TECHNICAL SPECIFICATION

ISO/TS 13498

> First edition 2011-08-01

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



Reference number ISO/TS 13498:2011(E)



© ISO 2011

<text> All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.org Web www.iso.org

Published in Switzerland

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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, Dentisty, 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 indications 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.

iv

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

 $M_{\sf max}$

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