

A PROSPECTIVE, MULTICENTER, 4-YEAR STUDY OF THE ACE SURGICAL RESORBABLE BLAST MEDIA IMPLANT

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KEY WORDS

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This article reports on the 50-month results of the evaluation of the ACE Surgical resorbable blast media (RBM) dental implant. There were 1077 implants placed in 348 patients: 950 in the mandible and 127 in the maxilla. A total of 78.6% of the implants were used to support anterior, mandibular, bar-retained overdentures. The 3.75- to 4.00-mm-diameter implant was used in 91.1% of cases, with the remainder being 3.3 mm (2.2%) or 4.75 mm (6.7%). The implants of 10-, 13-, and 15-mm lengths were used in almost equal amounts in the mandible, maxilla, and anterior or posterior aspects of either jaw. There were 7 failures, all in the mandible and before stage 2 surgery. The overall implant success rate in this 50-month interim report is 99.3% in the mandible and 100% for the maxilla. There was no discernible crestal bone loss during the study period. No differences in bone response were seen in RBM implants with roughened surfaces on the entire implant, up to the collar, or up to the first 2 threads below the collar.

INTRODUCTION

Much of the emphasis in the implant field today is toward the development of surface technology that will improve the reliability and predictability of the clinical outcome. It has long been accepted that pure titanium has excellent biocompatibility with bone and that there is direct cellular attachment of bone to the oxide layer of the titanium, resulting in implant stability.¹ There is also increasing evidence that modifying the surface morphologic features, especially surface roughening, can influence cel-

lular activity.²⁻⁴ This may be critical to long-term implant function and survival.

Many human and animal histologic studies have shown that the microtopographic surface changes will allow earlier bone-to-implant contact than that with machined surfaces.^{5,6} This would allow the bone to achieve a functional osseous state more quickly and to resist functional loading sooner. The most common methods used to alter titanium implant surfaces are (1) surface blasting,⁷ (2) plasma spraying,⁸ and (3) acid etching.⁹ Within the surface blasting there are 2 main groups:



FIGURE. The ACE Surgical resorbable blast media implant.

those created by media blasting, such as aluminum oxide¹⁰ or titanium oxide,¹¹ and those using calcium phosphate as a resorbable blast media (RBM).¹² The latter method creates a

textured surface by blasting a traditional machined titanium implant with calcium phosphate ceramic, which is then passivated without acid etching to remove residual media. This article is

a report of the first 4 years of an ongoing prospective study designed to evaluate the clinical performance of an RBM roughened surface implant (ACE Surgical, Brockton, Mass; Figure) in various anatomic settings and prosthetic requirements.

MATERIALS AND METHODS

The study involved 348 consecutive patients treated during a 50-month period (March 1999 to January 2003) with prosthetic loading. There were 8 indications for implant placement, defined by arch, dentition, and type of prosthesis. The categories included a fixed prosthesis on a totally edentulous maxilla (indication 1) or mandible (indication 2) or a partially edentulous maxilla (indication 3) or mandible (indication 4). A single implant, used to replace one tooth with a freestanding, single-unit prosthesis, was represented as indication 5 in the maxilla and indication 6 in the mandible, respectively. A removable prosthesis (overdenture) on implants in the maxilla (indication 7) or mandible (indication 8) represented the final indications (Table 1).

During the yearly evaluation visit, the prostheses were removed and examined clinically for signs of movement or pain. Mobility was determined by horizontal force with hand instruments. Calibrated panoramic radiographs were taken preoperatively, at second-stage surgery, after prosthesis delivery, and once a year thereafter. Any significant changes in crestal bone level adjacent to the implant were verified, noting change as the differences in the distance from the abutment-implant junction to the bone level on both mesial and distal surfaces. If there was bone loss that required bone graft therapy, it was considered a failure. The criteria for success or failure were based on implant integration rather than the functional viability of the prosthetic result. Osseointegration was determined on the basis of the absence of clinical signs of pain, mobility, inflammation, infection, or the absence of any radiolucency. Any detectable mo-

TABLE 1

Implant	Implant in relation to prosthetic indication							
	Indications							
	1	2	3	4	5	6	7	8
Anterior	5	5	36	4	26	2	8	846
Posterior		5	45	68	7	20		
Total (N = 1077)	5	10	81	72	33	22	8	846
%	0.5	0.9	7.5	6.7	3.1	2.0	0.7	78.6

bility or continuous crestal bone loss was considered a failure. Loosening or fracture of prosthetic screws was not considered a failure.

The surgical and restorative guidelines and patient selection followed the recommendations and guidelines that are widely accepted today. Those patients with histories of alcohol, tobacco, or other drug abuse, immunodeficiencies, uncontrolled diabetes, and radiation therapy were excluded from the study. All patients received initial consultation and evaluation from both the surgeon and the restorative dentist. All options, limitations, and complications were discussed with the patient, and, when indicated, oral pathologic abnormalities were removed before the stage 1 surgery. All implant surgery in this study was performed under local anesthesia on an outpatient basis. The incision was always midcrestal and osteotomies for the implants created in relation to the requirements for each implant diameter. The implant, with cover screw in place, was seated so that the head of the cover screw was at the height of the alveolar bone crest. All patients received oral antibiotics on a prophylactic basis. The use of chlorhexidine digluconate (0.12%) mouth rinse was routine, and patients were asked to refrain from wearing a prosthesis for 14 days. Visits were scheduled for 1 and/or 2 weeks postoperatively. For all patients, existing prostheses were relieved and relined with appropriate soft-line materials, and patients were instructed to maintain soft diets during the first 2 to 4 weeks after stage 1 surgery.

The stage 2, or abutment, surgery was performed after a minimum of 3

months in the mandible and 6 months in the maxilla. This healing phase was sometimes extended, dependent on the assessment of bone quality by the surgeon at stage 1 surgery. At stage 2 surgery, the implants were tested for mobility and temporary healing abutments placed. A border of attached gingiva was created around the healing abutments whenever possible.

Final abutment connection was performed 2 to 4 weeks later, allowing time for gingival healing. The selection of the final abutment was most often left to the restorative dentist and was dependent on multiple factors, including interarch space, angulation of the implant, esthetics, and the requirements of the remaining prosthodontic treatment. Starting in the year 2000, stages 1 and 2 were combined as a 1-step procedure for 20 implants in 8 patients. The implant was placed in the usual fashion. A cylindrical hexed abutment with a separate center screw was then attached as the mucosal element and covered with a healing cap. This assembly was not loaded, and a temporary prosthesis with soft-line conditioner was placed 2 weeks after implant placement. Patients were seen after prosthesis delivery and the follow-up time began from that date. Appropriate clinical examination and radiographs confirmed stability of the entire assembly and hygiene instructions were given. Visits were then scheduled at 6-month intervals for the first year and once a year thereafter.

RESULTS

During a 50-month period, from October 1998 to January 2003, patients underwent rehabilitation using the

ACE Surgical endosseous RBM-surfaced implant. At the time the data were analyzed, patients with 6 implants were lost to follow-up. One of these patients had relocated. Three others refused to return for follow-up. This left a total of 348 patients, consisting of 243 women (64.3%) and 105 men (27.8%) and providing a female-male ratio of 2.3:1. This also represented a total of 1077 implants, with 950 (88.2%) placed in the mandible and 127 (11.8%) in the maxilla. The age distribution of patients extended from 17 to 81 years, with a mean \pm SD age of 55 ± 11 years. There was no significant difference in the age of women and men. The largest percentage of the patient population was in the 51- to 60-year age grouping (38.8%). The age group of 41 to 70 years represented 81.9% of the entire population and the largest percentage of implants (88.3%). The overwhelming number of implants (79.3%) was used for bar-retained overdentures (indications 7 and 8), with 78.6% of these implants in the anterior mandible (Table 1).

This study used the ACE Surgical RBM screw implants in diameters of 3.3, 3.75, 4.00, and 4.75 mm. The lengths were 8, 10, 13, 15, and 18 mm. The 8-mm length was used in one case only and consisted of 4 implants of the 4.75-mm diameter for a mandibular anterior overdenture. Most implants (Table 2) were 3.75 or 4.00 mm in diameter (91.1%), with the remainder being 3.3 mm (2.2%) or 4.75 mm (6.7%). The implant lengths of 10, 13, and 15 mm were used in almost the same amounts in the mandible, maxilla, and anterior or posterior aspects of either jaw, respectively.

For the purposes of this study, each implant came in 1 of 3 surface configurations. The first configuration had a variable surface with a machined implant surface down to the second thread, with the remainder being an RBM surface. The second configuration was an RBM surface from the apex up to the collar. The third configuration was a machined implant surface with

TABLE 2
Implant distribution by diameter and length

Length (mm)	Diameter (mm)				Total No. (%)
	3.3	3.75	4.00	4.75	
8			3	10	13 (1.7)
10	5	203	103	18	329 (37.7)
13	13	249	102	20	384 (43.7)
15	5	228	78	24	335 (37.8)
18	0	16	0	0	16 (1.7)
Total No. (%)	23 (2.2)	696 (64.8)	286 (26.3)	72 (6.7)	1077 (100.0)

TABLE 3
Life table analysis*

	Time 1 (mo)	Time 2 (mo)
No. of implants	1077	949
Median	36.7	30.4
Minimum	12.6	8.0
Maximum	50.8	43.5
Mean (SD)	33.1 (19.2)	27.8 (16.8)

*Time 1 was between first stage and last follow-up (January 2003). Time 2 was between prosthetic loading and last follow-up (January 2003).

no RBM treatment. These groups were placed randomly, with no regard to bone type or jaw region. In addition, in the 3.75- to 4.00-mm diameter, 10 implants in each of the 3 lengths were also made available with an RBM surface on their entire length, including the collar. The variable RBM surface represented more than 60% of the implants in the 3.75- to 4.00-mm diameter. In the 3.3- and 4.75-mm diameter, the implants with RBM up to the collar represented more than 60%. In all clinical and radiographic assessments, no differences have been apparent among the 4 categories up to this follow-up period.

Seven implants, in 4 patients, failed to integrate. Three implants failed in the posterior and 4 in the anterior mandible, all before stage 2 surgical procedures. Two of the posterior implants were in one patient and 3 anterior implants in another patient. In both cases, the implants were placed as a 1-step procedure and became mobile 3 to 4 weeks after insertion. The remaining posterior implant was removed due to a complaint of implant-related pain. The remaining anterior implant exhibited mobility during manual examination.

A life table analysis of all the implants (Table 3) shows that the earliest implants were in place for more than 50 months, with the longest loading period being 43.5 months. With no implant failures after loading, the effective survival rate for loaded implants is 100% for the study period. No significant crestal bone loss was seen in the 50 months covered in this study. Fractures of implants, center screws, or prosthetic screws were not identified as problems.

DISCUSSION

During the past few years, there has been ever-increasing attention given to implants with rough-textured surfaces, citing preclinical mechanical and animal studies for acid etching,¹³ aluminum,¹⁴ titanium,¹¹ grit blasting, and RBM preparation.¹⁰ Recent histologic studies for both acid etching¹⁵ and media blasting¹⁶ show high bone-to-implant contact, indicating that the modified topography of titanium implants may create favorable osteoconductive behavior.

Recently, Cooper,¹⁷ in a comprehensive review, looked at the role of surface topography in creating and maintaining bone at titanium implants

and concluded that the increased surface improves bone-to-implant contact and mechanical properties. In addition, Davies¹⁸ hypothesized that improved "wettability" and increased clot retention on the roughened surfaces resulted in improved osseointegration through mechanisms that promote osteoconduction at the titanium surface.

Buser et al¹⁹ studied bone-to-implant response in long bones of miniature pigs, using implants with 6 different treated surfaces. They demonstrated a positive correlation between increased roughness values and bone-to-implant contact. After 6 weeks, the roughest surface had the greatest amount of bone contact. This has been confirmed by Cochran et al.¹² Wennerberg et al²⁰ compared implants with 2 different blast surfaces and machined implants in rabbit bone. Although each surface showed different degrees of roughness, the blasted surfaces showed stronger bone fixation by virtue of significantly greater removal torque values and percentage of bone-to-implant contact.

It is now well established that optimal bone cell apposition occurs at a higher percentage on surfaces that are roughened compared with machined.²¹⁻²³ Two studies by Piattelli et al,^{24,25} comparing bone response in rabbits to machined and RBM titanium implants, showed a significantly higher bone-implant contact percentage with the RBM implants. Their conclusion was that the RBM surface could be considered more osteoconductive than one that is machined. Similar results were obtained in another recent study in which scanning electron microscopy and electron spectroscopy for clinical analysis of machined and sandblasted and acid-etched surfaces showed that increased implant roughness can improve in vitro cellular adhesion and proliferation.²⁶ The increased surface area created by a roughened surface permits more area for bone cell attachment. A machined implant would need to be 30% to 40% larger to achieve a similar surface area.

If surface morphologic features are accepted as being a critical character-

istic for enhancing the bone-to-implant contact, identification of the optimal surface for bone cell formation is still in the early stages. Currently, as described in the literature, osseointegration has been enhanced as a direct function of the increased surface area, when the dental implant surface is roughened rather than left smooth. Based on this information, defining the optimal roughened surface has been described by both the implant surface roughness (Ra), which is the arithmetic average of the deviation of peaks and valleys from a mean line on the surface of the implant, and the micropit diameters in this roughened surface. In general, the literature has described the optimal Ra range as 2 to 4 μm and the micropit diameters of this roughened surface as 3 to 11 μm . The ACE Surgical RBM implant has an average surface Ra of 3.09 μm , with micropit diameters that range from 5 to 10 μm ,²⁷ placing it entirely within the desired optimal surface characteristics for both parameters.

Buser et al²⁸ studied removal torque in acid-etched (3i Osseotite, 3i, Palm Beach Gardens, Fla) and sandblasted and acid-etched (Straumann SLA, Institut Straumann, Waldenburg, Switzerland), surface-treated implants. The removal torque is the amount of torque required to screw an implant out of bone and is considered a rough measure of osseointegration. The removal torques were significantly higher for the SLA implant.

The SLA and Osseotite Ra's are 2 and 1.3 μm , respectively, with a 1- to 2- μm micropit diameter for both. The ACE Surgical RBM implant, with a slightly rougher surface than the SLA implant, but still in the optimal range, would seem to offer the same characteristics of early bone apposition as the SLA implant.

A 5-year study of the IMZ titanium plasma-sprayed cylinder implants reported success rates of 95.8% for the mandible and 92.9% in the maxilla.²⁹ Babbush and Shimura,³⁰ in a 5-year life table statistical analysis and clinical ob-

servation of the IMZ implants, showed an overall 95.0% survival rate. Both partially and totally edentulous patients were at the 96.0% rate, with the maxilla at 92.0% and the mandible at 99.0%. They noted that the major factors that positively influenced long-term survival were the use of the longest and largest diameter implants appropriate for the clinical situation. Leimola-Virtranen et al,³¹ using ITI titanium, plasma-sprayed screw implants in the edentulous mandible and with up to a 10-year follow-up, were able to show overall success rates of 94.9%. A study on partially edentulous patients by Jemt and Lekholm³² showed 5-year success rates of 97.2%. Zarb and Schmitt,^{33,34} using Nobelpharma implants, showed 94.3% success rates in patients with partially edentulous posterior areas and 91.5% in the partially edentulous anterior regions.

In a retrospective, multicenter report of 3i implants during a 5-year period, Lazzara et al³⁵ evaluated both pure titanium threaded implants and titanium plasma-sprayed implants in totally and partially edentulous patients. They calculated a mean implant survival rate of 95.0% for both the threaded and cylindrical implants. In particular, the success rate for the threaded implants was 97.0% in the mandible and 93.8% in the maxilla.

More recently, Davanpanah et al,³⁶ in a prospective 3-year evaluation of the 3i ICE implants, showed 94.3% and 92.9% survival rates after 1 and 3 years of prosthetic loading, respectively. The rate of late failures (4.7%) was greater than the rate for early failures (2.3%). In a 4-year interim report on the Osseotite implant,³⁷ the cumulative success rate was 98.7%, with a 99.4% success rate in the posterior mandible and 98.4% in the posterior maxilla, with no failures after loading.

Similar results were achieved by Grunder et al,³⁸ whose 5-year report with the Osseotite implant showed a 100% cumulative survival rate in anterior implants and 98.4% for posterior implants. The cumulative postloading

implant survival rate was 100% for both anterior and posterior implants. This may suggest that the surface can significantly reduce postloading failures, thereby providing a high level of prosthetic predictability. These results are markedly different from those seen with machined-surface implants, where late failures accounted for nearly half of all the reported failures.^{15,39}

A 5-year follow-up report on the ITI, nonsubmerged, solid screw implant with blasted surface⁴⁰ showed a cumulative survival rate of 95.3%, which was comparable to the 5-year survival rates with the submerged Branemark system implant.⁴¹ The present study, which shows success rates of 99.3% for the mandible and 100% for the maxilla, is similar to the previously mentioned results. There was no difference in the rates based on implant length or prosthetic indication, although a longer follow-up time will be required before a more definitive statement may be made. Within the number of implants considered as failures, loss of integration was the major cause, although the incidence was so small that it cannot be seen to represent a significant overall problem. The fact that some of these failures were in the 1-step procedure highlights the need to study the long-term success rates with that technique.

Dental implants of high quality, either titanium screw design or the titanium cylindrical form with a plasma-sprayed surface, achieve osseointegration with high success rates. Therefore, choosing an implant system that is manufactured from high-strength biocompatible materials, structurally high-tolerance design features, and close-fitting tolerances will promote its functional success.

In conclusion, the success rates in the present interim clinical study show that the ACE Surgical RBM implant is comparable to other similar implants in terms of implant survival and prosthetic stability. These success rates are high, independent of the variety of clinical situations in which they are

used, and influenced by careful case planning and communication of the surgical and prosthetic teams. It should be noted again that this is an on-going study, and post-5-year results will be detailed in the near future.

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