Early Function of Splinted Implants in Maxillas and Posterior Mandibles, Using Brånemark System® TiUnite™ Implants: An 18-Month Prospective Clinical Multicenter Study

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ABSTRACT

Background: Immediate or early loading of implants placed in maxillas and posterior mandibles has been a concern as bone density is often low in these areas, making it difficult to establish good initial implant stability. By adapting implant design and insertion protocols, however, high initial implant stability may be achieved in these regions. Further, a modified implant surface texture has been proved to help in maintaining stability during the initial healing period.

Purpose: The aim of the present study was to investigate the clinical performance of oxidized titanium implants (TiUnite™, Nobel Biocare AB, Gothenburg, Sweden) when used for early function in the maxilla and in the posterior mandible, locations where the bone density often is low. A further aim was to evaluate the marginal bone level at oxidized implants and compare it with that of machined-surface implants used in a previous study.

Materials and Methods: Thirty-one patients were consecutively included in the study, and 37 edentulous areas in maxillas and posterior mandibles were treated. Bruxism and uncontrolled periodontal disease were exclusion criteria. Temporary prostheses were generally placed within 9 days but not after 16 days from implant placement. A previous study applying the same study design and clinical protocol but using machined-surface implants was used for comparisons.

Results: Of the 111 implants installed, 1 failed, giving an overall survival rate of 99.1% after 18 months. The prosthesis survival was 100%. The marginal bone resorption was 0.8 mm (standard deviation [SD], 1.0), as opposed to 1.6 mm (SD, 1.3) in the previous study with machined-surface implants, but was not statistically significantly different ($p = .10$).

Conclusion: The present clinical protocol (aiming at high primary stability) and the use of oxidized titanium implants for early functional loading in the maxilla and the posterior mandible resulted in a high implant survival rate and a favorable marginal bone level during a follow-up of 18 months. The difference in marginal bone resorption between the oxidized implants in the present study and the machined implants from a previous investigation with the same study design was not statistically significant.

KEY WORDS: dental implants, early function, oxidized implants, posterior regions, prospective clinical multicenter study, provisional prosthesis

The original protocol for implant treatment described by Brånemark and colleagues[1] included 3 to 6 months of submerged healing time before prosthesis attachment. The results of this technique have been documented in numerous clinical trials.[2–5] The two most evident disadvantages of this approach are the need for a second surgery and a long waiting time for the patient before prosthetic rehabilitation.

Several studies[6–10] have demonstrated that in terms of success rate, a one-stage surgical technique is comparable to the traditional submerged one. At the beginning of the 1990s, the terms *early loading* and *immediate loading* started to appear in scientific publications and indicated the possibility of applying functional loads to an implant before the conventional period of 3 to 6 months.

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Henry and Rosenberg[11] applied an immediate loading protocol in mandibles, anterior to the mental foramina, and obtained complete success up to a 2-year observation period. These results were confirmed by Ericsson and colleagues,[12] who placed five to six implants anterior to mental foramina, loaded them with a fixed bridge within 3 weeks after placement, and achieved 100% success during the 5-year observation period.

A study by Schnitman and colleagues[13] highlighted the risks of immediately loading implants in the posterior mandible. The 10-year follow-up showed a 100% success rate in the unloaded group, compared to 84.7% in the immediately loaded group. The majority of the failures occurred in the areas distal to the mental foramina.

Another area in which immediate loading procedures seem to be less successful is the posterior maxilla, as demonstrated by Glauser and colleagues.[14] They reported a success rate of 91% for implants placed in regions other than the posterior maxilla, as opposed to 66% for implants installed in the posterior maxilla.

As well as the implant's geometry, the implant's surface properties are argued to influence bone healing and implant stability over time.[15] Nowadays a wide range of implant surfaces are available, such as sandblasted and acid-etched surfaces,[16,17] acid-etched surfaces,[18] and surfaces with a hydroxyapatite coating.[19]

Hall and Lausmaa[20] presented a method for increasing the titanium oxide layer and creating a porous surface on the implant by using anodic oxidation, which has resulted in the commercially available implant surface TiUnite™ (Nobel Biocare, Gothenburg, Sweden). In a prospective clinical study by Glauser and colleagues,[21] these implants were placed in soft bone regions, and a cumulative success rate of 97.1% was achieved after 1 year of loading. In a prospective randomized study with immediately loaded implants in the posterior part of the mandibles, Rocci and colleagues[22] indicated a 10% higher success rate with such surface-modified implants compared to machined-surface implants.

An animal study by Henry and colleagues[23] demonstrated that greater torque was required to remove such anodic oxidized implants after healing than was required for machined implants, indicating that the bone anchorages of the former are more stable.

The stability of implants with the same respective type of oxidized and machined surfaces was also evaluated by Rompen and colleagues,[24] who used resonance frequency analysis (RFA). After 3 weeks of healing, the stability values decreased significantly in the control but not in the test group. This decrease was ascribed to a demineralization of the bone following surgery (resorption). It was hypothesized that the oxidized implants' surfaces allow earlier bone formation directly to the implant surface, a compensation for the resorption.

In a histomorphometric and biomechanical analysis in rabbits, Albrektsson and colleagues[25] analyzed bone response to oxidized test implants and machined-surface control implants. The authors found both greater bone-to-implant contact and greater removal torque values in the test group than in the control group.

On the basis of the above findings, it was hypothesized that the use of implants with the described oxidized surface at early loading in maxillas or mandibles distal to mental foramina would yield a survival rate at least as good as that of the conventional two-stage protocol.

In a previous prospective multicenter clinical study, Vanden Bogaerde and colleagues[26] evaluated the possibility of early implant function in oral locations where bone density often is low, namely, in the maxilla and in the posterior part of the mandible. The authors treated 31 patients. At the 18-month follow-up the cumulative survival rate was 96.8%.[26] The initial implant stability that was achieved with the slightly tapered implant used was suggested to play a fundamental role in the implant's capacity to bear occlusal loads in the initial phase.

The aim of the present study was to investigate the clinical performance of oxidized titanium implants (TiUnite) applying the same protocol used in the previous study. A further aim was to evaluate the marginal bone level at oxidized implants and to compare it with that found at the machined-surface implants used in the previous study.

MATERIALS AND METHODS

Patient Selection

A total of 31 patients (18 females and 13 males; mean age of 54 years [range, 36–78 years]) were consecutively included in the study, which was conducted in four private centers in north Italy during the year 2001. A total of 111 implants were inserted in 37 edentulous areas. Of these, 69 implants were inserted in 22 partial ridges in maxillas, and 42 implants were inserted in 15 partial posterior ridges in mandibles.

The inclusion criteria were nonsmoking, good general health, and partial edentulism in the maxilla or the mandible posterior to the mental foramina. The most important prerequisite for the treatment was that the bone height had to be sufficient for placing implants with a minimum length of 8.5 mm. The insertion torque before complete implant seating had to be a minimum of 40 Ncm.

Patients affected with bruxism and patients with uncontrolled periodontal disease were excluded from the study. Patients were informed of the benefits and risks of the early loading procedure and gave informed consent to the treatment. They also agreed to follow the scheduled maintenance program of radiographic examinations.

In total, 111 implants with a TiUnite surface (Brånemark System®, Nobel Biocare AB, Gothenburg, Sweden) were placed. The lengths of the implants ranged from 8.5 to 15 mm both in maxillas and in mandibles (Table 1). Of the 111 installed implants, 93 were Brånemark System Mk IV implants and the remainder were Mk III implants.

Surgical and Prosthetic Procedures

The initial surgical incision was made in the middle of the crest and continued with a vertical distal incision to allow a complete release of the mucogingival flap. By means of a surgical stent, the aimed positions of the implants were marked on the cortical bone surface with a round bur. In preparing the implant site, twist drills of increasing diameters were used, allowing individual adaptation of site dimensions to local bone density (underpreparation). Countersinking was completely eliminated to maintain the cortical bone, allowing the stable seating of the implant. In the presence of dense bone (both in the maxilla and in the mandible), the Mk III implant was used ($n = 18$).

The final abutments (Multi-Unit and Procera®, Nobel Biocare AB, Gothenburg, Sweden) were connected to the implants at surgery. After the connection of the prosthetic transfers to the abutments, the mucoperiosteal flap was carefully adapted to the abutments and secured by interrupted suture. Impressions were taken in a traditional manner with an open tray and a polyether rubber material (Impregum™ F, 3M ESPE AG, Seefeld, Germany). After complete hardening, the impressions were removed from the mouth, and the healing copings were immediately screwed onto the abutments. Centric relation was recorded with wax bites.

Postsurgical care consisted of an antibiotic (amoxicillin trihydrate/potassium clavulanate [Augmentin®, GlaxoSmithKline, Uxbridge, Middlesex, UK], 1 g twice daily for 1 week, starting just before surgery) and an antiinflammatory medication (nimesulide [Aulin®, Helsinn Birex Therapeutics Ltd., Dublin, Ireland]) twice

TABLE 1 Number of Implants by Position and Length

	Position in Maxilla													
Length (mm)	17	16	15	14	13	12	11	21	22	23	24	25	26	27
8.5	—	1	—	—	—	—	—	—	—	—	—	—	—	—
10.0	—	1	2	—	—	—	—	—	—	—	1	1	2	—
11.5	—	—	2	1	—	—	—	—	—	—	—	1	—	—
13.0	—	1	4*	6	5	2	4	5	3	6	4	5	—	—
15.0	—	1	2	3	1	—	1	1	1	—	2	—	—	—

*Site of implant failure.

	Position in Mandible													
Length (mm)	47	46	45	44	43	42	41	31	32	33	34	35	36	37
8.5	—	—	—	—	—	—	—	—	—	—	—	—	—	1
10.0	—	3	1	1	—	—	—	—	—	—	1	1	1	1
11.5	1	1	4	2	—	—	—	—	—	—		1	3	1
13.0	1	3	3	2	—	—	—	—	—	—	3	3	3	—
15.0	—	—	—	—	1	—	—	—	—	—	—	—	—	—

daily for 4 days. Patients were also instructed to rinse with 0.2% chlorhexidine solution twice daily for 20 days.

Temporary prostheses were attached an average of 9 days after implant installation (range, 4–16 days). During the waiting period patients were instructed not to wear any type of removable denture.

The prostheses had metal frameworks without distal cantilevers and had acrylic occlusal surfaces with narrow platforms and flat cusps. The occlusion was adjusted to light centric contacts, avoiding any contact laterally or in protrusion. Indicator papers had to leave less evident signs on the implant-supported prostheses than on the neighboring teeth.

Permanent fixed prostheses were delivered after the conventional healing time of 3 to 6 months. Prostheses were fabricated with porcelain fused to gold alloy.

Radiographic Examination

Standardized intraoral radiography was performed at four specific times: (1) at implant installation (baseline), (2) 1 month after implant installation, (3) 3 to 6 months after implant installation, and (4) 1 year after final prosthesis delivery (15–18 months after implant installation). Radiography was performed with a modified collimator device (Dentsply RINN, Elgin, IL, USA) in order to achieve high reproducibility over time with a parallel technique. The radiographs were analyzed by an independent radiologist and were evaluated with a magnifying glass with a fixed ruler. The reference level was the implant-abutment interface. Bone levels were registered mesially and distally to the implant.

Implant Survival Criteria

Survival is related to the implant function at the time of the checkup, whereas success also includes the probability of the implant remaining stable as judged by annual bone loss. As the patients in the present study were observed for only 18 months, the success classification could not be applied. Therefore, implants were classified as survivals when they were clinically stable and when they fulfilled their purported function without any discomfort to the patient.

Patients with Machined-Surface Implants

In a previous prospective study the same study protocol was used (ie, the patients were selected according to the same inclusion and exclusion criteria), and the treatment also followed the same clinical protocol.[26] However, this group of patients received implants with a machined surface. The group (n = 31) had a gender distribution and mean age similar to those of patients in the present study. Sixty-eight implants were inserted in 17 partial ridges in maxillas, 56 implants were inserted in 19 partial ridges in mandibles, and 23 implants were inserted in 3 full-arch maxillas.[26]

Statistics

Descriptive statistics and conventional life table analysis with regard to cumulative survival rates (CSRs) were used in the present study. In the analysis of marginal bone loss, a comparison was made to a previous prospective study[26] that applied the same study protocol but on implants with a machined surface. The previous study was used as an external control, according to Bailar and colleagues.[27] The difference in marginal bone loss between the groups was tested with the Mann-Whitney U test. Furthermore, a t-distributed variable was used to calculate 95% confidence intervals for differences. The statistical tests were based on the patient as the unit (not on implants), that is, a mean of all loaded implants was calculated per patient in the analysis of marginal bone loss. Significance tests were two-tailed and were conducted at the 5% significance level.

RESULTS

All patients were observed for 18 months, and no patient withdrew or was excluded from the study. Two cases are illustrated: Figure 1 demonstrates a patient with partial edentulism in the maxilla, and Figure 2 shows a patient with partial edentulism in the posterior part of the mandible.

Clinical Examination

Of the 111 installed implants, 1 failed. This failed implant was located in the distal maxilla (see Table 1). The cumulative implant survival rate was 99.1% at the end of the 18-month observation period. All prostheses remained stable for the whole study period without any complication or discomfort for the patients.

The failed implant was detected 1 year after implant installation, on the occasion of a checkup. The patient had not complained of any discomfort. The lost implant was the distal one of a three-unit bridge located in the posterior part of the maxilla. The reason for the failure remains unknown. It can only be speculated that as the site of failure was the distal abutment of the bridge, overloading

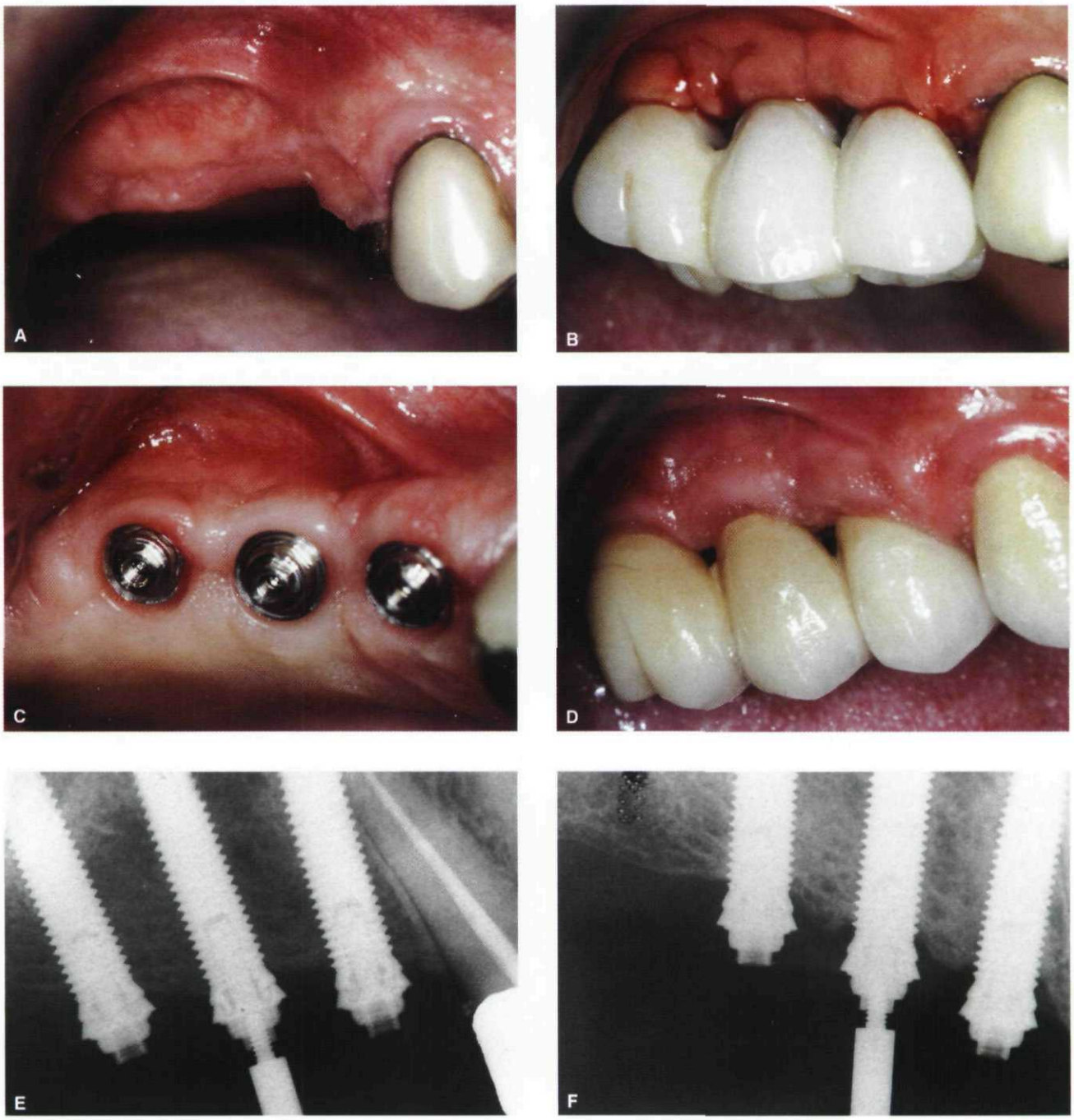

Figure 1 A patient with partial edentulism in the maxilla. *A*, Edentulous area before treatment. *B*, The temporary prosthesis in place. *C*, Soft tissue conditions 1 month after surgery. *D*, The final prosthesis in place. *E*, Radiograph made at baseline. *F*, Radiograph made after 18 months.

caused the failure. The non-osseointegrated implant was removed, and the bridge was shortened and was successfully supported by the two remaining implants.

Radiographic Examination

The radiographs were readable for 81% of the implants at baseline, 84% at placement of the final prosthesis, and 88% at 1 year after placement of the final prostheses. The implant platforms were positioned at a mean distance of 0.7 mm (SD, 0.8) above the bone crest. The marginal bone resorption was 0.5 mm (SD, 1.0) during the first 6 months after surgery. After placement of the final prostheses, the additional bone resorption was 0.2 mm (SD, 0.7), giving an accumulated bone resorption of 0.8 mm (SD, 1.0) 18 months after surgery (Table 2 and Figure 3).

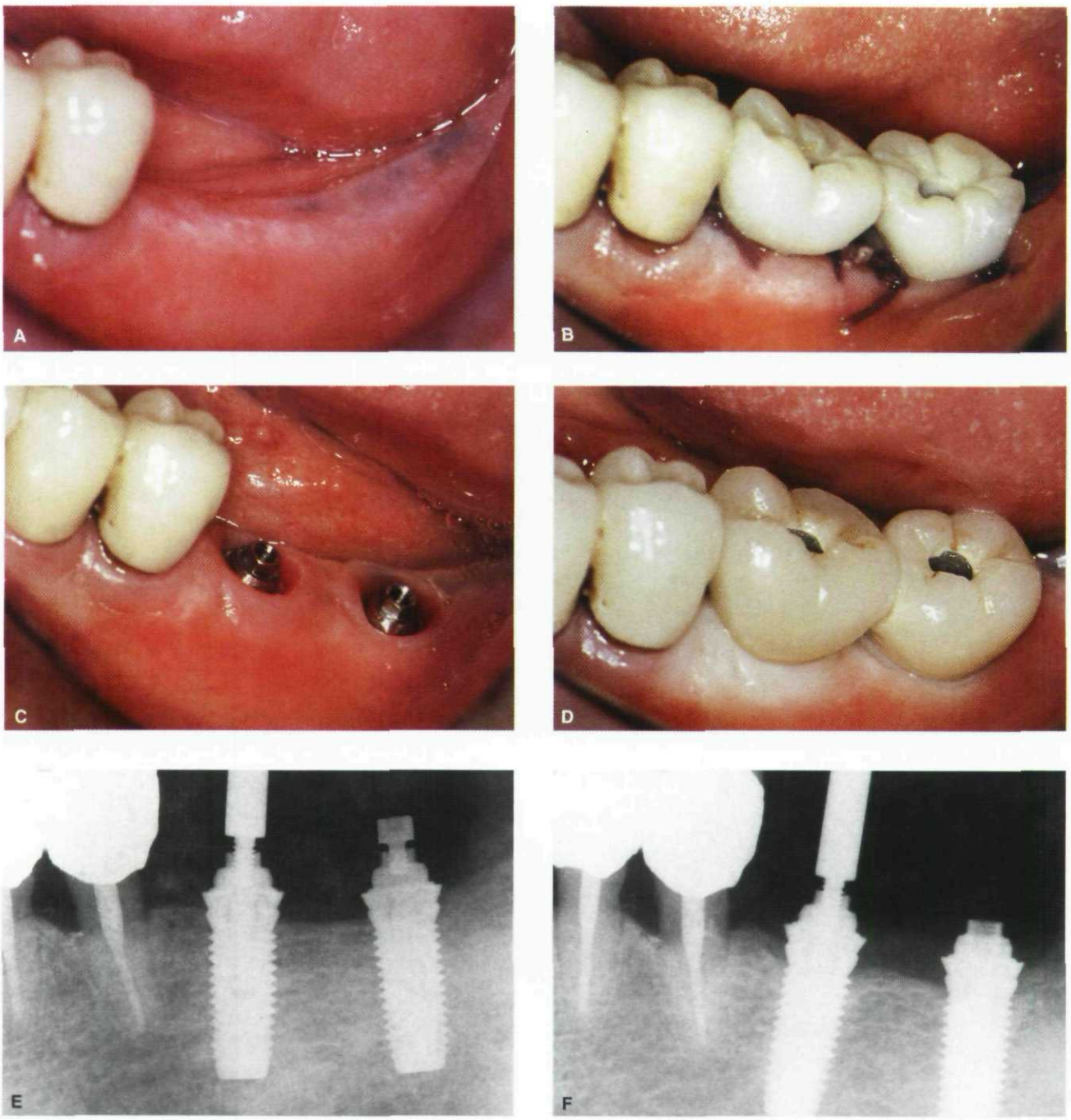

Figure 2 A patient with partial edentulism in the posterior mandible. *A*, Edentulous area before treatment. *B*, The temporary prosthesis in place. *C*, Soft tissue conditions 1 month after surgery. *D*, The final prosthesis in place. *E*, Radiograph made at baseline. *F*, Radiograph made after 18 months.

Eighteen of the 31 patients in the first study had readable radiographic images.

In that study the marginal bone resorption after 18 months was 1.6 mm (SD, 1.3). The difference in the change in marginal bone level between the two studies was statistically significant at the implant level ($p < .001$) but not at the individual level ($p = .10$) (Table 3 and Figure 3).

DISCUSSION

Primary implant stability and controlled loading are probably the most important prerequisites for successful early and immediate loading procedures.[14] Even if high initial implant stability is achieved, there is a risk that implant stability will be reduced as a result of the initial resorption process after bone surgery.[21] Rompen and colleagues[24] observed that oxidized implants maintained

TABLE 2 Change in Marginal Bone Level during 18 Months after Implant Insertion (1 Year after Final Prosthesis Placement)

	Mesial ($N = 86$)		Distal ($N = 88$)		Average* ($N = 90$)	
Bone Loss (mm)	*n*	%	*n*	%	*n*	%
< 0.0	16	19	13	15	16	18
0.0	6	7	12	14	4	4
0.1–1.0	33	38	31	35	38	42
1.1–2.0	22	26	22	25	22	24
2.0–3.0	8	9	8	9	8	9
> 3.0	1	1	2	2	2	2

*(Mesial + Distal)/2.

stability better than machined ones did during a 6-week healing period in the dog mandible, as measured with RFA. In a clinical RFA study, Glauser and colleagues demonstrated that oxidized implants maintained stability better than machined ones did when subjected to immediate loading in the posterior maxilla.[28]

The overall implant survival rate in the present study was 99.1% after an 18-month observation period. Only one implant failed at a late stage for unknown reasons, and as a consequence of this failure, the bridge was shortened distally. All the other implants and related prostheses were stable and without complications over the entire follow-up period. Also, the previous study by the same authors,[26] using the same protocol but machined-surface implants, showed a high survival rate (96.8%) in the maxilla and in the posterior part of the mandible where bone density often is low.

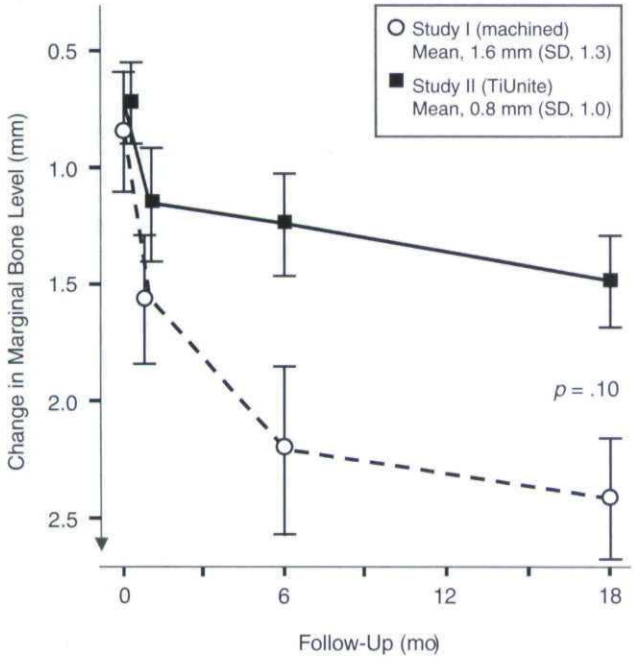

Figure 3 Comparison of changes in marginal bone level during the 18 months after implant insertion (1 year after final prosthesis placement) between a previous study using machined implant surfaces (Study I, $n = 54$ implants) and the present study using the TiUnite implant surface (Study II, $n = 90$ implants). Dots and lines show mean values and confidence intervals.

In a study using the same modified implant surface texture as in the present study at immediate loading, Glauser and colleagues[21] reported a CSR of 97.1% after 1 year, compared to 91% in an earlier study by the same authors,[14] which used machined implant surfaces. In a prospective randomized study with immediately loaded implants, Rocci and colleagues[22] reported a 10% higher success rate with such modified-surface implants (95.5%) compared with that achieved with machined-surfaced implants (85.5%). These studies and the present material indicate that the described oxidized surface plays a significant role in securing implant survival during the first weeks of healing, probably because of its osseoconductive capacity.[25]

The present study had the same design as the previous study, used as a historical control with regard to marginal bone level measurements. The result of a comparison with historical data must be taken with caution since the influence of factors such as patient selection and learning curve is not known. In the present study the bone resorption was 0.8 mm (SD, 1.0) compared to 1.6 mm (SD, 1.3) in a previous study using the same clinical protocol with machined-surfaced implants ($p = .10$). The difference in change in marginal bone level between the two studies is statistically significant only at implant level (ie, all implants included in the analysis [$p < .001$]). However, a dependency among the implants cannot be excluded.

CONCLUSION

The present clinical protocol (aiming at high primary stability) and the use of oxidized titanium implants for early functional loading in the maxilla and posterior mandible resulted in a high implant survival rate (99.1%) and a favorable marginal bone resorption (0.8 mm) during a follow-up of 18 months. The difference in marginal bone resorption when comparing the oxidized implants in the present study with machined implants from a previous investigation with the same study design was not statistically significant.

TABLE 3 Changes in Marginal Bone Level during 18 Months after Implant Insertion (1 Year after Final Prosthesis Placement) in Previous Study of Machined Implant Surface versus Present Study of TiUnite Implant Surface

	Implant Based Study I (Machined, n = 54) vs Study II (TiUnite, n = 90)					Individual Based Study I (n = 18)* vs Study II (n = 26)†	
	I 0–18 mo Mean (SD)	II 0–18 mo Mean (SD)	Difference Mean	95% CI	p Value	95% CI	p Value
Mesial (mm)	1.59 (1.24)	0.72 (1.10)	0.87	0.47–1.27	< .001	0.08–1.21	.034
Distal (mm)	1.56 (1.35)	0.76 (1.12)	0.80	0.38–1.22	< .001	–0.30–1.02	.21
Average‡ (mm)	1.58 (1.26)	0.76 (1.02)	0.82	0.44–1.20	< .001	–0.04–1.12	.10

CI = confidence interval; SD = standard deviation.
*Eighteen patients had readable radiographs.
†Twenty-six patients had readable radiographs.
‡(Mesial + Distal)/2.

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