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CLINICAL RESEARCH

Trephination-based, guided surgical implant placement: A clinical study

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ABSTRACT

Statement of problem. Conventional guided implant surgery promises clinical success through implant placement accuracy; however, it requires multiple drills along with surgical sleeves and sleeve adapters for the horizontal and vertical control of osteotomy drills. This results in cumbersome surgery, problems with patients having limited mouth opening, and restriction to specific drill or implant manufacturers. A protocol for using trephination drills to simplify guided surgery and accommodate multiple implant systems is introduced.

Purpose. The purpose of this clinical study was to evaluate the accuracy of implant placement using this novel guided trephine drill protocol with and without a surgical sleeve.

Material and methods. Intraoral scanning and preoperative cone beam computed tomography (CBCT) scans were used for implant treatment planning. Surgical guides were fabricated using stereolithography. Implant surgery was performed using the guided trephination protocol with and without a surgical sleeve. Postoperative CBCT scans were used to measure the implant placement deviations rather than the implant planning position. Surgical placement time and patient satisfaction were also documented. One-tailed *t* test and F-test (P=.01) were used to determine statistical significance.

Results. Thirty-five implants in 17 participants were included in this study. With a surgical sleeve, implant positional deviations were 0.51 ±0.13 mm vertically, 0.32 ±0.10 mm facially, 0.11 ±0.11 mm lingually, and 0.38 ±0.13 mm mesially. Without a surgical sleeve, implant positional deviations were 0.58 ±0.27 mm vertically, 0.3 ±0.14 mm facially, 0.39 ±0.16 mm lingually, and 0.41 ±0.12 mm mesially. No statistically significant difference was found between the 2 protocols (P>.01), except that the sleeve group had greater vertical control precision (F-test, P=.006), reduced placement time, and the time variation was reduced (*t* test, P=.003; F-test, P<.001).

Conclusions. This trephination-based, guided implant surgery protocol produces accurate surgical guides that permit guided surgery in limited vertical access and with the same guided surgery protocol for multiple implant systems. Guided sleeves, although not always necessary, improve depth control and reduce surgical time in implant placement. (J Prosthet Dent 2019;121:411-6)

The surgical placement of dental implants requires meticulous analysis through the examination of soft and hard tissues. Cone beam computed tomography (CBCT) enhances osseous implant-site examination and the precise selection of an implant.[1] CBCT together with computer-aided implant treatment planning software also improves implant placement accuracy.[2] Computer-aided implant planning without surgical guides requires surgical training and experience.[2,3] Recent systematic reviews[3-8] suggest that guided implant surgery, which combines CBCT, computer-aided implant planning, and precise fabrication of the surgical guide, is the most accurate way to place dental implants.[9-11]

Guided implant surgery has therefore been shown to provide a safeguard by improving implant placement accuracy, especially in the esthetic zone.[9-12] Recent developments in computer-aided implant treatment planning software, such as 3Shape Implant Studio (3Shape), combine the advantages of

Conflicts of Interest: The guided system is being developed as a commercial universal guided system.

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Clinical Implications

Clinicians may use trephination-based, guided implant surgery as a non–system-specific universal guided system that may be compatible with most implant systems with acceptable placement accuracy. This technique can be used with or without a guide sleeve.

intraoral scanning and CBCT and initiate implant treatment planning from digital diagnostic waxing. This digital waxing would then be used as a template for the surgical planning of implant placement. Surgical guides can then be fabricated. In addition, this advancement in implant planning software has recently been supplemented by the introduction of low-cost, high-precision, 3-dimensional (3D) printers.[1,13,14] This in turn expands the application for guided surgery.

While contemporary guided surgery provides accuracy and precision, current guided implant systems require proprietary surgical sleeves and sleeve adapters. This means guided surgery can be limited because of the availability of surgical sleeves and adapters or because surgical sleeves cannot be positioned when the horizontal or vertical space is restricted. This in turn prevents the use of guided surgery in a narrow single implant site and in the posterior area where limited vertical opening is an issue. In addition, each specific implant system would require a specific implant guided system. This inhibits cross use of each guided surgery kit and increases costs when multiple implant systems are used in a practice. Also, surgeons do not have the flexibility to change implant systems once the guides specific to a single system have been produced.

In this study, a novel guided implant surgery protocol using trephination was evaluated as a means for guided surgical osteotomy. The trephination guided protocol was developed to control the width and angulation of trephination osteotomy (Fig. 1). Each trephine drill also has a vertical stop providing depth control (Fig. 2). The trephination of implant osteotomy sites also provides advantages of minimizing drill numbers and potentially eliminating the use of the surgical sleeve and sleeve adapter. Moreover, the technique allows cross-utilization for different implant systems. A serial drilling protocol is commonly used in the preparation of the implant osteotomy. The osteotomy is initially prepared with a small diameter pilot drill and then progressively enlarged by a series of larger drills. The osteotomy site would eventually be from 2 to 6 mm in size to accommodate a corresponding implant that is often slightly larger than the osteotomy site. This serial drilling protocol is used to permit angulation correction if needed during the

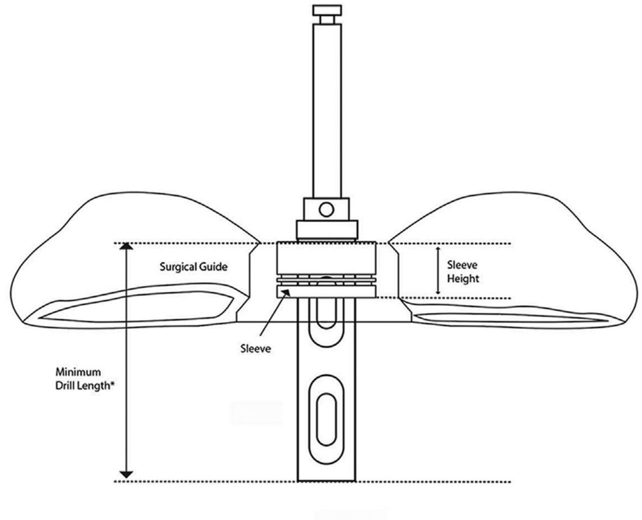

Figure 1. Guided trephine drill. * indicates drill length defined in implant planning software.

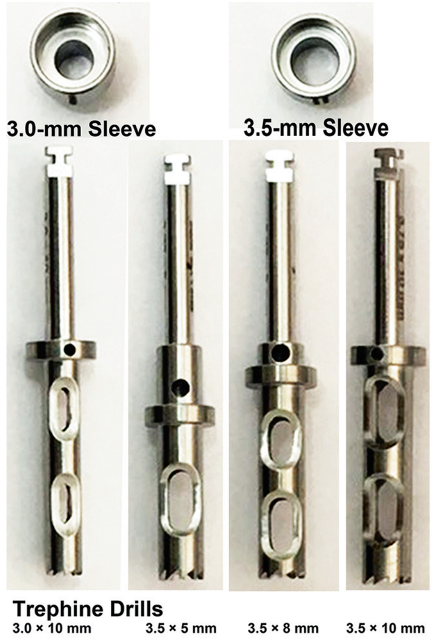

Figure 2. Trephine guide sleeves and drills.

osteotomy preparation and has been reported to reduce heat generated by drilling.[15,16]

Although the serial drilling protocol is appropriate for unguided surgery, the technique becomes cumbersome for the guided surgery protocol as it requires a guided sleeve and a series of sleeve adapters to fit with the series of drills. Applying trephination to guided surgery permits surgical guide fabrication without a surgical sleeve because the cutting of the trephine drill is located at the end of the tool. There would be no cutting action on the side of the drill as occurs with a conventional implant drill. This potentially eliminates a surgical sleeve and sleeve adapter series. In addition, it simplifies the drilling protocol to 2 drills, a trephine drill, and a final drill of the particular implant. This simplified drilling protocol has been shown to have better accuracy[2,17,18] while maintaining similar heat generation and osteoblastic/bone regeneration activity.[15,16]

This recently developed trephination-based guided implant surgery can be performed similar to conventional guided surgery using a 3D-printed surgical guide with or without a surgical sleeve. Removing the surgical sleeve eliminates the vertical and horizontal space requirements for the surgical sleeve, and therefore, short drills can be used. However, a surgical sleeve allows for easy placement of the trephine drill during osteotomy site preparation. Furthermore, trephination provides additional autogeneous bone that can be harvested for implant grafting or histological analysis. The trephine drills have a lateral access hole to assist in bone harvesting. The harvested bone can be pushed out of the trephine drill using a small surgical instrument. The smallest trephine drill is 3.0 mm in diameter and can accommodate a 3.3-mm implant diameter (Fig. 2).

The purpose of this study was to determine the accuracy of this trephination-based guided implant surgery system with and without a surgical sleeve. The null hypothesis was that the placement accuracy would be similar with or without a surgical sleeve. A secondary purpose was to compare time spent in implant placement and patient satisfaction, with the null hypothesis that no differences would be found in implant placement time and participant satisfactory scores between the groups with and without a surgical sleeve.

MATERIAL AND METHODS

The study protocol was approved by the hospital human ethics committee (ethical approval number: PPHO-REC 2559/001). The study population was composed of all participants presenting for the evaluation and management of single or multiple implant placement using tooth-supported guided surgery between October 2016 and October 2017. To be included in the study, participants had to have a requirement for at least 1 implant placement, have at least 4 natural teeth to support implant guides, agree to have a follow-up postoperative CBCT scan, and not require major grafting during implant surgery that would require flap opening or guided bone regeneration with barrier membrane. Participants were excluded as study participants if they had fewer than 4 natural remaining teeth in the same arch to support the implant surgical guides, if they refused postoperative CBCT scans, or if a flap surgery and/or guided bone regeneration with barrier membrane was used.

The general treatment protocol followed a previously published 3Shape digital workflow (Fig. 3).[1] Briefly, each

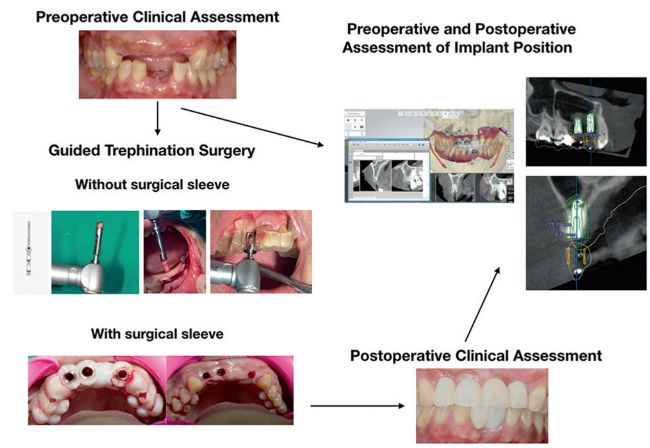

Figure 3. Clinical and radiographic assessment protocol.

participant received preoperative intraoral scans and CBCT scans. A digital waxing was then made in 3Shape Implant Studio 2017. The digital cast with digital diagnostic waxing was then superimposed onto the CBCT 3D model. Implant positions were then planned based on the digital diagnostic waxing and CBCT data. A digital surgical cylinder replicating the final cylinder of the trephine drill for each implant was then positioned. This digital surgical cylinder allowed angulation and depth control for the trephine drill that would later be converted into a polymethyl methacrylate surgical guide. The guide design was extended to, at least 1, 2 or more adjacent teeth. Windows were also created to allow visualization of the guide intraorally. Once the design was completed, the standard tessellation language file was exported into the PreForm software (Formlabs),[13,14] and the digital guide was positioned. Appropriate supports were then created to provide adequate flow of the resin to be polymerized. The printed guide was rinsed twice in isopropanol, air-dried, and exposed to 405-nm wavelength light for 1 hour to polymerize.[13,14] A surgical sleeve was then placed in the guide in the group with a sleeve. The guide was then autoclaved before surgery.

At the surgical visit, each participant was asked to rinse with 0.12% chlorhexidine gluconate for about 2 to 3 minutes. The area was anesthetized with 2% lidocaine with 1:100 000 epinephrine. The surgical guide was evaluated intraorally, and any necessary adjustment was made. An appropriate trephine drill was then used to create an initial osteotomy (Fig. 1); the guide was removed, and the depth and angulation of this initial osteotomy was evaluated. The angulation was adjusted if necessary. The final drill of the chosen implant system was used to complete the osteotomy before the implant was placed. Appropriate healing abutments and/or fixed or removable interim prostheses were then inserted, and postoperative CBCT scans were made. This postoperative CBCT model was superimposed onto the planned

Table 1. Demographics, implant positions, and systems used

	Without Sleeve	With Sleeve
Demographics		
Average age	55.1	59.5
Number of participants	13	4
Sex (female/male)	9/4	1/3
Number of implants	22	13
Implant locations		
Maxillary central incisor	12	1
Maxillary lateral incisor	10	3
Maxillary canine	6	1
Maxillary first premolar	2	1
Maxillary second premolar	—	1
Mandibular first premolar	—	2
Mandibular second premolar	—	2
Mandibular first molar	—	2
Implant systems		
CAMLOG	10	9
BEGO	2	4
Zimmer	3	—
Straumann	3	—
OSSTEM	4	—

Table 2. Implant deviations with-sleeve group (n=13)

	Vertical	Buccal	Lingual	Mesial	Time Used	Satisfactory
Average	0.51	0.41	0.38	0.41	6.62	9.69
Standard deviation	0.13	0.11	0.13	0.07	1.26	0.48
Sample size	13	13	13	13	13	13
Confidence coefficient	1.96	1.96	1.96	1.96	1.96	1.96
Margin of error	0.07	0.06	0.07	0.04	0.69	0.26
Upper bound*	0.58	0.47	0.45	0.45	7.30	9.95
Lower bound*	0.44	0.35	0.30	0.38	5.93	9.43
Max	0.76	0.58	0.65	0.58	8	10
Min	0.32	0.23	0.18	0.32	5	9

*95% confidence interval or 95% probability of deviation.

Table 3. Implant deviations without-sleeve group (n=22)

	Vertical	Buccal	Lingual	Mesial	Time Used	Satisfactory
Average	0.58	0.37	0.39	0.41	10.59	9.5
Standard deviation	0.27	0.12	0.16	0.12	6.02	0.67
Sample size	22	22	22	22	22	22
Confidence coefficient	1.96	1.96	1.96	1.96	1.96	1.96
Margin of error	0.11	0.05	0.07	0.05	2.52	0.28
Upper bound*	0.69	0.422	0.46	0.46	13.11	9.78
Lower bound*	0.47	0.32	0.32	0.36	8.08	9.22
Max	1.25	0.58	0.78	0.78	25	10
Min	0.31	0.21	0.16	0.22	4	8

*95% confidence interval or 95% probability of deviation.

diagnostic waxing. The primary outcome variables were the differences between the planned and actual implant position in the vertical, facial, lingual, and mesial dimensions. The primary predictor variables were the guided protocols, with and without a surgical sleeve. The 95% confidence interval and box plots, 25% to 75%, were used to determine the range of implant deviations. The *t* test without equal variances of the means and the F-test of the variances were used to determine accuracy and precision of the guided protocol with and without surgical sleeve (*P*=.01). The surgical time starting from the initial osteotomy preparation to implant placement was recorded. Each participant was also asked to rate satisfaction with the surgical procedure on a scale of 1 to 10 from lowest to highest. The *t* test without equal variances was used to determine the statistically significant difference between surgical time and participant satisfaction.

RESULTS

Seventeen participants were enrolled in the study. A total of 35 implants were placed using 4 implant systems (Table 1). Twenty-two implants were placed in the without-sleeve group, and 13 implants were placed in the with-sleeve group.

Examining both the groups together in terms of the accuracy and precision of implant placement, the overall positional deviations ranged from 0.16 to 1.25 mm. The highest deviations were in the vertical dimension, and the lowest ones were in the facio-lingual dimension (Tables 2 and 3). Both the highest values were in the group without a sleeve. With surgical sleeves, implant positional deviations were 0.51 ±0.13 mm vertically, 0.41 ±0.11 mm facially, 0.38 ±0.13 mm lingually, and 0.41 ±0.07 mm mesially (Table 2). Without a surgical sleeve, implant positional deviations were 0.58 ±0.27 mm vertically, 0.37 ±0.12 mm facially, 0.39 ±0.16 mm lingually, and 0.41 ±0.12 mm mesially (Tables 3 and 4). Upper and lower bounds in Tables 2 and 3 refer to 95% probability of implant positional displacement. Figures 4 and 5 demonstrate 75% range of deviation shown in box plots compared with the total range of deviation shown in lines. The 95% probability values and 75% ranges demonstrated the precision of each guide protocol. No statistically significant difference was found between the accuracy (*t* test of the means) or precision (F-test of the variances) of the 2 protocols (*P*>.01), except that the group with a surgical sleeve showed higher precision in vertical control (F-test, *P*=.006) than the group without a sleeve (Table 4).

The surgical time used for a single implant placement ranged between 5 and 25 minutes; it was 6.26 ±1.26 minutes in the group with a sleeve compared with 10.59 ±6.02 minutes in the group without a sleeve. The group with a surgical sleeve required significantly less placement time and had a lower time variation (*t* test, *P*=.003; F-test, *P*<.001) than the group without a sleeve (Tables 2-4). Patient satisfaction ratings of the surgical procedure ranged between 9 and 10 for the group with a sleeve and between 8 and 10 for the group without a sleeve, with averages of 9.69 ±0.48 (with sleeve) and

Table 4. Summary of statistics

	Vertical (mm)		Facial (mm)		Lingual (mm)		Mesial (mm)		Time (minute)		Satisfaction	
	S	NS	S	NS	S	NS	S	NS	S	NS	S	NS
Mean	0.58	0.51	0.37	0.38	0.39	0.38	0.41	0.42	10.59	6.62	9.5	9.69
Variance	0.07	0.02	0.01	0.01	0.03	0.02	0.01	0.01	36.25	1.59	0.45	0.23
Number of participants	22	13	22	35	22	13	22	13	22	13	22	13
P(T≤t) one tail[a]	.166	–	.324	–	.374	–	.442	–	.003[b]	–	.167	–
P(F≤f) one tail[c]	.006[b]	–	.47	–	.217	–	.034	–	<.001[b]	–	.115	–

NS, without-sleeve group; S, with-sleeve group. [a]*t* test: Two-Sample Assuming Unequal Variances. [b]Level of significance á=.01. [c]F-test: Two-Sample for Variances.

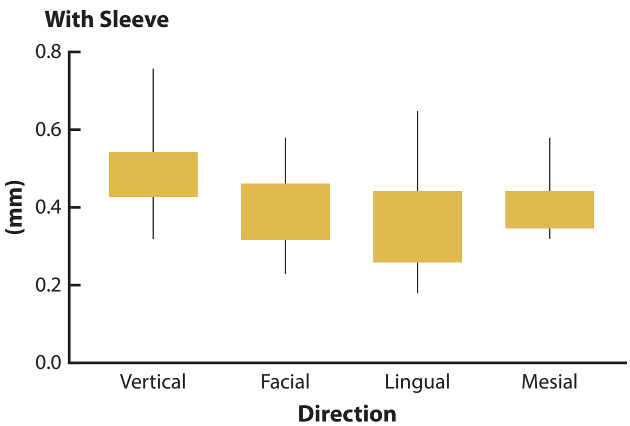

Figure 4. Box plots of 75% of implant deviations and overall implant deviations for with-sleeve group.

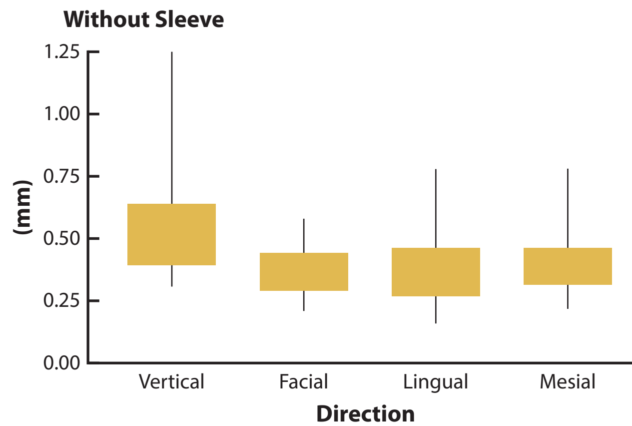

Figure 5. Box plots of 75% of implant deviations and overall implant deviations for without-sleeve group.

9.5 ±0.67 (without sleeve). No statistically significant difference was found between the 2 groups in terms of patient satisfaction (Tables 2-4).

DISCUSSION

This study evaluated the use of a trephination drill in guided implant surgery. Trephination can eliminate the use of guided surgical sleeves or sleeve adapters, allowing the guide to be placed closer vertically to the osteotomy site. This protocol is also applicable with most implant systems because the final drill of any implant system can be used. Implant guided trephination was recently described as a way of removing a dental implant.[19]

The dimensional accuracy of this system was approximately 0.5 mm vertically and 0.3 mm in other dimensions. This accuracy is comparable with that of other guided systems.[4-8] The time of 6 to 10 minutes for single implant placement was also comparable to other studies.[4-8] Although no statistical differences were found among almost all values determining implant placement accuracy and precision, surgical sleeves appeared to improve vertical control and reduce surgical time. However, in the present study, several participants had limited vertical and horizontal space that would not allow for a surgical sleeve. Even without a surgical sleeve, guided implant surgery can be carried out with clinically acceptable accuracy. However, in the present study, 3 implants were placed with over 1-mm deviation in the vertical direction. The implant restorations replaced small incisors, and placement of a guided sleeve was difficult. Therefore, more anterior implants were in the group without a surgical sleeve. In addition, using only 1 trephine drill and 1 final implant drill provided sufficient accuracy, similar to previous reports.[2,17,18] The use of trephine drills provides additional autogeneous graft material that can also be used for peri-implant augmentation (Fig. 3). These trephined bone plugs also allow for histologic examination if necessary.

This study has a few limitations. The number of participants was limited, and a larger sample will be needed to further examine whether this protocol will work for different populations. In addition, the learning curve for this technology is not known. Research on education and training will be needed.

CONCLUSIONS

Based on this clinical study, the following conclusions were drawn:

1. A trephination-based guided implant surgery protocol can provide a new avenue for guided implant surgery.
2. This protocol may expand the use of guided surgery and therefore improve patient care with dental implant therapy.

3. This technique simplifies implant guided surgery and can be used in patients with limited vertical mouth opening.
4. Surgical sleeves, although unnecessary in this trephination-based guided surgery, improve vertical control and surgical implant placement time.
5. Surgical sleeves do not improve accuracy and precision in the horizontal dimension or patient satisfaction.

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