



Revised American National Standard/
American Dental Association
Standard No. 127

Dynamic Loading Test for Endosseous Dental Implants

Identical adoption of ISO 14801:2016, *Dentistry — Implants — Dynamic loading test for endosseous dental implants*

ADA American
Dental
Association®

Standards Committee on Dental Products

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REVISED AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION STANDARD NO. 127 FOR DYNAMIC LOADING TEST FOR ENDOSSEOUS DENTAL IMPLANTS

The ADA Standards Committee on Dental Products (SCDP) has approved ANSI/ADA Standard No. 127 for Dynamic Loading Test for Endosseous Dental Implants. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA SCDP. The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Committee has adopted the standards, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the standards be approved as American National Standards. The American National Standards Institute granted approval of ADA Standard No. 127 as an American National Standard on May 18, 2018.

The ADA Standards Committee on Dental Products thanks the officers of SCDP Subcommittee 8 on Dental Implants and the organizations with which they were affiliated at the time the standard was developed:

Floyd Larson (chairman), PaxMed International, Carlsbad, CA; and

Jack Lemons, University of Alabama, Birmingham, AL.

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FOREWORD

(This Foreword does not form a part of the revised ANSI/ADA Standard No. 127 for Dynamic Loading Test for Endosseous Dental Implants).

This standard is an identical adoption of ISO 14801:2016, Dentistry – Implants – Dynamic loading test for endosseous dental implants. ADA SCDP Subcommittee 8 on Dental Implants examined the international standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 127. This revision cancels and replaces ADA Standard No. 127:2012.

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1 Scope

This standard specifies a method of dynamic testing of single post endosseous dental implants of the transmucosal type in combination with their premanufactured prosthetic components. It is most useful for comparing endosseous dental implants of different designs or sizes. This International Standard is not a test of the fundamental fatigue behavior of the materials from which the endosseous implants and prosthetic components are made.

This standard is not applicable to dental implants with endosseous lengths shorter than 8 mm nor to magnetic attachments.

While this standard simulates the functional loading of an endosseous dental implant under “worst case” conditions, it is not applicable for predicting the *in vivo* performance of an endosseous dental implant or dental prosthesis, particularly if multiple endosseous dental implants are used for a dental prosthesis.

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 — Terminology*

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

ISO 1099, *Metallic materials — Fatigue testing — Axial force-controlled method*

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

(ISO standards are available from the American National Standards Institute, <http://www.ansi.org>)

3 Terms and definitions

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

3.1

endosseous dental implant system

device that consists of integrated components including the ancillary instruments and specific equipment necessary for the clinical and laboratory preparation and placement of the implant, and for the construction and insertion of the dependent dental prosthesis

Note 1 to entry: In addition to providing resistance to displacement of an implant superstructure, an endosseous dental implant may be used as an anchorage for orthodontic appliances.

Note 2 to entry: An endosseous dental implant may consist of one or more parts.

Note 3 to entry: The term implant superstructure includes crowns and fixed and removable prostheses, but excludes implant abutments.

3.2

prosthetic components

implant components to be used for two part implant or multi-part implant

Note 1 to entry: Implant abutments, dental implant connecting parts, abutment screws, and implant connecting part screws are used as prosthetic components in this International Standard.

3.3

endosseous dental implant assembly

dental implant assembly for endosseous dental implant

3.4

load-cycle diagram

diagram summarizing the dynamic loading behavior of an endosseous dental implant by showing for each value of the applied peak load the number of cycles endured by each specimen at the time of failure

Note 1 to entry: See Annex A.

3.5

endosseous dental implant body

implant body of endosseous dental implant

4 General principles

4.1 Finished device testing

Testing shall be performed on specimens that are representative of the finished device (i.e. implant components that have undergone the same manufacturing process and sterilization as the device that is to be marketed). If the manufacturer intends the endosseous dental implant to be sterilized by the clinician prior to surgery, sterilization shall be carried out as specified in the manufacturer's instructions for use before testing. However, if there is evidence that the specified sterilization method has no significant effect on the behavior of all the materials of the specimens being tested, then sterilization is not necessary prior to testing.

4.2 Multi-part endosseous dental implants

A multi-part endosseous dental implant shall be tested as assembled according to its intended use. An endosseous dental implant component recommended by its manufacturer to be used in conjunction with components of another manufacturer shall be tested as assembled according to the recommending manufacturer's statement. Where a multi-part device is assembled by means of screw joints, then these shall be used according to the manufacturer's recommendations and shall be tightened to the manufacturer's recommended torque using the equipment (implant screwdriver, torque wrench, etc.) which is provided together with the implant system or using a device that provides torque within $\pm 5\%$ of the recommended value if no original instruments are available. The tightening sequence shall be as recommended by the manufacturer.

4.3 Worst-case testing

If a part of the endosseous dental implant system is available in various dimensions and/or configurations, testing shall be carried out for the worst-case conditions within the recommended use.

The choice of worst case shall be justified and documented. Guidance on how to choose the worst case is given in Annex B.

5 Test methods

5.1 Testing machine

The testing machine shall

- be capable of applying the prescribed load with an error not exceeding $\pm 5\%$ at maximum load (in accordance with ISO 7500-1),
- be capable of applying the load at the prescribed frequency,
- include instrumentation to monitor the values of maximum and minimum loads, and loading frequency, and to detect failure of the specimen, and
- be capable of recording the number of loading cycles during the test.

5.2 Loading geometry

5.2.1 The loading force (see Figure 1 and Figure 2, arrow F) of the testing machine shall be applied in such a way that

- no lateral constraint occurs,
- the position of the intersection of the loading axis (Line AB) with the axis of the endosseous dental implant (Line DE), is well-defined, such that the moment arm (y) can be measured or calculated (see Figure 1 and Figure 2).

5.2.2 An endosseous dental implant from a system that includes only straight implant abutments shall be clamped such that its central longitudinal axis makes a $30^\circ \pm 2^\circ$ angle with the loading direction of the testing machine (see Figure 1).