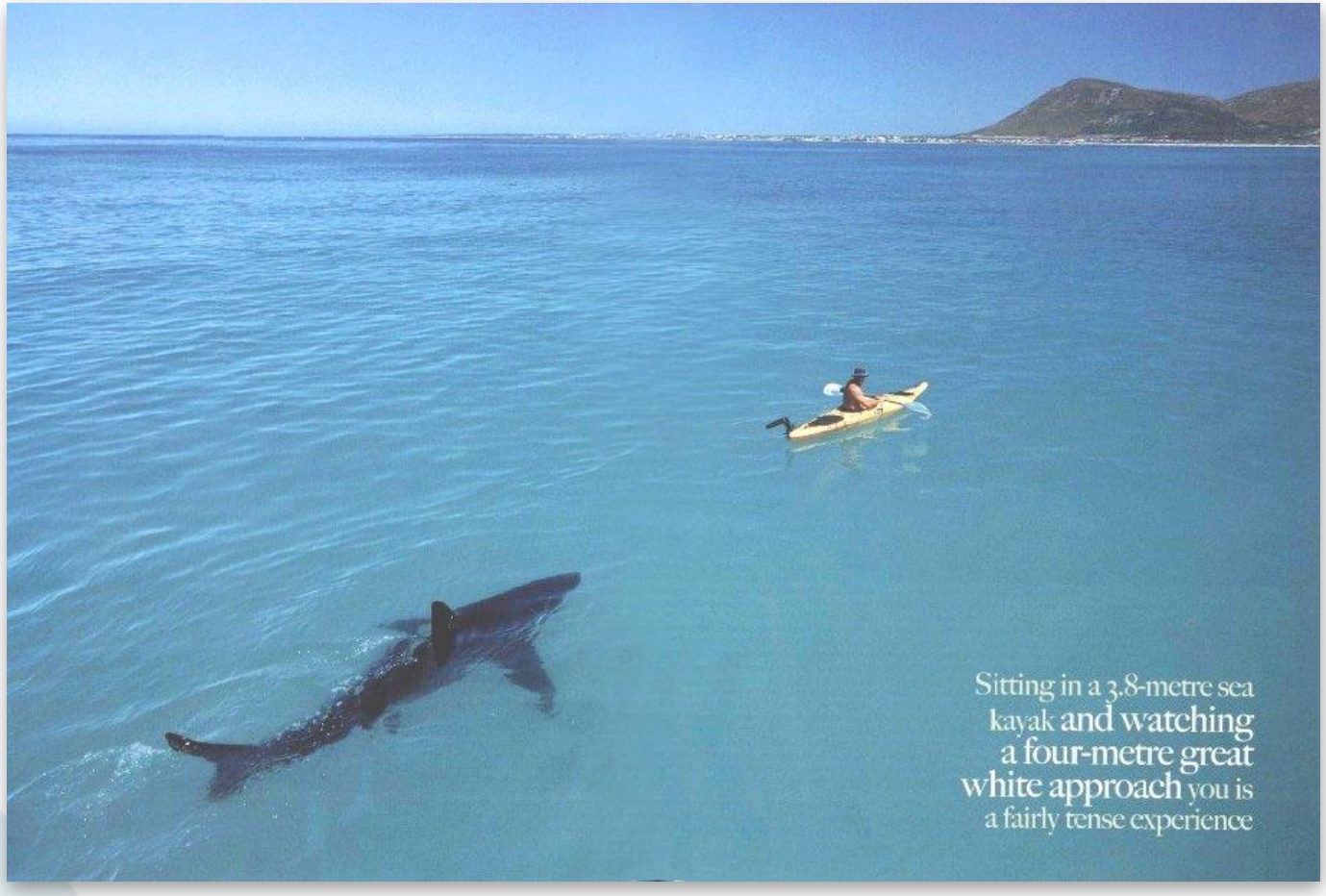
ASTM Material Test methods for assessing the performance of orthopedic devices

PERU Workshop. January 25, 2017

EMPIRICAL

Sometimes how it feels to be in the medical industry…



Overview

- All regulatory agencies are constantly evolving to keep pace with new technology advances - this translates to potential changes in testing requirements
- Regulatory agencies utilize testing standards for accuracy, reproducibility, and traceability
- Test laboratory Quality Systems – ISO 17025
- Mechanical Testing 101 & Deviations
- Specific methods that address materials for orthopedic applications

General Rules for Successful Mechanical Testing

- Each submission is a custom evaluation based upon experience and current knowledge.
- Understand regulatory strategy – Class I, II, or III (FDA, MDD, etc.)
- Understand that different devices (indications) may have different requirements for the testing evaluation
- Understand the requirements of the regulatory agency (global harmonization efforts)
- Determine worse case scenario, including a protocol with acceptance criteria

Why ISO 17025?

ISO 17025 is critical to testing as it ensures that a test (or calibration) lab is technically competent. If a lab is 17025 accredited, you can have confidence that the data is precise as well as accurate. In addition to providing consistent, reliable data, an ISO 17025 test lab has also been proven to show continual improvement in their management system. Continual improvement yields efficiency gains, decreased error rates, and task consistency.

Mechanical Testing 101

- Measure for safety and effectiveness
- Goal: Characterize the overall performance of the system and any ***unique features (FMEA)***
- Most testing per ASTM and/or ISO standard; geared towards specific device type or intended use
- Generally required for Class II & III devices (different levels of testing depending on the regulatory agency)
- Risk assessment is required for all classifications. Even instruments are required to be developed using design controls, which require risk assessment.
- Predicate device testing – availability and legality

Mechanical Testing – why do it right?

- Significant investment (time & $$$)
  - Cost of test specimens (destructive testing)
  - Cost of testing activities ($1K to $250K)
  - Multiple rounds of testing
  - Time for testing
    - Usually at end of product development timeline
    - Dynamic testing can range from several weeks to 6-9 months
- Provides the fundamental information about the system being evaluated
- Feasibility (product development testing) vs. regulatory testing
- Critical component in product development cycle

General Rules for all Mechanical Testing

- New specimens used for each test (unless non-destructive)
- New test blocks (unless non-destructive)
- Perform testing on the correct number of specimens
- Any test method can be modified – with good science and justifications
- Adding/removing degrees of freedom will impact either test device or fixtures

Factors that may impact the test results

- Test configuration
- Frequency of dynamic tests
- Test block/fixture material
- Test block interface and fit
- Environment
- Data collection rate
- Specimen variability (especially if there are preparation steps)
- Test equipment (load cell size, etc.)
- Conditioning of the specimens: gamma sterilization for some polymers, pre-soaking of the specimens, etc.

Anatomy of a Test Method

1. *Scope*
2. *References*
3. *Terminology*
4. *Summary of Test Methods*
5. *Significance and Use*
6. *Apparatus*
7. *Sampling*
8. *Procedure*
9. *Report*
10. *Precision & Bias*
11. *Appendices*

Why do deviations exist?

- Test methods cannot account for device evolution and innovation
- Device manufacturers develop and perform tests prior to formal methods are developed.
  - Leads to historical data and reluctance to change/conform to new methods
- Details of standard overlooked or misinterpreted
- Testing to publication
- Common Deviations
  - Test rate or frequency
  - Test specimen assembly
  - Moment arms
  - Load spans
  - Test Fixtures

Anatomy of a Test Method vs. FDA Guidance vs. Industry Practices

	ASTM or ISO Std	FDA Guidance
Number of test specimens - static	n=5	n=6
Number of test specimens - dynamic	Varies but generally states "The final sample size is recommended by Practice E 739"; industry generally follows FDA guidance	n=6 with n=2 reaching endurance cycle count at same load value
Test Modes	Generally axial compression (bending), torsion (axial rotation), shear (45), flexion-extension, cantilever bending	Depends on device level, indication, geometry, material, other factors

ASTM Standards – Materials in Orthopedic Applications

- **ASTM F732**: 2011 Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses
- **ASTM F1044**: 2011 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- **ASTM F1147**: 2011 Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- **ASTM F1160**: 2014 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
- **ASTM F2118**: 2014* Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials
- **ASTM F2183**: 2008 Standard Test Method for Small Punch Testing of Ultra-High Molecular Weight Polyethylene Used in Surgical Implants
- **ASTM F2977**: 2013 Standard Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants

ASTM F732 (Wear testing)

- Fully understand and document all specimen manufacturing methods and processes
  - Critical for bearing surfaces as preparation methods may have adverse effect on wear (polishing compounds may imbed into specimen)
  - Sterilization methods may have an effect on material wear characteristics
- Characterize polymer absorption with test medium prior to initiating wear testing, can also use control soak
  - Can mask wear rate if not fully understood
- Characterize bearing surfaces roughness and geometric features prior to testing (helps with wear assessment later on in process)
- Three primary test methods: must be justified
  - Nominally linear motion delamination
  - Fixed bearing ball-cup such as hips
  - Linear reciprocating wear motion

ASTM F732 (Wear testing) - continued

- Specimen must be thoroughly cleaned
  - Reference ASTM F2025 for polymers
- Test medium is typically bovine serum with a specific protein level matched to device indication. Bovine dilution or level of protein content should be validated/justified.
  - Experiments have shown the DI water and saline do not duplicate the lubricating properties of serum or synovial fluid
  - Storage of the bovine serum before and after the testing may also impact the results

ASTM F1044 (Shear) , F1147 (Tension), and F1160 (Shear Fatigue)

- All material coatings standards
- Coating application and substrate processing must be same as final device
- Specimen preparation is critical
  - Specimen alignment during curing (poor alignment = poor results)
- Lead time to acquire recommended epoxy can be long 6-12 weeks
- Coating manufacturer may have data for common coatings
- Evaluation of the coating itself is different than evaluating the coating on the device (in it's final configuration)
- Dynamic shear above 15Hz should perform dynamic verification per ASTM E467

ASTM F2118* (PMMA Fatigue)

*** reviewed by Dr. Woods**

- Consistent method for specimen molding
- High quality specimen molds to produce consistent specimens
- Specimen grip method must be properly aligned to minimize bending and premature failure (experiments have shown drill chucks are not a good gripping method)
- Tapered wedge grips and collets work well for specimen gripping

ASTM F2183 and F2977 (Punch Testing)

- F2183 applied only to UHMWPE
- F2977 applies to all polymers and considers all manufacturing and post-manufacturing processes
- Specimen preparation is critical, including the pre-conditioning
  - Testing is temperature sensitive
  - Materials may be sensitive to humidity
  - Orientation of the specimen is critical
  - Test rate will impact the results

In Summary…

- Understand the regulatory path and current requirements
- Understand the testing options and requirements, with a solid protocol
- Use good science with a repeatable process
- Seek advice and input from experts
- Testing can be expensive & time consuming
  - Start testing early – redesigns & timeline
  - Plan ahead
  - Understand the information learned
  - Maximize the information learned

EMPIRICAL BACKGROUND

- Empirical: A Family of Companies
  - Empirical Testing Corp. – Dec, 1998
  - Empirical Machine, LLC – May, 2007
  - Empirical Consulting, LLC – Feb, 2013
- Member of the Entrepreneurs-in-Residence (EIR) Program with CDRH; 2012-2013
- Active members of ASTM F04.25, F04.22, F04.21
- FDA Educational Seminars (Sep 2015, Aug 2014, Mar 2010, and Jun 2006)

Integrity • Innovation • Industry Expertise

Thank You!

Empirical Machine

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