Accuracy of Computer-Aided Oral Implant Surgery: A Clinical and Radiographic Study

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Purpose: *Computer-aided oral implant surgery offers several advantages over the traditional approach. The purpose of this study was to evaluate the in vivo accuracy of computer-aided, template-guided oral implant surgery by comparing the three-dimensional positions of planned and placed implants.* ***Materials and Methods:*** *Oral implant therapy was performed in two treatment centers on eligible patients using computerized tomography (CT)–based software planning and computer-aided design/computer-assisted manufacture stereolithographic templates. A second CT scan was obtained after surgery. Preoperative and postoperative CT images were compared (planned vs actual implant positions), and the accuracy of this type of image-guided therapy was assessed.* ***Results:*** *Twenty-five adult patients were included in this retrospective study; 17 (11 partially and eight fully edentulous arches) were treated in center 1, and eight (six partially and two fully edentulous arches) in center 2. Of the 104 implants inserted with the computer-aided method, 100 integrated, giving a cumulative survival rate of 96% (mean follow-up, 36 months). There were no major surgical complications. With regard to accuracy, 89 implants were available for comparison; mean lateral deviations at the coronal and apical ends of the implants were 1.4 mm and 1.6 mm, respectively. Mean depth deviation was 1.1 mm and mean angular deviation was 7.9 degrees. There was a statistically significant correlation in the accuracy of any implants placed with the same guide. There was no difference in accuracy data from the two private centers; nor could a learning curve be demonstrated.* ***Conclusions:*** *Based upon this clinical study of 25 patients, the following observations were made:* (1) *computer-aided oral implant surgery used in two treatment centers provided a high likelihood (96%) of implant survival, and* (2) *deviations from planned implant positions existed in the coronal and apical portions of the implants as well as with implant angulation. Mean deviations were less than 2 mm in any direction and less than 8 degrees.* INT J ORAL MAXILLOFAC IMPLANTS 2009;24:234–242

Key words: *computer-assisted surgery, dental implant, minimally invasive surgery, stereolithography, surgical template*

The medical field is undergoing a remarkable trend toward minimally invasive[1] and computer-aided[2] surgical procedures. In implant dentistry, such approaches are possible thanks to the integration of computerized tomographic (CT) scans, three-dimensional (3D) surgical plannning software, and computer-aided design/computer-assisted manufacture (CAD/CAM) oral appliances that transfer the computerized planning to the surgical field.

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Possible but inadequately demonstrated advantages of computer-aided oral implant surgery include:

1. The possibility of operating with a minimally invasive approach (without flap elevation), which has been associated with shorter surgical time[3] and reduction of patient morbidity[4–6]
2. The integration of the restorative determinants into the surgical planning, resulting in predictability of the prosthetic outcome and allowing for the production of the prosthesis before the surgery, thereby simplifying immediate loading protocols[7,8]
3. Simplification of the technique-sensitive and operator-dependent surgical procedure, which can have a profound impact on current implant practices[9]

Fig 1a Dual-purpose appliance. The provisional restoration also serves as a scanning prosthesis with the addition of radiopaque barium sulfate to the acrylic resin.

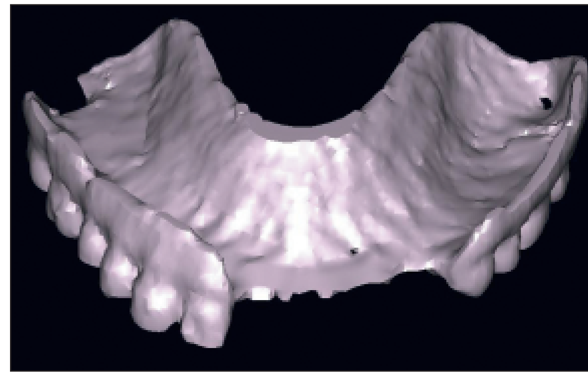


Fig 1b Scan prosthesis as it appears in the 3D pane of the software.

However, the evidence supporting such benefits of computer-aided oral implant placement is still inconclusive, and several issues are open to debate. In the medical field, the introduction of a new product (drug, device, or technique) raises several questions: first, regarding the safety of the new product, and second, with regard to its effectiveness, ie, the efficacy of the procedure in a routine clinical setting. For computer-assisted surgery, both safety and effectiveness are related to accuracy. In fact, since implants are inserted in close proximity to vital structures such as vessels and nerves, it is essential for the technique to be accurate. Indeed, grave and even fatal complications have been attributed to inaccurate implant placement.[10]

Documentation of the accuracy of computer-aided/template-assisted oral implant surgery is scarce. Only case reports and case series are available, with a resulting level of evidence 3 and strength of recommendation D according to one prominent grading system.[11] Analysis of this literature yields heterogeneous results. Generally, in vitro or ex vivo proof-of-principle studies[9,12–15] have demonstrated better accuracy, with mean deviations slightly less than 1 mm both coronally and apically and with low variability. However, in vitro and ex vivo studies may overestimate accuracy and underestimate error. In vivo studies generally report higher deviations between planning and surgery: Vrielinck et al[16] reported mean deviations of 1.5 and 3 mm, at implant base and apex, respectively, and a mean angular deviation of 10.5 degrees in a study of 24 regular implants; in a study of 21 implants, Di Giacomo et al[17] detected mean coronal, apical, and angular deviations of 1.4 mm, 3 mm, and 7.2 degrees, respectively. In both studies, variability was also greater than in the in vitro studies.

The present knowledge of computer-aided oral implant placement requires in vivo evaluation of its accuracy in private practice. The purpose of this clinical study was twofold:

1. Evaluate the in vivo accuracy in private practice settings of computer-aided, template-guided oral implant surgery by comparing the three-dimensional positions of planned and placed implants.
2. Assess the influence of surgical variables (arch, center, surgical technique, and type of guide support) on the accuracy of the technique.

MATERIALS AND METHODS

All patients consecutively treated with computer-aided oral implant surgery between February 2004 and June 2006 in two separate surgical centers were included in this retrospective study. Informed consent was obtained from all subjects. The surgical interventions were performed in two separate centers (center 1: Genoa, Italy; center 2: Rome, Italy). The same operator in each center performed the virtual surgical planning and surgical procedures. The treating clinicians were experts in implant dentistry but not in computer-aided oral implant surgery. Both practices had their own hardware and software.

The protocol employed in this clinical study has been described in detail elsewhere[18] and consisted of an integrated treatment sequence that involved the following steps.

1. Fabrication of a radiopaque diagnostic appliance, which was an exact replica of the definitive prosthesis accepted by the patient (Figs 1a and 1b).

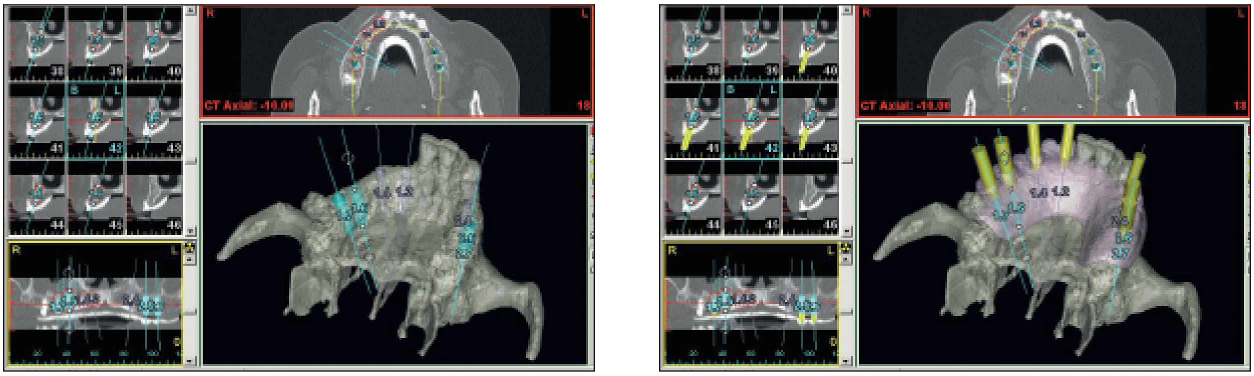


Fig 2 During virtual surgery, prosthetically ideal emergence of the implants is checked by placing the scan prosthesis over the bone.

Fig 3a The stereolithographic template (SurgiGuide) is positioned in the mouth.

Fig 3b The operated arch upon completion of minimally invasive surgery.

Fig 4a Titanium abutments are created with a computer-aided design/computer-assisted manufacture process (Procera) and secured to the implants.

Fig 4b Provisional restoration in place.

2. CT scan of the patient's arch, performed with spiral CT devices. The Asteion Multi (Toshiba Medical Systems, Rome, Italy) was used at center 1 and the Somatom Sensation (Siemens, Milan, Italy) was used at center 2. The scans included the radiopaque template to integrate the anatomic data with the functional and esthetic determinants.
3. Digital 3D CT-based surgical planning. The computer program employed in the present study is SimPlant (Materialise Dental, Leuven, Belgium), which uses the original CT data to produce axial, 3D, panoramic, and cross-sectional images, all of which are visible at the same time in four interactive windows on the computer monitor. With this software the implants are virtually placed according to bone anatomy and prosthetic design (Fig 2).

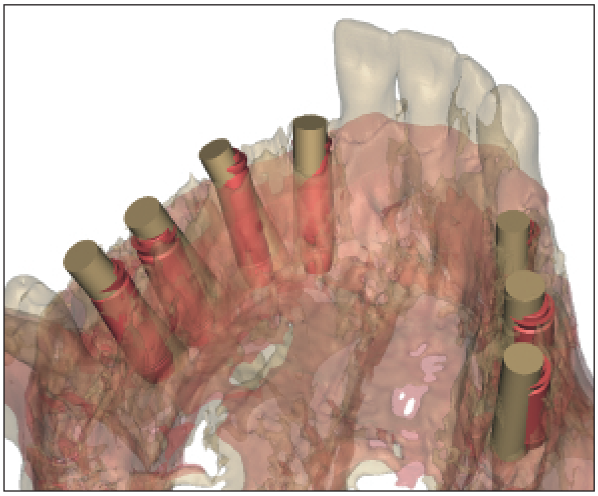


Fig 5 Fusion of 3D images (presurgical and postsurgical scans).

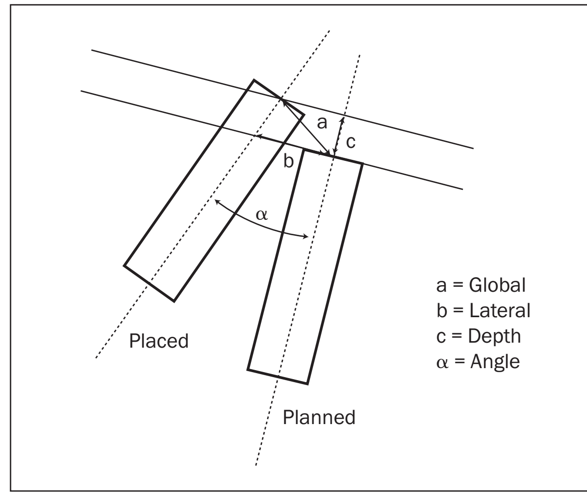


Fig 6 Measurement of deviations between placed and planned implants.

4. CAM of stereolithographic oral appliances (SurgiGuide, Materialise Dental) that transfer the digital planning to the surgical environment.
5. Computer-aided surgery (Figs 3a and 3b). Surgeries were executed according to the protocols of the implant system used in each surgical center. In center 1, Tapered Screw-Vent implants (Zimmer Dental, Carlsbad, CA) were used and, in center 2, Nobel Biocare MkIII and MkIV TiUnite implants (Nobel Biocare, Agrate Brianza, Italy) were used. The surgical guides were classified according to the type of supporting anatomic structure (bone, mucosa, teeth). Three surgical guides were employed in each patient to accommodate the three specified drills of increasing diameters used for osteotomy preparation. Implant insertion was executed without guidance according to the protocol of the surgical guides. During surgery, any complications were recorded (Figs 4a and 4b).

A second CT scan was obtained after surgery. Preoperative and postoperative CT scans were conducted by the same radiologists with the same apparatus and settings. The preoperative and postoperative scans were then aligned pairwise using an iterative closest point algorithm,[19] which allowed for comparison between planned and actual implant positions (Fig 5). Four deviation parameters between each virtual (ie, planned) and corresponding actual (ie, placed) implant were measured: lateral deviation, depth deviation, global 3D distance, and 3D angular deviation (Fig 6). All measurements were performed using Mimics software (Materialise). Measurements were rounded to the nearest 0.1 mm.

Statistical Analysis

Data were appraised using Statistical Analysis System version 9 software (SAS Institute, Cary, NC). Quantitative data are described with frequency distribution, mean values, standard deviations, and median values. Lateral deviation data were categorized into three groups: 0 to 1 mm (slight, clinically negligible deviation); 1 to 2 mm (moderate, probably clinically irrelevant); and > 2 mm (potentially clinically relevant). Accuracy data were illustrated using box plots and histograms.

Correlations among the different deviation parameters were tested with the Pearson correlation coefficient. The random effects model (SAS mixed procedure) was used to test for possible interdependence of accuracy parameters between implants inserted with the same guide and to determine the influence of surgical variables. The following influencing variables were defined as categorical factors: jaw (maxilla/mandible), center (center 1/center 2), surgical technique (flapless/flap), SurgiGuide support (teeth/mucosa/bone support), and type of edentulism (complete/partial). The significance of surgical and accuracy parameters was analyzed with generalized score statistics (Wald-Z test and Chi-square test).[20] Significance was set at $P \leq .05$.

The same framework was used to evaluate intraoperator variability of accuracy and to determine whether a learning curve was present. Patients were divided by center and deviations regressed vs time. Again, significance was set at $P \leq .05$.

Table 1 Patients and Treatment Characteristics

	Center 1	Center 2	Total
No. of implants	73	35	108
No. of subjects	17	8	25
Gender			
Female	10	2	12
Male	7	6	13
Mean age (y)	55	55	
Type of edentulism			
Fully edentulous	8	2	10
Partially edentulous	11	6	17
Type of arch			
Maxilla	9	6	15
Mandible	10	2	12
Surgical technique			
Flapless	6	8	14
Open flap	12	0	12
Flap/flapless	1	0	1
Surgical guide support			
Mucosa	2	2	4
Teeth	5	6	11
Bone	12	0	12

Table 2 Deviations Between Planned and Actual Implant Positions (n = 89)

	Mean	SD	Range
Lateral coronal deviation (mm)	1.4	1.3	0.2–6.5
Lateral apical deviation (mm)	1.6	1.2	0–6.9
Depth deviation (mm)	1.0	1.0	0–4.2
Angular deviation (deg)	7.9	4.7	0.7–24.9

Table 3 Frequency Distribution of Lateral Deviations (n = 89)

	Coronal deviation		Apical deviation	
	No. of implants	%	No. of implants	%
Slight (0–1 mm)	50	56	32	36
Moderate (1–2 mm)	20	22	32	36
Relevant (> 2 mm)	19	21	25	28

Table 4 Pearson Correlation Coefficients (*P* Values) (n = 89)

	Coronal deviation	Depth deviation	Angle
Depth deviation	0.28 (.01)		
Angle	0.23 (.03)	−0.05 (.63)	
Apical deviation	0.34 (.001)	0.12 (.28)	0.534 (< .001)

Table 5 Wald Z test for Implant Covariance Parameters (n = 89)

	Estimate	SE	Z test	*P*
Lateral coronal deviation (mm)	1.105	0.344	3.21	.0007
Lateral apical deviation (mm)	0.827	0.310	2.67	.0038
Depth coronal deviation (mm)	0.308	0.158	1.95	.0256
Angular deviation (deg)	7.85	3.820	2.05	.0200

SE = standard error.

Table 6 χ^2 Test for Influence of Covariates (Surgical Variables) on Apical Deviation (n = 89)

Covariate/ paired comparisons	Difference (mm)	SE (mm)	*P*
Type of guide support			
Bone versus mucosa	0.38	0.331	.25
Bone versus teeth	−0.26	0.417	.52
Mucosa versus teeth	−0.65	0.298	.03*
Arch			
Maxilla versus mandible	−0.78	0.423	.02*
Edentulism			
Full versus partial	−0.47	0.370	.05*
Center			
Center 1 versus center 2	0.17	0.292	.55

SE = standard error. *indicates a statistically significant value.

RESULTS

Patients and Implants

Twenty-five adults were included in this study. Two patients were treated in both arches, and therefore the number of computer-aided surgical interventions was 27, for a total of 108 planned implants. In three sites, the guided osteotomy resulted in loss of the entire buccal plate, and implant insertion was halted in the planned site. In one site, a significant dehiscence occurred, and a small flap had to be raised to treat it. The total number of implants inserted with computer-aided oral implant surgery was 104. Four implants failed to integrate in center 1, giving a cumulative survival rate of 96% at a mean follow-up time of 36 months (range, 20 to 49 months). The mean number of guided implants in each dental arch was 4 (range, 1 to 8).

The length of 11 implants differed from planning to surgery. The reasons for choosing shorter implants were insufficient mouth opening and fear of injuring vital structures. For these 11 implants, reliable measurements from the image fusion process could not be obtained, therefore they were excluded from the overall accuracy calculations.

No nerve injuries, abnormal hemorrhages, or sinus pathologies were seen in this population as a sequela of implant insertion. In one template, the metal tubes detached, but they were successfully

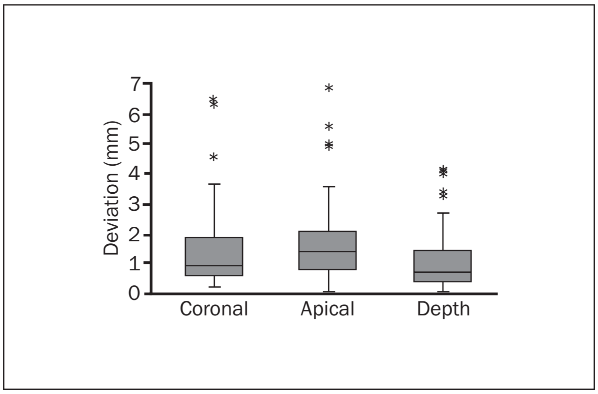


Fig 7 Box plots showing median, quartile, and extreme values of deviations (in mm) of implants (n = 89). Boxes contain 50% of all values; the horizontal lines inside the box indicate the medians, vertical lines extend to 1.5 of the interquartile range. Asterisks depict outliers.

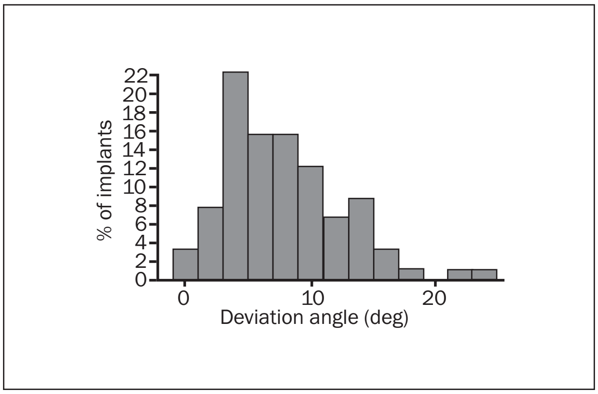


Fig 8 Percent distribution of deviation angles of inserted implants (n = 89).

replaced. One template cracked without breaking and served its purpose until the end of the surgery.

Patient and treatment characteristics for each center are summarized in Table 1.

Accuracy

Eighty-nine implants were available for a comparison of accuracy via the image registration technique. Mean lateral deviations between planned and placed implants at the coronal and apical ends of the implants were 1.4 mm and 1.6 mm, respectively. The mean depth deviation was 1.1 mm, and the mean angular deviation was 7.9 degrees. Deviation outcomes are shown in Table 2.

The frequency distributions of coronal and apical lateral deviations are displayed in Table 3 and Figs 7 and 8. A higher frequency of moderate and relevant deviations was observed at the apical portion of the implants.

The Pearson correlation coefficient demonstrated that, in both centers, there were significant linear correlations at the implant level in coronal lateral deviation, apical lateral deviation, and angular deviation (Table 4). In contrast, depth deviations were not significantly correlated with apical and angular deviations and were only slightly correlated to coronal deviations. However, this last correlation was strongly influenced by the data of one patient, who showed extreme deviation.

The Wald Z test, performed for the implant covariance parameters, demonstrated that there was interdependence for each of the accuracy parameters between implants inserted with the same guide (Table 5). In particular, highly significant correlations were found between lateral deviations, both coronally and apically (P = .0007 and P = .0038, respectively).

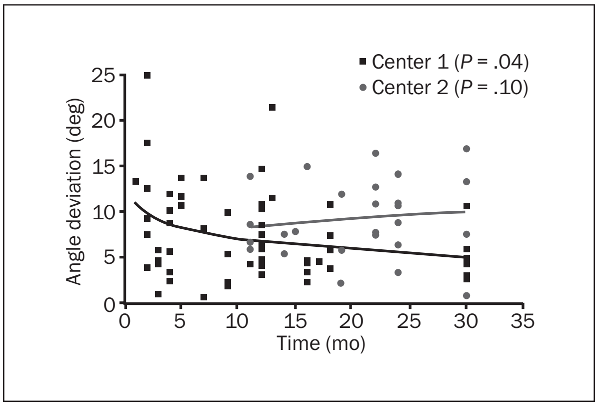
As a result of χ^2 tests on the influence of the aforementioned variables (arch, center, surgical technique, and type of guide support) on the deviation parameters, it seems that most variables did not exert a significant effect on accuracy. However, paired comparisons demonstrated better accuracy regarding apical deviation of mucosa-supported guides compared to teeth-supported guides (P = .03), of the maxilla compared to the mandible (P = .02), and of completely edentulous patients compared to partially edentulous patients (P = .05). With respect to interoperator variability (center effect), the analysis demonstrated no statistically significant difference between the centers in terms of accuracy (Table 6).

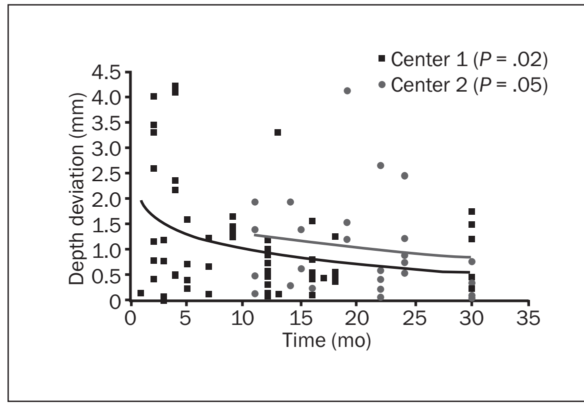
As for intraoperator variability analysis, except for angle deviation in center 1 (P = .04) and depth deviation in both centers 1 (P = .02) and 2 (P = .05), a clear learning curve was not demonstrated in this material (Figs 9 and 10).

DISCUSSION

The clinical outcomes of computer-aided oral implant surgery in the current study proved to be comparable with those of the traditional approach in terms of implant survival and complications. In a recent systematic review,[21] the survival rate of conventionally inserted implants was 96.5%, which is consistent with that seen in the present study. Other clinical studies of computer-aided oral implant surgery showed similar results.[7,16]

To be correctly interpreted, the accuracy of computer-aided oral implant surgery should be compared to the accuracy of standard therapy. Unfortunately,





Figs 9 and 10 Scatter plots depicting the fitted learning curves for center 1 (n = 62) and center 2 (n = 27) regarding angle deviations (*left*) and depth deviations (*right*).

data about the accuracy of conventional implant placement are lacking. In two in vitro studies,[9,22] the accuracy of computer-aided oral implant surgery was better than that of conventionally placed implants. The accuracy outcomes obtained in the present private practice study are consistent with those of two university-based in vivo studies using the same system[16,17] and are inferior to the accuracy reported for several in vitro and ex vivo studies.[9,12–15,23] With respect to frequency distribution analysis, the choice of cutoff points for categorizing the data is a necessarily subjective and arbitrary operation and, as such, is prone to criticism. It was felt that a deviation up to 1 mm could not be defined as more than slight, and a 2-mm cutoff point was set for a clinically relevant deviation because it is generally maintained that 2 mm is the recommended safety margin around vital structures.[24] Although the majority of implants showed deviations within 1 and 2 mm, the fact that about one fourth of the implants showed clinically relevant deviations warrants further investigation and points to a need for technique refinement.

The significant linear correlations found at the implant level for coronal lateral deviation, apical lateral deviation, and angular deviation were expected, because lack of accuracy is likely to be reflected in all three parameters.

Statistical analysis confirmed the clinical impression that implants placed with the same guide are not independent from each other and therefore the errors are interactive and possibly cumulative.[25] This is a noteworthy and plausible finding because the implants are linked to each other at various stages of the image-guided pathway: losses of accuracy produced during CT scanning, surgical template fabrication, and surgery are likely to involve all implant sites within the same template, to an extent. Error propagation can derive also from the common practice of stabilizing the template using the first drilled osteotomies. Any error at the first site dislocates the template, which carries over to the other implant sites.

Within the limit of this sample, with only two centers involved, the similarity in accuracies between the two clinicians and the absence of a clear learning curve provide preliminary support to the hypothesis that human factors can play a limited role in computer-guided, template-assisted surgery. Limiting human error is indeed only one justification for computer-aided oral implant surgery. However, this hypothesis should be confirmed by more extensive studies involving several centers and larger experimental populations. Furthermore, since the two centers used different implant systems, the absence of a significant difference in accuracy seems to suggest that the accuracy of computer-aided oral implant surgery is not dependent on the type of implant used.

Of interest is the fact that the apical deviation was significantly influenced by arch type, edentulism, and guide support. However, given the fact that no such effect of the covariates could be demonstrated for angular, coronal, and depth deviations, and given the limited experimental sample, these findings should be approached with caution and no definite conclusions can be drawn.

Computer-aided oral implant surgery involves a sequence of diagnostic and therapeutic events, and error can creep in at different stages. Therefore the described cumulative loss of accuracy is indeed the sum of the following single errors:

1. Errors during image acquisition and data processing, on average less than 0.5 mm.[26]
2. Error during surgical template production, typically around 0.1 to 0.2 mm for CAM with stereolithography.[13]

3. Error during template positioning and movement of the template during the drilling.
4. Mechanical error caused by the bur-cylinder gap. The Surgiguide is equipped with 5-mm-long guiding cylinders with an inner diameter that is 0.15 to 0.20 mm larger than the respective bur. This tolerance theoretically allows a deviation angle of approximately 2.29 degrees which, at a hypothetical distance of 20 mm from the cylinder, results in a lateral deviation of approximately 1 mm. These calculations cannot be extended to other systems, which have different tolerances between drills and guiding cylinders.
5. Deviation from the planned axis of insertion in those instances where freehand drilling must be employed. In template-assisted surgery, the height of the template necessitates very long burs. In several sites, however, when the planned implant was long, even the longest bur could not reach the needed osteotomy depth; in other cases, the mouth opening did not allow the use of such long burs. Therefore the final bur was frequently used without a guide, at least for the most apical part of the osteotomy. Furthermore, in one of the centers the final bur was sometimes used without a template because of a lack of compatible guide tubes for the implant system used. This could explain, in part, the deviations experienced in the present study.
6. Human error, for example, setting the bur stop in an incorrect position.

CONCLUSIONS

Within the limitations of this retrospective study, the following conclusions can be drawn:

- Computer-aided placement of oral implants in the two treatment centers provided a high likelihood (96%) of implant survival.
- Deviations from planned implant positions existed in the coronal and apical portions of the implant as well as in the angulation of the implants. The average accuracy was clinically adequate in about three quarters of the implants. In about one quarter of all implants, the accuracy was less than ideal, although in this patient population, this did not result in major clinical complications.
- Because of the possible errors, virtual planning should be executed judiciously, with an adequate safety margin left to avoid damage to vital structures.

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