Comparative Evaluation of the Accuracy of Dynamic Navigation and Free Hand Methods During Zygomatic Implant Placement: A Randomized Controlled Trial

Gautami S. Penmetsa, MDS[1]*
Rahul Manhar Shah, MDS[2]
M. A. K. V. Raju, MDS[3]
Praveen Gadde, MDS[4]
Ramaraju Alluri Venkata, MDS[5]

To assess and compare the precision and predictability of zygomatic implants in atrophic maxilla using conventional and dynamic navigation methods. This study was a randomized controlled clinical trial conducted in patients requiring zygomatic implant placements in the atrophic maxilla. Forty zygomatic implants were placed in systemically healthy individuals. Zygomatic implant placement was done using the freehand technique in the control group, and the test group involved implant placement using a dynamic navigation system, and the entry, apex, and angular deviations were evaluated. The mean deviations at the site of entry (2D) in the navigation system (2.531.42) as compared with the freehand (4.151.29) were statistically significant. The variation in the freehand group was greater than the navigation method at the apex (3D) ($P < .05$). The navigation method had a higher accuracy in angular deviation than the freehand method (4.02 ± 1.80 and 12.67 ± 2.11). Also, the accuracy was checked on the right and left sides in both the conventional and dynamic groups. The dynamic navigation technology had better predictability in terms of accuracy and precision, and it is the need of the hour for clinicians to master this technology and thereby aid in better prognostic level of implant placements.

Key Words: zygomatic implants, dynamic navigation, atrophic maxilla

INTRODUCTION

Implant dentistry has revolutionized modern dentistry in terms of replacing the missing teeth. Due to most patients undergoing implant surgery, complications are also on the rise owing to inaccuracies in placing implants, thereby compromising the precision and predictability of implant surgery.[1] The accurate positioning of implants plays a pivotal role in prosthetic rehabilitation, enhancing the survival and longevity of implants. With the advent of guided implant surgery in the early 21st century and recent advancements in digital technologies, biologically and prosthetically ideal implant positioning has become the crux of implant dentistry. Implant placements aiding computer-guided technology have evidenced 2 different approaches, one being the static guided system and the other the dynamic navigation system.[2] Dynamic navigation surpasses static-guided implant surgery by addressing limitations such as the inability to adjust intraoperative positional changes and challenges like restricted mouth opening in patients. Literature indicates dynamic navigation offers superior accuracy for zygomatic implant placement compared with static navigation or freehand methods. Static surgical guides also obstruct direct vision to surgical sites and involve a complex manufacturing process.[3]

Zygomatic implants introduced by Branemark in 1988 offer a solution for attaining anchorage of the maxillary posterior regions and play a vital role in oral rehabilitation.[1] Their unique feature of lengthened/long screw-shaped nature posed themselves as alternatives to bone augmentation procedures in case of severely atrophic maxilla.[4] Most recent research stated that Dynamic navigation systems have an approximate entry error of 0.4 mm and an approximate angular deviation of 4 mm,[5–8] which is far more minimal and accurate than conventional surgery. This advantage of dynamic surgery over conventional implant surgery in terms of precision and predictability would overcome the limitations of conventional implant surgery, thereby enhancing the long-term benefits of patient-related outcomes in the overall enhancement of functionality and esthetics.[9] With this technique, diagnosis, and treatment can be completed more quickly, safely, and precisely.[10] Static-guided implant surgery does not allow for intraoperative positional changes, and the implant's position is

[1] Department of Periodontics and Implantology, Vishnu Dental College, Andhra Pradesh, India.
[2] Sahyog Maxillofacial Center, Thane, Maharashtra, India.
[3] Department of Department of Orthodontics, Vishnu Dental College, Andhra Pradesh, India.
[4] Department of Public Health Dentistry, Vishnu Dental College, Andhra Pradesh, India.
[5] Department of Prosthodontics and Implantology, Vishnu Dental College, Andhra Pradesh, India.
* *Corresponding author*, e-mail: gautamipenmetsa@gmail.com
https://doi.org/10.1563/aaid-joi-D-23-00096

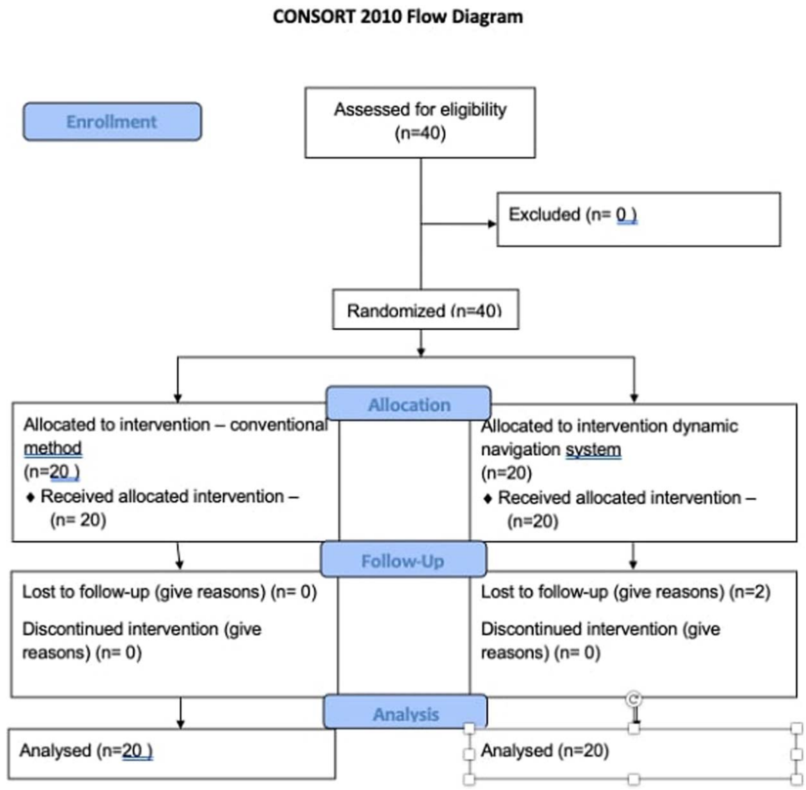

FIGURE 1. CONSORT flowchart.

fixed by the stent. With cone-beam computed tomography (CBCT) imaging and other coordinating data, osteotomy evaluation, surgical techniques, and restorative outcomes can be predetermined during guided surgery, reducing surgical challenges and ensuring accuracy. Utilizing CBCT images in conjunction with implant planning software allowed the virtual planning of the ideal implant location concerning surrounding critical anatomic structures and future prosthetic requirements. As dynamic technology strengthens practice, competitive advantage, and patient experience and expands the potential for more immediate, more accurate, and less invasive treatment options with an overall increase in treatment acceptance rates, more and more clinicians globally recognize the benefits of dynamic guided surgery.[11] Essentially, the navigation approach offers virtual surgical guidance that can be adjusted based on the circumstances that arise during the procedure.[12]

However, computer-aided implants, a more recent innovation in Implantology, have limited research literature. Hence, there is a dire need to conduct this research to evaluate the precision and predictability outcomes of conventional and dynamic navigation methods.

Materials and Methods

Study design and setting

This randomized controlled clinical trial, conducted between March 2021 and December 2022, investigated zygomatic implant placements in atrophic maxilla. In this 2-arm parallel study design, subjects were randomly assigned to groups using a coin toss method.

Calculation of the sample size

Using G*power version 3.1.9.4, calculations were made to establish the sample size with angular deviation as the primary outcome. The calculations were made using a parallel design, an effect size of 0.923, an alpha level of 0.05, and a target power of 80%. The estimated sample size was 40 subjects. Forty systemically healthy individuals were randomly assigned, with 20 in both test (DNS) and control (freehand) groups (Figure 1).

Ethical approval and informed consent

The institutional ethics committee approved the study (reference no. IECVDC/22/F/PI/IVV/112) and registered in Clinical Trials of India (reference no. REF/2022/09/058911). The nature and objectives of the trial were explained to all subjects, written informed consent was obtained, and recruitment was carried out in accordance with the Declaration of Helsinki on Medical Protocols and Ethics.

Patient selection and inclusion/exclusion criteria

The trial was conducted among patients who required implants in the maxillary region. The inclusion criteria were as follows: Patients with good systemic and oral health who were willing to participate and agree to give informed consent were included in the study. Patients with uncontrolled systemic disorders, habit of smoking, restricted mouth opening, and received head and neck radiation therapy in the past were excluded.

Figure 2. Initial incision in freehand placement.

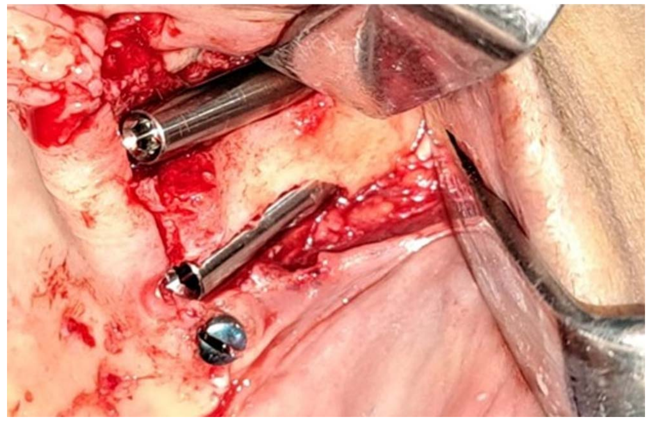

Figure 3. Freehand implant placement.

Preoperative preparation

All patients underwent a thorough oral examination as well as a CBCT examination by Planmeca ProMax using industry-standard exposure parameters (voxel size of 0.2 mm, tube voltage of 90 KV, current of 6.00 mA, and exposure time of 120 seconds). The recommended local prophylactic treatment (Clindamycin 600 mg/os or amoxicillin/clavulanic acid 2 g/os 60 minutes before surgery) was adhered to.

Imaging and software planning

An operator skilled in digital implant design created preoperative implant position designs for both groups. A digital intraoral optical scan (3Shape) and DICOM files were used to generate virtual casts. For the dynamic navigation group, the DICOM and planned STL files were uploaded to the dynamic navigation system (Navident 2.0, ClaroNav Technology, Inc, Toronto, Canada) for treatment planning. Optimal 3-dimensional implant positioning was determined using virtual crowns based on restorative and biologic requirements. In the freehand group, a surgical stent based on diagnostic wax-up was used to assess implant position during surgery.

Preoperative planning

Four mono-cortical screws were inserted under local anesthesia at the canine and first molar regions on each side of the maxilla preoperatively to aid in subsequent registration with the dynamic navigation system. Preoperative CBCT scans were taken and loaded into the Navident software to plan the position of 4 zygomatic implants, 2 on each side. The software guided the surgeon in selecting the implants' optimal length, direction, and position based on zygomatic bone thickness and remaining alveolar bone height.

Registration and calibration process

Two trackers, one on the nasal bridge and the other on the handpiece, were used for registration. Stereo cameras recorded their positions and also tracked surgical instruments, including drills, in relation to CBCT scans. Four screws in the maxilla served as fiducial points linked to CBCT scans via digitization. Drill tips were positioned for software learning. The dynamic navigation system provided real-time 3D guidance of instruments and accurately tracked instruments and implant positions throughout the procedure.

Surgical process of freehand implant placement

Local infiltration anesthesia was given, the implant recipient site underwent a midcrestal incision, and a full-thickness flap was elevated (Figure 2). The Osteotomy site was prepared using sequential drills, and the cover screw was placed (Figure 3).

The surgical process of dynamic navigation system

Local infiltration anesthesia was given. The jaw tag was fastened to the appropriate jaw, and the drill tag was fastened to the handpiece. Calibration of hand piece and drill tips was carried out (Figure 4). The planned position on the computer screen of the dynamic navigation system guided the placement of zygomatic implants. The surgical drill's starting position and the osteotomy's depth were monitored in real-time via the computer screen. A changing color display from green to yellow guided the operator to the depth of the drill; it changed into red when the planned depth was achieved (Figure 5).

Figure 4. Instrument calibration.

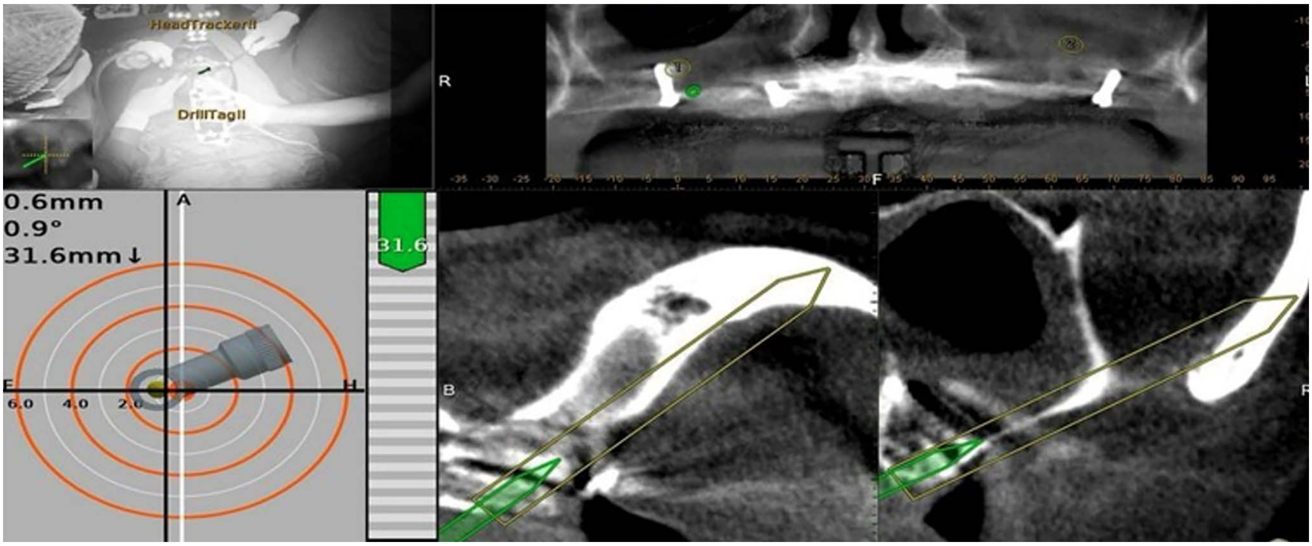

Figure 5. Angulation assessment in dynamic navigation system software.

Postoperative Treatment

All patients underwent CBCT scans using the same parameters described before and after surgery. They were also given mouthwash for a week and antibiotics for 3 days.

Evaluation of Accuracy

The Navident software "EvaluNav" compared postoperative scans with preoperative planning (Figure 6). Deviations in implant position were calculated for coronal, apical, and angular aspects. Coronal deviation measured the separation between implant coronal platforms, apical deviation used the distance between implant apices, and angular deviation was assessed by implant axis angle.

Statistical analysis

The data were analyzed using Statistical Package for Social Sciences (SPSS) software, version 25.0 (IBM Corporation). Normality was assessed using the Kolmogorov-Smirnov test. Descriptive analyses were conducted. The Mann-Whitney *U* test was used to compare deviations between freehand and navigation methods.

Results

The navigation system resulted in lower mean deviations at the entry point (2D) on the left side (2.53 ± 1.42) compared with the freehand method (4.15 ± 1.29) with a statistically significant

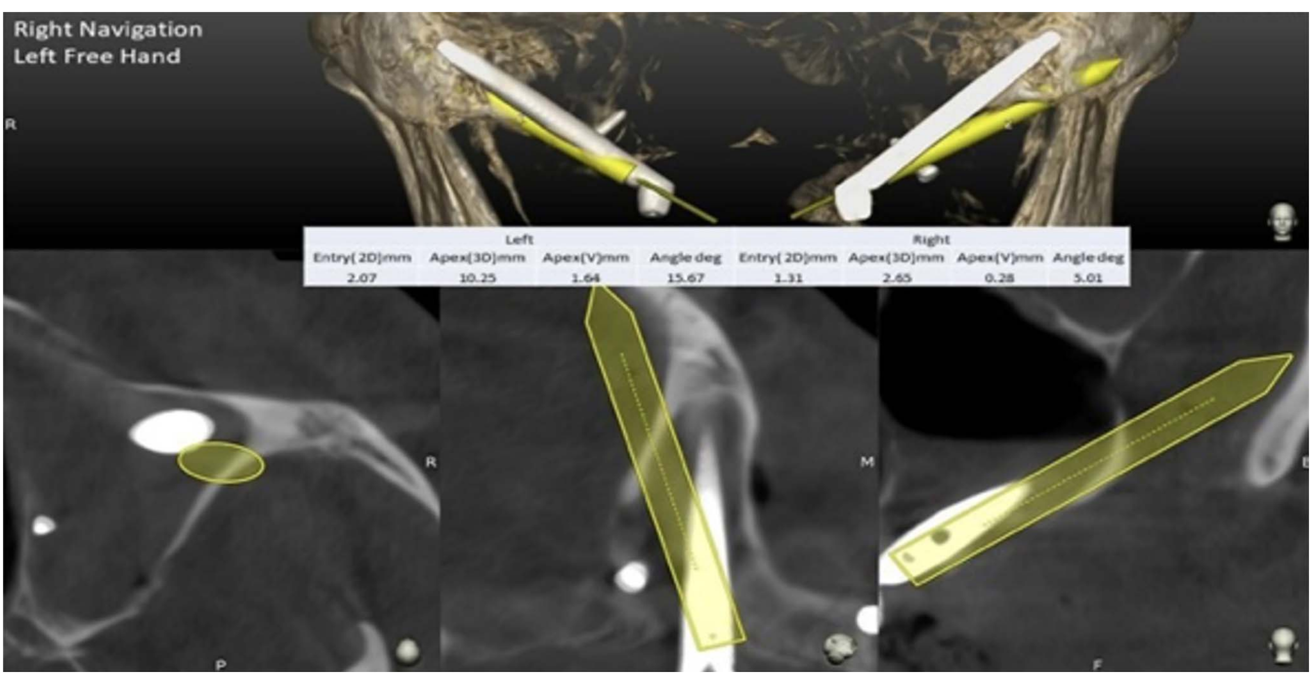

Figure 6. Digital assessment of deviation.

Table 1

Comparison of deviations between the groups on the left side

S no.	Parameter	Method	Samples	Mean	SD	P value
1	Entry (2D), mm	Navigation	20	2.5315	1.42647	.001*
		Freehand	20	4.1540	1.29853	
2	Apex (3D), mm	Navigation	20	3.4065	1.53546	.001*
		Freehand	20	6.4470	1.64293	
3	Apex (V), mm	Navigation	20	2.1485	1.17369	.001*
		Freehand	20	4.6305	1.96047	
4	Angle deg	Navigation	20	4.0270	1.80428	.001*
		Freehand	20	12.6730	2.11702	

*Statistically significant, Mann-Whitney *U* test.

Table 3

Comparison of deviations between the right and left sides in the dynamic navigation method

S no.	Parameter	Method	Samples	Mean	SD	P value
1	Entry (2D), mm	Right	20	2.0250	1.05740	.223
		Left	20	2.5315	1.42647	
2	Apex (3D), mm	Right	20	3.0440	1.35196	.317
		Left	20	3.4065	1.53546	
3	Apex (V), mm	Right	20	1.5570	1.37132	.053
		Left	20	2.1485	1.17369	
4	Angle deg	Right	20	3.9115	1.74164	.766
		Left	20	4.0270	1.80428	

difference ($P = .001$). At the apex (3D) and apex (V), the freehand group showed higher deviations compared with navigation ($P < .05$). Navigation also exhibited greater accuracy in angular deviation (4.02 ± 1.80) compared with freehand (12.67 ± 2.11); a significant difference was observed ($P = .001$; Table 1). On the right side, the navigation system had mean deviations at the entry point (2D) of 2.02 ± 1.05, while the freehand method had deviations of 4.13 ± 0.87. Navigation showed significant accuracy improvements at apex (3D) and apex (V) compared with freehand. Additionally, the angular deviation was significantly lower with navigation (3.91 ± 1.74) compared with freehand (12.8 ± 2.20; Table 2). In the navigation method, deviations at entry were higher on the left side (2.53 ± 1.42) compared with the right side (2.02 ± 1.05), but this difference was not statistically significant ($P > .05$). Similarly, the left side exhibited more deviations at the apex (3D), apex (V), and angular deviation compared with the right side (Table 3). For the freehand method, mean deviations at the entry point were 4.13 ± 0.87 on the right side and 4.15 ± 1.29 on the left side. No statistically significant differences were found at the apex (3D) and apex (V) on either side (right: 6.99 ± 1.25 and 5.40 ± 1.05; left: 6.44 ± 1.64 and 4.63 ± 1.96). Additionally, no significant differences were found for angular deviation between the right side (12.81 ± 2.20) and the left (12.67 ± 2.11; Table 4).

Discussion

Oral rehabilitation has become the primary objective of any practicing dental surgeon due to the increasing demands from the patients as well. In this regard, replacing natural teeth with dental implants has become a common domain in dentistry. As the main challenge lies in optimal implant positioning and placement, sufficient training and acquaintance with computer-aided technology become the need of the hour. While conventional methods offer simplicity, controlled irrigation, and patient accessibility, they are prone to more errors than navigation methods. Navigation technology enhances depth control accuracy and reduces the risk of damaging vital anatomical structures. Additionally, it allows for flapless or limited flap elevation, improving postoperative patient comfort.[8]

The flapless surgical protocol utilized in this study helps reduce unpredictable crestal bone resorption, often associated with flap reflection, which can alter bone periosteum vascularization and impact final esthetic results.[9] Hence, this study was a novel attempt to assess the precision and predictability of freehand vs conventional implant placements.

In this study, compared with the dynamic navigation system, there was a statistically significant increase in deviation at the point of entry (2D), apex (V), and angular deviation for freehand. Our findings align with the recent systematic review and meta-analysis by Tahmaseb et al,[13] which included 24 clinical and preclinical studies. They reported a total mean error of 1.12 mm (maximum of 4.5 mm) at the entry point, measured across 1530 implants, and 1.39 mm at the apex (maximum of 7.1 mm), measured across 1465 implants.[10] One of the most recent systematic reviews by Pellegrino et al[14] analyzed the disparities between dynamic and freehand methods and the intraoperative

Table 2

Comparison of deviations between the groups on the right side

S no.	Parameter	Method	Samples	Mean	SD	P value
1	Entry (2D), mm	Navigation	20	2.0250	1.05740	.001*
		Freehand	20	4.1325	.87736	
2	Apex (3D), mm	Navigation	20	3.0440	1.35196	.001*
		Freehand	20	6.9970	1.25791	
3	Apex (V), mm	Navigation	20	1.5570	1.37132	.001*
		Freehand	20	5.4080	1.05628	
4	Angle deg	Navigation	20	3.9115	1.74164	.001*
		Freehand	20	12.8115	2.20399	

*Statistically significant, Mann-Whitney *U* test.

Table 4

Comparison of deviations between the right and left sides in the freehand method

S no.	Parameter	Method	Samples	Mean	SD	P value
1	Entry (2D), mm	Right	20	4.1325	.87736	.850
		Left	20	4.1540	1.29853	
2	Apex (3D), mm	Right	20	6.9970	1.25791	.273
		Left	20	6.4470	1.64293	
3	Apex (V), mm	Right	20	5.4080	1.05628	.199
		Left	20	4.6305	1.96047	
4	Angle deg	Right	20	12.8115	2.20399	.850
		Left	20	12.6730	2.11702	

complications and failures. Thirty-two research papers were included, of which 10 dealt with complications and implant failures (1039 implants) and 10 reported accuracy values (2756 implants). At the entry point, the pooled mean implant placement errors were 0.81 (95% CI) mm, and at the apex, they were 0.910 (95% CI) mm. The average vertical and angular deviations were 0.899 mm and 3.807 (95% CI) degrees, respectively. When compared with the freehand technique, the navigation group dramatically reduced implant positioning errors, and when compared with the static method, it demonstrated comparable accuracy values ($P < .05$). The pooled prevalence of failures was 1% (95% CI). Based on the results of the above study, dynamic navigation is greater in precision and accuracy than freehand implant surgery, even adding to minimal placement errors and a more accurate technique.[12,13]

In contrast to the in vitro study by González Rueda et al,[11] our research showed that the freehand conventional technique for placing zygomatic implants was more accurate than computer-aided dynamic navigation at the coronal and apical levels. However, the dynamic navigation technique outperformed the conventional technique at the angular level.[11] Similarly, in a study by Aydemir and Arısan,[15] the computer-aided dynamic navigation technique produced lower angular deviation than the freehand conventional technique, but the conventional freehand technique offered greater accuracy at the coronal entry-point and apical endpoint levels when placing zygomatic implants.[15] The outcomes support the hypothesis that the differences between the dynamic navigation system and the freehand technique may be attributed to the steep learning curve needed to acquaint the computer-aided dynamic navigation systems. Furthermore, Jung et al[15] found comparable safety, outcomes, morbidity, and efficiency with conventional-length dental implants between computer-aided navigation and freehand techniques. Both studies suggest that deviations at apical and coronal endpoints may be due to the learning curve, particularly challenging with dynamic navigation, requiring patience and persistence. Brief et al argued that the accuracy achieved with the conventional freehand approach is typically adequate for most clinical situations compared with dynamic navigation systems. They highlighted an entry error of approximately 0.4 mm and an angular deviation error of 4 degrees, which they considered acceptable in practice.[6]

Our study compared accuracy between the left and right sides using conventional and dynamic navigation systems, a novel approach. However, no statistically significant variations were found between implants on either side in both groups. This can be attributed to all 40 implants a single experienced surgeon placed, minimizing interoperator bias. Additionally, the surgeon's mastery of surgical skills and learning curve likely contributed to consistent results. Despite the cost and learning curve associated with dynamic navigation technology, its superior predictability in accuracy and precision makes it essential for clinicians to master. With literature supporting its advantages, clinicians can enhance the prognostic level of implant placements by adopting this technology.

Conclusion

Dynamic navigation technology has proven to be more effective in terms of precision and accuracy, emphasizing that computer-aided implantology will be the future of implant dentistry.

Acknowledgments

Dr Gautami S. Penmetsa has contributed to study conception, design and preparation of manuscript. Dr Rahul Manhar Shah performed clinical procedures and collected the data. Dr M. A. K. V. Raju critically evaluated the manuscript. Dr Praveen Gadde has contributed to evaluation and analysis of data. Dr Ramaraju A. V. has contributed to manuscript preparation.

Note

The authors do not have any conflict of interest.

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