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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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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

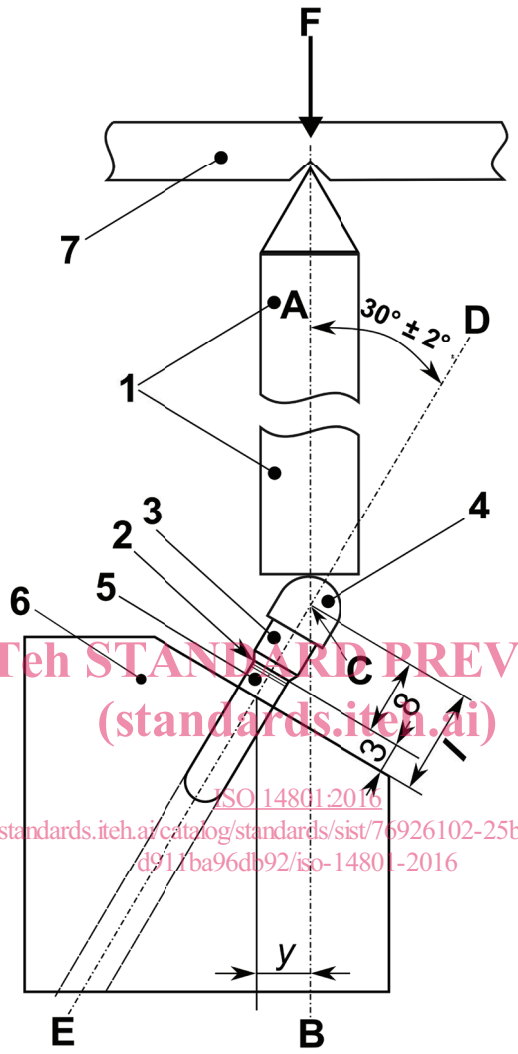
5.2 Loading geometry

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).

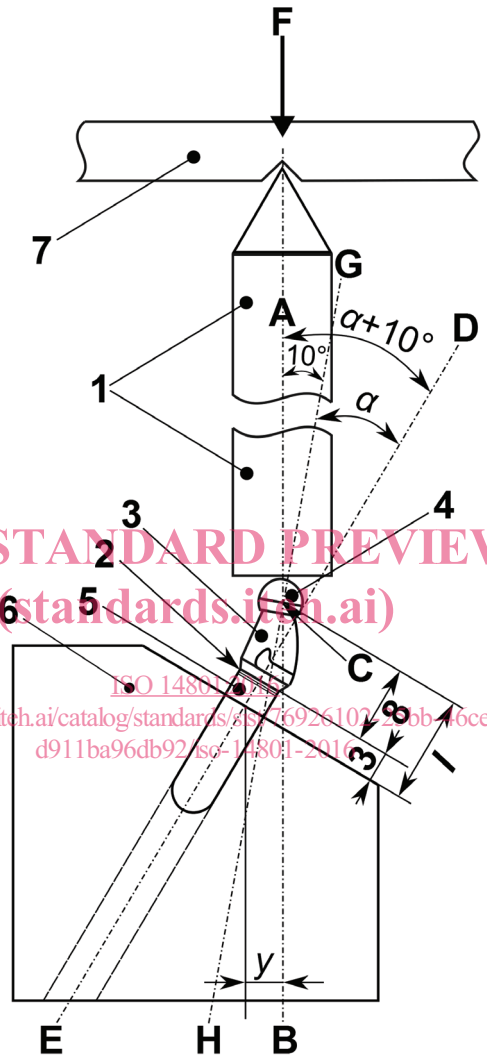
b See 5.3.2.

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.



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1 loading device[a]
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[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.