Accuracy of Virtually Planned and Template Guided Implant Surgery on Edentate Patients

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ABSTRACT

Purpose: Scientific evidence regarding the accuracy of implants placed into patients by the aid of a surgical template is limited. The objective of the present study was to verify if any variation exists between virtually planned implants' position using a computer, compared with the subsequently clinically placed implants with the aid of a surgical template in the mandible and the maxilla.

Material and Methods: A total number of 25 edentate jaws were treated with the aid of a surgical template. In total, 139 implants were inserted. Fifty implants were inserted in the mandible and 89 in the maxilla. A voxel-based registration method was used to match two separate cone-beam computed tomography scans of the patients. The implant positions were calculated and compared between the planned implants and the implants' clinical position after more than 1 year after surgery. The results included the linear differences in distance at the level of the hex, the apex, and the depth. The angular differences were presented in degrees.

Results: Statistical results indicated some factors with significant deviations. The greatest errors were found when comparing between patients moving during the computed tomography scans and those that did not move. The results showed significant divergence at the level of the hex and apex of the implants.

Conclusion: The hypothesis was rejected, as the statistical results indicated that there were significant differences between virtually planned implants' position and the final position of implants placed clinically.

KEY WORDS: accuracy, CAD/CAM, CBCT, dental implant, guided-surgery, stereolithography, surgical template

INTRODUCTION

Today, the installation of implants is a routine method in the rehabilitation of partially dentate as well as edentate jaws. Successful results have been shown in a number of studies at the long-term follow-up.[1–5] Nobel Guide™ (Nobel Biocare AB, Gothenburg, Sweden) is one of the new approaches for dental implant treatment, including a pretreatment planning procedure based on high-resolution three-dimensional computed tomography (CT) scan images.[6–10] The combination of a digital three-dimensional planning system and a customized drilling template allows for implant placement using flapless surgery. The treatment concept includes a three-dimensional planning program based on CT scan images. The radiographic protocol is based on a two-step procedure. The bone and prosthesis are scanned separately and are later matched together using specific software by the aid of spherical markers. The radiographic guide includes a prosthesis function, with a tooth setup and a surface that fits the soft tissue of the patient, thus making it possible to visualize the jaws anatomy, and pre-plan implant positions and prosthetic considerations. The combination of the CT-based treatment planning and a computer-aided design/

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computer-aided manufacturing (CAD/CAM) surgical template allows the clinician to plan the treatment outcome in advance. The surgical template has guided sleeves that are positioned according to the treatment plan to direct the surgical positioning of the drills and the implants.

Limited scientific evidence is available that compares the position of the postoperative implants to the preoperative planning on patients with the voxel-based matching technique.[11] To date, only a few accuracy studies have been presented using the NobelGuide system, albeit on human cadavers only.[12,18] Other types of matching techniques have been used for accuracy studies, with other implant-guiding systems performed on humans.[14–17] Therefore, more knowledge is needed on the differences between preoperative implant planning compared with postoperative results. Considering the angle between the long axis, as well as the distance between the center of the apex and hex level of the implants in the X, Y, and Z directions will be of great value. Results from such studies would be beneficial for clinicians to improve their knowledge and to avoid harming anatomically important structures, to closely interfere between implants, or to risk misfit of a prefabricated bridge for example.

The objective of the present study was to verify the position of virtually planned implants compared with implants placed with a surgical template in edentate patients. The main hypothesis was that there were no significant statistical differences between virtually planned implants and implants' position after surgery.

MATERIAL AND METHODS

Subjects

Between September 2003 and May 2007, 30 patients (10 females, 20 males) with an edentulous maxilla, mandible, or both were treated with Nobel Guide. A total number of 191 Brånemark System® MkIII TiUnite RP (Regular Platform) implants (Nobel Biocare AB) were inserted into a total of 34 edentulous jaws (maxilla: 21, mandible: 13).

Of the 34 edentulous jaws (number of jaws = number of cases), nine were excluded in this analysis because of various reasons, including fixture loss (4 cases), poor health conditions excluding postoperative scanning (3 cases), and withdrawal from study by patients (2 cases) to the follow-up. In 25 jaws (maxilla: 15, mandible: 10), the implant-supported suprastructure was removed after a minimum of 1 year (mean: 18 months) of functional loading and a follow-up scan was made. In total, 139 implants were included in the follow-up, 89 in the maxilla and 50 in the mandible. Mean age of the subjects at the time of re-scanning was 72.1 years old (range: 44–92 years).

Sixty-three implants in 11 cases were inserted using prelaunch components and an acrylic surgical template. The prelaunch surgical products utilized a special implant guide, which was inserted in the sleeve of the surgical template. The acrylic surgical template was produced by a dental technician during prelaunch period. The remaining 76 implants in 14 cases were placed using a CAD/CAM-based rapid prototype manufactured surgical template, after the launch of the Nobel Guide. The launched components used an implant mount including guiding capabilities, which guided the implant through the sleeve.

All the patients were treated by one surgeon and were monitored at the Department of Dental Medicine, Division of Periodontology, Karolinska Institutet, Huddinge, Sweden. The patients underwent follow-up examinations at 1 day, 1 week, 1, 3, 6, and 12 months after implant insertion and delivery of the suprastructure. The study was approved by the Ethics Committee at the Karolinska University Hospital, Huddinge, Sweden (Dnr: 278/03), and the Swedish Radiation Safety Authority. All the patients were informed of the study protocol and signed an informed consent form.

Methods

Presurgical Treatment. Before treatment, the patients underwent clinical and radiographic examinations. The patient's denture was assessed regarding occlusion, teeth alignment, and fitting to the mucosa. The denture or replica was made in acrylic resin with non radio-opaque properties such as Meliodent (Heraeus Kulzer GmbH, Hanau, Germany).

At least six spherical gutta-percha markers (diameter of 1–1.5 mm and depth of 0.5 mm) were placed into the optimized radiographic guide as reference points. The markers were distributed both in the buccal and lingual or palatal sites, and at different levels related to the occlusal plane so that the markers did not overlap each other when the CT data of the radiographic guide was matched to the corresponding markers of the patient in software. A radiographic index (Silagum®-

Bite; DMG, Hamburg, Germany) was created by the clinician in the patient's mouth, in order to register the correct occlusion.

CT Scan and Surgical Planning. After the radiographic guide was produced, all the patients were referred to the Division of Image and Functional Odontology for a CT scan using a cone-beam CT (CBCT; NewTom QR-DVT 9000; QR s.r.l., Verona, Italy). The protocol was followed using generic instructions for CBCT scanners in the Procera® Software (Nobel Biocare AB). The scan settings used were between 4 and 6 mAs and 110 KV with 0.3 mm in voxel size. The reconstructed slice thickness was 0.3 mm. The data of the axial reconstructed slices were exported in Digital Imaging and Communications in Medicine (DICOM) file format to a CD.

The patient was scanned with the radiographic guide and the radiographic index in the first scan. The radiographic guide was scanned separately in the second scan. After the CT scans of the patient and radiographic guide were complete, the resulting DICOM data were transferred into the Procera software (Procera software version 1.5 build 75; Nobel Biocare AB), and converted into three-dimensional reconstructions. The CT scan of the radiographic guide was matched to the CT scan of the patient by the help of radio-opaque markers.

The clinician specified the locations of the implants, sleeves and the anchor pins, and ordered a surgical template along with components needed for surgery in the Procera software.

When completed, the planning data were sent to production (Nobel Biocare AB), where an individually customized surgical template was manufactured. The bridge was ordered and finished by a dental technician prior to the surgery. A surgical index was made by the dental technician that recorded the relationship between the surgical template and the opposing dentition (Silagum®-Putty; DMG, Hamburg, Germany).

Surgery and Prosthesis Connection. All implants were inserted by means of the surgical template for flapless surgery according to the protocol of NobelGuide (Nobel Biocare AB). The patient was instructed to bite on the surgical index with a similar pressure to that used during the preoperative CT scan to stabilize the template in a corresponding position to the radiographic guide during the first CT scan. Each surgical template contained guide sleeves. A diameter of 1.5 mm drill (Guided Twist Drill 1.5 mm; Nobel Biocare AB) was used to drill to a predefined stop and anchorpins (Guided Anchor Pin 1.5 mm; Nobel Biocare AB) were positioned in the sleeves. The surgical index was then removed. A counterbore (Guided Start Drill/Counterbore; Nobel Biocare AB) was used to remove any soft tissue and bone according to the planned position. The drilling protocol for the implant placement included twist drills with diameters of 2.0, 2.8, 3.0, and 3.2 mm (Guided Twist Drill; Nobel Biocare AB). The first implant was then inserted with an implant mount (Guided Implant Mount; Nobel Biocare AB) using guiding capabilities, when engaging the sleeve in the surgical template. Once the first implant was inserted in position, a template abutment (Guided Template Abutment; Nobel Biocare AB) was attached to the platform of the implant to further secure the sleeve of the surgical template. Subsequently, a second implant was inserted and a template abutment was fixed with the same procedure. All remaining implants were then inserted in sequence. On some occasions, a screw tap was used, depending on bone quality and clinical judgment. A prefabricated prosthesis, including specially designed expandable abutments, was connected onto the implants immediately after implant placement in all cases but one. Detail of the treatment procedure has been described previously.[9]

Postoperative CT Scan. One year or more after surgery, the patients were re-CT scanned. The suprastructure including abutments were removed prior to the CT scan to avoid artifacts from metal. Plastic impression copings were temporarily attached to the individual implant to prevent collapse of the peri-implant soft tissue (Figure 1). The impression copings were specially designed for this study and produced of plastic material in order to minimize the artifact at the CT scanning. The patients were CT scanned using the same cone beam CT-equipment, with the same settings, as for the preoperative CT scan.

Matching

The preoperative CT scan was matched with the postoperative CT scan using a three-dimensional voxel-based registration, previously described.[11] The postoperative data were registered to the preoperative data with the help of calculation of mutual information between the corresponding voxels in the two datasets and into one coordinate system. The voxel-based

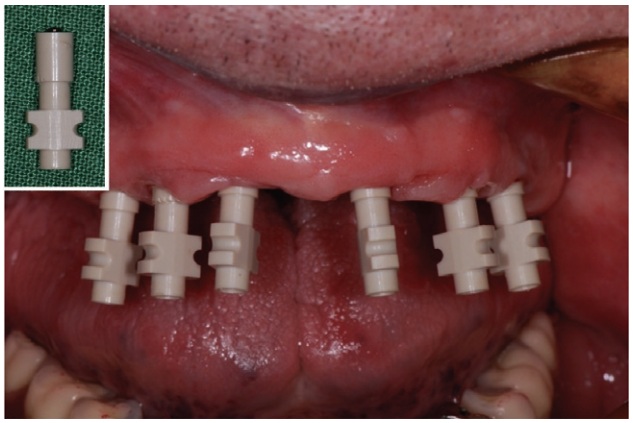

Figure 1 Plastic impression copings were attached to the individual implants to prevent collapse of the peri-implant soft tissue without yielding artifact during the re-computed tomography scan.

matching software searched for corresponding grey values in the two data sets and aligned them together. The implants from the postoperative scan were segmented from the data set and the position and orientation of the clinically placed implants were compared with the virtually planned implants' position in coordinate system obtained from the voxel-based matching.

Linear and angular deviations between the actually placed and virtually planned implants position were analyzed in 3D. The Euclidean distance between the actually placed and virtually planned implant position was measured at the center of the apex and center of the hex of the implant. The angular discrepancy between the main axes of the actually placed and virtually planned implant position was calculated. The results were expressed as the distance between the apex, the hex, the depth difference, and the angular deviations between the implants placed after surgery compared with the virtually planned implants with measurements calculated in three-dimension by software (Nobel Guide Validation 2.0.0.4) (Figure 2).

Statistics

All analyses were done in STATISTICA 7.0 (Statsoft Inc., Tulsa, OK, USA). The data variation was not normally distributed; therefore, in order to attain approximately normally distributed data, the outcome variables apex, hex and angle, except depth, were e-log transformed. In these three variables (apex, hex, and angle), mean deviation at implant level was presented as the geometric mean while mean of depth deviation was presented as arithmetic mean. Subsequently, parametric tests were used. Statistical analyses were performed using the *t*-test for the positional difference between virtually planned

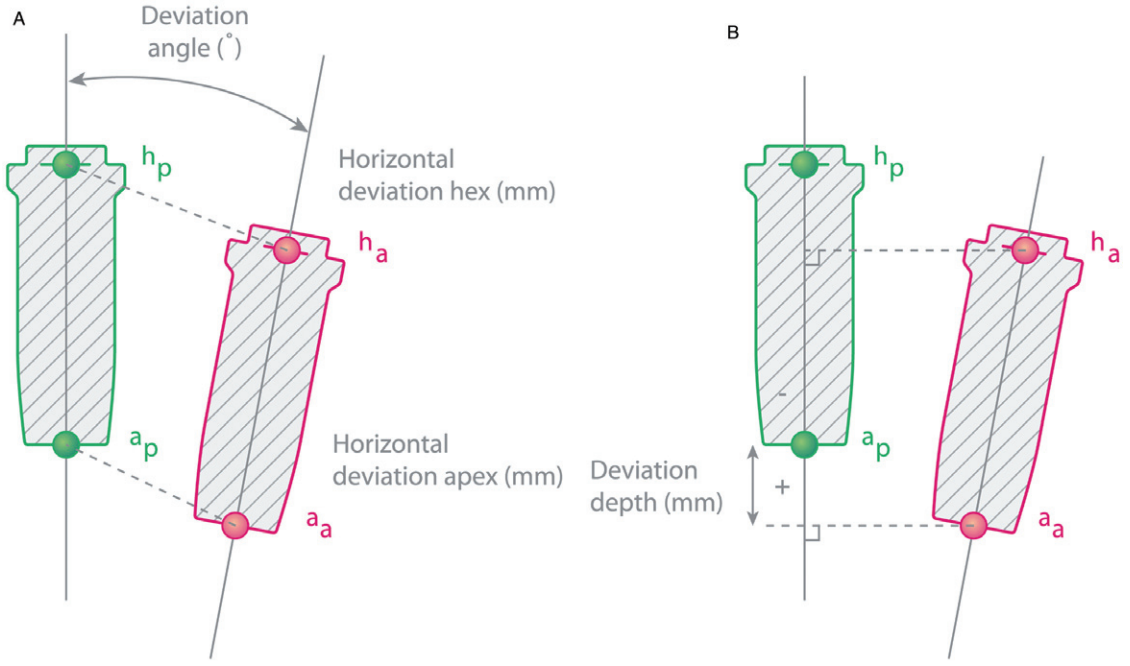

Figure 2 *A*, Illustrating the measurement deviation calculation at the level of the hex, apex, and angular deviation. *B*, Represents the measurement deviation calculation of the depth between the virtually planned implant and implant placed after surgery (aa = apex actual; ap = apex planned, ha = hex actual; hp = hex planned).

implants and inserted implants in the following outcome variables: apex, hex, angle, and depth. The analysis of variance (ANOVA) was used when fixed factors, such as mandible and maxilla, prelaunch and launched components, and movement of the jaw in the preoperative and postoperative CT scans, were included. All tests were two sided and $p < .05$ was considered as statistically significant. All data were presented using descriptive statistics, for example, number of observations, mean, standard deviation (SD), median, minimum, and maximum. The outcome variables that were e-log transformed and further analyzed using the ANOVA model were presented with the corresponding 95% confidence interval (95% CI). The estimates of the mean and the 95% CI were back transformed.

RESULTS

A summary of the deviation in each case is presented in Table 1. Mean differences between planned and inserted implants were significantly different in all four outcome variables: depth, apex, hex, and angle ($p < .05$). Box plots of deviation in apex, hex, angle, and depth are shown in Figure 3. Mean value for apex was 1.09 mm (range: 0.24–3.62), and corresponding 95% CI of 1.001; 1.18. Mean value for hex was 0.80 mm (range: 0.10–2.68), 95% CI of 0.72; 0.89, for angle 2.26 degrees (range: 0.24–11.74), 95% CI of 2.01; 2.53 and for depth −0.15 mm (range:−2.33–2.05) (SD = 0.76) with 95% CI of −0.27; −0.02, respectively. In the maxilla, mean value for apex was 1.05 mm (range: 0.25–2.63), 0.80 mm (range: 0.10–2.68) for hex, 2.31 degrees (range: 0.24–6.96) for angle, and −0.06 mm (range:−1.65–2.05) for depth. Mean value in the mandible was 1.15 mm (range: 0.24–3.62) for apex, 0.80 mm (range: 0.16–2.45) for hex, 2.16 degrees (range: 0.27–11.74) for angle, and −0.29 mm (range: −2.33–0.94) for depth.

Differences were observed between the virtually planned and the inserted implants in both the maxilla and mandible. However, when all four variables were taken into consideration, no statistically significant difference was observed when comparing the results from the maxilla and mandible, despite the deviation being slightly larger in the maxilla than in the mandible for angulation.

During the matching procedure, it was apparent that in some cases the segmented implants from the 1-year follow-up CT scan were not cylindrical in shape as the original implant shape (Figure 4). This could be attributed to movement by the patients during their CT scans. One radiologist reviewed all the CT images obtained from the patients' preoperative and postoperative scan. Double contours, implying that the patient had moved during the scans, were found from both the preoperative and postoperative CT data (Figure 5). Although, the "movement" factor was not originally considered as a variable for inclusion, additional calculations were incorporated to include this factor for exploratory analyses. The numbers of the implants classified as "movement" are presented in Table 2.

The mean e-log apex and mean e-log hex results showed statistically significant differences between the presence and absence of movement during the pre- and postoperative CT scans (Figure 6). In addition, differences in the mean e-log angle between the presence and absence of movement during postoperative CT scans were also statistically detected. However, no differences in depth were statistically demonstrated.

If the "movement" factor was included in the analysis, the angular deviation indicated a difference between the maxilla and the mandible of 3.1 degrees in the maxilla and 2.4 degrees in the mandible, albeit, no statistically significant differences were observed between the maxilla and the mandible, on any other occasion.

Deviation of implants without any movement (90 implants in 16 patients) and implants with movement at both during the preoperative and the postoperative CT scan (15 implants in 3 patients) is presented in Table 3.

Significant differences were observed in the mean depth when comparing pre- and postlaunched components. Implants inserted using prelaunch components were 0.25 mm deeper than those inserted using postlaunched components.

DISCUSSION

Implant surgery using a CAD/CAM surgical template is a relatively recent concept designed to facilitate the placement of implants. Such a system enables clinicians to address considerations, such as the final position of the implants prior to the surgery and the prosthetic work. In addition, it also allows for several clinicians to collaborate at the planning stage and combine their knowledge in advance of the final surgical placement of the implants for the most optimal position. However, as this is a fairly new concept, it is important to understand more about the technique and the final positioning of implants placed by the aid of a surgical template. An

TABLE 1 Summary of Deviations in Each Case

		Deviation Apex					Deviation Hex					Deviation Angle					Deviation Depth				
Patients	No.	Mean	Median	SD	Min	Max	Mean	Median	SD	Min	Max	Mean	Median	SD	Min	Max	Mean	Median	SD	Min*	Max*
1(MAX)	6	0.93	0.88	0.24	0.67	1.31	0.51	0.52	0.25	0.13	0.84	2.86	3.33	1.55	0.79	4.59	0.13	0.19	0.42	0.03	0.61
2(MAX)	6	1.03	1.10	0.44	0.45	1.47	1.02	1.05	0.45	0.45	1.51	2.42	2.66	1.31	0.84	3.71	0.41	0.34	0.51	0.07	1.07
3(MAX)	6	0.84	0.76	0.19	0.65	1.11	0.79	0.89	0.39	0.10	1.11	3.31	3.13	0.93	2.18	4.70	0.44	0.54	0.31	0.01	0.76
4(MAX)	6	1.01	1.01	0.33	0.57	1.53	0.86	0.80	0.28	0.58	1.36	1.63	1.78	0.61	0.59	2.39	−0.78	−0.69	0.30	0.51	1.27
5(MAX)	6	0.96	0.60	0.73	0.47	2.34	0.83	0.89	0.33	0.22	1.18	3.08	2.87	1.71	1.33	5.46	−0.07	−0.10	0.23	0.08	0.37
6(MAX)	5	1.94	1.81	0.42	1.52	2.63	1.63	1.63	0.22	1.42	1.98	3.07	2.71	2.23	1.14	6.82	−1.08	−0.95	0.46	0.54	1.65
7(MAX)	6	2.14	2.08	0.30	1.84	2.55	2.21	2.31	0.46	1.49	2.68	4.83	4.99	1.43	2.71	6.96	1.39	1.59	0.70	0.23	2.05
8(MAX)	6	1.43	1.51	0.43	0.81	2.05	1.07	1.11	0.25	0.71	1.36	2.15	2.12	1.53	0.24	4.12	0.23	0.30	0.27	0.05	0.50
9(MAX)	6	1.27	1.24	0.36	0.83	1.90	1.05	0.97	0.39	0.64	1.79	2.82	2.81	0.95	1.68	4.42	−0.86	−0.75	0.41	0.49	1.63
10(MAX)	6	0.94	0.84	0.31	0.71	1.55	0.50	0.50	0.10	0.40	0.66	2.30	2.06	0.79	1.52	3.63	−0.05	−0.16	0.28	0.07	0.45
11(MAX)	6	1.17	1.11	0.36	0.73	1.74	1.12	1.04	0.30	0.84	1.60	2.17	2.09	1.05	1.00	3.92	−0.45	−0.38	0.49	0.22	1.07
12(MAX)	6	0.94	0.91	0.48	0.25	1.64	0.50	0.47	0.24	0.20	0.88	2.88	2.97	1.94	0.57	5.52	−0.16	−0.07	0.42	0.05	0.87
13(MAX)	6	0.89	0.93	0.36	0.45	1.30	0.91	0.90	0.16	0.74	1.15	2.49	2.65	0.90	1.42	3.61	−0.54	−0.45	0.38	0.19	1.15
14(MAX)	6	0.91	0.96	0.20	0.66	1.14	0.47	0.43	0.10	0.36	0.64	1.93	1.80	0.64	1.28	2.84	−0.05	−0.02	0.26	0.07	0.38
15(MAX)	6	1.10	1.09	0.26	0.82	1.45	0.83	0.97	0.33	0.28	1.17	2.81	3.19	1.24	0.62	4.15	0.33	0.45	0.39	0.15	0.71
16(MAN)	5	0.96	0.95	0.23	0.66	1.22	1.04	1.07	0.16	0.87	1.21	1.37	1.41	0.41	0.80	1.94	0.49	0.49	0.25	0.27	0.90
17(MAN)	5	0.60	0.50	0.20	0.44	0.93	0.38	0.34	0.09	0.31	0.53	1.54	1.23	0.84	0.86	2.84	−0.24	−0.32	0.19	0.02	0.46
18(MAN)	5	1.47	1.41	0.63	0.82	2.43	0.90	0.64	0.72	0.16	1.93	3.83	3.81	0.91	2.98	5.27	0.16	0.03	0.60	0.03	0.94
19(MAN)	5	1.35	1.24	0.42	0.85	1.80	0.99	1.04	0.18	0.69	1.19	2.57	2.30	0.96	1.71	3.98	0.04	0.06	0.43	0.03	0.67
20(MAN)	5	1.22	1.39	0.50	0.54	1.72	0.72	0.70	0.30	0.31	1.16	2.73	2.96	1.27	0.96	4.32	−0.21	−0.20	0.58	0.08	1.09
21(MAN)	5	0.94	1.03	0.41	0.24	1.28	0.38	0.45	0.14	0.20	0.54	2.34	2.78	1.20	0.27	3.34	−0.15	−0.16	0.17	0.01	0.42
22(MAN)	5	1.06	1.08	0.25	0.75	1.39	0.93	0.96	0.14	0.79	1.10	1.21	0.93	1.02	0.35	2.97	−0.73	−0.60	0.20	0.56	0.96
23(MAN)	5	3.29	3.35	0.27	2.92	3.62	2.21	2.31	0.27	1.75	2.45	8.40	8.09	2.23	5.81	11.74	−1.92	−1.88	0.37	1.46	2.33
24(MAN)	5	1.33	1.01	0.71	0.69	2.37	1.11	1.01	0.63	0.55	2.17	2.61	2.18	0.74	1.97	3.61	0.04	0.43	1.17	0.18	1.99
25(MAN)	5	1.25	1.31	0.40	0.57	1.56	0.98	0.73	0.52	0.52	1.61	1.86	1.37	1.11	0.66	3.12	−0.40	0.03	1.01	0.03	1.50

Deviations in apex, hex, and angle are represented in mm. Angle deviation is in degrees.
*Maximum and minimum deviations in depth are represented as the distance from the baseline (planning).
MAN = mandible; MAX = maxilla.

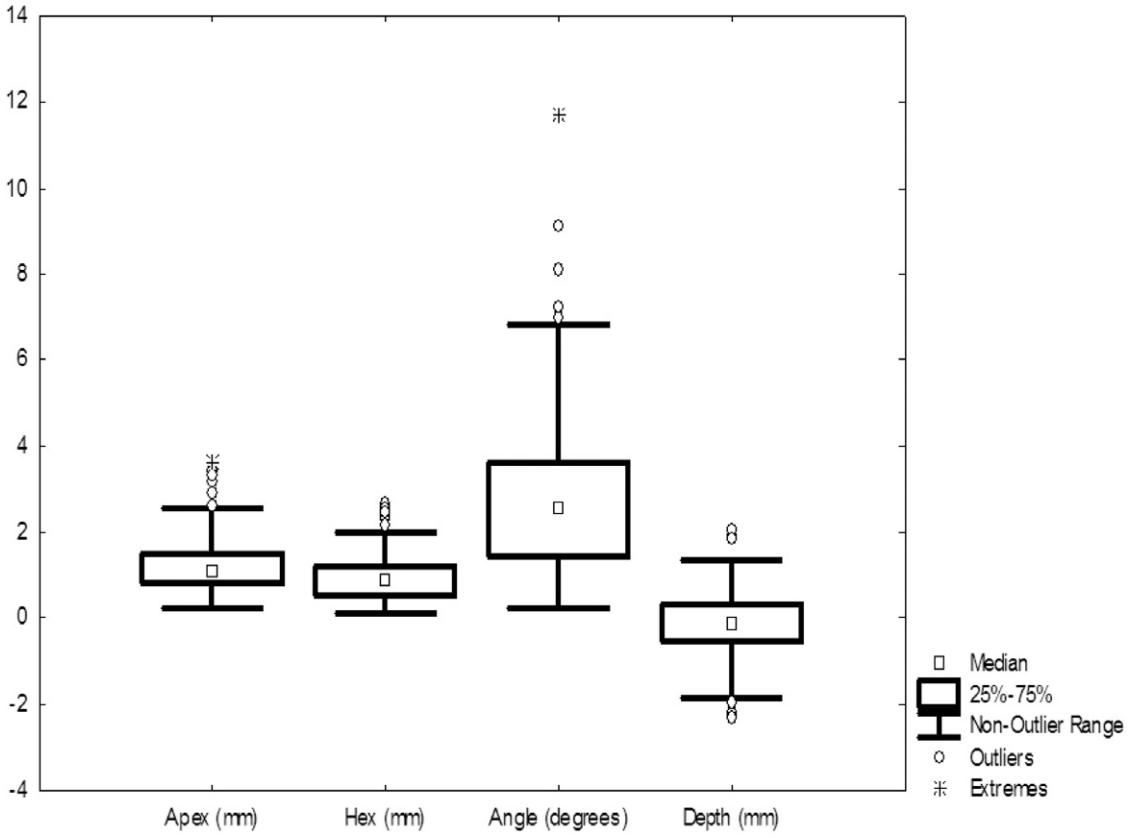

Figure 3 Box plots of deviation in apex, hex, angle, and depth.

obvious question is what type of accuracy is possible to achieve with CAD/CAM surgical templates. The results of this study are well in line with the limits of previous studies.[18] When comparing clinical results from implants placed with CAD/CAM surgical templates on previous studies performed on mucosa, this study shows similar or better results. Comparing previously published results on teeth supported guided surgeries, this study corresponds with similar or better results.[18]

Clinicians need to learn about possible variations that could occur when placing implants with a CAD/CAM surgical template, to avoid anatomical risks, as well as for the final prosthetic reconstruction. For instance, the variation might cause an implant to be inserted too close to anatomical sensitive structures. The delivery of an immediately loaded prefabricated bridge requires the accurate placement of the corresponding implants, regarding the position and angulations, in

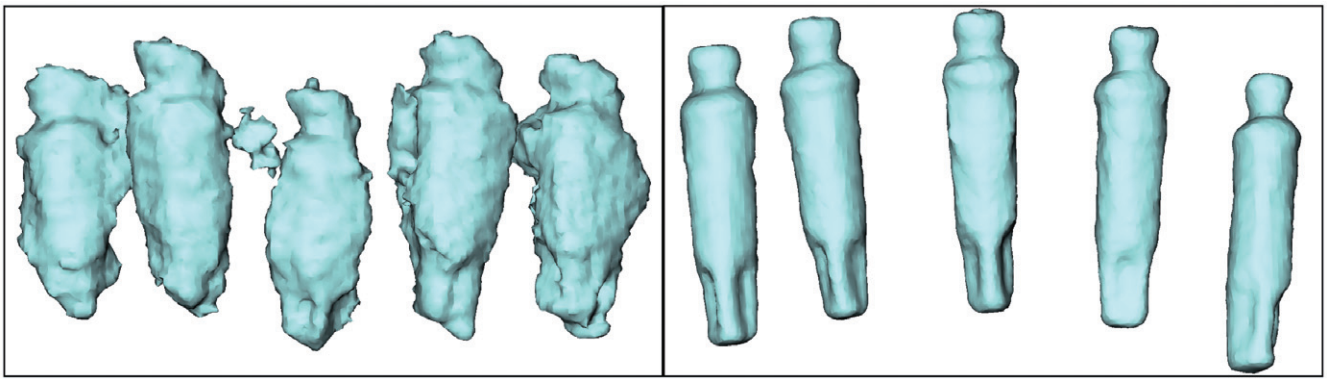

Figure 4 Upper left picture illustrating segmented three-dimensional implants from a patient with movement. Upper right picture illustrating segmented three-dimensional implants from a patient without movement.

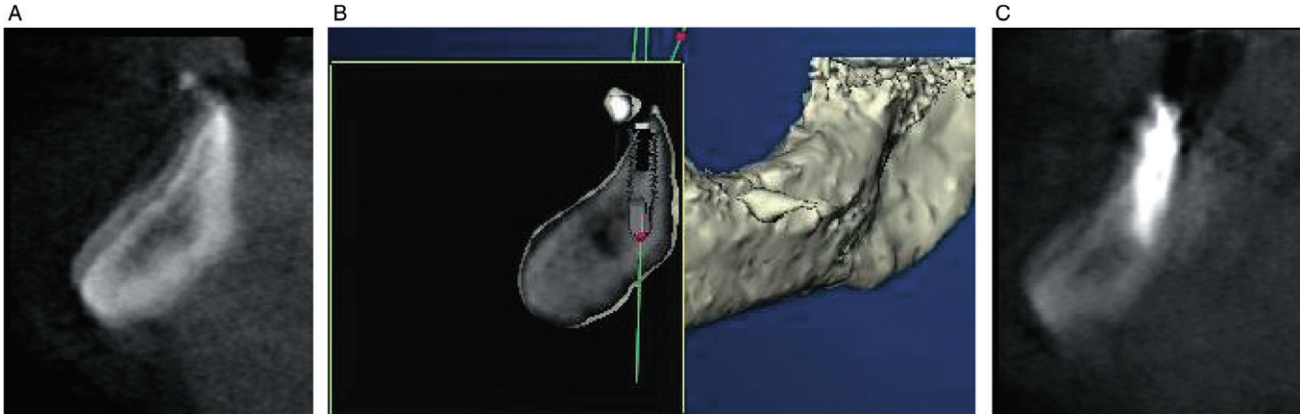

Figure 5 *A*, Trans-axial computed tomography (CT) image obtained from a patient (mandible) with movement during the preoperative scan. *B*, Trans-axial three-dimensional image reconstructed based on the CT data of a patient (mandible) with movement during the preoperative scan (the patient movement not clearly detectable at the three-dimensional reconstruction). *C*, Trans-axial CT image obtained from a patient (mandible) with movement during the postoperative scan.

order to ensure the placement of the framework directly onto the implants.

In this study, differences were observed between the virtually planned implants and actually inserted implants compared after surgery, using similar matching methods to those presented by Van Assche and colleagues.[13] The obvious difference between this study and that of Van Assche and colleagues was that they performed their study on formalin-fixed cadavers and the implants were placed with teeth-supported partial surgical templates. The Van Assche and colleagues study presented results with a range of 0.3 to 2.3 mm for the hex and a mean value of 1.1 mm. Deviation differences and the measures of apex, hex, angle, and depth deviation were evaluated in the present study, as well as comparisons between the maxilla and the mandible. During the matching procedure, it was apparent that some of the segmented implants from the postoperative CT scan were deformed, having a different shape and size

TABLE 2 Movement During the Preoperative and Postoperative Scanning (*n* = number of implants included)

	Postoperative Scan Movement	Postoperative Scan Nonmovement
Preoperative scan movement	15	6
Preoperative scan Nonmovement	28	90

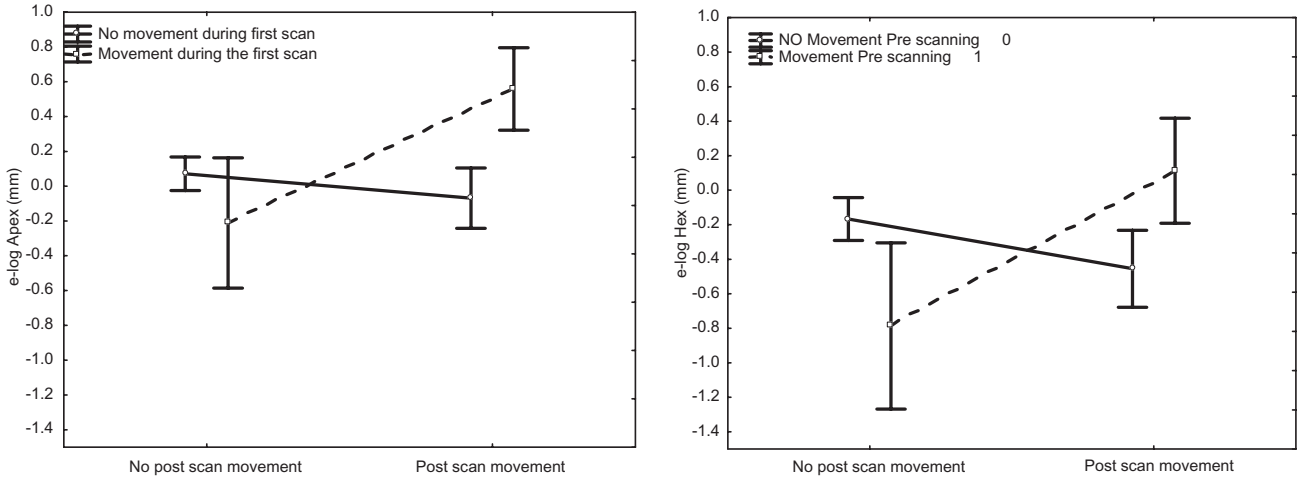

Figure 6 Mean e-log apex and mean e-log hex differences between presence and absence of movement during preoperative and postoperative scans.

TABLE 3 Deviation of Implants

Deviation	No. of Implants	Mean	Min	Max
Without any movement (90 implants)				
Hex	90	0.85	0.20	2.68
Apex	90	1.07	0.24	2.63
Angle	90	2.00	0.24	6.96
Depth	90	–0.09	0.01*	2.05*
With movement both during pre- and postoperative computed tomography scan				
Hex	15	1.12	0.16	2.45
Apex	15	1.75	0.69	3.62
Angle	15	4.27	1.97	11.74
Depth	15	–0.57	0.03*	2.33*

*Minimum and maximum in depth are presented using distance from base line.

compared with the normal implant size and shape. When some of the segmented implants were measured, it was found that they had an oval shape. Originally planned implants had a diameter of 3.75 or 4 mm, although one specific implant did vary in shape from 3.5 to 7.1 mm. As some of the implants had a different shape compared with the normal implants, the patients' movement during the preoperative CT scan and the postoperative CT scan were reviewed by a radiologist. Of all the 139 placed implants, 90 implants were placed in patients who did not move during the preoperative and postoperative scan. However, movement was observed on 21 implants at the preoperative CT images and on 43 implants during the postoperative scan of the patients. Finally, 15 implants from three patients included movement, both from the preoperative and the postoperative CT scans (see Table 2). It should be emphasized that the patient movements, in most cases, were not visible on the 3D images at the stage of virtual planning. Furthermore, the automatic superimposing procedure of guttapercha markers on the patient CT data and prosthesis CT data sometimes proceeded without any notification of errors, even in the case with patient movement. Comparing the results, statistical significance was found when combining the movement of the preoperative and the postoperative scan with the results of the deviation at the level of the hex and apex of the implants.

Individually reviewing patient's movements from the preoperative and the postoperative scan, it was found that the deviations were not greater than the normal distribution from the deviation between the virtually planned implants compared with the implants placed after surgery. Including the "movement" factor into the statistical analysis, significance was found relating to the differences between the maxilla with 3.1 degrees and 2.4 degrees for the mandible. However, this statistically significant difference may not prove to be clinically relevant.

In addition, an evaluation to determine whether there was a significant difference between prelaunch components, including 63 fixtures and postlaunched components including 76 fixtures, was done. One example was that the surgical template was produced by a dental technician during prelaunch, whereas when the guided concept was launched, the surgical template was manufactured using the CAD/CAM technique. The results showed a difference of 0.25 mm deeper for the fixtures inserted with the postlaunched components. This is statistically significant but it is questionable if the calculated magnitude is of any clinical relevance.

As the mean deviation between planned and placed implants were statistically significant different in all four outcome variables: depth, apex, hex, and angle, the hypothesis was rejected.

The following possible sources of variation may have influenced the observed deviation differences but have not been measured within the scope of this study. It is crucial to have the optimal fitting of the patient's soft tissue when positioning the radiographic guide. If the radiographic guide was placed wrongly, the implants would be placed incorrectly by aid of the surgical template compared with the virtual planning. The clinician needs to take this into consideration and carefully evaluate the fitting of the radiographic guide on to the patient. In addition, it is necessary that the clinician review on the patient, the fitting and the biting force when occluding, and practice this before the preoperative CT scan together with the patient. During the preoperative CT scan, the fitting can be evaluated using the software to determine whether air is visible between the radiographic guide and the soft tissue.

Another factor for consideration occurred when the surgical template is positioned during surgery, as it is important to ascertain the correct position of the implant that corresponds to the radiographic guide applied during the preoperative scan. In one patient, the protocol was not followed correctly and the radiographic index was included in the radiographic guide. In

another case, the surgical template was broken, which was only noticed after surgery. In this case, one of the anchor pins was also bent. This might have been caused by an excessive force being applied to the surgical template and it may have contributed to the movement of the surgical template during surgery. It is crucial to find the corresponding position between the radiographic guide and the surgical template during guided surgery. Therefore, patient selection criteria was important, such as a severely resorbed jaw could lead to possible positioning errors when aligning the radiographic guide during the CT scan and inserting the surgical template during surgery.

In this study, no statistically significant difference was observed between the maxilla and the mandible. The radiographic guide covered the palate in the maxilla, whereas in the mandible it covered only the alveolar crest. Therefore, it was surprising to find no significant difference between the mandible and the maxilla from the current results. Only if patient movement factor was included, a significant difference was found regarding the angle deviation. The movement factor introduced an error when performing the matching, as the implants' center axis was difficult to be positioned correctly if the segmented implants were not cylindrical. Thus, a movement error included in the matching procedure contributed to the final error and it was difficult to determine the real position of the placed implants in these cases. The scanning time, using the equipment in this study, was 70 seconds. This is a long time to lay totally still, especially considering the elderly age group included in this study. Imaging techniques represent a very rapidly evolving field and newer generations of CBCT equipment have a much reduced scanning time and included holders to keep the patient in position during scanning. This will also likely reduce the "movement" error during the scanning procedure. Other sources of variation include the thickness of the mucosa. To minimize this source of error, it could be important to bite the occlusal index with a constant force, during the CT scan and the surgery.

The protocol was not followed in all cases included in this study. Five of the patients were rejected in the CT-converter software because gutta-percha was not used, and that the markers that were used had a different threshold (grey value) than accepted. In one case, the markers were not spherical; hence, it was not possible to perform matching according to the protocol with the standard settings of the software. However, because of clinical consideration, respecting the situation of the old fragile patients, a decision was made to proceed with the transfer of data and the patient treatment.

The guided surgery concept involves a lot of steps that result in deviations between the planned and the placed implants if strict protocols are not carefully followed. When reviewing the results from this study, it was difficult to pinpoint a certain factor of particular significance to the final outcome. The results represent divergence obtained at this specific clinic, as only one surgeon performed the treatments; two different dental technician laboratories were used, and no specialist prosthodontist was involved during the procedures. Further studies are warranted to ascertain more information about the accuracy of guided surgery, and to determine whether they find similar results to the deviations observed during this study.

SIGNIFICANCE

The significance of the project for human health was to increase the basic knowledge of planning and placement techniques of dental implants, to improve treatment to the patients. The results from this study give us a better understanding of the deviations that could occur when using the guided surgery concept for dental implants. Furthermore, the findings could be used to implement more structured directions on how to use computerized planning software, such as instructions for clinicians to take into consideration when planning their treatments.

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