less than half the patients in both the activator groups (with and without headgear) achieved this in a mean of 8 months. The authors explain this finding by the increased dento-alveolar changes induced by the Jasper Jumpers, especially involving the 1st molars, as opposed to the presumed relatively-more skeletal effects of activators (although the between-group comparisons for statistical significance do not show such a clear-cut difference).

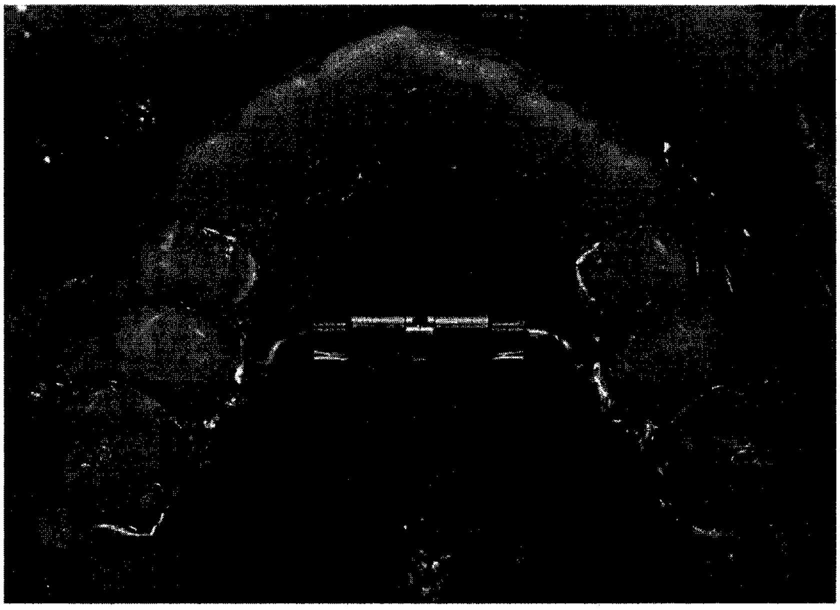
Overall, the skeletal component of the Class II correction appears to be less than 50%, with one study finding as low as 7-10%[51]. Cope[53] quotes appliance creator Jasper as stating the Jasper Jumper achieves its corrections by 20% maxillary skeletal basal restraint, 20% posterior maxillary dento-alveolar movement, 20% anterior mandibular dento-alveolar movement, 20% condylar growth stimulation, and 20% downward/forward glenoid fossa remodeling, which would lead one to believe 60% of its effect would be skeletal. In Cope's study[53] itself, statistically significant maxillary skeletal base restraint, and indeed posterior movement, was shown, as well as significant dento-alveolar movements, but mandibular protrusion via either forward glenoid fossa remodeling or condylar growth were not observed, as landmarks such as B Point and Pogonion actually showed a posterior movement relative to the reference plane used, due to the clockwise rotation of the jaw.

1.2.5 CrossBow

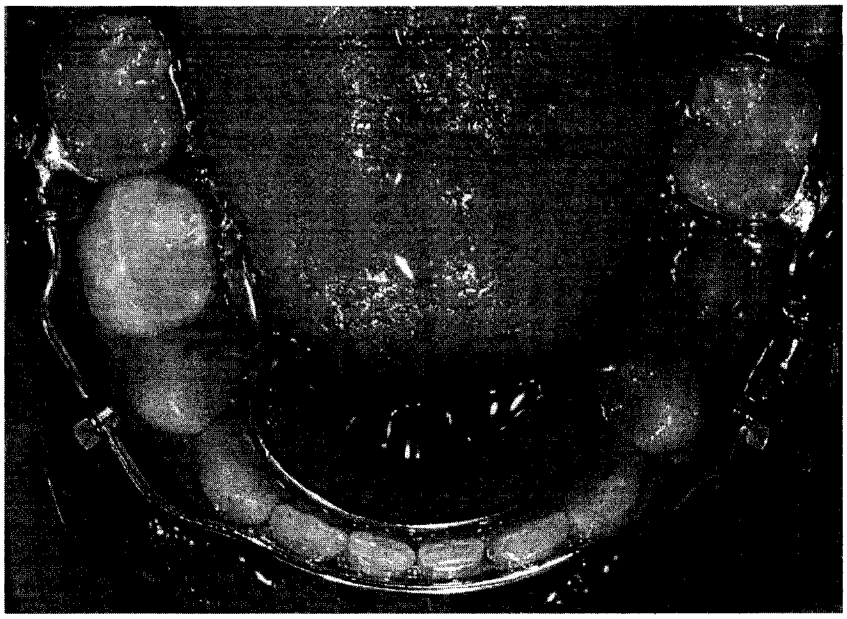
The CrossBow (or $XBow^{TM}$) appliance was patented by Dr. Duncan Higgins, who works in a private orthodontic practice in Delta, BC. Photographs of the appliance in use can be seen in Figure 1-7.



(a)



(b)



(c)

Figure 1-7, CrossBow Appliance in use intra-orally (a) lateral view (b) maxillary occlusal view (c) mandibular occlusal view (images taken from www.crossboworthodontic.com)

The Xbow has three main components: a palatal jack-screw attached via orthodontic bands on the maxillary 1st premolars and 1st molars, a mandibular labial and lingual arch connected to orthodontic bands on the mandibular 1st molars and bonded occlusal rests on the 1st premolars, and Forsus FRD Springs connected to the maxillary 1st molar band head-gear tube and the mandibular labial bow in the 1st premolar area, contained by a Gurin lock (3M Unitek, Monrovia, California) anteriorly. A new variation involves using a K-X module (3M Unitek, Monrovia, California) extending forward from the lower molar band instead of securing the anterior end of the Forsus FRD onto the labial bow with the Gurin lock. Either of these designs allow for the possibility of bonding brackets on the maxillary incisors if initial alignment is needed.

No articles have been published regarding the Xbow appliance. The design is somewhat similar to that of a Herbst appliance, but the Forsus FRD springs allow the mandible to still function in centric occlusion. Forsus FRD Springs should apply around 200g of force. Higgins purports that most correction takes place via dental compensation for the Class II skeletal discrepancy.

1.2.6 Burlington Growth Study

This study, containing records of orthodontically untreated children took place from 1952-1972, using the population of the city of Burlington, Ontario, which is situated within an hour of Toronto. This type of study, unprecedented in Canada, took various extra- and intra-oral radiographs (including lateral cephalographs) of most of the children in the Burlington school system in order to be able to study "normal" growth patterns in a large group. Dental models were also taken, as well as height, weight, and other developmental indicators recorded (i.e.: menarche). This predominantly Caucasian population base thus provides thousands of possible cases to examine, covering any and all facial/profile types. This study was modeled after similar ones in the United States, including the Michigan Growth Study and the Bolton-Brush Growth Study, both of which started in the 1920's and 1930's, respectively.

1.2.7 Historical Reference Groups

There is some debate in the current thinking as to if using a control population from a generation ago is scientifically valid. In Herman-Giddens et al[58], they found that menarche in females seems to be happening at younger ages than ever before recorded. While there is no conclusive evidence that this is true of cranio-facial growth spurts, there is at least reason to believe it could be so. Incidental reports from long-practicing orthodontists also bear this out, albeit not in any concrete or documented way. Some could speculate that using such a relatively antiquated control group to compare to similar-aged children in the new millennium has, at very least, mild validity issues. It is worth noting that many published, peer-reviewed orthodontic studies continue to use the Burlington data as "untreated controls" [59-63], as it is very difficult to get a large sample of untreated children. Ethical issues prevent us not only from exposing children to unnecessary radiation, but also from not treating children who would be best served by treatment.

1.2.8 Landmark Reliability

Cephalometric radiographic studies are only as accurate as the locating of the landmarks used therein. Over the past decade, numerous studies have looked at the reliability and accuracy of landmarking on digital radiographs versus film-based images[64-69]. Geelen et al[66] compared the reproducibility of cephalometric landmarks on conventional films and monitor-displayed digital version. The digital images were captured via storage phosphor plates, and thus a single exposure was used to produce both film and digital images. They found a statistically significant difference between the reproducibility of film and monitor-displayed images in 11 of the 21 landmarks, but could not conclude which method was superior. They also found a relatively low reproducibility for the monitor-displayed images, but concluded it was probably of little clinical significance.

In another recent study[70] computer digitization and measurement of landmarks using the popular Dolphin Imaging Software (Version 8.0) was compared to hand-tracing of films. The findings indicated that both techniques were at the 95% level of both reproducibility and reliability. The authors made an excellent point that the precise magnification of the radiograph must be used to properly compare measurements between modalities.

Interestingly only one study was found that compared landmark identification reliability between charge coupled device direct digital (CCD) images with that of conventional film-based images[69]. In that study the vertically scanning Orthophos DS Ceph from Sirona Dental Systems was used, which is a CCD unit. This study found comparable errors in landmark identification for both the conventional and CCD machines.

1.3 Research Questions

What are the short-term skeletal and dental effects of the CrossBow appliance when compared to an equivalent untreated control group as measured on lateral cephalographs?

1.4 Null Hypothesis

There is no difference in the skeletal and/or dental effects of patients treated with the Xbow appliance compared to a similar untreated control group.

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Chapter 2

Box Test Study

2.1 Introduction

Digital cephalometry is enjoying increasing usage in orthodontic offices. Despite the increased costs of the digital units, they offer significant advantages over film-based units. These include reduced radiation exposure, immediate image viewing, computer archiving and transferring, and the lack of processing chemicals[1, 2]. Original extra-oral digital radiographs were created using photostimulatable phosphor plates[3], which could be used with traditional film-based units, but did not allow immediate image viewing and necessitated additional time and steps to view.

Measurements taken on radiographic images can differ from the true length of the object by two ways: magnification or distortion. Magnification is inherent in any radiographic image as the x-rays leaving their source travel in a divergent beam. Thus the image created on the x-ray sensor or film is always larger than the object it is representing. The geometry of this can be seen in Figure 2-1. With static beams, this occurs equally in both the vertical and horizontal planes.

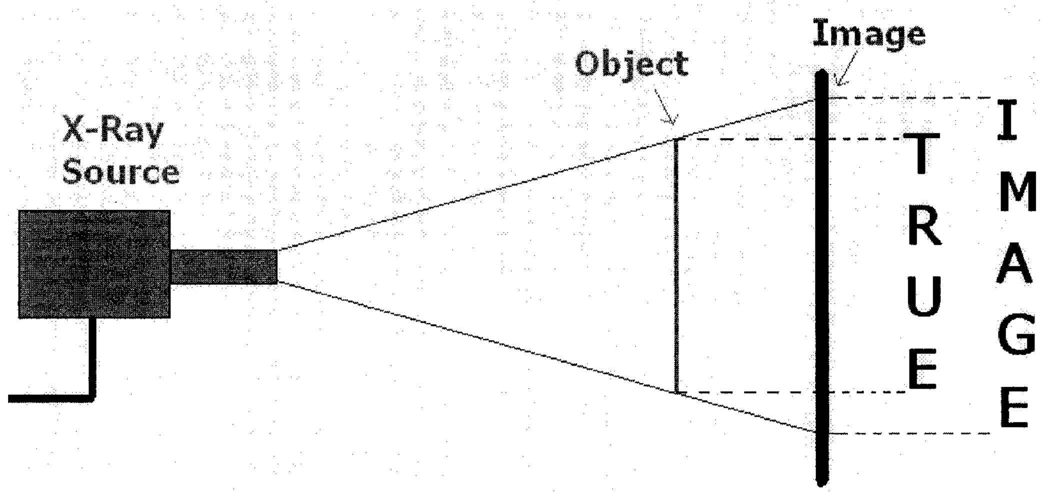

Figure 2-1 Diagram of x-ray beam geometry and inherent magnification

Distortion is the amount of differential magnification in the vertical and horizontal planes. The pyramid-shaped static beams of film-based units theoretically should have no distortion, as the beam is diverging from the source at the same angle in all planes. This is not true for scanning CCD digital units, as a linear array is swept across the object in a V-shaped beam. Thus for a vertically-oriented beam than sweeps horizontally across an object, theoretically this should produce magnification (from the diverging beam) in the vertical plane, but none in the horizontal plane. This difference in horizontal versus vertical magnification is a source of distortion. Another source of distortion can occur when 3 dimensional objects are imaged in 2 dimensions, as with the skull in lateral cephalographs. The side of the object farthest from the sensor or film is magnified more than the contralateral side, often producing double-images. This is frequently seen in lateral cephalographs with the mandible, as one side (the right, as this is closest to the x-ray source) is magnified slightly more than the other (the left). This geometry also produces greater distortion near the edges of the object, while the parts of the object near the central ray should have almost no distortion. Thus objects which are longer in one dimension than another (such as the skull, which is longer in the vertical direction than the sagittal or coronal) show different amounts of distortion in each plane. This has become an accepted part of cephalometric radiography[4].

2.1.1 Scanning CCD Digital Cephalographs

Most current extra-oral machines now utilize charge couple devices (CCD) to allow near instant viewing on a computer monitor even as the image is being taken. These units have been modified to use a scanning method of image acquisition to manage the cost of the CCD's. The CCD is arranged in a linear array and combined with a V-shaped x-ray beam, and the beam is swept across the patient in either a horizontal or vertical manner, depending on the manufacturer. Either of these would produce different image geometries from each other, as well as from static beams[4] (see Figure 2-2). In theory, a beam that is V-shaped in the vertical plane and thus scans across the sensor horizontally will show some magnification in the vertical, but not the horizontal, plane. This is especially important when the ruler incorporated onto the patient-positioning nose-piece is used to aid in digital analysis, as it may not be representative of linear measurements in the horizontal plane[5].

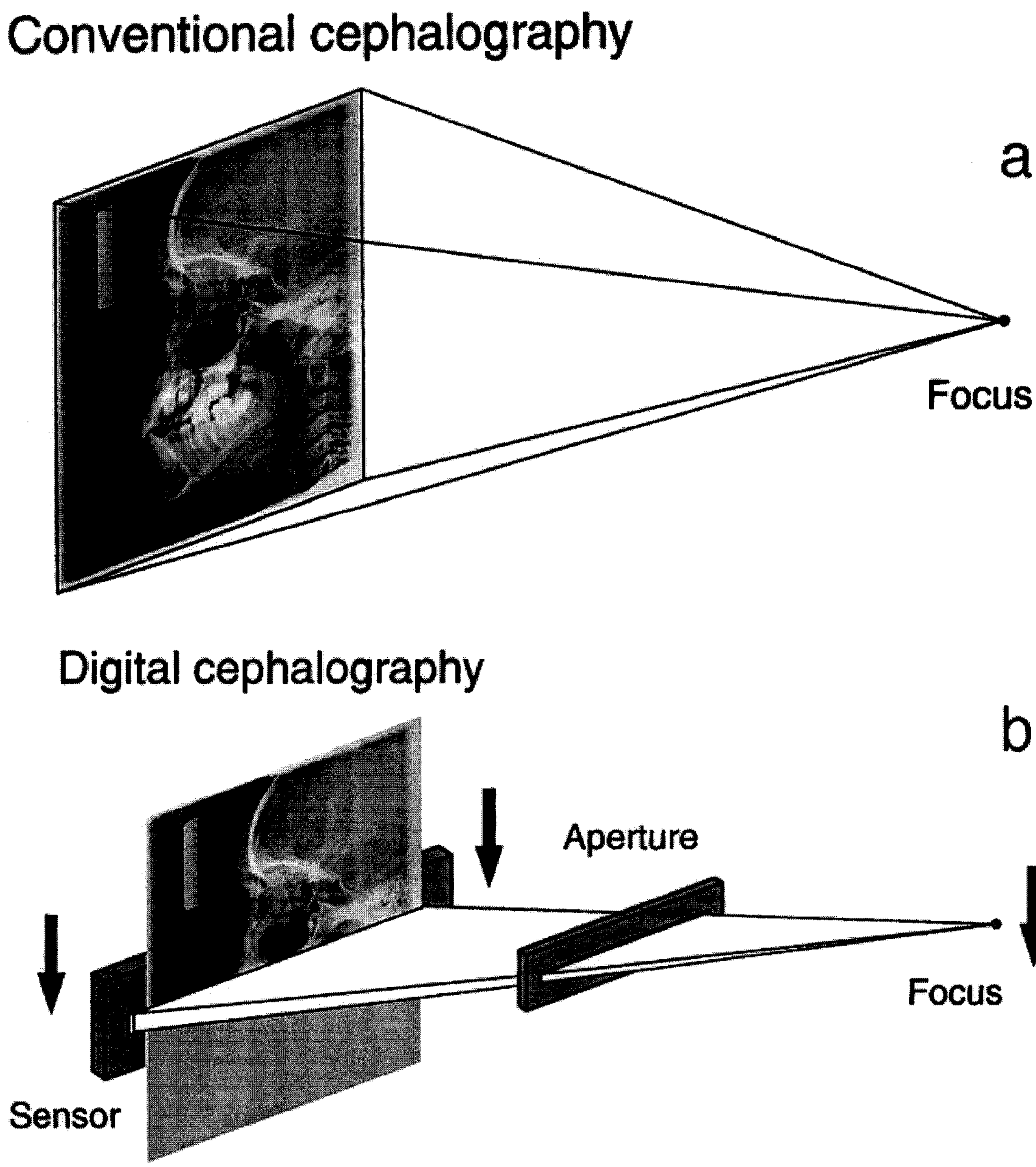

Figure 2-2 Static beam geometry (top) and vertically-scanning beam geometry (bottom) (image taken from Visser 2001[1])

2.1.2 Patient Positioning Error

Another source of variation in cephalometric analysis is patient positioning error. Yoon et al.[6] examined the effects of head rotation on linear and angular measurements in lateral cephalographs. They found that horizontal linear measurements decreased as the patient rotated their heads in the Z-axis (see Figure 2-3), with a fifteen degree rotation producing a decrease of 5.78%. Vertical measurements also change, as a 15 degree rotation towards the film decreased distances by 1.5%. Ahlqvist[7, 8] found that if the patient's head was turned less than 5 degrees, distortion was less then 1% of the linear measurements and less than 1 degree of angular distortion.

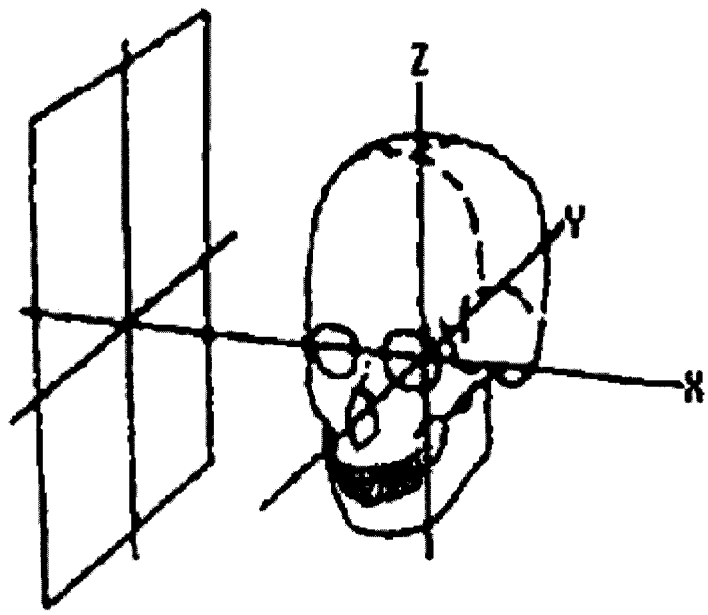

Figure 2-3, Axes of rotation as described in Yoon 2001[6]

The Orthoceph OC100D uses a vertical fan-shaped beam that scans across the patient from anterior to posterior to obtain the image. Thus vertical distances could be magnified to a greater degree than horizontal ones. The ruler imbedded on the nose-piece of the machine will be used for calibration when obtaining measurements for the Xbow patients, and thus the amount of vertical vs. horizontal distortion must be known.

The purpose of this study is to assess the differential distortion in the vertical and horizontal planes for the Orthoceph OC100D. This will allow proper comparison of patient radiographs procured with this unit to those taken with other machines/technologies, such as the static-beam film-based unit used with in the Burlington Growth Study.

2.2 Materials & Methods

The instruction manual that accompanies the Orthoceph OC100D states the magnification factor is 14%. However, scanning units also build "correction" into their software, claiming to eliminate the effect of magnification in one plane (in this case, the vertical plane). To validate this, a phantom was used.

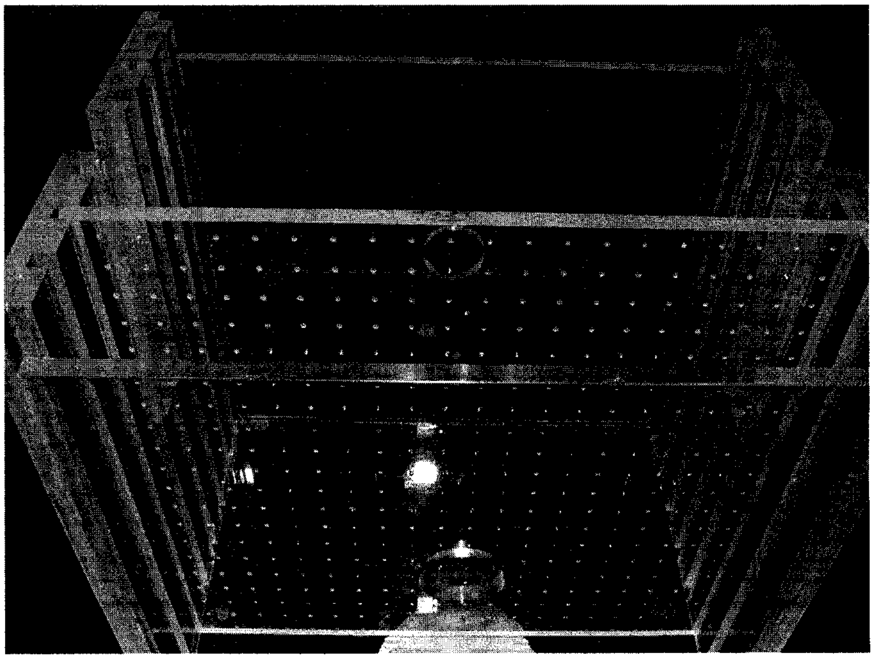

Figure 2-4 "Phantom" acrylic box. Note acrylic sheet which contains the steel balls was used in the centre slot of the box

The custom designed phantom was fabricated in the University of Alberta Medicine and Dentistry Workshop, and has been used in previous investigations[5]. The phantom was fabricated out of acrylic with the dimensions of 21 cm x 21 cm x 15 cm internally. A 21 cm x 21 cm x 0.5 cm sheet of acrylic was prepared using a Dekel Maho (DMG Canada Inc., Mississauga, ON) milling machine with a digital read out calibrated at 10 mm increments. Radio-opaque markers consisting of 1.58 mm steel balls (Small Parts, Inc. Miami Lakes, FL) were placed 1 cm on center from each other horizontally and vertically in concentric squares. The plate containing the markers was placed in the centre of the box to approximate the mid-sagittal plane when the entire apparatus was placed in the x-ray unit. A camera tripod (Opus, Ontario, CA) was attached to the base of the box with the aid of a Denar (Waterpik Technologies, Ft. Collins, CO) mounting plate fixed with cold cure acrylic to the base of the phantom. The ruler on the nose-piece of the x-ray unit was included in the radiograph, and thus validity of using the ruler in subject radiographs as "true" can be tested, and the difference between the horizontal and vertical magnifications of the machine can be assessed. The true distance measurements were confirmed using the Coordinate Measuring Machine (Starrett Corporation, Athol, MA). The distances were measured 3 times as past of a previous investigation[5] and found a mean of 110.0mm with a standard deviation of 0.03mm and 0.04mm in the vertical and horizontal directions, respectively. An example of the image produced can be seen in Figure 2-6.

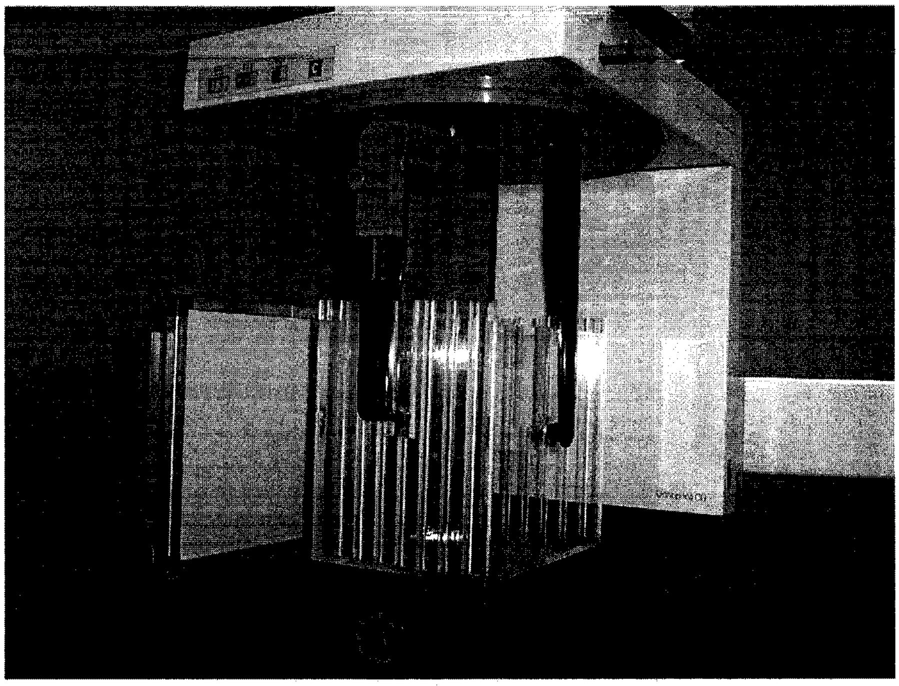

Figure 2-5, "Phantom" box in place in x-ray unit

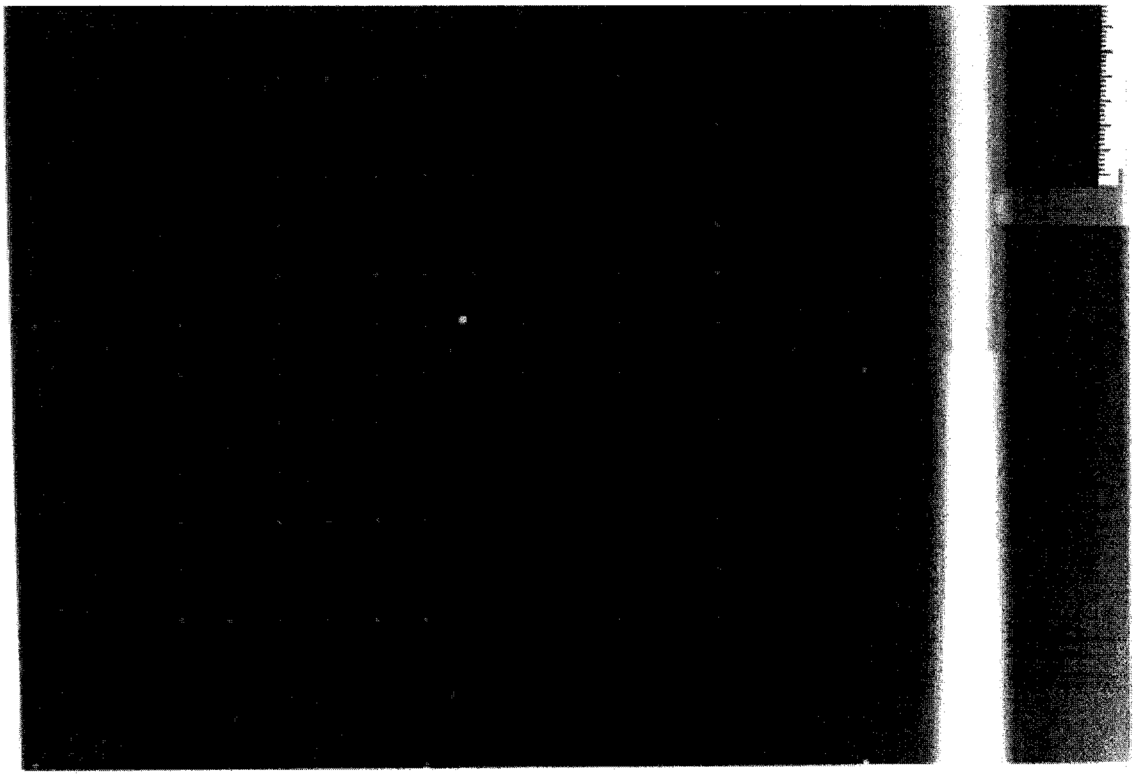

Figure 2-6, Image produced by Phantom. Note nose-piece ruler present in image

Six exposures were taken of the phantom. This number was chosen arbitrarily presuming the differences would be very small and within what was considered to be clinically insignificant values (<1.0% difference) of magnification or distortion. Before each exposure, the apparatus was removed from the unit and then replaced, to mimic patient positioning error inherent to the subjects of the study, and the innate minor head rotations that can exist. The phantom was aligned as perpendicular as possible to the x-ray beam, using only the ear-rods to aid in clinical judgment, as one would with patients. Two vertical and two horizontal measurements were used from each image, using the longest spans available (110mm) on the image. The measurements were done using Viewbox 3 software (dHAL Orthodontic Software, Athens, Greece) loaded onto a personal laptop computer (Dell Inc., Round Rock, Texas). The image was magnified 2000% (maximum magnification allowed by the program) to aid in determining the precise centre of the markers. Statistical testing was done using SPSS 14.0 for Windows (SPSS Inc., Chicago, IL).

2.3 Results

The results measured from the six radiographs can be seen in Table 2-1. The mean horizontal measured distance (true=110.00mm) was 109.6mm and had a range of 0.4mm. The mean vertical measured distance was 110.1mm and had a range of 0.3mm. This gives a mean increase of 0.09% in the vertical plane, and a decrease of 0.36% in the horizontal plane.

Table 2-1: Measurements of distances in Phantom images (n=6), true distance 110.0mm

Line Measured	Mean Measurement (mm)	Std. Deviation (mm)
Hor. Top	109.60	.11
Hor. Bottom	109.63	.14
Vert. L	110.14	.12
Vert. R	110.12	.10

A paired t-test was run to determine any differences between the right vs. left vertical lines and the top vs. bottom horizontal lines. The results can be seen in Table 2-2. The paired t-tests showed no difference between the paired vertical or horizontal measurements at the $\alpha=0.05$ level. There was a difference found between all combinations of horizontal vs. vertical measurements (Top vs. Right, Bottom vs. Left, etc).

Table 2-2: Paired t-test for various lengths measured in phantom images

Lengths Being Compared		Mean Difference (mm)	Standard Deviation (mm)	Paired t-test *p* Value
Pair 1	Hor. Top - Hor. Bottom	-.03	.05	.204
Pair 2	Vert. L - Vert. R	.02	.13	.771
Pair 3	Hor. Top - Vert. L	-.53	.08	<.001
Pair 4	Hor. Top - Vert. R	-.52	.13	<.001
Pair 5	Hor. Bottom - Vert. L	-.50	.11	<.001
Pair 6	Hor. Bottom - Vert. R	-.49	.13	<.001

2.4 Discussion

The variation in the measurements seen between the six sets of images can be attributed at least partially to phantom positioning variation (specifically in regards to rotation around the Z-axis for horizontal measurements and the Y-axis for vertical measurements. See Figure 2-3). The (albeit very minimally) shortened horizontal distances are probably a factor of the phantom being slightly off perpendicular to the x-ray beam (rotation around Z-axis), and the 2-dimensional image produced is measured as slightly shorter than the true distance. While some fore-shortening of the vertical measurements could have occurred via rotation in the Y-axis, the overall slight magnification masks any effect of this nature. This Y-axis rotation can account for the variation in vertical measurements seen. Landmark location variation ("landmarking error") also plays a part, although this was probably minimized due to the amount the image was magnified upon landmarking (2000%).

Due to pixilation, the exact centre of one of the steel balls may be impossible to landmark, and thus the best fit possible is used at this high magnification. While the size of 1 pixel in these radiographs is 0.0786mm, if this "error" occurs at each end of the distance being measured, the total possible error would be 0.157mm. As a percentage of the total 110mm distance, this is only 0.143%. This alone can explain the differences seen between the two horizontal or vertical measurements taken on the same radiograph (mean difference for horizontal 0.03mm, 0.02mm for vertical). It also encompasses the mean vertical magnification seen (0.13mm). While distances of this small magnitude would have negligible clinical significance for distances used in measuring lateral cephalographs in orthodontics, it is worth noting its existence for this study.

Another possible source of error could come from the method of calculating the "true" distance of 110mm. While CMMs are very precise and have error ranges of a 2-3 microns, the steel balls have a more relevant diameter of 1.58mm. Thus the accuracy with which the CMM could used to measure the distance between the steel balls will be subject to human placement of the CMM landmarker in the correct position. Theoretically, the CMM landmarker could be anywhere on the diameter of the ball, or up to 0.79mm off of the centre of the ball on each side of the distance being measured. This gives a total maximum error of 1.58mm for any distance. Basically, this means "true" 110mm distance between the steel balls in the phantom could be actually 110 ± 1.58mm. As mentioned, a previous study found repeated measurements of the 110mm distance using the CMM gave a standard deviation of 0.03mm (vertical) to 0.04mm (horizontal)[5]. So while the 1.58mm error is theoretically possible, in practice it is much less.

Other sources of error include the degree to which the acrylic sheet is truly parallel to the sides of the cube containing it; if the slots that hold the sheet are not parallel to the outer walls of the box (which are used to align the box to the x-ray beam), differences will be seen in the horizontal and/or vertical measurements, depending on the direction in which the slot is misaligned. The amount of space between the acrylic sheet and the slot walls also can effect the sheet's true orientation. If the sheet is free to move in the slot, it will not be parallel to the outer walls of the box, causing similar errors as mentioned above.

Although both of these factors are likely small, it is important to recognize that they do exist.

While these differences were statistically significant at the $\alpha=0.05$ level, they are of questionable *clinical* significance, as the distortions are very small. The various sources of error mentioned above also cast doubt on the clinical significance. This study shows that the horizontal and vertical measurements are nearly equal, and the mean difference between them being approximately 0.5mm. This is well within common "usual error" seen with landmarking repeatability testing[9-12]. Indeed, O'Callaghan[13] found that landmarking on digital radiographs using a computer mouse and crosshairs is only accurate to within 0.5mm. While most linear measurements used in the study are roughly horizontal, they are also partly vertical, the amount of which depends on both the patients head angulation and occlusal plane angulation in each image.

2.5 Conclusions

The phantom box tested the vertical and horizontal magnification and distortion inherent in images created using the Orthoceph OC100D. While statistically significant differences at the $\alpha=0.05$ level were found between horizontal and vertical measurements over a span of 110mm, the size of those differences is very small and not clinically significant, and well within "normal" landmarking and measuring error. Statistical significance was no doubt found due to the very small standard deviation of the measurements. This investigation legitimizes not using any magnification- or distortion-correcting measures in the subsequent study involving patient images created using the Orthoceph OC100D.

2.6 **References**

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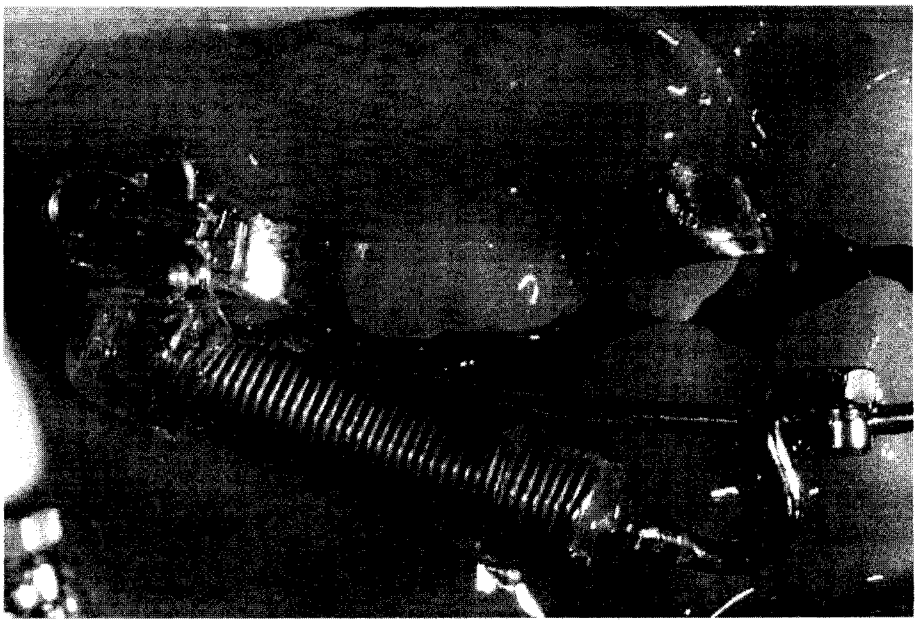
Chapter 3

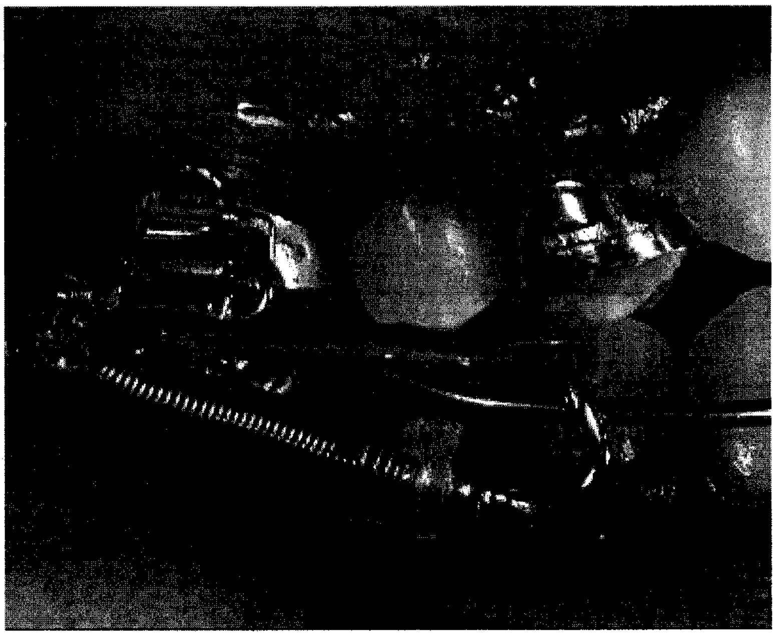
Xbow Study

3.1 Introduction

The CrossBow (or Xbow) is a fixed Class II corrector developed in 2002 in British Columbia, Canada by Dr. Duncan Higgins. It consists of three main components: a maxillary hyrax expander, a mandibular labial and lingual bow, and Forsus FRD springs (3M Unitek, Monrovia, California) connecting the two bilaterally. The maxillary hyrax is connected via bands on the 1st molars and 1st premolars. The Forsus spring is inserted in the buccal tubes of the 1st molar band and hooks around the labial bow at around the mandibular 1st premolar-canine area, contained anteriorly by a Gurin lock (3M Unitek, Monrovia, California). The mandibular labial and lingual bows are in passive contact with the lower incisors and are retained in the mouth by bands on the 1st molars and an occlusal rest bonded to the 1st premolars. Forsus FRD springs do not rigidly hold the mandible forward and allow the patient to function in centric occlusion. It could thus be categorized as a non-protrusive inter-arch Class II corrector. Higgins very recently has begun using latex K-X modules (3M Unitek, Monrovia, California), extending mesially from the lower 1st molars, to attach the anterior portion of the Forsus spring (in place of Gurin lock on the labial bow), calling it the Xbow SA (for "Self Activating"). A comparison between the "traditional" Xbow and the Xbow SA are seen in Figure 3-1(a) and (b), respectively.



(a)



(b)

Figure 3-1, (a) Xbow, note anteriorly the Forsus spring is hooked around the labial bow and contained anteriorly by a Gurin lock. (b) K-X module connected to mandibular 1st molar band.

The existence of the lower labial bow precludes the placement of orthodontic brackets on mandibular teeth, and thus the Xbow is used in the late-mixed or early-permanent dentition as a "phase I" appliance. The ends of the springs can be protected by Spring Caps (Comfort Solutions Inc., Langley, BC). The hyrax jackscrew allows posterior expansion for constricted arches or compensatory maxillary expansion. Maxillary incisor teeth can be bracketed and aligned in a "2x4" arrangement, and the archwire can be segmented from lateral incisor to lateral incisor while the Forsus springs are active if excessive incisor retroclination/retraction is not desired. Higgins prefers this segmented set-up to avoid heavy forces on the incisors and claims the incisors retract passively via gingival fiber tension, thus minimizing the chances of root resorption.

The literature is rife with different kinds of fixed Class II correctors[1-14]; there is certainly no lack of options for the clinical practitioner facing a Class II patient. More popular appliances such as headgear, the Herbst appliance, and Activators have been well-studied in the orthodontic literature for decades. With increasing interest in compliance-free appliances, as well as published randomized control trials that shed some doubt onto the ability of functional appliances and headgear to truly alter skeletal growth in the long term, the Xbow could find a large niche in the orthodontic armamentarium. The Xbow is a newly designed appliance that is gaining attention; claims of fast treatment times and freedom from relying on patient compliance are of great interest to practitioners. Currently there is no published data on the method by which it achieves Class II correction nor the time it takes to do so. This investigation will endeavour to determine the short-term skeletal and dental effects of the CrossBow appliance when compared to an equivalent untreated control group as measured on lateral cephalographs.

3.2 Materials & Method

3.2.1 Samples

Dr. Duncan Higgins collected the sample of lateral cephalographs from his Delta, BC private office. All patients in whom Xbow treatment was started were included that had both pre- and post-treatment lateral cephalographs taken between September 26, 2002 and September 30, 2006. Failure to reach desired orthodontic goals, whether by pre-emptive removal of the appliance or otherwise, was *not* an exclusion criterion, and thus these patients are included in this "intent to treat" sample. All radiographs were taken with an Orthoceph OC100D (General Electric, Tuusula, Finland), which is horizontally-scanning direct digital unit. It has a CCD receptor that is coupled with a V-shaped x-ray beam, which yields an image with a pixel matrix of 2052 x 2348 and a resolution of 5lp/mm. The exposure parameters were 85 kV, 12 mA and 10-16 seconds, depending on patient size.

This resulted in a sample of 67 (29 male, 38 female) consecutively started patients. All patients were treated with the "traditional" Xbow; no Xbow SA's were used. Higgins treatment protocol was to leave the Forsus springs active until the 1st molars are in an over-corrected Class III relationship. The springs are then removed and the physiologic recovery is monitored for several months. A summary of the sample can be seen in Table 3-1.

Table 3-1: Summary Statistics for Xbow Group

Parameter	Mean	Min.	Max.	Std. Dev.
Age at T1 (years-months)	11-11	9-6	14-9	1-3
Age at T2 (years-months)	13-2	10-4	16-2	1-3
Total Time Between Cephs T1-T2 (months)	14.67	6	37	5.27
Ceph T1 – Xbow Insertion (months)	3.73	0	25	4.19
Xbow Use (months)	4.54	2	11	1.56
Xbow Removal - CephT2 (months)	6.43	0	14	3.12

As noted in the Table 3-1, a mean of almost 6.5 months elapse between Xbow deactivation and the T2 cephalograph. No retention appliances are used during this time to help hold the Class II correction.

To factor out the effects of growth over the treatment period, an untreated age-matched Class II control group with similar skeletal and dental characteristics was obtained from the Burlington Growth Centre at the University of Toronto, Faculty of Dentistry. All available cases with cephalometric radiographs of similar time interval as the Xbow sample were included. This yielded the final subject group of 30 patients (20 male, 10 female). The 60 radiographs were then loaded into Viewbox 3 (dHAL Orthodontic Software, Athens, Greece) where they were landmarked and measured. A summary of the sample can be seen in Table 3-2.

Table 3-2: Summary Statistics for Control Group

Parameter	Mean	Min.	Max.	Std. Dev.
Age at T1 (years-months)	11-9	10-0	13	0-9
Age at T2 (years-months)	12-7	12-0	14-4	0-10
Total Time Between Cephs T1-T2 (months)	21.90	11	28	4.65

All radiographs were taken on the same x-ray unit, manufactured by Keleket (Covington, Kentucky), which was a film-based unit. As this machine is no longer in use, verification of the magnification is not possible. The manufacturer states a magnification of 9.84%. Traditional x-ray units such as this use a pyramid-shaped beam applied in a static manner, and thus magnification should theoretically be equal in both the horizontal and vertical aspects at equal distances from the centre of the central ray. Radiographs were scanned using an Epson Expression 1680 (Epson America, Long Beach, CA) digital scanner at 300dpi with a 100mm marking system incorporated into the scan. The scanning of film-based images has been investigated recently by Bruntz et al.[15], and deemed to have only minimal effects on landmarking (mean difference measurements on film and software-digitized tracings of 0.8mm vertically, 0.45mm horizontally) and no clinical significance.

3.2.2 Magnification of Radiographs

All cephalometric landmark measurements were done with the proper magnification accounted for, in that the value recorded are "true patient size", and not what one would necessarily measure directly on the radiograph itself. This was done by setting the scale magnification to the nose-piece ruler in the Xbow sample (which, since it is present in the radiograph, has been magnified – at least in the vertical plane-- by the same amount as the patient). Validity of using this ruler for the horizontal measurements was addressed in Chapter 2, and no allowance for differential magnification or distortion were needed for this sample. No ruler was visible in the Control sample radiographs, rather one was included in the scan, and thus it is "unmagnified" in respect to the patient image. Correction was done to the scale by the following calculation:

Let "True Anatomic Distance" = x   Magnification = 9.84%

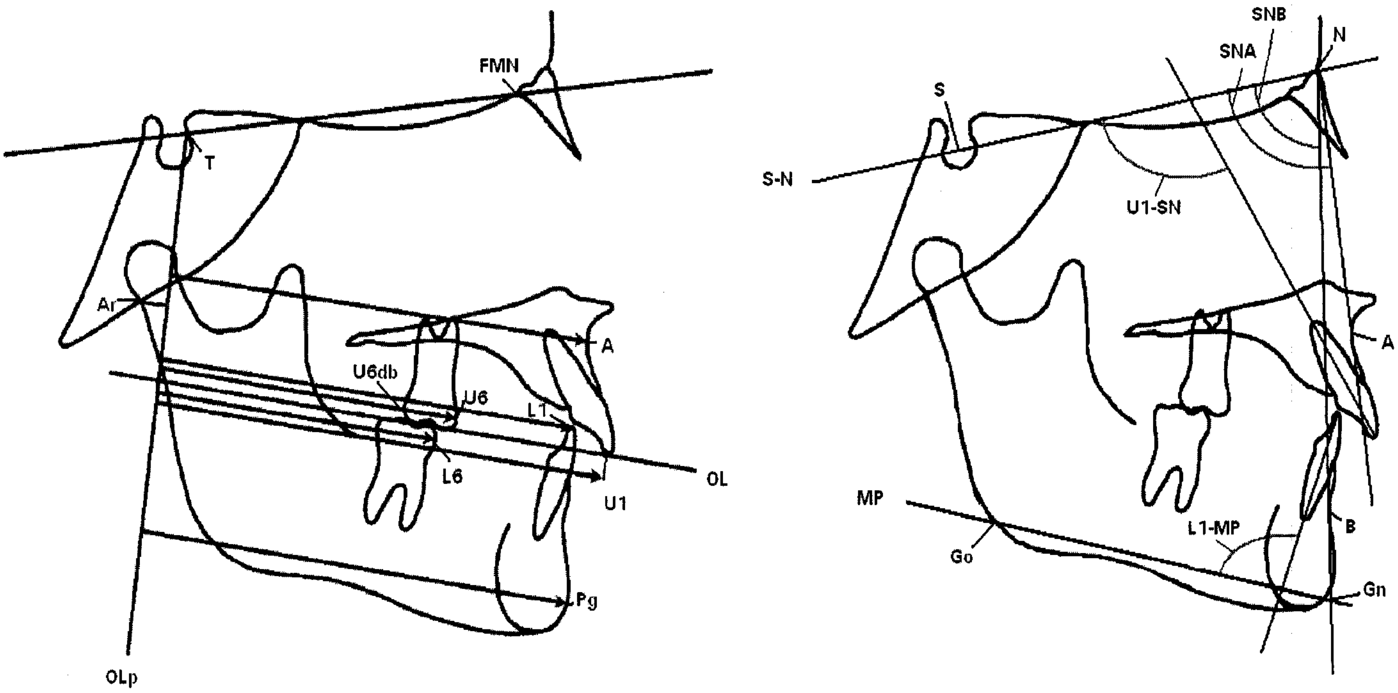
Therefore a structure that measures 100.0mm on radiograph is 109.84% of True Anatomic size

Therefore 109.84x = 100.0   x=100/109.84   x= 91.04

Thus the ruler visible on the scans (measuring 100.0mm) was set as a scale of 91.04mm in Viewbox 3 when the analysis was being carried out.

3.2.3 Landmarks and Cephalometric Analysis

All radiographs were landmarked and measured using Viewbox 3. A modified Pancherz analysis[16] was used. The following landmarks, reference planes, and measurements were used (see Figure 3-2).



(a) (b)

Figure 3-2, (a) Landmarks and linear measurements (modified Pancherz Analysis), (b) Reference planes and angular measurements

Landmarks:

- sella (S): centre of the roughly circular hypophyseal fossa (sella turcica)
- nasion (N): junction of the nasal and frontal bones at the most posterior point on the curvature of the bridge of the nose
- A Point (A): point of greatest concavity on the anterior surface of the maxilla between the anterior nasal spine and the crest of the maxillary alveolar process.

- B Point (B): point of greatest concavity on the anterior bony curvature of the mandible between the chin and the mandibular alveolar crest
- pogonion (Pg): most anterior point on the contour of the chin
- gnathion (Gn): the most outward and everted point on the profile curvature of the symphysis of the mandible
- gonion (Go): point midway between the point representing the middle of the curvature at the left and right angles of the mandible. If each side of the mandible was distinctly visible on the radiograph, the midpoint between the right and left gonion was used
- articulare (Ar): point midway between the two posterior borders of the left and right mandibular rami at the intersection with the basilar portion of the occipital bone.
- T Point (T): most superior point of the anterior wall of sella turcica, at the junction with tuberculum sellae
- frontomaxillary-nasal suture (FMN): the posterior junction of the nasal bone with the frontomaxillary bones.
- U1: incisal tip of most prominent maxillary central incisor
- root apex of same maxillary incisor used for U1
- L1: incisal tip of most prominent mandibular central incisor
- root apex of same mandibular incisor used for L1

- U6: most mesial surface of the crown of the maxillary 1st permanent molars. If right and left molars were visible separately, the midpoint between their respective mesial surfaces was used
- L6: most mesial surface of the crown of the mandibular 1st permanent molars. If right and left molars were visible separately, the midpoint between their respective mesial surfaces was used.
- U6db: disto-buccal cusp-tip of the maxillary 1st permanent molars. If right and left molars were visible separately, the midpoint between their respective cusp-tips was used.

Reference Planes:

- OL: the occlusal line as constructed by connecting U1 and U6db.
- OLp: a line constructed perpendicular to OL that passes through T point. The OLp line from the T1/pre-treatment cephalographs was transferred to the T2/post-treatment cephalographs to avoid any influence of occlusal plane inclination during treatment on the post-treatment measurements.
- Mandibular plane (MP): line connecting Gonion and Gnathion
- S-N: line connecting sella and nasion
- T-FMN line: used for orientation of all cephalographs in order to properly transfer OLp from T1 to T2 radiographs.

FMN and T point have been used previously[17, 18] as substitutes for nasion and sella, respectively, as stable reference points are needed to correctly transfer the OLp when using the Pancherz analysis. Melsen[19] found that sella can be displaced by the floor and posterior wall of the hypophyseal fossa remodeling, while the anterior area around the junction with tuberculum sellae remained unchanged. Similarly, nasion can be displaced by enlargement of the frontal sinus. Thus the line connecting T point and FMN should be unchanged by remodeling between successive radiographs. The angle between the T-FMN line and OLp is kept constant between radiographs, ensuring no iatrogenic effect on the actual OL in the post-treatment radiograph is altering the measurements. Viewbox 3 has a feature where the two radiograph images can be overlaid, as well as the landmarks and analysis lines displayed. Thus in the T2 image, the operator can make the T-FMN line from the T1 image visible, and the T2 image is aligned to it. The T2 image is then landmarked as one would normally do, with exception of U6db, which is placed in a manner that re-creates the same OLp line visible from T1 (as the sole function of landmark U6db is to create the OL, and thus OLp, it does not have to actually be placed in its "correct" position on the disto-buccal cusp tip of the maxillary 1st molar, it is merely a way of transferring the OLp accurately from one image to another).

Both angular and linear measurements were used, many taken from the Pancherz analysis, as mentioned. The greater the number of measurements taken, the less reliable the statistical conclusions that can be drawn when small sample sizes are used, and thus care was taken to keep the measurements to a relevant minimum.

The angular measurements include: SNA, SNB, U1-SN, L1-MP, and MP-SN. Further to these measured angles, the ANB angle could be computed from the difference between SNA and SNB. The unit of measurement is degrees, measured to the closest tenth of a degree.

The S-N line was still used for the angular measurements (as opposed to the T-FMN line) as orthodontists are familiar with values associated with these measurements, and it was felt simple interpretation of equivalent angles involving T-FMN would not be possible for readers of this investigation.

The linear measurements used will be: A-OLp, Pg-OLp, U1-OLp, L1-OLp, U6-OLp, L6-OLp, and Ar-OLp. Distances anterior to the OLp are given positive values, while those posterior to it are given negative values. The unit of measurement is millimeters, measured to the closest tenth of a millimeter. Further to these measured distances, Overjet (OJ) can be computed by subtracting the L1-OLp distance from the U1-OLPp distance. Tooth movement within the alveolar bone during treatment can also be computed, by subtracting the change (for example) in Point A from U6. This gives a more accurate picture of what kind of sagittal tooth movement has occurred during treatment, as growth of the supporting bony base the tooth is located in is factored out. This can be computed for each tooth (U1, L1, U6, and L6) included in the study. These are delineated as: U1 minus A, L1 minus Pg, U6 minus A, and L6 minus Pg. This gives a total of 14 variables (6 angular, 8 linear) for which change can be measured.

3.2.4 Error

Two sets of fifteen cephalographs were chosen randomly and re-measured at least 4 weeks after original measurement. One group was taken entirely from the T1 set, and the second from both T1 and T2 sets. The first group was used to evaluate the error in locating each landmark for one time-point. The second group includes the error involved with transferring the OLp from the T1 to T2 image, and the possibly compounded error involved with this process. Intraclass Correlation Coefficients (ICC) and Dahlberg's Error of the Method[20] were both used to assess the degree of any landmark error, and the means of errors were calculated. Dahlberg's formula is: Error = $\sqrt{\sum d^2/2n}$ where d is the difference between the paired measurements and n is the number of re-measured radiographs (in this case, 15).

All statistical tests were run with SPSS 14.0 for Windows (SPSS Inc., Chicago, IL).

3.3 Results

3.3.1 Error Results

Table 3-3 shows the results of the error tests for each variable for the set. For both sets, the greatest mean variations seen with the angular measurements were with U1-SN and L1-MP. The greatest variations seen with the linear measurements differed for each set. For the T1 set, the greatest variations were seen with U6-OLp and Pg-OLp. For the T1-T2 set, the incisor measurements (U1-OLp and L1-OLp) showed the greatest variation.

Dahlberg's Error of the Method yielded results ranging between 0.31 and 0.66 for linear measurements in the T1 only set. The T1-T2 set showed greater error, ranging between 0.31 and 1.01. For angular measurements, the both sets showed similar ranges, covering 0.16 to 1.66. Absolute Agreement ICCs were also calculated. The results showed very high agreement between the sets of measurements, and ranged between 0.964 (U6-OLp) and 0.993 (U1-OLp and L1-OLp) for the T1 set. The T1-T2 set showed slightly lower ICCs, ranging between 0.938 (OJ) and 0.989 (SNA). The calculated error and correlations are comparable to or better than those seen in other studies[12, 17, 21-25].

Table 3-3: Descriptive Statistics: Error Test of 15 T1 Radiographs (Absolute Differences)

Variable	Mean (T1 only/T1-T2)	Std. Dev. (T1 only/T1-T2)	Dahlberg's Error (T1 only/T1-T2)	ICC (T1 only/T1-T2)
SNA (°)	0.5 / 0.4	0.3 / 0.3	0.44 / 0.33	0.985 / 0.989
SNB (°)	0.3 / 0.4	0.2 / 0.3	0.24 / 0.35	0.992 / 0.985
ANB (°)	0.3 / 0.2	0.3 / 0.1	0.28 / 0.16	0.965 / 0.986
MP-SN (°)	0.7 / 0.6	0.6 / 0.5	0.65 / 0.56	0.977 / 0.988
U1-SN (°)	1.6 / 1.5	1.0 / 1.1	1.29 / 1.31	0.982 / 0.962
L1-MP (°)	1.7 / 1.8	1.0 / 1.6	1.36 / 1.66	0.971 / 0.958
U1-OLp (mm)	0.5 / 1.1	0.3 / 1.0	0.39 / 1.01	0.993 / 0.952
L1-OLp (mm)	0.5 / 1.1	0.3 / 0.8	0.37 / 0.93	0.993 / 0.944
OJ (mm)	0.4 / 0.4	0.3 / 0.2	0.31 / 0.31	0.976 / 0.938
U6-OLp (mm)	0.7 / 0.8	0.7 / 0.5	0.66 / 0.64	0.964 / 0.951
L6-OLp (mm)	0.5 / 0.9	0.4 / 0.7	0.41 / 0.76	0.986 / 0.950
A-OLp (mm)	0.4 / 0.8	0.3 / 0.8	0.34 / 0.82	0.992 / 0.943
Pg-OLp (mm)	0.8 / 0.9	0.5 / 0.6	0.65 / 0.76	0.979 / 0.975
Ar-OLp (mm)	0.5 / 0.6	0.4 / 0.4	0.47 / 0.53	0.972 / 0.973

3.3.2 Starting Forms

A composite superimposition tracing of the experimental and control groups at T1 can be seen in Figure 3-3. On cursory examination, the two groups appear similar at T1 with the exception of the positions of U1 (2.9mm greater in Xbow group) and Point A (2.8mm greater in Xbow group). These contribute to an increased OJ in the Xbow group (1.7mm) as well. Table 3-4 also shows a significant difference of 1.2mm for L1-OLp greater for the Xbow group. The Control group had 20 males and 10 females, while the Xbow group had 29 males and 38 females.

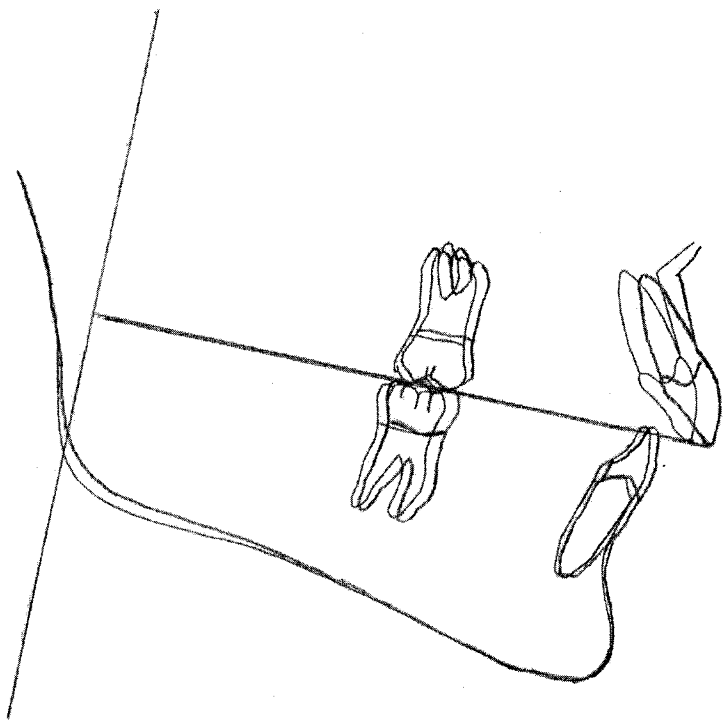


Figure 3-3 Composite tracings at T1, aligned on OL. Xbow group composite in Black, Control group composite in Red

To establish whether any significant differences exist between the starting dentofacial forms at T1, a MANOVA with Group and Gender included was performed. The Interaction term was not significant (p=0.300). A new MANOVA with the interaction term removed showed significant differences between both gender and group ($p<0.001$ for both).

The MANOVA *p* values at T1 for Group and Gender can be seen in Table 3-4. For Group, differences valid at $\alpha=0.05$ were U1-OLp, L1-OLp, OJ, and A-OLp). For Gender, significant differences at $\alpha=0.05$ for Age T1, MP-SN, U1-OLp, L1-OLp, U6-OLp, L6-OLp, A-OLp, and Pg-OLp.

Table 3-4: MANOVA Results by variable as tested by Group (Xbow vs. Control) and Gender (Male vs. Female) at T1

Factor	Variable	Xbow (mean / SD)	Control (mean / SD)	*p* value
Group	Age (years)	11.9 / 1.2	11.8 / 0.8	.162
	SNA(°)	81.1 / 3.2	80.6 / 4.1	.344
	SNB(°)	75.8 / 2.7	76.0 / 3.8	.924
	ANB(°)	5.3 / 1.6	4.6 / 1.5	.054
	MP-SN(°)	31.9 / 5.1	32.5 / 4.6	.348
	U1-SN(°)	103.7 / 8.1	100.9 / 8.8	.206
	L1-MP(°)	99.5 / 7.2	99.0 / 6.7	.878
	U1-OLp(mm)	**77.5 / 4.4**	**74.6 / 4.2**	**<.001**
	L1-OLp(mm)	**70.4 / 4.3**	**69.2 / 4.1**	**.032**
	OJ(mm)	**7.1 / 1.8**	**5.4 / 1.8**	**<.001**
	U6-OLp(mm)	47.4 / 3.7	46.5 / 3.9	.080
	L6-OLp(mm)	46.5 / 3.9	45.6 / 4.1	.091
	A-OLp(mm)	**69.4 / 4.1**	**66.6 / 3.7**	**<.001**
	Pg-OLp(mm)	70.8 / 5.1	70.2 / 4.8	.119
	Ar-OLp(mm)	-12.5 / 3.0	-11.8 / 3.3	.315
Factor	**Variable**	**Male (mean / SD)**	**Female (mean /SD)**	***p* value**
Gender	**Age (years)**	**12.2 / 1.1**	**11.6 / 1.0**	**.002**
	SNA(°)	81.3 / 3.1	80.6 / 3.8	.235
	SNB(°)	76.4 / 2.8	75.4 / 3.3	.116
	ANB(°)	4.9 / 1.5	5.2 / 1.7	.643
	MP-SN(°)	**31.2 / 4.5**	**33.0 / 5.2**	**.044**
	U1-SN(°)	101.7 / 8.5	104.0 / 8.2	.296
	L1-MP(°)	98.6 / 6.1	100.1 / 7.9	.354
	U1-OLp(mm)	**77.7 / 5.0**	**75.5 / 3.7**	**.001**
	L1-OLp(mm)	**71.3 / 4.5**	**68.7 / 3.5**	**<.001**
	OJ(mm)	6.4 / 1.8	6.78 / 2.1	.870
	U6-OLp(mm)	**48.1 / 4.4**	**46.1 / 2.8**	**.004**
	L6-OLp(mm)	**47.3 / 4.3**	**45.2 / 3.3**	**.003**
	A-OLp(mm)	**69.9 / 4.6**	**67.1 / 3.1**	**<.001**
	Pg-OLp(mm)	**72.7 / 5.6**	**68.5 / 3.3**	**<.001**
	Ar-OLp(mm)	-12.2 / 3.5	-12.4 / 2.6	.977

BOLD indicates statistically significance at the α=0.05 level

3.3.3 Differences During Treatment/Observation Period

Differences between T2 and T1 measurements can be seen summarized in Table 3-5. Composite superimposition tracings at T2 can be seen in Figure 3-4.

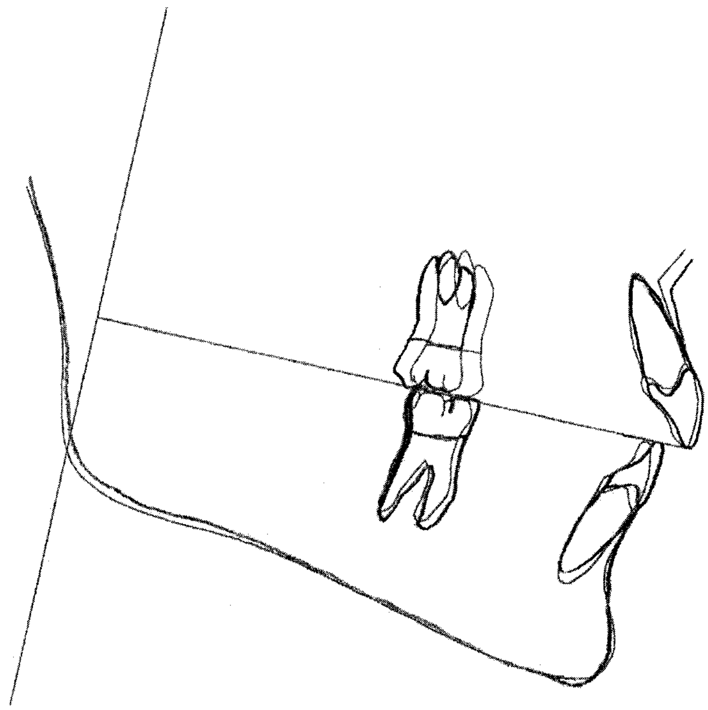


Figure 3-4 Composite Tracings at T2, aligned on OL. Xbow group composite in Black, Control group composite in Red

The actual measured values are shown in the columns in Table 3-5 labeled "Xbow" and "Control", with the difference between them in the column labeled "Group Difference". All variables with the exception of Ar-OLp were found to be significant at the $\alpha=0.05$ level.

An independent samples t-test was run on the "Months between Cephs", treated as a variable. It was found to be significantly different between the two groups, with a mean of 21.9 months for the control group and 14.7 months for the Xbow group ($p<0.001$). This was a factor of limited availability of suitable sample patients for the control group. The variable of "Months Between Cephs T1-T2" was included as a covariate in the analysis; this allows for the difference in time-span between the two groups to be taken into account in the analysis. MANOVA was again run for comparison of the groups, first with the interaction for Group and Gender. The interaction term was not significant, so it was omitted and the MANOVA run again. Gender was considered not significant at the $\alpha=0.05$ level, so it was thus removed. MANOVA was run a final time with "group" as a factor and Months Between Cephs remaining as a covariate. Estimated Marginal Means were calculated for the two treatment groups based on the analysis with the Months Between Cephs as a covariate, and the group differences for this is shown in the column labeled "EMM Group Difference". The p-values obtained for this analysis are seen in the column labeled "p value for EMM Group Difference".

Table 3-5: MANVOA Results For Difference Between Treatment Groups T2-T1. (EMM = Estimated Marginal Means)

Variable	Xbow (mean / SD)	Control (mean / SD)	Group Difference (mean)	*p* value for Group Difference	EMM Group Difference	*p* value for EMM Group Difference
SNA (°)	-0.4 / 0.9	0.9 / 0.8	**-1.3**	**<.001**	**-1.0**	**<.001**
SNB (°)	0.5 / 1.0	1.0 / 0.9	**-0.5**	**.013**	-0.3	.234
ANB (°)	-0.8 / 0.8	-0.2 / 0.7	**-0.6**	**<.001**	**-0.8**	**<.001**
MP-SN (°)	-0.1 / 1.3	-1.3 / 1.3	**1.2**	**<.001**	**1.0**	**.005**
U1-SN (°)	-3.5 / 5.3	-0.4 / 3.6	**-3.1**	**.004**	-1.8	.148
L1-MP (°)	4.7 / 4.1	1.1 / 2.5	**3.6**	**<.001**	**3.8**	**<.001**
U1 minus A (mm)	-0.9 / 1.4	0.2 / 1.2	**-1.1**	**.001**	-0.5	.111
L1 minus Pg (mm)	0.9 / 1.2	-0.5 / 0.8	**1.4**	**<.001**	**1.2**	**<.001**
OJ (mm)	-3.0 / 1.4	-0.4 / 1.2	**-2.6**	**<.001**	**-2.4**	**<.001**
U6 minus A (mm)	-0.9 / 1.2	1.2 / 1.1	**-2.1**	**<.001**	**-2.0**	**<.001**
L6 minus Pg (mm)	1.1 / 1.3	0.5 / 1.0	**0.6**	**.015**	**0.6**	**.045**
A-OLp (mm)	0.7 / 1.1	1.9 / 1.0	**-1.2**	**<.001**	**-0.5**	**.047**
Pg-OLp (mm)	2.0 / 1.8	3.0 / 1.7	**-1.0**	**<.001**	0.0	.913
Ar-OLp (mm)	-0.2 / 1.0	-0.5 / 1.0	0.3	.313	0.1	.691

BOLD indicates statistically significance between groups at the α=0.05 level

One subject in the Xbow group was identified as a possible outlier in regards to Months Between Cephs with 37 months, the longest of either group. The next longest time-span in the Xbow group is 27 months. This can be appreciated in the histogram in Appendix A. The statistical analysis was run with and without this subject included, and no significant changes in the results were observed, so it was left in analysis.

Here we see that statistically significant differences produced over the observation period for nine of the fourteen variables at the α=0.05 level once the difference in observation period (Months Between Cephs) is taken into account. Those differences "favouring" the CrossBow for changes in the direction of Class II correction include SNA, ANB, L1-MP, L1 minus Pg, OJ, U6 minus A, L6 minus Pg, and A-OLp. Meanwhile the Control group showed a statistically significant decrease in mandibular plane angle compared to the Xbow group, as measured by MP-SN (-1.3 degrees for control, -0.1 for Xbow). The Xbow and Control groups showed no significant differences in SNB, U1-SN, U1 minus A, Pg-OLp, and Ar-OLp.

3.4 Discussion

The error tests show reasonable levels of error when compared to similar orthodontic studies involving landmarking lateral cephalographs. The set involving both T1 and T2 images, and thus the transfer of the OLp from one image to another, showed on average greater error than the set just involving T1 radiographs for the linear variables. The angular variables showed similar amounts of error in both sets, which is expected as these do not involve the transferred-OLp and any inherent error that occurs during the transfer process.

The comparison of the T1 forms prior to treatment/observation showed statistically significant differences for the variables U1-OLp, L1-OLp, OJ, and A-OLp. The purpose of comparing the starting forms is two-fold: to document any pre-existing differences between the two groups that may effect any changes seen, and most importantly to assess how similar a growth pattern the untreated group should theoretically have to the treatment group. The purpose of including an untreated Control group is that this group can serve as an estimate for what should have happened to the treated subjects if no intervention had occurred, and thus the true effect of the intervention (in this case, use of the CrossBow appliance) can be appreciated. It is therefore desirable to have a Control group that should have a growth pattern similar to that of the Xbow group. The Xbow group has a definite Class II skeletal pattern; thus a reasonable Control group should have one as well. It would be of limited use to employ a Class I or III skeletal group as the Control group, as the growth displayed over the observation period would not be representative of those in the (Class II) Xbow group. The angular variables SNA, SNB, ANB, and MP-SN give the best indication of skeletal and potential growth pattern; none of these variables show significant differences between the two groups.

One drawback of using historical untreated Control samples, such as those from the Burlington Growth Study or similar databases, is that the timeframes used for record-taking may not fit the cohort one investigating. This is evident in this study as the mean time between T1 and T2 cephs for the Xbow group is 14.7 months and 21.9 months for the Control group. Records taken at the Burlington Growth Study were taken at ages 9, 12, and 14 for most patients. The T1 to T2 time difference in the current study is just over 7 months. Histograms for the times T1, T2 and for Months Between Cephs can be seen in Appendix A. This "extra" time and the growth that would occur during it could account for the contra-intuitive finding that the Xbow group showed a trend for *less* increase in Pg-OLp and SNB measurements. The mandible is typically "catching up" to the maxilla around the time the subjects in this study were examined (Control group T1 ages mainly between 11-12.5 years of age, T2 12.5-14.5 years of age)[26-28]. By using "Months Between Cephs" as a covariate in the MANOVA, this is taken into account when determining p values, and thus these two variables showed no statistically significant differences between the two groups once the effect of time was factored out.

The EMMs reflect, mathematically, what the p values are showing once the unequal time-spans are accounted for.

Since the Forsus FRD springs do not posture the mandible forward out of the glenoid fossa, acceleration in mandibular growth would not necessarily be anticipated. This has been reported in several other studies involving non-protrusive inter-arch Class II correctors[29-31]. The current study found that the Xbow not only restricted maxillary skeletal anterior movement (as determined by Point A), but actually displaced it posteriorly. Again, this "head-gear effect" as been noted in other studies of no-protrusive inter-arch Class II correctors[6, 29-34]

The Xbow group showed a statistically significant increase in MP-SN angle by 1.0° (EMM) relative to the Control group. This also could account for the SNB and Pg-OLp findings. It is important to note that this change is relative, as the Xbow group's mean MP-SN was virtually unchanged (measured mean -0.1° change), while the Control group showed a -1.3° change. If the mandible is rotating in a counter-clockwise direction, as is seen in the Control group, both the SNB angle and the Pg-OLp distance will tend to be larger. Thus even if the mandible grew forward in both groups identical amounts over treatment period, the relative clockwise rotation could partially negate some of that expressed change in the Xbow group.

When the short duration of Xbow treatment (mean 4.54 months) and the fact that most dental and musculo-skeletal relapse has occurred before the measurements were taken[35]

(T2 radiographs taken a mean of 6.43 months after appliance removal), the results seen here compare quite favourably to other appliances reported in the literature This is in contrast to some studies where "post-treatment" records are taken relatively soon after appliance removal, when various amounts of dental and musculo-skeletal physiologic recovery will not be yet visible, thus overstating the true results.[4, 17, 21, 24, 36].

Direct comparison is difficult, as studies vary in landmarks/measurements used, time from appliance removal to the post-treatment cephalographs, and use of "active retainers" between appliance removal and post-treatment cephalographs. The recent systematic review[37] included only crown or banded Herbst studies that had similar Class II Division 1 untreated control groups and no adjunctive appliances, similar to the Xbow group in the present study, but the three articles selected for the review[16, 36, 38] all used post-treatment cephalographs taken immediately upon appliance removal, so the results reported are not as comparable in that regard. A summary of the findings of this systematic review and a comparison to the present results can be seen in Table 3-6.

Table 3-6: Selected results of Crown/Banded Herbst systematic review[37]. Only those results comparable to the variables used in the present study are shown. Bold numbers indicates a significant difference relative to the Control group used in each study

Measurement	de Almeida 2005	Pancherz 1982 SDJ	Pancherz 1982 AJO	Current Xbow Study (EMMs)
n Herbst/Xbow	30	22	22	67
n Control	30	20	20	30
Mean Tx Time (months)	12	6	6	4.5
Mx Skeletal Sagittal				
SNA (degrees)	-0.4			**-1.0**
Nperp – A (mm)	-0.7			
Co-A (mm)	-0.5			
Nperp - ANS (mm)	-0.8			
OLperp - A (mm)			-0.4	**-0.5**
U1 Angulation				
U1-NA (degrees)	**-5.7**			-1.8 (to SN)
U1 Sagittal				
U1-NA (mm)	**-1.5**			
OLperp- U1 minus OLperp -A (mm)			-0.5	-0.5
U6 Sagittal				
OLperp – ms minus Olperp - A (mm)			**-2.8**	**-2.0**
Md Skeletal Sagittal				
SNB (degrees)	**0.6**			-0.3
Co-Gn (mm)	**1.6**			
OLperp – Pg (mm)			**2.5**	0.0
Md Angulations				
NSL/ML (MP-SN) (degrees)	0.4	0.2		**1.0**
L1 Angulation				
IMPA (degrees)	**4**			**3.8**
L1-NB (degrees)	**5.4**			
L1 Sagittal				
L1-NB (mm)	**1.0**			
OLperp – L1 minus OLperp - Pg (mm)			**1.8**	**1.2**
L6 Sagittal				
OLperp – L6 minus OLperp - Pg (mm)			**1.0**	**0.6**
Inter-Incisor Relationships				
OJ (mm)			**-5.2**	**-2.4**
Profile Skeletal				
ANB (degrees)	**-1.0**			**-0.8**

Both appliances show such dental changes as proclination and anterior movement of the lower incisors, retroclination and posterior movement of upper incisors (although not with statistical significance for the Xbow group), OJ reduction, small anterior movement of lower 1st molars and greater posterior movement of upper 1st molars. Skeletally ANB angle is reduced, but the mandibular measurements are the significant contributor with the Herbst, while maxillary measurements are only significant for the Xbow. This may not be surprising as the Herbst appliance postures the mandible forward so the patient cannot close in centric occlusion, whereas with the Xbow patients can overcome the forces produced by the Forsus springs (reportedly around 200g) and seat the condyles as they would normally. Thus the remodeling of the glenoid fossa and/or increased condylar growth to "reach back" to the glenoid fossa does not occur with the Xbow.

Another explanation is that since the radiographs were taken immediately after Herbst removal, any "muscle-splinting" effect or any other form of physiologic recovery were yet to occur, and thus the mandible is in a somewhat falsely protruded position when the radiographs were taken, making it appear that pogonion and B Point are more anterior than they truly are. Pancherz states that approximately 30% of the OJ correction and 25% of the molar correction relapses, and that 90% of that occurs during the first 6 months after appliance removal[35] In Pancherz and Hansen[39], they examined 40 Herbst-treated patients. Treatment time had been 7 months. Patients had lateral cephalographs taken prior to Herbst placement, upon Herbst removal, and again at 6 and 12 months intervals post-Herbst. 15 of the patients had no retention whatsoever, 19 had Activators, and the remaining 6 had a combination of upper plate and lower holding arch. They found only dental relapse in 58% of the patients, and in the 42% that did show some "unfavourable maxillary-mandibular growth relationship", it "contributes only to a minor degree"[39].

The Xbow accomplished its OJ reduction primarily by dental movement. OJ was reduced by 3.0mm; 0.9mm of this was from maxillary incisor posterior movement (U1 minus A) and 0.9mm from mandibular incisor anterior movement (L1 minus Pg). This totals 1.8mm – or 60% of the total OJ reduction. The remaining 1.2mm (40%) is attributed to the mandible's outgrowth of the maxilla (as shown by changes in Pg-OLp and A-OLp) (Table 3-6 shows 1.3mm due to rounding) over the observation period. These figures do not account for normal growth changes. Due to the different times over the observation period, direct comparison is not possible. While growth does not occur in a purely linear fashion, if the changes are viewed as "average amount of mandibular growth above maxillary growth per month", an approximation of the contributions of normal growth and the effects of the Xbow appliance can be done.

The Xbow group shows a mean 0.088mm/month more growth of the mandible, while the Control group shows 0.050mm/month. Using these mean growth values, the mandible would have outgrown the maxilla in the Control group by 0.74mm over 14.7 months. This attributes (1.2mm minus 0.74mm) 0.47mm to the Xbow. 0.47mm is approximately 15% of the total OJ correction; the remaining 25% of the change is due to normal growth. This method of comparison does not delineate which jaw is responsible for the skeletal changes.

Weiland reports that the dental component of functional appliance treatment ranges from 23-80%. Jasper Jumpers (American Orthodontics, Sheboygan, WI) have shown varying results in studies, some showing maxillary skeletal restraint[30, 31], while others show mandibular skeletal change[34, 40-42] as the predominant component of skeletal correction. Dental correction is frequently found to be the main means of correction in many Jasper Jumper studies[29-32, 43], as well as by Stromeyer with the Eureka Spring (Eureka Spring Co, San Luis Obispo, CA)[44].

3.5 Conclusions

From the results of the present study, several conclusions can be drawn:

1. Treatment with the Xbow appliance in Class II patients resulted in favourable dental and skeletal changes in the direction of Class II correction.
2. Of the fourteen variables measured for changes, four angular (SNA, ANB, MP-SN, and L1-MP) and five linear (L1 minus Pg, OJ, U6 minus A, L6 minus Pg, and A-OLp) measurements showed statistically significant change at the $\alpha=0.05$ level when compared to a similar untreated Control group.
3. The angular variables SNB and U1-SN and the linear variables U1 minus A, Pg-OLp, and Ar-OLp all did not show statistically significant changes.
4. From the samples used in this investigation, Xbow treatment appears to be equally effective on both male and female patients.

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Chapter 4

Discussion and Recommendations

4.1 General Discussion

This study was a retrospective study comparing patients treated with the newly-designed CrossBow appliance with a similar untreated Control group. From the data, it appears that the Class II correction occurs mainly by dental movements, although there is a small component of skeletal correction over-and-above what would be considered normal growth. Some caution should be used in interpreting the results, simply because of the retrospective nature of this study; a true causal inference can only be made based on randomized control trials.

The results of this study is consistent with the findings of other non-protrusive inter-arch Class II correctors such as the Jasper Jumper (American Orthodontics, Sheboygan, WI) [1-4], Forsus Flat Nitinol Springs (3M Unitek, Monrovia, CA)[5, 6], and Eureka Springs (Eureka Spring Co, San Luis Obispo, CA) [7]. The results also compare favourably to the results shown in a recent systematic review of crown or banded Herbst appliances, an appliance to which the CrossBow will ultimately be compared. While the Herbst results showed greater skeletal and dental changes compared to untreated controls, the measurements were taken immediately after appliance removal and thus no relapse had occurred. The CrossBow sample had a mean of 6.43 months between removal of the Forsus FRD (3M Unitek, Monrovia, CA) springs and the T2 image, which is generally considered adequate time for any relapse to be almost fully expressed[8]. Thus the results for the Xbow group are perhaps a better indication of what changes will remain in the long-term, although much longer follow-up investigations would be the only way to be certain.

The CrossBow offers several advantages over both Jasper Jumpers and Herbst appliances. In comparison to Jasper Jumpers (American Orthodontics, Sheboygan, WI) (or any other spring-device utilized with archwires), it can be placed prior to full bracketing, and thus offering a decreased time spent with full brackets in place. This means it can be utilized at a younger age, as many orthodontists choose to wait until all the permanent teeth have erupted before beginning comprehensive treatment. This younger starting age may allow better opportunity to take advantage of the adolescent growth spurt, especially in females who have often surpassed this stage by the time all of the permanent teeth are erupted. In comparison to the Herbst appliance, the CrossBow offers greater comfort for patients as they can still function in centric occlusion, and lateral jaw movements are not as restricted. The Forsus FRDs can be engaged on one side longer than the other if needed, which is not possible with a Herbst. The primary disadvantage is the theoretical increased mandibular growth that occurs when the condyles are held anteriorly out of the glenoid fossa by the Herbst appliance would not occur with the CrossBow. The treatment time for the CrossBow (mean 4.54 months) is also less than most Herbst appliances are used[8-18], a factor both patient and practitioner will appreciate.

4.2 **Limitations**

The present study has several inherent limitations. The retrospective nature of the investigation implies that delivery of the treatment was not stringently controlled, as one could do in a prospective study. Conversely, the "intent to treat" analysis used by including each and every consecutive patient that *started* treatment (not consecutively *finished* patients, which only then measures successful cases) is a way of including all possible treatment derivatives that may have been used to give a "real-life" picture of the results.

The Control group used has several limitations. The subjects in the Xbow group were treated within the last five years in the Vancouver, BC area. The sample from the Burlington Growth Centre contains subjects who are a generation or two older than the Xbow group. Generational changes and secular trends in physical maturation have been noted[19]. Thus while the two groups were nearly identical at T1 regarding age, whether or not an 11 year old from the 1950's and one from the early 2000's have the same maxillo-facial growth potential or patterns over the subsequent years has not been answered. The Control group had 67% male subjects, while the Xbow group was 42% male. The Control group was almost exclusively of Northern European descent. The Xbow group, while still primarily Caucasian, reflected the multi-cultural diversity of the Vancouver area, and thus had several Asian and East Indian subjects. The largest limitation of the Control group, however, was the lack of yearly records that necessitated a longer T1-T2 time-span than the Xbow group. The majority of untreated subjects in the Burlington Growth Study had records taken at age 9, 12, and 14. A select few had additional records at ages 10, 11, and 13. Many also had some interceptive orthodontics, which further limited the number of "untreated" subjects available. Finally, as the Keleket (Covington, KY) x-ray unit is no longer in existence, the magnification could not be verified, and the manufacturer's stated magnification of 9.84% had to be used. It is possible that this was not accurate, and thus the measurements used in this study are flawed.

Initially, this investigation was to include a Herbst-treated sample as well. The lack of an equivalent sample prevented this comparison. This was mainly due to the rather unique – albeit arguably preferable – radiographic protocol used by Dr. Higgins for the Xbow group of over-correcting and allowing several months of physiologic recovery to occur before taking the T2 radiograph. Despite a search that reached internationally, no comparable protocol for Herbst-treated subjects could be found, as radiographs were either taken just prior to Herbst removal, immediately after, at the completion of Phase II treatment, or after several months with a functional appliance as a "retainer". It was felt that any comparison of results would ultimately have so many limitations and qualifications that it would be more misleading that truly useful, and thus the Herbst group was abandoned.

Lastly, no vertical measurements were undertaken (with the exception of MP-SN which does give some indication of growth pattern). Measurements involving molar and incisor intrusion/extrusion, as well as such measurements as lower face height would be interesting to study. The measurements in this investigation were kept to a relative minimum to maximize statistical efficacy while still covering the most pertinent variables. The CrossBow will inevitably be compared to the Herbst appliance, and the Pancherz analysis is by far the most popular analysis used in the Herbst literature; thus it makes sense to use many of the same variables to facilitate judgment of these two appliances.

4.3 **Future Research**

Randomized control trials are generally regarded as the best form of scientific investigation[19, 20]. To truly judge the effects of the CrossBow, a randomized control trial could be undertaken involving a CrossBow group, a Herbst group, and an untreated group. The relatively short treatment and observation times (around 1 year) could allow the untreated group to receive orthodontic care while still at an acceptable age (i.e. immediately after the conclusion of the observation period), thus preventing any ethical issues of delaying treatment to those that need it. This would provide subjects from the same population pool and generation to have records taken with the same x-ray units, circumventing some of the limitations of the current investigation. Gender distribution could be equalized between the groups and other factors controlled to ensure equal variation across the three groups. Relevant vertical measurements of lower face height and the vertical positions of the teeth themselves could also be included. Ideally this study could provide records at a similar schedule to that used by Dr. Higgins (pre-treatment and then after several months of recovery), as well as several years into the future, to assess the long-term effects of CrossBow use. A separate study involving aesthetic ratings of the three groups in profile, perhaps involving both orthodontists and lay-people blinded to treatment group, could also shed light onto what affect the dental compensations have on appearance, if any.

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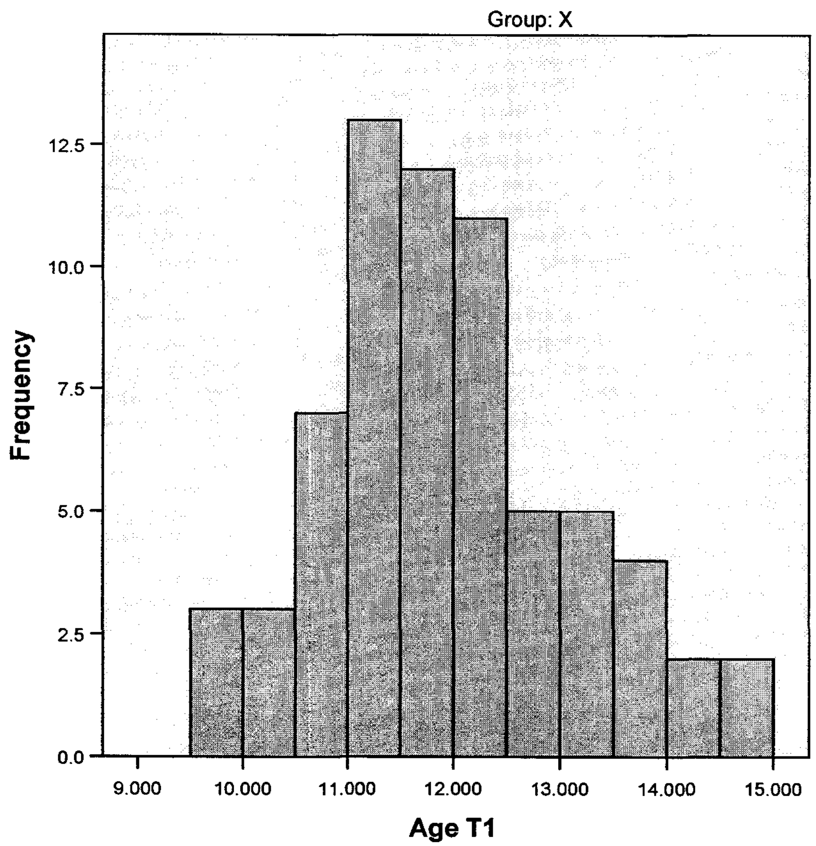
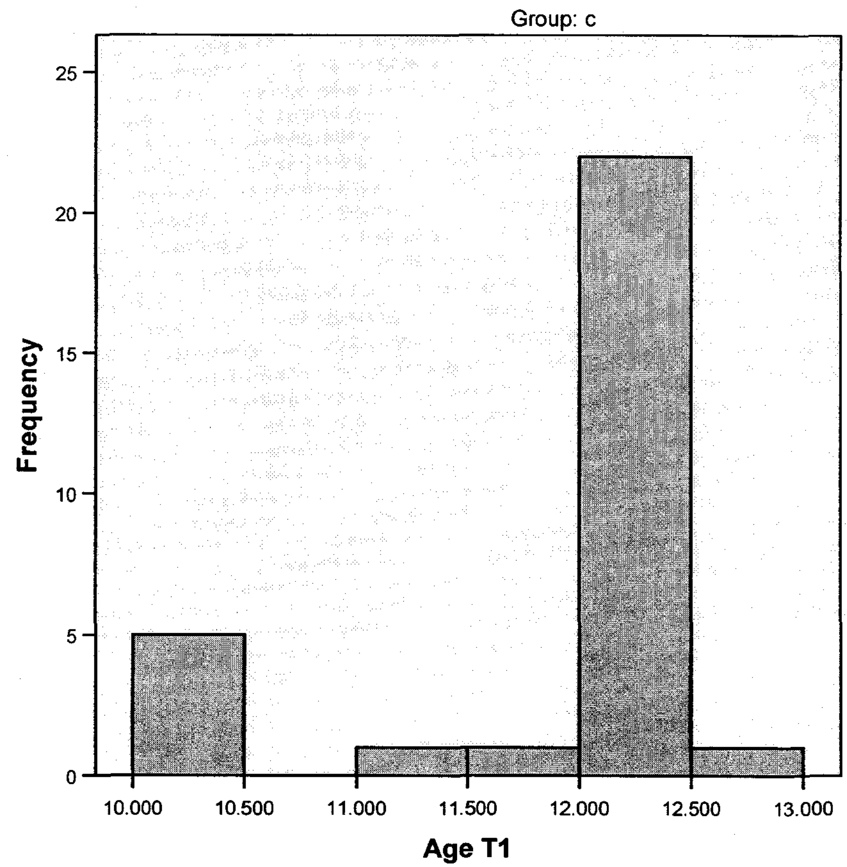
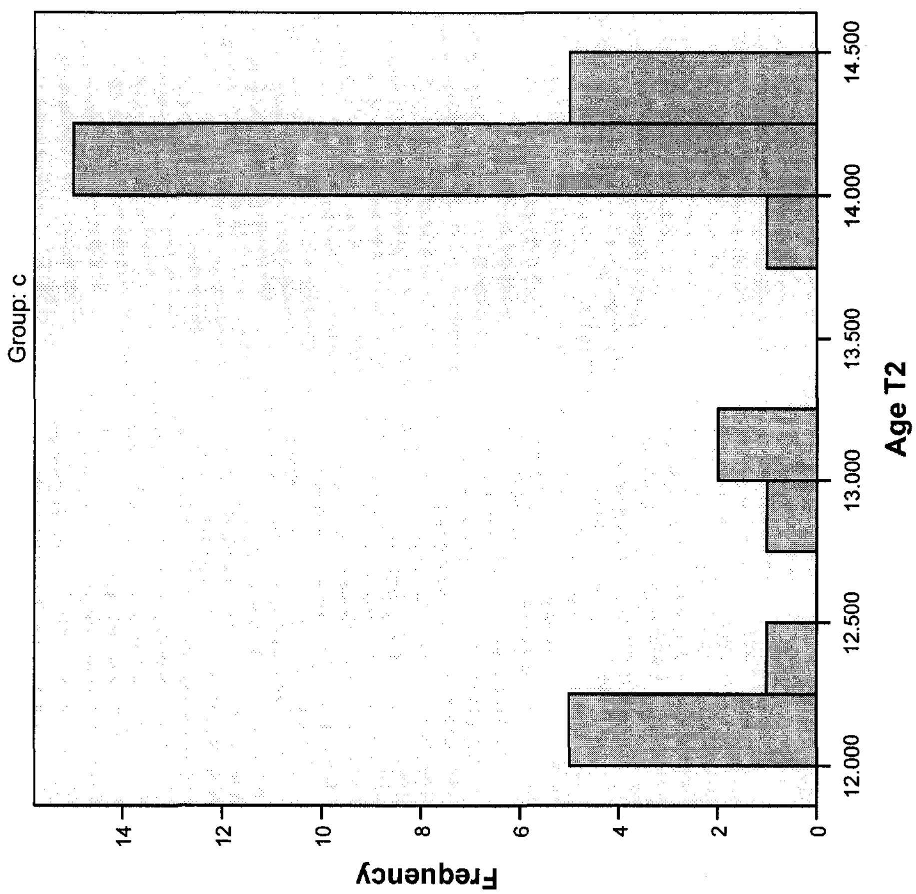
Appendix

<u>**Appendix A**</u>

Histograms for the ages for both the Xbow ("Group X") and Control ("Group c") groups, as well as for "Months Between Cephs".






Group: c
Frequency
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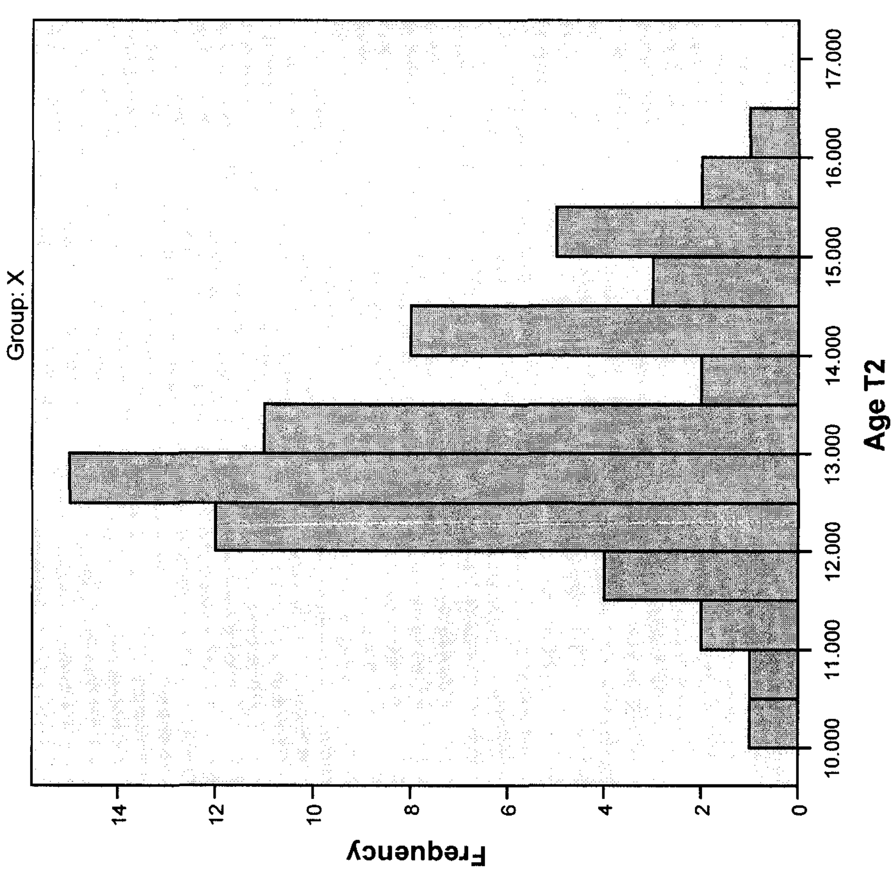
2
4
6
8
10
12
14
12.000
12.500
13.000
13.500
14.000
14.500
Age T2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4
6
8
10
12
14
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13.000
14.000
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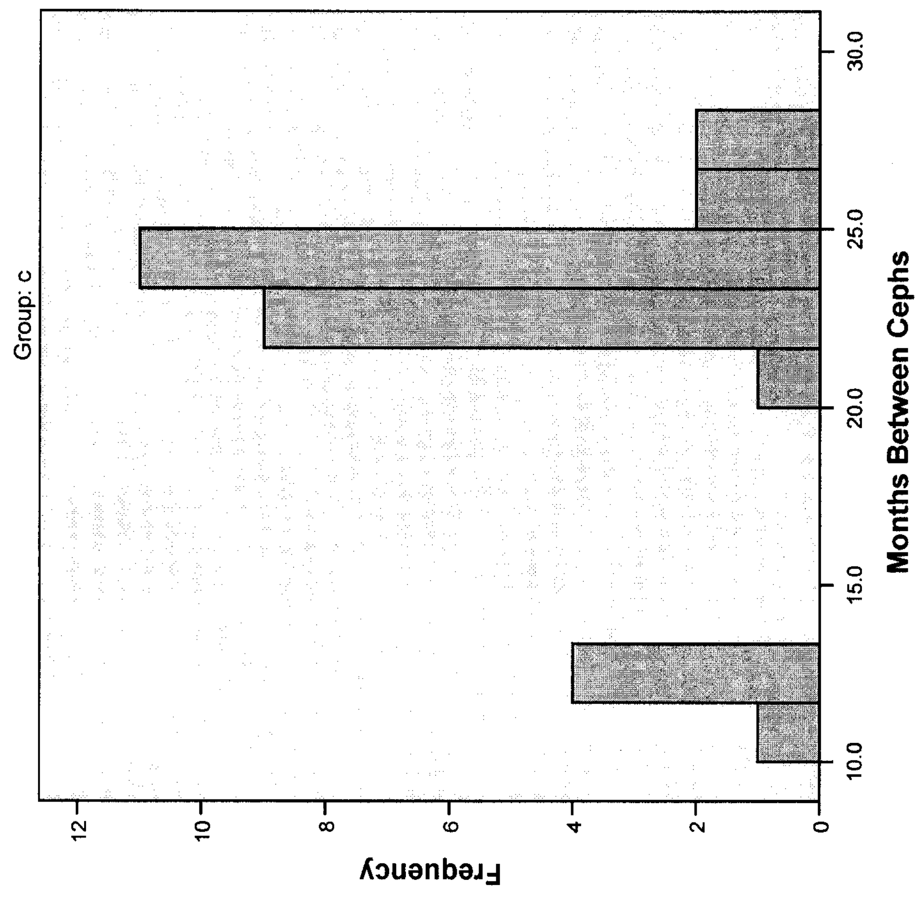
16.000
17.000
Age T2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6
8
10
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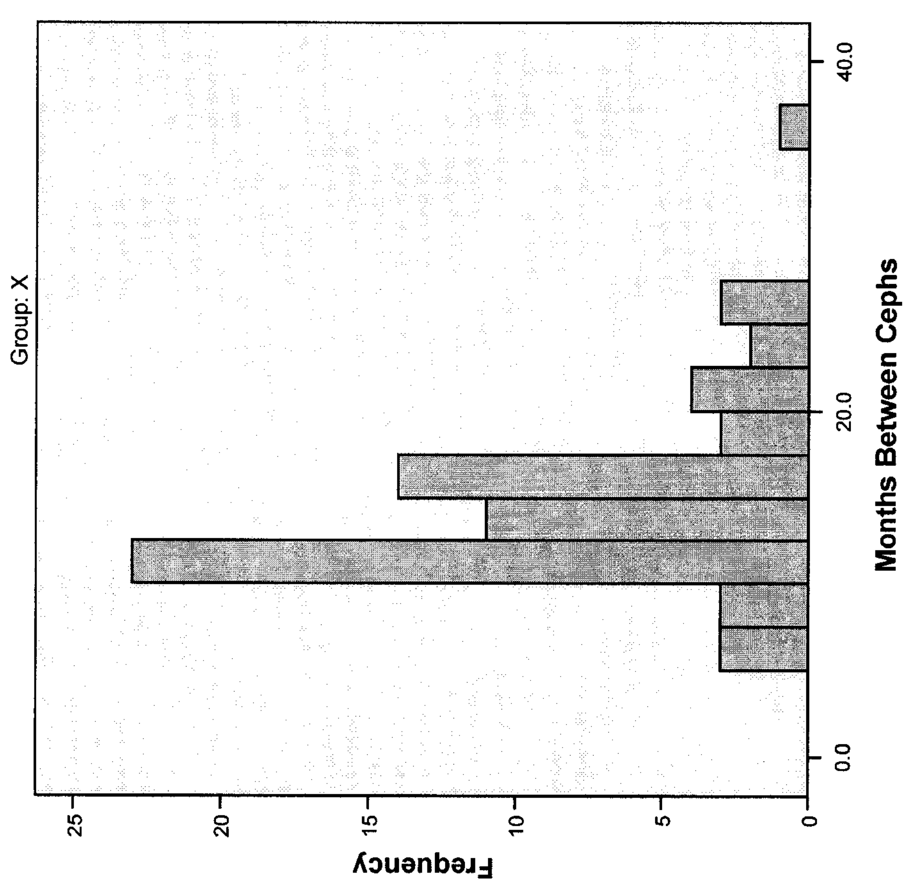
10.0
15.0
20.0
25.0
30.0
Months Between Cephs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Frequency
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10
15
20
25
0.0
20.0
40.0
Months Between Cephs