

Gold-Tite[®] Screw
and SureSeal[™] Technology



Gold-Tite Screw and SureSeal Technology

Implant-Abutment Seal Strength with the Gold-Tite Screw

Clinical Challenges

Clinicians require solutions that deliver long-term aesthetics and physical integrity to support their patients' needs.



Peri-implant Mucositis

The prevalence of peri-mucositis has been reported as high as 80% of all dental patients.¹



Peri-implantitis

The prevalence of implants experiencing peri-implantitis has been reported in excess of 12%.^{2,3}



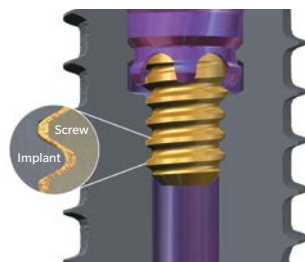
Crestal Bone Loss

Average implant crestal bone remodeling can exceed 1.5 mm following the first year of function, leading to compromised aesthetics.³

SureSeal Technology shall be designed for superior seal integrity through the Implant-Abutment Junction (IAJ). This shall be achieved with the combination of the proprietary Gold-Tite Screw, Certain® Internal Connection and precision manufacturing processes.

Implant/abutment seal strength

Use of the Gold-Tite Screw increases Certain Implant/abutment clamping force by up to 113% as compared to a non-coated titanium alloy screw.^{4,*}



Implant/abutment clamping force

Designed to reduce microleakage through exacting interface tolerances and maximized clamping forces.

Proprietary Gold-Tite Screw surface lubrication allows the screw to rotate further as compared to an uncoated screw, thereby increasing the clamping force and maximizing abutment stability.⁵

1. Zitzmann NU, Berglundh T. Definition and prevalence of peri-implant diseases. *J Clin Perio.* 2008;35:286–291.

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. Fransson C, Lekholm U, Jemt T, Berglundh T. Prevalence of subjects with progressive bone loss at implants. *Clinical Oral Implants Research.* 2005;16:440–446.

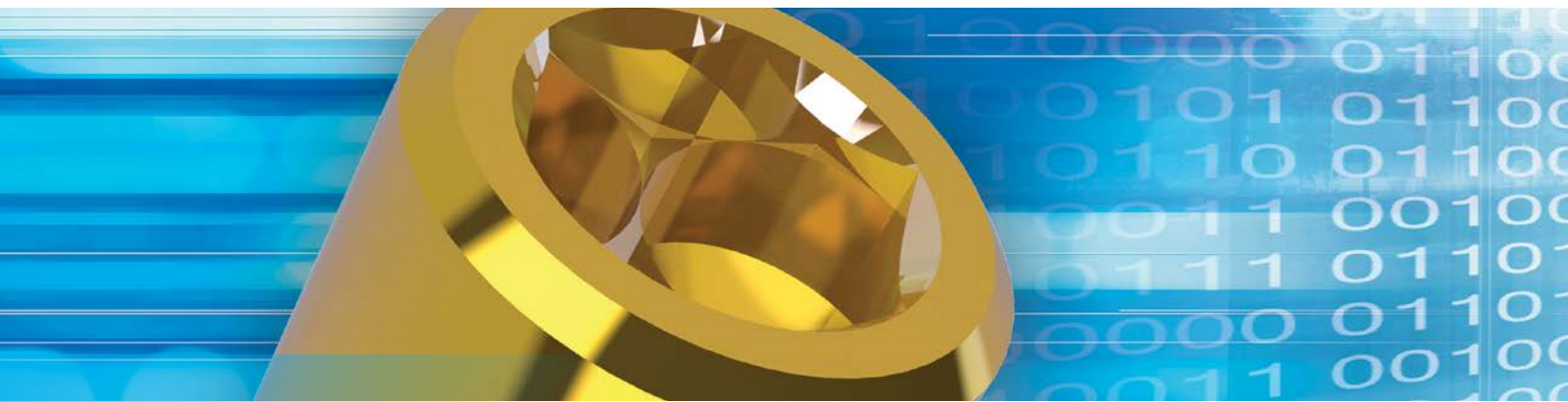
4. Suttin Z††, Towse R††. Effect of abutment screw design on implant system seal performance. Presented at the European Association for Osseointegration, 20th Annual Scientific Meeting; October 2012; Copenhagen, Denmark. http://biomet3i.com/Pdf/Posters/P-450_Effect_of_Screw_Design_on_Implant_Seal.pdf.

5. 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.

† These clinicians have or had financial relationships with Zimmer Biomet Dental resulting from speaking engagements, consulting engagements and other retained services.

†† These authors conducted their research while employed at Biomet 3i, LLC.

* Bench test results do not always necessarily reflect human clinical experience.



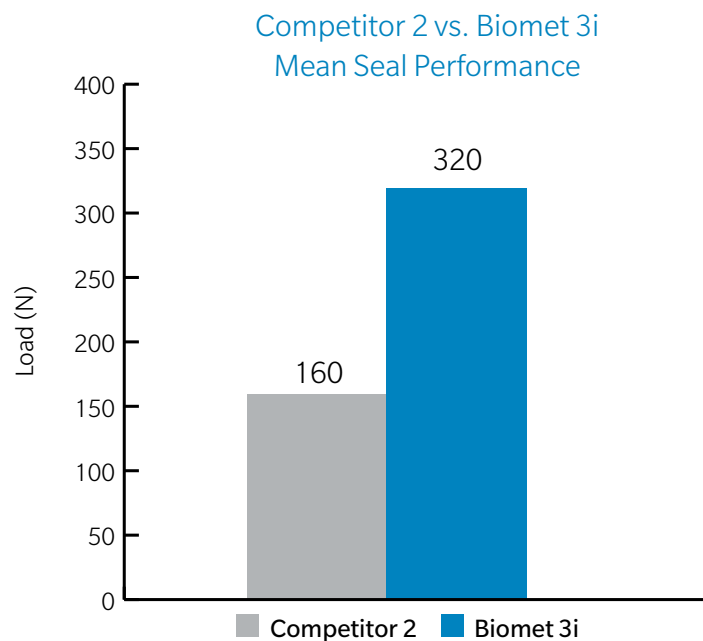
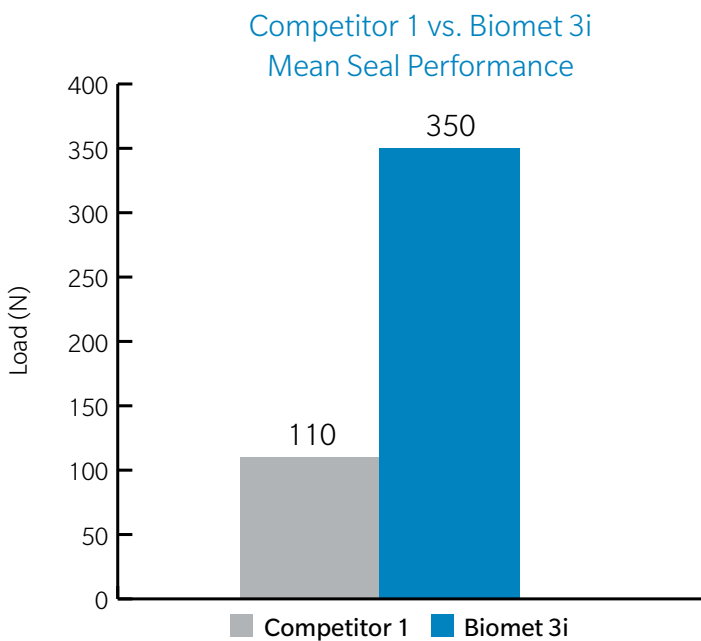
Dynamic Fluid Leakage Evaluation of Original Equipment Manufacturer and Aftermarket CAD/CAM Abutments¹

Center: Biomet 3i, Palm Beach Gardens, Florida, USA.

Study Design: Select aftermarket abutments were digitized and then replicated by Biomet 3i. Utilization of this process enabled researchers to create control abutments with the equivalent external geometry to the external geometry of the aftermarket test abutments. Abutments were cyclically loaded on an Instron testing system until a breach or fracture occurred.

Sample Size: Three (3) CAD/CAM abutment manufacturers; n=5 per group.

Relevance to SureSeal Technology: Biomet 3i original equipment manufacturer CAD/CAM abutments demonstrated enhanced implant-abutment junction seal performance as compared to their competitor's abutment.*



1. Baumgarten H[†], Meltzer A[†]. Poster Presentation: The 11th Annual International Symposium on Periodontics and Restorative Dentistry, June 2013, Boston, Massachusetts, USA. To view the poster, please visit: biomet3i.com/PDF/Posters/Dynamic%20Loading%20Fluid%20Leakage%20Characterization%20of%20CAD/CAM%20Abutments.pdf

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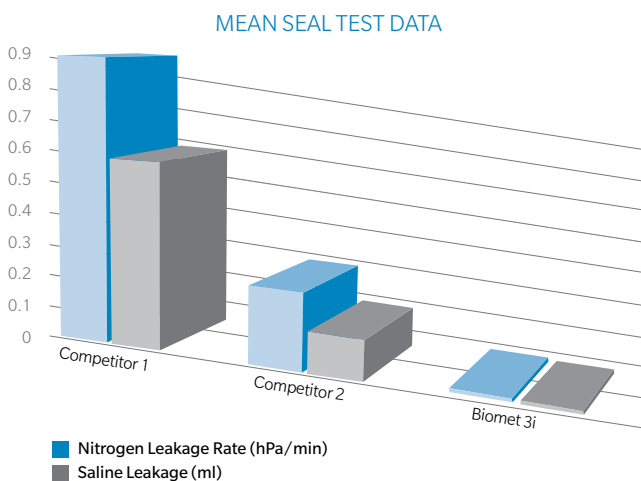
“The Seal is the Deal”: Gas-Enhanced Leakage Testing (GELT) for Implants Comparison of three in vitro implant leakage testing methods¹

Center: Department of Preventative Dentistry, Periodontology and Cardiology, Center for Dental Medicine, University of Zürich, Switzerland.

Study Design*: An environmentally controlled device allowing gas pressure measurement and fluid volume infiltration at 35°C was developed to assess seal leakage.

Sample Size: Three (3) implant systems; n=20 per group (Four of each group were negative controls).

Relevance to SureSeal Technology: Under simulated conditions, Biomet 3i showed better sealing ability among the tested systems. Under the simulated test conditions, the Biomet 3i test groups exhibited the better sealing ability. The test methods have proven to reliably detect small differences in gas and water leakage between different systems.*



IMPLANT TYPE	MEAN SLOPE VALUE	INFILTRATED SALINE VOLUME (ml)
Competitor 1	0.85±0.71 ^A	0.56±0.50
Competitor 2	0.23±0.03 ^B	0.12±0.20
Biomet 3i	0.01±0.01 ^C	0.00±0.00

Mean values and SD for detected leakage (stat. significant differences are marked with superscript capitals (read vertically)).

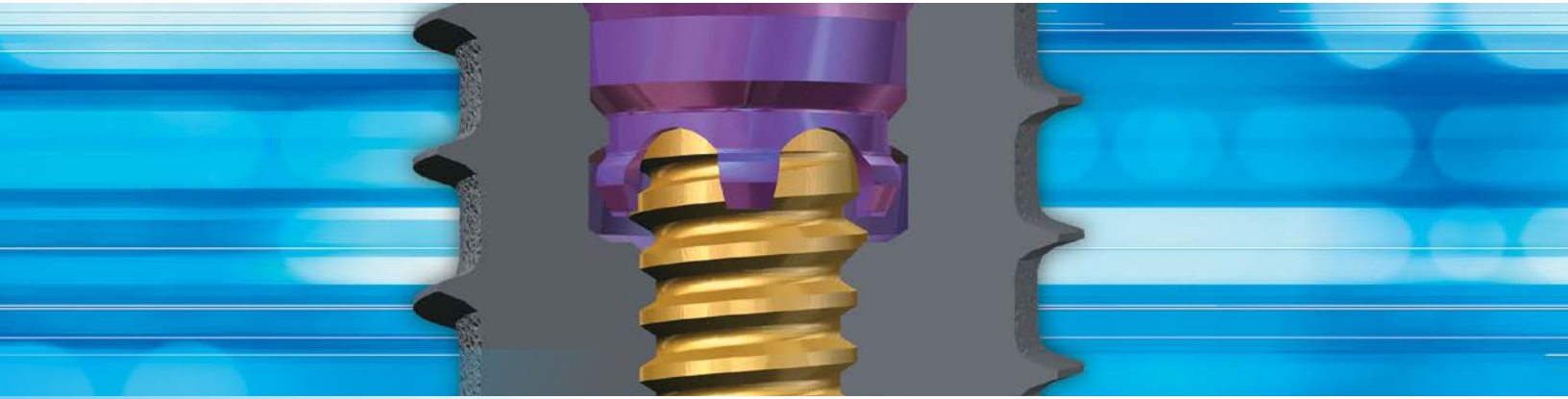
The primary researcher’s PhD was supported by Biomet 3i. The research was funded by Biomet 3i, LLC.

1. Al-Jadaa A, Attin T, Peltomäki T, Schmidlin PR[†]. Comparison of three in vitro implant leakage testing methods. Clin Oral Implants Res. 2013 Dec 16. doi: 10.1111/clr.12314.

To view the poster, please visit: biomet3i.com/PDF/Posters/Poster_Al-Jadaa_et_al_GELT.pdf

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

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



A New Method for Assessing Implant-Abutment Connection Seal Robustness¹

Center: Biomet 3i, Palm Beach Gardens, Florida, USA.

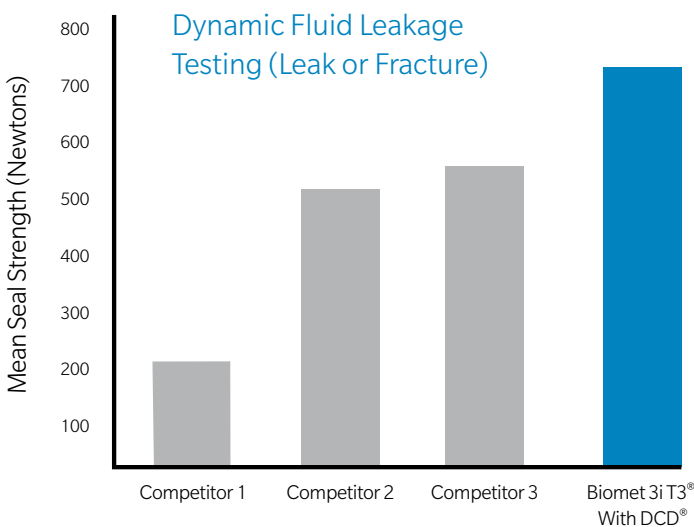
Study Design: Abutments were cyclically loaded on an Instron testing system until a breach or fracture occurred.

Sample Size: Four (4) implant systems; n=5 per group.

Relevance to SureSeal Technology: Certain PREVAIL® Implant/ Abutment connection exhibits a robust seal without breach or failure at loads higher than the other implant systems tested.*

Seal Strength Test

A study assessed the Implant-Abutment Junction (IAJ) seal robustness of industry leading dental implant systems subjected to a dynamic loading test.



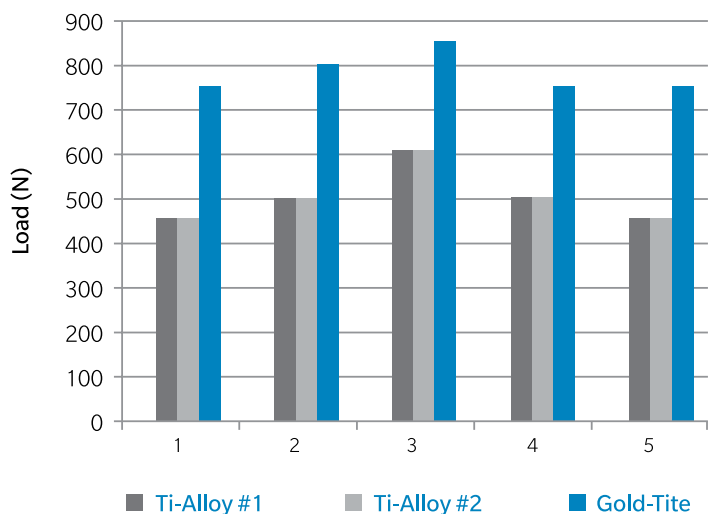
Effect of Abutment Screw Design on Implant System Seal Performance²

Center: Biomet 3i, Palm Beach Gardens, Florida, USA.

Study Design: Abutments were cyclically loaded on an Instron testing system until a breach or fracture occurred.

Sample Size: Four (4) Biomet 3i Implant System components were tested. Five (n=5) samples were tested for each system evaluated.

Relevance to SureSeal Technology: A correlation has been established between the magnified pre-load produced by the Gold-Tite Screw and the statistically significant increase in seal robustness in comparison to the Ti-Alloy screw. Screw design can have a significant impact on stabilizing the connection and resisting leakage.



1. Suttin Z[†], Towse R[†], Cruz J[†]. Poster Presentation: Academy of Osseointegration, 27th Annual Meeting, March 2012, Phoenix, Arizona, USA. To view the poster, please visit: biomet3i.com/PDF/Posters/P16-Suttin.pdf

2. Suttin Z[†], Towse R[†]. Effect of abutment screw design on implant system seal performance. Presented at the European Association for Osseointegration, 20th Annual Scientific Meeting; October 2012; Copenhagen, Denmark. http://biomet3i.com/Pdf/Posters/P-450_Effect_of_Screw_Design_on_Implant_Seal.pdf.

[†] The authors conducted this research while employed at Biomet 3i.

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