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Effectiveness of the 'Mesiodistal Guide Set' in Dental Implant Placement: A Clinical Trial

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Abstract

Objectives: This study used a newly designed mesiodistal guide set to assess and compare the precision of the mesiodistal positioning of dental implants relative to adjacent teeth. The cost-effective and convenient guide set was compared to the conventional freehand surgery technique in partially edentulous patients.

Methods: The study enrolled 38 patients requiring at least one implant. Participants were divided into case and control groups, receiving 30 implants in each group: 10 in free-end areas, and 20 in single-tooth edentulous spaces. In the case group, implants were placed using the mesiodistal guide set, while the control group underwent the freehand procedure. The postoperative evaluation involved taking parallel periapical radiographs to measure distances and angles between the implants and adjacent teeth using Photoshop CS4. The data was rigorously analyzed using the Generalized Estimating Equations (GEE) method, a statistical technique for modeling clustered data, with statistical significance set at $p<0.05$.

Results: Measurements of the mesiodistal distances between implants and adjacent teeth showed reduced deviations in the case group, with statistically significant differences in mesial (P=0.001) and distal (P=0.036) distances. The tooth-supported area exhibited better outcomes compared to the free-end area. However, there were no significant differences in implant-tooth angulation, whether mesial (P=0.503) or distal (P=0.188).

Conclusion: The study indicated that the mesiodistal guide set offers practical guidance for positioning implants next to teeth in partially edentulous patients. This finding has significant practical implications, providing tangible evidence for the clinical application of the guide set. Despite some limitations, the findings fall within clinically acceptable parameters, and the guide set proved to enhance accuracy over the freehand method.

Keywords Dental implants; Guided surgery; Equipment design

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Introduction

Dental implants are widely recognized as the optimal solution for restoring fully and partially edentulous areas due to their impressive functional and aesthetic outcomes and durability. However, this therapeutic option has complications that can affect its longevity and effectiveness.[1,2] The precise placement of the implant is a critical factor in avoiding potential risks such as damage to nearby anatomical structures, including the mandibular canal, maxillary sinus, nasal cavity, and neighboring teeth.[3-5] Incorrect positioning may also increase the risk of periodontal bone loss in adjacent teeth and lead to peri-implantitis due to inappropriate buccolingual and mesiodistal placement.[6-8]

In response to the challenges of achieving precise implant placement, technological advancements have led to the development of computer-aided surgery (CAS), divided into static and dynamic categories.[9,10] However, these systems have their limitations. Static surgical guides, for instance, use digital imaging from CBCT or intraoral scanners and CAD/CAM processes to create templates that offer varying levels of guidance (pilot, partial, or full).[11] Although these guides enhance the accuracy of implant placement, their use is sometimes limited by factors such as the time and cost of template production, rigidity during surgery, obscured surgical views, suboptimal cooling, and challenges in patients with restricted mouth opening.[12-14]

Dynamic systems provide real-time surgical navigation displayed on a computer screen, attempting to mitigate some static systems' limitations. Nevertheless, these systems introduce other challenges, such as high costs, spatial demands, simultaneous focus on the surgical field and display, and specific surgeon training requirements.[13,15]

Despite evidence indicating that any degree of guidance can improve results during implant placement, the freehand method is widely employed due to its simplicity and lower cost.[16-19] Nonetheless, its reliance on the surgeon's skill and experience can lead to variations in implant placement accuracy. This can underscore the need for a more cost-effective and convenient system in dental implant placement.

This context has stimulated the introduction of various commercially available surgical guides. These guides often prioritize cost-efficiency and ease of use, although their clinical validity and overall effectiveness frequently still need to be assessed.[20-25]

This study examined a newly patented, cost-effective surgical guide set designed for straightforward use.[26] This set comprises four double-ended probes with different sizes, which facilitates accurate mesiodistal positioning of the initial drill during osteotomy and holds the promise of significantly improving the effectiveness and efficiency of dental implant placement. The primary aim of this pivotal clinical trial was to evaluate and compare the efficacy of this surgical guide set with the traditional freehand method.

Methods

Participants

The study enrolled 38 patients, who were divided into case and control groups. The case group consisted of 19 patients representing 30 implant sites, where the mesiodistal guide was used for implant placement. The remaining 19 patients, similarly with 30 implant sites, formed the control group, which received implants placed by the freehand method without a physical guide. This study's inclusion criteria were as follows:

- Patients who needed at least one implant for free end or single-tooth edentulous area
- Provision of informed consent

Before surgery, all patients underwent sectional CBCT at the implant site for radiographic evaluation. The surgeries were performed in a private dental office. The ethics committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran, approved the study protocol. (IR.SBMU.DRC.REC.1402.157)

Sample Size

Based on a pilot study conducted with ten patients and assuming a confidence interval of 95% and a power of 80%, the minimum sample size was determined to be at least 27 dental implants per group. Thirty samples were included in each group to ensure more accurate results.

Surgical procedure

Patients were instructed to rinse with a chlorhexidine solution for 30 seconds. Local anesthesia was then applied to the surgical site. A surgeon with ten years of experience in implant treatment performed the surgical procedures. The surgery commenced after confirming the effectiveness of the anesthesia and elevating the mucoperiosteal flap.

The appropriate probe size was selected based on two parameters to position the starter drill (Figure 1) correctly:

1. The diameter of the implant
2. The space required between tooth and implant

For the implant placement in a single-tooth edentulous space, the largest probe size fitting the available mesiodistal distance was used to place the implant in the center of a single-tooth edentulous space. The starter drill was then positioned against the middle groove of the probe and drilled through it, ensuring the correct positioning of the implant in the center of the edentulous space.

The same parameters were considered for inserting the implant distal to the last existing tooth in the free end area (Figure 1). The starter drill was then positioned against the middle groove of the probe and drilled through it.

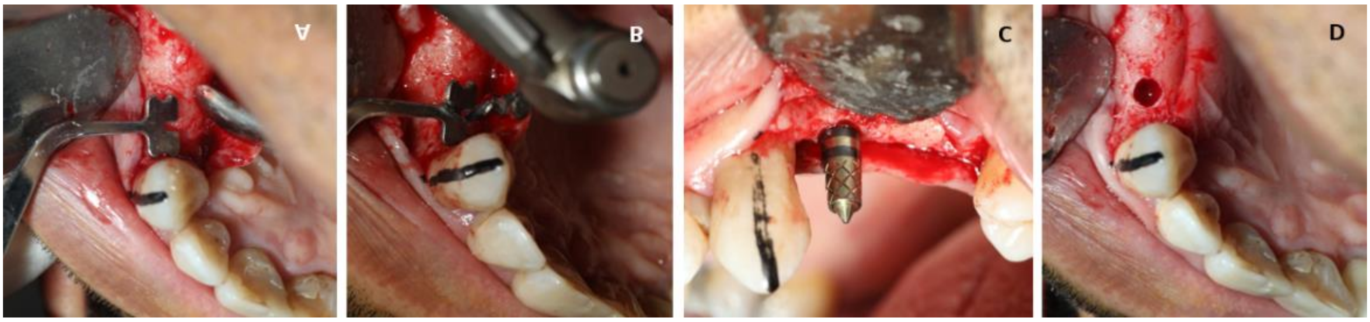

Figure 1: (A) Placing the probe with proper size (B) Drilling through the middle groove of the probe (C) Placing parallel pin to check the mesiodistal position and angulation of the drilling (D) Final osteotomy preparation

Data analysis

A parallel periapical radiograph was taken after the implant was placed (Figure 2). The length-to-width ratio of the radiographs was corrected to correspond to the actual size of the implant. Mesiodistal distances and implant angulations were measured in Photoshop CS4 by a senior dental student. Variables measured in this study included:

1) Mesiodistal linear distance between the implant axis and a line tangent to the HOC of the adjacent teeth.

2) Angle between the axis of the implant and adjacent teeth.

Two weeks later, ten cases were remeasured to assess intra-examiner error. This data was used to calculate intraclass correlation coefficients. The reliability of the measurement method was quantified using this calculation. The intraclass correlation coefficient is a numerical representation indicating the agreement level between consecutive measurements. Larger values of this numerical representation indicate a more vital agreement. Excellent agreement is denoted by values exceeding 0.9, which, in this case, was calculated to be 0.94 that suggested a high level of reliability for the method.

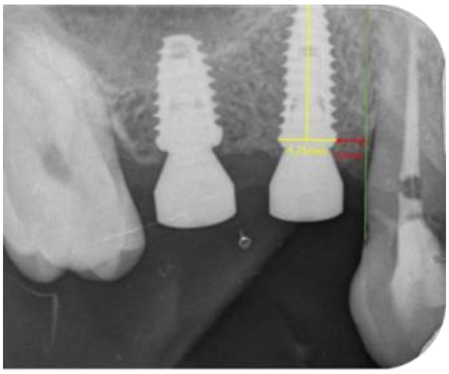

Figure 2: Parallel radiograph of the implant shown in figure 1. The implant was parallel to the line tangent to the height of contour of the adjacent tooth. Considering 2.5 mm space between the tooth and the implant and half of the implant's diameter (approximately 2.5 mm), a probe with 10 mm head size was used. By drilling through the middle groove of the probe, appropriate mesiodistal distance can be achieved

Statistical Analysis

SPSS version 26 (SPSS Inc., IL, USA) was used to analyze the collected data. The clustered data was managed using a generalized estimating equations (GEE) approach. The accuracy of guided osteotomy drilling compared to freehand drilling was examined using the GEE approach. In our GEE model, an unstructured working correlation was used to address possible dependencies in the data. The identity function was utilized as the link function, enabling a straightforward interpretation of the regression coefficients. Furthermore, we assumed an exponential distribution family for the outcome variable, which is especially advantageous in analyzing time-to-event or survival data. A significance level of 0.05 was considered.

Results

In the case group, the mesiodistal guide was utilized to place 30 implants for 19 patients. In the control group, 19 patients received 30 freehand implants. Each group had ten implants placed in the free end areas and 20 in single-tooth edentulous areas. Following implant placement, measurements were taken to determine the mesiodistal distance between the implant axis and a line tangent to the HOC of the adjacent tooth, as well as the angle between the implant and the adjacent tooth.

Based on the measurements of the mesial distance between the implants and adjacent teeth in the case group, 1.1 mm and 0.1 mm were found as the maximum and minimum deviations between the planned and actual distances. The maximum and minimum differences between the control group's planned and actual mesial distances were 2.5 mm and 0 mm, respectively.

As a background variable, the effect of mesial angulation was adjusted to analyze mesial distance differences. According to the GEE analysis, there were significantly fewer errors in the case group than in the control group (P=0.001). The estimated difference between the two groups was 0.6 mm, which means the case group was 0.6 mm more accurate than the control group. The type of edentulous space (whether tooth-supported or free end) had no significant effect (P=0.567). Also, the interaction between the mesiodistal guide and the type of edentulous space was not statistically significant (P=0.097), meaning the case group had lower errors in both free-end and single-tooth edentulous areas than the control group. However, in the case group, the accuracy of mesial distance in single-tooth edentulous areas was 0.37 mm higher than in free-end areas.

Measurements of the distal distance between the implants and adjacent teeth in the case group revealed a maximum and minimum deviation of 2.9 mm and 0 mm, respectively. There was a maximum and minimum difference of 1.45 mm and 0.1 mm between the planned and actual distal distances in the control group. The result of GEE statistical analysis showed that the case group had significantly less error than the control group when distal angulations and the age of patients were adjusted as background variables (P=0.036). There was a difference of 0.31 mm between the case and control groups, showing that the case group had 0.31 mm less error than the control group.

The mean value and standard deviation of distal and mesial distance differences in the free end and single-tooth edentulous areas are shown in Table 1.

Table 1- Linear distance between the implant axis and a line tangent to the HOC of the adjacent tooth

Variable	Group	Number	Mean	Std. deviation	95% confidence interval	
					Lower	Upper
Mesial distance difference (Free end area)	case	20	0.325	0.27	-0.56	0.43
	control	20	0.585	0.61		
Mesial distance difference (Single-tooth edentulous area)	case	10	0.095	0.06	-1.01	-0.24
	control	10	0.725	0.56		
Distal distance difference	case	10	0.415	0.88	-0.85	0.47
	control	10	0.605	0.47		

The independent samples t-test did not indicate any significant differences between the case and control groups regarding angulation between the implant axis and the mesial tooth (P=0.503). There was also no significant difference between the case and control group considering the angulation between the implant axis and the distal tooth, according to independent samples t-test (P=0.188) (Table 2).

Table 2- The angle between the longitudinal axis of the implant relative to the axis of the adjacent tooth

Variable	Group	Number	Mean	Std. deviation	95% confidence interval	
					Lower	Upper
Mesial angulation	case	30	4.86	5.86	-4.56	2.26
	control	30	6.01	7.28		
Distal angulation	case	10	6.75	7.48	-11.92	2.52
	control	10	11.45	7.88		

Discussion

The prevailing method in implantology that prioritizes prosthetic outcomes highlights the critical need for precise implant placement. Even minor deviations from the planned location of an implant can complicate the creation of an ideal prosthetic restoration.[27,28] Moreover, the construction of the prosthetic is crucial not only for aesthetic reasons but also for its impact on the health of the implant.[29,30]

Guided implant surgery ensures the precision of osteotomy procedures and avoids damaging nearby teeth and other anatomical structures.[31] In light of the limitations of both static and dynamic systems, as previously discussed, and the uncertain effectiveness of other available surgical guides, the present study focused on assessing the precision of a novel pilot drill surgical guide. This guide was precisely engineered to direct the mesiodistal placement of implants next to teeth in patients with partial edentulism.

The primary outcome of this study highlighted a significant improvement in the accuracy of implant placement in terms of mesiodistal distance between the implant and adjacent tooth in the case group compared to the control group. This finding underscored the efficacy of the surgical guide set in providing precise mesiodistal guidance. Specifically, we noted a mean distal distance discrepancy of 0.41±0.88 mm, a mesial distance discrepancy of 0.32±0.25 mm in the free end area, and a lower discrepancy of 0.095±0.06 mm in the tooth-supported area. The superior results in the tooth-supported area may be due to the surgeon's increased reliance on tactile sensation rather than visual guidance in the tooth-supported area. However, the statistical significance of this finding was not established. Notably, even when using fully guided dynamic implant navigation systems, a higher variability in placement accuracy at the free end area was observed.[32]

The present findings aligned closely with those reported in recent systematic reviews about dynamic navigation systems. The mean global platform deviation noted was 0.91 mm in model-based studies and 1.11 mm in clinical trials.[33], both of which exceeded the deviations observed. Similarly, the global coronal deviation reported was 1.03 mm in laboratory studies and 1.00 mm in clinical settings[34], surpassing the present measurements. Various factors have been identified as contributors to the inaccuracies of dynamic navigation systems, such as imaging techniques, software processing, system calibration and tracking, the learning curve of the surgeon, and patient movement during surgery or imaging.[35,36] While the present results were similar to those of dynamic systems, the specific advantages of three-dimensional guidance offered by dynamic navigation need to be acknowledged.

Marques-Guasch and colleagues analyzed 1880 implants and found an average coronal horizontal deviation of 0.86 mm in dynamic navigation, 1.03 mm with static guidance, and 1.61 mm using freehand surgery.[12] In a different systematic review, the reported average coronal deviation was 1.10±0.09 mm in clinical settings and 0.77±0.15 mm in lab settings with static guides.[37] These deviations in static guides could be linked to cumulative errors arising at various stages of template construction. In comparison, the observed mean deviations were consistently lower than those associated with static guidance and fell within clinically acceptable ranges.

Compared to studies with similar innovative designs, Amid et al. found an average mesiodistal discrepancy of 0.28±0.19 mm in their lab-based research.[38] The superior outcomes could be due to the design of the guide, which supports both tooth and mucosa. The system includes various crown-guide accessories designed to fit into a device called a "rocket," which adjusts to the height of contour between adjacent teeth. An end ring stabilizes this rocket on a ridge, enhancing its steadiness.

In the secondary outcomes of this study, a trend towards improved angulation, both mesially and distally, was observed in the case group compared to the control group. However, these improvements did not reach statistical significance. Angulation, influenced by biomechanical factors, is crucial in planning prosthetic treatments. Considering the pros and cons of different restorative connections, switching from screw-retained to cement-retained restorations for implants that are not correctly aligned might be necessary.[39,40]

In a systematic review, the mean angular deviation observed was 4.1° for in vitro dynamic navigation studies and 3.7° for clinical ones. At the same time, the present findings showed deviations of 4.8°±5.8° and 6.7°±7.4° for mesial and distal angulations, respectively, in the case groups.[34] As detailed in their review, Wei et al. noted a mean global platform deviation of 4.2° in clinical trials using dynamic navigation.[33] Another review documented mean angular deviations of 3.40° with dynamic navigation, 3.44° with static guidance, and 6.99° with freehand surgery.[19] Overall, the angular guidance accuracy of our probes was within a clinically acceptable range and generally better than what is typically seen with freehand surgery.

When interpreting the results, it is crucial to consider the limitations of this study, such as the small sample size and the focus on implants placed next to a tooth. Our probes can also provide pilot guidance next to another implant, and the accuracy of this approach could be further assessed. The higher standard deviation compared to the mean values may suggest that the data distribution is not uniform. Additionally, the same surgeon conducted all implant procedures in this study, which could skew the results. A dual-operator method, incorporating surgeons with varying experience levels as independent variables, might have provided more comparative insight. It is important to note that while this device aids in implant placement, it does not replace the extensive knowledge required for implant procedures. Future research should explore how variables like surgical expertise, the number of implants, and the anatomical context (such as proximity to a tooth or another implant) influence the outcomes of implant treatments.

Conclusion

In summary, the mesiodistal guide set is adequate in the mesiodistal dimension of implant placement in osteotomy procedures, surpassing freehand methods. It meets clinical standards and compares favorably with static and dynamic computer-aided surgical techniques in the mesiodistal dimension, particularly for patients with partial edentulism.

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Ethical Approval Code:
The ethics committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran, approved the study protocol. (IR.SBMU.DRC.REC.1402.157)

Informed Consent Statement: Informed Consent Statement has been obtained from all participants involved in this research.

Data Availability Statement: The data from this study is available upon request.

Conflict of Interest: No Conflict of Interest Declared ■

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