An Evaluation of Clear Aligners for Buccolingual Root Control in Maxillary Posterior Teeth

by

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DEDICATION

I would like to dedicate this thesis to my parents for their tireless support throughout my life. Thank you for teaching me to always aim high and instilling in me the spirit of hard work, perseverance and courage to achieve my goals. I also want to dedicate this thesis to my beloved sisters, Anthoula and Dominica for their unconditional love, dedication and partnership in everything I do.

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ABSTRACT

Objective: To examine to determine if clear aligners can efficiently control buccolingual root movement in maxillary posterior teeth. **Materials and Methods:** Pre- and post-treatment CBCTs of 22 non-growing patients were selected for this retrospective study. Patients were treated with Invisalign aligners in a private practice setting. Long axis buccolingual inclination of maxillary molars and premolars, as well as inter-first premolar width, inter-second premolar width, and inter-first molar widths at the levels of root apex, CEJ, and crown tip were measured in the coronal view from CBCT DICOM data, using the commercially available Dolphin 3D imaging software program. 3D superimposition of pre- and post-treatment CBCT models was performed to verify results. **Results:** Inter-first premolar, inter-second premolar, and inter-first molar widths were greater after treatment at all three levels. The changes were significant at the CEJ and crown tip level but not at the apex level. Mean buccolingual inclination of all teeth increased significantly with the exception of the maxillary left first molar which increased but not significantly. Results indicate a buccal inclination of the teeth post-treatment. **Conclusions:** This study presents indications that efficient root control in maxillary posterior teeth with the use of clear aligners, albeit statistically insignificant, can be possible. Future research is needed to expand the results of this study.

Keywords: aligners, torque, buccolingual control, CBCT

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REVIEW OF THE LITERATURE

Conventional fixed orthodontic appliances have been the backbone of orthodontic mechanics. However, along with the increasing number of adult patients seeking orthodontic treatment came the quest for more esthetic alternatives. In 1945, Kesling[1] devised the concept of using clear overlay orthodontic appliances with the "Tooth Positioning Appliance, an active treating appliance for the final artistic positioning of the teeth". Almost two decades later, Ponitz[2] fabricated clear, plastic overlay appliances for staged orthodontic treatment in order to move teeth in "reasonable new positions". Further development of such appliances continued by other clinicians.[3-5]

In 1997, Align Technology (San Jose, California) evolved Kesling's concept into a more feasible orthodontic treatment option.[6] More specifically, Align Inc. incorporated modern CAD/CAM stereolithographic technology to fabricate a series of custom-made clear thermoplastic aligners, known as Invisalign®, from a single impression. Based on the doctor's treatment plan, Align Technology generates a virtual, staged correction of the malocclusion. For every stage of the correction, a set of aligners is made respectively and each aligner is programmed to perform 0.25 mm of tooth movement over a two week period.[6]

Invisalign's® consumer demand and professional use has been increasing over the years and it was reported that, as of 2008, more than 730,000 patients had completed or were undergoing treatment with Invisalign®.[7] Over the years, Invisalign® has been continuously developing, introducing new features and materials in order to become more efficient and address a wider spectrum of treatment demands. One of the important landmarks in the evolution of the Invisalign® appliance was the introduction of SmartTrack™, a patented thermoplastic material that provides more constant, light forces.[8] Another important landmark has been the integration of the iTero intraoral scanner with the Invisalign® platform. Digital impressions have been shown to be more accurate than scanned models or polyvinyl siloxane impressions.[9, 10]

Research on the efficacy of clear aligner therapy – although quite rigorous- includes primarily case reports, descriptive studies, surveys, systematic reviews, and only a small number of Randomized Controlled Clinical Trials.[11-14]

In 2000, Boyd et al.[15] performed the first university based clinical study examining how well Invisalign® works in the treatment of mild crowding and space closure in adult patients. Their study reported that Invisalign® produced successful results in four Invisalign® cases with 3 to 6 mm

of crowding and/or 5 to 6 mm of space closure. The following year, the same group[16] studied the effects of Invisalign® in more complex malocclusions, requiring dental expansion, Class II and Class III correction, extraction treatment and correction of overbite. Their results showed; expansion -mainly of a tipping nature- in the range of 2 to 4 mm, bodily movement of teeth (i.e. molar distalization and extraction space closure), correction of rotation up to 45 degrees and intrusion of molars. Extrusion was proven to be one of the most challenging and unsuccessful movements. Additionally, the authors reported the necessity of using proper attachments for the aforementioned movements to be performed. This study, like their first one, was based primarily on clinical observations and did not quantify all the observations that were made. The authors concluded that "this appliance is a potentially useful alternative approach to fixed appliances for treatment of a variety of malocclusions in patients with fully erupted permanent teeth".[16]

Later on, Joffe[17] defined more specific and limiting case selection criteria which contradicted the results of Boyd's studies. More specifically, he stated that caution should be taken when treating malocclusions with more than 5 mm of crowding and/or spacing, rotations greater than 20

degrees, extrusion in general, tipping greater than 45 degrees, anteroposterior discrepancies greater than 2 mm, centric occlusion and central relation discrepancies, anterior and/or posterior open bites, teeth with short clinical crowns and arches with multiple missing teeth.

In 2005, Lagravère et al.[14], in an attempt to unravel the existing controversy on case selection criteria, published the first systematic review on the efficacy of Invisalign® aligners. Only two studies met their inclusion criteria; a clinical trial[18], and a randomized clinical trial[19]. They stated that “no strong conclusions could be made about the indications for, limitations of, and outcomes of use of the Invisalign system because we found no study that quantified treatment effects or accomplishment of treatment goals using it”.[14]

Due to scarcity of specific quantified data on Invisalign® efficacy and its mechanics, clinicians had to rely to a great extent on their clinical experience and professional judgment, the opinion of experts and the limited existing evidence.

In the first cohort study, Djeu et al.[20] compared treatment effects of the Invisalign system with those of braces, using the American Board of Orthodontics (ABO) grading system. They concluded that treatment results of

braces are superior to those of Invisalign®. Invisalign® scored a passing rate 27% lower than braces, with the worst scores for posterior torque, occlusal contacts, anteroposterior occlusal discrepancies and overjet. In fact, when the initial discrepancy was more severe, the score for Invisalign® was lower. This study was followed by another cohort study by Kuncio et al.[21], who also used the ABO grading system, but this time to compare the relapse in patients treated with Invisalign® and traditional fixed appliances. They concluded that patients treated with Invisalign® relapsed more.

In 2009, Kravitz et al.[11] used 3D software to virtually superimpose the post-treatment models of the predicted result as designed by Invisalign® with the post-treatment models of the achieved result made from post-treatment impressions. They showed that there was great variation in the efficacy of Invisalign® treatment, with the mean accuracy of tooth movement being 41%. Their findings, although slightly lower, agree with Nguyen and Cheng[22] who reported a mean accuracy of anterior tooth movement of 56%.

Over the years, research on clear aligners became more specific. Investigators shifted towards more biomechanical approaches, oriented on specific tooth movements.[23] In more

recent years, forces and moments generated by clear aligners have been increasingly investigated.[12, 19, 24]

It is consistent from all the studies that extrusion is the least accurate tooth movement to perform with clear aligners[11, 25], and when compared to other types of movements, it can result in larger deviations.[26] Maxillary and mandibular incisors show the least amount of accuracy.[11, 12]

On the other hand, intrusion is a more efficiently achieved movement. Several studies[15, 18, 27] confirm that 0.25 mm to 0.5 mm posterior intrusion can be achieved. Regarding anterior teeth, Kravitz et al.[11] report that, when an average of 0.72 mm of intrusion was attempted with Invisalign®, maxillary and mandibular incisors showed 45% and 47% of accuracy, respectively. Maxillary lateral incisors showed 33% of accuracy, which was the lowest score. In 2014, Rossini et al.[28] performed the last –to date- systematic review on the efficacy of clear aligners in controlling orthodontic tooth movement. On intrusion, they report that “the average true intrusion obtained with clear aligners in non-growing subjects was comparable to the true intrusion obtained in a similar sample of a population with continuous arch technique but lower than the one reported for the segmented arch technique”.[28]

Studies reveal low degree of control and predictability for rotations especially when attempted on round shaped teeth, due to loss of anchorage caused by the absence of sufficient undercuts and the subsequent failure of the aligner to track.[11, 25, 29] However, interproximal reduction and the use of attachments can improve the efficacy of such movements.[20, 25, 29] Nguyen at al.[22] report that accuracy of incisor rotation was up to 60%, whereas canines and premolars scored only 39%. In 2014, Simon et al.[25] examined the efficacy of Invisalign® when premolar derotation greater than 10 degrees was requested by comparing scanned pre- and post-treatment models with ClinCheck®. Their results show that the amounts of tooth movement per aligner, as well as the overall derotation, significantly influence the accuracy. Specifically, when rotations greater than 15 degrees are attempted the accuracy for premolar derotation drops by 46%. Additionally, when rotations greater than 1.5 degrees per aligner are attempted, the accuracy decreases from 41.8% to 23.2%. In their follow up study,[23] investigating the specific moments and forces generated by the aligners when derotating premolars, they state that derotating a cylindrical tooth is one of the most critical movements to be achieved with aligners and is possible only to a limited

extent unless attachments are used. Rossini et al.[28] recommend planning overcorrections, using attachments and reducing staging to less than 1.5 degrees per aligner in order to achieve better rotation control (especially if the desired rotation exceeds 15 degrees).

It is generally established that clear aligners can perform tipping movements.[11, 28, 30] Teeth with larger roots, such as canines, are more challenging and uncontrolled tipping could be predominant in those cases.[11] Kravitz et al.[11] showed a mean accuracy of 41% for mesiodistal tipping, with the highest accuracy achieved by the maxillary and mandibular lateral incisors and the lowest by the maxillary and mandibular canines and maxillary central incisors. On the buccolingual dimension, lingual crown tip was shown to be significantly more accurate than buccal crown tip, especially for maxillary incisors.[11]

In 2015, Rossini et al.[28] published the most recent –to date- systematic review of the efficacy of clear aligners. They included 11 articles; two Randomized Controlled Clinical Trials (RCT), five prospective non-randomized trials, four retrospective non-randomized trials. The authors report that most of the studies performed so far present with methodological problems, such as small sample sizes, high risk of bias and absence of proper control

groups, blinding procedures and sample randomization procedures. More RCTs with rigorous methodology are needed in order to develop specific guidelines and treatment protocols for the use of clear aligners. Nevertheless, from the existing studies, certain conclusions could be drawn with caution. Clear aligners are effective in anterior intrusion, controlling maxillary molar translation when a distalization of 1.5 mm is desired, tipping and aligning and leveling of the arches. On the contrary, they have limited efficiency in controlling rotations –especially of rounded teeth- and they are not effective in controlling anterior extrusion. Lastly, studies emphasize the importance of using interproximal reduction (IPR)and auxiliaries, such as attachments and interarch elastics, in order to improve the predictability of the desired tooth movements.

All of the aforementioned studies examine crown movements. Most of the interventions are based primarily on models, digital or plaster, which are analyzed with various methods (use of ABO grading system to evaluate final results, comparison with ClinCheck®, superimposition of initial and final digital casts, etc.). Clinical measurements and/or observations are also utilized. But what happens to the roots of the teeth? Can clear aligners

control buccolingual root movement? Can root torque be performed? In answer to these questions, limited data exist.

Change in the position of a tooth in the buccolingual dimension can occur with different three movements; 1) uncontrolled tipping 2) controlled tipping 3) torque. The main factor that determines what type of movement occurs is the moment to force ratio. Uncontrolled tipping is generated by a single force and a round archwire (i.e. moment to force ratio is 0:1). The crown and the root move in opposite directions, while the tooth rotates around the center of rotation which is coincident with the center of resistance. In the case of controlled tipping, the moment to force ratio is 7:1, meaning that a couple and a single force are produced. Hence, a rectangular wire is needed. In this case, the center of rotation is at the root apex and the crown tips buccally or lingually while the root apex remains stationary. Finally, torque is somewhat of an opposite movement relative to controlled tipping, meaning that the center of rotation is now at the crown tip whereas the root moves buccally or lingually. Moment to force ratio is equal to or greater than 12:1, so a couple and a force are needed and generated by a rectangular wire.[31-34]

Controlling the root movement with clear aligners also requires the creation of effective moment to force ratios.[13, 30] However, the forces are generated in different ways that are still not completely clarified. So far, studies report that the couple consists of a tipping force near the gingival margin, which moves the tooth against the inner opposite surface of the aligner, resulting in a force of opposite direction near the incisor edge.[13, 35]

In 2010, Hahn et al.[35] aimed to describe “the forces and moments exerted by removable thermoplastic appliances on an upper central incisor during torqueing”. The investigators fabricated a force-torque measuring device, described in a previous study,[24] on which a resin model was fixed. On the model, a separated measuring tooth (upper central incisor) was placed and was reproducibly fixed on a sensor by a clamp. A goniometer was used to simulate torquing motion around a defined axis and aligners of three different companies (Invisalign® not included) were used to perform the movements. Their study concluded that, “the greater the amount of root movement planned in one step increments, the less the likelihood that the appliance fits the teeth initially; it will remain, to a certain extent, above the teeth when placed in position”.[35] Due to this “lift up” of the aligners, there is no close fit of the

incisor edge with the inner surface of the aligners and, therefore, no effective force couple is established for root control. In fact, during the intended torque movement, an intrusive force also develops. This unintended intrusive movement was also described by Brezniak, who called it “the water melonseed effect”.[30]

In 2013, Castroflorio et al.[36] tested the efficacy of Invisalign® in controlling the buccolingual inclination of upper incisors. The material used during their sample collection was SmartTrack™. What was new in this study was that it incorporated Invisalign’s® “Power Ridges®”, a new feature introduced by Align Tech. to make control of root movement more efficient. Power Ridges® are a twist in the aligner surface at the gingival margin, aiming to prevent the aforementioned “lift up”. The investigators examined 12 upper incisors needing lingual root torque and used pre- and post- treatment virtual set ups as generated by ClinCheck®, as well as 3D scans of the pre- and post-treatment plaster models. A line tangent to the facial surface of each upper incisor and a true vertical line formed the angle of reference that they used to test the amount of torque achieved. This preliminary study showed that “Invisalign® represents a good alternative for control of upper incisor root torque” and “when a torque correction

of about 10 degrees is required, torque loss is negligible. Therefore, it is possible that aligners with Power Ridges® may provide better control of the upper central incisors than can be achieved with a preadjusted system, at least in some prescriptions".[36]

Simon et al.[25] also used scanned pre- and post-treatment models as well as virtual set ups as generated by ClinCheck® to investigate if a requested 10-degree upper incisor torque was achieved. However, their sample size was collected prior to introduction of SmartTrack™. Using surface/surface-matching algorithm, they superimposed the pre-treatment model with the post-treatment model (achieved result) and then with the planned ClinCheck® result. Contrary to the previous study's findings, they found a loss of torque of up to 50%, even when Power Ridges were used. Moreover, there was a statistically significant difference between the planned movement and the clinical achieved movement. Nevertheless, as they state in their discussion, torque loss (the so-called "torque play") occurs constantly even with fixed appliances where it is almost impossible to calculate the amount of torque expression achieved. Taking this into account, it could be said that, although challenging, upper incisor torque movement can be performed with clear aligners.

Overcorrections or refinement may be needed to achieve the desired result.

In 2016, Grünheid et al.[37] published the first study that examined the efficacy of clear aligners in controlling root movement with the use of Cone Beam Computed Tomography (CBCT). Specifically, they examined they effect of aligners compared to those of fixed appliances in the buccolingual inclination of mandibular canines and intercanine distance at the cusp tip level, as measured by pre- and post-treatment CBCTs. Their results showed that clear aligner therapy led to increased intercanine distance with relatively unchanged buccolingual inclination, indicating both crown and root movement. On the contrary, fixed orthodontic treatment resulted in more upright mandibular canines with unchanged intercanine distance, which means that the root moved whereas the crown remained mostly stable. Those results indicate relatively poor control of root movement with aligners.

It is apparent that, while the efficacy of aligner therapy is well documented, objective evidence of its treatment effects is limited. One of the least examined effects is root control. In fact, the small number of studies that examine root movement, with the exception of the latter, test only maxillary incisors. Additionally,

only the latter study used CBCT to evaluate efficacy of aligners in root control. To date there is no mention in the literature about buccolingual root control of posterior teeth with clear aligners. Lack of such scientific data is of significant importance, since teeth are 3-dimensional and that is how they need to be considered when planning their proper position. There are six parameters that define the location of every tooth; three are positional (mesiodistal, faciolingual and occlusogingival), and three are angular (mesiodistal angulation, faciolingual inclination and axial rotation).[38]

Historically, buccolingual inclination of posterior teeth has been of great interest for the dental field. During the 1910s, Dr. Wilson described the importance of the mediolateral curve that contacts the buccal and lingual cusp tips on each side of the maxillary arch, known as the “Curve of Wilson”.[39] The Curve of Wilson is of great significance in establishing a balanced and functional occlusion with bilateral, simultaneous and equal contacts, as well as freedom of movement during functional excursions of the mandible. An exaggerated Curve of Wilson with premature contacts on palatal cusps that are “hanging” lower than buccal cusps has been associated, although not on a level of a cause-and-effect relationship, with

temporomandibular disorders.[40, 41] Moreover, in patients prone to periodontal disease, interferences in the lateral movements could affect in the long term the periodontium and the level of attachment.[42]

Buccolingual inclination of posterior teeth is of equal importance in the orthodontic discipline. In 1972, Dr. Lawrence Andrews published his landmark article “The Six Keys to Normal Occlusion”.[43] In this article, he presents the six characteristics that he observed upon examination of 120 casts of nonorthodontic patients with normal occlusion. The significance of those characteristics lies not only in the fact that they were present in all 120 cases, but also in the fact that lack of even one of them resulted in a non-ideal treatment result. His third key, crown inclination (i.e. labiolingual or buccolingual inclination of the long axis of the crown) indicates that maxillary posterior teeth present with a minus crown inclination (lingually inclined), which slightly increases from canine to second molar. Andrews pointed out that variation in buccolingual inclination of teeth affects the arch size. Hence, it is a determining factor in achieving proper inter- and intra-arch relationships.

During the 1990s, the American Board of Orthodontists (ABO) established an Objective Grading System (ABOGS) to

evaluate final dental casts and panoramic radiographs.[44] From 1994 to 1998, they performed four extensive field tests in order to systematically develop the scoring system. Based on the cumulative and collective results of the field tests, ABO decided to establish 8 criteria for scoring dental casts and panoramic radiographs; alignment, marginal ridges, buccolingual inclination, occlusal relationships, occlusal contacts, overjet, interproximal contacts and root angulation. According to ABOGS, “in order to establish proper occlusion in maximum intercuspation and avoid balancing interferences, there should not be a significant difference between the heights of the buccal and lingual cusps of the maxillary and mandibular molars and premolars”.[44] Flat surfaces placed transversely on the casts between the left and right occlusal surfaces of posterior teeth are used to evaluate the buccolingual inclination in both arches. In the maxilla, the straight edge should contact the palatal cusps of the molars and premolars. The buccal cusps should be within 1 mm.

In 2003, Marshall et al.[45] used dental casts taken from the Iowa Facial Growth Study to evaluate longitudinal changes in molar crown inclinations from the time of first molar eruption to early adulthood. More specifically, similar to the ABOGS method, they placed flat surfaces

transversely against the occlusal surfaces of every cast and measured the distance of the buccal and palatal molar cusps from the flat surface. The principal finding of this study was that “maxillary molars erupt with buccal crown torque and upright lingually with age, whereas mandibular molars erupt with lingual crown torque and upright buccally with age”.[45] This important finding supports the ABO’s treatment goal of uprighting and leveling the posterior teeth, because it is in agreement with the natural molar uprighting that occurs with growth.

Ideal buccolingual inclination has also been described using, instead of occlusal surface inclination, the inclination of the facial surface.[46] However, it has been shown that facial crown surface morphology is characterized by great variability, even in teeth of the same type, with standard deviations ranging from +/- 2.6” to +/- 6.4”. Great variability also exists in the relationship between the facial crown surfaces and the actual long axes of the crowns.[47]

Since the importance of proper buccolingual inclination has been firmly established, it is imperative that every orthodontic system should be able to effectively control buccolingual tooth movement. Clear aligners should not be an exception. As aforementioned, there is lack of

sufficient data investigating their effectiveness in such movements. In addition, none of the studies (with the exception of one[37]) use radiographic imaging to assess torque, i.e. the buccolingual root movement necessary to achieve proper inclination. It is evident that using only the clinical crowns of the teeth to assess their buccolingual inclinations bares inevitable limitations. Anatomic variability, attrition of cusp tips and/or restorations are only a few factors that could lead to inaccuracies or inconsistencies in measurements.

In the early 2000s, Cone Beam Computed Tomography (CBCT) was added in the armamentarium of orthodontists for 3D diagnosis and treatment planning.[48] It is an invaluable tool clinicians can use for reliable and accurate measurements that cannot be performed on a 2D lateral cephalogram.[49, 50] Buccolingual inclination is one of them and several methods have been developed in order to measure it.

In 2004, Podesser et al.[51] performed a methodological study of a new method, aiming to quantify a series of factors in the transverse dimension of the maxilla using CT scanning. Buccolingual inclination of first molars and canines was included in their measurements using coronal slices at the level of first molars and canines,

respectively. Specifically, having a horizontal line tangent to the inferior nasal cavity, they measured the molar angulation with a line connecting the apex of the palatal root and the tip of the mesiobuccal cusp. For the canines, they used the same reference line and a line connecting the canine apex and the canine tip. Their results showed that all measurements were highly reproducible, as long as one operator performed them.

In 2012, Miner et al.[52] from Boston University developed a transverse analysis based on CBCT and valid skeletal and dental landmarks. Their goal was to determine normative data for the maxillary and mandibular molars and their relationship with the related skeleton. In order to achieve reproducible measurements, they standardized a method for orienting the CBCTs in the axial, coronal and sagittal plane. Buccolingual molar angulation was measured as the angle between the long axis of the first molar and the axial plane in the coronal plan. The results were shown to be highly reliable and reproducible.

During the same year, Tong et al.[38] from the University of South California (USC) developed the USC root vector analysis program in order to measure the mesiodistal and faciolingual inclination of each whole tooth (including the root) by using 3-dimensional volumetric images generated

from CBCT scans. “The faciolingual inclination was measured from the projection of the tooth's long axis on the faciolingual plane to the vertical line formed by the same intersection of the mesiodistal and faciolingual planes”.[38] In agreement with the study from Boston University[52], their method proved to be clinically applicable, reliable and accurate.

Studies performed at Case Western Reserve University, School of Dental Medicine also developed protocols for measuring buccolingual inclinations of different tooth types.[53, 54] Karamitsou et al.[53] created a reliable method to measure buccolingual inclinations of maxillary molars and canines with the use of CBCT. Molar inclination was measured in the coronal view and defined as the angle formed between the line passing through the long axis of the molar (apex of palatal root to the mesiopalatal cusp tip) and a line tangent to the inferior border of the nasal cavity. Canine inclination was defined as the angle between the long axis of the canine and the same horizontal reference line. Intraclass correlation values for all measurements were greater than 0.96, indicating (as in the previous studies) a high degree of reliability. It is noteworthy that in this study there was a statistically significant difference of the measurements between the

right and left side and, hence, the two sides were reported separately. A similar study was performed by Shewinvanakitkul et al.[54] who measured mandibular molar and canine inclination.

The aforementioned studies established protocols for measuring buccolingual inclination on CBCTs. However, there are limited data on the actual effect of treatment in buccolingual inclination and on how the latter changes upon orthodontic treatment. In 2012, Miyamoto et al.[55] used the method described by Karamitsou et al.[53] to examine the changes in the buccolingual inclination of maxillary molars and canines after orthodontic treatment with traditional orthodontic appliances in patients 11 to 16 years old. Once more, intraclass correlation values indicated high reliability of the method. Their results showed no statistically significant differences between the right and left sides. Additionally, orthodontic treatment tended to increase inclination of maxillary molars and decrease inclination of maxillary canines. Interestingly, the result of the molars is contradictory with previous studies, which showed that maxillary teeth erupt buccaly and then tend to upright during growth. There was a significant, albeit weak, positive association between angulation and

intermolar and intercanine widths. In general, as the width increased, the angulation also increased.

It is evident that CBCT could become an irreplaceable tool in orthodontics, offering unique ways to evaluate the position of teeth and the skeletal structures in all 3-dimensions of space. Recent advancements in imaging software made superimposition of CBCT scans possible, offering clinicians a state-of-the-art technique in assessing treatment outcomes.[56]

There are three types of 3D superimposition; landmark based, surface based, and voxel based. The latter is considered the most efficient method. It compares non-changing reference structures in volumetric data voxel by voxel and excels the other two in that it does not depend on landmark identification nor is limited by segmentation errors, respectively.[57]

Cevidanes et al.[58] were the first to introduce the voxel-based method in dentistry, using the cranial base as the reference for the superimposition of two or more scans. Their method can be applied in growing and non-growing patients.[59, 60] Recently, techniques for maxillary and mandibular superimposition have started to be developed.[57, 61]

Literature has established the importance of buccolingual root movement in orthodontics, the unique advantages CBCT technology offers in assessing it and the lack of investigation for the effectiveness of clear aligners in achieving it. The purpose of this thesis is to interconnect those parameters and evaluate the effectiveness of clear aligners in controlling buccolingual root movement though the use of CBCT imaging.

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STATEMENT OF THESIS

The objective of this study is to determine if clear aligners can efficiently control buccolingual root movement in maxillary posterior teeth. Changes at the apex level were examined in relation to the CEJ and crown tip levels respectively.

Null Hypothesis: The Invisalign appliance is not able to control the root and provide either torque or controlled tipping.

Alternative Hypothesis: The Invisalign appliance is able to control the root and provide either torque or controlled tipping.

An Evaluation of Clear Aligners for Buccolingual Root Control in Maxillary Posterior Teeth

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ABSTRACT

Introduction: Our objective was to determine if clear aligners can efficiently control buccolingual root movement in maxillary posterior teeth. **Methods:** Pre- and post-treatment CBCTs of 22 non-growing patients were selected for this retrospective study. Patients were treated with Invisalign aligners in a private practice setting. Long axis buccolingual inclination of maxillary molars and premolars, as well as inter-first premolar width, inter-second premolar width, and inter-first molar widths at the levels of root apex, CEJ, and crown tip were measured in the coronal view from CBCT DICOM data, using the commercially available Dolphin 3D imaging software program. 3D superimposition of pre- and post-treatment CBCT models was performed to verify results. **Results:** Inter-first premolar, inter-second premolar, and inter-first molar widths were greater after treatment at all three levels. The changes were statistically significant at the CEJ and crown tip level but not at the apex level. Mean buccolingual inclination of all teeth increased significantly. Results indicate controlled buccal tipping of the teeth post-treatment. Individual cases show torque expression. **Conclusions:** This study presents indications of efficient root control in maxillary posterior teeth with the use of clear aligners. Controlled buccal tipping occurs reliably, whereas torque expression is observed in individual cases.

Keywords: aligners, torque, buccolingual root control, CBCT

INTRODUCTION

The influence of the type of orthodontic appliance to the amount, type and rate of tooth movement has always been an object of research in the orthodontic field. For more than a decade, clear aligners have been gaining popularity as an orthodontic appliance among clinicians.[1] However, their treatment efficacy and their ability to perform specific tooth movements are still not clarified. The clear aligner concept is not new. The “Tooth Positioning Appliance” was already introduced in 1945 for the “final artistic positioning of the teeth” by Kesling.[2] During the following decades, other clinicians developed similar appliances attempting more extensive tooth movements.[3-5] However, it was with the Invisalign® appliance introduced in 1997 by Align technology that the interest in clear aligners increased, as it was promoted as a complete system for comprehensive orthodontic treatment.[6] The combination of the SmartTrack™ material with special auxiliaries (attachments, bite ramps, etc.) is claimed to deliver light, constant forces and efficiently achieve crown and root movements.[7] Integration of the iTero intraoral scanner with Invisalign® has shown to provide digital impressions that are more accurate than polyvinyl siloxane impressions.[8, 9] While the efficacy of clear aligners is well documented, objective evidence of specific treatment effects is limited. Buccolingual root control is the movement least examined and the few studies that exist focus primarily on anterior teeth where buccolingual root control is proven to be accomplished.[10]

The importance of proper buccolingual inclination of posterior teeth is critical in orthodontic treatment. Described by Andrews[11] in 1972, it is the third

key to normal occlusion and it is a determining factor in achieving optimal inter- and intra-arch relationships. In agreement with Andrews, the American Board of Orthodontics (ABO)[12] recognizes buccolingual inclination as one of the eight criteria for assessing the quality of orthodontic treatment.

Change in buccolingual tooth inclination is achieved with three different movements: uncontrolled tipping, controlled tipping and torque. The main factor that determines what type of movement occurs is the moment to force ratio. Uncontrolled tipping is generated by a single force and a round archwire (i.e. moment to force ratio is 0:1). The crown and the root move in opposite directions, while the tooth rotates around the center of rotation which is coincident with the center of resistance. In the case of controlled tipping, the moment to force ratio is 7:1, meaning that a couple and a single force are produced. Hence, a rectangular wire is needed. In this case, the center of rotation is at the root apex and the crown tips buccally or lingually while the root apex remains stationary. Finally, torque is somewhat of an opposite movement relative to controlled tipping, meaning that the center of rotation is now at the crown tip whereas the root moves buccally or lingually. Moment to force ratio is equal to or greater than 12:1, so a couple and a force are needed and generated by a rectangular wire (Fig 1).[13, 14]

Torque can be built in the bracket prescription, bent in the archwire, or both. In either case, when a rectangular wire is engaged in the bracket slot a third order couple is generated causing buccolingual tooth movement.[15, 16] In theory, third order moments could be calculated from the dimensions of the

brackets and the archwires. However, it has been shown that there is a significant discrepancy between desired movement and achieved movement.[17, 18]

In the case of aligners, in order to achieve torque, creation of an effective couple is also needed, although generated in a different manner. It is reported that, when torquing anterior teeth, the couple consists of a tipping force near the gingival margin, which moves the tooth against the inner opposite surface of the aligner resulting in an equal and opposite force near the incisor edge. However, the way to generate the proper moment to force ratio is not clarified.[19] Studies show that upper incisor torque movement, although challenging, can be performed with clear aligners. Yet again, there is a discrepancy between the expected amount and the amount of torque clinically observed.[20, 21]

Assessment of buccolingual inclination changes in two-dimensions (2D) via superimposition of pre- and post- treatment cephalograms has been proven to be problematic.[22, 23] Indeed, to assess and quantify treatment changes, three-dimensional (3D) imaging techniques are needed. Cone-beam Computed Tomography (CBCT) combines the benefits of treatment assessment in all planes of space, the ability to accurately quantify changes, as well as a significant lower effective radiation compared to medical CT.[24]

The aim of this study was to examine if buccolingual root control of maxillary posterior teeth is possible with the use of clear aligners. Pre- and post-treatment CBCT scans were analyzed to assess torque expression of maxillary premolars and molars upon orthodontic treatment with aligners. To date, there is

no study in the literature examining the efficiency of clear aligners in buccolingual root control of maxillary posterior teeth as assessed with the use of CBCT.

MATERIALS AND METHODS

The Case Western Reserve University (CWRU) Institutional Review Board (IRB) approved this study (IRB 2015-1359). Data was collected retrospectively from the records of patients treated in the private practice of J.W. and are compiled from pre- and post- treatment Cone Beam Computed Tomography (CBCT) scans (GALILEOS Comfort^{PLUS}, Dentsply Sirona - York, PA, USA). Images were taken at the patients' initial and final records appointments prior to December 17, 2015. Records included medical and dental history forms, initial and final intraoral/extraoral photographs, self-reported demographic data, intraoral scans (iTero Intraoral Scanner, Align Technology, Inc. – San Jose, CA, USA) as well as radiographs. All the patients signed an informed consent form allowing the use of records for research (Fig 2), and no patients were contacted during the course of the research project.

The following inclusion criteria were used:

1. Full treatment completed exclusively with Invisalign® aligners (Align Technology, Inc. - San Jose, CA, USA)
2. Non-growing patients
3. Request for buccal crown torque in the Invisalign® prescription for at least one premolar and/or first molar
4. Orthodontic treatment completed without extraction of permanent teeth

5. Use of SmartTrack™ material (initiation of treatment after January 21, 2013)
6. Pre- and post- treatment full field of view CBCT scans
7. No previous major restorations
8. Cusp tips, cementoenamel junction and root apices of maxillary premolars and molars clearly visible in the CBCT scans.

All measurements were performed on de-identified CBCT scans using version 11.8.06.24 Dolphin3D Imaging (Patterson Dental Supply, Inc., St. Paul, MN) software for all pre- and post- treatment scans. One examiner performed all the measurements (S.X.). For standardization purposes, all images were oriented prior to any measurement according to the internal landmark protocol proposed by Wu at al.[25] (Fig 3). Once orientation of the subject was completed, it was critical for it to remain unchanged for the subsequent measurements. All measurements were performed at two time points; pre-treatment (T1) and post-treatment (T2).

Assessment of premolar and molar inclination

CBCT axial and coronal slices were used to place markers at the root apices and crown tips of the measured teeth. Each coronal slice included one pair of teeth (first premolars, second premolars and first molars respectively). Measurement of premolar inclination was accomplished by passing a line through the root apex and the palatal cusp tip. In case of two rooted premolars, the palatal root apex was used. Measurement of first molar inclination was

accomplished by passing a line through the palatal root apex and the mesiopalatal cusp tip. A second line was drawn tangent to the axial plane. Inclinations were calculated by measuring the internal angle formed by the respective intersecting lines viewed in the transverse slice (Fig 4). In case of dilacerated roots, a “best fit” line was constructed passing through the propagation of force down the long axis of the tooth.

Assessment of inter-premolar and inter-molar width

Using the same coronal slices used for the inclination, the inter-premolar and inter-molar widths were measured respectively at three levels; root apices, cementoenamel junctions (CEJs) and crown tips. The markers previously used for the root apices and crown tips were maintained to ensure that the same points would be selected for both inclination and width. Inter-teeth widths were measured at all three levels as the distance between the apices, CEJs and crown tips, respectively (Fig 5).

3D Superimposition

Voxel based 3D superimposition of the pre- and post-treatment scans was performed to verify and aid in the visualization of the results collected from the pre- and post- treatment measurements. The anterior cranial base (sphenoid bone) was used for registering and superimposing the pre- and post-treatment CBCT models (Fig 6).[26] After superimposition, each pair of teeth (first premolars, second premolars and first molars) was located on coronal and axial slices, in the

same manner used for the inclination. Treatment change verification and quantification was performed (Fig 7).

Statistical Analysis

Statistical analysis was performed with SPSS version 17.0 for Windows (Statistical Package for the Social Sciences, SPSS 17.0, Inc. – Chicago, IL, USA). Testing of normal distribution was performed on each parameter. Descriptive statistics (means, standard deviations and ranges) was used to evaluate the data (Table I). Paired sample t-tests were used to evaluate the statistical significance of the mean differences between the pre- and post-treatment measurements for every pair of teeth respectively (first premolars, second premolars and first molars). The significance level, alpha, was set at 0.05. For all measurements, the error of method was calculated on double measurements after a two-week interval of 11 randomly selected patients. Cronbach intraclass correlation was determined based at a 95% confidence interval (Table II).

RESULTS

A total of 110 patients had treatment initiated after January 21, 2013 and completed prior to December 17, 2015. From them, 52 were non-growing patients and 41 had undergone full orthodontic treatment. On 35 patients, buccal root torque in at least one maxillary posterior tooth was requested. Finally, 22

patients had pre- and post- treatment full field of view CBCTs, and clearly visible maxillary molars and premolars without major restorations.

The final sample population consisted of 14 females and 8 males with an average age at the start of treatment of 29.6 years, ranging from 17.0 to 54.5 years. Average number of aligners used was 32, ranging from 18 to 72. All variables met the parametric test assumptions, as indicated by the Shapiro-Wilk test. The error of the method was found to be small for all respective measurements (0.05 mm, 0.08 mm, and 0.12 mm for the apices of first premolar, second premolar and first molar respectively). Cronbach intraclass correlation was higher than 0.9 (95% confidence interval) indicating excellent repeatability of measurements (Table II).

Table III shows the mean changes in the linear measurements (inter-teeth widths) at both time points (T1 and T2). Overall, all measurements showed an increase after treatment and for all pairs of teeth the distance progressively got larger from the apex to the crown tip. This type of inter-teeth width increase is positively associated with buccal tipping. At the level of the CEJ and the crown tip this increase was statistically significant whereas at the apex level it was not, indicating that the root apex did not move. Buccal tipping with no movement at the apex level is suggestive of controlled tipping. Mean changes for angular measurements (buccolingual inclination) are shown in Table IV. All angles were significantly greater after treatment with the exception of the maxillary left first molar angle, which increased but not significantly. This post-treatment increase in buccolingual inclination is also an indication of buccal tipping.

No correlation was found between the amount of post-treatment changes and the number of aligners used during treatment. Examining the raw data, there were individual cases where the increase of inter-teeth width at the apex level was greater than the increase at the tip level, suggesting torque expression on individual cases.

The 3D analysis was consistent with the previous measurements confirming that there was an increase in the inter-teeth distances at all three levels. When the changes were quantified in the superimpositions, the results were similar to the measurements performed in the separate pre- and post- treatment CBCTs.

DISCUSSION

For more than a decade, clear aligner popularity has been consistently increasing in the orthodontic clinical practice and they have become the appliance of choice for many orthodontists. Aligners are relatively new and, despite the rigorous research that has been initiated, treatment applicability and efficacy are not fully understood yet. Root control has always been a challenging task for orthodontists, especially in the buccolingual dimension. Taking this into account, it is not surprising that one of the last barriers yet to be overcome regarding the efficacy of aligners is root control. Only a few studies investigated root control with clear aligners and none examined their effect on posterior teeth. For this reason, it was the goal of this study to explore the effects of orthodontic treatment with clear aligners on the buccolingual root movement of maxillary premolars and molars.

The only way to assess and quantify root movement is with the use of radiographs. However, 2D radiographic images have many limitations especially in the transverse dimension.[24] To avoid this issue, in this study, CBCT scans were used for all the assessments. Despite the unquestionable benefit of optimal evaluation and quantification of treatment outcomes with 3D imaging techniques, the increased exposure to ionizing radiation is an important issue, which might raise concerns.[27] For this reason, a low dose CBCT scanner was used minimizing the effective dose of radiation significantly (only three times the effective dose of a 2D radiograph).[27]

In the present study, the main research question was dichotomous and focused on whether root control can be achieved, either with controlled tipping or torque. No attempt was made to quantify the amount of torque expression clear aligners might produce on posterior teeth. Since there was no evidence in the literature on even the possibility of posterior buccolingual root control with aligners, it was important that addressing this issue took precedence.

Invisalign® was the appliance under examination, as it is by far the oldest type of clear aligner in the market, the most researched and the most widely used. However, again due to its brief presence in the orthodontic market and the continuous research, there is constant developing and improvement of features and materials associated with it. As a result, collecting a uniform sample population was rather challenging. The first parameter that had to be addressed was the aligner material. More specifically, all cases should have been treated with aligners fabricated with the SmartTrack™ material, which was launched in

January 2013. Considering that a full orthodontic treatment, especially in adult patients who comprise the sample population in this study, takes an average of two years the issue of sample size arose. Nevertheless, even though we are aware that the small sample size might cause statistical limitations, we believe that this information is highly valuable and sets an important path to the potential of clear aligner therapy as well as the goals for future research.

The findings of this study show statistically significant interdental width increases at the CEJ and crown tip levels. At the apex level, the changes were not statistically significant indicating that the apex remained stationary. If aligners failed to control root movement, considering the increase in buccolingual angulation and the buccal movement of the crown tip, the root apex should have moved in the opposite direction, i.e. toward the palate, as observed in uncontrolled tipping. Instead, controlled tipping occurred in a reliable fashion. Additionally, when examining the raw data, there were individual cases that showed torque expression. 3D model superimposition of the initial and final CBCTs confirms those changes.

Taking all the above under consideration, there is strong indication that Invisalign® can at the least control root movement in a consistent manner. Actual torque expression, albeit not reliably yet, was observed in individual cases. However, one must consider the biomechanical limitations that exist when attempting torque expression even with conventional brackets. Multiple studies have been published investigating specific amounts of torque achieved by different types of bracket designs. The majority of those studies show the

discrepancy between desired, or prescribed, root movement and the clinical result. Posterior maxillary teeth are rather problematic.[15, 28, 29] Even when root movement is achieved, it is almost impossible to prevent any crown tipping. Most importantly, to our knowledge, there are no similar studies that examine root apex movement in CBCTs even with conventional brackets. Given the fact that Invisalign® is a relatively new appliance there is a learning curve not only for clinicians but also for manufacturers and researchers.

This study showed indications of effective root control with the use of clear aligners. Future research is needed to expand the present study with larger sample sizes and determine if torque expression can be accomplished in a reliable, consistent manner. In any case, it is important to use 3D imaging technology for outcome assessment since this is the only means of truly examining root position in the buccolingual dimension.

CONCLUSIONS

Clear aligners can control root movement. Control tipping happens in a reliable manner, and clinically significant torque was seen in individual cases.

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TABLES

Table I. Descriptive summaries of CBCT patients

	N	Minimum	Maximum	Mean	Std. Deviation
Gender (M=0, F=1)	22	0.00	1.00	0.63	0.49
Age	22	17.00	54.50	29.63	12.25
UR6T1	21	83.20	111.50	98.85	7.32
UR6T2	21	85.90	110.90	101.32	6.33
UL6T1	21	88.80	110.30	101.25	5.80
UL6T2	21	90.00	110.30	102.69	5.55
U6_6T1apex	21	25.40	40.70	31.80	3.75
U6_6T1CEJ	21	27.00	45.20	32.53	3.85
U6_6T1tip	21	31.80	54.30	38.61	5.06
U6_6T2apex	21	25.20	43.70	32.11	4.03
U6_6T2CEJ	21	28.20	44.00	33.85	3.49
U6_6T2tip	21	32.90	51.10	40.13	4.49
UR5T1	21	70.30	91.90	82.21	6.03
UR5T2	21	69.10	94.30	85.27	5.77
UL5T1	21	71.40	96.50	83.41	6.92
UL5T2	21	68.50	98.70	86.12	6.80
U5_5T1apex	21	30.00	44.40	37.86	3.83
U5_5T1CEJ	21	26.20	35.60	31.14	2.65
U5_5T1tip	21	27.20	38.00	33.21	2.90
U5_5T2apex	21	31.50	46.70	38.45	3.74
U5_5T2CEJ	21	27.60	37.50	32.81	2.52
U5_5T2tip	21	29.30	40.50	35.54	2.99
UR4T1	22	71.60	101.70	85.25	7.71
UR4T2	22	77.20	101.40	88.95	6.56
UL4T1	22	72.00	96.90	86.49	6.52
UL4T2	22	71.30	97.00	89.06	6.69
U4_4T1apex	22	23.60	39.40	31.70	4.50
U4_4T1CEJ	22	21.10	34.60	26.30	2.99
U4_4T1tip	22	24.10	39.20	28.72	3.30
U4_4T2apex	22	24.90	40.00	32.30	4.52
U4_4T2CEJ	22	21.10	33.50	27.86	2.70
U4_4T2tip	22	24.10	38.60	31.39	3.07
Valid N (listwise)	20				

Table II. Reliability of clinical measurements

	Cronbach's Alpha
UR6T1	0.994
UR6T2	0.990
UL6T1	0.982
UL6T2	0.988
U6_6T1apex	0.994
U6_6T1CEJ	0.991
U6_6T1tip	0.996
U6_6T2apex	0.993
U6_6T2CEJ	0.998
U6_6T2tip	0.995
UR5T1	0.991
UR5T2	0.976
UL5T1	0.995
UL5T2	0.974
U5_5T1apex	0.993
U5_5T1CEJ	0.953
U5_5T1tip	0.991
U5_5T2apex	0.996
U5_5T2CEJ	0.946
U5_5T2tip	0.993
UR4T1	0.994
UR4T2	0.988
UL4T1	0.994
UL4T2	0.987
U4_4T1apex	0.992
U4_4T1CEJ	0.977
U4_4T1tip	0.997
U4_4T2apex	0.996
U4_4T2CEJ	0.954
U4_4T2tip	0.986

Table III. Means for pre-treatment (T1) and post-treatment (T2) linear measurements at apex, CEJ, and crow tip levels
Data are shown as mean differences (95% CI).

Variable	T1 mean (SD)	T2 mean (SD)	Delta Mean (SD)	P value
6-6				
apex	31.80 (3.66)	32.11 (3.93)	0.31 (0.14)	0.323
CEJ	32.53 (3.76)	33.85 (3.41)	1.32 (0.18)	0.000*
tip	38.62 (4.94)	40.14 (4.39)	1.52 (0.28)	0.002*
5-5				
apex	37.87 (3.75)	38.46 (3.66)	0.59 (0.04)	0.188
CEJ	31.14 (2.59)	32.81 (2.46)	1.67 (0.07)	0.000*
tip	33.21 (2.84)	35.54 (2.93)	2.33 (0.04)	0.000*
4-4				
apex	31.70 (4.40)	32.30 (4.42)	0.60 (0.01)	0.117
CEJ	26.30 (2.93)	27.87 (2.65)	1.57 (0.14)	0.000*
tip	28.72 (3.23)	31.39 (3.00)	2.67 (0.12)	0.000*

6, first molar; 5, second premolar; 4, first premolar.
*p<0.05 was considered statistically significant.

Table IV. Means for pre-treatment (T1) and post-treatment (T2) angular measurements
Data are shown as mean differences (95% CI).

Variable	T1 mean (SD)	T2 mean (SD)	Delta Mean (SD)	P value
UR6	98.86 (7.15)	101.33 (6.18)	2.47 (0.48)	0.019*
UL6	101.25 (5.67)	102.70 (5.43)	1.45 (0.12)	0.088
UR5	82.22 (5.89)	85.28 (5.63)	3.06 (0.13)	0.002*
UL5	83.41 (6.76)	86.12 (6.64)	2.71 (0.06)	0.016*
UR4	85.26 (7.54)	88.95 (6.41)	3.69 (0.56)	0.000*
UL4	86.49 (6.38)	89.07 (6.54)	2.58 (0.08)	0.025*

6, first molar; 5, second premolar; 4, first premolar.
*p<0.05 was considered statistically significant.

FIGURES

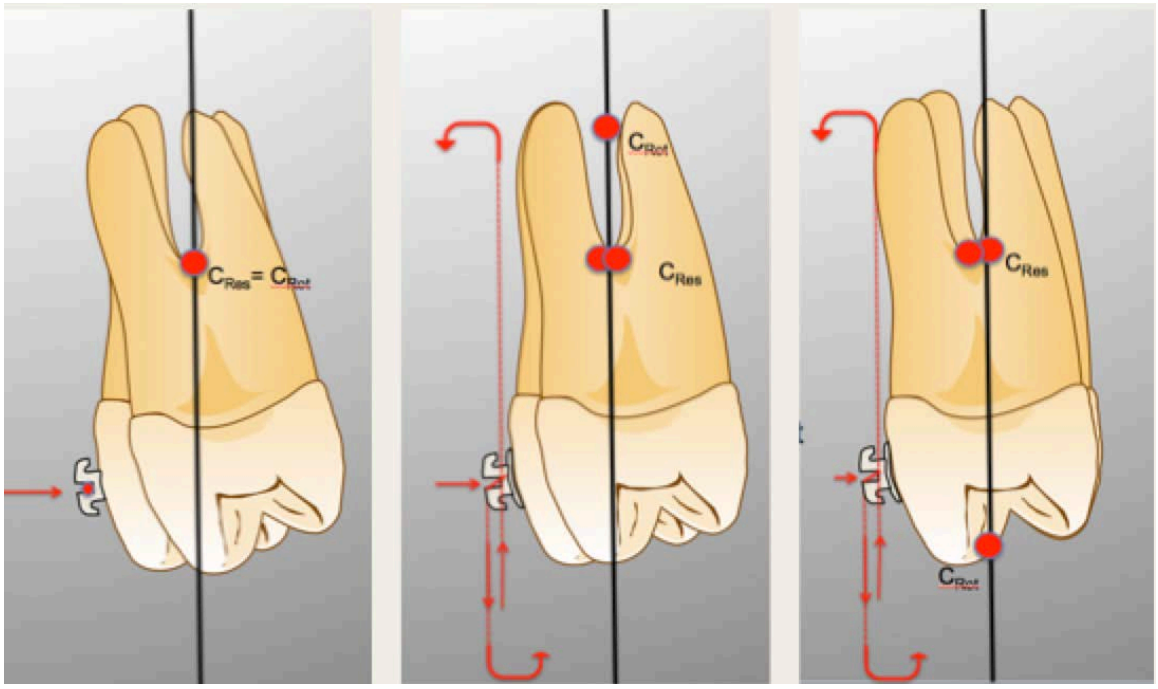
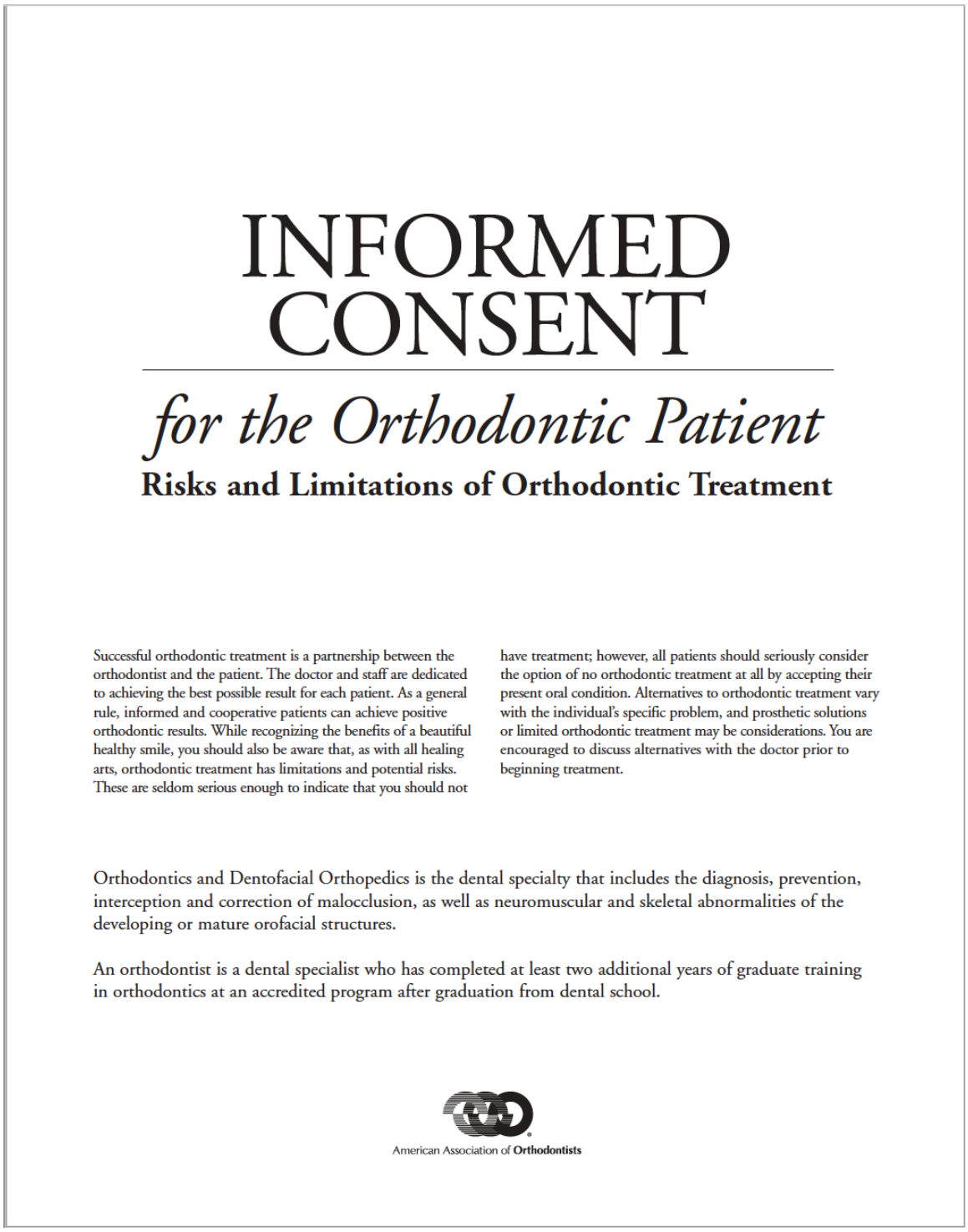


Figure 1. Movements in the buccolingual dimension. **A,** Uncontrolled tipping. Root and crown move at opposite directions (moment to force ratio 0:1). **B,** Controlled tipping. Root apex remains stationary and crown rotates (moment to force ratio 7:1). **C,** Torque. Root movement while the crown tip remains stationary (moment to force ratio 12:1).



INFORMED CONSENT

for the Orthodontic Patient

Risks and Limitations of Orthodontic Treatment

Successful orthodontic treatment is a partnership between the orthodontist and the patient. The doctor and staff are dedicated to achieving the best possible result for each patient. As a general rule, informed and cooperative patients can achieve positive orthodontic results. While recognizing the benefits of a beautiful healthy smile, you should also be aware that, as with all healing arts, orthodontic treatment has limitations and potential risks. These are seldom serious enough to indicate that you should not have treatment; however, all patients should seriously consider the option of no orthodontic treatment at all by accepting their present oral condition. Alternatives to orthodontic treatment vary with the individual's specific problem, and prosthetic solutions or limited orthodontic treatment may be considerations. You are encouraged to discuss alternatives with the doctor prior to beginning treatment.

Orthodontics and Dentofacial Orthopedics is the dental specialty that includes the diagnosis, prevention, interception and correction of malocclusion, as well as neuromuscular and skeletal abnormalities of the developing or mature orofacial structures.

An orthodontist is a dental specialist who has completed at least two additional years of graduate training in orthodontics at an accredited program after graduation from dental school.

American Association of **Orthodontists**

Fig 2. Informed consent for CBCT scans.

Fig 3. CBCT orientation: Set the axial plane by centering the right and left optical foramina in the coronal view. Set the coronal plane by centering the right and left foramina ovale in the axial view. Set the sagittal plane by viewing foramen cecum in the axial view and placing the axial plane along McRae's line (basion to opisthion). Adjust pitch (clockwise or counterclockwise) to have palatal plane flush with axial plane.

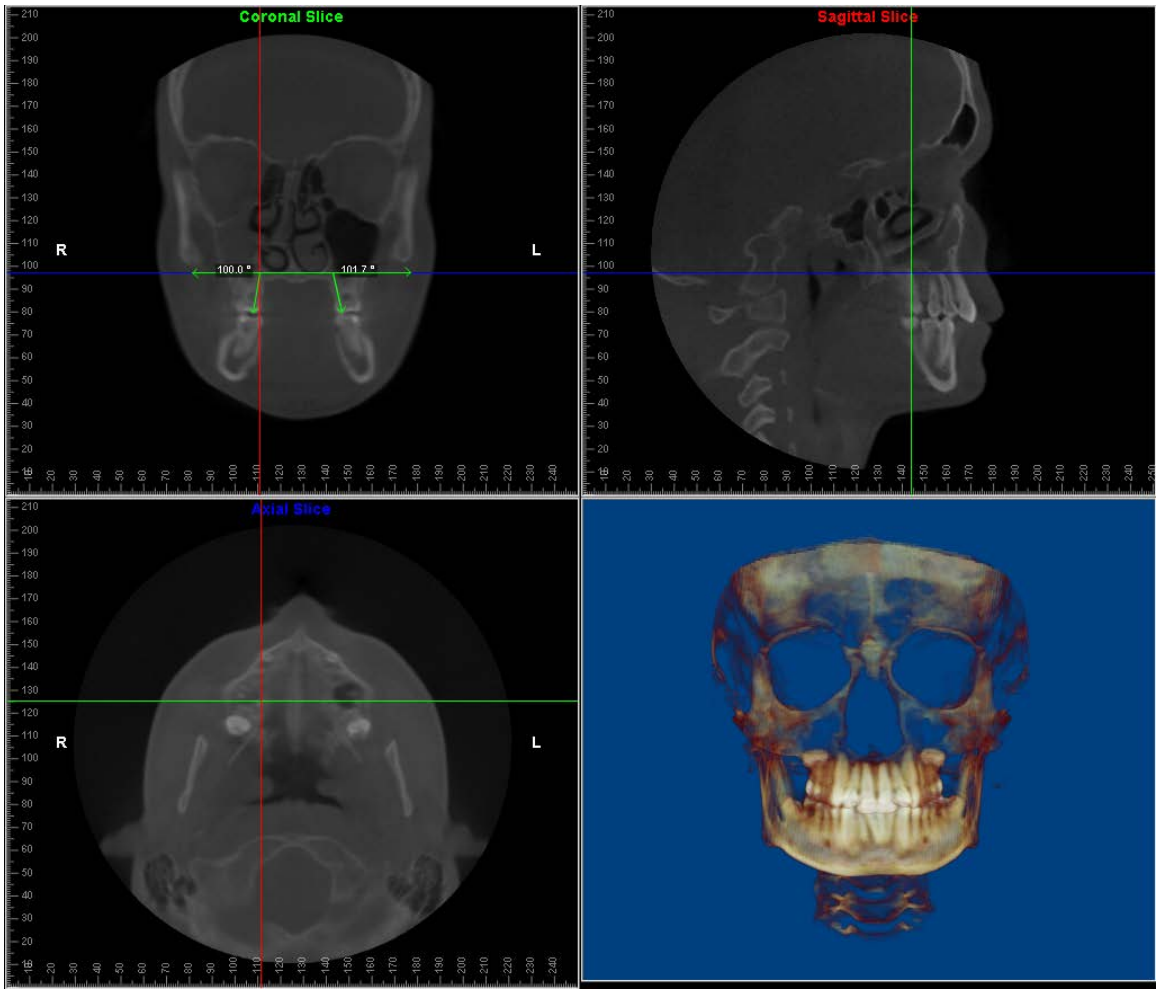


Fig 4. Buccolingual inclination: In the axial view, the palatal root apices of the right and left molar were located. In the coronal view, a reference line was placed tangent to the axial plane and through the inferior border of the nasal cavity. The internal angle between the long axis of the molar (mesiopalatal cusp tip to palatal root apex) and the reference line was measured.

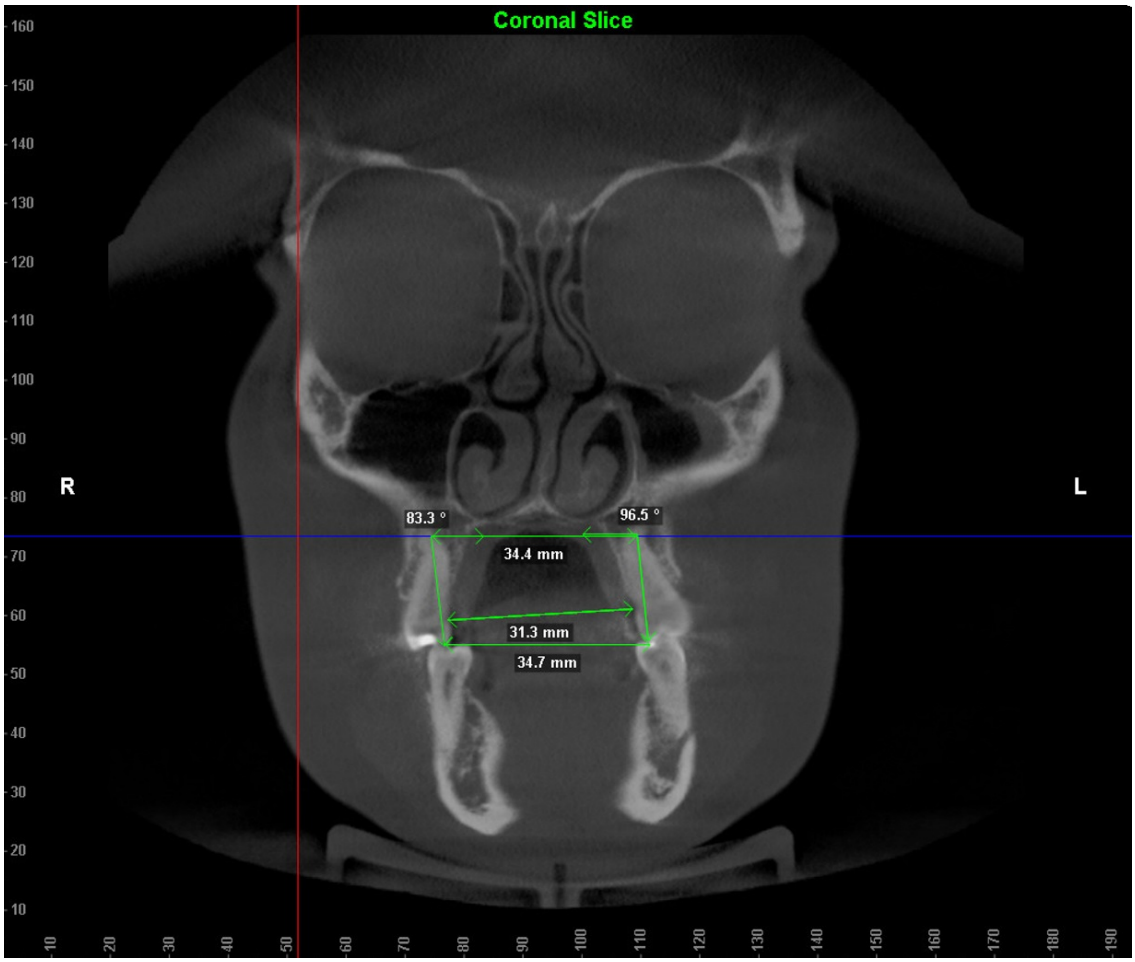


Fig 5. Second premolar angulation and interpremolar width at the levels of root apices, CEJs, and crown tips respectively.

Fig 6. Voxel based 3D superimposition of pre- and post- treatment CBCTs. Images are superimposed on the anterior cranial base (sphenoid bone).

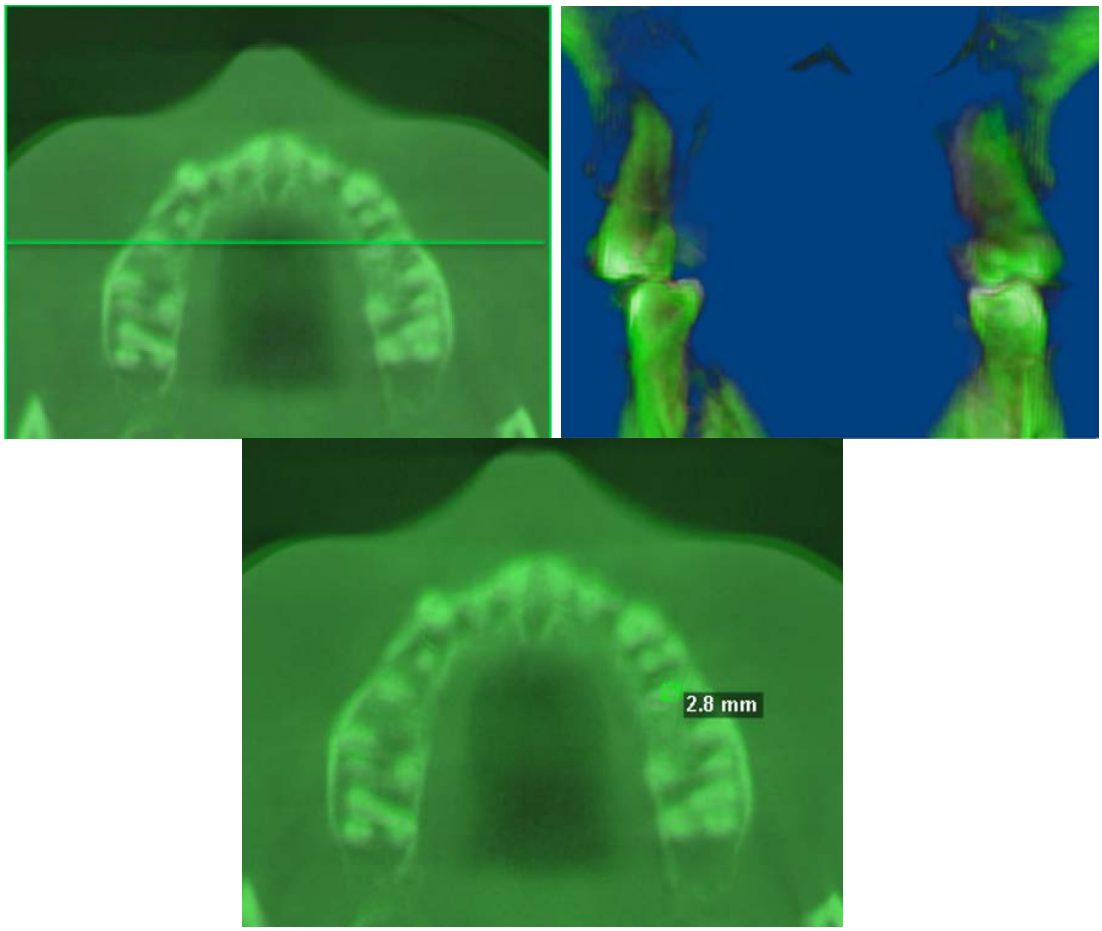


Fig 7. Superimposed pre- and post- treatment CBCT models. White color represents pre-treatment image and green post-treatment image. **A,** Axial slice at the apex level. **B,** Coronal slice at the level of second premolars, which indicates the achievement of buccal root torque on the left premolar. **C,** Measuring the change for the second premolar apex.

APPENDIX 1

IRB approval

CASE WESTERN RESERVE UNIVERSITY EST. 1826

NOTICE OF EXEMPTION #4

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

CWRU IRB Protocol Number:	**IRB-2015-1359**
Protocol Title:	***Buccolingual root control of molars and premolars with the use of aligners.***
Responsible Investigator (RI):	**Juan Martin Palomo**
Co-Investigator (CI):	**Sofia Xofylli**
RI Department:	**Case Western Reserve University IBC and SBER IRB - DEN - Orthodontics**
Exemption Date:	**12/17/2015**

This protocol is exempt under the #4 category because this involves *EXISTING RETROSPECTIVE DE-IDENTIFIED* data. Prospective data is NOT included in this exemption. If you intend to collect prospective data for this study, then this study might not be eligible for an exemption and you must contact the Institutional Review Board (IRB) office as soon as possible.

De-identified pre-existing data collected **after 12/17/2015** are NOT covered by this exemption.

The CWRU IRB has deemed the above protocol EXEMPT under 45 Code of Federal Regulations (CFR) part 46.101(b)(4). The IRB will not conduct subsequent reviews of this protocol.

PLEASE NOTE THAT THIS ONLY APPLIES TO EXISTING DATA.

IF YOU WISH TO CHANGE THIS EXEMPTED PROTOCOL IN ANY WAY, YOU MUST SUBMIT AN ADDENDUM REQUEST AND WAIT FOR IRB APPROVAL PRIOR TO IMPLEMENTING ANY PROTOCOL CHANGE.

Any changes to the protocol that put it under the purview of the CWRU IRB would require a formal application to, and approval of, the CWRU IRB prior to implementation of the change. Contact the CWRU IRB office for further assistance.

APPENDIX 2

Key

Age	Age (years)
# Aligners	Number of aligners used in treatment
T1	Pre-treatment
T2	Post-treatment
UR	Maxillary right inclination (degrees)
UL	Maxillary left inclination (degrees)
4	Maxillary first premolar
5	Maxillary second premolar
6	Maxillary first molar
4_4	Interfirst premolar width (mm)
5_5	Intersecond premolar width (mm)
6_6	Interfirst molar width (mm)

APPENDIX 3

Raw Data

Subject	Gender (M=0, F=1)	Age	# of Aligners	UR6T1	UR6T2	UL6T1	UL6T2	U6_6T1apex	U6_6T1CEJ	U6_6T1tip	U6_6T2apex	U6_6T2CEJ	U6_6T2tip
1	1	41.11	24	92.70	95.60	107.40	110.30	31.40	32.60	38.30	30.90	32.60	39.80
2	1	32.40	20	93.10	95.90	100.10	101.80	27.20	27.80	31.80	26.90	28.20	32.90
3	1	25.80	21	104.20	101.90	104.00	107.90	28.60	31.40	37.60	28.00	31.90	38.70
4	0	18.30	20	110.60	110.90	110.30	108.30	29.70	34.70	45.30	32.40	37.20	47.70
5	1	19.70	38	83.20	85.90	88.80	94.40	39.30	30.80	36.80	37.90	31.40	37.50
6	1	34.30	30	102.40	102.80	106.60	110.10	33.00	35.40	42.10	33.30	36.20	43.40
7	0	30.11	45	101.10	104.40	107.60	107.70	29.80	33.70	39.90	30.90	34.40	42.30
8	0	19.40	30	101.70	103.20	98.40	100.40	35.50	35.00	43.00	36.60	36.80	44.70
9	1	17.70	23	93.80	93.20	95.00	90.00	31.90	30.30	35.30	34.20	32.00	35.40
10	1	24.40	18	93.30	96.60	97.30	102.20	34.30	31.80	37.60	32.90	33.50	39.20
11	0	54.50	10										
12	1	50.10	60	98.60	110.20	103.20	105.90	25.40	27.00	32.40	25.20	30.30	37.40
13	1	17.30	26	102.30	102.60	94.90	96.70	28.30	28.30	33.70	30.70	31.50	37.20
14	0	20.50	78	87.70	97.70	100.20	103.90	36.10	33.50	38.90	35.10	36.50	42.20
15	0	37.10	27	89.10	96.80	92.80	95.10	32.90	30.80	33.70	32.00	31.80	36.80
16	0	27.10	63	104.80	107.20	108.40	108.60	30.40	35.20	42.30	29.80	35.80	42.50
17	1	24.90	29	97.70	104.80	100.50	101.20	30.70	30.10	36.10	30.80	32.60	38.30
18	1	47.90	19	107.40	107.00	101.40	102.30	31.00	35.40	40.90	32.20	35.80	41.20
19	1	20.00	46	100.70	105.60	100.80	104.70	29.00	30.20	35.90	28.20	31.90	36.80
20	1	17.00	47	100.60	105.90	101.10	106.60	31.40	33.50	39.10	32.10	36.80	43.90
21	1	51.11	20	99.50	93.90	97.50	99.00	31.30	30.50	36.00	30.50	29.70	33.90
22	0	21.20	18	111.50	105.60	110.00	99.50	40.70	45.20	54.30	43.70	44.00	51.10

Subject	Gender (M=0, F=1)	Age	# of Aligners	UR5T1	UR5T2	UL5T1	UL5T2	U5_5T1apex	U5_5T1CEJ	U5_5T1tip	U5_5T2apex	U5_5T2CEJ	U5_5T2tip
1	1	41.11	24	83.10	85.70	96.50	95.50	34.00	30.40	34.70	35.90	31.70	36.30
2	1	32.40	20	84.80	86.00	89.30	85.80	33.60	28.90	32.00	35.00	30.40	32.70
3	1	25.80	21	87.60	91.00	86.80	88.10	36.50	33.40	34.90	37.00	34.10	35.40
4	0	18.30	20	91.80	91.60	91.90	87.20	36.80	33.30	38.00	40.50	35.30	40.50
5	1	19.70	38	74.80	80.00	82.10	85.50	38.70	30.30	31.20	38.40	30.50	33.30
6	1	34.30	30	82.50	83.80	86.50	89.40	39.60	31.90	35.60	39.70	33.30	37.00
7	0	30.11	45	85.60	90.60	86.30	92.60	36.20	30.10	33.30	36.10	31.70	37.00
8	0	19.40	30	85.10	88.80	81.60	89.40	41.50	34.20	36.60	40.20	37.50	39.60
9	1	17.70	23	70.30	69.10	71.40	68.50	44.40	31.80	30.90	46.70	32.90	31.30
10	1	24.40	18	85.40	85.60	86.50	90.00	37.20	31.80	35.00	38.70	34.30	37.70
11	0	54.50	10	85.40	89.40	74.60	88.30	43.90	35.60	37.00	38.60	34.50	38.00
12	1	50.10	60	84.30	86.20	96.30	98.70	30.00	26.40	30.10	31.90	29.70	33.10
13	1	17.30	26	74.50	78.80	81.10	80.00	34.80	26.20	27.20	38.40	30.70	32.30
14	0	20.50	78	72.80	84.30	87.70	85.60	41.10	34.40	35.60	43.30	36.80	40.00
15	0	37.10	27	74.30	77.90	74.80	73.10	43.50	32.60	33.10	45.00	34.10	35.80
16	0	27.10	63	91.90	84.90	81.90	88.00	38.70	33.90	36.70	40.20	35.60	37.90
17	1	24.90	29	82.60	90.70	80.40	87.90	37.20	29.30	32.00	36.80	32.60	36.40
18	1	47.90	19	85.10	86.30	81.60	82.70	37.70	32.40	32.90	37.70	32.60	33.50
19	1	20.00	46	86.80	94.30	81.90	89.30	33.00	27.30	29.40	31.50	29.50	33.10
20	1	17.00	47	77.50	86.20	72.20	80.40	41.60	31.20	31.80	40.60	33.70	36.20
21	1	51.11	20	80.40	79.60	80.30	82.60	35.20	28.60	29.50	35.40	27.60	29.30
22	0	21.20	18										

Subject	Gender (M=0, F=1)	Age	# of Aligners	UR4T1	UR4T2	UL4T1	UL4T2	U4_4T1apex	U4_4T1CEJ	U4_4T1tip	U4_4T2apex	U4_4T2CEJ	U4_4T2tip
1	1	41.11	24	82.30	88.30	93.70	96.50	29.00	25.50	27.10	28.40	26.80	29.50
2	1	32.40	20	79.00	80.20	74.20	85.70	33.30	23.60	25.00	33.10	25.10	28.20
3	1	25.80	21	95.10	92.30	94.80	96.60	29.30	29.60	32.80	29.40	28.80	32.30
4	0	18.30	20	86.80	92.40	87.90	88.20	33.80	27.80	31.80	34.80	29.70	35.00
5	1	19.70	38	76.90	80.40	83.70	83.80	33.00	23.10	26.40	34.70	24.80	28.90
6	1	34.30	30	79.60	83.50	83.00	86.10	34.90	27.30	29.10	35.10	28.30	31.60
7	0	30.11	45	86.30	93.60	86.30	96.00	29.80	24.30	27.60	29.30	27.20	32.20
8	0	19.40	30	84.70	93.80	86.90	90.60	35.00	30.10	32.00	33.50	30.20	34.60
9	1	17.70	23	71.90	77.20	72.00	71.30	39.40	26.60	26.10	40.00	28.50	29.00
10	1	24.40	18	82.90	89.50	77.90	93.40	32.40	25.70	26.60	31.80	28.90	32.20
11	0	54.50	10	85.50	91.50	81.80	88.00	34.80	27.40	29.80	35.10	30.30	35.10
12	1	50.10	60	90.70	91.70	92.80	95.00	23.60	21.10	24.10	27.00	25.20	28.70
13	1	17.30	26	85.70	89.30	90.00	85.20	30.30	25.50	29.20	30.50	27.40	29.30
14	0	20.50	78	85.20	88.60	96.90	96.80	27.80	25.00	28.20	31.80	28.60	33.10
15	0	37.10	27	79.50	84.90	84.50	77.00	35.10	28.90	29.60	39.80	31.80	33.70
16	0	27.10	63	71.60	79.00	83.50	87.60	39.10	27.80	29.30	37.90	30.10	32.90
17	1	24.90	29	90.00	96.70	94.00	97.00	26.70	24.00	27.80	25.70	25.30	30.10
18	1	47.90	19	101.70	101.40	90.50	93.70	25.50	26.60	29.20	24.90	25.70	29.50
19	1	20.00	46	98.50	100.40	90.70	92.60	24.90	24.30	27.30	27.40	27.20	31.30
20	1	17.00	47	86.60	88.20	85.40	84.10	32.00	27.80	29.50	32.90	28.60	30.70
21	1	51.11	20	81.10	82.80	82.30	85.30	29.30	22.10	24.20	28.20	21.10	24.10
22	0	21.20	18	94.10	91.00	90.00	89.00	38.50	34.60	39.20	39.30	33.50	38.60