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Facial, Dental, and Skeletal Responses To Treatment With Headgear And Pendulum, As Compared To A Control Group Of Untreated Patients

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Abstract:

INTRODUCTION: The purpose of this retrospective, cephalometric study is to examine the general dental, skeletal and soft tissue effects of treatment change between headgear and pendulum appliances, versus untreated controls. Specifically, differences in upper incisor proclination and lip protrusion were studied, as were skeletal vertical and sagittal dimensions of the face.

METHODS: The sample of 77 patients with Class II malocclusion was divided into 3 groups. Group 1 patients (n = 27; treatment time, 2.3 years) were treated with a cervical headgear and fixed orthodontic appliances. Group 2 patients (n = 26; treatment time, 2.3 years) were treated with a pendulum followed by fixed appliances. Group 3 patients (n = 24; observation time, 2.7 years) were orthodontically-untreated adolescents. Subjects were matched to similar Class II skeletal and dental patterns, duration of T1-to-T2 observation interval, and level of skeletal maturation (CVMS).

RESULTS: Class II treatment with both appliance protocols during the pubertal growth spurt induced significant, favorable changes, with a high level of success at the occlusal level (correction of overjet, overbite, and molar relationship). Statistically, there were no significant differences in the amount of change between pendulum and headgear groups, except for interincisal angle; however, at the end of treatment, both appliance groups finished with clincally acceptable values. No clinically or statistically significant differences in changes to soft tissue profile were observed between treatment protocols, and both methods produced statistically significant differences from control group changes from T1 to T2 for 5 measures. During the observation period, the initially protrusive maxillary position continued to advance forward (SNA); intermaxillary relationship did not improve (Wits); Y-Axis decreased; and overbite increased. Through the permanent dentition and cessation of the pubertal growth spurt, untreated Class II skeletal and dental patterns did not self-correct.

CONCLUSIONS: In an era when clinicians are concerned with maintaining, and even improving, a patient's profile, the results of this paper suggest that correction of a Class II malocclusion with either headgear or pendulum can provide surprisingly similar skeletal, dental, and soft tissue results.

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<u>Introduction</u>:

In addition to the classic principles of establishing function, stability, and health, modern orthodontic treatment planning places a high premium on patient aesthetics. The latter decades of the twentieth century saw clinicians incorporating soft tissue analyses into records review and treatment planning decisions. The importance of maintaining, or perhaps improving, a patient's soft tissue profile is often a critical factor in an orthodontist's decision whether or not to extract permanent teeth. Today there is strong trend to avoid removing teeth while creating a stable, biologically sound result.

Nonextraction treatment for a Class II malocclusion frequently demands distal movement of the maxillary molars. Traditionally, correction of this malocclusion involved extraoral force to these teeth with a headgear. However, these appliances require unconditional patient compliance to be an effective therapy for Class II correction.

Poor patient compliance inspired many clinicians to develop intraoral devices for maxillary molar distalization. The dentoalveolar effects of one type of appliance, the pendulum, have been evaluated in multiple studies (1-11). Some of these projects compared treatment effects between the pendulum and other molar distalizing appliances. Currently, however, there is debate within the literature regarding the pendulum's effect upon the patient's vertical dimension, and there is little discussion of its impact on patient soft tissue profile.

Overview of Class II malocclusion

In his seminal 1907 paper "Treatment of Malocclusion of the Teeth," Edward Angle proposed a dental arch classification scheme, based solely upon the relationship of the mandibular first molar to the maxillary first molar (12). Dr. Angle described the Class II malocclusions as having a distal relationship of the lower first molar to upper first molar of more than one-half the width of a cusp (**Fig. 1**). Over the past one hundred years, however, clinician reliance upon this narrow description as the main criterion for classifying an occlusion has been debated. Each of Angle's classes of malocclusion covers many dental, skeletal, and soft tissue profile variations that, in turn, significantly vary treatment plan approaches. Despite these limitations, Angle's scheme is today embraced for its simplicity as a tool for communication between dental professionals.

Dr. Angle (12) specified two *divisions* of Class II malocclusion, based upon the inclination of the maxillary central incisors. In a recent study of 900 white subjects, Uslu reported incidences of 36.1% Class II division I and 5.7% Class II division 2 malocclusions (13). Class II division I malocclusions contain labially inclined maxillary incisors and an increased overjet, with or without a constricted upper arch (**Fig 1**). Vertical overlap of the incisors may vary from a deep, impinging overbite to an anterior open bite.

Pronounced lingual inclination of the upper incisors, partially overlapped on the labial by the adjacent lateral incisors, indicates a Class II division 2 malocclusion (**Fig. 2**). In some cases, all four upper incisors are lingually tipped, and the canines partially overlap the laterals on their labial surfaces (14). A deep overbite and minimal overjet accompanies this malocclusion, and the incisal relationship can be very traumatic to the

attached soft tissues. The incisal edges of the lower anterior teeth may even contact the palatal tissue of the maxillary arch, in cases of extreme deep bite (15-16). In some cases, the labial gingival tissues may be traumatized by excessive lingual inclination of the lower incisors. The clinician often observes two distinct occlusal planes, with the anterior segment supra-erupted and the posterior in relative infra-occlusion (17). Within the lower arch, there may be an exaggerated Curve of Spee, with extrusion of the mandibular incisors (18).

Skeletal Contribution to Class II malocclusion

Dr. Angle's succinct classification scheme does not speak to skeletal discrepancies underlying a clinical Class II presentation. Its oversimplification may not account for an abnormality in jaw size or spatial relation to its antagonist. Relying on Angle's description alone, the clinician risks overlooking a transverse, vertical, or anteroposterior skeletal discrepancy within the Class II malocclusion.

In a longitudinal study comparing normal and untreated Class II children, Bishara and his coworkers (19) described dental arch changes of width and length from the primary through the mixed and permanent dentitions. Their findings suggested that both the normal and Class II division 1 patterns continue their respective courses through the permanent dentition, for both males and females. Specifically, they observed greater differences of maxillary and mandibular intermolar widths within the normal groups than those with a Class II molar relationship. Relative maxillary constriction within Class II malocclusions, in other words, can be observed in early stages of arch development and will not self-correct.

Meanwhile, it has also been documented that an unfavorable, skeletal anteroposterior pattern will not improve. Whether this relationship exists in the deciduous, mixed, or permanent dentition, an imbalance will not self-correct without orthopedic intervention (20-21). Often the discrepancy presents as a retrusive mandible; however, excessive maxillary growth may have directed the skeletal Class II malocclusion.

Skeletal characteristics of Class II malocclusion

An individual's skeletal dysplasia is typically described by relating his or her dentofacial characteristics to the malocclusion Class of those with "normal" occlusion and facial relationships. The clinician may often employ more than one cephalometric analysis, to study an existing condition or review the progress of a patient's treatment. One might assume that patients with a specific malocclusion Class share common cephalometric characteristics, and that these measurements are significantly different from "normal" or other malocclusion Classes. Further, a clinician might assume individuals with similar cephalometric characteristics may present with common soft tissue profile characteristics. These assumptions are open to question and debate.

Lateral cephalometric evaluation of a Class II malocclusion may reveal skeletal discrepancies in a pair of dimensions. In general, a patient with an anteroposterior skeletal discrepancy possesses an above-average ANB angle and Wits appraisal; this indicates a poor relationship between the maxilla and mandible. The antero-posterior discrepancy may be accompanied by a fault within the vertical relationship, as the patient

may present with a relatively long or short face. The cephalometric characteristics of each Class II division, however, deserve further elaboration.

Multiple authors have used Angle's classification scheme to describe the cephalometric characteristics of Class II division 1 malocclusion. Fisk et al. (22) delineated the six possible morphological variations within the dentofacial complex:

1. The maxilla and its teeth are anteriorly positioned in relationship to the cranium.

2. The maxillary teeth are anteriorly positioned with a normally situated jaw.

3. A normal sized mandible is posteriorly positioned.

4. The mandible is underdeveloped.

5. The lower teeth are posteriorly situated within a normally positioned mandible.

6. Multiple combinations of these relationships.

Multiple cephalometric studies of the late 1940's through the early 1950's, comparing Class II division 1 with matched normal occlusions, revealed little statistically significant differences in the positions of the maxillae with their cranial bases (23-27). Further, these tracings also demonstrated significantly retrusive mandibles, with the chin points located further posteriorly, resulting in greater angles of facial convexity. Craig (23) summarized these paired findings by suggesting that normal and Class II individuals present similar composite patterns, except that the mandibular body appears shorter and the lower first molars are more posterior in the latter group.

During this same period of research, however, other authors maintained that a high degree of variability may be observed cephalometrically between these two

malocclusions (27-28). In their review of 220 lateral cephalograms, Maj et al (29) measured total mandibular length in Class II division 1 subjects to be very similar to that of normal subjects of matched age. Additionally, in ninety six percent of the cases, anteroposterior positions of upper and lower incisor apices approximated the limits of their normal counterparts. Accounting for a steeper mandibular plane in one third of the Class II cases, the authors suggested inclination of the anterior teeth can exaggerate or disguise differences between the two jaws. This important study concluded that skeletal differences may not be due to abnormal development in the size of any specific bony part; instead, the discrepancy may result from an abnormal relationship between the component skeletal structures, in the direction of the discrepancy.

Class II division 2 malocclusions, meanwhile, may present with cephalometric characteristics very different from their Class II division 1 counterparts. In comparing both divisions of Class II malocclusion as well as normal bites, Wallis (30) noted larger posterior cranial bases in the division 2 cases. Consistent within the variants of this facial pattern were more acute gonial and mandibular plane angles, shorter lower anterior facial heights, and excessive deep bites. Noting a greater angle of facial convexity within division 2 facial profiles, Hedges (31) hypothesized an enlarged or more anteriorly positioned maxilla; however, he observed comparable ranges of skeletal variation within both divisions of Class II patients. Hedges admitted the only consistent finding within his tracings was the lingual inclination of the upper central incisors.

In conclusion, the orthodontist cannot afford to oversimplify the description of any skeletal discrepancy accompanying a Class II malocclusion as "a skeletal Class II relationship." Unfavorable positioning of either or both jaws must be described. The

maxilla may rest in a normal or protruded relationship to the mandible, and the lower jaw may rest in a normal or retrusive relationship to the upper jaw. For each patient, the clinician must evaluate occlusal relationships, anteroposterior and vertical discrepancies, and soft tissue facial relationships, before deciding treatment objectives and ultimately mechanics.

Strict reliance on cephalometrics alone, however, may pose significant risks to the development of a comprehensive treatment plan that provides optimal soft tissue profile characteristics. In contemporary orthodontics, the clinician seeks to employ treatment mechanics that will ensures both stable dentoalveolar positioning as well as aesthetically pleasing soft tissue characteristics.

Treating the dentition to the face:
Treatment planning with priority to the soft tissue profile.

Harmonious, balanced facial aesthetics and a functional, stable occlusion have long been recognized as two important goals of orthodontic treatment. Treatment planning to maintain, or even improve a patient's profile can be difficult, especially when these two objectives are combined. Unfortunately, correction of a malocclusion does not always lead to the correction, or even the preservation, of the patient's profile. Occasionally, rigid adherence to cephalometric dentoskeletal analysis to resolve the malocclusion may in fact diminish facial attractiveness. Knowledge of craniofacial growth, differences among racial profiles, soft tissue responses to orthodontic tooth movements, and the patient's own soft tissue thickness can assist the development of a treatment plan that benefits the profile.

The cephalometric advances of the mid-twentieth century were initiated to improve clinician understanding of skeletal analysis and facial aesthetics. During the three decades following Down's cephalometric analysis (32), emphasis was placed on skeletal and dental structures. Almost all of the proposed measurements were included to evaluate teeth positions relative to skeletal structures. In addition to Down's, prominent analyses still used today include those of Margolis (33), Tweed (34), and Steiner (35). Sporadic attempts were made to include an element of soft tissue study, such as Ricketts esthetic plane (36), the Holdaway Line (37), and Burstone's soft tissue analysis (38). These elements were passing references to establish harmony of facial profile.

It was assumed, however, that the soft-tissue profile configuration was related primarily to its underlying skeletal template. Subtelny (39), in 1959, wrote that the correlation between hard and soft tissue changes was not linear. He measured horizontal and vertical relationships, and he noted that *not all components* of the soft tissue profile directly follow the development of the underlying skeleton. Burstone agreed with Subtelny, maintaining that a parallel relationship between soft tissue profile and skeletal pattern may not exist, because of variation in soft tissue thickness covering the facial skeleton (40). Esthetic compromises may result, therefore, when the orthodontists attempts to predict soft tissue outcomes using only hard tissue normal values (41).

Realizing their specialty had perhaps gone too far with an obsession to place teeth at certain angulations over basal bone and its potential risk on facial aesthetics, many clinicians today direct their treatment plans to achieve an overall facial balance. In other words, their objective is to treat the dentition to their patient's face. It has been demonstrated a patient's facial contours change with orthodontic treatment, and even

more so with combined orthodontic-orthognathic procedures. In deciding between an extraction versus non-extraction approach to resolve a Class II malocclusion, the orthodontist must anticipate facial changes induced by comprehensive treatment as well as growth.

Facial traits most often studied by orthodontists include the positions of the upper and lower lips, relative to a facial line or angle. Tooth extraction can affect multiple soft tissue traits, such as increasing the facial angle, nasolabial angle, lip length, maxillary sulcus while decreasing lip protrusion, upper incisor exposure, and interlabial gap (41). When considering a decision to extract teeth, the orthodontist must consider how these facial traits may be impacted. Further, these qualities must be balanced with the position of the teeth in bony support for long-term stability and periodontal health. When the patient presents with an enlarged nose or chin, however, the clinician must use caution when considering retraction of the lips. In cases where optimum correction of facial aesthetics calls for surgery, and orthognathic treatment is denied by the patient, greater soft tissue compensations may be necessary. The orthodontist must inform the patient in advance of any treatment that may compromise facial attractiveness and balance.

When analyzing profile, lip retraction, and horizontal changes in lip posture concurrent with growth or orthodontic treatment, two positions of the upper and lower lips are reproducible and suitable for study: at rest and at maximum smile, commonly referred to as the "smile line." Peck cautions, however, that an important aspect of reproducibly taking measurements in the former position (often taken with the patient's mouth *open*) is the care with which "true" rest position is achieved, since perioral soft

tissue and mandibular posture must *both* be unstrained (42). These factors have prompted many researchers to evaluate profile changes with lips closed.

Treating the maxilla to correct a Class II (Angle) Malocclusion

As previously discussed, a variety of skeletal patterns may exist within the Class II (Angle) category of malocclusion. Maxillary protrusion, mandibular retrognathia, or even a normal skeletal pattern may be accompanied by a dento-skeletal vertical discrepancy. Should the clinician seek correction of a discrepancy within the upper jaw, Moore (43) listed five possible treatment objectives to guide his choice of mechanics:

A. Inhibit normal forward growth of the maxilla.

B. Inhibit the normal forward growth of the maxillary denture.

C. Control or alter the normal eruption pattern of the maxillary teeth.

D. Move the maxillary denture posteriorly.

E. Create spaces in which to move teeth by selective extraction.

Each objective strives either to control forward, vertical maxillary growth or to reduce protrusion of the maxillary anterior teeth.

Headgear

The debate within the literature, regarding the effectiveness of inhibiting maxillary growth, has undergone a significant evolution. First, in 1941, Brodie (44) wrote that maxillary growth pattern is established early and, furthermore, orthodontic treatment may influence only the alveolar processes. Eighteen years later, Moore (43) followed with the proclamation that headgear force to the upper molars did not influence

forward growth of the maxilla; instead, he believed the appliance affected the maxillary denture. However, Weislander (45) in 1963, presented evidence indicating headgear's greater influence on the facial complex than previously reported. Reviewing thirty cases treated with a cervical pull headgear, he observed posterior change in the position of the pterygomaxillary fissure, significantly less movement forward of the anterior nasal spine versus the control group, and downward tipping of the anterior palatal plane.   Denying any post-treatment change of maxillary length, he recorded slight clockwise rotation of the sphenoid bone. Studies by Watson (46), Newcomb (47), and Klein (48) confirmed Weislander's contention that headgear worn during the growth period may influence the future growth pattern of the entire craniofacial complex.

Extraoral traction with the headgear has persevered as an effective method to restrict maxillary growth and to distalize the upper molars. Since the initial reports by Kingsley (49) and Angle (50) over a century ago, the headgear has been shown by many authors (47, 51-57) to be very effective for maxillary molar distalization in three planes of space (58).   Today, the primary advantage to this method is unquestioned: stability of extraoral anchorage with fewer side effects on the non-distalized teeth.   Compliance, however, remains the principle obstacle to achieving its intended clinical effect(s).

Non-compliance

A child's reluctance to accept and employ treatment strategies poses a serious threat to a healthy, stable outcome. Unfortunately, noncompliance increases from childhood through adolescence, the age range for the majority of orthodontic patients. In a study by Cureton et al (59), patients were asked to wear their headgear 12 hours a day.

The subjects produced an average of only 6.5 hours wear. Cooperation seemed to be age-related, as 10- to 12-year olds wore the appliance more than the 14- to 16-year olds. It is difficult for the clinician (60) to predict with accuracy which child will be poorly compliant, and noncompliance likely prolongs required treatment time. Additionally, it is generally understood within orthodontic practice that poor compliance can lead to patient "burnout," degeneration of supporting tissues, decalcification, and other adverse health effects.

A serious concern to clinicians over the past fifty years, noncompliance has received great attention within the orthodontic literature. (60-66). In fact, the high degree of non-compliance prompted research on a range of potential variables (67-68). Although many clinicians may be inclined to attribute decline of appliance wear to the age factor, research findings are very conflicting (69-74). The relationship between age and compliance assumes a "complex, nonlinear nature" (75), whereas the duration of treatment is clearly associated with a steady deterioration of protocol adherence. Appliance wear steadily becomes more of a problem as the child approaches puberty, no matter how long the patient has been receiving orthodontic treatment (76).

Treatment-related attitudes may certainly influence achievement of desired treatment outcomes. Favorable cooperation is often demonstrated by the patients of multiply motivated parents (75). The role of an ordered, family background, as well as a satisfactory child-parent relation, has been summarized as conducive to treatment success (71). Further study identified positive parental attitude toward the appliance, degree of parental concern for the malocclusion, and parental desire for treatment as strong

predictors of patient cooperation (60). On the other hand, patient complaints about appliance discomfort tend to result in poor cooperation.

According to the findings of Woolass et al. (74), behavior of general conformity with social expectations (sociability, obedience, academic success) is very predictive of strong orthodontic compliance. However, this study failed to explain the variation in cooperation as it was affected by a combination of these attributes. Bartsch elaborated that subjective qualities of quietness, obedience, and external (parental) control are closely related to protocol adherence (65). Often limited to a written questionnaire and a brief personal interview, the orthodontist generally overestimates the level of patient compliance (66). Not every patient who presents to an orthodontic practice may come from a steady family environment, perform well scholastically, or demonstrate sound manners.

Non-compliance based mechanics to "distalize" upper first molars

As the literature consistently documents unfavorable performance by children with headgear, many clinicians have been prompted to design treatment mechanics and use appliances that reduce the need for patient participation.   Most intraoral molar distalizing systems proposed throughout the literature include an anchorage unit (usually incorporating a premolar or deciduous molar) and a force-generating unit. Upper first molar distalization techniques, less dependent on patient cooperation, include repelling magnets (76-78), transpalatal arches (79), compressed coil springs on a continuous archwire (80), Pancherz's Herbst appliance (81), and compressed coil springs on a sectional archwire (Jones Jig [82], Keles slider [83], distal jet [84-86]).

Gianelly's approach of repelling magnets coupled with a Nance anchorage apparatus unquestionably yields forces capable of moving teeth (76-77, 87-88); however, the drawbacks to this protocol include expense, bulkiness, force dissipation with increasing intermagnet distance, and speculative biologic effects. Compressed nickel titanium or stainless steel coils have been prescribed, instead of the magnets, to distalize upper molars (82). The coils typically require activation once a month, unlike the magnets which must be activated once every 1 to 2 weeks. The deflection of wires, not coils, has also been used to produce distal molar movement. Compressed between the maxillary first premolar and first molar, a wire made of nickel titanium, as shown by Gianelly (87-88), or titanium molybdenum alloy (TMA), as illustrated by Kalra (89), results in molar distalization and associated anchorage loss as observed with magnets and coils springs. In addition to its well-documented effects on the lower arch, the Herbst appliance has maxillary distalization effects (81). However, this therapy is prone to breakage, and its application is limited to patients who can afford to have proclination of the lower incisors.

Hilgers' Pendulum

Considering the shortcomings of the strategies mentioned above, Hilgers (90) introduced in 1992 an appliance to expand the maxilla and simultaneously distalize the maxillary first molars. Modification of this design one year later resulted in the "pendulum (**Fig. 3**)," a new mechanism for maxillary molar distalization in non-compliant patients with Class II malocclusions (91). Hilgers claimed that up to 5mm of distal molar movement could be accomplished within 3 to 4 months with the pendulum.

Hilgers' original design of the appliance includes a palatal acrylic button attached to the first premolars, through occlusally bonded rests or retaining wires soldered onto the bands of these teeth (**Fig. 3**). This apparatus served as anchorage for a pair of springs, which originate from the acrylic and are passively extending distally toward the soft palate. Upon successful insertion of the appliance, the clinician bends each spring anteriorly and engages its foot into lingual sheaths on maxillary first molar bands. The amount of force delivery depends upon the degree to which the spring must be bent for insertion into the molar sheath. His initial recommendation of 60 degree activation provides a force of 230 gm per side, and the author proposed overcorrection toward a Class III molar relationship (91). Hilgers maintained his upper molar distalization via a Nance holding arch, short-term headgear wear, utility arches, or stopped continuous archwires. Correction (or over-correction) is retained after 6 to 10 weeks. Hilgers then called for the disengagement of the stabilizing arms to the premolar/deciduous molar to allow transseptal fibers to move these teeth posteriorly. Within his landmark study, he estimates 20% of the space opening between molar and premolar can be attributed to anterior anchorage loss.

Review of pendulum studies: Non-comparative investigations

Case reports and clinical studies have investigated Hilgers' appliance effects on molar distalization, anchorage loss, and changes in facial vertical dimension. Ghosh and Nanda (1) evaluated 41 subjects treated with the pendulum, and found that 57% of space created in the posterior maxilla resulted from molar distalization. The remaining 43% of space gained, therefore, was achieved through "anchorage loss," mesial movement and/or

proclination of the supporting structures, measured from the maxillary first premolars and anterior teeth. They also calculated an average of 8.48 ° of upper first molar distal tipping. This early report, however, was hindered by the absence of either comparison or control groups.

Byloff and Darendeliler (2) studied 13 patients in whom a "pendex" (a combination of pendular molar distalizing and maxillary arch expansion) version of the appliance was used (**Fig. 4**). In their follow-up companion study (3), these authors examined an additional 20 patients, 12 of whom wore a pendulum appliance while the other 8 received slow maxillary expansion (1 turn of the appliance key a week) with the pendex appliance. Each version of the appliance was modified, after molar distalization was achieved (approximately 16 weeks) by shaping an uprighting bend into the molar distalizing spring during the second phase of treatment (approximately 11 weeks). This adjustment served to eliminate, or greatly reduce, excessive distal tipping of the maxillary molars, by uprighting their roots. Comparing results to their original study, the bends reduced molar tipping with minimal anteroposterior effects, aside from slight flaring of the upper incisal edges. Also, they observed no significant difference in anchorage loss between the patients who did and did not receive arch expansion (3).

The presence of second molars had been suspected an obstacle to traditional methods of distalization, such as headgear. However, Joseph and Butchart (4) demonstrated this was not the case with the pendulum. In a study of 7 patients in late mixed and early permanent dentitions, they observed successful distalization regardless of the status of the adjacent second molars, patient age, or molar classification. Three individuals, whose second molars were erupted, achieved correction as quickly as those

who had not. Ghosh and Nanda (1) agreed that they had not observed hindering of molar distalization relative to second molars. These findings contradicted the initial reports of Gianelly (76), who suggested second molar presence impeded distalization of first molars with magnets. A more recent study by Kinzinger (6) advises that the best time to start therapy with a pendulum appliance is before eruption of the second molars, since presence of the second molar will lead to longer treatment duration, the need for greater force application, and additional loss of anchorage.

As researchers began to agree that the pendulum produces some degree of molar tipping (ranging from 18.4° to 15.7°) and some percent of anchorage loss (ranging from 19% to 43%), clinicians became concerned that distal tipping may induce unfavorable bite opening. Evaluations of treatment effects with pendulum, as well as with the distal jet, on vertical skeletal relationships have resulted in conflicting outcomes. According to most pendulum studies (1, 3, 7-8), significant increases in the vertical dimension should be anticipated. These changes include a slight opening of the mandibular plane angle (approximately 1°) and an increase in the anterior lower facial height (approximately 2-3 mm).

Bussick and McNamara (7), however, examined the appliance's effects in Class II patients at varying stages of dental development and with varying facial patterns. They found no significant alterations of the lower anterior facial height among patients with high, neutral, and low mandibular plane angle. Ghosh and Nanda (1) had previously reported that increases in lower anterior facial height are greater in patients who presented with higher pretreatment mandibular plane angles. This trend, however, was found not to be statistically significant. Although their study was limited to a sample size

of only 7 subjects, Joseph and Butchart (4) observed very little posttreatment change in vertical dimension. Nonetheless this was an important discovery because the study population presented with predominately hyperdivergent skeletal patterns (pretreatment mandibular plane angles of 36.1°). Bussick and McNamara further concluded that the pendulum is used most effectively, with minimal increase in lower anterior facial height, when the appliance is built with anchorage support from maxillary second primary molars and when maxillary second molars are unerupted (7). A pendulum study with one of the largest sample sizes to date (101 subjects), this study lacked a control group and did not take into consideration its subjects' level of skeletal maturity. In other words, it failed to account for mandibular growth's possible contribution to Class II correction.

Pendulum versus headgear

Greater predictability of treatment effects and interpretation of cephalometric changes prompted many investigators to begin comparing the pendulum to other maxillary molar distalization mechanics. Within the past three years, there have been three projects comparing effects of the pendulum with the headgear (9-11). They maintain that both treatment modalities are effective in correcting the Class II malocclusions, that the pendulum appliance produces mostly dentoalveolar effects, and that the headgear can improve the skeletal maxillomandibular relationship. Like the non-comparative pendulum studies, however, their study design could have been improved if there were a control group.

Mossaz et al. (9) offered two treatment alternatives for Class II dental malocclusion correction to their subjects: full fixed edgewise appliance combined with

cervical pull headgear or the pendulum followed by fixed edgewise appliance. The primary purpose of this study was to estimate whether both options, compliance and non-compliance based, could be offered to patients with a dental Class II with moderate skeletal discrepancy, and whether the same outcome can be expected. The headgear group in this study experienced better maxillary growth restriction than did the pendulum group: SNA angle reductions were 1.3° in the headgear group and 0.3° in the pendulum group. Second, the treatment duration with the pendulum followed by fixed appliance therapy was longer when compared with headgear combined with the same full edgewise technique. However, the authors incorporated sample bias with their headgear participants. Only patients who were successfully treated with fixed appliances and cervical headgear were selected. In fact, some patients in this group who exhibited poor compliance in wearing the headgear were provided with another treatment option (i.e., a distal jet or the removal of 2 maxillary premolars). These subjects were omitted from the study's results. Thus, compliance and its relationship to treatment duration were not evaluated completely in the Mossaz investigation.

De Almeida-Pedrin et al. (10) used a sample of 82 subjects to compare the cephalometric results and appliance efficiency of Class II treatment with the pendulum appliance, cervical headgear, or extraction of 2 maxillary premolars. The three different protocols yielded results generally similar from both the occlusal and the cephalometric standpoints. The authors concluded treatment with extraction of maxillary teeth was more efficient than the other 2 protocols because of the shorter treatment time; yet, they cautioned that slightly more retraction of the upper lip, relative to the esthetic plane, was noted after treatment in this group. This difference might have been related to the

slightly greater maxillary dentoalveolar protrusion in this group at the beginning of treatment.

Angelieri et al. (11) also compared the cephalometric effects of cervical headgear and the pendulum. Both distalizers were effective in correcting the Class II malocclusions, but the pendulum appliance produced only dentoalveolar effects. Their report of statistically significant skeletal changes with the headgear agreed with the observations of Mossaz: extraoral force induced restriction and redirection of maxillary forward displacement, resulting in improvement of the skeletal maxillomandibular relationship (ANB angle). The authors also described similar soft tissue changes with the treatment mechanics: they suggested that there were similar antero-posterior changes of the maxillary and mandibular incisors which induced similar repositioning of upper and lower lips. The mild retrusion of the upper lip in both groups may be explained by the greater mandibular sagittal anterior displacement compared with the maxilla. This caused forward displacement of the Sn–Pg′ line and lead to a perceived retrusion of the upper lip. Meanwhile, protrusion of the lower lip in both groups may have been related to labial tipping and protrusion of the mandibular incisors (11).

Specific Aims and Hypotheses:

Specific Aims
1. To examine differences in lip protrusion, upper incisor proclination, and vertical dimension following treatment with two methods of Class II correction, compared with untreated controls.

2. To describe general dental, skeletal, and soft tissue effects of treatment change between the headgear and pendulum, versus untreated controls.

Hypothesis:

When compared to untreated controls, the appliances produce different amounts of lip protrusion, incisor protrusion, and changes in vertical dimension.

Research Design and Methods:

This study was approved by the Tufts University Health Sciences Campus Institutional Review Board. A retrospective, chart review was designed to evaluate cephalometrically the facial, dentoalveolar, and skeletal effects of Class II correction obtained by two different treatment modalities. The first treatment group (HG) consisted of 27 patients (12 females, 15 males) treated with a cervical pull headgear followed by fixed upper and lower appliances. The second treatment group (P) included 26 patients (14 females, 12 males) treated with the pendulum followed by fixed upper/lower appliances. The third study group included 24 orthodontically untreated people (14 females, 10 males), with a similar Class II skeletal and dental patterns. Using Baccetti's revised version for evaluating skeletal maturation (95), we selected patients who were approaching, or had begun to experience pubertal growth spurt. As described in the literature, this phase often coincides with mandibular growth. The Control Group (C) was included to account for skeletal changes stemming from differential jaw growth, as opposed to orthodontic and orthopedic treatment.

A conventional cervical headgear was used in the first study group. The outer bows were bent slightly upward to avoid first molar distal crown tipping, and a force of approximately 450 grams was applied bilaterally. As documented within the chart notes, these patients were asked to wear the appliance 12 hours per day. In the second study

group, all patients received the pendulum appliance as described by Hilgers (90), or a modification of this design, the "Pendex" (**Fig. 4**). A transverse expansion mechanism was included within the palatal Nance button, available to expand a constricted maxilla in addition to providing molar distalization. Slow expansion was prescribed as needed, with .25mm expansion per day achieving slight transverse overcorrection, and then the distalization springs were released by the orthodontist. The 0.032 TMA wires were activated 45° to produce a force of approximately 200 to 250 grams per side (85.92). On average, the springs were re-activated two months later, with additional activation as necessary until a super Class I (Angle) molar relationship was observed. Total distalization time was four to six months from the final turn of the expansion screw. A second phase of therapy was then initiated: the clinician removed the pendulum and placed a Nance button, or a palatal plate with reverse C-clasps on the upper first molars. Fixed upper and lower appliances were bonded within four weeks. Treatment time for the P group is described from the moment a pendulum or Pendex was placed.

The *primary outcome* in the study was the change (from pre-treatment to post-treatment) for the upper lip to Rickett's soft tissue E-line. Using well-established norms, we predicted the control group would experience little or no change, resulting in a mean change of 0mm, with flattening of the facial profile. Based on data from other studies (de Almeida), we anticipated that the pendulum group will experience a mean change of -1.0mm and the headgear group will experience a mean change of -1.1mm. Thus, assuming a common standard deviation of 1.0mm, we had 87% power to detect a difference between the 3 groups using one-way ANOVA with sample sizes of 24

(Control), 26 (Pendulum), and 27 (Headgear) subjects per group, given alpha=0.05

(nQuery Advisor 7.0).

The Inclusion Criteria for final study subjects include the following:

(1) Initial Skeletal Maturation of CVMS 2-4 for the growing child, as described by Baccetti (95). We matched the subjects based upon this measure of skeletal maturity.

(2) Permanent dentition.

(3) Bilateral, half-cusp Class II (Angle) molar dental classifications, or more greater, as demonstrated on diagnostic study casts or intraoral photographs.

(4) Each child's treatment plan initiated as a non-extraction approach, as documented within chart notes.

(5) Headgear protocol included placement of inner bow within first molar tube slots prior to application of full fixed upper and lower appliances. Headgear treatment was maintained during a portion of the comprehensive treatment.

(6) At both timepoints, each subject's lateral headfilms included a ruler, to allow for equilibration of linear measurements.

(7) Lips closed.

The Exclusion Criteria for final study subjects include the following:

(1) Cranio-facial syndrome of anomaly.

(2) Full-coverage restoration of upper first molar or upper central incisor.

(3) Treatment plan altered to allow change of molar distalization mechanics or

extractions. These excluded cases were tallied for the two treatment groups.

The Independent Variables were the choice of mechanotherapy (cervical pull headgear, pendex), and the Dependent Variables were established cephalometric measurements.

Sample Collections

The first study group constructed was the headgear participants. The Information Technology Department of the Tufts School of Dental Medicine developed a search engine to assist locating electronic charts of subjects treated with a cervical pull headgear. Multiple variations of possible clinician code for the appliance were considered to develop a program that yielded 868 charts. The resident reviewed each chart's notes for documentation of headgear treatment plan and delivery, as well as availability of diagnostic and final lateral headfilms. In all, the records of 27 headgear patients, treated without extractions, met the requirements for study. Level of initial skeletal maturation (CVMS), sex, and duration of orthodontic treatment was noted for each headgear case, to permit subsequent matching of pendulum and control subjects.

Two private practitioners within the New England area then provided headfilms of Class II cases corrected with a pendulum. The clinicians, both faculty members at a

dental school in the Boston area, shared the same mechanics protocol for upper molar distalization with a pendulum, and no extractions were part of either protocol. Each office applied this investigation's requirements for subject inclusion: both orthodontists and the resident verified bilateral half-cusp molar relationship, or greater, through intraoral photographs or study casts. This study group was gathered from sequentially treated cases, and no exclusions based on extractions were necessary to compile the pendex samples. Digital reproductions of the qualifying headfilms and demographics spreadsheets were uploaded into a removable electronic storage device. The resident reviewed the coded data, selecting 26 cases that matched the headgear group's demographics.

The resident built a historical cohort of longitudinal observations on untreated Class II subjects. A sample of 24 subjects was selected from the University of Michigan Growth Study, using the same dentoskeletal characteristics and skeletal maturation levels of the 2 appliance groups. Effort was made also to match the duration of T1-to-T2 observation interval in the control group to the intervals of the headgear and pendulum subjects (**Table 1**). Selected control samples came from both the Michigan and Denver Growth Studies, archived within the University of Michigan's Center for Human Growth and Development research laboratory. Each sample was coded, and enlargement factors were registered for each headfilm (12.9% for the Michigan samples and 4% for the Denver samples.

Samples lost due to extractions

During the chart review search for headgear study group, 43 cases satisfying this study's inclusion criteria were treatment planned with a cervical pull headgear to correct the Class II (Angle) molar relationship. As the investigator reviewed the progress chart notes, however, it was discovered that only 27 of the cases finished non-extraction: in 16 instances, poor patient compliance with the headgear resulted in change of treatment plan to a pattern of extraction (usually upper first premolars). In other words, only 63% of the cases treated planned with headgear were successfully finished to an acceptable non-extraction result. None of the patients treatment planned with a pendex in our samples required extractions to achieve an acceptable result.

Cephalometric Analysis

Within the school's electronic chart system, a research file was created for uploading of the three study groups' headfilms. A customized digitized regimen and analysis developed within the cephalometric software (version 11.0 Premium, Dolphin Imaging) was used for all cephalograms in this study. One investigator replaced the codes used during subject acquisition with a new code, blinding the tracer to any mechanotherapy or timepoint. Upon completion of the tracing cycle, this investigator returned all original identification codes to the headfilms for data compilation.

Skeletal, dental, and soft tissue measurements were traced by a third-year resident at the dental school (D.D.), at two time points for each subject. *T1* represents time of initial presentation and diagnosis, while *T2* represents time of appliance removal. To reduce the error of landmark identification, each point was verified by *two* associate

clinical faculty members of the orthodontic department. In the event of location disagreement, point location was often negotiated to an average of the discrepancy. Disputes were resolved to satisfaction of all three observers. The assessment of the stages in cervical vertebrae maturation on lateral cephalograms for each subject was performed by one investigator and verified by a second, and any disagreement was resolved to the satisfaction of both observers. The cephalometric analysis required digitization of 54 landmarks and adopted measurements of Steiner (96), Jacobson (97), Ricketts (98), and McNamara (99), generating 14 variables- 10 angular and 4 linear- for each tracing. Outcome variables are expressed as the millimetric or angular changes from diagnostics [(*T2*) – (*T1*)], for all three study groups.

Central to the dento-skeletal measures was the construction of the nasion perpendicular (**Fig. 5**), as described in the McNamara method of cephalometric evaluation (99). This vertical reference was created first by defining Frankfort horizontal plane, using anatomic porion (external auditory meatus) and orbitale (the lower border of the eye) as its reference points. A vertical line, the *nasion perpendicular*, was then drawn perpendicular to the Frankfort horizontal line and extended inferiorly from the nasion. The linear distance from point A (subnasale) to the nasion perpendicular related the maxilla to the cranial base. To relate the anteroposterior position of the upper central incisor to the maxilla, a vertical line was drawn through the point A, parallel to the nasion perpendicular. The perpendicular planar line distance, from this *constructed point A perpendicular* to the most labial surface of the upper incisor, was then measured (mm). A post-treatment incisor position difference of 1mm between the pendulum, headgear, and untreated controls was considered clinically significant.

Many of the pendulum studies, when describing the anteroposterior position of the maxillary incisor, used cranial base structures for reference. However, measuring the upper incisor to the nasion-point A line, is valid only if the maxilla rests in a neutral position anteroposteriorly relative to its cranial base. A retrusive position of the maxilla relative to nasion would cause the incisor to appear more protrusive; meanwhile, a protrusive maxilla would cause this tooth to appear more retrusive (99). By relating the upper incisor to the maxilla, using the constructed *point A perpendicular*, we sought to avoid this source of error.

To evaluate change in the patient's vertical dimension, mandibular plane angle (as related from gonion/gnathion to the Frankfort horizontal plane) was used (**Fig. 5**). A post-treatment difference of 1° between the pendulum, headgear, and controls was considered clinically significant.

Finally to evaluate change in the position of the upper lip, Ricketts suggested measuring its position relative to a tangent between the soft-tissue chin and tip of the nose (**Fig. 5**). He found this position to be ideally 4.0 mm posterior to this plane for females, while in males it may be "slightly more retracted" (98). A post-treatment lip position difference of 1mm between the pendulum, headgear, and controls was considered clinically significant.

*Statistical Analysis***:**

Means and standard deviations were calculated for initial age, duration of treatment, and all cephalometric measures at T1 and T2 for the three study groups. Additionally, mean differences and standard deviations were calculated for the changes

between T1 and T2 and for each group. Q-Q plots were used to evaluate whether the data were approximately normal and could be analyzed with parametric techniques.   They revealed a normal distribution of post-treatment change of upper lip position from Rickett's E-Line (**Fig. 6**). Therefore, parametric statistics with analysis of variance (ANOVA) with the Tukey post-hoc tests were used. The data were analyzed with SAS (Statistical Analysis System), and statistical significance was tested at $p < .05$. The following comparisons were made for dentoskeletal and soft tissue variables: HG versus P versus C on the T1 values, and these three groups were compared on the values of (T2 minus T1) changes ("treatment effects").

Results:

Treatment Demographics

As seen in **Table I**, the mean ages at T1 were similar in the two treatment groups (12.3 years for the HG group, 12.75 years for the P group), but the mean age for the untreated controls was younger (11.4 years). Overall, the different treatment ages were statistically significant (*p= 0.005*). Duration of observation differences, however, were not statistically significant (*p= 0.244*) between any of the samples. The mean durations of observation for the appliance groups were the same (2.3 years), while the average time of observation for the controls was slightly larger (2.7 years).

Initial Starting Measurements

All three groups presented with comparable skeletal profiles, as the baseline means for SNA, SNB, ANB, Wits, FMA, and Y-Axis were not statistically significantly

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different (**Table II**). The statistical comparison of starting forms for dentoalveolar measurements between the two treatment groups and the untreated control group showed no significant differences except lower incisor position (*p= 0.046*), overbite (*p= 0.034*), and interincisal angle (*p= 0.007*). IMPA was statistically different between the untreated controls and the pendulum study group (*p= 0.036*), with lower incisors initially more proclined in the latter sample (mean 94.9°, SD 6.2). Overbite and interincisal angle were the only two variables significantly different between the treatment groups. Initial overbite was greater for the pendulum group (3.6mm, SD 1.5) than the headgear group (2.2mm, SD 1.3), with a *p-value 0.029*. Mean initial interincisal angles were 134.5° for the pendulum group and 126.2° for the headgear group (*p= 0.008*). At treatment outset, upper and lower incisors were generally more upright in the pendulum sample and more proclined in the headgear group.

The statistical comparison of initial soft-tissue measurements seemed to follow their underlying dentoalveolar structures. For each variable, the statistical difference rested between headgear and pendulum groups, with *p-values* of *0.033* for upper lip position and *0.015* for lower lip position. At baseline, the soft tissue profile for the headgear group was more "full," with upper and lower lips more closely approximating Ricketts' E-Line (-1.5mm and -0.2mm, respectively) than those of the pendulum group (corresponding mean values of -3.0mm and -1.8mm).

T1-T2 differences: treatment versus non-treatment

Between T1 and T2, five variables displayed significantly different amounts of change between the control and each of the two appliance groups, *with each treatment*

group producing similar changes. In other words, for the following measurements, treatment versus non-treatment resulted in statistical differences of change, but the T1 to T2 changes were statistically similar between the two appliance groups. Four of these variables were skeletal measurements, while one measure was interdental.

Maxillary and mandibular positions relative to cranial base were affected by treatment. For SNA, there were highly significant differences between the control and appliance groups, with *p-values* of *0.00* for Control-Pendulum and *0.003* for Control-Headgear. For the untreated subjects, mean SNA increased by 1.1°, but the pendulum (-2°) and headgear (-1.5°) mean changes were comparable. For SNB, there were also significant differences between the treated and non-treated subjects, with *p-values* of *0.018* for Control-Pendulum and *0.031* for Control-Headgear. For the untreated sample, mean SNB increased by 1.7°, while the pendulum (0.1°) and headgear (0.2°) mean values both demonstrated similarly minimal changes.

Intermaxillary change, as measured by Wits appraisal, was highly statistically significant with treatment.   Comparison of control versus pendulum (*0.00*) and headgear (*0.001*) *p-values* showed that the maxillo-mandibular relationship did not improve without orthopaedic or orthodontic intervention. The sagittal correction was statistically similar between appliance groups. Y-axis change was also influenced by treatment: control versus pendulum (*p 0.024*) and headgear (*p 0.017*) differences were significant, but not between the appliances.

During the observation period, the control sample demonstrated increased overbite. T1 to T2 changes were very significant for the control group, when compared to the pendulum (*p 0.00*) and headgear (*p 0.001*) groups. Mean overbite increased by

0.5mm for the untreated subjects; however, the P and HG groups experienced mean overbite decreases of -2.7mm and -1.5mm respectively.

T1-T2 differences: Control versus Pendulum

Between the two timepoints, four measures exhibited statistically significant change between the control and pendulum groups, but not between the control and headgear groups. Two of these measurements were skeletal, while two were dental. ANB change was different (*p 0.046*), with the pendulum group experiencing a marked reduction of 2.1° but the control value decreasing by only 0.6°. Mandibular plane angle change was different between the two groups (*p 0.031*), with a slight mean increase of 0.3° in the pendulum group and a decrease of 2.1° in the untreated group.

There were differences of lower incisor position (*p 0.008*) and overjet (*p 0.013*) between these two study groups. Mean lower incisor position proclined by 6.5° in the pendulum group but reclined -3.7° in the control group. Mean overjet was reduced by -2.7mm in this treatment group but remained relatively unchanged in the control sample (0.1mm).

T1-T2 difference: Control versus Headgear

Only one variable experienced a statistically significant change between the control and headgear groups: upper lip position in relation to Ricketts' E-Line (*P 0.041*). With headgear treatment, this soft tissue measurement retracted by 2.1mm. Without orthopedic or orthodontic intervention, the upper lip moved only 1.0mm posterior to this line.

T1-T2 difference: Pendulum versus Headgear

Only one variable experienced a statistically significant change between the two treatment groups: interincisal angle (*p 0.049*). After treatment, this measure decreased in both samples, with a mean reduction of 5.6° in the headgear sample and a more pronounced 13° in the pendulum sample.

Discussion:

This study was a review of skeletal, dento-alveolar, and soft tissue effects of pendulum versus headgear mechanotherapies, compared with untreated Class II controls. With fewer adolescents willing to accept appliances demanding strict compliance, including headgear (61), orthodontists often apply treatment strategies that do not involve patient participation. Particularly when avoiding permanent tooth extractions, the clinician must fully anticipate any vertical or antero-posterior impacts on his patient's profile with non-compliance based treatment. The results of this study revealed no statistically different changes of soft tissue profile between the pendulum and headgear.

Sample bias was minimized within the design of this study. Both private practitioners who provided samples for pendulum group have dismissed the headgear, in favor of this appliance as their primary mechanic for Class II correction. At one clinician's office, the pendulum is the sole appliance for Class II treatment, and *only cases consecutively treated with the pendulum* were selected. At the other practice, *cases were reviewed alphabetically and selected until the sum total of pendulum cases required*

for matching with the other two study groups was achieved. This approach avoids sample bias, researcher "cherry-picking" pendulum cases for specific dento-skeletal presentation (i.e. skeletal growth pattern, progress of second molar eruption, etc.). Meanwhile, at the institution that provided samples for the headgear group, this appliance remains a popular choice for specific attending faculty. During the institutional chart review, any case treatment planned as non-extraction, with use of a cervical pull headgear, was selected for inclusion.

In this study, there were no remarkable differences between the three study groups in measures of maxillary, mandibular, or vertical skeletal relationships at the outset of treatment or observation. Each study group's initial skeletal profile was very similar, both in terms of each jaw's relationship to anterior cranial base as well as each other. This consistency significantly reduces the impact of susceptibility bias (102-103) when treatment assignment is based on diagnostic criteria (i.e. not randomized) and may cause a patient treated with one mechanotherapy to present differently than patients treated with another appliance.

Skeletal changes

The maxillary changes for the two treatment groups reflect a restriction of forward growth during the observation periods, combined with adaptations of maxillary dentoalveolar structures, specifically at Point A.   Both treatment groups demonstrated a reduction of maxillary skeletal protrusion (in terms of SNA angle), while there were statistically significant differences between these samples and the untreated controls. Through the permanent dentition and cessation of the pubertal growth spurt, Class II skeletal and dental patterns did not self-correct. Without clinical intervention, as

expected, mean maxillary position continued to advance anteriorly from its initially protrusive position (82.6° at first observation to 83.7° at T2). Although the orthopedic effect of headgear treatment on the maxilla (restriction of forward displacement) during our sample's observation period has been widely reported in the literature (45-49, 51), our finding of no statistical significance between the pendulum and headgear groups opposes the finding of Angelieri et al. (11) but agrees with the result of Almeida-Pedrin et al. (10).

The comparable reduction of SNA angle between the two appliance groups (mean 2° for P, 1.5° for HG) is surprising, given theoretically different modes of action between headgear and pendulum. This similarity may be explained by similar upper incisor labial retraction distances in pendulum and headgear samples (less than 1mm difference of mean post-treatment position change). In a study assessing cephalometric impacts of extractions in Class II, Division 1 cases, Janson (102) demonstrated that the anterior contour of the maxilla remodels during retraction of the upper incisor. Mean upper incisor crown position for the pendulum moved slightly forward of the nasion perpendicular line (from 3.9mm to 4.3mm), while mean upper incisor crown position moved slightly backward (from 4.4mm to 4.2mm) in the headgear group. Further, with greater mean overjet reduction observed in the pendulum group, and with significant reduction of interincisal angle (13°), it may be suggested upper incisors within this sample finished with slightly greater palatal root torque. Following reclined root apex position, A-point may have repositioned a greater mean distance in the pendulum group compared to that of the headgear sample.

Previous evaluations of the pendulum's effect on the vertical dimension have shown conflicting results. Our results support those studies showing minimal change in vertical dimension with the pendulum. With regard to Frankfort-mandibular plane angle, the two appliance groups showed similar changes. There was only a slight increase of the angle in the P group (+0.3°) compared to the HG group (-0.3°). This clinically and statistically insignificant difference compares favorably with the finding of Angelieri et al (11), who reported a -0.6° post treatment change with headgear versus a -0.25° change with the pendulum. Byloff and Darendeliler (2) also reported no increase of mandibular plane angle with pendulum treatment, and their reported increase of the y-axis angle (0.81°) approximates our finding of 0.4°. In their non-comparative study of 41 patients treated with the pendulum, Ghosh and Nanda (1) observed a backward rotation of the mandible (mean 1.1° change of mandibular plane angle). Bussick & McNamara (7) and Chaques-Asensi & Kalra (8) found that lower anterior facial height was increased 2.2 to 2.8mm respectively after pendulum treatment. They also reported no significant differences in lower anterior facial height increases between patients with high, neutral, or low initial mandibular plane angles.

Compared to each the two treatment samples, the Control group demonstrated a statistically significant greater amount of mandibular growth during the observation period (*p-values* of 0.018 and 0.031, respectively for C-P and C-HG). Mean SNB increased by 1.7° during the timepoints for the untreated controls, whereas this outcome increased by only 0.1° for the pendulum and 0.2° for the headgear samples. Although great effort was invested to match the three study groups by level of skeletal maturation at T1 (**Table I**), mean CVMS for the control sample (2.2) was lower than the pendulum

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(2.8) and headgear (2.7) groups. Baccetti (95), in his revised version of using CVMS for assessing mandibular growth, stipulates that peak growth takes place between CVMS II and III. One may argue, therefore, that the slightly "earlier" initial timepoint selection for the untreated controls provided for the greater amount of observed mandibular growth, when compared to the two treatment groups.

McNamara has proposed that in mixed dentition patients with Class II Division1 malocclusions, rapid palatal expansion can sometimes lead to spontaneous correction of the Class II malocclusion (103). He compares the forward movement of the mandible after maxillary expansion to "a foot in a narrow shoe," after the once-constricted "shoe" has been widened (104). McNamara implies that the mandible, in centric occlusion, is initially in a distal position relative to centric relation because a constricted maxilla "prevents" it from assuming centric relation. This analysis is similar to the belief that conversion of a Class II Division 2 malocclusion to a Class II Division 1 malocclusion will result in forward movement of the mandible and, in turn, improvement of the intermaxillary relationship. Haas contended that the mandible could advance by "as much as one half premolar width" with this conversion (105).

These "post-locked" hypotheses, that the mandible may advance forward when released from a constricted maxilla or with proclined upper incisors, may account for the fact that WITS changed similar amounts in both the headgear and pendulum groups.. One can argue that early transverse correction, or the proclination of retruded upper incisors in the fixed appliance phase, provided for the improved intermaxillary relationships in the two appliance groups.

Dental Effects

After treatment, the overjet and overbite in the two treatment groups were significantly improved, *without* statistically or clinically significant differences in the amount of upper incisor position change. This finding refutes the idea that use of the pendex significantly flares upper incisors in the final orthodontic result. Our result agrees with the report of Angelieri et al. (11), which describes only 0.9° greater forward proclination of the maxillary incisor in the pendulum group compared to the headgear group. Also using nasion perpendicular as a vertical reference line, Bussick and McNamara (7) reported a post-pendulum treatment advancement of the upper incisor position by 0.8mm, only 0.4 mm greater than our finding of 0.4mm.

Although a significant percent of molar distalization accomplished during pendulum and headgear phases of treatment can be lost during the follow-up phase with full fixed appliances, the Class I (Angle) molar relationship is maintained and the overjet is corrected (106). The upper molar is corrected to a Class I (Angle), or even to a "super Class I" relationship, which is maintained as the lower molar advances with treatment and forward mandibular growth. Solow explains that preserving the molar relationship while improving the overjet can be due to a favorable growth pattern (skeletal change) and dentoalveolar compensation (i.e. intercuspation) (107). During normal growth, the mandible outgrows the maxilla and becomes more prognathic relative to the cranial base (108). Johnston has demonstrated that 9 out of 10 Class II patients have a favorable growth pattern in which the mandible outgrows the maxilla (109). Therefore, maxillary molars must follow the mandibular molars anteriorly; without such skeletal and dental compensations, a Class III (Angle) molar relationship would result.

Interincisal angle was the *only* variable to experience statistically significant change between the headgear and pendulum samples. After treatment, this measure decreased in both samples, with a mean reduction of 5.6° in the headgear sample and a more pronounced reduction of 13° in the pendulum sample. At T1, however, interincisal angle varied significantly between treatment groups (*p 0.008*): upper and lower incisors were more upright in the pendex group than headgear sample. It appears that in general, pendulum incisors proclined to reduce interincisal angle to 121.5°, while headgear incisors proclined to a lesser extent, reducing mean interincisal angle to 120.6°. *At the end of treatment, however, both appliance groups finished with comparable and clinically acceptable values for this measure.*

One might assume that anchorage loss during molar distalization induced the proclination of upper incisors and, in turn, reduced interincisal angle in the pendulum group. This study did not evaluate anchorage loss at the end of maxillary first molar distalization, as Bussick and McNamara have already demonstrated 0.9 +/- 1.2mm of maxillary incisor mesial movement can be expected at immediate cessation of molar "distalization" (7). *At the end of fixed appliance treatment in this study, however, there was no statistically significant difference in change of upper incisor labial crown position relation to nasion-perpendicular between the two treatment groups*. It is possible the two clinicians using pendulum applied greater palatal root torque during the use of Class II mechanics (elastics) to retract incisors moved mesially during the molar distalization phase. Finishing with increased palatal root torque, furthermore, may have contributed to the greater change in interincisal angle in the pendulum cases, when compared to the

headgear sample. The pendulum cases may have presented with more anterior crowding, although this was not measured in our study.

In both treatment groups, mean lower incisor angulation increased relative to its bony base. While the untreated controls experienced an average IMPA change of -3.7° over the observation period, lower incisors advanced statistically similar amounts: 3.9° and 6.6° respectively for the headgear and pendulum groups. This statistically insignificant difference of lower incisor proclination may have been due to Class II elastic wear or the alignment of crowded, non-reshaped teeth.

Soft tissue effects

Movement of the upper incisors has more of an effect on the lips than movement of the lower incisors, likely due to the overlap of the maxillary incisors on the mandibular incisors in the sagittal direction. It has been shown that the upper lip follows retracted incisors, but the retraction observed at the labial level is less dramatic than the incisor retraction (110). This difference may be the result of a decrease in lip tension, which in turn leads to a slight increase in soft tissue volume (110). When attempting to predict soft tissue response to upper incisor retraction, however, the orthodontist must take patient sex and upper lip thickness into consideration. Bergman notes that from ages 8 to 18, the upper lip increases in thickness by 46% in boys, but by only 15% in girls (111). When the tissue thickness is more than 18mm in the upper lip, the lip does not follow the upper incisor, and when the upper lip is thinner that 12mm, the upper lip moves back as the teeth are retracted (112).

Due to the similar antero-posterior changes of the maxillary incisors, the upper lips also demonstrated similar changes in the two treatment groups. The mild retrusion of the upper lip in the pendulum (-1.8mm) and headgear (-2.1mm) groups may be explained, in part, by the mild mandibular sagittal anterior displacement compared with the maxilla, inducing a forward displacement of Ricketts' E-line. Without intervention, upper lip position retracted in the untreated control group, which experienced the greatest forward movement of the mandible relative to the cranial base (SNB increase of 1.7°).

Naidu has recently shown that our selected measure for evaluating upper and lower lip position change, Ricketts' E-Line, when compared to other methods for evaluating lip position, has a very small coefficient of variation and provides narrow dispersion (113). His study also showed that this measure is particularly influenced by growth of the nose (113). In other words, it is likely that soft tissue growth of the nose, as well as chin, displaced Rickett's E-Line forward and created the appearance of upper lip retraction in all three samples.

This study supports other research showing minimal difference of lip position change with headgear and pendulum, and it refutes those that suggest one might expect a "fuller profile" due to anchorage loss with a pendulum. Almeida-Pedrin et al. (10) found that relative to Ricketts' aesthetic plane, change of upper lip position for the pendulum (-1.0mm) and headgear (-1.1mm) groups was not as retracted for their extraction group (-2.6mm). Burkhardt observed 2.1mm (106) retraction from E plane in pendulum group, when comparing results to the Herbst appliance.

Though reduction of overjet was greater in the pendulum group (-2.7mm) than the headgear group (-1.4mm), upper lip retraction relative to Ricketts' E-Line was slightly

greater in the headgear group (-2.1mm) than the pendulum group (-1.8mm). Soft tissue dimensions may have varied between these two study groups, in terms of thickness, length, and postural tone. When seeking to maintain, or improve, a patient's facial profile, the orthodontist must evaluate the soft tissue on its own merit. It cannot be assumed, therefore, that with successful reduction of overjet, the soft tissue will automatically follow in a linear fashion (39-40, 111).

Our study indicates, however, that given a sample of pubertal patients with similar dento-skeletal profiles, the orthodontist may expect similar changes of profile soft tissue when selecting a headgear or pendulum for Class II correction.

Limitations to this study

There were no distinctions made between divisions of Class II malocclusion and degree of upper arch constriction within each study sample. Their inclusion could have been used to support, or challenge, the "post-locked" hypotheses that the mandible may advance forward when released from a constricted maxilla, or with proclined upper incisors.

Second, to complete the three samples, subjects were gathered from different regions of the country: a metropolitan, northeastern dental school (headgear), two suburban private practices in the northeast (pendulum), and a midwestern dental school (control). Such highly-varying patient demographics provided for significant differences in racial profiles. Since ethnicity has been shown to play a role in response to incisor retraction (114), standardizing to race could have improved this study's strength.

Third, larger sample sizes would have enabled us to detect more subtle differences between the groups. However, clinically significant differences in the amounts of change between treatment groups were not found, other than for interincisal angle.

Conclusions:

The main findings of this retrospective review on the outcomes of 2 approaches to non-extraction treatment for Class II (Angle) malocclusion (headgear and pendulum), when compared to untreated controls, were as follows:

1. Class II treatment with either protocol during the pubertal growth spurt induced significant, favorable dentoskeletal changes, with a high success rate at the occlusal level (correction of overjet, overbite, and molar relationship). Statistically, there were no significant differences in the amount of change between these two groups, except for interincisal angle. However starting forms for this measurement were different: upper and lower incisors were more upright in the pendex group than headgear sample. In general, pendulum incisors proclined to reduce interincisal angle to 121.5°, while headgear incisors proclined to a lesser extent, reducing mean interincisal angle to 120.6°. At the end of treatment, however, both appliance groups finished with clinically comparable and acceptable values for this measure.

2. No clinically or statistically significant differences in the changes to soft tissue profile (upper and lower lip positions relative to Ricketts' E-Line, nasolabial angle) were observed between the two treatment protocols.

3. Both treatment methods resulted in statistically significant differences from control group changes from T1 to T2 for 5 measures. During the observation period, the initially protrusive maxillary position continued to advance forward (SNA); intermaxillary relationship did not improve (Wits); Y-Axis decreased; and overbite increased. Through the permanent dentition and cessation of the pubertal growth spurt, Class II skeletal and dental patterns did not self-correct. Interestingly, SNB remained relatively unchanged among the two treatment groups but increased 1.7° in the control sample. This might be attributed to a greater growth of the mandible within the Class II controls.

In an era when clinicians are concerned with maintaining, and even improving, a patient's profile, the results of this paper suggest that correction of a Class II malocclusion with either headgear or pendulum can provide surprisingly similar skeletal, dental, and soft tissue results. Orthodontists continue to face increased pressure from general dentists, patients, and their parents to deliver biologically sound, aesthetic results within quoted periods of time, and with reliable success. Given the alarming percentage of the headgear sample lost to extraction "bailout" in this study, however, the clinician may wish to consider a non-compliance based mechanic, such as the pendulum, when seeking to distalize maxillary first molars, *without* fear of producing drastically different treatment outcomes than in successful headgear cases.

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