Early Loading of Osseotite Implants 2 Months After Placement in the Maxilla and Mandible: A 5-year Report

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Purpose: In this multicenter study, the performance of Osseotite implants after a 1-stage surgery and abbreviated healing period of 2 months is reported. The implants were followed for up to 5 years. Materials and Methods: Partially or completely edentulous patients treated at 10 private practice centers were included in the study. Oral hygiene was assessed using the plaque index and the gingival index prior to surgery and at recall visits at 6 months, 1, 2, 3, 4, and 5 years after initial loading. Bone density and implant/bone fit were evaluated at the time of surgery. Implants were loaded after a healing period of about 2 months. **Results:** The mean age of the patients at time of enrollment was $60.4 \pm$ 13.0 years; 44% (86) of the patients were men and 56% (109) were women. In all, 526 implants were placed, 65.4% in the mandible and 34.6% in the maxilla, with 23.0% placed in anterior locations and 77.0% in the posterior. The cumulative success rate of these 526 implants was 97.9% at 5 years. Eight of the 11 implant failures occurred during nonsubmerged healing prior to prosthetic loading. Provisional restorations were placed at 2.1 ± 0.5 months, at which time implants were evaluated for mobility, gingival health, symptomology, and radiolucency. The distribution of prosthesis types included 118 single-tooth restorations (118 implants), 134 short-span prostheses (327 implants), and 16 long-span restorations (81 implants). Discussion: The benefits of early loading cannot be fully appreciated if there is a substantive increase in implant failures. In this study, a cumulative success rate greater than 97% was maintained throughout 5 years of observation. Conclusion: These results suggest that success can be expected with Osseotite implants after a nonsubmerged reduced healing period of 2 months in this patient population. INT J ORAL MAXILLOFAC IMPLANTS 2005;20:905–912

Key words: cumulative success rate, dental implants, early loading protocol, osseointegration

The attainment of osseointegration, the biologic process of establishing bone-implant contact, is characterized by immobility of the implant, absence of soft tissue between the bone and the implant surface, and lack of radiolucency around the implant. Traditionally following implant placement, the tissue is allowed a healing period during which the implants are not functionally loaded. It is during this period that osseointegration occurs. This period has traditionally been 3 to 4 months for implants placed

in the mandible and 6 months for those placed in the maxilla.¹ The surgical convention has been a 2stage protocol; it was recommended that the implant be submerged beneath the mucosa after placement and that prosthetic loading take place after second-stage surgery and soft tissue healing. The determination of these healing times, however, was based on clinical observations of machined-surfaced implants rather than on histologic evidence of osseointegration.²

A dual thermal etching process involving a combination of hydrochloric acid and sulfuric acid (HCl/H₂SO₄) produces the microsurface topography of the Osseotite implant (3i/Implant Innovations, Palm Beach Gardens, FL). The performance of this implant has been shown in vitro and in clinical studies to be significantly different than machined-surfaced implants in regard to bone-implant contact and clinical success rates.^{3–10}

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In a previous study, the performance of this implant placed with the traditional 2-stage surgical technique (4 to 6 months of unloaded healing) was evaluated in a multicenter study¹¹ of 219 implants for which the cumulative success rate after 50 months of loading was 100% for anterior implants and 98.4% for posterior implants. Data pooled from multicenter studies have shown that the implant's dual acid-etched surface can perform better and have a higher survival rate than machined-surfaced implants in poor-quality bone⁹ and in patients who smoke.¹² Because of the increased surface complexity of these implants, it has been postulated that osseointegration could occur at a more rapid rate and that prosthesis placement could take place sooner.

In a study of implants placed in rabbit tibias, titanium implants with 4 different surface topographies were evaluated: a machined surface, a grit-blasted surface, a plasma-sprayed surface, and the dual thermal acid-etched surface.¹³ After a 5-week healing period the peak removal torques for each group were measured, and the dual thermal acid-etched group had a statistically significant greater removal torque, indicating an enhanced mechanical interlocking of the implant to bone. Furthermore, histomorphometric results indicated that 33% more of the acidetched surface interfaced with bone in comparison to the other surfaces studied. After short-term healing in rabbit tibia, the acid-etched surface demonstrated more rapid development of pull-out resistance, especially between 5 and 8 weeks, when the acid-etched surface maintained a resistance 3.2 times greater than the machined-surfaced implants.¹⁴

For the present study, the initial findings demonstrating the integration success of implants loaded after 2 months of nonsubmerged healing were reported after 1 year of functional loading.¹⁵ In this report, the results of a clinical study of early loading of Osseotite implants after 5 years of follow-up are presented. The objective of this multicenter clinical study was to evaluate the effect of reducing the unloaded healing time on the performance of implants with a dual thermal acid-etched surface topography.

MATERIALS AND METHODS

The partially or completely edentulous patients enrolled in this early loading study were treated at 10 private practice centers after meeting admission criteria. Prosthetic determination was based on individual patient needs for incorporating implants into their dental treatment and included single-tooth replacement, short-span implant-supported fixed partial dentures, and implant-supported long-span restorations. Demographic data were recorded as well as concomitant diseases, smoking history, and, for women, menopausal status and any related treatment. Inclusion criteria consisted of patients of either sex and any race greater than 18 years of age who were physically able to tolerate conventional surgical and restorative procedures. In all cases a decision had already been made to use dental implants to treat an existing dental condition prior to the start of the study.

Exclusion criteria consisted of active periodontal infection, diabetes, pregnancy, recent radiation to the head, a smoking habit of > 10 cigarettes/day, the need for concomitant bone augmentation, and evidence of severe parafunctional habits.

Prior to surgery the patient's gingival index (GI) and plaque index (PI) scores were documented as a baseline to assess general oral hygiene conditions. Index scores were recorded again at all recall appointments. The scoring criteria for the GI were 0 = normal gingiva; 1 = mild inflammation, slight change in color, slight edema, no bleeding on probing; 2 = moderate inflammation, redness, edema, bleeding on probing; and 3 = severe inflammation, marked redness and edema, ulcerations, and tendency toward spontaneous bleeding. The scoring criteria for the PI were 1 = no plaque in gingival area; 2 = plague invisible to the unaided eye but visible on the point of the probe after it has scraped across the surface at the entrance of the gingival crevice; 3 = a thin to moderately thick layer of plague visible to the naked eye; and 4 = a heavy accumulation of soft matter, interdental area stuffed with soft debris.

At the time of surgery, bone quality was assessed based on the hand-felt perception of the drilling resistance and categorized into 3 classes of bone quality. Bone density was scored as 1 (soft), 2 (normal), or 3 (dense) according to a method that emphasizes that clinicians are capable of distinguishing 3 bone quality types by drilling resistance but not 4.¹⁶ Prior to the surgeries, study investigators were provided with solid foam blocks (Pacific Research Labs, Vashon, WA) with 3 simulated bone densities to gauge drilling resistance.

Implants were placed using conventional surgical techniques and instrumentation without countersinking. In soft bone, implants were self-tapped through the last apical half to compact bone. Implant bone fit was clinically assessed as "tight" (required use of a ratchet), "firm" (the drill unit required a high torque-limit setting), or "loose" (the implant could still rotate at low torque at completion of placement). A 1-stage (nonsubmerged) surgical procedure was used whereby a 1- or 2-piece healing abutment was placed on the implant immediately following



Fig 1a Distribution of implants by diameter.

surgery. An impression was made either immediately or 4 to 6 weeks after implant placement to allow time for fabrication of provisional restorations.

Prosthetic loading using provisional prostheses was scheduled to take place 2 months after implant placement, at which time implant integration was first evaluated. Evidence of site-specific gingival inflammation, suppuration upon peri-implant probing, and mobility as determined by manual assessment and peri-implant radiolucency were evaluated and recorded as was patient-reported symptomology and discomfort during implant manipulation and abutment placement. Any adverse events were recorded at the follow-up visits. Any implant diagnosed as a failure was removed, and details of the evaluation and explant procedures were recorded.

Single- and multiple-unit provisional restorations, either cement-retained or screw-retained, and overdenture abutments were placed. Manufacturer-recommended screw-torque values were used during attachment of screw-retained prosthetic abutments and components (20 and 32 Ncm). Once secured, the prosthesis was evaluated by the prosthodontist for retention, stability, esthetics, and phonetics using a 4point scale where 1 = excellent, 2 = good, 3 = fair, and 4 = poor. Baseline values for overall patient satisfaction were established by patient interview at the time of prosthesis seating and monitored at each subsequent follow-up appointment.

Follow-up evaluations were scheduled for 6 months and at 1-year intervals following prosthesis seating (the date of initial loading) for 5 years. At each follow-up interval patients returned for assessment of both implant and prosthesis function. Periapical radiographs were obtained and processed for evaluation of crestal bone levels on the mesial and distal aspects of each implant and compared to radiographs obtained immediately postloading to determine bone loss and monitor for any radiolucencies. The evaluation criteria for implant success included lack of mobility (digital mobility testing); lack of peri-



Fig 1b Distribution of implants by length.

implant radiolucency; absence of persistent or irreversible signs and symptoms of pain, infection, neuropathy, or paresthesia; and violation of the mandibular canal. At the time restorations were placed and at subsequent follow-up visits patients were evaluated for symptoms of pain and infection. Bone loss was not considered a success criterion in this study.

Implant success was analyzed using the life table approach. Success analyses, including tables and plots of survival distributions using Kaplan-Meier methods, were used as the primary demonstration of implant survival.

RESULTS

An initial one-year interim analysis of this study was reported in 1998,⁵ at which time patient enrollment was not yet complete. At that time 81.6% (429) of the ultimate number of implants (526) that would be analyzed were being followed. The number of patients since then has increased from 155 to 195, and the number of cases has increased from 212 to 268. A study patient may have more than 1 case (prosthesis) contributing to the study.

The analysis of data in this report includes all data throughout the entire study period. The mean age of the patients at time of enrollment was 60.4 ± 13.0 years. Forty-four percent (n = 86) of the patients were men; 56% (n = 109) were women. Eighteen percent of the patients reported smoking, with an adjusted daily consumption of an average of 11.3 cigarettes. Forty-eight percent of the female population (n = 52) was postmenopausal; 18 were receiving hormone replacement therapy and 34 were not.

Diameter and length distributions of the implants are reported in Fig 1. Distribution of the implants by tooth site is illustrated in Fig 2, which shows the majority of implants located in the molar and premolar regions. Of the 526 implants, 11.8% (62) were placed in the anterior mandible, 53.6% (282) in the



Fig 2 Distribution of implants by tooth site.

posterior mandible, 11.2% (59) in the anterior maxilla, and 23.4% (123) in the posterior maxilla. According to the clinicians' assessment of bone density, 18.1% (95) of the implants were placed in bone identified as soft, 64.3% (338) in bone identified as normal, and 17.7% (93) in dense bone. During placement 53.4% (281) of the implants were identified as having a tight fit, 44.7% (235) as a firm fit and 1.9% (10) as a loose fit. Abutments were attached using either titanium or gold-coated, gold-alloy retaining screws torqued to 20 or 32 Ncm. No implant-related surgical complications were reported.

The prosthetic restorations were placed at 2.1 ± 0.5 months and included 134 short-span prostheses (327 implants), 118 single crowns (118 implants), and 16 long-span prostheses (81 implants). Of the 134 short-span prostheses, 14 were single-unit cantilevers and 17 were supported intermediate pontics. A baseline assessment of oral hygiene at the restorative appointment was conducted; the mean PI score was 1.41, and the mean GI score was 1.21. These values, which are good indicators for evaluating patient compliance in the maintenance protocol, remained consistent throughout the study (Fig 3).

The mean values for crestal bone levels at followup evaluations were compared to baseline values established at the time of prosthesis placement. The change from baseline at 12, 18, 24, 36, and 48 months was 1.37, 1.87, 2.32, 1.73, and 1.62 mm, respectively. These values represent the amount of bone loss.

During the 2-month healing period, 8 implants were identified as failures prior to the time of loading. Three postloading failures were observed: 1 was evident 1 month after loading, another at a 6-month follow-up evaluation, and 1 at 22 months after loading. A cumulative success rate of 97.9% for these 526 implants is described in the life table analysis (Fig 4) and presented in success intervals in Table 1. A 1.3% failure rate was obtained prior to loading and a 0.6% failure rate after loading. Ten implants failed because of mobility and 1 because of peri-implant infection. No pain or neuropathy was reported. Radiographic evaluation of the failed implant cases showed that none of the implants demonstrated radiolucency. Four of the failed implants were placed in soft bone. For 2 of the failed implants the clinician reported that excess heat might have been generated during preparation of the osteotomy. These implant failures are presented in Table 2, which includes the demographics, clinical characteristics, and evidence of failure for each of the 11 implants.

DISCUSSION

A single-stage early loading protocol such as the one evaluated in this study translates into a number of benefits. Overall chair time for the clinician and the patient is reduced compared to a 2-stage surgical approach, and a quicker restoration to function and



Fig 3a Mean GI at baseline examination and follow-up evaluations. 0 = normal gingiva; 1 = mild inflammation, slight change in color, slight edema, no bleeding on probing; 2 = moderate inflammation, redness, edema, bleeding on probing; 3 = severe inflammation, marked redness and edema, ulcerations, and tendency toward spontaneous bleeding. Baseline (2 mo).

Fig 4 Cumulative success rate of implants according to the life table analysis.



Fig 3b Mean PI at baseline examination and follow-up evaluations. 1 = no plaque in gingival area; 2 = plaque invisible to theunaided eye but visible on the point of a probe after it has beenscraped across the surface at the entrance of the gingivalcrevice; 3 = a thin to moderately thick layer of plaque, invisible tothe naked eye; 4 = heavy accumulation of soft matter, interdentalarea stuffed with soft debris. Baseline (2 mo).



Table 1	Cumulative Success Rates at 6-month Intervals									
Interval (mo)	Implants at risk at start of interval	Failures in interval	Censored	Interval success (%)	Cumulative success rate (%)					
0-6	526	9	3	98.3	100.0					
7-12	514	1	23	99.8	98.3					
13-18	490	0	12	100.0	98.1					
19-24	478	0	18	100.0	98.1					
25-30	460	1	2	99.8	98.1					
31-36	457	0	0	100.0	97.9					
37-42	457	0	12	100.0	97.9					
43-48	445	0	5	100.0	97.9					
49-54	440	0	21	100.0	97.9					
55-60	419	0	10	100.0	97.9					

Interval: Implant placement surgery was considered the baseline.

Implants at risk at start of interval: The number of implants continuing at the beginning of the time interval.

Failures in interval: The number of implants declared as failed within the time interval.

Extent of duration: For successful implants, this represents the time from implant placement surgery to the date of the last documented determination of success.

Censored: The number of successful implants in patients who died or were declared lost to follow-up. Interval success: Calculate the failure rate as follows:

No. at risk – ½ no. censored

Subtract the failure rate from 100 to obtain interval success.

Cumulative success rate: Interval success for previous row imes cumulative success for previous row.

Table 2 Implant Failure Analysis												
Age (y)	Gender	Tooth no.	Quadrant	Bone quality	Diameter (mm)	Length (mm)	Elapsed time (mo)	Reason				
69	М	19 (36)	Post/mand	2	4	11	1.2	Infection				
31	F	18 (37)	Post/mand	2	5	11	1.2	Mobility				
56	Μ	30 (46)	Post/mand	2	5	15	1.5	Mobility				
64	Μ	13 (25)	Post/max	3	5	10	1.7	Mobility				
53	F	16 (28)	Post/mand	3	3.75	10	2.1	Mobility				
62	Μ	19 (36)	Post/mand	1	5	15	2.2	Mobility				
38	F	10 (22)	Ant/max	3	3.25	10	2.2	Mobility				
64	Μ	23 (32)	Ant/mand	1	3.75	13	2.3	Mobility				
48	Μ	19 (36)	Post/mand	3	5	15	2.8*	Mobility				
45	Μ	31 (47)	Post/mand	2	5	8.5	9.2*	Mobility				
43	Μ	30 (46)	Post/mand	2	5	11	23.4*	Mobility				

Ant = anterior; post = posterior; max = maxilla; mand = mandible.

*Failure occurred postloading in the cases indicated; in all other cases, failure occurred preloading.

esthetics for the patient is achieved. A reduction in chair time and number of surgeries can ease financial burden for the patient and increase patient satisfaction. Patient satisfaction was high, with good appreciation of implant function and prosthetic results throughout the duration of the study.

As 8 of the 11 implants failures occurred prior to loading, these failures were unrelated to the early loading protocol. Of the 11 implants that failed, 2 were placed in "soft" bone. Most implant failures associated with bone quality have been related to soft bone.^{17–22} Crestal bone levels for failed implants were not analyzed because most of the failures occurred prior to loading (ie, baseline). The objective of the study's exclusion criterion for smoking habit (> 10 cigarettes/day) was to minimize this variable as a risk factor. Despite this criterion, the reported cigarette consumption during the study was 11.3 because patients admitted to underreporting their smoking habit at the screening interview in order to gain access to the study. This value reflects the adjusted rate after patients revealed their actual cigarette consumption.

The rationale for employing shorter healing times emerged from animal studies that reported mechanical, histologic, and histomorphometric evidence for the percentage area of direct bone-to-implant contact, ie, interfacing bone occurring earlier than previously assessed.^{23,24} The degree of bone-to-implant contact has been correlated to the surface roughness of the implant.^{25–27} Increased surface roughness can enhance mechanical interlocking between the implant surface and bone, which results in increased resistance to compression, tension, and shear stress.^{25,26,28,29} During the initial healing phase differentiating osteogenic cells migrate through the clot's fibrin scaffold. Fibrin remains anchored more firmly to a roughened implant surface than to a machined surface.³⁰ The osteoblasts synthesize de novo bone directly onto the implant surface through a process termed "contact osteogenesis."

In a human study, histologic analysis indicated a greater degree of osseointegration for the Osseotite surface as compared to opposing machined surfaces on the same implant in the same patient.³ After 6 months of unloaded healing in type 3 or type 4 bone in the posterior maxilla the implants were removed by trephine with surrounding hard tissue. The mean bone-to-implant contact values for the acid-etched surface (72.96% ± 25.13%) were significantly higher than those for the opposing machined surface (33.98% ± 31.04%). Collectively these studies suggest that acid-etched implants can achieve a greater degree of integration and become capable of being loaded sooner than machined-surfaced implants because of more rapid development of apposing bone. This hypothesis was further explored in a baboon model established for the study of human diseases,^{31,32} including periodontitis.³³ Implants with the acid-etched surface were placed with either a 1or 2-month healing interval and compared histomorphometrically after 3 months of function.³⁴ The analysis showed that reducing the healing time did not affect the amount of bone-implant contact, which was $78.4\% \pm 12.8\%$ for the 1-month group and 77.1% \pm 12.2% for the 2-month group.

The results of this multicenter clinical study are consistent with studies evaluating the mechanical and histologic indicators of osseointegration and indicate that implant success in these cases of early loading is comparable to that for implants loaded after conventional 4- to 6-month healing periods.^{35,36} Other clinical studies have shown that early loading of implants is a predictable procedure, especially for rough-surfaced implants and implants placed in the mandible.^{37–40}

The data presented here are follow-up to the interim 1-year report and show that the long-term

success rate is not substantially different than the early results. The reduction in the cumulative success rate from 98.5% at 12.6 months to 97.9% after 5 years represents the occurrence of only 3 failures, all of which occurred after prosthesis placement. Throughout the study all successful implants showed healthy peri-implant soft tissue, normal peri-implant bone tissue, and stable bony anchorage, indicating clinical evidence of maintained osseointegration. Early loading, therefore, had no appreciable effect on the health of the soft tissue. Furthermore, no radiographic evidence of clinically relevant crestal bone loss or radiolucency or clinical observations of tissue pathology were reported, which reflects the continued success of these prosthetically restored implants.

CONCLUSION

The results of this multicenter prospective study indicate that Osseotite endosseous implants can achieve successful osseointegration when loaded after 2 months of healing and remain stable during 5 years of implant function in this patient population. With a postloading success rate of 99.4%, this implant has provided a high level of predictability. This study suggests that similar clinical outcomes and implant survival can be expected whether a single-stage surgical approach and an early-loading protocol or 2-stage surgical approach and a traditional loading protocol are used.

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