Differential Hardness Bearings in Hip Arthroplasty

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Second-generation metal-an-metal (MOM) bearing couples produce less wear debris than first-generation implants due to a better understanding of design parameters coupled with improved manufacturing processes. Wear debris generated by MOM bearings is extremely small compared with that from conventional metal-an-polyethylene bearings and can potentially be larger in number. Reductions in metal wear debris may be achieved by the use of differential hardness (DH) bearings for use with surface or total hip replacement implants. Laboratory testing has demonstrated that DH bearings exhibited less abrasive, adhesive, and surface fatigue damage than previous-generation MOM bearing couples. In addition, recent clinical trials have demonstrated a reduction in metal ion levels in patients who were implanted with a differential hardness bearing system. DH bearings may represent a third generation of hard bearing implants for use in hip replacement surgery that may potentially result in less complications and better success rates. (Journal of Surgical Orthopaedic Advances 17(1):40-44, 2008)

Key words: clearance, differential hardness, form, lubrication, metal ions, surface roughness, wear

Osteolysis induced by polyethylene wear debris is a major concern in the performance of artificial hip joints. Recently, there have been many developments aimed at reduction of wear debris to increase the life of the hip joints. Second-generation metal-on-metal (MOM) bearing couples that are currently available produce less wear debris than the metal-on-metal components of the first generation, as a result of improved manufacturing techniques and better understanding of the role of carbon and diametric clearances, and also significantly less wear debris than traditional metal-on-polyethylene (MOP) bearing couples. Wear debris is the major source of metal ions. MOM bearing couples generate wear particles that are measured in nanometers (1, 2), whereas those produced from MOP bearing couples are micron to submicron in size (3, 4). The number of wear particles generated from MOM bearing couples is, therefore, large when compared with MOP bearing couples. It has been shown that these particles are responsible for the majority of the metal ions released into blood and tissues. The clinical implications of these elevated ion levels have yet to be understood. The application of MOM implants in young, active patients exposes them to the effects of metal ions for significantly longer times than older, less active patients. Thus the current focus is on achieving bearing couples that produce even less wear when compared with contemporary MOM bearing couples.

History of MOM Bearings

The history of MOM bearings in hip arthroplasty dates back to 1938 when a few stainless steel implants were used by Dr. Philip Wiles in London. The first use of CoCr implants in hip arthroplasty was in 1950 by Dr. George McKee. The original devices of McKee-Farrar were investment cast versions of CoCr material. There was only a 50% success rate for the MOM hip implants that were implanted between 1956 and 1960 as stated by McKee (5), due to poor surface finish and sphericity of the bearings. The manufacturing processes available at the time did not have the capability to provide excellent surface finish and a high degree of dimensional control, which are needed for good results. The designers did not try to achieve optimum clearance between the components and they did not understand if equatorial or polar contact was superior. Equatorial contact was reported to be an issue by Walker and Gold (6). They showed high frictional torques due to equatorial contact as opposed to polar contact and there were concerns that frictional loading contributed to acetabular loosening. MOM hip bearings

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apparently fell out of favor following the early success of Charnley's low-friction arthoplasty.

Although McKee-Farrar implants showed short-term failures, many of them survived over 20 years, thus renewing interest in metal- metal articulation. Much of the recent literature by McKellop et al. (7), Wagner et al. (8), and Brown et al. (9) on metal-metal articulation refers to the long-term survival of a significant number of post -1968 McKee-Farrar implants. The most impressive clinical results were by Jacobsson et aI. (10), who concluded that the 20-year cumulative probability of aseptic survival was 77% for McKee-Farrar implants and 73% for the Charnley prosthesis. Improvement in the design tolerances, such as surface finish, form, and manufacturing techniques, led to the resurgence of metal-metal hip bearings. Second-generation metal-metal hip bearings exhibited good in vivo and in vitro wear performance. Issues related to frictional torque were controlled with metal- metal bearings demonstrating significantly lower frictional torque.

Despite the advantages offered by second-generation metal-metal hip bearing couples, the wear debris generated by them is extremely small and can generate a high number of particles. These particles have the potential to migrate through the lymphatic system and accumulate in the liver, spleen, and lymph nodes (11, 12). There are concerns about the reaction of tissue to the wear debris. Reduction in wear, which in turn reduces particle generation, is desirable.

Design Issues

Much of the work published in the literature has focused on the following design parameters that influence the life of hip implants.

Material

Metal-metal hip bearings are generally fabricated from surgical grade Co-Cr-Mo alloy because of corrosion and wear resistance. They are also known for their selfhealing capacity that helps the bearings to be typically polished out with time rather than worn out with continued cycles in service. Cast and wrought forms of Co-Cr-Mo alloys were used with reasonable success. Carbon content in these forms plays an important role in the wear of hip bearing couples. High-carbon alloys (i.e., alloys with carbon content between 0.2% and 0.3%) generate lower wear rates than alloys with low-carbon content (Le., alloys with less than 0.2% carbon) (13-16).

Clearance

Optimum clearance between the bearing couples is essential to avoid problems with high frictional torque and equatorial seizing. This ensures polar contact between femoral head and acetabular cup. Chan et aI. (13) and others confirmed that this is the most influential factor in wear behavior. Too little clearance can result in congruent head-cup surfaces resulting in equatorial contact. Proper clearance is essential for the egress of the wear particles and ingress of lubricant to the articulating surfaces to maintain fluid film lubrication, a phenomenon by which a thick film is formed, thus reducing the wear. Wear and wear rates increase if the clearance between the component is too small or too large (17, 18).

Form

Form has not been specifically quantified as a parameter that affects the wear. However, it has been suggested that better sphericity may result in low run-in wear and thus lower total wear.

Lubrication

Strict control over design and manufacturing tolerances produces a favorable condition for lubrication. According to elasto-hydrodynamic lubrication theory, lubrication regime depends on diametric clearance between the bearing couples, surface roughness of the bearing components, and Young's modulus of the bearing materials (19). Hard-on-hard bearings would experience improved lubrication compared with hard-on-soft bearings due to low diametric clearances and surface finish.

Surface Roughness

Surface roughness has been identified as a parameter that can control the wear performance of the bearings. Lower surface roughness values can result in an effective lubricant layer because the lower the surface roughness is, the less is the film thickness required to separate articulating surfaces. Rougher surfaces require higher film thickness to separate the articulating surfaces.

Head Size

Large-diameter bearing couples tend to develop full fluid film, lubricant film thickness due to greater sliding velocity, which is dependent on femoral head size, thus reducing friction and wear.

Biological Concerns

A lot of research has been conducted to date to assess the biological responses of wear debris. There are many articles that explain the level of metal particles/ions released, the nature of their reactions and the regions where they reside, and their long-term effects. According to Doom et al. (2) and Campbell et al. (3), the wear debris generated by MOM bearings is extremely small (nanometer range) compared with the micron to submicron range with polyethylene bearings. Thus the small size of particles yields a large number of particles. The particles are classified into two types: crystalline particles that are high in Co and Cr and noncrystalline particles that are high in Cr and oxygen. Elevated levels of Co and Cr were found in the blood and urine of the patients with MOM implants (20-22).

Differential Hardness Bearings

Among many factors that govern the wear is the hardness. Wear generated by the bearings is proportional to the hardness of the bearings. Bearings with high hardness generate lower wear than bearings with lower hardness. Thus lower wear is expected between ceramic-on-ceramic (COC) bearings and MOM bearings compared with MOP bearings. COC bearings t<;:> date generate lower wear than MOM bearings. Although COC bearings generate lower wear, there is always fracture risk associated with these bearing couples. Second-generation bearings produce low wear, but the wear debris generated by them is extremely small with a large number of particles. Thus there is a need to generate bearing couples that generate even lower wear than the second-generation bearing couples and reduce the number of wear particles.

Differential hardness MOP bearing couples have been used in orthopedics for decades. Although MOP bearing couples generate more wear than hard-hard bearing couples, the wear generated by the femoral head is insignificant compared with wear generated by polyethylene liner. No wear can be detected on the harder femoral heads. Earlier studies from surface-damaged Charnley implants demonstrated superior frictional properties for MOP bearings compared with MOM bearings. The superior frictional properties and lower surface damage of the femoral head from differential hardness MOP bearings and the longevity of MOM bearings use the concept of differential hardness with hard-on-hard bearings. These results led to the resurgence of differential hardness MOM and ceramic-on-metal (COM) bearing couples. Coatings and surface modifications, such as oxidizing the outer layers of metals in an effort to make them harder, have been proposed. Unfortunately, coatings sometimes flake off and generate third-body wear particles. Moreover, surface modifications that are very thin may not last for the life of the implant. Another way to reduce wear is to create a bearing couple whose surface properties are different. Differential hardness hard-on-hard bearings were earlier studied by Firkins et a1. (23). They performed wear testing on COM bearing couples and reported wear reduction of l0-fold when compared with like-hardness, conventional MOM bearings.

The concept of differential hardness bearings is also extensively used in other industries apart from the medical device industry. As per the technical note issued by NASA, differential bearings when used in ball and racer bearings increase the maximum fatigue life. Their results demonstrated a potential four to five times greater fatigue life with the use of differential hardness bearings (24, 25).

Effects of Differential Hardness Bearings on Tribology Properties

Wear in hip bearing couples is governed mainly by three mechanisms: I) abrasive wear, 2) adhesive wear, and 3) surface fatigue wear mechanism. Abrasive wear is a phenomenon in which material in one surface is removed by harder particles. These harder particles may result from the presence of hard asperities on the other surface or from the presence of third-body particles between the two surfaces. Abrasive wear usually results in scratches on the smooth surface of the bearing component. Adhesive wear is a phenomenon in which surface asperities of the bearing surfaces are plastically deformed and eventually welded together with high pressure. As the motion between the two bearing surfaces continues, the bond between the two bearing surfaces is broken, which produces cavities on the surfaces and leaves some material welded onto another surface. The tiny particles that are broken during the adhesion wear can also act as third-body wear particles. Adhesive wear is usually higher between the same materials. Surface fatigue wear takes place when the surface stress beneath the contact area exceeds the endurance limit of the material. Differential hardness bearings reduce the wear in bearings by reducing abrasive, adhesive, and surface fatigue wear of the bearing component most susceptible to wear. Wear occurs predominantly on one component surface (an acetabular shell in the case of hip articulation). Firkins et al. (23) reported a lO-fold decrease by using differential hardness bearings instead of like-hardness MOM bearings.

Friction is another important tribologic property. Friction between the bearing couples is dependent on many factors. Wang et a1. reported that friction factor varied with clearance and peak load. Friction factor decreased with increased radial clearance and peak load (26). O'Connor et al. (27) found that friction was influenced by' the head size. Brockett et a1. (28) examined the friction of differential hardness COM implants. Friction of COM bearing couples was less than like-hardness MOM bearing couples and was similar to COC bearing couples. According to this article, like-hardness MOM bearings often result in an adhesive junction where the asperities meet. The high shear stress required to break this bond results in a high friction coefficient. This phenomenon was not observed in metal surfaces articulating with alternative materials or in ceramic contacts.

In Vivo and In Vitro Differential Hardness Wear Particles Analysis

A study of preliminary metal ion levels compared in patients with differential hardness bearings and conventional MOM bearings found a 61 % decrease in serum chromium levels and a 3% decrease in serum cobalt levels in patients with differential hardness implants at 6 months (29). Brown et al. (30) analyzed in vitro metal wear particles from differential hardness COM bearing couples and MOM bearing couples under standard and adverse wear conditions and found no significant difference in particle morphology or size distribution for any of the bearing combinations regardless of wear conditions (standard or adverse). Particles were found to be rounded and irregular in shape and typically less than 40 nm in size. Because the differential hardness bearing couples and MOM bearing couples generate wear debris with same size and shape, the lower wear on differential hardness bearing couples would generate lower wear particles than conventional MOM bearing couples.

Overview

In summary, improving the durability of total hip replacements requires a reduction in the total production and release of wear particles into the biological environment. With improvements in design, manufacturing, operative techniques, and outstanding tribological properties, third-generation differential hardness MOM bearings should improve the durability of hip implant by reducing the wear particles.

References

I. Catelas, I.. Medley, J. B., Campbell, P. A., et al. Comparison of in vitro with in vivo characteristics of wear particles from metalmetal hip implants. J. Biomed. Mater. Res. B Appl. Biomater. 70: 167 - 178, 2004.

2. Doorn, P. F., Campbell, P. A., Worrall, J., et al. Metal wear particles characterization from metal on metal total hip replacements: transmission electron microscopy study of peri prosthetic tissues and isolated particles. J. Biomed Mater. Res. 42:103-111,1998.

3. Campbell, P., Ma, S., Yeom, B., et al. Isolation of predominantly submicron sized UHMWPe wear particles from periprosthetic tissues. J. Biomed. Mater. Res. 29:127-131, 1995.

4. Shanbhag, A. S., Jacobs, J. J., GIant, T. T., et al. Composition and morphology of wear debris in failed uncemented total hip replacement. J. Bone Joint Surg. 76-B:60-67, 1994.

5. McKee, G. K. Developments in total hip joint replacement. Proc. Inst. Mech. Eng. 181(31):85-89, 1967.

6. Walker, P. S., Gold, B. L. The tribiology (friction, lubrication, and wear) of all-metal artificial hip joints. Wear 17:285-299, 1971.

7. McKellop, H., Park, S. H., Chiesa, R., et al. In vivo wear of 3 types of metal on metal hip prostheses during two decades of use. Clin. Orthop. Relat. Res. 329(suppl):SI28-SI40, 1996.

8. Wagner, M., Wagner, H. Preliminary results of uncemented metal on metal stemmed and resurfacing hip replacement autoplastic. Clin. Orthop. Relat. Res. 329(suppl):S78-S88, 1996.

9. Brown, S. R., Davies, W. A., DeHeer, D. H., et al. Long term survival of McKee-Farrar total hip prostheses. Clin. Orthop. Relat. Res. 402:157-163, 2002.

10. Jacobsson, S. A., Djerf, K., Wahlstrom, O. Twenty year results of McKee-Farrar versus Charnley prostheses. Clin. Orthop. Relat. Res. 329(suppl):S60- S68, 1996.

II. Case, C. P., Langkamer, V. *G.*, James, C.. et al. Widespread dissemination of metal debris from implants. J. Bone Joint Surg. 76-B(5):701-712, 1994.

12. Urban, R. M., Jacobs, J. J., Tomlinson, M. J., et al. Dissemination of wear particles to the liver, spleen, and abdominal lymph nodes of patients with hip or knee replacement. J. Bone Joint Surg. 82A(4):457 -477, 2000.

13. Chan, F. W., Bobyn, J. D., Medley, J. B., et al. Wear and lubrication of metal-on-metal hip implants. Clin. Orthop. Relat. Res. 369: 10- 24, 1999.

14. Dowson, D., Hardaker, c., Flett, M., et al. A hip joint simulator study of the performance of metal-on-metal joints. J. Arthroplasty 19(8):118-123,2004.

15. St. John, K. R., Poggie, R. A., Zardiackas, L. D., et al. Comparison of two cobalt-based alloys for use in metal-on-metal hip prostheses: evaluation of the wear properties in a simulator. ASTM STP 1365, 1999.

16. Firkins, P. J., Tipper, J. L., Saadatzadeh, M. R., et al. Quantitative analysis of wear and wear debris from metal-on-metal hip prostheses tested in a physiological hip joint simulator. Biomed. Mater. 11(2):143-157,2001.

17. Rieker, c., Schon, R., Kottig, P. Development and validation of a second-generation metal-on-metal bearing. J. Arthroplasty 19(8):5-11, 2004.

18. Nolan, F. J., Farrar, R., Schmidt, M. D., et al. Effect of head size and diametrical clearance on wear production of a new metal-on-metal hip prosthesis. 42nd Annual Meeting of the Orthopaedic Research Society, Poster #71, 1997.

19. Jin, Z. M.. Dowson, D., Fisher, J. Analysis of fluid film lubrication in artificial hip joint replacements with surfaces of high elastic modulus. Proc. Inst. Mech. Eng. [H] 211(3):247-256, 1997.

20. Jacobs, J. J., Skipor, A. K., Doorn, P. F., et al. Cobalt and chromium concentrations in patients with metal on metal total hip replacements. Clin. Orthop. Relat. Res. 329(suppl):S256-S263, 1996.

21. Lhotka, C., Szekeres, T., Steffan, I., et al. Four-year study of cobalt and chromium blood Ivels in patients managed with two different metal-on-metal total hip replacements. J. Orthop. Res. 21:189-195,2003.

22. MacDonald, S. J., McCalden, R. W., Chess, D. *G.*, et al. Metal-onmetal versus polyethylene in hip arthroplasty: a randomized clinical trial. Clin. Orthop. Relat. Res. 406:282-296, 2003.

23. Firkins, P. J., Tipper, J. L., Ingham, E., et al. A novel low wearing differential hardness, ceramic-on-metal hip joint prosthesis. J. Biomech. 34: 1291-1298,2001.

24. Zaretsky, E. V., Parker, R. J., Anderson, W. J., et al. Effect of component differential hardness on residual stress and rollingcontact fatigue. NASA technical note, Accession No. ADA393880, March 1965.

25. Zaretsky, E. Y., Parker, R. J., Anderson, W. 1., et al. Bearing life and failure distribution as affected by actual component differential hardness. NASA technical note, Accession No. ADA399803, Nov. 1965.
26. Wang, A., Essner, A., Klein, R., et al. Effect of contact stress on friction and wear of ultra-high molecular weight polyethylene in total hip replacement. Proc. Inst. Mech. Eng. [H] 215(2):133-139,200\.
27. O'Connor, D.O., Burke, D. W., Bragdon, CR., et al. Dynamic frictional comparison of different femoral head sizes and different lubricants. J. Biomech. 31(suppl 1):113, 1998.
28. Brockett, C, Williams, S., Zhongmin, J., et al. Friction of IOtal hip replacements with different bearings and loading conditions. J. Biomed. Mater. Res. B Appl. Biomater. 8IB(2):508-515, 1996.
29. Jacobs, J. J., Skipor, A. K., Markovich, G., et al. Preliminary results of the A-CLASS Advanced Metal on Metal Bearing Serum Ion Study. Society for Biomaterials Meeting, 2007.
30. Brown, C, Williams, S., Tipper, J. L., et al. Characterization of wear particles produced by metal on metal and ceramic on metal hip prostheses under standard and microseparation simulation. J. Mater Sci. Mater Med. 18(5):819-827,2006.