

The BIOMET *3i* Dual Acid-Etched Surface & Peri-implantitis Risk Mitigation

Outcome Of A Prospective, Randomized-Controlled Clinical Study



Peri-implantitis: Potential For Implant Failure

Peri-implantitis presents itself as a potentially serious clinical problem for patients and clinicians. It also impacts the viability of the dental implant as a treatment option for missing teeth. It can be a prominent cause for late implant failure leading to loss of the prosthesis.

What Is Peri-implantitis

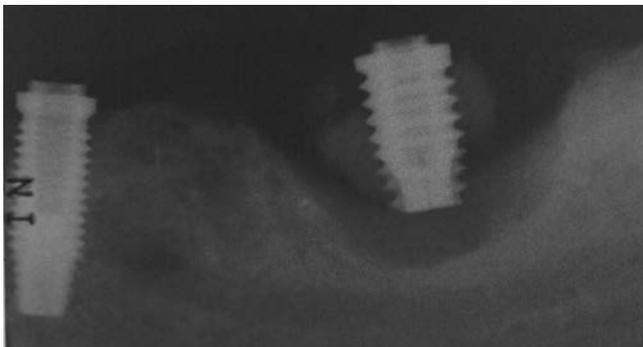
Peri-implantitis is a syndrome characterized by three clinical findings.

- Severe mucosal inflammation (mucositis)
- Marked soft-tissue Clinical Attachment Loss (CAL)
- Progressive crestal bone regression

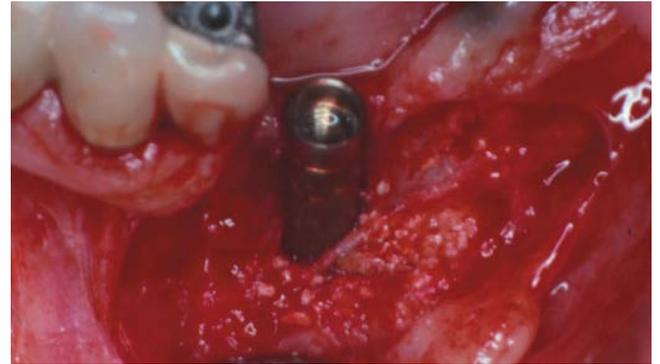
In order for a case to be declared as peri-implantitis, all three must be present with a primary microbial etiology.¹



Occlusal image of the implant (mandibular left side), reflecting suppuration and severe tissue inflammation due to microbial infection.



Periapical radiograph of the implant in the above clinical image. Significant bone loss is evident around the implant. The implant had +3 mobility and required removal and replacement.



Large peri-implantitis defect undergoing revision. Note the distance of the defect margin to the implant surface.

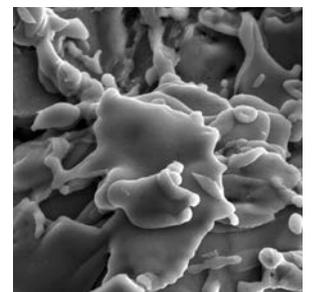
Peri-implantitis And Roughened Surfaces

Peri-implantitis is difficult to treat and may often lead to progressive bone loss and implant failure. Implants with roughened surfaces on coronal-implant collars may be perceived as having higher risks of peri-implantitis or, at the very least, other mucosal complications.

The incidence of peri-implantitis has been reported to be in excess of 12%.^{2,3} The risk of peri-implant disease had been thought to increase with greater implant surface roughness. Historically, very roughened implants (TPS and HA legacy coated implants) were reported as having improved initial integration success,⁴ but were also associated with a higher proportion of late failures, some due to peri-implantitis.⁵



Patient case demonstrating peri-implantitis around Titanium Plasma Sprayed (TPS) Implants.



SEM of TPS surface at 2000x magnification.

Concerns about implant failure remain with roughened implants. Is this perception a reality for all roughened-surface implants?

The BIOMET 3i™ Dual Acid-Etched Surface

Addressing concerns about peri-implantitis and roughened-surface implants.

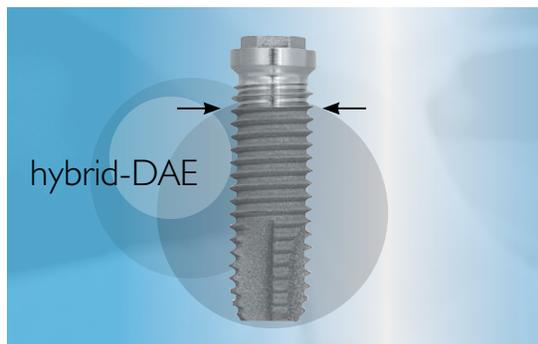
Historically, a machined surface implant has been recognized for its ability to be decontaminated as compared to roughened surfaces.^{6,7,8}

Acknowledging a clinical concern about the occurrence of peri-implantitis, BIOMET 3i initially offered the OSSEOTITE Implant with a hybrid surface design where the implant was machined from the abutment seating platform to the third thread with the remainder of the implant body dual acid-etched (DAE) to the apex.

The potential benefit of having the dual acid-etched surface complexity along the entire length of the implant was considered and developed. Yet, the question remained: How would the benefits of this dual acid-etched surface play against the possibility of increasing the incidence of peri-implantitis? This led to a specific effort to quantify the risk of adverse events for fully-etched implants as compared to the hybrid surface design.

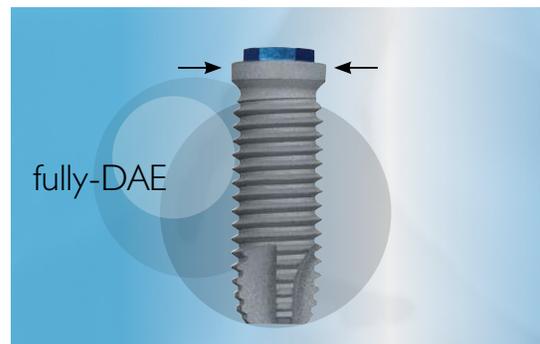
BIOMET 3i sponsored a prospective, randomized-controlled clinical trial to determine if a difference exists in the incidence of peri-implantitis between hybrid and fully-etched implants.⁹

Control Implant:



The control implant is dual acid-etched (DAE) from the apex to the third coronal thread. A machined surface continues to the seating platform.

Test Implant:



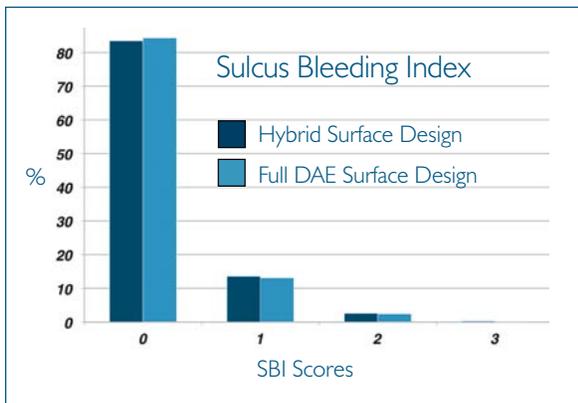
The test implant is dual acid-etched (DAE) from the apex to the abutment seating platform. Both test and control implants are cpTi with straight walls and apical cutting features.

Study Outcomes

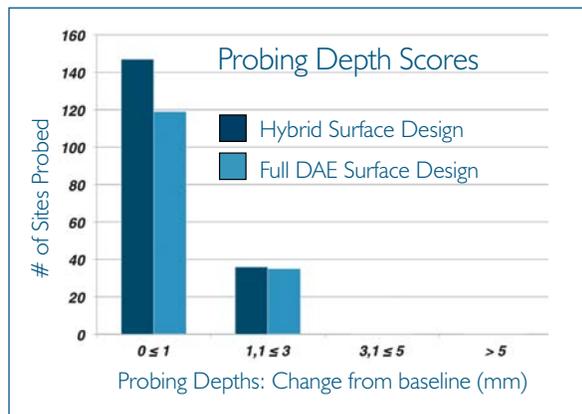
One hundred twelve patients who were enrolled at seven centers received 139 control and 165 test implants (total: 304 implants).

Follow-up evaluations included:

- **Sulcus Bleeding Index Scores (SBI)**
- **Probing for suppuration**
- **Assessments for mobility**
- **Serial Periapical radiographs to identify radiolucencies and crestal bone levels**



84% of all SBI scores were "0" (absence of bleeding); 13% of scores were "1" - isolated bleeding spot.

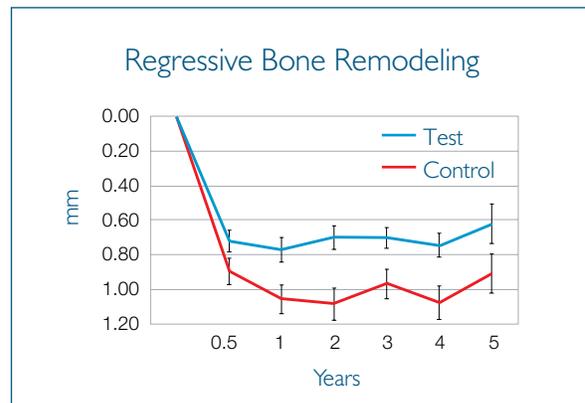


No implant (test or control) showed changes in probing depths greater than 3mm.

No substantial differences in mucosal health outcomes between test and control groups were observed throughout the 5-year follow-up.

Only one observation of suppuration was recorded and it was for a control implant at the baseline evaluation. There was one diagnosis of peri-implantitis for a control implant 3.5 years after implant placement.

Radiographic analyses of crestal bone recession demonstrate that the mean change from baseline (provisionalization) is less for test implants in comparison to control implants ($P < .0001$).



Fully DAE implants averaged less bone regression as compared to the hybrid DAE Implants over the five-year period of follow-up.

These findings are consistent with previous studies showing that the DAE implant surface had no difference in soft-tissue response when compared to a machined surface.^{10, 11}

For dental implants, a combination of optimal osseous fixation properties and a low risk for peri-implantitis is desired. The DAE surface has more than fifteen years of clinical use and evidenced-based research to support its efficacy. The results of this multicenter study show no increased risk in soft-tissue complications or peri-implantitis for the studied fully dual acid-etched implants.

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- [†]Abrahamson I, Feldman S, Rotter B and Zetterqvist L have had financial relationships with BIOMET **3i** LLC resulting from speaking engagements, consulting engagements and other retained services.

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