The quality system of JDentalCare Srl is certified with respect to EN ISO 13485. The dental implants and the surgical instruments of IIA class are certified by TUV Product Service CE 0123.

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Mechanical Tests
Static and fatigue tests on JDEvolution® implant

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Materials and Methods

Description of the implant tested

The experimental campaign* was performed on Two Stage Dental Implant JDEvolution® D 3.7 L15 (with a diameter of 3.7 mm and a length of 15 mm, Fig. 1). The implant is made in Titanium, grade 4, according to the International Standards ASTM F67, ISO 5832-2.

The implant JDEvolution® is a multi-part one: also with reference to the recommendations contained in ISO 14801, it was tested as assembled according to its intended use. In particular, an abutment was connected to the endosseous dental implant body by a threaded connection, using a screw. This screw was tightened, by carefully measuring the applied twisting moment with the use of a torque wrench. The tightening process was conducted up to a measured torque of 35 Ncm = 0.35 Nm. Both the abutment and the screw are made in Titanium, grade 5, in agreement with the International Standards ASTM F 136, ISO 5832-3.

* The experimental tests were performed by the DIEM Department of the University of Bologna (Italy).
Materials and Methods

Testing configuration

The loading-constraining system (Fig. 2) for both the static and the fatigue tests was developed with reference to the Standard ISO 14801. Such standard regards structural experimentation for endosseous dental implants, describing the best testing conditions for result reliability and repeatability. The endosseous dental implant was clamped, so that its axis formed a 30° (± 1°) angle with the machine loading direction. The loading force of the testing machine was applied, through a hemispherical loading member placed over the free end of the dental implant.

All the tests were performed on an INSTRON (8032 model) servo hydraulic testing machine (Fig.3). This is a two-column tension-compression machine, equipped with a regularly calibrated INSTRON loading cell, having a capacity at full scale of 25 kN. This machine can be used for both static and fatigue tests: an electronic console by INSTRON makes it possible to perform tests in load, strain or position controlled conditions.
Experimental tests

Static tests

Six tests were conducted, according to the scheme in Fig. 2. The experimental procedure consisted first of all in placing the hemispherical loading member over the specimen. Then, the implant was mounted on the holder (Fig. 4). Every trial was conducted in actuator position controlled conditions, by moving the actuator in the vertical direction at a constant speed. For tests performed according to the scheme in Fig. 2 the speed was initially of $5 \times 10^{-3} \text{ mm/s} = 5 \mu \text{m/s}$; just after the first crack (with sudden decrease of the measured force), the speed was increased up to $10^{-2} \text{ mm/s} = 10 \mu \text{m/s}$, and the test was generally continued until final rupture took place.

Fatigue tests

Fatigue tests were performed by applying a maximum flexural load calculated as a percentage with respect to the maximum flexural load resisted and a minimum load of 10% as stipulated by the UNI-EN ISO 14801 standard. Thus, one test at 80% of the maximum flexural load, two tests at 65%, two at 50%, two at 35%, two at 20% and two tests at 12% of the maximum flexural load were performed. The load applied in these tests was sinusoidal, and it ranged from an established maximum load to 10% of that same load. Frequency for all tests was 15 Hz.
Test Results

Static tests

The following histogram (Fig. 5) summarizes the experimental results. The strength was determined in terms of the maximum force transmitted by the machine actuator before the first crack occurrence and in terms of the maximum bending moment, depending on the aforementioned maximum force and on distance $l$ (Eq. 1).

Mean strength resulted **1460 N** in terms of maximum force (Standard Deviation: 196 N, Standard Error : 13%) and **8 Nm** in terms of maximum bending moment (Standard Deviation: 1.1 Nm).

$$M_{\text{max}} = F_{\text{max}} \cdot \sin \left( \frac{\pi}{6} \right) \cdot l = 0.5 \cdot F_{\text{max}} \cdot l$$  \hspace{1cm} (1)

*Fig. 5: Strength of JDEvolution® Implant in terms of maximum force and of maximum bending moment*
Test Results

Fatigue tests

The graph in figure 6 shows the fatigue test data points and the fatigue strength curve in a clear way. This graph represents the maximum force applied in each test with respect to the number of cycles resisted by the implant. Fatigue strength resulted 175 N in terms of maximum force that the implant can withstand for more than 7000000 cycles.

*Fig.6: JDEvolution® D 3.5 L 15: Fatigue Testing*
Conclusions

The 3.7 x 15 mm JDEvolution® implant showed a maximum flexure strength of 1460 N (Standard Deviation: 196 N, Standard Error : 13%).

Different fatigue test were performed on 3.7 x 15 mm JDEvolution® implant by applying a sinusoidal load between different maximum flexural load calculated as percentages (80%, 65%, 50%, 20% and 12%) with respect to the maximum flexural load resisted and a minimum load of 10% as stipulated by the UNI-EN ISO 14801 standard. Fatigue strength resulted 175 N in terms of maximum force that the implant can withstand for more than 7000000 cycles.