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Long-term reliability of dental implants: Development of a multivariate test rig for accelerated testing under realistic conditions

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Abstract: Demographic change means that the demands on the healthcare system are constantly increasing. Therefore dental implantology is an important part of the healthcare system against the backdrop of increasing life expectance: the requirements for long-term reliability, installation situations and load spectra are increasing worldwide. Testing is required so that statements can be made about the long-term reliability and degradation behavior of the dental implant before it is approved and, accordingly, before it is implanted and used in the human body. Worldwide, the approval of a dental implant based on dynamic tests is mandatory, which is why manufacturers of dental implants are currently testing the long-term reliability and quality in accordance with the DIN EN ISO 14801 standard. However, the test conditions according to this standard do not represent the real operating conditions of a dental implant in the human body under widely varying load scenarios. In order to analyze and guarantee the long-term reliability respectively acceptable degradation behavior of dental implants, fatigue tests with multivariate, complex load scenarios (chewing, biting, high temperature gradients, various media such as acids and sugar etc.) are required, which go far beyond the current standard. Although manufacturers test their dental implants in accordance with standards, they are unable to carry out reproducible fatigue tests under realistic test conditions, as there are no test rigs that enable multivariate testing of dental implants. As part of the presented research work results, a new test rig has been developed. Dental implants can be tested for the first time under realistic operating conditions. The new test rig has already been verified to ensure that testing is carried out in accordance with DIN EN ISO 14801. In order to reduce the required test time, tests were carried out with different load angles to increase the load and different loading frequencies. The recorded test data is analyzed using various statistical methods to determine whether the acceleration of the tests does not lead to a different damage pattern or degradation behavior. Furthermore, the degradation behavior is analyzed in order to improve the technical long-term reliability of dental implants and to enable possible prognosis models for predicting imminent failures. Potential acceleration models for different load angles as well as for increasing the load frequency could be determined, which are presented in this paper.

Keywords: Dental implant, long-term reliability analysis, degradation analysis, accelerated testing

1. INTRODUCTION

The development of today's established dental implants is based on a long history. Next to bamboo pegs in ancient China and gold wires in ancient Egypt, wood, stones and seashells were used to compensate for occurring tooth loss. In addition to artificial materials, biological teeth from animals or other people have also been used as implants (Marin 2023). Although implant replacement often provided significant relief, it frequently induced a host immune response, typically resulting in rejection and loss of the implant (Suleiman 2008). Over the past 100 years, the average global life expectancy has increased from 67 to 72 years (World Health Organization 2019, Deutsche Stiftung Weltbevölkerung 2022). Consequently, the required lifespan of dental implants has also risen (Straumann Holding AG 2022). Advances in healthcare have also enhanced the quality of modern implants, which are designed to last as long as possible. A prevalent modern solution involves the use of biocompatible screwed attachments in the jawbone, on which artificial teeth are placed, connected by an abutment (see Figure 1).

This approach has proven to enhance the durability of implants compared to older methods, positively impacting the patient's overall health (Marin 2023). Despite the increased lifespan of implants over

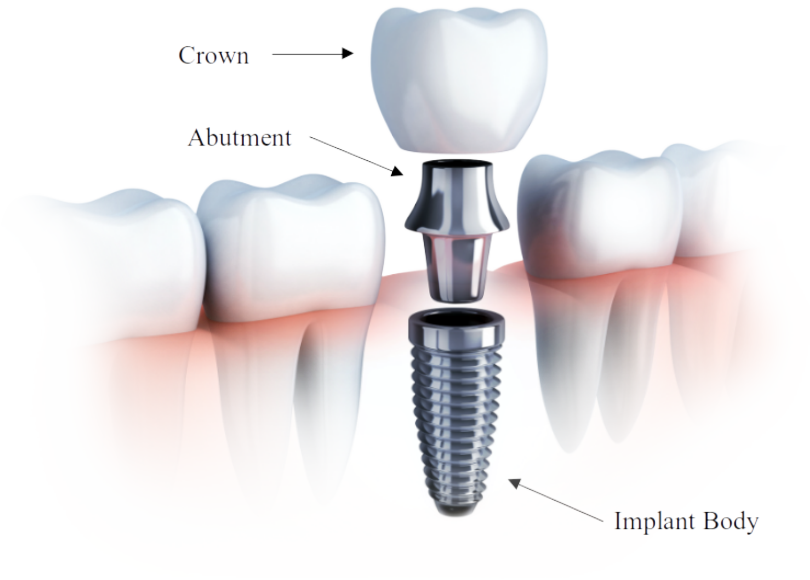

Figure 1. Exemplary structure of a dental implant (cf. Sa Presi 2024)

recent decades, several factors can still cause early or late implant failure. Early failures are commonly due to poor bone quality and quantity, bone healing issues, health status, smoking, infection, and inadequate surgical and prosthetic techniques, whereas late failures are often caused by excessive loading, Peri-implantitis, and inadequate prosthetic design (Sakka et al. 2012, Albrektsson et al. 2008). As a result of many years of development, three types of dental implants have been established over the past 60 years: subperiosteal, transosseous and endosseous. The subperiosteal implant is a custom-made metal frame that rests on the alveolar bone below the periosteum. It is fabricated from an impression of the edentulous jaw taken after surgical reflection of the muco-periosteum. The frame, cast in a cobalt-chromium-molybdenum alloy, is placed in a second surgical procedure. These frames have posts that penetrate the oral mucosa and are typically used to support overdentures. The transmandibular staple, as an example of transosseous implants, is limited to the anterior mandible and consists of a plate with post abutments. Some of the posts are inserted into the lower jawline, while others penetrate the bone and extend through the mucosa covering the edentulous ridge. The current state of the art is osseointegration. Unlike the other types, osseointegrated implants are embedded in the jawbone rather than resting on it. They are classified into three categories: blade implants, cylinder-shaped implants, and screw thread implants. The insertion of blade implants consists of the preparation of a precise hollow in the jawbone into which the implant is inserted to achieve primary stability. Due to its slim body design, the implant can be inserted into narrow bones. Cylinder-shaped and screw thread implants, also referred to as root form variety, are the most prevalent implants. For both types of implants, an exact hole must be drilled into the jawbone. Cylinder-shaped implants are then pressed into position, while implants with screw threads are either self-tapping, allowing for insertion by rotating, or the osteotomy site can be threaded (Suleiman 2008).

2. TESTING DENTAL IMPLANTS

Currently, implants are tested according to DIN EN ISO 14801 to identify defects prior to implantation. Long-term reliability is analyzed by applying different loads under different conditions. In accordance with the standard, test specimens are subjected to at least four distinct loads at a frequency of ± 2 Hz up to 2×10^6 cycles and at a frequency of > 2 Hz up to 5×10^6 cycles. Once a lower limit is reached at which at least 3 test specimens survive, the measured points are plotted on a Wöhler curve, and the fatigue strength range is determined (Deutsches Institut für Normierung 2017). This standard testing method is currently employed globally. The same procedure is also described in the American NSI/ADA Standard No. 127 (American Dental Association 2018) and the Japanese standard JIS T 6005 (Japanese Standards Association 2020).

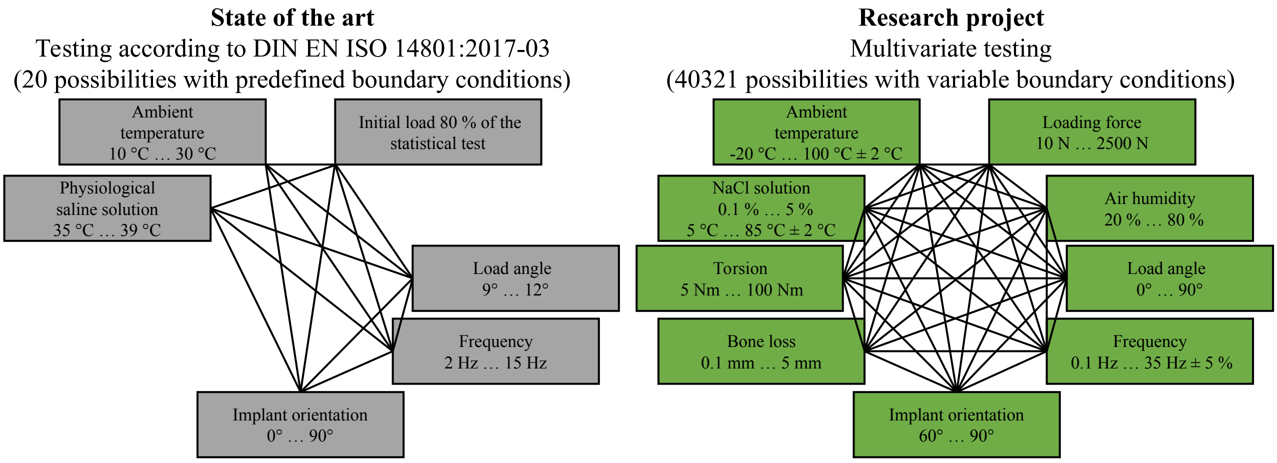

Figure 2. Testing according to DIN EN ISO 14801 (left) and multivariate testing (right) achieved by the new test rig (Heß et al. 2024)

Although this is currently sufficient for the certification of implants, it does not take into account various conditions that occur in a human dentition. The DIN EN ISO 14801 standard does not address the boundaries with regard to food-like media, torsion, bone loss, and other factors. Moreover, it does not account for more realistic differences in the load angle, ambient temperature and frequency (Figure 2). In conclusion, the test procedure in accordance with the DIN EN ISO 14801 is currently insufficient to map the long-term behavior of an implant in the human body.

Figure 3. New developed fully assembled test rigs for fatigue tests of dental implants (Heß et al. 2024)

In order to test the long-term reliability and quality of dental implants in a more realistic manner, the test rig developed as part of the research project (Figure 3) includes new functions for using additional load scenarios and combinations of loads for fatigue tests (Figure 2). Further information and details on the development process and the requirements and specifications of the newly developed test rig have already been published in Heß et al. (2024).

3. METHODS

To evaluate the reliability of dental implants and the significance of the newly developed test rig, the research will use the Weibull distribution and analysis, sample size determination, and accelerated testing. These methods are described below.

3.1. Weibull distribution and analysis

Named after Waloddi Weibull, the Weibull distribution is an extension or generalization of the exponential distribution (Birolini 1999, Marshall and Olkin 2007). The two-parameter Weibull distribution has the distribution function $F(t)$ according to Equation 1 and the density function $f(t)$ according to Equation 2 (Birolini 1999, Nelson 2004, Rinne 2009, Weibull 1951). Examples of the density function $f(t)$ and distribution function $F(t)$ for various β and λ combinations of the Weibull distribution are shown in Figure 4. The curve depends on the characteristic lifetime λ and the shape parameter β.

$$F(t) = 1 - e^{-(\frac{t}{\lambda})^{\beta}}, \quad t \geq 0, \;\; \lambda, \beta > 0 \tag{1}$$

$$f(t) = \frac{\beta}{\lambda}\left(\frac{t}{\lambda}\right)^{(\beta-1)} e^{-(\frac{t}{\lambda})^{\beta}}, \quad t \geq 0, \;\; \lambda, \beta > 0 \tag{2}$$

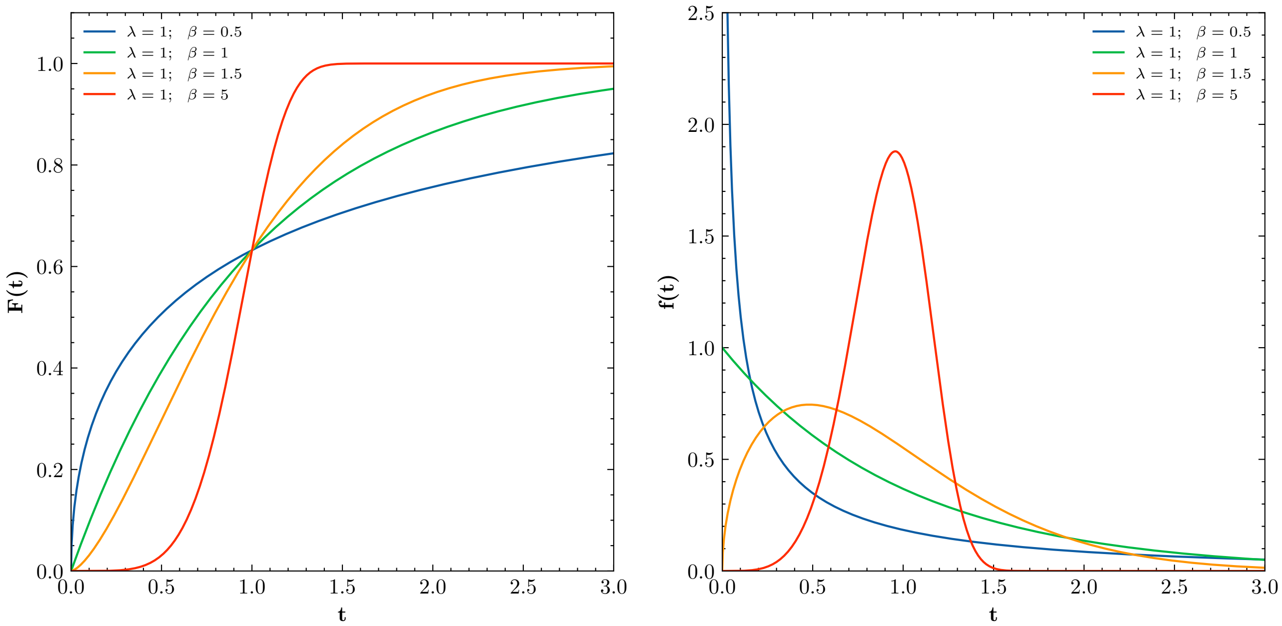

Figure 4. Distribution function $F(t)$ and density function $f(t)$ of the Weibull distribution of different λ and β combinations

In practice, the Weibull distribution is used to make statements about reliability (e.g. of field data) and failure behavior (Bracke 2024a, Pfeifer 2001) by interpreting the shape parameter β and the position parameter λ. The early failure behavior has a value $\beta < 1$, the random failure behavior $\beta \approx 1$ and the wear failure behavior $\beta > 1$. The calculated distribution is based on a sample, so a deviation from the distribution of another sample and from the population is very likely. By calculating the confidence interval for the shape parameter β (Equation 3) and the characteristic lifetime λ (Equation 4) this deviation can be calculated (Bracke 2024a).

$$\beta_{LL} \leq \beta \leq \beta_{UL} : \hat{\beta}\frac{1}{1+\sqrt{\frac{k}{n}}} \leq \beta \leq \hat{\beta}\left(1+\sqrt{\frac{k}{n}}\right) \tag{3}$$

$$\lambda_{LL} \leq \lambda \leq \lambda_{UL} : \hat{\lambda}\left(\frac{2n}{\chi^2_{2n,1-\alpha/2}}\right)^{\frac{1}{\hat{\beta}}} \leq \lambda \leq \hat{\lambda}\left(\frac{2n}{\chi^2_{2n,\alpha/2}}\right)^{\frac{1}{\hat{\beta}}} \tag{4}$$

The quantiles of the χ^2 distribution are used as a function of the sample size n and the probability of error α in order to calculate the confidence interval. The required values are available in a table in Bracke (2024b) or (Papula 2017).

3.2. Required Sample Size

Dental implants must be subjected to tests to ensure the reliability required for permanent tooth replacement in patients. Even if the industrially manufactured implants appear equal, the fatigue behaviour and the time of failure vary. Therefore, the significance increases with the sample size n. In order to determine the required number of samples, the failure probability of the sample collective $F_A(t)$ respectively the failure of at least one sample and the survival probability of a sample $R_i(t)$ must be estimated on the basis of empirical values. It is required that all test specimens are of the same design, have the same status and are tested within the same test program. Therefore, the survival probability of the individual samples is the same (Equation 5). The failure probability is defined as the complement to the survival probability, resulting in Equation 6. By rearranging Equation 6 to n, Equation 7 is formed and provides the required sample size n as a function of the estimated $F_A(t)$ and $R_i(t)$ (Bracke 2024a). The exact relationship between failure probability $F_A(t)$, survival probability $R_i(t)$ and sample size n can be seen in Figure 5 (left).

$$R_1(t) = R_2(t) = ... = R_n(t) \tag{5}$$

$$F_A(t) = 1 - R_i^n(t) \tag{6}$$

$$n = \frac{ln(1 - F_A(t))}{ln(R_i(t))} \tag{7}$$

Example: According to DIN EN ISO 14801, dental implants under dry conditions are tested to a maximum of 5×10^6 cycles. It is assumed that 3 out of 10 specimen survive the cycling process, resulting in $R_i(t = 5 \times 10^6) = 0.3$. To achieve a high level of significance, the failure probability is set to $F_A(t = 5 \times 10^6) = 0.99$. Using Equation 7 the required sample size is calculated as $n = 3.82$, thus at least 4 specimen should be tested. Now 5×10^6 cycles might be too many, so the decision is made to test only 5×10^4 cycles estimating each implant surviving at a higher rate of $R_i(t = 5 \times 10^4) = 0.9$. With the failure probability remaining the same, the required sample size now results in $n = 43.71$.

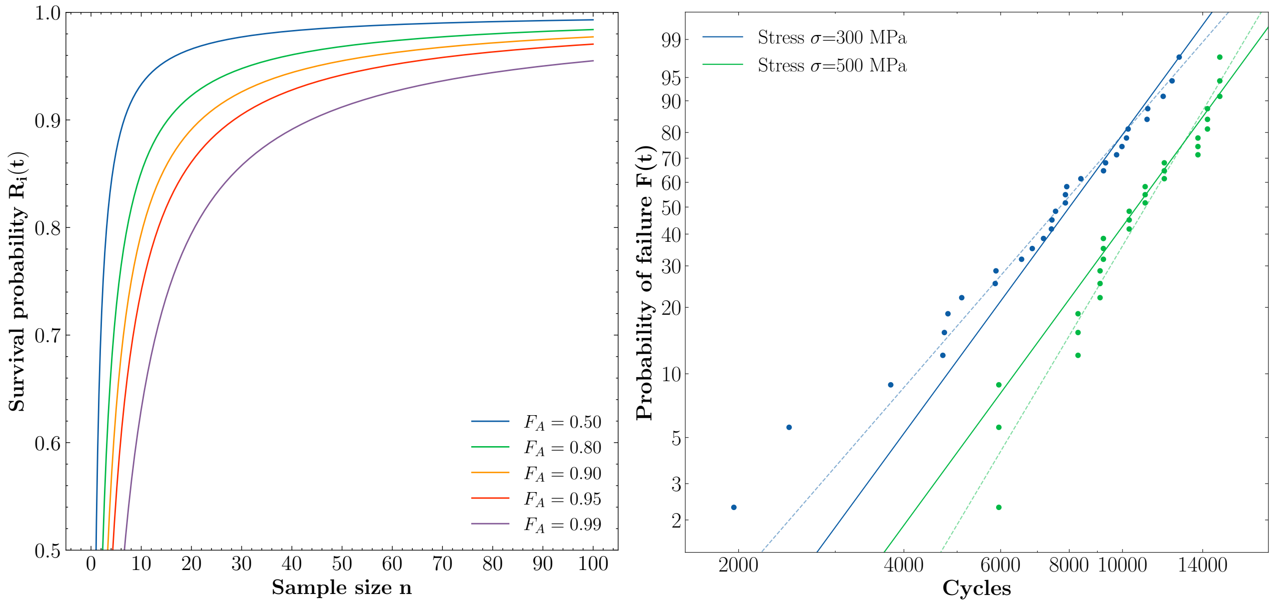

Figure 5. Left: Functional relationship between sample size n, failure probability $F_A(t)$ and survival probability $R_i(t)$ (cf. Bracke 2024a), Right: Example of a probability diagram of ALT showing probability of failure $F(t)$ [%] over test cycles for two different load levels σ [Mpa] (cf. Heß 2024)

3.3. Accelerated Testing

Accelerated testing describes the method of testing a sample collective under increased load in order to determine the fatigue behavior or the expected lifetime in a fraction of the time. This can be achieved by increasing the usage rate or the stress, whereby a fatigue behavior similar to use should be aimed for in order to map the actual failure behavior (Collins et al. 2013, Härtler 2016, Meeker et al. 2009, Nelson 2004). Once the samples have been successfully tested, numerous models and methods for analyzing performance are provided. By fitting degradation models to the collected data, the relationship between performance, age and stress can be determined (Nelson 2004, Escobar and Meeker 1995).

The influence of acceleration on the test result is shown as an example in Figure 5 (right). When fitting an acceleration model to the test data, the Weibull distribution is used in the example and it is also assumed that the damage pattern or failurre characteristics does not change. The original shape parameter β (dashed lines) is adjusted accordingly for both test series so that β is identical, so that the two straight lines run parallel to each other (solid line). The characteristic lifetime λ (position parameter) shifts as the load increases. Provided that the confidence intervals of the characteristic lifetimes λ of the two test series do not overlap, it is ensured that failures do not occur randomly at the respective other load level. Accordingly, an acceleration factor AF can be calculated for the load level.

4. DATA ANALYSIS

To derive or develop acceleration models that can be used to reduce the test time required for fatigue tests, tests are carried out on the basis of a test plan and then evaluated using various statistical methods. Two different stress factors are considered, different load angles and different load frequencies. The analysis aims to determine the functional relationship and the interactions between different parameters. Indicators are also determined as to whether the increase in stress factors causes the same damage pattern that occurs under regular operating conditions.

4.1. Different Load Angles

One method for accelerating the fatigue testing of dental implants is to apply force at varying load angles. In accordance with the DIN standard, fatigue tests are conducted at a load angle of $W = 30°$ (Deutsches Institut für Normierung 2017). An increase in this load angle results in a notable increase in the force applied to the dental implant due to the lever arm. The tests in Table 1 were conducted to evaluate the effects of varying load angles.

Table 1. Overview of all test series with varying load angle W [°]

Test	Angle W [°]	β	β_{LL}	β_{UL}	λ	λ_0	$\lambda_{0\ LL}$	$\lambda_{0\ UL}$
1	35	0.55	-0.12	1.22	338913	286946	-110733	684627
2	40	0.55	-0.12	1.22	270386	241599	-93234	576433
3	45	0.55	-0.12	1.22	103133	91030	-35129	217190
4	50	0.55	-0.12	1.22	63426	55119	-21270	131510
5	55	0.55	-0.12	1.22	64477	63979	-24690	152649
6	60	0.55	-0.12	1.22	37577	34980	-13499	83460

The load angle was incrementally elevated from 35° to 60° (in 5° increments). Within each test, two dental implants were subjected to the same conditions until failure. The only variable that was varied was the load angle. All other variables, including the load, load frequency, and so forth, were maintained and thus identical for all tests. The corresponding results and cycles to failure are presented in Figure 6.

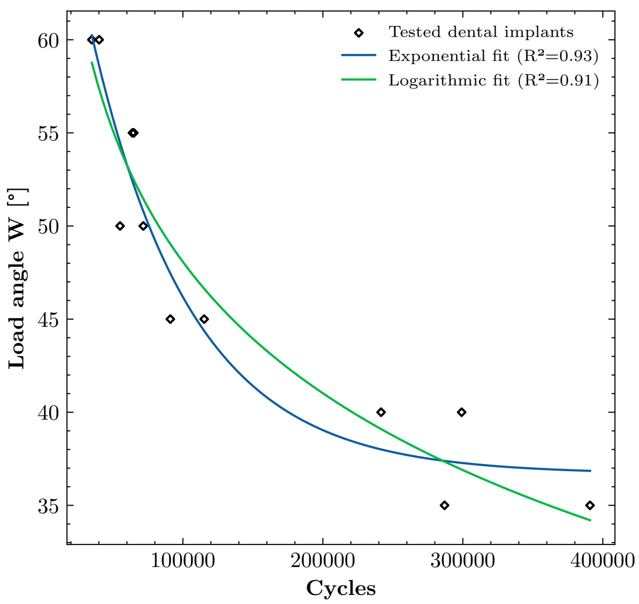

Figure 6. Dental implants tested with various load angles W. Exponential and logarithmic fit of the measurement data

In order to ascertain the relationship between load angle and failure behaviour or cycles to failure, various distribution models were applied to the failure data. The exponential function (coefficient of determination $R^2 = 0.93$) and the logarithmic function (coefficient of determination $R^2 = 0.91$)

exhibited the highest coefficient of determination R^2. The high coefficients of determination permit the demonstration of a clear exponential or logarithmic trend. If it can be demonstrated that increasing the load angle leads to identical damage characteristics, then the two distribution models can be used to significantly reduce the required test time and determine the acceleration factor AF. The approximate points for the same damage characteristic result from the parameters of the three-parameter Weibull distribution. Assuming the same failure behaviour (β is identical for all tests), the characteristic lifetime λ, the location parameter λ_0 and the associated confidence intervals can be considered. If two load levels are definitely two significantly distinguishable load levels, the confidence intervals do not overlap so that both load levels can be clearly distinguished.

The calculated shape parameter β and the corresponding limits β_{LL} and β_{UL} of the confidence band have the same values for all load levels based on the angle W (Table 1). However, the limits $\lambda_{0\ LL}$ and $\lambda_{0\ UL}$ of the confidence bands of the calculated position parameters λ_0 of the individual load levels overlap to such an extent that a clear distinction cannot be made at this point. As a result, it cannot be ruled out that the damage symptoms of one load level may also be caused by another load level. This indicates that the variation of the load angle W is not a reliable indicator of the suitability of accelerating the tests. However, it should be noted that only two dental implants were tested per load level. Consequently, the test result may differ when a larger sample size is used.

4.2. Different Load Frequencies

An alternative method for accelerating fatigue tests is to increase the load frequency F, which is 15 Hz as standard according to DIN EN ISO 14801 (Deutsches Institut für Normierung 2017). The newly developed test rig was initially employed to assess the standard load case of the standard. Subsequently, two additional load levels (30 Hz and 35 Hz) were subjected to testing. The results are presented in Table 2. Assuming that the standard load level defines the acceleration factor $AF = 1$, an increase in the load frequency F results in the acceleration factors AF for 30 Hz and 35 Hz. Each load level was tested on ten dental implants in this series of tests.

Table 2. Overview of all test series with varying test frequency F [Hz]

Test	**Frequency F [Hz]**	**AF**	β	β_{LL}	β_{UL}	λ	λ_0	$\lambda_{0\ LL}$	$\lambda_{0\ UL}$
1	15	1	0.45	0.20	0.71	142913	86986	33073	140899
2	30	2	0.44	0.21	0.69	138619	87041	35604	138478
3	35	2.33	0.55	0.17	0.94	75223	4632	926	8337

In order to analyze a possible acceleration of the tests by increasing the load frequency F, shape parameter β, characteristic lifetime λ, the location parameter λ_0 and the corresponding confidence intervals of the three-parameter Weibull model are considered. In contrast to the previous case (load angle W), there is a potential for acceleration if the shape parameters β, the location parameters λ_0 and their confidence bands β_{UL}, β_{LL}, $\lambda_{0\ UL}$ and $\lambda_{0\ LL}$ overlap. This results in the same failure times (cycles) being achieved in a shorter time period t, due to the higher load frequencies F.

The three-parameter Weibull distribution is visually observed for all three load levels 15 Hz, 30 Hz and 35 Hz (Figure 7). The distribution function F(t) and the density function $f(t)$ of the Weibull distribution show no deviations between the load frequencies 15 Hz and 30 Hz. Both curves of the load frequency 35 Hz deviate significantly from the curves of the load frequencies 15 Hz and 30 Hz. The two load levels 15 Hz and 30 Hz exhibit minimal differences in the shape parameter β in the characteristic lifetime λ and in the location parameter λ_0 (Table 2). The confidence bands exhibit only minor differences as well. At the load level of 35 Hz, however, the shape parameter β deviates slightly from the other two load frequencies while the characteristic lifetime λ and the location parameter λ_0 deviate significantly from the other two load levels as well as the corresponding confidence bands.

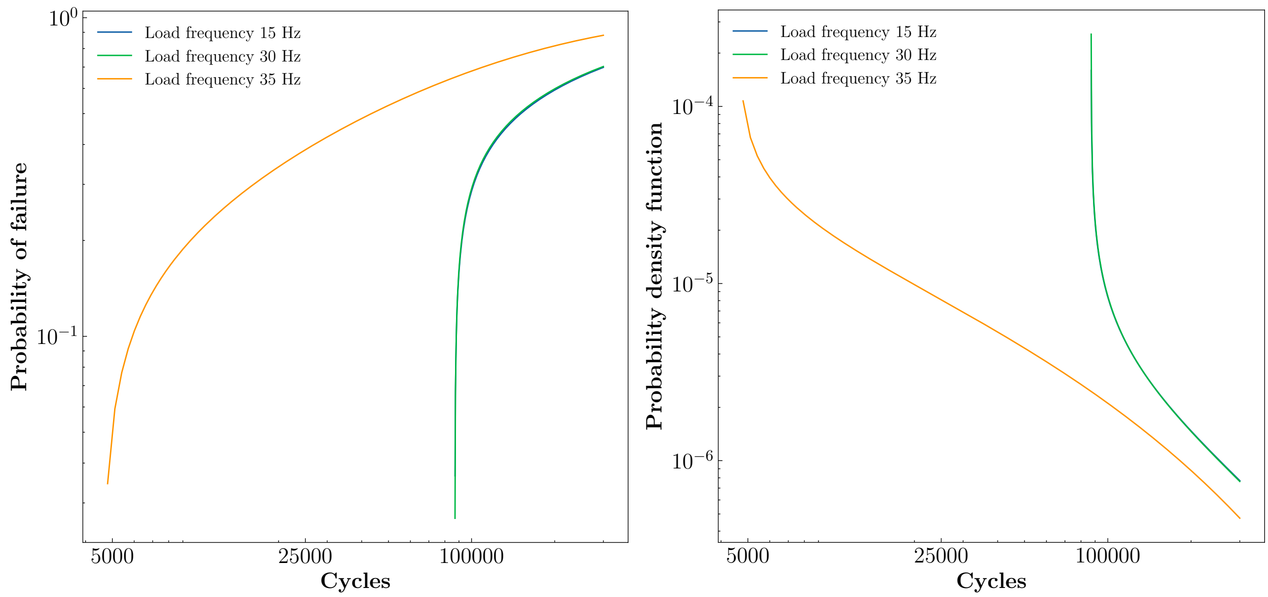

Figure 7. Distribution function $F(t)$ and density function $f(t)$ of the three-parameter Weibull distribution of load frequencies 15 Hz, 30 Hz and 35 Hz

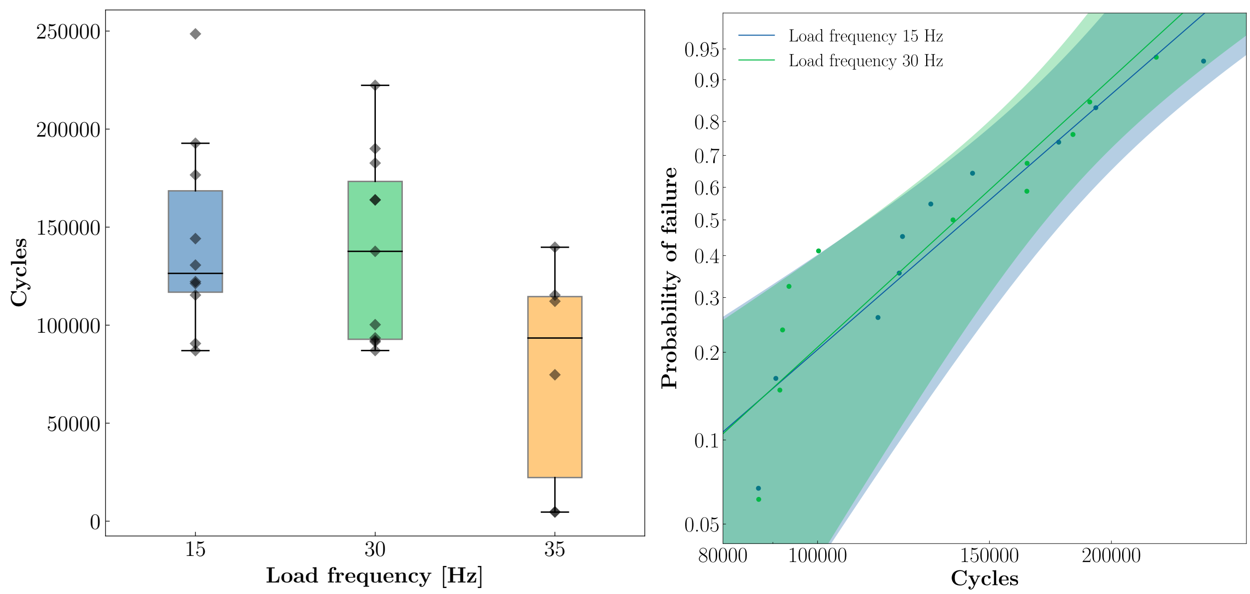

Figure 8. Left: Boxplots of all three load frequencies, Right: Acceleration model based on the three-parameter Weibull distribution of load frequencies 15 Hz and 30 Hz including confidence bands

At 35 Hz, there is a greater prevalence of random or early failure behavior, because the confidence band has the limits $\beta_{LL} = 0.17$ and $\beta_{UL} = 0.94$. At 30 Hz and 15 Hz, however there is only a tendency towards early failure behavior ($\beta_{LL} \approx 0.2$ and $\beta_{UL} \approx 0.7$). The boxplot in Figure 8 (left) illustrates this. There is no significant difference between the load levels 15 Hz and 30 Hz (p-value of t-test $p = 0.8436$), while the load level of 35 Hz differs significantly from the other two load levels (p-value of t-test $p = 0.0272$ and $p = 0.0296$). As the load level $F = 35$ Hz does not permit a suitable acceleration of the fatigue tests due to the deviation in the shape parameter β and the characteristic lifetime λ and the location parameter λ_0, this load level is not considered further in the following.

In Figure 8 (right), the probability of failure is plotted logarithmically over the cycles until failure for the load levels 15 Hz and 30 Hz. Both lines are almost congruent, as are the confidence bands (see also Table 2). This is a strong indicator that the damage characteristics are the same, which provides a suitable opportunity to accelerate the fatigue tests. The fatigue tests can thus be realized in half the test time (acceleration factor $AF = 2$).

5. CONCLUSION

It is essential to test dental implants extensively before they can be released for use in the human body. There are several norms and standards for this worldwide, all of which are based on the german standard DIN EN ISO 14801. However, the load scenarios defined by these standard(s) do not reflect the real conditions and load collectives in later use. As part of a research project, a test rig was developed that enables dental implants to be tested under realistic operating conditions. This article presents this test rig. Subsequently, two possibilities for accelerated tests are presented and the test data generated are analyzed in order to investigate the suitability of these accelerations. The first option involves increasing the load angle compared to the standard DIN EN ISO 14801 load angle of 30°. The load angle was gradually increased in 5° steps up to 60°. As this results in a deviating characteristic lifetime and location parameter of the three-parameter Weibull distribution, it can be stated that increasing the load angle is not suitable for accelerating the fatigue tests. The second possibility is to increase the load frequency, which is 15 Hz as standard according to DIN EN ISO 14801. Fatigue tests were carried out at 15 Hz, 30 Hz and 35 Hz. At 35 Hz, there is a significant deviation in the characteristic lifetime and the location parameter of the three-parametric Weibull distribution, which makes this load level unsuitable. In contrast, there is no significant difference between 15 Hz and 30 Hz, which is a strong indicator of the same damage characteristic. The required test time for fatigue tests can therefore be halved by increasing the frequency from 15 Hz to 30 Hz.

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