

A CALL TO ARMS: STANDARDS DETERMINE MEDICAL DEVICE AVAILABILITY & SURGEONS MUST CONTRIBUTE TO THE PROCESS!

William M. Mihalko, MD, PhD; Stuart B. Goodman, MD, PhD; A S. Greenwald, DPhil Oxon;
Warren O. Haggard, PhD; Jack E. Lemons, PhD

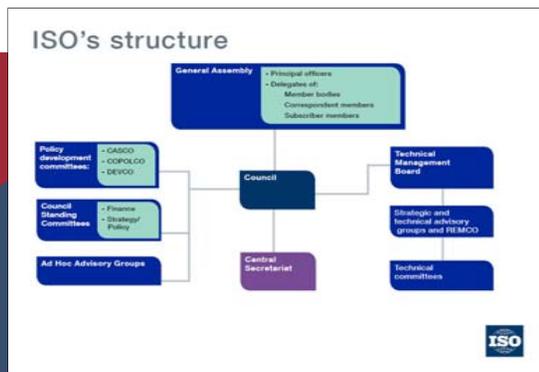
AAOS members participate in the development of consensus standards for orthopaedic devices through two international standards development organizations.

International Organization for Standards (ISO)

Founded in 1947

Independent, non-governmental organization made up of members from the national standards bodies of 161 countries

Has published more than 19,500 International Standards covering almost all aspects of technology and business



ASTM International

Founded in 1898 as an organization committed to building a consensus on standards for industrial materials

Provides a global forum for the development and publication of international voluntary consensus standards for materials, products, systems and services

Membership comprised of more than 30,000 technical experts from 150 countries

12,000 standards published each year

143 Technical Committees develop and maintain ASTM standards. They are grouped by designation according to related activities within a particular scope of work

ISO TECHNICAL COMMITTEE 150

Scope: Standardization in the field of implants for surgery 1) and their required instrumentation, covering terminology, specifications and methods of tests for all types of implants, and for the materials both basic and composite used in their manufacture and application.

Workgroups and Subcommittees: Use and retrieval of surgical implants (WG 10), implant coatings (WG 12), materials (SC 1), bone and joint implants (SC 4), osteosynthesis and spinal devices (SC 5), active implants (SC 6), and tissue engineered medical products (SC 7)

Leadership: John Goode, chair through 2016

Next Meeting: September 15-19, 2014, Seoul, South Korea

- 139 published standards related to the technical committee
- 11 standards published under the direct responsibility of TC-150
- 24 participating countries
- 19 observing countries

ASTM COMMITTEE F04

Mission Statement: To be recognized globally as the premier developer and provider of voluntary consensus standards, related technical information, and services that:

- promote public health and safety, support the protection and sustainability of the environment, and the overall quality of life;
- contribute to the reliability of materials, products, systems and services; and
- facilitate international, regional, and national commerce.

Committee F04: Founded in 1962. Four divisions - Resources, Orthopaedic Devices, Medical/Surgical Devices, and Tissue Engineered Medical Products. 34 subcommittees.

Scope: the development of standardized nomenclature and definitions of terms, test methods, recommended practices, guides, specifications and performance standards for medical and surgical materials and devices. The Committee will encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards. The Committee will promote liaison with other ASTM Committees and other organizations with mutual interests.

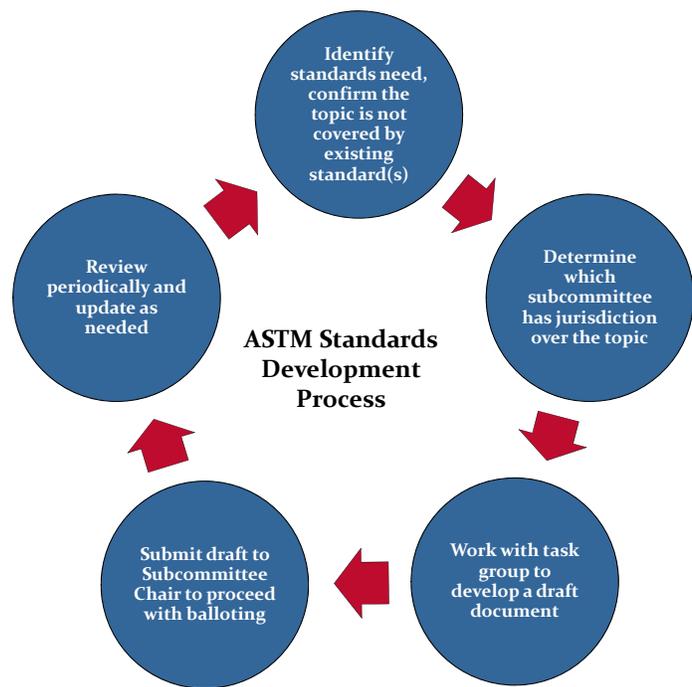
Next Meetings: May 6-9, 2014, Toronto, CA and November 11-14, 2014, New Orleans, LA.

ASTM INTERNATIONAL COMMITTEE Fo4

ASTM International Committee Fo4 on Medical and Surgical Materials and Devices was formed in 1962. The Committee has jurisdiction of over 250 standards, which play an ongoing, preeminent role in all aspects important to materials, orthopaedic devices, testing, tissue engineering, and medical/surgical instruments.

Committee membership is voluntary and involves committed individuals with expertise in the above areas deriving from industry, academia, regulatory agencies, healthcare professions and independent research facilities.

The work of ASTM International may begin with a single concern raised by any member particular to its mission and results in the establishment of a Task Force, which works together to formulate solutions to the concern. As example, physical fatigue testing standards derived for femoral stem implants to assure their mechanical integrity in a simulated clinical environment (Figure 2).



What emerges from a Task Group is a consensus document which is balloted among Task Group members and then sent to a Subcommittee tasked with the general area for review and commentary. This is an iterative and time-consuming process with the endpoint being a reasonable, if not optimal, testing standard.

Once a standard has successfully cleared the three levels of peer review provided by ASTM (subcommittee, main committee, and Society), it is assigned a fixed alphanumeric designation and receives an official approval date. The document is now considered to be an ASTM standard and is capable of being cited in contractual language, referenced by a code body, or mandated by a state or local government.

During the main committee ballot and Society Review, the ASTM editorial department works to ensure that the standard is in the correct format and is correctly tagged using standard generalized markup language (SGML).

Approximately eight weeks after a standard is approved, it is available for distribution. All ASTM International standards are housed in specific volumes of ASTM's annual book of standards.

The importance of this seemingly laborious process is that many of these standards are ultimately recognized by the US Food and Drug Administration (FDA) as well as other international standards and regulatory bodies to assist the process of medical device approval. The standards serve to assure the safety and effectiveness of medical device products.

There is great need for orthopaedic surgeons, whose appreciation of the biological environment in which these devices function as well as their implantation, to contribute their expertise. Orthopaedic surgeons have an opportunity to serve on ASTM subcommittees, in the interest of the profession and the safety of their patients.

For further information, please visit the ASTM International website, www.ASTM.org.

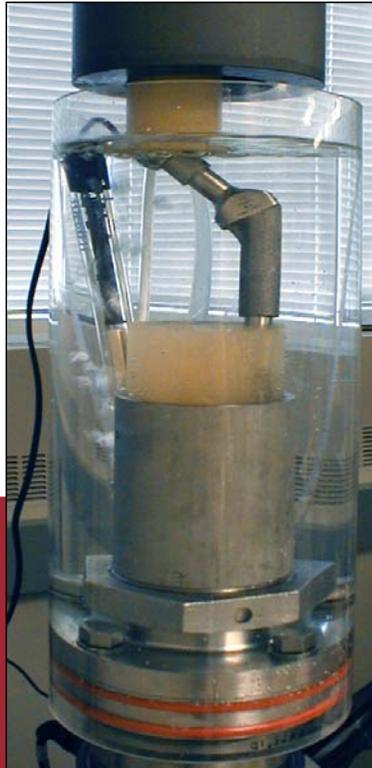
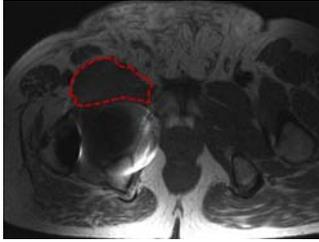


Figure 2

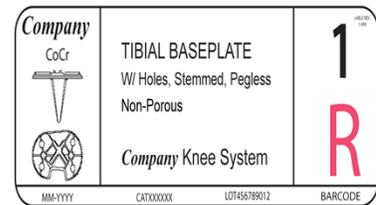
HOW HAVE CLINICAL ISSUES DRIVEN ASTM STANDARDS ACTIVITY?

Examples of some of the clinical problems in orthopaedic surgery that have resulted in new standards activity and development.



Metal on Metal Total Hip Arthroplasty Following reports from federal regulatory agencies and national registries about the possible local and systemic effects concerning certain metal on metal total hip arthroplasty bearings, ASTM held a workshop and a symposium focused on the clinical issues with MoM bearings. The papers from the symposium have been published and new standards activities are now underway to better assess these types of hard on hard bearings.

Implant Labeling Standard All standards are designed to improve the quality of devices and, therefore, increase patient safety. Dr. Kent Jason Lowry of the Biomedical Engineering Committee had witnessed the lack of consistency in the location and content of device manufacturer implant labels and the possible detrimental effects it may have on the patient. He proposed a new implant labeling standard and shepherded it from draft to approved standard over the course of four years. Dr. Lowry's efforts concerning this standard in large part led to him being nominated for the Joseph S. Barr Award in 2013.



Total Hip Arthroplasty Wear Simulator Standards Although wear simulator standards for bearings had been in place for years there was a disconnect between simulator results and clinical findings. A symposium on clinical applications to hip and knee arthroplasty standards explored these discrepancies and initiated new standards activity to incorporate various cycles into simulator protocols that model clinical findings from gait and retrieval studies. These include for the hip: impingement maneuvers, lower head coverage and higher loads to simulate more demanding activities.

Mobile Bearing Knee Replacement MBK replacement have been under a class III designation despite decades of safe use on the market. A symposium and publication on the clinical differences between fixed and MBK replacements was conducted and highlighted the needed standards that were lacking to prove safety. These activities may be the necessary pieces for eventual FDA down classification of MBK in the near future.



Implant Modularity and Local Effects of Corrosion The November 2013 workshop addressed issues with modular junctions of orthopaedic devices and their possible local tissue reactions. The program highlighted the clinical problems that have been identified and the basic science behind clinical findings and the topic was fast-tracked to include a symposium and publication Fall 2014.

ASTM International encourages and relies on surgeon input for topics such as those outlined above. The standards organization is now investigating ways to offer surgeons CME credits for their attendance and input. Surgeons should also realize that any subcommittee that meets during the ASTM week, may be attended by web type meeting services. This allows a surgeon to be involved without taking out time from their busy practices to travel.

EXAMPLES OF TEMP_s AND BIOLOGIC STANDARDS

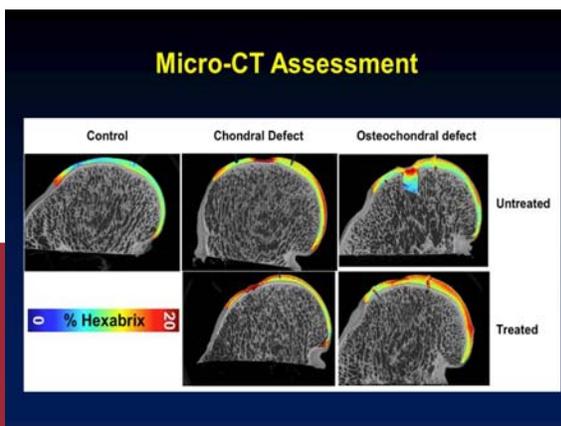
Biologics, tissues, and tissue engineered medical products (TEMPs) are being used with increasing frequency in orthopaedic surgery. Examples of these products include various tissue scaffolds, allograft musculoskeletal tissues (bone, cartilage, tendon etc.), demineralized bone matrix, and biomolecules such as the bone morphogenetic proteins, cells, etc. These products must be safe and effective in order to accomplish their intended use in humans. Although safety and efficacy of medical products is under the auspices of the FDA, many governmental agencies and other stakeholders depend on specifications and standards that are formulated, discussed, amended and voted upon by members of ASTM.

Traditionally, ASTM standards were generally written and voted upon by members of ASTM who, by and large, were not orthopaedic surgeons. These members usually included biological researchers and engineers, industrial participants including manufacturers, government employees and others. While this widespread participation is highly desirable, the end-user of the biological device is the medical practitioner. It is the clinician who is in the best position to determine the clinical indications for use of the biological device, how and when it is to be used, the method, timing and frequency of delivery, and the standards for monitoring and managing potential outcomes and complications associated with the device. Thus, it behooves orthopaedic surgeons who use biological devices to become actively involved in ASTM TEMP_s and development of biologic standards.

The ASTM TEMP_s division has currently 31 published standards and many more developing draft standards. Two examples of TEMP_s standards that can impact your clinical treatments and outcomes are:

F2451 Standard Guide for In-Vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage

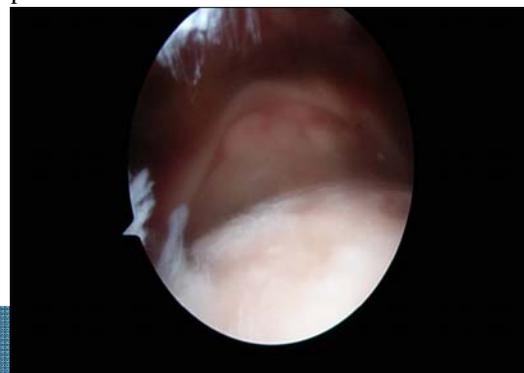
This standard was an earlier TEMP_s standard and used by multiple companies in developing regenerative cartilage implants or treatments and by the FDA in review regulatory applications. An example of cartilage regenerative treatments that uses this published standard and is a component of a funded NIH project cartilage animal model standard development is shown below.



Micro-CT assessments are illustrated for a NIH funded project for a standardization of an animal model for cartilage repair assessment. (Photograph provided by Synthasome, Inc.)

F2903 Standard Guide for In-Vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage

This recent standard is used by companies in developing and commercialization reinforcement devices for tendon and ligament surgical repair. Examples of a damaged rotator cuff and a commercial reinforcement device for the surgical repair of the rotator cuff are shown below.



a) A photograph illustrates rotator cuff requiring surgical repair.

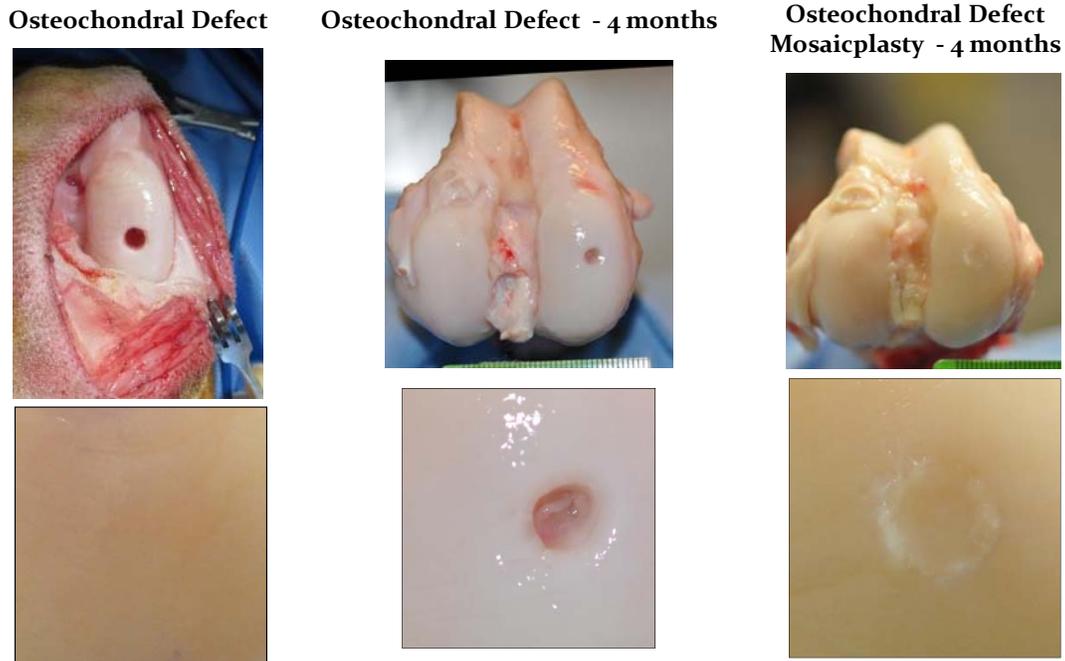


b) A photograph of the surgical repair of the torn rotator cuff with a commercial reinforcement device. (Photographs were provided by Synthasome)

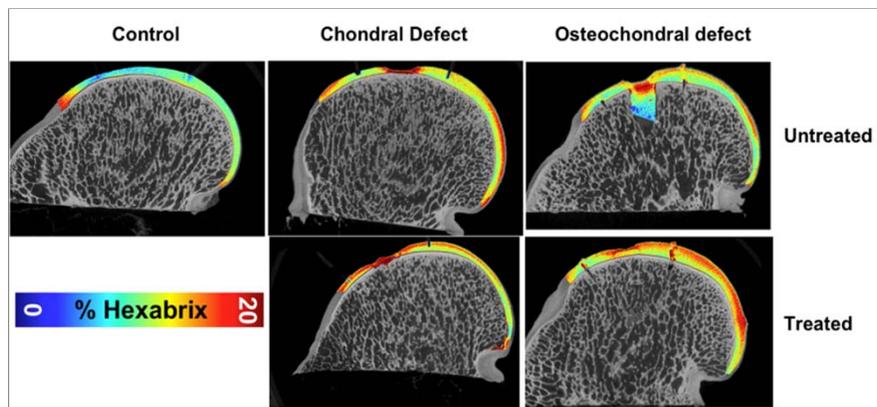
GOAT MODEL FOR ARTICULAR CARTILAGE REPAIR

Objective: Establish ASTM standard methods (a large animal model and outcome measures) for assessing the safety and therapeutic effectiveness of treatments for articular cartilage repair

Articular Repair Sites at 4 months



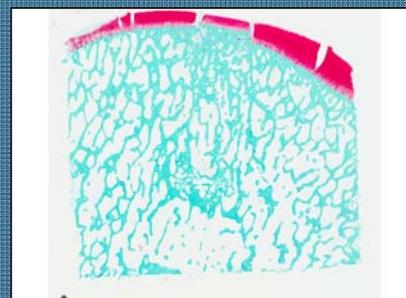
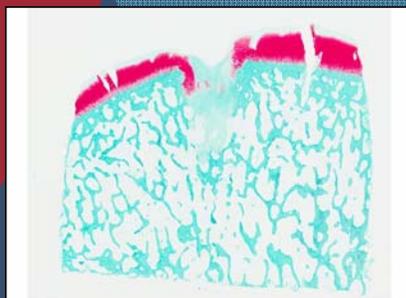
Micro-CT Assessment



Histology and Histomorphometry

Osteochondral defect

Osteochondral Defect + Mosaicplasty



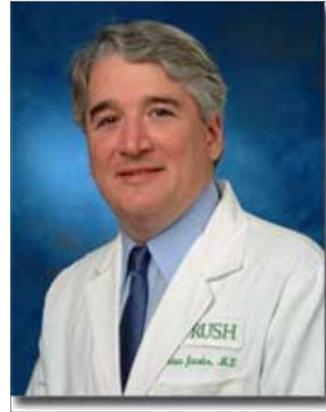
Treatment	% Repair (filling of defect)
Osteochondral repair	75 + 14
Osteochondral repair + Mosaicplasty	28 + 27

ASTM AND ORTHOPAEDIC LEADERSHIP

Fo4 CHAIRS



1974-1979
Victor Frankel, MD,
PhD
1st surgeon chair



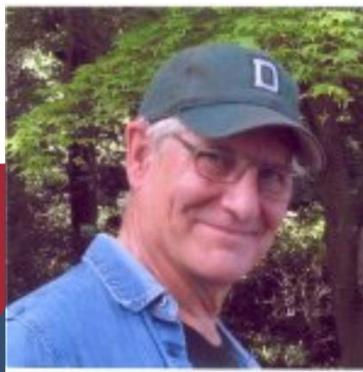
2000-2003
Joshua Jacobs, MD
President, AAOS, Past Chair, AAOS
Biomedical Engineering Committee &
Council on Research



1979-1988
Patrick Laing, MBBS,
FRCS



2004-2007
John Kirkpatrick, MD
Past Chair, AAOS Biomedical Engineering
Committee



1988-1994
Michael Mayor, MD



2014
William Mihalko, MD, PhD
Chair, AAOS Biomedical Engineering Committee &
Orthopaedic Device Forum