SPECIAL SUPPLEMENT

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Abstracts from Selected Publications and Poster Presentations
BIOMET 3iT3® Implants
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Introduction
In the more than 30 years since Per-Ingvar Brånemark introduced North American dental researchers to his work with endosseous dental implants, surgical and prosthetic components and implant-treatment protocols have evolved dramatically. Most recently, the realization has been growing that complex biological processes can sabotage even the most beautiful results over time.

There is a growing appreciation of the importance of establishing and sustaining the aesthetics of implant restorations. Four important factors for achieving this goal are implant primary stability, the implant surface, the implant-abutment junction geometry, and the implant-abutment connection. Each of these factors has played a role in the design of the 3i T3® Tapered Implant System (Fig. 1).

Implant Primary Stability
Excessive micromotion during the early implant-healing process has been well documented to impede or prevent osseointegration; it may be the most common cause of implant failure.1 A number of design elements can enhance the likelihood of achieving primary stability with a given implant system.

For example, the 3i T3 Tapered Implant System utilizes depth- and diameter-specific drills to create osteotomies that fit the shape (i.e. minor diameter) of the implants being placed. Implants placed so that their entire surface intimately contacts the full length of the osteotomy have been described as having high Initial Bone-To-Implant Contact (IBIC),2 which enhances primary stability. Furthermore, the 3i T3 Tapered Implant design incorporates additional macrogeometric elements to enhance primary stability,3 including tall, thin threads that penetrate laterally into the bone for secure long-term engagement.

In a prospective immediate loading study by Östman et al, the investigators placed 139 BIOMET 3i NanoTite™ Tapered Implants in mostly healed sites and reported a mean insertion torque of 53.1Ncm, a mean ISQ of 73.3, and a survival rate of 99.2%.4 Placing the tapered implants into fresh molar extraction sockets, Block reported mean ISQ values of 77 in the mandible, 73 in the maxilla, and a survival rate of 97.2%.5 Even when accelerated treatment is not applicable, (e.g. when bone quality is poor), good primary stability minimizes micromotion and reduces the risk of non-integration.1 When clinical conditions are good, primary stability can provide additional benefits, permitting early or immediate provisionalization and/or tissue sculpting to better meet aesthetic demands.
Implant Surface
The surface of dental implants is critical to establishing and sustaining aesthetic outcomes.

BIOMET 3i first refined the implant-roughening process with the introduction of the dual acid-etched (DAE) OSSEOTITE® Surface. Its topography includes 1-3 micron pitting superimposed on a minimally rough surface (Sa, Absolute Mean Roughness <1.0 μm). To reduce the risk of mucosal complications, the OSSEOTITE Implant initially was made available in a hybrid configuration that included the historically-proven turned surface on the first 2-3.0mm of the coronal aspect and the dual acid-etched surface on the remainder of the implant body. However, a prospective five-year multicenter, randomized-controlled study that compared OSSEOTITE hybrid and fully etched implant configurations in 2010 demonstrated that the fully etched surface did not increase the incidence of peri-implantitis as compared to the hybrid design. It also provided additional evidence that the fully etched surface reduced crestal bone loss (0.6mm versus 1.0mm, p<.0001). Continued research into the OSSEOTITE Surface culminated in a new surface enhancement – the 3i T3 Implant. More than just another roughened surface, the 3i T3 Implant surface targets different needs in two distinct regions of the implant (Fig. 2).

- The coronal aspect of the implant has a microtopography similar to the fully etched OSSEOTITE Implant.
- From the base of the collar to the apical tip, the 3i T3 Implant has an increased coarse roughness, resulting in a tri-level surface. The tri-level surface consists of submicron features superimposed on 1-3 micron pitting, overlaid on a moderately rough surface topography (Sa = 1.0 - 2.0 μm).

The 3i T3 Implant Surface represents a significant step forward, with multiple topography levels and features along the implant body designed to influence osseointegration and crestal bone levels, and lower the risk of peri-implantitis.

Implant-Abutment Junction Geometry
A third crucial factor for long-term maintenance of aesthetic restorations is the influence of the implant-abutment junction (IAJ) geometry on the biologic width. The biologic width is the natural seal that develops around any object protruding from the bone and through the soft tissue into the oral environment.

The discovery that implant design could impact biologic width occurred when standard 4.0mm diameter abutments were routinely used in the early 1990s to restore 5.0mm and 6.0mm diameter implant designs. Radiographic follow-up of these “platform-switched” implants yielded the surprising finding of greater preservation of the crestal bone. This led to the development of an implant system that incorporated platform switching into its design (PREVAIL® Implant).

Extensive study of the mechanisms at work ensued, and a recent systematic review and meta-analysis of ten clinical studies including 1,238 implants found significantly less marginal bone loss around platform-switched implants, as compared to platform-matched ones.
The 3i T3 Tapered Implant incorporates integrated platform switching into its design. By eliminating or reducing bone resorption at the top of the implant, the papillae and facial gingival marginal tissue remain supported. Tissue support is critical to the establishment and sustainability of functional and aesthetic outcomes.

Implant-Abutment Connection

A fourth factor that influences immediate and long-term aesthetic outcomes is the implant system connection design. The 3i T3® Tapered Implant was designed with the Certain® Internal Connection to meet user requirements for ease of use, versatility, strength, stability, fit, and accuracy—which correlate with aesthetics.

The stability and tightness of the implant/abutment connection may also affect aesthetics. A stable, tight implant/abutment interface minimizes abutment micromotion and reduces potential microleakage. Improved performance in these areas has been theorized to reduce the inflammatory processes associated with bone or tissue loss. The Certain System has been designed with exacting interface tolerances for precise abutment mating and Gold-Tite Abutment Screw (Fig. 3) technology to maximize clamping forces while reducing the potential for micromotion.

In summary, the 3i T3 Tapered Implant System has been engineered to provide:

- The primary stability necessary for early aesthetic provisional restoration and/or tissue sculpting.
- A refined surface design to assist osseointegration, with no increased risk of peri-implantitis as compared to hybrid implants.
- The system strength for long-term aesthetic function.
- An implant/abutment geometry and related connection features designed to preserve bone at and around the implant to provide support for the development and maintenance of soft tissue.
- An accurate connection well positioned to meet current and future digital restorative needs.

References


Richard J. Lazzara, DMD, MScD

Dr. Lazzara received his Certificate in Periodontics and a Master of Science in Dentistry at Boston University. He is formerly a Clinical Assistant Professor at the University of Southern California School of Dentistry, Associate Clinical Professor at the University of Maryland, Periodontal and Implant Regenerative Center and Associate Professor at the University of Miami. He has lectured internationally on the surgical and prosthetic applications of implant dentistry.
The role of different scale ranges of surface implant topography on the stability of the bone/implant interface

Davies E, Ajami E, Moineddin R, Moineddin R, Mendes VC

**Center:** Institute of Biomaterials and Biomedical Engineering, University of Toronto, Toronto, Canada

**Study Design:** Pre-clinical, rat femur model

**Sample Size:** n=20 per surface/time point; total=300

**Reported Outcomes:** Bone-to-implant tensile strength after 6, 9, and 12 days of healing

**Relevance to 3i T3® Implants:** This study provides pre-clinical evidence that the scale range of surface topography impacts the resultant bone-to-implant tensile strength at different points in the healing phase. Surfaces that include multiple scale ranges of topography appear to provide a more robust stability profile over the healing time course tested. The 3i T3 Implant features multiple scale ranges of topography.

We sought to deconvolute the effects of submicron topography and microtopography on the phenomena of bone bonding and interfacial stability of endosseous implants. To address this experimentally, we implanted custom-made titanium alloy implants of varying surface topographical complexity in rat femora, for 6, 9 or 12 days. The five surfaces were polished, machined, dual acid etched, and two forms of grit blasted and acid etched; each surface type was further modified with the deposition of nanocrystals of calcium phosphate to make a total of 10 materials groups (n=10 for each time point; total 300 implants). At sacrifice, we subjected the bone-implant interface to a mechanical disruption test. We found that even the smoothest surfaces, when modified with submicron scale crystals, could be bone-bonding. However, as locomotor loading through bone to the implant increased with time of healing, such interfaces failed while others, with submicron features superimposed on surfaces of increasing microtopographical complexity remained intact under loading. We demonstrate here that higher order, micron or coarse-micron, topography is a requirement for longer-term interfacial stability. We show that each of these topographical scale-ranges represents a scale-range seen in natural bone tissue. Thus, what emerges from an analysis of our findings is a new means by which biologically-relevant criteria can be employed to assess the importance of implant surface topography at different scale-ranges.
Abstract

![Average Tensile Force Values for Bone-to-Implant Disruption](image)

**Fig. 1.** Average Bone-to-Implant tensile strength for implants with single and combinations of topography scale ranges after 6, 9, and 12 days of healing.

### Key to Surface Groups

<table>
<thead>
<tr>
<th>Scale ranges of topography</th>
<th>Surface Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>“no topography”</td>
<td>Polished (P)</td>
</tr>
<tr>
<td>coarse micron</td>
<td>Grit-blasted (GB)</td>
</tr>
<tr>
<td>micron</td>
<td>Acid-etched (AE)</td>
</tr>
<tr>
<td>submicron</td>
<td>Discrete crystalline deposition (DCD®)</td>
</tr>
</tbody>
</table>

### Conclusions

- “Surface implant topography is multidimensional and can be described by employing three distinctly different scale-ranges, each of which is analogous to those that are seen at remodeling sites in natural bone tissue.”
- “Submicron features with undercuts on the implant surface present a three dimensional structure with which the cement line matrix of newly formed bone can interdigitate.”
- “Micron-scale features are analogous to those created by single osteoclast resorption pits.”
- “Higher-order coarse-micron features are analogous to the functional interface created by osteoclast resorption tracts in bone.”
- “While bone-bonding relies exclusively on submicron features, the micron- and coarse-micron scale features on the implant surface are essential to provide long-term interfacial stability under loading.”
Topographic scale-range synergy at the functional bone/implant interface

We sought to explore the biological mechanisms by which endosseous implant surface topography contributes to bone anchorage. To address this experimentally, we implanted five groups of custom-made commercially pure titanium implants of varying surface topographical complexity in rat femora for 9 days; subjected them to mechanical testing; and then examined the interfacial bone matrix by electron microscopy. The five implant surfaces were prepared by combinations of dual acid-etching and grit blasting the titanium substrates and, in some cases, modifying the created surfaces with the deposition of nanocrystals of calcium phosphate, which resulted in 10 samples per group. In parallel, we cultured rat bone marrow cells on surrogate implants constructed from polymer resin coated with the same calcium phosphate nanocrystals, and monitored the deposition of bone sialoprotein by transmission electron immunohisto-micrography. We found that implant samples modified with submicron scale crystals were bone-bonding, as described by the interdigitation of a mineralized cement line matrix with the underlying implant surface. The in vitro assay showed that bone sialoprotein could be deposited in the interstices between, and undercuts below, the nanocrystals. In addition, when mineralized, the cement line matrix globules occupied micron-sized pits in the implant surfaces, and in part obliterated them, creating an additional form of anchorage. Our results also showed that collagen, elaborated by the osteogenic cells, wrapped around the coarse-micron features, and became mineralized in the normal course of bone formation. This provided a mechanism by which coarse-micron implant features contributed to a functional interface, which we have previously described, that is capable of resisting the mechanical loading that increases as peri-implant bone matures. Thus, our findings provide mechanistic explanations for the biologically relevant criteria that can be employed to assess the importance of implant surface topography at different scale-ranges.
Abstract

**Fig. 1:** Average force values (N) required for mechanical rupture of implant sample from rat femur after 9 days healing. Forces are recorded at a crosshead speed of 30mm/min.

Surfaces having features at the submicron scale-range level superimposed over substrates having micron scale-range topography (DAE/DCD and GB/DAE/DCD) presented the highest disruption force values (statistically significant). These results corroborate the disruption outcomes from the authors’ previous publication. Not only do the results confirm data using implants of a similar scale-range of surface topography, but the study implants were cpTi rather than titanium alloy as in the previous study.

**Fig. 2:** Illustration of bone growing on a GB/DAE (3i T3®) implant surface. The direction of osteoconductive bone growth is right to left (arrow).

**Sequence of cellular events in contact osteogenesis:**

1) Undifferentiated cells (gray) are being recruited to the implant surface where they will become osteogenic cells.

2) The flattened pink cells are differentiating osteogenic cells, which secrete the initial, individual globules (blue) of the collagen-free cement line matrix that forms an interface with the implant surface.

3) Cells change shape and initiate collagen production, which will become the osteoid seam (red).

4) Cells continue to change shape until they become fully differentiated cuboidal osteoblasts (OSB) and the osteoid layer (red) they produce separates them from the underlying bone. The collagen fibers of bone are laid down and become encrusted in the cement line matrix. When the osteoid calcifies, it results in a fully formed bone matrix (green). As OSBs continue to lay down bone on the implant, some become buried in the matrix they produce as osteocytes (OST).

High resolution microscopy (FE-SEM) elaborates the relationship between the collagen component of early bone formation and the micron, and course micron features of the GB/AE surface. Mineralized collagen fibers can be seen following the curvature of cement line globules and can also be seen wrapping around the three dimensional features of the implant surface topography.

(Figure is courtesy of Dr. J E Davies. To view FE-SEM photomicrographs associated with figure, refer to the publication and for animation of the figure visit: http://www.cecfutoronto.ca/~bonehead/).
Abstract

The osseointegration properties of titanium implants with hydroxyapatite submicron-scale features in the rabbit tibia

The objective of this study was to biomechanically and histologically assess the stability and integration of titanium implants that include hydroxyapatite based submicron-scale features. Thirty-four 3.4mm x 6.5mm implants, equally split between test (grit blasted, etched, and submicron scale deposition) and control (grit blasted and etched) groups, were placed in the tibiae of New Zealand White rabbits. At 3-weeks follow-up, the group with the submicron deposition showed significantly improved bone response as compared with the control group. The test group required higher removal torque values, with its post-torque histology demonstrating both enhanced bone formation and an intact interface indicative of a robust bone-to-implant bond.

Center: University of Gothenburg, Gothenburg, Sweden
Study Design: Preclinical, New Zealand white rabbit model; randomized-tibia
Sample Size: n=17 custom CP-Titanium implants per each animal; total=34
Reported Outcomes: Resonance Frequency Analysis (RFA/ISQ); Removal Torque (RTQ) and mean new bone formation for implants at three weeks of healing; scanning electron microscopy.
Relevance to 3i T3® Implants: In this study at three weeks of healing, biomechanical outcomes representing the 3i T3 with DCD® Surface were higher and a greater degree of de novo bone formation was observed.

Table 1: The difference between Test (T) and Control (C) surfaces is the addition of discrete crystalline depositions (DCD) of hydroxyapatite, the submicron features it renders to the implant surface topography and its chemistry. (ND = not detected)

<table>
<thead>
<tr>
<th>Surface Groups</th>
<th>Coarse Micron</th>
<th>Micron</th>
<th>Submicron</th>
<th>Surface Chemistry (atomic %)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10-1μm</td>
<td>1 to 3μm</td>
<td>10 to 100nm</td>
<td>Carbon</td>
</tr>
<tr>
<td>C blast (B) acid-etched (AE)</td>
<td>X</td>
<td>X</td>
<td>NOT present</td>
<td>3.1</td>
</tr>
<tr>
<td>T blast (B) acid-etched (AE) hydroxyapatite (DCD)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>4.2</td>
</tr>
</tbody>
</table>

Table 2: Differences were statistically significant at 3 weeks for resonance frequency analysis (RFA), removal torque measurements (peak RTQ at 360°) and for mean percent new bone formation (de novo). The 3-week healing time point was selected to isolate the biomechanical impact of the variable of the submicron features of DCD of the Test Group.

<table>
<thead>
<tr>
<th>Groups</th>
<th>RFA (ISQ)</th>
<th>RTQ-Peak (Ncm)</th>
<th>de novo (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>75.58 ± 6.47</td>
<td>20.6</td>
<td>29.9</td>
</tr>
<tr>
<td>T</td>
<td>77.75 ± 3.07</td>
<td>32.6</td>
<td>39.9</td>
</tr>
</tbody>
</table>

†The author conducted this research while employed at BIOMET 3i.
Objectives
This study presents a biomechanical comparison of bone response to commercially pure titanium screws with four different types of surface topographies placed in the tibial metaphysis of 30 rabbits.

Materials and Methods
One hundred twenty implants were tested double-blinded: (a) blasted, acid-etched, and discrete crystalline deposition (DCD), (b) blasted, (c) acid-etched, and (d) blasted and acid-etched. Resonance frequency analysis (RFA/ISQ), reverse torque values (RTV), and Bone-To-Implant Contact (BIC) were measured at the time of implant insertion (day 0), 15, 28, and 56 days of healing.

Results
All groups tested demonstrated increased RFA/ISQ and RTV results over the time course. At 15 days, the blasted, acid-etched, and DCD group demonstrated a non-significant trend toward higher values when compared to the blasted and etched group (33.0 ± 16 vs. 26.3 ± 12 Ncm, p = .16). At 56 days, the groups utilizing blasting to create additional surface roughness (Sa > 1 micron) showed a statistically significant difference in RTQ versus the non-blasted group (38.5 ± 14 vs. 29.5 ± 9 Ncm, p = .03).

Conclusions
Within the limitations of this study, only the increase in surface roughness (Ra > 1) at 56 days demonstrated statistically significant effects on RTQ. Other additional surface features, such as submicron scale DCD, demonstrated improved healing trends but without significance for clinical applications.

Center: University of Murcia, Murcia, Spain

Study Design: Preclinical, New Zealand white rabbit model; randomized-tibia

Sample Size: n=4 custom implants per each animal; one of each surface type; total=120

Reported Outcomes: Resonance Frequency Analysis (RFA/ISQ); Reverse Torque Analysis (RTQ) and Bone-Implant-Contact (BIC) for implants at intervals more than 56 days of healing.

Relevance to 3i T3® Implants: Of the four implant surface treatments tested in this study, both 3i T3 and T3 with DCD® are represented. Implant groups having both of these surfaces show trends towards higher ISQs and removal torque values during the healing phase.
Abstract

<table>
<thead>
<tr>
<th>Surface</th>
<th>Abbreviation</th>
<th>Treatment</th>
<th>Mean Sa (microns)</th>
<th>Relevant BIOMET 3i Surface</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>BAE + DCD®</td>
<td>Blasted/acid-etched with DCD</td>
<td>1.37</td>
<td>3i T3® with DCD</td>
</tr>
<tr>
<td>B</td>
<td>B</td>
<td>Blasted</td>
<td>1.63</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>AE</td>
<td>Double acid-etched</td>
<td>0.5</td>
<td>OSSEOTITE®</td>
</tr>
<tr>
<td>D</td>
<td>BAE</td>
<td>Blasted/acid-etched</td>
<td>1.37</td>
<td>3i T3</td>
</tr>
</tbody>
</table>

Table 1: Surface treatment groups and roughness characterization. Sa = arithmetic 3D mean of the departures of the roughness profile from the midline.

**Fig. 1:** Reverse Torque Values (RTV) required to remove integrated implants from rabbit tibia harvested at different evaluation periods are reported as the percent of samples per group with torque readings >20Ncm. After 56 days, the RTV was higher for the group with surface D. The micro roughness of the surfaces had impact on the implant-bone union strength after 56 days.

**Table 1:** Reverse Torque Outcomes

<table>
<thead>
<tr>
<th>Percent Samples &gt;20Ncm</th>
<th>15 days</th>
<th>56 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td></td>
<td></td>
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</table>

**Fig. 2:** The BIC values at 15 days were higher for Group A, however after 56 days show a slight reduction. Group D showed a gradual pattern of increased BIC during all the periods.
Abstract

Early bone healing around two different experimental, HA grit-blasted, and dual acid-etched titanium implant surfaces: A pilot study in rabbits*

Gobbato L, Arguello E, Martin IS, Hawley CE, Griffin TJ

*Preclinical results are not necessarily indicative of clinical performance.

Center: Tufts University, Massachusetts, USA
Study Design: Pre-clinical rabbit randomized-tibia model
Sample Size: n=2 implants per surface/time; total=16
Reported Outcomes: Bone-To-Implant Contact (BIC) and bone multicellular units (BMU) at 1, 6, 21, and 90 days
Relevance to 3I T3® Implants: The test implants (designated BAE-2) in this pre-clinical study include a multi-scale topography surface with submicron, micron, and coarse micron levels highly similar to 3I T3 with DCD®. The test implants demonstrated a higher degree of integration versus control implants (without submicron features) as demonstrated by BIC at 21 days.

Purpose
To compare early bone healing around different experimental titanium implant surfaces and to evaluate the role of a calcium phosphate – coated implant surface as it relates to Bone-To-Implant Contact (BIC).

Methods
An experimental hydroxyapatite (HA) grit-blasted and dual acid-etched titanium surface (BAE-1) was compared to an experimental HA grit-blasted and dual acid-etched surface treated with nanometer-scale crystals of HA (BAE-2). Both experimental implant surfaces were implanted onto the tibias of four New Zealand white rabbits. The animals were killed at 1, 6, 21, and 90 days after implant surgery. Descriptive histology was performed at the healing responses of both implant surfaces. Quantitative morphology assessment provided measurements of BIC, number of bone multicellular units (BMUs), average penetration of BMUs, and maximum penetration of BMUs that were manually made using computer imaging software.

Result
The overall BIC for the BAE-2 implant was higher than that for the BAE-1 implant at 21 days of healing. However, there was no significant difference at 90 days of healing.

Conclusion
It is concluded from this animal pilot study that the bioactive BAE-2 implant surface provided a better BIC with healthy bone remodeling at 21 days of healing.
Abstract

The dental community’s interest in early loading of endosseous implants provides the stimulation to test the ability of modified implant designs as well as surgical techniques to enhance the establishment and maintenance of implant stability. This preclinical canine study examined this potential by implementing several implant design and surgical technique modifications to an existing tapered implant system. The design and site preparation changes were intended to induce different compression states on the native bone, hypothetically affecting the primary stability and the rate and extent of osseointegration. The outcomes of the modifications were evaluated using resonance frequency analysis, radiographic analysis, light microscopy, and histomorphometric measurements. Three compression scenarios were tested, with each demonstrating excellent clinical, radiographic, and histologic results throughout the evaluation period. However, the scenario intended to induce a moderate degree of compression provided the best overall results, supporting its use in early loading protocols.

**Fig. 1:** Examples of Bone Formation at 7, 14, 28, and 56 Days (moderate compression group).
Conclusions

• “The implant system evaluated demonstrated substantial BIC percentages as well as high ISQ values for each of the three compression scenarios tested.”

• “The moderate compression scenario, created by the self-cutting implant design, demonstrated the most promise for enhanced establishment and maintenance of implant stability.”

• “The RFA and histomorphometric outcomes of this study can be compared to similar published canine research. For example, in 2009, investigators reported an 8 week mean BIC of 58% for implants with a sandblasted, large grit, acid-etched surface and BIC of 37% for a turned control. In this same study, the ISQ results for the implants tested reached maximum values in the 60’s. In comparison, the implants in this study consistently achieved ISQ values exceeding 80 and 70% or greater BIC at an equivalent 8 week time point.”

Reference:

†Dr. Nevins has a financial relationship with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.
*Preclinical results are not necessarily indicative of clinical performance.
Abstract

Comparison of three in vitro implant leakage testing methods

Al-Jadaa A†, Attin T, Peltomäki T, Schmidlin SR

Center: Clinic of Preventive Dentistry, University of Zurich, Zurich, Switzerland
Study Design: Characterization of the implant-abutment seal capability of contemporary implant systems utilizing gas-leakage, molecular and bacterial test methodologies.
Sample Size: 20 per each of three implant systems; total=60
Reported Outcomes: Implant-abutment interface of three competitive systems subjected to: 1) nitrogen gas-enhanced permeation (Hecto Pascal/minute) with saline infiltration; 2) molecular spectrophotometry and 3) 28-day bacterial leakage test.
Relevance to 3i T3® Implants: The BIOMET 3i Certain® Connection subjected to testing in this study is included on the 3i T3 Implant. When used with the Gold-Tite® Screw, the BIOMET 3i Certain Connection demonstrated significantly less gas leakage than the other systems evaluated as well as a corresponding low leakage pattern in the subsequent bacterial testing in the study.

Aim
To assess the accuracy and sensitivity in detecting implants leakage with a gas-enhanced permeation test (GEPT) and to compare with molecular- and bacterial-based leakage tests.

Materials and Methods
Three implants systems were tested (n=20 per group): Nobel Biocare (NB); Astra Tech (AT) and BIOMET 3i. Implants (B3i) were mounted in PVC disks and were first tested for gas pressure change and infiltrated saline volume over 40 minutes. The same implants were then subjected to a molecular leakage evaluation using fluorescent Dextran for 28 days. After cleaning and sterilization, bacterial permeation (E. faecalis) was evaluated by selective media turbidity for another 28 days. Slopes in the pressure change and the perfused saline rate were used as a measure of leakage in the GEPT model and the times of positive events, that is, color change, after molecular and bacterial tests were recorded. Data was analyzed using Kolmogorov–Smirnov/Shapiro–Wilk, Kruskal–Wallis H and Spearman’s Rho tests (P<0.05).

Results
The gas and saline (ml) leakage values accounted for 0.85 ± 0.71 and 0.56 ± 0.50 ml (AT), 0.23 ± 0.030 and 0.12 ±0.20 ml (NB) and 0.01 ± 0.01 and 0 ± 0 ml (B3i), respectively, and were significantly different from each other (P<0.001). Slope in the pressure change over time showed a significant positive correlation with the collected saline solution (r=0.91; P < 0.001). Molecular and bacterial leakage was positive at the same implants, which also showed increased leakage values in the GEPT setup. The development of positive events in the timeline of the bacterial leakage evaluation corresponded well to the GEPT leakage model.

Conclusion
The GEPT proved to be a reliable method to quantify leakage. BIOMET 3i Implants showed the best sealing among the tested systems.

†Al-Jadaa A. PhD fellowship is supported by BIOMET 3i.
Microgap analysis at the implant-abutment interface of various dental implant systems*

Gubbi P†, Suttin Z†, Towse R†
Poster Presentation (P-98): Academy of Osseointegration 28th Annual Meeting, March 2013, Tampa, Florida, USA.

Center: BIOMET 3i, Palm Beach Gardens, Florida, USA
Study Design: Electron microscopy characterization of the full-length implant-abutment interface of contemporary implant systems
Sample Size: n=1 per implant system
Reported Outcomes: Qualitative images of cross-sectioned implant-abutment interfaces and quantitative measurements of the overall microgap size
Relevance to 3i T3® Implants: The study results demonstrated that the BIOMET 3i Certain® Implants evaluated (3i T3 with DCD®) displayed microgaps averaging ~1μm. Several areas where the gap approached 0μm was identified along the length of the interface. Two of the remaining three systems tested demonstrated larger microgap sizes.

Objective
This study evaluates the microgaps that exist at the implant-abutment interface of implant systems made from various manufacturers (Astra Tech, Straumann®, Nobel Biocare and BIOMET 3i). The study quantitatively compares the microgaps resulting after the assembly of the implant and abutment with the recommended screw in a scanning electron microscopic (SEM) study.

Materials and Methods
OsseoSpeed™ implants (Dentsply/Astra Tech, 3.5mm D x 15.0mm L and 4.5mm D x 13.0mm L), Bone Level implants (Straumann®, 3.3mm D x 12.0mm L and 4.1mm D x 12.0mm L), Active implants (Nobel Biocare, 4.3mm D x 13.0mm L and 5.0mm D x 11.5mm L), and novel tri-topography 3i T3 Implants (BIOMET 3i, 3.25mm D x 13.0mm L and 4.0mm D x 13.0mm L), were used for evaluation in the study. All the implants were assembled with matching abutments with screws torqued to recommended values. Each assembly was mounted in phenolic resin, sectioned close to vertical central axis and polished to a metallurgical finish. SEM images of the implant-abutment interface were taken at similar magnification and microgaps were measured at intervals of 100μm using image analysis software.

Results
Figure 1 shows the graphical representation of the measured mean microgaps for various implant systems. It can be seen that the Dentsply/ Astra Tech implant systems showed highest microgaps among the four implant systems, followed by Straumann implant systems whereas Nobel Biocare and BIOMET 3i Implant systems exhibited comparable lower microgaps.
Abstract

Conclusion

Microgap analysis at the implant-abutment interface on four different implant systems (2 sizes in each) from various manufacturers revealed that the Dentsply/Astra Tech implant systems had highest microgaps whereas Nobel Replace® and BIOMET 3i Implant systems showed lowest micro-gaps with Straumann® implant systems being slightly lower than Dentsply/Astra Tech implant systems.

*Bench test results are not necessarily indicative of clinical performance.
†The authors conducted this research while employed by BIOMET 3i.
To view the poster, please visit http://iird.com/pdf/P001_Gubbi.pdf
A novel method for assessing implant-abutment connection seal robustness*

Suttin Z†, Towse R†, Cruz J†

Abstract

A novel method for assessing implant-abutment connection seal robustness*

Suttin Z†, Towse R†, Cruz J†

Center: BIOMET 3i, Palm Beach Gardens, Florida, USA.
Study Design: Characterization of the implant-abutment seal capability of contemporary implant systems subjected to a dynamic loading fluid-leakage test.
Sample Size: n=5 per implant system
Reported Outcomes: Seal strength (N) of contemporary implant systems. The seal strength is the average force of the final load step endured when the system leaked, yielded-leaked, or fractured-leaked.
Relevance to 3i T3® Implant: The BIOMET 3i Certain® Connection, which is included on the 3i T3 Implant was evaluated in this study. The BIOMET 3i Certain Connection demonstrated the highest seal strength of the systems evaluated.

Objective
The aim of this study was to develop a method for characterizing the implant-abutment seal capability of dental implant systems subjected to dynamic loading conditions.

Background
The seal integrity of the implant-abutment-junction (IAJ) is of significant interest due to the potential detriments associated with an inferior seal: bacterial invasion and subsequent colonization of the internal aspect, microleakage, malodor, inflammation, peri-implantitis, and crestal bone loss.

Materials and Methods
The apex of a test implant was modified to have a barb fitting, and a thru hole was machined through the internal aspect. The implant was fixated in a block, exposing 3.0mm of the coronal portion while allowing axis to the apical barb. Tubing was connected to the apical barb, and an abutment and screw were loosely assembled to the implant. Red dye was bled through the system utilizing a peristaltic pump. The manufacturer’s recommended screw torque was applied, and the system was thoroughly rinsed. The block was mounted at 20 degrees off-axis in a clear tank full of fresh water. The pump was turned on and a high resolution video camera at 50x magnification was focused on the implant-abutment junction to qualify the seal (i.e. lack of red dye leaking from the 7 PSI pressurized volume). If no breach was detected, the abutment was cyclic loaded for 100,000 cycles at 100N with the pump off to represent system wear. After the wear cycle, the seal was qualified by turning the pump on and once again, visually monitoring the IAJ while loading at 2HZ, 100N, for 1000 cycles. If the sample successfully completed the qualification, the entire process (100,000 cycles wear; 1000 cycles qualification) was completed at 50N higher load. This protocol was repeated until fluid leakage was detected. A comparison test was conducted on the results of the four contemporary implant systems tested.
Results
14 of the 20 samples tested resulted in a leakage-only failure mode at the implant abutment junction. Six of the samples appeared to leak via a structural yielding or fracture prior to leakage. Individual implant system failure loads ranged from 100N to 900N, representing an accumulation of 100,000 to 1.7 million cycles. An ANOVA analysis was conducted to statistically compare the implant results. The system with a seal strength of 810N was statistically higher than the other systems tested.

Conclusions
A new test method has been developed to qualitatively assess the seal robustness of implant systems subjected to clinically relevant cyclic loading conditions. Because the failure modes vary, an absolute assessment of the “pure leakage” failure mode could not be conducted. Amongst the implant systems tested, the BIOMET 3i Certain® Connection exhibited a robust seal without breach or failure at loads significantly higher than the other implant systems. This can be attributed to the interface design and screw pre-load.

Fig. 1. Seal strength comparison of contemporary implant systems (n=5).

*Bench test results are not necessarily indicative of clinical performance.
†The authors conducted this research while employed by BIOMET 3i.
To view the poster, please visit http://iird.com/pdf/P16-Suttin.pdf
Quantitative and qualitative characterization of various dental implant surfaces

Gubbi P†, Towse R†
Poster Presentation (P-421): European Academy of Osseointegration 20th Annual Meeting, October 2012; Copenhagen, Denmark.

Center: BIOMET 3i, Palm Beach Gardens, Florida, USA
Study Design: Electron microscopy and interferometer characterization of contemporary implant surfaces to qualify and quantify surface features present within the submicron, micron, and coarse micron scale range.
Sample Size: n=1 implant per manufacturer/surface
Reported Outcomes: 30,000x magnification images for submicron features, 2,000x magnification images for micron features, 312.5x interferometer images and an Sa measurement (mean absolute height deviation) for coarse micron features.
Relevance to 3i T3® Implants: This characterization study includes an implant featuring the 3i T3 with DCD® Surface. The analysis demonstrates three scale ranges of topography on this implant design. Additionally, the study provides evidence that the majority of the competitive surfaces evaluated do not possess three distinct scale ranges of surface topography.

Background
An endosseous implant’s surface characteristics play a substantial role in the mechanism of osseointegration. In particular, surface topographies of specific scale and geometry have been shown to influence the pre-cursors to de novo bone formation, thereby impacting the extent and rate of formation as well as providing surface features for interlocking of the de novo bone throughout the peri-implant healing phase.

Aim
The current study is intended to characterize the scales and geometries of the leading dental implant companies’ surface topographies.

Methods
The following implant surfaces were characterized as: OSSEOTITE® (BIOMET 3i) with a hybrid surface of both turned coronal and remaining dual acid-etch, MTX™ implant (Zimmer Dental) with a blasted surface, Replace implant (Nobel Biocare) with anodic oxidation TiUnite® surface, Osseospeed™ implant (Astra Tech) with a blasted and fluoride etched surface, Bone Level implant (Straumann®) with a blasted and etched SLActive® surface, and a new implant design (BIOMET 3i) with a blasted, dual acid-etched, and discrete HA crystalline deposition surface. In order to adequately assess the scale and geometries of the various surface topographies, multiple evaluation methodologies are employed namely Field Emission Scanning Electron Microscopy (FE SEM) analysis for submicron features (<1.0μm), Scanning Electron Microscopy (SEM) for micron features (1–10μm), and Light Interferometry for coarse micron features (>10μm, commonly quantified with output measures such as Sa – Absolute Mean Height Deviation).
Results

<table>
<thead>
<tr>
<th>Methodology</th>
<th>FESEM (30000x)</th>
<th>SEM (2000x)</th>
<th>Interferometer (312x)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptor</td>
<td>Actual Features (nm)</td>
<td>Actual Features (µm)</td>
<td>Quantitative Proxy: Sa (µm)</td>
</tr>
<tr>
<td>BIOMET 3i OSSEOTITE® (turned area)</td>
<td>Minimal features noted</td>
<td>Minimal features noted</td>
<td>0.18</td>
</tr>
<tr>
<td>BIOMET 3i OSSEOTITE (dual acid-etched area)</td>
<td>Minimal features noted</td>
<td>Homogenous coverage of 1-3µm pits</td>
<td>0.48</td>
</tr>
<tr>
<td>Zimmer MTX™</td>
<td>Minimal features noted</td>
<td>Irregular blasted facets, 5-10µm range</td>
<td>0.79</td>
</tr>
<tr>
<td>Nobel Replace TiUnite®</td>
<td>Minimal features noted</td>
<td>Homogenous coverage of spaced, 5-10µm tubular structures</td>
<td>1.06</td>
</tr>
<tr>
<td>Astra Tech Osseospeed™</td>
<td>Minimal features noted</td>
<td>Irregular, angular facets, 10µm range</td>
<td>1.50</td>
</tr>
<tr>
<td>Straumann SLActive®</td>
<td>Homogenous coverage of 10-20µm rod shaped oxide features</td>
<td>Homogenous coverage of 1-3µm pits</td>
<td>1.60</td>
</tr>
<tr>
<td>BIOMET 3i New Implant Design</td>
<td>Homogenous coverage of 20-100nm irregularly shaped HA crystals</td>
<td>Homogenous coverage of 1-3µm pits</td>
<td>1.39</td>
</tr>
</tbody>
</table>

Table 1: Results summary – FESEM, SEM, and Interferometer.

Fig. 1: BIOMET 3i new implant design surface images.

Conclusions
The current evaluation demonstrated that these modern implant surfaces are highly complex, comprising multiple scales of topographies and differentiated geometries.

† The authors conducted this research while employed by BIOMET 3i.
Abstract

Marginal accuracy of three implant-ceramic abutment configurations*

Baldassari M, Hjerpe J, Romeo D, Fickl S, Thompson VP, Stappert CF†

Center: New York University, New York, New York, USA
Study Design: Electron microscopy characterization of the exterior aspect of the implant-abutment interface of contemporary implant systems.
Sample Size: n=1 per implant system
Reported Outcomes: Qualitative images of the exterior aspect of the implant-abutment interface and quantitative measurements of microgap size
Relevance to 3i T3® Implants: The BIOMET 3i Certain® Connection, which is included on the 3i T3 Implant, was evaluated in this article with different abutment configurations. Titanium BellaTek® Abutments combined with implants with the Certain Connection demonstrated the smallest average microgap of the groups tested.

Objective

Microgaps at the implant-abutment interface allow for microbial colonization, which can lead to peri-implant tissue inflammation. This study sought to determine the marginal accuracy of three different implant-zirconium oxide (zirconia) abutment configurations and one implant-titanium abutment configuration.

Materials and Methods

Three combinations of implants with custom-made zirconia abutments were analyzed (n=5/group): NobelProcera™ abutments/titanium inserts on Replace Select™ Tapered TiUnite® implants (Nobel Biocare) (NP); BellaTek Abutments/NanoTite™ Tapered Certain Implants (AT); Atlantis abutments/BIOMET 3i NanoTite Tapered Certain Implants (AT). Five custom-made BellaTek Titanium Abutments/NanoTite Tapered Certain Implants (Ti) were used as a control group. All abutments were fabricated with computer-aided design/computer-assisted manufacture. One-hundred twenty vertical gap measurements were made per sample using scanning electron microscopy (15 scans x 4 aspects of each specimen [buccal, mesial, palatal, distal] x 2 measurements). Analysis of variance was used to compare the marginal fit values among the four groups, the specimens within each group, and the four aspects of each specimen.
Results
Mean (± standard deviation) gap values were 8.4 ± 5.6μm (NP), 5.7 ± 1.9μm (B3i), 11.8 ± 2.6μm (AT), and 1.6 ± 0.5μm (Ti). A significant difference was found between BIOMET 3i and AT. No difference resulted between NP with the other two groups. Gap values were significantly smaller for Ti relative to all zirconia systems. For each ceramic abutment configuration, the fit was significantly different among the five specimens. For 12 of the 15 ceramic abutment specimens, gap values sorted by aspect were significantly different.

Conclusion
The implant-titanium abutment connection showed significantly better fit than all implant-zirconia abutment configurations, which demonstrated mean gaps that were approximately 3-7 times larger than those in the titanium abutment system.

*Bench test results are not necessarily indicative of clinical performance.
†Dr. Stappert has a financial relationship with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.
Purpose
To evaluate the torque stability of different UCLA retention screws of single implant-supported crowns submitted to mechanical cycling.

Materials and Methods
Crowns fabricated from nickel-chromium-molybdenum alloy were attached to external-hexagon implants and grouped by the different retention screws used (n=10): Ti, titanium screws (BRUNIHT, BIOMET 3i); Au, gold-palladium screws with 24-carat gold coating (Gold-Tite, BIOMET 3i); TiC, titanium alloy (Ti-6Al-4V) screw with diamond-like carbon coating (Neotorque™, Neodent); and TiN, Ti-6Al-4V screw with aluminum-titanium-nitride coating (Ti-Tite, Conexão). Three initial removal torque (RT) values were obtained for each screw after torque insertion using an analog torque gauge. The final RT was measured after mechanical cycling (1×10⁶ cycles at 2Hz under 130N). Data were submitted to analysis of variance and the Fischer test.

Results
Statistically significant differences were observed between the initial RT in groups Ti and TiN, and between TiC and TiN. No statistically significant difference was seen between mean RT obtained before and after mechanical cycling, except for the Ti screws. All groups exhibited similar torque maintenance after mechanical cycling.

Conclusion
Although no significant difference was observed among groups for the final percentage of torque maintenance, the final RT values of the coated screws were higher than those of the non-coated screws.
Abstract

**Table 1:** Reverse torque value outcomes for retention screw groups.

The coated screws (Au, TiC, and TiN) exhibited a greater tendency toward torque stability after mechanical cycling.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Screw and Manufacturer</th>
<th>Retention Screw Type</th>
<th>Insertion Torque (N/cm)</th>
<th>Initial</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ti</td>
<td>BRUNIHT, BIOMET 3i</td>
<td>titanium alloy (Ti-6Al-4V)</td>
<td>20</td>
<td>15.45(1.89)</td>
<td>13.80(1.42)</td>
</tr>
<tr>
<td>Au</td>
<td>Gold-Tite®, BIOMET 3i</td>
<td>gold alloy (Au-Pd) with 24-carat gold coating</td>
<td>20</td>
<td>14.67(1.84)</td>
<td>14.40(1.73)</td>
</tr>
<tr>
<td>TiC</td>
<td>Neotorque, Neodent</td>
<td>titanium alloy with diamondlike carbon coating</td>
<td>32</td>
<td>25.47(1.27)</td>
<td>24.10(1.63)</td>
</tr>
<tr>
<td>TiN</td>
<td>Ti-Tite, Conexão Sistema de Prótese</td>
<td>titanium alloy (Ti-6Al-4V) with aluminum titanium nitride coating</td>
<td>35</td>
<td>24.67(0.85)</td>
<td>24.10(2.58)</td>
</tr>
</tbody>
</table>

Ti-6Al-4V = titanium-aluminum-vanadium; Au-Pd = gold palladium

*Means and (standard deviations), in Ncm.
Project Scuderia: 3i T3® clinical data generation – interim results at one year

Kenealy J†

Center: European and Asian multi-center university and private practices
Study Design: Prospective, observational clinical evaluation
Sample Size: 90 clinical evaluators from 19 countries with 555 implants
Reported Outcomes: Enrollment rate and implant dimensions
Relevance to 3i T3® Implants: This clinical evaluation demonstrates the performance characteristics intended by the 3i T3 design. Follow-up evaluations continue.

Objective
This prospective observational clinical evaluation documents the effectiveness of 3i T3 Implants for treating partially edentulous patients.

Methods
Evaluators were requested to document at least 10 cases from their University or private practice clinics. Information on the new system was provided along with osteotomy preparation procedures and implant placement steps. Patient selection and the type of cases to be included in the evaluation were at the discretion of the evaluators as part of the clinical treatment of their patients. The restorative solutions were also based upon the preference of the evaluators.

Results
To date, a total of 90 clinical evaluators from 19 countries provided case information for over 250 patients and over 500 implant placements as illustrated in Table 1. Implant lengths range from 8.5 to 11.5mm as illustrated in Figure 2.
Abstract

Interim Analysis

Over 500 3i T3® Implants made available to the project evaluators were placed within nine months. Implant placement procedures were done in various bone conditions all with placement success. Follow-up evaluations continue to be made with positive and constructive feedback from the evaluators. With up to twelve months of observations, and seven implant non-integrations reported, the 3i T3 Implant is demonstrating the performance characteristics that were intended with its design in a diverse patient population.

†The author was employed by BIOMET 3i when this research was conducted.
Affect of surface on mucosal health and integration testing: A prospective, randomized-controlled clinical study of multi-topography surfaced implants in early loading cases

Montoya C, Nappe C
Poster Presentation: The 11th Annual International Symposium on Periodontics and Restorative Dentistry, June 2013, Boston, Massachusetts, USA.

**Center:** Mayor University, Santiago, Chile
**Study Design:** Prospective, randomized-controlled clinical trial
**Sample Size:** 49 patients, 137 study implants (108 test, 29 control)
**Reported Outcomes:** Implant integration assessment via countertorque test at 6, 8, and 10 weeks
**Relevance to 3i T3® Implants:** Micromotion of the implant during the early healing phase is considered to be a primary reason for implant failure. The test implants in this clinical study have a surface topography identical to the T3 Implants with the DCD® surface. These implants show a higher degree of osseous fixation in the early healing period as compared to the control implants.

**Background**
A new implant with a novel surface topography design is under evaluation. The implant's apical surface includes three distinct levels of topography including coarse micron (calcium phosphate media blasting), micron (dual acid-etching), and submicron (hydroxyapatite discrete crystalline deposition). At least 1.5mm of the implant's coronal aspect has the coarse micron topography, resulting in a coronal surface with a level of roughness consistent with the OSSEOTITE® (BIOMET 3i) dual acid-etched surface. This new implant design may promote bone healing, allowing for earlier loading procedures while maintaining conditions that preserve long-term mucosal health.

**Study Design**
This prospective randomized-controlled study has patients randomly assigned (in an 80:20 ratio) to groups receiving test and control implants, respectively. Control cases are commercially-available implants of a similar macro design allowing an evaluation of surface effects. All implants are placed single-stage with implant integration assessed by resistance to 20 and 32Ncm counter-torque force done at 6, 8, and 10 weeks using a calibrated torque-indicating ratchet wrench. Restorative cases consist of single, short fixed prosthesis or long-span fixed prosthesis with each patient receiving at least two study implants. Final prosthesis insertion takes place at six months.

**Results**
A total of 49 patients with 94 restorative cases have been treated with 137 study implants of which 108 are test and 29 control implants. The two implant groups were found to have similar baseline conditions. Similar patterns of implant dimensions and locations are observed and the three healing groups having similar bone conditions, insertion torque profiles, and ISQ readings. Integration assessments show a trend for more liberations at the earlier healing groups. Overall results show a lower number of liberations for the test group implants. Two clinical implant failures were recorded for a CSR of 99% and 97% for the test and control groups respectively.
Abstract

Conclusion

This study design was capable of isolating the effect of the implant surface using counter-torque integration assessments. Implants with a multi-level surface topography are found to have greater resistance to liberation force than control implants with lower surface complexity.

Counter-Torque Testing: Test and Control Groups at 20 and 32Ncm

Fig. 1. Integration Assessments: After abutment removal and RFA measurement, a torque-indicating ratchet wrench was used to apply counter-torque force. Implants demonstrating no motion at 20Ncm were then tested at 32Ncm. Any sensation of rotation at counter-torque force was recorded. At the completion of testing, any implant that was found to rotate during force application was returned to position with positive 20Ncm torque force and allowed to heal.

To view the poster, please visit http://iird.com/pdf/P30-Montoya.pdf
Abstract

Immediate occlusal loading of NanoTite™ Prevail® Implants: A prospective one-year clinical and radiographic study

Östman PO†, Wennerberg A, Albrektsson T†

Center: Private Practice, Gothenburg University, Gothenburg, Sweden
Study Design: Prospective, observational, immediate loading clinical study.
Sample Size: n=102 implants
Reported Outcomes: One year cumulative survival and marginal bone resorption results.
Relevance to 3i T3® Implants: The implants studied have several features in common with 3i T3 Implants, including the Certain® Connection and PREVAIL® platform switching. Additionally, the coronal aspect surface topography studied is consistent with 3i T3 with DCD®, including 1-3 micron peak to peak and submicron features. The implants studied experienced high one-year survival and success rates.

Background
Recently, a new implant surface texture, featuring application of nanometer-scale calcium phosphate has been shown to enhance early bone fixation and formation in preclinical studies and in human histomorphometric studies, which may be beneficial in immediate loading situations.

Aim
The purpose of the present prospective clinical study was to, during one year, clinically and radiographically evaluate a nanometer-scale surface-modified implant placed for immediate loading of fixed prostheses in both maxillary and mandibular regions.

Materials and Methods
Thirty-five out of 38 patients who needed implant treatment and met inclusion criteria agreed to participate in the study and were consecutively enrolled. Surgical implant placement requirements consisted of final torque of a least 25Ncm prior to final seating and an implant stability quotient above 55. A total of 102 NanoTite PREVAIL (NTP) Implants (BIOMET 3i, Palm Beach Gardens, FL, USA) (66 maxillary and 36 mandibular) were placed by one investigator, and the majority of these were placed in posterior regions (65%) and in soft bone (69%). A total of 44 prosthetic constructions...
were evaluated consisting of 14 single-tooth restorations, 26 fixed partial dentures, and four complete fixed restorations. All provisional constructions were delivered within one hour, and the final constructions were placed after four months. Implants were monitored for clinical and radiographic outcomes at follow-up examinations scheduled for 3, 6, and 12 months.

<table>
<thead>
<tr>
<th>Marginal Bone Resorption at One-Year Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>NanoTite® PREVAIL®</td>
</tr>
<tr>
<td>( (m + d)/2 )</td>
</tr>
<tr>
<td>( (%) )</td>
</tr>
<tr>
<td>Number</td>
</tr>
<tr>
<td>101</td>
</tr>
<tr>
<td>Mean value (SD)</td>
</tr>
<tr>
<td>0.37 (0.39)</td>
</tr>
<tr>
<td>(&lt;0)</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>(0)</td>
</tr>
<tr>
<td>17</td>
</tr>
<tr>
<td>(0.1–1.0)</td>
</tr>
<tr>
<td>69</td>
</tr>
<tr>
<td>(1.1–2.0)</td>
</tr>
<tr>
<td>6</td>
</tr>
<tr>
<td>(2.1–3.0)</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>(&gt;3.0)</td>
</tr>
<tr>
<td>0</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>101</td>
</tr>
<tr>
<td>100</td>
</tr>
</tbody>
</table>

Results
Of the 102 study implants, one implant failed. The simple cumulative survival rate value at one year was 99.2%. The average marginal bone resorption was 0.37mm (SD 0.39) during the first year in function. According to the success criteria of Albrektsson and Zarb, success grade 1 was found with 93% of the implants.

Conclusion
Although limited to the short follow-up, immediate loading of NanoTite PREVAIL Implants seems to be a viable option in implant rehabilitation, at least when good initial fixation is achieved.

†Dr. Albrektsson and Dr. Östman have financial relationships with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.
Background

The dual acid-etched (DAE) implant was commercially introduced in 1996 with a hybrid design incorporating a machined surface at 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 at the coronal region. The objective of this prospective, randomized-controlled clinical trial was to determine the incidence of peri-implantitis for a fully etched implant with the DAE surface extending to the implant platform.

Methods

Patients had implant sites randomly assigned to receive one hybrid control implant and at least one fully etched 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, suppurative, and probing depths. Evaluations also included radiographic and mobility assessments.
Abstract

Results
A total of 49 patients with 94 restorative cases have been treated with 137 study implants of which 108 are test and 29 control implants. The two implant groups were found to have similar baseline conditions. Similar patterns of implant dimensions and locations are observed and the three healing groups having similar bone conditions, insertion torque profiles, and ISQ readings. Integration assessments show a trend for more liberations at the earlier healing groups. Overall, results show a lower number of liberations for the test group implants. Two clinical implant failures were recorded for a CSR of 99% and 97% for the test and control groups respectively.

Conclusion
This study design was capable of isolating the effect of implant surface using counter-torque integration assessments. Implants with a multi-level surface topography are found to have greater resistance to liberation force than control implants with lower surface complexity.

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

Fig. 2. No implant (test or control) showed changes in probing depths greater than 3.0mm.

*Sulcus Bleeding Index*

<table>
<thead>
<tr>
<th>Probing Depth Scores*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hybrid Surface Design</td>
</tr>
<tr>
<td>Full DAE Surface Design</td>
</tr>
</tbody>
</table>

*SBI Scores*:
- 0: 84% (absence of bleeding)
- 1: 13% (isolated bleeding spot)

*SBI Scores*:
- 0: 84% (absence of bleeding)
- 1: 13% (isolated bleeding spot)

Probing Depths: Change from baseline (mm)

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

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.

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

¹ 0.37mm bone recession not typical of all cases.

² 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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