

***Dynamic Loading Fluid Leakage Characterization
of Dental Implant Systems***

Dynamic Loading Fluid Leakage Characterization of Dental Implant Systems

Introduction

The integrity of the dental implant-abutment junction (IAJ) has clinical relevance due to the potential detriments associated with an inferior seal. Specifically, it has been hypothesized that a poorly sealed IAJ permits contamination of microbes within the implant connection to leak into the surrounding tissues.^{1,2} This contamination may lead to inflammation and the potential for localized tissue loss.

The loss of significant amounts of hard tissue may decrease the stability of the implant, potentially threatening its function. However, a negative aesthetic impact is more common due to the secondary effect of crestal bone loss on soft-tissue height and/or volume.³

Over the past thirty years the dental implant industry has developed and marketed a wide array of implant and connection designs. The connection design of a three-part dental implant system generally consists of the dental implant mating feature, the abutment mating feature, and the retaining screw. These three components should be engineered to work in concert to provide adequate retention, anti-rotation, strength, stability, predictable seating, and seal.

The objective of this study was to characterize the IAJ seal robustness of several industry-leading dental implant systems subjected to a dynamic loading leakage test.

Materials and Methods

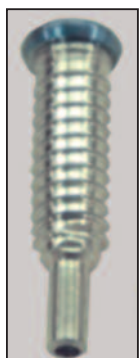


Figure 1: Representative implant with the tube-connection barb.

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,⁴ which is the standard test method utilized by the industry to demonstrate system strength.

Specifically, the apex of the implant sample was modified to have a barb fitting and a hole was machined to reach the internal

aspect (Figure 1). The implant was fixated in a phenolic-resin block, exposing 3.0mm of the coronal portion while allowing access to the apical barb (Figure 2). Per ISO14801, 3.0mm of bone loss should be simulated to represent a worst case condition with respect to bone retraction.⁴ Tubing was connected to the implant barb and a straight abutment and screw were loosely assembled to the implant. Red dye was bled through the system using a peristaltic pump to eliminate air bubbles and confirm flow. The manufacturer's recommended screw torque was then applied to the retaining screw and the system was thoroughly rinsed.



Figure 2: Representative implant mounted with 3.0mm simulated resorption.

The block was mounted in an electrodynamic test instrument (ElectroPuls™ E-1000, Instron®, Norwood, Massachusetts) at 20 degrees off-axis in a clear tank filled with fresh water (Figure 3). The 20 degree off-axis load was selected to simulate a worst-case prosthetic loading condition. Based on manufacturer recommendations, if an implant is placed in a position greater than 15 degrees off-axis, a pre-angled versus a straight abutment should be utilized.⁵ The pump was turned on and the internal volume was pressurized to approximately 7 PSI. The IAJ was monitored through utilization of a high resolution video camera at 50x magnification to qualify the seal integrity (Figure 4).

If no leakage was initially detected, the abutment was cyclically loaded at 100 Newtons (N) for 100,000 cycles with the pump off to represent system usage.

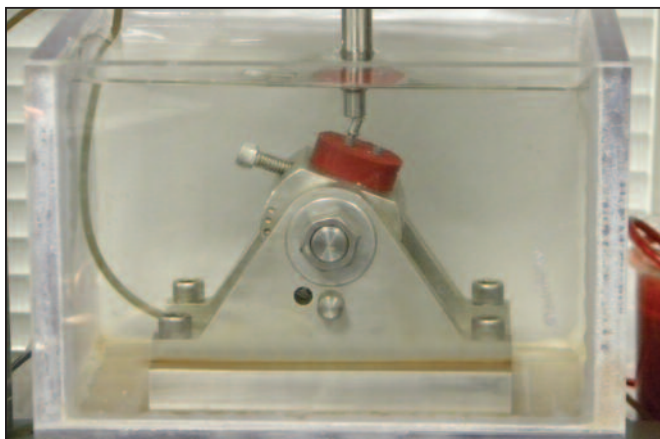


Figure 3: Test system mounted on the electrodynamic testing machine (with water tank).

After the usage cycle, the seal was qualified by turning the pump on and visually monitoring the IAJ while loading at 2 Hz, 100 N, for 1,000 cycles. If the sample successfully completed the qualification, the entire process (100,000 cycles usage cycle, 1,000 cycles qualification) was repeated at a 50 N higher load. This protocol was continued with incremental loads until leakage, yield (permanent deformation) and/or fracture was detected.



Figure 4. Representative implant magnified interface.

Five (n=5) samples were tested for each system, then evaluated. Depending upon the normality of the results' distribution, the data sets were statistically compared using a student t-test of means or a non-parametric Mann-Whitney test of medians. Differences were considered significant when $P \leq .05$.

The study was broken down into two subsections. The first section evaluated and compared the performance of four industry representative implant systems. A description of the four systems is included in Table 1.

Implant (material)	Implant Connection Type	Implant Size	Abutment Size	Abutment Screw
Thommen SPI® Element (CP Ti)	Horizontal / Flat on Flat	4mm (Diameter) x 14mm (Height)	4mm (Connection) x 8mm (Height)	Titanium Alloy Screw
Astra Tech™ OsseoSpeed™ (CP Ti)	Vertical / Conical	4mm (D) x 14mm (H)	4mm (C) x 9mm (H)	Titanium Alloy Screw
Straumann® BoneLevel (CP Ti)	Vertical / Conical	4.1mm (D) x 14mm (H)	4.1mm (C) x 9mm (H)	Titanium Alloy Screw
3i T3™ with DCD™ – Platform Switching Tapered Implant, BNPT (CP Ti)*	Horizontal / Flat on Flat	4/3.4mm (D) x 15mm (H)	3.4 (C) x 8mm (H)	Certain® Gold-Tite® 316L SS Screw (20Ncm)

Table 1: Industry representative implant systems evaluated.

In the second section of the study, a single manufacturer's system was explored more thoroughly. In this section, BIOMET **3i** Implant System were further characterized to evaluate the impact of a change in implant material and/or screw material/coating. A description of the additional BIOMET **3i** Implant Systems tested is included in Table 2.

The two additional systems tested shared an equivalent macrogeometric design to the **3i** T3 with DCD – Platform Switching Tapered Implant (BNPT) used in the first section, therefore permitting the implant material and/or screw material/coating to be treated as independent variables.

Results

Implant (material)	Implant Connection Type	Implant Size	Abutment Size	Abutment Screw
BIOMET 3i Certain NanoTite™ Tapered PREVAIL®, NIITP (Ti Alloy)	Horizontal / Flat on Flat	4/3.4mm (D) x 15mm (H)	3.4 (C) x 8mm (H)	Titanium Alloy Screw (20Ncm)
BIOMET 3i Certain NanoTite Tapered PREVAIL, NIITP (Ti Alloy)	Horizontal / Flat on Flat	4/3.4mm (D) x 15mm (H)	3.4 (C) x 8mm (H)	Certain Gold-Tite 316L SS Screw (20Ncm)

Table 2: Additional BIOMET **3i** Implant Systems evaluated.

*Not yet available for sale in the United States.

Study Section 1: The raw data for study section 1 is summarized in Table 3.

The implant systems with horizontal/flat on flat interfaces (BIOMET **3i** and Thommen) always experienced leakage failure modes, but their seal strength was quite different. The systems with a vertical conical-based interface (Astra Tech™ and Straumann) displayed one of two failure modes. In several circumstances, the implant/abutment system fractured completely (e.g. the implant or screw broke), while in others, the retaining screw appeared to “yield” or “bend,” resulting in leakage.

System Failure Load (N)				
Sample	Thommen SPI® Element	Astra Tech OsseoSpeed™	Straumann® Bone Level	3i T3™ with DCD
1	200 (L)	500 (Y/L)	550 (F)	700 (L)
2	200 (L)	550 (Y/L)	550 (F)	750 (L)
3	150 (L)	500 (F)	550 (F)	750 (L)
4	350 (L)	550 (Y/L)	600 (F)	750 (L)
5	250 (L)	500 (F)	600 (Y/L)	750 (L)
Mean	230	520	570	740
Standard Deviation	76	27	27	22

Table 3: Seal strength test data from industry representative samples.

The statistical analyses for Study Section 1 are summarized in Table 4.

The Thommen system failed at the lowest values overall. Its results were statistically lower than all other systems tested. The Astra Tech system had the next lowest set of values. Its results were statistical lower than Straumann and the **3i** T3 System. The **3i** T3

Comparison	Normal Distributions per Anderson Darling Test	2-Sample T-Test of Means (if applicable)	Mann-Whitney Test of Medians	Statistical Difference(s)
Thommen vs. Astra Tech	No	NA	P<.05	YES, Thommen’s median was lower than Astra Tech.
Thommen vs. Straumann	No	NA	P<.05	YES, Thommen’s median was lower than Straumann.
Thommen vs. 3i T3	No	NA	P<.05	YES, Thommen’s median was lower than BIOMET 3i .
Astra Tech vs. Straumann	No	NA	P<.05	YES, Astra Tech’s median was lower than Straumann.
Astra Tech vs. 3i T3	No	NA	P<.05	YES, Astra Tech’s median was lower than BIOMET 3i .
Straumann vs. BIOMET 3i	No	NA	P<.05	YES, Straumann’s median was lower than BIOMET 3i .

Table 4: Statistical comparisons of industry representative systems.

System provided the highest values, demonstrating a statistically significant difference in seal strength versus the three other systems evaluated.

Study Section 2: The BIOMET **3i** Implant System was explored in additional depth to characterize the variables responsible for its high level of performance. The raw data for section 2 is included in Table 5.

System Failure Load (N)			
Sample	3i T3 w/ Gold-Tite® Screw (CP Ti Implant)	BIOMET 3i NIITP w/ Gold-Tite Screw (Ti Alloy Implant)	BIOMET 3i NIITP w/ Ti Alloy Screw (Ti Alloy Implant)
1	700 (L)	700 (L)	450 (L)
2	750 (L)	950 (L)	500 (L)
3	750 (L)	850 (L)	600 (L)
4	750 (L)	750 (L)	500 (L)
5	750 (L)	750 (L)	450 (L)
Mean	740	800	500
Standard Deviation	22	100	61

Table 5: Seal strength test data from BIOMET **3i** Systems.

The three BIOMET **3i** Implant Systems evaluated all experienced leakage failure modes, although the forces resisted were quite different based on the retaining screw utilized.

The statistical analyses for study section 2 are summarized in Table 6.

The study analyses did not indicate a statistically significant difference between the BIOMET **3i** Implant Systems utilizing different implant materials (P=.4083). However, the analyses demonstrated that usage of the Gold-Tite Retaining Screw is an important variable in

Comparison	Normal Distributions per Anderson Darling Test	2-Sample T-Test of Means (if applicable)	Mann-Whitney Test of Medians	Statistical Difference (s)
3i T3™ (CP Ti) with Gold-Tite® Screw vs. BIOMET 3i NIITP (Ti Alloy) with Gold-Tite Screw	NO	NA	P=.4083	NO, a statistical difference was not detected between the BIOMET 3i implants of different material construction.
3i T3 (CP Ti) with Gold-Tite Screw vs. BIOMET 3i NIITP (Ti Alloy) with Ti Alloy Screw	NO	NA	P<.05	YES, the 3i T3 System's median was greater than the NIITP with Ti Alloy Screw.
BIOMET 3i NIITP (Ti Alloy) with Gold-Tite Screw vs. BIOMET 3i NIITP (Ti Alloy) with Ti Alloy Screw	YES	P<.01	NA	YES, the NIITP with Gold-Tite Screw mean was greater than the NIITP with Ti Alloy Screw.

Table 6: Statistical comparisons of BIOMET **3i** Systems.

seal strength. In both comparisons where the Gold-Tite Screw was utilized as an independent variable, the seal strength of the system with the Gold-Tite Screw was found to be significantly greater than the corresponding group utilizing an uncoated titanium alloy screw.

Discussion

The seal properties of two-part dental implant systems are a popular topic of study. As such, researchers have developed multiple methodologies to characterize them including, but not limited to:

- Scanning electron microscopy microgap analysis⁶
- Fluid microleakage testing⁷
- Microbial leakage analysis⁸

Each of these methods has potential limitations in regards to its representation of the clinical scenario.

Baldasari et al used Scanning Electron Microscopy (SEM) analysis to physically evaluate the marginal gap values of the implant-abutment interface.⁶ They reported an average gap distance of 1.7 microns for the BIOMET **3i** Implant System using a BellaTek™ Encode® Titanium Abutment with a Gold-Tite Screw.⁶ As a comparison, in the same study, Nobel Replace® implants with Procera® Zirconia abutment samples averaged 8.2 microns of marginal gap.⁶ A limitation of this analysis was in its inability to measure the complete marginal gap. Baldasari's methodology examined the external surface of the abutment-implant interface, therefore restricting the analysis to the circumferential portion of the interface.

An additional, complementary method involves mounting and cross-sectioning the assembled system to obtain a more complete view of the interface. Figure 7 examines the IAJ of a cross sectioned, **3i** T3 4.0/3.4mm Implant, GingiHue® Abutment and Gold-Tite Screw. The representative scanning electron microscopy images (JSM-6460LV, JEOL, Tokyo, Japan) demonstrate similar results to Baldasari et al with a ~2 micron gap at the external interface. However on further examination inward, the gap was witnessed to decrease to ~0 microns providing an indication of a complete 360° IAJ physical seal.

While SEM analysis is an important analytical tool, an additional limitation of this type of methodology is its static, non-loaded nature. In-vivo, implant systems are exposed to dynamic occlusal loading forces. If these forces are off-axis and high enough, it is anticipated that flexing of the screw and/or abutment could occur, resulting in micromotion at the IAJ. These off-axis forces may cause the abutment to “rock” back and forth, potentially affecting the resultant size of the IAJ microgap and its subsequent sealing attributes during each mastication cycle.

The size of the microgap required to permit leakage is dependent upon the media composition intended to be sealed. In general, all matter is made up of molecules and as such the theoretical allowable size of a gap to prevent all leakage must be smaller than a molecule (e.g. a water molecule has a maximum diameter of <0.0002 microns).⁹ However, factors such as a decrease in the media's molecular density can

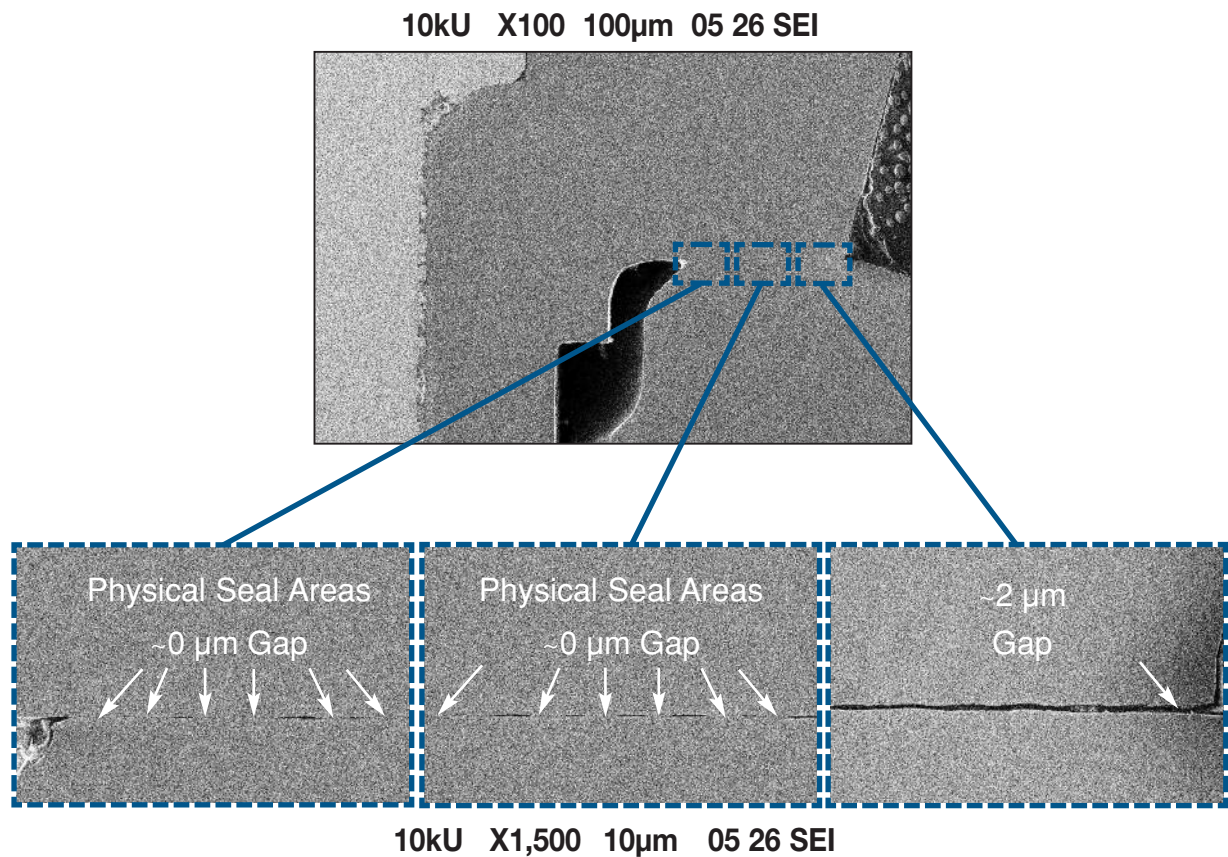


Figure 7: Scanning electron microscopy images of cross sectioned BIOMET **3i** System implant-abutment interface. The interface area is magnified at 1500x magnification to adequately view and quantify the potential microgap.

contribute to their ability to leak in/out of a gap. Gases are well known to have the lowest densities, followed by liquids and then solids. In the dental environment, one is typically concerned with the transfer or leakage of “solid” organisms, such as bacteria. The bacteria species in the oral microbiota generally average 1-2 microns in diameter and 2-6 microns in length.¹⁰ In comparison to a liquid media, the density and overall size of the bacteria are much larger.

For this study, a new test was developed to improve and build upon the existing “seal” data sets. The test incorporated off-axis dynamic loading to simulate occlusal forces, liquid dye to provide a low molecular density media to be sealed, pressurization of the liquid media to challenge the seal, and 50x visual magnification for measurement sensitivity. Additionally, the method included a step-wise loading protocol in order to ensure a definitive failure end-point was reached for statistical comparison.

Three of the four systems tested were able to withstand cyclic loads of 500 N or greater before failure (Figure 8). This load is clinically possible in the molar regions as a single maximum occlusal force event,¹¹ but repeated loading at this off-axis angle and high force level would

not be anticipated. The test method required these high forces to demonstrate the differences between the systems, however it was understood that survival at these cyclic load levels may not be required for clinical success.

The 50x magnification visual dye leakage detection method utilized was found to be appropriate for comparison testing, but its ultimate level of sensitivity is unknown. Therefore, the test method did not definitively prove that any of the implant systems tested were fluid leak “proof.” Rather, the testing could only be used as a comparison of relative performance under equivalent test and detection conditions. Subsequently, a direct correlation has not been established between the results of this particular test and other “seal integrity” outcomes. For example, this dynamic fluid leakage test did not detect leakage in the Straumann® or Astra Tech™ Systems at up to 500 N of cyclic force. However, the published results of several static microbial leakage tests have found contradictory results. For example, Proff et al demonstrated “out to in” colonization while Rimanchian et al showed “in to out” bacterial leakage with the Straumann system.^{12,8} Similarly in 2010, Harder et al published that the Astra Tech system was unable to prevent endotoxin leakage.¹³

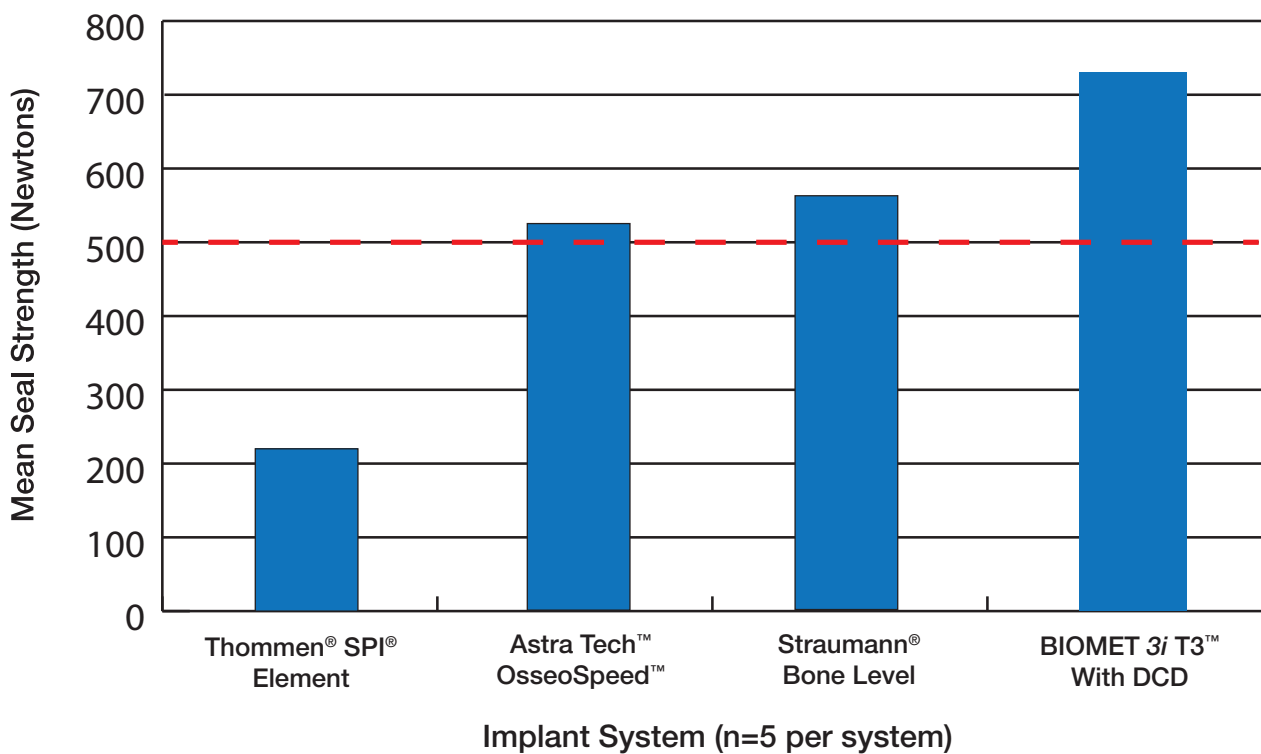


Figure 8: Graphical representation of mean seal strength results of 4mm dental implant systems.

In this study, two horizontal / flat-on-flat connections were evaluated and compared. These systems demonstrated significant differences in performance characteristics (740 vs. 230 N). The second portion of this study determined that approximately half of this difference could be attributable to the BIOMET **3i** Gold-Tite® Screw technology and its resultant increase in clamping (pre-load) force.¹⁴ The other half of the difference was most likely related to variations in design and/or the precise manufacturing of the interfaces. Nonetheless, these fluid leakage results demonstrate that not all horizontal / flat-on-flat connections perform the same. Therefore, it is important to be cautious when reaching generalized performance conclusions based on broad connection-type definitions.

Conclusion:

The implant-abutment junction seal robustness of BIOMET **3i**, Straumann, Astra Tech and Thommen Implant Systems was assessed utilizing a dynamic fluid leakage test. The implant systems withstood average forces of 740 N, 570 N, 520 N and 230 N prior to failure. The BIOMET **3i** Implant System withstood statistically higher cyclic forces than the other systems tested (p -value<.05).

In a secondary evaluation of the BIOMET **3i** Implant System, it was determined that the use of a Gold-Tite Abutment Retaining Screw provided a statistically significant increase in cyclic force resistance prior to failure (p -value<.05).

References

1. Lazzara RJ, Porter SS. Platform switching: A new concept in implant dentistry for controlling post-restorative crestal bone levels. *Int J Periodontics Restorative Dent* 2006;26:9-17.
2. Fickl S, Zuhr O, Stein JM, Hürzeler MB. Peri-implant bone level around implants with platform-switched abutments. *Int J Oral Maxillofac Implants* 2010 May-Jun;25(3):577-581.
3. Vela X, Méndez V, Rodríguez X, Segalá M, Tarnow DP. Crestal bone changes on platform-switched implants and adjacent teeth when the tooth-implant distance is less than 1.5 mm. *Int J Periodontics Restorative Dent* 2012 Apr;32(2):149-155.
4. ISO 14801 – Dentistry – Implants – Dynamic fatigue test for endosseous dental implants, ISO, 2007.
5. BIOMET **3i** Product Catalog for Restorative Technologies, CATRES, Rev B. Feb 2011: page 1.
6. Baldassarri M, Hjerpe J, Romeo D, Fickl S, Thompson VP, Stappert CF. Marginal accuracy of three implant-ceramic abutment configurations. *Int J Oral Maxillofac Implants* 2012 May-Jun;27(3):537-543.
7. Gross M, Abramovich I, Weiss EI. Microleakage at the abutment-implant interface of osseointegrated implants: a comparative study. *Int J Oral Maxillofac Implants* 1999 Jan-Feb;14(1):94-100.
8. Rismanchian M, Hatami M, Badrian H, Khalighinejad N, Goroohi H. Evaluation of microgap size and microbial leakage in connection area of four abutments with Straumann (ITI) Implant. *J Oral Implantol* 2011 Nov 2. [Epub ahead of print]

9. "water". Encyclopedia Britannica. Encyclopedia Britannica Online. Encyclopedia Britannica Inc., 2012. Web. 11 Jul. 2012. <http://www.britannica.com/EBchecked/topic/636754/water>.
10. do Nascimento C, Miani PK, Pedrazzi V, Gonçalves RB, Ribeiro RF, Faria AC, Macedo AP, de Albuquerque RF Jr. Leakage of saliva through the implant-abutment interface: in vitro evaluation of three different implant connections under unloaded and loaded conditions. *Int J Oral Maxillofac Implants* 2012 May-Jun;27(3):551-560.
11. Blamphin CN, Brafield TR, Jobbins B, Fisher J, Watson CJ, Redfern EJ. A simple instrument for the measurement of maximum occlusal force in human dentition. *Proc Inst Mech Eng H* 1990;204(2):129-131.
12. Proff P, Steinmetz I, Bayerlein T, Dietze S, Fanghänel J, Gedrange T. Bacterial colonisation of interior implant threads with and without sealing. *Folia Morphol (Warsz)* 2006 Feb;65(1):75-77.
13. Harder S, Dimaczek B, Açil Y, Terheyden H, Freitag-Wolf S, Kern M. Molecular leakage at implant-abutment connection in vitro investigation of tightness of internal conical implant-abutment connections against endotoxin penetration. *Clin Oral Investig* 2010 Aug;14(4):427-432.
14. Byrne D, Jacobs S, O'Connell B, Houston F, Claffey N. Preloads generated with repeated tightening in three types of screws used in dental implant assemblies. *J Prosthodont* 2006 May-Jun;15(3):164-171.

Prepared By: Ross Towse, Director, Research & Technology Development
Zach Suttin, Project Manager, Research & Technology Development

Certain, GingiHue, Gold-Tite and PREVAIL are registered trademarks of BIOMET **3i** LLC. DCD, NanoTite and **3i** T3 are trademarks of BIOMET **3i** LLC. Astra Tech and OsseoSpeed are trademarks of Astra Tech. Nobel Replace and Procera are registered trademarks Nobel Biocare. Straumann is a registered trademark of Straumann. Thommen SPI is a registered trademark of Thommen Medical. ©2012 BIOMET **3i** LLC.



ART1205EU
REV A 09/12