Minimally Invasive Flapless Implant Surgery: A Prospective Multicenter Study

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ABSTRACT

Background: Placement of implants with a minimally invasive flapless approach has the potential to minimize crestal bone loss, soft tissue inflammation, and probing depth adjacent to implants and to minimize surgical time.

Purpose: The aim of this multicenter study was to evaluate implant placement using a minimally invasive one-stage flapless technique up to 2 years.

Materials and Methods: Fifty-seven patients ranging in age from 24 to 86 years were recruited from three clinical centers (Tucson, AZ, USA; Tel Aviv, Israel; Göteborg, Sweden). Seventy-nine implants were placed. A small, sharp-tipped guiding drill was used to create a precise, minimally invasive initial penetration through the mucosa and into bone (Nobel Biocare, Yorba, Linda, CA, USA). Implants were placed according to the manufacturer's instructions, with minimal countersinking. The parameters evaluated were total surgical time, implant survival, bone quality and quantity, implant position by tooth type, depth from mucosal margin to bone crest, implant length, probing depth, inflammation, and crestal bone changes. At 2 years, for 79 implants placed in 57 patients, the cumulative success rate using a minimally invasive flapless method was 98.7%, indicating the loss of 1 implant. Changes in crestal bone for 77 baseline and follow-up measurements were insignificant (radiograph 1: mean 0.7 mm, SD 0.5 mm, range 2.8 mm, minimum 0.2 mm, maximum 3.0 mm; radiograph 2: mean 0.8 mm, SD 0.5 mm, range 3.4 mm, minimum 0.12 mm, maximum 3.5 mm). Using descriptive statistics for 78 patients (one implant lost), mean changes for probing depth and inflammation were clinically insignificant. The average time for implant placement was 28 minutes (minimum 10 minutes, maximum 60 minutes, SD 13.1 minutes). Average depth from mucosal margin to bone was 3.3 mm (SD 0.7 mm, minimum 2 mm, maximum 5 mm, range 3 mm). Thirty-two implants were placed in maxillae and 47 in mandibles.

Conclusions: The results of this study demonstrate that following diagnostic treatment planning criteria, flapless surgery using a minimally invasive technique is a predictable procedure. The benefits of this procedure are lessened surgical time; minimal changes in crestal bone levels, probing depth, and inflammation; perceived minimized bleeding; and lessened postoperative discomfort.

KEY WORDS: bone quality, bone quantity, Brånemark dental implants, flapless, minimally invasive, one stage, precision drilling guide

Minimal access surgery has revolutionized the practice of medicine.[1] Laparoscopic surgery for gynecology, orthopedics, and abdominal surgery has improved surgical outcomes and minimized patient hospital stays. Laparoscopic surgery and the use of robotics for prostate surgery have minimized blood loss, transfusion rates, postoperative pain, and length of hospitalization when compared with open radical prostatectomy.[2] Humphreys and colleagues[2] have challenged surgeons to perform minimally invasive procedures and to strive for a new standard of care above traditional approaches.

Traditional access for implant placement has been by a flap approach. Original protocols called for burying implants from 4 to 6 months with mucosal flaps.[3,4] The primary purpose of burying implants is to eliminate bacterial contamination and minimize micromotion.

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Over the past 20 years, flap designs for implant placement have been modified.[5] Implants are placed in either one or two stages.[6–9] Minimized access for implant placement by a flapless approach has been reported.[10] The results of a retrospective study using flapless surgery reported implant survival rates from 74.1% for the first year the procedure was applied to 100% at the tenth year, and others used a punch technique when placing implants in predetermined positions.[11] Using retrospective analysis, at 3 years, the survival rate was 91%, with an average of 1.0 mm marginal bone resorption during the first year and 0.4 mm after the second year and 0.1 mm for the third year. Computer-assisted drilling guides have recently been used to provide provisional and final implant-supported prostheses.[12–15] Case reports have described various techniques for using minimally invasive approaches for implant placement.[16–19] Minimally invasive implant surgery potentially has several advantages. There may be less postoperative bleeding, less discomfort, minimized crestal bone loss, and shorter surgery and recovery time.

The purpose of this multicenter study was to present findings related to implant placement using a minimally invasive flapless technique. Measurements from the mucosal margin to bone crest, cumulative success rates, and changes in marginal bone levels, probing depth, and bleeding scores were evaluated. The total time from the start to the end of surgery was also recorded.

MATERIALS AND METHOD

Fifty-seven patients ranging in age from 24 to 86 years were recruited from three clinical centers (Tucson, AZ, USA; Göteborg, Sweden; Tel Aviv, Israel). Thirty-three female patients (age range 24–86 years) and 24 male patients (age range 27–81 years) were recruited for this study.

Entry criteria included the following:

1. Absence of uncontrolled or poorly controlled diabetes
2. Minimum crestal bone width of 4 mm
3. Vertical bone height from bone crest to top of mandibular canal or maxillary sinus 12 mm or greater
4. Agreed to follow-up visits for 1 year
5. Signed surgical consent forms

Exclusion criteria included the following:

1. History of cardiovascular accident within previous year
2. Radiation to the head and neck
3. Surgical site would require bone augmentation or sinus grafting

The study purpose was explained to all patients, and surgical consent forms were signed. All treatment was performed within the Helsinki accords.[20] Prior to treatment, panograms 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. If tomograms were not available, ridge mapping was used to determine ridge crest width. One hour prior to surgery, patients took 2 g of amoxicillin or, if allergies were present, 600 mg of clindamycin. Patients were anesthetized with an appropriate anesthetic and in some instances were medicated with conscious sedation. The time from the beginning to the end of the procedure was recorded. Surgical guides were used at the discretion of the surgeon. Figure 1, A through J, demonstrates treatment of a patient using the flapless procedure. Prototype precison drills (Nobel Biocare, Yorba Linda, CA, USA) were used to make the initial osteotomy, penetrating through the mucosa and into bone (Figure 1A). This drill has depth markings at 10 and 13 mm. A measurement was made from the mucosal margin to the bone crest. This measurement 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 head of the implant to be placed 3 mm below the mucosal margin. Standard drilling procedures according to the manufacturer's recommendations (Nobel Biocare, Göteborg, Sweden) were followed using a minimized countersinking protocol. TiUnite™ (Nobel Biocare, Sweden, USA, Tel Aviv, Israel) implants were installed without water irrigation. All implants were inserted to a minimum torque of 30 Ncm. Following a one-stage approach, healing abutments were inserted into the implants.[6,21] Bone quality, quantity, location of the implant, and placement by tooth position were recorded onto computer data forms. A baseline periapical radiograph was taken immediately after implant installation, and photographic documentation was accomplished. Patients were seen weekly for 4 weeks. At 4 weeks, baseline probing depth and gingival inflammation scores were taken. Probing depth was recorded using Michigan O

probes with Williams's markings (Hu-Friedy Manufacturing Company, Chicago, IL, USA). Probing depths were taken at four surfaces around the healing abutments (distal, buccal, mesial, and lingual). Bleeding was recorded according to the number of surfaces that bled within 1 minute after probing. 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. The average time from baseline to follow-up radiograph was 10.5 months (SD 2.5 months, minimum 6 months, maximum 16 months). One implant was lost between insertion and abutment connection, and for two patients, radiographs could not be located. The radiographs were scanned into a personal computer at 300 dpi and saved as tiff files. They were measured in *NIH*

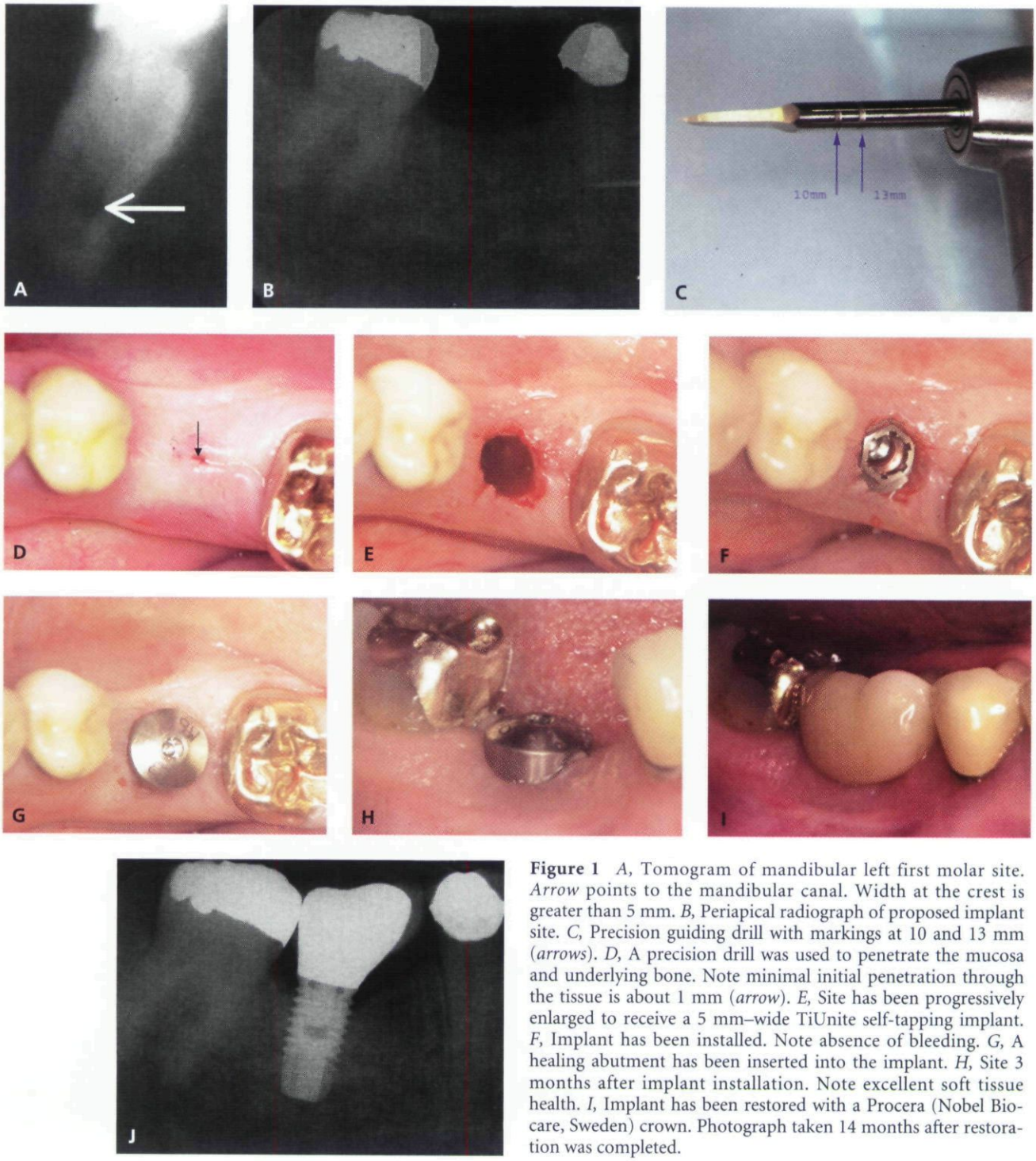

Figure 1 *A,* Tomogram of mandibular left first molar site. *Arrow* points to the mandibular canal. Width at the crest is greater than 5 mm. *B,* Periapical radiograph of proposed implant site. *C,* Precision guiding drill with markings at 10 and 13 mm (*arrows*). *D,* A precision drill was used to penetrate the mucosa and underlying bone. Note minimal initial penetration through the tissue is about 1 mm (*arrow*). *E,* Site has been progressively enlarged to receive a 5 mm–wide TiUnite self-tapping implant. *F,* Implant has been installed. Note absence of bleeding. *G,* A healing abutment has been inserted into the implant. *H,* Site 3 months after implant installation. Note excellent soft tissue health. *I,* Implant has been restored with a Procera (Nobel Biocare, Sweden) crown. Photograph taken 14 months after restoration was completed.

Image for PC (Scion Corporation, Bethesda, MD, USA) at 11.58 pixels/mm. The measurements were saved for statistical evaluation. If more than one implant was placed per patient, the bone scores were averaged. Implant survival criteria were absence of periapical radiolucencies, pain, numbness, and infection.[22,23]

DATA EVALUATION

Kaplan-Meier[24] survival tables were used to determine implant survival. If patients received more than one implant, the measurements were averaged, providing a single patient measurement. Descriptive statistics were used to evaluate changes in probing depth, gingival inflammation, crestal bone loss, total surgical time, and number of implants placed according to tooth position. Total time was compared by groups (10–20 minutes, 21–30 minutes, 31–40 minutes, and 41–60 minutes). Average depth from the mucosal margin to the alveolar crest was also determined.

RESULTS

At 2 years, for 79 implants placed in 57 patients, the cumulative success rate using a minimally invasive flapless method was 98.7%, indicating the loss of one implant (Table 1). Implant placement according to bone quality and quantity can be seen in Table 2.[25] Sixty-seven implants were placed in bone shape A (no resorption), whereas 12 implants were inserted into shape B (minimal resorption). Seventy implants were placed in type 2, seven in type 3, and one in type 4 bone. Table 3 lists the number of implants placed by size and the number of implants placed and lost. Of the 79 implants placed, 22 were 5 mm–wide TiUnite (Nobel Biocare, USA) implants. Changes in probing depth, gingival inflammation, and crestal bone loss, as evaluated from radiographs, can be seen in Table 4. Changes in probing depth and bleeding between baseline and 1 month after restoration (mean time 5.5 months, SD 1.8 months, minimum 3 months, maximum 11 months, range 8 months)

TABLE 1 Cumulative Success Rate for Implants Placed with Flapless Surgery

Time Period (yr)	Patients	Implants	Lost	SR	CSR
0	57	79	0	100	100
0–1	56	78	1	98.7	98.7
1–2	25	35	0	100	98.7

CSR = cumulative success rate; SR = success rate.

TABLE 2 Bone Quality and Quantity for Flapless Surgery

Quality	A*	B	C	C	Total
1	1	0	0	0	1
2	61	9	0	0	70
3	5	2	0	0	7
4	0	1	0	0	1
Total	67	12	0	0	79

Adapted from Lekholm and Zarb.[25]

were clinically insignificant (probing depth, first examination: 2.2 mm, SD 0.9; probing depth, second examination: 2.3 mm; SD 0.8; bleeding, first examination: 0.35, SD 0.04; bleeding, second examination: 0.36, SD 0.5). Changes in crestal bone measurements were clinically insignificant (0.07 mm). Thirty-two implants were placed in maxillae and 47 in mandibles. Figure 2 describes the number of implants placed by tooth position. Implants were placed in posterior sextants and in the esthetic zone. Measurements from the mucosal margin to the alveolar crest ranged from 2 to 5 mm. Eight sites were 2 mm, 43 were 3 mm, 25 were 4 mm, and 2 were 5 mm (SD 0.7 mm, minimum 2 mm, maximum 5 mm, range 3 mm) (see Table 3). Figure 3 demonstrates the number of implants placed according to time group. The average time from the start of implant surgery to completion was 28 minutes (SD 13.08 minutes, minimum 10 minutes, maximum 60 minutes, range 50 minutes).

TABLE 3 Number and Size of Implants Placed and Lost

	Study		
Flapless	Implant Sizes	Implants Lost	Number of Implants Placed
	3.75 × 8.5		2
	3.75 × 10		22
	3.75 × 15		1
	3.75 × 13	1	10
	3.75 × 15		5
	4.00 × 10		3
	4.00 × 11.5		4
	4.00 × 13		10
	5.00 × 10		19
	5.00 × 12		1
	5.00 × 13		2
Total		1	79

TABLE 4 Average Measures between Baseline (1) and Second (2) Examinations for Probing Depth, Bleeding Scores, and Radiographs

	Number	Mean	SD	SE Mean	Minimum	Maximum	Range
PD1	78	2.20	0.9	0.11	1.0	4.5	3.5
PD2	78	2.30	0.8	0.09	0.25	4.0	3.75
Bleeding 1	78	0.35	0.41	0.04	0.00	1.5	1.5
Bleeding 2	78	0.36	0.45	0.05	0.00	1.75	1.75
Radiograph 1	75	0.72	0.48	0.05	0.2	3.0	2.8
Radiograph 2	75	0.79	0.49	0.05	0.1	3.5	3.4

PD = probing depth; SE = standard error.

DISCUSSION

Minimally invasive implant surgery offers advantages over the traditional flap access approach. There may be minimized bleeding, decreased surgical times, minimized patient discomfort, and, possibly, less cost. To our knowledge, this is the first multicenter, prospective clinical trial evaluating minimally invasive flapless implant surgery. At 2 years, the cumulative success rate is 98.7%, indicating loss of one implant. The high success rate is 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 drill creates an opening into mucosa and bone about the size of a periodontal probe tip and guides preparation of the final osteotomy. Once the angulation and trajectory are correct, the osteotomy can be prepared in the usual manner. Crestal bone loss, as measured from radiographs, was clinically insignificant (average bone loss 0.05 mm). This clinically insignificant bone loss may be attributable to several factors, including measurement error, minimal countersinking, and use of a flapless procedure. In dog studies, flap exposure during periodontal mucoperiosteal procedures resulted in 2 to 4 mm of crestal bone loss.[26–28] This loss may occur from bone exposure and trauma during flap reflection and manipulation. Flapless surgery may minimize or eliminate crestal bone loss. Campelo and Camara[10] reported the results from a retrospective clinical trial evaluating one-stage flapless surgeries over a 10-year period. Survival for implants placed during 1990 was 74.1%, whereas implant survival for implants placed in 2000 was 100%. Early implant loss was associated with the learning curve and patient selection. Changes in crestal bone loss were not evaluated. Diagnostic bone mapping was used to preoperatively determine bone morphology, after which a tissue punch gained minimal access to the underlying bone.[11] All implants were placed in the maxilla and immediately loaded. Survival at the 12- to 24-month interval was 90.7%. Interestingly, all implant loss occurred during the first 8 weeks after loading single implants. The decreased survival rate may be related to immediately loading maxillary implants. During the first year, there was an average of 1 mm bone loss, whereas the average bone loss for the second year was 0.1 mm. Slight differences between our study and the previously cited article may be related to measurement methods, the amount of countersinking, and the effect of immediate loading.

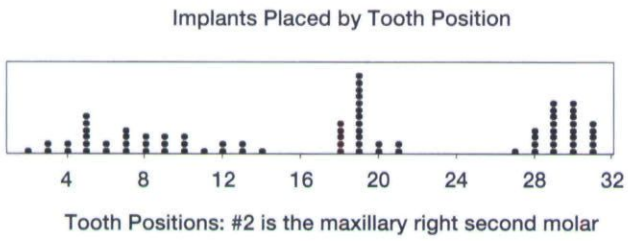

Figure 2 Number of implants placed according to tooth position.

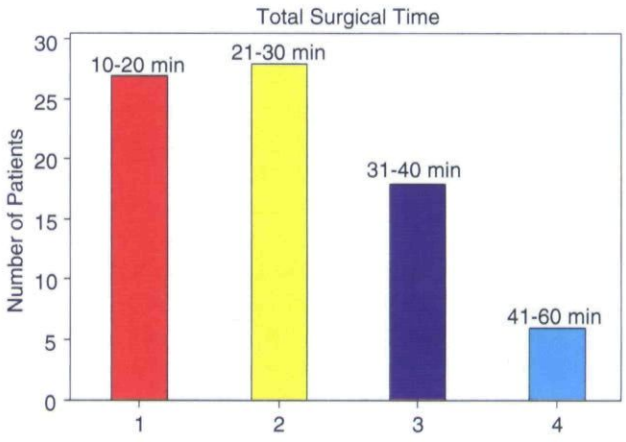

Figure 3 Total surgical time according to the number of treated patients.

In the present study, 32 implants were placed in the maxillary arch and 47 in mandibles, indicating high success rates for implants placed in both arches. Sixteen implants were placed from maxillary canine to canine, providing evidence that flapless surgery can be performed in the esthetic zone with favorable outcomes. Further, in the esthetic zone, this method provides the possibility of retention of almost all keratinized tissues, thus providing enhanced soft tissues for implant esthetics.

CONCLUSIONS

Within the limits of this study, the results demonstrate that following diagnostic treatment planning criteria, a minimally invasive flapless implant placement protocol achieves predictable results (98.7% cumulative success rate). The benefits of this procedure are lessened surgical time, perceived minimized bleeding, and minimal changes in crestal bone loss and probing depth. Although not measured, there was perceived lessened postoperative discomfort when compared with an open approach.

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