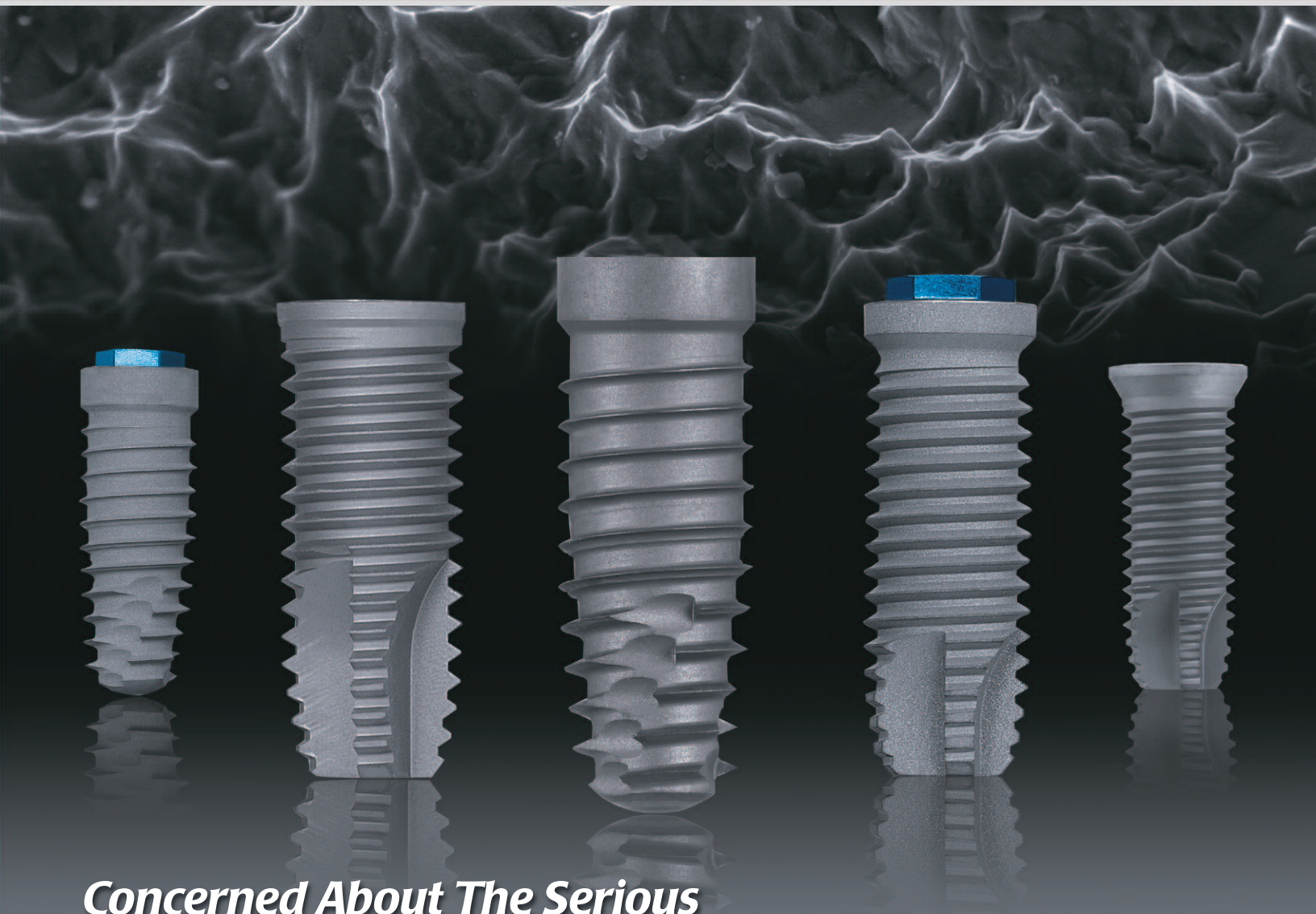
BIOMET 3i™



# Concerned About The Serious Consequences Of Peri-implantitis?

*BIOMET **3i**'s Prospective, Multicenter, Randomized-Controlled Five-year Study Of Hybrid OSSEOTITE® And Full OSSEOTITE Implants For The Incidence Of Peri-implantitis*

# *Peri-implantitis: Potential For Implant Failure*

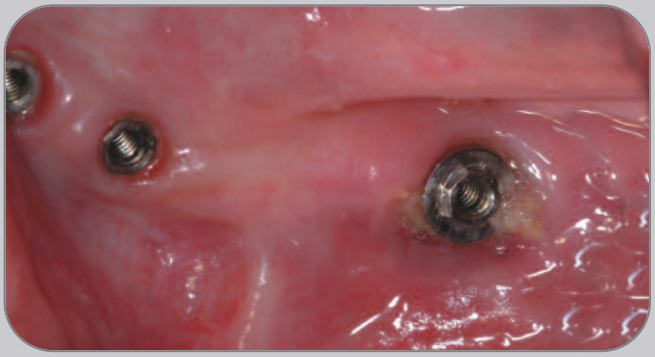
Peri-implantitis presents as a potentially serious clinical problem for patients and clinicians. It also impacts the viability of the dental implant as a treatment option for missing teeth. It can be a prominent cause for late implant failure leading to loss of the prosthesis.

## What Is Peri-implantitis?

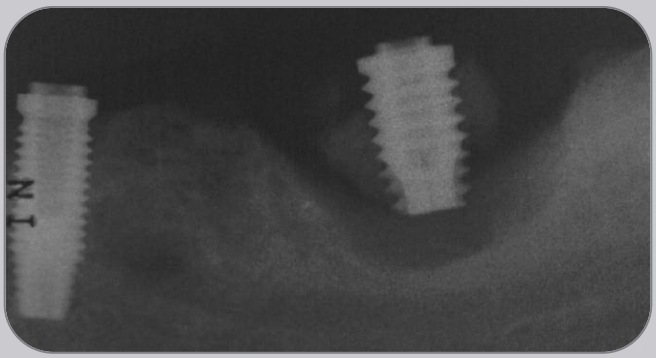
Peri-implantitis is a syndrome characterized by three clinical findings.

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

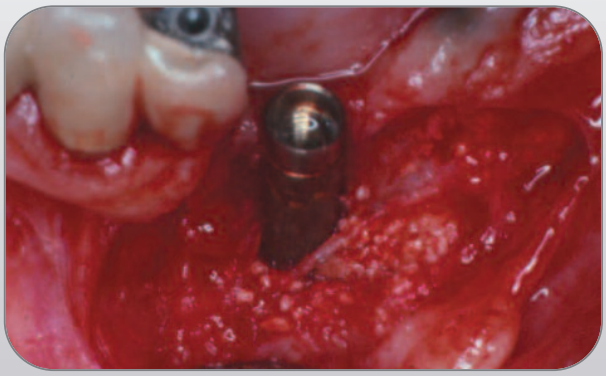
In order for a case to be declared as peri-implantitis, all three must be present with a primary microbial etiology.[1]



**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.**

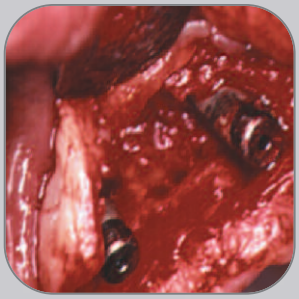


**Large peri-implantitis defect undergoing revision. Note the distance of the defect margin to the implant surface.**

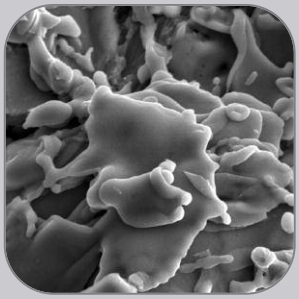
## Peri-implantitis And Roughened Surfaces

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 as high as 14.4%[2] and the prevalence as high as 28%.[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 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?

# *One-Of-A-Kind Study*

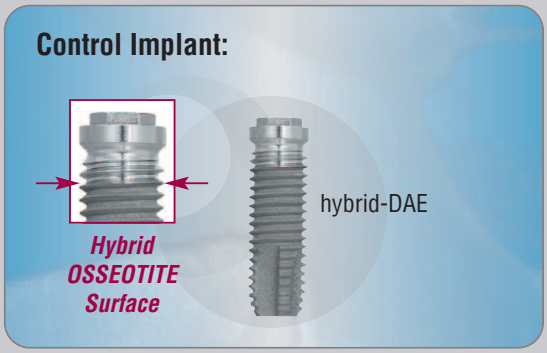
**Addressing concerns about peri-implantitis and roughened-surface implants.**

Historically, a machined surface implant has been recognized for it's ability to be decontaminated, compared with 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 and dual acid etched (DAE) to the apex.

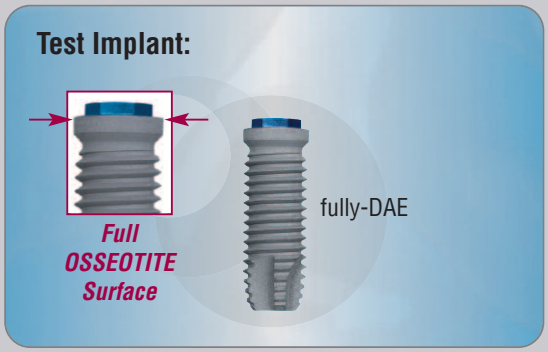
The potential benefit of having the dual acid etched OSSEOTITE Surface complexity along the entire length of the implant was considered and developed. Yet, the question remained: How would the benefits of this dual acid etched surface play against the possibility of increasing the incidence of peri-implantitis?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

Recognizing the responsibility as an implant manufacturer to pursue evidence-based research, 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]

**After a review of the published literature, this is the only prospective, randomized-controlled study with peri-implantitis as the primary outcome.**




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




**The test OSSEOTITE Implant is dual acid etched (DAE) from the apex to the abutment seating platform. Both test and control implants are cpTi with straight walls, apical cutting features and an external hex connection.**

# Study Outcomes

A total of 304 implants were placed, supporting 127 prostheses, with a distribution of 139 control and 165 test implants in 112 patients.

***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***

### Sulcus Bleeding Index

| | | Hybrid Control (%) | FOSS Test (%) |
|---|---|---|---|
| SBI Scores | 0 | 83.5 | 84.3 |
| | 1 | 13.6 | 13.1 |
| | 2 | 2.6 | 2.4 |
| | 3 | 0.3 | 0.2 |

**84% of all SBI scores were "0" (absence of bleeding); 13% of scores were "1" - isolated bleeding spot for both Full OSSEOTITE® (FOSS) and hybrid OSSEOTITE Implants.**

### Probing Depth Scores (Number Of Sites Probed)

| | | Control (N) | Test (N) |
|---|---|---|---|
| Probing Depths: Change From Baseline (mm) | 0 ≤ 1 | 147 | 119 |
| | 1.1 ≤ 3 | 36 | 35 |
| | 3.1 ≤ 5 | 0 | 0 |
| | > 5 | 0 | 0 |

**No implant (test or control) showed changes in probing depths greater than 3.0mm.**

**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).

### Regressive Bone Remodeling


**Full OSSEOTITE (FOSS) averaged less bone regression vs. hybrid OSSEOTITE Implants over the five year period of follow-up.**

These findings are consistent with previous studies showing that the OSSEOTITE 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 are desired. The OSSEOTITE Surface has more than a decade 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 FOSS Implants.**

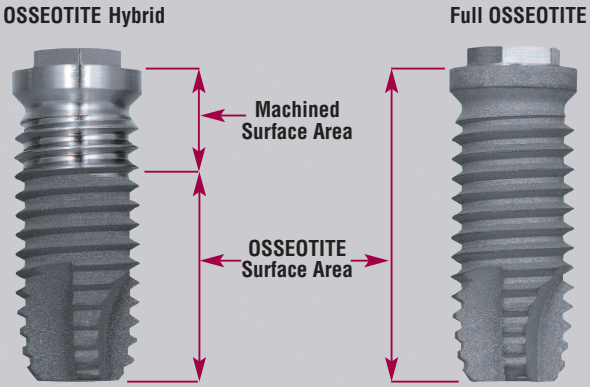
# *Hybrid OSSEOTITE® Vs. Full OSSEOTITE Surface Comparison*

Full OSSEOTITE (FOSS) Implants have increased OSSEOTITE Surface area as compared to a hybrid OSSEOTITE Implant as shown below. With increased surface area, the FOSS Implant provides more contact for osteogenesis.

Scenarios in which FOSS Implants could be used:

- ***Poor quality bone***
- ***Short implant cases***
- ***Sinus graft cases***
- ***Immediate loading cases***
- ***Platform switching cases***

## Representative Differences In OSSEOTITE Surface Area




| Implant | % More OSSEOTITE Surface Area |
|---|---|
| FOS410 | 32.1% |
| FOS510 | 51.7% |
| FOS685 | 60.9% |

## References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# Ordering Information

## Certain® Internal Connection
IMPLANT SYSTEM

### Full OSSEOTITE® Parallel Walled Certain Implants

| Length | 3.25mm (D) | 4.0mm (D) | 5.0mm (D) | 6.0mm (D) |
|---|---|---|---|---|
| 8.5mm | IFOSM385 | IFOS485 | IFOS585 | IFOS685 |
| 10.0mm | IFOSM310 | IFOS410 | IFOS510 | IFOS610 |
| 11.5mm | IFOSM311 | IFOS411 | IFOS511 | IFOS611 |
| 13.0mm | IFOSM313 | IFOS413 | IFOS513 | IFOS613 |
| 15.0mm | IFOSM315 | IFOS415 | IFOS515 | IFOS615 |

### Full OSSEOTITE XP® Certain Implants

| Length | 4/5mm (P) | 5/6mm (P) |
|---|---|---|
| 8.5mm | IFOS4585 | IFOS5685 |
| 10.0mm | IFOS4510 | IFOS5610 |
| 11.5mm | IFOS4511 | IFOS5611 |
| 13.0mm | IFOS4513 | IFOS5613 |
| 15.0mm | IFOS4515 | IFOS5615 |

### Full OSSEOTITE Tapered Certain Implants

| Length | 3.25mm (D) | 4.0mm (D) | 5.0mm (D) | 6.0mm (D) |
|---|---|---|---|---|
| 8.5mm | IFNT3285 | IFNT485 | IFNT585 | IFNT685 |
| 10.0mm | IFNT3210 | IFNT410 | IFNT510 | IFNT610 |
| 11.5mm | IFNT3211 | IFNT411 | IFNT511 | IFNT611 |
| 13.0mm | IFNT3213 | IFNT413 | IFNT513 | IFNT613 |
| 15.0mm | IFNT3215 | IFNT415 | IFNT515 | IFNT615 |

### OSSEOTITE Certain PREVAIL® Implants

| Length | 3/4/3mm (P) | 4/3mm (P) | 4/5/4mm (P) | 5/4mm (P) | 5/6/5mm (P) |
|---|---|---|---|---|---|
| 8.5mm | IIOS3485 | IIOS4385 | IIOS4585 | IIOS5485 | IIOS5685 |
| 10.0mm | IIOS3410 | IIOS4310 | IIOS4510 | IIOS5410 | IIOS5610 |
| 11.5mm | IIOS3411 | IIOS4311 | IIOS4511 | IIOS5411 | IIOS5611 |
| 13.0mm | IIOS3413 | IIOS4313 | IIOS4513 | IIOS5413 | IIOS5613 |
| 15.0mm | IIOS3415 | IIOS4315 | IIOS4515 | IIOS5415 | IIOS5615 |

## External Hex Connection
IMPLANT SYSTEM

### Full OSSEOTITE Parallel Walled Implants

| Length | 3.25mm (D) | 3.75mm (D) | 4.0mm (D) | 5.0mm (D) | 6.0mm (D) |
|---|---|---|---|---|---|
| 7.0mm | FOSM307 | FOS307 | FOS407 | FOS507 | FOS607 |
| 8.5mm | FOSM385 | FOS385 | FOS485 | FOS585 | FOS685 |
| 10.0mm | FOSM310 | FOS310 | FOS410 | FOS510 | FOS610 |
| 11.5mm | FOSM311 | FOS311 | FOS411 | FOS511 | FOS611 |
| 13.0mm | FOSM313 | FOS313 | FOS413 | FOS513 | FOS613 |
| 15.0mm | FOSM315 | FOS315 | FOS415 | FOS515 | FOS615 |

### Full OSSEOTITE XP Implants

| Length | 3/4mm (P) | 4/5mm (P) | 5/6mm (P) |
|---|---|---|---|
| 7.0mm | FOS3207 | FOS4507 | FOS5607 |
| 8.5mm | FOS3285 | FOS4585 | FOS5685 |
| 10.0mm | FOS3210 | FOS4510 | FOS5610 |
| 11.5mm | FOS3211 | FOS4511 | FOS5611 |
| 13.0mm | FOS3213 | FOS4513 | FOS5613 |
| 15.0mm | FOS3215 | FOS4515 | FOS5615 |

### Full OSSEOTITE Tapered Implants

| Length | 3.25mm (D) | 4.0mm (D) | 5.0mm (D) | 6.0mm (D) |
|---|---|---|---|---|
| 8.5mm | FNT3285 | FNT485 | FNT585 | FNT685 |
| 10.0mm | FNT3210 | FNT410 | FNT510 | FNT610 |
| 11.5mm | FNT3211 | FNT411 | FNT511 | FNT611 |
| 13.0mm | FNT3213 | FNT413 | FNT513 | FNT613 |
| 15.0mm | FNT3215 | FNT415 | FNT515 | FNT615 |

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