

Accuracy of Dynamic Navigation for Dental Implant Placement—Model-Based Evaluation

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The purpose of this model-based study was to determine the accuracy of placing dental implants using a new dynamic navigation system. This investigation focuses on measurements of overall accuracy for implant placement relative to the virtual plan in both dentate and edentulous models, and provides a comparison with a meta-analysis of values reported in the literature for comparable static guidance, dynamic guidance, and freehand placement studies. This study involves 1 surgeon experienced with dynamic navigation placing implants in models under clinical simulation using a dynamic navigation system (X-Guide, X-Nav Technologies, LLC, Lansdale, Pa) based on optical triangulation tracking. Virtual implants were placed into planned sites using the navigation system computer. Post-implant placement cone-beam scans were taken. These scans were mesh overlaid with the virtual plan and used to determine deviations from the virtual plan. The primary outcome variables were platform and angular deviations comparing the actual placement to the virtual plan. The angular accuracy of implants delivered using the tested device was $0.89^\circ \pm 0.35^\circ$ for dentate case types and $1.26^\circ \pm 0.66^\circ$ for edentulous case types, measured relative to the preoperative implant plan. Three-dimensional positional accuracy was 0.38 ± 0.21 mm for dentate and 0.56 ± 0.17 mm for edentulous, measured from the implant apex.

Key Words: *dynamic image navigation, dental implants, model study, computer-assisted surgery*

INTRODUCTION

Dental implants are commonly used to replace lost teeth and have benefits over alternative restoration options such as bridges and dentures. Implants restore form and function without damaging adjacent teeth, stabilize alveolar bone, and have predictable long-term outcomes. However, implant placement comes with several challenges, as they must often be planned and placed in narrow bone with slim margins for avoiding cortical perforations or impinging on other critical anatomical structures such as the inferior alveolar nerve.¹ They must also be positioned and angled accurately to support restorations that esthetically and functionally align with adjacent and occluding dentition.² These challenges are being met by the recent development and utilization of visualization tools that assist in improving the accuracy of implant planning as well as surgical guides that assist in accurate placement of implants.³

The use of cone-beam computed tomography (CBCT) imaging for dental implant planning has increased significantly in recent years. CBCTs significantly decrease the exposure to radiation compared with conventional computed tomography.⁴ With voxel sizes down to tenths of a millimeter and the ability to visualize and measure anatomic structures in 3 dimensions,

CBCT and new planning software allow 3-dimensional (3D) planning of implants to a level of accuracy and a margin of safety that were not previously achievable.⁵ With the improved ability to accurately plan implant locations, CBCT imaging has also been an enabling technology in the development of computer-assisted surgical (CAS) implant placement systems.

CAS systems can be categorized as either static or dynamic.⁶ Static CAS systems use guides fabricated with computer-aided design/computer-aided manufacturing (CAD/CAM) based on 3D scans of the patient.^{6,7} In contrast, dynamic CAS systems track the patient and surgical instruments and present real-time positional and guidance feedback on a computer display.⁸ The vast majority of dental implants are placed using a freehand approach or laboratory-fabricated stents.⁷ While the literature demonstrates that CAS systems provide improved accuracy, the complex workflow of available systems and their cost have prevented broader adoption.⁶⁻⁸

Recent development of new software and hardware has given the dental surgeon a larger selection of CAS devices. An understanding of the indications and limitations of both types of CAS systems is important.^{9,10} While both static and dynamic image navigation are highly accurate, dynamic navigation systems have the following advantages:

1. The patient can be scanned, planned, and undergo surgery on the same day.
2. The plans can be altered during surgery when clinical situations dictate a change.
3. The entire field can be visualized at all times.
4. Accuracy can be verified at all times.

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To evaluate any new surgical navigation system, its accuracy must be evaluated.¹¹ Model-based studies allow the evaluation of the navigation system with consistent variables in surgical simulation.

Few model-based studies have been done to evaluate the accuracy of dynamic CAS systems for dental implant placement.^{8,12} These prior studies evaluated systems that used optical triangulation to track components using up to a dozen tracking points. This study evaluates the accuracy of a new optical triangulation dynamic navigation system designed for implant placement, which uses tracking components that have hundreds of distinct tracking points. None of the prior studies evaluates the accuracy of CAS systems on edentulous anatomy, which typically requires a different approach to securing a patient referencing device. To the authors' knowledge, this study is the first to evaluate the accuracy of edentulous implant placement using a dynamic guidance system.

The primary outcome variables of this study are platform and apical position deviations and angular deviations of a placed implant compared with the implant plan. These outcome variables are typical of those reported in prior studies, which facilitates direct accuracy comparison between this study and prior work.

METHODS

This study evaluates the accuracy of implant placement in dental models under guidance from the X-Guide Surgical Navigation System (X-Nav Technologies, LLC, Lansdale, Pa). X-Guide is a dynamic CAS system operating on the principles of stereo triangulation from optical cameras. X-Guide dynamically tracks the motion of 2 dynamic reference frames (DRFs) during surgery, 1 rigidly attached to the patient's surgical anatomy and 1 rigidly attached to the surgeon's surgical hand piece. X-Guide uses the tracking data to compute real-time guidance information, which is displayed in real time to assist surgeons in guiding their drill to an implant location they previously planned based on an imported CBCT scan.

Study design

The overall design of the study consisted of a single doctor planning each implant on a CBCT scan of a jaw model and performing a mock surgery and implant delivery on the jaw model under guidance.

Accuracy is evaluated by comparing the location and axis of the placed implant to the implant plan in a process of (1) locating the implant in a postoperative CBCT scan, (2) registering the preoperative scan to the postoperative scan, and (3) computing accuracy metrics between the planned location and the placed implant.

Participant biases were minimized by the following procedures: (1) The doctor was not involved in the accuracy evaluation process nor privy to the accuracy data until completion of the study; (2) the operator performing CBCT scan alignment and determining the location of the implant in the postoperative CBCT scan was blinded to the preoperative plan data; and (3) the final step of computing accuracy metrics was automated. No results were ever retabulated, nor were any data discarded.



FIGURE 1. X-Clip holding the patient-tracking array on Sawbones model.

Models

Four types (dentate and edentulous maxilla, dentate and edentulous mandible) of custom polyurethane Sawbones models (25–35 lb/ft³, 0.40–0.56 g/cm³; Sawbones, Vashon Island, Wash) were created from accurate 3D models of bony anatomy (and dentition in the case of dentate models) and were used to simulate the surgical anatomy for CBCT scanning, implant planning, affixing the patient DRF device, and for drilling osteotomies and delivering implants.

Scanning protocol for dentate models

Prior to acquisition of the CBCT, a small thermoplastic device with 3 radiopaque markers, fiducials (X-Clip, X-Nav Technologies, LLC) were placed on the teeth on the arch that was planned to receive the dental implants. After the clip was adapted to the teeth on the same arch as the planned implant placement, a CBCT scan (Imaging Sciences International, LLC, Hatfield, Pa) was taken at 0.3 voxel resolution. This device is designed to hold the DRF on the patient during surgery (Figure 1). The clip device was removed after CT and appropriately labeled and stored for later use during implant surgery.

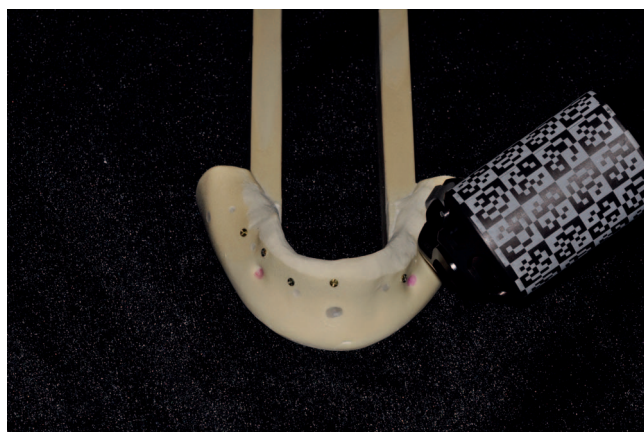


FIGURE 2. Edentulous fiducials on Sawbones model with patient-tracking array attached using the E-Clip.

Scanning protocol for edentulous models

Prior to acquisition of the CBCT, five 1.5- × 4-mm self-drilling, self-tapping screws (KLS Martin, Jacksonville, Fla), “edentulous fiducials,” were placed around the arch where the implants were to be located, in the region that would be exposed during surgery. In the clinical environment, they would be placed via a stab incision and left submucosal until the time of surgery (Figure 2).

After the edentulous fiducials were placed, a CBCT scan was taken at 0.3 voxel resolution.

Implant planning

The DICOM data set from the CBCT was uploaded to the dynamic navigation system and entered into its planning system. The planning software was used to define the arch, nerve mapping, and implant dimensional manipulation. Multiple views were used to ideally orient the virtual implants. Virtual 4.0-mm × 13-mm parallel wall dental implants were planned in the maxillary and mandibular models in both dentate and edentulous cases. The position and angle were determined based on the specific tooth sites. Files from intraoral scanners or laboratory-based scanners can be superimposed on the DICOM images for fine detail while treatment planning; however, planning in this study was based solely on the CBCT data sets.

Locating edentulous fiducials: Edentulous cases

Prior to simulated surgery, the edentulous fiducials are located in the planning software. The surgeon marks each screw’s head and tip on the system software. The software then determines the 3D coordinates and axis of the edentulous fiducial. The edentulous fiducials will later be used to register the patient-tracking array and DRF using a special plate that is customized and fixated to the arch in which the implants will be placed (E-Clip, X-Nav Technologies LLC).

Simulated surgery procedures

Each model was mounted into a dental manikin frame, including opposing dentition, limited mouth opening, and a latex face to simulate limited visibility and pressure due to facial soft tissue.



FIGURE 3. Simulated surgical situation showing manikin, Sawbones model, and patient-tracking array with X-Guide above.

The manikin frame was fixed on a surgical chair in the operatory, and the operatory was then set in the standard fashion for patient treatment. Overhead ambient lighting and a surgical headlamp simulated the clinical environment and light (Figure 3). Standardized implants were placed in all cases (Zimmer/Biomet 3i, Palm Beach, Fla; 4.0- × 13-mm parallel wall, internally hexed).

Calibration of hand piece

Calibration of the surgical hand piece was performed prior to surgical simulation. The hand piece calibration determines the relationship between the geometry of the hand piece tracking array and the axis of the drill.

Calibration of dentate models

The DRF calibration relates the geometry of the patient-tracking array to the CT fiducials, hence providing a link between the preoperative planning coordinate system and a trackable coordinate system. The stereo tracking system simultaneously triangulated each tracking array to determine their precise position and orientation in a common coordinate frame. In combination with the aforementioned calibrations, this real-time link allowed the drill’s body and tip to be related

to the patient's preoperative CT coordinate system as it is dynamically manipulated by the surgeon.

The patient DRF included the clip with the connected patient-tracking cylinder. It was placed onto the teeth in the same location as for CBCT acquisition. The tracking software algorithm triangulated the 2 arrays continuously. Two live video windows allowed the surgical team to get virtual feedback from the navigation system to visualize site preparation and monitor the quality of tracking in the surgical field volume.

Calibration of edentulous models

In the edentulous clinical situation, surgery begins after hand piece calibration with the exposure of the edentulous fiducials via a subperiosteal incision. The patient-tracking array plate (E-Clip) is customized by the surgeon. The tracker arm is attached and the plate fixated, with bone screws, proximal to the planned area of the implants in a way that minimizes optical interference. In the mandible, a right-handed surgeon would place it on the left mandibular body. The patient-tracking array cylinder is then screwed onto the arm. The rigid patient-tracking array is ready for calibration to become the DRF. The software now prompts the surgeon to measure the drill length and touch each fiducial in sequential order while being tracked. The software then calibrates the DRF relating the geometry of the patient-tracking array to the CT edentulous fiducials, hence providing a link between the preoperative planning coordinate system and a trackable coordinate system. The system now functions in the same manner as in dentate cases. In the clinical situation, the plate holding the DRF and the edentulous fiducial screws would be removed after the implants are placed. If an edentulous fiducial interfered with implant placement, it could be removed any time after the calibration process.

The lengths of the drills were calibrated for each drill as they were used. The drills were used in their normal sequence. All implants were placed under full guidance with complete seating of the implant with guidance.

Following implant placement, a second, postoperative CBCT scan was taken at 0.3 voxels.

Accuracy analysis

Implant delivery accuracy was assessed by superimposing the preoperative virtual surgical plan and the postoperative CBCT scan and quantifying deviations of the delivered implant from the planned position and orientation. In this process, a trained engineer first identified the precise location of the delivered implant in the postoperative CBCT with the X-Guide implant-planning software. Next, the preoperative and postoperative CBCT scans were registered by aligning the Sawbones structure in each scan via a rigid transformation. To generate the registration, polygonal meshes representing the outer Sawbones surfaces were extracted from the pre- and postoperative CBCT scans via conventional iso-surface thresholding techniques. The meshes were then cleaned of any artifacts and aligned in the open-source MeshLab software suite. Using the rigid transform defined by the MeshLab registration, the virtual preoperative implant plan was projected onto the postoperative CBCT scan, where its position and orientation are compared with those of the delivered implant.

	Dentate		Edentulous	
	Mandible	Maxilla	Mandible	Maxilla
Number of models	10	11	4	2
Tooth number (count)	20	7	20 (2)	2
	22	9	21	3 (2)
	23 (2)	10	22 (2)	5
	26	11	24	6 (2)
	28 (2)	12	25 (2)	7
	29 (2)	13 (3)	27 (3)	10 (2)
	30 (2)	14		11 (2)
		15 (2)		14 (2)
				15

The following deviations from the virtual plan were calculated for the entry and apex of the delivered implant:

- Depth deviation (mm): difference in depth along the implant long axis
- Lateral deviation (mm): a 2-dimensional measure of the difference in mesial/distal (*y*-axis) and buccal/lingual (*x*-axis) placement of the implant (disregarding depth deviation)
- Global deviation (mm): overall 3D distance taking depth and lateral deviation into consideration
- Angular deviation (°): largest angle in 3D space between center axes

RESULTS

Results were categorized and tabulated by case type (ie, edentulous or dentate) and by surgical jaw (ie, mandible or maxilla). The surgical sites (tooth number) are listed for each category in Table 1. In total, there were 11 dentate maxilla models and 10 dentate mandible models, with 11 implants in each group. Using a single implant per model ensures independence between measurements. In the edentulous case, 4 mandibular models with a total of 11 implants were used to simulate the typical 2 to 5 implant arrangements, and 2 maxilla models with a total of 14 implants were used to simulate the need for more implants in the soft maxillary bone. Implant deviation measurements cannot be assumed to be completely uncorrelated when their source implants share a common model; however, for the purposes of computing means and standard deviations, each implant was treated with equal weight.

Table 2 shows the deviations of the planned implant location from the final implant position. Means, standard deviations, and maximal values were computed for each of the metrics described in the analysis section and reported for each category and overall. Implants with the dentate case type had deviations of $0.89^\circ \pm 0.35^\circ$ angular and 0.38 ± 0.21 mm global apex position, compared with $1.26^\circ \pm 0.66^\circ$ angular and 0.56 ± 0.17 mm global apex position for the edentulous case type.

DISCUSSION

Most dental implants are placed using a freehand approach with or without a conventional laboratory-fabricated guide. This may

TABLE 2

X-Guide deviations broken out by surgical jaw and attachment method*

	Entry Deviations			Apex Deviations			
	Angular Deviation	Global	Depth	Lateral	Global	Depth	Lateral
Dentate							
Mandible	1.00 ± 0.40 (1.52)	0.35 ± 0.16 (0.75)	0.23 ± 0.16 (0.54)	0.24 ± 0.12 (0.52)	0.31 ± 0.16 (0.68)	0.20 ± 0.15 (0.50)	0.20 ± 0.13 (0.47)
Maxilla	0.78 ± 0.24 (0.92)	0.38 ± 0.25 (0.92)	0.33 ± 0.25 (0.91)	0.18 ± 0.09 (0.39)	0.44 ± 0.23 (1.01)	0.34 ± 0.25 (0.96)	0.23 ± 0.12 (0.40)
Edentulous							
Mandible	1.25 ± 0.65 (2.47)	0.49 ± 0.16 (0.84)	0.26 ± 0.18 (0.55)	0.37 ± 0.17 (0.66)	0.48 ± 0.13 (0.79)	0.26 ± 0.18 (0.55)	0.38 ± 0.10 (0.57)
Maxilla	1.26 ± 0.67 (2.18)	0.58 ± 0.18 (0.84)	0.23 ± 0.19 (0.60)	0.50 ± 0.18 (0.83)	0.63 ± 0.17 (0.93)	0.21 ± 0.18 (0.56)	0.57 ± 0.18 (0.91)
Combined	1.09 ± 0.55 (2.47)	0.46 ± 0.20 (0.92)	0.26 ± 0.19 (0.91)	0.33 ± 0.19 (0.83)	0.48 ± 0.21 (1.01)	0.25 ± 0.19 (0.96)	0.36 ± 0.20 (0.91)

*Values are mean ± SD (max) deviations. Angular deviation is expressed in degrees and others in millimeters.

lead to poor implant position, damage to adjacent anatomic structures, difficulty with esthetics, peri-implantitis, and possible implant failure.¹³ As techniques for the restoration of dental implants have matured, the demands for esthetics and hygiene have increased. Ideal positioning of the dental implant body through prosthetically driven planning is essential to achieve this goal.¹⁴ The use of computer-assisted surgery improves the accuracy of implant placement.^{6-8,12} A split-mouth comparison of the accuracy of CAD/CAM static guides to laboratory-fabricated conventional stents revealed improved accuracy in all dimensions measured.¹⁵ A single-blind clinical comparative study of the freehand method with conventionally fabricated stent to a CAD/CAM static guide revealed an increased incidence of errors, interproximal emergence (odds ratio [OR] = 2.82, $P < .0001$), insufficient interimplant distance (OR = 1.42, $P < .001$), and improper parallelism (OR = 1.24, $P = .01$) using the freehand method. The improved accuracy of static CAD/CAM guides increases the predictability of implant placement and restoration.¹⁶ When using CAS systems, minimal incision approaches can also be used, decreasing the morbidity associated with implant placement.

The use of CAS systems has been limited by the cost and complexity of static or dynamic guidance. Until recently, there were few dynamic guidance systems for dental implants available for use in the United States. The visual light dynamic system described in this study allows the guidance of any type of implant restoration: single tooth, partially dentate, or edentulous. The patient can be scanned and the surgical plan implemented on the same day with no need for laboratory fabrication of stents or guides. This is done in a cost-efficient manner. The system also allows the surgeon to directly observe the surgical site during surgery. There is no intervening stent obstructing the surgical field. Further clinical indications of dynamically guided systems include:

- limited mouth opening,
- tight interdental spaces that preclude the use guidance tube in CAD/CAM guides,
- distal implants (ie, second molars) that are precluded from CAD/CAM static guides by prolongation height, and
- the inability to take impressions due to hyperexaggerated gag reflex.

Generally, the studies of accuracy in a guided system fall into model-based studies or clinical trials. Model-based studies

are ideal to evaluate the differences between systems. They remove many of the confounding factors related to patient treatment, such as variation in bone densities and patient movement. Model-based studies also remove some of the variables associated with the limitations of imaging. The prediction of depth in clinical trials is significantly affected by the inability to image/visualize thin buccal or labial bone. The presence of immature bone after prophylactic bone grafts also hinders bone visualization and can affect the prediction of depth. Anatomic variability results in larger depth deviations from the plan in clinical trials and often results in depth not being reported.^{6,7} For the reasons stated, model-based studies

TABLE 3

Deviations for implants placed using dentate case type with X-Guide compared with published deviations from model-based accuracy studies of dynamic and static guides

	Mean	SD	Max	No. of Implants
Angular, °				
X-Guide	0.89	0.35	1.52	22
Robodent ⁸	2.12	0.78	3.64	15
IGI ⁸	4.21	4.76	20.43	15
NaviDent ¹²	2.99	1.68	11.94	80
Static ⁷	1.44	3.36	—	64
Freehand ^{8,17,18}	10.40	5.41	25.30	173
Entry lateral, mm				
X-Guide	0.21	0.11	0.52	22
Robodent ⁸	0.35	0.17	0.75	15
IGI ⁸	0.65	0.58	2.37	15
NaviDent ¹²	1.14	0.55	3.64	80
Freehand ⁸	1.35	0.56	2.16	15
Apex lateral, mm				
X-Guide	0.22	0.13	0.47	22
Robodent ⁸	0.47	0.18	0.72	15
IGI ⁸	0.68	0.31	1.22	15
NaviDent ¹²	1.18	0.56	3.19	80
Freehand ⁸	1.62	0.68	2.68	15
Entry global, mm				
X-Guide	0.37	0.21	0.92	22
Static ⁷	0.36	0.57	—	74
Apex global, mm				
X-Guide	0.38	0.21	1.01	22
Robodent ⁸	0.60	0.20	0.92	15
IGI ⁸	0.94	0.40	1.88	15
NaviDent ¹²	1.71	0.61	3.92	80
Static ⁷	0.73	2.02	—	64
Freehand ⁸	1.89	0.8	2.95	15

TABLE 4		
Meta-analysis of published model-based angular deviations of freehand implant placement (mean ± SD [max], n denotes the number of implants)		
	N	Angular Deviation (°)
Brief et al. ⁸	15	4.59 ± 2.84 (10.66)
Hoffman et al. ¹⁷	112	11.20 ± 5.60 (25.3)
Nickening et al. ¹⁸	23	9.80 ± 4.25 (17.0)

allow direct comparison of the navigation accuracy of the systems themselves.

Table 3 provides a comparison between X-Guide and comparable values from the available literature. X-Guide summary statistics in Table 3 represent only the dentate case type, because only dentate case types are included in the literature values for dynamic guidance.

Table 3 displays the published accuracy for static tooth-borne guides and dynamic navigation systems. The model-based result from a meta-analysis⁷ was used to illustrate the accuracy measures in this study to those of model-based static guide studies. Literature-based values for dynamic navigation

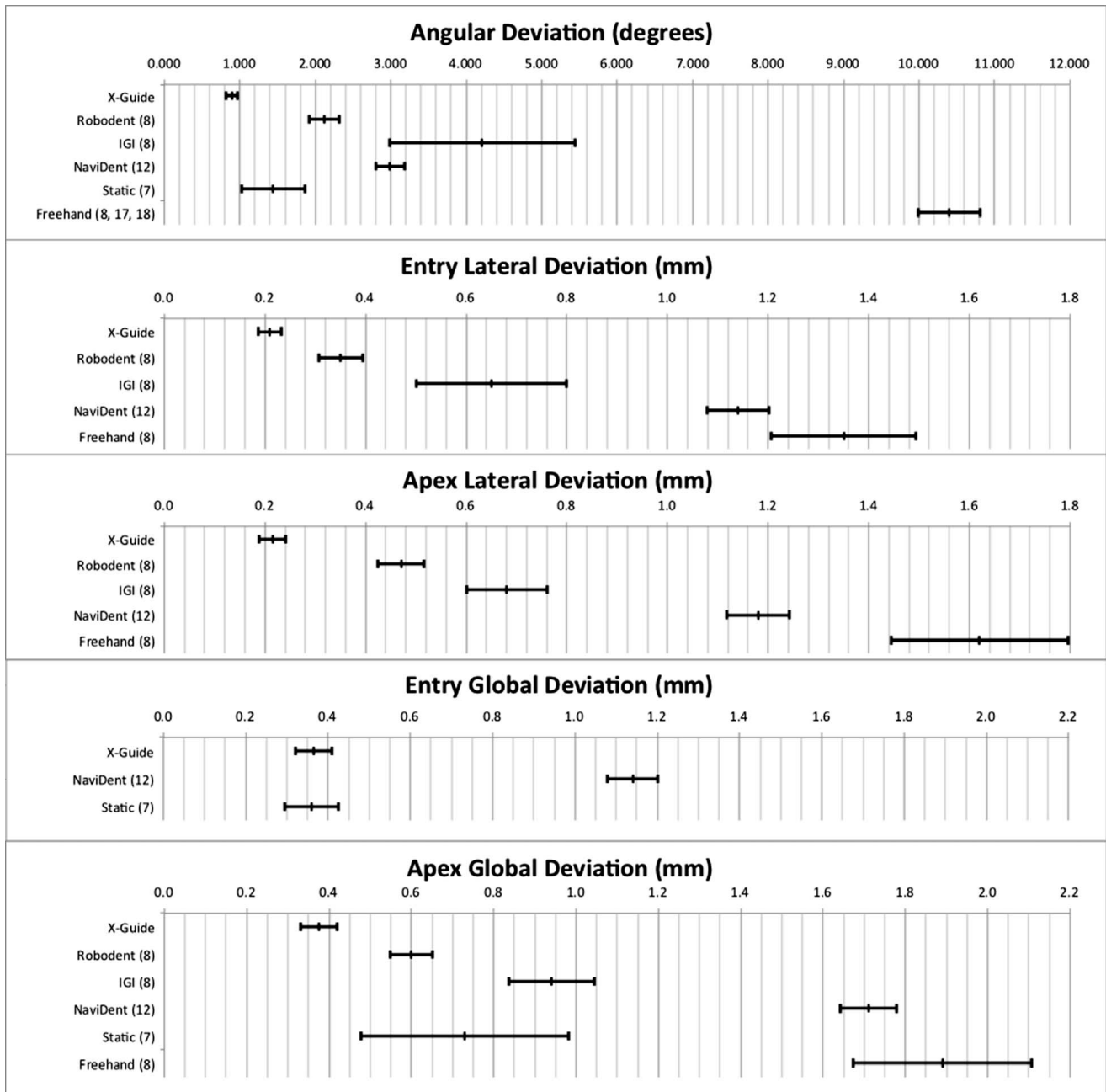


FIGURE 4. Summary of angular, entry, and apex deviation by device.

systems approved for implant placement are limited.^{8,12} The same metrics, although named differently, were adopted across studies: “error of entry” and “error at apex” are termed “lateral entry” and “lateral apex” deviations, respectively, in this study. Table 4 displays the model-based data of implants placed freehand.^{8,17,18} Figure 4 provides a summary of the deviations of the test device and the published model data. X-Guide’s measurements are provided in Table 3 for comparison. While the mean deviations for X-Guide are lower than those of freehand or of any other dynamic guidance system, no statistical inference is attempted in this study. Figure 4 graphically presents the comparison between the devices presented in Table 3, with error bars representing the standard error of each measurement.

The studies used here for dynamic guidance comparison were limited to bore hole drilling and did not include the delivery of an implant.^{8,12} However, some of the studies in the above-quoted meta-analysis⁷ for static guides did include implant delivery. In our clinical simulation, parallel wall 4 × 13-mm implants (Zimmer, Biomet 3i) were delivered to the planned depth, “fully guided,” which have the potential to decrease the accuracy of the final results of the tested device when considering 3D accuracy. The distinction between fully guided, partially guided (osteotomy made but implants not delivered to depth), and pilot drill-only CAS guidance is a recent categorization that is not mentioned historically. This distinction is important for future accuracy studies of CAS systems to capture the true utilization of these rapidly evolving techniques. Shortcomings of this study include the small number of models in the edentulous group and the fact that there was a single surgeon with direct involvement in the development of the device. As most implants are presently placed with no CAS techniques, future studies should be directed at comparing new devices and techniques to freehand placement.

CONCLUSION

The angular accuracy of implants delivered using the tested device was $0.89^\circ \pm 0.35^\circ$ for dentate case types and $1.26^\circ \pm 0.66^\circ$ for edentulous case types, measured relative to the preoperative implant plan. Positional accuracy was 0.38 ± 0.21 mm for dentate and 0.56 ± 0.17 mm for edentulous measured at the implant apex and 0.37 ± 0.21 mm for dentate and 0.54 ± 0.17 mm for edentulous measured at the implant platform. Future studies directly comparing dynamic navigation to freehand placement are recommended.

ABBREVIATIONS

3D: 3-dimensional
 CAD/CAM: computer-aided design/computer-aided manufacturing
 CAS: computer-assisted surgical
 CBCT: cone-beam computerized tomography
 DRF: dynamic reference frames
 OR: odds ratio

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In the 42(5), October 2016, issue of *Journal of Oral Implantology*, the article titled, “Accuracy of Dynamic Navigation for Dental Implant Placement—Model-Based Evaluation,” by Robert W. Emery, Scott A. Merritt, Kathryn Lank, and Jason D. Gibbs was published with an incomplete Acknowledgment. The correct Acknowledgment statement is as follows: “This work was conducted using a grant provided by X-Nav Technologies, LLC. Robert W. Emery is the Chief Medical Officer of X-Nav Technologies, LLC, and has an equity interest in X-Nav Technologies, LLC. Scott A. Merritt is the Chief Optical Engineer of X-Nav Technologies, LLC. Jason D. Gibbs is a Software Engineer at X-Nav Technologies, LLC.”