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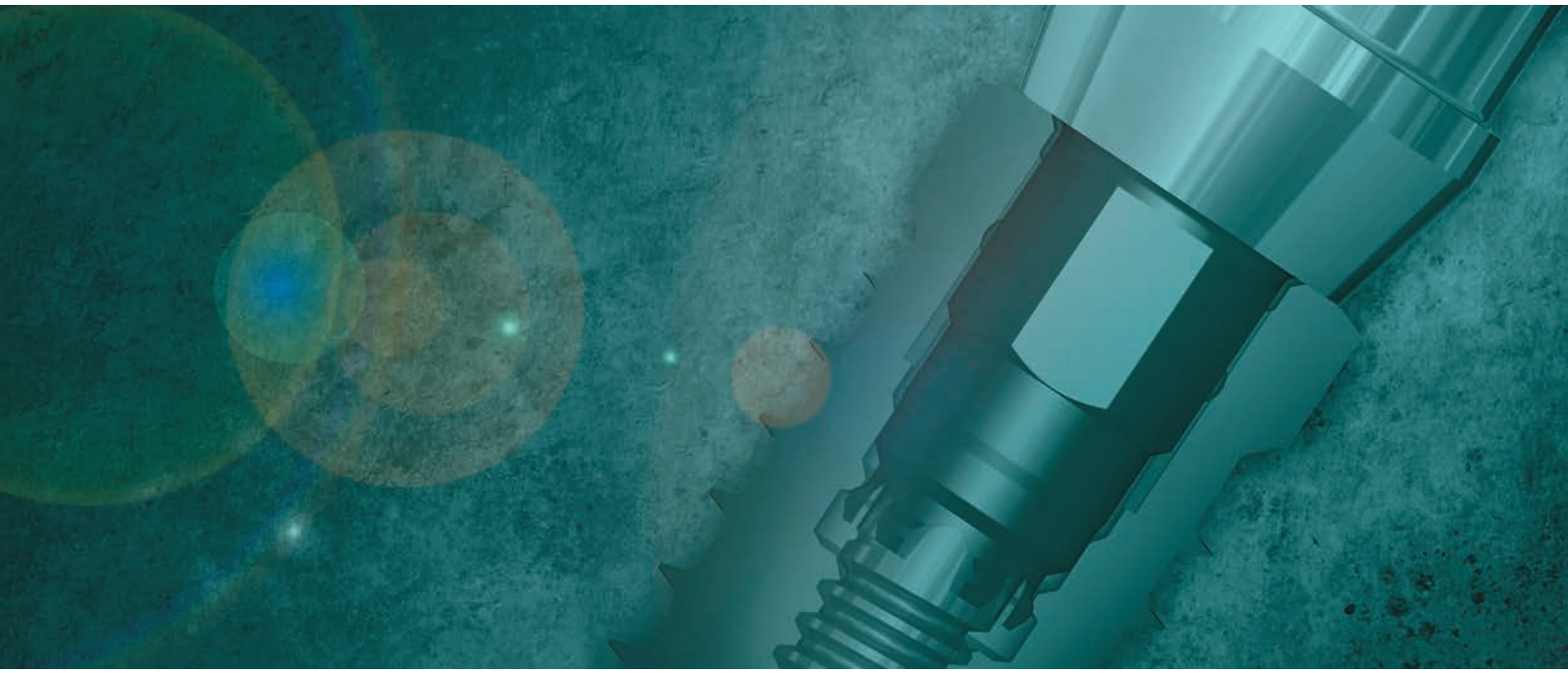

SPECIAL REPRINT, JIRD Vol. 5, No. 2, 2014

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Official Publication of The INSTITUTE for Implant & Reconstructive Dentistry®

2014 | No. 2

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

aesthetics

Dental implant system seal integrity and the quest for sustainable aesthetics

Harold Baumgarten, DMD,[±] Zachary Suttin, MSME,[†] Patrick R. Schmidlin, Prof. Dr. med. dent.,[±] and Stephan S. Porter, DDS, MSD, MS[‡]

The absence of an effective seal between the implant and abutment can have both short- and long-term negative consequences. To ensure a robust implant/abutment connection, numerous designs have been developed over the years. This article reviews the results of recent research into the comparative effectiveness of flat-on-flat versus conical designs, as well as that of original equipment manufacturer (OEM) versus aftermarket components. The impact of screw design on stabilizing the connection and resisting leakage is also explored.

Key Words: implant-abutment junction (IAJ), seal strength, microleakage, seal performance

Previous publications have discussed the importance of dental implant system design in achieving sustainable aesthetics.[1] In particular, the roles of implant primary stability, implant surface treatments, and the implant-abutment junction (IAJ) geometry have received widespread attention. The strength of the implant-abutment connection has been less thoroughly examined. This article reviews recent research exploring the question of which design elements can contribute to the effective seal between the implant and abutment.

The implant-abutment seal integrity has clinical relevance because the absence of a tight seal has been hypothesized to permit microbial invasion and colonization of the internal aspect of the implant. From a biological perspective, the aesthetics may be compromised if bacterial contaminants subsequently leak through the IAJ into the surrounding tissues,[2,3] leading to inflammation and the potential for localized tissue loss.

The dental implant industry has developed and marketed a wide array of implant and connection designs over the past 30 years. In 2007, a standardized test method (ISO 14801)[4] was accepted by the industry to determine implant-system strength. A variety of methods have also been devised to detect leakage at the IAJ. Although many such investigations have used static *in vitro* analysis of the IAJs of various implant systems, the ability to assess seal robustness under dynamic loading conditions more closely approximates actual clinical conditions.

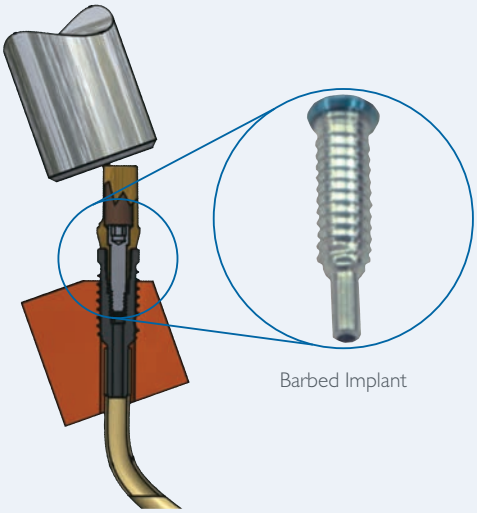
Recently published results assessing dynamic loading leakage using an adaptation of ISO 14801 are enlightening. Presented in 2012,[5] this research tested five implant/abutment assemblies; each from four established implant systems (Astra Tech OsseoSpeed™, BIOMET ***3i*** Certain® PREVAIL®, Straumann® Bone Level, and Thommen SPI® Element).

In this study, the apex of each test implant was machined to form a tube with a hollow bore (barbed implant end) extending into the implant's screw chamber to accommodate attachment of a clear plastic tube (Fig. 1). After embedding the implant body in a phenolic-resin block that left the apical barb and 3mm of the coronal portion of the implant exposed, clear tubing was connected to the apical barb, and a straight abutment was loosely attached to the implant using the corresponding abutment screw. Using a peristaltic pump, red dye was bled through each implant/abutment/screw assembly to eliminate air bubbles and confirm flow through the IAJ. The manufacturer's recommended screw torque was then applied to the retaining screw, and the assembly was thoroughly rinsed to remove any residual dye.

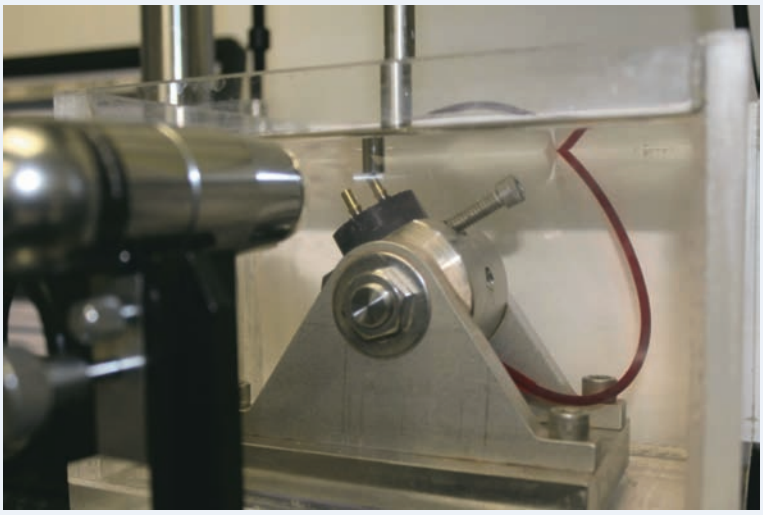
The block was mounted off-axis in an electrodynamic test instrument and submerged in a clear tank filled with water. A 20-degree off-axis load was chosen to simulate a worst-case prosthetic loading condition. The pump was activated to pressurize the dye solution within the implant body to approximately 7 psi, and a high-resolution video camera was focused on the IAJ to observe for dye leakage. If no leakage was detected, the pump was turned off, and the abutment was cyclically loaded at 100N (Newtons), 30Hz (hertz) for 100,000 cycles to simulate system function. The pump was then turned on, and the IAJ was monitored while loading the abutment at 100N, 2Hz for 1,000 cycles. Increasing the load by 50N increments, this protocol was repeated until either leakage, permanent deformation, and/or fracture within the test assembly was detected.

Results for the two systems with conical (vertical) interfaces (Astra Tech™ and Straumann®) were similar. Both experienced component yielding and/or fractures, resulting in dye leakage from the IAJ of the assembly. The difference between the mean failure loads (520N and 570N respectively) was not statistically significant. The Thommen test assemblies did not break or bend but did leak under statistically significantly lower loads (mean=230N) as compared to the Astra Tech and Straumann test assemblies. The BIOMET ***3i*** test assemblies also did not break or bend, and they withstood statistically significant higher loads (mean=810N) before leaking than the other three systems tested (Fig. 2).

It has been hypothesized that the constant seating position of a flat-on-flat connection may eliminate potential error sources associated with conical interface connections.[6,7] These errors include inconsistent vertical restorative positioning of the abutment resulting from screw torque (e.g. up to 21 microns per 5Ncm of torque) and the manufactured fit of the mating cones.



Test Setup Schematic



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

Fig. 1. Seal robustness test method set up.

Hypothesizing that screw pre-load contributed to the seal robustness of the BIOMET ***3i*** System, Suttin† and Towse† undertook a subsequent study focusing on the impact of the abutment screw on seal integrity.[8] They used the same experimental set-up to dynamically load five samples of platform-switched tapered implants (***3i*** T3® Implants with DCD®) that were secured to Certain® GingiHue® Abutment (BIOMET ***3i***) using Certain Titanium Alloy Screws. Testing with a load cell, torque indicator, and digital force gauge had shown these screws to have a pre-load of 263+7N at 20Ncm of torque.

As with the prior study, the dynamic test loads were increased in increments of 50N until leakage, deformation, and/or fracture was/were observed. In every instance, leakage was eventually detected. Subsequent disassembly of the BIOMET ***3i*** test systems revealed that no components had yielded and/or fractured. The components in each test system were then reassembled for a second time using a new titanium screw, and testing was reinitiated at the prior failure load to determine if use of a fresh screw would increase seal performance. In every case, leakage occurred immediately, suggesting that breach associated with the initial titanium screw was unrelated to screw loosening, loss of pre-load, or permanent deformation.

Each assembly was then disassembled, reexamined, and reassembled for a third time using a Gold-Tite® Abutment Screw. Gold-Tite Screws are coated with up to 40 microns of 99.9% pure gold. The gold coating acts as a dry lubricant, reducing the friction between the screw and the implant threads. The gold coating permits the screw to undergo additional rotation and stretch, resulting in a significantly higher clamping force between the two components. Pre-load testing of the Certain® Gold-Tite Screw at 20Ncm produced a value of 561+78N– a greater than 100% increase in pre-load as compared to the Certain Titanium Allow Screw at 20Ncm of torque.

Testing was resumed at the prior failure load to establish whether the change in the screw technology (Gold-Tite) would improve the seal strength. The test results showed that with the use of the Gold-Tite Screw, a greater than 50% average increase in the seal strength (780± 45 N vs. 500± 61 N) was achieved. No fracture or deformation occurred for any of the samples tested (Fig. 3).

While these results confirm that the performance of the abutment screw plays a critical role in maintaining IAJ seal integrity, there are additional performance considerations. The implant and abutment should fit together as seamlessly as possible, so as to mitigate microgaps within the assembly.

Scanning electron microscopy (SEM) analysis has been used to determine whether such microgaps exist in the interface

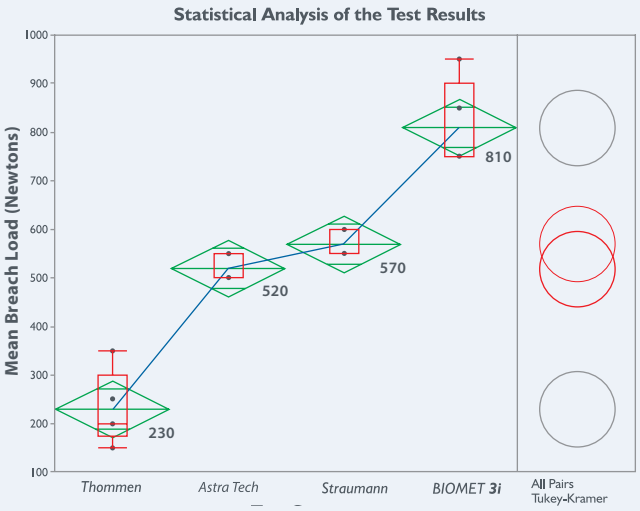


Fig. 2. Statistical analysis of the test results for the four implant groups in the study.

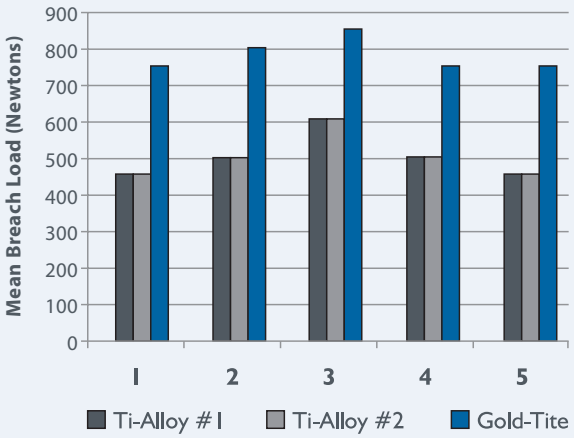


Fig. 3. Breach Load (N) for the BIOMET *3i* T3® Implant and GingiHue® Abutment with either a Ti Alloy or Gold-Tite® Abutment Screw.

between various implant and abutment systems. Baldasarri et al used SEM analysis to compare different combinations of implants and abutments. At the two extremes, they found an average gap distance of 1.7 microns for BellaTek® Titanium Abutments (using Gold-Tite Screws) connected to BIOMET *3i* Implants and an average 8.2-micron gap for the Procera® Zirconia Abutments (using titanium screws) connected to Nobel Replace® Implants (Nobel Biocare).[9]

A limitation of this analysis was that gap distance was only measured at the outer circumference of the IAJs. A complementary method of conducting such analysis involves mounting and cross-sectioning the assembled system to obtain a more extensive view of the interface. This approach was taken in a 2013 study that microscopically assessed the IAJs of systems from four different implant manufacturers (BIOMET *3i* T3, Dentsply Astra Tech OsseoSpeed™, Nobel Biocare NobelActive™, and Straumann® Bone Level.)[10]

After assembling the implants and abutments and tightening the abutment screws to each manufacturer's recommended torque value (using a calibrated torque meter), the assemblies were mounted in phenolic resin, sectioned along the vertical/central axis, and polished. Each assembled cross section was evaluated at 500x magnification using SEM analysis (JEOL USA, Inc., Peabody, Massachusetts). Microgap dimensions were measured at 100-micron intervals along the IAJ using image-analysis software.

The results showed microgaps in the IAJs of all of the systems evaluated, as illustrated in Figure 4. However, when comparing the gap size on each side of the cross section, the variation was greater for the Dentsply Astra Tech and Straumann Systems, as compared to the Nobel Biocare and BIOMET *3i* Systems.

An emerging concern has developed regarding the fit between implants and abutments as increasing numbers of aftermarket abutments and screws manufactured to fit original equipment manufacturer (OEM) implants have appeared on the market. Such components are marketed as being equivalent to the OEM abutments and screws. However, the question arises: is their functional performance (such as IAJ seal integrity) indistinguishable from the OEM components they are intended to mimic?

One recent study evaluated the seal performance of aftermarket abutments and screws connected to BIOMET *3i* T3 with DCD® Tapered Implants and compared seal integrity to that achieved by connecting GingiHue Abutments to the same implants with Gold-Tite Screws.[11] The performance of all of the

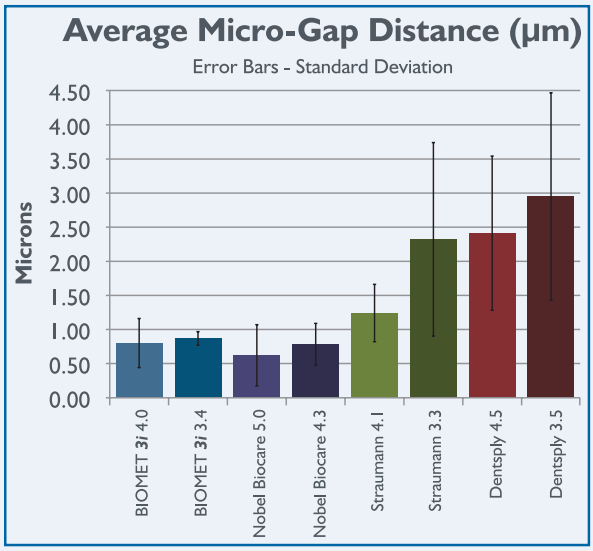


Fig. 4. Average microgap measurements in microns.

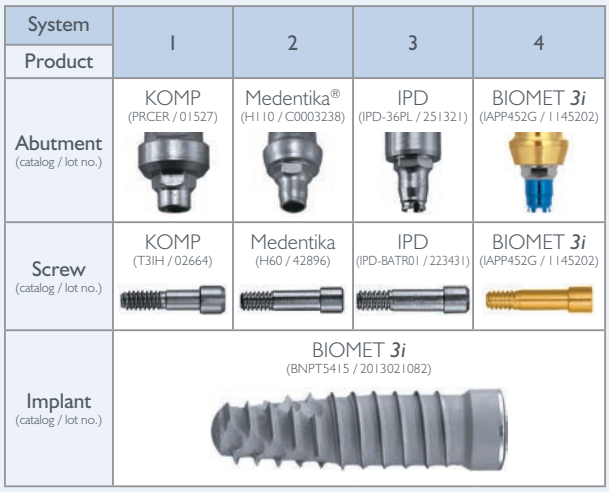


Fig. 5. Test systems.

assemblies was assessed under dynamic loading conditions using the same experimental design as described earlier for the modified ISO 14801 Test Method. The aftermarket abutments and screws (five per group) came from three manufacturers (KOMP, Medentika, and IPD) as shown in Figure 5. While no statistically significant differences in seal strength (dye leakage) were detected among the three types of aftermarket components, a significant difference ($p \leq 0.00001$) was found between each of the aftermarket components and the BIOMET ***3i*** OEM components. The average load required to breach the seal of the KOMP, Medentika, and IPD abutments was 63%, 60%, and 52% lower, respectively, than the systems assembled with the BIOMET ***3i*** Abutments.

Patient-specific abutments produced by aftermarket suppliers using computer-aided design and computer-aided manufacturing (CAD/CAM) processes have also proliferated. The same question arises: is the seal created at the IAJ when using these aftermarket CAD/CAM abutments as robust as achieved when using CAD/CAM abutments from the OEM?

When CAD/CAM abutments from two aftermarket suppliers (Brand X and Brand Y) were tested under dynamic loading conditions until seal failure, the results were unequivocal.[12] The aftermarket abutments had been digitized with a 3Shape D800 Scanner (3Shape, Copenhagen, Denmark) to capture the external abutment geometry. The unique designs from each supplier were then replicated using BIOMET ***3i*** CAD/CAM abutment blanks and "copy-milled" using the BIOMET ***3i*** OEM IAJ connection dimensions (Fig. 6). A statistically significant difference in seal integrity was found, when comparing the test (aftermarket) abutments to the control abutments (those with the OEM connection). The seals of the Brand X components breached at an average load of 69% less as compared to their respective controls. One of the Brand X test assemblies experienced a breach with application of initial pressure alone (prior to being cyclically loaded). The Brand Y components performed slightly better, breaching at an average load of 50% less as compared to their respective controls.

One limitation of the dynamic dye-leakage test employed in the studies cited earlier is that the level of sensitivity of detecting dye leakage depends on visual acuity for identification of a breach. Increasingly sophisticated means of assessing IAJ seal performance continue to develop. These include a recently introduced gas-enhanced permeation test that allows for ease of precision mounting of implants for multiple testing time points, while also enabling precise control of environmental conditions.[13] When the developers of this test method evaluated gas-pressure

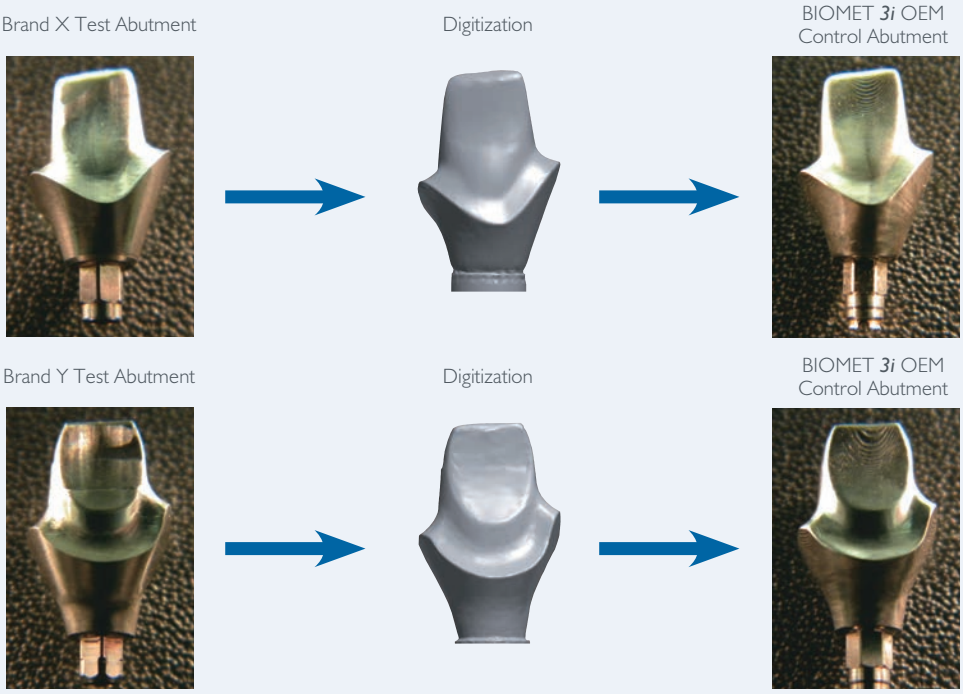


Fig. 6. Utilization of the copymill process enabled the investigators to create "control abutments" (possessing the OEM connection) with equivalent external geometry to the aftermarket "test abutment."

and saline volume changes across the IAJs of three implant systems (Astra Tech, BIOMET ***3i***, and Nobel Biocare), they found significant differences within the three test systems. In the initial phase of the test, 25% of the Astra Tech and 12.5% of the Nobel Biocare implants failed, wherein total pressure loss occurred. During the subsequent phase, the BIOMET ***3i*** Implants showed the lowest gas-leakage values (mean=0.01± 0.01 hPa/min), followed by Nobel Biocare (0.23±0.03 hPa/min) and then Astra Tech (0.85±0.71 hPa/min). Saline infiltration through the IAJ was 0.56±0.50ml (Astra Tech), 0.12±0.20ml (Nobel Biocare), and 0±0ml (BIOMET ***3i***).¥

Conclusion

The three primary components of dental implant systems – the implant mating surface and features, the abutment mating surface and features, and the abutment screw – must work in concert to resist rotation and provide sufficient retention, strength, stability, seating predictability, and seal integrity to withstand the rigors of function within the oral environment. The research presented in this article demonstrates that an optimally designed and manufactured flat-on-flat connection between the implant and abutment can provide a robust and precise connection. While the design and interaction of all implant system components are critical to seal integrity, it has been demonstrated that screw design has a highly significant impact on stabilizing the implant-abutment connection and resisting microleakage. The tight clamping that can be achieved with a gold-coated screw maximizes the stability of the IAJ interface and minimizes the potential space between the two components.

The implant-abutment seal integrity may have clinical relevance because the absence of a tight seal has been hypothesized to permit microbial invasion and colonization of the internal aspect of the implant. Under this hypothesis, bacterial contaminants may subsequently leak through the IAJ into the surrounding tissues,[3,14] leading to inflammation and the potential for localized tissue loss. The loss of supportive crestal bone may decrease the implant's stability, threatening its overall function. Crestal bone loss can also have a negative impact on soft-tissue height and/or volume, disrupting results that were initially highly aesthetic.[15] Future pre-clinical and clinical research should focus on the biologic impact of bacterial leakage at implant component interfaces as it relates to tissue preservation and long-term aesthetics.

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Acknowledgements

≠ *The author has a financial relationship BIOMET **3i** LLC resulting from speaking engagements, consulting engagements, and other retained services; however, the author was not compensated by BIOMET **3i** for this study/article.*

± *The author has a financial relationship with BIOMET **3i** LLC resulting from speaking engagements, consulting engagements, and other retained services.*

† *The author was employed by BIOMET **3i** at the time the research was conducted.*

¥ *Implant systems were obtained directly from each manufacturer for this study with funding through a research grant by BIOMET **3i** LLC.*

∏ *Al-Jadaa A, PhD fellowship was supported by BIOMET **3i** LLC.*

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

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