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Designing, fabrication, and efficacy assessment of a new surgical guide for dental implant placement in partial edentulism

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Objectives Several tools have been introduced to increase the accuracy of dental implant placement. This study aimed to design and fabricate a new surgical guide for dental implant placement in partial edentulism and assess its efficacy.
Methods The designed aluminum surgical guide has eight accessories and one graded rocket. The accessories have 6, 7, 8 and 9 mm diameter, and 6 mm height. Each accessory pair has a hole for passage of 2 mm and 2.8 mm drills. The efficacy of the designed surgical guide was tested by placement of 15 dental implants in jaw models. Cone-beam computed tomography (CBCT) scans were obtained, and analyzed to assess the implant-tooth and inter-implant distances and inter-implant angulation using NNT Viewer software. Data were analyzed using one-sample t-test. P<0.05 was considered significant.
Results A significant difference was noted between the planned and actual values in the implant-adjacent tooth mesiodistal distance (P<0.001), and inter-implant distance (P=0.005). However, no significant difference existed in inter-implant angulation (P=0.073). The mean implant-tooth and inter-implant distances, and the mean inter-implant angulation were 0.284±0.199 mm, 0.0350±0.176 mm, and 3.883±4.20°, respectively.
Conclusion The designed surgical guide had high accuracy in achieving optimal inter-implant angulation and linear implant-adjacent tooth and inter-implant distances, and the obtained mean values were clinically acceptable.
Keywords Dental Implants; Jaw, Edentulous, Partially; Equipment Design

Introduction

Dental implants are a relatively novel treatment option with extensive applications for dental rehabilitation of patients with partial or complete edentulism(1). Despite the existing controversies, the success rate of dental implants is reportedly as high as 93%(2). On the other hand, by an increase in demand for any clinical procedure, the risk of associated complications also increases(3).
Several influential factors have been suggested to be involved in failure of dental implant treatments, such as not achieving optimal osseointegration, peri-implant defects, biodynamic failures, and inappropriate implant positioning(4). Suboptimal implant placement can bring about unfavorable results, and adversely affect the success rate and survival of implant-retained prosthetic restorations(5). This is particularly important when dental implants are placed in partially edentulous jaws adjacent to natural teeth since they may compromise the soundness and vitality of the adjacent teeth(2). Thus, some tools have been designed to guide the path of implant insertion such as the computer-aided surgical guide, which uses the computer technology for correct placement of dental implants. At present, two approaches, namely the static guidance and dynamic navigation, are used for computer-aided implantology. They have advantages such as transfer of prosthetic treatment plan to the jaw, enabling flapless surgery or surgical procedures with small flaps, decreased risk of iatrogenic trauma to the adjacent anatomical structures, and more efficient dental rehabilitation due to higher accuracy of implant placement(6). However, despite high accuracy, these techniques have shortcomings such as high cost of equipment, requiring software equipment, and being influenced by the degree of mouth opening, vision of surgical site, and tactile sense of surgeon(7, 8). Moreover, there is no ideal protocol for surgery with a surgical guide, and many studies have reported variable degrees of angular, horizontal and vertical deviations between the digitally planned values and the actual surgical results(8, 9).
Surgical guides are designed to enhance placement of dental implants. The Abrahami Drill Guide kit is a commercially available surgical guide, which has an extension arm that determines the appropriate drilling site for dental implants by observing a safe inter-implant distance(10). The EZ stent is a type of surgical template that can be formed due its thermoplastic property in warm water. It is placed at the site of implant placement and serves as an accurate surgical guide. It has a titanium sleeve with 2.3 mm diameter, which is compatible with the diameter of the pilot drill of most implant systems and enables implant placement in patients with different classes of edentulism (single and multiple). Moreover, it does not require additional equipment or patient exposure to X-ray radiation, which are among its advantages. However, incomplete adaptation of the thermoplastic template to the site allows guiding of the pilot drill only in single tooth set model, which limits its extensive use(11). The Salvin implant guidance system contains three colored, non-transparent guides, which are used for placement of

short, medium and long implants. Inability to adjust the implant-tooth and inter-implant distances in placement of multiple implants and instability during drilling are among the drawbacks of this surgical guide(12).

A novel technique was introduced in 2018 for dental implant surgery with the help of software programs. However, no statistical data are available regarding preliminary in vitro or clinical studies on the accuracy or efficacy of this technique. Despite the manufacturer's claims regarding the many advantages of this tool, and great enhancement of implant surgery, it has drawbacks such as complex use, long waiting time since it needs to be fabricated in a dental laboratory, and inefficacy if even the slightest modification is required at the surgical site(13). Although many strategies have been suggested for implants placed out of occlusion (such as the use of angulated and customized abutments), treatment planning and surgical placement of implants should be ideally performed with correct angulation from the first place(14). Thus, considering the significance of correct osteotomy and placement of implants in the desired position, this study aimed to design and fabricate a new surgical guide for enhanced placement of dental implants in cases with partial edentulism. Also, drilling and implant placement were performed on jaw models with this tool to assess its efficacy.

Methods and Materials

This study was carried out in three phases of (I) designing the surgical guide, (II) fabrication of prototype and final model, and (III) in vitro efficacy assessment on jaw models, which were all conducted at the Periodontics Department of School of Dentistry, Shahid Beheshti University of Medical Sciences, Tehran. The study protocol was approved by the ethics committee of this university (IR.SBMU.DRC.REC.1398.12).

Designing the surgical guide:

The surgical guide was designed using Solid Works 2019 software program and has the following components:

- A graded rocket (in millimeters) with two grooves along its lateral sides. The accessories can enter the rocket through the entrance of these grooves and stop at the closed end of the grooves. The other end of this rocket has a ring that is held by finger pressure and confers further stability to the device during use while maintaining its flexibility. Eight cubic-shaped accessories with sizes corresponding to the diameter of final prosthetic crowns with 6 mm height were also designed, each with two components at their mid-height for locking in the rocket at both sides and movement in the rocket grooves. The first accessory pair had 6 mm height and width, and one of them had a hole for the passage of 2.0 mm drill and the other had a hole for the passage of 2.8 mm drill. The second accessory pair had 7 mm height and width, and one of them had a hole for the passage of 2.0 mm drill and the other had a hole for the passage of 2.8 mm drill. The third accessory pair had 8 mm height and width, and one of them had a hole for the passage of 2.0 mm drill and the other had a hole for the passage of 2.8 mm drill. The fourth accessory pair had 9 mm height and width, and one of them had a hole for the passage of 2.0 mm drill and the other had a hole for the passage of 2.8 mm drill. To allow movement of drills through the holes, according to the table of tolerances, 0.3 mm tolerance was considered for smooth movement of drills through the holes designed in the accessories. The diameter of the hole for 2.0 mm pilot drill was 2.3 mm, and the diameter of the hole for the 2.8 mm twisted drill was 2.8 mm, which were compatible with the drills of most implant systems. The accessories were designed to maintain minimum mesiodistal distance of 1.5 mm between the external implant surface and a line tangent to the height of contour (HOC) of the adjacent tooth. The 6 mm accessory was suitable for implants with 3 mm or smaller diameters, the 7 mm accessory was suitable for 4 mm and smaller implant diameters, the 8 mm accessory was suitable for 5 mm and smaller implant diameters, and the 9 mm accessory was suitable for 6 mm and smaller implant diameters. These sizes corresponded to the diameter of wide, standard, and narrow implants manufactured by most implant system manufacturers. The lateral sides of the accessories that were located adjacent to the other accessories had a magnet that enabled their placement in the same direction, conferring further stability during drilling (Figure 1A).

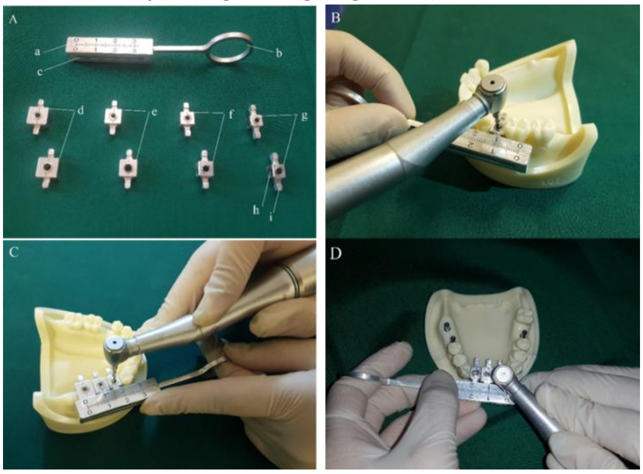

Figure 1- (A) Components of the surgical guide: (a) graded rocket, (b) hand grip of the device, (c) groove at one side of the rocket for engagement of accessories, (d) 9 mm accessory pair, (e) 8 mm accessory pair, (f) 7 mm accessory pair, (g) 6 mm accessory pair. In each accessory pair, the upper-part hole is used for the passage of 2 mm drill and the lower-part hole is used for the passage of 2.8 mm drill, (h) magnet of the lateral surface, (i) accessory component for engagement in the rocket; (B) drilling of implant hole in a single edentulous space by resting on a posterior tooth, (C) drilling of implant hole in multiple edentulous spaces in a free-end posterior region; (D) drilling of implant hole in multiple edentulous spaces in the anterior region

Manufacturing process:

The primary resin models were first fabricated with transparent and non-transparent resins. After eliminating the shortcomings, the design was finalized. Next, all components were fabricated from 6061t6 aluminum alloy with a computer numerical control machine. The rocket components were assembled, and a sleeve made of 304 steel was fabricated and pressed inside the accessories to minimize the wear of this part by the movement of drills. Laser was used for grading of the working arm of the rocket in degrees to enable measuring the size of edentulous space before and after the procedure. Each accessory was marked at the center by the same manner to match the grading on the rockets (Figure 1A).

Executive protocol:

Identical partially edentulous jaw models (HT 107 and HT 103 models; Haseban, Iran) were obtained. Fifteen implants (SIC max implant, SIC Invent, Switzerland) with 4.2 mm diameter and 9.5 mm height were placed in edentulous areas. Drilling was performed by a senior dental student with no prior surgical experience according to the protocol suggested by the implant manufacturer with the implant motor operating at 1200 rpm for the drills, and 40 rpm and 25 Ncm torque for placement of fixtures.

After selecting the number and type of accessories corresponding to the available edentulous spaces according to the routine principles of treatment planning for clinical cases, they were selected in appropriate diameter and number based on the presence of single or multiple edentulous spaces, and placed in the rockets. Drilling of the implant holes was started at the designated sites in a parallel manner relative to each other and perpendicular to the alveolar bone using the designed surgical guide.

The accessories were adapted to the alveolar ridge with the help of the rocket, and after resting the lateral surfaces of the accessories on the proximal surfaces of the adjacent teeth, osteotomy of the implant site was performed (Figure 1B to D).

Data collection:

Cone-beam computed tomography (CBCT) was then performed in high-resolution mode using a NewTom VGI CBCT scanner (QRL, Verona, Italy) with the exposure settings of 110 kVp, 3.3-10 mA, minimum voxel size of 150 µm, and 12 x 8 cm field of view; the DICOM files were saved. The following measurements were made on cross-sectional images using NNT Viewer version 8 (NewTom VGI, Italy): (I) mesiodistal linear distances between the longitudinal axis of the placed implants and a line tangent to the HOC of the adjacent tooth/teeth, (II) the mesiodistal linear distance between the longitudinal axes of adjacent implants, (III) angulation of the longitudinal axis of implants placed in multiple edentulous spaces compared with 0° (ideal inter-implant angulation/parallel placement of implants relative to each other). All measurements were made in a blinded manner (Figure 2).

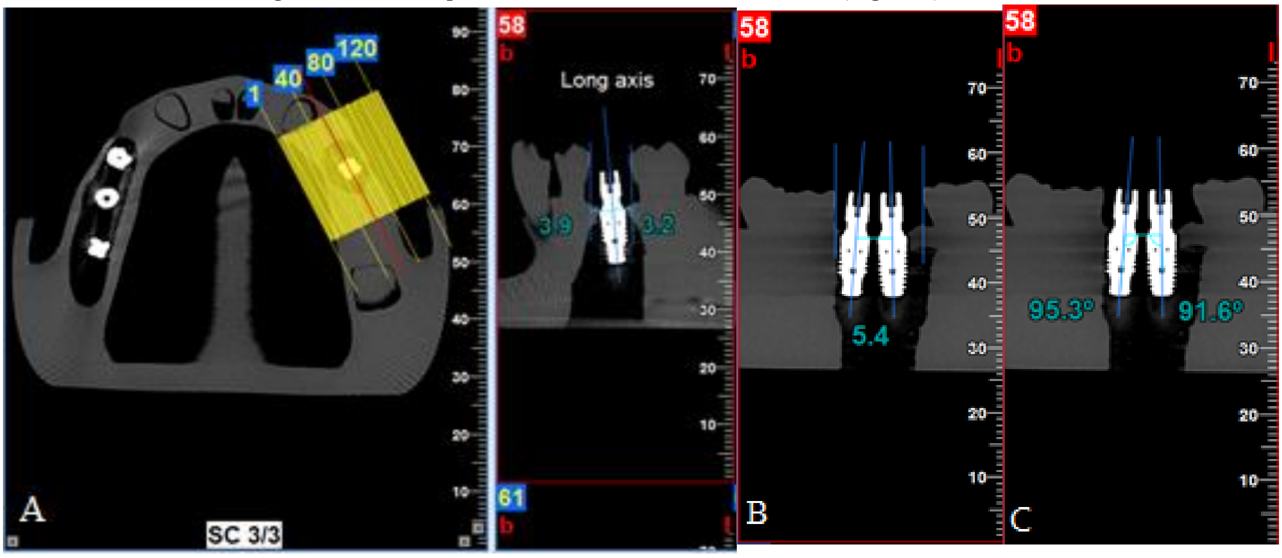

Figure 2- (A) Mesiodistal linear distance between the longitudinal axis of implant and a line tangent to the HOC of the adjacent teeth; (B) mesiodistal linear distance between the longitudinal axes of adjacent implants; (C) angle between the longitudinal axis of each implant and a line connecting the platforms of adjacent implants

The collected data were analyzed using SPSS version 21 (SPSS Inc., IL, USA). One-sample t-test was applied to compare the planned values with the values measured on radiographs. $P<0.05$ was considered statistically significant.

The first null hypothesis of the study was that no significant difference would be found between the planned linear distances and the actual values after implant placement. The second null hypothesis was that there would be no significant difference in the angulation of planned and placed implants.

Results

A total of 15 implants were placed in the jaw models using the designed surgical guide. Of all implants, 12 were placed in multiple edentulous spaces in order to measure the mesiodistal distance between the implant axis and the adjacent teeth, the linear inter-implant distance, and the inter-implant angulation.

In assessment of the mesiodistal distance between the implants and the adjacent teeth, the maximum and minimum difference between the planned and actual values was 0.7 mm and 0 mm, respectively. According to one sample t-test, this difference was statistically significant ($P<0.001$, Table 1).

In assessment of the mesiodistal linear distance between two adjacent implants, the maximum and minimum difference between the planned and actual values was 0.6 mm and 0.2 mm, respectively. According to one sample t-test, this difference was statistically significant (P=0.005, Table 1).
In assessment of the inter-implant angulation, the maximum and minimum difference between the planned and placed implants was 11° and 0°, respectively. According to paired t-test, this difference was not significant (P=0.073, Table 1).

Table 1- Linear distance between the implant axis and a line tangent to the HOC of the adjacent tooth, linear distance between the longitudinal axes of the adjacent implants at the implant platform, and the angle between the longitudinal axes of adjacent implants relative to the line connecting the adjacent implant platforms

Variable	Number	Mean	Std. deviation	95% confidence interval of the difference		Sig. (2-tailed)
				Lower	Upper	
Mesiodistal linear distance between implant and adjacent tooth (mm)	13	0.28	0.19	0.1641	0.4051	<0.001
Mesiodistal linear distance between two adjacent implants (mm)	6	0.35	0.17	0.1652	0.534	0.005
Inter-implant angulation (degrees)	6	3.88	4.20	-0.5250	8.2917	0.073

Discussion

Damaging the natural tooth adjacent to an edentulous space during implant placement can bring about unwanted consequences and even lead to dental implant treatment failure. Thus, it is extremely important to prevent the occurrence of such events. On the other hand, inappropriate implant placement in terms of angulation or position, or implant insertion at an inadequate distance from the adjacent teeth can also cause complications(4). Thus, considering the significance of correct osteotomy and implant placement in an appropriate position, this study aimed to design a new surgical guide for correct implant placement in patients with partial edentulism. The efficacy of the designed surgical guide was also evaluated in vitro by drilling and implant placement in jaw models using the designed surgical guide.
In assessment of the mesiodistal linear distance between the longitudinal axis of implants and the adjacent teeth, the mean difference between the planned position and the actual position of implants on CBCT scans was 0.28±0.19 mm (range 0 to 0.7 mm; P<0.001). In assessment of the linear distance between two adjacent implants, the mean difference between the planned position and the actual position of implants on CBCT scans was 0.35±0.17 mm (range 0.2 to 0.6 mm, P=0.005).
In assessment of implant placement accuracy with the help of a static computerized surgical guide, it was reported that the accuracy of the surgical procedure was within the clinically acceptable range with an overall mean error rate of 1.2 mm at the implant entry point and 1.4 mm at the implant apex. Also, it has been stated that a 2-mm range of errors should be expected in use of this surgical guide(15). Linear measurements were made at two sites of implant entry point and implant apex in the abovementioned study. However, in our study, the mesiodistal linear distance was measured between the outermost point of the implant platform and a line tangent to the HOC of the adjacent tooth, or the outermost point of the platform of the adjacent implant. In total, the mean values obtained in our study were within the reported acceptable range. Statistically, computer-aided implant surgeries, either static or dynamic, did not show a significant difference in coronal or apical position of implants(16). Comparison of implant placement accuracy with the help of a navigation system, a laboratory guide, and by freehand drilling revealed that the total error rate at the point of entry of drilling was 1.07±0.48 mm, 1.02±0.46 mm, and 0.56±1.44 mm, respectively. The total error rate at the implant apex was 1.35±0.55 mm, 1.50±0.79 mm, and 0.79±2.00 mm, respectively. Although the navigation system had the highest accuracy, it required more time and its success depended on optimal cooperation between the technician and surgeon. The freehand drilling showed maximum error rate in implant positions(17). Comparison of our obtained values with those reported by the abovementioned study indicates that the error rate in our study was lower than the error rate of all three techniques in the abovementioned study at the entry point and apex of implants.
To the best of our knowledge, the available studies on the accuracy of implant placement with regard to adequate tooth-implant and inter-implant distances have not reported separate statistical data regarding these parameters; however, we separately evaluated and reported these values in our study.
In assessment of the inter-implant angulation, the present results revealed a mean inter-implant angle of 3.88±4.20 mm. The difference in this respect was not significant between the planned and actual values (P=0.073). Since the maximum and minimum deviation, compared with parallel positioning of implants (ideal position), was 11° and 0°, respectively, higher standard deviation value than the mean value may be due to non-homogenous distribution of data,

and calls for assessment of a larger sample size. Assessment of the accuracy of implant surgeries conducted with computer-aided static navigation revealed an overall angular deviation of 3.5°(15). Comparison of the accuracy of implant surgery with regard to angular deviation revealed a significant difference between computer-aided dynamic and static navigations; although both systems increased the accuracy of implant placement(16). The angular accuracy of dental implant placement with the help of a navigation system, a laboratory guide, and by freehand drilling was 4.45±1.97, 6.02±3.71, and 9.26±3.62°, respectively. Our results indicated a lower mean error rate (3.88±4.20°) compared with all three modalities in the aforementioned study, particularly the freehand drilling technique(17).

Considering the present results, some cases showed too large or too small values, compared with the mean (e.g. 1° angular difference between the adjacent implants), which may indicate that efficient use of this tool requires a training course. Moreover, possession of this device alone does not eliminate the need for adequate knowledge and expertise for implant placement.

In general, this surgical guide was designed and introduced as an easily available and cost-effective tool to help maintain a standard distance between implants or between an implant and the adjacent tooth and aid in parallel positioning of implants. Moreover, it allows simultaneous drilling of two or more implant holes next to each other to save time and increase patient cooperation. Also, it can be easily used in patients with different classes of partial edentulism in any part of the alveolar ridge.

The efficacy of this surgical guide was evaluated by drilling the implant holes in jaw models placed on a table, which is different from implant placement conditions in the oral environment, and can affect the results. In some measurements, the reported standard deviation values are larger than the mean values, which may indicate non-homogenous distribution of data. This device only guides the pilot and twisted drills; although it supports most of the available implant kits, deviation from the correct path in the sequence of drilling and upon the use of drills with diameters larger than 2.8 mm is also possible.

Future studies are recommended to simulate the clinical setting by implant placement in phantom heads with a face. Moreover, in future studies, dental implants are suggested to be placed by clinicians with different levels of experience and expertise in implant surgery with the help of this surgical guide, to assess the duration of procedure with the use of this device. The current results cannot be generalized to the clinical setting, and further complementary studies are required in this respect. However, comparisons revealed that this surgical guide has the potential for use in the clinical setting. Thus, future studies are recommended emphasizing on further development and improvement of this tool.

The mean difference in the assessed parameters revealed that they were all clinically acceptable and this tool can maintain the standards and minimum required distances between two adjacent implants or an implant and its adjacent tooth, as well as the proper implant angulation. It appears that by increasing its accuracy via further studies and acquiring adequate expertise in using it, this device can be used as an efficient, available and cost-effective tool for precise implant placement by surgeons.

Conclusion

The designed tool had high accuracy in achieving optimal angulation and distance between two adjacent implants or an implant and its adjacent tooth, and the obtained mean values were within the clinically acceptable range.

Conflict of Interest

No Conflict of Interest Declared ■

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