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Dentistry — Implants — Dynamic fatigue test for endosseous dental implants

Art dentaire — Implants — Essai de fatigue dynamique 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 second edition cancels and replaces the first edition (ISO 14801:2003) which has been technically revised to include manufactured pre-angled connecting parts.

Dentistry — Implants — Dynamic 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 and their premanufactured prosthetic components. It is most useful for comparing endosseous dental implants of different designs or sizes.

While this International Standard simulates the functional loading of an endosseous dental implant body and its premanufactured prosthetic components under "worst case" conditions, it is not applicable for predicting the *in vivo* performance of an endosseous dental implant or prosthesis, particularly if more than one implant is 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 (all parts), *Dental vocabulary*

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 document, the terms and definitions given in ISO 1942 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 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
load-cycle diagram
diagram summarising the fatigue 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

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 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 (screw driver, 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.

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 and ISO 4965);

— 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;

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

5.2 Loading geometry

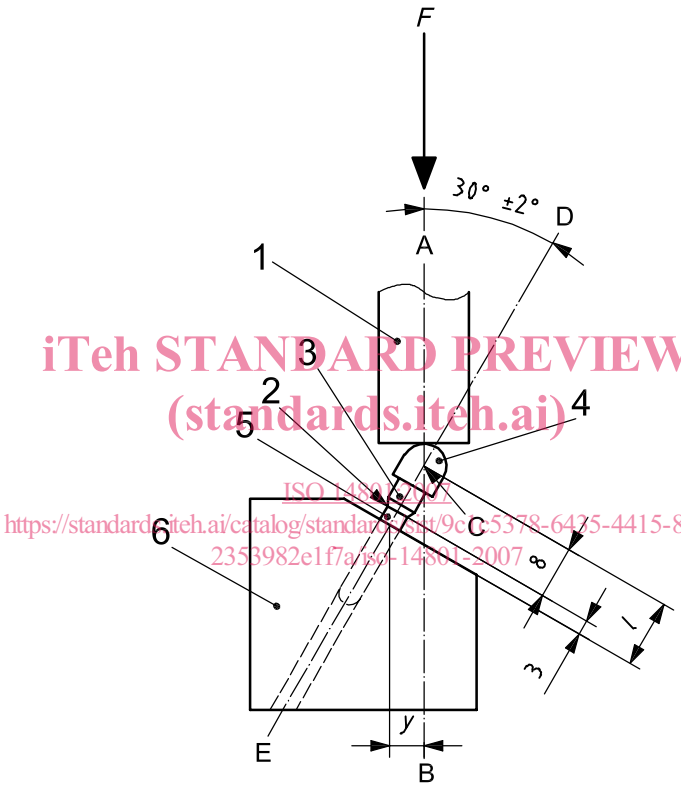
5.2.1 The loading force, F, (see Figures 1 and 2) of the testing machine shall be applied in such a way that:

— no lateral constraint occurs;

— the loading centre (Point C in Figures 1 and 2) is well-defined, such that the moment arm, y, can be measured or calculated.

5.2.2 For dental implant systems that include no pre-angled connecting parts, these requirements will be met by the test set-up shown schematically in Figure 1.

Dimensions in millimetres



Key

1 loading device [shall be allowed free movement transverse to loading direction (see 5.2.6)]
2 nominal bone level (see 5.3.2)
3 connecting part
4 hemispherical loading member
5 dental implant body
6 specimen holder

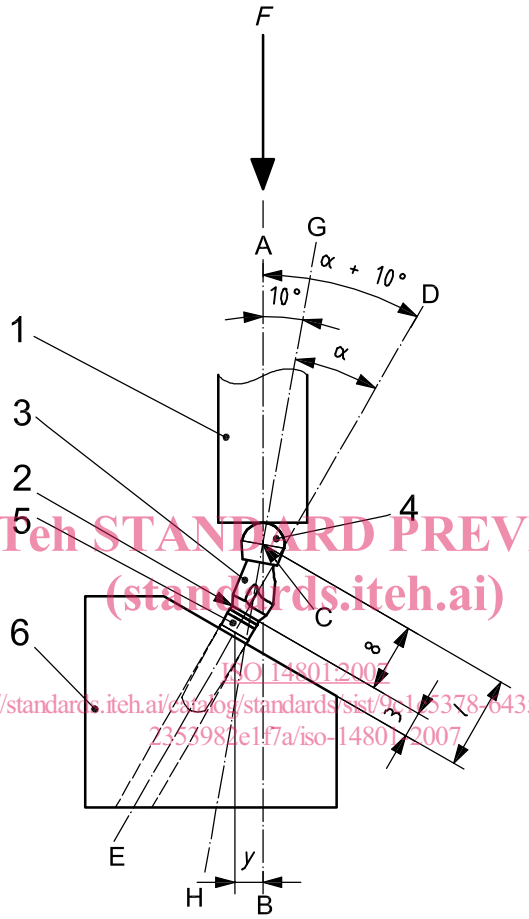
Figure 1 — Schematic of test set-up for systems with no pre-angled connecting parts

5.2.3 An endosseous dental implant from a system that includes no pre-angled connecting parts shall be clamped such that its axis makes a $30^{\circ} \pm 2^{\circ}$ angle with the loading direction of the testing machine (see Figure 1).

5.2.4 An endosseous dental implant body of a system that includes pre-angled connecting parts shall be clamped such that the angle with the loading direction of the testing machine is $10^{\circ}\,^{+2}_{-1}$ greater than the angle

between the implant axis and the axis of the angled portion of the connecting part, 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 connecting part and the plane normal to the longitudinal axis of the implant and located 11 mm (l in Figure 2) from the support level of the implant.

Dimensions in millimetres



Key

1 loading device [shall be allowed free movement transverse to loading direction (see 5.2.6)]
2 nominal bone level (see 5.3.2)
3 connecting part
4 hemispherical loading member
5 dental implant body
6 specimen holder

Figure 2 — Schematic of test set-up for systems with pre-angled connecting parts

5.2.5 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 connecting part. For endosseous dental implant systems that include no pre-angled connecting parts, the loading centre, which is the centre (C) of the hemisphere, shall be on the central longitudinal axis of the endosseous dental implant. For endosseous dental implant systems that include pre-angled connecting parts, the loading centre shall be on the central longitudinal axis of the free end of the connecting part.

5.2.6 The loading force shall be applied to the hemispherical loading surface by a loading device with a plane surface normal to the loading direction of the machine. The loading device 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 a universal joint or point contact 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 surface.

5.2.7 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 is observed, the deformed component shall be replaced and the test shall be repeated.

5.2.8 For an endosseous dental implant body and/or connecting part that lacks rotational symmetry around either the central longitudinal axis of the implant body or 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 loading geometry shall be justified and documented.

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 Figures 1 and 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 pre-angled connecting parts, the dimensions of the loading member, as specified in 5.2.4, shall be chosen to define a distance $l = 11{,}0$ mm ± 0,5 mm from the centre (C) of the hemisphere to the clamping plane (see Figures 1 and 2). The moment arm, y, is defined as $l \times \sin 30°$. For the standard configuration, the moment arm is $0{,}5 \times l$, or 5,5 mm. In the case of a long endosseous dental implant, for which $l = 11$ mm cannot be readily achieved, a larger value for l may be chosen. The choice shall be justified and documented.

Bending moment, M, is defined by the expression

$$M = y \times F$$

For the case illustrated in Figure 1, bending moment is

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

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

$$M = 5{,}5 \times F \text{ (N·mm).}$$

5.3.4 For endosseous dental implant systems which include pre-angled connecting parts, the free end of the connecting part shall be provided with a hemispherical loading member, the centre of which lies on the central longitudinal axis of the free end of the connecting part 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. In the case of an endosseous dental implant body and connecting part for which $l = 11$ mm cannot be readily achieved, a larger value for l 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

$$M = y \times F,$$

and should be reported in N·mm.

