LABORATORIO di MECCANICA delle STRUTTURE BIOLOGICHE
LABORATORY of BIOLOGICAL STRUCTURE MECHANICS

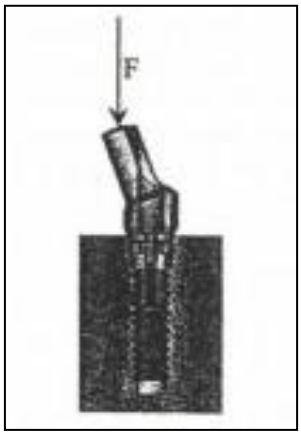
Politecnico di Milano
Dipartimento di Bioingegneria – Dipartimento di Ingegneria Strutturale Laboratorio di Meccanica delle Strutture Biologiche

STATIC AND UNDER STRESS MECHANICAL TESTS MADE ON ENDOSSEOUS SELF-TAPPING SCREWS DENTAL IMPLANTS MANUFACTURED BY TITANMED SRL

1. ***Aim of the research***. The aim of the mechanical trials is to experimentally determine the static mechanical and under stress resistance of endosseous dental implants with self –tapping screw, manufactured by Tecom Implantology – Galbiate (LC).

2. ***Materials***

2.1 **Tests samples**. The tests have been made using implants composed by an endosseous component with self-tapping screw, an abutment and a connection screw. This system has been assembled and positioned into a proper aluminium support, suitable to the handles preset on the test machine, as shown in picture. 6 samples have been used in total (3 for the static resistance tests and 3 for the under stress resistance tests).



3. ***Test***

3.1 **Resistance tests at static load**

3.1.1 **Method**. The resistance tests at static load are made applying the load on the angled abutment, in order to have the load oriented according to the implant axis, but eccentric due to the abutment inclination. This creates a heavy load situation for the implant-connection screw-abutment system, which causes the mechanical breakdown connection screw (the most feeble element of the system). This breakdown happens for the traction to which the shank of the screw is submitted, due to the

flexion of all the system. Moreover, this breakdown can damage the interface surfaces between implant and abutment. The tests foresee to apply a growing load up to breakdown of the system. Considering the value of the normal chewer loads, and the particularly heavy load situation, it is thought that a system for implant-prosthesis is mechanically reliable if the breakdown load is more than 800N. This load and the application method cause to the system a surely bigger effort than the normal effort's situations made by the chewer loads and so, the indicated value is surely over the safety limits. In case the system overpasses the same tests, the test described is sufficient to guarantee the mechanical reliability of the system for dental implant prosthesis. Furthermore, it has to be considered that the reliable mechanical tests for this kind of medical device have not yet been standardized and, consequently, the above mentioned test methods have been identified. In fact, these tests are so heavy to guarantee that their going over can be considered a reliability index.

3.1.2 **Test equipments**. The sample is inserted into the equipment for the compression test, which drawing is in attachment.

3.1.3 **Test conditions**. The test is made compressing the sample in displacement control, with an actuator speed lowering of 2mm/min. The compression is stopped after the sample breaking. The actuator displacement values and the ones of the force measured to the load cellule are achieved by the control software of the test machine.

3.1.4 **Test results**. The results are: 1. Maximum load (of sample breaking) 2. Load-displacement curve, from which the implant strength is calculated

3.2 **Under stress tests**

3.2.1 **Methods**. The resistance tests to the cyclic stress (fatigue) are made using the load with the same direction used for the static resistance tests. The load has a periodical trend of sinusoidal law with a frequency of 7 cycles/sec. and it goes between 20 and 500N. The maximum value is around 60% of the required static resistance. Considering the particularly mechanical heaviness of the test (both the implant inclination and the maximum load value) it is thought that the system is mechanically reliable if it goes over 5 million cycles of load. The test is made at humidity and room temperature: during the tests period the temperature is kept between 25+- 2°C and the humidity between 60±5.

3.2.2 **Test equipment**. An equipment which allows to test up to 3 samples together has been designed and realized. The three samples was positioned in series in comparison with to the load direction, so, they got all the same load levels. The complete drawing of the test equipment is in attachment (Picture 5).

3.2.3 **Test procedure**. The tests begin with three samples assembled in their supports and positioned in the equipment guide. The supports, as shown in the drawing, are separated by the intermediary load flat. The test is made in force control, using sinusoidal loadable stress between 20N and 500N. Since the stress tests of metallic materials have not influence on the test frequency (in fact, only the cycles number counts), the maximum frequency was used, compatible with the control possibilities of the machine (that is with the correct obtaining of the wave form and the

imposed load limit values). Value zero is the one entered in the actuator displacement in correspondence of the position in which there is the contact between the upper load flat and the buffer. A displacement limit value of 4mm was input. If this value is overpassed, this means that minimum one implant was broken; he machine automatically stops, blocking the actuator position. During the test, in case one of the implants breaks, it will be replaced by a buffer, the number of the cycles made when the breaking happened is registered, and the test is finished on the remaining samples.

3.2.4 **Results**. If the sample is broken the number of cycles to the breaking is given. If the sample resists to 5.000.000 cycles, the test finishes successfully.

4. **Test results**

4.1 **Resistance tests to static load** (the charts of the load curves are mentioned in the pictures at the bottom of the report). For all the tested samples the breaking happened due to the connection screw breaking.

Test Number	Implant Code	Abutment Inclination	Breaking Load	Load Curve
1	02/011/ID01	15°	1219 N	Pic. 6
2	02/011/ID02	15°	1315 N	Pic. 7
3	02/011/ID03	15°	1262 N	Pic. 8

4.2 **Final result**. The three tested implants went over the test resisting without any breaking to 5.000.000 load cycles.

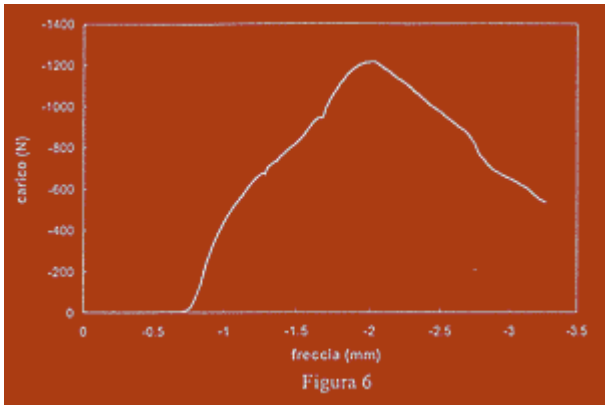


Figura 6

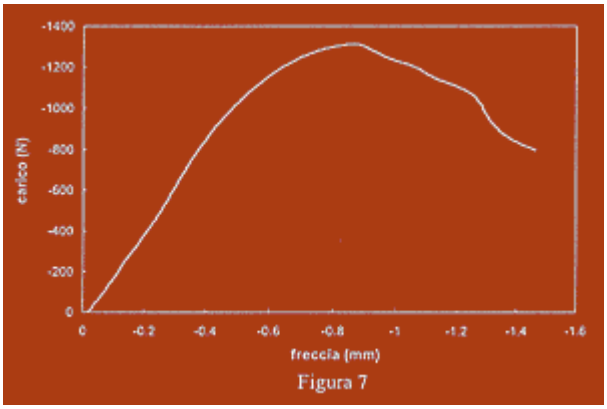


Figura 7

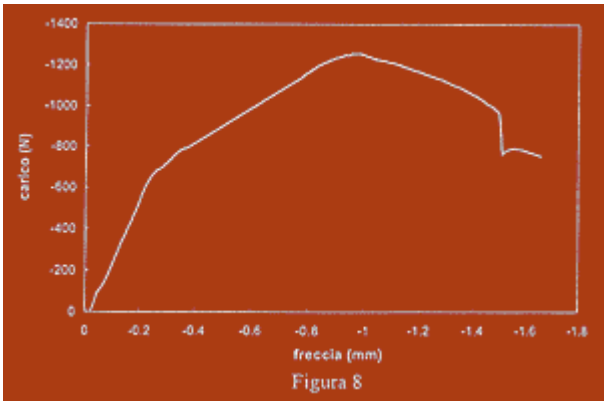


Figura 8

Prodotto da:

TITANMED s.r.l. unipersonale

Uffici: I–24040 Lallio - BG - Via Sforzatica, 31/A. **Sede**: I – 23851 Galbiate – LC - Via E. Monti, 23 Fraz. Visconti
Tel. 0039 035 691574 - Fax 0039 035 690214 – e mail info@tecomimplantology.com
Reg.imp.LC, Codice Fiscale e Partita Iva 03166920136 - N. R.E.A. 308887 - Cap. Soc. 15.000,00 € I.V.

www.tecomimplantology.com