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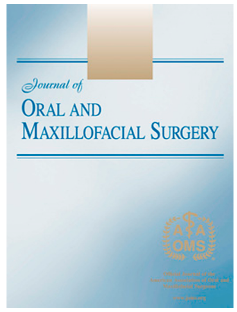

Implant Placement is more accurate using dynamic navigation

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Implant Placement is more accurate using dynamic navigation

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Abstract

The **purpose** of this prospective study is to measure and compare the accuracy and precision of dynamic navigation and free-hand implant fixture placement. Our **hypothesis** is that the evaluated dynamic navigation system has high accuracy and precision and is superior to free hand methods.

Methods: The investigators designed and implemented a prospective cohort study and enrolled a sample composed of patients who had implants placed between December 2014 through December 2016. The predictor variable is implant placement technique comparing Fully Guided (FG) and Partially Guided (PG) dynamic navigation to Freehand (FH) placement. The outcome variables are accuracy measured as deviation from the virtual plan, and precision represented as the standard deviation of the measures. ANOVA was used to compare measures.

Virtual implant placement was compared to post implant placement using mesh analysis. Deviations from the virtual plan were recorded for each implant for each surgeon. FH implant placement was evaluated by comparing a virtual plan with postoperative scans for patients who did not have the navigation system used for their implant placement. A one-way analysis of variance was performed to determine within group and between groups, to determine if there were significant differences between surgeons and methods (FG, PG, and FH) of placement.

Results: Prospective data from 478 patients involving 714 implants were evaluated. There were no demographic differences between surgeons. The sample size differed due to the number of implants placed by each surgeon. Within each method group the only difference between surgeons was for angular deviation. When all surgeons' data were combined, for FG navigation, the mean angular deviation was 2.97 +/- 2.09 degrees. The mean global platform position deviation was 1.16 +/- 0.59 mm. The mean global apical position deviation was 1.29 +/- 0.65 mm. For PG navigation the mean angular deviation was 3.43 +/- 2.33 degrees. The mean global platform position deviation was 1.31 +/- 0.68 mm. The mean global apical position deviation was 1.52 +/- 0.78 mm. For FH placement the mean angular deviation was 6.50 +/- 4.21 degrees, the mean global platform position deviation was 1.78 +/- 0.77 mm, and the mean global apical position deviation was 2.27 +/- 1.02 mm.

Differences in measures comparing FG and PG navigation to freehand indicated a significant**ly less deviation from the virtual plan** ($p < .05$) ~~improvement~~ using navigation.

Conclusions: Accuracy and precision for implant placement was achieved using dynamic navigation. The use of this type of method results in smaller deviations from the planned placement compared to FH approaches.

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Introduction

Clinical problem

When an implant is placed in the ideal position, the restoration process will have less need for complicated prosthetics. Deviations in implant position include but are not limited to angulation, platform position, apical implant position, and depth. Deviations from an ideal placement may result in the additional cost and time using custom fabricated parts and variations in restorative methods. The use of the Freehand (FH) approach where the clinician placing the implants uses adjacent teeth or laboratory fabricated stents to guide implant placement can result in accurate implant placement (1-4). However, the FH approach is less accurate when compared to implant placement using navigation (1-3). FH data has been reported using model surgery (5) and in clinical trials (6-8) however the clinical data lack a large sample size.

The accuracy and precision of implant placement should be the same for every patient and for every clinician. The use of navigation has been shown to result in accurate implant placement (9-35). For the clinician to use navigation on every patient receiving an implant, the navigated surgery method must provide the surgeon compelling reasons to adopt the technology and appreciate improvements in accuracy, precision, efficiency including time and cost, and ergonomics. Additional benefits may include improved methods for teaching novice surgeons.

Navigation methods for implant placement utilize either a static or dynamic system (2, 3). The static systems utilize a tooth-borne, mucosa-borne, or bone-borne guide with metal tubes, which allows use of a coordinated surgical kit to place the implant into the planned positon. The plan cannot be easily changed. During implant placement no changes can be made to implant angulation, size, depth, or implant selection. The implant choice cannot be easily changed. The cost of the guides varies according to manufacturers and requires time to fabricate the static guide. The software used to create a static guide may be difficult to learn with the need for a third party to help design the case on the computer. The physical dimensions of the static guide may prevent its use in the second molar regions or in patients with restricted opening. Because of these limitations static guides are not used for every implant case, only those with strict requirements.

If implant placement accuracy is superior when using navigation then it is desirable to use navigation on every patient. Dynamic navigation systems have been developed to allow for efficient use of in-mouth fiducial registration during a cone beam scan, software for virtual implant planning, and a user-friendly setup to allow for efficient time management when placing the implants using dynamic navigation. This type of workflow can result in navigation use for every patient who will receive a dental implant. If necessary, changes in the plan can be made at the time of surgery, including implant size, length, width, shape, and changes in positioning as required clinically to achieve accurate implant position. Dynamic navigation is a real-time coordination of the surgeon's hands and eyes by 3-dimensional visualization of the preparation with high magnification.

Accuracy and precision must be established with all navigation systems. This paper reports on the accuracy and precision of implant placement for multiple surgeons, for 714 implants placed in over 478 patients.

Hypothesis to be tested: The evaluated dynamic navigation system has high accuracy and precision and is superior to FH implant placement methods.

Methods

This protocol was approved and administered under IRB Protocol number 2014-10-15 BioMed IRB, San Diego California.

Trial Design: The study is a prospective evaluation of the accuracy and precision for placing implants. Four surgeons contributed patient data in this study. The surgeons agreed to follow the manufacturer's protocol with IRB consent by each patient.

Participants: Patients were consecutively included in this study within each surgeon's private practice. Patients were excluded from the study if they refused to sign a consent form. There was a difference in the number of included patients for each surgeon, reflecting the number of implants placed by each surgeon within their private practice. The total number of patients was grouped together for analysis. The demographic data comparing each surgeon was compared to insure similar group demographics for the combined analyses (Table 1).

Each surgeon received one full day of training which included simulation. At the conclusion of the training they must have achieved proficiency as measured by angular deviation using the navigation screen's live feedback on bur angulation compared to the virtual plan. The second day of training included over the shoulder training to further reduce of their learning curve.

Patient recruitment: All patients who required at least one implant and had sufficient teeth for clip registration were consecutively enrolled in this IRB-approved protocol. Patients had to be over 21 years old and able to understand and sign a consent form. Inclusion criteria included the presence of at least three adjacent teeth in the arch to hold the clip which contained the fiducials necessary to register the jaw to the navigation computer system. Exclusion criteria included those who refused to sign a consent form for prospective data evaluation, those who could not accept the normal risks associated with dental implants, or if the patient's remaining teeth were unable to support the patient tracking array. This could be the result from provisional restorations, tooth shape with minimal retention form to stabilize the clip, or unstable teeth secondary to bone loss.

Scanning protocol for dentate patients

To register the jaw into the navigation computer, a clip with three metallic fiducial markers was adapted onto the patient's teeth after heating in a water bath. The clip was placed in the same jaw as the planned implant, on the opposite side of the arch, avoiding the surgical site. The cone beam scan was taken and the digital information transferred to the navigation system's computer. Using the supplied software, nerve mapping was performed for mandibular posterior implants and virtual teeth placed. If available, intraoral or laboratory laser scans as .stl files were superimposed on the patient's jaw image using the planning software to guide implant placement. Virtual implants were placed and oriented in a position that allowed for the planned restorative care. The planned implant's platform diameter, apical diameter, length, and shape were entered in a generic fashion into the software so the planned implant's geometry was identical to the implant to be placed in the patient. This system does not contain an implant library. Because of this the implant's dimensions are used to plan the case.

Surgery Procedures

The handpiece and patient tracking array were calibrated prior to each surgery. After staff calibrated the handpiece and tracking array, the surgeon performed the surgery. Each drill length was calibrated as it was used by the surgeon, in the normal sequence of implant site preparation. System checks were performed to insure accuracy of tracking, and the implant was guided into final position using the navigation screen.

The surgeon used the navigation screen to guide position and angulation of the implant preparation (Figure 1). This is a real-time coordination of the surgeon's hands and eyes by 3-dimensional visualization of the preparation and important adjacent anatomy. If necessary, changes in the plan were made at the time of surgery, including implant size, length, width, shape, and changes in positioning as required clinically to achieve accurate implant position.

A post-implant placement cone beam computerized tomography (CBCT) scan was taken. The plan and post op CBCT scan were uploaded for analysis by an individual not involved in patient treatment. Data were then entered on a spreadsheet with no patient identifiers except for case number.

Fully guided (FG) is used to describe use of the navigation system to place the implant at its final depth. Partially Guided (PG) is used when the preparation site is performed using the navigation system however the final seating of at least 50% of the implant's length is by hand. This is done when the torque generated by the implant exceeded the torque available from the implant drill system, or when the surgeon felt the need to directly visualize the implant's depth during seating.

Freehand placement occurred for several reasons. During the initial phase of this prospective study, the use of the navigation system was not used in order to complete an early data analysis to confirm that the accuracy of the system was appropriate for continued use of the system. During this short time period patients had a virtual plan in place, but the implants were placed freehand. The early data was found to be accurate so the study was continued using the navigation system. Another reason for freehand placement was when the patient tracking array was not stable due to lack of tooth contour definition. Another reason was the placement of provisional restorations or changes in restorations that were previously in place when the patient tracking array was used for scanning. At the time of surgery the clips did not fit because of the new restorations.

FH data included those implants that were not delivered with the guidance system or when the guidance system was not use to prepare the osteotomy.

Mesh Analysis Accuracy:

Mesh analysis has been used to measure various objects (36-41). For this study, a variant of the analysis was used (42).

The mesh registration accuracy was assessed prior to its use in this study, and was used in the FDA submission for the dynamic navigation system used in this study. Twenty sawbones models each had three ball bearings (BBs) inserted into sawbone jaw models. The sawbones were then cone beam scanned with a patient tracking array in place on the sawbones model. An implant was placed according to a virtual plan using the sawbones models. A second post-implant insertion cone beam was taken.

The accuracy test was then performed with registration of an isosurface mesh extracted from the initial cone beam scan and registered to the secondary CT scan, finding a “best fit” transform that related the vertices of the mesh in the primary scan to those in the secondary scan with minimal cumulative displacement between the vertices. The computed mesh to mesh transform provided a mapping from one cone beam coordinate system to the other since the mesh vertices are defined within the cone beam coordinates.

To verify the transform was accurate, a second set of isosurfaces was extracted from the initial and secondary CT. These isosurfaces displayed only the metal inserted into the Sawbones. An automated analysis method was used to determine deviations in measures. The errors were determined. The mean BB displacement was 169 um. The mean angular error was 0.375 degrees. Based in this error analysis this method was chosen to assess accuracy.

Accuracy Analysis Process

The pre- and post-operative CBCT scans and the virtual plan file from the navigation system were uploaded to a computer for analysis. These three files were meshed in MeshLab. A virtual implant with the same dimensions as the plan was placed on the post-operative CBCT, where the actual implant was delivered during surgery. This was accomplished because the implant was radiopaque. The virtual plan was superimposed onto the post-operative CBCT. A mathematical algorithm was utilized on the pre-surgical case with the plan, the post-surgical case with the virtual implant overlaid on the actual implant, and the meshed CBCT scans to calculate angular and positional deviations between the planned and actual implant positions in three dimensions.

The following deviations (mean +/- standard deviation) from the virtual plan were calculated (1) and are depicted in Table 2:

- Angular deviation (degrees): largest angle in 3D space between the center axes of the planned and placed implants.
- Global Platform deviation (mm): overall deviation of the planned and placed implant (takes angle, depth, and position into consideration).
- Global Apical deviation (mm): overall deviation of the planned and placed implant (takes angle, depth, and position into consideration).
- Depth deviation (mm): difference in depth (z-axis) of the implant between the planned and placed implants. Absolute values were used.
- Lateral Platform deviation (mm): differences in lateral entry position of the implant between the planned and the placed implants.
- Lateral Apical deviation (mm): difference in the lateral apical position of the implant between the planned and the placed implants.

Statistical methods: A one-way analysis of variance with post-hoc Tukey HSD tests was performed to determine whether there was a statistically significant difference between methods (FG, PG, and FH) of placement. The ANOVA was performed on the entire data set to determine if the surgery method had significant effect on the accuracy measure. A Chi-square test of independence was used to determine differences in the patient population between surgeons.

Results

Patient Sample: Table 1 shows the demographic summary for the guided methods. A Chi-square test of Independence was performed to examine the demographics of patients between surgeons. There were no significant differences between surgeons (χ^2 (3) = 4.41437, p = 0.2464).

Between-Surgeons Analysis: A one-way ANOVA was conducted to compare surgeons within each method. Within FH cases, the surgeons did not show statistically significant ($p > 0.05$) differences across all accuracy measures. Within PG cases, the surgeons showed statistically significant ($p < 0.05$) differences for all accuracy measures. Within FG cases, the surgeons showed statistically significant ($p < 0.05$) differences for all measures except Apical Depth Deviation and Platform Depth Deviation.

Within-Surgeon Analysis: A one-way ANOVA was conducted to compare differences in accuracy measures across methods for each surgeon. Surgeons 1 and 3 each showed statistically significant differences across the three methods in all accuracy measures. Surgeon 2 showed statistically significant differences across the three methods in all accuracy measures except Platform Depth Deviation and Apical Depth Deviation. Surgeon 4 showed a statistically significant difference across three methods for only one accuracy measure, Angular Deviation. Table 2 shows the average deviations from virtual plan for each surgeon. For most of the accuracy measures, each surgeon had better average accuracy and precision using guided methods than in freehand.

The Analysis of Variance (ANOVA) results are listed in Table 3. When all three methods were evaluated together, differences in surgery methods were statistically significant ($p < 0.05$) for all measures. When comparing FG navigation to FH methods, all measures were significantly different ($p < 0.05$). When comparing PG navigation to FH method, all measures were significantly different ($p < 0.05$). When comparing the FG navigation to PG navigation, there were significant differences for six of seven measures. The differences between Angular

Deviation and Platform Lateral deviation were not significant. The remaining six measures were significantly different.

One-way ANOVA applied to the data set shows statistically significant ($p < 0.05$) differences between the three guidance methods on all accuracy measures. All combinations of comparisons between the guidance methods are outlined in Table 3.

Table 4 shows the 95% confidence intervals broken down by surgeon and guidance method for Angular Deviation. The confidence interval shifts between guidance methods for each surgeon across all accuracy measures.

Table 5 shows the 95% confidence intervals broken down by guidance method and accuracy measure. For each accuracy measure, the confidence interval shifts between the guidance methods. For each accuracy measure, the means and standard deviations are smaller for guided (FG and PG) methods compared to FH.

Figure 2 graphically shows that the FG and PG methods were both more accurate compared to FH methods. Figure 3 shows the mesh analysis.

Discussion

Accuracy of implant placement is essential to allow for efficient and routine care of our patients. If an implant is not accurately placed, it may still be restorable, but requires additional prosthetic manipulation through the use of custom abutments, angled screws, deeper cement margins, increased chair time, and additional costs for the dentist and patient.

Advances in dynamic navigated surgery have allowed us to understand the various levels of guidance: FG, PG, and FH. Often these levels of guidance are driven by the clinical situation at the time of surgery, including limited mouth opening or clip stability. Our findings are similar to other large trials, confirming that navigated guidance increases the accuracy and precision for implant placement (2).

As shown in Table 2, FG implant placement had the least deviation from the virtual plan compared to the other two methods. In a situation where the implant site was prepared but the implant was placed with more than half its length placed without navigation guidance (PG), accuracy decreased. This is most likely the result of the implant following the course of least resistance within the bone, due to the presence of dense bone. FH placement was less accurate compared to guided methods.

When a laboratory fabricated or static guide is used to place the implants, the presence of the guide may limit visualization of the implant's crestal depth location. Using the dynamic navigation system the surgeons can always see the implant's location either on the screen or in the mouth, without prosthetic interference. It is easier to fully guide the fixtures without such interference.

Precision is the tightness of the pattern of placement. For implants, each placement should have the same precision with minimal deviation between patients. Routine precise implant placement should be our goal for all implant placements, not a standard of only a few. Clinicians should be aware of advances that allow for both accuracy and precision, within an efficient workflow in the practice setting. If there are methods that definitively improve the accuracy and precision of implant placement, all of our patients should benefit from this method. Navigation does improve the accuracy and precision of implant placement and should be widely used. This method should have a practical workflow and a reasonable learning curve to allow for proficiency to be achieved by the clinician performing the surgery. There is a learning curve with dynamic navigation (1). With static guides the learning curve was decreased when the inexperienced surgeon learned from observing an experienced surgeon (43). Cardiothoracic surgeons have been shown to have learning curves specific to their procedure (44). The learning curve for colonoscopy has been shortened by using simulation in their training (45). The investigating surgeons feel their efficiency and ergonomics were improved using the device once proficiency was reached.

The evaluated dynamic guided system is at least as accurate as static guides and is an improvement over FH implant placement. Even with the aid of a laboratory fabricated guide which is not true guidance, the error with the FH approach is greater (1-4). It is difficult to find data on the accuracy of implants placed with the diverse type of laboratory fabricated guides used by clinicians, which range from vacuum forms to solid guides. Most of these laboratory fabricated guides are not designed with the underlying bone visualized.

Even though experienced surgeons can place implants FH within a sphere of accuracy, in this report involving 4 experienced surgeons, the angular deviation was the variable most controlled by navigation. The difference was significant. The data in Tables 4 and 5 show the binary limits of the ranges between the 4 surgeons for each method. It is obvious that the guided methods were more accurate with greater precision as per confidence intervals compared to FH placement.

Global positions are 3-dimensional measures affected by depth. Final depth positions are difficult to visualize prior to surgery. Thin labial bone and soft tissue margins may be impossible to visualize on CBCT. The inability to visualize depth during planning may result in less precision. The final decision regarding depth is often made during surgery. The tested dynamic navigation system has a software tool that allows the surgeon to easily adjust the plan depth during surgery. Thus depth may be the least effected variable when any form of guidance is used. In this study depth was the most accurate measure and the least precise. The ability to change final depth position at the time of surgery is an important benefit of dynamic navigated surgery that is easy to overlook.

As seen in Table 2, the insertion point as reflected in the lateral platform deviation was similar comparing navigation and FH as categorized in this trial. Depth placement was also similar reflecting expected visual aspects of placing the implant at the level of the crestal bone or a specific amount subcrestal depending on clinician preference. These values were clinically close however the differences in precision of the measure did result in significant differences.

The hypothesis that dynamic navigation is an improvement in accuracy and precision compared to freehand methods was tested and confirmed.

Using dynamic navigation does have additional benefits for the patient. There is a paralleling tool to aid the clinician in virtual implant placement. Incisions can be limited and flap reflection decreased since there is less need for broad bone exposure. A unique advantage using dynamic navigation is the ability to modify the surgical plan in real time. **In this study the final positon and implant size that was actually placed was used in the mesh analysis.**

Because there is less surgical instrumentation length, this dynamic system can be used in second molar regions and in patients who have restricted opening. **With navigation we expect fewer complications involving the inferior alveolar nerve or implant impingement on adjacent tooth roots.** There is no specific drill system or surgical instruments needed for dynamic navigation systems, in contrast to static navigation with their cylinders within the guides. Because the surgeon visualizes the surgery on a monitor, the surgeon will be able to maintain excellent posture, decreasing clinician morbidity.

A clinician placing implants must be concerned with perfecting implant position. This paper clearly indicates that navigation methods provide a statistically significant improvement over FH methods. Clinicians placing implants must consider improving their precision and accuracy as a routine method, not just for a "special" case. Implants that are not parallel complicate restorative care. When adjacent implants are not properly spaced, the subsequent problems with maintenance and esthetics can affect long term results. Axial alignment of the implants to optimize occlusal force distribution should result in less screw breakage and other prosthetic complications.

Dynamic navigation will improve accuracy and precision of implant placement. Angulation deviation was the most significant measure improved by using dynamic navigation.

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Table 1: Demographic variables of patients treated by each surgeon.

Surgeon	Total Number patients	Total males (%)	Average age (range)	Total Number of Implants
1	263	135 (51.3 %)	59 (21-87)	407
2	128	58 (45.3 %)	61 (21-89)	188
3	37	18 (48.6 %)	52 (21-73)	45
4	50	31 (62.0 %)	58 (22-77)	74
Total	478	242 (50.6%)	59 (21-89)	714

Table 2: Summary of Fully Guided, Partially Guided, and Freehand Method Surgical Measures (means and standard deviations)

Surgeon	Angular deviation (degree)	Global Platform (mm)	Platform depth deviation (mm)	Platform lateral deviation (mm)	Global Apical (mm)	Apical depth deviation (mm)	Apical lateral deviation (mm)	Number of Implants
Fully Guided								
1	2.43 (1.36)	1.00 (0.49)	0.74 (0.55)	0.57 (0.30)	1.13 (0.53)	0.73 (0.54)	0.76 (0.37)	85
2	3.14 (2.54)	1.31 (0.56)	0.81 (0.58)	0.94 (0.42)	1.38 (0.63)	0.82 (0.59)	0.98 (0.57)	77
3	2.46 (1.05)	1.07 (0.61)	0.93 (0.71)	0.43 (0.17)	1.16 (0.64)	0.91 (0.71)	0.61 (0.31)	10
4	3.76 (2.23)	1.22 (0.70)	0.76 (0.68)	0.82 (0.52)	1.45 (0.81)	0.77 (0.70)	1.08 (0.73)	47
Total	2.97 (2.09)	1.16 (0.59)	0.76 (0.60)	0.74 (0.43)	1.29 (0.65)	0.78 (0.60)	0.90 (0.55)	219
Partially Guided								
1	2.86 (1.78)	1.20 (0.64)	0.85 (0.70)	0.70 (0.40)	1.39 (0.69)	0.86 (0.71)	0.95 (0.53)	255
2	4.86 (2.88)	1.55 (0.73)	0.89 (0.84)	1.08 (0.52)	1.77 (0.92)	0.88 (0.82)	1.34 (0.85)	78
3	4.81 (2.78)	1.70 (0.68)	1.38 (0.74)	0.87 (0.40)	2.01 (0.75)	1.48 (0.71)	1.31 (0.65)	24
4	3.41 (2.43)	1.27 (0.58)	0.82 (0.51)	0.88 (0.55)	1.51 (0.76)	0.84 (0.52)	1.20 (0.71)	16
Total	3.43 (2.33)	1.31 (0.68)	0.89 (0.73)	0.80 (0.49)	1.52 (0.78)	0.90 (0.74)	1.01 (0.65)	373
Freehand								
1	6.10 (4.14)	1.86 (0.76)	1.25 (0.73)	1.24 (0.70)	2.34 (1.04)	1.17 (0.75)	1.90 (0.95)	67
2	7.74 (4.71)	1.86 (0.84)	1.12 (0.99)	1.21 (0.69)	2.44 (1.04)	1.17 (0.99)	1.97 (1.17)	33
3	5.79 (3.45)	1.63 (0.41)	0.72 (0.73)	1.26 (0.47)	1.90 (0.80)	0.72 (0.67)	1.65 (0.76)	11
4	5.96 (4.21)	1.24 (0.71	0.77 (0.79)	0.78 (0.52)	1.68 (0.57)	0.84 (0.75)	1.30 (0.52)	11
Total	6.50 (4.21)	1.78 (0.77)	1.12 (0.83)	1.19 (0.68)	2.27 (1.02)	1.10 (0.82)	1.84 (1.05)	122

Table 3: Significance levels comparing Guidance Methods

	Angular Deviation	Global Platform Deviation	Platform Depth Deviation	Platform Lateral Deviation	Global Apical Deviation	Apical Depth Deviation	Apical Lateral Deviation
FH vs PG vs FG	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$
FG vs FH	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$
PG vs FH	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$	$p < .05$
FG vs PG	$p < .05$	$p < .05$	$p < .05$	ns	$p < .05$	$p < .05$	$p < .05$

FH = Freehand, PG = Partially Guided, FG = Fully Guided
ns = not-significant $p > .05$

Table 4: 95% Confidence Intervals For Surgeon To Method for Variable Angular Deviation

Surgeon	Method	Estimated Marginal Mean	Std error	95% Confidence Interval	
				Lower Bound	Upper Bound
1	FH	6.102	.317	6.851	8.624
	FG	2.431	.281	1.878	2.983
	PG	2.861	.162	2.542	3.180
2	FH	7.738	.452	6.851	8.624
	FG	3.145	.296	2.564	3.725
	PG	4.864	.294	4.287	5.441
3	FH	5.790	.782	4.254	7.326
	FG	2.456	.820	0.846	4.066
	PG	4.810	.529	3.770	5.849
4	FH	5.960	.782	4.424	7.326
	FG	3.762	.378	3.019	4.505
	PG	3.407	.648	2.134	4.681

FH = Freehand, FG = Fully Guided, PG = Partially Guided

Table 5: 95% Confidence Intervals of Accuracy Measures across Methods

Accuracy Measure	Method	Mean	Std. Error	95% Confidence Interval	
				Lower Bound	Upper Bound
Angular Deviation (deg)	Freehand	6.398	.309	5.791	7.004
	Fully guided	2.948	.248	2.462	3.435
	Partially guided	3.986	.225	3.543	4.428
Global Platform (mm)	Freehand	1.647	.078	1.493	1.801
	Fully guided	1.150	.063	1.027	1.273
	Partially guided	1.431	.057	1.318	1.543
Platform lateral deviation (mm)	Freehand	1.122	.057	1.011	1.234
	Fully guided	.686	.046	.597	.776
	Partially guided	.883	.042	.802	.965
Apical lateral deviation (mm)	Freehand	1.704	.083	1.541	1.866
	Fully guided	.859	.066	.729	.989
	Partially guided	1.201	.060	1.082	1.320
Global Apical (mm)	Freehand	2.093	.092	1.912	2.273
	Fully guided	1.280	.074	1.135	1.425
	Partially guided	1.684	.067	1.553	1.816
Apical depth deviation (mm)	Freehand	.974	.084	.808	1.139
	Fully guided	.810	.068	.677	.943
	Partially guided	1.015	.062	.894	1.136
Platform depth deviation (mm)	Freehand	.965	.084	.799	1.130
	Fully guided	.809	.067	.677	.942

Partially guided	.986	.061	.865	1.106

Figure Legends

Figure 1: The dynamic system in use. Note the light source above the patient reaching the patient tracking array and the array on the handpiece. The light is reflected from the arrays to two high definition cameras (arrows). The captured reflected light is transmitted to the system specific navigation computer to create the dynamic real time representation.

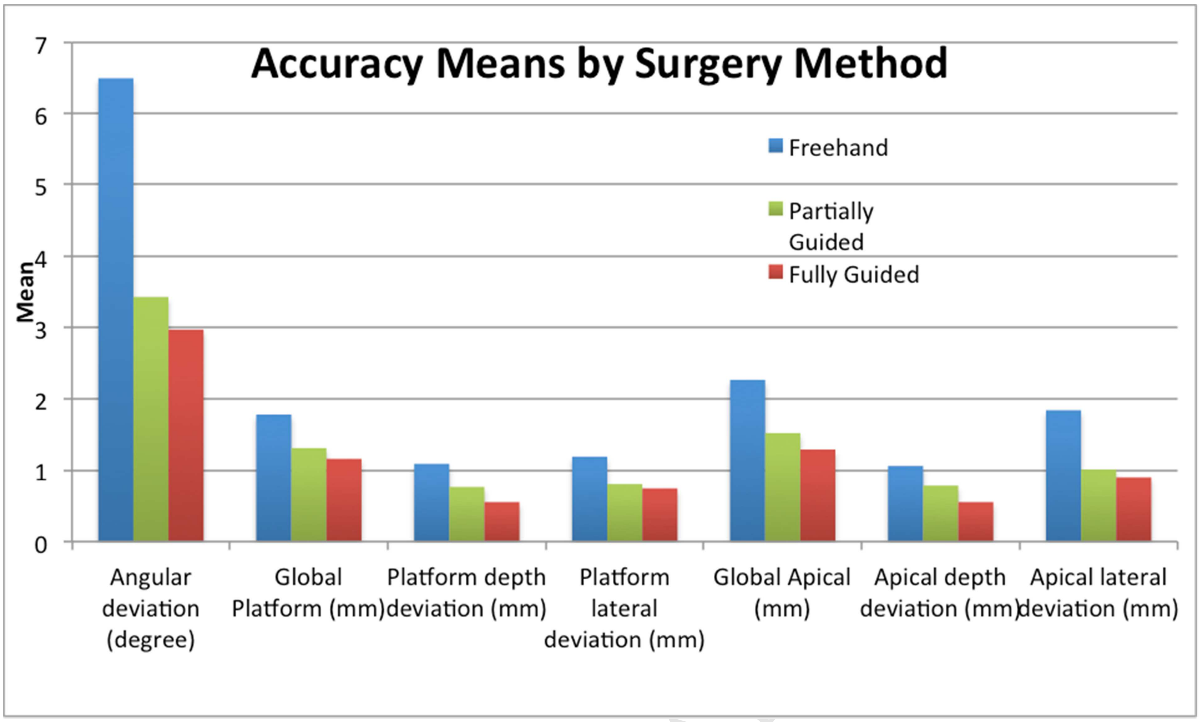
Figure 2: Accuracy Means by Surgery Method

Figure 3: An example of a mesh used to determine accuracy. The blue is the virtual plan and the implant image is the position of the implant taken from the immediate post placement cone beam scan.

Disclosure:

Dr. Block and Dr. Cullum own stock in X-Nav Technologies LLC. Dr. Emery is Chief Medical Officer of X-Nav Technologies LLC and has an equity interest in the company. Mr. Ali Sheikh is employed by X-Nav Technologies, LLC.


GUIDE
Depth: 9.0mm
Angle: 3.1°
13


Accuracy Means by Surgery Method
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3
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5
6
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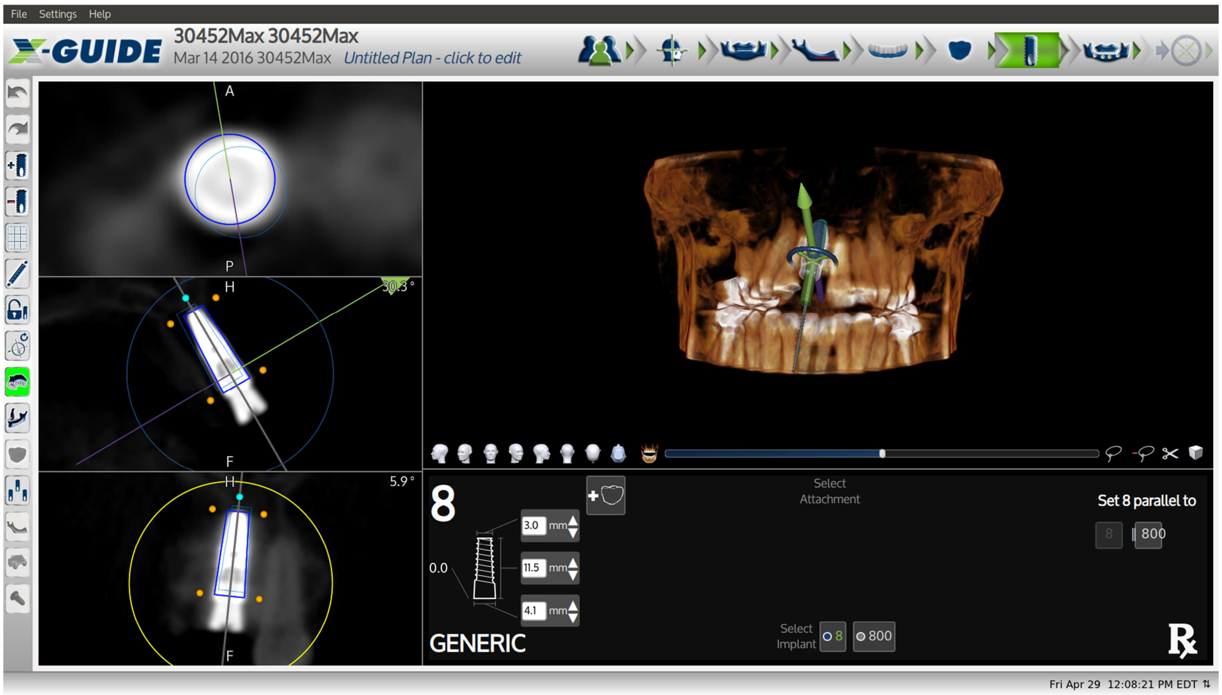
Freehand
Partially Guided
Fully Guided
Angular deviation (degree)
Global Platform (mm)
Platform depth deviation (mm)
Platform lateral deviation (mm)
Global Apical (mm)
Apical depth deviation (mm)
Apical lateral deviation (mm)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