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Original Article

Comparison of the accuracy of dynamic navigation and the free hand approaches in the placement of pterygoid implants in the completely edentulous maxilla: An in vitro study

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Abstract *Background/purpose:* Pterygoid implant is a promising solution for patients with a partially or fully edentulous atrophic maxilla. However, whether dynamic navigation system will improve the accuracy of pterygoid implant surgery is still unknown. This study aimed to compare the accuracy of dynamic navigation and free-hand approaches in pterygoid implant placement in completely edentulous maxilla models.
Materials and methods: Twenty three-dimensional (3D)-printed edentulous maxilla models were assigned to two groups: the dynamic navigation system group and the free-hand group. Two pterygoid implants were planned in the bilateral pterygomaxillary area and then placed in each model. The entry, exit and angle deviations of the pterygoid implants were measured after pre- and post-operative cone-beam CT (CBCT) image fusion. Student's t test and Mann–Whitney *U* test were used. A *P* value < 0.05 was considered statistically significant.
Results: A total of 40 pterygoid implants were placed in 20 models. The comparison deviation of the dynamic navigation group and the free-hand group showed a mean (±SD) entry deviation of 0.93 ± 0.46 mm vs. 2.28 ± 1.08 mm ($P < 0.001$), an exit deviation of 1.37 ± 0.52 mm vs.

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3.14 ± 1.82 mm ($P < 0.001$), and an angle deviation of 2.41 ± 1.24° vs. 10.13 ± 4.68° ($P < 0.001$). There was no significant difference in the accuracy with regard to the side factors between the navigation group and the free-hand group.
Conclusion: The dynamic navigation system has higher accuracy for pterygoid implant placement in a complete edentulous maxilla than the free-hand approach.

Introduction

At present, dental implant restoration has become the first choice for patients with missing teeth. The maxilla is mainly composed of cancellous bone with low bone density.[1] In particular, the posterior maxillary region has become one of the most difficult sites for dental implants due to poor bone conditions, lack of residual alveolar ridge bone volume and maxillary sinus pneumatization.[2–4] Clinically, cantilevers of prosthesis, short implants, maxillary sinus floor elevation or zygomatic implants are often used to solve the problem of insufficient bone volume in the posterior maxillary region.[5] However, these techniques may have disadvantages such as a high rate of complications, a long treatment period and severe trauma.[6,7]

Tulasne et al.[8] first introduced pterygoid implants in 1989, in which a tilted implant of 13–20 mm in length was placed in the pterygomaxillary region. The implant is inserted into the maxillary tuberosity, passing through the pyramidal process of the palatine bone and finally reaching the pterygoid process of the sphenoid bone. The pterygoid implant technique does not require bone grafting, which simplifies the treatment procedure, reduces the occurrence of postoperative reactions and pain, and shortens the treatment period. Moreover, it avoids the cantilever of restoration and improves the biomechanical stability of restoration.[9–11] Due to the cortical bone of the pyramidal process and pterygoid process, pterygoid implants can achieve high primary stability, which allows immediate loading for patients. This technique has received increasing attention, especially in the management of patients with a fully edentulous atrophic maxilla.[7] It was reported that the 10-year survival rate of pterygoid implants was 94.85 % in a systematic review,[12] which indicates that the method is feasible. The diameter of pterygoid implants was between 3.75 mm and 4 mm,[13] and in a retrospective cohort study, 160 out of 183 pterygoid implants had a diameter of 4.1 mm.[7] The pterygoids which were 4.3 mm in diameter were chosen in a CBCT-based virtual implant planning study.[5] However, the length of pterygoid implants was varied. It had minimum length of 13 mm according to a systematic review,[12] and according to Bidra et al.,[14] the length ranged from 11.5 mm to 20 mm. In a virtual pterygoid implant planning study, the mean implant length was 16.3 ± 4.2 mm.[5] Rodriguez et al. analyzed 202 Caucasian patients via CBCT and reported that an 18-mm long virtual pterygoid implant could be placed in 147 of the cases (72.8 %).[15] Stefanelli et al. also found that 15-mm and 18-mm implants could be placed in most of the patients who were included in the study.[16] Nonetheless, the high sensitivity of this technique, semi-blindness of the implantation process, and proximity to important anatomical structures such as the descending palatine artery[17] have hindered the promotion of this technique. Furthermore, complications associated with compromised implant positions of pterygoid implants, including bleeding and displacement to the pterygoid fossa and infratemporal fossa, have been reported.[18–20]

Currently, dynamic navigation systems have already been used in guiding implant placement. Through registration and calibration, the surgical tool can be tracked in real time.[21,22] The optimal implant position can be realized virtually by using preoperative planning software and then transferred to the operating field accurately.[23] Therefore, the use of dynamic navigation can play a significant role in guiding the precise placement of pterygoid implants and in the prevention of complications.

However, studies on the application of dynamic navigation for pterygoid implants are still limited.[16,24] To our knowledge, this is the first study comparing the accuracy of dynamic navigation and the free hand approach in pterygoid implant placement in fully edentulous maxilla models.

Materials and methods

The ethics committee of the Shanghai Ninth People's Hospital approved the study (SH9H-2023-T237-1), and it was conducted in accordance with the Helsinki Declaration of 1964, which was revised in 2013.

Model preparation and virtual planning

The inclusion criteria of patient whose cone-beam computed tomography (CBCT) data will be selected as the source for model preparation were that the patient has an atrophic edentulous maxilla and the bone volume of the bilateral pterygomaxillary region was needed to be sufficient to receive tilted implants 4.3 mm in diameter and 18 mm in length. According to Stefanelli et al.,[16] the sample size was calculated by two independent sample t tests using G*Power 3.1 software with a power of 95 % and a level of significance (α).[25] Six dental implants for each group were the minimum requirement.

The fully edentulous maxilla models, including the pterygomaxillary region, were created after 3D reconstruction in Geomagic Studio, version 2013 (3D Systems Inc., Rock Hill, SC, USA). The models were exported in STereoLithography (STL) format. Then, they were manufactured (Zhixi Biomedical Technology Co., Ltd, Shanghai, China) using stereolithography with a tolerance of 0.1 mm and Somos® EvoLVe 128 resin (Covestro AG, Leverkusen, Germany). A total of 20 edentulous maxilla models (Fig. 1) were printed, and 40 implants (NobelActive RP, φ4.3 × 18 mm) (Nobel Biocare Services AG, Zurich, Switzerland) were planned to be placed in the bilateral pterygomaxillary area of the models. The models were assigned to two groups: the dynamic navigation group (n = 10) and the free-hand group (n = 10). One implant was placed in each pterygomaxillary area, and a total of 20 implants were placed in each group.

Six carbon steel mini-screws (φ1.7 mm × 10 mm) (Jianwei Co., Ltd, Shenzhen, China) were inserted into the maxilla models as fiducial markers with polygonal distribution, with three placed on the buccal side of the alveolar crest of the anterior region and two in premolar region and one in the midline palatine suture.[26] The models underwent a CBCT scan (Planmeca ProMax) (Planmeca Oy, Helsinki, Finland) with the following parameters: 96 kV; 7.1 mA; voxel size of 0.4 mm; field of view of 23 cm (D) × 26 cm (H); and scan time of 18 s. The image data of the models in DICOM (Digital Imaging and Communication in Medicine) format were imported into the planning software of the Dcarer dynamic navigation system (Dcarer Medical Technology Co., Ltd, Suzhou, China). The virtual implant plan was designed by an operator (B.T) who did not perform the surgery. The implant position was planned as described by Graves et al.[17] The fiducial markers were then marked in the software.

Dynamic navigation protocol

A reference frame was fixed on the residual crest in the middle line using a mini-screw (φ3 mm × 10 mm) (Dcarer Medical Technology Co., Ltd, Suzhou, China) (Fig. 2a). A handpiece was used to contact each fiducial screw according to previous sequence in the navigation software to accomplish the registration procedure. Then, the surgeon performs a sequential drilling procedure based on the relationship between planned path and drill. All the pterygoid implants were placed under the guidance of the dynamic navigation system (Fig. 2b).

Free hand protocol

In the free-hand group, the operator had access to a virtual plan displayed on a computer screen without the use of navigation assistance. The operator manually followed the virtual position of the implants. All procedures in the dynamic navigation group and free-hand group were performed by a surgeon (N. W) with experience in dynamic navigation and pterygoid implant surgeries.

Accuracy assessment

After placing all implants in both groups, postoperative CBCT was performed using the same parameters. The postoperative images were fused on the preoperative

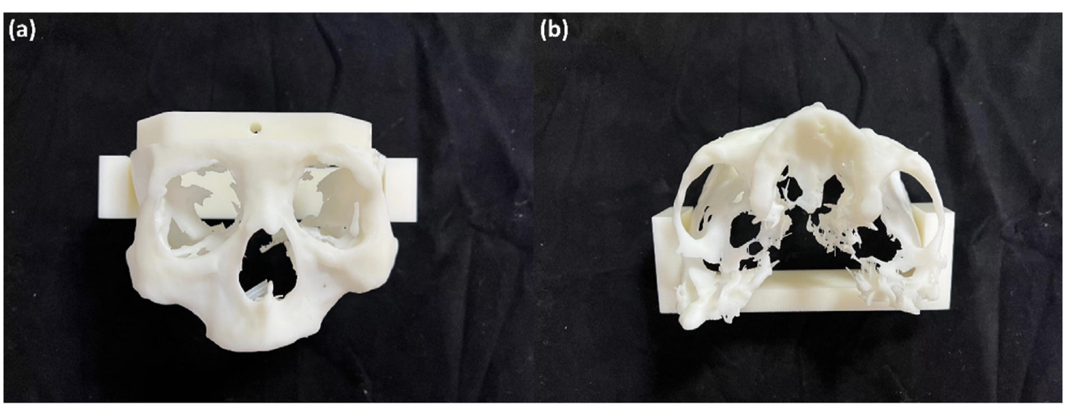

Figure 1 View of edentulous maxilla models. (a. Front view; b. Occlusal view).

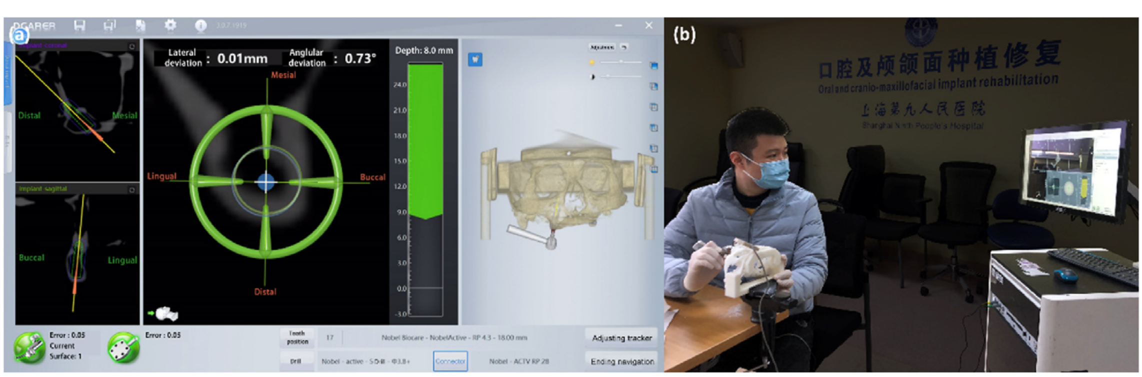

Figure 2 The dynamic navigation computer screen (a) and the operation procedure (b).

design by accuracy assessment software from the Dcarer dynamic navigation system (Dcarer Medical Technology Co., Ltd) to evaluate the entry, exit and angle deviation of the pterygoid implants (Fig. 3). The entry and exit deviation refer to the 3D distance of the centers of the platform and the apex of the planned and placed dental implants. The angle deviation was measured as the angle of the central axis of the implant (Fig. 4).

Statistical analysis

SPSS Statistic 24.0 software (IBM Corp, Armonk, NY, USA) was used for statistical analysis. Descriptive statistics, including the mean, standard deviation, median, minimum, and maximum, were calculated for the measured values, and data outliers were evaluated using box plots. The normality of the data was tested by the Shapiro–Wilk test, and the homogeneity of variance was tested by Levene's test. If the variances were homogeneous, the independent samples *t* test was used; otherwise, the approximate *t* test was used. If the data did not conform to a normal distribution, the Mann–Whitney *U* test was used. $P < 0.05$ was statistically significant.

Results

A total of 40 pterygoid implants were placed in 20 models. The entry, exit and angle deviations are summarized in Table 1. The means of the entry deviations for the dynamic navigation and the free-hand groups were 0.93 ± 0.46 mm and 2.28 ± 1.08 mm, respectively. The mean exit deviations were 1.37 ± 0.52 mm and 3.14 ± 1.82 mm, and the mean angle deviations were $2.41 \pm 1.24°$ and $10.13 \pm 4.68°$ for the two groups, respectively. There were significant differences in the entry, exit and angle deviations ($P < 0.001$).

The implant position (left/right) showed no significant effect on the entry deviation ($P = 0.54$ and 0.95, respectively), exit deviation ($P = 0.65$ and 0.61, respectively) or angle deviation ($P = 0.05$ and 0.06, respectively) in the dynamic navigation group and the free-hand group (Table 2).

Discussion

For partially or fully maxillary edentulous patients with severe pneumatization of the maxillary sinus, or those want to avoid sinus grafting, pterygoid implants become a suitable choice which can achieve posterior support.[27] Pterygoid implants were first introduced by Tulasne at the end of the 1980s and involve three types of bones (the maxillary tuberosity, pyramidal process and pterygoid process).[8] The bone quality of the maxillary tuberosity is mainly D3 to D4.[28] In comparison, the pyramidal process of the palatine bone and the pterygoid process of the sphenoid bone are composed of D1 to D2 bone, so pterygoid process implants have high primary stability.[17] Moreover, for patients with severely atrophic maxilla or maxillary defect, zygomatic implants are indicated,[29] which is another alternative to grafting. However, the surgical procedure is more complex and more prone to complications, and zygomatic implant surgery usually requires sedation, but pterygoid implant surgery is relative easier under local anesthesia.[27] The cost and chair time are also saved in pterygoid implant surgery.[8] However, one of the challenges of pterygoid implant placement is the proximity to vital structures and the potential risk of iatrogenic injury to great vessels, which underscores the importance of accurate implant placement. The most common complication was the intraoperative bleeding.[30] However, because of the narrow surgical space of the pterygoid region and limited mouth opening, the

Figure 3 Accuracy assessment of pterygoid implants.

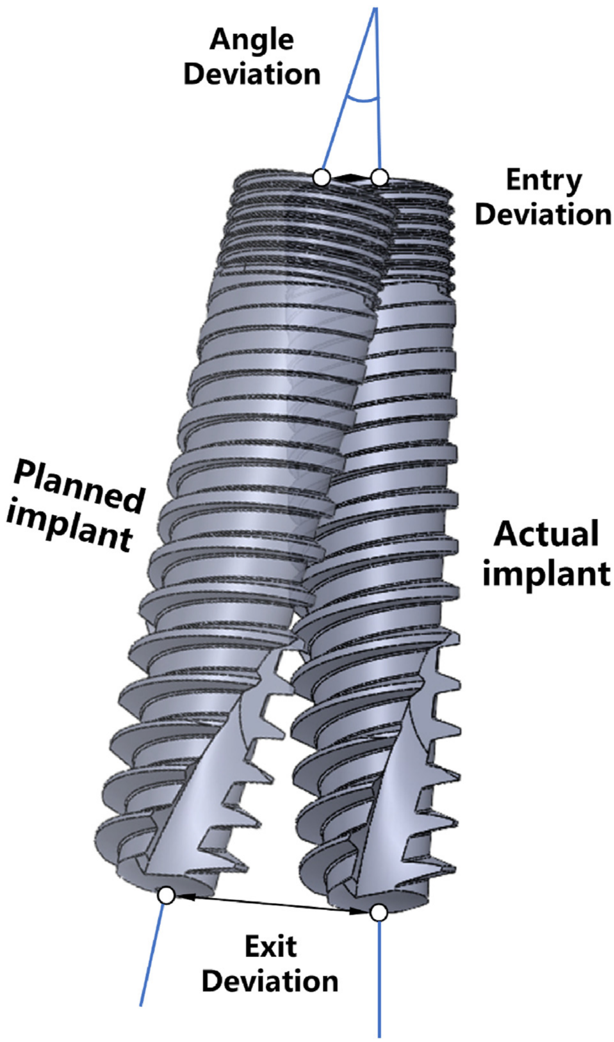

Figure 4 A diagram of entry, exit and angle deviations between the planned and actually placed implants.

surgical area is difficult to access and has limited visibility. The implant site preparation and implant placement process are highly dependent on the experience of the surgeon.[6]

Dynamic navigation is a reliable technique to assist dental implant placement.[31] The dynamic navigation system increased the visibility in an otherwise blind procedure, leading to a more accurate and safer surgery.[32] Furthermore, the entire surgery was real-time guided, which ensures optimal positioning of the implants. The surgical plan could have been adjusted in real time if deviations had been found between the preoperative plan and intraoral situation.[24] To our knowledge, this is the first study to compare the accuracy of pterygoid implant placement using dynamic navigation and the free hand approach in fully edentulous maxilla models. In the present study, the comparison deviation of the dynamic navigation group and the free-hand group showed a mean (±SD) entry deviation of 0.93 ± 0.46 mm vs. 2.28 ± 1.08 mm ($P < 0.001$), an exit deviation of 1.37 ± 0.52 mm vs. 3.14 ± 1.82 mm ($P < 0.001$), and an angle deviation of 2.41 ± 1.24° vs. 10.13 ± 4.68° ($P < 0.001$). Stefanelli et al.[16] reported that the mean deviations between the planned and actual positions for implants were 0.66 mm at the coronal level, 1.13 mm at the apical level, and 2.64° of angular deviation in the dynamic navigation group, compared to 1.54 mm, 2.73 mm, and 12.49°, respectively, in the free-hand approach for implant placement in partially edentulous patients. The results of the present study are consistent with the previous study. Moreover, the side factor has no effect on the accuracy result. The two studies demonstrated that dynamic navigation can be used for pterygoid implant placement with much higher precision than the free hand approach in both partially and fully edentulous patients. Because edentulous patients are lack of anatomical landmarks for pterygoid implant localization, a constant indication and real-time deviation between planned pterygoid implants and drills provided by the

Table 1 Deviations between the planned and placed pterygoid implants (DN: dynamic navigation group; FH: free-hand group).

	Group	Mean (±SD)	Median	P_{25}— P_{75}	Min- Max	*P* value
Entry deviation (mm)	DN	0.93 ± 0.46	0.93	0.56—1.22	0.13—1.89	<0.001
	FH	2.28 ± 1.08	2.23	1.42—3.14	0.60—5.12	
Exit deviation (mm)	DN	1.37 ± 0.52	1.41	0.96—1.93	0.50—2.09	<0.001
	FH	3.14 ± 1.82	2.86	1.65—4.55	0.21—6.77	
Angle deviation (°)	DN	2.41 ± 1.24	2.20	1.65—4.55	0.46—4.76	<0.001
	FH	10.13 ± 4.68	10.46	5.37—14.84	3.66—16.93	

Table 2 Deviations regarding the left and right sides of the dynamic navigation and free-hand groups.

	Dynamic navigation group			Free hand group		
	Entry deviation (mm)	Exit deviation (mm)	Angle deviation (°)	Entry deviation (mm)	Exit deviation (mm)	Angle deviation (°)
Left side	0.86 ± 0.48	1.31 ± 0.67	2.63 ± 1.42	2.29 ± 0.94	3.88 ± 1.84	12.32 ± 3.97
Right side	1.00 ± 0.45	1.42 ± 0.36	2.19 ± 1.05	2.26 ± 1.26	2.40 ± 1.54	7.95 ± 4.47
P value	0.54	0.65	0.05	0.95	0.61	0.06

dynamic navigation system is essential, which makes pterygoid implant surgery more predictable and accurate.[22,33] The incidences of both morbidity and intra- and postoperative complications will also be decreased.

Registration errors and systematic deviations may influence the overall accuracy of navigation surgery.[34] The registration procedure is the most crucial part of dynamic navigation surgery to establish connection between CBCT and real world. However, the registration procedure is different between partially edentulous patients and fully edentulous patients. In partially edentulous patients, the procedure can be completely noninvasive, but mini-screws should be placed as fiducial markers in fully edentulous patients. However, the invasive screw can provide the most accurate registration result compared with other noninvasive approaches.[35]

The limitation of this study is that it was conducted on artificial models. Additionally, this study was performed by a single surgeon, which may cause operator bias. And, the sample size is still small. Additional randomized controlled trials with multiple surgeons are needed to evaluate the accuracy and reliability of the dynamic navigation system in pterygoid implant surgery.

Within the limitations of this in vitro study, the accuracy of the dynamic navigation system was found to be higher than that of the free-hand approach in pterygoid implant surgery, and the left and right sides factors may not influence the final accuracy, suggesting that dynamic navigation-assisted pterygoid implant placement could be an accurate and promising approach. Further studies and corresponding developments are needed for its wide application.

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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