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Testing Dental Implants: Development Of Test Rig That Enables Testing Under Realistic Conditions To Ensure Long Term Reliability

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Abstract

Dental implantology is one of the most important topics in the healthcare of the population, especially against the background of demographic developments worldwide. Due to the increased life expectancy of the population, the implant requirements (long term reliability, installation situations, load spectra etc.) have risen sharply. Implant testing using test rig technology is therefore an essential step in ensuring implant quality and reliability in the long term. In many countries, approval for the market launch of implants is only possible on the basis of the results of a dynamic test. For this reason, manufacturers of dental implants in the field of dental medical technology are currently testing the quality and reliability of the implant in accordance with the DIN EN ISO 14801 standard. However, this standard test procedure only covers a small proportion of all possible load scenarios and load spectra for dental implants. Testing a broad spectrum under multiaxial loads (the implant can be loaded from different directions) is not covered by the DIN standard. There is currently no test rig available on the market that can be used for multivariate testing of dental implants. This means that manufacturers can test their implants only in accordance with the DIN standard, but cannot reproduce realistic conditions of use. However, complex, multivariate load scenarios (chewing, biting, high temperature gradients, various media such as acids and sugar etc.) are present in the subsequent use of the implants, which must also be taken into account during testing. For this reason, a test rig was developed as part of a research project to test dental implants under realistic conditions in order to ensure the long term reliability. This paper describes the development of the new test rig. First, the state of the art is presented and the resulting need for action is derived. Subsequently, all requirements for the test rig, which are necessary to test beyond the DIN standard, are presented in detail. Finally, the final concept of the test rig is described in detail.

Keywords: dental implantology, dental implant, implant testing, implant quality, data analysis, reliability analysis, degradation analysis, lifetime estimation, accelerated testing, testing program, test rig, realistic test conditions, long term reliability, risk prevention

1. Introduction

Compared to the other technologies and solutions of medical implants, the history of dental implants goes back a long way. Already ancient civilisations took advantage of common materrials including wood, stones and seashells to compensate occurring tooth loss. Besides artificial materials biological teeth by animals or other humans were also commonly used as implants (Marin, 2023). Although the replacement was a great relief, it often led to a host immune response which in most cases resulted in a rejection and the loss of the implant as well (Suleiman, 2008). Over the past 100 years the average global life expectancy increased from 67 to 72 years (World Health Organization, 2019; Deutsche Stiftung Weltbevölkerung, 2022). Because of this the required lifespan of dental implants grew as well (Straumann Holding AG, 2022). The increasing possibilities offered in healthcare also affect the quality of modern implants which are designed to last as long as possible. A common solution nowadays is the use of biocompatible screwed attachments in the jaw bone on top of which the artificial teeth are placed, connected by an abutment (see Figure 1). Compared to ancient solutions this has a positive impact on the durability of the implant thus on the overall health of the patient as well (Marin, 2023). Even

though the average service life of implants has been increased over the last decades, there are still different factors that can lead to an earlier or later failure of the implant. Common reasons for an early failure include poor bone quality and quantity, bone healing and health conditions, smoking, infections and inadequate surgical and prosthetic techniques whereas excessive loading, Peri-implantitis and inadequate prosthetic construction can lead to a late fatigue (Sakka et al., 2012; Albrektsson et al., 2008).

Fig. 1. Exemplary structure of a dental implant (Jahl, 2020).

It is essential to minimize the risk for the person who receives the implant. In the worst case, a broken implant can lead to death if swallowed. To ensure the adequate construction and long term reliability of a recently developed implant, it must be subjected to tests. The current situation refers to DIN EN ISO 14801 to test the behaviour of an implant under various boundary conditions. Even though it is a valid tool for certification, different boundaries such as food-like media or different angles of attack are not taken into account. The testing frequency is also limited to 15 Hz under dry and 2 Hz under wet conditions, which results in an average single test taking a couple of days (Bonfante and Coelho, 2016). A complete test thus as needed for certification requires weeks to months of testing. To allow faster testing under more realistic conditions, a new test rig has been developed as a part of a research project. An increase of the maximum frequency and loading force create the opportunity for accelerated testing thus a quicker development of the final implant.

2. State of the art

Over the years, research has led to a wide variety of different implants and material compositions. The three types of implants being used over the last 60 years are subperiosteal, transosseous and endosseous. Subperiosteal implants consist of a framework which has to be custom made to fit on the patients alveolar bone beneath the periosteum. Transosseous implants, such as the transmandibular staple, are limited to the anterior mandible and consist of a plate with post projections. Some of the posts are inserted into the lower border of the jaw, others penetrate the bone and protrude through the mucosa covering the edentulous ridge. Endosseous implantology is the current state of the art. In contrast to subperiosteal and transosseous implants, endosseous implants are embedded into the jawbone instead of resting on it. Three basic types exist: blade implant, cylinder-shaped implant and screw thread implant. The latter two, also summarised as root form variety, are the most common implants. For both an exact hole needs to be drilled into the jawbone. Cylinder-shaped implants are then pressed into position, while implants with screw threads are either self-tapping so that they can be inserted by rotating, or the osteotomy site can be threaded (Suleiman, 2008).

Common materials with suitable properties for osseointegrated oral implants are devided into metals (e.g. tantalum, niobium and titanium) and ceramics, also known as zirconia and mainly grouped into porcelain, glass–ceramics, and poly-crystalline ceramics. Zirconia implants are a promising focus of research due to the lower incidence of stress and the reduced accumulation of bacterial biofilms. Nevertheless, titanium remains the most commonly used material in oral implantology (Albrektsson et al., 2008; López-Píriz et al., 2019).

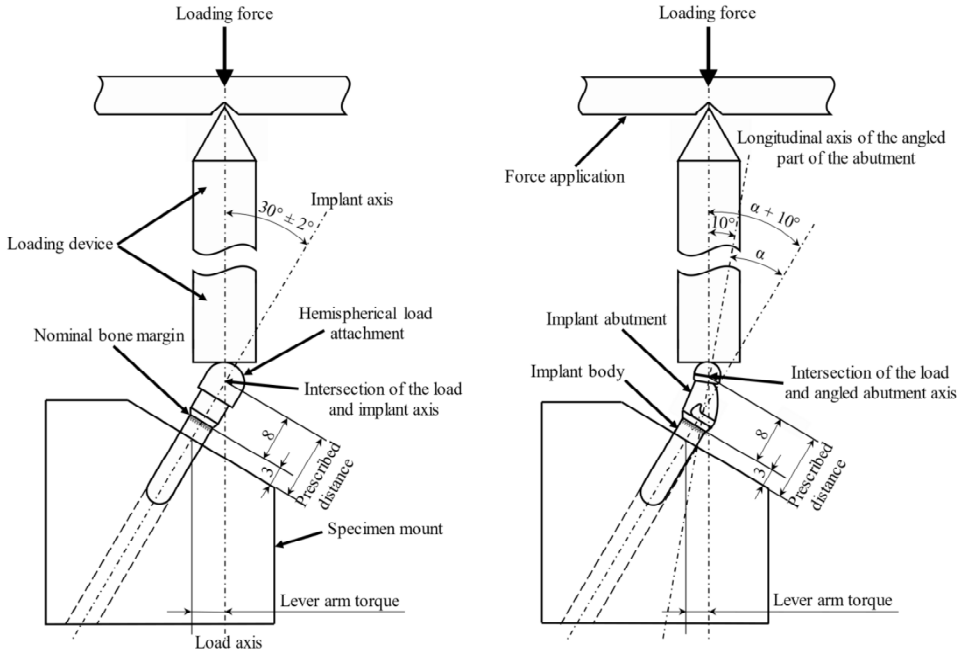

Fig. 2. Test specifications of DIN EN ISO 14801 (cf. Deutsches Institut für Normierung, 2017): Test setup for systems without angled implant abutments (left); Test setup for systems with angled implant abutments (right).

In testing materials for implants a distinction is made between zirconia and metal based implants. According to DIN EN ISO 13356, ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) must be tested for their bulk density, chemical composition, microstructure, strength (including Weibull modulus), accelerated ageing (monoclinic fraction), hardness, modulus of elasticity, fatigue strength, accelerated ageing (strength), monoclinic phase fraction and radioactivity. In contrast to the testing of metallic implants, the properties are performed on the raw material. Cyclic fatigue is tested at 5 Hz and 20 Hz in a physiological saline solution. To pass, no specimen may fail under 106 cycles (Deutsches Institut für Normierung, 2016a).

Metallic implants must be tested in assembled condition. DIN EN ISO 14801 describes the required setup for dynamic testing. A distinction is made between systems with angled implant abutments (Figure 2, right) and systems without (Figure 2, left). Systems without angled implant abutments must be tested at an angle of 30° ± 2° whereas systems with angled implant abutments must be tested at an angle 10° +2°/−1° greater than the angle between the central longitudinal axis of the implant and the central longitudinal axis of the angled part of the abutment α (Figure 2, right). A test in a dry environment is performed at 20 °C ± 10 °C with a maximum frequency of 15 Hz. Testing in physiological saline solution or in an alternative physiological medium is performed at 37 °C ± 2 °C and must not exceed a frequency of 2 Hz. In both scenarios, the load must alternate sinusoidally between a set maximum value and a minimum value being 10 % of the maximum load of 5 % of the set maximum value. Tests are carried out until at least two, preferably three, test specimens are subjected to at least four different loads. The test is performed at ≤ 2 Hz up to $2 \cdot 10^6$ cycles and at > 2 Hz up to $5 \cdot 10^6$ cycles. As soon as a lower limit is reached at which at least three test specimens survive, the measured points are mapped in a Wöhler curve and the fatigue strength range is determined (Deutsches Institut für Normierung, 2017).

This testing method is used all over the world, the American NSI/ADA Standard No. 127 (American Dental Association, 2018) and the Japanese standard JIS T 6005 (Japanese Standards Association, 2020) describe the same procedure although no realistic test conditions are modelled. Various environmental influences such as

torsion, bone loss and air humidity are not taken into account. Also the parameters that are tested, the frequency, angle of attack, loading force, ambient temperature, ambient medium and implant orientation, are not based on actual environmental factors. A comparison of the boundary conditions taken into account in the standard and the factors considered in the research project can be seen in Figure 3.

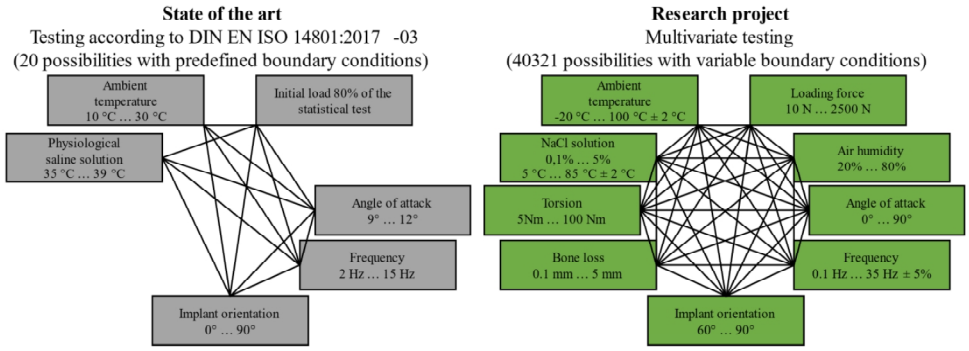

Fig. 3. Comparison of the boundary conditions that are currently taken into account in the state of the art (left) and that can be taken into account in the future by the research project (right).

The lack of relevant influencing factors in the testing of dental implants according to the standard is also seen as critical in other research studies, for example in the article by Bonfante and Coelho (2016) which was sponsored by the Institut Straumann AG. The paper by Shemtov-Yona and Rittel (2016) criticizes the limited requirements and discusses the random spectrum loading procedure as an alternative. Further studies are focusing on improving the test procedure through improved software (García-González et al., 2020) or increasing the possible number of samples in a test rig (Armentia et al., 2019). The article of Jokstad et al. (2003), on the other hand, criticizes the lack of a general international standard.

It can be summarized that the test procedure in accordance with the DIN EN ISO 14801 alone is currently not sufficient to map the long term behaviour of an implant in the human body. In order to be able to test the long term reliability and quality of dental implants more realistically, the test rig developed as part of the research project includes new functions for using additional load scenarios and combinations of loads for fatigue tests (see Figure 3).

3. The development of a new test rig

The development of a new test rig, with which significantly more realistic test conditions can be realized than with the test rigs according to the DIN standard, is one of the central aspects of a research project. The research project was funded by the German Federal Ministry for Economic Affairs and Climate Action (formerly: Federal Ministry for Economic Affairs and Energy). This chapter describes the development of the test rig in detail.

3.1. Requirements for the test rig

The requirements for the test rig can be grouped into requirements for the specimen mounting, the test parameters, the testing process and the design of the test rig. All requirements for the development of the test rig are listed as followed.

3.1.1. Requirements for specimen mounting

- Shear force-free force application
- Non-angled systems must include an angle of 30° ± 2° to the load direction
- Angled systems must include an angle of 10° +2°/−1° to the load direction
- At least 50 mm distance between load attachment and bearing of the load attachment
- Angle of attack of the implant variable in the range of 0° - 90°
- Implant orientation variable in the range of 60° - 90°

- Adjustable bone margin on the implant from 0.1 mm - 5 mm
- Precisely defined load center for lever arm calculation
- Deformation-resistant load attachment
- Possibility of applying compressive forces, torsional forces and tensile forces

3.1.2. Requirements for test parameters

- Travel speed in the static test: 1 mm/min ± 0.5 mm/min
- Force generation: 10 N - 2500 N ± 1 %
- Force curve: Sinusoidal
- Test temperature in liquid medium: 5 °C - 80 °C ± 2 °C
- Maximum load frequency: 35 Hz ± 5 %
- Torsional moment: 5 Nm - 100 Nm ± 1 %
- Humidity: 20 % - 80 % rel. humidity

3.1.3. Requirements for the testing process

- Force measurement: 10 N - 2000 N ± 0.1 N
- Possibility to carry out the test in a liquid medium
- Control of the force curve and the load frequency
- Logging of the number of cycles
- Detection of failure of a test specimen
- Detection of alignment of the test specimen:
    - Angle of attack
    - Implant orientation
    - Bone margin
- Application of thermal load changes or thermal shocks with liquid media
- Deflection measurement of specimen 0 mm - 1.5 mm ± 10 µm (in direction of force)

3.1.4. Requirements for the design of the test rig

- Accessibility to the test specimen during setup in accordance with DIN EN ISO 547-2
- Avoid the risk of crushing during setup of the test specimen
- Secure moving parts from contact during the test procedure
- Separating protective device to the test specimen
- Emergency stop device accessible in every operating mode

3.2. Design of the test rig

Figure 4 shows the final design of the test rig. In addition to the hardware assemblies and the electronic control system, the test rig also includes a Human Machine Interface (HMI) and appropriately programmed software for controlling the test sequence and recording measured values during the tests. The requirements for holding the specimen are met by a ball joint, which is positioned so that the force is applied at a distance of at least 50 mm to the implant. Furthermore, adjustment options in the following degrees of freedom are possible: Angle to the direction of force 0° - 90° via a swivel mount and angle to the bone margin 60° - 90° via a device for embedding the implant. The height of the bone margin in the range of 0.1 mm - 5 mm is also adjustable via an embedding that can be moved along the longitudinal axis of the implant. The specimen mounting realizes a rigid (tension, compression, torsion) clamping of the implant. The bone margin position is measured while the lever arm is calculated automatically via software.

The design and construction of the specimen chamber takes into account the specifications of DIN EN ISO 547-2 (Deutsches Institut für Normierung, 2009). The sample chamber is designed as a separate assembly. It is removed from the test rig by the user for set-up. This significantly reduces the risk of crushing, as the moving parts of the sample chamber have a low mass and no drive of their own. The moving parts and access to the test specimen are also protected against contact by a separating protective device in accordance with DIN 51233 and necessary safety distances realized in accordance with DIN EN ISO 13857 and DIN EN 349 (Deutsches Institut für Normierung, 2008; 2014; 2020). The test rig is further equipped with an emergency stop in compliance with DIN EN 13850 (Deutsches Institut für Normierung, 2016b), which is attached to the test rig in such a way that it is easy to reach in any operating mode of the test rig.

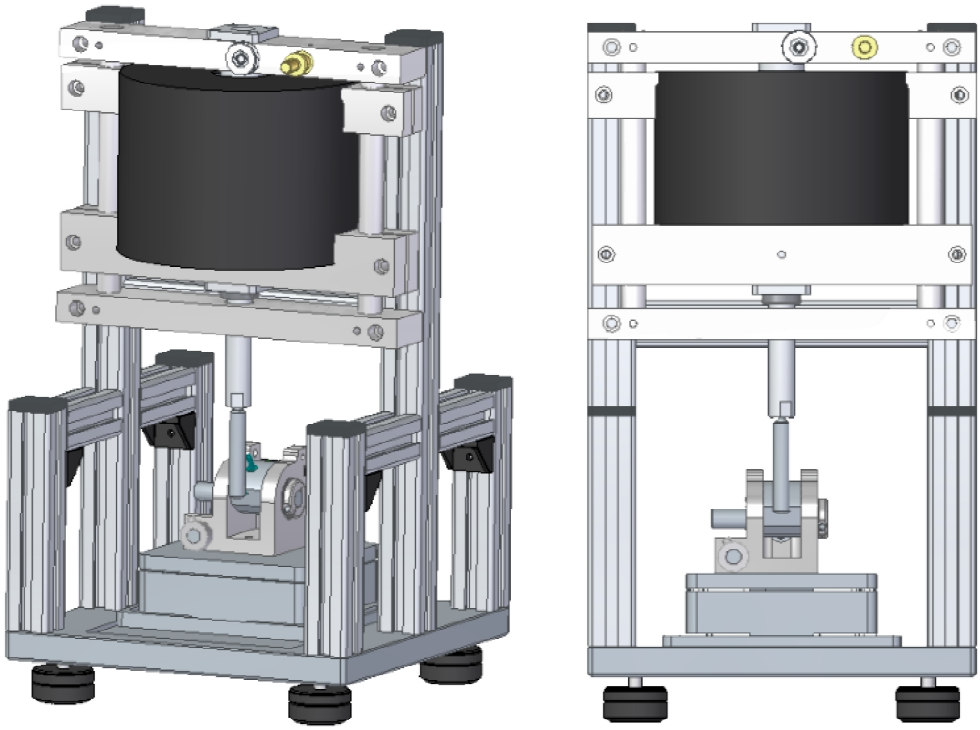

Fig. 4. Newly developed test rig for fatigue tests of dental implants to ensure the long term reliability: CAD-Model.

Fig. 5. Newly developed test rig for fatigue tests of dental implants to ensure the long term reliability:
Four fully assembled versions in the laboratory.

The test rig's drive system comprises ten electromagnets (electromagnetic drive system). A force sensor and a displacement sensor are connected to the drive system. On the one hand, the use of an appropriate force sensor ensures that the required forces can be measured. On the other hand, a resolution of the force measurement range of 16 bits ensures that the required accuracy of ± 0.1 N is also achieved up to the maximum force of 2.5 kN. By coupling the force measurement with the drive system control, a so-called closed-loop control is created, which enables constant monitoring and adaptation to the target value of the force curve as well as the load frequency. The displacement measurement is carried out after the force sensor in order to eliminate any influence on the displacement measurement due to the compliance of the force sensor. An optical non-contact system with a resolution of 1 µm is used as the displacement sensor. Integration of the displacement recorded by the displacement sensor allows the travel speed to be controlled. Rotation and torsional movement is realized with a stepper motor (rotary drive) and transmission through a planetary gearbox. The sinusoidal force curve is stored as standard with a parameter selection (frequency of the force curve, maximum force, minimum force) in the software and control.

A cooling unit provides cold water at a minimum temperature of 4 °C for thermocycling. The cooling unit is connected to the thermocycling unit, which has a storage tank with hot and cold water. The hot water is generated by a heater integrated in the thermocycling unit. On the one hand, the thermocycling is electronically connected to the control system of the tester in order to control the thermal load changes with the adjustable cycle times in the HMI (hot to 60 °C / cold to 4 °C). On the other hand, the thermocycling is connected to the sample chamber in order to provide the respective temperature-controlled liquid medium (usually distilled water or a NaCl solution). It is also possible to set the HMI to flush the sample with a liquid medium at 37 °C ± 2 °C. This can also be provided by the thermocycling. A humidifier and dryer are integrated into the test rig for tests at different air humidities. Figure 5 shows four assembled test rigs in the laboratory, each with a separate HMI. The current number of cycles and the number of cycles already performed are displayed on the HMI. The following measured values are also recorded by the software during the test:

- Parameters set for the test (load frequency and force curve);
- Force (measured for each cycle);
- Displacement (measured for each cycle);
- Number of thermal load cycles performed with temperature curve;
- Rel. Humidity;
- Angle of Attack;
- Implant orientation;
- Bone margin height.

The newly developed test rig was verified by numerous reference and comparative tests to ensure that the requirements of the DIN EN ISO 14801 are met (cf. Figure 6). Even with a higher load and correspondingly higher load delta, the test remains stable over more than 90000 cycles (Figure 6, right). This could also be observed in further tests, so that it can be stated that the newly developed test rig can carry out the tests in accordance with DIN EN ISO 14801 in a reproducible manner.

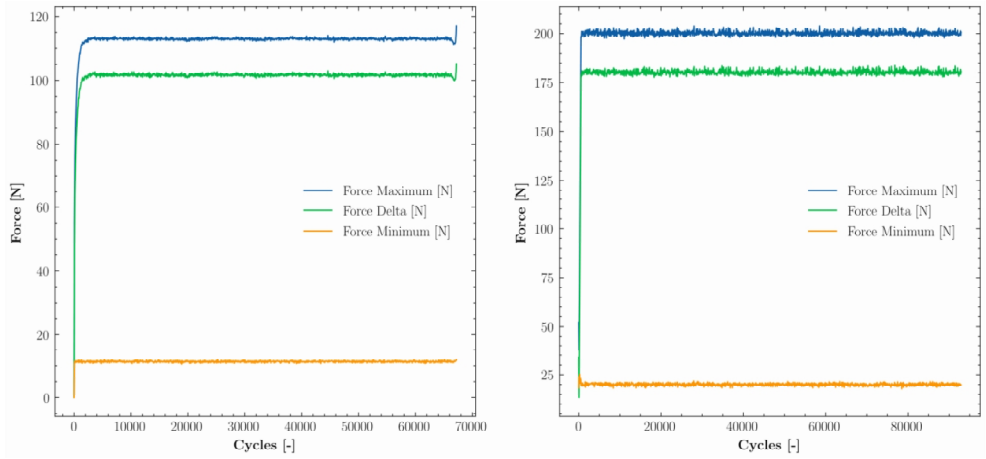

Fig. 6. Test results based on DIN EN ISO 14801: The measured values force minimum, force faximum and the calculated delta. Comparison of the conventional test rig (left) and the newly developed test rig (right).

In addition, it is now possible to use various load spectra for testing dental implants so that more realistic test conditions can be used beyond the DIN standard. The actual service life of a dental implant in use can thus be represented more realistically, so that the long term reliability can be improved and the risk of premature damage or failure of dental implants can be reduced. The developed test rig has the further advantage that comprehensive measured values of various parameters are recorded in real time during the fatigue tests with a high measurement frequency. Figure 7 shows the progression of various parameters (Voltage, Force of X-/Y-/Z-Axis, Deflection and Acceleration) of different cycles in detail (real time). The recorded data shows the change in the last 10% of cycles until the dental implant fails. All parameters show clear changes or trends between the cycles.

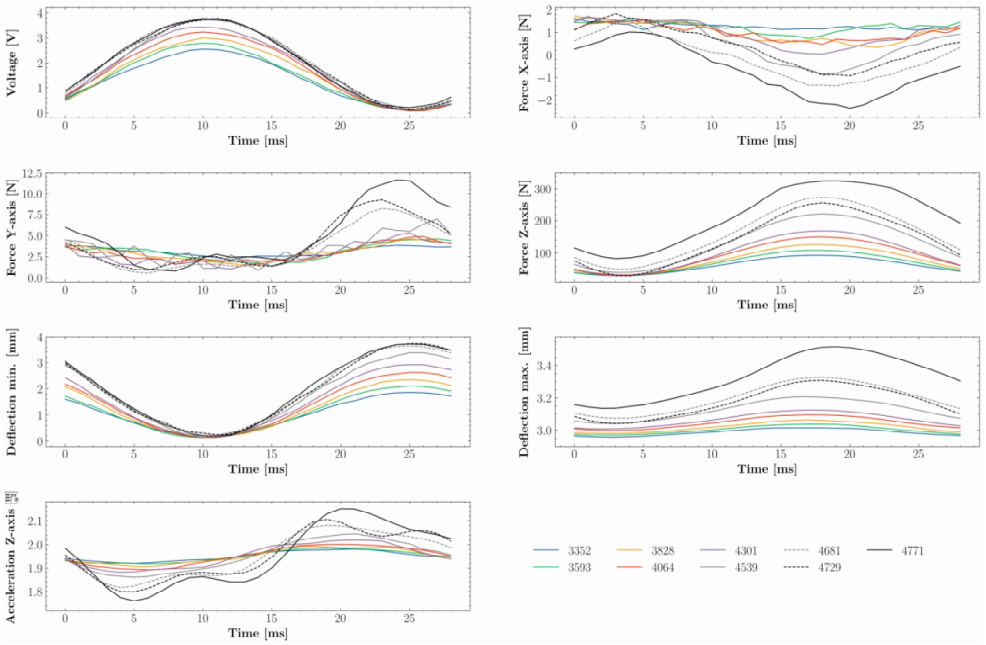

Fig. 7. Various recorded parameters of a fatigue test: Display of the real time measurement progression of certain cycles.

The analysis of the measurement data enables the detection of anomalies, the detailed analysis of the degradation behavior and the prediction of the (remaining) service life. Furthermore, by using different load

scenarios, accelerated testing can be applied to significantly reduce the required test time or the required development time of dental implants.

4. Summary and outlook

Due to demographic change, among other things, the expected lifespan of people worldwide is constantly increasing. Dental implantology is one of the key areas in this context, as the demands placed on implants (long term reliability, installation situations, load spectra, etc.) are rising sharply due to said increased life expectancy. In order to continue to guarantee the quality and reliability of dental implants, it is necessary to further improve implant testing before the implants are approved. Dental implants are currently being tested worldwide according to the DIN standard. However, this is a standard test procedure that only covers a selection of load cases. But in reality and in the subsequent use of dental implants, there is a broad spectrum of complex (multivariate) loads, which is not taken into account in the current tests according to the DIN standard, i.e. realistic application conditions cannot currently be mapped.

For this reason, a new test rig was developed in a research project, which can test various load scenarios beyond the DIN standard. All requirements for the test rig as well as the final design are described in detail in this paper. The requirements relate to the specimen mounting, the test parameters, the testing process and the design of the test rig. The test rig was verified by numerous comparative tests, which ensured that all requirements of DIN standard 14801 are met. Dental implants can now be tested under realistic conditions. Another advantage of the test rig is the data recording. By recording comprehensive measured values, it is now possible to carry out detailed analyses. The degradation behavior of dental implants can thus be further researched, anomalies can be analyzed and predictions of the (remaining) service life based on the measurement data can be made. Furthermore, accelerated testing can be applied by using different load scenarios or load levels.

Tests are currently being carried out with different load angles, load frequencies and forces in order to develop suitable acceleration models. Thermal cycling in different media is also planned. The results will be published in future publications.

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