Effect of Flapless Surgery on Pain Experienced in Implant Placement Using an Image-Guided System

Thomas Fortin, DDS, PhD[1,2]/Jean Luc Bosson, MD, PhD[2]/Michel Isidori, DDS[3]/Eric Blanchet, MS, DDS[3]

Purpose: *The aim of this study was to compare the pain experienced after implant placement with 2 different surgical procedures: a flapless surgical procedure using an image-guided system based on a template and an open-flap procedure.* ***Materials and Methods:*** *The study population consisted of 60 patients who were referred for implant placement. One group consisted of 30 patients who were referred for the placement of 80 implants and treated with a flapless procedure. The other group consisted of 30 patients who were referred for the placement of 72 implants with a conventional procedure. Patients were selected randomly. They were requested to fill out a questionnaire using a visual analog scale (VAS) to assess the pain experienced and to indicate the number of analgesic tablets taken every postoperative day from the day of the surgery (D0) to 6 days after surgery (D6).* ***Results:*** *The results showed a significant difference in pain measurements, with higher scores on the VAS with open-flap surgery (*$P < .01$*). Pain decreased faster with the flapless procedure (*$P = .05$*). The number of patients who felt no pain (VAS = 0) was higher with the flapless procedure (43% at D0 versus 20%). With the flapless procedure, patients took fewer pain tablets (*$P = .03$*) and the number of tablets taken decreased faster (*$P = .04$*).* ***Discussion:*** *Minimally invasive procedures may be requested by patients to reduce their anxiety and the pain experienced and thus increase the treatment acceptance rate.* ***Conclusion:*** *With the flapless procedure, patients experienced pain less intensely and for shorter periods of time.* INT J ORAL MAXILLOFAC IMPLANTS 2006;21:298–304

Key words: *computer-aided surgery, dental implants, minimally invasive surgical procedures, pain, radiography, surgical flap*

For oral implant placement, different approaches have been proposed to transfer the planned position to the surgical field using an image-guided system (IGS): navigating with an optical [1–3] or magnetic[4] tracking system, using a template as a drill guide on the surgical field fitted on soft tissue[5–8] or on bone,[9–13] or using a robot with a mechanical arm.[14]

Although IGSs are becoming more accepted in the dental field because they are expected to reduce the invasiveness of the surgical procedure,[15] make immediate loading easier,[11,12] and be useful in the placement of zygomatic implants, many questions remain regarding the improvement of patient outcomes, effectiveness, and cost. The use of IGS can be expected to increase, although its place in surgical and prosthetic practice is not yet perfectly clear. Criteria such as the duration of the intervention, pain, modification of the surgical and prosthetic procedure, and cost-benefit ratio have yet to be fully assessed.

The aim of this study was to compare pain after implant placement using an IGS and a flapless surgical procedure with pain after implant placement with a conventional surgical procedure.

[1]Assistant Professor, Department of Oral Surgery, Dental University of Lyon, France.
[2]Assistant Professor, Laboratoire TIMC, Medical University of Grenoble, France.
[3]Clinical Associate Professor, Implant Dentistry, Hospices Civils de Lyon, France; Private Practice, Lyon, France.

Correspondence to: Dr Thomas Fortin, 18 Avenue Marechal Leclerc, 38300 Bourgoin Jallieu, France.
E-mail: Thomas.fortin@rockefeller.univ-lyon1.fr

MATERIALS AND METHODS

Patients

The investigation involved 2 groups of 30 consecutive partially or completely edentulous patients who presented for the placement of implants in the Department of Oral Surgery of the Hospices Civiles de Lyon, France. Patients were asked to fill out a

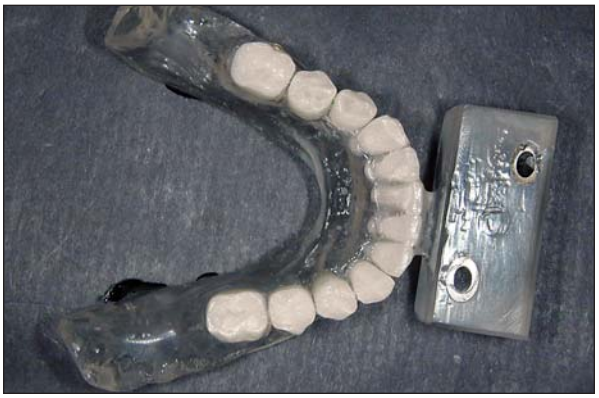


Fig 1a The diagnostic prosthesis was duplicated in acrylic resin and then used as a scanning template. The resin teeth were made with radiopaque resin so that they would be clearly visible on the radiograph.

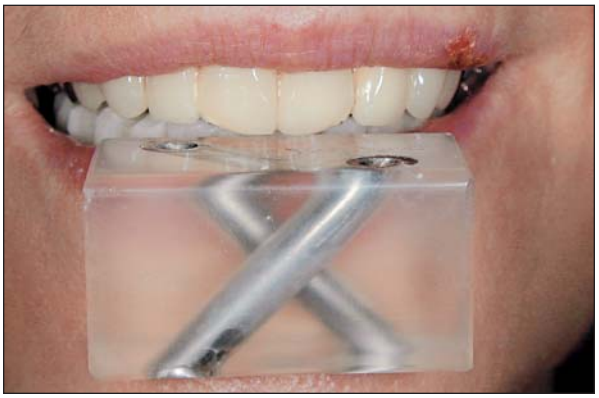


Fig 1b A cube was fixed at the front of the template outside the patient's mouth for the scanning procedure.

questionnaire to determine their eligibility of the study. Inclusion criteria were as follows: consent for the described procedure, implant placement required to support the prosthesis, and age of at least 18 years. Exclusion criteria were as follows: the need for tooth extraction during the surgical procedure, the need for bone grafting for implant placement, pregnancy at the time of evaluation, severe bone resorption, metabolic disorders, immunocompromised status, hemophilia, bleeding disorders, drug or alcohol abuse, treatment with steroids, history of radiation therapy in the head and neck, psychiatric disorders, and inability to understand the procedure described in the questionnaire.

Patients were treated by 1 of the 7 surgeons involved in the study and were randomly selected. All surgeons had experience in oral implant placement and were well trained with the IGS used. In group 1, patients (20 women and 10 men; age range, 19 to 82 years) were treated with a flapless procedure using the CADImplant System (CADImplant, Medfield, MA) for the placement of 80 implants. Postsurgical medication was limited to an antibiotic (penicillin for 6 days, 1 g at breakfast and 1 g at dinner) and 500 mg of paracetamol (Doliprane; Aventis, Paris, France) or 400 mg of a nonsteroidal anti-inflammatory drug such as an antalgic (Advil, Wyeth, Madison, NJ) whenever the patient felt it necessary. In group 2, patients (18 women and 12 men; age range, 20 to 79 years) were treated with a conventional procedure that included reflection of soft tissue flaps for the placement of 72 implants. Postsurgical medication was similar to that given to group 1; patients were also given a steroidal anti-inflammatory drug (prednisolone) for 4 days (Solupred; Aventis).

CADImplant System

The CADImplant protocol[6] was used for group 1 patients. The study prosthesis was duplicated in acrylic resin and then used as a scanning template. The resin teeth were made with radiopaque resin so that they would be clearly visible on the radiograph.

Planning Procedure

IGSs for oral implant placement consist of a software program for virtual implant placement and a suitable guidance system to carry out the predefined operative strategy. In the CADImplant protocol, a template is used with a drilling machine. Prior to surgery, the template is drilled according to the preoperative plan made with imaging software. An acrylic resin cube that includes 2 precisely positioned tubes made of titanium placed perpendicular to each other is used. 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 anteriorly to the previously fabricated scanning template so that it is outside the patient's mouth, in front of the maxilla (Figs 1a and 1b). The template is supported by residual teeth. For the completely edentulous patient, the template is stabilized under occlusal pressure by the individual form of the arch.

Axial images are obtained from a fan-beam spiral computed tomographic (CT) scan and transferred to the CADImplant planning software. For each patient, the practitioner had to define the positions of the implants with the software according to the diagnostic prosthesis landmarks included on the scanning template and the available bone volume (Fig 2).

Fig 2 CADImplant planning software was used for 3D planning. Reformatted views always passed through the planned implant axis. The practitioner could interactively change the position of the planned implant on each plane until the result was satisfactory. A simulation was carried out in real time on the 3 planes.

Surgical Procedure

For group 2 patients, the surgical procedure was conventional, with reflection of a soft tissue flap.

For group 1 patients, a drilled template was used in a flapless procedure.[15] Once the final positions of the implants were defined in the software, the scanning template was drilled in these exact positions by the drilling machine, making a 2.5-mm-diameter hole. After appropriate anesthesia had been obtained, the drilled template was placed in the mouth in the same position as during the CT examination. For the completely edentulous patient, the template was immobilized under occlusal pressure and secured to the underlying bone with 2 fixation screws in the labial plates to avoid inadvertent movement of the surgical guide during initial osteotomy. Drill sleeves were inserted in the template holes. The inner diameter of each hole was 2.1 mm; the first hole was drilled with a 2.0-mm-diameter drill by penetrating through the template and directly through the flapless mucosa to the desired depth (Figs 3a to 3d). The template was then removed. Two different types of incisions were used for the flapless technique. Either a circumferential scalpel to make a punch-style incision, or a simple midcrestal incision was used to limit the flap to the top of the crest in order to see the bone (Fig 4). The implants were placed as recommended by the manufacturer. An attempt was made to conform to the pilot drill.

Data Records

The patients were requested to complete 1 sheet of the questionnaire every evening for 1 week from the day of the surgery (D0) to 6 days after surgery (D6) to report the level of pain they experienced, the number and the name of medications taken during the day, and whether edema, hematoma, or paresthesia occurred.

The patient had to evaluate the pain on a 10-cm visual analog scale (VAS) ranging from 0 (no pain) to 10 (maximum pain possible), as suggested by Eli and coworkers.[16,17] Two days after surgery (D2) and 6 days after surgery (D6), the patient also had to qualify the pain experienced using "no," "weak," "moderate," or "strong."

Statistical Methods

The Stata Software 7.0 (StataCorp, Bryan/College Station, TX) package was used for all analyses.

Pain measurements for the 2 groups were compared using analysis of variance for repeated measurements after a treatment factor, after transforming the VAS into natural logarithms, which is a common transformation normalizing and in particular homogenizing variances, the 2 conditions necessary for using mean comparison tests.

RESULTS

At D0, patients reported pain within a range of 0 to 7.8 (75% within a range of 0 to 1.49) with the flapless procedure and 0 to 7.28 (75% within a range of 0 to 2.52) with the open flap procedure (Fig 5). Significant decreases in pain were observed day after day ($P < .01$). It was noted that pain was higher than 1.49 with the flapless procedure in patients with a high anxiety level. Pain was also higher than 1.49 in cases where an implant had been placed near a vital structure (eg, the mandibular canal, apex root, incisal nerve), probably the result of an endosseous edema. There was a significant difference in pain measurements, with a higher VAS score for the conventional procedure ($P < .01$). There was a significant interaction ($P = .05$), reflecting that changes in the pain experienced during the postoperative week were not similar for the 2 groups. These results indicated

Fig 3 *Surgical procedure with the drilled template.*

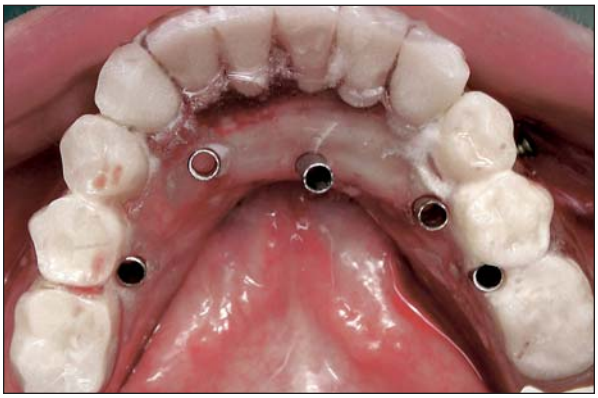


Fig 3a The scanning template was drilled with high accuracy according to the plan and then became a surgical guide. The template was placed in the mouth in the same position as during the CT examination. The template was fitted on the mucosa. Drill sleeves were inserted through the holes.

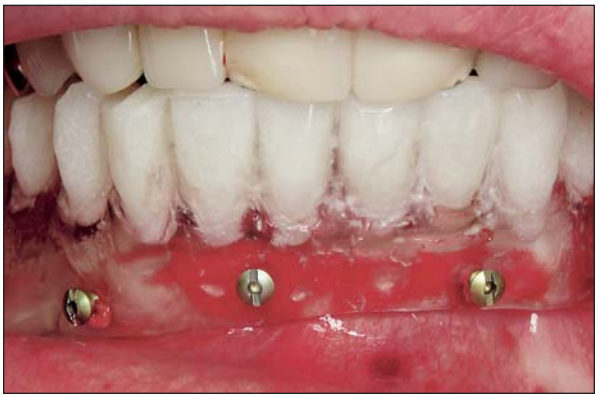


Fig 3b For the completely edentulous patient, the template was secured to the underlying bone with fixation screws in the labial plates to avoid inadvertent movement of the surgical guide during initial osteotomy.

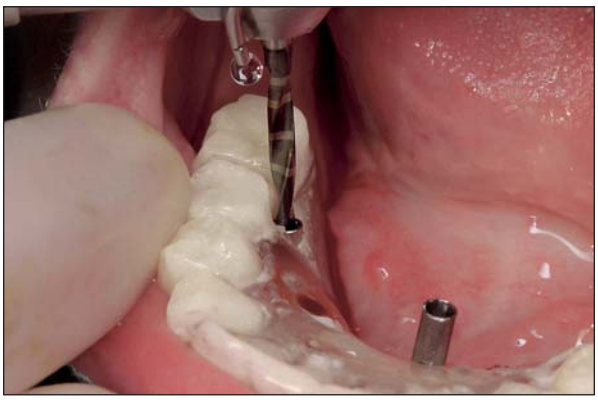


Fig 3c The pilot hole was drilled with a 2.0-mm-diameter drill by penetrating through the template and directly through the flapless mucosa.

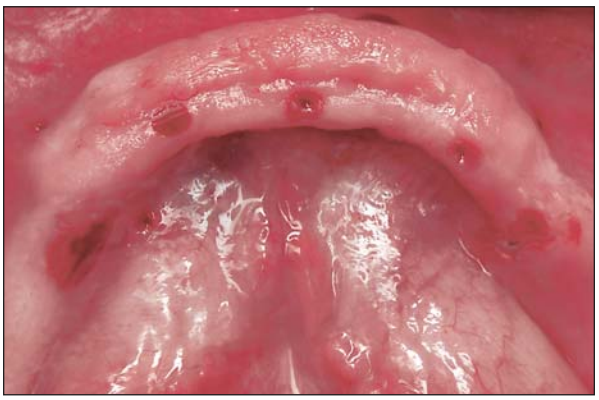
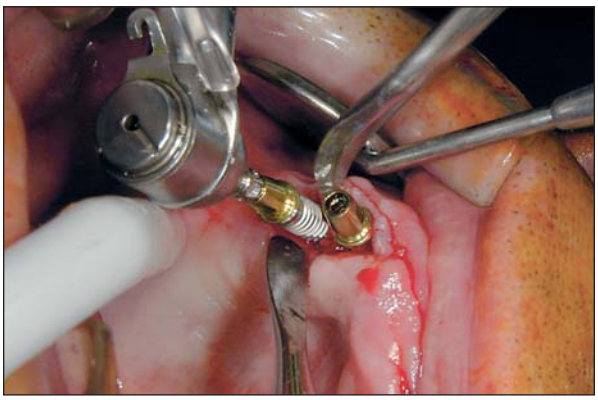


Fig 3d The template was removed after drilling with the pilot drill. Subsequent holes were drilled as recommended by the manufacturer. An attempt was made to conform to the pilot drill.



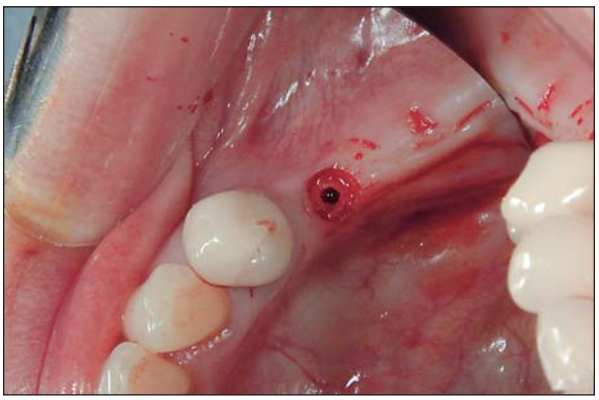


Fig 4 For the minimally invasive procedure, 2 incisions were made: *(left)* a midcrestal incision, and *(right)* a punch created using a circumferential blade.

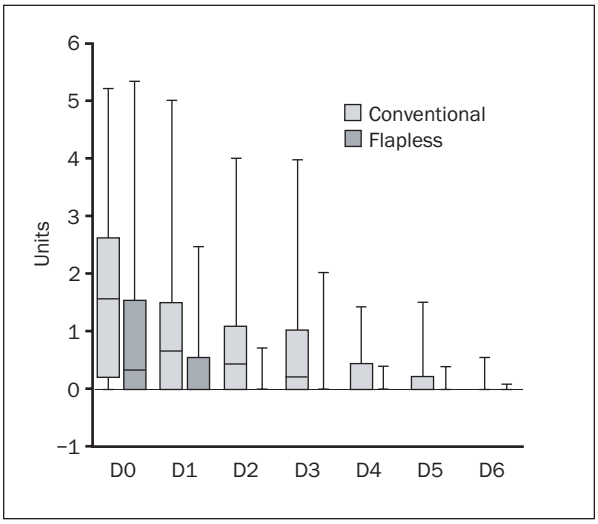


Fig 5 Box-plot graph showing pain rated on a VAS scale for each group and day of the study. There was a significant difference between the 2 groups ($P < .01$), and the decrease in pain was not similar ($P = .05$).

Table 1 Evaluation of Pain Experienced at Each Postoperative Day

	No pain (VAS = 0)			No analgesic medication taken			No. of analgesic tablets taken (mean)	
	Flapless*	Conventional*	*P*	Flapless*	Conventional*	*P*	Flapless	Conventional
D0	43	20	.05	43	10	.03	1.23	2.36
D1	60	30	.02	62	37	.03	0.83	1.80
D2	77	33	< .01	90	53	< .01	0.30	0.96
D3	83	37	< .01	87	67	.07†	0.33	0.70
D4	86	53	.01	90	73	.09†	0.20	0.53
D5	87	63	.04	97	83	†	0.10	0.46
D6	90	77	.02†	97	87	†	0.03	0.30

*Percentage of patients reported for each procedure.
†Not statistically significant.

Table 2 Pain Experience as Described by Patients on the Second and Sixth Postoperative Days

	Flapless		Conventional	
	D2	D6	D2	D6
No	21	28	12	21
Weak	5	2	13	6
Moderate	4	0	3	3
Strong	0	0	2	0

that with the flapless procedure patients experienced less pain for shorter periods of time.

To compare pain experienced with 2 different surgical procedures, the number of patients that did not experience pain (VAS = 0) was compared. Table 1 shows that there was a significant difference between the 2 groups over the 6 postoperative days. From D0 to D3, the number of patients who did not experience pain was more than double with the flapless procedure than with the conventional procedure.

To avoid the placebo effect related to the knowledge of the procedure used, the number of analgesic tablets was also recorded (Table 1). Using the logarithm transformation of the mean number of tablets, a significant difference was found. With the flapless procedure, patients took fewer tablets ($P = .03$), and the number of tablets decreased faster ($P = .04$). Table 1 shows a significant difference for the first 3 postoperative days between the 2 procedures with respect to the percentage of patients who took no medication. With the flapless procedure, patients took medications for a shorter period than with the open-flap procedure (2.1 ± 1.8 days; 3.2 ± 2.1 days; $P = .05$). It should be noted that 5 of 30 patients in group 2 took class 2 analgesics (Diantalvic; Aventis).

To compare the feeling of pain experienced, the patient had to assess the pain he or she experienced at D2 for the 2 preceding days and at D6 for the 6 preceding days (Table 2). Other outcomes recorded, such as edema, hematoma, and paresthesia, occurred more often with the conventional procedure. Edema

occurred in 13 of 30 patients (43.3%) with the conventional procedure and only twice with the flapless technique. Hematoma occurred in 6 patients (20%) with the conventional procedure and in only 1 patient with the flapless procedure.

DISCUSSION

One objective of an IGS is to reduce the invasiveness of surgery and thus reduce surgical outcomes such as pain, edema, and hematoma. Pain can have several origins: the skill of the surgeon, the procedure used, flap design, and particularly, trauma to the periosteum. Pain experienced can be increased by postoperative edema or hematoma. Pain is also related to the patient's emotions, eg, stress and anxiety.[16] This study demonstrated that a minimally invasive procedure decreased the pain experienced by patients when compared with the conventional procedure. Each type of data recorded to evaluate pain, both VAS and the number of analgesic tablets taken, confirmed this result. The latter measure of pain was less influenced by knowledge of the method used and the placebo effect. It should be noted first that differences between the 2 groups could have been increased by using steroidal anti-inflammatory drugs for both. Secondly, 5 patients in group 2 took a class 2 analgesic.

This study also demonstrated that the patient cannot be promised they will have no pain by using the flapless procedure, especially if implants are to be placed near a vital structure. However, they can be told that they will experience less pain, that their pain will be shorter in duration, and that the probability of experiencing no pain with no medication is relatively high (43%). This probability could be increased by taking steroidal anti-inflammatory agents.

Implant placement remains one of the most stressful and anxiety-provoking procedures in dentistry.[18,19] Oral implant treatment is not a health necessity; it is not required by medical necessity as is an implant for orthopedic treatment. The treatment is much more associated with quality of life. The treatment decision belongs to the patient, and acceptance is related to the level of anxiety that is related to the pain expected or experienced by the patient or reported by other patients. Likewise, outcome and compliance fall into this category. Minimally invasive procedures can be expected to be requested by patients to reduce their anxiety.

An IGS can be a useful way to manage patient anxiety and thus to reduce the subjective pain experienced before and after treatment, as demonstrated by the analysis of the qualitative evaluation of pain at D2 and D6. Reduction of anxiety, pain, and patient discomfort after surgery compliment the evolution of implant surgery from imprecision toward precision; from difficult toward simple surgery; from stress toward relative patient and surgeon comfort. These all suggest that flapless surgery can be advantageous.

The open-flap technique causes disruption in the periosteum and its blood supply to the underlying bone, whereas the flapless technique maintains periosteal attachment and blood supply to the bone. Flapless surgery avoids modification of the gingival form approximating the surgical wound. Because it maintains the blood supply, it should increase the success rate of immediately loaded implants. In flapless surgery, the periosteum is reinforced and the labial plate, which expands when an osteotome is pushed into the osteotomy site, is supported. Because reflection and reduces treatment time.[20–23]

One chief disadvantage of the flapless procedure, with or without IGS, is the possibility of contamination of the implant surface or the deposition of epithelial or connective cells in the hole in the bone, which can interfere with osseointegration. Even if this hypothesis is not confirmed by clinical[20,21] or histologic[24] studies, further investigations are required. In some clinical situations, a flap may be advantageous, since the soft tissue can be manipulated to place it in a desirable position after bone grafting, to achieve an esthetic appearance or to manage keratinized tissue around the implant.

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