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RESEARCH AND EDUCATION

Accuracy of a milled digital implant surgical guide: An in vitro study

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ABSTRACT

Statement of problem. An accurate surgical template for guided implant surgery is essential for the success of an implant restoration. However, reports on the accuracy of digitally designed and computer numeric controlled (CNC) machine-milled surgical templates are sparse.

Purpose. The purpose of this in vitro study was to investigate the accuracy of an implant surgical guide digitally designed by using data from cone beam computed tomography (CBCT) scans and milled with a 5-axis CNC machine.

Material and methods. Six representative radiographic templates were prepared from radiopaque resin plates. For each guide, a CBCT scan was made, and the extracted Digital Imaging and Communications in Medicine (DICOM) data were imported into a planning software program (ORGANICAL Dental Implant). Nine implants were virtually designed for each guide. The design data were imported into a 5-axis CNC machine, and the radiographic guides were fixed onto the CNC machine (Organical Multi S). Bore holes for surgical guide sleeves were milled directly in the radiographic template, which was converted into a surgical template. After the milling process, the surgical guides were scanned by using a laboratory cast scanner. The deviation between the position of the sleeve bore hole in the milled template and that in the virtual implant planning was digitally calculated.

Results. The mean global deviation of the surgical guide was 0.16 ±0.06 mm in the circle center of the sleeve top, and the mean angular deviation was 0.61 ±0.40 degrees. The sleeve-implant distance and the sleeve axis angle showed no significant influence on the in vitro accuracy of the implant surgical guide.

Conclusions. The mean deviation of the surgical guide prepared by using the virtual planning software program and 5-axis CNC milling procedure in this study was 0.16 ±0.06 mm in the center of the sleeve top. Thus, the guide had acceptable precision. (J Prosthet Dent 2022;127:453-61)

Surgical templates for guided surgery for implant-supported prostheses have become popular.[1] However, an accurate implant surgical template is essential for the success of the implant-supported restoration. With the development of computer-aided design and computer-aided manufacture (CAD-CAM) technology, digital workflows have been adopted in the design and fabrication of surgical guides.[2]

The reliability, accuracy, and precision of implant surgical templates have been investigated, with systematic reviews[3-5] concluding that the average deviation at the entry and apex points of implants placed by using surgical guides were 1.2 mm and 1.4 mm, with a maximum deviation of 4.5 mm and 7.1 mm. Each step in the computer-assisted guided surgery from examination to planning and execution has been reported to influence the final accuracy of the implant position.[5]

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Clinical Implications

When using implant surgical guides, the technical errors associated with CBCT imaging, virtual planning, and milling could all contribute to the deviation of the implant position in the guided surgery and should be evaluated before the surgery.

Deviations in implant position result from cumulative errors in designing and manufacturing the guide.[2] In the imaging process, errors can come from the radiographic scan or the acquisition of Digital Imaging and Communications in Medicine (DICOM) data and intraoral data (dentition or alveolar ridge). During the planning and production procedure, errors can be introduced by the fusion of multisource data and different fabrication techniques. During guided surgery, guide repositioning errors may contribute to the deviations, especially in completely edentulous patients.[6] During this procedure, errors may also be introduced by the tolerance of the guide instruments[7] and be related to the experience of the surgeon.[8]

Data acquisition, integration, virtual design, and fabrication methods can affect the accuracy of the CAD-CAM guides, which can be fabricated by rapid prototyping (RP) or milling. Kühl et al[9] reported that the processing error of surgical templates made by stereolithography (SLA) was 0.22 to 0.24 mm and that the mean angular deviation was 1.5 degrees. For milled guides, the radiographic template can be converted into a surgical guide by using computer numeric controlled (CNC) milling.[10,11] Few studies have evaluated the accuracy of surgical templates produced by a milling machine. Park et al[12] reported that the mean horizontal and vertical errors of digital guides made by the 5-axis milling method were 0.14 mm and 0.20 mm and that the maximum errors were 0.68 mm and 0.41 mm. They also reported that the RP-produced templates showed significantly larger deviations than those of the milled surgical guides.

With the optimization and improvement in CNC milling precision and algorithms, additional studies are needed to evaluate the processing precision of CNC-milled templates. Therefore, the purpose of this in vitro study was to investigate the deviation introduced in the surgical guide during the manufacturing process of digitally designed and 5-axis CNC machine milled implant guides. The null hypothesis was that no difference would be found in the linear deviation of the milled surgical guide between this and the values in a previous study.[12]

MATERIAL AND METHODS

Six representative radiographic guides were prepared from radiopaque resin plates (Organic PMMA; Organical CAD/CAM GmbH). The sample size was determined with reference to previous studies on the preclinical accuracy of implant surgical guides.[9,12,13] The guides were designed in a half round shape to mimic the maxillary edentulous arch. Characteristic grooves were created on the surface of the guides to facilitate registration alignment of the digitized templates. A diagnostic template (Diagnostic Template; Organical CAD/CAM GmbH) was attached to the radiographic guide by using autopolymerizing resin (Zi Ran; Nissin Dental Products Co, Ltd). This template contained 8 zirconia beads that were used as fiducial points for image registration and 3 holes for coordinate synchronization with the CNC milling machine (Fig. 1).

CBCT scans (VGI evo; NewTom) of the radiographic guide were made (voxel size, 0.25 mm^3; field of view, 12×8 cm; voltage, 110 kV; tube current, 3.5 mA). Image data were exported in the DICOM format and transferred into a virtual planning software program (ORGANICAL Dental Implant v1.1.0.5; Organical CAD/CAM GmbH).

For each radiographic guide, 9 implants were virtually designed (4.1×10 mm SLActive RC Bone level; Institut Straumann AG) (Fig. 2). Three groups of sleeve-implant distance (2, 4, 6 mm) and 3 groups of sleeve axis-template angle (70, 80, 90 degrees) were designed (Table 1). After virtual implant planning, the data were exported in the Initialization Graphics Exchange Specification (IGES) format.

Implant planning data were transferred to a milling software program (Organical Mill 2.0; Organical CAD/CAM GmbH). The radiographic guides were fixed onto the CNC machine (Organical Multi S; Organical CAD/CAM GmbH) by using the 3 positioning holes on the diagnostic template, thus synchronizing the 3D position of the guide with that of the CNC milling machine. Bore holes for surgical guide sleeves were milled directly in the radiographic template, and the radiographic guide was transformed into a surgical guide (Fig. 3). After the milling process, the representative surgical guides were scanned by using a laboratory cast scanner (D2000; 3Shape A/S), and the standard tessellation language (STL) files were recorded for accuracy analysis.

A 3D coordinate was built for accuracy evaluation, and the origin of the 3D coordinate was set at the middle of the lower border of the diagnostic template (Fig. 4). The STL data of the original radiographic guides (Fig. 5A) and virtually planned implants (Fig. 5B) were exported from the implant planning software program and imported into an imaging analysis software program (Geomagic Qualify 2012; 3D SYSTEMS). Then the digitized milled guides (Fig. 5C) were superimposed onto the digitized original radiographic template by using the characteristic grooves and the border of the resin plate (Fig. 5D, 5E). A matching virtual cylinder was fitted into the intaglio surface of each milled sleeve bore hole

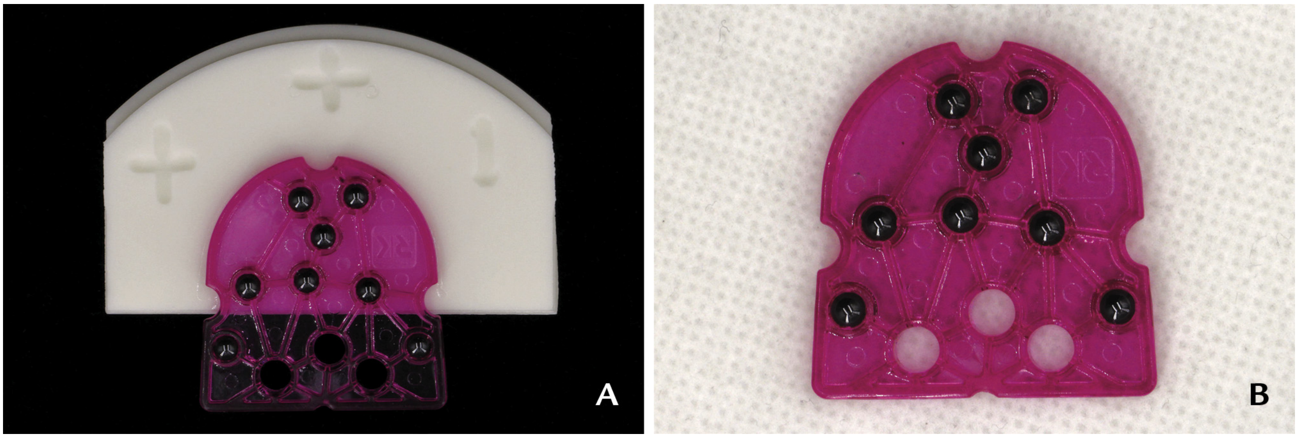

Figure 1. A, Radiopaque radiographic guide. B, Diagnostic template.

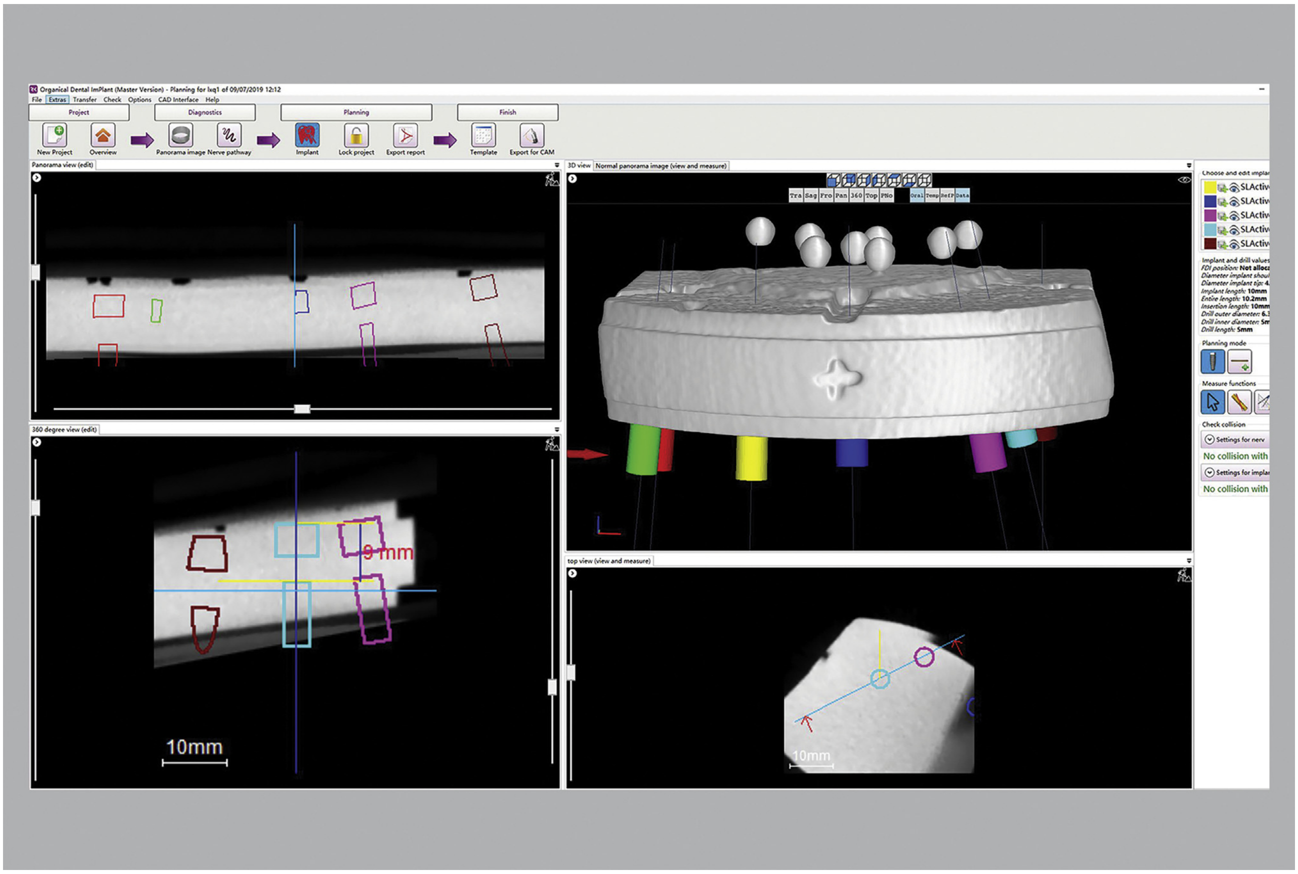

Figure 2. Positions of implants and sleeves virtually planned.

(Fig. 5F). The virtual planning of the sleeve could also be simulated with another virtual cylinder (Fig. 5G). Finally, the linear deviation of the sleeve reference points (the top circle centers of the sleeve simulation cylinders) and the angle deviation (the angle between the long axes of the 2 cylinders) were calculated (Fig. 5H, 5I).

The global deviation in the 3D coordinates was reported as D_{XYZ} (Fig. 6A). The deviations of the sleeve reference points in the x, y, and z directions of the coordinate were reported as D_X, D_Y, and D_Z (Fig. 6B). The angular deviation (the angle formed by long axes of the 2 simulation cylinders) was recorded as D_A (Fig. 6A).

The data were analyzed with a statistical software program (IBM SPSS Statistics, v20.0; IBM Corp). A general descriptive statistical analysis was performed for D_X, D_Y, D_Z, D_{XYZ}, and D_A. The influence of contributing

Table 1. Virtual planning parameters for 9 implants in each sample resin plate

Number of Implants	Sleeve-Implant Distance[a] (mm)	Sleeve Axis Angle[b] (Degrees)
1	2	90
2	2	80
3	2	70
4	4	90
5	4	80
6	4	70
7	6	90
8	6	80
9	6	70

[a]Distance from bottom of sleeve to neck of implant. [b]Angle between sleeve axis and diagnostic template.

factors such as the distance from the sleeve lower border to the neck of the implant and the angles of milling drill direction to the surface of the radiographic guide was analyzed by using analysis of variance (ANOVA) (α=.05).

RESULTS

The deviations of reference points between the virtual planning and the actual positions of the 54 sleeve bore holes are presented in Table 2. The mean global deviation (D_{XYZ}) was 0.16 ±0.06 mm, and the mean angular deviation (D_A) was 0.61 ±0.40 degrees. The mean deviation in the x, y, and z directions (D_X, D_Y, D_Z) was 0.06 ±0.05 mm, 0.08 ±0.05 mm, and 0.11 ±0.07 mm. The deviations of sleeve holes (both linear and angular deviation) showed no significant differences among the 6 resin specimens (P>.05).

The influence of the sleeve-implant distance on preclinical guide accuracy as analyzed by using ANOVA is presented in Table 3 and Figure 7. Three sleeve-implant distance groups (2, 4, 6 mm) were designed, and 18 sleeve holes were milled in each group. The deviations in each sleeve-implant distance group were normally distributed and met the homogeneity of variance. There was no significant difference (P>.05) in the deviation of sleeve hole positions (both linear and angular deviation) among the 3 sleeve-implant distance groups (Table 3 and Fig. 7).

The influence of the sleeve axis angle (angle between sleeve central axis and the surface of the radiographic template) on the preclinical guide accuracy was analyzed by using ANOVA and is presented in Table 4 and Figure 8. Three sleeve axis angle groups (70, 80, 90 degrees) were designed, and 18 sleeve holes were milled in each group. The deviations in each sleeve axis angle group were normally distributed and met the homogeneity of variance. There was no significant difference (P>.05) in the deviation of sleeve holes (both linear and angular deviation) among the 3 sleeve axis angle groups (Table 4 and Fig. 8).

DISCUSSION

The null hypothesis that no difference would be found in the preclinical linear deviation of the milled surgical guide between this and the previous study was accepted.[12] The mean global deviation for a milled implant surgical template made by using a digital workflow and the CNC milling process at the top center of the sleeve bore hole was 0.16 ±0.06 mm, and the mean angular deviation was 0.61 ±0.40 degrees. Park et al[12] reported that the mean horizontal and vertical deviations of a guide made by a 5-axis milling machine were 0.14 mm (horizontal) and 0.20 mm (vertical). Even though the mean fabrication deviations in the present study were close to or lower than those in prior studies evaluating the technical accuracy of the milled templates[12] and the accuracy of RP surgical guides,[9] it was difficult to conclude that the present results were comparable with or lower than those reported in previous studies because the standard deviations were large.

Differences between the present study and previous studies using the milled surgical guide technique included that, in the present study, with the radiopaque resin block, all the information needed for virtual implant planning was integrated in the CBCT scans. The sleeve bore holes were milled in the radiographic template, and the radiographic guide was directly transformed into a surgical template. This could simplify the synchronization which is an essential part of the conventional guide fabrication process. Additionally, the standardized diagnostic template (Diagnostic Template; Organical CAD/CAM GmbH) in the present study contained both the fiducial markers for spatial positioning in the virtual planning software program and 3 fixation holes for coordinate synchronization on the CNC milling system. These made it possible to transfer the virtual design information directly to the milling system. Thus, a cast-free milling process could be used without complex calculations or manual intervention.

For fabricating the laboratory-milled surgical guides, the most critical step is to translate the virtual implant position into coordinates for the milling machine. Several conversion methods have been reported for this purpose. In a study by Park et al,[12] the coordinates of 3 points extracted from the cast base were converted to those for the cast holder fixed on the coordinate synchronization plate of the milling machine. In 2 studies by Fortin et al,[10,11] a resin cube was fixed in front of the radiographic guide with radiopaque teeth for the CBCT scans. The cube contained 2 titanium tubes and was fixed to a dedicated device in the drilling machine. However, the fabrication accuracy was not reported. Peng et al[13] used a "geometric conversion method" (GCM) to locate the milling position. A pair of index rods was placed parallel and on the same level on the buccal and lingual sides in

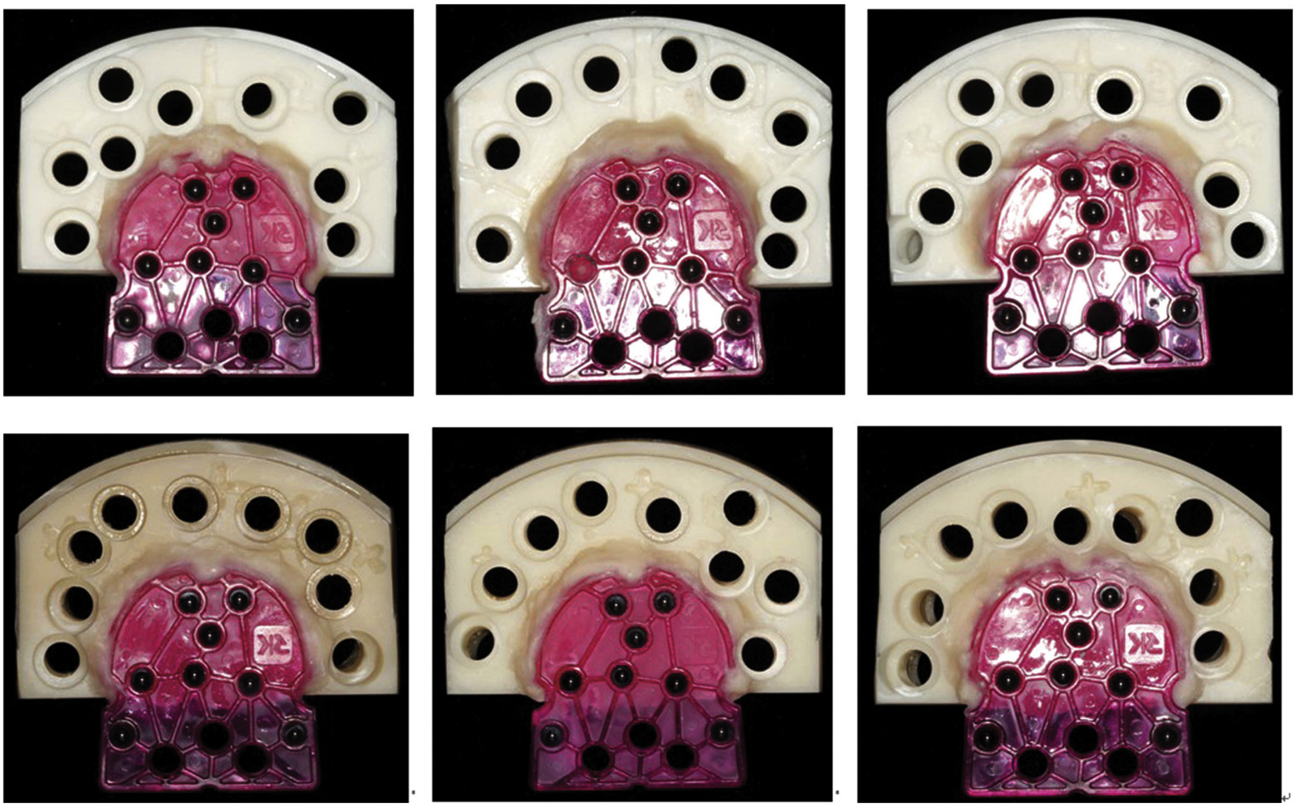

Figure 3. Radiographic guides with diagnostic template bonded on top.

each edentulous area of the radiographic guide to represent a plane perpendicular to the arch in the CBCT image, thus effectively yielding a geometric coordinate system. However, the authors did not report the fabrication accuracy either. All the laboratory-based milled surgical templates required multiple manual interventions, auxiliary appliances, stone casts, and complex coordinate synchronization processes.

Under clinical conditions, the laboratory-based CAD-CAM system used in this study (ORGANICAL Dental Implant; Organical CAD/CAM GmbH) provides a digital fabrication workflow, with only 2 steps involving manual interventions. One is fabrication of the acrylic base for the radiographic template. The second is the bonding of metal sleeves into the bore holes, which is the finishing process for all types of templates. Thus, the entire template manufacturing process was simplified, and the errors from many manual interventions could be avoided.

However, the preparation of this milled surgical guide also required multiple steps to collect all the information needed for radiographic guide production, including waxing, clinical evaluation, digitization of the waxed dentition, and milling of the radiopaque dentition. The total cost and the availability of laboratories that can perform this technique are other factors that need to be considered. With the development of digital technology, the establishment of centralized dental laboratories and efficient courier systems may improve the suitability of this surgical guide solution for clinical practice.

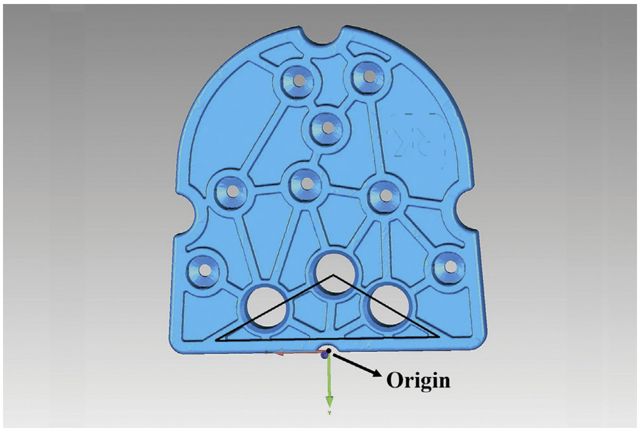

Figure 4. Origin of 3D coordinate set at middle point of straight border of diagnostic template.

The technical accuracy of SLA surgical templates has been evaluated in previous studies. Kühl et al[9] reported the deviation between the actual and the designed positions of the sleeves in SLA templates. The mean global deviations at the top and the bottom of the sleeve were 0.22 mm and 0.24 mm. In contrast, Park et al[12] reported the mean deviations of the RP surgical guide as 0.74 mm (horizontal), 0.54 mm (vertical), and 3.24

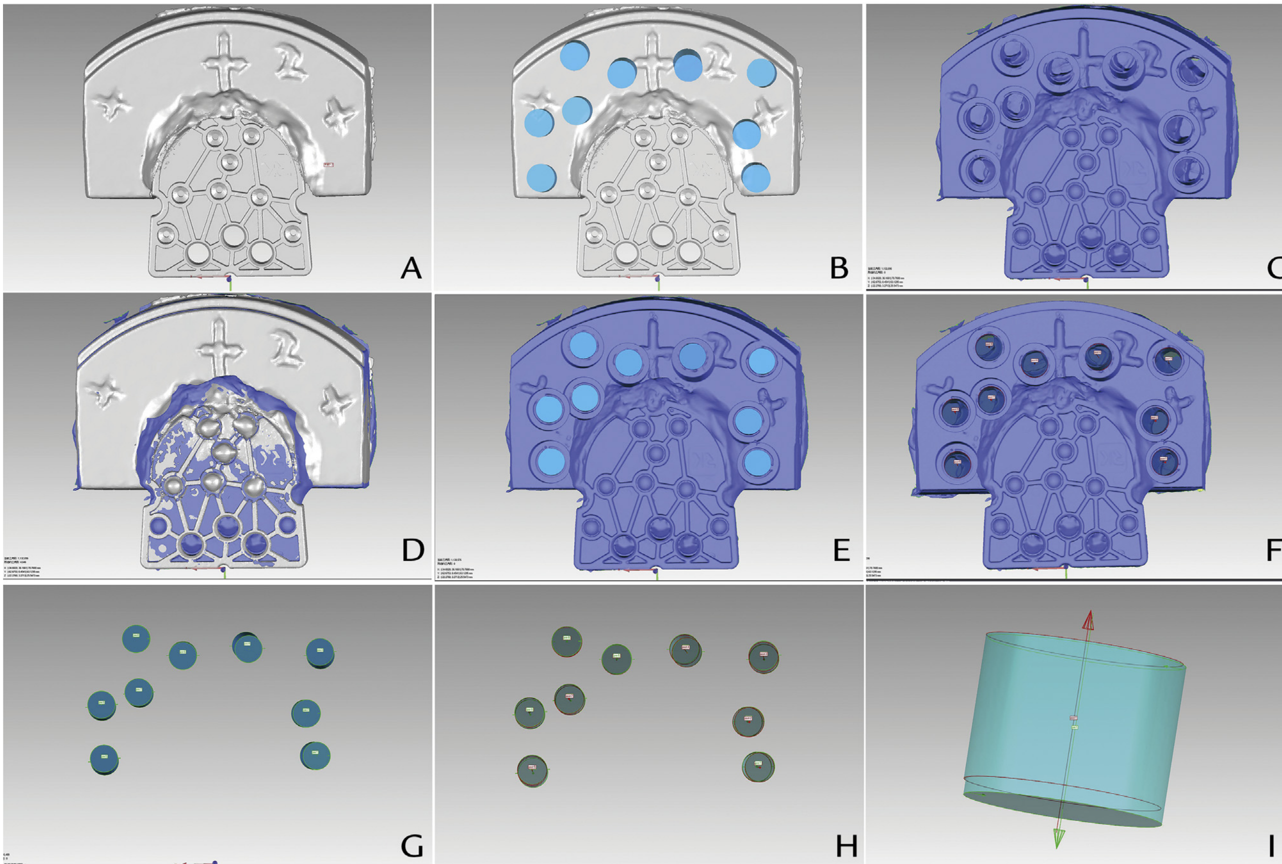

Figure 5. Accuracy evaluation process: A, Digitized radiographic guide imported into imaging analysis software program. B, Virtual implant planning and digitized radiographic guide in same coordinate system. C, Digitized surgical guide with actual milled sleeve bore holes imported into coordinate system. D, E, Digitized guides before and after milling superimposed by using characteristic grooves on surface of resin plate.

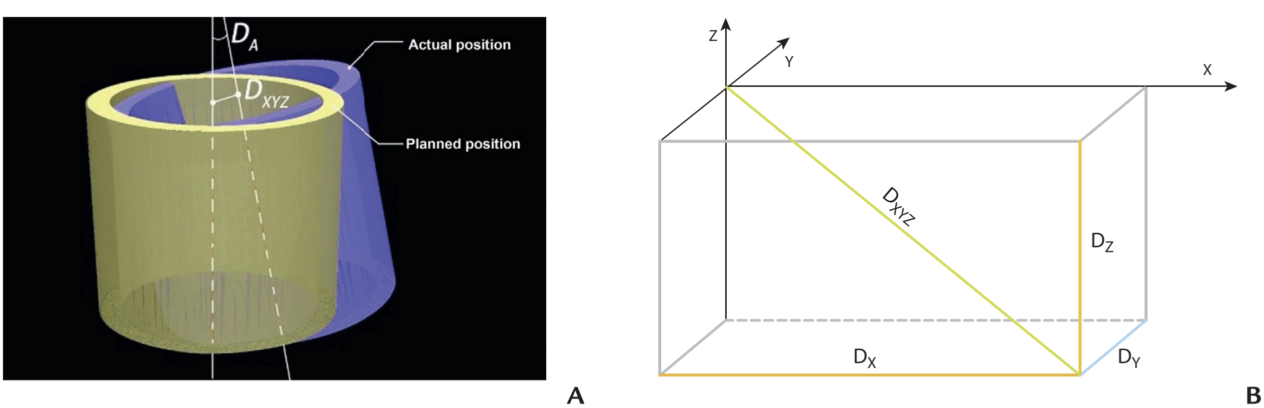

Figure 6. Deviation of sleeve reference points and axis angle. A, Global linear deviation in 3D coordinates (D_{XYZ}) and angular deviation (D_A). B, Linear deviations of surgical guide sleeves reported as D_X, D_Y, and D_Z in 3 directions of x, y, and z.

degrees (angular). They found that milled surgical guides showed significantly smaller deviations than did RP surgical templates. Additive manufacturing requires the fusion of digitized cast data, and errors may be introduced in the process of registration and fusion of multisource data. The present study used milling based on diagnostic template positioning and avoided the errors related to data fusion by drilling sleeve holes directly on the radiographic template. This approach may improve the accuracy of the surgical guide.

The fabrication deviation of the template evaluated in the present study was not simply equivalent to the

Table 2. Preclinical mean deviations of sample implant surgical guides

Deviations	Mean ±SD	SE	Max	Min
D_X*(mm)	0.06 ±0.05	0.01	0.19	0.00
D_Y*(mm)	0.08 ±0.05	0.01	0.25	0.00
D_Z*(mm)	0.11 ±0.07	0.01	0.25	0.00
D_{XYZ}*(mm)	0.16 ±0.06	0.01	0.29	0.03
D_A*(Degrees)	0.61 ±0.40	0.06	1.86	0.01

SD, standard deviation; SE, standard error. *D_X, D_Y, D_Z represented linear deviation in x, y, and z directions. D_{XYZ} represented 3D global deviation. D_A represented angular deviation.

mechanical milling deviation of the CNC machine itself. It included the error from CBCT acquisition, the software-derived positioning error, the machine milling error, and measurement error (Fig. 9). The spatial resolution of CBCT scans is typically approximately 0.3×0.3×0.3 mm.[14] The high-resolution reconstruction of CBCT scans (VGi evo; NewTom) adopted in this study was 0.15×0.15×0.15 mm space resolution, which could have contributed to the result of fabrication deviation.[15,16] The milling accuracy of

Table 3. Mean deviations and 95% CI of reference point between virtual planning and actual position of sleeve bore hole in different sleeve-implant distance groups (2, 4, 6 mm)

	Sleeve-Implant Distance			
Deviations (95% CI)	2 mm	4 mm	6 mm	*P* (F, *df*)
D_X* (mm)	0.06 (0.04, 0.10)	0.06 (0.03, 0.09)	0.06 (0.04, 0.08)	.919 (0.084, 2)
D_Y* (mm)	0.08 (0.05, 0.11)	0.07 (0.05, 0.09)	0.07 (0.05, 0.90)	.637 (0.454, 2)
D_Z* (mm)	0.11 (0.07, 0.15)	0.10 (0.06, 0.14)	0.12 (0.07, 0.15)	.612 (0.496, 2)
D_{XYZ}* (mm)	0.17 (0.14, 0.21)	0.15 (0.12, 0.18)	0.17 (0.14, 0.20)	.403 (0.925, 2)
D_A* (Degrees)	0.66 (0.52, 0.80)	0.62 (0.44, 0.80)	0.64 (0.37, 0.91)	.952 (0.049, 2)

*D_X, D_Y, and D_Z, linear deviation in x, y, and z directions; D_{XYZ}, 3D global deviation; D_A, angular deviation.

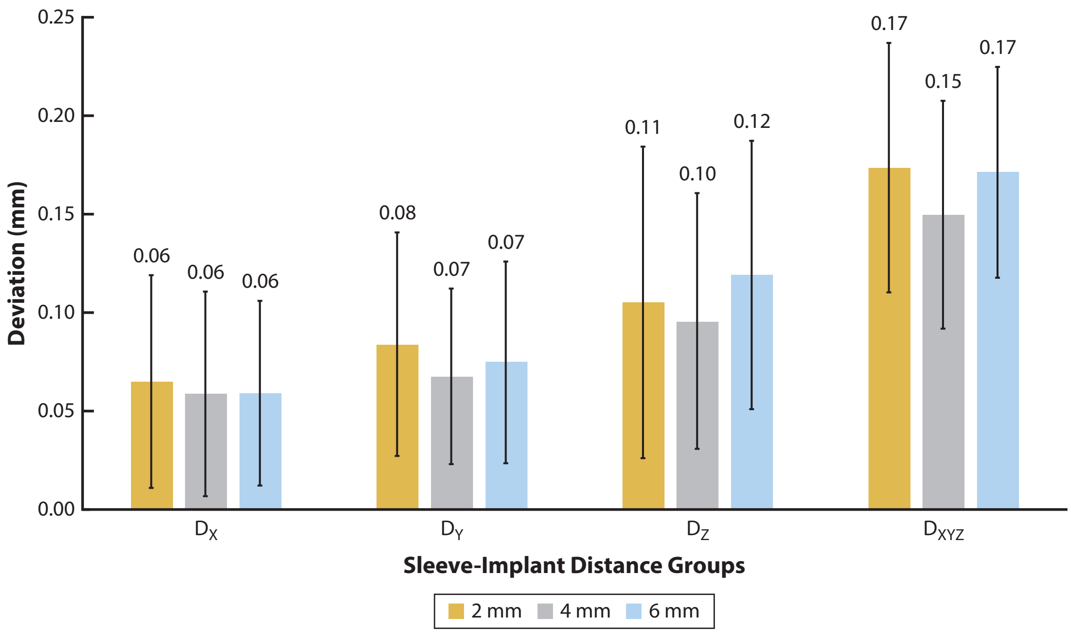

Figure 7. Mean deviations of sleeve bore holes in 3 groups of different sleeve-implant distance (2, 4, 6 mm). D_X, D_Y, and D_Z represent deviation in x, y, and z directions. D_{XYZ} represents 3D global deviation.

Table 4. Mean deviations and 95% CI of reference point between virtual planning and actual position of sleeve bore hole in different sleeve axis angle groups (70, 80, 90 degrees)

	Sleeve Axis Angle			
Deviations (95% CI)	70 Degrees	80 Degrees	90 Degrees	*P* (F, *df*)
D_X* (mm)	0.06 (0.03, 0.09)	0.05 (0.03, 0.07)	0.07 (0.04, 0.10)	.701 (0.358, 2)
D_Y* (mm)	0.07 (0.04, 0.10)	0.09 (0.07, 0.11)	0.06 (0.04, 0.08)	.248 (1.435, 2)
D_Z* (mm)	0.10 (0.06, 0.14)	0.10 (0.07, 0.13)	0.11 (0.08, 0.14)	.933 (0.070, 2)
D_{XYZ}* (mm)	0.16 (0.13, 0.19)	0.17 (0.15, 0.19)	0.17 (0.15, 0.19)	.989 (0.011, 2)
D_A* (Degrees)	0.59 (0.45, 0.74)	0.57 (0.44, 0.70)	0.77 (0.48, 1.06)	.297 (1.242, 2)

*D_X, D_Y, and D_Z, Linear deviation in x, y, and z directions; D_{XYZ}, 3D global deviation; D_A, angular deviation.

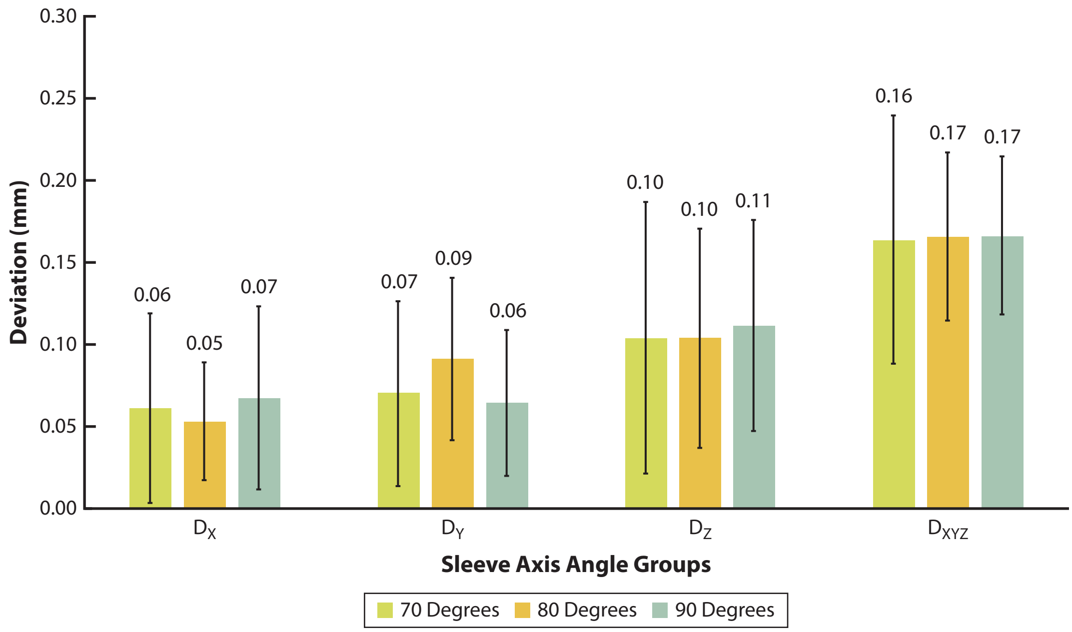

Figure 8. Mean deviations of sleeve bore holes in 3 sleeve axis angle groups (70, 80, 90 degrees). D_X, D_Y, D_Z represent deviation in x, y, and z directions, and D_{XYZ} represents 3D global deviation.

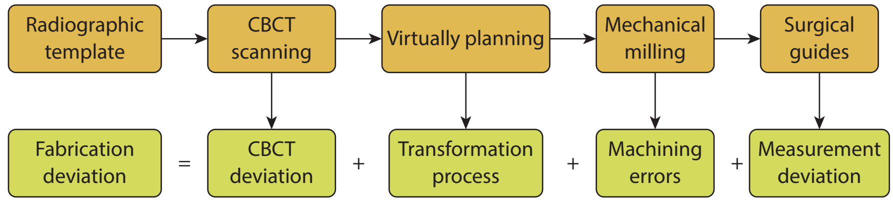

Figure 9. Factors contributing to preclinical deviations of milled implant surgical guide. CBCT, cone beam computed tomography.

the CNC machine (Organical Multi S; Organical CAD/CAM GmbH) was less than 2 µm. However, the wear of the bur and fretting of the radiographic template during milling could have caused an increased system error. In addition, the method used to measure the fabrication deviation in this study could also affect the results. The system error of the tabletop scanner (inEos X5; Dentsply Sirona) was 5 to 8 µm according to the manufacturer. The fitting deviation resulting from digital model superimposition was less than 0.05 mm. These factors could also contribute to the measurement error.

The deviations reflected the sum of all errors occurring from imaging to the transformation of data into a guide.[2] Accuracy measurement should be performed after the guide is produced to ensure that the accuracy of the technical procedure is within acceptable limits.

Limitations of the present study include that the fabrication deviation caused by the tolerance of the sleeve hole after the bonding of the sleeve was not evaluated. Additionally, the sample size at the resin sample level was relatively small, which could explain the large standard deviations. Future in vitro studies with larger sample sizes and clinical trials evaluating the deviation between the virtual planning and actual implant position with surgical guides made by the CNC milling technique in this study are needed.

CONCLUSIONS

Based on the findings of this in vitro study, the following conclusions were drawn:

1. The mean deviation of the surgical guide prepared by using the virtual planning software program and 5-axis CNC milling procedure was 0.16 ±0.06 mm in the center of the sleeve top.
2. The guide had acceptable precision.

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Noteworthy Abstracts of the Current Literature

Tolerances in the production of six different implant scanbodies: a comparative study

Henriette, Katalin Nagy, Fabrizia Luongo, Giuseppe Luongo, Oleg Admakin, Francesco Guido Mangano

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Purpose. To investigate and compare the production tolerances of six different commercially available implant scan bodies (SBs), with the null hypothesis that there would be no tolerances in the production or significant differences between the different SBs.

Material and methods. Six different implant SBs (IO 6A-B and IO 2B-B, Nobel Biocare; RC 4.1 mm 025.4915 and RN 4.8 mm 048.168, Straumann; KR 352KR1A0, BTK BIOTEC; and AANISR4013T, MegaGen) were evaluated. Five specimens of each SB type (a total of 30 samples) were screwed onto the corresponding implant analogs and underwent dimensional analysis with optical microscopy (QVI Smartscope Flash 200, Optical Gaging Products) and precision probing (R 0.25, Renishaw). The outcome variables were SB height, diameter, and angle of the flat face on the top (plane). All measurements were compared with the corresponding computer-assisted design library measurements used as a reference to assess the manufacturing tolerances. Statistical analyses were performed to compare the results obtained with the different SBs.

Results. Tolerances in the manufacture of the SBs were reported in height, diameter, and plane measurements, and statistically significant differences between the different types of SBs were found. Therefore, the null hypothesis was rejected. Most of the deviations and tolerances were reported in height measurements with conical connection implants.

Conclusions. Tolerances in the production and statistically significant differences were found among the six commercially available SBs evaluated in this study. Additional studies with larger sample sizes and other types of SBs are needed.