

# Early Loading of ITI Implants Supporting a Maxillary Full-Arch Prosthesis: 1-year Data of a Prospective, Randomized Study

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**Purpose:** This prospective, randomized study investigated the safety, feasibility, and reliability of the early loading of implants in edentulous maxillae. **Materials and Methods:** Twenty-four patients with completely edentulous maxillae were randomized into a test group ( $n = 16$ ) and a control group ( $n = 8$ ). All patients received 5 or 6 solid screw-type titanium implants. These were loaded with full-arch prostheses after 9 to 18 days in the test group and after 2.5 to 5.1 months in the control group. Periapical radiographs were taken and routine clinical assessments were made at loading, after 6 months, and after 12 months. **Results:** The implant survival rate 1 year after loading was 100%. Modified Plaque Index scores and Sulcus Bleeding Index scores were better in the test group than in the control group ( $P \leq .05$ ). There was a significant difference in peri-implant bone height between the 2 groups ( $P < .001$ ) and this difference converged with time ( $P < .001$ ). **Discussion:** This clinical, prospective, randomized, controlled study fulfilled the criteria for a comparable study. Owing to the small patient sample, the conclusions drawn were based on feasibility analyses of the results. Standard materials and methods were used. Only patients with maxillary bone of sufficient height and width were selected. The use of a single operator in each discipline—maxillofacial surgery, prosthodontics, and dental technology—may have improved the chances of achieving consistent standards and opinions. **Conclusion:** These results indicate that early loading in selected patients was as safe and reliable as delayed loading in this small patient population and may offer a satisfactory alternative to the standard protocol. INT J ORAL MAXILLOFAC IMPLANTS 2004;19:374–381

**Key words:** dental implants, early loading, edentulous maxillae

Oseointegrated dental implants have been successful in the long-term rehabilitation of completely edentulous patients. Most standard protocols recommend a healing time of between 3 and 6 months<sup>1–3</sup> and require that transitional complete dentures be worn during the healing period. For many patients this is very difficult or unacceptable. To avoid these disadvantages it would be beneficial to load implants with a prosthesis as soon as possi-

ble after implant placement. Studies of different types of prostheses have shown that, for selected patients, early loading of mandibular implants can provide treatment outcomes comparable to those achieved using standard healing periods before loading.<sup>4–8</sup>

The early loading of implants supporting a full-arch prosthesis in the edentulous maxilla also has been studied.<sup>9–11</sup> Scortecchi<sup>9</sup> used a specially designed “disk implant,” which engages lateral and crestal cortical bone to obtain better primary stability. However, this implant requires a special surgical technique and special equipment. Of the 783 implants in his study, only 18% were screw-type and were axially placed according to conventional surgical practice. Jaffin and associates<sup>10</sup> described a single subject with a full-arch, implant-supported prosthesis. Tarnow and coworkers<sup>11</sup> demonstrated good results in 4 patients immediately fitted with a

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provisional, rigid, full-arch prosthesis in the maxilla. To date, the authors have not found any randomized, prospective clinical studies that specifically address the early loading of implants with a full-arch fixed prosthesis in the edentulous maxilla.

The purpose of this study was to compare treatment outcomes of implants loaded early (< 14 days postimplantation) with those of implants loaded after a healing period of 3 to 4 months. This article reports 1-year follow-up data of a 3-year prospective study.

## MATERIALS AND METHODS

### Patients

Subjects were selected from patients referred to the Department of Oral and Maxillofacial Surgery, County Hospital, Falun, Sweden, and the Department of Prosthodontics, Specialist Centre for Oral Rehabilitation, Falun, Sweden, between April 1999 and September 2000 who requested maxillary implant treatment. Patients were randomized and consecutively enrolled in the study according to predefined inclusion and exclusion criteria. Inclusion criteria were

- A completely edentulous maxilla
- The expectation of good occlusion
- Adequate bone quality and sufficient bone height and width to support 5 or 6 implants

Exclusion criteria were

- General health conditions not permitting implant surgery
- Smoking more than 10 cigarettes per day
- Unhealed extraction sites
- The use of bone grafting or a membrane at the intended implant sites

The test group comprised 16 patients, 10 women and 6 men, with a mean age of 65 years. The control group comprised 8 patients, 6 women and 2 men, with a mean age of 62 years.

### Pretreatment

At the first examination, an orthopantomogram, a lateral radiograph of the skull, and a computerized tomography (CT) scan were obtained. Potential sites for dental implant placement were assessed; any pathologic conditions were noted. The CT scan was used to evaluate the width and height of the bony ridge. An acrylic resin template was fabricated to cover the surface of the maxillary alveolar ridge. Steel ball bearings 5 mm in diameter were fixed to



**Fig 1** Implants after placement in a test-group patient.

the template at the locations where the authors intended to place implants, and a panoramic radiograph was taken with the template in position to evaluate the intended implant positions. These were adjusted where necessary. The opposing dentition was assessed. Prior to surgery intraoral photographs were taken, oral hygiene instructions were given, and each patient's written agreement to comply was obtained.

### Surgical Procedure

All patients were sedated with midazolam (Alpharma, Stockholm, Sweden), administered orally 30 minutes prior to surgery. All patients except 1 received 1 g penicillin (Kåvepenin; Astra, Södertälje, Sweden) 1 hour preoperatively and 3 g daily for 7 days postoperatively. In 1 patient with an allergy to penicillin, 150 mg clindamycin (Dalacin; Pfizer/Pharmacia, New York, NY) was given 1 hour preoperatively, followed by 150 mg 3 times daily for 7 days. For local anesthesia approximately 10 mL 2% lidocaine with 12.5 µg epinephrine (Xylocaine-Adrenalin; Astra) were given. Surgical procedures followed the guidelines provided for ITI implants (Straumann, Waldenburg, Switzerland) and accepted practice (Fig 1). The implant placement sites, determined using the ball bearings, were marked on the oral mucosa prior to surgery. All surgical treatment was performed by the same clinician.

Solid screw-type ITI implants (4.1 mm diameter) with a sandblasted, large-grit, acid-etched (SLA) surface, Octa abutments, and all associated components were supplied by Straumann and placed from maxillary left second premolar to maxillary right second premolar. To avoid rotational forces on the implant following placement as much as possible, implants with Octa abutments attached at the factory were used in the test group. The use of preattached abutments eliminated the 35-Ncm forces that would have been necessary to connect the abutment

**Table 1** Distribution of 4.1-mm-Diameter Implants by Length

Implant length (mm)	No. of implants	
	Test group (n = 16)	Control group (n = 8)
8	18	9
10	39	17
12	38	21
Total	95	47

n = no. of patients in each group.

to the implant. In the control group, EstheticPlus implants were used in all but 1 case (in that patient, standard ITI implants were used), and the abutments were connected to the implants at the time of impression making. A total of 142 implants were placed. Distribution of implant lengths between the groups is shown in Table 1. Bone quality was assessed at surgery using the classification system described by Lekholm and Zarb<sup>12</sup>; each implant site was scored independently.

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

### Prosthetic Procedure

**Test Group.** Immediately after placing Octa transfer copings and suturing the mucoperiosteal flaps, impressions (Impregum Penta; ESPE, Seefeld, Germany) were made of the maxillary and mandibular arches. An Octa titanium coping prosthesis was attached to the abutments in the canine regions, and centric relation was recorded using a silicone putty material (Provil Novo; Heraeus Kulzer, Hanau, Germany). Octa protective caps were then placed on the abutments. Before placing the protective caps, small grooves were made on the inside of the caps to reduce the retentive force between the cap and the abutment, thereby reducing the amount of rotational force needed to screw the cap into place and remove it. Patients were instructed to not wear a maxillary denture.

Octa implant abutment analogs were placed in the impressions of the maxilla, and casts of the maxillary and mandibular arches were poured in stone. The casts were mounted in an articulator and a waxup of the prosthesis was completed. As soon as possible (normally within days), the vertical dimension, occlusion, esthetics, phonetics, and fit of the waxup were checked intraorally. Once the waxup had been verified, a rigid titanium framework was cast. Following suture removal, the framework was attached to the abutments by SCS titanium occlusal screws (Straumann) and the fit assessed both clinically and

**Table 2** Length (in mm) of Distal Cantilevers in Test and Control Groups

	Left		Right	
	Mean	Range	Mean	Range
Test group	7.6	2 to 13	8.9	3 to 14
Control group	9.3	5 to 15	10.0	5 to 16

radiologically. Where the fit was inadequate, the framework was sectioned and the components were individually attached to the abutments by occlusal screws and joined using acrylic resin (Duralay; Reliance, Worth, IL). The framework was removed from the mouth and laser welded, and another try-in was performed. Once an acceptable fit had been achieved, the full-arch titanium-resin prosthesis was completed and permanently fitted to the abutments within 9 to 18 days. All prostheses were fabricated by the same dental technician. Patients were given oral hygiene instructions. An orthopantomogram and intraoral radiographs and photographs were taken, and clinical parameters were assessed as per protocol.

**Control Group.** After implant placement, patients were told not to use their dentures until sutures had been removed (approximately 9 days after surgery). Following suture removal the maxillary denture was relined with the soft base material GC Reline Extra Soft (GC Corporation, Aichi, Japan). The relined denture was used until the abutments were placed after 2.5 to 5.1 months (mean 3.7 months). At this appointment, the protective caps were removed, Octa abutments were connected to the implants, and Octa transfer copings were mounted on them. The old soft base lining material was replaced by new material. Impressions were made and prostheses were fabricated using the same procedures described for the test group.

All prosthetic treatment was provided by the same clinician. Data regarding distal extension of the cantilevers of the prostheses for both groups are shown in Table 2. Data depicting the opposing dentition for both groups are shown in Table 3.

### Follow-up Investigations

Clinical and radiographic examinations, assessments of implant mobility, and prosthesis assessment were carried out according to the schedule shown in Table 4. One patient missed the 3-month visit. Oral hygiene, the Sulcus Bleeding Index, Plaque Index (modified), and width of the keratinized gingiva were clinically evaluated by the prosthodontist.

**Table 3 Mandibular Dentition**

Dentition	Support	No. of patients			
		At treatment planning		At 12-month checkup	
		Test	Control	Test	Control
Removable prostheses					
Complete denture	Mucosa	0	1	0	0
Partial denture	Tooth	4	2	1	0
Conus construction	Tooth	1	0	0	0
Fixed prostheses					
Complete	Tooth	1	0	1	0
	Implant	1	0	3	3
Partial	Tooth	2	3	5	3
	Implant	0	0	1	1
Single crown	Implant	0	0	1	0
Natural		6	2	3	1
None (edentulous)		1	0	1	0
Total		16	8	16	8

**Table 4 Timetable of Follow-up Investigations**

	Time postloading (mo)			
	0*	3	6	12
Assessment				
Bone loss	×	×	×	×
Dental history		×	×	×
General health		×	×	×
Mobility	×	×	×	×
Oral hygiene		×	×	×
Pain	×	×	×	×
Peri-implant infection	×	×	×	×
Restoration	×	×	×	×
Soft tissue		×	×	×
Photographs taken	×			
Radiographs taken				
Existing teeth				×
Implants	×		×	×
Maintenance		If needed	If needed	If needed

\*At loading.

**Radiographic Examination.** The method for taking intraoral radiographs was not standardized. Films were exposed with a paralleling technique such that the cervical implant threads were clearly visible. Marginal bone level was measured by an independent specialist in oral radiology according to the method of Buser and colleagues.<sup>13</sup> Retention, mobility, and stability of the implants were indirectly assessed based upon subjective peri-implant radiolucency findings.

**Maintenance.** At each follow-up appointment, the prosthesis was checked for fracture, component failure, or clinical signs of bruxism that could affect the outcome. If one of these conditions was found, the appropriate repair or treatment was initiated.

### Statistical Analysis

The investigation was devised as an observational study of 2 randomized groups. The statistical variables (ie, the responses) were observed at the time of loading and at 1 year postloading in a repeated-measures model.

Each patient had multiple implants. The effect of multiple implants is a generally positive correlation of implant-specific response variables. The patients build the clusters 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, the graphic representations of the implant distribution were carefully

**Table 5 Summary of Statistical Evaluation of Clinical Parameters at 1-year Follow-up: Comparison Between Test and Control Groups**

	Better results?	P
Oral hygiene	Neither group	NS
Sulcus Bleeding Index	Test	.002
Modified Plaque Index	Test	.001
Width of keratinized gingiva	Control	.004
Cantilever length (left)	Neither group	NS
Cantilever length (right)	Neither group	NS

NS = not significant ( $P \geq .05$ ).

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 1 method of data analysis.<sup>14</sup>

The mixed model with random cluster-specific effect (using time, treatment, and time  $\times$  treatment as fixed effects), a suitable statistical model for a correlated continuous response, was used. This model is robust against the assumption of normality. In addition, the Friedman test (2-factorial nonparametric analysis of variance) was applied as a control. SPSS software (Chicago, IL) was used for these analyses.

In the case of a categorical (ordinal) correlated response, general estimation equations were applied using certified commercial software (aML Multi-process Multilevel Modeling; EconWare, Los Angeles, CA). The model is a cumulative logit model with a correlated response. The variables analyzed with this technique were the Sulcus Bleeding Index<sup>15</sup> and the modified Plaque Index.<sup>16</sup> The nonparametric Mann-Whitney test was used in the analysis of this data.

## RESULTS

### Implants

Of the 142 implants placed, 139 were loaded with complete prostheses, 94 in the test group and 45 in the control group. Three implants, 1 in the test group and 2 in the control group, failed prior to loading. Based on radiologic findings and mobility tests of the prostheses, all of the loaded implants were successful at 1 year postloading.

### Clinical Evaluation

Significant differences were found between the groups for the Sulcus Bleeding Index, the Plaque Index, and the width of keratinized gingiva (Table 5). The Sulcus Bleeding Index was lower for the test

group than for the control group at the 1-year follow-up (95% of test group implants scored 0 versus 75% of control group implants). The test group also scored lower on the Plaque Index (85% of test group implants scored 0 versus 65% of control group implants). The average width of keratinized gingiva at 1 year was 3.6 mm for the test group and 4.5 mm for the control group.

**Mobility/Stability.** These parameters were estimated directly by manipulating the seated prosthesis and indirectly by the presence of radiolucency around the implants. No mobility or loss of stability was recorded at any follow-up appointment in either treatment group.

**Peri-implant Radiolucency.** Radiolucencies were seen in 3 patients (1 in the test group and 2 in the control group) at the 6-month follow-up and in 2 patients (1 in the test group and 1 in the control group) at the 12-month follow-up. To date the stability of the prostheses has not been visibly reduced despite these observations.

**Prosthesis Evaluation.** Retention and esthetics were evaluated and graded on a scale of 1 (excellent quality) to 4 (poor quality). Prosthesis retention in both groups was rated as excellent; there was no mobility when the prostheses were manually pressed and pulled.

**Oral Hygiene.** Oral hygiene was evaluated and graded either excellent (no plaque), good (plaque on running probe), fair (plaque seen by naked eye), or poor (an abundance of soft matter). Ninety-four percent of the test group subjects and 63% of control group subjects were rated excellent or good in terms of oral hygiene.

### Complications/Adverse Events

No implant-associated problems were recorded after loading. Six prosthesis-related problems were reported; 5 in the test group and 1 in the control group. These consisted of fractured or lost crowns, mostly in the incisal region. Pathologic soft tissue was seen in 3 patients (1 in the test group and 2 in the control group). The test group patient exhibited redness of the oral mucosa following impression making; the tissue returned to normal after a few days. One control group patient reported pain on the connection of 1 abutment, but the pain was not present at the follow-up investigations. In the other control group patient, swelling of the mucosa around 1 implant disappeared spontaneously.

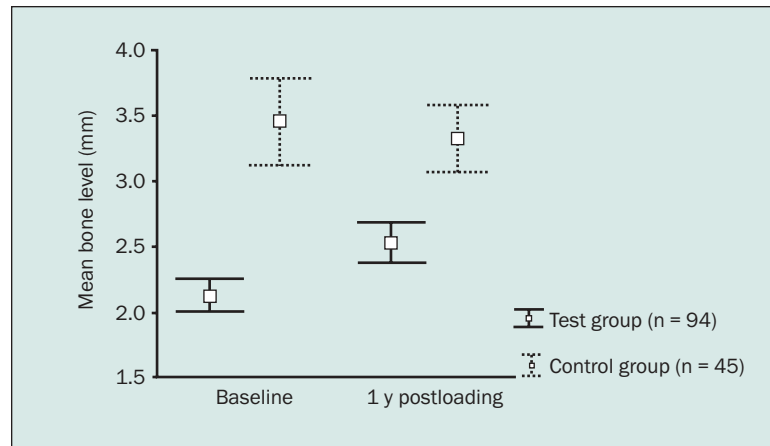
### Radiographic Results

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

**Table 6 Mean Crestal Bone Levels (in mm) at Baseline and 1 Year Postloading**

	Baseline			1 year		
	Minimum	Maximum	Mean	Minimum	Maximum	Mean
Test group	0.93	4.95	2.13	1.18	6.13	2.54
Control group	2.18	6.76	3.46	1.90	5.32	3.33

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

**Fig 2** Mean crestal bone levels at baseline and 1 year postloading with 95% confidence limits.

indicated bone loss around the implant. The minimum, maximum, and mean bone levels for each group at baseline and at 1 year are given in Table 6. These data are also plotted in Fig 2 along with the 95% confidence levels for the test and control groups.

The statistical analysis showed that the differences between the groups at baseline and at 1 year was significant ( $P < .001$ ). The measurements for the 2 groups also converged with time ( $P < .001$ ). Bone loss around test group implants averaged 0.41 mm. The bone level of the control group was greater than that of the test group by 0.79 mm at 1 year.

## DISCUSSION

The authors of an extensive meta-analysis<sup>17</sup> concluded that “one of the major difficulties in evaluating the oral implant literature is the lack of comparable prospective studies.” This clinical, randomized, controlled study fulfils the criteria for a comparable study. As a result of the small patient sample, the conclusions drawn are based on feasibility analyses of the results. In an article outlining the determinants of correct clinical reporting, Albrektsson and Zarb<sup>18</sup> stated that prospective studies are preferable to retrospective studies, and that if different patients

are used for control and test procedures, proper randomization of these patients must be carried out. The importance of having clearly adequate randomization and allocation concealment has also been stressed in an article on the quality assessment of randomized controlled trials of oral implants.<sup>19</sup> These criteria have been fulfilled in this study.

Patients were consecutively randomized but it must be noted that only patients having sufficient height and width of maxillary bone were selected. This likely resulted in generally better treatment outcomes than a study of consecutive patients from the general population.

The test and control groups were approximately equivalent in terms of the ages and genders of the participants, number of implants per patient, and implant lengths used. This study shows that early loading can be successfully employed using axially placed solid screw-type standard implants in the maxilla.

Bone status was analyzed and found to be equal in both treatment groups, thereby eliminating bias in judging treatment outcomes. In the control group the mean healing time before implant loading was 3.7 months. Thus at loading osseointegration had already been underway for more than 2 months in most of the patients. By contrast, in the test group the peri-implant bone was in the phase of osteolysis

at loading. Therefore, to have comparable baselines for crestal bone measurements, the bone level at implant placement should be used. The mean length of distal cantilevers in the control group was longer than those in the test group by 1.69 mm on the left side and 1.06 mm on the right side. Longer cantilevers result in higher loading forces being applied to the implants during masticatory function, especially where the cantilevers extend into the zone of activity of the masseter muscle. The framework was very rigid and could distribute forces to all implants.

The condition of peri-implant soft tissue can be important in making better diagnostic judgments. The modified Plaque Index has been shown to be a predictor in differentiating patients with progressive peri-implantitis from those with stable peri-implant conditions.<sup>20</sup> Normal connective tissue is necessary in order to maintain the epithelial and connective tissue attachment to the titanium implant.<sup>21</sup> Health of the peri-implant mucosa, as determined by bleeding on probing, cannot be related to the width of keratinized mucosa.<sup>22</sup> Two patients in this study showed increased radiolucency around some implants after 1 year. Both had restarted smoking. In most studies,<sup>23–26</sup> smoking has been shown to be a contributing pathogenic factor in the failure of dental implants<sup>23,26</sup> and marginal bone loss around osseointegrated implants,<sup>24</sup> and to be a risk factor for osseodisintegration.<sup>25</sup>

The use of a single operator in each discipline—maxillofacial surgery, prosthodontics, and dental technology—during the first year of the study may have improved the chances of achieving consistent standards.

The implants were not individually assessed. Since implants must be individually assessed to determine success, only the survival figures of the implants can be presented here. All implants will be individually analyzed at the 3-year follow-up, based upon success criteria defined in the literature.<sup>27</sup>

It is undesirable for patients in the test group to be edentulous for about 2 weeks, but for some patients, wearing a transitional prosthesis for 2 to 3 months would be even worse. Early loading avoids microtrauma from the use of a transitional prosthesis, but the operator must be aware of the risks of microtrauma from the opposing jaw or pieces of hard food. Loading as early as possible should reduce the risk of microtrauma.

A systematic review of 73 articles found immediate loading and a nonsubmerged procedure to be associated with the biologic failure of oral implants.<sup>17</sup> The results of the present study demonstrate that it is possible to load maxillary implants early and achieve treatment outcomes comparable

to those achieved with implants loaded after the conventional 3- to 4-month healing time, at least for the first year postloading. However, it should be emphasized that these results are based on the treatment of patients with a more favorable bone status than the general population.

## CONCLUSION

These results indicate that in selected cases the early loading of ITI solid screw-type implants in the edentulous maxilla may achieve similar treatment outcomes to those obtained using the standard protocol. The early loading method described enables restoration with a complete implant-supported fixed prosthesis in approximately 2 weeks instead of 3 to 4 months.

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