TECHNICAL REPORT

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Dentistry — Screw loosening test using cyclic torsional loading for implant body/implant abutment connection of endosseous dental implants

Medecine bucco-dentaire — Essai de dévissage d'une vis utilisant une charge de torsion cyclique pour le corps d'implant/pilier implantaire des implants dentaires endo-osseux

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Foreword

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

Introduction

Most endosseous dental implants currently marketed employ a dental implant body that is inserted within the jaw bone and to which other components may be joined when constructing a prosthetic superstructure. The connection between these components and the implant body should be sufficiently rigid to resist vertical masticatory loads, which have a significant torsional component. Endosseous dental implants may, therefore, incorporate features to restrict rotation at the connection. If this is insufficiently strong, then undesirable incidents, including screw loosening, distortion and fracture of the linked components will occur. A cyclic torsional screw loosening test for the connection between implant body and implant abutment would facilitate comparative evaluation.

Dentistry — Screw loosening test using cyclic torsional loading for implant body/implant abutment connection of endosseous dental implants

1 Scope

This Technical Report provides guidelines for a method to determine the extent of screw loosening of the metallic implant body/implant abutment joint of endosseous dental implants, such as two-part implants or multi-part implants under cyclic torsional loading. This test is most appropriate for evaluating new types of joints fixed using screw(s) and metallic connecting parts. This Technical Report provides a protocol for torsional cyclic torque on an implant body/implant abutment joint, but its intended use is for prefabricated implant bodies, implant abutments and, if appropriate, implant connecting parts that are made of metallic materials.

It is not applicable to ensure the *in vivo* performance of endosseous dental implants and is not derived from observations of clinical failures.

NOTE This Technical Report is not intended for use with temporary abutments.

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 –Vocabulary*

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

3 Terms and definitions

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

3.1
cyclic torque
repeated torsional force alternatively clockwise and counter clockwise

3.2
screw loosening
decrease in screw removal torque relative to the removal torque when the abutment screw was first installed

3.3
screw tightening torque
torque value for screw required to tighten the implant abutment, and the implant connecting part if appropriate, to the implant body as per specified by the manufacturer

3.4
screw removal torque
torque value for screw required to deconstruct the connection between the implant body and the implant abutment, and the implant connecting part if appropriate

3.5
temporary abutment
implant abutment for temporary usage

4 General principle

The endurance properties of implant body/implant abutment interface should be tested by applying a cyclic alternating torsional load to the implant body and implant abutment clamped in the testing device.

Testing should be performed on finished devices or specimens that have an implant abutment joint equivalent to 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 the implant components to be sterilized by the clinician prior to surgery, sterilization should be carried out before testing as specified in the manufacturer's instructions for use. 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, sterilization is not necessary prior to testing. If so, this should be documented in the test report.

If a dental implant system to be tested consists of several types of implant abutments with the same connecting interface, a straight implant abutment having a metallic connecting interface should be selected for testing.

NOTE Angulated implant abutments cannot be tested because the central axis of connected test specimens is not straight.

5 Test methods

5.1 Test condition

Carry out the test at (25 ± 10) °C.

5.2 Torque meter

Use a torque meter with an accuracy of 0,3 N·cm or less.

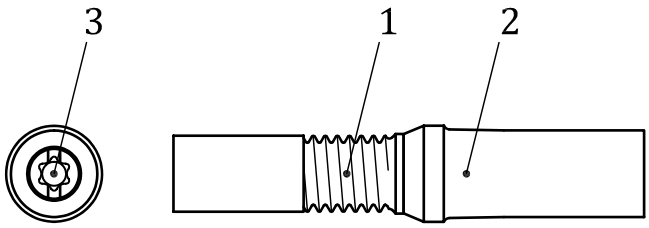
NOTE An example of a torque meter is HDP-5[1)] manufactured by HIOS INC, Japan.

5.3 Preparation of test specimens

The implant abutment, and implant connecting part if appropriate, should be fixed on the implant body using the specified/recommended screw at screw tightening torques stated by the manufacturer's instructions for use. The screw tightening torque should be applied using a torque meter. The ends of the test specimens may be modified into shapes larger than the maximum diameter of implant body and/or implant abutment to more easily clamp with the holders. An example of a test specimen is illustrated in Figure 1.

NOTE At least six specimens for each test according to 5.4 and 5.5 are required to compare the mean of the screw removal torques after cyclic torque test with the mean of the initial screw removal torques.

1) HDP-5 is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.



Key

1 implant body
2 implant abutment
3 abutment screw

Figure 1 — Schematic of a test specimen

5.4 Initial screw removal torque

5.4.1 Procedure

The initial screw removal torque of six specimens should be measured according to the following procedure.

a) The implant abutment, and implant connecting part, if appropriate, should be fixed on the implant body using the specified screw at screw tightening torques stated in the manufacturer's instructions for use. These implant components should be new ones that have never previously been assembled.

b) After 5 min, measure the screw removal torque by torque meter.

c) Calculate the mean and standard deviation of initial screw removal torque from the obtained values for the at least six specimens.

5.5 Screw removal torque after cyclic torque test

5.5.1 Cyclic torque tester

The test device should have the following parts:

— specimen holders (the implant body and implant abutment should each be held at a maximum of 5 mm from the joint line between them);

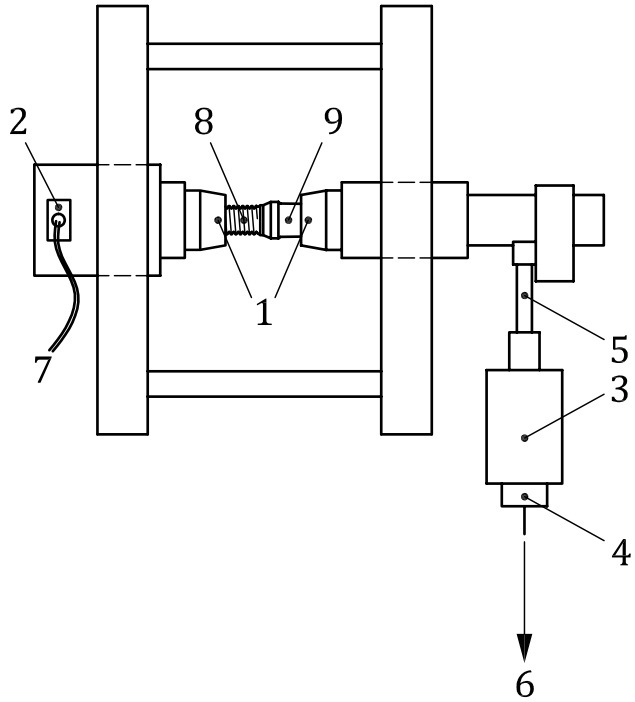
— torque transducer;

— torsional cyclic driving device that can apply cyclic torque greater than 10 % of screw tightening torque;

— torsional cyclic displacement transducer.

An example of a torsional testing device is illustrated in Figure 2.

The central long axes of the shafts of the torque transducer and torsional driving device should coincide.



Key

1 specimen holder
2 torque transducer
3 torsional cyclic driving device
4 torsional cyclic displacement transducer
5 lever arm
6 output of torsional displacement to recorder
7 output of torsional torque to recorder
8 implant body
9 implant abutment

Figure 2 — Example of testing device for cyclic torque test

5.5.2 Torque transducer

The accuracy of the torque transducer equipped in the cyclic torque tester (see 5.5.1) should be less than ± 1 % of the maximum torque to be tested.

5.5.3 Procedure

a) The implant abutment, and implant connecting part, if appropriate, should be fixed on the implant body using the specified screw at screw tightening torques as stated in the manufacturer's instructions for use. These implant components should be new ones that have never previously been assembled.

b) After 5 min, clamp the retaining portions of the implant body and implant abutment of a test specimen into the specimen holders of the testing device. The implant body and implant abutment should each be held at a maximum of 5 mm from the joint line between them.

c) Apply cyclic torque (clockwise and counter clockwise) up to 10 % of the screw tightening torque stated in the manufacture's instruction to the implant abutment with the velocity of 10 degree per minute. Repeat this cyclic torque up to 100 000 cycles.

d) When the specimen survives without deformation and/or fracture after 100 000 cycles, measure the screw removal torque by torque meter. When the specimen does not survive, record the number of cycles which it survives.

e) After the test, observe the wear and deformation of the implant body/connecting joint by a microscope.

f) At least six specimens should be tested.

g) Calculate the mean and standard deviation of the measured screw removal torque after cyclic torque test of at least six specimens

NOTE 1 Implant body and implant abutment joint part are sealed by screw tightening and the part may not be affected by corrosion during 100 000 times cyclic torque test (e.g. 1 d or 2 d).

NOTE 2 An example of the testing machine is AG-XR[2)] manufactured by Shimadzu Corporation, Japan.

5.6 Evaluation

Calculate the ratio of the mean initial screw removal torque to the screw tightening torque. Calculate the ratio of the mean screw removal torque after cyclic torque test to the mean initial screw removal torque.

6 Test report

The test report should include at least the following information:

a) a reference to this Technical Report, i.e. ISO/TR 18130;

b) the identification of the employed test specimens, including the type of connection (internal anti-rotation: taper-fit, notch-fit, hexagonal, etc.; external anti-rotation: hexagonal, etc.), manufacturer(s), part numbers and lot numbers of the tested parts, material(s) of the tested parts, diameter and length of the implant body and implant abutment;

c) if applicable, the documented evidence that the specified sterilization method has no significant effect on the properties of all materials;

d) the test method including the test condition, testing device, screw tightening torque applied to the screws, cyclic torque, number of cycles, distance from the interface at which the components were held and a drawing of the employed test specimens;

e) the results obtained, namely

   1) the initial screw removal torque and the ratio to the screw tightening torque,

   2) the screw removal torque if the specimen survived 100 000 cycles and the ratio to the initial screw removal torque,

   3) if the specimen does not survive, the number of cycles which the testing specimen survives,

   4) the microscopic observation on deformed and/or fractured parts of test specimens.

2) AG-XR is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

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