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Accuracy Assessment of 3D-Printed Surgical Guide with Custom-Made Sleeve versus Freehand Technique for Zygomatic Implant Placement: A Randomized Clinical Trial

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ABSTRACT

Background: Zygomatic implants offer a graftless solution for severe maxillary atrophy. However, the accuracy of computer-guided versus freehand placement remains debated. This randomized clinical trial aimed to compare accuracy of these two techniques using CT-based deviation analysis.

Methods: Eight patients requiring zygomatic implants were randomized into two equal groups: computer-guided ($n = 4$) and freehand placement ($n = 4$), with a total of 16 implants. Radiographic accuracy was assessed by comparing planned and actual implant positions using postoperative CT superimposition. Deviations were quantified in linear (mediolateral and anteroposterior) and angular dimensions. Statistical analysis was conducted using independent t-tests and Mann-Whitney U tests (significance level $\alpha = 0.05$).

Results: The guided group demonstrated significantly higher radiographic accuracy compared to the freehand group. Linear deviation in the mediolateral plane was 49.66 ± 1.87 mm versus 53.47 ± 1.70 mm ($p < 0.001$), and in the anteroposterior plane was 49.78 ± 14.61 mm versus 21.84 ± 4.54 mm ($p < 0.001$). Angular deviation was significantly reduced in the guided group ($5.17° \pm 2.31°$) compared to the freehand group ($11.80° \pm 8.48°$, $p = 0.050$).

Conclusion: Computer-guided placement of zygomatic implants significantly improves the accuracy over the freehand approach. These findings support the use of guided techniques in cases requiring precise maxillary rehabilitation, particularly in anatomically complex or severely atrophic maxillae.

Keywords: *APH, Maternal outcomes, Fetal outcomes*

1. INTRODUCTION

Dental implants have transformed oral and maxillofacial rehabilitation, providing a predictable solution for restoring missing teeth. However, their success depends on sufficient bone volume for anchorage and stability. In cases of severe maxillary atrophy or maxillary defects, conventional dental implants may not be viable due to inadequate bone support. These challenges necessitate alternative techniques to restore function and aesthetics in affected patients[1, 2].

Traditional approaches to rehabilitating the atrophic maxilla include bone augmentation techniques such as sinus lifts, guided bone regeneration, onlay grafting, and distraction osteogenesis. While these methods are effective, they often require prolonged treatment time, multiple surgical interventions, and increased patient morbidity[3]. Moreover, autogenous bone grafting, despite being the gold standard, is associated with donor site complications, extended healing periods, and variable resorption rates(4).

Zygomatic implants (ZIs) offer a graftless alternative for patients with severe maxillary atrophy or maxillary defects, eliminating the need for extensive bone augmentation. First introduced by Brånemark in 1988, ZIs are anchored in the zygomatic bone, bypassing the maxilla and providing excellent primary stability(5, 6). This approach not only reduces surgical complexity but also allows for immediate or early prosthetic loading, enhancing patient outcomes(7).

The success of zygomatic implants is attributed to their four-cortical engagement, which ensures high mechanical stability. However, placement remains surgically demanding due to the complex anatomy of the zygomatic bone and proximity to vital structures such as the orbit and maxillary sinus(8). Inaccurate placement can lead to complications, including sinusitis, orbital injury, and soft tissue dehiscence(9). Advances in computer-aided implantology have introduced guided surgical techniques to enhance accuracy. Both static and dynamic navigation systems aim to improve precision, reduce complications, and standardize outcomes, particularly for less experienced surgeons(10, 11). In a cross-sectional survey, Carlos Aparicio suggests that guided techniques reduce angular and linear deviations, others highlight challenges in achieving the ideal three-dimensional implant trajectory(12). Additionally, the impact of guided vs. freehand placement on long-term stability and postoperative complications remains underexplored.

The primary aim of this randomized controlled trial was to compare accuracy of computer-guided versus freehand zygomatic implant placement

2. PATIENTS AND METHODS

Trial Design

This study was conducted as a randomized, parallel-arm clinical trial with a 1:1 allocation ratio. It was based on a null hypothesis, assuming no statistically significant difference in implant positioning accuracy between the freehand and fully guided zygomatic implant placement techniques. The study was retrospectively registered at ClinicalTrials.gov (Identifier: NCT06925438), and ethical approval was obtained prior to study initiation (Approval Code: 880/62). The study was reported according to the updated CONSORT (Consolidated Standards of Reporting Trials) guidelines for reporting randomized clinical trials(13).

Trail Setting

The trial was conducted at a single center (Faculty of Dental Medicine Hospital, Al-Azhar University) Where participants were recruited from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dental Medicine, Al-Azhar University, Cairo, Egypt. Ethical approval for the study was granted by the Research Ethics Committee of the Faculty of Dental Medicine, Al-Azhar University (Ethical Approval Code: 880/62, dated December 23, 2022). All eligible participants provided written informed consent after receiving a comprehensive explanation of the study objectives and procedures. The study duration was from January 10, 2023, to March 12, 2025.

Inclusion Criteria

Eligible participants were male or female patients aged 40 years or older with Cawood and Howell Class V or VI atrophic maxillae[(14)], or acquired maxillary defects resulting from trauma, pathology, or previous surgical resection, and requiring zygomatic implant-supported prosthetic rehabilitation.

Exclusion Criteria

Patients were excluded if they had acute sinusitis; uncontrolled systemic diseases that could compromise osseointegration, intraoral pathological lesions involving the maxilla, maxillary sinus, or zygoma, or were heavy smokers (more than 20 cigarettes per day).

Interventions

All patients underwent a preoperative evaluation, including clinical and radiographic assessments, a detailed dental and medical history, and a preoperative CT scan. The CT scan was used to identify any pathological conditions in the maxilla or zygoma and to assess the quality and volume of the zygomatic bone, ensuring appropriate planning and selection of the zygomatic implants (Figure *1*).

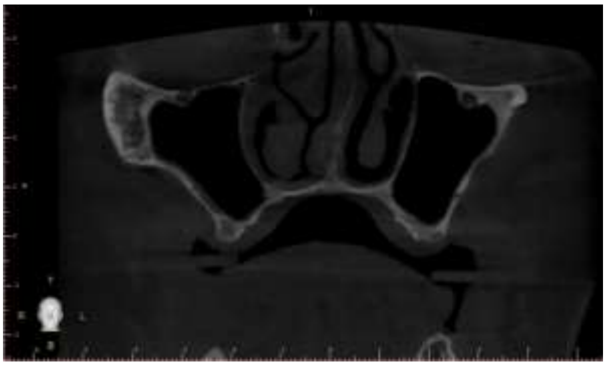

Figure 1: Coronal CT scan of the zygomatic bone and maxillary sinus for preoperative evaluation (computer-guided group)

Coronal CT scan illustrates the anatomical relationship between the zygomatic bone and the maxillary sinus. This view is crucial for evaluating bone quality, sinus anatomy, and spatial orientation in preparation for zygomatic implant placement.

Surgical Procedure

Patient Grouping:

- Group A (control group) : Patient receive free hand zygomatic implant placement
- Group B (test group) : Patient receive Guided zygomatic implant placement by using 3D-Printed Surgical Guides with Custom-Made Sleeves

Group A (Control Group): Zygomatic implants were planned and Implant placement was done using the freehand technique, with intra-sinus or extra-sinus paths determined according to individual anatomical variations. The osteotomy was performed under continuous saline irrigation to minimize thermal damage. A sequential drilling protocol was followed using osteotomy drills of 2.9 mm, 3.2 mm, and 3.6 mm in diameter, applied in a steady in-and-out motion to maintain precision and prevent overheating. A depth gauge was used throughout the procedure to confirm the correct depth and angulation, ensuring alignment with the planned trajectory. Care was taken to preserve the integrity of adjacent bone and soft tissues.

Group B (Study Group): A fully guided approach was employed based on digital preoperative planning. Digital Imaging and Communications in Medicine (DICOM) data from preoperative 3D CT scans were imported into implant planning software (Mimics Medical 19.0, Materialise Dental, Leuven, Belgium)[15]. Virtual simulations were performed to determine the optimal entry point, angulation, and exit point of each implant into the zygomatic bone, following the Zygomatic Anatomy-Guided Approach (ZAGA classification). Using software-based segmentation, a 3D stereolithographic (STL) model of the patient's maxilla and zygomatic bone was generated and fabricated at a 1:1 scale using 3D printing. This model facilitated preoperative simulation and the design of a customized surgical guide to ensure accurate and predictable implant placement (Figures *2*).

Surgical guides were constructed with Metal sleeves or guide cylinders used to guide the drills in vertical height were manually inserted into the pre-defined holes in the resin during the finishing phase of the surgical guide(Figures *3*).

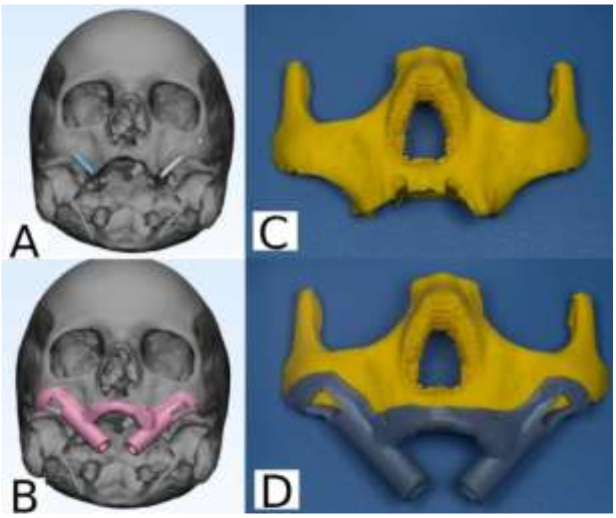

Figure 2: Digital workflow for virtual planning and surgical guide fabrication in zygomatic implant rehabilitation.

(a) Virtual implant planning on a segmented 3D maxillary model.

(b) Digital design of the surgical guide constructed over the virtual model.

(c) 3D-printed STL model of the maxilla for pre-surgical assessment.

(d) 3D-printed surgical guide ready for clinical application

Figure 3: custom made titanium metallic sleeve for drills (2.9mm, 3.2mm and 3.6 mm)

Surgical Guide Placement

under G A and complete aseptic condition, following mucoperiosteal flap elevation, the surgical guide was carefully positioned to ensure proper seating on the bone-bearing surface without interference with the gingival flap. The guide was stabilized using mono-cortical osteosynthesis screws to prevent movement or tilting during the procedure. Stability of the guide was critical for maintaining the planned implant trajectory and ensuring precise osteotomy preparation (Figures *4*).

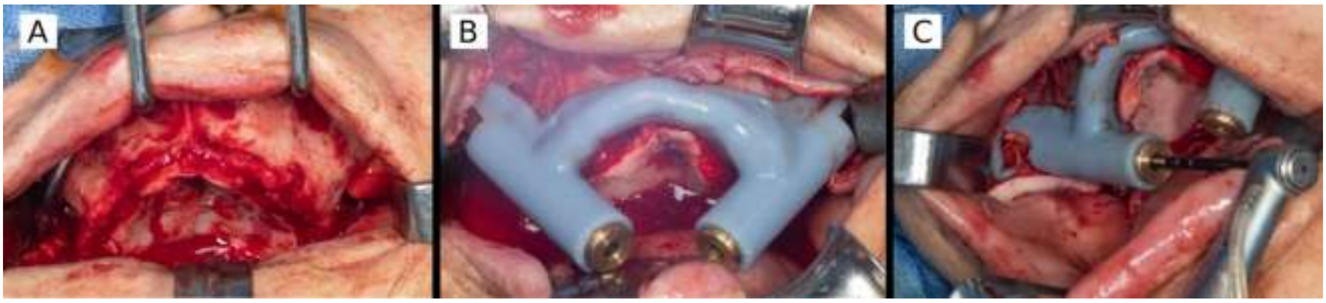

Figure 4: Intraoperative steps for zygomatic implant placement using a guided surgical approach.

(a) Surgical flap reflection exposing the alveolar crest and zygomatic bone.

(b) Placement of a bone-supported surgical drill guide for accurate trajectory control.(c) Sequential osteotomy drilling performed according to the manufacturer's protocol.

A sequential osteotomy drilling protocol followed using drills of 2.9 mm, 3.2 mm, and 3.6 mm in diameter. The surgical guide was equipped with metallic sleeves to control the drilling depth and angulation, minimizing deviation and enhancing reproducibility. Osteotomies were performed directly through the guide, and implant receptor sites within the zygomatic bone were prepared with precision

according to the preoperative plan. Zygomatic implants were then placed manually, following the guided trajectory. A Smart Peg was attached to each implant, and insertion torque values were recorded using the Osstell device to assess primary stability.

Wound Closure

A double-layer closure technique was utilized to reduce the risk of wound dehiscence around the implant sites. The buccal fat pad was mobilized and placed as a first layer over the implant area to enhance soft tissue coverage and support healing. The overlying buccal flap was then sutured using 3-0 Vicryl sutures in a tension-free manner Figure 5.

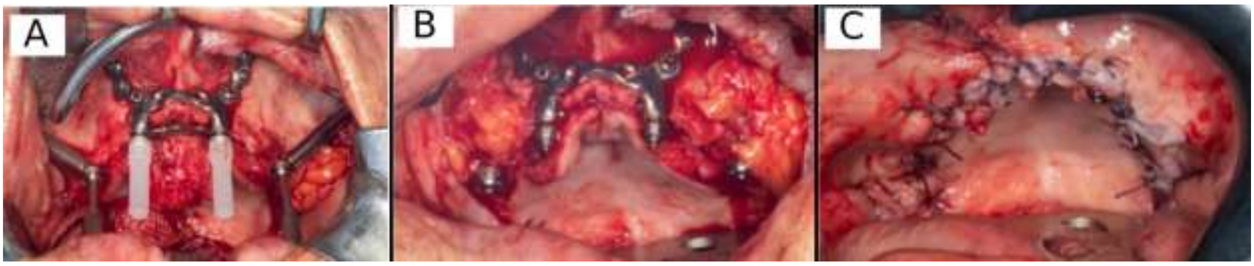

Figure 5 : Double-layer soft tissue closure technique following zygomatic implant placement.

A: Final position of the zygomatic implants after guide removal

B: Intraoperative view showing placement of the buccal fat pad over the zygomatic implant area to enhance soft tissue coverage.
C: Postoperative view following tension-free closure with 3-0 Vicryl sutures. This dual-layer approach supports wound healing and minimizes the risk of dehiscence or exposure.

A two-stage surgical protocol was followed, with implants left submerged during the healing phase. A healing period of six months was allowed to ensure adequate osseointegration before abutment placement and prosthetic rehabilitation Figure 6.

Postoperative Care

Postoperative care was standardized for all patients to promote healing and minimize complications. A seven-day course of systemic antibiotics was prescribed to prevent infection. Patients also received nasal decongestant drops and analgesics for the management of nasal congestion and postoperative pain. To maintain oral hygiene and reduce the risk of local infection, patients were instructed to use 0.12% chlorhexidine mouth rinses twice daily for two weeks. Additionally, a soft diet was recommended for two weeks to avoid applying undue pressure on the surgical site.

Figure 6: Postoperative follow-up and final restoration after zygomatic implant placement.

(a) Postoperative evaluation at 6 months following implant placement.

(b) Final restoration with a fixed hybrid prosthesis, featuring a titanium framework and zirconium crowns

▪ **Radiographic evaluation**

- using computed tomography (CT) scans. The CT scans were used to compare the virtual preoperative plan with the actual position of the implants.

This comparison allowed for an accurate assessment of the following:

- Implant Position and Direction: The alignment, angulation, and depth of the implants were evaluated to ensure they matched the planned position.
- Injury to Vital Structures: The scans were carefully analyzed to identify any potential damage to adjacent vital structures, such as nerves, blood vessels, or the maxillary sinus.

<u>Post operative deviations assessment</u>

- A new CT scan was carried out after implants insertion to compare deviations between planned and achieved implants. The accuracy was assessed overlapping the postoperative CT scan (with the achieved implants) with the pre-operative one (with the planned implants).
- The accuracy evaluation involved angular and linear (coronal, apical and depth) deviations.
- The DICOM images of the post-operative CT were uploaded in a dedicated software (mimics Medical 19.0, materialize dental, Leuven, Belgium). A segmentation based on tissue density was carried out to separate implants

from the surrounding bone. The STL files of the maxillary bone with the planned implants obtained from the pre-operative CT scan, were uploaded into the software.

- The superimposition of the pre-operative and post-operative CT images was achieved by using the best fit alignment tool.
- The planned and inserted implants were considered as cones with a base and an apex and their spatial coordinates (the center of the base and the apex) were registered by using a dedicated software (3-matic Medical 11.0, materialize dental, Leuven, Belgium) and were exported in an excel sheet to calculate coronal, apical, depth and angular deviations.
- To assess the accuracy of a guided implant procedure, positional deviations were analyzed by defining two reference points per zygomatic implant (coronal and apical). The distances from these points to three anatomical planes—the midsagittal plane (MSP), the Frankfort horizontal plane (FH), and the coronal plane (CP)—were measured[16]. Deviations were quantified in the mediolateral, cephalocaudal, and anteroposterior directions, with the overall mean deviation calculated for each implant. Additionally, the direct distances from each reference point in the postoperative scan to its corresponding virtual surgical plan position were measured. Furthermore, the angular deviation between the implant axes in the VSP and the postoperative scan were assessed to evaluate the overall positional accuracy Figures 7,8,9 .

VSP implants Postop implants

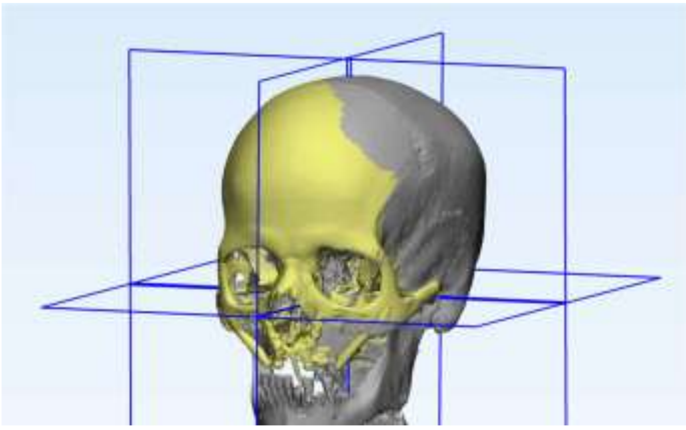

Figure 7 : superimposition between the planned and placed zygomatic implants

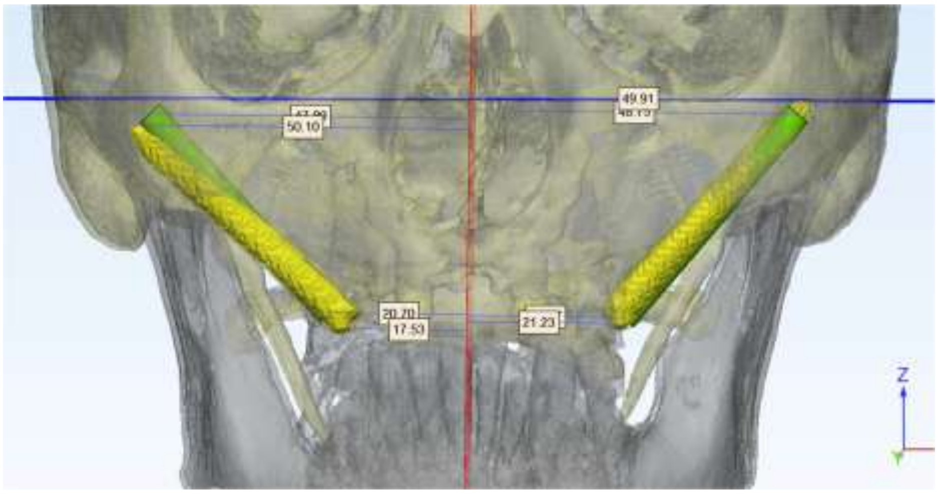

Figure 8: superimposition between the planned and placed zygomatic implants to measure Distances from implant points to the midsagittal plane (MSP)

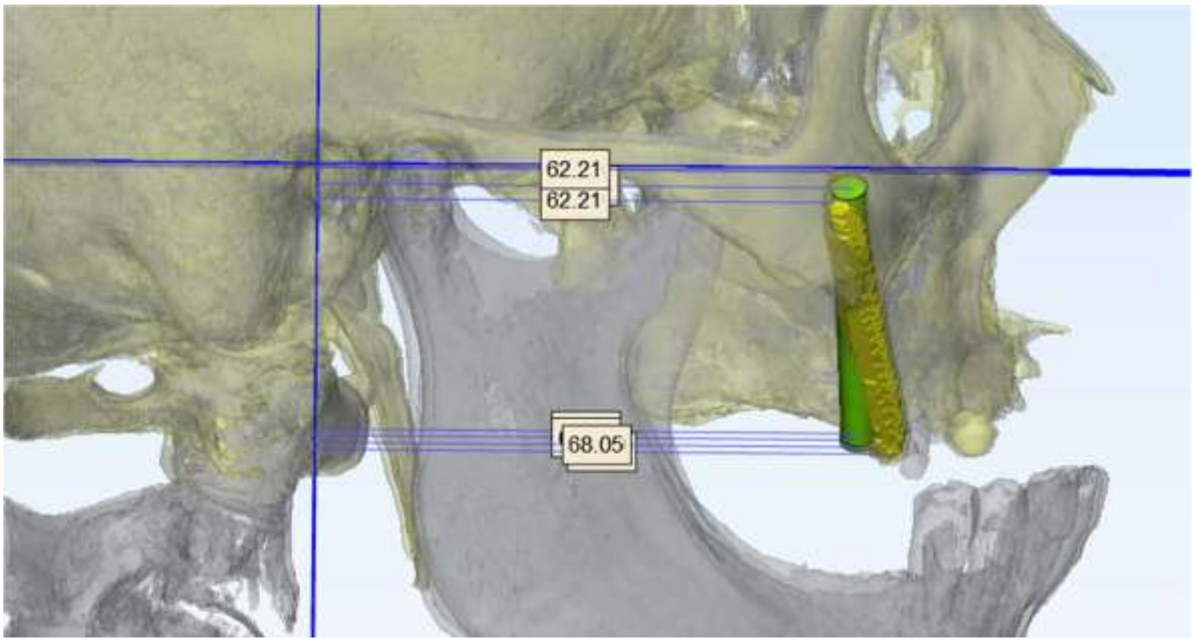

Figure 9 : superimposition between the planned and placed zygomatic implants to measure Distances from implant points to Coronal Plane (CP)

Sample size

The sample size was calculated using MedCalc® Statistical Software version 12.3.0.0 (Ostend, Belgium). The calculation was based on a 95% confidence interval, a study power of 90%, and an alpha error (α) of 5%., According to a previous study(11) . which reported a statistically significant difference in angular deviation (°) between guided surgery using surgical templates and the freehand technique. The mean angular deviation in the surgical template group was 1.19 ± 0.40°, compared to 4.92 ± 1.71° in the freehand group, with a p-value < 0.001. , based on this assumption, the calculated sample size will be at least 16 implants (8 implants in each group).

Randomization and blinding

The allocation sequence was generated using a computer-generated random sequence by Random.org and a 1:1 allocation ratio. It was concealed using sequentially numbered opaque sealed envelopes containing folded paper with the type of PSI written on it. The allocation sequence generation and concealment were conducted by a researcher who was not involved in the surgical procedures or the outcome assessment. This study was a single-blinded trial with only the outcome assessor blinded since the operator and the patient were aware of the intervention due to its nature.

Statistical methods

Statistical analysis was performed using the Statistical Package for Social Sciences program (SPSS Inc., Chicago, IL). Numerical data were described as means and SDs. Categorical data were summarized as proportions. Continuous data were compared using an independent t-test. Categorical data were compared using the chi-square test. The level of significance was set at P < 0.05.

3. RESULT

A total of eight patients (16 zygomatic implants) were included and equally allocated into two groups: computer-guided (n=4) and freehand placement (n=4). Each group received 8 implants. Demographic variables, including age and sex, showed no statistically significant differences between groups (p > 0.05) in Table *1*, confirming adequate baseline comparability, Detailed results of the outcomes are shown in Tables *2*, *3*.

Accuracy Assessment

Postoperative CT superimposition revealed that the computer-guided technique achieved significantly superior precision compared to the freehand approach:

- Mediolateral deviation (To MSP): 49.66 ± 1.87 mm (guided) vs. 53.47 ± 1.70 mm (freehand), p < 0.001

Anteroposterior deviation (To CP): 49.78 ± 14.61 mm vs. 21.84 ± 4.54 mm, p < 0.001

- Angular deviation: 5.17° ± 2.31° vs. 11.80° ± 8.48°, p = 0.050

These findings confirm a significant reduction in linear and angular discrepancies with the use of computer guidance.

Superimposition Assessment

In the guided group, the difference between virtual plan and actual implant placement was statistically significant in the mediolateral axis (p = 0.002), while cephalocaudal and anteroposterior changes were not significant.

In contrast, the freehand group exhibited a significant postoperative shift in the anteroposterior dimension (p = 0.018), with no notable deviation in the other planes.

Demographic data	Guided group (n=4)	Free hand Group (n=4)	Test value	p-value
Age "years"				
Mean±SD	54.00±4.32	47.50±6.45	1.801	0.145
Range	50-60	40-55		
Sex				
Female	3 (75.0%)	2 (50.0%)	0.533	0.465
Male	1 (25.0%)	2 (50.0%)		
Number of implant	8 (100.0%)	8 (100.0%)	0.000	1.000

Table 1: Comparison between guided group and free hand group according to demographic data.

Using: t-Independent Sample t-test for Mean±SD; Using: x2: Chi-square test for Number (%) or Fisher's exact test, when appropriate

p-value >0.05 is insignificant There is no statistically significant difference between guided group and free hand group according to demographic data, about age "years" and sex, with p-value (p>0.05).

Parameter	Guided Group	Freehand Group	p-value*
Direct Distance Deviation (mm)	3.15 ± 0.75	8.80 ± 5.41	0.011†
Direct Angle Deviation (°)	5.17 ± 2.31	11.80 ± 8.48	0.050†
Mediolateral deviation (mm)	49.66 ± 1.87	53.47 ± 1.7	0.001†
Anteroposterior deviation (mm)	49.78 ± 14.61	21.84 ± 4.54	0.0001†

Table 2: Radiographic Accuracy Comparison Between Computer-Guided and Freehand Zygomatic Implant Placement

*Independent-samples t-test and Chi-square/Fisher's exact test were used as appropriate.

†Statistically significant at p < 0.05.

Axis / Plane	Guided Group Median Δ	Freehand Group Median Δ	p-value*
Apical – Anteroposterior (To CP)	–0.33 (–2.09–2.3)	–0.56 (–3.9–6.7)	0.720

Apical – Mediolateral (To MSP)	1.12 (0.28–2.29)	–0.50 (–2.92–2.58)	0.209
Coronal – Cephalocaudal Δ (To FHP)	0.38 (–0.81–2.51)	–2.66 (–11.4–0.5)	0.031†
Superimposition (Guided – MSP)	1.13 ± 1.22	—	0.002†
Superimposition (Freehand – CP)	—	–1.42 (–3.2–0.22)	0.018†

Table 3: Superimposition-Based Positional Accuracy Assessment of Zygomatic Implants: Guided Versus Freehand Placement

*Mann-Whitney U test was used for non-parametric comparisons.

†Statistically significant at $p < 0.05$.

Δ = Deviation (postoperative vs. virtual); CP = Coronal plane; MSP = Mid-Sagittal Plane; FHP = Frankfort Horizontal Plane.

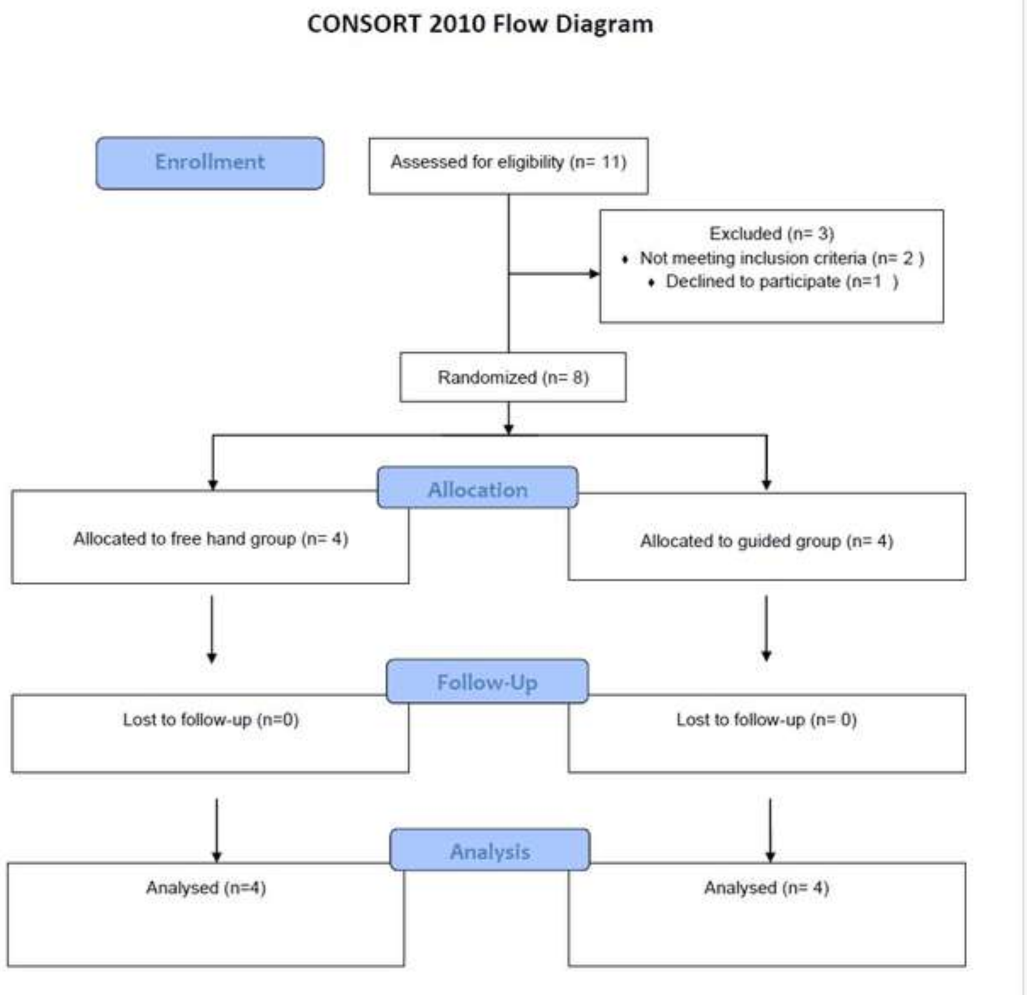

Figure 10: CONSORT flow diagram

CONSORT flow diagram of the randomized clinical trial evaluating computer-guided versus freehand zygomatic implant placement. Of 11 patients assessed for eligibility, 8 met criteria and were equally allocated to both groups (n=4 each). No participants were lost to follow-up. Exclusions (n=3) resulted from unmet inclusion criteria (n=2) or patient refusal (n=1).

4. DISCUSSION

This study investigated the comparative performance of computer-guided versus freehand techniques in placing zygomatic implants in patients suffering from severe maxillary atrophy or maxillary defects. The outcomes of this study concerning the guided zygomatic implant placement closely mirror and support the observations reported by several pivotal investigations into zygomatic implant placement. Grecchi et al. (2022) reported angular deviations of 1.19° ± 0.40 in guided versus 4.92° ± 1.71 in freehand zygomatic implants. This supports the importance of using full-length trajectory control through 3D planning and rigid templates. To overcome the difficulty in achieving accurate apical placement using conventional guides, due to limited surgical access, the flexibility of long drills, and irregular zygomatic bone surfaces [(11)].

Similarly, Chrcanovic et al. documented angular deviations exceeding 8° in the anteroposterior plane and 11° in the cranio-caudal view when using stereolithographic guides in cadaveric studies, attributing these deviations largely to manual final implant insertion and insufficient guide stability[(17)]. These studies focused on the fact that guided zygomatic implant placement must have rigid fixation and extended trajectory control. Likewise, Van Steenberghe et al. reported acceptable but variable deviations using CT-based bone-supported guides [(10)],

Vrielinck et al. emphasized the absence of trajectory control as a core limitation in traditional systems, where the average exit point deviation reached 4.46 mm and angular deviation exceeded 5°[(18)]. Moreover, Takamaru et al. proposed the pilot hole technique as a solution to similar anatomical challenges, underscoring the need for enhanced preoperative visualization and stabilization during insertion[(8)].

Jorba-García et al. (2019)[(9)], in vitro study reported enhanced accuracy through the use of surgical templates and preoperative planning tools. Importantly, mediolateral and angular precision in the guided group contributes to the avoidance of zygomatic arch perforation and improved alignment with prosthetic planning.

, these studies (8,9,10) Collectively reinforce the rationale behind the innovations applied in the surgical guide of the current study, providing both conceptual and empirical support to the accuracy and improvement.

The current study contributes to the ongoing evolution of guided zygomatic implantology by refining trajectory control, minimizing surgical risk, and enhancing reproducibility, all in alignment with the literature's recommendations and cautions(19).

To address the critical challenges associated with accurate zygomatic implant placement, the current study introduced a custom-designed, bone-supported surgical guide with multiple key innovations. This design was specifically engineered to overcome the limitations previously reported in the literature[(8-10, 17)] , Firstly, the custom -designed guide was firmly anchored to the maxilla using mono-cortical fixation screws, a feature shown to enhance stability and reduce micromovements during drilling.

Secondly, to accommodate the exceptionally long length of zygomatic drills—typically ranging between 35 mm and 60 mmm metallic sleeve with an extended guiding canal was designed. This enhancement minimized drill deviation during osteotomy in agreement with Grecchi et al. They reported difficulty in maintaining apical accuracy with shorter sleeve channels. Additionally, a significant modification in this system was the incorporation of custom-made sleeves tailored to each drill diameter and length. This customization eliminated rocking and vibration within the sleeve, offering enhanced control and directionality across the osteotomy depth.

These enhancements collectively addressed the drawbacks of conventional systems such as deviation due to full length control and those reported by Vrielinck et al., who observed deviations due to absence of full-length control, and by Chrcanovic et al[(8, 17)],They attributed angular errors to guide instability and manual final insertion. . The current guide in this study directly improved the alignment between virtual planning and surgical execution across the entire implant trajectory, from coronal entry to apical exit. Therefore, the current design aligns with recent advancements and extends them by ensuring trajectory control throughout the full length of the zygomatic osteotomy.

Guided surgery integrates CT imaging and CAD/CAM-generated templates, which streamline surgical execution and reduce intra operative guesswork. In contrast, freehand techniques rely heavily on the surgeon's spatial judgment and anatomical familiarity, leading to greater variation, particularly in the cephalocaudal plane. This variability, observed in the control group in this study, included technical Difficulty estimating correct inclination in agreement with Stella & Warner (2000)[(20)], they emphasized the technical difficulty in estimating correct inclination freehand. Although freehand placement is time-efficient and less cost-effective, it is inherently more prone to angular errors, which may compromise prosthetic outcomes.

Limitations

Despite the strengths of a prospective randomized design, this study was limited by its small sample size and relatively short follow-up (six months). As such, long-term data on marginal bone loss, prosthetic survival, and peri-implant soft tissue health remain to be established. Additionally, operator experience can influence outcomes in both guided and freehand techniques—while freehand skills improve with time, guided systems require digital proficiency and equipment access.

Recommendations and Future Directions

Future research should include larger multicenter trials with long-term follow-up to validate these results. Comparative studies involving dynamic navigation or robotic-assisted systems may also shed light on real-time accuracy and learning curves(21). Additionally, cost-effectiveness analyses are essential to evaluate whether guided surgery justifies its expense in diverse clinical settings.

5. CONCLUSION

Computer-guided zygomatic implant placement offers significantly improved accuracy without compromising implant stability or increasing complication rates. guided surgery provides greater precision in prosthetically critical dimensions and may reduce intraoperative risks in complex cases. Its adoption should be encouraged, particularly in centers equipped with digital planning infrastructure.

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