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Original Article

Accuracy of implant placement with a computer-aided fabricated surgical template with guided parallel pins: A pilot study

Rai-Jei Chang [a], Hui-Ling Chen [b,d], Liang-Gie Huang [a], Yong-Kie Wong [c,d,*]

[a] *Division of Endodontics & Periodontology, Department of Stomatology, Taichung Veterans General Hospital, Taichung, Taiwan, ROC*
[b] *Division of Dental Implant, Department of Stomatology, Taichung Veterans General Hospital, Taichung, Taiwan, ROC*
[c] *Division of Oral and Maxillofacial Surgery, Department of Dentistry, Chang Bing Show Chan Memorial Hospital, Changhwa, Taiwan, ROC*
[d] *School of Dentistry, National Yang-Ming University, Taipei, Taiwan, ROC*

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Abstract

Background: A precise positioning for dental implant placement is important for further prosthesis fabrication and maintenance. Computer-aided surgery has been developed to transfer digitally planned implant positioning to the patient over the past decades. This study aimed to evaluate the accuracy of a computer-aided laboratory-fabricated surgical template. A further objective was to compare the accuracy between in vivo and in vitro groups.

Methods: A total of 20 implants were placed in the posterior tooth region through the aid of surgical templates on 17 partially edentulous patients in the in vivo group. The surgical template was fabricated in laboratory after virtual implant planning was completed using computer software. In the in vitro group, the same procedures were performed on the models without placing fixture with the same templates used in surgery. Deviations of the implant access at the implant platform level and apical region, as well as the angle deviations between the virtual planning data and the surgical results, were measured using a follow-up Cone Beam Computerized Tomography (CBCT) investigation, and image fusion with planning data.

Result: The median deviation at platform level, apex and angulation was 0.95 mm (0.3−1.3 mm),1.35 mm (0.1−3.6 mm) and 3.92° (0.44−11.66°) respectively in the in vivo group; and 0.4 mm (0−1.0 mm), 0.65 mm (0.1−1.9 mm), 2.16° (0.17−6.91) respectively in the in vitro group. The in vitro group displayed significantly less deviation ($p < 0.05$).

Conclusion: The data from this study shows that computer-aided laboratory-fabricated template may be a reliable tool for implant placement. However, the clinical conditions seem to affect the accuracy of the template.

Keywords: Accuracy; Computer-aided surgery; Dental implant

1. Introduction

Many articles have already reported on the long term survival rate and reliability of dental implants.[1−3] During the early years of this procedure, in order to evaluate the success of the implant, most doctors focused on the bone level.[4] Gradually, the evaluation extended to the peri-implant soft tissue level, prosthetic level and eventually patient satisfaction.[5] To achieve the desired esthetic and functional outcome, a prosthesis driven positioning of the implant was proposed, so that the occlusal force could be exerted along the implant axis, and thus avoiding any biomechanical complications.[6,7] Additionally, the implant fixtures have to be placed in the bone housing, where the buccal bone is at least 1−2 mm away from the fixture, 1.5 mm from the natural tooth root surface and

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

* Corresponding author. Dr. Yong-Kie Wong. Chang Bing Show Chwan Memorial Hospital, Changhue, 6, Logong Road, Lukang, Changhua 505, Taiwan, ROC.

E-mail address: ykw2888@gmail.com (Y.-K. Wong).

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3 mm apart from the dental implant surface. Also, the implant has to be inserted at a 2–3 mm depth below the proposed cementoenamel junction level during the surgical phase for the esthetic emergence profile.[8,9]

To transfer the planning data to the operative site, there are many types of surgical guidance technology available to assist doctors during the implant procedure, including the traditional surgical guide and computer assisted guide.[10] The computer assisted surgical guide combines the computer 3-D image, which helps identify the anatomical structures of the bone, together with the prosthetic information, in order to find the ideal region to place the implant.[11] In addition, the computer assisted surgical guide offers two major types of procedures, dynamic image-guided surgery and static type surgical guide stent. Dynamic image-guided surgery is a real-time surgical guide system that can form 3-D images which display teeth, occlusion and oral mucosa. Alternatively, the static type uses Computer-aid Design/Computer-aid Manufacturing (CAD/CAM) in order to make the stent. This is taken from the computer designed treatment planning information. In general, the surgical stent can be generated through two different methods, rapid prototyping and the scan-stent modulation procedure. A common type of rapid prototyping uses a stereolithographic template which projects an ultraviolet laser onto a vat of photopolymer resin to form the surgical stent. Alternatively, the scan-stent modulation procedure must transfers the information of the treatment planning from computer to surgical stent manually, or by using the Computer Numerical Control (CNC) milling machine as a transferring tool.[7,10,12]

Many studies have proved that both the dynamic and static types can result in acceptable accuracy.[13–16] Whatever surgical guidance technology may be used, the key is transferring the planning data to the oral cavity in a precise manner. Any errors occurring between planning and implant placement should be minimized and evaluated.

The purpose of this study was to evaluate the accuracy of a newly developed static type surgical template by matching virtual planning and post-surgical images. The surgical template has a drill hole on the fixture location, along with a lingual side pin for angular reference for the fixture direction. This static type surgical template was neither generated by a rapid prototyping or scan-stent modulation procedure. Instead, the surgical template was fabricated in a laboratory after completion of virtual implant planning using computer software. The accuracy of this system has rarely been measured objectively.

Additionally, although there is a trend towards less deviation in the in vitro study than in the in vivo study,[17], there are no known study comparisons between the in vitro and in vivo models with the same surgical template. To realize the clinical effect of the accuracy of the template, we also compared its accuracy on both the tooth model and the actual patient. Finally, the causative factors of the errors were discussed.

2. Methods

This study was approved by the Taichung Veterans General Hospital IRB and all participants signed an informed consent agreement. A total of 20 fixtures were implanted in 17 patients in the in vivo group. The same osteotomy procedure was performed with the templates used in the in vivo group, on each patients' model in the in vitro group. All the principles outlined in the Helsinki Declaration were followed in all the experiments involving human subjects during the current study.

2.1. In vivo group

2.1.1. Patient selection

Seventeen subjects were included in the program at Taichung Veterans General Hospital. Informed consent was obtained from all the patients. Inclusion criteria were: 1) age between 20 and 65 years, 2) patient has a missing posterior tooth which can be reconstructed with an implant supported denture, 3) general healthy, and 4) able to read the informed consent form. The excluding criteria were: 1) betel nut chewer, 2) diagnosis of leukemia, 3) poor blood coagulation, 4) depression or bipolar disorder, 5) pregnancy, and 6) having received a previous dental implant.

2.1.2. Surgical template fabrication and implant planning

The Digital Imaging and Communications in Medicine (DICOM) data of the Cone Beam Computerized Tomography (CBCT) image was imported into the computer software (ImplantMax, Saturn Imaging, Taiwan). The scan template (Fig. 1) contained three porcelain balls as a registration template that could be used as the reference for both image data and image fusion. The models were mounted on a positional system (ImplantMax Workstation, Saturn Imaging, Taiwan) which integrates planning software with an articulate robot arm (Fig. 2). The implant position was then planned into the most optimal position towards both the anatomy landmark and prosthetic demands.

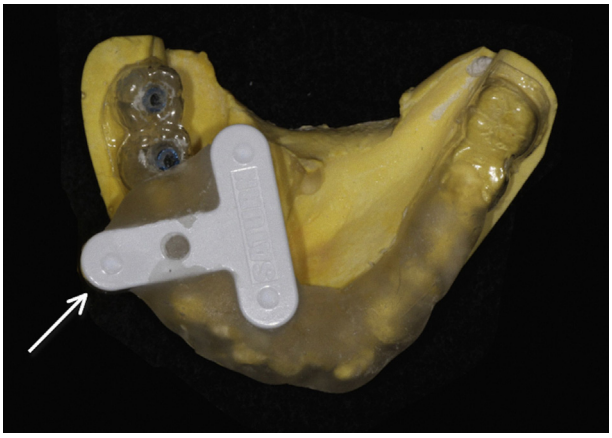

Fig. 1. Scan template with 3 porcelain balls (arrow) as a registration template.

Fig. 2. ImplantMax Workstation as a navigational system on the model.

After the treatment plan was completed, the surgical template was produced in the lab manually. The surgical template consisted of three parts, the basement part, guide pin part and metal sleeves (Fig. 3). The basement part consisted of a fixation base for fixing the guide pin part which indicated the drilling direction and guided the metal sleeves. The guide pin part consisted of a connector component and a guide pin screw. The connector component had a 4.5 mm internal diameter hole with an index pin which could be fixed on the fixation base. The metal sleeve part could be adapted to the connector component with different internal diameters.

2.1.3. Implant surgery

After anesthesia was administered, a crestal incision was made on the edentulous ridge and the full thickness flap was elevated. The surgical template was adapted to each patient's oral cavity and checked to see if it was firmly attached without any rocking motion. Drilling began with a Lance drill and 2 mm drill sequentially which were guided with a 2.0 mm internal diameter sleeve. The sleeve and connector component were then removed, leaving the guide pin screw which was along the proposed drilling direction. Implant osteotomy was performed sequentially to the final drill as per the manufacturer's instructions (Fig. 4). Implant fixtures (E system and C system, Royal dent, Taiwan) were placed with 35–45N torque. Cover screws were then engaged and the flap was closed with a 4-0 Vicryl suture without tension.

Postoperative antibiotics and analgesics were prescribed. Patients were told to avoid mechanical cleaning of the surgical region until after removal of the stitches. Rinsing with chlorhexidine 0.2% twice per day was recommended. The sutures were then removed after two weeks.

A postoperative CBCT image was taken two weeks after surgery. Stage II surgery was performed at least three months later. Prosthodontic treatment was performed one month after Stage II surgery.

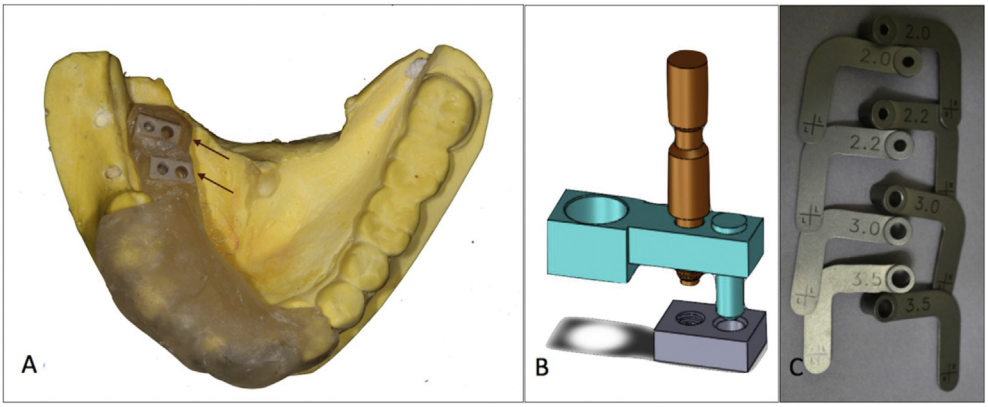

Fig. 3. Surgical template. A: Basement part with 2 fixation bases (arrow); B: Guide pin part consisting of a pin screw (brown), a connector component (blue) that could be fixed on the fixation base (gray); C: Metal sleeves with different internal diameters, only the size of 2.0 mm was used in this study.

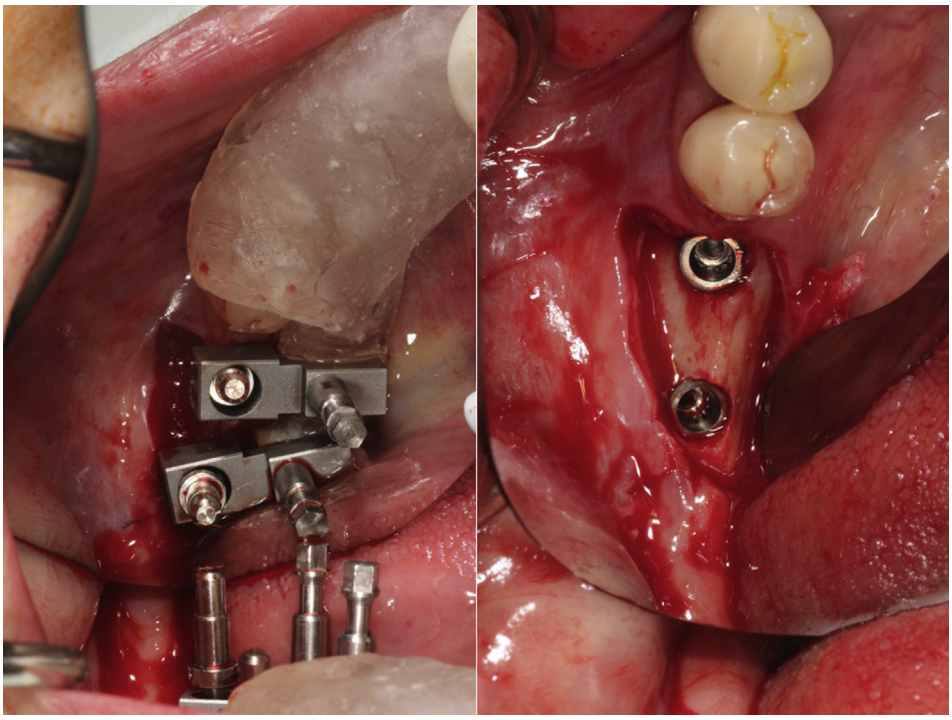

Fig. 4. Two implant placement with the template.

2.2. In vitro group

The models which were fabricated from the included subjects were preserved after completion of the surgery. Previously used surgical templates from the in vivo group were reused. The same drilling protocol was performed on the models, but without placing the fixture. After completion of the drilling procedure, the models were scanned with CBCT for accuracy verification.

2.3. Accuracy verification

We sought to understand the differences between the extra oral model versus the actual surgical result. This study used the tooth model to characterize the implant variation from the surgical template, versus the reality consequence which would be affected by not only the accuracy of the template but other clinical factors as well.

In brief, the post-operative CBCT data was superimposed on the pre-operative planning data using computer software (ImplantMax, Saturn Imaging, Taiwan), which automatically provided maximization of mutual information (Fig. 5). The superimposed image was verified and adjusted by a single technician. The same procedure was performed to match the CBCT data of the models and virtual planning. Since no fixture had been placed on the models, a virtual cylinder was manually adapted to the drill hole and the bottom of the hole was supposed the apex of the cylinder.

The following parameters were measured (Fig. 6):

- Coronal deviation: Distance between the coronal center of the planned implant and placed implant/virtual cylinder.

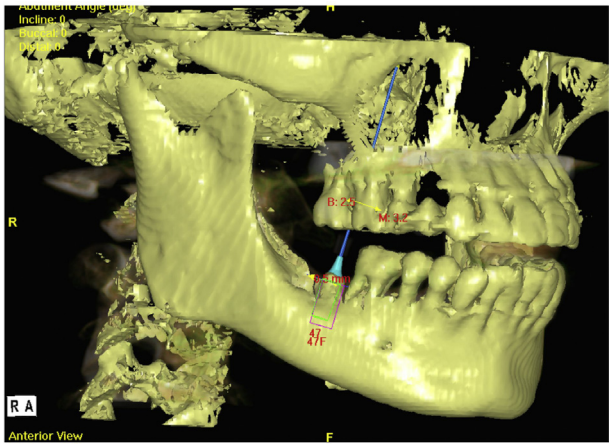

Fig. 5. The post-operative CBCT and the preoperative planning data was superimposed in order to measure the coronal, apex and angle deviation.

- Apical deviation: Distance between the apical center of planned implant and placed implant/virtual cylinder.
- Angular deviation: Angle difference of the planned implant axis and placed implant axis/virtual cylinder axis.

2.4. Statistical analysis

The data analysis was completed using the software, Statistical Product and Service Solutions (SPSS). The Shapiro–Wilk test showed that the data was not homogeneous. Therefore, the Wilcoxon signed ranks test was used to compare the in vivo and in vitro groups. Values of $p < 0.05$ were considered significant, while values of $p < 0.01$ were considered highly significant. For the purpose of comparing

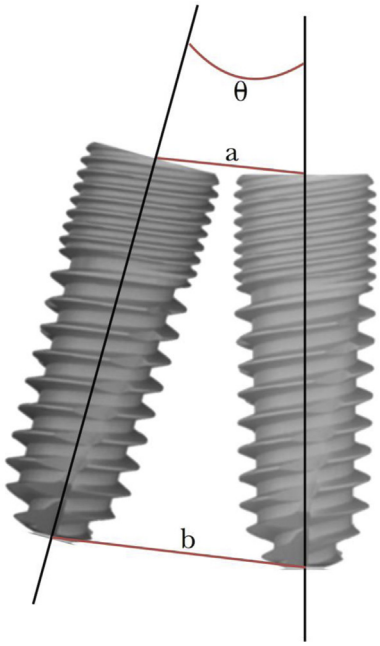

Fig. 6. Parameters used to analyze the accuracy of the implant placement, by matching the software planned implant position, with the final position of the implant/drill hole in patients' mouth/model. The following measurements were used: a = coronal deviation, b = apical deviation, θ = angular deviation.

with other studies, we displayed the data using both mean and median value.

3. Results

A total of 20 implants were installed in 17 patients. There were eight males and nine females, whose ages ranged from 28 to 52 years old. The mean age was 40.12 years old. Four fixtures were installed in the upper arch, while 16 fixtures were installed in the lower arch. The locations of the implant are shown in Table 1. The Shapiro–Wilk test shows that the data was not homogeneous. The median, minimal, maximal, Q1 and Q3 of the difference for all 20 implants are displayed (Table 2). In order to compare with other studies, the means are also tabulated (Table 3). In the in vitro group, the median of the linear deviation is 0.4 mm at the coronal level and 0.65 mm at the apex, with a maximum deviation of 1.0 mm at the coronal level and 1.9 mm at the apex. The median of angular deviation is 2.16° with a maximum of 6.91°.

Table 1
Implant distribution.

Location	Number of Implants
Maxillary 1st premolar	1
Maxillary 2nd premolar	1
Maxillary 1st molar	1
Maxillary 2nd molar	1
Mandibular 1st premolar	1
Mandibular 2nd premolar	1
Mandibular 1st molar	10
Mandibular 2nd molar	4

In the in vivo group, the median of the linear deviation is 0.95 mm at the coronal level and 1.35 mm at the apex, with a maximum deviation of 1.3 mm at the coronal level and 3.6 mm at the apex. The median of angular deviation is 3.92° with a maximum of 11.66°.

Comparing the in vitro group and in vivo group, all of the measured deviations show significant difference, with a highly significant difference observed at coronal deviation. The p values of coronal, apical and angular deviation were 0.002, 0.012 and 0.03 respectively.

4. Discussion

Schneider et al.[14] reviewed the articles and found that the mean coronal deviation was 1.07 mm, apical deviation 1.63 mm and angular deviation 5.26° of the computer-guided template-based implant dentistry. A review of Tahmaseb et al.[11] reported that the mean deviation was 1.12 mm at coronal level, 1.39 mm at apex and the mean angular deviation 3.89°. In this study, the clinical outcome showed a mean coronal deviation of 0.86 mm, mean apical deviation of 1.38 mm and mean angular deviation of 4.62° which are all comparable to previous studies. A comparison can be viewed in Table 3.

The causes of deviation are both cumulative and interactive. Both the factors related to manufacture and factors related to surgery procedure could affect the accuracy of the implant placement. The factors related to manufacture include: accuracy of image, fabrication error, template rigidity, support type, intrinsic error, accuracy of the dental impression and stone cast, and other mechanical errors related to manufacturing the template.[11,19–21] On the other side, the factors related to surgery procedure include: micro-movement during surgery, distal free-end situation, limited mouth opening ability, bone density and human error.[7,22–25]

To fabricate the surgical template, an CBCT image was taken with the patient wearing a scan template. A registration procedure was then performed with a positional system (ImplantMax Workstation, Saturn Imaging, Taiwan). The positional system works like a navigational system with a real-time image on a model. Taking a CBCT image with a scan template could avoid the need for a second scan of the model, known as double scan protocol. However, the accuracy of the image is rather important while taking the image with a scan template. A scan template contains three porcelain balls as fiducial points, which could make the template too bulky and affect its stability in the oral cavity. To avoid this error, the fitness and the stability of the scan template must be carefully checked before taking the CT image.

In an in vitro study, Birkfellner et al.[26] reported a mean fiducial localization error of 0.69 mm, a mean fiducial registration error of 0.7 mm, and a mean target registration error of 1.2 mm. As mentioned earlier, the template was fabricated after a registration procedure in this study. Therefore, the registration error should be considered in this protocol.

Ozan et al.[23] reported the correlation between bone density and angular deviation. They studied 94 fully guided implants

Table 2
The distribution of linear and angular deviation.

Deviation	In vitro group (n = 20)					In vivo group (n = 20)					p
	Median	Minimum	Maximum	Q1	Q3	Median	Minimum	Maximum	Q1	Q3	
Coronal (mm)	0.4	0	1	0.23	0.78	0.95	0.3	1.3	0.63	1.1	0.002**
Apical (mm)	0.65	0.1	1.9	0.33	1.05	1.35	0.1	3.6	1	1.68	0.012*
Angular (°)	2.16	0.17	6.91	0.98	3.54	3.92	0.44	11.66	2.18	6.52	0.030*

Wilcoxon Signed Ranks Test. *$p < 0.05$, **$p < 0.01$.

Table 3
Comparison of the accuracy of the surgical guide based on different reports.

Reported by	Coronal deviation (mm)			Apical deviation (mm)			Angular deviation (°)		
	Mean	Minimal	Maximum	Mean	Minimal	Maximum	Mean	Minimal	Maximum
This study	0.86	0.30	1.30	1.38	0.10	3.60	4.62	0.44	11.66
Van Asshce N[18]	N/A	N/A	N/A	2.00	N/A	2.40	2.00	N/A	4.00
Schneider D[14]	1.07	0.76	1.22	1.63	1.26	2.00	5.26	3.94	6.58
Tahmaseb A[11]	1.12	N/A	4.50	1.39	N/A	7.10	3.89	N/A	21.20

and 122 half-guided implants, where they found a highly negative correlation between angular deviation with the half-guides implants using free-hand to place the implant. In our protocol, the implant was placed using free-hand, and the patient's bone density might have affected the final result.

One of the advantages of the method used in this study is that the procedure only requires a Lance and a 2 mm drill for drilling with the sleeve. This prevents drilling debris from contaminating the implant wound. Moreover, using the guide pin as a guide while enlarging the bone hole and inserting the fixture, ensures the stability of the stent. Furthermore, this template can also be used for patients with a limited mouth opening width, while placing the implant in the posterior region more easily, since it can be used for implanting without a sleeve.

However, a partially guided protocol was performed in this study which only used a Lance drill and a 2 mm drill for drilling with the sleeve. The partially guided protocol may be a factor that could influence the accuracy. Better accuracy was obtained by the fully guided template than in the partially guided template in several studies.[22,27,28] Bover-Ramos et al.[17] compared 34 articles and found that fully guided implant surgery achieved greater accuracy than half-guided surgery. Alternatively, Kuhl et al.[27] reported that there was no significant difference in the accuracy of the fully guided template compared with the partially guided template. Additionally, the fully guided template could interfere with irrigation which may cause thermal injury to the bone while drilling.[22] Also, fully guided surgery may generate a higher cost and be influenced by insufficient interocclusal distance.

In order to minimize the deviation, a guide pin screw which runs along the planning implant axis could be used as a reference while drilling and placing the implant as designed. Although still considered controversial, the partially guided surgical stent used in this study demonstrated a reliable clinical result. However, to understand the difference in the accuracy between the fully guided and partially guided of this computer-aided fabricated template, a further randomized control trial is needed.

To realize the clinical effect of the accuracy of the template, we compared the in vivo and in vitro groups. Since the same templates were used in both the in vivo and in vitro groups, the errors related to the manufacturing between the groups were supposedly minimized. There were significant differences between the in vitro and in vivo groups in all the measured deviations in our study. A less coronal, apex and angular deviation was found in the in vitro group. In the in vitro group, there were better visual fields, better control of the stent and the density of the gypsum was homogenous, which are all possible reasons for the differences between the two groups. However, we have suggested that the most effecting factor is the patient's mouth opening width size and free-end position. Further research is necessary in order to determine whether the accuracy varies by mouth opening width size, distal free-end position, bone density, bone morphology, gender or any other factors.

In general, the clinical results show both the median of the linear deviation and angular deviation is in the clinically acceptable range. However there are still some “outliers'' which with greater deviation could cause clinical complications. All of the greatest deviations were presented in the mandibular molar region. A Kennedy Class I situation was observed in these cases. The free-end position may explain the greater deviation, since there is only partial tooth support.[24]

Finally, the cost-effectiveness of computer-aided surgery still requires further discussion. Computer-aided surgery could improve the accuracy of the implant position when compared with the free-hand implantation method.[23] However, computer-aided surgery is more expensive than traditional protocol. It is also beneficial for the inexperienced surgeon when compared to an experienced one.[29,30] However, Jung et al.[13] mentioned that there is not enough evidence regarding the effects of computer-aided surgery to the safety, outcomes, morbidity, or efficiency of the procedure. Brief et al.[31] even pointed out that the accuracy of manual implantation is sufficient for most clinical situations. Block et al.[25] discussed the indication of the computer-aided surgery, and mentioned that

the indication includes flapless surgery, a need for control of the distance between the near tissue, along with a need for a well-controlled angulation and depth of the implant. In short, computer-aided surgery is helpful in critical situations where there is a need to be aware of the anatomic structure and implant position.

In this pilot study, using the computer-aided fabricated surgical template made it possible to get the proper positioning for the dental implant installation. However, there still remains some outliers indicating that care must be taken. The deviation of the in vivo group is greater than that in the in vitro group. The clinical situation also seems to affect the accuracy. Further studies involving a larger sample size are still needed.

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