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Accuracy of a Newly Developed Guided Dental Implant Delivery System

Fallon D. Livingston

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LOMA LINDA UNIVERSITY
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Accuracy of a Newly Developed Guided Dental Implant Delivery System

by

Fallon D. Livingston

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A Thesis submitted in partial satisfaction of
the requirements for the degree
Master of Science in Periodontics

_____

June 2017

Each person whose signature appears below certifies that this thesis in his/her opinion is adequate, in scope and quality, as a thesis for the degree Master of Science.

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ABSTRACT

Accuracy of a Newly Developed Guided Dental Implant Delivery System

by

Fallon D. Livingston

Master of Science, Graduate Program in Periodontics
Loma Linda University, June 2017
Dr. Erik Sahl, Chairperson

Purpose: The purpose of this study was to evaluate the accuracy of a guided dental implant system with one operator comparing the treatment planned location to the actual location using a table top optical scanner. **Materials and Methods:** Twenty five patients were treated with a cone beam computed tomography (CBCT) scan. A stone cast was made of each patient and scanned using an optical table top scanner. The optical scan of the cast and the CBCT of the patient were superimposed and a single implant was placed virtually in the software program. A sterolithographic three dimensional (3D) surgical guide was printed. Implant sites in the patients were prepared using the surgical guides and the final drill to complete the osteotomy and implant placement was done without the guide. Four to six months after implant placement, impressions were made for the final restoration. A scanning body was placed in the master cast, and the scanning of these casts was performed with the same scanner. The overlay of the final working cast and the virtual planning was performed. Differences between actual and planned implant locations were calculated in linear measurement in millimeters and degrees from the center of the implant body at the most coronal and most apical

point. **Results:** 25 cases were evaluated. The average linear deviation at the shoulder and apex of the implant was: 0.68 +/-0.55mm p < 0.001, and 1.47mm +/- 0.92mm p < 0.001 respectively. The average deviation in height was -0.06mm +/- 1.27mm p= .966. The average angular deviation from the axis was 5.8 +/- 2.41 degrees p< 0.001 The deviation in height is statistically different in the maxilla -0.95 +/- 1.28mm compared to the mandible 0.47 +/- 0.95mm $p<.002$ with an alpha level of 05. **Conclusion:** The actual location of the implant compared to the planned location is significantly different at the location of the shoulder, apex and angle. It did not differ significantly in height except when evaluated by arch.

CHAPTER ONE

INTRODUCTION AND REVIEW OF THE LITERATURE

The surgically guided dental implant is being used more frequently for single tooth and full arch rehabilitations. Guided surgery allows clinicians the ability to plan the case prior to the surgical procedure eliminating chair-side time and improving outcomes. The comprehensive nature of the surgical planning can provide a pre-fabricated provisional for either: immediate or delayed restoration and optimum occlusion.

Many dental implant planning systems are available for computer aided design and computer aided manufacture (CAD/CAM) that generate surgical guides for implant placement. Each system varies slightly in the planning software, style of guide fabrication, and surgical armamentarium. Surgical guides can be categorized based upon their restriction of drills when placing the implant.[1] Non-limiting guides provide an entry point for drilling but do not limit angulation or depth. The most direct options include implant placement through the guide. Each type of guide has benefits and disadvantages. The least limiting may allow the clinician to make alterations based on actual site characteristics that appear differently on the planning software for better initial stability or more favorable location. However, it may also cause unintended deviation from location planned in the software.

Evaluating the accuracy of the systems, software and its armamentarium pose challenges. Studies have been conducted to measure the accuracy of these systems with the associated guides.[2-4] Most studies evaluated systems in-vitro or simulated clinical setting.[5] The clinical studies have used a variety of techniques to

produce the data for actual implant location. Linear measurement of the center of the implant in situ from fixed reference points to compare to virtual planning is challenging, and not reproducible. Using a post-operative cone beam computed tomography (CBCT) scan allows a useful and convenient method of comparison, due to the original data being derived from a pre-operative CBCT. However this introduces an unnecessary radiation exposure to the patient and has been shown to only be moderately accurate compared to actual measurements.[6]

Newer technologies exploring intra-oral digital impressions with scanning bodies and their accuracy have been shown to be acceptable for single implants and short anterior to posterior spans within a quadrant for multiple implants.[7,8] This method, which is becoming widely used and accepted, can introduce variables that may skew the error of placement.[9,10] Another method of measuring accuracy of placement is using a restoration designed from the virtually planned implant and determining that it seats passively with the accepted Sheffield test.[11] The restoration would be completely CAD/CAM generated based on the software's implant location and would introduce variables including the experience of restoration designer and thresholds of particular milling units.

The oldest method, and most generally accepted, is the use of the final working cast to be the true location of the implant. The errors introduced in the materials used for final impressions, final casts, and fabrication of restorations have been reported on at length. This method is still the currently accepted gold standard for quantifying implant placement accuracy.[12, 13]

The accuracy and reproducibility of digital table top scanners has shown to be high[14] in a recent study. It was reported that the measurement utilizing a table top scanner and traditional cast with different experience level operators; there was no statistical difference than linear measurements obtained on a dental cast directly with a digital caliper shown to be accurate to 0.01mm. Scanning of traditionally obtained final working casts along with traditionally obtained preoperative casts allows overlaying of preoperative and postoperative digital files to be compared. The planning software shows deviation of implant location to be quantified in linear measurement of millimeters and degrees of divergence in angulation as well.

A recent systematic review reported on different guided systems and found a wide range of deviation between intended implant location compared to actual location. The average of all included guided studies was shown to be 0.9mm at the entry point and 1.24mm at the apex with a mean angular deviation of 3.81 degrees. The deviation of implant placed free hand after a guided osteotomy was shown to be 1.34mm at the entry 1.69mm at the apex and 5.6 degrees of angular divergence.[15]

There is a lack of in-vivo clinical research with a single operator and single guided system. The aim of this study was to evaluate the accuracy of placement of a single dental implant in 25 patient's treated by one operator with the use of the Cyber Implant System. The null hypotheses are that there is no difference in location of the actual implant location to the virtually planned implant with respect to: location of the implant shoulder, location of the apex, depth of implant placement, and implant angulation. Additionally, it is our hypothesis that this guided implant

system is as accurate as data published in recent systematic reviews with the same

limitation of guide.

CHAPTER TWO

MATERIALS AND METHODS

Patient Selection

The records of 25 consecutive patients was selected from a faculty member

of Loma Linda University School of Dentistry's private practice. All patient

identifiers were removed prior to inclusion in the study. The subjects included in

the study using the eligibility criteria: patients older than 18 years, presenting no

signs of active periodontal disease, probing depth <3 mm and full-mouth plaque and

bleeding score ≤20%. This was to ensure the surrounding teeth were stable and

would serve as reference points. All sites included were healed sites of 6 months

since extraction or graft placement. If patient presented with multiple missing teeth

and was planned for more than 1 dental implant, only one implant at the most

anterior site was included in the study.

Implant Planning

The patients in the study received a CBCT scan pre-operatively using one

scanner(Carestream 9300 , Seal Beach, CA) scanner settings: 90kVp 4mA 6.2sec

180um 10x10cm FOV.

Pre-operative treatment planning began with full arch impressions made

with polyvinyl-siloxane (PVS) impression material (GC America). Dental casts were

made from these impressions using micro-stone (Whipmix). Using the

manufacture's positioning device (Cyber- Bite, Cyber-Implants, Huntington Beach

CA), bite registration material was loaded on both surfaces and placed in patient's

mouth with radio-opaque positioning arrows. (*Figure 1*) Creating a coordinate

system, centered in patient's facial midline and parallel with the plane of the floor.

(*Figure 2*) A CBCT scan was then taken and settings of patient with positioning

device in place intra-orally. (*Figure 3*) The patient's cast was then mounted with the

positioning device in which the patient was scanned using a specially designed non-

adjustable articulator (Cyber- Jig, Cyber-Implants, Huntington Beach CA). (*Figure 4*)

The mounted cast was scanned using an optical table top scanner (Rexcan DS2,

Solutionix) and converted into a Standard Tesselation Language (STL) file. The

patient's CBCT volume was converted into a digital imaging and communications in

medicine (DICOM) file format. The .STL file of the cast and the DICOM file of the

patient were superimposed using the radio-opaque positioning device. Using the

implant planning software a single implant was placed virtually in the software

program. (*Figure 5*) The planned placement was then used to manufacture a

sterolithographic three dimensional (3D) printed surgical guide. (*Figure 6*)

Surgical Phase

Surgical placement of all implants was done by one operator. Implants sites

in the patients were prepared using the guide manufacturer one time use drills and

surgical guides, but the final drill from the implant manufacturer was used to

complete the osteotomy was done without the guide. The implant was then placed

by the operator without using the guide. All implants placed were Nobel Biocare

Branemark MarkIII, (Nobel Biocare, Yorba Linda CA) When 35 Ncm of initial

stability was obtained, a healing abutment was placed. When less than 35 Ncm of

initial stability was achieved, a cover screw was placed. An uncovery surgery was performed 3-5 months after implant placement.

4-6 months after implant placement, impressions were made using open tray impression copings and PVS material. Casts were made for the final restoration. At restoration delivery, the implant was indexed and the final working casts were confirmed in the lab.

The final working cast was used as the master cast for the data collection. The master cast was mounted using the same positioning device and the same articulator. A scanning body was placed on the implant analog in the master cast. Scanning of these casts was performed with the same scanner (Rexcan DS2, Solutionix). The implant planning software was used to overlay the scanned master casts with scanning bodies over the preoperative virtual planning. The scanning body has a 2mm pin, the exact dimensions of the pin extending from the virtually planned implant. This allowed measurements to be taken in the software. *(Figure 7)* Difference between actual and planned implant locations was calculated in linear measurement in millimeters and degrees from the center of the implant body at the most coronal and most apical point were calculated. (*Figure 8-11*)

Statistical Analysis

A total of 25 single dental implant cases were used to test the hypothesis at 95% power with α at 0.05. A Wilcoxon Signed Rank test was performed to compare statistical significance between the location of implants placed using a stereolithographic surgical guide and the planned implant. The maxilla compared to

the mandible and the anterior to posterior was evaluated using the Independent

Samples Mann-Whitney U Test.

Figure 1. Positioning device

Figure 2. Patient in CBCT machine with positioning device placed
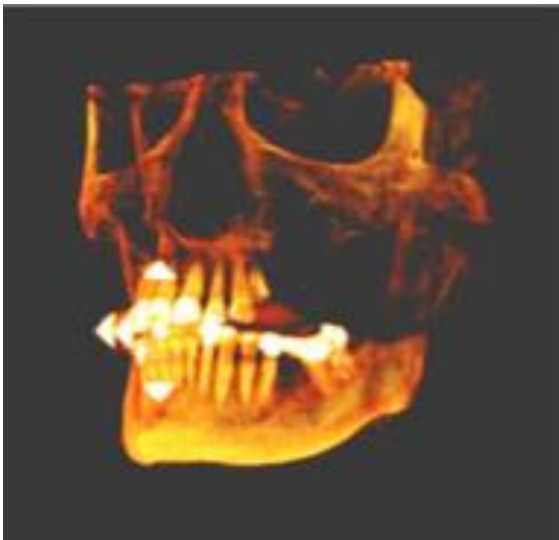
Figure 3. 3D rendering of patient scanned with positioning device
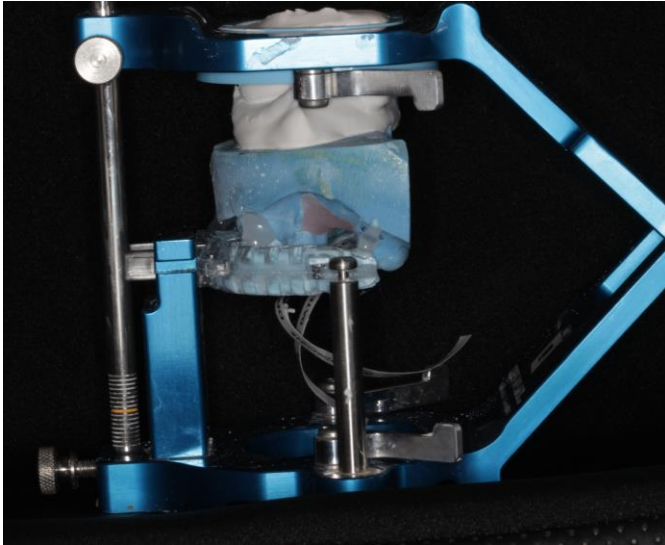
Figure 4. Patient cast mounted with manufacturer articulator and positioning device.
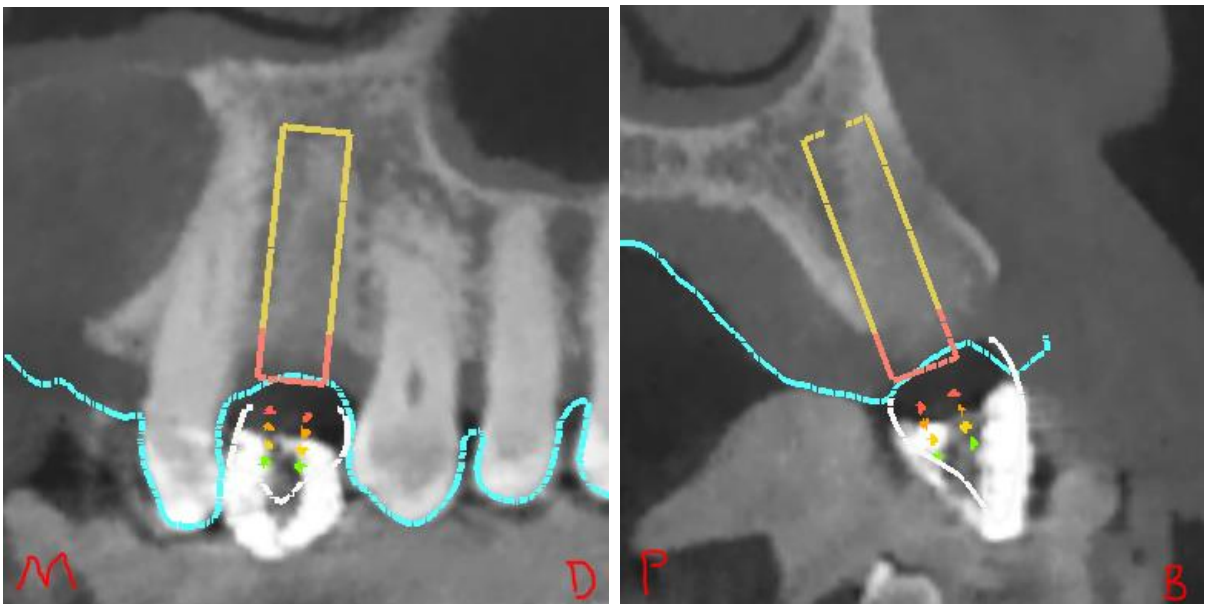
Figure 5. Implant placed virtually in software.

Figure 6. Surgical template with guide sleeve and corresponding drill.
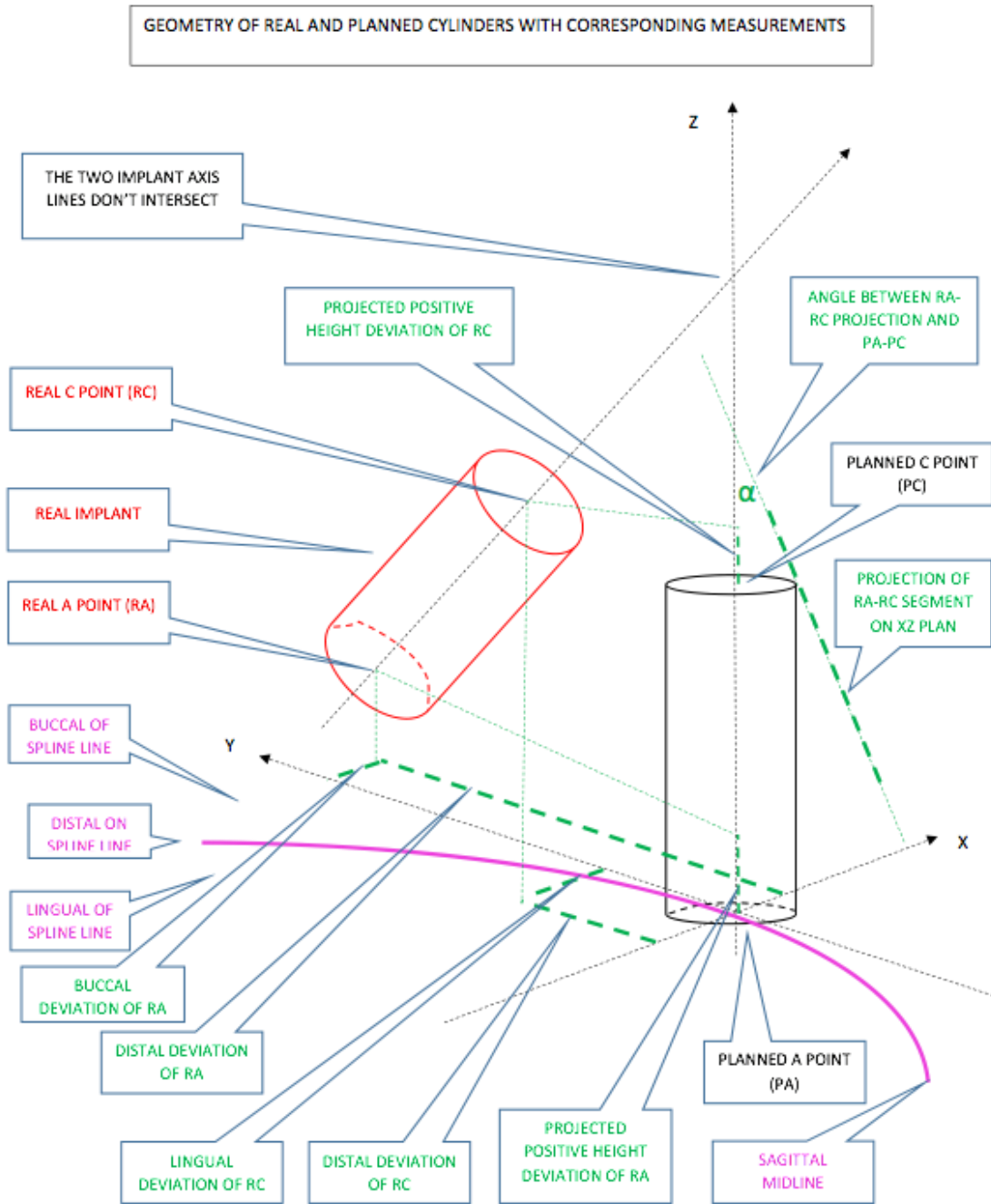
Figure 7. Graphical representation of the measurements taken to determine deviation.
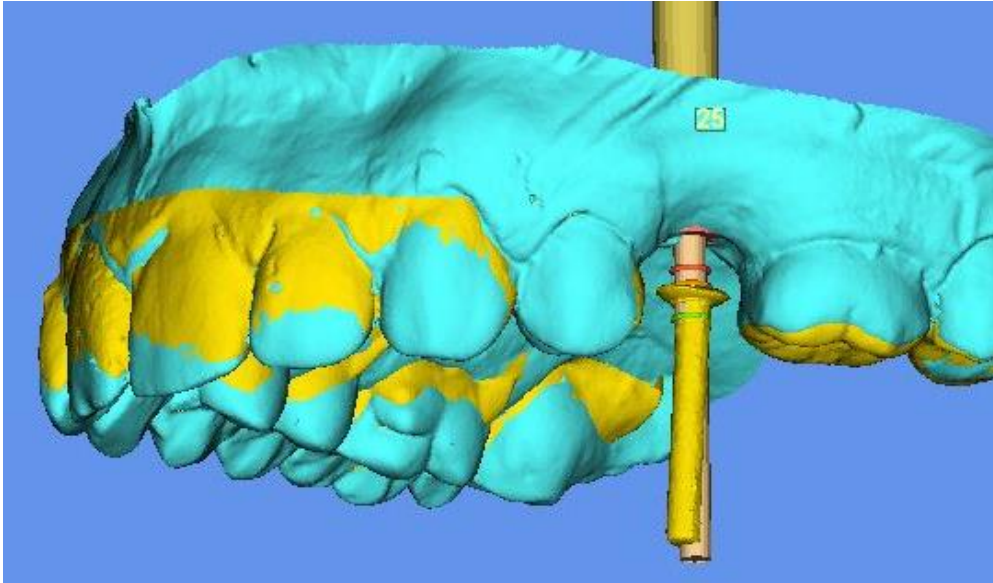
Figure 8. Measurements of deviations.
Planned implant location in brown. Actual implant location in Yellow.
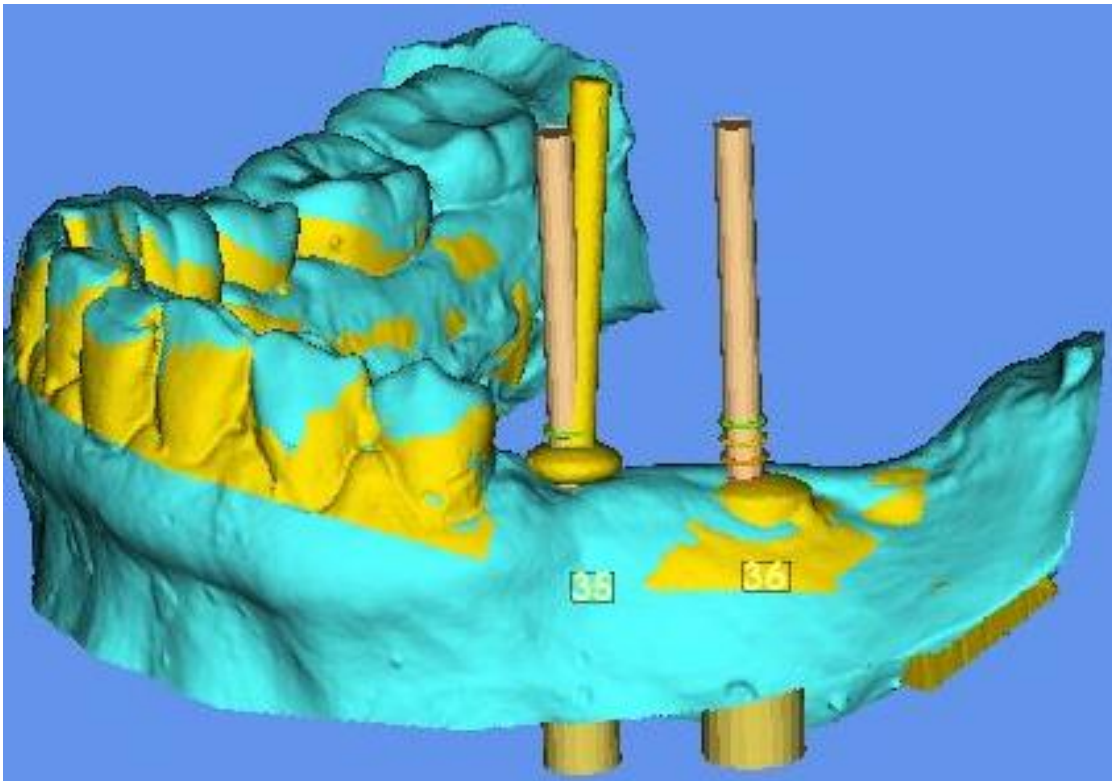
Figure 9. Measurements of deviations.
Planned implant location in brown. Actual implant location in Yellow.
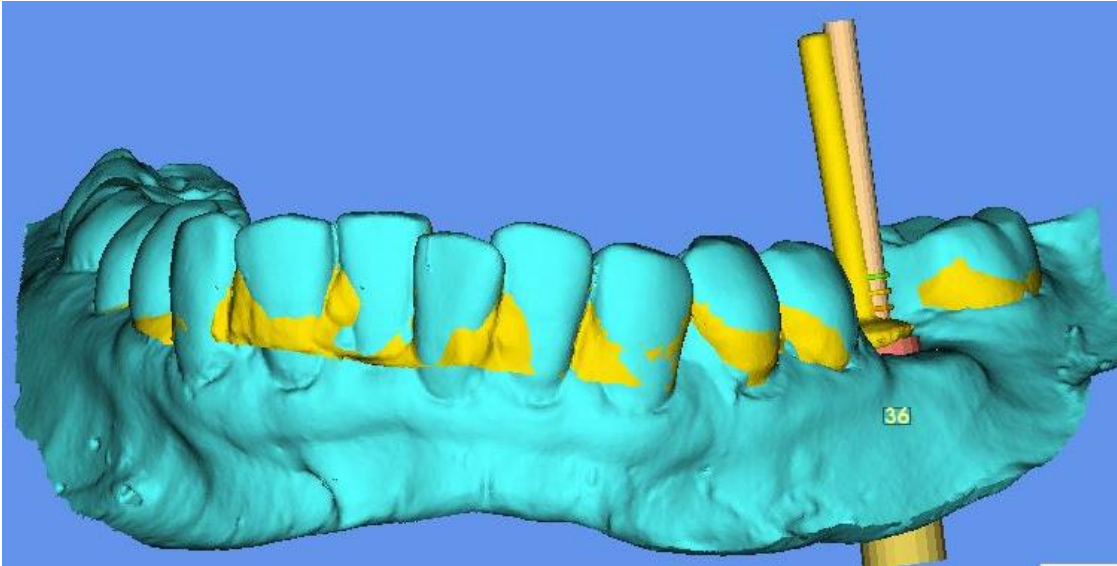
Figure 10. Measurements of deviations.
Planned implant location in brown. Actual implant location in Yellow.
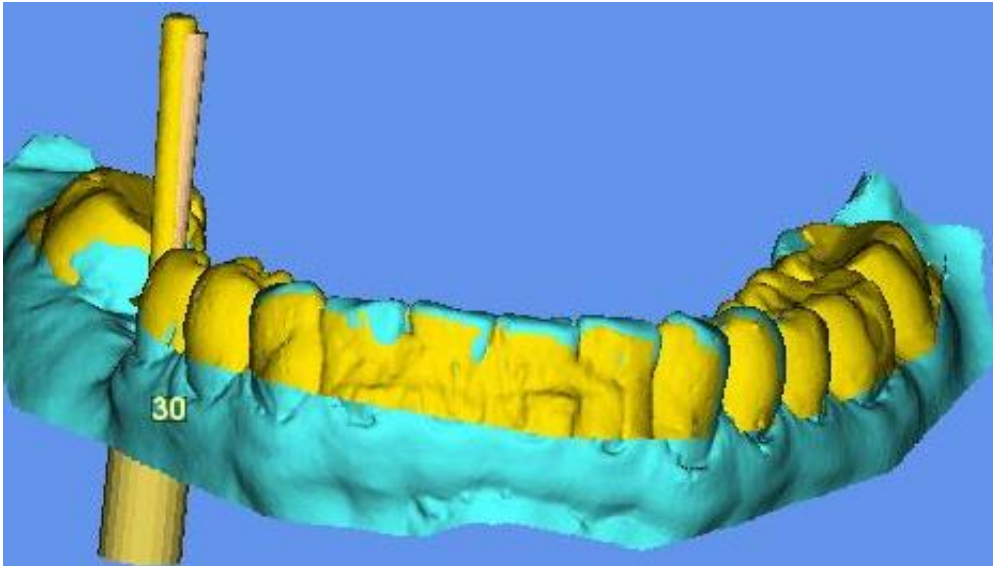
Figure 11. Measurements of deviations.
Planned implant location in brown. Actual implant location in Yellow

The deviation in depth, angulation from planned implant axis, and location of the shoulder and apex was measured for each of the 25 implants. The raw data for all cases evaluated is presented. (*Table 1 & Figure 12*)

The results show a range at the shoulder was 0.15 -2.3mm with an average of .68 ± .55mm SD. The shoulder of the placed implant was statistically different than the planned location of the implant shoulder, at *p*< .001.

The results show a range at the apex of 0.35-3.9mm with an average of 1.47 ±0.92mm. The deviation at the apex was statistically significant at *p*< .001. The results show a range of angular deviation of 1.4-10.7 degrees with an average of 5.80 ±-2.4 degrees and the angular deviation is statistically significant at *p*<.001 . The deviation in height ranges from-4.3 to1.87mm with an average of -.06 ± 1.27mm. The deviation in height is not statistically significant (*p*= .966).

Although there were limited number of cases when divided into maxilla and mandible anterior and posterior, the data was separated and evaluated to see if there were trends. (*Table 2 &3)* The total average deviation in angulation for the maxilla was 6.18+/- 2.36 degrees for the anterior it was 5.97+/- 3.35 degrees, and the posterior 6.28 +/- 2.74 degrees. The total average deviation at the shoulder in the maxilla was 0 .69 +/-0.63mm for the anterior 0.45+/-0.40mm and for the posterior 0.74+/-0.70mm. The total average deviation in height in the maxilla -0.95 +/- 1.28mm for the anterior it was -0.42+/-0.41mm and the posterior -1.14+/- 1.56mm. The total average deviation at the apex in the maxilla was 1.65mm+/-

0.94mm for the anterior 0.92+/-0.87mm and for the posterior 1.86+/- 1.01mm. The

total average deviation in angulation for the mandible was 5.57+/- 2.50 degrees for

the anterior it was 3.67+/- 3.59 degrees, and the posterior 6.04 +/- 2.09 degrees.

The total average deviation at the shoulder in the mandible was 0 .67 +/-0.52mm

for the anterior 1.05+/-1.10mm and for the posterior 0.57+/-0.27mm. The total

average deviation in height in the mandible 0.47 +/- 0.95mm for the anterior it was -

0.81+/-0.63mm and the posterior -0.39+/-1.02mm. The total average deviation at

the apex in the mandible was 1.36mm+/-0.93mm for the anterior 1.74+/-1.92mm

and for the posterior 1.26+/- 0.62mm. We can reject the null hypothesis in one

deviation measurement. The deviation in height is statistically different in the

maxilla compared to the mandible. In the maxilla height deviation of -0.95mm and in

the mandible 0.47mm *p*<.002.

Table 1. Measurement of deviations.

Case	Angular Deviation (°)	Total Deviation at Shoulder (mm)	Deviation Height (mm)	Total Deviation at Apex (mm)
29433	7.40	0.75	-1.51	1.05
30197	6.10	0.27	0.35	1.27
30660	5.20	0.27	-0.75	1.17
30693	2.40	0.40	0.19	0.43
30694	5.30	0.95	-0.08	1.68
30713	3.90	0.72	-0.69	0.38
31615	6.60	0.40	0.50	1.55
31616	6.40	0.29	-0.31	1.40
34133	3.90	0.25	1.15	0.86
37179	6.00	2.22	-4.31	3.42
37426	1.40	0.26	0.96	0.35
37986	1.80	0.59	0.11	0.94
40199	6.50	0.85	-0.84	1.83
41960	7.80	2.31	1.35	3.93
43253	9.20	0.52	-0.34	2.03
43616	7.80	0.79	1.45	2.17
44648	6.70	0.91	-0.73	1.93
44784	5.80	0.40	-0.35	1.61
44789	7.60	0.61	1.68	1.92
46677	10.70	0.16	-0.69	2.39
47213	7.50	0.23	-0.16	1.47
47480	2.10	0.48	-0.46	0.40
47481	7.80	1.07	1.87	0.58
50798	3.20	0.60	0.12	0.41
Average	5.80	0.68	-0.06	1.47
Standard Deviation	2.41	0.55	1.27	0.92
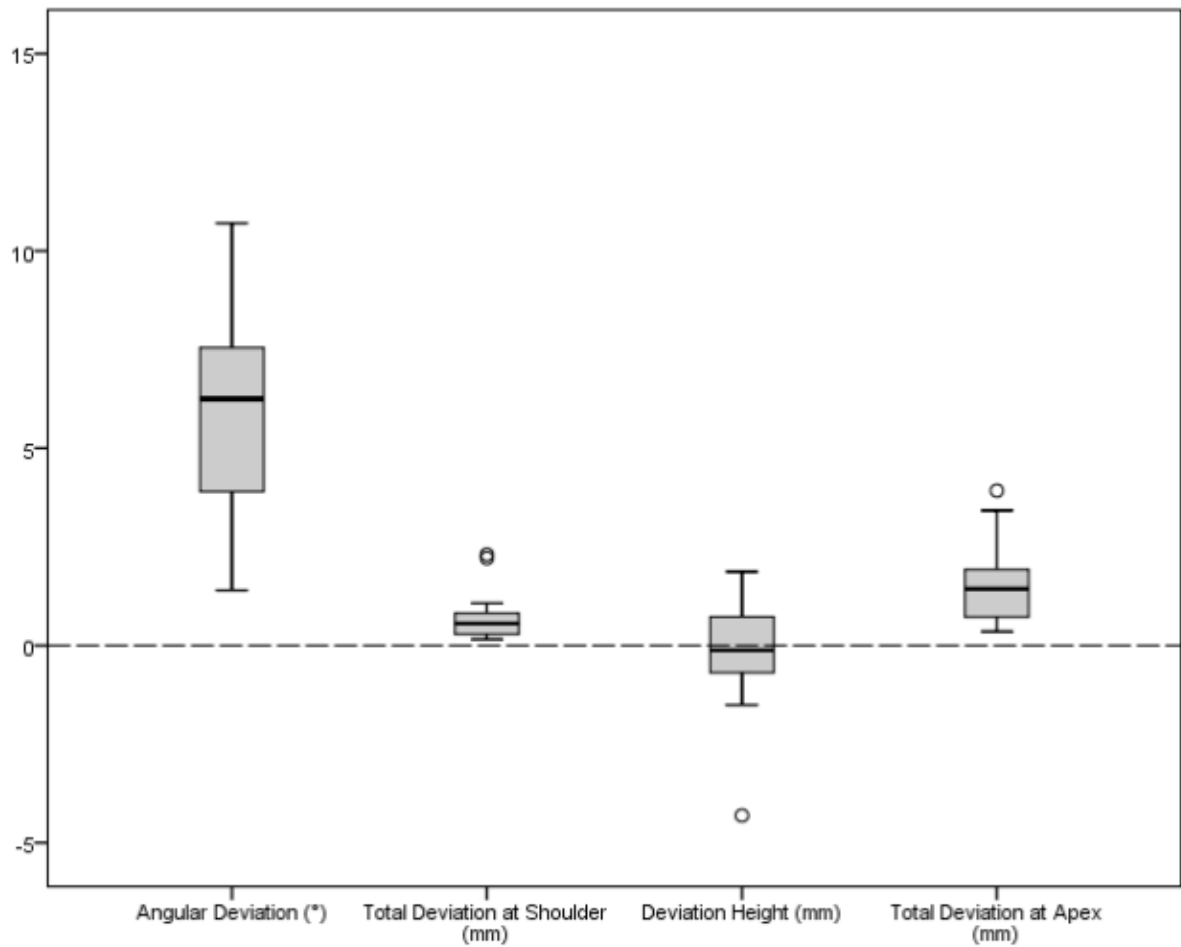
Figure 12. Box-plot of data represented in Table 1.

Table 2. Data for maxillary cases.

Maxilla Case	Angular Deviation (°)	Total Deviation at Shoulder (mm)	Deviation Height (mm)	Total Deviation at Apex (mm)	Site #
47480	2.10	0.48	-0.46	0.40	4
46677	10.70	0.16	-0.69	2.39	4
31616	6.40	0.29	-0.31	1.40	5
30713	3.90	0.72	-0.69	0.38	8
40199	6.50	0.85	-0.84	1.83	8
47213	7.50	0.23	-0.16	1.47	9
44648	6.70	0.91	-0.73	1.93	12
44784	5.80	0.40	-0.35	1.61	13
37179	6.00	2.22	-4.31	3.42	13
Average Max	6.18	0.69	-0.95	1.65	
STD	2.36	0.63	1.28	0.94	
Average Max Anterior	5.97	0.45	-0.42	0.92	
STD	3.35	0.40	0.41	0.87	
Average Max Posterior	6.28	0.74	-1.14	1.86	
STD	2.74	0.77	1.56	1.01	

Table 3. Data for mandibular cases.

Mandible Case	Angular Deviation (°)	Total Deviation at Shoulder (mm)	Deviation Height (mm)	Total Deviation at Apex (mm)	Site #
30660	5.20	0.27	-0.75	1.17	18
47481	7.80	1.07	1.87	0.58	18
30693	2.40	0.40	0.19	0.43	19
50798	3.20	0.60	0.12	0.41	19
43253	9.20	0.52	-0.34	2.03	19
44789	7.60	0.61	1.68	1.92	20
34133	3.90	0.25	1.15	0.86	21
37426	1.40	0.26	0.96	0.35	23
37986	1.80	0.59	0.11	0.94	26
41960	7.80	2.31	1.35	3.93	26
29433	7.40	0.75	-1.51	1.05	29
30694	5.30	0.95	-0.08	1.68	30
30197	6.10	0.27	0.35	1.27	30
31615	6.60	0.40	0.50	1.55	30
43616	7.80	0.79	1.45	2.17	30
Average Man	**5.57**	**0.67**	**0.47**	**1.36**	
STD	2.50	0.52	0.95	0.93	
Average Man Anterior	**3.67**	**1.05**	**0.81**	**1.74**	
STD	3.59	1.10	0.63	1.92	
Average Man Posterior	**6.04**	**0.57**	**0.39**	**1.26**	
	2.09	0.27	1.02	0.62	

CHAPTER FOUR

DISCUSSION

The results of this study reject the null hypothesis; there is a significant difference in the actual location of the implant shoulder, apex and angulation compared to the planned location; it is significantly different in height when divided into maxillary and mandibular arch.

The measurements of deviations found in this study are within the range of published data from other clinical studies with regards to stereolithographic surgical guides. A previous systematic review reported deviations of: 1.34mm at entry point, 1.69mm at the apex and 5.6 degrees of the implant with a non-fully guided implant.[15] The same review showed deviation of the fully guided implant: .88mm at the entry point, 1.15mm at the apex, and 3.06 degrees. The system in this study has smaller deviation at the entry point than the fully guided systems evaluated. At the apical point the deviation was between the non-fully guided and fully guided systems. The angular divergence in this study was 5.8 degree with a 95% confidence interval of 4.78- 6.82 degrees, this is similar to published findings of 5.6 degrees for non-fully guided systems. It is important to understand that the current guided system evaluated requires the last drill to be used without the guide at the most coronal portion of the osteotomy. This could explain the divergence in angle is greater than reported data in the literature. The type of implant placed, Nobel Biocare Branemark Mark III with no aggressive thread and the parallel body might explain why the entry divergence and height are minimal.

It was observed that implant site specific characteristics could attribute to divergence. For example in two of the cases in this study, the apex of the implant was planned in a dense cortical bone. (*Figure 13& 14*) This can impact implant placement, when the implant is placed without the guide and the apical portion of the osteotomy has a side with thick cortex adjacent to trabecular bone the implant will tend to move away from the cortical bone and may explain the higher divergence at the apex. When treatment planning the clinician must evaluate the CBCT and type of bone the apex is located. If it shows dense cortical bone at the apex it should be determined if it is necessary to utilize a fully guided system to decrease deviation in angle or apex location as the implant was deflected away from the cortical bone.

The data separated by arch and location also showed some trends that support the density of the bone playing a role in divergence. The anterior cases showed less divergence than the posterior cases in this study. The placement was significantly more shallow in the maxilla (-0.95mm) compared to the mandible (.047mm). A possible explanation these surgeries are flapless and the ability to see when the implant is at the crest may be easier in the mandible.

There are many steps in the treatment planning of implant placement with possibility of error. The study was designed to limit variables by utilizing only tooth borne guides. The goal of standardization was achieved with the use of: the same operator, CBCT machine, optical scanner, and dental laboratory.

Although each site evaluated was a healed site, site specifics were not the same. Implants were placed in all types of bone in both the maxillary and

mandibular arches. This could attribute to some variance in the current study. This study did not have enough cases to find statistical significance based on arch and location for all measurements. In the future, studies with a larger sample size investigating the impact of the implant location and bone density should be done.

More clinical studies should be done to better understand when and how to utilize surgical guides for dental implants. These studies should include a larger number of cases in both partially edentulous and fully edentulous patients, with both tapered and parallel implants and all types of bone.
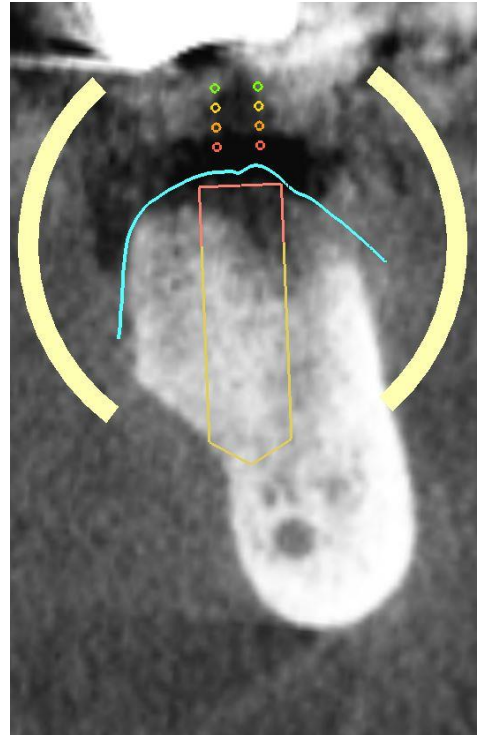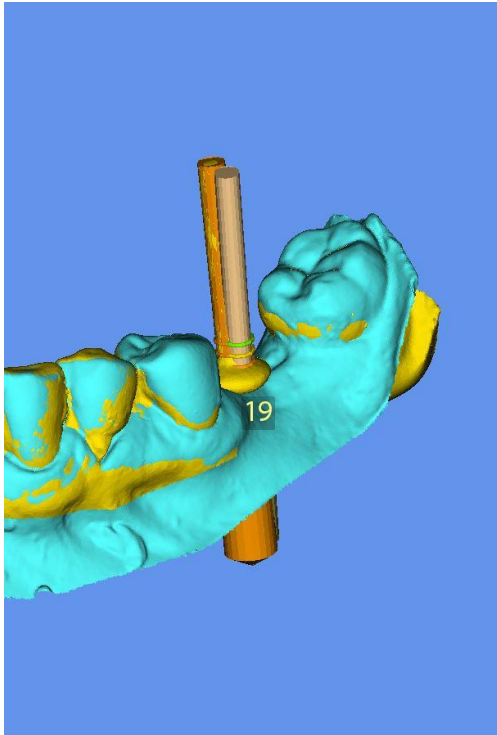
Figure 13. Measurements of deviations (432533) with greater deviation in angle and apex location.
Planned implant location in brown. Actual implant location in Yellow.
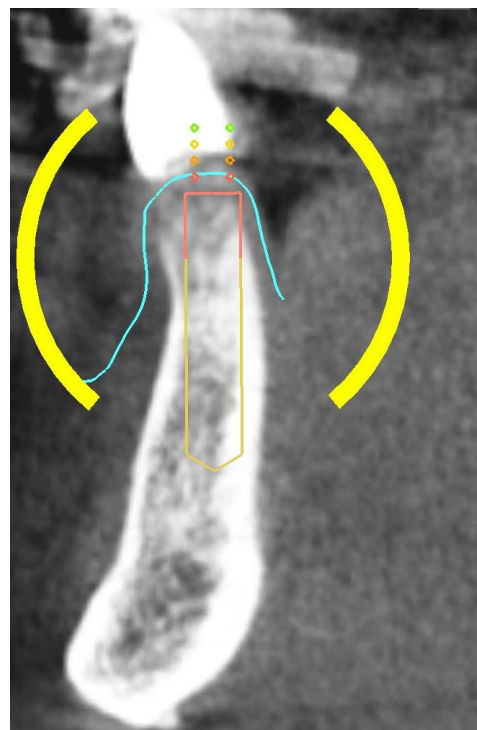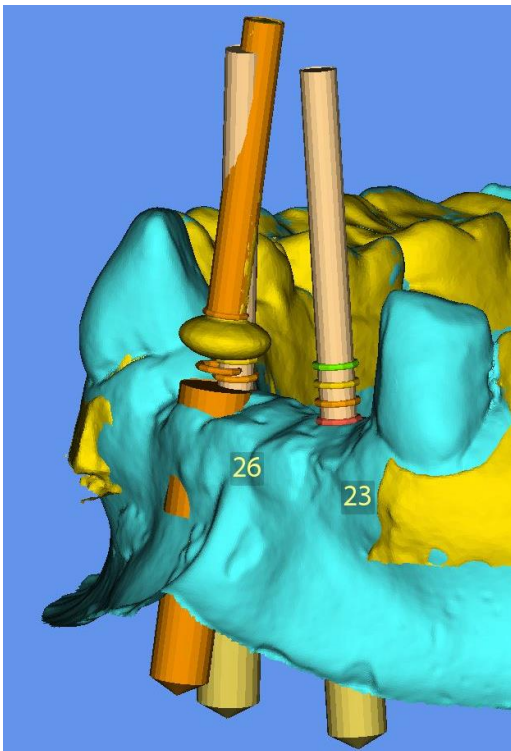
Figure 14. Measurements of deviations (41960) with greater deviation in angle and apex location.
Planned implant location in brown. Actual implant location in Yellow

CHAPTER FIVE

CONCLUSION

Within the limits of this study, it is concluded that there is no significant difference in height between the planned and actual implant. When the data is compared between maxilla and mandible there is a statistically significant difference in height. There is a statistically significant difference in deviation of implant location at the entry point, apex and degrees of angulation.

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