



SPECIAL SUPPLEMENT

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Peri-implant disease



Joseph Carpentieri, DDS†

Despite the high implant success rates achieved today, unanticipated late-stage complications are a reality. One such complication is peri-implant disease, which may require surgical intervention and lead to additional costs, lowered patient satisfaction, and ultimately, implant failure.

Peri-implant disease as described by Lindhe et al is a collective term for inflammatory reactions within the tissues surrounding an implant that are infective in nature and present clinically in two distinct forms. Mucositis appears as inflammation of the soft tissue without loss of crestal bone, whereas peri-implantitis is characterized as inflammation with loss of supporting bone.

Similar to periodontal disease, the etiology of peri-implantitis is endogenous bacteria, with the pathogenesis being a manifestation of a host response against the bacterial challenge. Mucositis around implants is not fundamentally different from gingivitis around teeth and is reversible. When comparing peri-implantitis to periodontitis, there are several physiologic differences. Peri-implant tissues present with an altered connective tissue fiber orientation and a diminished blood supply as compared to teeth, which may lead to an impaired defense mechanism with the potential for irreversible changes. Accordingly, the clinical presentation is accompanied by crater-like defects with exudate as a common finding. Periodontal diseases are more self-limiting and responsive to treatment. Peri-implantitis lesions are more aggressive, often extending into the marrow and are more difficult to stop once the process has been initiated.

Therefore, before treatment recommendations can be established, it is essential that clinicians have the ability to recognize and treat peri-implant disease, but even more importantly, clinicians need to have a good understanding of how to prevent the onset. As clinicians, we cannot directly control patient-based risk factors (i.e., oral hygiene compliance, host response, and medical considerations). There are, however, a number of decision-based factors within our purview. These include selecting proper prostheses/abutment designs and ensuring the presence of an adequate circumferential zone of keratinized tissue. Perhaps one of the most important factors is an understanding of recent publications that suggest the role the implant surface contributes to the process. Additional factors for optimizing peri-implant health include patient education, adherence to a strict oral hygiene regimen, a professional maintenance protocol, proper record-keeping, and early diagnosis and treatment.

The purpose of this special supplement is to review landmark studies on implant surface characteristics and their relationship to peri-implant disease. These studies have led to an evolution of designs and the current state-of-the-art implant-surface treatment. Through this understanding, the goal of optimizing peri-implant health to sustain long-term functional and aesthetic outcomes is attainable.

† Dr. Carpentieri has a financial relationship with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.

editorial

Implant surface: An evolution



Richard J. Lazzara,
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Peri-implant disease is a complex and challenging phenomenon. Many factors may be involved in its etiology, with the implant surface playing an important role. For at least two decades, BIOMET **3i** has been actively working to better understand the relationship between surface roughness and its effect on peri-implant health.

The four articles chosen for inclusion in this publication represent key milestones in advancing this understanding. Each reports on research that was initiated after the hybrid OSSEOTITE® Implant was successfully introduced in 1995.

The introduction of OSSEOTITE was a direct response to a couple of key insights. Implants with a machined surface had long been understood to be effective at resisting peri-implant disease. However, research by Berman and Jaffin had made it clear that such machined implants functioned more poorly in areas of poor bone quality than did implants coated with hydroxyapatite or titanium plasma spray (TPS). Unfortunately, by the early 1990s, reports were increasing of significant peri-implantitis and subsequent bone loss around some of these coated surfaces.

The developers of the hybrid OSSEOTITE design sought to marry the best of the two material treatments in the same implant – roughened in the area exclusively surrounded by bone and machined in the coronal region, where contact with the soft tissue might occur.

Enthusiastic about the success of the OSSEOTITE Surface, clinicians appealed to BIOMET **3i** for the surface treatment to be extended all the way to the top of the implant. Eventually, this design was provided on a limited basis and first tested in animals. The results from back-to-back 2002 publications (Abrahamsson et al and Zitzmann et al) showed that OSSEOTITE in the coronal region had no negative impact on the peri-implant soft tissues. Subsequently, testing began in humans. Zetterqvist et al (2009) and Baldi et al (2009) showed similar outcomes not only for mucosal health but also for preservation of crestal bone. Collectively, these findings provided the scientific basis for launching the full OSSEOTITE Surface (FOSS), which since then has undergone further refinement in surface topography and design, leading to the current **3i** T3® and **3i** T3 with DCD® Implants.

As you can see, a number of iterations have been involved in developing new and improved implant surface treatments. BIOMET **3i** has long been committed to approaching this development process from a safe, logical, and meticulous scientific manner. That commitment continues today.

study

The mucosal attachment to titanium implants with different surface characteristics: An experimental study in dogs

Abrahamsson I,¹ Zitzmann NU,¹ Berglundh T,¹ Linder E,¹ Wennerberg A,^{2,3} Lindhe J¹
J Clin Periodontol 2002;29:448-455.

Why Was This Research Done?

Studies have shown that materials used for implant abutments directly influence attachment of the peri-implant mucosa. Whereas a similar epithelial-connective tissue attachment is found adjacent to abutments made of titanium and ceramic, the mucosa at abutments made of gold alloy do not have a connective tissue component. Further research indicated that surface topography had an affect on the proliferation and orientation of cells grown *in vitro* on titanium. This led to the present project and the objective to determine whether there is a difference in mucosal attachments to titanium abutments having either a smooth or a roughened surface, such as the dual acid-etched OSSEOTITE® (BIOMET 3i, Palm Beach Gardens, Florida, USA).

What Was Done?

A preclinical study was performed to compare the histologic peri-implant mucosal attachment adjacent to implants and abutments with either OSSEOTITE or smooth surfaces.

How Was It Done?

In this randomized-controlled study, each of five beagle dogs received four CP-titanium OSSEOTITE Implants (3.75mm x 8.5mm) placed 1.0mm subcrestally in healed mandibular extraction sites. Second-stage surgery was performed at three months for placement of the two types of study abutments: OSSEOTITE Surface and regular smooth-surfaced abutments. Both types of abutments in lengths of 4.0mm and 5.5mm were connected with 32Ncm of torque in a random order to the four implants in each dog.

Following a six-month period during which the dogs were fed a soft diet and had their teeth and implants hygienically maintained, a clinical exam was performed, and the animals were sacrificed. Tissue samples including the implant and surrounding soft and hard tissues were processed for light and electron microscopy. A confocal He-Ne profilometer was used to study the surface topography of the abutments.

What Were the Results?

No obvious signs of inflammation were found at any of the implant sites while the animals were under observation. Based on both the light and the electron microscopy, there were no consistent differences between the peri-implant mucosal tissue attachments at the OSSEOTITE and smooth surfaces. The soft tissue was similar, both qualitatively and quantitatively and consisted of a barrier epithelium and a zone of connective tissue. The orientation of the fibroblasts in the zone of connective tissue attachment was similar for both, and the inner zone of the connective tissue attachment contained about 30-33% fibroblasts and 63-66% collagen.

Clinical Relevance

The roughness of the OSSEOTITE Surface does not change the attachment between soft tissues and titanium implants and abutments. The composition and configuration of the soft-tissue components were exactly the same. Therefore, one would expect the tissues to function in the same way.

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This research was funded by BIOMET 3i.

Study

Soft-tissue reactions to plaque formation at implant abutments with different surface topography: An experimental study in dogs

Zitzmann NU,¹ Abrahamsson I,¹ Berglundh T,¹ Lindhe J¹
J Clin Periodontol 2002;29:456-461.

Why Was This Research Done?

The suggestion had been made that implant abutments with roughened surfaces might accumulate more plaque than smooth-surfaced abutments. If so, such an enhanced rate of plaque build-up might favor the development of inflammatory lesions in the peri-implant mucosa.

What Was Done?

A study was designed to compare reactions of peri-implant mucosa to plaque accumulation on implant abutments with OSSEOTITE® (BIOMET 3i, Palm Beach Gardens, Florida, USA) and smooth (turned) surfaces.

How Was It Done?

Four titanium implants were placed in the mandibular left premolar region of each of five one-year-old beagle dogs and allowed to heal, submerged, for three months. At second-stage surgery, two of each type of abutment (dual acid-etched OSSEOTITE and smooth surface) were connected to the four implants in a randomized order. For the first four weeks after abutment connection, the dogs were subjected to a meticulous plaque-control program. For the next six months, the oral hygiene regimen was suspended, and the dogs were fed a soft diet that allowed

for gross plaque formation. The animals were sacrificed, and biopsies were obtained. Tissue samples were prepared for light microscopy and for histomorphometric analysis.

What Were the Results?

As intended by the six-month period without plaque control, both the OSSEOTITE and smooth-surfaced abutments harbored biofilm and calculus. The surrounding mucosa showed obvious signs of inflammation. Histological observations revealed the establishment of a large inflammatory lesion in the peri-implant mucosal connective tissue. In most peri-implant tissue samples, a second inflammatory cell infiltrate was also seen lateral to the implant-abutment junction. There were numerous plasma cells and lymphocytes within these plaque-associated lesions.

Clinical Relevance

The soft-tissue reaction to plaque formation appears to be similar for OSSEOTITE and smooth abutment surfaces. Importantly, there was no difference in the soft-tissue reaction when comparing OSSEOTITE to a machined surface in the presence of large amounts of plaque and inflammation after a six-month period.

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This research was funded by BIOMET 3i.

Study

A prospective, multicenter, randomized-controlled 5-year study of hybrid and fully etched implants for the incidence of peri-implantitis

Zetterqvist L,¹ Feldman S,^{2,3} Rotter B,⁴ Vincenzi G,⁵ Wennström JL,⁶ Chierico A,⁵ Stach RM,^{7,†} Kenealy JN^{7,†}
J Periodontol 2010;81:493-501. [Epub 2009 Dec 23]

Why Was This Research Done?

The OSSEOTITE® Implant (BIOMET 3i, Palm Beach Gardens, Florida, USA) was commercially introduced in 1996 with a hybrid design incorporating a machined surface in the coronal region from approximately the third thread to the seating surface. This design was intended to reduce the risks of peri-implantitis and other related soft-tissue complications that were reported for implants with surface roughness in the coronal region.

What Was Done?

The objective of this prospective, randomized-controlled clinical trial was to determine the incidence of peri-implantitis for a fully etched OSSEOTITE Implant with the DAE surface extending to the implant platform. Also, the study was designed to confirm results in humans that had previously been reported in animal studies.

How Was It Done?

Patients had implant sites randomly assigned to receive one hybrid control implant and at least one full OSSEOTITE test implant in support of a short-span fixed restoration to ensure that variables (e.g., demographics, jaw locations, and bone density) were consistent between groups. Prostheses were inserted two months after implant placement with follow-up evaluations scheduled annually for five years to assess mucosal health based on bleeding on probing, suppuration, and probing depths. Evaluations also included radiographic and mobility assessments.

What Were the Results?

One hundred twelve patients who were enrolled at seven centers received 139 control and 165 test implants (total: 304 implants). With more than five years of post-loading evaluation, there was one declaration of peri-implantitis associated with a control implant that was successfully treated later. Clinical probing and radiographic assessments did not reveal differences between groups in mucosal health outcomes or other signs of peri-implantitis. Five-year results of this randomized and controlled study showed no increased risk of peri-implantitis for fully etched implants as compared to hybrid-design implants. In addition, radiographic analysis showed less bone resorption on the full OSSEOTITE Implants (0.6mm versus 1.5mm) at five years.

Clinical Relevance

This is the only published prospective clinical trial designed specifically for comparing implant surfaces for their susceptibility to peri-implant disease after five years. The study shows that the OSSEOTITE Surface extending to the top of the implant does not increase the incidence of peri-implant disease as compared to the machined surface. This important clinical safety finding is a relevant reference for clinicians seeking to select an implant that will have long-term stability. In addition, after five years, the OSSEOTITE Implants had high bone levels as compared to the machined-surfaced implants. This can help in the support of the soft tissues.

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 This research was funded by BIOMET 3i.

Study

Plaque accumulation on exposed titanium surfaces and peri-implant tissue behavior. A preliminary 1-year clinical study

Baldi D,¹ Menini M,¹ Pera F,¹ Ravera G,² Pera P³
Int J Prosthodont 2009;22:447-455.

Why Was This Research Done?

The original BIOMET 3i OSSEOTITE® Implant (BIOMET 3i, Palm Beach Gardens, Florida, USA) included the proprietary dual acid-etching (DAE) treatment on surfaces of the body with the exception of the collar ("hybrid design"). The basis for leaving the 3.0mm coronal portion untreated was to feature a smoother, proven machined surface that would be less retentive of plaque and therefore limit soft-tissue inflammation, as well as other localized soft- and hard-tissue reactions to adherent bacteria, such as peri-implantitis. The present research was done to assess peri-implant tissue responses adjacent to machined and DAE titanium surfaces in humans.

What Was Done?

A randomized-controlled clinical study was designed for which clinical, soft-tissue, radiographic, microbial, and histologic outcomes could be compared for DAE and machined surfaces.

How Was It Done?

Each study patient required at least two implants. Hybrid and fully acid-etched OSSEOTITE Implants were randomly assigned to these sites and placed following a single-stage surgical procedure. Test sites received fully etched OSSEOTITE Implants along with abutments modified by the investigators using a DAE process. Control sites received hybrid OSSEOTITE Implants along with standard, machined-surfaced healing abutments.

Patient evaluations included assessments for bleeding on probing (BOP) and plaque (O'Leary plaque index-PI) and

periapical radiographic follow-up. Samples for microbiology and tissue biopsies for histology were also taken.

What Were the Results?

A total of ten implant pairs were placed in the posterior quadrants of eight patients (mean 59.75 years). PI scores on DAE healing abutments were higher as compared to the machined-surfaced healing abutments. None of the bacteria strains were pathogenic. Histologic findings for the samples taken from both test and control sites were all considered to be consistent with normal healing and configuration. Granulation tissue with a poor inflammatory infiltrate was observed. The BOP outcomes revealed no bleeding for the majority of both test and control sites at all intervals and no significant difference at one year. Radiographic analysis of interproximal crestal bone levels showed significant differences at both six months and one year, with the test (FOSS) implants having less bone resorption (0.61mm versus 1.47mm), even without platform switching.

Clinical Relevance

This study provides human evidence duplicating earlier publications regarding DAE surfaces exposed to the oral environment. Both pre-clinical studies (Abrahamsson, Zitzmann) and this clinical trial show no detrimental (bacteriologic, inflammatory, or histologic) effect from exposed DAE surfaces in the given time frames, which were more than adequate to demonstrate any detrimental soft-tissue or inflammatory effects. In addition, the crestal bone outcomes are consistent with those in Zetterqvist et al showing the bone-preserving effect of OSSEOTITE.

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This study was supported by BIOMET 3i in the form of providing dental implants.

Introducing the

3i T3 IMPLANT™



Preservation By Design®

- Contemporary hybrid surface design with a multi-level surface topography.
- Designed for peri-implantitis risk mitigation utilizing the proven OSSEOTITE® Surface technology at the coronal aspect of the implant.

In a five-year study, the dual acid-etched surface of the full OSSEOTITE Implant presented no increased risk of peri-implantitis or soft-tissue complications versus a hybrid implant with a machined collar.¹

- Incorporates a platform switching feature with as little as 0.37mm of bone recession.*²
- Designed to reduce microleakage through exacting interface tolerances and maximized clamping forces.



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BIOMET 3i™
PROVIDING SOLUTIONS – ONE PATIENT AT A TIME™

1. Zetterqvist L, Feldman S, Rotter B, Vincenzi G, Wennström JL, Chierico A, Stach RM†, Kenealy JN†. A prospective, multicenter, randomized-controlled 5-year study of hybrid and fully etched implants for the incidence of peri-implantitis. J Periodontol 2010 April;81:493-501.

2. Östman PO††, Wennerberg A, Albrektsson T. Immediate occlusal loading of NanoTite™ PREVAIL® Implants: A prospective 1-year clinical and radiographic study. Clin Implant Dent Relat Res 2010 Mar;12(1):39-47. n = 102.

†The authors contributed to this article while employed by BIOMET 3i.

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Reference 2 discusses BIOMET 3i PREVAIL Implants with an integrated platform switching design, which is also incorporated into the 3i T3® Implant.

*0.37mm bone recession not typical of all cases.

For additional product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the product package insert and the BIOMET 3i Website: www.ifu.biomet3i.com

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