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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 for high demand test features that may need to be added to an overall wear test regime. Device articulating components manufactured from other metallic alloys, ceramics, or with coated or elementally modified surfaces without significant clinical use could possibly be evaluated with this guide. However, such materials may include risks and failure mechanisms that are not addressed in this guide.

1.2 Hard-on-hard hip bearing systems include metal-on-metal (for example, Specifications F75, F799, and F1537; ISO 5832-4, ISO 5832-12), ceramic-on-ceramic (for example, ISO 6474-1, ISO 6474-2, ISO 13356), 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.7 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

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

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F799 Specification for Cobalt-28 Chromium-6 Molybdenum 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)

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

F3018 Guide for Assessment of Hard-on-Hard Articulation

[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.

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[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.

Total Hip Replacement and Hip Resurfacing Arthroplasty Devices

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 6474-1 Implants for Surgery—Ceramic Materials—Part 1: Ceramic Materials Based on High Purity Alumina

ISO 6474-2 Implants for Surgery—Ceramic Materials—Part 2: Composite Materials Based on a High-Purity Alumina Matrix with Zirconia Reinforcement

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

ISO 13356 Implants for Surgery—Ceramic Materials Based on Yttria-Stabilized Tetragonal Zirconia (Y-TZP)

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 Implants for Surgery—Wear of Total Hip-Joint Prostheses—Part 3: Loading and Displacement Parameters for Orbital Bearing Type Wear Testing Machines and Corresponding Environmental Conditions for Test

ISO 14242-4 Implants for Surgery—Wear of Total Hip-Joint Prostheses—Part 4: Testing Hip Prostheses Under Variations in Component Positioning Which Results in Direct Edge Loading

ISO 17853 Wear of Implant Materials—Polymer and Metal Wear Particles—Isolation and Characterization

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

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 *alloy fabricated form*—the raw material form of the metallic alloy (such as Specifications F75, F799, and F1537; ISO 5832-4, ISO 5832-12) and any processing techniques (such as Practice F86, Specification F2033, and ISO 7206-2) used to fabricate the final form of the implant.

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

3.1.5 *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 multiple 'episodic' events during the otherwise steady-state conditions as illustrated in Fig. 2.

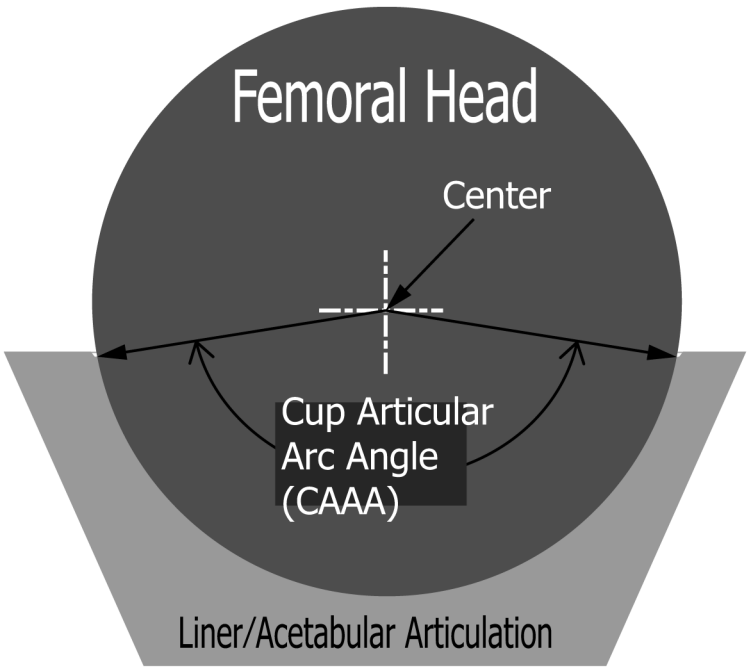

FIG. 1 Illustration of Cup Articular Arc Angle

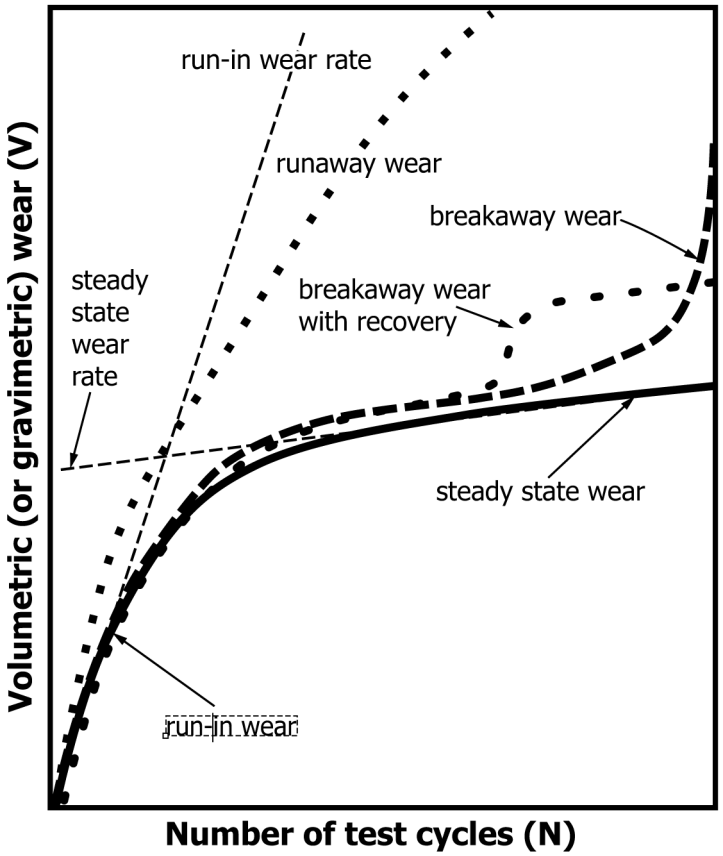

FIG. 2 Different Modes/Phases of Wear Illustrated Schematically

3.1.6 *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 (such as ISO 6474-1, ISO 6474-2, and ISO 13356). 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.

3.1.7 *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. See Fig. 2 of Guide F3018.

3.1.8 *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.

3.1.9 *cup articular arc angle*—the angle subtended by the articular surface of the acetabular component. It can be determined with a computer aided design (CAD) system or manual measurements.

3.1.10 *cup inclination angle*—the angle between the Superior-Inferior axis of the patient and the radiographic projection of the acetabular axis (or polar axis of the cup) as measured on an A/P pelvic radiograph.

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