

Case Series

Minimally Invasive Flapless Implant Placement: Follow-Up Results From a Multicenter Study

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Background: The placement of implants using a minimally invasive flapless approach has the potential to reduce operative bleeding and postoperative discomfort and minimize crestal bone loss. This article presents follow-up data on a prospective clinical study of implants placed using a flapless procedure.

Methods: The original study reported on 57 patients (33 female patients with an age range of 24 to 86 years; 24 male patients with an age range of 27 to 81 years) recruited from three clinical centers (Tucson, Arizona; Gothenburg, Sweden; and Tel Aviv, Israel) who received 79 implants. After an average of 3 years and 8 months, the patients were contacted and invited to return to their respective clinics for reexamination. Thirty-seven patients with 52 implants returned for a follow-up examination; the remaining 20 patients (27 implants) were not available for reexamination and were considered study drop-outs.

Results: The cumulative survival rate at the 3- to 4-year follow-up examination remains at 98.7%, reflecting the loss of one implant. The mean probing depth at abutment connection was 2.2 mm, as reported in the initial study (examination 2 at ~2 years postplacement); it was 2.4 mm at the 3- to 4-year second follow-up examination. This change was not clinically or statistically significant. Bleeding score changes also were not significant between the two intervals. The average crestal bone level was -0.7 mm at examination 2 and -0.8 mm at examination 3, a change that approached significance ($P < 0.06$).

Conclusions: Minimally invasive flapless surgery offers patients the possibility of high implant predictability with clinically insignificant crestal bone loss for up to 4 years. Proper diagnosis and treatment planning are key factors in achieving predictable outcomes. J Periodontol 2009;80:347-352.

KEY WORDS

Case series; follow-up studies; implants, dental; minimally invasive; multicenter studies; surgery.

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Minimal access surgery has had a major impact on the practice of medicine.¹ Humphreys et al.² challenged surgeons to perform minimally invasive procedures and to strive for a new standard of care above traditional approaches. Although minimal access surgery has increased in popularity, there is a learning curve requiring practice and an understanding of basic surgical principles.

Minimal access implant placement using a flapless approach has been reported. The results of a retrospective study³ using flapless surgery reported an implant survival rate of 74.1% the first year the procedure was used, which increased to 100% at year 10. Other investigators⁴ used a punch technique when placing implants in predetermined positions. Using a retrospective analysis, the survival rate at 3 years was 91%, with an average of 1.0 mm marginal bone resorption during the first year, 0.4 mm after the second year, and 0.1 mm after the third year. Computer-assisted drilling guides have been used recently to provide provisional and final implant-supported prostheses.⁵ Recently, an article⁶ reported on flapless implant placement using computerized tomography (CT). Implants were placed in stone models covered with a soft tissue replicating material. Malpositioning occurred as a consequence of implant placement, and perforations were seen in 59.7% (43/72) when the artificial mucosa was removed from the models. Diagnosis and treatment planning for flapless implant placement frequently require the use of CT of the proposed implant sites, which subjects patients to increased doses of potentially harmful radiation.⁷⁻⁹ Case reports have described various techniques for using minimally invasive approaches for implant placement.^{10,11} Minimally invasive implant surgery may have several advantages over conventional surgery, including less postoperative bleeding, less discomfort, minimized crestal bone loss, and shorter surgery and recovery time. Before attempting flapless procedures, surgeons should have experience in placing implants in various clinical situations. Further, clinicians should be familiar with reading CT scans and have a clear understanding of regional anatomy.

We previously published 2-year findings on implants placed using minimally invasive surgery in all edentulous areas except the esthetic zone.¹² At 2 years, the cumulative survival rate using a minimally invasive flapless method was 98.7% for 79 implants placed in 57 patients; one implant was lost. Changes in crestal bone, probing depth, and bleeding scores from baseline to follow-up were insignificant. This article briefly reviews the methods reported in the original paper and presents additional data from that prospective clinical study/trial.

MATERIALS AND METHODS

In 2003, 57 patients (33 females with an age range of 24 to 86 years; 24 males with an age range of 27 to 81 years) were recruited from three clinical centers (Tucson, Arizona; Gothenburg, Sweden; and Tel Aviv, Israel).

Entry criteria included the absence of uncontrolled or poorly controlled diabetes; minimum crestal bone width of 4 mm; vertical bone height from the bone crest to the top of the mandibular canal or maxillary sinus ≥ 12 mm; agreement to follow-up visits for 1 year; and signing a surgical consent form. Patients were excluded for the following reasons: cardiovascular accident within the previous year; radiation to the head and neck; surgical site requiring bone augmentation or sinus grafting; or insufficient bone height and width for implant placement.

Implant survival criteria were the absence of periapical radiolucencies, pain, numbness, and infection.^{13,14}

The study purpose was explained to the patients, and all treatment was carried out according to the Helsinki Declaration.¹⁵ The diagnostic and surgical protocols were described previously. Briefly, prior to treatment, panoramic and parallel cone periapical films were taken of proposed implant sites. Linear tomograms were used to measure crestal bone width and distance to the floor of the maxillary sinus or top of the mandibular canal. Surgical guides facilitated implant placement in most, but not all, sites. Prototype precision drills,** with markings at 7, 10, 13, and 15 mm, were used to make the initial osteotomy, penetrating through the mucosa and into bone. A measurement made from the mucosal margin to the bone crest was recorded and used to determine the appropriate osteotomy depth and implant length. If the planned implant depth as measured from the tomogram was 10 mm and the distance from the mucosal margin to the bone crest was 3 mm, the site was prepared to 13 mm (line on the guiding drill). This allowed the prosthetic table to be placed 3 mm below the mucosal margin. Standard drilling procedures, according to the manufacturer's recommendations, were followed using a minimized countersinking protocol. Implants^{††} were installed without water irrigation. All implants were inserted to a minimum torque of 30 Ncm. Following a one-stage protocol, healing abutments were inserted into the implants.¹⁶ Bone quality and quantity,¹⁷ implant location, and placement by tooth position were recorded on computer data forms. Figure 1 shows a patient who received flapless implant placement and was followed for 41 months post-implant placement. Seventy-nine implants were placed. A baseline periapical radiograph was obtained immediately after implant placement,

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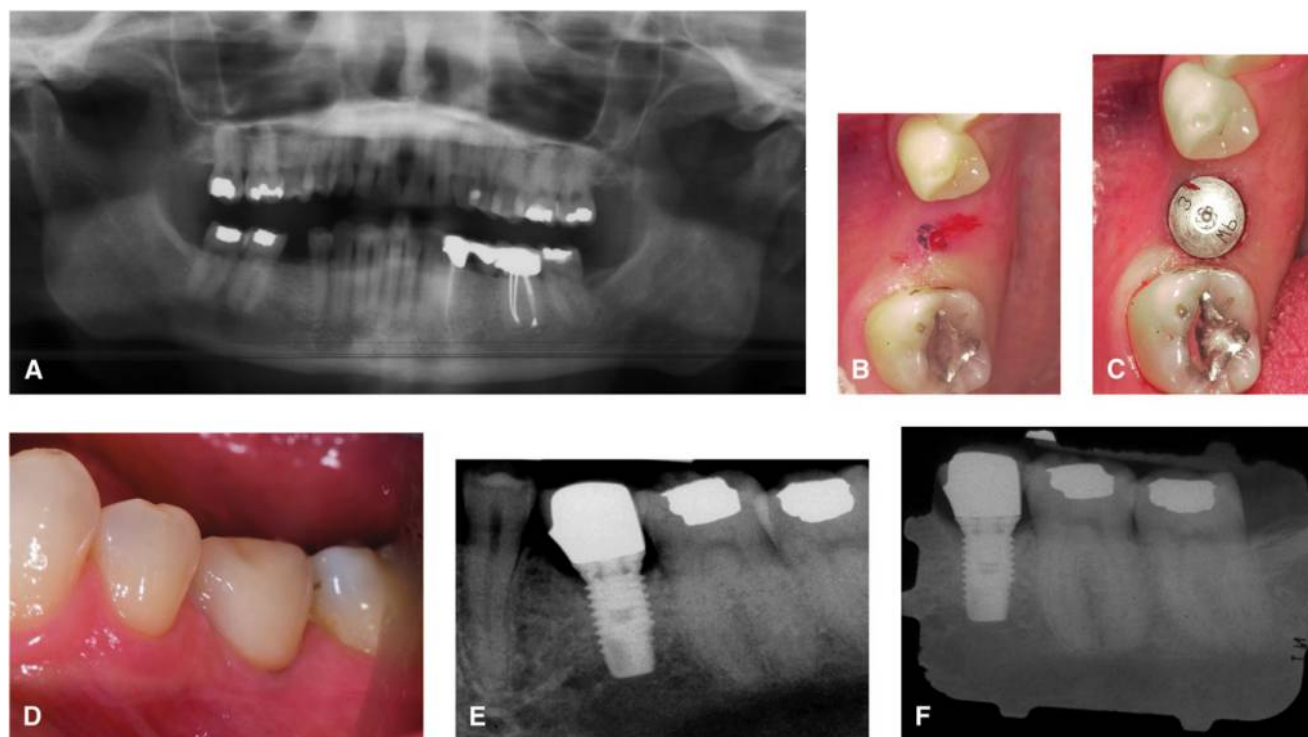


Figure 1.

A) Panogram reveals missing mandibular right second bicuspid. **B)** Initial osteotomy made with pilot drill. **C)** Implant was placed without flap reflection. Note the absence of bleeding. **D)** 41-month follow-up of implant restoration. **E)** Radiograph taken 30 days after completion of implant restoration. **F)** Radiograph taken 41 months after implant restoration.

and a photograph was taken pre- and post-surgery. Patients were seen weekly for 4 weeks. At 4 weeks, probing depth was recorded at the distal, lingual, mesial, and buccal surfaces using a Michigan O periodontal probe with Williams markings.^{††} Gingival bleeding was recorded according to the number of surfaces that bled within 1 minute after probing.¹⁸ These measurements were retaken 1 month after the implant restoration. The measurements were averaged, providing a mean patient score. Radiographs were available for 75 implants and were not available for two patients (four implants). The average time from baseline to follow-up radiograph was 10.5 ± 2.5 months (range: 6 to 16 months). One 3.75×13 -mm implant was lost between abutment connection and the 1-year examination. The radiographs were scanned into a personal computer at 300 dots per inch and saved as tiff files. They were measured in an image-processing program.^{§§} The program converts pixels to millimeters. Measurements were made in millimeters (11.58 pixels/mm) from the top of the implant platform to the first implant thread in contact with bone. The distance from the top of the implant platform for the implants used was 1.9 mm, and the distance from the bottom of the platform to the first implant thread was 0.8 mm. Mesial and distal measurements were made and averaged providing implant and patient means.

Follow-Up

After an average interval of 3 years and 8 months, the 57 patients who initially participated in the study were contacted up to three times and invited to return to their respective clinics for reexamination. Thirty-seven patients (52 implants) returned for reexamination. One patient died, four patients moved, and 15 patients could not be located or did not respond. The examination included review of their health history. Probing depth recordings were made with a Michigan O probe with Williams markings^{|||} at four surfaces for each implant (distal, buccal, mesial, and lingual) from the mucosal margin to the deepest point of probe resistance. Bleeding was recorded according to the number of surfaces that bled within 1 minute after probing. A parallel cone periapical radiograph of each implant site was taken to measure crestal bone levels. Implant mobility was not measured; however, the implant that was lost was mobile. The clinical measurements were recorded on data entry forms. Using the method for measuring bone levels described above, an independent examiner (DK) measured all radiographs. Implant survival criteria were the absence of periapical radiolucencies, pain, numbness, and infection.¹³

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Data Analysis

Kaplan-Meier survival tables were used to determine implant survival.¹⁹ Survival analysis was performed using a computer program designed to track patients, implants, bone quality, quantity, and other variables and to generate survival tables. Survival criteria, as described by Albrektsson et al.¹³ and Roos et al.,²⁰ were used. Grade 2 survival was defined as the absence of soft tissue infections, persistent pain, paresthesia, and discomfort. Further, radiographs revealed ≤ 1 mm of marginal bone resorption during the first year of loading, followed by ≤ 0.2 mm of resorption per year with the absence of peri-implant radiolucencies. If patients received more than one implant, probing and radiographic measurements were averaged, providing a single patient measurement. Generalized estimating equations were used to compare pre- and postmeasurements (identity link and Gaussian error) and to compare changes in probing depth, bleeding, and crestal bone loss. The statistics test used was the z-scores test.

RESULTS

The cumulative survival rate at the 3- to 4-year follow-up examination was 98.7%. These rates are based on

the 37 patients with 52 implants who returned for the follow-up examination. The cumulative survival rate for the study population is given in Table 1. Changes in probing depth, gingival bleeding, and crestal bone loss, as evaluated from radiographs, are given in Table 2. The mean probing depth was 2.2 mm at examination 2 and 2.4 mm at the final examination (exam 3). These changes were not clinically or statistically significant. Bleeding score changes also were not significant between the two examination intervals (exams 2 and 3). The average crestal bone level was -0.7 mm at examination 2 and -0.8 mm at examination 3, indicating a small change that approached significance ($P < 0.06$; Table 2).

DISCUSSION

Minimally invasive implant surgery offers advantages over the traditional flap access approach. There may be minimized bleeding, decreased surgical times, and less patient discomfort. The average time for implant placement was 28 ± 13.08 minutes (range: 10 to 60 minutes).¹² Bleeding during surgery and postoperative patient discomfort were not measured. Anecdotally, patients frequently remarked that there was minimal

Table 1.
Implant Survival Table

Interval	Patients (n)	WDP (n)	Implants* (n)	Lost (n)	WDI (n)	SR (%)	CSR (%)
Placement to abutment	57	0	79	0	0	100	100
Abutment to 1 year	57	6	79	1	6	98.7	98.7
1 to 2 years	51	8	72	0	11	100	98.7
2 to 3 years	43	6	61	0	9	100	98.7
3 to 4 years	37	17	52	0	31	100	98.7

WDP = withdrawn patients; WDI = withdrawn implants; SR = survival rate; CSR = cumulative survival rate.

Grade 2 survival rates based on Roos et al.²⁰ classification.

* Triton Implant Management System, Tucson, AZ.

Table 2.
Mean Probing Depth (PD), Bleeding Scores, and Radiographic Measurements Between Examinations 2 and 3

Examination	n	Mean (mm)	Minimum (mm)	Maximum (mm)	Difference Between PD 2 and PD 3	95% Confidence Interval
PD 2	52	2.2	1.0	4.5	$P < 0.11$	-0.03 to 0.32
PD 3	52	2.4	0.25	4.0		
Bleeding 2	52	0.3	0	1.5	$P < 0.96$	-0.13 to 0.12
Bleeding 3	52	0.3	0	1.3		
Radiograph 2	52	0.7	0.2	1.9	$P < 0.06$	-0.01 to 0.23
Radiograph 3	52	0.8	0.2	1.7		

to no postoperative discomfort. To our knowledge, this was the first multicenter, prospective clinical trial evaluating minimally invasive flapless implant surgery. Linear tomograms or CT were used for diagnostic purposes. These scans revealed available bone height and width and the location of vital structures, such as the mandibular canal, mental nerve, and maxillary sinuses, as well as bone undercuts or aberrations. At the 3- to 4-year follow-up, the cumulative survival rate was 98.7%, reflecting the loss of one implant. It is important to recognize that there is patient drop-out in long-term clinical trials. Loss of patients should be accounted for in follow-up studies. The effect of patient drop-out is accounted for by reporting survival tables. Survival tables reflect patient compliance in returning for follow-up examinations and give a true picture of how many patients returned for follow-up examinations.^{21,22} The use of survival tables strengthens the relevance of clinical trials. These tables require that every patient and implant in the study be entered into a database capable of following patients and implants over time. The tables are based on Kaplan-Meier statistics, which measure the survival of patients with cancer.¹⁹ Survival rate indicates implants being present during the period of follow-up. Cumulative survival reveals the implants present over the entire study period.

In this study, the high implant survival rates were attributable to careful diagnosis and treatment planning and following a simple, yet predictable, surgical protocol. The initial osteotomy was made with a pointed-tipped precision guiding drill. This instrument produces a small initial opening through the mucosa and into bone. Once the trajectory is evaluated, preparation of the final osteotomy is completed. The small penetration through mucosa and bone removed a small amount of mucosa. Enlarging the osteotomy removed more mucosa. Although not measured, removal of this apparently small amount of tissue did not seem to have a negative effect on the clinical outcome. It seems that second-stage surgery also removes mucosa overlying implants. There are varying opinions on the necessity of having keratinized mucosa surrounding dental implants. In a dog study,²³ the investigators determined that keratinized tissue was not necessary for the maintenance of tissue health adjacent to dental implants. Other investigators²⁴ reported from an exhaustive review of the literature that there is inconclusive evidence on the importance of having keratinized tissue adjacent to dental implants. Ideally, it would have been advantageous to have controls. The survival rates for dental implants are exceedingly high. Using a flapless approach minimized access for implant placement and was not a major deviation from standard implant placement; as such, the use of controls was not deemed necessary. A randomized controlled clinical trial is necessary to

determine whether flapless implant placement is superior or equivalent to implant surgery with access flaps.

At the final examination, probing depth changes between implant restoration and follow-up were not clinically or statistically significant. Changes in mucosal inflammation as evidenced by bleeding were also insignificant. At abutment connection, crestal bone loss, as measured from radiographs, was clinically insignificant (average bone loss -0.7 mm). After 3 to 4 years, the average crestal bone loss was -0.8 mm. The difference between examinations approached statistical significance ($P < 0.06$), but it was considered clinically insignificant, indicating stable osseous crests from implant restoration to the 3- to 4-year follow-up examination. This minimal bone loss may be attributed to several factors, including measurement error, minimal countersinking, and the use of a flapless procedure. Results from dog studies²⁵⁻²⁷ indicated that exposure of bone during periodontal surgery led to bone loss. A clinical study¹² on flapless implant placement reported clinically and statistically insignificant bone loss.

The safety and efficacy of placing implants using a flapless approach has also been evaluated in dogs.²⁸ In that study, implants were placed in dogs using a flapless approach on one side of the mandible and an open approach on the opposite side. The animals were sacrificed following 3 months of healing, and the histologic evaluation showed a high bone-implant contact (flapless surgery: $54.7\% \pm 8.4\%$; control: $52.2\% \pm 13.0\%$; $P > 0.05$) without evidence of gingival tissue or foreign body intrusion. There were no significant differences in marginal bone level between the surgical protocols. Another study²⁹ examined the effect of flapless implant surgery on crestal bone loss and osseointegration in a canine mandible model. Implants were placed using a flapless technique on one side of the mandible, whereas the other side received implants using a flapped approach. After a healing period of 8 weeks, micro-CT was performed at the implantation sites. Osseointegration was calculated as the percentage of implant surface in contact with bone. Mean osseointegration was greater at flapless sites (70.4%) than at sites with flaps (59.5%; $P < 0.05$). Furthermore, the mean peri-implant bone height was greater at flapless sites (10.1 mm) than at sites with flaps (9.0 mm; $P < 0.05$).

Results from the present prospective, multicenter study demonstrated that flapless surgery is capable of achieving excellent clinical results. None of the 37 patients reexamined reported paresthesia or impaired speech. When indicated, flapless surgery can achieve results comparable to surgery with reflected flaps. The procedure requires clinical experience as well as an awareness of dental anatomy and the location of vital structures.

CONCLUSIONS

Minimally invasive flapless surgery offers patients the possibility of having high implant predictability with clinically insignificant crestal bone loss for up to 4 years. Proper diagnosis and treatment planning are key factors in achieving predictable outcomes.

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