

Early Loading of Sandblasted, Acid-Etched Implants in the Posterior Maxilla and Mandible: A 1-year Follow-up Report from a Multicenter 3-year Prospective Study

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Purpose: The aim of the present study was to evaluate the concept of an immediate loading protocol in the posterior maxilla and mandible through analysis of implant survival at 1 year. **Materials and Methods:** One year follow-up data of a multicenter study are reported. Eighty-two ITI sandblasted, acid-etched (SLA) implants in 40 patients were loaded between 0 and 11 days after implant placement (mean 4.3 ± 2.8 days). The restorations consisted of either 2 splinted crowns or a 3-unit fixed prosthesis. All restorations were put into full functional occlusion. Periapical radiographs were evaluated for changes in crestal bone level from baseline to 1 year postloading. Primary stability of the implants was checked initially and before the fitting of the definitive prosthesis. The restorations were evaluated by the practitioners for retention, stability, and esthetics. **Results:** Three patients' implants were not loaded because of lack of primary stability, and a fourth patient was excluded from the study because of a protocol violation (more than 4 implants were used). All 4 patients were successfully treated outside the protocol. The overall survival rate of the remaining implants at 1 year was 98.8%. The mean bone loss at 1 year was 0.52 ± 0.98 mm, which is within the reported limits of less than 1 mm (range 0.4 to 1.4 mm) loss in the first year. **Discussion and Conclusion:** The early results from this study indicate that early and immediate loading of 2 implants in the posterior maxilla and mandible may be suitable in selected patients. On the basis of 1 year of observation, the results appear similar to those achieved with a delayed procedure. INT J ORAL MAXILLOFAC IMPLANTS 2005;20:84-91

Key words: clinical study, crestal bone levels, dental implants, immediate loading

Osseointegrated dental implants have shown long-term success in the rehabilitation of totally or partially edentulous patients and patients with single tooth loss.¹⁻³ They have been successful largely because of the development of designs and implantation procedures that result in direct bone-implant interface without detectable intervening fibrous tissue.⁴ Strict observance of certain procedures was proposed by Brånemark⁵ in 1977 to

achieve a successful osseointegration. Brånemark proposed a healing period with the implant buried beneath the oral mucosa. However, examples appear in the literature in which clinically defined osseointegration was achieved with early or immediate loading of splinted endosseous implants. The main emphasis in the last 10 years has been the avoidance of micromovement, which can prevent osseointegration.^{6,7} If excessive micromovement is avoided, it is possible to achieve osseointegration under loading conditions.

Immediate loading stimulation was thought to prevent crestal bone loss; however, the results were unpredictable.⁸ Ledermann⁹ reported a 1-month follow-up of 138 patients who received 476 titanium plasma-sprayed (TPS) implants immediately loaded with overdentures in the mandible. He reported a short-term survival rate of 91.2%. A success rate of 98.1% on 53 ITI cylindrical implants (Straumann,

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Waldenburg, Switzerland) with a TPS surface immediately loaded with overdentures in the mandible was later reported by Schroeder and associates.¹⁰ Babush and coworkers¹¹ published a multicenter study involving 484 patients. Success was achieved in the early loading of 4 bar-splinted TPS screw-type implants with clip-retained overdentures in the mandible.

Schnitman and colleagues¹² reported data from a 10-year cohort study whereby 28 implants in 10 patients were immediately loaded at placement, providing support for fixed mandibular provisional prostheses. In addition, 35 adjacent implants were allowed to heal submerged and stress free (standard Brånemark protocol). Following a 3-month healing period, these implants were exposed and the definitive restoration was placed. All 10 prostheses supported by 28 implants placed into immediate function were successful during the 3-month healing period; 4 of the implants subsequently failed. Of the 35 submerged implants, all remained osseointegrated after 10 years. Ten-year life table analysis demonstrated a survival rate of 84.7% for immediately loaded implants and 100% for the submerged implants, with an overall survival rate of 93.3%. Failures were attributed to implant length and position, in that the majority of failed implants were distal to the incisors and appeared to be susceptible to failure because of poor bone quality.

A retrospective multicenter study on 904 immediately loaded implants retaining overdentures was published by Chiapasco and coworkers.¹³ Four different implant systems were used: TPS and ITI implants (Straumann), hydroxyapatite-coated titanium implants (Mathys Dental Implants, Bettlach, Switzerland), and NLS screw-type implants (Friatec, Mannheim, Germany). A success rate of 96.9% was reported, with a mean follow-up that ranged from 3 to 13 years. Sagara and associates¹⁴ also provided corroborative histologic evidence of osseointegration after 1-stage screw implants were placed, immediately loaded, and splinted in a dog model. Similar results in humans were later demonstrated by Piatelli and colleagues.^{15,16} Tarnow and associates¹⁷ described immediate loading of threaded implants with single-stage surgery in edentulous arches, with data up to 5 years postplacement. Overall, a total of 107 implants were placed in 10 patients (6 mandibular arches and 4 maxillary arches). Sixty-nine were immediately loaded and 38 were submerged. Each patient had immediately loaded and submerged implants, some of which were in the posterior mandible, where bone quality is generally poorer. Two immediately loaded implants and 1 submerged implant failed. These data indicated that osseointe-

Table 1 Investigator List, Center No., and Unique Patient Sequence

Center no.	Location	Investigator	Patient no. sequence
1	Palermo	Di Raimondo R.	101–110
2	Verona	Filippini P.	201–210
3	Bergamo	Gualini F.	301–310
4	Roma	Luongo G.	401–410
5	Firenze	Massagli M.	501–510
6	Terni	Podda G.	601–610
7	Forlì	Provvigionato M.	701–710
8	Firenze	Paoleschi G.	801–810

gration occurred in both groups, with no difference between maxillary and mandibular arches.

Currently, because of improved implant design and understanding of the physiology of mechanical stresses inherent in the jaw and bone remodeling processes, immediate loading of implants placed in completely or partially edentulous jaws has gained acceptance in dental practice. Therefore, this technique is an option for patients with sufficient bone quality to achieve good primary stability.^{18–20} More recently some publications have addressed the immediate loading of single-tooth restorations both in the maxilla and mandible. Some have shown the results and crestal bone changes to be equivalent to the those with an established conventional protocol.^{21,22}

The aim of this study was to assess the clinical results of early and immediate loading in the posterior maxilla and mandible of partially edentulous patients.

MATERIALS AND METHODS

This was a multicenter investigation conducted in Italy in 8 private practices (Table 1). Each center was given a number from 1 to 8 and a unique sequence of patient numbers, and each patient was enrolled sequentially. All enrolled patients fulfilled the same inclusion and exclusion criteria.

To participate, patients were required to be

- At least 18 years of age
- Partially edentulous in either the maxilla or the mandible in the molar or premolar region, with sufficient bone volume in the planned implant placement sites to permit initial primary stability
- Desirous of an implant-supported restoration

Exclusion criteria included all the contraindications mentioned in the current package insert

section 2 for the placement of implants (systemic diseases, metabolic bone disorders, uncontrolled hematologic diseases, alcohol and tobacco abuse, uncontrolled endocrine diseases, etc). Patients were also excluded if

- They were pregnant or pregnancy was suspected.
- They had undergone preimplantation bone surgery (bone grafts, guided bone regeneration, or any technique for bone enhancement).
- They had insufficient bone width to place implants.
- They had a condition or circumstances that, in the opinion of the investigator, could prevent completion of study participation or interfere with the analysis of the study results, such as a history of noncompliance or unreliability.
- They had unhealed extraction sites.
- An insertion torque of < 15 Ncm on the implants was attained at implantation.

The total number of patients was 45 (26 women and 19 men); they ranged in age from 27 to 67 years (mean \pm SD of 48.7 ± 10.5 , respectively).

The protocol was approved by an independent Ethics Committee (Freburger Ethics Committee International, Freiburg, Germany), and the study was monitored regularly by the sponsor (Straumann) to ensure protocol compliance. Furthermore, safety and recording of complications were monitored throughout the study. All patients signed a written informed consent form countersigned by a witness. Patients were advised of the need for prescribed follow-up visits for their ongoing care and for the collection of data. They were also informed that they were free to withdraw from the study at any time without prejudice. If necessary, an alternative treatment related to their dental conditions was offered.

Forty-five patients with partial edentulism in the posterior mandible or maxilla desiring implant-supported restorations who fulfilled the presurgical inclusion and exclusion criteria were selected for treatment. Patients eligible for the study had 2 to 3 missing teeth in areas posterior to the canines in either the maxilla or mandible. Each patient received 2 standard 2-part Straumann ITI sandblasted acid-etched (SLA) solid screw-type titanium implants with diameters of 4.1 mm and lengths of 8 to 14 mm. A provisional restoration that formed a rigid connection between the 2 implants was fabricated with a fiber- or metal-reinforced framework. This consisted either of 2 splinted crowns or a 3-unit fixed partial prosthesis. All provisional restorations were put into functional occlusion at loading. The definitive restorations were ceramometal.

Treatment Planning

Periapical and panoramic radiographs of the implant sites were performed routinely, while a computerized tomography scan was performed only when indicated. An accurate description of the intended sites for implant placement was recorded, including any pathologic condition of the surrounding teeth (eg, bleeding, status of periodontium). The radiographs were used to confirm that adequate bone was available at the proposed implant sites.

Surgical Procedure

Surgery was performed under aseptic conditions according to current implant placement procedures. Prophylactic antibiotic therapy and analgesia were administered as required according to the investigators' standard practice, and any given therapy was recorded in the relevant section of the report form. Surgery was performed under a local anesthetic with the aim of conscious sedation if the patient's general condition required it.

At surgery a crestal incision was made and if necessary 1 or 2 mesial and/or distal relieving incisions were made. A full-thickness mucoperiosteal flap was reflected. Where required, a ridge alveoloplasty was performed to achieve a flat bone surface of sufficient width. Bone preparation and placement of the implants followed the current standard ITI surgical protocol. The implants were placed in the recipient site by means of an insertion device, and the maximum torque required to place the implants was measured. All torque values were recorded in the patient report form.

Suture removal was performed according to each practitioner's standard practice within 7 to 14 days of implantation. Patients were instructed not to brush in the treated area and to rinse 3 times per day for 1 minute with chlorhexidine digluconate 0.12% until suture removal. If a torque value of < 15 Ncm was required to place one or both of the implants, the patient was withdrawn from the study and the delayed protocol or a different form of treatment offered.

Prosthetic and Follow-up Procedures

Impression making (indexing) was done intraoperatively or immediately postoperatively. A reinforced acrylic resin fiber or metal temporary prosthesis was fitted the same day of surgery in 25% of the patients in full occlusion; 75% were loaded between 2 and 11 days. Table 2 shows the time to loading of the temporary prosthesis and the distribution of patients loaded in the 0- to 11-day period. Primary stability and ongoing stability of the implants were checked prior to the fitting of the temporary prosthesis.

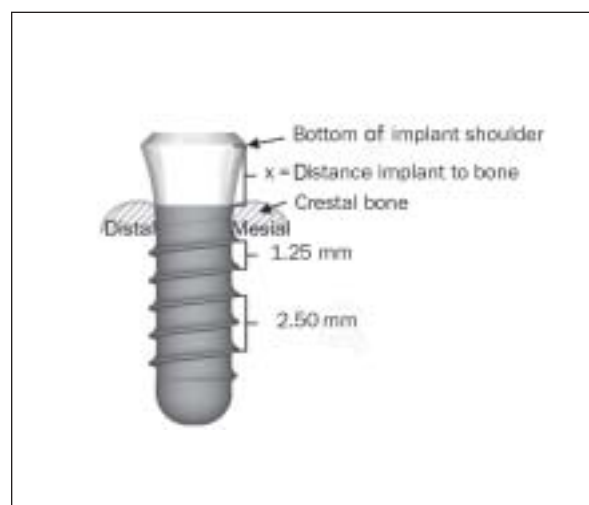
Table 2 Implant Loading Times

Loading time (d)	Patient	
	n	%
0-1	10	25.0
2	2	5.0
3	3	7.5
4	4	10.0
5	4	10.0
7	15	37.5
8	1	2.5
11	1	2.5
Total	40	
Min	0	
Max	11	
Median	5	
Mean	4.3	
SD	2.8	

At other follow-up examinations, when the prosthesis was not removed, the implants were checked indirectly for persistent or irreversible pain, inflammation, peri-implant infection, and radiolucency. If mobility of the prosthesis was detected, the prosthesis was removed and the implants checked individually for mobility. In addition, the peri-implant mucosa was examined at each follow-up visit. Patients were followed up to 8 weeks postsurgery. At follow-up visits, all the aforementioned parameters were assessed, and oral hygiene instruction was given. At 3 months postimplantation, new impressions were made for the fabrication of a definitive restoration and evaluation of the occlusion. Periapical radiographs of the implants for evaluation of crestal bone loss were obtained at implant placement (baseline) and at 12 months. Direct implant mobility following removal of the prosthesis was assessed at 3 months postloading (ie, at the loading of the definitive prosthesis) and at 12 months postloading. Implant success was defined by Albrektsson and associates²³; implants had to fulfill the following criteria at the 12-month postloading visit:

- Absence of implant mobility
- Absence of any continuous peri-implant radiolucency
- Absence of recurrent peri-implant infection, pain, neuropathy, paresthesia, or protrusion into the maxillary sinus or mandibular canal
- Ability to support a prosthesis

Soft tissue measurement, gingival health, and oral hygiene were measured at all visits. Patient satisfaction regarding comfort, esthetics, and ability to chew and overall satisfaction with the restoration were evaluated. The quality of the restoration was

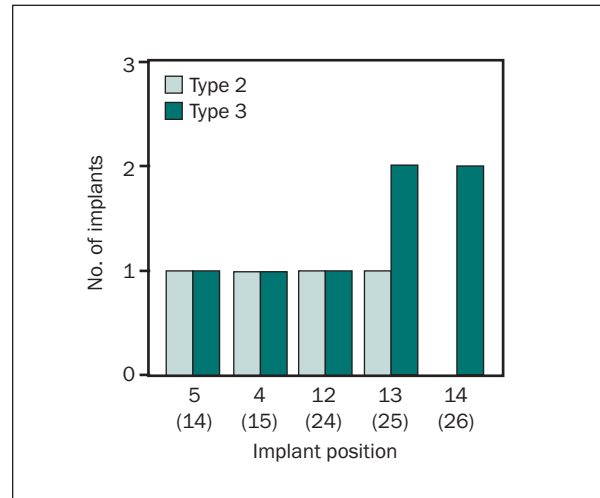
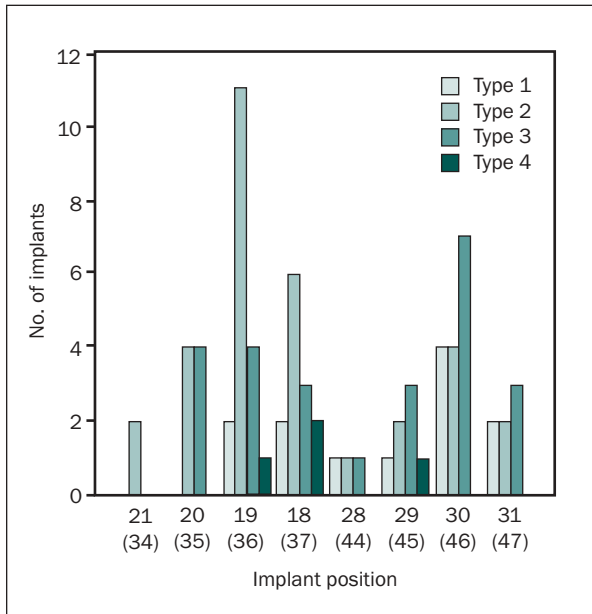
**Fig 1** Crestal bone level measurement.

assessed by the practitioner with regard to retention, stability, and esthetics. Patient complaints and complications were continuously monitored and recorded. The gingival parameters were measured according to the criteria proposed by Mombelli and coworkers.²⁴

Radiographic Evaluation

Radiographs were obtained at the times specified in the schedule of assessments for follow-up of the implants; ie, immediately after implant placement and at the 1-year follow-up visit. Radiographic procedures were performed that allowed for the measurement of vertical bone loss from the mesial and distal aspects and for the detection of radiolucency around the implant. Special care was taken to position the film parallel to the implant and also to align the x-ray beam perpendicular to the implant axis to provide an optimal, undistorted image of the implant threads.

The crestal bone level (Fig 1) was measured from the bottom of the implant shoulder to the point of first bone contact.²³ To allow for distortion, the measurements were corrected using the distance between 2 threads on each implant. The ratio of the absolute values versus the measurement observed on radiographs was calculated and multiplied by the distance in millimeters to the level of the crestal bone using a validated algorithm. The radiographs were evaluated independently by the same radiologist (Dr Anders Frykholm, Stockholm, Sweden). The marginal bone level was measured with a scale in tenths of a millimeter with 7× magnification using the upper edge of the implant as a reference point. On each occasion, the proximal bone level was determined in relation to the reference point to the tenth of a millimeter. The corrected mesial and distal values



Figs 2a and 2b Bone quality as a function of implant position in (left) the mandible and (above) the maxilla. Universal (FDI) tooth numbers shown.

for each implant were calculated and the mean values determined. This mean value was compared to the baseline and recorded as a positive or a negative change (ie, as a bone loss or gain, respectively).

Statistical Analysis

The data were analyzed statistically for changes over time. A linear mixed model was used, with “patient” considered a random effect (as there were multiple implants). The absolute values of crestal bone measurement for the mesial and distal aspects alone and the mean data (combined mesial and distal) were used, with a significance level of $P = .05$. The Kolmogorov-Smirnov test did not reject the null hypothesis of normal distribution. The null hypothesis in the mixed model was that there is no time effect. This was rejected in all cases.

RESULTS

A total of 45 patients were enrolled in the study. One patient withdrew from the study prior to implant surgery. In the remaining 44 patients, 97 implants were placed. In 3 patients (6 implants), primary stability and a torque of 15 Ncm was not achieved for all implants, requiring the patient to be withdrawn as per protocol. Another patient received 9 implants; this was considered a protocol violation, and the patient was excluded from the evaluable population analysis.

After these patients were excluded, 40 evaluable patients with 82 implants received 41 treatments (one patient had contralateral implants). These 82 implants were loaded between 0 and 11 days

postimplantation with a provisional prosthesis, with a mean \pm SD of 4.3 ± 2.8 days. Eight patients were restored with a 3-unit fixed partial prosthesis, and 32 patients with 2 units splinted. Bone quality and implant placement torque were assessed and recorded at each implant site. Figs 2a and 2b show the bone quality distribution as a function of tooth position. The figures represent data from 40 patients with 82 implants, with most implants placed in type 2 or type 3 bone and 12 patients in type 1 bone. Only 4 sites were judged to be type 4 bone.

The torque value at implant placement was between 15 and 45 Ncm for the evaluable population (Table 3).

The time to loading with the temporary prosthesis varied from within 24 hours of surgery to within 11 days. In a breakdown of the time to loading shown in Table 2, 25% of patients had their implants loaded within 24 hours of surgery. The definitive prosthesis was placed between 0 and 12.3 months postsurgery, with a mean of 4.5 ± 2.5 months.

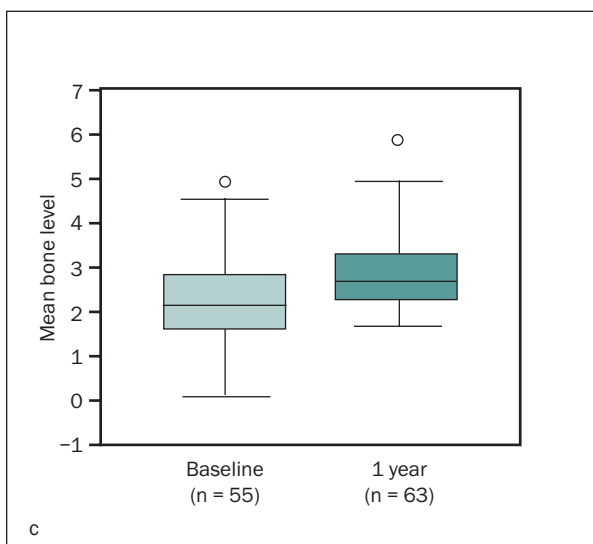
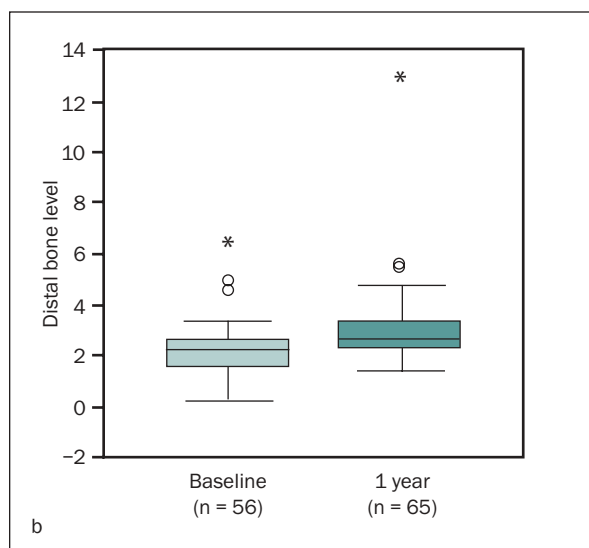
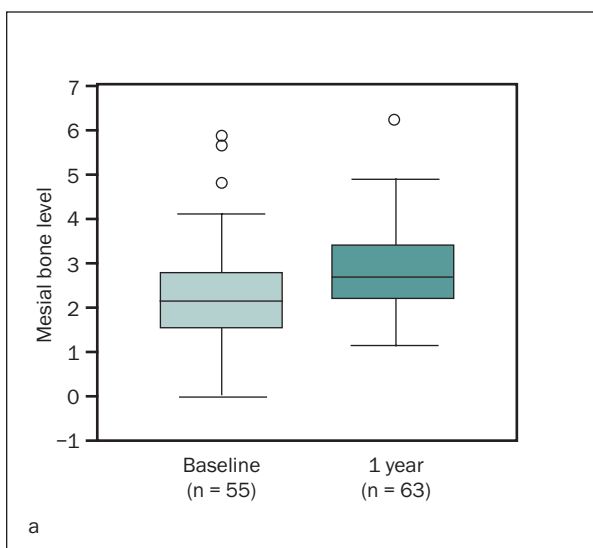
Crestal Bone Evaluation

Figures 3a to 3c show the level of crestal bone at baseline (measured on radiographs obtained immediately after placement) and at the 1-year follow-up examination presented as box plots. The crestal bone level was measured on both the mesial and distal aspects of the implants. These data were evaluated for the mesial and distal aspects separately and also for the mean of 2 values for each implant. Fifty-five of 82 mesial and 56 of 82 distal radiographs were evaluable at baseline. At 1 year, 63 of 80 mesial and 65 of 80 distal radiographs were evaluable. Analysis of the

Table 3 Torque Values (Ncm) Related to Tooth Position

Implant position	No. of implants evaluated	Torque (Ncm) at placement				
		Minimum	Maximum	Median	Mean	SD
5 (14)	2	20	45	33	33	18.0
4 (15)	2	20	45	33	33	18.0
12 (24)	2	40	40	40	40	0.0
13 (25)	3	30	40	35	35	7.1
14 (26)	1	20	30	25	25	7.1
21 (34)	2	35	45	40	40	7.1
20 (35)	7	15	45	30	30	10.6
19 (36)	18	20	45	30	30	7.0
18 (37)	13	15	45	30	30	8.5
28 (44)	3	18	30	20	20	6.4
29 (45)	7	15	35	25	25	7.7
30 (46)	15	15	45	30	30	9.9
31 (47)	7	15	40	33	33	9.3
Total	82	15	45	30	30.7	8.9

Analysis of 40 evaluable patients with 82 implants.
Universal (FDI) tooth numbers shown.



Figs 3a to 3c Crestal bone analysis as an effect of time (baseline to 1 year). Paired sample statistics and paired sample test.

Fig 3a Mesial bone level. ° = outliers; gray area represents the 25th and 75th quartiles; error bars represent the 95% and 5% limits.

Fig 3b Distal bone level. ° = outliers; gray area represents the 25th and 75th quartiles; error bars represent the 95% and 5% limits; *extreme cases.

Fig 3c Mean bone level. ° = outliers; gray area represents the 25th and 75th quartiles; error bars represent the 95% and 5% limits.

distal, mesial, and mean bone level values showed that there was a significant loss of bone level from baseline to 1 year (0.57 ± 1.12 mm distally, 0.47 ± 1.08 mm mesially; mean of 0.52 ± 0.99 mm). Thus, the null hypothesis, "there was no change over time," was refuted. Radiographic data for other implants could not be analyzed because the film was under- or over-exposed, angulation was incorrect, or the reference point of 2 threads was not visible.

Implant Survival

During the first year, 1 implant was lost at 5.5 months; this patient was withdrawn from the study as 1 implant failure and 1 treatment failure. There were 39 patients and 80 implants remaining at 1 year. Therefore, the survival rate of implants at this time was 98.8%. Of 42 patients, 41 still had a functional prosthesis at the 1-year follow-up, providing a success rate of 97.5%. Adverse events and complications were monitored; none were remarkable. In 1 case temporary paresthesia occurred, which is now resolved. Two cases of discomfort and pain around an implant were observed. One of these resolved spontaneously, while the other evolved into a severe infection, resulting in implant mobility and removal before fabrication of the definitive prosthesis. No prosthetic complications were observed. Patient satisfaction regarding comfort, appearance, and chewing ability was evaluated. Oral hygiene was also evaluated throughout the study. The proportion of patients whose oral hygiene was rated excellent or good increased from 87.5% at baseline to 93.5% at 1 year postloading.

Opposing Dentition

Data on 78 implants and their opposing dentition were available. Seventy (89.7%) of the implants were placed opposing natural teeth or fixed restorations. The remaining 8 implants (10.3%) opposed removable dentures or missing teeth.

DISCUSSION

The time frames for immediate and early loading were not strictly defined; loading within 0 to 7 days was considered immediate. However, after the protocol used in this study was written, a consensus meeting was organized by Sociedad Espanola de Implantes held at its World Congress in Barcelona²⁶ on May 23, 2002. The definitions of immediate, early, and delayed loading times have since been revised as follows:

- Immediate loading: The prosthesis is attached to the implants the same day the implants are placed.

- Early loading: The prosthesis is attached at a second procedure, earlier than the conventional healing period of 3 to 6 months; loading should occur within days or weeks.
- Delayed loading: The prosthesis is attached at a second procedure after a conventional healing period of 3 to 6 months.

In this study of 45 patients recruited from 8 centers, 5 patients were excluded. Eighty-two implants were subsequently loaded and have been followed for at least 12 months. In this period 1 implant was lost; all others remained in function. This failure rate is comparable to earlier studies on early loading.^{27,28} These authors concluded that a healing period of 6 weeks is enough to allow loading with a risk rate comparable to that of the standard procedure.

Oral hygiene instruction was given throughout the study. Oral hygiene compliance was good throughout and improved to a 1-year postloading rating of > 90% with a rating of excellent or good for oral hygiene status. Ninety-five percent of patients scored a 0 (ie, no plaque or bleeding) using the Plaque Index and Sulcus Bleeding Index at 1 year. These results are typical for dental implant patients. Although these parameters were monitored, no data were accumulated for analysis.

Bone loss at 1-year postloading was within the accepted limits for this time frame. It is expected that the largest loss (0.4 to 1.5 mm) will be within the first year.²⁹ Following the success criteria proposed by Albrektsson and associates,²³ all loaded implants were classified as successful except 1 failure at 5.5 months postloading.

In this study, based on recommendations for immediate loading, the immediate splinting of the implants with a rigid connection was stressed as crucial for obtaining osseointegration, although recent publications³⁰⁻³² have reported good success rates for immediately loaded single-tooth implants.

All 4 bone classes were represented in the evaluable population and appear not to have had an influence on the success of the treatment.

CONCLUSIONS

The early results from this study indicate that immediate loading of 2 implants in the posterior maxilla or mandible may be suitable in selected patients, provided that the implants are stabilized with splinting. On the basis of this 1-year observation period, early loading of SLA implants appeared to be a viable option in this patient population.

ACKNOWLEDGMENTS

Other contributing authors were Dr G. Gualini, MD, DDS, Lovere, Italy; Dr M. Massagli, MD, DDS, Florence, Italy; Dr G. Podda, MD, DDS, Rome, Italy; Dr M. Prowisionato, MD, DDS, Forli, Italy; and Dr L. Galasso, MD, DDS, Naples, Italy. The authors thank Dr H. Toutenberg and colleagues of the Statistics Institute, Munich, Germany, for their assistance with the statistical evaluation. Thanks are also due to Dr J. Simpson and Ms M. Kings, MSc, of Straumann for help in writing this publication.

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