Immediately Loaded Implants Supporting Fixed Prostheses in the Edentulous Maxilla: A Preliminary Clinical and Radiologic Report

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Purpose: *To evaluate the survival rate of immediately loaded ITI sand-blasted, large-grit, acid-etched (SLA) solid-screw dental implants in the edentulous maxilla after 8 months of loading.* ***Materials and Methods:*** *Twenty-eight patients (mean age 63 years) with edentulous maxillae each received 6 implants and 1 implant-supported fixed provisional prosthesis within 24 hours after surgery. After a mean healing time of 15 weeks, the patient received a definitive, screw-retained, implant-supported fixed prosthesis. A total of 168 implants were placed. Clinical parameters were registered after 1 month of loading with the implant-supported fixed prostheses as well as 8 months after implant placement. Radiologic examinations and assessments were made at implant placement and after 8 months.* ***Results:*** *The mean marginal bone level at implant placement was 1.6 mm (range 0 to 5.1; SD 1.1) apical of the reference point (the implant shoulder). The mean marginal bone level at the 8-month follow-up was 3.2 mm (range 0.4 to 5.9; SD 1.1) apical of the reference point. Three implants failed during the healing period.* ***Discussion:*** *The improved results in the present study might be a result of the positive effect of splinting the implants immediately after placement.* ***Conclusion:*** *ITI SLA solid-screw implants immediately loaded (ie, loaded within 24 hours of placement) and supporting fixed prostheses had successful survival rates after 8 months. The present results constitute a solid baseline for future follow-up studies.* Int J Oral Maxillofac Implants 2005;20:399–405

Key words: *dental implants, edentulous maxillae, immediate loading, implant splinting, implant survival rates*

The replacement of missing teeth with dental implants has become a common treatment method in recent decades. In addition to demands from patients for high reliability and optimal esthetics, it is desirable to shorten the treatment period for economic and social reasons. One way of reducing the treatment period is to use 1-stage surgery and nonsubmerged implants.[1–3] The ITI dental implant system (Straumann, Waldenburg, Switzerland) was originally designed to be placed in a 1-stage surgical technique. The clinical results of this system have been satisfactory and well documented.[4–6]

Another way of reducing the treatment period is to shorten the time between implant placement and the placement of a prosthetic suprastructure on the implants.[7,8] During the healing period, in cases of complete or partial edentulism, the patient usually wears some sort of removable prosthesis. Normally, the patient has to refrain from wearing the removable prosthesis during the first 2 weeks after implant placement and thereafter must wear it during the entire healing period of about 3 to 6 months. In recent studies, the problems of unfavorable loading caused by removable prostheses after 1-stage surgery have been discussed.[9–12] The idea has arisen that the prostheses cause the implants exposed through the mucosa to undergo micromotion, leading to crater-shaped marginal bone defects. One possible way to minimize micromotion is to enhance

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Table 1 Age and Sex Distributions of Patients

	Age (y)				
	40–50	51–60	61–70	71–80	81–90
Women (n = 13)	1	5	4	2	1
Men (n = 15)	2	4	4	5	0
Total (n = 28)	3	9	8	7	1

Table 2 Length and Diameter of Placed Implants (n = 168) Related to Bone Quantity and Quality at Implant Sites, Assessed According to Lekholm and Zarb

Bone quality	Length (mm)	Bone quantity B Diameter (mm)			Bone quantity C Diameter (mm)			Total
		3.3	4.1	4.8	3.3	4.1	4.8	
Type 2								
	10							0
	12		12		3	3		18
Type 3								
	10		3		1	12		16
	12	4	11		15	54	2	86
Type 4								
	10		2		1	2		5
	12		10		9	24		43
		4	38	0	29	95	2	168

the stability of the implants by splinting the implants with a provisional, screw-retained, implant-supported prosthesis in a fixed position immediately after surgery.[13] A prerequisite for such an immediate technique is 1-stage surgery with nonsubmerged implants.

Few studies have been published on the effects of immediate loading of implants. In the mandible, success rates similar to those with healing times of 3 to 6 months before loading have been reported.[14–18] Studies on immediate loading of maxillary implants are scarce, but the results reported indicate that this method is also viable.[13,19–22] The scientific documentation, however, is poor.[23]

Therefore, the aim of this study was to evaluate clinically and radiologically the survival rate of ITI implants immediately loaded (ie, within 24 hours) in the edentulous maxilla after 8 months. Eight months postloading was selected as the first follow-up point so that the results could be compared with those from a previous study with ITI implants on delayed loading in the edentulous maxilla.[9] In that study, the baseline for the follow-up examinations was the time when the definitive restoration was placed, ie, 8 months after implant placement.

MATERIALS AND METHODS

Patient Selection

The patients included in this prospective study were treated between March 2001 and March 2003 in a private practice and in maxillofacial surgery and prosthetic dentistry clinics in Norrköping, Sweden, by 1 private practitioner, 1 oral surgeon, and 1 specialist in prosthetic dentistry. The study protocol was approved by the Research Ethics Committee at the University Hospital in Linköping, Sweden. Thirty patients were referred for implant treatment and 28 patients—13 women and 15 men with a mean age of 63 years (range, 45 to 88 years)—were included in the study (Table 1). Inclusion criteria were edentulism in the maxilla and a minimum alveolar bone width of 4 mm, as judged by the oral surgeon in the clinical examination or determined by computerized tomography. The mandible had to have a sufficient number of teeth to provide a stable occlusion. Generally, teeth had to be present from second premolar to second premolar. Those patients who met the inclusion criteria and gave their informed consent to participate in the study were consecutively included. Twelve patients were smokers; 6 smoked more than 20 cigarettes a day. It was recommended that smokers refrain from smoking before surgery and during the healing period.

Surgical and Provisional Prosthetic Procedures and Postoperative Care

One hour prior to surgery the patients received 2 g penicillin (Kåvepenin; AstraZeneca, Södertälje, Sweden), 600 mg ibuprofen (Ibumetin; Nycomed, Lidingö, Sweden), and 20 mg diazepam (Stesolid; Dumex-Alpharma, Copenhagen, Denmark). After the operation they received 2 g penicillin twice a day for 10 days. The surgical procedure followed the manufacturers' instructions and the procedure described by Buser and colleagues.[24] However, the implants were placed with the border between the rough and smooth surfaces 1 to 2 mm below the level of the alveolar crest to improve primary implant stability. All surgery was performed under local anesthesia—2% lidocaine and 12.5 µg epinephrine (Xylocaine-Adrenaline; AstraZeneca).

Altogether, 168 sand-blasted, large-grit, acid-etched (SLA) solid-screw implants were placed. Two implants had a diameter of 4.8 mm, 133 implants (79%) had a diameter of 4.1 mm, and 33 implants (20%) were of the narrow type with a diameter of 3.3 mm. Implant lengths of 12 or 10 mm were used (Table 2). Six implants were placed in each patient according to previous conventional protocols.[9,11,25] The implants were placed in the anterior, canine, and premolar regions. The quantity and quality of the alveolar bone tissue were assessed during surgery according to the index described by Lekholm and Zarb[26] and were found to be predominantly of quantity C and quality 3 (Table 2). In 17 patients, only implants with a diameter of 4.1 mm were placed. Nine patients received implants of 2 different widths. In 3 of these patients, the majority of the implants had widths of 3.3 mm. After placement, the stability of 114 implants was assessed using resonance frequency analysis (RFA) (Osstell; Integration Diagnostics, Göteborg, Sweden)[27–29]; the implant stability quotient (ISQ) values ranged from 22 to 64 (mean 50). Octa-abutments (Straumann) were mounted on the implants, and impression caps were mounted before the mucosa was sutured. An impression was made using a polyether material (Impregum; ESPE, Seefeld, Germany). The entire maxillary denture, which had been hollowed out over the impression caps, was used as an impression tray. After impression making, protection caps were mounted on the abutments. The removable prosthesis was reshaped by a dental technician into a provisional, screw-retained, implant-supported fixed prosthesis (ISFP) using the impression caps. The provisional fixed prostheses were made of autopolymerizing acrylic resin without any metallic reinforcement (Permadent; Forshaga Dentaldepå, Forshaga, Sweden). Special attention was paid to minimizing the horizontal and vertical relations and making the occlusal surface flat to reduce unfavorable forces.

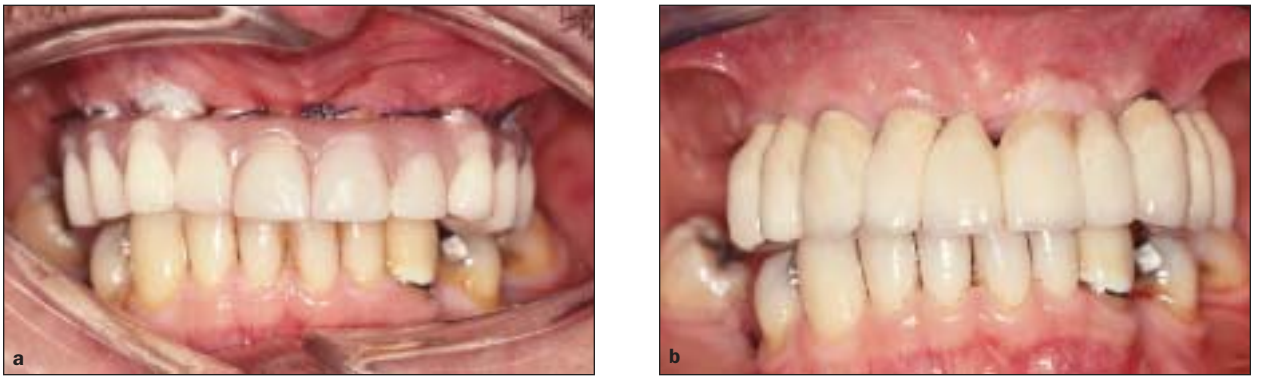
The provisional prostheses were made without cantilevers and were delivered within 24 hours (mean time 19 hours) after implant placement. After surgery, all patients rinsed their mouths twice a day for 10 days with an antimicrobial chlorhexidine solution (2 mg/mL Corsodyl; SmithKline Beecham, Brentford, United Kingdom). They were advised to follow a soft, nutritious diet (soups, mashed food, etc) and to refrain from chewing during the first 4 weeks of the healing period. The provisional prostheses were removed after 10 to 12 days for removal of the sutures, after which they were seated again and retained by screws. After the mucosa had healed, the patients were instructed to use interdental brushes daily with a chlorhexidine gel (1% Corsodyl).

Creation and Placement of the Definitive Prosthesis

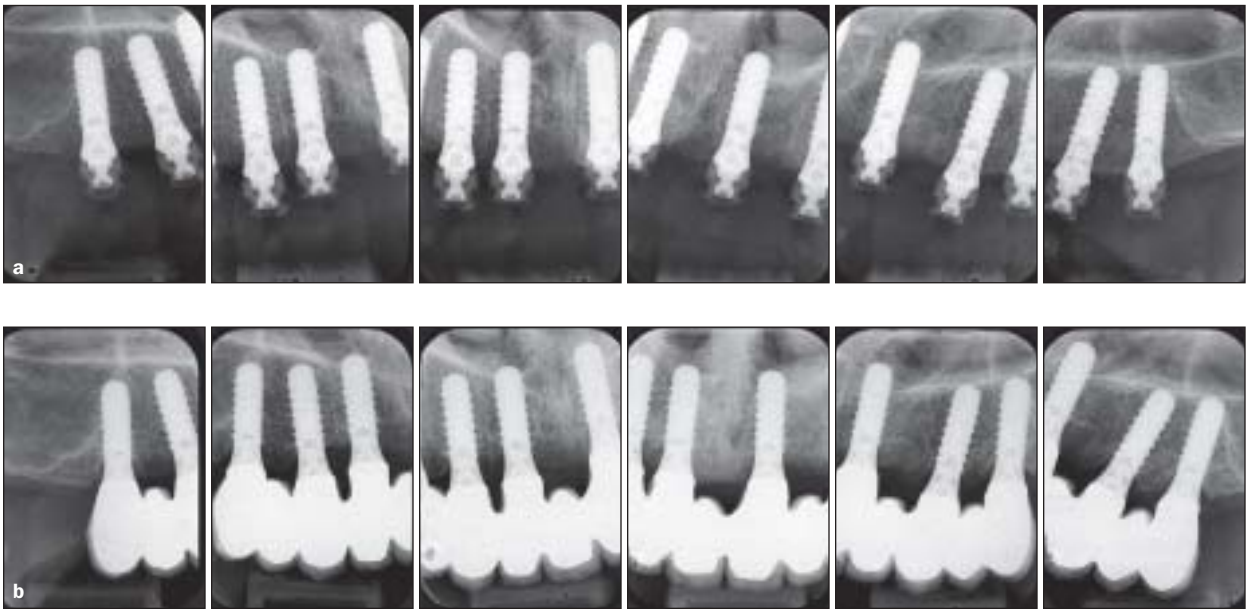
The provisional fixed prostheses were in use for a mean of 15 weeks (range 8 to 22 weeks) (Fig 1a). Before impression making, the abutments were checked with a manual torque-control device that delivered a torque of 35 Ncm. All patients were rehabilitated with ISFPs (Fig 1b). Ceramic fused to metal was used for esthetic reasons in 19 patients; gold and acrylic resin or titanium and acrylic resin were used in 9 patients. Acrylic resin was used when the jaw relation was unfavorable for ceramic fused to metal or when cost was a concern. The ISFPs were all screw retained to enable future modifications. The occlusal contacts were evenly distributed over the arch with anterior guidance in lateral excursions and only light contact on the distal cantilevers.

Follow-up

After 1 month of adaptation, baseline for clinical registrations, the ISFPs were "permanently" retained and access holes to the prosthesis screws were sealed with composite resin. The following clinical parameters were registered: plaque scores, bleeding index, presence of hyperplasia, a visible prosthesis/implant margin, occlusion, pain, and prosthesis mobility. The presence of plaque was registered according to Ainamo and Bay.[30] Bleeding as a sign of reversible plaque-induced mucosal inflammation was diagnosed as peri-implant mucositis[31] and was registered after light pressure with a probe on the surrounding mucosa at 4 surfaces of each implant as described by Smedberg and associates.[32] Pockets were probed if signs of peri-implant mucositis were present. Peri-implantitis was defined as mucosal bleeding after gentle probing together with increased probing depth, occasional suppuration, and radiographic loss of



Figs 1a and 1b *(a)* A provisional ISFP 19 hours after implant placement and *(b)* a definitive ISFP at the 8-month follow-up.



Figs 2a and 2b Radiographs of the same patient shown in Fig 1 *(a)* at delivery of the provisional ISFP and *(b)* at the 8-month follow-up.

crestal bone.[31] Survival was defined as an implant stable in the patient's jawbone with no signs of periimplantitis and failure as a mobile or removed implant.[33]

All patients were followed for 8 months after loading. During the follow-up period, a dental hygienist regularly checked the patients. Further follow-ups will be made after 20 and 32 months of loading. The ISFPs will be removed at the 32-month follow-up to allow implant stability to be measured with RFA.

Radiographic Examination and Evaluation

Intraoral radiographic examinations were made when the provisional prosthesis was delivered (Fig 2a); provisional prosthesis delivery constituted the baseline for measurements of marginal bone level. Intraoral radiographic examinations were also conducted at the 8-month follow-up (Fig 2b). The periapical radiographs were made using a paralleling technique with a film holder (Eggen, Lillehammer, Norway). Care was taken to clearly image threads on both sides of the implant. Kodak Ektaspeed film (Eastman Kodak, Rochester, NY) was used, and the radiographs were processed in a Durr AC 245 L developing processor (Dürr Dental, Bietigheim-Bissingen, Germany).

A specialist in oral radiology assessed the radiographs. The changes in marginal bone height over time were measured. The bone-implant interface zone was also inspected for changes indicating loss of osseointegration, vertical and crater-shaped bone defects, and any other changes that would indicate a

pathologic condition. The marginal bone level was assessed from a reference point to the point where the bone tissue met the implant surface at the mesial and distal sides, as described previously.[9] The distance was measured in increments of 0.1 mm using a magnifying lens with a magnification factor of 7. For 20 randomly chosen implants, measurements of the marginal bone height on the mesial and distal surfaces were repeated after 1 month. The precision of a single measurement was expressed using the formula suggested by Dahlberg[34], $s = \sqrt{\Sigma d^2/2n}$, where d is the difference between 2 measurements and n is the number of double measurements. The measurement precision was estimated to be 0.46 mm.

Statistics

The mean marginal bone level was calculated at baseline and at the 8-month follow-up. Differences between mean bone levels were calculated using a pairwise *t* test. Comparisons between the baseline and 8-month follow-up values for marginal bone level relative to implant diameter were made using an independent sample *t* test. A difference was considered significant when $P < .05$.

RESULTS

Surgical and Prosthetic Procedure

The surgical procedure was uneventful. There was minor swelling of the mucosa and good adaptation to the provisional prostheses.

One of the provisional ISFPs fractured during the healing phase but was successfully repaired. One occlusal screw fractured in another provisional ISFP.

After the definitive ISFPs were fabricated, 1 denture tooth fractured in an autopolymerizing acrylic resin restoration. No complications were registered for the ceramic-fused-to-metal restorations. During the first month, 1 denture tooth fractured in a definitive gold-acrylic resin ISFP. None of the ceramic-fused-to-metal restorations or other implant components fractured.

Clinical Registrations

At the baseline for clinical registrations, plaque accumulation was found on 1.5% of the implant surfaces and after 8 months on 4.5%. Twenty-four of the patients had no plaque registered at baseline. The bleeding index at baseline was 2.5% and increased after 8 months to 6.1%. There were no signs of peri-implantitis. Mucosal hyperplasia was registered on 0 implant surfaces at baseline and on 4 implant surfaces at the 8-month follow-up. A visible prosthesis/implant margin at the buccal region—assessed as visible or nonvisible—was registered at 52 (31%) implants at baseline and at 55 (33%) after 8 months. All ISFPs had a smooth and even occlusion. No pain was reported and no prosthesis mobility was registered.

Table 3 No. of Implant Surfaces in Relation to Reduction of Marginal Bone Level Between Baseline and the 8-month Follow-up

Bone reduction (mm)	No. of implant surfaces
0.0–1.0	11
1.1–2.0	50
2.1–3.0	72
3.1–4.0	108
4.1–5.0	63
5.1–6.0	18
6.1–7.0	2

Radiographic Evaluation

The mean marginal bone level at baseline was 1.6 mm (range 0 to 5.1 mm; SD 1.2) apical of the reference point. At the 8-month follow-up, the mean marginal bone level was 3.2 mm (range 0.4 to 5.9 mm; SD 1.1) apical of the reference point. The reduction in marginal bone, as measured from the reference point, was 4.0 mm or less at a majority of the implant surfaces (Table 3). At 6 implant surfaces the bone level could not be measured because of nonparallel projection. At the 8-month follow-up, the narrow implants (those with a diameter of 3.3 mm) exhibited significantly more marginal bone resorption than the standard implants (those with a diameter of 4.1 mm) at the mesial ($P < .001$) and distal ($P = .013$) surfaces. Implants placed in the canine regions had significantly ($P = .049$) more bone resorption mesially at the 8-month follow-up compared with implants placed in the premolar regions.

Implant Survival Rate and Complications

A total of 165 implants were followed for 8 months. A life table analysis was constructed (Table 4). The cumulative survival rate was 98%.

Three implants failed in 2 patients. In 1 patient 1 implant in the premolar region was not osseointegrated after 6 weeks of healing when checked with the torque device at 35 Ncm. This implant was left in place without intervention but was subsequently removed 4 weeks later when clinical signs of peri-implantitis appeared and osseointegration had still not occurred. A definitive ISFP was fabricated for the remaining 5 implants. In a second patient, the provisional ISFP fractured after 3 weeks in the posterior region on the right side. At this time, 2 implants, 1 in the right canine region and 1 in the left second premolar region, were loose and showed clinical signs of

Table 4 Implant Survival Rate

Time period	No. of surviving implants	No. of failed implants	No. of withdrawn implants	Survival rate for interval (%)	Cumulative survival rate (%)
Placement – 15 wk	168	3	0	98	98
15 wk – 8 mo	165	0	0	100	98
8 – 20 mo	90	0	12	100	98
20 – 32 mo	24				

peri-implantitis. They were removed, and the provisional restoration was affixed to the remaining 4 implants, which showed good stability.

DISCUSSION

The present study demonstrated that it is possible to place ITI SLA solid-screw dental implants in the edentulous maxilla and immediately apply a load to the implants through a provisional, screw-retained, fixed prosthesis.

Of 30 patients referred to the clinic for implant treatment, only 2 were excluded. Exclusion was based on the computerized tomographic examination, which revealed that the height and width of the alveolar crest were insufficient for implant placement. A prerequisite for immediate implant loading, supported by several studies,[16,19–22] is primary implant stability based on good bone quality. The bone quality of the 28 patients included in this study was assessed during surgery according to the index by Lekholm and Zarb.[26] This index is based on a subjective evaluation and can be questioned. Seventy-one percent of the patients in the present study were assessed as having bone quantity/bone quality C3 or C4, which according to earlier reports could be an aggravating circumstance for osseointegration.[35] However, only 3 of the 168 implants that were placed failed during the first 8 months, and 2 of these were in the same patient. These primary results are presented not only as a baseline for future follow-up studies, but also as evidence that this treatment modality might be effective.

Earlier studies have indicated that the degree of micromotion is an important factor in the achievement of osseointegration.[36–38] It has also been suggested that when a denture is used during the healing period, unfavorable forces can unpredictably load the implants.[11] In a previous study,[9] crater-shaped bone defects, which might have been caused by unfavorable forces during the initial healing period, were found at several implant surfaces at a follow-up examination 8 months after implant placement. These findings were the impetus behind the present study to investigate connecting a rigid fixed prosthesis to the implants within 24 hours. Immediate loading of such a prosthesis might decrease micromotion at the bone-implant interface and thus facilitate proper healing. In this study, indications of crater-shaped bone defects were observed at only 5 implant surfaces at the 8-month radiologic follow-up.

Six implants were placed in each patient. This is fewer implants than have been used in some other studies on immediate loading in the maxilla; often, 8 to 10 implants have been placed in these circumstances.[19–22] However, it is probable that the provisional ISFP, which was fabricated with a flat occlusal surface and without distal cantilevers, facilitated a favorable force distribution. The definitive prostheses were all made with distal cantilevers.

Assessment of the marginal bone level showed less mean bone loss at the 8-month follow-up, 3.2 mm from the implant shoulder, than was observed at the 8-month examinations in comparative studies adopting a conventional loading protocol.[9,11] These studies reported bone levels of 4.5 and 4.7 mm, respectively. The improved results in the present study might be a result of the positive effect of splinting the implants immediately after placement.

CONCLUSION

The results of this study indicated that immediate splinting of the implants with a fixed provisional prosthesis might protect nonsubmerged implants from unfavorable and uncontrolled loading and improve the healing conditions. Immediately loaded ITI SLA solid-screw dental implants supporting fixed prostheses in the edentulous maxilla can be a viable treatment alternative when restoring the edentulous maxilla. Follow-up examinations are planned for the same time intervals as those used in a previous study[9] on delayed loading of maxillary implants.

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