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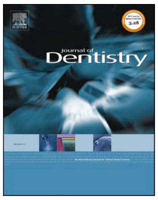

Dynamic navigation for zygomatic implant placement: A randomized clinical study comparing the flapless versus the conventional approach

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ABSTRACT

Objectives: The assessment of the accuracy of flapless placement of zygomatic implants in edentulous maxilla using dynamic navigation.
Methods: A randomized controlled trial was carried out on 20 patients. Patients were randomized into two groups, the flapless (Group 1; n=10) and the conventional (Group 2; n=10). In each case two zygomatic implants were inserted under local anaesthesia, one on the right and one on the left side guided by a dynamic navigation system. The surgical procedure was identical in the two groups except for the reflection of the mucoperiosteal flap which was eliminated in the flapless cases. Postoperative CBCT scans were used to assess the accuracy of the placement of zygomatic implants.
Results: Osseointegration was achieved for all the implants, except one case in the flapless group. Statistically significant differences in the accuracy of the position of the zygomatic implants was found between the flapless and the conventional groups, measured at the apex and the entry points of the implants ($p < 0.01$). The average apical and coronal deviations were 5 mm and 3 mm, respectively; the angular deviation was 6°, and 2 mm vertical apical disparity was detected between the planned and the achieved surgical position. Perforation of the Schneiderian membrane was noted in three cases, one in flapless group and two in the conventional group.
Conclusions: Flapless placement of zygomatic implants guided by dynamic navigation offered satisfactory safety and accuracy.
Clinical significance: This is the first clinical trial to prove the feasibility and accuracy of flapless placement of zygomatic implant with minimal morbidity. The study highlights the innovative reflection of the Schneiderian membrane under guided surgical navigation. The procedure can be performed under local anaesthesia, which offers clinical advantages. Adequate training on the use of dynamic navigation is mandatory before its use in clinical cases.

1. Introduction

Zygomatic implants offer a reliable option for the rehabilitation of the atrophic edentulous maxilla and following maxillectomy [1]. The placement of zygomatic implants is challenging due to its proximity to the maxillary sinus, the orbital cavity, and the infra-temporal fossa [2]. The conventional surgical approach for placement of zygomatic implants requires the reflection of a mucoperiosteal flap for the wide exposure of the maxilla and the buttress part of the zygoma. This approach also provides access to the Schneiderian membrane, which is routinely protected through a bony window, cut in the buccal wall of the maxillary sinus. Therefore, in most of the cases, the procedure is carried out under general anaesthesia to facilitate the accurate placement of the zygomatic implants with minimal morbidities. The literature has highlighted the morbidities associated with the standard approach for the placement of zygomatic implants, including facial bruising, and paraesthesia due to damage to the infra-orbital and zygomatico-facial nerves [3].

On the other hand, the flapless placement of dental implants preserves a healthy peri-implant soft tissue contour and maintains the blood supply, which improves postoperative recovery. It also reduces the operating time and patient discomfort [4]. The flapless technique for the placement of zygomatic implants has been tried on cadavers with the use of a surgical template guides [5].

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To improve the surgical accuracy, static guides have been used to transfer the pre-planned position of zygomatic implants to the surgical site. Even though the surgical stent guides the location and trajectory of the zygomatic implant it does not control the depth of the preparation or the correct angulation [6]. Dynamic navigation promises a more accurate anatomical placement of the implants that resembles the planned preoperative position [7]. In a recent study [8] dynamic navigation was used in ten patients who required at least one implant in the aesthetic area. No implant failed, and no biological or mechanical complications occurred during the follow-up, accounting for a cumulative success rate of 100%. The authors explained that the drills and implant movements, which were monitored in real-time using a dynamic guided navigation system, provided better tactile sensation during osteotomy preparations. It was concluded that the dynamic guided navigation system has several advantages in comparison with the freehand and the static surgical guided placement of dental implants. The static surgical guides have the disadvantage that they block the direct view to the surgical sites and require complex manufacturing processes.

The literature on dynamic navigation suggests that it offers superior accuracy for zygomatic implant placement in comparison with both the static navigation and the freehand techniques. The investigation by Gao et al. evaluated the freehand placement of 14 zygomatic implants. They reported the entry, exit, and angular deviations of 4.99 ± 2.66 mm, 6.11 ± 4.28 mm and 8.36 ± 5.3°, respectively [9]. Vrielinck et al. reported on the accuracy of 18 zygomatic implants, which were guided with customized surgical templates, and found mean entry, exit, and angular deviations of 2.77 mm, 4.46 mm, and 5.1°, respectively [10]. A comprehensive study confirmed a static guide is not as effective as a dynamic guide for the accurate placement of implants [11].

To avoid the complications associated with the insertion of zygomatic implants and to improve the placement accuracy, various navigation systems have been used to guide the surgical procedure. These include: Vector Vision Brain Lab [12] VoXim [13], IPlan Navigator [14] X Guide [15], IGOIS [16], AccuNavi [17], ImplaNav [18], VISIT [19]. The mean differences between the planned and surgically achieved positions of the placed zygomatic implants were measured. However, in most of these studies the sample size was limited.

Hung et al. [20] studied the accuracy of 40 zygomatic implants, which were placed using a real time dynamic navigation system in 10 patients. The deviations in the entry, exit and implant angulation were 1.35 ± 0.75 mm, 2.15 mm ± 0.95 mm, and 2.05 ± 1.02°, respectively. These were not statistically significant. More significant inaccuracies have been associated with the use of stereolithographic surgical guides for placement of zygomatic implants. Chrcanovic et al. [21] reported on placement errors associated with zygomatic implants. The anterio-posterior view showed an angular deviation of 8.06 ± 6.40°, with the caudal-cranial view showing deviations of 11.20 ± 9.75° when compared with the planned position.

In an effort to reduce the postoperative morbidity associated with the full exposure of the zygoma for the placement of zygomatic implants, the flapless approach has been studied in formalin-fixed human cadavers. The results appeared promising, and the authors recommended further investigation [22].

It is therefore logical for our team to explore the accuracy of the flapless placement of zygomatic implants guided by dynamic navigation. The rationale of the study was to encourage this procedure to be carried out under local anaesthesia with minimal operative complications, limited postoperative morbidities, and with satisfactory accuracy.

The null hypothesis was that there would be no statistically significant difference in the accuracy between the flapless and the conventional approach for the placement of zygomatic implants guided by dynamic navigation.

2. Materials and methods

A prospective randomized controlled trial was carried out on 20 patients in accordance with CONSORT guidelines 2010 (Flowchart Fig. 1). Institutional ethical committee clearance was obtained (IHEC/SDC/PhD/OMFS-1611/21/244). The study was registered as clinical trial (CTRI/2022/08/044951). An informed consent was obtained, and recruitment was carried out in accordance with the Declaration of Helsinki on Medical Protocols and Ethics. The study was limited to patients who require the rehabilitation of atrophic edentulous maxilla using two standard dental implants, one at each canine region, and two zygomatic implants, one on each side, either intra or extra sinus (ZAGA classification 0 to 4) [23]. The power calculation was carried out using G power version 3.1.5 based on apical deviation of the implants with a confidence level of 90%, Z-score of 1.65, effect size of 6.7 and α error 0.01. This required 15 implants in each group to reach a statistically significant difference at $p<0.01$ and power of 80%. Anticipating 20% drop out, the sample size was planned as 20 implants in each group [24].

Patients were randomized into two groups to evaluate the accuracy of placement of zygomatic implants, the flapless (Group 1; n=10), and the conventional (Group 2; n=10). For each case two zygomatic implants were inserted, one on the right side and one on the left side, guided by the Navident dynamic navigation system (ClaroNav, Toronto, USA). Therefore, the study assessed the accuracy of 40 zygomatic implants, 50% were placed *via* the flapless approach (Group 1) and the other 50% *via* the standard conventional technique (Group 2).

Patients with deficient anterior alveolar height "less than 12 mm", and of Lekholm & Zarb Type I and Type II bone density were excluded from the study. In type I, the entire bone is composed of very thick cortical bone, in type II, thick layer of cortical bone surrounds a core of dense trabecular bone; [25]. Exclusion criteria also included sufficient alveolar height for insertion of dental implants posteriorly, chronic sinusitis, uncontrolled diabetes mellitus, chronic smoking, and immunocompromised cases.

A single operator performed the procedure after completing a comprehensive training on the use of dynamic navigation to guide the placement of zygomatic implants. A pilot study was carried out which preceded the main investigation to standardize the methodology and the assessment protocol. The patients were randomized to the study and

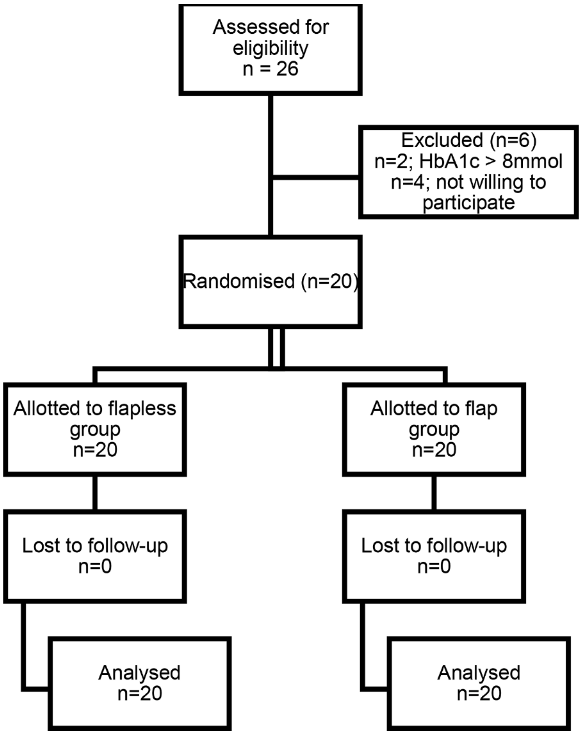

Fig. 1. The flowchart of the recruited, included, randomized, and the followed-up patients in the study.

control groups before commencement of the procedure by picking a chit from sequentially numbered opaque sealed envelope. Each of the 20 patients was asked to draw a chit which was labelled with either group 1 or group 2. This has guaranteed the random and equal allocation of the recruited cases into the study “flapless” and the control “conventional” groups. The accuracy of placement of the zygomatic implant was evaluated by two independent assessors, who were blinded to the surgical approach.

2.1. *Preoperative planning*

In all the cases the maxilla was fully edentulous, therefore, four mono-cortical screws were inserted under local anaesthesia at the canine and first molar regions on either side of the maxilla before surgery. These were used for the subsequent registration process of the dynamic navigation system. Preoperative CBCT scans were taken and then loaded into the Navident software package for planning of the position of the zygomatic implants. For each case, two zygomatic implants were planned, one on each side. The Navident planning software guided the surgeon to choose the optimal length, direction, and position of the zygomatic implants according to the thickness of the zygomatic bone and the height of the remaining alveolar bone. The dynamic navigation software allowed the selection of a generic implant including its diameter and length. The planned position of the zygomatic implants was transferred to the operating site using the Navident Dynamic Navigation system.

2.2. *Registration and calibration process*

The registration process was achieved using two trackers, one on the nasal bridge and the other was attached to the handpiece (Fig. 2). The position of the trackers in relation to the pair of stereo-cameras of the Navident dynamic navigation was recorded. The stereo cameras also captured the tracker attached to the surgical instruments which were used, including the drills and curettes, to allow the recording and tracking of their position in relation to the preoperative CBCT scans.

The four mono-cortical screws which were inserted in the maxilla before the preoperative CBCT scanning have acted as fiducial points to register and link the tracking process of the dynamic navigation system. The direct digitization of the four screws, using the digitizer provided by the manufacturer, allowed the position of the patient’s maxilla to be registered to its position in the preoperative CBCT scans. The tips of the drills were placed in front of the stereo cameras so the software could ‘learn’ and register their geometry in relation to the patient. This provided dynamic real time guidance of the 3D position of the instruments that could be viewed on the monitor of the dynamic navigation system throughout the course of the surgical procedure). The geometry of the tracking arrays relative to the instrument was determined by the tracking system. This allowed the operator to accurately track the 3D position of the surgical instrument throughout the course of the procedure as well as the position of the implant during its placement in relation to the planned position.

Fig. 2. The registration process for the dynamic navigation using two trackers, one on the nasal bridge and the other attached to the handpiece.

2.3. *Surgical technique*

The surgical procedures were carried out under local anaesthesia using Xylocaine 2% with adrenaline 1/80000. The placement of zygomatic implants was guided by the planned position on the computer screen of the dynamic navigation system. The starting position of the surgical drill and the depth of the bone cut were monitored, in real time, *via* the computer screen. A changing colour display from green to yellow guided the operator to the depth of drill penetration, it changed into red when the planned depth of the bone cut was achieved.

In the flapless technique, the first bone cut was achieved using the lance drill, 30 mm long and 8 mm wide (Fig. 3a). It pierced the mucoperiosteum at the alveolar crest, guided by the real time tracking and monitoring of the screen of the dynamic navigation system (Fig. 3b). This was followed by the second drill to extend the depth of the bone cut up to the floor of the maxillary sinus. A surgical curette was calibrated (Fig. 3c) and inserted delicately through the flapless bone cut (Fig. 3d) to allow the in-fracture of the floor of maxillary sinus. This was, followed by careful retraction of the Schneiderian membrane upwards off the posterior wall of the maxillary sinus, up to the lateral superior corner, exactly where the zygomatic implant was planned to be inserted. This procedure was guided by the dynamic tracking of the position of the edge of the curette (Fig. 3e). Inspection of the sinus membrane perforation was achieved by asking the patient to perform the Valsalva manoeuvre. Absence of air bubbles confirmed the sinus membrane was intact. A collagen membrane was inserted through the created bine cut to the maxillary sinus to seal any detected perforations. The final drill was used for the bone cut at the posterior superior corner of the maxillary sinus where the implant was inserted in ZAGA 1, ZAGA 2 cases. In ZAGA 3, ZAGA 4 cases, following the initial pilot drill, the osteotomy preparation was performed on the lateral surface of the zygomatic using the calibrated drill, the procedure was monitored on the computer screen in real time guided by dynamic navigation.

In all the cases the calibrated zygomatic implant was inserted using the calibrated handpiece following the displayed planned position and guided by real time tracking (Fig. 3f).

In the conventional group, the same calibration process and surgical techniques were carried out. The only difference was that a full thickness mucoperiosteal flap was reflected which included a 2 cm horizontal incision of the alveolar crest mucosa and two semi-vertical incisions, one at the canine region and the other at the maxillary tuberosity. This allowed a full exposure of the zygomatic buttress and the infraorbital nerves. The position of the first bone cut at the crest of the ridge, using

Fig. 3a. The flapless penetration of the alveolar mucoperiosteum crest using a tracked lance drill, 30 mm long and 8 mm width.

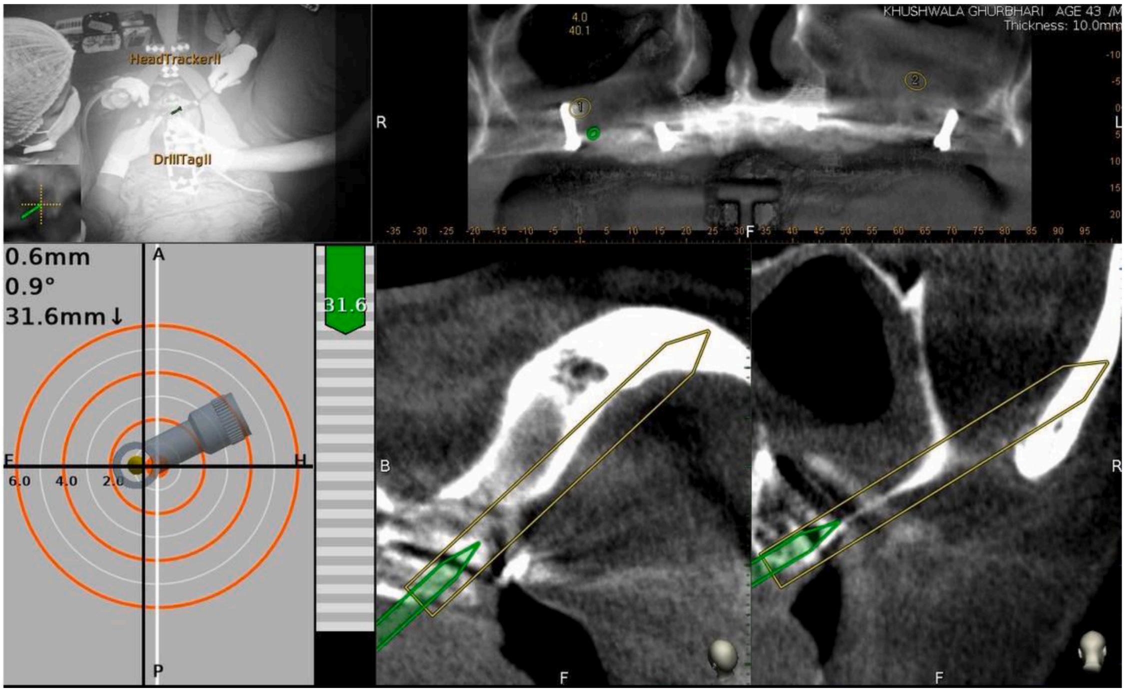

Fig. 3b. The real time tracking and monitoring the position of the drill on the screen of the dynamic navigation system.

Fig. 3c. The calibration of the surgical curette to guide and monitor the reflection of the maxillary sinus membrane.

Fig. 3d. The flapless insertion of the calibrated curette for the reflection on the Schneiderian membrane.

the pilot drill, was guided by the real time tracking, and monitoring the dynamic navigation screen. The sequence of the drilling was identical to the flapless cases, but in addition to the monitoring of the position of the surgical drills on the computer screen, this approach allowed the visualization of the surgical site throughout the procedure.

The surgical procedure was standardized in the two groups of the study to achieve the necessary reproducibility and validity. The diameter of the bone cut was wider than that of the drills which allowed the continuous cooling throughout the procedure using saline solution.

A five-day course of an antibiotic - Trimox 500 mg (Amoxicillin, Selco Enterprises Private Limited, Mumbai, India) was prescribed along with an analgesic Paraden 650 mg, (Paracetamol, Den Mark Pharmaceuticals Private LTD, India) three times daily for three days. In addition, normal saline nasal spray and 0.2% chlorhexidine mouth wash (Chlorhexidine gluconate, NICHOLAS PIRAMAL, LTD, INDIA.) were prescribed. Standard postoperative instructions were given including oral hygiene measures, avoidance of nose-blowing and forceful mouth-rinsing for ten days.

In all the cases two additional implants were placed at the canine regions of the maxilla, and the loading of the implants was delayed to 4 months after surgery.

2.4. Postoperative assessment of placement accuracy

Postoperative CBCT scans were captured on the same day of surgery using the same standardized protocol and the same radiographic machine. The accuracy of the position of the zygomatic implants was assessed by superimposition of the postoperative CBCT scan on the preoperative planning (Fig. 4). Using the Navident software “EvaluNav”.

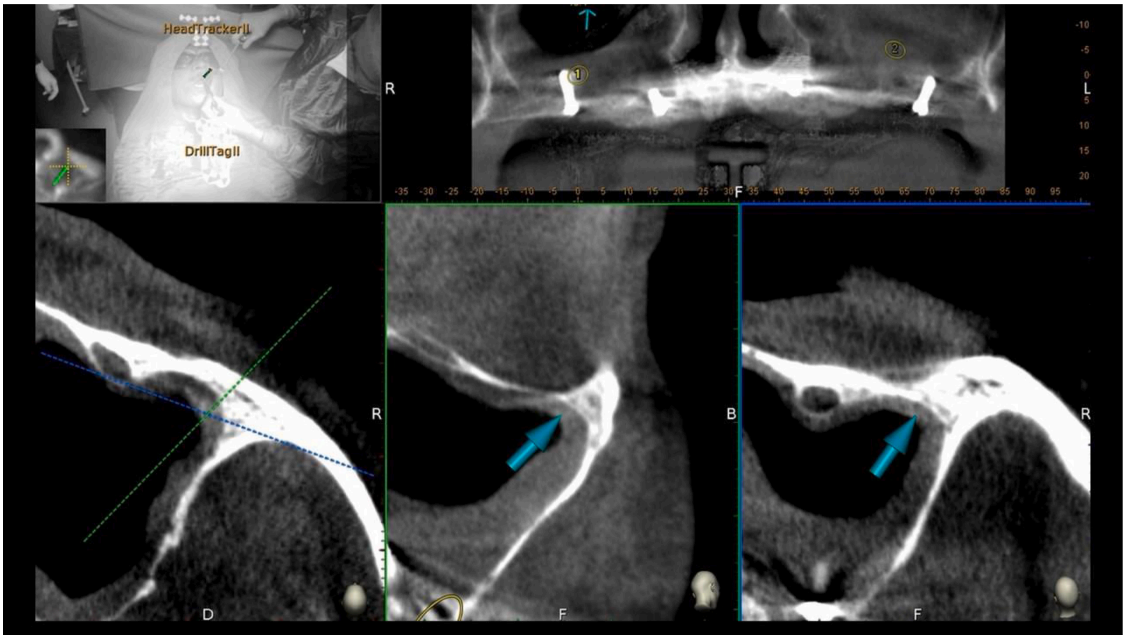

Fig. 3e. The tracking of the position of the edge of the curette during the reflection of the Schneiderian membrane, the arrow points to the superior lateral corner of the maxillary sinus where the zygomatic implant is placed.

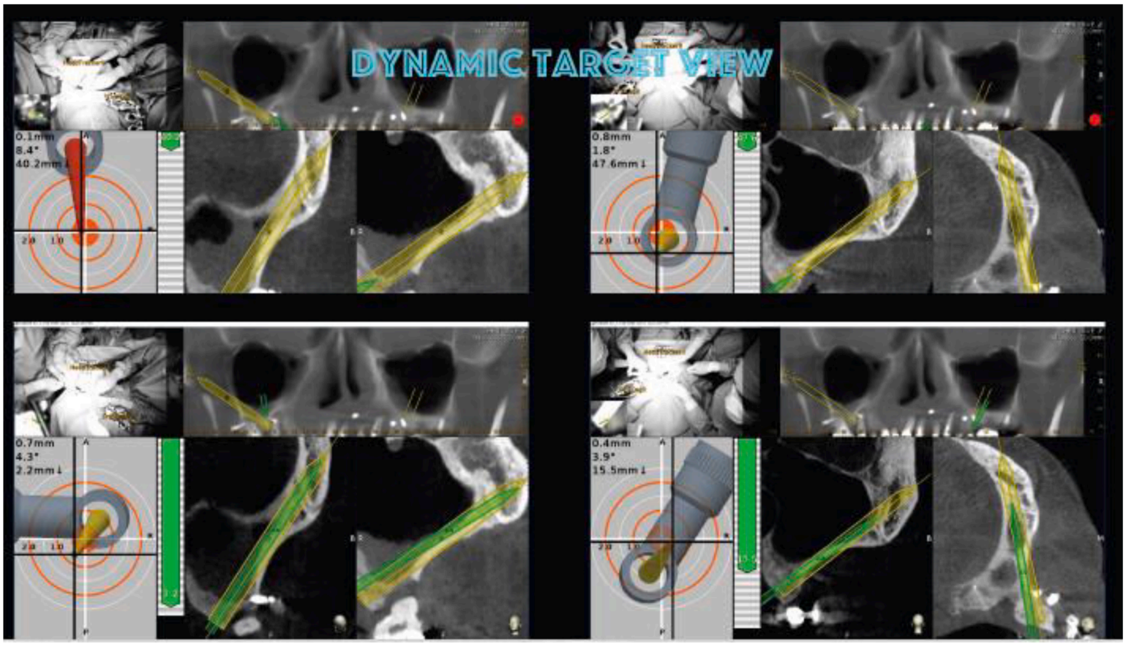

Fig. 3f. The real time tracking and monitoring during placement of the zygomatic implant guided by its planned position.

The accuracy of the position of the zygomatic implants was measured according to the following parameters:

1. 3D apical deviation between the actual and planned positions of the apices of the zygomatic implants.
2. Accuracy of the entry points of the zygomatic implants.
3. Angular deviation between the actual and the planned positions of the zygomatic implants.
4. The vertical disparity in the apical positions of the zygomatic implants.

All patients were followed up at standard intervals including 24 h, 7 days, and then 1, 3 and 4 months after surgery. Prosthetic rehabilitation was commenced at the end of the 4th postoperative month once osseointegration was confirmed clinically.

2.5. *Statistical analysis*

Data were checked for normality using Kolmogorov–Smirnov and Shapiro Wilk tests. Data were found to be parametric, therefore, unpaired Student t-test was applied to detect statistical differences between the two groups at $p<0.01$.

The measurements of the radiographic accuracy of placement of zygomatic implants were repeated after an interval of 8 weeks. The

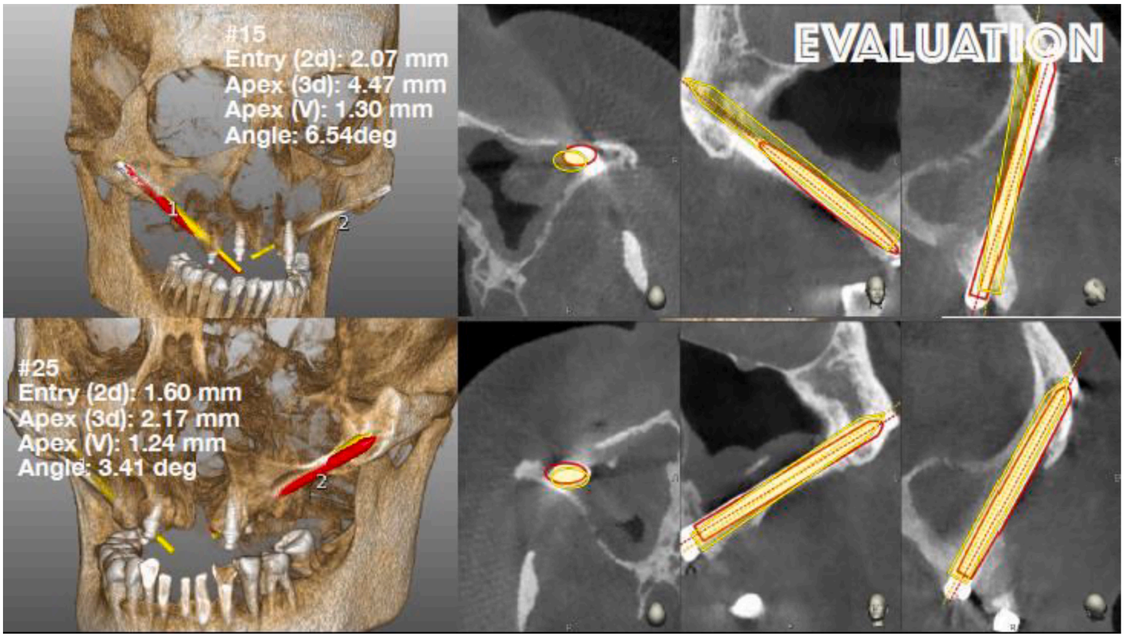

Fig. 4. The assessment of the accuracy of the placed zygomatic implant in relation to its planned position using Navident software "EvaluNav".

statistically significant differences of the repeated measurements were assessed using Student t-test ($p<0.01$).

3. Results

The average age of the patients of the flapless group was 57.2 years, ranged from 51 to 65 years, 80%males and 20% females. In the conventional group the average age of the patients was 58.7 years, ranged from 53 to 68 years, 90% males and 10% females,

Minimal oedema and bruising were noted postoperatively in the flapless group. None of the patients in the two groups developed alteration in sensation of the cheek, upper lip, and the nose. The details of the assessment of the postoperative pain, swelling, and alteration of sensation following surgery are beyond the scope of this manuscript.

Osseointegration of the zygomatic implants was confirmed at 70 Ncm using a torque wrench. All zygomatic implants have osseointegrated except one case in the flapless group which was successfully replaced after 4 months. No clear explanation for this failure was identified, apart from possible direct trauma, which might have affected the initial stability of the implant. All the patients proceeded to the prosthetic rehabilitation phase. Regarding the anatomical position of the zygomatic implants "Zaga1 to 4″, these were equally distributed between the study and the control groups. The diameter of the zygomatic implant was 4.2 mm and the length ranged from 37.5 to 47.5 mm.

No statistically significant differences were detected of the repeated measurements ($\rho=0.79$), with a high correlation coefficient ($r=0.8$). A greater statistically significant coronal and apical accuracies were noted in placement of zygomatic implants of the flapless group ($p < 0.01$), (Tables 1–3). Therefore, the null hypothesis was rejected. The placement of zygomatic implants was more accurate on the left side.

The average apical deviation of the zygomatic implants was about 5 mm, the shift in the coronal entry point was 3 mm, the angular deviation was 6°, and 2 mm vertical apical disparity between the planned and the achieved surgical position. No statistically significant difference in the placement accuracy between the extra-sinus versus the intra-sinus implants was found, except on the left side, where a highervertical accuracy was noted in the intra-sinus implants ($p<0.01$) (Table 4).

Perforation of the Schneiderian membrane was noted in three cases: one in the flapless group and two in the conventional control group. This was confirmed by positive Valsalva manoeuvres. A collagen membrane was applied at the surgical site, using a thin calibrated pair of tweezers. The Valsalva manoeuvre was then repeated and once a satisfactory seal was confirmed the implant was inserted. One patient, in the conventional group, who had a perforation of the sinus membrane during surgery has developed the classic symptoms of unilateral chronic maxillary sinusitis three months following surgery. This issue was managed by antibiotics and nasal decongestants.

Table 1
Comparison of mean accuracy of left sid zygomatic implants between the conventional and the flapless groups.

Accuracy left	Type of Implant Placement	N	Mean	Standard deviation	Standard Error mean	P value
Apical	Flapped	10 patients (20 implants)	6.57	2.79	0.88	0.002*
	Flapless	10 patients (20 implants)	4.43	2.07	0.65	
Coronal	Flapped	10 patients (20 implants)	3.77	1.69	0.54	0.008*
	Flapless	10 patients (20 implants)	2.03	1.96	0.62	
Angular	Flapped	10 patients (20 implants)	8.89	4.33	1.37	0.049
	Flapless	10 patients (20 implants)	5.25	3.32	1.05	
Vertical	Flapped	10 patients (20 implants)	2.72	1.96	0.62	0.320
	Flapless	10 patients (20 implants)	1.98	1.20	0.38	

Test applied: Independent Unpaired t- Test. *Indicates Statistical Significance ($p < 0.01$).

Apical: 3D deviation of zygomatic implants at the apex; **Coronal**: Inaccuracy at the entry point of the implants; **Angular:** Angular deviations between the actual and the planned position of the implants; **Vertical:** Vertical deviation of the apex of the implant.

Table 2
Comparison of the mean accuracy of right side zygomatic implants between the flapped and the flapless groups.

Accuracy right	Type of Implant Placement	N	Mean	Standard Deviation	Standard Error Mean	P value
Apical	Flapped	10 patients (20 implants)	5.52	3.11	0.98	0.002*
	Flapless	10 patients (20 implants)	3.69	1.93	0.61	
Coronal	Flapped	10 patients (20 implants)	4.07	3.01	0.95	0.006*
	Flapless	10 patients (20 implants)	1.94	0.99	0.31	
Angular	Flapped	10 patients (20 implants)	8.06	4.13	1.30	0.060
	Flapless	10 patients (20 implants)	4.47	3.86	1.22	
Vertical	Flapped	10 patients (20 implants)	3.58	3.06	0.97	0.001*
	Flapless	10 patients (20 implants)	1.56	1.25	0.39	

Test applied: Independent Unpaired t- Test. * Indicates Statistical Significance ($p < 0.01$).
Apical: 3D deviation of zygomatic implants at the apex; **Coronal**: Inaccuracy at the entry point of the implants; **Angular:** Angular deviations between the actual and the planned position of the implants; **Vertical:** Vertical deviation of the apex of the implant.

Table 3
Comparison of the mean accuracy of the zygomatic implants between flapless and conventional groups.

Accuracy	Flapless			Conventional		
	Mean	Standard deviation	P value	Mean	Standard deviation	P value
Apical	4.43	2.07	0.002*	6.57	2.79	0.002*
Coronal	2.03	1.96	0.008*	3.77	1.69	0.008*
Angular	5.25	3.32	0.049	8.89	4.33	0.049
Vertical	1.98	1.20	0.320	2.72	1.96	0.320

Test applied: Independent Unpaired t- Test. * Indicates Statistical Significance ($p < 0.01$).
Apical: 3D deviation of zygomatic implants at the apex; **Coronal**: Inaccuracy at the entry point of the implants; **Angular:** Angular deviations between the actual and the planned position of the implants; **Vertical:** Vertical deviation of the apex of the implant.

4. Discussion

The present study has provided the first clinical evidence in the English literature of the accuracy of flapless placement of zygomatic implants, guided by dynamic navigation under local anaesthesia. The presented surgical technique enables accurate placement of zygomatic implants with the elimination of the standard bony window technique for the preservation of the sinus lining. One interesting finding of the study is the higher accuracy of the apical positioning of the inserted implants in the flapless group, which proved to be statistically significant.

Another interesting finding is the higher accuracy of the apical positioning of the intra-sinus implants in comparison with the extra-sinus ones. This could be explained by the fact that the confinement of the implant to the posterior superior corner of the maxillary sinus eliminated minor manual inaccuracies, which are associated with the bone cut, for the extra-sinus placement of the apex of the zygomatic implants.

Wu et al., assessed the accuracy of 231 zygomatic implants placed in 74 patients guided by dynamic navigation and using a skull-based tracker fixed with three titanium screws [26]. The deviations in entry, exit, and angle of the implants were 1.57 ± 0.71 mm, 2.1 ± 0.94 mm, and 2.68 ± 1.25°, respectively. Statistically significant differences were found in entry and exit deviation between the planned and actual surgical positions. However, one of the main limitations of the study was the heterogeneity of the sample. Five groups were included in the study according to the number of zygomatic implants, (single, dual, triple and quadrable, unilateral implants in some cases, and bilateral in others).

Therefore, it is reasonable to infer that dynamic navigation offers a satisfactory accurate approach for placement of zygomatic implants due to the effective mechanism of physically controlling the drilling trajectory. According to our findings and the published data [27,28], dynamic navigation offers excellent margins of safety and reduces the risks of intraoperative and postoperative complications. In our study, the average 3D apical deviation was about 5 mm, the inaccuracy of the coronal entry point was 3 mm, the angular deviation was 6°, and the vertical apical disparity between the planned and the achieved surgical position was about 2.5 mm. Our results are comparable with published data. The slight increase in the angular deviation in our cases could be attributed to the length of the zygomatic implants that were used for the

Table 4
A comparison of the accuracy between the Extra-sinus and s Intra-sinus placement of zygomatic implants.

Side	Parameter	Technique	N	Mean	Standard Deviation	Standard Error Mean	P value
Left	Accuracy	Extra sinus	5 patients (10 implants)	4.39	1.40	0.63	0.959
	Apical	Intra sinus	5 patients (10 implants)	4.46	2.77	1.24	
	Accuracy	Extra sinus	5 patients (10 implants)	2.93	2.31	1.03	0.159
	Coronal	Intra sinus	5 patients (10 implants)	1.14	1.16	0.51	
	Accuracy	Extra sinus	5 patients (10 implants)	4.22	3.57	1.59	0.355
	Angular	Intra sinus	5 patients (10 implants)	6.28	3.07	1.37	
	Accuracy	Extra sinus	5 patients (10 implants)	2.95	0.56	0.25	0.002*
	Vertical	Intra sinus	5 patients (10 implants)	1.01	0.76	0.34	
Right	Accuracy	Extra sinus	5 patients (10 implants)	2.99	1.55	0.69	0.281
	Apical	Intra sinus	5 patients (10 implants)	4.38	2.19	0.97	
	Accuracy	Extra sinus	5 patients (10 implants)	2.17	1.10	0.49	0.497
	Coronal	Intra sinus	5 patients (10 implants)	1.71	0.93	0.42	
	Accuracy	Extra sinus	5 patients (10 implants)	3.08	2.71	1.21	0.282
	Angular	Intra sinus	5 patients (10 implants)	5.85	4.63	2.06	
	Accuracy	Extra sinus	5 patients (10 implants)	2.09	1.18	0.52	0.188
	Vertical	Intra sinus	5 patients (10 implants)	1.02	1.18	0.53	

Test applied: Independent Unpaired t- Test. *Indicates Statistical Significance ($p < 0.01$).
Apical: 3D deviation of zygomatic implants at the apex; **Coronal**: Inaccuracy at the entry point of the implants; **Angular:** Angular deviations between the actual and the planned position of the implants; **Vertical:** Vertical deviation of the apex of the implant.

rehabilitation of the severely atrophic maxilla. The margin of inaccuracies associated with the placement of zygomatic implants guided with dynamic navigation could be attributed to several factors including imaging errors, registration, and calibration inaccuracies, as well as human factors [29,30]. The accuracy of the captured images depends on the voxel size and the viewed pixel size. The registration process, which links the digital coordinate system of the 3D image to the physical patient coordinate system through the screw markers, is subjected to errors [29], as well as the calibration process, which links the surgical instruments, handpiece, and surgical instruments, to the head tracker. The head tracker in our cases was maintained at the bridge of the nose which might have contributed to the measured angular deviation of the placed zygomatic implants. The combined effect of these registration errors has been considered acceptable in image-guided surgery when it is kept below 1.5 mm [30]. The limitations of human perception and presence of hand tremors are also well recognized sources of errors [31], which affect the overall accuracy of the implant placement. The reported apical deviation of the zygomatic implants in our study was between 5 and 6 mms, which may be challenging in the placement of quad zygomatic implants. The shape and thickness of the zygomatic bone should be carefully analysed before planning the position and the number of zygomatic implants for maxillary rehabilitation.

The placement of zygomatic implants is usually carried out after reflection of a mucoperiosteal flap to expose the anterior wall of the zygoma. The reflection of the mucoperiosteal flap and the full exposure of the zygomatic prominence enables the direct visual inspection of the surgical site, which might be a distraction to the operator throughout the course of the surgical procedure. The flapless insertion of zygomatic implants, guided by dynamic navigation, was associated with significantly greater accuracy in the present study. A possible explanation for this is the fact that, in comparison with the conventional technique, the flapless placement eliminated the frequent shifting of the operator's visual focus between the surgical field and the computer screen. With the flapless approach, the surgeon's attention is therefore more likely to be undivided and entirely focused on monitoring the virtual position of the surgical instruments. This may have eliminated potential distraction and the related well-recognized surgeon' fatigue [32].

In our cases it was the roll of the operator standing on the right side of the patients to place the left zygomatic implants. The slight rotation of the patient's head towards that side during surgery disclosed the trackers and allowed the unobstructed detection by the stereo cameras of the dynamic navigation system. This explains our findings of the more accurate placement of zygomatic implants on the left side.

The Valsalva manoeuvre is a well-recognized test to check perforation of the Schneiderian membrane [33]. This only suitable for conscious patients, which was the case in this study. Endoscopic evaluation of the integrity of the membrane would have been necessary if an indirect sinus lift was carried out under general anaesthesia. Perforation of the Schneiderian membrane during the insertion of zygomatic implants should be avoided to prevent postoperative sinusitis [34]. In our study, the perforation of the Schneiderian membrane was detected in three cases: two in the flapless group, and one in the conventional group, which is similar to the reported incidences ranging from 7 to 44% for the direct maxillary sinus lift *via* the lateral window technique [35]. Indirect elevation of the sinus membrane through the extraction socket has proved successful for conventional endosseous implants [36,37], and the incidence of Schneiderian membrane perforation has been found to be significantly less with the trans-crestal maxillary sinus floor elevation technique [38]. In our study, three out of 40 implants were associated with a positive Valsalva manoeuvre test, but this did not affect osseointegration or implant survival, which agrees with the recently published study on sinus floor elevation [39].

A 5-year randomized clinical trial conducted by Cannizzaro et al., compared direct versus indirect sinus lift procedures [40]. The results indicated no differences between the techniques. Furthermore, the lateral window approach was associated with a higher complication rate including biomaterial infections and implant failures [40]. In a meta-analysis by Al-Moraissi, the indirect osteotome sinus lift with immediate implant placement was the recommended treatment [41]. These findings are also supported by Taschieri et al. who confirmed that the crestal sinus lift approach was associated with less morbidity when compared with the lateral window procedure, resulting in a significantly better postoperative healing e.g., less inflammation, less pain and faster resumption to the daily activities [42]. Our study also supported their findings and showed that the flapless approach for the insertion of zygomatic implants was associated with less pain and swelling when compared with the conventional approach, but the details of these findings are beyond the scope of this manuscript.

Gabbert et al. reported 26% perforation rate of the Schneiderian membrane had no impact on implant osseointegration or implant survival rate, and concluded that small tears may not be detected clinically [43]. The Valsalva manoeuvre is a simple and reliable method to assess the intactness of the sinus membrane when the patient is awake. Studies have shown that this membrane has an average elasticity of 5 mm which justifies the reliability of positive and negative Valsalva manoeuvre [44,45]. This was also highlighted in our latest publication [46]. We accept the argument that in our cases that micro perforations may have occurred during the dynamically guided sinus membrane lift procedure which may have not been detected with the Valsalva manoeuvre, yet these did not appear to have affected the rate of postoperative infections, which was minimal. We also acknowledge that the application of collagen membrane in positive Valsalva manoeuvre cases may not have been perfectly accurate on the perforated Schneiderian membrane. Nevertheless, we believe the collagen membrane has provided the required seal with minimal complications as explained in the literature [47]. Minimal postoperative infection was encountered in our study. Maxillary sinusitis was limited to three cases; two in the flapless group and one in the conventional group. This may be attributed to the low perforation rate of the Schneiderian membrane, and the absence of graft or bone substitute material being left in the sinus cavity [48]. These cases were readily managed with a course of antibiotics and nasal inhalations to improve drainage.

The prosthetic guided implant principle was applied in this study. In consultation with the prosthodontist, the entry points of the zygomatic implants were either at the premolar or first molar region. Patient's old dentures were not captured with the preoperative CBCT scan, and the decision regarding the entry points and the direction of the zygomatic implants was guided by the remaining alveolar bone height, and the morphology of the zygomatic bone. We followed this protocol, which is well established in the literature, as explained by Pellegrino et al. [49]. They confirmed that the radiographic capture of the prosthetic template should not always be used for the planning of zygomatic implants. They explained the potential misalignment between the implant and the prosthetic axis of the abutment that defines the implant emergence. Their study highlighted the importance of engaging the implants in the zygomatic bone as the prime determinant of the position and entry point of the implants. We followed this protocol in our study.

We acknowledge our study suffers from some limitations including a single centre, one multidisciplinary team, one dynamic navigation system, and one ethnic group of patients. We recommend multicenter studies to confirm the findings of this study. Further investigations are required to include patients of diverse ethnic background, operators of various surgical experience and to test the accuracy of other dynamic navigation systems. We acknowledge the steep learning curve in using dynamic navigation and highlight the importance of preclinical training. The use of robotic arms should be investigated to improve the accuracy of the placement of zygomatic implants.

5. Conclusions

The flapless placement of zygomatic implants, guided by dynamic navigation, has offered satisfactory safety and accuracy.

Osseointegration was achieved in all the implants except in one case in group 1 where one implant was lost and successfully replaced after 4 months. Statistically significant highercoronal and apical accuracy wasfound in placement of zygomatic implants of the flapless group ($p < 0.01$). The average error of apical deviation was about 5 mm, 3 mm shift of the coronal entry point, angular deviation was 6°, and 2 mm vertical apical disparity was detected between the planned and the achieved surgical position. Postoperatively, minimal oedema and bruising were noted in the flapless group. This is the first clinical study to prove the feasibility and accuracy of flapless placement of zygomatic implants with minimal morbidity. The present study highlights the innovative reflection of the Schneiderian membrane under guided surgical navigation. This procedure can be performed under local anaesthesia, which offers noteworthy clinical advantages.

CRediT authorship contribution statement

Ashwini Bhalerao: Conceptualization, Data curation, Funding acquisition, Formal analysis, Writing – original draft, Supervision. **Madhulaxmi Marimuthu:** Formal analysis, Writing – original draft, Data curation. **Abdul Wahab:** Conceptualization, Data curation, Funding acquisition, Formal analysis, Writing – original draft, Supervision. **Ashraf Ayoub:** Conceptualization, Data curation, Funding acquisition, Formal analysis, Writing – original draft, Supervision.

Declaration of Competing Interest

All authors disclose that we do NOT have any financial or personal relationships with other people or organizations that could inappropriately influence the submitted work.

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