ROBOTICS IN ORTHODONTICS: EFFICACY OF CAD/CAM-MANUFACTURED ARCHWIRES IN PREDICTING AND IMPLEMENTING CLINICAL OUTCOMES

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ABSTRACT

Introduction: The advent of intraoral scanning, computer-aided design and manufacturing, and three-dimensional radiographic imaging has made orthodontic diagnosis and treatment planning more comprehensive and multi-dimensional. With the aid of such advances, the SureSmile® technology eliminates manual wire bending performed by the orthodontist through robotically fabricated wires. These wires incorporate all the requisite bends to achieve the tooth movements desired by the clinician. The purpose of this retrospective study was to evaluate the accuracy of the tip and torque virtual predictions that are expressed by the robotically manufactured wires of SureSmile®.

Materials and Methods: CBCTs taken after treatment using the SureSmile® technology were procured from a private practice. These CBCT images were superimposed with the predicted tooth positions using stable skeletal structures in the Dolphin Imaging Software. The tooth apex and crown were digitized and used to calculate tip and torque values for each tooth type. A paired samples t-test was performed to assess if differences in tip and torque values are present between the predicted and actual final outcomes.

Results: 16 patients were utilized in this study, which encompassed evaluation of 339 teeth. Paired samples t-test show that: 1) SureSmile® predictions of most teeth were statistically similar to the actual clinical outcomes (p≥0.05); however, 2) torque expression on upper canines (p=0.003) and lower lateral incisors (p=0.007) were not accurately predicted.
**Conclusions:** SureSmile® archwires can reliably predict tooth tip and torque positions and translate them to clinical movements for most of the types of teeth studied. It is recommended that overcorrections for upper canine torques and lower lateral incisors are incorporated into the planned movements if the clinician deems it clinically necessary.

Keywords: Computer-assisted treatment, SureSmile, robotics, Treatment effectiveness, Predicted outcomes, Virtual treatment plan, Whole tooth inclination and angulation, Cone-beam computed tomography
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CHAPTER 1
INTRODUCTION

In orthodontic treatment, the parallel alignment of the tooth roots in their correct axial inclinations is important to establish a stable occlusion (Bouwens, 2011). In Lawrence F. Andrews’ publication in 1972, he defined the six keys to normal occlusion based on 120 casts of patients with teeth that (1) had never had orthodontic treatment, (2) were straight and pleasing in appearance, (3) had a bite which looked generally correct, and (4) in his judgement would not benefit from orthodontic treatment (Andrews, 1972). These factors supplemented and augmented Edward Angle’s classic guideline that the cusp of the upper first permanent molar must occlude in the groove between the mesial and middle buccal cusps of the lower first permanent molar (Angle, 1897). Andrews’ six keys of occlusion included:

1. Molar relationship where the distal surface of the distobuccal cusp of the upper first permanent molar occludes with the mesial surface of the mesiobuccal cusp of the lower second molar.

2. Crown angulations (mesiodistal tip) where the gingival part of the long axis of the crown is distal to the incisal part of the axis. The extent of angulation varies according to tooth type.

3. Crown inclinations (labiolingual, buccolingual) such that the incisors are at a sufficient angulation to prevent overeruption. Upper posterior teeth where the lingual tip is constant and similar from canine to second premolar and increased in the molars. Lower posterior teeth where the lingual tip increases progressively from the canines to the molar.
4. Rotations are not present.

5. There are no interdental spaces, and

6. There is a flat plane of occlusion.

Using the guidelines that Andrews and Angle reported, specific mesiodistal, faciolingual and in/out angulations and positions for optimal esthetics and stability is now available for each tooth type. Conventional straight-wire process employs brackets with already pre-defined first, second and third order prescriptions that incorporate these ideal angulations. Even with these advances in bracket and wire manufacturing to ensure ease of treatment, however, clinicians are still limited by the patient’s individual biological limitations such as skeletal and soft tissue features. The jaw shape, bone density, tooth size, and other considerations are still the limiting factors cannot be easily overcome by these advances. For example, tooth shape and size differences do not always allow the clinician to express the proper prescriptions built in to these brackets (Balut, 1992 & Bryant, 1984). In addition, it has been extensively shown in literature that it is difficult to anticipate the exact amount of torque that is expressed on the bracket by the wire due to numerous factors such as bracket placement, variations in tooth structure, and mechanical limitations such as play between the bracket slot and the arch wire. Typically, the clinician overcomes these mechanical limitations by adding additional torque, tip and rotation bends to the prefabricated straight wires. These techniques are usually applied at the end of treatment to achieve the best results possible for the patient. Wire-bending with high accuracy requires experience, time and dexterity. Oftentimes, introduction of
these manual bends might introduce error and unwanted side effects and tooth movements that could prolong treatment time and compromise the overall treatment.

The advent of intraoral scanning, computer-aided design and manufacturing, and accessible three-dimensional imaging has made orthodontic diagnosis and treatment planning more comprehensive and multi-dimensional. Similarly, the proliferation of new technology and innovations available to clinicians make it possible to improve clinical outcomes and increase patient satisfaction.

One of the solutions to minimize manual wire bending is offered by SureSmile® (Orametrix, Richardson, TX). The company utilizes a computer-aided method to facilitate the finishing stages of orthodontic treatment. They employ robotics to create bends in straight arch wires to achieve the clinician’s desired final results. Automation of the bending mechanism can potentially minimize error and side effects that can be caused by the clinician-added bends on the finishing wires. SureSmile® utilizes standard treatment mechanics where any brand of brackets and bands are employed. No special consideration needs to be taken into account with regards to bonding and/or appliance placement prior to SureSmile® treatment. Another benefit of SureSmile® is that the virtual model provides an accurate 3-dimensional representation of the anatomical boundary when the initial scan provided is a CBCT. The rendering provides insights on the initial and final positions of the root with respect to its alveolar housing before and after treatment, respectively. The use of SureSmile® requires significant treatment planning before wire manufacture and delivery. Further, there is a great deal of emphasis is placed on the concepts of biomechanics, familiarity on the limits of biological systems, and the ability to accurately visualize and predict tooth movement in all three planes of
Clinicians, however, must be able to determine what is possible – biologically and mechanically – versus what is shown digitally on a virtual simulation and deduce decisions and modifications based on these limitations.

The SureSmile® process begins by capturing a 3D image of the patient’s tooth and bracket positioning at the beginning of SureSmile® treatment. This can be done with either an intraoral optical scanner or a cone beam computerized tomography (CBCT) scan. The scan data captures the current placement of the brackets and bands on each tooth. From the scan, SureSmile® constructs the therapeutic model. The clinician can then manipulate the teeth as independent objects in three dimensions using the software controls (Mah, 2001). This process to manipulate digitized teeth and simulate orthodontic tooth movement is similar to what ClinCheck™ by Invisalign® employs for their aligner treatment. Similar to ClinCheck™, the amount of tooth movement that is planned in the x, y, and z directions can be displayed, and the corresponding predicted difficulty can then be estimated based on this. In addition, the clinician or operator can simulate different treatment modalities, such as interproximal disking, extraction, and elastic wear.

Lastly, the SureSmile® software then take into account the tip, torque and offset prescriptions built into the bracket to simulate the movements desired by the clinician. The software also has the ability to calculate and apply a “slot-filling torque” compensation to the wire that will overcome the slot play for idealized tooth positions.

All the information is then used to fabricate bends in archwires using automated robotic machines. The bends are custom-made to the specific bends, geometry, and torque required to move the patient’s teeth to its final position based on the virtual treatment plan as dictated by the clinician. The wire-bending robots process thermally
activated shape memory alloy wires that allow for large working ranges (Larson, 2013). Previous studies have shown that the precision of the bends and twists in the stainless steel wires has a less than 1° of error (Mah, 2001). The wire size, material, and properties (such as stiffness and modulus of elasticity) can be changed based on clinician preferences. Based on this information, force values applied to each tooth can be estimated and appropriate changes to wire size and material, as well as the degree of correction desired in each wire, can be made.

In summary, the usual treatment sequence for SureSmile® is as follows:

1. Patients are bonded with the doctor’s bracket system of choice. The SureSmile® treatment can begin at this point, or alternatively, some initial leveling, aligning, and space closure can be done prior to starting SureSmile® treatment using stock wires.

2. At some point during treatment, an intraoral optical scanner or CBCT scan is captured to initiate the SureSmile® protocol.

3. The clinician will simulate desired movements and final positions of individual teeth in the virtual treatment planning software.

4. Blank archwires are bent by robotically-driven machines based on the clinician’s desired outcome.

Numerous variables can affect the efficacy of treatment such as bracket placement, wire bending, wire selection, operator acuity, variations in adhesive thickness, and the ability to accurately monitor treatment. Whereas the SureSmile® technology can
potentially provide more predictable treatment outcomes and eliminate some of the
discussed variables, the efficacy and reliability of the predicted tooth movements in
digital orthodontics using this modality have only been studied sporadically. The ability
to visualize and predict the final outcome of the treatment is valuable. Therefore,
knowing the accuracy and limitations of the software to predict changes could aid the
practitioner in clinical decisions. Specifically, it is helpful in terms of determining
possible need for overcorrections or considerations of modifications in biomechanics.

This retrospective study aims to evaluate the accuracy of tooth positions in SureSmile®’s
virtual treatment predictions of patients who underwent orthodontic treatment.

Accordingly, this study is designed to provide empirical data as to the predictability of
3D tooth movements with the SureSmile®-manufactured archwires. The findings can
help the clinician to formulate a guidance in the strengths and limitations of robotically-
manufactured archwires, and if any modifications or overcorrections are needed to the
virtual treatment planning with SureSmile® treatment plans based on the desired final
tooth positions.
CHAPTER 2

REVIEW OF THE LITERATURE

2.1 Manual Wire Bending

In conventional wire bending, thorough understanding of the effects of bends placed to the wire is important. In addition, the effects of these bends on the rest of the archwire must also be taken into consideration. The manually placed bends are particularly important in the original edgewise appliance, as it does not have “prescriptions” built into the individual tooth brackets. These prescriptions dictate the specific tip, torque, inset, offsets, etc., of each individual tooth as they relate with the arch and the other teeth in the mouth. Clinicians who use the original edgewise appliance that does not have the prescriptions built into the bracket place each bend manually to allow for precise control of each tooth movement in all dimensions. In contemporary orthodontics, the prescriptions of each individual tooth position and angulation is built into the bracket itself to minimize the amount of wire-bending necessary. This is the concept of the straight-wire appliance. If more precise and accentuated control of the tooth position is needed, bends are manually placed in the archwire during the working and finishing stages. These additional manipulations also allow the clinicians to have full control of tooth movement and prevention of unwanted side effects. In orthodontics, there are three different types of bends that the clinician utilizes to direct movement of teeth. These are first-, second-, and third-order bends.

First order bends are in and out bends that move the teeth in the buccal and lingual directions. In other words, these bends affect expansion or contraction of certain teeth within the arch. In the traditional edgewise appliance, first order bends are placed
for the maxillary lateral inset, as well as upper and lower canine and molar offsets. If placed appropriately, first order bends can also produce rotational movement.

Second order bends are tip bends made in the occlusogingival direction that produce up-down movements to the teeth. Second order bends can be also be placed to provide tip to the teeth, as it was done in the traditional edgewise appliance. Second order bends, when exaggerated, can also be used for anchorage preparation when needed.

Lastly, third order bends are torsional (twist) bends along the long axis of the rectangular arch wire. The type of movement that can be produced when this bend is the buccal/labial inclination of the crown, with a corresponding opposite palatal/lingual inclination of the root. In the straight-wire appliance, torque values are built into the brackets. A variation of torque in a segment or for an individual tooth may be required for proper finishing of the treatment. It is important to note that a wire twisted to produce lingual root torque to the maxillary incisors will also intrude them. Conversely, a wire twisted to produce labial root torque to the maxillary incisors will also extrude them.

2.1.1 Efficacy of Manual Wire Bending

Beyond the possible inaccuracy of bracket placement, compounded with the fact that it is impossible to bond the bracket to the tooth’s center of resistance to have better control of the tooth, one has to take into account the play between the arch wire and bracket slot. This limitation can be minimized by using large, stiff arch wires that closely approximately the size of the bracket slot. There are five reasons why current pre-adjusted orthodontic appliances do not achieve ideal tooth positions according to Creekmore et al. (Creekmore, 1993):
1. Inaccurate bracket placement: The facial surface of the tooth is curved both mesiodistally and occlusogingivally. Misplaced bracket in the mesiodistal direction can result in rotational irregularities, whereas those in the occlusogingival plane result in torque and height errors. In addition, brackets not aligned with the long axis of the tooth result in tip variations.

2. Variations in tooth structure, such as irregular facial surfaces, angulation of crown relative to the root, and unusual crown shapes would require variations in their tip, torque, rotation, and height parameters.

3. Variations in the vertical and anteroposterior jaw relationships require variations in the positions of maxillary and mandibular incisors. For instance, compared with Class I skeletal patients, patients with a Class III skeletal presentation will have proclined maxillary and upright mandibular incisors. In contrast, Class II skeletal patients will have upright maxillary and proclined mandibular incisors. This normal variation cannot be successfully treated by just one type of appliance.

4. Overcorrections of rotations are recommended due to tendency of tissue rebound or relapse. In addition to rotations, overcorrections for heights, tips and torques will also need to be done as well.

5. In terms of mechanical deficiencies, there are three factors that are considered inherent limitations in orthodontic tooth movement:
   a. Force applied to the teeth is away from the center of resistance. This causes unwanted side effects to the orthodontic tooth movements that are needed to be achieved.
b. Play between the archwires and the bracket slot are necessary for ease of wire placement and removal, but does not allow for the full expression of the bracket prescription.

c. Force diminution of the archwire, which is the reduction of the force produced by the archwire as it returns to its original shape after it is deflected within its elastic limits.

2.2 Comparison with Conventional Treatment

Bending wire manually in successive increments has been one of the traditional ways to finish and detail treatment. With the advent of SureSmile®, this process can potentially be more predictable. The comparability of the quality of finished cases based on objective measures has been studied. A study utilized the American Board of Orthodontics (ABO) cast/radiographic evaluation (CRE) and Discrepancy Index (DI) scores to compare models that were finished with manual wire bending versus SureSmile® (Alford, 2011). These assessments were initiated by the ABO to objectively assess clinical outcomes and aided in the facilitation of the board certification process. The Discrepancy Index (DI) is a measure of case complexity that can be useful not only as an objective assessment pre-treatment, but also for orthodontic treatment outcomes. The Cast/Radiographic Evaluation (CRE) utilizes eight different parameters that assess dental morphology and occlusion. The aforementioned study utilized casts of non-extraction patients finished with SureSmile® and conventional wire-bending and found that SureSmile® patients had significantly lower Discrepancy Index (DI) scores and better CRE scores for first-order alignment-rotation and interproximal space closure. A
limitation in this study was that the initial malocclusions and the second-order root alignments were initially less severe in the SureSmile® patients than the manual wire bending patients. In addition, the SureSmile® patients were not treated with orthopedic appliances, and root angulation was scored only on panoramic radiographs.

2.2.1 Treatment Time

Treatment time is one of the factors considered by patients undergoing orthodontic treatment. Because of SureSmile®’s use of robotics to express very precise bends in a wire, it can be deduced that the elimination of human error can theoretically decrease treatment time. Hickory et al. conducted a study using survey responses from 1,520 patients, in which they concluded that many patients are willing to cover greater cost for shorter treatment times (Hickory, 2004). This trend is echoed by studies conducted by other studies, further stating that extended length of care can negatively affect patient compliance and the overall quality of care (Cunningham, 1996 & Keim, 2006 & Shia, 1986).

In the study conducted by Alford et al., SureSmile® resulted in less treatment time of approximately 7 months when comparing to conventional treatment methods (Alford, 2011). Similarly, Saxe et al. showed a reduction in treatment time in SureSmile® patients (14.7 months) versus conventional treatment (20 months) (p=0.001), which is approximated to be 25% faster than conventional treatment (Saxe, 2010).

A robust study performed by Sachdeva et al. evaluated 12,335 patients over 142 practices from 2003 to 2008 as a part of Comparative Effectiveness Research Program (CERP) (Sachdeva, 2012). This program received patient data on SureSmile®’s impact
on the duration and factors that affect treatment time. In their study, they found that SureSmile® patients had an average of 15 months of treatment time, as compared to 23 months of treatment time with the conventionally-treated patients. The trend was the same when patients with different Angle’s classifications were compared. Class I, II and III patients with SureSmile® experienced treatment times that are 7, 9 and 8 months shorter, respectively, than conventionally treated patients. Figure 1 below is from the aforementioned study, showing the median treatment times for both SureSmile® and conventional patients. This study may have had some degree of bias, however, as some of the authors either had financial interest or was employed by SureSmile® at the time.

![Figure 1: Treatment time between conventional and SureSmile® patients](image)

### 2.2.2 Effectiveness in Predicting Final Tooth Positioning

The effectiveness of SureSmile® to predict final tooth positioning was reported by Larson et al (Larson, 2013). The investigators studied the crown positions of teeth in 23 patients with various initial severity of malocclusion, and were treated both extraction and non-extraction. The study superimposed the SureSmile®’s virtual treatment plan models to scans of the patient’s occlusion from plaster models after SureSmile®
treatment. Best-fit registration between the two scans using the mesiobuccal cusps of the first molars and the incisal contact point of the lower incisor as the initial registration and then refined using an iterative closest-point algorithm was performed. Surface features were then analyzed, and the direction and magnitude between the two models were quantified to determine individual discrepancies of each tooth. In their study, they considered deviations of more than 2 degrees and 0.5mm to be clinically significant. These were selected as these are the values that are used in the American Board of Orthodontics (ABO) objective grading system. Points are subtracted for teeth that deviate 0.5mm or more in the “alignment” and “marginal ridge” categories. Likewise, a crown-tip discrepancy of 2 degrees causes a marginal ridge discrepancy of 0.5mm in an average-sized molar. Their results show SureSmile® directed tooth movement was most effective in the vertical dimension. In the faciolingual direction, all teeth (except maxillary central incisors and mandibular second molars tended to position more lingual compared to the virtual treatment plan. This could mean that the predicted transverse expansion prescribed in the SureSmile® treatment was not fully expressed. Maxillary posterior teeth had increased buccal crown torque than the SureSmile® treatment plan, which supports the idea that the expansion that occurred was due to buccal crown tipping instead of bodily tooth movement. Other discrepancies, such as crown torque effects on the maxillary and mandibular incisors, increased distal tip of maxillary molars, and increased mesial tip of mandibular molars, are most likely due to the side effects of Class II mechanics. Overall, their study concluded that the effectiveness of computer-assisted orthodontic treatment technology to achieve predicted tooth position varies with the type and dimension of movement.
Similarly, Müller et al (Muller-Hartwich, 2016) studied the precision of the digital virtual setup with the actual final outcomes of a group of 26 patients with various skeletal and dental malocclusions. They initiated SureSmile® treatment after leveling and alignment and compared the pre-treatment digital virtual setup from the final casts. Similar to the study above, they used a best-fit superimposition based on teeth without adjacent skeletal structures as a reference. They then analyzed the absolute value deviations between the two models using three distances (mesiodistal, orovestibular, vertical) and three angles (inclination, angulation, rotation). This study came up with similar results, noting the highest precision on translational and rotational movements of incisors.

Even with this technology, proper diagnosis, treatment planning, and selection of mechanics is paramount to treatment efficacy. In addition, the clinician must take into account patient variations such as bone density, soft tissue architecture, root anatomy and occlusal forces -- factors that are currently not taken into account by the SureSmile® technology. These variations in anatomy between – and even within patients – can prevent the planned mechanics to be fully expressed. Alford et al. suggested that clinicians are encouraged to build in compensations into the virtual treatment plan with the consideration that the final tooth position is often less consistent than the predicted positions (Alford, 2011).

2.2.3 Root Resorption

A study performed by Patel et al. analyzed CBCTs for the amount of linear root resorption when comparing conventional edgewise treatment and the SureSmile®
technique (Patel, 2012). The decrease in root length that occurs in maxillary and mandibular permanent incisors during orthodontic treatment were measured in this study of 28 patients (14 conventional, 14 SureSmile®). They found that there were no statistically significant difference in mean root resorption between the two treatment modalities, and that the root resorption found in either treatment was found to be less than 1mm. In this study, patient and treatment factors that may be correlated with root resorption were also considered. They found that patients with a Class II malocclusion, severe overjet, and a treatment time greater than or equal to 25 months were more prone to increased resorption. These findings corroborate the meta-analysis performed by Segal et al., which reports that the mean apical root resorption was strongly correlated with total apical displacement (r=0.822) and treatment duration (r=0.852) (Segal, 2004). On the contrary, sex and the use of Class II elastics showed no significant differences in mean root resorption.

2.2.4 Tip and Torque Effects

The first report of a study to explore the precision of SureSmile® in terms of its mesiolingual tip and faciolingual torque prediction was done by Smith et al (Smith, 2015). The study compared the final CBCTs with SureSmile®’s treatment outcome simulation. They concluded that tip and torque discrepancies varied by tooth type and what a clinician considers clinically significant. They saw clinically significant tip discrepancies (greater than 2.5°) between predicted and actual outcomes on the maxillary and mandibular second molars. The torque discrepancies were found on the maxillary second molar, and mandibular central and lateral incisors. A limitation in this study is
that the final CBCTs were taken an average of 2.9 months after debonding. The tip and torque discrepancies that were found in this study can be attributed to the settling that occurs very rapidly after debonding (Fink, 1992).

### 2.3 Accuracy of other CAD/CAM Orthodontic Systems (Invisalign®)

One of the technologies that is widely utilized in orthodontics is the ClinCheck™ feature of Invisalign®. It parallels SureSmile® in that clear plastic aligners, instead of wires, are made to move teeth to a final desired position based on a predicted digital simulation. Several studies have been done to compare the predicted final position from ClinCheck to actual final position. Two studies in the accuracy of the transverse plane predictions between the ClinCheck and the actual outcome has been done (Houle, 2017 & Solano-Mendoza, 2017). These 2 studies employed comparable measurement points (canine tip, canine gingival width, first premolar tip, first premolar gingival width, second premolar tip, second premolar gingival width, first molar tip, and first molar gingival width) to compare the predicted outcome to the actual outcome. Both studies arrived at the same conclusion that there was a statistically significant difference between the ClinCheck™ prediction and the final outcome. Both studies inferred that an overcorrection is recommended in relieving transverse issues in patients treated with Invisalign since the predictions are not fully expressed.

In the anterior region, it was demonstrated that the predicted outcomes by Invisalign was accurate to what is seen in the patient’s mouth in upper/lower arch length, intercanine distance, overjet, and dental midline deviation in one study (Krieger, 2012). In contrast, overbite was not accurately predicted. A separate study reached the same
conclusions in that the predicted outcome was mostly accurate to what was seen clinically at the end of treatment, specifically with expansion, constriction, intrusion, extrusion, and tip (Kravitz, 2009). In contrast, however, rotations were not accurately predicted by the ClinCheck™ software. Based on these, it can be concluded that ClinCheck™ has a reasonable accuracy in predicting movement in the anterior region. There is an inherent flaw in this comparison, however, as one study employed anterior Invisalign, where only the 6 front teeth were treated (Kravitz, 2009), while the other treated patients comprehensively (Krieger, 2012). In addition, it has to also be kept in mind that the two studies did not measure the same parameters.

A study by Simon et al. studied the efficacy of ClinCheck™ to predict incisor torque, premolar derotation and molar distalization (Simon, 2014). In this study, they showed that molar distalization is most predictable and is the only statistically significant variable among the three parameters studied. Incisor torque and premolar rotation prediction accuracy were 42% and 40% respectively, but did not reach statistical significance.

2.4 Cone Beam Computed Tomography (CBCT)

The introduction of the panoramic radiograph allowed clinicians to have a broader and more comprehensive image of the jaws, dentition, and other maxillofacial structures. Limitations on this technology are that there are magnification, distortion and superimposition factors that are inherent in all 2D imaging technology. The development of cone-beam computed tomography (CBCT) as one of the imaging modalities for orthodontic treatment has supplemented the knowledge that clinicians have on each case.
CBCT imaging confers advantages such as accurate measurements, improving localization of impacted teeth, providing visualization of airway abnormalities, as well as identifying and quantifying asymmetries. It can also be used to assess periodontal structures, to identify endodontic problems, to plan placement sites for temporary skeletal anchorage devices, and to view condylar positions and temporomandibular joint (TMJ) bony structures (Machado, 2015). Moreover, CBCT imaging involves only a minimal increase in radiation dose relative to combined diagnostic modern digital panoramic and cephalometric imaging (Machado, 2015), although some studies state otherwise (Abdelkarim, 2019). In addition to potentially having a higher radiation dose, other limitations of CBCTs include scatter due to metal artifacts and limitations in detecting thin cortical bone (Abdelkarim, 2019). The latter of the two limitations pose an important point that is relevant to the current study, as the clinicians utilizing CBCTs to determine the biological boundaries when moving teeth will need to consider this limitation.

2.5 Future Directions

Currently, the aforementioned studies were performed to evaluate the accuracy of robotically-manufactured wires in the finishing stages of orthodontic treatment using only the crown positions. The studies also utilized some form of best-fit surface-based registration between the pre-treatment prediction and post-treatment outcomes to measure the accuracy of the different types of tooth movements (Alford, 2011 & Larson, 2013 & Muller-Hartwich, 2016). Although the crown movements can be evaluated, the root positioning was not and could not be directly assessed in these studies’ samples since they did not utilize stable anatomic structures as point of references in comparing the
scans. The study by Smith et al. utilized CBCTs to determine root positioning is an important study. This study was paramount in providing direction to the present study.
CHAPTER 3
AIMS OF THE INVESTIGATION

Specific Aims:

The purpose of this retrospective study is to evaluate the accuracy and efficacy of virtual treatment predictions of patients who underwent orthodontic treatment and finished with SureSmile® technology. The null hypothesis is that there are no differences in how the teeth are positioned in bone between pre-treatment prediction and post-treatment outcomes.

Significance:

The significance of the study is to determine if any modifications and/or overcorrections are needed to the virtual treatment planning with SureSmile® based on the desired final tooth positions.
CHAPTER 4
MATERIALS AND METHODS

This research protocol was approved to comply with the regulations for ethical research by the Institutional Review Board at the Maurice H. Kornberg School of Dentistry at Temple University with IRB Protocol 25557. The main author successfully completed the Collaborative Institutional Training Initiative courses on Biomedical Research and Practice Runs Training developed at the University of Miami. Official approval for, and the subsequent initiation of the research protocol, was given in Jan 7, 2019, and terminated in Jan 7, 2020. IRB approval is attached on Appendix B.

4.1 Inclusion/Exclusion Criteria

In this study, CBCTs of patients that received treatment at Rittenhouse Orthodontics (PC) located in Philadelphia, PA were used in the sample collection process. Inclusion criteria include: (1) Non-growing patients (female $\geq$ 15 years of age, or males $\geq$ 17 years of age), (2) patients who signed an informed consent to use their treatment records for research purposes, and (3) patients that had CBCT scans taken at the beginning and end of the SureSmile® protocol, will be used in this study. The exclusion criteria include: (1) Patients who received dental treatment during the execution of the SureSmile® protocol such as extractions or restorations (2) Patients with significant health history or currently taking medications that could alter orthodontic tooth movement, and (3) pregnant women. Orthognathic surgery patients are included in
this study, as long as the jaw that is being analyzed is not the jaw that received orthognathic surgery (i.e. the untreated jaw in a one-jaw surgery patient). After the initial inclusion and exclusion criteria screen, the pre-treatment and post-treatment CBCTs were analyzed for potential evidence of root resorption. If a tooth is found to exhibit significant shortening of the root as evidenced by blunting and/or flattening of the apex in the post-treatment CBCT that was not initially evident in the pre-treatment scans. In these cases, the individual tooth will not be included in the measurement and data analysis. Unaffected teeth in the same patient will still be included in the study.

Pre- and post-treatment CBCTs were taken from February 1, 2013 to November 30, 2018. All patient information are de-identified and nominally labeled during the analysis. As previously mentioned, the patients who are included in the study have signed a statement allowing permission to use their treatment records. The authorization statement is included in the informed consent form patients sign at the beginning of their treatment. The following authorization statement, as outlined below, is included in the informed consent form patients sign at the beginning of their treatment and is also included in Appendix A:

“Any other uses or disclosures of your health information not addressed in this Notice or otherwise required by law will be made only with your written authorization. You may revoke such authorization at any time. We ask you to give us permission to the use of your photographic or radiographic images for teaching or research:

□ I hereby give permission to the use of my treatment records for teaching or research
□ I do not give permission to the use of my treatment records for teaching or research”
4.2 Initial Leveling and Alignment Phase and CBCT Acquisition for SureSmile®

Processing

Patients included in this study were started with bonding .022-slot MBT brackets (3M Unitek, St. Paul, MN). Initial leveling and alignment were done utilizing .018 CuNiTi archwires, and then progressing to a .017x.025 CuNiTi archwire. Once sufficient leveling and alignment has been obtained, a CBCT is taken to initiate the SureSmile® protocol. CBCTs are taken as a set of DICOM images that comprise the entire scan.

A CareStream Kodak 9300 CBCT machine was used for both the scan sent to SureSmile® and the final CBCT scan with the same scan parameters: 10x10cm FOV, 0.18mm voxel size, 80 sec scan time, 90kV and 5mAs. The patients were placed in a sitting position, eyes closed, with teeth in slight disocclusion, restricted movement, and the Frankfort Horizontal plane perpendicular to the floor. The generated DICOM files are then sent to SureSmile®, where they generate a “diagnostic model”. This diagnostic model is then approved, and then a digital setup with the planned movements and final tooth positions is submitted by SureSmile®. This digital setup can be manipulated by the clinician based on their preference. After all modifications are completed and the submission of the final setup is done, SureSmile® then manufactures a set of progressing archwires that take the case to completion. The treating clinic’s standard set of archwires used are as follows: (1) .017x.025 CuNiTi, (2) .019x.025 CuNiTi, and (3) .019x.025 Elgiloy. The wires are changed when they are passive on the bracket and their pre-insertion shape has been restored.
4.3 Prediction and CBCT Scan Processing, Coordinate axis establishment

The final CBCTs are uploaded in the Dolphin Imaging software (Version 11.9, Release Build 24) for analysis. These volumes are not downsized so as to prevent loss of quality in the visualization and digitization of the scan. After upload of the DICOM files, a coordinate axis is then established using the following guidelines (Figure 2):

1. Mid-sagittal plane: A line through the mesial contact points of the maxillary central incisors (Figure 3).
2. Axial plane: A line touching the mesiobuccal cusp of the maxillary first molar and the buccal cusps of the maxillary first and second premolar on the right and left sides (i.e., The occlusal plane) (Figure 4).
3. Coronal plane: A line intersecting the mesiobuccal cusp of the maxillary first molars (Figure 5).
Figure 2: Established completed coordinate axis

Figure 3: Mid-sagittal plane

Figure 4: Axial plane
The pre-treatment predictions are obtained from the SureSmile® website as stereolithography files (.stl). Two .stl files are exported:

1. Predicted final positioning of the teeth in bone – a rendering based on the patient initial CBCT that was submitted to SureSmile®. This rendering is accurate to the patient’s craniofacial anatomy, which is critical since the superimposition is based on stable anatomical landmarks present in both the CBCT image and the SureSmile® prediction rendering (Figure 6).

2. Predicted final positioning of just the teeth without the bone rendering (Figure 7).
Figure 6: SureSmile® prediction, rendering of teeth in bone

Figure 7: SureSmile® prediction, rendering of teeth not in bone
4.4 Superimposition

The final CBCT and SureSmile® prediction volumes of the teeth in the bone is superimposed using a best-fit surface overlay method via the Dolphin Imaging Software. This superimposition utilizing stable surface landmarks will allow for analysis of the dentition without using any teeth as reference points. This allows for the most accurate representation of individual tooth positions since it is relative to the respective bone housing the teeth.

The two volumes are first manually aligned in three dimensions, then auto-superimposed using the best-fit analysis. In this step, a separate superimposition is done for the maxilla and the mandible, which is done through the sculpting tool of the Dolphin Imaging Software. The sculpting process is done to isolate the bone of interest (Figure 8).

![Figure 8: Sculpting process](image)
For instance, when isolating the maxillary arch, the mandibular bone is sculpted out, leaving the maxillary and zygomatic bones to be superimposed (Figure 9). The same is done for the mandibular arch – the mandible is isolated from the maxilla and other cranial base structures (Figure 10).

![Figure 9: Maxilla sculpted; View from anterior and posterior](image)

![Figure 10: Mandible sculpted; View from anterior and posterior](image)

Having two superimpositions (one for each arch) increases the accuracy and eliminate possible errors in analysis when superimposing the entire volume. For example, a superimposition of the just the mandible between the predicted SureSmile® and final CBCT scan will allow for a more accurate analysis of the changes in the mandibular
teeth, since the jaws are independent of each other. When superimposing the entire volume, differences in the occlusion between the predicted scan and the final CBCT – in the transverse, vertical or sagittal dimension can affect the accuracy of the superimpositions.

In the superimposition menu, a color map is toggled to view and confirm the quality and accuracy of the superimposition. The blue areas indicate an exact superimposition, and the red areas indicate areas without exact superimposition (Figures 11 and 12).

Figure 11: Sculpted maxilla (from SureSmile® prediction scan) superimposed with final CBCT
After the first set of superimpositions, the prediction volume with the bone rendering is then superimposed with the prediction volume without the bone (only teeth) (Figure 13). This is done to set the prediction volume without the teeth in the established coordinate axis, allowing for future digitization of the teeth without the surrounding bony structures, which allows for ease of digitization. As with the previous step, a separate maxillary and mandibular superimposition was performed. The principal author of the study performed all superimpositions.
Figure 13: Superimposition of the prediction volumes with bone and without bone. Note that the blue areas have perfect superimposition, which is expected in this case as the two volumes of the teeth are identical except for the inclusion of the skeleton in one volume.
4.5 Digitization

In this study, the aim was to find and quantify the differences in tip and torque – if any exist – between pre-treatment prediction scans and post-treatment CBCT volumes. Using the digitize/measure module of the Dolphin Imaging Software, two points are digitized in each tooth:

(1) Root apices, and

(2) A point in the crown

A total of three volumes will be digitized: (1) The final CBCT volume, (2) The prediction volume (teeth, no bone) of the maxilla and (3) The prediction volume (teeth, no bone) of the mandible. It is imperative that the anatomical landmarks of the points digitized are consistent between the final CBCT and the prediction scans. For instance, when digitizing a maxillary molar – if the palatal root was chosen as the apical reference point in the final CBCT volume, then the same landmark must be chosen when digitizing the prediction volume. Consequently, when digitizing a mandibular molar – if the mesial root was chosen as the apical reference point in the final CBCT volume, then the same landmark must be chosen when digitizing the prediction volume (Figures 13 and 14).
Figure 14: Final CBCT digitization

Figure 15: Prediction volume digitization
The software then records the precise location of each point made in the x-, y-, and z-axes based on the previously established coordinate system. Vector calculus – specifically, the dot product and the cross product – is utilized to generate values for torque and tip using the recorded x-, y-, and z-positions. These are derived as follows:

1. Coordinate definitions:
   We define the cardinal directions as the following:
   x: Left to right direction
   y: Top to bottom direction
   z: Front to back direction
   In addition, we define two vectors:
   i. From the tooth to the global coordinate plane (Vector R), as previously defined in Figures 2a-2d:
      \[ R \equiv [x_{crown} - x_0, y_{crown} - y_0, 0] \]
   ii. Tooth inclination (Vector T), defined by a line connecting two points (apex and crown):
      \[ T \equiv [x_{root} - x_{crown}, y_{root} - y_{crown}, z_{root} - z_{crown}] \]

2. Vector calculus:
   \( \Phi \) represents torque. It is calculated as follows:
   \[
   \Phi = 90^\circ - \cos^{-1}\left(\frac{R \cdot T}{|R||T|}\right)
   \]
   \( \Theta \) represents tip. It is the cross product of R and T, which is defined as \( \rho = R \times z \)
   Based on this, tip can then be calculated as follows:
   \[
   \Theta = 90^\circ - \cos^{-1}\left(\frac{\rho \cdot T}{||\rho|||T|}\right)
   \]
4.6 Statistical Analysis

4.6.1 Intrarater and Interrater reliability tests

Two raters performed the digitization: (1) The principal author, and (2) A junior dental student. An intraclass correlation coefficient was tested to determine the degree of agreement among repeated administrations performed by each individual rater through measurement of the same points at different points in time (i.e., intra-rater reliability test). In addition, an interrater reliability test was also performed to determine the degree of agreement between raters through measurement of the same points (i.e., Interrater reliability test). A sample of 28 points on the patient CBCT and another 28 points on the SureSmile® prediction scan are digitized in the Dolphin Imaging Software (version 11.9, release build 24) by each of the 2 raters.

4.6.2 Tip and Torque comparison of final CBCT and prediction scan volumes

A statistical evaluation was be performed to assess if the differences that are seen between the predicted outcomes and the actual outcomes, and if they reach statistical significance. Measurements for the right and left sides of each tooth type were not averaged, but will be tested independently. After testing for normality, a student’s paired t-test was performed between the two measurements. A value of $p \leq 0.05$ was considered statistically significant. The statistical evaluation will be done using the software SPSS (Statistical Package for Social Sciences).
Figure 16: Flowchart for research protocol

1. Acquire SureSmile® prediction scan and final CBCT scan
2. Upload all scans to Dolphin Imaging Software
3. Establish global coordinate system
4. Isolate maxilla and mandible using the sculpting tool
5. Superimpose prediction scan and final CBCT scan
6. Digitize crown and apex points
7. Generate tip and torque values
8. Analysis
CHAPTER 5

RESULTS

5.1 Intrarater and Interrater reliability

The intraclass correlation coefficient test was used to determine reliability of the raters with digitizing points both within (i.e., intrarater) and between (i.e., interrater) raters (Table 1).

The average individual intraclass correlation coefficients for Rater 1 and Rater 2 was made using 12 teeth taken from both the prediction scan the final CBCTs (24 total points digitized). Both raters took measurements that were taken 2 weeks apart. The intrarater ICC for Rater 1 and Rater 2 are both 0.957. The interrater ICC for Rater 1 and Rater 2 is 0.998.
The high ICC values, along with the long duration between digitizations means that the raters can consistently digitize the same points within themselves and between each other.

### 5.2 Tip and Torque comparison of final CBCT and prediction scan volumes

In total, torque and tip of 339 teeth from 16 patients were analyzed in this study. Teeth included were central incisors, lateral incisors, canines, 1st premolars, 2nd premolars, and 1st molars. In several instances, teeth were not included in the study due to:

1. Root resorption – where the final apex location could possibly be different than the predicted location due to the shortened length.
2. Artifacts – due to metallic restorations in the final CBCT volume.

3. Affected teeth in surgical cases – because of the imprecise nature of the SureSmile® surgical prediction and the ensuing inaccuracy in the superimposition with the final CBCT, teeth within the jaws of patients that underwent orthognathic surgery were not included in the analysis. In contrast, unaffected jaws were still included since the SureSmile® scan prediction did not include any jaw movements and that superimpositions were possible in these cases.

A paired t-test was performed to determine if there are statistical differences between the tip and torque values. In the analysis, the left and right values for each tooth type were averaged. The paired t-test is testing for difference between the tip and torque difference between the prediction scan and the final CBCT. Therefore, when the test is positive for significance (p ≤ 0.05), the SureSmile® prediction and the final outcome is statistically different. This occurred in the torque prediction of the upper canines (p=0.003) and lower lateral incisors (p=0.007). All other teeth had p-values greater than 0.05, which indicates that the SureSmile® accurately predicted the tip and torque values all these teeth.
### Table 2: Tip

<table>
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<tr>
<th>Tooth Type</th>
<th>Tip Mean difference</th>
<th>Tip Standard deviation</th>
<th>Tip t-test</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
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Table 2: Paired t-test for tip values between the SureSmile® prediction scan and final CBCT scan

### Table 3: Torque

<table>
<thead>
<tr>
<th>Tooth Type</th>
<th>Torque Mean difference</th>
<th>Torque Standard deviation</th>
<th>Torque t-test</th>
<th>df</th>
<th>Sig. (2-tailed)</th>
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Table 3: Paired t-test for torque values between the SureSmile® prediction scan and final CBCT scan

* Statistically significant values between the predicted and final scans
CHAPTER 6

DISCUSSION

6.1 Discussion of Results

Although there is significant variation in what a clinician deems clinically relevant or significant in terms of the accuracy of predicted outcome of certain appliances and technologies, it is still important to quantitatively assess exactly how much the difference is. There are differing results in the literature on the amount of change in the tooth tip and torque that is considered clinically relevant. While some authors suggested ranges of ±2.0 degrees (Larson, 2013), ±2.5 degrees (Tong, 2012b), and even ±5.0 degrees (Bouwens, 2011) from the predicted clinical outcome is irrelevant, it is by large the individual clinician’s tolerances in what they deem to be clinically acceptable and harmonious.

It is important to have an understanding of the limitations of technologies as they develop so that the clinician can adapt and supplement them with overcorrections or auxiliary appliances that will accomplish the same goal. As an example, the Invisalign® technology and clear aligner treatment in general has added to the clinician’s arsenal of available orthodontic treatments, specifically adults. Based on current literature and systematic reviews, however, the limitations of the Invisalign® technology is still not well understood (Papadimitriou, 2018). This has led some clinicians to supplement Invisalign® treatment with brackets and wires, elastomers, and TADs to supplement or enhance the movements of the Clincheck when necessary.
The goal of this study was to evaluate the efficacy of the predicted tip and torque outcomes of SureSmile® in comparison to the actual outcomes. So far, there has been four studies that aim to evaluate the technologies’ different aspect, such as, quality of treatment based on objective criteria (Alford, 2011), time of treatment (Alford, 2011) and comparison of predicted versus actual outcomes (Larson, 2013 & Muller-Hartwich, 2016 & Smith, 2015). Of these four studies, only one evaluated root positions (Smith, 2015). The aim of the present study was to evaluate the tip and torque differences of the predicted versus actual outcome of SureSmile®, much like it did in the study done by Smith et al. (Smith, 2015), but with different methodologies in obtaining the tip and torque values. The study done by Smith et al. used a novel root vector analysis program developed by Tong et al. at the University of Southern California incorporated on the Dolphin Imaging software (Tong, 2012a). The present study calculated the tip and torque values from two points using vector calculus. The tip and torque values obtained between these two methodologies are different; the method by Tong et al. output tip and torque values based on the individual tooth position, much like how it is in prescription brackets. In contrast, the novel method presented in this study output tip and torque values based on a global coordinate system, so it is more useful for academic studies and in comparing values relative to the same coordinate planes rather than on a clinical level.

Post-debond settling occurs most rapidly during the first two months after debond (Fink, 1992). This settling – if the CBCTs used were not taken immediately – could affect the effective tip and torque values that were obtained via the SureSmile® wires. In this study, however, that confounding factor is not taken into account and considered because the CBCT scans were taken at the debond appointment. This is different from the
study done by Smith et al., where the post-debond CBCTs were taken on an average of 2.9 months after debond.

In the study, the tip and torque values predicted by the SureSmile® virtual setup coincided well with the final tooth positioning of the patients during the deband appointment, with the exception of the torque of the upper canine and lower lateral incisors. It should be noted, however, that the difference in the upper canine torque between the predicted and actual outcome is 2.9 degrees. Likewise, the difference in the lower lateral incisor torque between the predicted and actual outcome was 2.0 degrees. Some clinicians may consider this clinically insignificant (Bouwens, 2011).

One probable cause as to why the torque of the upper canine is not accurately followed is because these are the longest teeth in the mouth. Compounded to this fact is that torque/root uprighting is also a movement that requires the one of greatest amount of force to generate an effect. Additional studies could focus on correlations of the duration of wires in the mouth and root movements that were predicted and achieved.

SureSmile® has the slot-filling torque feature, where there is an overcompensation built in to the wires due to the inherent play in the bracket slot. This could contribute to the high degree of accuracy found in the expression of the robotically-manufactured wires.

In the study by Smith et al., they recorded tip values beyond the clinically significant mean difference of 2.5 degrees on the maxillary and mandibular second molars for tip and mandibular central and lateral incisor for torque. This is painting a similar picture with the results of the present study in that SureSmile® is accurate in its prediction and execution of the planned movements. One difference of the present study
and the study by Smith et al., however, is the number of patients/teeth analyzed – this study used 24-31 teeth per tooth type, whereas Smith et al. used 58-60 teeth per tooth type studied. In another study done by Larson et al., they reported that only the mandibular second premolars and first molars were within 2 degrees of the planned tip movements and only the mandibular second molars were within 2 degrees of the planned torque movements. In this study, however, they used a stricter criteria – where anything outside of 2 degrees is considered clinically significant values. The aforementioned studies also included second molars, when it was not included in this study.

6.2 Limitations of the study

In performing the current study, a limitation encountered was that the prediction volume scan does not offer the same level of resolution and quality as the CBCT volumes. This may affect the landmarks on the teeth that were chosen to be digitized. This limitation was mitigated by choosing landmarks that were clear and distinctive on both volumes. Cusp tips, apical foramen and other distinct anatomical features such as talon cusps were chosen as the landmarks almost exclusively over occlusal fossae and marginal ridges, as the former has definitive points that were more reproducible between the scans.

Another inherent limitation of the study was CBCT scans of the dentition have scatter and streak artifacts due to metal dental restorations. In contrast, digital scans do not have the same scatter artifacts that are present in the CBCT scans. In these patients with metal dental restorations, it was not possible to digitize a landmark that can be duplicated in the prediction scan. Another inherent limitation is due to a degree of root
resorption that occurred in some patients. In the case when there is a severe root resorption that occurred, the tooth was not included in the samples to be analyzed, as the landmark to be chosen for the actual outcome would be more coronal than where it actually is, which could bring inherent error to the comparison.

Lastly, the superimposition method was not quantified, and is based on algorithms set by the system as to what is the best fit between the predicted and final outcome. In the event where a superimposition is not perfect based on the color map, the entire sample was not included for analysis.
CHAPTER 7

CONCLUSIONS

SureSmile® archwires can reliably predict tooth tip and torque positions and translate them to clinical movements for most of the types of teeth studied. Values for the torque of the upper canines and lower lateral incisors were statistically different between the planned movements and the actual outcomes. It is recommended, then, that overcorrections for torque of the upper canines and lower lateral incisors are incorporated into the planned movements if the clinicians deem them necessary. Further investigation is needed to determine if the amount of planned tooth movement, time elapsed in each of the wire, and if auxiliaries (i.e., elastics, and the like) are correlated to the degree of success that the SureSmile® system can achieve.
BIBLIOGRAPHY


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APPENDICES

APPENDIX A – INFORMED CONSENT AND AUTHORIZATION

STATEMENT
Other Allowable Uses and Disclosures Without Authorization: Other uses or disclosure of your health information that may be made include:
- Contracting you to provide appointment reminders for treatment or medical care, as well as to recommend treatment alternatives;
- Notifying you of health-related benefits and services that may be of interest to you.

Required Uses and Disclosures: Under the law, we must make disclosures when required by the Secretary of the Department of Health and Human Services to investigate or determine our compliance with federal privacy law.

Uses and Disclosures Requiring Authorization

Any other uses or disclosures of your health information not addressed in this Notice or otherwise required by law will be made only with your written authorization. You may revoke such authorization at any time. We ask you to give us permission to use of your photographic or radiographic images for teaching or research.

☐ I hereby give permission to the use of my treatment records for teaching or research by Dr. Tuncay
☐ I do not give permission to the use of my treatment records for teaching or research by Dr. Tuncay

YOUR INDIVIDUAL RIGHTS UNDER HIPAA

1. You have the right to request restrictions on certain uses and disclosures of your protected health information. By example, you may wish to restrict your employer from knowing about a medical condition. Regardless of your request, please know that the HIPAA rules allow our office to share your Protected Health Information with the Covered Entities.
2. You have the right to receive your Protected Health Information in a confidential communication from our office, such as the U.S. Mail.
3. You have the right to inspect and copy your Protected Health Information. Copies of your Protected Health Information are available for a reasonable fee paid to our office to cover our expenses of reproducing them.
4. You have the right to request that we amend your Protected Health Information. In some cases, we may require these requests to be in writing and be supported by a reason for the change. Generally, this will not apply to such routine changes as address and phone number listings.
5. You have the right to receive, upon request, an accounting of your Protected Health Information that we have provided to Non-Covered entities.
6. If you have read and responded to this notice through electronic media such as our practice website (if any) or e-mail, you have the right to receive a paper copy of this notice upon request.

RITTENHOUSE ORTHODONTICS is required by law to maintain the privacy of your Protected Health Information and to provide you with this notice of our legal duties and privacy practices as they apply to your Protected Health Information. We are also required to abide by the terms of this notice, which is currently in effect.

In the future, we reserve the right to change the terms contained in this notice and make any new provisions effective for all the Protected Health Information we maintain. In the event we elect to change the terms of this notice, a new notice will be posted in our office and on our practice website (if any). In addition, you may receive notification by direct mail, e-mail, or other such communication as our practice may implement from time to time.

Should you ever believe your privacy rights have been violated, we request you to file a complaint with our office by contacting Dr. Orhan C. Tuncay in our office at (215) 772-0775 or e-mail at mdri@rittenhouseortho.com. You may also register your complaint with the Secretary of the U.S. Department of Health and Human Services, Office of Civil Rights. As part of our commitment to you, we value your privacy and take every precaution in our practice to preserve your right to that privacy. Any complaint you file will be used strictly to improve our operating procedures and in no way will you be retaliated against for filing a complaint. Should you have any questions or concerns, please contact Dr. Orhan C. Tuncay in our office at (215) 772-0775 or e-mail at mdri@rittenhouseortho.com to obtain further information.

I understand that I have the right to privacy of my Protected Health Information as maintained by RITTENHOUSE ORTHODONTICS. By my signature below, I certify that I have read and understood my rights to the privacy of my Protected Health Information as well as the terms and conditions of this notice.

Patient/Legal Representative Signature: ____________________________
Name of Legal Representative: ____________________________ Relationship to Patient: ____________________________
Date: ___/___/___
APPENDIX B – IRB APPROVAL

Research Integrity & Compliance
Student Faculty Center
3340 N. Broad Street, Suite 304
Philadelphia PA 19140

Institutional Review Board
Phone: (215) 707-3390
Fax: (215) 707-9100
e-mail: irb@temple.edu

Certification of Approval for a Project Involving Human Subjects

Date: 07-Jan-2019

Protocol Number: 25557
PI: TUNCAY, ORHAN
Review Type: EXPEDITED
Approved On: 07-Jan-2019
Approved From: 07-Jan-2019
Approved To: 06-Jan-2020
Committee: A2
School/College: DENTAL SCHOOL (0700)
Department: DENTAL (0700)
Sponsor: NO EXTERNAL SPONSOR
Project Title: Robotics in orthodontics: Efficacy of CAD/CAM-manufactured archwires in predicting and implementing clinical outcomes

The IRB approved the protocol 25557.

If the study was approved under expedited or full board review, the approval period can be found above. Otherwise, the study was deemed exempt and does not have an IRB approval period.

If applicable to your study, you can access your IRB-approved, stamped consent document or consent script through ERA. Open the Attachments tab and open the stamped documents by clicking the Latest link next to each document. The stamped documents are labeled as such. Copies of the IRB approved stamped consent document or consent script must be used in obtaining consent.

Before an approval period ends, you must submit the Continuing Review form via the ERA module. Please note that though an item is submitted in ERA, it is not received in the IRB office until the principal investigator approves it. Consequently, please submit the Continuing Review form via the ERA module at least 60 days, and preferably 90 days, before the study’s expiration date.

Note that all applicable Institutional approvals must also be secured before study implementation. These approvals include, but are not limited to, Medical Radiation Committee (“MRC”); Radiation Safety Committee (“RSC”); Institutional Biosafety Committee (“IBC”); and Temple University Survey Coordinating Committee (“TUSCC”). Please visit these Committees’ websites for further information.

Finally, in conducting this research, you are obligated to submit the following:

* Amendment requests - all changes to the study must be approved by the IRB prior to the implementation of the changes unless necessary to eliminate apparent immediate hazards to subjects
• **Reportable new information** - using the **Reportable New Information form**, report new information items such as those described in the Investigator Guidance: Prompt Reporting Requirements HRP-801 to the IRB **within 5 days**

• **Closure report** - using a closure form, submit when the study is permanently closed to enrollment; all subjects have completed all protocol related interventions and interactions; collection of private identifiable information is complete; and Analysis of private identifiable information is complete.

For the complete list of investigator responsibilities, please see the Policies and Procedures, the Investigator Manual, and other requirements found on the Temple University IRB website: [http://research.temple.edu/irb-forms-standard-operating-procedures/POLICY](http://research.temple.edu/irb-forms-standard-operating-procedures/POLICY)

Please contact the IRB at (215) 707-3390 if you have any questions
On 07-Jan-2019, the Temple IRB approved the waiver of HIPAA authorization. The waiver was reviewed and approved under expedited review procedures.

The IRB has determined that all the specified criteria for a waiver of HIPAA authorization were met:

The description of the PHI for which use or access is included in the protocol summary and is necessary for the research.

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: an adequate plan to protect the identifiers from improper use and disclosure; an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

The research could not practicably be conducted without the waiver.

The research could not practicably be conducted without access to and use of the protected health information.

Please contact the IRB at (215) 707-3390 if you have any questions.