

**Mesio-Distal Tip and Facio-Lingual Torque Outcomes in
Computer-Assisted Orthodontic Treatment**

BY

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THESIS

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This thesis is dedicated to my lovely, diligent, and supportive wife, Alicia, and my beloved children, Dakota, Pepper, and Carson. I couldn't have done it without them!

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TLS

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LIST OF ABBREVIATIONS

2D	Two Dimensional
3D	Three-Dimensional
ABO	American Board of Orthodontics
ABO-OGS	American Board of Orthodontics-Objective Grading System (ABO-OGS), also known as the Cast Radiograph Evaluation (ABO-CRE)
CBCT	Cone-Beam Computed Tomograph(y)
DI	Discrepancy Index of the ABO
SD	Standard Deviation
SS	SureSmile™

SUMMARY

This study investigates the outcome root inclination (facio-lingual torque) and angulation (mesio-distal tip) of SureSmile™ (SS) treated cases to the tip and torque of the three-dimensional (3D) dental model plan, known as the SS target model. The purpose of this study was to determine if the discrepancy between the outcome tip and torque of the teeth as measured on a cone-beam computed tomograph (CBCT) and the tip and torque as measured on the SS target model are the same. It was hypothesized that no significant difference exists between these variables.

Initial SS CBCT (therapeutic or initial CBCT), SS therapeutic model (initial model), post-treatment CBCT (outcome or final CBCT), and SS target model (plan or simulation) were collected for 40 consecutively finished SS cases of a single provider. 30 cases were randomly selected and Dolphin™ 3D root analysis software was used to measure the tip and torque values for SS target model and post-treatment CBCT. The discrepancy between these variables was compared against the mean discrepancy between the initial CBCT and initial model for 10 randomly selected cases, which was a baseline for expected mean discrepancy for like samples. Correlation analyses and paired *t*-tests were used to evaluate repeated measures testing of the initial models and CBCTs. *T*-tests were conducted to assess if a difference between tooth tip and torque outcome versus plan discrepancies was different that found for initial model versus initial

CBCT discrepancies, overall and for each tooth type (ie., maxillary central incisor, maxillary lateral incisor, etc.).

The study concludes that although statistically different, the overall mean discrepancy of the SS target models to the outcome CBCT are within the clinically acceptable range ($\pm 2.5^\circ$). Mean outcome discrepancies were also found to be statistically significant for several tooth types, but clinically significant mean discrepancy (beyond $\pm 2.5^\circ$) was limited to the maxillary and mandibular second molars for tip, and the maxillary second molar and mandibular central and lateral for torque. In general, overall tip outcomes were closer to the plan than torque outcomes and for most tooth types. The mandibular arch had more teeth with mean discrepancies of statistical significance, fewer outcomes within 2.5° of the plan, and had greater overall discrepancy from the plan. Further research is necessary to determine the cause of these findings.

1. INTRODUCTION

Mesio-distal tip and facio-lingual torque of each tooth are important for esthetics and functional use of the dentition. Tooth angulation (tip) and inclination (torque) can have important implications for the orthodontist and successful treatment outcomes (Andrews, 1972; Hussels and Nanda, 1987; Knösel et al., 2009a). Andrews (1972) evaluated a sample of patients he considered to have optimal occlusion and strove to describe the three-dimensional position and the angular relationship which represent optimal outcomes. Andrews based most of his analysis on the coronal anatomy and did not take the entire tooth or root anatomy into account. Knowledge of the human dentition has improved with time and it is becoming more evident that the angulation of a crown does not always depict the angulation of the root, or vice versa (Bryant, 1984; Harris et al., 1993; Knösel et al., 2009a; 2009b). With this in mind the whole tooth inclination should be evaluated for treating orthodontic patients in modern practice.

In recent decades cone-beam computed tomography and three-dimensional imaging have become routinely available allowing the orthodontist to visualize the maxillo-mandibular complex in three dimensions (Peck et al., 2007; Bouwens et al., 2011; Pliska et al., 2011). Several companies have attempted technological advancements in 3D treatment planning, including but not limited to Invisalign™ (Align Technology, San Jose, CA), Incognito™ (3M-Unitek,

Monrovia, CA), Insignia™ (Ormco, Orange, CA), and SureSmile™ (Orametrix, Richardson, TX) (Larson et al., 2012). Most of these techniques approach the orthodontic treatment plan similar to Andrews, in that they focus primarily on the treatment and positioning of the dental crowns. However, by incorporating CBCT and full tooth digital models into the planning process, SureSmile™ enables the orthodontist to plan the position and angular placement of every tooth from crown to root (Mah and Sachdeva, 2001; Sachdeva, 2001). The purpose of this study is to evaluate the effectiveness of the angular control of the whole tooth in SureSmile™ treatment.

2. REVIEW OF LITERATURE

2.1 SureSmile™

SureSmile™, introduced in 1998 and available commercially as of 2005, has developed a novel three-dimensional software and wire bending system to aid the orthodontist in visualizing and treating towards a 3D treatment goal (Mah and Sachdeva, 2001; Sachdeva, 2001; Alford et al., 2011). The initial system was developed to be used with a 3D intra-oral scanner from which a computer model of the coronal dentition would be created. Once obtained, the 3D model software would allow for manipulation of each tooth and creation of a proposed “target position” (Mah and Sachdeva, 2001; Sachdeva, 2001). From this plan a specialized wire-bending robot creates custom wires with bends in place for use in finishing an orthodontic case (Mah and Sachdeva, 2001; Sachdeva, 2001).

The company claims, “SureSmile can substantially reduce many common errors in fixed appliance treatment, and it can enhance the quality of care afforded to the patient by compressing the treatment cycle and reducing the number of appointments” (Suresmile.com, 2011). They purport more patient comfort, faster treatment times, and potentially a more precise finish leading to less relapse probability. “While SureSmile™ treatment time is averaging about 15 months, a two month reduction in overall treatment time means a 13% pickup in production time” (Lin and Getto, 2008).

In 2008, SS released another innovation to their system by incorporating 3D cone-beam computed tomography (CBCT) imaging into their software (Lin and Getto, 2008). Lin and Getto claim that the system will allow for “distortion-free accuracy of the subsurface anatomy” allowing the clinician to “view the entire tooth anatomy (clinical crowns plus roots and other surface structures), manipulate teeth and jaws for simulating orthodontic treatment, and measure the changes any proposed treatment would make.”

In order to treatment plan the position of the patient’s whole tooth, rather than just the crown, a *SS therapeutic model* must be obtained from a CBCT scan. The *SS therapeutic model* is a 3D representation of the patient’s dentition created by SS to correspond to the patient’s dentition at the time of the initial SS CBCT scan. Using the SS software and system the doctor creates a proposed “target position” of the teeth. This is referred to as the *SS target model* and is a 3D model representing the final goal for treatment outcomes and from which the wire prescription is submitted to SS. The wire bending robot then creates a sequence of custom arch wires to aid the orthodontist in obtaining the desired 3D orientation of each tooth (Mah and Sachdeva, 2001; Sachdeva, 2001; Lin and Getto, 2008).

The wire bending robot is reported to have a bend positioning error of ± 0.1 mm, and angular/torsional error ± 1.0 degree (Sachdeva, 2001). This may

have led to the statement, “the SureSmile system controls torque on every tooth concurrently to within one degree of accuracy” (SureSmile brochure, 2007).

Another version of the system was released in March 2012 which added the ability to view the alveolar bone in the plan. This feature will potentially improve the orthodontist’s ability to visualize limitations to planned tooth movements, the orthodontist can now “plan movement in 3 planes of space and simulate outcome with respect to bone” (Suresmile.com, 2012). This feature was not available to evaluate as part of this study.

2.2 **Evaluating Tip and Torque in 3D**

In orthodontics, the tip of a tooth is evaluated in the mesio-distal dimension and the torque is evaluated in the bucco-lingual dimension, but the reference for each tooth changes about the curvature of the arch form. This means that the tip and torque of each tooth is not measured relative to x, y, and z dimensions as is common for computer 3D systems. A new method for evaluation of a CBCT has recently been established for measuring root tip and torque in 3D space (Kwon, 2011; Tong et al., 2012a; 2012b). A specific analysis was built into the Dolphin™ 3D analysis (Patterson Dental System, Chatsworth, CA) to allow a user to enter marker points for teeth and arch form. The computer automatically calculates the tip and torque relative to this form and the user established occlusal plane (Kwon, 2011; Tong et al., 2012a; 2012b).

Kwon (2011) had the research intent of establishing a 3D standard for “normal occlusion,” in hopes that future developments might allow for treatment towards these values and allow for improved treatment outcomes and stability. The author indicated that no treatment system currently allowed for 3D treatment planning of the whole tooth. He was apparently unaware of the 2008 SS update which allowed for visualization of the entire root and treatment planning with this system which might allow the clinician to treat towards a specific or desired inclination and angulation.

The measuring technique for Kwon’s thesis study involved placement of marker points for the midpoint of the crown and the midpoint of the root and additional points for the establishment of maxillary and mandibular arch forms (Kwon, 2011; Tong et al., 2012a). In another study, the marker points were placed at the radio-opaque centers of stainless steel ball gauges placed at the crown and root of a test typodont on multiple CBCTs (Tong et al., 2012b). For both studies the occlusal plane was established by orienting the 3D volume relative to their definition of that plane. Tip and torque values were then calculated by and exported from the software for analysis. The second study had the goal of validating the measurements obtained using the Dolphin™ 3D software against that of a gold standard coordinate measuring machine (Tong et al., 2012b). They report the method and vector analysis to be valid and applicable to clinical patients, with a reported measuring error of approximately 1°.

2.3 **Keys to Normal Occlusion**

Andrews' (1972) article *The Six Keys to Normal Occlusion*, discussed his observations from 120 non-treated orthodontic models which had excellent occlusion such that orthodontic treatment would not benefit the patient, and 1,150 excellent outcome cases gathered at national meetings. Andrews' focus was to evaluate the characteristics of the occlusion, and describe attributes which were consistently found among them. The first of the six keys discussed molar relation and contacts of the maxillary first molar to the lower first and second molar. The second and third keys related to the tip (mesio-distal crown angulation) and torque (labio, bucco, or facio-lingual crown inclination) of the teeth, while the remaining three keys were rotations, space, and occlusal plane. Andrews states, "The degree of the tip of the incisors, for example, determines the amount of mesio-distal space they consume and, therefore, has a considerable effect on the posterior occlusion as well as anterior esthetics."

Andrews' focus of evaluation was the clinical crown of the tooth as he felt that orthodontists "work specifically with the crowns of the teeth" and that should be used as reference. The inclination and angulation of the entire tooth including the root was, therefore, not taken into account. At that time, Andrews did not have access to 3D imaging and was also unable to obtain an accurate evaluation of the entire root. Other studies indicate that the angulation of the root with respect to the crown varies significantly. Root angle is often evaluated separate from the crown as related to the malocclusion type, overbite, overjet, or other

developmental and genetic factors (Bryant et al., 1984; Harris et al., 1993; van Loenen et al., 2005; Knösel et al., 2009a). However, the axis of the entire tooth in radiographic analysis is usually evaluated as a straight line from tip of the root to tip of the crown (Steiner, 1959; Proffit and Ackerman, 2000; Knösel et al., 2009a). It is important to remember that regardless of the method of angular assessment the entire tooth is always treated. In fact, the dental alveolus and entire dental, periodontal, and most of the craniofacial complex is being altered, or at least affected by the alterations to the teeth.

2.4 **Radiography in Orthodontics**

It is common in the current orthodontic case evaluation systems to evaluate root angulations on a panoramic radiograph in order to insure that appropriate root angulations exist, which will limit potential periodontal problems and other pathologies such as concrescence due to contacting adjacent teeth (Deguchi et al., 2005; Saxe et al., 2010; Alford et al., 2011). However, it is also well documented in the literature that panoramic radiographs are inadequate for evaluating root angulations due to distortion (McDavid et al., 1985; Makee et al., 2002; Bouwens et al., 2011; Phillip and Hurst, 1978).

CBCT is considered the standard of care for 3D radiography in dentistry (Pliska et al., 2011). This imaging technology uses ionizing radiation to capture images from several angles during a 360 degree rotation about the subject which is then computed into a 3D rendering (Kwon, 2011; Pliska et al., 2011). CBCT

has several well known advantages over conventional computed tomography, the most significant of which may be reduced ionizing radiation exposure for the patient (Pliska et al., 2011). The accuracy of CBCT in linear and angular measurements is becoming well established (Bouwens et al., 2011; Peck et al., 2007).

As technological advancements are made in this field it is becoming increasingly more feasible to utilize a single CBCT to aid in evaluation of a patient rather than exposing the patient to several smaller images which are then pieced together in the clinician's mind to evaluate the patient. Although it will likely never be possible for the ionizing radiation level of a CBCT to reach as low as the levels used to obtain a single two dimensional (2D) radiograph. This is due to the relationship of 2D and 3D technology; as 3D ionizing technology improves and decreases the ionizing radiation to the patient, there is a concurrent technological improvement and decrease in 2D imaging radiation exposure. CBCT remains very useful in orthodontic patient evaluation. Localization of impacted teeth, mixed dentition evaluation, temporary anchorage device planning, pathology identification and localization, airway evaluation, growth and development assessment, and surgical planning are some of the more common uses of CBCT in dentistry (Pliska et al., 2011).

The controversy of CBCT radiation and overall risk to benefit for the patient is an ongoing debate (Pliska et al., 2011). If SS can aid the orthodontist

in evaluating, planning, and achieving specialized and individualized treatments with accuracy, then 3D radiographic imaging and 3D treatment planning will become invaluable to the future of the profession.

2.5 **Independent SureSmile™ Publications**

Very few publications are available about this new technology, and even fewer publications from independent (non-industry supported) researchers. Two recent studies have been published which have focused on the treatment speed and outcomes of SS treated cases.

Saxe et al. (2010) compared outcomes of 38 SS treated patients and 24 conventionally treated patients treated by three orthodontists. The American Board of Orthodontics (ABO) Discrepancy Index (DI) and the American Board of Orthodontics - Objective Grading System (ABO-OGS) rating systems were used for analysis. They reported that SS treatments resulted in better ABO-OGS outcomes with less treatment time. Limitations of the project included unclear patient selection methods, and unclear distribution of cases among the three orthodontists. They did not evaluate outcomes as compared to the plan.

Alford et al. (2011) evaluated clinical outcomes for patients finished with the SS method compared with conventional fixed orthodontic therapy. The study examined 132 non-extraction cases treated by one clinician and rated by a blinded rater. SS patients had lower initial DI, shorter treatment time, and better

ABO-OGS outcomes. However, the SS group scored worse in the root angulation category of the ABO-OGS. They indicated that a definitive comparison using 3D imaging for assessment is needed.

Larson et al. (2012) completed a mathematical superimposition of the SS target models to the outcome models. The study did not utilize CBCT or 3D volumetric dental scans, rather it utilized 3D models and coronal surface superimposition software to evaluate the mesio-distal, facio-lingual, vertical, tip, torque, and rotational outcomes of the crown. Overall they found that the vertical dimension was best predicted by the SS target model, however, no skeletal vertical references were used which are needed to have shown actual vertical outcomes of a specific tooth in 3D. For tip and torque, which are most relevant to this study, they found that crown tip discrepancies were elevated in the posterior segments and crown torque deficiencies were found to be the most common significant deficiency.

2.6 **Specific Aims**

The aims of this project are to confirm the reliability of measuring root tip and torque on 3D volumes and 3D models using Dolphin™ 3D; second, to evaluate the amount of discrepancy between initial CBCT and corresponding SS therapeutic models, which might also indicate whether the therapeutic models are an adequate representation of the actual tip and torque; and third, to evaluate

the ability of the treating doctor and SureSmile™ to replicate the outcome tip and torque as simulated by the 3D plan.

2.7 **Hypothesis**

The mean tip and torque discrepancy of the of the SureSmile™ target model (treatment simulation) and the final CBCT (outcome) is not different than the mean tip and torque discrepancy of the initial CBCT and corresponding SureSmile™ therapeutic model.

3. MATERIALS AND METHODS

3.1 Data Acquisition and De-identification

The University of Illinois at Chicago Office for the Protection of Research Subjects reviewed and approved the project, Institutional Review Board #20120407-67650-1. To test the hypothesis, CBCT volumes and 3D models were collected for 40 consecutively finished, labial treated, SS cases from existing cases of Dr. Edward Y. Lin, Green Bay, WI.

For each patient the initial SureSmile™ CBCT scan (therapeutic CBCT) and post-treatment CBCT (outcome or final CBCT) were obtained. The SS therapeutic model (initial model) and SS target model (the plan/simulation) were also collected after de-identification by the provider. Additionally, the following descriptive information was obtained for each patient: occlusal classification, age at the start of orthodontic treatment, duration of treatment segments, record of which teeth had elastics during SS treatment, listing of teeth which had brackets replaced after SS scan, listing of teeth extracted during treatment, and a listing of additional appliances used during phase 2 treatment (such as temporary anchorage devices, headgear, expander, etc).

Exclusion of the cases occurred if the final CBCT was obtained more than 14 weeks after debond; this resulted in the removal of 4 cases. Therefore, two 3D models and two CBCT volumes of 36 cases remained available. It was also

planned to remove cases if the following criteria occurred: 1) If more than 2 brackets per case were replaced due to debonding, or repositioned for any other reason after the initial SS scan; 2) If fewer than 10 treatment teeth remain per arch; or 3) If the CBCT or 3D models had errors which prevented the localization of crown and root points (as defined below) and limits the measurable treatment teeth to fewer than 10 per arch. However, of the cases collected, no case required further exclusion.

Age was recorded as years (e.g. 12.5 for a 12 year 6 months) at the initiation of overall treatment. Gender was not recorded or evaluated. The orthodontic brackets used by the provider for all cases were DENTSPLY GAC Innovation R or C brackets with 0.018" by 0.025" slot. The finishing arch wire was a 0.017" by 0.025" copper nickel titanium (Ormco™ Orange, CA) with SS wire bends in place. Statistical analysis was completed using SPSS version 19 (IBM, Chicago, IL). CBCTs were obtained after initial leveling and alignment was satisfactory as determined by the provider. CBCT images were obtained using the i-CAT® Classic (Imaging Sciences International, Hatfield, PA) CBCT and were 0.4mm voxels at the SS therapeutic scan and for most final scans.

3.2 **Reliability Testing and Rater Comparison**

The first step was to determine the reliability of the raters with the Dolphin™ 3D analysis for obtaining tip and torque readings of 3D volumes and 3D models. Dolphin™ 3D version 11.7 was used following the root analysis

technique described previously by Tong et al. (2012a; 2012b). With permission from Tong et al. (2012a; 2012b), the software and measuring technique was adapted for this study to evaluate the accuracy of SS treatment outcomes.

This project placed coronal marker points at the mesio-buccal cusp tip and root marker points at the buccal and mesial most root tip of molar teeth. For premolars and canines, markers were placed at the buccal cusp tip and root tip of single rooted teeth, and for incisors, markers were placed at the midpoint of the incisal edge and root tip. For multi-root premolars or anterior teeth the buccal and mesial most root was used. Figures 1 and 2 represent the Dolphin™ 3D root module with marker point placement for CBCT and model, respectively.

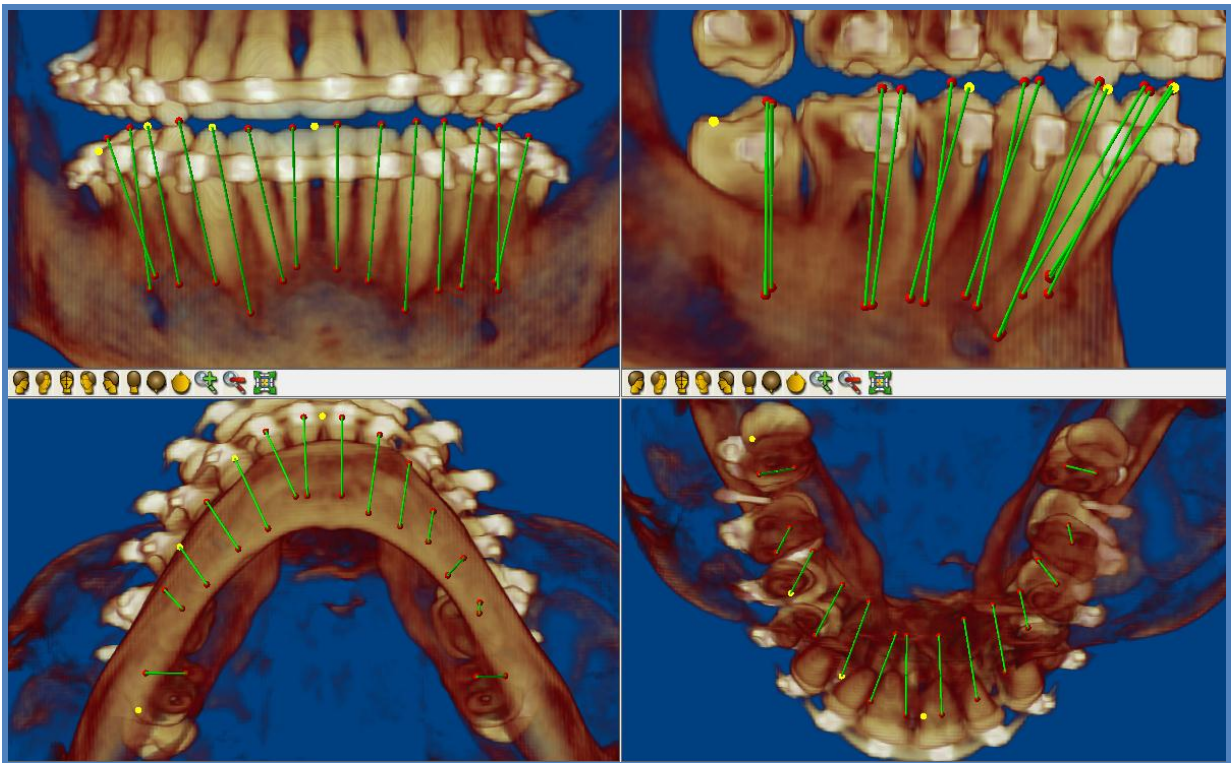


Figure 1. Example of 3D CBCT marker points and angles, after rater placement.

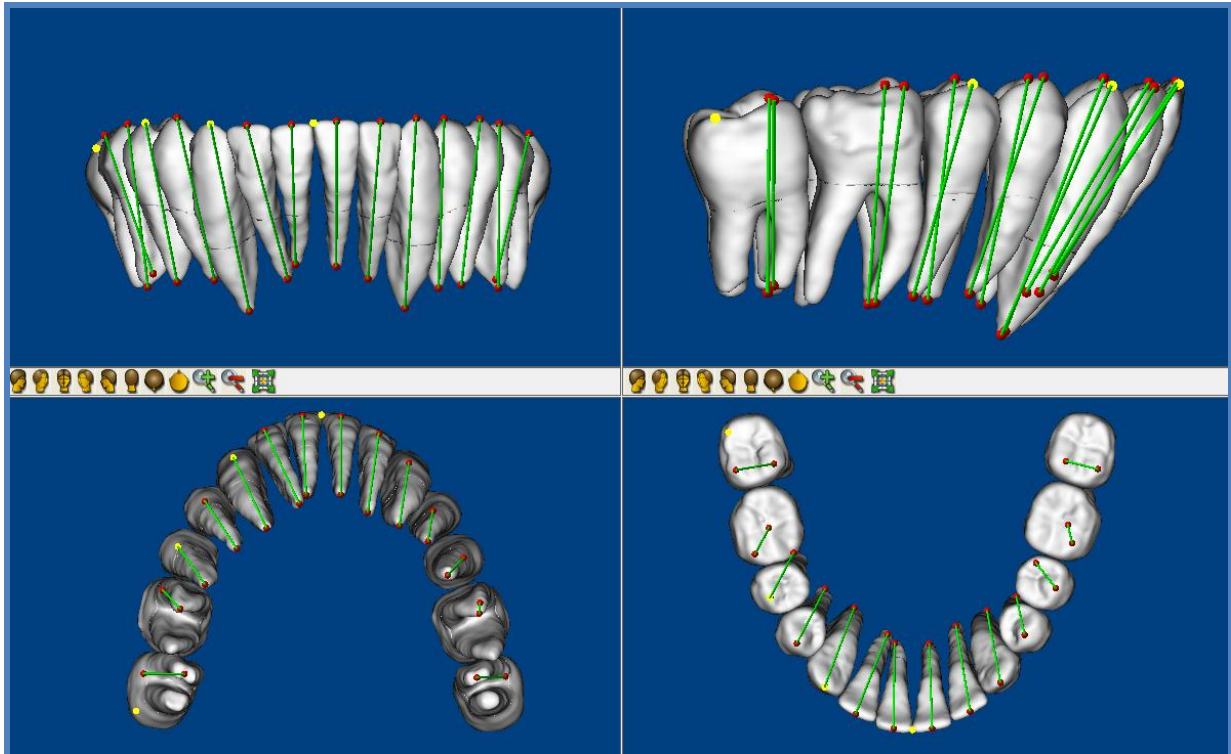


Figure 2. Example of 3D Model marker points and angles, after rater placement.

Ten therapeutic CBCT volumes and corresponding SS therapeutic models were randomly selected from the group of 36 de-identified cases. Tip and torque values of the CBCT volumes and 3D models were obtained by two raters at two time points separated by more than one week. The raters were blinded to the case number as well as the pairing of the volume to the corresponding model. The volumes and models were given new blinded identifying numbers for each rating period which were revealed only after completion of the measures.

Each tooth was evaluated as a separate specimen for statistical analysis. Pearson correlation analyses were completed to ensure the reliability of the initial

3D CBCT and SS therapeutic model measurements. Paired samples *t*-tests were also used to further demonstrate the amount of variation between raters.

3.3 **Evaluation of Changes to the Occlusal Plane**

One might be concerned that any changes to the occlusal plane might affect tip and torque outcomes, however, since the 3D SS models are only teeth suspended in a 3D digital matrix, this is of minimal concern. The SS arch wires are also continuous and any effect on the occlusal plane on one side should be expressed across all teeth such that the tip and torque should match the target model. However, in the interest of improving the quality of the project, and since previous SS related publications have not evaluated this change, measures were obtained to evaluate whether the occlusal plane changed during treatment. A method of measuring the occlusal plane relative to skeletal landmarks was first established.

To complete the evaluation, occlusal angular references from perpendicular 2D x-ray builds in the frontal, lateral, and sub-mental views were created using the 3D software. Only the maxillary occlusal plane was evaluated. In the lateral view, the angle formed by the mesio-buccal cusp tips of the maxillary first molars and the incisal tip of the maxillary right central and the point nasion was measured (Figure 3). In the frontal view, the angle formed by the mesio-buccal cusp tips of the maxillary first molars and the most lateral inferior tangent to the right zygomatic arch were measured (Figure 4). In the sub-mental

view, the angle formed by the intersection of a line connecting the anterior most point of the zygomatic arch depressions (radiolucent inner and anterior most point) to the line formed by the midline of the maxillary incisors and a point equidistant between the maxillary first molars was measured (Figure 5).

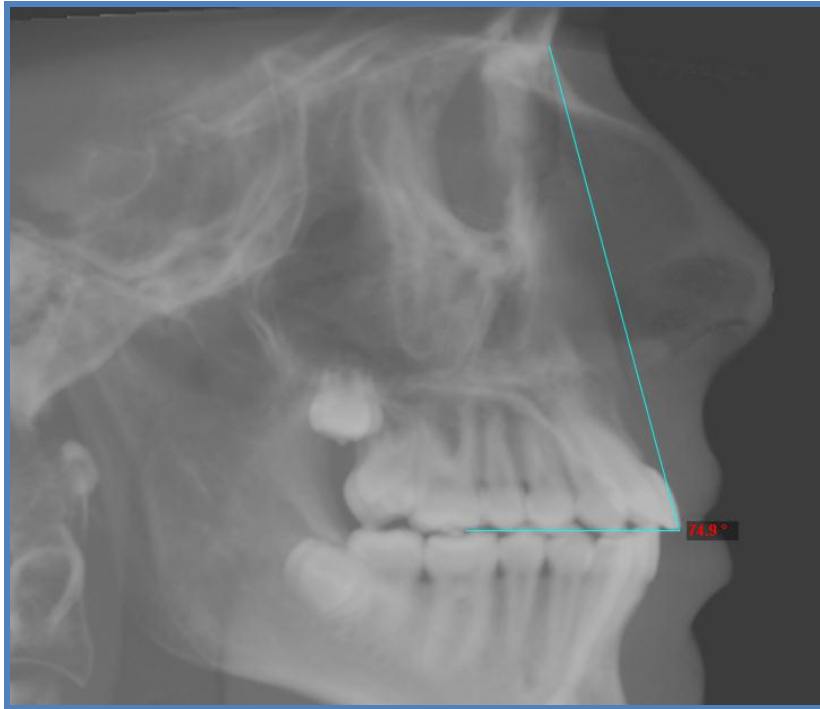


Figure 3. Example of an occlusal plane measure for the lateral view. Segmentation of the radiograph and placement of reference lines for the localization of the maxillary right first molar mesio-buccal cusp tip and maxillary right central incisal tip was completed prior to the final measurement angle to nasion. This image is from a final CBCT after removal of appliances.

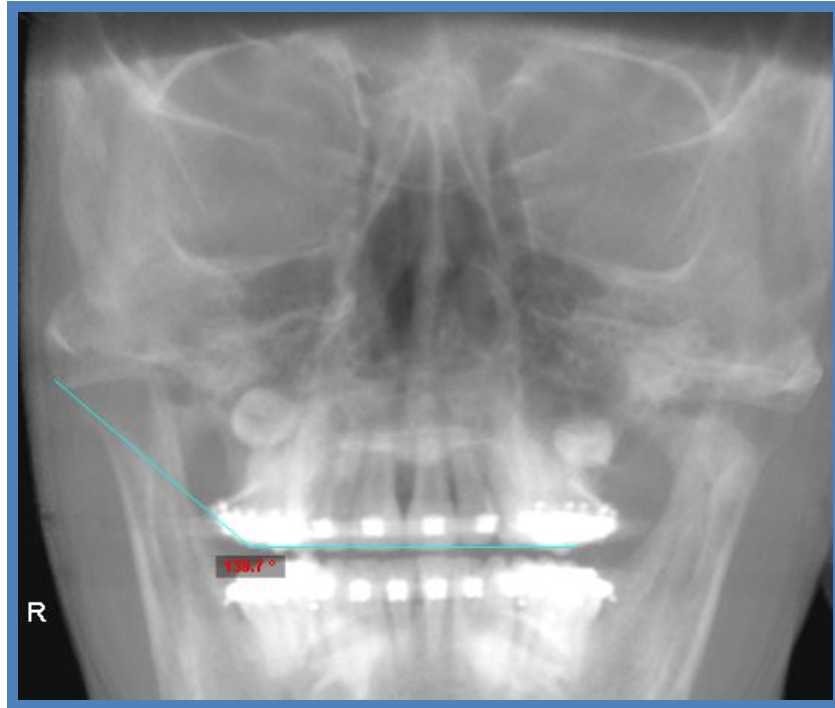


Figure 4. Example of an occlusal plane measure for the frontal view. Segmentation of the radiograph and placement of reference lines for localizing the mesio-buccal cusp tips of both maxillary first molars was completed prior to the final measurement of the angle to the zygomatic arch. This image is from an initial CBCT scan with brackets in place.

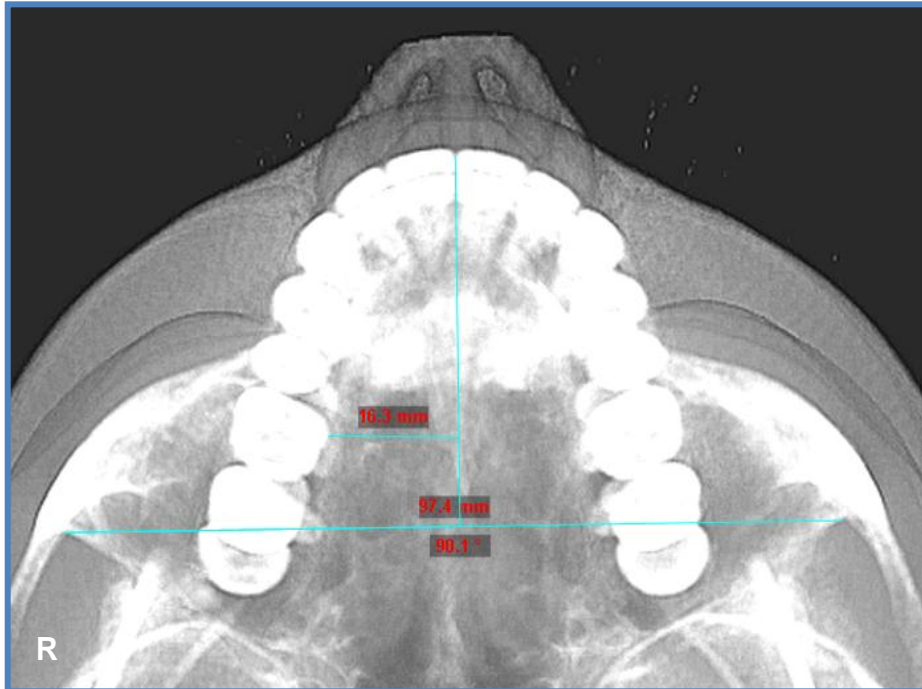


Figure 5. Example of an occlusal plane measure for the sub-mental view. Some reference lines can be seen in this image as were used to locate the point equidistant between the molars, and to the anterior most point of the zygomatic arch depressions. The angular measure originating between the central incisors and terminating at right zygomatic arch can also be seen. This image is from a final CBCT after removal of appliances.

The same 10 therapeutic CBCT volumes from the previous section for reliability were measured from the lateral, frontal, and sub-mental views by two raters at two time points separated by more than one week. The volumes were given blinded identifying numbers for each rating period and were revealed only after completion of the measures. Five of the 10 cases were then selected for measurement of the final CBCT and one sample *t*-tests were used to evaluate for statistical differences between the outcome and initial CBCT occlusal plane measures.

3.4 **Evaluation of the Discrepancy between SureSmile™ Therapeutic Model and Initial CBCT**

After establishing the reliability of the raters at two separate time points for the models and the volumes and for the occlusal plane references, the next step was to evaluate the discrepancy between the SS therapeutic model tip and torque values relative to their corresponding initial CBCT volumes. This is very important to validate the methodology of this research and demonstrate the amount of discrepancy. It also aids the clinician in understanding the amount of tip and torque discrepancy that may exist in the SS therapeutic models as the teeth are arranged on the 3D treatment plan.

The previously measured volumes and models were paired and the mean discrepancy calculated. Hypothetically, the model and CBCT tip and torque measures would be exactly equal and the discrepancy between the CBCT measure and the model measure would be 0.0° . However, this project does include human raters and therefore variation may be expected in the measuring of the tip and torque. One sample *t*-tests were used to determine if the mean discrepancy of the tip and torque values from initial model to initial CBCT differed from 0.0° , and by how much.

3.5 **Evaluation of SureSmile™ Treatment Outcomes**

The number of assessment techniques available for clinical whole tooth mesio-distal tip and facio-lingual torque evaluation is extremely limited, and the

Dolphin™ 3D root module was treated as a gold standard for comparing to the outcomes on live patients. The discrepancy of the measures obtained by the rater between two like samples, initial CBCT and initial model, were used as a standard (or baseline discrepancy) against which the outcome CBCT and SS target model discrepancies were compared.

To evaluate whether the treating doctor is able to obtain the SS target model tip and torque, 30 outcome CBCT volumes and corresponding SS target models were randomly selected from the group of 36 de-identified cases. The rater with the most consistent measurements, rater #1, was blinded to the case number and as well as the pairing of the volume to the corresponding model and measured all teeth. The case numbers were coded by a separate individual such that the data for the two measures were correctly paired only after completion of these measures.

One sample *t*-tests were then used to evaluate the discrepancy between the tip and torque of the SS target model and final CBCT to the mean discrepancy of the initial 3D models and corresponding CBCT for all teeth collectively. The subject teeth were then divided into tooth types: maxillary and mandibular central, lateral, canine, first premolar, second premolar, first molar, second molar. One sample *t*-tests were then used to compare the outcome discrepancy data to the mean for that tooth type's initial discrepancy. To evaluate what tooth types had outcomes very near the plan, the percent of teeth

within 2.5° of the plan was calculated and graphed. Additional correlation analyses of the descriptive variables were completed to explore if any of the descriptive variables correlate to the outcome of having more teeth within 2.5° of the planned tip and torque.

4. RESULTS

4.1 Results of the Reliability Testing and Rater Comparison

Pearson correlation analyses were completed between time point 1 and time point 2 measures for tip and torque values. The pairwise intra- and inter-rater Pearson correlations for initial CBCT mesio-distal tip are shown in Table I. Table II shows the therapeutic (initial) model mesio-distal tip pairwise intra- and inter-rater Pearson correlations.

TABLE I
MESIO-DISTAL TIP INITIAL CBCT CORRELATIONS

Pearson correlations	Rater #1 CBCT Time Point 1	Rater #1 CBCT Time Point 2	Rater #2 CBCT Time Point 1	Rater #2 CBCT Time Point 2
Rater #1 CBCT Time Point 1	1	.988 [*]	.983 [*]	.984 [*]
Rater #1 CBCT Time Point 2		1	.985 [*]	.986 [*]
Rater #2 CBCT Time Point 1			1	.983 [*]
Rater #2 CBCT Time Point 2				1

^{*}All correlations had p-value of 0.000 which was significant at the 0.01 level. N=272 for each time point.

TABLE II
MESIO-DISTAL TIP THERAPEUTIC MODEL CORRELATIONS

Pearson correlations	Rater #1 Model Time Point 1	Rater #1 Model Time Point 2	Rater #2 Model Time Point 1	Rater #2 Model Time Point 2
Rater #1 Model Time Point 1	1	.993 [*]	.986 [*]	.979 [*]
Rater #1 Model Time Point 2		1	.986 [*]	.978 [*]
Rater #2 Model Time Point 1			1	.982 [*]
Rater #2 Model Time Point 2				1

^{*}All correlations had p-value of 0.000 which was significant at the 0.01 level. N=272 for each time point.

The pairwise intra- and inter-rater Pearson correlations for initial CBCT facio-lingual torque are shown in Table III. Table IV shows the therapeutic (initial) model facio-lingual torque pairwise intra- and inter-rater Pearson correlations.

TABLE III
FACIO-LINGUAL TORQUE INITIAL CBCT CORRELATIONS

Pearson correlations	Rater #1 CBCT Time Point 1	Rater #1 CBCT Time Point 2	Rater #2 CBCT Time Point 1	Rater #2 CBCT Time Point 2
Rater #1 CBCT Time Point 1	1	.997 [*]	.993 [*]	.993 [*]
Rater #1 CBCT Time Point 2		1	.994 [*]	.994 [*]
Rater #2 CBCT Time Point 1			1	.994 [*]
Rater #2 CBCT Time Point 2				1

*All correlations had p-value of 0.000 which was significant at the 0.01 level. N=272 for each time point.

TABLE IV
FACIO-LINGUAL TORQUE THERAPEUTIC MODEL CORRELATIONS

Pearson correlations	Rater #1 Model Time Point 1	Rater #1 Model Time Point 2	Rater #2 Model Time Point 1	Rater #2 Model Time Point 2
Rater #1 Model Time Point 1	1	.997 [*]	.991 [*]	.992 [*]
Rater #1 Model Time Point 2		1	.992 [*]	.994 [*]
Rater #2 Model Time Point 1			1	.986 [*]
Rater #2 Model Time Point 2				1

*All correlations had p-value of 0.000 which was significant at the 0.01 level. N=272 for each time point.

To further evaluate the inter-rater agreement, time point 1 and time point 2 measures were combined for each rater. The discrepancy between the CBCT and the model measures was calculated and analyzed with a paired sample *t*-test.

For tip, rater #1 had a mean discrepancy of -0.06° between model and CBCT measures with a standard deviation of 1.23° . Rater #2 had a mean discrepancy of 0.00° with a standard deviation of 1.56° . These values are found in Table V.

TABLE V
MESIO-DISTAL TIP DESCRIPTIVE STATISTICS

	Mean	N	Std. Deviation	Std. Error Mean
Rater #1 CBCT vs. Model	-0.06°	544	1.23°	.053
Rater #2 CBCT vs. Model	$.00^{\circ}$	544	1.56°	.067

A paired *t*-test found the means not to be statistically different with a mean discrepancy of -0.06° and a standard deviation of 1.63° and a *p*-value of 0.368.

The results are shown in Table VI.

TABLE VI
MESIO-DISTAL TIP PAIRED SAMPLES *T*-TEST

	Mean	Std. Deviation	t	df	p
Pair 1 Rater #1 CBCT vs. Model Rater #2 CBCT vs. Model	-0.06°	1.63°	-.901	543	.368

**p*-value is significant at the 0.05 level.

For torque, rater #1 had a mean discrepancy of 0.24° between model and CBCT measures with a standard deviation of 1.42° . Rater #2 had a mean discrepancy of 0.98° with a standard deviation of 2.02° . These values are found in Table VII.

TABLE VII
FACIO-LINGUAL TORQUE DESCRIPTIVE STATISTICS

	Mean	N	Std. Deviation	Std. Error Mean
Rater #1 CBCT vs. Model	.24°	544	1.42°	.061
Rater #2 CBCT vs. Model	.98°	544	2.02°	.087

A paired *t*-test found the means to be statistically different with a mean discrepancy of -0.74° and a standard deviation of 2.07° and a p-value of 0.000.

The results are shown in Table VIII.

TABLE VIII
FACIO-LINGUAL TORQUE PAIRED SAMPLES T-TEST

	Mean	Std. Deviation	t	df	p
Pair 1 Rater #1 CBCT vs. Model Rater #2 CBCT vs. Model	-.74°	2.07°	-8.332	543	.000*

*p-value is significant at the 0.05 level.

4.2 **Results of the Evaluation of Changes to the Occlusal Plane**

To evaluate the occlusal plane changes during treatment, one sample *t*-tests were used to compare the outcome angles to the original as measured from each of the three planes of space for 5 cases. Only one angle, case 14 from the lateral view, was statistically different from the original angular measurements with a p-value of .027, a mean of 78.1 and an outcome measure of 78.7 having 0.6° discrepancy. See Table IX.

TABLE IX
PLANE OF OCCLUSION EVALUATION

Case number and view	Mean Initial (4 measures)	SD pre-treatment	Outcome measure	Difference outcome to Initial	t	df	p	95% CI of the Difference	
13 Frontal	133.8	.48	133.7	.1	.414	3	.707	-.669	.869
14 Frontal	134.8	.52	135.1	-.3	-1.606	3	.367	-1.101	.551
15 Frontal	128.0	.70	128.0	.0	-.142	3	.896	-1.171	1.071
22 Frontal	131.6	.63	130.7	.9	2.916	3	.062	-.085	1.935
28 Frontal	137.9	.93	138.1	-.2	-.540	3	.627	-1.723	1.223
13 Lateral	72.9	.66	-	-	-	-	-	-	-
14 Lateral	78.1	.29	78.7	-.6	4.076	3	.027*	-1.068	-.132
15 Lateral	81.9	.90	82.8	-.9	-1.945	3	.147	-2.306	.556
22 Lateral	77.1	.50	77.3	-.2	-.805	3	.480	-.990	.590
28 Lateral	79.3	.87	79.4	-.1	-.289	3	.792	-1.502	1.252
13 SMV	89.0	.98	88.5	.5	.917	3	.427	-1.112	2.012
14 SMV	89.2	1.05	89.7	-.5	-.905	3	.432	-2.146	1.196
15 SMV	90.1	1.84	91.6	-1.5	-1.653	3	.197	-4.460	1.410
22 SMV	90.4	1.07	90.8	-.5	-.844	3	.461	-2.146	1.246
28 SMV	137.9	.93	138.1	-.2	-.540	3	.627	-1.723	1.223

*p-value is significant at the 0.05 level. Case 13 Lateral could not be measured due to absence of the point nasion.

4.3 Results of the Evaluation of the Discrepancy between SureSmile™

Therapeutic Model and Initial CBCT

Rater #1 demonstrated lower standard deviations and standard errors; therefore, final measures were only completed by rater #1. One sample *t*-tests were used to test if the mean tip and torque discrepancy of the initial CBCT and therapeutic model for rater #1 were statistically different from 0.0° of difference.

For tip, the mean discrepancy between initial model and CBCT was 0.06° with a standard deviation of 1.23°. The *t*-test found this value not to be statistically different from 0.0°. Refer to Table X.

TABLE X
INITIAL MESIO-DISTAL TIP ONE SAMPLE T-TEST

	Test Value = 0.0					
	t	df	p	Mean Discrepancy	95% CI of the Difference	
					Lower	Upper
Discrepancy Initial CBCT vs. Initial Model Rater #1 for Tip	-1.136	543	.256	-.06°	-.164	.044

p-value is significant at the 0.05 level.

For torque, the mean discrepancy between initial model and CBCT was 0.24° with a standard deviation of 1.42°. The *t*-test found this value to be statistically different from 0.0°. Refer to Table XI.

TABLE XI
INITIAL FACIO-LINGUAL TORQUE ONE SAMPLE T-TEST

	Test Value = 0.0					
	t	df	p	Mean Discrepancy	95% CI of the Difference	
					Lower	Upper
Discrepancy Initial CBCT vs. Initial Model Rater #1 for Torque	3.952	543	.000*	.24°	.121	.361

p-value is significant at the 0.05 level.

4.4 Results of the Evaluation of SureSmile™ Treatment Outcomes

The discrepancy between the final CBCT (outcome) and the SureSmile™ target model (SS plan) measures for tip were calculated and can be found in Table XII.

TABLE XII
OUTCOME MESIO-DISTAL TIP DESCRIPTIVE STATISTICS

	Mean discrepancy	N	Std. Deviation	Std. Error Mean
SS Plan vs. Final CBCT	.630°	829	3.44°	.1195

A one sample *t*-test was used to compare the discrepancy of the outcome CBCT to the SS target model tip and the mean discrepancy of initial CBCT to initial model tip for rater #1 to the baseline discrepancy for that rater of -0.06°. The test found the measures to be statistically different by a mean of 0.69° with a *p*-value of 0.000. Refer to Table XIII.

TABLE XIII
OUTCOME MESIO-DISTAL TIP ONE SAMPLE *T*-TEST

	Test Value = -0.06 (mean of rater #1 initial CBCT vs. initial model)					
	t	df	p	Mean Discrepancy	95% CI of the Difference	
					Lower	Upper
Discrepancy Initial CBCT vs. Initial Model Rater #1 for Tip	5.777	828	.000*	.69°	.456	.925

p-value is significant at the 0.05 level.

Histograms were created to provide a visual representation of the discrepancy between the final CBCT to the SS plan for tip (Figure 6) in contrast to the initial CBCT and initial model for tip (Figure 7).

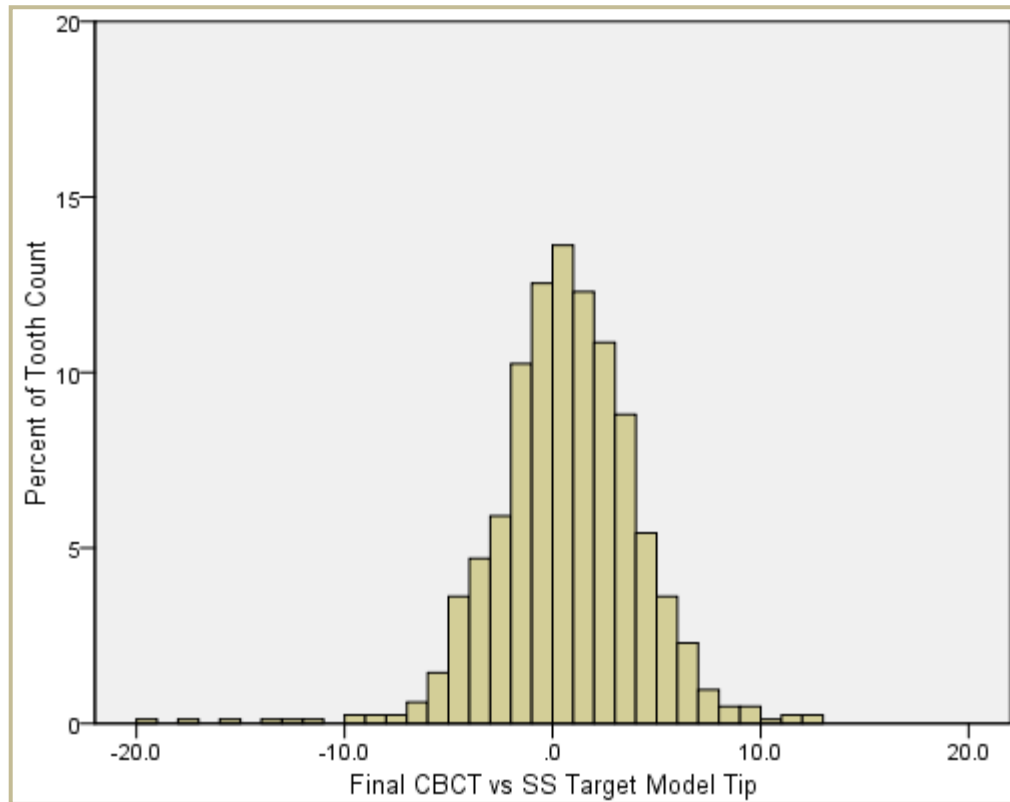


Figure 6. Histogram of the mesio-distal tip discrepancy between final CBCT and the SS target model.

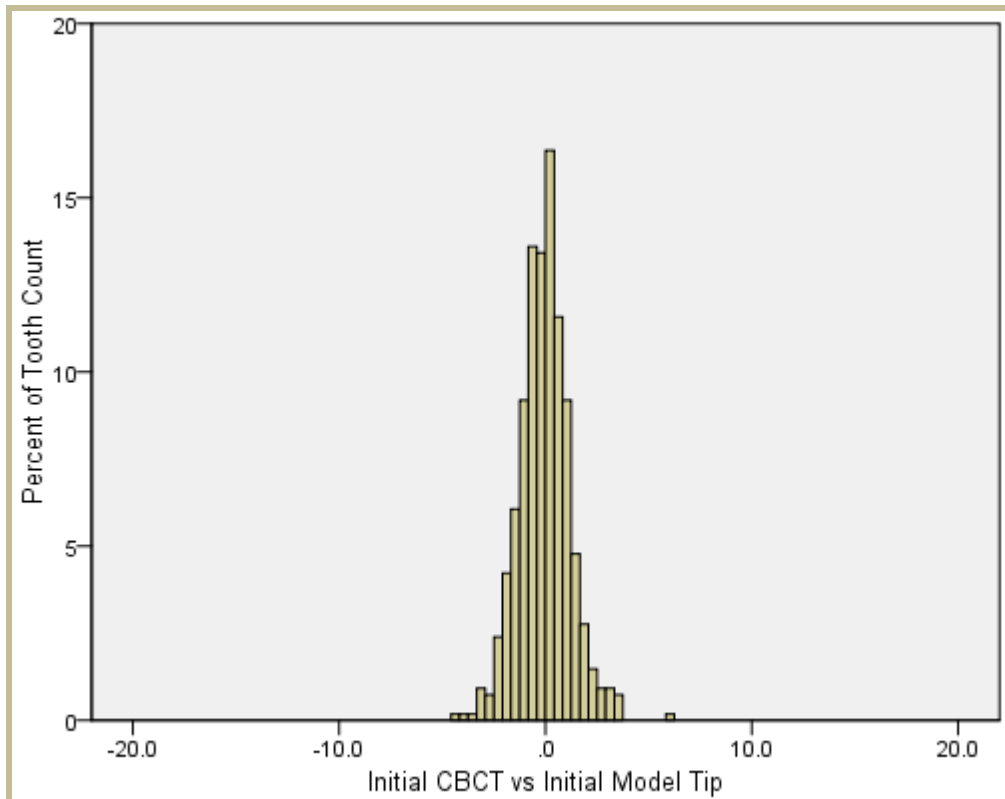


Figure 7. Histogram of the mesio-distal tip discrepancy between initial CBCT and the initial model.

The torque discrepancy between the final CBCT (outcome) and the SureSmile™ target model (SS plan) measures were calculated and can be found in Table XIV.

TABLE XIV
OUTCOME FACIO-LINGUAL TORQUE DESCRIPTIVE STATISTICS

	Mean discrepancy	N	Std. Deviation	Std. Error Mean
SS Plan vs. Final CBCT	.994°	829	4.55°	.1579

A one sample *t*-test was used to compare the discrepancy of the outcome CBCT to the SS target model torque and the mean discrepancy of initial CBCT to initial model torque for rater #1 to the baseline discrepancy for that rater of 0.24°. The test found the measures to be statistically different by a mean of 0.75° with a p-value of 0.000. Refer to Table XV.

TABLE XV
OUTCOME FACIO-LINGUAL TORQUE ONE SAMPLE T-TEST

	Test Value = 0.24 (mean of rater #1 initial CBCT vs. initial model)					
	t	df	p	Mean Discrepancy	95% CI of the Difference	
					Lower	Upper
Discrepancy Final CBCT vs. SS Target Model for Torque	4.773	828	.000*	.75°	.444	1.064

p-value is significant at the 0.05 level.

Histograms were created to provide a visual representation of the discrepancy between the final CBCT to the SS plan for torque (Figure 8) in contrast to the initial CBCT and initial model for torque (Figure 9).

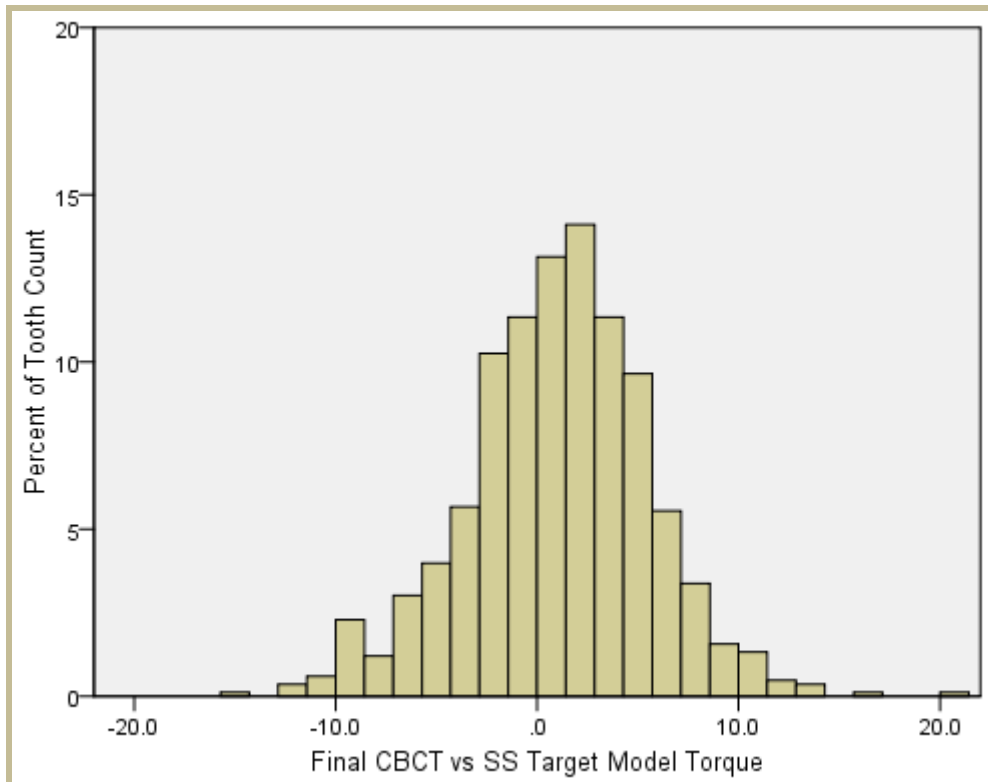


Figure 8. Histogram of the facio-lingual torque discrepancy between final CBCT and the SS target model.

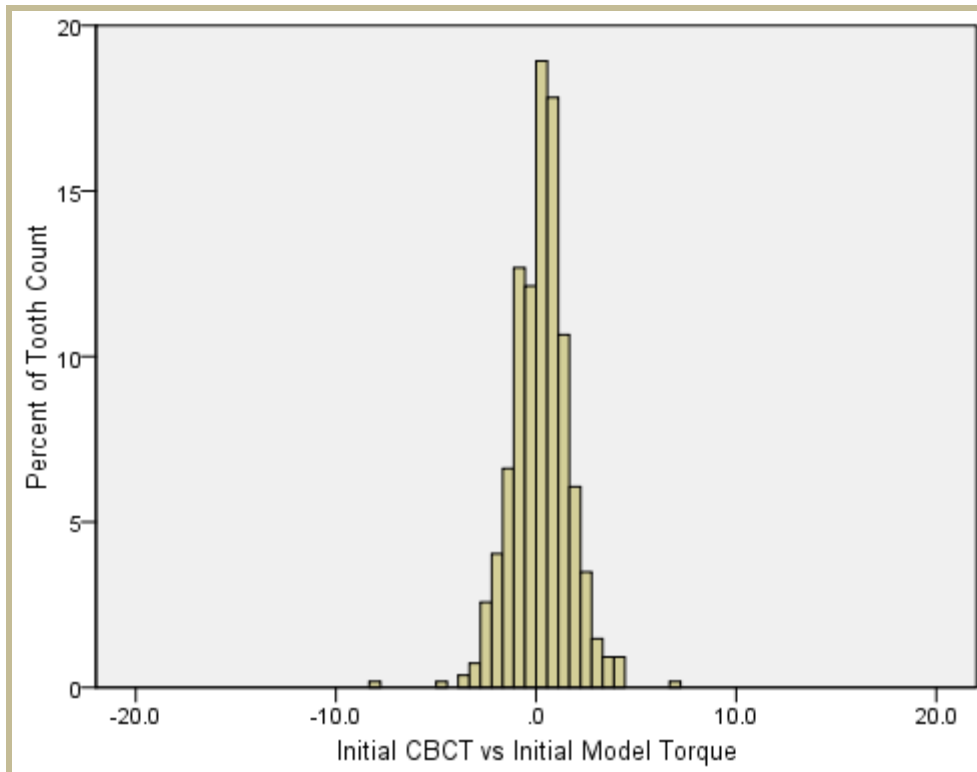


Figure 9. Histogram of the facio-lingual torque discrepancy between initial CBCT and the initial model.

To obtain a better understanding if specific tooth types were more prone to greater mean discrepancy between the SS plan and the final CBCT, t -tests were used to compare tooth types. The tests found no statistical difference between the tip discrepancy of the outcome CBCT and the SS target model as compared to the mean discrepancy of the initial CBCT and initial model for the maxillary central, first premolar, second premolar, and first molar; and for the mandibular central and lateral, p -values $> .05$. For the remaining teeth: maxillary lateral, canine, second molar; and the mandibular canine, first premolar, second premolar, first molar, and second molar the tests found the means to be

statistically different with a p-value < 0.05. Refer to Table XVI, Figure 10 is a bar graph representing the values from this table.

**TABLE XVI
TOOTH TYPE COMPARISON TIP**

	Mean discrepancy initial CBCT and model	N initial CBCT to model	SD	Mean discrepancy final CBCT to SS plan	N final CBCT to SS plan	SD	t	p	95% Confidence Interval of the Difference	
Maxilla Tip										
Central	0.17	40	1.01	0.12	60	2.49	-0.145	.885	-0.665	0.575
Lateral	0.17	40	1.42	-1.15	60	2.73	-3.740	.000*	-2.026	-0.614
Canine	-0.17	40	0.99	0.5	60	1.95	2.677	.010*	0.170	1.179
First Premolar	-0.16	32	1.51	0.1	56	2.17	0.889	.373	-0.321	0.842
Second Premolar	0.01	40	0.98	0.5	59	2.47	1.538	.129	-0.149	1.139
First Molar	-0.35	40	1.26	-0.35	60	3.07	0.013	.990	-0.787	0.797
Second Molar	0.49	40	1.64	-2.81	58	5.73	-4.388	.000*	-4.804	-1.793
Mandible Tip										
Central	0.08	40	1.1	0.3	59	2.43	0.678	0.5	-0.419	0.849
Lateral	0.26	40	1.4	0.16	60	2.83	-0.278	.782	-0.833	0.630
Canine	0.37	40	0.82	1.56	60	2.55	3.612	.001*	0.532	1.852
First premolar	-0.23	32	1.34	2.24	58	2.31	8.122	.000*	1.864	3.084
Second Premolar	-0.41	40	0.98	1.91	60	2.44	7.371	.000*	1.693	2.954
First Molar	-0.93	40	0.99	1.26	60	3.52	4.839	.000*	1.291	3.110
Second Molar	-0.17	40	1.07	4.43	59	4.14	8.532	.000*	3.522	5.682
Maxilla Combined	0.02	272	1.30	-0.44	413	3.32	-2.796	.005*	-0.778	-0.136
Mandible Combined	-0.15	272	1.18	1.69	416	3.23	11.628	.000*	1.528	2.150
Overall	-0.06	544	1.23	0.63	829	3.44	5.777	.000*	0.456	0.925

*p-value is significant at the 0.05 level.

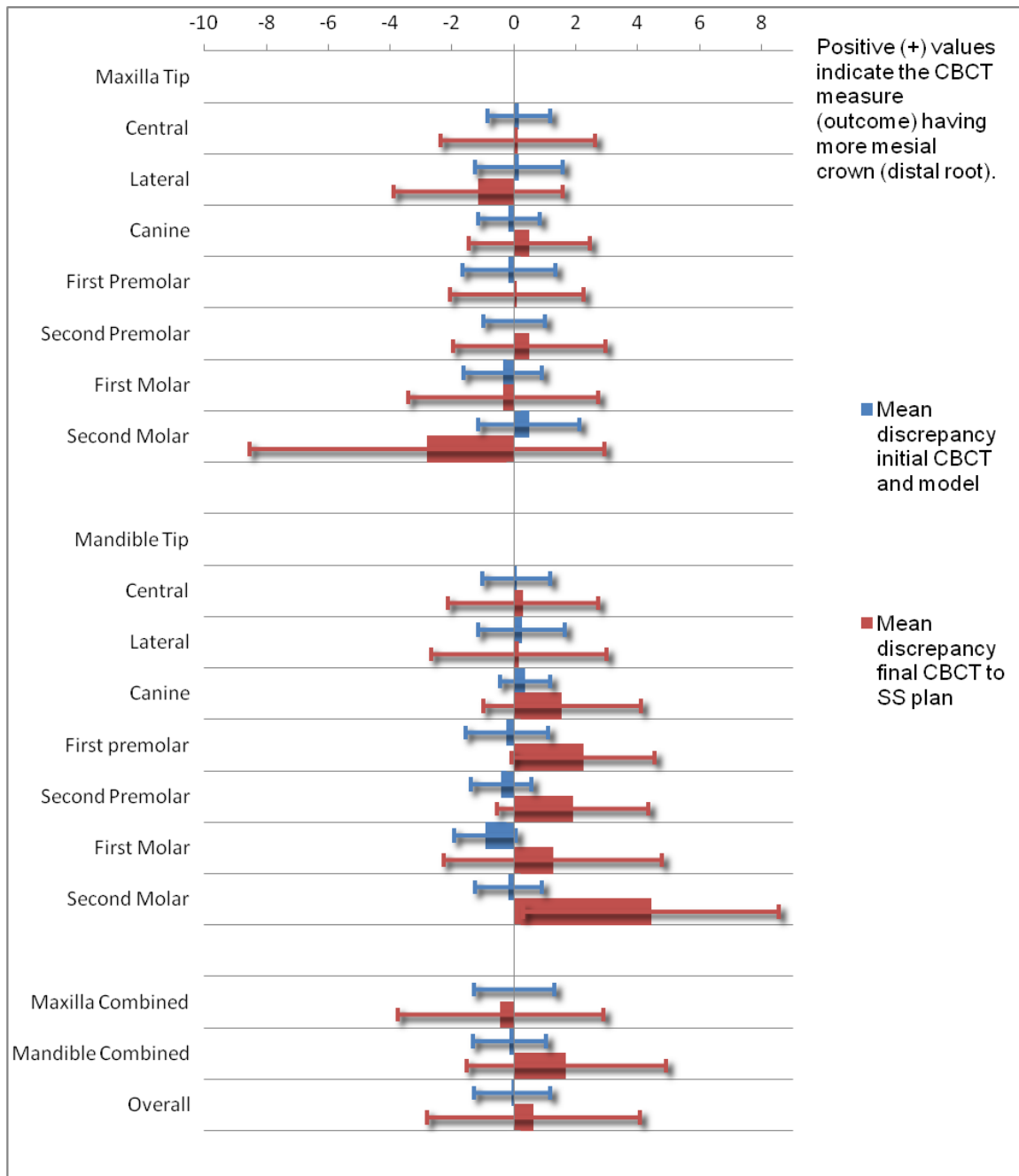


Figure 10. Bar graph representing the values in tooth type comparison for tip in degrees. Error bars represent standard deviations. The thicker bars represent the amount of mean deviation from 0.0° for the category.

For torque, the *t*-tests found no statistical difference between the mean discrepancy of the outcome CBCT and the SS target model as compared to the discrepancy of the initial CBCT and initial model for the maxillary central, canine, first premolar, and second premolar; and for the mandibular first premolar, *p*-values > .05. For the remaining teeth: maxillary lateral, first premolar, first molar, second molar; and the mandibular central, lateral, canine, second premolar, first molar, and second molar the tests found the means to be statistically different with a *p*-value < 0.05. Refer to Table XVII, Figure 11 is a bar graph representing the values from this table.

TABLE XVII
TOOTH TYPE COMPARISON TORQUE

	Mean discrepancy initial CBCT and model	N initial CBCT to model	SD	Mean discrepancy final CBCT to SS plan	N final CBCT to SS plan	SD	t	p	95% Confidence Interval of the Difference	
Maxilla Torque										
Central	0.27	40	1.09	0.24	60	3.53	-0.077	.939	-0.946	0.876
Lateral	0.68	40	1.28	2.78	60	3.82	4.271	.000*	1.118	3.089
Canine	0.13	40	1.34	-0.59	60	3.91	-1.437	.156	-1.734	0.284
First premolar	0.25	32	1.35	0.14	56	4.29	-0.193	.847	-1.259	1.037
Second premolar	0.40	40	1.50	0.84	59	4.23	0.811	0.42	-0.656	1.551
First molar	0.25	40	1.72	2.10	60	3.22	4.452	.000*	1.018	2.681
Second molar	0.26	40	1.63	3.47	58	5.20	4.708	.000*	1.848	4.584
Mandible Torque										
Central	0.52	40	1.24	4.06	59	4.44	6.135	.000*	2.388	4.701
Lateral	-0.04	40	0.93	4.03	60	3.88	8.135	.000*	3.070	5.073
Canine	0.01	40	0.87	1.43	60	4.24	2.587	.012*	0.320	2.509
First premolar	0.66	32	2.00	0.50	58	3.76	-0.316	.753	-1.145	0.833
Second premolar	0.35	40	1.28	-2.33	60	3.96	-5.243	.000*	-3.700	-1.656
First molar	0.27	40	1.96	-0.81	60	3.66	-2.271	.027*	-2.019	-0.127
Second molar	0.09	40	1.20	-1.93	59	5.02	-3.082	.003*	-3.328	-0.707
Maxilla Combined										
Maxilla Combined	0.23	272	1.44	1.28	413	4.27	5.014	.000*	0.641	1.467
Mandible Combined										
Mandible Combined	0.25	272	1.44	0.71	416	4.79	1.939	.050*	-0.006	0.918
Overall										
Overall	0.24	544	1.42	0.99	829	4.55	4.773	.000*	0.443	1.063

*p-value is significant at the 0.05 level.

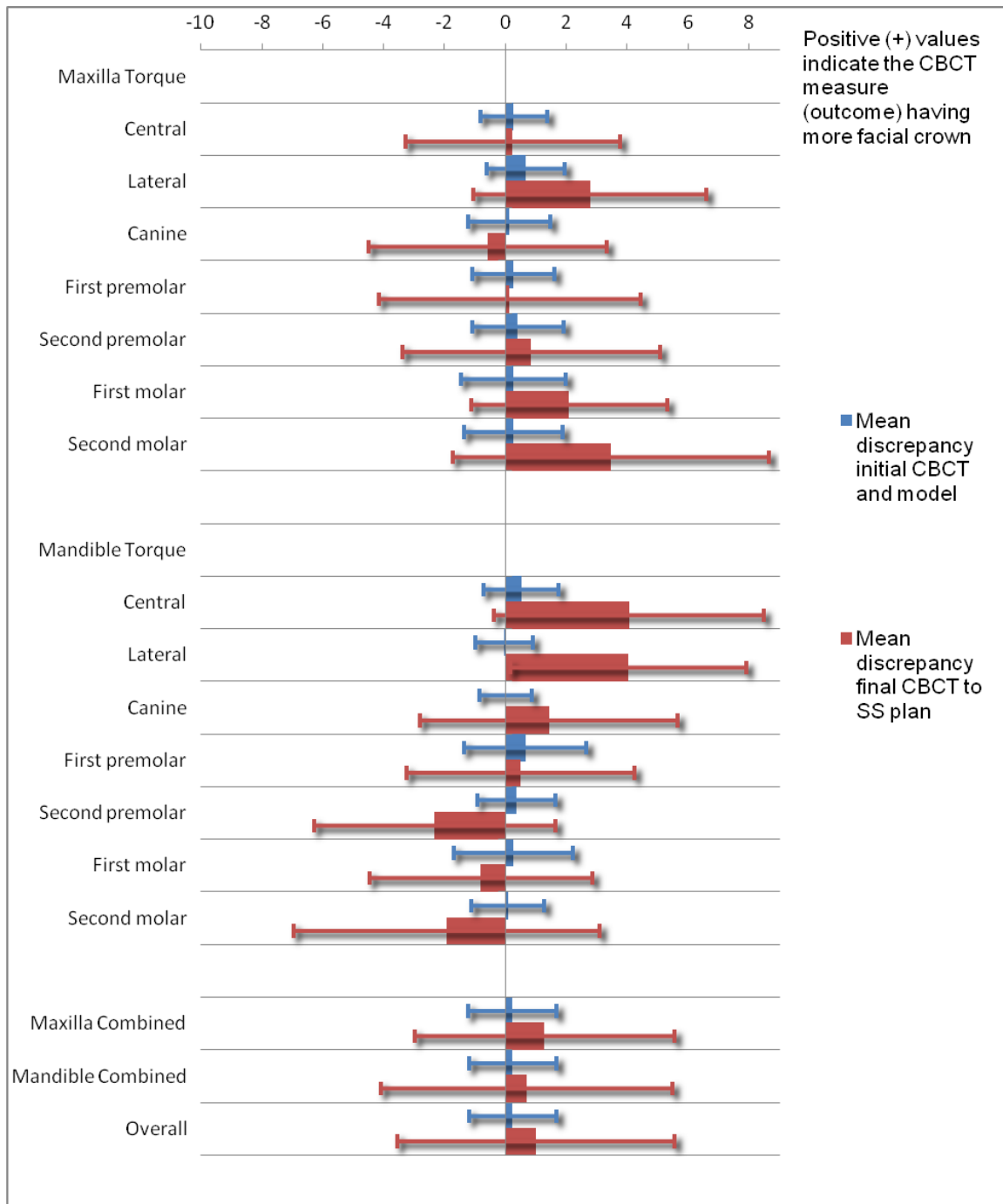


Figure 11. Bar graph representing the values in tooth type comparison for torque in degrees. Error bars represent standard deviations. The thicker bars represent the amount of mean deviation from 0.0° for the category.

As a final comparison, the percent of each tooth type for which the outcome was found to be within the 2.5° of the plan was calculated. Refer to Table XVIII. A graphic representation of this can be seen in Figure 12.

TABLE XVIII
OUTCOMES WITHIN 2.5 OF THE PLAN BY TOOTH TYPE

	Percent within 2.5° of Planned Tip	Count within 2.5° of Planned Tip	Total	Percent within 2.5° of Planned Torque	Count within 2.5° of Planned Tip	Total
Maxillary						
Central	67	40	60	65	39	60
Lateral	57	34	60	43	26	60
Canine	82	49	60	50	30	60
First premolar	82	46	56	54	30	56
Second premolar	73	43	59	47	28	59
First molar	60	36	60	52	31	60
Second molar	41	24	58	31	18	58
Mandibular						
Central	69	41	59	31	18	59
Lateral	60	36	60	30	18	60
Canine	62	37	60	38	23	60
First premolar	48	28	58	55	32	58
Second premolar	52	31	60	48	29	60
First molar	53	32	60	52	31	60
Second molar	17	10	59	32	19	59
MAXILLA COMBINED	65.9	272	413	48.9	202	413
MANDIBLE COMBINED	51.7	215	416	40.9	170	416
OVERALL	58.7	487	829	44.9	372	829

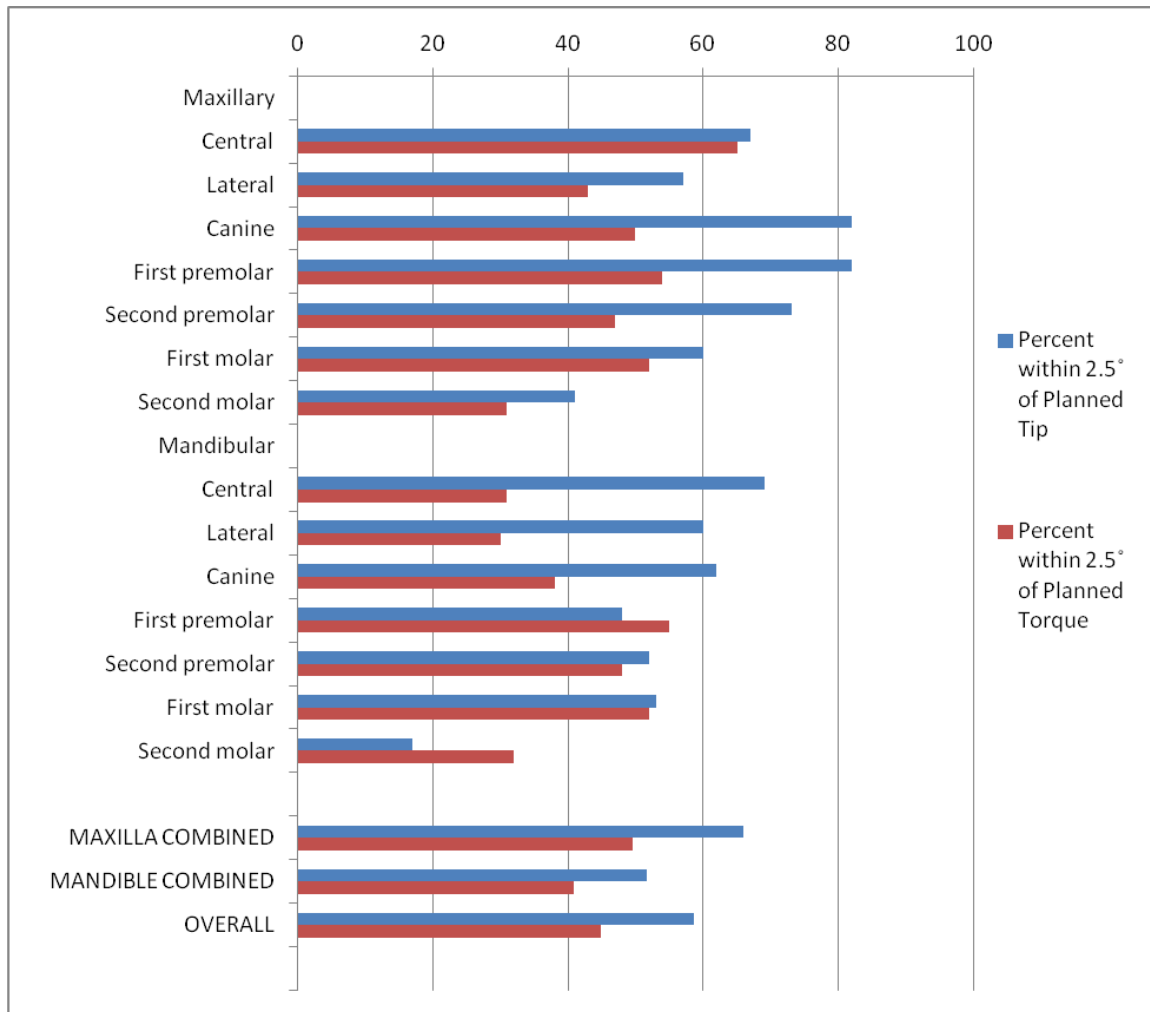


Figure 12. Percent tip and torque within 2.5° of the plan, by tooth type.

Of the 30 cases in the final evaluation, the mean and standard deviation for the age and treatment components were calculated and can be found in Table XIX.

TABLE XIX
AGE AND TREATMENT DURATION DESCRIPTIVE STATISTICS

	Mean	Standard Dev.
Age at start (years)	13.8	4.1
Braces treatment total (months)	14.9	4.3
Total SS wire treatment (months)	7.9	2.6
Debond to final CBCT (months)	2.9	0.2

5. DISCUSSION

Reports in the literature differ in the amount of tip and torque change considered clinically relevant or ideal. For example, Larson et al. (2012) considered $\pm 2.0^\circ$ of variation to be clinically ideal, Tong et al. (2012b) considered $\pm 2.5^\circ$ to be clinically significant, while Bouwens et al. (2011) indicated that 5° of tip change is not likely to alter treatment decisions. After deliberation it was determined that 2.5° would be the criteria followed to represent clinically acceptable variation in tip and torque. However, this is only a measuring gauge applied to the data to represent clinically significant values, and does not indicate unacceptable outcomes for teeth which do not meet this criteria. The same standard has not been tested for other therapeutic systems, customized or not. In this regard, SureSmile™ is being evaluated against a different standard than is usual for conventional treatment or other 3D treatment planning systems.

Attention must be drawn to the significance of the duration between removal of the appliances and obtaining the final CBCT. The final CBCTs were obtained an average of 2.9 months after debond (Table XIX). Settling occurs most rapidly during the 2 months immediately after debond (Bauer et al., 2010). This post debond settling period is likely to impact the tip and torque outcomes which were actually achieved with the SS treatment. Therefore, only general evaluations and global comparisons should be completed for this data. Considering an average settling time of 2.9 months, and variation in the patient's

adherence to retention protocols, outcomes were still found within 2.5° of the plan for tip in 59% and for torque in 45% of the sample teeth (Table XVIII, Figure 12).

It is also important to consider the following points when evaluating the findings of this study. Continuous arch wires yield reciprocal forces on adjacent teeth and the potential to respond to the applied forces varies with each tooth type and by biological, physical, and temporal constraints, and will often manifest the applied forces in an unpredictable manner (Proffit, 2000). In addition, the treatment decisions remain with the provider; this begins with the determination of the treatment plan and ends with the decision to remove the appliances. SureSmile™ is a tool used by the clinician to strive for these goals.

With regards to tip, the maxillary lateral, maxillary canine, maxillary second molar, mandibular canine, mandibular first premolar, mandibular second premolar, mandibular second premolar, mandibular first molar, and mandibular second molar had mean discrepancies statistically different from the planned angulation (Table XVI). Only the maxillary second molars and mandibular second molars had mean tip discrepancies greater than 2.5° (from the initial) indicating clinical relevance. Larson et al. (2012) used strict determinations of acceptable outcome tip ($\pm 2.0^\circ$) and obtained records immediately following debond. They report only the mandibular second premolars and first molars to be within their definition of clinical ideal of the plan for tip. In contrast to the findings of Larson et al. (2012), the mandibular second premolars and first

molars in this study had only 52% and 53% of the tip outcomes within 2.5° of the plan and which were 4th and 5th worst of the 14 tooth types, respectively. This indicates that different tooth types had tip outcomes best matching the plan. This variation seen with SS for different providers may be due to the provider's method of treating using SS (wire selection, brackets etc.) and/or the method the provider used to create the treatment simulation.

With regards to torque, the maxillary lateral, maxillary first molar, maxillary second molar, mandibular central, mandibular lateral, mandibular canine, mandibular second premolar, mandibular first molar, and mandibular second molar had mean discrepancies statistically different from the planned inclination (Table XVII). Only the maxillary second molar, mandibular central, and mandibular lateral, and mandibular second premolar had mean torque discrepancies greater than 2.5° (from the initial) indicating clinical relevance. In contrast, Larson et al. (2012) reported absolute torque discrepancy in excess of $\pm 2.0^\circ$ for all tooth types except the mandibular second molars. This indicates that different tooth types had torque outcomes corresponding to the plan, and are potentially due to differences in the provider's individual SS technique.

Provider specific modifications could potentially improve the overall outcome tip and torque values relative to the plan. For example, the mandibular central and lateral incisors were found to have a mean torque discrepancy of 4°. The positive discrepancy indicates that the outcome had more facial crown

torque than the plan by the same amount. Since this is an average result for the provider's treatment method, it may be possible for an accommodation to be built into the SS prescription, adding 4 more degrees of lingual crown for those teeth than the target model would indicate. Further investigation would be required to determine if these provider specific modifications would result in all tooth types having mean discrepancies within clinically ideal of the plan. Additionally, the physiologic and anatomical limitation of each patient must also be considered to limit negative sequel from the orthodontic treatment.

It is interesting to note that the standard deviations for torque were generally higher than the standard deviations for tip, and a lower percent of the teeth had outcome torque values within 2.5° of the plan. A similar trend was also found by Larson et al. (2012). It is suspected that this indicates a potential deficiency of the bracket and wire combination to express the desired torque. Wire and bracket slot dimensions limit the ability to obtain desired outcomes. Slot tolerances and arch wire to bracket slot discrepancy studies (often referred to as slop) are ubiquitous in the orthodontic literature and contribute to this problem (Proffit and Ackerman, 2000). As compared to the maxilla, the mandible also had more tooth types statistically different from the plan and fewer mean torque discrepancies within 2.5° of the plan. A possible explanation for this may be the physiologic or anatomic differences when compared to the maxillary arch such as increased bone density of the lower arch. One must also consider the duration for which the arch wire is worn, if the allowed to express over a longer

period, the response may be closer to the target. All cases were also treated using inter-arch elastics for some period with the SS arch wires in place which may also influence the angular outcomes.

Of the 30 patients outcomes (829 teeth) evaluated in the study, the mean age was 13.8 years at the start of treatment (range 10.7-34.8 years) (Table XIX). This is younger than the mean age for SS patients reported by Alford et al. (2011) (18.1 years), which was the only other SS publication with this information. The mean overall treatment duration was 14.9 months (range 8.5-31.7 months). The average total treatment duration is much lower than reported values for conventional treatment of 23-31 months (Fink and Smith, 1992; Mavreas and Athanasiou, 2008). This is also lower than the average reported for SS treatments by Alford et al. (22.7 months) and nearly identical to that reported by Saxe et al. (2010) (14.7 months). The overall mean treatment with SS wires was 7.9 months (range 5.8-19.6 months). This value could not be located in other SS outcome publications (Saxe et al., 2010; Alford et al. 2011; Larson et al., 2012).

Severity of the initial malocclusion was not considered. Angle classification was obtained for descriptive purposes according to the diagnosis of the clinician. There were 14 Class I (3 having Class III tendency), 10 Class II division 2 (6 were subdivisions), 3 Class II division 1 (2 were subdivisions), and 3 Class III patients.

The overall results demonstrated that the mean discrepancy between the outcome CBCT and SS target model for both tip and torque were within 1° degree of the planned. This is within the 1° measuring error of the software measuring technique to the coordinate measuring machine reported by Tong et al. (2012b). The average tip discrepancy 0.630° and torque discrepancy of 0.994° are within the error for the measuring technique in spite of statistically significant findings of the mean discrepancies to the initial model and CBCT.

The data were reviewed and correlation analysis completed to determine if variables such as age, duration of treatment, duration of SS wire wear, and duration from debond to final CBCT, contributed to better outcomes. There were no significant correlations to the descriptive variables resulting in a higher or lower percent of the treatment teeth with an outcome within 2.5° of the plan. Additionally, no significant correlation existed between cases with tip outcomes having more teeth within 2.5° of the plan and the torque outcomes within 2.5° of the plan; in other words good tip does not equate to good torque. This is likely due to the multiple factors which affect the treatment outcome such as patient compliance and initial treatment severity as well as the retention period during which additional settling and variation were introduced (Deguchi et al., 2005; Mavreas and Athanasiou, 2008; Bauer et al., 2010).

5.1 **Occlusal Plane Changes**

This study made efforts to evaluate whether changes to the plane of occlusion occurred during the SS treatment duration until the final records were obtained. Of the published studies evaluating SS treatment outcomes, none could be found which evaluated, or took into account, the skeletal changes to the occlusal plane (Saxe et al., 2010; Alford et al., 2011; Larson et al., 2012). Of the cases tested, only one showed statistically significant change (p -value $< .05$) of 0.6° . This represented a change of the occlusal plane from 78.1° to 78.7° in the lateral view. However, a change of only 0.6° is not likely clinically significant and would not indicate a necessary compensation in the evaluation of tip and torque outcomes of the SS treatment. For purposes of the study, all occlusal planes were assumed relatively constant from initiation of SS treatment to final CBCT.

5.2 **Strengths and Limitations**

The study included a large sample size and demonstrated strong intra- and inter-rater correlation. All patients were treated by the same provider using the provider's standard treatment approach. This reduces variation which would be introduced by multiple providers and treatment approaches. The patients were treated according to the provider's best clinical judgment and represents actual conditions of the SS system in private practice. By utilizing angular measurements, a quantitative result which is more readily understandable and applicable to clinical settings was obtained.

However, there are multiple limitations to this study. This study is only representative of the treatment of one provider, and different results may likely be found for other providers. The provider completed a “virtual wire-bending session” prior to completing each case. This represents a change from the original treatment prescription and potentially an alteration to the tip and torque of the sample teeth. Many of these changes were minor and completed a short period before debond but would still express changes to the outcome.

Final CBCTs were also obtained an average of 12.5 weeks after debond. Settling occurs most rapidly during the period immediately after debond. There was significant opportunity for changes to the inclination and angulations of the teeth to occur, either closer or further away from those planned.

Human measurement error is also a significant limitation to the study. In addition to the error of the human rater, actual changes to the root and/or crown may also have occurred and played a role in changes to the outcome measurements. Due to patient age, many of the premolars, canines, and second molars had incomplete apical root formation at the time of the therapeutic SS scan. These teeth experienced some apical root calcification which may have possibly changed the angle representing the whole tooth tip and torque relative to the SS target model, which was derived from the earlier initial CBCT. Additionally, some teeth may have experienced root resorption or undergone attrition, abrasion, or enamoplasty of the coronal anatomy resulting in deviation

of the final CBCT landmarks as compared to the SS target model. These errors were most likely minor but must be considered.

5.3 **Future Research**

There are multiple potential research directions which would be beneficial to explore for all methods of 3D treatment planning (Invisalign™, Incognito™, Insignia™, etc.) to compare and contrast different 3D orthodontic setup systems available on the orthodontic market. It would be informative to evaluate tip and torque control of the existing systems in a similar fashion, yet other than SS, none of these systems currently plan the entire tooth movement including the root. The overall goal would be as alluded to by Kwon (2011), when he attempted to establish 3D root norms for Class 1 normal occlusions: namely, to treat each tooth to an ideal angulation, inclination, and occlusion for a potentially more stable, natural, or ideal dentition.

In preparation for future studies more 3D norms need to be established. An example of this would be “untreated norms” for 3D whole tooth tip and torque as it changes over time for growing and adult patients. Once established these norms could be used to evaluate the typical post orthodontic changes to tip and torque during the immediate and prolonged retention periods in order to determine the role which whole tooth tip and torque play in treatment stability.

To evaluate the stability of the outcomes and angulations would require a prospective research project in which all patients would be treated towards a desired “normal” or “ideal” tip and torque and then followed longitudinally for stability and having untreated norms against which the data could be compared. However, treating to a prescribed tip and torque for each tooth is nearly impossible without 3D imaging and precise robotic wire bending assistance.

Hopefully, the future of orthodontics will improve in this area, allowing for increasingly more predictable outcomes and eventually tailored treatment plans which can take into account the multiple factors which limit or dictate the actual best final arrangement for the patients tooth alignment, including inclination and angulation.

6. CONCLUSION

Given the limitations, this study concludes that although statistically different, the mean discrepancy of the SS target models to the outcome CBCT are within the tolerance of the measuring technique ($\pm 1^\circ$) and clinically acceptable range ($\pm 2.5^\circ$) for tip in 59% of the sample teeth and for torque in 45% of the sample teeth (Table XVIII, Figure 12). Outcomes varied by tooth type; this was demonstrated by the mean discrepancies for each tooth type and the differences in tooth types having outcomes within 2.5° of the plan. Clinically significant mean discrepancy (beyond $\pm 2.5^\circ$) was limited to the maxillary and mandibular second molars for tip, and the maxillary second molar and mandibular central and lateral for torque. Tip outcomes were closer to the plan than torque outcomes over all and for most tooth types. Teeth in the mandibular arch had fewer outcomes within 2.5° of the plan, fewer teeth with mean discrepancies closest to the plan, and had greater overall discrepancy from the plan. Further investigation needs to be completed in order to determine the cause of these findings; the results validate the need for careful planning in 3D to achieve desired outcomes.

CITED LITERATURE

- Alford TJ, Roberts WE, Hartsfield, JK Jr., Eckert GJ, Snyder RJ. Clinical outcomes for patients finished with the SureSmile method compared with conventional fixed orthodontic therapy. Angle Orthod. 81:383-388, 2011.
- Andrews LF. The six keys to normal occlusion. Am. J. Orthod. 62:296-309, 1972.
- Bauer EM, Behrents R, Oliver DR, Buschang PH. Posterior occlusion changes with a Hawley vs Perfector and Hawley retainer. A follow-up study. Angle Orthod. 80:853-860, 2010.
- Bouwens DG, Cevidanes L, Ludlow JB, Phillips C. Comparison of mesiodistal root angulation with posttreatment panoramic radiographs and cone-beam computed tomography. Am. J. Orthod. Dentofacial Orthop. 139:126-32, 2011.
- Bryant RM, Sadowsky PL, Hazelrig JB. Variability in three morphologic features of the permanent maxillary central incisor. Am. J. Orthod. 86:25–32, 1984.
- Deguchi T, Honjo T, Fukunaga T, Miyawaki S, Roberts WE, Takano-Yamamoto, T. Clinical assessment of orthodontic outcomes with the peer assessment rating, discrepancy index, objective grading system, and comprehensive clinical assessment. Am. J. Orthod. Dentofacial Orthop. 127:434-443, 2005.
- Fink DF, Smith RJ. The duration of orthodontic treatment. Am. J. Orthod. Dentofacial Orthop. 102:45–51, 1992.
- Harris EF, Hassankideh S, Harris JT. Maxillary incisor crown-root relationships in different angle malocclusions. Am. J. Orthod. Dentofacial Orthop. 103:48-53, 1993.
- Hussels W, Nanda RS. Effect of maxillary incisor angulation and inclination on arch length. Am. J. Orthod. Dentofacial Orthop. 91:233-239, 1987.
- Knösel M, Jung K, Attin T, Attin R, Kubein-Meesenburg D, Gripp-Rudolph L. Systematic evaluation of the features influencing the accuracy of third order measurements. Euro. J. Orthod. 31:547–555, 2009a.
- Knösel M, Jung K, Attin T, Engelke W, Kubein-Meesenburg D, Gripp-Rudolph L, Attin R. On the interaction between incisor crown-root morphology and third-order angulation. Angle Orthod. 79(3):454-461, 2009b.

- Kwon D. Proper mesio-distal angulation and bucco-lingual inclination of the whole tooth in three-dimensional space – a standard for orthodontic patients. Master's thesis, University of Southern California, California, 2011.
- Larson B, Vaubel C, Grunheid T. Effectiveness of computer-assisted orthodontic treatment technology to achieve predicted outcomes. Angle Orthod. Online early, November 28, 2012.
- Lin E, Getto P. SureSmile applies CBCT to custom orthodontic therapy. OraMetrix, Inc. Richardson, Texas. 2008.
- Mah J, Sachdeva R. Computer-assisted orthodontic treatment: The SureSmile process. Am. J. Orthod. Dentofacial Orthop. 120:85-87, 2001.
- Makee IW, Williamson PC, Lam EW, Heo G, Glover KE, Major PW. The accuracy of 4 panoramic units in the projection of mesiodistal tooth angulations. Am. J. Orthod. Dentofacial Orthop. 121:166-175, 2002.
- Mavreas D, Athanasiou AE. Factors affecting the duration of orthodontic treatment: A systematic review. Euro. J. Orthod. 30:386-395, 2008.
- McDavid WP, Tronje G, Welander U, Morris CR, Nummikoski P. Imaging characteristics of seven panoramic x-ray units: projection angle. Dentomaxillofac. Radiol. 8:21-28, 1985.
- Peck JL, Sameshima GT, Miller A, Worth P, Hatcher DC. Mesiodistal root angulation using panoramic and cone-beam ct. Angle Orthod. 77:206-213, 2007.
- Phillip RG, Hurst RV. The cant of the occlusal plane and distortion in the panoramic radiograph. Angle Orthod. 48:317-323, 1978.
- Pliska B, DeRocher M, Larson BE. Incidence of significant findings on CBCT scans of an orthodontic patient population. Northwest Dent. 90:12-16, 2011.
- Proffit WR, Ackerman JL. Contemporary Orthodontics. 3rd ed. St. Louis, Mosby, 2000.
- Sachdeva R. Suresmile technology in a patient-centered Orthodontic Practice. J. Clin. Orthod. XXXV:245-253, 2001.
- Saxe AK, Louie LJ, Mah J. Efficiency and effectiveness of SureSmile. World J. Orthod. 11:16-22, 2010.

- Steiner C. Cephalometrics in clinical practice. Angle Orthod. 29:8-29, 1959.
- SureSmile brochure. "Not since 1792 has the idea of using metal to straighten teeth been this revolutionary." Oramatrix, Inc. 2007.
- Suresmile.com [Internet]. Richardson (TX): SureSmile™ Oramatrix; c2011 [n.d.; cited 2011 April 13]. Available from: <http://www.suresmile.com/I-am-a-Doctor/Case-Studies/Class-II.aspx>.
- Suresmile.com [Internet]. Richardson (TX): SureSmile™ Oramatrix; c2012 [n.d.; cited 2012 January 26]. Available from: <http://www.suresmile.com/For-Doctors/Technical-Information/SureSmile6>.
- Tong H, Kwon D, Shi J, Sakai N, Enciso R, Sameshima GT. Mesiodistal angulation and faciolingual inclination of each whole tooth in 3-dimensional space in patients with near normal occlusion. Am. J. Orthod. Dentofacial Orthop. 141:604-17, 2012a.
- Tong H, Enciso R, Van Elslande D, Major PW, Sameshima GT. A new method to measure mesiodistal angulation and faciolingual inclination of each whole tooth with volumetric cone-beam computed tomography images. Am. J. Orthod. Dentofacial Orthop. 142:133-43, 2012b.
- van Loenen M, Degrieck J, De Pauw G, Dermaut L. Anterior tooth morphology and its effect on torque. Euro. J. Orthod. 27:258-262, 2005.

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Watts AK, Thikkurissy S, Smith TL, Smiley MK, McTigue DJ. Intraoperative Local Anesthesia affects physiologic parameters of children undergoing general anesthesia for dental rehabilitation. Ped. Dent. 31:414-419, 2009

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