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Dentistry — Implants — Dynamic loading test for endosseous dental implants

Médecine bucco-dentaire — Implants — Essai de charge dynamique pour implants dentaires endo-osseux

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Foreword

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106 *Dentistry*, Subcommittee SC 8 *Dental implants*.

This third edition cancels and replaces the second edition (ISO 14801:2007), which has been technically revised.

Dentistry — Implants — Dynamic loading test for endosseous dental implants

1 Scope

This International Standard specifies a method of dynamic testing of single post endosseous dental implants of the transmucosal type in combination with their premanufactured prosthetic components. It is most useful for comparing endosseous dental implants of different designs or sizes. This International Standard is not a test of the fundamental fatigue properties of the materials from which the endosseous implants and prosthetic components are made.

This International Standard is not applicable to dental implants with endosseous lengths shorter than 8 mm nor to magnetic attachments.

While this International Standard simulates the functional loading of an endosseous dental implant under "worst case" conditions, it is not applicable for predicting the *in vivo* performance of an endosseous dental implant or dental prosthesis, particularly if multiple endosseous dental implants are used for a dental prosthesis.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Terminology*

ISO 16443, *Dentistry — Vocabulary for dental implants systems and related procedure*

ISO 1099, *Metallic materials — Fatigue testing — Axial force-controlled method*

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 16443, and the following apply.

3.1
endosseous dental implant system
device that consists of integrated components including the ancillary instruments and specific equipment necessary for the clinical and laboratory preparation and placement of the implant, and for the construction and insertion of the dependent dental prosthesis

Note 1 to entry: In addition to providing resistance to displacement of an implant superstructure, an endosseous dental implant may be used as an anchorage for orthodontic appliances.

Note 2 to entry: An endosseous dental implant may consist of one or more parts.

Note 3 to entry: The term implant superstructure includes crowns and fixed and removable prostheses, but excludes implant abutments.

3.2
prosthetic components
implant components to be used for two part implant or multi-part implant

Note 1 to entry: Implant abutments, dental implant connecting parts, abutment screws, and implant connecting part screws are used as prosthetic components in this International Standard.

3.3
endosseous dental implant assembly
dental implant assembly for endosseous dental implant

3.4
load-cycle diagram
diagram summarizing the dynamic loading properties of an endosseous dental implant by showing for each value of the applied peak load the number of cycles endured by each specimen at the time of failure

Note 1 to entry: See Annex A.

3.5
endosseous dental implant body
implant body of endosseous dental implant

4 General principles

4.1 Finished device testing

Testing shall be performed on specimens that are representative of the finished device (i.e. implant components that have undergone the same manufacturing process and sterilization as the device that is to be marketed). If the manufacturer intends the endosseous dental implant to be sterilized by the clinician prior to surgery, sterilization shall be carried out as specified in the manufacturer's instructions for use before testing. However, if there is evidence that the specified sterilization method has no significant effect on the properties of all the materials of the specimens being tested, then sterilization is not necessary prior to testing.

4.2 Multi-part endosseous dental implants

A multi-part endosseous dental implant shall be tested as assembled according to its intended use. An endosseous dental implant component recommended by its manufacturer to be used in conjunction with components of another manufacturer shall be tested as assembled according to the recommending manufacturer's statement. Where a multi-part device is assembled by means of screw joints, then these shall be used according to the manufacturer's recommendations and shall be tightened to the manufacturer's recommended torque using the equipment (implant screwdriver, torque wrench) which is provided together with the implant system or using a device that provides torque within ±5 % of the recommended value if no original instruments are available. The tightening sequence shall be as recommended by the manufacturer.

4.3 Worst-case testing

If a part of the endosseous dental implant system is available in various dimensions and/or configurations, testing shall be carried out for the worst-case conditions within the recommended use. The choice of worst case shall be justified and documented. Guidance on how to choose the worst case is given in Annex B.

5 Test methods

5.1 Testing machine

The testing machine shall

— be capable of applying the prescribed load with an error not exceeding ±5 % at maximum load (in accordance with ISO 7500-1),

— be capable of applying the load at the prescribed frequency,

— include instrumentation to monitor the values of maximum and minimum loads and loading frequency and to detect failure of the specimen, and

— be capable of recording the number of loading cycles during the test.

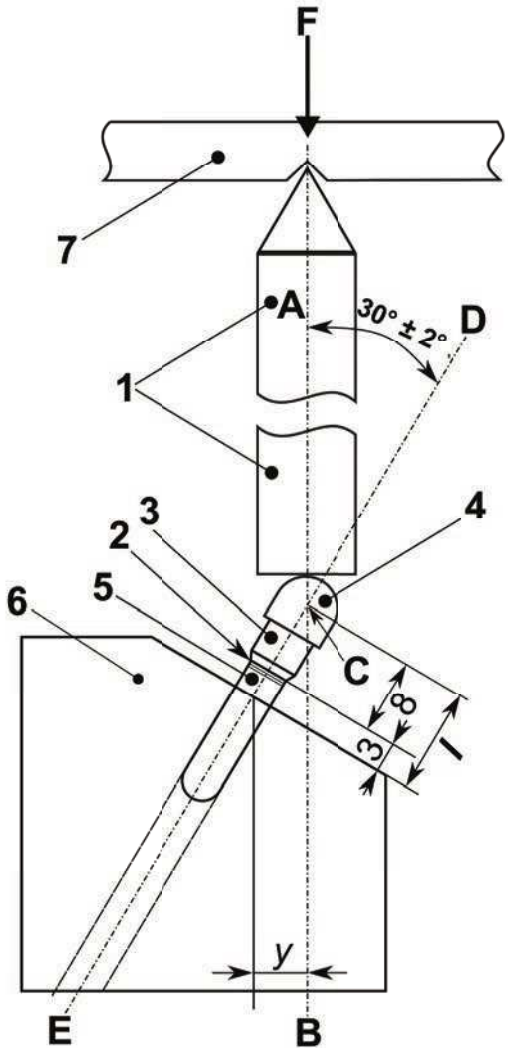
5.2 Loading geometry

5.2.1 The loading force (see Figure 1 and Figure 2, arrow F) of the testing machine shall be applied in such a way that

— no lateral constraint occurs,

— the position of the intersection of the loading axis (Line AB) with the axis of the endosseous dental implant (Line DE), is well-defined, such that the moment arm (y) can be measured or calculated (see Figure 1 and Figure 2).

5.2.2 An endosseous dental implant from a system that includes only straight implant abutments shall be clamped such that its central longitudinal axis makes a 30° ± 2° angle with the loading direction of the testing machine (see Figure 1).



Key

1 loading device[a]
2 nominal bone level[b]
3 implant abutment
4 hemispherical loading member
5 implant body
6 specimen holder
7 force application

a Shall be allowed free movement transverse to loading direction (see 5.2.5).

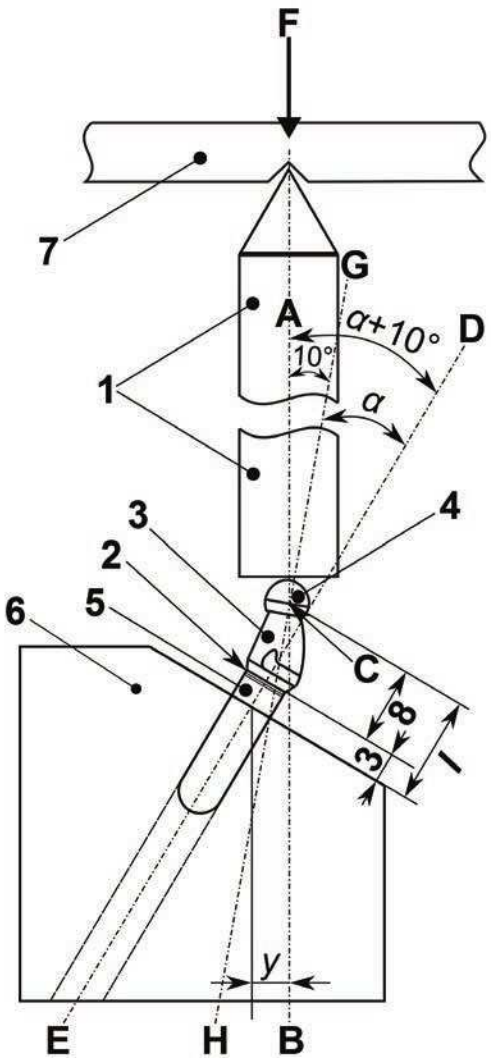
b See 5.3.2.

Figure 1 — Schematic of test set-up for systems with no angulated implant abutments

5.2.3 An endosseous dental implant body of a system that includes angulated implant abutments shall be clamped such that the angle with the loading direction of the testing machine is 10° + 2°/-1° greater

than the angle between the central longitudinal axis of the implant and the central longitudinal axis of the angled-portion of the abutment, designated as α in Figure 2.

This represents a simulated undercorrection of 10°. The loading method shall be the same as that shown in Figure 1. The loading centre shall be located at the intersection of the central longitudinal axis of the free end of the abutment and the plane normal to the longitudinal axis of the implant and located 11 mm (Figure 2, *l*) from the support level of the implant.



Key

1 loading device[a]
2 nominal bone level[b]
3 implant abutment
4 hemispherical loading member
5 implant body
6 specimen holder
7 force application

[a] Shall be allowed free movement transverse to loading direction (see 5.2.5).

[b] See 5.3.2.

Figure 2 — Schematic of test set-up for systems with angulated implant abutments

5.2.4 The loading force (F) of the testing machine shall be applied through a deformation resistant loading member with a hemispherical contact surface for load transfer, attached to or placed over the free end of the implant abutment.

The yield strength and the hardness of the loading member should be higher than that of the member that is used to apply the load. The loading centre, which is the centre of the hemisphere, shall be on the central longitudinal axis of the endosseous dental implant or, for endosseous dental implant systems which include angulated implant abutments, shall be on the central longitudinal axis of the free end of the abutment.

5.2.5 The loading force shall be applied to the hemispherical loading surface by a loading device (labelled 1 in Figure 1 and Figure 2) that contacts the hemispherical cap (labelled 4) with a plane surface normal to the loading direction of the machine.

The loading device containing the plane surface that applies the loading force to the hemispherical loading surface shall be unconstrained in the transverse direction, so as to not reduce the magnitude of the applied bending moment. This shall be accomplished by means of point contact or a universal joint at the junction of the loading device (labelled 1) and the test machine structure, or by means of a thrust plate with bearings which permits free transverse movement in the direction of abutment deflection under the applied load. If point contact or a universal joint at the junction of the loading device and the test machine structure is used, the junction shall be located at least 50 mm from the hemispherical loading surface.

5.2.6 The hemispherical loading surface and the surface of the loading device shall be examined visually after each test to ensure that permanent deformation has not occurred. If permanent deformation of either surface is observed, the deformed component shall be replaced and test shall be repeated.

5.2.7 For an endosseous dental implant body and/or implant abutment that lacks rotational symmetry around either the central longitudinal axis of the implant body or the central longitudinal axis of the implant abutment, the loading geometry shall be selected to test the worst case compatible with the intended use of the implant.

The loading geometry shall be justified and documented.

5.2.8 The surface condition of the implant and abutment shall be described.

Surface damage during mounting in the test setup shall be strictly avoided.

5.3 Specimen holder and load application

5.3.1 The bone-anchoring part of the specimen shall be fixed in a rigid clamping device. If an embedding material is used, it shall have a modulus of elasticity higher than 3 GPa.

The geometry of the clamping device shall be such that the testing geometry specified in 5.2 is achieved. The clamping device shall be designed so as not to deform the test specimen.

5.3.2 The device shall clamp the specimen at a distance 3,0 mm ± 0,5 mm apically from the nominal bone level as specified in the manufacturer's instructions for use (see Figure 1 and Figure 2).

If the nominal bone level is not specified in the manufacturer's instructions for use, the worst-case situation shall apply.

NOTE For many endosseous dental implants, it is known that the marginal bone level can move apically following implantation to a relatively steady-state level. The distance of 3,0 mm is chosen to provide a representative case with respect to bone loss.

5.3.3 For dental implant systems that do not include angulated implant abutments, the dimensions of the loading member which shape is specified in 5.2.4, shall be chosen to define a distance l = 11,0 mm ± 0,5 mm from the centre of the hemisphere to the clamping plane (see Figure 1).

The moment arm (y) is defined as $l \times \sin 30°$. For the standard configuration, the moment arm is 0,5 × l, or 5,5 mm. In the case of a long or a short implant abutment, for which l = 11 mm cannot be readily achieved, a different value for l may be chosen. The choice shall be justified and documented.

Bending moment, M, is defined by Formula (1):

$$M = y \cdot F \tag{1}$$

For the case illustrated in Figure 1, bending moment is as follows:

$$M = 0{,}5 \cdot l \cdot F \tag{2}$$

or, when l = 11 mm and F is expressed in newtons,

$$M = 5{,}5 \cdot F \text{ (Nmm)} \tag{3}$$

5.3.4 For endosseous dental implant systems which include angulated implant abutments, the free end of the abutment shall be provided with a hemispherical loading member, the centre of which lies on the central longitudinal axis of the free end of the abutment and is l = 11,0 mm ± 0,5 mm from the support level of the implant, measured on a line parallel to the central longitudinal axis of the implant body, as shown in Figure 2.

The moment arm y (see Figure 2) may be measured directly from the test specimens and fixtures or may be calculated. Because of the allowable tolerances on angulation of the test specimen, calculated values of the moment arm y may be less reliable than measured values. In the case of an implant body and an implant abutment for which l = 11 mm cannot be readily achieved, a value for l different from 11 mm may be chosen. The choice shall be justified and documented. Bending moment, M, may be calculated from the measured or calculated value of y, as Formula (4):

$$M = y \cdot F \tag{4}$$

and should be reported in Nmm.

5.4 Testing environment

For endosseous dental implant systems that include materials in which corrosion fatigue has been reported or is expected to occur, or for systems that include polymeric components, testing shall be carried out in normal saline or in an alternative physiologic medium. The fluid and the test specimen shall be kept at 37 °C ± 2 °C during the testing. For all other systems, testing may be conducted in air at 20 °C ± 10 °C . The testing environment shall be justified and reported.

5.5 Loading frequency and wave form

Testing shall be carried out with a uniaxial load along axis A-B (see Figure 1 and Figure 2). The load shall vary sinusoidally between a nominal peak value and 10 % of this value.

The loading frequency shall be no more than 15 Hz. Testing in liquid media shall be conducted at frequencies ≤2 Hz.

5.6 Procedure

5.6.1 The general principles for fatigue testing as described in ISO 1099 shall apply.

5.6.2 Generate the data for a load-cycle diagram by testing specimens at a series of loads until a lower limit is reached at which at least three specimens survive and none fail in the specified number of cycles (maximum endured load).

Plot the measured points in a load-cycle diagram. If testing is conducted at frequencies ≤2 Hz, testing shall be conducted to 2×10^6 cycles. For testing conducted at frequencies >2 Hz, testing shall be conducted to 5×10^6 cycles. Tests are performed at a series of loads, resulting in a curve similar to that shown in Annex A. At least two, and preferably three, specimens shall be tested at each of at least four loads.

5.6.3 Describe the failure pattern of the affected implant components and, if possible, the failure process (e.g. screw fracture with subsequent implant abutment fracture).

Failure is defined as material yielding, permanent deformation, loosening of the implant assembly or fracture of any implant component. Draw the load-cycle curve to show the maximum magnitude of the force at which the endosseous dental implant assembly will withstand 5×10^6 cycles or, for frequencies ≤2 Hz, 2 million cycles. At least three specimens shall be tested and every specimen shall reach the specified number of cycles with no failures. Calculate the maximum bending moment (M, see 5.3.3 and 5.3.4), corresponding to this load. If additional specimens were tested and survived at loads lower than the maximum endured load, they shall be listed in the report and shall be checked for failures in the same way as the others. If they do not show any damage (failure), they shall not be considered with respect to the quantitative result.

NOTE The number of cycles for stopping the test is arbitrarily determined. It does not mean that the specimen will survive forever without fracture when testing below the load at which three specimens reach the specified number of cycles without fracture.

5.7 Alternative procedure — Stair case method

5.7.1 As an alternative to the method described in 5.6, the stair case method may be used.

NOTE Stair case method is described in detail in ISO 12107.

5.7.2 Estimate the maximum endured load to be expected, e.g. using existing data of comparable systems or, if static strength has been determined using the same test configuration, by dividing the static strength value by two.

5.7.3 Define the step width, d, as 10 % of the estimated maximum endured load.

5.7.4 Start the test with the value of the estimated maximum endured load.

Do the test according to 5.5 until the specimen fails or it survives 2×10^6 cycles at frequencies ≤2 Hz or 5×10^6 cycles at frequencies >2 Hz.

5.7.5 If the specimen fails, decrease the load by d.

If the specimen survives, increase the load by d.

5.7.6 Repeat the procedure described in 5.7.4 and 5.7.5 until at least four failures are observed and at least four specimens survive.

5.7.7 Calculate the arithmetic mean value of the maximum endured load (m) as follows.

Count the numbers of survivals and failures. Use survivals or failures whichever has the lower number of samples for calculation.

a) in case of survivals:

$$m = \frac{\sum_{i=1}^{n}(f_i + 0,5 \cdot d)}{n} \quad (5)$$

b) in case of failures:

$$m = \frac{\sum_{i=1}^{n}(f_i - 0,5 \cdot d)}{n} \quad (6)$$

where

f_i load used for testing of a specimen;

n total number of specimens used for calculation.

5.7.8 Calculate the standard deviation, σ, using Formula (7):

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(f_i - m)^2}{(n-1)}} \quad (7)$$

5.7.9 The maximum endured load can then be given as $m + \sigma$.

The 10 %, 50 %, and 90 % survival probabilities can then be calculated as follows:

$F_{10\%} = m + 1,28 \cdot \sigma$

$F_{50\%} = m$

$F_{90\%} = m - 1,28 \cdot \sigma$

6 Reporting

6.1 The test report shall include full details of all aspects of the test apparatus, the test specimens, the procedures followed, and the results obtained, with particular attention to the following.

6.1.1 Identification of the endosseous dental implant and its components, in particular,

— type of implant body (e.g. threaded, tapered, cylindrical),

— type of implant abutment (e.g. screw-retained, cemented, taper-fit, cylindrical, conical),

— manufacturer(s),

— part and lot numbers of the tested parts,

— material(s) of the tested parts, including any coating material(s) and other surface treatments,

— diameter and length of the endosseous dental implant body,

— geometric dimensions of the dental implant abutment including the angle, α, of the angulated implant abutment, and

— description and dimensions of the joints between the endosseous dental implant body and the abutment, and between the abutment and the functional loading structure.

6.1.2 Intended use of the endosseous dental implant.

6.1.3 Reference to this International Standard, i.e. ISO 14801:2016.

6.1.4 In the case of an endosseous dental implant available in various dimensions and/or configurations (see 4.3), the rationale for choice of test specimens.

6.1.5 In the case of an endosseous dental implant lacking rotational symmetry (see 5.2.7), the rationale for the selection of loading geometry.

6.1.6 The moment arm, y.

6.1.7 The values of all geometric measurements and calculations used to determine the moment arm.

6.1.8 The geometric location of the nominal bone level used to establish the clamping location. If the nominal bone level is not specified in the manufacturer's instructions for use, the justification for the choice of nominal bone level for testing purposes.

6.1.9 In the case of $l \neq 11$ mm (see 5.3.3 and 5.3.4), the rationale for choice of the value of l.

6.1.10 Description of the specimen holding geometry and material, including the modulus of elasticity of any embedding medium.

6.1.11 In the case of a multi-part endosseous dental implant, the characteristics of assemblage [including assembly torque(s) of screw(s) such as abutment screw(s) and implant connecting part screw(s)].

6.1.12 Description of the hemispherical loading surface, including its spherical radius, and the rationale for its design.

6.1.13 Loading frequency.

6.1.14 Testing environment, including medium (saline, water, or air) and temperature.

6.1.15 Results of dynamic testing:

— load-cycle diagram (see Annex A), if method according to 5.6 is used, together with maximum endured load at 5×10^6 cycles or, for tests at frequency ≤2 Hz, 2×10^6 cycles, and in either case the bending moment, M, for the maximum endured load (see 5.6.3 and 5.6.4);

— $F_{10\%}$, $F_{50\%}$, and $F_{90\%}$, if the stair case method according to 5.7 is used, together with the corresponding Moments $M_{10\%}$, $M_{50\%}$, and $M_{90\%}$ calculated according to 5.3.3 or 5.3.4.

— tabulation of testing load, number of cycles to failure or termination, and description and location of critical failure point for each test specimen.

Annex A
(informative)

Load-cycle diagram

Dynamic loading testing of materials or devices is carried out in compression-bending at predetermined loading amplitudes and the number of load cycles until failure occurs is recorded. The properties of the test object are determined by testing a number of specimens at different values of the peak load. The results are summarized by representing in a diagram the number of load cycles endured by each specimen (on a logarithmic scale) and the corresponding peak load (on a linear scale). This yields the load-cycle diagram for the test object.

From the load-cycle diagram, the maximum endured load of the object can be determined, being the maximum peak load for which failure does not occur at the number of cycles, NF, selected for termination of each test. Each cross represents a specimen of the test object that failed. Circles with an arrow represent specimens that did not fail and were removed from test upon reaching NF. NF is defined for this test as 5×10^6 cycles or, for frequency ≤2 Hz, 2×10^6 cycles. LF is the maximum endured load.

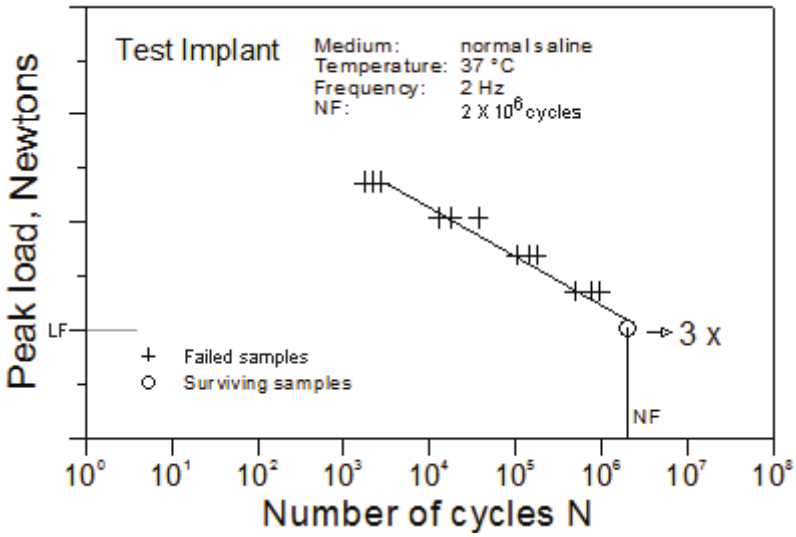


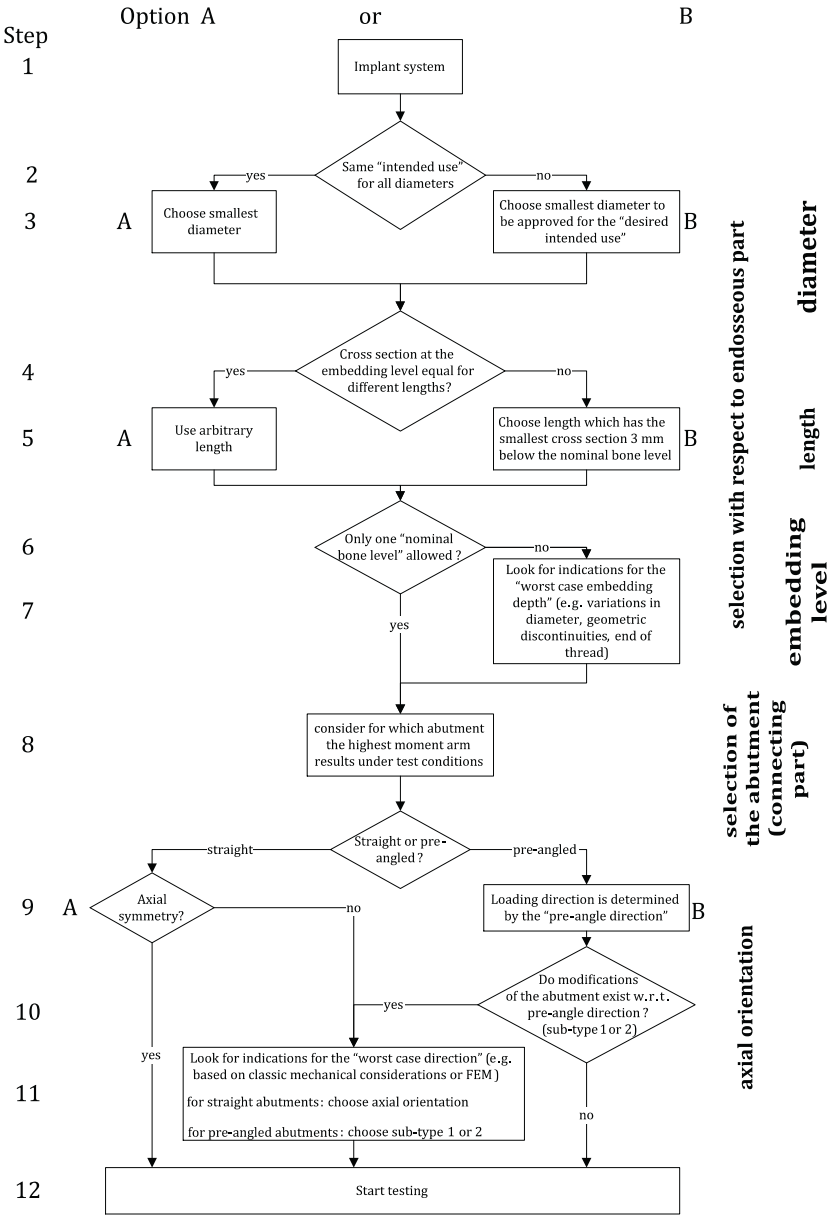
Figure A.1 — Example of a load-cycle diagram for tests run until 2×10^6 cycles

Annex B
(informative)

Guide to determination of worst-case conditions

B.1 Guide to determination of worst-case conditions

(The steps and decision criteria of the diagram B.1 are explained in B.2.)



B.2 Comments on the flow chart (numbers refer to the steps on the flow chart)

The scheme is intended to give some support in the selection of the "worst case". Not in all cases it is possible to consider the different aspects to the same extent. Furthermore, additional considerations might be necessary for the test of certain implants. For example, if it is known that the failure of an implant system is mainly an implant abutment or abutment screw failure or a failure of the connecting interface, special care has to be taken to select the weakest combination with respect to these parts [in this, case some considerations below (e.g. 4 to 7) might be of minor importance].

1. An endosseous dental implant is to be tested for approval.

The next steps describe the selection and the embedding depth of the endosseous part of the implant system, which can either be the "implant body" of a multi-part implant (which is to be completed by an implant abutment) or the endosseous part of a monopart implant.

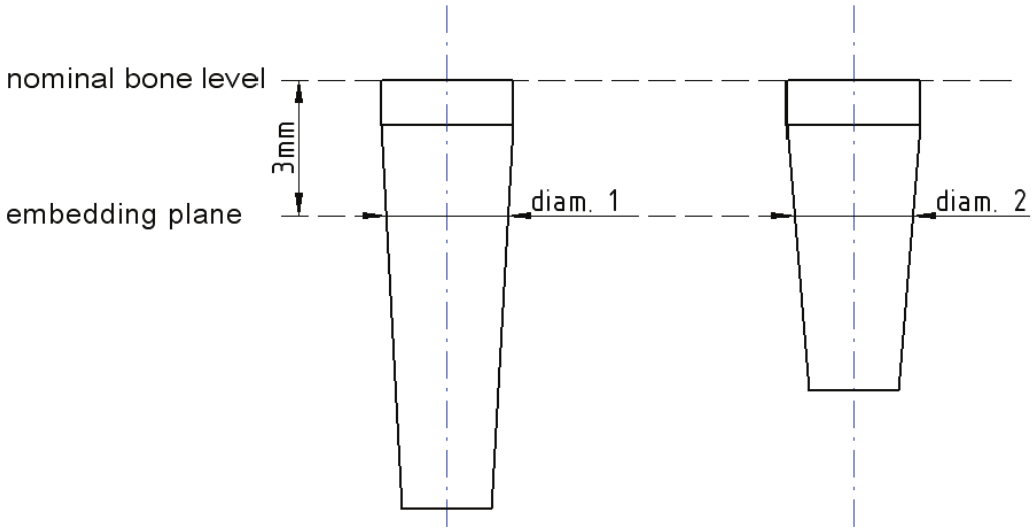
2. Is the intended use equal for all diameters or are there restrictions for special diameters (e.g. for anterior teeth only)?

3A. If no restrictions exist, choose the smaller diameter.

Remark: In special cases (e.g. if a new implant abutment is to be tested and only the abutment is to be assessed), it can happen that it sustains a higher load on a thin implant body than on a thicker one due to different stiffness conditions. If this is known, the test on the thicker implant body would be justified to represent the "worst case".

3B. If there are restrictions for a certain diameter, this type is to be treated as a "different" implant body or monopart implant and shall be tested separately.

4. Is the cross-section at the prospective embedding plane (3 mm - 5 mm below nominal bone level) equal for all lengths or are there differences (e.g. by tapered shape)?



5A. If cross-sections are equal, longer implant body or monopart implants having longer implantable part are recommended, because reliable embedding is easier.

5B. If cross-sections are not equal, choose the implant with the smallest diameter at the prospective embedding plane. Consider remark at 3A.

Limitation: Reliable embedding is difficult for very short implant body or monopart implants having very short implantable part. This International Standard is not applicable to implants with endosseous lengths shorter than 8 mm. Choose the smallest implant ≥8 mm endosseous length.

6. Is a specified embedding depth mandatory or does the manufacturer allow a variety of embedding depths?

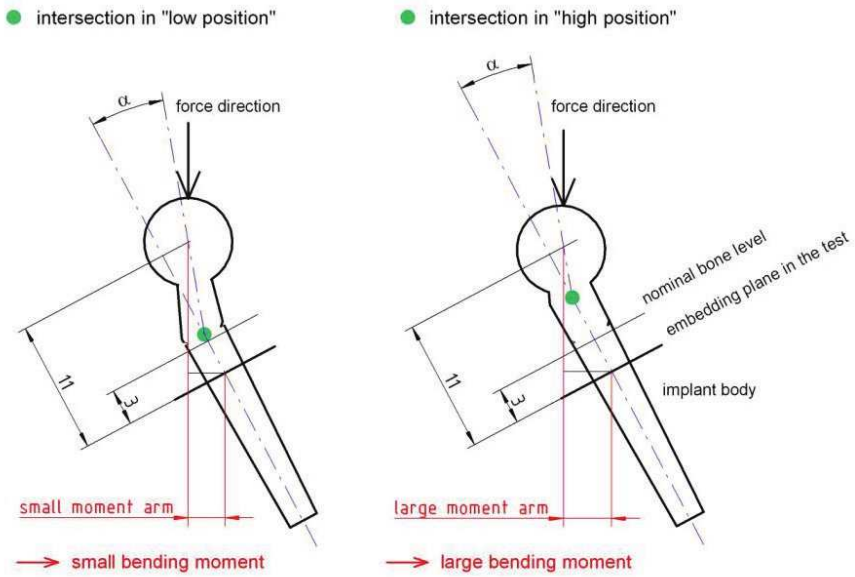
NOTE The distance between the embedding plane and the centre of the hemispherical loading member always is 11 mm. Therefore, the loading conditions do not become worse (more unfavourable) solely by a higher protrusion of the implant.

7. One of the most stressed regions is the cross-section at the level of the embedding plane.

By varying the embedding depth, a possible "weak point" of the implant can coincide with the embedding level. Examples of "weak points": smaller diameter (tapered implant), discontinuities, (changes of inner or outer diameter, end of thread, end of screw, etc.).

8. Determination of the moment arm

First, due to the specifications of ISO 14801, the loading angle and, thus, the moment arm (according to 5.3.4) is dependent on the angulation of the abutment and additionally on the position of the intersection between the central longitudinal axis of the implant body and the central longitudinal axis of the free end of the implant abutment or monopart implant. The position of this intersection differs for abutments which are used for different gingiva thicknesses, for example. The moment arm should be calculated and/or measured to determine which configuration represents the worst case.

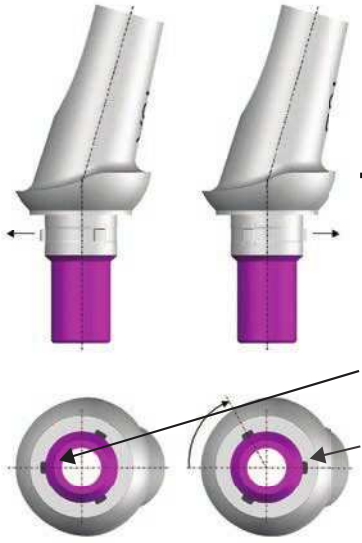


9-10. The following decisions depend on the question of whether the abutment is angulated.

9A. Straight implant abutment or monopart implant: If the connection of an abutment to the implant body is axially symmetric (no lock against rotation), the axial orientation of the implant body with respect to the loading direction in the test is arbitrary, otherwise, see 11.

9B. Angulated implant abutment: The axial orientation of the implant with respect to the loading direction is determined by Figure 2 and there is no choice, but:

10. There are angulated implant abutments that consider different situations of the *in situ* situation of the implant body, i.e. this abutment is available in two "sub-types", 1 or 2. An example is shown in the following figure:



Two sub-types (1 and 2) with respect to the implant body

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11. If a lock against rotation is present in case 9A (straight implant abutment or monopart implant) or 10 applies (angulated implant abutment with different sub-types), the loading direction is not arbitrary.

For a straight abutment, *choose the loading direction* which seems most sensitive to the connecting interface.

For the angulated implant abutment with two sub-types, choose the *sub-type* which loads the connection to the highest extent.

For both cases, the assessment can be based on general mechanical considerations or FEM analyses, for example. Static tests have only minor significance, because they often lead to a failure behaviour that is different from fatigue failure.

12. Start the test.

Bibliography

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[3] ISO 10451, *Dental implant systems — Contents of technical file*

[4] ISO 12107, *Metallic materials — Fatigue testing — Statistical planning and analysis of data*

[5] ASTM E466, *Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials*

[6] ASTM E468, *Standard Practice for Presentation of Constant Amplitude Fatigue Test Results for Metallic Materials*

[7] United States of America, Food and Drug Administration, Center for Devices and Radiological Health, *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments — Guidance for Industry and FDA Staff,* 2004-05-12.

1) Withdrawn. Replaced by ISO 6892-1.

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