Designation: F3047M – 15

Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations[1]

This standard is issued under the fixed designation F3047M; 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 The objective of this guide is to advise researchers on the possible high demand wear test features that should be included in evaluation of hard on hard articulations. This guide makes suggestions of what high demand test features may need to be added to an overall high demand wear test regime. Device articulating components manufactured from other metallic alloys, ceramics or with coated or elementally modified surfaces could possibly be evaluated with this guide. However such materials may include risks and failure mechanisms which are not adressed in this guide.

1.2 Hard-on-hard hip bearing systems include metal-on-metal, ceramic-on-ceramic, ceramic-on-metal, or any other bearing systems where both the head and cup components have high surface hardness. An argument has been made that the hard-on-hard THR articulation may be better for younger more active patients. These younger patients may be more physically fit and expect to be able to perform more energetic activities. Consequently, new designs of hard-on-hard THR articulations may have some implantations subjected to more demanding and longer wear performance requirements.

1.3 Total Hip Replacement (THR) with metal-on-metal articulations have been used clinically for more than 50 years (**1**, **2**).[2] Early designs had mixed clinical results. Eventually they were eclipsed by THR systems using metal on polyethylene articulations. In the 1990s the metal-on-metal articulation again became popular with more modern designs (**3**), including surface replacement.

1.4 In the 1970s the first ceramic-on-ceramic THR articulations were used. In general, the early results were not satisfactory (**4**, **5**). Improvement in alumina, and new designs in the 1990s improved the results for ceramic-on-ceramic articulations (**6**).

1.5 The values stated in SI units are to be regarded as the standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F799 Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)

F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)

F1814 Guide for Evaluating Modular Hip and Knee Joint Components

F1820 Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices

F1877 Practice for Characterization of Particles

F2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials

2.2 *ISO Standards:*[4]

ISO 5832-4 Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy

ISO 5832-12 Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy

ISO 7206-2 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 2: Articulating Surfaces Made of

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

Current edition approved March 15, 2015. Published May 2015. DOI: 10.1520/F3047M-15.

[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

Metallic, Ceramic and Plastics Materials
ISO 14242-1 Implants for Surgery—Wear of Total Hip-Joint Prostheses. Part 1: Loading and Displacement Parameters for Wear-Testing Machines and Corresponding Environmental Conditions for Test
ISO 14242-2 Implants for Surgery—Wear of Total Hip-Joint Prostheses. Part 2: Methods of Measurement
ISO 14242-3:2009 Implants for Surgery—Wear of Total Hip-Joint Prostheses—Part 3: Loading and Displacement Parameters for Orbital Bearing Type Wear Testing
ISO 17853 Wear of Implant Materials—Polymer and Metal Wear Particles—Isolation, Characterization and Quantification

3. Terminology

3.1 *Definitions:*

3.1.1 *acetabular liner*—portion of the modular acetabular device with an internal hemispherical socket intended to articulate with the head of a femoral prosthesis. The external geometry of this component interfaces with the acetabular shell through a locking mechanism which may be integral to the design of the liner and shell or may rely upon additional components (for example, metal ring, screws, and so forth).

3.1.2 *acetabular shell*—the metallic external, hollow structure that provides additional mechanical support or reinforcement for an acetabular liner and whose external features interface directly with the bones of the pelvic socket (for example, through bone cement, intimate press-fit, coatings for attachment to bone cement or tissue, integral screw threads, anchoring screws, pegs, and so forth). The acetabular shell may be solid or contain holes for fixation to the pelvis or attachment of instrumentation.

3.1.3 *acetabular liner/shell angle*—the angle between the polar axis of the acetabular articulating surface and the horizontal (see ISO 14242 Part 1 paragraph 7.4).

3.1.4 *alloy fabricated form*—the raw material form of the metallic alloy and any processing techniques used to fabricate the final form of the implant.

3.1.5 *breakaway wear*—a 'higher' unexpected wear rate that follows a period of steady-state wear as illustrated in Fig. 2.

3.1.6 *breakaway wear with recovery*—a breakaway wear rate that returns to the lower steady state wear rates. The breakaway/recovery phenomenon can be a single event or as multiple 'episodic' events during the otherwise steady-state conditions as illustrated in Fig. 2.

3.1.7 *ceramic-on-ceramic hip prosthesis*—a device intended to replace a human hip joint in which the ball and cup articulating surfaces are composed of high purity alumina or alumina matrix composite ceramics. The ball is attached to an intramedullary femoral stem. Device articulating components manufactured from other ceramic materials or with coated or elementally modified surfaces may have special concerns which are not addressed in the scope of this guide.

3.1.8 *contact patch edge to rim (CPER) distance*—for a given acetabular liner orientation the arc distance between the edge of a calculated Hertzian contact area caused by a 3 kN joint reaction force and the last portion of articulating surface on the acetabular liner as illustrated in Fig. 1.

3.1.9 *coordinate measuring machine (CMM)*—an automated system that is capable of making and recording measurements in three dimensions with high precision in a controlled volume of space.

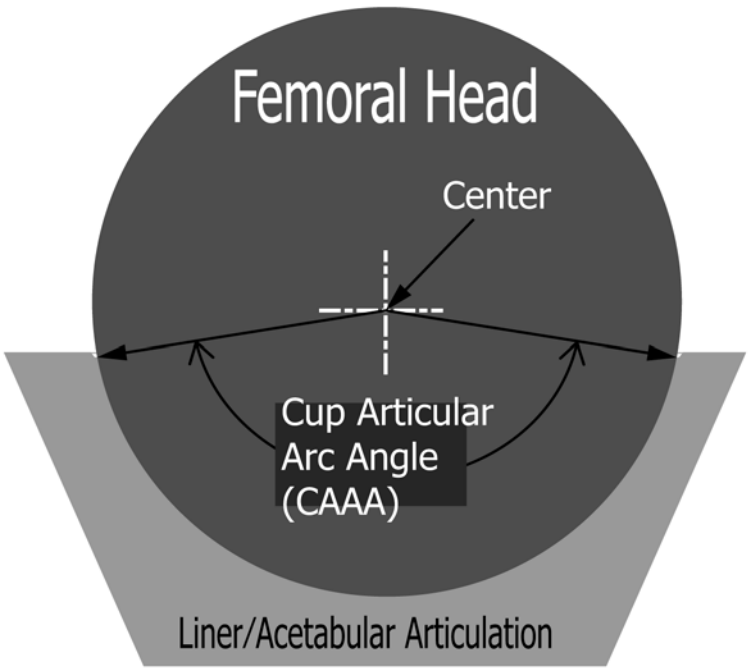

FIG. 1 Illustration of Cup Articular Arc Angle

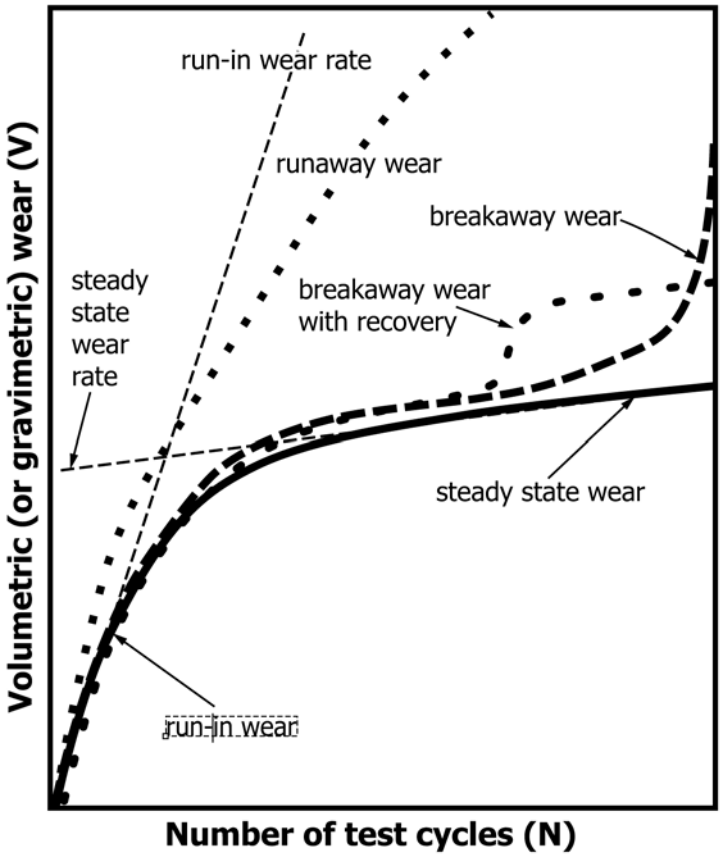

FIG. 2 Different Modes/Phases of Wear Illustrated Schematically

3.1.10 *cup articular arc angle*—the angle subtended by the articular surface of the acetabular component. It can be determined with a computer aided design system or manual measurements. With the head placed in the acetabular liner, it is the minimum angle in a plane bisecting the head and the liner, formed by the last contact points between the bearing surfaces and the rotational center of the head. It will be 180° or less. It is illustrated in Fig. 2.

3.1.11 *dwell duration*—the length of time that a wear test is paused in a test mode in order to evaluate the effect of periodically stopping and starting the hip simulator articulation.

3.1.12 *head to cup radial clearance*—the radius of the cup bearing articular surface minus the radius of the head articular surface.

3.1.13 *lubricant film*—a fluid film trapped between the articulating surfaces of a hip joint that helps limit direct contact between the articulating surfaces.

3.1.14 *metal-on-metal hip prosthesis*—a device intended to replace a human hip joint in which the ball and liner articulating surfaces are often composed of high carbon version of Co28Cr6Mo cobalt alloy. The ball may be attached to an intramedullary stem or a surface cover for the femoral head.

3.1.15 *runaway wear*—an initial high wear rate, that shows no sign of achieving a lower steady-state wear rate as illustrated in Fig. 2.

3.1.16 *run-in wear*—wear that occurs when the components are first implanted in-vivo, or during the initial phase of an in-vitro hip simulator test as illustrated in Fig. 2. During this period, wear rates are typically higher than during steady-state as the head and cup wear into conformity with each other and any initially contacting surface asperities or form errors are worn away. In hip simulator wear tests, the run in phase is often considered to be about 1 million cycles. The transition to steady-state wear can be estimated graphically from the plot of total wear vs. number of cycles.

3.1.17 *serum protein content*—the concentration of protein molecules present in serum, usually expressed in grams per liter. The value is usually supplied by the commercial source for the serum.

3.1.18 *steady-state wear*—wear rates that occur after a transient run-in wear period as illustrated in Fig. 2. Typically, the steady-state wear rate is less than the run-in wear rate. In hip simulator wear tests the steady state rate typically is reached after 1 million cycles and above.

3.1.19 *third body wear*—the increased wear that occurs due to particle(s) not permanently attached to the articulating surfaces being present in the articulation. The source of particle(s) can be external to the articulating surfaces or coming from the articulating surfaces.

3.1.20 *volumetric wear rate*—the rate of material volume lost from both articulating surfaces.