Accuracy of a real-time surgical navigation system for the placement of quad zygomatic implants in the severe atrophic maxilla: A pilot clinical study

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Abstract

Background: A real-time surgical navigation system potentially increases the accuracy when used for quad-zygomatic implant placement.

Purpose: To evaluate the accuracy of a real-time surgical navigation system when used for quad zygomatic implant placement.

Materials and Methods: Patients with severely atrophic maxillae were prospectively recruited. Four trajectories for implants were planned, and zygomatic implants were placed using a real-time surgical navigation system. The planned-placed distance deviations at entry (entry deviation) points, exit (exit deviation) points, and angle deviation of axes (angle deviation) were measured on fused operation images. The differences of all the deviations between different groups, classified based on the lengths and locations of implants, were analysed. A P value of < 0.05 indicated statistical significance.

Results: Forty zygomatic implants were placed as planned in 10 patients. The entry deviation, exit deviation and angle deviation were 1.35 ± 0.75 mm, 2.15 mm ± 0.95 mm, and 2.05 ± 1.02 degrees, respectively. The differences of all deviations were not significant, irrespective of the lengths (P = .259, .158, and .914, respectively) or locations of the placed implants (P = .698, .072, and .602, respectively).

Conclusion: A real-time surgical navigation system used for the placement of quad zygomatic implants demonstrated a high level of accuracy with only minimal planned-placed deviations, irrespective of the lengths or locations of the implants.

Keywords
accuracy, computer-assisted surgery, edentulous maxilla, real-time surgical navigation system, zygomatic implants

1 INTRODUCTION

When considering oral rehabilitation in patients with maxillary atrophy, the placement of dental implants can be a significant clinical challenge. Patients with an insufficient bone volume in the maxilla may require more than one operation in order to increase the quantity and quality of bone made available for implant placement. This increase in the number of operations required will extend the treatment time, which will increase patient morbidity and, possibly, the likelihood of postoperative complications, including failure. Zygomatic implants can be regarded as an alternative to formal bone grafting where there is inadequate bone for conventional implants in patients with severe maxillary atrophy.12 The utilization of zygomatic implants can negate the need for bone grafting and can also allow the clinician to perform immediate
rehabilitation in some cases. It has been reported that oral rehabilitation using zygomatic implants in patients with severely atrophic maxillae has good long-term survival rates from 94.2% to 100% and can be comparable to conventional implants. However, when placing zygomatic implants, either freehand or using a surgical template for guidance, there are risks, particularly the risk of inaccurate placement within the alveolus, penetrating the orbital cavity or infra-temporal fossa and inappropriate placement within the zygomatic prominence. Furthermore, these risks are increased by the placement of multiple zygomatic implants, the irregular shape of zygoma and the limited visibility within the operative field. The real-time surgical navigation system provides a different approach for operating with the provision of completely visualized trajectories through analysis of the preoperative and intraoperative computed tomography (CT) images. On the preoperative CT images, the most appropriate trajectories for implant placement can be precisely planned. Combining the planned placement strategy with the visualized operative field, it can be observed that the real-time surgical navigation system enables minimal deviations between the planned and placed trajectories. Many implant-placement-related studies, including three zygomatic implant studies, have indirectly shown the effective minimization of planned-placed deviations by reporting the reduction of intraoperation and postoperation complications when using the real-time surgical navigation system. However, two studies performed the planned-placed deviations of implants that were placed in either models or cadavers and one case report evaluated the deviations of three zygomatic implants that were placed in one patient. Therefore, the aim herein was to investigate the clinical accuracy of a real-time surgical navigation system on quad-zygomatic implant placement by measuring the deviations between the positions of the planned and placed implants.

2 | MATERIALS AND METHODS

2.1 | Patients

This study prospectively recruited patients starting in October 2015 with local ethical approval. The inclusion criteria were the following: (1) patients presenting with a complete edentulous maxilla or partial edentulous maxilla with few extremely loose teeth and (2) patients presenting with severe atrophy of the maxilla with insufficient bone volume for conventional implant placement in the anterior and/or posterior maxillae. The exclusion criteria were the following: (1) patients with sufficient bone for conventional implant treatment; (2) patients with narrow residual bone for whom buccal bone grafts were considered more appropriate; (3) patients with untreated maxillary sinusitis or a maxillary sinus cyst; and (4) patients with local or systemic contraindications for oral surgery and implant placement. The degree of bone absorption was estimated from preoperation cone-beam computed tomography (CBCT) (i-CAT, Imaging Sciences International, Hatfield, PA) scanning.

2.2 | Planning procedure

All recruited patients were planned to receive two zygomatic implants on each zygoma. The intraoral coronal entry points of the anterior and posterior implants should be at or near the top of the alveolar crest at the level of lateral incisor/canine region and the second premolar/first molar region, respectively. The extra-oral apical points of the anterior and posterior implants were on zygoma, and implants were kept contactless. The path of the implants should not run through the critical anatomical structures. Eight miniscrews (CIBEI, China) were dispersedly implanted in the remaining maxilla to act as registration points on each patient before the trajectories were planned (Figure 1). CBCT was performed and imported to preoperation planning software (iPlan Navigator, BrainLAB AG, Germany) after the miniscrews were placed. Cylindrical trajectories were planned as the drilling path, and all miniscrews were marked as registration points for intraoperation imaging registration (Figure 2).

2.3 | Surgical and prosthetic procedure

(1) After general anaesthesia, the skull reference base was rigidly secured to the calvaria with a single self-tapping titanium screw. The reference array was then secured to the base assembled with three reflective marked spheres (Figure 3). (2) The navigation system was calibrated to the specific patient by using a positioning probe to contact the miniscrews. After registration, the available sagittal, coronal, axial, and three-dimensional reconstruction images were displayed. (3) Then, a custom-made rigid bracket integrated the reference array with a zygoma handpiece so that constant visualization of the drilling trajectory could be displayed on the screen in real time. (4) All zygomatic implants (Branemark system, Nobel Biocare, Goteborg, Sweden) were placed with the guidance of the same real-time surgical navigation system.
system (VectorVision², BrainLAB AG, Germany), and the entire drilling procedure followed the trajectories from entry point to exit point as planned (Figure 4). (5) After placing the zygomatic implants (Figure 5), multiunit abutments and healing caps were placed on the implants, and the incision was closed. All operation procedures were performed by one surgeon who has over 10 years of experience in implantology. All patients were given 5-day prescriptions of antibiotics, analgesics, and mouthwash solution (chlorhexidine 0.12%). Immediate restoration was performed within 72 hours for all patients.

2.4 | Accuracy analysis

Postoperative CBCT was performed within 72 hours after surgery. Software (iPlan Navigator, BrainLAB AG, Germany) was used to fuse the preoperation images with the postoperation images. The distance deviation at the entry points (entry deviation) and exit points (exit deviation) and angle deviation of axes (angle deviation) between the planned and the placed implant were measured and recorded (Figure 6). The distance deviation was defined as the three-dimensional distance between the coronal (or apical) centers of the corresponding planned and placed implants. The angle deviation was measured as the three-dimensional angle between the longitudinal axes of the planned and placed implant. All deviations were independently measured twice, and the average values were obtained and recorded.

2.5 | Statistical analysis

Statistical analysis was performed with SPSS for Windows (16.0) computer software (SPSS Inc., Chicago, IL, USA). The inter-rater reliability was analysed and Cronbach’s α Coefficient (α) was obtained. The differences of all the parameters were compared based on the implant lengths and locations. A non-parametric analysis was performed (Mann-Whitney U test). Differences were considered statistically significant for \( P < 0.05 \).

3 | RESULTS

3.1 | Surgical and prosthetic procedures

This study recruited 10 consecutive eligible patients (male = 5, female = 5; mean age = 57.1 years; age range: 37-69 years) from October 2015 to May 2016. In total, forty zygomatic implants were placed...
with the guidance of the real-time surgical navigation system. Implant characteristics are summarized in Table 1. All patients underwent immediate restoration within 72 hours. The lengths of all postoperatively placed implants were consistent with the planned lengths. No complications occurred within the operation period.

3.2 | Accuracy analysis

Entry deviations, exit deviations and angle deviations of forty zygomatic implants between preoperatively planned and postoperatively placed implants were measured twice (measurement 1: \(1.33 \pm 0.74\) mm, \(1.94 \pm 0.94\) mm, and \(2.22 \pm 1.10\) degrees, respectively, and measurement 2: \(1.42 \pm 0.82\) mm, \(2.05 \pm 0.99\) mm, and \(2.28 \pm 0.99\) degree, respectively). The analysis of inter-rater reliability showed very high reliability between two measurements (\(\alpha = 0.95, 0.96, \) and \(0.95, \) respectively). The average median, mean, and standard deviation and the range of entry deviation, exit deviation, and angle deviation from the two measurements are shown in Table 2. Placed implants were classified into two groups based on the lengths (short lengths: from 40 to 45 mm; long lengths: from 47.5 to 52.5 mm). The differences of all deviations between these two groups were not significant (Table 3). When the placed implants were classified based on the placed locations, although there was a slight tendency that the posterior implants had larger exit deviations, the differences in all the deviations between the anterior and posterior implants groups were not statistically significant (Table 4).

4 | DISCUSSION

This study aimed to identify the feasibility of using a real-time surgical navigation system to guide the placement of quad zygomatic implants in patients with severe atrophic maxilla. The results showed that the real-time surgical navigation system guided placement of implants with an entry deviation of \(1.35 \pm 0.75\) mm, exit deviation of \(2.15 \pm 0.95\) mm, and angle deviation of \(2.05 \pm 1.02\) degrees, and the
differences of all the deviations were not significant, irrespective of the lengths or locations of the implants.

The placement of two implants in each side of the zygoma is suggested for patients with insufficient bone volume from the anterior maxilla. However, the irregular shape of the zygoma and limited intraoperation visibility increase the risk of complications when placing multiple implants.

A surgical template is regarded as a reliable method for guiding the placement of a conventional implant. However, for patients with severe atrophic maxilla, it is difficult to maintain a surgical template that is stable throughout the entire drilling procedure. A slight deviation in the entry point or initial direction may result in a magnifying deviation at the exit point. Chrcanovic et al. reported the placement of 16 zygomatic implants with the guidance of a stereolithographic surgical template on human cadavers with an angle deviation of the long axis between the planned and placed implants of 8.06 ± 6.40 degrees for the anterior-posterior view and 11.20 ± 9.75 degrees for the caudal-cranial view, of which one emerged in the infratemporal fossa and one emerged inside the orbit. Another study reported the placement of zygomatic implants with the guidance of a surgical template on patients with entry deviations and apexes of the zygomatic implants of 2.77 mm (range 1.0-7.4 mm) and 4.46 mm (range 0.3-9.7 mm). Additionally, two of the implants failed, which was attributable to excess apical emergence. Supposedly, a surgical template should be used to locate the entry point of zygomatic implant, but the same template may no longer be practicable to guide the drilling procedure when operating the zygomatic implant.

To achieve precise three-dimensional placement of the zygomatic implant and minimal invasiveness, a real-time surgical navigation system has been proposed. Different from the use of a surgical template, the real-time surgical navigation system is a dynamic guidance system wherein the whole drilling procedure could be visually monitored and adjusted to the planned trajectory, resulting in better accuracies compared to the use of a surgical template for the placement of zygomatic implant. Several studies have reported the accuracy of using a real-time surgical navigation system for the placement of regular implants. In regards to the use of this system for the placement of zygoma implants, the entry and exit deviations of implants were 1.36 ± 0.59 mm and 1.57 ± 0.59 mm on the models, and they were 1.30 ± 0.8 mm and 1.7 ± 1.3 mm on the cadavers. However, regarding clinical data, only one case report stated that the mean entry and exit deviations of all the deviations were not significant, irrespective of the lengths or locations of the implants.

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<table>
<thead>
<tr>
<th>Implant length (mm)</th>
<th>Anterior implant</th>
<th>Posterior implant</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>40</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>42.5</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>45</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>47.5</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>50</td>
<td>2</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>52.5</td>
<td>18</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>20</td>
<td>40</td>
</tr>
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</table>

| TABLE 2 | The distance deviations at entry point (entry deviation), exit point (exit deviation), and angle deviation |
|-----------------|-----------------|-----------------|-----------------|-----------------|
|                | Median | Mean  | SD     | Minimum | Maximum |
| Entry deviation (mm) | 1.35 | 1.37  | 0.75  | 0.2    | 2.9     |
| Exit deviation (mm)  | 2.15  | 1.99  | 0.95  | 0.3    | 4.0     |
| Angle deviation (°)  | 2.05  | 2.25  | 1.02  | 0.9    | 4.9     |

Abbreviation: SD, standard deviation.
deviations of three implants were 1.13 ± 0.30 mm and 1.64 ± 0.19 mm, respectively. Theoretically, the deviations of implants on the models and cadavers should be smaller than on patients because the immobility of the models and cadavers and lack of saliva and bleeding provide better access and visual control of the drilling axis. The current study showed that the entry and exit deviations of the implant were 1.35 ± 0.75 mm and 2.15 ± 0.95 mm, which were similar to the deviations obtained from the placed implants on models and cadavers. The deviations between the planned and placed positions probably resulted from several factors, which are as follows: (1) the imaging registration (the deviations were not only determined by the accuracy of marker localization, they were also influenced by their number and distribution) and (2) the clinical operation skills where the surgeon should perform the drilling procedure following the trajectory from the entry to exit point. Spreading and keeping markers close to the target as well as arranging markers in a nonlinear manner could increase the accuracy of image registration. Because the severe atrophic maxilla that underwent an operation continued to have limited bone for placing miniscrews, all miniscrews could only be placed on the front maxilla, mid-palatal suture, and maxillary tuberosity regions. To decrease the deviations of registration, bone markers (miniscrews) were chosen for all patients. Moreover, the clinical operation skills where the surgeon should perform the drilling procedure following the trajectory from the entry to exit point.

It is worth mentioning that although no significant difference was found between the anterior and posterior implants, there was a slight tendency to have larger apical deviations for the posterior compared to the anterior implants. This observation could be attributed to the length of the drill, the patients’ limited mouth opening and mandibular dentition affecting the drilling access of the posterior implant.

In our current study, with the guidance of the real-time surgical navigation system to place the implants on the zygoma, the entry deviation, exit deviation, and angle deviations are 1.35 ± 0.75 mm (range: 0.2-2.9 mm), 2.15 mm ± 0.95 mm (range: 0.3-4.0 mm), and 2.05 ± 1.02 degrees (range: 0.9-4.9 degrees), respectively, and the deviations obtained from the use of surgical templates were 2.77 ± 1.61 mm (range: 1.0-7.4 mm), 4.46 ± 3.16 mm (range: 0.3-9.7 mm), and 5.14 ± 2.59 degrees (range: 0.8-9.0 degrees), respectively. Although our study showed the overlapped deviations compared to the deviations obtained from the guidance of the surgical template, the ranges of all deviations and standard deviations were much smaller. Further analyses showed the use of the real-time surgical navigation system for the placement of implants can be clearly identified. This study did not assess all the deviations that were correlated with implant failure or the invasion of important anatomical structures because no patients had those complications during or following the operation. Moreover, the patients did not undergo long-term postoperation follow-up to obtain the prognosis of the implants, which is one of the indirect parameters to evaluate the placed implants for supporting prosthesis.

5 | CONCLUSION

This pilot study investigated the clinical accuracy of using a real-time surgical navigation system for quad zygomatic implant placement in patients with severe atrophic maxilla, and the results suggest that the real-time surgical navigation system provided stable and safe trajectories as preoperative planning for placing zygomatic implants, irrespective of the lengths of implants or the placed locations of implants. These advantages may help minimize the risk of complications and ensure anchorage for better support of the prosthesis.

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TABLE 3 Differences of three deviations between different lengths of implants

<table>
<thead>
<tr>
<th>Length</th>
<th>Entry deviation (mm)</th>
<th>Exit deviation (mm)</th>
<th>Angle deviation (°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 47.5 mm (n = 30)</td>
<td>1.15 ± 0.80</td>
<td>1.40 ± 0.58</td>
<td>2.00 ± 1.05</td>
</tr>
<tr>
<td>&lt; 47.5 mm (n = 10)</td>
<td>1.60 ± 1.03</td>
<td>2.35 ± 0.58</td>
<td>2.15 ± 0.99</td>
</tr>
</tbody>
</table>

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TABLE 4 Differences of three deviations between different locations of implants

<table>
<thead>
<tr>
<th></th>
<th>Anterior implant (n = 20)</th>
<th>Posterior implant (n = 20)</th>
<th>P values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entry deviation (mm)</td>
<td>1.25 ± 0.83</td>
<td>1.35 ± 0.68</td>
<td>.698</td>
</tr>
<tr>
<td>Exit deviation (mm)</td>
<td>1.60 ± 1.08</td>
<td>2.35 ± 0.75</td>
<td>.072</td>
</tr>
<tr>
<td>Angle deviation (°)</td>
<td>2.05 ± 0.98</td>
<td>2.15 ± 1.08</td>
<td>.602</td>
</tr>
</tbody>
</table>
DISCLOSURES

The authors do not have any financial interests, either directly or indirectly, in the products or information listed in the paper.

REFERENCES


