Comparison of AdvanSync™ and Intermaxillary Elastics in the Correction of Class II Malocclusions: A Cephalometric Study

By

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Abstract

Objectives: To compare the skeletal, dentoalveolar and soft tissue effects of the AdvanSync™ appliance and intermaxillary elastics in the correction of Class II malocclusions in growing patients.

Materials and Methods: A retrospective study was conducted using lateral cephalograms of patients taken pre-treatment (T1) and post-comprehensive orthodontic treatment (T2). 41 patients consecutively treated with AdvanSync™ were compared to 41 similar patients treated with intermaxillary Class II elastics. All patients had significant growth potential during treatment as assessed by cervical vertebral maturation. A comparison group was generated from historical databases and matched to the experimental groups for skeletal age, gender and craniofacial morphology. Treatment changes were evaluated between the time points using a custom cephalometric analysis generating 31 variables as well as regional superimpositions. Data was analyzed using one-way analysis of variance and Tukey-Kramer tests.

Results: Initially (T1), the three groups were well matched in terms of cephalometric measurements. The effects of AdvanSync™ and fixed orthodontics (T2-T1) included maxillary growth restriction, protrusion, proclination and intrusion of mandibular incisors and mesialization of mandibular molars ($p<0.01$). The effects of Class II elastics and fixed orthodontics were similar to AdvanSync™, with the exceptions of less maxillary growth restriction and greater retrusion and retroclination of maxillary incisors ($p<0.01$). Significant mandibular growth stimulation, relative to untreated controls, did not occur with either modality.

Conclusion: AdvanSync™ and intermaxillary elastics were effective in normalizing Class II malocclusions during comprehensive fixed orthodontics. AdvanSync™ produced its effects through maxillary skeletal growth restriction and mandibular dentoalveolar changes. Class II elastics worked primarily through dentoalveolar changes in both the maxilla and mandible.

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Dedication

I dedicate this work to my parents and my sisters for their endless love, encouragement and faith.

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Chapter 1

Introduction

Treatment of Class II malocclusions remains an important topic in orthodontics and has been a prime focus of orthodontic investigators for decades. Through advancements in technology and increasing knowledge, several appliances, aiming to be the most efficient and effective, have been developed in order to correct these malocclusions. The mechanisms by which these appliances work vary considerably, and therefore their effects are significantly different (Jones et al. 2008).

Many of the earlier methods for treatment of Class II patients typically involved removable, compliance based modalities such as removable functional appliances and intermaxillary Class II elastics. Over time, lack of patient compliance and the desire to produce more predictable results in a more efficient manner led to the development of numerous fixed appliances, which did not require patient compliance for efficacy. There are advantages and disadvantages for each type of appliance, and the orthodontist must choose the most appropriate modality for each individual patient (Jones et al., 2008).

With the constant arrival of new techniques and appliances, orthodontists are now equipped with more options than ever before, but have the responsibility to base their treatment decisions on sound evidence. It is crucial for orthodontic appliances to be thoroughly investigated in order to fully understand their true effects. Appliances designed to correct Class II malocclusions provide their effects through a combination of skeletal and dentoalveolar changes (McSherry et al., 2000). Understanding the specific skeletal and dental effects of each appliance is vital to proper appliance selection based on individual patient requirements.

This study was designed to evaluate the effects of a relatively new appliance for treatment of Class II malocclusions. AdvanSync™ is a fixed appliance developed by Ormco™ to treat Class II malocclusions. The appliance consists of crowns cemented to permanent upper and lower first molars which are connected by telescoping rods. The AdvanSync ™ was designed to allow for simultaneous fixed orthodontic appliance treatment, as the crowns are equipped with 0.022” x 0.028” slots; this has been claimed to reduce overall treatment times. AdvanSync™ is meant to posture the mandible forward, and therefore can be classified as a fixed functional appliance. According to Ormco™, Advansync™ produces stable orthopedic change by skeletal advancement of the mandible, while eliminating the need for patient compliance.

The purpose of this study is to comprehensively investigate the skeletal, dentoalveolar and soft tissue effects of the AdvanSync™ appliance in the correction of Class II malocclusions in growing patients. AdvanSync™ will be compared to a typical compliance based method of Class II correction – intermaxillary elastics (Class II elastics). Patients treated with AdvanSync™ and intermaxillary elastics will also be compared to a non-treated Class II control sample generated from historical databases. To date, there has only been one study that has evaluated the effects of AdvanSync™ (Al-Jewair et al., 2012). No study has directly compared the effects of AdvanSync™ to Class II elastics.

The following review of the literature will describe the scope of the Class II problem in orthodontics and the challenges it poses. Important topics pertaining to patients with Class II malocclusion including classification, etiology and growth will be discussed first. Literature regarding the appropriate timing of treatment for these patients is discussed next. The controversy regarding the true efficacy of functional appliances in producing significant skeletal change will then be discussed. Finally, the literature pertaining to various methods of Class II correction, both compliance and non-compliance based modalities, will be summarized.

Chapter 2

Review of the Literature

2.1 Classification of Malocclusion

Class II malocclusions continue to pose significant challenges in orthodontics. The significance of this problem is reflected in the National Health and Nutrition Estimates Survey III (NHANES III), which was an extensive national survey of health care problems and needs in the United States in 1989-1994. The survey of about 14,000 individuals provided weighted estimates for approximately 150 million people in the samples' racial/ethnic and age groups. This study currently provides the best estimates of the prevalence of malocclusion in North America. According to the NHANES III, overjet of 5mm or more, which is suggestive of Angle Class II malocclusion, occurs in 23% of children age 8 to 11, 15% of youths age 12 to 17, and 13% of adults age 18 to 50 (Proffit et al., 1998). Studies have shown that approximately 75% of individuals with a dental Class II division 1 malocclusion also have a corresponding skeletal malocclusion (Beresford et al., 1969; Milacic et al., 1983). The data clearly indicates that Class II malocclusion is the most prevalent skeletal disharmony encountered in all age groups.

Throughout history, many systems have been developed to classify malocclusions. Each system attempts to identify key features that differentiate a malocclusion from an ideal occlusion (Angle, 1900; Dewey, 1915). Edward Angle provided the first clear and simple definition of normal occlusion in the late 1890's (Angle, 1900). He also devised a system to subdivide the major types of malocclusions. Angle stated that the maxillary first molars were the key to occlusion and the mesiobuccal cusp should occlude in the buccal groove of the mandibular first molar in an ideal occlusion. He stated that if the teeth were arranged along a smooth curve with this molar relationship, normal occlusion would result. This concept is still accepted today, except when a tooth size discrepancy exists. Angle described Class II malocclusion as a distally positioned lower molar relative to the upper molar. Although many other classifications, both quantitative and qualitative, have been developed over the years, Angle's classification of malocclusion remains the most utilized in orthodontics (Proffit et al., 2013).

Class II malocclusion can be further subdivided into two types (Angle, 1900). Class II division 1 malocclusion is characterized by proclined and protruded maxillary incisors resulting in an increased overjet and overbite. Key features of Class II division 2 malocclusion include retroclined maxillary central incisors, proclined maxillary lateral incisors, reduced overjet and increased overbite. If only one side is affected, the malocclusion is classified as a subdivision of the affected side.

Although still extremely useful, the Angle classification does have some important limitations. Perhaps most importantly, the system focuses only on dental relationships, while soft tissue and skeletal jaw relationships are not included. With advancement in cephalometry and facial analysis, it is clear that not all dental Class II malocclusions are the same (McNamara, 1981). Using Angle's classification system, a Class II malocclusion due to maxillary prognathism would be no different than a Class II malocclusion due to mandibular retrognathism. This is an important difference with critical treatment implications. In contemporary orthodontic treatment, the goal is to provide the best balance of facial esthetics, occlusal function and stability (Proffit et al., 2013). This is quite different from the Angle paradigm where priority was placed on occlusal relationship, while everything else was assumed to follow. Therefore, when an Angle Class II malocclusion is present, clinicians must use soft tissue and cephalometric analyses in order to uncover the true etiology behind the malocclusion.

2.2 Etiology and Development of Class II Malocclusion

The development of Class II malocclusion is a complex process involving many factors and typically arises due to both skeletal and dental abnormalities (Mossey 1999). These abnormalities may result due to a genetic predisposition and/or a wide variety of environmental influences. Establishing the etiology and the degree to which each factor is involved varies from patient to patient, and must be determined in order to provide the most appropriate treatment.

The genetic component of Class II malocclusion has been established in the literature (Harris, 1963 & 1975; Nakasima et al., 1982). Nakasima et al. (1982) conducted a study comparing craniofacial morphologic correlations between 96 Class II patients , 104 Class III patients, and their parents. Lateral and frontal cephalograms were obtained for the patients and their parents. Correlation coefficients were calculated for various cephalometric measurements. The authors found significant differences between the Class II and III groups, but high correlation coefficients between parents and their offspring within each group. Therefore, they concluded that a strong familial tendency exists for the development of Class II malocclusion.

Various environmental and physiological factors are also known to contribute to Class II malocclusion. Harvold et al. (1981) studied the effects of oral respiration on craniofacial development of primates. When nasal respiration was blocked in primates using silicone plugs, the investigators noted that they reverted to open mouth posture and subsequently developed more vertical growth patterns and greater tendency toward Class II malocclusion, likely due to backward rotation of the mandible. Similar findings were noted by Melsen et al. (1987) when they compared mouth breathing patients to nasal breathers. Melsen et al. (1979) studied the effects of swallowing pattern on malocclusion. They found that children who exhibited a swallowing pattern with tooth contact had a significantly lower prevalence of vertical and sagittal discrepancies compared to children with other swallowing patterns. It is also known that individuals with decreased masticatory muscle function have a tendency toward a vertical growth pattern, Class II malocclusion, and anterior open bite (Kiliaridis 2006). Prolonged digit sucking has also been known to contribute to malocclusion. Melsen et al. (1979) found that prolonged thumb sucking results in maxillary constriction, clockwise rotation of the mandible and subsequent Class II malocclusion. Finally, Solow et al. (1998) found that children who constantly exhibit posture with head extension (raised position of the head in relation to cervical column) are more likely to present with vertical growth patterns and Class II malocclusion. Therefore, it is clear that environmental adaptations and physiological functions, in addition to genetics, play an important role in development of Class II malocclusion.

Several cephalometric studies have aimed to characterize the key features of Class II malocclusion. According to Bishara (2006), Class II division 1 malocclusion may be characterized by the anterior position of the skeletal maxilla and/or maxillary teeth relative to the cranium, a posterior position of the mandible and/or mandibular teeth, an underdeveloped mandible, or a combination of these factors. McNamara (1981) reviewed previous studies and investigated the frequency of occurrence of key components in children with Angle Class II malocclusion. He evaluated the lateral cephalograms of 277 children aged 8-10 with Class II malocclusion and recorded the characteristics contributing to the malocclusion in each patient. He found that the maxilla exhibited a neutral position in most cases and true skeletal protrusion was only present in a small percentage of the patients. When not neutrally located, the maxilla was found to be in a retruded position more often than a protruded position. McNamera (1981) found that mandibular skeletal retrusion was the single most common characteristic among the sample. Additionally, about half of the sample exhibited excess vertical development. From these findings, the author suggested that treatment to alter the amount and direction of mandibular growth may be more appropriate than those directed at restricting maxillary development.

The early identification of patients with significant Class II malocclusion would definitely be helpful in considering the applicability of early intervention. Varrela (1998) investigated the early developmental traits in Class II malocclusion. He found that Class II occlusions in the primary dentition are not typically associated with skeletal discrepancies. According to Varrela, skeletal characteristics of Class II malocclusion develop later than the occlusal features, but this is not well supported in the literature (Moyers & Wainright, 1977; Bishara et al., 1988; Baccetti et al., 1997). Varella concluded that the first skeletal signs of Class II malocclusion are a narrow maxilla and reduced sagittal mandibular growth; other skeletal features may develop as secondary adaptations.

Baccetti et al. (1997) also studied the early dentofacial characteristics of Class II malocclusion from the primary through the mixed dentition. They found that through the transition to the mixed dentition, Class II features were either maintained or became more prominent. They also reported that significant mandibular retrusion and size deficiency were present in the deciduous dentition in Class II patients. Compared to the Class I control sample, the Class II group cephalometrically showed greater maxillary growth increments and smaller mandibular increments as well as greater downward and backward rotation of the mandible. The authors concluded that clinical signs of Class II malocclusion, both skeletal and dental, are evident in the primary dentition and persist into the mixed dentition. The findings of Baccetti et al. (1997) are in strong agreement with previous studies (Moyers & Wainright, 1977; Bishara et al., 1988).

2.3 Growth in Individuals with Class II Malocclusion

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

These conclusions had already been drawn by Buschang and Martins (1998) in their longitudinal study of 99 Class I and II subjects. They found that anteroposterior relationships (measured as horizontal distance from ANS to pogonion) usually improved during childhood, but worsened during adolescence. Differences in the horizontal growth of the mandible was the primary reason. They also concluded that vertical skeletal changes (vertical distance from gonion to pogonion) increased in the majority of subjects. This study also supports the idea that Class II malocclusion does not self-correct over time and appropriate intervention is necessary.

2.4 Current Evidence on Treatment Timing

The timing of treatment for Class II patients is critical. Franchi et al. (2013) analyzed long-term skeletal and dentoalveolar effects in Class II patients treated with functional appliances either before or during puberty in order to evaluate treatment timing. They cephalometrically evaluated a group of 40 patients (22 females and 18 males) with Class II malocclusion treated with a bionator or activator removable functional appliances followed by fixed orthodontic appliances and compared them to an untreated Class II control group. The treated sample was divided into two groups based on skeletal maturity (according to the method outlined by Baccetti et al., 2005): an early treatment group of 20 subjects (12 females and 8 males) treated before puberty and a late-treatment group of 20 subjects (10 females and 10 males) treated at puberty. Lateral cephalograms were available at the start of treatment, end of treatment with functional appliances, and long-term observation (mean of 8.6 years after start of treatment). The authors found that treatment during the pubertal peak was able to produce significantly greater increases in mandibular length (4.3 mm) and height (3.1 mm) as well as advancement of the bony chin (3.9 mm) when compared with earlier treatment. Therefore, the authors concluded that treatment of Class II malocclusions with functional appliances may be more effective during active pubertal growth. This conclusion had previously been drawn by several investigators based on studies of various fixed and removable functional appliances (Hagg et al., 1988; Hansen et al., 1991; Baccetti et al., 2000; Faltin et al., 2003).

2.5 Current Evidence on the Efficacy of Growth Stimulation in Class II Patients

Several treatment modalities have been developed for Class II malocclusions. These include selective extraction patterns, orthopedic forces delivered with headgear, functional jaw orthopedics using functional appliances, fixed Class II correctors, molar distalization and orthognathic surgery to reposition one or both jaws (Pangrazio et al., 2012). Several factors, including the etiology of the malocclusion, the growth potential of the patient and expected patient compliance need to be taken into consideration while selecting the most appropriate treatment modality (Nelson et al., 2000). This literature review will focus on functional appliances in which one of the mechanisms of Class II correction involves advancement of the mandibular teeth, mandible, or both.

Removable or fixed functional appliances are designed to alter the sagittal and vertical position of the jaws, resulting in orthodontic and orthopedic changes (Pangrazio et al. 2012). Despite their long history of use, the efficacy of these types of appliances is a controversial topic in orthodontics. Advocates of functional appliances cite stimulation of mandibular growth (Hagg et al., 1988; Hansen et al., 1991; Baccetti et al., 2000; Hagg et al., 2002; Faltin et al., 2003; Meikle et al., 2007). Histological studies involving laboratory animals have consistently shown the enhancement of cellular activity and mandibular growth with the use of bite-jumping appliances (Charlier et al., 1969; Elgoygen et al., 1972; McNamara JA Jr. et al., 1987; Rabie et al., 2001 & 2003). It has been speculated that these changes do occur in humans as well (Moss et al., 1969; Balthers, 1984; McNamara JA Jr. et al., 1985). However, many investigators (Schulof et al., 1982; Creekmore et al., 1983; Tulloch et al., 1998) believe that the changes produced by functional appliances may be significant in the short-term, but in the long-term are not significantly different from changes due to normal growth or conventional edgewise therapy. These investigators cite that patients who received a functional appliance phase I treatment in the mixed dentition followed by phase II full fixed orthodontic treatment in the permanent dentition, do not show any significant differences compared to patients treated with one phase of fixed orthodontic treatment in the permanent dentition. Additionally, it was shown that phase I functional appliance treatment did not reduce the likelihood of needing extractions or orthognathic surgery in the second phase of treatment (Tulloch et al., 1998). It is evident that the ability to stimulate mandibular growth with a functional appliance is still very controversial with strong arguments for both sides.

2.6 Compliance Based Treatment Modalities

Appliances used to correct Class II malocclusion may be classified as compliance based or non-compliance based; this is a convenient way to divide these appliances as many clinicians place a high importance on this distinction. In general, removable appliances are compliance based and dependent on patient obedience with instructions given by the clinician. Fixed appliances, on the other hand, are non-compliance based since the patient cannot remove the appliance.

Removable Functional Appliances

Removable functional appliance therapy is one compliance based treatment modality for Class II malocclusions. Over the last century, a wide array of functional appliances have been developed and utilized extensively in growing patients. Three such appliances include the Bionator, Twin-Block and Fränkel-2.

The Bionator was designed and introduced by Balters in the 1960's (Bigliazzi et al., 2014). Bigliazzi et al. (2014) studied the long-term dentoskeletal effects induced by treatment with the appliance in 23 growing Class II patients (8 males, 15 females). Lateral cephalograms were analyzed at three time points: start of treatment (mean age 10 years 2 months), end of Bionator therapy (mean age 12 years 3 months), and long-term follow-up (mean age 18 years 2 months). An untreated control sample was used for comparison. The authors found that the Bionator was able to produce favorable forward and downward mandibular shape changes while not restraining the maxilla (numerical measurements were not provided in this study). These shape changes contributed significantly to the correction of the Class II malocclusions and the results were maintained in the long term. Similar results had been previously drawn by Malta et al. (2010) and Franchi et al. (2013). Malta et al. (2010) reported an average long-term increase in mandibular length of 3.3 mm compared with untreated controls, while Franchi et al. (2013) reported a 3.6 mm increase.

The Twin-Block appliance was developed by Clark in the 1980's (Clark 1988). In a recent study, Giuntini et al. (2015) studied the effects of the Twin-Block appliance and Forsus™ Fatigue Resistant Device (FRD) in Class II patients. 28 growing patients treated with Twin-Block therapy followed by fixed appliances (mean age 12.4 years pre-treatment) were compared to 36 growing patients treated with FRD (mean age 12.3 years) in combination with fixed appliances. An untreated sample of 27 subjects was used as a control. Mean observation interval was 2.3 years in all groups. The Twin-Block sample exhibited a greater increase in mandibular length compared to the FRD and control samples (2.0 mm more than FRD and 3.4 mm more than control). The SNB angle also increased significantly in the Twin-Block group (1.9° more than FRD and 1.5° more than control). The authors concluded that the Twin-Block appliance is able to produce significant mandibular advancement to correct Class II malocclusion. The results of this study supported those found by Mahamed et al. (2012). These results are contrasted by those found by O'Brien et al. (2009) in a multi-center controlled trial. O'Brien et al. (2009) randomly divided 174 children aged 8 to 10 into two groups: one receiving Twin-Block therapy, the other left initially untreated. The subjects were then followed until the end of comprehensive orthodontic treatment. The results of the study indicated that there were no differences between subjects who received early Twin-Block treatment and those who received one later course of treatment in adolescence in terms of skeletal pattern, extraction rate and self-esteem. The authors concluded that early treatment with the Twin-Block followed by fixed appliances has no advantages compared to fixed orthodontic treatment alone started at a later age.

The Fränkel-2 appliance (FR-2) was developed by Rolf Fränkel and introduced to orthodontics in 1966 (Perillo et al., 2011). Numerous articles have been published in the literature with regards to this appliance. Perillo et al. (2011) summarized the effects of the appliance in a meta-analysis. From nine articles that were included in the analysis, the Fränkel-2, in growing patients, was associated with enhancement of mandibular body length (0.4 mm/year), total mandibular length (1.069 mm/year), and mandibular ramus height (0.654 mm/year). Therefore, the authors concluded that the Fränkel-2 does have a statistically significant effect on mandibular growth. These results are not well supported by other systematic reviews (Cozza et al., 2006; Koretsi et al., 2014).

Cozza et al. (2006) conducted a systematic review of mandibular changes produced by functional appliances in growing patients. 18 controlled clinical trials and 4 randomized control trials were included in the review. Two-thirds of the studies reported a clinically significant supplementary elongation in total mandibular length (2mm more than control group). It was found that mandibular growth enhancement appears to be greater if the functional appliance is used during the pubertal growth peak assessed by skeletal maturity. However, of the 4 RCTs included in the review, none of them showed a significant change in mandibular length with functional appliance therapy. The Herbst (a fixed functional appliance) had the highest coefficient of efficiency of 0.28mm per month, followed by the Twin Block (0.23mm per month), Bionator (0.17mm per month), and Fränkel-2 (0.09mm per month).

Another systematic review regarding the treatment effects of removable functional appliances in growing patients was completed by Koretsi et al. (2014). From the 17 studies included in the review, they found that functional appliance treatment was associated with a minimal reduction in SNA angle (-0.28°/year) and minimal increase in SNB angle (0.62°/year) compared to untreated controls. Removable functional appliances produced significant dentoalveolar changes (primarily retroclination of the maxillary incisors) and soft tissue changes. Skeletal changes were minimal, but seemed to be more evident with the Twin-Block. These results are only for the short-term as inadequate evidence was available for the long-term.

Class II Elastics

Another compliance-based modality to correct Class II malocclusions is through the use of intermaxillary elastics. Class II elastics are used in combination with full fixed orthodontic appliances and are typically worn from maxillary canines to mandibular first molars. The effects of Class II elastics have been previously investigated in several studies. Nelson et al. (1999) studied the effects of Class II elastics (Begg technique) in 18 Class II division 1 patients. The overall reduction in overjet was 5.8 mm, with 71.1% of the reduction being due to dental changes. The molar correction of 3.0mm in the total treatment period, was due to 63% dental changes (1.9 mm) and 37% skeletal changes (1.1 mm). Of the dental changes, the primary factor was forward movement of the mandibular molars (2.0 mm). The mandibular plane angle increased an average of 1.0°, while the lower anterior facial height increased 5.0 mm. In summary, the Class II correction occurred primarily through dental changes, while vertical skeletal measurements increased.

In a later study, Nelson et al. (2000) studied the long-term effects of Class II correction with the Begg appliance and Class II elastics compared to the Herbst appliance. Lateral cephalograms were taken at the start of treatment, immediately after treatment, and after long-term follow-up. Initially, more favorable effects were seen in the Herbst group. However, many of the changes reversed during the follow-up period and both treatment modalities were comparable in their effects in the long-term.

Gianelly et al. (1984) investigated the effects of Class II elastics with both Begg and edgewise appliances. SNA decreased in both the Begg (0.4°) and edgewise (1.5°) groups, while SNB increased 0.3° in both groups. The mandibular plane angle increased 1.3° in the Begg group and 0.6° in the edgewise group. Overall mandibular size increased by almost 3 mm in both groups, likely due to normal growth. Overall, the effects of Class II elastics were consistent with other studies and there were no significant differences between the two groups.

Janson et al. (2013) recently completed a systematic review on the treatment effects of Class II elastics. The review consisted of 11 studies: 4 that tested the effects of Class II elastics alone, and another 7 that compared the effects of Class II elastics to another method of Class II malocclusion correction. From the 4 studies that solely focused on the effect of Class II elastics, the following effects were found:

- Restriction of forward maxillary growth, and insignificant movement of maxillary molars
- Forward growth of mandible, and 1.2mm forward movement of mandibular first molars
- Proclination of mandibular incisors
- Overjet reduction of 5.8mm: 28.9% skeletal change and 71.1% dental change
- Overbite reduction of 3.0mm and molar correction of 3.0mm: 37% skeletal change and 63% dental change
- Increase in lower anterior facial height by an average of 5.0mm
- Soft tissue effects only vaguely mentioned
- Overall, Class II elastics are effective in correcting Class II malocclusion, mainly via dentoalveolar effects

When Class II elastics were compared with the Fränkel appliance, headgear (Gianelly et al., 1984), the cortical anchorage principle (Ellen et al., 1998), and the Forsus™ appliance (Jones et al., 2008), no differences were found in the changes produced. According to Nelson et al. (2000), the Herbst appliance appears to produce greater skeletal change when compared to Class II elastics in the short term (51% vs 4% skeletal overjet correction and 66% vs 10% skeletal molar relationship correction). However, the authors suggested that with longer post-treatment periods (2-3 years), natural growth could mask the effects of the appliance and make the two groups comparable. Overall, in terms of long-term effects, the comparative studies showed that there are no significant differences between Class II elastics and removable or fixed functional appliances.

Class II elastics remain heavily utilized by orthodontists to correct Class II malocclusions. As seen in various studies (Gianelly et al., 1984; Ellen et al., 1998; Nelson et al., 2000; Jones et al., 2008), this treatment modality does produce several, usually unwanted, side effects including clockwise rotation of the occlusal plane and proclination of the mandibular incisors. The clockwise rotation of the occlusal plane acts to exacerbate the Class II relationship and therefore must be taken into consideration and limited whenever possible. Significant mandibular incisor proclination is known to be unstable and measures should be taken to prevent this. Despite these side effects, Class II elastics will undoubtedly continue to play an important role in orthodontics, as they are easy to use, inexpensive and effective in normalizing Class II malocclusions in compliant patients.

2.7 Non-Compliance Based Treatment Modalities

The efficacy of removable appliances and Class II elastics in correcting Class II malocclusion is entirely dependent upon patient compliance. The needed compliance is out of the control of the clinician, making results unpredictable. In order to eliminate the dependence on patient compliance and produce more predictable results, several fixed appliances have been developed to correct Class II malocclusions. Appliances such as the Herbst, Mandibular Anterior Repositioning Appliance, and AdvanSync™ utilize rigid inter-arch attachments in order to force the patient to constantly posture the mandible forward. Other appliances such as the Saif Spring, Eureka Spring, and Forsus™ Fatigue Resistant Device rely on inter-arch spring-force delivery systems to correct Class II malocclusion.

The Herbst Appliance

The Herbst appliance was likely the first well-known fixed appliance for Class II correction (Pancherz, 1982). This appliance acts as an artificial joint between the upper and lower jaws. Telescoping mechanisms on both sides, attached to orthodontic bands, keeps the mandible continuously held in a forward position during mandibular functions; hence it is classified as a fixed functional appliance (Pancherz, 1982). The telescoping mechanism typically attaches at the maxillary first molar and mandibular first premolar bands. Although it is possible to place brackets on the anterior teeth while the Herbst appliance is in place, it is not possible to bracket mandibular posterior teeth due to the telescoping mechanism. For this reason, the appliance is typically used by itself during the initial 6 to 8 months prior to full edgewise orthodontic treatment (Pancherz, 1997).

Several investigators have described the effects of the Herbst appliance. Pancherz (1982) did a lateral cephalometric study of 22 growing Class II, division 1 patients (mean pre-treatment age of 12 years 1 month) treated for an average of 6 months with the Herbst appliance and compared them to a similar untreated control group. He found that all cases treated with the Herbst appliance resulted in Class I occlusal relationships and the improvements were due to approximately equal skeletal and dental changes. The average molar Class II correction was 6.7 mm (due to 2.2 mm mandibular length increase, 2.8 mm distalization of upper molars, and 1.0 mm mesialization of the lower molars.) The average overjet correction was 5.2mm (due to 2.2 mm increase in mandibular length and 1.8 mm mesial movement of lower incisors). The author also noted a direct relationship between the amount of initial bite jumping and mandibular growth. Therefore, Pancherz suggested the Herbst appliance be constructed with the mandible jumped anteriorly as much as possible (in a single activation), usually to an incisal edge-to-edge position.

Pancherz (1997) also reviewed the effects of the Herbst appliance in the short and long term. Marked mandibular morphological changes were evident during treatment with the Herbst appliance. Effects on the maxillary complex were found to be similar to those expected with high-pull headgear; in a study of 45 growing patients treated with Herbst for an average of 6 months, the upper molars were intruded in 69% of the subjects and distalized in 96%. Pancherz (1997) noted that without retention, effects of the appliance are of a temporary nature. Post-treatment, it has been shown that most of the mandibular morphological changes revert, and in the long term (average of 7.5 years post-treatment), there are no differences in mandibular growth between patients treated with the Herbst appliance and untreated controls. Long-term stability seems to depend on obtaining a stable cuspal interdigitation. For this reason, it is suggested that treatment not be started in the mixed dentition due to the propensity for relapse. Compared to removable functional appliances, the Herbst appliance is said to have the benefits of working 24 hours a day, not being reliant on patient compliance and having a shorter active treatment time.

A known disadvantage of the Herbst appliance is its tendency to procline the mandibular incisors. Martin (2007) investigated this further by studying the mandibular incisor changes based on the amount of bite jumping. During Herbst treatment, intrusion, protrusion and proclination of the lower incisors occurred in all patients. In patients with greater bite jumping (>9.5mm), greater intrusion, protrusion, and proclination were evident. Following treatment with full fixed multibracket appliances, recovering tooth movements occurred in all patients regardless of the amount of bite jumping. Incisor position changes was unaffected by sagittal and vertical jaw relationships, age, and growth period.

Mandibular Anterior Repositioning Appliance (MARA)

The MARA was first described by Eckhart and Toll in 1998. The MARA was introduced as an alternative to the Herbst appliance, with its major advantage being that it treats Class II malocclusion in combination with comprehensive fixed appliances. The MARA uses an inclined plane as an obstacle to be avoided during mandibular movement, thereby inducing the lower jaw to move forward. The appliance consists of crowns cemented on maxillary and mandibular first molars, lower arms soldered to the crowns and upper elbow tubes soldered to the crowns and shimmed to provide the desired advancement. Various modifications of the appliance are possible to allow for expansion, distalization and other desired movements.

Pangrazio-Kulbersh et al. (2003) studied the effects of the MARA in 30 Class II patients (12 boys with average age 11.2 years and 18 girls with average age of 11.2 years) treated for an average of 10.7 months. The results were compared to a non-treated control sample and groups treated with the Fränkel and Herbst appliances from previous reports. In the MARA group, the maxillary molars moved distally 1.1mm while in the control group they moved mesially 1.3mm. Vertical inferior movement of the maxillary first molar was 0.1mm per year in the MARA group compared to 0.9mm per year in the control group. The MARA group showed significant mesial movement of the mandibular molars and incisors (1.2mm and

0.6mm respectively) compared to the control group, which showed 0.5mm mesial molar movement and 0.4mm distal incisor movement. Additionally, the MARA group exhibited significantly greater lower incisor proclination compared to the control group (3.9° versus 0.3°). Vertical movements of the mandibular molars and incisors were not significantly different between the MARA and control groups. Skeletally, maxillary changes were not significantly different between the MARA and control group; therefore the maxilla grew down and forward at the same rate. On the other hand, mandibular skeletal changes were significant. In the MARA group, mandibular length increased 4.8mm compared to 2.1mm in the control group; the chin moved forward an average of 2.3mm versus 0.3mm in the control group. The ANB angle decreased an average of 1.4° in the MARA group compared to 0.1° in the controls. Additionally, mandibular anterior face height increased 2.5mm and posterior face height increased 4.0mm in the MARA patients compared to 1.0mm and 1.3mm, respectively, in the control group. Overall, treatment effects of the MARA appeared to be similar to the Herbst appliance but with less headgear effect and less lower incisor proclination.

Ghislanzoni et al. (2011) investigated the effects of the MARA in 2011. They cephalometrically compared the effects of the appliance in 23 growing patients (treated at pre-pubertal or pubertal stages, as assessed by the cervical vertebral maturation method) to an untreated control group. During the active treatment phase, there was an average increase in mandibular length of 2.2mm and increase in lower incisor proclination of 5.8°. Patients were followed up for an average of 2.4 years after appliance removal. There was a significant relapse tendency for lower incisor proclination (-2.1°) post-treatment. However, increases in mandibular length (2.0mm) and headgear effects of the maxilla (SNA decreased by an average of -1.2°) were significant in the long term.

Another study was conducted by Pangrazio et al. (2012). They examined the cephalometric changes induced by the MARA in 30 growing Class II patients (treated at pre-pubertal or pubertal stages, as assessed by the cervical vertebral maturation method) and compared them to untreated controls. The results of this study were contrasted with previous studies. It was found that while the MARA was effective in restricting maxillary growth, there was no significant enhancement of mandibular growth with the appliance. The Class II correction with the MARA occurred as a result of slight maxillary molar distalization and intrusion along with mesialization of the lower molars and proclination of the lower incisors.

Al-Jewair (2015) completed a meta-analysis on short- and long-term effects of the MARA on mandibular dimensions in growing patients. Overall, seven retrospective controlled studies were used in the analysis. Short-term effects revealed a significant increase in total mandibular unit length (1.16mm per year) and ramus height (1.58mm per year) and non-significant increases in corpus length (0.21mm per year). When analyzing the long-term effects, treatment with MARA showed a statistically significant advantage over controls for all three variables, but the effect sizes were small and may not be clinically significant. In general, the ability of MARA to produce clinically significant changes in mandibular growth is controversial.

Spring Force Delivery Systems

Other methods of non-compliance Class II correction involve the use of spring force delivery systems. A wide variety of these appliances have been designed and have been gaining popularity over the last couple of decades. Among the most popular appliances are the Saif Spring, Jasper Jumper ™, Eureka Spring, Forsus™ Fatigue Resistant Device, and XBow™ Appliance.

Saif Spring

Saif Springs, introduced in the 1960's, are long nickel-titanium closed coil springs used in combination with full fixed appliances to produce Class II intermaxillary traction. They were introduced as a fixed alternative to Class II elastics and the force vector and location of attachment are similar to conventional Class II elastics. The springs are tied in place with steel ligatures. There have been no longitudinal research studies on this appliance, so its effects are not well known.

Jasper Jumper ™

The Jasper Jumper™, introduced in 1994, consists of two vinyl coated auxillary springs fitted to fully bonded fixed orthodontic appliances. The springs are attached to the upper first molars posteriorly and the lower archwire anteriorly. Cope et al. (1994) investigated the effects of the appliance in a group of 31 growing patients (average age of 12.9 years at start of treatment and treated for 0.4 years) and compared them to an untreated, matched control group. The maxilla underwent significant posterior displacement as evidenced by posterior movement of ANS and A-point by 0.91mm per year and 0.60mm per year respectively. There was no evidence of enhanced mandibular growth in patients treated with the Jasper Jumper™ compared to controls. The majority of the Class II correction was due to dental changes. Significant distal movement of the maxillary molars (4.3mm per year) and incisors (4.7mm per year) was evident. Additionally, mandibular molars and incisors exhibited significant mesial movement (4.24 and 5.29mm per year respectively). Overall the net effects of the Jasper Jumper ™ included distal maxillary skeletal and dental movements, mesial mandibular dental movements and clockwise mandibular rotation.

A similar study was conducted by Covell et al. (1999) on 36 growing Class II patients (average age of 13 years 2 months at the time of appliance insertion) treated with the Jasper Jumper ™ (for average of 5 months) compared to an untreated control group. Compared to controls, the treated group showed significant maxillary skeletal restriction (SNA angle decreased 1.6°), clockwise rotation of the occlusal plane (0.6°), and proclination of the lower incisors (5.3°). The maxillary molars were distalized and intruded, while the mandibular molars were mesialized (2.6mm) and extruded (0.9mm). These results are largely in agreement with those found by Cope et al. (1994).

Kucukkeles et al. (2007) also investigated the effects of the Jasper Jumper™ in 45 skeletal Class II growing patients (mean age of 11.83 years pre-treatment). Their results were similar to Cope et al. (1994). The appliance was effective in correcting Class II malocclusion, however, 80% of the changes were dentoalveolar. Maxillary growth was restricted and pogonion moved slightly forward, improving the profile. This forward movement of pogonion compared to the untreated control group is in contrast to the findings of Cope et al. (1994) and Covell et al. (1999).

Eureka Spring™

The Eureka Spring™, introduced in 1997, is another intermaxillary force delivery system. Designed for use with full fixed edgewise appliances, the Eureka Spring utilizes an open wound coil spring encased in a telescoping plunger. The spring attaches to the upper molar headgear tubes and lower archwire distal to the canines. The telescoping mechanism is different from other appliances and allows mouth opening of up to 60 mm.

To date, only one study has described the effects of the Eureka Spring. Stromeyer et al. (2002) investigated the effects of the appliance on 37 consecutively treated bilateral Class II patients (mean age of 16 years at appliance insertion). The average overjet correction of 2.1mm was primarily due to dental changes (90%). The overjet correction resulted from 1.1mm distal movement of the maxillary incisors and 0.8mm mesial movement of the mandibular incisors. Similarly, of the average molar relationship correction of 2.7mm, 93% was due to dental changes. The maxillary molars distalized 0.9mm, while the mandibular molars mesialized 1.6mm. The rate of molar correction was 0.7mm per month. It is important to note that the investigators did not compare the results to a control group. Overall, the Class II correction occurred almost entirely by dentoalveolar movement and the changes were fairly equally distributed between the maxillary and mandibular dentitions.

Forsus™ Fatigue Resistant Device (FRD)

The Forsus™ Fatigue Resistant Device, more simply known as Forsus™, incorporates a superelastic nickel-titanium coil spring with a semirigid telescoping system. The Forsus ™ is used in combination with complete fixed appliances and attaches at the upper first molar headgear tube and anteriorly on the mandibular archwire by a push-rod distal to the canine or first premolar bracket.

Franchi et al. (2011) described the effects of the Forsus™ appliance in 32 consecutively treated, growing Class II patients (mean age 12.8 years pre-treatment) and compared them to a matched, untreated control group. The mean duration of Forsus™ treatment was 5.3 months, while comprehensive treatment was 2.4 years. The treated group showed significant restriction of maxillary sagittal growth as the SNA angle decreased by 1.6° compared to an increase of 0.5° in the control group. Also, the linear length of the maxilla (measured from condylion to A point) increased only 2.2mm in the treated group compared to 3.6mm in the control group. The effective mandibular length (measured from condylion to gnathion) was significantly greater in the Forsus™ group (7.5mm) compared to the control group (5.7mm). The treated group also showed a significantly greater decrease in the ANB angle and Wits appraisal. The lower anterior facial height (measured from anterior nasal spine to menton) increased significantly more in the Forsus™ group (4.0mm compared to 2.7mm in the control group). Dentally, the treatment group showed significant retrusion and extrusion of the maxillary incisors, while movement of the maxillary molars did not differ from the control group (slight extrusion and mesialization). The most significant findings contributing to the Class II correction were found in the mandibular dentition. The mandibular incisors significantly proclined (6.1°) and intruded (0.5mm) compared to controls (0.9° proclination and extrusion of 1.5mm). The mandibular first molars extruded 3.6mm (compared to 0.9mm in controls) and moved mesially 2.4mm (compared to 0.9mm in controls). The authors concluded that the major skeletal effect of the Forsus™ appliance is maxillary restriction and the effects on the mandible are primarily dentoalveolar in nature.

Jones et al. (2008) compared the effects of the Forsus™ appliance to intermaxillary elastics in the treatment of Class II malocclusion. 34 consecutively treated, growing Class II patients (mean age 12.6 years pre-treatment) treated with the Forsus™ appliance were compared to a matched sample of patients treated with intermaxillary elastics (mean age 12.2 years pre-treatment). Average treatment duration was 2.7 years for the Forsus™ group and 2.4 years for the intermaxillary elastics group. Using the pitchfork analysis, in the Forsus™ group, the maxilla moved forward 1.7mm, while the mandible moved forward by 4.4mm. Dentally, the upper molar moved forward 1.2mm, while the lower molar moved forward 1.8mm. The results in the intermaxillary elastic group were very similar; the maxilla and mandible moved forward 1.5mm and 3.8mm respectively, while the upper and lower molars moved forward 0.6mm and 0.7mm respectively. Incisor movement was also similar in both groups and was mainly forward movement of the mandibular incisors. The authors concluded that the effects of the Forsus™ appliance appeared to be comparable to those of intermaxillary elastics and therefore the Forsus™ appears to be a suitable non-compliance alternative to Class II elastics.

Cacciatore et al. (2014) investigated the treatment and post-treatment effects of the Forsus™ appliance in 36 consecutively treated, growing Class II patients (mean age 12.3 years pre-treatment) compared to an untreated control group. Lateral cephalograms were taken immediately prior to starting treatment, at the end of comprehensive treatment (average of 2.3 years) and at a follow-up period (average of 2.3 years from end of comprehensive treatment). At the end of comprehensive treatment, the Forsus™ group showed significant restriction in maxillary saggital position (SNA decreased 1.7°), but no significant mandibular skeletal changes. The maxillary incisors exhibited significant retrusion (1.6mm), while the mandibular incisors showed significant proclination (5.6°) and protrusion (1.5mm). The movement of both the maxillary and mandibular molars was not significantly different than the control group. At the end of the post-retention period, only the dentoalveolar changes remained significant, while no significant saggital or vertical skeletal change was present. Overall, it can be concluded that the Forsus™ appliance is effective in correcting Class II malocclusion, but its effect are at the dentoalveolar level.

Xbow™ (Crossbow)

The Xbow™ Appliance, developed by Dr. Duncan Higgins and introduced in 2006, is another appliance that utilizes Forsus™ springs in Class II correction. The Crossbow consists of a maxillary Hyrax expander and Forsus™ springs. Mandibular labial and lingual bows are used for anchorage. Unlike some other appliances discussed previously in this review, the Crossbow does not allow for simultaneous use of full fixed orthodontic appliances. Instead, the goal of the appliance is to correct the sagittal and transverse dimensions in phase I, followed by full fixed orthodontic appliances in phase II. In theory, phase II should be shorter since the sagittal and transverse correction has already been addressed.

Flores-Mir et al. (2009) investigated the effects of the XBow™ in 67 consecutively treated patients (mean age 11 years, 11 months pre-treatment) compared to an untreated control group. The treatment time with the appliance was an average of 4.5 months. The results were consistent with other studies involving the Forsus™ appliance (Jones et al., 2008; Franchi et al., 2011; Cacciatore et al., 2014). Skeletally, the treated group showed mild restriction of maxillary forward growth, with no changes in mandibular advancement or vertical dimension. Overjet correction was accomplished by lower incisor protrusion. The upper molars were distalized while the lower molars were mesialized. A study by Chana et al. (2013) showed that the effects of the XBow™ appliance are consistent across different facial growth patterns.

AdvanSync™

The focus of the present investigation is the AdvanSync™ appliance, developed by Dr. Terry Dischinger (2010) in conjunction with Ormco™ as a treatment option for skeletal Class II patients. The appliance is described by Ormco™ as an evolution of the Herbst appliance designed to advance the mandible to Class I occlusion within 6 to 9 months, while allowing for simultaneous use of fixed orthodontic appliances. The advantages of the AdvanSync™ are claimed to be shorter overall treatment times since fixed appliances are used simultaneously and there is constant activation with no need for patient compliance. Also, 50% shorter arms compared to traditional Herbst appliances are said to provide more patient comfort, more discrete appearance compared to other Class II appliances and enhanced lateral jaw movements.

The effects of the AdvanSync™ appliance have not been well described in the literature. To date there has only been one published study involving the appliance.

Al-Jewair et al. (2012) investigated the effects of AdvanSync™ in 30 patients treated during their skeletal growth spurt. The comparison groups included 40 patients treated with MARA and an untreated Class II control group (24 subjects) from the University of Michigan growth study. Lateral cephalometric radiographs were taken pre-treatment (T1), post-functional appliance treatment (T2), and at fixed orthodontic treatment completion (T3). When looking at changes from T1 to T2, AdvanSync ™ restricted maxillary growth (SNA decreased 1.6° compared to a 0.4°

increase in the control group and 0.5° decrease in the MARA group). Total length of the mandible (measured from condylion to gnathion) significantly increased with the AdvanSync™ (4.0mm) and MARA (4.5mm) compared to the untreated controls (2.6mm). Ramus heights and anterior and posterior facial heights were also significantly increased in both treatment groups. Dentoalveolar measurements revealed significant retroclination of the maxillary incisors in the AdvanSync™ patients (8.4°) as well as non-significant eruption and distalization of the maxillary molars. Mandibular dental changes were similar in both treatment groups and significant compared to controls. Mandibular incisors proclined 5.3° with AdvanSync™ and 5.4° with MARA™, while mandibular molars mesialized 2.8mm with AdvanSync™ and 3.0mm with MARA™. The post-orthodontic net treatment changes (T3-T1) showed a significant headgear effect in the AdvanSync™ group (SNA decreased 3.3° compared to 0.4° increase in controls and 1.1° decrease in MARA). Total mandibular length was significantly increased with MARA™ (8.1mm) but not AdvanSync™ (5.4mm) compared to controls (5.4mm). There were no statistically significant maxillary dental changes in both treatment groups compared to controls, while mandibular incisors remained significantly proclined (>5.0°) and mandibular molars remained mesialized (>3.0mm). Overall, both MARA and AdvanSync™ were found be effective in normalizing Class II malocclusions. The authors concluded that AdvanSync™ appears to show more headgear effect (maxillary restriction), but less mandibular length enhancement compared to MARA. Both appliances produced similar dentoalveolar changes.

No other studies have been published regarding the effects of AdvanSync™. In order to truly understand the effects of this appliance and determine its suitability for treating Class II patients, more studies need to be completed. The goal of this investigation is to thoroughly investigate the effects of AdvanSync™ by comparing its effects to intermaxillary elastics and also a closely matched untreated control group. No other study has directly compared AdvanSync™ to a compliance based method of Class II correction. The results of this study will provide further insight into the effects of AdvanSync™ as well as determine whether it would be a suitable alternative to Class II elastics in non-compliant patients.

Table 2.1. Summary of Non-Compliance Class II Appliances (McSherry et al., 2000)

Appliance	Indications	Typical Anchorage	Mechanics
Herbst	- Dental Class II malocclusion - Skeletal Class II mandibular deficiency - Upper molar distalization - Lower incisor advancement	Lower lingual arch or lower acrylic splint	Bilateral telescoping mechanism advancing the mandible into new position
Jasper Jumper™	- Dental and skeletal Class II malocclusion with maxillary excess deep bite with retroclined incisors	Fully banded lower arch with torque control	Inter-maxillary springs in compression
MARA	- Skeletal Class II with mandibular deficiency - Lower incisor advancement	Lower lingual arch and transpalatal arch	Bilateral cams fitted to molar stainless steel crowns to advance mandible
Saif Spring	- Class II traction	Fully banded lower arch with torque control	Class II coil spring in tension
Eureka Spring™	- Dental Class II malocclusion - Upper molar distalization - Lower incisor advancement	Fully banded upper and lower arch with torque control with transpalatal arch	Telescopic rods with integral light force compression springs
Forsus™	- Class II traction - Non-compliance alternative to Class II elastics - Lower incisor advancement	Fully banded lower arch with torque control	Intermaxillary Nitinol spring providing reciprocal push forces distally against upper molar and mesially against lower canine or premolar
AdvanSync™	To be determined	Fully banded upper and lower arch with torque control	Bilateral telescoping mechanism attached to first molars advancing the mandible into new position

Chapter 3

Purpose

This study aims to comprehensively investigate the skeletal, dentoalveolar and soft tissue effects of the AdvanSync™ appliance in conjunction with comprehensive multi-bracket orthodontic appliances in the correction of Class II malocclusions in growing patients. AdvanSync™ will be compared to a typical compliance based method of Class II correction – intermaxillary elastics (Class II elastics). Patients treated with AdvanSync™ and intermaxillary elastics will also be compared to a non-treated Class II sample generated from historical databases.

Chapter 4

Null Hypotheses

1. There are no statistically significant differences regarding the skeletal, dentoalveolar and soft tissue changes observed with multi-bracket orthodontic treatment in conjunction with AdvanSync™ compared to intermaxillary Class II elastics in patients with skeletal Class II malocclusions.

2. There are no statistically significant differences regarding the skeletal, dentoalveolar and soft tissue changes observed with multi-bracket orthodontic treatment in conjunction with AdvanSync™ and/or intermaxillary Class II elastics compared to spontaneous growth in untreated controls.

Chapter 5

Materials and Methods

5.1 Sample Selection

Ethics approval for this study was obtained in June 2014 from the University of Manitoba Health Research Ethics Board. Treatment samples (AdvanSync™ and Class II elastics patients) were all obtained from a single private orthodontic practice in Stadskanaal, Netherlands. Records and data that were obtained for each patient included dated pre-treatment and post comprehensive treatment cephalometric radiographs, gender, date of birth, and date of AdvanSync™ insertion and removal. Pre-treatment overjet and severity of Class II malocclusion (molar relationship) was also obtained from clinical exam notes. The Kodak 8000C digital imaging system (Carestream Health, Inc. Rochester, NY) was used for all digital radiographs.

The AdvanSync™ and Class II elastics subjects were selected based on the following inclusion criteria:

1. Pre-treatment Class II malocclusion of ½ cusp or end-to-end at the molars or greater
2. Skeletal Class II indicated by ANB angle >4°
3. Post-treatment molar relationship at or very near Angle Class I
4. Pre-pubertal stage of development before commencing treatment according to the cervical vertebral maturation (CVM) method (stage 1-3)
5. Post-pubertal stage of development at treatment completion according to the cervical vertebral maturation method (stage 4-6)
6. No missing teeth (excluding 3rd molars)
7. Patients treated only with Class II elastics and/or AdvanSync™ in combination with conventional fixed appliances (non-extraction)
8. Available pre- and post-treatment (or just prior to debonding) cephalometric radiographs of acceptable quality
9. No syndromes or craniofacial anomalies present
10. No medical condition or prescription medication that may affect growth

Initially, records and data of 46 patients consecutively treated with AdvanSync™ were obtained. Two patients were excluded due to initial ANB of <4°. One other patient was excluded due to post-comprehensive treatment molar relationship of ¼ cusp Class II. Another patient was excluded due to inadequate cephalometric radiographs. Finally, one other patient was excluded for not being post-pubertal at the end of treatment as assessed by the CVM method (Baccetti et al., 2005). Therefore the AdvanSync™ sample consisted of 41 patients.

Records of 43 patients treated with Class II elastics were also obtained. These patients were randomly selected (with the exception of gender matching to the AdvanSync™ group) from the database of treated patients between 2009 and 2013. One patient was excluded due to an initial ANB of <4°. Another patient was excluded for not being post-pubertal at the end of treatment. Therefore the Class II elastics sample also consisted of 41 patients.

A sample of untreated Class II subjects was selected from the historical databases of the Michigan and Bolton-Brush growth studies. 45 subjects were initially chosen to match the treated groups in terms of age, gender and observation period. After cephalometric analysis, four subjects were excluded due to initial ANB values of <4° and another four were excluded for not being post-pubertal at the end of the observation period. Therefore, the untreated Class II control sample consisted of 37 subjects.

Table 5.1. Descriptive Statistics for Treatment and Control Groups

Group	Mean (±SD) Age at T1, years	Mean (±SD) Age at T2, years	Observation Period (±SD), years	Males/Females
AdvanSync™	11.55 ± 1.58	14.30 ± 1.33	2.74 ± 0.88	24/17
Class II Elastics	11.54 ± 1.45	14.40 ± 1.38	2.85 ± 0.43	24/17
Control	11.55 ± 0.58	14.34 ± 0.66	2.79 ± 0.61	22/15

Patients in the AdvanSync™ and Class II elastics groups were treated in a similar fashion by a single practitioner (Dr. Sandra Hayasaki in Stadskanaal, Netherlands). All patients were treated with the same prescription of Damon™ Q brackets (.022" x .028" slot size) and archwire sequencing was consistent in the two groups (.014" CuNiTi, .018" CuNiTi, .014 x .025 CuNiTi, .018 x .025 CuNiTi and .019 x .025 TMA). All patients were initially prescribed elastics in order to correct the Class II malocclusion. In compliant patients, elastics were used until the sagittal discrepancy was corrected (approximately 22-24 months). Elastics were typically ¼ inch and 3.5 oz. (supplied by ORMCO™). In patients who were not compliant with elastics, the AdvanSync™ appliance was installed and utilized to correct the malocclusion. In these patients, due to the non-compliance, the molar relationship had not improved since the start of treatment. AdvanSync™ was utilized following a similar protocol to that suggested by Dr. Dischinger, who helped develop the appliance (Al-Jewair et al., 2012). The appliance was activated in increments until an edge-to-edge incisor relationship was achieved. Following slight overcorrection of the sagittal discrepancy, the appliance was removed and treatment was finished with the conventional appliances. Average length of AdvanSync™ treatment was 12.5 months (± 1.5 months). Interproximal reduction was not utilized in any of the AdvanSync™ or Class II elastics patients. Intraoral photographs of AdvanSync™ and the pre-adjusted edgewise appliances used in this study are shown in Figure. 5.1.

Figure 5.1. Intraoral Photographs of AdvanSync™ and Pre-adjusted Edgewise Appliances

The AdvanSync™ and Class II elastics groups were treated in a similar fashion, except for the method of Class II correction. As one single practitioner treated all the patients, the variation in treatment technique was controlled. It is important to note that all of the patients in both treatment groups were initially planned for Class II correction with Class II elastics only. As treatment progressed, some patients showed non-compliance with elastic wear and were then prescribed the AdvanSync™ appliance as a fixed alternative. Therefore, some AdvanSync™ patients may have worn Class II elastics for some time prior to insertion of the appliance, but due to their non-compliance, the severity of their malocclusion did not improve during this time. Most were also requested to wear elastics after removal of the appliance in order to maintain the occlusal relationship, which is common practice following use of any Class II corrector or functional appliance. Nonetheless, the AdvanSync™ was the appliance that produced the substantial Class II correction in these patients, and is the only major difference in treatment between the two groups (AdvanSync™ and Class II elastics).

5.2 Data Collection

The pre and post-treatment cephalometric radiographs were imported into commercial software (Dolphin Digital Imaging system version 11.7, Chatsworth, CA, USA). For the AdvanSync™ and Class II elastics patients, the magnification of the radiographs was accounted for using known ruler measurements that were captured on the cephalograms. The radiographs from the Michigan growth study and the Bolton Brush study had magnifications of 12.9% and 6% respectively. In order to standardize the radiographs to match those of the treated groups, the magnifications were corrected to 0%. Radiographs were digitally traced using a custom digitized analysis, adapted and modified from Al-Jewair et al. (2012), which included 37 landmarks and produced 31 measurements. The analysis included a combination of variables described by Steiner (1953), Jacobson (1975), Ricketts (1981), and McNamara (1984).

Regional superimpositions were conducted manually in order to evaluate sagittal and vertical dentoalveolar changes. Overall craniofacial treatment changes were evaluated by superimposing on the S-N line, registering at Sella (Al-Jewair et al., 2012). Maxillary superimpositions were made along the palatal plane, registering at on the internal structures of the maxilla and the surfaces of the hard palate (Ricketts, 1981; McNamara, 1984). Mandibular superimpositions were made on the inner contour of the posterior symphysis, the outline of the inferior mandibular canal, and the germ of the third molar, if present (Ricketts 1981; McNamara, 1984). Once superimposed, the vertical and sagittal changes of the maxillary and mandibular incisors and molars could be measured using the method described by McNamara et al. (1984). Skeletal maturity was also assessed on each radiograph, using the cervical vertebral maturation (CVM) method outlined by Baccetti et al. (2005), in order to ensure that the treated subjects still had significant growth potential remaining.

The principle investigator carried out all tracings and measurements. The same investigator retraced 15% of the sample (randomly selected), including CVM assessments, three weeks following completion of initial data collection in order to test for intra-rater reliability. A second investigator (first year orthodontic resident at the University of Manitoba) also traced the randomly selected sample to test for inter-rater reliability.

5.3 Cephalometric Analysis

A cephalometric landmark is a distinguishable point on a radiograph that represents the location of an anatomical structure (may be hard or soft tissue). Constructed landmarks are not true anatomic structures, but are formed by the intersection of lines. Cephalometric planes or lines are drawn by connecting various landmarks. The landmarks and planes are then used for numerical determination of cephalometric measurements. The measurements will vary based on the specific cephalometric analysis utilized. In this study, landmarks from the Ricketts, Steiner and McNamara analyses were used (Steiner, 1953; Ricketts, 1981; McNamara, 1984). The cephalometric landmarks used in this study are illustrated in Figure 5.2 and described in Table 5-2. The cephalometric measurements used in this study are described in Table 5-3.

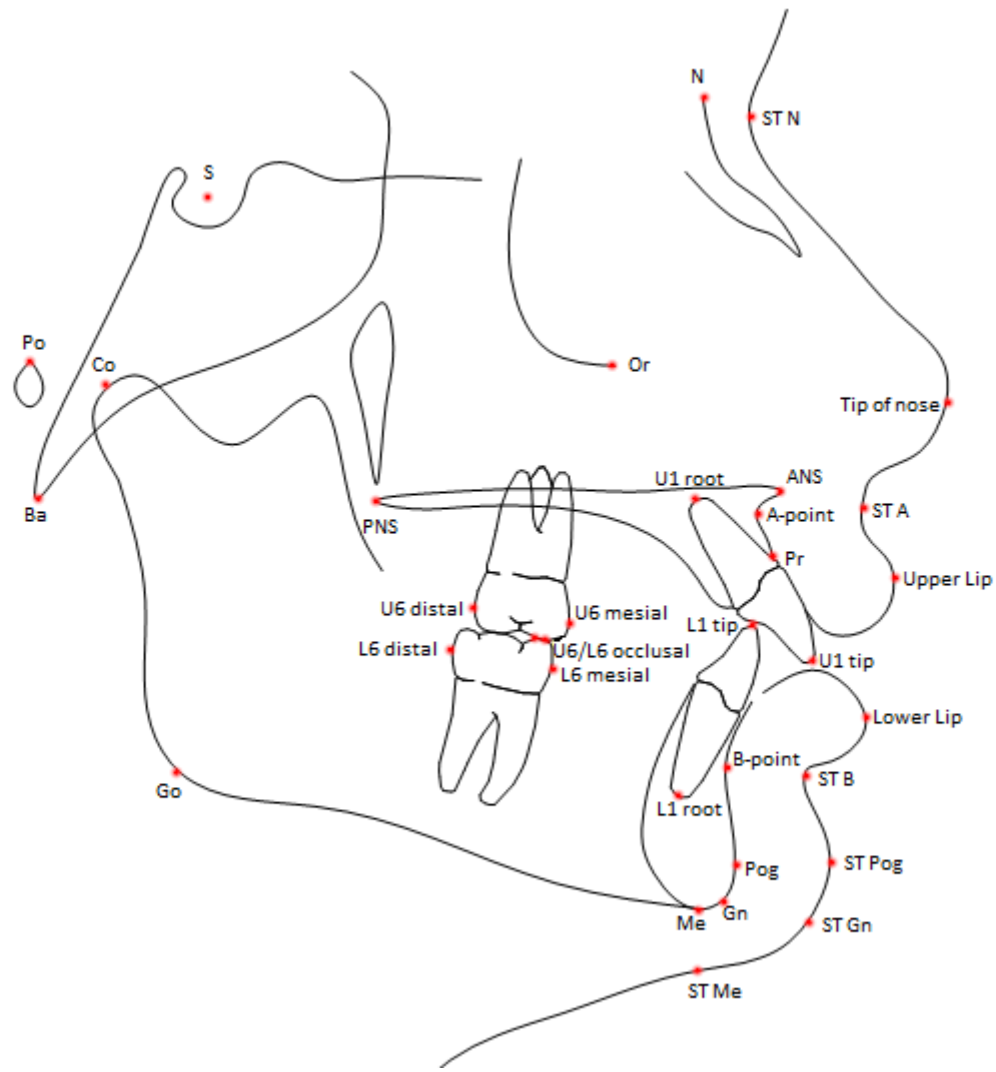

Figure 5.2. Illustration of Cephalometric Landmarks

Table 5.2. Description of Cephalometric Landmarks (Broadbent, 1975 & Jacobson, 1995)

Landmark	Description
Skeletal	
A-point (Subspinale, ss)	Deepest, most posterior midline point on the curvature between the ANS and prosthion.
Anterior nasal spine (ANS)	Tip of the bony anterior nasal spine at the inferior margin of the piriform aperture, in the midsagittal plane.
B-point (Point B, Supramentale, sm)	Deepest most posterior midline point on the bony curvature of the anterior mandible, between infradentale and pogonion.
Basion (Ba)	Most anterior inferior point on the margin of the foramen magnum, in the midsagittal plane. Located on the inferior border of the basilar part of the occipital bone to its posterior limit, superior to the dens of the axis.
Condylion (Co)	Most superior posterior point on the head of the mandibular condyle.
Glabella (G)	Most prominent point of the anterior contour of the frontal bone in the midsagittal plane.

Gnathion (Gn)	Most anterior inferior point on the bony chin in the midsagittal plane. A constructed landmark by using the mid point between the anterior (pogonion) and inferior (menton) points of the bony chin.
Gonion (Go)	Most posterior inferior point on the outline of the angle of the mandible. Constructed by bisecting the angle formed by the intersection of the mandibular plane and the ramal plane and by extending the bisector through the mandibular border.
Menton (Me)	Most inferior point of the mandibular symphysis, in the midsagittal plane.
Nasion (N, Na)	Intersection of the internasal and frontonasal sutures, in the midsagittal plane.
Orbitale (Or, O)	Lowest point on the inferior orbital margin.
Pogonion (Pog, P, Pg)	Most anterior point on the contour of the bony chin, in the midsagittal plane.
Porion (Po)	Most superior point of the outline of the external auditory meatus.
Posterior nasal spine (PNS)	Most posterior point on the bony hard palate in the midsagittal plane; the meeting point between the inferior and the superior surfaces of the bony hard palate (nasal floor) at its posterior aspect. Located by

	extending the anterior wall of the pterygopalatine fossa inferiorly, until it intersects the floor of the nose.
Prosthion (Pr, Superior prosthion, Supradentale)	The most inferior anterior point on the maxillary alveolar process, between the central incisors.
Sella (S)	The geometric center of the pituitary fossa (sella turcica).
Soft Tissue	
Lower Lip	Most anterior point on the curve of the lower lip.
Soft tissue A-point (ST A-point)	Most concave point between subnasale and the anterior point of the upper lip.
Soft tissue B-point (ST B-point)	Most concave point between the lower lip and the soft tissue chin.
Soft tissue Gnathion (ST Gn)	The midpoint between the most anterior and inferior points of the soft tissue chin in the midsaggital plane.
Soft tissue Menton (ST Me)	The most inferior point of the soft tissue chin.
Soft tissue Nasion (ST N)	Soft tissue profile's most concave point where the bridge of the nose meets the frontal bone.
Soft tissue Pogonion (ST Pog)	Point on the anterior curve of the soft tissue chin.
Tip of nose (pronasale)	Point of the most anterior curve of the nose.
Upper Lip	Most anterior point on the curve of the upper lip.

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

Table 5.3. Description of Cephalometric Measurements (Broadbent, 1975 & Jacobson, 1995)

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

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

		measurement. An evaluation of the anteroposterior relationship between the maxilla and mandible.
Mx/Md Diff, mm	Co, Gn, ANS	The linear distance between condylion and ANS subtracted from the linear distance between condylion and gnathion. Measurement of the difference in length of the maxilla and mandible.
Convexity, mm	N, A-point, Pog	Linear distance between A-point and the N-Pog line. Measurement of the anteroposterior relationship between the maxilla and mandible.
Vertical Skeletal		
PP, °	Po, Or, ANS, PNS	The posterior angle formed by the palatal plane (anterior nasal spine and posterior nasal spine) and the FH plane. Measurement of the steepness of the palatal plane.
FMA, °	Po, Or, Go, Me	The anterior-inferior angle formed by the Frankfort Horizontal plane and the Mandibular line (gonion-menton). Assessment of the steepness of the mandibular plane; indicator of mandibular growth direction.
MPA, °	S, N, Go, Me	The anterior-inferior angle formed by the S-N

		line and the Go-Me line. Assessment of the steepness of the mandibular plane relative to the cranial base; indicator of growth pattern.
Y-axis, °	N, S, Gn	The anterior-inferior angle formed by the S-N line and the Gn-S line. Assessment of the direction of mandibular growth.
LFH, mm	ANS, Me	The linear distance from Menton to ANS. The linear measurement gives an indication of the growth pattern.
Maxillary Dentoalveolar		
U1-A perp, mm	Po, Or, A-point, U1-tip	The linear distance between the A-perpendicular (to FH) line and the U1 tip. Assessment of the anteroposterior position of the maxillary incisors.
U1-FH, °	Po, Or, U1 tip, U1 root	The posterior-inferior angle formed by the long axis of the maxillary central incisor and the FH plane. An assessment of the angulation of the maxillary incisors.
U1-SN, °	S, N, U1 tip, U1 root	The posterior-inferior angle formed by the long axis of the maxillary central incisor and the S-N line. An assessment of the angulation of the

		maxillary incisors.
Mandibular Dentoalveolar		
L1-APo, mm	L1 tip, A-point, Pog	The linear distance from the incisal edge of the mandibular central incisor to the A-Pog line. An assessment of the anteroposterior position of the mandibular incisors.
IMPA, °	Go, Me, L1 tip, L1 root	The posterior-superior angle between the long axis of the mandibular central incisor and the mandibular plane (Go-Me). An assessment of the angulation of the mandibular incisors.
Interdental		
OJ, mm	U1/L1 tip, U6/L6 occlusal	The distance between the incisal edges of the upper and lower central incisors measured along the occlusal plane (line from horizontal bisection of U6/L6 occlusal and U1/L1 tip).
OB, mm	U1/L1 tip, U6/L6 occlusal	The vertical distance between the incisal edges of the upper and lower central incisors measured perpendicular to the occlusal plane.
U1/L1, °	U1/L1 tip, U1/L1 root,	The intercisal angle, which is the posterior angle formed at the intersection of the long axes of the

		maxillary and mandibular central incisors.
Molar relation, mm	Distal U6/L6 U6/L6 occlusal, U1/L1 tip	The distance from between the distal crown convexities of the upper and lower permanent first molars, measured along the occlusal plane. Positive value denotes mesial position of upper molar relative to lower molar and vice versa.
Soft Tissue		
A-VRL, mm	S, N, ST A-point	Linear distance from ST A-point to VRL (vertical reference line which is drawn from sella and is perpendicular to the S-N line). Allows for measurement of maxillary soft tissue changes (ST A-point) by use of a stable posterior VRL.
B-VRL, mm	S, N, ST B-point	Linear distance from ST B-point to VRL. Allows for measurement of mandibular soft tissue changes (ST B-point) by use of a stable posterior VRL.
Pg-VRL, mm	S, N, ST Pg	Linear distance from ST Pg to VRL. Allows for measurement of mandibular soft tissue changes (ST Pg) by use of a stable posterior VRL.
U lip to E-plane, mm	Tip of nose, ST Pg, Upper	Linear distance from the upper lip to a line connecting the tip of the nose and the most

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

5.4 Statistical Analysis

Statistical software, SAS 9.2 (SAS Institute Inc. Cary, NC), was used to analyze the data. All variables collected in this study were continuous with the exception of CVM values. Normal distribution of all continuous study variables was confirmed initially. Descriptive statistics were performed and reported as mean, standard deviation and 95% confidence interval for all variables within each group.

Comparison of initial and post-treatment forms (cephalometric values) of the treatment groups and the control group was carried out by one-way analysis of variance (ANOVA). If ANOVA results were significant, the Tukey-Kramer test was used to determine where the significant differences occurred and adjust for multiple comparisons. Initial and post-treatment CVM values were compared between the three groups using the Fisher's Exact test. Inter- and intra-rater reliability was examined using Intraclass Correlation (ICC) tests. All statistical tests were interpreted at the 5% significance level.

Chapter 6

Results

6.1 Comparison of Initial Measurements (T1) of Treatment and Control Groups

In order to appreciate post-treatment changes within the groups, it is important to know the starting point in each group. The sample characteristics of the 3 groups are shown in Table 6.1. The patients within each group had nearly an identical age at T1 (11.5 years), while the overall follow-up time was also very similar (range from 2.74 years to 2.85 years). In order to exclude gender biases, the male to female ratios was also accounted for in each group. There was a ratio of approximately 59% males to 41% females in each group. From these characteristics, it is clear that the treatment and control groups are closely matched in terms of age, follow-up time and gender.

Table 6.1. Comparisons of Sample Characteristics

Group	Mean (±SD) Age at T1, years	ANOVA Sig	Mean (±SD) Obs. Time, years	ANOVA Sig	Male:Female %
AdvanSync™	11.55 ± 1.58	0.99	2.74 ± 0.90	0.76	58.5:41.5
Class II Elastics	11.54 ± 1.45		2.85 ± 0.44		58.5:41.5
Control	11.55 ± 0.58		2.79 ± 0.62		59.5:40.5

The initial cephalometric characteristics of the treatment and control groups are shown in Table 6.2. The significance levels of comparisons between the three groups, obtained from ANOVA and Tukey-Kramer tests, are also reported. Negative values indicate a posterior position of the landmark with respect to the reference plane.

Table 6.2. Comparisons of Initial Parameters

Variables	AdvanSync™ (A) Mean ± SD	Class II Elastics (E) Mean ± SD	Control (C) Mean ± SD	Significance A-C	E-C	A-E
Cranial Base						
Ba-S-N, °	131.97 ± 4.23	130.93 ± 4.12	131.17 ± 4.59	0.70	0.97	0.52
Maxillary Skeletal						
SNA, °	81.25 ± 3.96	81.28 ± 3.35	80.19 ± 3.46	0.40	0.38	0.99
A-Na Perp, mm	-1.07 ± 3.38	-0.01 ± 2.87	-1.97 ± 2.98	0.40	<0.01*	0.27
Co-A, mm	81.75 ± 4.39	80.94 ± 3.36	80.73 ± 3.89	0.48	0.97	0.61
Mandibular Skeletal						
SNB, °	76.10 ± 3.47	75.44 ± 3.33	75.24 ± 2.81	0.47	0.96	0.63
Pg-Na Perp, mm	-8.33 ± 6.27	-8.13 ± 5.73	-10.28 ± 4.46	0.27	0.20	0.99
Co-Gn, mm	106.11 ± 5.43	104.86 ± 5.14	105.36 ± 5.39	0.81	0.91	0.54
Co-Go, mm	52.56 ± 4.20	50.76 ± 4.09	50.45 ± 4.37	0.07	0.94	0.14
Inter-maxillary						
ANB, °	5.14 ± 0.75	5.49 ± 0.83	5.17 ± 0.97	0.99	0.71	0.65
Wits, mm	4.16 ± 2.22	4.31 ± 2.18	3.05 ± 1.90	0.06	0.02*	0.94
Mx/Md Diff, mm	21.50 ± 3.56	20.95 ± 3.91	21.86 ± 4.04	0.91	0.55	0.80
Convexity, mm	3.26 ± 2.13	3.80 ± 1.74	3.45 ± 2.21	0.91	0.72	0.45
Vertical Skeletal						
PP, °	1.78 ± 3.09	2.55 ± 2.67	0.01 ± 3.91	0.06	<0.01*	0.53
FMA, °	24.67 ± 4.66	25.22 ± 5.14	26.54 ± 3.35	0.16	0.40	0.84

MPA, °	32.83 ± 5.22	33.97 ± 5.29	34.23 ± 4.03	0.42	0.97	0.55
Y-axis, °	67.94 ± 3.51	68.97 ± 3.63	68.04 ± 3.50	0.99	0.48	0.39
LFH, mm	60.86 ± 4.81	61.22 ± 5.05	60.40 ± 4.78	0.91	0.74	0.94
Maxillary Dentoalveolar						
U1-A perp, mm	3.35 ± 3.00	4.65 ± 2.23	3.05 ± 2.27	0.86	0.02*	0.06
U1-FH, °	110.34 ± 8.94	113.80 ± 6.97	109.88 ± 6.10	0.96	0.06	0.09
U1-SN, °	102.69 ± 9.07	105.05 ± 7.26	102.19 ± 6.02	0.96	0.22	0.34
Mandibular Dentoalveolar						
L1-APo, mm	-0.23 ± 2.57	-0.05 ± 2.34	1.24 ± 2.37	0.02*	0.06	0.94
IMPA, °	97.29 ± 5.72	94.26 ± 6.21	98.13 ± 5.98	0.81	<0.01*	0.06
Interdental						
OJ, mm	6.80 ± 2.40	8.21 ± 2.22	5.83 ± 1.77	0.12	<0.01*	<0.01*
OB, mm	4.68 ± 2.56	4.65 ± 2.21	5.01 ± 2.15	0.81	0.78	0.99
U1/L1, °	128.67 ± 13.4	126.72 ± 8.46	125.46 ± 8.93	0.37	0.86	0.68
Molar relation, mm	2.16 ± 1.15	1.94 ± 1.37	1.50 ± 1.00	0.04*	0.24	0.67
Soft Tissue						
A-VRL, mm	77.80 ± 4.78	76.51 ± 4.46	78.54 ± 4.60	0.78	0.16	0.41
B-VRL, mm	67.03 ± 5.41	63.61 ± 6.12	67.04 ± 4.95	1.00	0.03*	0.02*
Pg-VRL, mm	68.42 ± 6.95	65.26 ± 7.11	68.17 ± 5.76	0.99	0.17	0.09
U lip to E-plane, mm	-1.43 ± 2.81	-0.45 ± 2.01	-0.11 ± 2.39	0.06	0.83	0.16
L lip to E-plane, mm	-1.02 ± 3.18	-0.51 ± 2.75	0.73 ± 2.78	0.04*	0.18	0.71

* p significant if ≤0.05

Maxillary skeletal characteristics were shown to be well matched among the three groups, as there were no significant differences in the SNA angles and Co-A measurements. The only significant difference was the A-Na Perp measurements between the Class II elastics and control group (-0.01mm vs -1.97mm; $p<0.01$). The mandibular skeletal measurements were also closely matched since there were no statistically significant differences in the SNB angles and Pg-Na Perp, Co-Gn and Co-Go measurements. Intermaxillary skeletal measurements indicated no major differences in terms of the ANB angle, Mx/Mn Diff, and Convexity. However, the Wits appraisal was statistically significant between the Class II elastics and control group (4.31mm vs 3.05mm; $p<0.05$). Vertical skeletal measurements were closely matched in terms of the FMA, MPA, Y-axis and LFH. The palatal plane angle was significantly different when comparing the Class II elastics group to the control group (2.55° vs 0.01°; $p<0.01$).

Maxillary incisor angulation was not significantly different among the three groups according to U1-FH and U1-SN angles. U1-A perp was increased in the Class II elastics group compared to the controls (4.65mm vs 3.05mm; $p<0.05$). Mandibular incisors in the AdvanSync™ group appear to be slightly retruded compared to the control group (L1-APo of -0.23mm vs 1.24mm; $p<0.05$). Also, the lower incisors in the Class II elastics group appeared to be slightly retroclined compared to the controls (IMPA of 94.26° vs 98.13°; $p<0.01$).

The initial overjet in Class II elastics patients (8.21 mm) was greater than the AdvanSync™ (6.80 mm; $p<0.01$) and control patients (5.83 mm; $p<0.01$). The initial molar relation was slightly more Class II in the AdvanSync™ group compared to the control group ($p<0.05$). Soft tissue characteristics were well matched among the groups except B-VRL was reduced in the Class II elastics group (63.61 mm) compared to AdvanSync™ (67.03 mm; $p<0.01$) and controls (67.04 mm; $p<0.01$). Also, L lip to E-plane measurements indicated that the lower lip in AdvanSync™ patients (-1.02 mm) was slightly retruded compared to the control group (0.73 mm; $p<0.05$).

6.2 Comparison of Changes (T2-T1) in AdvanSync™ and Control Groups

The changes in cephalometric measurements over the follow-up period in the AdvanSync™ and control groups are reported in Table 6.3. The significance levels of comparisons between the groups, obtained from ANOVA and Tukey-Kramer tests, are also reported. Vertical dentoalveolar changes are reported as positive for extrusive movements and negative for intrusive movements. Horizontal dentoalveolar movements are reported as positive for mesial movements and negative for distal movements.

Table 6.3. Comparison of Changes (T2 – T1) in AdvanSync™ and Control Groups

Variables	**AdvanSync™ (A)** Mean ± SD	**Control (C)** Mean ± SD	**Diff** A-C	**Sig**
Maxillary Skeletal				
SNA, °	-2.05 ± 1.39	0.52 ± 1.71	-2.57	<0.01*
A-Na Perp, mm	-1.99 ± 1.34	0.01 ± 1.88	-2.00	<0.01*
Co-A, mm	1.66 ± 2.84	4.19 ± 3.00	-2.53	<0.01*
Mandibular Skeletal				
SNB, °	0.41 ± 1.24	0.74 ± 1.44	-0.33	0.54
Pg-Na Perp, mm	0.79 ± 1.97	0.38 ± 2.94	0.41	0.76
Co-Gn, mm	7.53 ± 4.09	7.01 ± 2.57	0.52	0.78
Co-Go, mm	5.03 ± 3.65	4.49 ± 2.83	0.54	0.71
Inter-maxillary				
ANB, °	-2.46 ± 1.18	-0.20 ± 1.20	-2.26	<0.01*
Wits, mm	-3.80 ± 1.73	0.54 ± 1.89	-4.34	<0.01*
Mx/Md Diff, mm	5.58 ± 2.67	3.21 ± 2.76	2.37	<0.01*
Convexity, mm	-2.47 ± 1.24	-0.24 ± 1.23	-2.23	<0.01*
Vertical Skeletal				
PP, °	-0.13 ± 1.92	-0.80 ± 2.08	0.67	0.31
FMA, °	-0.32 ± 2.23	-0.46 ± 1.59	0.14	0.93
MPA, °	-0.39 ± 2.56	-0.84 ± 1.55	0.45	0.57
Y-axis, °	0.37 ± 1.30	0.11 ± 1.15	0.26	0.66

LFH, mm	3.70 ± 2.42	3.41 ± 2.07	0.29	0.84
Maxillary Dentoalveolar				
U1-A perp, mm	0.20 ± 2.74	-0.32 ± 1.44	0.52	0.60
U1-FH, °	-1.23 ± 8.54	-1.55 ± 3.64	0.32	0.98
U1-SN, °	-1.17 ± 8.57	-1.16 ± 3.28	-0.1	1.00
U1-vertical, mm	1.7 ± 1.7	0.9 ± 1.1	0.8	0.03*
U1-horizontal, mm	0.3 ± 2.7	0.2 ± 1.6	0.1	0.99
U6-vertical, mm	1.7 ± 1.4	2.4 ± 1.3	-0.7	0.09
U6-horizontal, mm	1.8 ± 2.3	1.3 ± 1.6	0.5	0.53
Mandibular Dentoalveolar				
L1-APo, mm	3.39 ± 2.00	-0.08 ± 1.35	3.47	<0.01*
IMPA, °	8.98 ± 6.83	0.36 ± 3.70	8.62	<0.01*
L1-vertical, mm	-0.6 ± 2.2	2.4 ± 1.3	-3.0	<0.01*
L1-horizontal, mm	1.9 ± 2.5	0.1 ± 1.4	1.8	<0.01*
L6-vertical, mm	2.4 ± 1.7	1.7 ± 1.4	0.7	0.09
L6-horizontal, mm	2.6 ± 1.5	1.3 ± 1.3	1.3	<0.01*
Interdental				
OJ, mm	-4.21 ± 2.25	-0.57 ± 1.40	3.64	<0.01*
OB, mm	-2.92 ± 2.51	0.09 ± 1.29	-2.99	<0.01*
U1/L1, °	-7.44 ± 12.02	1.63 ± 5.03	9.07	<0.01*
Molar relation, mm	-4.90 ± 1.50	-0.19 ± 0.88	4.71	<0.01*

Soft Tissue				
A-VRL, mm	2.10 ± 2.78	3.51 ± 3.22	-1.41	0.08
B-VRL, mm	3.17 ± 3.48	3.19 ± 3.21	-0.02	1.00
Pg-VRL, mm	3.55 ± 3.75	4.34 ± 3.55	-0.79	0.63
U lip to E-plane, mm	-2.54 ± 1.90	-1.84 ± 2.34	-0.70	0.27
L lip to E-plane, mm	-1.00 ± 2.13	-1.80 ± 2.41	0.80	0.28

* p significant if ≤0.05

The AdvanSync™ group showed significant skeletal maxillary growth restriction compared to the controls (SNA, A-Na Perp, Co-A; $p<0.01$). In contrast, all skeletal mandibular changes were not statistically significant. The inter-maxillary skeletal measurements all showed highly significant improvements towards Class I in the AdvanSync™ patients compared to the control group (ANB, Wits, Mx/Md Diff, Convexity; $p<0.01$). Vertical skeletal changes were not significantly different between the two groups. Most of the maxillary dentoalveolar changes were not significantly different, with the exception of greater maxillary incisor extrusion in the AdvanSync™ group (U1-vertical; $p<0.05$). Mandibular incisors displayed significant protrusion and proclination in AdvanSync™ patients compared to controls (L1-APo, L1-horizontal, IMPA; $p<0.01$). Mandibular molars showed significant mesial movement in the AdvanSync™ group (L6-horizontal; $p<0.01$). There was also greater extrusion of the lower molars in the treated group; however, the difference was not statistically significantly. Interdental changes were all statistically significant ($p<0.01$). The AdvanSync™ patients experienced significant reduction of overjet, overbite, and interincisal angle, while the molar relationship also showed significant improvement towards Class I (OJ, OB, U1/L1, Molar relation; $p<0.01$). Soft tissue changes were not statistically significant.

6.3 Comparison of Changes (T2-T1) in Class II Elastics and Control Groups

The changes in cephalometric measurements over the follow-up period in the Class II elastics and control groups are reported in Table 6.4. Maxillary skeletal changes in Class II elastics patients and the control group were insignificant according to SNA and A-Na Perp. However, Co-A measurements did indicate significant maxillary restriction in the elastics group ($p<0.05$). Mandibular skeletal changes were not significant. Improvement of inter-maxillary skeletal relationship in the elastics group was significant in terms of ANB and Wits ($p<0.05$), but insignificant with regards to Mx/Mn Diff and convexity. Vertical skeletal changes were not significantly different in the Class II elastic group and control group. Maxillary incisors in the elastics group showed significant retrusion (U1-A Perp, U1-horizontal; $p<0.01$), retroclination (U1-FH, U1-SN; $p<0.01$), and insignificant extrusion compared to the controls. Maxillary molar movement was not significantly different. Mandibular incisors displayed highly significant protrusion, proclination and intrusion in the treated group (L1-APo, L1-horizontal, IMPA, L1-vertical; $p<0.01$), while mandibular molars displayed mesial movement (L6-horizontal; $p<0.01$) and extrusion (not statistically significant). Class II elastics patients experienced significant reduction in overjet and overbite, as well as improvement of the molar relationship towards Class I (OJ, OB, Molar relation; $p<0.01$). Soft tissue changes were insignificant, with the exception of greater forward movement of the lower lip (L lip to E-plane; $p<0.05$) in elastics patients compared to the control group.

Table 6.4. Comparison of Changes (T2 – T1) in Class II Elastics and Control Groups

Variables	Class II Elastics (E) Mean ± SD	Control (C) Mean ± SD	Diff E-C	Sig
Maxillary Skeletal				
SNA, °	-0.17 ± 1.26	0.52 ± 1.71	-0.69	0.10
A-Na Perp, mm	-0.23 ± 1.32	0.01 ± 1.88	-0.24	0.78
Co-A, mm	2.63 ± 2.09	4.19 ± 3.00	-1.56	0.03*
Mandibular Skeletal				
SNB, °	0.80 ± 1.37	0.74 ± 1.44	0.06	0.97
Pg-Na Perp, mm	1.07 ± 2.70	0.38 ± 2.94	0.69	0.46
Co-Gn, mm	7.11 ± 3.30	7.01 ± 2.57	0.10	0.99
Co-Go, mm	4.69 ± 2.40	4.49 ± 2.83	0.20	0.95
Inter-maxillary				
ANB, °	-0.97 ± 1.32	-0.20 ± 1.20	-0.77	0.02*
Wits, mm	-2.70 ± 1.86	0.54 ± 1.89	-3.24	<0.01*
Mx/Md Diff, mm	4.44 ± 2.76	3.21 ± 2.76	1.23	0.12
Convexity, mm	-0.79 ± 1.26	-0.24 ± 1.23	-0.55	0.13
Vertical Skeletal				
PP, °	-0.58 ± 2.08	-0.80 ± 2.08	0.22	0.88
FMA, °	0.11 ± 1.58	-0.46 ± 1.59	0.57	0.35
MPA, °	0.07 ± 1.59	-0.84 ± 1.55	0.91	0.11
Y-axis, °	0.33 ± 1.46	0.11 ± 1.15	0.22	0.75

LFH, mm	4.61 ± 2.34	3.41 ± 2.07	1.20	0.06
Maxillary Dentoalveolar				
U1-A perp, mm	-2.80 ± 2.68	-0.32 ± 1.44	-2.48	<0.01*
U1-FH, °	-6.47 ± 9.22	-1.55 ± 3.64	-4.92	<0.01*
U1-SN, °	-6.41 ± 9.17	-1.16 ± 3.28	5.25	<0.01*
U1-vertical, mm	1.5 ± 1.4	0.9 ± 1.1	0.6	0.11
U1-horizontal, mm	-2.9 ± 2.7	0.2 ± 1.6	3.1	<0.01*
U6-vertical, mm	2.7 ± 1.6	2.4 ± 1.3	0.3	0.66
U6-horizontal, mm	1.2 ± 1.9	1.3 ± 1.6	-0.1	0.99
Mandibular Dentoalveolar				
L1-APo, mm	2.66 ± 1.58	-0.08 ± 1.35	2.74	<0.01*
IMPA, °	9.33 ± 5.49	0.36 ± 3.70	8.97	<0.01*
L1-vertical, mm	-0.3 ± 2.0	2.4 ± 1.3	-2.7	<0.01*
L1-horizontal, mm	1.6 ± 1.9	0.1 ± 1.4	1.5	<0.01*
L6-vertical, mm	2.2 ± 1.6	1.7 ± 1.4	0.5	0.25
L6-horizontal, mm	2.9 ± 1.9	1.3 ± 1.3	1.6	<0.01*
Interdental				
OJ, mm	-5.84 ± 2.43	-0.57 ± 1.40	-5.27	<0.01*
OB, mm	-3.01 ± 2.32	0.09 ± 1.29	-3.10	<0.01*
U1/L1, °	-2.98 ±10.48	1.63 ± 5.03	-4.61	0.10
Molar relation, mm	-4.39 ± 1.38	-0.19 ± 0.88	-4.20	<0.01*

Soft Tissue				
A-VRL, mm	2.27 ± 2.35	3.51 ± 3.22	1.24	0.15
B-VRL, mm	4.48 ± 2.96	3.19 ± 3.21	1.29	0.22
Pg-VRL, mm	3.52 ± 3.56	4.34 ± 3.55	0.82	0.61
U lip to E-plane, mm	-2.51 ± 1.43	-1.84 ± 2.34	-0.67	0.30
L lip to E-plane, mm	-0.41 ± 2.09	-1.80 ± 2.41	1.39	0.03*

* p significant if ≤0.05

6.4 Comparison of Changes (T2-T1) in AdvanSync™ and Class II Elastics Groups

The changes in cephalometric measurements over the follow-up period in the AdvanSync™ and Class II elastics groups are reported in Table 6.5. AdvanSync™ patients showed significant maxillary restriction compared to Class II elastics patients based on SNA and A-Na Perp measurements ($p<0.01$). However, Co-A measurements were not significantly different. Differences in mandibular skeletal changes were not significantly different between the two groups. ANB, Wits and Convexity measurements indicated that the AdvanSync™ group experienced significantly greater improvement in intermaxillary skeletal relationship compared to the elastics group ($p<0.05$). Mx/Mn Diff also improved more with AdvanSync™, but this difference was not statistically significant. Vertical skeletal changes were not significantly different. Maxillary incisors retruded and retroclined significantly more in the elastics group (U1-A perp, U1-horizontal, U1-FH, U1-SN; $p<0.01$), while extrusion of maxillary molars was inhibited in the AdvanSync™ group (U6-vertical; $p<0.01$). Mandibular dentoalveolar changes were not significantly different between the two groups. Both groups experienced proclination, protrusion and intrusion of the lower incisors and mesial movement of the lower molars. The overjet was reduced significantly more in the elastic group compared to AdvanSync™ ($p<0.01$). Differences in overbite, interincisal angle and molar relationship changes were not statistically significant. Soft tissue changes were also not significantly different. Overall changes (T2-T1) for all the three groups are displayed together in Table 6.6. Overall superimpositions for typical subjects in each treatment group, comparing changes from T1 to T2, are shown in Figures 6.1 and 6.2.

Table 6.5. Comparison of Changes (T2 – T1) in AdvanSync™ and Class II Elastics Groups

Variables	**AdvanSync™ (A)** Mean ± SD	**Class II Elastics (E)** Mean ± SD	**Diff** A-E	**Sig**
Maxillary Skeletal				
SNA, °	-2.05 ± 1.39	-0.17 ± 1.26	-1.88	<0.01*
A-Na Perp, mm	-1.99 ± 1.34	-0.23 ± 1.32	-1.76	<0.01*
Co-A, mm	1.66 ± 2.84	2.63 ± 2.09	-0.97	0.23
Mandibular Skeletal				
SNB, °	0.41 ± 1.24	0.80 ± 1.37	-0.39	0.39
Pg-Na Perp, mm	0.79 ± 1.97	1.07 ± 2.70	-0.28	0.87
Co-Gn, mm	7.53 ± 4.09	7.11 ± 3.30	0.42	0.84
Co-Go, mm	5.03 ± 3.65	4.69 ± 2.40	0.34	0.87
Inter-maxillary				
ANB, °	-2.46 ± 1.18	-0.97 ± 1.32	-1.49	<0.01*
Wits, mm	-3.80 ± 1.73	-2.70 ± 1.86	-1.10	0.02*
Mx/Md Diff, mm	5.58 ± 2.67	4.44 ± 2.76	1.14	0.15
Convexity, mm	-2.47 ± 1.24	-0.79 ± 1.26	-1.68	<0.01*
Vertical Skeletal				
PP, °	-0.13 ± 1.92	-0.58 ± 2.08	0.45	0.57
FMA, °	-0.32 ± 2.23	0.11 ± 1.58	-0.43	0.54
MPA, °	-0.39 ± 2.56	0.07 ± 1.59	-0.46	0.55
Y-axis, °	0.37 ± 1.30	0.33 ± 1.46	0.04	0.99

LFH, mm	3.70 ± 2.42	4.61 ± 2.34	-0.91	0.17
Maxillary Dentoalveolar				
U1-A perp, mm	0.20 ± 2.74	-2.80 ± 2.68	3.00	<0.01*
U1-FH, °	-1.23 ± 8.54	-6.47 ± 9.22	5.34	<0.01*
U1-SN, °	-1.17 ± 8.57	-6.41 ± 9.17	5.24	<0.01*
U1-vertical, mm	1.7 ± 1.7	1.5 ± 1.4	0.2	0.84
U1-horizontal, mm	0.3 ± 2.7	-2.9 ± 2.7	3.2	<0.01*
U6-vertical, mm	1.7 ± 1.4	2.7 ± 1.6	-1.0	<0.01*
U6-horizontal, mm	1.8 ± 2.3	1.2 ± 1.9	0.6	0.43
Mandibular Dentoalveolar				
L1-APo, mm	3.39 ± 2.00	2.66 ± 1.58	0.73	0.13
IMPA, °	8.98 ± 6.83	9.33 ± 5.49	-0.35	0.96
L1-vertical, mm	-0.6 ± 2.2	-0.3 ± 2.0	-0.3	0.75
L1-horizontal, mm	1.9 ± 2.5	1.6 ± 1.9	0.3	0.85
L6-vertical, mm	2.4 ± 1.7	2.2 ± 1.6	0.2	0.84
L6-horizontal, mm	2.6 ± 1.5	2.9 ± 1.9	-0.3	0.76
Interdental				
OJ, mm	-4.21 ± 2.25	-5.84 ± 2.43	1.63	<0.01*
OB, mm	-2.92 ± 2.51	-3.01 ± 2.32	0.09	0.98
U1/L1, °	-7.44 ± 12.02	-2.98 ±10.48	-4.46	0.10
Molar relation, mm	-4.90 ± 1.50	-4.39 ± 1.38	-0.51	0.14

Soft Tissue				
A-VRL, mm	2.10 ± 2.78	2.27 ± 2.35	-0.17	0.96
B-VRL, mm	3.17 ± 3.48	4.48 ± 2.96	-1.31	0.16
Pg-VRL, mm	3.55 ± 3.75	3.52 ± 3.56	-0.03	1.00
U lip to E-plane, mm	-2.54 ± 1.90	-2.51 ± 1.43	-0.03	0.99
L lip to E-plane, mm	-1.00 ± 2.13	-0.41 ± 2.09	-0.59	0.45

* p significant if ≤0.05

Table 6.6. Comparisons of Changes (T2 – T1) in All Groups

Variables	AdvanSync™ (A) Mean ± SD	Class II Elastics (E) Mean ± SD	Control (C) Mean ± SD	Significance A-C	E-C	A-E
Cranial Base						
Ba-S-N, °	0.19 ± 1.75	-0.51 ± 1.42	1.04 ± 2.30	0.11	<0.01*	0.20
Maxillary Skeletal						
SNA, °	-2.05 ± 1.39	-0.17 ± 1.26	0.52 ± 1.71	<0.01*	0.10	<0.01*
A-Na Perp, mm	-1.99 ± 1.34	-0.23 ± 1.32	0.01 ± 1.88	<0.01*	0.78	<0.01*
Co-A, mm	1.66 ± 2.84	2.63 ± 2.09	4.19 ± 3.00	<0.01*	0.03*	0.23
Mandibular Skeletal						
SNB, °	0.41 ± 1.24	0.80 ± 1.37	0.74 ± 1.44	0.54	0.97	0.39
Pg-Na Perp, mm	0.79 ± 1.97	1.07 ± 2.70	0.38 ± 2.94	0.76	0.46	0.87
Co-Gn, mm	7.53 ± 4.09	7.11 ± 3.30	7.01 ± 2.57	0.78	0.99	0.84
Co-Go, mm	5.03 ± 3.65	4.69 ± 2.40	4.49 ± 2.83	0.71	0.95	0.87
Inter-maxillary						
ANB, °	-2.46 ± 1.18	-0.97 ± 1.32	-0.20 ± 1.20	<0.01*	0.02*	<0.01*
Wits, mm	-3.80 ± 1.73	-2.70 ± 1.86	0.54 ± 1.89	<0.01*	<0.01*	0.02*
Mx/Md Diff, mm	5.58 ± 2.67	4.44 ± 2.76	3.21 ± 2.76	<0.01*	0.12	0.15
Convexity, mm	-2.47 ± 1.24	-0.79 ± 1.26	-0.24 ± 1.23	<0.01*	0.13	<0.01*
Vertical Skeletal						
PP, °	-0.13 ± 1.92	-0.58 ± 2.08	-0.80 ± 2.08	0.31	0.88	0.57
FMA, °	-0.32 ± 2.23	0.11 ± 1.58	-0.46 ± 1.59	0.93	0.35	0.54

MPA, °	-0.39 ± 2.56	0.07 ± 1.59	-0.84 ± 1.55	0.57	0.11	0.55
Y-axis, °	0.37 ± 1.30	0.33 ± 1.46	0.11 ± 1.15	0.66	0.75	0.99
LFH, mm	3.70 ± 2.42	4.61 ± 2.34	3.41 ± 2.07	0.84	0.06	0.17
Maxillary Dentoalveolar						
U1-A perp, mm	0.20 ± 2.74	-2.80 ± 2.68	-0.32 ± 1.44	0.60	<0.01*	<0.01*
U1-FH, °	-1.23 ± 8.54	-6.47 ± 9.22	-1.55 ± 3.64	0.98	<0.01*	<0.01*
U1-SN, °	-1.17 ± 8.57	-6.41 ± 9.17	-1.16 ± 3.28	1.00	<0.01*	<0.01*
U1-vertical, mm	1.7 ± 1.7	1.5 ± 1.4	0.9 ± 1.1	0.03*	0.11	0.84
U1-horizontal, mm	0.3 ± 2.7	-2.9 ± 2.7	0.2 ± 1.6	0.99	<0.01*	<0.01*
U6-vertical, mm	1.7 ± 1.4	2.7 ± 1.6	2.4 ± 1.3	0.09	0.66	<0.01*
U6-horizontal, mm	1.8 ± 2.3	1.2 ± 1.9	1.3 ± 1.6	0.53	0.99	0.43
Mandibular Dentoalveolar						
L1-APo, mm	3.39 ± 2.00	2.66 ± 1.58	-0.08 ± 1.35	<0.01*	<0.01*	0.13
IMPA, °	8.98 ± 6.83	9.33 ± 5.49	0.36 ± 3.70	<0.01*	<0.01*	0.96
L1-vertical, mm	-0.6 ± 2.2	-0.3 ± 2.0	2.4 ± 1.3	<0.01*	<0.01*	0.75
L1-horizontal, mm	1.9 ± 2.5	1.6 ± 1.9	0.1 ± 1.4	<0.01*	<0.01*	0.85
L6-vertical, mm	2.4 ± 1.7	2.2 ± 1.6	1.7 ± 1.4	0.09	0.25	0.84
L6-horizontal, mm	2.6 ± 1.5	2.9 ± 1.9	1.3 ± 1.3	<0.01*	<0.01*	0.76
Interdental						

OJ, mm	-4.21 ± 2.25	-5.84 ± 2.43	-0.57 ± 1.40	<0.01*	<0.01*	<0.01*
OB, mm	-2.92 ± 2.51	-3.01 ± 2.32	0.09 ± 1.29	<0.01*	<0.01*	0.98
U1/L1, °	-7.44 ± 12.02	-2.98 ±10.48	1.63 ± 5.03	<0.01*	0.10	0.10
Molar relation, mm	-4.90 ± 1.50	-4.39 ± 1.38	-0.19 ± 0.88	<0.01*	<0.01*	0.14
Soft Tissue						
A-VRL, mm	2.10 ± 2.78	2.27 ± 2.35	3.51 ± 3.22	0.08	0.15	0.96
B-VRL, mm	3.17 ± 3.48	4.48 ± 2.96	3.19 ± 3.21	1.00	0.22	0.16
Pg-VRL, mm	3.55 ± 3.75	3.52 ± 3.56	4.34 ± 3.55	0.63	0.61	1.00
U lip to E-plane, mm	-2.54 ± 1.90	-2.51 ± 1.43	-1.84 ± 2.34	0.27	0.30	0.99
L lip to E-plane, mm	-1.00 ± 2.13	-0.41 ± 2.09	-1.80 ± 2.41	0.28	0.03*	0.45

* p significant if ≤0.05

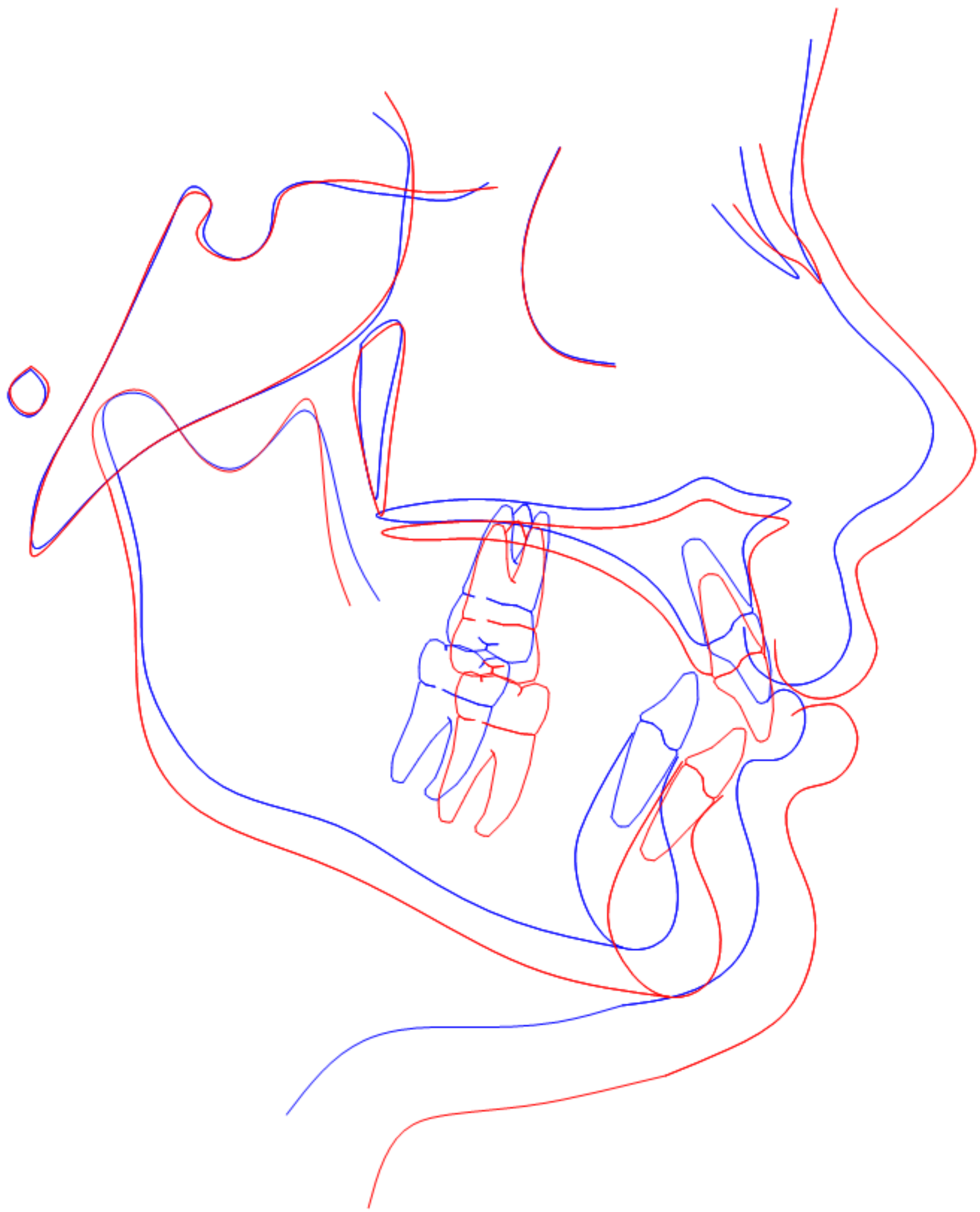

Figure 6.1. Overall Superimposition (S-N @ S) for Typical AdvanSync™ Patient. T1 (blue) and T2 (red).

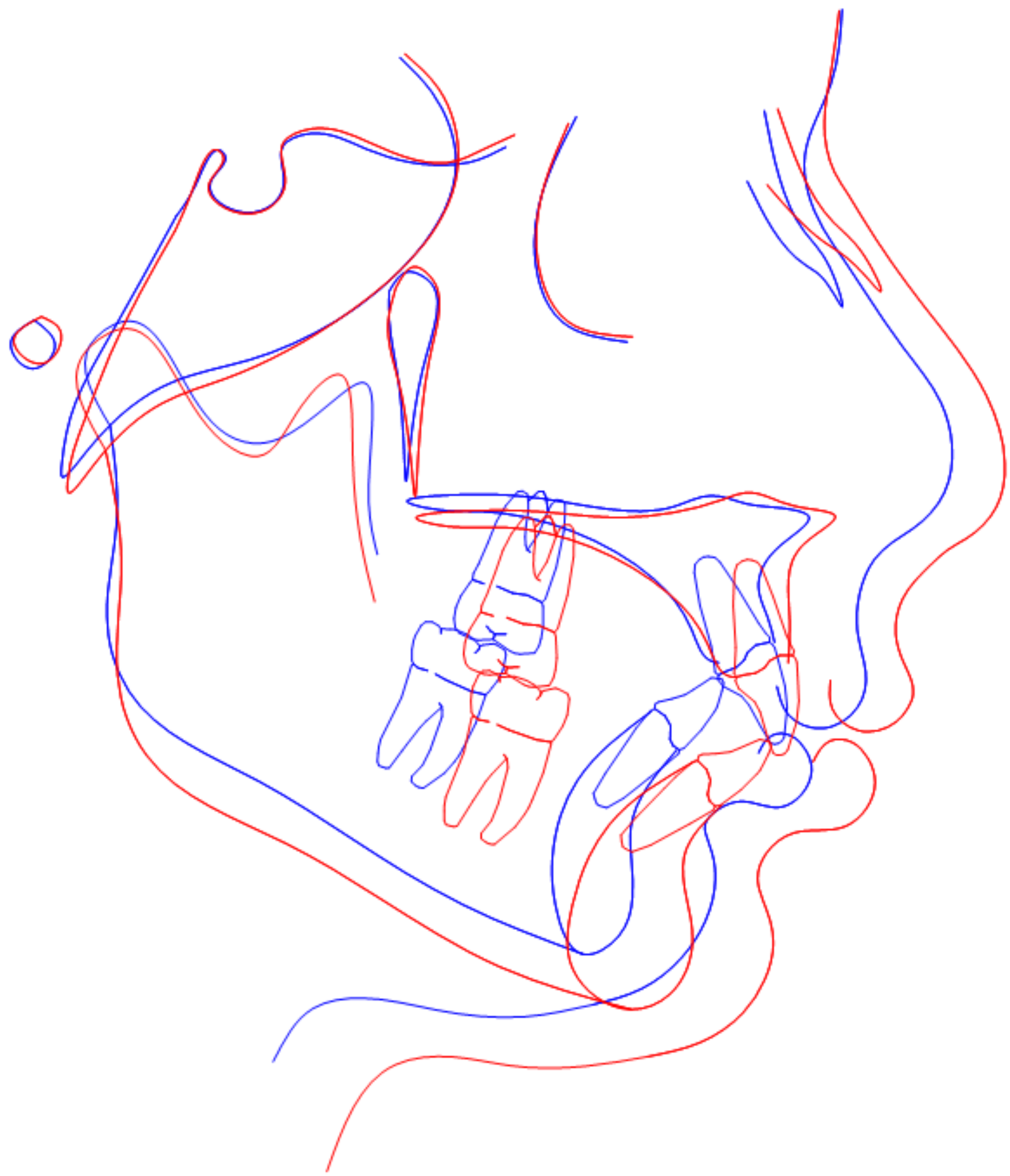

Figure 6.2. Overall Superimposition (S-N @ S) for Typical Class II Elastics Patient. T1 (blue) and T2 (red).

6.5 Assessment of Skeletal Maturity

As discussed previously, the ability to alter growth to correct a Class II malocclusion is dictated by the growth capabilities of the patient. A convenient and reasonably effective method of assessing growth potential is the cervical vertebral maturation (CVM) index as outlined by Baccetti et al. (2005). The summary of the CVM statistics for each group at T1 and T2 is provided in Table 6.4. Significance level, obtained using the Fisher's Exact test, is also reported. It is clear that all three groups are well matched in terms of CVM stage at T1 and T2.

Table 6.7. Comparisons of CVM Stages

Group	**CVM stage at T1**				**CVM stage at T2**			
	Mean	Quartiles 1st/2nd/3rd	Range	Sig	Mean	Quartiles 1st/2nd/3rd	Range	Sig
AdvanSync™	2.32	2/2/3	1-3	0.96	4.54	4/4/5	4-6	0.99
Class II Elastics	2.24	2/2/3	1-3		4.63	4/4/5	4-6	
Control	2.24	2/2/3	1-3		4.57	4/4/5	4-6	

6.6 Reliability

Intraclass Correlation (ICC) values for intra- and inter-rater reliability are shown in Table 6.5. ICC values can be interpreted by the method suggested by Landis and Koch (1977): poor to fair (below 0.4), moderate (0.41–0.60), excellent (0.61–0.80), and almost perfect (0.81–1). The intra-rater ICC values, with an average of 0.975 and range from 0.945 to 0.990, showed an almost perfect level of consistency in the measurements. Similarly, the inter-rater ICC values (average of 0.948 and range from 0.841 to 0.993) also indicated an almost perfect level of consistency. Based on these results, it is clear that the cephalometric measurements and CVM index used in this study are reliable.

Table 6.8. Reliability Tests

Variable	Intra-rater Intraclass Correlation	Inter-rater Intraclass Correlation
Ba-S-N, °	0.982	0.894
SNA, °	0.980	0.954
A-Na Perp, mm	0.969	0.895
Co-A, mm	0.945	0.882
SNB, °	0.981	0.972
Pg-Na Perp, mm	0.960	0.904
Co-Gn, mm	0.990	0.975
Co-Go, mm	0.965	0.909
ANB, °	0.985	0.975
Wits, mm	0.972	0.966
Mx/Md Diff, mm	0.979	0.955
Convexity, mm	0.970	0.988
PP, °	0.945	0.841
FMA, °	0.958	0.910
MPA, °	0.973	0.944
Y-axis, °	0.981	0.979
LFH, mm	0.989	0.982
U1-A perp, mm	0.969	0.954

U1-FH, °	0.979	0.957
U1-SN, °	0.985	0.971
L1-APo, mm	0.985	0.984
IMPA, °	0.974	0.909
OJ, mm	0.988	0.992
OB, mm	0.978	0.945
U1/L1, °	0.983	0.924
Molar relation, mm	0.948	0.914
A-VRL, mm	0.962	0.967
B-VRL, mm	0.987	0.978
Pg-VRL, mm	0.978	0.983
U lip to E-plane, mm	0.988	0.980
L lip to E-plane, mm	0.990	0.993
CVM	0.958	0.912
Average	**0.975**	**0.948**
Range	**0.945 – 0.990**	**0.841 – 0.993**

Chapter 7

Discussion

Fixed Class II correctors have been gaining popularity over the last few decades and will continue to occupy a significant role in orthodontics. Numerous appliances have been created with the goal of minimizing the reliance on patient compliance and reducing treatment time (Jones et al., 2008). It is important for each appliance to be investigated through well-designed studies in order to understand their effects. It is known that these appliances vary in their mechanisms of action and therefore produce different dental and skeletal effects (McSherry et al. 2000). Orthodontists have the responsibility to understand the effects of the appliances they prescribe to their patients.

The present investigation is a retrospective cephalometric study comparing the dental, skeletal and soft tissue treatment effects of the AdvanSync™ appliance and Class II elastics in the treatment of skeletal Class II malocclusions in growing patients used in combination with edgewise fixed appliances. Both treated groups were also compared to an untreated control sample generated from the University of Michigan and Bolton-Brush growth studies and matched to the experimental groups for skeletal age, gender and craniofacial morphology. The following will be a discussion regarding the results of this study as well as comparisons to others that have investigated the effects of Class II elastics and fixed Class II correctors.

The results of the present investigation showed that the two treatment modalities produced similar effects with some exceptions. The AdvanSync™, compared to untreated controls, produced maxillary skeletal growth restriction (SNA, A-Na Perp, Co-A; $p<0.01$), improvement in the inter-maxillary skeletal relationship (ANB, Wits, Mx/Mn Diff, Convexity; $p<0.01$), maxillary incisor extrusion (U1-vertical; $p<0.05$), mandibular incisor protrusion, proclination and intrusion (L1-APo, L1-horizontal, IMPA, L1-vertical; $p<0.05$) and mandibular molar mesialization (L6-horizontal; $p<0.01$). The Class II elastics group, compared to untreated controls, showed slight maxillary skeletal restriction (Co-A; $p<0.05$), improvement in inter-maxillary skeletal relationship (ANB, Wits; $p<0.05$), maxillary incisor retrusion and retroclination (U1- A perp, U1-horizontal, U1-FH, U1-SN; $p<0.01$), mandibular incisor protrusion, proclination and intrusion (L1-APo, L1-horizontal, IMPA, L1-vertical; $p<0.05$), mandibular molar mesialization (L6-horizontal; $p<0.01$) and slight protrusion of the lower lip (L lip to E-plane; $p<0.05$). Although, when comparing to controls, the AdvanSync™ and Class II elastics groups appeared to show similar effects, some differences became evident when comparing the two groups directly. AdvanSync™, compared to Class II elastics, appeared to produce more significant skeletal effects as demonstrated through greater maxillary skeletal growth restriction (SNA, A-Na Perp; $p<0.05$) and improvement in the intermaxillary relationship (ANB, Wits, Convexity; $p<0.05$). On the other hand, Class II elastics appeared to produce more significant dentoalveolar effects as shown by maxillary incisor retrusion and retroclination (U1- A perp, U1-horizontal, U1-FH, U1-SN; $p<0.01$). AdvanSync™ also appeared to inhibit maxillary molar extrusion compared to Class II elastics (U6–vertical; $p<0.01$). Mandibular skeletal and dentoalveolar changes as well as soft tissue changes were not significantly different in the two groups.

At this time, there is only one other study published in the literature that has investigated the effects of the AdvanSync™ appliance (Al-Jewair et al., 2012). The results of the present study are fairly consistent with those of Al-Jewair et al. (2012). In the previous study, as in our study, the major skeletal effect of AdvanSync™ was found to be maxillary restriction. Al-Jewair et al. (2012) reported an overall decrease in SNA of 3.3 ± 2.9°, increase in maxillary length (Co-A) of 1.8 ± 3.1mm (due to natural growth) and decrease in A-Na Perp of 3.3 ± 3.3mm. In our study, SNA decreased 2.1 ± 1.4°, Co-A increased 1.7 ± 2.8mm and A-Na Perp decreased 2.0 ± 1.3mm. In both studies, overall mandibular skeletal changes with AdvanSync™ did not differ significantly from untreated controls. The improvement in intermaxillary skeletal relationship with AdvanSync™ was also similar between the two studies. Al-Jewair et al. (2012) reported a decrease in ANB of 2.6 ± 1.9° and an increase in Mx/Mn Diff of 4.7 ± 2.5mm; while our study found ANB to decrease 2.5 ± 1.2° and Mx/Mn Diff to increase 5.6 ± 2.7mm. In both studies, changes in vertical skeletal measurements with AdvanSync™ did not differ significantly from untreated controls. Maxillary dentoalveolar changes with AdvanSync™ were similar in the two studies, with no significant changes compared to untreated controls (with the exception of slight incisor extrusion in the present study, likely due to fixed appliance mechanics). Mandibular dentoalveolar changes were also consistent among with the two studies, with AdvanSync™ patients exhibiting incisor protrusion and proclination and molar mesialization compared to their respective control groups. However, Al-Jewair et al. (2012) reported significant mandibular molar extrusion with AdvanSync™ compared to controls, which was not found in the present study. This may also be attributed to variations in the fixed appliance mechanics used. In general, the findings reported in the two studies are very similar. Minor differences may be attributed to methodological differences in the studies as well as differences in clinical protocol utilized by the different practitioners. It is also important to note that the follow-up period in the present study for the AdvanSync™ patients was 2.7 ± 0.9 years compared to 2.3 ± 0.7 years in the previous study.

Detailed comparisons of the skeletal and dentoalveolar effects of various Class II appliances according to different studies are provided in Tables 7.1, 7.2 and 7.3. In contrast to AdvanSync™, the MARA has shown to produce significant enhancement of mandibular growth relative to untreated controls without maxillary growth restriction (Ghislanzoni et al., 2011; Al-Jewair et al., 2012). The MARA and

AdvanSync™ show similar maxillary and mandibular dentoalveolar effects (Ghislanzoni et al., 2011; Al-Jewair et al., 2012). Similar to the MARA, the Herbst appliance has been shown to enhance mandibular growth relative to controls (Baysal et al., 2014), but also concurrently restrict maxillary growth (Valant et al., 1989; Baysal et al. 2014). The mandibular dentoalveolar effects of the Herbst appliance are similar, but to a lesser extent, compared to AdvanSync™(Valant et al., 1989; Baysal et al. 2014). The Herbst appliance may have a distalization effect on the maxillary molars (Valant et al.; 1989). These findings indicate that the MARA and Herbst may be able to effectively protract the condyle out of the glenoid fossa and therefore enhance mandibular growth. Although the AdvanSync™ forces the patient to posture the mandible forward during closure, as the muscles relax, the force may be transmitted through the appliance to deliver a distal force on the maxillary molars and an opposite mesial force on the mandibular molars. The distal force on the maxillary molars is likely heavy and causes maxillary growth restriction. The mesial force on the mandibular molars may be transmitted through all of the more anterior teeth and results in mesialization of the dentition. Perhaps the MARA and Herbst possess a mechanism that forces the patient to more actively posture their mandible forward using their own musculature; this would prevent the muscles from relaxing and transmitting force to the maxilla.

Compared to AdvanSync™, the Jasper Jumper™ produces less skeletal effects (maxillary restriction), and has been shown to produce primarily dentoalveolar effects (Cope et al., 1994; Covell et al., 1999). The Jasper Jumper™ produces greater maxillary dentoalveolar effects compared to AdvanSync™ (especially incisor retrusion and molar distalization) and similar mandibular dentoalveolar effects (Cope et al., 1994; Covell et al., 1999). In general, the effects of the Jasper Jumper™ (except for maxillary molar distalization), are in line with those of Class II elastics (Cope et al., 1994; Covell et al., 1999; Jones et al., 2008). Similar to the Jasper Jumper™, the Forsus™ Fatigue Resistant Device produces less maxillary skeletal growth restriction compared to AdvanSync™ and produces overall skeletal and dental effects that are consistent with Class II elastic treatment (Jones et al., 2008; Franchi et al., 2011). It is important to note that although the measurements provided in Tables 7.1, 7.2 and 7.3 provide a useful comparison tool, direct comparisons need to be interpreted with caution; the overall observation periods vary among the studies, there may have been differences in the use of the appliances due to clinician preferences and the methods by which data were measured may have varied among the studies.

The correction of Class II malocclusions in the elastics group was primarily due to dentoalveolar changes. This supports the conclusions drawn from several previous studies (Gianelly et al., 1984; Ellen et al., 1998; Nelson et al., 1999 & 2000; Jones et al., 2008; Janson et al., 2013). These studies have demonstrated that the effects of Class II elastics in conjunction with conventional fixed appliances include minor maxillary forward growth restriction, retrusion, retroclination and extrusion of maxillary incisors, protrusion, proclination and intrusion of mandibular incisors and mesialization of mandibular molars. In our study, minor skeletal growth restriction, according to the SNA angle, was evident but not statistically significant (-0.2 ± 1.3° compared to 0.5 ± 1.7° in controls). This finding was in agreement with Gianelly et al. (1984) who reported a decrease in SNA of 0.4° and Nelson et al. (1999) who reported a decrease of 0.7°. In our study, patients treated with Class II elastics demonstrated significant maxillary incisor retrusion (2.9 ± 2.7mm) and retroclination (6.4 ±9.2°). The amount of retrusion of maxillary incisors has shown a wide range in the literature. Nelson et al. (1999), Nelson et al. (2000) and Jones et al. (2008) reported 3.7mm, 5.0mm and 2.0mm, respectively. These differences may be due to different starting positions of the maxillary incisors in the different studies. According to the systematic review by Janson et al. (2013), Class II elastics produce maxillary incisor extrusion. This is contrasted by our study, in which the maxillary incisors did extrude compared to controls, but the difference was not statistically significant. The results from Janson et al. (2013) may not be extrapolated to our sample due to the fact that none of the studies included in the systematic review utilized an untreated control group for comparison. In our study, Class II elastics patients exhibited significant mandibular dentoalveolar changes, including incisor protrusion (1.6 ± 1.9 mm), proclination (9.3 ± 5.5°) and intrusion (0.3 ± 2.0mm) as well as molar mesialization (2.9 ± 1.9mm). The observed intrusion may not be true intrusion, but rather an effect of the proclination, which naturally brings the crown apically. These results are similar to Nelson et al. (1999), who reported incisor protrusion of 1.4mm and molar mesialization of 2.0mm. Similarly, Ellen et al. (1998) reported incisor protrusion of 3.1mm, proclination of 8.8° and molar mesialization of 3.2mm. The systematic review by Janson et al. (2013) is also in agreement with our mandibular dentoalveolar changes with Class II elastics. The effects of Class II elastics may be explained by the light forces that they produce compared to some fixed Class II correctors. The light distal forces in the maxillary arch and mesial forces in the mandibular arch are ideal for tooth movement, but not orthopedic change. Detailed comparisons of the skeletal and dentoalveolar effects of Class II elastics as reported by various studies are provided in Tables 7.1, 7.2 and 7.3. Differences in the findings among the studies may be attributed to differences in starting positions of the teeth, differences in ages and skeletal maturity of patients, follow-up period, strength and time period of elastic wear and individual treatment preferences of various clinicians. It is also important to consider that other studies (Gianelly et al., 1984; Ellen et al., 1998; Nelson et al., 1999 & 2000; Jones et al., 2008; Janson et al., 2013) involving Class II elastics did not utilize a non-treated control group for comparison.

There are some limitations with our study that need to be considered. In most studies involving a functional appliance, there are typically three time points with records taken at each: T1 – immediately pretreatment, T2 – post-functional appliance treatment, and T3 – post-comprehensive treatment. In our study, there were only two time points: T1 – pre-treatment and T2 – post-comprehensive treatment. Because of this, we were not able to investigate the short-term effects of AdvanSync™ immediately following removal of the appliance. Although this is a limitation, we are more concerned with the long-term effects of the appliances we use. Additionally, the primarily goal of our study was to compare the effects of AdvanSync™ and Class II elastics as part of a comprehensive treatment with conventional fixed appliances. For these reasons, our study design is justified.

Since we did not have a cephalometric or hand-wrist radiograph immediately prior to AdvanSync™ insertion and immediately after removal, we cannot be sure that the patients were treated with the appliance during their growth peak. As indicated in Table 6.4, the majority of the subjects used in our study were CVM stage 2 at T1. According to Baccetti et al. (2005), the peak in mandibular growth will occur on average 1 year after this stage. In our study, AdvanSync™ was inserted in patients an average of 10 months (± 2 months) after the initial T1 cephalometric radiograph. The reason for this delay was due to the fact that the appliance was only installed in patients who were non-compliant with elastics. Additionally, it is normal for a few months to elapse following the initial consultation appointment (when the radiograph would have been taken) and the start of treatment in a private practice setting. Therefore, we can be confident that the majority of the subjects were either at or close to the peak rate of mandibular growth when the appliance was inserted. Once installed, the AdvanSync™ remained in place for an average of 12.5 months (±2.5 months). As this is a significant period of time, it increases the chances that the majority of patients were treated with the appliance at least partially during their peak growth phase. Additionally, as indicated in Table 6.4, post-comprehensive treatment, the majority of patients were at CVM stage 4 or 5. According to Baccetti et al. (2005), the peak in mandibular growth has occurred within 1 or 2 years before stage 4. Similarly, the peak in mandibular growth has ended at least 1 year before stage 5 (Baccetti et al., 2005). Given that the AdvanSync™ was removed an average of 10.5 months (± 3 months) prior to the T2 radiograph, this further increases the likelihood that the majority of subjects were treated with AdvanSync™ at least partially during their peak growth phase. Although we cannot absolutely confirm that the subjects in this study were all treated during their peak growth phase, we can be very confident that the majority did have the AdvanSync™ in place for at least some time during their peak growth and at the very least, all subjects did have significant growth potential remaining while the appliance was activated; this was possible due to the inclusion criteria we utilized where subjects were required to be pre-pubertal at T1 and post-pubertal at T2. Class II elastics patients also likely experienced their sagittal correction at least partially during their growth peak due to the same inclusion criteria and since elastics were typically worn for about 22-24 months from the start of treatment. Figure 7.1 illustrates the estimated CVM stages of the patients at different phases of treatment. Great care was taken to ensure that the two treatment groups (AdvanSync™ and Class II elastics) and the untreated control group were very well matched in terms of age and gender in order to draw more meaningful conclusions.

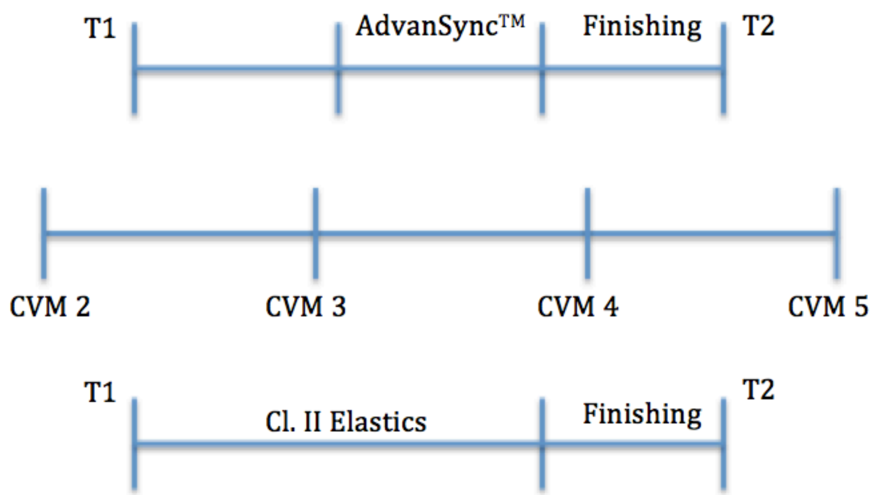

Figure 7.1. CVM Stages at Different Phases of Treatment. AdvanSync™ group (top) and Class II Elastics group (Bottom).

It is important to note the way in which AdvanSync™ was prescribed to the subjects in this study. All subjects were initially prescribed elastics to correct the sagittal discrepancy. AdvanSync™ was utilized in patients who were non-compliant with elastics and typically installed after initial leveling and aligning. AdvanSync™ is intended to be installed at the beginning of treatment along with the conventional fixed appliances. In our subjects, due to their non-compliance, the severity of their sagittal discrepancy (molar relationship) had not improved since the start of treatment until AdvanSync™ insertion. Therefore we can be confident that AdvanSync™, and not elastics was the primary modality that corrected the sagittal discrepancy in these patients. Additionally, as all patients (in both the AdvanSync™

and Class II elastics groups) were initially prescribed elastics, this confirms the homogeneity of the two groups and validates the comparisons of the treatment modalities.

All three groups were shown to be well matched in terms of cephalometric characteristics at T1. This is important since a similar baseline is needed in order to make valid comparisons of outcomes. Although very well matched, there were some minor differences (protruded maxillary incisors and retroclined mandibular incisors in the Class II elastics group relative to controls; more significant dental Class II in the AdvanSync™ group relative to controls). This is not a concern, as all of the major characteristics that may have an influence on growth (mandibular skeletal, maxillary skeletal and vertical skeletal) are extremely well matched among all of the groups and therefore we are confident in attributing the changes seen over the observation period to the treatment modalities utilized. Additionally, it is important to note that only compliance, and not any initial characteristics, was the deciding factor in the treatment modality used for each patient.

There are also inherent limitations with the use of a historical database to generate an untreated control group. We cannot be sure that the subjects in the control group are similar to the treated groups in terms of average growth potential and environmental factors (nutrition, socioeconomic status, etc.). Also, careful calculations needed to be done to account for differing radiographic units and magnifications in order to allow for valid comparisons. Although there are definite limitations to this type of control group, it remains heavily utilized in the orthodontic literature, particularly for retrospective studies. An untreated control group generated from historical databases remains a relatively quick, effective (if properly calibrated) and ethical way to form a valid comparison group.

The results of this study and the comparisons to others are meant to provide orthodontists with information in order to make more informed treatment decisions. It is clear that the various appliances have different treatment effects. Therefore it seems reasonable that the appliance of choice should be dictated by the individual patient requirements. According to our study and that of Al-Jewair et al. (2012), patients requiring restriction of maxillary growth and proclination and protrusion of mandibular incisors, while maintaining the growth pattern in the vertical dimension, seem ideally suited for AdvanSync™ treatment. Therefore, growing patients with skeletal Class II malocclusion due to maxillary prognathism who can afford mesialization of the mandibular dentition are the prime candidates for AdvanSync™ therapy. According to McNamara et al. (1981), maxillary prognathism is not common with skeletal Class II malocclusion as the maxilla is usually in a neutral position. In fact, the maxilla is more often in a retruded position than a protruded position in Class II patients (McNamara et al., 1981). Therefore, patients who ideally match the requirements for AdvanSync™ therapy seem to be less common. In patients who present with skeletal Class II malocclusions due to mandibular retrognathism (most common), it seems more appropriate to utilize an appliance that has shown the ability to enhance mandibular growth such as the MARA or Herbst (Valant et al., 1989; Ghislanzoni et al., 2011; Al-Jewair et al., 2012; Baysal et al., 2014). In patients who present with skeletal Class II malocclusions due to both maxillary prognathism and mandibular retrognathism, the Herbst appliance would be a reasonable treatment modality since it can restrict maxillay growth while enhancing mandibular growth (Valant et al., 1989; Baysal et al., 2014). In patients with dental Class II malocclusions, but well positioned skeletal bases, it may be desirable to correct the malocclusion through primarily dentoalveolar changes. Class II elastics would be a reasonable treatment modality in these cases since their effects are primarily dentoalveolar in nature (Ellen et al., 1998; Nelson et al., 1999; Jones et al., 2008; Janson et al., 2013). In patients who are non-compliant with elastics, the Jasper Jumper™ and Forsus™ appliances are reasonable alternatives since their effects are comparable to those of Class II elastics (Cope et al., 1994; Covell et al., 1999; Jones et al., 2008). In general, orthodontists need to thoroughly evaluate each individual patient to determine their specific treatment needs. Once problem lists and treatment goals are established, the appliance that is most likely to produce the desired effects should be selected.

Table 7.1. Summary of the Skeletal Effects of Class II Appliances

Appliance	Authors	SNA, °	Mx Length, mm	SNB, °	Md Length, mm	MPA, °	LFH, mm
Class II Elastics	Present Study	-0.2	2.6	0.8	7.1 (Co-Gn)	0.1	4.6
Class II Elastics	Jones et al. (2008)	N/A	1.5	N/A	3.8 (sagittal)	N/A	N/A
Class II Elastics	Nelson et al. (1999)	-0.7	1.0	0.1	2.1 (sagittal)	1.0	5.0
Class II Elastics	Ellen et al. (1998)	-1.7	0.0	-0.1	1.7 (sagittal)	1.8	6.2
AdvanSync™	Present Study	-2.1	1.7	0.4	7.5 (Co-Gn)	-0.4	3.7
AdvanSync™	Al-Jewair et al. (2012)	-3.3	1.8	-0.6	5.4 (Co-Gn)	0.0	0.1
MARA	Al-Jewair et al. (2012)	-1.1	3.2	1.8	8.1 (Co-Gn)	-1.6	-0.2
MARA	Ghislanzoni et al. (2011)	-0.8	4.9	1.6	11.5 (Co-Gn)	-1.2	5.6
Herbst	Baysal et al. (2014)	N/A	0.7	N/A	5.7 (Co-Gn)	N/A	4.4
Herbst	Valant et al. (1989)	-0.7	-0.2	1.3	3.5 (Co-B)	-0.2	N/A
Jasper Jumper™	Covell et al. (1999)	-1.6	N/A	0.7	5.6 (Ar-Pg)	-0.8	2.3
Jasper Jumper™	Cope et al. (1994)	-0.6	N/A	-0.4	0.0 (sagittal)	N/A	N/A
Forsus™	Franchi et al. (2011)	-1.6	2.2	0.3	7.5 (Co-Gn)	-1.1	4.0
Forsus™	Jones et al. (2008)	N/A	1.7	N/A	4.4 (sagittal)	N/A	N/A

- Positive values indicate an increase in the measurement post-treatment compared to pre-treatment
- Negative values indicate a decrease in the measurement post-treatment compared to pre-treatment

Table 7.2. Summary of the Maxillary Dentoalveolar Effects of Class II Appliances

Appliance	Authors	U1-SN or U1-FH, °	U1-vert, mm	U1-horiz, mm	U6-vert, mm	U6-horiz, mm
Class II Elastics	Present Study	-6.4	1.5	-2.9	2.7	1.2
Class II Elastics	Jones et al. (2008)	0.6	1.2	0.3	2.0	0.6
Class II Elastics	Nelson et al. (1999)	N/A	N/A	-3.7	N/A	0.1
Class II Elastics	Ellen et al. (1998)	1.4	3.7	0.2	3.0	0.0
AdvanSync™	Present Study	-1.2	1.7	0.3	1.7	1.8
AdvanSync™	Al-Jewair et al. (2012)	-1.2	0.8	0.1	1.7	2.5
MARA	Al-Jewair et al. (2012)	1.1	0.7	2.6	2.0	1.6
MARA	Ghislanzoni et al. (2011)	1.2	1.3	1.0	2.8	2.0
Herbst	Baysal et al. (2014)	N/A	1.4	1.0	0.8	1.0
Herbst	Valant et al. (1989)	0.1	N/A	0.5	0.2	-1.5
Jasper Jumper™	Covell et al. (1999)	-0.5	0.6	0.5	1.5	-2.0
Jasper Jumper™	Cope et al. (1994)	N/A	2.5	-4.7	1.0	-4.3
Forsus™	Franchi et al. (2011)	-1.2	1.6	-1.1	1.6	1.0
Forsus™	Jones et al. (2008)	3.7	0.5	0.7	1.5	1.2

- Vertical dentoalveolar changes are reported as positive for extrusive movements and negative for intrusive movements
- Horizontal dentoalveolar movements are reported as positive for mesial movements and negative for distal movements

Table 7.3. Summary of the Mandibular Dentoalveolar Effects of Class II Appliances

Appliance	Authors	IMPA, °	L1-vert, mm	L1-horiz, mm	L6-vert, mm	L6-horiz, mm
Class II Elastics	Present Study	9.3	-0.3	1.6	2.2	2.9
Class II Elastics	Jones et al. (2008)	3.8	-3.7	0.8	3.2	0.7
Class II Elastics	Nelson et al. (1999)	N/A	N/A	1.4	N/A	2.0
Class II Elastics	Ellen et al. (1998)	8.8	-1.0	3.1	2.6	3.2
AdvanSync™	Present Study	9.0	-0.6	1.9	2.4	2.6
AdvanSync™	Al-Jewair et al. (2012)	5.4	0.8	1.4	3.6	3.4
MARA	Al-Jewair et al. (2012)	5.3	1.5	1.1	3.7	3.6
MARA	Ghislanzoni et al. (2011)	3.3	2.3	1.4	4.3	3.1
Herbst	Baysal et al. (2014)	N/A	0.5	1.8	2.1	1.2
Herbst	Valant et al. (1989)	2.5	N/A	1.2	1.0	1.6
Jasper Jumper™	Covell et al. (1999)	5.3	0.7	1.6	2.6	2.6
Jasper Jumper™	Cope et al. (1994)	N/A	-1.7	4.4	1.5	3.8
Forsus™	Franchi et al. (2011)	6.1	-0.5	2.3	3.6	2.4
Forsus™	Jones et al. (2008)	6.3	-5.9	1.2	3.3	1.8

- Vertical dentoalveolar changes are reported as positive for extrusive movements and negative for intrusive movements
- Horizontal dentoalveolar movements are reported as positive for mesial movements and negative for distal movements

Evaluation of the Null Hypotheses

1. There are no statistically significant differences regarding the skeletal, dentoalveolar and soft tissue changes observed with multi-bracket orthodontic treatment in conjunction with AdvanSync™ compared to intermaxillary Class II elastics in patients with skeletal Class II malocclusions.
    - This hypothesis is **rejected** because there were statistically significant differences between AdvanSync™ and Class II elastics, particularly in maxillary skeletal growth and maxillary dentoalveolar changes.

2. There are no statistically significant differences regarding the skeletal, dentoalveolar and soft tissue changes observed with multi-bracket orthodontic treatment in conjunction with AdvanSync™ and/or intermaxillary Class II elastics compared to spontaneous growth in untreated controls.
    - This hypothesis is **rejected** because there were statistically significant differences between both AdvanSync™ and Class II elastics compared to untreated controls in terms of skeletal and dentoalveolar changes.

Chapter 8

Conclusions

1) AdvanSync™ and intermaxillary elastics were effective in normalizing Class II malocclusions
2) AdvanSync™ corrected Class II malocclusions through maxillary skeletal growth restriction and mandibular dentoalveolar changes (incisor protrusion and proclination as well as molar mesialization)
3) Intermaxillary elastics corrected Class II malocclusions primarily through dentoalveolar changes in both the maxilla (incisor retrusion and retroclination) and mandible (incisor protrusion and proclination as well as molar mesialization)
4) AdvanSync™ and intermaxillary elastics did not produce significant soft tissue changes relative to untreated controls
5) Both treatment modalities did not yield mandibular growth enhancement relative to spontaneous growth in untreated controls

8.1 Recommendations for Future Studies

1) Follow-up of subjects over 5 and 10 year periods to understand long-term effects
2) Study of short-term effects of AdvanSync™ by addition of third time point (post-functional appliance treatment)
3) Investigation of the effects of AdvanSync™ in different facial growth patterns
4) Prospective randomized controlled trials in order to compare the effects of AdvanSync™ to other Class II appliances

Chapter 9

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Chapter 10

Appendix

10.1 Abstract and Article

Comparison of AdvanSync™ and Intermaxillary Elastics in the Correction of Class II Malocclusions: A Cephalometric Study

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ABSTRACT

Objectives: To compare the skeletal, dentoalveolar and soft tissue effects of the AdvanSync™ appliance with intermaxillary elastics in the correction of Class II malocclusions in growing patients.

Materials and Methods: A retrospective study was conducted using lateral cephalograms of patients taken pre-treatment (T1) and post-comprehensive orthodontic treatment (T2). 41 patients consecutively treated with AdvanSync™ were compared to 41 similar patients treated with intermaxillary Class II elastics. All patients had significant growth potential during treatment, as assessed by cervical vertebral maturation. A comparison group was generated from historical databases and matched to the experimental groups for skeletal age, gender and craniofacial morphology. Treatment changes were evaluated between the time points using a custom cephalometric analysis generating 31 variables as well as regional superimpositions. Data was analyzed using one-way analysis of variance and Tukey-Kramer tests.

Results: Initially (T1), the three groups were well matched in terms of cephalometric measurements. The effects of AdvanSync™ and fixed orthodontics (T2-T1) included maxillary growth restriction, protrusion, proclination and intrusion of mandibular incisors and mesialization of mandibular molars ($p<0.01$). The effects of Class II elastics and fixed orthodontics were similar to AdvanSync™, with the exceptions of less maxillary growth restriction and greater retrusion and retroclination of maxillary incisors ($p<0.01$). Significant mandibular growth stimulation, relative to untreated controls, did not occur with either modality.

Conclusion: AdvanSync™ and intermaxillary elastics were effective in normalizing Class II malocclusions during comprehensive fixed orthodontics. AdvanSync™ produced its effects through maxillary skeletal growth restriction and mandibular dentoalveolar changes. Class II elastics worked primarily through dentoalveolar changes in both the maxilla and mandible.

INTRODUCTION

Treatment of Class II malocclusions has been a prime focus of orthodontic investigators for decades. Class II malocclusion occurs in 23% of children age 8 to 11, 15% of youths age 12 to 17, and 13% of adults age 18 to 50, thereby making it the most prevalent skeletal disharmony encountered in all age groups.[1]

Numerous treatment modalities have been developed for Class II malocclusions. These include selective extraction patterns, orthopedic forces delivered with headgear, jaw orthopedics using functional appliances, removable and fixed intra-arch and inter-arch appliances as well as orthognathic surgery to reposition one or both jaws.[2] Intermaxillary Class II elastics, a typical inter-arch modality, is perhaps the most common method utilized to correct Class II malocclusions. Numerous studies have investigated the effects of Class II elastics,[3-7] including a systematic review,[8] which have consistently shown that Class II elastics produce their effects primarily at the dentoalveolar level: mesial movement and extrusion of mandibular molars, mesial movement and proclination of mandibular incisors and distal movements, retroclination and extrusion of maxillary incisors.[3-8]

Fixed or removable functional appliances are designed to alter the position of the jaws both sagittally and vertically, resulting in orthopedic and orthodontic changes.[2] Although the effects of some fixed functional appliances such as the Herbst and Mandibular Anterior Repositioning Appliance (MARA) have been well documented in the literature, the effects of the AdvanSync™ appliance are not well understood. AdvanSync™ is a fixed functional appliance developed by Ormco™ (Glendora, CA). The appliance consists of crowns cemented to permanent upper and lower first molars which are connected by telescoping rods. AdvanSync ™ was designed to allow for simultaneous use of conventional edgewise appliances, as the crowns are equipped with 0.022" x 0.028" slots. The telescoping mechanism acts to constantly posture the mandible forward upon closure, with the goal of enhancing mandibular growth to correct Class II malocclusions. Intraoral photographs of AdvanSync™ and the pre-adjusted edgewise appliances used in this study are shown in Figure 1.

Figure 1. Intraoral Photographs of AdvanSync™ and Pre-adjusted Edgewise Appliances

To date, there has only been one study published in the literature that has evaluated the effects of AdvanSync™. Al-Jewair et al.[9] compared the effects of AdvanSync™ to MARA and found that both were effective in normalizing Class II malocclusions; AdvanSync™ appeared to show more of a headgear effect (maxillary restriction), but less mandibular length enhancement compared to MARA. Both appliances produced similar dentoalveolar changes (mesial movement of mandibular molars and proclination and protrusion of mandibular incisors). No known study has compared the effects of AdvanSync™ to Class II elastics.

The purpose of this study was to compare the cephalometric skeletal, dentoalveolar and soft tissue effects of the AdvanSync™ appliance and intermaxillary elastics in the correction of Class II malocclusions in growing patients when used in conjunction with pre-adjusted edgewise appliances. Both treatment groups were also compared to an untreated control group.

MATERIALS AND METHODS

Ethics approval was obtained from the University Health Research Ethics Board. Treatment records were all obtained from a single private orthodontic practice. Records included dated pre-treatment (T1) and post-comprehensive treatment (T2) cephalometric radiographs, gender, date of birth, and date of AdvanSync™ insertion and removal. Pre-treatment overjet and severity of Class II malocclusion (molar relationship) was also obtained from clinical exam notes. All digital radiographs were taken with a Kodak 8000C digital imaging system (Carestream Health, Inc. Rochester, NY).

Inclusion criteria included: Pre-treatment Class II malocclusion of ½ cusp (end-to-end) at the molars or greater, skeletal Class II indicated by ANB angle >4°, post-treatment molar relationship at or very near Class I, pre-pubertal stage of development at T1 and post-pubertal at T2 according to the cervical vertebral maturation (CVM) method[10], no missing teeth (excluding 3rd molars), non-extraction treatment protocol and no syndrome or craniofacial anomalies.

The AdvanSync™ group included 41 consecutively treated Class II malocclusion patients (24 males, 17 females). The Class II elastics group included 41 randomly selected patients (with the exception of gender matching to the AdvanSync™ group) from the database of treated patients between 2009 and 2013.

An untreated Class II control sample of 37 subjects was generated from the University of Michigan and Bolton-Brush growth studies and matched with the treated groups for skeletal age, gender, and observation period. Mean ages, observation periods and gender distribution for each group are listed in Table 1.

Table 1. Descriptive Statistics for Treatment and Control Groups

Group	Mean (±SD) Age at T1, years	Mean (±SD) Age at T2, years	Observation Period (±SD), years	Males/Females
AdvanSync™	11.55 ± 1.58	14.30 ± 1.33	2.74 ± 0.88	24/17
Class II Elastics	11.54 ± 1.45	14.40 ± 1.38	2.85 ± 0.43	24/17
Control	11.55 ± 0.58	14.34 ± 0.66	2.79 ± 0.61	22/15

Patients in the AdvanSync™ and Class II elastics groups were treated in a similar fashion by a single practitioner. All patients were treated with the same prescription of Damon™ Q brackets (ORMCO™) and consistent archwire sequencing. All patients were initially prescribed elastics in order to correct the Class II malocclusion. In compliant patients, elastics were used until the sagittal discrepancy was corrected (approximately 22-24 months. Elastics were typically ¼ inch, 3.5 Oz. and worn from maxillary canines to mandibular first molars. In patients who were not compliant with elastics, the AdvanSync™ appliance was installed and utilized to correct the malocclusion. In these patients, the molar relationship had not improved since the start of treatment and before delivery of the appliance. AdvanSync™ was utilized following a similar protocol to that suggested by Dischinger, who helped develop the appliance.[9] The appliance was activated in increments until an edge-to-edge incisor relationship was achieved. Following overcorrection of the sagittal discrepancy, the appliance was removed and treatment was completed with conventional appliances. Average length of AdvanSync™ treatment was 12.5 months (± 1.5 months). Interproximal reduction was not utilized in any of the AdvanSync™ or Class II elastics patients.

Cephalometric Analysis

The pre- and post-treatment cephalometric radiographs were imported into a commercial software (Dolphin Digital Imaging system version 11.7, Chatsworth, CA, USA). For the AdvanSync™ and Class II elastics patients, the magnification of the radiographs was accounted for using a digital calibration within the software, which matched actual known ruler distances captured on the lateral cephalogram. The radiographs from the Michigan growth study and the Bolton Brush study had magnifications of 12.9% and 6% respectively. In order to standardize the radiographs, all magnifications were corrected to 0%. Radiographs were digitally traced using a custom digitized analysis adapted and modified from Al-Jewair et al.[9], which included 35 landmarks and produced 31 measurements. The analysis included a combination of variables described by Jacobson, McNamara, Ricketts, and Steiner.[11-14]

Regional superimpositions were conducted manually in order to evaluate sagittal and vertical dentoalveolar changes. Maxillary superimpositions were made along the palatal plane, registering on the internal structures of the maxilla and the surfaces of the hard palate.[12-13] Mandibular superimpositions were made on the inner contour of the posterior symphysis, the outline of the inferior mandibular canal, and the germ of the third molar, if present.[12-13] Once superimposed, the vertical and sagittal dentoalveolar changes were measured using the methods described by McNamara.[12] Skeletal maturity was also assessed on each radiograph, using the CVM method.[10]

A single investigator carried out all tracings and measurements. The same investigator retraced the records of 10 subjects in each group (randomly selected), including CVM assessments, two weeks following completion of initial data collection in order to test for intra-rater reliability. A second investigator traced the same randomly selected sample to test for inter-rater reliability.

Statistical Analysis

Statistical software, SAS 9.2 (SAS Institute Inc. Cary, NC), was used to analyze the data. Normal distribution of study variables was confirmed. Descriptive statistics were performed and reported as mean, standard deviation and 95% confidence interval for all variables within each group. Comparison of initial and post-treatment measurements of the treatment groups and the control group was carried out by one-way analysis of variance (ANOVA). If ANOVA results were significant, the Tukey-Kramer test was used to determine where the significant differences occurred and adjust for multiple comparisons. Initial and post-treatment CVM values were compared between the three groups using the Fisher's Exact test. Inter- and intra-rater reliability was examined using Intraclass Correlation tests. All statistical tests were interpreted at the 5% significance level.

RESULTS

The comparison of the initial parameters (T1) of the treatment and control groups is shown in Table 2. Only two measurements were significantly different between the two treatment groups. Class II elastics patients initially presented with a greater overjet (OJ; $p<0.01$) and retruded soft tissue B point (B-VRL; $p<0.05$) relative to the AdvanSync™ group. Three measurements were significantly different between the AdvanSync™ and control groups (L1-APo, Molar relation, L lip to E-plane; $p<0.05$) and seven were significant between the Class II Elastics and control groups (A-Na Perp, Wits, PP, U1- A perp, IMPA, OJ, B-VRL; $p<0.05$).

Table 2. Comparisons of Initial Parameters (T1)

Variables	AdvanSync™ (A)	Class II Elastics (E)	Control (C)	Significance		
	Mean ± SD	Mean ± SD	Mean ± SD	A-C	E-C	A-E
Cranial Base						
Ba-S-N, °	131.97 ± 4.23	130.93 ± 4.12	131.17 ± 4.59	0.70	0.97	0.52
Maxillary Skeletal						
SNA, °	81.25 ± 3.96	81.28 ± 3.35	80.19 ± 3.46	0.40	0.38	0.99
A-Na Perp, mm	-1.07 ± 3.38	-0.01 ± 2.87	-1.97 ± 2.98	0.40	<0.01*	0.27
Co-A, mm	81.75 ± 4.39	80.94 ± 3.36	80.73 ± 3.89	0.48	0.97	0.61
Mandibular Skeletal						
SNB, °	76.10 ± 3.47	75.44 ± 3.33	75.24 ± 2.81	0.47	0.96	0.63
Pg-Na Perp, mm	-8.33 ± 6.27	-8.13 ± 5.73	-10.28 ± 4.46	0.27	0.20	0.99
Co-Gn, mm	106.11 ± 5.43	104.86 ± 5.14	105.36 ± 5.39	0.81	0.91	0.54
Co-Go, mm	52.56 ± 4.20	50.76 ± 4.09	50.45 ± 4.37	0.07	0.94	0.14
Inter-maxillary						
ANB, °	5.14 ± 0.75	5.49 ± 0.83	5.17 ± 0.97	0.99	0.71	0.65
Wits, mm	4.16 ± 2.22	4.31 ± 2.18	3.05 ± 1.90	0.06	0.02*	0.94
Mx/Md Diff, mm	21.50 ± 3.56	20.95 ± 3.91	21.86 ± 4.04	0.91	0.55	0.80
Convexity, mm	3.26 ± 2.13	3.80 ± 1.74	3.45 ± 2.21	0.91	0.72	0.45
Vertical Skeletal						
PP, °	1.78 ± 3.09	2.55 ± 2.67	0.01 ± 3.91	0.06	<0.01*	0.53
FMA, °	24.67 ± 4.66	25.22 ± 5.14	26.54 ± 3.35	0.16	0.40	0.84
MPA, °	32.83 ± 5.22	33.97 ± 5.29	34.23 ± 4.03	0.42	0.97	0.55
Y-axis, °	67.94 ± 3.51	68.97 ± 3.63	68.04 ± 3.50	0.99	0.48	0.39
LFH, mm	60.86 ± 4.81	61.22 ± 5.05	60.40 ± 4.78	0.91	0.74	0.94
Maxillary Dentoalveolar						
U1-A perp, mm	3.35 ± 3.00	4.65 ± 2.23	3.05 ± 2.27	0.86	0.02*	0.06
U1-FH, °	110.34 ± 8.94	113.80 ± 6.97	109.88 ± 6.10	0.96	0.06	0.09
U1-SN, °	102.69 ± 9.07	105.05 ± 7.26	102.19 ± 6.02	0.96	0.22	0.34
Mandibular Dentoalveolar						
L1-APo, mm	-0.23 ± 2.57	-0.05 ± 2.34	1.24 ± 2.37	0.02*	0.06	0.94
IMPA, °	97.29 ± 5.72	94.26 ± 6.21	98.13 ± 5.98	0.81	<0.01*	0.06
Interdental						
OJ, mm	6.80 ± 2.40	8.21 ± 2.22	5.83 ± 1.77	0.12	<0.01*	<0.01*
OB, mm	4.68 ± 2.56	4.65 ± 2.21	5.01 ± 2.15	0.81	0.78	0.99
U1/L1, °	128.67 ± 13.35	126.72 ± 8.46	125.46 ± 8.93	0.37	0.86	0.68
Molar relation, mm	2.16 ± 1.15	1.94 ± 1.37	1.50 ± 1.00	0.04*	0.24	0.67
Soft Tissue						
A-VRL, mm	77.80 ± 4.78	76.51 ± 4.46	78.54 ± 4.60	0.78	0.16	0.41
B-VRL, mm	67.03 ± 5.41	63.61 ± 6.12	67.04 ± 4.95	1.00	0.03*	0.02*
Pg-VRL, mm	68.42 ± 6.95	65.26 ± 7.11	68.17 ± 5.76	0.99	0.17	0.09
U lip to E-plane, mm	-1.43 ± 2.81	-0.45 ± 2.01	-0.11 ± 2.39	0.06	0.83	0.16
L lip to E-plane, mm	-1.02 ± 3.18	-0.51 ± 2.75	0.73 ± 2.78	0.04*	0.18	0.71

* p significant if ≤0.05

Table 3. Comparisons of Treatment Changes (T2 – T1)[a]

Variables	AdvanSync™ (A)	Class II Elastics (E)	Control (C)	Significance		
	Mean ± SD	Mean ± SD	Mean ± SD	A-C	E-C	A-E
Cranial Base						
Ba-S-N, °	0.19 ± 1.75	-0.51 ± 1.42	1.04 ± 2.30	0.11	<0.01*	0.20
Maxillary Skeletal						
SNA, °	-2.05 ± 1.39	-0.17 ± 1.26	0.52 ± 1.71	<0.01*	0.10	<0.01*
A-Na Perp, mm	-1.99 ± 1.34	-0.23 ± 1.32	0.01 ± 1.88	<0.01*	0.78	<0.01*
Co-A, mm	1.66 ± 2.84	2.63 ± 2.09	4.19 ± 3.00	<0.01*	0.03*	0.23
Mandibular Skeletal						
SNB, °	0.41 ± 1.24	0.80 ± 1.37	0.74 ± 1.44	0.54	0.97	0.39
Pg-Na Perp, mm	0.79 ± 1.97	1.07 ± 2.70	0.38 ± 2.94	0.76	0.46	0.87
Co-Gn, mm	7.53 ± 4.09	7.11 ± 3.30	7.01 ± 2.57	0.78	0.99	0.84
Co-Go, mm	5.03 ± 3.65	4.69 ± 2.40	4.49 ± 2.83	0.71	0.95	0.87
Inter-maxillary						
ANB, °	-2.46 ± 1.18	-0.97 ± 1.32	-0.20 ± 1.20	<0.01*	0.02*	<0.01*
Wits, mm	-3.80 ± 1.73	-2.70 ± 1.86	0.54 ± 1.89	<0.01*	<0.01*	0.02*
Mx/Md Diff, mm	5.58 ± 2.67	4.44 ± 2.76	3.21 ± 2.76	<0.01*	0.12	0.15
Convexity, mm	-2.47 ± 1.24	-0.79 ± 1.26	-0.24 ± 1.23	<0.01*	0.13	<0.01*
Vertical Skeletal						
PP, °	-0.13 ± 1.92	-0.58 ± 2.08	-0.80 ± 2.08	0.31	0.88	0.57
FMA, °	-0.32 ± 2.23	0.11 ± 1.58	-0.46 ± 1.59	0.93	0.35	0.54
MPA, °	-0.39 ± 2.56	0.07 ± 1.59	-0.84 ± 1.55	0.57	0.11	0.55
Y-axis, °	0.37 ± 1.30	0.33 ± 1.46	0.11 ± 1.15	0.66	0.75	0.99
LFH, mm	3.70 ± 2.42	4.61 ± 2.34	3.41 ± 2.07	0.84	0.06	0.17
Maxillary Dentoalveolar						
U1-A perp, mm	0.20 ± 2.74	-2.80 ± 2.68	-0.32 ± 1.44	0.60	<0.01*	<0.01*
U1-FH, °	-1.23 ± 8.54	-6.47 ± 9.22	-1.55 ± 3.64	0.98	0.01*	0.01*
U1-SN, °	-1.17 ± 8.57	-6.41 ± 9.17	-1.16 ± 3.28	1.00	0.01*	0.01*
U1 – vertical, mm	1.7 ± 1.7	1.5 ± 1.4	0.9 ± 1.1	0.03*	0.11	0.84
U1 – horizontal, mm	0.3 ± 2.7	-2.9 ± 2.7	0.2 ± 1.6	0.99	<0.01*	<0.01*
U6 – vertical, mm	1.7 ± 1.4	2.7 ± 1.6	2.4 ± 1.3	0.09	0.66	0.01*
U6 – horizontal, mm	1.8 ± 2.3	1.2 ± 1.9	1.3 ± 1.6	0.53	0.99	0.43
Mandibular Dentoalveolar						
L1-APo, mm	3.39 ± 2.00	2.66 ± 1.58	-0.08 ± 1.35	<0.01*	<0.01*	0.13
IMPA, °	8.98 ± 6.83	9.33 ± 5.49	0.36 ± 3.70	<0.01*	<0.01*	0.96
L1 – vertical, mm	-0.6 ± 2.2	-0.3 ± 2.0	2.4 ± 1.3	<0.01*	<0.01*	0.75
L1 – horizontal, mm	1.9 ± 2.5	1.6 ± 1.9	0.1 ± 1.4	<0.01*	<0.01*	0.85
L6 – vertical, mm	2.4 ± 1.7	2.2 ± 1.6	1.7 ± 1.4	0.09	0.25	0.84
L6 – horizontal, mm	2.6 ± 1.5	2.9 ± 1.9	1.3 ± 1.3	<0.01*	<0.01*	0.76
Interdental						
OJ, mm	-4.21 ± 2.25	-5.84 ± 2.43	-0.57 ± 1.40	<0.01*	<0.01*	<0.01*
OB, mm	-2.92 ± 2.51	-3.01 ± 2.32	0.09 ± 1.29	<0.01*	<0.01*	0.98
U1/L1, °	-7.44 ± 12.02	-2.98 ±10.48	1.63 ± 5.03	<0.01*	0.10	0.10
Molar relation, mm	-4.90 ± 1.50	-4.39 ± 1.38	-0.19 ± 0.88	<0.01*	<0.01*	0.14
Soft Tissue						
A-VRL, mm	2.10 ± 2.78	2.27 ± 2.35	3.51 ± 3.22	0.08	0.15	0.96
B-VRL, mm	3.17 ± 3.48	4.48 ± 2.96	3.19 ± 3.21	1.00	0.22	0.16
Pg-VRL, mm	3.55 ± 3.75	3.52 ± 3.56	4.34 ± 3.55	0.63	0.61	1.00
U lip to E-plane, mm	-2.54 ± 1.90	-2.51 ± 1.43	-1.84 ± 2.34	0.27	0.30	0.99
L lip to E-plane, mm	-1.00 ± 2.13	-0.41 ± 2.09	-1.80 ± 2.41	0.28	0.03*	0.45

* p significant if ≤0.05

[a] Dentoalveolar changes: positive (+) for extrusive and mesial movements; negative (-) for intrusive and distal movements. Dimensional changes: positive (+) for increases, negative (-) for decreases.

The treatment effects (T2-T1) are presented in Table 3. The AdvanSync™ in combination with pre-adjusted edgewise appliances, compared to untreated controls, produced maxillary skeletal growth restriction (SNA, A-Na Perp, Co-A; $p<0.01$), improvement in the inter-maxillary skeletal relationship (ANB, Wits, Mx/Mn Diff, Convexity; $p<0.01$), maxillary incisor extrusion (U1-vertical; $p<0.05$), mandibular incisor protrusion, proclination and intrusion (L1-APo, L1-horizontal, IMPA, L1-vertical; $p<0.01$) and mandibular molar mesialization (L6-horizontal; $p<0.01$). The magnitude of maxillary skeletal restriction relative to controls was 2.57° according to SNA, 2.00 mm according to A-Na Perp and 2.53 mm according to Co-A.

The Class II elastics group, compared to untreated controls, showed slight maxillary skeletal restriction (Co-A; $p<0.05$), improvement in inter-maxillary skeletal relationship (ANB, Wits; $p<0.05$), maxillary incisor retrusion and retroclination (U1- A perp, U1-horizontal, U1-FH, U1-SN; $p<0.01$), mandibular incisor protrusion, proclination and intrusion (L1-APo, L1-horizontal, IMPA, L1-vertical; $p<0.01$), mandibular molar mesialization (L6-horizontal; $p<0.01$) and slight protrusion of the lower lip (L lip to E-plane; $p<0.05$).

Although, when comparing to controls, the AdvanSync™ and Class II elastics groups appeared to show similar effects, some differences became evident when comparing the two groups directly. AdvanSync™, compared to Class II elastics, appeared to produce more significant skeletal effects as demonstrated through greater maxillary skeletal growth restriction (SNA, A-Na Perp; $p<0.01$) and improvement in the intermaxillary relationship (ANB, Wits, Convexity; $p<0.05$). On the other hand, Class II elastics appeared to produce more significant dentoalveolar effects as shown by maxillary incisor retrusion and retroclination (U1- A perp, U1-horizontal, U1-FH, U1-SN; $p<0.01$). AdvanSync™ also appeared to inhibit maxillary molar extrusion compared to Class II elastics (U6–vertical; $p<0.01$). Mandibular skeletal and dentoalveolar changes as well as soft tissue changes were not significantly different in the two groups. CVM stages were found to be comparable in all three groups at both time points (shown in Table 4). All measurements were found to be reliable according to Intra-Class Correlation tests (intra-rater mean 0.975 and range 0.945-0.990; inter-rater mean 0.948 and range 0.841-0.993).

Table 4. Comparisons of CVM Stages

Group	**CVM stage at T1**				**CVM stage at T2**			
	Mean	Quartiles $1^{st}/2^{nd}/3^{rd}$	Range	Sig	Mean	Quartiles $1^{st}/2^{nd}/3^{rd}$	Range	Sig
AdvanSync™	2.32	2/2/3	1-3		4.54	4/4/5	4-6	
Class II Elastics	2.24	2/2/3	1-3	0.96	4.63	4/4/5	4-6	0.99
Control	2.24	2/2/3	1-3		4.57	4/4/5	4-6	

DISCUSSION

This is a retrospective cephalometric study comparing the dental, skeletal and soft tissue treatment effects of the AdvanSync™ appliance and Class II elastics in the treatment of skeletal Class II malocclusions in growing patients wearing pre-adjusted edgewise fixed appliances. The results of the present investigation showed that the two treatment modalities produced similar effects with some exceptions.

The major skeletal effect of AdvanSync™ was maxillary restriction. This is in agreement with the only other study published in the literature investigating the same appliance.[9] The authors[9] reported an overall decrease in SNA of 3.3°, increase in maxillary length (Co-A) of 1.8 mm (due to natural growth) and decrease in A-Na Perp of 3.3 mm. In our study, SNA decreased 2.1°, Co-A increased 1.7 mm and A-Na Perp decreased 2.0 mm. In both studies, overall mandibular and vertical skeletal changes with AdvanSync™ did not differ significantly from untreated controls.[9] Maxillary restriction has already been demonstrated with the Herbst and MARA,[2,15-17] but they have the ability to enhance mandibular growth as well.[9,15-17]

Maxillary dentoalveolar changes with AdvanSync™ in the present study were similar to the previous study[9], with no significant changes compared to untreated controls (with the exception of slight incisor extrusion, likely due to fixed appliance mechanics). Mandibular dentoalveolar changes were also consistent with the previous study,[9] with AdvanSync™ patients exhibiting incisor protrusion and proclination and molar mesialization compared to their respective control groups.[9] However, Al-Jewair et al.[9] reported significant mandibular molar extrusion with AdvanSync™ compared to controls, which was not found in the present study. This may be attributed to variations in the fixed appliance mechanics used. The observed dentoalveolar changes with AdvanSync™ were overall consistent with those reported in studies involving the Herbst and MARA.[2,9,15-17]

The correction of Class II malocclusions in the elastics group was primarily due to dentoalveolar changes. This supports the conclusions drawn from several previous studies.[3-8] In our study, minor skeletal growth restriction, according to the SNA angle, was evident but not statistically significant (-0.2° compared to 0.5° in controls). This finding was in agreement with Gianelly et al.[5] who reported a decrease in SNA of 0.4° and Nelson et al.[3] who reported a decrease of 0.7°. In our study, patients treated with Class II elastics demonstrated significant maxillary incisor retrusion (2.9 mm) and retroclination (6.4°). The amount of retrusion of maxillary incisors has shown a wide range in the literature. Nelson et al.[3], Nelson et al.[4] and Jones et al.[7] reported 3.7mm, 5.0mm and 2.0mm, respectively. These differences may be due to different starting positions of the maxillary incisors in the different studies. In our study, Class II elastics patients exhibited significant mandibular dentoalveolar changes, including incisor protrusion (1.6 mm), proclination (9.3°) and intrusion (0.3 mm) as well as molar mesialization (2.9 mm). The observed intrusion may not be true intrusion, but rather an effect of the proclination, which naturally brings the crown apically. These results are similar to Nelson et al.[3], who reported incisor protrusion of 1.4 mm and molar mesialization of 2.0 mm. Similarly, Ellen et al.[6] reported incisor protrusion of 3.1mm, proclination of 8.8° and molar mesialization of 3.2mm. The treatment effects of Class II elastics have also been shown to be consistent with some fixed inter-arch Class II correctors such as the Forsus™ and Jasper Jumper™ appliances.[7,18-20]

A limitation with this retrospective study is that a time point immediately following functional appliance removal was not included. Therefore, the short-term effects could not be investigated. Even without the third time point, we can be fairly confident that the majority of subjects did have the AdvanSync™ in place for at least some time during their peak growth due to the inclusion criteria utilized where subjects were required to be pre-pubertal at T1 and post-pubertal at T2. There are also inherent limitations with the use of a historical database to generate an untreated control group.

It is clear that the various appliances have different treatment effects, hence different indications. According to our study and that of Al-Jewair et al.[9], patients requiring restriction of maxillary growth and proclination and protrusion of mandibular incisors, while maintaining the vertical growth pattern, seem ideally suited for AdvanSync™ treatment. Therefore, growing patients with skeletal Class II malocclusion due to maxillary prognathism who can afford mesialization of the mandibular dentition are the prime candidates for AdvanSync™ therapy. According to McNamara[21], maxillary prognathism is not common with skeletal Class II malocclusion. Therefore, patients who ideally match the requirements for AdvanSync™ therapy seem to be less common. In patients who present with skeletal Class II malocclusions due to mandibular retrognathism (most common),[21] it seems more appropriate to utilize an appliance that has shown the ability to enhance mandibular growth such as the Herbst or MARA.[9,15-17] In patients with dental Class II malocclusions, but well positioned skeletal bases, it may be desirable to correct the malocclusion through primarily dentoalveolar changes using Class II elastics.[3-8] If these patients are not compliant with elastics, the Jasper Jumper™ and Forsus™ appliances would be reasonable fixed alternatives since their effects are comparable to those of Class II elastics.[7,18-20] It is important to note that we limited our discussion to fixed functional appliances, Class II correctors and Class II elastics; many other modalities are available. In general, appliances should be selected for their likelihood of fulfilling the individual patient requirements based on sound evidence.

CONCLUSIONS

- AdvanSync™ and intermaxillary elastics were effective in normalizing Class II malocclusions
- AdvanSync™ corrected Class II malocclusions through maxillary skeletal growth restriction and mandibular dentoalveolar changes (incisor protrusion and proclination as well as molar mesialization)
- Intermaxillary elastics corrected Class II malocclusions primarily through dentoalveolar changes in both the maxilla (incisor retrusion and retroclination) and mandible (incisor protrusion and proclination as well as molar mesialization)

ACKNOWLEDGMENTS

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10.2 Ethics Approval and Renewal

UNIVERSITY OF MANITOBA | BANNATYNE CAMPUS
Research Ethics Board

P126 - 770 Bannatyne Avenue
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HEALTH RESEARCH ETHICS BOARD (HREB)
CERTIFICATE OF FINAL APPROVAL FOR NEW STUDIES
Delegated Review

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. S. Jayachandran	UofM/Preventive Dental Science	H2014:214
APPROVAL DATE: June 18, 2014	**EXPIRY DATE:** June 18, 2015	
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. F. Pinheiro		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE;
NA	Cephalometric Evaluation of Class II Correction Using the Advansync Appliance in Different Facial Patterns
SPONSORING AGENCIES AND/OR COORDINATING GROUPS: NA	

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
May 30 and June 17, 2014	June 2 and June 17, 2014

THE FOLLOWING ARE APPROVED FOR USE:

Document Name	Version(if applicable)	Date
Protocol:		
Proposal submitted June 17, 2014		
Consent and Assent Form(s):		
Other:		
Data Collection/Capture Sheet		May 30, 2014
Master List		June 30, 2014

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

- 1 -

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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**.

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HEALTH RESEARCH ETHICS BOARD (HREB)

CERTIFICATE OF ANNUAL APPROVAL

PRINCIPAL INVESTIGATOR:	INSTITUTION/DEPARTMENT:	ETHICS #:
Dr. S. Jayachandran	UofM/)Preventive Dental Sciences	HS17720 H2014:214)
HREB MEETING DATE (If applicable):	**APPROVAL DATE:** May 18, 2015	**EXPIRY DATE:** June 18, 2016
STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable): Dr. B. Pinheiro		

PROTOCOL NUMBER:	PROJECT OR PROTOCOL TITLE:
NA	Cephalometric Evaluation of Class II Correction Using the Advansync Appliance in Different Facial Patterns
SPONSORING AGENCIES AND/OR COORDINATING GROUPS:	

Submission Date of Investigator Documents:	HREB Receipt Date of Documents:
May 12, 2015	May 12, 2015

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

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

Document Name(if applicable)	Version(if applicable)	Date

Annual approval

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

Consent and Assent Form(s):

CERTIFICATION

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

HREB ATTESTATION

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

QUALITY ASSURANCE

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

CONDITIONS OF APPROVAL:

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

10.3 Manuscript Submission

Elsevier Editorial System(tm) for American Journal of Orthodontics & Dentofacial Orthopedics
Manuscript Draft

Manuscript Number:

Title: Comparison of AdvanSyncTM and Intermaxillary Elastics in the Correction of Class II Malocclusions: A Cephalometric Study

Article Type: Original Article

Corresponding Author: Dr. Fabio Henrique de Sa Leitao Pinheiro, DDS, MSc, Ph.D

Corresponding Author's Institution: Faculty of Dentistry, University of Manitoba

First Author: Santhosh Jayachandran, BMSc, DDS

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Abstract: Objectives: To compare the skeletal, dentoalveolar and soft tissue effects of the AdvanSyncTM appliance with intermaxillary elastics in the correction of Class II malocclusions in growing patients.
Materials and Methods: A retrospective study was conducted using lateral cephalograms of patients taken pre-treatment (T1) and post-comprehensive orthodontic treatment (T2). 41 patients consecutively treated with AdvanSyncTM were compared to 41 similar patients treated with intermaxillary Class II elastics. All patients had significant growth potential during treatment, as assessed by cervical vertebral maturation. A comparison group was generated from historical databases and matched to the experimental groups for skeletal age, gender and craniofacial morphology. Treatment changes were evaluated between the time points using a custom cephalometric analysis generating 31 variables as well as regional superimpositions. Data was analyzed using one-way analysis of variance and Tukey-Kramer tests.
Results: The effects of AdvanSyncTM and fixed orthodontics (T2-T1) included maxillary growth restriction, protrusion, proclination and intrusion of mandibular incisors as well as mesialization of mandibular molars ($p<0.01$). The effects of Class II elastics and fixed orthodontics were similar to AdvanSyncTM, with the exceptions of less maxillary growth restriction and greater retrusion and retroclination of maxillary incisors ($p<0.01$). Significant mandibular growth stimulation, relative to untreated controls, did not occur with either modality.
Conclusion: AdvanSyncTM and intermaxillary elastics were effective in normalizing Class II malocclusions during comprehensive fixed orthodontics. AdvanSyncTM produced its effects through maxillary skeletal growth restriction and mandibular dentoalveolar changes. Class II elastics worked primarily through dentoalveolar changes in both the maxilla and mandible.

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