TALLADIUM ESPAÑA

STATIC AND FATIGUE ANALYSIS OF THE COMPRESSIVE BENDING STRENGTH OF THE NB ACTIVE NP+MULTI-UNIT 4.8 GINGIVAL HEIGHT+G-CAM DIRECT IMPLANT TOOTH SYSTEM.

Date: August 2021

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Static and Fatigue Analysis of the Compressive Flexural Strength of the most critical Dental System Nobel Biocare Active NP + NB Multi-Unit 4.8 GH1,5mm + G-CAM® + Direct Implant Dynamic Screw®.

SIGNATURES AND AGREEMENT OF CONDITIONS

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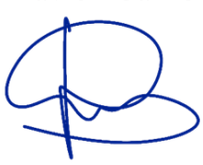
Signature:  Date: 09/08/2021

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CONTENT:

1. INTRODUCTION

Through the continuous bibliographic reviews that are constantly being carried out, several scientific studies have been found, where indicative values have been obtained for the maximum bite force of incisors, canines, premolars and molars, which will serve as a guide in the analysis and evaluation of the set of samples for the static resistance tests to compression bending in dental implants.

Several evaluations are carried out to compile the corresponding results of static resistance to compression bending tests in accordance with the UNE-EN ISO 14801:2008 standard, which is the Spanish version of ISO 14801:2016 "Dentistry - Implants - Dynamic load test for endosseous dental implants"; for the 20° angled set composed of a Graphenano Dental direct-to-implant G-CAM crown, with the external connection for the NB Multi-Unit 4.8 brand of implants. The study has been performed using an RP platform evaluating the most critical situation and a fixture with an angulation of 30°, in compliance with article 5.2.3 of Figure 2 of the standard, to which 10° must be added to the test installation plane for angled implant abutment systems.

2. OBJECTIVE

The objective of this test is to find the static and fatigue resistance to compression bending for the direct set to dental implants with Graphene for **NB Multi-Unit 4.8.**

3. MATERIALS AND METHODS

The list of medical devices used to perform the static resistance to compression bending test is provided below. (See table 1):

Image	Element	Reference	Batch number	Description	Material
	Corona de G-CAM	PT00265	L21041120139	Grapheno 20º Pilar Abutment Ø4,80mm(closure) Ø5,30mm (Plat.)	G-CAM
	Tornillo	41.314.048.33	07524T21-1	M=1.4; L=5.0mm 20N.cm Ø2,60mm	Titanio 6Al-4V Grade 5
	Conección Cónica	38878	12175057	Multi-Unit Abutment Plus External Conección GH1,5mm	Titanio 6Al-4V Grade 5
	Implante dental	34125	12178763	dental Implant NB Active NP, Ø3,0mm(closure) Ø4,80mm (Plat.)	Titanio Pure Grade 4

Table 1: Elements used in the NB Multi-Unit system 4.8

The following equipment and conditions were used to perform the static compressive bending strength test (see Table 2):

Conditions, Material and/or Equipment	Description
Equipment used	Dyna-Mess Tipo: TP 5 HF
	Capacity (static) 5 KN
	Displacement 12mm
	Maximum test frequency 35 Hz
Date of trial	14/07/2021
Environmental conditions (day of test)	23.4 °C and 37.8% humidity
Pre-trial	Tightening torque of the set 35N.cm, Tightening torque of the screw 20N.cm
Manufactured by	Talladium España.

Table 2: Conditions, Material and/or Equipment.

4. METHOD OF TESTING STATIC STRENGTH BY COMPRESSION TEST.

The loading geometry for performing the static strength test by compression bending test is described in section 5 of the standard. ISO 14801:2016. (See image 1)

Legend:
1. Loading device (a)
2. Nominal bone level (b)
3. Implant abutment
4. Hemispherical loading element
5. Dental implant body
6. Sample holder

(a) Application of forcé
(b) It must allow free transverse movement to the direction of the load (see 5.2.5, ISO 14801:2016)
(c) See section (5.3.2), standard ISO 14801:2016

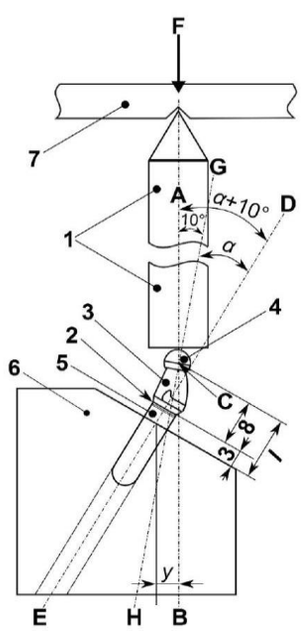


Image 1: Load geometry for the test (ISO 14801:2016

5. STATIC TEST

Static strength testing and analysis by compression bending test was carried out using the testing machine (DYNA-MESS) for implants and dental materials. **(See image 2)**

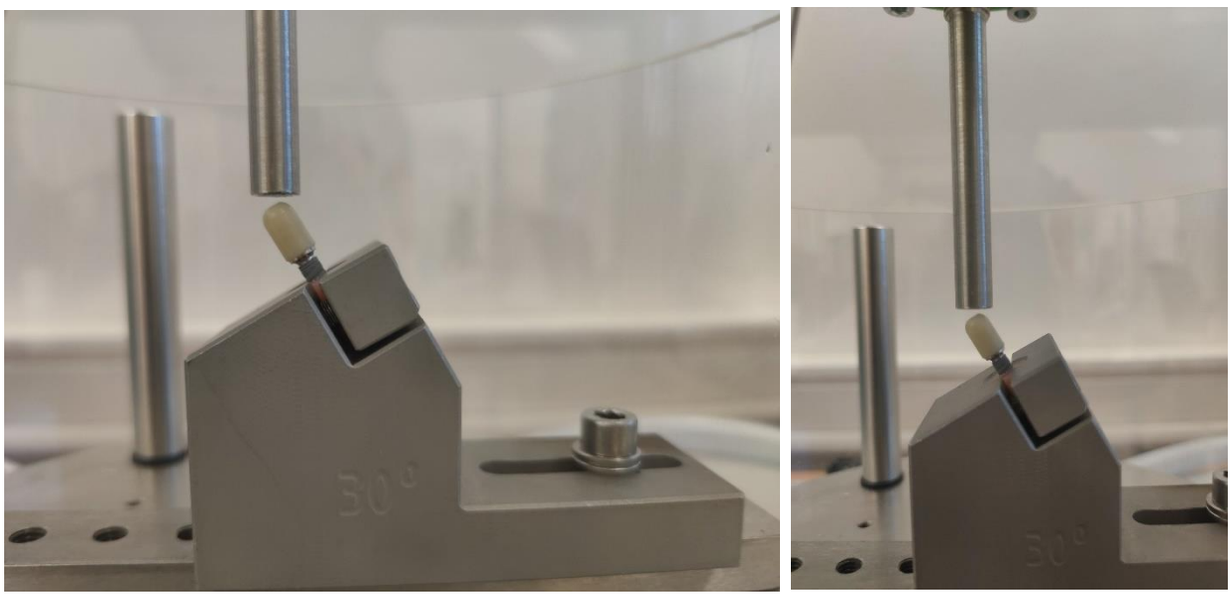
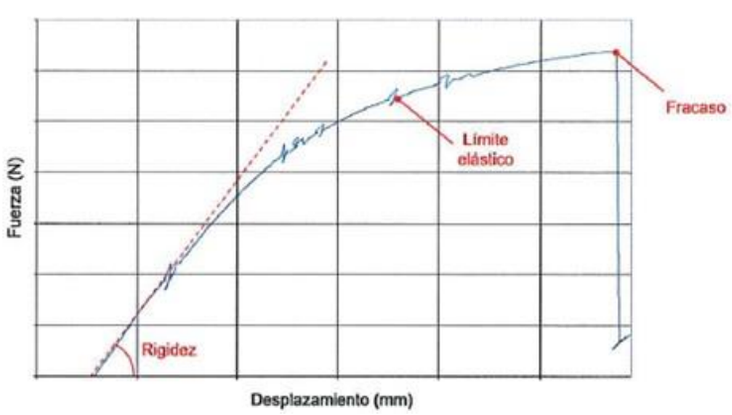
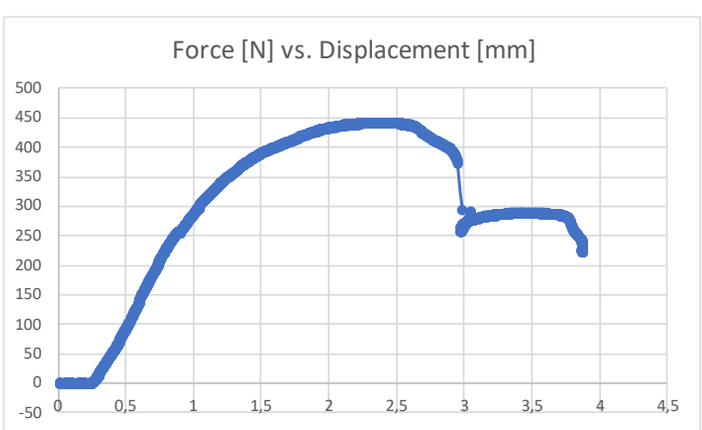


Image 2: Set of the NB Active NP + external conical connection set of NB Multi-Unit 4.8. + G-CAM Static Test.

The static strength of the set was assessed by means of a compression bending test to determine the load and displacement at the breaking point, the load and displacement at the yield point and the stiffness. The test environment conditions have been those indicated by the ISO 14801:2016 standard section 5.4 **(see graphs 1 and 2)**



Graph 1: Parameters of the static strength test



Graph 2: Static load vs. displacement chart
(NB Active NP +NB Multi-Unit 4.8+G-CAM)

6. STATIC TEST RESULTS

The results of the static tests carried out on the set, as well as the breaking point of the samples, have been obtained with the testing machine for implants and dental material. **(See table 3)**.

Rigidity (N)	Yield strength (N)	Limit displacement (mm)	Breaking load (N)	Displacement to breakage (mm)	Comments
667,33	401,77	2,31	443,40	3,880	[1]

Table 3: Static test results on the testing machine for dental implants and dental materials (NB ActiveNP +NB Multi-Unit 4.8)

[1] The failure of the system is caused by rupture of the Transepithelial and deformation of the implant. The fracture of the set can be seen in the following image (See image 3 and 4**)**

Image 3: Failure of the first sample. Static test. (NB ActiveNP + NB Multi-Unit 4.8)

Image 4: Breakage of the first sample. Static test. (NB ActiveNP +NB Multi-Unit 4.8)

The static strength failure of the tested system has occurred due to material deformation.

The breaking load of the system obtained with the testing machine for Implants and dental materials of the NB Multi-Unit 4.8 conical external connection system was 443.40 ± 10 N with the indicated load geometry according to ISO 14801: 2016.

7. CONCLUSIONS OF THE STATIC TEST

Considering studies carried out on Maximum Bite Force where it is established that, for anterior teeth, the values range between 210.5 ± 69.3 and 206 ± 24 N; canine teeth range between 153.6 ± 89.9 and 196 ± 42 N; premolars range between 231 ± 145.3 and 398 ± 103 N and molars range between 60 and 645 N; it can be concluded that the static test carried out on the NB Multi-Unit 4. 8 is satisfactory, as the sets have tolerated static loads within the values indicated in the literature. The value of this study is **443,40 N.**

8. FATIGUE TEST.

The analysis and evaluation of the compressive bending fatigue testing of the set under study was carried out using the testing machine for implants and dental materials. **(See image 5)**

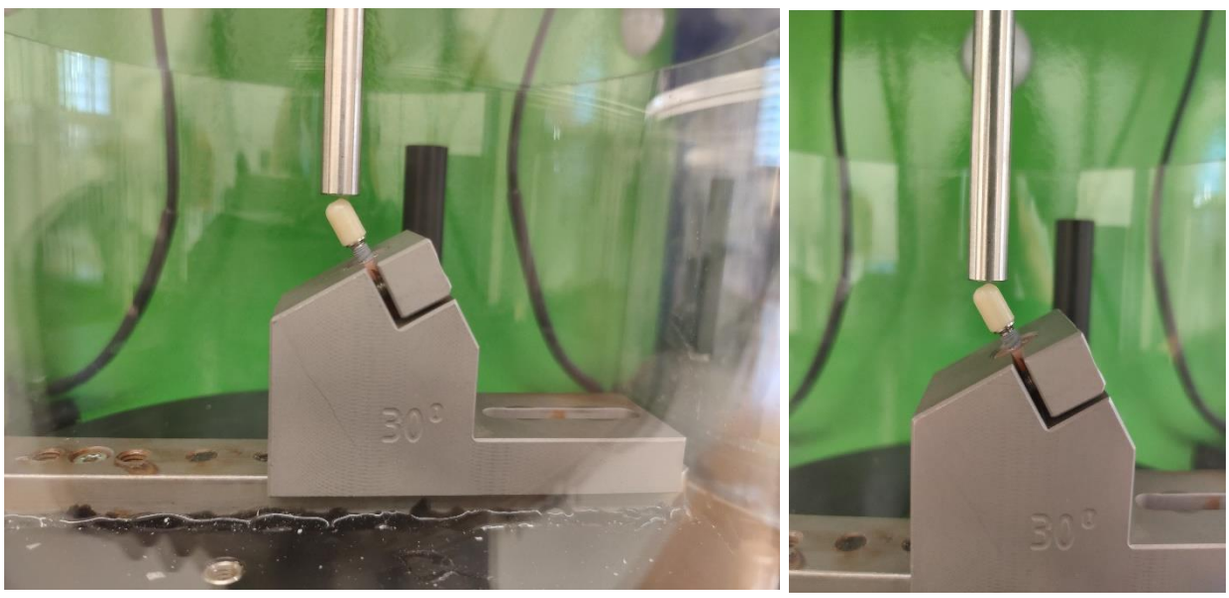
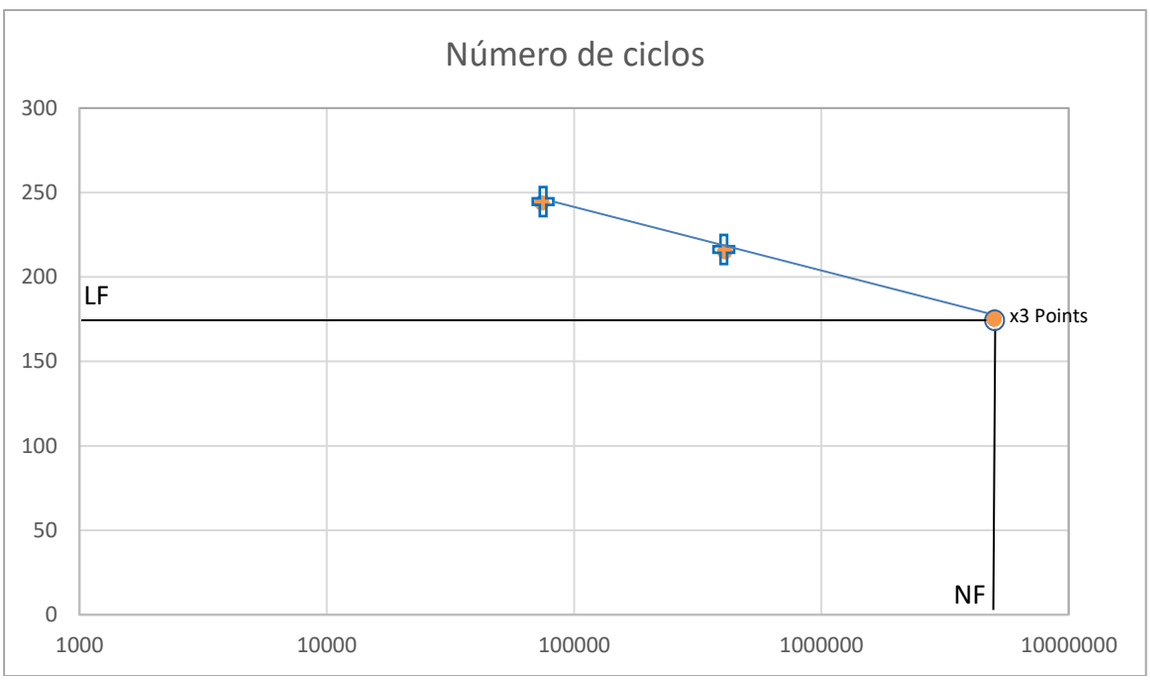


Image 5: NB Active NP+ Multi-Unit 4.8 conical connection set + G-CAM screw + Dynamic fatigue test screw set

The compressive bending fatigue strength of the dental abutment and implant system was evaluated by means of a load/cycle diagram (S-N curve or Wöhler curve). The devices have been tested with cyclically varying loads of predetermined amplitude and the number of load cycles until failure has been recorded. The results have been summarised by plotting the number of load cycles endured by each sample (on a logarithmic scale) and the corresponding maximum load (on a linear scale). From the load cycle diagram, the fatigue limit (Lf) of the specimen can be determined, which is the maximum peak load for which fatigue does not occur in an infinite number of load cycles or in a number of cycles (nf) selected for test termination. **(See table 4 and graph 3)**

BREAKAGE (N) (Performance in burst test)	(FU) % (BREAKAGE)	(FL)10% (BREAKAGE)	A= (FU-FL) / 2 (N)	FM = (A+FL) -(N)	Number of samples
443,40	(55%) 243,87	24,39	109,74	-134,13	1
	(48,5%) 215,05	21,51	96,77	-118,28	1
	(39,5%) 175,14	17,51	78,81	-96,33	3

Table 4: Cargas aplicadas para el ensayo de fatiga hasta $5x10^6$ ciclos (NB Multi-Unit 4.8)



Graph 3: Cyclic load curve for tests up to 5x10^6 cycles (NB Multi-Unit 4.8)

In order to generate a load/cycle diagram for the dental implant and abutment system, ISO 14801: 2016 (section 5.6.3) recommends testing samples in a series of loads until a lower limit is reached where at least three samples survive and none fail in the specified number nf of 5x10 ^ 6 cycles for tests performed in air at frequencies between 2 Hz and 15 Hz. The recommended initial load is 80% of the load previously achieved in a static test, performed using the same test geometry and environmental conditions. The standard recommends testing the samples at at least four load levels and performing at least two, and preferably three repetitions at each level, with at least three samples needing to survive the maximum supported load.

9. FATIGUE TEST RESULTS

In order to perform the cyclic loading curve of the compressive bending fatigue strength of the Ti-Base implant set at different loads, the number of load cycles until failure has been recorded. The results are shown in the following diagram where the number of cycles for each load applied to the set is represented.

ISO 14801: 2016 standard recommends starting the process by applying a load of 80% of the breaking value obtained in a previous static test. The standard recommends testing devices at at least four load levels.

Table 5 shows in chronological order the test procedure followed using the testing machine for dental implants and dental materials.

This test has been tested within a range and tolerance of 500 N ± 5 N of the load.

LOAD VALUE (N)	NUMBER OF TESTED SAMPLES	NUMBER OF CYCLES	COMMENTS
243,87±5N	1	73.976	[1]
215,05±5N	1	406.513	[2]
175,14±5N	3	5 milions	[3]
		5 milions	[3]
		5 milions	[3]

Table 5: Number of cycles achieved per load applied to NB Multi-Unit 4.8 set.

Breakage of the NB 4.8 Multi-Unit set

[1]. Failure of the system occurs by implant rupture at 55% of the failure load reached in the static test. **(See image 6)**

Image 6: Fatigue strength sample of the Nobel Active NP+ NB Multi-Unit 4.8 Implant fatigue strength with rupture test.

[2]. Failure of the system occurs by breakage of the screw at 48.5% of the failure load reached in the static test. **(See image 7)**

Image 7: Fatigue strength specimen of the compressive bending test with screw breaking.

Maximum strength of the NB Active NP + NB 4.8 Multi-Unit implant set

[3]. The samples of the Nobel Active NP+ NB 4.8 Multi-Unit implant set were tested, each with the same load of 175.14N, which corresponds to 39.5% of the ultimate load reached in the static test. **(See image 8)**

Image 8: No breakage of the NB Novel Active NP +4.8 Multi-Unit set.

The fatigue limit of the set has been **175.14±5N** to reach 5x10 ^ 6 cycles, with the test geometry indicated in the ISO 14801: 2016 standard.

10. CONCLUSIONS OF THE FATIGUE TEST

Annex B:

The measurement of the masticatory forces according to ISO 10451, annex B, table B.1; the maximum masticatory load is:

Table B.1- Dynamic loading for different indications

Tooth position (See Figure)	Dental implant without splint [N]	Transitional dental implant without splinting [N]	Dental implant with splint [N]	Transitional dental implants with splinting [N]
12, 22 31,32,41 & 42	120	70	90	50
11 & 21	140	80	110	70
13-15, 23-25,33-35 & 43-45	170	100	140	80
16-18, 26-28,36-38 & 46-48	210	130	170	100

it can be stated that the results obtained from the fatigue tests for the direct implant set of GH1.5mm of Multi-Unit 4.8 Rotating and Graphene crown, are satisfactory for placement in incisors, canines, premolars and molars (see Table B.1-Dynamic load for different indications, dental implant without splint [N]), as the fatigue limit obtained is higher than the usual masticatory forces found in the ISO 10451 standard. The fatigue limit being **175.14N**.

Table B.2- Tooth positions according to ISO 3950

Top right								**Top left**							
18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
Bottom right								**Bottom left**							

Graphenano Dental's Nobel Active NP+ Multi-Unit 4.8 external connection and G-CAM crown set can be used on incisors, premolar canines and molars because the fatigue limit obtained is higher than the loads expected during normal activity of the abutment and implant system. (Table B.2 - Tooth positions according to ISO 3950, shows where the Multi-Unit 4.8 implant system can be used).