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Impact of Digital Planning on Free-hand Placement of Zygomatic Implants: An In Vitro Pilot Study

Free-hand Yöntemiyle Zigomatik İmplantların Yerleştirilmesinde Dijital Planlamanın Etkisi: İn Vitro Pilot Çalışma

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ABSTRACT

Objectives: Zygomatic implants represents a treatment alternative to bone augmentation procedures in patients with advanced maxillary atrophy. However, there is a risk of damaging surrounding anatomical structures during implant placement. To minimize the risk, accurate determination of implant positioning is crucial and three-dimensional planning is strongly recommended. The aim of this study is to assess the angular and linear deviations of zygomatic implants placed free-hand on a study model.

Materials and Methods: A total of 16 zygomatic implants were placed on four high-density polyethylene models. Cone beam computed tomography (CBCT) scans were performed for digital planning. Preoperative and postoperative images were overlaid using anatomical landmarks to assess tridimensional deviation, which was measured by the angular deviation, coronal entry and apical end point. The one-sample Kolmogorov-Smirnov test and the Mann Whitney-U test were used to analyze the results.

Results: A notable discrepancy was found between the digitally planned and the physical model with reagrd to the coronal entry point (p=0.029) and angular deviation (p=0.043), while no significant difference was observed in the apical end point. Furthermore, a significant difference was observed in the coronal entry point between the anterior and posterior implants (p=0.028)

Conclusion: Digital planning enables the pre-determination of the number, length and ideal positioning of zygomatic implants, reducing the risk of anatomical damage and optimizing the use of the limited zygomatic bone. Preoperative modeling provides a detailed anatomical overview and helps create a patient-specific treatment plan. The accurate identification of the coronal entry point is of particular significance in posterior implants, as it may influence the apical deviation.

Keywords: *Anatomic Models, Digital Technology, Zygoma.*

ÖZET

Amaç: Zigomatik implantlar, ileri derecede maksiller atrofiye sahip hastalarda kemik ogmentasyonu işlemlerine alternatif bir tedavi seçeneği olarak görülmektedir. Ancak, implantların yerleştirilmesi sırasında çevredeki anatomik yapılara zarar verme riski bulunmaktadır. Bu riski en aza indirmek için implantın pozisyonunun doğru belirlenmesi ve üç boyutlu planlama yapılması önerilmektedir. Bu çalışmanın amacı, free-hand yöntemiyle çalışma modeli üzerinde yerleştirilen zigomatik implantların açısal ve doğrusal sapmalarını değerlendirmektir.

Gereç ve Yöntemler: On altı zigomatik implant, dört adet yüksek yoğunluklu polietilen model üzerine yerleştirildi. Dijital planlama amacıyla konik ışınlı bilgisayarlı tomografi taramaları yapıldı. 3 boyutlu sapmayı değerlendirmek için preoperatif ve postoperatif görüntüler anatomik referans noktaları kullanılarak üst üste bindirildi. Sapma, koronal giriş noktası, apikal bitiş noktası ve açısal sapma üzerinden ölçüldü. Sonuçların analizinde tek yönlü Kolmogorov-Smirnov testi ve Mann Whitney-U testi kullanıldı.

Bulgular: Dijital planlama ile model arasında koronal giriş noktası (p=0.029) ve açısal sapmada (p=0.043) anlamlı bir fark bulunurken, apikal bitiş noktasında anlamlı bir fark gözlenmedi. Buna ek olarak, anterior ve posterior implantlar arasında koronal giriş noktasında anlamlı bir fark bulundu. (p=0.028)

Sonuç: Dijital planlama, zigomatik implantların sayısını, uzunluğunu ve ideal konumunu önceden belirlemeyi mümkün kılarak, anatomik oluşumlara hasar riskini azaltmakta ve zigomatik kemiğin daha iyi kullanılmasını sağlamaktadır. Preoperatif modelleme ise detaylı bir anatomik inceleme sunarak hasta özelinde bir tedavi planı oluşturulmasına yardımcı olmaktadır. Koronal giriş noktasının doğru belirlenmesi, apikal sapmayı etkileyebileceğinden özellikle posterior implantlarda oldukça önemlidir.

Anahtar Kelimeler: *Anatomik Örnekler, Dijital Teknoloji, Zigoma.*

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Introduction

The World Health Organisation posits that maxillary edentulism is typically the consequence of a prolonged history of oral disease.[1] The prevalence of completely edentulous patients in people aged 20 years and over is approximately 7% worldwide. In people aged 60 years and over, this rate is increased to be 23%.[2]

Dental implants can be used to rehabilitate the maxilla in patients with sufficient residual bone with predictable long-term results.[3] However, in cases where conventional implant treatment is contraindicated due to advanced bone resorption or the presence of pneumatised maxillary sinuses, advanced surgical techniques are used to rehabilitate the atrophic maxilla. These include sinus floor elevation[4], bone splitting, sandwich osteotomy[5], tilted or short implants[6] and guided bone regeneration (GBR).[7] In cases where advanced surgical intervention was not a viable option, the potential use of pterigomaxillary bone[8], piriform rim[9], nasal floor [9], suborbital floor [10] and zygomatic bone[11] takes place. It is important to acknowledge, that many of these techniques are associated with different risks. However, the complication rate for zygomatic implants is relatively low with a medium-term survival rate of 96.2%.[12]

Zygomatic implants were developed by Prof. Brånemark in 1998. Over the following years, numerous clinicians made improvements to the original technique, taking into account the position of the sinus and the condition of the crest. In 2010, the zygomatic anatomy-guided approach (ZAGA) classification was proposed by Aparicio based on a cross-sectional study of 200 human radiographs.[13]

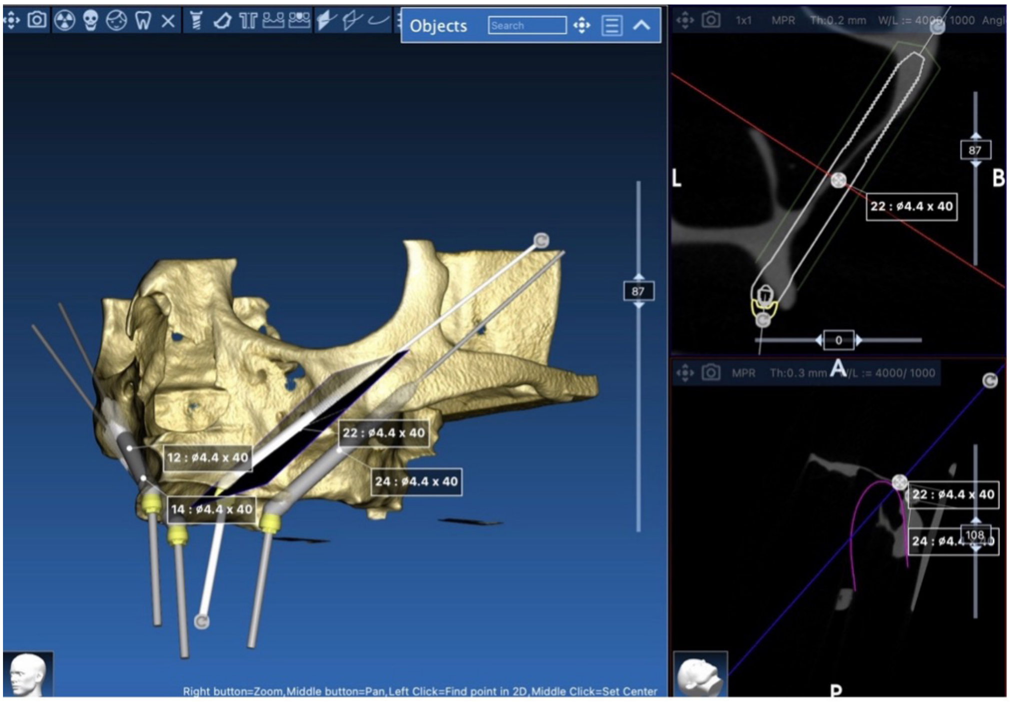
Zygomatic implant surgery is regarded as a ‘semi-blind’ procedure due to the presence of anatomical challenges and restricted intraoperative field of vision, which elevates the likelihood of surgical complications.[14] The complexity of the revision process represents a further significant challenge.[15] It is therefore of great importance to ensure that the zygomatic implants are placed in the optimal position in order to avoid the aforementioned complications. Furthermore, the available zone for zygomatic implant is approximately 1 cm, and the margin of error is minimal.[16] In order to minimize the error, researchers have focused both on static and dynamic guides.[17] However, this is preceded by a simple, yet effective method of model generation. Study models prior to surgical intervention allows for a comprehensive and easier examination of the residual bone around the zygomatic arch and the remaining alveolar crest to be conducted. Furthermore, these analogues are essential in determining the angle and coronal entry point of the implant, as well as the relationship between the implant body, the maxillary sinus and the lateral wall. This enables of a precise, personalised treatment plan, eliminating the necessity for additional or revision surgical procedures. This study aimed to assess the three-dimensional deviations of free-hand placed zygomatic implants on model analogues obtained from patient Digital Imaging and Communications in Medicine (DICOM) files.

Materials and Methods

Experimental Design

The study was conducted in the Department of Oral Implantology, Faculty of Dentistry, Istanbul University. Four high-density polyethylene (HDPE) models were constructed using the preoperative cone beam computed tomography (CBCT) data from four patients (obtained from ZAGA Center, Barcelona, Spain). CBCT scans were undertaken for the purpose of digital planning (Scanora® 3Dx, İstanbul, Turkey). (Figure 1)

Figure 1. Preoperative digital planning image



The imaging parameters were; 4 mA, 90 kV, 4 seconds, and a field of view of 6 mm × 14 mm. A preliminary plan was formulated using a dedicated software (Software Suit, RealGUIDE™). The anterior implants were positioned in the lateral tooth area, while the posterior implants were placed in the first premolar area, if applicable (Figure 2). The procedure was performed by a specialist with over 10 years of experience who had previously performed zygomatic implant surgeries. A total of 16 implants (NobelZygoma®45°; 40 mm, Nobel Biocare, Göteborg, Sweden) comprising two anterior and two posterior implants, were utilized in each model. Following the placement of the implants, a further CBCT scan was conducted. Preoperative and postoperative images were overlaid using anatomical landmarks reference points to evaluate the three-dimensional deviation, measured at the angular deviation (◦), coronal entry and apical end point (mm). (Figure 3). Any deviations observed in the implants were analyzed and compared across the axial, sagittal and coronal views by an independent radiologist. The study was approved by the Istanbul University Faculty of Dentistry Clinical Research Ethics Committee (2024/43) and conducted in accordance with the Declaration of Helsinki (revised in 2011).

Figure 2. HDPE model after the placement of zygomatic implants **A)** occlusal view **B)** frontal view

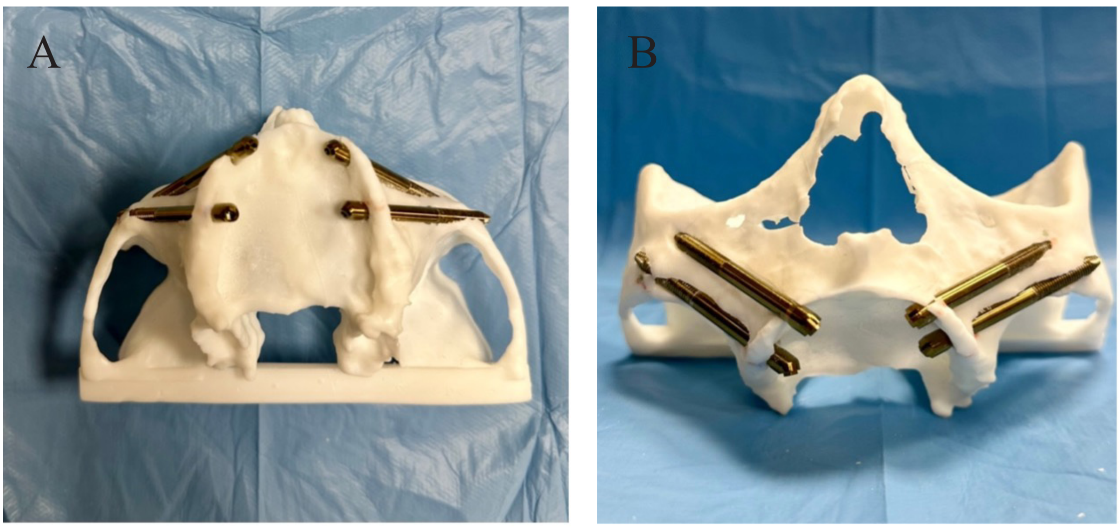
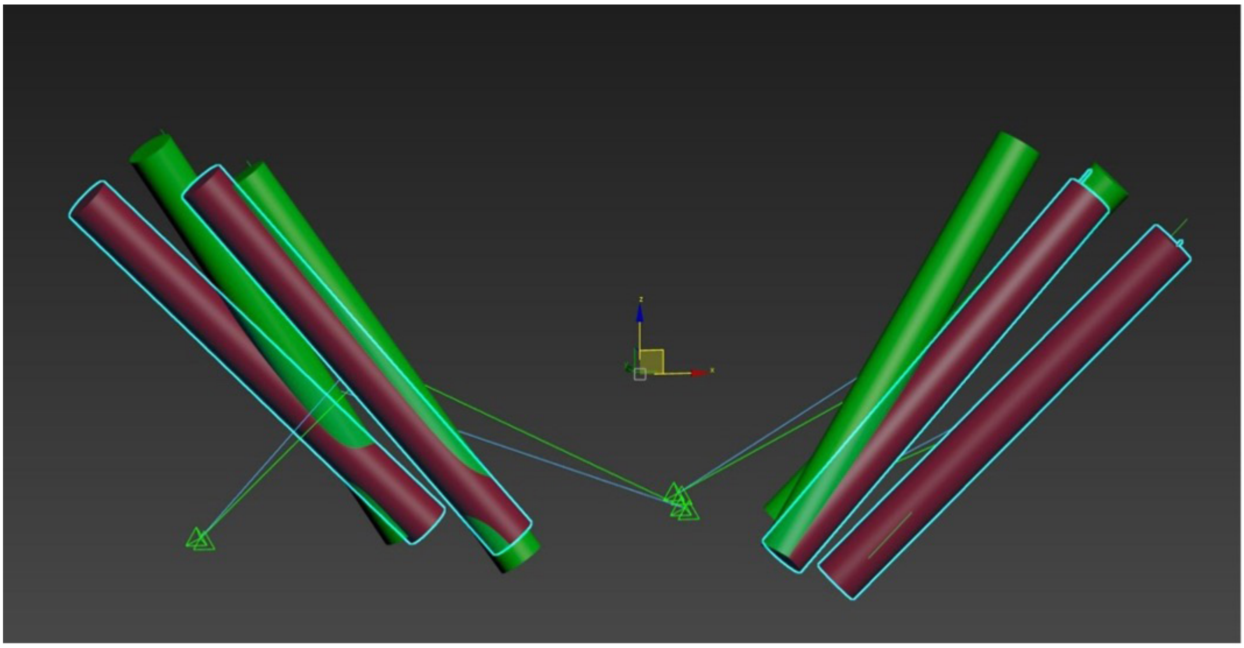


Figure 3. The superimposed image from the digital planning (red cylinders) and the model. (green cylinders)



Sample Size Calculation

In order to identify an appropriate sample size, the study conducted by Xing Gao et al., in 2021 was taken as a reference.[18] The three-dimensional deviation between the digital planning and the final position of the implants was used as a reference point. A total sample size of 9 (implant) was determined to achieve the critical t of 2,30 and noncentrality parameter of 4,28 with a statistical power of 0.95 (G Power version 3.1, Düsseldorf, Germany).

In order to account for potential separation due to the model fractures and in consideration of the fact that four implants were to be created in each model, seven additional implants were incorporated into the final sample size, resulting in a total of 16 implants across four models.

Statistical Analysis

The normality of the distribution of the data were assessed using Kolmogorov Smirnov. Due to the small sample size, non-parametric tests were conducted using a dedicated software (SPSS®, version 29.0.20.0 for Mac; IBM Corporation, Armonk, NY, USA, 2024). A one-sample K-S test was employed to assess the degree of deviation between the digital planning and the model. Additionally, the Mann-Whitney U test was performed for the purpose of evaluating the anatomical position dependent deviations of the implants. $P < 0.05$ was considered as statistically significant.

Results

A total of 16 oxidized TiUnite surface, 45° angulated, 40 mm long zygomatic implants (Nobel Biocare® Goteborg, Sweden) were placed on four HDPE models, with two implants positioned in the anterior and two in the posterior area. In the digital planning software (Software Suite, RealGUIDE™), the planned implants were superimposed with the CBCT images of the implants in accordance with their placement on the model. Subsequently, measurements of coronal entry point, apical end point, and angular deviation were performed. The results demonstrated a significant difference in the coronal entry point and angular deviation, while no significant difference was observed in the apical end point (Table 1). The degrees of deviation were then compared based on the position of the implant. A notable distinction was observed in the coronal entry point, whereas no significant difference was identified in the apical end point or angular deviation (Table 2).

Table 1. Three-dimensional deviations of the placed implants

	n	Minimum	Maximum	Mean	SD	p
Coronal Entry Point	16	2.25	28.40	8.62	7.34	.029*
Apical End Point	16	4.87	25.15	11.12	5.49	.200
Angular Deviation°	16	3.6	12.45	5.52	2.24	.043*

*p <0.05; One sample K-S test

Table 2. Three-dimensional deviations of the placed implants according to the position

		n	Minimum	Maximum	Mean	SD	p
Coronal Entry Point							
	Anterior	8	2.25	8.51	4.79	2.32	.028*
	Posterior	8	3.44	28.4	12.46	8.75	
Apical End Point							
	Anterior	8	4.87	25.15	11.24	6.63	.798
	Posterior	8	6.05	18.78	11.002	4.53	
Angular Deviation°							
	Anterior	8	3.98	12.45	6.32	2.88	.161
	Posterior	8	3.60	6.42	4.71	1.01	

* p <0.05; Mann-Whitney-U test

Discussion

The objective of this in vitro study was to investigate the discrepancies between the apical end points, coronal entry points, and angular deviations of zygomatic implants placed on HDPE anatomical models and those indicated in the preoperative digital plan. Moreover, the three-dimensional deviations were evaluated in accordance with the placement of the implants, namely, anterior and posterior. The results indicated statistically significant findings for linear and angular deviations, with the exception of the apical end point. The posteriorly placed implants demonstrated a statistically significant difference, particularly at the coronal entry point.

The zygomatic bone provides a substantial surface area and sufficient bone volume for the anchorage of zygomatic implants. Zygomatic implant placement is a highly effective approach for patients with atrophic maxilla, demonstrating long-term survival rates ranging from %94.2 to %100. [16,19] The placement of zygomatic implants is commonly performed through the combination of two zygomatic implants with conventional ones.[20]

Following the successful demonstration of the efficacy of the single zygomatic implant in conjunction with conventional implants, the quad concept was subsequently introduced into clinical practice.[20]

The quad zygoma concept is typically employed in cases of severe maxillary atrophy [21,22,23] and as a rescue implant in regions where previous implant failure has occurred.[24] The concept was initially proposed by Duarte and colleagues in 2007 and is distinguished by its high implant survival rates.[25] One of the most significant challenges associated with quad implants is the necessity of intrasinus placement, particularly in cases where there is buccal is concave. Over time, several techniques for zygomatic implant surgery have been introduced for this purpose, such as the sinus slot technique by Stella and Warner [26] and the extrasinus placement technique by Migliorança et al. [27]

As the most recent technique, Aparicio introduced the ZAGA approach. The ZAGA approach involves guiding the placement of the zygomatic implant based on both anatomical and prosthetic considerations.[28] The implant path may be intrasinus, extrasinus, or a combination, utilizing the maxillary wall for additional anchorage.[28] Compared to other techniques, the ZAGA approach makes more effective use of the available crestal bone and provides superior soft tissue management. [29] Therefore, a variety of models were employed in this study to align with the principles of the ZAGA approach. In order to achieve the optimal position for zygomatic implants, it is essential to ensure that the implant's apical part is in contact with the higher-density zygomatic bone, resulting in increased bone-to-implant contact and primary stability.[30] Hung et al. and Takamaru et al. concluded that the most suitable sites for zygomatic implants are the upper posterior and central regions of the zygomatic bone to provide ideal primary stability.[1630] Furthermore, it is crucial to undertake preoperative planning in order to avoid malposition and associated complications (extraocular injury from penetration of the orbital cavity[31], sinusitis [32], implant fracture[33] and zygomatic bone fracture [34]) that may arise as a result of the complex anatomy of the zygomatic bone. In our study, the aim was to simulate complex and advanced cases where traditional implant placement is not feasible due to severely atrophic maxillae. Given the limited volume of the zygomatic bone, we chose a method with a high success rate, and thus, the quad zygoma technique was applied.

Over the last few decades, technological advancements have transformed surgical practices into a digital realm, with the incorporation of computer technology. Digital planning has made significant advancements, allowing clinicians to accurately visualize the procedure before the operation.[35] Furthermore, it facilitates the determination of the optimal number of implants in the ideal implant position by providing preoperative data.[36] CBCT and dedicated softwares are employed in preoperative digital planning to ascertain optimal positioning of the implants.[37] The efficacy of zygomatic implants is assessed through the analysis of their precision in accordance with the digital planning that preceded their implementation. The success of the implant is determined by a comparison of the coronal entry point, apical end point and angular deviation, which is achieved through the overlap of the anatomical points of the before and after CBCT scans. [38]

Preoperative model analysis enables a comprehensive assessment of the bone structure surrounding the zygomatic arch and alveolar crest. This method facilitates the development of a precise, patient specific treatment plan, thereby minimizing the risk of complications or revision surgeries.[39] Study models can be generated through various methods. It has been documented that a variety of materials are employed in the fabrication of study models including polyurethane[38], acrylic resin[40], polyjet dental materials [41] and white polylactic acid (PLA)[42]. In the present study, HDPE was utilized, derived from the patients' DICOM data, to obtain model analogues. HDPE is a thermoplastic polymer derived from petroleum. It is characterised by high resistance to chemical agents, durability and resistance to tensile forces and impacts, exhibiting radiopaque properties.[43]

In vitro accuracy is typically greater than in vivo, which can be attributed to better access, improved visual control of the handpiece, and the lack of patient mobility, saliva, and blood.

However, the acquisition of CBCT and surface scan images, data processing, the process of transferring digital planning to the model, and operator errors are important limitations of an in vitro study.[44]

In their in vitro study, Pellegrino et al. investigated the impact of the operator's experience on implant placement accuracy and operating time. They reported that, with respect to coronal and apical 3D deviations, no statistically significant differences were observed among the four operators.[45] In our study, a single operator performed all procedures to ensure consistency and standardization, as they were the only clinician at our faculty with experience in zygomatic implants.

Previous studies have extensively evaluated the accuracy of different methods in zygomatic implant placement.

Xing et al. evaluated the clinical utility of digital planning for the placement of zygomatic implants using the free-hand method and identified significant differences in apical three-dimensional (6.114 ± 4.28) ($p < 0.05$). However, no other variable yielded significant differences.[18] In our study apical deviation is 11.12±5.49 mm and yielded no significant differences. In contrary coronal entry point and angular deviation demonstrates significant differences. A notable discrepancy between the two studies is that the present study was conducted on a patient, whereas our study employed a model. Indeed, the study reports that the apical deviation exceeded 10 mm in one patient due to limited buccal aperture. Furthermore, the study emphasized the importance of transfer error between preoperative planning and the surgical field, highlighting the crucial role of surgical experience. The accepted range was accepted for transfer error in implant surgery is typically between 0.3 and 0.6 mm.[46] The lack of a significant difference at the apical endpoint in this study may be attributed to the fact that the apical endpoint is typically located in a deeper, more stable area, which leads to less deviation in digital planning placements in vitro. However, when performed on a patient, the anatomical challenges, bone structure, and limitations of the surgical field, such as a restricted buccal aperture, may contribute to a larger apical deviation.[18]

In a separate study by Rueda et al., alternative techniques were employed in comparison to the freehand technique. The authors demonstrated that the free-hand technique exhibited reduced deviation values at the apical end point (3.20 ±1.45) and coronal entry point (4.75 ± 1.58) when compared to the dynamic navigation and static guide. Nevertheless, it exhibited higher angular deviation values (8.47° ± 4.40) when compared to the aforementioned techniques. Furthermore, this study found that zygomatic implants in the posterior regions exhibited elevated deviation values at the angular level, coronal entry and apical end point.[38] When evaluating the position of the implants in our study, elevated differences were found only at the coronal entry point in favour of posteriorly placed implants.

In a study on human cadavers, Grecchi et al., found that the guided surgery system showed greater accuracy in all evaluated variables compared to the freehand technique. The angular deviation (1.19°±0.40° and 4.92°±1.71°), coronal entry point (0.88 mm±0.33 mm and 2.04 mm±0.56 mm) and apical end point (0.79 mm±0.23 mm and 3.23 mm±1.43 mm, p<0.001) was significantly lower.[47] This study concluded that the use of a guide yielded more accurate results compared to the free-hand technique, suggesting that our research could be expanded by incorporating different techniques.

In their systematic review, Fan et al., examined the accuracy of zygomatic implant placement in patients with severely atrophic, edentulous maxillae using static and dynamic computer-aided surgery and a freehand technique. The pooled mean deviations of zygomatic implants in the free-hand group were 2.04 mm at the coronal entry point and 3.23 mm at the apical end point and 4,92° with angular deviations [48] The findings of this study indicate that the freehand method yielded less precise results for all assessed parameters. This finding also lends support to the high degrees of deviation observed in the present study. Similarly, Chen et al., compared three methods in terms of conventional implant placement accuracy. They found that the accuracy achieved using either static or dynamic guide systems was higher than the free-hand method. The mean deviations of implants in the free-hand group were 1.44 ± 0.56 mm at the coronal entry point and 2.00 ± 0.79 mm at the apical end point and 9.26° ± 3.62 with angular deviations.[49] On the contrary, Van Steenberghe et al., reported that the differences between planned and actual implant positions are very similar. The mean difference found was 2.0-2.5 mm for linear discrepancies and 3 degrees for angular discrepancies.[50] The measured deviations between digital planning and model analysis was 8.62 ± 7.34 at the coronal entry point, 11.12 ± 5.49 at the apical end point, and 5.52° ± 2.24 for angular deviation. Notably, significant differences were observed at the coronal entry point (p = 0.029) and in angular deviation (p = 0.043), with no significant difference at the apical end point. These findings highlight the impact of implant positioning on accuracy and align with prior research, emphasizing the critical influence of technique on minimizing deviation.

Nevertheless, it is important to acknowledge the limitations of this study. As a pilot study, the limited sample size hinders the ability to achieve statistically significant results. Having a single operator is among the limitations of the study in terms of variability and reproducibility. Additionally, the lack of a control group prevents direct comparison with other procedures, limiting the ability to accurately assess the the true impact of the intervention. Finally, it is important to note that although model surgery is a valuable preoperative tool, it does not accurately reflect the actual surgical situation. This can often result in deviations due to the material used in the model. While digital planning provides useful preliminary information regarding implant characteristics and positioning, the lack of an effective method to fully transfer this planning onto the model remains a major limitation.

Conclusion

Zygomatic implant surgery is a complex surgical procedure. Digital planning allows, the number, length, and optimal positioning of zygomatic implants to be determined in advance, minimizing the risk of damage to anatomical structures and maximizing the use of the limited area of zygomatic bone. Working with a preoperative model facilitates a comprehensive understanding of the anatomy and allows for the development of a patient-specific treatment plan. The accurate identification of the coronal entry point is of particular significance in posterior implants, as it may influence the apical deviation. The precision and safety attained through the free-hand technique primarily rely on the practitioner's expertise and skills.

Ethical Approval
The necessary ethical approval for this study was obtained from Istanbul University Faculty of Dentistry Clinical Research Ethics Committee (2024/43).

Conflict of interest
None of the authors of this article has any relationship, connection or financial interest in the subject matter or material discussed in the article.

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Authorship Contributions
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