Accuracy of a Dynamic Dental Implant Navigation System in a Private Practice

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Purpose: To evaluate the in vivo accuracy of dental implants placed using a dynamic computer-aided dental implant (CAI) navigation system. The impact of various factors on accuracy was also analyzed. Materials and Methods: A retrospective in vivo study was performed during the period of October 2015 to December 2017. Data were obtained on all implants placed during this time frame. A chart review was conducted to identify the type of flap, number of implants placed, number of patients treated, and factors related to the description of edentulism (partial or complete). To evaluate accuracy outcomes, the preoperative cone beam computed tomography (CBCT) plan was volumetrically registered to a post-implant placement CBCT scan. Deviations between the planned and placed implant positions were analyzed. Data were statistically analyzed for factors that may affect the accuracy during usage. Results: Data were obtained on 231 implants placed in healed ridges using a flapless or minimal flap approach under dynamic guidance by a single surgeon. In the 89 arches operated on, 28 (125 implants) were fully edentulous. For all implants, the mean (SD) discrepancies were: 0.71 (0.40) mm for entry point (lateral) and 1.00 (0.49) mm at the apex (3D). The mean angle discrepancy was 2.26 degrees (1.62 degrees) from actual vs planned implant positions. The accuracy measurements for partially edentulous patients using a thermoplastic stent attachment and for fully edentulous patients using a mini-implant–based attachment were nearly identical. No significant accuracy differences were found between implant positions within the different sextants. Guided insertion of the implant itself reduced angular and apex location deviations. The accuracy of implant placement improved during the study period, with the mean entry point and apex deviation as well as overall angle discrepancy measured for the last 50 implants being better (0.59 mm, 0.85 mm, and 1.98 degrees, respectively) compared with the first 50 implants (0.94 mm, 1.19 mm, and 3.48 degrees, respectively). Conclusion: Dynamic surgical navigation is an accurate method for executing CBCT-based computer-aided implant surgery. In addition, an increased experience level of the surgeon with dynamic navigation appears to improve accuracy outcomes. Int J Oral Maxillofac Implants 2019;34:205–213. doi: 10.11607/jomi.6966

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Computer-aided implantology (CAI) refers to the use of computerized technology to plan and guide the placement of dental implants based on a three-dimensional (3D) cone beam computed tomography (CBCT) image of the jaw. This approach has many benefits.1–8 These benefits include:

- The ability to transfer a prosthetically driven implantation plan to the jaw
- Enabling flapless/minimal flap surgery, potentially leading to reduced patient discomfort, reduced chair time, reduced morbidity (infection, bleeding), and faster recovery
- Reduced risk of iatrogenic damage to nearby anatomical structures
- Increased efficiency such as reduced chair time; elimination of the need for plaster models, wax-ups,
and fabrication of scan guides; as well as improved communication between restorative team members by using shared treatment plan alternatives

- A more efficient restorative process owing to increased implant accuracy
- Reduced intraoperative mental and ergonomic surgical stress

To date, two different approaches to CAI have been developed: static guidance and dynamic navigation. In the static approach, a custom drilling guide is digitally designed as part of the planning process and manufactured prior to surgery. During the surgery, the custom guide is positioned on the patient’s jaw, mucosa, or teeth, and metal sleeves are used to guide the osteotomy preparation (drilling) process prior to the insertion of the implant.\(^9\)\(^,\)\(^10\) In the dynamic approach, the computer registers the jaw with its appearance in the volumetric CT image, then provides on-screen real-time guidance to the surgeon, who operates freehand. This guidance includes real-time visual feedback showing the difference between the drill tip’s position, angulation, and depth compared with its virtually planned position, angulation, and depth.\(^11\)\(^,\)\(^12\) Dynamic navigation provides real-time verification and validation of osteotomy site preparation and implant placement.

While requiring an upfront investment in training and workflow adjustments, dynamic CAI has the potential to provide important advantages over the static approach, including\(^6\)\(^,\)\(^8\)\(^,\)\(^10\)\(^,\)\(^13\):

- Enables CBCT scanning, planning, and surgery in a single appointment (when a CBCT is available on site)
- Increases safety and predictability because of the ability to verify guidance accuracy at any time during the surgery
- Simpler and faster planning (no surface segmentation or guide design)
- Ability to view and modify the plan during the surgery in order to accommodate tactile feedback or unexpected complications
- Theoretically lower per-procedure costs
- Improved irrigation, reducing risk of bone damage due to overheating
- No implant manufacturer-dependent armamentarium required
- Improved ergonomics: Guidance can still be provided when interocclusal or interdental space is limited since a physical intraoral guide is not necessary.
- Elimination of guidance failures due to fractured or poorly fitting guides

Several studies have compared the accuracy of dynamic and static navigation in vitro and found them to be similar.\(^14\)\(^,\)\(^15\) Accuracy is assessed in vivo by comparing the planned and actual positions of implants using accurately registered preoperative and postoperative CBCT scans. This approach has been used to measure and compare entry point and apex deviations as well as angle discrepancies of guided and non-guided implant placement.\(^6\)\(^,\)\(^13\) To the authors’ knowledge, Block et al (2017) is the only published study to date measuring in vivo placement accuracy obtained with the use of a navigation system (X-Guide, X-Nav Technologies) in the treatment of partially edentulous arches.\(^6\) The navigation system utilized in this publication is similar to the X-Nav system in both the preoperative and surgical workflow, but is more compact, can attach to any surgical handpiece, and utilizes room light as opposed to blue light.

The aim of this study was to assess the in vivo placement accuracy obtained when using a dynamic navigation system to treat a representative range of patients encountered in a private practice. The data also provide for evaluation of the impact that partially vs totally edentulous patients, maxillary vs mandibular arch, different mouth sextants, fully navigated implant placement vs partially navigated implant placement, as well as the amount of user experience may have on accuracy outcomes.

**MATERIALS AND METHODS**

**Study Approach**

A retrospective observational in vivo study was performed using a dynamic computer-aided dental implant navigation system (CAI, Navident, ClaroNav) in a private practice setting. All implants were placed in patients between October 2015 and December 2017 using a prosthetically directed CBCT-based plan and dynamic surgical guidance. Following implant placement, a postoperative CBCT scan was obtained to determine entry point and apex deviations as well as angle discrepancies. All CBCT imaging was performed using a Soredex Scanora 3D CBCT (14-bit gray density, 0.25-mm voxel size, 90 kV). All CBCT imaging and surgery were performed by a single surgeon (L.V.S.) in a private practice.

**Navigation System Design**

The CAI navigation system tracks the position of the tip of the drill and maps it to a pre-acquired CBCT scan of the jaw to provide real-time drilling and placement guidance. When the drill approaches a pre-planned implant location, the system provides a cross-hair display to guide the surgeon to precisely locate the drill tip at the planned entry point, adjust the drill orientation to the planned entry angle, and to drill to the planned...
depth. Once the osteotomy preparation is complete, the same approach can be used to guide the insertion of the implant itself. The workflow (stent, scan, plan, place) and a case report have been published by Mandelaris et al (2018).16

The CAI navigation system consists of five main components (Figs 1 and 2):

1. A notebook computer running the planning and guidance software
2. An optically marked handpiece attachment (named “DrillTag”)
3. An optically marked patient jaw attachment: A partially edentulous arch utilizes a moldable stent part (named “NaviStent,” Fig 3) and a fully edentulous arch utilizes a mini-implant and a matching bracket (Fig 4).
4. An optical position sensor (named “MicronTracker”)
5. A mobile cart carrying the laptop and the optical position sensor

Guided Implant Placement Workflow
When a stable partial dentition was available, a hot-water thermoplastic retainer was molded over the dentition, left to harden, and then removed and trimmed to provide access to the intended implantation regions. An arm made of the same thermoplastic material was then shaped and glued to the retainer, creating the “NaviStent” (Fig 3). The “CT-Marker,” containing a fiducial aluminum body, was connected to the distal end of the arm using a thumbscrew during the CT scan. The portion of the NaviStent to which the CT-Marker attaches is known as a “fix plate” and is the common reference point in the NaviStent for both the imaging process and the surgical procedure. The algorithms utilized for real-time positioning use this as their reference point.

In fully edentulous arches, or when the teeth are insufficiently stable or expected to be removed during the implantation procedure, a single mini-implant is temporarily inserted in the arch to provide a stable anchor for the arm. A retainer arm with a bracket designed to provide rigid and stable coupling to the head of the implant was used to attach the CT-Marker to the jaw (Fig 4).

Following CBCT imaging of the respective arch to be operated on, the DICOM data were imported to the navigation software. Virtual crowns were placed in the software and adjusted to simulate the desired restoration for prosthetically directed implant planning. The supporting virtual implants were placed based on these planned restorations and considering the regional anatomy.

Prior to osteotomy site preparation, a drilling axis calibration was performed, followed by a drill tip calibration and an accuracy check. The coordinate mapping steps are shown in Fig 5. Osteotomy site preparation was then performed in a minimally
invasive approach (either flapless or with a minimal flap) and under dynamic navigation guidance.

During drilling, the operator is presented with different views (Fig 6). The target view (Fig 7) enables the surgeon to observe, in real time, the distance (mm) between the drill tip and the path of the planned osteotomy, the angle of the drill in relation to the planned osteotomy axis, and the depth difference (mm) between the tip of the drill and the apical end of the planned osteotomy.

Following osteotomy site preparation, the implant was placed in one of two protocols:

- The implant tip was calibrated and the implant was placed using dynamic navigation to ensure accuracy of the entry, angle, and depth (guided implant placement).
- The implant was placed either partially or fully utilizing a manual torque wrench without dynamic navigation assistance (freehand manual/nonguided implant placement).

**Placement Accuracy Evaluation**

The CAI system used in this study provides an accuracy evaluation software application called “EvaluNav”. Using EvaluNav, the preoperative planned CBCT and postoperative CBCT scans are registered to each other, and the position of each implant is detected in the postoperative CBCT (Figs 8 and 9). Angle deviations between the actual and planned positions are automatically computed and reported (Figs 10 and 11). The application has been validated on models by the manufacturer.

**RESULTS**

Accuracy data were obtained for 231 implants placed in healed ridges under dynamic guidance by a single surgeon (L.V.S.) in a private practice. Prior to the implants placed in this study, the surgeon (L.V.S.) had been trained but had not performed surgery with the CAI navigated implant system. The data here represent the first 231 implants placed with dynamic navigation by the surgeon (L.V.S.). Eighty-nine arches were operated on, 28 of which (125 implants) were fully edentulous. Seven fully edentulous cases were treated using a slightly different jaw attachment approach where an acrylic stent was fabricated to mate with the mucosal surface and was anchored to the bone prior to the CT scan using small fixation screws. The other 21 fully edentulous cases were treated in the manner
Stefanelli et al previously described (mini-implant attached to a horizontal or vertical retainer arm). No adverse events associated with the use of dynamic navigation were encountered.

The case distribution is shown in Table 1. The accuracy statistics for all implants placed, as analyzed using EvaluNav, are demonstrated in Table 2. Overall, the mean (SD) deviations for the 231 implants studied were 0.71 (0.4) mm at the entry point, 1.00 (0.49) mm at the apex (3D), and the angle discrepancies were 2.26 degrees (1.62).

The error distribution histograms are shown in Fig 12. It is noted that the distributions are not symmetrical around the peak as expected of a normal distribution because the errors are bound by 0 on the left and unbound on the right, a condition shared by all guidance systems. Thus, accuracy statistics commonly published (mean and standard deviation), cannot be translated into error margins or confidence intervals in a manner that assumes a normal distribution. To make the information more clinically relevant, Table 3 shows the fraction of samples that fall below the mean, mean + SD, mean + 2SDs.

The statistics for different subsets of the implants are shown in Tables 3 to 8.

The accuracy obtained with partially edentulous arches using a thermoplastic NaviStent and fully edentulous arches using a mini-implant were nearly identical (Table 5). Using a rigid stent with fixation screws, a method used for only seven patients in the study, was slightly less accurate.

No significant differences were found between maxillary and mandibular arches or between the different mouth sextants (Tables 5 and 6). Statistical significance for the two-tailed $t$ test was selected as $P$ value less than .05. Accuracy was significantly better when the final implant insertion was fully guided, rather than freehand/nonguided (Table 7).

The first 50 implants placed in this study were significantly less accurate than the final 50 implants placed (Table 8). The improvement in accuracy is likely

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Case Characteristics</th>
<th>No. of arches</th>
<th>No. of implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td></td>
<td>89</td>
<td>231</td>
</tr>
<tr>
<td>Partial edentulism</td>
<td></td>
<td>61</td>
<td>106</td>
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<tr>
<td>Total edentulism</td>
<td></td>
<td>28</td>
<td>125</td>
</tr>
<tr>
<td>Maxilla</td>
<td></td>
<td>47</td>
<td>132</td>
</tr>
<tr>
<td>Mandible</td>
<td></td>
<td>42</td>
<td>99</td>
</tr>
<tr>
<td>Sextant 1 (Max R) (1.7 – 1.4)</td>
<td></td>
<td>32</td>
<td>45</td>
</tr>
<tr>
<td>Sextant 2 (Max Ant) (1.3 – 2.3)</td>
<td></td>
<td>26</td>
<td>48</td>
</tr>
<tr>
<td>Sextant 3 (Max L) (2.4 – 2.7)</td>
<td></td>
<td>27</td>
<td>39</td>
</tr>
<tr>
<td>Sextant 4 (Mand L) (4.7 – 4.4)</td>
<td></td>
<td>24</td>
<td>29</td>
</tr>
<tr>
<td>Sextant 5 (Mand Ant) (4.3 – 3.3)</td>
<td></td>
<td>18</td>
<td>37</td>
</tr>
<tr>
<td>Sextant 6 (Mand R) (3.4 – 3.7)</td>
<td></td>
<td>23</td>
<td>33</td>
</tr>
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Max R = maxillary right; max ant = maxillary anterior; max L = maxillary left; mand L = mandibular left; mad ant = mandibular anterior; mand R = mandibular right.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Key Deviation Statistics of All Implants Inserted (n = 231)</th>
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<tbody>
<tr>
<td>Deviation</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Entry (2D, mm)</td>
<td>0.71 (0.40)</td>
</tr>
<tr>
<td>Apex (3D, mm)</td>
<td>1.00 (0.49)</td>
</tr>
<tr>
<td>Angle (deg)</td>
<td>2.26 (1.62)</td>
</tr>
</tbody>
</table>
due to surgical experience with the navigation system. However, software updates of the dynamic navigation system during the study period may have also contributed to accuracy improvements. The mean entry deviation, apex deviation, and angle discrepancy measured for the first 50 implants in this study were 0.94 mm, 1.19 mm, and 3.48 degrees, respectively, compared with 0.59 mm, 0.85 mm, and 1.98 degrees for the last 50 implants placed.

**DISCUSSION**

Computer-aided implantology (CAI), especially when practiced in a flapless/mini-flap approach, has the potential to provide many advantages over the freehand, nonguided approach to osteotomy site preparation and implant placement. Of the two known guidance approaches, static and dynamic, only static guidance is routinely used in practice. Early dynamic navigation...
systems have so far failed to gain acceptance. As a new generation of navigation systems is now appearing on the market, it is important to assess their usability and accuracy in clinical practice.

In this study, a new dynamic navigation system was incorporated into a private practice, and data related to its use are presented. The data collected were used to assess placement accuracy using a novel method based on precise volumetric registration and automated model fitting. The results obtained demonstrate accuracy that is equal to or better than the in vivo accuracy reported in the literature for static guides and other navigation systems. It is much better than for nonguided freehand placement.

Sources of Guidance and Placement Errors
Accuracy of the osteotomy site preparation (drilling) depends on the navigation system accurately mapping the drill tip to the CBCT image of the jaw used for planning the surgery. Errors in the drill-tip to CBCT image mapping can appear at any step in the coordinate mapping chain (Fig 5). This may be due to slight deviations between geometric assumptions made by the mapping software and reality (eg, manufacturing tolerances of all parts, changes to the NaviStent shape between the scan and the placement) or due to optical tracking noise or “drift” away from perfect calibration because of mechanical, thermal, or optical changes from the time the motion tracking system was last calibrated. Furthermore, any looseness, or “play”, in the rigid coupling between the components involved could further degrade accuracy. These include, but are not limited to: patient motion during the CBCT scanning process, unstable seating of the jaw attachment, bending of arms or connectors during surgery, and movement of the tip of the drill relative to the handpiece handle being tracked.

The aforementioned factors can be tightly controlled when performing in vitro experiments to produce results that are more accurate than in clinical practice. For example, using a similar dynamic navigation system (X-Guide, X-Nav Technologies) with partially edentulous arches, very low in vitro mean apex deviations of 0.38 mm/0.89 degrees were reported, while in vivo, reported mean deviations across all studies were 1.12 (4.5) mm at the entry point, 1.39 (7.1) mm at the apex, and 4.21 degrees for angle discrepancies.6,17 The authors note that the maximal deviation and angle discrepancy outcomes were far from clinically acceptable and highlight the risks associated with guide usage. Unlike dynamic navigation, it is not easy or feasible to evaluate the accuracy of static guidance prior to or during osteotomy site preparation. A unique aspect of dynamic navigation is that their registration accuracy can be quickly evaluated prior to the first osteotomy by using the drill tip to easily touch visible jaw locations and observing how accurately that location is mapped to the CT image. Following the pilot drill preparation, the pilot hole entry location can be used to instantly evaluate the accuracy at the entry of subsequent drills. In other words, dynamic navigation enables “on-the-spot” surgical accuracy verification, greatly reducing the likelihood of unacceptably large guidance errors.

Vercruyssen et al (2014) reported on a randomized, prospective study comparing the accuracy obtained using static pilot-drilling templates from several providers with that obtained from freehand (“mental navigation”) surgery in 72 fully edentulous arches.13 Mean deviations (SD) measured with the static guides were: 1.4 (0.7) mm at entry point (3D), 1.6 (0.7) mm at the apex, and 3.0 (2.0) degrees for angle deviations.13 These compared favorably with the corresponding nonguided outcome means (SD) of 2.8 (1.5) mm, 2.9 (1.5) mm, and 9.9 (6.0) degrees.13 The study concludes that guided implant placement is more accurate than freehand surgery.13 No statistically significant differences between the accuracy obtained with different static guide systems were observed.

A limited number of studies have evaluated the accuracy of dynamic navigation systems, generally reporting an accuracy of 1 to 2 mm in vitro when using first-generation dynamic navigation systems.19–22 Somogyi-Ganss et al (2014) used an early prototype of the system that was used in this study.15 Eighty in vitro osteotomies were created using dynamic navigation with an accuracy of 1.14 mm for entry point deviation, 1.71 mm for apex deviation, and 2.99 degrees for mean angle deviation (compared with preoperative plan).17 The deviations measured in the present in vivo study are significantly lower than the ones reported in that earlier in vitro study. Since the in vitro study was done using a prototype, this is likely due to improvements in the design or manufacturing of the system.

Comparison with Prior Accuracy Studies
Currently, digitally designed static drill guides are a commonly used approach to dental implant placement. Tahmaseb et al (2014) published a systematic review on the accuracy of static guidance.18 Not surprisingly, it was reported that deviations measured in clinical studies are significantly higher than when in vitro models are used.18 The mean (max) deviations across all studies reported were 1.56 mm/3.62 degrees were four times larger.6,17
Block et al (2017) reported on the placement accuracy obtained by three surgeons using a different dynamic navigation system (X-Guide, X-Nav Technologies) to treat 100 patients. Only partially edentulous cases were included. The mean (SD) outcomes reported were 0.87 (0.42) mm at the entry point (lateral/2D), 1.56 (0.69) mm at the apex (3D), and 3.62 (2.73) degrees for angle deviations. Nonguided (freehand) entry point deviations, apex deviations, and angle discrepancies had corresponding means (SD) of 1.15 (0.59) mm, 2.51 (0.86) mm, and 7.69 (4.92) degrees. No statistically significant differences between individual surgeons were observed in the navigated placement. The accuracy data support the conclusion that implant placement under dynamic navigation guidance is at least similar to, if not better than, static guides and superior to nonguided/freehand implant surgery. While only one surgeon was involved in the present study, the number of implants placed by that surgeon is more than double those placed in the Block et al (2017) study.

To compare placement predictability and safety under various methods in a simpler and more meaningful manner, the authors propose using 95% confidence margins. This value is expected to be exceeded, on average, only once in every 20 placements. In a symmetrical normal distribution, the interval between two standard deviations on either side of the mean includes approximately 95% of the samples. However, as demonstrated in Fig 12 and Table 3, the deviations are distributed asymmetrically, with 95% of the samples containing below only the right side of that interval, ie, mean + 2*SD.

Using mean + 2*SD to compute the 95% confidence margin for implant deviation, this study obtained 1.5 mm at the entry point, 2.0 mm at the apex, and 5.6 degrees off of the planned implant angulation. These numbers compare favorably to the in vivo, 95% confidence margins derived from the previously reported measurements of implant placement in partially edentulous ridges by Block et al (2017) when using dynamic navigation (1.7 mm at the entry point, 2.9 mm at the apex, and 9.1 degree deviations) and freehand placement (2.3 mm at entry, 4.2 mm at the apex, and 17.5 degree deviations).

The deviations in the present study also compare favorably with the results previously reported by Vercruysse et al (2014) when placing implants in fully edentulous ridges using a static guide (2.8 mm at the entry point [in 3D], 3.0 mm at the apex, and a 7 degree deviation) or freehand placement (5.8 mm at the entry point [in 3D], 5.9 mm at the apex, and a 21 degree deviation).

These data suggest that in vivo implant placement guided by the current system provides predictability and safety at least equivalent to these other guidance technologies and better than freehand (unguided) surgery for both partially and fully edentulous arches.

Errors in the process of assessing placement accuracy are an added source of variability, potentially affecting the deviations being recorded. Previous assessment methods have extracted surfaces from the volumetric data, edited and registered these surfaces to each other, and manually analyzed the model fitting to the implant, leading to both inter- and intra-operator variability. Compared with the method used in this study, previous methods were more labor intensive and, therefore, likely to be more operator dependent. It is not known whether this factor may have increased or decreased the reported deviations compared with their true value.

Using the mini-implant–based jaw attachment approach (reported here for the first time), placement accuracy in edentulous cases was equivalent to that obtained in partially edentulous arches. While more invasive, the mini-implant–based attachment approach was faster and simpler to apply compared with the construction of a NaviStent used in the partially edentulous patient population.

One limitation of the present study is that all implant placement surgery was completed by a single surgeon in a private practice setting. A single surgeon was selected in order to minimize the confounding variables of surgical skill and overall surgical experience that would exist between two or more clinicians. While this may impact the external validity or comparability to existing data, this allowed for the evaluation of other factors that impact accuracy. One of these factors was how the amount of experience with this CAI system significantly improved the accuracy of the operator. The surgeon was previously trained in the use of this technology, but these implants represent the first 231 implants placed by the surgeon in private practice. The first 50 implants demonstrated the greatest amount of accuracy deviation. As demonstrated in Table 8, the placement of the last 50 implants was significantly more accurate than the placement of the first 50 implants, most likely due to skill acquisition. It is uncertain whether these results can be applied to other surgeons of different skill and experience levels. Additional in vivo studies are needed in order to substantiate the data prior to generalizing the results reported here.

Using a dynamic navigation system presents a substantial change to existing clinical workflow and work habits. It also requires an up-front investment in equipment, training, and skill acquisition, which may burden the practice during the workflow transition and may slow the adoption of this technology. Improvements in software design and future applications to simplify the workflow of dynamic navigation...
surgery may decrease preparation and treatment time for this technology. Although the surgical time is similar, or often shorter, using dynamically navigated implant placement, the overall time for case preparation and planning is more than freehand surgery. Current research is in progress to eliminate the need for a pre-made thermoplast stent through the use of “trace registration mapping” (using skeletal/dental landmarks as references to relate the CBCT image to the patient). Innovations such as this will continue to simplify the workflow while still offering excellent surgical outcomes.

CONCLUSIONS

The data demonstrate excellent accuracy of implant placement using a dynamic computer-aided dental implant surgical navigation system (measured by entry point deviations, apex deviations, and angle discrepancies). The single most significant factor on accuracy outcomes in this study was the experience of the surgeon.

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