Section VI
Summary of Testing

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SUMMARY OF TESTING (Published/Unpublished)

This section contains Dr. Harry McKellop's comprehensive report on preclinical testing, including both published and unpublished references, to address issues raised by the agency with respect to the types of preclinical information needed to develop Special Controls. Dr. McKellop is the Vice President for Research of Orthopaedic Hospital in Los Angeles, California, and is a Professor-in-Residence in the Department of Orthopaedic Surgery at UCLA.

In the Federal Register notice published on September 6, 2002, the Deputy Director determined that additional preclinical testing, including the validation of hip simulation and non-ideal wear testing of the devices at extreme loading angles, higher than normal loads and start-stop cyclic loading are necessary to develop special controls to ensure the safety and effectiveness of metal-on-metal devices.

I. Validation of joint simulator tests of metal-on-metal total hip prostheses.

The ability of laboratory hip simulators to accurately predict the clinical (in vivo) wear of a particular bearing material depends on the answer to two questions, in order of importance: a) does the laboratory simulator generate the same *type* of wear (i.e., the same combination of wear mechanisms as occurs in vivo (typically including *adhesive* wear, *abrasive* wear and *surface fatigue* wear), and b) does it generate the same *amount* of wear. The first question is of much greater importance since, if the correct wear mechanisms are being generated, then the *relative* wear resistance of two hip bearings being compared on the simulator is very likely to be the same as will occur in vivo, across a wide range of activity levels in different patients.

Park and colleagues [1] used light microscopy and scanning electron microscopy to compare the morphology of the wear of metal-metal hip prostheses that had been tested in modern hip joint simulators in five independent laboratories to that present on eight Metasul™ (Sulzer Medical Technology) 2nd generation metal-metal hips that had been retrieved from patients. Park found strong similarities in the morphology of the worn surfaces among the implants, indicating that the hip simulators generated the same type of wear mechanisms that occur in vivo, including their general distribution over the bearing surfaces. Similarly, Wimmer and colleagues [2] observed evidence that the tribo-chemical actions between the metal bearing surfaces and the serum lubricant used in the simulator were closely comparable to those between the bearing surfaces and the joint fluid in vivo. These studies and others have provided assurance that the relative wear rates of two types of metal-metal bearings tested in a hip simulator should be comparable to their relative wear rates in vivo.

In laboratory wear tests, the amount of wear during a given interval (typically about 250K to 500K cycles) can be measured by weighing the specimens and/or measuring them, e.g., using a coordinate measuring machine (CMM), and comparing to the pre-test values. Based on such measurements, a number of investigators have reported that metal-metal bearings undergo substantially more rapid wear during the initial wear-in phase (about 1 million cycles) and then a slower, steady-state wear [3] [4] [5] [6] [7]. Park and colleagues [1] suggested that the wear-in phase consists of (Fig. 1) fragmentation and dislodgement of surface carbides and other asperities, which then act as 3rd body abrasives to accelerate the wear, which leads to an improved surface finish and a higher degree of conformity in the bearing zone, which enhances the potential for fluid film separation, lower friction and lower wear. Other researchers are in general agreement with this model. Consistent with this model, Rieker and colleagues [7] demonstrated that both the *duration* of the run-in phase and the *amount of wear* that accumulated were relatively independent of the diameter of the bearing, but increased in direct proportion to the initial ball-socket clearance.

In the case of clinical retrievals, the initial weight of the implant components is seldom known to sufficient accuracy to allow the total wear to be determined by weight loss. Rather, investigators can use a CMM machine to identify and measure the depth of the wear zone below the original spherical surface. Dividing the total wear depth by the duration of use gives an overall average wear rate, i.e., in microns per year. However, for a given implant, this method cannot distinguish the wear that accumulated during the wear-in phase from that during the subsequent state, or even whether a wear-in phase occurred. Nevertheless, in their analysis of a set of retrieved Metasul™ metal-metal hips, Rieker and colleagues [4] [8] found that the overall average wear rate of the hips that had been retrieved after two year or less use was substantially higher than for longer term hips (Fig. 2). Although Rieker emphasized that the early retrievals included primarily hips that were revised due to dislocation (which could have artificially increased the wear rates), the data were consistent with the metal-metal hips having exhibited a high wear-in phase in vivo. If correct, this is additional evidence that the wear processes generated in the hip simulators are closely comparable to those in vivo.

Similarly, based on the "rule of thumb" that patients with hip replacements walk an average of about one to two million cycles per year [9] [10] [11], the in-vitro and in-vivo studies have indicated comparable steady-state wear rates for metal-metal bearings, i.e., on the order of a few microns per million cycles or per year, respectively, again indicating that the same types of wear are occurring in both.

Even if the wear per million cycles is known accurately for a metal-metal bearing, it is difficult to predict the amount of wear that will occur in a specific patient, due to the very wide range in activity level among patients. For example, Silva and colleagues [11] used an electronic step counter to record the activity level of 33 patients with total hip replacements. The overall mean activity level was about 1.9 million cycles per year, which tended to decrease with age. However, some of the highest levels were recorded for older patients. Fortunately, it also is unnecessary to make such predictions for each patient. Rather, in deciding whether or not to permit the clinical use of a particular candidate bearing, it is sufficient to know whether its wear performance in vivo will be substantially worse, the same, or better than that of conventional metal-metal bearings, over a clinically realistic range of activity levels.

In addition to the above general considerations, Jim Nevelos, Ph.D., [12] has prepared an in-depth quantitative comparison showing good correspondence between the wear rates of metal-metal hips as tested on hip simulators and as measured on clinical retrievals. Because of this close similarity of wear mechanisms and the wear rates, investigators have a high level of confidence that state-of-the-art hip simulators can accurately predict the relative in-vivo performance of a new metal-metal bearing, at least in the case of "ideal" conditions. A standard guideline for wear testing in three-axis hip joint simulators has been adopted by the ISO (#14242), and a comparable guideline has been proposed for two-axis hip simulators, the most common being the "orbital bearing machine" or "OBM", which also is the most widely used hip simulator internationally. The techniques presented in each of these documents may be applied to the evaluation of metal-on-polyethylene, ceramic-on-polyethylene, metal-on-metal and ceramic-on-ceramic bearings.

The usefulness of testing under less-than-ideal ("adverse") conditions is discussed in the following sections.

II. Wear Testing under "Adverse Conditions"

In the case of a hip prosthesis in vivo, any or all of the classical wear mechanisms (adhesive, abrasive and fatigue) may occur while the prosthesis is functioning in one of four distinct wear modes (Fig. 3). [13] [14] Mode 1 refers to *intentional* articulation between two *bearing surfaces* only, which is necessary for the prosthesis to function. Mode 2 refers to *unintentional* articulation between a *bearing surface* and a non-bearing surface, for example, if the femoral ball dislocates and impinges against the rim of the socket. Mode 3 refers to intentional motion between two bearing surfaces, but with *third-body abrasive contaminants* entrapped between the surfaces. Mode 4 refers to *unintentional* motion between two *non-bearing surfaces*. This may include "backside" wear between an polyethylene acetabular liner and the metal acetabular shell, impingement between the rim of the socket and the neck of the femoral component, fretting wear at the Morse taper junction between the ball and the stem, and so on. Non-cemented prostheses that tend to shed particles from their porous coatings are particularly susceptible to Mode 3 wear, and the loaded interfaces between the components of a modular prosthesis provide additional opportunities for Mode 4 wear. Furthermore, the debris produced in Mode 4 may contribute directly to osteolysis, or it can migrate to the bearing surfaces, initiating rapid Mode 3 wear.

Ideally, bearing surfaces for prosthetic joints should have high wear resistance under the ideal conditions of Mode 1, and should be designed to *avoid* the adverse conditions of Modes 2, 3 & 4. Similarly, in evaluating the suitability of a particular bearing material for use in a hip prosthesis, it is important to clearly distinguish among these four wear modes.

A. Extreme Load Angles

In hip simulators for which the direction of the load axis is fixed relative to the cup, the angle between the polar axis of the cup and the load vector is typically about 30 degrees (e.g., see the ASTM and ISO standards for 3-axis hip joint simulators.) This is intended to model the location of the force vector in a "typical" patient, although the load direction in vivo varies substantially among patients, and may move considerably in a given patient during the gait cycle. Because of the spherical shapes of the ball and socket, moving the load axis somewhat closer or further from the cup axis (but remaining in Mode 1) can be expected to have little if any effect on the type or amount of wear that occurs with a metal-metal hip bearing. Rather, it simply moves the *location* of the wear within the cup.

In contrast, if the angle between the polar axis and the load is large enough (for example, in modeling a cup that has been placed in the pelvis in a nearly vertical orientation), the load axis will be very near to the edge of the cup. This can result in a substantially smaller contact area, proportionately greater contact stress and, consequently, increased rate of wear. The percentage increase in wear might vary somewhat among different designs of metal-metal hips, but a vertically placed cup would not be expected to cause catastrophic wear as long as the ball remains within the cup (i.e. in Mode 1). With a nearly vertical cup, the hip would likely fail by repeated dislocation (causing Mode 2 wear between the ball and the rim of the acetabular component) and/or gross loosening of the cup, either prior to or along with excessive wear of the bearing surfaces. However, the latter events are not inherent in the tribology of metal-metal bearing surfaces.

B. Higher than Normal Loads

Both theoretical calculations and laboratory tests strongly indicate that most metal-metal hips operate under "mixed lubrication," [3, 15, 16] that is, with some solid-solid contacts (that are probably boundary-lubricated by proteins) but with much of the bearing zone separated by a thin layer of fluid ("fluid-film" lubrication.) With a fluid-film, there is very low friction and possibly negligible wear. In general, the thickness of the film and, therefore, the percent of the bearing area that is separated by it, increase with increasing speed of oscillation, decreasing clearance (up to a point), increasing viscosity of the lubricant, and decreasing applied load. Essentially, there is a balance between the fluid being dragged between the bearing surface by viscous shear during motion, and the fluid being squeezed from between the surfaces due to the applied load. Because typical metal-metal bearings operate in the mixed lubrication mode, any change in one of the key parameters may shift the lubrication in favor of fluid film separation, substantially reducing the friction and wear, or in the direction of solid-solid contact, increasing friction and wear.

Williams and colleagues [17] demonstrated this principle when they ran metal-metal hips under a fixed motion pattern and fixed maximum load, but with two values of the *minimum* load during the "swing phase" of gait, i.e., from 100 N to 280 N. This increased the rate of wear ten-fold, presumably because the higher load during swing phase increased the rate of squeeze-out of the lubricant, reducing the film thickness (increasing the solid-solid contacts) during the highly loaded phase of gait, and, therefore, increasing the rate of adhesive-abrasive wear.

Similarly, Bowsher and colleagues [18] compared the wear of metal-metal bearings under normal walking conditions (2450 N max, one cycle per second) and simulated "jogging" (4500 N max, 1.75 cycles per second.) Under the jogging conditions, the rate of wear was about nine times greater than under walking conditions. Although the higher cycling rate for jogging might have increased the thickness of the fluid film somewhat, this also could increase the rate of frictional heating, which could, in turn, degrade the boundary lubricating properties of the serum, increasing wear. In addition, as in Williams's study [17], the higher maximum load during jogging might have shifted the balance away from fluid film lubrication, resulting in the observed increase in wear rate.

Whatever the explanation, as with the increased loading during swing phase, it is not apparent that wear tests under "jogging" conditions need be repeated for every candidate metal-metal bearing, unless there is reason to suspect that a proposed new material may be substantially more susceptible to these adverse conditions than conventional cobalt-chrome metal-metal bearings.

C. Stop-Start Cycling

Paré and colleagues [19] pointed out that, unlike the non-stop cycling typically used in hip simulators, patients with hip prostheses walk with frequent pauses (i.e., standing or sitting.) To assess the potential effect of this "start-stop" motion on wear, they ran metal-metal hips in a hip simulator under continuous walking conditions (2100 N max load 50 N during swing phase, with continuous motion), and with a start-stop motion protocol (360 seconds continuous motion, pausing for 60 seconds at 1400 N, resuming cycling 1400 N load for 360 seconds.) Under the start-stop testing, the wear rate increased substantially for four of the hips, but was not changed for the remaining three. Although Paré and colleagues offered no explanation for the different behavior, it is likely that the increased wear was due to a shift away from fluid film lubrication under the stop-start conditions.

Once again, because the higher wear rate during start-stop motion is predicable from fundamental principles of tribology, and there is no reason to expect that the use of these conditions would markedly alter the rank-order of wear resistance of the currently used metal-metal bearings, this type of testing may be reserved for substantially new alloys and/or bearing designs.

D. Negative Clearance and Frictional Torque

As early as 1971, Walker and Gold [20] emphasized the importance of having a positive clearance between the ball and socket in metal-metal bearings. Even a slight negative clearance causes "equatorial" contact, extremely high pinching forces between the ball and cup and, in turn, very high frictional torque and wear (Fig. 4). For example, with McKee-Farrar hips, they measured frictional torques ranging from 3.7 Nm with a "broad" contact area, to about 25 Nm with equatorial contact. Walker and Gold suggested that such high frictional torque may have been the primary cause of high rate of early failure with some designs of 1st generation metal-metal hips.

Consistent with Walker and Gold's early report [20] Semlitsch and colleagues [21] pointed out that a high percentage of the early failures of 1st generation metal-metal hips occurred among a subset prostheses from a single source that had been manufactured with a very small clearance between the ball and cup, and with a cup wall thickness of only 2 mm. Semlitsch hypothesized that the small clearance in combination with excessive deformation of the cup led to ball-socket "clamping," predisposing the implants to failure.

As with other bearing materials, the total frictional torque generated by a metal-metal bearing is a function of the external load, the coefficient of friction of the bearing surfaces, the adequacy of the lubrication mechanisms, and the *distribution* of the contact stress over the bearing surfaces. As Walker and Gold estimated [20], when the contact zone is near the equator (i.e., due to negative clearance) the resultant frictional torque may be an order of magnitude greater than when the contact zone is near the pole. (Theoretically, the minimum frictional torque occurs when the load is transmitted through a single point at the pole, but the resultant extremely high contact stress would likely lead to severe wear.)

In the absence of equatorial binding, the frictional torque of 1st generation metal-metal hip prosthesis appears to have been in a safe physiological range. In 1972, Andersson et al. [22] reviewed the existing literature and reported that, in laboratory tests, the frictional torque at the point of maximum load during "gait" ranged from 2.3 to 17.4 Nm for 1st generation McKee-Farrar metal-metal hips, compared to 0.4 to 0.47 Nm for Charnley metal-polyethylene hips. In contrast, in cadaver tests, they found that the minimum torque required to loosen a well-cemented acetabular cup ranged from 92 to 188 Nm. Andersson and colleagues concluded that "the results of these tests suggest that the frictional moment exerted on the prosthetic cup is most unlikely to approach the *static* failing strength of either the bond between the cup and the cement or that between the cement and the bone." However, they did speculate that "if the moments applied in service are indeed about one-quarter of the magnitude of the moments required to cause static failure [of the acetabular bone], it seems possible that stresses may locally be high enough to cause fatigue fracture in the bone."

With the hindsight of three decades, this last statement by Andersson and colleagues appears to be overly cautious, in that there is no evidence that the frictional torque generated by 1st generation metal-metal hips (having a positive clearance) was sufficient to routinely loosen a well cemented acetabular cup through fatigue failure of the fixation. For example, in a five-year follow-up, Bentley and Duthie [23] reported that only one out of 101 McKee-Farrar acetabular components was revised for loosening, and there was no acetabular loosening in 128 metal-polyethylene Charnleys. In another clinical study, Djerf et al., [24] reported higher incidences of "radiological" loosening of acetabular cups at five years, but the rate was actually lower for McKee-Farrars (22 of 84, or 26%) than for Charnleys (18 of 54, or 33%). Similarly, Jacobsson and colleagues [25] reported a 20-year survival rate of 77% for McKee-Farrar hips, compared to 73% for Charnleys.

Tribologists at Biomet, DePuy and Zimmer have recently used hip simulator tests to verify that negative clearance also causes severe frictional torque and wear of 2nd generation metal-metal hips. Consequently, manufacturers use a positive clearance in the range of 25 to 250 microns (Table 1), in part as a safety factor against the detrimental effects of equatorial contact. Since a state of the art coordinate measuring machine (CMM) can detect eccentricities on the order of one micron, ensuring that the clearance exceeds the eccentricity in all positions for a given design of metal-metal hip is essentially a quality-assurance issue, and does not need to be routinely verified through hip simulator testing.

E. Third Body Abrasion

Although a number of investigators have evaluated the effect of third-body abrasion (Mode 3) on the wear of metal-polyethylene bearings and ceramic-polyethylene hip bearings, [26-29] this has not been widely examined in the case of metal-metal hips. The laboratory models for third-body wear with polyethylene cups have included 1) placing the particles directly between the ball and cup, 2) adding particles to the lubricant or 3) intentionally damaging the femoral balls and then running them against polyethylene cups under clean conditions. The latter technique is intended to reproduce the key adverse effect of the third-body particles, i.e., rapid wear of the polyethylene, but without the particles becoming embedded in the polyethylene, which renders wear measurement by weight loss unreliable. Not surprisingly, these third-body wear models can induce very rapid wear of the polyethylene, depending on the type and amount of abrasive third-body particles used (e.g., fragments of bone, PMMA, or porous metal coatings), or the amount of intentional scratching of the femoral ball. The difficulty of interpreting the results lies in determining how much third-body damage is clinically relevant.

Lu and colleagues [30] measured the wear of six cobalt-chrome alloy metal-metal hip prostheses (Robert Mathys Foundation) running under clean conditions for one million cycles, then with titanium particles placed between the ball and cup (two sets of specimens) for one million cycles, and then again clean for an additional three million cycles. Addition of the particles increased the wear rates (cup plus ball) to 15 and 61 microns per million cycles. Under subsequent clean conditions, the scratching that was induced by the third-body particles was substantially polished out and, by the 3 to 5 million cycle interval, the wear rates decreased to negligible levels.

These results by Lu et al. [30] demonstrated a fundamental difference between metal-metal and metal-polyethylene bearings. In both cases, the presence of hard third-body particles can markedly accelerate the wear rate. However, with metal-metal bearings, the wear rates have the potential to return to normal low levels through self-polishing, provided that the source of the third-body particles is eliminated. Since it is predictable that metal-metal bearings will exhibit greater wear in the presence of third-body abrasives, there is no apparent rationale for repeating such testing for metal-metal hips comprising the conventional cobalt-chrome alloys. Rather, this could be reserved for metal-metal bearings that incorporate a change in metallurgy substantial enough to raise the possibility of a greater susceptibility to abrasive wear than current metal-metal hips, including, for example, metal surface with hard coatings.

F. Ball Distraction Tests

Komistek and colleagues [31] used fluoroscopy to demonstrate that, in a hip prosthesis with a *polyethylene* acetabular component, the femoral ball may sublux several millimeters during each cycle of gait. However, they did not detect such distraction with metal-metal bearings. This could, in part, be due to the "suction" effect caused by the smaller ball-cup clearance with the metal-metal hips, such that the subluxation, if any, was below the resolution of the fluoroscope (about 750 microns.)

On the other hand, Nevelos and colleagues [32] and others [33, 34] have observed "striped wear" present on retrieved alumina-alumina hips, and have shown that this type of wear can be generated in a hip simulator by distracting the ball from the cup by several hundred microns and then driving it against the rim of the socket when re-seating (a form of Mode 2 wear, Fig. 3). While this suggests that a similar distraction-impingement phenomenon may occur with some alumina-alumina hips in vivo, Walter and colleagues [33] concluded that the *location* of the stripe wear on retrieved implants indicated that it probably occurred during high flexion activities, such as rising from a chair or stair climbing, rather than walking. In any case, stripe wear has not been reported on retrieved metal-metal hips. This may be because distraction and rim-impingement do not occur in vivo, or, if they do, the damage is subsequently polished out during normal gait.

Thus, subjecting a metal-metal bearing to Mode 2 distraction wear in a hip simulator will have the predictable effect of generating substantial stripe wear, but it is not clear that this type of wear is of consequence with metal-metal hips in actual clinical use. Again, the rationale for doing so with a candidate metal-metal hip would be concern that it would be substantially more vulnerable to distraction-impingement wear damage than current metal-metal bearings.

III. Nominal Design Parameters for Metal-Metal Bearings

1. Neck-Socket Impingement: The adverse effects of neck-socket impingement (Mode 4) are well understood, particularly including severe wear of the rim of the socket, which may lead to fracture and/or loosening, and notching of the neck of the prosthesis, which can lead to neck fracture. The likelihood and severity of neck-socket impingement is a function of the extent of coverage by the cup, the shape of the socket rim, the size and shape of the neck, and the orientation of the components in the pelvis and femur. However, while it may be important to evaluate these for a given design of hip prosthesis (regardless of the type of bearing surface used), as with ball-socket dislocation, neck-socket impingement is not particularly a function of the Mode 1 tribological properties of the metal-metal bearing surfaces.

2. Diameter
   Current bearing diameters for metal-metal hips range from 28 to 60 mm (Table 1). It is not straightforward to predict the relationship between diameter and the rate of wear (Fig. 5). While the contact area tends to increase with increasing diameter, leading to a reduced contact stress and, therefore, a reduction in the *depth* rate of wear, the wear is occurring over a larger area, such that the *volumetric* rate of wear (per unit sliding distance) is unchanged.

   On the other hand, in a given patient, the total sliding distance of the bearing surfaces increases in proportion to the diameter which, all other factors equal, would cause the total volumetric wear to be greater for a given distance walked. However, the sliding *speed* of the bearing surfaces also increases in proportion to the bearing diameter, which, as noted above, tends to favor fluid film separation. Because of this complex interaction of parameters, it is difficult, if not impossible, to calculate accurately the effect of ball diameter on wear. Fortunately, it may be measured experimentally. In a hip simulator study by Smith et al. [15] the wear of metal-metal hips increased with diameter going from 16 to 22 mm, but dropped sharply at 28 mm and decreased further at 32 mm, presumably due to increased fluid entrainment with the larger diameters. Consistent with this, simulator tests of large diameter hip surface replacements have indicated very low steady-state wear rates. [5] [7, 35]

   In summary, for the range of diameters currently used (Table 1), ball diameter is not likely to have a strong effect on the clinical wear performance of cobalt-chrome alloy metal-metal bearing surfaces.

3. Ball-Cup Clearance and Sphericity

   As discussed above, because of the need to avoid the pinching, high friction and high wear that occurs with negative clearance, the positive clearance used in current metal-metal bearings ranges from about 25 to 250 microns (Table 1). Clearances of 1st generation retrieved devices were certainly not ideal in terms of current design standards. (See Retrieved MoM Report in the Unpublished Information section in Appendix 2.)

4. Surface Roughness

As produced by the manufacturers, modern metal-metal bearings have surface finishes on the order of 0.05 microns Ra or less (Table 1), substantially better than what was typical of 1st generation devices. In addition, due to the "self-polishing" capability of metal-metal bearings, the long-term steady state wear rates are not markedly affected by small differences in the original roughness. For example, in a hip simulator study Chan et al. [3] reported that the total volumetric wear accumulated during 3 million cycles with metal-metal hips decreased to about 1/3 as the *initial* surface finish was improved from 0.035 to 0.005 microns (CLA). However, most of the difference in wear rate occurred during the initial run-in phase, such that there was no correlation between the initial roughness and the steady state wear rate for the period from 1 to 3 million cycles (personal communication, June 2005). Similarly, Rieker and colleagues [7] observed self-polishing of large diameter metal-metal bearings that were tested in a hip joint simulator. In clinical use, it also appears that, in the absence of substantial third-body abrasives, the bearing surfaces may undergo self-polishing, such that the residual scratching from the manufacturer's final polishing step are gradually removed.[1]

On the other hand, abrasive wear by third-body particles can markedly *increase* the surface roughness, such that the *functional roughness* in vivo is highly dependent on the cleanliness of the joint fluids. Because of this, it is questionable whether the production of bearings with an initial "super-finished" surface, which may add substantially to the cost, is likely to have a marked effect on the clinical performance of a metal-metal hip prosthesis beyond the wear-in phase.

5. High or Low Carbon Alloy

In laboratory tests using pin-on-disk machines or joint simulators (Table 2), metal-metal bearings using high-carbon cobalt chrome alloy (or with one surface of high-carbon and one of low-carbon) have consistently exhibited wear resistance superior to that of low-carbon against low-carbon. Consequently, the majority of metal-metal bearings now in use have one or both bearing surface of high-carbon alloy.

IV. Recommendations for Special Controls

Based on the comprehensive body of research on the tribology of 1st and 2nd generation metal-metal hip prostheses, it is reasonable to propose a two-tier program of laboratory evaluation of new bearings prior to their clinical use. For brevity, these may be divided into the categories of "Conventional" and "Experimental" bearings.

A. Conventional Bearings

A Conventional metal-metal bearing would be defined as one whose composition and design parameters fall within the range of those presently in use (as detailed below), such that it may be assumed with reasonable reliability that its tribological performance in vivo will be comparable as well.

Establishment that a device fit the definition of a Conventional bearing could include the following:

1. Certification that the alloy used satisfied ASTM F75 or F1537
2. Certification that the bearing included at least one surface of high-carbon alloy.
3. Certification, based on CMM or other suitable measurement technique, that the clearances and sphericity are within the conventional range. (Table 1)
4. Certification that the surface roughness parameters are within the conventional range.

Testing of a Conventional bearing could include the following:

1. Range-of-motion testing (or analysis using computer modeling) to ensure that the range of motion without neck-socket impingement is adequate.
2. For modular components, validation of the integrity of liner locking mechanism through suitable push-out, lever-out and/or fatigue testing.
3. Wear testing for at least five million cycles under load and motion conditions simulating normal walking, using simulator test conditions that have been shown to closely reproduced the wear that occurs in vivo. The purpose would be to verify that the wear rates during the wear-in phase and the steady state are comparable to conventional metal-metal bearings. The specific bearings used in the wear test should include the potentially worst-case (highest wear) combinations, i.e.
    a. Smallest clearance (in case of potential equatorial contact)
    b. Largest clearance (i.e., smallest contact area, longest potential wear-in phase)
    c. Roughest initial surface finish

    Full characterization of the wear processes would include the weight loss of the components, dimensional changes (from CMM), periodic re-measurement of roughness (to document self-polishing, if any) and SEM of the surface morphology before and after wear testing.

B. Experimental Bearings

An Experimental bearing would be defined which varied substantially from a Conventional bearing in one or more of the four parameters listed above (alloy, carbon content, clearance & sphericity, roughness). For example, Experimental bearings would include those with an unusual alloy composition, with intentional micro-texturing ("golf ball" surfaces), surface hardening by ion-implanting or vapor deposition, or ceramic or diamond coatings. *In addition* to the testing listed above for Conventional bearings, an Experimental bearing could be subjected to the following:

4. Frictional torque measurement over a suitable range of diameters and clearances, possibly before and after wear testing.
5. Hip wear simulation under normal gait conditions to at least 10 million cycles.
6. Hip simulator testing to detect an unusual sensitivity to severe conditions, including:
   a. 3 million cycles of start-stop testing
   b. 1 million cycles of ball distraction testing
   c. 1 million cycles of third-body abrasion
   d. 1 million cycles of "jogging" (i.e., higher load and cycling rate)
7. Analysis of the morphology of the wear particles (size distribution and shapes)
8. Bulk biocompatibility and biocompatibility of the wear debris (if the composition and/or morphology of the latter deviate substantially from that of Conventional bearings.)

This two-tiered evaluation program would avoid unnecessary and expensive testing on metal-metal bearings for which there is no reasonable expectation of tribological problems that have not been encountered by the currently used bearings, while providing intensive evaluation of new bearing combinations that might have unusual sensitivity to one or more of the conditions that can be encountered in vivo in some patients.

Table 1: Composition and Dimensions of Conventional Metal-Metal Hip Bearings

	Biomet	**Biomet**	**Biomet**	**DePuy**	**Zimmer**	**Corin**
Product Name	M2a-Taper	M2a-38 MOM	M2A Magnum	Ultima	Metasul	Cormet resurfacing and total hip
Material Head Neck Cup	Cup-Titanium Porous coating-Titanium alloy Tapered liner-Cobalt chrome Head-cobalt chrome	Cup-Cobalt Chrome Porous coating-Titanium alloy	Cup-CoCr Porous coating-Titanium alloy	Bearing insert-cocrmo ASTM 1537 Outer shell-Ti6Al4V Grain size-ASTM 10-12	Cup-Titanium alloy w/ Titanium porous coating Head & Inlay – CoCr alloy	
Cup Sizes OD	48-70 mm	48-70 mm	44-66 mm		49-81	46-62 mm in 2 mm increments
Cup Sizes ID	28 and 32 mm	38 mm	38-60 mm	28 mm	28 & 32	40, 44, 48, 52 and 56 mm
Head Sizes	28, 32 mm	38 mm	38 to 60 mm	28 mm	28 & 32	40, 44, 48, 52 and 56 mm
Neck Lengths	-6 and -3,Std, +3,+6, +9, +12	Same as M2a Taper	Same as M2A for 38 and 40 mm heads, but there is no +12 size for 42-60 mm heads		-4, Neutral, +4, & +8	
ROM	28 mm-126 deg and 32 mm-132 degrees	154 degrees	151.74 to 162.82 degrees		28mm – 114 deg 32mm – 127 deg	Approx 45 degrees for resurfacing and 80 degrees for

						total hip
Wear Rate	28 mm- .73 $mm^3/10^6$ cycles 32 mm- .15 $mm^3/10^6$ cycles	0.039 $mm^3/10^6$ cycles	46 mm- .191 $mm^3/10^6$ cycles 56 mm- .209 $mm^3/10^6$ cycles		Linear- 3 micron per year (clinical data)	.24 $mm^3/10^6$ cycles
Sphericity	<5 microns	<5 microns	<5 microns	<5 microns	<5 microns	<10 microns
Radial Clearance Between Head and Liner	25-75 microns	25-75 microns	75-150 microns	20-40 microns	MMC: 70 microns LMC: 170 microns	70-250 microns
Surface Finish	0.005 microns	0.005 microns	0.005 microns	0.01 microns max	0.005 micron	<0.05 microns

Table 2: Summary of studies showing lower wear with high carbon CoCr alloys

Study	Type of Wear Tester
Wang et al. 1999 [36]	Disk-on-disk
Tipper et al. 1999 [37]	Pin-on-flat
Scholes & Unsworth 2001 [38]	Pin-on-flat
St. John et al. 1999 [39]	Hip joint simulator
Chan et al. 1999 [3]	Hip joint simulator
Firkins et al. 2001 [40]	Hip joint simulator

Initial: Large clearance, small contact area, surface carbides

Wear in : Surface carbides dislodged, third-body abrasion, high wear rate

Steady state: High polish, large contact area, high conformity, fluid film separation, low frictional torque and low wear rate

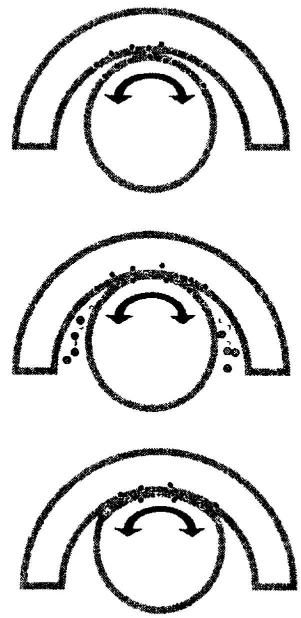

Fig. 1: Schematic diagram of the changes in the roughness and conformity during the wear-in phase of metal-metal hip bearings (the clearance is exaggerated for clarity)[1]

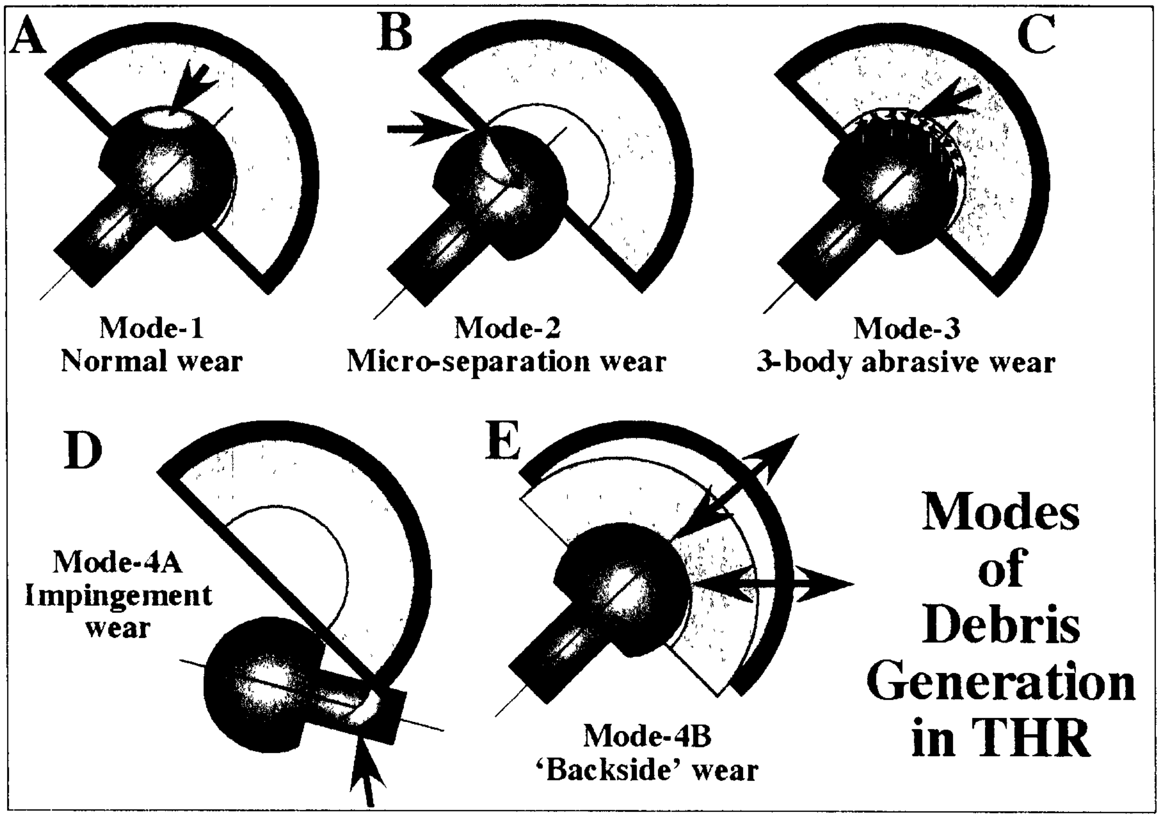

Figure 3: The four Wear Modes for a hip prosthesis [13] [14]

A) Mode 1 involves wear between only the intended bearing surfaces; B) Mode two involves a bearing surface contacting a non-bearing surface, this example being the ball and the rim of the socket; C) in Mode 3, the intended bearing surfaces are in contact, but with interposed third-body abrasive particles (e.g., fragments of bone, PMMA, metal porous coatings); D) in Mode 4, two non-bearing surfaces are in contact, these examples being neck-socket impingement and backside wear between the poly liner and the metal shell. (Drawing courtesy of Ian Clarke, Ph.D., Loma Linda University.)

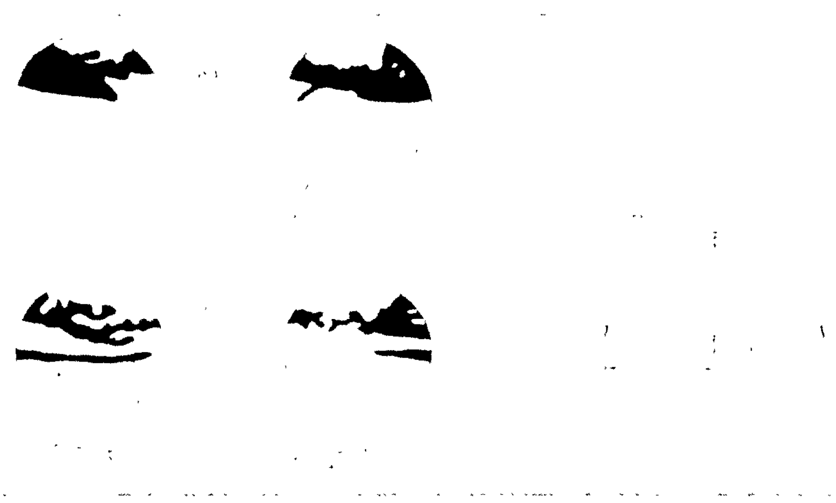

Figure 4: Illustration of the regions of "equatorial" contact, high frictional torque and high wear (left) that are caused by a "negative" clearance between the ball and socket (right): from Walker and Gold, 1971 [20] (Permission to reproduce this figure has been requested.)

Figure 5. With a small diameter (left) there is less sliding *distance* per step, which, all other factors equal, would result in less wear for a given distance walked by a patient. However, with a larger diameter (right), there is greater sliding *velocity* of one surface over the other, which may enhance fluid film separation, thereby reducing friction and wear. Laboratory wear experiments tend to support the concept that the steady-state wear rates with large diameter metal-metal bearings (such as hip surface replacements) may be as low as or lower than those with smaller diameter bearings.

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