Mechanical Reliability Evaluation of an Oral Implant-Abutment System According to UNI EN ISO 14801 Fatigue Test Protocol

Enrico Marchetti, DDS, PhD,* Stefano Ratta, DDS,* Stefano Mummolo, DDS, PhD,* Simona Tecco, DDS, PhD,† Raffaella Pecci, Eng, PhD,‡ Rossella Bedini, MS,§ and Giuseppe Marzo, MS, DDS¶

Purpose: *The aim of this in vitro study was to evaluate the mechanical reliability of a dental implant system by testing its maximum fracture load and mechanical performance under cyclic fatigue stress.*

Methods: *An experimental study according to the international standards (UNI EN ISO 14801: 2008) was performed using 13 implants (3.80 mm in diameter and 12 mm in length) with straight titanium abutments tightened to 30 N. Five samples were subjected to compression stress at break. Based on the mean fracture load value obtained in this test, the levels of dynamic loading range were set and were carried on at a frequency of 15 Hz for 5 × 10^6 cycles.*

Results: *The compression stress at break mean value of the tested implants was 430 N (SD ± 35.66 N). In the mechanical fatigue stress test, the fatigue limit for 5 × 10^6 load cycles was 172 N.*

Conclusions: *The evaluated implant system proved to withstand considerable mechanical loads under the "worst-case" loading situation performed according to UNI EN ISO 14801 standard. The reliability of this test protocol makes it suitable to be accomplished for understanding and comparing mechanical properties of implant systems. (Implant Dent 2016;25:613–618)*

Key Words: fixture-abutment connection, fracture strength, fatigue stress test

The use of osseointegrated dental implants has become a successful procedure for the treatment of complete or partial edentulism and single-tooth replacements in both the anterior and posterior regions of the mouth. Implant-supported rehabilitations are subject to substantial masticatory cyclic loadings during function; consequently, mechanical complications of the implant-prosthetic system, such as failure or loosening of the abutment screw or fracture of the fixture, may occur.[1] To reduce the incidence of these phenomena and to increase the predictability of rehabilitations, several designs have been marketed to solve the problems in the fixture-abutment interface.[2]

The clinician must be careful in properly evaluating the mechanical characteristics of different implant-prosthetic systems regarding the extreme complexity of intraoral environment. More than twenty implant-abutment interface models are licensed to be distributed. Current designs of fixture-abutment connections can be schematically grouped into two base configurations: the "butt-joint" model, with its 2, flat parallel-contacting surfaces; the "cone-in-cone" or "taper design" model, which is characterized by coupling between the cones of the implant and the abutment. Butt-joint models include "external" or "internal" types, depending on whether the interface geometric antirotational component protrudes beyond the implant surface or is internal to the structure, respectively. These connections are marketed in several different forms, each one having its distinct advantages and disadvantages.[3,4]

However, dental literature provides various testing protocols for the evaluation of dental implant mechanical reliability,[5–7] but in most of available scientific studies, testing is performed by applying only part of the procedures provided by international standards (UNI EN ISO 14801:2008).[8] Such heterogeneity makes it difficult to compare

*Assistant Professor, Department of Life, Health and Environmental Sciences, University of L'Aquila, L'Aquila, Italy.
†Researcher, Dental Clinic, University Vita-Salute San Raffaele, Milan, Italy.
‡Researcher, Technologies and Health Department, Italian National Institute of Health, Rome, Italy.
§First Researcher, Technologies and Health Department, Italian National Institute of Health, Rome, Italy.
¶Professor, Department of Life, Health and Environmental Sciences, University of L'Aquila, L'Aquila, Italy.

Reprint requests and correspondence to: Stefano Ratta, DDS, Dental Clinic, via Vetoio, Delta 6 building, 67100 L'Aquila, Italy, Phone: (+39) 0862/701882, Fax: (+39) 0862/701882, E-mail: rattaste182@libero.it

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Fig. 1. Experimental sample of the investigated implant-abutment system glued in resin.

their performances and highlights the need for studies that are based on the standardized methods described in the European normative.[9–11]

The purpose of this study has been to evaluate the mechanical performance of a modern, commercially available implant-abutment system subjecting it to a fatigue test executed according to UNI EN ISO 14801 standards.[12] The scrupulous adherence to procedures indicated by the norm may provide significant data that are universally recognized for the mechanical evaluation of implant systems available on the market.

MATERIALS AND METHODS

The Bio Horizons Tapered Internal Laser-Lok implant-abutment system (BioHorizons Implant Systems Inc., Birmingham, AL) was studied. The system components are made of titanium alloy (Titanium-6Aluminium-4Vanadium). The selected implant fixtures were Ø = 3.8 mm in diameter and l = 12 mm in length and had an internal hex connection 1.5-mm deep with a lead-in tapered bevel.

Thirteen samples were assembled, wherein each contains one implant with a straight standard titanium abutment joined with their screw. Commercially available implant-abutment systems were used, and each one was assembled, in accordance with the manufacturer's recommendations, using a dynamometric key until a preload of approximately 30 N × cm was reached. The samples were included in a resin, with a Young's modulus of less than 3 GPa (Leocryl model; Leone, Sesto Fiorentino FI, Italy), polymerized in a brass mold in the shape of a truncated cone, and drilled in the center using a calibrated milling cutter with a parallelometer. The implant was positioned in such a way that the distance between the resin platform and the top of the fixture was equal to 3 ± 0.1 mm, thus simulating the "worst situation" of osseous resorption (Fig. 1).

Table 1. Values of the Maximum Tolerated Loads in the Static Loading Tests Performed on 5 Experimental Samples

Mechanical Test at Break	
Sample	Load at Break (N)
BH 1 s	377
BH 2 s	438
BH 3 s	428
BH 4 s	477
BH 5 s	430
Mean ± SD	430 ± 36

Each sample was subject to an increasing load until the mechanical failure of the complex occurred. The mean value was used to set the dynamic testing protocol.

According to the European normative used for the mechanical tests, an indicated geometry for sample positioning and loading was used during the tests. Figure 2 shows this positioning system specific for testing implants without angled connection, as in our research. In particular, the sample was placed at 30 ± 2 degree, with respect to the loading axis, and it was connected to a fixing device in such a way that the distance I, which was from the center of the loading unit to the fixing device platform, was equal to 11 mm. For the correct positioning of the samples, *ad hoc* designed devices have been manufactured, which consisted of:

1. A steel disc for the connection to the loading cell, with gripping points for the fixing of the mobile sample support to obtain the correct alignment of the sample with the loading axis of the load actuator
2. A support for the samples with a 30 degree inclined platform
3. A steel cylinder (diameter = 15 mm), through which the load was applied

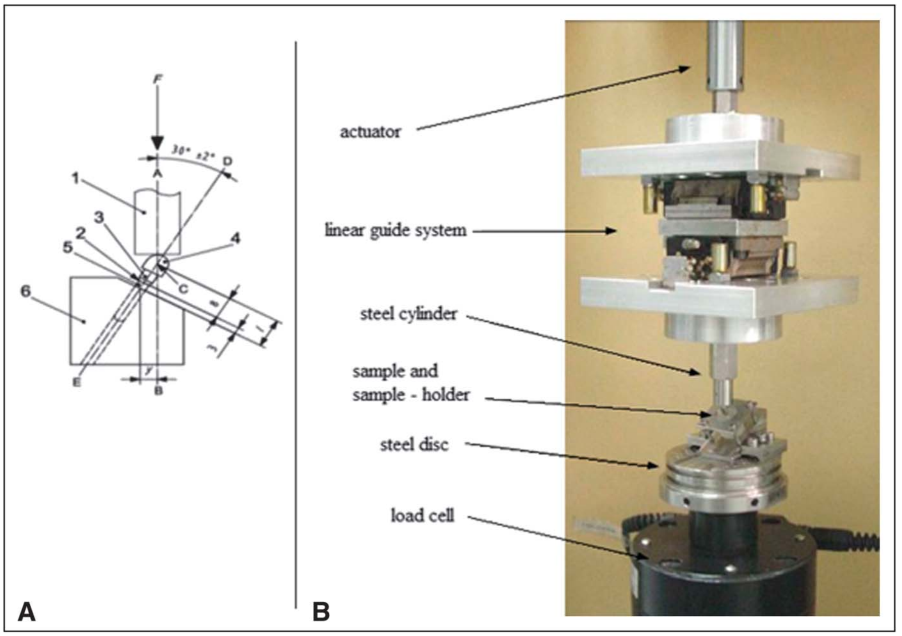

Fig. 2. Scheme of the sample positioning during the test (**A**) and image (**B**) of the complete fatigue test system: 1, loading device; 2, nominal bone level; 3, connecting part; 4, hemispherical loading member; 5, dental implant body; 6, specimen holder.

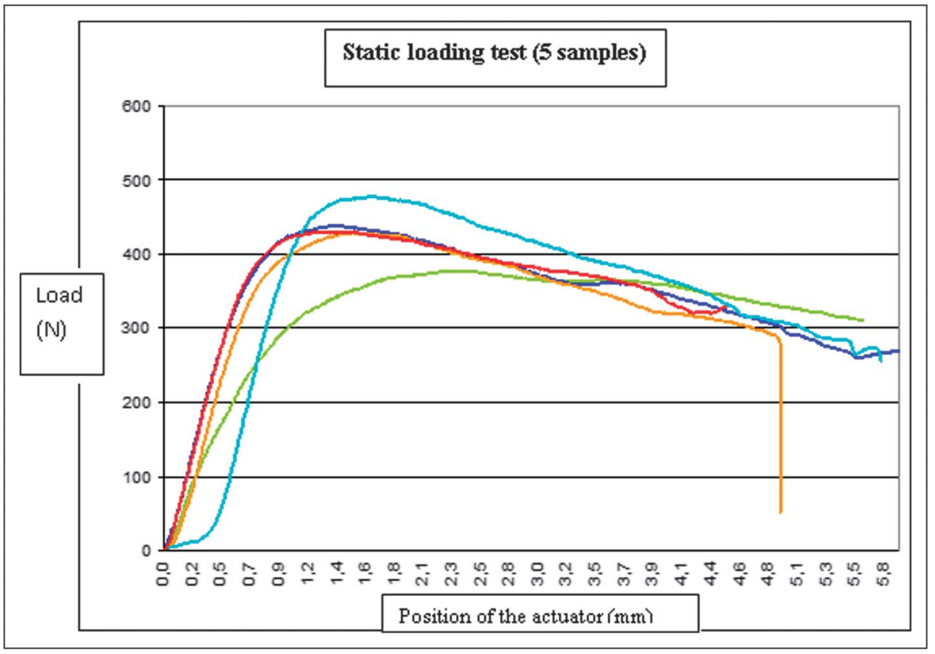

Fig. 3. Graph representing the trend of the load as a function of the position of the hydraulic actuator during the compression test at break. It is possible to follow sample's performance under mechanical loading and to recognize the point of "maximum breakage load" at which the failure of the implant system occurs with collapse of the curve. Green curve indicates BH 1 s; blue curve, BH 2 s; orange curve, BH 3 s; light blue curve, BH 4 s; and red curve, BH 5 s.

4. A system with 2 orthogonal linear rails, which was connected to the actuator with the upper part and to the steel cylinder with the lower part.

Fig. 4. Sample subjected to the compression stress test until failure. The implant were glued in resin with 3 ± 0.1 mm distance between the resin platform and the top of the fixture to simulate bone resorption and stressed with load forming an angle of 30 ± 2 degree with implant axis.

UNI EN ISO 14801 also specifies that a rigid cylindrical loading unit with a flat head must act on a hemispherical contact surface connected to the implant-abutment system. This structure, called the "cap," was built with the "lost wax casting technique" in golden alloy. The cap was placed in the correct position, in compliance with the parameters stated by the normative. The above-mentioned whole system allows the free translation and application of the load, without altering its stress intensity during the loading test.

Five samples were used to identify the maximum breaking load by means of a compression stress at break test. Furthermore, the principles for fatigue testing laid down by the normative state that at least 2 specimens shall be tested with a sinusoidal load oscillating between a nominal peak value and 10% of this value with a 15 Hz stress frequency until a maximum number of 5×10^6 loading cycles.[13] We selected nominal peak levels equal to 40%, 45%, 50%, and 80% of the previously obtained maximum breaking load, testing 2 samples for each load protocol.

For data recording and collection, the MultiPurpose TestWare software connected to the servohydraulic loading machine 858 MiniBionix (MTS, Minneapolis, MN) was used; after the tests were performed, the software recorded the maximum number of cycles that the implant system could bear (nf) and the fatigue limit (Lf), which indicated the number of cycles that the implant system was able to tolerate without ever breaking. The test results were evaluated in comparison to the minimum requirements suggested by the normative as and to other data provided by literature.

RESULTS

The five samples subjected to compression stress test gave different results (Table 1), with a mean breaking value of 430 N (SD ± 35.66 N). Figure 3 shows the trend of the load as a function of the position of the hydraulic actuator during the compression tests: this figure clearly shows the precise point of the maximum rupture load, where failure of the implant system occurred. The sample failure depended on the fixing

Table 2. Results of the Fatigue Stress Tests Performed on 10 Samples

Fatigue Test			
Loading Level (%)	Minimum and Maximum Sinusoidal Loading (N)	Sample/No. Performed Cycles	
80	34–344	BH 1D/13,526	BH 3D/8452
50	21–215	BH 4D/5,000,000	BH 6D/417,350
45	19–193	BH 7D/1,383,744	BH 5D/5,000,000
40	17–172	BJ 8D/5,000,000	BH 2D/5,000,000

Two samples were tested for each of the 4 dynamic load protocols set to a percentage of the maximum breaking load. The cyclic loading was performed at a frequency of 15 Hz up to a maximum of 5 × 10⁶ sinusoidal load cycles.

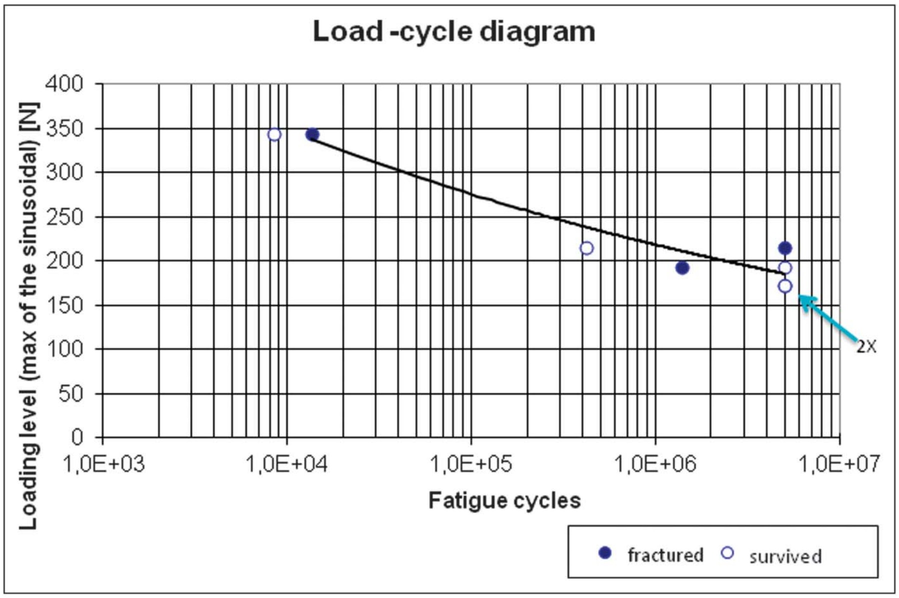

Fig. 5. Graph of fatigue stress test: the diagram shows the number of fatigue cycles executed by each samples at every defined loading levels. Fractured samples are marked with a blue dot, survived samples with a white dot; ×2 = 2 dot overlapped. "Lf-fatigue limit" red line indicates fatigue limit; "nf-fatigue cycles number" red line, maximum number of cycles that the implant system could bear.

screw breaking or on the rupture of the fixture (Fig. 4), which caused a sudden collapse of the actuator that was promptly detected by the machine.

Table 2 shows the percentage load values for the fatigue stress tests, the maximum and minimum sinusoidal load values for each level, and the number of fatigue cycles supported by each sample without breaking. During the fatigue tests, four samples were subjected to the applied loading levels up to 5×10^6 cycles without breaking, whereas the other samples broke earlier. Figure 5 shows the number of fatigue test cycles obtained from each sample for each of the chosen loading levels. Implant samples that were subjected to cyclic loading with a maximum load of 172 N (40% of the breaking load), survived 5×10^6 cycles, whereas the samples subjected to the highest loads failed between 8452 and 13,526 cycles. In one case, with a maximum load of 215 N (50% of the breaking load), 5×10^6 cycles were completed. For the analyzed implant system, the nf value was 5×10^6, and the fatigue limit value for 5×10^6 cyclic loading, Lf, was 172 N.

DISCUSSION

The mechanical reliability of a dental implant system is strongly influenced by the coupling mechanism of the implant-abutment and the retentive properties of the screw joints. In fact, the mechanical failure of an implant-prosthetic system may be related to an excessive bending of the screw joint against insufficient tightening force or to intrinsic limits in the material strength. Furthermore, it can also be related to an "adjustment" effect and loosening of the components or to a design misfit, and others.[14–16] However, the effect of a specific connection design on the mechanical resistance of the screw joint of a dental implant remains uncertain, as demonstrated by the large number of commercially available configurations. For these reasons, the study of mechanical properties of prosthetic implant systems is a critical subject of research.

The problem of screw loosening was thoroughly documented in the classic Brånemark butt-joint system: the external hex connection was initially developed only to engage the implant during its surgical positioning, but it also constitutes an antirotational device for the coupling and lateral stabilization of the abutment to the fixture; in this way, it was exposed to high loads and bending moments leading to joint failure. Literature revealed that the short external hexagon in this connection system does not stabilize the joint against lateral loads but rather discharges its strength only on the screw, often subtracting its clamping force and causing its loosening.[17,18] Improved performances have been achieved by using modified geometries and different materials that increased the tightening torque of the abutment screw with higher joint resistance. In contrast to these external butt-joint models, implant systems with internal connections avoid excessive loading on the abutment screw by transferring the occlusal loads more deeply into the implant, thereby ensuring a lower incidence of mechanical complications.[19] Moreover, implants with internal conical connections seem to show high resistance to flexural moments because of the shape adjustments and the reduced friction of cone-in-cone designs.[20]

In the proposed work, an implant system that is commonly used in modern clinical practice has been tested. The fixture has a conical design with an internal hexagonal antirotational coupling mechanism that engages the superstructure for a depth of 1.8 mm. The testing method adopted for this in vitro study was in accordance with UNI EN ISO 14801 standards, which seems to be extremely effective in studying the mechanical predictability of implant-abutment systems. Preset positioning parameters aim to best simulate the oral cavity conditions: the samples are angled at 30 degree against loading system being stressed by both vertical and horizontal loads; the implant protrudes 3 mm from the supporting resin, simulating the "worst-case" situation of an osseous support reduction.

The normative suggest that an implant system should survive 100% if it is stressed by a sinusoidal load with a maximum value of 10% its breaking load as a minimum requirement; 100% mortality of implants is, however, considered acceptable when the sinusoidal load reaches a maximum value that is equal to 80% of the breaking load. On the basis of these criteria, the tested implants gave positive results with respect to the fatigue test, since the 50% of all samples exceed the test and the Lf value corresponded to 40% of its breaking load. The early failure of the sample that had undergone cyclic stress to 45% of the breaking load must be attributed to a problem in the inclusion of the sample in the resin base.

Moreover, in evaluating the test results, it is meaningful to compare them with the bite forces reached in physiological chewing activity. Regardless of the individual's anatomical and physical characteristics, the maximum occlusal strength varies substantially, depending on the region of the oral cavity. The maximum bite strength has been measured in first molar region, whereas the incisors reach only one-third to one-fourth of this force: the occlusal strength values in the molar region range between 216 and 847 N, and the values in the incisor region range between 108 and 299 N.[21–23] The implant-abutment system investigated in this study showed a maximum failure strength that was approximately 430 N during static loading and 172 N during fatigue loading (defined as the "fatigue limit" for 5×10^6 loading cycles). These data clearly show how the functional dynamic loads gradually reduce the frictional forces between the implant-abutment system connection components culminating with screw joint loosening or fracture. The investigated system, in the tested size, could safely withstand masticatory loads usually developed in the maxillary and mandibular incisor region; however, cyclic loading with higher multidirectional forces such as such as in the molar area strongly affects the mechanical properties of the prosthetic implant system, determining a situation of dynamic fatigue, leading the rehabilitation to fail even if the static breaking limits were not exceeded.[24]

CONCLUSIONS

In this in vitro study, the mechanical reliability of a dental implant system was evaluated. The study of cyclic loading performed following carefully the UNI EN ISO 14801 standard provides a powerful and accurate tool for the mechanical reliability evaluation of endosseous dental implants in accordance with globally recognized data that may allow identify indications and limitations of their use.[25]

The international standard foresees the adoption of different and multidirectional cyclic loads that put a strain on the implant-abutment complex by trying it in the "worst-case" loading situation. Within the limits of this study, the results suggest that the investigated implant-abutment system is characterized by good mechanical reliability, overcoming the minimum requirements set by the normative. The Bio Horizons Tapered Internal Laser-Lok implant-abutment system ($\text{Ø} = 3.8$ mm, $l = 12$ mm) proved to constantly withstand the mean bite force value reported in the literature for incisal restorations, whereas care must be taken in its use in molar region, wherein occlusal forces are greater and mechanical reliability has not been demonstrated.

DISCLOSURE

The authors claim to have no financial interest in any company or any of the products mentioned in this article.

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