Cephalometric Evaluation of Soft Tissue Effects Induced By a Class II Corrector in Different Facial Patterns

By

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Abstract

Objective: To determine the magnitude of soft tissue changes in subjects with different facial patterns following Class II correction using the Xbow™ appliance.

Materials and Methods: A retrospective sample of 80 subjects exhibiting Class II malocclusions was used. Subjects were categorized into facial types according to pre-treatment values of MPA and Y-axis, which yielded 20 brachycephalic, 40 mesocephalic, and 20 dolichocephalic subjects. Data collection included digital analysis on the pre-treatment (T0) and post-treatment (T1) cephalometric radiographs. A paired t-test statistic was used to investigate the differences between the three facial groups at T0 and T1.

Results: Soft tissue changes induced by the Xbow™ appliance during Class II correction included: reduction in facial convexity (2.11-2.63°±0.27° $p<0.05$), protrusion of soft tissue pogonion (0.99-1.20mm±0.28 $p<0.05$), increase in mentolabial angle (7.96-13.87° ±1.14° $p<0.05$) and decrease in H-angle (-2.44° to -3.11° ±0.25° $p<0.05$). Upper lip to E-Plane increased (-1.04 to -1.61mm±0.06mm $p<0.05$), and lower lip protruded (0.99-1.48mm±0.21mm $p<0.05$). The mesocephalic group had a significantly larger increase in upper lip to E-plane than the other two facial patterns ($p<0.05$). The dolichocephalic group showed a significant opening of the mentolabial fold compared to the mesocephalic group ($p<0.05$).

Conclusions: There are differences in the soft tissue effects observed in patients treated with the Xbow™ appliance which are related to the pre-existing facial pattern ($p<0.05$): The mesocephalic group showed increased retrusion of the upper lip to E-Plane compared with brachycephalic, and dolichocephalic groups. The dolichocephalic group showed significantly more flattening of the mentolabial fold compared to the mesocephalic group.

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Chapter 1

Introduction

1.1 PREAMBLE

Successful orthodontic treatment depends on patient acceptance and compliance with the orthodontic techniques being used (Graber, Vanarsdall, Vig, 2005). Fixed interach spring-force sagittal correction appliances were primarily developed to eliminate the need for patient compliance with the correction of Class II malocclusions. Examples of these appliances include the Jasper Jumper (American Orthodontics), the Eureka Spring (Eureka Orthodontics, San Luis Obispo, California), the Twin-Force (Ortho Organizers, San Marco, California), and Forsus Fatigue Resistant Device (FRD) (3M/Unitek, Monrovia, California).

The Xbow (crossbow)™ appliance patented by Dr. Duncan W. Higgins uses inter-arch springs as a phase one appliance to correct sagittal discrepancies in the late mixed or early permanent dentition (Higgins, 2006; Mir, Barnett, Higgins, Heo, Major, 2009). Effectively, the Xbow is a fixed Class II corrector that consists of three main components: a maxillary hyrax expander, a mandibular labial and lingual bow, and Forsus FRD springs (connecting the other two components bilaterally or unilaterally) (Higgins, 2006; Flores-Mir et al. 2009). The maxillary hyrax includes bands on the first molars and first premolars. The Forsus FRD spring is attached in the head-gear tube of the maxillary first molar band and hooked around the labial bow near the mandibular canine-first premolar area, contained anteriorly by a Gurin lock (3M

Unitek) (Flores-Mir et al. 2009). This lock allows for reactivation of the Forsus device without the need for a longer push rod or split tubing shims (Flores-Mir et al. 2009) The mandibular labial and lingual bows are in passive contact with the mandibular incisors and are retained in the mouth by bands on the first molars and occlusal rests bonded to the first premolars (Flores-Mir et al. 2009). The Forsus FRD is categorized as a non-protrusive inter-arch Class II correction (Flores-Mir et al. 2009). The springs do not rapidly hold the mandible forward, which allows the patient to function in centric occlusion. (Fig 1-1).

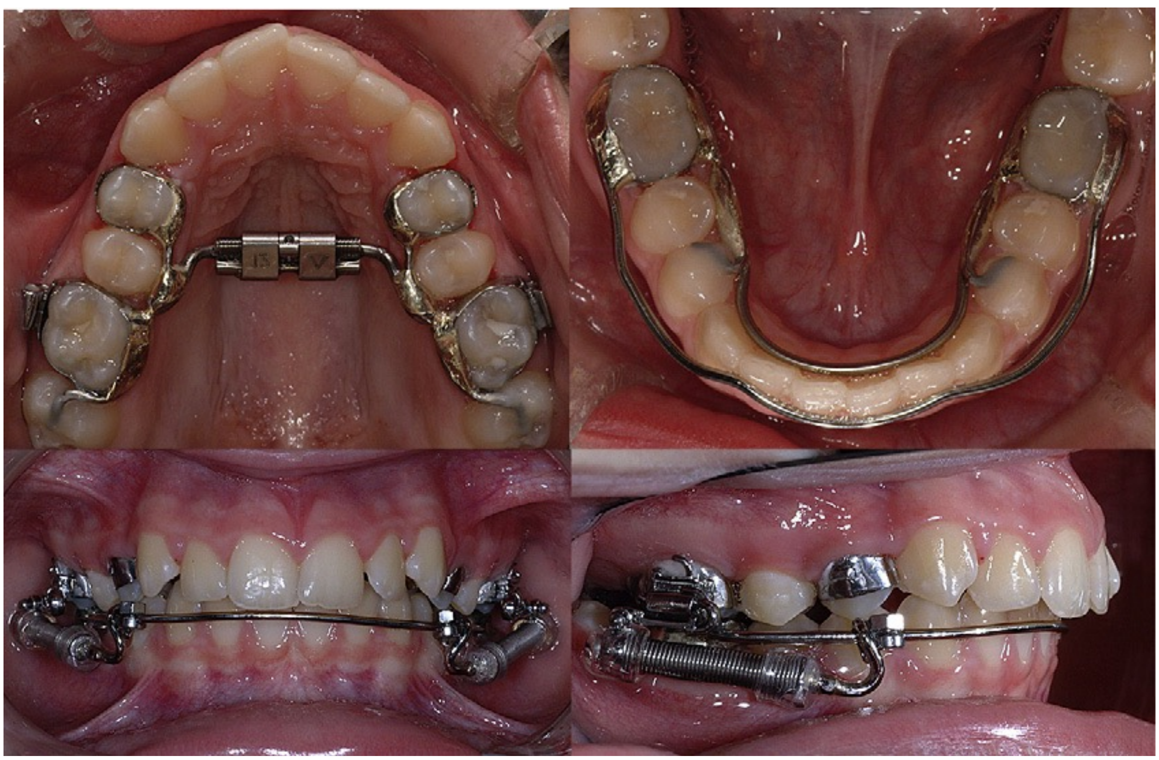


Fig 1-1 Xbow™ appliance (Flores-Mir 2009)

Published research data are available on the skeletal and dental effects of the Xbow appliance (Flores-Mir et al., 2009; Chana, Hechter, Wiltshire, Ahing S., 2013). A study by

Flores-Mir et al. (2009) examined the skeletal and dental effects of the Xbow appliance irrespective of facial type. Findings were maxillary protrusion without mandibular advancement, and an increase of vertical dimension with an increase in the mandibular plane angle. Dentally, the maxillary molars were distalized whereas the mandibular molars were mesialized. Over-jet correction was accomplished by an increase in mandibular incisor protrusion without maxillary incisor movement (Flores-Mir et al., 2009).

A study completed by Chana et al. (2013) also compared the skeletal and dental changes of patients treated with the Xbow appliance. However, this study also classified and compared patients having brachycephalic, mesocephalic, or dolichocephalic facial patterns. Results have shown correction of Class II malocclusions with the Xbow appliance is the result of mesial movement of the mandibular molar, proclination/protrusion of the lower incisor and retrusion of the upper incisor (Flores-Mir et al., 2009; Chana et al., 2013) . Facial growth pattern appears to be unrelated to the amount of dental movement, and there is a trend for pronounced movement of the lower incisor in brachycephalic patients.

Both studies listed above made use of retrospective analysis of lateral cephalograms. Similar studies have been conducted to measure soft tissue changes when utilizing other appliances such as the Twin Block or Herbst (Baysal and Uysal 2013, and Quintão et al. 2006). In these studies soft tissue convexity decreased primarily from forward advancement of soft tissue pogonion.

There is no evidence currently available investigating the soft tissue effects of the X-bow appliance on different facial patterns. Therefore clinicians may benefit from increased awareness of appliance induced soft tissue effects.

1.2 PURPOSE

The purpose of this research was to quantitatively compare the soft tissue effects observed in patients after being treated with the Xbow^{TM} appliance, and to differentiate between patients exhibiting a brachycephalic, mesocephalic, or dolichocephalic facial pattern.

1.3 NULL HYPOTHESIS

The null hypothesis for this study states that: “There are no changes or differences in the facial soft tissue effects observed in patients treated with the Xbow^{TM} appliance regardless of facial pattern.”

Chapter 2

Literature Review

2.1 FACIAL AESTHETICS AND THE SOFT TISSUE PROFILE

Aesthetics is the a key motivation for patients seeking orthodontic treatment (Rosvall et al 2009). The desire for improved facial and dental aesthetics is effectively driven by how individuals assess themselves, however, the perceptions of their peers, family and orthodontist may also play a role (Bonetti et al. 2011, Mejia-Maidl et al. 2005 and Tung and Kiyak, 1998). Negative feelings of self-image and self-esteem may develop in patients with increased overjet and unfavourable profile (Baysal and Uysal 2013 and Tung and Kiyak, 1998). These patients (and/or their parents) would seek out treatment to acquire and maintain optimal facial aesthetics. However, what determines “optimal facial aesthetics?”

Establishing the definition of an ideal face has been attempted many times by various professions including artists, physical anthropologists, reconstructive surgeons, and orthodontists (Bergman 1999). The constructed profiles show large variances in soft tissue convexity and lip protrusion. (Bergman 1999). However, an average or normal face, is still considered more aesthetic than one that is dysplastic (Bergman 1999 Burstone 1958). However, what is considered average or normal would have to take into account ethnicity, as great variation exists in what is considered 'normal' within a given culture (Bergman 1999).

An orthodontist’s professional opinion regarding dentofacial aesthetics is made more objective due to the institution of guidelines, norms and ideal ratios (Yin et al. 2014). However, patient perceptions are more subjective, and largely motivated by peer groups and social norms in their culture (Trulsson et al. 2002 and Yin et al. 2014). Studies have found obvious differences in perceptions between laypersons and orthodontists. (Yin et al. 2014 and Zange et al. 2011). Also, studies have found that psychological factors have effects on the perception of facial profile and dental aesthetics (Rivera et al. 2000, Tung and Kiyak 1998).

This ultimately begs the question "how should an orthodontist approach treatment of the soft tissue profile?" An example of a suggested treatment approach is defined within the "soft tissue paradigm" of orthodontic treatment (Proffit and Fields, 2012). The objective of the soft tissue paradigm is to restore soft tissue relationships (Proffit and Fields, 2012). However, even in this paradigm the "ideals" are open to interpretation. An overview of criteria is described in Table 2.1.

Parameter	***Soft Tissue Paradigm***
Primary treatment goal	Normal soft tissue proportions and adaptations
Secondary goal	Functional occlusion
Hard/soft tissue relationships	Ideal soft tissue proportions define ideal hard tissues
Diagnostic emphasis	Clinical examination of intraoral and facial soft tissues
Treatment Approach	Plan ideal soft tissue relationships and then place teeth and jaws as needed to achieve this relationship
Function emphasis	Soft tissue movement in relation to display of teeth
Stability of result	Related primarily to soft tissue pressure/ equilibrium effects

Table 2.1 Soft Tissue Paradigm of Orthodontic Treatment (Proffit and Fields, 2012).

2.2 FACIAL PATTERNS

Facial shapes are divided into three categories – brachycephalic (short, wide, horizontal growth), dolichocephalic (long, narrow, vertical growth), and mesocephalic (intermediate or average growth) (Nanci, 2012). There are three sections of the head used to determine the facial pattern: the cranium, the maxilla, and the mandible (Nanci, 2012). The cranial floor represents the pattern that predetermines the facial features (Nanci, 2012). This is based on the assumption that the facial bones forming the midfacial region are attached to the cranial base. (Nanci, 2012).

Brachycephalics present a closed cranial base flexure, which leads to a more upward mandibular rotation or flatter mandibular plane angle (Nanci, 2012). Whereas the dolichocephalics form a more open cranial base flexure, which in turn leads to downward mandibular rotation or steeper mandibular plane angle (Nanci, 2012). The mesocephalic facial pattern is an intermediary between the brachycephalic and dolichocephalic facial patterns, and is the most common facial pattern (Nanci, 2012).

Ricketts described how individuals with different facial patterns also have varying musculature patterns (Ricketts, 1979). Stronger musculature could counteract or oppose orthodontic forces, potentially leading to undesirable outcomes (Ricketts, 1979). Brachycephalics generally exhibit this stronger musculature, and are often characterized by a deep overbite, and low mandibular plane angle (Ricketts, 1979). Therefore mechanics to open the bite (or increase the vertical dimension of the face) may be combated by the strong facial musculature (Ricketts, 1979). Congruently, modification of treatment procedures for individuals with weaker musculature may also be required (Ricketts, 1979). Individuals presenting with a dolichocephalic pattern (vertical or open bite tendency), generally exhibit weaker musculature, and are therfore less likley to overcome orthodontic forces that open the bite and rotate the mandible downwards (Ricketts, 1979).

Lateral cephalometric analysis is used to evaluate the relationships between the teeth, facial skeleton, and soft tissues (Bergman 1999). The orthodontist is able to determine the skeletal pattern of the patient's malocclusion from this sagittal view (Bergman 1999). The differences between brachycephalics and dolichocephalics can also be visualized cephalometrically. Several studies have confirmed dolichocephalics have a short posterior facial height, a longer lower anterior facial height, an underdeveloped mandible with antigonial notching, and a receded skeletal chin (Sassouni, 1969, Nanda 1990). Conversely, brachycephalic facial patterns demonstrate larger posterior facial heights, shorter lower anterior facial heights, well developed mandibles and a stronger skeletal chin (Sassouni, 1969).

The mandibular plane angle is often used to classify a vertical or horizontal growth pattern. Vertical growers tend to exhibit backwards (downward) rotation of the mandible (Bjork et al. 1972). When the vertical growth of the alveolus exceeds the vertical growth of the condyle, the mandible rotates in a downward direction subsequently increasing the mandibular plane angle (Sassouni, 1969, Bjork and Skieller, 1972). In contrast, excessive growth at the condyle results in upward rotation of the mandible and a flatter mandibular plane angle. Therefore, the mandibular plane is a simple and identifiable indicator of growth pattern, however, it is widely believed that use of one single parameter cannot accurately discriminate facial patterns (Nanda, 1990; Bishara, 1975, Opdebeeck, 1978; Baumrind, 1984).

Soft tissue analysis may also be used to identify facial patterns. The phenotypic expression of the soft tissues exhibited in horizontal and vertical growers has been described in the literature (Sassouni, 1969). The backwards rotation of the mandible seen in dolichocephalics increase tension disturbing the balance of the orofacial muscles (Sassouni, 1969). This disruption of muscle tension equilibrium results in constriction of the maxilla (Bjork and Skieller, 1972). Implant studies by Bjork et al. have reported lower incisor crowding due to increased mandibular growth rotations (Bjork and Skieller, 1972). The increase in vertical dimension increases interlabial gap. Thus, hyperactivity of the mentalis muscle is stimulated in an attempt to maintain lip competence, ultimately contributing to lower incisor crowding (Bjork and Skieller, 1972). Brachycephalics exhibit excessive growth at the posterior cranial base and condyle resulting in upward rotation of the mandible (Sassouni, 1969). The upward rotation favors muscle laxity allowing the maxillary arch to broaden (Sassouni 1969, Bjork and Skieller, 1972). Also, more mesial eruption of posterior teeth and increased lower incisor proclination in horizontal growers with forward rotation is observed (Bjork, 1969). This contributes to lip protrusion, and deepens the mentolabial fold (Nanda, 1990).

2.3 DESCRIPTION OF A CLASS II MALOCCLUSION

A patient's occlusion may be placed into one of three categories: Class I is considered normal; Class II is considered to be a relative mandibular deficiency, while the Class III is a relative mandibular prognathism (Gorlovsky, 2009).

Class II malocclusions may have diverse features depending on the dental, skeletal, and/or functional components. From the dental perspective, a Class II malocclusion is defined as "the mesial buccal cusp of the first maxillary molar is mesial, or in front of the first mandibular molar" (Papel, 2009). However, due to the variance within this category, divisions of Class II malocclusions also exist. A Class II division 1 malocclusion is characterized by proclination and protrusion of the maxillary incisors lending to an increased overjet and reduced overbite.

Whereas a Class II division 2 malocclusion is characterized by retroclined maxillary central incisors, proclined lateral incisors, a reduced overjet, and an increased overbite (Papel, 2009). Class II malocclusions are also subdivided by the unilateral or bilateral relationship of molars. Unilateral cases of Class II malocclusion are usually denoted as the affected side subdivision. (Papel, 2009)

Specific cephalometric characteristics of both divisions of Class II malocclusions have been described (Bishara, 2006).

A Class II division 1 malocclusion is characterized by the following features:

- Anterior location of the maxilla and teeth in relationship to the cranium.
- Anterior location of the maxillary teeth in a normally positioned maxilla.
- Posterior location of the mandible, which is of normal size.
- Deficient development of the mandible.
- Posterior placement of the mandibular teeth on a mandible situated in the normal position.
- A combination of any of the above characteristics.

A Class II division II malocclusion is characterized by the following features:

- Larger posterior cranial base.
- More acute gonial and mandibular plane angles.
- Shorter lower anterior face height
- Excessive overbite.
- Larger angle of convexity.

Studies by McNamara et al. also state that Class II malocclusions do not occur as a single clinical entity, but rather as the result of combinations of contributing factors (McNamara, 1981).

In regards to the skeletal components, only a small number of the reviewed cases included maxillary skeletal protrusion relative to the cranial base structures (McNamara, 1981). This suggests that the maxilla is predominantly found in the neutral position (McNamara, 1981). When the maxilla is not in the neutral position, the retruded position is more frequent than the protruded one (McNamara, 1981). Therefore, in these studies the most typical characteristics of a Class II malocclusion were mandibular skeletal retrusion with excessive vertical development (McNamara, 1981).

2.4 AETIOLOGY OF A CLASS II MALOCCLUSION

The aetiology and development of a Class II malocclusion is multifactorial because the discrepancy can be a combination of skeletal and dental abnormalities (Rakosi et al. 1993). Contributing factors include: deciduous tooth loss, eruption sequence, familial inheritance influencing the growth, soft tissue influence of growth of cranial structures, and the position of teeth within the dental arches (Graber, 2012). Congenital factors also play a role in the development of malocclusion, and present as developmental malformations at birth (Phulari, 2011). General factors include: abnormal state during pregnancy, malnutrition, intrauterine pressure, endocrinopathology, and trauma (Phulari, 2011). Local congenital factors include: abnormalities of jaw development due to the irregular intrauterine position of the fetus, macroglossia, microglossia, cyst of the face and palate, and cleidocranial dystosis (Phulari, 2011). A summary of etiological factors can be seen in Table 2.2 (Graber, 2012)

General factors	***Local factors***
• Congenital defects (cleft palate, torticollis; cerebral palsy; syphilis)	• Anomalies of number (missing or supernumerary teeth)

• Environment (prenatal – trauma, maternal diet and metabolism; German measles; post-natal – birth injury, TMJ injury, etc.) • Heredity • Nutritional deficiency • Predisposing metabolic climate and diseases (endocrine imbalance; infections, metabolic disturbance) • Pressure habits and functional aberrations (abnormal sucking, thumb and finger sucking, lip and nail biting, abnormal swallowing habits, speech defects, etc.) • Posture • Trauma and accidents	• Anomalies of tooth size • Anomalies of tooth shape • Abnormal eruption • Ankylosis • Delayed eruption • Dental caries • Improper restoration • Mucosal barriers, persistent frenums • Premature loss of teeth • Prolonged retention

Table 2.2 Graber's Classification of Etiological Factors Influencing Malocclusion

2.5 CLASS II TREATMENT AND SOFT TISSUE EFFECTS

Treatment planning in orthdontics is challenging, especially when the two goals of facial aesthetics and bite correction are combined (Arnett and Bergman 1993). Unfortunately, bite correction does not always lead to improvement, or even maintenance, of facial aesthetics (Arnett and Bergman 1993). In fact, it's possible that bite correction may even result in a decrease of facial attractiveness (Arnett and Bergman 1993). Therefore special attention to facial aesthetics must be paid in order to achieve the aesthetic goal desired.

Relying on cephalometric dentoskeletal analysis for treatment planning can potentially lead to esthetic problems (Holdaway 1983 and Bergman 1999). Especially when the orthodontist attempts to predict soft tissue outcomes using only hard tissue normal values (Bergman 1999 and Burstone 1958). The soft tissue drape can also vary so greatly that the dentoskeletal pattern may be an inadequate guide in evaluating facial disharmony (Bergman 1999 and Burstone 1958). Skeletal norms aid in defining treatment and stability goals, but soft tissue appearance is only partially dependent on the underlying skeletal structure (Arnett and Bergman 1993). The orthodontist must understand soft tissue behavior in relation to orthopedic and orthodontic effects, and must also take into account growth and development (Bergman 1999).

Therefore, modern treatment of class II malocclusions strives to place the skeletal and dentoalveolar tissues in a normal and healthy state, while satisfying facial esthetic goals (Graber et al. 2012). Key objectives of orthodontic treatment are (Graber et al. 2012):

1. Improving the smile and facial appearance to improve the individual's self esteem and social wellbeing.
2. Obtaining optimal proximal and occlusal contacts of the individual's teeth.

3. Establishing the normal oral function that allows for adequate physiologic adaptation.
4. Achieving stability of the dentition within the boundaries of the expected physiologic relapse.

Treatment of a Class II malocclusion should be designed to obtain the treatment outcomes necessary for each particular case, and should take into account the maxilla and mandibular components.

Treatment of the maxilla can be accomplished by (Bishara, 2006):

- Inhibiting the normal forward and downward displacement of the maxilla.
- Inhibiting the normal forward movement of the maxillary denition.
- Moving the maxillary dentition distally.
- Influencing the eruption pattern of the maxillary teeth.
- Creating spaces by selective extractions to allow for differential tooth movement.

Treatment of the mandible can be accomplished by (Bishara, 2006):

- Stimulating the horizontal growth of the mandible.
- Anterior repositioning of the body of mandible.
- Influencing the eruption pattern of the mandibular teeth.
- Moving the mandibular dentition forward on its skeletal base.
- Creating space by selective extractions to allow for the desired tooth movements.

Once treatment objectives have been determined, the modality for delivering treatment must be selected.

2.6 CLASS II CORRECTION APPLIANCES

There are several options for correction of a class II malocclusion. The treatment is often a collaborative process between the orthodontist and the patient, where the level of patient cooperation directly influences the extent of correction observed. (McSherry et al. 2000)

When dealing with a growing patient, correction of a skeletal class II malocclusion may be achieved using headgear, or removable myofunctional appliances such as an activator, Frankel's appliance or Twin Block (Chaukse et al. 2011). However, positive treatment outcomes still depend on patient compliance with respect to wearing the appliance correctly for the prescribed period of time (McSherry et al. 2000). Unfortunately, many patients are not cooperative with appliance wear, thus compromising the treatment outcome. Therefore selection of treatment modality sometimes depends on the level of patient compliance (McSherry et al. 2000).

Non-compliance approaches provide an important treatment alternative for patients who present minimal or no cooperation, especially when non-extraction protocols are to be utilized. (Papadopoulos, 2006). Advancements made in non-compliance techniques and appliances have minimized the need for patient cooperation (Papadopoulos, 2006). Fixed class II correctors may be divided into inter and intra-arch appliances (McSherry et al. 2000). These appliances aim to correct the class II malocclusion through advancement of the mandible, and/or the distalization of the maxillary molars into a Class I relationship (Papadopoulos, 2006). However, controversy still exists over the contribution of skeletal correction of tooth borne fixed correctors (Papadopoulos, 2006).

An example of a fixed class II correction modality is the Herbst appliance. Introduced in Berlin by Emil Herbst in 1909, the Herbst appliance is an upper and lower fixed appliance linked by a telescopic mechanism (Pancherz 1994). The mandible is held forward in a protruded position throughout treatment to modify mandibular growth through condylar distraction. (Chaukse et al. 2011). The Herbst is considered to be effective, but it is also expensive and hard to assemble (Chaukse et al. 2011).

Spring-force delivery appliances have gained popularity over the past decade. These fixed sagittal correctors were developed as a substitute for elastics and headgear requiring more patient compliance (McSherry et al. 2000).

An example of a spring force delivery appliance is the Forsus™ appliance. A fixed inter-arch Class II corrector consisting of two auxiliary springs fitted to upper and lower fixed appliances. The springs are attached to the maxillary first molar bands, and anteriorly to the mandibular archwire in the canine area. These spring attachments protrude the mandible, ultimately contributing to the Class II correction (Flores Mir et al. 2009). A variation of the Forsus™ exists in the Xbow™ (crossbow) appliance.

2.7 XBOW™ APPLIANCE

Created by Dr. Duncan W. Higgins, the Xbow™ appliance uses inter-arch springs to correct sagittal discrepancies in the late mixed or early permanent dentition (Flores-Mir et al. 2009). The Xbow™ appliance is comprised of a maxillary hyrax expander, a mandibular labial and lingual bow, and Forsus™ springs (3M Unitek, Monrovia, Calif) (Flores-Mir et al. 2009). The Forsus™ spring is stopped anteriorly by a Gurin lock (3M Unitek) around the mandibular canine area (Flores-Mir et al. 2009). This Gurin lock (3M Unitek) lock allows for reactivation of the Forsus™ springs, without requiring a longer push rod (Flores-Mir et al. 2009).

The idea of the Xbow™ emerged in 1979, and has significantly evolved over the years (Higgins 2006). During this time Higgins focused his attention towards the deficiencies in fixed class II correctors, such as the breakage and side effects of spring based appliances (Higgins 2006). Ultimately, this lead to experimentation with the spring-loaded Herbst system, which Higgins later adapted to become the Xbow™ appliance (Higgins, 2006).

Philosophically, Higgins felt that the best maintenance of a Class I occlusion following Class II correction is “socked in” buccal segments (Higgins 2006). Therefore, the basic objectives of the Xbow™ appliance, as described by Dr. Higgins, included (Higgins, 2006):

- Achieving a Class I buccal occlusion by means of over-correcting the first maxillary bicuspids and allowing for physiologic rebound.
- A reduction in treatment time with the use of non-compliance Forsus™ Fatigue Resistant Devices in the correction of Class II malocclusions.
- Space maintenance and regaining through maxillary sutural expansion and preservation of leeway space.
- Reduced risk of root resorption and decalcification associated with prolonged treatment times.

Studies have demonstrated the efficacy of the Xbow™ appliance in the correction of Class II malocclusions. Flores-Mir et al. 2009 analyzed pre and post-treatment lateral cephalometric radiographs of Xbow™ patients and compared them to non-treated controls. The mean treatment time was 4.5 months, and the post-treatment radiographs were taken an average of 6.4 months after Forsus™ removal. Analysis of the control group, selected from the Burlington growth study, proved growth was not a contributing factor. Based on the results of this study, the following conclusions were drawn regarding the short-term skeletal and dental effects of the Xbow™ appliance (Flores-Mir et al. 2009):

- Class II correction was due to a combination of dental and skeletal changes. Skeletally, the

ANB angle was reduced due to a diminution of maxillary protrusion (decrease in A Point) without mandibular advancement.

- Significant differences contributing to Class II correction included SNA, ANB, L1-MP, L1 minus Pg, overjet, U6 minus A, L6 minus Pg, and A-OLp.
- Insignificant differences following Xbow™ treatment included SNB, U1-SN, U1 minus A, Pg-OLp, or Ar-OLp.
- Overjet was reduced by 3.0 mm; 0.9 mm of this was from maxillary incisor posterior movement (U1 minus A) and 0.9 mm from mandibular incisor anterior movement (L1 minus Pg). The remaining 1.2 mm (40%) was attributed to the mandible's outgrowth of the maxilla (shown by changes in Pg-OLp and A-OLp).
- The maxillary molars were significantly distalized, and the mandibular molars were significantly mesialized.

Further studies on the observed skeletal and dentoalveolar effects when treated with the Xbow™ appliance have been undertaken (Flores-Mir et al. 2010 and Chana et al. 2013). Flores-Mir et al. 2010 sought out to further evaluate changes in lower incisor inclination in Xbow™ patients with different vertical facial types. This study divided Xbow™ patients into three groups based on their vertical facial type (24 short, 122 normal, and 25 long facial types) (Flores-Mir et al. 2010). The mean age was 11.11 years prior to treatment, with a mean active treatment time of 4.5 months (Flores-Mir et al. 2010). A mean time of 6.4 months passed after Xbow™ deactivation, at which time a post-treatment radiograph was taken. The results of this study found no significant association between the amount of lower incisor proclination and vertical facial type. Due to large individual variability the differences between the groups could not be statistically supported. However, a trend was identified for more proclination of the lower incisor in the shorter face types. Consequently, the authors concluded that despite the fact that lower incisors do procline with the use of the Xbow™ appliance, the vertical facial type does not influence the amount of proclination due to large individual variability (Flores-Mir et al. 2010).

Chana et al. 2013 set out to determine the magnitude of the skeletal and dental movements in subjects with different facial patterns following Class II correction using the XbowTM appliance. A retrospective sample of patients treated with XbowTM Class II malocclusions were categorized into three facial patterns (27 brachycephalic, 70 mesocephalic, and 37 dolichocephalic) according to pre-treatment cephalometric variables (MPA and Y-axis) (Chana et al. 2013). The mean age was 12.6 years prior to treatment, with a mean active treatment time of 4.3 months (Chana et al. 2013). A mean time of 3.1 months passed after XbowTM deactivation, at which time a post-treatment radiograph was taken. The results of this study showed dental changes consisting of proclination of the lower incisors, protrusion of the lower incisors, mesial movement of the mandibular first molar, and retrusion of the maxillary incisor (Chana et al. 2013). Skeletally, reduction of the skeletal Class II relationship was represented by a significant decrease of the Wits value in all three groups (Chana et al. 2013). Based on the results of this study, the following conclusions were drawn regarding the magnitude skeletal and dental effects of the XbowTM appliance in different facial patterns (Chana et al. 2013):

1) Correction of Class II malocclusions with the XbowTM appliance is the result of:

- mesial movement of the mandibular molar,
- proclination and protrusion of the lower incisor,
- retrusion of the upper incisor,
- reduction of the Class II skeletal relationship represented by a reduction of the Wits value, but not by the ANB measurement.

2) Facial growth pattern appears to be unrelated to the amount of dental movement, however, there is a trend for pronounced proclination of the lower incisor in brachycephalic patients (Chana et al. 2013).

2.8 EVALUATION OF SOFT TISSUE EFFECTS

Facial soft-tissue effects observed following treatment with class II correction appliances have been described in the literature. Studies evaluating soft tissue effects following treatment with the Bionator (Lange et al. 1995 and Morris et al. 1998), activator (Maltagliati et al. 2004 and Quintão et al 2006), twin-block (Baysal and Uysal 2013 and Quintão et al 2006), Herbst (Baysal and Uysal 2013 and Pancherz 1994), and FMA (Frye et al. 2009) appliances have been undertaken.

Flores-Mir et al. performed three systematic reviews of studies investigating soft-tissue effects with bionator/activator, twin-block or fixed functional appliances. The results showed that twin-block appliances led to reduction in facial convexity but no sagittal movement of the lower lip and soft-tissue menton (Flores-Mir et al. 2006). Treatment with fixed functional appliances showed improvements in facial convexity and limited upper-lip advancement, but did not demonstrate movement of the lower lip and soft-tissue menton (Flores-Mir et al. 2006). The review also documented there was considerable disagreement between studies utilizing activator and bionator appliances, such that no conclsuions could be drawn (Flores-Mir et al. 2006).

These reviews by Flores-Mir et al. 2006 also indicate that although statistically significant soft tissue effects are demonstrated, the magnitude of the changes may not be perceived as clinically significant (Flores-Mir et al. 2006). Further research on soft tissue effects induced by functional appliances is indicated (Flores-Mir et al. 2006).

Chapter 3

Materials and Methods

3.1 SUPPLEMENTARY STUDY DESIGN

This study was designed to supplement research undertaken by Chana, Wiltshire, Hechter and Ahing, 2013. Therefore, the protocols instituted in this study mirrored those used in Chana et al. 2013 as closely as possible.

3.2 ETHICS

Ethics approval was obtained on July 12, 2013 from the Human Research Ethics Board (Bannatyne Campus, University of Manitoba) prior to commencement of this retrospective study (Attachment 1).

3.3 SAMPLE SELECTION

The retrospective patient sample was acquired from the private orthodontic practice of an orthodontist in Winnipeg, Manitoba. All digital cepahlometric radiographs were taken with a ProMax S3 Pan/Ceph (Planmeca, Inc. Helsinki, Finland).

Both pre-treatment (T0) and post-treatment (T1) lateral cephalometric radiographs were taken between January 23rd, 2008 and July 30th, 2011. The total sample size of 80 consisted of 38 males and 42 females. Due to the even gender distribution, the sample is described as gender neutral. The mean age of the patients was 12 years 6 months (SD 1yr. 6mo.) at T0 and 13 years 1 month (SD 1yr. 6mo.) at

T1. Standard treatment protocol involved activation of the distalizer springs every 4-6 weeks until a Class III overcorrection in the buccal segments was accomplished. Following the active phase (3.9 months SD 1.1 mo.), the appliance was passively retained for an additional average time of 3.0 months SD 1.06 mo. Therefore, the total mean time the appliance was in the mouth was 6.9 months SD 1.09 mo. at which time the appliance was removed and a T1 radiograph was taken. A summary of the treatment sample is described in Table 5-1.

Parameter	***Mean***	***Min.***	***Max.***	***SD***
Age at T0 (years)	12.5	9.9	15.9	1.52
Age at T1 (years)	13.1	10.9	16.5	1.48
Total time between T1/T2 (months)	6.9	4.10	13.1	1.09

Table 3-1. Summary statistics for the treatment group.

Inclusion criteria:

1. A complete permanent dentition;
2. Subjects with a ¾ to 1 full cusp unilateral or bilateral Class II dental malocclusion;
3. Subjects treated with the Xbow appliance;
4. Subjects with a pre and post cephalometric radiograph of acceptable quality.

Excluded criteria:

1. Subjects missing either a pre or post cephalometric radiograph;
2. Cephalometric radiographs of poor diagnositic quality;
3. Mutilated dentitions;
4. Congenitally missing teeth other than third molars;

5. Previous orthodontic treatment.

3.4 DATA COLLECTION

3.4.1 Calibration

The radiographs were labeled with a code for blinding purposes. No information on the radiographs indicated the age, gender, or if the radiograph was from pre or post Xbow treatment. All of the lateral cephalometric radiographs were digitally traced by a single investigator using the Dolphin™ 11.7 treatment planning software (Dolphin Imaging and Management Systems, Chatsworth, CA, USA). Magnification was accounted for using a digital calibration within the software, which matched actual known ruler distances captured on the lateral cephalogram.

The intra and inter-examiner reliability of the measurements was assessed on 10% of the studied sample. Cephalometric radiographs were chosen randomly and re-measured by two separate examiners 12 weeks after the original measurements to identify landmark identification error.

3.4.2 Defining facial types

Subjects were categorized into three growth types according to two pre-treatment cephalometric variables; mandibular plane angle (MPA) and growth axis (Y-axis). Subjects within two standard deviations for MPA (32° SD 2°) and one standard deviation for Y-axis (66° SD 5°) yielded; 20 brachycephalic, 40 mesocephalic, and 20 dolichocephalic subjects.

3.4.3 Growth Considerations

Post-treatment cephalometric radiographs used to examine the effects of Xbow™ treatment were taken the day of removal of the appliance. The mean treatment time with the Xbow™ in place was 6.9 months (SD 1.09 mo). Dolphin Imaging™ 11.7 software was used to predict the amount of growth that occurred over the period of treatment. Dolphin Imaging™ software uses growth prediction algorithms to quantify the amount of growth given parameters of age and time of treatment. Several computer programs using growth prediction algorithms have been shown to be accurate, with respect to a clinical reference mean of 1.5mm, including the Bolton growth prediction used for this sample (Sanun 2012).

The Bolton growth forecast of Dolphin Imaging™ allows (dolphinimaging.com):

1. Simulation of growth on a traced x-ray, or tracing overlaid on a photo by inputting current skeletal age and desired duration of growth.
2. Superimposition of one or more growth tracings over original tracing, aligned to any desired reference plane.
3. Viewing and analysis of post-growth measurements and the growth image.
4. A choice of Bolton or Ricketts growth algorithms.

The skeletal and dental effects of growth over the treatment period were assessed on 30% of the studied sample. Cephalometric radiographs were chosen randomly from each group and were subject to the Bolton growth prediction algorithm.

3.5 STATISTICAL ANALYSIS

For intra and inter-examiner reliability: measurements were assessed using an interclass correlation coefficient (ICC) test on 10% of the studied sample.

For facial type definition: a Kolmogorov-Smirnov test was used to determine if the samples were of normal distribution. A paired *t*-test was used to determine if there was a significant difference between the three groups prior to Xbow™ treatment. The p-value was considered significant at $\alpha<0.05$.

For the Bolton growth prediction group (Control): a Kolmogorov-Smirnov test was used to determine if the samples were of normal distribution. A paired *t*-test was used to determine if there was a significant difference between the cephalometric variables from expected growth versus pre-treatment cephalometric variables. The p-value was considered significant at $\alpha<0.05$.

For treatment sample groups: a Kolmogorov-Smirnov test was used to determine if the samples were of normal distribution. Following confirmation of normal distribution, an analysis of variance (ANOVA) statistic was used analyze the observed soft tissue effects between the three groups. The p value was considered significant at $\alpha<0.05$.

For all statistical tests: statistical software SAS 9.4 was used to analyze the data.

3.6 Xbow™ APPLIANCE

The appliance used in this study was the Xbow™ fixed Class II corrector. The Xbow™ consisted of 3 main components: a maxillary hyrax expander, a mandibular labial and lingual bow, and Forsus™ fatigue resistant device (FRD) springs (3M Unitek, Monrovia, Calif) (Higgins 2011). The maxillary hyrax included bands on the maxillary first molars and first premolars.

One end of the Forsus™ spring was inserted into the headgear tube of the maxillary first molar band and the opposite end was hooked around the labial bow near the mandibular canine area. The Forsus™ spring was stopped anteriorly by a Gurin lock (3M Unitek) on the lower labial bow. The mandibular labial and lingual bows were in passive contact with the mandibular incisors and were retained in the mouth by bands on the first molars and occlusal rests bonded to the first premolars. (Figure 5-1).

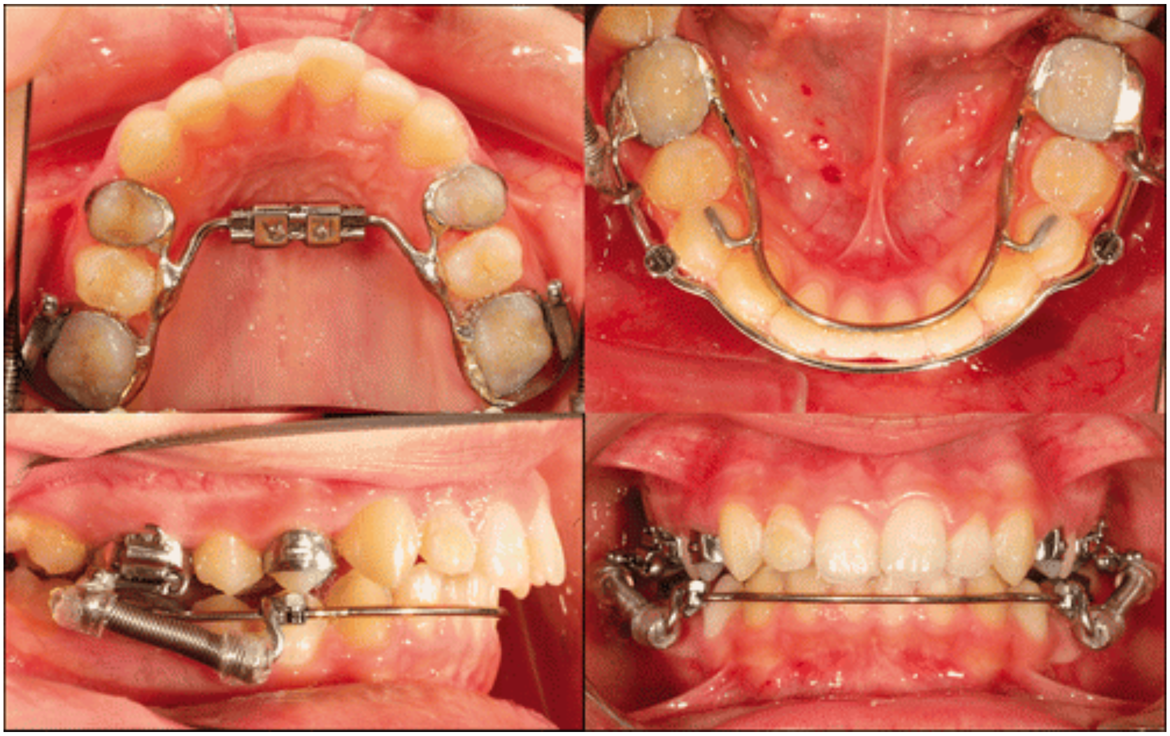


Figure 3-1. Intra-oral photos of the Xbow™ (Mir, Barnett, Higgins, Heo, Major 2009).

The treatment protocol used on the sample was similar irrespective of the amount of expansion required or if there was a Class II dental asymmetry.

The maxillary and mandibular appliance was inserted on the same day with Forsus™ springs bilaterally on every patient. Standard treatment protocol involved activation of the springs every 4-6 weeks until a Class III overcorrection in the buccal segments was accomplished.

Transverse discrepancies were calculated pre-treatment and expansion was completed prior to AP correction. The hyrax screw was activated if expansion was deemed necessary. If expansion was completed it was retained for 4 months with the hyrax passively in place. The Xbow™ appliance was left in place for the entire treatment period of 6.9 months (SD 1.09 mo) on average.

Following Class II overcorrection, phase two treatment (not analyzed in this study) involved full fixed upper and lower braces with the use of inter-arch elastics if required.

3.7 CEPHALOMETRIC ANALYSIS

3.7.1 Natural Head Position

Consistent patient positioning during the cephalometric radiographs was assumed for this retrospective study. It is also assumed that the patients were positioned in the natural head position. Natural head position (as defined by C.F. Moorrees and M.R. Kean in 1958) is a standardized orientation of the head that is reproducible for each individual allowing for standardized analysis of cephalometric radiographs (Jacobson, 2006). To accomplish natural head position, patients are asked to gaze ahead as if he/she were looking at the horizon with the interpupillary line parallel to the floor.

All radiographs for this study were taken with the same Pan/Ceph ProMax S3 (Planmeca, Inc. Helsinki, Finland). The radiograph of the head was taken with the x-ray beam perpendicular to the patient's sagittal plane. The beam entered on the patient's left side, with the film cassette adjacent to the patient's right side. Each radiograph was analyzed with the patient's head oriented to the right.

3.7.2 Computerized Cephalometrics

The cephalometric data was transferred in JPEG digital format into Dolphin Imaging™ 11.5 for cephalometric analysis. The images were then 'digitized' to allow for tracing the digital image. Digitization is defined as "the conversion of landmarks on a radiograph or tracing to numerical values on a two dimensional coordinate system, usually for the purpose of computerized cephalometric analysis" (Jacobson, 2006). The process allows for automatic measurement of landmark relationships. Once digitized, manual landmark identification was carried out by the principle investigator.

3.7.3 Growth Visual Treatment Objective (VTO) – Growth Prediction

A growth VTO is a prediction of a patient's expected growth over a definitive period of time (Ricketts 1979). To rule out if growth that may have had a significant contribution to any skeletal or dental movements over the treatment period, thirty percent of the total sample's pretreatment tracings were subject to Dolphin Imaging™Bolton growth prediction algorithm. The Bolton growth prediction algorithm has been shown to be accurate, with respect to a clinical reference mean of 1.5mm (Sanun, 2012). Therefore, the pre-treatment cephalograms had growth effects(that would have otherwise occurred in the treatment time period) simulated with the Dolphin Imaging™ Bolton growth prediction algorithm. . This data was then subject to statistical analysis to quantify growth changes of the subjects.

3.7.4 Cephalometric Landmarks and Measurements

A cephalometric landmark is a recognizable, and repeatable point on a tracing that represents a hard or soft tissue anatomical structure (Phulari, 2013). A line or plane may be drawn between two landmarks, and subsequently linear or angular measurements may be taken between two or more landmarks or planes (Phulari, 2013). These measurements in turn may then be used to analyze cephalometric radiographs (Phular,i 2013). Therefore, this study utilized soft tissue landmarks that have been proven (Phulari, 2013) and analyses that are recognized in the literature (Morris, Illing and Lee 1998; Baysal and Uysal 2013).

The cephalometric landmarks, as well as the linear and angular measurements used in this study are illustrated in Figures 3-2, 3-3, and 3-4. The definitions of the landmarks and measurements used in this study are provided in Tables 3-2, 3-3, and 3-4.

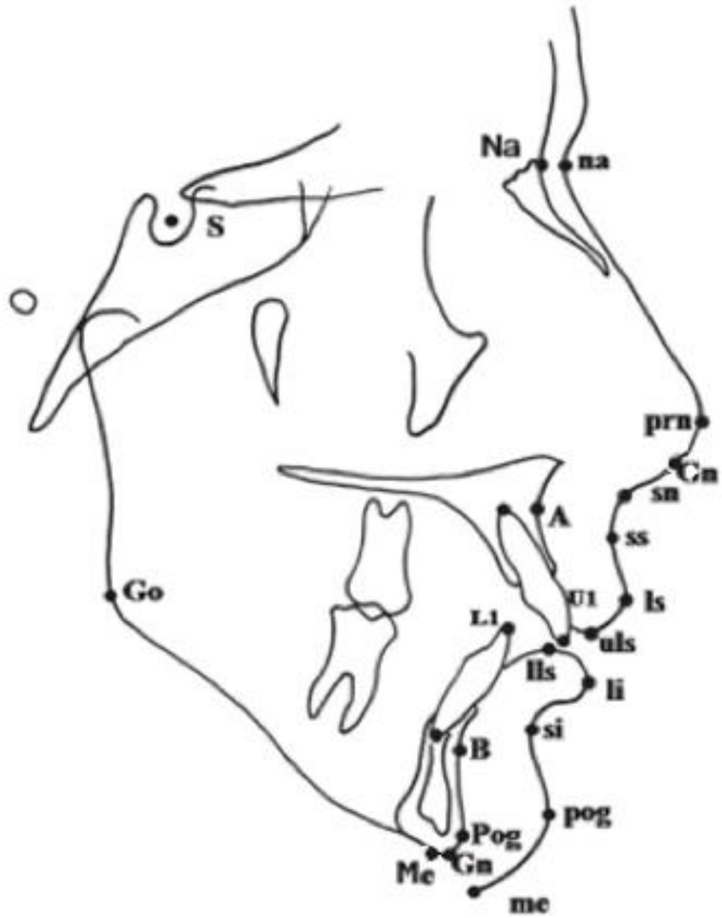
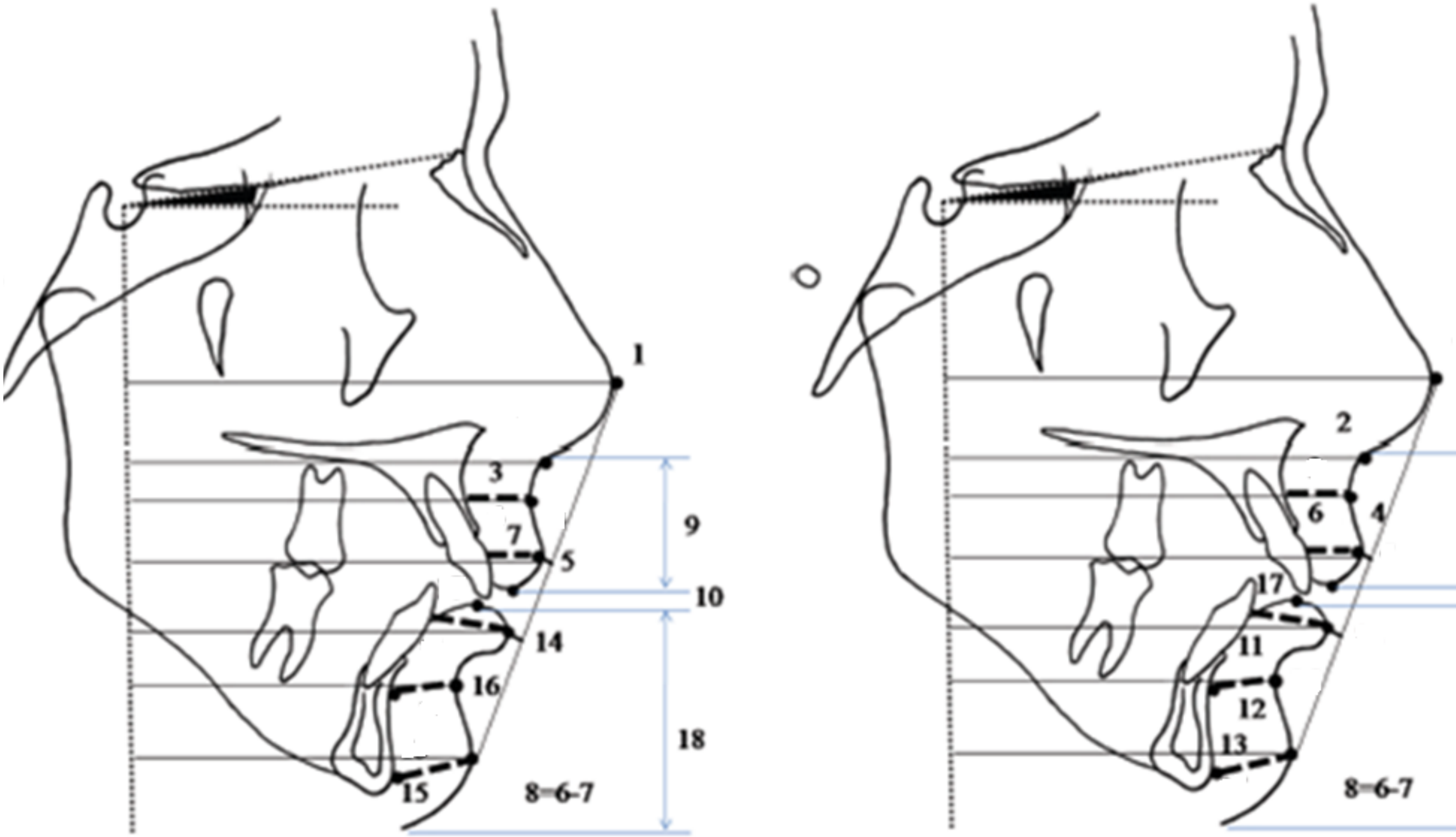


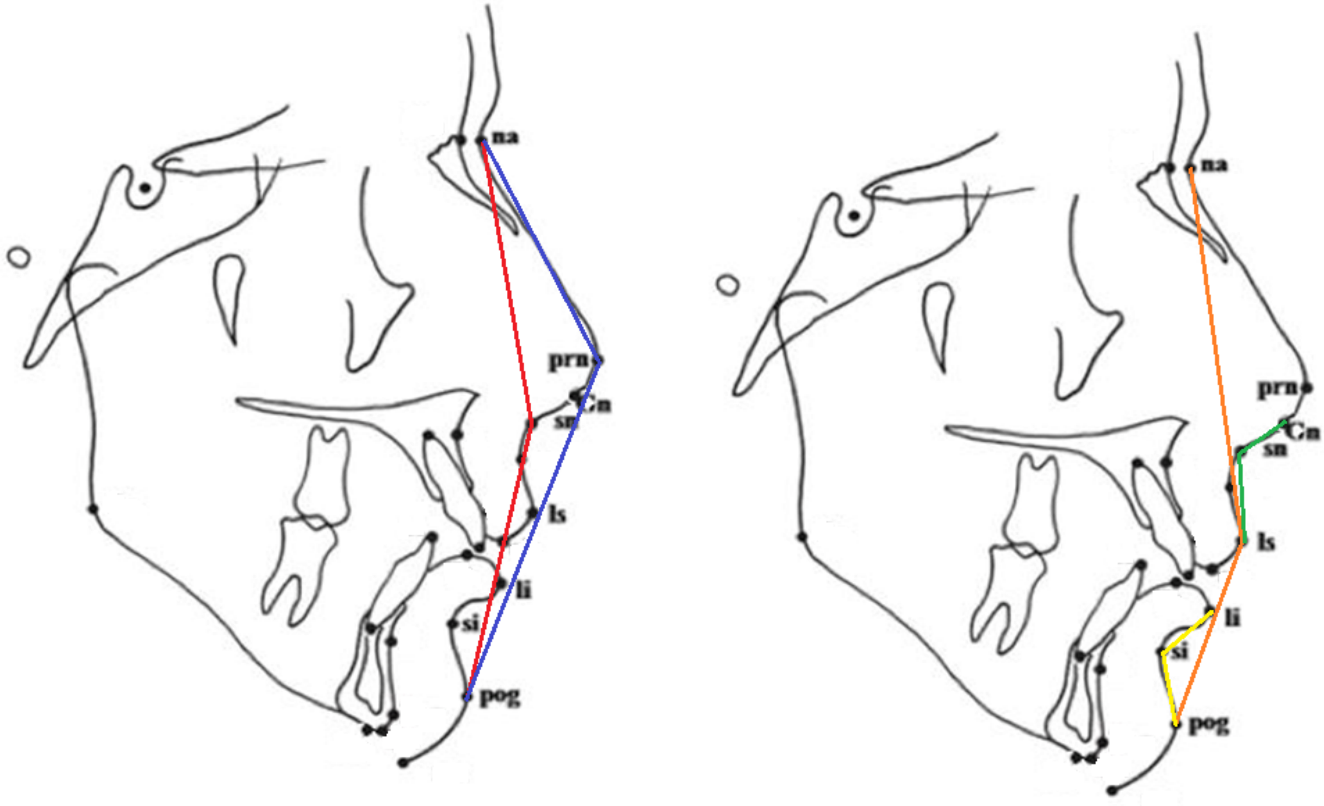
*Image adapted from Baysal and Uysal (2013)

Figure 3-2. Landmarks used in soft tissue analysis (adapted from Baysal and Uysal 2013): S=sella, Na=naison, Go=gonion, Gn=gnathion, Pog=pogonion, A=A point, B= B point, UI=upper incisor, Li=lower incisor, na=soft tissue nasion, prn=pronasale, Cm=columella, sn=subnasale, ss=sulcus superior, ls=labrale superior, uls=stomion superius, li=labrale inferior, lls=stomion inferius, si=sulcus inferior, pog=soft tissue pogonion, Me=menton, me=soft tissue menton.



*Images adapted from Baysal and Uysal (2013)

Figure 3-3. Linear measurements taken for soft tissue analysis (adapted from Baysal and Uysal 2013) (1) VRL-prn, (2) VRL-sn, (3) VRL-ss, (4) VRL-ls, (5) E-ls, (6) basic upper lip thickness, (7) upper lip thickness, (8) upper lip strain=difference between 6th and 7th measurements, (9) upper lip length, (10) interlabial gap, (11) VRL-li (12) VRL-si, (13) VRL-pog, (14) E-li, (15) soft tissue chin thickness (Pog-pog), (16) si-B, (17) lower lip thickness, (18) lower lip length.



*Images adapted from Baysal and Uysal (2013)

Figure 3-4. Angular measurments taken for soft tissue analysis (adapted from Baysal and Uysal 2013): Convexity angle, including the nose (BLUE), Convexity angle, excluding the nose (RED), Nasolabial angle (GREEN), Mentolabial angle (YELLOW), H angle (ORANGE).

Landmark	***Description***	***Reference***
Sella (S)	Center of the roughly circular hypophyseal fossa (sella turcica)	Broadbent 1975; Jacobson 1995
Nasion (N)	Junction of the nasal and frontal bones.	Broadbent 1975; Jacobson 1995
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 Go will be used.	Broadbent 1975; Jacobson 1995
Pogonion (Pog, P, Pg)	Most anterior point on the contour of the bony chin, in the midsagittal plane. Located perpendicular to mandibular plane, tangent to the chin.	Broadbent 1975; Jacobson 1995
Gnathion (Gn)	Most anterior inferior point on the bony chin in the midsagittal plane.	Broadbent 1975; Jacobson 1995
Menton(Me)	Point most inferior on mandibular symphysis	Broadbent 1975; Jacobson 1995

A-point (Subspinale, ss)	Deepest, most posterior midline point on the curvature between the ANS and prosthion.	Broadbent 1975; Jacobson 1995
B-point (Point B, Supramentale, sm)	Deepest most posterior midline point on the bony curvature of the anterior mandible, between infradentale and pogonion.	Broadbent 1975; Jacobson 1995
Incision superius (UI)	Incisal tip of the most labially placed maxillary central incisor.	Broadbent 1975; Jacobson 1995
Incision inferius (Li)	Incisal tip of the most labially placed mandibular incisor.	Broadbent 1975; Jacobson 1995
Soft tissue nasion(na)	The concave or retruded point in the tissue overlying the area of the frontonasal suture.	Phulari 2013
Pronasale (Tip of Nose) (prn)	The most prominent or anterior point of the nose.	Phulari 2013
Columella (Cm)	The most anterior point on the columella of the nose	Phulari 2013
Subnasale (sn)	The point at which the nasal septum between the nostrils merges with the upper cutaneous tip in the midsagittal	Phulari 2013

	plane.	
Sulcus superior (ss) Soft tissue A point Soft tissue subsnpinale	The point of greatest concavity in the midline of the upper lip between subnasale and labrale superius	Phulari 2013
Labrale superior (ls)	The most anterior point on the margin of the upper membranous lip.	Phulari 2013
Stomion Superius (uls)	The median point on the upper lip of the oral embrasure when the lips are closed.	Phulari 2013
Labrale inferior (li)	The most anterior point on the lower margin of the lower membrane lip.	Phulari 2013
Sulcus inferior (si) Soft tissue B point Soft tissue Submentale	The point of greatest concavity in the midline of the lip between labrale inferius (Li) and soft tissue pogonion (Pog’ or Pogs).	Phulari 2013
Stomion Inferius (lls)	the median point on the lower lip of the oral embrasure when the lips are closed.	Phulari 2013
Soft tissue pogonion (pog)	The most prominent or anterior point on the soft tissue chin in the midsagittal plane.	Phulari 2013

Soft tissue menton (me)	Most inferior point of the soft tissue of the chin	Phulari 2013

Table 3-2. Definition of hard and soft tissue landmarks

Line or Plane	*Description*	***Reference***
Vertical Reference Line	A line drawn perpendicular (vertical) to the horizontal reference line constructed constructed 7° less than the sella – nasion line.	Morris et al. 1998 and Baysal and Uysal 2013
Tip of Nose – VRL (mm)	Horizontal distance between vertical reference plane and pronasale	Baysal and Uysal 2013
Subnasale – VRL (mm)	Horizontal distance between vertical reference plane and subnasale	Baysal and Uysal 2013
Soft Tissue A Pt. – VRL (mm)	Horizontal distance between vertical reference plane and sulcus superius	Baysal and Uysal 2013
Upper Lip – VRL (mm)	Horizontal distance between vertical reference plane and labrale superius	Baysal and Uysal 2013
Upper Lip to E-Plane (mm)	The distance from labrale superius to a line joining the nasal tip and soft tissue pogonion	Baysal and Uysal 2013

Upper lip thickness (UL-U1) (mm)	The dimension between the vermilion point and the labial surface of the maxillary incisor	Baysal and Uysal 2013
Upper Lip Length (mm)	Vertical distance between upper lip stomion and subnasale	Baysal and Uysal 2013
InterLabial Gap (mm)	Vertical distance between stomion superius and inferius	Baysal and Uysal 2013
Lower Lip – VRL (mm)	Horizontal distance between vertical reference plane and labrale inferius	Baysal and Uysal 2013
Soft Tissue B Pt. – VRL (mm)	Horizontal distance between vertical reference plane and sulcus inferius	Baysal and Uysal 2013
Soft Tissue Pogonion – VRL (mm)	Horizontal distance between vertical reference plane and soft tissue pogonion	Baysal and Uysal 2013
Lower Lip to E-Plane (mm)	The distance from labrale inferius to a line joining the nasal tip and soft tissue pogonion	Baysal and Uysal 2013
Lower lip - Lower 1 Most Labial (mm)	Horizontal distance between and the most prominent point on buccal surface of lower incisor	Baysal and Uysal 2013
Lower Lip Thickness at Bpt (B-B') (mm)	Horizontal distance between sulcus inferius and point B	Baysal and Uysal 2013

Lower Lip Length (mm)	Vertical distance between lower lip stomion and soft tissue menton	Baysal and Uysal 2013

Table 3-3. Definition of soft tissue linear measurements

Plane	*Description*	***Reference***
Soft Tissue Convexity	The angle formed between soft tissue nasion, nasal tip, and soft tissue pogonion	Baysal and Uysal 2013
Soft Tissue Profile	The angle formed between soft tissue nasion, subnasale, and soft tissue pogonion	Baysal and Uysal 2013
Nasolabial Angle	The angle formed between columella, subnasale, and labrale superius	Baysal and Uysal 2013
MentoLabial Angle	The angle formed between labrale inferius, sulcus inferius, and soft tissue pogonion	Baysal and Uysal 2013

H-Angle	The angle formed between soft tissue nasion, labrale superius, and soft tissue pogonion	Baysal and Uysal 2013
MP – SN	A line passing through the mandibular borders (bilaterally) joining points gonion and menton.	Broadbent 1975; Jacobson 1995
Y-Axis	A line connecting points sella and gnathion. This angle gives an indication of the direction of mandibular growth.	Broadbent 1975; Jacobson 1995

Table 3-4. Definition of hard and soft tissue angular measurements

Chapter 4

Results

4.1 Sample Group Statistics

Group 1 represents the brachycephalic group with mean Y-axis of 60.5°±0.5° and a mean MPA of 25.5°±0.4°.

Group 2 represents the mesocephalic group with a mean Y-axis of 68.0°±0.2° and a mean MPA of 32.1°±0.4°.

Group 3 represents the dolichocephalic group with a mean Y-axis of 74.5°±0.2° and a mean MPA of 39.5°±0.4°.

A summary of the three groups prior to Xbow™ treatment is described in Table 6-1.

Variables	Group 1	Group 2	p-value
Y-Axis (SGn-SN) º	60.5±0.5	68.0±0.2	<0.0001
MPA MP - SN º	25.5±0.4	32.1±0.4	<0.0001
	Group 1	**Group 3**	**p-value**
Y-Axis (SGn-SN) º	60.5±0.5	74.5±0.2	<0.0001
MPA MP - SN º	25.5±0.4	39.5±0.4	<0.0001
	Group 2	**Group 3**	**p-value**
Y-Axis (SGn-SN) º	68.0±0.2	74.5±0.2	<0.0001
MPA MP - SN º	32.1±0.4	39.5±0.4	<0.0001

Table 4-1. Differences in Y-Axis and MPA between groups prior to Xbow™ treatment (Time 0). Group 1 – brachycephalic, Group 2 - mesocephalic, Group 3 – dolichocephalic.

4.2 Sample Distribution Statistics

The Kolmogorov-Smirnov test was used to determine if the samples were of normal distribution for each variable measured.

A summary of distribution type is in Table 4-2.

Variable	***Distribution***
Soft Tissue Convexity	Normal
Soft Tissue Profile	Normal
Nasolabial Angle	Normal
Mentolabial Angle	Normal
H-Angle	Normal
Tip of Nose – VRL (mm)	Normal
Subnasale – VRL (mm)	Normal
Soft Tissue A Pt. – VRL (mm)	Normal
Upper Lip – VRL (mm)	Normal
Upper Lip to E-Plane (mm)	Normal
Upper lip thickness (UL-U1) (mm)	Normal
Upper Lip Length (mm)	Normal
InterLabial Gap (mm)	Normal
Lower Lip – VRL (mm)	Normal
Soft Tissue B Pt. – VRL (mm)	Normal
Soft Tissue Pogonion – VRL (mm)	Normal
Lower Lip to E-Plane (mm)	Normal
Lower lip - Lower 1 Most Labial (mm)	Normal
Lower Lip Thickness at Bpt (B-B') (mm)	Normal
Lower Lip Length (mm)	Normal
Chin Thickness (mm)	Normal
MP - SN	Normal
Y-Axis	Normal

Table 4-2. Sample distribution type for variables examined

4.3 Reliability

The reliability of the measurements was assessed using an intraclass correlation coefficient (ICC) test on 10% of the studied sample. Radiographs were chosen randomly and re-measured by two separate examiners 12 weeks after the original measurements to identify landmark identification error. The level of reliability was assessed based on ICC values which ranged from 0 (no agreement) to 1 (perfect agreement).

4.3.1 Intra-examiner reliability

The intra-examiner results showed a high consistency in the repeated measurements; all ICC values were greater or equal to 0.935. An F test was used to confirm that there were no significant differences between the cephalometric variables from T0 to T1 (Table 4-3).

Variables examined T_0 to T_1	Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
		Lower limit	Upper limit	Value	df 1	Df2	Sig
Soft Tissue Convexity	.998	.988	1.000	1001.500	6	6	.000
Soft Tissue Profile	.971	.844	.995	68.613	6	6	.000
Nasolabial Angle	.974	.855	.995	74.583	6	6	.000
Mentolabial Angle	.953	.757	.992	41.991	6	6	.000
H-Angle	.997	.985	1.000	768.601	6	6	.000
Tip of Nose – VRL (mm)	.935	.672	.988	29.640	6	6	.000
Subnasale – VRL (mm)	.966	.913	.997	128.027	6	6	.000
Soft Tissue A Pt. – VRL (mm)	.978	.939	.998	186.371	6	6	.000
Upper Lip – VRL (mm)	.984	.982	.999	646.618	6	6	.000
Upper Lip to E-Plane (mm)	.997	.985	1.000	771.949	6	6	.000
Upper lip thickness (UL-U1) (mm)	.989	.902	.997	112.629	6	6	.000
Upper Lip Length (mm)	.997	.930	.998	160.852	6	6	.000
InterLabial Gap (mm)	.999	.940	.998	186.749	6	6	.000

Lower Lip – VRL (mm)	.982	.974	.999	442.097	6	6	.000
Soft Tissue B Pt. – VRL (mm)	.988	.861	.996	140.888	6	6	.000
Soft Tissue Pogonion – VRL (mm)	.989	.870	.996	83.452	6	6	.000
Lower Lip to E-Plane (mm)	.995	.948	.998	217.740	6	6	.000
Lower lip - Lower 1 Most Labial (mm)	.975	.921	.998	141.672	6	6	.000
Lower Lip Thickness @ Bpt (B-B') (mm)	.976	.962	.999	300.179	6	6	.000
Lower Lip Length (mm)	.991	.954	.999	246.382	6	6	.000
Chin Thickness (mm)	.986	.913	.983	100.676	6	6	.000
MP - SN	.993	.967	.991	258.112	6	6	.000
Y-Axis	.992	.936	.988	322.770	6	6	.000
Average	**.983**	**.913**	**.996**	**279.656**	**6**	**6**	**.000**

Table 4-3. ICC and F test values for the intra-examiner reliability.

4.3.2 Inter-examiner reliability

Inter-examiner ICC values had a wider reliability interval (0.926

-0.994) and overall lower average correlation (0.976). However, there was still strong agreement of the values with correlation coefficients greater than 0.926 (Table 4-4). Once again, an F test was used to confirm there were no significant differences between the cephalometric variables from T0 to T1 (Table 4-4). Based on these results, we can be confident that the reproducibility of the cephalometric variables are reliable within a 12 week period.

Variables examined T_0 to T_1	**Intraclass Correlation**	**95% Confidence Interval**		**F Test with True Value 0**			
		Lower limit	Upper limit	Value	df1	df2	Sig
Soft Tissue Convexity	.978	.877	.996	0.476	6	6	.000
Soft Tissue Profile	.979	.885	.996	95.702	6	6	.000
Nasolabial Angle	.960	.786	.993	48.645	6	6	.000
Mentolabial Angle	.926	.899	.954	31.147	6	6	.000
H-Angle	.993	.958	.999	273.664	6	6	.000
Tip of Nose – VRL (mm)	.947	.729	.991	37.063	6	6	.000
Subnasale – VRL (mm)	.983	.906	.997	118.207	6	6	.000
Soft Tissue A Pt. – VRL	.956	.766	.992	43.994	6	6	.000

(mm)							
Upper Lip – VRL (mm)	.978	.880	.996	91.346	6	6	.000
Upper Lip to E-Plane (mm)	.996	.980	.999	562.931	6	6	.000
Upper lip thickness (UL-U1) (mm)	.989	.936	.998	176.342	6	6	.000
Upper Lip Length (mm)	.943	.709	.990	34.124	6	6	.000
InterLabial Gap (mm)	.976	.968	.987	99.004	6	6	.000
Lower Lip – VRL (mm)	.964	.807	.994	54.494	6	6	.000
Soft Tissue B Pt. – VRL (mm)	.998	.998	1.000	4768.200	6	6	.000
Soft Tissue Pogonion – VRL (mm)	.978	.880	.996	91.560	6	6	.000
Lower Lip to E-Plane (mm)	.991	.950	.998	225.949	6	6	.000
Lower lip - Lower 1 Most Labial (mm)	.993	.961	.999	289.310	6	6	.000
Lower Lip Thickness @ Bpt (B-B') (mm)	.997	.997	1.000	4406.333	6	6	.000
Lower Lip Length (mm)	.996	.976	.999	479.554	6	6	.000

Chin Thickness (mm)	.978	.877	.996	89.058	6	6	.000
MP - SN	.988	.934	.998	170.863	6	6	.000
Y-Axis	.967	.823	.994	59.919	6	6	.000
Average	**.976**	**.891**	**.994**	**532.512**	**6**	**6**	**.000**

Table 4-4. ICC and F test values for the inter-examiner reliability.

4.4 GROWTH CONSIDERATIONS

Dolphin Imaging™ 11.5 software was used to predict the amount of growth that occurred over the treatment period (mean time of 6.9 months SD 1.09 mo.). Dolphin Imaging™ software uses growth prediction algorithms to quantify the amount of growth, given parameters of age and time of treatment. Several computer programs using growth prediction algorithms have shown to be accurate, with respect to a clinical reference mean of 1.5mm, including the Bolton growth prediction used for this sample (Sanun, 2012). A *t*-test showed that the mean differences of all variables were insignificant (Table 4-5). The p value was considered significant at $\alpha<0.05$.

Variables	Mean	Std Err	Upper 95% CL	Lower 95% CL	p-value	Sig.
Soft Tissue Convexity	0.100	0.025	-0.073	0.273	0.243	NS
Soft Tissue Profile	0.0746	0.071	-0.281	0.014	0.075	NS
Nasolabial Angle	-0.487	0.017	-0.097	-0.029	0.081	NS
Mentolabial Angle	-0.617	0.312	-0.028	1.261	0.059	NS

H-Angle	-0.162	0.006	-0.004	0.020	0.162	NS
Tip of Nose – VRL (mm)	0.054	0.042	-0.033	0.141	0.211	NS
Subnasale – VRL (mm)	0.013	0.007	-0.027	0.002	0.083	NS
Soft Tissue A Pt. – VRL (mm)	0.017	0.010	-0.037	0.004	0.104	NS
Upper Lip – VRL (mm)	0.033	0.018	-0.070	0.003	0.073	NS
Upper Lip to E-Plane (mm)	0.050	0.025	-0.101	0.001	0.056	NS
Upper lip thickness (UL-U1) (mm)	0.021	-0.012	-0.004	0.046	0.096	NS
Upper Lip Length (mm)	0.017	-0.041	-0.041	0.007	0.162	NS
InterLabial Gap (mm)	0.004	0.009	-0.024	0.015	0.664	NS
Lower Lip – VRL (mm)	0.096	0.051	-0.200	0.009	0.071	NS
Soft Tissue B Pt. – VRL (mm)	0.092	0.048	-0.191	0.008	0.069	NS
Soft Tissue Pogonion – VRL (mm)	0.065	0.062	-0.250	0.008	0.065	NS
Lower Lip to E-Plane (mm)	0.029	0.015	0.001	0.058	0.057	NS
Lower lip - Lower 1 Most Labial (mm)	0.033	0.021	-0.076	0.009	0.119	NS
Lower Lip Thickness at Bpt (B-B') (mm)	-0.029	0.015	-0.061	0.003	0.070	NS
Lower Lip Length (mm)	0.046	0.026	-0.099	0.007	0.086	NS
Chin Thickness (mm)	0.029	0.016	-0.063	0.005	0.090	NS
MP - SN	0.100	0.051	-0.206	0.006	0.064	NS
Y-Axis	0.158	0.077	-0.318	0.001	0.052	NS

Table 4-5. Growth prediction of 30% of the sample (n=24). Mean change; Std Dev - Standard deviation; Std Err – Standard error; CL – Confidence limit; S - Significant difference (p≤0.05); NS – No significant difference (p>0.05).

4.5 DIFFERENCE IN FACIAL PATTERN AND SOFT TISSUE EFFECTS OBSERVED BETWEEN GROUPS FOLLOWING XBOW^{TM} TREATMENT (T1-T0)

4.5.1 Brachycephalic (n=20) and Mesocephalic (n=40) Groups

i) *Facial Pattern Effects***-** No statistically significant differences were observed between brachycephalic and mesocephalic groups following Xbow^{TM} treatment ($p<0.05$) (Table 4-6)

ii) *Soft Tissue Effects*- The observed changes in upper lip to E-Plane (mm) were shown to be significantly different between the brachycephalic and mesocephalic groups following Xbow^{TM} treatment ($p<0.05$) (Table 4-6).

Variables	**Group 1 (Brachy)**	**Group 2 (Meso)**	**p-value**
	Mean±SE	Mean±SE	
Soft Tissue Convexity	0.49±0.40	0.67±0.40	0.7059
Soft Tissue Profile	2.63±0.55	2.43±0.38	0.9538
Nasolabial Angle	0.32±0.91	0.13±0.64	0.9844
Mentolabial Angle	7.96±2.21	8.37±1.56	0.9872
H-Angle	3.10±0.51	-2.44±0.35	0.5263
Tip of Nose – VRL (mm)	0.59±0.37	0.42±0.26	0.7078
Subnasale – VRL (mm)	0.57±0.46	0.18±0.33	0.4957
Soft Tissue A Pt. – VRL (mm)	0.22±0.47	0.24±0.33	0.9993

Upper Lip – VRL (mm)	-0.50±0.48	-0.40±0.34	0.8657
Upper Lip to E-Plane (mm)	**-1.04±0.17**	**-1.61±0.17**	**0.0175**
Upper lip thickness (UL-U1) (mm)	0.64±0.39	0.29±0.28	0.7442
Upper Lip Length (mm)	0.17±0.34	0.11±0.24	0.9901
InterLabial Gap (mm)	-0.39±0.24	-0.21±0.17	0.8239
Lower Lip – VRL (mm)	1.48±0.41	0.99±0.41	0.4536
Soft Tissue B Pt. – VRL (mm)	1.39±0.56	1.01±0.56	0.6699
Soft Tissue Pogonion – VRL (mm)	1.2±0.56	0.99±0.56	0.8137
Lower Lip to E-Plane (mm)	0.10±0.07	0.06±0.05	0.7057
Lower lip - Lower 1 Most Labial (mm)	0.24±0.18	0.50±0.18	0.3656
Lower Lip Thickness at B pt (mm)	0.31±0.43	0.86±0.43	0.5571
Lower Lip Length (mm)	0.73±0.40	1.37±0.40	0.3166
Chin Thickness (mm)	0.46±0.40	0.37±0.28	0.9811
MP - SN	0.19±0.42	-0.10±0.29	0.5690
Y-Axis	0.07±0.23	-0.10±0.17	0.5605

Table 4-6. Difference between brachycephalic and mesocephalic following Xbow™ treatment (T1-T0).

4.5.2 Brachycephalic (n=20) and Dolichocephalic (n=20) Groups

i) *Facial Pattern Effects*- No statistically significant differences were observed between brachycephalic and dolichocephalic groups following Xbow™ treatment ($p<0.05$) (Table 4-7).

ii) *Soft Tissue Effects*- No statistically significant differences were observed between the brachycephalic and dolichocephalic groups following Xbow™ treatment ($p<0.05$) (Table 4-7).

Variables	**Group 1 (Brachy)**	**Group 3 (Dolicho)**	**p-value**
	Mean±SE	Mean±SE	
Soft Tissue Convexity	0.49±0.40	0.77±0.40	0.6235
Soft Tissue Profile	2.63±0.55	2.11±0.38	0.7735
Nasolabial Angle	0.32±0.91	0.73±0.91	0.7518
Mentolabial Angle	7.96±2.21	13.87±2.21	0.1407
H-Angle	3.10±0.51	-2.91±0.50	0.9594
Tip of Nose – VRL (mm)	0.59±0.37	0.53±0.37	0.9093
Subnasale – VRL (mm)	0.57±0.46	0.35±0.46	0.9418
Soft Tissue A Pt. – VRL (mm)	0.22±0.47	0.13±0.47	0.9985
Upper Lip – VRL (mm)	-0.50±0.48	-0.39±0.48	0.9843
Upper Lip to E-Plane (mm)	-1.04±0.17	-1.05±0.20	0.9698
Upper lip thickness (UL-U1) (mm)	0.64±0.39	0.21±0.39	0.7247
Upper Lip Length (mm)	0.17±0.34	0.35±0.33	0.9190
InterLabial Gap (mm)	-0.39±0.24	-0.30±0.24	0.9633
Lower Lip – VRL (mm)	1.48±0.41	1.09±0.41	0.7779
Soft Tissue B Pt. – VRL (mm)	1.39±0.56	0.86±0.56	0.7782
Soft Tissue Pogonion – VRL (mm)	1.20±0.56	1.10±0.56	0.9973

Lower Lip to E-Plane (mm)	0.10±0.07	-0.09±0.07	0.0625
Lower lip - Lower 1 Most Labial (mm)	0.24±0.18	0.21±0.18	0.9068
Lower Lip Thickness at B pt (mm)	0.31±0.43	0.64±0.43	0.8444
Lower Lip Length (mm)	0.73±0.40	0.54±0.40	0.3570
Chin Thickness (mm)	0.46±0.40	0.63±0.40	0.9503
MP - SN	0.19±0.42	0.60±0.42	0.4942
Y-Axis	0.07±0.23	0.39±0.23	0.3314

Table 4-7. Difference between brachycephalic and dolicocephalic following Xbow™ treatment (T1-T0).

4.5.3 Mesochocephalic (n=40) and Dolichocephalic (n=20) Groups

i) *Facial Pattern Effects*- No statistically significant differences were observed between mesocephalic and dolichocephalic groups following Xbow™ treatment ($p<0.05$) (Table 4-8).

ii) *Soft Tissue Effects*- The observed changes in mentolabial angle, and upper lip to E-Plane (mm) were shown to be significantly different between the mesocephalic and dolichocephalic groups following Xbow™ treatment ($p<0.05$) (Table 4-8).

Variables	**Group 2 (Meso)**	**Group 3 (Dolicho)**	**p-value**
	Mean±SE	Mean±SE	
Soft Tissue Convexity	0.67±0.40	0.77±0.40	0.9701

Soft Tissue Profile	2.43±0.38	2.11±0.38	0.5970
Nasolabial Angle	0.13±0.64	0.53±0.91	0.8528
Mentolabial Angle	**8.37±1.56**	**13.87±2.21**	**0.0256**
H-Angle	-2.44±0.35	-2.91±0.50	0.7254
Tip of Nose – VRL (mm)	0.42±0.26	0.53±0.37	0.8083
Subnasale – VRL (mm)	0.18±0.33	0.35±0.46	0.9513
Soft Tissue A Pt. – VRL (mm)	0.24±0.33	0.13±0.47	0.9804
Upper Lip – VRL (mm)	-0.40±0.34	-0.39±0.48	0.9996
Upper Lip to E-Plane (mm)	**-1.61±0.17**	**-1.05±0.20**	**0.0199**
Upper lip thickness (UL-U1) (mm)	0.29±0.28	0.21±0.39	0.9876
Upper Lip Length (mm)	0.11±0.24	0.35±0.33	0.8274
InterLabial Gap (mm)	0.21±0.17	0.30±0.24	0.9540
Lower Lip – VRL (mm)	0.99±0.41	1.09±0.41	0.9662
Soft Tissue B Pt. – VRL (mm)	1.01±0.56	0.86±0.56	0.9732
Soft Tissue Pogonion – VRL (mm)	0.99±0.56	1.10±0.56	0.9787
Lower Lip to E-Plane (mm)	0.06±0.05	-0.09±0.07	0.0689
Lower lip - Lower 1 Most Labial (mm)	-0.50±0.182	-0.21±0.182	0.3113
Lower Lip Thickness at B pt (mm)	0.86±0.43	0.64±0.43	0.9190
Lower Lip Length (mm)	1.37±0.40	0.54±0.40	0.1588
Chin Thickness (mm)	0.37±0.28	0.63±0.40	0.8530
MP - SN	-0.10±0.29	0.60±0.42	0.1721
Y-Axis	-0.10±0.17	0.39±0.23	0.0968

Table 4-8. Difference between mesochocephalic and dolichocephalic following Xbow^TM treatment (T1-T0).

4.6 FACIAL PATTERN AND SOFT TISSUE EFFECTS OBSERVED WITHIN EACH GROUP FOLLOWING XBOW^{TM} TREATMENT (T1-T0).

4.6.1 Brachycephalic Group (n=20)

i) *Facial Pattern Effects*- Facial pattern did not change within the brachycephalic group following Xbow^{TM} treatment. No significant differences were observed ($p<0.05$) (Table 4-9).

ii) *Soft Tissue Effects*- Soft tissue profile, mentolabial angle, H-angle, upper lip to E-Plane (mm), lower lip – VRL (mm), soft tissue B pt. –VRL (mm), and soft tissue pogonion – VRL (mm) showed statistically significant differences within the brachycephalic group following Xbow^{TM} treatment ($p<0.05$) (Table 4-9).

Variables	Group 1 (Brachy) T0/T1	p-value
	Mean±SE	
Soft Tissue Convexity	0.49±0.40	0.2210
Soft Tissue Profile	**2.63±0.55**	**<0.0001**
Nasolabial Angle	0.32±0.91	0.7244
Mentolabial Angle	**7.96±2.21**	**0.0003**
H-Angle	**-3.10±0.51**	**<0.0001**
Tip of Nose – VRL (mm)	0.59±0.37	0.1273
Subnasale – VRL (mm)	0.57±0.46	0.2204
Soft Tissue A Pt. – VRL (mm)	0.22±0.47	0.6498

Upper Lip – VRL (mm)	-0.50±0.48	0.2982
Upper Lip to E-Plane (mm)	**-1.04±0.17**	**<0.0001**
Upper lip thickness (UL-U1) (mm)	0.64±0.39	0.1061
Upper Lip Length (mm)	0.17±0.34	0.6215
InterLabial Gap (mm)	-0.39±0.24	0.1105
Lower Lip – VRL (mm)	**1.48±0.41**	**0.0003**
Soft Tissue B Pt. – VRL (mm)	**1.39±0.56**	**0.0132**
Soft Tissue Pogonion – VRL (mm)	**1.20±0.56**	**0.0352**
Lower Lip to E-Plane (mm)	0.10±0.07	0.1694
Lower lip - Lower 1 Most Labial (mm)	0.24±0.18	0.1982
Lower Lip Thickness @ Bpt (B-B') (mm)	0.31±0.43	0.4756
Lower Lip Length (mm)	0.73±0.40	0.0886
Chin Thickness (mm)	0.46±0.40	0.2444
MP - SN	0.19±0.42	0.6484
Y-Axis	0.07±0.23	0.7642

Table 4-9. Difference within the brachycephalic group following Xbow™ treatment (T1-T0).

4.6.2 Mesocephalic Group (n=40)

i) *Facial Pattern Effects*- Facial pattern did not change within the mesocephalic group following Xbow™ treatment. No significant differences observed ($p<0.05$) (Table 4-10).

ii) *Soft Tissue Effects*- Soft tissue profile, mentolabial angle, H-Angle, upper lip – E-Plane (mm), lower lip – VRL (mm), soft tissue B Pt. – VRL (mm), and soft tissue pogonion – VRL (mm) showed statistically significant differences within the mesocephalic group following Xbow™ treatment (p<0.05) (Table 4-10).

Variables	Group 2 (Meso) T0/T1	p-value
	Mean±SE	
Soft Tissue Convexity	0.67±0.40	0.1024
Soft Tissue Profile	**2.43±0.38**	**<0.0001**
Nasolabial Angle	0.13±0.64	0.8364
Mentolabial Angle	**8.37±1.56**	**<0.0001**
H-Angle	**-2.44±0.35**	**<0.0001**
Tip of Nose – VRL (mm)	0.42±0.26	0.1020
Subnasale – VRL (mm)	0.18±0.33	0.5809
Soft Tissue A Pt. – VRL (mm)	0.24±0.33	0.4827
Upper Lip – VRL (mm)	-0.40±0.34	0.2392
Upper Lip to E-Plane (mm)	**-1.61±0.17**	**<0.0001**
Upper lip thickness (UL-U1) (mm)	0.29±0.28	0.3093
Upper Lip Length (mm)	0.11±0.24	0.6415
InterLabial Gap (mm)	-0.21±0.17	0.2188
Lower Lip – VRL (mm)	**0.99±0.41**	**0.0003**
Soft Tissue B Pt. – VRL (mm)	**1.01±0.56**	**0.0132**

Soft Tissue Pogonion – VRL (mm)	**0.99±0.56**	**0.0352**
Lower Lip to E-Plane (mm)	0.06±0.05	0.2374
Lower lip - Lower 1 Most Labial (mm)	0.50±0.18	0.0625
Lower Lip Thickness @ Bpt (B-B') (mm)	0.86±0.43	0.4756
Lower Lip Length (mm)	1.37±0.40	0.0886
Chin Thickness (mm)	0.37±0.28	0.1855
MP – SN	-0.10±0.29	0.8386
Y-Axis	-0.10±0.17	0.6279

Table 4-10. Difference within the mesocephalic group following Xbow™ treatment (T1-T0).

4.6.3 Dolichocephalic Group (n=20)

i) *Facial Pattern Effects***-** Facial pattern did not change within the dolichocephalic group following Xbow™ treatment. No significant differences observed ($p<0.05$) (Table 4-11).

ii) *Soft Tissue Effects-* Soft tissue profile, mentolabial angle, H-Angle, tip of nose – VRL (mm), upper lip to E-Plane (mm), lower lip – VRL (mm), and soft tissue pogonion – VRL (mm), showed statistically significant differences within the dolichocephalic group ($p<0.05$) following Xbow™ treatment (Table 4-11).

Variables	**Group 3 (Dolicho) T0/T1**	**p-value**
	Mean±SE	
Soft Tissue Convexity	0.77±0.40	0.0560
Soft Tissue Profile	**2.11±0.38**	**<0.0001**
Nasolabial Angle	0.73±0.91	0.4212
Mentolabial Angle	**13.87±2.21**	**<0.0001**
H-Angle	**-2.91±0.50**	**<0.0001**
Tip of Nose – VRL (mm)	0.53±0.37	0.1683
Subnasale – VRL (mm)	0.35±0.46	0.4478
Soft Tissue A Pt. – VRL (mm)	0.13±0.47	0.7918
Upper Lip – VRL (mm)	-0.39±0.48	0.4231
Upper Lip to E-Plane (mm)	**-1.05±0.20**	**<0.0001**
Upper lip thickness (UL-U1) (mm)	0.21±0.39	0.5931
Upper Lip Length (mm)	0.35±0.33	0.2949
InterLabial Gap (mm)	-0.30±0.24	0.2196
Lower Lip – VRL (mm)	**1.09±0.41**	**0.0079**
Soft Tissue B Pt. – VRL (mm)	0.86±0.56	0.1273
Soft Tissue Pogonion – VRL (mm)	**1.10±0.56**	**0.0447**
Lower Lip to E-Plane (mm)	-0.09±0.07	0.0878
Lower lip - Lower 1 Most Labial (mm)	0.21±0.18	0.2578
Lower Lip Thickness @ Bpt (B-B') (mm)	0.64±0.43	0.1344
Lower Lip Length (mm)	0.54±0.40	0.1828
Chin Thickness (mm)	0.63±0.40	0.1109

MP – SN	0.60±0.42	0.1465
Y-Axis	0.39±0.23	0.1063

Table 4-11. Difference within the dolichocephalic group following Xbow^{TM} treatment (T1-T0)

4.7 DIFFERENCE BETWEEN CONTORL GROUP (n=24) AND ENTIRE SAMPLE POPULATION (n=80) FOLLOWING XBOW^{TM} TREATMENT (T1-T0).

i) *Facial Pattern Effects***-** No statistically significant differences were observed between control group and entire sample population following Xbow^{TM} treatment ($p<0.05$) (Table 4-12).

ii) *Soft Tissue Effects*- The observed changes in soft tissue profile, mentolabial angle, H-angle, upper lip to E-Plane (mm), lower lip – VRL (mm), soft tissue pogonion – VRL (mm), and lower lip length (mm) were shown to be significantly different between the control group and entire sample population following Xbow^{TM} treatment ($p<0.05$) (Table 4-12).

Variables	**Control**	**Total Sample**	**p-value**
	Mean±SE	Mean±SE	
Soft Tissue Convexity	0.10±0.03	0.64±0.20	0.1440
Soft Tissue Profile	**0.08±0.07**	**2.39±0.27**	**<0.0001**
Nasolabial Angle	-0.49±0.02	0.39±0.46	0.2989
Mentolabial Angle	**-0.62±0.31**	**10.07±1.14**	**<0.0001**
H-Angle	**-0.16±0.01**	**-2.82±0.25**	**<0.0001**

Tip of Nose – VRL (mm)	0.05±0.04	0.51±0.19	0.1901
Subnasale – VRL (mm)	0.01±0.01	0.37±0.23	0.9932
Soft Tissue A Pt. – VRL (mm)	0.02±0.01	0.20±0.24	0.6831
Upper Lip – VRL (mm)	0.03±0.02	-0.43±0.24	0.2981
Upper Lip to E-Plane (mm)	**0.05±0.03**	**-1.23±0.06**	**<0.0001**
Upper lip thickness (UL-U1) (mm)	0.02±-0.01	0.38±0.20	0.3282
Upper Lip Length (mm)	0.02±-0.04	0.21±0.17	0.5441
InterLabial Gap (mm)	0.04±0.01	-0.30±0.12	0.1252
Lower Lip – VRL (mm)	**0.10±0.05**	**1.19±0.21**	**0.0057**
Soft Tissue B Pt. – VRL (mm)	0.09±0.05	1.09±0.28	0.0543
Soft Tissue Pogonion – VRL (mm)	**0.07±0.06**	**1.10±0.28**	**0.0477**
Lower Lip to E-Plane (mm)	0.03±0.01	0.02±0.04	0.8920
Lower lip - Lower 1 Most Labial (mm)	0.03±0.02	0.32±0.09	0.0822
Lower Lip Thickness at B pt (mm)	0.03±0.02	0.60±0.22	0.1605
Lower Lip Length (mm)	**0.05±0.03**	**0.88±0.21**	**0.0335**
Chin Thickness (mm)	0.03±0.02	0.49±0.20	0.2124
MP - SN	0.10±0.05	0.23±0.22	0.7482
Y-Axis	0.16±0.08	0.12±0.12	0.8587

Table 4-12. Mean difference between control group and entire sample after Xbow™ treatment (T1-T0).

Chapter 5

Discussion

5.1 Facial Growth and Soft Tissue Response

It would be expected that the dental and skeletal effects induced in Class II orthodontic correction would result in similar effects observed in the soft tissue response (Riedel, 1957; Rains and Nanda, 1982; Quintao et al., 2006). As a general guideline, this relationship has been shown to be true (Wisth, 1972). However, studies have shown that soft tissues, within limits, have their own growth potential and may mask underlying skeletal discrepancies (Burstone, 1959; Subtelny, 1959; Wisth, 1972). Subtelny (1959) indicated that the correlation between hard and soft tissue effects is not completely linear. Also, facial relationship measurements (horizontal and vertical) demonstrate that not all components of the soft tissue profile directly follow the underlying skeletal structures (Subtenlny, 1959). Burstone (1959) also observed that the soft tissue profile might differ from the skeletal pattern due to the variation in the thickness of the soft tissue covering.

Therefore, if the goal of orthodontic treatment is to harmonize an undesirable profile, knowledge of the normal growth changes of the face is necessary (Wisth, 1972). Identifying these growth areas, determining the amount of growth, and at what age the growth occurs would have a dramatic effect on treatment timing (Wisth, 1972). If it is possible to affect the soft tissue drape by orthodontic manipulation, a lack of information about facial growth changes would render the final outcome impossible to predict (Wisth, 1972).

A number of methods have been used to evaluate facial growth including anthropometry, photogrammetry, and computer imaging (Bishara, Jakobsen, Hession and Treder, 1998). However, growth studies that have specifically investigated soft tissue profile changes have traditionally utilized cephalometric or photometric linear and angular measurements (Bishara et al., 1998).

Behrents (1985) utilized the Bolton records to evaluate subjects from 17-40 years of age. Behrents found numerous changes in soft tissue between the ages of 25 to 40, however, he suggested that after age 40 fewer parameters continue to change (Behrents, 1985; Bishara, 1998). Behrents also stated that subjects had a tendency to continue to grow vertically, rather than maintaining the horizontal growth observed in earlier years (Behrents, 1985; Bishara, 1998). Behrents further noted that the tip of the nose moved further downward and forward than subnasale, or A-point (Behrents, 1985; Bishara, 1998). This increase in nasal prominence was observed concurrently with an increase in upper lip length, as stomion superius translated downward (Behrents, 1985; Bishara, 1998).

Bishara et al. (1998), set out to describe the soft tissue changes in patients (5-45 years of age) that are commonly used by orthodontists in diagnosis and treatment planning. Their findings were (Bishara et al., 1998):

> "(1) Changes in males and females were similar in both magnitude and direction. On the other hand, the timing of the greatest changes in the soft tissue profile occurred earlier in females (10 to 15 years) than in males (15 to 25 years).
>
> (2) The angle of soft tissue convexity that excludes the nose expressed little change between 5 and 45 years.

(3) The upper and lower lips became more retruded in relation to the esthetic line between 15 and 25 years of age in both males and females; the same trends continued between 25 and 45 years of age.

(4) The Holdaway soft tissue angle progressively decreased between 5 and 45 years of age."

These findings in the literature may act as guidelines in treatment planning, especially the finding that soft tissue convexity rarely improves on its own (Bishara, 1998).

Subjects with Class II malocclusions generally present with convex facial profiles and a retruded soft tissue pogonion (Qunitao et al., 2006). In these cases, facial muscles will routinely compensate for skeletal disharmony (Ward, 1994; Quintao et al. 2006). A common example of this compensation is seen in dolichocephalic (vertical) patients with hyperactive mentalis activity to achieve an anterior lip seal (Ward, 1994; Quintao et al. 2006). However, in the absense of muscular compensation, the influence of the hard tissues on the soft tissues still remain (Ward, 1994; Qunitao et al., 2006). Therefore, further understanding of expected soft tissue effects with orthodontic treatment would be benefical in planning predictable outcomes.

5.2 Treatment Timing

One of the major concerns for functional appliance therapy is treatment timing. Treatment effects induced by functional appliances are thought to be maximized when the mandibular growth spurt is included in the treatment period (Baccetti, Franchi, Toth and McNamara, 2000). Malmgren, Omblus, Hägg, and Pancherz (1987) found that to obtain optimal results, functional appliances should be utilized during (or just after) the peak growth period. Pancherz and Hägg (1988) have shown that skeletal improvement with the Herbst appliance is related to somatic maturation. Petrovic, Stutzmann, Lavergne, and Shaye (1991) also reported that the induced effects of Frankel and Bionator appliances were most favourable when the patient is in the ascending portion of pubertal growth spurt.

Given the general consensus on utilizing puebertal growth during functional appliance therapy, clinicians may assume this treatment timing philosophy for Class II correctors, such as the Xbow™ (Chana et al., 2013). However, more research is still required to determine the skeletal and dental impact of these appliances on growing vs. non-growing patients (Chana et al., 2013). Furthermore, even if the dental and skeletal effects of these appliances were fully understood, the true relationship of hard and soft tissue effects would still remain in question (Wisth, 1972; Quintao et al., 2006). Ultimately, the understanding of the induced dental, skeletal, and soft tissue effects of these appliances remains controversial.

5.3 Growth Considerations (Control Group)

In this study actual experimental treatment time (including passive retention) was of short duration (6.9 ±1.09 months at T1 radiograph). To serve as a control group, Bolton growth prediction algorithms where used to quantify the amount of growth that may have occurred between the initial and final radiographs. Not surprisingly, no significant changes were noted in the prediction tracings to simulate growth ($p<0.05$). Therefore, based on the absence of significant differences in the control group between T0 and T1, growth was deemed not to be a significant factor in this study.

Proffit and Fields (2012) stated that the best method to evaluate treatment effects is to compare the treated samples with an untreated control group. Therefore, a criticism of this study is that actual live subjects were not measured in the control. Due to the retrospective nature of this study, the alternative method would have been to resort to a historical growth study database. However, the disadvantage of historical growth studies is that the radiographs are usually taken over a 2 to 3 year period (Chana et al. 2013). This gap between radiographs far exceeds the treatment time oobserved in this study. Thus, the approximation (or average calculation) of the growth, that may or may not have occurred in the treatment period, is inheritently flawed.

Unfortunatley, at this time only one source (Sagun, 2012) can verify the accuracy of this growth prediction to a mean difference of 1.5mm. In lieu of the lack of evidence, more studies should be performed to confirm the accuracy of this method of growth prediction (Chana et al., 2013).

5.4 Differences Between Facial Patterns

Ricketts stressed that treatment should be modified in order to counteract the unwanted effects of orthodontic forces in patients with either stronger or weaker musculature patterns (Ricketts et al., 1979; Chana et al., 2103). The facial pattern influences the underlying dental compensations that counteract vertical growth deviations (Janson, Metaxas, Woodside, 1994; Enoki, Telles, Matsumoto, 2004; Kuitert, Beckmann, van Loenen, Tuinzing, Zentner, 2006; Flores-Mir et al., 2010; Chana et al. 2013). Given that different dental compensations exist for varying facial patterns, it is therefore important to investigate the potential difference in soft tissue effects for the different facial types.

In this study, the number of soft tissue parameters demonstrating significant differences between facial patterns was low (3 out of 21). According to the results, the group with the highest number of significant differences was the mesocephalic group ($p<0.05$). Whereas the brachycephalic group demonstrated only one significant difference with the mesocephalic group ($p<0.05$), and did not significantly differ from the dolicocephalic group ($p<0.05$).

Variables	**Group 1 (Brachy)**	**Group 2 (Meso)**	**p-value**
	Mean±SE	Mean±SE	
Upper Lip to E-Plane (mm)	**-1.04±0.17**	**-1.61±0.17**	**0.0175**
	Group 2 (Meso)	**Group 3 (Dolicho)**	
Mentolabial Angle	**8.37±1.56**	**13.87±2.21**	**0.0256**
Upper Lip to E-Plane (mm)	**-1.61±0.17**	**-1.05±0.20**	**0.0199**

Table 5-1 Summary of significant differences observed between facial patterns

The mesocephalic group had a significantly larger increase in the upper lip to E-plane distance than the other two facial patterns. Upper lip to E-plane is influenced by both retraction of the upper lip, and anterior movement of the tip of nose and soft tissue pogonion (Baysal and Uysal, 2013). Given that soft tissue pogonion was significantly advanced anteriorly, any retraction of the upper lip, or anterior growth of nose would exaggerate this finding. In this case, the largest difference was 0.57 mm (brachycephalic and mesocephalic), which although statistically significant, may not be clinically relevant.

The Dolichocephalic group showed a significant opening of the mentolabial fold compared to the mesocephalic group. Mentolabial angle is influenced by the positions of labrale inferius, sulcus inferius (soft tissue B point), and soft tissue pogonion (Baysal and Uysal, 2013). A potential factor exists in Class II, division 1 malocclusions where the lower lip is distorted behind the upper incisors. This results in a deeper mentolabial sulcus and an acute mentolabial angle. Other studies have reported similar increases in mentolabial angle after Class II correction (Lange, Kalra, Broadbent, Powers, Nelson, 1995; Baysal and Uysal, 2013). These studies suggest that the elimination of overjet or the change in the tonicity and posture of perioral muscles could be responsible for the effect observed (Lange et al., 1995; Baysal and Uysal 2013). When overjet is reduced, the physical obstruction of the upper incisors is also reduced, thus resolving distortion of the lower lip (Baysal and Uysal, 2013). Also, if the patient attempts to maintain lip seal while wearing the appliance, lip strain may be increased subsequently changing the posture and tonicity of perioral muscles (Baysal and Uysal, 2013). As a result, the lower lip distortion is reduced, and mentolabial angle is increased (Baysal and Uysal, 2013).

With these results it would be possible to *reject the null hypothesis* of this study. However, consideration should be given to the fact that differences, although statistically significant, may or may not be clinically relevant. For example, clinical changes of less than 4 mm in soft tissue chin protrusion have been demonstrated to be "unnoticeable" in the literature (Naini, Donaldson, McDonald, Cobourne, 2012). Therefore, subjective perception of what constitutes a significant soft tissue profile change may play a role in determining successful treatment outcomes.

5.5 Differences Within Facial Patterns

As growth was not a significant factor in this study, significant differences observed following appliance therapy may be considered treatment induced. A summary of the significant differences observed within each group is listed in table 5-2.

Variables	**Group 1 (Brachy) T0/T1**	**p-value**
	Mean±SE	
Soft Tissue Profile	**2.63±0.55**	**<0.0001**
Mentolabial Angle	**7.96±2.21**	**0.0003**
H-Angle	**-3.10±0.51**	**<0.0001**
Upper Lip to E-Plane (mm)	**-1.04±0.17**	**<0.0001**
Lower Lip – VRL (mm)	**1.48±0.41**	**0.0003**
Soft Tissue B Pt. – VRL (mm)	**1.39±0.56**	**0.0132**
Soft Tissue Pogonion – VRL (mm)	**1.20±0.56**	**0.0352**
	Group 2 (Meso) T0/T1	
Soft Tissue Profile	**2.43±0.38**	**<0.0001**
Mentolabial Angle	**8.37±1.56**	**<0.0001**
H-Angle	**-2.44±0.35**	**<0.0001**
Upper Lip to E-Plane (mm)	**-1.61±0.17**	**<0.0001**
Lower Lip – VRL (mm)	**0.99±0.41**	**0.0003**
Soft Tissue B Pt. – VRL (mm)	**1.01±0.56**	**0.0132**
Soft Tissue Pogonion – VRL (mm)	**0.99±0.56**	**0.0352**
	Group 3 (Dolicho) T0/T1	
Soft Tissue Profile	**2.11±0.38**	**<0.0001**
Mentolabial Angle	**13.87±2.21**	**<0.0001**
H-Angle	**-2.91±0.50**	**<0.0001**
Upper Lip to E-Plane (mm)	**-1.05±0.20**	**<0.0001**
Lower Lip – VRL (mm)	**1.09±0.41**	**0.0079**
Soft Tissue Pogonion – VRL (mm)	**1.10±0.56**	**0.0447**

Table 5-2. Summary of significant differences observed within each facial pattern.

Facial convexity excluding the nose (soft tissue profile) was found to be significantly different following treatment in all three facial patterns ($p<0.05$). Facial convexity is influenced by the anterior-posterior position of soft tissue nasion, subnasale, and soft tissue pogonion. In each group soft tissue pogonion showed a significant anterior movement ($p<0.05$), which would in turn reduce the facial convexity (Baysal and Uysal, 2013).

Mentolabial angle was also shown to have significant differences following treatment in all three facial patterns. As previously discussed, the mentolabial sulcus would have likely been influenced by the elimination of overjet, or a change in the tonicity/posture of perioral muscles (Lange et al. 1995; Baysal and Uysal, 2013).

H-Angle significantly decreased in all three facial patterns. It has been reported in the literature that H angle is associated with facial convexity (Holdaway, 1983; Baysal and Uysal 2013). Holdaway (1983) stated as the facial convexity increases, the H angle must also increase (Holdaway 1983; Baysal and Uysal, 2013). Therefore, should there be a reduction in facial convexity, there must also be a subsequent decrease in H angle. This phenomena was in fact observed in all three facial types.

Upper lip to E-Plane distance significantly increased in all three facial patterns. As previously mentioned, upper lip to E-plane (mm) is influenced by both retraction of the upper lip, and anterior movement of the tip of nose and soft tissue pogonion (Baysal and Uysal, 2013). As aforementioned,soft tissue pogonion was significantly advanced anteriorly, any retraction of the upper lip, or anterior growth of nose would exaggerate this finding.

Lower lip (at labrale superius) was significantly advanced anteriorly in all three facial types. Again, lower lip distortion may play a role, but this finding may also reflect the soft tissue adaptability to hard (dental) tissue changes (Baysal and Uysal, 2013).

Soft tissue B-point was also significantly advanced anteriorly in brachycephalic, and mesocephalic groups. This finding coincides with an increase in mentolabial angle as soft tissue B point moves anteriorly in response to hard tissue (dental) changes (Baysal and Uysal, 2013).

Although all these findings are statistically siginifcant, consideration should be given to the small magnitude of these effects. Ultimately, these findings may not have a high level of clinical significance.

5.6 Differences Between Control Group and Total Sample

As growth was not a significant factor in this study, significant differences between the control group and the total sample may be considered treatment induced. A summary of the significant differences observed is listed in table 5-3.

Variables	**Control**	**Total Sample**	**p-value**
	Mean±SE	Mean±SE	
Soft Tissue Profile	**0.08±0.07**	**2.39±0.27**	**<0.0001**
Mentolabial Angle	**-0.62±0.31**	**10.07±1.14**	**<0.0001**
H-Angle	**-0.16±0.01**	**-2.82±0.25**	**<0.0001**
Upper Lip to E-Plane (mm)	**0.05±0.03**	**-1.23±0.06**	**<0.0001**
Lower Lip – VRL (mm)	**0.10±0.05**	**1.19±0.21**	**0.0057**

Soft Tissue Pogonion – VRL (mm)	**0.07±0.06**	**1.10±0.28**	**0.0477**
Lower Lip Length (mm)	**0.05±0.03**	**0.88±0.21**	**0.0335**

Table 5-3. Summary of significant differences between control and total sample.

To our knowledge the soft tissue effects of the Xbow™ appliance have not been investigated in other studies to date. Therefore direct comparison to other studies is impossible. However, studies do exist investigating the induced soft tissue effects of other Class II correction appliances (Quintao et al., 2006; Baysal and Uysal, 2013).

Quintao et al. (2006) set out to evaluate changes in the facial profile resulting from the use of a Twin Block functional appliance. The soft tissue analysis employed in this study was similar to the soft tissue analysis used in our study (anterior-posterior changes measured with the use of a vertical reference line). The sample was comprised of a treatment group (19 subjects) with a mean age of 9.5 years (SD 10 months), and a control group (19 subjects) with a mean age of 9.9 years (SD 13 months). All subjects presented with a Class II division 1 malocclusion. The treatment group received functional appliance therapy while the remaining 19 subjects, who did not undergo any intervention, served as the control. Lateral cephalograms were obtained for all subjects at the initial consultation (T1) and again after 12 months (T2). In the treatment group, a significant improvement in the facial profile (reduction in convexity) was observed, which closely followed the underlying dentoskeletal changes ($p<0.05$) (Quintao et al., 2006). Other significant soft tissue effects observed were: retraction of the upper lip, and anterior movement of soft tissue pogonion ($p<0.05$) (Quintao et al., 2006). In the control group, the only significant soft tissue effect observed was a decrease in the angle of Frankfort plane to most anterior point of the upper lip (not measured in our study) ($P<0.05$) (Quintao et al., 2006). This finding was believed to be a result of dental changes (retroclination of the upper incisor) and not skeletal/growth changes as the condylion- A-point (absolute length of maxilla) distance did not change significantly between T1 and T2 (Quintao et al., 2006).

Although, the results in the Quintao et al. (2006) study mirrored those found in our study, it is important to note the age discrepancy of subjects included. The subjects in the Quintao et al., (2006) study were significantly younger (9.5 years compared to 12.5 years in our study), and thus may have played a role in the results.

Baysal and Uysal (2013) conducted a study to evaluate soft tissue effects observed following treatment with Twin Block and Herbst appliances. Subjects were divided into treatment (Twin Block and Herbst), and untreated control groups. Pre-treatment (T0) and post-treatment (T1) cephalograms were used to evaluate skeletal, dentoalveolar, and soft tissue changes. The groups were compared at T0 and T1 using analysis of variance, and treatment/observation differences (T1 − T0) were evaluated with a paired samples t-test ($p < 0.05$). The soft tissue analysis employed in the Baysal and Uysal (2013) study was used as a model for the soft tissue analysis used in our study. The mean age of the subjects was also similar to those in our study (12.74 ± 1.43 years Herbst appliance and 13.0 ± 1.32 years Twin Block), but the treatment sample was half the size (40 subjects divided into two groups). Also, the treatment time was increased (15.81 years ± 5.96 months and 16.20 years ± 7.54 months for Herbst and Twin Block groups respectively), more than twice that utilized by the Xbow™ (6.9±1.09 months). The untreated control group for the Baysal and Uysal (2013) study included 20 subjects with a mean age of 12.17 years ± 1.47 months and a mean observation period 15.58 years ± 3.13 months. Given the extended treatment time in the Baysal and Uysal (2013), it would be expected growth would be more likely to play a role than in our study. However, only one significant difference was noted (anterior movement of soft tissue pogonion) in the control group ($p<0.05$). In both treatment groups, significant soft tissue effects observed were: decrease in facial convexity and H angle, and increase in mentolabial angle, upper lip –E plane distance, lower lip thickness, lower lip length and soft tissue pogonion advancement (Baysal and Uysal, 2013).

A comparison of the Quintao et al., (2006) and the Baysal and Uysal, (2013) studies to our study yields similar results. However, the mechanism of action of these appliances is quite different. The Herbst appliance, for example, has the ability to distract the condyle from the glenoid fossa theoretically influencing growth of the mandible (Pancherz 1982). Although, a similarity exists between the Xbow™ and these appliances, as achieving lip seal during wear may influence lip strain leading to increased lower lip thickness, lower lip length, and mentolabial angle (Lange, 1995; Baysal and Uysal 2013). Ultimately, the longer treatment time with the Herbst and Twin block appliances may have an influence on this phenomena, and could be investigated in future research.

Overall, based on soft tissue effects observed with the Xbow™, and the similarity to other Class II correctors, it would be fair to conclude that treatmentinduced significant soft tissue effects when compared to the control. However, considering the small magnitude of the soft tissue changess, induced by the Xbow™ appliance, arguably the clinical changes are of minor significance.

Chapter 6

Conclusions and Recommendations

6.1 Conclusions:

1) There are differences in the soft tissue effects observed in patients treated with the Xbow^{TM} appliance which are related to the pre-existing facial pattern ($p<0.05$):
    - The mesocephalic group showed increased retrusion of the upper lip to E-Plane than the brachycephalic, and dolichocephalic groups.
    - The dolichocephalic group showed significantly more flatteningof the mentolabial fold compared to the mesocephalic group.
2) Soft tissue changes ($p<0.05$) observed with the Xbow^{TM} appliance regardless of facial pattern were:
    - A decrease in facial convexity (excluding the nose).
    - An increasein the retrusion of the upper lip to E-Plane.
    - An increase in mentolabial angle.
    - Protrusion of the lower lip.
    - Protrusion of the soft tissue pogonion.
    - Increase in lower lip length.

6.2 Recommendations:

1) Other appliances/techniques should be sought if the clinician is seeking to induce major

profile changes (eg. functional appliance therapy in growing patients, or orthognathic surgery), since the class II corrector , the Xbow™, although providing statistically significant changes limited to a few millimeters, or degrees, may not be of clinical relevance.

2) When treating patients with soft tissue profile preservation in mind, clinicians may not require any special precautions when using the Xbow™ appliance, based on the patient's pre-existing facial pattern.

Future Studies:

1) Further investigation of the relationship between hard tissue changes and concomitant soft tissue response is required with several Class II type correctors to fully understand the relationship between the effect of skeletal and dentoalveolar changes on soft tissue.
2) Further investigation of soft tissue changes observed with varying treatment duration is required to further understand the influence of the tonicity/posture of perioral muscles on treatment outcomes.
3) Future studies on fixed Class II correctors should focus on the soft tissue effects of these appliances in growing individuals.

Chapter 7

References

Arnett G., Bergman R. Facial keys to orthodontic diagnosis and treatment planning. Part I. Am J Orthod. 1993; 103;299-312.

Baccetti, T., Franchi, L., Toth, L., McNamara, J. Treatment timing for Twin-block therapy. Am J Orthod Dentofac Orthop. 2000; 118;159-170.

Baumrind S. Korn E., and West E. Prediction of mandibular rotation; An empirical test of clinical performance. Am J Orthod. 1984; 86;l371-385.

Baysal A, Uysal T. Soft tissue effects of Twin Block and Herbst appliances in patients with Class II division 1 mandibular retrognathy. Eur J Orthod. 2013; 35;71−81

Bishara S., and Augspurger F. The role of mandibular plane angulation in orthodontic diagnosis. Angle Orthod. 1975; 45;273-281.

Bishara, S., Jakobsen, J., Hession, T., Treder, J. Soft tissue profile changes from 5 to 45 years of age. Am J Orthod Dentofac Orthop. 1998; 114;698–706.

Bishara, S. Class II Malocclusions: Diagnostic and Clinical Considerations With and Without Treatment Seminars in Orthodontics. 2006; 12;11-24

Bjork A, and Skieller V. Facial development and tooth eruption. An implant study at the age of puberty. Am J Orthod. 1972; 62;339-338.

Boeck, E., Marcantonio, N., Lunardi, A., dos Santos Pinto, K., Eiras Dela Coletta, P., and

Rodolfo Jorge Boeck, N. “Occurrence of skeletal malocclusions in Brazilian patients with dentofacial deformities”. Brazilian Dental Journal. 2011; 22;340-345

Bonetti, G., Alberti, A., Sartini, C., Parenti S. Patients' self-perception of dentofacial attractiveness before and after exposure to facial photographs Angle Orthod, 2011; 81;517–524

Broadbent BH Sr., Broadbent BH Jr., Gloden WH. Bolton standards of dentofacial development growth. St. Louis: Mosby, 1975.

Burstone C. The integumental profile. Am J Orthod. 1958; 44;1–25

Burstone, C. Integumental contour and extension patterns. Angle Orthod. 1959; 29;93–104

Chana RS, Hechter FJ, Wiltshire WA, Ahing S. (2013) Cephalometric evaluation of dental class II correction using the XbowTM appliance in different facial patterns University of Manitoba

Chaukse, A., Sandhya J., Reddy M., Dubey R., Shan Mummen J., and Suma S. “Treatment of Skeletal Class II Malocclusion Using the “Forsus” Appliance: A Case Report”. People’s Journal of Scientific Research. 2011; 4;39-42.

Dolphin Imaging. Bolton Growth Predictions. Web 25 Aug. 2014
< http://www.dolphinimaging.com/imaging_txsim.html>

Enoki C, Telles Cde S, Matsumoto MA. Dental-skeletal dimensions in growing individuals with variations in the lower facial height. Braz Dent J. 2004;15;68–74.

Frye L., Diedrich P., and Kinzinger G. Class II treatment with fixed functional orthodontic appliances before and after the pubertal growth peak—a cephalometric study to evaluate differential therapeutic effects. J Orofac Orthop. 2009; 70;511–527

Flores-Mir C., and Major P. A systematic review of cephalometric facial soft tissue changes with the Activator and Bionator appliances in Class II division 1 subjects. Eur J Orthod. 2006; 28;586–593

Flores-Mir C., and Major, P. Cephalometric facial soft tissue changes with the twin block appliance in Class II division 1 malocclusion patients. A systematic review. Angle Orthod. 2006; 76;876–881

Flores-Mir C., Major M., and Major P. Soft tissue changes with fixed functional appliances in Class II division 1. Angle Orthod. 2006; 76;712–720

Flores-Mir, C., Barnett G., Higgins D., Heo, G., and Major, P. Short-term skeletal and dental effects of the Xbow appliance as measured on lateral cephalograms. Am J Orthod. 2009; 136;822-832.

Flores-Mir, C.,Young, A., Greiss A., Woynorowski, M., and Peng, J. Lower incisor inclination changes during Xbow treatment according to the vertical facial type. Angle Orthod. 2010; 80;1075-1080.

Flores-Mir C., Aziz T., Nassar U. Prediction of lower incisor proclination during Xbow treatment based on initial cephalometric variables. Angle Orthod. 2012; 82:472-9.

Graber TM, Vanarsdall RL, Vig KW. Orthodontics: Current Principles & Techniques. Fourth Edition. Elsevier Inc. St. Louis, Missouri 2005.

Higgins, D. "Xbow™: Straight to the Target when Straight is the Target". Orthodontic Perspectives XIII, 2006. Web. 25 Aug. 2014. <http://multimedia.3m.com/mws/mediawebserver?SSSSSu7zK1fslxtUNx_ePxmxev7qe17zHvTSevTSeSSSSSS→

Hägg, U. and Pancherz, H.: Dentofacial orthopaedics in rela-tion to chronological age, growth period and skeletal develop-ment: An analysis of 72 male patients with Class II division I malocclusion treated with the Herbst appliance, Eur. J. Orthod. 1998; 10:169-176

Holdaway R. A soft-tissue cephalometric analysis and its use in orthodontic treatment planning: part I Am J Orthod 1983; 84;1–28

Jacobson A, Jacobson RL. Radiographic cephalometry: From basics to 3-D imaging. Quintessence Publishing Co., Illinois. 2006.

Janson GR, Metaxas A, Woodside DG. Variation in maxillary and mandibular molar and incisor vertical dimension in 12-year-old subjects with excess, normal, and short lower anterior face height. Am J Orthod Dentofacial Orthop. 1994;106:409–418.

Kim, Y., Nanda, R., and Sinha P. Transition of molar relationships in different skeletal growth patterns. Am J Orthod Dentofacial Orthop 2002; 121;280-290.

Kuitert R., Beckmann S, van Loenen M, Tuinzing B, Zentner A. Dentoalveolar compensation in subjects with vertical skeletal dysplasia. Am J Orthod Dentofacial Orthop. 2006; 129:649–657.

Lange, D., Kalra, V., and Broadbent, B. Changes in soft tissue profile following treatment with the bionator. Angle Orthod. 1995; 65;423–430

Malmgren, O.; Omblus, J.; Hägg, U.; and Pancherz, H.: Treatment with an orthopedic appliance system in relation to treat-ment intensity and growth periods: A study of initial effects, Am. J. Orthod. 1987; 91;143-151,

Maltagliati L., Henriques J., Janson G. Influence of orthopedic treatment on hard and soft facial structures of individuals presenting with Class II, Division 1 malocclusion: a comparative study. J Appl Oral Sci. 2004; 12;164–170

McNamara, A. Components of Class II Malocclusion in Children 8-10 Years of Age. The Angle Orthod. 1981; 51;177-200.

McSherry, P., and Bradley, H. Class II Correction-Reducing Patient Compliance: a Review of the Available Techniques. Journal of Orthodontics. 2000; 27;219-225.
Mejia-Maidl M., Evans C., Viana G. Preferences for facial profiles between Mexican Americans and Caucasians. Angle Orthod. 2005; 75;953-8

Morris, D., Illing, H., Lee, R. A prospective evaluation of Bass, Bionator and Twin Block appliances. Part II: the soft tissues. Eur J Orthod Am J Orthod. 1998; 20;663–684

Mugonzibwa E., Kuijpers-Jagtman A., van't Hof M., et al. Perceptions of dental attractiveness and orthodontic treatment need among Tanzanian children. Am J Orthod Dentofacial Orthop. 2004; 125;426-433

Nanci A. Ten Cate's Oral histology, 8th Edition. Development, Structure and Function. Mosby, 2012.

Nanda S. Growth patterns in subjects with long and short faces. Am J Orthod Dentofacial Orthop. 1990; 98;247-258.

Opdebeeck, H, and Bell, W. The short face syndrome. Am J Orthod. 1978; 73;499-511.

Opdebeeck, H, Bell W., Eisenfeld J., Mishelevich D. Comparative study between the SFS and LFS rotation as a possible morphologic mechanism. Am J Orthod 1978; 74;509-521.

Pancherz, H. The mechanism of Class II correction in Herbst appliance treatment. A cephalometric investigation. Am J Orthod. 1982; 82;104-13.

Pancherz. H, Anehus-Pancherz, M. Facial profile changes during and after Herbst appliance treatment. Eur J Orthod. 1994; 16;275–286

Papadopoulos, and A. Moschos. Orthodontic Treatment of the Class II Noncompliant Patient. Maryland Heights, MO: Mosby. 2006. Print.

Papel, I. Facial plastic and reconstructive surgery. Germany: Thieme. 2009. Print.
Petrovic, A., Stutzmann, J., Lavergne, J., Shaye, R. Is it possible to modulate the growth of the human mandible with functional appliance? International Journal of Orthodontics 1991; 21; 15-20

Phulari, B. Orthodontics: Principles and Practice. New Delhi, India: JP Medical Ltd. 2011.Print.

Proffit, W., Fields, H., and Sarver. D., Contemporary Orthodontics. 5th ed. St. Louis, MO: Elsevier. 2012. Print.

Quintão C, Brunharo HVP, Menezes RC, Almeida MAO. Soft tissue facial profile changes following functional appliance therapy. Eur Journ. of Orthod. 2006; 28;35-41.

Rains M., Nanda R. Soft-tissue changes associated with maxillary incisor retraction. Am J Orthod. 1982; 81;481–488

Rakosi, T., Jonas, T., and Graber, T. Orthodontic Diagnosis. Germany: Thieme. 1998. Print

Ricketts, RM, Bench RW, Gugino CF, Hilgers JJ, Schulhof RJ. Bioprogressive Therapy. Rocky Mountain/Orthodontics. USA 1979.

Riedel R., An analysis of dentofacial relationships. Am J Orthod. 1957; 43;103–119

Rivera S., Hatch J., Rugh J. Psychological factors associated with orthodontic and orthognathic surgical treatment Semin Orthod.2000; 15;259–269

Rosvall M., Fields H., Ziuchkovski J. Attractiveness, acceptability, and value of orthodontic appliances. Am J Orthod Dentofacial Orthop. 2009; 135;276-276

Sassouni V. A classification of skeletal facial types. Am J Orthod. 1969; 55;109-123.

Sagun M. Assessment of computerized cephalometric growth prediction: A comparison of three methods. University of Illinois. 2012.

Subtelny J. A longitudinal study of soft tissue facial structures and their profile characteristics, defined in relation to underlying skeletal structures. Am J Orthod. 1959; 45;481–507

Trulsson U., Strandmark M., Mohlin B., and Berggren U. A qualitative study of teenagers' decisions to undergo orthodontic treatment with fixed appliance J Orthod.2002; 29;197–204

Tung, A., and Kiyak, H. Psychological influences on the timing of orthodontic treatment. American Journal of Orthodontics Dentofacial Orthopedics 1998; 113;29-39.

Ward, D. Angle Class II, division 1 malocclusion. Am J Orthod Dentofacial Orthop. 1994; 106;428–433

Wisth PJ.Changes of the soft tissue profile during growth. Trans Eur Orthod Soc. 1972; 123-31.

Xbow™. Crossbow Orthodontic. 2014. Web. 25 Aug. 2014. <http://www.crossboworthodontic.com/xbow.htm>

Yin, L., Jiang, M., Chen, W., Smales, R., Wang, Q., Tang, L. Differences in facial profile and dental esthetic perceptions between young adults and orthodontists. Am J Orthod Dentofacial Orthop. 2014; 145;750-6.

Zange S., Ramos A.,Cuoghi O., de Mendonça M., and Suguino R. Perceptions of laypersons and orthodontists regarding the buccal corridor in long- and short-face individuals Angle Orthod.2011; 81;86–90

Appendix

8.1 Ethics approval

UNIVERSITY OF MANITOBA | BANNATYNE CAMPUS
Research Ethics Boards

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

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

PRINCIPAL INVESTIGATOR:	**INSTITUTION/DEPARTMENT:**	**ETHICS #:**
Dr. R. Ward	UofM/Preventative Dental Sciences	H2013:282
APPROVAL DATE: July 12, 2013	**EXPIRY DATE:** July 12, 2014	
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. W. Wiltshire		

PROTOCOL NUMBER:	**PROJECT OR PROTOCOL TITLE;**
NA	Soft Tissue Effects of the X-bow Appliance on Different Facial Patterns (Linked to H2012:007)
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents:	**HREB Receipt Date of Documents:**
July 1, 2013	July 9, 2013

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Proposal		July 1, 2013
Consent and Assent Form(s):		
Other:		

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

HREB ATTESTATION
The University of Manitoba (UM) Research Board (HREB) is organized and operates according to Health Canada/ICH Good Clinical Practices, Tri-Council Policy Statement 2, and the applicable laws and regulations of Manitoba. In respect to clinical trials, the HREB complies with the membership requirements for Research Ethics Boards defined in Division 5 of the Food and Drug Regulations of Canada and carries out its functions in a manner consistent with Good Clinical Practices.

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

- 1 -

www.umanitoba.ca/faculties/medicine/ethics

CONDITIONS OF APPROVAL:

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

Sincerely,

[redacted]

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

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

8.2 Journal Article Submission

Cephalometric evaluation of soft tissue effects induced by a Class II Corrector in different facial patterns

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ABSTRACT

Objective: To determine the magnitude of soft tissue changes in subjects with different facial patterns following Class II correction using the Xbow™ appliance.**Materials and Methods:** A retrospective sample of 80 subjects exhibiting Class II malocclusions was used. Subjects were categorized into facial types according to pre-treatment values of MPA and Y-axis, which yielded 20 brachycephalic, 40 mesocephalic, and 20 dolichocephalic subjects. Data collection included digital analysis on the pre-treatment (T0) and post-treatment (T1) cephalometric radiographs. A paired t-test statistic was used to investigate the differences between the three facial groups at T0 and T1. **Results:** Soft tissue changes induced by the Xbow™ appliance during Class II correction included: reduction in facial convexity (2.11-2.63°±0.27° $p<0.05$), protrusion of soft tissue pogonion (0.99-1.20mm±0.28 $p<0.05$), increase in mentolabial angle (7.96-13.87° ±1.14° $p<0.05$) and decrease in H-angle (-2.44° to -3.11° ±0.25° $p<0.05$). Upper lip to E-Plane increased (-1.04 to -1.61mm±0.06mm $p<0.05$), and lower lip protruded (0.99-1.48mm±0.21mm $p<0.05$). The mesocephalic group had a significantly larger increase in upper lip to E-plane than the other two facial patterns ($p<0.05$). The dolichocephalic group showed a significant opening of the mentolabial fold compared to the mesocephalic group ($p<0.05$).

Conclusions: There are differences in the soft tissue effects observed in patients treated with the

Xbow™ appliance which are related to the pre-existing facial pattern ($p<0.05$): The mesocephalic group showed increased retrusion of the upper lip to E-Plane compared with brachycephalic, and dolichocephalic groups. The dolichocephalic group showed significantly more flattening of the mentolabial fold compared to the mesocephalic group.

KEY WORDS: Class II Corrector; Xbow; Facial type; Facial Soft tissue; Profile, Cephalometrics

INTRODUCTION

Successful orthodontic treatment depends on patient acceptance and compliance with the orthodontic techniques being used.[1] Fixed inter-ach spring-force sagittal correction appliances were primarily developed to eliminate the need for patient compliance with use of Class II/III elastics and/or headgear. Examples of these appliances include the Twin-Force (Ortho Organizers, San Marco, California), the Esprit (Opal Orthodontics, Jordan, Utah) and the Forsus Fatigue Resistant Device (FRD) (3M/Unitek, Monrovia, California). The Xbow™ (crossbow) appliance, recently patented by Higgins, uses inter-arch springs as a phase 1 appliance to correct sagittal discrepancies in the late mixed or early permanent dentition.[2]

The Xbow™ appliance (Fig. 1) is a fixed Class II corrector that consists of a maxillary Hyrax expander, a mandibular labial and lingual bow, and use of the Forsus fatigue resistant device (FRD) springs of 3M Unitek (Monrovia, Calif).[2] The Forsus spring is placed in the head-gear tube of the maxillary first molar band and hooked around the labial bow stopped by a Gurin lock (3M Unitek) around the mandibular canine area.[2] This lock allows for reactivation of the Forsus device without the need for a longer push rod.[2] The mandibular labial and lingual bows are in passive contact with the mandibular incisors.[2] Forsus FRD springs do not rigidly hold the mandible forward and allow the patient to function in centric occlusion.[2] It could thus be categorized as a non-protrusive inter-arch Class II corrector.[2]

Previously published research describes the skeletal and dental effects of the Xbow™ appliance. Flores-Mir et al. (2009) examined the skeletal and dental effects of the Xbow™ appliance irrespective of facial type.[2] Whereas a study completed by Chana et al. (2013) examined the skeletal and dental effects of the Xbow™ appliance, but also classified and compared patients having brachycephalic, mesocephalic, or dolichocephalic facial patterns.[3] Their results have shown that correction of Class II malocclusions with the Xbow™ appliance are the result of mesial movement of the mandibular molar, proclination and / or protrusion of the lower incisor and retrusion of the upper incisor.[2,3] Facial growth pattern were shown to be unrelated to the amount of dental movement induced by the Xbow, and there is a trend for more pronounced movement of the lower incisor in brachycephalic patients.[3]

The above mentioned studies made use of retrospective analyses of lateral cephalograms. Similar studies measured soft tissue changes when utilizing appliances such as the Twin Block and the Herbst.[4,5] In these studies soft tissue convexity improved due to advancement of soft tissue pogonion. Noteworthy opening of the mentolabial fold also occurred.

To date there is insufficient evidence describing soft tissue effects of the Xbow™ appliance on different facial patterns; yet clinicians may benefit from increased awareness of appliance- induced soft tissue effects.

The purpose of this research was to quantitatively compare the soft tissue changes observed in patients after being treated with the Xbow™ appliance, and to differentiate between patients exhibiting a brachycephalic, mesocephalic, or dolichocephalic facial pattern.

MATERIALS AND METHODS

Sample

The retrospective patient sample was acquired from a private orthodontic practice. The total sample size of 80 consisted of 38 males and 42 females. The mean age of the patients was 12.6 +/- 1.6 years at T0, and 13.1 +/- 1. 6 years at T1. Following the active phase of the Xbow™ lasting3.9 +/- 1.1 months, the appliance was passively retained for an additional average time of 3 ±1 months. The total mean time the appliance was in the mouth was 6.9 ±1 month at which time the appliance was removed and a T1 cephalometric radiograph taken.

Cephalometric analysis

The soft tissue analysis utilized by Baysal and Uysal (2013) was adopted to analyze the skeletal and dental changes[4]. The commonly used landmarks (S, Na, Go, Gn, Pog, A, B, UI, Li, na, prn, Cm, sn, ss, ls, lls, li, lls, si, pog, Me, me) may be found and are defined in the literature.[14] Hard and soft tissue measurements used in the present study are listed in Table 1.

The cephalometric radiographs were labeled with a code for blinding purposes. No information on the cephalometric radiographs indicated the age, gender, or if the radiograph was from pre or post Xbow™ treatment. All of the cephalometric radiographs were digitally traced by a single investigator using Dolphin™ 11.7 software (Dolphin Imaging and Management Systems, Chatsworth, CA, USA).

Magnification was accounted for using a digital calibration within the software that matched actual known ruler distances captured on the lateral cephalogram.

Subjects were categorized into three growth types according to the pre-treatment MPA and Y-axis values. Subjects within two standard deviations for MPA (32° +/- 2°) and one standard deviation for Y-axis (66° +/- 5°) yielded; 20 brachycephalic, 40 mesocephalic, and 20 dolichocephalic subjects.

The reproducibility of the measurements was assessed on 10% of the sample. Cephalometric radiographs were chosen randomly and re-measured by two separate examiners 12 weeks after the original measurements to identify landmark identification error.

To determine if growth had a significant contribution on soft tissue effects over the treatment period, growth was assessed on 30% of the sample. Cephalometric radiographs were chosen randomly from each group and subjected to the Bolton growth prediction algorithm. Dolphin Imaging™ software uses growth prediction algorithms to quantify the amount of growth, given parameters of age and time of treatment. Several computer programs using growth prediction algorithms (including Bolton) have been shown to be accurate with respect to a clinical reference mean of 1.5mm.[13]

Statistical software SAS 9.4 was used to analyze the data. A Kolmogorov-Smirnov test was used to confirm that the distribution of the sample was normal. A paired t-test was used to examine the reliability of the tracings, and to quantify the amount of growth over the treatment period. The p value was considered significant at < 0.05 with CI 95%.

RESULTS

Reliability

The intra-examiner results showed a high consistency in the repeated measurements; all ICC values were ≥ 0.935. The F test confirmed that there were no significant differences between the cephalometric variables from T0 to T1 ($p<0.05$).

Inter-examiner ICC values had a wider reliability interval (0.891-0.994) and overall lower average correlation (0.976). However, there was still strong agreement of the values with correlation coefficients > 0.926. The F test confirmed there were no significant differences between the cephalometric variables from T0 to T1 (p>0.05). Based on these results, we are confident that the reproducibility of the cephalometric variables are reliable within a 12 week period.

Growth patterns

A paired t-test for normally distributed variables was used to examine the differences between the groups before Xbow™ treatment. There were very highly statistically significant differences between the three groups prior to Xbow™ treatment ($p<0.0001$). The p value was considered significant at $\alpha<0.05$.

Group 1 represents the brachycephalic group with a mean Y-axis of 60.5°± 0.5° and a mean MPA of 25.5°± 0.4°.

Group 2 represents the mesocephalic group with a mean Y-axis of 68.0 ± 0.2° and a mean MPA of 32.1° ± 0.4°.

Group 3 represents the dolichocaphalic group with a mean Y-axis of 74.5° ± 0.2° and a mean MPA of 39.5° ± 0.4°.

A summary of the three groups prior to Xbow™ treatment is described in Table 3.

Growth Considerations

The Bolton growth prediction algorithm was used on this sample and the mean differences of all the variables were insignificant when subject to a *t*-test.($p\geq0.05$). Growth effects are thus deemed not to be a significant factor in this study.

Differences between the initial and final treatment variables for the Brachycephalic group (n=20): (Table 3)

i) *Facial Pattern Effects*
Facial pattern did not change within the brachycephalic group following Xbow™ treatment. No significant differences were observed (p>0.05).

ii) *Soft Tissue Effects*
Soft tissue profile, mentolabial angle, H-angle, upper lip to E-Plane (mm), lower lip – VRL (mm), soft tissue B pt. – VRL (mm), and soft tissue pogonion – VRL (mm) showed highly

statistically significant differences within the brachycephalic group following Xbow™ treatment ($p<0.0001$).

Differences between the initial and final treatment variables for the Mesocephalic group (n=40) (Table 4).

iii) *Facial Pattern Effects*
Facial pattern did not change within the mesocephalic group following Xbow™ treatment. No significant differences were observed ($p>0.05$)

iv) *Soft Tissue Effects*
Soft tissue profile, mentolabial angle, H-Angle, upper lip – E-Plane (mm), lower lip – VRL (mm), soft tissue B Pt. – VRL (mm), and soft tissue pogonion – VRL (mm) showed highly statistically significant differences within the mesocephalic group following Xbow™ treatment ($p<0.0001$)

Differences between the initial and final treatment variables for the Dolicephalic group (n=20) (Table 5.)

iii) *Facial Pattern Effects*-
Facial pattern did not change within the dolichocephalic group following Xbow™ treatment. No significant differences were observed ($p>0.05$)

iv) *Soft Tissue Effects-*
Soft tissue profile, mentolabial angle, H-Angle, tip of nose – VRL (mm), upper lip to E-Plane (mm), lower lip – VRL (mm), and soft tissue pogonion – VRL (mm) all showed highly statistically significant differences within the dolichocephalic group following Xbow™ treatment ($p<0.0001$)

Differences in facial pattern and soft tissue effects observed between groups following Xbow™ treatment (T1-T0) (Table 6)

iii) *Facial Pattern Effects*- The facial pattern did not change significantly within any group following Xbow™ treatment ($p>0.05$). The groups remained significantly different based on facial pattern following Xbow™ treatment ($p<0.05$)

iv) *Soft Tissue Effects-*

The mesocephalic group showed increased retrusion of the upper lip to E-Plane than the brachycephalic, and dolichocephalic groups. The Dolichocephalic group showed a significant flattening of the mentolabial fold compared to the mesocephalic group ($p < 0.05$).

DISCUSSION

Ricketts described how individuals with different facial patterns also have varying musculature patterns.[6] Brachycephalics generally exhibit stronger musculature, and are often characterized by a deep overbite, and low mandibular plane angle.[6] Conversely, dolichocephalics generally exhibit weaker musculature and will have a vertical or open bite tendency.[6] Stronger musculature could counteract or oppose orthodontic forces, for example resisting bite opening.[6] A weaker musculature is less likely to overcome orthodontic forces that open the bite and rotate the mandible downwards.[6] Therefore Ricketts stressed that treatment mechanics should be modified in order to counteract the unwanted effects of orthodontic forces in patients with either stronger or weaker musculature patterns[6]. The facial pattern influences the underlying dental compensations that counteract vertical growth deviations. [7-10] Therefore, given that different dental compensations exist for varying facial patterns, it is important to investigate the potential differences in soft tissue effects that may be observed with orthodontic treatment.

Differences Within Facial Patterns

The decrease in facial convexity excluding the nose was found to be statistically significant following treatment in all three facial patterns ($p<0.05$). Facial convexity is influenced by the anterior-posterior position of soft tissue nasion, subnasale, and soft tissue pogonion. In each group soft tissue pogonion showed a statistically significant protrusion ($p<0.05$), which contributed to the reduction in the facial convexity.

Mentolabial angle was also shown to have a statistically significant increase following treatment in all three facial patterns. A potential explanation for this finding exists in Class II, division 1 malocclusions where the lower lip is trapped behind the upper incisors. This entrapment results in a deepening of the mentolabial sulcus and an acute mentolabial angle. Other studies have reported similar increases in mentolabial angle after class II correction.[4,11] The authors of these studies suggest that the elimination of overjet and/or the change in the tonicity and posture of perioral muscles are responsible for the changes observed.[4,11] When overjet is reduced, the physical obstruction of the upper incisors is also reduced, thus resolvingentrapment of the lower lip.[4] Also, if the patient attempts to maintain lip seal while wearing the appliance, lip strain may be increased subsequently changing the posture and tonicity of perioral muscles.[4] As a result, the lower lip entrapment is reduced, and mentolabial angle is increased.[4]

H-Angle significantly decreased in all three facial patterns. It has been reported that H angle is associated with facial convexity.[4] Therefore, should there be a reduction in facial convexity, there must also be a subsequent decrease in H angle.[4] This phenomena was in fact observed in all three facial types.

Upper lip retruded relative to E-Plane significantly in all three facial patterns. The upper lip to E-plane dimension is influenced by retraction of the upper lip, and both protrusion of the tip of nose and soft tissue pogonion.[4] Given that soft tissue pogonion showed statistically significantprotrusion, any retraction of the upper lip, or protrusion of the tip of nose would exaggerate this finding.

Lower lip (at labrale superius) protrusion was statistically significant in all three facial types. Again, lower lip distortion may play a role, but this finding may also reflect the soft tissue adaptability to hard (dental) tissue changes.[4]

Soft tissue B-point was also statistically significantly advanced anteriorly in brachycephalic and mesocephalic groups, but not in dolichocephalics. This finding coincides with an increase in mentolabial angle as soft tissue B point moves anteriorly in response to hard tissue (dental) changes.[4]

Although all these findings are statistically significant, consideration should be given to the small clinical magnitude of these effects. Ultimately, these findings may not have a high level of clinical relevance.

Differences Between Facial Patterns

In this study, the number of soft tissue parameters demonstrating significant differences between facial patterns was low (3 out of 21 parameters). Overall, the mesocephalic group had the highest number of significant differences in comparison to the other facial patterns ($p<0.05$). Whereas the brachycephalic group demonstrated only one significant difference compared to the mesocephalic group ($p<0.05$), and did not significantly differ from the dolicocephalic group ($p<0.05$) (Table 6).

Individuals with a mesocephalic facial pattern had a significantly larger retraction of the upper lip to E-plane ($p<0.05$) than the other two groups. The largest difference was 0.57 mm between mesocephalic and brachycephalic subjects, which although statistically significant, may not be clinically relevant.

The dolichocephalic group showed a larger flattening of the mentolabial fold compared to the mesocephalic group ($p<0.05$). Mentolabial angle is influenced by the positions of labrale inferius, sulcus inferius (soft tissue B point), and soft tissue pogonion.[4] As previously discussed, the mentolabial angle may have been influenced by the elimination of overjet, or a change in the tonicity/posture of perioral muscles. [4,11]

Overall Comparison

To our knowledge the soft tissue effects of the Xbow™ appliance have not been investigated in other studies to date. Therefore direct comparison to other studies is difficult. However, other authors have investigated the induced soft tissue effects of Twin Block and Herbst appliances.[4,5] The findings of these studies include: decreased facial convexity and H angle, and increases in mentolabial angle, upper lip –E plane distance, lower lip thickness, lower lip length and soft tissue pogonion protusion.[4,5]

Overall, our study yielded similar results to prior studies measuring soft tissue effects of other Class II correctors. However, the mechanism of action of these appliances is very different.[12] The Herbst appliance, for example, has the ability to distract the condyle from the glenoid fossa theoretically influencing growth of the mandible.[12] Although, patient attempts to achieve lip seal during wear these appliances may influence lip strain leading to increased lower lip thickness, lower lip length and mentolabial angle[4,11]. However, the Herbst and Twin block appliances have longer treatment durations, which may have an influence on this phenomena. Future research investigating this topic is indicated.

In our study the actual treatment time including passive retention was of short duration, (6.9±1 months at the T1 radiograph). This makes acquiring a control group retrospectively, problematic. The classic approach to obtain a control sample would be to resort to historical growth studies. However, the disadvantage of historical growth studies is that the radiographs are usually taken over a 2 to 3 year period, which would far exceed the treatment time used in this study. Therefore, Bolton growth prediction algorithms were used to quantify the amount of growth that may have occurred between the initial and final radiographs. As this growth prediction technology continues to improve and more studies confirm the accuracy of this method of growth quantification, it could serve as a valuable control for future studies.

No significant differences were observed in the control group ($p>0.05$). Hence, growth was not a significant factor, and significant soft tissue effects are deemed appliance therapy induced.

Overall, based on the observed soft tissue changes, and the similarity to the results of other Class II correctors, it would be fair to conclude that treatment with the Xbow™ did induce significant magnitudes of cephalometric soft tissue changes. However, considering the small clinical magnitude of these soft tissue changes, arguably the differences are of minor clinical relevance.

CONCLUSIONS

1) There are differences in the soft tissue effects observed in patients treated with the Xbow™ appliance which are related to the pre-existing facial pattern ($p<0.05$):
   - The mesocephalic group showed increased retrusion of the upper lip to E-Plane compared to the brachycephalic, and dolichocephalic groups.
   - The dolichocephalic group showed significantly more flattening of the mentolabial sulcus compared to the mesocephalic group.

REFERENCES

1. Graber TM, Vanarsdall RL, Vig KW. Orthodontics: Current Principles & Techniques. Fourth Edition. Elsevier Inc. St. Louis, Missouri 2005.
2. Mir CF, Barnett, Higgins DW, Heo G, Major PW. Short-term skeletal and dental effects of the Xbow appliance as measured on lateral cephalograms. Am J Orthod Dentofac Orthop 2009;136:822-32.
3. Chana RS, Hechter FJ, Wiltshire WA, Ahing, S. (2013) Cephalometric evaluation of dental class II correction using the XbowTM appliance in different facial patterns. University of Manitoba http://mspace.lib.umanitoba.ca/browse?type=author&value=Chana%2C+Randeep+S.
4. Baysal A, Uysal T. Soft tissue effects of Twin Block and Herbst appliances in patients with Class II division 1 mandibular retrognathy. Eur J Orthod 2013 35:71−81
5. Quintão, C., Helena, I., Brunharo V. et al (2006) Soft tissue facial profile changes following functional appliance therapy. Eur J Orthod 28:35–41
6. Ricketts, RM, Bench RW, Gugino CF, Hilgers JJ, Schulhof RJ. Bioprogressive Therapy. Rocky Mountain/Orthodontics. USA 1979.
7. Janson GR, Metaxas A, Woodside DG. Variation in maxillary and mandibular molar and incisor vertical dimension in 12-year-old subjects with excess, normal, and short lower anterior face height. Am J Orthod Dentofac Orthop. 1994;106:409–418.
8. Enoki C, Telles Cde S, Matsumoto MA. Dental-skeletal dimensions in growing individuals with variations in the lower facial height. Braz Dent J. 2004;15:68–74.
9. Kuitert R, Beckmann S, van Loenen M, Tuinzing B, Zentner A. Dentoalveolar compensation in subjects with vertical skeletal dysplasia. Am J Orthod Dentofac Orthop. 2006; 129:649–657.
10. Flores-Mir C, Young A, Greiss A, Woynoroski M, Peng J. Lower incisor inclination changes during Xbow treatment according to vertical facial type. Angle Orthod. 2010;80:1075-1080.
11. Lange, W., Kalra, V., Broadbent, B., Powers, M., Nelson, S. Changes in soft tissue profile following treatment with the bionator. Angle Ortho. 1995;65:423-430.
12. Pancherz, H. The mechanism of Class II correction in Herbst appliance treatment. A cephalometric investigation. Am J Orthod. 1982;82:104-13.
13. Sagun M. Assessment of computerized cephalometric growth prediction: A comparison of three methods. University of Illinois. 2012.
14. Phulari, B. Orthodontics: Principles and Practice. New Delhi, India: JP Medical Ltd. 2011. Print.

8.2 Manuscript Submission