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Dentistry — Fatigue test for endosseous dental implants

Art dentaire — Essai de fatigue pour implants dentaires endosseux

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14801 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

This corrected version of ISO 14801:2003 incorporates a change in 5.2.4 of the incorrect dimension 5 mm to the correct dimension 50 mm.

Dentistry — Fatigue test for endosseous dental implants

1 Scope

This International Standard specifies a method of fatigue testing of single-post endosseous dental implants of the transmucosal type. It is most useful for comparing endosseous dental implants of different designs or sizes.

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

2 Normative references

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

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

ISO 1942-1, *Dental vocabulary — Part 1: General and clinical terms*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 4965, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*

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

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942-1 and the following apply.

3.1
endosseous dental implant
device specially designed to be placed surgically within the bones surrounding the oral cavity, the primary purposes of which are to support and to resist displacement of a dental prosthesis

NOTE 1 In addition to providing resistance to displacement of a dental prosthesis, an endosseous dental implant may be used as an anchorage for orthodontic appliances.

NOTE 2 An endosseous dental implant may consist of one or more parts.

NOTE 3 The term dental prosthesis includes crowns and fixed and removable prostheses.

3.2
endosseous dental implant body
primary single component or portion of an endosseous dental implant that is intended to remain within tissue

3.3
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 prosthesis

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

See Annex A.

4 General principles

4.1 Finished-device testing

Testing shall be performed on specimens that are representative of the finished device (i.e. components that have undergone the same manufacturing process as the device that is to be marketed). If the manufacturer intends for 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. If there is evidence that the specified sterilization method has no significant effect on the properties 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. If a multi-part device is assembled by means of screw joints, then these shall be tightened to the manufacturer's recommended torque using a device that provides torque within ± 5 % of the recommended value. The tightening sequence shall be as recommended by the manufacturer.

4.3 Worst-case testing

If a part of the endosseous dental implant is available in various dimensions and/or configurations, the manufacturer shall carry out the testing for the worst-case situation within the recommended use. The choice of worst case shall be justified and documented.

5 Test method

5.1 Testing machine

The testing machine shall have the following characteristics:

— be capable of applying the specified load with an error not exceeding ± 5 % at maximum load (in accordance with ISO 7500-1 and ISO 4965);

— be capable of applying the load at the specified frequency;

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

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

5.2 Loading geometry

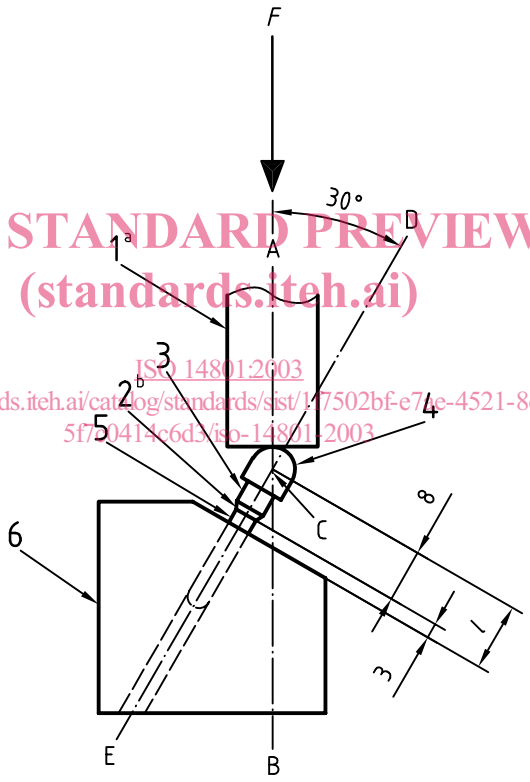
5.2.1 The loading force (F, see Figure 1) of the testing machine shall be applied in such a way that

— no lateral constraint occurs,

— the loading centre (Point C, Figure 1), being the intersection of the loading axis (Line AB) with the axis of the endosseous dental implant (Line DE), is well defined.

NOTE These requirements are met by the test set-up shown schematically in Figure 1.

Dimensions in millimetres



Key

1 loading device
2 nominal bone level
3 abutment
4 hemispherical loading member
5 dental implant body
6 specimen holder

a Shall be allowed free movement transverse to loading direction.
b See 5.2.6.

Figure 1 — Schematic of test set-up

5.2.2 The endosseous dental implant shall be clamped such that its axis makes a 30° ± 1° angle with the loading direction of the testing machine (see Figure 1). The maximum bending moment in the implant can be calculated as

$$M = 0{,}5 \times F \times l$$

where

M is the bending moment;

F is the applied loading force;

l is the distance from clamping plane to loading centre, C.

5.2.3 The loading force of the testing machine shall be applied through a hemispherical loading member attached to or placed over the free end of the endosseous dental implant. The loading centre, which is the centre of the hemisphere, shall be on the axis of the endosseous dental implant.

5.2.4 The loading force shall be applied to the hemispherical loading member by a plane surface normal to the loading direction of the machine. The member containing the plane surface that applies the loading force to the hemispherical loading member shall be unconstrained in the transverse direction, so as to not reduce the magnitude of the applied load. This shall be accomplished by means of a universal joint or a pin at the junction of the loading member and the test machine structure. The junction shall be located at least 50 mm from the hemispherical loading member.

5.2.5 For an endosseous dental implant that lacks rotational symmetry around the axis of nominal prosthetic loading, the loading geometry shall be selected to test the worst case compatible with the intended use of the implant. The choice of worst case shall be justified and documented.

5.2.6 If the nominal bone level is not specified in the manufacturers' instruction for use, the worst-case situation shall apply.

5.3 Specimen holder

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 ± 0,1 mm apically from the nominal bone level as specified in the manufacturer's instructions for use (see Figure 1).

NOTE For many endosseous dental implants, it is known that the marginal bone will retract following implantation to a steady-state level. The distance 3,0 mm is chosen to provide a worst case with respect to bone retraction.

5.3.3 The free end of the endosseous dental implant shall be provided with a hemispherical loading member to achieve load application as specified in 5.2. The surface of this member interfacing with the endosseous dental implant shall be designed such that the load is applied to the implant in the same way as the prosthetic load would be applied. The dimensions of the loading member shall be chosen to define a distance l = 11,0 mm ± 0,1 mm from the centre of the hemisphere to the clamping plane (see Figure 1). In the case of a long endosseous dental implant, for which l = 11,0 mm cannot be readily achieved, a larger value for l may be chosen. The choice shall be justified and documented.

5.4 Testing environment

For endosseous dental implants 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 water of Grade 2 according to ISO 3696, in normal saline or in 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 ± 5 °C. The testing environment shall be reported.

5.5 Loading frequency and wave form

Fatigue testing shall be carried out with a unidirectional load. 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 $\leqslant$ 2 Hz.

5.6 Procedure

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

5.6.2 Generate 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 (2×10^6 cycles for tests conducted at frequencies $\leqslant$ 2 Hz, or 5×10^6 cycles for tests conducted at frequencies $>$ 2 Hz and $<$ 15 Hz, see 5.5). An appropriate starting load is 80 % of the load to failure in a static test performed using the same test geometry. At least two, and preferably three, specimens shall be tested to failure at each of at least four loads. Measure the distance from the loading centre (Figure 1) to the section of critical failure.

5.6.3 Identify the critical failure point and the location of failure initiation. Failure is defined as material yielding, permanent deformation or fracture of any component. Draw the load-cycle curve to show the maximum load at which the endosseous dental implant system will withstand 5×10^6 cycles or, for frequencies $\leqslant$ 2 Hz, 2×10^6 cycles. At least three specimens shall reach the specified number of cycles with no failures. Calculate the nominal static bending moment, M, as defined in 5.2.2, corresponding to this load,.

6 Test report

In the test report, the following shall be addressed:

a) identification of the endosseous dental implant and its components, in particular:

- type of endosseous dental implant body (e.g. threaded, tapered, cylindrical);
- type of connecting part(s) (e.g. screw-retained, cemented, taper-fit, cylindrical, conical);
- manufacturer(s);
- 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 connecting part(s);
- description and dimensions of the joints between the endosseous dental implant body and the connecting part(s), and between the connecting part(s) and the functional loading structure.

b) intended use of the endosseous dental implant;

c) reference to this International Standard;

d) 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;