Arch expansion predictability using Invisalign®

By

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Abstract

OBJECTIVES: To investigate the predictability of transverse changes with Invisalign®.

MATERIALS AND METHODS: Sixty-four adult Caucasians patients were selected to be part of this retrospective study. Pre and post-treatment digital models created from an iTero® scan were obtained from a single orthodontist practitioner. Digital models from Clincheck® were also obtained from Align Technology® to measure the prediction models. Linear values of upper and lower arch widths were measured for canines, premolars and first molars. A paired t test was used to compare transverse changes planned on Clincheck® with the post-treatment measurements. Variance ratio tests were used to determine if larger changes planned were correlated with larger errors.

RESULTS: For every maxillary measurement, there was a statistically significant difference between Clincheck® and final outcome. ($P < .05$) For every lower arch measurement at the gingival margin, there was a statistically significant difference between the Clincheck® planned expansion and the final outcome. ($P < .05$) Points measured at the cusp tips of the lower arch teeth showed non-statistically significant differences between the Clincheck® prediction and the final outcome. ($P > .05$) Variance ratios for upper and lower arches were recorded as significant. ($P < .05$)

CONCLUSIONS: The mean accuracy of expansion planned with Invisalign® for the maxilla was 72.8%, (82.9% for the cusp tips and 62.7% for the gingival margins.) Lower
arch presented an overall accuracy of 87.7%, (98.9 % for the cusp tips and 76.4% for the gingival margins.) Clincheck® overestimates transverse changes by body movement; more tipping is observed.
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Dedication

This thesis is dedicated to my beautiful wife and our two amazing children. Thank you for making my life better every single day.
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1.1 Preamble

Although Invisalign® (Align Technology, San Jose, CA) was marketed for the first time in the United States in 1999, the concept of moving teeth with overlay appliances goes back to 1945 when Dr. H. D. Kesling described a flexible tooth positioning appliance. (Kesling; Tuncay, 2006; Wong, 2002) It was possible to accomplish various minor tooth movements with this appliance. Kesling predicted that major tooth movements would be possible with a series of positioners fabricated as the treatment progresses. (Phan & Ling, 2007)

Throughout the next decades, various improvements have been made to the concept. Clear Essix appliances alignment involving interproximal reduction was described by Sheridan. (Sheridan, LeDoux, & McMinn, 1993). It is in 1997 that two students of Stanford University came with the idea of combining Kesling’s and other’s principles with CAD-CAM technology to found Align Technology® and launch the Invisalign® system a few years later. (Tuncay, 2006)

The system is now available in more than 80 countries and has been used to treat over 1.5 million patients. (Align technology 2014). In their third quarterly report of 2014, Align Technology® reported having manufactured 167 million clear aligners since the company was founded. The
report also stated that there is now more than 91,500 Invisalign® trained doctors around the world. (Align Technology Q3 report 2014).

Invisalign® involves a series of plastic aligners that move the teeth. The aligners are removable and are made of 0.75mm thick polyurethane. (Ali & Miethke, 2012; Lagravere & Flores-Mir, 2005) Patients are to wear an aligner for a period of 1-2 weeks and then change to the next one. Each aligner is programmed to produce a precise movement on a tooth of about 0.15-0.25 mm. (Vlaskalic & Boyd, 2001) The stereolithographic technology is used to fabricate custom aligners from an impression or an intraoral digital image scanned in the dental office. Virtual models are set up by the company in order to elaborate digitally the treatment plan. Treatment mechanics are planned with a software named Clincheck® (Align Technology, San Jose, CA). It is a 3D visual representation of the practitioner treatment plan. Every stage of the treatment plan can be visualized from the software as an animation movie. (Tuncay, 2006) The series of digital models serves as a template to fabricate the aligners. Patient compliance is mandatory to achieve good results with Invisalign® and it is important for patients to wear their aligners 22 hours a day or more. (Malik, McMullin, & Waring, 2013)
Some reports suggest that Invisalign® should be used to treat non skeletal mild crowding cases. (Joffe, 2003) Others suggest it is suitable to treat moderately complex orthodontic cases. (Lagravere & Flores-Mir, 2005; Vlaskalic & Boyd, 2002)

Arch expansion is possible with Invisalign® and may be required as a perceived need to improve the aesthetics of the smile by broadening the dental arches, (Krishnan, Daniel, Lazar, & Asok, 2008) or as a mechanism to create space for resolution of crowding. (Lee, 1999; Womack, Ahn, Ammari, & Castillo, 2002). It can also be used as a way of correcting dentoalveolar posterior crossbites.

There is limited data to assess how much discrepancy there is between predicted and actual achieved movements. (Krieger et al., 2012) In a prospective clinical study by Kravitz (Kravitz, Kusnoto, BeGole, Obrez, & Agran, 2009), the mean accuracy of tooth movement in the anterior region was found to be 41% with Invisalign®. The following types of movements were studied: expansion, constriction, intrusion, extrusion, mesiodistal tip, labiolingual tip, and rotation. It was reported in the study that the most accurate movements were the rotation of maxillary incisors as well as lingual constriction of mandibular canines. As of January 2015, there seemed to be no study assessing the accuracy of Invisalign® in predicting transverse changes in the posterior region of the arches.
Align technology is reporting that 20-30% of their cases require mid-course correction or refinement. (Sheridan, 2004) On the other hand, some orthodontists have reported that 70-80% of their cases need a refinement, mid-course correction or conversion to fixed appliance. (Kravitz et al., 2009)

Given the scarcity of data in the literature, especially regarding to posterior transverse changes, the present study aims at comparing the Clincheck® treatment planning with the actual clinical outcome. Knowing the accuracy of the software at predicting changes could help the practitioner to anticipate the need of overcorrection, thereby reducing refinements, mid-course corrections and treatment time.
Many theories have been proposed to explain what motivates the patients in seeking orthodontic treatment. Themes such as transverse growth of the jaws, dental arch expansion, records needed to start Invisalign® treatment and previous methodologies to assess transversal changes of the dental arches will be covered in this section. This literature review will also cover the reasons why some patients want Invisalign® as an orthodontic treatment option. Studies about the predictability and limitations of Invisalign® will also be reviewed. Although the literature is vast on many of these topics, this paper will focus on transverse changes in the dental arches with the Invisalign® technique.

2.1 Normal transverse growth of the jaws
During normal growth, the dimension of jaws and dental arches increases in the three planes of space. Transverse growth of the mandible or maxilla, ends first, followed by
the length and height. Transverse growth of the jaws including dental arches is normally completed before puberty. Changes related to growth during adolescence does not affect or minimally affect the width of the dental arches. (Proffit, Fields, & Sarver, 2007) In 1999 Lee summarized arch width changes as follow:

1- Lower intercanine width does not increase after the age of 12 in the permanent dentition
2- The interpemolar width changes little after the age of 12.
3- From 12 to 15, very small changes in width in the molar area is seen only in males. (De Koch 1972)
4- Increase in width occurs mainly between the ages of 7 and 12

According to Bishara (Bishara, Jakobsen, Treder, & Nowak, 1997), no appreciable change in intermolar width occurs between 13 to 26 and 26 to 45 years. Intercanine and intermolar widths significantly increase between 3 and 13 years of age in both the maxillary and mandibular arches. After the complete eruption of the permanent dentition, there is a slight decrease in the dental arch widths, more in the intercanine than in the intermolar widths. The practitioner should either expect a slight decrease or no changes in arch width when the eruption of permanent dentition is completed (Bishara 1997) (figure 2.1 and 2.2)
Therefore, there is no increase in arch dimensions attributed to growth when studying orthodontic transverse changes in an adult population. In fact, a slowly progressive decrease, especially at the mandibular intercanine width, can occur as an individual ages.

Figure 2.1
Changes in intercanine maxillary and mandibular widths from age 3 to 45. A) maxilla  B) mandible  (Reproduced with permission from Bishara et al. 1997)
2.2 The basics of arch expansion

In orthodontics, different techniques can be used in order to increase dental arch perimeter. The aim can be to correct maxillary constriction, or resolve dental crowding. (Lagravere, Major, & Flores-Mir, 2005) One way to correct crowding is by reducing tooth mass with extractions. However since the 1960’s, a trend towards non-extraction treatment has gained popularity. Arch expansion has become a quite common approach to increase the perimeter of the dental arch without the need for extractions in cases of mild to moderate crowding (Buschang, 2006). This holds true especially in cases with concomitant maxillary constriction.

Figure 2.2 Changes in intermolar widths in the maxilla and in the mandible between the age of 3 and 45. A) maxilla B) mandible (Reproduced with permission from Bishara et al. 1997)
The incidence of transverse maxillary deficiency is estimated between 8% and 18% in children presenting for orthodontic consultation. (Gabriel de Silva Fo, Boas, & Capelozza, 1991) This incidence has not been reported for skeletally mature individuals, (Suri & Taneja, 2008), but it is expected to be similar or slightly higher in adults. After adolescence, treatment invariably requires surgically assisted palatal expansion. (Lagravere et al., 2005)

Maxillary arch expansion can be classified as orthodontic (or dentoalveolar), orthopedic, or surgically assisted. (Bell, 1982). In both orthopedic and surgical approaches, a combination of dental and skeletal changes is the commonly expected outcome. However, appliance design, activation protocol and overall planning shall focus on maximizing skeletal changes to correct maxillary constriction, regardless of the presence of a posterior crossbite.

Expansion with orthopedic appliances to open the midpalatal suture can be achieved relatively easily before and during adolescence. As the years pass, it becomes increasingly difficult to open the suture and obtain the desired skeletal effect. The probability of opening the midpalatal suture is close to 100% before the age of 15, but then gradually reduce with the gradual interdigitation of the suture. (Proffit et al., 2007). After this age, the expansion is not predictable, and a combination of dental tipping as
well as alveolar remodeling prevails in detriment of than skeletal movement. (Vanarsdall, 1999) Pain, soft tissue necrosis, tipping and extrusion of the maxillary teeth as well as periodontal problems and uncontrolled relapse may follow palatal expansion in skeletally mature adolescents or adults. (Graber, Vanarsdall, & Vig, 2005). A study by Krebs, (Krebs, 1964) has shown that the observed changes are increasingly dentoalveolar as an individual matures. They can be of the order of 50% skeletal and 50% dentoalveolar in children, but 35% and 65% in adolescents, respectively. That is why the recommendation of overcorrection of up to 50% was observed in the literature. (Vanarsdall, 1999) For mature teens or adults, if the maxillary deficiency is less than 5 mm, camouflage of the transverse dimension by dental tipping can be considered.

Orthopedic expansion can be accomplished rapidly or slowly (RPE vs. SPE). The objective of RPE is to use high forces to achieve maximal skeletal effects and less dental tipping. (Lima Filho & de Oliveira Ruellas, 2008) In 2005, a systematic review by Lagravère et al. concluded that RPE skeletal changes are statistically significant only if patients are treated before the peak of puberty. The purpose of SPE is to use more physiological forces to reduce the relapse potential. (Lima Filho et al. 2008). Profft et al. 2007 reported that 2-3 months after active expansion with RPE or SPE the overall result is similar.
When treating a patient with orthopedic expansion, palatal changes are more significant in the canine region than in the molar region with a ratio calculated at 3:2. This is the result of a combination of skeletal, dental and alveolar changes, as it is normally the case. (Vanarsdall, 1999)

Surgically assisted rapid palatal expansion (SARPE) allows fully grown patients to benefit from an opening of the midpalatal suture to reduce a severe transverse deficiency greater than 5mm. (Lagravère et al., 2005). It can be performed as a single procedure or associated with a segmental two-piece osteotomy of the maxilla with the aim of enhancing the amount of expansion. (Suri & Taneja, 2008) It was reported that the expansion by segmental maxillary osteotomy can be unstable, especially when trying to obtain more than 8 mm. In reality, this procedure has been reported to be the most unstable orthognathic procedure. (Proffit et al., 2007) On the other hand, SARPE was reported as being extremely stable or reasonably stable. (Bays & Greco, 1992; Pogrel, Kaban, Vargervik, & Baumrind, 1992)

According to Suri et al. in 2008, the indications for surgically assisted rapid palatal expansion for a skeletally mature patient with constricted upper arch are:

1. To increase the perimeter of the maxillary dental arch when correcting a posterior crossbite
2. As a preliminary procedure to widen the maxilla when segmental maxillary osteotomy is not recommended.

3. To provide space to resolve crowding when extractions are inappropriate.

4. To reduce dark buccal corridors when smiling.

5. When conventional orthopedic expansion failed at an earlier age.

6. When no other surgical movement is necessary while addressing the aforementioned problems.

At the mandible, orthopedic expansion is not feasible without distraction osteogenesis. (Guerrero, Bell, Contasti, & Rodriguez, 1997) In 1978, Schulhof et al. (Schulhof, Lestrel, Walters, & Schuler, 1978) summarized the recommendations for dentoalveolar expansion in the mandible as follows:

1. Intercanine dimension expansion poses the greatest risk of relapse following treatment.

2. First premolar width expansion has the best stable change potential.

3. First molars may be expanded to some extent, but this change tends not to affect arch length.

In those patients with mild transverse deficiency and/or mild crowding, dentoalveolar expansion is a possible avenue. Dentoalveolar expansion can be accomplished with
different orthodontic appliances containing orthodontic wires, elastics or devices to tip buccally the crown of posterior teeth. (Graber et al., 2005)

In a study by Ricketts et al. in 1982, it was calculated that for each mm of movement of the incisors, 2mm of extra space can be created to the perimeter in the dental arch. Expanding the intercanine width 1mm creates an extra 1mm of space in the dental arch perimeter. The same amount of expansion at the molar level adds 0.25 mm to the perimeter. Expansion with a Hyrax increases the arch perimeter by 0.7 times the changes induced in the interpremolar width. (Adkins, Nanda, & Currier, 1990)

Changes in the arch width and form will also have an impact on buccal corridor ratios. (Akyalcin, Erdinc, Dincer, & Nanda, 2011) Buccal corridors have been defined as the space between the buccal surfaces of the maxillary teeth and the corners of the mouth during smile. (Martin, Buschang, Boley, Taylor, & McKinney, 2007) An increase in arch width in the premolar area might help reduce the buccal corridor space. (Yang, Nahm, & Baek, 2008) According to Moore et al. (Moore, Southard, Casko, Qian, & Southard, 2005), laypersons found more esthetic the smiles of men and women with minimal buccal corridors when compared to larger ones. The same findings were observed when orthodontists were surveyed. (Akyalcin et al., 2011)
Whether is to correct maxillary constriction, a posterior crossbite, crowding or to improve smile esthetics, arch expansion is an important treatment modality in everyday orthodontics.

There are guidelines provided by Align Technology® on what type of malocclusion can be treated with Invisalign®. They claim that dental expansion can be delivered effectively when using aligners. (Boyd, 2008; Djeu, Shelton, & Maganzini, 2005; Pavoni, Lione, Lagana, & Cozza, 2011) In their 2001 publication on treatment of complex malocclusion using Invisalign®, Boyd and Vlaskalic reported that buccal expansion can be achieved with the aligners to alleviate crowding or to modify the arch form. The range of the expansion would be of 2-4 mm. It was expected that the expansion would be at the expense of more tipping than bodily movement. In an article by Ali et al., in 2012, it was stated that dentoalveolar expansion is possible with Invisalign and can be an alternative to interproximal reduction. According to the same authors, expansion of the dental arches should be limited to 2-3 mm of arch width per quadrant to minimize the risk of relapse and gingival recession. Malik et al. in 2013 reported that expansion is an indication to use Invisalign® when having to resolve 1-5mm of crowding. In the same paper, dental expansion using Invisalign® was reported to be indicated for blocked out teeth, but this was considered to be a more complex treatment. According to Phan and Ling (2007), greater success can be obtained when planning expansion with Invisalign® when treating non-skeletally constricted arches by tipping movement.
their prospective clinical study in 2009, Kravitz et al. studied dental expansion on the anterior teeth with Invisalign®. They came to the conclusion that dental expansion had an accuracy of 40.1%. In comparison, dental retraction was reported to be twice as accurate. They concluded that alleviating anterior crowding with Invisalign® is more accurate with interproximal reduction and retraction than with expansion and proclination. On the other hand Krieger et. al, in 2012, concluded that correction of the crowding in the anterior part of the arch with Invisalign® appears to be easy to implement and predict when using proclination and interproximal reduction.

2.3 Reasons why some patients prefer clear aligners such as Invisalign®

Although orthodontics offers the possibility of improving dentofacial esthetics, wearing an orthodontic appliance may temporarily interfere with esthetics. (Ziuchkovski, Fields, Johnston, & Lindsey, 2008) In the last decades many, appliances such as smaller brackets, ceramic brackets, plastic brackets, lingual braces and clear aligners have been developed to try to improve this issue. (Ziuchkovski et al. 2008). Aesthetic innovations of the orthodontic appliances could be one of the factors that explain the increasing demand of adults for orthodontics. (Jeremiah, Bister, & Newton, 2011)

Any aesthetic concern must be taken seriously when planning orthodontic treatment, especially for adult women. As clear aligners are used to maintain aesthetics without interfering with speech such as lingual appliances do, they have become a popular
choice among the adult population. (Ali & Miethke, 2012) In a study by Rosvall et al. (Rosvall, Fields, Ziuchkovski, Rosenstiel, & Johnston, 2009), people were asked to classify orthodontic appliances according to aesthetics, acceptability and value for money. In descending order of aesthetics, devices have been classified as follows: clear aligners and lingual appliances, ceramic brackets, self-ligating ceramic brackets and metallic brackets. The authors also concluded that people were willing to pay more for their orthodontic treatment if it is considered to be more aesthetic. Ziuchkovski et al. reported that lingual appliances and clear aligners had the highest rating of attractiveness compared to ceramic and metal brackets. It was also stated that these results could explain why these systems have gained such popularity in the last years. Although the popularity of aesthetic orthodontic appliances is rising, it was found in a survey by the British Lingual Orthodontic Society in 2009, that 72% of people were unaware of the existence of invisible braces. (Malik et al., 2013)

In another study on adults by Meier et al. (Meier, Wiemer, & Miethke, 2003), it was reported that 87% of those surveyed were seeking orthodontic treatment for aesthetic reasons and mainly to relieve anterior crowding. Of these, 62% reported being interested only in an invisible orthodontic solution.

2.4 Plaster models vs. digital models for treatment planning with Invisalign®
Dental models and measurements are an important part of diagnosis and treatment planning in orthodontics. Historically, orthodontists and other dental professionals
have used models made from plaster or stone. With adequate impression and pouring technique, these models can accurately reproduce the dentition and related oral structures. (Grunheid et al., 2014)

Technology now makes it possible to measure orthodontic models digitally on a computer. Previously, the only technique available was to measure directly on the plaster models using a ruler or calipers. The use of digital models allows to easily share information between different practitioners. Ability to visualize models from different perspectives specifically for transverse relation of models in occlusion is also an advantage. (Sousa, Vasconcelos, Janson, Garib, & Pinzan, 2012) Creating digital models is achievable by scanning plaster models, scanning of an impression or the direct acquisition of digital images. A study done by Grüheid et al. in 2014 reported that digital models are as accurate as plaster models. Moreover, the measurements done on digital models were reported to be more reproducible and faster than the ones done on plaster models. Santoro (Santoro, Galkin, Teredesai, Nicolay, & Cangialosi, 2003) also reported that digital models are an acceptable alternative to stone casts when it comes to model measurements. In a systematic review on the linear measurements of virtual models by Luu et al. (Luu et al., 2012), it was concluded that digital models are as valid as plaster models when considering the intra-rater reliability and validity. The systematic review by Fleming et al. (Fleming, Marinho, & Johal, 2011) also found that plaster and virtual models were as reliable. In a study by Sousa et al. in 2012 using Geomagic® (Geomagic,
Morisville, NC) software, the authors found that virtual models were as accurate as plaster in respect to transverse measures and length of the dental arch.

2.5 Itero® scanner
Three dimensional scanning of the dental arches offers the possibility to create digital study models for treatment planning in orthodontics. The models offers the practitioner the opportunity to visualize the arches, the position of the teeth and the occlusion in these dimensions. (AlignTechnology, 2014)

The Itero® scanner (Align Technology, San Jose, California) has been used in conjunction with the Invisalign® system since 2011. It avoids polyvinylsiloxane impression for the virtual planning process known as Clincheck®. According to the company, the use of scanner reduces by 10 times the rejection of impressions and by 7 times the problems related to poor adaptation of aligners. (www.itero.com). The Itero® scanner uses optical scanning and laser to capture the dentition, the gingival contours and the bite registration. (AlignTechnology 2014) Light is emitted at different wavelengths, making it possible to create an image and a three-dimensional separation of hard and soft tissues. (Garino, Garino, & Castroflorio, 2014). Acquisition is done through multiple images that are assembled together by a process called stitching. (Flugge, Schlager, Nelson, Nahles, & Metzger, 2013) In 2013, a study by Flügge et al. has shown that the accuracy of the Itero® scanner is adequate and that it can be used to
create virtual orthodontic models and treatment planning. Its accuracy would therefore be in the same level as that of the polyether which is of 61.3 ± 17.9 microns. In 2013, Akyalcin et al. (Akyalcin, Cozad, English, Colville, & Laman, 2013) verified the accuracy of the virtual models with the Itero ® scanner. They came to the conclusion that the digital models were accurate enough to be used as a diagnostic tool and to aid in the treatment planning in orthodontics.

Once the digital impression is sent to Invisalign®, the three dimensional study models are manipulated to achieve the final position of the teeth. Every stage of the treatment is represented by a .stl file. Files put together will produce an animation illustrating how the teeth should move within each aligner until completion of treatment.

2.6 Methods of transverse measurements and Geomagic Control®
Numerous studies on transverse dental arch changes brought different ways of measuring interdental widths. In 1982, McDougall et al. (McDougall, McNamara, & Dierkes, 1982) measured the changes in the upper arch width while wearing a Fränkel II type appliance. Changes in the transverse dimension were quantified by measurements between canine, first premolar, second premolars and first molars. They described the following points to measure dental and alveolar changes. (Figure 1).

- Lingual: at the cervical margin from the point of greatest convexity of a tooth to its contralateral.
- Buccal: at the cervical margin from the point of greatest convexity of a tooth to its contralateral.

- Alveolar measurements: buccally and 4.0 mm below the gingival margin from the point of greatest convexity of a tooth to its contralateral.

Figure 2.3 Interdental widths measurements. (Reproduced with permission from McDougall et al. 1982)

A study by Adkins et al. (Adkins et al., 1990) assessed the changes in arch perimeter after palatal expansion treatment. Point of greatest convexity of the tooth at cervical gingival margin was also used for this study. These points were used for the upper and lower canines, upper and lower premolars and upper molars. For the lower molars, the
central groove of the distal fossa was chosen as the reference point.

Handelman et al. (Handelman, Wang, BeGole, & Haas, 2000), investigated the use of a Haas-type appliance for palatal expansion. Transverse dimensions of the arches was calculated. The measurements were taken at the maximum convexity of the tooth at the gingival margin for canines, first and second premolars. For the molars, the point on the gingival margin adjacent to the lingual groove of the molar was selected. An additional measure at the upper molars was also collected; mesio-lingual cusp tip of a molar and its antimere. Mandibular measures were limited to the point of greatest convexity at the gingival margin.

McNamara et al. (McNamara, Baccetti, Franchi, & Herberger, 2003) studied the long-term changes of the arch dimensions after maxillary expansion followed by fixed appliances. One of the points used during measurement is called the centroid point. (Figure 2.4). To find the centroid point, a line connecting the buccal and lingual midpoints of a tooth (A) and a line connecting the mesial and distal midpoints of the same tooth (B) is drawn. The centroid point is located halfway between these two points. (C)
In 2006, Fleming et al. measured changes in the mandibular arch during the leveling and alignment phase. The points used to measure the interdental widths using a digital caliper were as follows:

- Canines: measured from the cusp tip to cusp tip
- First premolars: measured from the buccal cusp tip to buccal cusp tip
- Second premolars: measured from the buccal cusp tip to buccal cusp tip
- First molars: measured from the mesial buccal cusp tip to mesial buccal cusp tip

In case of wear facets at the cusp tip, the confluence of the inclined planes was estimated representing the cusp tip.
Prado et al., in 2014, studied the stability of the surgically assisted palatal expansion. They used Geomagic Qualify ® 12.0 (Geomagic, Morisville, NC) 3D imaging software.) When measuring transversal changes, the following points were selected:

- The distance between the palatal cusp tips of the upper first premolars.
- The distance between the mesio-lingual tips of the upper first molars.
- The distance between the most palatal points at the gingival margin of the first premolar and its antimere.
- The distance between the most palatal points at the gingival margin of the first molar and its antimere.

Virtual models created from an intraoral digital scanner are stored as stereolithography files (.stl). They can be exported into a software that has the capabilities to visualize and rotate the models for accurate measurements. Geomagic Control ® (Geomagic, Morrisville, NC) is a 3D design software that enables the use of these .stl files on a computer. The software is equipped with a digital caliper that allows for precise linear measurements to the hundredth of a millimeter.

2.7 Invisalign® limitations
Since Invisalign ® uses polyurethane trays that are removable, one of the greatest challenges facing the orthodontist is motivation and patient compliance. (Phan & Ling, 2007) Invisalign® recommends patients to wear the aligners for a minimum of 22 hours
per day. (Malik et al., 2013) Each aligner should be worn for a total of 400 hours before changing to next one. (Phan & Ling, 2007) Attempt in improving patient cooperation during treatment through a reward system yielded mixed results. Results showed a positive change in patient who were already above average in terms of compliance. Little effect was noted on below average cooperation patients. (Phan & Ling, 2007)

There is no possibility of achieving orthopedic changes when wearing aligners. It is therefore imperative to limit the choice of cases to those that need dental movements only. (Boyd, 2008) Furthermore, when establishing the final treatment plan on the ClinCheck® software, it is not possible to see the root of the teeth. It is therefore possible to decide on a crown position that seems appropriate while the root is not. It has been suggested that Invisalign® can be used to correct dental crossbites and mild anterior open bites (Boyd, 2008). On the other hand, crowding or spacing of more than 5 mm, dental expansion for blocked out teeth, molar uprighting, severe rotations and alignment of high canines have been reported as more difficult to treat with Invisalign®. (Malik et al., 2013)

In 2005, Lagravère et al. published a systematic review on the treatment effects of Invisalign®. They concluded that Invisalign® indications or limitations are not supported with scientific evidence. Randomized clinical trials would be needed to evaluate scientifically the clear aligner system. Hence, contemporary practitioners will
have to rely on the limited evidence presented so far, clinical experience and experts' opinions when using Invisalign®.

To date, some clinical studies such as, case series, retrospective studies and prospective studies have assessed the efficacy of the Invisalign® system. However, randomized controlled trials have not been completed yet. (Malik et al. 2013)

2.8 Predictability of Invisalign®

Clinical studies on the effectiveness and predictability of the Invisalign® system have been published to date. These studies are in limited number so far. In 2005, Djeu et al. compared the results of cases treated with braces with those treated with Invisalign®. Cases were graded using the scoring system of the American Board of Orthodontics. They concluded that Invisalign® was not as effective as conventional brackets. Treatment outcomes were graded 27% lower with Invisalign® when compared to conventional braces. The shortcomings of the aligners system were particularly posterior torque, occlusal contacts, overjet and anteroposterior occlusal relationship.

In 2009, Kravitz et al. evaluated the effectiveness of the movement of the anterior teeth using the Invisalign® technology. In this study, 37 patients were selected and a total of 401 teeth were analyzed. The movement predicted by the software was compared with the actual clinical performance. They came to the conclusion that the average accuracy
of the software was 41%. Tooth movements included in the study were: expansion, constriction, intrusion, extrusion, mesiodistal tip, rotation and labiolingual tip. The most predictable movement was lingual constriction (47.1%). The less predictable movement was extrusion with an average score of 29.6%. Overall movement of the mandibular canine was reported to be the most difficult to predict by Clincheck®. The authors also reported that rotations of more than 15 degrees of the maxillary canines are unpredictable.

In 2012, Krieger et al. published a study on the accuracy of dental movement in the anterior region. Resolution of the crowding was particularly studied. 50 patients aged between 15 and 63 years were included in this study. The average crowding was 5.39 mm in the upper arch and 5.96 mm in the lower arch. The authors concluded that even severe crowding can be corrected with Invisalign®. Therefore, the ClinCheck® software is an accurate tool for the clinician when it comes to plan tooth movement in the anterior region. Lastly, it was found that, in the anterior region of the arch, the movements in the transverse dimension were more predictable than in the vertical dimension.

There have been no studies assessing the accuracy of the Clincheck® software to predict the clinical outcomes when it comes to transverse changes in the posterior region of the arches.
Chapter 3

Purpose and Null hypothesis

3.1 Purpose
The purpose of this study is to investigate the predictability of transverse changes with the Invisalign® system.

3.2 Null hypotheses
1. There is no statistical difference between the treatment outcome and the expansion planned on Clincheck®.

2. There is no association between the amount of expansion planned on Clincheck® and the magnitude of error.

Objectives:

- To evaluate the difference between expansion planned on Clincheck® and the outcome

- To evaluate the association between the amount of expansion planned and the magnitude of error post-treatment. (or at first refinement)
Chapter 4

Material and methods

4.1 Ethics
Ethics approval certificate was delivered by the Bannatyne Campus Research Ethics Boards at the University of Manitoba on May 14th 2014 before the beginning of this study. (Appendix 1)

4.2 Sample size calculation
Assumption was made that 70 % of the expansion predicted would be achieved with a margin of error of 10%. Sample size calculation was based on a power of 0.8 and a confidence interval of 95 %. According to these numbers, the minimum sample size for this study would be 64. Sample obtained was 64.

4.3 Sample selection
Consent was obtained for each patient participating in the study. (Appendix 2) A second consent was also obtained to allow Align Technology® to release the files needed for the study. (Appendix 3). Every patient included in the study had previously signed the two consent forms.
The sample was obtained from a single specialist at an orthodontic practice in Adelaide, Australia. Patient’s age and gender as well as the three .stl files required (pre-treatment, predicted treatment and post-treatment) were recorded. Personal information was deleted from the data by an assistant who assigned a different identification number for every set of records included in the study.

Records were obtained randomly for patients who met the inclusion/exclusion criteria set below.

**Inclusion criteria:**

- Cases for which expansion had been planned, with or without posterior crossbite
- Cases with three .stl files available (pre-treatment, Clincheck®, post-treatment or first refinement)
- Permanent dentition with second molars fully erupted
- Completed growth (over 18)
- Any amount of crowding
- Good compliance during treatment as assessed by the practitioner
- Interproximal reduction (IPR) completed as prescribed in the treatment
- Aligners worn for 2 weeks at a time and then changed
Exclusion criteria:

- Midcourse correction
- Extraction cases
- Missing teeth
- auxiliary treatment (including elastics)
- Posterior IPR
- Any cases treated after the introduction of the Smart Track® material

The final sample size was 64 patients: 31 females and 23 males. Their mean age was 31.2 years. The age of the patients in the study ranged from 18 to 62 years old. (Table 4.1). Twenty of these patients had a dentoalveolar crossbite involving at least one tooth, mostly premolars. All patients had both arches treated with Invisalign® only. Mean treatment duration was of 56 weeks. The study only looked at the first round of aligners. No refinements were included.
<table>
<thead>
<tr>
<th>Gender</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>23</td>
<td>35.94</td>
</tr>
<tr>
<td>Female</td>
<td>31</td>
<td>64.06</td>
</tr>
<tr>
<td>Total</td>
<td>64</td>
<td>100</td>
</tr>
</tbody>
</table>

*Table 4.1 Gender distribution of the sample size*

4.4 Data Collection
The data was collected from an orthodontic practice in Adelaide, Australia and from Align Technology®. Pre and post-treatment digital models created from an iTero® scan were obtained for the sixty-four patients included in the study. Digital models from were requested from Align Technology® to measure the planning accuracy. Models obtained from Align Technolgy® were corresponding to the last worn aligner by the patient without overcorrection. Patient confidential data was de-identified by an assistant who assigned a unique number for each patient.

The digital .stl files from the iTero® scanner and Clincheck® were uploaded in Geomagic Qualify® software. Arch widths measurements using the software’s digital caliper were recorded by the primary investigator. Linear values of upper and lower arch widths were measured according to the following points:
• **Inter-canine width: (figure 4.1)**
  
  o Canine cusp tip to canine cusp tip on the contralateral side (mm)
  
  o Most lingual point at the cervical margin of the canine to the same point on the contralateral side (mm)

*Figure 4.1 Intercanine width: cusp tip and most lingual point at the cervical margin*

• **Inter-premolar (first and second) width: (figures 4.2-4.3)**
  
  o Lingual cusp tip of the premolar to the same point on the contralateral side (mm)
Most lingual point at the cervical margin of the premolar to the same point on the contralateral side (mm)

*Figure 4.2 Interpremolar width: lingual cusp tip of first and second premolar*

*Figure 4.3 Interpremolar width: Most lingual points at the cervical margin of first and second premolars*

- **Inter-molar width: (Figures 4.4-4.5)**
  
  Mesiolingual cusp tip of the first molar to the mesiolingualcusp tip of the first molar on the contralateral side (mm)
Most lingual point at the cervical margin of the first molar to the same point on the contralateral side (mm).

Figure 4.4 Intermolar width: Mesiolingual cusp tips

Figure 4.5 Intermolar width: Most lingual points at the cervical margins
Data was recorded for every interdental width on a Microsoft Excel® spreadsheet (Excel, Microsoft Corp., Redmond, WA, USA) at three different time points. The measurements were recorded pre-treatment, on the Clincheck® plan and at first refinement or post treatment if no refinement was done. In cases of wear, the point of the cusp tips was estimated. The following variables were recorded:

- Gender and age of the patient
- Intercanine, interpremolar and intermolar widths at cusp tip and gingival margin: pretreatment, from Clincheck® and at first refinement or post treatment.
- Presence of any crossbite presented by the patient.
- Mean treatment duration in weeks

4.5 Calibration
All the digital models were measured with Geomagic Qualify® (Geomagic Morisville, NC) by the principal investigator. To test the intra and inter-examiner reliability, 20% of the sample size was randomly chosen to be measured again 2 weeks after the first assessment. (Houston, 1982) Thirteen patients were re-measured by the principal investigator (JPH) and thirteen by another independent investigator (LD). The reliability of the measures was assessed by the mean of an interclass correlation coefficient (ICC) with the Shrout-Fleiss derivation. SPSS® (Statistical Package for the
social sciences) version 18.0 (IBM Corp., Chicago, USA) was the software chosen to analyze the data.

4.6 Statistical analysis
Normality of distribution was assessed using the QQ-plots method. A paired $t$ test to investigate if there was a statistical difference in linear measurements of each tooth between pretreatment and Clincheck® plan. Paired $t$ test was also selected to compare the Clincheck® plan with the post-treatment measurements. The test allowed to analyse if Clincheck® was reliable when planning the outcome of the treatment. This was done for every measurement, in order to analyse if there was a statistical difference in linear distance for a tooth at each measurement site. Level of significance was set at 5%. The amount of change achieved was also calculated in terms of percentage of accuracy of tooth movement. (Kravitz et al. 2009): Percentage of accuracy= $100\% - \left[\frac{(l_{\text{predicted}}-l_{\text{achieved}})}{l_{\text{achieved}}}\right] \times 100\%$. This equation ensures that the value calculated will not exceed 100%.

Variance ratio tests were used to determine if larger changes predicted was correlated with larger errors. (Tu, Baelum, & Gilthorpe, 2005) This was chosen to compare the amount of expansion predicted (pre-treatment - Clincheck®) to the difference between Clincheck® and the outcome at the end of treatment. (Clincheck®- post-treatment). Simple correlation could not be used because when comparing the variables, the
Clincheck® measurement prediction is present in both equations. Assumption was made that if there was an association between expansion planned and expansion obtained, variances should be almost equal.

Chapter 5

Results

5.1 Reliability and reproducibility
The ICC test showed almost perfect agreement in regards with inter rater reliability with a score of 0.97. The value 0.98 for the intra rater reliability also represented an almost perfect agreement. (Cicchetti, 1994)

5.2 Comparison between pretreatment measurements and Clincheck® plan
Pretreatment interdental widths were compared with those on the Clincheck® plan. The paired t test revealed a statistical difference between every pretreatment measurements and Clincheck® for both upper and lower arches. (Tables 5.1-5.2)
Table 5.1 Comparison between pretreatment and Clincheck® measurements for the upper arch

<table>
<thead>
<tr>
<th>Tooth type</th>
<th>Mean interdental pre-treatment widths (mm)</th>
<th>Mean interdental Clincheck® widths</th>
<th>Predicted change as per Clincheck® (mm)</th>
<th>SD</th>
<th>95% CI</th>
<th>Clincheck® vs. Pretreatment P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine tip</td>
<td>32.27</td>
<td>34.19</td>
<td>1.92</td>
<td>2.05</td>
<td>1.42-2.42</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>Canine gingival</td>
<td>22.44</td>
<td>24.29</td>
<td>1.85</td>
<td>1.76</td>
<td>1.41-2.28</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>1st premolar tip</td>
<td>27.86</td>
<td>31.63</td>
<td>3.77</td>
<td>2.34</td>
<td>1.90-4.19</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>1st premolar gingival</td>
<td>24.93</td>
<td>29.54</td>
<td>4.61</td>
<td>3.06</td>
<td>2.36-5.29</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>2nd premolar tip</td>
<td>32.93</td>
<td>37.04</td>
<td>4.11</td>
<td>3.06</td>
<td>2.36-5.29</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>2nd premolar gingival</td>
<td>29.86</td>
<td>34.31</td>
<td>4.45</td>
<td>2.56</td>
<td>2.20-4.80</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>First molar tip</td>
<td>37.86</td>
<td>37.14</td>
<td>3.28</td>
<td>2.13</td>
<td>2.51-4.04</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>First molar gingival</td>
<td>31.80</td>
<td>35.32</td>
<td>3.52</td>
<td>2.58</td>
<td>2.39-3.75</td>
<td>*&lt;0.001</td>
</tr>
</tbody>
</table>

*P <0.05

Table 5.2 Comparison between pretreatment and Clincheck® measurements for the lower arch

<table>
<thead>
<tr>
<th>Tooth type</th>
<th>Mean interdental pre-treatment widths (mm)</th>
<th>Mean interdental Clincheck® widths</th>
<th>Predicted change as per Clincheck® (mm)</th>
<th>SD</th>
<th>95% CI</th>
<th>Clincheck® vs. Pretreatment P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine tip</td>
<td>32.41</td>
<td>35.18</td>
<td>2.77</td>
<td>2.12</td>
<td>1.89-3.59</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>Canine gingival</td>
<td>22.31</td>
<td>25.19</td>
<td>2.88</td>
<td>2.12</td>
<td>1.93-3.68</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>1st premolar tip</td>
<td>27.83</td>
<td>32.73</td>
<td>4.90</td>
<td>2.88</td>
<td>2.79-5.11</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>1st premolar gingival</td>
<td>23.77</td>
<td>28.67</td>
<td>5.00</td>
<td>2.64</td>
<td>1.96-8.64</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>2nd premolar tip</td>
<td>31.87</td>
<td>36.94</td>
<td>5.07</td>
<td>2.64</td>
<td>2.20-8.32</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>2nd premolar gingival</td>
<td>28.98</td>
<td>33.56</td>
<td>5.58</td>
<td>2.51</td>
<td>1.96-8.56</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>First molar tip</td>
<td>36.23</td>
<td>37.34</td>
<td>1.11</td>
<td>1.99</td>
<td>1.46-2.73</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>First molar gingival</td>
<td>31.68</td>
<td>35.53</td>
<td>3.85</td>
<td>1.99</td>
<td>1.36-2.33</td>
<td>*&lt;0.001</td>
</tr>
</tbody>
</table>

*P <0.05

5.3 Comparison between Clincheck® and posttreatment measurements

A mean of planned transverse changes has been calculated as well as the mean difference between prediction and final outcome (Tables 5.3-5.4).

Results from table 5.3 show that for every maxillary measure, there was a statistically significant difference between Clincheck® and the final outcome. The lingual cervical margin at the first molar was the less accurate point with 52.9% (figure 5.1) of the movement achieved corresponding to a mean difference of 1.42 mm. The most reliable
area at predicting transverse change in the maxilla was the canine cusp tip with 88.9% of the change achieved, a mean difference of 0.22 mm. This difference is also statistically significant.

For maxillary measurements done at the cusp tip, the mean difference between the prediction and the outcome were as follows:

- Canine: 0.22 mm
- First premolar: 0.58 mm
- Second premolar: 0.75 mm
- First molar: 0.77 mm

For maxillary measurements at the gingival margin, the mean difference between Clincheck® and the final outcome were as follows:

- Canine: 0.60 mm
- First premolar: 1.09 mm
- Second premolar: 1.30 mm
- First molar: 1.42 mm
<table>
<thead>
<tr>
<th>Tooth type</th>
<th>Predicted change as per Clincheck® (mm)</th>
<th>SD</th>
<th>95% CI</th>
<th>Mean difference (Post-treatment - Clincheck®)</th>
<th>SD</th>
<th>CI 95%</th>
<th>Clincheck® vs. Post-treatment P Value</th>
<th>Accuracy of change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine tip</td>
<td>1.92</td>
<td>2.05</td>
<td>1.42-2.42</td>
<td>0.22</td>
<td>0.74</td>
<td>0.03-0.40</td>
<td>*0.0225</td>
<td>88.7</td>
</tr>
<tr>
<td>Canine gingival</td>
<td>1.85</td>
<td>1.76</td>
<td>1.41-2.28</td>
<td>0.6</td>
<td>1.02</td>
<td>0.34-0.85</td>
<td>*&lt;0.001</td>
<td>67.8</td>
</tr>
<tr>
<td>1st premolar tip</td>
<td>3.77</td>
<td>2.34</td>
<td>3.20-4.35</td>
<td>0.58</td>
<td>1.14</td>
<td>0.03-0.58</td>
<td>*0.001</td>
<td>84.7</td>
</tr>
<tr>
<td>1st premolar gingival</td>
<td>3.36</td>
<td>2.04</td>
<td>2.86-3.86</td>
<td>1.09</td>
<td>1.22</td>
<td>0.78-1.39</td>
<td>*&lt;0.001</td>
<td>67.6</td>
</tr>
<tr>
<td>2nd premolar tip</td>
<td>4.11</td>
<td>3.06</td>
<td>3.36-4.85</td>
<td>0.75</td>
<td>1.54</td>
<td>0.37-1.13</td>
<td>*&lt;0.001</td>
<td>81.7</td>
</tr>
<tr>
<td>2nd premolar gingival</td>
<td>3.45</td>
<td>2.56</td>
<td>2.83-4.08</td>
<td>1.3</td>
<td>1.61</td>
<td>0.90-1.7</td>
<td>*&lt;0.001</td>
<td>62.3</td>
</tr>
<tr>
<td>First molar tip</td>
<td>3.28</td>
<td>3.13</td>
<td>2.51-4.04</td>
<td>0.77</td>
<td>1.84</td>
<td>0.31-1.23</td>
<td>*0.001</td>
<td>76.6</td>
</tr>
<tr>
<td>First molar gingival</td>
<td>3.02</td>
<td>2.58</td>
<td>2.39-3.65</td>
<td>1.42</td>
<td>1.9</td>
<td>0.95-1.90</td>
<td>*0.001</td>
<td>52.9</td>
</tr>
</tbody>
</table>

*P <0.05

*Table 5.3 Predictability of change for maxillary measurements*
Table 5.4 shows that all the measurements done at the gingival margin at the lower arch have a statistical difference between the Clincheck® prediction and the final outcome. Prediction accuracy ranged from 61.0 % (canine) to 88.4% (first premolar) (figure 5.2). The mean difference from the Clincheck® to the final outcome on these teeth ranged from 0.27 mm (first premolar) to 0.65 mm (canine). Measurements at the cusp tips in the lower arch showed non-statistically significant differences between Clincheck® and the final outcome.
For mandibular measurements at the gingival margin, the mean difference between the prediction and the outcome were as follows:

- Canine : 0.65 mm
- First premolar : 0.27 mm
- Second premolar: 0.38 mm
- First molar : 0.54 mm

<table>
<thead>
<tr>
<th>Tooth type</th>
<th>Predicted change as per Clincheck®(mm)</th>
<th>SD</th>
<th>95%CI</th>
<th>Mean difference (Post-treatment Clincheck®)</th>
<th>SD</th>
<th>CI 95%</th>
<th>p-value</th>
<th>Accuracy of change (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine tip</td>
<td>1.39</td>
<td>1.84</td>
<td>0.93-1.84</td>
<td>-0.08</td>
<td>0.81</td>
<td>-0.28-0.12</td>
<td>0.430</td>
<td>100</td>
</tr>
<tr>
<td>Canine gingival</td>
<td>1.66</td>
<td>2.12</td>
<td>1.14-2.18</td>
<td>0.65</td>
<td>1.01</td>
<td>0.39-0.90</td>
<td>*&lt;0.001</td>
<td>61</td>
</tr>
<tr>
<td>1st premolar tip</td>
<td>2.47</td>
<td>2.88</td>
<td>1.77-3.18</td>
<td>0.07</td>
<td>0.96</td>
<td>-0.16-0.32</td>
<td>0.520</td>
<td>96.9</td>
</tr>
<tr>
<td>1st premolar gingival</td>
<td>2.3</td>
<td>2.64</td>
<td>1.65-2.94</td>
<td>0.27</td>
<td>1</td>
<td>0.02-0.52</td>
<td>*0.037</td>
<td>88.4</td>
</tr>
<tr>
<td>2nd premolar tip</td>
<td>3.07</td>
<td>3.12</td>
<td>2.30-3.83</td>
<td>0.07</td>
<td>1.15</td>
<td>-0.25-0.32</td>
<td>0.810</td>
<td>98.9</td>
</tr>
<tr>
<td>2nd premolar gingival</td>
<td>2.58</td>
<td>2.51</td>
<td>1.96-3.20</td>
<td>0.38</td>
<td>1.16</td>
<td>0.09-0.66</td>
<td>*0.012</td>
<td>85.5</td>
</tr>
<tr>
<td>First molar tip</td>
<td>2.14</td>
<td>2.38</td>
<td>1.56-2.72</td>
<td>0.03</td>
<td>1.33</td>
<td>-0.36-0.3-</td>
<td>0.849</td>
<td>100</td>
</tr>
<tr>
<td>First molar gingival</td>
<td>1.84</td>
<td>1.99</td>
<td>1.36-2.33</td>
<td>0.54</td>
<td>1.34</td>
<td>0.21-0.87</td>
<td>*0.002</td>
<td>70.7</td>
</tr>
</tbody>
</table>

*P <0.05 Table 5.4

Predictability of changes for mandibular measurements
Figure 5.2 Accuracy of transverse measurements in the mandibular arch:

a) cusp tip  b) cervical margin

Profile plots were generated to demonstrate the difference between Clincheck® planned expansion and the final outcome. If Clincheck® prediction was perfect, a straight line should be seen on the profile plots. The more prediction error there is, the higher the slope. (Figures 5.3-5.6)
Figure 5.3 Profile plots for cusp tip points maxillary arch a) canine b) first premolar c) second premolar d) first molar
Figure 5.4 Profile plots for gingival margin points maxillary arch a) canine b) first premolar c) second premolar d) first molar
Figure 5.5 Profile plots for cusp tip points mandibular arch a) canine b) first premolar c) second premolar d) first molar
Figure 5.6 Profile plots for gingival margin points mandibular arch a) canine b) first premolar c) second premolar d) first molar
5.4 Comparison between the magnitude of expansion planned and the magnitude of error.

Another objective of the study was to investigate if the magnitude of transverse change planned with Clincheck® was associated with the magnitude of error at the end of the treatment. The results are showing that this is not the case. We used variance ratios to test our hypothesis. Variance is not equal for any of the measurements done, meaning that larger expansion is not associated with larger prediction error. All the P values were recorded as significant for the variance ratio tests. (Tables 5.5-5.6)

<table>
<thead>
<tr>
<th>Tooth type</th>
<th>Ratio of variance</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine tip</td>
<td>7.66</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>Canine gingival</td>
<td>2.96</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>1st premolar tip</td>
<td>4.25</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>1st premolar gingival</td>
<td>2.82</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>2nd premolar tip</td>
<td>3.96</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>2nd premolar gingival</td>
<td>2.52</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>First molar tip</td>
<td>2.91</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>First molar gingival</td>
<td>1.85</td>
<td>0.02*</td>
</tr>
</tbody>
</table>

*P <0.05

Table 5.5 Variance ratios for upper arch measurements
<table>
<thead>
<tr>
<th>Tooth type</th>
<th>Ratio of variance</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canine tip</td>
<td>5.12</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>Canine gingival</td>
<td>4.43</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>1st premolar tip</td>
<td>8.91</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>1st premolar gingival</td>
<td>6.96</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>2nd premolar tip</td>
<td>7.32</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>2nd premolar gingival</td>
<td>4.72</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>First molar tip</td>
<td>3.2</td>
<td>≤0.001*</td>
</tr>
<tr>
<td>First molar gingival</td>
<td>2.22</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

*P < 0.05

Table 5.6 Variance ratios for lower arch measurements

Profile plots were generated to demonstrate that more change is not related with more prediction error for the sample studied. The profile plot is showing on the y axis the amount of expansion planned with Clincheck®. The x axis is the prediction error calculated after treatment. If Clincheck® would have predicted exactly the outcome for all the measurements at a point on a tooth, all the lines would point to zero on the right
side of the graph. If more change was correlated with more error, the slope would have been less when the change on the y axis is higher. (Figure 5.5-5.9)

Figure 5.7 Association between the magnitude of change and the prediction error for the cusp tip points in the maxillary arch a) canine b) first premolar c) second premolar d) first molar
Figure 5.8 Association between the magnitude of change and the prediction error for the gingival margin points in the maxillary arch a) canine b) first premolar c) second premolar d) first molar
Figure 5.9 Association between the magnitude of change and the prediction error for the cusp tip points in the mandibular arch a) canine b) first premolar c) second premolar d) first molar
Figure 5.10 Association between the magnitude of change and the prediction error for the gingival margin points in the mandibular arch a) canine b) first premolar c) second premolar d) first molar
Chapter 6
Discussion

The purpose of this study was to assess the reliability of Clincheck® when planning for transverse changes using Invisalign® as an orthodontic appliance. Expansion is one way to resolve crowding in an orthodontic treatment but it can also be utilized as a way to reduce buccal corridor space. (Yang et al., 2008)

An adult population was chosen as a sample for this study to avoid normal transverse growth of the jaws affect our results. As stated by Bishara et al. in 1997 the practitioner should not expect arch width change when the eruption of the permanent dentition is completed. It offered the possibility of measuring the effect on arch width of the aligners only.

There is only a limited number of studies comparing of Clincheck® to the outcome of the orthodontic treatment. (Kravitz et al., 2009; Krieger et al., 2012; Tuncay, 2006) From these studies, only a few assessed the expansion. (Kravitz et al., 2009; Tuncay, 2006) To our knowledge, as of July 2015 no study evaluated posterior expansion accuracy with Invisalign®.
6.1 Accuracy of Clincheck® prediction for transverse changes in the upper arch

Our results showed large variability depending on the tooth studied, the point of measurement and whether maxillary or mandibular arch was investigated. Transverse changes in the upper arch were found to be 72.8% accurate overall, 82.9% at the cusp tips and 62.7% at the gingival margins. The most accurate prediction was canine cusp tip with an accuracy of 88.7%, meaning that 0.22 mm of the 1.92 mm expansion requested was not achieved. (Table 5.1) This difference was statistically significant, but may not be clinically relevant. On the other hand, at the first molar gingival margin the accuracy was 52.9%. Almost half of the change planned at the gingival margin of the upper first molars did not occur (1.42 mm not realized compared to 3.02 mm planned). At the cusp tip of the same tooth, 0.77 mm of the 3.28 mm planned were not achieved with the aligners, an accuracy of 76.6%. Overall, the upper first molars were the teeth with lowest tracking accuracy. In fact, there was a trend observed in the upper arch showing that Clincheck® accuracy decreases when moving posteriorly into the arch. This difference is most likely the result of root anatomy, cortical plate thickness, higher mastication loading and greater soft tissue resistance from the cheeks in the posterior region.

The expansion planned in the upper premolars area was the largest of all the teeth. First premolar had a mean of 3.77 mm at the cusp tip and 3.36 mm at the gingival margin. The second premolar had 4.11 mm planned at the cusp tip and 3.45 at the gingival margin. The results for these teeth are similar with a mean achieved of 84.7%
(first premolar) vs. 81.7% (second premolar) at the cusp tips and 67.6% (first premolar) vs. 62.3% (second premolar) at the gingival margins.

6.2 Accuracy of Clincheck® prediction for transverse changes in the lower arch

The lower arch presented an overall accuracy of 87.7%, 98.9% at the cusp tips and 76.4% at the gingival margins. Cusp tip post-treatment measurements were all found to be close to 100% accuracy. (Table 2) In terms of gingival margin measurements, the lower canines were found to be the area with the biggest prediction error with 62% accuracy, followed by the molar (70.7%), the second premolar (85.5%) and the first premolar (88.4%). These differences were all found to be statistically significant. Results were different at the cusp tips where all the differences between Clincheck® and the clinical outcome were not statistically significant. This means that the software was able to predict accurately the amount of change that occurred. Better result in the lower arch may be explained by the fact that the amount of change requested is usually less than in the upper arch. Also, resistance is reduced given the fact that the upper arch is being expanded simultaneously.

The trend observed at the upper arch that Clincheck® accuracy decreases anterior to posteriorly, was not observed at the lower arch.
6.3 Magnitude of expansion and prediction error

It was found in the present study that more transverse change planned on Clincheck® is not associated with less accuracy. In other words, the tracking won`t necessarily be lower if the amount of change requested is larger. This needs to be interpreted with caution as the amount of expansion in this study was overall small. The largest amount of expansion was of 4.11 mm at the upper second premolar cusp tip. Lack of association may also derive from the experience of the clinician. Knowing the limitations of the appliance help to minimize errors.

According to (Phan & Ling, 2007) greater success can be obtained when planning expansion with Invisalign® when treating non-skeletally constricted arches by tipping movement, which is usually in the range of 0.1 mm and 5.0 mm. (Vanarsdall, 1999) A clinician might not want to try to treat skeletally constricted arches and expect the same accuracy. Also, the lowest expansion requested was 1.39 mm at the cusp tip of the lower canine. This correlates with recommendations from Schulof et al. (Schulhof et al., 1978) who stated that expansion of mandibular intercanine width poses the greatest risk of relapse following treatment.

A study by Duncan et al. 2015, assessing crowding reduction by buccal expansion with Invisalign®, found that pre-treatment arch width can show large variations while post treatment measurements do not vary as much. Pre-treatment arch form can possibly be utilized as a predictor of how much dentoalveolar expansion can be achieved in a
treatment. Lingually tipped teeth might offer more magnitude of expansion. This assumption would have to be verified in a future study. From our results, magnitude of expansion is not associated with less accuracy form Clincheck®

6.4 Comparison with other studies

To our knowledge no studies has been conducted on the predictability of transverse changes with Invisalign®. Kravitz et al. (Kravitz et al., 2009) reported 40.5 % accuracy of tooth movement for labial expansion of the anterior teeth. One of their recommendations was to treat cases with severe lower crowding mostly by IPR instead of dentoalveolar expansion. This recommendation comes from the finding that retraction is more accurate than dentoalveolar expansion of the lower anterior teeth. The higher accuracy found in this study may be explained by the fact that the database is coming from a single well experienced practitioner who has been working with the Invisalign® system for many years. Also, this study was completed a few years later than the study mentioned above. New versions of the software, changes in the algorithm and improvements to the technique may also explain why the accuracy of Clincheck® was found higher in our study. A new study looking at the accuracy of anterior teeth expansion would help validate this assumption.

Study by Kravitz et al. used digital model superimpositions to compare pre and post treatment models to the Clincheck® prediction. No posterior movement of the teeth
was allowed since the superimpositions of the models were made on the posterior teeth. It was a prospective study and patients were selected and monitored by the study team. This study is different by the means of being retrospective. Our investigation used the database of a single Invisalign® clinician and randomly selected the cases that were meeting our inclusion criteria.

Overcorrection aligners did not lead to bias in this study because every digital model requested to Align Technology was obtained before the overcorrection trays. No further expansion during overcorrection was planned for any of the patients included in the study. The clinician may have planned for expansion overcorrection during Clincheck® knowing that all the expansion required could not be obtained as requested. This was one of the recommendations from the Nguyen and Chen study (Tuncay, 2006) to think of overcorrection and even refinement in order to achieve the best results.

Geomagic® software was selected to make the linear measurements required for this study. The accuracy of Geomagic® to make linear measurements was demonstrated by Sousa et al. in 2012. Due to the very high values of ICC tests, it was possible to ascertain that linear measurements to assess transverse changes in digital dental arches is reproducible using Geomagic®. The software abilities include the possibility to rotate and magnify the digital models which may explain such high values for ICC test. (Duncan et al. 2015)
Two landmarks (cusp tip and gingival margin) were selected to represent transverse tipping and bodily movement respectively. Our data suggests that Clincheck® is predicting more bodily movement than Invisalign® actually can achieve. This conclusion is similar to Pavoni et al. in 2011 (Pavoni et al., 2011) who compared dentoalveolar expansion between Invisalign® and the Damon® system.

6.5 Clinical relevance

It has been reported that as much as 70% to 80% of the patients treated with Invisalign® would require a mid-course correction or a refinement. (Kravitz et al., 2009) These numbers are suggesting that the accuracy of treatment planning with Clincheck® is low. Mid-course corrections or refinement have some consequences: longer treatment time for the patient, increased chair and material time for the orthodontist and more manufacturing for Align Technology®. (Duncan et al. 2015) Some of these inaccuracies can come from practitioner inexperience with the technique, the software or patient compliance. Studies on the accuracy of Clincheck® may help reducing the rate of mid-course corrections and refinements.

Knowing that Invisalign® can achieve posterior transverse accurately can help the orthodontists in offering more aesthetic solutions for adults seeking treatment. It was
reported that Meier et al. in 2003 that 62% of the adults interested in orthodontic treatment would request only an invisible solution. Moreover, Ziuchokovski et al. (2008) reported that clear aligners have the highest rating of attractiveness compared to ceramic or metal brackets.

Even though accuracy found in this study was good, there was a statistical difference between Clincheck® prediction and the treatment outcome for all upper measurements. Upper molars had the lowest tracking accuracy with regards to expansion. It is important to note that no treatment auxiliaries such as cross bite elastics were used for any case included in the study. The clinician might want to think about an auxiliary when thinking about expanding in the molar area. Overexpansion planned on the software might also be an alternative that would help reduce refinements and mid-course corrections. Another point that the orthodontist might want to include in his treatment planning process is tipping of the teeth. It was found in this study that the teeth are more tipped than they are bodily expanded. The orthodontist might want to be careful when expanding teeth that are already tipped buccally.
6.6 Limitations of the study

There is some limitations involving doing a retrospective study about Invisalign® accuracy. Patient compliance being a known issue with the technique (Phan & Ling, 2007) we had to rely on the assessment of the practitioner to know if patients were compliant or not. On the other hand, having data from a single practitioner might have helped limiting this issue.

Another limitation of this study is that all the data is coming from a sample who was treated with Invisalign® before the introduction of the new Smart Track® material in October 2012. All cases treated with Invisalign® are now manufactured with Smart Track®. The new material was designed to deliver more constant force, higher elasticity, more precise fit and improved patient comfort. (Align Technology 2014). It is not clear how this change could affect results of a study on expansion.

The sample is coming from an adult Caucasian Australian population. The results may be interpreted with caution when looking at another population. Differences in bone architecture, gingiva and even root configuration may change the results. To date, there is no study comparing the efficacy of Invisalign® with people with different racial backgrounds.
In 2012, it was shown that linear measurements on .stl files converted from intraoral scanners is valid and reproducible. (Cuperus et al., 2012) It was not possible to find a study that assesses the reliability of measurements on digital model coming from Clincheck® (Duncan et al 2015). An assumption was made that quality of the file from Clincheck® is the same as the one coming from an Itero® scan.

This study is the first know to look at the reliability of posterior expansion using Invisalign®. Sample size included patients without dental crossbites and some with crossbites involving one or more teeth. It is not known if a dental crossbite involving one or more teeth would affect the accuracy of Clincheck® to predict the treatment outcome.

This study was designed only to assess the reliability of Invisalign® to produce the transverse changes that was planned by the orthodontist on the Clincheck® software. Stability of dentoalveolar expansion was not assessed here.

6.7 Revisiting the null hypothesis

Null hypothesis #1
There is no statistical difference between the treatment outcome and the expansion predicted by Clincheck®.
– There were statistically significant differences between the Clincheck® plan and the treatment outcome for all upper teeth and lower teeth at the gingival margin point. (p<0.05). Therefore, we reject the null hypothesis.

– There were no statistically significant differences between the Clincheck® plan and the treatment outcome for lower teeth at the cusp tip point. (p>0.05). Therefore, we accept the null hypothesis.

Null hypothesis #2

There is no association between the amount of expansion predicted and the magnitude of the error at first refinement or at the end of treatment.

– No association was found between the amount of expansion predicted and the magnitude of the error, the null hypothesis was accepted.
Chapter 7:

Conclusion

From the results obtained during this study it is possible to conclude that:

- The mean accuracy of dentoalveolar expansion planned with Invisalign® for the maxilla is 72.8%, 82.9% at the cusp tips and 62.7% at the gingival margins. Invisalign® becomes less accurate going from the anterior to the posterior region.

- Lower arch presented an overall accuracy of 87.7%, 98.9% for the cusp tips and 76.4% for the gingival margins. All cusp tip post-treatment measurements were found to have a non-statistical difference when compared to Clincheck®.

- Clincheck® prediction of expansion involves more bodily movement of the teeth than it can be seen clinically. More dental tipping was observed.

- Careful planning with overcorrection and other auxiliary methods of expansion may help reduce the rate of mid-course corrections and refinements, especially in the posterior region of the maxilla.
7.1 Recommendations

- Orthodontists can use Invisalign® when planning dentoalveolar expansion. However, practitioners might want to include overcorrection on upper teeth to reduce number of mid-course corrections or refinements. Treatments auxiliaries like elastics or pre-treatment expansion may be necessary, especially for upper molars.

- The clinician has to keep in mind that expansion is coming more from tipping and might be careful when expanding buccally tipped teeth.

- Requesting more expansion on a tooth during treatment planning on Clincheck®, will not necessarily result in less accuracy. A lot of factors are involved.

7.2 Future studies

- Invisalign® is a technique that evolves and changes rapidly. Comparing these results with a study done on Smart Track® material and new version of Clincheck® might show some differences.

- It would be of interest to do a similar study with pre-treatment arch forms placed in different groups to know if arch form has an influence on Clincheck® accuracy.

- While dentoalveolar expansion can be conducted successfully with Invisalign®, stability is something that would need to be studied. A 5 year follow-up that investigates long-term stability of the changes achieved would be of interest.
References


Appendices

Appendix 1
Certificate from Bannatyne Campus Research Ethics Boards at the University of Manitoba
Welcome To Our Office

**Personal Information:**

Title ______________

First Name ___________________________  Surname

______________________________

Preferred Name ___________________________  Male/Female

______________________________

Date of Birth _______________  Age ______  Occupation/School

______________________________

Home Address ___________________________  Phone (H)

______________________________  Phone

(W)______________________________  Phone (M)

Hobbies/Interests ___________________________

______________________________

Email Address

____________________________________

**Account Information (Parent/Guardian)**

Is the patient responsible for the account? Y/N

If NO, please continue with this section:

Title ______________

Relationship to Patient -

______________________________

First Name ___________________________  Surname

______________________________
Preferred Name ______________________     Male/Female

Home Address ______________________     Phone (H)

____________________________     Phone (M)

Email Address ______________________     Phone (W)

***Are there other Responsible Parties (eg. Other family members to receive correspondence and accounts)? Please list their details on the back of this form.

Referral/Health Insurance Information
Do you have private health insurance?  Y/N   Fund Name

Is this your first visit to an orthodontic practice? Y/N
Do you have siblings or family members who also attend this practice (please list names)?

How did you first hear about our practice?

Who is your dentist? __________________ Who is your GP?

Are you on Facebook? Y/N   Check out our page!!

Health Information

Do you suffer from:     Y     N
➢ Heart/Vascular Disorder     ☐     ☐
➢ Blood Disease/Bleeder     ☐     ☐
➢ Blood Pressure Problem     ☐     ☐
➢ Rheumatic Fever     ☐     ☐
➢ Arthritis     ☐     ☐
➢ Diabetes     ☐     ☐
Liver or Kidney Disease  ☐ ☐
PTO  ☐ ☐
Asthma  ☐ ☐
Epilepsy  ☐ ☐
Cold Sores  ☐ ☐
Hepatitis or HIV  ☐ ☐
Allergy/Hypersensitivity  ☐ ☐
Is there a possibility that you could be pregnant? ☐ ☐
Do you require antibiotic cover for dental procedures? ☐ ☐
Other (please give details)  ☐ ☐

________________________________________________________________________
________________________________________________________________________

I consent to having my x-rays, models and photographs published for continuing dental education purposes. ☐ ☐
I consent to Duncan Orthodontics using my images in social media networks and newsletter. ☐ ☐

Signature __________________ Relief to Patient __________________
Date __________

***Details of other Responsible Parties (if applicable):
Appendix 3

Invisalign® consent

INVISALIGN INFORMED CONSENT AND AGREEMENT FOR THE INVISALIGN® PATIENT

Notice to treating office: This form is to be signed by your Invisalign® patients prior to treatment and kept for your records and should not be sent to Align Technology, Inc.

PATIENT'S INFORMED CONSENT AND AGREEMENT REGARDING INVISALIGN® ORTHODONTIC TREATMENT
Your doctor has recommended the Invisalign system for your orthodontic treatment. Although orthodontic treatment can lead to a healthier and more attractive smile, you should also be aware that any orthodontic treatment (including orthodontic treatment with Invisalign aligners) has limitations and potential risks that you should consider before undergoing treatment.

DEVICE DESCRIPTION
Invisalign aligners, developed by Align Technology, Inc. (“Align”) consist of a series of clear plastic, removable appliances that move your teeth in small increments. Invisalign’s product line combines your doctor’s diagnosis and prescription with sophisticated computer graphics technology to develop a treatment plan which specifies the desired movements of your teeth during the course of your treatment. Upon approval of a treatment plan developed by your doctor, a series of customized Invisalign aligners is produced specifically for your treatment.

PROCEDURE
You may undergo a routine orthodontic pre-treatment examination including radiographs (x-rays) and photographs. Your doctor will take impressions of your teeth and send them along with a prescription to the Align laboratory. Align technicians will follow your doctor’s prescription to create a ClinCheck® software model of your prescribed treatment. Upon approval of the ClinCheck treatment plan by your doctor, Align will produce and ship a series of customized aligners to your doctor. The total number of aligners will vary depending on the complexity of your malocclusion and the doctor’s treatment plan. The aligners will be individually numbered and will be dispensed to you by your doctor with specific instructions for use. Unless otherwise instructed by your doctor, you should wear your aligners for approximately 20 to 22 hours per day, removing them only to eat, brush and floss. As directed by your doctor, you will switch to the next aligner in the series every two weeks or as directed by your doctor. Treatment duration varies depending on the complexity of your doctor’s prescription. Unless instructed otherwise, you should follow up with your doctor at a minimum of every 6 to 8 weeks. Some patients may require bonded aesthetic attachments and/or the use of elastics during treatment to facilitate specific orthodontic movements. Patients may require additional impressions and/or refinement aligners after the initial series of aligners.

BENEFITS
- Invisalign aligners offer an aesthetic alternative to conventional braces.
- Aligners are nearly invisible so many people won’t realize you are in treatment.
- Treatment plans can be visualized through the ClinCheck software.
- Aligners allow for normal brushing and food intake.
- Aligners do not have the metal wires or brackets associated with conventional braces.
- The wearing of aligners may improve oral hygiene habits during treatment.
- Invisalign patients may notice improved periodontal (gum) health during treatment.

RISKS AND INCONVENIENCES
Like other orthodontic treatments, the use of Invisalign product(s) may involve some of the risks outlined below:

(i) Failure to wear the appliance for the required number of hours per day, not using the product as directed by your doctor, missing appointments, and failing or not properly closed bands can lengthen the treatment time and affect the ability to achieve the desired results;

(ii) Dental tenderness may be experienced after switching to the next aligner in the series;

(iii) Gum, cheek and tongue may be scratched or irritated;

(iv) Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency;

(v) Tooth decay, periodontal disease, inflammation of the gums, or permanent staining (e.g. discoloration) may occur if patients consume foods or beverages containing sugar, do not brush and floss their teeth properly before wearing the Invisalign products, or do not use proper oral hygiene and preventative maintenance;
(v) The aligners may temporarily affect speech and may result in a nasality, although any speech impediment caused by the Invisalign® products should disappear within one or two weeks.

(vi) Alginers may cause a temporary increase in salivary or mouth dryness and certain medications can heighten this effect.

(vii) Attachments may be bonded to one or more teeth during the course of treatment to facilitate tooth movement and/or appliance retention. These will be removed after treatment is completed.

(viii) Teeth may require interproximal recontouring or sandblasting in order to create space needed for dental alignment to occur.

(ix) The bite may change throughout the course of treatment and may result in temporary patient discomfort.

(x) At the end of orthodontic treatment, the bite may require adjustment ("occlusal adjustment").

(xi) Supplemental orthodontic treatment, including the use of bonded bumpers, orthodontic elastics, auxiliary appliances/dental devices (e.g., temporary anchorage devices, sectional fixed appliances), and/or restorative dental procedures may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome.

(xii) Teeth which have been overlapped for long periods of time may be missing the gingival tissue below the interproximal contact once the teeth are aligned, leading to the appearance of a "black triangle" space.

(xiii) Aligners are not effective in the movement of dental implants.

(xiv) General medical conditions and use of medications can affect orthodontic treatment.

(xv) Health of the bone and gums which support the teeth may be impaired or aggravated.

(xvi) Oral surgery may be necessary to correct unwanted or severe jaw imbalances that are present prior to wearing the Invisalign product. If oral surgery is required, risks associated with anesthesia and proper healing must be taken into account prior to treatment.

(xvii) A tooth that has been previously traumatized, or significantly restored may be aggravated. In rare instances the useful life of the tooth may be reduced; the tooth may require additional dental treatment such as endodontic and/or additional restorative work and the tooth may be lost.

(xviii) Existing dental restorations (e.g., crowns) may become dislodged and require re-cementation or in some instances, replacement.

(xix) Short clinical crowns can pose appliance retention issues and inhibit tooth movement.

(xx) The length of the roots of the teeth may be shortened during orthodontic treatment and may become a threat to the useful life of teeth.

(xxi) Product breakage is more likely in patients with severe crowding and/or multiple missing teeth.

(xxii) Orthodontic appliances or parts thereof may be accidentally swallowed or aspirated.

(xxiii) In rare instances, problems may also occur in the jaw joint, causing joint pain, headaches or ear problems.

(xxiv) Allergic reactions may occur.

(xxv) Teeth that are not at least partially covered by the aligner may undergo supereruption.

INFORMED CONSENT

I have been given adequate time to read and have read the preceding information describing orthodontic treatment with Invisalign aligners. I understand the benefits, risks, alternatives and inconveniences associated with treatment as well as the option of no treatment. I have been sufficiently informed and have had the opportunity to ask questions and discuss concerns about orthodontic treatment with Invisalign’s product line with my doctor from whom I intend to receive treatment. I understand that I should only use the Invisalign product line after consultation and prescription from an Invisalign trained doctor, and I hereby consent to orthodontic treatment with Invisalign’s product line that has been prescribed by my doctor. Due to the fact that orthodontics is not an exact science, I acknowledge that my doctor and Align Technology, Inc. ("Align") have not and cannot make any guarantees or assurances concerning the outcome of my treatment. I understand that Align is not a provider of medical, dental or health care services.
Invisalign® Informed Consent and Agreement for the Invisalign® Patient

I understand that use of my Medical Records may result in disclosure of my “Individual Identifiable Health Information” as defined by the Health Insurance Portability and Accountability Act (“HIPAA”). I hereby consent to the disclosure(s) as set forth above. I will not, nor shall anyone on my behalf seek legal, equitable or monetary damages or remedies for such disclosure. I acknowledge that use of my Medical Records is without compensation and that I will not nor shall anyone on my behalf have any right or approval, claim or compensation, or seek or obtain legal, equitable or monetary damages or remedies arising out of any use such that comply with the terms of this consent.

A photostatic copy of this Consent shall be considered as effective and valid as an original. I have read, understood and agree to the terms set forth in this Consent as indicated by my signature below.

Signature

Name

Address

City

State

Zip

Witness

Signature of witness

If signature is under 18, the parent or legal guardian must also sign in right of assent.

Algin Technology

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Appendix 4

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TERMS AND CONDITIONS
Mar 04, 2015

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**Abstract**

OBJECTIVES: To investigate the predictability of arch expansion using Invisalign®, MATERIALS AND METHODS: Sixty-four adult Caucasians patients were selected to be part of this retrospective study. Pre and post-treatment digital models created from an IntraScan were obtained from a single orthodontist practitioner. Digital models from Clincheck® were also obtained from Align Technology®. Linear values of upper and lower arch widths were measured for canines, premolars and first molars at two different points; lingual gingival margins and cusp tips. A paired t test was used to compare expansion planned on Clincheck® with the post-treatment measurements. Variance ratio tests were used to determine if larger change planned was associated with larger error. RESULTS: For every maxillary measurement, there was a statistically significant difference between Clincheck® and final outcome, (P < .05) with prediction worsening toward the posterior region of the arch. For the lower arch measurements at the gingival margin, there was a statistically significant difference between the Clincheck® planned expansion and the final outcome. (P < .05) Points measured at the cusp tips of the lower arch teeth showed non-statistically significant differences between Clincheck® prediction and the final outcome. (P > .05) Variance ratios for upper and lower arches were significant (P < .05). CONCLUSIONS: The mean accuracy of expansion planned with Invisalign® for the maxilla was 72.8%. Lower arch presented an overall accuracy of 37.7%. Clincheck® overestimates expansion by body movement, more tipping is observed. Overcorrection of expansion in the posterior region of the maxillary arch seems appropriate.

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