REPORT

INSTITUTO DE BIOMECÁNICA DE VALENCIA

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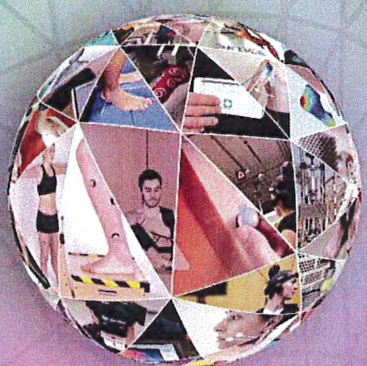
Assessment of Static and Fatigue Resistance to compression Bending of Dental Implant System

On request of: **TALLADIUM ESPAÑA, S.L.**

Date 6/11/2018



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1. The Instituto de Biomecánica (IBV) is only responsible for the results stated in this report, which refer exclusively to the materials or samples indicated in it and which will remain in our hands. Unless otherwise stated, the samples have been freely chosen and sent by the petitioner.
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SIGNATURES AND AGREEMENT CONDITIONS

Date 6/11/2018

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CONTENTS

1. DESCRIPTION OF THE PROBLEM AND OBJECTIVES

This report presents the results related to static and fatigue tests of compression bending for a dental implant system, according to the standard UNE-EN ISO 14801:2017 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*.

The tests have been requested by the company TALLADIUM ESPAÑA, S.L. sited in Avda. Blondel, 54-3, 25002 – LLEIDA, in collaboration with the companies VITA Zahnfabrik and Fresdental Innovación y Manufacturas, S.L. for the present project.

2. MATERIAL AND METHODS

The description of the tested specimens is presented in Table 1.

Table 1. Description of the tested specimens.

CODE	MANUFACTURER DESCRIPTION	
MU18-0267	Dental implant consists of: ✓ Dental Implant: Zimmer NP Ø3.7mmx13mm; Ø3.5mm. REF: TSVTB13; LOT:63236787. ✓ Dynamic abutment screw Ti-Base 3.0 compatible with Zimmer implant. ✓ Angled abutment at 30º of VITA ENAMIC® cemented; REF:31.312.040.01-2; Lot:04080T17-3.	 

The loading geometry for the tests (Figure 1) is described in section 5 of the standard UNE-EN ISO 14801:2017. Figure 2 shows some pictures of the test set-up.

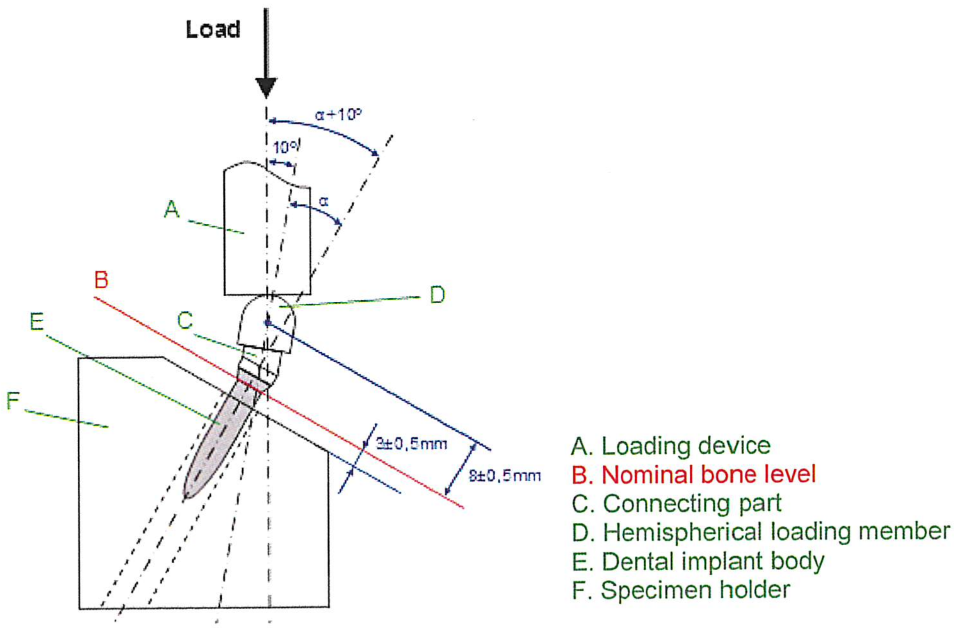

Figure 1. Loading geometry for the tests (UNE-EN ISO 14801:2017)

Figure 2. Test set-up for the dental system.

2.1. STATIC TESTS

The static resistance to compression bending of the dental abutment and implant system has been evaluated with the aim of determining the load and displacement at the rupture point, the load and displacement at the yield point and the stiffness (Figure 3). Testing environment conditions have been the ones indicated by the standard UNE-EN ISO 14801:2017.

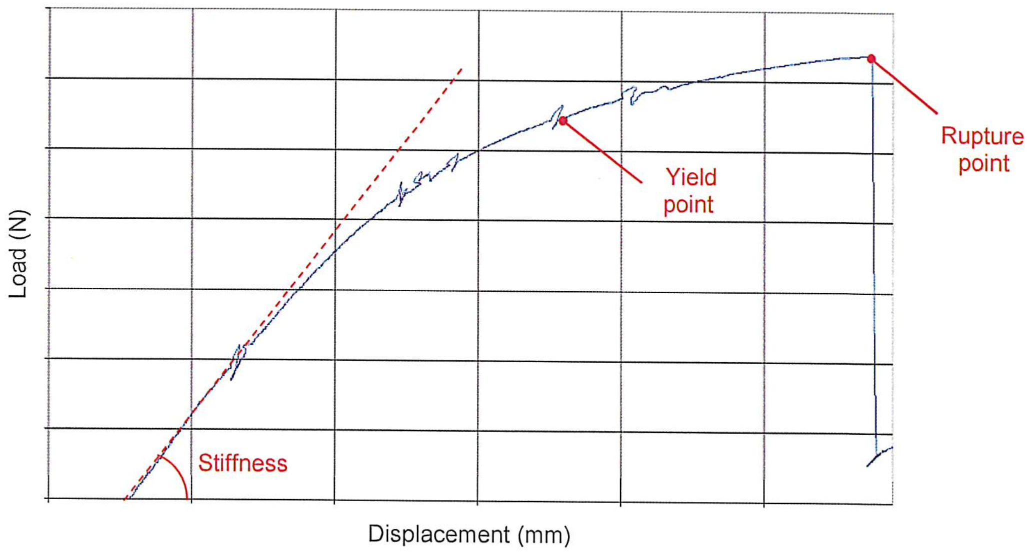

Figure 3. Parameters of the static resistance test

2.2. FATIGUE TESTS

Fatigue resistance to compression bending of the dental abutment and implant system has been evaluated by building a load-cycle diagram (S-N curve or Wöhler curve). The devices have been tested at cyclically varying loads of predetermined amplitude and the number of load cycles until failure occurs has been recorded. Results have been summarized by representing in a diagram the number of load cycles endured by each specimen (on a logarithmic scale) and the corresponding peak load (on a linear scale) (Figure 4). From the load-cycle diagram, the fatigue limit (L_F) of the object can be determined, being the maximum peak load for which fatigue does not occur at an infinite number of loading cycles or at a number of cycles n_F selected for termination of the test.

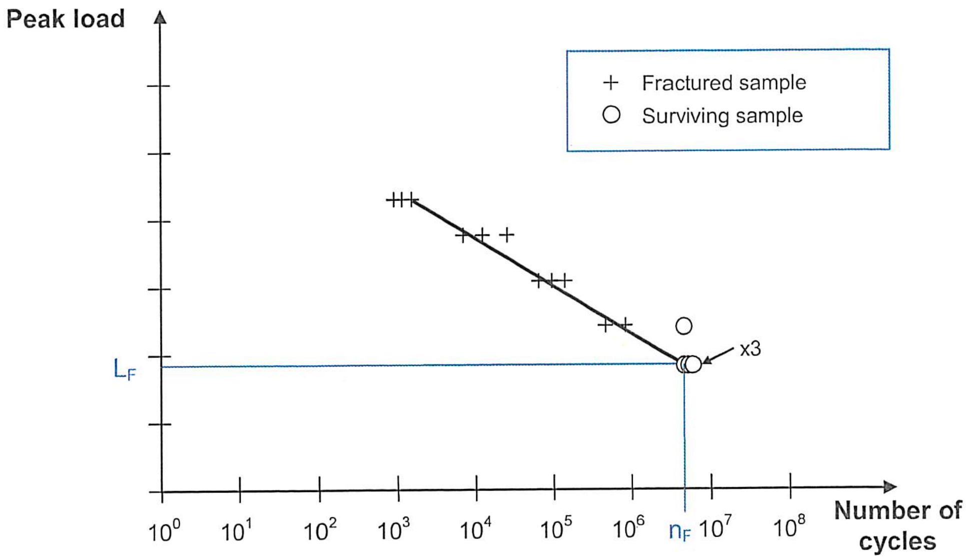

Figure 4. Load-cycle diagram for tests run until 5x10⁶ cycles.

With the aim of generating a load-cycle diagram for the dental abutment and implant system, the standard UNE-EN ISO 14801:2017 recommends to test the specimens at a series of loads until a lower limit is reached at which at least three specimens survive and none fails in the specified number n_F of $5x10^6$ cycles for testing conducted in air at frequencies between 10 Hz and 15 Hz. An appropriate starting load is 80% of the load to failure reached in a previous static test performed using the same test geometry and environmental conditions. The standard recommends to test the devices in at least four load levels and to carry out at least two, and preferably three, repetitions at each level, being necessary that at least three specimens survive at the maximum endured load.

3. RESULTS

3.1. STATIC TESTS

Table 2 presents the results of the static tests for the dental abutment and implant system. The values of this table correspond to the mean and standard deviation of the five specimens tested. The results, as well as the mode of failure of the specimens, are described in detail in the report: *"180158a - PV18/0367: Dental implants. Evaluation of static resistance to compression bending"*.

Table 2. Results of static tests.

Stiffness (N/mm)	Load Yield (N)	Displ. Yield (mm)	Load Rupture (N)	Displ. Rupture (mm)
1675,19	354,60	0,30	376,50	0,38
938,90	447,70	0,54	553,28	0,77
1456,50	481,60	0,38	517,90	0,56
1457,34	595,10	0,51	618,70	0,58
1253,22	616,30	0,58	622,50	0,65
1356,23±276,94	**499,06±108,14**	**0,46±0,12**	**537,78±100,46**	**0,59 ± 0,14**

3.2. FATIGUE TESTS

According to the recommendation of the standard UNE-EN ISO 14801:2017, the starting load level for the fatigue tests of the dental abutment and implant system has been defined as 80% of the load to static failure. Depending on the results obtained for each load level, the following procedure has been followed: if the system has withstood $5x10^6$ cycles at a specified load level then the next level load has been increased, otherwise it has been decreased. The total number of load levels applied has been four, and two specimens have been tested at each level except for the fatigue limit at which three specimens have been tested. Therefore, the total number of specimens tested has been nine.

Table 3 shows in chronological order the testing procedure followed, and Figure 5 presents the resulting load-cycle diagram for the dental abutment and implant system. Results, as well as the mode of failure of the specimens, are described in detail in the report: *"180159a - PV18/0367: Dental implants. Evaluation of fatigue resistance to compression bending"*. From the results obtained it can be concluded that the fatigue limit of the tested system is **188,2 N**, at which three specimens have survived.

Table 3. Number of cycles for each load applied and failure mode.

PEAK LOAD (N)	NUMBER OF SPECIMENS TESTED	NUMBER OF CYCLES
430,2	2	1.554.202
		35.924
349,6	2	38
		67169
268,9	2	5.000.000
		3.599.159
188,2	3	5 Millones

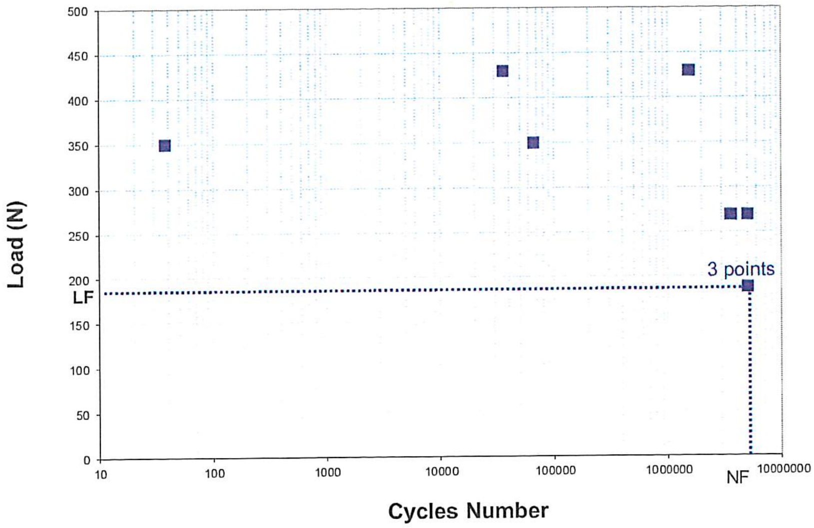

Figure 5. Load-cycle diagram for the dental abutment and implant system.

4. ANALYSIS OF RESULTS

4.1. STATIC TESTS

The failure to static resistance of the tested systems has been produced due to the material yielding.

The load at the yield point for the system has been **499,06±108,14 N** (mean of five specimens), with the loading geometry indicated by the standard UNE-EN ISO 14801:2017.

On the other hand, the IBV has found scientific studies on the measurement of maximum bite forces in ongoing reviews of the literature. In these Scientific studies about **maximum bite forces** have observed values from **210,5 ± 69,3 N to 206,0 ± 24,0 N** for the maximum bite force with incisive teeth (Paphangkorakit and Osborn, 1997; Fontijn-Tekamp *et al.*, 2000; Regalo *et al.*, 2008), from **153,6 ± 89,8 to 196,0 ± 42,0 N** for the maximum bite force with canine teeth (Sinn *et al.*, 1996; Fontijn-Tekamp *et al.*, 2000) and from **231,0 ± 145,3 to 398,0 ± 103,0 N** for the maximum bite force with premolar teeth (Sinn *et al.*, 1996; Fontijn-Tekamp *et al.*, 2000), and between 60 and 645 N for the maximum bite force with molar teeth (Sinn et al., 1996 ; Fontijn - Tekamp et al., 1998 ; Pereira - Cenci et al., 2007; Regalo et al., 2008).

4.2. FATIGUE TESTS

Fatigue limit of the dental abutment and implant system has been **188,2 N**, with the test geometry indicated in the standard UNE-EN ISO 14801:2017.

On the other hand, the IBV has found scientific studies on the measurement of masticatory forces in ongoing reviews of the literature. In these Scientific studies about masticatory forces have observed peak of values between 5 and 54 N for incisive and canine teeth (Gay et al., 1994; Dan et al., 2003; Kohyama et al., 2004a, 2004b, 2005; Johnsen et al., 2007; Xu et al., 2008) and peak values between 50 and 284 N for premolar and molar teeth (Morneburg and Pröschel, 2003; Kohyama et al., 2004a, 2004b; Johnsen et al., 2007).

5. CONCLUSIONS

5.1. STATIC TESTS

In conclusion, it can be stated that the results obtained in the static tests for the dental implant system are satisfactory, for placement on incisors, canines places and premolar teeth, since the system has endured values above the maximum static load bite forces found in the literature.

In the static tests, the system has reached a load value at the yield point of **499,06±108,14 N**. The maximum bite force with incisive teeth ranges from 210,5 ± 69,3 N to 206 ± 24 N, the maximum bite force with canine teeth ranges from 153,6 ± 89,8 to 196 ± 42 and the maximum bite force with premolar teeth ranges from 231 ± 145,3 to 398 ± 103 N. Therefore, results of the static tests are satisfactory because the measured static loads are higher than the ones expected during the usual activity of the dental implant system.

5.2. FATIGUE TESTS

In conclusion, it can be stated that the results obtained in the fatigue tests for the dental implant system are satisfactory, for placement on incisors and canines places, since the fatigue limit obtained is higher than the usual masticatory forces found in the literature.

In the fatigue tests, the dental abutment and implant system has reached a fatigue limit of **188,2 N**. The masticatory peak load with incisive and canine teeth ranges from 5 to 54 N. Therefore, **results of the fatigue tests are satisfactory, for incisive and canine teeth** because the fatigue limit obtained is higher than the loads expected during the usual activity of the dental abutment and implant system.

6. BIBLIOGRAPHY

Dan, H., Watanabe, H., Kohyama, K., 2003. Effect of sample thickness on the bite force for apples. J. Texture Studies. 34, 287-302.

Fontijn-Tekamp, F.A., Slagter, A.P., Van'T Hof, M.A., Geertman, M.E., Kalk, W., 1998. Bite forces with mandibular implant-retained overdentures. J. Dent. Res. 77(10), 1832-1839.

Fontijn-Tekamp, F.A., Slagter, A.P., Van Der Bilt, A., Van'T Hof, M.A., Witter, D.J., Kalk, W., Jansen, J.A., 2000. Biting and chewing in overdentures, full dentures and natural dentitions. J. Dent. Res. 79(7), 1519-1524.

Gay, T., Rendell, J., Majoureau, A., Maloney, F.T., 1994. Estimating human incisal bite forces from the electromyogram/bite-force function. Arch. Oral Biol. 39(2), 111-115.

Johnsen, S.E., Svensson, K.G., Trulsson, M., 2007. Forces applied by anterior and posterior teeth and roles of periodontal afferents during hold-and-split tasks in human subjects. Exp. Brain Res. 178, 126-134.

Kohyama, K., Hatakeyama, E., Sasaki, T., Azuma, T., Karita, K., 2004a. Effect of sample thickness on bite force studied with a multiple-point sheet sensor. J. Oral Rehabil. 31, 327-334.

Kohyama, K., Hatakeyama, E., Sasaki, T., Dan, H., Azuma, T., Karita, K., 2004b. Effects of sample hardness on human chewing force: a model study using silicone rubber. Arch. Oral Biol. 49, 805-816.

Kohyama, K., Hatakeyama, E., Dan, H., Sasaki, T., 2005. Effects of sample thickness on bite force for raw carrots and fish gels. J. Texture Studies. 36, 157-173.

Morneburg, T.R., Pröschel, P.A., 2003. In vivo forces on implants influenced by occlusal scheme and food consistency. Int. J. Prosthodont. 16(5), 481-486.

Paphangkorakit, J., Osborn, J.W., 1997. The effect of pressure on a maximum incisal bite force in a man. Arch. Oral Biol. 42(1), 11-17.

Pereira-Cenci, T., Pereira, L.J., Cenci, M.S., Bonachela, W.C., Del Bel Cury, A.A., 2007. Maximal bite force and its association with temporomandibular disorders. Braz. Dent. J. 18(1), 65-68.

Regalo, S.C., Santos, C.M., Vitti, M., Regalo, C.A., De Vasconcelos, P.B., Mestriner, W.J.R., Semprini, M., Dias, F.J., Hallak, J.E., Siéssere, S., 2008. Evaluation of molar and incisor bite force in indigenous compared with white population in Brazil. Arch. Oral Biol. 53(3), 282-286.

Sinn, D.P., De Assis, E.A., Throckmorton, G.S., 1996 Mandibular excursions and maximum bite forces in patients with temporomandibular joint disorders. Journal of Oral and Maxillofacial Surgery 1996; 54(6); 671-679.

Xu, X., Wright, P.S., Hector, M.P., Heath, M.R., Ferman, A.M., 2008. Force, rate and work used during incisor penetration on different textural foods. J. Texture Studies. 39, 115-128.

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