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Retrospective study to determine the accuracy of template-guided implant placement using a novel nonradiologic evaluation method

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Objectives. With a novel, noninvasive method for determining three-dimensional accuracy, the realized implant position relative to the planned implant position was analyzed retrospectively. Additional postoperative cone beam computed tomography was thus dispensable.
Study Design. Twelve cases with distal extension situations (DESs) or single tooth gaps (STGs) were evaluated. The data sets of the planned implant position were superimposed on the actually achieved implant position, retrieved from digitizing the implant impression. The deviations were measured and statistically analyzed.
Results. The mean deviation was 5° in the DES group and 4° in the STG group for the implant axes, 1 mm (DES) and 0.9 mm (STG) at the implant neck, and 1.6 mm (DES) and 1.5 mm (STG) at the implant apex. The mean height discrepancy was 0.5 mm (DES) and 0.5 mm (STG). No significant differences ($P > .05$) were found between the DES and STG groups.
Conclusions. The innovative, noninvasive evaluation method is suitable and sufficiently accurate for the assessment of larger cohorts. The results of our study showed a sufficiently high degree of accuracy when using a virtual planning program for which no radiopaque template is needed when performing cone beam computed tomography. (Oral Surg Oral Med Oral Pathol Oral Radiol 2016;121:e72-e79)

The computer-aided planning of implants with subsequent static or dynamic implementation of the implant position (three-dimensional implant planning and insertion [3-DII]) aims to predictably achieve the best possible prosthetic restoration of the implants and to make optimal use of the available bone for this purpose.[1] Based on a knowledge of the bone as radiologically depicted in three dimensions and of the prosthetically driven wax-up/set-up and focusing on the prosthodontic needs, the software is used to plan the positions of the implants.

In dynamic systems, the drill is navigated in three dimensions relative to the patient. For static, stent-based methods, the proposed implant position is realized with the help of surgical templates (stents or guides).

Drilling and insertion templates help complete the preparation of the implant bed and the insertion of the implant. Several methods available for this purpose: reworking of laboratory-fabricated scanning templates, templates milled during the computer-aided design/computer-aided manufacturing (CAD/CAM) process, or stereolithographic templates (3-D printing). Systems utilizing a drilling sequence with increasing drill diameters require the use of additional inner sleeves within the templates. Depending on the system, the implant bed can be prepared and the implant placed with or without a height stop.

Alternatively, the depth can be adjusted visually. A possible simplification is to drill only the pilot hole with the help of a template and then to widen the implant bed manually. The surgical effort might be reduced by inserting implants at an angle because this can help avoid augmentation procedures.[2] Prosthetic restoration options will have to be taken into account when inserting implants at an angle.

Where suitable, 3-DII facilitates a minimally invasive approach without the need to reflect a soft tissue flap. This "flapless surgery" has been described as causing less pain, swelling, and patient discomfort.[3] The flapless approach yields results similar to the conventional flap approach with regard to the remodeling of the crestal bone around the implant.[4] Possible disadvantages included the fact that the

Statement of Clinical Relevance

Dispensing with templates for implant planning with cone beam computed tomography saves time and money. Instead, information can be gained by digitizing the existing gypsum models. Data can be aligned to the cone beam computed tomography data (matching). The results show a sufficiently high degree of accuracy.

Table I. Patients and treatment characteristics of the distal extension situation (DES) and single-tooth gap (STG) groups

Group		Arch		Surgical technique		Implant length		
		Maxilla	Mandible	Open flap	Flapless	9 mm	11 mm	13 mm
DES	No.	5	7	3	9	—	11	1
STG	No.	7	5	5	7	1	5	5

insertion depth (vertical endpoint) of the implant cannot be visually checked, and no corrective manipulation of the soft tissue around the implant is possible. Punching results in loss of keratinized gingiva, with possible aesthetic and functional disadvantages.[5]

The additional time and money required with 3-DII can be justified if the implants are placed more accurately, which would yield better results in terms of function or aesthetics. Comparative studies of 3-DII implants clearly show more accurate placement results.[6-8] Although some studies are now available on the subject, the number of in vivo studies and the follow-up sample sizes are still limited.[1] The follow-ups compare different systems with different software programs and different template-fabrication processes (conventional production, stereolithography, or milling). Possible factors that may influence the 3-D design, template fabrication, or implant placement have not been described.

The studies on the accuracy of 3-DII are based on 3-D data sets that include planning data and actually realized implant positions in a common coordinate system. The mostly frequently used analytical method is based on additional postoperative cone beam computed tomography (CBCT) data on which the planning data are superimposed. Since the increased radiation exposure of CBCT, compared with conventional two-dimensional X-ray images,[9] must be justified on a case-by-case basis and a CBCT should be performed only if a strict indication exists, the use of this analytical method—making an evaluation CBCT in addition to the necessary planning CBCT—in larger cohorts is limited for ethical reasons. A method based on CBCT images of master casts with implant analogs[10] has been described as an alternative. Digitizing the master casts instead of obtaining a CBCT image could lower systematic errors in the evaluation procedure. First, using a high-accuracy digitizer (measurement uncertainty less than 10 μm) will reduce data acquisition errors. Second, the precise digital master model data will allow for reduce alignment errors in preimplant and postimplant insertion data.

The objective of this article is to present a new evaluation method for studying the 3-D accuracy of the realized implant position relative to the proposed position without performing additional postoperative CBCT. The clinically resulting implant position after using an online implant planning software (Swissmeda online implant planning [SMOP], Swissmeda, Zürich, Switzerland) will be evaluated.

MATERIALS AND METHODS

In this retrospective study, the implant positions of 24 patients from the first-named author's practice were evaluated. Consecutive cases were considered for inclusion if 3-D implant planning and template-guided implant placement were performed between February 2012 and June 2013. Twelve cases with a distal edentulous situation (DES) and 12 cases with either a single tooth gap (STG) or an edentulous space were included and evaluated (Table I).

One criterion required for inclusion in this study was that in the patients with STG, the drilling template had to have tooth-supported rests mesial and distal to the edentulous space. In the patients with DES, a contact area on the gingiva of the alveolar ridge had to be present distal to the implant position. Only implants for which the drilling protocol required no exchange of inner sleeves were examined (Camlog Biotechnologies, Basel, Switzerland).

All cases with documentation that showed that the final position of the implant had been corrected after removing the template were excluded.

Patient-related inclusion criteria were a minimum age of 18 years and written consent to the treatment provided. Exclusion criteria for implant placement were a poor overall health status; uncontrolled diabetes; drug, nicotine, or alcohol abuse; a history of radiation therapy in the relevant area; or serious mental disorders.

One implant per patient was evaluated. If several implants were present, the one located farthest anteriorly with respect to the remaining dentition was examined. The patient group comprised 15 female and 9 male patients with a mean age of 52.2 years (range 34−76 years).

Institutional approval was granted by the local Ethics Committee at the University of Ulm (No. 339/14, dated April 12, 2014).

Implant planning, surgical procedures, and prosthetic treatment were all performed by the same surgeon (SiS), who is a specialist in oral implantology and an experienced implant prosthodontist.

Planning process

To plan the implant positions, a CBCT scan (CB500; Gendex Dental Systems, Des Plaines, IL) was taken. The thickness of the layer was set to 0.2 voxels. The CBCT scan was taken without a reference template. While scanning, care was taken to ensure that the maxilla and the mandible were kept well apart to avoid overlaps.

At the time of taking the CBCT scan, impressions of both jaws were taken with alginate. Plaster casts made from a special digitizable dental stone (HS-CAD/CAM plaster, type 4; Henry Schein, Melville, NY) were poured, and the prosthetically driven set-up was performed, focusing on the prosthodontic needs rather than on the surgical or anatomic aspects. As a matter of course, the latter cannot be entirely ignored.

The intraoral situation at the time of the CBCT scanning and the prosthetic planning using prefabricated denture teeth (set-up) were optically digitized (3 Shape D700; 3 Shape, Copenhagen, Denmark). The matching procedure was performed in a semi-automated process (SMOP 2.6; Swissmeda, Zürich, Switzerland). The final positioning was carried out manually, using the tooth structures for orientation, by the first author (SiS).

The implants were planned in three dimensions, and a drilling template was designed (by SMOP; Swissmeda, Zürich, Switzerland). The drilling templates with rests on the residual dentition was produced by 3-D printing (SMOP; Swissmeda, Zürich, Switzerland).

Surgical protocol

In cases where no augmentation was planned and where the width of the attached gingiva was sufficient, the implant bed was prepared in a minimally invasive procedure after removing the gingiva by punching. In other cases, the bone was exposed with a more orally placed incision, followed by further bone preparation. The height of the guiding sleeves was 4 mm; the distance from the lower margin of the sleeve and the coronal end of the implant was 3.5 mm. Whenever thick gingiva (>3.5 mm) was detected during planning, the flap preparation technique had to be used. The guiding sleeves of the Camlog Guide system (Camlog Biotechnologies, Basel, Switzerland) were inserted into the template at the dental practice and connected with the use of an adhesive (Sekundenkleber No. 1733; Renfert, Hilzingen, Germany). The cleaned and disinfected (Chlorhexamed forte 0.2%; GlaxoSmithKline Consumer Healthcare, Bühl, Deutschland) drilling template was placed in the mouth and checked for proper seating. The protocol used was that of the Camlog Guide surgery system (Camlog Biotechnologies AG, Basel, Switzerland): First, an internally irrigated Camlog Guide predrill was used. The definitive shaping was performed

Fig. 1. Implant impression with custom tray and screwed in implant analogs. Between the impression post and the implant analog, there is a nonreflective bit of parchment paper to mark the transition.

with ascending drill lengths (9, 11, or, if necessary, 13 mm). The implant was inserted by hand through the guiding sleeve of the drilling template into the implant bed. The implant was then tightened in place with the torque wrench. The final vertical position was reached when the implant shoulders made contact with the top of the guiding sleeve.

In cases with gingival punching, a healing cap was used. When preparing a flap, the wound margins were closed tightly with an appropriate suture material (Resolon 5-0; Resorba Medical, Nürnberg, Germany).

The implants were left to osseointegrate for 1.5 to 3 months, depending on their primary stability and on the anatomic situation. After re-entry and soft tissue healing, an open-tray impression of the implant was taken in polyether (Permadyne; 3 M ESPE, Neuss, Germany) and a custom tray.

Matching proposed and realized implant positions

The planned 3-D implant position and the model situation were exported from the planning program (SMOP; Swissmeda, Zürich, Switzerland) as stereolithography data (proposed implant position [IP]). The realized implant position (implant position realized [IR]) was determined at the time of taking the impression for the restorative superstructure. To this end, implant analogs were inserted into the impression posts (Figure 1), whereupon the situation was digitized (3 shape D 700). Case numbers were assigned to the data sets, which were then anonymously forwarded for further processing and evaluation. The evaluation was carried out in a different location by an investigator (CE) different from the one who had acquired the data.

The IP and IR data were superimposed, based on the data of the overall dentition (Geomagic Studio 9;
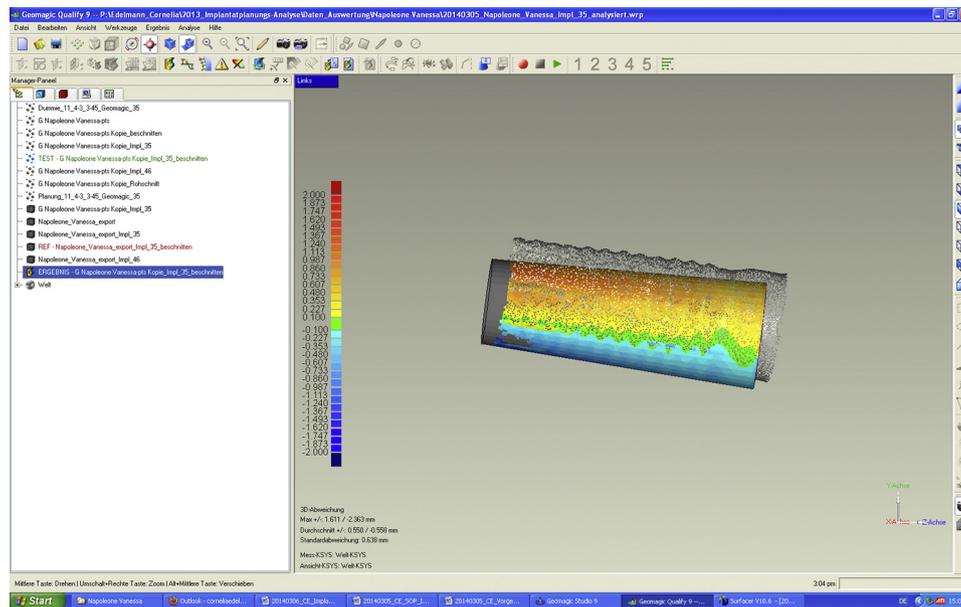
Fig. 2. Once an outer wall of the clinical implant position impinged on the center of the proposed implant, no three-dimensional comparison was possible. This could be verified by way of the proposed axis and the point cloud of the clinical implant position.
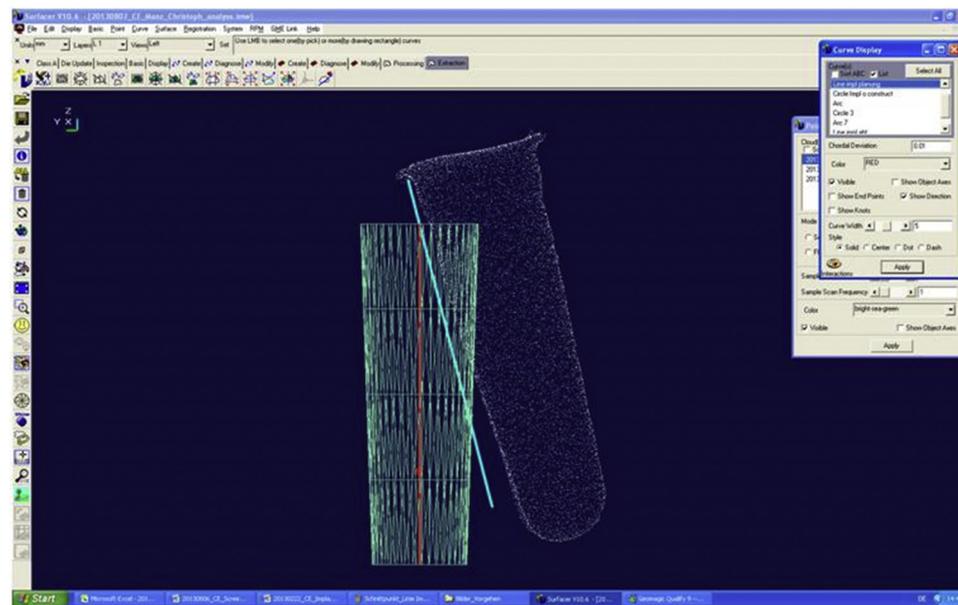
Fig. 3. The angle and distance (cervical and apical) between the proposed and realized implant positions were calculated (Surfacer).

Geomagic, Research Triangle Park, NC). For this purpose, the digital impression data (IR) were converted from surface data to point cloud data, which was trimmed to the point that a mapping of IP and IR could be performed by way of teeth and the adjacent gingival margins.

The angular deviation of the implant axes (α), the deviation at the implant neck (d_1), and the deviation at the implant apex (d_2) were measured in all cases. In addition, if the IP and IR data were in good agreement, a 3-D comparison was made by using data analysis software (Geomagic Qualify 9, Geomagic, Research Triangle Park, NC). No 3-D comparison was made if an outer wall of the clinical implant position impinged on the center of the proposed implant (Figure 2), since the software was unable to differentiate between corresponding and opposing implant walls.
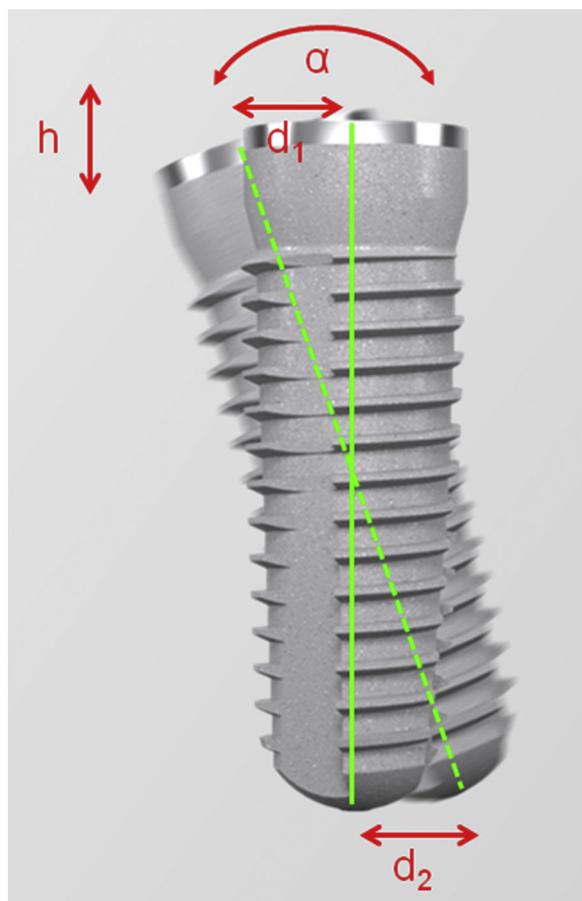
Fig. 4. Calculated deviations: Height (h), d_1 (implant neck) and d_2 (implant apex) in millimeters, and angle (α) between implant axes [°].

Colored segments indicated the deviations between IP and IR visually and quantitatively. The distances and angles between the IP and IR implant axes were calculated for all cases (Surfacer 10.6; Imageware, Ann Arbor, MI) (Figure 3).

Target parameters were the linear deviations and the angular deviations (Figure 4):

- *Radial deviation:* The horizontal deviation between the center axis of the IP and IR implant positions as measured at the implant shoulder (d_1) and at the apex of the implant (d_2).
- *Height deviation:* The vertical deviation in implant axis alignment as measured at the implant shoulder (h) at the center of the coronal implant surface.
- *Axial deviation:* The deviation of the planned implant axis from the axis actually realized (α).

Statistical analysis

The measurement data were analyzed statistically (SPSS version 21; SPSS Inc., Chicago, IL). The level of significance was set at $\alpha < 0.05$.

RESULTS

The 3-D accuracy of IR compared with IP was measured in all 24 patients.

In the DES group, the mean angular deviation of the implant axes (α) was 5° (95% confidence interval [CI]: 3.0−7.0). In the STG group, α was 4° (95% CI: 3.0−5.0). The mean deviation at the implant neck (d_1) was 1.0 mm (95% CI: 0.7−1.3) for DES and 0.9 mm (95% CI: 0.6−1.2) for STG. The mean deviation at the implant apex (d_2) was 1.6 mm (95% CI: 1.1−2.0) for DES and 1.5 mm (95% CI: 1.0−1.9) for STG (Table II).

No significant differences ($P > .05$) were found between the DES and STG groups.

The mean values for all measured parameters showed no statistically significant differences; however, the scatter was considerably higher in the DES group reported compared with that in the STG group (Figures 5 and 6).

DISCUSSION

To exclude confounders from this retrospective study, only those cases that were made with the same implant system and drilling sequence were chosen for the evaluation. As the implant system used (Camlog Guide; Camlog Biotechnologies AG, Basel, Switzerland) does not include inner sleeves, an exchange of inner sleeves was one of the exclusion criteria. Furthermore, based on the documentation, all cases with deviating position in height (apical−coronal direction), resulting from lack of primary stability after insertion through the template or because of unusually hard bone quality, were excluded.

The benefits of template-guided implant placement in terms of accuracy cannot be quantified in a single-arm study. One aspect to be taken into account is that there is no gold standard for either 3-D implant planning or for the analysis of the actually realized implant position.

Implant planning, in the procedure examined, requires the manual superimposition of CBCT data on the one hand and the digital data for the baseline model and the wax-up on the other. This superposition is done without radiographic reference markers and is based solely on the anatomic structures. The superimposition can be prone to error and inaccurate and requires separate investigation. The accuracy of the superimposition is also influenced by the accuracy of the CBCT data,[11,12] the selected voxel size, artefacts of the dense (metal) structures in the postoperative CBCT scan, or motion artefacts.[13]

An advantage of this method might be that inadequacies of fit or an unnoticed lifting of the radiographic stent off the residual dentition during the CBCT

Table II. Results for 24 patients (12 in each group)

Group		Height h [mm]	Angulation α [°]	Deviation at implant neck d_1 [mm]	Deviation at implant apex d_2 [mm]
DES	Mean	0.5	5.0	1.0	1.6
	SD	0.7	3.1	0.5	0.7
	95% CI	0.0−1.0	3.0−6.9	0.7−1.3	1.1−2.0
STG	Mean	0.5	4.0	0.9	1.5
	SD	0.6	1.5	0.5	0.7
	95% CI	0.1−0.9	3.1−5.0	0.6−1.2	1.0−1.9

DES, distal extension situation; *SD*, standard deviation; *CI*, Confidence interval; *STG*, single tooth gap.
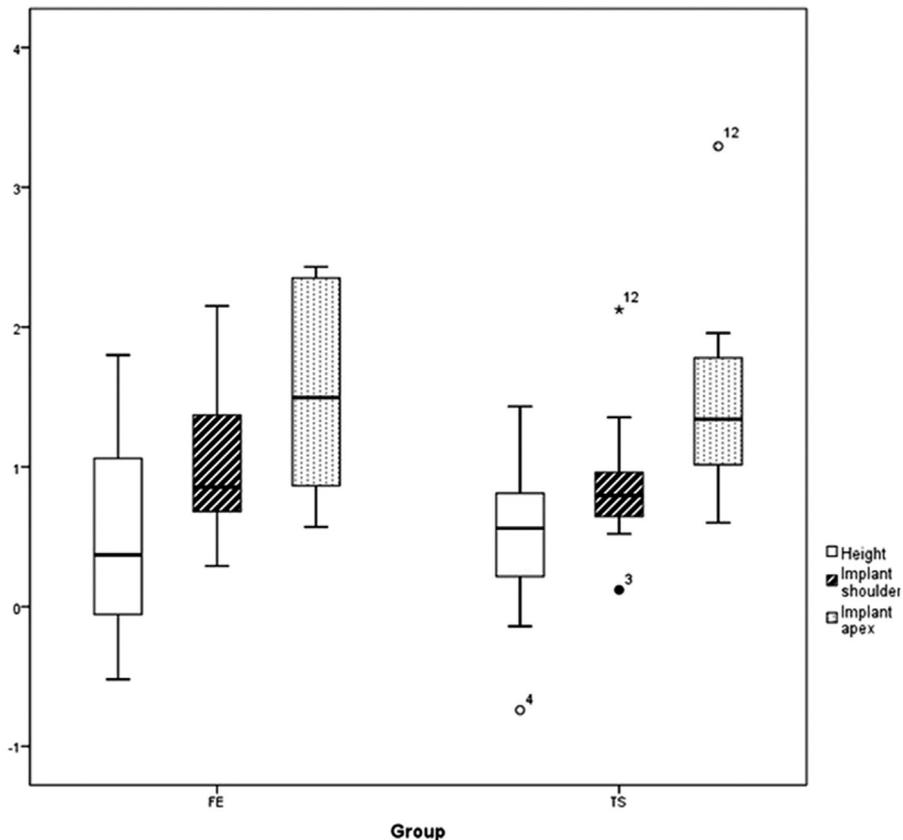
Fig. 5. Box plots of the mean deviations in height and horizontal deviations (mm) at the implant shoulder and implant apex in the distal extension situation (DES) and single-tooth gap (STG) groups.

scan has no influence on the transfer of the proposed position to the drilling and insertion template.

For the evaluation, the IP, including the data set of the plaster cast are superimposed on the data of an impression of the IR. The transfer of the implant position by means of an impression can be considered sufficiently accurate.[14] Deviations of 0.6°, on average, in axial inclination have been described and therefore should be assigned no clinical relevance.[15]

Since the superimposition is not based on CBCT scans with their low resolution of 0.2 voxels and possible artefacts, the method described can be said to exhibit greater precision. Casts based on alginate impressions are used for planning; here, a margin of error of about ±130 μm has been reported.[16] For the determination of the IR, polyether impressions with error margin of about ±20 μm are used.[17] The superposition of models or casts can be performed with a high degree of accuracy.[18,19] Based on the individual tooth, the precision of a directly digitized impression is comparable with the precision of digitizing after taking the impression and pouring the plaster cast.[20]

The most widely used method for determining the 3-D accuracy of the actual realization of proposed implant positions is by superimposition of preoperative and postoperative CBCT data. Because of radiation exposure, the usefulness of this method is limited in cases
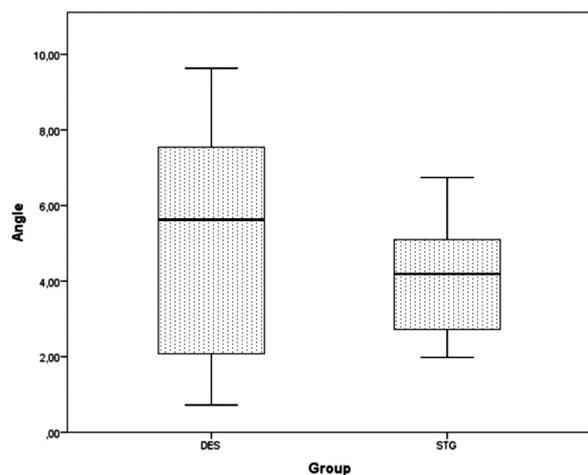
Fig. 6. Box plots of the mean deviations in angle (°) between the proposed and realized implant positions in the distal extension situation (DES) and single-tooth gap (STG) groups.

where there is no appropriate indication for postoperative CBCT. Beyond the aspect of limiting radiation loads, the accuracy of the superimposition is influenced by the accuracy of the CBCT data,[11,12] voxel size, artefacts of the dense metal implants on the postoperative CBCT scan, or motion artefacts.[13] The fact that there no additional study-related interventions are required but only information from the clinical prosthetic treatment workflow is used makes this method suitable for follow-up of larger groups of patients. An alternative method is based on CBCT images of master casts with implant analogs.[10] No second CBCT scan is required, although the limitations due to voxel size remain.

The transfer of the IP to the printed template was also prone to 3-D deviations. These were found to be on average 0.2 mm, as measured at the center of the top edge of the guiding sleeve, and 1.5° in terms of inclination.[21]

The data of the present study are comparable with data from other clinical studies.[22-26] In a recent meta-analysis evaluating 19 publications, the mean error was given as 0.99 mm (range 0.01−6.5) at the implant shoulder and as 1.24 mm (range 0.0−6.9) at the apex. The mean angular deviation was 3.81° (range 0.04−24.9).[27]

In our study, there was no differentiation by flapless/open-access surgery because of the small number of cases. This procedural parameter exhibited no significant difference in implant angulation in another study (flapless, 4.7° ± 2°; open-access: 5° ± 2.6°).[28]

Similarly, there was no differentiation between jaws because of the small sample size. In this regard, results are contradictory. The 2012 meta-analysis did not show any significant differences between the maxillary and mandibular implants.[27] In contrast, other studies reported that a greater, statistically significant difference was found in the mandible,[27] that a lesser, but still statistically significant, difference was also found in the mandible,[25,29] or that no difference was found at all.[30]

The template used in the method implemented also seems to have an influence on the accuracy of template-guided implantations. However, there are few clinical studies that highlight the differences between methods. In evaluating drilling templates, a distinction must be made between manufacturing processes (laboratory-made, milled, stereolithographically produced),[21,31] the method of fixation in the jaw (tooth-supported, mucosa-supported, bone-supported, secured with a pin),[29] and the implemented surgical protocol. For example, two studies have shown significantly more inaccurate implant positions with tooth-supported surgical templates than with mucosa-supported surgical templates.[23,24] However, these results could not be confirmed in a further study,[32] where the implant positions determined by a tooth-supported stereolithographic template exhibited higher accuracy. To eliminate this source of error as far as possible, only the implant that was located farthest anteriorly relative to the residual dentition was included in our evaluation. This restriction was introduced to keep the distance between the distal-most tooth rest of the surgical template and the implant region sufficiently constant and to eliminate the influence of possible extraneous factors.

In addition, the tolerance of the drills within the guiding sleeves is dependent on the system.[33] Maximum horizontal deviations of 1.3 mm at the implant shoulder and 2.4 mm at the implant apex, as well as angular deviations of 5.2°, were observed with a 13-mm long implant.[34]

CONCLUSIONS

Within the limitations of this retrospective study with its small number of patients, the results show sufficiently high accuracy when using the innovative evaluation procedure. The digitizing of master models requires very little extra time (minutes). The evaluation method employed is suitable for the assessment of larger cohorts, thanks to its noninvasive approach. This is of special importance because, for reasons of radiation hygiene, national legislation prohibits the use of radiation without a clear clinical indication.

The evaluation method can be applied to prospective studies to assess the agreement between planned and clinically resulting implant position. The results showed sufficiently high accuracy when using the SMOP procedure.

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