



American National Standard/
American Dental Association
Standard No. 127

Fatigue Testing for Endosseous Dental Implants

Identical adoption of ISO 14801:2007, *Dentistry — Fatigue test for endosseous dental implants*.

ADA American
Dental
Association®
Council on
Scientific Affairs

This is a preview of "ANSI/ADA 127-2012". [Click here to purchase the full version from the ANSI store.](#)

FATIGUE TESTING FOR ENDOSSEOUS DENTAL IMPLANTS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Standard No. 127 for Fatigue Testing for Endosseous Dental Implants. This and other standards for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council 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 June 6, 2012.

The ADA Standards Committee on Dental Products thanks the members of Working Group 8.49 on Mechanical Properties and the organizations with which they were affiliated at the time the standard was developed:

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TESTING FOR ENDOSSEOUS DENTAL IMPLANTS

FOREWORD

(This Foreword does not form a part of ANSI/ADA Standard No. 127 for Fatigue Testing for Endosseous Dental Implants).

This standard is an identical adoption of ISO 14801:2007, *Dentistry - Fatigue test for endosseous dental implants*.

ADA SCDP Working Group No. 8.49 on Mechanical Properties of Implants examined the international standard and found it acceptable for identical adoption as ANSI/ADA Standard No. 127.

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TESTING FOR ENDOSSEOUS DENTAL IMPLANTS

1 SCOPE

This standard specifies a method of fatigue testing of single post endosseous dental implants of the transmucosal type and their premanufactured prosthetic components. It is most useful for comparing endosseous dental implants of different designs or sizes.

While this standard simulates the functional loading of an endosseous dental implant body and its premanufactured prosthetic components under “worst case” conditions, it is not applicable for predicting the *in vivo* performance of an endosseous dental implant or prosthesis, particularly if more than one implant is used for a prosthesis.

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

ISO 1942 (all parts), *Dental vocabulary*

ISO 4965, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*

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

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or <http://catalog.ada.org>. Other ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

3 TERMS AND DEFINITIONS

For the purposes of this document, the terms and definitions given in ISO 1942 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 prosthesis

NOTE 1 In addition to providing resistance to displacement of a dental prosthesis, an endosseous dental implant may be used as an anchorage for orthodontic appliances.

NOTE 2 An endosseous dental implant may consist of one or more parts.

NOTE 3 The term dental prosthesis includes crowns and fixed and removable prostheses.

3.2 load-cycle diagram

diagram summarising the fatigue properties 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

See Annex A.

4 GENERAL PRINCIPLES

4.1 Finished device testing

Testing shall be performed on specimens that are representative of the finished device (i.e., 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