

DD ISO/TS 13498:2011



BSI Standards Publication

Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/106/8, Dental implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Amendments issued since publication

Date	Text affected
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**Dentistry — Torsion test of implant
body/connecting part joints of
endosseous dental implant systems**

*Médecine bucco-dentaire — Essai de torsion sur l'interface corps
d'implant/élément de connexion des systèmes d'implants dentaires
endo-osseux*





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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/TS 13498 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

Introduction

Most dental implant systems currently on the market employ a dental implant body that is inserted within the jaw bone, to which other components can be joined when constructing a prosthetic superstructure. The connection between these components and the implant body should be sufficiently rigid to resist masticatory loads, which have a significant torsional component. Implant systems therefore often incorporate features to restrict rotation at the connection. If this is insufficiently strong, then distortion/fracture of the linked components will occur. A standardised torsion test for the joint between the implant body and connecting part facilitates comparative evaluation.

Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems

1 Scope

This Technical Specification establishes a method to determine the torsional yield strength and maximum torque of the implant body/connecting part joints of endosseous dental implant systems. This test is most appropriate for evaluating new types of joints and connecting parts, as well as new materials.

This Technical Specification provides a protocol for torsional loading of an implant body/connecting part joint. It is not applicable for predicting the *in vivo* performance of an endosseous dental implant system and it is not derived from observations of clinical failure.

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 1942, *Dentistry — Vocabulary*

3 Terms and definitions

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

3.1

torsional yield strength

M_{tors}

torque required to produce a rotation of 2° offset from the straight-line portion on the torque versus rotation angle curve

NOTE See Figure 3.

3.2

maximum torque

M_{max}

largest value of torque recorded on the torque versus rotation angle curve

NOTE See Figure 3.

4 Principle

The torsional yield strength and maximum torque of the implant body/connecting part interface are determined by clamping the implant body and connecting part to be tested in a testing device.

Testing shall be performed on finished devices or specimens that have an equivalent connecting part joint to the finished device (i.e. components that have undergone the same manufacturing process and sterilisation as

the device that is to be marketed). If the manufacturer intends the endosseous dental implant to be sterilised by the clinician prior to surgery, sterilisation shall be carried out as specified in the manufacturer's instructions for use before testing. However, if there is evidence that the specified sterilisation method has no significant effect on the properties of all the materials of the specimens being tested, sterilisation is not necessary prior to testing.

5 Test methods

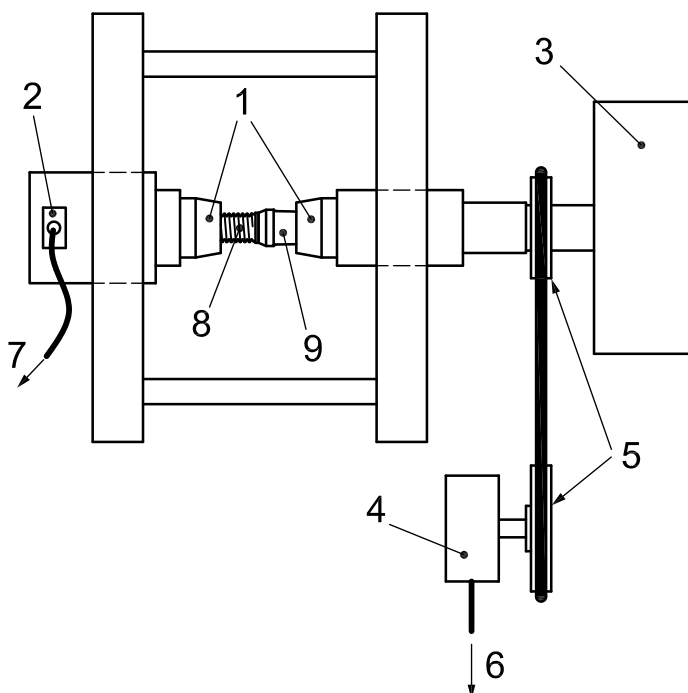
5.1 Testing device

The test device shall have the following parts:

- specimen holders (the implant body and connecting part shall each be held at a maximum of 5 mm from the interface between them);
- torque transducer;
- torsional driving device, able to apply a torque no less than the anticipated maximum torque;
- torsional displacement transducer.

An example of a torsional testing device is illustrated in Figure 1.

The central long axes of the shafts of the torque transducer and torsional driving device shall be coincident.



Key

- | | |
|-------------------------------------|------------------------------------|
| 1 specimen holder | 6 output to X-axis of X-Y recorder |
| 2 torque transducer | 7 output to Y-axis of X-Y recorder |
| 3 torsional driving device | 8 implant body |
| 4 torsional displacement transducer | 9 connecting part |
| 5 pulley | |

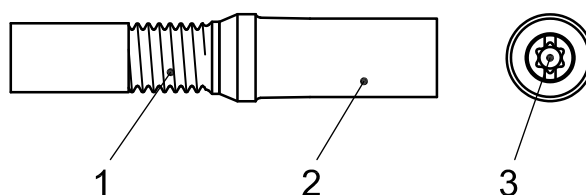
Figure 1 — Example of a testing device

5.2 Torque transducer

The torque transducer shall have a range not exceeding the quintuple of the anticipated minimum torsional yield strength. The maximum inaccuracy of the torque transducer shall be $\pm 1\%$ of the maximum torque to be tested.

5.3 Preparation of test specimen

The connecting part shall be fixed on the implant body using the specified screw at tightening torques stated in the manufacturer's instructions for use. The ends of the implant body and connecting part shall be fixed in a rigid clamping device. These ends may be modified into shapes larger than the maximum diameter of implant body and/or connecting part and they should be easy to clamp with the holders. An example of a test specimen is illustrated in Figure 2.



Key

- 1 implant body
- 2 connecting part
- 3 connecting part screw

Figure 2 — Schematic of a test specimen

5.4 Test conditions

Carry out the test at room temperature (20 ± 5) °C in air.

5.5 Procedure

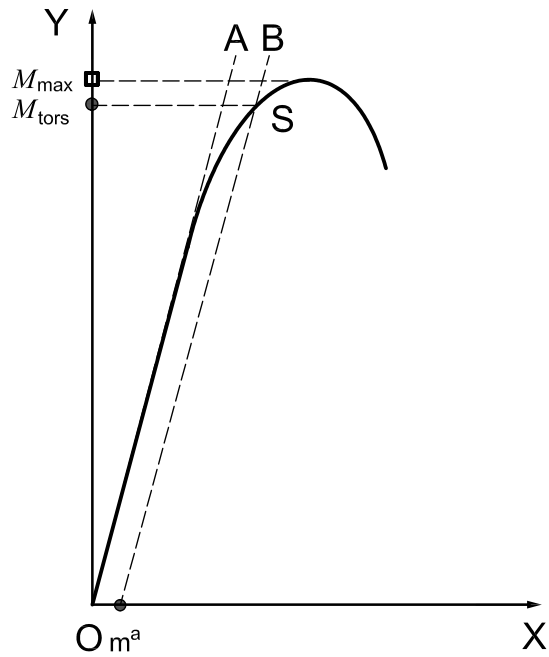
5.5.1 The connecting part shall be fixed on the implant body using a specific screw at tightening torques stated in the manufacturer's instructions for use. Clamp the retaining portions of the implant body and connecting part of a test specimen into the specimen holders of the testing device. Apply torque continuously to the connecting part at a rate of between 1 and 10 degrees per minute and record the torque versus rotation angle curve. Measure the torsional yield strength and the maximum torque of at least six test specimens as described below.

5.5.2 The torsional yield strength is determined by the 2° offset method^[2] (see Figure 3) using the torque versus rotation angle curve produced as described in 5.5.1.

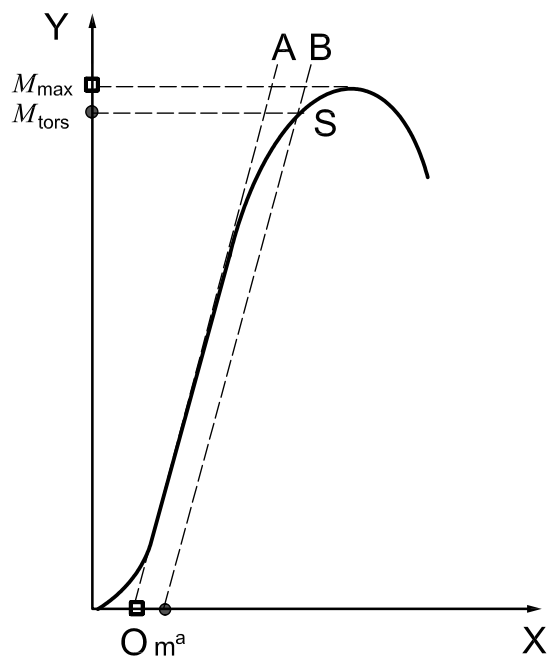
5.5.3 On the torque versus rotation angle curve, locate a point, m, corresponding to 2° of rotation angle and draw a line, mB, parallel to a line, OA. Locate a point S, which is the intersection of mB with the torque versus rotation angle curve. Torque, M_{tors} , is defined as the torsional yield strength.

5.5.4 The maximum torque, M_{max} , is determined by the largest value of torque on the torque versus rotation angle curve.

NOTE It is possible that a sag appears on the torque versus rotation angle curve depending on the testing configuration. In such cases, the torsional yield strength and the maximum torque are determined according to Figure 3 b).



a) Without sag



b) With sag

Key

- X rotation angle, in degrees (°)
- Y torque, in N·m
- O initial contact
- M_{max} maximum torque
- M_{tors} torsional yield strength
- ^a Rotation angle is 2°.

Figure 3 — Method to determine torsional yield strength and maximum torque

5.5.5 Observe the deformed or fractured part of the implant body/connecting part joint under a low-magnification microscope.

5.6 Evaluation of torque test

Calculate the mean of the measured values of test specimens.

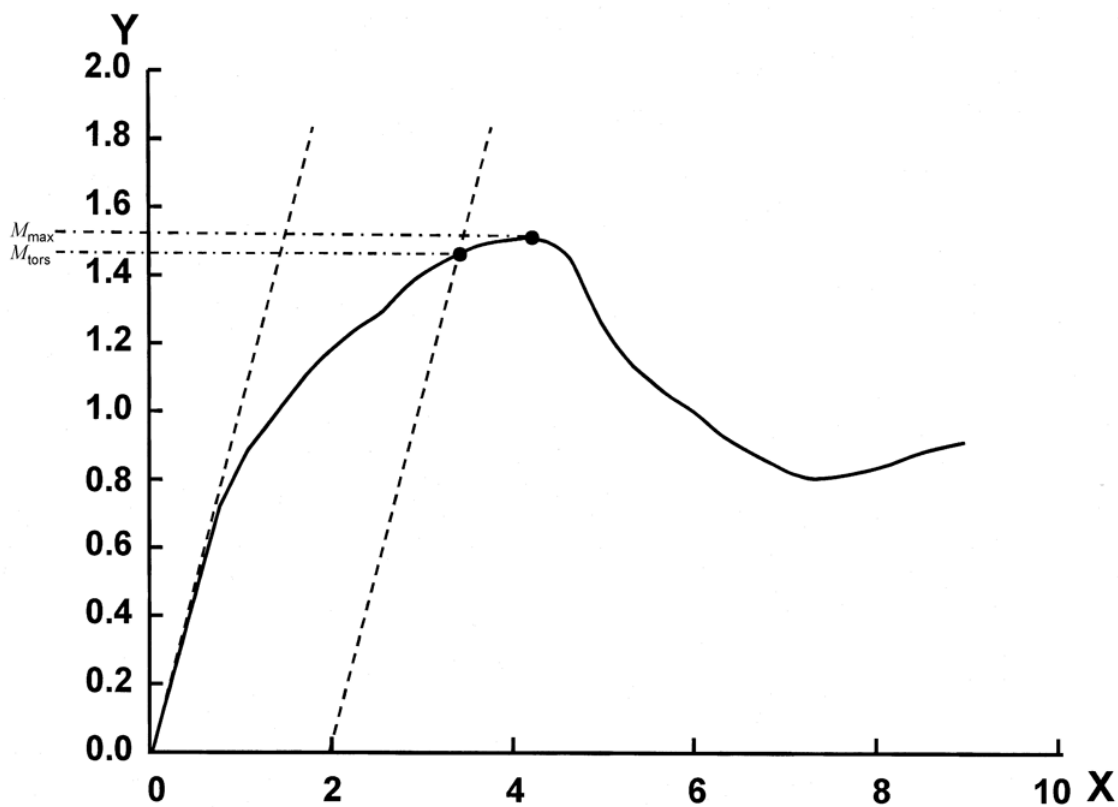
6 Test report

The test report shall include at least the following information:

- a) identification of the test specimens, including
 - 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 connecting part;
- b) test method, including test condition, testing device, rotational rate, distance from the interface at which the components were held and a drawing of the test specimens;
- c) results obtained, namely
 - torsional yield strength and maximum torque,
 - microscopic observation on deformed and fractured parts of the test specimens;
- d) reference to this Technical Specification, i.e. ISO/TS 13498:2011.

Annex A (informative)

Example of test performance



Key

X rotation angle, in degrees (°)

Y torque, in N-m

M_{max} maximum torque

M_{tors} torsional yield strength

Figure A.1 — Example of test performance (see Reference [3])

Bibliography

- [1] ISO 898-7, *Mechanical properties of fasteners — Part 7: Torsional test and minimal torques for bolts and screws with nominal diameters 1 mm to 10 mm*
- [2] ASTM F 543-07, *Standard Specification and Test Methods for Metallic Medical Bone Screws*
- [3] WATANABE, F, ISHIGURO, T, TAKASE, I, UEDA, K, *Torsion test at the interface between implant and implant abutment of CAMLOG Implant*, International College of Prosthodontics, Cape Town, Sept.10, 2009

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