Prospective 10-Year Cohort Study Based on a Randomized Controlled Trial (RCT) on Implant-Supported Full-Arch Maxillary Prostheses. Part 1: Sandblasted and Acid-Etched Implants and Mucosal Tissue

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ABSTRACT

Background: There have been very few long-term controlled studies (i.e., over 5 years duration) focusing on marginal conditions for implants with a sandblasted, large grit, and acid-etched (SLA) surface.

Purpose: To evaluate and report 10-year data on outcomes of implants with an SLA surface placed in the edentulous maxilla.

Materials and Methods: In a randomized controlled trial (RCT) cohort of 24 patients, the outcomes of implants with an SLA surface were registered. The RCT cohort has previously been reported after 1 year, 3 years, and 5 years of loading.

Results: One patient dropped out of the study prior to the 10-year control. Of the 23 remaining patients, the implant survival rate was 95.1%. If implants of unknown status were also considered lost, that is, one drop-out patient with three implants for whom no information could be obtained, the implant survival rate was 93%. The mean marginal bone loss from baseline (139 implants) to 10 years (102 implants) was 1.07 mm (standard deviation 0.98). One implant out of 102 available for radiographic examination according to the original protocol showed a bone loss exceeding 4 mm. Of the 84 implants available for clinical examination, none showed a Plaque Index or sulcus bleeding index of 3. The mean implant stability quotient was significantly higher for mesial–distal versus buccal–palatal measurements.

Conclusion: The implant survival was 95.1%. The mean value of bone loss after 10 years was 1.07 mm. Peri-implantitis were noted at the 5-year follow-up for one patient with a previous history of periodontitis; this patient did not attend the 10-year follow-up. This study shows that sandblasted and acid-etched implants offers predictable long-term results as support for full-arch maxillary prostheses.

KEY WORDS: 10-year data, acid-etched, dental implants, edentulous maxilla, large-grit, marginal bone loss, peri-implantitis, prospective cohort study, RFA, sandblasted, SLA

INTRODUCTION

Oral rehabilitation with osseointegrated implants for anchorage of fixed bridges has become a routine and predictable clinical procedure and is undoubtedly one of the most significant scientific breakthroughs in dentistry. After more than 40 years of experience, many new implant systems, surface preparations, and treatment protocols have been introduced. Although historically, most treatments have been performed using a healing

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period of several months between implant placement and loading, the last 10 years of research have increasingly focused on loading immediately or a few weeks after implant placement. The use of so-called immediate/early loading protocols has obvious advantages for the patient because the treatment time is drastically reduced, including the time for using a transitional prosthesis or provisional crown. However, concerns have been raised about increased failure rates because the original concept of osseointegration prescribed an unloaded healing period of 3–6 months before loading.[1,2]

The initial studies on osseointegration were conducted on implants with turned surfaces. Since then, enhanced implant surface technology has been developed to improve the predictability, rate, and degree of osseointegration. The aim was to attain a greater surface area for bone attachment. Implant surfaces have been modified through additive or subtractive techniques. Surface roughness has been demonstrated to be effective in enhancing the biomechanical properties of bone-anchored implants; the amount of bone in contact with an implant surface is greater around moderately rougher than around smoother or even rougher implant surfaces, and moderately rough surface implants have stronger bone-to-implant bonds.[3] In a preclinical study, Buser et al. showed that the bone-implant contact increased from 37.5% for titanium plasma sprayed implants to 55% for those with a sandblasted, large grit, and acid-etched (SLA) surface.[4] The SLA surface is produced by a large grit sandblasting process with corundum particles, which produces macro-roughness of the titanium surface. The sandblasting is followed by immersion for several minutes in a strong acid-etching bath of HCl/H_2SO_4 at elevated temperature. This produces 2–4 µm micropits superimposed on the rough-blasted surface. The surface is not microporous. Based on experimental results, clinical studies were subsequently performed with loading of SLA implants after a reduced healing period of only 6 weeks. The survival rate up to 5 years has been shown to be greater than 99%.[5,6]

The purpose of this prospective 10-year controlled cohort study based on a randomized trial was to evaluate implant survival including marginal conditions of implants with an SLA surface and also to report the outcome of the supporting full-arch prostheses in the edentulous maxilla. The study is presented in two parts.

MATERIALS AND METHODS

Materials and methods have previously been described in detail in 1-year,[7] 3-year,[8] and 5-year[9] publications; therefore materials and methods will be outlined here.

Patients and Implants

At start, a total of 24 patients (16 females, eight males, mean age 64 years) with totally edentulous maxilla were enrolled in the study.

In total, 142 implants were placed; the distribution of implant lengths is shown in Table 1. Three implants were lost before time for loading.

One hundred and thirty-nine implants were loaded with full-arch screw-retained prostheses (Figure 1).

Another four implants in two patients were lost between the 3- and 5-year evaluations.

At the 10-year follow-up, one patient with three implants was lost, and no data were found.

Fifteen patients (84 implants) were registered according to the original RCT protocol with medical records, radiographic and clinical examinations.

Eight patients were lost to the original RCT protocol concerning clinical registrations; three out of these patients (18 implants) were followed by radiographic examinations according to RCT protocol, and five patients (30 implants) were followed via radiographic information from the general dental practitioner.

The protocol for the study was approved by the regional research ethics committee, Uppsala, Sweden. Informed consent was obtained from all patients.

Surgical Procedure

All surgical procedures were performed by the same clinician and followed the guidelines provided for the Straumann Dental Implant System® and accepted practice. In each patient, five or six solid screw implants (diameter 4.1 mm, lengths 8–12 mm) with an SLA

TABLE 1 Distribution of 4.1 mm Diameter Implants by Length

Implant Length	Test Group (n = 16)	Control Group (n = 8)
8 mm	18	9
10 mm	39	17
12 mm	38	21
Total	95	47

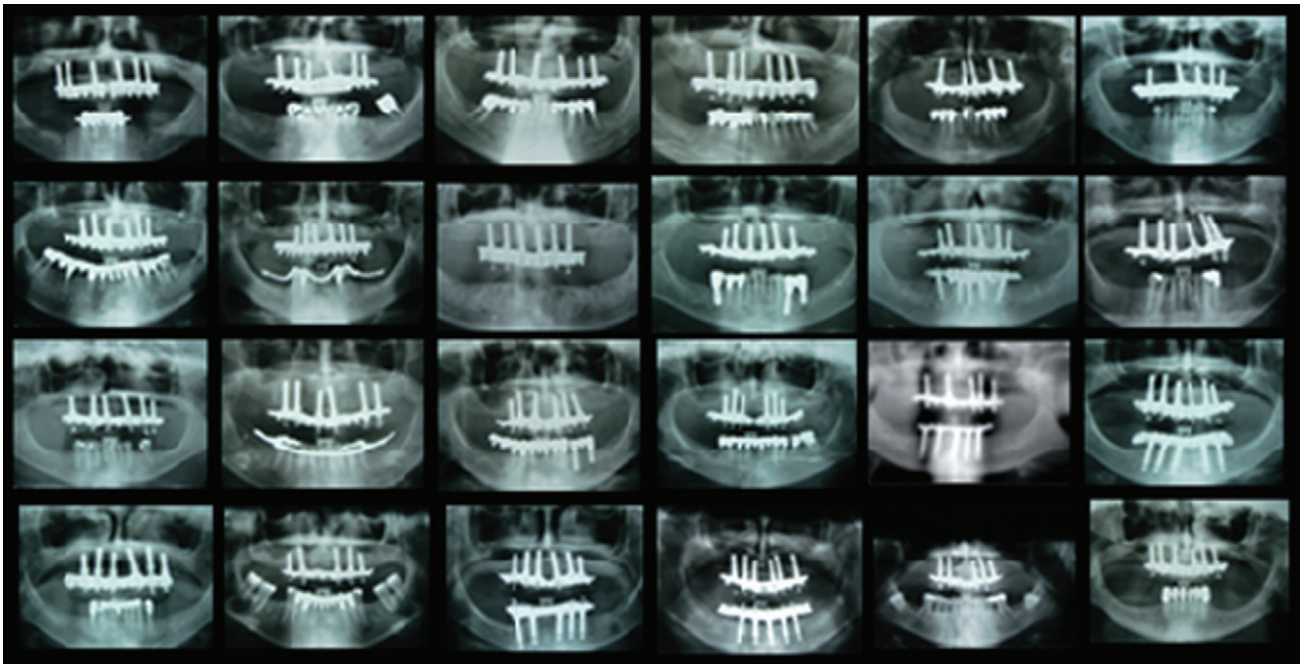

Figure 1 Panoramic radiographs of implant-supported, screw-retained full-arch maxillary prostheses in all 24 patients at time of loading.

surface (Institut Straumann AG, Basel, Switzerland) were placed in the maxilla between the left and right second premolar positions. Octa® abutments and associated components (Institut Straumann AG) were used. Bone quality, determined according to the Lekholm and Zarb[10] classification, was assessed independently for each implant at surgery.

Prosthetic Procedure

Casted titanium alloy prostheses with resin teeth were used. Panoramic radiographs of the prostheses for all 24 patients at time for loading can be seen in Figure 1. All prosthetic and technical works were performed by one person within each profession. Further details can be found in Part II of this publication.

Implant Stability

After removal of the prosthesis at the 3-, 5- and 10-year follow-ups, implant stability quotient (ISQ) was recorded for each implant via resonance frequency analysis (RFA) as described by Meredith et al.[11] and Meredith et al.[12] using the Osstell™ device (Instrument Device Integration Diagnostics AB, Gothenburg, Sweden). The transducer was attached to each implant, and measurements were made with the beam perpendicular to the alveolar crest (buccal–palatal) at the 3-year follow-up, and perpendicular (buccal–palatal) and parallel (mesial–distal) to the alveolar crest at the 5- and 10-year follow-ups.

Clinical Examinations

An implant was seen regarded as a failure if removed for any reason. The sulcus bleeding index (SBI) and modified plaque index (mPI) were clinically evaluated according to Mombelli et al.[13] (SBI: 0 = no bleeding, 1 = isolated bleeding, 2 = blood forms red line on margin, 3 = heavy or perfuse bleeding; mPI: 0 = no plaque, 1 = plaque on running a probe, 2 = plaque seen by naked eye, 3 = abundance of soft matter). Peri-implantitis was defined as loss of supporting bone > 4 mm plus perfuse bleeding including suppuration.

Radiographic Examination

Radiographic examinations were performed by the same staff member at time for loading and at every follow-up investigation over 10 years. Periapical radiographs were taken using films in a film holder placed in a vertical position parallel to the implant with the x-ray beam aligned perpendicularly so that the implant threads were clearly visible. The implants were imaged on at least two films. All films were automatically processed. All radiographs were examined by one independent specialist

TABLE 2 Marginal Bone Height Changes from Baseline to 10-Year Postloading

	Bone Height Change Mean mm (Standard Deviation)	Number of Implants	Max Bone Loss mm	Max Bone Gain mm	Number of Patients
Baseline – 1 year	–0.24 (0.68)	139	–3.8	2.1	24
Baseline – 3 years	–0.39 (0.90)	139	–7.7	2.2	24
Baseline – 5 years	–0.71 (1.63)	129	–5.8	2.4	23
Baseline – 10 years	–1.07 (0.98)	102	–4.3	1.8	18

using the method of Buser et al.[14] The distance from the implant shoulder to the most coronal bone-to-implant contact point at the crestal bone was measured (Figure 2). For vertical bone pockets, the deepest level of the pocket was measured. The known distance between two threads was used for calibration of each radiograph. The ratio of the absolute values versus observed measurements was calculated using a validated algorithm. Baseline was set as time for loading meaning either 9–18 days or 2.5–5.1 months after surgery.[7–9] The baseline bone level of the 139 loaded implants was in mean 2.56 mm below the implant shoulder.[7,8]

Data Analysis

Data using the patient and the implant as units are presented descriptively. Mean mesial and distal bone level measurements were used to calculate bone level change for each implant. Means and standard deviations were reported.

RESULTS

Radiographic Findings

The mean marginal bone loss was 1.07 mm (standard deviation, 0.98) after 10 years. Implant-based bone height changes from baseline to each follow-up, and measured as a mean value of distal and mesial implant surfaces, showing bone loss with negative numbers and bone growth with positive numbers as shown in Table 2. Bone loss of between 3 and 4 mm was found in four patients, in each at one implant; one of these four patients presented a fifth implant with a bone loss of 4.29 mm as shown in Table 3. The marginal bone levels relative to the upper part of the implant shoulder exhibited in mean a change of 0.91 mm from baseline to 10 year as shown in Table 4.

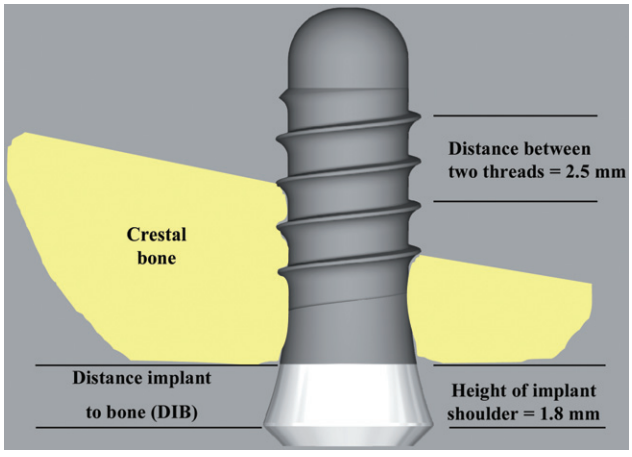

Figure 2 Measurement of radiographic bone level.

Soft Tissue Conditions

None of the 15 evaluated patients presented with a PI score of 3, and five patients showed no plaque. Plaque scores are shown in Table 5. The distribution of SBI for all 15 patients is displayed in Table 6; two patients showed no bleeding.

Implants and Peri-Implantitis

Considering implant losses, the implant survival rate was 95.1%. Increasing bone loss at several implants was observed in one patient at the 1-year, 3-year, and 5-year follow-ups. In addition, perfuse bleeding and suppuration was observed at the 5-year control, and three out of six implants were lost. This patient did not show up at the 10-year control. If this patient's three remaining implants are also considered as lost, the implant survival

TABLE 3 Incidence of Bone Loss of 3–4 mm and >4 mm on Patient and Implant Level after 10 Years

		Implants (n = 102)		
Bone Loss	Patients (n = 18)	Implants	Minimum (mm)	Maximum (mm)
3.0–4.0 mm	4	4	3.4	3.7
>4.0 mm	1	1		4.3

TABLE 4 Marginal Bone Levels Relative to the Upper Part of the Implant Shoulder

	Marginal Bone Level Mean mm (Standard Deviation)	Number of Implants
Baseline	2.56 (1.11)	139
1 year	2.79 (0.86)	139
3 years	2.95 (1.39)	139
5 years	3.14 (1.26)	129
10 years	3.47 (1.17)	102

rate was 93%. The mean ISQ value from 84 implants in 15 patients was significantly higher for mesial–distal versus buccal–palatal measurements (67.1 ± 5.7 versus 57.2 ± 8.8).

Peri-implantitis were noted at the 5-year follow-up for one patient with a previous history of periodontitis and relapse as smoker; this patient did not attend the 10-year follow-up. After 10 years, one patient was registered with bone loss exceeding 4 mm at one implant; however, measurements of the mucosal tissue could not be performed as the patient refused to be clinical examined.

TABLE 5 Plaque Index at the Patient and Implant Level After 10 Years

	Total	
Score	Patients (n = 15)	Implants (n = 84)
0	5	27
1	4	24
2	6	33
3	0	0
Σ 1 + 2 + 3	10 (67%)	57 (68%)

0 = no plaque.
1 = plaque on running probe.
2 = plaque seen by naked eye.
3 = abundance of soft matter.

TABLE 6 Sulcus Bleeding Index at the Patient and Implant Level After 10 Years

	Total	
Score	Patients (n = 15)	Implants (n = 84)
0	2	11
1	10	57
2	3	16
3	0	0
Σ 1 + 2 + 3	13 (87%)	73 (87%)

0 = no bleeding.
1 = isolated bleeding.
2 = blood forms red line on margin.
3 = heavy or perfuse bleeding.

DISCUSSION

Analysis of the marginal bone level for the SLA implants in the present study showed a bone loss after 10 years of in mean 1.07 mm. However, a bone loss of more than 3 mm was measured at five implants in four patients, one of which had an implant with a bone loss of more than 4 mm. Although radiographs were not standardized, analysis was performed at every follow-up by the same staff member in the same manner using a parallel technique showing the threads on mesial and distal sides of the implants clearly. The precision of radiographic bone level measurements was high, and the apparent dimensions of each implant were compared with the known distance between two threads. The results in the present study showed bone loss well within accepted criteria for implant success, for example, 1 mm of bone loss during the first year and up to 0.2 mm annually thereafter, equaling a total 2.8 mm of bone resorption after 10 years, as defined by Albrektsson et al.[15] In light of new improved data based on modern oral implants, a stricter set of implant success criteria is subjected to a quite recently started discussion.

Other studies on the same implant design have reported similar figures of marginal bone levels as in the current study.[6,16,17] A recently published study on another implant system supporting fixed prostheses in the edentulous maxilla reported 0.3 mm (0.72) marginal bone loss in 99 implants after 8 years.[18] Sundén Pikner et al. found in a long-term follow-up of turned implants with different prosthetic restorations a bone loss of significantly increase with increasing age of the patient at surgery and reported a marginal bone loss of ≥3 mm in 15.2% of the implants after 10 years.[19] Neither could be verified in the present study.

None of the patients showed any implant with heavy or perfuse bleeding or an abundance of plaque at the 10-year control. The mPI results indicated that 61% and 60% of the implants and patients, respectively, had a satisfactory oral hygiene status (grade 0 and 1; Table 2) after 10 years. Bleeding on probing showed a 20% incidence of bleeding in the peri-implant mucosa (grade 2;

Table 3) for both patients and implants, while heavy or perfused bleeding (grade 3) was not observed; however, the patient identified with peri-implantitis at the 5-year follow-up did not attend 10-year recall and no medical records could be obtained. One implant showed bone loss exceeding 4 mm; however, no clinical data is obtained as the patient refused to have the full-arch prosthesis removed at the 10-year control.

Prognoses criteria for implant treatment has been discussed, and several authors have concluded that a history of periodontitis, smoking, and poor oral hygiene increases the risk of poor prognosis and occurrence of peri-implantitis.[20,21] This has also been reported in extensive literature reviews as well as in a 9- to 14-year follow-up of implants with a turned implant surface.[22–25] The negative influence of a history of periodontitis and smoking on long-term implant success was not well known when patients were being recruited into the current study. However, one of the exclusion criteria for being enrolled in the study more than 10 years ago was smoking more than 10 cigarettes per day.

Different criteria for definition of peri-implantitis have been used. For example, Roos-Jansåker et al. defined peri-implantitis as bleeding on probing and/or pus combined with a total peri-implant bone loss of ≥1.8 mm during 8–13 years after the first follow-up.[26] Fransson et al. defined progressive bone loss at implants as bone level alterations occurring between 1 and 5 years follow-up and reported that in patients restored with fixed dentures on implants with a mean function time of about 10 years, 28% exhibited peri-implantitis at ≥1 implant and about 10% had ≥3 affected implants.[27] The description of bone loss in follow-up studies has been questioned in a review by Jemt and Albrektsson, who suggested that as the inclusion criteria for bone loss around implants vary so much in follow-up studies, it cannot be used for comparison between studies.[28] Zitzmann and Berglundh used bleeding on probing plus bone loss as criteria for peri-implantitis.[29] In this study, peri-implantitis is defined as perfuse bleeding including suppuration after probing in combination with bone loss exceeding 4 mm. None of the patients who agreed to be examined at the 10-year control according to the original RCT protocol was presented with both of these variables, and none of them reported any subjective complaints from the mucosa. Perhaps the definition of peri-implantitis is more of an academic issue than patient related. However, the implication the amount of bone loss has on the prosthesis survival is of significant importance for the patient.

Seven implants were registered as lost during the 10-year control. One patient lost three implants out of six at the 5-year examination. The remaining three implants were still stable after 5 years but showed extensive bone loss. These implants were assumed lost after 10 years, but this could not be confirmed as the patient did not attend for the 10-year examination. The survival rate of implants in the remaining 23 patients was 95.1% after 10 years. In a 20-year follow-up of implants with a turned surface and placed in 21 edentulous maxillae and mandibles, only one implant was lost giving a survival rate of 99.2%.[30] Maybe the requirements were stricter to get implant treatment at the beginning of the 1990s than in the late 1990s.

RFA was used to assess implant stability at the 3-, 5-, and 10-year follow-ups. After 10 years, mean RFA values were significantly higher for mesial–distal than for buccal–palatal measurements, which is in line with the findings of Veltri et al.[31] The RFA technique measures stability as a function of interface stiffness and the results indicate a higher stiffness in mesial–distal direction, which can be explained by the fact that the bone is thinner at the buccal and palatal aspects of the implants.

A number of drop-out patients have been observed in previous long-term studies.[19,30,32,33] The possibility that patients with less favorable long-term results are less likely to attend follow-up visits has been described by several authors.[30,32] In the current study, no data at all was available for one patient after 10 years; a patient whom may have lost the full-arch prosthesis including all supporting implants. Treatment of the patients in the present study at follow-up investigations at 6 months and 1, 2, 3, 5, and 10 years were performed by the authors, while in the interim times most patients were regularly examined by a general practitioner or a dental hygienist in their home district. However, due to the aging of the individuals, it was increasingly inconvenient for patients to attend an appointment. As a result, five patients were unable to attend the 10-year follow-up because of various handicaps as Alzheimer's disease, hip replacement, arm fractures, and infirmity. However, medical records and radiographs examined by the general practitioner for the follow-up period were accessible for these patients. Unfortunately, three patients refused to have the full-arch prosthesis removed at the 10-year control because of a very unpleasant experience

at earlier performed controls. Although all patients had agreed on to participate in a clinical study, 10 years later, one cannot force a patient to have the prosthesis removed.

CONCLUSION

In this 10-year follow-up of SLA implants in the edentulous maxilla supporting full-arch prostheses, the implant survival rate was 95.1%, and there were no implant losses between the 5- and 10-year follow-up visits. The mean value of bone loss after 10 years was 1.07 mm. This study shows that SLA implants offers predictable long-term results supporting full-arch maxillary prostheses.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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