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TEST REPORT

Of the Wöhler Curve of the *SIC®* Implant-System (SIC®max) during alternating load cycles

1. Conceptual Formulation

The aim of the in-vitro experiment commissioned by the company SIC® Invent AG is to determine the fatigue limit of the given *SIC®*-Implant system (SIC®max in combination with the Standard-Abutment 0°) with a defined alternating load cycle. For this purpose, the strength durability in a shearing test was determined. Thereafter a Wöhler Curve for the dynamic alternating load cycles was recorded. In addition 14 sterilely packed implant screws Ø=3,7mm x 11,5mm; 14 titan Standard-Abutments (0°) and 14 titan screws were prepared. The titan screws were mounted onto the implants with 20Ncm and loaded with the following specified test parameters:

<u>Shearing test:</u>

Load:	until the connections fail - 5 pieces
Loading direction:	30° to the axis (0° Abutment made of Titanium)
Load:	on the Standard-Abutment (cemented metal cap)
Cap cementing:	*Nimetic® Cem* ESPE Dental
Embedding:	Implant screw, in casting resin synthetic material

Cyclic loading:

Load:	275N, 300N, 325N und 350 N
Frequency:	4 Hz
Number of cycles:	5 Million
Loading direction:	30° to the axis (0° Abutment made of Titanium)
Load:	on the Standard-Abutment (cemented metal cap)
Cap cementing:	*Nimetic® Cem* ESPE Dental
Embedding:	Implant screw, in casting resin synthetic material

2. Materials and Method:

The alternating load test was carried out with the specified parameters in the test laboratory of the University Clinic of Frankfurt am Main. The applied experimental methods are described as follows:

2.1 Shearing test

In order to determine the basic value for the recording of the Wöhler curve, 5 implant-abutment-connections were sheared 30° to the implant axis. The experiment was carried out with the universal testing machine from the company Zwick (ZWICKI- 1120). The measuring data evaluation took place with the help of the software test expert from the company Zwick. The implant-abutment-connections were treated in the same procedure and in the same embedding apparatus as the cyclic loads.

2.2 Cyclic alternating loads (Experiment set-up)

The chewing simulator-machine 3.1.09 from the company Willytec (www.willytec.de) was used in order to generate the alternating loads. This testing machine, which has a motor-control unit, moves a metal beam (in which 8 rods were each mounted with a degree of freedom shown in Fig. 1) orthogonally up and down to the machine base plate. The metal beam was moved at a constant speed v_k at the respective inverse point of the direction of movement. The metal rods lie on the metal beams and they load the test pieces with a weight-force F_{pot} and dynamic force F_{kin} when the rods impinge the test pieces. The designated height of the force, which has an affect on the test piece, is controlled with the respective weights and this controlling takes place over the loading of the metal rods. The rod impinges with a constant speed v_k on the test piece and degenerates according to the construction simultaneously to the drive motor (Fig. 1). A negative acceleration a_{Brems} (dv_K/dt) develops and it is dependant on the flexibility, which is conditioned by the test piece clamped support. This negative acceleration along with the moved mass m_{total} ($m_{total} = m_{rod} + m_{weight} + m_{Sensor}$) creates a force F_{kin} which acts on the test piece.

The weight force $F_{pot\ i}$ is calculated by the product of the total volume m_{total} and the acceleration of gravity g. The total force, which acts on the test piece is defined by the sum of F_{kin} and F_{pot}:

$F_{total} = F_{kin} + F_{pot}$
$F_{total} = dv_k/dt * m_{total} + g * m_{total}$

A load cell was used to measure the force F_{total} on each of the 9 examined test pieces.

Fig. 1 shows a technical diagram of the experiment set-up:

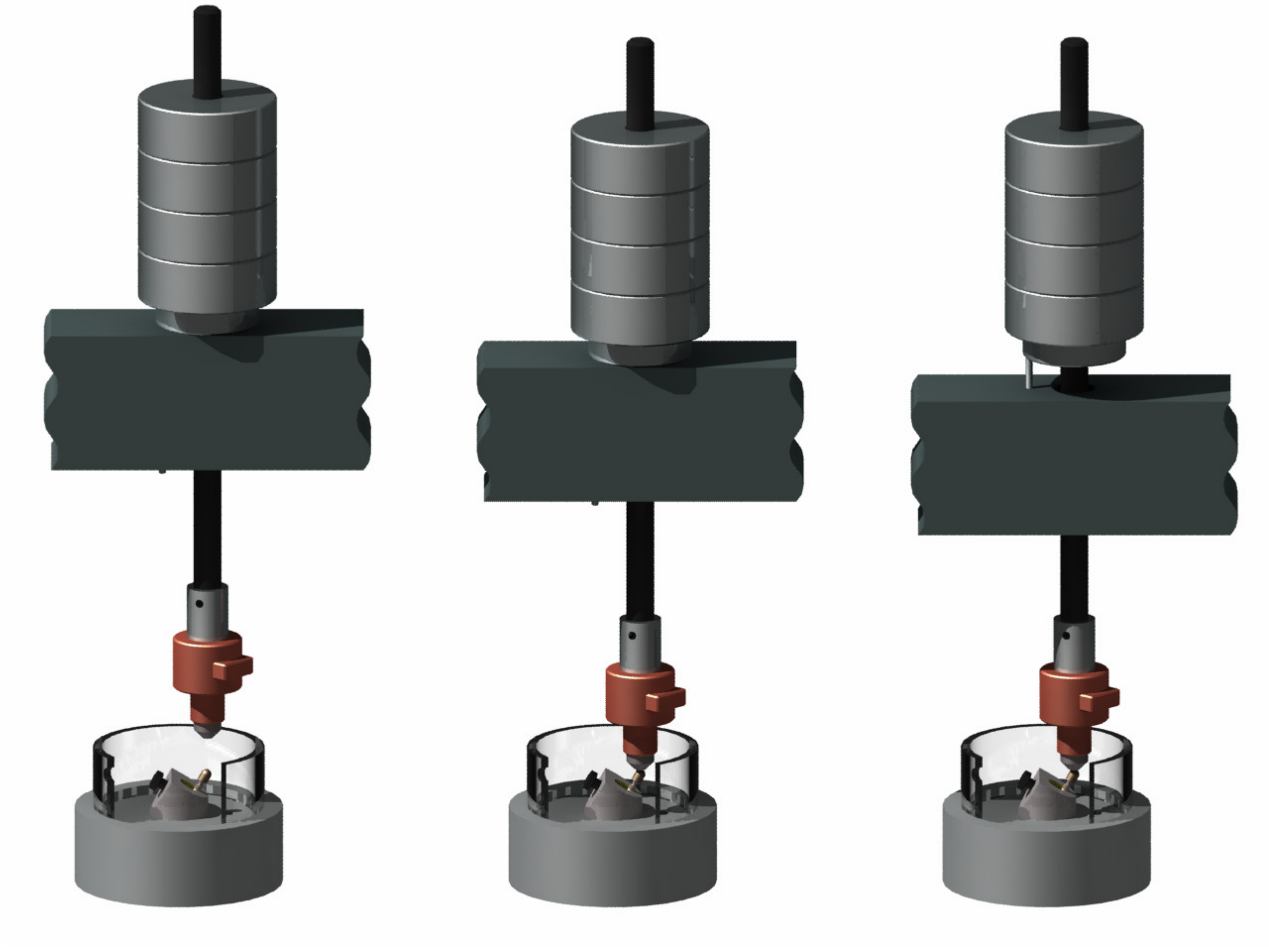


Fig. 1: Set-up of the experiment showing the different phases of the introduction of force on the test pieces.

The apparatus, which is supposed to carry the implant, is shown in Fig. 2:

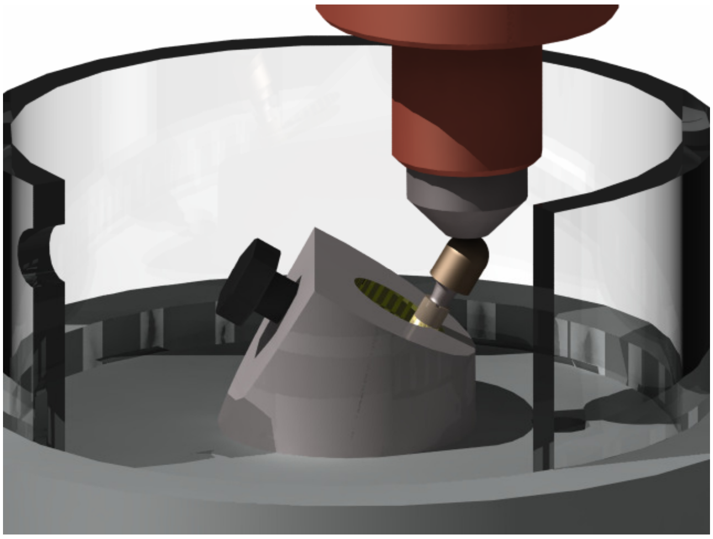
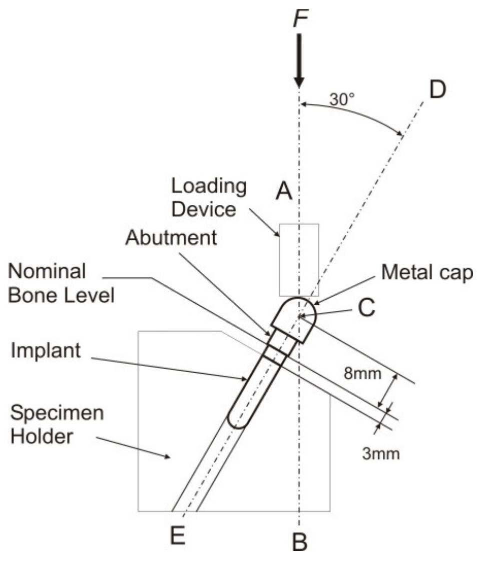


Fig. 2: Apparatus, which is to carry the implant

The implant was positioned at 30° to the axis (Fig.3). The abutment which is tilted at 0° was mounted with 20Ncm. After the embedding of the implant in synthetic material, a metal cap was fastened on the abutment with Nimetic® Cem. All the 9 test pieces were treated using the same procedure so that at F_{total} = 275N - 350N different torques prevailed (Fig. 3).



F:	Load
A:	Load axis
B:	Load axis
C:	Cap
D:	Abutment axis
E:	Implant axis

Fig. 3: Dimension of the implant screw, the implant abutment and the metal cap

2.3 Experiment parameters

The alternating load test was carried out with the following adjusted parameters:

F_{total} :	275N - 350N
Frequency:	4Hz
Number of Cycles:	5 Million
Height of stroke:	1,5 mm
Stroke speed:	40 mm/s
Sinking speed:	40 mm/s
Moved mass per test piece:	
Weight:	6-12 kg
Rod:	1,0 kg
Flange 1:	0,1 kg
Force sensor:	0,8 kg
Flange 2:	0,07 kg

2.4 Materials and Equipment

The following material and equipment was used for the experiment set-up:

2.4.1 Chewing Simulator

- Typ 3.1.09 (Fa. Willytec www.willytec.de)

2.4.2 Test Piece Clamp

- V2A 1.4305
- Casting resin VIAPAL UP 223 BS (E-Modul = 3500MPa, Fa. Bootsservice Andreas Behnke)

2.4.3 Metal cap

- Lathe cylinder made out of Aluminum

2.4.4 Cap cementing

- Nimetic® Cem (Fa. ESPE Dental)

2.4.5 Load cell

- 8 x Typ U2B (Fa. HBM www.hbm.de)

Rated force F_{nom} kN	0,5
Class of accuracy	0,2
Rated Sensitivity C_{nom} mV/V	2
rel. tensile/compressive sensitivity variance d c %	<0,2/1,5
rel. zero signal variance d s,o %	<1
Rel. inversion span (0.2Fnom bis Fnom) hysteresis u%	<0,2
Linearity variance dlin %	<0,2
Influence on temperature on sensitivity/10K	
Relative to nominal sensitivity TK c %	0,1
Influence on temperature on the zero signal/10K	
Relative to nominal sensitivity TK c %	0,05
Influence of eccentricity (1mm) d E %	0,05
Influence of lateral force (Lateral force 10% F nom) 1) d Q %	0,1
Rel. creep over 30 min d crF+E %	< ± 0,06
Input resistance R e Ω	>345
Output resistance R a Ω	300...400
Insulation resistance R is Ω	>2ç10 9
Reference excitation voltage U ref V	5
Service range of excitation voltage B U,G T V	0.5...12
Rated temperature range B t,nom °C	–10...+70
Service temperature range B t,G °C	–30...+85 (120)3)
Storage temperature range B t,S °C	–50...+85
Reference temperature tref °C	+23
Max. Operating force (FG) %	130
Breaking force (FB) %	>300
Static lateral force limit 1) (F Q) %	25 (100)2)
Nominal displacement Snom mm	<0,1
Fundamental resonance frequency fG kHz	4
Weight kg	0,8
Rel. permissible vibration loading Frb %	100
Protection system according to DIN EN 60529	IP67 (IP68)4)

2.3.6 Analogue-Digital-Converter / Measuring Amplifier

- Typ Spider8 (Fa. HBM www.hbm.de)

Accuracy class	0.1
Digital resolution in the case of final value of the measuring range	Digit _25000
Sampling rate (21 levels) per channel 1/s	1...9600 Baud

2.3.7 Implant / Abutment / Binding screw

Type	Dimension	Lot No.:
SIC - max Implants	3,7 x 11,5mm	603035
SIC - Standard-Abutment	3,3mm	00000263
SIC - Binding-Screw	3,3mm	00000768

2.4 Measuring Data Evaluation

The measuring data evaluation was carried out with the software program *LabVIEW® 8.2* (Company National Instruments www.ni.com). The forces which respectively took place on the load cells for each cycle were all recorded online. The time-force-function was determined and saved in each case with a software routine of the maximal force value. In this way one could monitor the implant set-up-connections which were to be tested.

2.5 Calibration of the Load Cells

The load cells, which were integrated into the experiment set-up, were calibrated before the alternating-load experiment as follows:
The load cell was initialised in an unloaded state. This means that the measured voltage value was set to Zero N. Thereafter the test piece was statically loaded with the known mass m_{total} (rod, weight (10kg), load cell, flange 1 and 2). This voltage value was set to a value of 117,4257 N ($F_{pot} = m_{total} * g$).

2.6 Evaluation of the Test Pieces

The test pieces were inspected after the alternating load-cycle experiment in order to recognize the following occurrences:

- Fracture of the implant
- Fracture of the implant screw
- Fracture of the abutment
- Loosening of the Abutments
- Other occurrences

3. Results:

3.1 Shearing test:

The maximal loading-forces of the 5 sheared implants are shown in Table 1. The result of the maximal values provides an average of 404,97N.

Implant No.	1.1	1.2	1.3	1.4	1.5
Force when failure occurred	396,51N	412,49N	398,30N	410,50N	407,03N
Failure mode	Plastic deformation of the implant and the abutment	Plastic deformation of the implant and the abutment	Plastic deformation of the implant and the abutment	Plastic deformation of the implant and the abutment	Plastic deformation of the implant and the abutment

Table 1

3.2 Cyclic alternating loads:

Table 2 shows the achieved life span, the appropriate loads and the type of failure (see Chapter 2.5) of the individual implants.

Implant No.	Load [N]	Bending moment [Ncm]	Achieved number of cycles [n]	Failure mode
2.01	350N	192,50Ncm	86.936	Fracture of the Implant, the Abutment & the binding-screw
2.02	350N	192,50Ncm	50.276	Fracture of the Implant, the Abutment & the binding-screw
2.03	325N	178,75cm	748.325	Fracture of the Implant & the binding-screw
2.04	325N	178,75Ncm	1034.548	Fracture of the Implant & the binding-screw
2.05	300N	165,00Ncm	2505.838	Fracture of the Implant & the binding-screw
2.06	300N	165,00Ncm	3195327	Fracture of the Implant & the binding-screw
2.07	275N	151,25Ncm	5.000.000	No failure
2.08	275N	151,25Ncm	5.000.000	No failure
2.09	275N	151,25Ncm	5.000.000	No failure

Table 2

The resultant Wöhler-curve of the life span and the load on the implants is shown in Fig. 4.

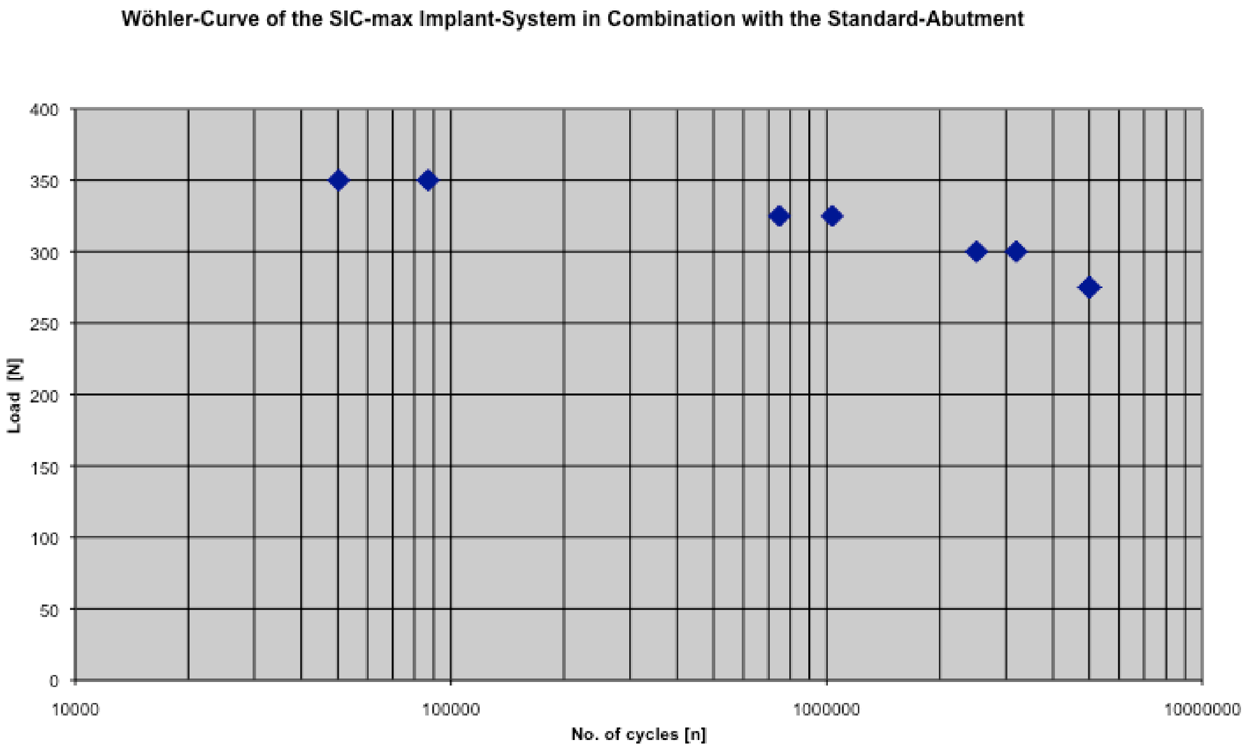


Fig. 4 *Wöhler Wöhler-curve of the SIC Implant system*

Fig. 5
Plastic deformation of the Implant body and the Abutment

Fig. 6
Fracture of the implant body

From the measuring results (Table 2) and the Wöhler curve (Fig. 4) results a durability of 275N for the *SIC* Implant (SIC max 3,7mm x 11,5 mm, 0° tilted abutments and metal caps) under cyclic loading according DIN 14801. The agent bending moment was 151,25Ncm.

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