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T3[®] Implants – A Scientific Compendium

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

Richard J. Lazzara, DMD, MScD[†]

Introduction

In 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 that complex biological processes can sabotage even the most beautiful results over time has been growing.

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 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 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 aids in primary stability. Furthermore, the T3 Tapered Implant design incorporates additional macrogeometric elements to achieve primary stability,³ including tall, thin threads that penetrate laterally into the bone for secure long-term engagement.

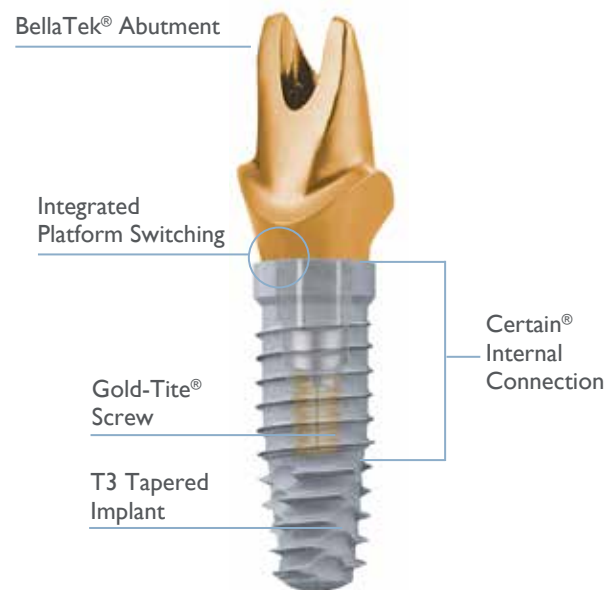


Fig. 1. Schematic of a T3 Tapered Implant.

In a prospective immediate loading study by Östman et al, the investigators placed 139 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 <math><1.0 \mu\text{m}</math>).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 2-3.0 mm 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 risk of peri-implantitis as compared to the hybrid design. It also provided additional

evidence that the fully etched surface reduced crestal bone loss (0.6 mm versus 1.0 mm, $p<.0001$).⁷ Continued research into the OSSEOTITE Surface culminated in a new surface enhancement – the T3 Implant surface. More than just another roughened surface, the 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 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).⁶

The T3 Implant Surface represents a significant step forward, with multiple topography levels and features along the implant body designed to assist in osseointegration and crestal bone levels.

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 4.0 mm diameter abutments were routinely used in the early 1990s to restore 5.0 mm and 6.0 mm 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 18 clinical studies with 1216 platform-switched implants and 1157 platform-matched implants found a significant effect for platform-switching on marginal bone loss.⁹

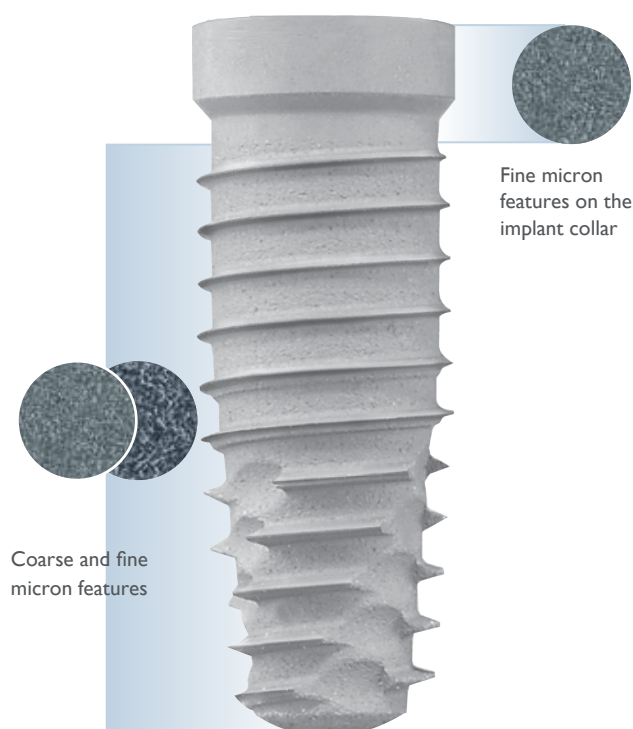


Fig. 2. Schematic of the contemporary hybrid design of the T3® Tapered Implant.

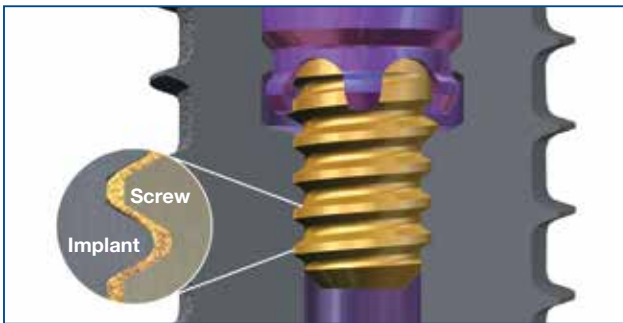


Fig. 3. A Gold-Tite® Abutment Screw, coated with a minimum of 40 microinches of 99.99% pure gold, acts as a dry lubricant, thus permitting the screw to stretch and applying greater clamping force.

The 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 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 summary, the 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.

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†Dr. Lazzara has a financial relationship with Zimmer Biomet Dental resulting from speaking engagements, consulting engagements, and other retained services.

Abstract

Human histologic analysis of an immediately loaded single-tooth mandibular first molar implant

Amato F,† Polara G, Traini T.
Int J Periodontics Restorative Dent. 2015;35(4):499-505.

Center: Private practice, Catania, Italy

Study Design: Clinical case and histological report

Sample size: One patient treated with T3 Certain® Tapered implant with platform-switching (4.0 mm × 10 mm)

Reported Outcomes: Histology, histomorphometrics (%BIC) and scanning electron microscopy (SEM)

Relevance to T3® Implants: The immediate loading of single-tooth implant cases can be successful especially when the implant's macro-geometric design helps achieve primary stability and surface leads to osseous fixation. This case shows that a T3 Tapered Implant can achieve a rapid rate and high level of histologic bone apposition when used for immediate single-tooth restoration in the posterior mandible.

Case presentation

This report presents the unique case of a human histologic analysis of an immediately-loaded single-tooth implant after eight weeks of healing. The 45-year-old male patient was treated at the right mandibular molar site with a 4 mm × 10 mm T3 Certain® Tapered Implant delivered with a final insertion torque of 80 Ncm. The implant was immediately restored with platform-switching using a 3.25 mm PreFormance Post and screw-retained provisional crown.

Because after one-month, the patient requested implant removal based on a complaint of "feeling the presence of a foreign body" in his jaw and could not be dissuaded, he consented to retrieval of the implant for the investigation. At 8 weeks, the provisional crown was replaced with a healing abutment and radiographed prior to removal with a 6 mm trephine drill (Fig. 1a and b). The specimen was processed, sectioned and stained (azure II or toluidine blue and acid fuchsin) for histologic analysis.

Results

Marginal bone levels at both the buccal and lingual coincide with the original bone relationship to the

implant shoulder at the time of implant placement, with no signs of bone resorption (Fig. 2). The histology revealed evidence of a very high bone-to implant contact for the three sections that were examined (mean 64.2% ± 3.0) without observation of epithelial downgrowth. Newly formed bone with a low mineral content was observed between the implant shoulder and first thread whereas further away bone with high mineral content was observed. Under circularly polarized light microscopy (CPLM), the microstructure of the peri-implant bone reveals transverse collagen fibers within the plane of the section having contact with the implant (Fig. 3a). Under light microscopy (LM), an image of the same section shows bone tissue contacting the implant body (Fig. 3b).

The analysis demonstrates radiographic and histologic features of successful osseointegration. The authors conclude that an immediately-loaded single-tooth T3 Implant when placed with high insertion torque in poor quality bone can lead to rapid bone apposition and good marginal bone stability.

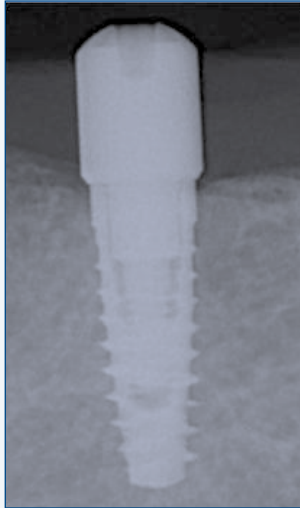


Fig. 1a. 8 weeks post-implant placement, a healing abutment was placed in lieu of the provisional crown and a periapical radiograph was taken.

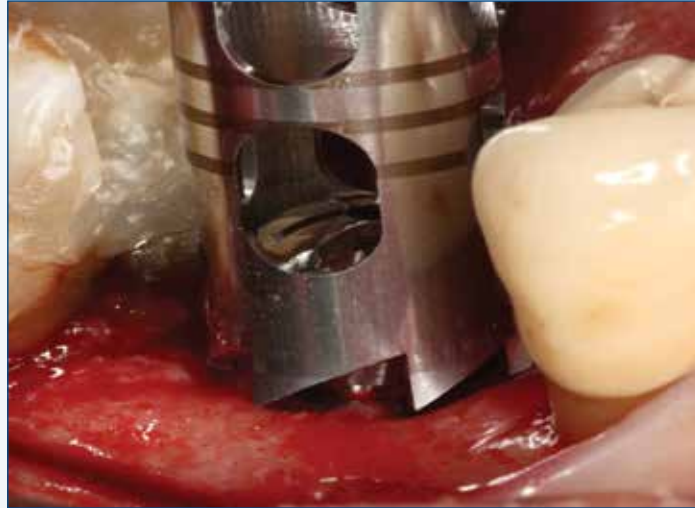


Fig. 1b. A 6 mm diameter trephine bur was used to remove the implant.



Fig. 2. Light microscopic section of a bucco-lingual section stained with acid fuchsin and azure II at 32x magnification.

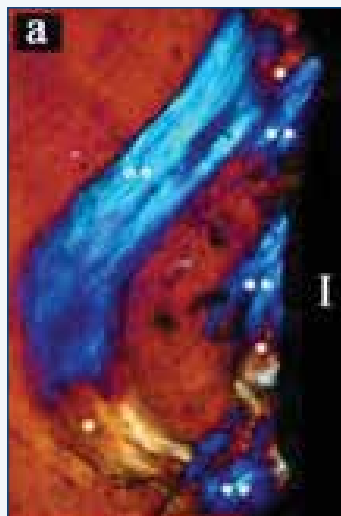


Fig. 3a. CPLM shows longitudinal collagen fibers (*) and blue-white transverse collagen fibers (**) contacting the T3 Implant (I).

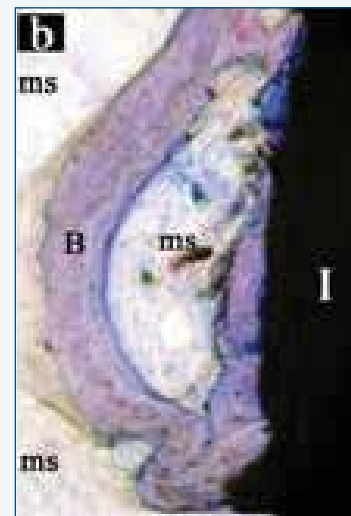


Fig. 3b. LM shows well-structured bone (B), in advanced stages of maturation with several marrow spaces (ms). (I = T3 Implant).

†Dr. Amato has a financial relationship with Zimmer Biomet Dental resulting from speaking engagements, consulting engagements and other retained services.

A prospective evaluation of a novel implant designed for immediate loading

Amato F[†], Polara G.
Int J Periodontics Restorative Dent. 2014;34 Suppl 3:s43-49.

Center: Private practice, Catania, Italy

Study Design: Prospective, observational immediate-loading clinical study

Sample Size: N = 240 implants

Reported Outcomes: Cumulative survival

Relevance to T3® Implants: A preliminary report from one of the first clinical investigations of the T3 Tapered Implant shows promising results for immediate loading of various prosthetic applications in a large patient population.

Abstract

This prospective study evaluated the survival rate of immediately loaded anatomically tapered implants with a dual acid-etched, microtextured surface. Patients in a private practice were recruited for placement of T3 Tapered Implants in single, multiple, and full-arch applications in the mandible and maxilla, in both fresh extraction and healed placement sites. Ninety patients were treated, and 240 implants were placed

and immediately loaded: 124 in the maxilla and 116 in the mandible. One hundred twelve definitive prostheses were delivered between 4 and 6 months after implant placement. Over the course of 2 to 12 months of follow-up (mean: 4.8 months), five implants failed in the maxilla and no implants failed in the mandible, a survival rate of 96% for the maxilla and 100% for the mandible. The cumulative survival rate was 98%.



Fig. 1. A T3 Tapered Implant 5 mm x 13 mm is placed in a palatally-oriented osteotomy at the right canine tooth site.

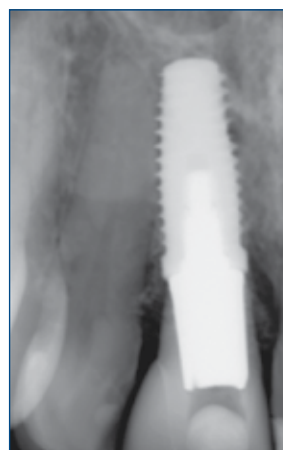


Fig. 2. A postoperative periapical radiograph taken at 1.5 years after implant placement shows excellent preservation of crestal bone levels. Particles of Endobon Xenograft Granules embedded in the soft tissue are evident, which is beneficial for maintaining the tissue contours.

[†]Dr. Amato has a financial relationship with Biomet 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.

Project Scuderia: T3 clinical data generation – interim results at one year

Kenealy J†
European Limited Launch Clinical Experience White Paper, Biomet 3i, 2013.

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 T3 Implants: This clinical evaluation demonstrates the performance characteristics intended by the T3 design. Follow-up evaluations continue.

Objective

This prospective observational clinical evaluation documents the effectiveness of 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.

Production of over 1,000 T3 Implants was done specifically for the evaluation project. Evaluators were provided standardized forms to document cases. Baseline variables included implant site location, implant dimension, osteotomy conditions, implant placement torque, the surgical approach (single-stage, two-stage), and the intended restorative solution. Implant procedures took place from May 2012 to March 2013.

Results

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

Abstract

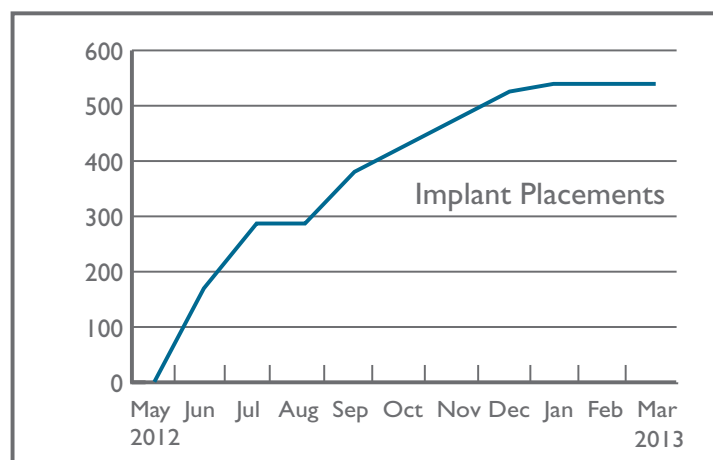


Fig. 1. Implant placements during enrollment period.

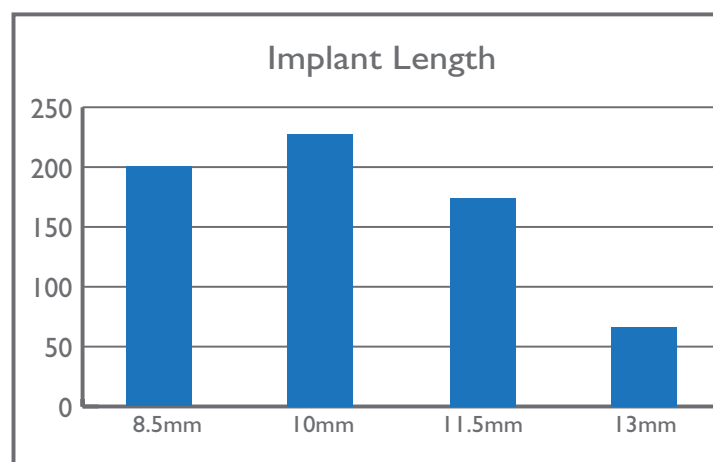


Fig. 2. Implant length used.

Interim Analysis

Over 500 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 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 counter-torque test at 6, 8, and 10 weeks

Relevance to 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 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: coarse micron (calcium phosphate media blasting), micron (dual acid-etching), and submicron (hydroxyapatite discrete crystalline deposition). At least 1.5 mm 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® 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

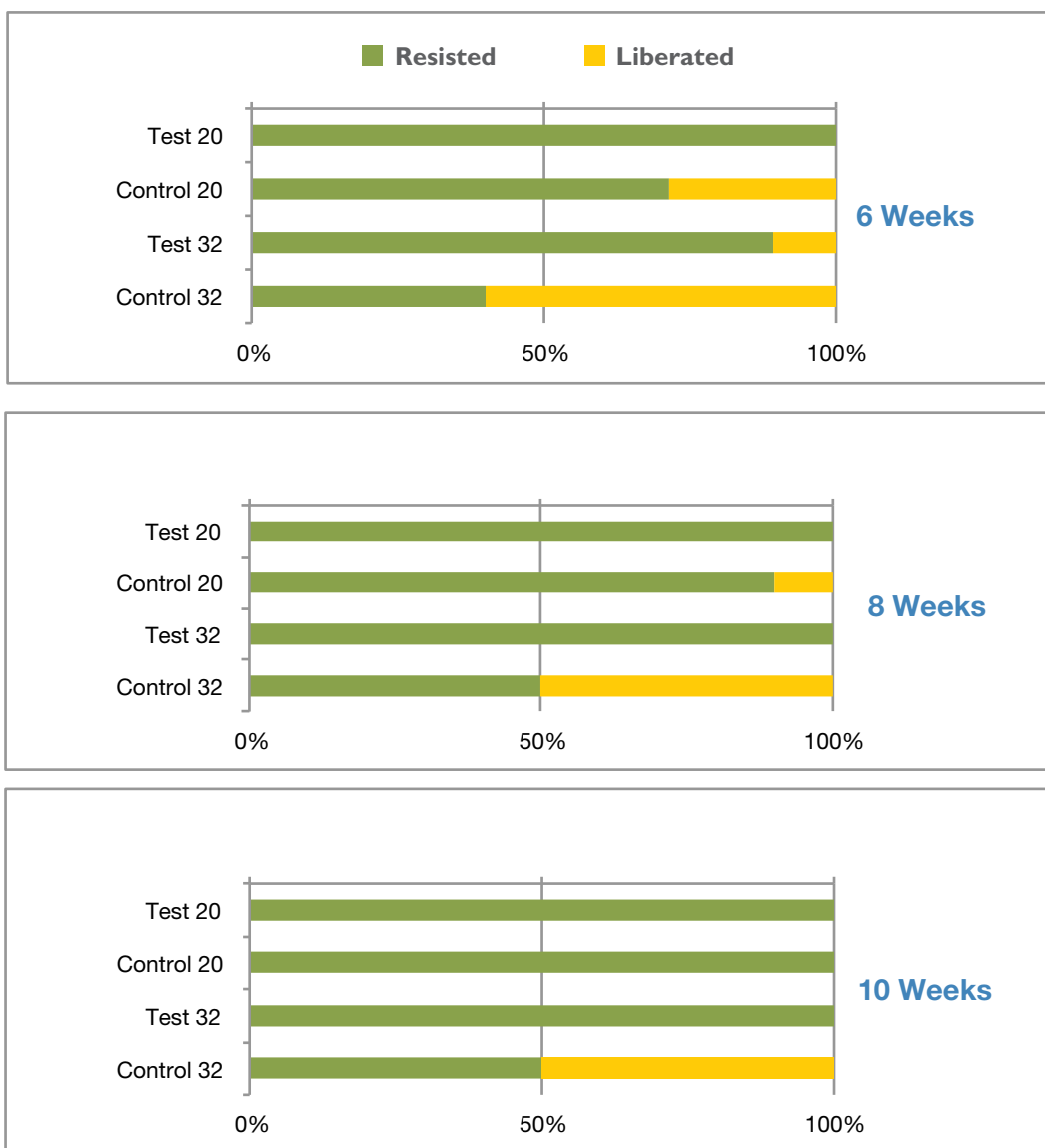


Fig. 1. Integration Assessments: After abutment removal and RFA measurement, a torque-indicating ratchet wrench was used to apply counter-torque force. Implants demonstrating no motion at 20Ncm were then tested at 32Ncm. Any sensation of rotation at counter-torque force was recorded. At the completion 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.

Soft-tissue contour changes at immediate postextraction single-tooth implants with immediate restoration: A 12-month prospective cohort study

Cardaropoli D, Tamagnone L, Roffredo A, Gaveglio L.
Int J Periodontics Restorative Dent. 2015;35(2):191-198.

Center: Private practice, Turin, Italy

Study Design: Prospective, observational clinical study

Sample size: Twenty-six patients each treated for an immediate maxillary single-tooth replacement with a T3 Tapered Implant with DCD and platform switching. N = 26 implants. Reported Outcomes: Soft tissue dimensions and Pink Esthetic Scores after one year of follow-up.

Relevance to T3 Implants: Treating fresh extraction sockets immediately with dental implants along with a provisional restoration remains one of the most challenging of all clinical cases. T3 Implants with DCD were 100% successful in such cases in this study and the restorations also show evidence of optimal soft tissue contours and esthetics after one-year of function.

Objective

The selection of regenerative and restorative approaches can have an ultimate effect on the esthetics and soft tissue parameters of immediately replaced and restored implants. The aim of this prospective clinical study was to evaluate the influence of a bone preservation technique and a custom restorative procedure on immediate maxillary anterior single-tooth implants after one year of function.

Materials and Methods

For each study patient, flapless extraction of an anterior maxillary single-tooth was carefully executed avoiding trauma to socket walls which were debrided of granulation tissue prior to performing the osteotomy. T3 Tapered Implants with DCD were inserted and seated with a calibrated torque hand ratchet wrench (H-TIRW). The regenerative approach consisted of filling the bone-implant gap of the extraction socket with a bovine bone mineral blended with collagen.

The clinician's restorative procedure includes steps aimed at maintaining the dimensions of the

extraction socket. A provisional acrylic crown, fabricated prior to surgery, was connected to a GoldTite screw-retained PreFormance Post abutment (Biomet 3i) and adjusted out of functional occlusion. Composite resin was flowed below the free gingival margin to specifically create subgingival contours that duplicated the pre-extraction status of the site. Following 3 months of healing, the clinician used a prefabricated custom impression coping designed with subgingival contours matching the provisional restoration.

Clinical parameters for soft tissue outcomes were the following: HW = horizontal width at the most prominent buccal and lingual points of the ridge; MP = mesial papilla level; DP = distal papilla level; ML = midfacial gingival level. A periodontal probe was used to measure the distance from a reference point on an acrylic stent to the landmarks represented in Fig. 1. Pink Esthetic Score (PES) was determined based on the seven locations designated in Fig. 2. Outcomes were reported at baseline (tooth extraction) and at one year.

Abstract

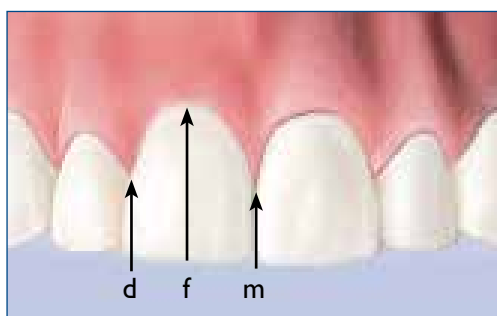


Fig. 1. Landmarks for soft tissue measurements:
 d = distal papilla
 f = midfacial gingival level
 m = mesial papilla

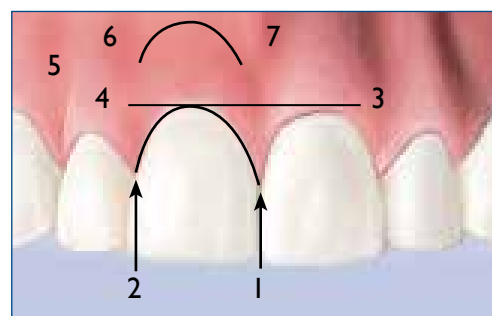


Fig. 2. PES evaluates soft tissue with a 2-1-0 score for 7 variables. 1 = mesial papilla; 2 = distal papilla; 3 = level of soft tissue margin; 4 = soft tissue contour; 5 = alveolar process; 6 = soft tissue color; 7 = soft tissue texture. The highest possible score is 14.

Parameter	Baseline	1 year	Difference
HW (mm)	8.42 ± 0.64	7.69 ± 0.77	0.46 ± 0.65
MP (mm)	5.37 ± 0.78	5.19 ± 0.71	0.17 ± 0.28
DP (mm)	5.48 ± 0.75	5.56 ± 0.73	0.08 ± 0.18
ML (mm)	8.12 ± 0.82	8.33 ± 0.76	0.21 ± 0.32
PES	11.77 ± 1.24	11.46 ± 1.45	0.31 ± 0.55

Table 1. Clinical parameters for soft tissue outcomes (mean ± SD)

Results

Twenty-six consecutive patients (12 men and 14 women) with a mean age of 42.35 ± 9.41 years were successfully treated without complications. During one year of follow-up observations, T3 Implants achieved 100% survival. Outcomes for soft tissue parameters are presented in Table 1. Horizontal, interdental, and midfacial soft tissue dimensions remained stable.

Conclusion

An extraction socket preservation technique in conjunction with the immediate provisional restorative treatment resulted in successful outcomes for single-tooth implants with maintenance of soft tissue contours and aesthetics.

†Dr. Albrektsson and Dr. Östman had financial relationships with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services at the time the study was conducted.

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, Vincenzi G, Wennström JL, Chierco A, Stach RM†, Kenealy JN†
J Periodontol 2010;81(4):493-501.

Centers: Multiple private practice and university centers in the United States and Europe

Study Design: Prospective, randomized-controlled clinical trial

Sample Size: n=304 implants (165 test, 139 control)

Reported Outcomes: Peri-implantitis incidence, marginal bone resorption

Relevance to T3® Implants: The fully etched test implant has the same minimally rough surface topography featured at the coronal region of T3 Implants. The results of this long-term clinical study show no increased risk of peri-implantitis for implants featuring this surface topography at the mucosal interface as compared to implants with a machined surface at the coronal region.

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.

Abstract

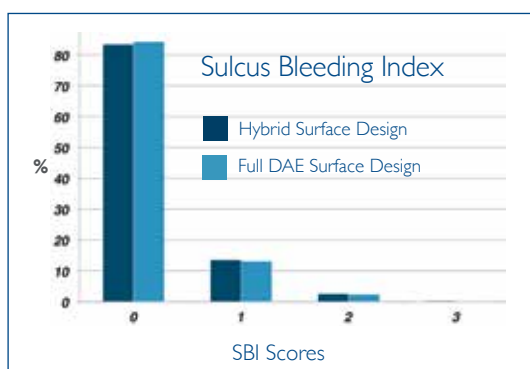


Fig. 1. 84% of all SBI scores were “0” (absence of bleeding); 13% of scores were “1” - isolated bleeding spot.

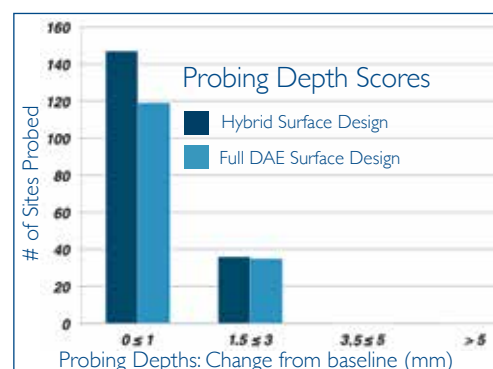


Fig. 2. No implant (test or control) showed changes in probing depths greater than 3.0 mm.

	Control (%)	Test (%)	Control (n)	Test (n)
SBI* Scores				
0	83.5	84.3		
1	13.6	13.1		
2	2.6	2.4		
3	0.3	0.2		
PD intervals† (changes from BL [mm])				
0 to 1			147	119
1.5 to 3			36	35
3.5 to 5			0	0
≥5			0	0

SBI Scores and Probing Depth Intervals for control and Test Implant Groups

Table 1.

– = not applicable; BL = baseline; n = numbers of sites where there was a finding of increased probing depth corresponding to intervals.

* 0 = no bleeding; 1 = an isolated bleeding spot was visible; 2 = blood formed a confluent red line on the mucosal margin; and 3 = heavy or profuse bleeding.

† Probing depth intervals (millimeters) are changes from baseline (BL) to the 6-month permanent prosthesis.

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

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

Surface

The discovery of τ a new and important biologically relevant measurement of implant-surface performance

John E. Davies, BDS, PhD, DSc[‡], Zachary Suttin, MSME[†], Robert Liddell BAsC

Abstract

The rate and extent of bone formation around newly placed dental implants has been thoroughly studied in numerous in vivo preclinical and human models in conjunction with advancements in implant-surface technology. However, no measurement exists for objectively comparing the osseointegration performance of variously designed implant surfaces. This article presents the concept of tau, a new mathematical parameter that can be used to compare the osseointegration potential of different implant surface designs.

Introduction

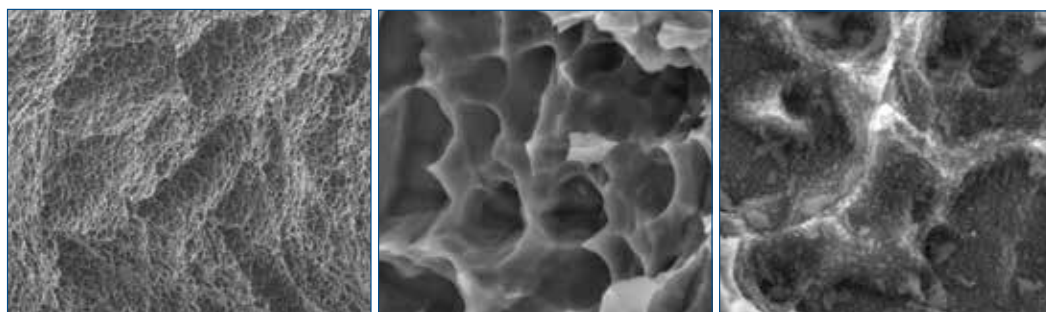
The discovery in the 1950s by Swedish physician Per-Ingvar Brånemark that titanium chambers, used to study circulation within the bone marrow, became anchored into the bone so firmly they couldn't be removed¹ led to his introduction of the term "osseointegration." Brånemark defined this as "direct structural and functional connection between ordered living bone and the surface of a load-carrying implant."² Placement of an endosseous implant initially disrupts homeostasis in the bone tissue, but as peri-implant bone healing progresses, a new equilibrium state develops in which homeostasis is restored. Unlike orthopedic devices that rely on numerous methods for fixation in bone, dental implant fixation depends entirely upon the biological process of osseointegration.

The mechanisms that allow dental implants to become anchored in bone are now so well understood that strategic approaches to implant materials design can be employed that

influence the biologic phenomena underlying these mechanisms. Primary stability, obtained at the time of implant placement,³ involves securing the implant rigidly into the osteotomy to preclude any significant micromotion⁴ and is considered a prerequisite to osseointegration.³ Primary stability is attributed to dependence on the implant macro-design, the bone quality and quantity at the site, and surgical technique.⁵ Optimizing the geometry of both the implant and the osteotomy can increase the likelihood of achieving rigid fixation of the implant within the host bone site. Once primary stability has been attained, it is gradually replaced by a biological, secondary stability.⁶ During this stage, bone tissue is deposited directly on the implant surface, a process known as contact osteogenesis. This results from a complex cascade of cellular and molecular events. Osteoconduction, the migration of osteogenic cells to the implant surface, and de novo bone formation are recognized as the key mechanisms.⁷

Implant-surface characteristics can significantly influence the attainment of secondary implant stability. This realization was made in the early 1990s with the observation that roughened implant surfaces demonstrated increased histologic bone-to-implant contact (BIC) during healing.⁸ More recently, the functional relevance of different topographic scale ranges in implant-surface design has been acknowledged.⁹ In vivo studies of implants with topographically complex surfaces such as the T3[®] Surface, (Figs. 1a-c) which combines grit blasting, acid etching, and deposition of nanometer-scale calcium

Editorial



Figs. 1a-c. The T3 Implant Surface with nano topography. A.) 500x B.) 50,000x DAE surface C.) 50,000x DAE + nanodeposition of CaP

phosphate crystals, have shown increased shear strength and removal resistance after healing. The observation of increased bone-implant contact has also been made on implants with microtopographically complex surfaces as compared to smoother surfaces.^{10,11}

To assess the biological effect of any given surface treatment, it is most common to apply some variation of a bone/implant disruption test, in which the force required to release the implant from bone is measured. In a study by one of the authors and colleagues that was designed to remove implants from rat femurs at 6, 9, and 12 days, two different surface treatments were compared: grit-blasted and acid-etched versus grit-blasted, acid-etched, and deposition of nano-scale calcium phosphate crystals.¹² The results showed that the addition of the third topographic level substantially increased the removal force at each of the early healing time points (Fig. 2).

At the University of Murcia in Spain, the reverse torque test used to liberate healed implants from rabbit tibia specifically examined the impact of coarse micron (grit blast), fine micron (acid-etched), and submicron (nanotopography DCD) at three time points: 15, 28, and 56 days.¹³ In accordance with the rat femur study, their data also reflected a correlation between scale ranges of topography and biomechanical retention forces: the smaller the topography scale, the

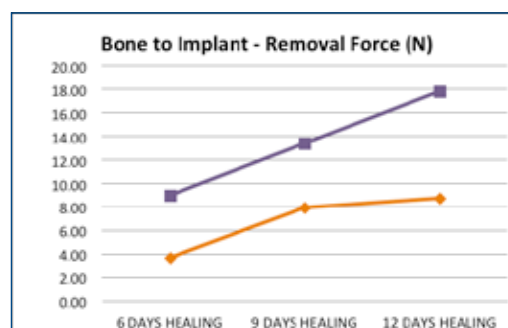


Fig. 2.

earlier the impact on reverse torque, and the larger the scale, the later the impact (Fig. 3).

Results from a prospective randomized-controlled study by Montoya and Nappe of implant groups with two types of surface treatments (control = DCD; test = T3 with DCD) placed in humans and reverse-torque tested with 20 Ncm at six, eight and ten weeks found a higher degree of osseous fixation (resistance to reverse torque) in the test implants at the earlier time points (six and eight weeks).¹⁴ Implants resisting the 20 Ncm test were further subjected to a 32 Ncm reverse torque test to which implant groups with the test surface outperformed control groups at all time points.

As research on the effects of various implant-surface treatments has continued throughout industry and academia, attempts have been made to describe surfaces mathematically,

and the use of so-called “roughness values” has emerged. However, these efforts do not capture the intricate three-dimensional nature of complex surfaces, nor do they provide any significant insight into the biological relevance of implant-surface topography. Nevertheless, it can be hypothesized that every implant surface has an objective osseointegration potential and that this potential could be numerically quantified. Therefore, in order to derive a parameter that provides insight into the osseointegration potential of any given surface, a novel approach was recently initiated at the University of Toronto to apply mathematical modeling techniques to experimental implant disruption-force data resulting in an original concept, and a new perspective on osseointegration.

The Discovery of Tau

The data selected for development of the parameter were obtained from a laboratory study that tested the effects of adding nano-scale surface features to a micro-roughened implant surface.¹⁵ Rectangular titanium implants (1.3 mm × 2.5 mm × 4 mm) were placed bi-cortically in 244 femurs of 122 Wistar rats. All implant surfaces were grit-blasted and acid-etched, and half the implants were further modified by deposition of nano-scale calcium-phosphate crystals (test group). The samples that were grit-blasted and acid-etched represented the control group. Each bone specimen containing an implant was potted in a light-cured dental composite, and the force to disrupt the bone/implant anchorage for each surface type was tested at 5, 9, 14, 28, 84 and 168 days in either tension or shear (Fig. 3). The effects of surface treatment, healing time, and testing mode were determined, and values were compared using the Wald test. Data was compiled using a MATLAB script and analyzed by the statistical software “R.” P values of less than 0.05 were considered significant. A mathematical model was then fitted to the resulting data using the method of least squares, of the form $F=C(1-e^{-x/\tau})$, where F is

the force required to disrupt the implant x days post-operatively, C is the maximum disruption force, and τ is the time constant represented by the time it takes to reach 63.2% of the maximum “C” value. A smaller τ thus represents a shorter time to achieve osseointegration. Curve-fitting was validated by all curves having an $R^2 \geq 0.83$ and plotting 95% confidence intervals. From the plots that were generated (Fig. 4) and the statistical analysis performed, the value of τ was found to be significantly lower ($P < .01$) for the nano-surfaced implants than for the controls when tested in shear. This suggests that nano-scale features accelerate osseointegration. When the value of τ was compared between mechanical testing methods, no significant differences were observed.

Using this model requires both the C and τ parameters for an accurate evaluation of osseointegration performance. But, it is only that provides a means of comparing the rate of osseointegration for different implant surfaces. Implants must have values of C that are sufficiently high to support functional loading, but ideally should be low enough to provide rapid osseointegration. Depending on the values determined by fitting the proposed function, an implant surface will fall into one of four categories: slow to integrate and weak, fast-integrating and weak, slow to integrate but strong, and both strong and fast-integrating. The latter is ideal (Fig. 5).

Clinical Relevance

Application of mathematical modeling techniques to experimental bone/implant disruption force data yields a new parameter, τ , that signifies the time required for an implant to osseointegrate. It is a biologically and functionally relevant means of quantifying implant-surface performance. The value of τ is independent of the test method and only changes with the implant-surface design. The data show that such an exponential function, typical of many biological systems, can

Editorial

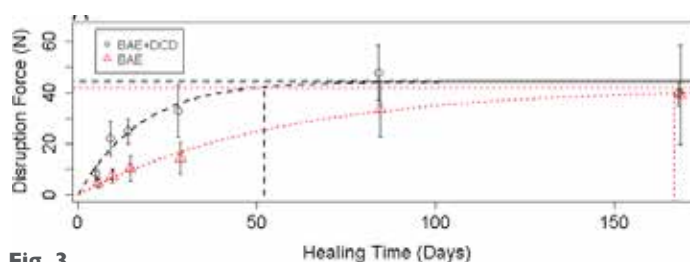


Fig. 3.

also be applied to osseointegration. It promises to influence how the osseointegration potential of various implant-surface technologies can be developed, interpreted, and compared from this point forward.

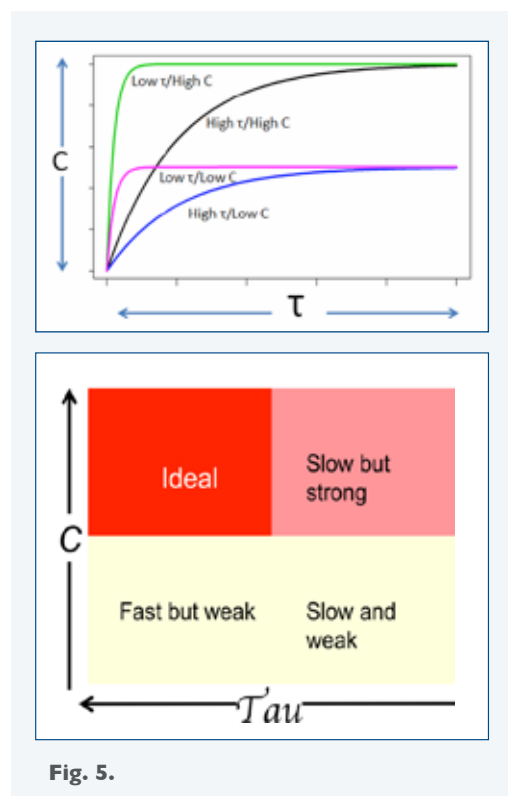


Fig. 5.

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[‡]Dr. Davies has a financial relationship with Zimmer Biomet Dental resulting from speaking engagement, consulting engagements, and other retained services.

[†]Mr. Suttin was employed by Biomet 3i at the time this study was conducted.

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

Davies JE, Ajami E, Moineddin R, Moineddin R, Mendes VC
Biomaterials 2013;34(14):3535-3546.

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 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 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.

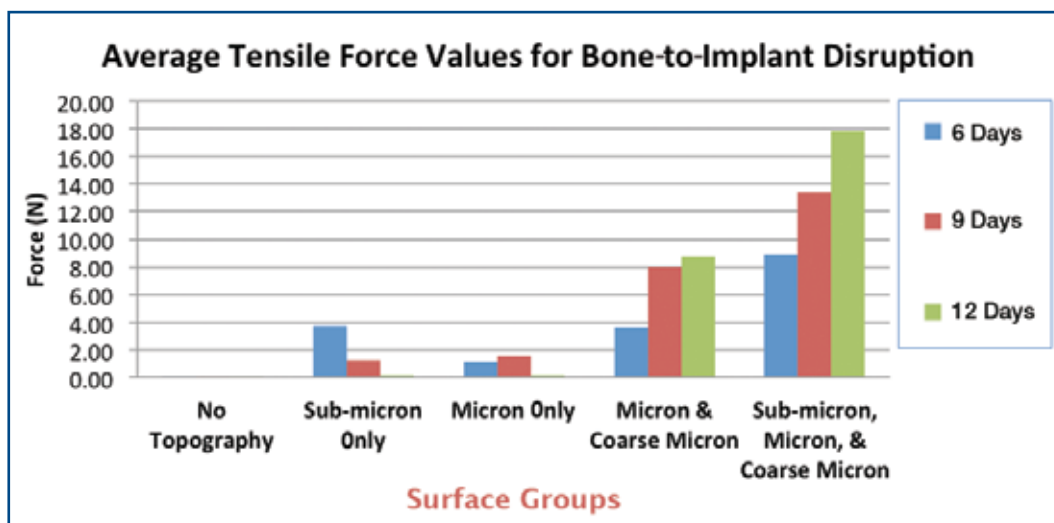


Fig. 1. Average Bone-to-Implant tensile strength for implants with single and combinations of topography scale ranges after 6, 9, and 12 days of healing.

Key to Surface Groups	
Scale Ranges of Topography	Surface Treatment
“No Topography”	Polished (P)
Coarse Micron	Grit-blasted (GB)
Micron	Acid-etched (AE)
Submicron	Discrete crystalline deposition (DCD®)

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

Davies JE, Mendes VC, Ko JC, Ajami E
Biomaterials 2014;35:(1)25-35.

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

Study Design: Preclinical rat femur model; rat bone marrow derived cell assays; field emission scanning electron microscopy (FE-SEM)

Sample Size: n=10 samples per surface group; total=50 custom-made implants

Reported Outcomes: Disruption force value results (newtons) for implant groups from mechanical testing in rat femur model and statistical analysis.

Relevance to T3® Implants: This publication includes data that specifically identify properties of the titanium surface that directly influence the strength of osseous fixation. The data show that the combination of submicron, micron, and coarse micron topographies available on the T3 Implant System lead to synergistic increases in bone fixation. These effects are pronounced during the early period of implant healing. As resistance to the effects of micromotion is recognized as a primary factor in implant integration success, this advancement in surface science contributes to the understanding of dental implant treatment success.

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 undercut 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.

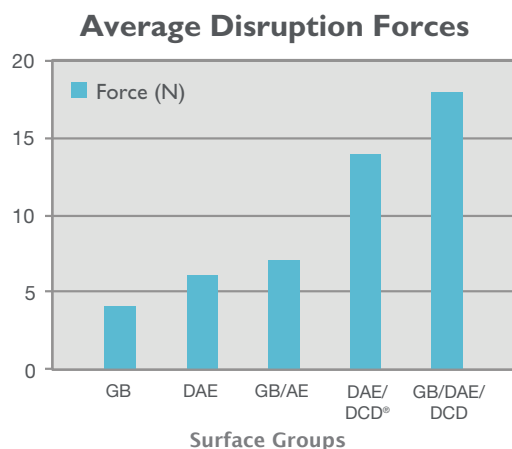


Fig. 1: Average force values (N) required for mechanical rupture of implant sample from rat femur after 9 days healing. Forces are recorded at a crosshead speed of 30 mm/min.

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.

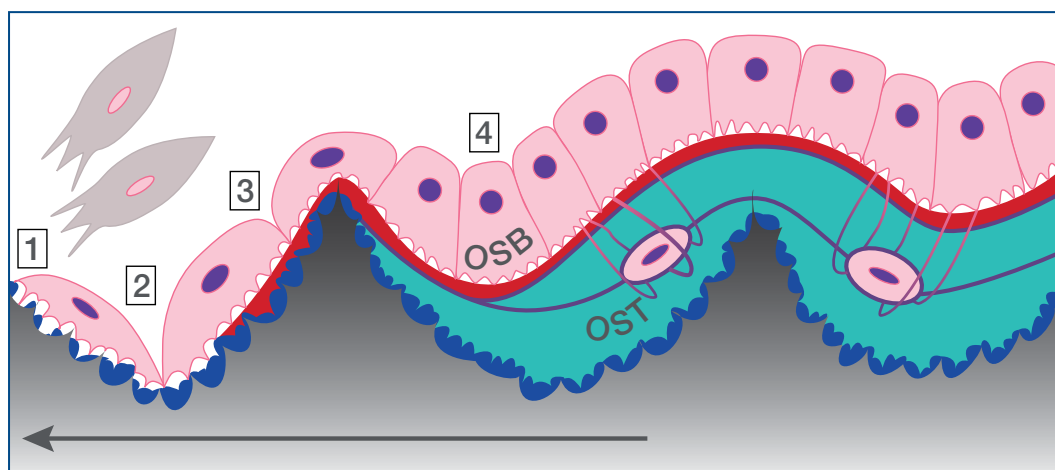


Fig. 2: Illustration of bone growing on a GB/DAE (T3®) implant surface. The direction of osteoconductive bone growth is right to left (arrow).

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 into 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.

(Fig. 2 is courtesy of Dr. J E Davies. To view FE-SEM photomicrographs associated with Fig. 2, refer to the publication and for animation of the Fig. visit: <http://www.ecf.utoronto.ca/~bonehead/>).

[†]Dr. Davies had a financial relationships with BIOMET 3i LLC at the time the study was conducted.

Influence of surface treatment on osseointegration of dental implants: Histological, histomorphometric and radiological analysis *in vivo*

Calvo-Guirado JL, Satorres-Nieto M, Aguilar-Salvatierra A, Delgado-Ruiz RA, Maté-Sánchez de Val JE, Gargallo-Albiol J, Gómez-Moreno G, Romanos GE.
Clin Oral Investig. 2015;19(2):509-517.

Center: University of Murcia, Murcia, Spain.

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

Sample size: custom Biomet 3i tapered, threaded implants (3.25 mm x 8 mm);
N = 4 per animal; 120 = total

Reported Outcomes: Histology and histomorphometrics (%BIC); SEM analysis of chemical composition of surrounding bone.

Relevance to T3® Implants: Both T3® and T3® with DCD surface treatments are represented in the implant groups and show trends for higher histomorphometric outcomes.

Objective

The objective of this study was to compare the influence of surface treatment on implant integration in bone of rabbit tibias after 14, 28 and 56 days of healing as suggested by histological bone-implant contact values. Measurement of the chemical composition of the bone above the implants helps to define the quality of the newly formed bone.

Materials and Methods

A total of 30 female New Zealand white rabbits had each tibia randomized to receive two of the total four implant treatment groups: Surface A) blasted, acid-etched (AE) and discrete crystalline deposition (DCD); Surface B) blasted; Surface C) AE; Surface D) blasted, AE. Animals were divided into three groups to be sacrificed at 14, 28 and 56 days at which time samples were extracted and processed for histological and chemical processing.

Results

Average Bone-Implant-Contact (BIC), measuring both cortical and trabecular mineralized bone contact, produced the results presented in Fig. 1 and Table 1. The differences between surfaces are not statistically significant. When the average of all BIC values was calculated for each surface, the value for Surface A has 9.1% more BIC than the second-best Surface D. Average BIC for Surface A is also 15.4% higher than Surface C and 40.9% higher than Surface B. The authors discuss how normal biological patterns for integration show higher BIC values during initial and at final time periods than during the intermediate time period as is observed for the surfaces under evaluation, especially for Surface A. Measurement of the chemical composition of bone above the implants resulted in the outcomes presented in Fig. 2 for carbon, oxygen, phosphorous, calcium and titanium. Ca/P Ratios for the four surfaces are as follows: A = 1.762, B = 1.625, C = 1.663 and D = 1.722. Higher Ca/P ratios indicate better maturation of bone and better bone metabolism, and the outcomes here also show an association with the trend for better BIC results.

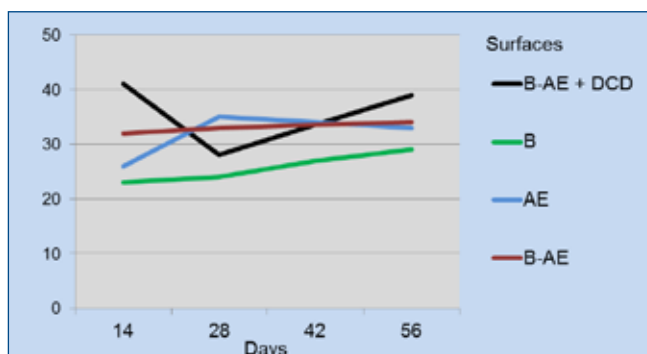


Fig 1. Percentage of bone-implant contact for all surfaces and all time points evaluated.

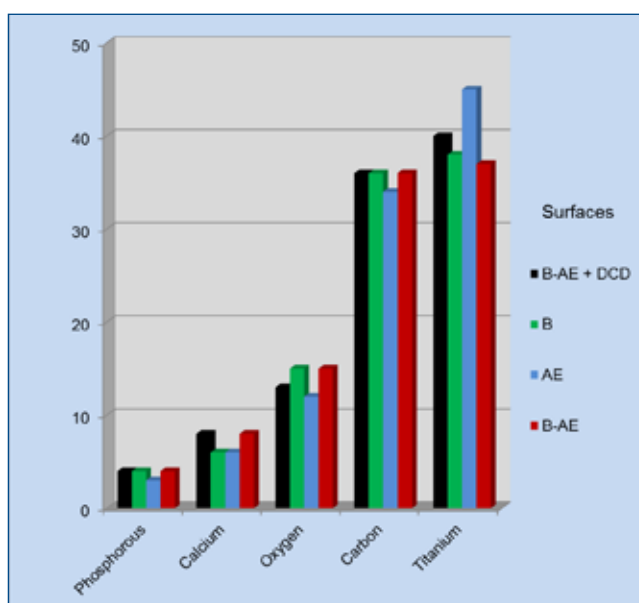


Fig 2. Measurements of the chemical composition of the bone above the implants with the four different surfaces.

Days	Surface A BIC ± SD	Surface B BIC ± SD	Surface C BIC ± SD	Surface D BIC ± SD
14	40.80 ± 2.3%	23.34 ± 2.1%	25.72 ± 2.3%	32.00 ± 2.5%
28	27.75 ± 1.1%	23.77 ± 1.9%	34.92 ± 2.2%	32.85 ± 1.4%
56	39.40 ± 1.4%	29.47 ± 1.7%	32.91 ± 1.6%	34.04 ± 2.3%

Table 1. Percentages of bone-implant contact (BIC ± standard deviation) for each of the surfaces at all time points.

Conclusion

According to this preclinical model, tapered, threaded titanium implants having surfaces with either a blasted, acid-etched with DCD or a blasted, acid-etched treatment show a tendency to better overall integration during 8 weeks of healing as compared to the other two surfaces evaluated: blasted alone or acid-etched alone.

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

Sul Y-T, Towse R†
 Int J Periodontics Restorative Dent 2014;34(1):e18-25.

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 T3® Implants: In this study at three weeks of healing, biomechanical outcomes representing the T3 with DCD® Surface were higher and a greater degree of *de novo* bone formation was observed.

Abstract

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 3.4 mm x 6.5 mm 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.

Surface Groups		Coarse Micron	Micron	Submicron	Surface Chemistry (atomic %)				
		10+ μ m	1 to 3 μ m	10 to 100nm	Carbon	Oxygen	Calcium	Phosphorous	Titanium
C	blast (B) acid-etched (AE)	X	X	NOT present	3.1	ND	ND	ND	96.9
T	blast (B) acid-etched (AE) hydroxyapatite (DCD)	X	X	X	4.2	27.9	1.0	0.8	66.1

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)

Groups	RFA (ISQ)	RTQ-Peak (Ncm)	<i>de novo</i> (%)
C	75.58	\pm 6.47	29.9
T	77.75	\pm 3.07	39.9

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 biomechanic impact of the variable of the submicron features of DCD of the Test Group.

†The author conducted this research while employed at Biomet 3i.

Abstract

Biomechanical and histological evaluation of four different titanium implant surface modifications: An experimental study in the rabbit tibia

Calvo-Guirado JL, Satorres M, Negri B, Ramirez-Fernandez P, Maté-Sánchez JE, Delgado-Ruiz R, Gomez-Moreno G, Abboud M, Romanos GE
Clin Oral Investig 2014;18(5):1495-1505.

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 T3® Implants: Of the four implant surface treatments tested in this study, both 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.

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.

Surface	Abbreviation	Treatment	Mean Sa (microns)	Relevant BIOMET 3i Surface
A	BAE + DCD®	Blasted/acid-etched with DCD	1.37	T3® with DCD
B	B	Blasted	1.63	—
C	AE	Double acid-etched	0.5	OSSEOTITE®
D	BAE	Blasted/acid-etched	1.37	T3

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

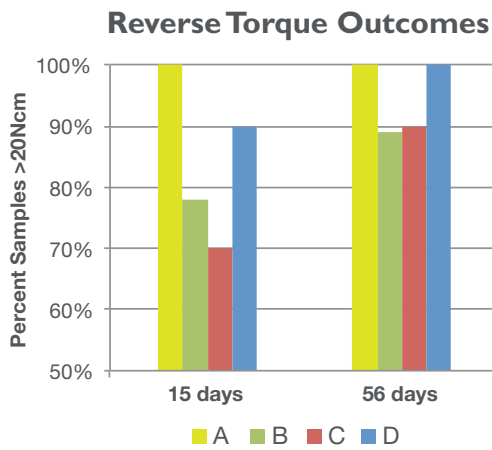


Fig. 1: Reverse Torque Values (RTV) required to remove integrated implants from rabbit tibia harvested at different evaluation periods are reported as the percent of samples per group with torque readings >20Ncm. After 56 days, the RTV was higher for the group with surface D. The micro roughness of the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

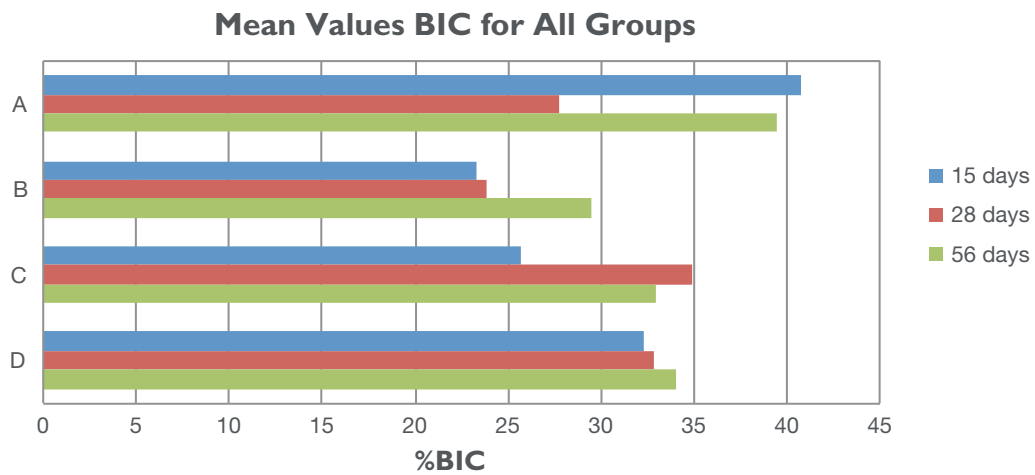


Fig. 2: The BIC values at 15 days were higher for Group A, however after 56 days show a slight reduction. Group D showed a gradual pattern of increased BIC during all the periods.

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
Implant Dent 2012;21(6):454-460.

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 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 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.

*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 ML, Schupbach P, Fiorellini J, Lin Z, Kim DM
 Int J Periodontics Restorative Dent 2012;32(6):637-645.

Center: Perio Imp Research Inc., investigators affiliated with Harvard University, Massachusetts, USA

Study Design: Pre-clinical canine mandible model

Sample Size: n=2-4 per test surface/time point; total=40 implants

Reported Outcomes: Histology, Bone-to-Implant Contact (BIC), radiography, and stability (Osstell ISQ) at 0, 7, 14, 28, and 56 days

Relevance to T3® Implants: All study implants have the 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.

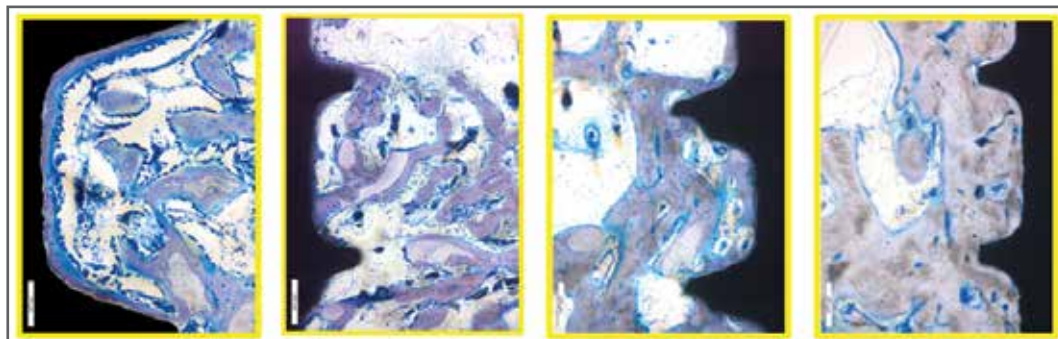


Fig. 1: Examples of Bone Formation at 7, 14, 28, and 56 Days (moderate compression group).

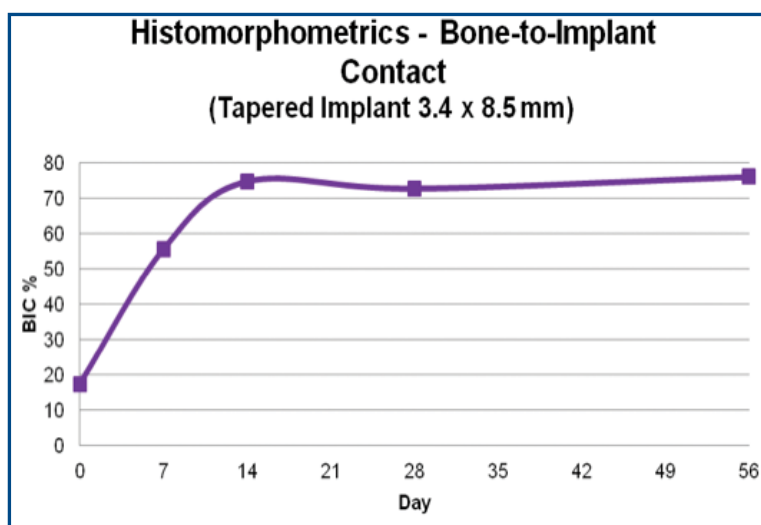


Fig.2. Bone-to-Implant Contact (moderate compression group).

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 60s.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:

9. Abrahamsson I, Linder E, Lang NP. Implant stability in relation to osseointegration: An experimental study in the Labrador dog. *Clin Oral Implants Res* 2009;20:313-318.

[†]Dr. Nevins had a financial relationship with Biomet 3i LLC resulting from speaking engagements, consulting engagements, and other retained services at the time the study was conducted.

*Preclinical results are not necessarily indicative of clinical performance.

Comparison of three *in vitro* implant leakage testing methods

Al-Jadaa A†, Attin T, Peltomäki T, Schmidlin SR
Clin Oral Implants Res. 2015;26(4):e1-7.

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 T3® Implants: The Biomet 3i Certain® Connection subjected to testing in this study is included on the 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 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 was supported by Biomet 3i.

Abstract

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 four contemporary implant systems

Sample Size: n=1 per implant system/diameter

Reported Outcomes: Qualitative images of cross-sectioned implant-abutment interfaces and quantitative measurements of the overall microgap size

Relevance to T3® Implants: The study demonstrates that the microgap for the Biomet 3i Certain® Connection system, available on T3 Implants, measured ~1.0 μ on average and approached 0 μ in several areas along the connection. As compared to three other commercial implant systems, two showed larger microgaps at the interface.

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, 3.5 mm D × 15.0 mm L and 4.5 mm D × 13.0 mm L), Bone Level implants (Straumann, 3.3 mm D × 12.0 mm L and 4.1 mm D × 12.0 mm L), Active implants (Nobel Biocare, 4.3 mm D × 13.0 mm L and 5.0 mm D × 11.5 mm L), and novel tri-topography T3 Implants (Biomet 3i, 3.25 mm D × 13.0 mm L and 4.0 mm D × 13.0 mm 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

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

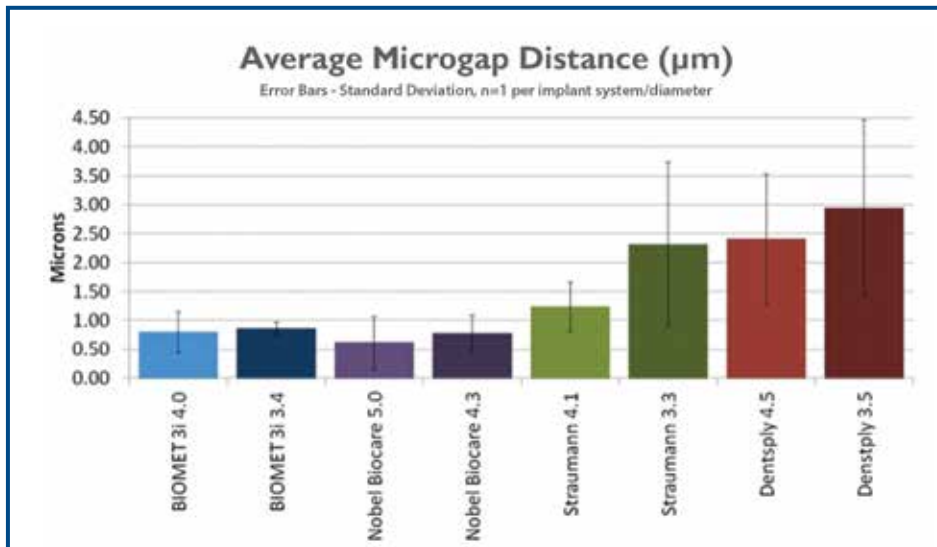


Fig. 1. Average microgap measurement (microns).

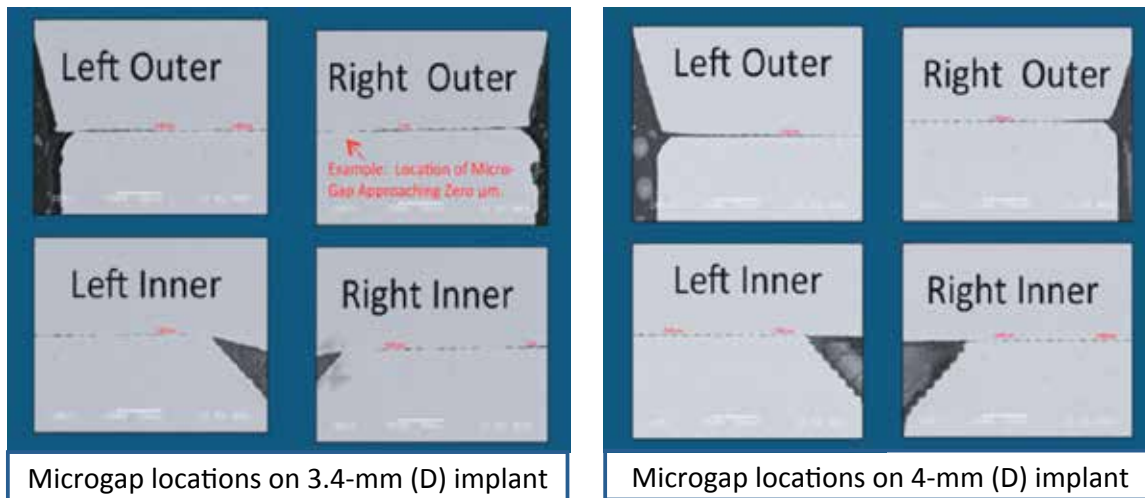


Fig. 2. T3 with DCD microgap images.

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 system 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.

Abstract

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.

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 T3® Implant: The Biomet 3i Certain® Connection, which is included on the 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 3.0 mm of the coronal portion while allowing access 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.

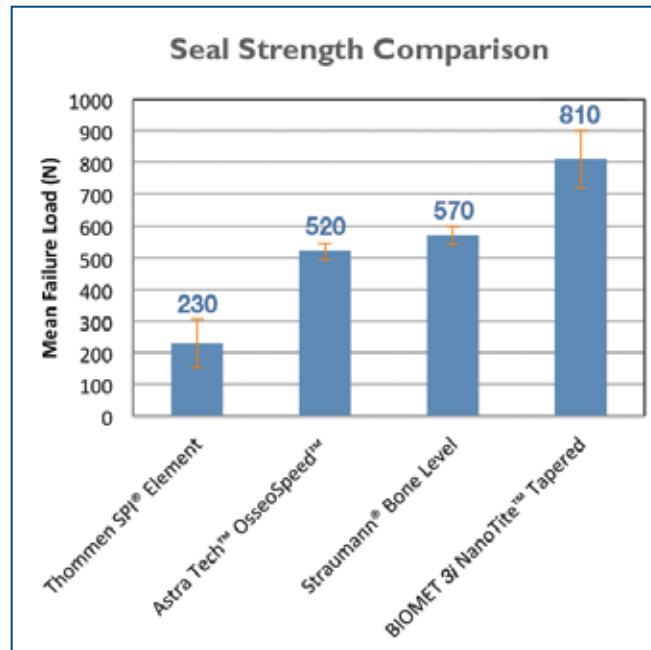


Fig. 1. Seal strength comparison of contemporary implant systems (n=5).

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

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

Abstract

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 T3® Implants: This characterization study includes an implant featuring the 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 a turned surface at the coronal aspect and the remaining surface was dual acid-etched,

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

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.

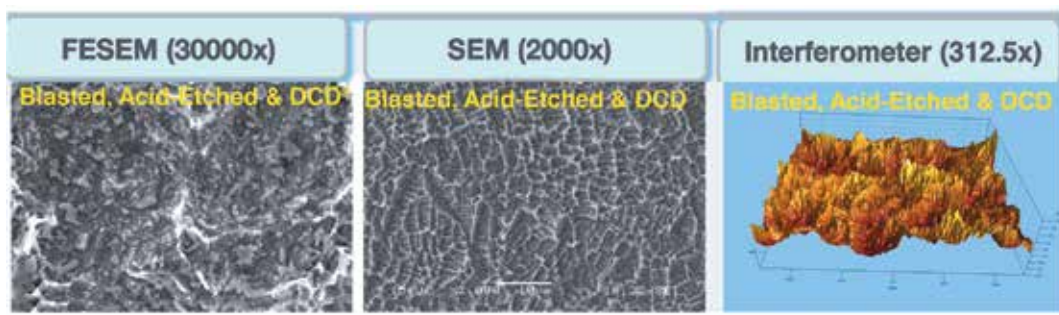


Fig. 1: Biomet 3i new implant design surface images.

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

Torque stability of different abutment screws submitted to mechanical cycling

Vianna Cde A, Delben JA, Barão VAR, Ferreira MB, dos Santos PH, Assunção WG.
Int J Oral Maxillofac Implants. 2013;28(5):e209-214.

Center: Aracatuba Dental School, University of Sao Paolo, Brazil

Study Design: Characterization of retention screw stability at implant-abutment assembly based on mechanical torque testing

Sample Size: n=10 for each of the four groups; total=40 retention screw assemblies

Reported Outcomes: Torque removal values (newtons) for retention screws measured before and after mechanical cycling (1×10^6 cycles at 2Hz under 130N) and statistical analysis

Relevance to T3® Implants: The Biomet 3i Gold-Tite® Screw belongs to the assembly of restorative components for the T3 Implants. The final reverse torque outcomes were higher with the Gold-Tite Screws versus non-coated screws, which suggests that the probability of screw loosening is lower for Gold-Tite Screws.

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 (1×10^6 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.

Table I RT Values (Means and Standard Deviations, in Ncm) of groups Ti, Au, TiC, and TiN Before (Initial) and After (Final) Mechanical Cycling					
Groups	IT	RT		% torque maintenance	
		Initial	Final	Initial	Final
TI	20	15.45 (1.89)	13.80 (1.42)	77.25 (9.44) ^{aA}	69.00 (7.09) ^{aB}
AU	20	14.67 (1.84)	14.40 (1.73)	73.33 (9.22) ^{abA}	72.00 (8.64) ^{aA}
TIC	32	25.47 (1.27)	24.10 (1.63)	79.58 (3.97) ^{aA}	75.31 (5.09) ^{aA}
TIN	35	24.67 (0.85)	24.10 (2.58)	70.47 (2.42) ^{ba}	68.86 (7.37) ^{aA}

Table I: Reverse torque value outcomes for retention screw groups.

^{a,b} Means followed by different lowercase letters in the same column represent statistically significant differences (P < .05; Fisher test).

^{A,B} Means followed by different uppercase letters in the same row represent statistically significant difference (P < .05; Fisher test).



Preservation
by Design®

T3® Implant

- 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 0.37 mm of bone recession.*²
- Designed to reduce microleakage through exacting interface tolerances and maximized clamping forces.



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

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

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

*0.37 mm bone recession not typical of all cases.

†The authors contributed to this article while employed by ZimVie.

††Dr. Östman had a financial relationship with ZimVie at the time the study was conducted.



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