Root Parallelism in Invisalign® Treatment

Ву

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Abstract

AIM: To assess root parallelism after Invisalign[®] treatment.

MATERIALS AND METHODS: The sample consisted of 101 patients (mean age: 22.7 years, 29 males, 72 females) treated non-extraction with Invisalign[®] by one orthodontist. Root angulations were assessed using the 4-point angulation tool (Dolphin imaging[®]); the long axes of adjacent teeth were traced, yielding a convergence/divergence angle. Acceptable root parallelism was assessed if the root angulation did not converge/diverge more than 7 degrees. Sites evaluated: between 1st molars and 2nd premolars, 2nd and 1st premolars, lateral and central incisors, and between central incisors in all four quadrants. The average change in mesio-distal root angulation was assessed between pre- and post-treatment panoramic radiographs.

RESULTS: Paired t-tests were used to analyze the average change in mesiodistal root angulation. Statistically significant differences were obtained indicating a reduction in the convergence/divergence angles between teeth #16-15, #15-14, #11-21, #24-25, #25-26, #45-44, #42-41, #41-31, #31-32, and #34-35 (at p-value <0.05). The average change in root angulation was not affected (p>0.05) by age (Pearson correlation coefficient), gender, occlusion type (I, II, or III), or elastic use (unpaired, 2 sample t-test at p<0.05). Intra and inter-rater reliability for 20% of the studied sample was assessed using the interclass correlation coefficient

test. All measured areas except teeth #16-15, #26-25, and #36-35 yielded good ICC reliability scores above 0.7.

CONCLUSION: Root parallelism was improved post-Invisalign[®] treatment in ten of the fourteen areas evaluated. Thus, Invisalign[®] may be an effective treatment modality in controlling root angulation in non-extraction cases.

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Chapter 1

Introduction

1.1 PREAMBLE

Achieving root parallelism in orthodontic treatment has been long established by The American Board of Orthodontics (ABO) as one of the many criteria used to assess clinical excellence (Chiqueto et al., 2011; Melkos, 2005; Miethke & Vogt, 2005; Simon, Keilig, Schwarze, Jung, & Bourauel, 2014; The American Board of Orthodontics, June 2012). Specifically, root parallelism promotes better long-term stability and facilitates upright teeth for an ideal orthodontic finish (Andrews, 1976; Mckee et al., 2002). In a classic study measuring 120 dental models with normal occlusion, Andrews showed the importance in achieving proper mesio-distal root inclinations in order to produce normal occlusion, proper distribution of occlusal forces, and tight interproximal contacts (Andrews, 1976). Conversely, orthodontically treated teeth with converging or diverging roots and the absence of root parallelism may have less long-term stability and be at greater risk for root resorption (Chiqueto et al., 2011). To this end, severe root resorption may require a patient to undergo future dental treatment, including endodontic therapy or even extraction of a tooth (Simon et al., 2014). Moreover, achieving parallel roots during orthodontic treatment becomes even more critical after premolar extractions as these extraction spaces are more likely to re-open if root parallelism is not established between the adjacent teeth (Chiqueto et al., 2011; Graber, 1966). It has therefore been recommended that the best way to maintain parallel roots is to ensure that the teeth are both upright and parallel towards the end of orthodontic treatment, and have an equal degree of alveolar bone approximating them (Hatasaka, 1976).

Secondly, accurate and readily available means to measure root parallelism have been analyzed in the literature and continuously updated with the advent of the latest radiographic technologies. Historically, orthodontists have relied on panoramic radiographs as a useful diagnostic tool to measure root parallelism in both pre- and post-treatment (Atchison, Luke, & White, 1991; The American Board of Orthodontics, June 2012). Panoramic radiographs are routinely taken both before and after orthodontic treatment, and thus, contribute to the orthodontic diagnostics (Garcia-Figueroa, Raboud, Lam, Heo, & Major, 2008a). Moreover, panoramic radiographs are used by the American Board of Orthodontics (ABO) as grading criteria in order to adequately assess root parallelism (The American Board of Orthodontics, June 2012). Although periapical radiographs and cone beam computed tomography (CBCT) images could also provide excellent image detail, they are not always taken as pre- and post-orthodontic records due to additional radiation exposure and availability of the latest CBCT machines in mainstream orthodontic practices (Chiqueto et al., 2011; Peck, Sameshima, Miller, Worth, & Hatcher, 2007). Panoramic radiographs are therefore used more frequently by practicing orthodontists when evaluating the mesio-distal root angulations of teeth before, during, and after orthodontic treatment due to lower radiation doses and machine costs (Lucchesi,

Wood, & Nortje, 1988; Mckee et al., 2002; Ursi, Almeida, Tavano, & Henriques, 1990).

Finally, before clinicians can accurately assess root parallelism in extraction space closure, the literature must first support root parallelism in Invisalign® treatment with respect to non-extraction orthodontic treatment. Clinicians would then be able to improve the dental health of their patients by providing them with comprehensive evidence-based dentistry while promoting Invisalign® as an esthetic treatment alternative to conventional braces in achieving ideal occlusion with parallel roots.

Invisalign® treatment has been shown to be an orthodontic treatment modality as it lends itself well to controlled and predictable treatment outcomes, it is associated with facilitation of good oral hygiene, and it is a more esthetic alternative to conventional braces (Mckee et al., 2002; Melkos, 2005; Miethke & Vogt, 2005). Although Invisalign® was initially focused on treating mild malocclusions when first introduced in 1997, it has since evolved with the development of more sophisticated 3D treatment planning software and better aligner materials (Tuncay, 2006). With these recent technological advancements, clinicians have utilized and applied Invisalign® treatment to more complex orthodontic tooth movements, including the closing of extraction spaces (Boyd, 2008; Womack, 2006).

However, there is little evidence in the current literature regarding the efficacy of space closure with Invisalign[®] while maintaining parallel roots and upright teeth. This is especially important given the challenge of minimizing

crown tipping and maintaining parallel roots during closure of extraction spaces. Moreover, most of the current literature regarding the efficacy of Invisalign® revolves around case reports and not randomized controlled clinical trials (RCT). In this respect, there are few RCT's that support Invisalign's® effectiveness with respect to extraction space closure, root parallelism, intrusion, and arch width. In comparison to conventional braces, Invisalign® has not had as much time in clinical use and thus its product refinement is not yet complete. Additional research, including randomized controlled clinical trials, are needed to assess Invisalign's® effectiveness and compare it to traditional fixed orthodontics.

1.2 PURPOSE

The purpose of this study was to measure and assess root parallelism in orthodontic patients after completing Invisalign[®] treatment.

1.3 OBJECTIVES

- 1) Measure root angulation and assess parallelism between Maxillary and Mandibular 1st molars, 2nd premolars, 1st premolars, and incisors in pre and post-treatment panoramic radiographs of orthodontic patients who were treated with Invisalign[®].
- 2) Compare root parallelism of patients treated with Invisalign[®] before and after panoramic radiographs.

Question: Can satisfactory root parallelism be achieved in orthodontic patients treated with Invisalign®?

Chapter 2

Literature Review

2.1 ROOT PARALLELISM

Establishing parallel roots during orthodontic treatment has been supported in the literature as one of the main criteria in defining treatment success (The American Board of Orthodontics, June 2012). Correct axial inclinations with respect to a tooth's mesio-distal inclination help define whether a tooth's crown and roots are parallel to the adjacent teeth (Mayoral, 1982; Mckee et al., 2002). Striving for parallel roots is necessary in order to align the teeth within their apical bases and attain ideal occlusion (Mayoral, 1982). As supported by Andrews in his classic study where tooth inclinations were analyzed from 120 dental casts with normal occlusion, parallelism was a critical element in defining the best tooth position (Andrews, 1976). However, Andrews analyzed tooth parallelism based on the clinical crowns of dental models and not on root positions.

As studied by Tanne, Sakuda, and Burstone, translatory tooth movement was preferred over tipping as the stresses on the periodontal ligament (PDL) from the applied forces were significantly less when the tooth was moved by translation. Moreover, forces were more constant in teeth that were moved through translation whereas teeth that were tipped experienced higher and more inconsistent force loads. The authors concluded that translatory tooth movement

was deemed "more physiologic" than tipping as the stresses were more evenly distributed within the associated periodontium (Tanne, Sakuda, & Burstone, 1987). Ultimately, Tanne et al. showed that translatory tooth movement gave greater control in achieving the final outcome of upright teeth.

2.1.1 Root parallelism in extraction treatment

With respect to occlusal load, it has been shown that the distribution of masticatory forces on non-parallelled roots can have a negative impact on the associating structures (Jarabak, I. R., and Fizzell, J. A., 1972; Mayoral, 1982). Jarabak et al. showed how the occlusal load over the associated structures of an extraction site could produce rotational forces causing posterior teeth to rotate and tilt in a mesial direction, and cuspids to tilt and rotate in a distal direction (Jarabak, I. R., and Fizzell, J. A., 1972).

Root parallelism has also been associated with better long-term stability, appropriate distribution of occlusal forces, and tight interproximal contacts (Hatasaka, 1976; Jarabak, I. R., and Fizzell, J. A., 1972; Mayoral, 1982). In a study measuring 28 orthodontically treated cases involving 110 extraction sites treated with conventional edgewise brackets, Hatasaka analyzed the root angulations approximating these extraction sites over a 13 year follow-up period (Hatasaka, 1976). From the multiple root angulation configurations studied, it was concluded that upright and parallel crowns and roots, with equal amounts of approximating bone resulted in the greatest long-term stability. As well, in this ideal post-treatment root configuration, minimal extraction spaces that remained tended to close over time (Hatasaka, 1976). With respect to non-parallel root

configurations, the author concluded: 1) Overparalleled roots with touching apices did not relapse to an ideal upright position; 2) Overparalleled roots with no apical root contact resulted in spaces between the crowns; and 3) Teeth with underparalleled roots either remained the same or diverged even further from an upright ideal position over time (Hatasaka, 1976).

Non-parallel roots with increased crown tipping can also lead to periodontal injuries (Hatasaka, 1976; Jarabak, I. R., and Fizzell, J. A., 1972). For instance, oral hygiene can be difficult in cases where crowns are tipped and the roots diverge (Jarabak, I. R., and Fizzell, J. A., 1972; Mayoral, 1982). Similarly, in non-parallel root configurations with extreme root convergence or root proximity, both oral hygiene and periodontal scaling and root planning becomes difficult to carry out (Hatasaka, 1976). In turn, inflammatory processes can occur between the teeth leading to a breakdown of the small interdental bone and ultimately result in periodontal pockets. To this end, root proximity can increase the risk of developing periodontitis (Chiqueto et al., 2011; Kim, Miyamoto, Nunn, Garcia, & Dietrich, 2008; Smukler, Nager, & Tolmie, 1989). Furthermore, when the roots of approximating teeth are severely divergent, their interproximal contacts can be altered. These uneven contact points can result in unaesthetic dark triangular spaces and increase food retention (Chiqueto et al., 2011; Cho et al., 2006; Kurth & Kokich, 2001).

In addition to being a negative consequence of orthodontic forces, root resorption has been observed in orthodontic treatment where root parallelism was not obtained (Mayoral, 1982). Typically, root resorption has been seen in

cases with excessive orthodontic forces, prolonged duration of forces, and increased wire stiffness (Kanjanaouthai, Mahatumarat, Techalertpaisarn, & Versluis, 2012; Mayoral, 1982; Proffit, Fields, & Sarver, 2013). Although the risk of root resorption for all orthodontically treated teeth is typically less than 1% overall and approximately 3% for maxillary incisors, the detrimental effects that root resorption may cause can lead to extensive endodontic treatment, and ultimately the loss of a tooth (Kaley & Phillips, 1991; Proffit et al., 2013). With respect to root parallelism, an original study measuring root resorption in premolar extraction cases where conventional edgewise brackets and light wires were used, only 1.8% of measured teeth showed signs of root resorption when roots were upright and parallel (Mayoral, 1982). The author explained that this low occurrence of root resorption in paralleled roots was a result of the mesial and distal movements of the apical bases of the canines and premolars respectively during space closure with little deviation in the lingual or buccal directions. Therefore, traditional fixed orthodontic treatment has some inherent consequences. However, appropriate case selection is key when trying to minimize such side effects. Similarly, appropriate case selection should be maintained when using Invisalign® so as to respect its documented treatment limitations and side effects.

Some studies have shown that when approximating teeth are unparalleled and moved primarily through tipping, stress analyzed from the PDL showed increased pressure around the cervical area of the tooth (Kanjanaouthai et al., 2012; Shaw, Sameshima, & Vu, 2004). However, several studies observed that

when teeth adjacent to extraction sites are approximated primarily through bodily movement, stresses are mainly observed at the mid-root level and not at the apical base where root resorption often occurs (Cobo, Arguelles, Puente, & Vijande, 1996; Kanjanaouthai et al., 2012; Tanne et al., 1987). More importantly, Tanne, Sakuda, and Burstone showed that the final upright position of teeth could be achieved using translatory movements. To this end, maintaining upright teeth through bodily movement is preferred over tipping in order to achieve root parallelism, minimize stresses at the root apices, and thus, minimize chances for root resorption.

2.2 RADIOGRAPHIC ASSESSMENT OF ROOT PARALLELISM

For quite some time, orthodontists have been using panoramic radiographs as a diagnostic tool to evaluate root parallelism during orthodontic treatment. For instance, in addition to taking pre-orthodontic panoramic radiographs, surveys have shown that 57.9% of orthodontists took progress panoramic radiographs and 79.1% of orthodontists took post-treatment panoramic radiographs in order to assess the maxillary and mandibular dentition (Garcia-Figueroa, Raboud, Lam, Heo, & Major, 2008b; Keim, Gottlieb, Nelson, & Vogels, 2002). In addition, the ABO currently utilizes panoramic radiographs in their grading scheme in order to ascertain the overall quality of the completed orthodontic treatment (The American Board of Orthodontics, June 2012). Specifically, the ABO states that despite the fact that panoramic radiographs are not ideal, they still offer a "reasonably good" evaluation of tooth and root positions. In assessing mesio-distal root angulations, the ABO grading scheme

states that the maxillary and mandibular dentition be parallel to one another and be perpendicular as compared to the occlusal plane (The American Board of Orthodontics, June 2012). If the roots are tipped mesially or distally, the teeth cannot be considered as being parallel. As well, the severity of mesial or distal root angulation will serve as a general guide for the degree of root parallelism being observed. The ABO also recognizes the varying distortion observed around the canines when projected onto a panoramic radiograph (Mckee et al., 2002; The American Board of Orthodontics, June 2012). To this end, the ABO does not include the mesio-distal angulation of the canines and their adjacent roots when grading root parallelism in completed orthodontic cases.

With regard to the clinical usefulness of panoramic radiographs in orthodontics, they continue to be used in diagnostic records as much information can be obtained from them. For instance, Rushton et al. showed that when panoramic radiographs were appropriate, they were useful in locating pathologic lesions, unerupted teeth, carious lesions with obvious clinical presentations, and swellings among other findings (Rushton, Horner, & Worthington, 2002). Panoramic radiographs are also particularly useful to orthodontists in identifying teeth with possible root resorption, missing teeth, as well as areas with periodontitis and bone loss (Proffit et al., 2013). Panoramic radiographs may also potentially limit the amount of supplementary intra-oral radiographs required per patient. Providing a previous detailed clinical examination was performed, panoramic radiographs can help locate potential problem areas that may warrant further radiographic examination (Molander, Ahlqwist, & Grondahl, 1995). To this

end, only those intra-oral radiographs that are deemed necessary may be taken, which in turn can reduce the overall number of radiographs and radiation exposure for each patient.

With regard to evaluating root parallelism on panoramic radiographs, it has been shown that while the assessment of linear and angular measurements is not ideal, panoramic radiographs are diagnostically useful. Panoramic radiographs can have image distortion and magnification errors. However, much of these errors are known to be the result of poor head positioning while taking the radiograph (Choi et al., 2012; Nikneshan, Sharafi, & Emadi, 2013). Nikneshan et al. showed that angular measurements on panoramic radiographs were accurate and had no significant changes with respect to variations in the occlusal plane of ten degrees or less when compared to the Frankfurt Horizontal plane (Nikneshan et al., 2013). Specifically, the study showed there were less angulation errors as measured on panoramic radiographs providing the occlusal plane was tilted between zero and eight degrees. Conversely, if the occlusal plane was tilted more than ten degrees, a significantly increased number of angulation errors were recorded (Nikneshan et al., 2013).

Although panoramic radiographs have been shown to produce image distortion and in some studies, unreliable measurements, consistent image capturing and reproducibility within the same patient have been shown to negate some of these image errors (Chiqueto et al., 2011; Mckee et al., 2002). With respect to the panoramic radiograph's inadequacies, its lack of fine detail and dependence on proper patient positioning within the machine's focal trough can

lead to horizontal and vertical image distortions, and subsequently, angular measurement errors (Chiqueto et al., 2011; McDavid, Tronje, Welander, & Morris, 1986; Mckee et al., 2002).

In some cases, overestimations and underestimations of actual root angulations are possible. For instance, McKee et al. postulated that in the maxilla, root angulations could be underestimated in the lateral and central incisors, whereas root angulations can be overestimated in the molar and premolar areas (Mckee et al., 2002). For the mandible, root angulations in general can be underestimated. Moreover, discrepancies between true root angulations and projected root angulations on panoramic radiographs were often larger on the mandibular dentition (Mckee et al., 2002). However, it is important to note that if the same patient has repeated panoramic radiographs taken over time using the same machine and operator techniques, the expected image distortions should be similar (Chiqueto et al., 2011; Mckee et al., 2002). Therefore, changes in root angulation should not be affected by image distortions as the same patients were subjected to similar radiographic parameters by the same experienced technicians over time. Similarly, image interpretation errors would be smaller if the same experienced clinician was evaluating the radiographs longitudinally for all patients.

Furthermore, studies have shown that if the patient was properly positioned within the focal trough, absent major inclinations in buccolingual dimensions, mesio-distal root angulations could be assessed on panoramic

radiographs with a tolerable five degrees of error in patient head position (McDavid et al., 1986; Mckee et al., 2002)

In an original study demonstrating the usefulness of panoramic radiographs in evaluating root parallelism, Mayoral assessed root angulations and incidence of root resorption in 53 first premolar extraction cases (Mayoral, 1982). Tracing of the long axes of the second premolars and canines were completed and the converging or diverging root angle was assessed. Due to apical root dilacerations in the second order, the cervical two thirds of the root was used for long axis tracing. Positive angles were those with occlusal root convergence, whereas negative angles were those with apical root convergence (Mayoral, 1982). Four groupings of root parallelism were established based on the traced root angulations: 1) Good root parallelism (Maxilla: -5 to +5 degrees, Mandible: 0 to +12 degrees), 2) Acceptable root parallelism (Maxilla: +6 to +10 degrees, Mandible: +13 to +18 degrees), 3) Poor root parallelism (Maxilla: 11 degrees and over, Mandible: +19 degrees and above), and 4) Overtreatment (Maxilla: less than -6 degrees, Mandible: below 0 degrees). The mandible was given a greater acceptable range of root parallelism than the maxilla as more root parallelism was observed in the maxilla.

In a more recent study investigating the relationship between root parallelism and relapse of extraction site closure, panoramic radiographs were used to measure root angulations (Chiqueto et al., 2011). In this premolar extraction study, the long axes of the teeth were traced with a disregard for apical root dilacerations. As in earlier studies, the angulation of roots with occlusal

convergence was deemed positive, whereas the angulation of roots with apical convergence was negative (Chiqueto et al., 2011; Ursi et al., 1990). The authors' assessment of root parallelism between canines and second premolars using panoramic radiographs could be categorized as: 1) "Satisfactory" (root angulation of -6 to +6 degrees), 2) "Convergence" (apical root convergence below -7 degrees, or 3) "Divergence" (apical root divergence greater than +7 degrees) (Chiqueto et al., 2011; Ursi et al., 1990). Group 2 was considered as overtreatment, whereas group 3 was considered as undertreatment. Although panoramic radiographs were very useful in assessing root parallelism in this study, it is also important to note that canine measurements were involved, thus increasing the potential for additional measurement errors (The American Board of Orthodontics, June 2012).

As an alternative to panoramic radiographs, CBCT images can also be used to evaluate root parallelism. Unlike panoramic radiographs where a 3D object is projected onto a two dimensional image, CBCT images take full volumetric 3D scans of the desired field of view and allow the clinician to evaluate the true anatomical area in question using 3D software (Peck et al., 2007). Accuracy and detail of CBCT images are higher than that of traditional panoramic radiographs (Mckee et al., 2002; Peck et al., 2007). Moreover, CBCT also provides clinicians with the ability to evaluate root angulations using a modified traditional format by rendering two-dimensional pan-like images from the 3D CBCT software (Mckee et al., 2002; Van Elslande, Heo, Flores-Mir, Carey, & Major, 2010). Although these CBCT pan-like images tend to be more

accurate than conventional panoramic radiographs, radiation dose is often higher and can be equivalent to a full mouth series of intraoral radiographs (Van Elslande et al., 2010). Furthermore, some of the newest CBCT machines are advertised as having lower radiation doses than some conventional panoramic radiograph units. However, costs of the machines are high, and thus, full adoption of CBCT in mainstream orthodontic offices are not yet standard practice (Mckee et al., 2002; Van Elslande et al., 2010).

Similar to conventional panoramic radiographs, interpretation of CBCT rendered pan-like images is important, as some mesio-distal root angulations may appear different than their true positions. For instance, McKee et al showed that aside from teeth 26 and 16, maxillary roots as projected on CBCT rendered pan-like images had a greater distal projection as compared to control study models (Mckee et al., 2002). On the mandibular arch, all teeth except for 36, 47, and 44 showed a greater propensity for mesial root angulation projections. According to the same authors, the opposite holds true for root angulation projections on conventional panoramic radiographs. Teeth 41 and 13 to 23 showed greater mesial inclinations, whereas teeth 24, 14, 26, 16, and the remaining mandibular dentition showed greater distal root angulations than the true angles (Mckee et al., 2002). Moreover, consistent provider techniques and head position plays just as important of a role in CBCT images as they do for panoramic radiographs. For instance, Van Elslandie et al described how variations in horizontal head position to the left or right sides by as little as five degrees could cause a change in root angulation from 4 to 22.3 degrees (Van Elslande et al., 2010). If the head position was changed by as little as five degrees down or up in the vertical dimension, the root angulation measurements varied from 7.6 to 14.9 degrees. To this end, despite the higher accuracy of CBCT images as compared to panoramic radiographs, interpretation of mesiodistal root angulation, and subsequent root parallelism, must be approached by experienced clinicians who are familiar with possible root projection errors on these images. Ultimately, clinicians must compare the increased cost and higher radiation potential of CBCT imaging with its added benefits of image accuracy and detail. As well, clinicians must decide whether or not to take routine CBCT radiographs and their corresponding timing with orthodontic treatment, or take CBCT images only as necessary.

2.3 INVISALIGN® TREATMENT

The Invisalign® System was created in 1997 as an orthodontic appliance to provide patients with a more esthetic alternative to conventional braces. The Invisalign® System builds upon the previous use of tooth positioning appliances (overlay appliances) in orthodontics that were designed to produce minor tooth movements through custom fitted tooth positioners. Historically, Vulcanite positioners were introduced by Kesling who demonstrated the various reconfigurations of teeth on stone models and the fabrication of tooth positioning appliances to achieve specified dental setups (Kesling, 1945; Tuncay, 2006). Secondly, Harry Barrer employed a similar method of aligning teeth using a spring-loaded retainer with acrylic surrounding the anterior teeth. A minimal Kesling setup would be done on the models for the desired tooth alignment, a

spring loaded retainer with acrylic would then be formed on these models, and tightened accordingly on the patient to achieve the prescribed movements (Barrer, 1975). Similarly, Sheridan brought forth tooth positioner techniques using Raintree Essix clear aligners that were custom fabricated using stone models with prescribed tooth configurations (Sheridan, LeDoux, & McMinn, 1993; Tuncay, 2006). Invisalign® built upon these overlay appliance philosophies and combined them with CAD/CAM technologies in order to use three dimensional computer imaging to design custom thermoplastic appliances with the goal of treating to a pre-approved 3D dental setup. Multiple Invisalign® aligners are typically fabricated, whereby each aligner is designed for specific tooth movements in a chronological sequence of movements with regards to rotations, tip, torque, space closure, extrusion, intrusion, and many other factors (Tuncay, 2006).

The Invisalign® process begins with taking a full set of diagnostic records at the orthodontist's office, including: panoramic radiographs, extra-oral and intra-oral photos, bite registration, and maxillary and mandibular impressions. Impressions can be taken either through traditional polyvinyl siloxane impressions (PVS), or through the use of digital intra-oral scanners (Tuncay, 2006). Digital scanners are typically more convenient for the patient as they can reduce the number of impression errors normally encountered in PVS impressions (Nedelcu & Persson, 2014). Furthermore, digital scanners help expedite the tray fabrication process and turnaround time back to the provider's office since the patient's digital records can be scanned and uploaded to

Invisalign® immediately with no need for model pour-up. Moreover, digital intraoral scanning lends itself well to Invisalign®'s esthetic nature as no messy alginate or PVS materials need to be used throughout the patient's orthodontic experience.

Once the patient's records and impressions are received by Invisalign®, specially trained technicians setup the patient's 3D treatment as prescribed by the orthodontist. Invisalign® uses their patented Clincheck software, which illustrates the patient's virtual treatment setup and progression per tray sequence, and serves as a tool for the orthodontist to convey any required adjustments before case approval and tray fabrication (Tuncay, 2006). The most current version of this software, ClinCheck Pro, allows the provider to make their own adjustments to individual teeth directly on the virtual setup without the constant need of lengthy instructions to the Align technician. Moreover, the latest software has multiple user interfaces to address almost every aspect of specified tooth movements and treatment timing by manipulating the 3D dental models (Align Technology, 2015).

Correct staging is a key component to successful Invisalign® treatment. Staging, as defined by Invisalign®, is the series of steps and processes by which the end-result is achieved by using the Clincheck software and by respecting sound biologic and clinical principles (Tuncay, 2006). After the orthodontist's prescription is reviewed with the impressions and diagnostic records, the technician uses the Invisalign® software to move the dentition from the initial stage (stage 0), to the final tooth position (stage 1). The technician then stages

all the intermediate steps for the necessary tooth movements to occur based on the orthodontist's preferences (Tuncay, 2006). For instance, Invisalign® has set their tooth movement speed at 0.25mm per stage/aligner, where each aligner is typically worn for 14 days (Tuncay, 2006). If the desired tooth movement occurred too quickly on the virtual software, the technician can slow down the movement by dispersing the required tooth movements through additional aligners. Currently, there are tooth accelerating products on the market, like AcceleDent, which produces vibrational frequencies of 30Hz and forces of 0.2 N on the maxillary and mandibular dentition, in the hopes of speeding up tooth movement by wearing the appliance a minimum of 20 minutes per day (Woodhouse et al., 2015). Although orthodontists are trying to use these tooth accelerating products to speed up the staging process and reduce the number of days each aligner is needed to be worn, current evidence is lacking.

Other elements of the staging process include the timing of each tooth movement incorporated into the aligners (i.e.: rotations, translation, tipping, extrusion and intrusion), anchorage, overcorrection, space closure, interproximal reduction, and the application of attachments (Tuncay, 2006). For instance, orthodontists may have preferences to place all attachments at the patient's first Invisalign® appointment for convenience while others may request that the bonding of attachments be staged at the second or third visit so as not to overload the patient at the beginning of their treatment (Boyd, 2008; Gomez, Pena, Martinez, Giraldo, & Cardona, 2014; Tuncay, 2006). Similarly, when interproximal reduction (IPR) is required to correct tooth size discrepancies,

orthodontists may request for IPR to be staged only after all the initial alignment is complete so that the interproximal stripping will be more likely to reduce the interproximal surfaces of the teeth and not the facial or lingual surfaces (Boyd, 2008). However, overall clinical efficacy of such movements using Invisalign[®] is based primarily on case reports. More RCT's with larger sample sizes are needed to properly assess Invisalign[®] treatment outcomes.

In addition, overcorrection of specific movements can be staged at the end of treatment after the final tooth position is achieved on the virtual setup (Tuncay, 2006). This overcorrection stage provides clinicians with the ability to request additional correction of specified tooth movements that are not expected to fully express throughout treatment. For example, some difficult movements for the Invisalign® System include incisor and canine rotations, and extrusive mechanics with deep bite correction (Kravitz, Kusnoto, Agran, & Viana, 2008; Kravitz, Kusnoto, BeGole, Obrez, & Agran, 2009; Tuncay, 2006). To this end, clinicians can request additional aligners or components to express additional rotations or extrusion on specific teeth.

The materials used in the Invisalign[®] system also have a tremendous impact on the clinical efficacy of tooth movement and the eventual outcome of orthodontic treatment. Two of the most important materials in consideration are the clear aligner properties, as well as attachments that are bonded to the dentition. The thermoplastic polymer materials incorporated into Invisalign[®]'s aligners are fabricated to provide clarity, durability, ease of use, and to be appropriately rigid to apply the correct orthodontic forces, yet flexible enough to

facilitate easy patient insertion and removal (Tuncay, 2006). When the aligner is placed onto the dentition, a specified force is applied to locations with prescribed tooth movement. This force is a result of the aligner's material being displaced (Tuncay, 2006). Initially, Invisalign[®] used a 0.030-mil (Ex30) thickness in their aligner production to facilitate all treatment goals. Due to the relatively small thickness of this material and polymer makeup, it was effective in early stage tooth movement, but lacked the rigidity in some final stage detailing.

A thicker material, like the Ex40 (0.040-mil), added stiffness to the aligner and was tested for its detailing performance. However, clinical results showed it did not reduce the number of case refinements needed towards the end of Invisalign® treatment (Tuncay, 2006). Moreover, due to the thickness and specific properties of the Ex40 thermoplastic polymer, Invisalign® incorporated it as part of their clear retainers (Vivera) to be used post-treatment (Align Technology, 2015). Conversely, a thinner and more flexible Ex15 material is currently used to fabricate attachment templates as they need to provide additional flexibility for attachment filling and tray removal post-bonding, yet they do not require the added thickness and stiffness for detailed tooth movements (Align Technology, 2015; Tuncay, 2006).

As described by Invisalign[®] in 2013 as part of their G4 summit, current aligners are fabricated using their SmartTrack material. Invisalign[®] claims this material provides greater patient comfort and a more constant force delivered to the dentition over an aligner's two week wear time (Align Technology, 2015). In addition, a study conducted by Invisalign[®] with 1015 patients and >99.9%

confidence interval showed the SmartTrack material displayed more constant forces, higher elasticity, a more precise fit of aligners, and increased patient comfort levels (Align Technology, 2015). Specifically, the SmartTrack material facilitated more controlled tooth movements with respect to extrusion and rotations at p<0.001. As well, patient progress was shown to be significantly closer to the staged sequence of tooth movements after five months into treatment (Align Technology, 2015). However, independent research regarding the biomechanical properties and overall effectiveness of the SmartTrack material is needed.

As an integral part of Invisalign®'s success, bonded attachments help facilitate aligner retention and difficult tooth movements (Tuncay, 2006). Attachments serve as undercuts to promote the aligner's adaptation to the dentition and prevent unwanted displacement. They are typically comprised of curable filled resins (bis-GMA) to provide long periods of use with minimal wear, and come in multiple configurations depending on the company and product used (Boyd, 2008; Simon et al., 2014; Tuncay, 2006). Attachments come in a variety of pre-calculated shapes and sizes as per Invisalign®, and are placed on the virtual ClinCheck setup according to the orthodontist's prescription. Once approved, the attachment well is built into the attachment template and is then filled with the orthodontist's composite of choice until the attachment's shape is formed (Tuncay, 2006).

The shape of the attachment used, as well as its exact location will differ depending on the tooth being moved and the type of movement in question. For

example, difficult extrusive mechanics on premolars may warrant longer rectangular attachments with a beveled gingival border to increase the range of retentiveness of the aligner on that tooth (Simon et al., 2014). Moreover, recent advances in attachment shape and tray design help reduce tracking errors through the use of power ridges, optimized deep bite attachments, and deep bite ramp protocols (Align Technology, 2015; Simon et al., 2014). Power Ridges consist of pressure lines at the gingival margins of the aligners, which have been shown to help facilitate torque and bodily tooth movement (Simon et al., 2014). One study by Castroflorio et al., which tested the clinical efficacy of such PowerRidge attachments, concluded they were effective in torque correction of approximately ten degrees (Castroflorio, Garino, Lazzaro, & Debernardi, 2013). However, these attachments are only effective in the buccolingual directions. In addition, the Invisalign® G5 protocol in 2014 introduced a deep bite setup consisting of bite ramps built into the outline of the aligners, as well as optimized ellipsoid attachments for premolars to optimize extrusion. Despite Invisalign®'s claims of improved extrusive mechanics, evidence thoroughly testing these particular advancements is minimal (Align Technology, 2015).

Other advances in Invisalign[®] materials included the introduction of their optimized root control attachments. Initially, these attachments were available to upper central incisors and canines to facilitate better root control and rotations respectively (Align Technology, 2015). These attachments consisted of two small semi-circular attachments placed by the technician using the 3D software. At the G4 summit, Invisalign[®] extended their optimized root control attachments to

include lateral incisors and all premolars. When considering anterior-posterior changes, space opening, or space closing mechanics, these optimized attachments are designed to facilitate mesio-distal root uprighting, as well as bodily movement in the mesial or distal direction (Align Technology, 2015). Although studies have shown there to be an increased risk for root/crown tipping when no attachments are used during Invisalign® treatment, no current independent studies have shown any statistically significant advantages of these optimized attachments over regular aligner attachments in controlling root angulation (Gomez et al., 2014). Moreover, the ClinCheck software has not been shown to predict root positions. Rather, only the clinical crown position is reflected in the virtual tooth setup. To this end, controlling root parallelism remains a difficult aspect of Invisalign® treatment. In addition, achieving parallel roots using Invisalign® without additional auxiliaries (i.e.: buttons, brackets, wires etc...) has been presented as a challenge, especially given the propensity for roots to tip in extraction cases (Honn & Goz, 2006; Proffit et al., 2013; Tuncay, 2006).

When considering the use of the Invisalign® System in extraction treatment, the treating orthodontist must have a comprehensive understanding of the biomechanical force applications applied by the aligners, as well as its limitations. For instance, when large spaces are to be closed, controlled tooth movement facilitating upright roots is difficult with Invisalign® as most of the contact between the tooth and aligner occurs more coronally and is limited in the direction of the force being applied (Tuncay, 2006). Thus, without the use of

auxiliary attachments, it is difficult to generate the required moment to counter the tipping movement that is commonly seen. In a premolar extraction study by Honn, the author demonstrated how Invisalign® could be used effectively in extraction space closure providing appropriate case selection was adhered to (Honn & Goz, 2006). The author explains that extraction treatment is more likely to be successful in cases where less bodily tooth movement is required in closing the extraction space. As such, complete extraction space closure remains a difficult task for Invisalign® treatment, especially during the initial aligners (Bollen, Huang, King, Hujoel, & Ma, 2003; Phan & Ling, 2007). Moreover, several studies emphasize the difficulty in preventing root tipping during space closure using the Invisalign® System, both in premolar and lower incisor extraction cases (Bollen et al., 2003). Furthermore, there are several limitations with respect to the current literature as most Invisalign® studies involving extractions consist of case reports with limited sample sizes.

Finally, despite the difficulties in treating more complex orthodontic cases with the Invisalign[®] System, its use and popularity have increased among orthodontists due to its advantages. Some of these advantages include; optimal esthetics, better oral hygiene, controlled tooth movement with pre-treatment setups, removability, less pain and discomfort, minimal root resorption and less chair time (Melkos, 2005; Miller et al., 2007; Tuncay, 2006). Esthetically, Invisalign[®] is widely accepted by patients as they are clear, comfortable, and appear less invasive than conventional fixed orthodontics (Melkos, 2005). Moreover, because the aligners are clear, they do not deteriorate smile esthetics

during the course of orthodontic treatment. As well, Invisalign[®]'s removability lends itself well to evaluating smile esthetics for both patients and orthodontists, without the interferences of fixed appliances.

Improved oral hygiene has also been shown to be a key advantage to using the Invisalign® system over conventional braces. Miethke et al. measured the modified plaque index scores of patients who used both Invisalign® and full fixed appliances (Miethke & Vogt, 2005). Their study showed the modified plaque index score to be significantly lower in the Invisalign® group. Moreover, the authors concluded that despite the fact that Invisalign® aligners covered the entire dentition and keratinized gingiva, periodontal health was not adversely affected as the appliance is removable and provided patients with unimpeded access to oral hygiene.

Pain levels were also shown to be significantly lower in patients treated with the Invisalign[®] System as compared to those who were treated with conventional braces. Miller et al. showed how patients treated with Invisalign[®] reported taking significantly lower levels of pain medications (ibuprofen, Tylenol) on days 1, 2, and 3 after the start of treatment as compared to patients treated with fixed appliances (Miller et al., 2007). Furthermore, Fujiyama et al. showed significantly lower levels of reported pain using the visual analogue scale in Invisalign[®] patients at three days post-tray delivery or adjustments within the first five weeks of treatment (Fujiyama, Honjo, Suzuki, Matsuoka, & Deguchi, 2014). The authors further explained that when patients did report pain with their Invisalign[®] treatment, it was often associated with tray deformation. To this

extent, proper patient compliance with appropriate aligner usage and close inspections of tray integrity by the orthodontist is necessary for increased patient comfort. Moreover, patients who used Invisalign[®] reported higher scores in quality of life indices (Miller et al., 2007).

Finally, the clinical efficacy of the Invisalign® System in delivering esthetic results with predictable outcomes has been shown in various studies. Simon et al. showed how molar distalization, incisor torque, and premolar derotations were all effective in Invisalign® treatment using the latest SmartTrack material with PowerRidge attachments (Miller et al., 2007). However, the total amount of complex movements needed may impact the extent to which they can be realized using the aligners. To this extent, a certain amount of overcorrection needs to be planned into the ClinCheck setup as not all complex movements are reflected clinically (Kravitz et al., 2009).

With respect to anterior tooth movement, Krieger et al. demonstrated predictable results using Invisalign[®] in patients with moderate-severe maxillary and mandibular crowding (Krieger et al., 2012). In the fifty patients considered in this study, all measurements regarding arch length, inter-canine distance, dental midlines, overjet, and tooth irregularity index were achieved in accordance with the predicted ClinCheck models when compared to post-treatment dental casts. Only overbite did not significantly reflect the prescribed tooth movements.

In a recent review of the literature, Rossini et al. studied the effectiveness of clear aligner therapy in controlling tooth movement (Rossini, Parrini, Castroflorio, Deregibus, & Debernardi, 2014). In their review, the results of two

randomized controlled, four non-randomized (retrospective), and five non-randomized (prospective) clinical trials were studied. Results showed that clear aligners were effective in leveling and aligning the dental arches, anterior intrusion, posterior buccolingual inclination, and upper molar distalization (up to 1.5mm of prescribed movement). It was not effective in extrusion with only 30% accuracy, rotation of cylindrical shaped teeth (predominantly canines), and anterior buccolingual inclination. With regards to mesio-distal movements, Kravitz et al. showed that of 180 teeth measured, only 21 attempted mesio-distal movements that were greater than 1.0mm, whereas only 8 teeth attempted to move more than 2mm (Kravitz et al., 2009). Maxillary and mandibular lateral incisors showed the greatest accuracy in mesio-distal movements ranging from 43-48% accuracy. Maxillary and mandibular canines showed lower accuracy in mesio-distal movements, whereby the authors suggested that teeth with larger roots might have greater difficulties in mesio-distal movements.

Additional treatment considerations, including age, gender, occlusion type, and elastics use, can also be evaluated when treating patients with Invisalign[®]. Providing that all growth is complete, age should not have any major effects on treatment as maxillary and mandibular growth begins to slow down. Growth is typically complete between 16 and 21 years of age when the spheno-occipital synchondrosis fuses (Proffit et al., 2013). As well, providing patients are under the age of 40, the risk for increased periodontitis and bone deficiencies are low.

There is also little evidence to suggest that gender has any effect on treatment outcomes using Invisalign[®]. What the literature does show is a female

predilection for choosing Invisalign[®] over traditional braces (72-78%) when compared to males (Nedwed & Miethke, 2005). The authors explained that females were more likely to accept Invisalign[®] treatment over males as they were more concerned with their esthetic appearance.

When considering occlusion type, mild malocclusions being treated with non-extraction Invisalign® treatment should have minimal effects on root parallelism. This is primarily due to the fact that non-extraction cases with mild malocclusions have a lower risk for major root movements (Honn & Goz, 2006; Proffit et al., 2013; Tuncay, 2006).

Elastics can also be used during Invisalign® treatment. Typically, elastics can be used in extraction cases to facilitate space closure and increase anchorage support (Dixon, Read, O'Brien, Worthington, & Mandall, 2002). However, in non-extraction Invisalign® treatment, elastics are more likely to be used solely for anchorage support across the aligners and not for individual tooth movements (Boyd, 2008). Therefore, major changes in root positions would not be expected from elastics use. Moreover, there are no current Invisalign® studies that show any significant effects with respect to root parallelism and age, gender, occlusion type, and elastics use.

In regard to the clinical efficacy of Invisalign[®], some serious limitations remain in the current literature. For instance, very few randomized controlled clinical trials exist measuring the effectiveness of Invisalign[®], especially with consideration of the latest materials and ClinCheck software. Moreover, most of the current literature consists of case studies whereby a significant portion of the

results may be biased due to the orthodontist's experience and proficiency with the Invisalign® System (Kravitz et al., 2009). Kravitz et al. suggested that although age, periodontal condition, alveolar bone support, root length, and bone density may play a role in the effectiveness of Invisalign® treatment, appropriate measures to study these factors are difficult as multiple periapical radiographs and/or CBCT scans would be required, which would present the investigators with ethical challenges. Furthermore, given the constant evolution of Invisalign[®]. as well as the orthodontist and patient's strong desire for an effective and esthetic treatment modality, clinicians must gain a greater understanding of the biomechanics with respect to complex and difficult Invisalign® prescriptions. Among the more difficult tooth movements using Invisalign®, bodily movement of teeth approximating extraction spaces while maintaining parallel roots remains a challenge. However, the current literature on achieving root parallelism in Invisalign® treatment is lacking. To this end, the objective of this study is to evaluate root parallelism in Invisalign® treatment of non-extraction cases.

Chapter 3

Materials and Methods

3.1 STUDY DESIGN

Similar to previous studies that measured root parallelism on panoramic radiographs, the root angulations between selected teeth were measured and compared from pre- and post-treatment radiographs for clinical and statistically significant differences (Chiqueto et al., 2011). Specifically, 14 areas of measurements were analyzed. These areas included root angulations between the following teeth for all four quadrants: 1st Molars and 2nd pre-molars, 2nd pre-molars and 1st pre-molars, lateral incisors and central incisors, and between central incisors. The selected areas of measurement were chosen so as to maximize the results of this study by analyzing all of the common locations where root parallelism may be affected by orthodontic treatment. However, as per ABO guidelines, root angulations adjacent to the canines were not included as the degree of canine dimensional distortion in panoramic radiographs yields unreliable mesio-distal axial measurements (The American Board of Orthodontics, June 2012).

3.2 ETHICS

Prior to the start of this retrospective study, ethics approval was obtained on August 8th, 2014 from the Human Research Ethics Board (Bannatyne Campus, University of Manitoba) (See Appendix A). As well, all participants

consented to sharing their records for research purposes as indicated on their informed consent for orthodontic treatment (See Appendix B).

3.3 SAMPLE SELECTION

The retrospective sample consisted of 101 patients from the Greater Toronto Area, Ontario, who were treated in private practice by one certified orthodontic specialist. The mean age was 22.7 years, with 29 males and 72 females. Additional characteristics were recorded, including molar classification and use of elastics. Molar classification was based on standard Angle classification (CI I, II, III) as was used in the orthodontist's office. Specific type of elastics and pattern were not analyzed due to the variation of elastics use among patients. Rather, whether elastics were actually worn or not was specified to see if any further investigation was warranted. See tables 3-1 and 3-2 for participant summary data.

Inclusion criteria:

- 1. Completion of comprehensive orthodontic treatment using Invisalign[®].
- 2. Non-extraction treatment was indicated.
- 3. Patients must have a full complement of dentition.
- Availability of pre- and post-treatment panoramic radiographs of diagnostic quality.
- 5. Acceptable age range of 10-85 years.
- 6. Both males and females are to be included.
- Patients must be in good general and dental health and have no contraindications to orthodontic treatment.

Exclusion criteria:

- 1. Treatment currently in progress.
- 2. Patients with missing teeth or planned extractions.
- 3. Panoramic radiographs of poor diagnostic quality.
- 4. Patients who required any extensive adjunctive fixed orthodontic treatment outside of typical Invisalign[®] treatment protocols.

Parameter	N
Males	29
Females	72
Total	101

Table 3-1. Summary statistics of the participants

Average Age		Molar classific	Elast	tics (N)	
(Years)	ClI	CI I CI II CI III		Yes	No
22.7	69	28	4	44	57

Table 3-2. Frequency distribution of the participants

The diagnostic quality of selected panoramic radiographs was based on acceptable film exposure, image resolution, contrast, sharpness, and acceptable field of view containing all pertinent dental structures. If the panoramic radiographs of selected participants did not adhere to the above criteria, the patient was rejected from the sample.

As well, the decision to specify non-extraction treatment as part of the inclusion criteria was made in order to first study the effects that Invisalign[®] may have on root angulations in cases where difficulties in controlling mesio-distal

root angulations are typically not expected. Moreover, since the current literature regarding root parallelism in Invisalign[®] treatment is lacking, establishing first if Invisalign[®] can adequately control root angulations in non-extraction treatment is necessary before considering potential future studies involving extractions and other more complex tooth movements.

3.4 DATA COLLECTION

3.4.1 Chart Review

After a random chart review of 400 participants completed by the principle investigator, 101 participants were selected who met all study criteria. Patient information, such as age, gender, molar classification, and elastics use was recorded onto a coded data capture sheet with any possible patient identifiers removed for blinding purposes and patient identity protection. A master list of study participants was placed on a secured hard drive and locked in a secure office at the University of Manitoba, Division of Orthodontics. As well, 101 preand 101 post-treatment panoramic radiographs were collected and saved onto a secured hard-drive, coded for appropriate referencing on the data capture sheet with all patient identifiers removed for blinding purposes, and secured in a separate office at the University of Manitoba, Division of Orthodontics.

3.4.2 Panoramic Radiograph Capture

Selected panoramic radiographs were taken on a digital 2009 Sirona Orthophos xg5 Pan/Ceph machine by certified dental hygienists in the same orthodontic office. All hygienists were trained to take panoramic radiographs

using their standard office protocols in order to ensure consistency among the images. All images were saved at the office as full resolution JPEGs and calibrated accordingly by image resolution.

3.5 MEASURING ROOT ANGULATION WITH DOLPHIN® SOFTWARE

All coded panoramic radiographs were uploaded onto the latest version of Dolphin Imaging[©] software for orthodontics and appropriately labeled as "pre-" and "post-treatment" accordingly. The 4-point measuring tool was used to trace the long axes of all specified teeth in order to calculate the converging/diverging root angulation. Specifically, the 4-point measuring tool works by placing 2 points on each of the 2 adjacent teeth being measured. One point is placed on the cusp tip of the tooth, at which point Dolphin[©] generates a straight line that eventually terminates at the second selected point. The second point is typically placed at the root apex in order for the generated line to best parallel the long axis of the tooth. Once the 2 points are selected on one tooth, the same process is repeated for the adjacent tooth. After all 4 points are selected and both root axis lines are drawn, Dolphin[©] automatically calculates the converging/diverging mesio-distal root angulation and projects the value between the two teeth. This process was completed for the 14 areas of measurement on all 101 pre- and 101 posttreatment panoramic radiographs (Fig. 3-1).

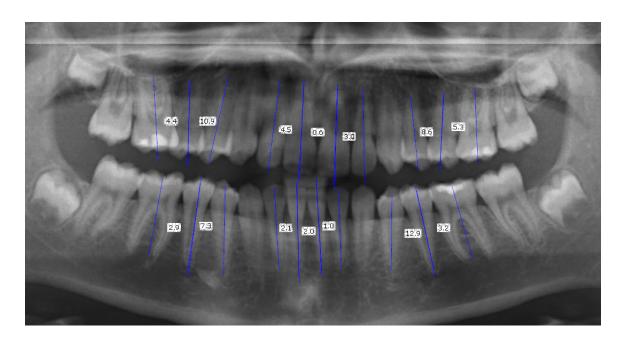


Figure 3-1. Sample panoramic radiograph with mesio-distal root angle measurements using Dolphin's[©] 4-point measuring tool

3.5.1 Measurement Variations

Due to anatomical variations among the measured dentition, perfect tracing of the root axis with intersecting points on the root apex and cusp tip was not always possible. For example, some teeth displayed marked curvatures at the root apices. Root dilacerations are typically observed in the apical third of pre-molar, incisor, and canine roots(Malcic et al., 2006). In order to overcome this, a line of best fit was used to parallel the straightest portions of the root canal and crown, which ignored the apical 1/3rd containing extreme root curvatures. This root tracing method was in-line with another similar root parallelism study (Chiqueto et al., 2011). In addition, molars, which are multi-rooted, were traced by averaging the root axes and placing a line of best fit down the center of the tooth. For example, the long axes of mandibular first molars were typically

assessed by tracing a line down the center of the crown extending between both projected roots along a parallel trajectory. A similar method was used for maxillary first molars in cases where the palatal root was not clear enough on the image for root canal tracing. In doing so, approximate tracings of root axes were possible for those teeth. All mesio-distal root angulations for pre- and post-treatment measurements were recorded on a data capture sheet (See Appendix C).

3.6 STATISTICAL ANALYSIS

For all statistical tests, SAS v9.4 statistical software was used.

3.6.1 Change in mesio-distal root angulation

Paired t-tests were used to analyze the average change in mesio-distal root angulation among the pre- and post-treatment panoramic radiographs. The average change in root angulation was considered significant at **p<0.05**. In addition, the direction of change in root angulation was noted for each area of measurement with a positive value indicating a smaller post-treatment angle (became more parallel) and a negative value indicating a larger post-treatment angle (became less parallel).

3.6.2 Statistical differences among gender, occlusion type, and elastics use

Unpaired, 2-sample t-tests were used to test for any significant differences in the average change scores in root angulation among male/female gender,

occlusion type (I, II, or III), and elastics use. A **p-value < 0.05** rejects the hypothesis that the change scores are the same on average.

3.6.3 Statistical differences among age

Age, being continuous, was compared to average root angulation change scores using Pearson correlation coefficients. A correlation approaching +/- 1.0 would indicate an association. A correlation close to 0 would indicate the opposite.

3.6.4 Intra-rater reliability

20% of the studied sample was tested for intra-rater reliability within the principle investigator using the interclass correlation coefficient (ICC) test in order to ensure consistency and repeatability among the measured values. In order for the repeated measurements to represent an equal distribution of the sample, a separate set of 10 pre- and 10 post-treatment panoramic radiographs were selected at random from the original measurements. These repeated samples also represented the various time points from when the original measurements were taken in order to account for examiner fatigue. A score of 0 implies no agreement, whereas a score of 1 implies perfect agreement. For the purposes of this study, and in most clinical settings, a minimum of 0.7 is expected for good reliability (Rankin & Stokes, 1998).

3.6.5 Inter-rater reliability

In addition to intra-rater reliability within the principle investigator, inter-examiner reliability was also measured using the ICC test. The second examiner was

highly qualified for the task as he was an orthodontic resident in training with an additional 20 years of radiographic experience as a practicing general dentist. A brief training period was conducted for the 2nd examiner in order to familiarize himself with the Dolphin[®] 4-point measuring tool and root tracing protocols as used in this study. After demonstrating good satisfactory root tracings, 20% of the studied sample was tested for inter-rater reliability between the principle investigator the 2nd examiner. Similarly to intra-rater reliability, a separate set of 10 pre- and 10 post-treatment panoramic radiographs were selected at random from the original measurements, which also represented the various time points from when the original measurements were taken in order to account for examiner fatigue.

Chapter 4

Results

4.1 SAMPLE GROUP SUMMARY

The data collected for the purposes of this study was divided into 14 groups for both pre- and post-treatment measurements (Table 4-1):

Pre-treatment groups	Post-treatment groups
Pre 16-15	Post 16-15
Pre 15-14	Post 15-14
Pre 12-11	Post 12-11
Pre 11-21	Post 11-21
Pre 21-22	Post 21-22
Pre 24-25	Post 24-25
Pre 25-26	Post 25-26
Pre 46-45	Post 46-45
Pre 45-44	Post 45-44
Pre 42-41	Post 42-41
Pre 41-31	Post 41-31
Pre 31-32	Post 31-32
Pre 34-35	Post 34-35
Pre 35-36	Post 35-36

Table 4-1. Pre- and post-treatment groups

"Pre-treatment groups" (Pre) represent measurements taken from the panoramic radiographs of patients before starting Invisalign® treatment, whereas "Post-treatment groups" (Post) represent measurements taken from the panoramic radiographs of patients after the completion of their Invisalign® treatment.

All teeth in the measurement groups were labeled in accordance with the "Federation Dentaire Internationale" (FDI) numbering system, which is used worldwide and within Canada as the standard tooth labeling system.

- 16-15 represents the mesio-distal root angle between teeth #16
 (Upper right 1st molar) and #15 (Upper right 2nd pre-molar)
- 15-14 represents the mesio-distal root angle between teeth #15
 (Upper right 2nd pre-molar) and #14 (Upper right 1st pre-molar)
- 12-11 represents the mesio-distal root angle between teeth #12
 (Upper right lateral incisor) and #11 (Upper right central incisor)
- 11-21 represents the mesio-distal root angle between teeth #11
 (Upper right central incisor) and #21 (Upper left central incisor)
- 21-22 represents the mesio-distal root angle between teeth #21
 (Upper left central incisor) and #22 (Upper left lateral incisor)
- 24-25 represents the mesio-distal root angle between teeth #24
 (Upper left 1st pre-molar) and #25 (Upper left 2nd pre-molar)
- 25-26 represents the mesio-distal root angle between teeth #25
 (Upper left 2nd pre-molar) and #26 (Upper left 1st molar)
- 46-45 represents the mesio-distal root angle between teeth #46
 (Lower right 1st molar) and #45 (Lower right 2nd pre-molar)
- 45-44 represents the mesio-distal root angle between teeth #45
 (Lower right 2nd pre-molar) and #44 (Lower right 1st pre-molar)
- 42-41 represents the mesio-distal root angle between teeth #42
 (Lower right lateral incisor) and #41 (Lower right central incisor)

- 41-31 represents the mesio-distal root angle between teeth #41
 (Lower right central incisor) and #31 (Lower left central incisor)
- 31-32 represents the mesio-distal root angle between teeth #31
 (Lower left central incisor) and #32 (Lower left lateral incisor)
- 34-35 represents the mesio-distal root angle between teeth #34
 (Lower left 1st pre-molar) and #35 (Lower left 2nd pre-molar)
- 35-36 represents the mesio-distal root angle between teeth #35
 (Lower left 2nd pre-molar) and #36 (Lower left 1st molar)

4.2 MEASUREMENT RELIABILITY

The reliability for all measurements was evaluated using the ICC test for 20% of the study sample. Panoramic radiographs were selected at random to include 10 pre- and 10 post-treatment images at various time points throughout the measurement process in order to ensure an appropriate reliability sample and limit measurement bias. Angulations were re-measured by two separate examiners; including the principle investigator and another qualified professional as previously indicated. Reliability measurements were conducted 12 weeks after the initial measurements in order to limit fatigue error and statistical bias. Reliability was based on the calculated ICC values ranging from zero (no agreement) to one (perfect agreement), whereby a minimum of 0.7 is referenced as good reliability within clinical settings (Rankin & Stokes, 1998).

4.2.1 Intra-rater reliability

Intra-examiner reliability measurements displayed a high consistency among most of the measurement groups. Specifically, an ICC score of 0.71 or

higher was noted for 11 of the 14 groups with 7 of those scores being above 0.85. The 3 groups to score an ICC below 0.71 consisted of #16-15 (ICC: 0.22), #25-26 (ICC: 0.34), and #35-36 (0.67). See table 4-2.1 for intra-rater ICC scores.

Treatment groups	ICC scores
# 16-15	0.22
# 15-14	0.92
# 12-11	0.85
# 11-21	0.88
# 21-22	0.77
# 24-25	0.78
# 25-26	0.33
# 46-45	0.94
# 45-44	0.93
# 42-41	0.82
# 41-31	0.71
# 31-32	0.78
# 34-35	0.88
# 35-36	0.66

Table 4-2.1 Intra-examiner ICC scores

In review of the distribution of absolute difference scores among intraexaminer measurements, the range of mean differences among the 14 groups ranged from as low as 0.025 degrees to as high as 0.845 degrees. A larger range of difference scores can be noted for groups #16-15, #25-26,and #35-36. See table 4-2.2 for intra-examiner absolute difference scores.

Distribution of Absolute Difference Scores (Degrees)

(first occasion measurement minus second occasion)

Variable	N	Mean	Median	Minimum	Maximum	Std Dev
teeth_16_15_diff	20	-0.28	-0.25	-5.70	6.00	2.37
teeth_15_14_diff	20	-0.56	-0.70	-3.20	2.00	1.43
teeth_12_11_diff	20	-0.24	-0.10	-5.50	3.40	1.80
teeth_11_21_diff	20	-0.13	0.20	-2.60	1.40	1.21
teeth_21_22_diff	20	-0.84	-0.50	-5.00	2.30	1.98
teeth_24_25_diff	20	-0.02	0.10	-4.80	5.70	2.51
teeth_25_26_diff	20	0.30	0.65	-3.50	6.20	2.19
teeth_46_45_diff	20	0.07	-0.15	-4.50	4.10	2.06
teeth_45_44_diff	20	0.29	0.30	-1.90	3.20	1.28
teeth_42_41_diff	20	0.41	0.45	-1.70	2.10	1.07
teeth_41_31_diff	20	0.06	0	-2.90	2.80	1.53
teeth_31_32_diff	20	-0.24	-0.35	-2.20	2.60	1.59
teeth_34_35_diff	20	0.49	0.05	-2.10	5.00	1.73
teeth_35_36_diff	20	-0.34	-0.40	-5.40	4.30	2.45

Table 4-2.2 Distribution of intra-examiner absolute difference scores

4.2.2 Inter-rater reliability

Inter-examiner reliability was very high with ICC scores ranging from as low as 0.70 to as high as 0.98, and most scores being above 0.81. This suggested good agreement between examiners for most groups. See table 4-2.3 for inter-rater ICC scores.

Treatment groups	ICC scores
# 16-15	0.70898
# 15-14	0.96262
# 12-11	0.88878
# 11-21	0.93832
# 21-22	0.89048
# 24-25	0.95891
# 25-26	0.81144
# 46-45	0.96268
# 45-44	0.98022
# 42-41	0.89504
# 41-31	0.88250
# 31-32	0.91469
# 34-35	0.96105
# 35-36	0.88402

Table 4-2.3 Inter-examiner ICC scores

In review of the distribution of absolute difference scores between both examiners, the range of mean differences among the 14 groups ranged from as low as 0.03 degrees to as high as 0.51 degrees. A larger range of difference scores can be noted for group #16-15. See table 4-2.4 for inter-examiner absolute difference scores.

Distribution of Absolute Difference Scores (Degrees) (first rater minus second rater)

Variable	N	Mean	Median	Minimum	Maximum	Std Dev
PAN_16_15_diff	20	-0.51	0.10	-5.20	1.50	1.55
PAN_15_14_diff	20	-0.09	0.10	-2.90	1.80	1.00
PAN_12_11_diff	20	-0.16	0	-5.60	1.40	1.50
PAN_11_21_diff	20	-0.19	-0.05	-2.40	1.10	0.88
PAN_21_22_diff	20	-0.30	-0.10	-2.50	2.10	1.21
PAN_24_25_diff	20	0.04	-0.05	-3.40	1.90	1.19
PAN_25_26_diff	20	-0.03	0.10	-3.10	1.80	1.18
PAN_46_45_diff	20	0.11	-0.05	-3.60	3.80	1.58
PAN_45_44_diff	20	-0.14	-0.05	-1.60	0.80	0.68
PAN_42_41_diff	20	0.30	0.25	-1.60	2.00	0.86
PAN_41_31_diff	20	-0.28	-0.10	-3.30	1.40	0.99
PAN_31_32_diff	20	-0.17	-0.10	-2.00	1.40	1.00
PAN_34_35_diff	20	0.13	0.20	-1.50	2.30	0.98
PAN_35_36_diff	20	-0.45	-0.25	-2.70	2.30	1.40

Table 4-2.4 Distribution of inter-examiner absolute difference scores

4.3 SAMPLE GROUP STATISTICS

Mean intervention angles were calculated for all pre-treatment (Table 4-3.1) and post-treatment (Table 4-3.2) groups. Clinically, all pre- and post-treatment scores were below 7 degrees, indicating acceptable mesio-distal root angulations as per the established parameters of this study.

Variable	N	Mean	Median	Minimum	Maximum	Std Dev
pre 16 15	101	3.23	2.70	0	12.30	2.64
pre 15 14	101	4.04	3.50	0.10	11.40	2.90
pre 12 11	101	4.49	3.50	0.10	13.70	3.97
pre 11 21	101	3.81	2.70	0.00	12.90	3.30
pre_21_22	101	4.86	4.40	0.10	24.10	3.73
pre_24_25	101	4.40	3.30	0	18.30	3.69
pre_25_26	101	3.87	3.40	0.10	23.50	3.63
pre_46_45	101	5.51	4.70	0.10	23.40	4.13
pre_45_44	101	6.50	5.70	0.00	21.70	4.15
pre_42_41	101	3.40	2.80	0	12.70	2.92
pre_41_31	101	3.75	3.10	0.10	15.00	3.21
pre_31_32	101	3.47	3.00	0	10.40	2.48
pre_34_35	101	6.80	6.20	0.90	18.80	4.15
pre_35_36	101	4.66	4.30	0.10	14.20	2.94

Table 4-3.1 Pre-intervention angles (Degrees)

Variable	N	Mean	Median	Minimum	Maximum	Std Dev
post 16 15	101	2.53	2.10	0	12.80	2.37
post_15_14	101	3.10	2.90	0	10.10	2.19
post 12 11	101	4.94	4.50	0.40	15.00	3.10
post 11 21	101	3.21	2.60	0.10	11.20	2.66
post 21 22	101	4.81	4.60	0.10	14.40	3.10
post_24_25	101	3.57	3.00	0	14.80	3.02
post 25 26	101	2.96	2.30	0.20	11.70	2.36
post_46_45	101	5.30	4.70	0.20	20.70	3.67
post 45 44	101	5.29	4.70	0	18.90	4.09
post 42 41	101	2.36	1.90	0	12.20	2.03
post 41 31	101	2.62	2.20	0	9.60	2.07
post 31 32	101	2.62	2.30	0	12.00	2.26
post 34 35	101	5.27	4.20	0	15.80	3.75
post_35_36	101	4.81	4.20	0	14.80	3.03

Table 4-3.2 Post-intervention angles (Degrees)

The summary statistics for overall changes in pre- and post-treatment angles are indicated in table 4-3.3. These difference scores can be interpreted as "pre" minus "post", whereby a positive difference score indicates a larger pre-intervention angle (I.e.: became more parallel), and a negative difference score indicates a larger post-intervention angle (I.e.: became less parallel). From these calculations, actual clinical values among the 14 groups show a range of root angle changes from as low as 0.04 degrees (#21-22) to as high as 1.53 degrees (#34-35). Only two of the 14 groups (#12-11 and #35-36) showed negative root angle change scores, while the remaining groups showed clinical improvements in root parallelism (positive change scores). It is important to note that although the range of mean root angulation changes was not very large, small changes in mesio-distal root angulations may have important clinical implications.

Variable	N	Mean	Median	Minimum	Maximum	Std Dev
diff 16 15	101	0.70	0.80	-5.80	8.60	2.71
diff 15 14	101	0.94	0.70	-8.10	9.50	3.08
diff 12 11	101	-0.45	0	-11.30	7.50	3.18
diff_11_21	101	0.60	0.60	-7.40	8.00	3.05
diff 21 22	101	0.04	-0.60	-6.70	22.60	3.68
diff_24_25	101	0.82	0.80	-5.90	9.60	3.06
diff_25_26	101	0.91	0.30	-5.80	21.40	3.63
diff_46_45	101	0.20	0.40	-7.80	8.20	3.14
diff_45_44	101	1.20	1.10	-5.40	14.20	3.33
diff 42 41	101	1.03	0.80	-4.90	9.30	3.10
diff_41_31	101	1.12	0.60	-7.30	13.50	3.38
diff_31_32	101	0.84	1.20	-7.10	7.10	2.58
diff_34_35	101	1.53	1.30	-8.20	11.50	3.29
diff_35_36	101	-0.15	-0.20	-6.30	8.20	2.81

Table 4-3.3 Change in angles ("pre" minus "post", degrees)

4.4 PAIRED T-TESTS MEASURING THE AVERAGE CHANGE IN MESIO-DISTAL ROOT ANGULATION

Paired t-tests were used in order to calculate if the average changes in mesio-distal root angulation were statistically significant.

4.4.1 Paired t-test sample distribution

The sample distribution among all 14 groups followed a normal distribution. Graphs 4-4.1 through 4-4.14 show the sample's approximation to kernel (normal distribution) for each of the 14 groups.

Distribution of Difference: pre_16_15 - post_16_15 With 95% Confidence Interval for Mean Normal Kernel 15 - 10 - 5 - 0 - 95% Confidence 95% Confidence

Graph 4-4.1 Sample distributions for Pre#16-15 minus Post#16-15

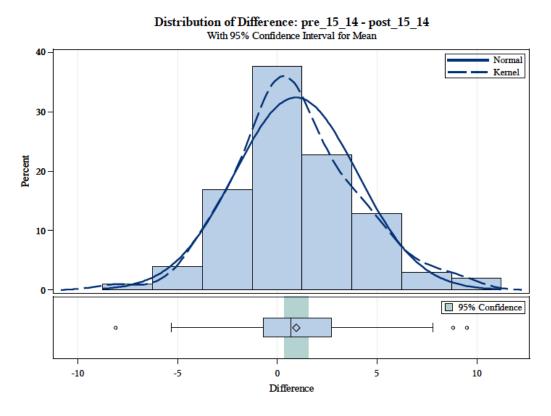
Difference

-5

-10

10

5



Graph 4-4.2 Sample distributions for Pre#15-14 minus Post#15-14

Distribution of Difference: pre_12_11 - post_12_11 With 95% Confidence Interval for Mean Normal Kernel 10 -

\rightarrow

0

5

10

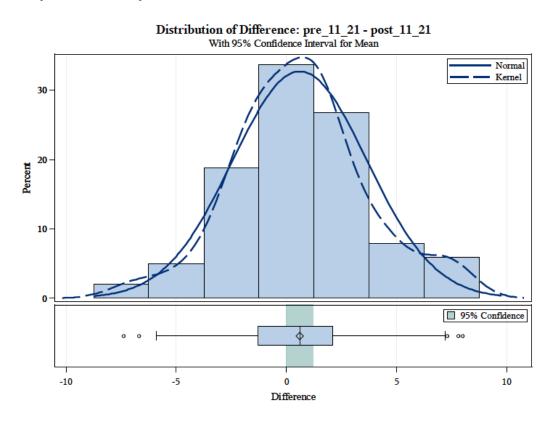
Graph 4-4.3 Sample distributions for Pre#12-11 minus Post#12-11

Difference

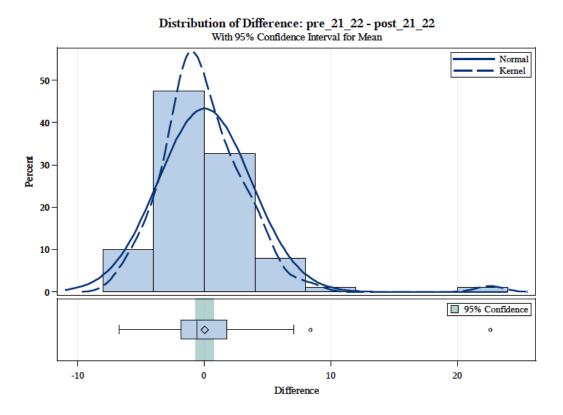
-5

-10

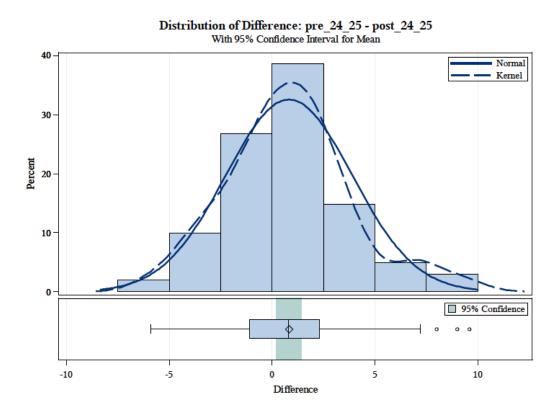
-15



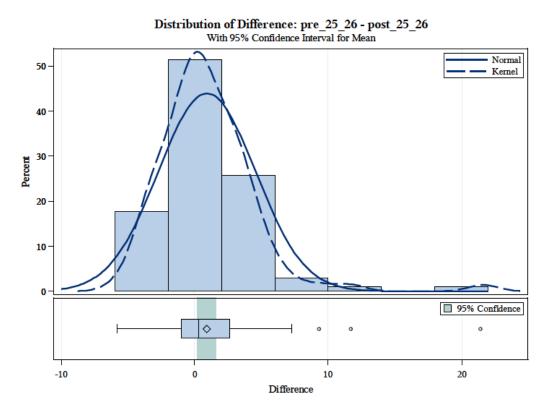
Graph 4-4.4 Sample distributions for Pre#11-21 minus Post#11-21



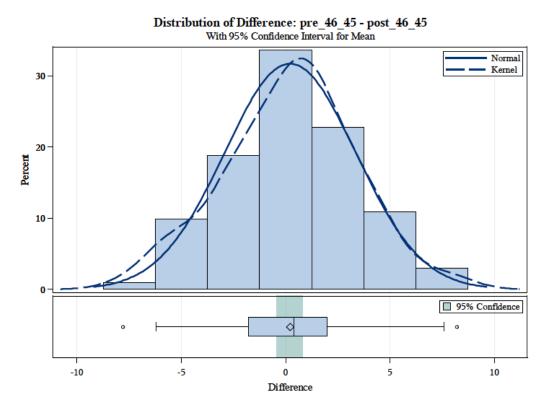
Graph 4-4.5 Sample distributions for Pre#21-22 minus Post#21-22



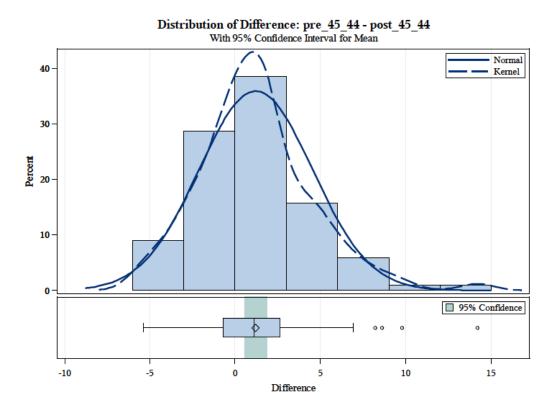
Graph 4-4.6 Sample distributions for Pre#24-25 minus Post#24-25



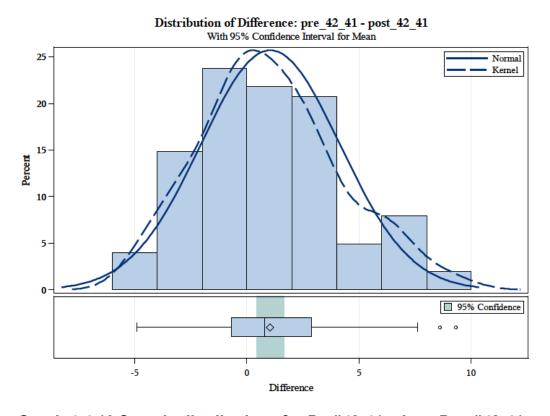
Graph 4-4.7 Sample distributions for Pre#25-26 minus Post#25-26



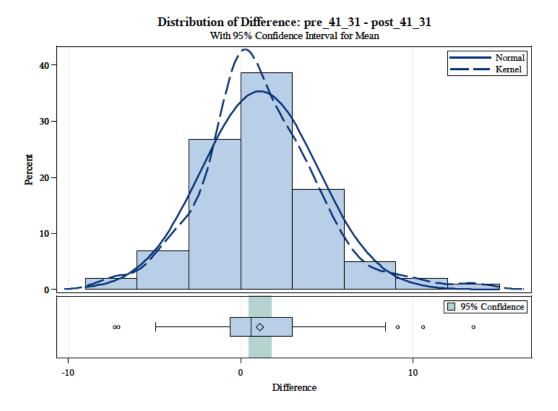
Graph 4-4.8 Sample distributions for Pre#46-45 minus Post#46-45



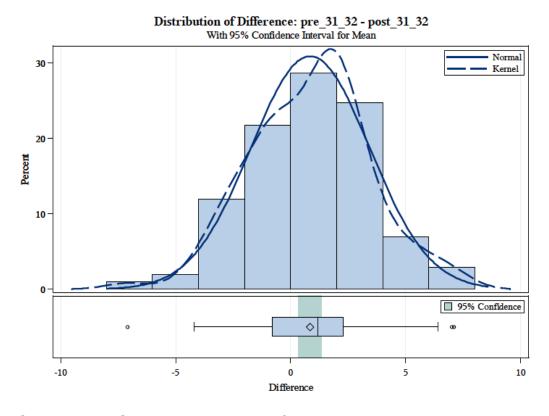
Graph 4-4.9 Sample distributions for Pre#45-44 minus Post#45-44



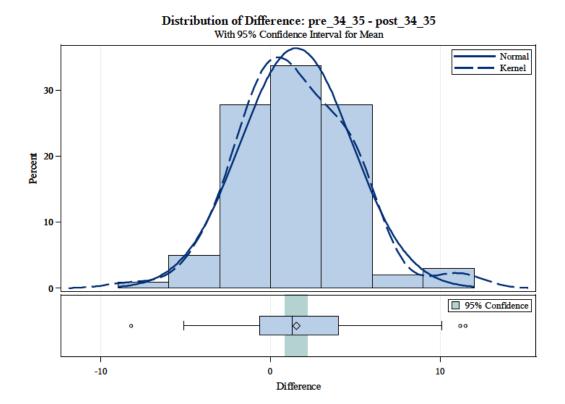
Graph 4-4.10 Sample distributions for Pre#42-41 minus Post#42-41



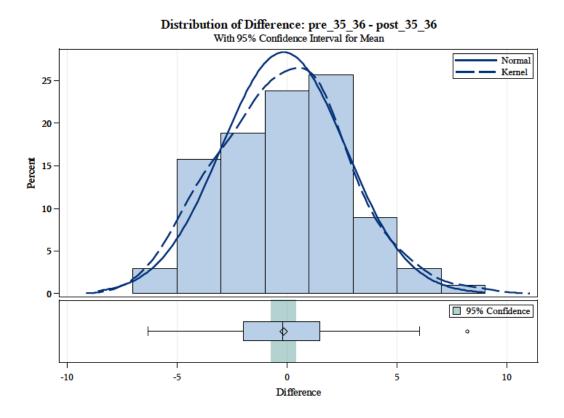
Graph 4-4.11 Sample distributions for Pre#41-31 minus Post#41-31



Graph 4-4.12 Sample distributions for Pre#31-32 minus Post#31-32



Graph 4-4.13 Sample distributions for Pre#34-35 minus Post#34-35



Graph 4-4.14 Sample distributions for Pre#35-36 minus Post#35-36

4.4.2 Paired t-test summary

Overall, the tests revealed 10 of the 14 groups assessed showed a statistically significant change on average with respect to pre- and post-treatment mesio-distal root angulations (p<0.05). Only 4 groups (#12-11, #21-22, #46-45, and 35-36) did not show statistically significant root angle change scores. Summary p-values and detailed group statistics can be found in tables 4-4.2 and 4-4.3. As well, comparison statistics between mean change scores, p-values and ICC scores are summarized in table 4-4.4.

Group	p-value
Pre 16-15 - Post 16-15	0.01
Pre 15-14 - Post 15-14	0.00
Pre 12-11 - Post 12-11	0.15
Pre 11-21 - Post 11-21	0.04
Pre 21-22 - Post 21-22	0.90
Pre 24-25 - Post 24-25	0.00
Pre 25-26 - Post 25-26	0.01
Pre 46-45 - Post 46-45	0.50
Pre 45-44 - Post 45-44	0.00
Pre 42-41 - Post 42-41	0.00
Pre 41-31 - Post 41-31	0.00
Pre 31-32 - Post 31-32	0.00
Pre 34-35 - Post 34-35	<0.00
Pre 35-36 - Post 35-36	0.58

Table 4-4.2: Paired t-tests p-value summary statistics; Average change in mesio-distal root angulation ("pre" minus "post"). *Measurements with statistical significance in bold.

Group	Mean	95%		Std Dev	95%		DF	t Value	Pr > t
	(N=101)	CL M	ean		CL St	d Dev			
#16-15	0.70	0.16	1.23	2.71	2.38	3.14	100	2.61	0.01
#15-14	0.94	0.33	1.55	3.08	2.70	3.57	100	3.08	0.00
#12-11	-0.45	-1.08	0.17	3.18	0.80	3.70	100	-1.43	0.15
#11-21	0.60	0.00	1.20	3.05	2.68	3.54	100	2	0.04
#21-22	0.04	-0.68	0.77	3.68	3.23	4.27	100	0.12	0.90
#24-25	0.82	0.22	1.43	3.06	2.69	3.55	100	2.72	0.00
#25-26	0.91	0.19	1.63	3.63	3.19	4.21	100	2.53	0.01
#46-45	0.20	-0.41	0.82	3.14	2.76	3.64	100	0.66	0.50
#45-44	1.20	0.54	1.86	3.33	2.92	3.86	100	3.64	0.00
#42-41	1.03	0.42	1.65	3.10	2.72	3.60	100	3.36	0.00
#41-31	1.12	0.46	1.79	3.38	2.97	3.93	100	3.35	0.00
#31-32	0.84	0.33	1.35	2.58	2.26	2.99	100	3.31	0.00
#34-35	1.53	0.88	2.18	3.29	2.89	3.82	100	4.67	<0.00
#35-36	-0.15	-0.70	0.40	2.81	2.47	3.26	100	-0.54	0.58

Table 4-4.3: Detailed paired t-tests summary statistics; Average change in mesio-distal root angulation ("pre" minus "post"). *Measurements with statistical significance in bold.

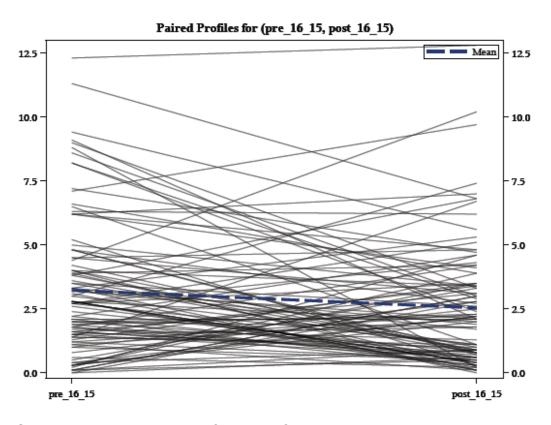
Group	Mean	p-value	ICC
	(N=101)		(Intra-examiner)
#16-15	0.70	0.01	0.22
#15-14	0.94	0.00	0.92
#12-11	-0.45	0.15	0.85
#11-21	0.60	0.04	0.88
#21-22	0.04	0.90	0.77
#24-25	0.82	0.00	0.78
#25-26	0.91	0.01	0.33
#46-45	0.20	0.50	0.94
#45-44	1.20	0.00	0.93
#42-41	1.03	0.00	0.82
#41-31	1.12	0.00	0.71
#31-32	0.84	0.00	0.78
#34-35	1.53	<0.00	0.88
#35-36	-0.15	0.58	0.66

Table 4-4.4: Comparison of mean change scores (+/-), p-value, and ICC; Average change in mesio-distal root angulation ("pre" minus "post").

^{*}Measurements with statistical significance in bold.

4.4.2.1 Summary statistics for group #16-15

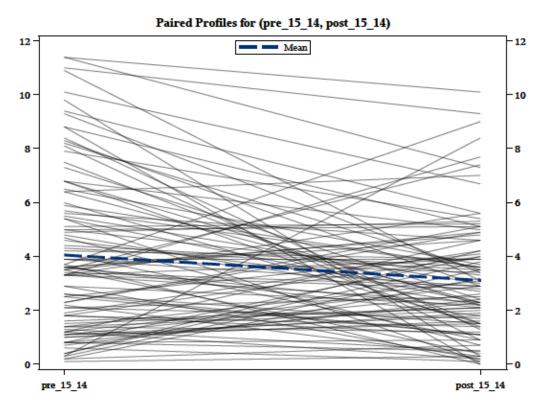
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #16-15 was 0.704 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). However, an intra-examiner ICC score of 0.22254 yielded poor reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.1. The dotted line (mean) reflects the change going from a larger to a smaller root angle. Outliers can be viewed from these plots as lines extending away from the mean line, and in some instances running in an opposite direction.



Graph 4-5.1 Individual profile plots for group #16-15

4.4.2.2 Summary statistics for group #15-14

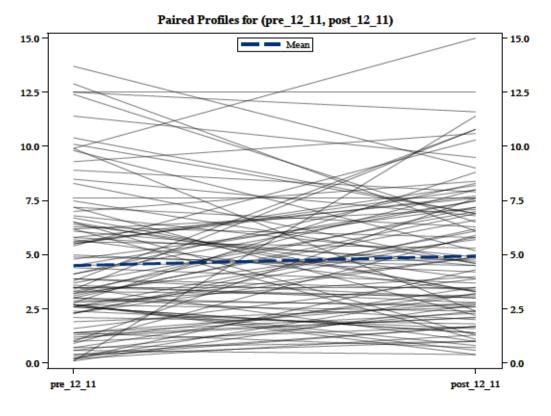
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #15-14 was 0.9436 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.92835 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.2. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.2 Individual profile plots for group #15-14

4.4.2.3 Summary statistics for group #12-11

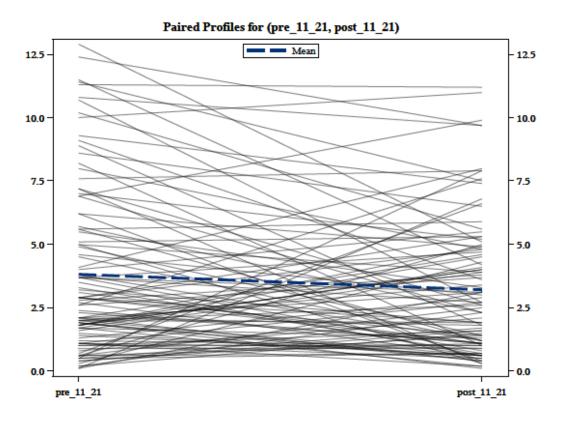
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #12-11 was -0.4525 degrees. This change was not statistically significant at p<0.05 and resulted in a larger average post-treatment angle (became less parallel). As well, an intra-examiner ICC score of 0.85368 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.3. The dotted line (mean) reflects the change going from a smaller to a larger root angle.



Graph 4-5.3 Individual profile plots for group #12-11

4.4.2.4 Summary statistics for group #11-21

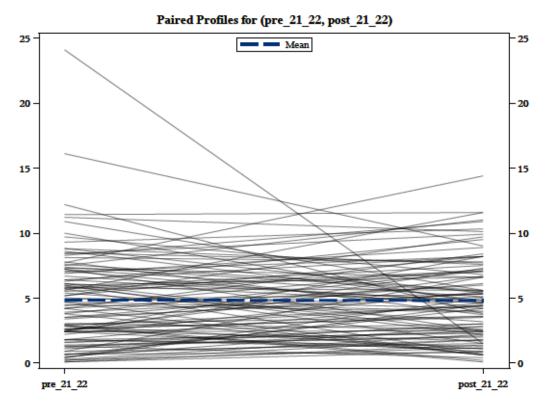
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #11-21 was 0.6059 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.88787 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.4. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.4 Individual profile plots for group #11-21

4.4.2.5 Summary statistics for group #21-22

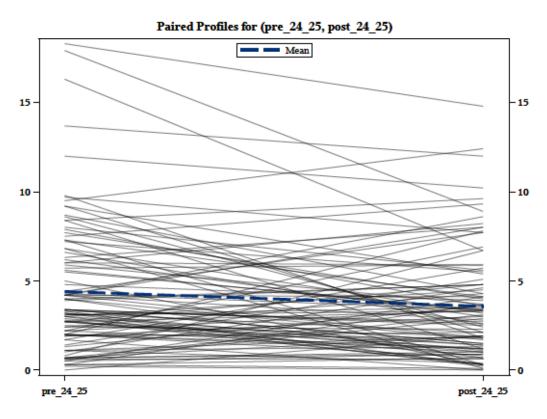
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #21-22 was 0.0426 degrees. This change was not statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.77654 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.5. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.5 Individual profile plots for group #21-22

4.4.2.6 Summary statistics for group #24-25

The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #24-25 was 0.8297 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.78675 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.6. The dotted line (mean) reflects the change going from a larger to a smaller root angle.

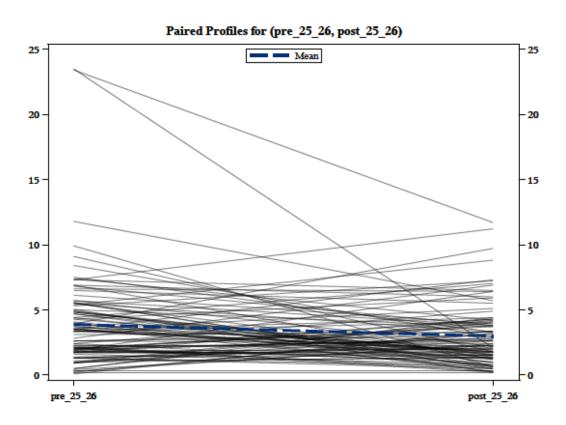


Graph 4-5.6 Individual profile plots for group #24-25

4.4.2.7 Summary statistics for group #25-26

The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #25-26 was 0.9139 degrees. This change was statistically significant at

p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). However, an intra-examiner ICC score of 0.33944 yielded poor reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.7. The dotted line (mean) reflects the change going from a larger to a smaller root angle.

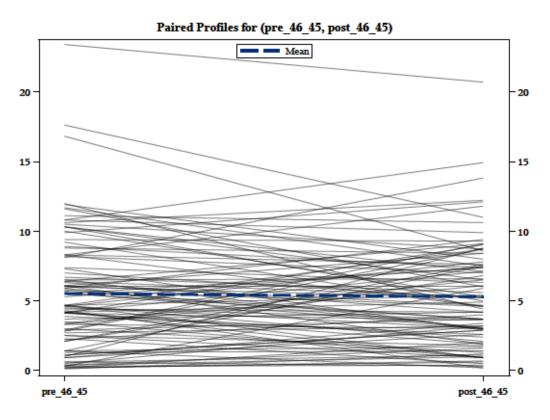


Graph 4-5.7 Individual profile plots for group #25-26

4.4.2.8 Summary statistics for group #46-45

The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #46-45 was 0.2079 degrees. This change was not statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.94021 yielded

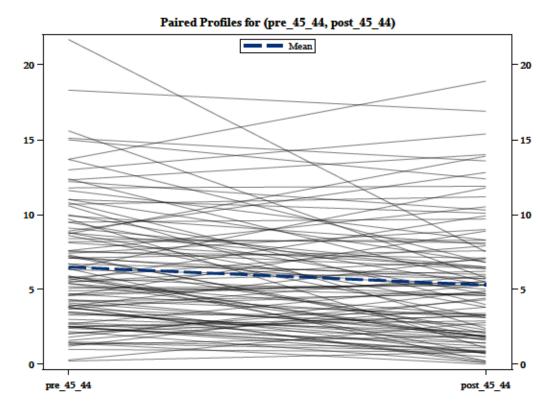
good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.8. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.8 Individual profile plots for group #46-45

4.4.2.9 Summary statistics for group #45-44

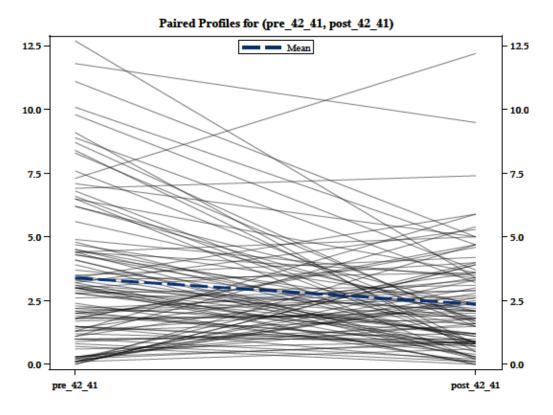
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #45-44 was 1.2059 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.93238 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.9. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.9 Individual profile plots for group #45-44

4.4.2.10 Summary statistics for group #42-41

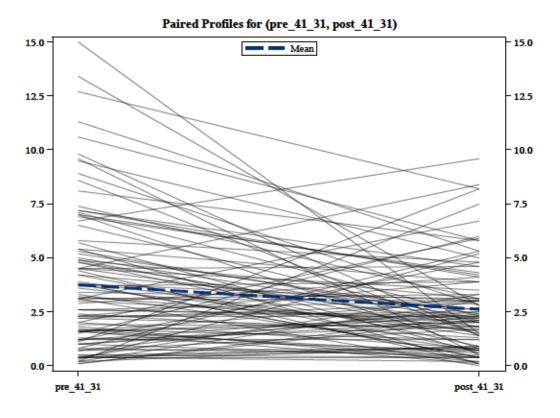
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #42-41 was 1.0386 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.82623 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.10. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.10 Individual profile plots for group #42-41

4.4.2.11 Summary statistics for group #41-31

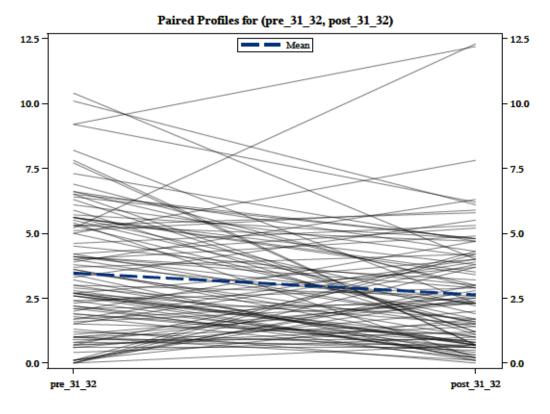
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #41-31 was 1.1297 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.71468 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.11. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.11 Individual profile plots for group #41-31

4.4.2.12 Summary statistics for group #31-32

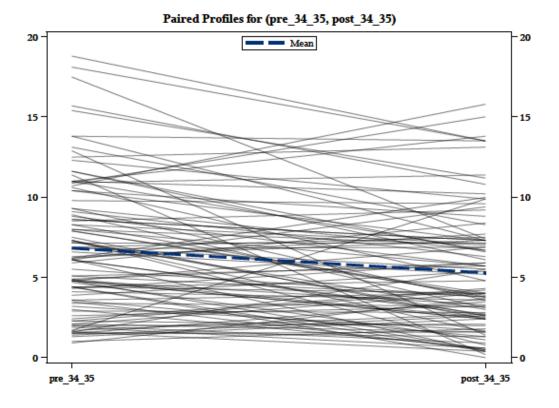
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #31-32 was 0.8495 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.78862 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.12. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.12 Individual profile plots for group #31-32

4.4.2.13 Summary statistics for group #34-35

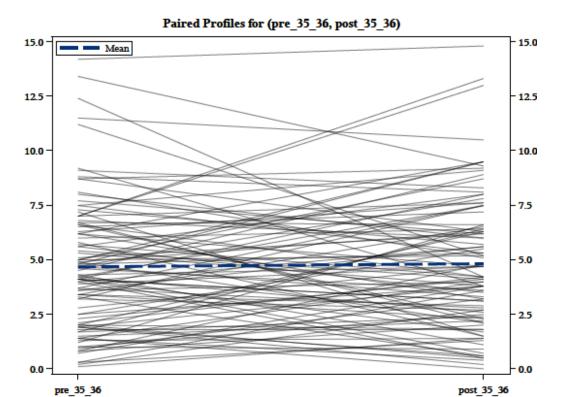
The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #34-35 was 1.5307 degrees. This change was statistically significant at p<0.05 and resulted in a smaller average post-treatment angle (became more parallel). As well, an intra-examiner ICC score of 0.88391 yielded good reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.13. The dotted line (mean) reflects the change going from a larger to a smaller root angle.



Graph 4-5.13 Individual profile plots for group #34-35

4.4.2.14 Summary statistics for group #35-36

The mean change score in "Pre" minus "Post" mesio-distal root angulation for group #35-36 was -0.1525 degrees. This change was not statistically significant at p<0.05 and resulted in a larger average post-treatment angle (became less parallel). As well, an intra-examiner ICC score of 0.6694 yielded poor reliability for this group's measurements. Profile plots for individual changes within this group can be seen in graph 4-5.14. The dotted line (mean) reflects the change going from a smaller to a larger root angle.



Graph 4-5.14 Individual profile plots for group #35-36

4.5 CHANGE IN ROOT ANGLES VS. AGE

Age, being continuous, was compared to root angle change scores using Pearson correlation coefficients. A correlation approaching +/- 1.0 would indicate an association, whereas a correlation close to 0 would indicate no association. Overall, the average change in root angulation for all 14 groups was not affected by age (p>0.05). See table 4-5 on summary statistics for comparison of change score with age.

Pearson Correlation Coefficient, N=101		
Group	Estimated	
	Correlation	
#16-15	-0.07	
#15-14	0.07	
#12-11	-0.03	
#11-21	0.09	
#21-22	0.09	
#24-25	0.07	
#25-26	-0.01	
#46-45	-0.01	
#45-44	-0.16	
#42-41	0.15	
#41-31	0.15	
#31-32	0.01	
#34-35	-0.24	
#35-36	-0.02	

Table 4-5: Root angle change scores Vs. Age

4.6 CHANGE IN ROOT ANGLES VS. GENDER

The average change in root angulation was compared to gender by use of the unpaired (two-sample) t-test. The specified data set included 29 males and 72 females. A p-value < 0.05 rejects the hypothesis that the change scores are the same on average. Overall, the patient's gender did not affect root angle change scores (p>0.05) as 12 of the 14 groups showed no statistically significant differences. See table 4-6 for summary statistics on root angle changes vs. gender.

Unpaired (2-sample) t-test, <i>N=29(M), 72(F)</i>		
Group	p-value	
#16-15	0.51	
#15-14	0.04	
#12-11	0.01	
#11-21	0.47	
#21-22	0.21	
#24-25	0.58	
#25-26	0.53	
#46-45	0.58	
#45-44	0.63	
#42-41	0.87	
#41-31	0.95	
#31-32	0.82	
#34-35	0.83	
#35-36	0.14	

Table 4-6: Root angle change scores Vs. Gender. *Statistically significant values shown in bold.

4.7 CHANGE IN ROOT ANGLES VS. OCCLUSION TYPE

The average change in root angulation was compared to molar occlusion by use of the unpaired (two-sample) t-test. For the specified data set, occlusion types included 69 CL I and 28 CL II patients. Since the CL III data set only consisted of 4 samples, they were not included in the overall analysis. A p-value < 0.05 rejects the hypothesis that the change scores are the same on average. Overall, the patient's occlusion type did not affect root angle change scores (p>0.05) for all 14 groups. See table 4-7 for summary statistics on root angle changes vs. occlusion.

Unpaired (2-sample) t-test, N=69(CL I), 28(CL II)		
Group	p-value	
#16-15	0.14	
#15-14	0.05	
#12-11	0.48	
#11-21	0.58	
#21-22	0.43	
#24-25	0.13	
#25-26	0.08	
#46-45	0.64	
#45-44	0.96	
#42-41	0.22	
#41-31	0.59	
#31-32	0.28	
#34-35	0.72	
#35-36	0.53	

Table 4-7: Root angle change scores Vs. Occlusion type (CL I & CL II).

4.8 CHANGE IN ROOT ANGLES VS. ELASTICS USE

The average change in root angulation was compared to the use of elastics by the unpaired (two-sample) t-test. The specified data set included 44 patients who used elastics and 57 patients who did not. A p-value < 0.05 rejects the hypothesis that the change scores are the same on average. Overall, the patient's elastics use did not affect root angle change scores (p>0.05) as 12 of the 14 groups showed no statistically significant differences. See table 4-8 for summary statistics on root angle changes vs. elastics use.

Unpaired (2-sample) t-test, N=44(Y), 57(N)		
Group	p-value	
#16-15		0.73
#15-14		0.26
#12-11		0.49
#11-21		0.76
#21-22		0.31
#24-25		0.82
#25-26		0.35
#46-45		0.75
#45-44		0.06
#42-41		0.74
#41-31		0.89
#31-32		0.02
#34-35		0.17
#35-36		0.01

Table 4-8: Root angle change scores Vs. Elastics use (Y: Yes, N: No).

Chapter 5

Discussion

5.1 RELIABILITY OF MESIO-DISTAL ROOT ANGLE MEASUREMENTS

The overall reliability of root angle measurements using the Dolphin Imaging[©] 4-point measuring tool on panoramic radiographs was very good. As previously indicated, the ICC scores yielded very good reliability for 11 of the 14 groups (Table 4-2.1). As per the literature, providing the panoramic radiographs are taken with consistent protocols - including good head position and proper focal troughs - and are done by skilled technicians, root angles can be assessed with a minimal five degrees of error in vertical head position (McDavid, Tronje, Welander, & Morris, 1986; Mckee et al., 2002). Moreover, assessment of root parallelism in general should not be significantly affected by distortions found in panoramic radiographs when they are evaluated longitudinally within the same patient. This is primarily due to the fact that any patient-specific deviations in jaw form and size that lie outside of the standard focal trough should be present in all serial panoramic images (Chiqueto et al., 2011; Garcia-Figueroa et al., 2008; Mckee et al., 2002). Accordingly, assessment of the correlation between angular root changes from pre- to post-treatment would not be affected by these distortions as they appear in all serial radiographs.

Furthermore, pursuant to ABO standards, panoramic radiographs are used regularly by orthodontists to assess root parallelism, provided such evaluations do not include canine angulations (The American Board of

Orthodontics, June 2012). It is important to note that the ABO standards, which are well accepted by the orthodontic community, assess root parallelism using a grading scheme that only involves a quick panoramic radiograph assessment by eye. In order to improve accuracy, this study mirrored other studies wherein mesio-distal root angulations were assessed using a measuring tool to trace the long axes of teeth (Chiqueto et al., 2011; Mayoral, 1982). To this end, measuring mesio-distal root angulations with Dolphin's[©] 4-point measuring tool on panoramic radiographs of good diagnostic quality provided a quick and reliable method for calculating mesio-distal root angulations without the need for comparisons to the occlusal plane. Only 1st molars proved unreliable.

Specifically, the only three groups to show poor ICC scores were #16-15 (ICC: 0.22), #25-26 (ICC: 0.34), and #35-36 (0.67). It is interesting to note that these 3 groups all involved measurements surrounding 1st molars. To this effect, initial reliability measurements were repeated for all groups involving 1st molars before running the ICC statistics as this trend of poor reliability around 1st molars was noticed on close inspection of the raw data. Repeated reliability measurements were very similar, and thus, the ICC was run accordingly.

One reason explaining poorer reliability of mesio-distal root angulations around molars may be the fashion in which these angles are projected onto a panoramic radiograph. For instance, root angulations can be overestimated on maxillary molars, whereas root angulations around mandibular molars tend to be underestimated on panoramic radiographs (Mckee et al., 2002). Although experienced clinicians may be able to overcome these radiographic errors

through clinical judgment and oral examination, for the purposes of this study, evaluation of these areas on panoramic radiographs alone may increase interpretation error. Thus, predicting overestimations or underestimations of root angles when tracing the long axes of molars may create difficulties in assessing root parallelism for those teeth. For these reasons, this study's assessment of root angulation changes scores involving 1st molars may have been effected as non-significant change scores were reported for groups #46-45 and #35-36.

Secondly, interpretation of a panoramic radiograph in general suffers from the fact that a panoramic radiograph is a two-dimensional image depicting projections of three-dimensional objects. Moreover, molars may not always project onto a panoramic image with complete accuracy as they have varying degrees of root configurations and positions within the alveolar bone. CBCT images improve on these shortcomings of panoramic radiographs as they represent the true anatomical characteristics of the teeth being evaluated in three-dimension (Peck et al., 2007). Accuracy of CBCT images is also higher than that of traditional panoramic radiographs, however, because of the greater complexity in evaluating angular measurements on a 3D structure, assessing root parallelism can be difficult using full volumetric CBCT scans (Mckee et al., 2002). It is possible to render 2D pan-like images from 3D CBCT scans for measuring changes in root parallelism (Mckee et al., 2002; Van Elslande et al., 2010). However, it has been shown that interpretations of these images can also be subject to error as maxillary 1st molars and premolars, and the remaining mandibular dentition may show greater distal angulations when compared to true angles (Mckee et al., 2002). Moreover, until radiation doses, liability issues, and CBCT machine prices provide conditions for mainstream use of CBCT images in orthodontics, panoramic radiographs remain a useful tool in assessing root parallelism (Mckee et al., 2002; Van Elslande et al., 2010).

5.2 STATISTICALLY SIGNIFICANT CHANGES IN MESIO-DISTAL ROOT ANGULATIONS

As per table 4-4.4, 10 of the 14 groups showed statistically significant changes in mesio-distal root angles from pre- to post-Invisalign® treatment. This would indicate that Invisalign® could effectively impact root parallelism, as interpreted on panoramic radiographs. With regards to the direction of change, these groups displayed positive root angle change scores, indicating smaller post-Invisalign® mesio-distal root angles. In turn, these smaller post-Invisalign® root angles reflect adjacent roots that became more parallel with treatment.

In terms of the magnitude of statistically significant root change scores (Table 4-3.3), changes ranged from 0.6 degrees (#11-21) to 1.5 degrees (#34-35). Although these change scores reflect only mild improvements in root positions, minor improvements can have significant clinical implications. For instance, while minor changes in interproximal root angles might not be easily detected at the apical convergence, they may be more noticeable closer to the occlusal, or diverging angular emergence. These increases in apical convergence or occlusal divergence can create difficulties in maintaining tight interproximal contact points, adequate oral hygiene, and may result in inflammatory periodontal conditions (Chiqueto et al., 2011; Hatasaka, 1976; Kim et al., 2008; Smukler et al., 1989). Moreover, slight changes in root angulation

can also impact the occurrence of unaesthetic dark triangles and food retention (Chiqueto et al., 2011; Cho et al., 2006; Kurth & Kokich, 2001).

Furthermore, the small degree of root changes that were seen in this study were consistent with expected root changes as the patients' pre-treatment levels of root parallelism were within acceptable norms to begin with. Accordingly, all study groups with statistically significant root change scores also showed acceptable levels of root parallelism post-treatment. Moreover, the orthodontic treatment plans for all patients consisted of non-extraction mechanics, where levels of root movement should be less than those observed in extraction treatment (Honn & Goz, 2006; Proffit et al., 2013; Tuncay, 2006). This consideration is especially important as the expectation is for significantly more root tipping in extraction cases, and thus, greater changes in root angulations. It is also important to note that this study measured the parallelism of teeth using root angulations, whereas Andrews and ClinCheck® used the clinical crowns to assess if the teeth were upright (Andrews, 1976). In this respect, this study's root measurements add an additional element of root parallelism analysis. Furthermore, the results of this study showed that for the most part, root parallelism in non-extraction Invisalign® treatment may be improved upon when mild 2nd order root angulation changes were required.

5.3 NON-STATISTICALLY SIGNIFICANT CHANGES IN MESIO-DISTAL ROOT ANGULATIONS

As per table 4-4.2, only 4 groups (#12-11, #21-22, #46-45, and 35-36) showed non-statistically significant root angle change scores. As previously

stated, non-significant change scores in these groups may be explained in general by their initial root position. Since their mesio-distal root angulations yielded acceptable levels of root parallelism before Invisalign® treatment, significant levels of root movement may not have been needed for these groups. To this extent, no significant root changes would be expected. However, this does not rule out the possibility of improving upon already acceptable levels of root parallelism. Future studies may also want to focus solely on those areas where root parallelism was not ideal to begin with. This may highlight potential areas of greater root angulation changes, providing it is the goal of the clinician to achieve ideal parallel roots.

Conversely, it is also possible that Invisalign® may have been ineffective in producing significant root changes for these groups. Specific reasons as to why this may be the case may involve the anatomy of the teeth in question, as well as the method for prescribing their movement using Invisalign's® Clincheck® software. For instance, groups #46-45 and #35-36 both involved large mandibular 1st molars with broad roots and varying degrees of root divergence. The forces required to translate first molars were significantly higher than those of other teeth due to their greater root surface area and corresponding anchorage value (Kravitz et al., 2009; Proffit et al., 2013). Moreover, translation forces (70-120gm) to move these teeth in a bodily fashion are higher than tipping forces (35-50gm). Tipping movements were also more likely given the nature of the Invisalign® appliance (Gomez et al., 2014; Honn & Goz, 2006; Proffit et al., 2013; Tuncay, 2006).

For groups #12-11 and #21-22, non-significant root change scores may also be associated with the method in which tooth movements are prescribed in Clincheck. For instance, a clear limitation of the Invisalign® system is the lack of computer generated root positions during the Clincheck process. All prescribed tooth movements are based on the clinical crown, whereas actual root positions are not yet integrated in the computerized models (Tuncay, 2006). Although Invisalign® advocates the use of optimized attachments and aligner power-ridges to ultimately control mesio-distal root tipping and bucco-lingual root torque, only the crowns are included as part of the simulated treatment (Align Technology, 2015). To this end, instant visualization of crown movement is possible using the Clincheck software, whereas simulated root positions are not.

Furthermore, when considering that these two specific groups - lateral and central incisors – are within a highly esthetic zone, it is reasonable to assume that the clinician's bias will be to treat towards an ideal esthetic crown position over root positions when using Clincheck's virtual setup. In this regard, Invisalign® research is lacking. Moreover, until CBCT images become part of the diagnostic records for Invisalign®, Clincheck will only accurately represent the scanned crowns of all teeth and not the roots. To this end, there are studies whose aim is to create accurate virtual dental models by fusing digital scans and CBCT data (Yau, Yang, & Chen, 2014). In doing so, it may be possible to use a comprehensive diagnostic model for simulation of both root and crown movements.

In addition, non-statistically significant results for groups #12-11, #21-22, #46-45, and 35-36 could also be attributed to the broad range of differences and multiple outliers as reflected in the normal distributions and group profile plots (See graphs: 4-4.3, 4-4.5, 4-4.8, 4-4.14, 4-5.3, 4-5.5, 4-5.8, and 4-5.14). Profile plots, especially for group #21-22 shows extreme outliers with large pre-intervention angles and very small post-intervention angles. These outliers have the potential to skew the means as assessed in the statistical analysis. For the other three groups, a broad range of differences can be seen in the normal distribution graphs whereby the longer base of the curve is less likely to fall within the statistically significant range at p<0.05.

5.4 CHANGE IN ROOT ANGLES VS. AGE, GENDER, OCCLUSION TYPE, AND ELASTICS USE

Overall, the change in mesio-distal root angles from pre- and post-Invisalign® treatment was not significantly affected by the patients' age, gender, occlusion type, or use of elastics. These findings coincide with the expectations of treatment outcomes. For instance, the average age in this study was 22.7 years, which would indicate that most patients in the study sample were adults with completed predominant growth cycles. After the pubertal growth spurt during adolescence, growth in the maxilla and mandible slows down considerably and stabilizes between 16-21 years of age, at which point the spheno-occipital synchondrosis fuses (Proffit et al., 2013). Conversely, patients in this study sample are not old enough whereby orthodontic treatment is compromised by an increased risk of periodontal problems. Increased risk for periodontitis and inadequate bone support are more commonly associated with adults over the

age of 40 (Proffit et al., 2013). To this end, no major dental changes or impediments to tooth movement are to be expected with regards to age, and thus, the patient's age should not significantly affect the biomechanics used during treatment.

Secondly, gender did not seem to have any significant effects on root change scores. The gender distribution in this study consisted of 29 males and 72 females. This 71% female distribution is in-line with other Invisalign® studies which showed a similar female predilection (72% and 78%) for accepting and undergoing Invisalign® treatment (Nedwed & Miethke, 2005)This female tendency was explained by women being more concerned with their appearance than men, and therefore, be more likely to accept an esthetic orthodontic option like Invisalign®. However, the literature does not show any specific studies with regards to efficacy of Invisalign® treatment in one sex over the other. To this end, no significant effects on root parallelism were expected with regards to gender differences.

Furthermore, the patient's type of occlusion did not significantly affect root parallelism during Invisalign® treatment. The range of occlusion types consisted of 69 class I, 28 class II, and 4 class III patients. Class III patients could not be properly assessed with the data as the sample number was too low to be considered. However, the severity of class I and II malocclusions that were analyzed were considered to be only mild or moderate as per the treating orthodontist, and thus would be unlikely to significantly impact mesio-distal root angulation change scores. This is the most likely explanation as the class I and II

malocclusions considered in this study were all non-extraction cases where the risk for major root movements are minimal (Honn & Goz, 2006; Proffit et al., 2013; Tuncay, 2006).

Finally, the use of elastics in conjunction with Invisalign® treatment did not significantly affect levels of root parallelism in this study's sample. 44 patients used elastics during treatment, whereas 57 patients did not. For the most part, elastics were used by the practicing orthodontist either for anchorage support or for mild class II correction. Thus, it was not the intention of the clinician to retract teeth for space closure, as this would be one common use of elastics in (Dixon et al., 2002). To this end, one would not expect extraction cases significant individual tooth movements associated with elastics use as the force from the elastics should be spread across the aligner for anchorage support (Boyd, 2008). This common practice of using elastics with Invisalign® whereby anchorage is increased is commonly used for staged distalization. Furthermore, isolating exactly what changes were attributed to the aligner vs. the elastics would be difficult to do given the multiple forces and moments occurring simultaneously. As well, accounting for the patient's level of cooperation with their elastics use would make it even more difficult to isolate an elastic effect on root parallelism.

5.5 LIMITATIONS

Although this study's sample provided a normal distribution across all groups, a larger sample could have added additional measures of statistical power to the results. However, given the lack of research regarding root

parallelism in Invisalign® treatment, this study can be viewed as a pilot study, whereby the attained sample of 101 patients was sufficient for this study's purposes. Moreover, in order to increase the sample size for possible future studies, it would be necessary to attain records from multiple orthodontic practices whose patients meet the inclusion criteria. Although sample size could be increased in this fashion, it would also create difficulties in controlling for consistency within acquiring patient records and Invisalign® treatment protocols as multiple orthodontists and their supporting staff would be involved.

Another limitation that can be argued for this study was the lack of information on patient-specific use of attachments and their associated teeth. All patients had attachments placed as per standard Invisalign® protocols by the treating orthodontist. However, which exact teeth had attachments and what type of attachment was used was not initially considered for this study. Given the nature of the results of this study whereby the root change scores for groups #12-11, #21-22, #46-45, and #35-36 did not prove to be statistically significant, perhaps it would be beneficial to include specific attachment details for these teeth as part of the inclusion criteria in future studies. In turn, additional measures of root parallelism could be assessed.

Chapter 6

Conclusions and Recommendations

6.1 CONCLUSIONS

With the exception of only four of the fourteen groups assessed (#12-11, #21-22, #46-45, and #35-36), Invisalign® was effective in improving levels of root parallelism in non-extraction cases. Moreover, providing consistent radiographic imaging protocols are followed and appropriate measuring tools applied, clinicians can reliably monitor and assess levels of root parallelism during non-extraction Invisalign® treatment. For those groups that produced statistically significant root change scores for improved root parallelism but did not produce high reliability scores (#16-15 and #25-26), clinicians should approach their panoramic radiograph evaluation with caution. To this end, reliability of assessing root parallelism around maxillary 1st molars is questionable. Furthermore, levels of root parallelism did not seem to be affected by age, gender, occlusion type, or use of elastics. In conclusion, Invisalign® remains an esthetic orthodontic treatment modality that clinicians may utilize in achieving root parallelism for non-extraction treatment.

6.2 RECOMMENDATIONS

1) Clinicians can use Invisalign[®] to provide small improvements on levels of root parallelism for non-extraction cases. Consistent protocols for taking panoramic radiographs must be followed and appropriate measuring tools

- should be used only for those groups deemed reliable under such evaluation methods.
- 2) The results of this study support the use of Dolphin's 4-point measuring tool to assess changes in root parallelism from pre- to post-treatment panoramic radiographs of the same patient, but not the evaluation of true root positions alone. For this diagnostic, clinicians would need to rely on CBCT imaging.

6.3 FUTURE STUDIES

- 1) Based on the results of this study, Invisalign[®] proved to be effective in improving root parallelism in non-extraction cases. A natural progression for this research would be to test Invisalign's[®] effectiveness in controlling root parallelism in extraction cases. In doing so, Invisalign's[®] ability to close the extraction space while maintaining ideal upright roots could be evaluated on multiple parameters.
- 2) It would also be beneficial to compare the effectiveness of measuring root parallelism using the clinical crown positions in ClinCheck® versus 2nd order root angulation measurements as seen in this study. This would serve to highlight the extent to which ClinCheck® can accurately predict root parallelism when compared to true root angulations.

Chapter 7

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Appendix A

Ethics approval certificate



UNIVERSITY | BANNATYNE CAMPUS OF MANITOBA | Research Ethics Board

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

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

Delegated Review

PRINCIPAL INVESTIGATOR: Dr. J. Nemes	INSTITUTION/DEPARTMENT: UofM/Dentistry	ETHICS #: H2014:237		
APPROVAL DATE:	EXPIRY DATE:			
August 8, 2014 August 8, 2015 STUDENT PRINCIPAL INVESTIGATOR SUPERVISOR (If applicable):				
Dr. F. Hechter				

PROTOCOL NUMBER: PROJECT OR PROTOCOL TITLE;
Root Parallelism in Invisalign Treatment

SPONSORING AGENCIES AND/OR COORDINATING GROUPS:
Self-funded

Submission Date of Investigator Documents:
August 7, 2014

HREB Receipt Date of Documents:
August 8, 2014

THE FOLLOWING ARE APPROVED FOR USE:

Document Name Version(if applicable)

Protocol:

Proposal submitted June 15, 2014l

Consent and Assent Form(s):
Informed Consent for the Orthodontic Patient

submitted August 7, 2014

Other: Data Capture Sheet

May 30, 2014

CERTIFICATION

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

HREB ATTESTATION

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

QUALITY ASSURANCE

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

CONDITIONS OF APPROVAL:

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



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

Bannatyne Campus Research Éthics Board

HEALTH RESEARCH ETHICS BOARD (HREB)

CERTIFICATE OF ANNUAL APPROVAL

PRINCIPAL INVESTIGATOR	₹:	INSTITUTION/DEPAR	TMENT:	ETHICS #:					
Dr. Jordan Nemes U of M/Denistry HS17741 (H2014:237)									
HREB MEETING DATE (If a	pplicable):	APPROVAL DATE:		EXPIRY I	DATE:				
		July 15, 2015		August 8,	2016				
STUDENT PRINCIPAL INVE	STIGATOR	SUPERVISOR (If appli	cable):						
Dr. F. Hechter									
200									
PROTOCOL NUMBER:	1	T OR PROTOCOL TITL							
NA		allelism in Invisalign Trea							
SPONSORING AGENCIES	AND/OR CO	ORDINATING GROUPS	5:						
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Submission Date of Investi	gator Docu		ne 16, 2015	e or Docu	ments.				
June 16, 2015									
June 16, 2015 REVIEW CATEGORY OF AI	NNUAL REV	/IEW: Full E	oard Review		Delega	ted Review 🛛			
REVIEW CATEGORY OF A			_	-	Delega	ted Review 🛚			
			_	USE:	Delega	ted Review 🛛			

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

Consent and Assent Form(s):

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

HREB ATTESTATION

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

QUALITY ASSURANCE

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

umanitoba.ca/research

CONDITIONS OF APPROVAL:

- 1. The study is acceptable on scientific and ethical grounds for the ethics of human use only. For logistics of
- performing the study, approval must be sought from the relevant institution(s).

 This research study/project is to be conducted by the local principal investigator listed on this certificate of approval. The principal investigator has the responsibility for any other administrative or regulatory approvals that may pertain to the research study/project, and for ensuring that the authorized research is carried out according to governing law.
- This approval is valid until the expiry date noted on this certificate of annual approval. A Bannatyne Campus Annual Study Status Report must be submitted to the REB within 15-30 days of this expiry date.
- Any changes of the protocol (including recruitment procedures, etc.), informed consent form(s) or documents must be reported to the HREB for consideration in advance of implementation of such changes on the Bannatyne Campus Research Amendment Form.
- Adverse events and unanticipated problems must be reported to the REB as per Bannatyne Campus Research Boards Standard Operating procedures.

 The UM HREB must be notified regarding discontinuation or study/project closure on the **Bannatyne Campus Final**
- Study Status Report.

Appendix B

Sample patient consent form



Informed Consent for the Orthodontic Patient

Patient's Name: Cookie Dough Responsible Party: Mr. Chocolate Chip

Onthodontics and Dentofacial Orthopedics is the dental specialty that includes the diagnosis, prevention, interception and correction of malocolusion, as well as neuromuscular and skeletal abnormalities of the developing or mature profacial structures. Dr. Luis Piedade is a specialist in Orthodontics who has completed tree additional years of graduate training in orthodontics at an accredited university after graducation from dental school.

The following information is important for you to have and understand. This information is routinely shared with all of our patients. We are excited about creating beautiful and healthy smiles. We also feel that anyone considering orthodontics should understand that orthodontic therapy has some risks and imilations. Our goel is to create the ideal smile, and we will do everything in our power to achieve that result. In dealing with the many differences in growth, development, genetics and patient cooperation, it is important to realize that perfection is not always possible. Sometimes, we must accept a functionally and

Before orthodonic treatment begins, it will be necessary to visit your family Dentist for a checkup and any necessary dental work. Once orthodonic treatment segms, you will be expected to continue to see your family Dentist for regular three- to six-month checkups and rountine care.

Orthodonic treatment usually proceeds as planned, and we intend to do everything possible to achieve the best results for every patient. However, we cannot quarantee that you will be completely satisfied with your results, nor can all complications or consequences be anticipated. The success of treatment depends on your cooperation in keeping appointments, maintaining good oral hygiene, avoiding loose or broken appliances, and following Dr. Luis' instructions carefully.

The length of treatment depends on a number of issues, including the severity of the problem, the patient's growth and the level of patient cooperation. The actual treatment time is usually close to the estimated treatment time, but treatment may be lengthened if, for example, unanticipated growth occurs, if there are habits affecting the dentofacial structures, if periodontal or other dental problems occur, or if patient cooperation is not adequate. Therefore, changes in the original treatment plan may become necessary. If treatment time is extended beyond the original estimate, additional fees may be assessed.

the mouth is very sensitive so you can expect an adjustment period and some discomfort due to the introduction of orthodontic appliances. Non-prescription dication can be used during this adjustment period.

kdverse Growth Pattern (Adverse Jaw Growth)

The Doctor is trained to estimate, not predict growth tendencies of their patients. They will design your orthodontic treatment taking into consideration these tendencies and attempt to modify and minimize any that are undesirable. Some individuals have a growth pattern that may improve or worsen the expected outcome for ormodonic treatment. The patient's actual growth experience may not be adequate or advantageous to achieve ideal treatment goals. Adverse growth is unpredictable in many cases and may increase treatment time and/ or affect the outcome of treatment. In some instances, Dr. Luis may recommend noval of teeth and/ or corrective law surgery to resolve and problems that have developed. If these undesirable growth changes occur after active treatment, d if they are substantial, they may require additional treatment with an additional fee for this treatment.

Some cases will require the removal of deciduous (baby) teeth or permanent teeth. There are additional risks associated with the removal of teeth which you ruid discuss with your family Dentist or oral surgeon prior to the procedure.

Some patients have significant skeletal disharmonies which require orthodontic treatment in conjunction with orthographic (dentofacial) surgery. There are additional risks associated with this surgery which you should discuss with your oral and/or maxillofacial surgeon prior to beginning orthodontic treatment.

These be aware that orthodontic treatment prior to orthographic surgery often only aligns the teeth within the individual dental arches. Therefore, patients intinuing orthodonic treatment without completing the planned surgical procedures may have a malocclusion that is worse than when they began

Decaicification and Dental Carles

Excellent one hygiene is essential during orthodontic treatment as are regular visits to your family Denist. Inadequate or improper hygiene could result in cavities, discolored teeth, periodental disease and/or decalcification. These same problems can occur without orthodontic treatment, but the risk is greater to an nativistual wearing braces or other appliances. These problems may be approvated if the patient has not had the benefit of fluoridated water or its substitute, or e patient often consumes sweetened beverages or foods.

The roots of some patient's leeth become shorter (resorption) during orthodontic treatment. It is not known exactly what causes root resorption, nor is it possible to predict which patients will experience it. However, many patients have retained teeth throughout life with severely shortened roots. If resorption is detected during enthadontic treatment, Dr. Luis may recommend a pause in treatment or the removal of the appliances prior to the completion of orthodontic treatment. Severe rescription can increase the possibility of premature tooth loss.

A both that has been traumatized by an accident or deep decay may have experienced damage to the nerve of the sooth. Orthodoxtic tooth movement may, in some cases, aggravate this condition. In some cases, root canal treatment may be necessary. In severe cases, the tooth or teeth may be lost.

Readite Orthogontics

Patient or Parent/Guardian Initials

Date: 20-Jan-2014

Periodontal Disease

Periodontal (gum and bone) disease can develop or worsen during orthodontic treatment due to many factors, but most often due to the lack of adequate oral hygiene. You must have your family Dentist, or if indicated, a periodontist monitor your periodontal health during orthodontic treatment every three to six months. If periodontal problems cannot be controlled, orthodontic treatment may have to be discontinued prior to completion and can cause bone loss.

Activities or foods which could damage, loosen or dislodge orthodontic appliances need to be avoided. This can result in orthodontic appliances being inhaled or swallowed by the patient. You should inform Dr. Luis of any unusual symptoms or of any loose or broken appliances as soon as they are noticed. Damage to the enamel of a tooth or to a restoration (crown, bonding, veneer, etc.) is possible when orthodontic appliances are removed. This problem may be more likely when esthetic (clear or tooth colored) appliances have been selected. If damage to a tooth or restoration occurs, restoration of the involved tooth/teeth by your dentist may be necessary.

Orthodontic headgears can cause injury to the patient. Injuries can include damage to the face or eyes. Patients must remove the elastic force prior to removing the headgear from the mouth so that it does not spring back. Refrain from wearing headgear in situations where there may be a chance that it could be dislodged or pulled off. Sports activities and games should be avoided when wearing orthodontic headgear.

Temporomandibular (Jaw) Joint Dysfunction

Problems may occur in the jaw joints, i.e., temporomandibular joints (TMJ), causing pain, headaches or ear problems. Many factors can affect the health of the jaw joints, including past trauma (blows to the head or face), arthritis, hereditary tendency to jaw joint problems, excessive tooth grinding or clenching, poorly

balanced bite, and many medical conditions. Jaw joint problems may occur with or without orthodonic treatment. Any jaw joint symptoms, including pain, jaw popping or difficulty opening or closing, should be promptly reported to Dr. Luis. Treatment by other medical or dental specialists may be necessary.

Impacted, Ankylosed, Unerupted Teeth Requiring Surgical Exposure

Teeth may become impacted (trapped below the bone or gums), ankylosed (fused to the bone) or just fail to erupt. These conditions can occur for no apparent reason and generally cannot be anticipated, impacted teeth can cause damage to adjacent teeth, as well as tooth loss. Treatment of these conditions depends on the particular circumstance and the overall importance of the involved tooth, and may require extraction, surgical exposure, surgical transplantation or prosthetic replacement. After surgical exposure, there is a slight possibility that an impacted both will not move because it is fused to the jaw bone (ankylosed). In these cases, the tooth may have to be extracted and replaced later with a proofhelic tooth or implant. Movement of impacted teeth can cause devitalization (loss of tooth vitality) that could require root canal treatment. Additional fees will apply to any procedures performed outside of our office.

You can expect minimal imperfections in the way your teeth meet following the end of treatment. An occlusal equilibration procedure may be necessary, which is a grinding method used to fine-tune the occlusion. It may also be necessary to remove a small amount of enamel in between the teeth, thereby "flattening" surfaces in order to reduce the possibility of a relapse.

As third molars (wisdom teeth) develop, your teeth may change alignment. Dr. Luis will monitor them during treatment and then later, your family Dentist will monitor them in order to determine when and if the third molars need to be removed.

Occasionally, patients can be allergic to some of the component materials of their orthodontic appliances. This may require a change in treatment plan or discontinuance of treatment prior to completion. Although very uncommon, medical management of dental material altergies may be necessary.

General Health Problems

General health problems such as bone, blood or endocrine disorders, and many prescription and non-prescription drugs (including bisphosphonates) can affect your orthodontic treatment. It is imperative that you inform Dr. Luis of any changes in your general health status.

Use of Totacco Products

Smoking or chewing totacco has been shown to increase the risk of gum disease and interferes with healing after oral surgery. Totacco users are also more prone to oral cancer, gum recession, and delayed tooth movement during orthodontic treatment. If you use totacco, you must carefully consider the possibility of a compromised orthodontic result. If any of the complications mentioned above do occur, a referral may be necessary to your family Dentist or another dental or medical specialist for treatment. Fees for these services are not included in the cost of orthodorisc treatment.

Due to the wide variation in the size and shape of the teeth, missing teeth, etc., achievement of an ideal result (for example complete closure of a space) may not be possible. Restorative dental seatment, such as eathetic bonding, crowns or bridges or periodontal therapy, may be indicated. You are encouraged to ask

Due to their brittle nature, ceremic brackets have been known to break on occasion. Ceramic braces on the lower teeth may cause wear of the opposing teeth if in contact, or if the patient is a heavy grinder. Enamel can be damaged when braces are removed, but is not common.

Lasers are sometimes used to remove excess gum tissue. Should laser treatment be needed results cannot be guaranteed.

A non vital or dead tooth is a possibility. A tooth that has been traumatized by a blow or other causes can die over a long period of sine with or without orthodortic treatment. A non vital tooth may flare up during orthodortic movement and require endodortic (root cane) treatment.

Temporary Anchorage Devices

Your treatment may include the use of a temporary anchorage device(s) (i.e. metal screw or plate attached to the bone.) There are specific risks associated with them. It is possible that the screw(s) could become loose which would require its/their removal and possibly relocation or representent with a larger screw. The screw and related material may be accidentally swallowed. If the device cannot be stabilized for an

Patient or Parent/Guardian Initials _____

adequate length of time, an alternate treatment plan may be necessary. It is possible that the tissue around the device could become inflamed or infected, or the soft sissue could grow over the device, which could also require its removal, surgical excision of the sissue and/or the use of antibiosics or antimicrobial rinses. It is possible that the screws could break (i.e. upon insertion or removal.) If this occurs, the broken piece may be left in your mouth or may be surgically removed. This may require referral to another dental specialist. When inserting the device(s), it is possible to damage the root of a tooth, a nerve, or to perforate the maxillary sinus. Usually these problems are not significant; however, additional dental or medical treatment may be necessary. Local anesthesic may be used when these devices are inserted or removed, which also has risks. Please advise the doctor placing the device if you have had any difficulties with dental anesthetics in the past. If any of the complications mentioned above do occur, a referral may be necessary to your family dentist or another dental or medical specialist for further treatment. Fees for these services are not included in the cost for orthodontic treatment.

Patient Cooperation

Lack of patient cooperation is the most common cause for compromised results. Instructions must be carefully followed. Crall hygiene, proper elastic wear, care of appliances, headgear wear, and keeping regular appointments are situations where problems most often arise. We encourage you to see your dentist every 3 to 6 months during orthodontic treatment for cleanings.

Relapse

Completed orthodontic treatment does not guarantee perfectly straight teeth for the rest of your life. Retainers will be required to keep your teeth in their new positions as a result of your orthodomic treatment. You must wear your retainers as instructed or teeth may shift, in addition to other adverse effects. Regular retainer wear is often necessary for several years following orthodontic treatment. However, changes after that time can occur due to natural causes, including habits such as longue thrusting, mouth breathing, and growth and maturation that continue throughout life. Later in life, most people will see their teeth shift. Minor irregularities, particularly in the lower front teeth, may have to be accepted. Some changes may require additional orthodontic treatment or, in some cases, surgery. Some situations may require non-removable retainers or other dental appliances made by your family Dentist.

Two-Phase Treatment

This phase of your child's early treatment is completed when the braces and/or appliances are removed, then a resting phase will begin. If retainers are used, they will be worn for only a short period because they can interfere with the eruption of the permanent teeth. Progress x-rays may be taken at regular intervals and are vital for the orthodorrist to monitor and guide your child's development. This resting phase may continue over several years. Once all or most of the baby teeth have come out and all or most of the permanent teeth have come in, another exam and consultation will be scheduled to evaluate if a second phase of treatment will be needed. At this time we will discuss a new treatment plan and fees for any future treatment. I understand that this is a two-phase treatment.

I hereby acknowledge that I have read and fully understand the treatment considerations and risks presented in this form. I also understand that there may be other problems that occur less frequently than those presented, and that actual results may differ from the anticipated results. I also acknowledge that I have discussed this form with the undersigned Orthodontist or Treatment Coordinator or Financial Coordinator and have been given the opportunity to ask any questions. I have been asked to make a choice about my treatment. I hereby consent to the treatment proposed and authorize Dr. Luis Piedade to provide the treatment. In addition, I give permission for dental auxiliaries to perform necessary treatment in Dr. Luis Piedade's absence in conjunction to the agreed upon treatment plan. I also authorize the orthodontist to provide my health care information to my other health care providers. I understand that my treatment fee covers only treatment provided by Dr. Luis Piedade, and that treatment provided by other dental or medical professionals is not included in the fee for my orthodontic treatment.

CONSENT TO UNDERGO ORTHODONTIC TREATMENT

I hereby consent to the making of diagnostic records, including x-rays, before, during and following orthodontic treatment, and to Dr. Luis Piedade and, where appropriate, staff providing orthodonic treatment described by the above doctor for the above individual. I fully understand all of the risks associated with the

Transferring from our Office

In the event you transfer out of our office or discontinue treatment, the amount of treatment rendered will be determined, and depending on your individual case, a refund to you or a final payment to us will be made based on a prorated amount. Invisalign: The case fee will be recalculated based on pre-treatment laboratory and set-up expenses along with the length of time in treatment. The minimum earned by and due to Dr. Luis Pledade will be \$3,000.00

Authorization for Release of Patient Information

I hereby authorize the Dr. Luis Piedade to provide other health care providers with information regarding the above individual's orthodorric care as deemed appropriate. I understand that once released, Dr. Piedade and staff has no responsibility for any further release by the individual receiving this information.

Consent to use of Records

I hereby give my permission for the use of orthodontic records, including photographs, made in the process of examinations, treatment, and retention for purposes of professional consultations, research, education, or publication in professional journals.

Signature of Patient / Parent / Guardian	Relationship to Patient
Print Name	have the legal authority to sign on behalf of
(Print Name)	(Print Patient's Name)
Signature of Orthodontist	Witness
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Appendix C

Data capture sheet

1	Patient number on master list	Pre-tx PAN Meas pre#16/15 pre		#12/11 pr	e#11/21 pre	e#21/22 pro	e#24/25 pre	e#25/26 pre	#46/45 pre	#45/44 pre	#42/41 pre	#41/31 pre	#31/32 pro	e#34/35 pr	e#35/36
1	2 4	3	10.1	2.8	2.6	0.7	7.3	4.8	8.1	5.5	1.5	0.2	10.4	8.8	7 6.2
1	5	3	3.5	5.6	3.7	7.3	9.8	2.1	2.9	7.2	4.5	5.8	5.1	7.2	3.7 5.3
11	9	4.4	10.9	4.5	0.6	3	8.6	5.3	2.9	7.3	2.1	2	1	12.9	3.2
17	11	2.1	3.4	12.9	11.5	8.8	1	2.6	0.5	3.7	0.9	4.2	1.1	4.3	6.7 2
19															4.2 0.7
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22	20	4	6.8	0.3	0.2	7.6	13.7	8.4	5.5	8.8	6.8	4.8	1.9	9.1	6.3
20	22	3.3	0.6	3.3	3.3	3.4	3	4.4	1.3	2.4	0.2	7.4	0	10.9	1
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29															8.8 4.9
10															5 4.8
22	30	8.6	6.8	5	3.7	1.8	2.2	2.3	3.3	1.5	4.5		2.6	6.1	0.2 5.8
35	32	2.7	8.8	0.2	2.9	6	4.2	2.8	10.3	3.3	4.9	0.7	2.7	12.3	8.1
38	35	1.9	0.8	2.3	1.9	0.3	2.7	0.9	4.7	2.8	3.1	0.5	5	3.9	7.2 5.4
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46	44	2.8	0.8	1.4	1.8	1.6	2	3.9	2.3	12.2	2.9	13.4	0.6	6.6	4.1 1.3
48	46	1.9	5.4	10.1	7.6	5	18.3	23.5	10.8	12.4	3.1	3.7	5.6	11.6	7.3 0.1
SO	48	3.3	1.2	2.6	2.3	3	1.7	1.7	0.6	2	2.8	6.7	0.1	1.6	4.1
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72	70	0.1	1.8	3.9	0.1	3.8	4.3	0.2	1.1	5.2	6.9	12.7	2.6	1.9	1.9 2.5
76	72	5		3	2.7	2.9	4.8	1.9	4.6	15	9.8	0.3	5.3	8.6	0.3 13.4
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80															2 11.5
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85	83	5.2	5.6	0.6	0.5	2.4	4.2	2.3	10.6	18.3	1.5	4.9	2.8	15.4	1.2
87	85	3.5	3.5	4.1	3.7	6.4	2	1.3	4.2	11.8	2.1	4.2	1	10.4	4.2 6
89 1.4 7.3 2.4 0.2 10.9 1.1 2.1 4.5 2.7 1 0.8 10.1 2 90 4.8 1.9 9.9 9.3 7.5 5 0.3 2.2 1.6 4.7 1.6 6.3 1.4 91 7.1 3.3 10.4 11.4 11.2 2 11.8 1.4 9.5 1.8 7.2 2.7 1.5 93 6.2 0.4 3.8 1.1 5.6 7.9 2.6 5.9 2.5 0.3 1.3 3.2 2 94 3.2 2.1 1 1.8 0.6 5.5 3.9 4.9 6.2 2.6 1.7 8.3 95 2.8 0.8 3.1 0.4 2.9 4 1.9 5.6 4.6 1 5.2 1.9 6.8 96 4 3.3 4.8 4 6.4 2.2 4.9 8.9 <t< th=""><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th>7.5 3.2</th></t<>															7.5 3.2
91 7.1 3.3 10.4 11.4 11.2 2 11.8 1.4 9.5 1.8 7.2 2.7 1.5 93 6.2 0.4 3.8 1.1 5.6 7.9 2.6 5.9 2.5 0.3 1.3 3.2 2 94 3.2 2.1 1 1 1 1.8 0.6 5.5 3.9 4.9 6.2 2.6 1.7 8.3 95 2.8 0.8 3.1 0.4 2.9 4 1.9 5.6 4.6 1 5.2 1.9 6.8 96 4 3.3 4.8 4 6.4 2.2 4.9 8.9 0.3 2.6 0.8 2.4 6.2 97 8.2 2.3 4.5 1.1 2.2 0.3 1.9 4.7 6.7 0.3 3.9 5.6 2.1 98 1.6 1.5 3 0.5 1.6 9.2 0.5 7 2.5 1.2 7.1 0.1 5.1 99 0.3 11.4 13.7 5 7.1 16.3 9.9 10.3 3.8 4.4 4.5 2.1 1.5 1.9 99 0.3 11.4 13.7 5 7.1 16.3 9.9 10.3 3.8 4.4 4.5 2.1 1.5 100 7.2 2.6 5.4 2 2.4 0.7 2.1 11.9 3 1.3 3.8 0.1 2.3 101 6.2 6.4 2.7 0.6 1.3 8 1.1 0.3 8 1.1 0.3 3.4 1.5 4.4 5.3 1 102 2.1 3.6 8.5 1.2 12.2 0.8 2.1 3.5 8.4 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 14 7.4 1.8 0.1 4.1 12.5 104 2 3.7 7.6 2.9 4.4 5.5 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 12.5 106 3.9 3.6 3.6 0.3 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 2.1 1.3 1.6 2.2 6.1 1.6 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 12 12.1 1.5 100 2 2.1 1.3 1.5 1.2 12.2 1.8 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0	88 89		7.3	2.4	0.2			2.4	4.5	2.7		0.0	40.4	-	3.3 3.7
93 62 0.4 3.8 1.1 5.6 7.9 2.6 5.9 2.5 0.3 1.3 3.2 2 94 3.2 2.1 1 1 1 1.8 0.6 5.5 3.9 4.9 6.2 2.6 1.7 8.3 95 2.8 0.8 3.1 0.4 2.9 4 1.9 5.6 4.6 1 5.2 1.9 6.8 96 4 3.3 4.8 4 6.4 2.2 4.9 8.9 0.3 2.6 0.8 2.4 6.2 97 8.2 2.3 4.5 1.1 2.2 0.3 1.9 4.7 6.7 0.3 3.9 5.6 2.1 98 1.6 1.5 3 0.5 1.6 9.2 0.5 7 2.5 1.2 7.1 0.1 5.1 99 0.3 11.4 13.7 5 7.1 16.3 9.9 10.3 3.8 4.4 4.5 2.1 1.5 100 7.2 2.6 5.4 2 2.4 0.7 2.1 11.9 3 1.3 3.8 0.1 2.3 101 6.2 6.4 2.7 0.6 1.3 8 1.1 0.3 3.4 1.5 4.4 5.3 1 102 2.1 3.6 8.5 1.2 12.2 0.8 2.1 3.5 8.4 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 1.4 7.4 1.8 0.1 4.1 12.5 104 2 3.7 7.6 2.9 4.4 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 105 0.3 3.3 2.6 4.1 0.6 2.7 6.5 12 2.1 1.3 1.6 2.2 6.1 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 3.2 3.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 1.3 1.6 2.2 6.1 109 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 111 2.8 2.5 1.6 2 8.8 3.2 5 1.8 0.2 5.8 11.8 9.6 6.5 8															0.8 1.5
95	93	6.2	0.4	3.8	1.1	5.6		2.6	5.9	2.5	0.3	1.3	3.2	2	7 1.4
97 8.2 2.3 4.5 1.1 2.2 0.3 1.9 4.7 6.7 0.3 3.9 5.6 2.1 98 1.6 1.5 3 0.5 1.6 9.2 0.5 7 2.5 1.2 7.1 0.1 5.1 99 0.3 11.4 13.7 5 7.1 16.3 9.9 10.3 3.8 4.4 4.5 2.1 1.5 100 7.2 2.6 5.4 2 2.4 0.7 2.1 11.9 3 1.3 3.8 0.1 2.3 101 6.2 6.4 2.7 0.6 1.3 8 1.1 0.3 3.4 1.5 4.4 5.3 1 102 2.1 3.6 8.5 1.2 12.2 0.8 2.1 3.5 8.4 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 1.4 7.4 1.8 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 5.1 1.4 7.4 1.8 0.1 4.1 12.5 104 2 3.7 7.6 2.9 4.4 5.5 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 12.5 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 12 2.1 1.3 1.6 2.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 10.8 0 1 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 2.2 0.1 2.2 3.5 5.1 10.9 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 11 2.8 2.5 1.6 2 8.3 2.5 1.8 9.6 6.5 8	95	2.8	0.8	3.1	0.4	2.9	4	1.9	5.6	4.6	1	5.2	1.9	6.8	5
99 0.3 11.4 13.7 5 7.1 16.3 9.9 10.3 3.8 4.4 4.5 2.1 1.5 100 7.2 2.6 5.4 2 2.4 0.7 2.1 11.9 3 1.3 3.8 0.1 2.3 101 6.2 6.4 2.7 0.6 1.3 8 1.1 0.3 3.4 1.5 4.4 5.3 1 102 2.1 3.6 8.5 1.2 12.2 0.8 2.1 3.5 8.4 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 1.4 7.4 1.8 0.1 4.1 12.5 104 2 3.7 7.6 2.9 4.4 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 12.5 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 2.1 1.3 1.6 2.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 16 5 0.4 0.4 1.4 1.2 1.8 1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 2 2.3 5.1 109 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 9.6 6.5 8	97	8.2	2.3	4.5	1.1	2.2	0.3	1.9	4.7	6.7	0.3	3.9	5.6	2.1	4.9 6.7
101 62 6.4 2.7 0.6 1.3 8 1.1 0.3 3.4 1.5 4.4 5.3 1 102 2.1 3.6 8.5 1.2 12.2 0.8 2.1 3.5 8.4 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 1.4 7.4 1.8 0.1 4.1 12.5 104 2 3.7 7.6 2.9 4.4 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 105 0.3 3.3 2.6 4.1 0.6 2.7 6.5 12 2.1 1.3 1.6 2.2 6.1 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 3.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 2 2.3 5.1 109 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4	99	0.3		13.7	5		16.3		10.3	3.8		4.5	2.1	1.5	1.4 11.2
102 2.1 3.6 8.5 1.2 12.2 0.8 2.1 3.5 8.4 0.1 0.7 2.7 7.9 103 12.3 8.2 3 6.2 8.6 3.4 3.5 1.4 7.4 1.8 0.1 4.1 12.5 104 2 3.7 7.6 2.9 4.4 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 12.5 105 0.3 3.3 2.6 4.1 0.6 2.7 6.5 12 2.1 1.3 1.6 2.2 6.1 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 3.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 2 2.3 5.1 109 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 11 2.8 2.5 1.6 2 8.3 2.5 1.8 9.6 6.5 8															0.3
104 2 3.7 7.6 2.9 4.4 5.5 5.5 0.2 7.2 0.3 3.4 0 4.1 105 0.3 3.3 2.6 4.1 0.6 2.7 6.5 12 2.1 1.3 1.6 2.2 6.1 106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 3.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 2 2.3 5.1 109 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 11 2.8 2.5 1.6 2 8.3 2.5 1.8 0.2 5.8 11.8 9.6 6.5 8															3.9 4.1
106 3.9 3.6 3.6 0.3 9.3 4.2 3.5 6.1 13 2 3.2 6.1 18.8 107 11.3 8.3 11.4 2.1 8.1 0.3 1 10.3 9.9 8.4 7.2 2.1 18.1 108 0 1 6.5 0.4 0.4 2.4 2.4 10.5 0.2 0.1 2 2.3 5.1 109 2.8 0.8 1.1 2 0.4 6.3 0.9 4.1 11 0.1 3.6 3.6 7.3 110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 11 2.8 2.5 1.6 2 8.3 2.5 1.8 0.2 5.8 11.8 9.6 6.5 8	104	2	3.7	7.6	2.9	4.4	5.5	5.5	0.2	7.2	0.3	3.4	0	4.1	0.8 6.2
108	106	3.9	3.6	3.6	0.3	9.3	4.2	3.5	6.1	13	2	3.2	6.1	18.8	7.5
110 1 8.8 6.2 2.8 7 7.7 1 6.5 6.4 3 1.2 5.3 11.4 111 2.8 2.5 1.6 2 8.3 2.5 1.8 0.2 5.8 11.8 9.6 6.5 8	108	0	1	6.5	0.4	0.4	2.4	2.4	10.5	0.2	0.1	2	2.3	5.1	8.7 2.8
	110	1	8.8	6.2	2.8	7	7.7	1	6.5	6.4	3	1.2	5.3	11.4	4.1 1.7
112 0.3 1.6 2.9 1.7 5.5 0.6 0.2 3.3 3.8 1.4 1.2 5.5 7.5	111 112	2.8 0.3	2.5 1.6	1.6 2.9	2 1.7	8.3 5.5	2.5 0.6	1.8 0.2	0.2 3.3	5.8 3.8	11.8 1.4	9.6 1.2	6.5 5.5	8 7.5	1 9.1
113 1.5 9.8 1.4 0.8 2.8 17.9 6.8 4.7 12.3 4.1 3 5.7 8 114 1.5 4.2 0.1 7.2 7.7 5.7 0.5 4.1 13.7 7.1 1.6 3.7 10.7	113	1.5	9.8	1.4	0.8	2.8	17.9	6.8	4.7	12.3	4.1	3	5.7	8	6.6 4.8
115 8.8 3.7 7 2.9 6.9 0.7 1.7 17.6 8.6 3.2 2.9 0.7 2.6 116 1.8 0.2 5.8 4.5 7.2 2.7 1.8 11.6 1 0.1 3.1 1.5 1.6	115	8.8	3.7	7	2.9	6.9	0.7	1.7	17.6	8.6	3.2	2.9	0.7	2.6	14.2 7.7
117 3.6 1.2 0.7 1.8 6.3 3.9 1.9 23.4 3.5 4.4 0.5 2.4 4.8	117	3.6	1.2	0.7	1.8	6.3	3.9	1.9	23.4	3.5	4.4	0.5	2.4	4.8	4.5
118 1.3 2.9 8.9 3.7 5.2 2.7 1 0.2 6.3 2 0.4 7.3 4.8 120 0.4 1.4 0.7 1.4 1.8 4.2 2.1 0.3 2.5 4.4 6.9 0 3.6	120	0.4	1.4	0.7	1.4	1.8	4.2	2.1	0.3	2.5	4.4	6.9	0	3.6	4 1.9
121 2.8 1.1 0.6 2.1 2.5 1.1 4.1 8.3 4.6 1.8 0.4 4.6 4.7 122 0.1 6 0.4 10.7 7.2 3.3 3.4 6.1 5.7 3 11.3 4.1 3.5															5.6 5.1
123 2.6 5.5 0.2 0.6 2.4 4.4 3.4 16.8 5.4 6.2 7 3.5 6.2 Total Sample Size, N = 101															9.2

1	Patient number on master list	Post-tx PAN M		oc+#13/11 ···	oc+#11/31 ::-	c+#21/22 ···	ne+#34/2F ···	ne+#3E/26	r+#46/4F	c+#4E/44 ~ - :	c+#42/41 ···	nost#41/21	nor##21 /22 ···	oct#2 <i>4</i> /2F	oct#25 /20
1	2														ost#35/36 13.3
1	4	3.1	7.4	4.5	7.9	0.6	0.7	3.7	4.7	1.1	4	6	1.6	3.1	9.5
10															2.8 3.8
11	9	10.2	3.1	4.8	2.5	3.6	2.4	7.2	9.1	1.8		5.9	2.3	1.4	7.5
13															6.6 1.8
13	16	3	0.7	5.7	3	7.6	3.5	2.3	8.4	5.5	4.7	7.5	1	7.3	2.6
12															3.8 4.1
27	19														4.2
20															7.6 5.6
20	22	0													0.9
20															0.2 1.8
20	26	0.8	1.1	6.2	4.6	4.6	0.9	1.5	5.3	9.7	3.9	1.3	4.7	6.6	8.1
28						-									6.3 8.7
11 0.8 0.2 4.6 0.5 4.6 0.5 4.6 0.2 1.2 2.3 0.3 4.4 4.5 4.7 1.8 0.5 0.6 1.3 1.3 1.3 1.2 1.2 1.3 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5	29	2.3	4.9	2.4	9.9	4.6	1	9.7	2.9	7.6	0.3	2.4	0.2	0.8	5.3
12															2.7 1.5
32 23 23 28 88 04 22 114 10 09 17 0 0 04 17 0 0 10 17 17 0 10 10 17 17 18 18 18 18 18 18 18 18 18 18 18 18 18	32	3.5	0	3.2	1.4	6.6	1.8	6.9	6.5	3.4	3.4	2.7	0.7	9.9	5.1
37 0.5 3.4 4.9 0.6 22 10.2 12.3 6.5 4 1.4 0.6 0.5 1.7 3 38 6.5 3.4 1.9 0.6 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5															1.5 4.1
180 556 16	37	0.5	3.4	4.9	0.6	2.1	10.2	1.2	6.5	4	3.4	0.8	0.5	1.7	3.1
40 04 36 76 59 68 55 22 37 128 12 17 63 108 22 31 14 4															2.3 0.5
46 133 39 2.1 18 1.5 1.1 33 2.6 0 0 0.2 18.4 6.2 2.4 1.1 4.6 0.3 1.1 1.1 1.1 1.1 1.1 1.1 1.1 1.1 1.1 1	42	0.4	3.6	7.6	5.9	6.8			3.7	12.8	1.2		6.3	10.8	2.9
46 05 23 69 79 42 148 21 1419 55 52 21 199 33 61 61 55 61 44 08 19 19 19 19 19 19 19 19 19 19 19 19 19															3.1 1.4
Main	46	0.5	2.3	6.9	7.9	4.2	14.8	2.1	14.9	5.5	2.1	3.9	3.8	6.1	5.7
Mo															1.4 0.7
S	49	0.6	0.9	2.2	2.3	7.7	2.6	1.3	0.9	10.5	2.5	3	1	2.6	2.4
10															3.5 1.1
54	52	6.2	4.6	7.6	1.6	2	1.2	0.8	8.8	4.8	4	2	4.8	2.4	6
55															9.5 7.2
57	55	0.8	2.8	3.7	4.8	4.4	3		7.1	3.3	1.6			5.5	3.6
99 0.3 2.9 8 4.9 8.2 19 2.1 3.1 4.4 2.9 0.4 0.8 13 13 60 0.0 0.5 2.6 4 11 2.8 1.9 2.1 3.9 1.9 1.2 1.19 3.4 2.3 1.1 6.7 7 61 28 1.4 2.8 0.7 0.2 0.2 0.2 0.3 3 0.0 5 2.1 1.9 0.4 1.8 2.3 3.3 62 1.3 1.2 3.7 1.9 1.9 1.9 1.9 1.9 1.9 1.9 1.9 1.9 1.9															6.5 4.7
61	59	0.3	2.9	8	4.9	8.2	1.9	2.1	3.1	4.4	2.9	0.4	0.8	1.3	4
62															7.8 0
66	62	2.1		7.2	9.7	1.5	0.1		7.6	11.8	2.2			4.3	4.2
66) 2.5 1.5 4.6 5.3 3.7 3.2 0.2 7 3.8 5.4 2.3 3.8 3.9 9. 66 67 4.8 3.4 7 4 4 8 3.7 2.4 7.4 4.6 2.1 3 2.5 3.2 8 68 0.9 4.2 8 3.3 9.9 0.7 8.8 12.1 9.9 12.2 0.2 12.2 3.8 4. 8 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0															3.3 5.5
Se	65	2.5	1.5	4.6	5.3	3.7	3.2	0.2	7	3.8	5.4	2.3	3.8	3.9	9.2
70															6 4.2
71															3.8
75															1.3
76 6.8 0.1 5.8 1 246 2.5 6.4 6 13.6 2.1 3.9 0.7 7.5 7.7 7.7 7.9 9.9 0.9 0.3 3 1.2 1.8 0.3 6 9.9 5.7 0.1 5.8 1 6.7 9.0 9.0 0.3 3 1.2 1.8 0.3 6 9.9 5.7 0.1 5.8 1 6.7 1.3 1.8 5.6 8.0 4.3 1.2 2.1 0.9 3.5 4.3 16. 8.7 5.3 0.2 2.9 4.9 13.8 5.8 1 8.2 0.7 3.6 1.3 11 1.7 12.4 3.8 3.6 6.5 1.6 0 2.3 6.9 4.9 13.8 1.8 1.8 1.8 1.8 1.8 1.8 1.8 1.8 1.8 1															9.3
Part															7.6
80															6.3
83															5.6
84 4.1 1.5 3.3 5.2 2.5 3 2 9.1 5.3 0.3 3 1.7 10.2 7.8 86 4.6 5.4 12.5 0.2 5.6 9.6 4.1 3.4 5.3 3 3.5 0.7 2.5 3.7 2.8 87 0.1 0.5 0.6 3.9 1.5 3.6 4.1 3.4 5.3 3 3.5 0.7 2.5 9.6 89 1 2.4 1.6 1.5 5.6 1.9 1 3.7 1.2 0.2 0.5 6.1 0.9 7.7 90 2.7 4.2 15 7.4 11 0.3 0.3 4 3.8 2.4 0.6 1.2 2.6 4.4 1.6 2.5 1.7 1.1 0.3 3 4 3.8 2.4 0.6 1.2 2.6 4.3 4.8 3.8 0.4 3.8 0.9 <t< th=""><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th>4.7</th></t<>															4.7
86 4.6 5.4 12.5 0.2 5.6 9.6 4.1 3.4 5.3 3 3.5 0.7 2.5 5 87 0.1 0.5 0.6 3.9 1.5 3.6 8.4 3.4 0.5 4.6 5.9 1.5 1.4 2.5 9.6 0 89 1 2.4 1.6 1.5 5.6 1.9 1 3.7 1.2 0.2 0.5 6.1 0.9 7.7 90 2.7 4.2 1.5 7.4 11 0.3 0.3 4 3.8 2.4 0.6 1.2 2.6 4 93 4.8 3.8 10.8 2.7 11.6 3.6 3 9.4 0.9 1.8 0.7 0.3 2.1 1.6 2.2 3.3 2.6 5.3 1.8 2.7 0.3 2.1 1.1 1.6 2.6 4.9 1.8 0.7 0.3 2.2 1.1															7.5
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118 3.5 2.2 7.9 4.7 8.2 3.3 1.4 0.6 5.7 3.3 3.3 4.7 2.4 0.0 120 0.9 3.1 1 0.6 1.1 2.8 2.6 0.4 0.8 5 4.3 4.2 4 0.0 121 0.4 1.8 0.4 1.8 6.7 1.3 0.7 4.6 8.9 2 0.9 5.3 1.1 122 0.9 1.5 1 2.7 2.5 0.3 1.8 8.4 1.8 2.1 5.3 2.3 0.5 6. 123 0.6 3 4.3 5 3 7.7 4.4 8.6 3.3 2.3 4.2 1.4 10 3.															6.2 8.9
121	118	3.5	2.2	7.9	4.7	8.2	3.3	1.4	0.6	5.7	3.3	3.3	4.7	2.4	0.5
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	122	0.9	1.5	1	2.7	2.5	0.3	1.8	8.4	1.8	2.1	5.3	2.3	0.5	6.2
	123 Total Sample Size, N = 101	0.6	3	4.3	5	3	7.7	4.4	8.6	3.3	2.3	4.2	1.4	10	3.8

Appendix D

Article submission to ANGLE

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Title	Root Parallelism in Invisalign® Treatment
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Manuscript Type	Original Article
Special Section	N/A
Corresponding Author	Jordan Nemes (University of Manitoba)
Contributing Authors	Frank Hechter , Luis Piedade , Reynaldo Todescan
Abstract	Objective: To assess root parallelism after Invisalign® treatment. Materials and methods: The sample consisted of 101 patients (mean age: 22.7 years, 29 males, 72 females) treated non-extraction with Invisalign® by one orthodontist. Root angulations were assessed using the 4-point angulation tool (Dolphin imaging®); the long axes of adjacent teeth were traced, yielding a convergence/divergence angle. Acceptable root parallelism was assessed if the root angulation did not converge/diverge more than 7 degrees. Sites evaluated: between 1st molars and 2nd premolars, 2nd and 1st premolars, lateral and central incisors, and between central incisors in all four quadrants. The average change in mesio-distal root angulation was assessed between pre- and post-treatment panoramic radiographs. Results: Paired t-tests were used to analyze the average change in mesio-distal root
Abstract	Results: Paired t-tests were used to analyze the average change in mesio-distal root

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