University of Alberta

Comparison of short-term skeletal and dental outcomes in Class II malocclusions treated by a combination of either Xbow or Twin-Block appliances with orthodontic brackets

by
Sayeh Ehsani

A thesis submitted to the Faculty of Graduate Studies and Research
in partial fulfillment of the requirements for the degree of

Master of Science

Medical Sciences - Orthodontics

Fall 2013
Edmonton, Alberta

Dedication

To my parents, for their endless love and support

Abstract

Objectives: To compare short-term skeletal and dental effects of a two-phase orthodontic treatment consisting of a phase 1 with either a Twin-block or a Xbow appliance and a phase 2 with orthodontic brackets.

Methods: Before and after treatment lateral head films of 50 consecutively treated Class II patients with either Twin-block or Xbow appliance as phase 1, followed by full fixed orthodontic treatment (brackets) as phase 2, were analyzed using a custom cephalometric analysis. The anteroposterior position of maxilla, mandible, as well as their sagittal relationship, maxillary and mandibular dimensions and lower anterior face height were evaluated. The mesio-distal movement of upper and lower first molars and changes in inclination of upper and lower incisors were also analyzed. To factor out growth, a control group (CG) consisting of untreated individuals with Class II malocclusion obtained from Burlington Growth Center at University of Toronto was used.

Results: A multivariate analysis of variance (MANOVA) of treatment/observation changes followed by univariate pairwise comparisons showed that in the treatment groups the maxilla moved forward less than the CG with the Xbow group (XG) demonstrating the least maxillary growth. As for mandibular changes, corpus length increase was larger with Twin-block group (TG). Other mandibular measurements were not different between treated and untreated subjects. Dentally, mesial movement of mandibular molars was larger in both treatment groups. Although no distalization of upper molars was found in either treatment group, restriction of mesial movement of maxillary molars was seen with both appliances. Treated subjects showed increase of upper incisor inclination likely as a result of the number of Class II division 2 cases in all three groups. Also, both treatment groups demonstrated increased lower incisor proclination with larger increases for XG. No differences are seen between responses of males and females to treatment.

Conclusion: Class II correction by Xbow and Twin-block occurs through a combination of dental and skeletal effects. The two appliances have similar overall treatment effects with some identified differences between them like restraint of maxillary growth, mesial movement of lower molars, restricted forward movement of upper molars and no vertical changes.

Acknowledgement

"This study was made possible by use of material from the Burlington Growth Centre, Faculty of Dentistry, University of Toronto, which was supported by funds provided by Grant (1) (No. 605-7-299) National Health Grant (Canada), (data collection); (2) Province of Ontario Grant PR 33 (duplicating) and (3) the Varsity Fund (for housing and collection)".

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1. Chapter 1

1.1. Introduction

Class II malocclusion is a prevalent type of malocclusion, which is seen in 1/3rd of the population. [1] Although it is usually associated with a wide variety of dental and skeletal characteristics, the most common single feature of Class II malocclusion is mandibular skeletal retrusion. [2] The ideal treatment for skeletal discrepancies among individuals that have not completed craniofacial growth is growth. modification so that differential growth of the jaws relative to each other resolves the skeletal problem. [3] Therefore in Class II malocclusions among still growing individuals, treatment is usually aimed at changing the direction and amount of mandibular growth. [2]

Mandibular displacement in a forward and downward posture is expected to result in increased mandibular growth with stimulation of condylar growth in a superior-posterior direction and bone apposition on the posterior aspects of the condyle and the ramus. Therefore, Class II correctors are designed to advance the mandible by making the patient posture the mandible forward. To this end, removable Class II correctors are made from registration bites taken with the mandible postured in a forward and downward position. The consequent growth modification results in increased mandibular length and a more favorable less convex facial profile. [4] In order to improve the facial profile of a retrognathic patient, the stimulated growth also has to be expressed in a vertical direction. [5] Therefore, use of appliances such as Twin-block, which allow the clinician to control the facial vertical dimension can be advantageous.

Before discussing Class II functional appliances, it must be noted that effectiveness of these appliances continues to be a topic of controversy. [6-8] It has been argued that dentofacial effects seen with orthopedic treatment might be merely a result of “catch-up effect” in mandibular growth during the treatment period which later subsides. [7] Some of these changes may be the result of normal growth [8] or not substantially different from treatment results with fixed appliance therapy alone [6,9]. Even when statistically significant treatment changes are detected, the changes might not be necessarily clinically meaningful. [7-9] Despite all the controversy, perhaps there is a place for functional appliances in orthodontic practice, although the treatment success depends on various factors mainly patient cooperation and the timing of the treatment. [6]

In growth modification, forces are usually indirectly applied to the bones through teeth, which translate into both skeletal and dental alterations. [3] To correct mandibular retrognathism, both fixed and removable functional appliances are widely used and each has their own merits. Unlike fixed functional appliances, removable Class II correctors are more tissue-borne; therefore it is believed that they result in less dental adaptations allowing for more orthopedic changes. [5] One of the drawbacks of removable functional appliances however is relying on patient's cooperation. Therefore choosing an appliance with higher patient compliance can potentially maximize the treatment efficiency. It has been suggested that patient's compliance may be better with Twin-block appliance [10] as it has been reported to be more acceptable to patients compared to other removable Class II correctors such as Bass and Bionator [11]. This may be due to its relatively small size and minimal interference with speech and the fact that the original Twin-block design has neither a labial bow nor an acrylic bulk in the anterior portion, making it a fairly esthetic appliance. [5]

Fixed functional appliances on the other hand are popular treatment modalities in early permanent dentition stage as they eliminate patient's compliance as a variable in treatment progress. One of the commonly used fixed Class II auxiliaries is 3M Unitek Forsus™ Fatigue Resistant Device which was first developed in 2001. The original system consisted of a push rod and inter-arch spring which attached to the upper molar attachment with an L pin module. The newer generation is connected to the upper molar attachment with a snap-fit module that fits into the buccal tube. The pin is attached on the lower archwire in canine-premolar area in a fully bonded orthodontic case. .[12] The Xbow appliance is a Class II corrector that uses the 3M Unitek Forsus™ Fatigue Resistant springs, a maxillary expansion appliance, lower rigid wire-like labial and lingual bows extended between two lower first molars and a pair of Gurin locks. [13] This ensemble is used as a phase 1 appliance followed by full fixed orthodontic bonding. Although treatment outcome with the two-phase approach, using Xbow as phase 1 and full fixed orthodontics as phase 2, has been shown to be similar to the outcome of a one-phase only approach, it has been shown to result in shorter overall treatment times. The authors attributed this shorter treatment duration to fewer side effects, namely less buccal flaring of the upper molars, in the two-phase treatment group. [14] Being a fixed appliance, Xbow eliminates patient cooperation as a factor in Class II correction making it a more desirable option than removable appliances such as Twin-block for the non-compliant Class II patient. Since Xbow appliance has been developed fairly recently, there are only a few studies [14-18] in the literature that have investigated its treatment effects. Therefore more investigations are needed to help clinicians make evidence based decisions regarding its efficiency and treatment outcome in comparison with other Class II correctors which have a longer history and a more extended body of evidence behind them.

1.2. Significance of the study

There are only few studies in the literature that evaluated treatment outcome with Xbow. [14,17,18] To date, the combined effect of a two-phase treatment with Xbow and full fixed appliances has not been compared to any other functional appliance. The objective of the present investigation is to study the skeletal and dental changes of subjects treated with Xbow followed by fixed appliances and to evaluate the extent of the maxillary and mandibular effects.

Due to individual variation, use of a certain appliance for correction of all Class II cases can't be advocated as each case needs to be assessed individually, [19] therefore the results of this investigation can provide clinicians with more information as to how Xbow accomplishes Class II correction and what changes can be expected with this appliance. The skeletal and dental changes with Xbow and Twin-block will also be compared and if significant differences exist between the two, they will be reported. If the outcomes are similar, Xbow could be an alternative for the non-complaint patient.

Reports on the effect of Twin-block on the maxilla have been controversial; it has been suggested that as the mandible is postured forward, the resulting reciprocal force on the maxilla restricts its growth. [20] As for its effects on the mandible, the main controversy is the same as it is with all functional Class II correctors; it is unclear if it results in an actual increase of the mandibular dimension or it merely accelerates growth without increasing the ultimate potential. Therefore, as an additional objective, the outcome of Twin-block therapy will also be evaluated with the use of an untreated sample.

1.3. Research Questions

1.3.1. Primary questions

Does additional mandibular growth occur in patients treated with Xbow equal to that of patients treated with Twin-block?

Does maxillary growth restraint occur in patients treated with Xbow equal to that of patients treated with Twin-block?

Is lower molar mesialization in patients treated with Xbow equal to that of patients treated with Twin-block?

Is upper molar distalization in patients treated with Xbow equal to that of patients treated with Twin-block?

Is lower incisor proclination in patients treated with Xbow equal to that of patients treated with Twin-block?

Is upper incisor retroclination in patients treated with Xbow equal to that of patients treated with Twin-block?

Is anterior lower face height change in patients treated with Xbow equal to that of patients treated with Twin-block?

1.3.2. Secondary questions

Compared to untreated individuals, does Xbow or Twin-block stimulate mandibular growth?

Compared to untreated individuals, does Xbow or Twin-block restrict maxillary growth?

Compared to untreated individuals, does Xbow or Twin-block mesialize lower molars?

Compared to untreated individuals, does Xbow or Twin-block distalize upper molars?

Compared to untreated individuals, does Xbow or Twin-block procline lower incisors?

Compared to untreated individuals, does Xbow or Twin-block retrocline upper incisors?

Does Xbow or Twin-block increase anterior lower face height compared to untreated individuals?

1.4. Null hypotheses

There is no difference between treatment effects of Xbow and Twin-block.

Treatment with Xbow produces no additional skeletal or dental effects in comparison to normal growth changes among class II malocclusion untreated controls.

Treatment with Twin-block produces no additional skeletal or dental effects in comparison to normal growth changes among class II malocclusion untreated controls.

1.5. Literature review

1.5.1. Class II malocclusion

Class II malocclusions are characterized as having certain dental and/or skeletal characteristics. These characteristics are usually expressed simultaneously, but to different extents. The dental component is characterized as distal relationship of mandibular teeth relative to maxillary teeth. [19] The skeletal component is characterized as anteroposterior disproportion of the two jaws relative to each other. [19] This proportion is usually due to mandibular retrusion, but maxilla may be protrusive as well. The total and lower face heights may be decreased, normal or increased. [19] The anteroposterior relationships of teeth with Class II malocclusion don't spontaneously improve with age. [19] Therefore correction of this type of skeletal problem in preadolescents is advocated.

1.5.2. Class II correctors

Class II correctors are appliances that are used to change the posture of the mandible through holding it forward. As soft tissues and muscles are stretched, the resultant pressures are transmitted to skeletal and dental structures and tooth movement and growth modification follow. [21] The first functional appliance was the Monobloc by Robin in early 1900's. However, the first widely used functional appliance was the Activator made by Andresen in 1920's. Functional appliances can be either removable or fixed. The main disadvantage of the removable appliances is being compliance-dependent, whereas the major drawback of the fixed appliances is their extensive contact with teeth, which can potentially result in dento-alveolar compensations which in turn minimize the potential for orthopedic changes. [5,22]

Removable functional appliances are further categorized as tissue-borne and tooth-borne. The only primarily tissue-borne Class II corrector is the Frankel appliance. Frankel consists of lingual acrylic pads, which contact the mucosa and posture the mandible forward; it also comprises acrylic buccal shields and lip pads which allow for expansion which is often needed in Class II correction. [23]

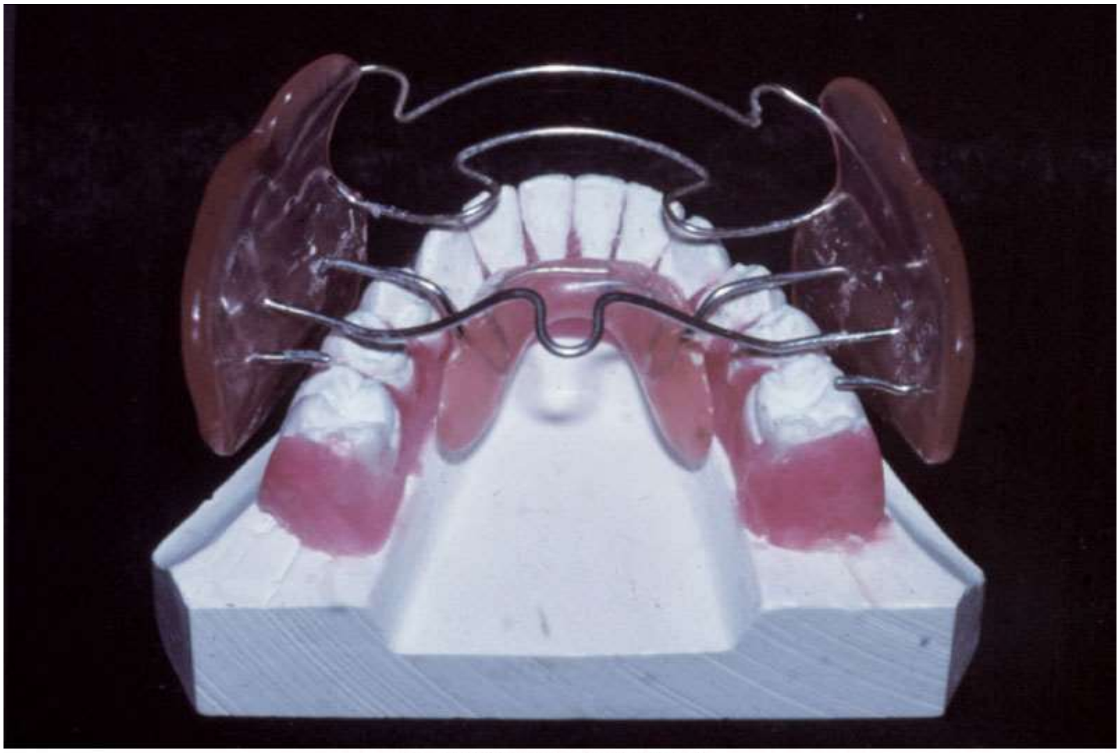

Figure 1-Frankel- Image from Proffit et al [24]

Other removable appliances are primarily tooth-borne; the Activator incorporates lingual acrylic flanges to advance the mandible in addition to acrylic shelves which can be selectively adjusted to manipulate the vertical dimension through prevention of eruption of maxillary, or less often mandibular, posterior teeth.

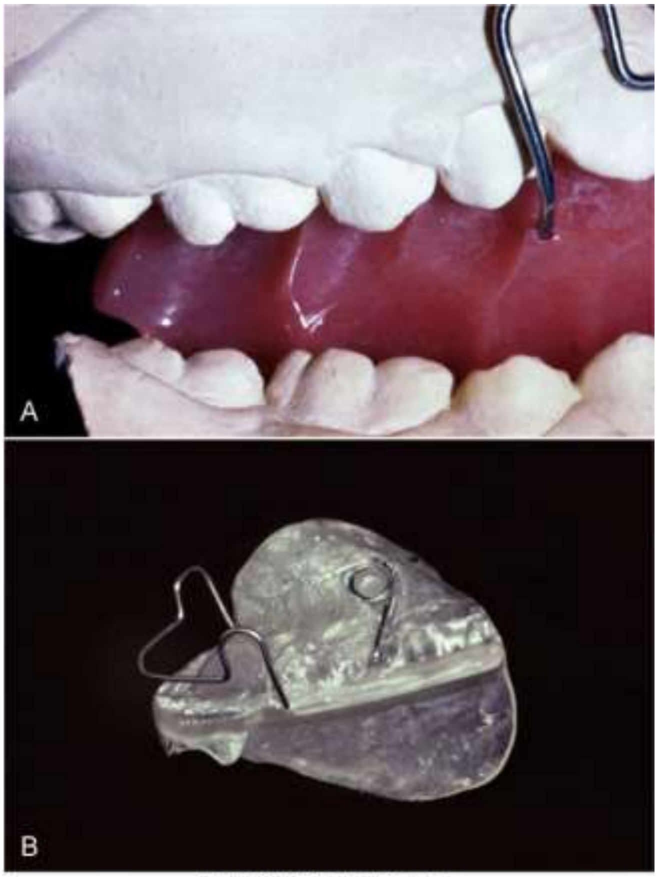

Figure 2-Activator- Image from Proffit et al [24]

The Bionator is a less bulky version of the Activator. Both Activator and Bionator incorporate a labial bow for added retention.

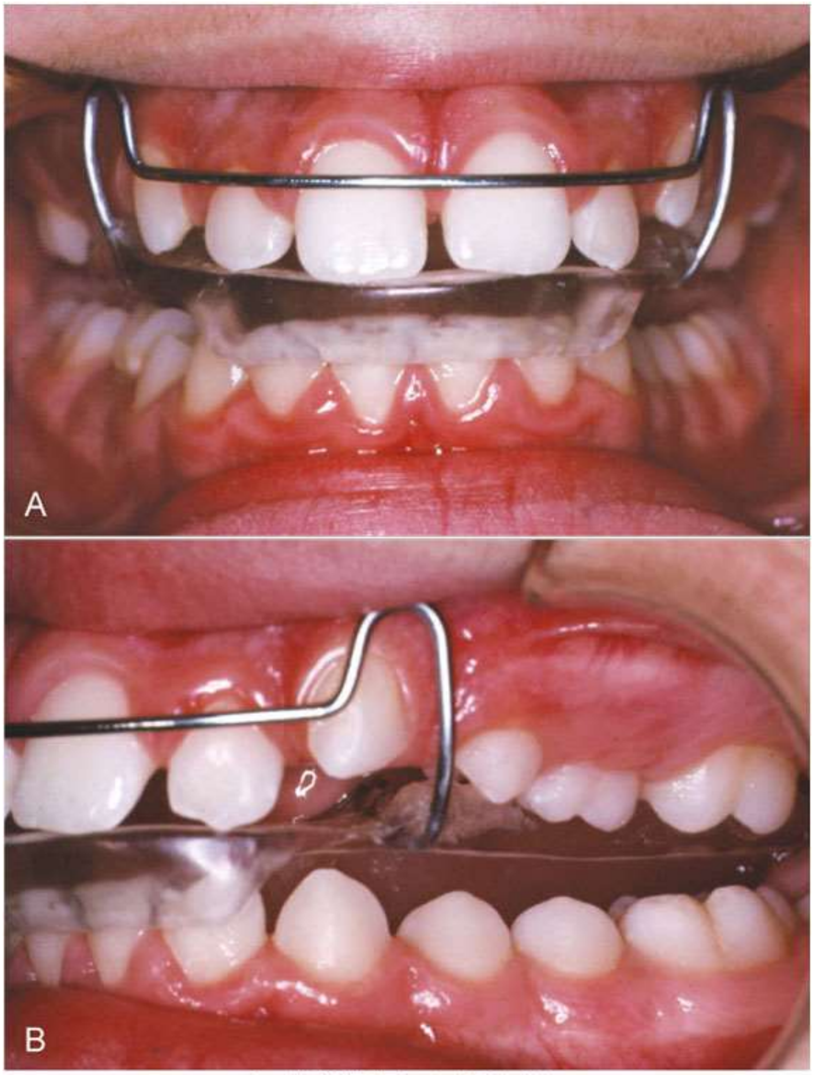

Figure 3-Bionator- Image from Proffit et al [24]

Twin-block, originally developed by Clark [25-27], is another tooth-borne Class II corrector which consists of individual maxillary and mandibular plates with ramps that guide the mandible forward; the acrylic ramps allow for alteration of the vertical dimension and an expansion screw, a labial bow or a headgear tube can be added to the maxillary plate. [28]

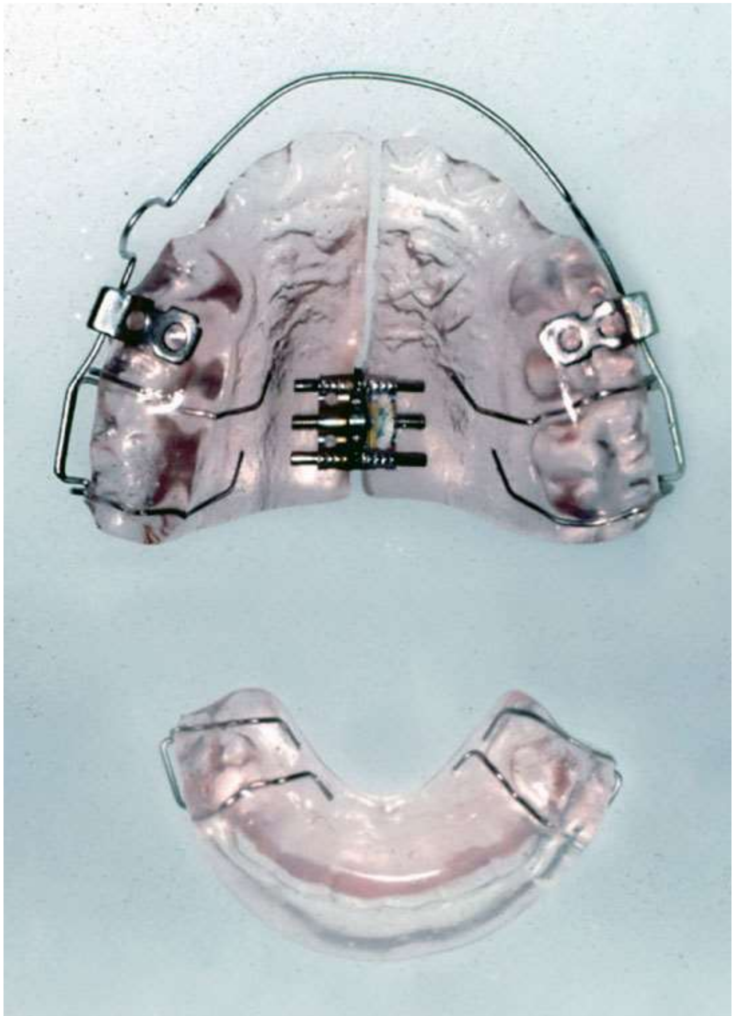

Figure 4-Twin-block- Image from Proffit et al [24]

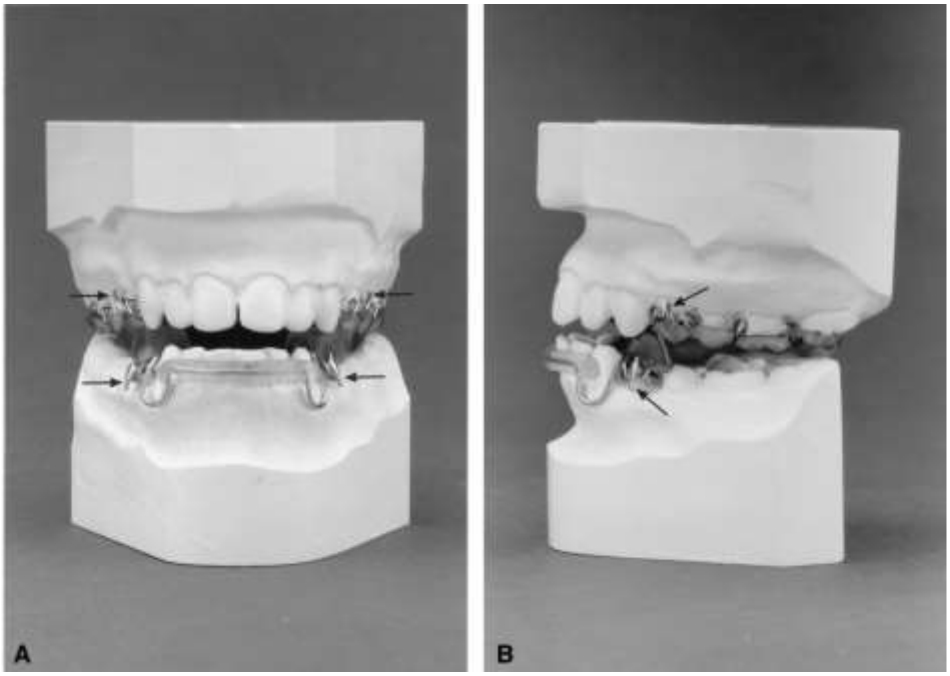

Figure 5-Twin-block- Image from Mills [5]

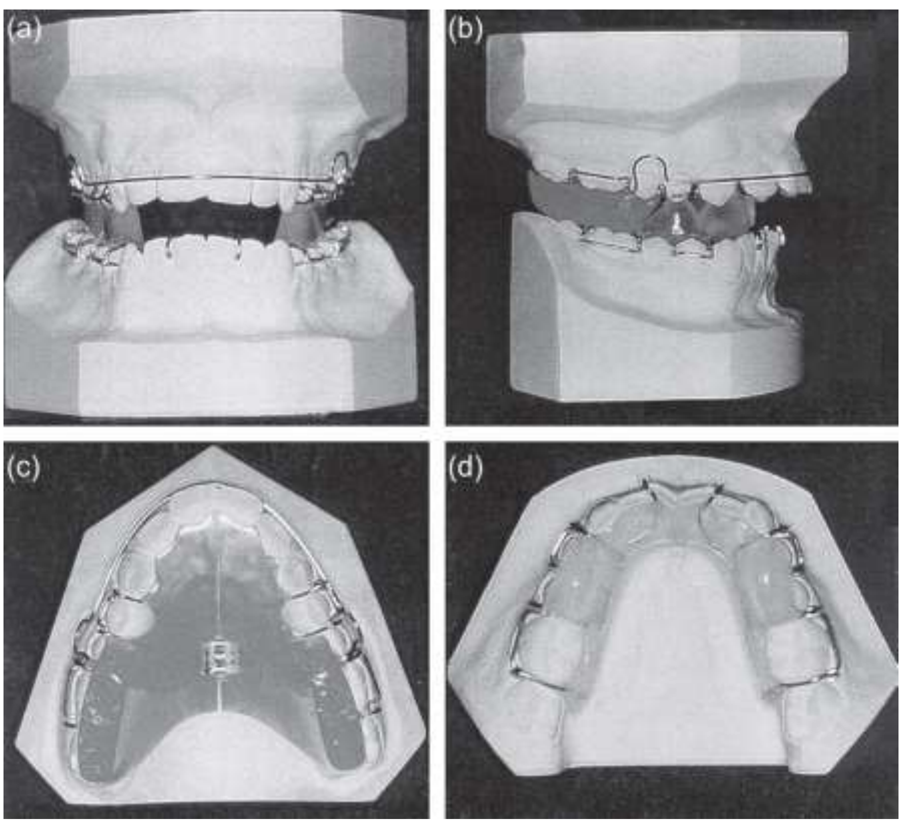

Figure 6-Twin-block- Image from Quintao et al [29]

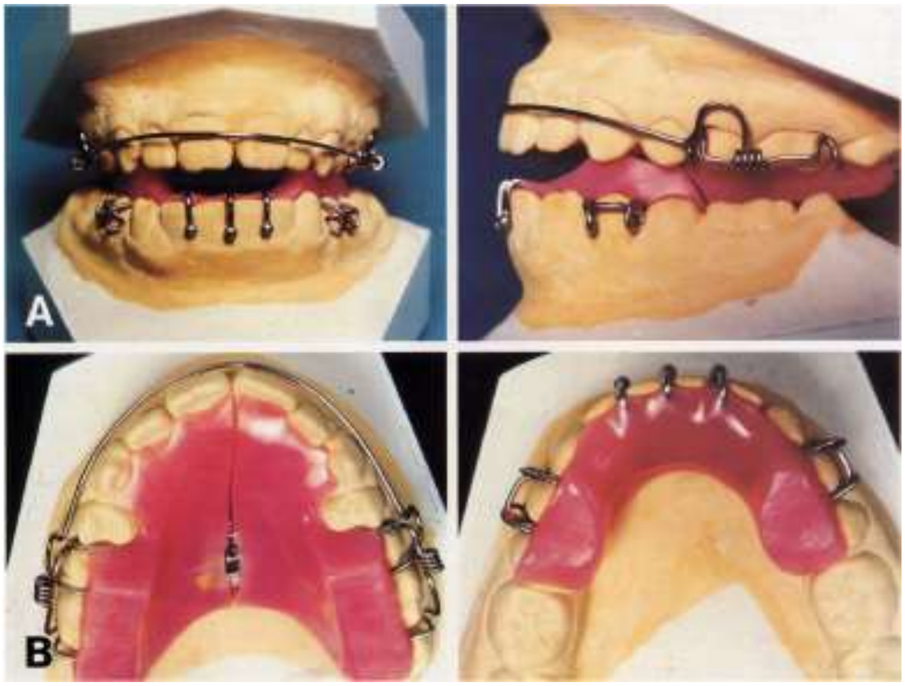

Figure 7-Original Twin-block appliance- Image from Clark [26]

Although Twin-block is occasionally bonded to the teeth to eliminate the problem of non-compliance, until recently, the only commonly used fixed Class II corrector was Herbst. Herbst has bilateral pin and tubes, which are attached to steel crowns on the maxillary molars and extensions from steel crowns on mandibular molars to posture the mandible forward. Transpalatal arch, lower holding arch and occlusal wire stops on lower premolars are components that can be added to Herbst's design as needed.

Figure 8-Herbst- Image from Proffit et al [30]

A variant of Herbst is the MARA (mandibular anterior repositioning appliance), which is less bulky. Unlike Herbst, which can be used with only anterior fixed appliances, MARA can be used with full fixed appliances as it extends from maxillary molars to mandibular molars only. However it has been reported to have more dento-alveolar effects than Herbst. [28]

Figure9- MARA-Image from Pangrazio et al [31]

Xbow is a fixed Class II corrector which consists of maxillary ad mandibular components and inter-arch 3M Unitek Forsus™ Fatigue Resistant springs. The upper part is made of bands cemented on upper 1st molars and either bands or occlusal rests on premolars and a maxillary expander to allow for expansion in conjunction with Class II correction to prevent lingual crossbite of buccal segments as a result of antero-posterior correction; the lower part consists of bands cemented on lower 1st molars and labial and lingual bows with adjustable Gurin locks; the upper and lower components are connected with 3M Unitek Forsus Fatigue Resistant springs. The springs are compressed by distalizing the Gurin locks using the Gurin lock wrench [13].

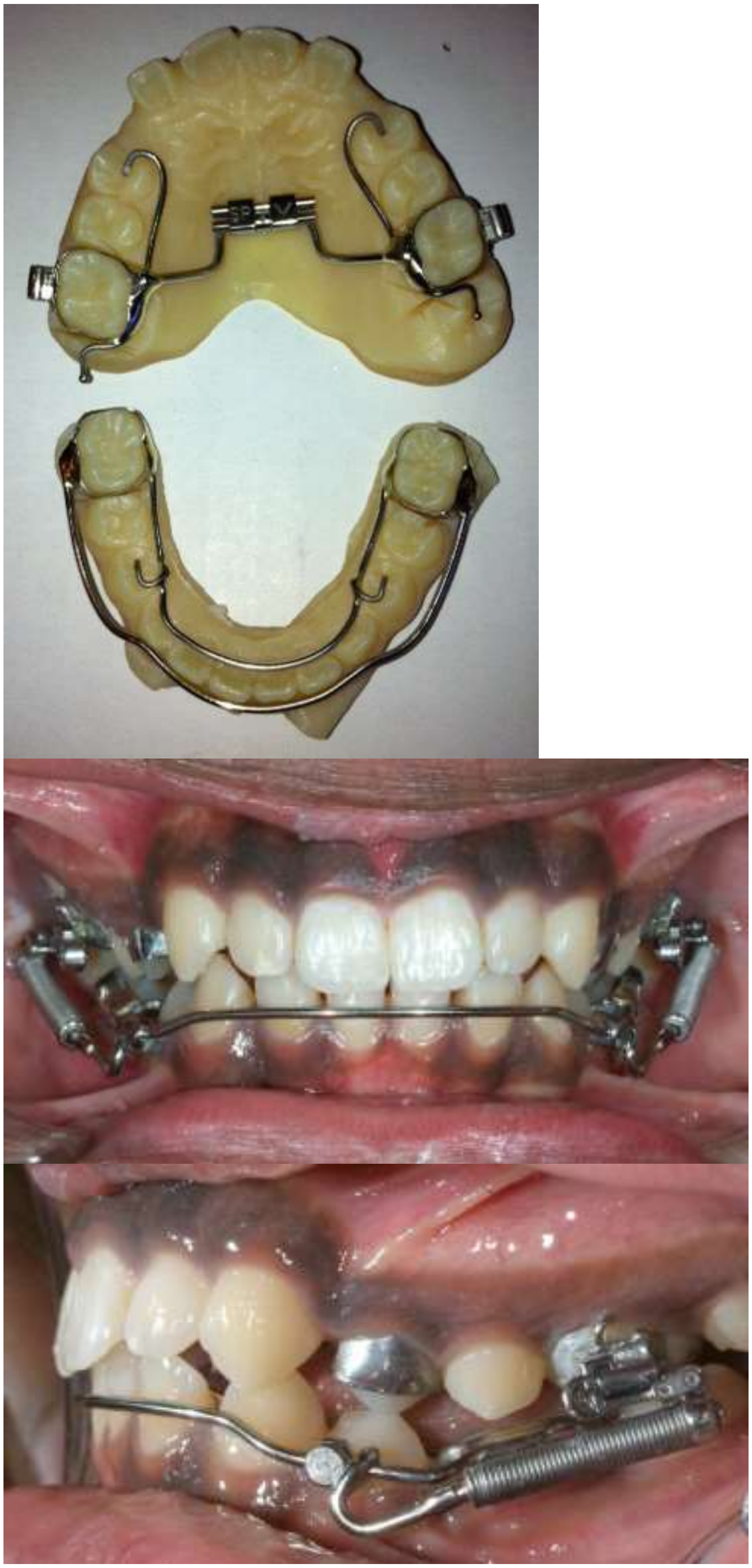

Figure 10-Xbow. Images from http://www.crossboworthodontic.com [13]

Treatment effects of Class II correctors

Orthodontic forces are able to significantly affect the dentition in an attempt to correct anteroposterior discrepancies, but the extent of their skeletal effect is greatly dependent on patient's growth potential, pattern of growth and compliance. [19] The relative skeletal and dental correction obtained by functional appliances is a controversial concept. [32]

Chadwick et al didn't find significant changes in SNB or SNA angle with Frankel appliance over an average of 1.6 years of treatment. However, they found a small overall change in intermaxillary sagittal relationship compared to untreated controls indicated by a larger reduction of ANB angle in the treated subjects. Although this difference was considered to be statistically significant, it was only 1.1 degrees and therefore not clinically significant. [33] On the other hand, Cozza et al reported a small but significant headgear effect on the maxilla with Activator treatment. They also found anterior displacement of the mandible indicated by further increase of SNB angle (>1 degrees) with no significant increases in mandibular length measured from Go to Me and attributed this displacement to remodelling of the glenoid fossa. They concluded that Class II correction was largely due to dento-alveolar changes, but relative advancement of the mandible was also a contributing factor. [32] Neither of the studies found significant vertical changes.

Basciftci et al reported 5.2 mm of increased total mandibular length measured from Co to Gn along with increased ramus height and corpus length with Activator treatment over a 16 month period [34], whereas Cozza et al didn't find any changes in mandibular dimension measured from Gn to Me during 18 to 24 months of Activator treatment. [32] Both studies however found an improvement in relative anteroposterior position of the two jaws: Basciftci found a small but statistically significant reduction of ANB angle whereas Cozza reported 3 mm anterior displacement of the mandible concomitant with a small but statistically significant headgear effect (maxillary growth was restrained by 1.26 mm based on anteroposterior position of ANS). The former study found a significant increase of anterior face height, whereas the latter found no changes in the vertical plane through measurements of anterior face height and mandibular plane angle. As for dental movements, the maxillary incisors tipped lingually in both studies, however due to the acrylic capping, the mandibular incisors were not proclined. Basciftci didn't investigate molar movements, but in Cozza's study no significant mesial and distal movements were seen in lower and upper molars, respectively. Furthermore, Cozza reported a forward displacement of the condyle, which suggested anterior remodelling of the glenoid fossa which could have potentially contributed to the Class II correction. In short, Cozza concluded that Class II correction was due to both dental and skeletal changes, mainly mandibular advancement. But Basciftci attributed the Class II correction to increases in mandibular dimension rather than its anteroposterior position.

Tulloch et al found statistically significant changes in both SNB angle and mandibular length with treatment with bionator in mixed dentition stage (average age 9.4 years) over a 15-month period. However these changes were small in magnitude; mandibular length measured from Co to Pog increased by only 1.6 mm and responses showed great variability in both treatment and control groups. [35] On the other hand, Faltin et al who studied effects of bionator treatment in two age groups, 9.7 and 10.8 years of age, reported clinically significant increases in mandibular length and ramus height, which amounted to 5.1 and 4.8 mm respectively in the later treatment group. They found these increases to be associated with a backward growth of the condyle expressed as opening of gonial and mandibular plane angles. They concluded that treatment is most effective when carried out during pubertal peak of growth [36]. It is noteworthy however that the treatment duration in this study was longer that 20 months and included the second phase of orthodontic treatment as well.

A systematic review of effects of Herbst [37] concluded that findings are controversial with regard to mandibular changes; although small increases (varying between 2 to 3 millimetres) in mandibular length have been reported by some investigations, it has not been established whether these changes were due to forward posturing of the mandible or an actual increase in its dimension. One of the sources of variability in findings is use of different measurements in different studies. As for Maxillary effects, the results are more unanimous; no Maxillary growth restraint (ie. Headgear effect) has been associated with Herbst appliance. [37] de Almeida et al [38] found a small increase of mandibular length (1.6 mm) over a 12 month period in the treatment group which was not deemed clinically significant. They suggested that smaller mandibular changes could be explained by the developmental age of the subjects who were in mixed dentition and not at their peak of growth stage. Pancherz on the other hand found differences greater than 2 mm between treatment and control group over a six-month period and attributed this increase to remodeling of condyle and articular fossa. Pancherz reported no changes in mandibular plane and therefore no autorotation of the mandible in the studied sample. [39] In a multicenter randomized controlled trial, O'Brien et al [40] found most of the changes with both Herbst and Twin-block to be dental rather than skeletal; they also found the skeletal effects to be considerably smaller than those reported by retrospective studies.

A study of 11 months of functional treatment with MARA in patients with average age of 11 showed significant increases in both mandibular length (Co-Gn) and face height by 2.7 and 1.5 mm's, but didn't find any skeletal effects on maxilla. Dental changed comprised of mainly distal movement of maxillary molars and also mesial movement of mandibular molars plus proclination of lower incisors. The investigators concluded that its treatment results were similar to those of the Herbst appliance without the headgear effect. [31]

The systematic review of Twin-block effects (Chapter 2 of this manuscript) found the dental effects of this appliance included proclination of lower incisors, retroclination of upper incisors, distal movement of upper molars and/or mesial movement of lower molars; the skeletal effects consist of increase in mandibular length and/or forward movement of the mandible with or without restriction of maxillary growth.

Comparison of Class II correctors

A systematic review of functional Class II appliances (including Herbst, Twin-block, Acticator, Bionator and Frankel) concluded that two thirds of the samples of the studies included in the review had clinically significant (i.e. greater than 2 mm) increase of total mandibular length as measured from Co to either Gn or Pog. The samples of the studies, which found such significant mandibular changes were treated during their peak of growth period, whereas samples that were treated prior to the peak of adolescent growth spurt didn't have significant mandibular changes. [41] At the average rate of 0.16 mm per month, clinically significant increases in mandibular length were observed over an average of 17 months of treatment with Class II functional appliances. Most efficient appliances were Herbst and Twin-block, with rates of 0.28 and 0.23 mm increases per month, respectively. Efficiency of Activator and Bionator was ranked as intermediate with 0.17 and 0.12 mm increases per month, respectively. Frankel showed the least efficiency at the rate of 0.09 mm per month. [41]

A meta-analysis of functional Class II appliances with treatment durations ranging from 9 to 22 months concluded that although sagittal intermaxillary changes occur with all investigated appliances, all functional appliances mainly affect the mandible. The only exception was the Twin-block, which also showed restriction effect on the maxilla. The meta-analysis reported that compared to untreated subjects, Activators and its variants such as Bionators increased the SNB angle by an average of 0.66 degrees, whereas Twin-block increased this angle by 1.53 degrees. The authors attributed these differences to the duration of appliance wear throughout the day, which is usually full-time for Twin-block. Twin-block also reduced the SNA angle by 1.03 degrees, resulting in an overall increase of ANB angle by 2.61 degrees. [8] It is noteworthy that although these differences were found to be statistically significant, their clinical significance is questionable.

In a multicenter randomized controlled trial, O'Brien et al found no differences between the effects of Twin-block and fixed crown Herbst; with both appliances they found most of the changes to be dental rather than skeletal. They did however find lesser patient's acceptance with Twin-block, which resulted in dropout rates two times larger than that of the Herbst group. They also experienced more breakages and therefore an average of 3 more appointments for appliance repair with Herbst. [40] On the other hand, Baccetti et al [4] found profound skeletal effects with Twin-block appliance, whereas patients with comparable skeletal maturation stages were found to have considerably smaller orthopedic changes with acrylic Herbst in a study by Franchi et al [42]. Baccetti attributed the difference to greater dental compensations in Franchi's sample. In another study of growth modification with bonded Herbst, Windmiller [43] found skeletal changes with bonded Herbst to be larger than that of Franchi's sample.

Factors affecting efficiency of Class II correctors

Treatment timing is an important variable that determines the skeletal outcome [8] ; to achieve maximum orthopedic effects, treatment should be carried out during the peak of growth. [41] Studies, which compared early and late treatment with the same functional appliance, also concluded that later treatment, during pubertal peak of growth, was more effective. [36] Baccetti et al [4] found that increase of mandibular dimension with treatment at or around peak of growth is almost twice as large as the changes at pre-adolescence. They found a posterior direction of growth in the condyle in the older treatment group, compared to forward condylar growth in the younger group. They suggested that the backward direction of the condylar growth ("posterior mandibular morphogenetic rotation") and consequent opening of the gonial angle in the older treatment group could explain the larger increases in total mandibular length and the additional growth expressed as increases in mandibular body length and ramus height. Baccetti further argues that aside from achieving maximum orthopedic effects with treatment during or slightly after pubertal growth, since treatment with full fixed appliances can be started immediately after the functional treatment, the retention period and chances for relapse will be minimized. Furthermore, the risk of a patient with Class II skeletal problem continuing to grow further with the original growth pattern during pubertal growth peak is high, especially when the growth peak occurs during the retention period. [4] Through a multi-center randomized controlled trial, O'Brien et al not only found early functional treatment, followed by a later second phase of full fixed treatment, to have no advantages over a one-phase treatment, but also found it to have greater burden for the patient as it was more costly and required more appointments and more appliance wear. [44]

Growth pattern is another factor, which is partly responsible for variations in responding to orthopedic treatment. [8] Horizontal direction of mandibular growth is an advantageous growth pattern for Class II functional treatment as it has been shown that patients whose gonial angle (Co-Go-Me) are smaller than 125.5 ° respond more favorably to orthopedic treatment. [45]

In a growing individual, changes of lower anterior face height significantly affect sagittal relationship of mandible and maxilla. [46] McNamara has shown that for every millimeter of increase in lower anterior face height, a similar increase of the mandibular length will be camouflaged. [46] In addition to patient's inherent growth pattern, changes of the vertical dimension during functional treatment can also affect the outcome of growth modification in Class II cases. Increase of lower anterior face height rotates mandible in a clockwise direction, moving the pogonion backwards thereby reducing chin projection. This backward displacement of the chin will mask the mandibular advancement associated with Class II correctors. Therefore, controlling the vertical dimension is critical in Class II correction [32,41] as it allows for mandibular growth to be expressed in a more horizontal pattern rather than in a vertical pattern. [19]

Another important factor, which affects efficiency of functional treatment, is patient's compliance. [8,40] In a multi-center randomized controlled trial, O'Brien et al found that patient's acceptance of Herbst was so much greater than Twin-block that the non-completion rate in latter group was twice as large as the former one. [40]

Dento-alveolar compensations resulting from functional treatment influence the effectiveness of growth modification through minimizing the potential for orthopedic effects. [4,5,22] One of the major compensations seen with Class II correctors regardless of the appliance design is labial tipping of lower incisors; therefore excessive lower incisor proclination has to be minimized during treatment with functional Class II correctors to allow for maximal orthopedic changes. [47]

Although some degree of dento-alveolar compensation is inevitable with all appliances, due to greater contact with teeth, fixed functional appliances are more likely to induce such compensations than removable appliances. [5] Baccetti et al [4] found larger orthopedic changes with Twin-block than did Franchi et al [42] with the acrylic Herbst, despite similar stages of skeletal maturation of the subjects. On the other hand, Franchi's Herbst group showed greater dento-alveolar changes expressed as distal movement of maxillary molars.

Severity of initial skeletal discrepancy has also been suggested to affect the efficiency of functional appliance treatment . [8,40] O'Brien argues that larger skeletal discrepancies don't respond more favorably to functional treatment because the treatment effect cannot fully counteract the initial skeletal discrepancy. [40]

Although there is not adequate evidence to indicate gender as a determining factor in efficiency of Class II correctors, O'Brien et al [40] found girls to have better sagittal correction than boys with either Twin-block or Herbst treatment. This could be attributed to better compliance in girls for the Twin-block group, but this doesn't apply to the Herbst group as appliance is fixed and not compliance-dependent.

Appliance breakage and/or debonding, for fixed correctors, are other factors that can adversely affect treatment efficiency. O'Brien et al found that Herbst appliance needed considerably more appointments for appliance repair compared to Twin-block. [40]

As a result, use of a certain Class II corrector for all patients is not recommended [19]; instead the appliance needs to be selected taking individual variations in to account. Etiology and severity of malocclusion, pattern of growth, patient's age and maturity and the anticipated level of compliance all need to be considered in choosing the Class II appliance. [8] Removable and fixed appliances both have their merits and if selected appropriately, they will aid the clinician achieve optimal results for the properly selected candidate.

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Chapter 2: Systematic Review of treatment effects with the Twin-Block appliance

2. Chapter 2

2.1. Introduction:

Class II functional appliances are indicated in the correction of mandibular deficiencies as they allow mandibular postural changes by holding the mandible forward and/or downward. [1] The muscles and soft tissues are stretched with the generated pressure transmitted to the skeletal and dental structures potentially resulting in skeletal growth modification and tooth movement. [2]

Both fixed and removable class II functional appliances are used to improve class II malocclusions. Since the success with removable appliances largely depends on patient's compliance, using a more tolerable appliance can increase the chances of a favorable outcome. Clark originally designed Twin-blocks in the 1980s' with the objective of developing a comfortable and aesthetically acceptable Class II functional appliance. [3] Twin-blocks are upper and lower acrylic bite blocks with occlusal inclined planes that interlock at a 70 degree angle and guide the mandible forward and downward. The inclined planes are positioned mesial to maxillary and mandibular molars where the acrylic shelves cover the maxillary molars and 2nd premolars (or primary molars) and the region anterior to the mandibular 1st premolars (or primary molars). Ideally Twin-blocks are supposed to be worn fulltime, including eating, to take advantage of forces of mastication. [3] Clark called the Twin-block a “patient friendly” appliance as it improves patient's appearance when it is in place and is also comfortable and esthetic. [4] Although there is no objective evidence in literature, it has been suggested that compared to other functional appliances, success rate with Twin-block is favorable because it is generally better tolerated by patients [5,6] as it is smaller than other functional appliances, has no visible acrylic portion anteriorly and its interference with speech is minimal [6].

Several studies have evaluated the skeletal and/or dental changes with Twin-block treatment, but to date, only one systematic review [7] of Twin-block's treatment effects has been conducted, which focused exclusively on soft tissue changes. The objective of the present chapter is to systematically evaluate dental, skeletal and soft tissue effects of treatment with Twin-block appliance. This information should serve clinicians considering the use of Twin-Blocks to better understand the potential treatment effects to be produced.

2.2. Materials and Methods:

2.2.1. Information sources

A systematic computerized search of electronic databases was carried out in Medline, PubMed, Embase, All EBM reviews (Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED), and Web of Science until June of 2012.

2.2.2. Search

The following search strategy was utilized in Medline: (Twin-block OR twin-block OR Twin-block) AND [(treatment outcome OR treatment effect$) OR (skeletal effect$ OR skeletal change) OR (dental effect$ OR dental change) OR (facial change or profile change or soft-tissue change)]. Similar strategies were used in PubMed, Embase, EBM reviews and the Web of Science databases. Detailed search strategies and search dates for the remaining databases can be found in Table 2-1. No restrictions were applied to the electronic searches. Duplicate results were removed upon identification.

Eligibility criteria

Titles and abstracts of the results were then scrutinized to identify the papers that met the initial selection criteria. The following criteria were chosen:

- Human studies
- Cephalometric studies

- Having treated with Twin-block appliance with a non-extraction and non-surgical approach to prevent introduction of confounding factors
- Having a control group of untreated cases with a class II malocclusion because mandibular growth of Class II individuals has been shown to be different from that of Class I cases [8]

Papers, based on the abstracts/titles, which did not meet the initial selection criteria, were removed. Papers, which were descriptive, editorial, letter, not investigating cephalometric variables or hadn't included untreated cases as a control group were also excluded.

Full texts of the articles were collected based on the abstracts/titles that met the initial selection criteria. Full text was also obtained for the abstracts which were either not available or had not clearly elaborated the above mentioned initial selection criteria.

If there were more than one publication for the same study, the one which was more detailed and informative was selected. Methodological quality of the papers was then evaluated. Papers which met the following quality criteria were finally selected and included in the review:

- Clearly stating an acceptable sample size
- Reporting the measurement error
- Using a sound statistical method
- Reporting the P-value's

A manual search was also conducted by going through the reference lists of the selected articles to ensure that no potentially acceptable articles were missing from the electronic searches.

2.2.3. Data items and collection

Skeletal and dental cephalometric findings including mandibular and maxillary dimensions, mandibular and maxillary antero-posterior positions, sagittal inter-maxillary relationship, mesio-distal position of maxillary and mandibular first molars, inclination of maxillary and mandibular incisors and vertical dimensions were collected from the articles. Two reviewers conducted both selection processes independently. Discrepancies between the two were resolved through discussion until a consensus was reached for the finally selected articles.

2.3.4. Risk of bias in individual studies

Risk of bias was assessed through the evaluation of methodological quality study characteristics as listed in Table 2-2. [9] It must be noted that the employed methodological scoring system is not validated and the quality assessment of the studies is subjective. Factors such as intra-rater reliability, inter-rater reliability and blinding of examiner and/or statistician were considered. If both inter-rater and intra-rater reliability were tested and randomization was carried out, the study was rated as low-risk for bias. If inter-rater reliability was not assessed and randomization was not performed either, the study was rated as high-risk for bias. All other studies were categorized as medium-risk for bias.

2.3.5. Risk of bias between studies

Based on the heterogeneity between the selected studies a meta-analysis was going to be considered.

Database	Search Strategy	Number of results	Number of selected papers
Medline (1948 to present)	(Twin-block OR twin-block OR Twin-block) AND [(treatment outcome OR treatment effect$) OR (skeletal effect$ OR skeletal change) OR (dental effect$ OR dental change) OR (facial change or profile change or soft-tissue change)]	52	7
All EBM Reviews - Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED	Same as Medline	25	3
PubMed: (1950 to the present)	Same as Medline	75	7
Web of Science: 1899-present	((TS=(twin-block OR Twin-block OR Twin-block) AND TS=(orthodont*)) AND ((TS=(treatment outcome) OR (TS=(treatment effect*) OR (TS=(skeletal change) OR (TS=(skeletal effect*) OR (TS=(dental change) OR (TS=(dental effect*)OR (TS=(facial change OR profile change OR soft-tissue change))) ; DocType=(Article);	21	2

	Language=All languages; Database(s)=SCI-EXPANDED		
Embase: 1980 to 2012 Week 04	Same as Medline	52	4
Manual search		0	0
Total		226	23
Duplicates		133	13
Total after removing duplicates		92	10

Table 2-1- Search Dates, Search Strategies, and Number of Results for Each Database

Methodological score used in the review	
I.	Study Design (6√)
A.	Objective – objective clearly formulated (√)
B.	Sample Size – considered adequate and estimated before collection of data (√)
C.	Baseline characteristics – similar baseline characteristics (√)
D.	Co-interventions (√)
E.	Randomization- Random Sampling (√); Random Allocation of treatment (√)
II.	Study Measurements (5√)
F.	Measurement method –appropriate to the objective (√)
G.	Blind measurement – blinding (examiner √, statistician √)
H.	Reliability - described (√), adequate level of agreement (√)
III.	Statistical Analysis (5√)
I.	Statistical analysis – appropriate for data (√); combined subgroup analysis (√)
J.	Confounders (co-interventions) –confounders included in analysis (√)
K.	Statistical significance level – P value stated (√); confidence intervals (√)
IV.	Other (1√)
L.	Clinical significance (√)
Maximum number of √s = 17	

Table 2-2- Methodological score used in the review

2.3. Results:

2.3.1. Search Process and study selection

Electronic searches yielded a total of 226 results: 52 hits were retrieved from Medline; out of the 75 results yielded from PubMed, only 26 were new and not duplicates; All EBM Reviews and Web of Science returned 25 and 21 results, respectively; only 3 of EBM reviews results and 9 of the Web of Science results were original; Embase returned 52 hits out of which 50 were duplicates of the Medline results. Once the duplicates were removed, the total number was reduced to 92. No additional results were found through the manual search of the references.

Based on initial inclusion criteria, out of the 92 results, 57 were excluded based on their title and/or abstracts and 21 were excluded after reading their full texts at the second selection stage. The articles were excluded if they were descriptive, used the same sample as another publication or were not cephalometric studies. Therefore 14 papers met the inclusion criteria [5,6,10-21]; but 4 were later excluded because of extremely small total sample size and fewer than 15 subjects in each treatment group [11], using adjunctive treatments [13] or not reporting measurement errors [11], statistical significances of the findings [12] or the applied statistical methods [10]. Therefore ultimately a total of 10 articles were included in the review.

2.3.2. Study characteristics and risk of bias

A summary of the methodological scores of the selected articles is illustrated in table 2-3.

Six of the selected articles were prospective controlled clinical trials [14-19], while the remaining four were retrospective controlled clinical studies [5,6,14,21].

Overall, all studies, except for Toth[5], examined and reported both inter and intra- rater reliability. Toth[5] however, only reported inter-rater reliability. On the other hand, blinding was done for neither the examiner nor the statistician in any of the studies except for the three studies (Illing[19], O'Brien[15] and Morris[16]), which had the examiners blinded. Based on randomization, blinding and reliability testing, studies were classified as having a low, medium or high risk of bias. (Table 2-3)

The age of the samples at baseline varied in the studies: O'Brien[16] and Mills[6] investigated patients at a younger age, whereas Lund[18], Varlik[15], Jena [19] and Illing[20] and Morris[17] studied older patients. Subjects of Sidlauskas[14] and Toth[5] were at neither of the extreme ends of the range.

Varlik[15] selected patients who were exhibiting maximum pubertal growth whereas Baccetti *et al* [21] were the only investigators who included two distinct age groups, one with CVM stages 1-3 (9 years) and one with CVM stages 4-6 (12 year 11 months), with the objective to determine the optimum timing for Twin-block treatment. They found that treatment in the older group resulted in more orthopedic changes and larger increases in mandibular length; therefore, they concluded that the optimum timing for treatment with Twin-block is either during or slightly after growth spurt, which usually coincides with late mixed or early permanent dentition stage.

All studies had combined samples of males and females, except for one [19] which only enrolled females in the trial.

Inclusion criteria for almost all the studies included having a class II molar relationship; the severity of the Class II varied from half cusp to full cusp. Some of the studies limited their samples to class II division 1 malocclusion. Some studies defined class II malocclusion based on criteria for overjet and/or ANB angle. Most studies required an OJ of 6 or larger, although there was a study in which OJ was equal to or larger than 5 [14]. As for ANB angle, in all studies this angle was at least equal to or larger than 4 degrees.

Only one study defined the mandibular plane angle and included samples with the "optimal (32±2°)" angle [15].

		Objective	Sample size	Baseline	No Co-interventions	Randomization: Random sampling Random allocation	Measurement method	Blinding : Examiner Statistician	Reliability testing: Intra rater Inter rater	Statistical analysis	Confounders included in analysis	P-value Confidence interval	Clinical significance	Total Score (out of 17)	Risk of bias
1	Baccetti *et al* 2000[21]	√	/	×	√	××	√	××	√√	/	×	√√	√	9	M
2	Illing *et al* 1998[20]	√	/	√	√	×√	√	√×	√√	√	√	√√	√	13.5	L
3	Jena *et al* 2006[19]	√	/	√	√	××	√	××	√√	√	√	√√	√	11.5	M
4	Lund *et al* 1998[18]	√	√	√	√	××	√	××	√√	√	√	√√	√	12	M
5	Mills *et al* 1998[6]	√	√	×	√	××	√	××	√√	√	×	√√	√	10	M
6	O'Brien *et al* 2003[16]	√	√	√	√	×√	√	√×	√√	√	√	√√	√	14	L
7	Sidlauskas 2005[14]	√	√	√	√	××	√	××	√√	/	√	√√	√	11.5	M
8	Toth *et al* 1999[5]	√	√	×	√	××	√	××	√×	√	×	√√	√	9	H
9	Morris *et al* 1998[17]	√	/	√	√	×√	√	√×	√√	√	√	√√	√	13.5	L
10	Varlik *et al* 2008[15]	√	√	√	√	×√	√	××	√√	√	√	√√	√	13	L

Table 2-3- Methodological Scores for the Selected Papers

√= Met, /= Partially met, ×= Not met

H=High, M=Medium, L=Low

Summary of selected studies

	Study type	Sample size		Mean age of combined groups at T1 (years)	Treatment duration (months)
		Twin-block	Control		
Baccetti *et al* 2000[21]	Retrospective	21 (early group)& 15 (late group)	16 (early group) &14(late group)	9 (early group)& 12.9 (late group)	16 (early group)& 15 (late group)
Illing *et al* 1998[20]	Prospective	16	20	11.2	9
Jena *et al* 2006[19]	Prospective	25	10	11.4	12.78
Lund *et al* 1998[18]	Prospective	36	27	12.4	14.4
Mills *et al* 1998[6]	Retrospective	28	28	9.1	14
O'Brien *et al* 2003[16]	Prospective	89	85	9.7	15
Sidlauskas 2005[14]	Retrospective	34	34	10.2	12
Toth *et al*	Retrospective	40	40	10.4	16

1999[5]					
Morris *et al* 1998[17]	Prospective	16	20	11.2	9
Varlik *et al* 2008[15]	Prospective	25	25	11.9	8

Table 2-4- Summary of Selected Papers

Treatment duration with Twin-block in the reviewed articles had a wide spectrum ranging from 8 to 16 months.

All the authors reported retroclination/retrusion of upper incisors (Lund: 10.8°, Toth: 4.3°, Mills: 2.5°, Illing: 7.2 °, Sidlauskas: 9.1°, Jena: 1.8 mm, O'Brien: 3 mm) and proclination/protrusion of lower incisors (Lund: 7.9°, Toth: 2.8°, Mills: 3.8°, Illing: 3 mm (relative to A-Pog line), Sidlauskas: 2.6°, Jena: 1.8 mm, O'Brien: 2mm). The only exception was Baccetti [21] who did not find any significant changes in position of upper incisors; they did however find significant proclination of mandibular incisors (1.4 and 2.2 mm per year in early and late treatment groups, respectively) as did all other included studies.

Both Baccetti[21] and Mills[6] reported distal movement of maxillary molars and also, to a lesser extent, mesial movement of the lower molars. Toth[5] too reported distal movement of upper molars with no mesial movement of lower molars; In contrast, Lund[18] only detected mesial movement of lower molars, with the distal movement of upper molars to be statistically non-significant, while Jena *et al* [19] found mesial movement of mandibular molars with restricted forward movement of maxillary molars.

Baccetti *et al* [21] found significant increases in total mandibular length (Co-Pog) in both early and late treatment groups (4.75 and 1.88 mm per year, respectively). They also found additional increases in mandibular body length (Go-Pog) (1.66 mm/year) and ramus height (Co-Go) (2.73 mm/year) in the older treatment group, but in the early group these changes were minimal when examined separately and did not reach statistical significance. Lund[18] and Sidlauskas[14] both detected significant increase of mandibular length (Ar-Pog) (2.4 mm/year and 2.3 mm/year, respectively); where Sidlauskas also found a significant increase in Ar-B point distance (2.9 mm /year). Illing [20] found significant increases of mandibular length (Ar-Gn)(2.2/ 9 months) Toth and Mills[5,6]both reported substantial increase of mandibular length (Co-Gn)(3 mm/ 16 months and 4.2 mm/14 months, respectively); in Mills' study, 2/3rds of the mandibular length was due to increase of ramus height (Co-Go), whereas 1/3rd was due to increase in mandibular body length (Go-Gn). Jena *et al* [19] reported significant total mandibular growth (1.65 mm/12.78 months) with Twin-block appliance. O'Brien [16] found statistically significant increases in mandibular base (Po-OLp)(1 mm/15 months).

Most of the studies found increases in the SNB angle (Lund: 1.5°, Toth: 1.3°, Mills: 2.2°, Illing: 1°, Sidlausakas: 1.3°). Illing [20] also found forward movement of the Pogonion (Pog-S vertical and S-N-Pog angle), whereas Toth[5] reported the Wits appraisal to reduce by 4 mm.

Most studies did not find any significant changes in Maxillary's sagittal position, based on either midface length [5,18,20,21] or sagittal position of A point [5,19-21]. However, Sidlauskas [14] and Mills [22] both reported a statistically significant decrease of SNA angle, suggesting some maxillary growth restraint; Sidlausakas [14] and O'Brien [16] also found restriction of maxillary base length (PTM-ANS and Ar-A point: -0.7 mm and A-OLp: -0.88 mm, respectively) with Twin-block, whereas Mills [22] did not detect any changes in midface length (Co-Sub ANS).

Only a few of the studies found changes in the mandibular plane angle: Toth[5] found an increase of mandibular plane angle (2.1°) with significant increase of anterior lower face height (3 mm vs. 1.1 in controls) and posterior lower face height (Co-Go) (3.2 mm vs. 1.5 in controls). Illing [20] and Sidlausaks [14] also found significant increase of anterior lower face height (3 mm/9 months and 1.8 mm/year, respectively). Mills *et al* [21] did not detect changes in Mandibular plane angle; they did however find significant increases of both anterior and posterior lower face height. Although Lund *et al* [18] did not report an increase of mandibular plane angle, they did detect an increase in the lower anterior face height (1.5 mm) due to eruption of lower molars. Toth [5] too reported extrusion of lower molars with no changes in eruption of upper molars, whereas Mills [22] reported significant extrusion of lower molars along with inhibited eruption of upper molars. Lund [18] also detected some extrusion of the maxillary molars, at least of the mesial cusps. Baccetti *et al* [21] reported significant increases in gonial angle (Ar-Goi-Me); this increase was even larger in their older treatment group. However, they did not find any changes in the vertical skeletal relationships. Mills [22] too reported a statistically significant, but clinically small increase of both the gonial angle (Ar-Go-Gn) and the saddle angle (N-S-Ar).

As for dental changes, all studies reported reduction of the OJ (Baccetti: 4.6 and 5.8 mm (early and late groups, respectively), Lund: 7.5 mm, Toth: 3.3 mm, Mills: 5.9 mm, Illing: 6.4 mm, Sidlauskas: 5 mm, Jena: 6.1 mm, O'Brien: 6.9mm). Toth [5] also reported a reduction in OB (2.2 mm).

As for soft-tissue changes, neither Morris [17] nor Varlik [15] found statistically significant changes in the upper lip position. Although Morris *et al* [17] did not find significant changes in facial convexity, they observed forward movement of soft tissue B point (2.9 mm) and lower lip (2.9 mm). They also detected increase of soft tissue lower face height (2.7 mm) and lower lip length (3.2 mm). Varlik [15] too found statistically significant differences for most of the mandibular soft tissue landmarks, including forward movement of soft tissue pogonion, and also increase of both nasolabial and labiomental angles.

2.4. Discussion:

Baccetti *et al* [21] detected that skeletal changes were predominant over the dental changes, regardless of timing of treatment, and that increases of both mandibular length and height were larger in the older treatment group who were treated during pubertal growth spurt. They also found that the main orthopedic effect occurred in the mandible, with no changes in sagittal position of maxilla and no changes in vertical facial relationships. Mills [22] attributed most of the OJ reduction to the mandibular skeletal changes. Lund *et al* [18] also found the mandibular changes (increase of SNB angle) to be the most significant change with Twin-block appliance, with no maxillary skeletal changes. However, unlike

Baccetti [21] and Mills [22], they found the dentoalveolar effects to be predominant over the skeletal effects; in fact, they attributed most of the OJ reduction to the dentoalveolar changes. The larger increases in Baccetti's late group could be due to the fact that, unlike other studies, they selected their subjects based on skeletal maturation staging. Furthermore, since Lund [18]used the distance between Ar and Pog to measure mandibular length, it is unclear if the improvement of sagittal relationship of the mandible was due to an actual increase in size or its anterior repositioning. Sidlauskas [14] and Jena [19] both attributed more than half of the OJ reduction to skeletal changes. Jena [19] also attributed over 70% of the molar correction to the skeletal changes.

On the other hand, O'Brien's [16] was one of the few studies which did not find significant skeletal changes; they only observed 1 mm mandibular growth with Twin-block and concluded that 73% of the OJ reduction and 59% of the molar correction was due to the dento-alveolar changes. As Jena *et al* [19] have suggested, the larger skeletal changes which they found compared to O'Brien [16] could be due to the difference in the timing of the treatment, as Jena's samples were treated at the peak of their pubertal growth spurt. On the other hand, O'Brien [16] argues that most of the studies which have reported significant skeletal improvements were retrospective and therefore exposed to selection bias, resulting in overestimated treatment effects.

Although most studies, except for O'Brien's [16], found statistically significant increases in SNB angle, some of these changes, as Sidlauskas [14] points out in regards to his own finding (1.3°/year), were not large enough to be considered clinically significant.

As for vertical changes, the mandibular plane angle in studies of Lund [18] and Mills [22] did not change with treatment as both anterior and posterior facial heights increased with treatment. Toth's [5] sample were treated using different approaches with regards to facial height: for some, the acrylic on the posterior bite blocks was trimmed to allow for lower molar extrusion and correcting the deep curve of spee, whereas for some the bite blocks were left intact to provide vertical control. Illing *et al* [20] too treated their cases based on individual considerations for vertical control as they added occlusal rests to prevent eruption of molars in high angle cases. Therefore, Illing's findings of increase of lower face height and Toth's results in terms of vertical control should be both interpreted with caution. Although Sidlausaks [14] found statistically significant increases in lower face height, they concluded that the increase (1.8 mm/year) was clinically negligible. More importantly, they point out that since the LAFH/TAFH ratio did not change the proportionality of upper and lower anterior face height was not affected. Finally, Lund *et al* [18] found that Twin-block did not restrict the upper molar eruption, however, as they suggested, their finding might have been due to merely distal tipping of upper molar (and subsequent extrusion of the mesial cusp), rather than a pure extrusion.

Not surprisingly, findings about maxillary skeletal effects were controversial. Although most studies (including Lund's) did not find a "head gear effect" with Twin-block, Lund *et al* [18] hypothesized that the retroclination of the upper incisors and labial tipping of their roots could result in remodeling of the A point to a more anterior position. This potential anterior remodeling could therefore mask any maxillary restraint effects that may have occurred. On the other hand, Mills [6] and Sidlauskas [14] both found statistically significant headgear effect based on SNA angle reduction (1° and 0.8°, respectively) and Sidlauskas [14] and O'Brien [16] both found statistically significant changes in maxillary base length (0.7 mm and 0.8 mm, respectively); however, these changes were too small to be considered clinically significant.

As for changes of incisors, most studies found retroclination/retrusion of upper incisors regardless of presence or absence of a labial bow. According to Jena *et al* [19], the headgear effect of the labial bow in addition to its contact with upper incisors during sleep could be a contributing factor to maxillary incisor retroclination. On the other hand, Toth *et al* [5] suggested that the retroclination/retrusion could be due to the pressure of upper lip musculature during functional treatment which could explain the retroclination in the absence of a labial bow in studies of Baccetti [21], Mills [6], Illing [20], Sidlauskas [14] and Toth [5]. Overall, all studies except for Baccetti's [21], found retroclination/retrusion of upper incisors with more severe changes in studies which had used an upper labial bow [16,18,19].

Also, all studies found proclination/protrusion of lower incisors with Twin-block treatment. This occurred even in studies where either a lower labial bow [6] or an acrylic extension covering edges of lower incisors [14] was used. As Jena *et al* [19] pointed out, the protrusion of the mandible results in a mesial force application on the lower incisors; in the absence of lower lip pressure, this mesial force proclines the lower incisors with Twin-block treatment.

Molars changes were very variable. Toth *et al* [5] appropriately suggested that the contrast of the findings could be due to the different measurement methods used: Mills [6] applied a custom analysis with a vertical line through Sella and perpendicular to palatal plane, whereas Lund [18] used SN and SN perpendicular. Toth [5] on the other hand used various constructed reference lines: a line tangent to pogonion and perpendicular to mandibular plane, lines perpendicular and parallel to Frankfort line at pterygomaxillary fissure and lines parallel and perpendicular to mandibular plane at pogonion.

As for soft tissue changes, Morris *et al* [17] emphasized that despite statistical significance, the large standard deviations of their findings make the clinical significance of the few soft tissue changes, such as lower lip position and length, questionable. Similarly, although Varlik *et al* [15] reported statically significant changes for many of the investigated soft tissue landmarks, the clinical significance of their findings is highly questionable as, just like Morris [17], they found large variations in individual responses. On the other hand, despite no statistical significance, Morris *et al* [17] reported a slight reduction of facial convexity with opening of the nasolabial angle and labiomental fold. These findings are in agreement with those of Varlik's. Varlik [15] suggested that uncurling of the lower lip which was initially trapped under the upper incisors could have contributed to the increase of the labiomental angle. Morris *et al* [17] argued that the large individual variation of these angles and the low accuracy of soft tissue measurements preclude reaching statistical significance. They pointed out that employing larger sample sizes through multi-center studies can address this issue, but it will introduce other sources of variability such as techniques, appliances, etc. As for elongation of lower lip, it could be perhaps explained by to the retraction of upper lip as a result of upper incisor retroclination [17,23].

The results of the present review should be interpreted with caution due to the limitations of both the review and the included studies. The included studies have used various measurements, some linear and some angular, to quantify the mandibular dimension, mandible's sagittal position and incisors position. The variability of the selected measurements makes it challenging to compare the findings of the studies. Moreover, some of the used measurements do not actually represent what the authors wanted to evaluate. For example, despite its limitations, SNB was used in most studies to evaluate sagittal position of mandible. However, this angle does not account for rotational changes of mandible and changes of lower anterior face height. Therefore, changes in face height have potentially masked or exaggerated the true sagittal changes. Furthermore, all studies only evaluated the short-term effects; therefore, the long-term treatment outcome continues to be a topic of controversy with functional Class II correctors.

2.5. Conclusions:

- Proclination of lower incisors, retroclination of upper incisors, distal movement of upper molars and/or mesial movement of lower molars, increase in mandibular length and/or forward movement of the mandible (increase in SNB angle) were consistently reported.
- Clinically significant restraint of maxillary growth was not found.

- Changes of lower face height and occlusal plane inclination varied, suggesting that vertical dimension can be manipulated in patients who would benefit from lower molar extrusion.
- As for lip position, findings were controversial and there is not enough evidence to suggest clinically meaningful changes of lip position.

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Chapter 3: Comparison of dental and skeletal outcomes in Class II malocclusions treated by either a Xbow or a Twin-Block appliances with orthodontic brackets

3. Chapter 3

3.1. Introduction:

The Xbow is a fixed Class II corrector that uses Forsus springs (3M Unitek) and is utilized as a phase 1 appliance for treatment in late mixed or early permanent dentition. [1] It consists of a maxillary hyrax expander with bands on upper first molars and first premolars and mandibular labial and lingual bows with bands on lower first molars and occlusal rests on lower first premolars. If 2nd molars are fully erupted then occlusal rests are also added to them. The two arches are connected with Forsus springs (3M Unitek) which are hooked on the mandibular labial bow in the canine or premolar area and are held in place with Gurin locks (3M Unitek). The springs are activated every 6 weeks by moving the Gurin locks distal on the labial bow, rather than switching to longer pushrods or using split shims. [1]

Twin-blocks were originally introduced by Clark in the 1980's. [2] The Twin-block appliance consists of upper and lower bite blocks with inclined occlusal planes that interlock and guide the mandible forward and downward. The acrylic shelves cover maxillary molar and 2nd premolar (or primary molar) in the upper arch and the region anterior to the 1st premolar (or primary molar) in the lower arch. [3] The interaction of the upper and lower ramps controls the vertical separation of the two jaws and the extent of mandibular advancement. [4] Clark advocated fulltime wear of the appliance for ideal results. [3]

Regarding previous research for these appliances, the Xbow is a relatively new appliance, which provides clinicians with a compliance-free alternative in mild to moderate Class II treatment. There has been limited research [1,5-7] about treatment effects of Xbow as to how it resolves the Class II malocclusion. The Twin-block appliance on the other hand has been used as a Class II corrector for decades and has been reported to be one of the most efficient Class II correctors [8]. In a systematic review of Class II correctors, the Twin-block was found to be the second most efficient appliance, only preceded by Herbst by merely 0.05 mm extra per month in mandibular dimensions increase. The authors defined efficiency of the appliance as its ability to induce mandibular elongation taking the months of active treatment into account [8]. Although the Twin-block has been reported to be better accepted by patients [9] compared to the other removable Class II correctors, it is still a compliance-dependent appliance, which is less acceptable to patients compared to fixed Class II correctors. [10] Therefore a comparison of the treatment outcomes of the two appliances, one compliance-free and one compliance-dependent, would be of interest. In addition to being compliance-free, the Xbow has the added advantage of giving the operator the opportunity of using it unilaterally or bilaterally, as needed. The aim of the present study is to compare short-term skeletal and dental effects produced by a combination of either the Xbow or the Twin-block followed by orthodontic brackets.

3.2. Methods and Materials:

Approval for this study has been obtained from Health Research Ethics Board, University of Alberta Edmonton, Canada (approval number Pro00023805 - 2011). Using data from previously published studies [11,12] a sample size calculation was carried out (Appendix A) using Wits as it was chosen as the primary outcome variable. A threshold for clinical significance of Wits has not been defined in literature. However, most of the literature investigating functional appliances considers a change twice as large as the method error to be clinically significant. Since most of these studies have reported method errors to be no larger than 1 mm and/or 1 degree, the smallest detectable meaningful change of Wits was chosen to be 2 mm for the purpose of sample size calculation. To detect a 2 mm change in Wits appraisal at a power of 80% and at significance level of 0.05, 23 patients per group were required.

50 consecutively treated patients were included in this study. Patients were treated with either Twin-block or Xbow appliance during early permanent dentition as phase 1, followed by full fixed orthodontic treatment as phase 2, at a private practice in Edmonton, AB by one of two clinicians (B.N. and K.H). Phase 2 was carried out using 22x28 slot edgewise brackets with MBT prescription; The archwire

sequence generally consisted of a round (16 or 18 mil) heat-activated NiTi followed by 16x22 NiTi for alignment, with progression to 18x25 stainless steel for leveling and 19x25 Beta-Titanium for finishing. Inter-arch elastics, including Class II pattern, were used if needed. Inclusion criteria were a non-surgical non-extraction treatment and at least half cusp class II occlusion at pre-treatment.

Lateral cephalograms were taken prior to treatment and also immediately after treatment. The pre-treatment cephalometric radiographs were taken either at the E.D.I. (Edmonton Diagnostic Imaging) with a General Electric/Instrumentarium OC100D (Instrumentarium Imaging, Milwaukee, WI) or at Align Orthodontics with a Sirona OrthophosDS (Sirona, Munich, Germany). All post-treatment images were taken at Align Orthodontics with the Sirona OrthophosDS (Sirona, Munich, Germany). All lateral radiographs were uploaded into Dolphin Imaging software, version 11.5 (Chatsworth, California) and traced using a custom cephalometric analysis (Appendix B). To account for magnification, which is integral to radiographic projection, the calibrated nose-piece of the machine, which was visible in all images, was used; two points on the ruler set 10 millimeters apart from each other were traced and used to adjust for magnification.

The employed custom analysis included 10 linear and 3 angular variables from the published analyses of McNamara, Harvold, Tweed, Pancherz and Wits appraisal.[13] To assess the sagittal inter-maxillary relationship, the Wits appraisal was chosen over Steiner's ANB angle. To evaluate the anteroposterior relationship of each jaw to the cranial base, distances from Point A and Pogonion to a vertical reference plane originally described by McNamara, drawn from Nasion perpendicular to Frankfort horizontal plane, was used. Unlike SNA, SNB and ANB, these measurements are not affected by vertical position of Nasion. To detect changes in dimensions of maxilla, the distance from ANS (Anterior Nasal Spine) to another vertical reference plane, a line perpendicular to Frankfort from most inferior point of Pterygomaxillary fissure (PTM), was measured. Dimensional changes of mandible were measured from both horizontal and vertical aspects through measurements of Gonion to Pogonion (Go-Pog) and Sella to Gonion (Sella-Go), respectively. Changes of total mandibular length were also measured from Condylion to Pogonion (Co-Pog). To evaluate vertical changes, one linear and one angular measurement, Lower Anterior Face Height (LAFH) measured from ANS to Menton and also Mandibular Plane angle to Frankfort plane, were used. As for dental measurements, upper incisor inclination to Palatal plane and lower incisor inclination to Mandibular plane were measured. A vertical reference plane modeled after Pancherz analysis was used to measure molar positions; the distances from the most mesial surfaces of crown of the first molars to a line drawn from Sella perpendicular to the occlusal plane were measured to evaluate changes in the anteroposterior positions of both maxillary and mandibular molars.

To factor out growth, which would occur regardless of treatment, a control group consisting of untreated individuals with Class II malocclusion was obtained from Burlington Growth Center at University of Toronto. Subjects of the control group were matched to the treatment groups with regards to age and sex. Lateral cephalometric radiographs of the control group (i.e. Burlington samples) were taken with a film based x-ray machine manufactured by Keleket (Covington, Kentucky) in 1950's and 1960's; therefore, the lateral images of this group were manually traced on tracing paper using the same above mentioned custom analysis. All linear and angular measurements were recorded to the closest 0.5 millimeters and 0.5 degrees, respectively. To correct for magnification, the manufacturer's reported magnification of 9.84% was used. In the following equation, A represents the *true anatomic distance* and B represents the corresponding *measurement on the radiograph*:

$A + 9.84\%A = B$

Therefore, the linear measurements on the radiographs were divided by 1.0984 to obtain the true non-magnified values. No adjustments were made to the angular measurements to correct for magnification, because it has been shown that magnification doesn't significantly affect angular measurements. [14]. Similar studies [11] of Class II correctors in literature have followed the same concept and applied the magnification correction to linear distances only.

To confirm reproducibility, 21 randomly selected lateral images (7 images from each group) were traced a total of 3 times with an interval of at least 4 weeks in between for the digital tracings of the treatment groups. The manual tracings of the control group were however repeated in a random order over a 2-day period as the lateral images of this group could not be removed from Burlington Growth Centre in Toronto and therefore had to be traced during one visit. The Intra-Class Correlation coefficients were calculated to assess reproducibility and measurement errors were calculated using Dahlberg's formula (Appendix D).

First, starting values of all three groups were compared using Multivariate Analysis of Variance for the T1 data. To evaluate treatment/observation changes, a second Multivariate Analysis of Variance was carried out for T2-T1 data. Normality and equal variance assumptions were checked for; however, due to equal sample sizes in all three groups, MANOVA is robust to deviations from normality and/or equal variance. Since the groups were not equal at baseline, tests of Univariate Analysis of Covariance were used to account for differences in starting characteristics. Post-hoc BonFerroni tests were then used for pairwise comparison of inter-group differences. All statistical tests were performed using PASW Statistics 18 (SPSS Inc., Chicago, IL) using a significance level of 0.05.

3.3. Results:

Intra-Class Coefficient (ICC) values and measurement errors calculated using Dahlberg's formula are illustrated in table 3-1. ICC values were all above .90, with their confidence intervals ranging between .818 and .976 indicating very high agreement between the 3 sets of measurements. Dahlberg's measurement error ranged between 0.8 mm for ANPerp and 1.6 mm for CoPog. The ICC values and measurement errors were similar to reported values in literature. [1,15-18] The first set of measurements for all groups was used in the study because the reliability values were considered excellent.

Variable	Intra-Class Correlation Coefficient (ICC)	95% Confidence Interval	Dahlberg's error (mm/°)
Wits	.938	(.874,.973)	0.9
ANPerp	.937	(.876, .972)	0.8
PogNPerp	.944	(.889, .975)	1.1
SGo	.967	(.933, .986)	1.1
GoPog	.950	(.900, .977)	1.3
CoPog	.960	(.920, .982)	1.6
ANSMe	.976	(.950, .989)	0.9
MPFH	.953	(.896, .980)	1.0
U1PP	.955	(.911, .980)	1.2
L1MP	.948	(.889, .978)	1.3
U6Olp	.906	(.818, .957)	1.4
L6Olp	.921	(.854, .964)	1.2
ANSPTMperp	.922	(.848, .965)	1.2
FH-SN	.916	(.822, .964)	0.7

Table 3-1- Intra-Class Correlation Coefficients (ICC) and 95% Confidence Interval; Measurement errors

	Sample size (n)	Sex		Age at T1 (years)	Age at T2 (years)	Time between first and second x-rays (years)
		Number of Male subjects	Number of Female subjects			
Control	25	16	9	12	15.6	3.46
Twin-block	25	15	10	11.88	15.26	3.38
Xbow	25	17	8	12.06	15.46	3.4
P-value for between group comparison	N/A	.846		.531	.433	.948

Table 3-2- Subjects demographics; Between-group differences at 0.05 significance level

Variable	Twin-block Mean (95% Confidence Interval)	Xbow Mean (95% Confidence Interval)	Control Mean (95% Confidence Interval)
Wits	-4.9 (-5.9, -4)	-3.4 (-4.4, -2.4)	0.3 (-0.2, 0.7)
ANPerp	-1.8 (-3.1, -0.4)	-1.6 (-2.5, -0.6)	-0.1 (-0.9, 0.8)
PogNPerp	2.3 (0.5, 4.2)	1.2 (-0.3, 2.6)	0.9 (-0.4, 2.2)
SGo	5.7 (4, 7.4)	7.3 (5.5, 9.1)	8.2 (5.5, 10.8)
GoPog	8.3 (6.5, 10.1)	4.4 (2.9, 5.9)	4.1 (3, 5.2)
CoPog	8.9 (7.4, 10.3)	8 (6.2, 9.8)	7.3 (5.5, 9.2)
ANSMe	4.5 (3, 6)	3.7 (2.3, 5.1)	4.3 (2.9, 5.6)
MPFH	-0.2 (-1.6, 1.3)	-1.4 (-2.7, -0.2)	-1.5 (-2.5, -0.6)
U1PP	3.4 (-0.4, 7.1)	6.7 (3, 10.5)	-0.4 (-2, 1.2)
L1MP	6.3 (4.2, 8.5)	9.6 (7.3, 12)	0.1 (-0.8, 1.1)
U6Olp	2.9 (1.8, 4)	2.9 (1.9, 3.8)	4.4 (3.7, 5.1)
L6Olp	6.8 (5.8, 7.9)	6.3 (5.3, 7.3)	3.7 (3, 4.4)
ANSPTMperp	2.1 (0, 4.1)	0.8 (-0.4, 2.1)	4.1 (2.8, 5.3)

Table 3-3- Descriptive statistics of Treatment/Observation (T2-T1) changes

All measurements in mm/°.

3.3.1. Statistical Analysis:

To compare starting forms, a multivariate analysis of variance (MANOVA) was run for pre-treatment values with Group and Sex as factors. The interaction term between Group and Sex was not significant (P=.272); therefore the model was reduced and run without the interaction term. With the reduced model, Sex had no significant effect (P=.296). Significant Group differences were found for Wits (P=.002), Go-Pog (P<.01), Co-Pog (P=.012), U1-PP (P=.011) and L1MP (P=.014). Post-hoc tests showed that Wits was 2.1 mm larger in Twin-block group compared to Control group (P=.001); GoPog was 3.6 and 5.1 mm smaller in Twin-block group compared to Xbow and Control groups, respectively (P=.003, P=.000); CoPog in Control group was 3.2 and 3 mm larger than both Twin-block and Xbow groups, respectively (P=.024, P=.033); U1PP values were 6.2 ° smaller in Xbow group than the Twin-block group (P=.010) and L1MP values were 4.8° smaller in Xbow group than control group (P=.015).

Variable	Twin-block Mean (95% Confidence Interval)	Xbow Mean (95% Confidence Interval)	Control Mean (95% Confidence Interval)	Significance		
				TB-XB	TB-C	XB-C
Wits	4.8 (4, 5.5)	3.5 (2.9, 4.1)	2.6 (1.6, 3.7)	NS	*	NS
ANPerp	2.2 (1, 3.5)	0.3 (-0.8, 1.3)	1.2 (-0.1, 2.6)	NS	NS	NS
PogNPerp	-4.7 (-7.1, -2.4)	-6.6 (-8.8, -4.4)	-6.1(-8.3, -3.9)	NS	NS	NS
SGo	71.1 (68.9, 73.3)	70.5 (68.6, 72.4)	68.3 (66.2, 70.4)	NS	NS	NS
GoPog	62.3 (60.8, 63.7)	65.9 (64.4, 67.5)	67.4 (65.9, 69)	*	*	NS
CoPog	98.6 (96.8, 100.3)	98.9 (97.1, 100.6)	101.8 (100.1, 103.5)	NS	*	*
ANSMe	59.9 (57.7, 62)	60 (58.3, 61.6)	57.8 (56.5, 59.2)	NS	NS	NS
MPFH	22.9 (20.2, 25.6)	24.7 (22.8, 26.6)	23.5 (22, 25.1)	NS	NS	NS
U1PP	111.5 (107.9, 115.1)	105.3 (102.7, 107.9)	107.5 (105, 110)	*	NS	NS
L1MP	95.1 (92.8, 97.4)	93.8 (91.2, 96.4)	98.7 (96.3, 101.1)	NS	NS	*
U6Olp	54.8 (53.4, 56.3)	55 (53.3, 56.6)	56.3 (54.5, 58)	NS	NS	NS
L6Olp	53.7 (52.2, 55.1)	53.8 (52.3, 55.3)	55.8 (54, 57.5)	NS	NS	NS
ANSPTMperp	49.9(48.9, 50.9)	50.5 (49.4, 51.7)	50.8 (49.7, 51.9)	NS	NS	NS

Table 3-4- T1 Values; All measurements in mm/°; TB=Twin-block, XB=Xbow, C=Control

***: Between-group significance at 0.05 significance value.**

NS: Group differences not significant at 0.05 significance value

A multivariate analysis of variance (MANOVA) of treatment/observation changes (T2-T1) was run with the interaction term (Group*Sex). The interaction term was not significant (P=.090), therefore the model was reduced and run without the interaction term. The reduced model found a multivariate significant effect for Group (P<.001), and no significant effect for Sex (P=.086). Due to unequal baseline values, as discussed above, follow-up univariate analyses of covariance (ANCOVA) were used. ANCOVA found significant treatment effects for Group for: Wits (P<.001), ANPerp (P=.029), GoPog (P=.009), U1PP (P=.001), L1MP (P<.001), U6Olp (P=.005), L6Olp (P=.001) and ANSPTMperp (P=.006). Pairwise comparisons showed that significant differences existed between Control group with both Twin-block and Xbow groups for Wits (P<.001; P<.001), ANPerp (P=0.019; P=0.026), U1PP (P=.002; P=.008), L1MP (P=.001; P=.000), U6Olp (P=.014; P=.015), L6Olp (P=.001; P=.012) and ANSPTMperp (P=.035; P=.009) respectively. They also showed that GoPog changes were significantly different from both Xbow and control groups (P=.009, P=.046). Differences in L1MP changes between the two treatment groups were also statistically significant (P=.047).

Wits reduction in Twin-block and Xbow groups was 5.2 and 3.6 mm larger than the Control group; increase of ANPerp in Twin-block and Xbow groups was 1.7 and 1.5 mm smaller than control group. Increase of GoPog in Twin-block group was 4.3 and 4 mm larger than Xbow and Control groups, respectively. Increase of U1PP in Twin-block and Xbow groups was 3.6 and 7.3 degrees larger than Control group, whereas increase of L1MP change in Twin-block and Xbow groups was 6.2 and 9.5 degrees larger than Control group; L1MP increase in Xbow group was also 3.3 degrees larger than Twin-block group. Increase of U6Olp in Control group was 1.4 and 1.6 mm larger than Twin-block and Xbow groups, whereas L6Olp increase was 3.2 and 2.6 mm smaller than Twin-block and Xbow groups, respectively.

3.4. Discussion:

Samples of all three groups were matched with regards to sex and age, at both pre and post-treatment. In other words, treatment and/or observation period was similar across all groups and males and females had similar distribution in all groups.

3.4.1. Starting craniofacial characteristics:

However, comparison of starting forms showed that pre-treatment values were not similar for all variables across the three groups. At baseline, both treatment groups had smaller mandibular unit length (Co-Pog) compared to the Control group, but they were not different from each other. However, the Twin-block group had a smaller mandibular corpus length (Go-Pog) and larger Wits values than both the Xbow and the Control groups, suggesting a higher severity of Class 2 malocclusion in this group based on a relatively smaller mandible. The Twin-block group also had larger values for upper incisor inclination compared to the Xbow group, which is explained due to the inclusion of more Class II Division 2 malocclusion subjects based on pre-treatment lateral cephalograms. Therefore, in evaluating the treatment effects, these baseline differences were accounted for by incorporating the pre-treatment values into the final statistical model.

3.4.2. Effects of appliances:

Unlike the control group, both treatment groups showed changes in favor of Class II correction through a combination of skeletal and dentoalveolar changes over the 3.4 years of two-phase treatment consisting of phase 1 with either Twin-block or Xbow appliance and phase 2 with fixed orthodontic appliances. The skeletal and dental changes are discussed below.

3.4.3. Sagittal Intermaxillary relationship:

The sagittal intermaxillary correction with Xbow and Twin-block was reflected in reduction of Wits appraisal values by 3.3 and 4.9 mm respectively.

3.4.4. Maxilla:

Although ANSPTMperp values increased in all three groups, the increase was substantially smaller in both treatment groups. These differences suggest that both appliances induced a restriction of forward maxillary growth, also known as "Headgear effect". The maxillary growth restraint with the appliances was also reflected in reduction of ANPerp in both treatment groups. Although the ANPerp values in the treatment groups decreased with treatment, a distalization of the maxilla cannot be automatically assumed; because Point A is an alveolar point, rather than a true skeletal landmark, and its location is altered with changes in inclination of maxillary incisors. [19] The treatment groups consisted of a considerable number of Class II division 2 cases that over the course of treatment likely experienced lingual root torque of the maxillary incisors; this alteration of incisor inclination resulted in remodeling of Point A in a posterior direction. Therefore, perhaps the posterior movement of Point A in treatment groups is due to a combination of alveolar remodeling and restraint of maxillary growth rather than just distalization of the maxilla. Greater forward movement of ANS in the Control group compared to both treatment groups confirms the maxillary restraining effect of both appliances.

3.4.5. Mandible:

Unlike the other two groups, the Twin-block group showed an increase in mandibular length in the horizontal dimension (GoPog), which is indicative of a "Class II functional effect" due to acceleration and/or true stimulation of mandibular growth. One of the mechanisms of mandibular growth is bone apposition on posterior surface of ramus [20] which may explain the increase in mandibular corpus length in the Twin-block group; this difference between Twin-block and Xbow may be explained by the fact that unlike Twin-block, Xbow does not displace the condyles out of the glenoid fossa, therefore increase of condylar growth with or without remodeling of the fossa is not anticipated [1]. On the other hand, Twin-block is a “functional” appliance, which forces the patient to posture the mandible forward.

On the other hand, changes of PogNPerp in Twin-block group did not reach statistical significance. Finding statistically significant differences for one variable and not the others with regards to mandibular size is not exclusive to this study. Changes with Twin-block have been reported to have large individual variations. [21] The variability of responses to class II correctors has been attributed to two factors: individual growth pattern and effect of treatment on the expression of growth. [22] This variability results in relatively large standard deviations associated with modest means; the more dispersed the data becomes, the more likely it is for the outcome to take extreme values, resulting in weaker evidence against the null hypothesis, therefore underestimating the treatment changes. [19] It is probable that sagittal changes of Pogonion did not reach statistical significance in the present study due to wide variability in Twin-block group; the 95% confidence interval for changes of PogNPerp with Twin-block was almost twice as large as that of Xbow and Control groups.

Finally, changes of mandibular unit length, Co-Pog, did not reach statistical significance either. This could be either due to the large variability as discussed above or due to errors in landmark identification for Co-Pog. Condylion is a particularly difficult cephalometric landmark to identify especially when the lateral head film is taken with the mouth closed [23]; findings of the present study with Co-Pog having the largest measurement error (1.6 mm) confirm the difficulty in accurately locating the Condylion point. The relatively large measurement error might have potentially confounded the findings, resulting in failure to accurately detect the changes.

3.4.6. Dentoalveolar changes:

Mesial movement of lower first molars were considerably larger in both treatment groups compared to untreated controls, whereas mesial movement of upper first molars were significantly smaller in these groups. These differences implicate that a forward movement of mandibular molars and restriction of mesial movement of maxillary molars occurred with both appliances and contributed to correction of the Class II malocclusion. These dental changes are expected findings of Class II correctors, especially the tooth-borne category; when patient relaxes the muscles, the reactive forces are distributed on the dentition moving the lower teeth forward and upper teeth backwards [24]. The net molar relationship added up to 3.9 mm for Twin-block group, 3.4 mm for Xbow group and -0.7 mm for the Control group, with plus sign indicating movement in direction of Class II correction and minus sign indicating the opposite.

Unlike the control group, lower incisor inclination increased with both appliances with a significantly larger increase in the Xbow group (9.7°) than the Twin-block group (6.4°). Again, lower incisor proclination is a typical dental movement, which is almost always seen with Class II correctors due to the previously mentioned reactive forces. The dental movement is affected by the extent of the contact of the appliance with the dentition [24] and duration of forces [25]; therefore it is not surprising that Xbow, which is a fixed tooth-borne appliance with continuous forces, resulted in larger dentoalveolar movements of lower incisors. It is noteworthy that there were a considerable number of Class II division 2 subjects in Xbow group who started off with upright lower incisors. This dissimilarity at baseline may have potentially affected the changes of lower incisor inclination making it challenging to compare the effects of the two appliances on incisor inclination. On one hand, smaller inclination values at baseline might be responsible for larger treatment changes in the Xbow group. On the other hand, it is probable that the lower incisors would finish more proclined at the end of treatment had the subjects started treatment with already proclined lower incisors.

Upper incisor inclination also increased in both treatment groups, whereas its changes were negligible in the control group. Although proclination of maxillary incisors seems contrary to the already established effects of Class II correctors, the explanation lies in the starting forms of the treatment groups. Since both division 1 and division 2 cases were included in the study, the established post-treatment torque of the maxillary incisors affected the mean changes of upper incisor inclination.

3.4.7. Vertical changes:

Changes of lower anterior face height (ANSMe) and mandibular plane angle (MPFH) were not statistically significant across the three groups, indicating no significant vertical changes. To further investigate the effect of growth pattern, patients were also grouped into 3 distinct groups with Normal, Short and Long face heights based on ANS-Me values at T1. Patients within one standard deviation (P=0.05) of the mean of the combined 3 groups were classified as Normal, whereas patients with values below and above the one standard deviation were classified as Short and Long, respectively [6]. Mean lower face height was 59.22 mm and SD was 4.25 mm; therefore 49 cases were categorized as Normal with lower face heights between 54.97 and 63.47 mm, whereas 14 and 12 cases were classified as Short and Medium. Multivariate analysis of variance for observation/treatment changes showed no multivariate effect for Vertical face Height (P=0.48) or its interaction with any of the main factors, Group (P=0.459) and Sex (P=0.535).

Changes of posterior face height (S-Go) were not statistically significant among the three groups either, also suggesting no vertical changes.

3.4.8. Occlusal plane inclination:

Functional appliances can also affect eruption of dentition. If eruption and mesial movement of upper posterior teeth is inhibited, while lower posterior teeth are allowed to erupt up and forward, the resulting upward rotation of occlusal plane posteriorly can potentially facilitate dental Class II correction. [26] Changes of occlusal plane inclination showed statistically significant differences between Xbow and Control groups (Appendix G). The rotation was 2.2 degrees larger for the Xbow group which can be deemed clinically meaningful. However, since vertical changes of the molars (intrusion and/or extrusion) were not evaluated, there is not adequate data to interpret these changes which can negate or exaggerate the FMA changes.

3.4.9. Sex:

No differences were found between responses of males and females to either type of treatment.

3.4.10. Summary of Findings:

In both treatment groups, Maxilla moved forward less than the Control group with the Xbow samples demonstrating the least Maxillary growth in the anteroposterior plane. As for mandibular changes, changes of corpus length reached statistical significance only in the Twin-block group and not in the Xbow group. Other mandibular measurements, including mandibular unit length and sagittal position of Pogonion, did not show significant differences. Although each individual measurement has its own merits, cephalometric changes must always be considered collectively. Corpus length increase was significantly larger with Twin-block. Judging by pre-treatment values of Wits, the Twin-block group started the treatment with relatively greater Class II malocclusions compared to the other two groups; Patient's growth pattern and growth potential difference of maxilla and mandible have been shown to affect treatment success [27]; therefore, the larger corpus length increases with Twin-block despite these pre-treatment differences of the treatment groups may suggest effectiveness of this appliance in Class II correction. On the other hand, changes of mandibular unit length (Co-Pog) were not significantly different from the other groups. As it was mentioned previously, the Co-Pog measurement might have been affected by landmark identification errors in locating the Condylion. Despite larger increase of corpus length with Twin-block, changes of Pogonion's sagittal position-although larger in Twin-block group- did not reach statistical significance. This finding might be due to the large variation of changes in Twin-block group.

Dentally, mesial movement of mandibular molars was significantly larger in both treatment groups. Although no distalization of upper molars was found in either treatment group, restriction of mesial movement of maxillary molars was seen with both appliances. Treated subjects showed increase of upper incisor proclination as a result of a considerable number of Class II division 2 cases in the samples of all three groups. Also, as expected, both treatment groups demonstrated increased lower incisor proclination with larger increases with Xbow appliance.

3.4.11. Comparison with literature:

Direct comparison of the findings of the present study to the literature is difficult for two reasons: First, most studies of Class II correctors have evaluated the treatment changes which occur during the first phase of treatment, whereas in this study the treatment changes of the two-phase treatment (Phase 1 with functional appliance therapy followed by Phase 2 with full fixed orthodontic appliances) were investigated. Secondly, most studies [17,19,28-31] only included Class II division 1 malocclusions, whereas samples of the present study consisted of both divisions of Class II malocclusion. None-the- less, the findings were compared to the literature, however the comparisons must be interpreted with caution.

Shaefer *et al* [32] conducted a similar retrospective study comparing the effectiveness of fixed crown Herbst and Twin-block. They studied two samples of 28 consecutively treated subjects per group that were treated with either Herbst or Twin-block followed by full fixed appliances. They found the outcomes to be similar except for a slightly larger sagittal intermaxillary correction with Twin-block mainly due to greater increases of mandible's dimension. Herbst and Xbow are different as Xbow is a non-protrusive Class II corrector [1], so comparison of the present study with that of Schaefer's must be made with caution; having said that, since Herbst is a passive fixed Class II corrector [33] a comparison of the findings of the two studies might be of interest. The results of the present study are in agreement with Schaefer's[32] as the only discernible difference between the two treatment groups is increase of mandibular length with Twin-block, whereas no such increases were found with Xbow appliance. As it was mentioned previously, given the fact that unlike Twin-block, Xbow does not posture the mandible out of the glenoid fossa, this is an expected finding [1].

O'Brien *et al* [10] also compared treatment effects of Twin-block and Herbst followed by full-fixed appliances in a multi-center randomized controlled trial. Again, keeping the differences of Xbow and Herbst in mind, findings of this study are also in agreement with O'Brien's who found comparable treatment effects for the two appliances.

In terms of treatment effects of Xbow, results of this study are in agreement with Flores *et al* [1] who found maxillary growth restraint without mandibular advancement. The molar changes are in partial agreement as unlike Flores *et al* [1], who found mandibular molar mesialization and maxillary molar distalization, the present study only found mandibular molar mesialization. The present study did however find a restrictive effect of Xbow on mesial movement of maxillary molars. Various factors might have led to these contrasting findings. One possible explanation could be that in this study the treatment effects were evaluated at the end of a two-phase treatment; molar relationships are usually overcorrected during the functional phase of treatment, with some relapse during the second phase of treatment [32]. Another potential explanation is inter-operator variability and different amounts of activation of the springs. Finally perhaps the most plausible explanation, which has been previously suggested in literature [11] to explain the contrast of the findings with regards to molar positions with Class II correctors, is utilization of different measurement methods for molar position. Findings of the two studies are in agreement for lower incisor proclination but contrasting for upper incisor inclination as unlike this study, the former study found no changes in upper incisors position. As it was previously explained, the proclination found in the present study is due to a relatively large number (9) of Class II Division 2 malocclusions in the Xbow sample, which affected the mean change of upper incisor inclination. Finally, unlike the present study, Flores *et al* [1] reported a small but statistically significant increase of vertical dimension, measured by increase of MP-SN angle by 1 degree. Although the increase was clinically negligible and therefore not really contrasting to the findings of this study, a possible explanation for the variation could be distal movement of maxillary molars in their study, which might have been transient in subjects of the present investigation. Both bodily distalization and distal tipping of the upper molar (with subsequent extrusion of the mesial cusp, rather than a pure extrusion) [29] could be responsible for increase of mandibular plane angle.

In comparison to literature, the findings for Twin-block appliance are in complete agreement with Baccetti [34] and Mills [9], who found increases in mandible's body length measured from Gonion to either Pogonion or Gnathion, and in partial agreement with Lund [29], Sidlauskas [17], Illing [19], Toth [11], Jena [28] and O'Brien [30] who all found increases in some dimension of mandible.

Previously reported changes in anteroposterior position of molars with Twin-block have had a wide range. Present results for lower molars agree with Baccetti [34] and Mills [9], but differ from Toth [11], who found no lower molar mesialization. The results for upper molars concur with Jena [28], who found restricted forward movement of upper molars, but differ from Baccetti [34], Mills [9] and Toth [11], who observed upper molar distalization. The findings are also in partial agreement with Lund [29], who found no upper molar distalization with Twin-block. The variations in the findings are perhaps largely due to the wide range of measurement methods used in different studies [11].

Findings of the present study are in complete agreement with literature for changes in lower incisor proclination [9,11,17,19,28-30], but are contrary to previous investigations for changes in upper incisor inclination, with the only exception being Baccetti's [34] study that found no changes in upper incisor inclination. As it was mentioned previously, the reason for this contrasting finding is that in previous investigations, unlike this study, patients started with proclined maxillary incisors; consequently the upper incisor inclination decreased during treatment [35]. Therefore, as O'Brien points out [35], although the inclination was reduced with treatment, the upper incisors at post-treatment may be normal and not necessarily over-retroclined. Since the sample of the present study comprised of both division 1 and division 2 malocclusions, in order to finish with a "normal" upper incisor inclination, substantial lingual root torque was needed for the division 2 cases, which resulted in a mean increase of upper incisor inclination.

As discussed in Chapter 2, reports of maxillary effects with Twin-block have been variable and controversial. The findings of the present study are in agreement with those of Sidlauskas [17] and O'Brien [30], who reported a "headgear effect" with Twin-block, but contrasting with Lund [29], Toth [11] and Trenouth [36], who didn't find such restraining effects. The variation is perhaps due to the differing amount of applied forces which result in various amounts of reactive forces; if the reactive forces from forward posturing of the mandible don't reach the optimal level, maxillary growth will not be altered [24].

Another variable aspect of Twin-block's treatment effect as reported in literature is vertical changes. The results of the present study concur with Mills [9] and Lund [29], who didn't find changes in mandibular plane angle, but differ from Toth [11]. The present findings are also in agreement with Baccetti[34], who found no changes in lower anterior face height, but contrasting to Toth [11], Illing [1619], Sidlausaks [17], Mills [9] and Lund [29]. The contrast in findings is due to individual variation, which necessitates individual considerations for vertical control [19]. Allowing the clinician to control the vertical dimension through adjusting the thickness of the acrylic shelves is one of the advantageous features of Twin-block [11], which is perhaps responsible for variety of the findings in the vertical dimension.

No differences were found between responses of males and females to treatment. These findings are in agreement with literature [1,19].

3.4.12. Clinical significance of the findings:

Statistically significant changes do not necessarily indicate a clinically discernible effect. [8] Most similar studies in the literature have considered a treatment effect of twice the method error to be clinically significant. [17,36] All of the statistically significant differences across the three groups in this study were at least as large as twice the respective measurement error in magnitude (Appendix F) except for differences of movements of upper molars in both groups and lower molars in Xbow group with the control group. Therefore, upper molar movement in both groups and lower molar movement in Xbow group must be interpreted with caution. It is noteworthy however that since the combined differential movement of upper and lower molars contributes to the correction of Class II malocclusion, the net molar change discussed previously may be deemed clinically significant. Other authors have also reported small but statistically significant changes with Class II correctors. [37] From a meta-analysis of effectiveness of these correctors, Antonarakis [38] concluded that treatment changes do occur, but they are unpredictable and not always different from full fixed appliance treatment alone. [38]

3.4.13. Clinical implications:

The findings of the present study showed that both appliances corrected Class II malocclusion cases with a combination of dental and skeletal effects with no vertical changes. Both Class II correctors restricted midface growth and corrected the molar relation through a combination of lower molar mesialization and restriction of upper molar mesialization. Compensatory incisor changes were seen with both appliances.

The appliances resulted in similar treatment outcomes with few inconclusive exceptions. Lower incisor proclination was larger with Xbow, however inequality at baseline may have potentially confounded the results by either mitigating or exaggerating the changes in inclination. Twin-block was also shown to have a stimulating effect on mandibular growth reflected in increased corpus length; changes in antero-posterior position of pogonion were not detected however, yielding the results inconclusive.

It is noteworthy that based on both Wits appraisal and mandibular corpus length, Twin-block group had greater Class II malocclusions at pre-treatment compared to Xbow cases. The comparable treatment outcome with both appliances may potentially be attributed to any inter-group differences including, but not limited to, proficiency of the operator and/or superior performance of Twin-block appliance. In absence of random allocation of treatment however, such assumptions must be made with caution.

The removable Twin-block appliance proved to be at least as effective as the fixed Xbow appliance suggesting that contrary to common belief, compliance with appliance wear was not a problem with subjects of the present study and did not affect the treatment outcome. Due to lack of random sampling, inferences to population cannot be made however.

3.4.14. Limitations:

The findings of the current study must be interpreted with caution; since the two treatment groups were treated by two clinicians, treatment outcome is potentially affected by inter-operator variability. Although there were no statistically significant differences between total treatment/observation duration of the three groups, individual variations in treatment length are likely to influence the treatment results as well. More importantly, chronological ages, rather than developmental ages, were used to match the subjects; chronological age is only a crude indicator of the development age [39] which is a more accurate guide for detecting adolescent growth spurt. Therefore, perhaps the variation in individual responses is at least partially due to the developmental stages of the subjects at the time of treatment. Limitations of the study are further discussed in Chapter 4 of the present manuscript.

3.5. Conclusions:

- The present study found the Class II correction by Xbow and Twin-block to be a combination of dental and skeletal effects.
- Xbow and Twin-block were found to have similar overall treatment effects.
- Skeletally, both appliances restrained maxillary growth; Twin-block also resulted in increased mandibular corpus length.
- Dentally, both appliances resulted in mesial movement of lower molars and restricted forward movement of upper molars. Upper and lower incisor inclination increased in both treatment groups, with larger proclination of lower incisors with Xbow appliance.
- No vertical changes were found with either appliance.
- No differences were seen between responses of males and females to treatment.

Copy of Ethics Letter of Approval-Pro00023805

Health Research Ethics Board

308 Campus Tower
University of Alberta, Edmonton, AB T6G 1K8
p. 780.492.9724 (Biomedical Panel)
p. 780.492.0302 (Health Panel)
p. 780.492.0459
p. 780.492.0839
f. 780.492.9429

Approval Form

Date:	November 18, 2011			
Principal Investigator:	Carlos Flores Mir			
Study ID:	Pro00023805			
Study Title:	Comparison of treatment outcomes in Class II malocclusions by either Crossbow or Twin Block orthodontic appliances			
Approval Expiry Date:	November 16, 2012			
Sponsor/Funding Agency:	9/28/2011 8/10/2011	9/28/2011 8/10/2011	ID00003764 ID00003487	McIntyre Orthodontic Funds N/A

Thank you for submitting the above study to the Health Research Ethics Board - Health Panel . Your application, including revisions received November 17, 2011, has been reviewed and approved on behalf of the committee.

The Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. The REB Panel determined that the research described in the ethics application is a retrospective chart review for which subject consent for access to personally identifiable health information would not be reasonable, feasible or practical. Subject consent therefore is not required for access to the personally identifiable health information described in the ethics application.

In order to comply with the Health Information Act, a copy of the approval form is being sent to the Office of the Information and Privacy Commissioner.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date, you will have to re-submit an ethics application.

Approval by the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Alberta Health Services or other local health care institutions for the purposes of the research. Enquiries regarding Alberta Health Services administrative approval, and operational approval for areas impacted by the research, should be directed to the Alberta Health Services Regional Research Administration office, #1800 College Plaza, phone (780) 407-6041.

Sincerely,

Doug Gross, Ph.D.
Associate Chair, Health Research Ethics Board - Health Panel

Note: This correspondence includes an electronic signature (validation and approval via an online system).

3.6. Appendix to Chapter 3

3.6.1. Appendix A:

Sample size Calculation:

$$n = (\sigma_1^2 + \sigma_2^2)\left[\frac{z_\beta^* + z_{\alpha/2}^*}{\delta}\right]^2$$

Given α=0.05, β=0.2, δ= 2, σ_1=2.7, σ_2=2.4:

n = $(2.7^2+2.4^2)[0.67+1.96/2]^2$ =22.57

- ⇨ n = 23

3.6.2. Appendix B:

Measurements and their descriptions:

Measurements	Explanation
Linear measurements	
Wits appraisal	Distance between perpendicular lines to occlusal plane drawn from points A and B
A-N perp	Distance from point A to a line drawn from Nasion perpendicular to Frankfort plane
Pog-N perp	Distance from Pogonion to a line drawn from Nasion perpendicular to Frankfort plane
Ptm Perp-ANS	Distance from ANS (Anterior Nasal Spine)to a line from PTM (most inferior point of Pterygomaxillary fissure) perpendicular to Frankfort plane
Co-Pog	Distance between Condylion and Pogonion
S-Go	Distance between Sella and Gonion
Go-Pog	Distance between Gonion and Pogonion
ANS-Me (LAFH)	Distance between ANS and Menton (Lower Anterior Face Height)
U6-OLp	Distance between most mesial point of crown of Upper first molar and a line perpendicular to occlusal line drawn from Sella
L6-OLp	Distance between most mesial point of crown of Lower first molar and a line perpendicular to occlusal line drawn from Sella
Angular measurements	
MP-FH	Angle between Mandibular plane (Gonion-Menton) and Frankfort Horizontal plane
U1-PP	Angle between Upper incisor (Upper incisor tip-Upper incisor root)and Palatal plane (ANS-PNS)
L1-MP	Angle between Lower incisor (Lower incisor tip-Lower incisor root) and Mandibular plane

3.6.3. Appendix C:

Magnification correction for Burlington's sample (Control group):

If A represented the *true anatomic distance* and B represented the corresponding *measurement on the radiograph*:

$A + 9.84\%A = B$

$1.0984 \times A = B$

$A = B/1.0984$

- ⇨ True anatomic distance= Radiographic measurement/1.0984

3.6.4. Appendix D:

Dahlberg's Statistical estimate of true Error= $\sqrt{\sum d^2/2n}$

d is the difference between pairs of measurements and n is the number of retraced cases

3.6.5. Appendix E:

MANOVA results for Treatment/Observation changes (T2-T1):

Variable	Twin-block EMM (95% CI)	Xbow EMM (95% CI)	Control EMM (95% CI)	P-value for Group Difference
Wits	-4.86 (-5.68, -4.04)	-3.29 (-4.13, -2.46)	.034 (-0.49, 1.17)	.000*
ANPerp	-1.85 (-2.90, -0.79)	-1.61 (-2.7, -0.53)	-0.11 (-1.18, 0.96)	.045*
PogNPerp	2.23 (0.72, 3.73)	0.94 (-0.59, 2.47)	0.70 (-0.82, 2.22)	.307
SGo	5.48 (3.47, 7.48)	6.85 (4.81, 8.89)	7.86 (5.84, 9.87)	.245
GoPog	8.07 (6.65, 9.49)	4.04 (2.60, 5.48)	3.76 (2.34, 5.19)	.000*
CoPog	8.60 (7.01, 10.48)	7.53 (5.91, 9.14)	6.98 (5.38, 8.58)	.345
ANSMe	4.47 (3.09, 5.86)	3.63 (2.22, 5.04)	4.19 (2.79, 5.58)	.683
MPFH	-0.04 (-1.24, 1.16)	-1.19 (-2.41, 0.02)	-1.37 (-2.58, -0.17)	.236
U1PP	3.77 (0.76, 6.79)	7.46 (4.40, 10.52)	0.17 (-2.86, 3.21)	.004*
L1MP	6.40 (4.53, 8.27)	9.76 (7.85, 11.66)	0.23 (-1.66, 2.12)	.000*
U6Olp	2.81 (1.89, 3.73)	2.68 (1.74, 3.61)	4.25 (3.32, 5.18)	.032*
L6Olp	6.75 (5.86, 7.65)	6.19 (5.28, 7.10)	3.57 (2.67, 4.48)	.000*
ANSPTMperp	1.98 (0.47, 3.49)	0.66 (-.088, 2.20)	3.93 (2.41, 5.46)	.011*

EMM=Estimated Marginal Means The EMMs reflect, mathematically, what the p values are showing once the unequal time-spans are accounted for.

CI= Confidence Interval

*Statistically significant at α=.05

3.6.6. Appendix F:

ANCOVA's results by variables at T2, with T1 values incorporated as covariates:

Variable	Twin-block EMM (95% CI)	Xbow EMM (95% CI)	Control EMM (95% CI)	Difference between pairs of EMM		
				TB-C	**XB-C**	**TB-XB**
Wits	-0.9 (-1.7, -0.1)	0.5 (-0.3, 1.4)	3.5 (2.7, 4.3)	-4.3* (-5.8, -2.9)	-2.9* (-4.4, -1.5)	-1.4 (-2.8, 0)
ANPerp	-0.5 (-1.6, 0.5)	-0.5 (-1.6, 0.5)	1.3 (0.2, 2.4)	-1.8 *(-3.3, -0.3)	-1.8* (-3.3, -0.2)	-0.1 (-1.6, 1.5)
PogNPerp	-3.7 (-5.2, -2.1)	-5.1 (-6.7, -3.4)	-4.8 (-6.4, -3.3)	1.2 (-1.5, 3.9)	-0.2 (-3, 2.6)	1.4 (-1.4, 4.1)
SGo	75.5 (73.5, 77.5)	76.6 (74.4, 78.7)	78 (75.9, 80.1)	-2.5 (-6.1, 1.1)	-1.4 (-5.1, 2.3)	-1.1 (-4.7, 2.5)
GoPog	72.5 (71, 74.1)	69.1 (67.6, 70.6)	69.6 (68.1, 71.1)	2.9* (0, 5.8)	-0.6 (-3.1, 2)	3.5* (0.7, 6.2)
CoPog	108.4 (106.7, 110)	106.8 (105.1, 108.5)	107.1 (105.4, 108.7)	1.3 (-1.6, 4.2)	-0.3 (-3.2, 2.7)	1.6 (-1.3, 4.4)
ANSMe	63.6 (62.2, 65)	62.7 (61.2, 64.2)	63.7 (62.2, 65.2)	-0.1 (-2.7, 2.4)	-1 (-3.6, 1.6)	0.8 (-1.7, 3.4)
MPFH	23.7 (22.5, 24.9)	22.5 (21.2, 23.8)	22.2 (20.9, 23.4)	1.5 (-0.6, 3.7)	0.3 (-1.9, 2.5)	1.2 (-1, 3.4)
U1PP	114.1 (111.6, 116.6)	113.5 (110.9, 116.1)	107.8 (105.3, 110.3)	6.3* (2, 10.6)	5.7* (1.2, 10.1)	0.6 (-3.9, 5.2)
L1MP	101.9 (100.1, 103.8)	105.2 (103.3, 107.1)	97 (95.1, 98.9)	4.9* (1.7, 8.2)	8.2* (4.8, 11.6)	-3.3* (-6.5, 0)
U6Olp	58 (57, 58.9)	57.9 (57, 58.9)	59.9 (59, 60.8)	-1.9* (-3.5, -0.3)	-1.9* (-3.6, -0.3)	0 (-1.6, 1.6)
L6Olp	60.9 (60, 61.7)	60.3 (59.4, 61.2)	58.4 (57.5, 59.3)	2.5* (0.9, 4)	1.9* (0.3, 3.4)	0.6 (-0.9, 2.1)
ANSPTMperp	51.8 (50.3, 53.3)	51.3 (49.7, 52.8)	54.6 (53.1, 56.1)	-2.8* (-5.4, -0.1)	-3.3* (-6, -0.7)	0.5 (-2.1, 3.2)

EMM=Estimated Marginal Mean

CI= Confidence Interval

TB= Twin-block, XB=Xbow, C=Control

* Statistically significant at α=.05

3.6.7. Appendix G:

Variable	Twin-block Mean (95% Confidence Interval)	Xbow Mean (95% Confidence Interval)	Control Mean (95% Confidence Interval)
Occl pl-FH	1.9 (0.3, 3.5)	1.8 (0.5, 3.1)	-0.8 (-1.8, 0.2)

Descriptive statistics of Treatment/Observation (T2-T1) changes (°)

Variable	Twin-block Mean (95% Confidence Interval)	Xbow Mean (95% Confidence Interval)	Control Mean (95% Confidence Interval)	Significance TB-XB	 TB-C	 XB-C
Occl pl-FH	4.9 (3.2, 6.6)	6.9 (5.2, 8.7)	9.4 (7.5, 11.3)	NS	*	NS

T1 Values; All measurements in °; TB=Twin-block, XB=Xbow, C=Control
*: Between-group significance at 0.05 significance value.
NS: Group differences not significant at 0.05 significance value

ANCOVA's results by variables at T2, with T1 values incorporated as covariates:

Variable	Twin-block EMM (95% CI)	Xbow EMM (95% CI)	Control EMM (95% CI)	Difference between pairs of EMM TB-C	 XB-C	 TB-XB
Occl pl-FH	-0.5 (-1.6, 0.5)	-0.5 (-1.6, 0.5)	1.3 (0.2, 2.4)	1.7 (-0.6, 4)	2.2* (0, 4.4)	-0.5 (-2.7, 1.6)

EMM=Estimated Marginal Mean
CI= Confidence Interval
TB= Twin-block, XB=Xbow, C=Control
* Statistically significant at α=.05

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Chapter 4: General Discussion

4. Chapter 4

4.1. General Discussion:

Literature has shown that most Class II correctors accomplish the correction through a combination of skeletal and dental effects [1]. The present study also found the Class II correction by the Xbow and Twin-block appliances to be a combination of dental and skeletal effects. Both appliances were found to have similar overall treatment effects. Twin-block's orthopedic effects consisted of a combination of maxillary and mandibular changes, whereas Xbow only resulted in skeletal changes of the maxilla. On the other hand, although lower incisor proclination was associated with both types of treatment, it was more pronounced in the Xbow sample. These findings are in agreement with literature for Twin-block [1-5] and for Xbow [6,7]. These findings also concur with the published literature as the extent of the skeletal and dental contributions to the correction has been a subject of debate [8-10].

The findings of the present study suggest that class II correction with Xbow or Twin-block functional appliances followed by fixed appliances occurs through a combination of dental and skeletal changes. Dental compensations included lower incisor proclination, lower molar mesialization and restraint of upper molar mesialization. For both appliances, skeletal changes were expressed mainly through maxillary growth restraint. Although treatment with Twin-block resulted in increased corpus length, the chin point did not show significant forward movement; these findings confirm that Class II correctors help correct Class II malocclusion through dental compensations combined with controlling maxillary growth while mandible is potentially allowed to catch up, with variable changes in mandible and chin's projection with Twin-block.

Due to individual variation, use of a certain appliance for correction of all Class II cases cannot be advocated and each case needs to be assessed individually. [11] Class II malocclusion is a clinical entity formed from several possible combinations of dental and skeletal features. [12] Although the skeletal component of Class II malocclusion is usually a combination of mandibular deficiency and maxillary excess [13], mandibular deficiency has been reported as the most common component of Class II malocclusions [12]. However, even when one jaw is mainly at fault, it is often difficult to determine with certainty if the other jaw is completely “normal” with regards to size and position. [13] With all these considerations in mind, if a patient presents with maxillary protrusion and/or horizontal excess, restraining midface growth would be of value. In the present study, both Xbow and Twin-block proved to be effective in providing maxillary restraint also known as the “headgear effect”. Even if the malocclusion is a combination of maxillary horizontal excess and mandibular deficiency, restraint of maxillary growth to allow the mandibular growth to catch up is a viable option, unless there is excessive retrusion of the midface which would warrant investigating other treatment modalities such as orthognathic surgery to differentially advance both jaws. If however, the mandibular deficiency clearly outweighs the maxillary protrusion, Twin-block may potentially be a preferred alternative over Xbow as it demonstrated greater increase of mandibular corpus length in this study. It must be stressed however that a recommendation cannot be made solely based on the findings of the present study due to dissimilar treatment/observation groups at baseline, inter-operator variability and contrasting findings with regards to mandibular measurements. The findings of the present study and existing literature collectively suggest that the Twin-block appliance may result in a larger mandibular length increase in comparison to the Xbow appliance, however the changes are often small [14] and the clinical significance of the changes is for each clinician to decide as expectations vary [15]. It is unlikely for the changes to be large enough to result in a noticeable change of facial appearance [15], as profile changes smaller than 2 mm have been shown to be undetectable by laypeople[16]. However in order to draw compelling evidence-based conclusions alternative studies are needed to assess the facial profile changes by clinicians and, perhaps more importantly, by laypeople.

The only other recommendation that can be made based on this study is patient selection with regards to lower incisor inclination. Lower incisor proclination has been reported as one of the major contra-indications for use of Class II functional appliances [17]. The findings of the present study not only confirm this recommendation, but also suggest that Xbow might procline lower incisors to a greater extent than Twin-block. But again the clinical significance of the difference (around 3 degrees) can be considered questionable for clinical decisions. Therefore, all other things being equal, a patient with moderately proclined lower incisors may benefit from Twin-block therapy more than Xbow treatment.

Finally, treatment success with functional appliances has been attributed to interplay of various factors including patient cooperation [15]. Although the importance of compliance is axiomatic, the comparable results of removable Twin-block and fixed Xbow appliances in the present study suggest that proper patient selection can effectively control this variable.

Based on the findings of this study and the current literature, Class II correctors are important treatment modalities in contemporary orthodontics provided that clinicians have reasonable expectations and understand the limitations. With proper patient selection, the issue of compliance can be resolved, bearing in mind that for the non-compliant patient, fixed correctors continue to be a valuable alternative. Lower incisor proclination must be expected with Class II functional appliances. For cases with moderately proclined lower incisors, Twin-block might be a preferred option, as long as patient's compliance is not a factor. Correction of molar relation and midface restraint can be achieved with both appliances. Absolute mandibular advancement and/or enlargement must not be anticipated with Xbow, whereas results of the present study are inconclusive for Twin-block; it is probable for Twin-block to accentuate the mandibular corpus length, but clinicians must realize that the potential increase is at best modest and widely variable and its clinical significance is indeed debatable.

4.2. Limitations:

One of the weaknesses of the present study is its retrospective nature as retrospective studies are lower than controlled and/or randomized prospective studies in the hierarchy of evidence-base literature [18]. Retrospective studies are understandably criticized for their potential biases: susceptibility bias which determines the treatment of choice for each patient from the outset; clinical bias which results from clinician's treatment philosophy; and proficiency bias which stems from a clinician's skill. [19] On the other hand, one of the problems with conducting RCT's in orthodontics is withholding treatment from the control group, which can be sometimes considered unethical. [1,19] Other challenges of RCT's in orthodontics are associated costs, impracticality of blinding the clinician and patient's autonomy; it would be challenging to recruit informed patients to be assigned to the treatment group with a higher burden (eg. discomfort) when all treatments are presumed to be equally effective unless proven otherwise. [19] Furthermore, although RCT's are indeed the gold standard for evaluating treatment effects of many interventions, when it comes to orthodontic functional appliances, the appliance, which can be randomly allocated to the patients, is merely one of the many variables that play a role in the outcome; individual variability, resulting from variations in duration and magnitude of pubertal growth spurt, and differing levels of compliance are other important factors [14] that contribute to the variability of the findings even with random allocation of treatment [20].

Another weakness of this study is use of chronological age of the patients rather than their developmental age, which is a better predictor of timing of the adolescent growth spurt. [21] This limitation is compounded by the use of historical controls; children of the current generation are shown to mature sooner than previous generations [22] and earlier maturation and onset of adolescent growth spurt can result in inequality of subjects of the treatment groups and control group.

Although all treatment subjects of this study were taken from the same practice and the operators used the same lab and treatment protocol, the existing inter-operator variability has the potential to introduce bias into the study and affect the outcomes.

Finally, the present study, like most studies in literature, has only investigated the short-term effects of treatment with functional appliances; therefore all inferences are limited to immediate post-treatment results and no inferences can be made about the long-term stability.

4.3. Future studies:

Due to the wide variation of treatment effects with functional appliances [23], using larger sample sizes is recommended. Prospective studies with random allocation of treatment, although not free of limitations of individual variability, are advisable. Taking the subjects of the control group from the current generation, perhaps from a waiting list at a school, rather than a historical database is recommended. Also, taking treatment subjects of all treatment groups from the same clinician to eliminate a potential source of variation is advisable.

Although patient cooperation with Twin-block wear seemingly did not affect treatment outcome in the present study, comparison of Xbow to other Class II correctors, especially fixed correctors, which preclude the compliance factor, is of interest.

Although longitudinal studies of untreated controls is perhaps no longer ethically justifiable, long-term follow-up of treated subjects can shed light on stability of the treatment results.

4.4. Clinical recommendations:

Although both appliances have their merits, there are certain circumstances where one might be preferred over the other. Unlike Xbow, Twin-block allows for resolution of deep bite simultaneous with the anteroposterior correction during phase 1 treatment. Twin-block is also applicable if the permanent second molars are not erupted and cannot be incorporated into the Xbow's design; with Xbow on the other hand there is risk of intrusion of first permanent molars before eruption of permanent second molars which can potentially deepen the bite. In late mixed dentition when premolars are not present yet, fabrication and adjustment of Twin-block is more practical than Xbow, as it does not require banding of the premolars and its acrylic blocks can be adjusted to prevent them from interfering with eruption of the premolars. However, all the potential benefits of Twin-block are moot if the patient does not wear the appliance. Therefore, Xbow is indicated for a patient whose compliance is anticipated to be an issue. It is also a good choice for a patient who can afford greater increase of lower incisor proclination and the potential increase in overbite if it is to be used before eruption of permanent second molars.

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