

# A 3-Arm Study of Early Loading of Rough-Surfaced Implants in the Completely Edentulous Maxilla and in the Edentulous Posterior Maxilla and Mandible: Results After 1 Year of Loading

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**Purpose:** The aim of the present prospective study was to evaluate the concept of early loading of rough-surfaced implants in the completely edentulous maxilla and in the edentulous posterior mandible and maxilla. **Materials and Methods:** Fifty-four consecutive patients were treated. Twenty patients were completely edentulous in the maxilla (group A), 19 patients were edentulous in the posterior left and/or right maxilla (group B), and 15 patients were edentulous in the posterior left and/or right mandible (group C). One patient in group B and 5 in group C were bilaterally treated. Two hundred thirty-four solid screw-type, sandblasted, large-grit, acid-etched (SLA) ITI implants were placed, 58 (25%) immediately after tooth extraction. Mean placement torque and standard deviations were measured at all sites. Sixty fixed prostheses were delivered after a mean delay of 9 days (range, 4 to 22 days). Mean marginal bone reduction was measured after 1 year of loading. **Results:** Two implants were lost (0.9%), 1 before functional loading and 1 after 1 year. All other implants were clinically stable, with a mean marginal bone loss of 0.75 mm ( $\pm$  1.3 mm). Marginal bone loss ranged from 0 to 3.5 mm. Mean placement torque on implants placed in healed bone or immediately after tooth extraction ranged from 29.1  $\pm$  9.3 Ncm to 35.5  $\pm$  5.8 Ncm. No statistical difference was found ( $P > .05$ ) between implants placed in healed bone and those placed immediately after tooth extraction. **Discussion:** There is little documentation for immediate or early loading in the areas studied. However, in this study, favorable results were obtained in 54 consecutive patients in these regions. **Conclusion:** In this study population, early loading protocols can be applied with predictable results using rough-surfaced implants for rehabilitation of the completely edentulous maxilla, posterior maxilla, and posterior mandible. INT J ORAL MAXILLOFAC IMPLANTS 2004;19:880–886

**Key words:** clinical studies, dental implants, early loading

There are many longitudinal investigations reporting successful treatment results with implant-supported fixed prostheses in partially or

completely edentulous jaws.<sup>1–4</sup> In these studies implant healing time varied from 3 to 6 months. Because long healing periods are an inconvenience for the patient, immediate or early loading of implants has become routine in many clinics. This method has been reported to be predictable in the mandible.<sup>5–16</sup> Many recent studies of immediate or early loading in completely edentulous maxillae and partially edentulous jaws have used samples of only 4 to 10 patients.<sup>17–23</sup> Only a few studies have reported on immediate loading.<sup>7,16,24</sup> Moreover, most of these studies were not prospective or controlled. There is also a lack of studies with multiple arms. In a retrospective study Degidi and Piattelli<sup>24</sup> reported cumulative success rates of 98.5% for implants placed in the completely edentulous maxilla and 100% for implants placed in the completely

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edentulous mandible. In the same study, an insignificant number of implants were placed in the posterior maxilla ( $n = 6$ , cumulative success rate = 100%), anterior maxilla ( $n = 16$ , cumulative success rate = 88%), and posterior mandible ( $n = 22$ , cumulative success rate = 91%).

Both immediate and early loading appear to be feasible. However, the limited study samples of reported investigations make it difficult to evaluate statistical interpretations of the results. This prospective investigation aimed to evaluate early loaded rough-surfaced implants placed in the completely edentulous maxilla and the posterior edentulous maxilla and mandible using a larger sample than those previously studied.

## MATERIALS AND METHODS

### Patients

Subjects were selected from patients referred to the Department of Oral and Maxillofacial Surgery and the Department of Prosthodontics of Sophiahemmet, a private hospital in Stockholm, Sweden, who requested implant treatment. The patients were divided into 3 groups. Group A consisted of 20 patients with completely edentulous maxillae, Group B of 19 patients with edentulous posterior left and/or right maxillae, and Group C of patients with edentulous posterior left and/or right mandibles. One patient from group B and 5 patients from group C were treated bilaterally. Patients were consecutively enrolled in the study according to predefined inclusion and exclusion criteria.

Patients were required to be medically healthy. No age limit was set. Patients receiving steroid treatment, those with known leukocyte dysfunction, those currently undergoing chemotherapy, and those with uncontrolled endocrine disorders, psychotic disorders, or known current alcohol abuse were excluded. Smokers were excluded if they smoked more than 10 cigarettes per day. Smokers were asked to reduce or stop smoking before undergoing treatment.

Implant recipient sites with radiographically detectable pathologic conditions or a history of local radiation therapy were excluded. Sites needed to have adequate bone volume, as judged clinically and radiographically by the surgeon.

The study sample comprised 54 consecutively treated patients (38 females, 16 males) with a mean age of 69.5 years (range, 40 to 96 years). All patients were examined by both an oral surgeon and a prosthodontist who also carried out the surgical and prosthodontic treatment. The radiographic exami-

nation included panoramic and intraoral radiographs and, if required, tomography. Following clinical and radiographic examinations, the patients were informed of the treatment possibilities and the design of the study. The patients were not enrolled in the investigation until immediately before surgery and after verification that they met the inclusion criteria and had given their written informed consent. The protocol for the study was approved by the Research Committee of Ethics at the Karolinska Hospital, Stockholm, Sweden.

### Surgical Procedure

All surgery followed the recommendations of the manufacturer of the implants.<sup>25</sup> All patients were treated under local anesthesia; approximately 10 mL (2%) lidocaine with epinephrine (1:80,000) (Xylocaine-Adrenalin; AstraZeneca, Södertälje, Sweden) were used in each patient. The patients were also periorally sedated with benzodiazepam (Triazolam; Gerard Laboratories, Dublin, Ireland). All patients were also given prophylactic antibiotics (2 g penicillin twice daily for 10 days; Kåvepenin; AstraZeneca).

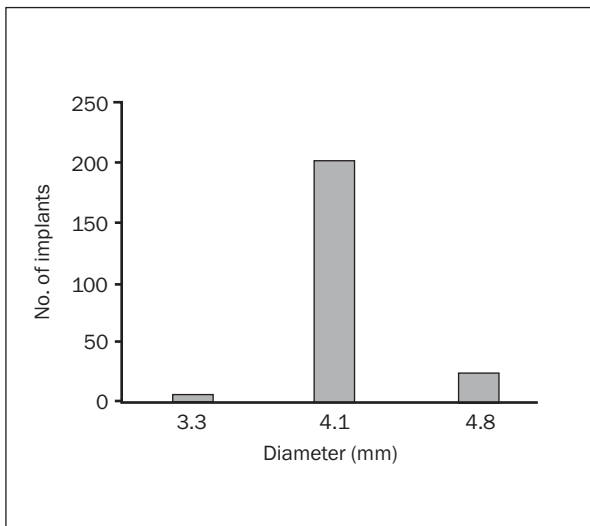
Between 2 and 7 solid screw-type ITI implants (Straumann, Waldenburg, Switzerland) with a sand-blasted, large-grit, acid-etched (SLA) surface were placed in each patient (Figs 1 and 2 show implant diameter and length). Octa abutments (Straumann) were mounted before the flaps were sutured. Placement torque was measured at all implant sites using a manual torque device (Torque Wrench Tool; Straumann) at the time the abutments were mounted. A scale of 0 to 40 Ncm was used. If, for example, the implant was rotating at 20 Ncm, this was measured as a placement torque value of 20 Ncm. The maximum torque could not be higher than 40 Ncm. According to the manufacturer, this tool was accurate within  $\pm 1$  Ncm in the 10- to 36-Ncm range and within  $\pm 2$  Ncm for torques  $> 36$  Ncm.

Patients were instructed to avoid brushing the treated area postoperatively and to rinse with chlorhexidine twice daily.

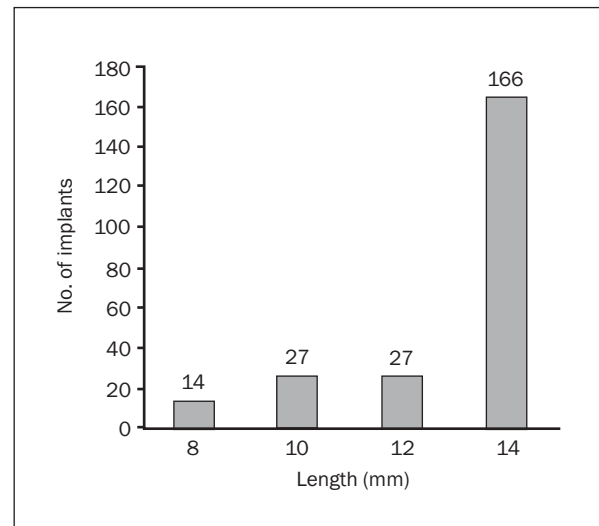
### Prosthetic Procedure

The prosthodontic treatment also followed the recommendations of the manufacturer, apart from the early loading of the implants. One prosthodontist performed all of the prosthodontic treatment. Octa abutments were used for all implants. In all cases impressions were made immediately after implant surgery. Screw-retained prosthetic restorations were used in all cases to restore 2 to 12 teeth.

All prostheses were removed at the 3-month recall. Functional examination results and patient



**Fig 1** Number and length of placed implants.



**Fig 2** Number and diameter of placed implants.

experiences were recorded. All the abutments were tightened to 35 Ncm. This procedure was repeated at the 6-month and 1-year clinical examinations.

### Follow-up

A number of variables were recorded at the time of implant placement, during the implant healing period, at delivery of the prosthesis (baseline), and 3 months, 6 months, and 1 year after prosthesis delivery. At implant placement, implant positions and dimensions, the primary stability of the implants, and complications were noted. During the healing period, complications were also recorded. At baseline and at the 3-month, 6-month, and annual recalls, all fixed prostheses were removed to enable clinical assessment of implant stability.

### Survival Criteria

An implant was considered successful if the following criteria were met<sup>26,27</sup>: (1) the implant was found to be clinically stable after the fixed prosthesis had been removed and the abutments tightened; (2) no signs of pathologic reactions, pain, or infection were found in the hard or soft peri-implant tissue; and (3) no peri-implant radiolucency was found. An implant was considered to have failed if it was removed for any reason. The implant success rate could not be evaluated because of incomplete data.

### Radiographic Examination

The implants were placed with the border between the rough surface and the smooth surface at the marginal bone level. Intraoral radiographs were obtained at the times specified by the protocol, ie,

baseline and after 1 year of functional loading. The radiographs were taken with the standard technique of the clinician.

All radiographs were evaluated by the same radiologist. Measurements were made using a Peak scale loupe (Peak, Tokyo, Japan) with a magnifying factor of 7× and had a scale calibrated to tenths of a millimeter. The level of the marginal bone was assessed mesial and distal to the implant; the distance from a reference point (the border between the implant shoulder and the crown, 2.8 mm from rough border of the implant) to the point at which the bone met the surface of the implant was measured. To compensate for magnification in the radiographs, the distance between threads 1 and 3 on each implant was measured, and the value was used to compensate for the magnification and calculate the true crestal bone height. For each implant the true value was calculated for the mesial and distal surfaces. The means of these 2 values were used to calculate the difference in bone level from baseline to 1 year.

### Data Collection

The records from all examinations were registered on a case record form. The data were transferred from these record forms to a computer for analysis. Before the data were entered into the computer, all personal identification information was removed.

### Statistical Analysis

The investigation was devised as an observational study of 3 groups. The statistical variables (ie, the responses) were observed at the time of loading and at 1 year postloading in a repeated measures model.

**Table 1 Adverse Events**

Event class	No. of events	Outcome	Comments
Framework/prosthesis-related complications	7	Resolved	<ul style="list-style-type: none"> <li>• Broken framework</li> <li>• Revision required to improve poor esthetics</li> <li>• Loose or fractured prosthesis</li> </ul>
Clinical complaints	4	Resolved	<ul style="list-style-type: none"> <li>• Gingivitis</li> <li>• Paresthesia</li> <li>• Irritation</li> </ul>
Implant instability	2	Removed	<ul style="list-style-type: none"> <li>• No primary stability</li> <li>• Implant failure at 10 days postsurgery in 1 case and after 1 year of loading in the other</li> </ul>

In addition, 1 patient died; death was related to natural causes.

The SPSS statistical package (Chicago, IL) was used for analysis. Quantitative measurements are described using summary statistics (number, mean, median, and standard deviation). The significance level was set at  $P < .05$ .

Each patient had multiple implants. The effect of multiple implants is a generally positive correlation of implant-specific response variables; clusters are built in the data set. In the case of a continuous response, it is necessary to check that the assumption of normal distribution cannot be rejected. The Kolmogorov-Smirnov test was used to check this. For each patient, a graphic representation of the implant distribution was carefully examined with emphasis on symmetry, outliers, and skew. Although good results in these areas cannot prove normal distribution, they did not disprove it and thus justified use of the models applied as one method of data analysis.

The Mann-Whitney test was used to compare the achieved placement torque in healed versus immediate extraction sockets. This test does not take into account the multiple-response situation and is used in a more exploratory or descriptive sense. Therefore, the cumulated ordinal regression model with random cluster effect was calculated as a correct model.

## RESULTS

Fifty-three of the 54 patients were seen at the 1-year follow-up examination. One patient had died. At the 3-month follow-up it was noted that 1 implant caused a patient pain when the abutment was tightened. The implant was classified as a failure and was removed at the 1-year follow-up. Two patients had temporary paresthesia in their mental nerve (Table 1).

One hundred twenty-two implants were placed in group A, 59 in group B, and 53 in group C. Figs

1 and 2 show implant length and diameter. Two of 234 implants were lost in 2 patients (ages 58 and 59), 1 before loading. The 2 lost implants were both placed in the maxilla; 1 penetrated the maxillary sinus and 1 was placed in the maxillary right canine region. No implant losses occurred among the 9 (15%) smokers.

The overall cumulative survival rate (CSR) was 99.1%. One of the lost implants was from group A, giving that group a CSR of 99.2%. The other lost implant was from group B (CSR = 98.3%). In group C, no implant was lost (CSR = 100%). For 4 implants, marginal bone resorption was  $> 2$  mm.

## Radiographic Results

The bone level was measured from the implant shoulder to the first bone apposition level detected on the radiographs. An increase in the bone level indicated bone loss around the implant. The minimum, maximum, and mean bone levels for each group at baseline and after 1 year, as well as mean change in bone level at 1 year, are given in Table 2.

For 8 implants no radiographs were taken preoperatively or postoperatively. In 12 other cases, the implant reference point could not be identified at baseline or after 1 year of loading, or more than 3 threads were not visible on the intraoral radiographs, and thus, measurement could not be completed. In a further 16 implants, additional measurements had to be done on panoramic radiographs. One patient (with 3 implants) died after 6 months, and 2 implants could not be measured because of failure. Altogether 15% of the mesial or distal implant surfaces were not measured appropriately according to the protocol. However, no indications of peri-implantitis or severe marginal bone loss were observed around these implants after radiography.

The implants seemed to have been placed deeper in group C than in the other groups. Overall mean

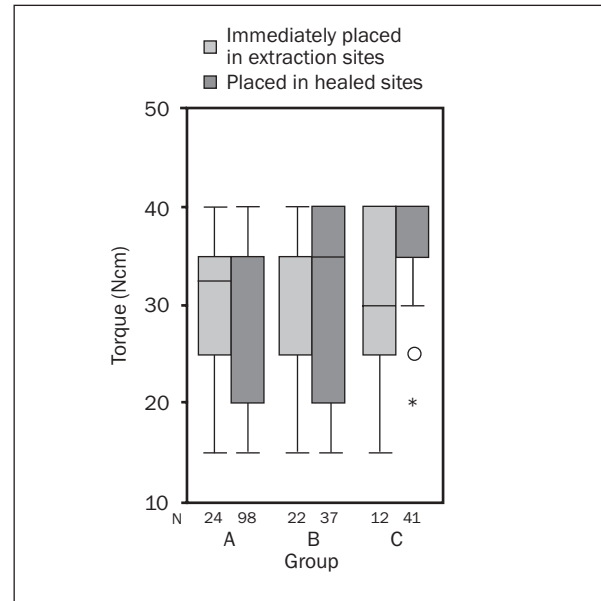
**Table 2 Mean Crestal Bone Levels (mm) at Baseline and 1 Year Postloading and Mean Change**

Group	Baseline			1 Year			Mean change		
	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean
A	0.00	6.25	2.20	1.01	6.49	2.79	-4.66	4.02	-0.63
B	0.00	5.18	2.05	1.51	4.95	2.91	-3.18	1.97	-1.03
C	0.00	3.03	1.03	0.00	3.41	2.65	-3.19	0.23	-0.96

The mean bone level is the mean of the distal and mesial measurement for each implant.

**Table 3 Torque on Implant at Surgery (Ncm) in Implants Placed Immediately in Extraction Sockets and in Implants Placed in Healed Bone**

Group	N	Min	Max	Mean	SD
A					
Immediate	24	15	40	30.42	8.330
Healed	98	15	40	29.13	9.251
B					
Immediate	22	15	40	30.23	7.316
Healed	37	15	40	30.95	9.919
C					
Immediate	12	15	40	30.42	9.405
Healed	41	20	40	34.49	5.788



**Fig 3** Mean torque at implant placement. The 25th and 75th percentiles, with 95% confidence limits, are shown. \*Outliers; \*out of range.

marginal bone level reduction after 1 year of loading was 0.75 mm ( $\pm$  1.3 mm), ranging from 0 to 3.5 mm. No statistical differences were found between the 3 groups ( $P > .05$ ). No statistically significant differences in marginal bone levels were found between implants placed in extraction sockets and those placed in healed bone ( $P > .05$ ).

**Placement Torque**

The mean torque among the 3 groups varied between 29 and 35 Ncm (range, 15 to 40 Ncm) (Table 3). No statistically significant difference ( $P > .05$ ) was found between implants placed immediately after extraction and those placed in healed bone (Fig 3).

**Prosthetic Considerations**

Efforts were made to give all patients a fixed definitive prosthesis within 10 days of implant placement. However, logistical problems arising between the prosthodontist and the technician meant that this was not possible in all cases. The mean time for

placement of definitive fixed prostheses was 9 days (range, 4 to 22 days). One patient had a temporary prosthesis delivered after 4 days and was given a definitive prosthesis after 144 days. After 3 months of loading, all abutments except 1 could be tightened to 35 Ncm. In many cases, plaque control was difficult to achieve.

**DISCUSSION**

An earlier study indicated that implants standing alone after 1-stage surgery are subject to premature loading and have a higher incidence of failure.<sup>11</sup> Therefore, splinting of implants placed in softer bone should be valuable. In the present investigation the implants were splinted together with definitive fixed restorations within 4 to 22 days (mean, 9 days) after implant surgery, and the patients did not wear removable dentures during this period. Only 1 implant was lost before loading; this implant was removed because of poor initial stability. After 1



year of loading, 1 additional implant in another patient was found not to be osseointegrated and was removed. Thus, the CSR for this study after 1 year of functional loading was 99.1%; this high CSR supports the assertion that early splinting of the implants could be the best solution even in situations where bone quality might be compromised.

In 25% of the implant sites, the implant was placed immediately after tooth extraction. This did not lead to reduced initial stability of the implants compared with implants placed in healed bone. Other studies with 2-stage protocols have produced contradictory results. Immediate placement of implants may or may not affect the survival rate.<sup>22,24,28</sup>

One aim of this study was to evaluate the reduction of the marginal bone level. In 36 of 234 implant sites (15%) this could not be done according to the prospective protocol, since these radiographs did not meet specific criteria. Therefore, implant success could not be evaluated. However, all implants were individually clinically assessed after 3 months and after 1 year of loading, and attendant radiography revealed no excessive marginal bone loss.

Schnitman and colleagues<sup>7</sup> published a study comparing machined implants submerged in the mandible with a subsequent healing period and nonsubmerged, immediately loaded implants. The CSR for the 2-stage group was 100%, compared with 85% in the 1-stage group. In another study,<sup>13</sup> 185 machined implants were placed in the completely edentulous mandible, 153 in healed bone and 31 in fresh extraction sites. Only 1 implant placed in healed bone was lost. Twelve of the 31 (39%) placed in extraction sites were lost, and it was recommended that early loading of implants placed immediately after extraction be avoided. This contradicts the results from the present study, in which no implant failures occurred after the early loading of implants placed in fresh extraction sites. Perhaps this is an indication that rough-surfaced implants clinically increase initial stability compared to machined surfaces. This has in fact been confirmed in several experimental studies.<sup>29–31</sup> In 1 recently published report,<sup>32</sup> 61 oxidized titanium implants were placed in 10 patients in completely edentulous maxillae, and fixed prostheses were delivered within 9 days (mean 2.5 days). Because of an infection, 4 implants (6.6% of placed implants) were lost in 1 patient after 10 weeks of loading. All other implants were stable after 1 year of loading. While high survival rates using rough-surfaced implants were realized, the possible risk should not be neglected.

In a controlled study by Fischer and Stenberg,<sup>33</sup> the feasibility and safety of early loading of implants

in the edentulous maxillae were evaluated. All patients received 5 to 6 solid-screw ITI SLA titanium implants. The implants in the test group (16 patients) were loaded within 9 to 18 days, while those in the control group (8 patients) were loaded within 2.5 to 5.1 months. After 1 year of loading, all implants in both groups were still in function, indicating equal results for both groups. Conclusions from this study could only be drawn from feasibility analyses of the results, and therefore there is still a need for controlled studies containing more patients.

## CONCLUSION

In this study population it was found that early loading of roughened (SLA-surfaced) screw-type ITI implants can be a reliable treatment method in the rehabilitation of completely edentulous maxillae and in the posterior maxilla and mandible.

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