

Test report NIKO DENTAL GmbH MR001

Dynamic fatigue testing for endosseous dental implants in accordance with EN ISO 14801:2007

Manufacturer test sample: NIKO DENTAL GmbH

Type:	Implant:	Optimum implant 3,6 x 13;
	Abutment:	Aesthetic Abutment 0° 1-2/6
	Screw:	fixing screw

Order no.: NIKO DENTAL GmbH [no Order Nr.]

NIKO DENTAL GmbH ordered fatigue testing of an implant with abutment. 19 pieces Optimum Implants Ø 3,6 L13 with Abutments 0°, 3,6mm, GH1 and fixing screws were provided.

Description:

Implant system general:

Description: titanium implant for single tooth restauration and bridgework restorations.

Actual test samples:

- **Shape of implant:** Conical selftapping implant.
- **Material:** Titanium Grade 4.
- **Implant surface:** Sandblasted and acid etched.
- **Connection implant / abutment:** Cone/Hexagon hybrid connection.
- **Abutment:** Titanium Grade 5 straigth.
- **Use of implant:** Crown and bridgework.
- **Use of abutment:** Tooth replacement.
- **Selected design:** Implant diameter Ø3.6 is the worst case diameter.
- **Nominal bone margin:** Implants have to be placed on bone-level. Bone-Level is structured implant area.

Testing system:

The test, consisting of a static fracture test and fatigue tests, was conducted with the electro-dynamically powered test device "DORA14801" by LARADO.

Control and recording of the measured data at the test stations is performed with the 8-fold Control Unit "DORA-CONTROL" and the control and operating software "DORA-SOFT".

The determined measured values (every single measuring point!) are available as encoded, subsequently unchangeable files on data carriers. The encoded measuring data can be opened, printed and converted into a csv file format using the special "Viewer" by LARADO.

Sample holder:

With a clamping device, the stainless steel or titanium sample holder holds the sample, embedded in a Ø 20mm x 18mm brass cylinder, at an angle of 30° to the load direction. The sample holder is placed centered on the force sensor located in the bottom of the testing machine.

Semi-spherical load adapter:

The semi-spherical load adapter is made from titanium on a milling machine. On the top, the hemisphere has a 3 mm radius. It is in each case adapted in length and drill hole diameter to the geometry of the abutment to be tested, and cemented to the abutment using "Harvard Cement".



Picture of specimen in sample Holder

Test:

A static fracture test was conducted on an implant to determine the initial force for the fatigue test. This fracture test determined the maximum force required to fracture the implant or the abutment.

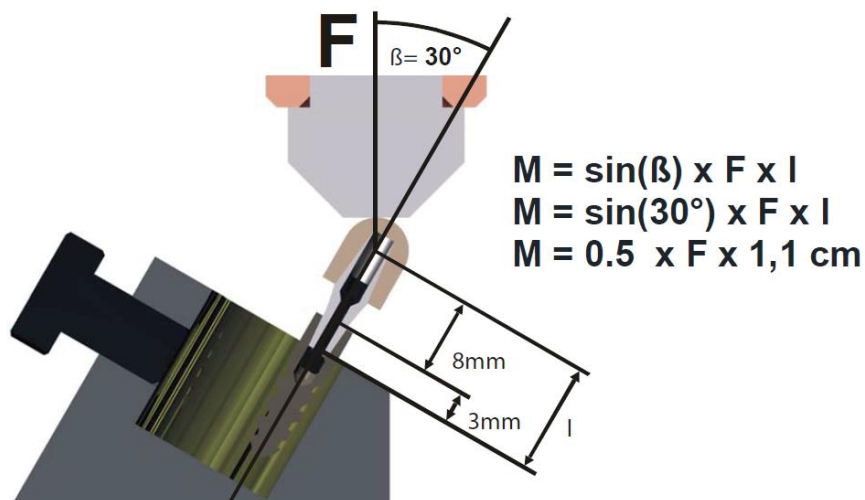
Following the static fracture test, the fatigue tests were conducted by loading the implants with different forces at 15Hz, usually beginning with about 50% of the previously determined static fracture force.

Preparation:

First, the implants with abutment were embedded in a Ø 20mm and approx. 18mm height brass cylinder with WEICON Fast- Metal and fitted with a sampling sleeve to achieve the dimensions required for testing in accordance with ISO14801.



Picture of specimen



14801 Loading geometry

Static fracture test:

Load:	continuous increase in force until connection fails.
Direction of load	30° to implant axis.
Loading	on the abutment with semi-spherical load adapter.
Embedding	implant in embedding material Fast- Metal (WEICON).

The static fracture test was conducted with a test sample as described above.

The static fracture test is conducted such, that the sample is placed under the stamp of the testing device and the test started with the configured values of maximum force and shearing rate.

The static fracture test is recorded in a diagram as record of the force and the travel over time.

The corresponding individual measuring points are available in an encoded file. The numerical results are given in the test protocol.

Fatigue testing:

Load :	200N, 220N; 230N, 240N, 250N, 260N, 280N
Frequency:	15Hz
Ambient temperature:	Air 23 ± 2 °C
Number of cycles:	up to 5,000,000
Load direction:	30° to implant axis
Loading	on the abutment with semi-spherical load adapter.
Embedding	implant in embedding material Fast- Metal (WEICON).

The fatigue tests were conducted with 13 test samples. To determine the fatigue strength, the individual samples were subjected consecutively to 7 different loads. As the magnitude of fatigue strength was known from previous tests, the tests were started with these loads.

The fatigue test is conducted such, that the sample is placed under the stamp of the testing device and the test started with the configured values of maximum force, minimum force, test frequency, number of cycles and maximum travel.

The results of the fatigue test are recorded in a diagram as record of maximum force and minimum force, as well as maximum travel and minimum travel over time. The corresponding individual measuring points are available in an encoded file. The numerical results are given in the test protocol.

Analysis:

The determined fatigue strength for the fatigue test is 220N.

Bingen, dated 13.02.2017



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Appendix:
Test protocol