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Accuracy assessment of computer-assisted flapless implant placement in partial edentulism

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Abstract

Aim: To assess the accuracy of implants placed flapless by a stereolithographic template in partially edentulous patients.

Material and Methods: Eight patients, requiring two to four implants (maxilla or mandible), were consecutively recruited. Radiographical data were obtained by means of a cone beam or a multi-slice CT scan and imported in a software program. Implants ($n = 21$) were planned in a virtual environment, leading to the manufacture of one stereolithographic template per patient to guide the implant placement in a one-stage flapless procedure. A postoperative cone beam CT was performed to calculate the difference between virtual implant ($n = 21$) positions in the preoperative planning and postoperative situation.

Results: A mean angular deviation of 2.7° (range 0.4–8, SD 1.9), with a mean deviation at the apex of 1.0 mm (range 0.2–3.0, SD 0.7), was observed. If one patient, a dropout because of non-conformity with the protocol, was excluded, the angular deviation was reduced to 2.2° (range 0.6–3.9, SD 1.1), and the apical deviation to 0.9 mm (range 0.2–1.8).

Conclusion: Based on this limited patient population, a flapless implant installation appears to be a useful procedure even when based on accurate and reliable 3D CT-based image data and a dedicated implant planning software.

Key words: computer-assisted surgery; cone beam computed tomography; dental implant; stereolithography; three-dimensional imaging

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Several published papers have described pre-treatment planning software based on radiologic images (for a review, see Widmann & Bale 2006, Vercruyssen et al. 2008). Such a concept allows the visualization of jawbone anatomy and the integration of implant placement and prosthetic re-constructions. Implant planning is both anatomically and prosthetically driven. The transfer of the ideal implant position from the computer planning to the surgical field is carried out using a stereolithographic drilling template.

Conflict of interest and source of funding statement

There are no conflicts of interests.
Oral implants were delivered free of charge by the Nobel Biocare company.

The combination of such a treatment planning and CAD–CAM technology also makes it possible to pre-manufacture individual prosthetic solutions that can be connected to the implants immediately after surgical placement.

Many publications describe the advantages of such a procedure, reporting promising clinical results (van Steenberghe et al. 2002, 2005, Ganz 2003), even with a medium-term follow-up (Sanna et al. 2007). In case of an atrophic edentulous maxilla, the use of a drill guide allows the placement of implants in less accessible sites such as the zygoma (Vrielinck et al. 2003, Malevez et al. 2004). The additional advantages of such a procedure are a shortened surgical time and a less invasive surgery, with less postoperative discomfort and pain (Fortin et al. 2006, Ozan et al. 2007).

The key issue is the maximal deviation between planning and placement. The latter should not just be expressed by linear measurements both coronally and at the apex of the implant. The angular deviation may even be considered as the most crucial factor affecting the linear deviation with an implant length dependence. Both in vivo (van Steenberghe et al. 2002, Vrielinck et al. 2003, Di Giacomo et al. 2005, Ersoy et al. 2008, Ozan et al. 2009) and ex vivo studies ((Sarment et al. 2003, van Steenberghe et al. 2005, Van Assche et al. 2007, Ruppin et al. 2008) revealed a mean angular deviation towards the planning, ranging from $1.8^\circ \pm 1.0$ to 10.5 (range 0–21). Also, in a horizontal plane, mean deviations at the apex of 0.8–3 mm have been reported within a range of 0.4–6.4 mm. Deviations in both a horizontal and a vertical plane allow the fabrication of a provisional, but not final, bridge. A guided surgery might create a ''safe surgical feeling'', and yet, when using such a system, it is essential to know the worst-case scenario where all deviations add up in the same direction. Even though the occurrence of such a scenario is minimal, it may have drastic consequences, such as inducing neurovascular trauma (e.g. nerve damage, life-threatening haemorrhages, etc.; Liang et al. 2008).

The present report is the first clinical study on the accuracy assessment of a computer-assisted implant placement in partial edentulism based on cone beam computed tomography (CBCT) imaging, besides multi-slice CT (MSCT).

Material and Methods

Patients

Eight patients (mean age = 56 years, five females, one smoker) with a sufficient amount of jawbone to place two to four implants in the posterior or frontal areas, in the lower ($n = 2$) or the upper jaw, were consecutively recruited. The remaining dentition had a healthy periodontium without excessive tooth mobility. Extraction sockets should have healed for at least 3 months. Sites with any disorders in the planned implant area, such as previous tumours, radiation or bone diseases, were excluded. The study was approved by the ethical committee of the University Hospital of the Catholic University of Leuven.

Planning Procedure

A radiographic template was prepared containing all information for future prosthetic restoration, starting from a wax-up. The template covered the occlusal surfaces of the complete arch, up to the coronal third of the dentition, and reached the gingiva in the edentulous sites. The template was manufactured by a qualified dental technician of the university technical laboratory using a methacrylate resin (Palapress vario®, Heraeus-Kulzer, Wehrheim, Germany). A minimum of six small gutta markers were inserted into each edentulous site. The gutta-percha points were placed at different levels in relation to the occlusal plane. This was accomplished using a warm gutta-percha injection technique (Obtura II®, Obtura Corporation, Fenton, MO, USA). These gutta-percha points served as radio-opaque feducials to allow visualization of the template in the software, using the dual scanning technique (Verstreken et al. 1996).

When an optimal fit of the template was achieved, a bite index in centric occlusion was made in putty impression material (Shera*Exact*® 85, Shera GmbH & Co., Lemförde, Germany)

To integrate the planned prosthesis into the virtual environment, the radiographic template was positioned into the mouth of the patient by the clinician, and a CBCT scan (3D Accuitomo®, Morita, Kyoto, Japan) was performed at 70 kV and 4 mA. A second scanning of the template alone was performed to achieve optimal image quality (Verstreken et al. 1996). Because of the limited field of view (3 cm × 4 cm) of the cone beam hardware, two of the eight patients requiring a bilateral rehabilitation were scanned using an MSCT scan (Somatom Volume Zoom®, Siemens, Erlanger, Germany) instead of a CBCT scan. Considering the difficulties for 3D segmentation of initial 3D CBCT datasets and the limited visualization volume, all radiographic templates were also scanned by MSCT. Today, with the larger field of view, this is no longer necessary.

Both sets of dicom images were imported in the Procera® software (Nobel Biocare AB, Göteburg, Sweden) to visualize the jawbone and the prosthesis at the same time. The slice viewer displays 2D reslices in all planes. The implants were planned in the most optimal position towards both the jawbone and the prosthetic demands. The planning was transferred to the manufacturing facility (Nobel Biocare AB) electronically for the fabrication of the stereolithographic drill guide.

Surgical Protocol

Surgery was performed under local anaesthesia without antibiotic prophylaxis because of the stringent asepsia conditions applied. The stereolithographic surgical template was positioned on the remaining teeth using the bite index to secure a proper position. One or two anchor pins were inserted into the jawbone to stabilize the template further. The drilling was performed using sequential drills with increasing diameters and removable sleeves in the drill template according to the manufacturer's instructions. The implant insertion was guided by the fixture mount that closely fitted in the sleeve. After implant installation, the template was removed and healing abutments or a provisional Procera® implant bridge (Nobel Biocare AB) were installed.

Twenty-one TiUnite® (Nobel Biocare AB) Brånemark implants with diameters of 3.3, 3.75 or 4 mm, and lengths ranging from 10 to 15 mm were inserted. Three to 6 months after implant placement, the final prosthetic superstructure was prepared.

Validation of the Technique

Two years after implant placement, a CBCT scan (Scanora® 3D, Soredex, Tuusula, Finland) was performed (settings: 85 kV, 8 mA) to check the position of the implants. The larger postoperative volume (7.5 cm × 10 cm) allowed to optimally match the small preoperative volume. The postoperative data were matched to the preoperative images using the Procera software to determine deviations in the three dimensions (Fig. 1). This is based on a multimodality image registration (Maes et al. 1997); the postoperative cone beam images are geometrically aligned with the planning images by automated image registration using maximization of mutual information. Each anatomical location is mapped to its corresponding location.

Results

Deviations between the planned position and the actual postoperative implant positioning were calculated for all 21 implants using a total of 12 tooth-supported stereolithographic templates (Table 1). The mean angular deviation of the long axis between the planned and the placed implants was 2.7° (range 0.4–8.0, SD 1.9), with a mean horizontal deviation of 0.7 mm (range 0.1–1.4) at

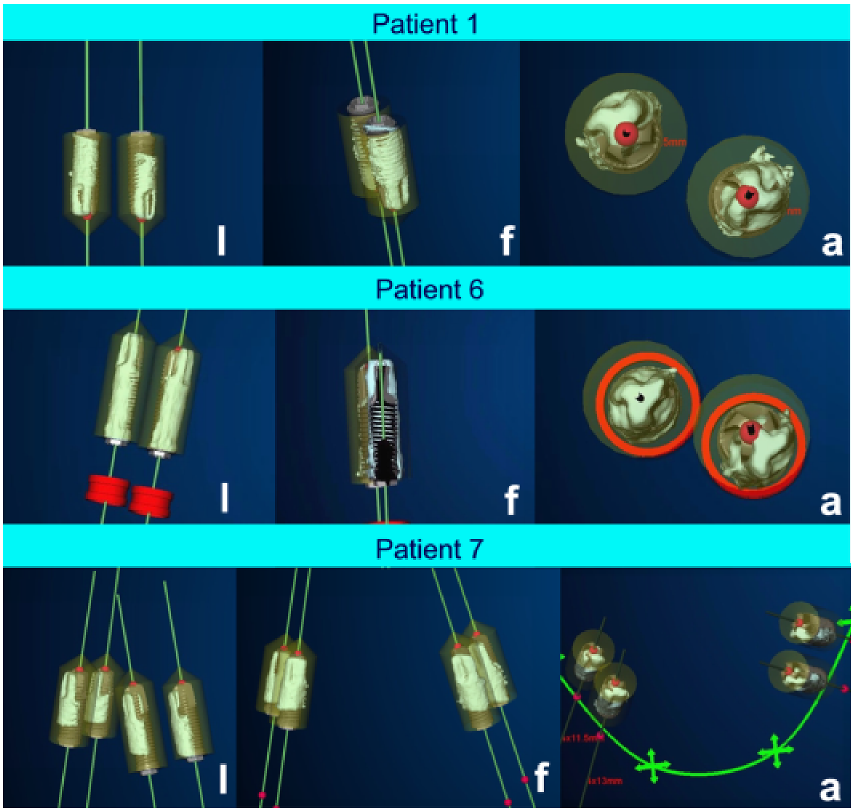

Fig. 1. The yellow halo is the safety zone available in the planning, and the grey-yellow implants represent the planning. The white structure represents the deviation of the actual implant towards the planning. Detailed view from lateral (l), frontal (f) and apical (a).

the neck and 1.0 mm (range 0.2–3.0, SD 0.7) at the apex. One patient (patient 8) was considered as a dropout because of violation of the actual protocol. After the stereolithographic process, the template was very brittle. To prevent fracture of the template, the manufacturer decided to add a new resin to the stereolithographic template while placed on a stone model. The hardening process of the resin may have deformed the template. When the results of this template (two implants) were excluded, owing to non-conformity with the protocol, the deviations were reduced, respectively, to 2.2° (range 0.5–3.9, SD 1.1), 0.6 mm (range 0.1–1.4, SD 0.3) at the implant neck and 0.9 mm (range 0.2–1.8, SD 0.4) at the apex. The maximal range of angular deviation of different implants within the same patient was 2.2°.

Discussion

The combination of the present software technique, to visualize the patient's anatomy, together with the prosthetic restoration, is a helpful operative planning tool (Jacobs et al. 1999). This accuracy study was the first one to demonstrate the clinical applicability of 3D CBCT-based preoperative planning for implant placement in partial edentulism.

No complications were observed during surgeries, and the deviations in comparison with the planning were acceptable when the dropout was excluded. For the latter patient, the template was modified on the stone model, which probably led to a deformation. This led, in this particular patient, to an angular deviation of 6.2° and 8.3° and a vertical inaccuracy of up to 2 mm.

To prevent this, it is essential to have a radiographic template of an overall thickness of at least 2.5–3.0 mm (as also mentioned in the NobelGuide protocol).

Three other in vivo studies (Di Giacomo et al. 2005, Ersoy et al. 2008, Ozan et al. 2009) have calculated the deviations of guided implant placement by tooth-supported stereolithographic guides (see Table 2). All these studies obtained patient's data from an MSCT scan. The study by Di Giacomo et al. (2005) found a higher angular deviation than that in the present study. The results were based on two templates and four implants in a single patient. Different templates were used for different drill diameters, and the use of anchor pins was not mentioned. Both the other two studies (Ersoy et al. 2008, Ozan et al. 2009), based on a larger number of implants, found deviations comparable with the present study. Both studies applied a flapless and an open flap technique, but Ersoy et al. (2008) could not find a difference for the implants placed according to the different approaches; angular deviations were 5° ± 2.6 for the flap procedure *versus* 4.7 ± 2° for the flapless procedure. Besides the results in the table, Ozan et al. (2009) found smaller deviations in the mandible than in the maxilla; however, this was not confirmed by the results of Ersoy and coworkers (Ersoy et al. 2008). The dataset of the present study was too small to analyse the influence of the location.

When these results are compared with a human cadaver study (Van Assche et al. 2007) using the same protocol, and the same software and guiding tool, better results could be found in vivo. There is no hard evidence to explain this, but it could be due to a better anchorage of the template over the intact teeth. Furthermore, cadavers' bone softening by demineralization of formalin may have an impact. Another cadaver study (Ruppin et al. 2008) calculated the overall deviation for partially and fully edentulous mandibles ($n = 40$) and found an angular deviation of 7.9 ± 5°.

In the present study, the deviations were present inter-patient and also intra-patient. Yet, no correlation could be found between the amount of deviation and (1) the sequence of implant placement (mean value = 2.4° *versus* 1.9° for the first and the last inserted implants, $p = 0.87$), (2) the mesial/distal position of the implant (mean value = 2.3° for mesial implants and 2.1° for distal implants, $p = 0.72$) or (3) the kind of template (mean for free ending template = 2.3° *versus* 2.1° for the distal tooth-supported template). Thus, these deviations might be related to the tilting of the template in the case of a unilateral anchor pin or to the tolerance within the guiding tool (Van Assche & Quirynen 2010). Should one use a maximal inclination of the drill, an angular deviation of 4.7° can be expected.

Table 1. The deviations calculated by the matching software are presented in this table

Patient	Implant	Implant length	Scan	Deviation				Free ending template	Order of placement
				hex (mm)	tip (mm)	angle (°)	depth (mm)		
1	35	11.5	CBCT	0.3	0.9	3.6	0.2	No	1
1	36	11.5		0.5	0.4	0.6	0.4	No	2
2	13	13	CBCT	0.4	1.0	3.0	− 0.5	No	1
2	14	15		0.5	1.4	3.7	− 0.2	No	2
2	15	10		0.4	1.1	3.9	0.2	No	3
4	24	15	CBCT	0.7	0.6	1.0	− 0.3	No	1
4	25	10		0.7	0.7	2.1	− 0.2	No	2
5	25	15	CBCT	0.1	0.3	0.8	− 0.1	No	1
5	26	10		0.3	0.7	2.7	0.0	No	2
6	14	15	CBCT	0.9	1.2	2.4	0.6	Yes	1
6	15	15		0.9	0.9	1.6	0.8	Yes	2
Mean			CBCT	0.5	0.8	2.3	0.1		
SD			CBCT	0.2	0.3	1.2	0.4		
3	12	15	MSCT	0.3	0.3	0.5	0.2	No	4
3	14	15		0.6	0.2	2.9	0.2	No	1
3	22	15		0.4	1.0	3.0	0.1	No	3
3	24	15		0.5	0.6	1.3	0.3	No	2
7	14	13	MSCT	0.6	1.1	2.6	− 0.4	Yes	1
7	15	11.5		0.6	0.5	1.7	− 0.2	Yes	2
7	24	15		1.4	1.8	4.0	− 1.0	Yes	3
7	25	13		1.2	1.5	1.4	− 1.0	Yes	4
Mean			MSCT	0.7	0.9	2.2	− 0.2		
SD			MSCT	0.4	0.6	1.1	0.5		
Overall mean				0.6	0.9	2.2	− 0.1		
Overall SD				0.3	0.4	1.1	0.5		
8	36	10		1.5	2.3	6.2	− 1.3	Yes	1
8	37	10		2.0	2.9	8.3	− 2.0	Yes	2

Patient 8 was considered a dropout because of non-compliance with the protocol. Templates where the implants are in a free-ending position as well as the sequence of implant insertion are visualized.
CBCT, cone beam computed tomography; MSCT, multi-slice CT.

Table 2. A summary of the reported accuracies for in vivo studies treating partially edentulous sites using a stereolithographic template

Study	R	P	T	I	S	Hex (mm)	Tip (mm)	Angle (°)
In vivo								
Di Giacomo et al. (2005)	CT	1	2	4	UJ	0.4 (r = 0.1–1.1)	2.0 (r = 0.8–3.0)	6.9 (r = 1.9–12.2)
Ersoy et al. (2008)	CT			26	UJ/LJ	1.1 ± 0.6	1.3 ± 0.7	4.4 ± 1.6
Ozan et al. (2009)	CT			30	UJ/LJ	0.9 ± 0.4	0.9 ± 0.6	2.9 ± 1.3
Van Assche and colleagues (present study)	CBCT CT	8	8	19	6 UJ/2 LJ	0.6 ± 0.3 (r = 0.1–1.4)	0.9 ± 0.4 (r = 0.2–1.8)	2.2 ± 1.1 (r = 0.6–3.9)
Cadaver study								
Van Assche et al. (2007)	CBCT	4	4	1	1 UJ/3 LJ	1.1 ± 0.7 (r = 0.3–2.3)	2.0 ± 0.7 (r = 0.7–2.4)	2.0 ± 0.8 (r = 0.7–4.0)

In the first three studies (in vivo), a spiral CT scan was taken to obtain the patient data.
R, radiographs to obtain patient information; P, number of patients; T, number of templates; I, number of implants; S, site; UJ, upper jaw; LJ, lower jaw; *r*, range, CT, computed tomography; CBCT, cone beam CT.

Although it is difficult to make final statements from this small sample size, we observed some shortcomings/conditions that might explain the larger deviations in patient 7, due to a tilting of the template, where implants were installed on both quadrants.

Also, in distal areas, especially where the mouth opening is limited, a tilting of the drill has to be prevented. A bilateral anchoring might be considered to prevent such a tilting.

Because errors are cumulative, all steps of the protocol have to be carefully managed to minimize the inaccuracy.

Different techniques exist to pre-manufacture a (provisional) bridge. To compensate for eventual deviations, expandable abutments (NobelGuide®, Nobel Biocare AB) were developed. An alternative solution could be the adaptation of the temporary cylinders in the prefabricated provisional bridge or the manufacture of a provisional bridge based on an impression taken immediately after placement. A bony interference, preventing the seating of the provisional bridge, has to be checked in the case of a flapless procedure (Yong & Moy 2008).

This study started in 2006, when the earlier type of CBCT devices had only a small visualization volume (3 cm × 4 cm). The latter had a high-resolution diagnostic image quality, but a lower segmentation quality. Recent studies have shown a significant improvement even for segmentation quality (Loubele et al. 2007, 2009). Because the surgical template is derived from the 3D volume in the software, we still preferred at that time to scan the radiographic template by the MSCT scan so as to optimize the support of the template on all the remaining teeth. Nowadays, segmentation accuracy is more than sufficient (up to 300 μm) (Loubele et al. 2008) to allow its use for dual scanning (template/template+patient).

Besides the rapid imaging advancements, the global planning and transfer approach is still being improved to reduce inaccuracies. The limited sample size does not allow one to make final statements. Therefore, this study should be confirmed by randomized-controlled clinical trials with a larger sample size.

Conclusion

The present study showed that implants in partially edentulous sites can be placed flapless via a computer-assisted planning procedure, with acceptable deviations towards their planned positions.

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Clinical Relevance

Scientific rationale: CT-based stereolithographic drill guides are currently used in clinical practice for implant placement in full and partial edentulism. Yet, the accuracy of flapless, drill-guide computer-assisted implant placement in partial edentulism remains scarce. This is the first report on the accuracy assessment of computer-assisted implant placement in partial edentulism using drill guides based on either cone beam CT ($n = 6$) or multi-slice CT ($n = 2$).

Principal findings: The inaccuracy is within the range of previous studies even when based on cone beam CT. The flapless approach does not have a negative influence on the surgical outcome.

Practical implications: Within the limitations of this pilot study, one can conclude that cone beam CT images can be used to acquire patient image data that have to be transferred to the surgical field using a stereolithographic drill guide procedure for flapless implant placement. At each step, precision and alertness are key factors for a successful outcome.