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ABSTRACT

WEAR AND FRICTION OF HYLAMER AND POLYETHYLENE AGAINST COBALT CHROMIUM A PIN ON DISC STUDY

Jerry D'Alessio II

Understanding friction and wear of biomaterials is essential to the success of any prosthetic joint. A pin-on-disc wear tester is used to find the friction and wear of pins of one material on a coupon of medical grade cobalt chrome. In this experiment six pins of UHMWPe (ultra high molecular weight polyethylene) and six pins of Hylamer® from Du Pont Manufacturing were tested. Four separate runs were made. The tests were performed for ten million cycles, stopping every one to one and a half million cycles for data acquisition. Volumetric wear, wear rate, and coefficients of friction were measured. Both polarized light photomicrography and Scanning Electron Microscopy (SEM) were used to analyze the samples. With the SEM, Kevex Analytical software for elemental analysis was used upon completion of the tests in order to determine and characterize the surface condition and its composition.

SEM and photomicrographic analysis indicated that although data between tests was not reproducible, early tests were reliable. Examination of the coupons showed that the Hylamer® tests had greater surface degradation than the UHMWPe and the Hylamer® itself wore at a moderately faster rate than the UHMWPe. More testing will be needed to firmly confirm this result.

**WEAR AND FRICTION OF HYLAMER AND
POLYETHYLENE AGAINST COBALT CHROMIUM
A PIN-ON-DISC STUDY**

**by
Jerry D'Alessio II**

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APPROVAL PAGE

**WEAR AND FRICTION OF HYLAMER AND
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CHAPTER 1

INTRODUCTION

The history of joint replacement dates back to the nineteenth century, and in the last forty years the procedure has gained widespread acceptance in the treatment of arthritis, the correction of congenital disorders, and in the consequences of trauma [1]. Whatever the reason or the joint to be corrected, the choice of the proper material for the implant is crucial for the success of the orthopedic articulation.

The material must be able to withstand the mechanical, chemical, physical, and biological requirements of the body. Although it is important for the implant to have the same mechanical and physical properties, the chemical and biological requirements are equally, if not more important for successful functioning of the prosthesis. The reactions the material will undergo or induce while in the body, such as the activation of the immune system, an inflammatory response, or a production of toxin; can effect the implant and overall life of the articulation.

The most common cause for joint replacement is arthritis [2]. Arthritis is a disease that affects over thirty seven million people in the United States alone [3,4]. It affects the joints in the body, and more importantly, the connective tissue. Arthritis has over one hundred known forms with no complete cures. All are categorized as rheumatic diseases which affects the joints, muscles, or tissues that serve as the supporting structures for the body. The treatment first starts with drugs to control the pain and inflammation caused by the disease. However, this does not replace the loss of cartilage or fix the problem. Total joint replacement is the only "real" cure because it replaces a diseased joint with a functioning one. Connective tissue, along with bone, provides the basis for the skeletal system of the human body. A joint in the human body is protected by a surrounding capsule of tissue called the synovial lining. This tissue contains a membrane that secretes a

lubricant, synovial fluid, to the joint. This lubricant has two basic functions. First, it slips in between the bones to keep them lubricated. Second, it helps to provide nutrition to the chondrocytes which are the basic cells in the cartilage, and cartilage is a tissue that covers the ends of a bone at a joint. Cartilage is a very firm type connective tissue and according to its distribution, constitution, and function several different types can be found in the body. Hyaline cartilage lines the end of bone at a joint and is what is ultimately destroyed by the arthritis. The purpose of this cartilage is to protect the ends of the bones in moving joints. It acts like a cushion, preventing bone to bone contact at the joint. When the cartilage starts to deteriorate, bones can rub together, and can be pushed out of natural alignment, or splinter; consequently, the end of the bone can form outgrowths (osteophytes), cysts, which can cause joint narrowing. Although there are several hundred forms of the disease, pain and immobility, are the unmistakable results. The two most common types of arthritis are rheumatoid and osteoarthritis.

Osteoarthritis or "wear and tear" arthritis, is caused by the frequent sliding motion of joints, thereby wearing out the cartilage, while rheumatoid arthritis involves the destruction of the cartilage. Despite the cause, the cartilage that lies between the joint is worn away. Consequently, bones rub together and the joint produces pain and swelling. Although drug treatment does exist, it only offers relief of the pain and swelling. In order to restore close to normal function total joint arthroplasty can be initiated. The two most common joints to be replaced are the hip and the knee.

The first significant attempts at total joint replacement were made in the hip by Wiles in 1938 [5]. A stainless steel acetabular cup and femoral component held in place by screws and a bolt was used. Before stainless steel was introduced, other materials such as gold, silver, lead, steel, iron, and ferrous alloys were used to try and find durable, biocompatible components. Some of the metals, such as gold and silver, had excellent biocompatibility; but they were too soft to withstand the tremendous loads impinged on them. Next, scientists turned to materials with better mechanical properties, such as lead

and steel; however, these materials displayed adverse reactions in the body, and in some cases such as lead produced toxic reactions. When stainless steel was suggested, it was felt it would be the perfect material because of its corrosive resistance and durability. However, Wiles only carried out six experiments because the stainless steel joints had a tendency to disintegrate and corrode early.

Although the hip and knee are the two most replaced joints, the hip has undoubtedly received much more attention because it is the joint most affected by disease, and it is a much simpler articulation than the knee [1,5,6]. The hip is a two component system consisting of a ball and socket joint. This configuration allows for a multitude of movements, flexion-extension, abduction-adduction, and external-internal rotation. The knee, however, is a three component articulation consisting of the femoral component, the tibial component, and the patellar component (Figure 1.1). Along with the complex

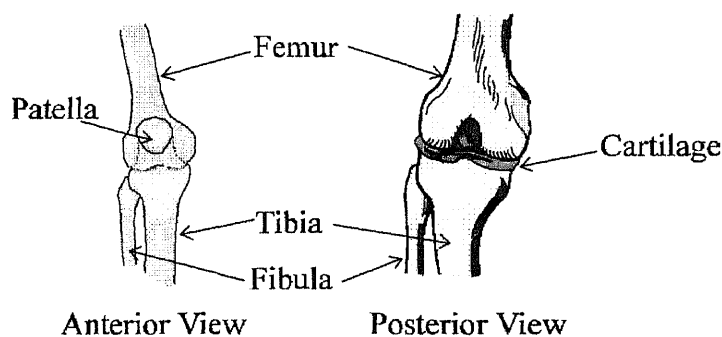


Figure 1.1. Anatomy of the Knee

configuration, there are complex movements; sliding and rotation coupled with flexion and extension. Also, due to the pelvis and other structures, the hip is more constrained than the knee; therefore, the hip is much more stable than the knee. All of these factors contribute to a multitude of designs, with no consensus of opinion on any one type.

Early knee designs were of the hinged type. This prosthesis only allowed for flexion and extension between the femur and the tibia. This resulted in high forces

transmitted to the bone prosthetic interface because of the high shear forces produced due axial rotation and anterior-posterior sliding. These problems initiated the design of non-hinged prostheses with separate femoral, tibial, and patellar components. Another important consideration in the design and implantation of the knee prosthesis is whether or not to leave the anterior and posterior cruciate ligaments after implantation. These ligaments provide stability to the joint and constrain movement posterior and anterior.

As stated earlier, although the design of the implant will relate to its success, the choice of materials for the articulation are extremely important. The most widely used combination is cobalt-chromium-molybdenum (Co-Cr-Mo) alloy against ultra-high molecular weight polyethylene (UHMWPe) [1]. The testing and use of titanium alloys (Ti-6Al-4V) has increased. When applied in combination with UHMWPe, it displays high wear properties [1]. Investigators have found that if the alloy is coated with another substance, such as titanium-nitride (Ti-N), the metal surface does not break down thereby improving the wear characteristics [7]. Ceramics on ceramics, and ceramics on polyethylene are gaining interest and have already been tested and used extensively in Europe. Ceramics such as Alumina have been found to have low wear rates when coupled with UHMWPe, but when paired with each other the wear will increase greatly if the components are not closely matched.

Whatever the material choices used, the goal is to select combinations that have good wear properties and low coefficients of friction. The combination selected for this up to now has been a polished metal alloy against polyethylene. Polyethylene was first used in a hip prosthesis by Sir John Charnley [8,9]. Since then it has been the relative standard for prosthetics. Charnley used high-density polyethylene (HDPE), and now ultra-high molecular weight polyethylene (UHMWPe) is used due to its improved mechanical properties. UHMWPe, as compared to HDPE, has a higher molecular weight; over one million compared to a half-million; and the polymer chains have very few branches. Because of the limited branches and symmetry of the chains, the chains undergo partial

crystallization and are surrounded by non-crystallized, amorphous materials. This results in a polymer that has high abrasive resistance, and good chemical resistance as compared to most other engineering plastics [8].

Since joint prosthesis are bearings, friction and wear are a major concern[1,10-13]. Survival times for the artificial hip and the knee are around 10 to 15 years [1]. As better designs and material choices become available, this life span may hopefully increase.

Friction is a force which is present between two moving surfaces and is required in order to produce movement. If the friction force is high enough, it can produce shearing stresses that can cause loosening of the prosthetic at the bone-prosthesis interface and cause fatigue failure. The highest friction forces are seen in metal on metal joints, next in metal on UHMWPe, and they are even lower in ceramic on UHMWPe [1,12]. Although metal on plastic does not have the lowest friction forces, the force produced is not believed to play a role in the failure of a prosthetic [1,8,14,15]. As previously stated, the major problem in joint replacement is the wear of the prosthetic, especially of the polyethylene bearing. There are many causes and results of wear and the wear debris, but there are also several different types of wear modes present. Each type produces a different effect; nevertheless, any one will cause prosthetic failure.

Three main types of wear exist in an articulation: adhesive wear, abrasive wear, and pitting or fatigue wear [10,16,17]. Adhesive wear results from the direct contact between metal and plastic components. Even highly polished surfaces have a microscopic roughness (Figure 1.2).

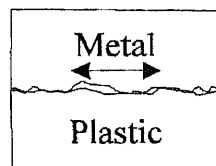


Figure 1.2. Abrasive Wear and Material Asperities [17]

When the plastic and metal come into direct contact, the peaks or asperities of the metal will cut into or abrade away at the plastic. To correct or eliminate the problems of surface roughness in a machine bearing a lubricant is used. The lubricant is placed between the moving surfaces and the hydrodynamic forces resulting allow one part to actually float or glide over the other without their surfaces ever coming into contact if the parts are moving. Also, the bearing is usually moving at a constant velocity and in a unidirectional motion. Under these conditions, abrasive wear is negligible (Figure 1.3). In the body, the motion is oscillating and the hydrodynamic film can not be maintained. Present is boundary film lubrication, which is the presence of some lubrication to separate the parts, and dry lubrication, which is the result of no lubrication at all.

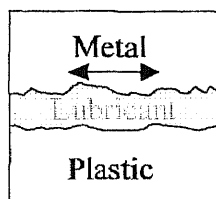


Figure 1.3. Hydrodynamic Lubrication [17]

A special type of abrasive wear is called third-body wear. This occurs when foreign substances such as bone cement, metal beads, bone debris, and wear particles generated from abrasive wear are present at the articulation. The harder substances become embedded into the softer plastic bearing. The embedded bodies can then quickly deteriorate the metal surface increasing both abrasive and adhesive wear.

Adhesive wear is described as localized welding and tearing of the contacting surfaces. The welding occurs when similar materials are in contact. In a metal-polyethylene articulation, the asperities on the metal will abrade the plastic and the plastic will also abrade the metal but in a slower fashion. As this happens, a film of UHMWPe

will adhere to the metal implant. Under high contact stresses present at the asperities, the two similar materials will become welded together. Subsequent movement will break or tear these welds disrupting the surface and causing wear. Adhesive wear is much higher in wear rate than abrasive wear. Therefore, the wear of an implant is dependent on the surface finish and the contact stress applied for these two modes of wear. The smoother the surface, the lower the wear. Current practice is to polish the implant to a 4 micro inch finish [17].

The last type of wear is pitting wear or surface-fatigue wear. This is the dominant wear mode that is related to knee prosthesis failure [14,16,17]. It occurs from incongruent contact between the metal implant and the plastic bearing. Under a load, these areas will deform. The highest von Mises stress will lie about one millimeter into the polymer at the center of the contact. Von Mises stress value indicates the value under which the material will deform plastically. The von Mises stress is also known as the crack initiating stress. As the prosthetic moves along the bearing, the von Mises stresses will move with it. If the von Mises stress is greater than the fatigue strength of the material, internal cracks will begin to form [16]. The cracks then consolidate to produce pitting, delamination, and ultimately failure. Delamination is a separation in layers from the bulk material in the implant. Thin sheets of polyethylene are separated from the tibial bearing. Pitting is the creation of small holes, indentations, or depressions on the surface of a material. This results from the cracks resulting in surface fractures and subsequently releasing large amounts of debris.

The unfavorable clinical effects on a prosthesis due to wear has been identified as a significant problem for some time now [15-19]. Extensive laboratory studies have focused on the friction, lubrication, and wear of prosthesis. These studies can utilize simple pin-on-disc type machines, elaborate joint simulators, or analysis of retrieved implants from patients. Each of them have their relative advantages and disadvantages.

The simple testing machines can have one of four different forms. Figure 1.4a

shows a pin-on-disc machine where a plastic pin is coupled with a flat metal rotating coupon. Figure 1.4b shows a block-on-disc setup in which a curved blocked is loaded and coupled with the curved side of a rotating disc. Figure 1.4c shows a disc-on-disc setup where the curved edge of a rotating disc is coupled with the flat of another disc. And finally Figure 1.4d shows and annulus-on-disc where bottom of the annulus is rotating and coupled with the flat of the disc. No matter what the setup, these machines have the same

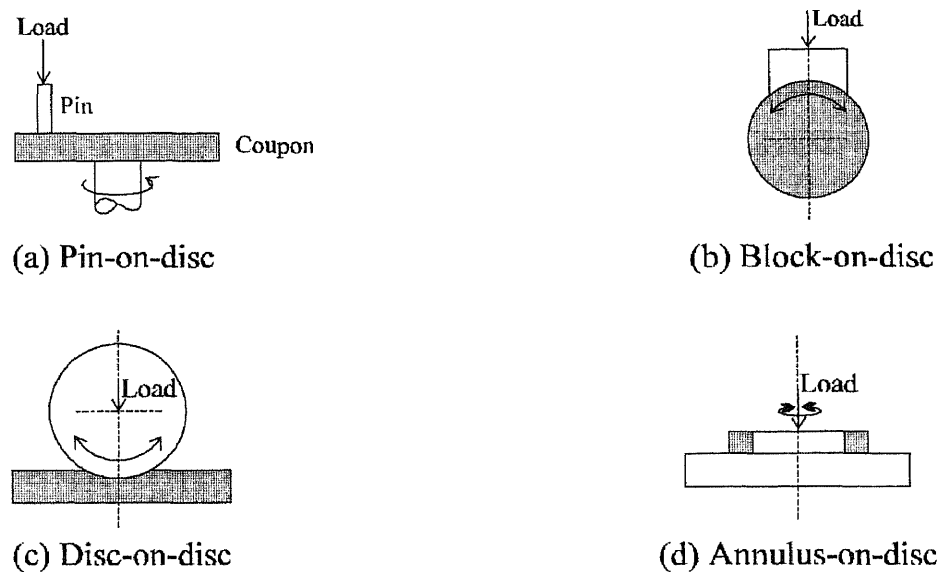


Figure 1.4. Simple Wear Machines [20]

basic purpose which is to rapidly and simply test the wear of two materials under loading and motion. The purpose of these tests is to screen materials for use in the body or joint simulators. Although these machines will not simulate implant designs or motions, by obtaining the correct physiologic loads, sliding speeds, environment, sliding velocities, and stresses, materials can be evaluated rather simply as to their functioning for use as implants. Also, the type of motion used by the machine is important. The motion could be either oscillating or uni-directional. Oscillatory machines have several advantages over unidirectional types. Human joint motion is oscillatory; therefore, non-oscillating

machines will not account for changes in both direction and velocity which are associated with joint motion. Also, these changes will affect lubrication by preventing boundary lubrication over sliding distances and hydrodynamic effects. Consequently, a more realistic test is performed by utilizing oscillating motion. Joint simulations are more accurate in predicting the actual wear rate of a material or a design because it tests the prosthesis under conditions that greater reflect what is encountered in the human body. Another way to investigate the effects of wear is to investigate retrieved prosthetics. By examining the retrieved implants, improvements in wear tests and prosthetics can be initiated in order to find suitable material combinations before they go into the body for testing.

Walker et al. utilized a pin-on-disc type machine to analyze several polymers against a stainless steel disc [20]. The specimens were placed under a contact stress of 19.6 MPa and a sliding speed of 0.028m/s. The samples were run dry and with synovial fluid. The wear was measured by weight loss and the authors concluded that high density polyethylene was the best for this application.

Harlan C. Amstutz analyzed ten different materials using a block-on-disc machine for both friction and wear [13]. The frequency was 89 cycles per minute through an arc of 90°, a sliding speed was 0.11 m/s, and a contact stress of 6.4 MPa. After performing several friction tests with different testing environments, (plasma, mineral oil, saline, ionosol B), mineral oil was selected due to its similarity with synovial fluid in coefficient of friction. The wear of the samples was measured by two methods. First, the wear was calculated from the weight changes of the samples. The other was to compute the wear from the dimensional changes of the problem. Due to creep of the polymers, the wear rate or loss from dimensional changes was ignored. Also, a soak control was introduced into the test in order to counteract the effect of oil absorption. This was discovered when one of the UHMWPe samples gained weight. Therefore, the introduction of the presoak produced differences in previous results. However, the author made certain conclusions

that polyimides and UHMWPe exhibit the best wear resistance while UHMWPe and Delrin provide the lowest coefficient of friction.

Rostoker and Galante utilized a disc-on-disc machine to evaluate over 25 different material combinations [20,21]. Two different sliding velocities were examined during the test, 0.0106 m/s and 1.483 m/s, a stress which ranged from 2.1 to 6.9 MPa, and a lubricating environment of water maintained at 37°C. Wear rates were determined by dividing the depth of wear by the total sliding distance. The conclusions made are as follows: (1) UHMWPe against Vitallium produced the lowest wear rates of commercially available materials, (2) ceramics such as aluminum oxide, silicon carbide, and boron carbide against themselves had wear rates too high for clinical use, (3) UHMWPe plus 25% graphite powder produced a wear rate between one-seventh and one-thirteenth than that of UHMWPe alone at a contact stress of 2.1 MPa; however, at higher stresses the wear rate difference was negligible.

McKellop et al. analyzed the wear of UHMWPe against 316 stainless steel or cobalt chrome alloy using a 12-channel wear tester of a pin-on-disc type [22]. The polymer specimen consisted of a 12 mm diameter cylinder with one tapered end to form a contact area of 64 mm² (0.1 in²). A constant testing load of 445 N (100 lb) was applied to each pin by utilizing a pneumatic cylinder. The system frequency was 100 cycles per minute and a sliding speed of 0.042 m/s for a test duration of two to three million cycles. The authors used weighing in this test also in order to quantify wear; however, in order to correct the fluid absorption of the pins two methods were used. The first method was called "dry" weighing. The specimens and controls were first washed in an ultrasonic cleaner and then dried in a vacuum-desiccator for three days and weighed prior to testing. After the wear test the wear specimens and controls were cleaned and desiccated for two weeks. The results showed that after one week the controls had gained about 300 to 400 µg, and after two weeks this value dropped to about 100-200 µg and remained relatively constant thereafter. It was assumed that the specimens had gained this amount

so the final wear was less 100-200 μg . The second method presoaked the specimens and controls in serum before testing. At several intervals during the test the specimens were cleaned and weighed along with the soaks. The average net gain or loss in the controls relative to the start of the wear test was added to or subtracted from the weights of the test specimens in order to correct the fluid absorption. The coefficient of friction and wear rate was determined as a function of lubricant, contact stress, and metallic surface roughness. Differences between friction and wear in serum, distilled water and saline was determined. Transfer layers of polyethylene were apparent on the coupons for the distilled water and saline environments but not the serum. Upon restart of the tests, the serum samples had an unusually high coefficient of friction for about one hour. The authors however indicate this is alright due to the fact that the transfer film increases the friction in the saline and water tests. Upon conclusion of the lubrication test, the authors indicated the serum produced wear results that correlated with removed prosthesis. The wear rate of polyethylene against cobalt chrome alloy was slightly lower than it was against stainless steel. Also, the wear rate increased with increasing surface roughness for polyethylene; however, the wear was still not that severe.

Many other tests were conducted on different materials, designs, configurations, etc. Although the testing indicates the survival and failure modes of a material or design, perhaps the best tool to analyze what is happening with a prosthetic is retrievals. Although wear is a problem in all prosthetics, wear in the knee is much more extensive than in the hip [14,18,19,21-24]. Therefore, investigators are trying to understand the factors that contribute to wear in a prosthetic, and then identify if new material or design choices will slow down the wear process. The types of wear present have been discussed previously; however, there are several additional factors that can contribute to the wear process (Figure 1.5).

When retrieved components are examined, investigators showed that the polyethylene bearing is the cause of prosthetic failure. As can be seen in Figure 1.5 there

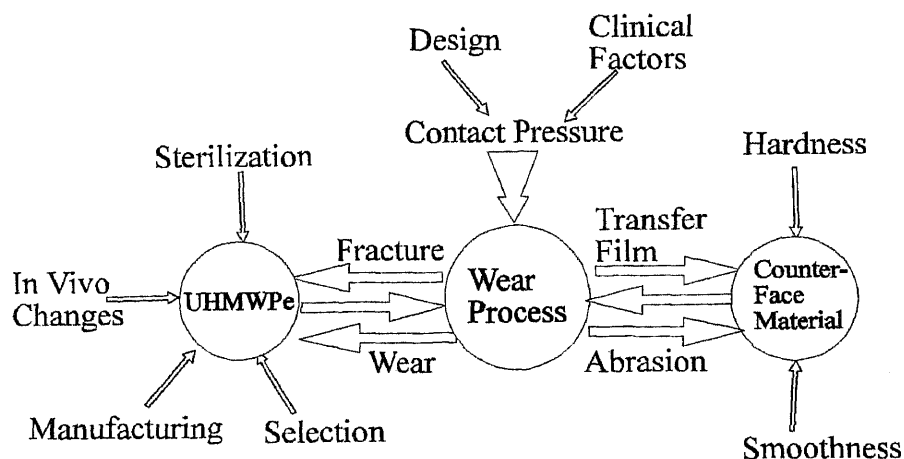


Figure 1.5. Factors Contributing to High Wear [17].

are many variables that can affect the mechanical properties and the functioning of the insert. One of these is sterilization. Before anything is placed in the body it must be sterilized. This is done by exposing the prosthetic to a fixed dose of gamma radiation, usually 2.5 Mrad. When the polyethylene is exposed to the radiation, the physical structure is altered by causing cross-links between polymer chains and chain scission of individual chains. The chain scission results from oxidative degradation of the polyethylene during sterilization, which shortens the chains. The shorter chains are more mobile, and they orient more easily, thereby increasing the percentage of the material that is crystalline. These changes affect four major mechanical properties of the polyethylene, modulus of elasticity, yield point stress, ultimate tensile strain and ultimate tensile stress. The modulus and yield point increase with increasing radiation, while the ultimate stress and the percent elongation at this stress decrease. Since the main cause for these changes seems to be oxidation, investigations of sterilization in nitrogen atmosphere instead of air have shown that the amount of change in material properties is decreased [8].

Another factor that changes the physical properties of the material are in vivo changes. Again, these changes are elicited by oxidation. This produces chain scission, which affects the variables stated above and decreases the molecular weight. The effects

of sterilization and in vivo conditions indicate that ultra-high molecular weight polyethylene is not a static material and will therefore change over time.

Polyethylene wear can also be related to the manufacturing of the component. Orthopedic polymer implants are manufactured either by machining components from large blocks of material, or by direct compression molding. The first method is the most common, and the block of material is obtained by extruding powdered polyethylene into simple shapes such as bars or rods. Direct compression molding uses molds which are filled with preheated powder and then heated and pressed to form a finished component of the desired geometry. Despite the method used, the polyethylene component can contain crack line defects between relatively poor bonded high-molecular weight regions, scratches on the surface due to machining, or scratches caused by the opposing metal articulating surface. Under loads, these defects can initiate fracture of the polyethylene by becoming cracks, demonstrating another way in which the prosthetic can fail.

Although polyethylene wear can be initiated by the above mentioned factors, the load that the implant experiences in vivo is an underlying cause in nearly every wear process [25]. Therefore, tests have shown the amount of wear or surface damage is associated with such clinical factors as patients weight and implant time [14,23]. In other words, the heavier the patient, the larger the applied load, the larger the stress on the implant. The implant time is defined as the number of cycles that the articulation undergoes, not the amount of time it is implanted. This is the reason fatigue is believed to be the major cause of failure

As already noted, wear is much more extensive at the knee than at the hip because the contact stresses are higher. The reason it is higher is due less conformity present in the geometry of the knee. Consequently, if the same load is applied to each joint, the incongruent contact at the knee will result in a smaller contact area, thereby producing a larger stress. However, the ball and socket joint of the hip has a more conforming geometry, and therefore lower stresses and wear rates. Another consideration beside

conformity is the contact areas at the knee can vary in location due to the complex flexion-extension, and rotation movements. The femoral condyles will contact different locations on the polyethylene bearing. Therefore the implant will be directly under area contact, to the edge of contact, or to be totally outside the contact region.

Incongruent contact between the metal and polyethylene insert can cause complex stress distributions on the surface of the polyethylene. These stresses induce fatigue failures pitting and delamination. As previously stated, these wear processes depend on von Mises stresses, which initiate crack propagation. The location of these stresses is directly related to the conformity of the prosthetic. The more congruent the contact, the closer to the surface these stresses will lie. The closer to the surface, the less likely for sub-surface crack propagation. Since total conformity of the prosthetic may not be totally advantageous, several studies have indicated that it is more important to have congruent contact in the medial-lateral direction [14,18].

Although the effects of conforming surfaces have been shown to be advantageous in the reduction of contact stresses, total conformity may cause problems. The knee joint is a complex articulation, consisting of flexion-extension, and internal-external rotational motions. In a normal, functioning knee, the rotational loads applied by the tibial movement are shared by the joint and the surrounding tissues. If there is highly-congruent contact between the femoral prosthetic and tibial insert, the bearing surface will receive most of the load, while the soft tissue structures obtain a smaller portion. This increased load will cause a higher transmitted load to the prosthesis-bone interface, affecting the bond and may even cause loosening. For this reason, a compromise must be made on how conforming the articulation must be; therefore, current knees employ incongruent contact in order to obtain the needed mobility.

An increase in wear rate of fifteen times can be seen between a highly incongruent knee and a mildly conforming knee; therefore, the effects of this so called compromise can be drastic [16]. This is the case with current, fixed bearing knees. These knees only allow

for flexion and extension while the amount of rotation needed is obtained through in congruency between the femoral prosthesis and the tibial tray. Mobile bearing knees are one answer to the question of high or mild congruent contact. The mobile bearing knee allows the plastic insert to move on the tibial implant permitting congruent contact between the femur and the bearing insert through all ranges of motion . Although the knee will still exhibit wear properties, the contact stress in the knee will be lower. This lower stress should reduce the wear as opposed to current fixed bearing knees, because high contact stress causes fatigue failure which is the major reason for wear in the knee.

Additional factors of the polyethylene insert have been investigated as to their role in the wear process. The thickness of the polyethylene bearing itself can play a role in the value of the contact stress. The thicker the polyethylene insert, the lower the contact stress, and consequently the wear rate. A minimum thickness of eight millimeters should be used whenever feasible [1,14,18]. Actually, the thicker the insert, the better; however, in order to provide a large thickness, a greater portion of the tibia must be sacrificed, and the prosthetic-bone interface may not be as strong due to the smaller area of contact. It can be seen in Figure 1.1 that the tibia is wide at the knee and tapers down toward the ankle. If a greater portion of the tibia is removed, the amount of contact area present between the tibia and the prosthesis will be smaller.

As can be seen from the previous discussion, failures of prosthesis due to wear can come in a variety of forms. Although failure can occur through wear of the prostheses, there usually is a restriction in the range of motion before this happens. This restriction can cause instability or misalignment of parts, which in turn can cause the joint to loosen. Another concern on the life of the prosthetic is the role of the wear debris. Polyethylene wear debris have been reported to cause aseptic loosening and late infection [16]. The reason for these problems is that wear debris illicit reactions from the surrounding tissues. Metallic wear debris can be dissolved, liberating metallic ions; however, polyethylene debris are transported to the regional lymph nodes. The major cause for adverse reaction

is therefore believed to be polyethylene debris.

In a metal-UHMWPe prosthesis, the majority of the wear debris is polyethylene. Cells will respond to the foreign matter by engulfing them through the process of phagocytosis. The cells that respond are macrophages and giant cells. The macrophages try to eliminate the fine particles, while the larger flakes are surrounded by the giant cells. It has been proposed that the wear particles cause adverse reactions in the surrounding tissues; specifically fibrosis, which is thickening or scarring of the connective tissue, and necrosis, which is death of cells. These reactions can cause endosteal bone resorption or bone death, and deterioration of the bone-implant interface [18].

There are many mechanisms and factors that contribute to the wear and failure of a prosthesis. The search for new designs in implants is rare but material selection and new discoveries are the focus of many research projects. As previously discussed, many tests from standard pin on disk to elaborate joint simulators have been performed in order to determine which materials have the lowest wear rate, are dimensionally stable, etc. Nearly all of the prosthetics today use a metal-polyethylene articulation configuration. The most common choice being cobalt chromium alloy on a polyethylene. DuPont, in a joint venture with DePuy® have created a new form of UHMWPe which they claim retains the advantages of conventional UHMWPe while improving its overall functioning. This material, Hylamer®, is created by realigning the long molecular chains present in conventional UHMWPe without changing the chemistry with fillers, fibers or additives [26]. During realignment, chains of length "L" are converted to extended folded chains of length "10L" during a special thermodynamic process. These folded chains strengthen Hylamer® and increase its crystallinity by 45% [26]. DePuy-DuPont Orthopedics indicate that the restructuring will increase creep resistance, provide a higher strength and stiffness, have greater resistance to oxidation, lower wear rate, and a greater resistance to failure. Hylamer® has a tensile strength 50% higher, yield strength 20 to 50% higher, and is stiffer than UHMWPe. A stiffer polymer may create a higher contact stress, and increasing

contact stress can increase wearing [25]. Therefore, although Hylamer® has increased dimensional stability, improved chemical resistance, and improved strength; it also unfortunately has improved stiffness which may not improve the wear.

CHAPTER 2

METHODS AND MATERIALS

The focus of this test is to analyze the wear volume and rate of surgical grade Ultra-High Molecular Weight Polyethylene (UHMWPe) and Hylamer® bearing materials against cobalt-chromium (Co-Cr) counter faces under an oscillating motion and a constant contact stress in order to compare the wear rates of these two orthopedic bearing materials.

The test simulates wear of the materials by coupling the oscillatory motion of three Hylamer® pins or UHMWPe pins against a flat Co-Cr metal coupon. The coupons are machined from Co-Cr stock and then polished to a 0.03 μm (1 μin) finish. The pins used for the test are manufactured from surgical grade Hostalen GUR-41 UHMWPe and Hylamer® bearing polymer rod stock. Each individual test pairs three pins of either UHMWPe or Hylamer® against the Co-Cr counter face. Neither polymer is subjected to sterilization prior to testing. The mechanical properties and dimensions for the materials used in this test are shown in Table 2.1.

Table 2.1. Material Properties and Dimensions

Material	Density (g/cm^3)	Diameter (mm)	Cross Sect. Area (mm^2)	Length (mm)	Exposed Length (mm)	Roughness (μm)
Pins						
UHMWPe	0.933	6.35	31.77	13	3	--
Hylamer	0.955	6.35	31.77	13	3	--
Coupon						
Co-Cr	--	31.75	791	6.35	--	0.03

The wear testing machine used for the test can be seen in Figure 2.1. The pins are placed in a containment cup which has three holes at 120° apart (Figure 2.2). The holes in the cup are milled to a specific depth so that the exposed or effective length of the pins are

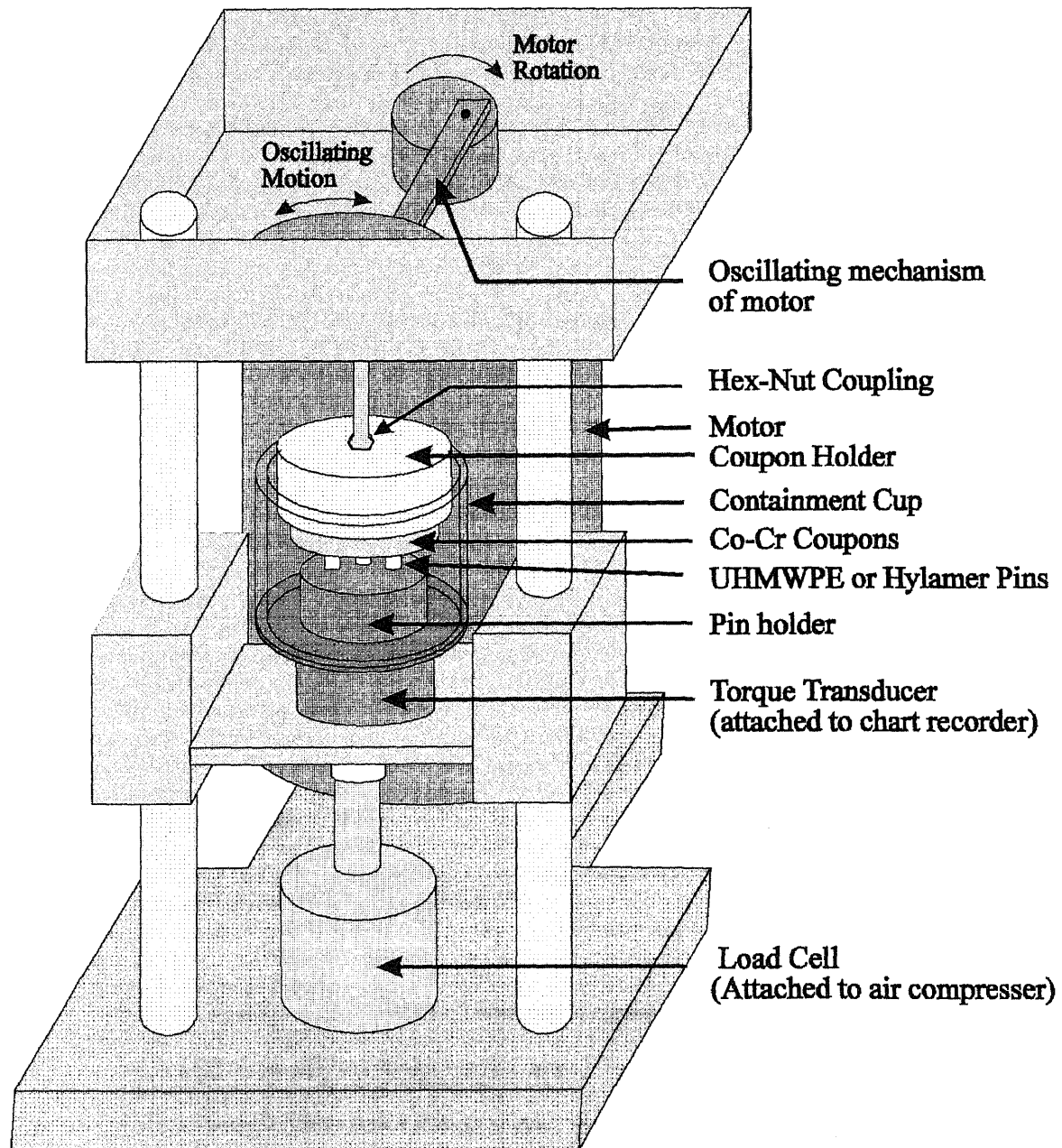


Figure 2.1. Oscillating Wear Tester (Pin-on-disc)

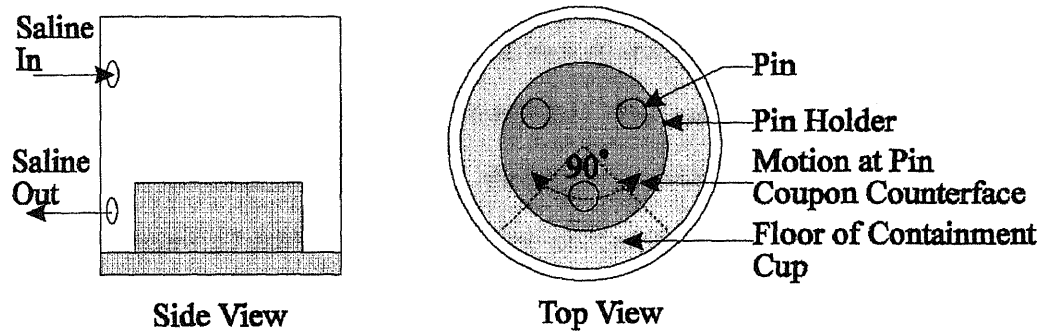


Figure 2.2. Containment cup and pin holder

around 3 millimeters. The reason for this exposed length is to minimize the tipping and bending of the pins under the forces produced from the oscillating motion. The metal coupon is attached to a coupon holder through a central cylinder and a pin (Figure 2.3).

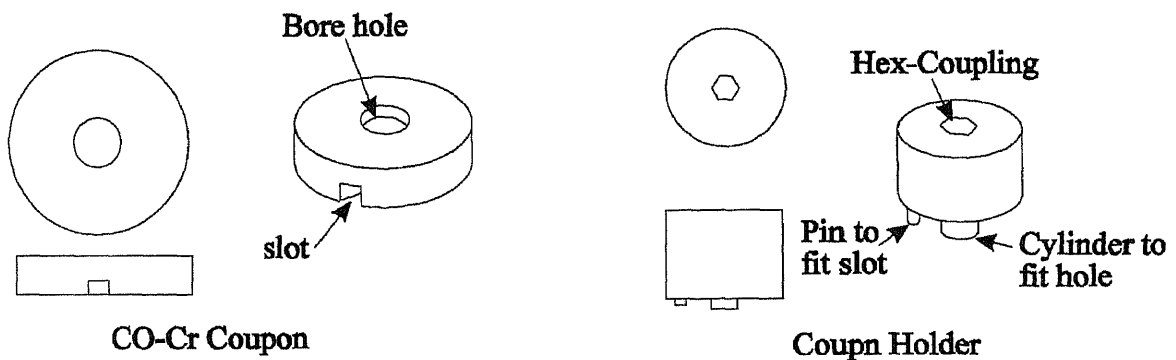


Figure 2.3. Coupon and Coupon Holder

The coupon holder has a rounded hex nut coupling which matches a hex nut driver which is attached to the motor (Figures 2.1 and 2.3). This coupling allows the coupon to oscillate through 90° while maintaining a flat, planer surface with the three pins as they wear and change in height. A small ball is placed between the coupon holder and the driver on the machine. The purpose of this ball is to keep the testing load centralized over the pins. Both the ball and the movable coupon permit the contact stress to be the same at all three points on the coupon by keeping the contact area and testing load the same.

The floor or bottom of the containment cup is attached to a torque transducer in a similar manner to that of the coupon and holder. The cup is filled with a normal saline solution and is continuously circulated through the system. The saline is made by dissolving 35 grams of sodium chloride in one gallon of distilled water. The purpose for this environment is to dissipate frictional heat, to circulate the wear particles throughout the system, and to simulate the conditions present in a human articulation. Several different environments could have been used in testing such as bovine serum, distilled water, types of oils, saline, and others. Saline was chosen for this test because of three reasons: convenience, more accurate stress corrosion effects, and a more conservative test. Bovine serum is a natural solution which is messy to work with and decomposes over time so it must be changed regularly. Since salt water is a corrosive environment, saline will better display the effects of stress corrosion on the materials. Also, saline will show how the materials work under more stringent conditions and which are still physiologically correct. The outlet on the containment cup is connected to a water pump through flexible tubing. The saline is circulated at six liters per hour and is maintained at a temperature of 36°C (98°F) with a heater throughout the testing (Figure 2.4). The volume of circulating fluid is kept constant by the adding saline in order to replace that lost through evaporation.

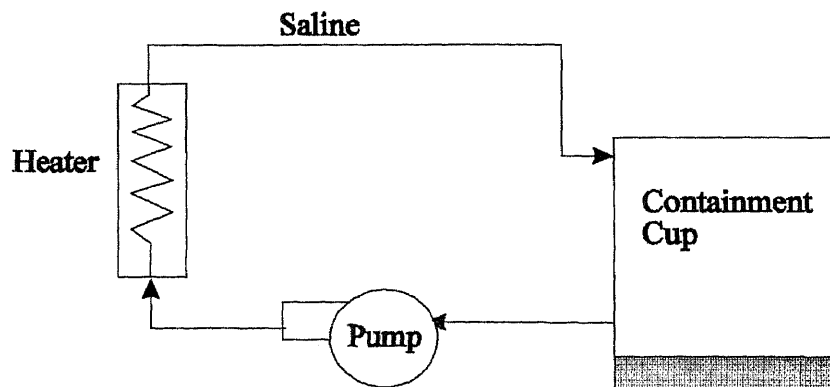


Figure 2.4. Schematic for Cooling-Lubricating System

Once the coupon and pins are placed in the machine a load of 190 N is applied to the bottom of the containment cup by an air cylinder. Since the load is kept centralized and there are three pins, the force applied to each pin is 63.3 N. Each pin has a cross sectional area of 31.7 mm²; therefore, at the pin coupon interface there exists a contact stress of 2.0 MPa. This contact stress is chosen because it is a common stress located at the hip and is equivalent to a 32 mm femoral head under 2.5 times the body weight of a 68 kg (150 lb) person [27,28]. The stress was calculated by dividing the force at the hip by the projected area of a 32 mm head. The force acting on the hip is assumed to be 2.5 times the body weight of a person and is found to be:

$$F = (68 \text{ kg}) \left(9.81 \frac{\text{m}}{\text{s}^2} \right) \cdot 2.5 = 1667 \text{ N}$$

The stress is then calculated by dividing the force by the projected area of $A = \frac{\pi d^2}{4}$:

$$\sigma = \frac{F}{A} = \frac{1667 \text{ N}}{\left[\frac{\pi \cdot (0.032 \text{ m})^2}{4} \right]} = 2.0 \times 10^6 \frac{\text{N}}{\text{m}^2} = 2.0 \text{ MPa}$$

The tests were run up to 10 million cycles with each million cycles being equivalent to 40 km of sliding distance. An average sliding speed of 0.024 meters per second is produced by an test speed of six hertz and a stroke of 0.04 meters. These values have shown to be reasonable for testing as long as the system is kept below pressure-velocity limits [7]. As previously stated, the coupon is suspended above the pins and oscillates through ninety degrees. By inverting the metal coupon, the wear particles are allowed to fall and be transported by the environment. If the coupon was placed on the floor of the containment cup and the pins allowed to oscillate, the wear particles could stay on the coupon and greater attribute to other forms of wear, such as third body or adhesive wear, thereby producing some bias which may not be present in vivo. All testing parameters are listed in Table 2.2.

Table 2.2 Test Parameters

Contact Stress/pin (MPa)	2.0	Frequency (Hz)	6
Load/pin (N)	63.3	Test Length (cycles)	10 ⁶
Motion	Oscillatory	Environment	
Oscillation angle (deg)	90	Solution	saline
Stroke (m/cycle)	0.04	Flow Rate (l/hr)	6
Sliding Velocity (m/s)	0.24	Temperature (°C)	36

Testing is interrupted every 1 to 1.5 million cycles and measurements are taken in order to evaluate the materials' mechanical properties. The pins are removed and rinsed with normal saline. Next the pins are weighed on Sartorius analytical balance with an accuracy of 100 μg and a maximum of 160 grams. Weights are recorded three times in order to minimize the likeliness of errors encountered during the weighing procedure. The height of the pins could also be measured in order to determine the amount of materials lost; however, since the pins are a viscoelastic material the deformation in height could be linked to both wear and creep. For this reason, only the weights will be used.

Since the pins are submerged in fluid and it is known that they will absorb fluids, another pin, a soak control, is also submerged in the heated saline and weighed with the other three pins at each test stop. The purpose of the soak control is to identify the amount, if any, of fluid absorption that takes place in the pins. Therefore, the amount of fluid that is absorbed (M_f) can be found by subtracting the soak control weight at each stop from its original weight. A soak control is used for each test and both UHMWPE and Hylamer®. It is assumed that the amount of fluid that is absorbed by the soak is the same amount actually absorbed by the pins. In order to determine the true weight of the pins being worn, their measured mass (M_m) must be adjusted by subtracting the fluid absorbed yielding the true mass (M_t).

$$M_t = M_m - M_f$$

Now that the true mass is obtained the mass loss (M_l) of each pin can be found by subtracting the true mass from the beginning or original mass (M_o) of each pin.

$$M_1 = M_0 - M_t$$

The volumetric wear of each pin can then be found by dividing the mass of the pin that is lost by the density of the material, ρ . Therefore:

$$\text{Vol. wear} = \frac{M_1}{\rho}$$

The torque that is being applied to the pins is also recorded and analyzed every 1 to 1.5 million cycles. A Transducer Techniques RTS-500 torque sensor is attached to the bottom of the containment cup. This transducer is connected to a Gould 2400S Chart Recorder which allows for a record of the torque transmitted across the pin specimens. Before the test is begun, the transducer is calibrated in order to determine the magnitude of the torque of the paper readout. The number of blocks is first read off the readout and is then multiplied by a calibration factor of 0.025 N-m per block of paper in order to provide the torque. Once the torque is obtained from the paper readout, the tangential force applied across each pin can be obtained by dividing the torque (T) by the radial distance (r) from the center of rotation of the center of each pin,

$$F = \frac{T}{r} \frac{(\text{N} \cdot \text{m})}{(\text{m})}$$

This tangential force is the frictional force. Now that the frictional force is obtained between the metal coupon and the pin, the coefficient of friction (μ) can be obtained for both Hylamer® and UHMWPe against Co-Cr by dividing this frictional force by the normal force (N), which is the testing load,

$$\mu = \frac{F}{N}$$

Along with weighing the samples, a visual inspection of the coupon is taken. Since the motion is oscillatory, the worn areas for the each pin can be identified (Figure 2.5).

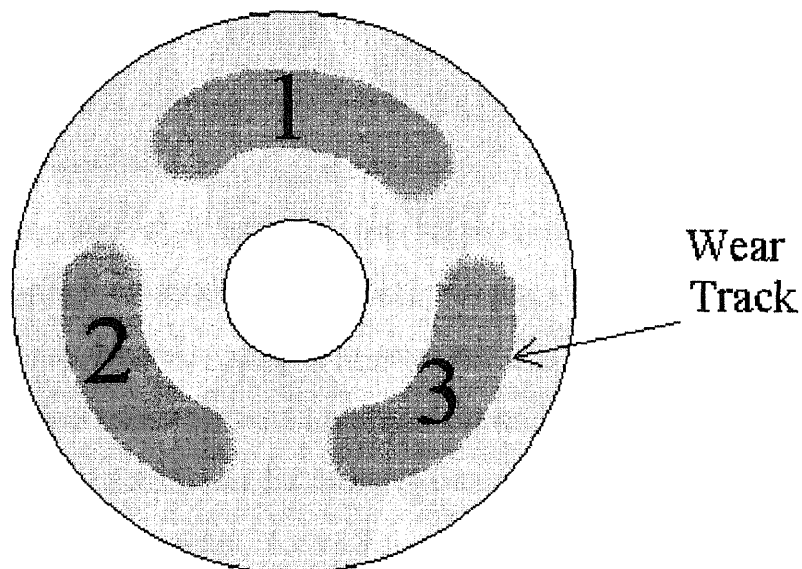


Figure 2.5. Wear Track

During this time any formation of transfer film or scratches are noted. After each test is completed, a permanent visual representation of both the pins and coupons is performed using polarized photo microscopy.

After the photo microscopy was performed, further analysis of the materials surface composition was performed. This was accomplished by using a JEOL JSM-T300 Scanning Electron Microscope and Kevex Analytical software for the elemental analysis. First the plastic pins have to be coated with a conductive medium in order for the electron microscope to function properly. The pins are placed in a vacuum type chamber and a rod of carbon is placed by an electrode. The electrode vaporizes the carbon and coats the top surfaces of the pins. The metal counterfaces do not have to be coated because it is conductive. The scanning electron microscope (SEM) passes an electron beam across the sample and the reflected electrons are gathered and processed in order to produce an image. Elemental analysis is achieved by determining the energy absorbed by the sample. A detector on the microscope determines the amount of energy that is returned from a

beam after it hits the sample. This value is then compared to known values for each element and a plot is displayed showing the elements found and the amount present. The SEM used also has a backscatter detector. The purpose of this detector is to analyze the electron beams that are reflected straight back from a sample. This is useful because materials such as plastic will not reflect the beam and will show up as dark spots. When viewing the coupons, any blotches or particles that are seen on the surface can be identified as polymer if the backscatter display shows them as dark spots. By utilizing the features of the SEM, the composition of the testing agents can be analyzed thereby giving some insight into the wearing procedure.

CHAPTER 3

RESULTS

The average volumetric wear for each test is shown in Figure 3.1. Since four individual tests were run, Hylamer® 1 & 2, and UHMWPe 1 & 2 identify the test number for each three test pins. The average volumetric loss ranged from a low of 0.6283 mm³ at one million cycles to a high of 11.27 mm³ at ten million cycles for Hylamer® 1, 1.408 mm³ at one million cycles to a high of 30.32 mm³ at ten million cycles for Hylamer® 2, 1.096 mm³ at one million cycles to a high of 2.953 mm³ at ten million cycles for UHMWPe 1, and 1.417 mm³ at one million cycles to a high of 24.04 mm³ at ten million cycles for UHMWPe 2.

Figure 3.2 shows the individual performance of each pin for all four tests against the Co-Cr counterfaces for volumetric wear. Hylamer® 1 values ranged from 0.5236 mm³ at one million cycles to 14.80 mm³ at ten million cycles for pin 1, 0.6283 mm³ to 6.283 mm³ for pin 2, and 0.7330 mm³ to 12.74 mm³ for pin 3. The volume loss for all three pins was similar until two million cycles. At this point the loss increased for all the pins; however, pins 1 and 3 showed a larger increase. After this increase, pins 1 and 3 showed a similar wear loss which is almost twice that of pin 2. UHMWPe 1 values were 1.358 mm³, 1.107 mm³, and 0.8217 mm³ at one million cycles, and 4.252 mm³, 2.465 mm³, 2.144 mm³ at ten million cycles for pins 1, 2, and 3 respectively. The wear volume for all the pins follows the same trend and is slowly increasing as the number of cycles increase. Hylamer® 2 pins ranged from 1.466 mm³, 1.536 mm³, and 1.222 mm³ at one million cycles to 29.11 mm³, 29.04 mm³ and 32.81 mm³ at ten million cycles for pins 1 through 3 respectively. All the pins follow the same trend; however, at about seven million cycles the wear volume begins to increase dramatically. At seven million cycles the wear for

Average Volumetric Wear of Co-Cr Against Hylamer and UHMWPe

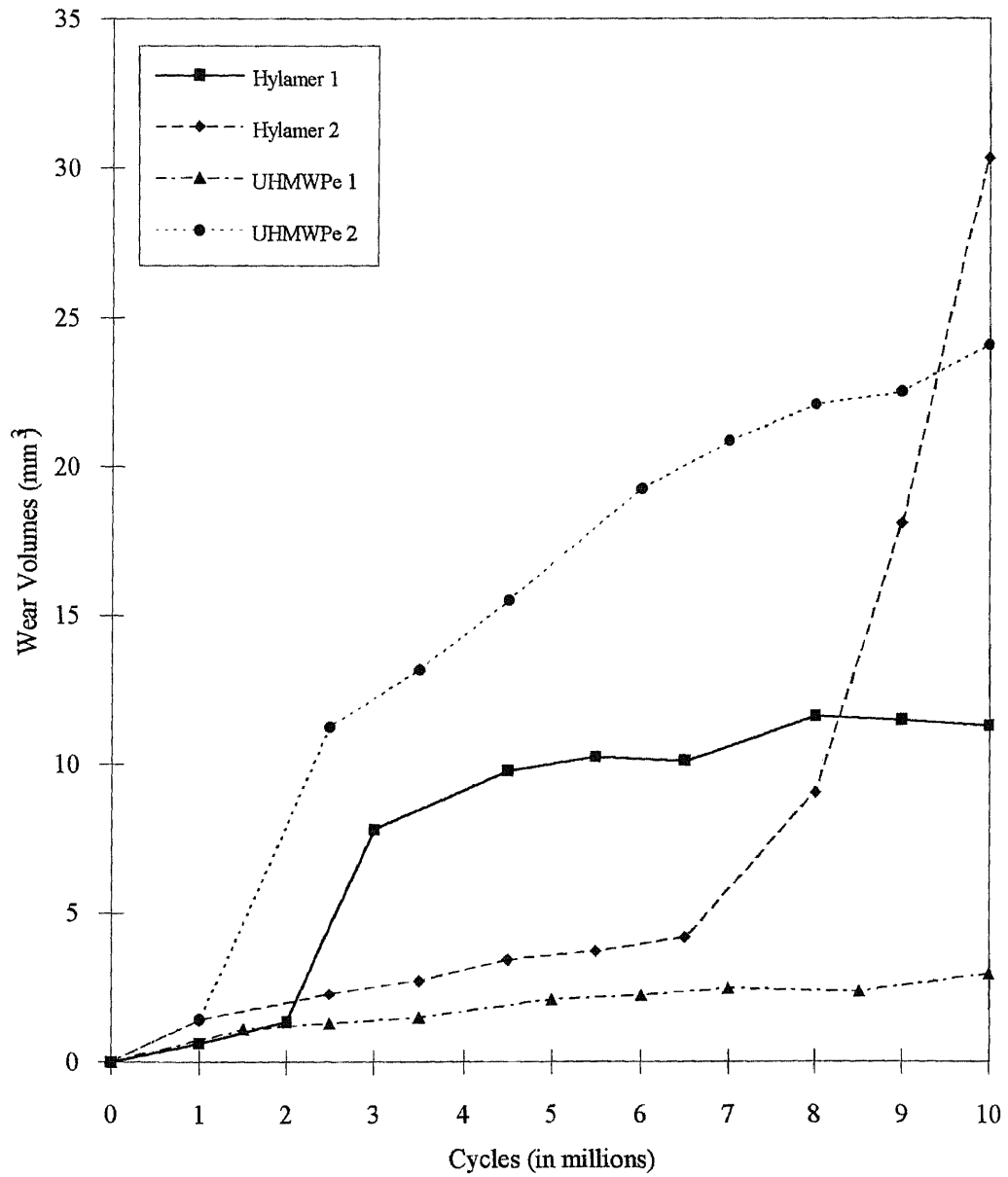


Figure 3.1. Average Volumetric Wear of Hylamer® and UHMWPe For Each Test

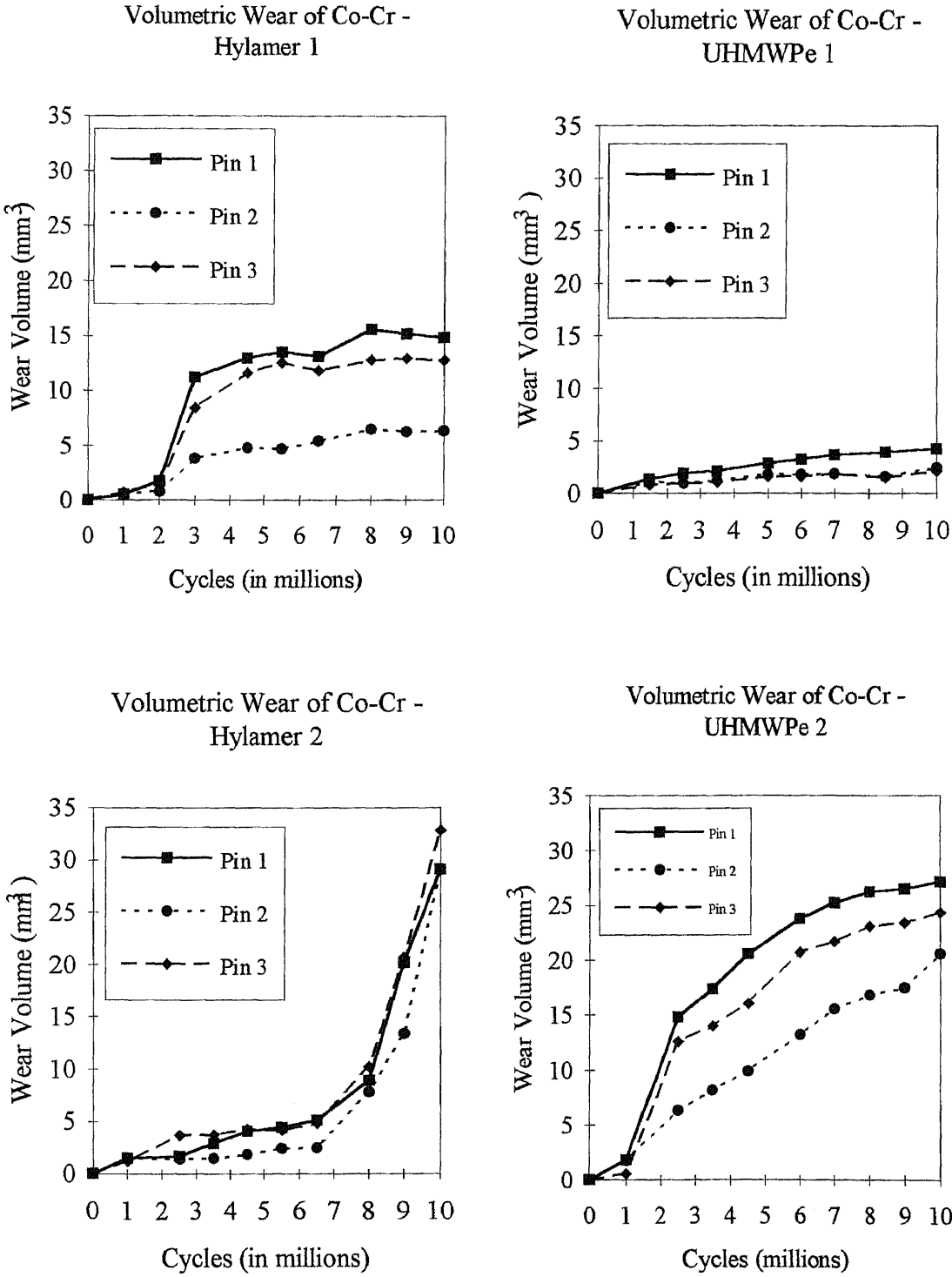


Figure 3.2. Volumetric Wear of Individual UHMWPE and Hylamer® Pins

Hylamer® 2 is 5.13, 2.51 and 4.85 mm³ for pins 1, 2 and 3 respectively. In three million cycles the wear rose approximately 25 mm³. UHMWPe 2 pins started at 1.858 mm³, 1.786 mm³, and 0.6074 mm³ at one million cycles and finished at 27.15 mm³, 20.58 mm³ and 24.40 mm³ at ten million cycles for pins 1 through 3 respectively. At approximately 2.5 million cycles the wear jumped noticeably to an increased value. After that pins 1 and 3 had similar and larger volumetric wear as compared to pin 2.

The average wear rates for each test is represented in Figure 3.3. The wear rates for all the tests are almost constant except for a couple of discrepancies. Hylamer® 1 wear rate increases at about 2.5 million cycles the wear rate increases to a high value of about 6×10^{-4} mm³/million cycles; however, it returns to a lower rate of about 2×10^{-4} mm³/million cycles. UHMWPe 1 shows no variability in the wear rate and is almost constant. It ranges from a minimum of 1.78×10^{-4} mm³/million cycles to a maximum of 3.83×10^{-4} mm³/million cycles. Hylamer® 2 shows no jumps in wear rate and remains relatively constant until 7 million cycles. After this there is a continually escalating wear rate. Before this, the wear rate lies in the range of 2.7×10^{-4} mm³/million to 1.34×10^{-4} mm³/million cycles.

Figure 3.4 display the wear rate for the individual pins of each test. At three million cycles, Hylamer® 1 has an accelerated jump in rate for all three pins. Pins 1 and 3 have higher jumps than pin 2, 9.0×10^{-4} mm³/million cycles, 6.6×10^{-4} mm³/million cycles and 2.9×10^{-4} mm³/million cycles; nevertheless, the wear rates drop back to almost the same values before the jump. All three pins for UHMWPe 1 follow the same trend, and no jumps or variations are present. Hylamer® 2 pins show a slight variation in wear rate before seven million cycles. After this the wear rate continually accelerates to values of almost ten times the previous values. UHMWPe 2 also displays a jump in the wear rate at 2.5 million cycles. The value does return to previous values; however, there is variance between the three samples after the jump. At the jump, pin 1 and 3 have a high wear rate of 1.47, 1.26×10^{-3} mm³/million cycles, and pin 2 rate is 0.632×10^{-3} mm³/million cycles.

Wear Rate of UHMWPe and Hylamer on Co-Cr

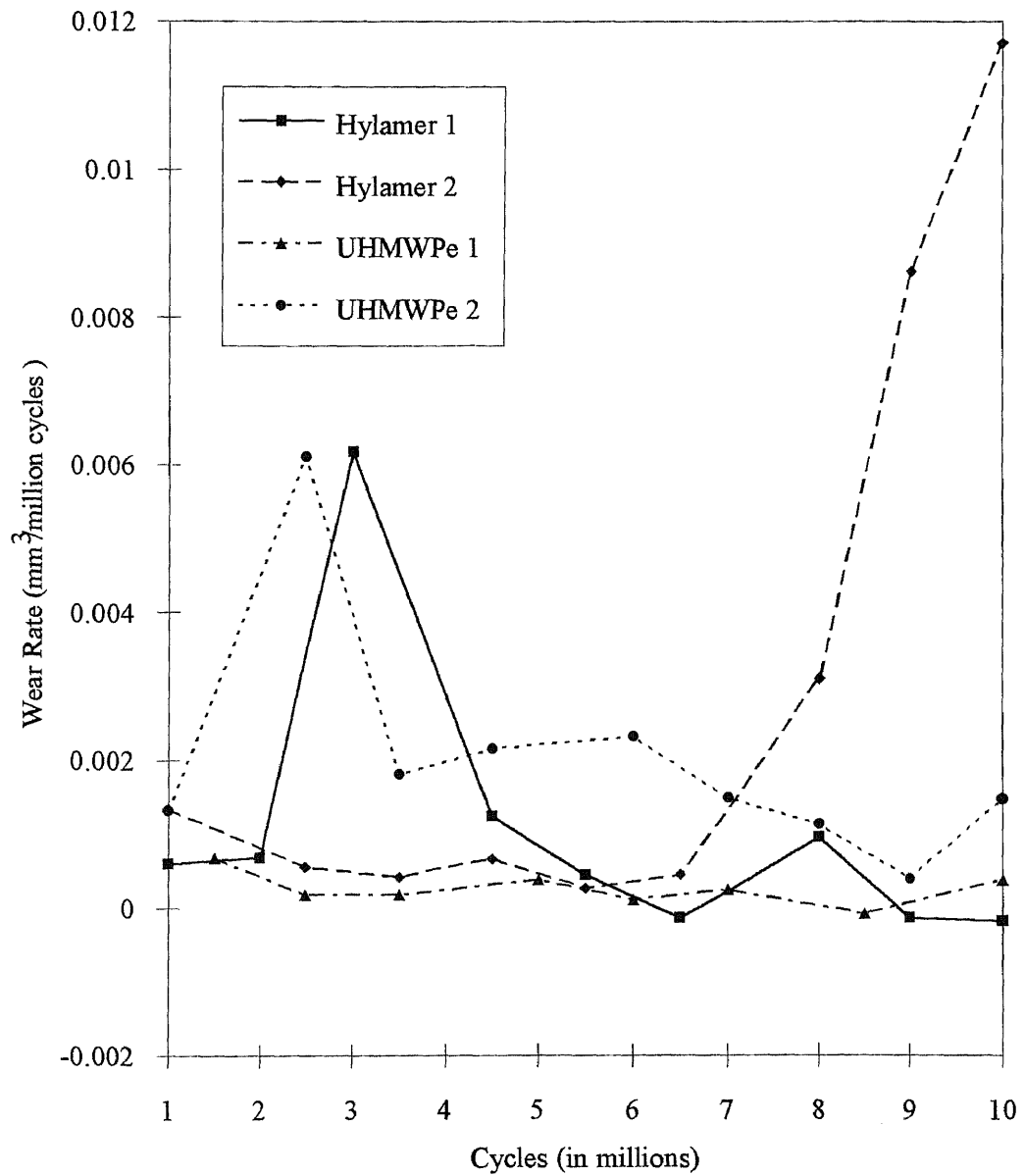


Figure 3.3. Average Wear Rate of Hylamer® and UHMWPe For Each Test

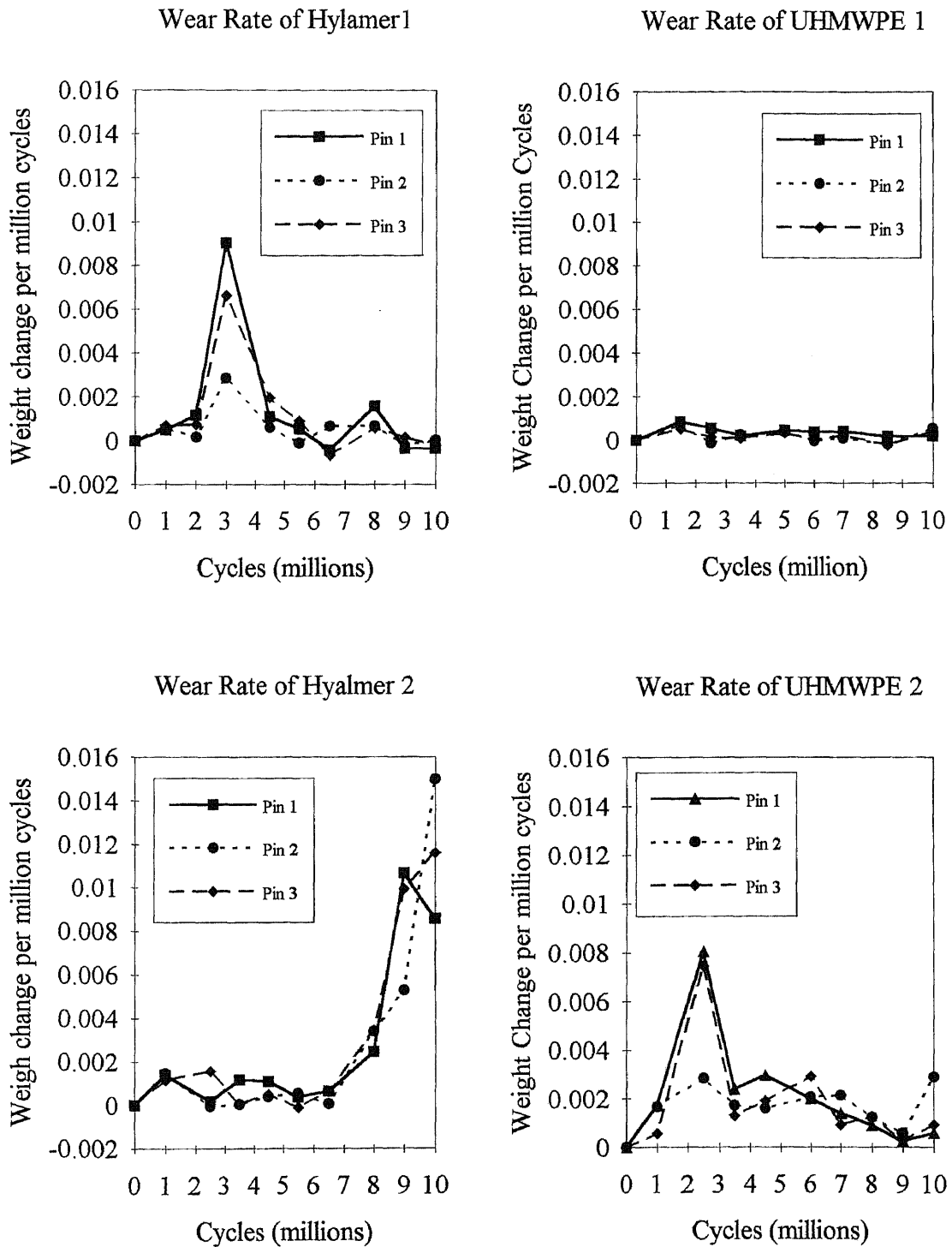


Figure 3.4. Wear Rate of Individual UHMWPE and Hyalmer® Pins on Co-Cr Coupons

The coefficients of friction (μ) for each test over ten million cycles is shown in Figure 3.5. The coefficients of friction ranged from 0.086 to 0.049 for Hylamer® 1, .035 to 0.08 for Hylamer® 2, 0.049 to 0.098 for UHMWPe 1 and 0.45 to 0.78 for UHMWPe 2, with averages of 0.070, 0.059, 0.072, and 0.063 respectively. The trends for the coefficients of friction is to decrease as the number of cycles increases. Some of the tests show dramatic decreases in the friction at certain cycles. UHMWPe 1 coefficient of friction drops to a low of 0.049 at 1.5 million cycles before rising to the highest values of all the tests. Hylamer® 1 was next followed by UHMWPe 2 and Hylamer® 2. Hylamer® 2 also showed a decrease to 0.035 at 8 million cycles, but also rose. It is important to note that the coefficients of friction were only recorded at certain intervals, not continuously. Therefore, the graphs represent instantaneous data recorded at the plotted intervals and changes in friction could therefore have gone undetected.

Photomicrography of pre and post-test conditions of the coupons are shown in Figures 3.6 through 3.10. Figure 3.6 shows the condition of the Hylamer® 1 Co-Cr coupon after 10 million cycles. It is important to note the differences between the scratches in the metal coupon itself and those in the polyethylene transfer film present on the coupon. On Figure 3.6 the letter "a" denotes scratches in the poly while "b" identifies scratches in the coupon. The transfer film scratches are identified by a non-distinct border on its edge. The metal scratch has a straight, distinct border. Heavy scratches were present on the Hylamer® 1 coupon as compared to Figure 3.7, the coupon for UHMWPe 1. They are much wider and deeper than those present in the UHMWPe samples. Figure 3.8 shows Hylamer® 2 upon completion of the test. Along with the scratch are blotches. This could be dirt, or other foreign matter. It could also be rips or breaks in the polyethylene transfer film. The coupon for UHMWPe 2, Figure 3.9, has slightly heavier scratches than the first UHMWPe test; however, they are not as heavy as the ones found in the Hylamer® tests. Figure 3.10 shows an unused coupon before testing which is a cobalt chromium alloy that has been polished. Notice that there are no scratches present, and the surface is clear.

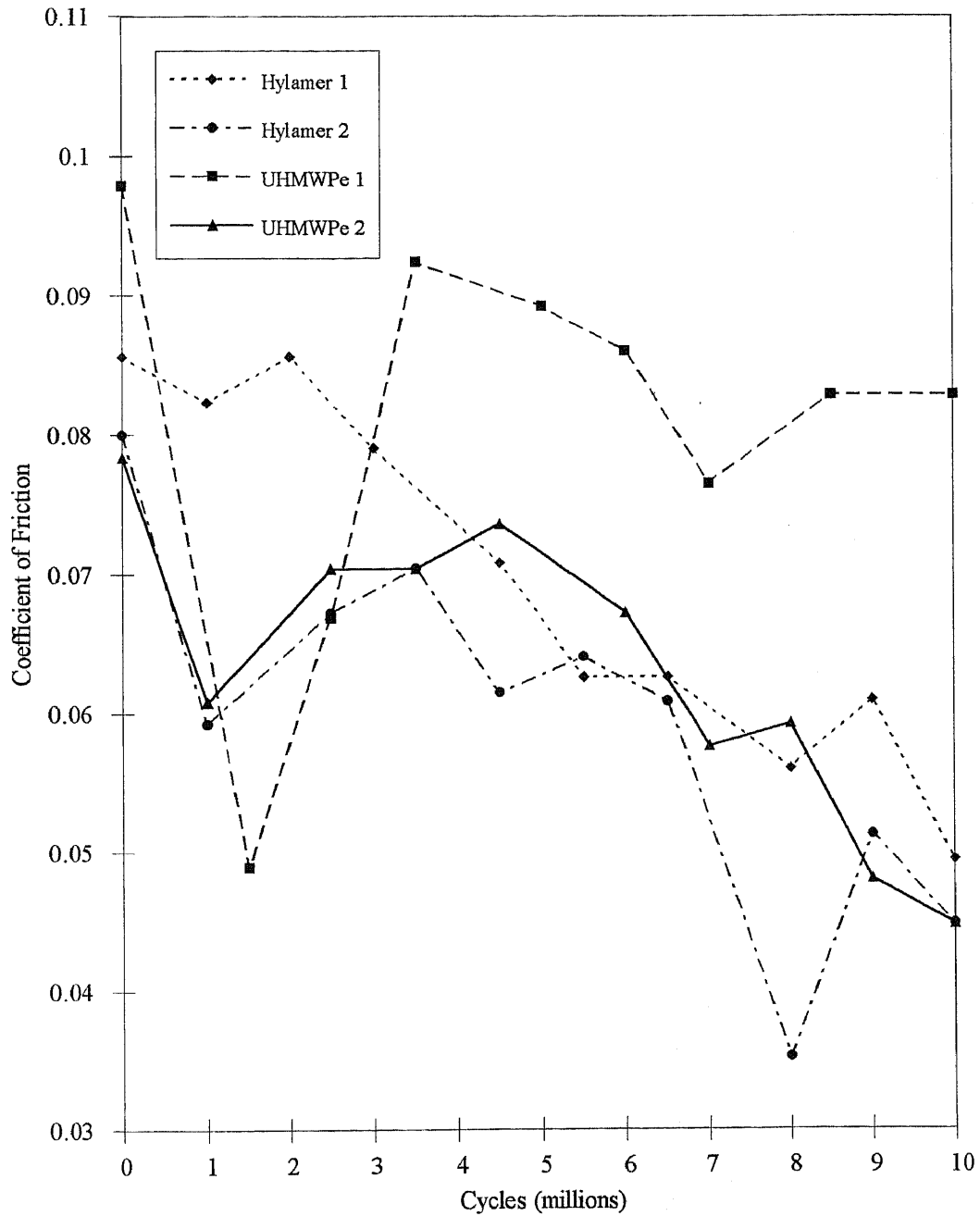


Figure 3.5. Coefficient of Fiction For Each Test

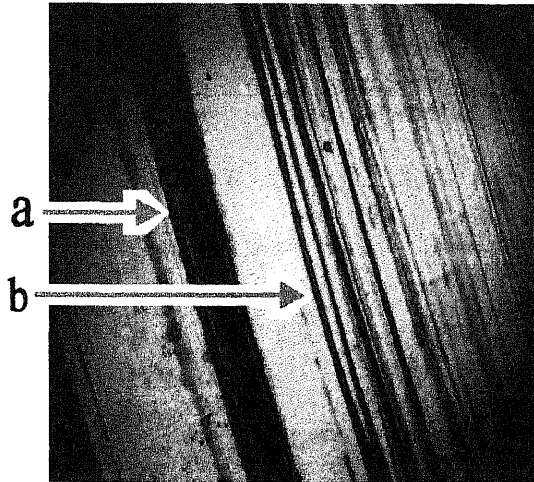


Figure 3.6. Hylamer® 1 Coupon After 10 million cycles @ 20x.

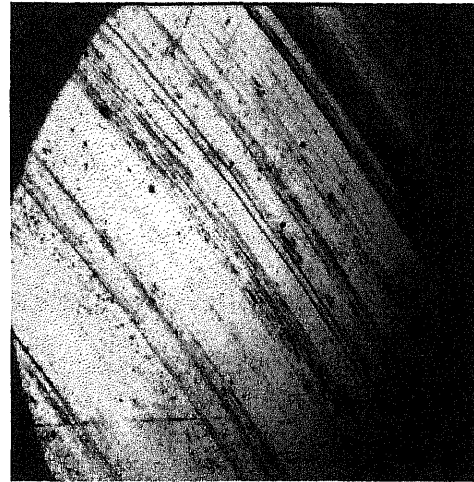


Figure 3.7. UHMWPe 2 Coupon After 10 million cycles @ 20x

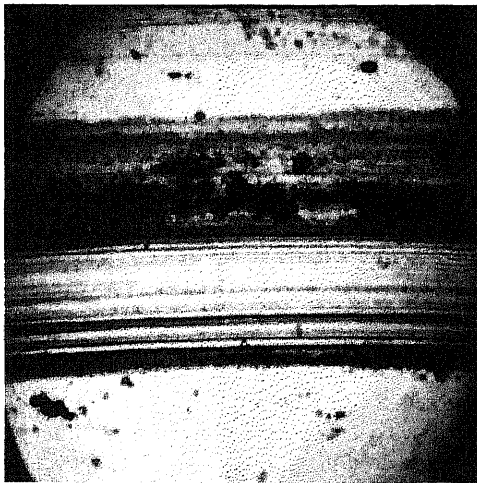


Figure 3.8. Hylamer® 2 Coupon After 10 million cycles @ 20x.

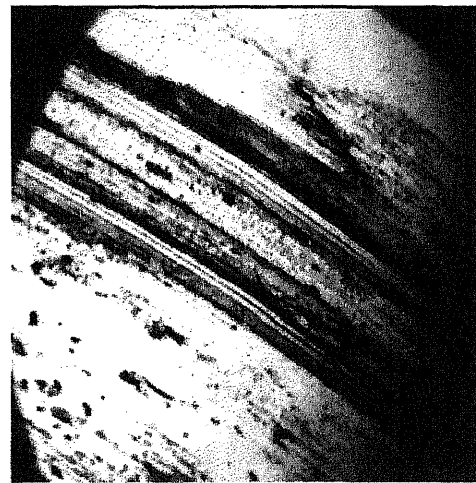


Figure 3.9. UHMWPe2 Coupon After 10 million cycles @ 20x.



Figure 3.10. Pre-Test Surface Condition @ 20x.

Also when using the microscope, the pins and coupons were examined and any unusual findings were photographed and later analyzed using a scanning electron microscope .

The Hylamer® 1 coupon was found to have a radial scratch that cut across the wear track (Figure 3.11). This scratch was examined under the microscope in order to determine its origin. It is important to determine if the scratch was caused during the test or after it. From the figure it can be seen that the track passes directly over the scratch, indicating that it may have been caused upon completion of the test.



Figure 3.11. Radial Scratch Across Wear Track in Hylamer® 1 Coupon.

Another discovery was found on the UHMWPe 1 coupon. Certain areas had any orange type shading with blotches on it. This can be seen in Figures 3.12 and 3.13. Figure 3.12 is a increase in magnification of the areas in Figure 3.13. This area is then broken up into coordinates as shown on the photo and analyzed using the elemental analysis software of the SEM. Area 1-1 depicts the darker area, 2-2 is the lighter, circular type defect, and 3-3 is the white area. Figure 3.14 is the elemental analysis for section 1-1 of Figure 3.13.

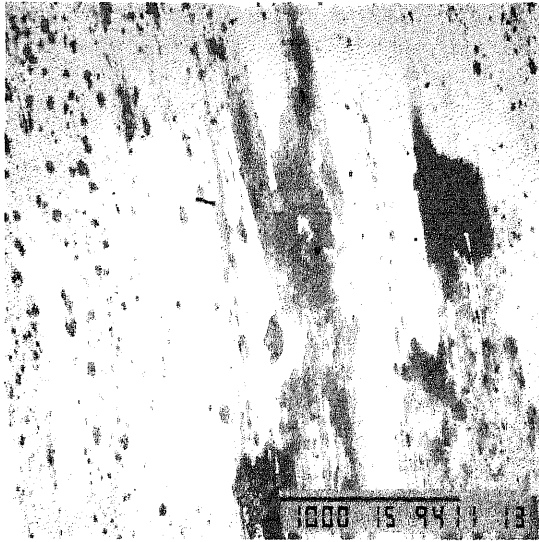


Figure 3.12. UHMWPe 1 Coupon

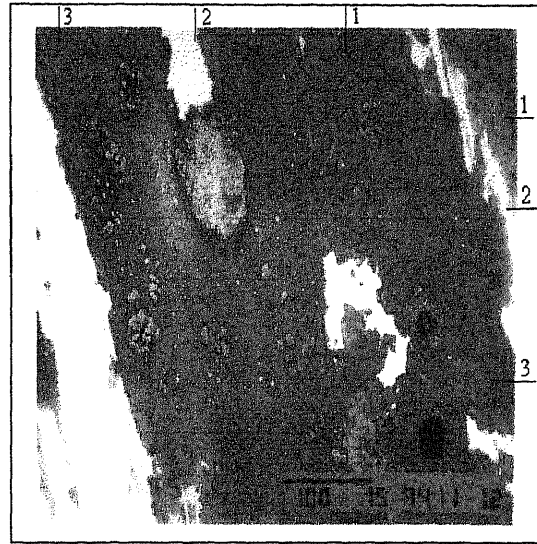


Figure 3.13. UHMWPe 1 Coupon

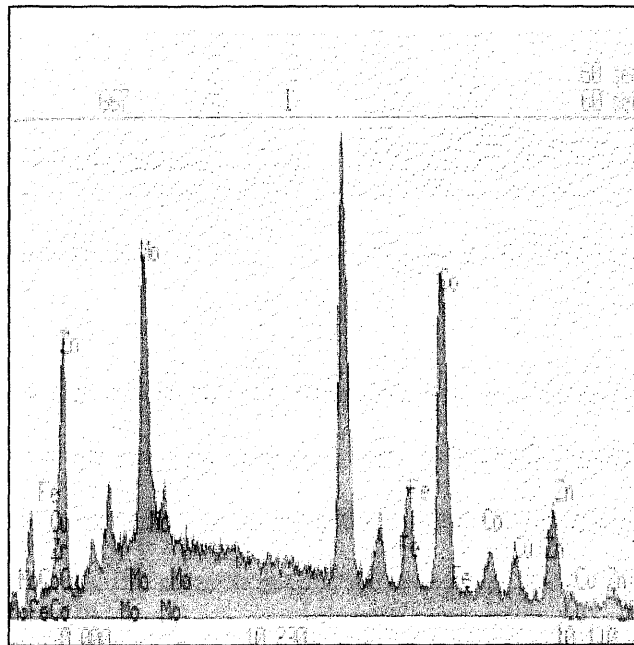


Figure 3.14. Elemental Analysis for UHMWPe 1 Coupon (1-1)

It shows that along with the elements for the cobalt chromium alloy coupon (Co,Cr, Mo), other elements such as zinc, iron, and copper are present. Figure 3.15 and 3.16 show the elemental analysis for sections 2-2 and 3-3 respectively. Section 2-2 has a similar composition of 1-1 with the exceptions of having a larger concentration of zinc. Section 3-3 is identified as simply the cobalt chromium alloy as being present.

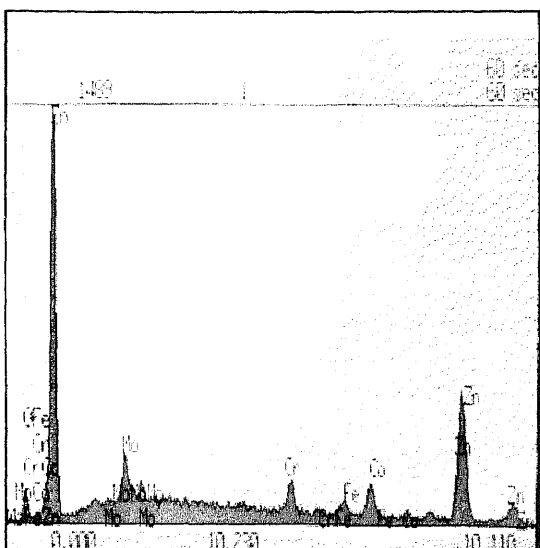


Figure 3.15. Elemental Analysis (2-2)

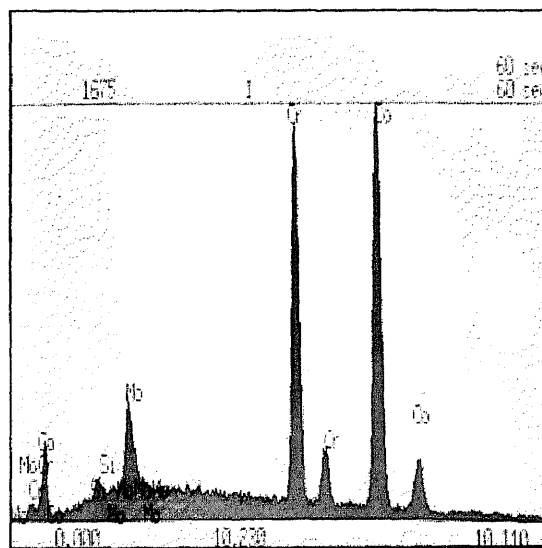


Figure 3.16. Elemental Analysis (3-3)

Figure 3.17 shows one of the heavier scratches that was observed. Upon completion of the test, two heavy scratches were present in the Hylamer® 2 coupon in the circular arc of the wear track. This scratch was investigated using the scanning electron microscope (SEM). Figure 3.18 shows the scratch magnified using the SEM. The composition of the scratch was determined two ways. First backscatter was used. By performing this all the black areas are elements of high atomic number of high density. Figure 3.19 is the backscatter picture of the same area shown in Figure 3.18. Notice the white areas, which are low in atomic number and are assumed to be polyethylene. Figure 3.20 shows the elemental analysis for the scratch is composed of cobalt, chromium, and molybdenum.

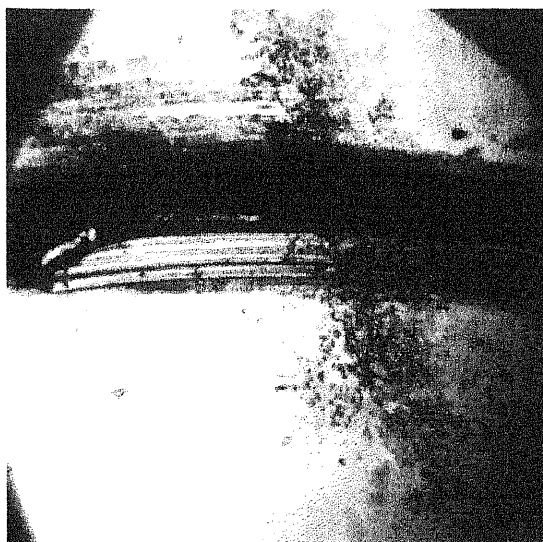


Figure 3.17. Heavy Scratch in Hylamer®
Coupon @ 20x



Figure 3.18. SEM of Hylamer® Scratch

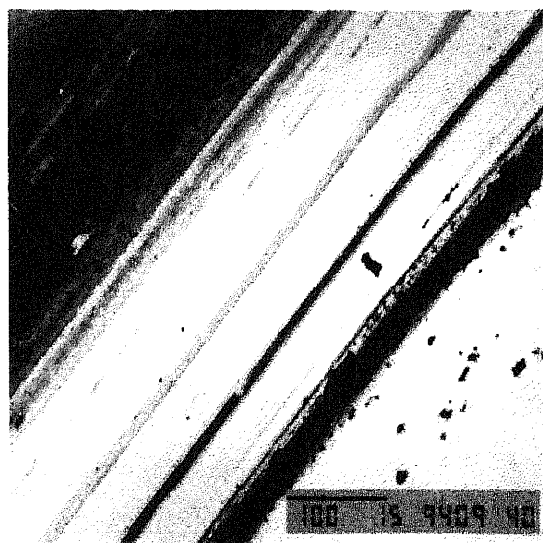


Figure 3.19. SEM Backscatter of Hylamer®
Scratch

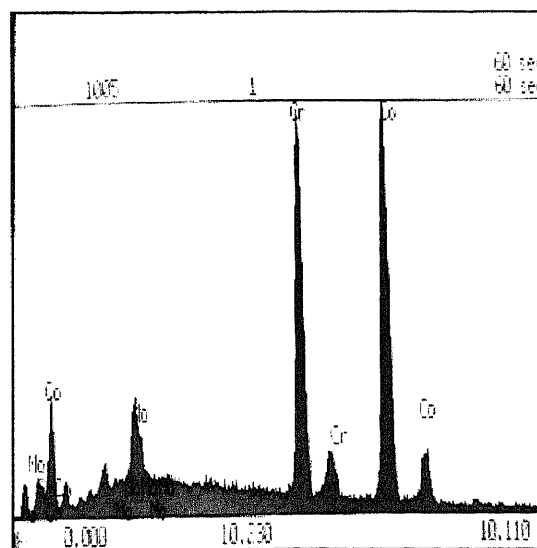


Figure 3.20. Elemental Software Analysis

Analysis of the pins showed fine, circular arc scratches in the plastic that corresponded to the scratches in the coupon. Also found were black spots on some of the Hylamer® pins (Figure 3.21). These spots were analyzed using the SEM in order to determine their composition. Figure 3.22 shows the makeup. It can be seen that present is cobalt, chromium, molybdenum, zinc, chlorine, and titanium. The vertical count of 1158 however indicates that although these elements are present, they are in small quantities.

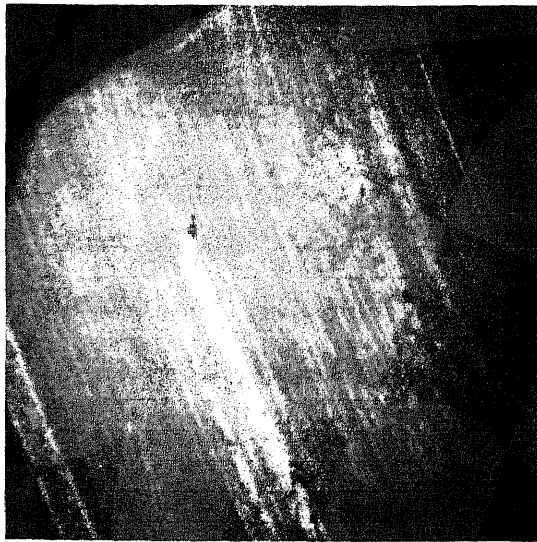


Figure 3.21. Hylamer® 2 - Pin 1 Black Particles Present @ 20x

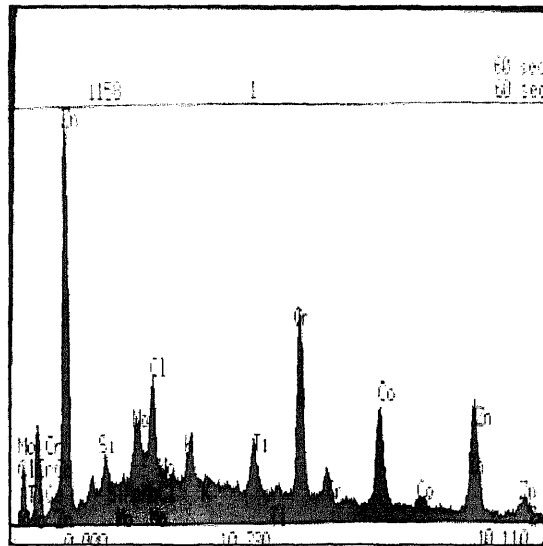


Figure 3.22. Elemental Analysis of Hylamer® 2 - Pin 1

CHAPTER 4

DISCUSSION

Even though the implants are polished, there are still small microscopic scratches from the machining process. This roughness will increase the amount of abrasive wear and is denoted by a relatively high wear rate in the first two million cycles. After this "bedding in" phase the wear should level off slightly. McKellop describes this phenomena and believes it may be related to the build up and eventual removal of a transfer film [22]. The high initial rates are expected; however, some of the tests in this study show jumps in wear which are unusual. There could be several reasons for these problems. Some are a buildup and breakdown of the transfer film after the initial transient stage, testing artifact of the machine, experimental errors, or the presence of unwanted third body particles.

As McKellop explains a transfer film is created on the coupon. This film will increase the amount of wear by providing a secondary mechanism for wear, adhesive wear. In Hylamer® 1 there is a jump at 3 million cycles. This could have been caused by a transfer film. The reason for the wear leveling off after this increase could be the fact that the transfer film breaks down and normal abrasion takes place.

Another factor could be a problem with the testing apparatus. Towards the end of the second Hylamer® test the machine failed. After repairing it, the test was completed and the second UHMWPE test was performed. These two tests showed abnormally high wear after machine repair. It is possible that the reason for this high wear in the poly and Hylamer® after 7 million cycles can be attributed to the machine. Both the wear volume and wear rate continually rise with a steep slope, not simply a jump like in Hylamer® 1 test. Since this increase in wear is seen in tests with different materials, and they both take place after the machine failed, the wear may be an artifact of the apparatus. Subsequently,

the second poly test and the second Hylamer® test (after 7 million cycles) should be excluded from the determination of their wear behavior.

When performing the photomicrography on the samples, small black particles were seen on several of the Hylamer® samples. These spots were investigated using elemental analysis software in conjunction with the scanning electron microscope in order to determine if these spots were the cause of any wear loss. Examination revealed that these spots were composed primarily of zinc, chlorine, and cobalt. The presence of chlorine is due to the saline solution which contains sodium-chloride. It is believed that the zinc originated from the in/out fittings on the containment cup. The floor of the cup is made from stainless steel, the sides from plastic, but the fittings are bronze. Bronze is an alloy of copper and zinc. When bronze is placed in a salt solution, which is saline, the zinc will come out into solution. Therefore, it is believed that the zinc releases into the solution and was trapped between the pin and the coupon. Although there was a third body artifact found, it is not believed that this caused the jump in wear due to the amount of it present. The vertical count from the SEM indicated that the element was present but in very minuscule quantities. If the third body artifact caused the jump, it should have caused a continuous escalation. Also, when the zinc actually embedded into the pin is unknown; however, since it was found post-testing it was present towards the end of the test and no abnormal volumetric loss is seen there. Another reason third body particles are not believed to affect the wear is due to their presence in another test. Some iron, zinc, and copper were found in the cobalt chromium coupon for the UHMWPe 1 test. The quantities were slightly higher; however, the volumetric wear for the UHMWPe 1 was the lowest of all the tests. Consequently, the lower values in the Hylamer® test are insignificant.

The fact that zinc was found in a sample brings up the question of third body artifacts getting into the solution thereby biasing the results and maybe explain some of the jumps. A foreign particle could affect the wear in several ways. First, it could become embedded

into the polymer causing the weight of the pin to increase thereby camouflaging the actual weight loss of the polymer. Second, it could increase the amount of wear contributed to third-body wear. Finally, it could scratch the coupon thereby increasing the wear due to the presence of the scratches. In both Hylamer® tests deep scratches were found on the coupons. Hylamer® 1 contained a radial scratch which went across the wear track of the coupon. It was analyzed under a microscope and was conjectured that it was caused after the test was completed. Hylamer® 2 contained heavy scratches in the wear track itself. These scratches were analyzed using the SEM to determine whether a hard, third body particle caused it. The analysis showed that the scratch and the pins contained no unusual elements. The particle could have caused the scratch and was then washed away, but it is assumed neither this happened nor did the scratch adversely affect the wear. This assumption was made because the scratch was found to be filled with polymer.

Although some of the coupons have been analyzed for unusually large scratches, all are marred. Analysis of the coupons shows scratching in the surface. Several other tests performed have found scratches in the direction of wear but it is noted by all that scratches do not appear on actual, retrieved prosthesis [7,12,13]. The differences whether the scratches are present in the metal itself or the transfer film have previously been discussed. One reason for these scratches could be that due to the repetitive, continual motion of the testing apparatus, a transfer film builds up quickly and scratches easily. Although a transfer film could occur in vivo, the speed and continuous nature of the testing movement is not present so scratching is not as severe. Another reason could be that the wear particles themselves are causing the scratches.

Several investigators suggest that wear is indirectly associated with the friction [7,22]. This was not the case in this study however. In fact the test with the lowest wear, UHMWPe 1, had the highest overall coefficient of friction. Values of the friction however tend to agree with the theory of the bedding in process. As the rough surfaces wear, the coefficient of friction is highest and over the ten million cycles it gradually declines.

McKellop et. al. agrees with the fact that with pin on disc testing he experienced fluctuations in measurement and could not find a relationship between the coefficient of friction and the wear [22] . Besides not correlating the wear and friction, some tests experience declines in friction for brief instances. These declines do not correlate with any jumps in wear volume or rate. Since a torque transducer was used to record frictional force values from which the coefficient was calculated from, the reason for this declines could be improper reading, misalignment, or problems with the chart recorder. Another explanation could be because the values of friction are not measured continually but instantaneously. Therefore, similar jumps due to transfer films or roughness may not be discovered.

Examination of the performance of the individual pins displays another unusual finding. The individual pins for all the tests indicate that pin 2 has a lower volumetric wear loss than pins 1 and 3. In some tests the difference is more pronounced; nevertheless, pin 2 is always the lowest. In all the tests, the pin number denotes both the pin and its placement in the containment cup so pin 2 is always in the same spot for all the tests. The obvious explanation for this is a problem with the machine. The load on the pins may not be evenly distributed due to a misalignment. Another reason could be that the hole for pin 2 in the coupon is a different depth than that of the other two pins. Coupled with the fact that the coupon may not be tilting indicates that the correct contact stress between the pin and the coupon is not being achieved.

Figure 5.1 shows the corrected average volumetric wear for the tests. The test for UHMWPe 2 and a portion of Hylamer® 2 have to be discarded due to problems with the machine. The jump in Hylamer® 1 is not corrected because it is believed to be caused by the formation of a transfer film and adhesive wear. This assumption is made because the presence of third body particles doesn't seem to be the cause for this jump. Although some were found, the magnitudes are small and insignificant. Also any scratches found are not believed to adversely affect the wear. Therefore, it is clearly seen in Figure 5.1.

Volumetric Wear of Co-Cr Against Hylamer and UHMWPe

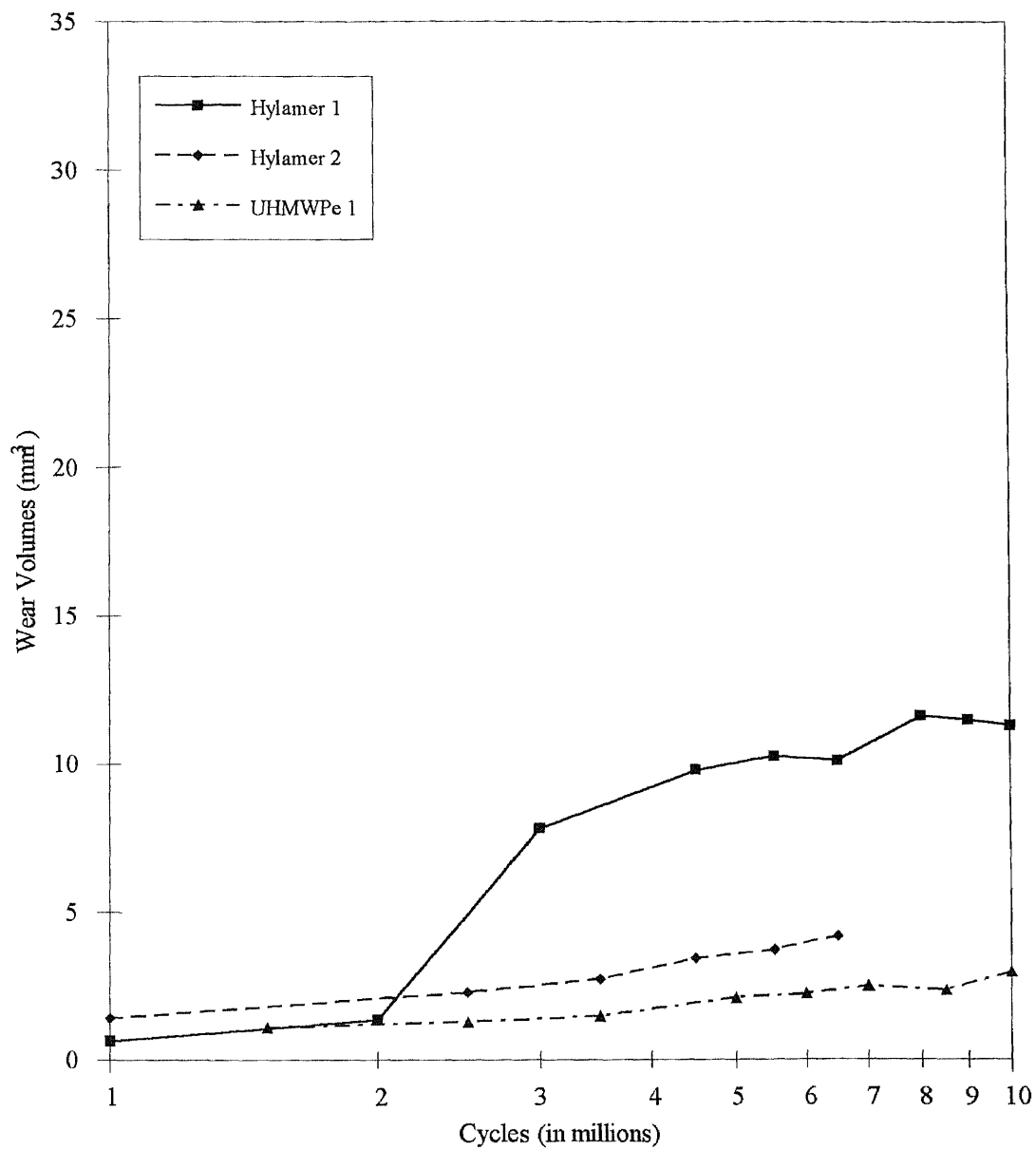


Figure 5.1 Corrected Average Wear of Hylamer and UHMWPe

that UHMWPe has the lowest volumetric wear. Even if the jump in Hylamer® is attributed to some other problems, the other three Hylamer® samples are still 30% to 50% higher in wear than the polyethylene.

CHAPTER 5

CONCLUSIONS AND SUGGESTIONS

Testing indicates that Hylamer® does not seem to provide improved wear characteristics as compared to UHMWPe. In fact UHMWPe has a 30 to 50% lower volumetric wear than the best Hylamer® test. This may be due to the fact that Hylamer®'s increased stiffness, which may increase the contact stress which will in turn increase the wear of a material. One test shows similarities to that of UHMWPe; however, Hylamer® is still slightly higher. The increase in number and depth of scratches could also indicate that the stiffness is more destructive to the metal, which in turn will increase the wear rate.

Although testing indicates that Hylamer® does not have lower wear, more testing should be done in order to provide enough data to make a definite decision. Future testing should try to determine whether the increased stiffness does have adverse effects to the wear. Also, the effect of washing and cleaning each sample and using a filter should be closely examined.

Modifications should be made to the machine in order to provide equivalent loading and wear acting on the three pins. The brass fittings should be removed, and stainless steel or plastic should be used throughout. The moveable coupon should be changed in order to better provide a planar surface during testing.

APPENDIX

VOLUMETRIC WEAR FOR ALL TESTS

VOLUMETRIC WEAR (mm³)												
Cycles millions	Hylamer 1			UHMWPe 1			Hylamer 2			UHMWPe 2		
	Pin 1	Pin 2	Pin 3	Pin 1	Pin 2	Pin 3	Pin 1	Pin 2	Pin 3	Pin 1	Pin 2	Pin 3
1	0.524	0.628	0.733	**	**	**	1.466	1.536	1.222	1.858	1.786	0.607
1.5	**	**	**	1.358	1.107	0.822	**	**	**	**	**	**
2	1.745	0.803	1.501	**	**	**	**	**	**	**	**	**
2.5	**	**	**	1.93	0.965	0.965	1.71	1.431	3.699	14.79	6.32	12.61
3	11.20	3.805	8.447	**	**	**	**	**	**	**	**	**
3.5	**	**	**	2.144	1.215	1.072	2.932	1.466	3.77	17.36	8.181	14.01
4.5	12.95	4.782	11.59	**	**	**	4.084	1.885	4.293	20.54	9.896	16.04
5	**	**	**	2.855	1.872	1.604	**	**	**	**	**	**
5.5	13.51	4.677	12.53	**	**	**	4.468	2.443	4.188	**	**	**
6	**	**	**	3.251	1.786	1.607	**	**	**	23.76	13.22	20.72
6.5	13.09	5.375	11.83	**	**	**	5.131	2.513	4.852	**	**	**
7	**	**	**	3.68	1.894	1.858	**	**	**	25.26	15.51	21.72
8	15.57	6.457	12.78	**	**	**	8.97	7.853	10.26	26.22	16.83	23.08
8.5	**	**	**	3.93	1.608	1.501	**	**	**	**	**	**
9	15.18	6.248	12.95	**	**	**	20.14	13.37	20.66	26.51	17.47	23.4
10	14.80	6.283	12.74	4.252	2.465	2.144	29.11	29.04	32.81	27.15	20.58	24.4

REFERENCES

1. Dumbleton, John H., "Wear And Prosthetic Joints", *Joint Replacement Arthroplasty*, pp. 47-59.
2. Mraz, Stephen J., "The Human Body Shop", *Machine Design*, pp. 90-95, (Nov. 7, 1991).
3. Fishman, Steve, "Rebuilding Bodies", *The New York Times Magazine*, pp. 28-33, (April 16, 1989).
4. Starr, Cynthia, "Joints That Sizzle:New Relief For Arthritis Patients?",*Drug Topics*, pp. 68-92, (May 1992).
5. Williams, David F., *Biocompatibility of Orthopedic Implants: Volume 1*, CRC Press Inc., New York (1982).
6. Williams, David F., *Biocompatibility of Orthopedic Implants: Volume 2*, CRC Press Inc., New York (1982).
7. Pappas, M.J., Makris, G., Buchel, F.F., "Comparison Of Wear Of UHMWPE Cups Articulating With Co-Cr And Ti-Ni Coated , Titanium Femoral Heads", *Transactions of the Society fo Biomaterials*, Vol. 3 (May 1990).
8. Wright, Timothy M., and Rimnac, Clare M., "Ultra-High-Molecular-Weight Polyethylene", *Joint Replacement Arthroplasty*, pp. 37-45.
9. DePuy, "Ultra-High Molecular Weight Polyethylene", *Current Issues in Orthopaedics*, Vol. 1, No. 3A, (1990).
10. Lipson, Charles, *Wear Considerations in Design*, Prentice-Hall Inc., Englewood Cliffs, New Jersey, (1973).
11. Davidson, J.A., Schwartz, G. and Lynch, G., "Wear Creep, And Fictional Heating Of Femoral Implant Articulating Surfaces And The Effect On Long-Term Performace--Part I, Friction, Heating, And Torque", *Biomedical Materials Research: Applied Biomaterials*, Vol. 22, No. A1, pp. 69-91 (1988).

12. McKellop, H., Clarke, I., Markolf, K., and Amstutz, H., "Friction And Wear Properties Of Polymer, Metal, And Ceramic Prosthetic Joint Materials Evaluated On A Multichannel Screening Device", *Journal of Biomedical Materials Research*, Vol. 15, pp. 619-653, (1981).
13. Amstutz, H. C., "Polymers As Bearing Materials For Total Hip Replacement: A Friction And Wear Analysis", *Journal of Biomedical Materials Research*, Vol. 3, pp. 547-568, (1968).
14. Wright, T.M. and Bartel, D.L., "The Problem Of Surface Damage In Polyethylene Total Knee Components", *Clinical Orthopaedics and Related Research*, No. 205, pp. 67-74 (April 1986).
15. Weightman, B., Isherwood, D.P., and Swanson, S.A.V., "The Fracture Of Ultrahigh Molecular Weight Polyethylene In The Human Body", *Journal of Biomedical Materials Research*, Vol. 13, pp. 669-672, (1979).
16. Pappas, M.J., Makris, G., and Buechel, F.F., "Contact Stresses In Metal Plastic Total Knee Replacements: A Theoretical And Experimental Study", *Biomedical Engineering Technical Report 003*, New Jersey Institute of Technology, Newark, NJ, 1986.
17. Pappas, Michael J., "Wear In Metal-Plastic Joint Replacements", Presented at the Mobile Bearings in Knee Replacement Meeting, Redhill England, Feb 1993.
18. Bartel, D.L., Bicknell, M.S., Ithaca, and Wright, T.M., "The Effect of Conformity, Thickness, And Material On Stresses In Ultra-High Molecular Weight Components For Total Joint Replacement", *The Journal of Bone and Joint Surgery*, Vol. 68-A, No. 7, pp. 1041-1051 (September 1986).
19. Revell, P.A., Weightman, B., Freeman, M.A.R., and Roberts, B. Vernon, "The Production And Biology Of Polyethylene Wear Debris", *Archives of Orthopaedic and Traumatic Surgery*, pp. 167-181, (1978).
20. Swanson, S.A.V., and Freeman, M.A.R., *The Scientific Basis of Joint Replacement*, Pitman Medical Publishing Co LTD., California, (1977).
21. Rostoker, B., "Some New Studies Of The Wear Behavior Of Ultrahigh Molecular Weight Polyethylene", *Jouranl of Biomedical Materials Research*, Vol. 10, pp. 303-310, (1976).

22. McKellop, H. Clarke, I.C., Markolf, K.L. and Amstutz, H.C., "Wear Characteristics Of UHMW Polyethylene: A Method for Accurately Measuring Extremely Low Wear Rates", *Jouranl of Biomedical Materials Research*, Vol. 12, pp. 895-927, (1978).
23. Rose, Robert M., Ries, Michael D., Paul, Igor L., Crugnola, Aldo M., and Ellis, Edward, "On The True Wear Rate Of Ultrahigh Molecular Weight Polyethylene In The Ttotal Knee Prosthesis", *Journal of Biomedical Materials Research*, Vol. 18, pp. 207-224, (1984).
24. Grood, Edward S., Shastri, Ranganath, and Hopson, Clark N., "Analysis Of Retrieved Implants :Crystallinity Changes In Ultrahigh Molecular Weight Polyethylene", *Jouranl of Biomedical Materials Research*, Vol. 16, pp. 399-405, (1982)
25. Rostoker, W. and Galante, J.O., "Contact Pressure Dependence Of Wear Rates Of Ultra High Molecular Weight Polyethylene", *Journal of Biomedical Materials Research*, Vol. 13, pp. 957-964, (1979).
26. DuPont & DePuy, "Hylamer® Orthopaedic Bearing Polymer", *Innovations For Success*, Vol 1, NO. 2 , (1992).
27. Mow, Van C., and Hayes, Wilson C., *Basic Orthopaedic Biomechanics*, Raven Press, New York, New York (1991).
28. Davy, D.T., Kotzar, G.M., Brown, R.W., Heiple, K.G., Goldberg, V.M., Heiple, K.G., Jr., Berilla, J., and Burstein, A.H., "Telemetric Force Measurements Across The Hip After Total Arthroplasty", *Journal of Bone Joint Surgery*, 70A: pp. 45-50, (1988).
29. DePuy and DuPont, "Hylamer-M In The AMK Total Knee System: Addressing The Issue Of Polyethylene Destruction", DePuy DuPont Orthopaedics, 1992.
31. *ASTM Stadard Practice for Reciprocating Pin-on-Flat Evaluation of Friction and Wear Properties of Polymeric Materials for Use In Total Joint Prosthesis*, Designation:F732-82.
32. Davidson, J.A. and Schwartz, G., "Wear, Creep, And Frictional Heat Of Femoral Implant Articulating Surfaces And The Effect On Long-Term Performace--Part 1, A review", *Biomedical Materials Research: Applied Biomaterials*, Vol. 21, No. A3, pp. 261-285 (1987).

33. Willert, H.G. and Semlitsch, M., "Reactions Of The Articular Capsule To Wear Products Of Artificial Joint Prostheses", *Journal of Biomedical Materials Research*, Vol. 11, pp. 157-164 (1977).
34. "Insights into the Causes of Arthritis", *Technology Review*, Vol. 89:72-73, (Feb 1986).