Effect of Abutment Screw Design on the Seal Performance of an External Hex Implant System

360

Zachary Suttin †† and *Ross Towse* ††

BIOMET 3i, Palm Beach Gardens, FL, USA

Topic: Material research

Background and Aim

Seal integrity of the implant-abutment-junction (IAJ) is a function of the design of the implant, the abutment, and the retaining screw, as well as the loading conditions to which the assembled dental implant system is subjected. The dental implant components should be engineered to resist microleakage at the IAJ interface. A robust seal can mitigate microbial transfer between the implant connection and surrounding tissues, thereby reducing the potential for inflammation and subsequent loss of these tissues[1-3]. Preservation of the hard and soft tissue is critical to the performance of an implant system in terms of stability and aesthetics[4].

The design of the retaining screw can have a significant impact on IAJ seal integrity, as it is the element which generates the pre-load required to create and maintain a tight seal. The objective of this study was to characterize the seal robustness of an external hex implant system subjected to dynamic loading with titanium (Ti Alloy) and Gold-Tite® retaining screws.

Methods and Materials

A dynamic loading leakage test adapted from ISO14801, Dentistry - Implants - Dynamic Fatigue Test for Endosseous Dental Implants, was executed to compare the seal performance of the implant systems outlined in Table 1.

	BIOMET *3i* Implant/Abutment System with GoldTite® Screw	**BIOMET *3i* Implant/Abutment System with Titanium Screw**
Implant	4mm (D) x 15 mm (L) Osseotite® Implant	4mm (D) x 15 mm (L) Osseotite Implant
Implant Item Number	OSS415	OSS415
Abutment	GingiHue® Post 4.1mm(D) x 5.0mm (P) x 2.0mm (D)	GingiHue Post 4.1mm(D) x 5.0mm (P) x 2.0mm (D)
Abutment Item Number	APP452G	APP452G
Screw	Gold-Tite® Square UniScrew	Titanium Square UniScrew
Screw Item Number	UNISG	UNIST

Table 1: Implant System Components Evaluated

The seal test setup is illustrated in Figure 1, and the protocol is described below. Five (n=5) systems were tested from each group.

1) A barb was machined at the apical tip of the implant to provide access to the internal aspect (Figure 2).
2) The implant was fixated in a phenolic-resin block, exposing 3.0mm of the coronal portion while allowing access to the apical barb.
3) Tubing was connected to the implant barb, and the abutment was loosely assembled to the implant.
4) Using a peristaltic pump, red dye was bled through the system to eliminate air bubbles and to confirm adequate flow.
5) 35 Ncm of torque was then applied to the abutment screw and the system was thoroughly rinsed.
6) The test block was mounted in an electrodynamic materials test machine (Instron ElectroPuls™ E-1000, Instron®, Norwood, Massachusetts) at 20 degrees off-axis in a clear tank filled with fresh water (Figure 3).
7) The pump was turned on and the internal volume of the implant was pressurized to approximately 7psi. The IAJ was monitored with the use of a high resolution video camera at 50X magnification to qualify the seal integrity.
8) If no leakage was visually detected without a system load (per the prior step), the abutment was then cyclically loaded at 100N at 30 Hz for 100,000 cycles with the pump off to simulate system usage.
9) After the usage cycle, the seal was qualified by turning the pump on and monitoring the IAJ while loading at 100N at 2 Hz for 1,000 cycles.
10) If the sample successfully completed the initial 100N dynamic load, steps 8 and 9 were repeated in load increments of 50N (Figure 4) until leakage was detected (Figure 5).

Methods and Materials (cont.)

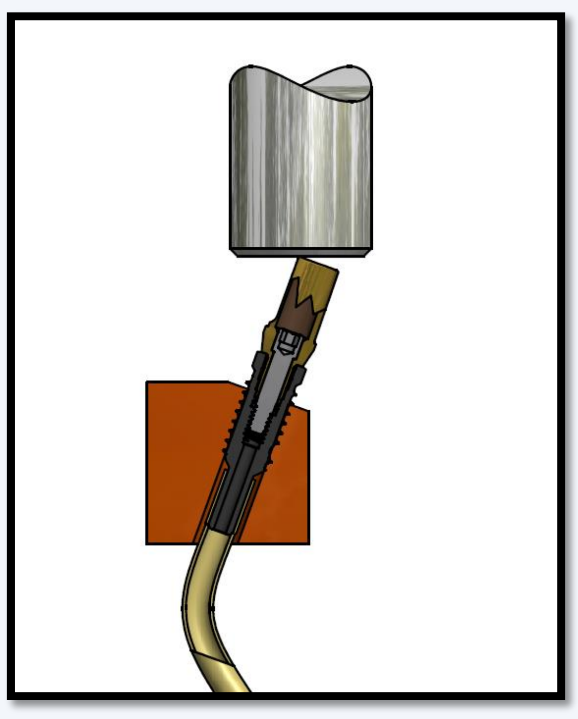

Figure 1: Test Setup Schematic

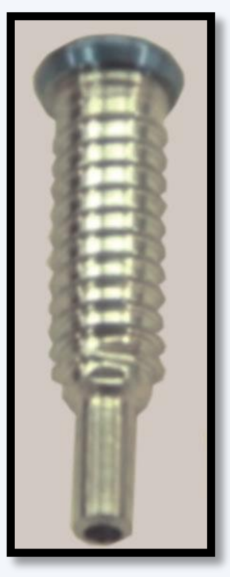

Figure 2: Barbed Implant

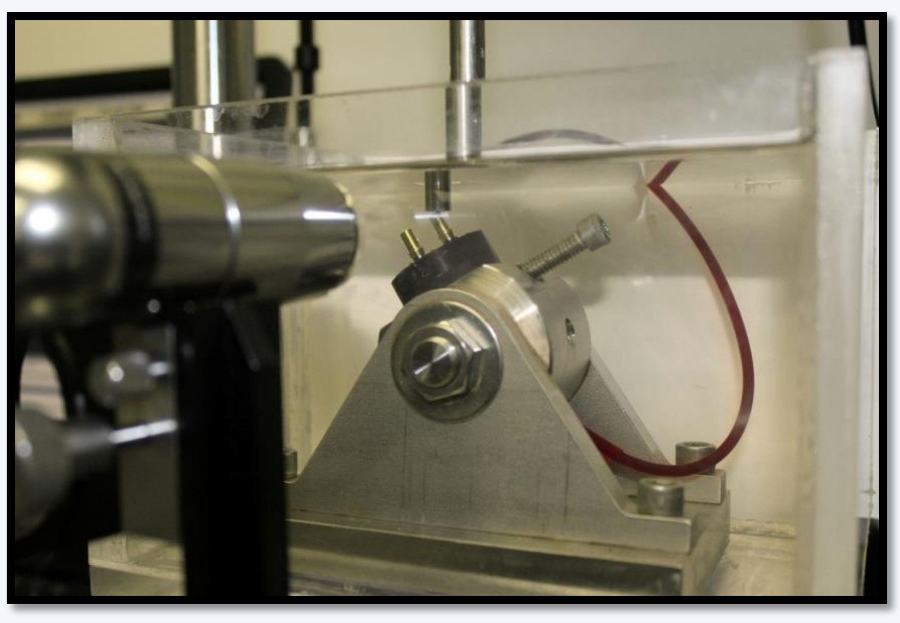

Figure 3: Test System Mounted on Electrodynamic Testing Machine (with water tank)

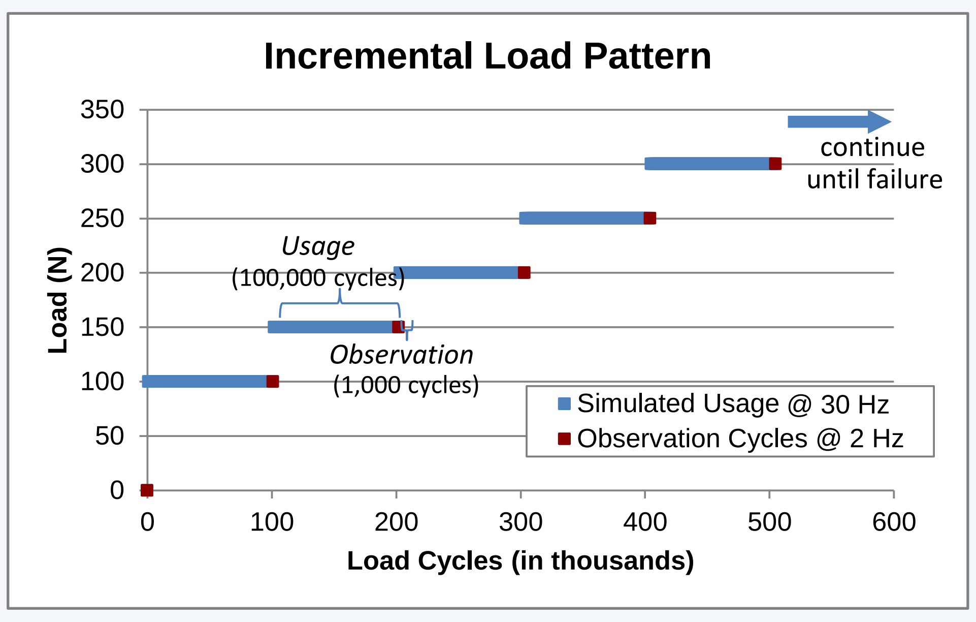

Figure 4: Incremental Test Load Pattern

Figure 5: Sample IAJ Breach

The pre-load created by each screw design (n=5) at 35 Ncm of torque was independently assessed aside from the seal test using a load cell and a digital force gauge.

Results

The seal test results (Figure 6) indicate that the Gold-Tite screw improved the average seal strength over the systems utilizing the Ti Alloy screw by more than 35% (650 ± 50 N vs 480 ± 91 N). An unpaired two-tailed t-test was used to compare the groups. A difference of P≤.05 was considered significant, and the statistical analysis showed that P=.006.

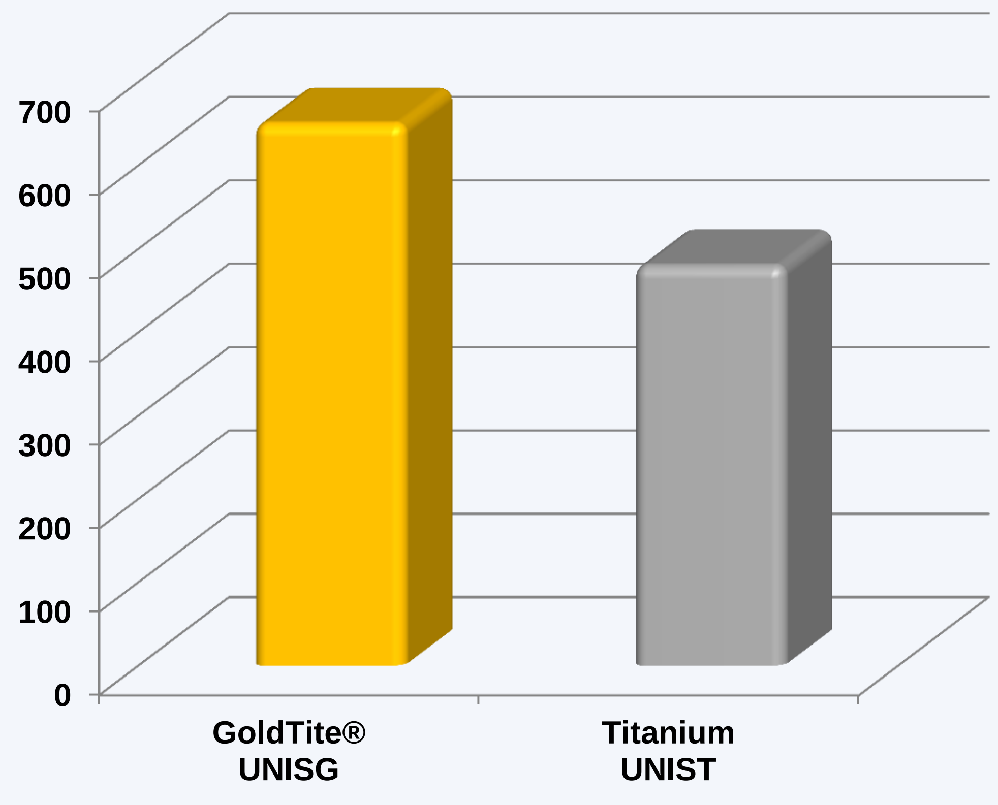

Figure 6: Mean breach load (N) results for implant systems tested with Gold-Tite vs Ti Alloy screws

Results (cont.)

The pre-load results (Figure 7) demonstrate that the Gold-Tite screw increases the average clamping force by 83% over the Ti Alloy screw (588 ± 7 N vs 321 ± 15 N) when subjected to 35 Ncm of torque. The same statistical techniques were applied to compare these groups, and the results show that P<.0001.

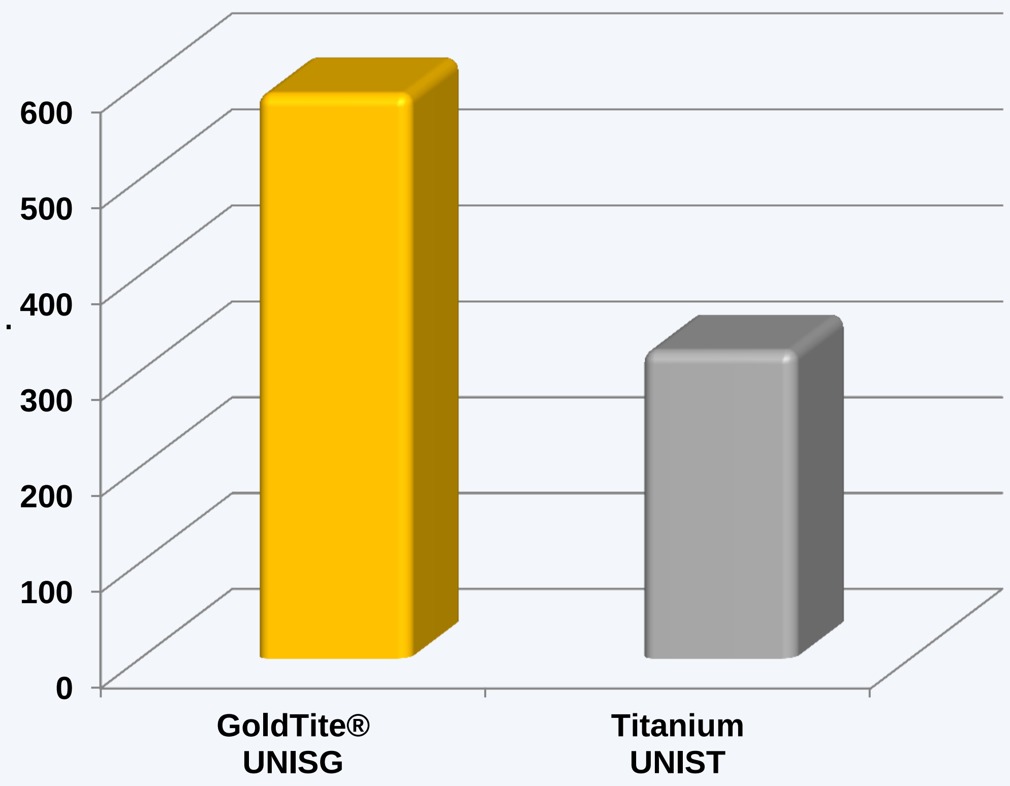

Figure 7: Mean pre-load (N) results for Gold-Tite vs Ti Alloy screws

Conclusions

The pre-load generated by a Gold-Tite abutment screw provides a statistically significant improvement over a Ti Alloy abutment screw. As one could predict, this same trend was evidenced when testing external hex implant systems for seal robustness with Gold-Tite and Ti Alloy abutment screws. The breach loads, although high for both test groups, are clinically relevant in terms of maximum bite forces[5]. Given the potential functional and aesthetic detriments associated with an inferior seal, a Gold-Tite abutment screw should always be selected to increase the probability of a positive and sustainable clinical outcome.*

*Results of preclinical testing are not necessarily indicative of clinical performance.

References

1. Al-Jadaa A, Attin T, Peltomäki T, Schmidlin† PR. "The Seal is the Deal": Gas-Enhanced Leakage Testing (GELT) for Implants. Poster Presentation (P4): The 11th International Symposium on Periodontics & Restorative Dentistry; June 2013; Boston, MA. Primary researcher's PhD fellowship was supported by BIOMET ***3i*** LLC. Aim of study was to develop a customized and standardized measurement device allowing repetitive non-destruction evaluation of implant leakage. Three implant systems were tested (n=20, four of each group which were negative controls). The research was funded by BIOMET ***3i*** LLC.
2. 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.
3. 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):577-81.
4. 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):149-55.
5. 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):129-31.

† These clinicians have or had financial relationships with BIOMET ***3i*** resulting from speaking engagements, consulting engagements and other retained services.

†† Dr. Porter, Mr. Sutton, and Mr. Towse conducted this research while employed by BIOMET ***3i***.

Correspondence

Zachary Suttin, M.S.M.E.
4555 Riverside Drive
Palm Beach Gardens, FL 33410
United States
(561) 776-6700
Email: Zachary.Suttin@Biomet.com

Presented at the 22nd Annual Scientific Meeting of the European Association of Osseointegration
17 - 19 October 2013, Dublin, Ireland