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ORIGINAL ARTICLE

Complete mechanical characterization of an external hexagonal implant connection: in vitro study, 3D FEM, and probabilistic fatigue

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Abstract

The aim of this study was to fully characterize the mechanical behavior of an external hexagonal implant connection (ø3.5 mm, 10-mm length) with an in vitro study, a three-dimensional finite element analysis, and a probabilistic fatigue study. Ten implant-abutment assemblies were randomly divided into two groups, five were subjected to a fracture test to obtain the maximum fracture load, and the remaining were exposed to a fatigue test with 360,000 cycles of 150 ± 10 N. After mechanical cycling, all samples were attached to the torque-testing machine and the removal torque was measured in Newton centimeters. A finite element analysis (FEA) was then executed in ANSYS® to verify all results obtained in the mechanical tests. Finally, due to the randomness of the fatigue phenomenon, a probabilistic fatigue model was computed to obtain the probability of failure associated with each cycle load. FEA demonstrated that the fracture corresponded with a maximum stress of 2454 MPa obtained in the in vitro fracture test. Mean life was verified by the three methods. Results obtained by the FEA, the in vitro test, and the probabilistic approaches were in accordance. Under these conditions, no mechanical etiology failure is expected to occur up to 100,000 cycles.

Keywords Compression fracture · Fatigue fracture · Finite element analysis · Mechanical behavior · Failure probability

1 Introduction

Implants are an alternative not only for the treatment of total edentulism but also for the replacement of one or more dental elements [1]. A suitable knowledge of technical parameters and biomechanical behavior, in addition to aesthetic requirements, is crucial [2]. Titanium abutments are commonly used to restore implants because of their excellent biocompatibility and mechanical properties [3]. An external hexagonal implant-abutment connection is a common dental implant-abutment system that is available for implant-supported prostheses [4].

Static fracture tests are used to determine the maximum load that the implant can withstand. However, these mechanical tests do not simulate masticatory functions; therefore, other tests should be applied to simulate physical situations [5]. Fatigue testing exposes implant components to cyclic loading.

These in vitro tests are best to meet the requirements of masticatory loads [6]. The life of implants depends, among other factors, on the stress distribution in all components, which in turn, depends on the implant design, material, position, location, and bone quality and quantity [7]. Some studies show that implants with a wide diameter have a more favorable stress distribution on both the implant and the cortical bone region than that of a regular diameter, regardless of the connection type (external, internal, or Morse taper) [8]. Finite element models are a common tool to explain the biomechanical behavior of implants and simulate real situations, and they are a good non-invasive option to analyze the critical loading situation of implants [9].

Although implant components are expected to fulfill ISO 14801 [10] before they are launched in the market, there are a huge number of studies published with various parameters used for cyclic loading. Dental literature does not present controlled and standardized environment for cyclic loading

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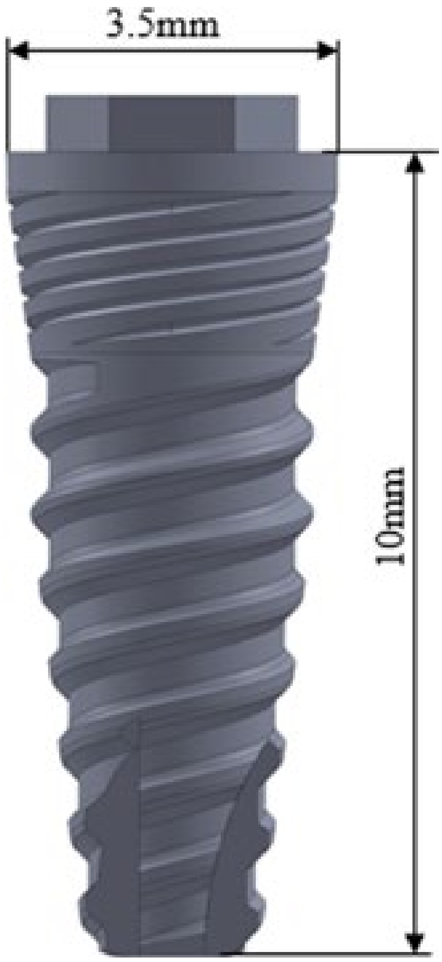

Fig. 1 Tested implant: OXTEIN N6 with 3.5-mm diameter, 10-mm length

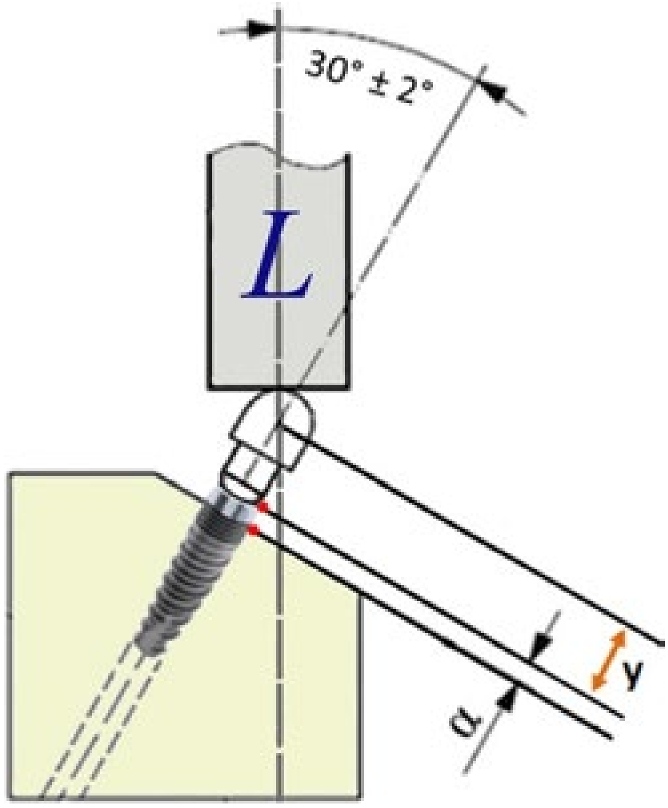

Fig. 3 The scheme used in the compression test, based on ISO 14801/2007 standards. The distance between the red points (α) shows the extent of the compression during the test. α represents the bone loss, and y is the moment arm as specified in ISO 14801/2007 (Color figure online)

conditions [5]. Additionally, due to the randomness of the fatigue phenomenon, a probabilistic study should be included to fully characterize the mechanical behavior of implants.

Fig. 2 A three-dimensional model assembled

Clinical observations have indicated that the primary causes of implant failure include incomplete osseointegration, complications from neighboring soft tissues, and biomechanical problems, as abutment screw loosening or fracture [11, 12]. Several factors influence screw loosing, such as the screw settling, the magnitude of functional loading, and the inability to apply sufficient tightening force to the screw [13]. With external hexagonal connections, the abutment is connected directly to the implant platform. The joint between the implant and the abutment is established by friction after torque application [4, 14]. Screw loosening can cause several clinical problems, such as, the displacement of the prosthesis and loss of prosthetic function [2]. Load or torque application causes plastic deformation and wear on the screw, which modifies the mechanical behavior [4]. Fatigue can induce micromovements of the contacting surfaces [4]. Therefore, the loading cycling at the implant-abutment joint is one of the potential factors on abutment screw failure [15].

This study presents a complete characterization of the mechanical behavior of implants with hexagonal external connections. A static fracture test and a fatigue test were carried out. A 3D finite element analysis was done to verify the results obtained by the mechanical tests. Then, a probabilistic fatigue model was computed with the aim to obtain the fatigue life (mean and variance) and the probability of failure associated

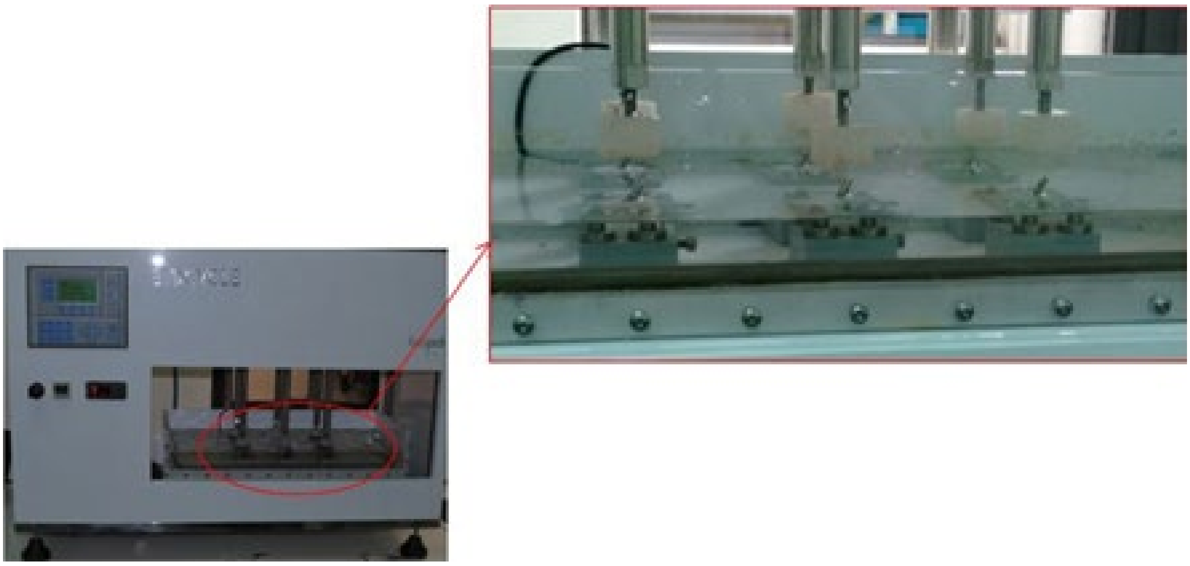

Fig. 4 Image showing the samples were immersed in water at 37 ± 2 °C and placed on a chewing simulator in the Biocycle machine

with each cycle. Therefore, the current study provides a complete mechanical characterization of external hexagonal implant connection.

The alternative hypothesis (H_a) is to verify that the results obtained from finite element methods are in accordance with those obtained by mechanical tests.

The aim of this study is to provide a complete characterization of the mechanical behavior of implants with hexagonal external connections by fracture test, numerical analysis, and probabilistic model. The main novelty of this study is the fact of employing a probabilistic approach as a method to be included during the process of the dental implants' design.

2 Methods

2.1 Implants, abutments, and crowns

The analyzed dental implants were the commercial Ti-6Al-4V, 3.5-mm diameter, 10-mm length implants, and hexagonal external connection called OXTEIN N6, manufactured by Avenir S.L. (Rimini, Italy). These conical implants have the following data: eight threads with a pitch of 1.00 mm and a depth thread of 0.23 mm. The threads have a 45° angulation thread with a progressive compression function during bone screwing, with a surface treatment of sandblasting and double acidification process, and decontamination of the surface by argon-cooled plasm. These implants have four microthread principles with a 30° angulation for 1.5 mm in the implant collar and an average depth 0.15 mm.

According to ISO 14801, implants with a smaller diameter available should be investigated [10]. The tested implant is shown in Fig. 1.

Ten implants were randomly divided into two groups by an independent researcher with the Microsoft Office Excel® RAND function; five of them were exposed to a compressive test and the others were exposed to a fatigue test. The abutments were connected to the implants with a torque of 30 Ncm, according to the manufacturer's recommendation, with a CME-30 Nm torque machine (Técnica Industrial Oswaldo Filizola, São Paulo,

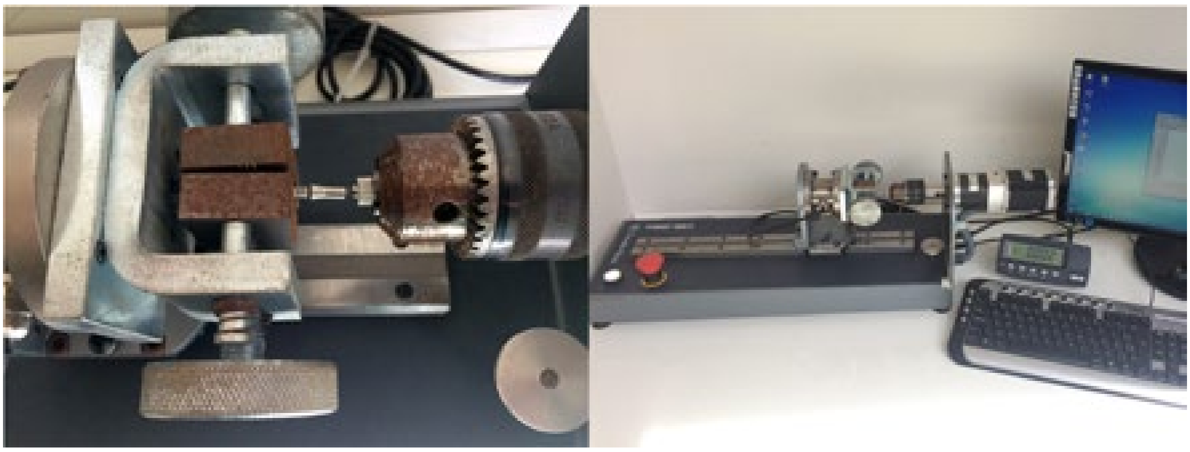

Fig. 5 **a** Scheme used in the torque test. **b** Torque machine

Table 1 Mechanical properties of materials used in this study. Titanium properties were provided by the manufacturer

Material	Young's modulus (GPa)	Poisson's ratio
Titanium alloy	100	0.3
CrCo alloy [20]	218	0.33
Cortical bone [19]	2.3	0.3

Brazil). To limit the effect of settling of the screws, which could reduce the preload, the components were retightened 10 min after the initial torque [16].

A metallic crown with a semi-circular shape was cemented on each abutment using zinc phosphate cement in accordance with the standard ISO 14801:2007 [10].

All implants were immersed in a rigid epoxy resin model GIV (Polipox, São Paulo, Brazil) with a Young's modulus similar to cortical bone, using cylindrical acrylic tubes with a 20-mm diameter. The sets (implant/abutment) were immersed, leaving 3 mm of the exposed implant to reproduce bone loss (Fig. 2).

2.2 Mechanical tests

2.2.1 Fracture test

The objective of this study is to determine the maximum loads that the implant will be able to withstand. This mechanical test provides an idea about the mechanical behavior of the implant. The static fracture of the dental implants was tested according to ISO guidelines (Fig. 3), which recommend the selection of the smallest diameter implant available for each model because this critically impacts the efficacy of the implant. Testing was performed at an implant angle of 30 ± 2° with respect to the applied load, with 3 mm of the exposed implant, reproducing bone loss.

According to the study design, all groups were subjected to quasi-static loading until fracture using a properly calibrated universal testing machine (model AME-5kN, Técnica Industrial Oswaldo Filizola Ltda, Guarulhos, Brazil) with a test capacity of 5.0 kN. Tests were conducted at the Testing Laboratory of Biomechanics (Biotecnos, Montevideo, Uruguay) at a test speed of 1 mm/min.

2.2.2 Dynamic loading test

After the resin polymerization, the samples were immersed in water at 37 ± 2 °C and placed on a chewing simulator (BioPDI, São Carlos, Brazil), and 360.000 cycles of 150 ± 10 N of controlled axial force were applied at 4 Hz (Fig. 4), as used in previous studies [11, 17].

Due to the fact that all implants must support the cyclic load, this study should be more important than the fracture test because results obtained from it are more relevant for the clinicians and for engineers in the design stage.

2.2.3 Torque analysis

As described previously, all the fixing screws of the abutments received an initial torque of 30 Ncm (Fig. 5a), which served as the baseline compared with the residual torque after completion of this test.

A after mechanical cycling, all samples were then fixed to the torque testing machine grip on one side of the implant and on the other side the prosthetic implant drive, and the removal torque was measured. Figure 5b shows the machine where this test was performed.

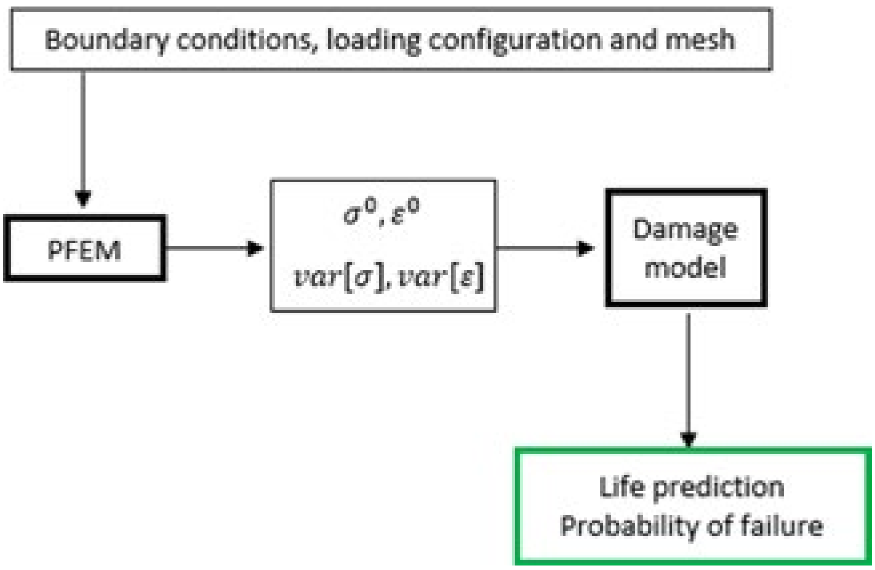

Fig. 6 Summary of the probabilistic methodology employed in this study

Fig. 7 Implant fracture after static fracture test

After mechanical cycling, all samples were attached to the torque-testing machine and the removal torque was measured. Torque values and removal torque values were measured in Newton centimeters by a Torque Testing Machine CME (Técnica Industrial Oswaldo Filizola, São Paulo, Brazil), which is fully controlled by the DynaView Torque Standard/Pro M software (Técnica Industrial Oswaldo Filizola, São Paulo, Brazil). The software performs calculations and generates reports automatically with test speed of 1 rpm and an angular measuring system with a resolution of 0.002°. Measurements of peak torque to initiate the reverse rotation

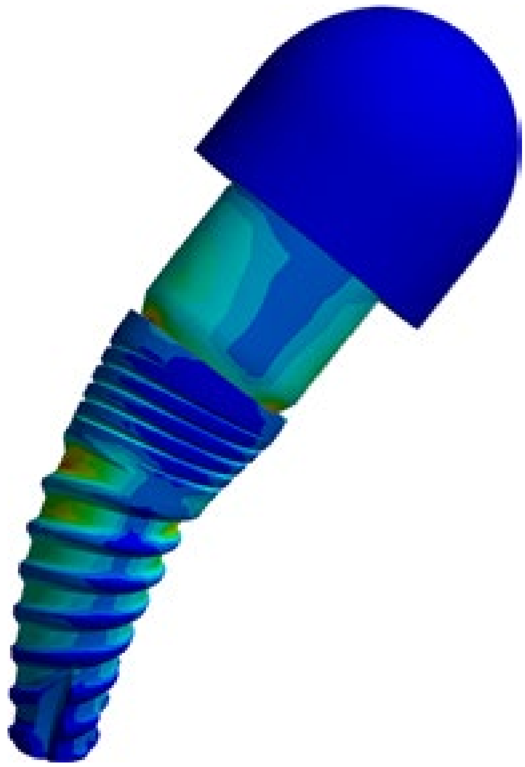

Fig. 8 Three-dimensional finite element model with enlargement of the implant and crown deformation

were recorded, and the mean torque values were calculated for each implant group.

Table 2 Values of maximum loads for all tested implants

Sample no.	Fracture load (N)
1	1018
2	1008,8
3	992,6
4	951,4
5	1027
Mean (N)	999,56
Standard deviation (N)	29,75

2.3 Three-dimensional finite element studies

A complete 3D finite element model of the tested samples was constructed with the aim of simulating the compressive and dynamic tests. The implant geometry was provided by the manufacturer. Crowns and the epoxy resin model were created using the CAD software SolidWorks 2016 (Dassault Systemes, SolidWorks Corp., Concord, MA, USA). Once all CAD models were assembled, they were imported into the ANSYS Workbench 16 (Canonsburg, PA, USA) and analyzed.

The convergence criterion was a change of less than 5% in von Mises stress in the model [18]. A good finite element mesh was crucial in this problem due to the stress singularities expected at the sharp corners. The number of elements and nodes employed in this study were 91,682 and 54,747, respectively.

Implants, crowns, and bones were modeled with linear, elastic, isotropic, and homogeneous properties [19]. Cylindrical geometry was modeled with cortical bone properties due to its similarities with this material.

The elastic properties of the materials used in the models were taken from the literature (CrCo alloy) and from the manufacturer (implant and resin), as shown in Table 1.

CrCo alloy properties were obtained from Bacchi et al. [20].

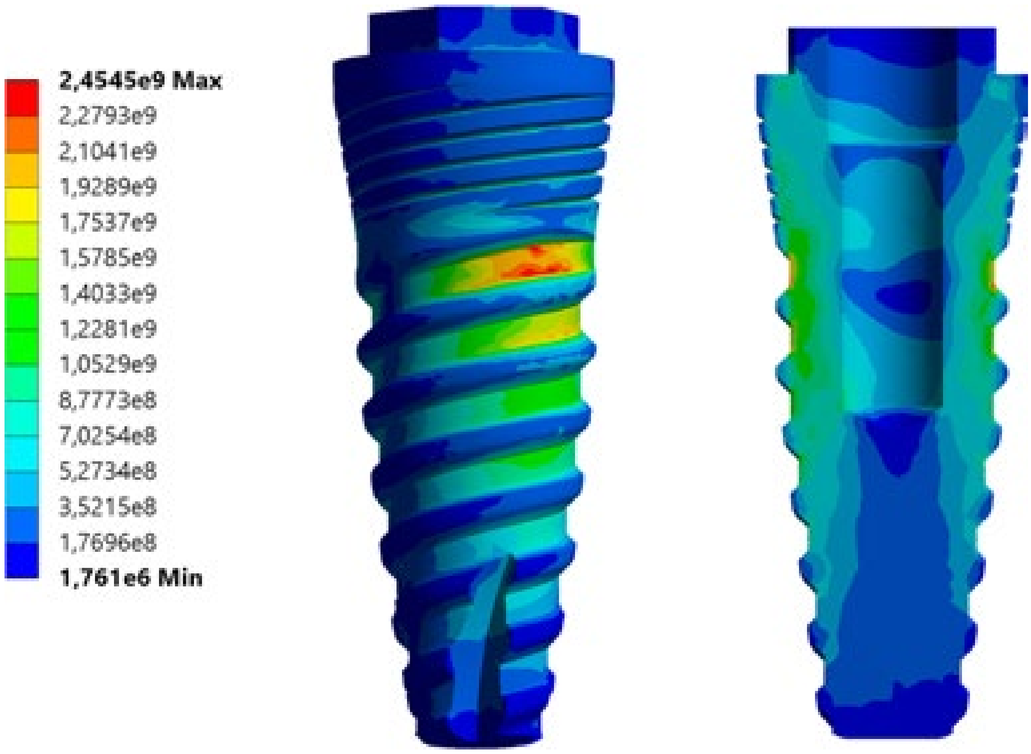

Fig. 9 **a** von Mises stress along the implant. **b** von Mises stress inside the implant

Fig. 10 Implants tested after fatigue

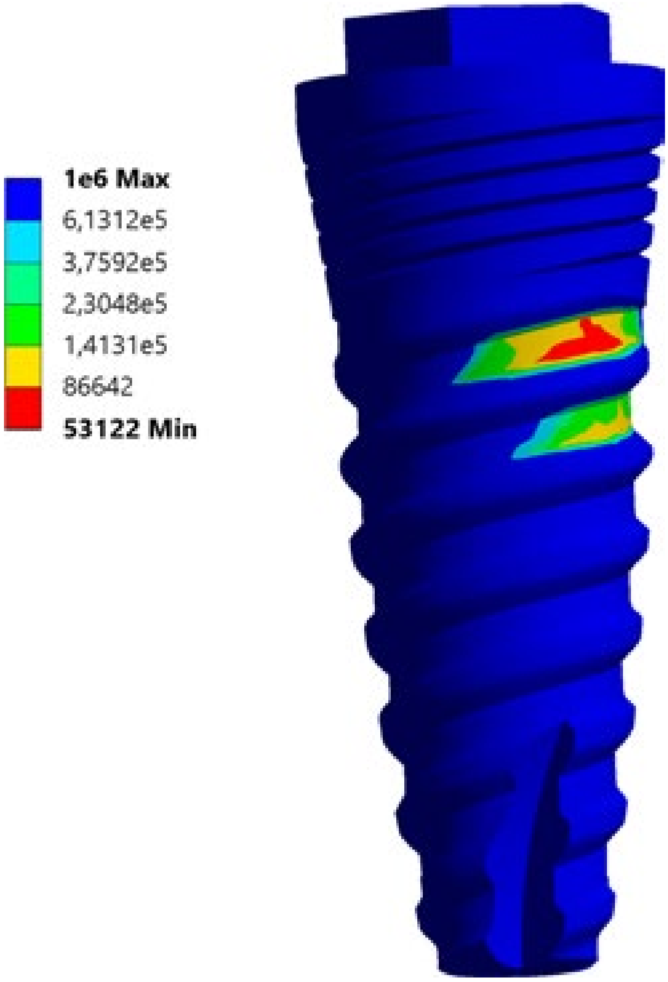

Fig. 11 Fatigue life distribution along the implant

The ultimate stress is an important value to know the limits of behavior of a material. The ultimate stress of cortical bone has been described as 170 MPa in compression and 100 MPa in tension [100]. The yield strength of titanium has been described as 626 MPa, and the ultimate tensile strength has been described as 737 MPa [21].

All analyses done in the present study were constrained as follows: all degrees-of-freedom in the bottom and lateral surface of the bone were restrained, following the same fixation that occurred during the in vitro test. For simulating the osseointegrated condition, the implants were rigidly bonded in the bone.

Table 3 Removal torque values before and after 360,000 cycles of loading

Sample no.	Torque before loading	Torque after loading	Difference
1	28	18,1	9,9
2	27	21,8	5,2
3	26	19,6	6,4
4	29	17	12
5	27	23,7	3,3
Mean [Ncm]	27,4	20,04	7,36
Standard deviation [Ncm]	1,14	2,72	3,53

2.4 Probabilistic approach

Physical magnitudes employed in fatigue problems are usually deterministic. However, there are many uncertainties that can seriously compromise the usefulness and validity of the system. Due to the probabilistic nature of the fatigue in dental implants, the use of probabilistic methods for its study is justified. Although the fatigue phenomenon has been studied, it still is a very experimental field [22]. Three different stages are considered during the fatigue process: cracks nucleation, crack propagation, and final failure of the component.

In this study, the authors will focus on the first stage (nucleation stage). Models used to study the crack nucleation process are based on the local strain approach, while the models developed for the other two stages are based on the concepts of fracture mechanics [23]. In this study, the authors consider the randomness of material properties of the titanium (Young's modulus and Poisson's ratio) and loads, due to their influence on the life of the structural components [24]. The authors have chosen the B-K unit step model due to its adaptation to the nucleation stage.

The authors refer to Prados-Privado et al. [25] for further details, although Fig. 6 represents a summary of the methodology employed in this study.

3 Results

3.1 Static fracture test

The failure mode was almost identical in all the samples. The fracture appeared in all implants in the first implant thread, at the level of the embedding resin, as shown in Fig. 7.

The maximum load of all the specimens is summarized in Table 2. The failure load is found to be $F = 999{,}56 \pm 29{,}75$ N.

For all the implants, the von Mises stresses were concentrated at the level of the embed resin, as shown in Figs. 8 and 9.

In Fig. 9, the highest value of stress is approximately 2454 MPa, which is greater than the ultimate tensile strength of titanium. This value of stress is in accordance with the mechanical tests. Figure 9b represents stress distribution in the interior of the implant. Maximum von Mises stresses appeared on the surface; therefore, no cracks or deformations can occur inside the implant.

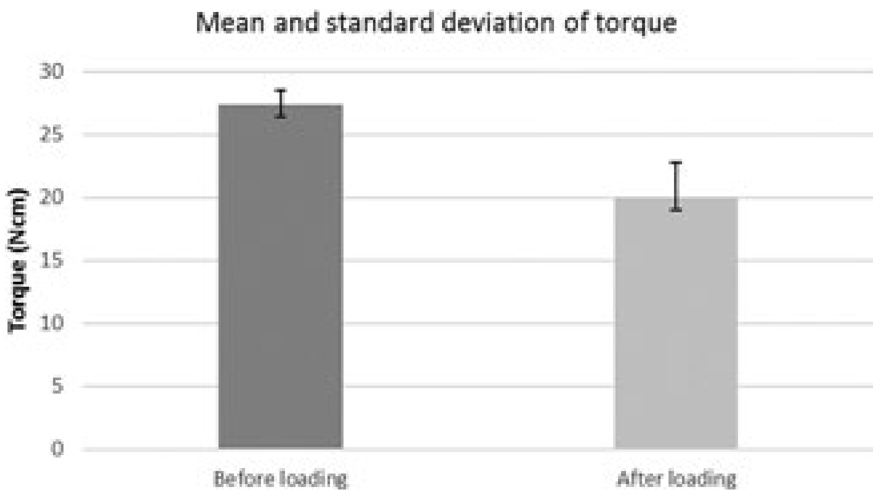

Fig. 12 Torque before and after dynamic loading

3.2 Fatigue analysis

Five dental implants were tested under the conditions described previously. After applying 360,000 cycles with 150 N, no deformations or cracks were observed, as shown in Fig. 10.

A finite element analysis was also computed to verify the results obtained by the in vitro analysis. Figure 11 represents the fatigue life distribution along the implants, obtained by the finite element model.

Minimum life is 530,122 cycles, which is in accordance with the mechanical test, where the implant did not fracture.

3.3 Torque test

The mean removal torque values and standard deviations found before and after 360,000 cycles of loadings are shown in Table 3.

The mean reverse torque values before and after dynamic loads are shown in Fig. 12.

The mean difference between the torque value before and after the cycled loading was 7.36 ± 3.53 Ncm.

3.4 Probabilistic fatigue

A probabilistic analysis was performed once the mechanical and finite elements tests were finished with the aim of completing characterization of the implants. The load and the elasticity modulus of titanium were chosen as random variables. A load of 150 ± 10 N and a Young's modulus of 100 ± 10 GPa were employed.

After solving the mathematical model, a mean life of 552,626 cycles and a variance of the fatigue life of 25,26 cycles^2 was obtained.

In view of these results obtained by this probabilistic approach, it is possible to conclude that OXTEIN N6 implant can support 360,000 cycles without any failure as detailed previously and also can support a higher life than that obtained by the numerical fatigue analysis.

A probability transition matrix (PTM) was constructed with the following data: a matrix dimension of 13, a probability of remaining in the same damage cycle, p, of 0.97, and a probability of jumping to the next damage cycle, q, of 0.03.

The probabilistic methodology applied allowed us to determine the reliability of the implant, which was the probability

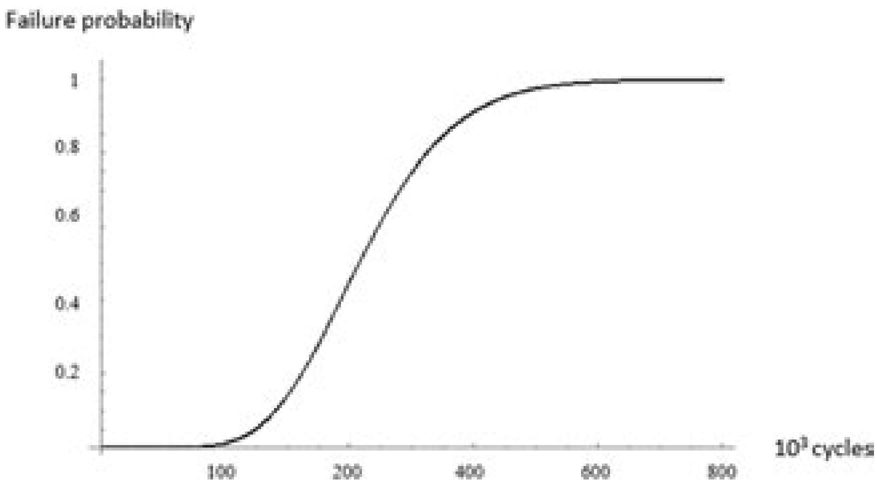

Fig. 13 Cumulative probability function

Table 4 Summary of the fracture test's results

	Fracture	Maximum load		Stress
		Mean	Deviation	
Compression test	Fracture on the first thread	999,56 N	29,77 N	–
FEM study	Maximum stress on bone insertion level	–	–	2454,5 MPa > 737 MPa

of local failure of the implant for a specific number of load cycles. The cumulative probability function is represented in Fig. 13.

Table 4 summarizes the results obtained from the fracture test. The weakest point of the implant is verified by the finite element analysis.

Table 5 summarizes the results obtained from the fatigue test. After applying 360,000 cycles, no fracture or cracks appeared. This outcome was corroborated by FEM, which obtained a minimum life of 530,122 cycles.

4 Discussion

This study analyzed the mechanical behavior of 10 titanium dental implants (diameter 3.5 mm) with a hexagonal external connection. Fracture test and fatigue test results were verified and completed with a finite element analysis. The removal torque was measured after the fatigue test. A probabilistic analysis was then performed to complete the characterization of the implants.

Dental implants were exposed to 360,000 cycles, and cracks were evaluated. A finite element analysis was then carried out to obtain the minimum value of fatigue life in the same situation. A higher fatigue life was obtained, which indicates that this implant will support any type of failure with more cycles. Finally, the mathematical model was computed with a minimum fatigue life similar to the value obtained in the numerical analysis. This was the method employed to verify our results, accepting the alternative hypothesis.

Table 5 Summary of the fatigue results

	Fracture	Fatigue behavior	
		Load applied	Cycles
Fatigue test	No cracks, no deformations	150 N	360.000
FEM study	Maximum stress lower than material limits	150	530.122

However, this study has some limitations and assumptions. Material properties of titanium, CrCo alloy, and bone were obtained from other scientific studies and were modeled with linear, elastic, isotropic, and homogeneous properties. This assumption is accepted and verified by several studies [19]. Other assumptions include regarding the resin epoxy where the implants were immersed. This resin had a Young's modulus similar to that of cortical bone; however, implants are placed in the cortical and trabecular bones. This hypothesis is accepted and detailed in ISO guidelines [10].

Another limitation is that we cannot verify our results with an in vivo study. Therefore, we cannot keep in mind other biological factors such as bacterium, corrosion, or osseointegration [26, 27].

To the authors' best knowledge, there are no studies published with a complete mechanical characterization and a probabilistic approach. With this new mathematical model, it is possible to include the effect of the variability of different parameters.

Due to the use of dental implants as a common tool in clinical practice, an increase in the number of failures is expected. The failure of dental implants is due not only to biological factors, such as unsuccessful osseointegration or the presence of periimplantitis but also as a result from mechanical complications that involve fracture in implants, abutments, or prosthesis [28]. Despite the high success rate of these treatments, an expert knowledge of the biomechanical behavior of the implants is crucial to avoid mechanical failures during the design process [29, 30]. Mechanical compression tests are common in dental studies, and it is customary to use five implants for the compression stress test [31], as in this study. Marchetti et al. analyzed five internal connection implants of 3.8 mm in diameter and 12 mm in length with a maximum load after break of 430 ± 35.66 N. Park et al. evaluated the resistance to deformation under static loads of different dental implants design, both in connection and in material [32]. There were significant differences in the maximum fracture load between the different commercial implants. Those values varied from 600 N in an internal hexagon connection to 1200 N in an external connection. These mechanical studies have the aim of knowing the maximum fracture load of different dental implants [31–34]. The implant analyzed in this study, OXTEIN N6, obtained a maximum load fracture of 999 ± 29,75 N. The mean fracture loads in this study exceeded the physiologic maximum posterior masticatory force of approximately 900 N [35].

Chrcanovic et al. suggested five factors that could influence in the risk of implant fractures: grade of titanium, implant diameter, implant length, prosthetic work with cantilever, and bruxism [36]. Other studies also suggested that small diameter implants tend to fracture more easily than large ones, especially when placed in a posterior location [36, 37]. Therefore, international standard guidelines suggest employing the smallest diameter available in the mechanical test.

There are several studies that show the biomechanical benefits of microthread design on the surrounded bone of dental implants. The microthread design may influence the formation and maintenance of the marginal bone loss from loading [38]. Chowdhary et al. concluded in their study that microthreads promote bone formation. There are other papers that show the effect of adding microthread on the stress distribution. As in our results, Chowdhary et al. [39] and Amid et al. [38] obtained lower stress levels in microthreads than those in threads in the neck of the implant.

Several publications include numerical studies to complement the mechanical test and to provide more complete studies [40–42]. Here, a dynamic load test was performed due to bite forces and cyclic loads, introducing a possible failure pertaining to fatigue. Most finite element studies on dental implants are static analyses [43, 19]. This study computed a realistic finite element model by considering the influence of mechanical fatigue behavior. The numerical results were in accordance with those obtained in the mechanical test. Yamaguchi et al. also demonstrated that the finite elements method was a good tool to study fatigue in dental implants [44].

This research provides a new method that engineers can employ during the design stage, and clinicians could also employ it if they would like to know the long-term behavior of different implants, especially in those cases with a compromise bone or parafunction habits.

Future works should evaluate of the effect of different bone densities and the geometry of the implants.

5 Conclusions

In the present study, a mechanical test has been verified by FEM and probabilistic fatigue. This study presents a complete mechanical characterization of an external dental implant and, as a novelty, obtained the probability of failure under certain conditions employing a probabilistic approach. All methods provided results that were in accordance between the tests.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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