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Dentistry — Rotational adaptability test between implant body and implant abutment in dental implant systems

Médecine bucco-dentaire — Essai d'évaluation de la liberté rotationnelle entre le corps d'implant et le pilier implantaire des systèmes d'implants dentaires

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The rotational adaptation between an implant body and an implant abutment is an important physical property as it affects the quality of fit between them and therefore resistance to loosening. In addition, correct adaptation between these components can influence the rotational positioning of the final prostheses, the accuracy of the occlusion which it provides, and its physical behaviour under load. The test is carried out when evaluating the physical properties of dental implant systems but there is currently no International Standard available, resulting in variance in the method and the requirements of adaptations.

Dentistry — Rotational adaptability test between implant body and implant abutment in dental implant systems

1 Scope

This document specifies a test method to evaluate the rotational adaptability between an implant body and an implant abutment in a dental implant system.

This document is applicable to the implant systems which do not have a friction-fit between implant body and implant abutment but incorporate only an anti-rotational feature between these components. Analog or replica components cannot be used to evaluate the adaptability of dental implant systems.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

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, ISO 16443 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
rotational angle between implant body and implant abutment
angle on a plane at right angles to the central long axis of the implant body described by the rotation between fully clockwise and fully counter-clockwise of a seated implant abutment without the use of an abutment screw, cement or friction and rotated clockwise or counter-clockwise

3.2
rotational adaptability between an implant body and an implant abutment
adequate fit between an implant body and an implant abutment in terms of the *rotational angle between implant body and implant abutment* (3.1)

3.3
dental implant system
integrated system of components which consists of implant bodies and implant abutments

4 Test methods

4.1 General

Due to machining tolerance, most dental implant systems which have an anti-rotational structure (e.g. a hexagonal anti-rotational structure) exhibit a rotational clearance angle between the implant body and implant abutment to facilitate clinical procedures.

However, if this rotational clearance angle is too large then loosening of the dental prosthesis can occur. Such loosening can be clinically detrimental and thus shall be mitigated.

Testing shall be performed on specimens that are representative of the finished devices (i.e. implant bodies and implant abutments that have undergone the same manufacturing process and sterilization as the devices that are to be marketed). However, if there is evidence that the sterilization method has no significant effect on the properties of all the materials of specimens being tested, then sterilization is not necessary.

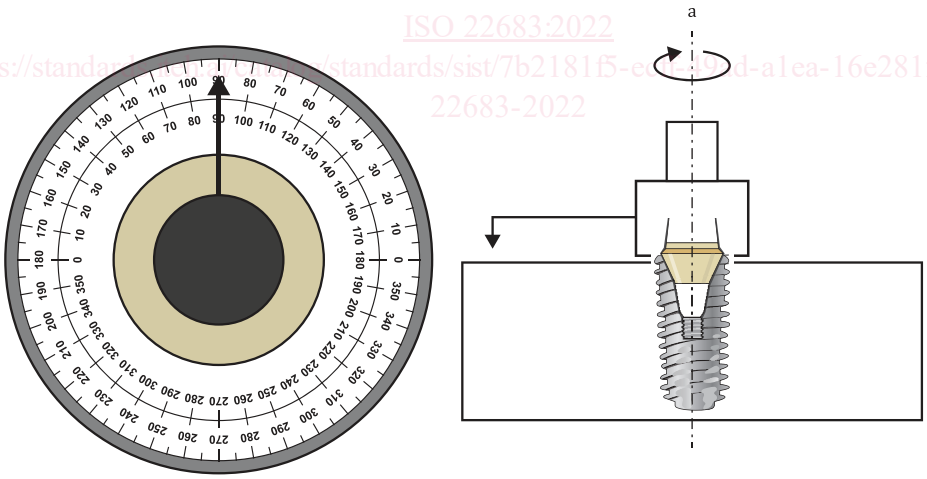
4.2 Apparatus

Rotatable testing device which is composed of two parts. A goniometer and a jig to hold the implant body and implant abutment, as shown in Figure 1. The two parts of the rotatable testing device shall not be in direct contact during the testing in order to prevent rotational friction.

The goniometer shall be capable of measuring to within 0,5°.

The jig for the implant body and implant abutment shall not deform the implant body and implant abutment.

NOTE The implant body can be embedded using a material in reference to ISO 14801.



a Axis of rotation.

Figure 1 — Example of the testing devices to measure the rotational angle between implant body and implant abutment

4.3 Sampling

Five implant bodies and five implant abutments shall be procured for this test.

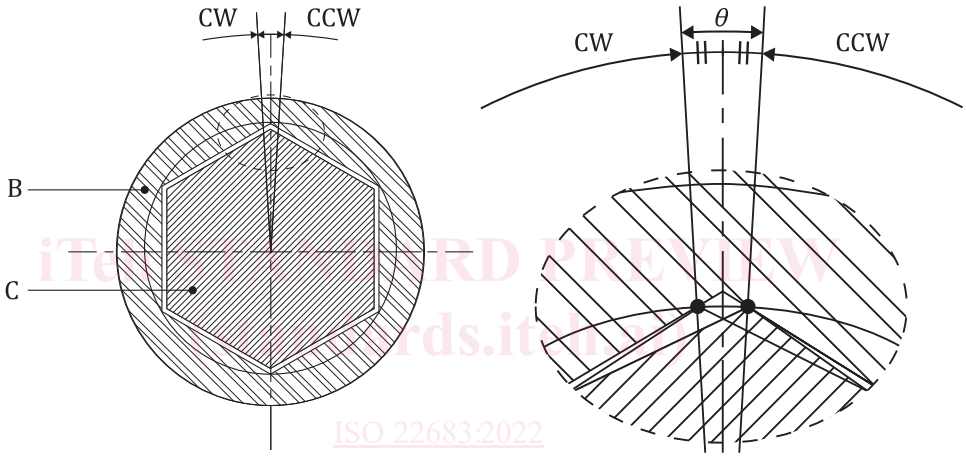
4.4 Procedure

Fix the implant body so that its central longitudinal axis is perpendicular to the horizontal upper surface of the lower jig of the rotational angle testing device (see Figure 1). Locate the implant abutment on the upper jig of the rotational angle testing device so that the joint between it and the implant body is engaged passively and as completely as possible without using a connecting screw (see Figure 1). The central rotational axis of the upper jig shall be coincident with that of the implant body.

The lower jig shall be secured against rotation, and the upper jig shall be free to rotate in clockwise and counter-clockwise directions around the central long axis of the implant body.

Rotate the implant abutment within its rotational limits around the central long axis of the implant body, both in clockwise and counter-clockwise directions, while measuring the maximum angle indicated by the rotational angle apparatus (θ in Figure 2).

Repeat the procedure with five different assemblies and record the angle in degrees.



Key

B	implant body
C	implant abutment
CW	clockwise direction of rotation
CCW	counter-clockwise direction of rotation

Figure 2 — Measurement of rotational angle in the relation to rotation of connected implant body and implant abutment

5 Test report

The test report shall include the following information:

a) all information necessary for the complete identification of the sample;

- name of product(s);
- name of the manufacturer(s);
- place of manufacturer(s);
- reference (catalogue number) if applicable;
- lot numbers / serial number of the tested parts;
- type of implant body;

- type of implant abutment(s);
- material(s) of the tested parts, including any coating material(s) and other surface treatments;
- diameter and length of the implant body;
- geometric dimensions of the dental implant abutment(s) including the angle, α, of the angulated abutment;
- description and dimensions of the joints between the implant body and the implant abutment(s);
- the use by date of this product(s) (if one is given);

b) a reference to this document with its publication date (i.e. ISO 22683:2022);

c) the name of the organization evaluating the product and the site of the evaluation;

d) the date of the evaluation;

e) the sampling method used;

f) the test method including the specification of the goniometer used;

g) the complete test result(s) and the rotational angle mean and standard deviation for the five assemblies;

h) all operating details not specified in this document, or regarded as optional, together with details of any incidents which may have influenced the test result(s) like accuracy of the test system, preload, environment;

i) any unusual features (anomalies) observed during the test.