
**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 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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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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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.

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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* <https://standards.iteh.ai/catalog/standards/sist/01e959d7-4385-41eb-98a6-819130e40cfc/iso-tr-18130-2016>

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

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5.1 Test condition

Carry out the test at $(25 \pm 10) ^\circ\text{C}$.
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5.2 Torque meter

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

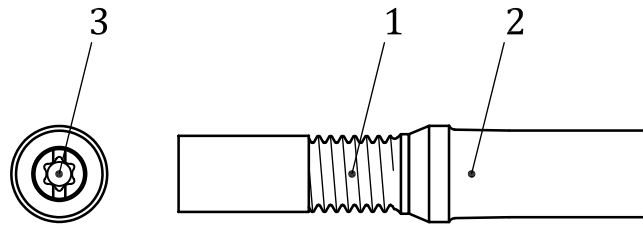
NOTE An example of a torque meter is HDP-5¹⁾ manufactured by HIOS INC, Japan.

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.