3-DIMENSIONAL ACCURACY OF SIMPLANT SAFEGUIDE FULLY GUIDED IMPLANT SURGERY

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ABSTRACT

Anthony Gragg: 3-Dimensional Accuracy of Simplant Safeguide Fully Guided Implant Surgery
(Under the direction of Ingeborg De Kok)

Purpose: The aim of this retrospective study was to determine the accuracy along the x,y, and z axis as well as rotational accuracy when comparing the planned implant position in Simplant with the final, impressed, implant position using Geomagic12 studio software to overlay the positions.

Materials: and Methods: Digital data for the pre-surgical planned implant location and post-surgical implant location as determined by an implant level impression was uploaded into Geomagic and computer modeling was used to compare the difference in 3-dimensional position, mesial-distal tip, buccal-lingual tip, apical depth and rotation.

Results: In 3-dimensional space, the difference between the planned and final implant locations was 0.34mm for the x and z dimension and 0.31mm for the y dimension, for an overall median difference of 0.33mm. The median final implant location apically, compared with the planned location, was 0.4mm apical to the planned position. Angular difference between planned and final implant location was 0.47 degrees tipped to the mesial and 0.22 degrees tipped to the lingual. The rotational timing of the implants compared to Simplant's decided timing for abutment placement was 3.19 degrees rotated clockwise.

Conclusions: This novel way of evaluating accuracy of fully guided surgery eliminates the need for post-healing CBCTs, decreasing the cumulative radiation dose of our patients. Further investigation with large study populations will be necessary to verify the results. However, this data helps support the efficacy of current guided surgeries and why they should continue to be used whenever the clinical situation is deemed appropriate.

ACKNOWLEDGMENTS

I would like to thank my committee, Drs. Lyndon Cooper, Ingeborg De Kok, Alexandra Yarborough and Glenn Reside for their endless motivation, support and encouragement. The growth and opportunities afforded by all of you during my time at the University of North Carolina will stay with me for the rest of my career.

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To my family and friends, for supporting me along this seemingly never ending educational journey. The support and love has not gone unnoticed, and I couldn't have done it without each and every one of you.

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3D	Three-Dimensional
B-L	Buccal-Lingual Directional Axis
CAD/CAM	Computer Aided Design/Computer Aided Manufacture
CBCT	Cone Beam Computed Tomography
DICOM	Digital Imaging and Communication in Medicine
EV	Evolution (Astra Tech EV)
FLO	Intraoral Feature Locating Object
ID	Identification Number
IRB	Institutional Review Board
.LMZA	Lempel-Ziv-Markov Chain-Algorithm (Digital File Format)
M-D	Mesial-Distal Directional Axis
MM	Millimeters
PES	Pink Esthetic Score
PreFLO	.STL File of Impression FLO marking Planned Implant Location
PreSTL	.STL File of Pre-Surgical Stone Model
PoFLO	.STL File of Impression FLO marking Final, Impressed Implant Location
PoSTL	.STL File of Post-Surgical, Implant Level Stone Model
STL	Stereolithography (Digital File Format)
.SVF	Serial Vector Format (Digital File Format)
.TMF	Transformation Matrix File (Digital File Format)
UCLA	University of California, Los Angeles
UNC	University of North Carolina at Chapel Hill

WES	White Esthetic Score
.XML	Extensible Markup Language (Digital File Format)

Chapter 1: 3-Dimensional Accuracy of Simplant Safeguide Fully Guided Implant Surgery

INTRODUCTION

The development of successful titanium osseointegration in human bone stands as one of the most significant single discoveries in the history of dentistry. Osseointegration can be defined as the direct structural and functional apposition of vital bone to the surface of a load bearing endosseous implant[1]. Its discovery offered the dentists the ability to anchor fixed dental prostheses to the alveolar ridge with a high level of predictability. The first dental implants were designed, manufactured and prescribed to work in complete edentulous jaws[2]. Once Brånemark, Adell and Eriksson established long term success of both implants (78% in the maxilla and 86% in the mandible at 15 years) and the prosthesis (92% in the maxilla and 99% in the mandible at 15 years)[3], the focus of implant research and design became finding a solution for partial edentulism. Since the introduction of the single tooth implant in 1986, many improvements have been necessary to combat biological and technical failures inherent to the fully edentulous system.

Advancements in surface technology, leading to micro- and nano- roughness, allowed single tooth implants to maintain hard and soft tissue far better than the previously manufactured smooth surface machined dental implants. This progression in technology increased long term, stabile esthetics and implant health. The switch from an external, hexagonal implant-abutment connection to an internal, conical connection significantly improved biologic and technical function[4]. Decreasing the micro-motion between the abutment and the implant proved to maintain bone levels, it also significantly reduced the occurrence of screw loosening and

complications related to the crown or abutment coming loose[5]. Abutment design was the final piece of the puzzle, and continues to be the main focus of implant related research today. The original "multi-unit" abutments designed for the fully edentulous patient intentionally prevented the prosthesis from contacting the soft tissue. Also, the nature of splinted implants positioned around the curve of an arch, geometrically neutralized rotational and torqueing forces. Finally, retention form was necessary similar to a crown prep for successful cementation of single unit implant supported crowns.

The first abutments to address these problems were manufactured as standard sizes and shapes, colloquially known as "stock" abutments. One of the early examples of a manufactured abutment was AstraTech's (Dentsply, York, PA) ST abutment, a simple design that accommodated for both anti-rotation features, appropriate retention form for crown cementation as well as a natural emergence profile allowing for adaptation of the mucosa by the abutment and the crown[6].

As single tooth implants, especially in the anterior esthetic zone, became more common, it became evident that establishment of an ideal, tooth-like emergence profile was necessary for long term stability of soft tissue esthetics and proper hygiene. The first major step in the customization of mucosal support was the development of the casted, screw retained crown; first described in 1988[7]. It became known as the UCLA abutment. It consisted of a plastic burn-out cylinder that attached directly into the implant allowing the technician to wax the transmucosal emergence profile and the clinical crown cut-back. The wax pattern was (consistency in verb tenses) then casted and porcelain was stacked resulting in a single piece, screw retained crown customized to fit not only the patient's tooth but their soft tissue contouring. ULCA abutment retained single crowns provided an excellent solution for single crowns in the posterior and

properly placed anterior crowns where the screw access hole was not an esthetic concern and total occlusal space was minimal. However, esthetic needs and malpositioned implants (and thus screw access holes) required a combination of cement retention of crowns in combination with customized emergence profiles. The next step was the custom waxing and casting of abutments designed to retain a cemented crown using the UCLA abutments. These custom, cast abutments were designed to support transmucosal tissue and place the crown margin slightly subgingivally for highly esthetic restorations with excellent cement removal[8].

With the introduction of CAD/CAM technology to abutment design in the early 21st Century, it was soon recognized that the design and fabrication of custom abutments and single-piece screw-retained crowns was no longer dependent on the lost-wax process. This eliminated many of the problems inherent to the UCLA custom abutment such as expense due to amount and cost of metals, fabrication time and misfit[9]. Distortion of the abutment during casting occasionally resulted in imperfect abutment-implant connection; misfit at the junction resulted in screw loosening[10], fractures of screws, abutments and crowns, and inflammation of the peri-implant mucosa[11]. With the changes in abutment design and implant improvements, a comprehensive and long standing data set has been established to evaluate and address the complications and limitations of single tooth implant therapy[12].

Systematic reviews have proven that implants are successful, both as a treatment modality and in comparison to conventional treatment options. Ten-year survival has been reported at 89.9% for single tooth implants as compared to 89.1% survival for tooth supported 3 unit fixed partial dentures[13,14]. The survival rates of implants fixtures supporting a single crown was reported at 97%, while the single implant crowns themselves has a survival rate of 96.3%[15].

These high success rates have solidified dental implant therapy as a commonplace approach to tooth replacement.

While survival rates are high for single crowns, complications that are manageable without the removal or replacement do occur. They can be classified into two group, biological and technical. Biological complications occur 7.1-9.7% at 5 years and consist of peri-implant mucositis, peri-implantitis, bleeding, suppuration and soft tissue dehiscence[16]. Technical complications include screw loosening, abutment screw fracture, fracture of veneering material, loss of retention, and implant fracture.

As materials, techniques and surface technologies have increased, complication rates have continued to improve since first reported in 1986 by Jemt et al. 2014 data, based on a systematic review of the literature, shows complications to include abutment screw fracture, loosening of abutment or abutment screws, loss of retention, ceramic chipping, framework fracture and loss of access hole restoration. The three most frequent complications rates, per 100 crown years, were loose abutments or screw (8.8%), loss of retention (4.1%) and ceramic chipping (3.5%) with rates[14]. However, in recent years, the loosening of abutments and abutment screws has dropped significantly as the majority of implant-abutment interfaces are now internal hex connections.

With the continued decrease in biologic and technical complications, in combination with increasing age of our single tooth implant supported restorations, a paradigm shift in the way we evaluate success occurred. Short and long term esthetic stability has become the emphasis of current implant research, mostly due to the complexity of corrective treatments and our lack of understanding as to why they happen[4,5,17]. Current knowledge suggests a 7.1% esthetic complication rate at 5 years[16]. The three most common of these complications are gingival

recession, unfavorable crown color, and visible crown margins. While these are the most common obstacles, other esthetic issues include soft tissue discoloration, buccal ridge deficiency and inter-proximal papilla deficiency. Two evaluation methods are currently being used to quantify both patient and doctor satisfaction with implant esthetics, the white esthetic score (WES) and the pink esthetic score (PES)[18]. Using this scoring system to assess single anterior implants placed in healed vs. healing sites, unfavorable esthetic outcomes were observed in 26% of all implants, as well as a 4% reporting of total esthetic failure[19].

It has become evident that the most important factor effecting the esthetics of single implant supported crowns is treatment planning[20]. While the development of CAD/CAM abutments has aided in the correction of some esthetic complications, prevention though careful patient evaluation and treatment planning is ideal. Implant position is paramount for the maintenance of esthetics. Dental implant therapy has been described as a tooth-driven, or crown-down, treatment. This implies that the planning process starts with the ideal placement of the new tooth. A systematic review investigating the effect of restorative procedures on single tooth implant esthetics supports importance of placement. It was determined that timing of provisionalization, platform size and connection, abutment material, final restorative material and screw vs. cement retention had no significant effect on esthetic outcome. However, it was repeatedly reported that implant position had a significant effect on esthetic outcomes. This was highlighted by a buccally positioned implant, which showed a significantly increased risk of facial tissue recession leading to soft tissue imbalance and abutment margin display. There are many procedures that can be managed by their restorative dentist to minimize esthetic complications. The most predictable method to avoid a mal-positioned implant affecting the esthetic outcome is the implementation of a surgical template based on the restorative plan[17].

Based on the location of the desired tooth, implant position and abutment design can be prescribed based on established principles, avoiding increased risk of esthetic problems. Implant position is best described by Cooper and Rojas as the "Three-Two Rule." The rules states that the buccal shoulder of the implant should be located 3mm apical to and 2mm lingual to the planned gingival zenith of the tooth being replaced. An implant placed 3mm deep of the gingival zenith allows for the biologic width to form around the abutment, which is usually 2mm. The facial margin can then be placed 0.5-1.0mm subgingival for esthetic purposes without invading the biologic width. Placement of the implant 2mm lingually helps maintain long term stability. This position ensures adequate hard tissue on the buccal surface of the implant, which is one of the most important predictors of soft tissue stability and avoiding gingival recession[21]. Understanding the ideal placement of an implant based on the restorative treatment plan is critical to planning the type of restoration, and the need for pre-surgical soft or hard tissue augmentation[22].

In order to place implants, the initial patient information is necessary to provide an accurate and complete treatment plan. The clinician also needs a 3-dimensional volumetric assessment of the patient's bone is obtained through CBCT, a cast with appropriate wax up of the planned final restoration including location of gingival zenith, and accurate soft tissue representation. Advancements in digital dental technology allow for these three data points to be merged into a single digital environment. A digital model of the soft tissue and the planned restoration can be merged and overlaid on the CBCT image of the patient's bone volume[23]. This allows the dental team to visualize all the information, surgical and restorative, in a very accurate, digital environment[24].

Manipulation of this information through virtual implant planning software continues to become easier and more accessible, making communication and implementation of a restoratively driven treatment plan less challenging. While many modes of guided surgery have been established over the last 20 years, CBCT technology, DICOM/STL merging has led to CAD/CAM fabrication becoming the new gold standard for implant surgical guides[25,26]. The first use of CBCT data for creation of surgical guides was, like implant therapy itself, used in the edentulous patient[27]. Beyond the accuracy of SLA guides and increasing long term esthetic stability, there are many additional benefits to fully guided implant surgery for both the surgeon and the patient. The most important benefit to the patient is less intra-operative pain and less post-operative morbidity, consistent with a flapless surgical procedure[28]. Both the clinician and the patient will spend less time in the chair, and the outcome is far more predictable and safe[29].

Table 1: Advantages and Disadvantages of Guided Surgery

	ADVANTAGES	**DISADVANTAGES**
PATIENT RELATED	Less Intra-operative Pain	Cost
	Less Post-operative Pain	Radiation Risk
	Decreased Appointment Time	Removal of Keratinized Tissue
SURGEON RELATED	3-Dimensional Control over Implant Location	Planning and Guide Fabrication Time
	Flapless Procedure	Reduced Irrigation and Cooling
	Increased Safety	Site Not Visible
	Decreased Chair Time	Procedure Can't be Altered

Guided surgery does come with additional cost to the patient, as well as increased planning time. Once the plan has been made, it is not possible to make alterations and visibility during surgery is limited by the guide. The major disadvantage to a flapless procedure is removal of keratinized tissue during punching. Each patient's tissue should be carefully evaluated to determine if a band of keratinized tissue can be maintained following flapless surgery[30].

The end goal of fully guided implant surgery is to minimize the deviation of the final implant placement from the planned implant position. The accuracy of the implant placement was recognized quickly for the fully edentulous patient, and single implant and partially edentulous guides were designed, significantly improving implant positioning[31,32,33,34].

The aim of this retrospective study was to determine the accuracy along the x,y, and z axis as well as rotational accuracy when comparing the planned implant position in Simplant with the final, impressed, implant position using Geomagic(Cary, NC) 12 studio software to overlay the positions.

MATERIALS AND METHODS

Data Acquisition:

Following IRB approval for the amended use of patient information, data was acquired from a previous study: Fabrication of a Definitive CAD/CAM Titanium Abutment Prior to Guided Surgery: A Pilot Study (IRB# 13-2376). Data was included for all patients that had, at time of collection, a final implant level impression made. The fabrication of final crown was not necessary for the inclusion in this study. Due to anonymous identifies on the casts and patient information, complications potentially affecting placement accuracy and the number and magnitude of adjustments to the provisionals or final prostheses was unknown to the investigator. 20 implant level casts were obtained, along with the study data pertinent to the each patient. This data included their anonymous identifiers (assigned numbers ranging from 1-34), tooth number treated (for verification of appropriate cast and implant location), Simplant ID and Atlantis order number (to provide the 3 dimensional location of the planned implant).

Data Preparation:

All models were sent to Simplant (Waltham, MA), and scanned with a Dentsply's (York, PA) Osseospeed EV implant FLO fitted into the implant analog. Scanning was completed by a 3shape D-700 power-free laboratory scanner. The scan produced an .STL file representing the digitized cast and the 3 dimensional, as well as rotational, location of the implant analog in relationship to the remaining teeth. Conversion programs were designed to convert data to the appropriate formats to be processed within Geomagic software and for final data analysis.

Atlantis (Waltham, MA) Web Order was accessed, and the order number used to locate the patient data. The .LMZA file was downloaded. This file contained data for pre-surgical casts of the patient (.SVF format) as well as the planned implant location derived from the CBCT plan (.XML format). Both of these formats are Simplant/Atlantis specific formats, so conversion was necessary. The .SVF pre-surgical casts were converted to an .STL file and the coordinates within the .XML file were converted to a .TMF file. The .TMF, or transformation matrix file, stores the 3-dimensional location in a series of 4x4 matrices for 3 points located on the FLO designated F, B and U (Figure 1).

Files designated for the final processing and analysis were: Pre-Surgical Cast(.STL)[PreSTL], Post-Surgical Cast w/ FLO(.STL)[PoSTL], Pre-Surgical FLO replica(.STL)[PreFLO], Post-Surgical FLO replica(.STL)[PoFLO], Planned Implant Location(.TMF)

Data Processing:

Geomagic Studio 12 was used for data processing. All the previously listed .STL files were uploaded. The PreSTL was pinned in 3-dimensioned. The .TMF file was loaded into the PreFLO, snapping it into place relative to the PreSTL and pinned (Figure 2). Then, the PoSTL

was grossly aligned to the previously pinned PreSTL via 3 points of reference. The alignment of the PoSTL to the pinned PreSTL ensures that the 4x4 matrix output (.TMF) will coincide in space (Figure 3). The global alignment tool was used for computed aided alignment. The models were then trimmed to leave teeth only. This allowed for more accurate alignment by removing the cast base which was non-common data, and leaving the teeth which is the most accurate and relevant common data between the two .STL files. The global alignment tool was run twice, or until the average distance of change was under 0.08mm (meaning the models had to be corrected less than 0.08mm by the software) and pinned (Figure 4). The PreSTL and PreFLO are hidden.

The PoSTL and PoFLO are aligned with manual 3 point alignment and refined with global alignment until the software corrections are under 0.02mm. The 3 dimensional location of the PoFLO can now be exported as a .TMF file, producing a 4x4 matrix describing its location relative to the PoSTL, PreSTL and PreFLO, allowing for comparative analysis (Figure 5).

Data Analysis:

Comparison of pre-operative planned implant location and post-operative placed implant location was accomplished using Geomagic Control 14. STL file of pre-operative FLO and post-operative FLO were uploaded. 4x4 TMF files were uploaded into the PreFLO and PostFLO, positioning it within 3-dimensional space (Figure 6). The 3-dimensional space was defined by the Z axis located perpendicular to the plane of occlusion, the X axis parallel to the plane of occlusion in a medial-lateral direction, and the Y axis parallel to the plane of occlusion in an anterior-posterior direction. Select the PreFLO and set as the reference STL, select the PostFLO and set as the test STL (Figure 7). Select 3D compare and note the directional deviations based on implant position (Figure 8), determining in which directions the placed implant varied from the planned location (M-D, B-L, A-C). The direction of these differences were be used to

allocate positive and negative values to the movement: mesial, buccal, apical movement and clockwise rotation are assigned a positive value.

The rest of the analysis was be completed using 2 dimensional slices, so the "Select Through Object" tab was opened. 3 standardized slices were made (Figure 9). The overlaid FLOs were rotated to be viewed directly from the top. The first slice was made from by connecting the medial and distal corners. The second slice was made by connecting the lingual point with a line bisecting the screw access hole. The third slice was made by a three point plane, these points were selected on the edge of the screw access hole, creating a plane that was perpendicular to the long axis of the post-operative FLO. The FLOs were then rotated until upright, and the plane was lowered until it crosses through the height of contour of the lingual point. With all three slices cut, labeled Section A-A, B-B and C-C, 2 dimensional analysis was selected. The first 2 dimensional overlay was a M-D slice, which was used to determine the apico-coronal difference and the M-D angular tip. The apico-coronal difference was measured by point difference analysis, where the two points selected were the edge of the screw access hole for the PreFLO and the PostFLO. The second slice, which is directly B-L is then selected. This slice was used to measure one the B-L tip of the placed implant. The last slice, the cross-section, was then selected and the angle was measured between two of the flat walls. This produced the rotational difference between the PreFLO and the PostFLO (Figure 10).

The final step was a validity test. Due to the high number of steps involved, it was important to determine the accuracy and repeatability of the steps to account for human error. Data for implant #16 was run through the entire protocol five times and the outputs were collected.

Following the data analysis, all data points were assembled (Figure 11). The difference between the X, Y and Z positions was calculated. The medians of all the data sets are calculated. Use of medians were selected over the use of means due to a small amount of included data.

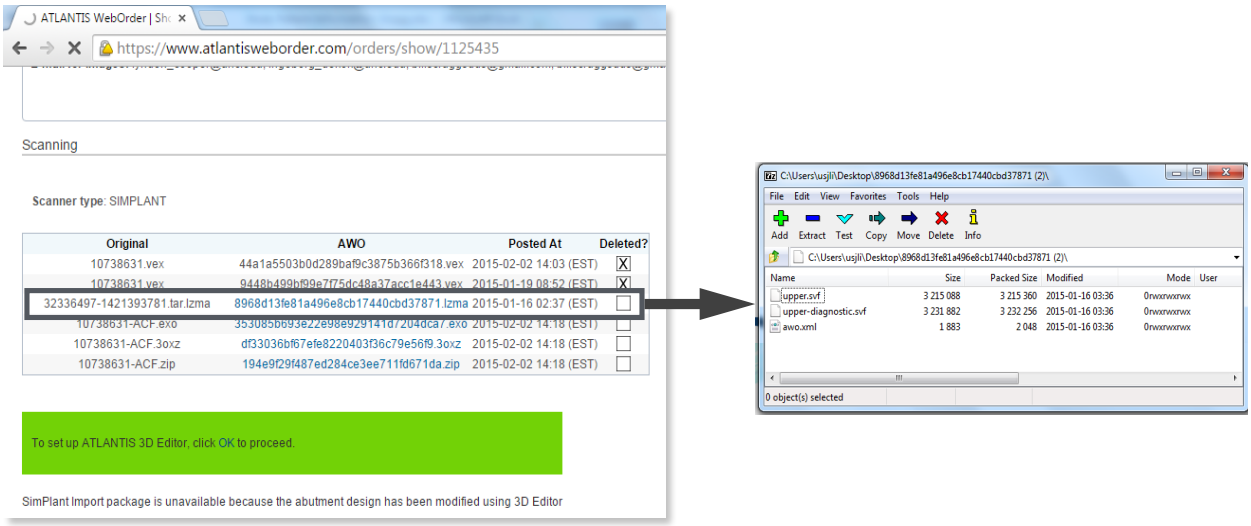

Figure 1. Data Download from Atlantis: .LMZA file unzipped and extraction of .SVF and .XML data

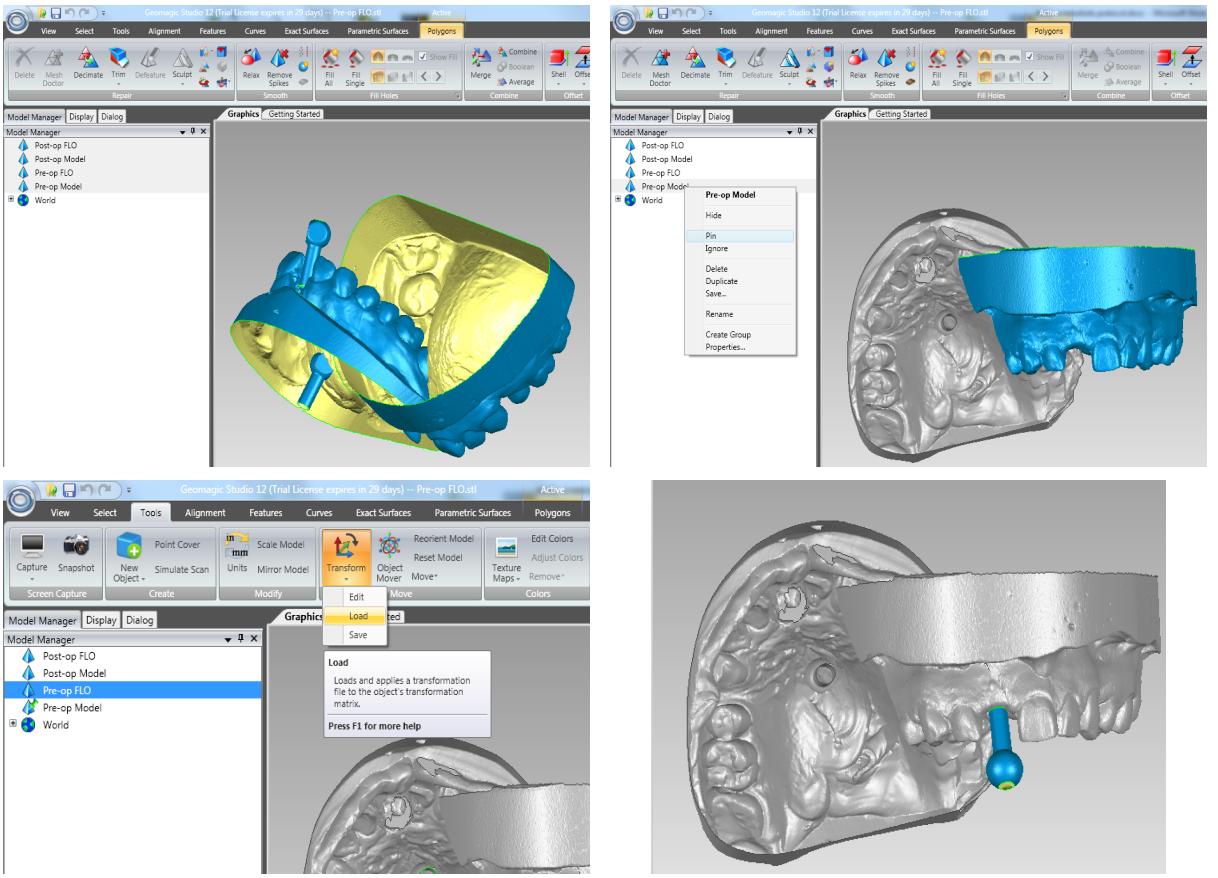

Figure 2. Data Upload to Geomagic: (a)Uploading all files into Geomagic 12, (b)Pinning of PreSTL, (c)Applying .TMF data to PreFLO, (d)PreFLO snapped into place relative to PreSTL

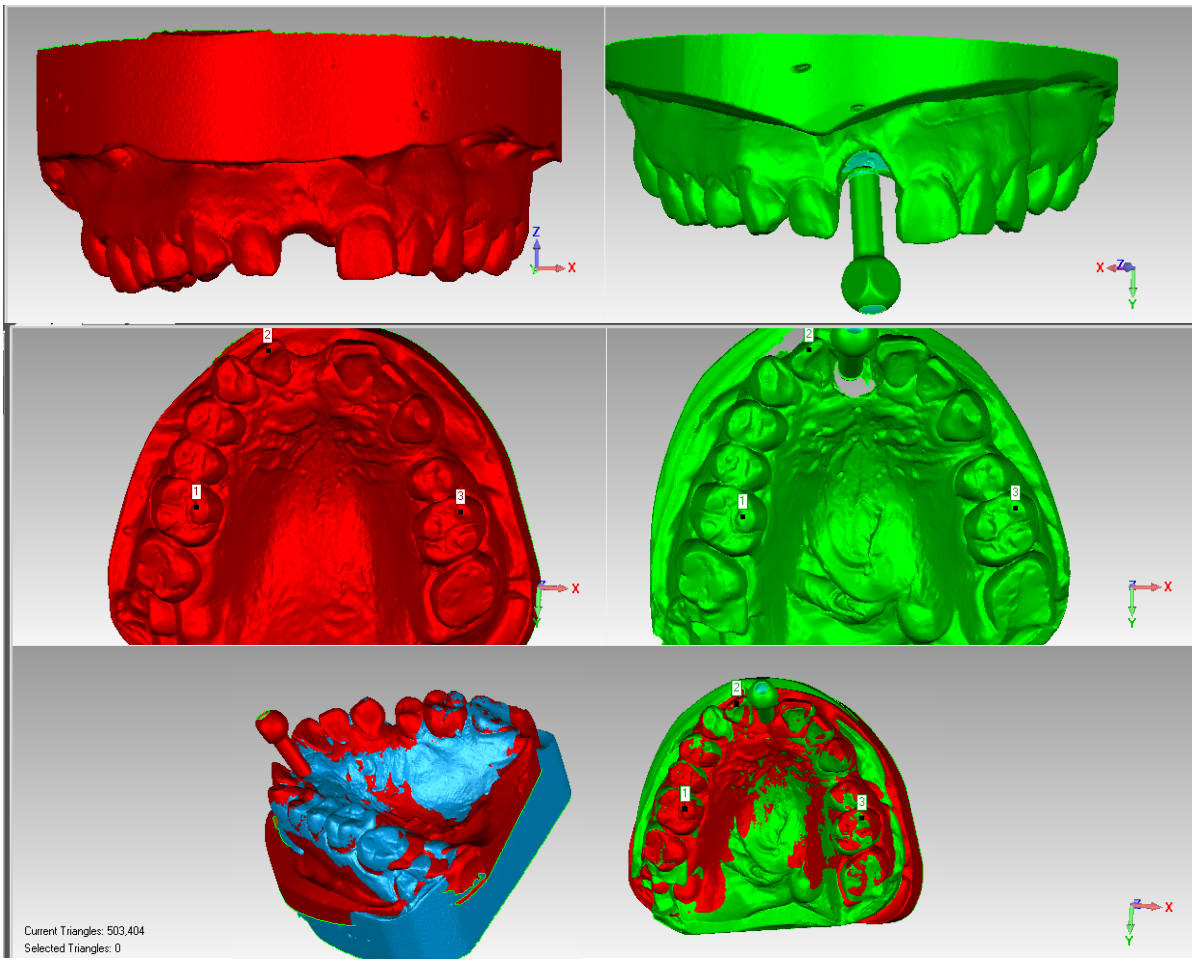

Figure 3. Cast Alignment: Three-point alignment of PreSTL and PostSTL

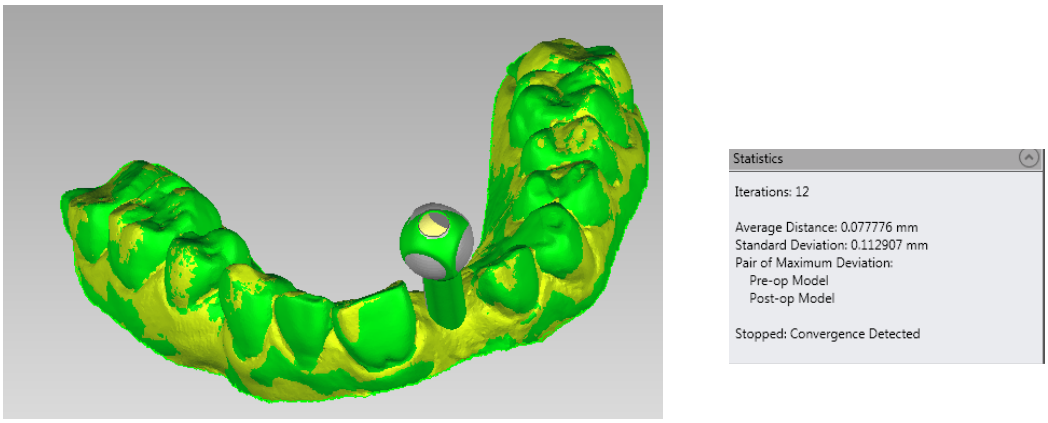

Figure 4. Global Alignment of Casts: Casts trimmed to teeth only, and globally aligned with an average correction of 0.078mm

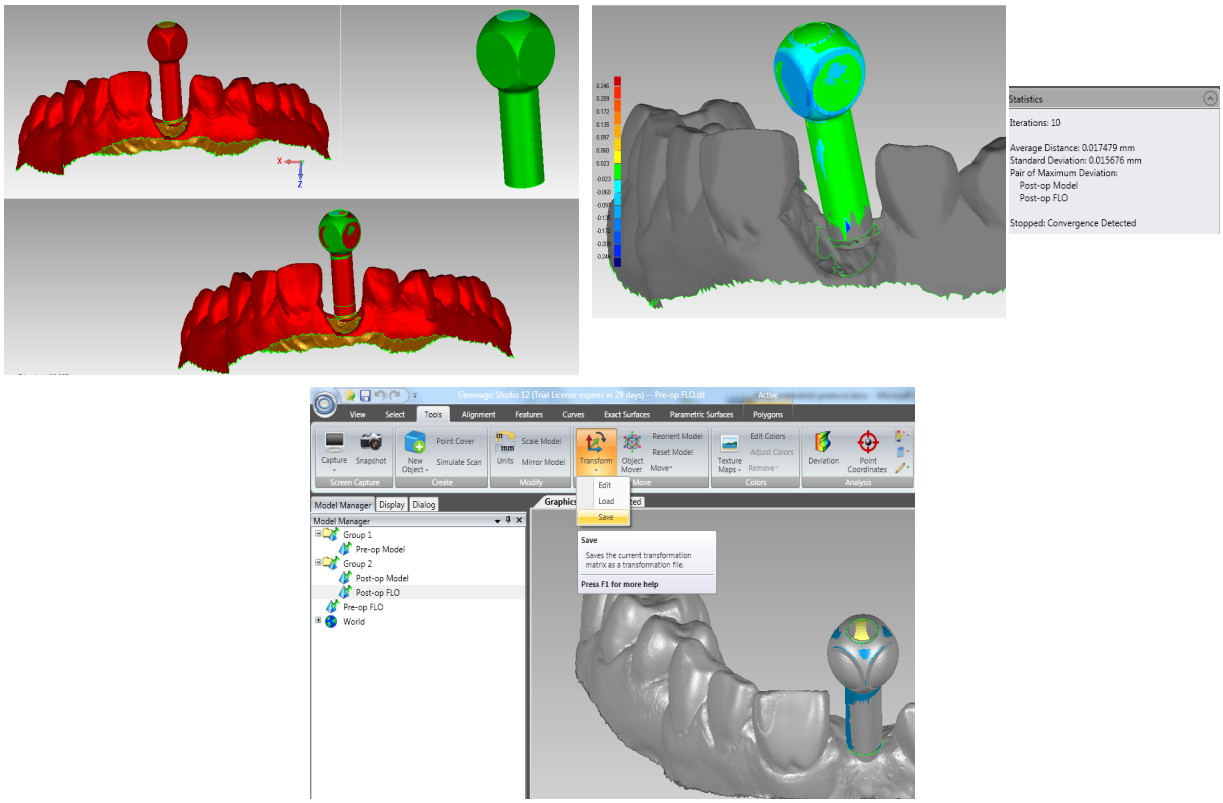

Figure 5. Alignment of FLOs and Data Acquisition: (a)Three-point alignment of PoFLO with PoSTL, (b)global alignment of PoFLO and PoSTL with average correction of 0.017mm, (c) 3D position of PoFLO exported as a .TMF file

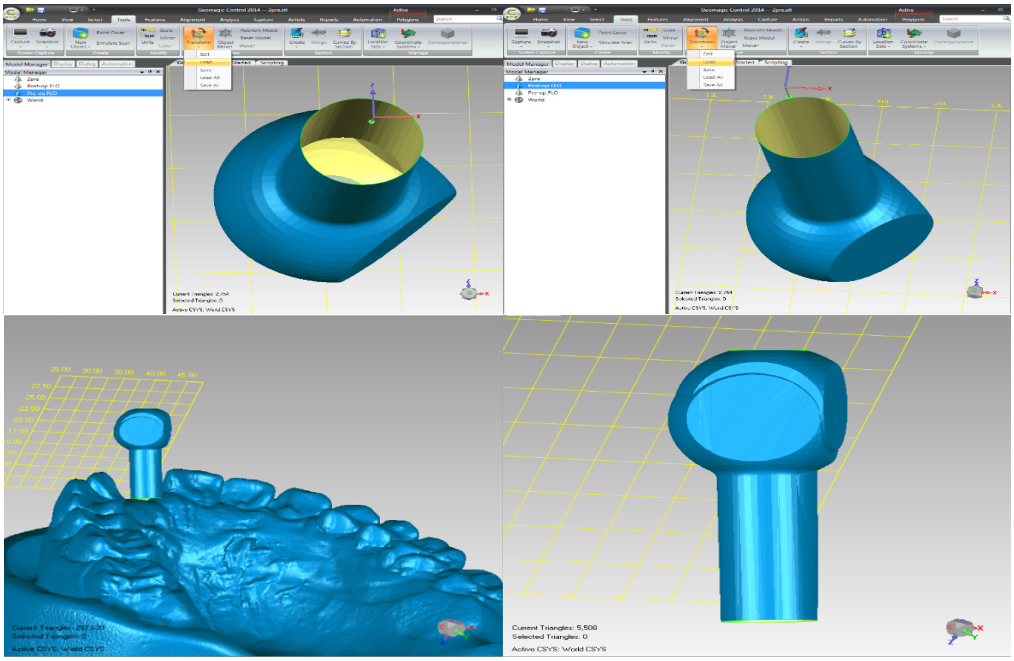

Figure 6. FLO Upload and Comparison: Positional data uploaded for both FLOs, snapping them into location relative to model and each other.

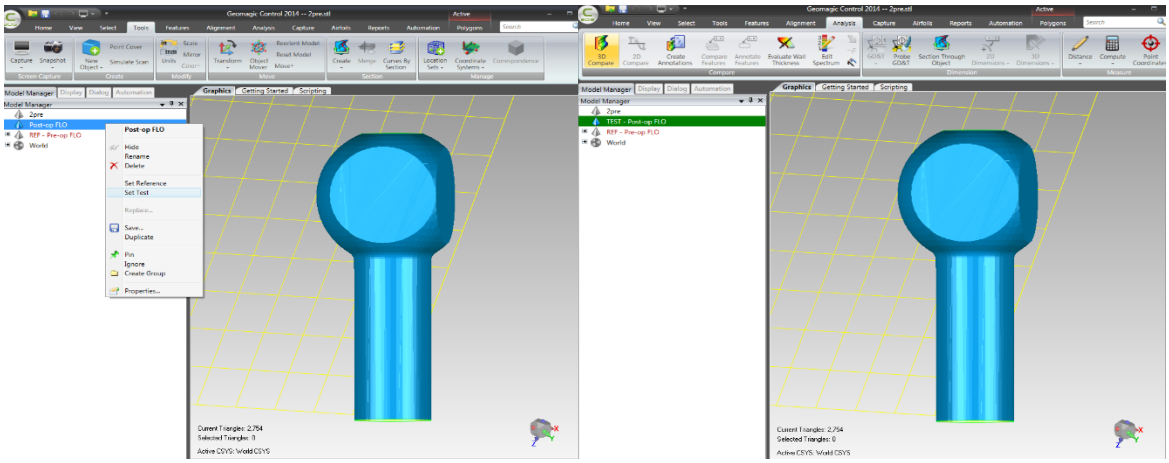

Figure 7. Reference and Test FLO: PreFLO is highlighted and set as Reference object, PoFLO set as Test object

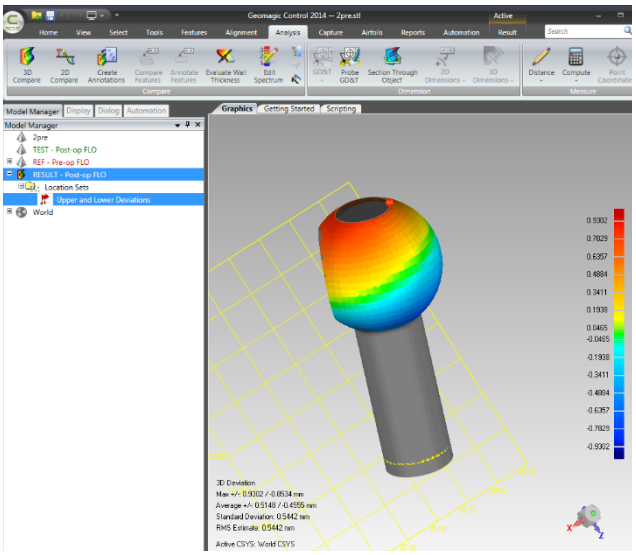

Figure 8. 3-Dimensional Comparison: Warm spectrum colors denote the Test object is outside the Reference object (positive value). Cool spectrum colors denote the Test object is inside the Reference object (negative value).

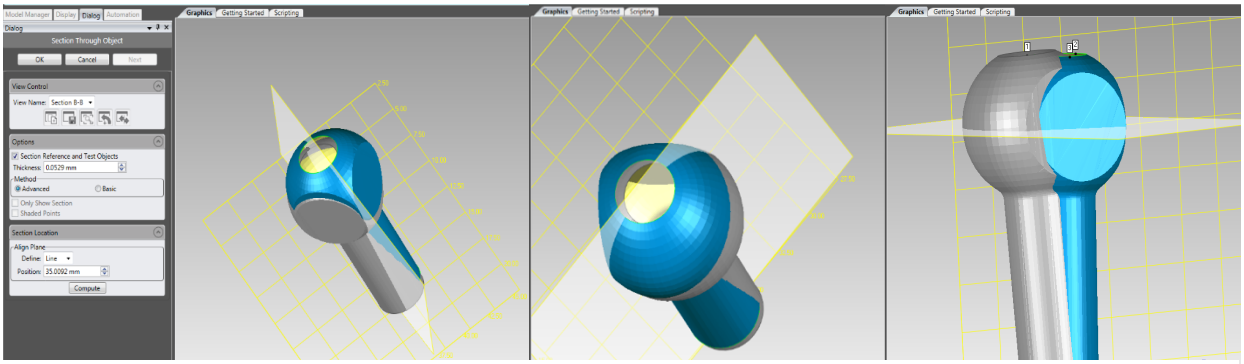

Figure 9. 2-Dimensional Comparison: Three slices are made through the FLOs

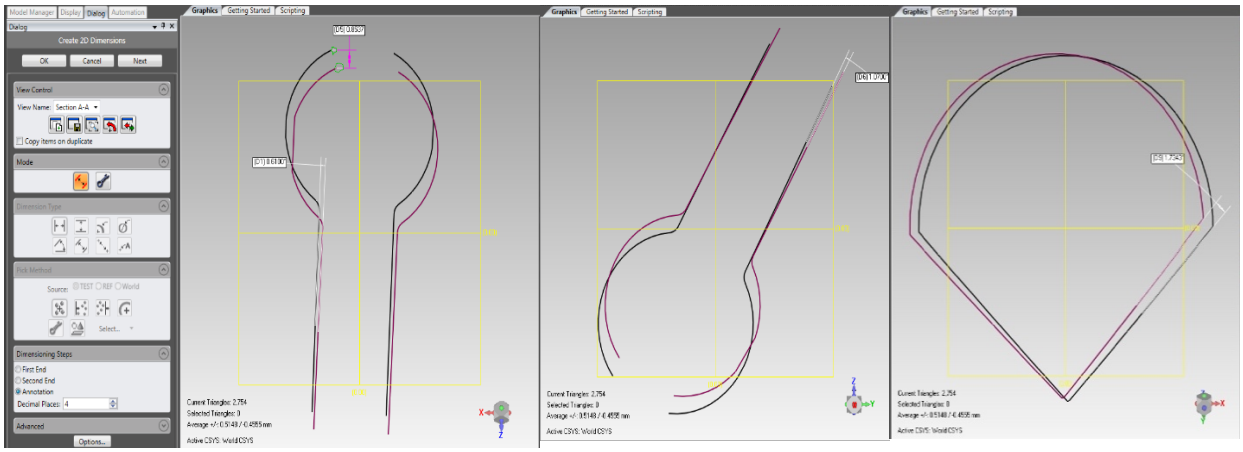

Figure 10. 2-Dimensional Measurements: The three slices and the corresponding measurements made from each

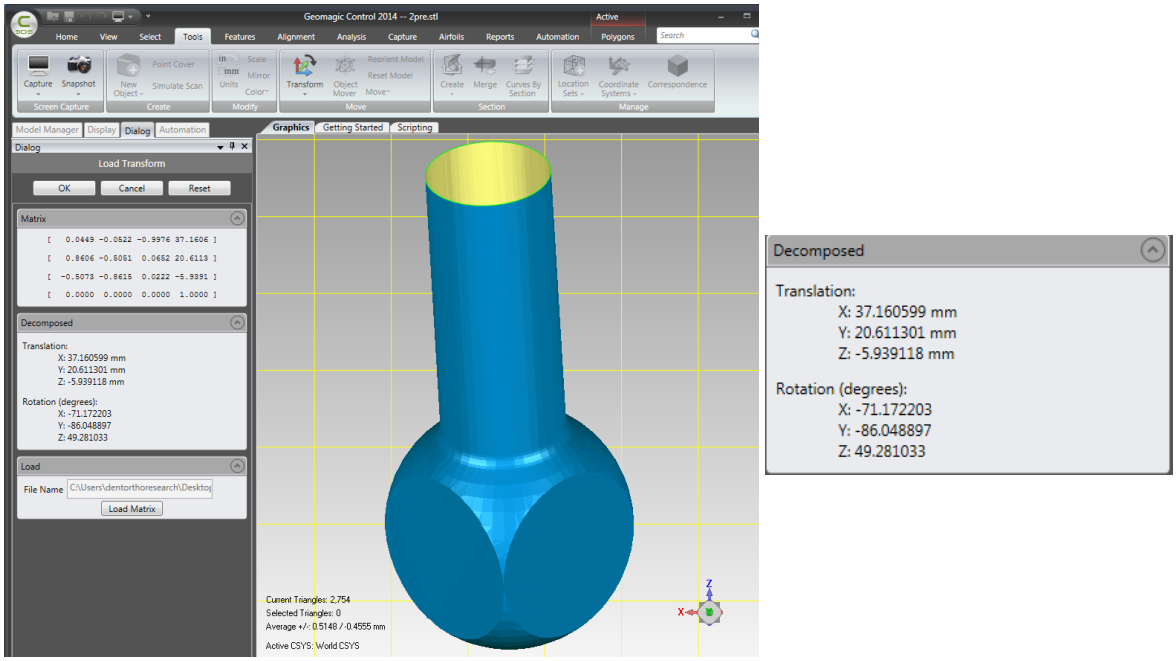

Figure 11. Data Collection: Data points extracted from FLO position, X, Y, and Z data collected to the hundredth of a millimeter

RESULTS

Data was acquired from 16 patients with treatment previously completed as part of UNC IRB Study #13-2376. For all patients, pre-operative planned implant location was extracted from

the Simplant planning file used for guide fabrication. Post-operative implant locations was gathered as stone models made from implant level final impressions for each patient.

The primary outcome measures of this study were 3-dimensional, angular, and rotational accuracy of guided implant placement. These results were reported on a continuous scale, to the hundredth of a millimeter (0.01mm).

Table 2: 3-Dimensional Changes of Implant Positon

	PRE OP 3-D LOCATION (IN MM)			**POST OP 3-D LOCATION (IN MM)**			**DELTA (IN MM)**		
PATIENT	x	y	z	x	y	z	x	y	z
1	37.16	20.61	-5.94	37.20	19.96	-6.54	0.04	0.65	0.60
2	22.15	42.98	-10.88	22.53	42.88	-10.28	0.38	0.10	0.60
3	18.89	42.32	4.10	18.53	42.38	3.83	0.35	0.07	0.27
4	56.24	34.78	-10.63	56.59	35.03	-10.22	0.35	0.25	0.41
5	65.81	34.24	-1.25	66.01	34.18	-1.61	0.21	0.06	0.35
6	28.26	40.10	-12.57	27.75	40.10	-12.77	0.51	0.00	0.20
7	61.67	47.44	-15.25	61.34	47.20	-15.49	0.33	0.24	0.24
8	23.26	30.19	-31.79	23.14	30.28	-31.99	0.12	0.09	0.20
9	20.57	28.56	-6.21	19.45	28.13	-4.58	1.13	0.43	1.62
10	52.16	58.78	-40.76	52.11	58.41	-39.79	0.04	0.37	0.97
11	37.60	17.95	-2.92	37.48	17.34	-2.91	0.12	0.61	0.01
12	48.69	21.78	-5.63	48.57	21.67	-5.85	0.12	0.11	0.23
13	61.43	43.29	-13.63	60.79	42.82	-12.82	0.64	0.47	0.81
14	57.33	38.42	-11.84	58.31	38.00	-11.50	0.98	0.42	0.33
15	36.24	18.01	9.05	35.76	17.03	8.50	0.49	0.98	0.54
16	60.16	35.83	-8.36	60.40	35.40	-8.07	0.24	0.43	0.29
						Median	0.34	0.31	0.34

Table 2 reports all of the pre-surgical planned locations reported by Simplant, The post-surgical impressed location and the difference between the two. Geomagic produced a 3-dimensional position of the FLO in the X, Y and Z coordinate system. All Delta values are reported as positive values, even if the grid location was negative, since they are all values of change. The medians in each plane are reported. Median was chosen over mean due to the small number of data points included. The median change in direction of the X axis was 0.34mm with a range of 0.04-1.13mm. The median change in direction of the Y axis was 0.31mm with a range of 0.00-0.98mm. The median change in direction of the Z axis was 0.34mm with a range of 0.01-

1.62mm.

Table 3: 3-Dimensional, Apical and Angular Changes of Implants

	DELTA (IN MM)			ANGLES (IN DEGREES)			
PATIENT	x	y	z	M-D	B-l	Apical (In mm)	Rot
1	0.04	0.65	0.60	0.61	1.07	0.85	1.73
2	0.38	0.10	0.60	2.47	3.06	0.75	55.72
3	0.35	0.07	0.27	3.77	-0.57	0.16	7.16
4	0.35	0.25	0.41	4.01	-2.65	0.41	4.26
5	0.21	0.06	0.35	-0.54	0.37	0.38	6.37
6	0.51	0.00	0.20	1.15	1.02	0.16	-1.67
7	0.33	0.24	0.24	-0.98	-1.32	0.66	6.90
8	0.12	0.09	0.20	-3.64	-4.52	-0.27	11.71
9	1.13	0.43	1.62	3.63	3.48	-1.70	173.58
10	0.04	0.37	0.97	-4.24	-4.55	0.84	10.76
11	0.12	0.61	0.01	0.33	0.13	0.25	179.78
12	0.12	0.11	0.23	-2.45	-1.01	0.28	-3.57
13	0.64	0.47	0.81	-2.46	-3.49	0.86	-1.74
14	0.98	0.42	0.33	3.24	0.29	0.42	-1.20
15	0.49	0.98	0.54	2.67	-4.63	0.84	2.11
16	0.24	0.43	0.29	-2.16	0.17	0.39	-1.18
MEDIAN	0.34	0.31	0.34	0.47	-0.22	0.40	3.19

Table 3 reports the change in 3-dimensional data from Table 1, along with the angular and rotational changes. The angular and rotational values are reported on a continuous scale, the hundredth of a degree. In the mesial-distal direction, positive values describe mesial tip. In the buccal-lingual direction, positive values describe buccal tip. When reporting rotation, positive values describe clockwise rotation. With respect to the apical-coronal positioning of the implant, reported in hundredths of a millimeter, positive values describe an implant placed apical to the planned location. The median M-D tip was 0.47 degrees to the mesial, with a range of -4.24 degrees (D) to 3.77 degrees (M). The median B-L tip was 0.22 degrees to the lingual, with a rage of -4.63 degrees (L) to 3.48 degrees (B). The median apical position of the implant was 0.4mm apical, with a range of -1.7mm (coronal) to 0.86mm (apical). The median rotational difference was 3.19 degrees clockwise, with a range of -3.57 degrees (counter-clockwise) to 55.72 degrees (clockwise).

Two of the rotational accuracy data points were excluded from the reported median. Both implants were rotated 180 degrees, on purpose, due to the clinical situation. One implant was turned back out 180 degrees because the patient returned reporting transient numbness associated with pressure on the inferior alveolar nerve. The other was turned 180 degrees to avoid surgical and restorative complications.

Table 4: 3-Dimensional Changes of Implants for Validity Test

	PRE OP 3-D LOCATION (IN MM)			**POST OP 3-D LOCATION (IN MM)**			**DELTA (IN MM)**		
PATIENT	x	y	z	x	y	z	x	y	z
16.1	60.16	35.83	-8.36	60.40	35.40	-8.07	0.24	0.43	0.29
16.2	60.16	35.83	-8.36	60.46	35.59	-8.02	0.29	0.25	0.34
16.3	60.16	35.83	-8.36	60.38	35.38	-8.07	0.21	0.46	0.29
16.4	60.16	35.83	-8.36	60.40	35.41	-8.06	0.23	0.42	0.29
16.5	60.16	35.83	-8.36	60.34	35.46	-8.04	0.17	0.37	0.32
						Median	0.24	0.43	0.29

Table 4 lists the pre-surgical location, post-surgical location and differences for the validity test. The median difference in the X axis was 0.24mm with a range of 0.17-0.29mm. The median difference in the Y axis was 0.43mm with a range of 0.25-0.46mm. The median difference in the Z axis was 0.29mm with a range of 0.29-0.34mm.

Table 5: 3-Dimensional, Apical and Angular Changes of Implants for Validity Test

	DELTA (IN MM)			**ANGLES (IN DEGREES)**			
PATIENT	x	y	z	M-D	B-L	Apical (In mm)	Rot
16.1	0.24	0.43	0.29	-2.16	0.17	0.39	-1.18
16.2	0.29	0.25	0.34	-1.57	0.18	0.38	-1.19
16.3	0.21	0.46	0.29	-2.42	0.19	0.38	-0.99
16.4	0.23	0.42	0.29	-2.39	0.22	0.37	-1.07
16.5	0.17	0.37	0.32	-2.06	0.07	0.41	-1.13
MEDIAN	0.24	0.43	0.29	-2.28	0.18	0.38	-1.13

Table 5 shows the 3-dimensional differences from Table 4, as well as the angular, apical and rotational differences for the validity test. The median M-D tip was -2.28 with a range of -

2.24 to -1.57 degrees. The median B-L tip was 0.18 degrees, with a rage of 0.07-0.22 degrees. The median apical position of the implant was 0.38mm apical, with a range of 0.37-0.41mm. The median rotational difference was 1.13 degrees counterclockwise, with a range of -1.19 to -0.99 degrees.

DISCUSSION

This investigation examined the accuracy of the Simplant SafeGuide surgical guide for single implant placement in a healed edentulous ridge. This was achieved by comparing the pre-surgically planned location of the implant in a CBCT using Simplant and the post-surgical location following complete osseointegration and an implant level impression. The primary outcome of the study was to measure the differences in position in 3-dimensional space (in mm), the angular difference in a Mesial-Distal and Buccal-Lingual direction (in degrees) and the rotational difference down the long axis of the implant (in degrees).

To the authors' knowledge, this is the first retrospective analysis of Simplant's Safeguide system. Previous studies evaluated guided implant systems that required a new guide for each drill size, which introduces a large amount of error as each guide would not fit the exact same. Also, a number of the systems previously reported on would call for osteotomy creation through the guide but placement of the implant via traditional freehand method. No matter how accurate

Figure 12. Stereolithographic Guide showing fit of drill, sleeve and guide.

the osteotomy is, placing the implant without using the guide introduces a significant chance of changing the implant position, especially in less dense bone. The Simplant Safeguide system uses a single guide that is seated once and remains in place until after implant placement. The individual drills, as well as the implant driver fit into the guide through the use of sleeves where the inner diameter matches the drill diameter and the outer diameter matches the diameter of the metal sleeve set in the milled guide.

This is also the first study to use computer modeling to compare pre-op and post-op positioning. Previous studies that compared planned implant location to placed implant location have used a post-op CBCT and overlay software to determine the positional change. While this novel modality of analyzing positional change does produce results that are reported differently than previous studies, it also limits some of the additional errors. CBCT scans have an inherent inaccuracy related to voxel size. In order to reduce the effective dose of radiation to the patient, the size of each data packet is limited; this results in the detail reproduction of the scan to only be reported at a minimum accuracy. No measurements can be made below that minimum accuracy, which in turn mean the results of the studies cannot be reported at an accuracy less than the voxel size. This study used computer produced 3-dimensional positioning represented by the transformation matrix file(.TMF), which gets reported to an accuracy of .000001mm, far greater than needed. This allows for the errors that are found within the measurements and the processing of the data to not be compounded by the initial data.

There are, however, errors present in the protocol. These errors start with the differences in materials used to make the pre-op and post-op models. Initial records used to plan implant placement were made with alginate and poured in microstone (Whipmix, Louisville, KY). The final, implant level impressions were made with polyvinyl siloxane impression material and

poured in die stone (Whipmix, Louisville, KY). The differences in material properties including expansion and dimensional stability will have some effect on both the relative 3-dimensional position of the implant and the ability to merge the two models accurately in Geomagic. The remaining errors come as a result of human error during the data processing within Geomagic Studio and Geomagic Control. The first introduction of error is during the merging of the pre and post op models and the merging of the FLO scan bodies. As noted in the materials and methods section, Geomagic reports the global accuracy of the merges. All overlays of models were accurate to less than 0.08mm. All overlays of FLOs were accurate to less than 0.02mm. Theoretically, this means that the merging process on the computer should account for no more than 0.1mm of error in the final reporting.

Although the errors throughout the process seem to account for very small discrepancies, there are enough individual sources of potential errors to justify calibration by running a validity test. Case number 15 was chosen as the test case. Starting with the initial data upload into Geomagic, every step of the protocol was followed to completion five times and the data was collected. The range of 3-dimensional accuracies was on average 0.09mm. The range of apical accuracies was 0.04mm and the range of rotational accuracy was 0.19 degrees. This small variation confirms that while there is inherent sources of error within the process, they are minimized and the results reported are validated as accurate. However, the range of data for the 3-dimensional accuracy during the validation test is still 26% of the 0.35mm difference between planned location and placed location. While this is a significant range when compared with the reported outcomes, it may not have clinical implications (0.35±.09mm). The implant placement is still far more accurate than previously reported studies and well within the 2mm safety circle that Simplant proposes around all implants during the planning process. The final deficiency of

this study is sample size. This study was a retrospective analysis of a previous pilot study, so the number of subjects was small. There were also a number of implant failures prior to final impression which excluded those subjects from inclusion in this study.

The final results show excellent accuracy in all measured outcomes. In 3-dimensional space, the difference between the planned and final implant locations was 0.34mm for the x and z dimension and 0.31mm for the y dimension, for an overall median difference of 0.33mm. The key dimensional accuracy for placement new anatomy is the apical positioning. The median final implant location, compared with the planned location, was 0.4mm apical to the planned position. Angular difference between planned and final implant location was 0.47 degrees tipped to the mesial and 0.22 degrees tipped to the lingual. The rotational timing of the implants compared to Simplant's decided timing for abutment placement was 3.19 degrees rotated clockwise. The first significant note regarding the data is the range. Throughout the data set, the range is very narrow, which suggests a repeatable process, and further validating the test case. All the implants placed, with the exception of one outlier, where within 1mm of the planned location, with the majority being placed within 0.4mm of ideal. Apically, all the implants were placed within 0.86mm of the planned apical position. Angularly, all implants were placed within 4.5 degrees of the planned position in both a mesial-distal tip and a buccal-lingual tip. Finally, with the exception of a few outliers, all implants were placed within 12 degrees of the planned timing, with most of the implants placed within 7 degrees. There were a few anomalies when the data was reviewed. The first is the rotational discrepancy of case number 2, a difference of 55 degrees. This surgery was the first lower posterior tooth placed in the original study. With the timing slot on the lingual side of the guide, the surgeon reported difficulty lining up the grooves to ensure the timing. A timing difference of 60 degrees means that one of the dots on the driver was probably lined up within 5

degrees of the slot, however it was not the large dot so the implants hex was turned once. Extra care and extra eyes were employed on all future mandibular posterior cases. The next two outliers are two implants turned 180 degrees from the planned implant location. Both of these were clinical decisions made at the time of surgery due to poor planning of implant depth. As a result of these clinical decisions to adjust the implant location for improved long term results, case number 9 is off in all its measurements far outside of the normal range that was seen with the rest of the implants. While their 3-dimensional angulation and apical measurements were included in the medians reported, the three outlying rotational discrepancies were excluded from the reported median.

The clinical and patient based implications for this study are profound. Guided surgery has significant patient benefits, but the most critical aspect of every surgery is safety. Previous studies showed accuracy of around 1mm, which is still within the 2mm safety zone that all planning softwares place around the implants. However, if it is possible to place an implant accurately within 0.3mm of the planned position, it may allow the dentist to plan the implant location with less of a buffer above the inferior alveolar nerve or below the maxillary sinus. It will also more accurate placement when bone volume is less than ideal. It is known that 2mm of bone buccal to a dental implant is ideal for the long term stability of tissues and esthetics. Due to residual ridge resorption the buccal-lingual bone volume is often less than ideal in the anterior, where it is most critical. Free hand, fully flapped surgeries are often the procedure of choice because placement of the implant while maintaining the buccal bone thickness is nearly impossible to predict with flapless surgeries. Yet, the inaccuracy of free-hand surgery often results in the violation of this 2mm rule and esthetics and stability are compromised. Previously studied guided surgical techniques that suggest accuracy of within a millimeter are troublesome

when the goal is to place an implant 3.5-4mm in diameter in bone with a buccal-lingual dimension of 6-7mm. The simple fact is we as surgeons are just not accurate enough to guarantee our patients the best possible long term solution. The results produced in this study would suggest that we can predictably and accurately place implants in minimum bone volume without introducing the pain and technique sensitivity consistent with surgical flaps. The bone can be visualized prior to surgery, in the CBCT scan, as opposed to having to reflect a flap in order to visualize it. This saves both the patient and the surgeon time, and the patient's healing is far more manageable. Guided surgery with the accuracy reported in this study also has the additional benefit of aiding in the determination of grafting needs prior to surgery. If the implant can be predictably placed with plenty of buccal bone, the need for hard tissue augmentation at the time of surgery will be reduced, especially grafting caused by an implant placed too far buccal in the boney housing. Surgically, we can now be more accurate, which allows the procedures to be safer for the patient, while permitting the surgeon to place implants in places that would have required the investment of time and money into additional pre-surgical therapies.

The restorative benefits of guided surgery, especially with high levels of accuracy, are almost as paramount as the surgical benefits. Accurate, pre-planned surgery that can then be carried out with the aid of a surgical guide gives much more control over the final implant location, and thus the long term success of the crown, to the restorative dentist. Prior to the surgery, screw vs. cement retention can be discussed and determined. Study after study continues to suggest the negative outcomes, sometimes not becoming evident for 10 years, of cement retained crowns. Even with an appropriately designed custom abutment and the use of provisional cements, destruction of the periodontium and bone around an implant. However, planning and executing a screw retained implant crown is very difficult and requires a high level

of interdisciplinary cooperation and skill. If the implant is angulated incorrectly, then the screw access may come out the facial surface of an anterior crown, requiring a cement retained crown for esthetics. Incorrect angulation can also result in axial loading that will put excess pressure on the abutment screw leading to loosening or fracture, the most common technical complication seen with screw retained implant crowns. If the implant is placed too far lingually, to compensate for the severe biological and technical complications from a facially placed implant, the material bulk required to wrap lingually around the screw access can result in crown contours that may be irritating to the tongue. The depth and location of the implant can be determined to best predict emergence profile. Most importantly, the restorative plan is not ignored or changes because things do not go as planned surgically. This all too often causes potentially avoidable headaches when it comes time to restore the implant. It is also beneficial if the patient can know the final treatment plan before it begins, for time and economic reasons. Removing the uncertainty of free-hand implant can help keep treatment on target, which will benefit both parties involved.

Evaluating the accuracy of Simplant's guided surgery protocol is a critical for supporting the one abutment-one time theory in conjunction with Atlantis custom abutments, a new treatment that takes the use of digital technology in dentistry to a new level. Denstply Implants have named this the Immediate Smiles Protocol. The protocol requires a pre-surgical CBCT scan and a merged wax up of the proposed tooth. The implant position is planned in Simplant software and the digital mock-up of the surgical guide is approved by the surgeon and the restorative dentist. Simplant, in conjunction with Dentsply Atlantis designs a custom abutment based on both the position of the implant and the proposed wax up of the final tooth. The custom abutment can be edited and approved by the restorative dentist, and a core file is produced. The core file is an .STL reproduction of the patient's dentition with the custom abutment in place

relative to the remaining teeth. This allows the lab to digitally produce a provisional crown. The implant, guide, final custom abutment and provisional crown are all planned, designed and delivered prior to the surgery. Following the creation of the osteotomy through the surgical guide, the implant is placed and aligned. The implant in inserted until it reaches the bottom of the osteotomy, but the rotational timing is not always accurate. The implant driver has marks on each of the 6 sides of the driver, which correspond with the internal hex connection of the Astra EV implant. However, one mark is larger than the rest. This slot is the timing slot and must be aligned with the slot in the guide to the lingual of the sleeve. Once the slots are aligned, the guide is removed and the abutment can be placed.

The ability for the timing of the implant to be accurate is paramount for the Astra EV system. The implant is designed with a seventh internal groove, in addition to the hex. The seventh groove is what allowed us to examine the accuracy of the rotational timing, since the FLO only fits in one direction and we can compare the angular difference between the flat sides. Atlantis custom abutments are only able to be seated in torqued into place in one direction, lining up the seventh groove. The tooth specific design, including the location of the crown margin, was developed on the core file which took the implant timing into account. Therefore, while the 3-dimensional accuracy of the surgery is important, the rotational timing will affect every aspect of the custom abutment and provisional crown simultaneously. An average rotational difference of 3.2 degrees is incredibly accurate, especially considering the size of the timing slot in the driver and the location of the guide's slot on the lingual aspect which greatly reduced visibility. 11 of the 13 implants were within 10 degrees of the planned timing. This level of rotational accuracy, along with the 3-dimensional accuracy, should be within the tolerances to justify designing, milling and fully torqueing the final custom abutment into place at the time of implant

surgery. According to the initial study for which this was a follow up, it was shown that by following our current understanding of implant planning in the anterior maxilla, the Denstply Immediate Smiles Protocol can predictably design and execute a custom abutment, provisional crown and definitive restoration without showing metal at the gingival margin and establish an appropriate emergence profile.

While this study quantitatively verifies the accuracy of the Simplant Safeguide, without the context of a clinical study it can only reassure surgeons and restorative dentists that, with the appropriate planning and attention to detail, a dental implant can be place 0.3mm and about 3 degrees rotation from a desired location in the maxilla or mandible. This is important data, but there are some important next steps to make this information truly valuable in the clinical setting. The first step is to increase the sample size. While the effect of the errors was low, the number of variables is high for such a straight forward research question. This means that the sample size would have to be substantial in order to see the true accuracy. It would also be beneficial to carry out this increased sample size in private practice or multi-center. While it is an additional variable, if the sample size is large enough the consistency between practitioners is a critical piece of information. In order for the Immediate Smiles Protocol to be widely accepted, the process and results should be repeatable across the field, by any surgeon with the knowledge base necessary to perform guided surgery. One of the most valuable purposes for this data would be a comparative study with the clinical pilot study that the data was acquired from. The ability to compare each individual outcome clinically and objectively has great power. The most important data comparison would be to see how the 3-dimensional and rotational accuracy corresponds with the amount of adjustments necessary when the provisional is delivered. Potentially a threshold of accuracy could be established that coincides with no adjustment of

occlusion or contact points, minimum adjustment or significant adjustment. This would help the development of further guided systems as a standard of accuracy could be established in order to place a final abutment on the day of surgery. It would also be valuable to compare this study data with the original study to see if tooth location influences accuracy. Due to the lingual placement of the timing groove, it may be worth investigating if posterior implant placement is less accurate than anterior placement, or if the mandibular is more or less accurate than the maxilla.

It may be worthwhile to investigate, using the novel computer assisted comparison, to evaluate the accuracy of full arch tissue supported guides. The accuracy will not be as good, simply due to the increased instability of soft tissue. However with current understanding of anchoring pins, a single guide used for all implants, and the ability to lock the guide in place with the first implant placement large improvements could be seen over many of the older studies. It would be important to examine two types of accuracy. First, the accuracy of the implants compared with the plan in relationship to the skull. This would test the preservation of the information through the guide and indicate how much the fit of the guide and the soft tissue affects the outcome. The second accuracy would be the inter-implant accuracy. If the whole guide shifts and the implants are not placed were they were planned they may still be very accurately placed with respect to each other. This is critical information with the development of full arch Immediate Smiles treatment. Being able to fabricate a full arch of teeth in the lab prior to surgery may be possible if the surgery can be proven to be accurate, and is worth further investigation as the field of dentistry continues to move into a fully digital world.

CONCLUSION

At the conclusion of this study, it became evident that the accuracy of Simplant Safeguide fully guided implant surgery is extremely precise. A 3-dimensional accuracy of less

than 0.35mm, an apical accuracy of 0.4mm and rotational accuracy of 3.2 degrees from the planned location are accuracies that have never been produced before. These results open the door to further studies to evaluate on a large scale the effectiveness of modern SLA fabricated guides. If these results are reproduced with bigger sample sizes, there is the potential that the safety zone around guided implants can be decreased. This would save our patients time and money on additional procedures and increase the safety of our procedures without introducing the pain of incisions and flap reflection.

This is a paradigm shift in the world of surgical dentistry. Guided surgery requires the surgeon and the restorative dentist to trust the accuracy of the scan, the planning process, the stereolithic guide and the surgical procedure. It takes away the ability of the surgeon to trust their training, experience and intuition. This has been guided surgeries biggest shortfall, surgeons often refuse it as a treatment modality because they believe that their experience and training are more accurate, and better for the patient, than putting what often feels like blind faith in the protocol and the technology. If guided surgery is to become fully integrated into the mainstream practice of experienced surgeons, full faith musts be placed in the system. This is only going to be possible when more studies show similar results, both raw data and clinically. At the end of the day, dentists are expected to treat the patient with the best modalities possible. Guided surgery does not work in every situation. Education about the treatment planning and requirements for a successful guided surgical case must continue to be pushed. However, if the patient fits the criteria for a guided implant placement, especially if esthetics or anatomy are of high concern, then it is a disservice and an oversight to not use the technology we have to better ourselves, our outcomes and our patient's quality of life.

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