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TEST REPORT

No.: 164.120917.50.113
Date: March 22, 2013
rev. 0

Test Material:	Trias, Dental Implant, REF33010/1TRA Trias, Abutment, REF 812332/1TRA Trias, Screw, REF 260000/1TRA
Test Method:	ISO 14801:2007 Dentistry - Fatigue test for endosseous dental implants

Customer:	Testing Laboratory:
Servo-Dental Rohrstraße 30 D-58093 Hagen-Halden	EndoLab® Mechanical Engineering GmbH
Person responsible: Jens Müller	Person responsible: Dipl.-Ing. C. Salaw
	Signature: C. Salaw, research engineer
	Signature: C. Findeiss, research engineer

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Note:
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The test results relate only to the items tested!

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ZLG-P-944.98.07

1 Subcontractors

-none-

2 Specimens

Date received: 11-Sep-2012
Test period: 27-Sep-2012 to 02-Nov-2012

13 pcs. Trias, dental implant, REF33010/1TRA, LOT 200900802-4026;

13 pcs. Trias, abutment, REF 812332/1TRA, LOT 2006001-3682;

13 pcs. Trias, screw, REF 260000/1TRA, LOT 5343M-20061032-Z4-4087;

1 pc. Trias, tool, REF 14033/1TRA, LOT 235041-3878;

Fig. 1: Specimen tested.

3 Objective

The objective of this report was to describe fatigue testing of single post endosseous dental implants of the transmucosal type and their pre-manufactured prosthetic components.

4 Test Procedure

4.1 Test Standard

ISO 14801:2007 Dentistry - Fatigue test for endosseous dental implants (accredited)

4.2 Test Equipment

EndoLab® test equipment ID used: 203, 292

4.3 Test Description

Prior to the test the implants were assembled and tightened usingthe provided tool with 25 Ncm according to the customer's instructions.

To determine the fatigue properties of the dental implant body, the implants were embedded up to 3 mm below the bone level.[1] A fitting hemispherical loading member was designed and manufactured by EndoLab® resulting in an active length of 11 mm. For load application the embedded specimens were fixed in a steel specimen holder at an inclination of 35°.

A servo-hydraulic test frame was subsequently used to apply a cyclic load to the dental implant body. The dynamic load was directly applied to the hemispherical top according to the ISO 14801 standard (Fig. 2) via a 60 mm push-rod that was supported by a steel ball to enable unconstrained loading of the abutment.

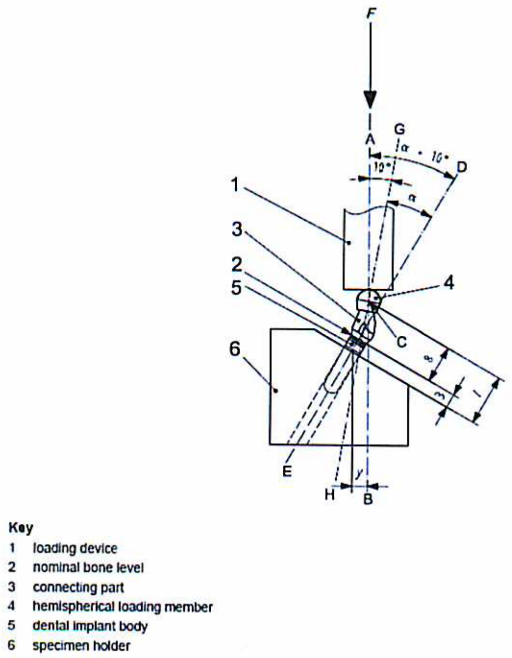

Fig. 2: Schematic test set-up.

[1] Information about the bone level as required by the test standard was provided by the customer.

The maximum bending moment M for pre-angled implants was calculated as follows:

$$M = y \times F \quad (1)$$

M: maximum bending moment
F: maximum load applied
y: moment arm measured

4.3.1 Static Test

Prior to the fatigue tests, one specimen was tested in a quasistatic compression mode.

An axial loading rate of 1 mm/min was used. The implant was loaded until failure occurred or the maximum load capacity of the test machine was reached.

The test was performed dry at room temperature.

4.3.2 Fatigue Test

All dynamic tests were carried out in ambient air and at room temperature with a maximum test frequency of 15 Hz for up to a 5 million cycles. The dynamic testing was started at a maximum load of approximately 80% of the static failure load. The maximum and minimum loads (R=0.1) used for dynamic testing are given in Tab. 3.

Tab. 1: Test parameter according to ISO 14801.

dynamic loading waveform	sinusoidal
frequency	15 Hz
number of run-out cycles	5,000,000 load cycles
test conditions	ambient air
temperature	room temperature
embedding medium	epoxy adhesive (Hysol 9514)
offset angle α (specimen holder)	35°
active length	11.0 mm
moment arm	4.0 mm

5 Results

5.1 Static Test

Plastic deformation of the dental implant and abutment as well as fracture of the connector screw was found as failure mode for the specimen tested herein. (Fig. 4)

Tab. 2: Results of the static test (specimen 1.1).

Specimen	Ultimate Load [N]	Ultimate Moment [Nm]	Ultimate Displacement [mm]	Stiffness [N/mm]
1.1	491	2.0	0.8	2,178

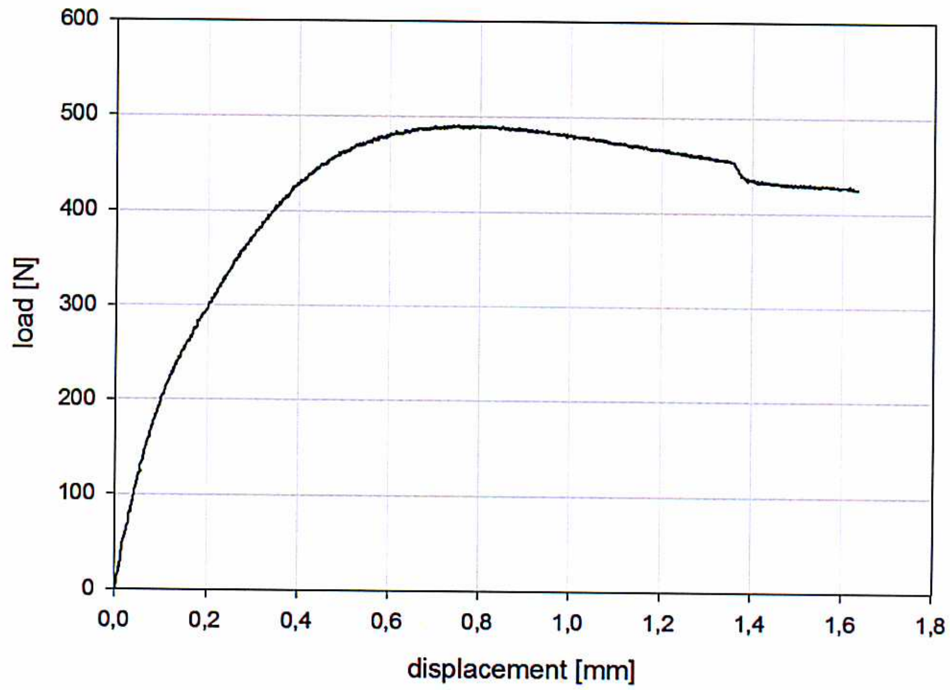

Fig. 3: Load vs. displacement curve for the static compression tests.

Fig. 4: Failure mode after the static test – specimen 1.1.

5.2 Fatigue Test

A run-out load of 225 N was established within this test series. According to equation (1) a maximum run-out bending moment of 0.9 Nm can be calculated.

Implants tested above the run-out load failed by fracture of the implant (see Fig. 7). The boundary of the 95% prediction interval for the run-out load was calculated as 131 N (= 0.5 Nm).

Tab. 3: Results for specimen 1.2 to 1.13

Specimen	Min. Load [N]	Max. Load [N]	Max. Bending Moment [Nm]	Cycles	Result
1.2	40	400	1.6	19,365	failure
1.3	35	350	1.4	43,177	failure
1.4	30	300	1.2	79,643	failure
1.5	25	250	1.0	133,939	failure
1.6	20	200	0.8	5,000,000	no failure
1.7	23	225	0.9	5,000,000	no failure
1.8	23	225	0.9	5,000,000	no failure
1.9	23	225	0.9	5,000,000	no failure
1.10	25	250	1.0	1,235,573	failure
1.11	30	300	1.2	1,001,399	failure
1.12	35	350	1.4	5,000,000	failure[2]
1.13	40	400	1.6	5,000,000	no failure

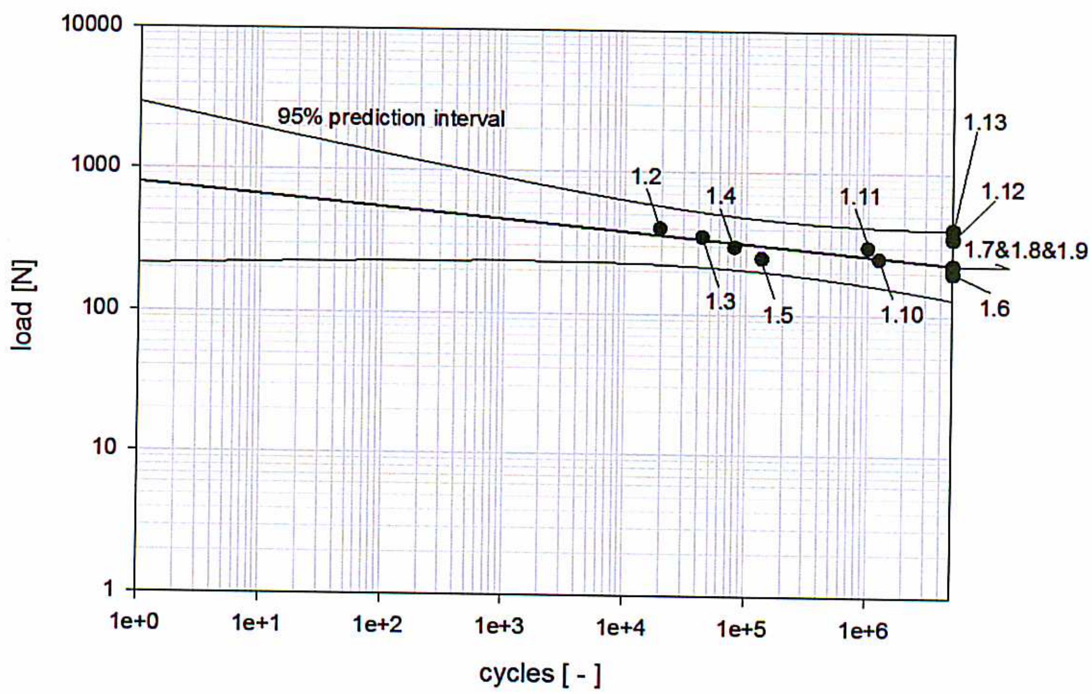

Fig. 5: AF-N curve of the dynamic axial compression test.

[2] After 5,000,000 cycles a fracture of the implant was observed.

Date: 22-Mar-13 Signature:________________

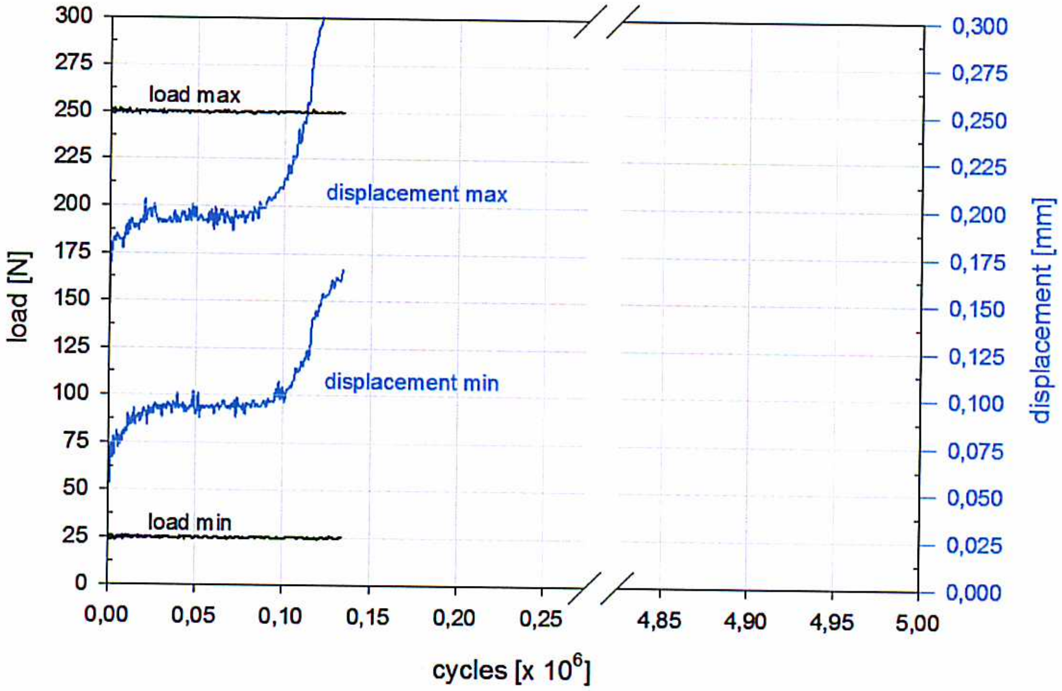

Fig. 6: Representative graph for load and displacement (min/max) by number of loading cycles – failed specimen 1.5.

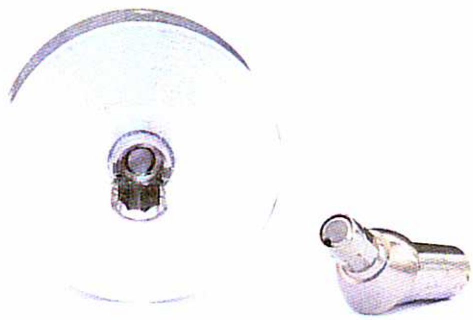

Fig. 7: Representative photograph of the failure mode observed. Fracture of specimen 1.5 occurred after 133,939 cycles at a load of 250 N.

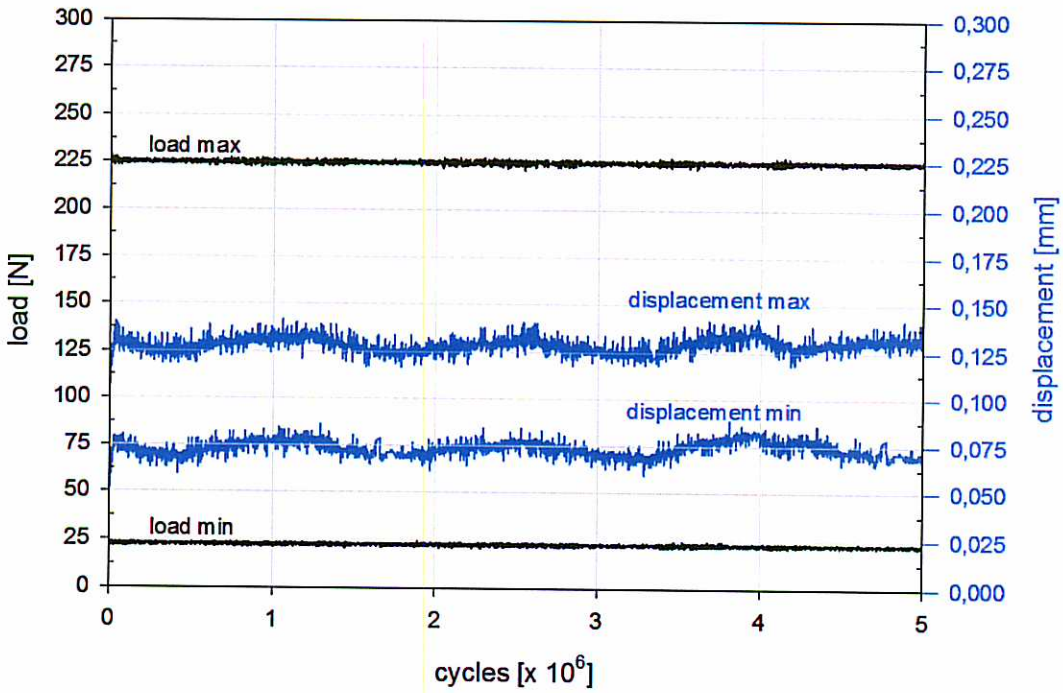

Fig. 8: Representative graph for load and displacement (min/max) by number of loading cycles – run-out specimen 1.9.

6 Summary and Conclusion

6.1 Static Test

Specimen 1.1 tested in a quasistatic compression mode failed at a maximum load of 491 N due to plastic deformation of the dental implant and abutment as well as fracture of the connector screw.

6.2 Fatigue Test

Three dental implants (specimen 1.7, 1.8 and 1.9) tested at a maximum load of 225 N withstood 5 million load cycles without failurecorresponding to a maximum run-out bending moment of 0.9 Nm.

The lower boundary of the 95% prediction interval forthe run-out load was calculated as 131 N (= 0.5 Nm).

Compared to the EndoLab® database (n=7), the run-out bending moment in these tests were within the range reached by dental implants of the predicate devices (metal dental implants with a diameter of 3.3 mm were chosen for comparison). Please note that the EndoLab®database comprises different implant designs and materials.

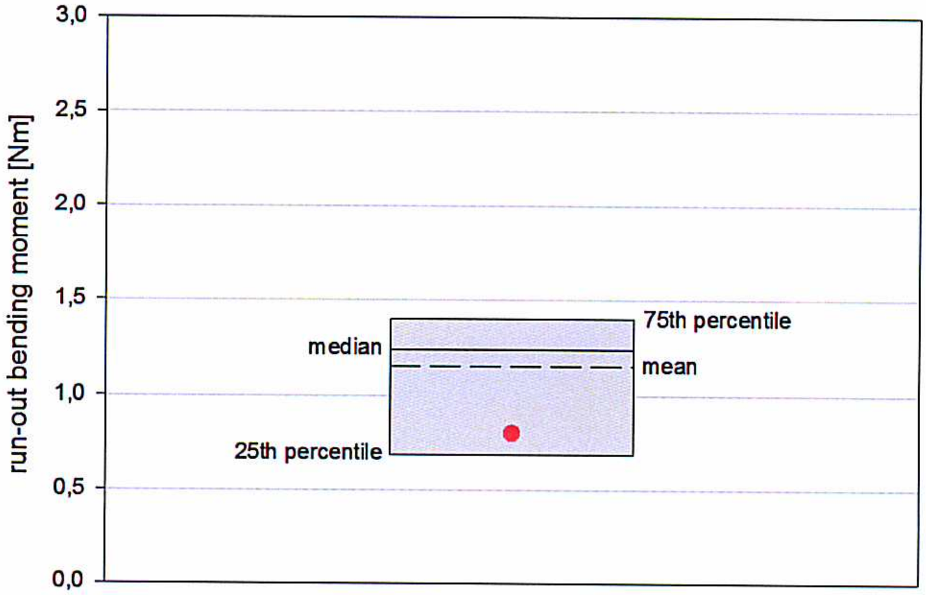

Fig. 9: Statistical data for the dynamic tests according to ISO 14801 established by EndoLab® GmbH (n=7). The value measured in this test (0.9 Nm) is shown as a red dot. The bending moment was calculated as applied load multiplied by active length a.

The worst case analysis and implant size selection were performed by customer.

General remarks:

The significance of the test results depends on the required confidence and reliability levels and the typical production lot size. This information was not taken into consideration in the tests performed by EndoLab® GmbH and described in this report.

Date: 22-Mar-13 Signature:__________