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Standard Guide for High Demand Hip Simulator Wear Testing of ~~Hard-on-hard~~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~~ hard-on-hard articulations. This guide makes suggestions ~~of what~~ for high demand test features that 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 without significant clinical use could possibly be evaluated with this guide. However, such materials may include risks and failure mechanisms ~~which~~that are not ~~adressed~~addressed in this guide.

1.2 Hard-on-hard hip bearing systems include ~~metal-on-metal, ceramic-on-ceramic,~~ 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~~ 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~~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.*

[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.

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)

~~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

F3018 Guide for Assessment of Hard-on-Hard Articulation 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 ~~14242-3:2009~~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, Characterization and Quantification~~Particles—Isolation and Characterization

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] 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.

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~~ 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.

3.1.6 *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.~~ 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 as illustrated in~~liner. See Fig. 2 ~~Fig. 1~~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. ~~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.~~

3.1.10 *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.

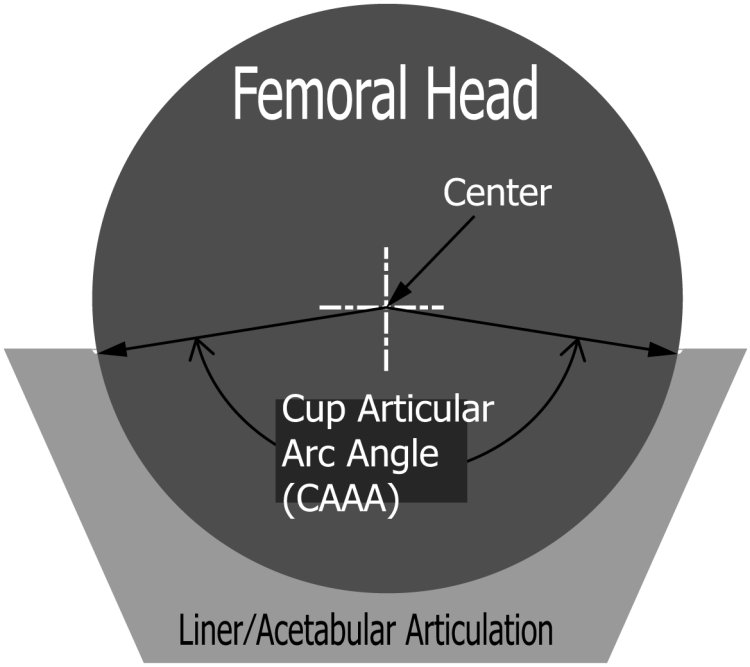

FIG. 1 Illustration of Cup Articular Arc Angle

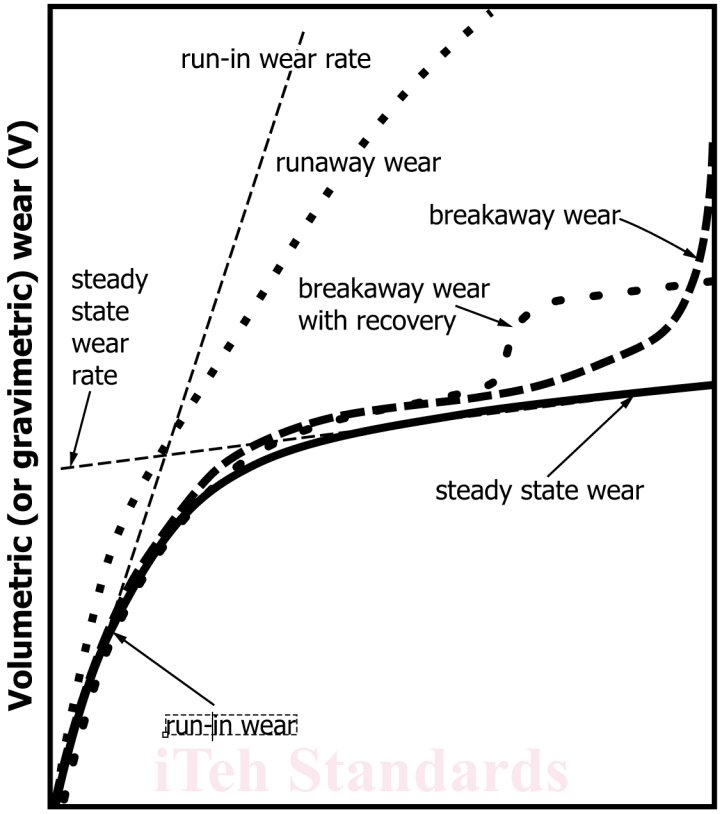

FIG. 2 Different Modes/Phases of Wear Illustrated Schematically

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,*~~ *in vivo,* or during the initial phase of an ~~*in-vitro*~~ *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~~ 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.~~versus 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~~ tests, the steady-state rate typically is reached after 1 million ~~cycles and above.~~or more cycles.

3.1.19 ~~*third body*~~ *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~~come from the articulating surfaces.

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

4. Summary of ~~Practice~~Guide

4.1 A conventional hip simulator wear test should be performed according to ISO ~~14242 Part 1 or Part 3 for five~~ 14242-1 or ISO 14242-3 for five (5) 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~~ ISO 14242-1 or ISO 14242-3 as the starting point and high demand parameters should be made as modifications to that standard. ~~The ISO 14242 Part 3 standard~~ ISO 14242-3 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~~ 14242-1 or ISO 14242-3 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)~~14242-1 or ISO 14242-3) stipulate only one load ~~wave form~~ waveform 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.~~ include can be written. 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 the 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~~ Particulate-based coating could be a source for ~~third body~~ 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~~ third-body particle sources.

6.3 No preconditioning is required for the test samples other than careful handling to ~~assure~~ensure 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".~~"worst case." The diameter of the articulation, ~~head to cup~~ 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"~~ create a "worst case" combination for wear. These factors and more should be considered in justifying a ~~"Worst Case".~~"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~~ 14242-2 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~~alternative 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~~ 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~~ 14242-2 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.~~ 14242-1 and ISO 14242-3. 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*~~*Cup Inclination Angle:*

7.2.1 Callanan et al. showed that for ~~metal-on-polyethylene~~ metal-on-polyethylene THR systems the acetabular component abductor angle placement can be as much as 15° off optimal and still survive long term (**7**). With this cup positioning, the main load axis is 15° 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~~ cup inclination angles of the load axis in relation to optimal position do cause increases in wear (**8, 9**). There have been reports (~~**10**~~**10-12**~~**, 11, 12**~~) of acetabular ~~cups~~cup angles as high as 60° and 65°.

7.2.2 The CPER distance shall be determined for all cup inclination 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~~ cup inclination angle is fixed for the life of the implant clinically, any high demand wear test should have that ~~liner/shell angle~~ cup inclination angle fixed throughout the entire test. The choice of the high angle shall be justified.

7.3 ~~*Third-Body*~~ *Third-Body Particles:*

7.3.1 As a result of the ~~intra-operative~~intraoperative 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~~zirconia-based radio-opacifiers from bone cement. Metallic ~~particulate~~particulates of titanium and CoCrMo could come from such sources ~~as,~~as neck impingement (**16**, **17**~~)~~**),** porous coatings, or tribocorrosion (**~~18~~18-20~~,~~ ~~19,~~ ~~20~~**). The presence of such types of ~~third body~~ third-body particulate may be of limited duration because such particles could take time to form, then possibly be broken down, and eventually be 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~~third-body particle replenishment should be justified.

7.3.4 Care must be taken during the portion of the test with the ~~third body~~ 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~~ funnel-shaped collection areas at the bottom of the test chamber where lubricant is collected for recirculation could help keep ~~third body~~ third-body particles in circulation.

7.3.5 The orbital bearing hip wear simulator has an advantage in the ~~third body~~ third-body wear evaluation, because the acetabular component(s) can be below the femoral component(s), letting gravity help keep the ~~third body~~ third-body particles in the area of the articulation. However, it can also be argued that gravity keeping ~~3rd body~~ third-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~~ 14242-1 or ISO 14242-3 waveforms or even replace the standard ~~wave forms.~~waveforms.

7.4.2 The number of cycles of each type of ~~wave form,~~ waveform, the cyclic frequency, and the amplitude of the peaks of the higher demand ~~wave forms~~ waveforms 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,~~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~~ 10 s before pausing, sitting down, or changing to a different activity like stair climbing. The highest frequency durations ~~were 2 to 5 seconds dwell.~~observed had a dwell time ranging from 2 to 5 s.

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~~24-26~~,~~ ~~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~~27**). The study found that ~~five second~~ 5 s 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~~ 5 s 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~~ten walking cycles, stop and dwell ~~5 seconds~~ 5 s under load, one walking cycle stop and dwell ~~5 seconds~~ 5 s under load, followed by 50 walking ~~cycles. Maintaining~~cycles, maintaining a mix of possible activities that would be representative of human activity.

7.6 *Microseparation:*