Technical Training: Medical Device Professional Society Perspective – ASTM Material Test Methods for Assessing Corrosion

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Evolution of Standards in Dentistry

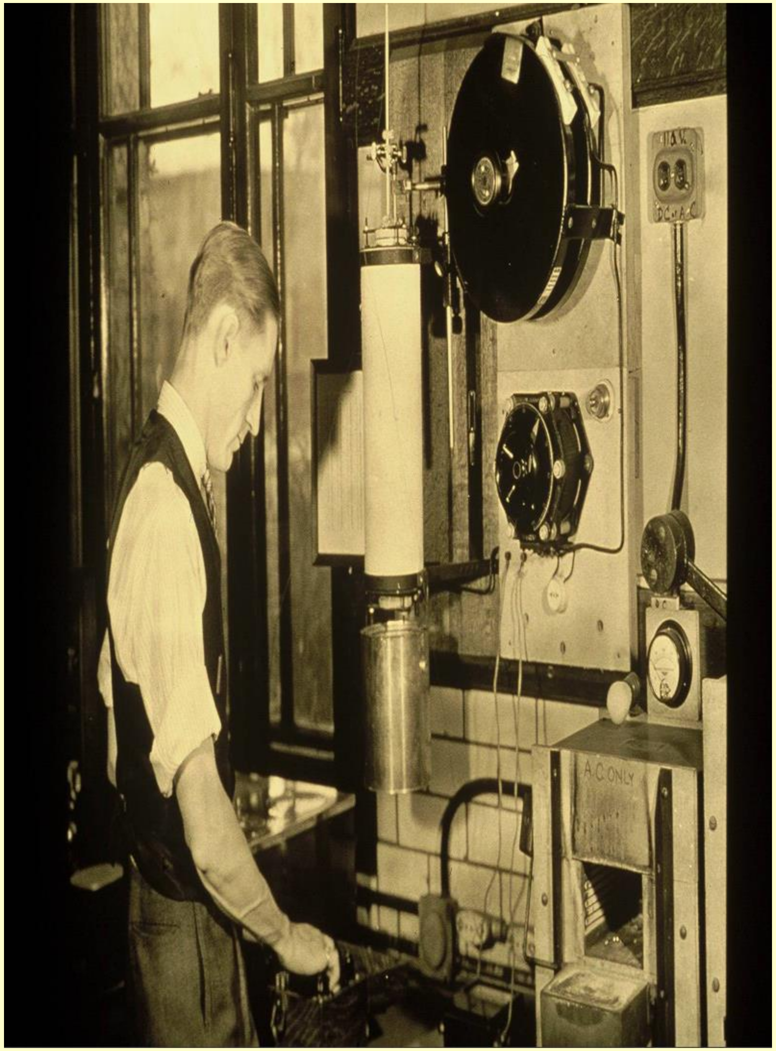
- Where have we been?
- Where are we now?
- Where are we going?
- Real question is…

Why are standards important?

- Simple answer: standards affect how dental and medical products are sold around the world
- May affect how R&D approaches development of new products by not limiting composition and other design factors and by clearly defining clinically relevant requirements for a product

Where Have We Been?

- 1928 –at the request of the war department the ADA in conjunction with the federal government began developing dental specifications at the National Bureau of Standards
- 1953 to 1970 – the Dental Materials Group of the International Association of Dental Research served as an advisor to the ADA in the development of specifications
- 1970 to present – ADA has developed specifications through standards committees
- 2000 – ADA was approved as an ANSI Accredited Standards Organization



Where have we been? (Standards Committees)

- The ADA Standards Committee on Dental Products (SCDP) is comprised of 9 subcommittees and 60+ working groups
- The ADA SCDP has 41 voting members and 1 liaison member from 26 organizations
- The working groups are comprised of volunteers from the profession, industry, academia, and government

ADA Standards Committee on Dental Products
SC1 Restorative and Orthodontic Materials
SC2 Prosthodontic Materials
SC3 Dental Terminology
SC4 Instruments
SC5 Infection Control, Barrier and Safety Products
SC6 Equipment
SC7 Abrasives and Oral Hygiene Devices
SC8 Dental Implants
SC9 CAD/CAM in Dentistry

Example of SC

Subcommittee 1: RESTORATIVE AND ORTHODONTIC MATERIALS

Chairman:	Dr. J. Horn
Vice Chairman:	Dr. S. Megremis

Chairman:	**Work Program:**
Dr. M. Chiang	**Working Group 1.1 on Adhesion:** • Proposed ANSI/ADA Standard No. 111 for Adhesion Test Methods to Tooth Structure
Dr. R. Mitchell	**Working Group 1.2 on Alloy for Amalgam, Dental Mercury:** • ANSI/ADA Standard No. 1 for Alloy for Dental Amalgam • ANSI/ADA Standard No. 6 for Dental Mercury • Proposed ANSI/ADA Standard No. 144 for Alloy for Dental Amalgam
Dr. S. Megremis	**Working Group 1.3 on Composite Resins:** • ADA Standard No. 27 for Resin-Based Filling Materials • Proposed ANSI/ADA Standard No. 27 Polymer-based Restorative Materials • Proposed ANSI/ADA Standard No. 150 Polymerization Shrinkage for Polymeric Dental Materials
Dr. J. Platt	**Working Group 1.4 on Dental Water-Based and ZOE Cements:** • ANSI/ADA Standard No. 30 for Zinc Oxide-Eugenol and Non-Eugenol Cements • ANSI/ADA Standard No. 96 for Dental Water-Based Cements
Dr. C. Primus	**Working Group 1.5 on Endodontic Filling Materials:** • ANSI/ADA Standard No. 57 for Endodontic Sealing Materials • ANSI/ADA Standard No. 73 for Dental Absorbent Points • ANSI/ADA Standard No. 78 for Dental Obturating Cones
Dr. P.L. Fan	**Working Group 1.59 on Amalgam Recycling:** • ANSI/ADA Standard No. 109 for Procedures for Storing Dental Amalgam Waste and Requirements for Amalgam Waste Storage/Shipment Containers
Dr. J. Horn	**Working Group 1.7 on Orthodontic Products:** • ANSI/ADA Standard No. 32 for Orthodontic Wires • ANSI/ADA Standard No. 100 for Orthodontic Brackets and Tubes • ANSI/ADA Standard No. 105 for Orthodontic Elastomeric Materials
Dr. F. Eichmiller	**Working Group 1.8 on Pit and Fissure Sealants:** • ANSI/ADA Standard No. 39 for Pit and Fissure Sealants

Where have we been?

- As a result of the war department’s request to investigate dental amalgam, the first ADA specification was Specification No. 1 “Alloy for Dental Amalgam”
- The procedure used to develop this specification was to test the properties of amalgam alloys that were performing successfully at the time and use these values as requirements in the specification
  - ✓ Composition
  - ✓ Diametral strength, dimensional change 5 min to 24 hrs, flow
  - ✓ Working qualities and foreign material
- Vertical Standard – a standard where composition or some other design factor (e.g., mech. prop.) is included
  - ✓ Based on materials in successful use at the current time
  - ✓ Revisions based on new research on materials and/or test methods
  - ✓ Directive was new clinically successful materials that did not meet requirements resulted in a new spec. or revision to existing spec.

ANSI/ADA No. 1

4 REQUIREMENTS

4.1 Chemical Composition

4.1.1 General

The elements present in the alloy may include silver, tin, copper, zinc, indium, mercury and/or the noble metals (gold, platinum and palladium). The total concentration of other elements shall not exceed 0.1 % (w/w) except as allowed by 4.1.2. Chemical analysis shall be conducted in accordance with 6.8.

4.1.2 Deviations in chemical composition

Elements other than those specified in 4.1.1 shall be permitted provided evidence is presented of adequate biocompatibility in accordance with ISO TR 7405 to show that the alloy is safe to use in the mouth when used as directed in the manufacturer's instructions.

4.2 Physical properties

When tested in accordance with 6.2 to 6.4, the material shall comply with the requirements given in Table 1.

Table 1 - Physical Properties

Creep (%)	Dimensional Change (%)	Compressive Strength (MPa)	
maximum	range	minimum after 1 h	minimum after 24 h
1.0	-0.15 to + 0.20	80	300

4.3 Mass

The coefficients of variation of the masses of the alloy and the mercury each shall not exceed 1.5% and the arithmetic means of the masses of the alloy and the mercury each shall be within ± 2 % of the manufacturer's stated masses when tested in accordance with 6.5.

4.4 Loss of mercury

The mercury in the capsules shall meet the following requirements:

A The mercury shall comply with ISO 1560;

B The loss in mass for each capsule during amalgamation shall not exceed 0.5 mg when tested according to 6.6.

4.5 Foreign material

When tested according to 6.7, the alloy shall contain no more than five particles of foreign material.

Where are we now? FDA

- The Food and Drug Modernization Act of 1997 amended the Food, Drug, and Cosmetic Act to allow the U.S. Food and Drug Administration (FDA) to recognize and use consensus standards in its review process of medical devices
- There are 18 ANSI/ADA Standards recognized by FDA under Section 514(c) of the Food and Drug Modernization Act along with 26 ISO/TC 106 dental standards*
  - ✓ Actually more because many ANSI/ADA Standards are identical adoptions of ISO standards
  - ✓ When there is difference, provide reasoning for FDA to approve national standard
- Dental products manufacturers may use FDA-recognized ANSI/ADA and ISO standards to meet 510(k) requirements

*Accessed on 1/18/2017 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Where are we now?

- The European Union through its standards organization (CEN, European Committee for Standardization) agreed to accepts standards developed by ISO TC 106 on Dentistry

- But…..CEN objected to a number of the standards and requested ISO TC 106 consider changing from vertical to horizontal standards

- 2000 - ADA SCDP formed an Ad Hoc group to investigate the consequences of changing from Vertical to Horizontal Standards

Where are we going? Performance Standards

- Vertical Standard – a standard where composition or some other design factor (e.g., mechanical properties) is included
- Horizontal Standard – **no composition requirements** and provides **requirements for successful use** (that is, safe and efficacious) of a product for a particular application.
  - ✓ Example is ANSI/ADA Standard No. 27 Polymer-Based Restorative Materials

4 Classification

For the purposes of this Standard, dental polymer-based restorative materials are classified as the following types.

a) **Type 1**: polymer-based restorative materials claimed by the manufacturer as suitable for restorations involving occlusal surfaces;

b) **Type 2**: all other polymer-based restorative materials, and luting materials.

The three classes of dental polymer-based restorative materials are as follows.

— **Class 1**: materials whose setting is effected by mixing an initiator and activator ("self-curing" materials).

— **Class 2**: materials whose setting is effected by the application of energy from an external source, such as blue light or heat ["external-energy-activated" materials, see also 8.3 e)]. They are subdivided as follows:

1) **Group 1**: materials whose use requires the energy to be applied intra-orally;

2) **Group 2**: materials whose use requires the energy to be applied extra-orally. When fabricated, these materials will be luted into place.

Certain materials may be claimed by manufacturers to be both Group 1 and Group 2. In this event, the material should fulfil the requirements for both groups.

NOTE Class 2 luting materials will fall into Group 1 only.

— **Class 3**: materials that are cured by the application of external energy and also have a self-curing mechanism present ("dual cure" materials).

Table 2 — Physical and chemical property requirements for restorative materials, excluding luting materials (see Table 1 for minimum flexural strength)

Material Class	Requirement (subclause)				
	Working time (5.2.3) s minimum	Setting time (5.2.5, 5.2.6) min maximum	Depth of Cure [a] (5.2.8) mm minimum	Water sorption (5.2.10) µg/mm³ maximum	Solubility (5.2.10) µg/mm³ maximum
Class 1	90	5 (5.2.5)	—	40	7,5
Class 2	—	—	1,0 (opaque shade) 1,5 (others)	40	7,5
Class 3	90	10 (5.2.6)	—	40	7,5

[a] The values for all materials shall be no more than 0,5 mm below the value stated by the manufacturer.

Table 3 — Physical and chemical property requirements for luting materials

Material Class	Requirement (subclause)					
	Film thickness [a] (5.2.2) µm maximum	Working time (5.2.4) s minimum	Setting time (5.2.5, 5.2.6) min maximum	Depth of cure [b] (5.2.8) mm minimum	Water sorption (5.2.10) µg/mm³ maximum	Solubility (5.2.10) µg/mm³ maximum
Class 1	50	60	10 (5.2.5)	—	40	7,5
Class 2	50	—	—	0,5 (opaque) 1,5 (others)	40	7,5
Class 3	50	60	10 (5.2.6)	—	40	7,5

[a] The determined value shall be no more than 10 µm above any value claimed by the manufacturer.

[b] In any event, the values for all materials, with the exception of opaque luting materials, shall be no more than 0,5 mm below the value stated by the manufacturer.

Where are we going? Performance Standards

- Horizontal Standard – no composition requirements and provides requirements for successful use of a product for a particular application. Problem is the following:
  - ✓ Test requirements are still for the most part based on existing products
  - ✓ Many of the tests lack Clinical Relevance
- 2007 – “Technical Report for a Road Map to Performance Standards”
- Performance Standard – provides requirements for safe and efficacious use of a product for a particular application based on clinically relevant test methods
  - ✓ Shouldn’t matter if it is metal or polymer. Just want to restore tooth.
  - ✓ STILL WORKING ON THIS!

American Dental Association
Technical Report

A Road Map to Performance Standards

ANSI/ ADA

ANSI/ADA Standard No. 1 Alloy for Dental Amalgam (2003, R2013)
ADA Standard No. 6 Dental Mercury (1987)
ANSI/ADA Standard No. 15 Artificial Teeth for Dental Prostheses (2008, R2013)
ANSI/ADA Standard No. 17 Denture Base Temporary Relining Resin (1983, R2014)
ANSI/ADA Standard No. 19 Dental Elastomeric Impression Materials (2004, R2014)
ANSI/ADA Standard No. 23 Dental Excavating Burs (1982, R2015)
ANSI/ADA Standard No. 25 Dental Gypsum Products (2015)
ADA Standard No. 26 Dental X-Ray Equipment (1991)
ANSI/ADA Standard No. 27 Polymer-based Restorative Materials (2016)
ANSI/ADA Standard No. 28 Root Canal Files and Reamers, Type K for Hand Use (2008, R2013)
ANSI/ADA Standard No. 30 Dental Zinc Oxide - Eugenol and Zinc Oxide - Non-Eugenol Cements (2013)
ANSI/ADA Standard No. 32 for Orthodontic Wires (2006, R2010)
ANSI/ADA Standard No. 33 Dental Terminology (2003, R2014)
ANSI/ADA Standard No. 34 Dental Cartridge Syringes (2013)
Proposed ANSI/ADA Standard No. 35 Dental Handpieces
ANSI/ADA Standard No. 37 Dental Abrasive Powders (1986, R2015)
ANSI/ADA Standard No. 38 Metal-Ceramic Dental Restorative Systems (2000, R2015)
ANSI/ADA Standard No. 39 Pit and Fissure Sealants (2006, R2011)
ANSI/ADA Standard No. 41 Evaluation of Biocompatibility of Medical Devices Used in Dentistry (2015)
ANSI/ADA Standard No. 43 Electrically Powered Mechanical Amalgamators (1986, R2015)
ADA Standard No. 44 Dental Electrosurgical Equipment (1979)
ANSI/ADA Standard No. 46 Dental Patient Chair (2016)
ANSI/ADA Standard No. 47 Dental Units (2006)
ANSI/ADA Standard No. 48 Visible Light Curing Units (2004, R2015)
ANSI/ADA Standard No. 48-2 LED Curing Lights (2010*, R2015)
ANSI/ADA Standard No. 53 for Polymer-Based Crown and Bridge Materials (2008, R2013)
ANSI/ADA Standard No. 54 Double-Pointed, Parenteral, Single Use Needles for Dentistry (1986, R2014)
ANSI/ADA Standard No. 57 Endodontic Sealing Materials (2000, R2012)
ANSI/ADA Standard No. 58 Root Canal Files, Type H (Hedstrom) (2010, R2015)
ANSI/ADA Standard No. 62 Dental Abrasive Pastes (2005, R2015)
ANSI/ADA Standard No. 63 Root Canal Barbed Broaches and Rasps (2013)
ANSI/ADA Standard No. 69 Dental Ceramic (2010, R2015)
ANSI/ADA Standard No. 71 Root Canal Filling Condensers (Pluggers and Spreaders) (2008, R2013)
ANSI/ADA Standard No. 73 Dental Absorbent Points (2008, R2013)
ANSI/ADA Standard No. 74 Dental Operator's Stool (2010, R2015)
ANSI/ADA Standard No. 75 Resilient Lining Materials for Removable Dentures – Part 1: Short-Term Materials (1997, R2014)
ANSI/ADA Standard No. 76 Non-Sterile Natural Rubber Latex Gloves for Dentistry (2005, R2015)
ANSI/ADA Standard No. 78 Dental Obturating Cones (2013)
ANSI/ADA Standard No. 80 Dental Materials-Determination of Color Stability (2001, R2013)
ANSI/ADA Standard No. 85 – Part 1 Disposable Prophy Angles (2004, R2009)
ANSI/ADA Standard No. 87 Dental Impression Trays (1995, R2014)
ANSI/ADA Standard No. 88 Dental Brazing Alloys (2000, R2012)
ANSI/ADA Standard No. 89 Dental Operating Lights (2008, R2013)
ANSI/ADA Standard No. 94 Dental Compressed Air Quality (1996, R2014)
ANSI/ADA Standard No. 95 Root Canal Enlargers (2013)
ANSI/ADA Standard No. 96 Dental Water-Based Cements (2012)
ANSI/ADA Standard No. 97 Corrosion Test Methods (2002, R2013)
ANSI/ADA Standard No. 99 Athletic Mouth Protectors and Materials (2001, R2013)
ANSI/ADA Standard No. 100 Orthodontic Brackets and Tubes (2012)
ANSI/ADA Standard No. 101 Root Canal Instruments: General Requirements (2001, R2010)
ANSI/ADA Standard No. 102 Non-Sterile Nitrile Gloves for Dentistry (1999, R2015)
ANSI/ADA Standard No. 103 Non-Sterile Poly Vinyl Chloride Gloves for Dentistry (1999, R2015)
ANSI/ADA Standard No. 105 Orthodontic Elastomeric Materials (2010, R2015)
Proposed ANSI/ADA Standard No. 106 Dental Amalgam Capsule
ANSI/ADA Standard No. 108 Amalgam Separators (2009)
ANSI/ADA Standard No. 108-2009 Addendum (2011)
ANSI/ADA Standard No. 109 Procedures for Storing Dental Amalgam Waste and Requirements for Amalgam Waste Storage/Shipment Containers (2006, R2012)
ANSI/ADA Technical Report No. 110 Standard Procedures for the Assessment of Laser-Induced Effects on Oral Hard and Soft Tissue (2008)
Proposed ANSI/ADA Standard No. 111 Adhesion Test Methods to Tooth Structure
ANSI/ADA Standard No. 113 Periodontal Curettes, Dental Scalers and Excavators (2015)
Proposed ANSI/ADA Standard No. 114 Portable Dental Unit, Dental Patient Chair and Dental Operator's Stool
ANSI/ADA Standard No. 116 Oral Rinses (2010)
Proposed ANSI/ADA Standard No. 117 Fluoride Varnishes
ANSI/ADA Standard No. 119 Manual Toothbrushes (2015)
ANSI/ADA Standard No. 120 Powered Toothbrushes (2009, R2014)
ANSI/ADA Standard No. 122 Dental Casting and Baseplate Waxes (2007, R2013)
Proposed ANSI/ADA Standard No. 124 Implantable Materials for Bone Filling and Augmentation in Oral and Maxillofacial Surgery-Contents of a Technical File
ANSI/ADA Standard No. 125 Manual Interdental Brushes (2012)
ANSI/ADA Standard No. 126 Casting Investments and Refractory Die Materials (2015)
ANSI/ADA Standard No. 127 Fatigue Testing for Endosseous Dental Implants (2012)
ANSI/ADA Standard No. 128 Hydrocolloid Impression Materials (2015)
Proposed ANSI/ADA Standard No. 129 Limits for Lead in Dental Materials
ANSI/ADA Standard No. 130 Dentifrices – Requirements, Test Methods and Marking (2013)
ANSI/ADA Standard No. 131 Dental CAD/CAM Machinable Zirconia Blanks (2015)
ANSI/ADA Standard No. 132 Scanning Accuracy of Dental Chair Side and Laboratory CAD/CAM Systems (2015)
Proposed ANSI/ADA Technical Report No. 133 Guide to Dental Lasers and Related Technologies
ANSI/ADA Standard No. 134 for Metallic Materials for Fixed and Removable Restorations and Appliances (2013)
ANSI/ADA Standard No. 135 for Denture Adhesives (2015)
ANSI/ADA Standard No. 136 for Products for External Tooth Bleaching (2015)
ANSI/ADA Technical Standard No. 137 for Essential Characteristics of Test Methods for the Evaluation of Treatment Methods Intended to Improve or Maintain the Microbiological Quality of Dental Unit Procedural Water (2014)
ANSI/ADA Standard No. 139 for Dental Base Polymers (2012)
Proposed ADA Technical Report No. 140 for Dental Shade Conformity and Interconvertibility
ANSI/ADA Standard No. 141 for Dental Duplicating Material (2013)
Proposed ANSI/ADA Technical Report No. 142 Dental Implant CAD/CAM Surgical Guides
Proposed ANSI/ADA Technical Report No. 143 for CAD/CAM Bonding Cements
Proposed ANSI/ADA Standard No. 144 for Alloy for Dental Amalgam
Proposed ANSI/ADA Technical Report No. 145 for Interfaces for CAD/CAM
Proposed ANSI/ADA Technical Report No. 146 for CAD/CAM Implant Abutments
Proposed ANSI/ADA Technical Report No. 147 for Accuracy of CAD/CAM SLA Models
Proposed ANSI/ADA Standard No. 150 for Polymerization Shrinkage for Polymeric Dental Materials
ANSI/ADA Standard No. 151 Screening Method for Erosion Potential of Oral Rinses on Dental Hard Tissues (2015)
Proposed ANSI/ADA Technical Report No. 152 for Oral Health Risk Assessment Tools
Proposed White Paper No. 153 on Genetic Testing for Oral Diseases
ANSI/ADA/AAMI Standard ST-55 for Table-top Steam Sterilizers (2010)
ANSI/ADA/AAMI Standard ST-40 for Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities (2004, R2010)

ADA Research & Standards Department

- Why does the ADA have a Research Group working on Standards?
- How does this Group support ADA Standards and Testing?
- How do ASTM Standards work with ANSI/ADA and ISO Dental Standards?
- What about ASTM Material Test Methods for Assessing Corrosion?

ADA Research & Standards Department

- Basic Research of Dental Materials and Products

DENTAL MATERIALS 29 (2013) 702–707

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dental materials

Comparison of the transformation temperatures of heat-activated Nickel-Titanium orthodontic archwires by two different techniques

Original Article

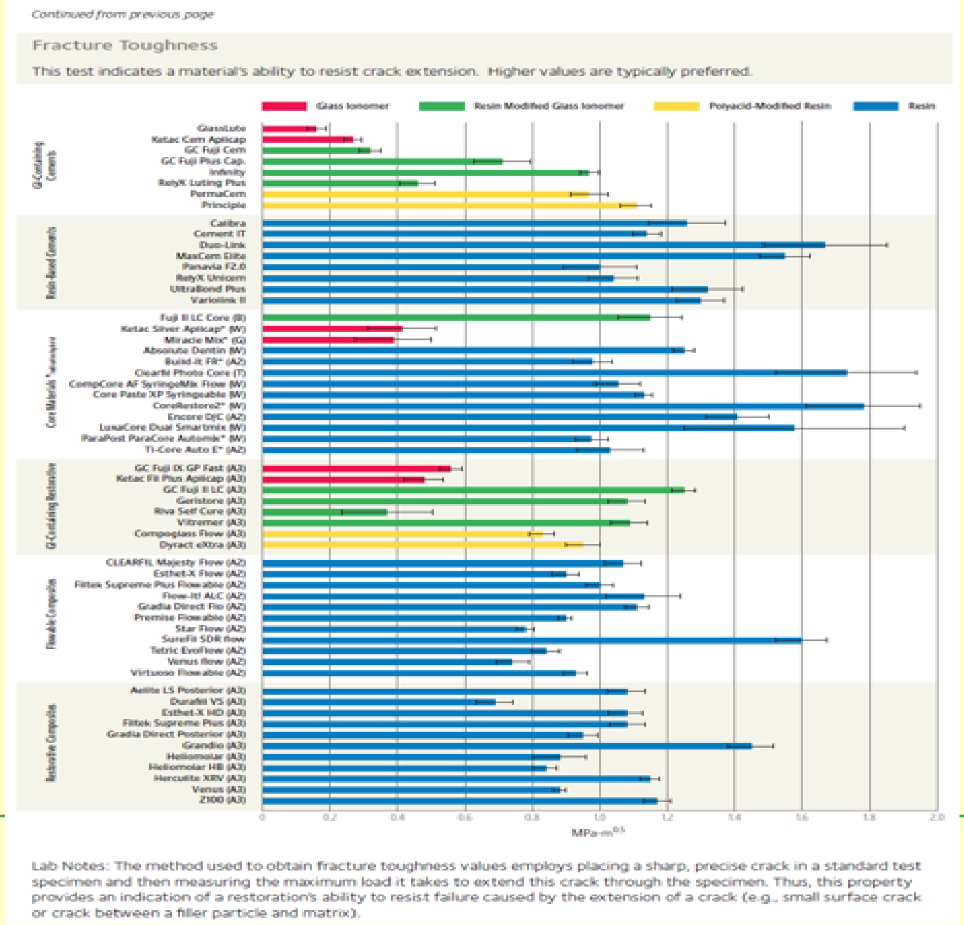
Contemporary esthetic nickel-titanium wires

Do they deliver the same forces?

ADA Research & Standards Department

- Evaluation of Dental Materials and Products

Materials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Fracture Toughness

This test indicates a material's ability to resist crack extension. Higher values are typically preferred.

Glass Ionomer | Resin Modified Glass Ionomer | Polyacid-Modified Resin | Resin

MPa·m^0.5

Lab Notes: The method used to obtain fracture toughness values employs placing a sharp, precise crack in a standard test specimen and then measuring the maximum load it takes to extend this crack through the specimen. Thus, this property provides an indication of a restoration's ability to resist failure caused by the extension of a crack (e.g., small surface crack or crack between a filler particle and matrix).

Equipment


Micromotor MX Series (Bien-Air), Ti-Max NL400 (Brasseler), and SIROTorque L+ (Sirona Dental Systems).

Each manufacturer provided the ADA Laboratories with three systems for the evaluation, which included a motor, control box, couplers and tubing associated with the system, along with a 1:1 (low-speed) contra-angle attachment and 1:5 (high-speed) contra-angle attachment.

We evaluated all seven handpiece systems for the following performance parameters: speed, eccentricity, noise, light profile, speed response to load (resistance), and extraction force. We present the dimensions and weight and balance for both the low- and high-speed attachment plus motor assemblies for ergonomic considerations. Some of the tests were conducted "pre-wear" and "post-wear." Extraction force was measured post-wear for each system.

Handpiece "wearing" consisted of 40 wear-sterilization cycles. (In previous issues of the Review, we referred to this as "Aging.") One wear-sterilization cycle is defined as having the handpiece make four cuts, using standard 557 burs, through a ceramic block specimen (Macor Corning Inc.), followed by one lubrication and sterilization (Figure 1). A steam autoclave capable of operating at 134 ± 2° C (273° F) and 0.21 MNm-2 (30 psi, or 2 bar) was used for sterilization. Cleaner and/or lubricant was applied according to manufacturer instructions. (This test was not intended to predict the longevity of electric handpieces.)

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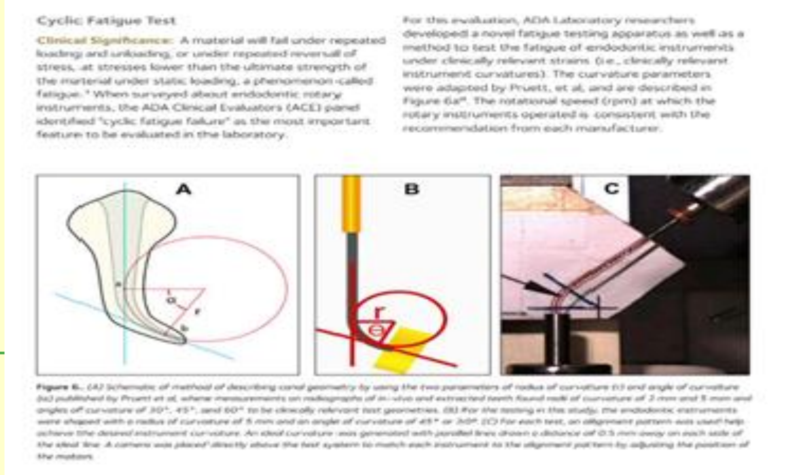
Instruments

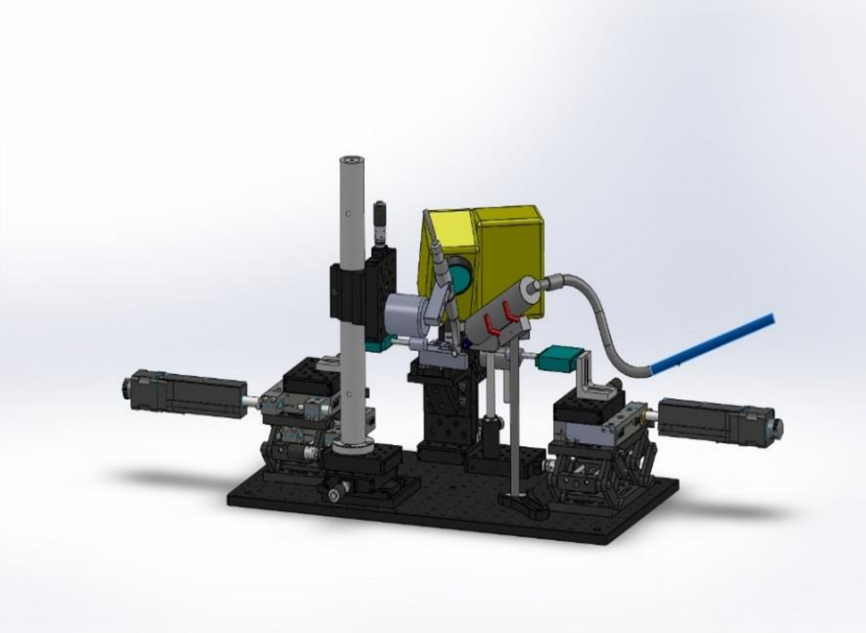

Cyclic Fatigue Test

Clinical Significance: A material will fail under repeated loading and unloading, or under repeated reversal of stress, at stresses lower than the ultimate strength of the material under static loading, a phenomenon called fatigue.[7] When surveyed about endodontic rotary instruments, the ADA Clinical Evaluators (ACE) panel identified "cyclic fatigue failure" as the most important feature to be evaluated in the laboratory.

For this evaluation, ADA Laboratory researchers developed a novel fatigue testing apparatus as well as a method to test the fatigue of endodontic instruments under clinically relevant strains (i.e., clinically relevant instrument curvatures). The curvature parameters were adapted by Pruett, et al, and are described in Figure 6a[8]. The rotational speed (rpm) at which the rotary instruments operated is consistent with the recommendation from each manufacturer.

ADA Research & Standards Department

- Develop Novel Test Methods and Equipment for Standards Development and Product Evaluations



(12) **United States Patent**
Njegovan et al.

(10) **Patent No.:** **US 8,398,454 B2**
(45) **Date of Patent:** **Mar. 19, 2013**

(54) **APPARATUS FOR TESTING THE POLISHABILITY OF MATERIALS**

(75) Inventors: **Nikola Njegovan**, Chicago, IL (US); **Spiro Megremis**, Chicago, IL (US); **Olga Sirovskaya**, Dublin, CA (US); **Hank Shepelak**, Lisle, IL (US)

(73) Assignee: **American Dental Association**, Chicago, IL (US)

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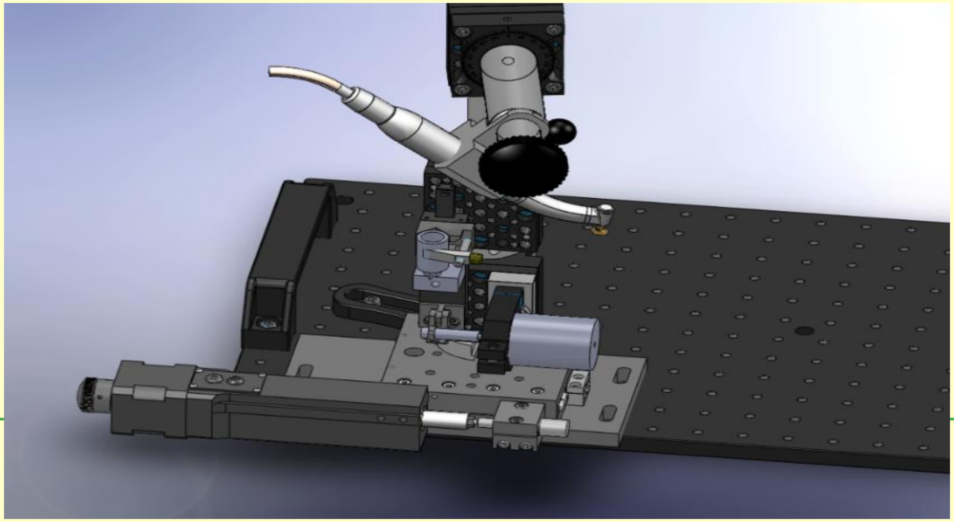
ANSI/ADA Specification 27, "Resin-Based Filling Materials," Jul. 16, 1993.
ISO/DIS 4049 "Dentistry—Polymer-based restorative materials," 2008.



(12) **United States Patent**
Megremis et al.

(10) **Patent No.:** **US 9,250,160 B2**
(45) **Date of Patent:** **Feb. 2, 2016**

(54) **METHOD AND APPARATUS FOR CHARACTERIZING HANDPIECES**

(71) Applicant: **American Dental Association**, Chicago, IL (US)

(72) Inventors: **Spiro John Megremis**, Chicago, IL (US); **Daniel Edward Halpin**, Glen Ellyn, IL (US); **Henry Lukic**, Chicago, IL (US); **Henry J. Shepelak, Jr.**, Lisle, IL (US); **Victoria K. Ong**, San Francisco, CA (US)

(73) Assignee: **American Dental Association**, Chicago, IL (US)

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3,598,999	A	8/1971	Hofmeister
3,717,205	A	2/1973	Wilderman

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ADA Research & Standards Department

- Support ADA Standards Development and Testing

ANSI/ADA Standard No. 134/ISO 22674:2006
Approved by ANSI: February 2013

ANSI

American National Standard/
American Dental Association
Standard No. 134

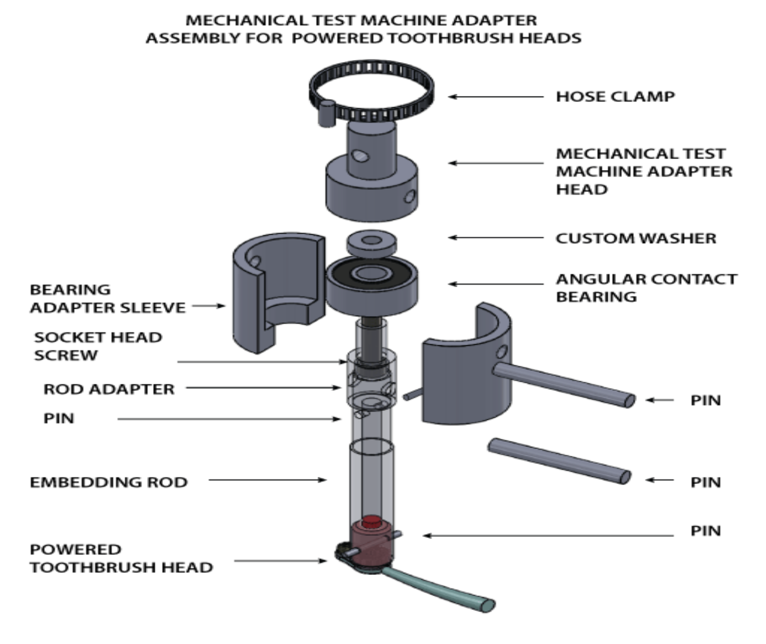
Metallic Materials for Fixed and Removable Restorations and Appliances

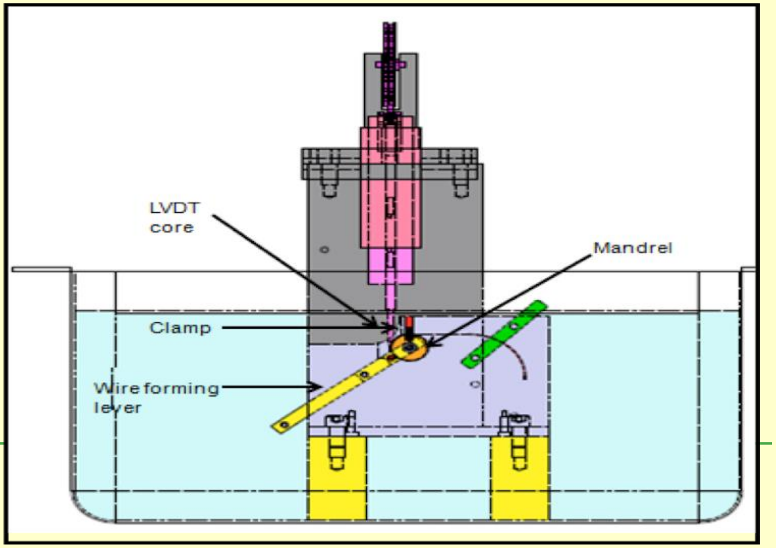
INTERNATIONAL STANDARD **ISO 10271**

Second edition
2011-08-01

Dentistry — Corrosion test methods for metallic materials

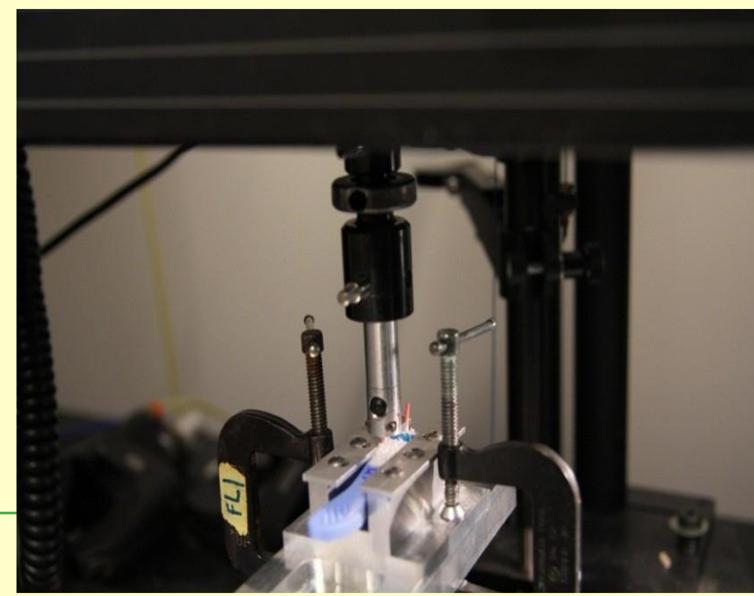
Médecine bucco-dentaire — Méthodes d'essai de corrosion des matériaux métalliques





ADA Research & Standards Department

- Support ADA Seal of Acceptance Product Testing and the *ADA Professional Product Review*



ADA American Dental Association®
America's leading advocate for oral health

STANDARDS EXECUTIVE SUMMARY FOR ADA MEMBERS

ANSI/ADA STANDARD NO. 130:2013
DENTIFRICES – REQUIREMENTS, TEST METHODS AND MARKING

WHAT IS ANSI/ADA STANDARD NO. 130 ABOUT?

This standard gives requirements and test methods for acceptable physical and chemical properties of dentifrices. It also gives the requirements for what information needs to be provided to the consumer on the labeling and packaging of the products for informed decision making.

WHAT ARE THE REQUIREMENTS I SHOULD KNOW ABOUT FOR DENTIFRICES?

ANSI/ADA Standard No. 130 sets the following requirements to ensure safety of the toothpaste for use by consumer:

Maximum Total Fluoride Concentration	No greater than 0.15% by mass (sodium fluoride 0.33%, sodium monofluorophosphate 1.14%, stannous fluoride 0.615% on toothpaste label)
Amount of Total Fluoride in a Single-Unit Container	No greater than 300 mg
Total Maximum Concentration of Heavy Metals	No greater than 20 mg/kg
Acidity	pH must be below 10.5
Abrasivity	Relative Dentin Abrasivity (RDA) no greater than 250
Stability	Expiration date required if product deteriorates in less than 30 months
Readily Fermentable Carbohydrates	None allowed in ingredients

WHAT'S THE BOTTOM LINE?

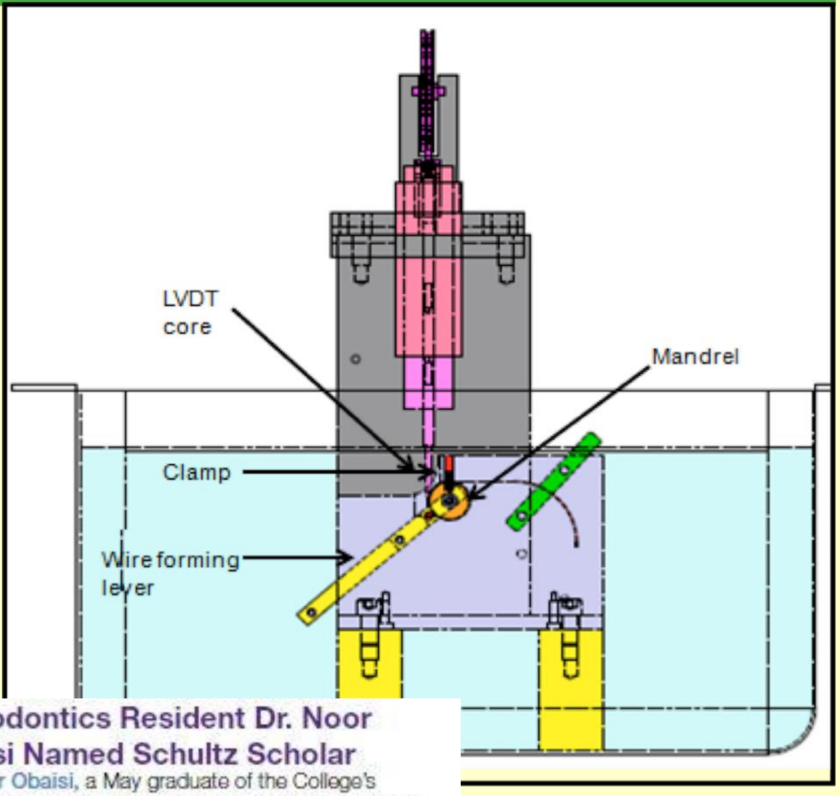
ANSI/ADA Standard No. 130 sets the fluoride concentration, acidity, and abrasivity limits for toothpastes that are safe for consumer use.

WHAT ARE ANSI/ADA STANDARDS?

ANSI/ADA Standards are technical documents developed through the expertise of a diverse group of volunteer stakeholders including dental professionals/consumers, scientific researchers, industry innovators and government. They are the safety net you never knew was there, setting requirements that ensure your needs are met for safe and reliable products and making sure you have the information you need to make informed purchasing decisions. The standards process works for you, setting the stage so that the dental products, processes, and systems you rely on every day work the way you need them to and operate effectively together. Dental standards give you greater purchasing power, more choices and lower costs by ensuring technologies work across manufacturers.

ASTM Standards used in ANSI/ADA and ISO Standards

- ASTM F2082 – Standard Test Method for Determination of Transformation Temperature of Nickel Titanium Shape Memory Alloys by Bend and Free Recovery



Designation: F2082 – 06

Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery[1]

This standard is issued under the fixed designation F2082; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

Dentistry — Wires for use in orthodontics

1 Scope

This International Standard specifies requirements and test methods for wires to be used in fixed and removable orthodontic appliances. It includes preformed orthodontic archwires but excludes springs and other preformed components.

This International Standard gives detailed requirements concerning the presentation of the physical and mechanical properties of orthodontic wires, the test methods by which they can be determined, and packaging and labelling information.

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 — Vocabulary*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ASTM F2082, *Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery*

Orthodontics Resident Dr. Noor Obaisi Named Schultz Scholar

Dr. Noor Obaisi, a May graduate of the College's Orthodontic specialty program, received the first place $1,000 prize in the Charley Schultz Resident Scholar research competition at this year's national meeting of the American Association of Orthodontists in Philadelphia.

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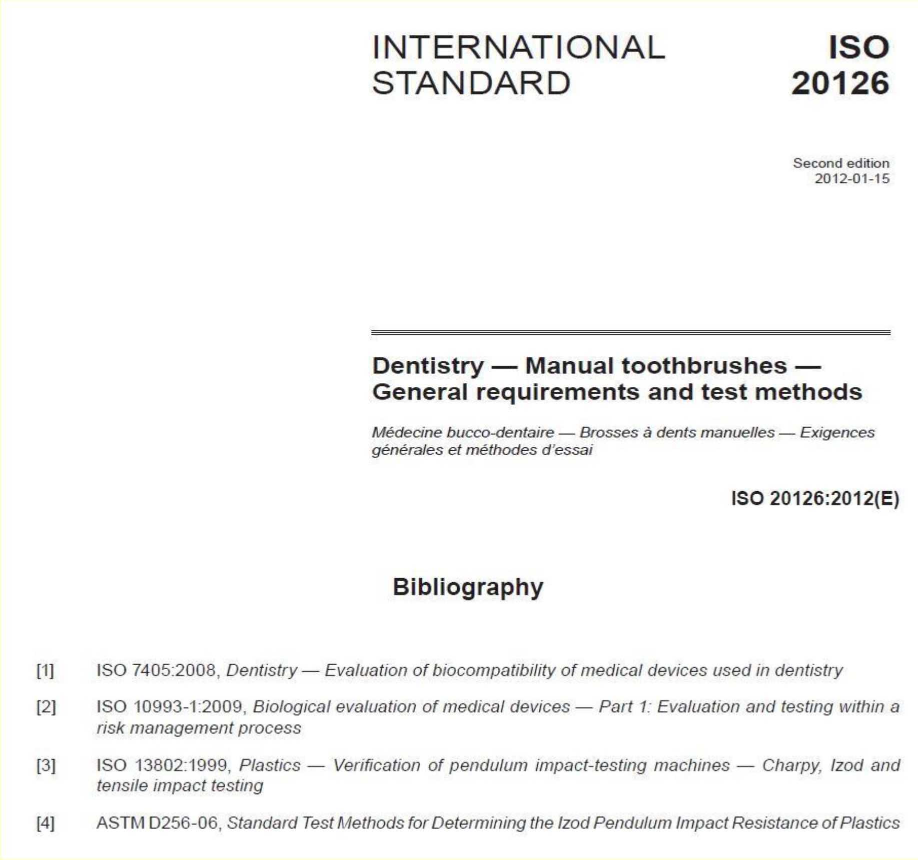
dental materials

Comparison of the transformation temperatures of heat-activated Nickel-Titanium orthodontic archwires by two different techniques

ASTM Standards used in ANSI/ADA and ISO Standards

- ASTM D256 – Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics



INTERNATIONAL STANDARD

ISO 20126

Second edition
2012-01-15

Dentistry — Manual toothbrushes — General requirements and test methods

Médecine bucco-dentaire — Brosses à dents manuelles — Exigences générales et méthodes d'essai

ISO 20126:2012(E)

Bibliography

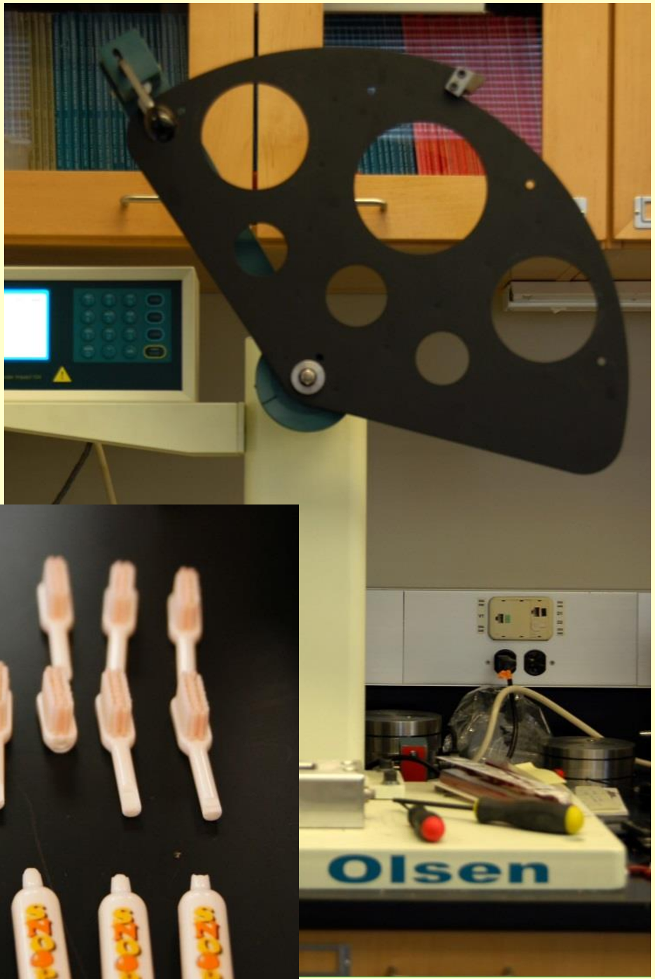
[1] ISO 7405:2008, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

[2] ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[3] ISO 13802:1999, *Plastics — Verification of pendulum impact-testing machines — Charpy, Izod and tensile impact testing*

[4] ASTM D256-06, *Standard Test Methods for Determining the Izod Pendulum Impact Resistance of Plastics*

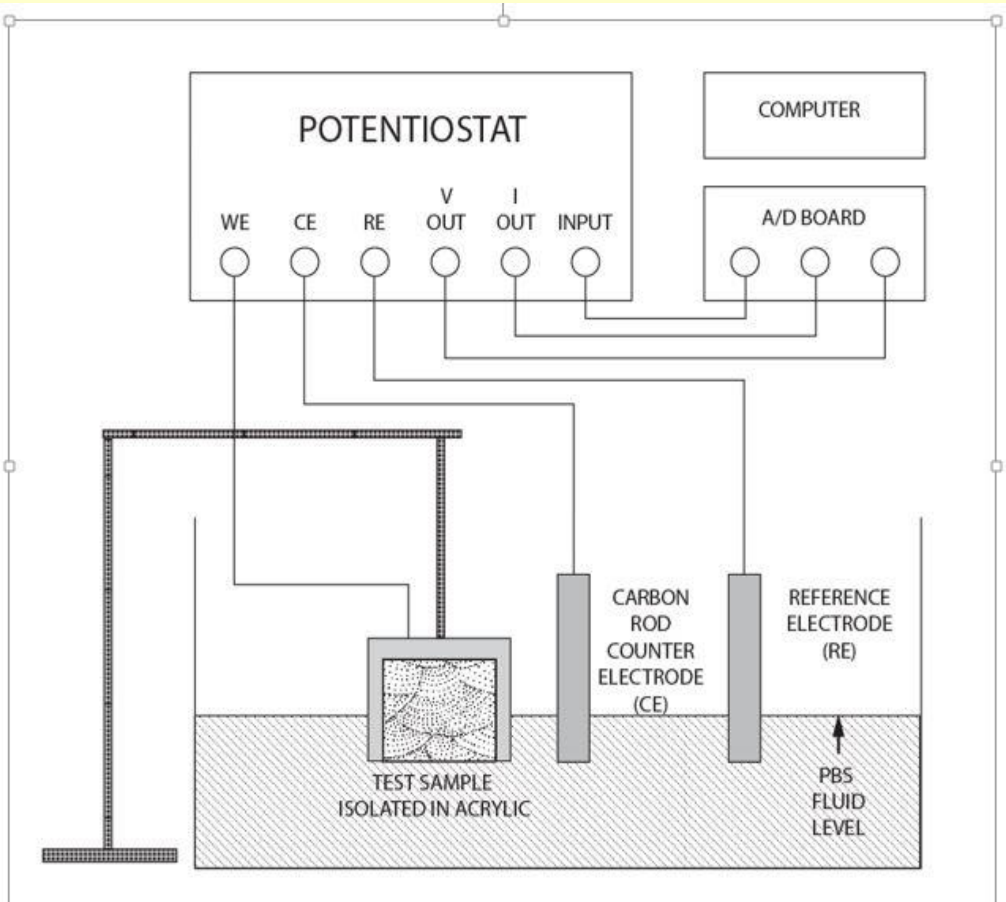
Tinius Olson Impact Tester Model 504 with ASTM D 256 Striker



ASTM F 2129

- ASTM F 2129 – Standard Test Methods for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices
- Illustration shows a typical test set-up for conducting cyclic potentiodynamic polarization measurements. It includes a high impedance potentiostat that is used to control the potential of the test specimen, while the resulting current is measured. This is done by using a 3-electrode electrochemical cell:

1. Working electrode, WE (test sample)
2. Counter electrode, CE, such as high purity platinum or vitreous carbon
3. Reference electrode, RE, such as standard hydrogen electrode (in practice usually use a secondary electrode such as saturated calomel electrode

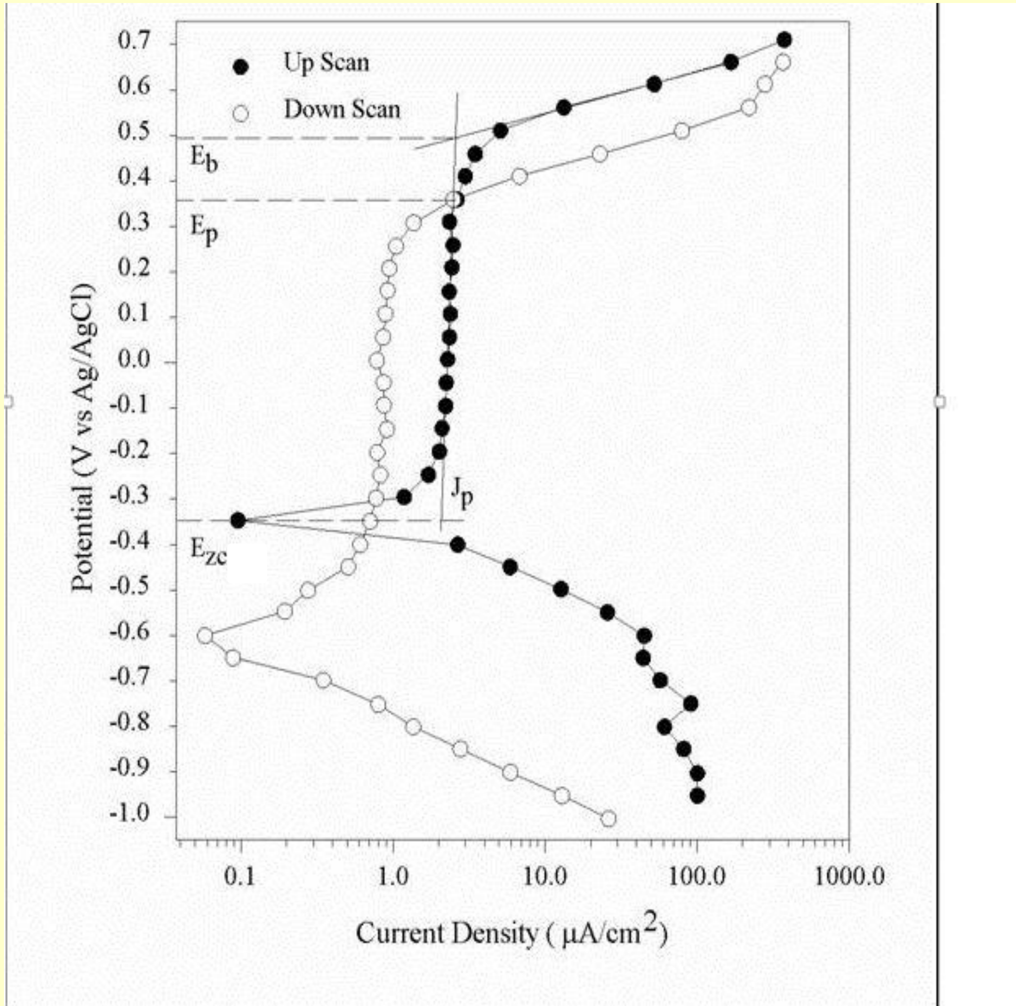


Typical test set-up for performing electrochemical polarization tests. The test set-up includes a potentiostat that controls a standard three-electrode cell containing a reference electrode (e.g., saturated calomel), a counter electrode (e.g., high-purity platinum), and the sample to be tested, which is termed the working electrode. Note that the sample is isolated, so that only a known surface area is exposed to the solution. This is so that current density (current per unit area) calculations can be made from the current data. Electric connection is made to the sample by a wire attached through the isolating material to the back of the sample.

ASTM F 2129

- The picture shows a polarization curve for an ASTM F75 CoCrMo alloy

1. As the potential increases above the **zero current potential** (Ezc, the potential at which the current reaches a minimum during the forward scan), some critical current density for passivity (Jp) is achieved, and above this potential the current density practically stays the same, until some critical potential is reached.
2. The point on the curve where the current density again increases with potential is the **Breakdown potential**, Eb.
3. Eb = Breakdown or Critical pitting potential – the least noble potential at which pitting or crevice corrosion or both will initiate and propagate
4. An increase in the resistance to **pitting corrosion** is associated with an increase in Eb



Polarization curve for a cast cobalt-chromium-molybdenum alloy, which meets ASTM F 75 (ASTM) requirements for surgical implants. The alloy was tested at a scan rate of approximately 1.5 mV/s in aerated physiologic phosphate buffered saline, which was heated and held at a temperature of 37 ± 1 °C with a pH of 7.4 ± 2. The sample was scanned from -1000 to +700 mV vs. Ag/AgCl and back down to -1000 mV vs. Ag/AgCl. Source: Megremis, 2001: p. 97.

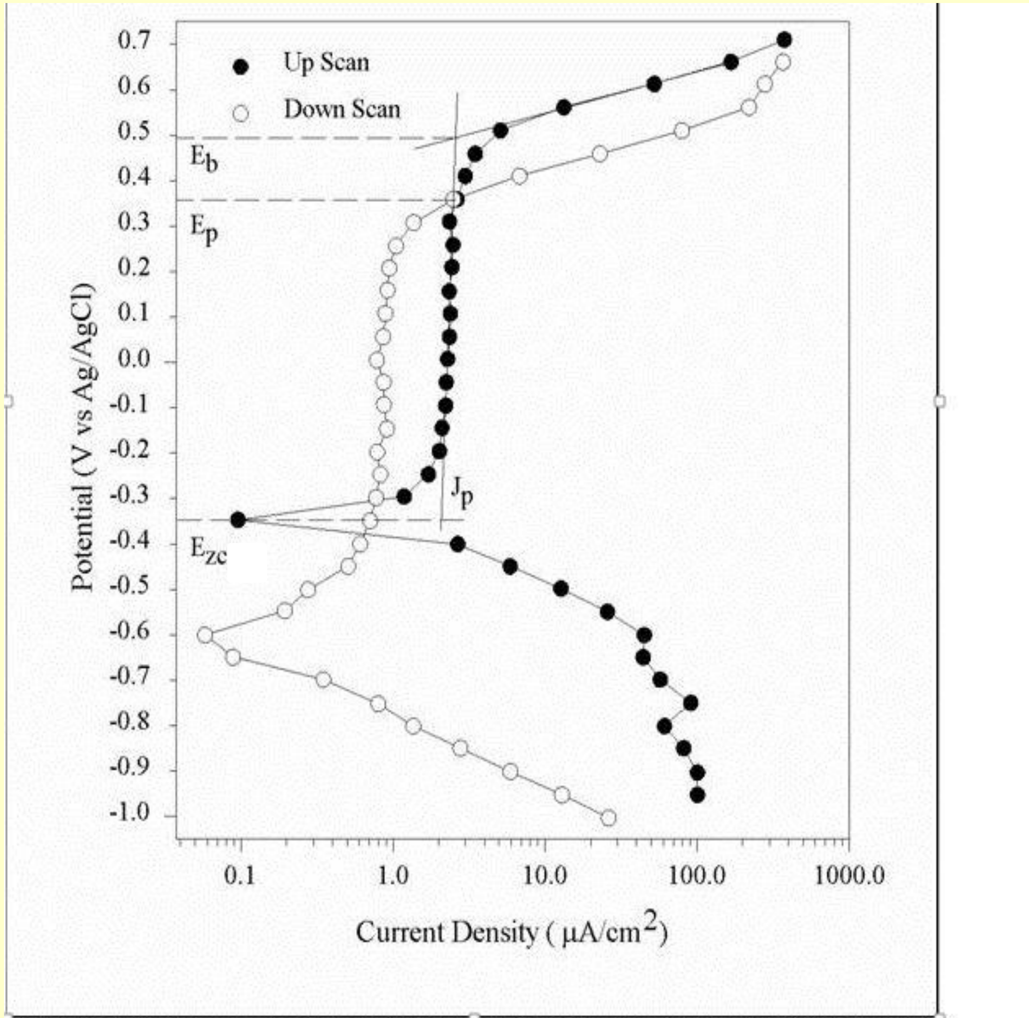
ASTM F 2129

5. On the reverse scan (down scan), the potential at which the reverse scan intersects the forward scan at a value that is less noble than Eb is the **Protection potential**, Ep.

6. Below Ep, existing pits will not grow (F2129 Appendix).

7. The magnitude of the hysteresis between the up and down scans is Eb-Ep, which is considered to be a measure of how resistant the material is **to crevice corrosion** (F2129 Appendix)

8. If Eb-Ep is minimal, then the material is **very resistant to crevice corrosion** (F2129 Appendix).

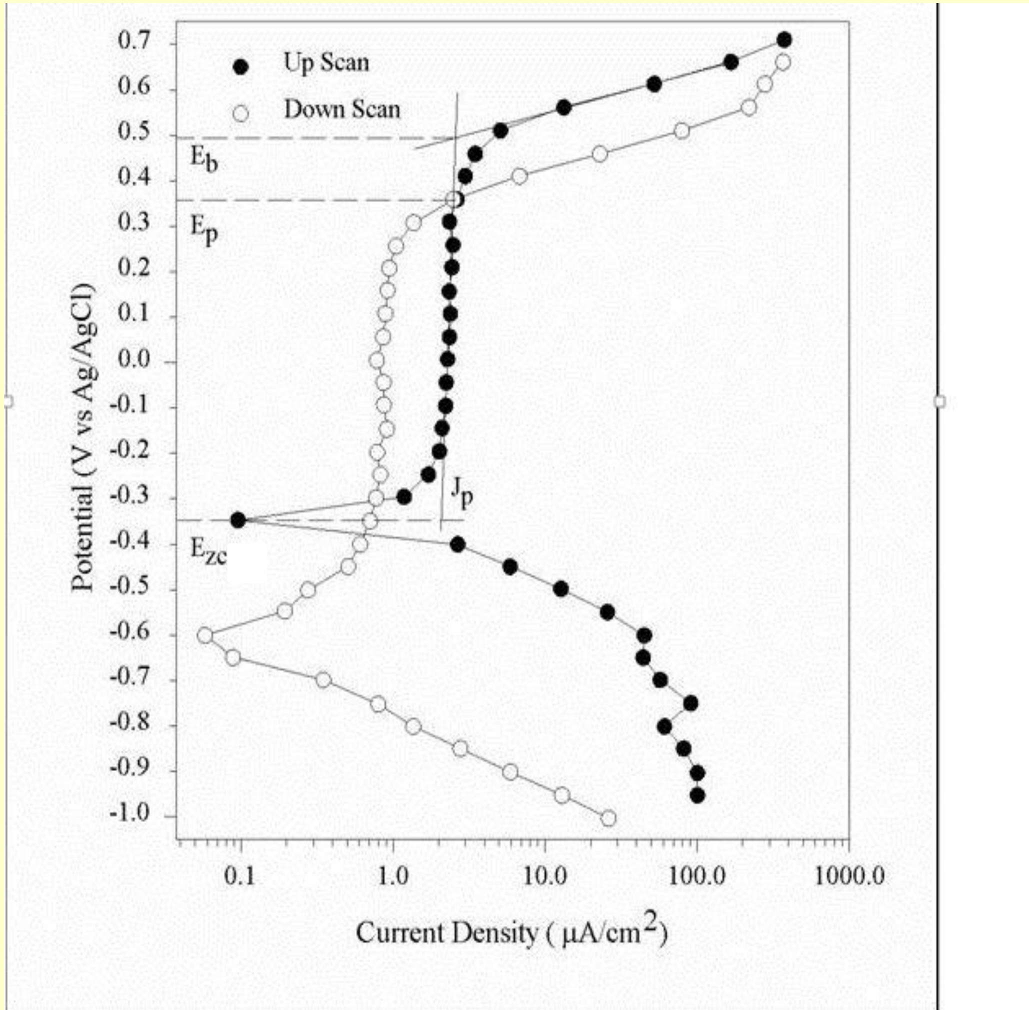


Polarization curve for a cast cobalt-chromium-molybdenum alloy, which meets ASTM F 75 (ASTM) requirements for surgical implants. The alloy was tested at a scan rate of approximately 1.5 mV/s in aerated physiologic phosphate buffered saline, which was heated and held at a temperature of 37 ± 1 °C with a pH of 7.4 ± 2. The sample was scanned from -1000 to +700 mV vs. Ag/AgCl and back down to -1000 mV vs. Ag/AgCl. Source: Megremis, 2001: p. 97.

ASTM F 2129

- Some of the test parameters for the polarization curve shown in the picture deviate from the test procedure in ASTM F 2129.

1. F 2129 specifies the use of a saturated calomel electrode for a reference electrode. In this test, a silver/silver-chloride electrode was used. However in the next revision this will be changed to read similar to F3044: "If another standard electrode is used (for example, Ag/AgCl), data should be adjusted so that it is reported with respect to SCE.
2. F2129 specifies a scan rate of either 0.167 mV/s or 1 mV/s. In this test, a scan rate of about 1.5 mV/s was used. F2129 has the following note: "…the scan rate may affect the breakdown potential of the device and the shape of the passive region of the polarization curve. Comparisons should not between test results using different scan rates, even if all other experimental parameters are held constant."

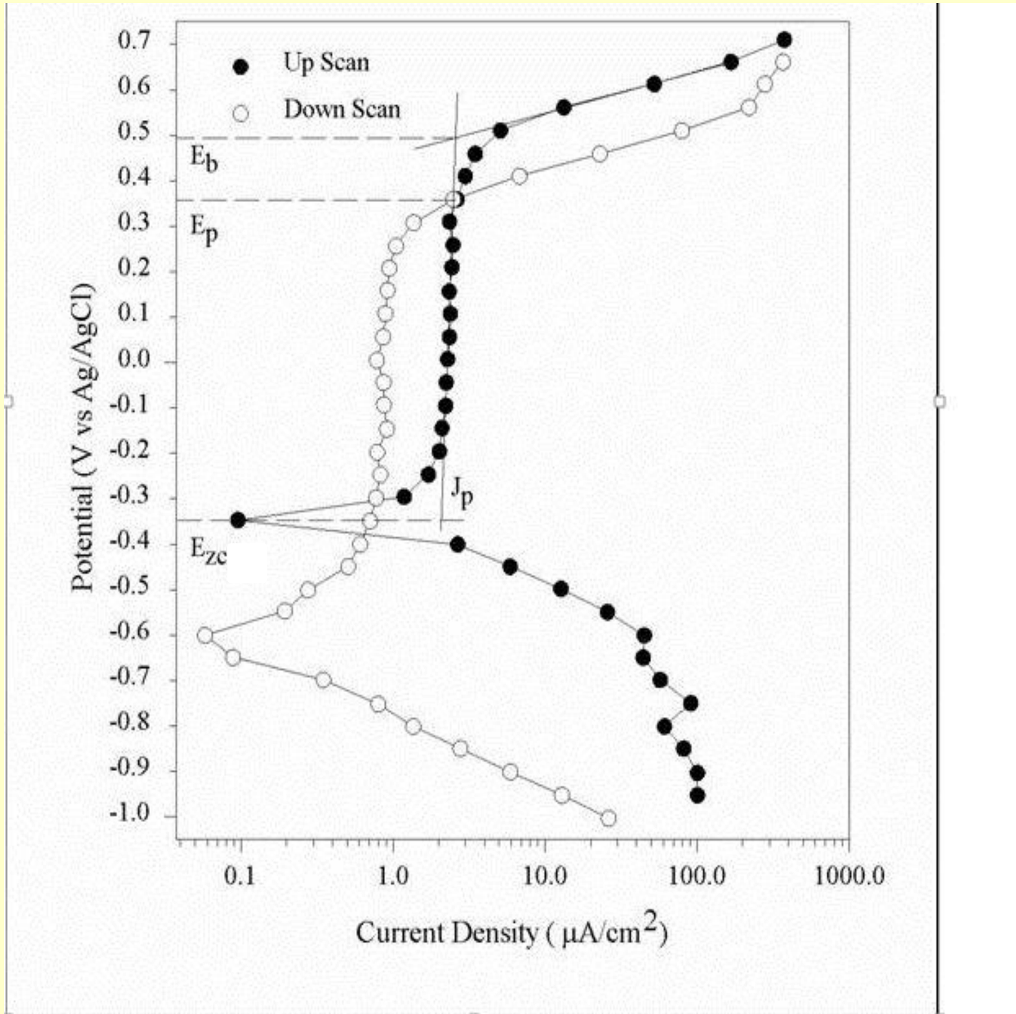


Polarization curve for a cast cobalt-chromium-molybdenum alloy, which meets ASTM F 75 (ASTM) requirements for surgical implants. The alloy was tested at a scan rate of approximately 1.5 mV/s in aerated physiologic phosphate buffered saline, which was heated and held at a temperature of 37 ± 1 °C with a pH of 7.4 ± 2. The sample was scanned from -1000 to +700 mV vs. Ag/AgCl and back down to -1000 mV vs. Ag/AgCl. Source: Megremis, 2001: p. 97.

ASTM F 2129

- Some of the test parameters for the polarization curve shown in the picture deviate from the test procedure in ASTM F 2129.

3. F2129 specifies the test specimen be placed in a deaerated simulated physiological solution. However, in this study, an aerated solution was used. The Appendix of F 2129 states that "Deaerating the solution with nitrogen gas before and during the test will lower the concentration of dissolved oxygen in the solution. This condition is **necessary** for the **determination of the critical potentials Eb and Ep**, if the actual values are close to or lower than the rest potential in the presence of oxygen…".

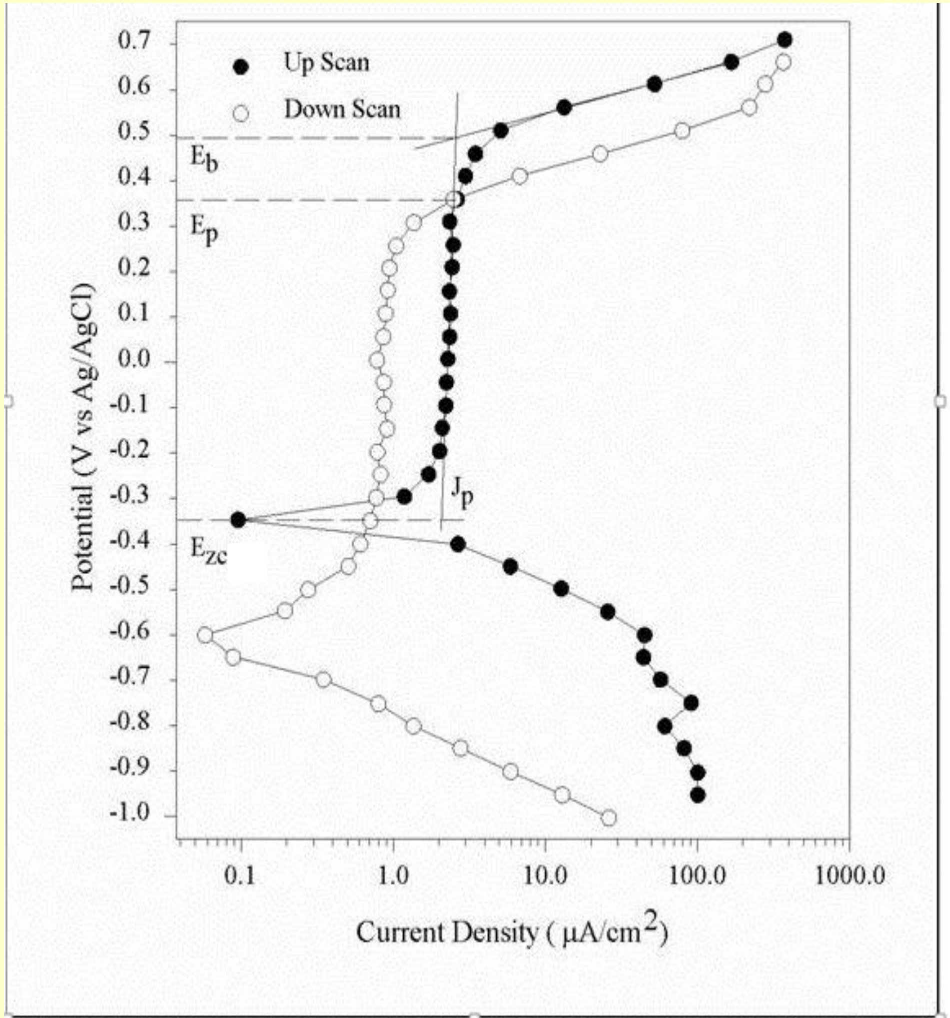


Polarization curve for a cast cobalt-chromium-molybdenum alloy, which meets ASTM F 75 (ASTM) requirements for surgical implants. The alloy was tested at a scan rate of approximately 1.5 mV/s in aerated physiologic phosphate buffered saline, which was heated and held at a temperature of 37 ± 1 °C with a pH of 7.4 ± 2. The sample was scanned from -1000 to +700 mV vs. Ag/AgCl and back down to -1000 mV vs. Ag/AgCl. Source: Megremis, 2001: p. 97.

ASTM F 2129

- **BOTTOMLINE:**

1. Details are very important in these types of tests.
2. It should be remembered that this is a screening test with a great deal of historical data in the literature and possessed by companies using this method. It does NOT replicate conditions *in vivo*.



Polarization curve for a cast cobalt-chromium-molybdenum alloy, which meets ASTM F 75 (ASTM) requirements for surgical implants. The alloy was tested at a scan rate of approximately 1.5 mV/s in aerated physiologic phosphate buffered saline, which was heated and held at a temperature of 37 ± 1 °C with a pH of 7.4 ± 2. The sample was scanned from -1000 to +700 mV vs. Ag/AgCl and back down to -1000 mV vs. Ag/AgCl. Source: Megremis, 2001: p. 97.

Acknowledgements

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Thank You!