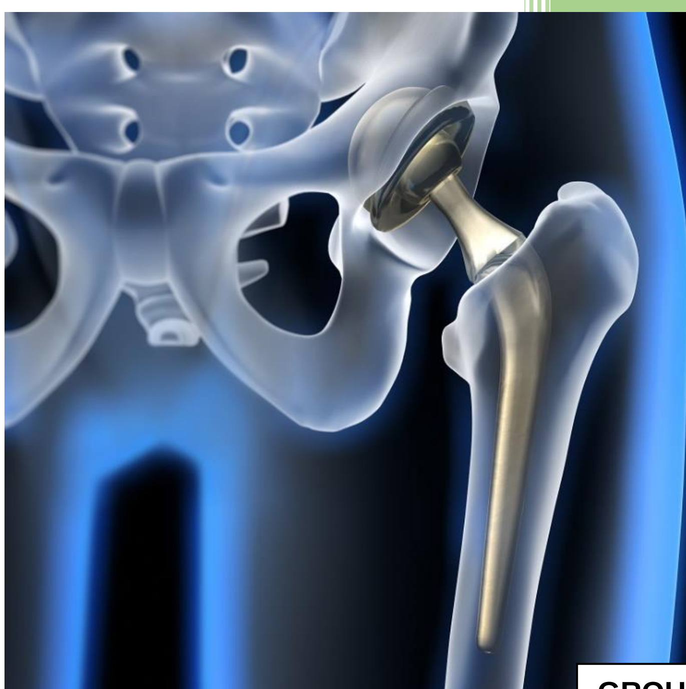
2016

METALLOSIS AND OSTEOLYSIS

Metal, Polyethylene and Ceramic Implants



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ABSTRACT:

An orthopedic implant is a medical device manufactured to replace a missing joint or bone or to support a damaged bone. There are many different procedure for implants, few of which are explained in this paper. It mainly focuses on the materials used in different types of implants, the types of implants i.e. Metal, Polyethylene, Ceramic and their combinations. The major risks with these implants are Metallosis and Osteolysis. The primary causes of premature failure in hip prostheses are due to wearing of the implants. The main cause of Metallosis and Osteolysis is wearing of implants. Various modes of wear are explained in this paper. The materials used in implants are Titanium, Polyethylene and Zirconium Nitride. Wear properties of different head sizes on various bearings are also studied and compared. Squeaking friction phenomena on ceramic bearings are also examined. Some of the major conclusions that can be drawn are that increase in head size reduces wear loss in M-o-M bearings. M-o-P have very low wear rate when the polyethylene used is of cross-lined type. Frictional coefficient was also found to have an impact on squeaking, with higher values leading to higher occurrences of resonance and acoustic instability. Furthermore, the effect of surface texturing showed positive results on the performance of bearings under boundary layer lubrication conditions.

Keywords:

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INTRODUCTION:

An implant is a medical device manufactured to replace a missing biological structure, support a damaged biological structure, or enhance an existing biological structure. Implants are categorized into groups by application.

- Sensory and neurological- implants are used for disorders affecting the major senses and the brain, as well as other neurological disorders
- Cardiovascular- medical devices are implanted in cases where the heart, its valves and the rest of the circulatory system is in disorder
- Orthopedic- implants help alleviate issues with bones and joints of the body.

In this paper we are going to focus on hip and knee implants in the human body. An orthopedic implant is a medical device manufactured to replace a missing joint or bone or to support a damaged bone. The medical implant is mainly fabricated using stainless steel and titanium alloys for strength and the plastic coating that is done on it acts as an artificial cartilage. Internal fixation is an operation in orthopedics that involves the surgical implementation of implants for the purpose of repairing a bone. Among the most common types of medical implants are the pins, rods, screws and plates used to anchor fractured bones while they heal.

Hip replacement is a surgical procedure in which the hip joint is replaced by a prosthetic implant. It can be performed as a total replacement or a hemi (half) replacement. A total hip replacement (total hip arthroplasty) consists of replacing both the acetabulum and the femoral head while hemiarthroplasty generally replaces only the femoral head. Total Hip Arthroplasty (THA) has become a common treatment for end-stage hip joint diseases. With improved implant design and surgical techniques, bearing surface wear, and the resultant wear-induced osteolysis have become a major limitation to prosthetic long-term survivorship. The various types of hip implants are as follows:

The direct anterior approach: the incision is made on the front of the hip; this approach may be less disruptive to the muscles and soft tissues surrounding the hip joint

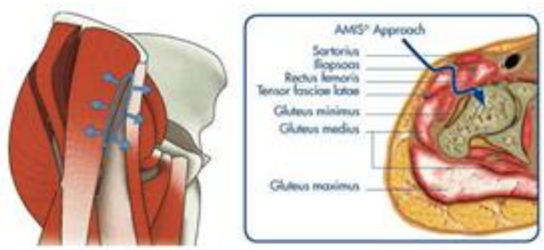

Figure 1: direct anterior approach

The anterolateral approach: the incision is made on the side of the hip, toward the front of the body

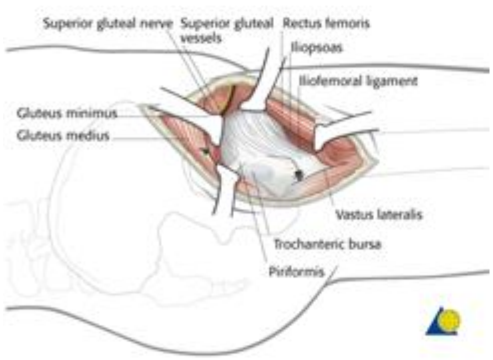

Figure 2: anterolateral approach

· ***The posterolateral approach***: the incision is made on the side of the hip toward the back of the body.

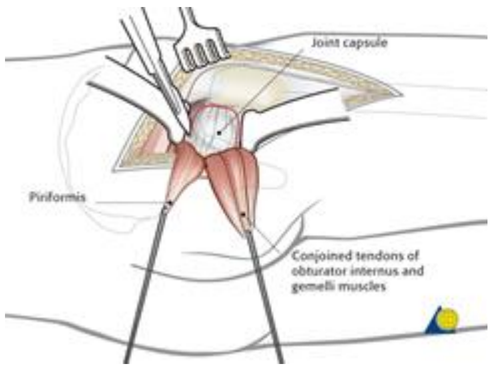

Figure 3: posterolateral approach

Knee replacement is medically referred as knee arthroplasty, is a surgical procedure to replace the weight-bearing surfaces of the knee joint to relieve pain and disability. It can be performed as a partial or a total knee replacement. In general, the surgery consists of replacing the diseased or damaged joint surface of the knee with metal and plastic components shaped to allow continued motion of the knee. The types in which knee replacement can be done are as follows:

Fixed-bearing implants: metal component is inserted into the tibia and a polyethylene (plastic) tray is locked into place on top of it

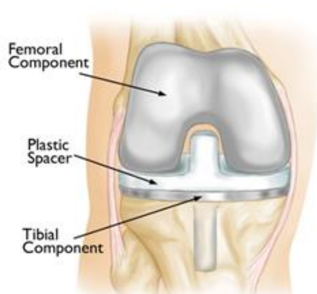

Figure 4: fixed-bearing implants

Rotating platform implants: metal implant is inserted into the tibia, but the polyethylene tray is placed on a circular stem that allows slight rotation of the tray on the metal tibial platform during knee motion. This mobile bearing design may allow for slight greater range of motion in the knee

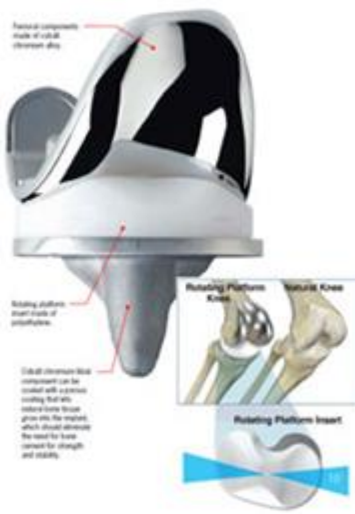

Figure 5: rotating platform implants

METALLOSIS

Metallosis is a rare, potentially fatal complication after arthroplasty and is generally associated with metal-on-metal prosthetic devices, but it has also been described in non-metallic prostheses. Metallosis defined as loosening of a device secondary to metal corrosion and release of wear debris. It occurs due to metallic erosion and release of metallic debris products, which include massive local cytokines liberation from inflammatory cells. Wear debris also results in mechanical instability of the joint, reduces joint mobility, increases pain with detrimental biologic responses, results in osteolysis and causes component loosening and implant failure.

Metallosis has been hypothesized to occur when metallic components in medical implants abrade against one another. The abrasion of metal components may cause metal ions to be solubilized. The hypothesis that the immune system identifies the metal ions as foreign bodies and inflames the area around the debris may be incorrect because of the small size of metal ions may prevent them from becoming haptens. Poisoning from metallosis is rare, but cobaltism is an established health concern. The involvement of the immune system in this putative condition has also been theorized but has never been proven.

Purported symptoms of metallosis generally include pain around the site of the implant, pseudotumors (a mass of inflamed cells that resembles a tumor but is actually collected fluids), and noticeable rash that indicates necrosis. The damaged and inflamed tissue can also contribute to loosening the implant or medical device. Metallosis can cause dislocation of non-cemented implants as the healthy tissue that would normally hold the implant in place is weakened or destroyed.

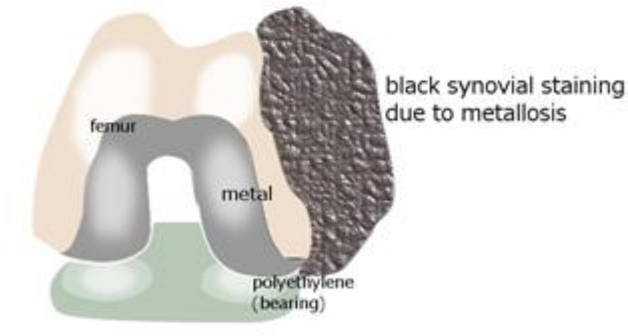

Figure 6: metallosis

OSTEOLYSIS

Osteolysis is an active resorption of bone matrix by osteoclasts and can be interpreted as the reverse of ossification. Although osteoclasts are active during the natural formation of healthy bone the term "osteolysis" specifically refers to a pathological process. It often occurs in the proximity of a prosthesis that causes either am immunological response or change in the bone's structural load. Osteolysis may also be caused by pathologies like bone tumors, cysts, or chronic inflammation.

Bone resorption is commonly associated with many diseases or joint problems, the term osteolysis generally refers to a problem common to artificial joint replacements such as total hip replacements and total knee replacements. It can also be associated with radiographic changes seen in those with bisphosphonate-related osteonecrosis of the jaw. There are several biological mechanisms which may lead to osteolysis. In total hip replacement, the generally accepted explanation for osteolysis involves wear particles. As the body attempts to clean up these wear particles (typically consisting of plastic or metal), it triggers an autoimmune reaction which causes resorption of living bone tissue. Osteolysis has been reported to occur as early as 12 months after implantation and is usually progressive. Although osteolysis itself is clinically asymptomatic, it can lead to implants loosening or bone breakage, which in turn causes serious medical problems.

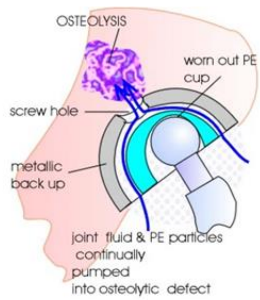

Figure 7: osteolysis

KNEE AND HIP IMPLANTS: RISKS AND COMPLICATIONS:

Hip replacement surgery (hip arthroplasty) has been touted by many experts as one of the most significant medical device innovations of the last 40 years. It has helped millions of people overcome painful arthritis, recover from hip fractures and improve their quality of life. However, hip implants do not come without risk or complications. A growing number of implant recipients have experienced implant failure and other severe hip replacement complications.

There are three types of hip replacement surgery. With total hip replacement, the entire hip joint (ball and socket), as well as femoral stem is replaced. Partial hip replacement requires only the ball (femoral head) to be replaced. In a hip resurfacing procedure, the cup is replaced, but the ball is not. Instead, the ball is reshaped and covered with a metal cap. Each procedure accomplishes its goal in a slightly different fashion, but they share some of the same potential for hip replacement problems.

Risks associated with hip replacement surgery include:

(i) Blood clots
(ii) Infection
(iii) Dislocation
(iv) Differing leg length
(v) Device loosening
(vi) Fracture

In some patients, a small amount of pain or instability can occur after surgery. There may also be some stiffness and bleeding as well as blood vessel or nerve injury. Many patients experience relief from hip pain caused by osteoarthritis and can increase mobility following surgery. But, like other surgeries, hip replacement carries its own set of risks and complications that require immediate medical attention or even additional surgeries to treat. The type of implant may also increase the risk for certain complications. For example, studies show metal-on-metal implants have greater risk of loosening or early failure because metal particles released from the device may weaken nearby bone and tissue.

In total hip replacement and hip resurfacing, particle debris from the cup and ball (or ball covering) can lead to complications and implant failure. As the implant recipient moves, the surfaces of these two components rub against each other. The friction and abrasive wear between these two components cause debris to be produced. It is estimated that every step taken with a hip implant produces between 100,000 and 1 million particulates of debris. The type of debris produced depends on the material the components of the implants are made of. Different materials can cause different long-term complications.

Some of the common complications associated with hip arthroplasty are:

(i) Mortality:

A 2003 study published in the Iowa Orthopedic Journal reviewed the results of nearly 5,000 hip arthroplasty surgeries. It found that the mortality rate for patients having the surgery for the first time was nearly 1 percent. For patients undergoing a revision surgery, the mortality rate skyrocketed to 2.5 percent. Researchers also found that the most important determining factor of mortality was age. Patients older than 70 were three times more likely to die from the surgery than younger patients.

(ii) Dislocation:
The natural hip is held in place by a ligament that connects the ball to the socket. It is also held in place by thick, dense tissue that surrounds the joint. During hip replacement surgery, this tissue is removed and dislocation can occur. Proper placement of the implant during surgery is vital to it remaining in place for the long term. Although dislocation is not very common, it occurs following 1 percent to 5 percent of initial surgeries. Following revision surgery, the risk for dislocation rises as high as 20 percent. Dislocation leading to implant failure is most likely to occur within the first few months after surgery.

(iii) Heterotopic Ossification:
Heterotopic ossification is the process of bone forming outside of the skeleton, meaning soft tissue is calcified. Typically, it occurs in areas of the body where severe trauma has occurred. In the case of hip arthroplasty, the muscles around the hip joint calcify and become stiff. Heterotopic ossification is considered one of the most common hip replacement complications, occurring in nearly 50 percent of patients. However, only about 10 percent of those suffer any side effects from the condition, including tenderness, swelling and a decreased range of motion. The condition can be treated with low-dose radiation and anti-inflammatory drugs. In severe cases, surgery is required to remove the calcified tissue.

(iv) Avascular Necrosis (Osteonecrosis)
Avascular necrosis is bone death caused by lack of blood and can lead to implant failure. It is more often associated with hip resurfacing than total hip replacement. With hip resurfacing, the metal cap that covers the femoral ball can reduce the amount of blood reaching the ball. If the bone is deprived of blood for an extended period of time, it will collapse, which will destroy the bone and use of the joint will be lost. In extreme cases, the implant will have to be replaced. Since the femoral ball is no longer usable, a total hip replacement is required.

(v) Component Loosening
Implant components can loosen over time, which is considered the most serious long-term complication because it is the strongest indicator that a revision surgery will be required. A component could loosen because it is worn out or because the cement fails to hold it in place. However, loosening of a hip implant could also point to a more serious condition like osteolysis or metallosis.

Even though the above-mentioned complications are serious conditions, the most dangerous complications are **Metallosis** and **Osteolysis.**

Mechanisms of Wear:

Wear occurs in four modes depending on the location (See Figure 8). Mode 1 is an articulation between intended bearing surfaces (American Academy of orthopedic Surgeons,2001). Examples include the femoral head and the acetabular cup of a total hip replacement, and the femoral condyle and the tibial plateau of a total knee replacement. Examples of mode 2, an articulation between a primary bearing surface and a surface that was never intended to be a bearing surface, are the femoral head and the metal backing of an acetabular cup and the femoral condyle and the metal backing of a patellar component. Mode 3 is an articulation between intentional bearing surfaces in the presence of third-body components, examples include the femoral head and the acetabular cup in the presence of cement debris, metallic debris, hydroxyapatite particles, bone particles or ceramic debris.

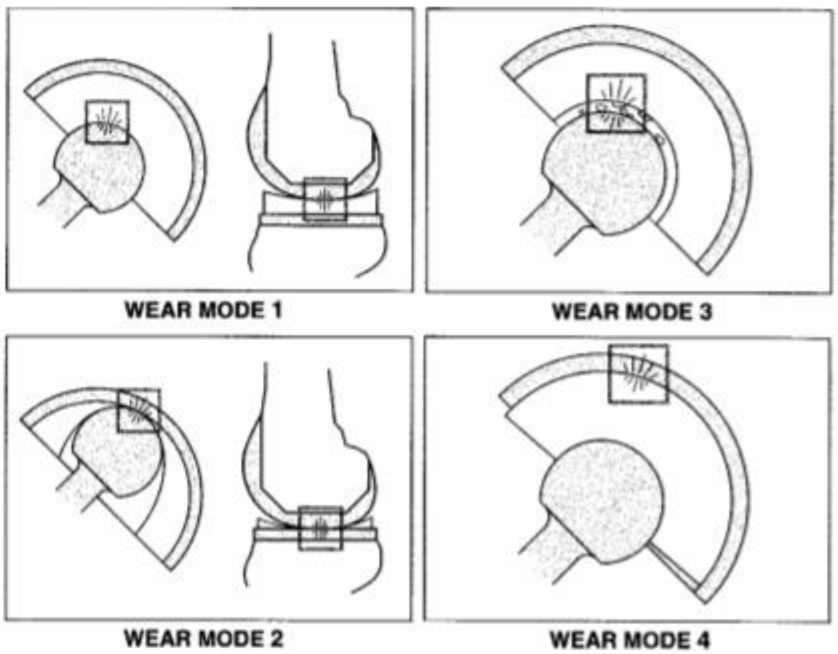

Figure 8: Modes of wear in orthopedic joints

Wear can occur through five major mechanisms-adhesion, abrasion, third body, fatigue and corrosion. *Adhesive wear* occurs when the atomic forces occurring between the materials in two surfaces under relative load are stronger than the inherent material properties of either surface (see Figure 9). For example, when there is relative motion between two surfaces, bonding of asperities occurs. Continued motion of the surfaces requires breaking the bond junctions. Each time a bond junction is broken, a wear particle is created, usually from the weaker material. In orthopedic joint replacements, adhesive usually occurs when small portions of the polyethylene surface adhere to the opposing metal bearing surface. The removal of polyethylene results in pits and voids so small that they may not be evident on visual inspection of the articulating surface.

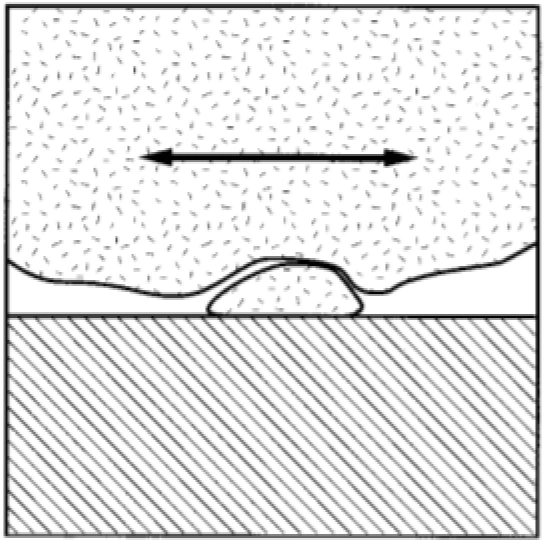

Figure 9: Adhesive wear

Abrasive wear occurs between surfaces of different relative hardness (See Fig 10). In an abrasive wear mechanism, micro-roughened regions and small asperities on the harder surface locally plow through the softer surface. Abrasive wear results in softer material being removed from the track traced by the asperity during the motion of the harder surface.

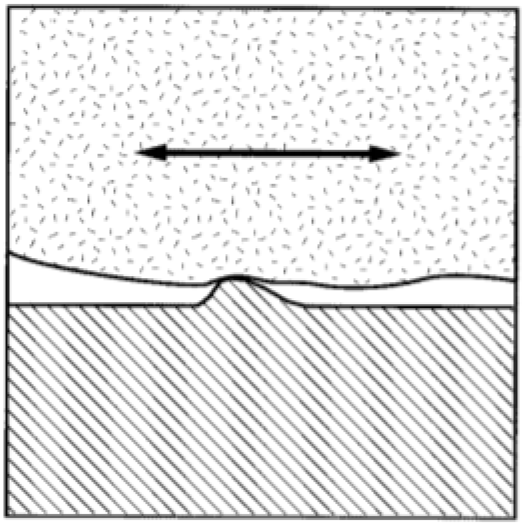

Figure 10: Abrasive wear

Third-body wear is a form of abrasive wear that occurs when hard particles become embedded in a soft surface (See Fig 11). Examples of third bodies include metallic or bone particles embedded in a polyethylene bearing surface. The particle acts much like the asperity of a hard material in abrasive wear, removing material in its path. Hard third-body particles such as bone cement can produce damage to both polyethylene articulating surface and the metallic alloy femoral bearing counterface. The extent of abrasive wear of polyethylene, metallic and ceramics has been shown to be a function of the surface roughness of the metallic or ceramic counterface and the presence or absence of hard third-body particles.

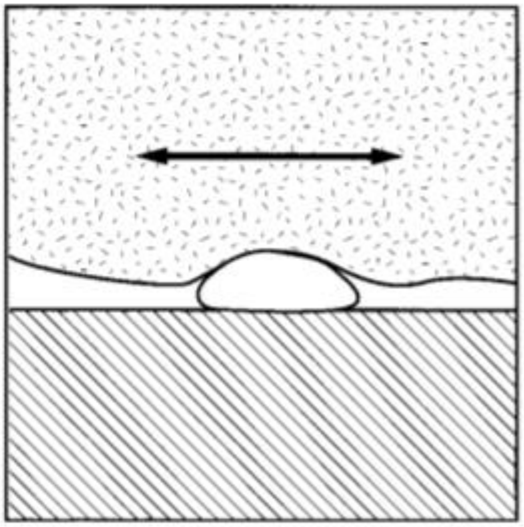

Figure 11: Third body wear

Fatigue wear occurs when the surface and subsurface cyclic shear stresses or strains in the softer material of an articulation exceed the fatigue limit for that material (See Fig 12). Because polyethylene is the weaker of the two materials in a bearing couple, fatigue wear damage to polyethylene component dominates. Under these repeated or cyclic loading conditions, surface delamination and cracking can occur, eventually leading to the release of polyethylene particles.

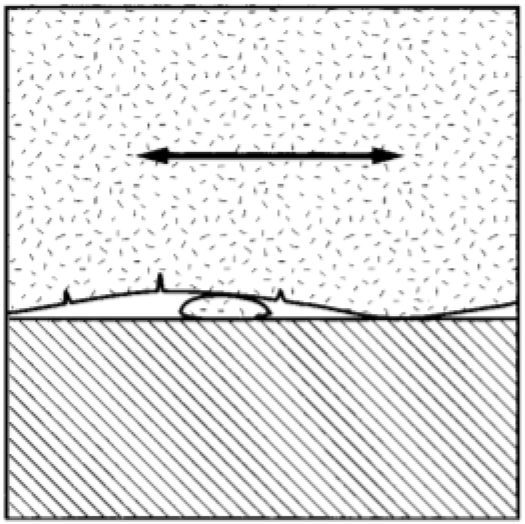

Figure 12: Fatigue wear

Corrosive wear is an indirect wear mechanism. A form of third-body wear, the liberated corrosive debris acts as an abrasive third body. Corrosive wear can also be considered an accelerating mechanism for corrosion itself, because the motion of an articulation can remove corrosive products and the protective passive layer sooner than interfaces with no relative motion. Liberation of corrosive products exposes a greater surface (with less protection to corrosion) to further corrosion, and hence accelerates the removal of even more material.

TRIBOLOGY IN HUMAN BODY:

The human body has 143 different joints that connect bones of the skeleton to one another. Of the majority of joints are the synovial ones, which usually allow free and sometimes extensive movement between the bones involved. Human synovial joints have to withstand complex, varied and often harsh loading regimes, been subjected to both dynamic and static loads under conditions of sliding and rolling. Peak resultant forces across human hip may reach seven times body weight during normal walking and the maximum contact pressure in normal hip can reach 3 MPa.

The human joint is a self-acting and dynamically load-bearing structure that uses a porous and elastic biomaterial (e.g. articular cartilage) as well as a highly non-Newtonian lubricant (e.g. synovial fluid) for its functioning. Relative motion between two surfaces in contact is characterized by frictional forces and wear of one surface or both. The friction coefficient is affected by the mechanical properties of the materials in contact, the operating conditions and the type of lubricant (if any) in the contact interface. It is well known that human synovial joints function with an extremely low friction coefficient (0.02).

Degradation of either part of the synovial fluid–articular cartilage system leads to increased friction, wear and reduction of mobility; degeneration of cartilage is characterized by softening and fibrillation that may lead to joint pain.

Most of the work concerning joint lubrication uses cartilage-on-metal, cartilage-on-ceramic and recently animal cartilage-on-cartilage setups are given below.

Comparison of friction coefficient measured on small cartilage specimens against different surfaces.

Reference	Tested surfaces	Friction Coefficient
McCutchen (1962) [15]	Articular cartilage on bone against glass	0.008–0.1
Dowson *et al*. (1968) [16]	Articular cartilage on bone against glass, rubber or plastic	0.15–0.8
Walker *et al*. (1970) [9]	Articular cartilage on bone against glass	0.0014–0.07
Malcom (1976) [14]	Bovine cartilage on bone against cartilage	0.002–0.03
Stachowiack *et al*. (1994) [2]	Rat cartilage against stainless steel	0.018–0.13
Forster and Fisher (1996) [10]	Bovine cartilage against metal and cartilage against cartilage	0.01–0.3
Mabuchi *et al*. (1998) [12]	Canine cartilage against cartilage on bone and cartilage against glass	0.005–0.457
Murakami *et al*. (1998) [8]	Articular cartilage against stainless steel	0.0075–0.015
Forster and Fisher (1999) [11]	Articular cartilage against metal	0.005–0.57
Naka *et al*. (2005) [17]	Pig articular cartilage against glass	0.037–0.05

Table 1: Different coefficient of friction of different surfaces tested along many years

TYPES OF MATERIALS:

•Metal:

Titanium, Stainless Steel, Cobalt-Chromium Alloy

•Polyethylene:

Ultra Highly Cross Linked Polyethylene (UHXLPE)

Ultra High Molecular Weight Polyethylene (UHMWPE)

•Ceramic:

Zirconium Nitride

Material	Hardness
Titanium	716-2770 MPa
Polyethylene	700-950 MPa
Zirconium Nitride	22.7±1.7 GPa

Table 2: Hardness (BHN) of different materials used in implants

Cross-Linked Polyethylene

The bearing component most commonly used for total hip replacement in the United States is a metal femoral head (ball) made of either stainless steel, cast or wrought cobalt, a metal-base alloy against a polyethylene (plastic)-lined acetabular cup.

Polystone Ultra	PE Polyethylene	0,1...0,15
Polystone 7000	PE Polyethylene	0.18
Polystone 7000SR	PE Polyethylene	0.20
Polystone 7000AST	PE Polyethylene	0.20
Polystone 500	PE Polyethylene	0,1...0,15
Polystone Fender	PE Polyethylene	0.18
Polystone 300	PE Polyethylene	0.15
Polystone 8000+	PE Polyethylene	0.22
Ertalyte	PETP Polyester	0.29
Polystone Ezyslide 78	PE Polyethylene	0.22
Polystone M-Flametech AST	PE Polyethylene	0.22

Table 3 Coefficient of friction of different polyethylene

Figure 13: polyethylene implants

⇨ Benefits

- Durable and versatile
- Long, successful clinical history
- Not toxic to the human body
- Adequate toughness for most lifestyles

⇨ Limitations

May wear down over time, which can lead to inflammation, bone loss, and/or a revision procedure

Not all polyethylene bearings are manufactured and processed the same. DePuy Orthopaedics, Inc., developed AltrX™ AltraLink™ Polyethylene. In laboratory tests, the wear of AltrX™ AltraLink™ Polyethylene has demonstrated a 92% reduction in wear.

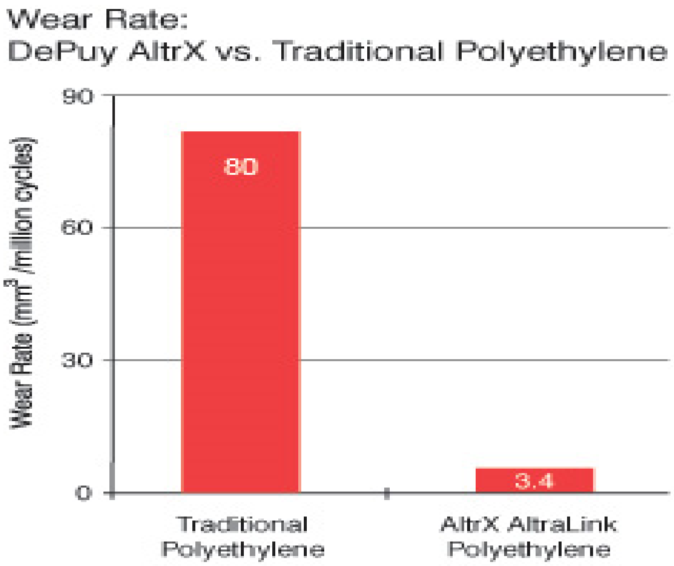

Figure 14: Comparison between wear rates of different polyethylene

Ceramic

Ceramic bearings are available in 2 configurations: a ceramic femoral head (ball) with a polyethylene liner, or a ceramic femoral head (ball) with a ceramic liner. No one material is right for every patient. Only your surgeon can determine what's right for you.

Figure 15: ceramic implants

- ⇨ Benefits

Reduced wear—improved lubrication and reduced friction4

Performance—lower wear rates compared with polyethylene and metal4

- ⇨ Limitations

Ceramic bearings may be:

More prone to fracture

Less forgiving in surgery

More likely to require the removal of greater quantities of healthy bone due to size limitations

More expensive than other bearing options

The Many Different Materials Used in Hip Replacement Devices

Category	Characteristics	Acronym
A	Metal head (cemented stem) on cemented polyethylene cup	CeMoP
B	Metal head (cementless stem) on cementless hydroxyapatite coated metal cup (polyethylene liner)	CeLMoP
C	Ceramic head (cementless stem) on cementless hydroxyapatite coated metal cup (ceramic liner)	CeLCoC
D	Hybrid metal head (cemented stem) on cementless hydroxyapatite coated metal cup (polyethylene liner)	HyMoP
E	Ceramic head (cemented stem) on cemented polyethylene cup	CeCoP

C=ceramic; Ce=cemented; CeL=cementless; Hy=hybrid; M=metal; P=polyethylene.

Table 4: Different material combinations for hip replacement

As stated earlier. The human bone-on-bone interaction has the coefficient of friction is in the range of 0.29 to 0.36. If we consider a constant 4N load on the joint, the coefficient of friction becomes around 0.3. So the material combination used in the joint replacement must be around the same. Here given are some of the basic material combination with their coefficient of friction.

Material Combination	Co-efficient of friction
Ti-Ti	0.25-0.30
PE-PE	0.1-0.22
ZrN-ZrN	About 0.28

Table 5: Coefficient of friction values of different basic material combinations

Hip replacement devices break into a few big categories:

Metal on Metal (MOM) – These are what they sound like. Both the socket and the ball are made of stainless steel, titanium, chromium, cobalt or some combination of these. One sub-type of a MOM hip is a minimally invasive model which usually is smaller in size, so it can be installed with a smaller incision.

Polyethylene and Metal on Polyethylene (MOP) – Polyethylene is basically plastic, so these hips usually have metal structural pieces and a plastic liner where the ball and socket meet. They can also have a metal ball meeting a plastic socket liner. A sub-type of a polyethylene hip is made with a newer plastic called cross linked polyethylene, which is more durable.

Ceramic on Metal (COM), Ceramic on Ceramic (COC), Ceramic on Polyethylene (COP) – Ceramic hips are made of specialized and more durable versions of the same type of material that plates and bowls are made from. There are ceramic on metal, ceramic on ceramic, and ceramic on polyethylene versions. While these are durable, they can be vulnerable to fracture and breaking under big stresses.

WEAR PARTICLES:

If for some reason I would need a hip replacement, my single biggest concern would be wear particles. This phenomenon first came to light about 5 – 7 years ago when surgeons began to replace the first worn out or failed metal on metal (MOM) hips. What they found in some patients was scary. Basically, the entire area directly around the hip replacement device had turned into a mass of black goo.

Then studies were published showing that those microscopic metal shavings were leaching into the bloodstream and causing elevated metal ion levels. Additional studies began to point out that some people's tissue was so sensitive to this junk that they formed pseudotumors, which are basically big solid masses of irritated tissues, some of which could press on important nerves. Finally, genetic studies showed that not only was this tissue visibly unhappy, the cells were getting damaged at a genetic level from the wear particles.

When all of this first came to light, it looked like only MOM hips were involved. However, as the research below shows, the issue of wear particles extends to every type of hip made.

RESEARCH

MOM or "Metal on Metal"

The "bad boy" of hip replacement types is clearly MOM hips. The funniest thing is that despite all of the absolutely horrific things published about these devices, you can still find Internet ads for many surgeons who will be happy to implant them. They do this by claiming that these are "minimally invasive" hips. While there's a tiny kernel of truth in that hogwash (the incisions needed to implant them are smaller), there is nothing minimally invasive about amputating a joint and inserting a prosthesis, no matter how you skin that cat. In addition, the smaller the device, the bigger the wear particle issue.

MOM hips produce metal wear particles locally that are then taken up in the bloodstream. In general, smaller MOM hip devices (usually those used for small framed women) have a higher likelihood of producing metal wear particles. This study showed more metal ions in the blood with MOM devices compared to conventional hip replacement prostheses. This randomized trial again demonstrated more metal ions in the blood of women with MOM hips when compared to conventional hip replacement, but also noted that pseudotumors occurred both around these MOM devices and the more conventional MOP devices as well. This recent study showed that metal debris was present in both large and small MOM hip replacement devices.

The latest 2015 consensus guidelines are now not to perform a MOM hip replacement in small women or anybody with a known metal allergy. The latest study on MOM hips and pseudo tumors concludes, “Adverse reactions to metal debris in MOM hips may not be as benign as previous reports have suggested.” Not good.

Polyethylene and Metal on Polyethylene (MOP)

When I initially began this literature search, I thought that MOP hips may be better in the wear particle department. After all, you don’t have metal rubbing on metal, but usually metal on plastic. However, I was wrong.

To see how bad things can get with MOP wear particles, I didn’t have to look far. This recent study from 2014 showed an awful side effect of both polyethylene and metal wear particles, a pseudotumor that invaded a woman’s vaginal tissues. This 2015 study was very concerning in that it compared MOP hips to MOM hips with regard to metal levels and chromosome damage in cells. It couldn’t conclude that one was better than the other. Based on this 2014 study, MOP hips wear less, but their wear particles produce slightly more tissue reaction than MOM hips. This is all consistent with a recent study I blogged on, showing that conventional polyethylene wear particles reduced stem cell activity in bone marrow and muscle.

If there is one bright spot in this category, it’s likely the newer highly cross linked polyethylene (HCLP). Based on this recent study, HCLP hips produced fewer wear particles than regular polyethylene. In another study of shoulder replacement devices, the lower debris for these devices was confirmed. In addition, based on this 2014 study HCLP devices seem to withstand unexpected wear and part failure better.

Ceramic on Metal (COM), Ceramic on Ceramic (COC), Ceramic on Polyethylene (COP)

Maybe ceramic is the way to go? After all, what could go wrong with installing a hip replacement device made of the same substance as dinner plates?

This 2015 randomized trial showed that COM hips still regrettably produced metal wear particles that ended up in the blood stream. Some good news for COM hips could be found in this 2015 study. It concluded that while there was swelling around these devices, when compared to minimally invasive MOM hips, there were no pseudotumors seen in COM hips. However, based on this analysis of many studies, there doesn’t seem to be any advantage of COC compared to COP. How does COM and COC compare? Ceramic on metal doesn’t seem to have the same durability as ceramic on ceramic based on this study.

Effect of lubrication:

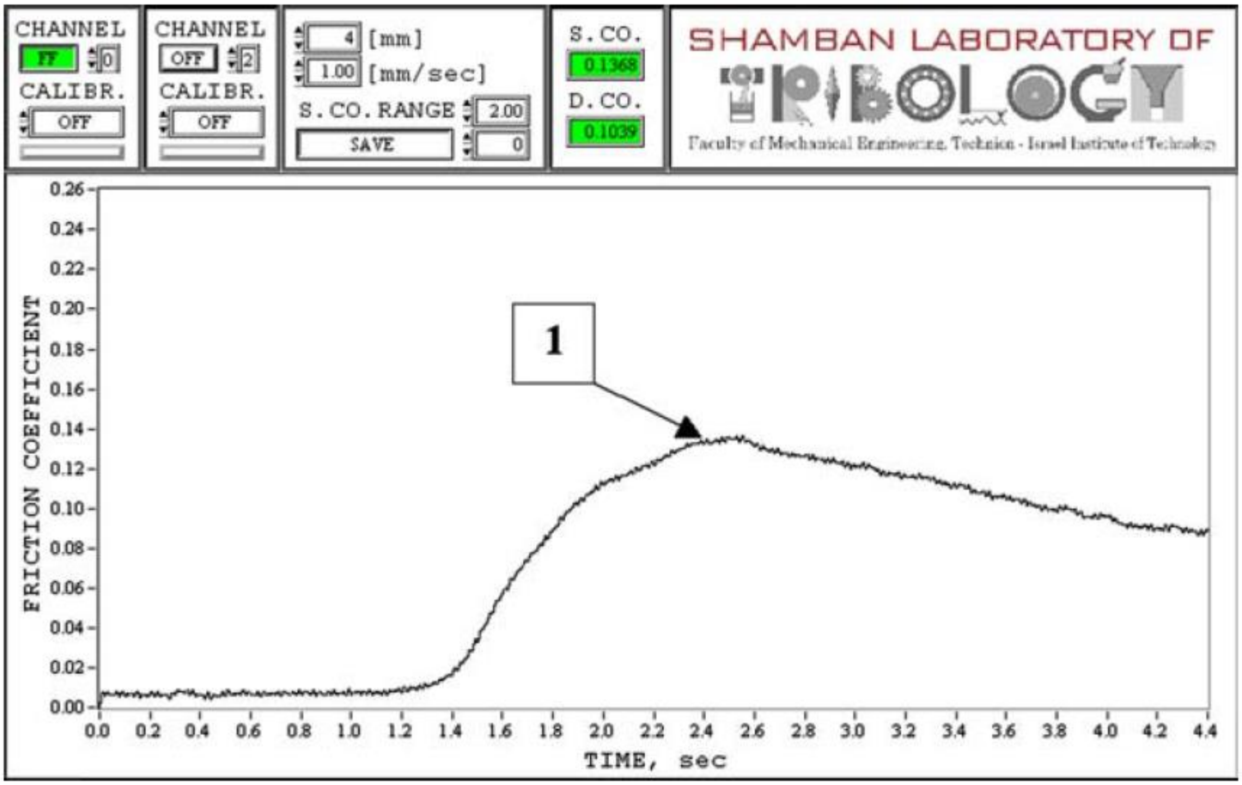

Figure 16: Changes in friction coefficient of lubrication with change of time

The case shown in the figure corresponds to saline lubricant, 10 N load, sliding speed of 1 mm/s, dwell time of 5 s, and temperature of 24 deg C.

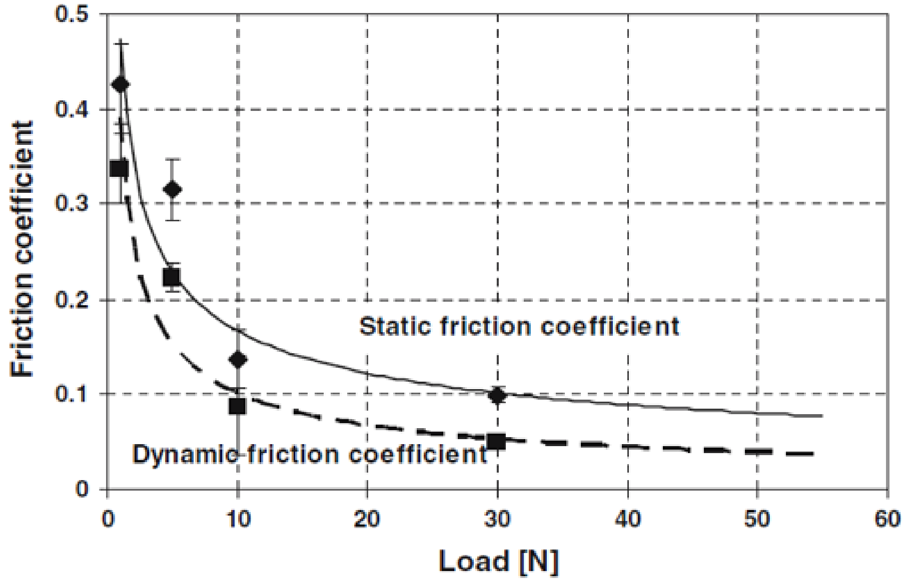

Figure 17: Static and dynamic friction coefficient results as functions of applied load in the presence of saline. Results above 30 N are extrapolated

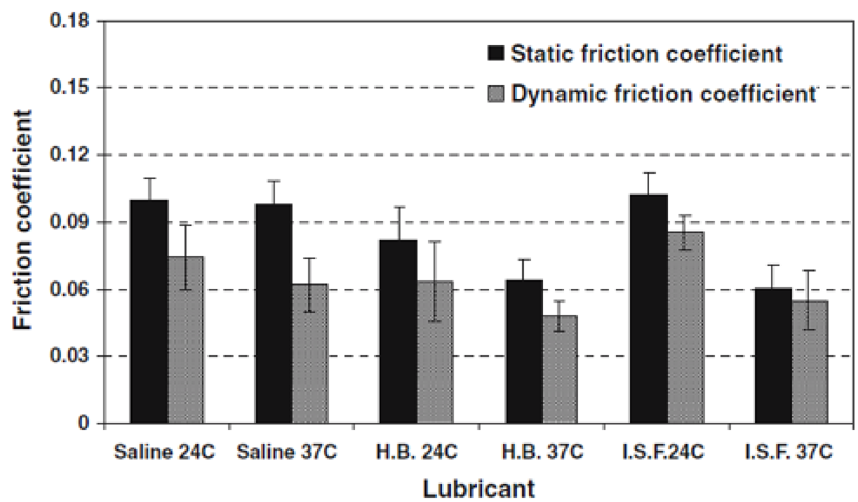

Figure 18: Friction coefficient measured at two temperatures (24 and 37 C) and different lubricating fluids under 30 N loading

Modelled 10 year revision rates (%) for 70 year old men and women

Category of total hip replacement	Bathtub model		Weibull model		Loglogistic model		Flexible parametric model	
	Male	Female	Male	Female	Male	Female	Male	Female
A (CeMoP)	3.18 (3.56 to 2.79)	2.97 (3.25 to 2.68)	2.78 (2.52 to 3.05)	2.53 (2.34 to 2.72)	2.79 (2.53 to 3.05)	2.53 (2.34 to 2.71)	2.93 (2.62 to 3.28)	2.67 (2.44 to 2.92)
B (CeLMoP)	4.65 (5.53 to 3.77)	3.62 (4.23 to 3.01)	3.98 (3.46 to 4.50)	3.03 (2.67 to 3.38)	4.01 (3.50 to 4.53)	3.07 (2.72 to 3.43)	4.31 (3.66 to 5.07)	3.37 (2.92 to 3.88)
C (CeLCoC)	4.84 (5.98 to 3.69)	4.08 (5.01 to 3.15)	4.23 (3.51 to 4.95)	3.22 (2.67 to 3.76)	4.25 (3.53 to 4.96)	3.24 (2.70 to 3.78)	4.39 (3.58 to 5.37)	3.76 (3.07 to 4.61)
D (HyMoP)	3.50 (4.40 to 2.60)	2.89 (3.48 to 2.30)	3.04 (2.48 to 3.60)	2.30 (1.94 to 2.65)	3.05 (2.50 to 3.61)	2.31 (1.95 to 2.67)	3.18 (2.54 to 3.98)	2.63 (2.17 to 3.18)
E (CeCoP)	2.26 (3.39 to 1.14)	1.80 (2.51 to 1.08)	2.12 (1.37 to 2.87)	1.68 (1.15 to 2.20)	2.11 (1.37 to 2.86)	1.67 (1.15 to 2.20)	2.10 (1.39 to 3.16)	1.68 (1.17 to 2.41)
A-E	3.53 (3.83 to 3.24)	3.11 (3.32 to 2.90)	3.10 (2.92 to 3.29)	2.53 (2.40 to 2.65)	3.12 (2.93 to 3.31)	2.53 (2.41 to 2.66)	3.25 (3.02 to 3.50)	2.79 (2.62 to 2.97)

C=ceramic; Ce=cemented; CeL=cementless; Hy=hybrid; M=metal; P=polyethylene.

Table 6: Modelled 10 years revision rates for 70 years old male and female with different models

Literature Review

Apart from evaluation of properties of individual materials by conducting tests in controlled environments, it is also necessary to study other parameters that effect the performance of the bearing during operation. Such analysis would greatly help improve the performance of such implants, irrespective of the material used. Some of the more recent properties studied in recent times, that seemed to have a significant effect on the implant system are discussed in the following pages. These include some well known parameters as well as some lesser known variables such as head size and surface texturing.

The first of such parameters that were looked into was the effect of head size. Increase in the size of the head was found to have a beneficial effect in terms of reduction of the wear encountered in both the acetabular cap and the femoral head. This analysis was done for metal-on-metal bearing surface only, however, due to the nature of tests, we can confidently say that this can be applied as a general rule to other bearings as well. However, it should be noted that at sizes beyond a certain limit, the effect of pressure caused increase in wear, contrary to the general trend. This effect should be analysed in detail to determine if there is a theoretical upper limit to how much the size of the bearing can be increased in order to effect a reduction in wear, and if so, a means to determine such a limit for various types of bearings. We will look at the exact methodology adopted for the experimentation in order to better understand the results.

In order to get results as close as possible to those that match the actual operation within the hip of a human body, several factors have to be taken into account to replicate the environment in which the bearing functions, along with the forces acting on it. This is achieved in the following steps. The loading conditions are specified by the International Organization of Standardization (ISO) in the ISO 14242-1 (2002) specification. It specifies both the variation of loading and the rotational movement that the joint undergoes during a normal walking cycle. The data is given in the form of a graph as shown below.

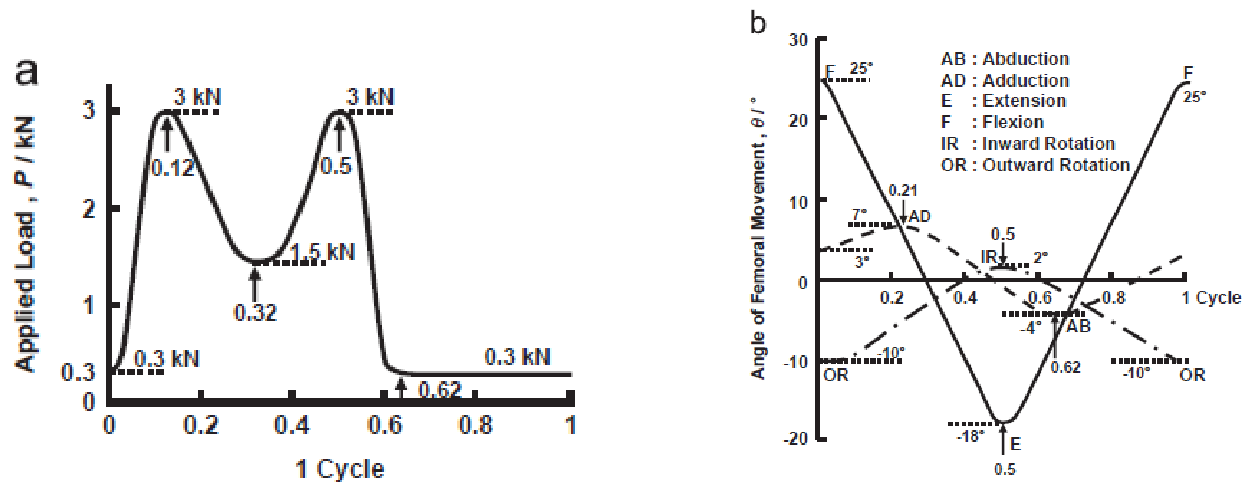

Figure 19: Loading conditions

The bearings selected for the study can be divided into the following into two groups : metal-on-metal and metal-on-polyethylene bearings. There were 4 types of metal-on-metal bearings having sizes ranging from 28 cm to 48 cm. The metal-on-polythene bearings were kept of constant size of 28mm for all 4 bearings. The following table summarizes the bearings:

Bearing Number	**Pieces**	**Sizes(mm)**
Bearing A	1	28
Bearing B	2	28 & 32
Bearing C	2	28 & 36
Bearing D	2	44 & 48

Table 7 : Distribution of bearings

As mentioned previously, the bearings were tested in conditions as close as possible to those found during the operation within the human body. The experimental setup is shown in the images below:

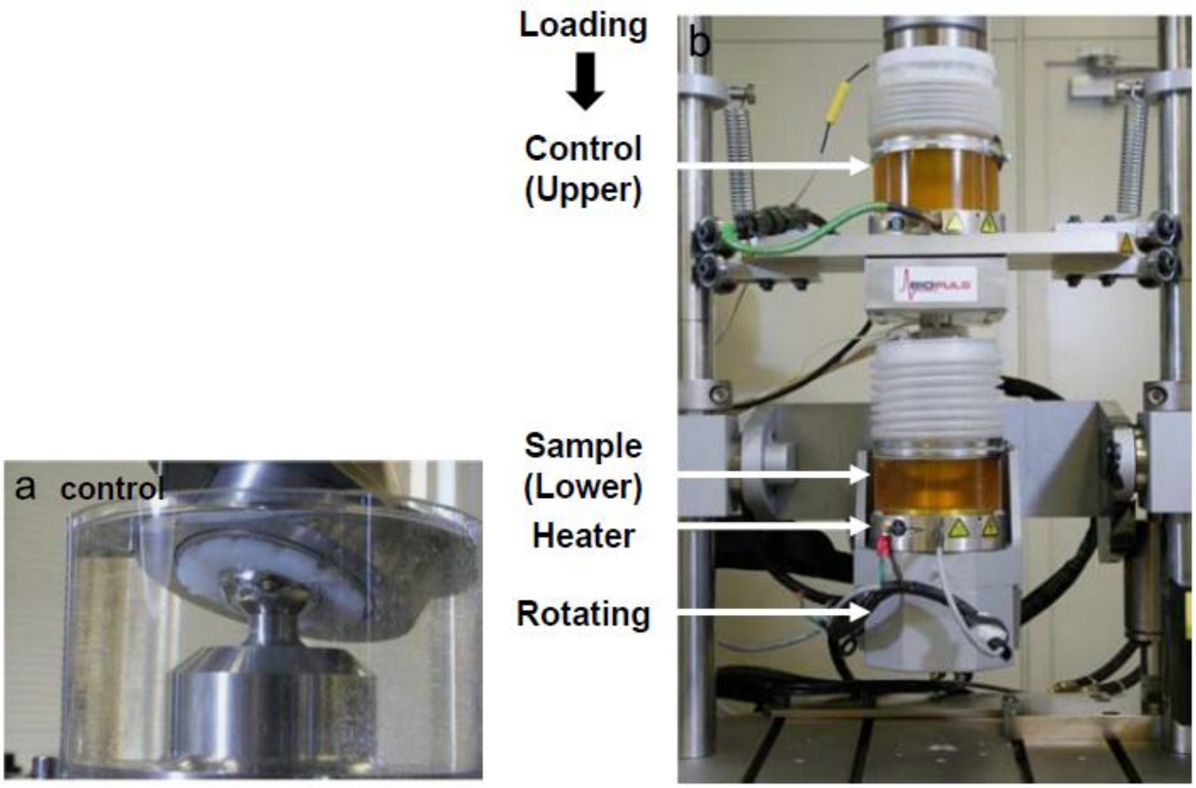

Figure 20 : Experimental setup

The results obtained were very interesting. The first set of experiments were conducted on the metal-on-metal bearings. It was noticed that the increase in head size lead to decrease in the wear rate of both the head and the cup. Only the Bearing D (48 mm) showed an exception to this rule. This result can be seen from the graph 1 plotted for wear cycles against the wear rate for bearings of different sizes. The negative values on the y-axis signify a decrease in weight of material, thus a greater negative value signifying greater wear in the part.

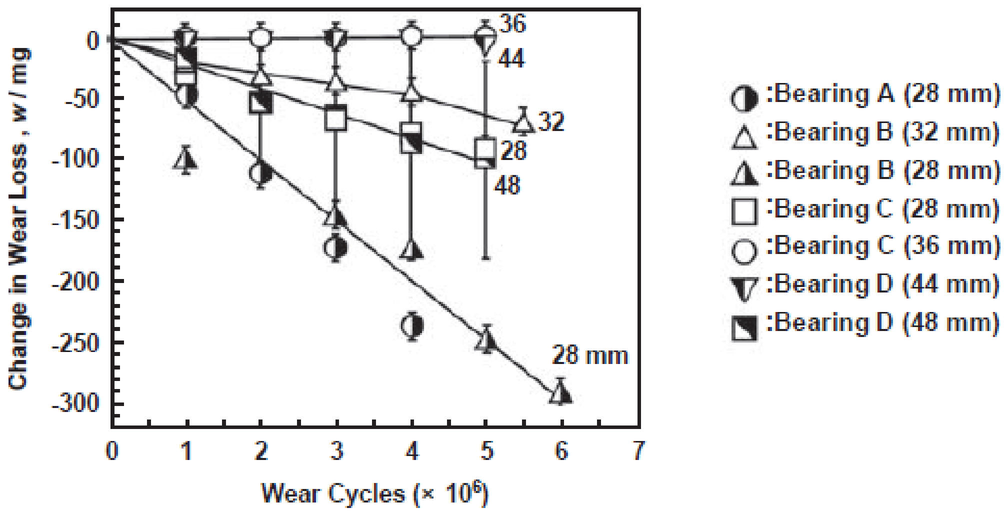

Figure 21: Wear cycles vs Wear rate

This trend can be visualized with much more ease in the following graph plotted for size of head vs wear loss. As the size increases, going towards the right on the x-axis, leads to reduction in wear. With the exception of the last bearing (D of size 48 mm), this trend has generally been found to be true.

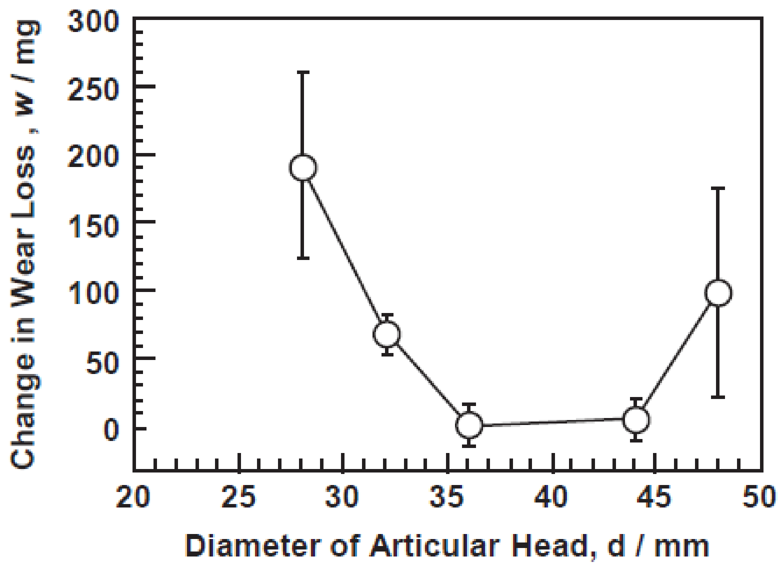

Figure 22: Diameter of head vs Wear rate

The metal-on-polyethylene bearings were subjected to the same tests. Among the 4 bearings, 3 were of cross-linked type polyethylene and the fourth was not. Cross-linking of the polyethylene molecules imparts greater strength and toughness to the material, thereby also improving its wear resistance. The results showed exactly this as expected. A graph plotted for wear cycles against the wear rate shows this result.

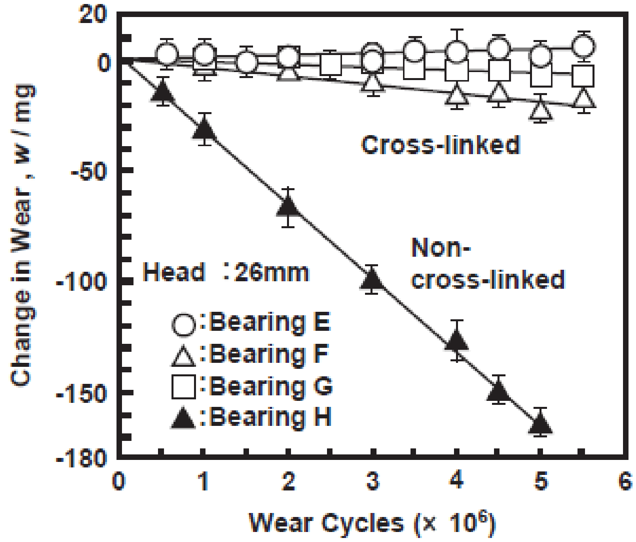

Figure 23: Wear cycles vs Wear rate

The bearing H of the non cross-linked type showed much higher wear rate as compared to the cross-linked types, which only experienced nominal wear.

A final comparison was done between the two types of bearings to see the overall performance between the tests. This can be summarized in the following chart.

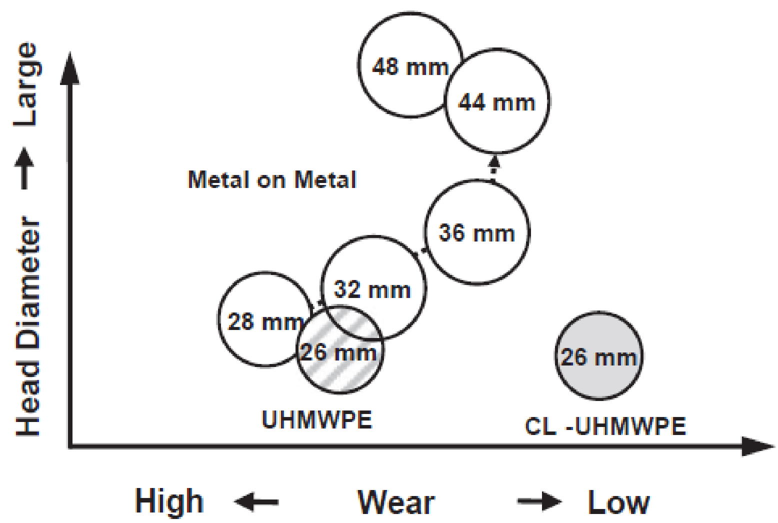

Figure 24: Wear cycles vs Wear rate

The best overall performance was shown by M-o-P bearings of the cross-linked type. The M-o-M bearings which were evaluated for their variation in head size show the result explained earlier, of lower wear rates with increase in head diameter. The non cross-linked M-o-P bearing showed poor performance which was almost close to that of the lowest size M-o-M bearing.

It will be interesting to conduct experiments of change in size of M-o-P bearings to see if an increase in the size shows similar trend of decrease in wear rate. Also due to the aberrant behavior exhibited by the Bearing D, it is important to analyze if there is a threshold to the limit to which the size can be increased for minimizing the wear. All factors that influence this limit should be analyzed and compared with corresponding tests on M-o-P bearings to see if there is any effect due to change in material.

The second paper analyzed evaluated the effect of surface texturing. The effect of surface texturing is a more recent advancement. In this particular instance the idea was similar to that of a golf ball which experiences lower drag force compared to a perfectly spherical ball due to the textured dimpling on its surface. The study consisted of both experimental and theoretical analysis in order to arrive at conclusions as well as validate the results.

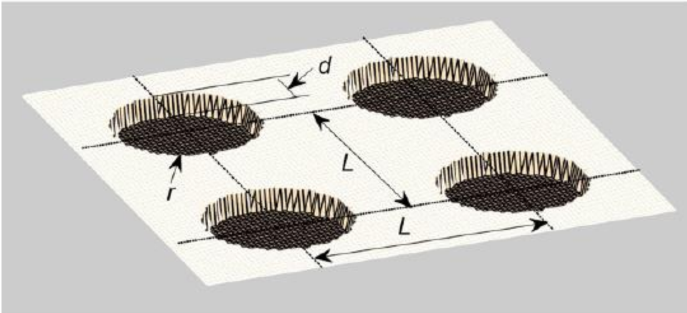

Figure 25: Texturing of surface

The experimental setup consisted of a complete hip implant assembly subjected to loading using a test bench. The texturing was obtained by making uniformly sized cylindrical holes on both the cup and the femoral head and testing for various parameters that help understand the overall performance of the system. The above diagrams show the numerical model developed, which was subjected to the same loading conditions. The most important results of the paper can be summarized in the following table. The table shows the difference in the values of minimum and average lubrication thickness, maximum pressure and contact ratio for smooth and textured surface.

Surface feature	h_{min} (μm)	h_{ave} (μm)	p_{max} (MPa)	cr (%)
Smooth	0.013	0.040	49.5	76.8
Dimpled	0.003	0.053	49.9	87.2

Table 8: Comparison of smooth and textured surface

As can be seen in the above table, despite the smooth surface having a higher minimum film thickness the average thickness of lubricant is higher in the case of the textured surface. Also noted is a higher pressure in the case of textured surface. Finally, the asperity contact ratio is the most important element in the analysis. It is defined as the ratio of the contact area of the asperities to the total area. The textured surface has a higher contact ratio at thick film lubrication but at boundary layer lubrication conditions, the performance of the textured bearings can be improved significantly.

Thus, we can conclude that surface texturing can be an important tool in improving bearing performance by reduction of loading at boundary layer lubrication conditions. However, it is important to research further to enable a greater control over the ability to maintain such a condition throughout the cyclic loading duration.

The third paper deals with analysis of squeaking friction. Squeaking occurs when resonance takes place. Thus, an analysis of the harmonic frequencies of the system will allow us to calculate the frequencies at which squeaking will take place.

The following diagrams show the simulating model used for calculations of harmonic frequency of the individual components as well as the combined assembly. The analysis was done both theoretically as well as by simulation.

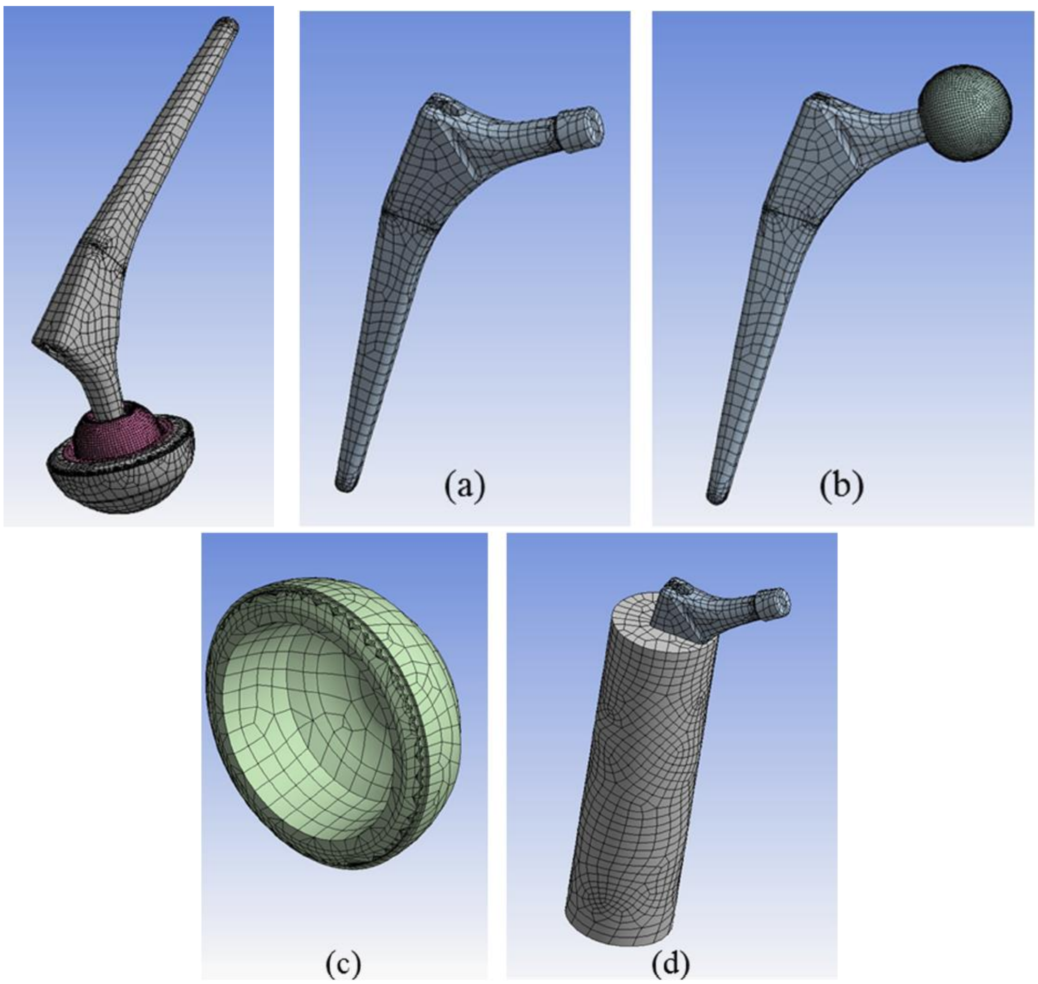

Figure 26: Model for simulations

Thus, we can conclude that surface texturing can be an important tool in improving bearing performance by reduction of loading at boundary layer lubrication conditions. However, it is important to research further to enable a greater control over the ability to maintain such a condition throughout the cyclic loading duration.

The third paper deals with analysis of squeaking friction. Squeaking occurs when resonance takes place. Thus, an analysis of the harmonic frequencies of the system will allow us to calculate the frequencies at which squeaking will take place.

The following is a standard curve used to analyze the frequencies. It shows the complete loading cycle used for evaluation. The cycle is divided into three phases. The first phase has no major acceleration disturbance. In phase II there is a higher level of disturbance and the highest level of acceleration can be found in the phase III.

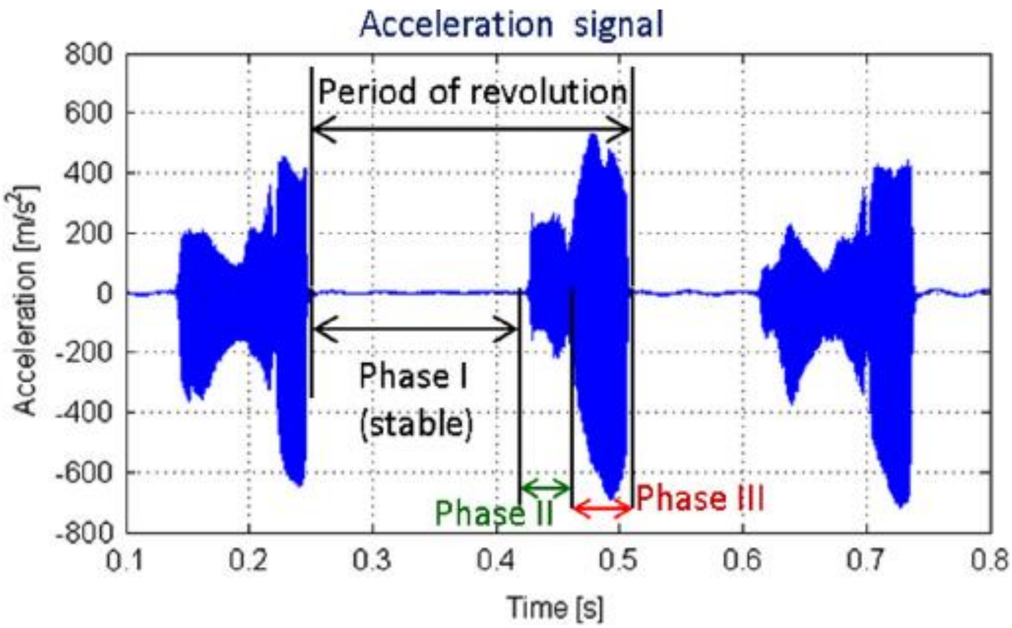

Figure 27: PSD diagram for frequency analysis

Finally the most important result was obtained by evaluation of the relation between the frictional coefficient and the frequencies which are used to pin point the exact points at which the squeaking occurs. On the graph shown below, the intersection of any two lines leads to what is termed as instability points. As can be seen in the graph, increase in the frictions coefficient leads to greater occurrences of instability points. Also no instability occurs at friction coefficient values below 0.5.

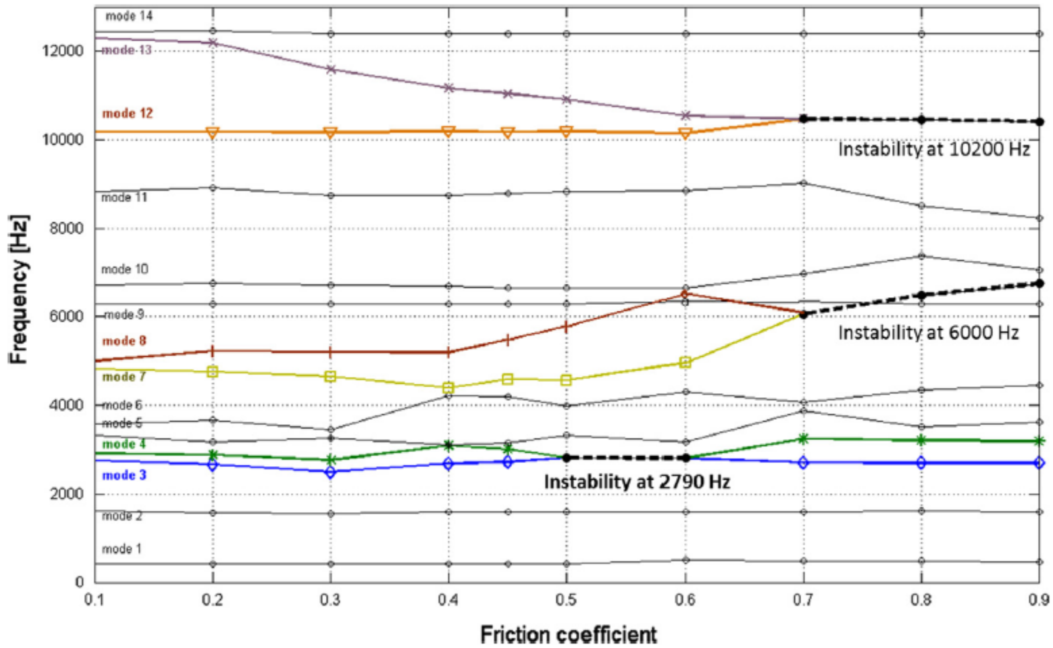

Figure 28: Frictional coefficient vs Frequency

CONCLUSION:

The main conclusions that can be drawn from our research are that increase in head size reduces wear loss in M-o-M bearings. This has been tested on M-o-M bearings manufactured from different vendors and are consistent in the trend shown. M-o-P have very low wear rate when the polyethylene used is of cross-lined type. Three different methods were used to manufacture the cross-linked parts, each of them showing consistently low wear rates, irrespective of the process used to create the cross-links. Frictional coefficient was also found to have an impact on squeaking, with higher values leading to higher occurrences of resonance and acoustic instability. However it is possible to reduce the harmonic resonance points. Furthermore, the effect of surface texturing showed positive results on the performance of bearings under boundary layer lubrication conditions. We propose that M-o-P bearings with larger head size and surface texturing can provide a very economical solution. However, ceramic bearing have lower wear rates at higher cost and the risk of total fracture. On fracture of the implant there needs to be a revision surgery done, which is quite expensive.

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