Accuracy of Implant Surgical Guides Fabricated Using Computer Numerical Control Milling for Edentulous Jaws: A Pilot Clinical Trial

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Abstract

Background

To evaluate the accuracy of a computer-aided design and computer-aided manufacturing (CAD-CAM) surgical guide for implant placement in edentulous jaws.

Methods

Nine patients with twelve edentulous jaws seeking implants were recruited. Radiographic guides with diagnostic templates were fabricated from try-in waxup dentures. Planning software (Organical® Dental Implant, Berlin, Germany) was used to virtually design the implant positions, and the radiographic templates were converted into surgical guides using computer numerical control (CNC) milling. Following the guided implant surgery protocol, forty-four implants were placed into twelve edentulous jaws. Cone-beam computed tomography (CBCT) scans were performed post-operatively for each jaw, and the deviations between the planned and actual implant positions were measured.

Results

All 44 implants survived, and no severe haematomas, nerve injuries or unexpected sinus perforations occurred. The mean three dimensional linear deviation of implant position between virtual planning and actual placement was 1.53 ± 0.48 mm at the implant neck and 1.58 ± 0.4 mm at the apex. The angular deviation was 3.96 ± 3.05 degrees. The mean deviation between virtual and actual implant position was significantly smaller in the maxilla than in the mandible. No significant differences were found in the deviation of implant position between cases with and without anchor pins.

Conclusions

The guides fabricated using the CAD-CAM CNC milling technique provided comparable accuracy as those fabricated by Stereolithography. The displacement of the guides on edentulous arch might be the main contributing factor of deviation.

Trial registration:

Chinese Clinical Trial Registry, ChiCTR-ONC-17014159

Background

Surgical templates for guided implant surgery have gained increasing importance in implant dentistry [1]. The fabrication of implant surgical guides usually follows a hybrid digital workflow [2]: Cone-beam computed tomography (CBCT) images of patients are converted into a virtual, three-dimensional (3D) digital model using planning software. This model provides a realistic view of the patient's bone structure and allows virtual implants to be placed in an ideal, prosthetically driven manner. The virtual implant position can then be transferred to a template made by computer-aided manufacturing (CAM).

Currently, there are two ways to fabricate surgical templates, namely, rapid prototyping (RP) and milling. Rapid prototyping or stereolithography (SLA) is the most widely used technique to fabricate surgical guides. Data from the CBCT scan, intraoral scan (or model scan) and digitalized try-in prosthesis are fused. A template is generated with respect to the digitalized supporting tissues. During the multisource data fusion process, errors can be introduced into the system and may cause deviations between the virtual and actual implant position, endangering critical anatomical landmarks or causing implant failure [3]. Linear RP processing error has been reported to be 0.22–0.24 mm [4]. For edentulous jaws, data fusion to fabricate a surgical guide is even more challenging due to the lack of rigid support by the natural teeth. The accuracy of the SLA surgical guide is influenced by the International Organization for Standardization (ISO) settings and calibration algorithm used in the planning software. Stumpel reported that the mean difference between the SLA duplicate denture printed from Digital Imaging and Communications in Medicine (DICOM) data and the original diagnostic prosthesis ranges from 0.56 mm to 2.17 mm [5].

Milled implant surgical templates are made based on coordinate alignment [6]. First, a wax-up denture is tried in patient mouth to ensure satisfactory teeth setup. Then a radiographic template is fabricated from radiopaque material. Patients take CBCT wearing the radiographic template, and the CBCT scan contains all the data necessary for implant planning. No data fusion is necessary. The radiographic guide is converted into a surgical guide using milling technique[7, 8]. Errors caused by the fusion of multisource data can be avoided.

For laboratory milled surgical guide, the most critical step is to transfer the virtual implant position into the coordinates of the milling machine. Previous studies have reported several transfer methods, such as the "X-cube", orthogonally designed acrylic rods or a standard template [8–10].

In 2018, a kind of implant surgical guide fabricated using a five-axis Computer Numerical Control (CNC) milling machine for guided implant placement in an edentulous jaw was introduced [11]. The laboratory-based CAD-CAM system provides a digital workflow in which only two steps involve manual interventions. The first step is the fabrication of the acrylic base for the radiographic template. The second step is the fixation of metal sleeves in the sleeve holes milled by the milling machine. Coordinates synchronization can be realized using a specially designed Diagnostic Template.

In many studies, the accuracy of stereolithography surgical guides for edentulous jaws has been investigated. In a recent systematic review, Seo and colleagues reported the accuracy of SLA mucosa-supported surgical guides for edentulous jaws [12]. The mean coronal deviation was less than 1.68 mm, and the mean apical deviation was less than 2.19 mm. However, there was only a few studies addressing the accuracy of the laoratory based CNC milled surgical guide. Chai and colleagues reported the preclinical fabrication accuracy of the CNC milled surgical guide as 1.06 mm at the neck and 1.12 mm at the apex [11]. Park reported the technical deviation of the milled template was 0.68 mm horizontally, and 0.41 mm vertically [6]. There was no study reporting the clinical accuracy of the CNC milled surgical guide for edentulous jaws.

Therefore, the aim of this study was to evaluate the accuracy of implants placed using a CAD-CAM fabricated CNC-milled implant surgical guide in edentulous jaws. The null hypothesis was that by using the CAD-CAM fabricated CNC-milled implant surgical guides, the position differences between the virtually planned and actually placed implants would be higher than those of SLA surgical guides reported in the literature.

Methods

1. Participants

The patients who were edentulous in one or in both jaws and seeking implant-supported prosthesis treatment in the Department of Prosthodontics at Peking University School and Hospital of Stomatology from December 2017 to June 2018 were included in this study. The inclusion and exclusion criteria are shown in Table 1. The study was reviewed and approved by the Institutional Review Board of Peking University School and Hospital of Stomatology. The study was registered in the Chinese Clinical Trial Registry (ChiCTR-ONC-17014159). This study was undertaken with the understanding and written informed consent of each individual participant and was conducted in accordance with the World Medical Association's Declaration of Helsinki (Version, 2013).

Table 1
Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Age > 20 years old • Being edentulous for more than 6 months • Willing to receive implant treatment	• Needing to undergo a complicated bone augmentation procedure • Having a local or systemic contraindication for implant therapy • Smoking more than 10 cigarettes per day • Not having enough keratinized tissue for flapless surgery

2. Design And Fabrication Of The Radiographic Template

The study protocol is summarized in Fig. 1. For each patient, after conventional impressions were taken for both the maxilla and mandible, stone models were fabricated. Maxillomandibular relationship registration was performed, and the models were mounted in an articulator. Complete try-in wax-up were fabricated (Fig. 2a). The wax-up dentures were tried in the patient’s mouth, and after clinically necessary corrections, the wax-up dentures were sent back to the laboratory for the production of radiographic templates.

The wax-up was digitize using a table-top scanner (D2000, 3shape, Copenhagen K, Denmark). A radiopaque polymethyl methacrylate (PMMA) blank (Organical® PMMA, Organical, Berlin, Germany) was used to mill the dentitions on a 5-axis CNC milling machine (Fig. 2b, Organical® Multi S, Organical, Berlin, Germany). A transparent self-cure resin base was built on the model (Fig. 2c and 2d). Finally, a registration template (Diagnostic Template, Organical®, Berlin, Germany) was bonded to the lingual side of the radiopaque dentition to complete the radiographic template (Fig. 2e and 2f).

3. Cbct Scan And Virtual Implant Planning

The radiographic template was placed in the patient’s mouth to confirm its fit. To further stabilize the template, a silicone index was used. With the templates in the patient’s mouth, a CBCT scan (VGi, New Tom, Verona, Italy, voxel size 0.25 mm^3, field of view 12 cm x 8 cm, voltage 110 kV, tube current 3.5 mA) was performed (Fig. 3). The image data were exported in the DICOM format and exported to virtual planning software (Organical® Dental Implant, ODI 1.1.0.5, Organical, Berlin, Germany). The radiopaque dentitions and the alveolar bone could be viewed in the software (Fig. 4).

Virtual implant planning was conducted in the software in accordance with the prosthetic treatment protocol (Fig. 4). The software aligned the spatial coordinates of the radiographic templates with its system coordinates by identifying the zirconia beads in the diagnostic plate in the images (Fig. 5). The position information of the virtually designed implants was then transferred into coordinate values that could be identified by the milling software. The planning data were then exported in the initial graphics exchange specification (IGES) format.

4. Milling Of Surgical Guides

The implant planning data were transferred into the milling software (Organical® Mill2, Organical, Berlin, Germany), and the radiographic guide with the diagnostic template was fixed on the 5-axis CNC machine (Organical® Multi S, Organical, Berlin, Germany). Bore holes for the guide sleeve of each implant were milled on the radiographic templates. The guide sleeves were precisely installed into the bored holes (Fig. 6). Thus, the radiographic template was transferred into an implant surgical guide.

5. Guided Surgery

All the surgeries were performed by two experienced general dentists. Before surgery, the surgical guide and the silicon index were disinfected in 0.12% chlorhexidine for 30 minutes, and positioned on the edentulous jaw with the interocclusal silicon index to confirm proper seating.

After local anaesthesia, the surgical guide was either fixed on the patient's alveolar ridge by three lateral fixation pins or retained using a fixation anchor through guide sleeves after the first twist drill. Flapless guided implant placement protocol was followed, and a punch drill was used to remove the mucosa on top of the alveolar ridge.

Based on the virtual planning, the correct combination of drill handles and guided instruments was used for osteotomy site preparation, and the implants were installed (Fig. 7). Guided bone regeneration (GBR) procedure was performed when necessary.

6. Deviation Measurement

After implant placement, a second CBCT scan was taken for each patient.The post-surgical CBCT data were imported into Mimics (Mimics 19.0, Materialise, Leuven, Belgium), and post-operative digital models in the Standard Tessellation Language (STL) format were generated from the DICOM data. A 1.25 mm layer of bone around the implant was removed using the Masks, Morphology, and Boolean function in the software. Finally, the data of the bone structure of the edentulous maxilla and mandible together with the isolated implants in the STL format were exported from Mimics software and imported into the virtual planning software, where the data were superimposed with the pre-surgical CBCT image that contained the virtually planned implant position (Fig. 8).

Deviation measurement

The deviation between the virtually planned and actually placed implant positions was measured at the neck and apex of each implant.

Four parameters were defined, namely, the global deviation, horizontal deviation, depth deviation, and angular deviation. All parameters, except for the angular deviation, were measured both at the implant neck and the apex.

The global deviation was defined as the 3D distance between the centres of the neck (or apex) of the corresponding virtually planned and actually placed implants. To calculate the lateral deviation, a plane perpendicular to the longitudinal axis of the planned implant and through its coronal or apical centre was defined and set as the reference plane. The horizontal deviation was defined as the distance between the coronal (or apical) centre of the planned implant and the point of intersection of the longitudinal axis of the placed implant with the reference plane. The depth deviation was defined as the distance between the coronal (or apical) centre of the placed implant and the reference plane. The angular deviation was defined as the three-dimensional angle between the longitudinal axis of the planned and placed implants (Fig. 9).

To analyse the factors contributing to implant deviation, the mean global deviation in the maxillary cases and that in the mandibular cases were compared. Mean global deviation in cases with and without lateral fixation pins were also compared.

Mean difference of inter-implant distance

The distances between each pair of neighboring implants were measured in the virtual planning and the actual post-operative CBCT scans. The mean differences between the virtual and actual inter-implant distance at implant neck and apex area were calculated, this will represent the random errors in the surgical template (Fig. 10).

Data analysis

Initially, the data were analysed descriptively using SPSS for Windows (SPSS 20.0, Chicago, IL, USA). To determine the contributing factors for the deviation in implant position, the deviation values between the upper and lower jaws as well as between cases in which fixation pins were used for the surgical guide and cases in which pins were not used were compared using *t*-tests.

Results

A total of 44 implants were placed using CAD-CAM CNC-milled guides. The patients' demographic data and distribution of the implants are summarized in Table 2. No post-operative complications, such as haemorrhages, sinus pathologies, severe pain, or inflammation, were recorded. Lateral fixation pins were used in three surgical templates with 14 implants placed, and the other nine surgical guides were retained with fixation anchors through the guide sleeves after the pilot drill for the osteotomy was performed. The average three-dimensional deviation at the implant shoulder was 1.53 ± 0.48 mm, and that at the apex was 1.58 ± 0.49 mm. The mean angle deviation was 3.96 ± 3.05 degrees. The global, horizontal and vertical deviations are shown in Table 3. No significant differences were found between the global coronal deviation and the global apical deviation. The horizontal deviation was significantly larger than the depth deviation at both the implant neck and apex ($p < 0.05$).

Table 2
Patients' demographic information and implant distribution

		Number (Percentage)
Patients	male	3 (33.3%)
	female	6 (66.7%)
Edentulous arches	upper	7 (58.3%)
	lower	5 (41.7%)
Implants	upper	21 (47.7%)
	lower	23 (52.3%)

Table 3
Deviation between the virtually planned and actually placed implant positions

		Mean	SD	Min	Max
Linear deviation at the implant neck (mm)	Horizontal	1.28	0.40	0.42	2.36
	Depth	0.67	0.58	0.01	2.20
	Global	1.53	0.48	0.61	2.58
Linear deviation at the implant apex (mm)	Horizontal	1.28	0.53	0.13	2.19
	Depth	0.70	0.58	0.01	2.21
	Global	1.58	0.49	0.47	2.74
Angular deviation (degrees)		3.96	3.05	0.60	16.72

The effects of several contributing factors on the deviation between the planned and actual implant positions were evaluated (Table 4). There was a trend showing that the mean global deviation in implant position in the maxilla was lower than that in the mandible at both implant neck and apex. However, the difference was not statistically significant ($p = 0.280$ for the value at the implant neck, $p = 0.084$ for the value at the implant apex). No significant difference was found in the implant deviation between the surgical guides with and without lateral fixation pins.

Table 4
Global deviation (mm) between the virtually planned and actually placed implant positions in the different subgroups

Global deviation	Edentulous arch			Lateral fixation pins		
	Upper (n = 7)	Lower (n = 5)	*p* value	With	Without	*p* value
Neck	1.45	1.61	0.280	1.51	1.54	0.865
Apex	1.44	1.70	0.084	1.81	1.47	0.060

Inter-implant distance for every two neighboring implants were measured in both the virtual planning CBCT and post-operative CBCT, and the difference of inter-implant distance between pre- and post-surgical digital models were calculated. The mean difference of the inter-implant distance was 0.48 ± 0.51 mm at the implant neck and 0.50 ± 0.43 mm at the implant apex. The minimum value was 0.04 mm coronally and 0.02 mm apically. The maximum value was 2.71 mm coronally and 1.81 mm apically.

Discussion

The null hypothesis was rejected. In this study, the accuracy of a CAD-CAM CNC-milled implant surgical template for edentulous jaws was investigated. The mean deviation between virtually planned and actual placed implant positions was 1.53 ± 0.48 mm in the coronal plane and 1.58 ± 0.49 mm in the apex area. These results are comparable to those of previous studies that reported the accuracy of surgical guides for implant placement in edentulous jaws.

In most of the previous studies, stereolithography (SLA) surgical guides were evaluated. Seo and colleagues [12] reported the accuracy of SLA mucosa-supported surgical guides for edentulous jaws. The mean coronal deviation was less than 1.68 mm, and the mean apical deviation was less than 2.19 mm. Few studies have investigated the accuracy of milled surgical guides for edentulous patients. The accuracy of the milled surgical guide from the present study is acceptable for clinical use. However, the factors that contributed to the deviation in implant position should be identified.

For the RP solution, the guide was designed with the digital model on the computer and fabricated by 3D printing techniques. Multisource data fusion was performed to provide clinicians with all the necessary information in digital form for virtual implant placement. The more data sources that are combined into the design software, the more errors that might be introduced into the final template. For example, the fusion of DICOM data extracted from the CBCT of edentulous patients wearing diagnostic prostheses and the data from the low-dose CBCT of the prosthesis is based on marker registration. Therefore, its accuracy is influenced by the number of markers used and their locations. The accuracy of the RP surgical template also depends on the 3D reconstruction of the marked denture. An excessively high or low grey value threshold will result in a surgical template that is too thin or thick [13].

For the workflow in our study, all necessary data were acquired by one single CBCT scan, and no intraoral or model scans were needed. The dentition in the radiographic guide was milled using digitalized wax-up and made of radiopaque PMMA material. The base was constructed directly on the stone model to guarantee a precise fit of the radiographic template. The CBCT scan was taken with the radiographic template in place, thereby providing data of the future dentition as well as the alveolar bone. Multisource data fusion or dual CBCT image fusion [14] was not needed for the virtual implant design, and errors generated in this procedure could be avoided. Another innovative design of this system is the diagnostic template. It provides both the spatial registration of the CBCT data for the design software and the positioning holes for the alignment of the coordinate systems between the radiographic template and the CNC milling machine. By mean of the diagnositc template, the planning information was transferred to the final surgical guides. The fabrication process of the surgical template comprised mostly of the digital workflow and reduced manual work to a current minimum. Many studies have reported laboratory-based milling techniques for surgical guide fabrication, and most of these prior studies required complicated steps and manual interventions [7]. The technique introduced in this study uses CAD-CAM in most of the workflow, thereby simplify the process and produce surgical templates with an accuracy comparable to that of templates made with the RP technique.

The mean difference between the virtual and actual inter-implant distance was significantly smaller than the mean global deviation for a single implant in both the coronal and apical areas. When the inter-implant distances were calculated, inherent systematic error was eliminated, while for a single implant, the deviation included systematic error. Only production errors and errors occurring during the surgical procedure were related to the inter-implant distance deviations [15]. The positioning error of the surgical template may be one of the principal contributing factors to the systematic error [15].

Surgical template repositioning on the edentulous arch can be challenging due to the resilient nature of the mucosa covering edentulous jaws. There is no rigid support for the template, and anaesthesia during surgery can also lead to changes in the position of the surgical guide. This can also be observed in the accuracy evaluation. The planned and actual implants were superimposed, and the actual implants were shifted towards the same direction, indicating a shift in the surgical guide during surgery (Fig. 11).

To reduce the effect of edentulous mucosa, some authors [15] have suggested that the base of the guides should cover as much mucosa as possible to guarantee more support. Some studies have shown that the deviation of the implants in the maxilla is smaller than that in the mandible. This result might be because the maxilla has a much larger supporting area than does the mandible. In the present study, the mean deviation in the implant position was smaller in the maxilla than in the mandible. However, no significant difference was found.

Some researchers have recommended anchor pins to fix the guides [16, 17]. However, Verhamme and colleagues found no significant difference in guide accuracy between cases in which anchor pins were used and cases in which anchor pins were not used [18]. This result is supported in the present study. No difference was found in guide accuracy when lateral fixation pins were and were not used.

Limitations

There are several limitations in the present study. First, this study investigated only the accuracy of CNC-milled implant surgical templates for edentulous jaws, and additional randomized controlled clinical trials comparing the accuracy of milled and SLA printed surgical guides are needed. Second, the limited sample size of the implants in this study may not be sufficient to detect differences between subgroups of patients. A larger sample size needs to be included in future studies. Third, the technique used to measure the differences between the intended and reached implant positions can also be a source of error since the process of superimposing two CBCT scans alone is known to be a potential source of mismatch. Fourth, the process of inserting series keys in the guide sleeves may also introduce minor deviations during the osteotomy, especially when the key is not properly seated on the surgical sleeves in the guide.

Conclusions

The guides fabricated using the CAD-CAM CNC milling technique provided comparable accuracy as those fabricated by Stereolithography. The displacement of the guides on edentulous arch might be the main contributing factor of deviation.

Declarations

Ethical approval andconsent to participate

The protocols were reviewed and approved by the Institutional Review Board of Peking University School and Hospital of Stomatology. Trial registrtion: Chinese Clinical Trial Registry, ChiCTR-ONC-17014159. Registered 26 December 2017, http://www.chictr.org.cn/showproj.aspx?proj=16824. This clinical trial was conducted in accordance with the ethical standards reported in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards on Ethical Principles for Medical Research.

Informed consent was obtained from all individual participants included in the study.

Consent for publication

Informed consent forpublication was obtained from all individual participants included in the study.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

S.P., J.S., and Y.Z. conceived the ideas; J.C., R.S. and X.L. collected the data; S.P., J.S., J.C., J.L. and X.L. analyzed the data; and S.P., J.C., R.S., J.L., X.L. led the writing.All authors have read and approved the manuscript.

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Figures

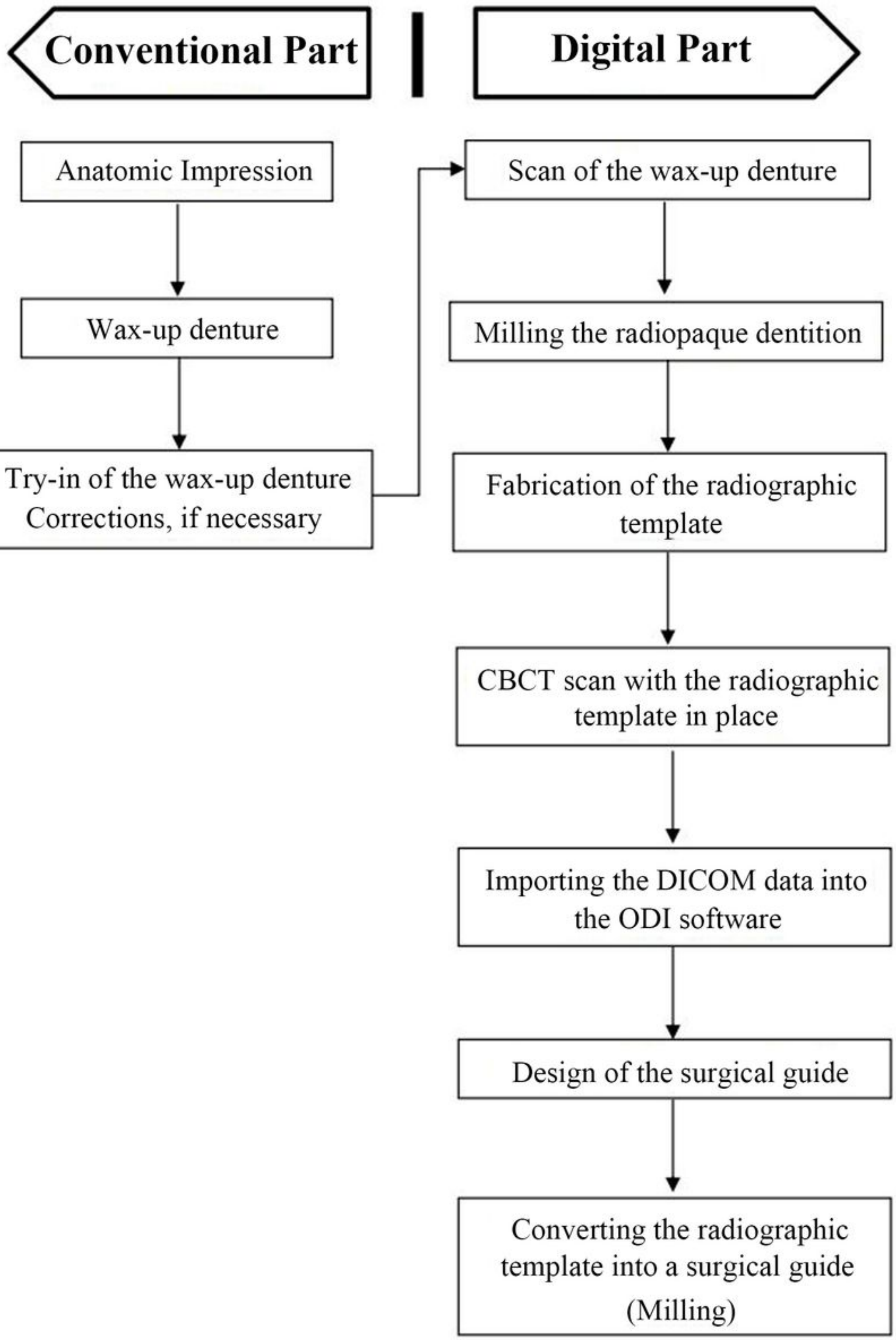

Figure 1

Workflow of the conventional and digital parts of the guide fabrication procedure

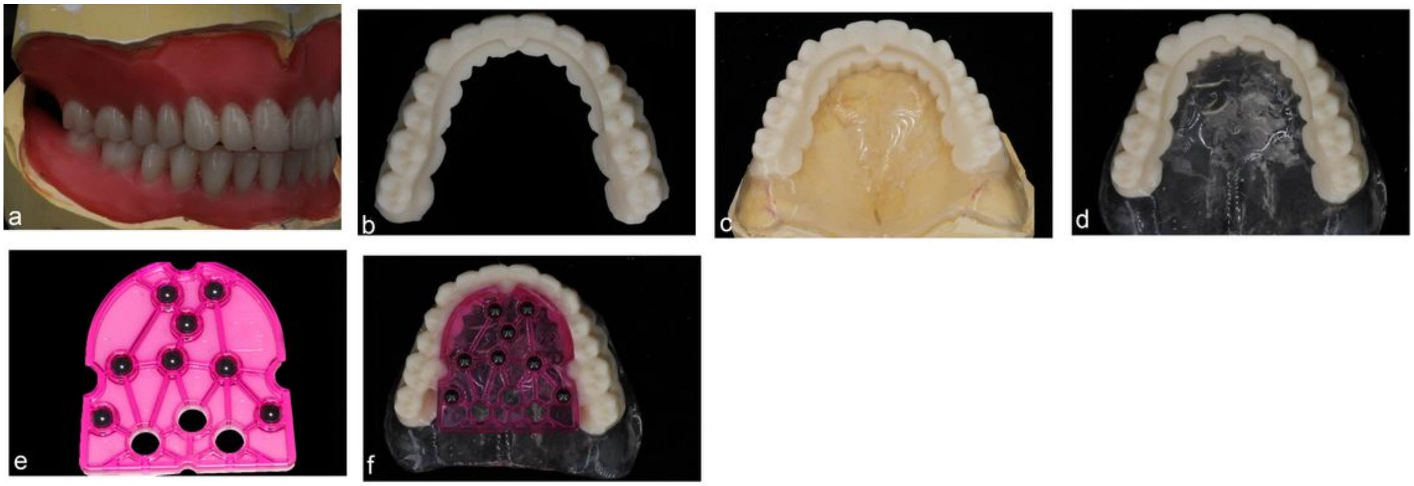

Figure 2

The radiographic template. a The wax-up on the maxillary and mandibular edentulous models. b Radiopaque PMMA dentition duplicated from the digitized wax-up. c Translucent resin base for radiopaque dentition built on the stone model. d Radiopaque dentition with the transparent resin base removed from the stone model. eDiagnostic template with eight zirconia beads. f The finished radiographic template.

Figure 3

Radiographic template was tried in the patient’s mouth with the silicon index between the upper and lower arches. The patient underwent a CBCT scan while wearing the radiographic template.

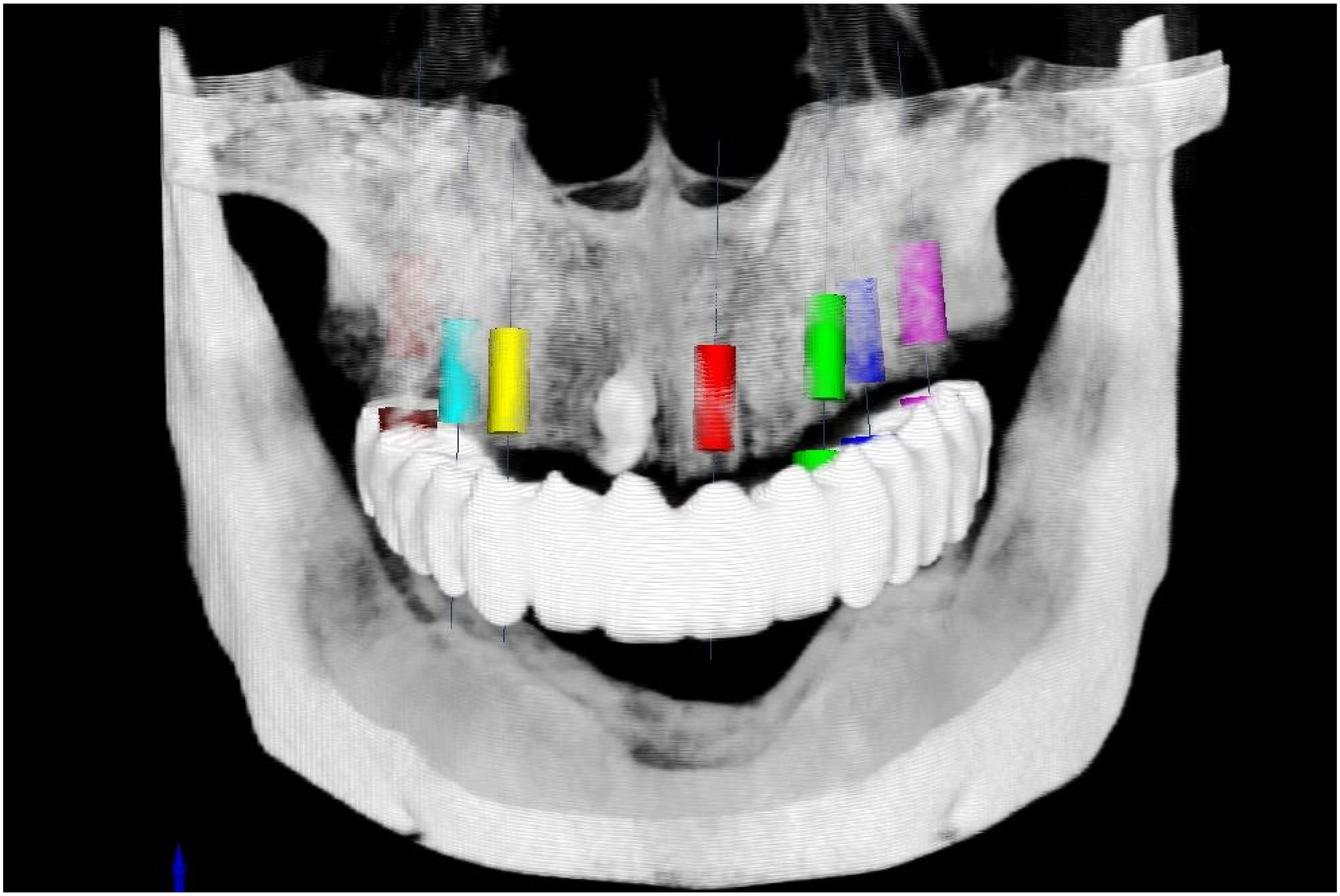

Figure 4

Virtual design of the implant positions in the virtual planning software (Organical® Dental Implant, ODI 1.1.0.5, Organical, Berlin, Germany)

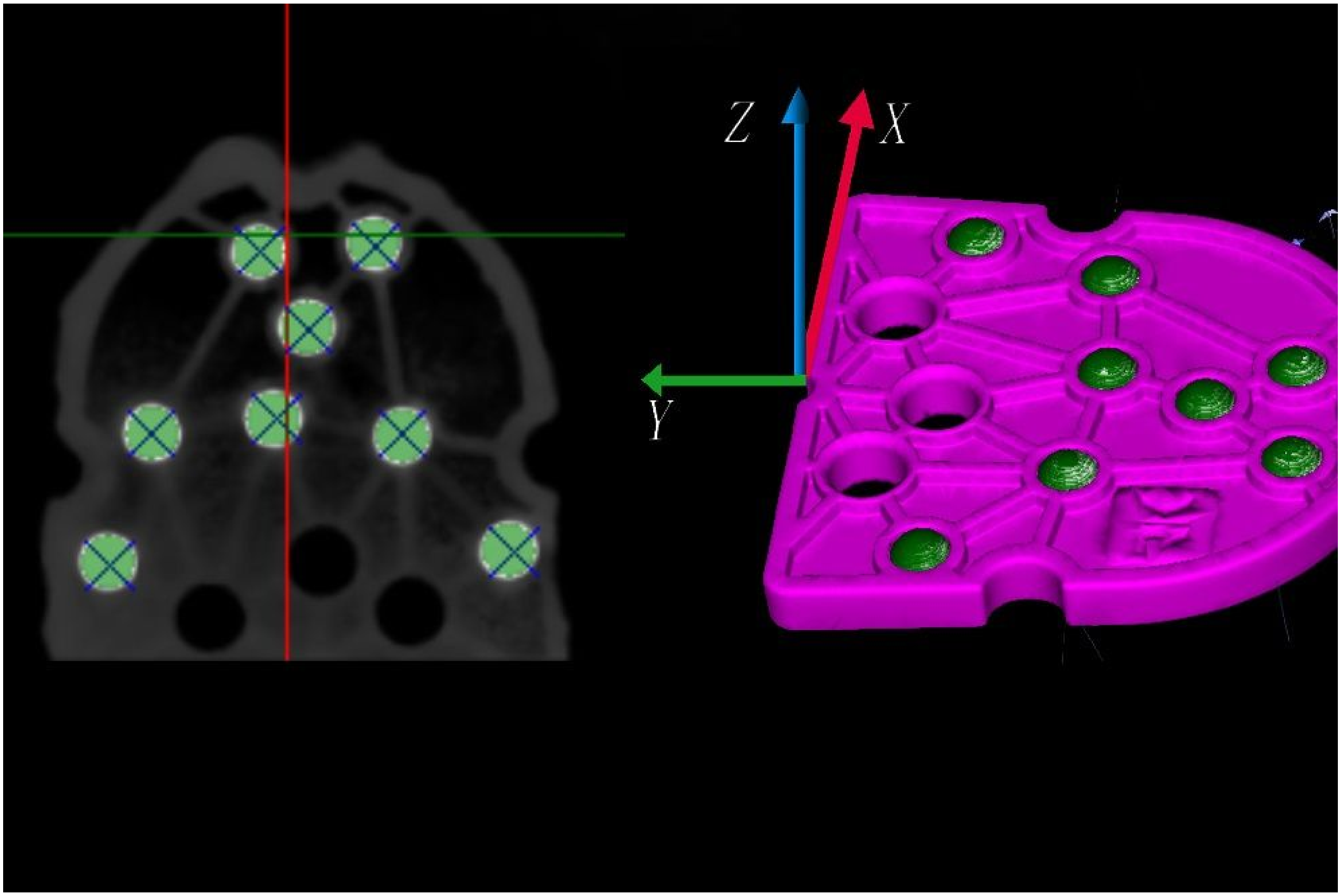

Figure 5

Coordinate alignment in the implant planning software. a The software identified the zirconia beads in the diagnostic plate in the image. b The positions of the diagnostic plate and the radiographic template were aligned with the coordinates of the software.

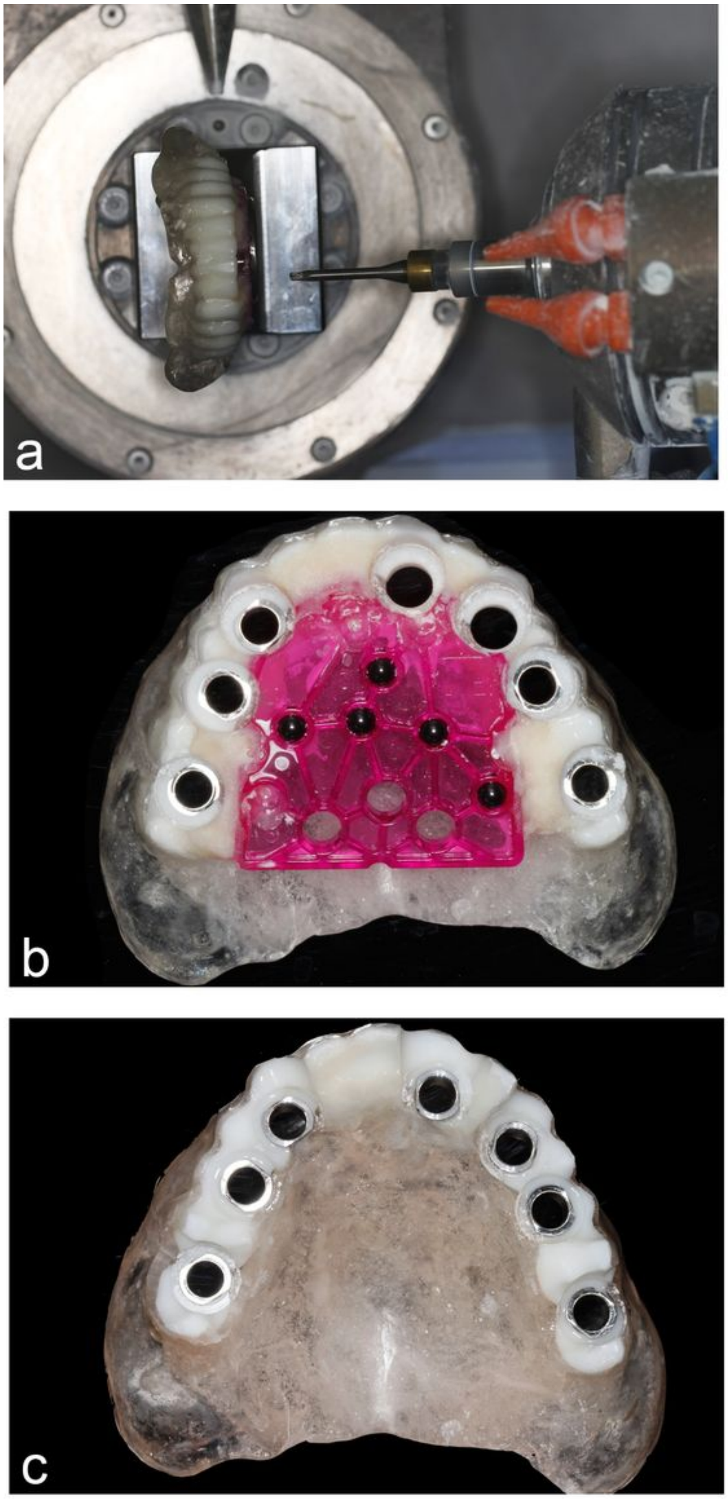

Figure 6

The radiographic template was transferred into the surgical guide by the CNC milling process. a The radiographic template was fixed on the holder of the CNC milling machine, and boreholes of the sleeves were milled on the radiographic template. b Steel guide sleeves were installed into the holes. cThe registration template was removed, and the radiographic template was transferred into a surgical guide

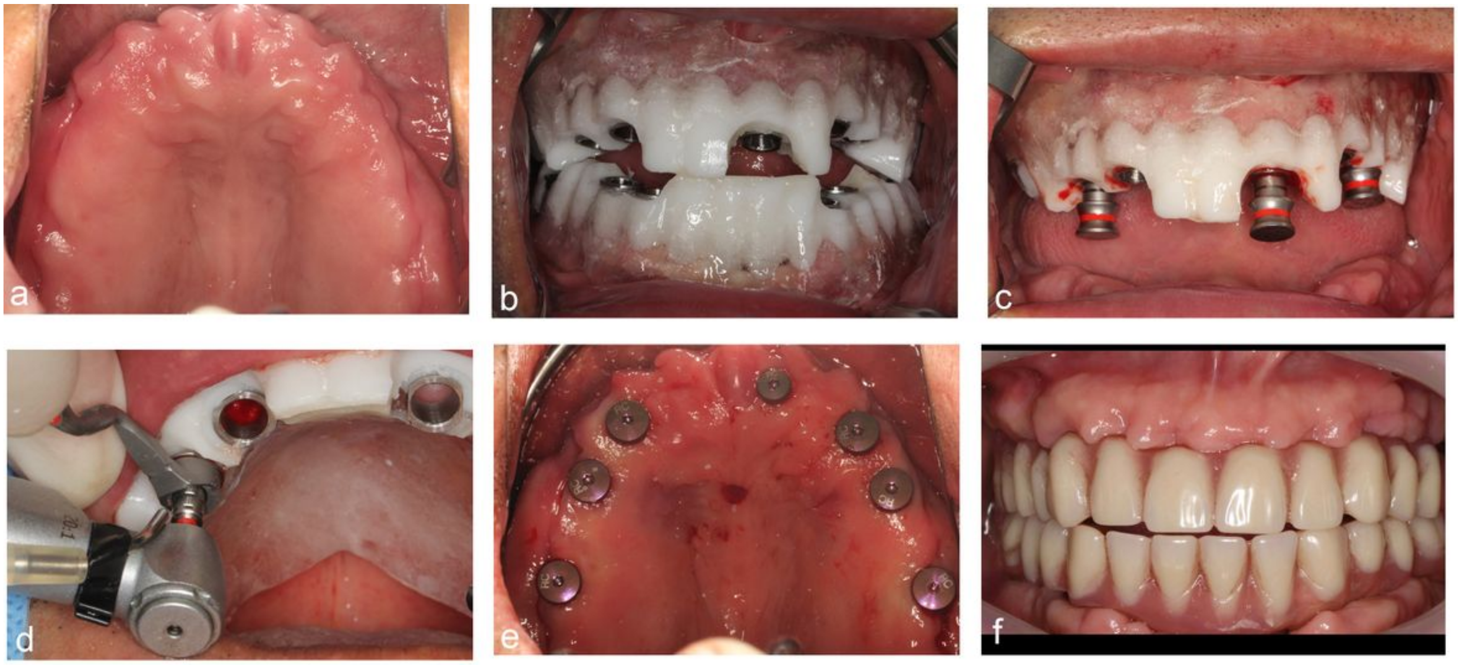

Figure 7

Guided surgery using CNC-milled mucosa-supported guide. a Edentulous maxilla with sufficient keratinized gingiva. b The upper and lower surgical guide. c The guide was fixed on the edentulous arch by a fixation anchor through the guide sleeves. d Osteotomy was performed using drill handles and guided instruments. eSeven implants were placed following a flapless protocol. fScrew-retained immediate fixed prosthesis modified from a previous complete denture

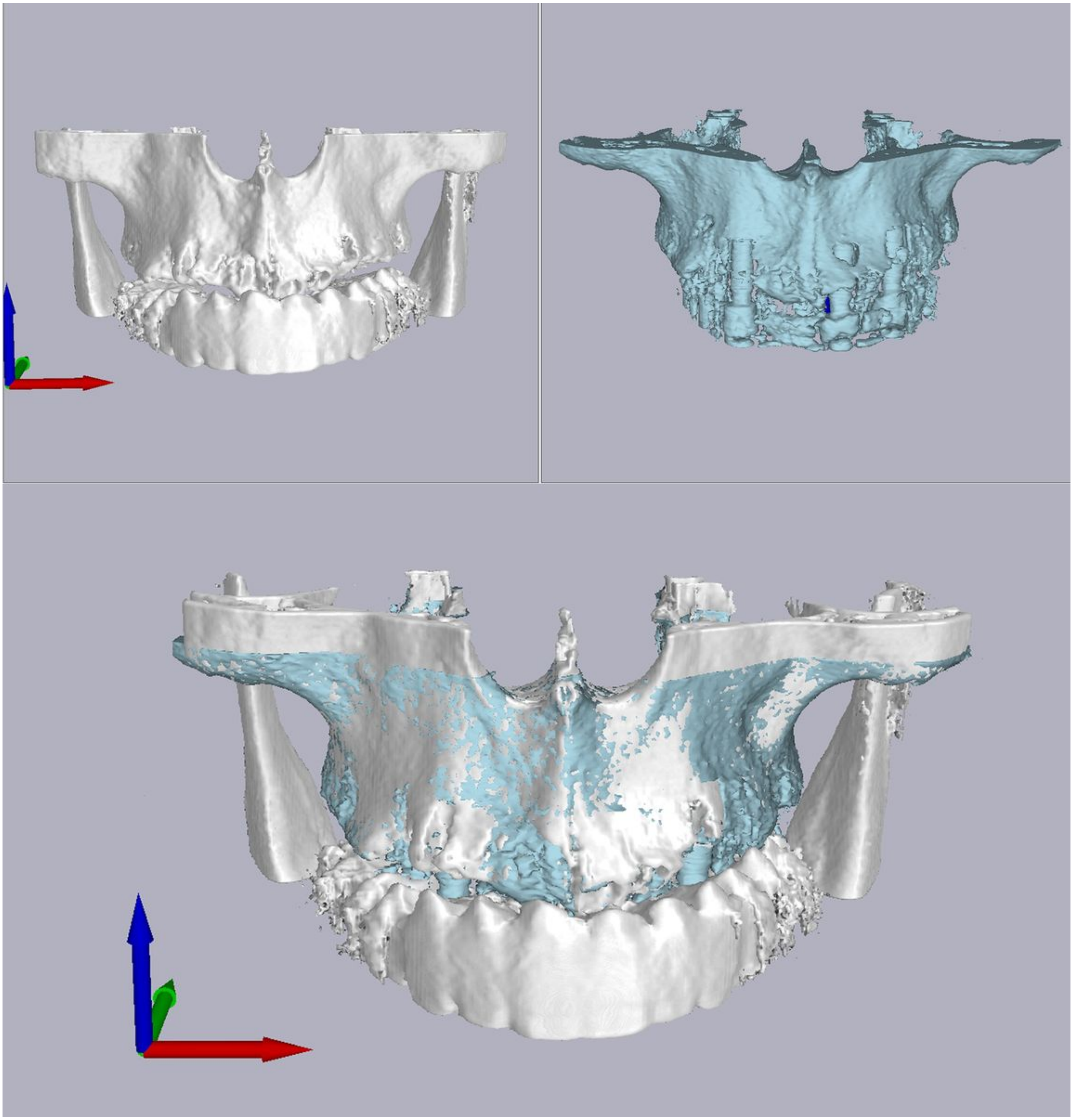

Figure 8

The superimposition of the pre- and post-operative data reconstructed from the CBCT scans

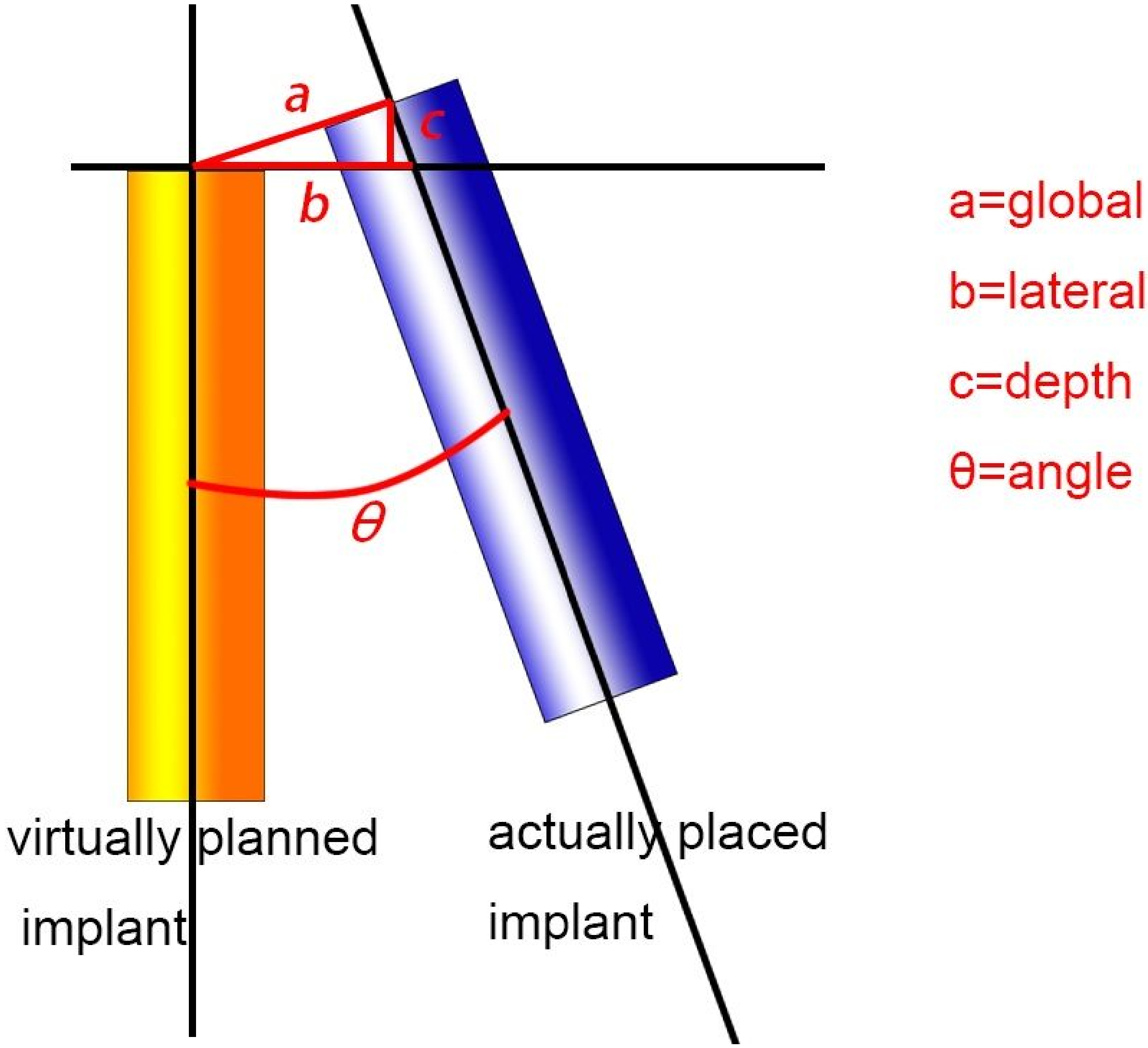

Figure 9

Evaluation of the three-dimensional deviation between the planned and actual implant position.

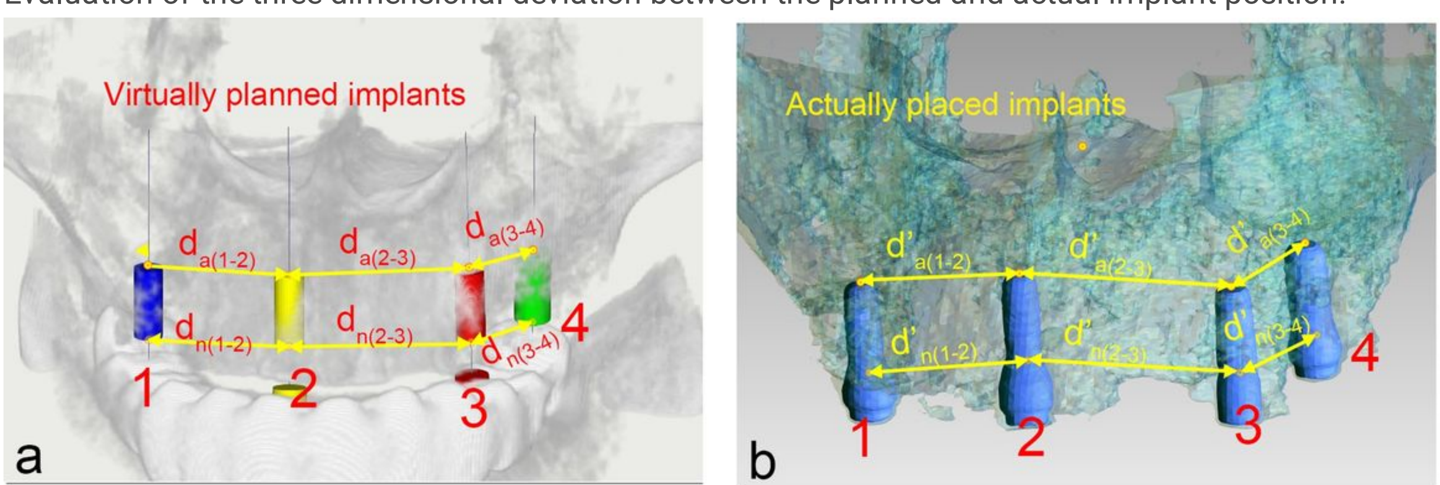

Figure 10

a, The inter-implant distance at the neck level of two neighbouring implants in the virtual planning model was named dn, and that at the apex level was named da; b, The inter-implant distance at the neck level of two neighbouring implants in the post-operative CBCT scan was named d’n, and that at the apex level was named d’a; The mean difference between the virtual and actual inter-implant distances of two adjacent implants was calculated

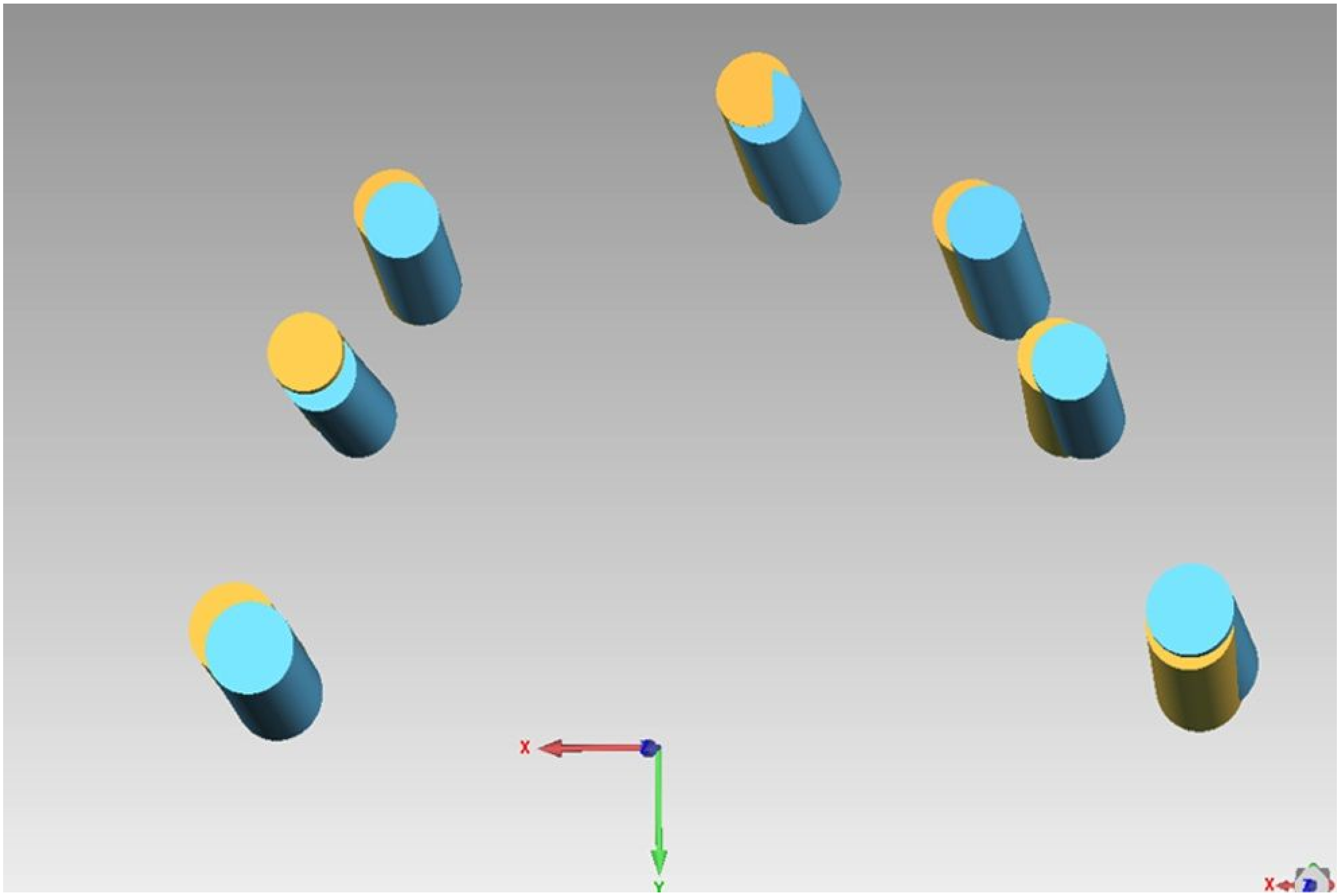

Figure 11

The virtually planned (yellow cylinder) and actually placed implants (blue cylinder) were superimposed, and it can be observed that the actual implants were shifted towards the same direction, indicating a shift of the surgical guide during surgery (systemic error).