Reliability of Preoperative Planning of an Image-Guided System for Oral Implant Placement Based on 3-dimensional Images: An In Vivo Study

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Purpose: *The purpose of this study was to assess the reliability of the planning software of an image-guided implant placement system based on a mechanical device coupled with a template stabilized on soft tissue during surgery.* ***Materials and Methods:*** *Thirty consecutive partially or completely edentulous patients were treated with the image-guided system. For each patient, a study prosthesis was fabricated and duplicated in acrylic resin and served as a scanning template. Axial images were obtained from a computerized tomographic scan and transferred to planning software that provides real 3-dimensional information to plan implant position. Once the final position of the implant was defined, preoperative data such as the size of implants and anatomic complications were recorded using the planning software. The scanning template was then drilled in that exact position by a drilling machine. During surgery, the drilled template was used as a drill guide. After implant placement, intraoperative data were recorded and statistically compared with the preoperative data using the Kendall correlation coefficient for qualitative data and the Kappa concordance coefficient for quantitative data.* ***Results:*** *Agreement between the preoperative and intraoperative data was high for both implant size and anatomic complications. The Kendall correlation coefficient was 0.8 for the diameter and 0.82 for the length. The Kappa concordance coefficient was 0.87 for both dehiscence and bone graft, 0.88 for osteotomy, and 1.0 for fenestration.* ***Discussion:*** *In the few instances where planning was not perfect, implant placement was completed in a clinically acceptable manner.* ***Conclusion:*** *The results suggest that the image-guided system presented is reliable for the preoperative assessment of implant size and anatomic complications. It may also be reliable for flapless surgery.* INT J ORAL MAXILLOFAC IMPLANTS 2003;18:886–893

Key words: *computer-aided surgery, dental implants, minimally invasive surgical procedures, surgical flap, x-ray computed tomography*

During oral implant placement with the open-flap surgical technique, the drill is guided by the surgeon according to the final form of the restoration and the shape of the residual ridge crest,

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particularly the labial plate. The open-flap technique causes disruption in the periosteum and its blood supply to the underlying bone. The flapless technique, on the other hand, maintains periosteal attachment and blood supply to the bone. It presents several advantages: *(1)* It avoids modification of gingival form following approximation of the surgical wound, *(2)* it should increase the success of immediately loaded implants by maintaining the blood supply, *(3)* the periosteum can act as a support for the labial plate as it expands when an osteotome is pushed into the osteotomy site, *(4)* treatment time is significantly reduced related to reflection and closure of the tissue flap, and *(5)* patient discomfort after surgery is reduced.[1–3]

Since no soft tissue flap is raised during implant placement with the flapless operative technique, the quantity and shape of the bone that would host the

implants must be assessed preoperatively. A variety of methods are available for this purpose, including digital palpation, calipers, and radiography, but cross-sectional images seem to be a prerequisite.[4,5] The latter can be obtained either by conventional spiral tomography or by computerized tomography (CT). To derive the greatest benefit from preoperative planning, accurate transfer to the surgical field must be assured. Several authors have proposed the use of templates fabricated on plaster casts. Templates can be easily created but remain a source of uncertainty. Recently, to promote minimally invasive surgery and accurate placement of implants, the use of an image-guided system has been proposed. Currently, the objectives of image guidance are twofold: to define an operative strategy that takes advantage of the localizing capabilities of imaging, and to perform the previously defined operative procedure using a suitable guidance system. The system consists of an imaging workstation to plan the surgery and a technologic tool to transfer the planned strategy to the surgical field with high precision.[6] Different approaches have been proposed for oral implant placement: navigation with an optical[7] or magnetic tracking system,[8] the use of a template as a drill guide on the surgical field stabilized on soft tissue without a flap[9,10] or on bone,[11,12] or the use of a robot with a mechanical arm.[13]

To be reliable for oral implant placement with the flapless technique, an image-guided system must provide dependable planning for the surgical procedure, since the practitioner cannot see the bone shape during the surgery. It should also be capable of transferring the planned axes onto the surgical field according to the presurgical plan, with submillimeter accuracy. The precision of different systems has been demonstrated.[7,12,14,15] However, the predictability of the planning software used has not yet been assessed.

The present study was undertaken to assess the reliability of the planning software of an image-guided implant placement system, which is based on a mechanical device coupled with a template stabilized on soft tissue during surgery. Reliability was assessed by comparing preoperative findings with intraoperative findings.

MATERIALS AND METHODS

Patients

The investigation involved 30 consecutive (partially or completely) edentulous patients (21 women and 9 men; age range, 18 to 70 years) who presented for the placement of 101 implants in the maxilla (n = 55) or the mandible (n = 46).

The study was performed within the guidelines of the Helsinki declaration for biomedical research involving human subjects. Thus, patients were informed about the study, and signed informed consent was obtained from each one.

Inclusion criteria were as follows: informed consent for the described procedure signed by the patients, a need for implant placement to support the prosthesis, and age over 18 years. Exclusion criteria were as follows: pregnancy at the time of evaluation, severe bone discrepancy, metabolic disorders, immunocompromised status, hemophilia or other bleeding disorders, drug or alcohol abuse, treatment with steroids, history of radiation therapy in the head and neck, psychiatric handicaps, inability of patient to understand the procedure described in the informed consent.

Methods

The CADImplant protocol[9] (Praxim, Grenoble, France) was used for each patient. After complete examination of the patient, a study prosthesis was made on a diagnostic cast according to the functional, biomechanical, and esthetic requirements of the prosthodontist. After satisfactory testing in the patient's mouth, this prosthesis was duplicated in acrylic resin and then served as a scanning template. A gutta-percha pin was inserted into all resin teeth along the main axis so that it would be clearly visible on the radiograph.

Planning Procedure. Image-guided systems for oral implant placement consist of a software program for virtual implant placement and a suitable guidance system to carry out the previously defined operative strategy. In the CADImplant protocol, a template is used, coupled with a drilling machine. Prior to surgery, the template is drilled according to the preoperative plan made with imaging software. To drill the template at its exact location, it is of primary importance to find a rigid mathematical transformation between the software program for virtual implant placement and the drilling machine. Therefore, an acrylic resin cube is used that included 2 precisely positioned tubes made of titanium placed perpendicular to each other and uncrossed (Fig 1a). The 2 titanium tubes can be easily linked to the drilling machine by placing the resin cube on a dedicated device in the drilling machine and by passing 2 metal shafts through the 2 titanium tubes. For the scanning procedure, the cube is fixed at the front of the previously fabricated scanning template so that it is outside of the patient's mouth, in front of the jaw of interest (Fig 1b). Axial images are obtained from a fan-beam spiral CT scan. They are transferred to the CADImplant planning software, which

Fig 1a *(Left)* An acrylic resin cube, which includes 2 precisely positioned tubes made of titanium, is used to make a link between the planning software and the drilling machine.

Fig 1b *(Right)* The study prosthesis is duplicated in acrylic resin. The cube is fixed at the front of the previously fabricated denture so that it is outside of the patient's mouth. This denture plus the cube serve as a scanning template. The template is drilled prior to surgery according to the preoperative plan made with imaging software by a numerically controlled drilling machine.

Fig 2 A simulation of the position of the planned implant is carried out in real time in 3 planes. One is perpendicular to the jaw arch *(above center),* one is tangential to the jaw arch *(above right),* and one is the axial cut *(above left).* The final position of the implant is defined according to the study prosthesis landmarks and the available bone volume. Preoperative planning data are recorded. Note the defect in the bone at the coronal part of the implant, which is apparent in the perpendicular image.

provides 3 anatomic planes: the axial cut and 2 reformatted views, perpendicular and tangential to the arch of the jaw. The orientation of the latter 2, reformatted by the planning software, is defined both by the jaw arch and the planned axis. One is perpendicular to the arch while the other is tangential, but both go through the planned axis whatever its orientation.

For each patient, the practitioner must define the positions of the implants with the software according to landmarks on the study prosthesis, which are included on the scanning template, and the available bone volume. The practitioner can interactively change the position of the planned implant on each plane until the result is satisfactory. A simulation is carried out in real time in the 3 planes. Recalcula-

tion of the other reformatted plane is performed instantaneously so that cross-sectional views always go through the planned implant axis (Fig 2).

At the end of the planning procedure, the preoperative planning data recorded for further analysis are:

- The number of implants
- The size of the implants (length and diameter)
- Possible defects in the bone overlying the implant(s) (fenestration)
- Possible defects in the bone in the coronal part of the implant(s) (dehiscence)
- Any need to enlarge the crest before implant placement (osteotomy)
- Any need to carry out a bone graft
- No primary stability

Fig 3a The scanning template is drilled according to the planned implant positions by a drilling machine. The drilled template is placed on the mouth in the same position as during CT examination. The first hole is drilled with a 1.5 mm diameter bur by drilling through the template and directly through the flapless mucosa.

Fig 3b After the first hole was drilled, the template was removed. A full-thickness flap was raised and preparation of the site was completed.

Fig 4 After implant placement, intraoperative data were recorded and compared to the preoperative data. See the defect in the bone at the coronal part of the implant.

Surgical Procedure. Once the final positions of the implants have been defined on the software, the scanning template is drilled in these exact positions by the drilling machine. Each hole is 1.5 mm in diameter. After appropriate anesthesia is obtained, the drilled template is placed in the mouth in the same position as during the CT examination (Fig 3a). For the completely edentulous patient, the template is secured to the underlying bone with two fixation screws in the facial plates to avoid inadvertent movement of the surgical guide during initial osteotomy.

The first hole is drilled with a 1.5-mm-diameter drill, penetrating through the template and directly through the flapless mucosa to the desired depth. The template is then removed (Fig 3b) and a full-thickness flap is raised. For complete preparation of the site, the standard protocol should be followed as suggested by the implant manufacturer. An attempt was made to conform to the pilot drill. After implant placement, intraoperative data are recorded and compared to the preoperative data (Fig 4). All implants should be placed at the planned site and anatomic requirements should always be fulfilled with the planned size(s) of implant(s).

Statistical Analysis

The Stata software 7.0 (Stata, College Station, TX) package was used for all of the analyses. Quantitative data are described with the mean value and the standard deviation. Agreement between the qualitative preoperative and intraoperative data was determined as the Kendall correlation coefficient, and for quantitative data, the Kappa coefficient was used.

RESULTS

It should be noted that 6 of the 10 implants planned in second molar sites were not placed using the surgical guide because of limited opening of the mouth; this is a limitation of the technique. These implants were therefore excluded from the statistical analysis. Ninety-four of the 95 planned implants were placed in the desired locations. One implant was not placed because of a lack of stability (unplanned) (Table 1). No implant was placed in an unplanned site. Once the surgical site was inspected, it was always evident that implant placement as planned was clinically acceptable. Anatomic requirements were always fulfilled. Intraoperative findings were always identifiable on the software, except for the implant that was not placed because of a lack of stability. Therefore, in 96.6% of patients, all implants planned were placed. In 86.6% of patients, all implants were placed at the planned sizes, with no difference between planned situation and the situation at placement. In the other patients, the differences between planned and actual outcome were always acceptable, and no modification of treatment was needed.

Agreement between planned and actual sizes was 98.9% for length and 96.8% for diameter. Table 2 shows the characteristics of implant size. The Kendall correlation coefficients were 0.80 for diameter (Fig 5) and 0.82 for length (Fig 6). In 2 patients, the implants were larger at placement than planned because the practitioner used a bone socket former that made the site oval instead of round. To obtain a round site, a larger drill than intended had to be used. In another patient, the implant placed was shorter than intended, not because of an

Table 1 No. of Implants Planned, No. of Implants Placed, and Differences Observed Between Planning and Placement

Patient no.	Implants planned* (n)	Implants placed at planned site (n)	Differences observed
1	1	1	
2	2	2	
3	1	1	Length at placement was smaller (13 mm instead of 15 mm)
4	2	2	
5	1	1	
6	1	1	
7	3	3	
8	6	6	
9	1	1	
10	10	9	(1) Lack of stability, (2) diameter at placement was bigger (4.1 to 4.8 mm), (3) a dehiscence was not planned, (4) an anatomic complication was overestimated
11	1	1	2 anatomic complications were overestimated (osteology, graft)
12	1	1	
13	1	1	
14	4	4	
15	1	1	
16	3	3	
17	1	1	
18	8	8	
19	3	3	
20	4	4	
21	10	10	
22	2	2	
23	7	7	
24	2	2	
25	2	2	
26	2	2	
27	3	3	
28	4	4	Diameter placed was bigger for 1 implant (4.1 to 4.8 mm)
29	6	6	
30	2	2	
Totals	95	94	

*Six implants planned in the second molar site were excluded from the statistical analysis.

Table 2 Characteristics of the Implants Planned and Placed in 30 Patients (n = 94 implants)

	Mean	SD	Minimum	Maximum
Planned length (mm)	10.8	2.0	7.0	15.0
Planned diameter (mm)	4.1	0.4	3.3	5.0
Length at placement (mm)	10.7	2.0	7.0	15.0
Diameter at placement (mm)	4.1	0.4	3.3	5.0

anatomic complication but because the practitioner decided during surgery that the shorter implant was of sufficient length (Fig 7).

Agreement between the preoperative and intraoperative anatomic complication data was 95.8%. The Kappa correlation coefficient was 0.87 for dehiscence and graft, 1.0 for fenestration, and 0.88 for osteotomy. In almost every case the planned characteristics were observed. In 2 patients, a graft or an osteotomy was planned but not carried out. In 1 patient a dehiscence was expected but was not found, and in 1 patient an unexpected dehiscence was found and a larger-than-planned implant was placed.
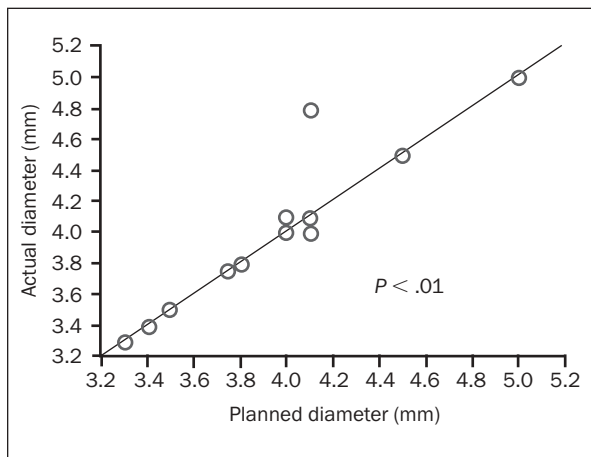
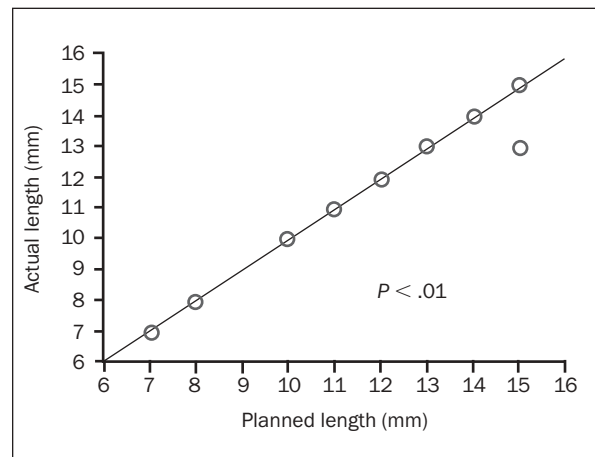**Fig 5**   Relationship between planned and actual implant diameter.

Fig 6   Relationship between planned and actual implant length.

DISCUSSION

Since flapless implant placement is a blind technique, care must be taken in the selection of the patient and in the surgical technique used. Preoperative planning must be reliable for the assessment of both the number and locations of implants in the jaws, the implant size needed, and the possible anatomic complications. Ridge-mapping calipers may provide reliable information on the overall shape of the bone without concavity.[16] Reformatted CT images coupled with a conventional surgical guide may not provide high predictability for the implant size needed and anatomic complications.[17] Thus, for the flapless technique, Campelo and Camara[3] have suggested that at least 7 mm of bone width be available and a large learning curve be a guide to using the appropriate technique.

The objectives of image-guided systems are twofold: to plan the surgery, and to carry out the previously defined operative procedure with high accuracy. Image guidance can be expected to reduce the invasiveness of surgery and to improve localization and targeting under appropriate imaging supervision. This study suggests that the present very simple mechanical system coupled with CT images can be reliable for the preoperative assessment of the surgical site. It may provide predictability for both the number and sites of jaw implants. It can also determine both the length and the diameter of the implant before surgery. In fact, the practitioner is able to evaluate the shape of the bone around the implant trajectory with the imaging software and thus predict potential anatomic complications such as a thin ridge crest, dehiscence, fenestration, or poor bone quality. The software can be reliable for preoperative planning of a surgical procedure such
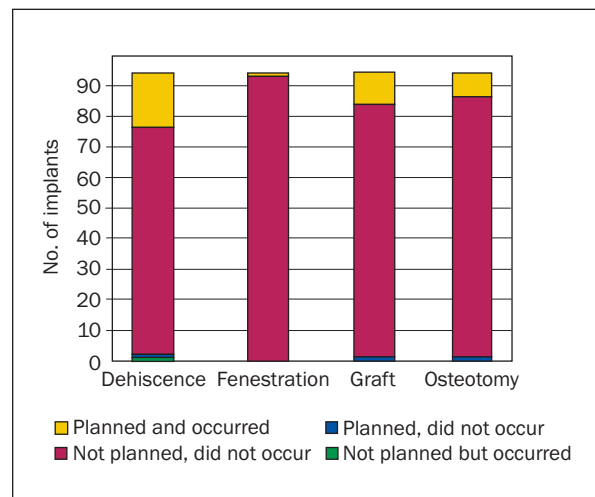

Fig 7   Anatomic complications encountered at planning and placement.

as bone grafting or bone expansion with a socket former to improve esthetic results or obtain better bone quality for primary stability. The image-guided system is also useful in eliminating the need for handling bone tissue. Thus, with this technique, handling soft and bone tissue is not necessary, and raising a full-thickness flap to determine bone shape and to guide the drill may not be necessary.

The reliability of the image-guided system stems from the planning software, which is true 3-dimensional software. The planned axis is precisely located in a 3-dimensional volume. Reformatted planes are instantaneously recalculated when the planned axis is changed, so that cross-sectional slices always go through the implant. There is no approximation, as is seen with many commercially available systems such as DentaScan (General Electric, Milwaukee,

WI), which provides precalculated multiplanar reformation perpendicular to the arch of the jaw and to the axial slices without taking into account the spatial orientation of the planned axis. The 3-dimensional approach outperforms the planning practice.[18,19] Two-dimensional image software may not provide acceptable predictability regarding anatomic complications and implant sizes.[17]

The reliability achieved with the image-guided system in reducing surgical invasiveness presented here is also related to the precision of the drilling machine. The custom drilling machine transfers the planned axis onto the template with a precision of 0.2 mm in translation and 1.1 degrees in rotation as the maximum.[9] This system is a semi-active one. Passive systems—for example, navigators—are known[6] to be more flexible because modifications in the drilling procedure are always possible during surgery. With semi-active systems, the drill axis is physically constrained by the planned axis under the surgeon's control with a mechanical device. Therefore, semi-active systems are considered to be more accurate. In fact, using an optical tracking system, Birkfellner and coworkers[7] reported a discrepancy of 1.23 ± 0.28 mm on average and 1.87 ± 0.47 mm as a maximum between the planned position of a reference point marker and its real position. Fortin and coworkers[15] have demonstrated that this system can provide consistent submillimeter accuracy with little dependence on image resolution.

The main drawback of the surgical template can be seen in the possible movement of the template during surgery and reproducibility of the splint position between the CT exam and the surgical procedure. This study demonstrated that the protocol used here can be safe for implant placement. The template is supported on the remaining dentition or stabilized by the individual form of the hard palate or of the mandible. For completely edentulous patients, the template is placed under occlusal pressure and secured on bone with screws.

The disadvantage of an image-guided system can be seen in the use of both software that should be cost-effective and the CT scan exam for providing 3-dimensional information. In comparison to conventional radiography,[20] the CT scan involves a higher radiation dose/higher cost method. But the CT scan is less time consuming when multiple implants are required, and it allows imaging of the entire jaw, making it possible to use software for virtual implant placement.[16,21] Furthermore, the higher radiation dose and higher cost can be significantly reduced with the cone-beam CT technique.[15,22,23]

CONCLUSIONS

Image-guided systems have been proposed to reduce the invasiveness of surgical techniques by providing both predictable preoperative assessment and accurate placement. True 3-dimensional software that is associated with a template to transfer the planned strategy to the surgical field with submillimeter accuracy can be reliable for preoperative planning. The system tested is reliable for the preoperative assessment of both the number and locations of implants and the implant size(s) needed, as well as potential anatomic complications. This tool may promote the use of a flapless surgical technique for oral implant placement.

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