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In Vitro Analysis of Post-fatigue Reverse-Torque Values at the Dental Abutment/Implant Interface for a Unitarian Abutment Design

Paul M. Cashman, BDentSc., MSc,[1] Robert L. Schneider, DDS, MS,[2] Galen B. Schneider, DDS, PhD,[3] Clark M. Stanford, DDS, PhD,[4] James M. Clancy, DDS, MS,[5] & Fang Qian, PhD[6]

[1]Clinical Lecturer, Department of Prosthodontics, Eastman Dental Institute, University College London, London, United Kingdom
[2]Clinical Professor, Department of Oral and Maxillofacial surgery, University of Iowa College of Dentistry, Iowa City, IA
[3]Professor, Department of Prosthodontics, University of Iowa College of Dentistry, Iowa City, IA
[4]Centennial Fund Professor, Dows Institute for Dental Research, University of Iowa College of Dentistry, Iowa City, IA
[5]Associate Professor, Department of Prosthodontics, University of Iowa College of Dentistry, Iowa City, IA
[6]Associate Research Scientist, Department of Preventive & Community Dentistry, University of Iowa College of Dentistry, Iowa City, IA

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Correspondence
Paul M. Cashman, Eastman Dental Institute, University College London, Department of Prosthodontics, 256 Gray's Inn Street, London WC1X 8LD, United Kingdom. E-mail: p.cashman@ucl.ac.uk

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Abstract

Purpose: This study analyzed baseline and post-fatigue reverse-torque values (RTVs) for a specific brand control abutment relative to a third party compatible abutment. The purpose of this study was to compare the abutments' fatigue resistance to simulated function, using RTVs as an indication of residual preload at the implant/abutment interface.
Materials and Methods: Forty Straumann tissue-level implants were mounted in resin and divided into four groups ($n = 10$). Forty abutments were seated, 20 control and 20 third-party abutments, according to manufacturer guidelines. Ten abutments from each manufacturer were evaluated for RTV without fatigue loading, using a calibrated digital torque gauge to provide a baseline RTVs. Fatigue loading was carried out on the remaining ten specimens from each manufacturer according to ISO 14801 guidelines. A moving-magnet linear motor was used to load one specimen per sequence, alternating from 10 to 200 N at 15 Hz for 5×10^6 cycles. RTV was recorded post-fatigue loading. The results were subjected to two-sample t-testing and two-way ANOVA. Scanning electron microphotography was carried out on three specimens from both manufacturers at baseline and post-fatigue cycling to visualize thread geometry and the abutment/implant interface.
Results: The data indicated that mean post-fatigue RTV observed for the control group was significantly higher than the third-party group (RTV 42.65 ± 6.70 N vs. 36.25 ± 2.63 N, $p = 0.0161$). Visual differences at the macro/microscopic level were also apparent for thread geometry, with third-party abutments demonstrating considerably greater variation in geometrical architecture than control specimens.
Conclusions: Within the limitations of this in vitro model, the effect of component manufacturer resulted in a significantly higher RTV in the control group (two-way ANOVA, $p = 0.0032$) indicating greater residual preload; however, there was no significant decrease in post-fatigue RTV for either manufacturer compared to baseline.

Based on more than 20 years of clinical studies, single-tooth dental implant prostheses are a viable treatment option for use in restorative dental care.[1] However, interface-associated complications occur, with a recent systematic review of the literature revealing the incidence of screw loosening to be 5.8% over 5 years.[2] Due to the short time span represented by existing clinical trials, this may underestimate the complication rate.[3,4]

Complications related to screw loosening may be due to variations in machining accuracy and material consistency, which affect the clamping force (preload) generated across the implant/abutment joint. This is particularly true when torque control is used to generate preload. Preload is defined as the clamping force between the abutment and implant fixture and is derived from the torque applied to the retaining screw.[5,6]

Reverse torque value (RTV) has been used as a surrogate measure of residual preload to evaluate interface stability following fatigue testing by numerous studies.[7-13]

Third-party manufactured components do not require independent fatigue testing if the design is based on substantial equivalence, as determined by US Food and Drug Administration (FDA) 510(k) approval guidelines, despite evidence demonstrating variation in machining tolerances.[14-16] A search of the PubMed database (www.pubmed.gov, June 2008) using Medical Subject Headings (MeSH) terms—"Dental implants AND Quality control AND abutments OR standards OR design," on the MeSH Database (United States Library, Bethesda, MD) failed to produce evidence to support compatibility of third-party internal-connection components. These components were compared due to the clinical advantage the third-party abutment has in relation to financial cost.

The prevalence of screw loosening, combined with a lack of evidence base for third-party component usage, provided the impetus for this in vitro study. The primary aim of this in vitro study was to investigate the effect of fatigue loading according to ISO 14801 guidelines,[17] on "brand" and third-party abutments, using RTV as an indicator of residual preload. A secondary aim was to visually compare a subset of the fatigue-loaded abutments to evaluate consistency and quality of the machining process. The null hypothesis stated that fatigue loading does not lead to a difference in RTV between the control and third-party manufactured abutments.

Materials and methods

Testing was in accordance with ISO 14801 protocol guidelines. Forty dental implant fixtures, (12-mm long, 4.1-mm diameter, regular neck, Article Number 043.033S, Straumann USA, Andover, MA) were embedded in autopolymerizing acrylic resin (Lecoset 7007, Leco Corporation, St Joseph, MI). The mounts were prepared with a drill press 30° to the perpendicular, permitting implant embedment 3 mm below the rough/smooth interface, according to ISO 14801 (Metalor MP3000; Metaux Precieux SA Metalor, Neuchatel, Switzerland). Implants were luted in place and numbered 1 to 40.

Twenty Straumann 4-mm high regular neck solid abutments formed group 1 (Article Number 048.540), while group 2 consisted of 20 Titan Implant Inc. "compatible" abutments (Item ITI-4ISA, Titan Implant Inc., Bergenfield, NJ). These groups were randomly divided to form baseline and test subsets with n = 10. Specimen testing alternated between manufacturers.

Abutments were seated as per manufacturer guidelines with a calibrated handheld digital torque gauge (MGT10Z Mark 10 Corporation, Copiague, NY). The application of 35 N abutment seating torque was carried out twice, 10 minutes apart. RTVs were obtained 1 hour later, without fatigue loading, to determine a baseline measurement. Group 1 and two test subsets underwent dynamic fatigue loading prior to evaluation of RTV with a hemispherical loading member in place (KaVo Everest 8.0.1.10 CAD system, KaVo Dental GmbH, Biberach, Germany). Only one specimen was fatigued at a time to ensure load was applied correctly. Figure 1 shows the abutment/implant complex embedded in acrylic following ISO guidelines, with the loading member wax-up in situ prior to scanning for Computer aided design/Computer aided manufacture (CAD/CAM) milling. Fatigue cycling was carried out using the Bose Electroforce 3300 (Bose Corporation, Eden Prairie, MA) linear electromotor. The applied load varied sinusoidally at 15 Hz for 5×10^6 cycles between 10 and 200 N. All specimens were stored for at least 1 hour prior to measurement of RTV.

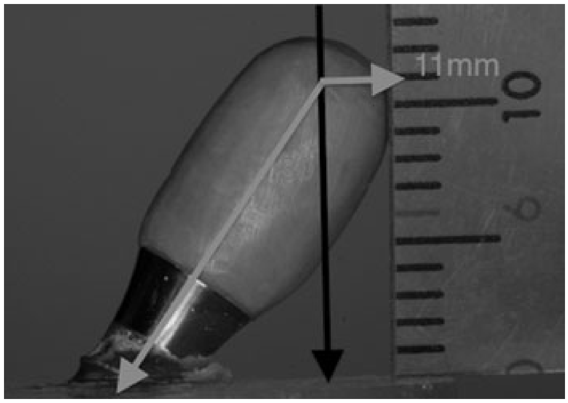

Figure 1 Implant/abutment complex embedded in acrylic according to ISO 14801 guidelines with wax-up of loading member in position.

Scanning electron microscopy (SEM) was carried out to determine the character of the interface microgap, to compare thread geometry, and evaluate surface characteristics between systems, (Amray 1800, Amray Inc., Bedford, MA) for three randomly assigned Straumann and Titan abutments, pre- and post-fatigue cycling at 20x to 500x magnification. Photomicrographs were digitized using the Edax Imaging and Mapping System P/N 9499.200.62100 revision 3.2 (Edax, Mahwah, NJ).

Statistical analysis was conducted using Microsoft Excel (Microsoft Corporation, Redmond, WA) and SAS software, version 9.1 (SAS Institute Inc., Cary, NC) with a 0.05 level of statistical significance assumed prior to testing. Descriptive statistics of RTV were calculated, and comparisons performed with two-way ANOVA testing for brand, time, and their interactions on the post-fatigue RTV.

Results

Ten RTVs were analyzed in each group; however, 11 specimens were required for the group 1 test subset, as one implant abutment fractured. Applied seating torque was evaluated for bias using a two-sample t-test, which determined no evidence of bias in torque application between groups 1 and 2 ($p = 0.4165$). Tables 1 and 2 summarize the descriptive statistics for the groups before and after cycling, respectively. Figure 2 illustrates mean RTVs and associated confidence intervals.

The Shapiro-Wilks' test applied to the independent variable, RTV, demonstrated a valid assumption of normality for all groups (Baseline subset: group 1, $p = 0.0895$; group 2, $p = 0.0882$; Test subset: group 1, $p = 0.6434$; group 2, $p = 0.1435$). Two-way ANOVA indicated a highly significant interaction between abutment groups ($p = 0.0032$). Subsequent post hoc analyses demonstrated a simple effect between test subsets for both groups ($p = 0.0161$) but no significant simple effect between the baseline subsets for both groups ($p = 0.1697$).

Table 1 Baseline mean force values by manufacturer. Input a = first application of input torque moment to screw in abutment; Input b = second application of input torque, 10 minutes later to counteract embedment relaxation; RTV = reverse torque value

Baseline					
Group 1—Control					
Variable	n	Mean (N)	Std Dev	Min (N)	Max (N)
Input a	10	34.98	0.14	34.88	35.33
Input b	10	35.71	1.62	34.09	39.60
RTV	10	33.75	1.86	31.61	37.01
Group 2—Third-party manufacturer					
Variable	n	Mean (N)	Std Dev	Min (N)	Max (N)
Input a	10	35.30	1.12	34.88	38.48
Input b	10	35.02	0.30	34.54	35.66
RTV	10	35.56	3.55	32.18	42.19

Table 2 Post-fatigue mean force values by manufacturer. Input a = first application of input torque moment to screw in abutment; Input b = second application of input torque, 10 minutes later to counteract embedment relaxation; RTV = reverse torque value

Post-fatigue					
Group 1—Control					
Variable	n	Mean (N)	Std Dev	Min (N)	Max (N)
Input a	10	35.27	0.21	34.99	35.55
Input b	10	35.38	0.79	34.88	37.46
RTV	10	42.65	6.70	35.21	53.33
Group 2—Third-party manufacturer					
Variable	n	Mean (N)	Std Dev	Min (N)	Max (N)
Input a	10	35.19	0.20	34.99	35.55
Input b	10	35.27	0.21	34.99	35.55
RTV	10	36.25	2.63	31.28	40.50

The data also suggest there was a simple effect within test and baseline subsets for group 1 ($p = 0.0022$).

SEM demonstrated increased variation in screw-thread geometry in the generic abutment group compared with the manufacturer's thread geometry. Figure 3 illustrates the differences in thread length and truncation between the control and third-party abutments. Figure 4 shows the first thread in profile (500x magnification), indicating differences such as a smooth surface on the control abutment (Fig 4A), while third-party abutments (Fig 4B) display increased surface roughness, with flash from the tooling still present at the thread tip.

SEM at the implant/abutment interface was carried out before and after fatigue cycling in the plane of the applied force from above and below the point of load application. No visual difference was apparent at 500x magnification at the implant/abutment interface when pre- and post-fatigue loading were compared. Figure 5A shows the Straumann implant pre-fatigue loading. Following fracture (Fig 5B), SEM demonstrates delamination of the material, consistent with ductile fracture. No stage I crack propagation was noted, indicating that once screw loosening occurred, stress concentration at the screw led to rapid failure.

Discussion

Differences in material fabrication and manufacturing processes are detailed in the product information as follows: Straumann implants and abutments are fabricated from

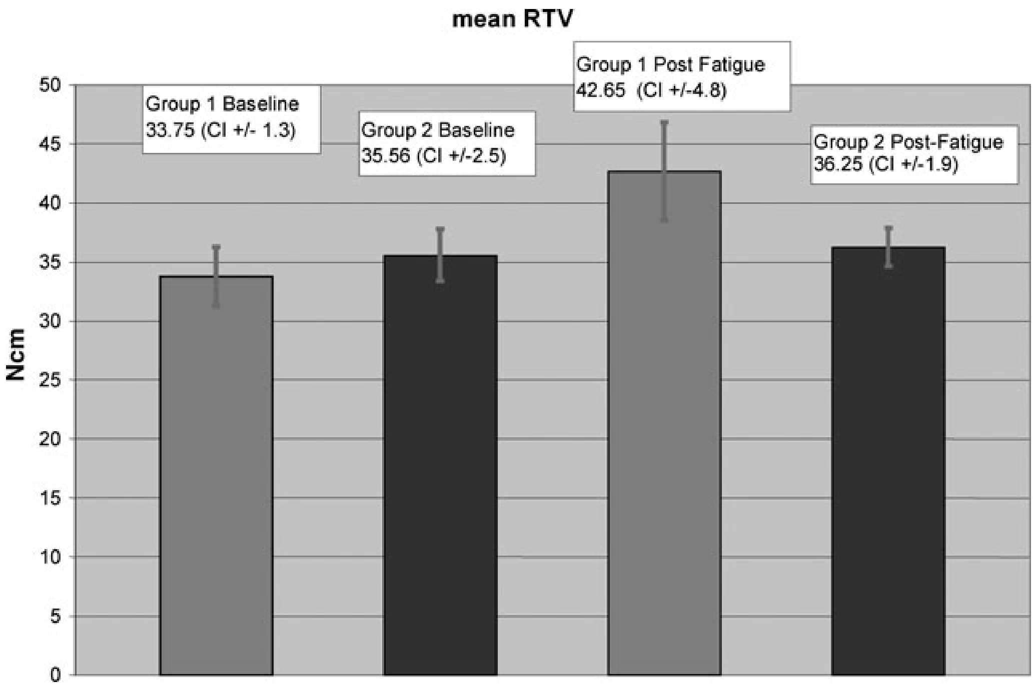

Figure 2 Mean reverse torque value.

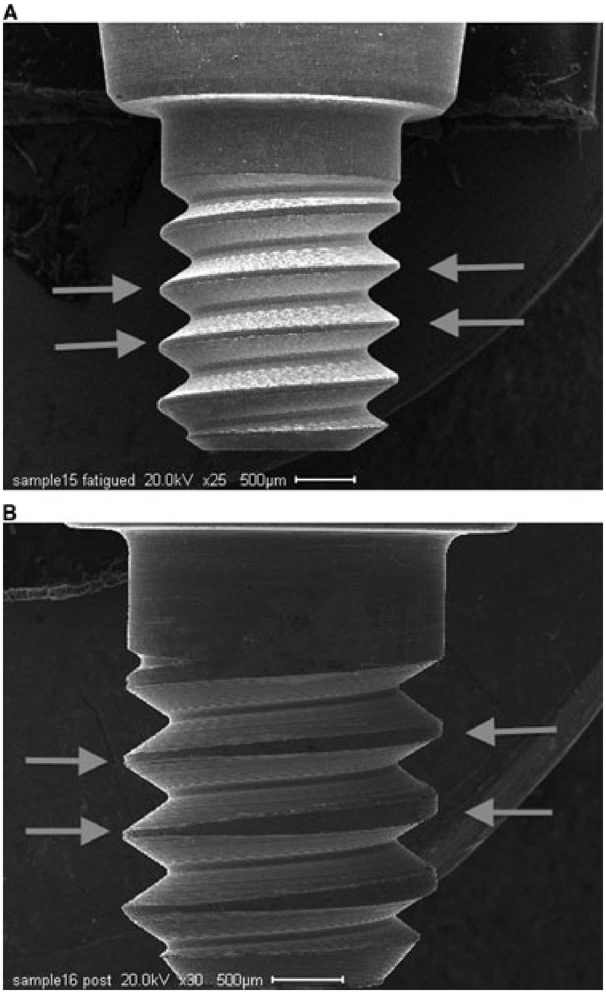

Figure 3 (A) Group 1 abutment threads in profile. Note arrows pointing out thread profile. (B) Group 2 abutment threads in profile. Note arrows pointing out thread profile.

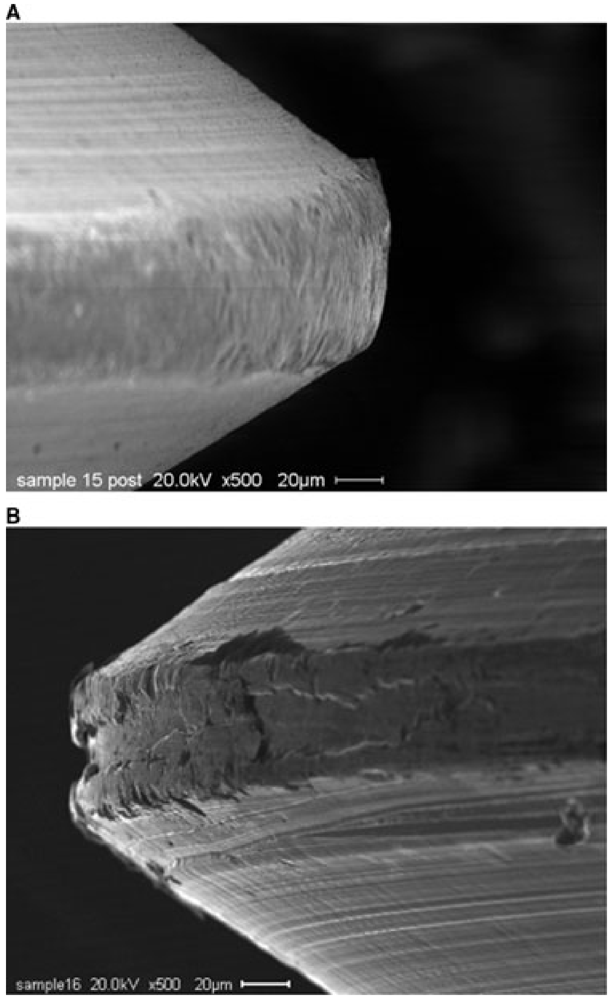

Figure 4 (A) Group 1 first thread in profile. Note smooth, rounded surface. (B) Group 2 first thread in profile. Note rough surface.

commercially pure grade IV titanium. According to Straumann, work hardening of the threads improves the physical properties, and application of a titanium-nitride surface coating (yellow) increases hardness and alters friction characteristics. The third-party manufacturer abutments were fabricated from a Ti alloy (ASTM grade 23 or Ti-6Al-4V), which generally demonstrates increased strength and modulus of elasticity compared to the commercially pure grades. The abutment consists of a grooved and roughened surface for improved cement retention. These differences in chemical composition, manufacturing, and surface treatment indicate a need for independent verification of functional compatibility.[5] This is particularly true for Ti when torque control is used to optimize preload and joint stability.[5] Ti is subject to galling, where friction leads to further roughening of the mating parts, affecting the generation of the optimum preload.

The available dental literature recognizes the importance of optimized screw tightening,[18,19] component uniformity, machining tolerances,[14,15,20,21] elongation, and preload[22,23] on stability of the implant/abutment interface; however, long-term fatigue-loading studies on component compatibility are not available to aid evidence-based clinical practice. The significant interaction between abutment brand and fatigue loading ($p = 0.0032$) indicates that greater preload exists post-fatigue loading for the control abutment ($p = 0.0161$). While ISO guidelines do not allow prediction of in vivo behavior, they do provide quantifiable information that provides an important step in the scientific process of evidence-based dentistry. Efforts to optimize fatigue testing are underway, to enable testing of interface designs and between-system compatibility.[24,25]

Evaluation of existing studies is complicated by the recognition of two fatigue-testing protocols (US FDA, Silver Spring, MD); the unidirectional bend-release model, as used in this study, and rotating-beam test setup.[11,26–30] The rotating-beam test should be avoided when testing screw-attained preload, because rotation during testing can affect preload, due to precession or fretting.[5] This indicates that the unidirectional bend-release model is more suitable for fatigue testing a screw-type

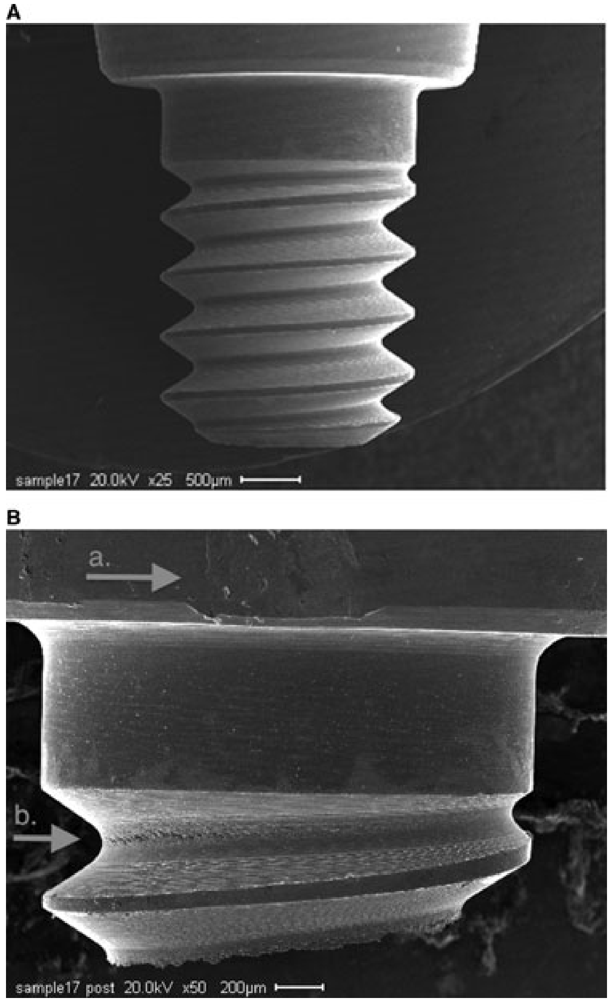

Figure 5 (A) Group 1 implant pre-fatigue cycling and prefracture. (B) Group 1 implant post-fatigue cycling and postfracture. Arrow "a" indicates the facet formed prior to fracture, while "b" demonstrates ductile delamination following screw loosening.

interface; however, many published bend/release studies loaded more than one specimen at a time on a single load cell.[8,12] While this speeds up the process of testing specimens, it prevents accurate control of loading on each specimen, a vital element in ensuring standardized testing. Thus, the literature contains few studies that use unidirectional bend-release models with a single load cell per specimen.[7,21] In conflict with these studies, we did not determine a significant loss of RTV post-fatigue loading, despite similar test parameters; however, these studies evaluated the external connection implant/abutment interface.[24] The focus of this study is limited to the comparison of internal-connection abutments from two manufacturers using the Unitarian design interface. The Unitarian design seats the prosthesis on the implant fixture, allowing direct stress transmission and encirclement. This stress transfer occurs at a more occlusal position than bone-level implants, reducing the lever-arm effect at the joint.[31]

Randomization of implant/abutment pairing was carried out prior to alternating manufacturer sequence during fatigue loading. Calibration of instruments was verified prior to torque application and fatigue loading. Torque was applied twice, 10 minutes apart, to counteract loss of preload due to embedment relaxation.[32] The free end of the implant/abutment complex was provided with a hemispherical loading member according to ISO guidelines. One coping milled from zirconia with a close tolerance fit was used for all specimens.

A single abutment, from the Straumann group, fractured at 1.7×10^6 cycles. Fracture occurred at the root of the first thread, considered the location of greatest stress concentration.[33] Seating torque values followed manufacturer guidelines, and SEM prior to fatigue testing did not demonstrate any defects; as such, it was considered a genuine extreme outlier. Due to the stochastic nature of fatigue loading, confounding outliers occur. The fractured specimen was omitted from the data analysis due to difficulties identifying a correct statistical "weight" to the fractured specimen data and the skewed distribution of failure in fatigue loading.[6] As a result, an extra specimen underwent fatigue cycling using a new implant/mounting and abutment, successfully completing the fatigue component of testing, whereby the RTV for the extra specimen was incorporated into the data collected. Figure 5 shows the abutment pre-fatigue cycling and postfracture.

The clinical relevance of this study is related to the risk of screw loosening, which is a significant occurrence and may be underestimated by the clinical evidence to date. The limitations of this study relate to the lack of correlation between in vitro and in vivo results. Indeed, recent in vivo studies demonstrate dichotomous results with regard to the incidence of screw loosening, which, in spite of relatively short-term clinical follow-up, vary from 0%[34-36] to 13%.[37-39] Also, in vitro trials have demonstrated high levels of screw loosening, differing from the results found in this study.[12,13] To address this dichotomy, one must first determine the most representative and feasible in vitro test model, an area where much progress needs to be made. Also, the validity of comparing pre- versus post-fatigue RTV should be examined due to the introduction of plastic deformation and cold welding during fatigue loading. Thus, more evidence is required prior to supporting the use of specific implant/abutment designs with third-party components.

Conclusions

According to the limitations of the representative model used:

(1) The null hypothesis was rejected, i.e., the independent variable, abutment manufacturer, does lead to a difference in RTV post-fatigue loading. Two-way ANOVA found a significant interaction between abutment brand and fatigue loading ($p = 0.0032$).
(2) The control abutment demonstrated a greater RTV than the third-party-manufactured component ($p = 0.0161$).
(3) At baseline, no significant difference in RTV was demonstrated between manufacturers.
(4) Differences in surface finish and machining tolerances were visualized with SEM.

Further investigation is required to address the lack of medium/long-term fatigue testing on current dental implant components and to develop a validated in vitro model of in vivo fatigue loading.

Acknowledgment

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