Standard Material Test Methods for Medical Device Development

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Outline

• Why are standards important to CDRH?
• Material Test Methods Standards
• Developing ASTM standards: Write the method and then test it
  – MRI
  – Pitting Corrosion
  – Bone Cement
Why are Standards Important to CDRH?

• Medical Device Amendments of 1976
  – FD&C Act section 514 ( 21 U.S. Code 360d. )

• CDRH was a leader in use of Standards

• Safe Medical Device Act of 1990
  – Promulgation of mandatory standards at the Agency’s discretion

• FDA Modernization Act of 1997
  – Revised Section 514(c)
  – Added ability to formally recognize a standard, “all or in part”
  – Added the ability to accept a formal Declaration of Conformity
Passage of the National Technology Transfer and Advancement Act (NTTAA) of 1995
Signed into law March 7, 1996
Grew out DoD’s experience of relying more on voluntary consensus standards and less on Military Specifications (MIL SPECs)
NTTA Objective

- National Technology Transfer and Advancement Act (NTTAA) P.L. 104 – 113

- ...Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.

- ...Federal agencies and departments shall consult [and “participate”] with voluntary, private sector, consensus standards bodies...
OMB Circular A-119

• Sets forth requirements for Agency participation in use & development of voluntary consensus standards

• Sets forth requirements for incorporation of standards into Agency regulations

• Goals:
  – Eliminate Government costs
  – Provide incentives that serve national needs
  – Encourage long-term growth for the US
  – Promote economic competition
FDA & Standards

- 21 CFR 10.95, Participation in outside standard-setting activities
- FDA Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines, 60 FR 53078 (Oct. 11, 1995).
- FDA Staff Manual Guide (SMG, adopted March 2007)
FDA SMG 9100.1

• Recognize by reference either in its entirety or in part standards developed by SDOs
• FDA will preferentially use internationally harmonized standards
• Guidances published by FDA will, wherever appropriate, reference standards
• FDA encourages sponsors of product applications and manufactures to cite standards
• FDA incorporates voluntary consensus standards
• We have partnered with ASTM for many years to develop consensus standards
Why are Standards Important to CDRH?

- Standards help us accomplish our mission & attain our vision
- Mission – to protect and promote the public health
  - to assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products
- Vision – to assure that patients have access to high-quality, safe, and effective medical devices of public health importance
- Standards are developed with input from CDRH, Industry, Government
  - Leveraging knowledge of all stakeholders
- Allows everyone to use the same method
  - Efficient for Industry and CDRH reviewers
Committee F04 Structure

• F04.01 Division I - Resources

• F04.02 Division II - Orthopaedic Devices

• F04.03 Division III - Medical/Surgical Devices

• F04.04 Division IV - TEMPs

• F04.05 Division V - Computer Assisted Orthopaedic Surgical Systems
Committee F04 Structure

- F04.01: Division I on Resources - Terry Woods
- F04.11 on Polymeric Materials - Jon Moseley/Steve Kurtz
- F04.12 on Metallurgical Materials - Rod McMillan
- F04.13 on Ceramic Materials - Gary Fischman
- F04.15 on Material Test Methods - Terry Woods
- F04.16 on Biocompatibility - Anita Sawyer
F04.15 Material Test Methods

- Approximately 50 standards
  - 5-10 under development
- Covering testing of materials (not specific devices)
  - Corrosion
  - MRI safety & compatibility
  - Cleanliness
  - UHMWPE & PAEK mechanical testing
  - Nitinol test methods
  - Bone Cement
  - Absorbable Polymers
  - Coatings
  - Biomechanics load measurement
  - Hydrogel mechanical testing
Types of Standards

• Guide — a compendium of information or series of options that does not recommend a specific course of action.
  – Increases awareness of information and approaches in a given subject area.

• Practice — a definitive set of instructions for performing one or more specific operations that does not produce a test result.
  – Examples include: application, assessment, cleaning, collection, decontamination, inspection, installation, preparation, sampling, screening, and training.

• Terminology standard — a document comprising definitions of terms; explanations of symbols, abbreviations, or acronyms.
Types of Standards

• Specification —an explicit set of requirements to be satisfied by a material, product, system, or service.
  – Examples: requirements for physical, mechanical, or chemical properties, & safety, quality, or performance criteria. It identifies the test methods for determining whether each of the requirements is satisfied.

• Test method —a definitive procedure that produces a test result.
  – Examples: identification, measurement, and evaluation of one or more qualities, characteristics, or properties. A precision and bias statement shall be reported at the end of a test method.
Developing ASTM Standards

- Write the method and then test it
- Interlaboratory studies – round robin testing
  - Testing the test method
  - Assessing within and between lab variability
- Examples
  - MRI
  - Pitting Corrosion
  - Bone Cement
MRI Example

- MRI is an invaluable imaging tool
- There are some safety issues

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Introduction

• First MRI scanners approved in 1984
• Safety Concerns produced by
  – Large Static Field and Spatial Gradients, dB/dx
    Current clinical scanners: 3T, > 1500 gauss/cm
    >50,000 times Earth’s magnetic field
  – Pulsed RF fields 128 MHz for 3T scanner
    used to elicit MR signal from tissue
Patient without braces

http://www.shc.uiowa.edu/cohrcd/artifact.htm

Patient with full set of braces

www.fda.gov
3D gradient echo image of knee with implanted metal screw

3D fast spin echo sequence image of knee with implanted metal screw

http://www.shc.uiowa.edu/cohrcd/artifact.htm

www.fda.gov
Standards for Implants and Other Medical Devices

- FDA asks for information demonstrating MR safety for finished devices
- Needed test methods did not exist
- In 1997, FDA requested ASTM International consider developing MR safety/compatibility standards
Standards for Implants and Other Medical Devices

• ASTM task group F04.15.11 on MR Safety and Compatibility of Materials and Medical Devices
  – Completed 5 standards addressing the principal issues that produce safety concerns for implants and other devices in the MR environment
ASTM MR Test Methods

• ASTM F2052 for Measurement of *Magnetically Induced Displacement Force* on Medical Devices in the MR Environment

• ASTM F2119 for Evaluation of *MR Image Artifacts* from Passive Implants

• ASTM F2182 for Measurement of Measurement of *Radio Frequency Induced Heating* Near Passive Implants During MRI

• ASTM F2213 for Measurement of *Magnetically Induced Torque* on Medical Devices in the MR Environment

• ASTM F2503 Standard Practice for *Marking Medical Devices and Other Items for Safety* in the Magnetic Resonance Environment
ASTM F2052 - Test Method for Displacement Force

• Interlaboratory study in progress
ASTM F2213 - Test Method for Torque

Acceptance Criterion: Torque less than worst case torque due to gravity, defined as (Weight)(Length)

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ASTM F2119 – Test Method for Image Artifact

• Defines standard sequences for determining artifact so the amount of artifact for different devices can be compared

• No acceptance criteria: Depending on region of interest, different amounts of artifact are acceptable

• In some cases, artifacts are desirable (biopsy needles, image guided surgery)
ASTM F2182 - Measurement of RF Induced Heating near Passive Implants

- Place device in gelled saline phantom
- Subject to RF field and measure worst case temperature rise during scan
ASTM F2503 - Practice for Marking Items for Safety in MRI

• Intent:
  – TO PREVENT MR RELATED ACCIDENTS
  – To introduce terms and MR icons consistent with international safety signs

• MR Safe
  ![MR Safe Icon]

• MR Conditional
  ![MR Conditional Icon]

• MR Unsafe
  ![MR Unsafe Icon]
Pitting Corrosion Example

Implants are subject to corrosion

- In the 1990s Nitinol use in implants was increasing
- CDRH labs noticed poor corrosion behavior for some devices
- No standardized test method existed

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Pitting Corrosion Example

• Drafted test method for pitting corrosion of small implants

• Worked with industry & universities to develop & test the method

Designation: F2129 – 15

Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices¹

This standard is issued under the fixed designation F2129; 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.

1. Scope

1.1 This test method assesses the corrosion susceptibility of small implant devices using cyclic polarization measurements.

2. Referenced Documents

2.1 ASTM Standards:²

D1103 Specification for Reagent Water

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What is Bone Cement?

- PMMA material used for over 50 years to fix joint implants to living bone
- ~750,000 hip & knee replacements/year
Fatigue Testing of Bone Cement

- Fatigue failures happen
- No standard test
- We helped write a test method
- Participated in interlaboratory study to help test the test method

Designation: F2118 – 14

Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials

This standard is issued under the fixed designation F2118; 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 (€) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method describes test procedures for evaluating the constant amplitude, uniaxial, tension-compression uniform fatigue performance of acrylic bone cement samples.

F451 Specification for Acrylic Bone Cement

2.2 ISO Standard:

ISO 16402 Flexural Fatigue Testing of Acrylic Resin Cements Used in Orthopedics
Interlaboratory Study

• Make bone cement fatigue specimens
• Set up testing machine and fixtures
• Perform testing using the method
Summary

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