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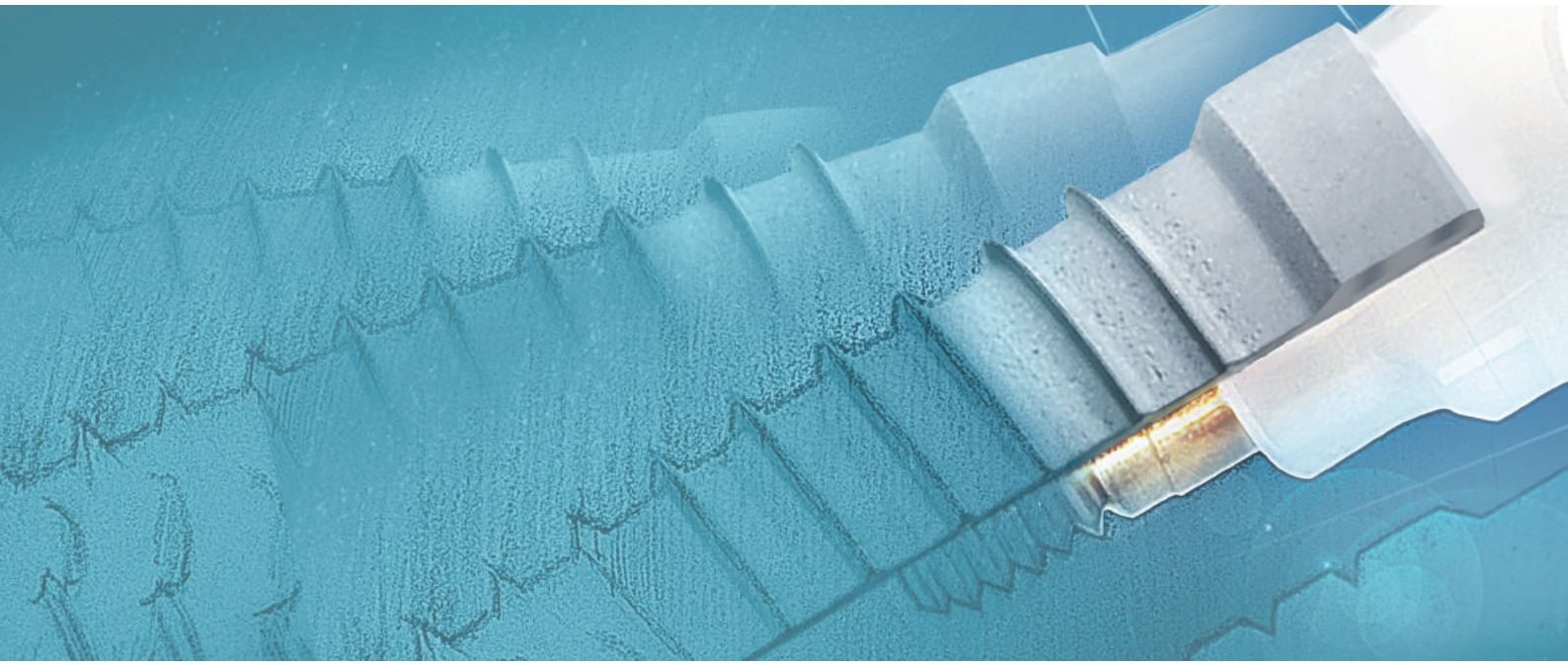

Special Supplement

Summaries of Select Publications and Poster Presentations

BIOMET *3i* T3® Implants

Official Publication of The INSTITUTE for Implant & Reconstructive Dentistry®

The Institute for Implant and Reconstructive Dentistry is the Training and Education Department of BIOMET 3i LLC.

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aesthetics

Dental implant system design and its potential impact on the establishment and sustainability of aesthetics

Richard J. Lazzara, DMD, MScD

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.

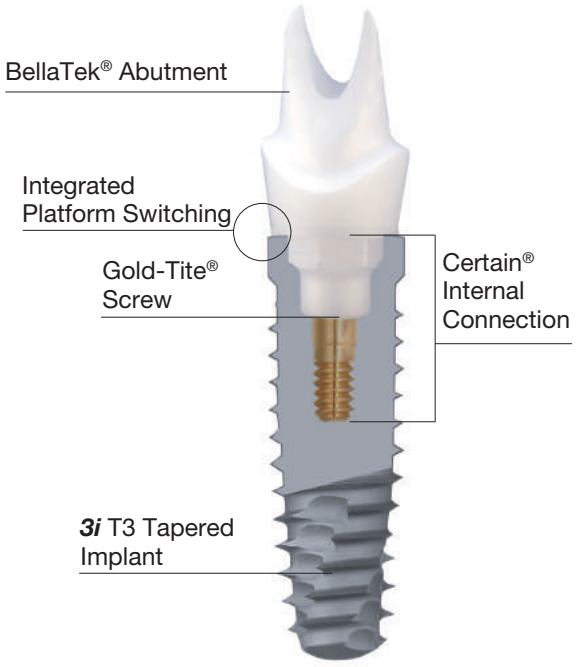

Fig. 1. Schematic of a ***3i*** T3 Tapered Implant.

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 53.1 Ncm, 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).[6] 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).[7]

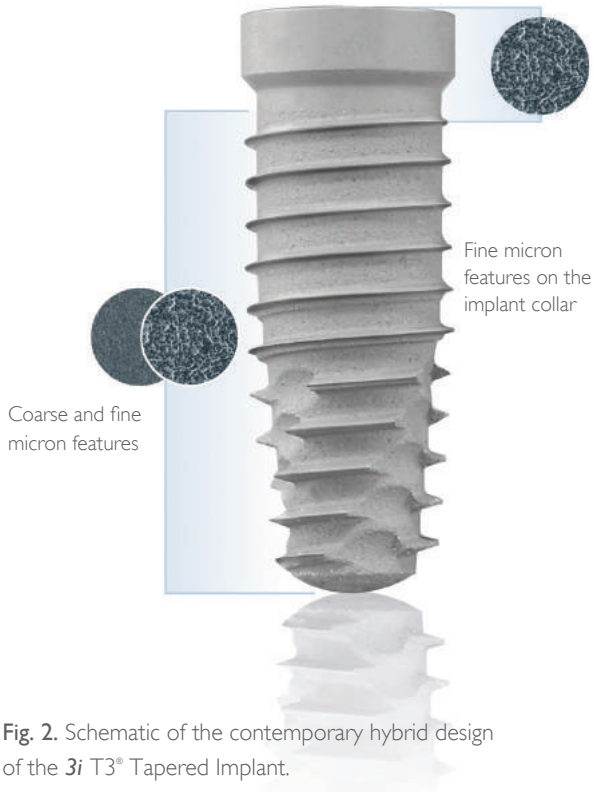

Fig. 2. Schematic of the contemporary hybrid design of the ***3i*** T3® Tapered Implant.

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 sub-micron features superimposed on 1-3 micron pitting, overlaid on a moderately rough surface topography (Sa = 1.0 - 2.0 µm).[6]

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.[8] 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.[9]

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.

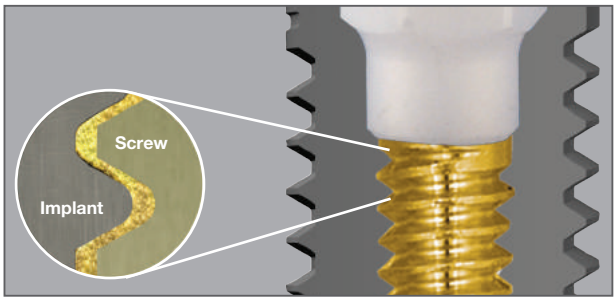

Fig. 3. A Gold-Tite® Abutment Screw, coated with a minimum of 40 microinches of 99.99% pure gold, acts as a dry lubricant, thus permitting the screw to stretch and applying greater clamping force.

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.[10]

In sum, 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 enhance 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.

On the following pages, there are clinical cases from European clinicians sharing their experiences with the ***3i*** T3 Tapered Implant System.

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Richard J. Lazzara, DMD, MScD

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The role of different scale ranges of surface implant topography on the stability of the bone/implant interface

Davies JE, Ajami E, Moineddin R, et al.

Biomaterials 2013;34(14):3535-3546. Epub 2013 Feb 14

Topic: Osseointegration
Center: University of Toronto, Toronto, Canada
Scenario: Prospective randomized controlled pre-clinical trial; rat femur
Sample Size: n=20 per surface/time point, 300 total implants
Reported Outcome(s): 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.

Abstract

We sought to deconvolute the effects of sub-micron 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 surface when modified with sub-micron 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 sub-micron 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.

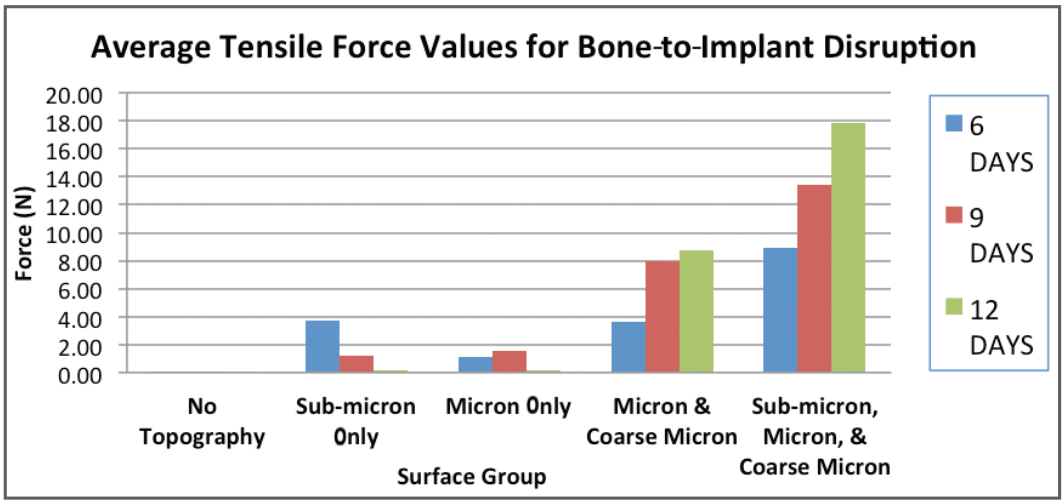

Table 1: Average Bone-to-Implant tensile strength for implants with single and combinations of topography scale ranges after 6, 9, and 12 days of healing.

Conclusions

- "Surface implant topography is multidimensional and can be described by employing three distinctly different scale-ranges, each of which are analogous to those that are seen at remodeling sites in natural bone tissue."
- "Sub-micron 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 sub-micron features, the micron- and coarse-micron scale features on the implant surface are essential to provide long-term interfacial stability under loading."

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.

Topic: Osseointegration
Center: BIOMET ***3i,*** Palm Beach Gardens, Florida, USA
Scenario: Electron microscopy and interferometer characterization of contemporary implant surfaces to qualify and quantify surface features present within the sub-micron, micron, and coarse micron scale range
Sample Size: n=1 implant per manufacturer/surface
Reported Outcome (s): 30,000 x magnification images for sub-micron 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 with 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

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 crystal 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 sub-micron 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).

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

Results:

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

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

Conclusions and Clinical Implications:

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

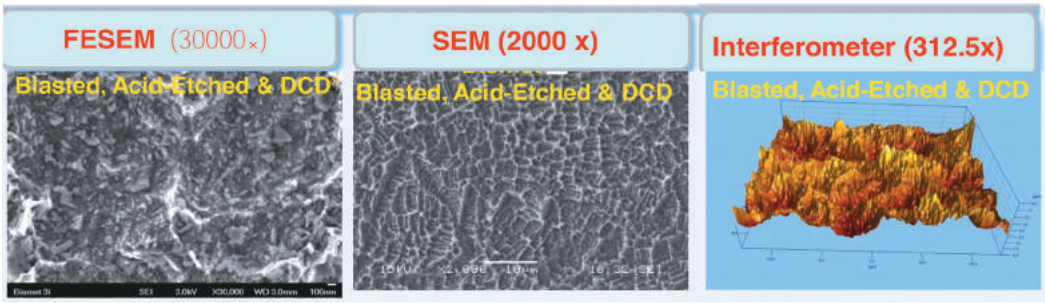

Figure 1: BIOMET *3i* new implant design surface images.

To view the poster please visit, http://iird.com/pdf/P20-Gubbi.pdf.

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

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

Topic: Osseointegration
Center: Mayor University, Santiago, Chile
Scenario: Prospective randomized controlled clinical trial
Sample Size: 49 patients, 137 study implants (108 test, 29 control)
Reported Outcome (s): Implant integration assessment via reverse torque check at 6, 8, and 10 weeks
Relevance to *3i* T3® Implants: The test implants clinically studied utilize a multi-topography surface identical to the ***3i*** T3 Implants with the DCD® Surface. The study demonstrates that implants with this multi-topography surface showed a higher degree of bone integration versus BIOMET ***3i*** NanoTite™, as demonstrated by countertorque resistance at six weeks.

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 sub-micron (hydroxyapatite discrete crystal 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.

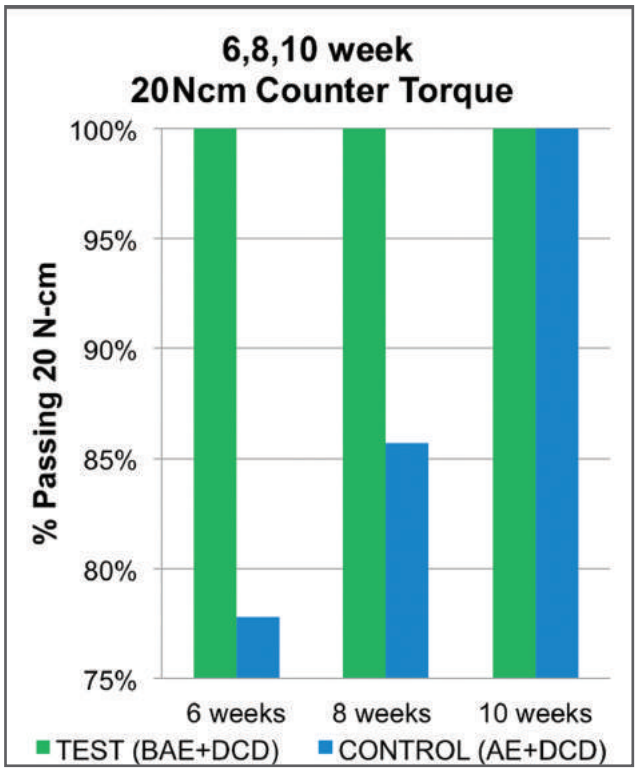

Figure 1: 20Ncm counter torque verification results.

Results

A total of 49 patients with 94 restorative cases have been treated with 137 study implants of which 108 are test and 29 are control implants. Test results at the three healing intervals demonstrate significant differences between the groups.

Conclusion

At the time of this report, the test implants have a higher degree of bone integration as determined by resistance to 20 and 32Ncm liberation forces.

To view the poster please visit, http://biomet3i.com/Resource%20Center/Clinical%20Information/Montoya%20Integration_PosterMontoya_EN.pdf

Project scuderia: *3i* T3® clinical data generation – interim results as of May 1, 2013

Kenealy J†

European Limited Launch Clinical Experience White Paper, BIOMET *3i*, 2013.

Topic: Osseointegration
Center: European and Asian multi-center university and private practices.
Scenario: Prospective, observational clinical evaluation.
Sample Size: 90 clinical evaluations from 19 countries with 555 implants
Reported Outcome (s): Cumulative survival rate
Relevance to *3i* T3 Implants: This clinical evaluation demonstrates the performance characteristics intended by the *3i* T3 design. Follow-up evaluations continue.

Methods

This prospective observational clinical evaluation documents the effectiveness of *3i* T3 Implants for treating partially edentulous patients. Evaluators were provided standardized forms to document cases from their University and private practice clinics. Production of over 1,000 *3i* T3 Implants was done specifically for the evaluation project. Information on the new system was provided along with osteotomy preparation procedures and implant placement steps. Otherwise, no other "protocol" was promoted in terms of patient selection or the type of cases to be included in the evaluation – these were to be selected by the evaluators as part of the clinical treatment of their patients. Each evaluator was requested to document at least 10 cases with restorative solutions based upon the preference of the evaluators.

Results

To date, a total of 90 clinical evaluators from 19 countries provide case information for over 250 patients and over 500 implant placement procedures from May 2012 to March 2013 as illustrated in Figure 1. Implant lengths range from 8.5 to 11.0mm as illustrated in Figure 2.

†The author conducted this research while employed by BIOMET *3i*.

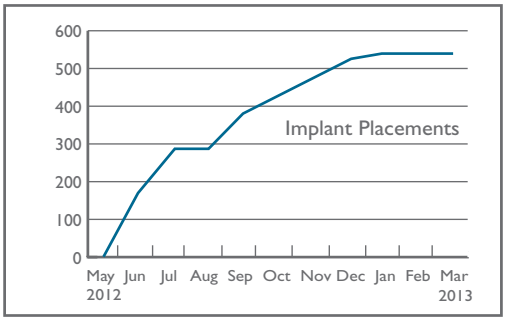

Table 1: Implant placements by month.

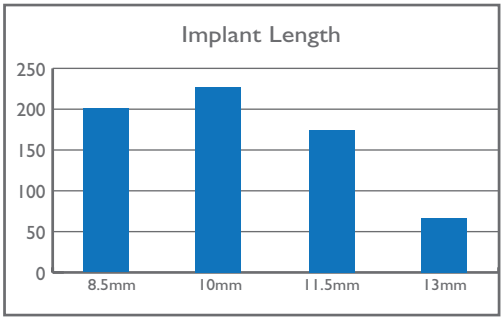

Table 2: Implant dimension.

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 situations and with 100% placement success. Follow-up evaluations continue to be made with positive and constructive feedback from the evaluators. To date, with 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.

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, et al.

Implant Dent 2012;21:454-460.

Topic: Osseointegration
Center: Tufts University, Massachusetts, USA
Scenario: Prospective randomized controlled pre-clinical trial; rabbit tibia
Sample Size: n=2 implants per surface/time
Reported Outcome(s): BIC (Bone-to-Implant Contact) and BMU (bone multicellular units) at 1, 6, 21, and 90 days
Relevance to *3i* T3® Implants: The test implants (designated BAE-2) pre-clinically studied included a multi-scale topography surface with sub-micron, micron, and coarse micron levels highly similar to ***3i*** T3 with DCD®. The test implants demonstrated a higher degree of integration versus control (without submicron) 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,

*Preclinical results are not necessarily indicative of clinical performance.

The impact of bone compression on bone-to-implant contact of osseointegrated implants: A canine study*

Nevins M†, Nevins M†, Schupbach P, et al.

Int J Periodontics Restorative Dent 2012;32(6):637-645.

Topic: Osseointegration
Center: Perio Imp Research Inc., investigators affiliated with Harvard University, Massachusetts, USA
Scenario: Prospective randomized controlled pre-clinical trial; canine mandible
Sample Size: n=2-4 per test surface/time point (40 implants total)
Reported Outcome(s): Histology, BIC (bone-to-implant contact), radiography, and stability (Osstell ISQ) at 0, 7, 14, 28, and 56 days
Relevance to *3i* T3® Implants: All study implants were the *3i* T3 with DCD® Surface. The study demonstrated substantial BIC percentages, as well as high ISQ values for all of the scenarios tested.

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.

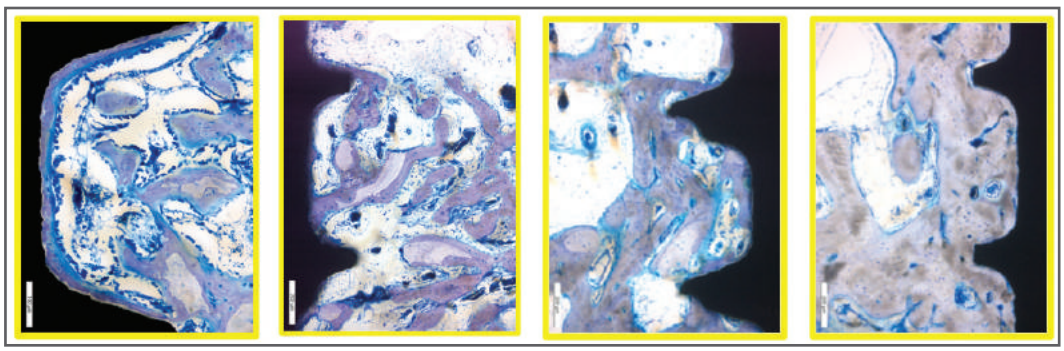

Figure 1: Examples of Bone Formation at 7, 14, 28, and 56 Days (moderate compression group)

*Preclinical results are not necessarily indicative of clinical performance.

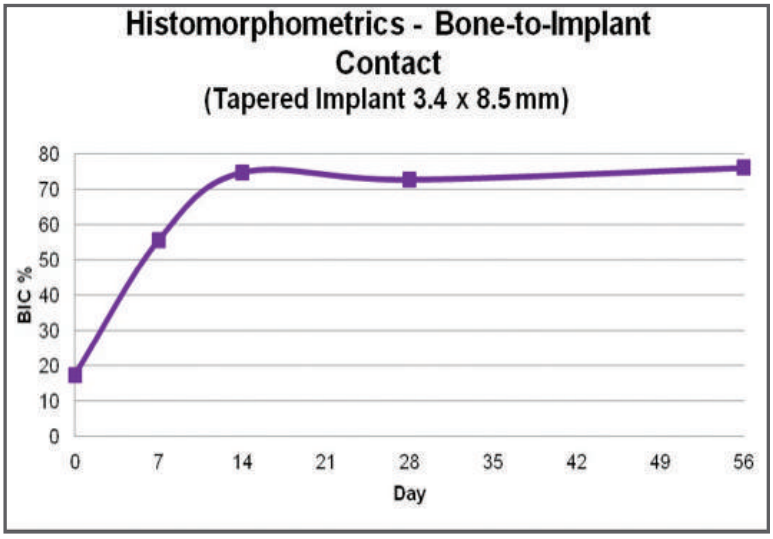

Figure 2: Bone-to-Implant Contact (moderate compression group)

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[9]. 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:

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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

Topic: Preservation
Center: BIOMET *3i*, Palm Beach Gardens, Florida, USA.
Scenario: Electron microscopy characterization of the full-length implant-abutment interface of contemporary implant systems
Sample Size: n=1 per implant system
Reported Outcome(s): 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 & 4.5mm D x 13.0mm L), Bone Level implants (Straumann®, 3.3mm D x 12.0mm L & 4.1mm D x 12.0mm L), Active implants (Nobel Biocare®, 4.3mm D x 13.0mm L & 5.0mm D x 11.5mm L), and novel Tri-Topography *3i* T3 Implants (BIOMET *3i*, 3.25mm D x 13.0mm L & 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.

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

Conclusion

Microgap analysis at the implant-abutment interface on four different implant systems (2 sizes in each) from various manufacturers revealed that the 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 Astra Tech implant systems.

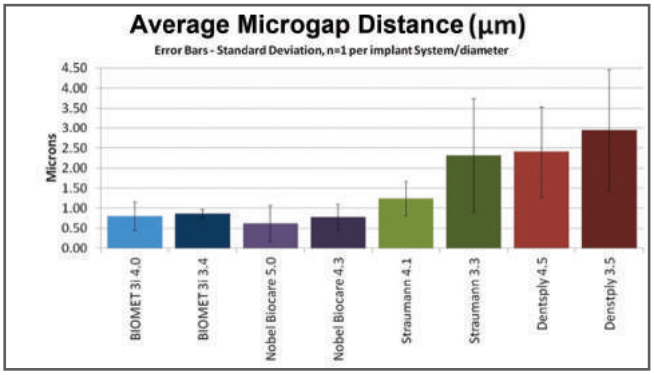


Fig. 1. Average microgap measurement (microns)

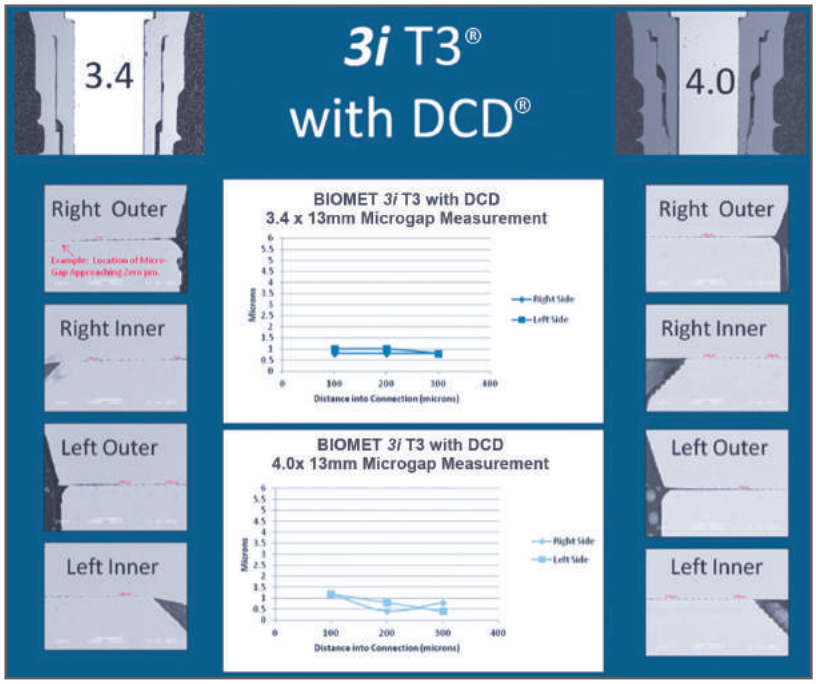


Fig. 2. ***3i*** T3 with DCD microgap images and measurements.

*Bench test results are not necessarily indicative of clinical performance.

To view the poster please visit, http://biomet3i.com/Resource%20Center/Clinical%20Information/gubbi%20microgap_postergubbi_EN.jpg

Marginal accuracy of three implant-ceramic abutment configurations*

Baldassarri M, Hjerppe J, Romeo D, et al.

Int J Oral Maxillofac Implants 2012;27(3):537-43.

Topic: Preservation
Center: New York University, New York, New York, USA.
Scenario: Electron microscopy characterization of the exterior aspect of the implant-abutment interface of contemporary implant systems.
Sample Size: n=1 per implant system
Reported Outcome(s): 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 (BIOMET ***3i***) (B3i); Astra Tech Dental 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 ± 2.6Mm (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.

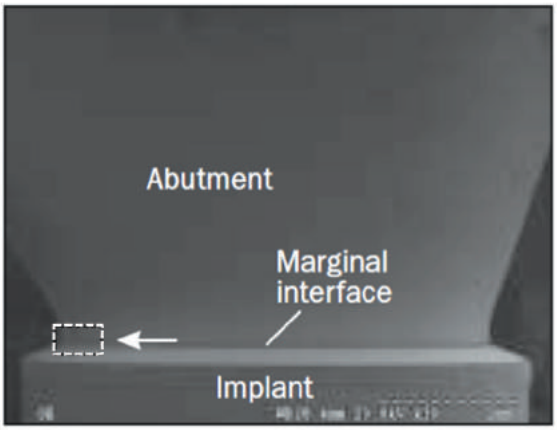


Fig. 1. Image courtesy of Dr. Christian Stappert†

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.

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

*Bench test results are not necessarily indicative of clinical performance.

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

Suttin Z†, Towse R†, Cruz J†

Poster Presentation (P188): Academy of Osseointegration, 27th Annual Meeting, March 2012, Phoenix, Arizona, USA

Topic: Preservation
Center: BIOMET ***3i***, Palm Beach Gardens, Florida, USA.
Scenario: 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 Outcome(s): 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.

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

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.

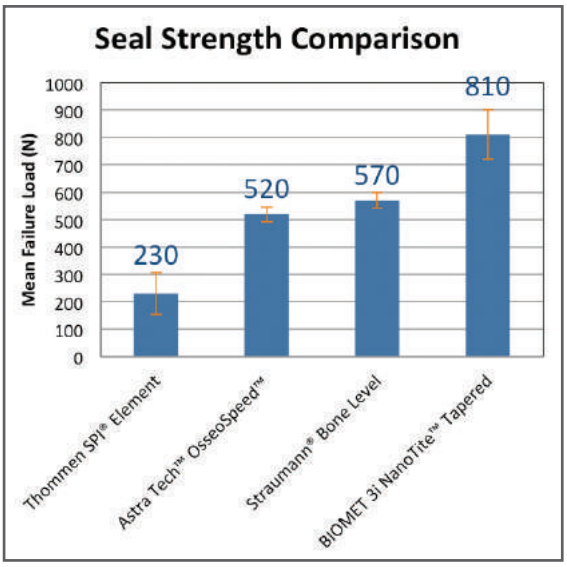


Table 1: Seal strength comparison of contemporary implant systems (n=5)

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.

*Bench test results are not necessarily indicative of clinical performance.

To view the poster please visit, http://iird.com/pdf/P16-Suttin.pdf

Effect of abutment screw design on implant system seal performance*

Suttin Z†, Towse R†

Poster Presentation (P451): European Academy of Osseointegration 20th Annual Meeting, October 2012, Copenhagen, Denmark

Topic: Preservation
Center: BIOMET ***3i***, Palm Beach Gardens, Florida, USA.
Scenario: Characterization of the implant-abutment seal capability of the BIOMET ***3i*** Certain® Connection with / without the Gold-Tite® Abutment Screw subjected to a dynamic loading fluid-leakage test
Sample Size: n=5 per implant system
Reported Outcome(s): Seal strength (N) of the Certain Connection with the Gold-Tite Screw versus a standard titanium alloy screw. 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® Implants: The BIOMET ***3i*** Certain Connection, which is included on the ***3i*** T3 Implant, was evaluated in this study. The BIOMET ***3i*** Certain Connection demonstrated a higher seal strength when utilizing the Gold-Tite Screw.

Background

Seal integrity of the implant-abutment-junction (IAJ) has significant clinical relevance due to the potential detriments associated with an inferior seal, such as microleakage. Abutment screw design is a paramount factor as the screw generates the preload required to establish and maintain system stability.

Aim

To characterize the IAJ seal robustness of implant systems subjected to dynamic loading with titanium and Gold-Tite Abutment Screws.

Methods and Materials

The apex of the 4/3.4mm Certain PREVAIL® test implants (n = 5) was modified to have a barb fitting and through hole. The implants were embedded in a phenolic block 3.0mm supragingival, and the implant barb was connected to a 7psi peristaltic pump containing red dye. A GingiHue® Abutment and titanium screw were assembled with the prescribed 20Ncm of torque. The block was mounted at 20° off-axis in a clear water tank, and the IAJ was magnified 50X with a video camera. The system was cyclically loaded at 100 N for 100k cycles at 30Hz. Following this wear phase, the pump was activated and the frequency was reduced to 2Hz for 1k cycles to monitor the IAJ. The wear-monitor routines were incremented in 50N load steps until a breach occurred, and the system components were then examined to detect yield and/or fracture damage. A new titanium screw was assembled, and the testing was reinitiated at the prior breach load. Upon breaching, the components were re-examined for damage and the testing was resumed at the prior breach load using a Gold-Tite Screw.

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

Results

All samples failed due to a "pure breach" at the IAJ, meaning that no components yielded and/or fractured. The initial titanium screw produced seal strength values averaging 500N, and the second screw provided no improvement in seal robustness. Use of the Gold-Tite® Screw increased the average seal strength to 780N.

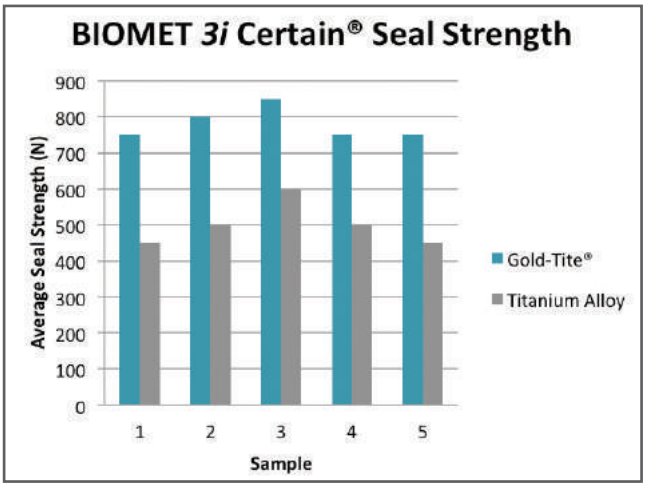


Table 1: Seal strength comparison of the Certain® Implant System with / without Gold-Tite (n=5)

Conclusions and Clinical Implications

A method has been developed to assess the seal robustness of implant systems subjected to clinically relevant loading conditions. The Gold-Tite Screw demonstrated a significant improvement as compared to titanium, indicating that the additional preload generated is beneficial to the seal integrity.

*Bench test results are not necessarily indicative of clinical performance.

To view the poster please visit, http://iird.com/pdf/P21-Suttin.pdf

The seal is the deal: Gas-Enhanced Leakage Testing (GELT) for implants*

Al-Jadaa A†, Attin T, Schmidlin Pr†

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

Topic: Preservation
Center: University of Zurich, Zurich, Switzerland.
Scenario: Characterization of the implant-abutment seal capability of contemporary implant systems utilizing a gas-leakage test methodology
Sample Size: n=16 + 4 controls per implant system
Reported Outcome(s): Nitrogen gas leakage rates (Hecto Pascal/minute) and corresponding saline infiltrate (ml) of contemporary implant systems.
Relevance to *3i* T3® Implants: The BIOMET ***3i*** Certain® Connection, which is included on the ***3i*** T3 Implant, was evaluated in this study. The BIOMET ***3i*** Certain Connection demonstrated significantly less gas leakage and saline infiltrate than the other systems evaluated in the study.

Background

The evaluation of leakage in dentistry plays a pivotal role in research as most oral pathologies develop at plaque retentive niches due to the accumulation of bacteria and their bi-products. The complex implant-abutment interface represents a typical example. Thus, implants should be favorably fabricated with a tight seal to prevent or limit pathological inflammatory changes of adjacent tissues.

Aim

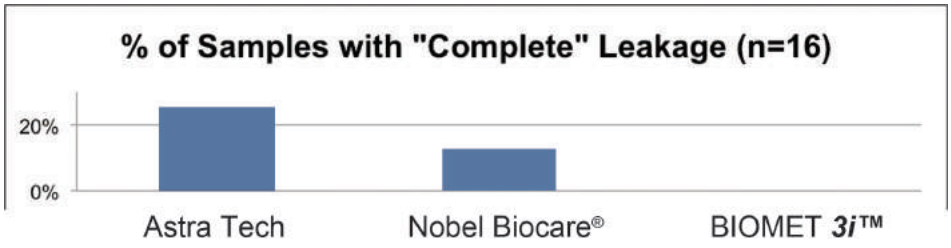
To develop a customized, standardized measurement device allowing repetitive non-destructive evaluation of implant leakage.

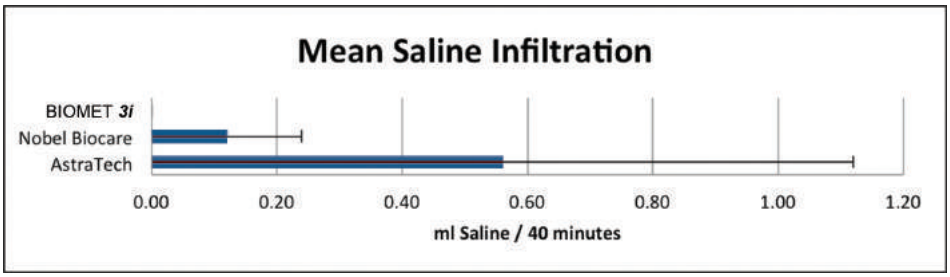
Materials and Methods

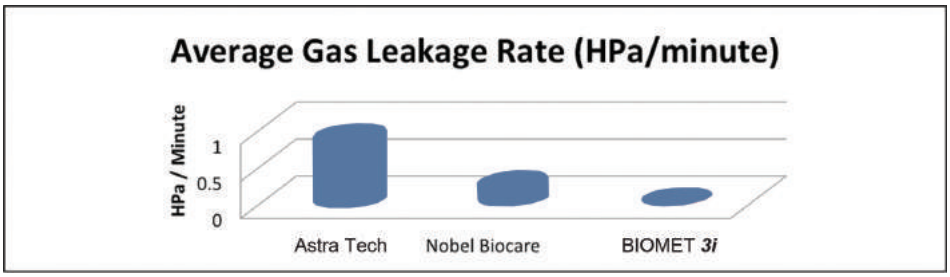
An environmentally controlled apparatus was developed, which consists of two chambers allowing gas pressure change measurement and fluid volume infiltration at 35°C. Three implants systems were tested (N=20 per group): Nobel Biocare® (NB), Astra Tech (AT) and BIOMET ***3i*** (B3i). Four implants in each group served as negative controls. The implants were mounted in a disk, which served as a tight separating holder between the two chambers. The upper chamber was filled with 2.5ml Normal Saline and pressurized with N2 gas at 860 hPa, while the lower chamber was set at -170 hPa containing no liquid (a total pressure difference of 1030 hPa). The pressure difference change over time was measured as the primary variable over 40 minutes to establish the baseline leakage through the set-up. To ensure temperature equilibrium, only the last 20 minutes of measuring were utilized to determine the rate of leakage expressed as pressure loss over time. In addition, the infiltrated saline volume into the lower chamber was measured over the same period. The samples were then removed, a small hole was drilled at the implant apex taking care to not damage the internal threads and the abutment was attached to the implant with the screw tightened according to the manufacturer's instructions.

†Dr. Al-Jadaa and Dr. Schmidlin have a financial relationship with BIOMET ***3i*** LLC resulting from speaking engagements, consulting engagements, and other retained services.

The screw access was sealed with a composite build-up before the sample was mounted again for further leakage evaluation. The baseline slope and fluid leakage values were subtracted from the test values to determine the absolute gas leakage rate and saline leakage amount. A non-parametric Mann-Whitney test was used to compare the results and linear correlation between pressure and water flow was calculated with a p-value set to 5%.







Results

Four samples of the AT and two of the NB group were excluded from further data analysis because they showed complete leakage before the observation leakage was terminated. The rate of gas pressure change (hPa/min) was significantly different between all groups with decreasing mean leakage values as follows: AT 0.85±0.71, NB 0.23±0.030 and B3i 0.01±0.01 ($p<0.05$). The saline infiltration through the implant abutment interface correlated to the pressure change rates and accounted for 0.60±0.50ml (AT), 0.12±0.20ml (NB) and 0±0ml (B3i), respectively. The correlation coefficient was high ($R2=0.965$).

Conclusion

Under the simulated conditions, the BIOMET *3i* Implants demonstrated the best sealing ability.

Acknowledgement

This research was supported by a research grant from BIOMET *3i*.

*Bench test results are not necessarily indicative of clinical performance.

To view the poster please visit, http://biomet3i.com/Resource%20Center/Clinical%20Information/Gas-Enhanced%20Leakage%20Testing%20(GELT)_PosterGELT_EN.png

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

Östman PO†, Wennerberg A, Albrektsson T†
Clin Implant Dent Relat Res 2010;12(1):39-47.

Topic: Preservation
Center: Private Practice, Gothenburg University, Gothenburg, Sweden
Scenario: Prospective, observational, immediate loading clinical study.
Sample Size: n=102 implants
Reported Outcome(s): 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 sub-micron features. The implants studied experienced high one-year survival and success rates.

Background

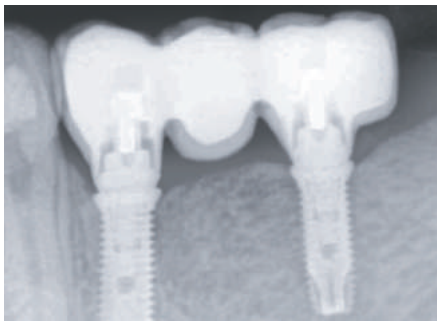
Recently, a new implant surface texture, featuring application of nanometer-scale calcium phosphate has been shown to enhance early bone fixation and formation in preclinical studies and in human histomorphometric studies, which may be beneficial in immediate loading situations.

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 a 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



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

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.

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.

Marginal Bone Resorption at One-Year Follow-up

	NanoTite™ PREVAIL®	
	(m + d)/2	(%)
Number	101	
Mean value (SD)	0.37 (0.39)	
<0	9	9
0	17	17
0.1–1.0	69	68
1.1–2.0	6	6
2.1–3.0	0	0
>3.0	0	0
Total	101	100

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.

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

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

Zetterqvist L, Feldman S, Rotter B, et al.

J Periodontol 2010;81(4):493-501

Topic: Preservation
Center: Multiple
Scenario: Prospective, randomized controlled clinical trial
Sample Size: n=304 implants (165 test, 139 control)
Reported Outcome(s): Peri-implantitis incidence, marginal bone resorption
Relevance to *3i* T3® Implants: The test implants studied have coronal surface features in common with ***3i*** T3 Implants, including 1-3 micron peak-to-peak surface features. This coronal surface configuration demonstrated no increased risk of longer term peri-implantitis and its progressive bone loss as compared to a machined surface.

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, suppuration, and probing depths. Evaluations also included radiographic and mobility assessments.

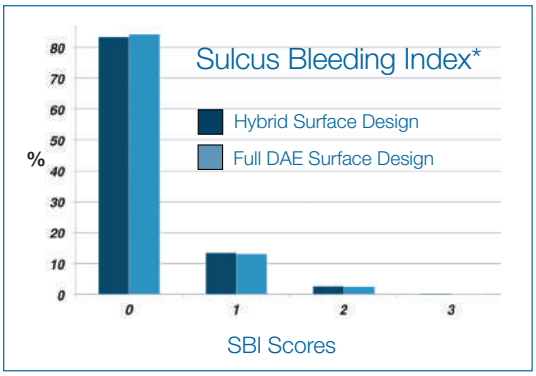


Table 1: 84% of all SBI scores were "0" (absence of bleeding); 13% of scores were "1" - isolated bleeding spot.

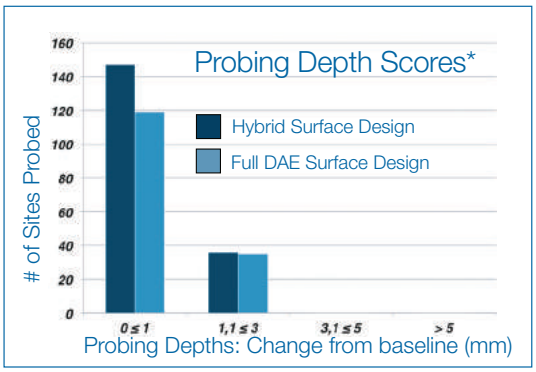


Table 2: No implant (test or control) showed changes in probing depths greater than 3.0mm.

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

Results

One hundred twelve patients who were enrolled at seven centers received 139 control and 165 test implants (total: 304 implants). With >5 years of postloading evaluations, 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.

Conclusion

Five-year results of this randomized-controlled study showed no increased risk of peri-implantitis for fully etched implants as compared to hybrid-designed implants.

Introducing the

3i T3 IMPLANT™

Preservation By Design®

- Contemporary hybrid surface design with multi-level surface topography
- Integrated platform switching with as little as 0.37mm of bone recession*[1]
- Designed to reduce microleakage through exacting interface tolerances and maximized clamping forces**[2,3]

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2. Suttin†† et al. A novel method for assessing implant-abutment connection seal robustness. Poster Presentation: Academy of Osseointegration, 27th Annual Meeting; March 2012; Phoenix, AZ. http://biomet3i.com/Pdf/Posters/Poster_Seal%20Study_ZS_AO2012_no%20logo.pdf
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†Dr. Östman has a financial relationship with BIOMET *3i* LLC resulting from speaking engagements, consulting engagements and other retained services.
††Mr. Suttin and Mr. Towse contributed to the above research while employed by BIOMET *3i*.

*0.37mm bone recession not typical of all cases.
**Seal integrity test was performed by BIOMET *3i* July 2011 - June 2012. In order to test the implant systems, a dynamic-loading leakage test was developed and executed. The test set-up was adapted from ISO14801, Dentistry - Implants - Dynamic Fatigue Test for Endosseous Dental Implants. Five samples each of the BIOMET *3i* and three competitive implant systems were evaluated. Bench test results are not necessarily indicative of clinical performance.

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