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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 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

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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.

[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.

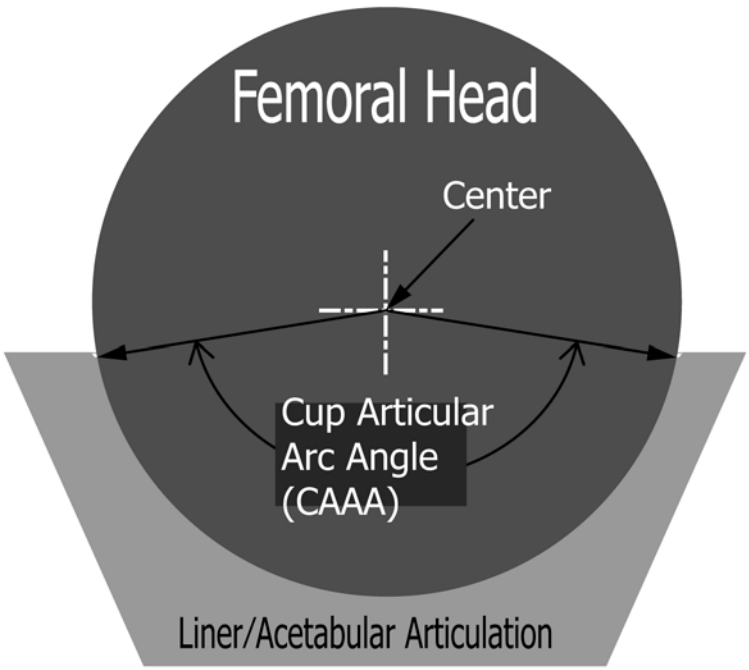

FIG. 1 Illustration of Cup Articular Arc Angle

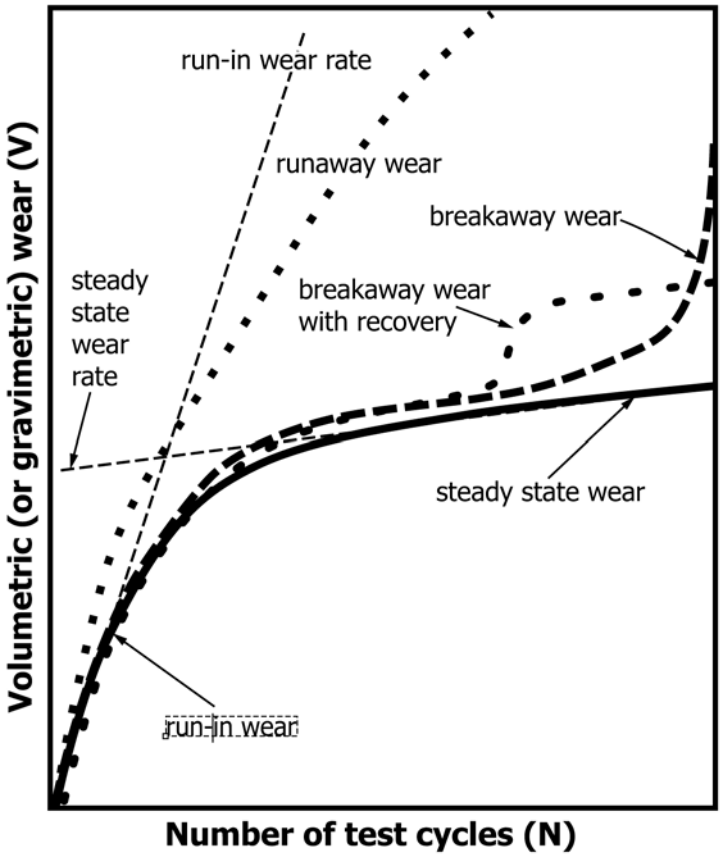

FIG. 2 Different Modes/Phases of Wear Illustrated Schematically

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.

4. Summary of Practice

4.1 A conventional hip simulator wear test should be performed according to ISO 14242 Part 1 or Part 3 for five million cycles. This will be used as a basis for comparison of the results of any high demand test regime. Any high demand wear test regime should use the ISO 14242 Part 1 or Part 3 standard as the starting point and high demand parameters should be made as modifications to that standard. The ISO 14242 Part 3 standard may not be suitable for high demand wear tests that require modification of the articulating motion, because the motion cycle is built into the test machine hardware and can't be modified.

4.2 The high demand wear test can be performed as a continuation of the conventional ISO 14242 Part 1 test or run as a separate test. High demand test features will be added to the high demand wear test and justified as clinically relevant. This will require an understanding of the potential interactions of the possible high demand modes which would indicate a series of shorter duration tests. A final high demand test(s) for the preclinical evaluation of a device shall include a test protocol of at least 5 million cycles. These high demand wear test cycles will be in addition to the conventional 5 million cycles of wear testing.

5. Significance and Use

5.1 The current hip simulator wear test standards (ISO 14242 Part 1 or Part 3) stipulate only one load wave form and one set of articulation motions. There is a need for more versatile and rigorous wear test regimes, but the knowledge of what represents realistic high demand wear test features is limited. More research is clearly needed before a standard can be written that defines what a representative high demand wear test should include. 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.

5.2 This guide makes suggestions of what high demand test features may need to be added to an overall high demand wear test regime. The features described here are not meant to be all inclusive. Based on current knowledge they appear to be relevant to adverse conditions that can occur in clinical use.

5.3 All the test features, both conventional and high demand could have interactive effects on the wear of the components.

6. Test Samples

6.1 The materials and articulating geometry of the hard-on-hard system should be representative of the system intended for clinical use. The acetabular components must have the same geometry as the acetabular system intended for clinical use because the stiffness of the acetabular system could affect the response to loads and motions at the articulating surface.

6.2 The test parts should receive all of the processing that is intended for product intended for clinical use including sterilization. There is no literature reporting any detrimental effects of gamma sterilization or any other sterilization methods used for orthopedic devices on the physical or chemical properties of metallic alloys. However, it may be advisable to sterilize everything prior to definitive tests for preclinical evaluation to make all parts as close to clinical product as possible. Coatings on non-articulating surfaces of the test parts could create problems with the handling of the parts and weight loss measurements during testing. It may be necessary to have test parts without the non-articulating surface coatings. However, any thermal processing the test parts would receive as part of any coating process should still be performed. Particulate based coating could be a source for third body wear particles, but random particle loss interferes with the repeatability of the test. Consideration should also be given to using particulate from the coatings as controlled third body particle sources.

6.3 No preconditioning is required for the test samples other than careful handling to assure that they remain clean and free of contamination prior to start of testing.

6.4 The diameter and acetabular sizing must be justified as worst case for the wear tests. There are many possible factors that could make a hard-on-hard couple a "Worst Case". The diameter of the articulation, head to cup radial clearance, the thickness of material in the liner and the shell, the design of modularity of the liner and the shell, or the sphericity of the articulations could all potentially cause a "Worst Case" wear. These factors and more should be considered in justifying a "Worst Case".

6.5 The usual small amount of material lost in hard-on-hard wear tests combined with the larger mass of the components may make weight loss characterization of wear according to ISO 14242 Part 2 more difficult. Another means of measuring loss of material from both the convex and concave surfaces of the metal-on-metal articulation is by measuring the change in the surface geometries. For this measurement method, both articulating surfaces must be measured with enough precision before testing to provide a baseline for estimating the volume of material lost from the surfaces due to the tests. This shall require a high precision coordinate measuring machine (CMM) or other high precision measurement devices. The volumetric measurement does have one advantage over the weight loss method, because it can indicate the distribution of wear on a surface. Both methods require precise techniques that shall have validated procedures before they are used in an actual wear test.

6.6 The geometry of both articulating surfaces should be characterized as to their original geometry and surface finish. The same techniques should be used to characterize both surfaces intermittently during testing and after completion of testing. These measurement results can be used to estimate the amount of material lost, but the alternate weight loss method should be used as a validation method for the volumetric measurement by making the alternate weight loss measurements at the beginning and the end of the tests.

6.7 Additional characterization of the surfaces in a scanning electron microscope or three dimensional digital optical microscopes may also be desirable.

6.8 For all measurement and characterization methods the cleaning methods of ISO 14242 Part 2 shall be used.

6.9 The serum protein content shall be the same as required by ISO 14242 Part 1 and ISO 14242 Part 3. If other serum protein content is used it shall be justified.

7. High Demand Features

7.1 There may not be a single "worst case" high demand feature. Different high demand modes could possibly interact with each other to make the wear worse than would occur by the individual high demand feature. Investigation of the possible interactions should be considered.

7.2 *Acetabular Liner/Shell Angle:*

7.2.1 Callanan et al. showed that for metal on polyethylene THR systems the acetabular component abductor angle placement can be as much as 15º off optimal and still survive long term (**7**). With this cup positioning, the main load axis is 15º closer to the equator of the acetabular component, reducing the effective contact area and consequently increasing the contact stresses on the articulating surfaces. In fact, for metal-on-metal THRs, there are reports in the literature that higher liner/shell angles of the load axis in relation to optimal position do cause increases in wear (**8, 9**). There have been reports (**10, 11, 12**) of acetabular cups angles as high as 60º and 65º.

7.2.2 The CPER distance shall be determined for all cup angles tested. The actual distance between the edge of the contact patch and the end of the articulating surface of the cup shall be estimated after completion of the tests.

7.2.3 Since the acetabular liner/shell angle is fixed for the life of the implant clinically, any high demand wear test should have that liner/shell angle throughout the entire test. The choice of the high angle shall be justified.

7.3 *Third Body Particles:*

7.3.1 As a result of the intra-operative procedure it is possible that the joint space could have small bone chips or particles of bone cement contamination. These particles could cause damage to the articulating surfaces (**13, 14**). There could be other possible sources of ceramic particles such as hydroxyapatite (**15**) or zirconia radio-pacifiers from bone cement. Metallic particulate of titanium and CoCrMo could come from such sources as, neck impingement (**16, 17**) porous coatings, or tribocorrosion (**18, 19, 20**). The presence of such types of third body particulate may be of limited duration because such particles could take time to form, then possibly be broken down, and eventually removed from the joint capsule.

7.3.2 There clearly needs to be a small particle size in order for there to be a potential that the particle could be entrapped between the articulating surfaces and cause damage. Trying to standardize on small bone particles is not practical.

7.3.3 The time and rate of 3rd body particle removal should be justified.

7.3.4 Care must be taken during the portion of the test with the third body particles that they remain suspended in the lubrication medium as much as possible to keep availability to the articulating surface high. Additional agitation of the lubricant, limiting crevice and corners in the test chamber, and funnel shaped collection areas at the bottom of the test chamber where lubricant is collected for recirculation could help keep third body particles in circulation.

7.3.5 The orbital bearing hip wear simulator has an advantage in the third body wear evaluation, because the acetabular component(s) can be below the femoral component(s), letting gravity help keep the third body particles in the area of the articulation. However, it can also be argued that gravity keeping 3rd body particles permanently in the area of articulation would not be representative of an actual THA.

7.4 *Changing Load Parameters:*

7.4.1 Higher demand tests may require some higher loads that could be representative of younger more active patients. There is literature that associates higher wear rates with higher loads (**21, 22**). These high loads could also come from activities with higher cyclic frequencies. However, even those patients are not always in a higher demand activity. Consequently, a spectrum of different higher load peaks might be included in the ISO 14242 Part 1 or Part 3 load wave forms or even replace the standard wave forms.

7.4.2 The number of cycles of each type of wave form, the cyclic frequency, and the amplitude of the peaks of the higher demand wave forms shall be justified.

7.5 *Stop-Dwell-Start (Stiction):*

7.5.1 Hip simulator tests are normally run continuously. However, patients with implants in activities of daily living usually walk relatively short distances, before stopping or performing another activity. In a study of activities of normal, healthy hip patients on a typical day (**23**), the patients averaged walking periods of 10 seconds before pausing, sitting down or changing to a different activity like stair climbing. The highest frequency durations were 2 to 5 seconds dwell.

7.5.2 Some testing has found that starting and stopping a metal-on-metal hip simulator wear test can increase the amount of wear (**24, 25**). Recent work has shown that the effect of the length of time stopped is not as important as the number of cycles between stops (**26**). The study found that five second stops after single or dual cycles had statistically significant effects on wear. Based on the previous patient activity study a stop every one or two cycles is well beyond the norm. It is possible that the dwell duration could be less than 5 seconds in order to shorten the total test time, but that would have to be justified. The study also used a dwell force representative of a standing load, which was about one half of the peak force. This suggests that a possible cycles set might be 10 walking cycles, stop and dwell 5 seconds under load, one walking cycle stop and dwell 5 seconds under load, followed by 50 walking cycles. Maintaining a mix of possible activities that would be representative of human activity.

7.6 *Microseparation:*

7.6.1 The hip simulator system will induce a controlled separation between the centers of the two articulations (**27, 28, 29, 30**). The maximum amount of microseparation, direction of the force driving microseparation, the contact force(s) during reseating after microseparation and timing within the flexion test cycle are important possible control parameters for microseparation. A paper published by Al Hajjar et. al. (**31**) suggests a microseparation of 0.5 mm with a 50 N force. The choice of control parameters shall be justified and their repeatability measured.

7.6.2 The choice of the amount, direction, and location within the test cycle shall be justified.

8. Report

8.1 Follow the reporting requirements of ISO 14242 Part 1 or ISO 14242 Part 3 if it is used for any part of the testing.

8.1.1 Report Volumetric wear.

8.1.2 Report the location of highest wear.

8.1.3 Report any other characterization of the wear that was performed.

8.2 *Acetabular Cup Angles:*

8.2.1 Report all acetabular cup angles used in the test.

8.2.2 Report the CPER of the test samples in the test.

8.2.3 Report the estimated distance between the edge of the contact patch and the end of the articulating after completion of the tests.

8.3 *High Demand Features:*

8.3.1 Report the cup/shell abduction and anteversion angles used for the test.

8.3.2 Report the load curve and peaks that exceed ISO 14242 Part 1 or Part 3 load curves and the number and location in the cyclic life of the test where they were used.

8.4 *Third Body Demand Parameters:*

8.4.1 Report the amount, size distribution, morphology, and type of third body debris used in the test.

8.4.2 Report when and how much debris was added.

8.4.3 Was the chamber cleaned at the time of serum changes?

8.4.4 Report test system features to keep the debris available to the articulation surfaces.

8.4.5 Report the number of cycles that were tested with debris present.

8.5 *Stop-Dwell-Start Parameters:*

8.5.1 Test frequency of cyclic wear portion of the test.

8.5.2 Number of cycles between periodic dwell stop.

8.5.3 Dwell duration.

8.5.4 Force during dwell duration.

8.5.5 Wave form transition from cyclic wear to dwell and back to cyclic wear.

8.5.6 Number of Stop-Dwell-Start cycles.

8.6 *Microseparation:*

8.6.1 Report the amount and direction of microseparation used in the test.

8.6.2 Report the repeatability of the microseparation control parameters.

8.6.3 Report where the microseparation occurred in the load and flexion cycle of the test.

8.6.4 Report the mechanism used to achieve the microseparation.

9. Keywords

9.1 ceramic-on-ceramic; hard-on-hard; high demand wear; hip simulator testing; insert/shell angle; metal-on-metal; third body wear

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 Total Hip Replacement (THR) with metal-on-metal articulations have been used clinically for more than 50 years (**1**, **2**). Early designs had mixed clinical results. Eventually they were eclipsed by THR systems using metal on polyethylene articulations. In the 1990's the metal-on-metal articulation again became popular with more modern designs (**3**), including surface replacement.

X1.2 Five modes of possible extreme wear demands that have been suggested for hard-on-hard bearings are included in this guide. The five chosen, acetabular angle, addition of third body particles, increased loads, stop-dwell-start (stiction), and microseparation; have some basis in the hard-on-hard bearing literature. All of them represent significant changes in current hip simulator wear testing techniques for Total Hip Arthroplasty. All of them also may have some application to high demand situations for more conventional metal/ceramic on polyethylene Total Hip Arthroplasty systems. None of the five high demand wear test modes will be simple to implement. Some may not be possible on some of the hip simulator wear testing equipment currently available.

X1.3 Although all the high demand modes have some connection to clinical history of devices, the difficulty is in deciding the parameters of the high demand modes, how many cycles of the high modes, and what combinations of the high demand modes constitute a clinically valid test regime for a hard-on-hard bearing system. The high demand tests could be constructed such that no type of acetabular bearing would survive. The problem is in deciding how these test methods could be used to represent what a well-designed hard-on-hard bearing system could realistically survive in a clinically long term.

X1.4 All of the test methods have limitations related to clinical knowledge and clinical expectations. The high acetabular cup angle relates to the surgical technique. The optimum angle for an acetabular cup can change with patient anatomy and, even if the optimum angle is known for the individual patient, achieving it surgically is difficult. How far from the optimum angle can we expect any acetabular system to function clinically for many years? Third body wear could also have a surgical technique aspect. There could be small

particles of bone left in the joint space from all the bone cutting operations. There could be small metallic particles from interactions of surgical instruments. There could be metallic particulate from porous tissue attachment systems for an acetabular shell or a femoral component. The metallic particles are best addressed by improving the products with methods unrelated to wear testing, and the bone particles may be a short term peri-operative issue.

X1.5 Microseparation also has a surgical technique relationship. The separation part of microseparation is due to laxity of the hip joint. If the postoperative soft tissue doesn't constrain the femoral articulating surface enough within the acetabular articulating surface during joint flexion the femoral articulating surface can move away from the acetabular articulating surface allowing some contact of the edge of the acetabular articulating surface with the femoral articulating surface. This could cause some damage to the femoral articulating surface which could be transferred to the acetabular articulating surface when the joint comes back together. Repeated edge contact damage could cascade into a significant wear problem. However, there can also be patient complications if the joint is too tight. The difficulty is in deciding how much laxity and consequent microseparation is allowable for a bearing system to be viable long term. How much joint laxity should be permissible, while still expecting long term performance of a hard-on-hard device? The severity of microseparation could also vary with cup angle placement. Would any acetabular systems be expected to survive long term with both acetabular angle and laxity deficiencies? This test mode would be very difficult to implement with repeatable control on most current hip wear simulators. The capability has only been available commercially in the past few years.

X1.6 Questions may also be raised about the stop-dwell-start test mode. In the Hadley paper (**26**) the most significant affect is when the stop and dwell periods have only one or two normal articulation cycles between each stop-dwell-start cycle. Even increasing the normal articulation cycles from one to two causes a 1/3 drop in the wear rate. Certainly there are functions of daily life that an individual may have similar stopping and starting episodes, but what percent of daily or annual activities do they really represent. To achieve the significantly higher wear rates reported in the Hadley paper the stop-dwell-start cycles were performed for 500,000 articulation cycles.

X1.7 A fast jogging cycle in a hip simulator (**21, 22**), where the peak load an test frequency were both nearly doubled produced highly elevated wear rates for one million cycles of test duration. However the reported wear rates return to normal levels following the fast jogging cycles. If the hard-on-hard bearing systems could have a benefit for younger patients in terms of longevity, this could be a concern. However, what is a realistic fast jogging amount in proportion to other daily activities and what is the patient responsibility if it is know that such activities increase wear.

X1.8 Changes of the motion path have also been suggested as reasons for increased wear, but it is difficult to understand how this could occur physiologically in a well fixed device.

X1.9 We are using the term Coordinate Measuring Machine (CMM) in a general sense covering any type of machine that is capable of determining surface position of a bearing surface. This CMM definition would also include a Talyrond machine of any other machine with sufficient volumetric resolution capability. There may be other devices that offer sufficient precision that could also be used for such measurements.

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