

Accuracy of Dynamic Navigation and Free Hand Surgery Using Zygomatic Implants for Rehabilitation of Atrophic Maxilla – A Split Mouth Study



Abstract

Aim

The zygoma implant has proven to be a viable treatment option for atrophic dentulous maxillae as well as in post maxillectomy conditions. This study aimed to assess the accuracy of implant placement using the conventional technique versus dynamic navigation technology.

Methods

Zygomatic implant placements were performed using the freehand technique in the control group and the dynamic navigation system in the test group. The deviations were assessed by comparing pre and post-operative CBCT scans using the "Evalunav" module in the software.

Results

The mean deviations at the entry site (2D) were significantly lower with the navigation system than with the freehand technique. At the apex (3D), the deviation in implant placement was greater in the freehand group compared to the navigation group. A further comparison was done between the right and left sides of the arch, where a greater deviation on the right side of the arch than on the left was observed with no statistical significance.

Conclusion

The Dynamic navigation system in implant surgery for accurately placing zygomatic implants in patients with atrophic maxilla requiring full-arch rehabilitation reduces variability/errors, ensuring more precise treatment outcomes.

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INTRODUCTION

The advent of dental implants has revolutionized the management of tooth loss, offering a highly effective treatment modality. With the increasing demand for optimal dental function and aesthetics, the utilization of dental implants has expanded substantially in recent decades (1). Zygomatic implants have been the implants of choice in indicated areas because of their predictability in areas of the severely atrophied maxilla (2). Zygoma implants that were introduced by Branemark in the year 1988 are a viable option in means of prosthetic rehabilitation of partially and fully edentulous patients due to their unique feature of lengthened/long screw-shaped nature as they aid as alternatives to bone augmentation procedures in case of severely atrophic maxilla. (3,4)

Position and placement of dental implants play a crucial role and failure of the above two parameters may lead to compromised outcomes resulting in deterioration of peri-implant tissues health (5). As per literature reviews, it was even documented that most of the complications associated with dental implants can be directly related to inaccurate positioning. (6) Freehand or limited guidance from prefabricated stents was used as conventional methods to place implants. Conventional techniques exhibited significant deviations and errors, highlighting the necessity for implant placement approaches that mitigate the risk of damage to adjacent anatomical structures while ensuring precise positioning aligned with prosthetic principles (7,8,9).

Computer-aided implantology is one recent innovation in the field of implant science that has enhanced the predictability and accuracy of implant placements (10). Dynamic navigation is a computer-aided technology that, like static guided surgery, involves an implant planning phase based on CBCT data. However, it additionally incorporates a navigation system that tracks the real-time position of surgical instruments on the CBCT scan, displaying it on a monitor. This guidance method offers continuous feedback throughout the surgery and eliminates the need for a surgical template (11). The accurate placement of implants ensures the long-term stability and functionality of dental implants, enhancing the enduring success of implant-supported restorations and positively impacting the patient's quality of life and well-being. When compared to conventional implant placement procedures, computer-aided implantology has evidenced superior accuracy and precision effectively translating the virtual implant position into the patient's actual clinical situation (12,13). According to research by Kramer et al, Brief et al, and Casap et al, dynamic navigation systems have an approximate entry error of 0.4 mm and an approximate angular deviation error of 4° (14-16). In our previous study the dynamic

navigation system demonstrated superior accuracy and precision in zygomatic implant placement compared to the freehand technique (17). However, despite the introduction of this advanced technology in dental implantology, there are currently only a limited number of studies in the literature comparing the dynamic navigation system and the freehand technique for zygomatic implant placement. Hence this study was taken up to compare the accuracy of freehand technique over dynamic navigation technology. The primary rationale of this study, following a split-mouth design, is to minimize inter-subject variability and enable a direct comparison of techniques (e.g., freehand vs. dynamic navigation) within the same anatomical and biomechanical environment, thereby yielding clinically meaningful conclusions.

MATERIALS AND METHODS

Study design and setting

The present study was a split-mouth randomized clinical trial carried out between March 2021 and December 2022 at Sahyog Maxillofacial center. Patients were selected consecutively from those who presented to the Sahyog Maxillofacial Center and met the inclusion criteria for zygomatic implant placement. Eligibility was determined based on clinical and radiographic evaluation indicating severely atrophic maxillae unsuitable for conventional implants. Patients were randomly assigned using a computer-generated sequence, ensuring equal distribution between freehand and navigated placement groups. The navigation group served as the test group, while the freehand group served as the control group. Ten patients were included in the study, with a total of 20 implants placed.

Calculation of the sample size

Calculations to determine the sample size were performed for angular deviation as the primary outcome using G*power version 3.1.9.4 (Heinrich Heine University, Düsseldorf, Germany). The calculations were based on an effect size of 1.25, an alpha level of 0.05, and a desired power of 80% for a split-mouth design. The estimated sample size was 8 subjects. The final sample size was rounded to 10 patients (18).

Ethical approval and informed consent

The study was approved by the institutional ethics committee and registered in Clinical Trials of India (reference no. REF/2022/09/058911). All the subjects were explained the nature and objectives of the trial and written informed consent was obtained.

Patient selection and inclusion/exclusion criteria

The trial was conducted among patients with severely

atrophic maxilla who required implant placement. Patients with an available alveolar width less than 3 mm and height less than 3 mm in posterior maxilla (distal to canine region) who were willing to participate and agree to give informed consent were included in the study. Patients who were heavy smokers, with limited mouth opening, a history of radiotherapy in the head and neck region, and patients with systemic diseases who were unsuitable for implantation were excluded.

Preoperative Preparation

All patients were subjected to a general oral examination and cone-beam computed tomography (CBCT) examination by Planmeca Promax with standard exposure parameters (voxel size of 0.2 mm, tube voltage of 90 KV, current of 6.00 mA, and exposure time of 120s).

Imaging and software planning

Preoperative implant planning for both the freehand group and the dynamic navigation group was performed by a single operator who was experienced in digital implant design. An intraoral scan (IOS) (MEDIT i700) was taken to obtain a virtual model in STL format. Data from the CBCT was exported in a DICOM file. The DICOM file and the STL file were uploaded into the software (Navident 2.0, ClaroNav Technology Inc., Toronto, Canada) and files were superimposed for carrying out the treatment plan of implant placement for both the groups. No stents were used to transfer the information as the surgery was done freehand. The STL file of the virtual wax-up was generated to aid in implant planning and the fabrication of a customized interim restoration. To integrate digital planning with the surgical procedure, both the DICOM file

(radiographic data) and the designed STL file (virtual wax-up) were uploaded into the dynamic navigation system (Navident 2.0, ClaroNav Technology Inc., Toronto, Canada). These files were then superimposed within the software to create an accurate and precise treatment plan for implant placement, ensuring optimal positioning based on the patient's anatomical structures and prosthetic considerations. All the implants were inserted by an oral and maxillofacial surgeon with more than 3 years of experience with zygomatic and navigational surgeries who is right-handed.

Surgical process of Freehand implant placement

The implant recipient site underwent a midcrestal incision, and a full-thickness flap was elevated. The osteotomy site was prepared using sequential drills and the polish collar implants (ZYGOMATIC™, Noris Medical Dental Implant solutions, Israel) were placed and immediate loading was applied (Fig 1). The torque in each case was measured and exceeded 50 Ncm.

The surgical process of Dynamic Navigation system

A quadrilateral flap was raised to expose the maxillary buttress, using a crestal incision extending from the maxillary lateral incisor to the distal aspect of the first molar. The drill tag was affixed to the drill, while the head tracker was secured (Fig 2). Three landmarks were selected on the virtual model for registration and were then contacted with the tracker. Three bone screws were placed in the regions of teeth 11, 17, and 27, and were used for registration of the patient's jaw. The registration accuracy in the navigation technique was typically checked by verifying the alignment between the patient's actual anatomy and the virtual anatomy



Fig. 1 Initial incision in dynamic navigation system



Fig. 2 Free hand implant placement

displayed on the navigation system. This is often done using a calibration tool, where the surgeon touches specific anatomical landmarks or reference points with a tracked instrument, and compares the physical location to the corresponding location on the CBCT image shown on the monitor. A minimal deviation between the two confirms accurate registration. The handpiece and drill tips were calibrated using a calibrator jig. Each drill was calibrated before drilling commenced (Fig 3). The surgeon used the navigation screen to guide the position and angulation of the osteotomy preparation site and implant placement (ZYGOMATIC™, Noris Medical Dental Implant solutions, Israel) (Fig 4, 5). Immediate loading was applied. The torque in each case was measured and exceeded 50 Ncm. This zygomatic anatomy-guided approach executes the placement of an implant through extra sinus paths wherein anchorage of the maxillary wall is chosen as an additional source (19).



Fig. 3 Instrument calibration

Fig. 4 Angulation assessment in dynamic navigation system software

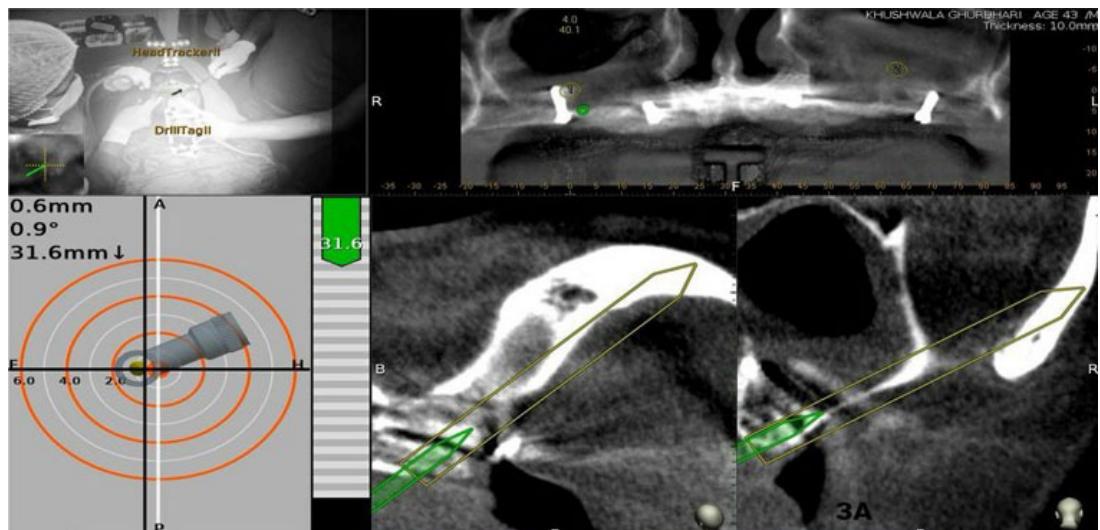
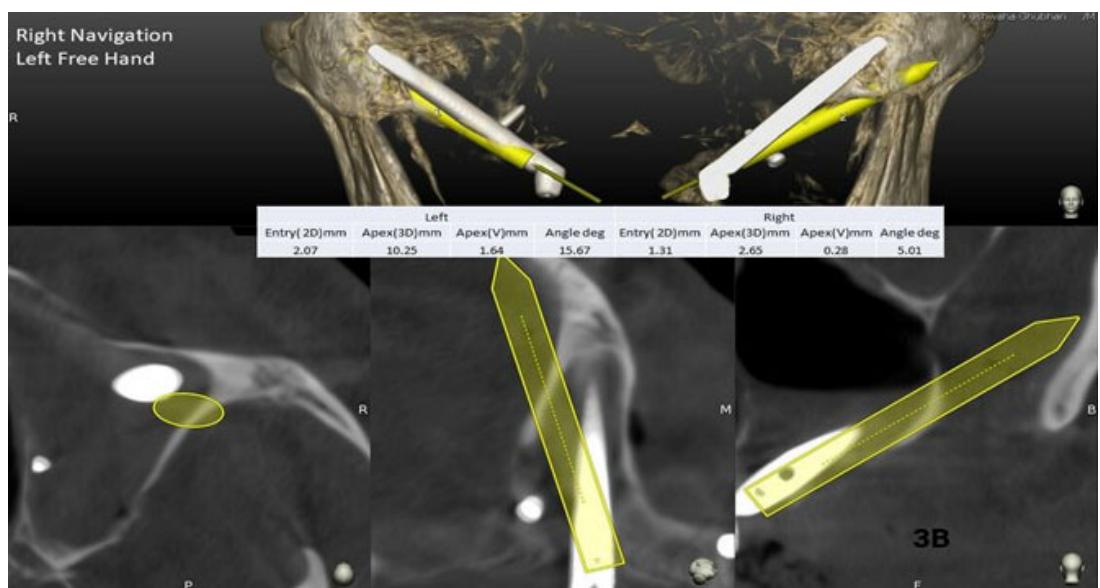


Fig. 5 Digital assessment of deviation



Postoperative treatment

Following surgery, all patients underwent a CBCT scan by Planmeca Promax with standard exposure parameters (voxel size of 0.2 mm, tube voltage of 90 KV, current of 6.00 mA, and exposure time of 120s). They were also all given antibiotics (amoxicillin 500 mg TID for 5 days, or clindamycin 300 mg for penicillin-allergic patients) for 3 days and mouthwash for 1 week. After 7–10 days, the sutures were removed. The patients are restored within 1 week with temporary acrylic prosthesis and permanent PFM prosthesis after 3 months.

Evaluation of accuracy

Both preoperative and postoperative CBCT image data were exported as DICOM files into the Navident software. The deviations were assessed using the “Evalunav” module by superimposing the preoperative and postoperative CBCT images. We analyzed coronal deviation, apical deviation, and angular deviation of the postoperative implant positions with the preoperative designs (Fig 6). The Entry (2d) deviation measured as the horizontal component of the distance (in mm) between the planned drilling point and the actual drilling starting point. The Apex (3d) deviation is the distance (in mm) between the planned and actual implant’s apex location. The Apex (V) deviation is the measurement of only the vertical component of the distance (in mm) between the planned and actual implant’s position. The angular deviation was measured as the angle (in degrees) between the planned and actual implant’s position.

Statistical Analysis

The data obtained were entered into a Microsoft office excel sheet. Data analyses were done using Statistical Package for Social Sciences (SPSS) software version

25.0 (IBM Corporation, USA). The normality of the data was done by using the Kolmogorov-Smirnov test. Wilcoxon Signed Ranks Test was used to compare deviations between freehand and navigation methods. P value <0.05 was considered statistically significant for all the comparisons.

RESULTS

The number of participants analyzed were 10 patients. A summary of patient characteristics and the implants placed is presented in the table. (Table 1). No implant failures were observed during the follow-up period. Complications included mild postoperative swelling (2 cases), transient paresthesia (1 case), and one case of minor wound dehiscence that resolved without intervention. On comparison between the free hand and navigation system, the mean deviations at the point of entry (2D) were 4.16 ± 1.67 mm and 1.85 ± 0.89 mm respectively which are statistically significant ($p=0.005$). At apex (3D) and Apex (V), the deviation in the free-hand group (6.4610 ± 1.77 and 4.49 ± 4.63) was higher compared to the navigation method (3.60 ± 3.54 and 1.25 ± 1.24) ($p<0.05$). A greater angular deviation was observed in the freehand method (11.84 ± 3.44 mm) compared to navigation (4.36 ± 1.51 mm) at a statistically significant level ($p=0.05$) (Table 2). A further comparison was made between the right and left sides of the arch in the navigation group. Though the deviations at entry, were more on the right side (1.94 ± 0.79 mm) compared to the left side (1.76 ± 1.06 mm) no statistical significance was found ($p>0.05$). Similarly, right side of the arch had more deviations as compared to the left side at the apex (3D), apex (V), and angular deviation.

Variable	Freehand Group (n=10)	Navigation Group (n=10)	Total (n=20)
Age (years), Mean \pm SD	61.3 ± 7.518	61.3 ± 7.518	61.3 ± 7.518
Gender (M/F)	6/ 4	6 / 4	10 / 10
Number of Zygomatic Implants per Patient, Mean \pm SD	1	1	2
Number of Remaining Teeth (if any), Mean \pm SD	No. Implants were placed in completely edentulous maxilla	No. Implants were placed in completely edentulous maxilla	No. Implants were placed in completely edentulous maxilla
Side of Arch (Right/Left, n)	5/5	5/5	10/10
Degree of Maxillary Atrophy	Mild=0	Mild=0	Mild=0
	Moderate=0	Moderate=0	Moderate=0
	Severe=10	Severe=10	Severe=20
Implant Characteristics (Length, mm; Diameter, mm)			

Tab. 1 Summary of patient characteristics

S no	Parameter	Method	Samples	Mean	Median	Standard deviation	P value
1	Entry (2D)	Free hand	10	4.1600	4.1650	1.67290	0.005*
		Navigation	10	1.8520	1.4600	.89133	
2	Apex (3D)	Free hand	10	6.4610	6.5500	1.77839	0.009*
		Navigation	10	3.6080	3.5450	1.29465	
3	Apex (V)	Free hand	10	4.4990	4.6300	1.94439	0.005*
		Navigation	10	1.2570	.8000	1.24536	
4	Angular deviation	Free hand	10	11.8450	12.4250	3.44440	0.005*
		Navigation	10	4.3680	4.7600	1.51885	

*Statistically significant, Wilcoxon Signed Ranks Test

Tab. 2 Comparison of different parameters between freehand and navigation methods

DISCUSSION

In the present study, there was a greater deviation at the point of entry (2D), apex (V), and angular deviation for freehand compared to the dynamic navigation system which was statistically significant. In a most recent systematic review by Gerardo Pellegrino et al, the pooled mean implant placement errors were 0.81 (95% CI: 0.677 to 0.943) mm at the entry point and 0.910 (95% CI: 0.770 to 1.049) mm at the apical point. The pooled mean vertical and angular deviations were 0.899 (95% CI: 0.721 to 1.078) mm and 3.807 (95% CI: 3.083 to 4.530) degrees. The navigation group showed significantly lower implant placement errors with respect to the dynamic navigation ($P < .01$) (11). The findings of this systematic review align with our study; however, the mean deviations observed in our study are higher. Similar to our present findings, our previous study demonstrated that the navigation system resulted in significantly lower mean deviations at the entry point (2D) compared to the freehand method. At both the apex (3D) and apex (V), the freehand group exhibited greater deviations than the navigation group. Additionally, the navigation system showed superior accuracy in terms of angular deviation, with a statistically significant difference observed (17). However, our findings are contrary to the invitro study done by Juan Ramon Gonzalez Rueda et al on the accuracy of a computer-aided navigation system in the placement of zygomatic dental implants which stated that the conventional freehand technique in the placement of zygoma implants was more precise at the coronal and apical end points (20). In a randomized controlled study conducted by González Rueda et al. in 2023, statistically significant differences were observed in apical end-point deviations between the freehand and navigation groups ($p = 0.0053$). Notably, the FHI technique demonstrated lower deviation values at the apical end point. They suggested that the freehand technique yields more accurate placement of zygomatic dental implants compared to computer-

assisted surgical methods, likely due to the influence of the learning curve associated with each placement technique (21).

A notable observation in this study was the presence of greater deviations on the right side compared to the left; however, this difference did not reach statistical significance. In a recent study conducted by our team, the accuracy of implant placement on the left and right sides was evaluated using both conventional and dynamic navigation systems, and no statistically significant differences were found between the two sides (17).

As the literature search has emphasized the accuracy of dynamic navigation, the learning curve associated with it has to be overcome which requires patience and practice (22, 23). Conversely, a study conducted by Wang W. et al. demonstrated that dynamic computer-assisted zygomatic implant surgery (dCAZIS) exhibited a learning curve in terms of operation time, but not in implant accuracy. While prior experience in zygomatic implant surgery had minimal influence on the learning curve, experience in navigation surgery was identified as a significant contributing factor (24). The advantages of the dynamic navigation system extend beyond accuracy to include the flexibility to adjust the planned surgical approach during the procedure, based on real-time clinician feedback (25). The primary limitation of our study is the relatively small sample size, which may affect the generalizability of the findings. Further studies with a larger sample size are needed to validate our findings and improve their generalizability. All procedures in this study were carried out by experienced clinicians under controlled clinical conditions. Consequently, it is uncertain whether similar outcomes could be consistently achieved by practitioners with varying levels of expertise in routine clinical settings. Factors such as the clinician's proficiency in implant placement, prosthetic planning, and overall case management may significantly influence the results. The study focused on a specific edentulous pattern, and it

remains uncertain whether the same clinical outcomes can be achieved across different types of edentation. These variations may require different surgical and prosthetic approaches, potentially affecting the predictability and success of the treatment.

CONCLUSION

The findings of the present study indicate that dynamic navigation technology offers significantly greater accuracy in implant placement compared to the freehand technique, particularly at the apex and entry point in patients requiring zygomatic implants. This suggests that dynamic navigation may be a more precise strategy for inserting zygomatic implants in patients with atrophic maxillae undergoing full-arch rehabilitation. To further strengthen the evidence base and enhance methodological validity, the authors recommend conducting additional clinical trials utilizing advanced computer-assisted navigation systems.

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