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Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-P-944.98.07

Test Report

No.: 165.081015.50.33
Date: 12 February 2009
Rev. 0

Test material:	PerioType X-Pert Implant, Ø4.1 mm x 15 mm, REF PXP4115 PerioType X-Pert Zirco-Seal Abutment, 0°, Ø4.2 mm x 2 mm, REF NAS420020
Customer:	
Company:	Clinical House Europe GmbH
Street:	Am Bergbaumuseum 31
Town:	D-44791 Bochum
responsible:	Jörg Ascherfeld
Test method:	ISO 14801:2007-11 (Dentistry -- Fatigue test for endosseous dental implants)
Machine No.:	329
responsible:	Dipl.-Ing. M. Leiderer

DIGITAL SIGNATURE
Signature: _____
M. Leiderer, research engineer

DIGITAL SIGNATURE
Signature: _____
M. Jackstien, research engineer

Final reports received as soft copies are signed digitally.

I. Subcontractors:

- none -

II. Specimens:

Date of receipt: 10-Oct-08
Test period: 22-Nov-08 to 02-Jan-09

11 pcs. PerioType X-Pert implant, Ø4.1 mm x 15 mm, REF PXP4115, LOT QT 09.5500.10;
11 pcs. PerioType X-Pert Zirco-Seal abutment, 0°, Ø4.2 mm x 2 mm, REF NAS420020, LOT C210208-01;
11 pcs. sleeve, no REF, LOT 110 001-002-00;

Fig. 1: Specimen tested herein.

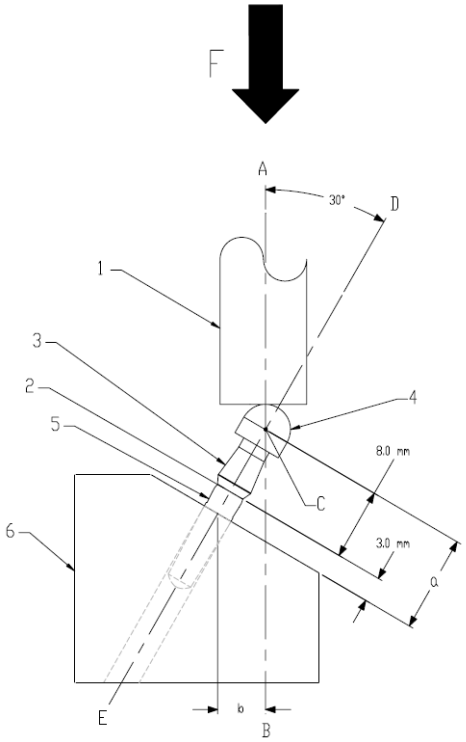
III. Test procedure:

ISO 14801:2007-11 (Dentistry – Dynamic fatigue test for endosseous dental implants) (certified).

This international standard specifies a method of fatigue testing of single post dental implants of the endosteal, transmucosal type. While it simulates the functional loading of a single root form dental implant body and its premanufactured prosthetic components under “worst case” conditions, it should not be used to predict the *in vivo* performance of a dental implant or prosthesis, particularly for an application in which multiple dental implants are used for a prosthesis. It is most useful for comparing dental implants of different designs or sizes.

The dental implant system has been assembled by the customer with a torque of 25 Ncm.

The dental implant body has been fixed in a specimen holder made of aluminium. The dynamic load was applied by a loading sleeve with a hemispherical top (provided by the customer) according to the ISO 14801 standard (Fig. 2).



1* loading device
2 nominal bone level
3 abutment
4 hemispherical loading member
5 dental implant body
6 specimen holder
b lever arm
a active length

*Shall allow free movement transverse to loading direction

Fig. 2: Schematic test set-up.

The active length was set to 11 mm. A 60 mm push-rod supported by a steel ball was used to enable unconstrained loading of the abutment.

The maximum bending moment M was calculated as follows:

$$M = 0.5 \times F \times a \quad (1)$$

where

M: maximum bending moment
F: maximum load applied
a: active length of implant (= 11 mm)

All dynamic tests have been carried out with a maximum test frequency of 15 Hz. The maximum and minimum loads (R=0.1) used for dynamic testing are given in Tab. 1. The run-out cycles were set to 5 million.

Tab. 1: Test loads used for individual specimens.

Specimen	Min. Load [N]	Max. Load [N]	Min. Bending Moment [Nm]	Max Bending Moment [Nm]
1.1	30	300	0.165	1.650
1.2	40	400	0.220	2.200
1.3	50	500	0.275	2.750
1.4	45	450	0.248	2.475
1.5	45	450	0.248	2.475
1.6	35	350	0.193	1.925
1.7	30	300	0.165	1.650
1.8	30	300	0.165	1.650
1.9	35	350	0.193	1.925
1.10	40	400	0.220	2.200
1.11	50	500	0.275	2.750

IV. Results:

Tab. 2: Results of the dynamic test.

Specimen	Min. Load [N]	Max. Load [N]	Min. Bending Moment [Nm]	Max Bending Moment [Nm]	Cycles	Result
1.1	30	300	0.165	1.650	5,000,000	no failure
1.2	40	400	0.220	2.200	5,000,000	failure
1.3	50	500	0.275	2.750	2,342,382	failure
1.4	45	450	0.248	2.475	2,754,000[1]	failure
1.5	45	450	0.248	2.475	1,816,260[1]	failure
1.6	35	350	0.193	1.925	1,042,650[1]	failure
1.7	30	300	0.165	1.650	5,000,000	no failure
1.8	30	300	0.165	1.650	5,000,000	no failure
1.9	35	350	0.193	1.925	5,000,000	failure
1.10	40	400	0.220	2.200	1,992,000[1]	failure
1.11	50	500	0.275	2.750	1,575,000[1]	failure

No S-N curve could be generated due to the large variation of the cycles to failure fo the different loads.

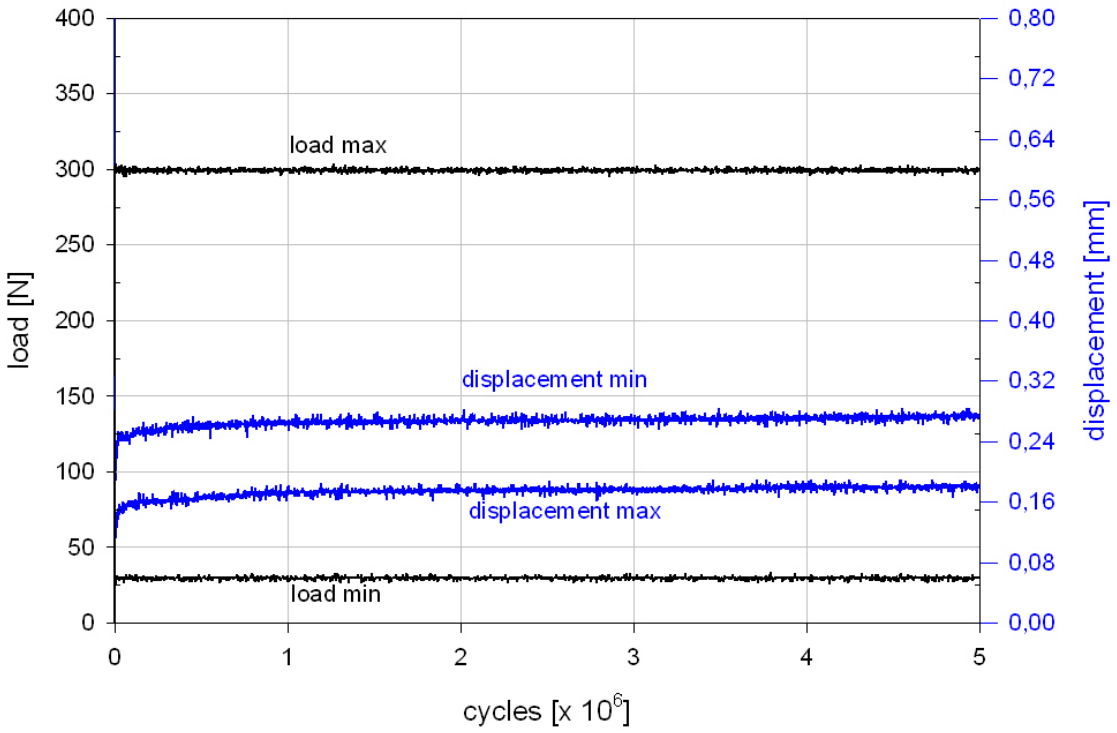


Fig. 3: Typical load (min/max) and displacement vs. test cycles graph – specimen 1.1.

[1] The number of cycles to failure is estimated on the basis of a change in the load and displacement vs. cycles curve which is usually a sign for failure.

Date: 12 February 2009 Signature:

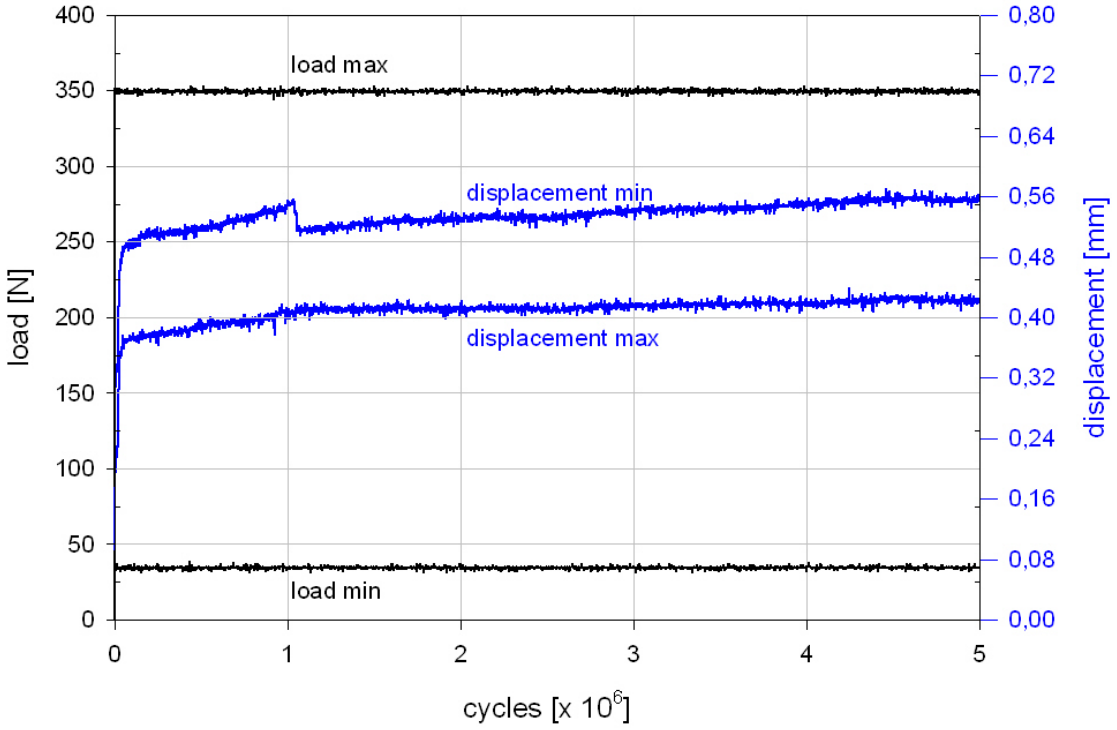


Fig. 4: Typical load (min/max) and displacement vs. test cycles graph – specimen 1.6.

Fig. 5: Fracture of the prosthetic screwafter the dynamic test – specimen 1.6.

V. Conclusion:

A run-out load of 300 N according to ISO 14801 could be established for the PerioType X-Pert implant tested herein. Tthree specimens reached 5 mio cycles without any failure. This load corresponds to a run-out bending moment of 1.65 Nm.

Comparing this value to the EndoLab database (n=5) the run-out bending moment can be regarded as within the common range of the predicate device (dental implants with a diameter of 4.1 mm have been chosen for comparison). Please note that the data base comprises different implant designs and materials.

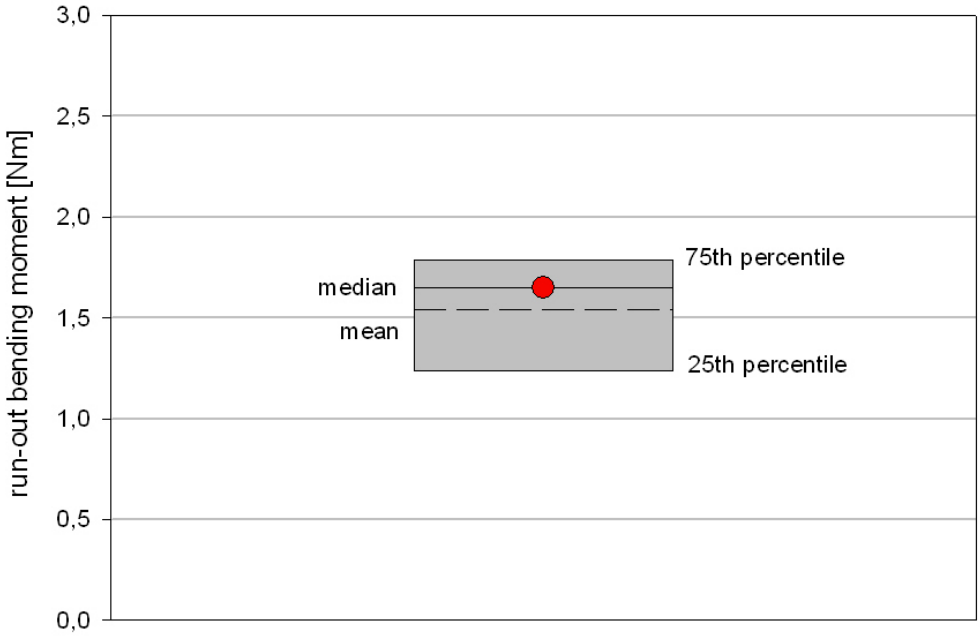


Fig. 6: Statistical data for the run-out bending moment established by EndoLab GmbH (n=5). The value established herein is marked by a red dot.