Fall 1-31-1995

Wear of polyethylene and hylamer on cobalt-chromium : a knee simulator study

Alessandro F. Canonaco
New Jersey Institute of Technology

ABSTRACT

WEAR OF POLYETHYLENE AND HYLAMER ON COBALT-CHROMIUM: A KNEE SIMULATOR STUDY

by
Alessandro F. Canonaco

Two tests were conducted to examine the wear characteristics of tibial bearings used in total knee replacement systems. Each test consisted of six A/P Glide Tibial Bearings each having a conical control arm. The plastic portion of the conical bearings were all made of UHMWPe. Each of these bearing systems was mounted onto a Co-Cr alloy tibial platform and Co-Cr alloy LCS (low contact stress) femoral component . These test samples were mounted onto the New Jersey Mark III Knee Simulator System. The simulator was configured to produce flexion and axial rotation to simulates normal gait. Each test ran at 2 Hz with saline being sprayed between articulating surfaces. Simulation I tested six UHMWPe bearings with an off-center load applied to the bearing by the femoral component 25^{o} from the articulating surface segment tangent. Simulation II tested three Hylamer® and three UHMWPe bearings without an off-center load.

Hylamer®'s volumetric loss and wear rate were found to be higher then UHMWPe. Hylamer® had a maximum volumetric loss of 12.86 mm^3 and a maximum wear rate of 6.19 mm^3/million cycles while UHMWPe had a maximum volumetric loss of 3.57 mm^3 and a maximum wear rate of 1.67 mm^3/million cycles. Hylamer®'s increase in crystallinity slightly increases its yield strength and ultimate tensile strength. However, by increasing the crystallinity, stiffness is also increased. This increase in stiffness increases the contact stress which in turn increases the wear. Although a slight increase in strength is gained when using Hylamer®, wear resistance, an important characteristic for total knee replacement systems, is reduced.

WEAR OF POLYETHYLENE AND HYLAMER ON COBALT-CHROMIUM: A KNEE SIMULATOR STUDY

by
Alessandro F. Canonaco

A Thesis
Submitted to the Faculty of
New Jersey Institute of Technology
in Partial Fulfillment of the Requirements for the Degree of
Master of Science in Biomedical Engineering

Biomedical Engineering Committee

January 1995

APPROVAL PAGE

WEAR OF POLYETHYLENE AND HYLAMER ON COBALT-CHROMIUM: A KNEE SIMULATOR STUDY

Alessandro F. Canonaco

Dr. Clarence W.Mayott, Thesis Advisor — Date
Assistant Professor of Mechanical Engineering, NJIT

Dr. Michael J. Pappas, Committee Member — Date
Research Professor of Mechanical Engineering, NJIT

George Makris, Committee Member — Date
Vice-President of Manufacturing, Endotec Inc.

BIOGRAPHICAL SKETCH

Author: Alessandro F. Canonaco

Degree: Master of Science in Biomedical Engineering

Date: January, 1995

Undergraduate and Graduate Education

- Master of Science in Biomedical Engineering,
  New Jersey Institute of Technology,
  Newark, New Jersey, 1995

- Bachelor of Science in Mechanical Engineering,
  New Jersey Institute of Technology,
  Newark, New Jersey, 1993

Major: Biomedical Engineering

Presentations and Publication:

Canonaco, Alessandro. "Wear of Polyethylene and Hylamer on Cobalt-Chromium: A Knee Simulator Study" Presented In Newark, New Jersey, December, 1994.

ACKNOWLEDGMENT

I wish to express sincere gratitude to my advisor, Dr. Clarence W. Mayott, for his guidance, time and patience throughout this research.

I would also like to express sincere appreciation to Dr. Michael Pappas and George Makris for their knowledge and assistance throughout this research and for serving on the committee board.

A very special thank you to Dr. David Kristol for his guidance throughout the graduate program.

I would like to extend my appreciation to Dr. Jack Ricci of the Hospital for Joint Diseases and Dr. Russel Parsons of the University of Medicine and Dentistry of New Jersey for their assistance during the microscopy work as well as the use of their facilities.

Finally, a special thanks to the employees of Endotec, Inc. and Biomedical Engineering Trust for all their support and for lending a helping hand when needed.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

Since the 19th century, prosthetic joints have been used to alleviate conditions caused by trauma or degenerative disease. Only since the 1960's has this procedure been universally accepted. At an estimated rate of 600,000 operations per year, joint replacement is second only to dental reconstruction as an invasive treatment of the body (1). Joints such as shoulders, elbows, ankles, and wrists make up a small percentage of all joint replacement surgery while the majority are performed on the knee and hip.

Prosthetic joints have been used for the treatment of many disorders, however three; trauma, osteoarthritis, and rheumatoid arthritis, are the most common. Trauma caused by sports injures and other accidents can tear ligaments and tendons. If they heal incorrectly they can misalign the bones that form a joint. This misalignment causes incongruent contact which can increase cartilage wear. The two forms of arthritis, osteoarthritis and rheumatoid arthritis, are also commonly treated with joint replacement. Osteoarthritis, which is the most common form of arthritis, is the most frequent reason for joint replacement. This form of arthritis is recognized by the formation of osteophytes or irregularities of the bone margin caused by mechanical stresses which degenerates the cartilage that lines the joint. Rheumatoid arthritis, the second most common form of arthritis, also destroys the cartilage lining in joints. This form of arthritis is an auto-immune disorder in which the bodies immune system acts against and damages joints and surrounding tissue.

The materials used for prosthetics in joint replacement are very important. These materials not only have to be strong, light weight, and corrosion resistant, but also biocompatible. Even when these criteria's are satisfied, friction and wear properties are also essential and must be considered.

Abrasive wear is caused by the direct contact of two materials. In many prosthetic joints, this occurs between a metal component and a plastic bearing. Most metal components are polished to a few micro inches. However, even this smooth surface is enough to cause substantial damage to a material. As a metal component glides across a plastic bearing, the peaks on the metal surface will act like sandpaper and grind the softer plastic surface. As well as abrading the plastic surface, a decrease in peak height or smoothening occurs to the metal component. The wear on the metal component is advantageous since it results in a reduction of wear rate between components. A lubrication film is formed during high velocity movement between joint surfaces which greatly reduces abrasive wear. However, in human joints an oscillating motion exists which does not allow a lubricating film to form (2).

As abrasive wear continues, a plastic film can form on the metal component. Aspertities that exist on both components cause high contact stress. Since similar materials are in contact due to the plastic film, a weld can be formed between components. As the components move with respect to each other, the peaks are torn off the surface. This type of wear is known as adhesive wear and has a much higher wear rate then abrasive wear. Adhesive wear can be avoided by replacing the metal component with a ceramic one (2).

Often, particles of bone, metal, or cement get between components and become embedded in the soft plastic. This hard debris then abrades the metal surface very quickly. Since a third particle is introduced, this type of wear is know as third body wear. Third body wear increases abrasive and adhesive wear but can be reduced by replacing the metal component with a harder material such as ceramic (2).

The most crucial type of wear found in joint prostheses is caused by fatigue. Stress is inversely proportional to area, therefore if contact area decreases stress increases. When incongruent contact exists, the contact area between components is relatively small. During compressive loading, this localized area of contact causes high stresses on the bearing. The highest stress is found about one millimeter below the surface near the center of the area of contact. During rotation, this point of high stress moves along the bearings inner surface. If the peak stress becomes higher then the fatigue strength of the material, cracks will begin to form just below the surface. As these cracks unite, failure may occur in several ways. The cracks may produce pitting or cause a splitting of the bearing surface into several layers. The cracks may also propagate through the bearing resulting in a complete fracture (2).

Although several materials exist for use in joint prostheses, certain combinations have become common. Ultra high molecular weight polyethylene (UHMWPe) has become the most widely used prosthetic material. When used as a bearing, such as the acetabular cup in a hip replacement, or the tibial component in a knee implant, its properties are found to be superior to other materials. The characteristics that make UHMWPe so superior are that it is light weight, biocompatible and has good wear properties. UHMWPe degrades with time in the body so that the wear at long implementation times may increase (3). This debris has been found to cause adverse effects to surrounding tissue as well as prosthetic loosening (3).

The use of a carbon fiber reinforced UHMWPe in place of non reinforced UHMWPe has caused some controversy. The reinforced UHMWPe is found to have a lower deformation then conventional UHMWPe, however, whether or not wear rate is improved has been debated (3,4). As the original surface layer of the carbon fiber reinforced UHMWPe was worn away, scratching and carbon fiber associated damage were found to be major wear mechanisms (4). The use of ceramic and alumina as an alternative to UHMWPe is ongoing in Europe (3).

Metal components, such as the femoral component in a knee replacement, are most commonly made of either a cobalt chromium molybdenum (Co-Cr-Mo) alloy or a titanium (Ti-6Al-4V) alloy. The Ti-6Al-4V alloy can also be coated with titanium nitride (TiN). An uncoated Ti-6Al-4V alloy has been found to have a higher abrasive wear then Co-Cr-

Mo alloy when tested against UHMWPe (4). However, when the Ti-6Al-4V alloy is coated with a TiN coating, wear properties are found to be even better then the Co-Cr-Mo alloy (4). Most metal coatings tend to wear off quickly, however the TiN coating remains effective during the life of the Ti-6Al-4V alloy that it is placed on (4).

The greatest cause of wear has been found to be contact stress (3,4). A poorly designed prostheses can greatly increase contact stress. Many designs have incongruent contact at the articulation which causes a decrease in contact area resulting in an increase in contact stress. Material durability does not seem to play a large role during short term use, however it is essential during extended use. Fragments of metal and plastic removed from components due to wear cause tissue inflammation which causes prosthetic loosening.

Prosthetic joint failure due to loosening is mainly dependent on the patients bone quality, the method of fixation, and the design of the prosthetic. Previously designed joint replacements were simply press fitted into the bone. However, two methods have been accepted as standards of joint fixation. A polymethylmethacrylate (PMMA) cement can be used as a grout to connect the prosthesis to the bone. However, the cement debris that is caused by wear causes the destruction of cells by the rupturing of their plasma membrane. Lysis of bone cells can be a major contributor to loosening. When a patients bone quality is high, lysis can be avoided by a cementless method of fixation. With the use of biocompatible materials such as Ti-6Al-4V and Co-Cr-Mo alloys, bone growth around the component will act as a sufficient fixation with out the need of any type cement. To improve bone growth on the prosthesis, tiny metal balls are sintered to the component. This porous coating increases the surface area of the component and forms pores which allow bone cells to grip the prosthetic component forming a stronger fixation. Since the porous coating causes no adverse effects in the body, it is often preferred. A combination of PMMA cement and porous coating is being used, when necessary, over a non-porous coated cement fixation.

Poorly designed prosthetics can increase stress and wear which will eventually lead to failure. In the 1950's, knee replacements were designed to work as a hinge (8). Motion was restricted to a single axis allowing only flexion and extension. This early design was simply press fitted on the bone. The high torque's caused by rotational and lateral flexion constrainment resulted in component loosening. Other problems such as limited motion, bone fractures around the fixation area, patellar pain, and infection also occurred. An allowance for rollback was also not taken into consideration which caused unnecessary moments. The first cemented metal-plastic replacement was introduced by Gunston in 1969 (7). Patellar replacement was introduced in the 1970's, bringing patellar wear as another problem. The Townley was an anatomic design with low femoral-tibial constraint, allowance for cruciate preservation, and a patellar component (7,8). This design was found to be moderately successful for long term use. Tibial loosening continued to be a problem which was improved on by using a metal backing. Axial rotation and lateral flexion were than made less constrained which improved tibial wear. As designs became less constrained, problems began to focus on high contact stress and material overloading as well as wear and loosening. In the mid 1970's, to reduce constainments even further, mobile bearing knee replacements were designed. This added another articulating surface between the tibial plateau and bearing. Conflicting views argue whether or not wear is increased with this added articulating surface.

In the United States, most knee replacements are fixed bearing. This means that the tibial bearing is fixed to the tibial plateau constraining any motion of this bearing with respect to the tibia. The testing of mobile bearing knee replacements, such as the New Jersey Low Contact Stress (LCS) knee replacement, show a decrease in contact stress and constraint forces as well as a an increase in congruent surface contact (2,5,6). Many experiments have tested mobile bearing and fixed bearing knee replacements separately, however, very little has been done to compare both in an identical testing environment.

To better understand the differences between these two knee replacement designs, a description of mobile bearing knee's will be discussed.

Mobile bearing knees have been designed to increase mobility without unnecessary constraints and keeping contact stresses relatively low. This is done by adding another articulating surface between the tibial bearing and plateau (Figure 1.1). This is known as

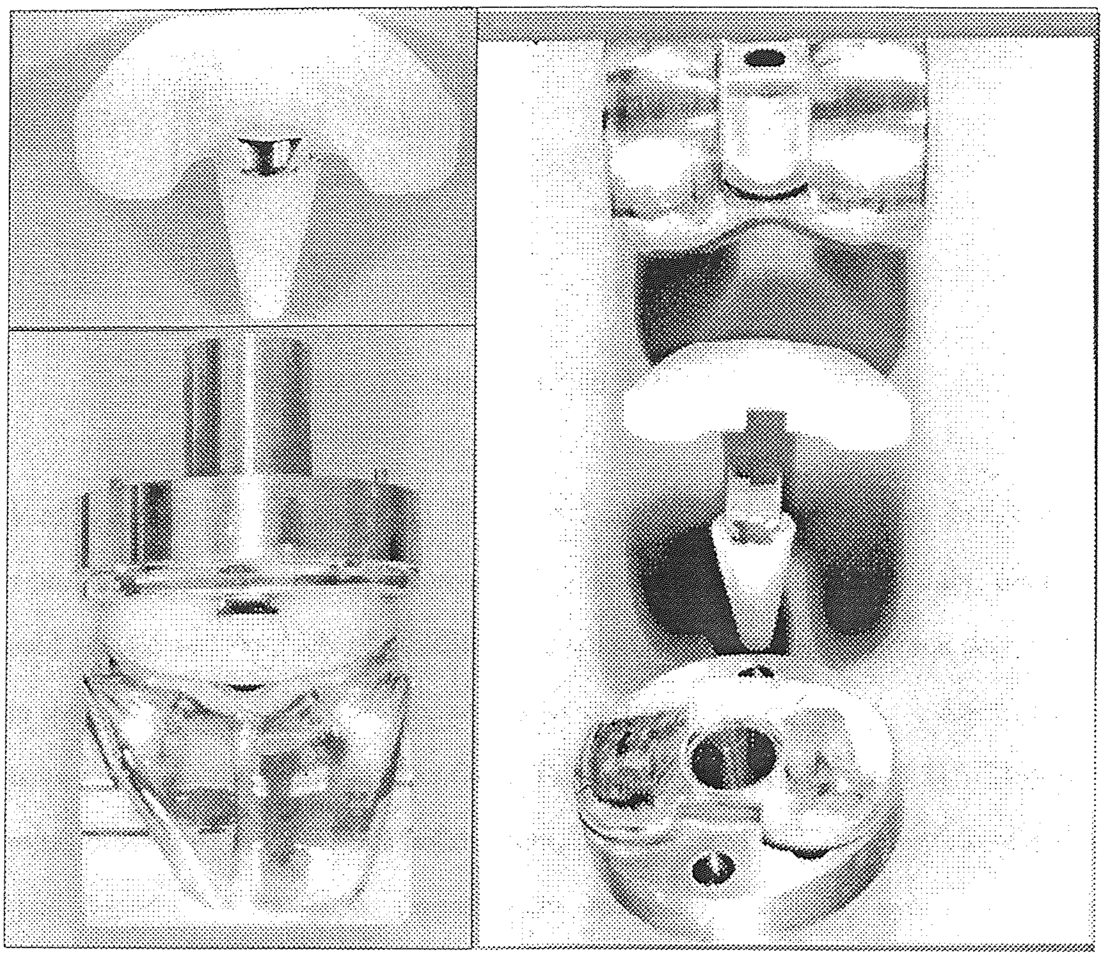

Figure 1.1. LCS A/P Glide Mobile Bearing Knee System

the secondary sliding surface while the femoral tibial articulating surface is known as the primary. One design of the secondary sliding surface is a bicruciate retaining platform. Two groves are added to the tibial plateau surface. Two UHMWPe bearings are then inserted into these grooves which allows anterior and posterior translation of these bearings. The Oxford mobile bearing design had two parallel grooves where dislocation was common (Figure 1.2). This was due to excessive posterior bearing displacement and

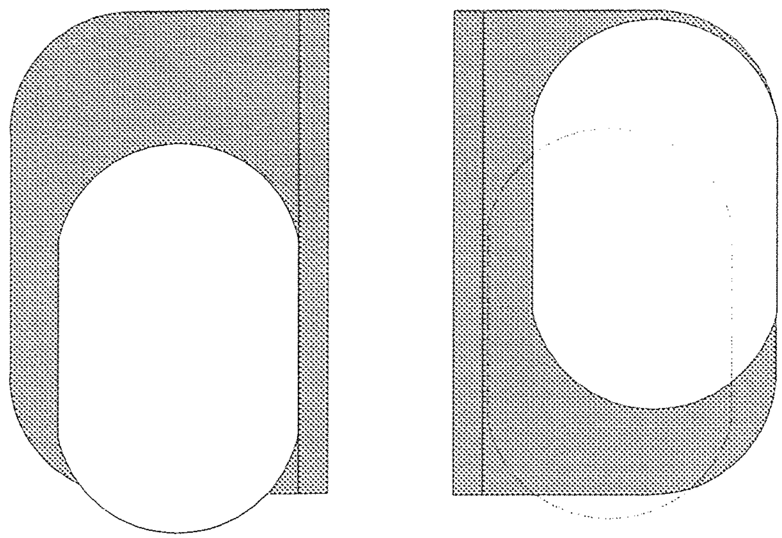

Figure 1.2. Oxford Mobile Bearing Design (8)

lack of adequate axial rotation (8). The New Jersey LCS mobile bearing design avoided this problem by using a dovetail groove (8). If ligaments are sufficiently tight, the bearing should never reach the angle of in which dislocation occurs. A curved track design, rather then the linear Oxford track design, allows for sufficient axial rotation. Another mobile bearing design is the Cruciate Sacrificing Rotating Platform (Figure 1.3). This design consists of a tibial plateau with a hollow conical stem that allows the insertion of a similar shaped bearing. The cone shaped stem reduces bone lose, avoids high stress concentration found in crossed fin stems, and provides a region for an effective load wear resistant bearing connection (6,8). The bearing insert allows for axial rotation and shear resistance. A third mobile bearing design is the posterior cruciate retaining platform. This design has the conical tibial stem of the cruciate sacrificing rotating platform and the platform grooves of the bicruciate retaining platform. When the anterior cruciate ligament can not be saved, this design is preferred. Mobile bearing elements offer additional advantages in that they accommodate surgical malalignment and allow intraoperative adjustment of the joint space or postoperative replacement of the bearing without disturbing prosthetic fixation.(6,8).

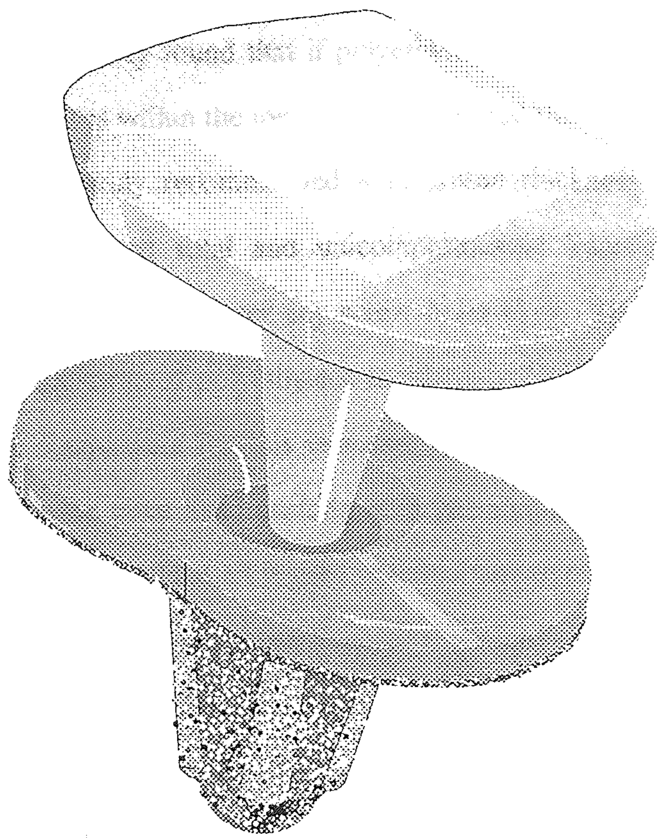

Figure 1.3. Cruciate Sacrificing Rotating Platform Design (8)

There is a misconception that the two articulating surfaces that exist in mobile bearing knee replacements have a higher combined wear then that of fixed bearing designs. This misconception has been found to be false (9). It was found that since the primary surface of the mobile bearing knee replacement was able to keep congruency through axial rotation and other motions as well as reducing constraining forces, contact pressure was reduced. The reduction in contact pressure greatly reduced primary wear when compared to the fixed bearing knee. Secondary wear of the mobile bearing implant was found to be even less then the primary wear due to the small sliding distance. Therefore, secondary wear is almost negligible when compared to the wear found in fixed bearing knee replacements.

The thickness of the bearing is also an important design factor. It has been found that as the tibial inserts thickness decreases, maximum principle stress increases at its surface (10). The same study found that if polyethylene inserts were less then 8 mm in depth, the deforming forces within the joint may well exceed the yield strength of polyethylene. Another study recommended a minimum thickness of 6 mm of actual polyethylene in metal backed total and unicompartmental knee replacements and a minimum of 8 mm of polyethylene over any screw holes (11). The problem that occurs when increasing the thickness of polyethylene is where an increase in bone loss on the tibial resection must compensate for this increase in height. Most tibial resections are made perpendicular to the tibial axis resulting in large amount of bone loss. However, when a ten degree posterior inclination is used, minimal amounts of bone are lost (12). It is also found that less bone is lost in the femoral resection, when aligned with this ten degree inclination, then if a perpendicular tibial resection was made.

The testing of wear in prosthetics is very important for the improvement of materials and design. The best method of testing wear in knee replacements is the examination of actual prosthetic knees used by patients. However, this is not practical for several obvious reasons. Not only is testing long term and the periodical examination of components unfeasible, but a controlled setting is impossible. This makes it very difficult to compare different designs. A pin on disk test would offer a controlled environment for the examination of wear properties for different material but would not be suitable for comparing the wear caused by different prosthetic designs. Since no standard device exists for the testing of wear in different knee replacements, several knee simulators have been devised for private use. Knee simulators have been designed for the simulation of simple gait or stair climbing. There are several benefits when using a knee simulator for prosthetic testing. A controlled environment is provided for the comparison of designs in similar environments. Loads and angles can be changed or fluctuated. The amount of cycles can be controlled and referenced for periodical examination. Testing time is greatly accelerated.

In most knee simulators, the femur was held fixed as hydraulic actuators are used for flexion and extension of the tibia (13,14,15). It was also found that some simulators employ a free weight pulley system to produce loading This does not allow for fluctuation of the load (13,16). Others used a hydraulic actuator for loading as well as a pulley system which acted as the quadriceps and gastrocnemius muscles (14,15). In one case, a hydraulic actuator was used to produce a foot to floor moment (14). However, a device was used to produce an axial rotation in only one of the simulators researched (4). The number of cycles performed in the testing of knee replacement wear is important in getting satisfactory results. The results of wear in short term testing can not necessarily be used to determine long term results. Some inconclusive findings in a test that ran for 100,000 and 500,000 cycles may have been the cause of insufficient cycling (4). It was also found that all of the knee simulators built were only able to test one knee at a time. An increase in the number of cycles could be made more efficient if multi station machines were used.

CHAPTER 2

MATERIALS AND METHODS

Two tests were conducted to examine the wear characteristics of tibial bearings used in total knee replacement systems. Each test consisted of six A/P Glide Tibial Bearings each having a conical control arm. Each of these bearing systems was mounted onto a Co-Cr alloy tibial platform and Co-Cr alloy LCS (low contact stress) femoral component (Figure 2.1). All metallic components were polished to a 0.05 micro meter (2 micro inch) finish and all plastic components to a 0.81 micro meter (32 micro inch) finish. These test samples were mounted onto the New Jersey Mark III Knee Simulator System (Figure 2.2).

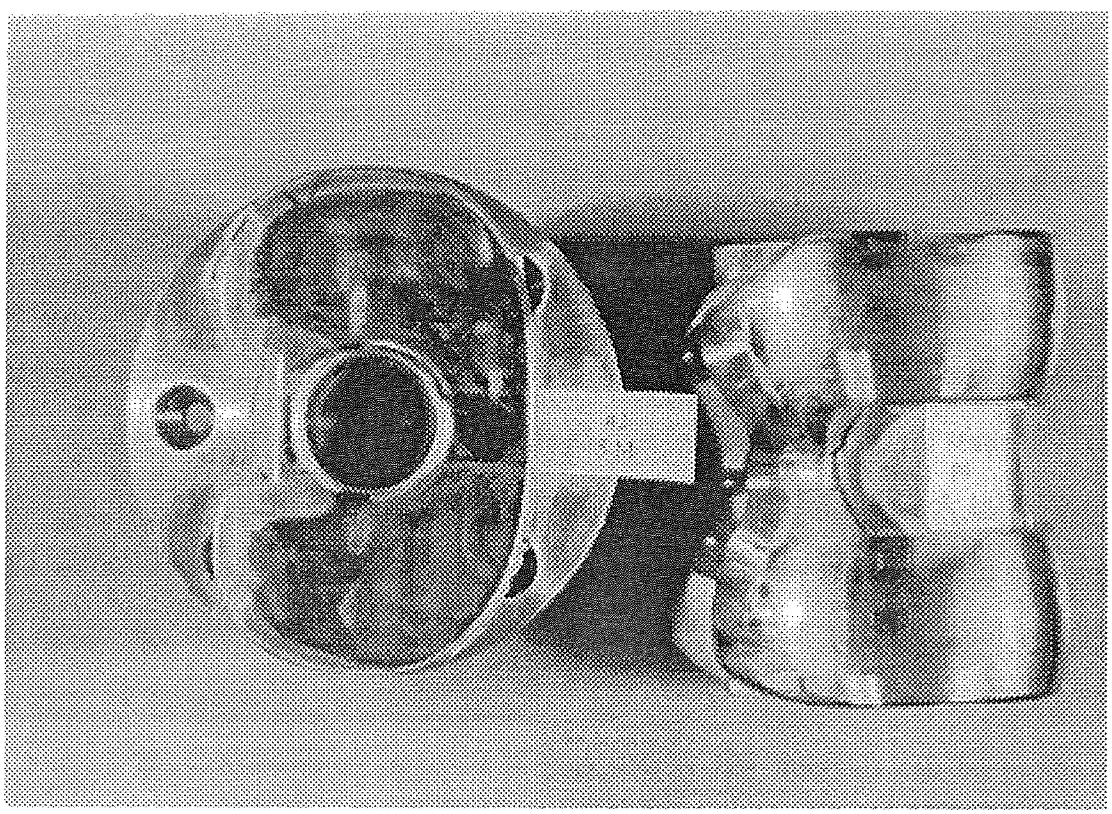

Figure 2.1. Tibial platform and femoral component

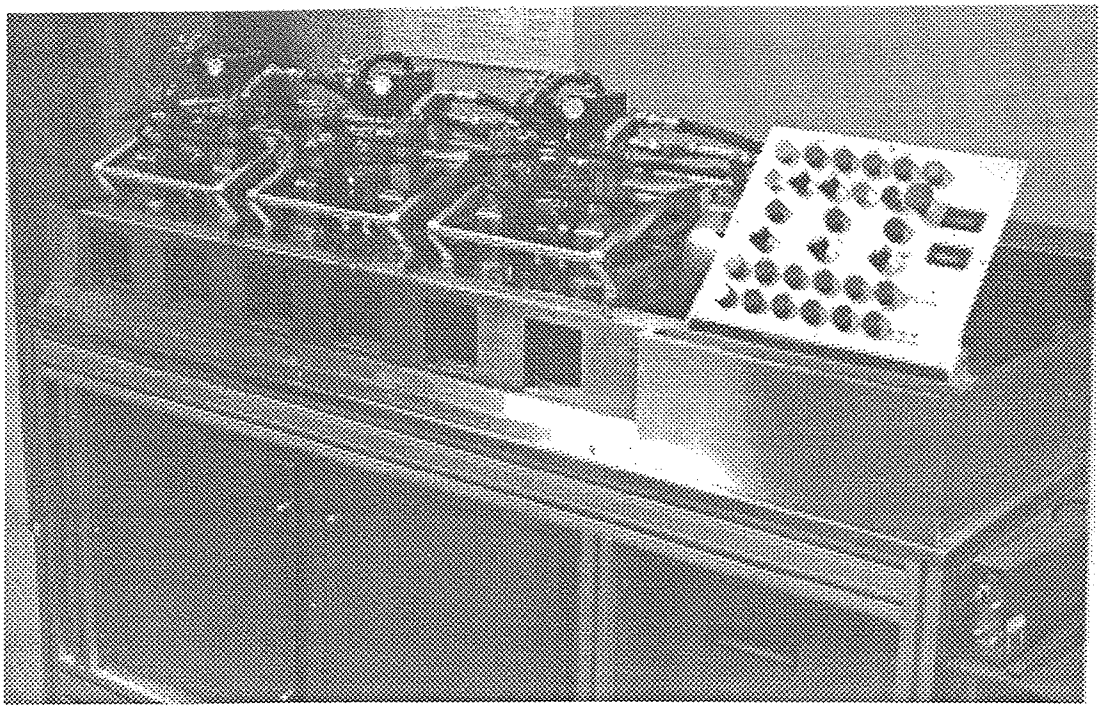

Figure 2.2. New Jersey Mark III Knee Simulator System (17)

The New Jersey Mark III Knee Simulator is a six station mechanical testing device used to simulate loading and motion of the knee in order to determine wear and load carrying characteristics of knee replacement systems. This device is derived from the New Jersey Mark II Knee Simulator (18). The Mark III has a change in mechanism generating the axial load as well as a design that allows the use of two, four, or six stations. This device includes flexion and extension as well as axial rotation and roll back to provide a more realistic motion and avoid bedding in. The motion normally simulates that of normal gait which consists of 0^{o} to 70^{o} flexion-extension and -6^{o} to $+6^{o}$ axial rotation. However, by disassembling the main crankshaft assembly and repositioning the connecting rod journal, flexion-extension angles of 40^{o} to 90^{o} in 10^{o} intervals can be produced. Axial rotation of up to +/- 15^{o} can be produced by a change in camshafts. For simplicity the motion profiles are approximately sinusoidal in shape and do not show the small reverse rotation present during the stance phase in normal human gait (17). A Hydraulic Cylinder Subsystem is used to produce axial loading (Figure 2.3). Intake and output control valves are used in this subsystem to regulate loading and loading rate. A Cooling-Lubrication Subsystem prevents all components from overheating and thermal damage (Figure 2.3). The cooling-lubrication fluid that is intended for use is normal saline or distilled water, however bovine serum or other physiological fluids can be used. Corrosion resistant material is used for all components that come in contact with this fluid. The cooling-lubrication fluid in each station flows individually by having its own reservoir. This fluid is also individually filter through 0.01 micro meter paper which collects wear debris that may later be extracted for examination. The Monitoring Subsystem insures that the Cooling-Lubrication Subsystem is functioning properly. If the fluid level is not maintained at a sufficient level, the system will automatically shut off. The tibial platform and femoral component are mounted to custom mounts in each test station (Figure 2.1). The design of the femoral mount requires the use of proprietary methodology to determine the proper location of the femoral component required to produce a desired amount of roll back of the femoral component on the tibial component (17).

2.1 Simulation I

Saline was used as the cooling-lubrication fluid for both simulation. Six UHMWPe bearings were initially soaked in saline for 72 hours, washed and dried. Each of these bearings, along with a conical bearing whose plastic portion was also made of UHMWPe, was then mounted onto the simulator (Figure 2.3). The simulator was configured to produce flexion from 0^{o} to 70^{o} and axial rotation of $+6^{o}$ to -6^{o} to simulate normal gait. The femoral mount is designed to produce an anterior-posterior motion of the bearing of about 1 cm. The test ran at 2 Hz with saline being sprayed between articulating surfaces.

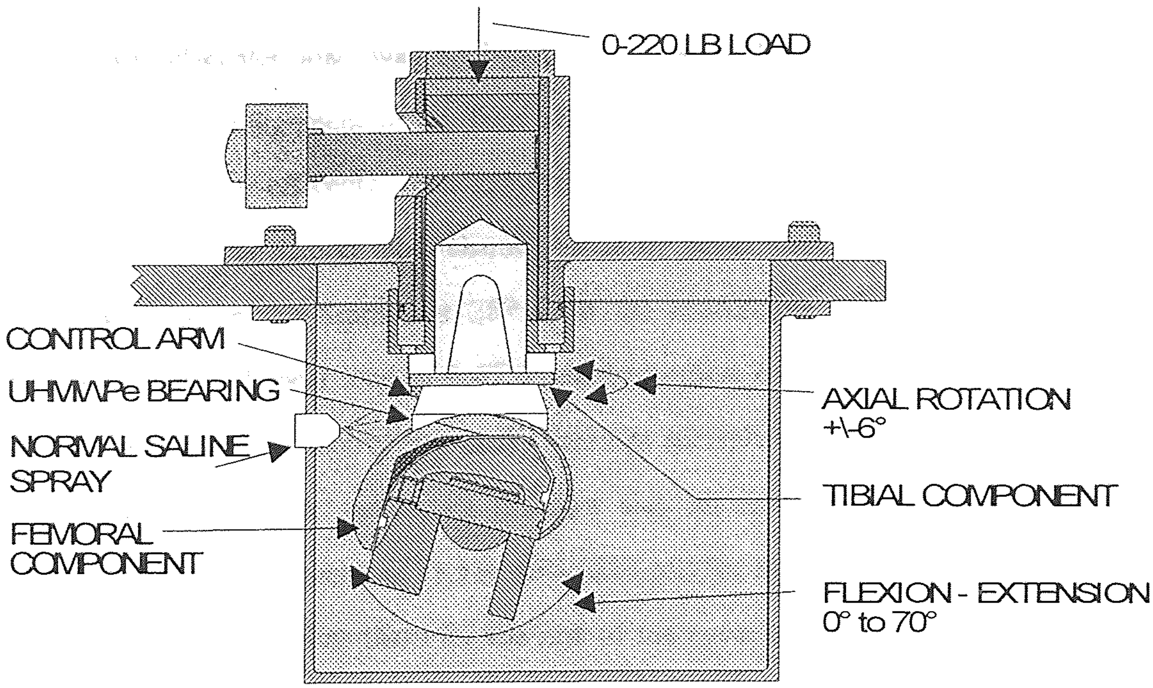

Figure 2.3. Sample mounted in a test station (17)

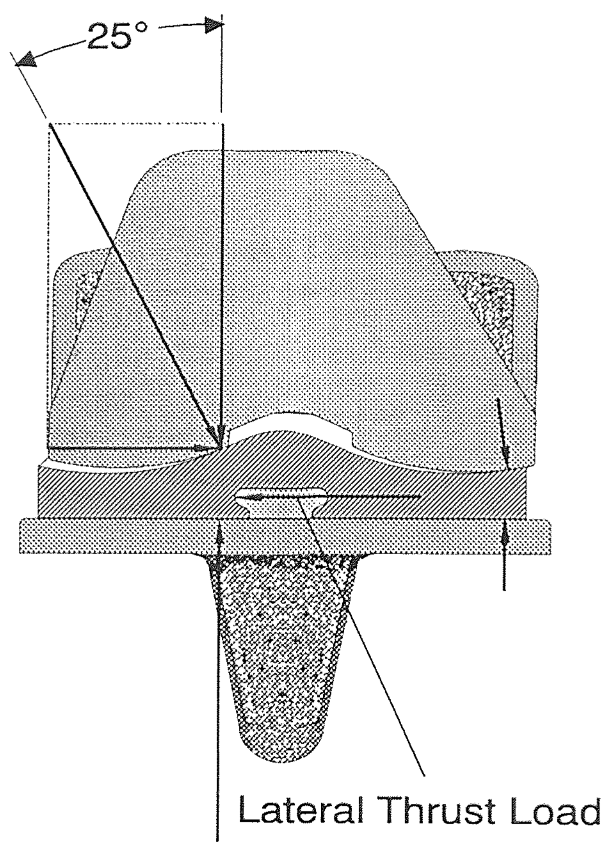

Figure 2.4. Method of producing lateral loading of the bearing to platform link (17)

An off-center load was applied to the bearing by the femoral component to account for a misalignment of the knee (Figure 2.4). Although this does not simulate normal loading, an off-center load provides critical loading on the control arm at both articulations so that lateral wear characteristics of the control arm could be examined. The load acts on the bearing at 25^{o} from the articulating surface segment tangent producing a lateral shear load of 0.47 times the vertical compressive load. This lateral load is resisted by the control arm at the bearings secondary slot and the tibial platform. The Hydraulic Cylinder Subsystem pressure was set to vary from 0 to 1,516 KPa (220 psi). The load remains at 1,516 KPa (220 psi) for a quarter of a cycle and slowly drops to zero and remains there for the rest of the cycle. Figure 2.5 compares normal walking profile to the simulated load profile. The normal double peak loading profile of normal gait is replaced by a single peak to make the loading more rigorous which should compensate for the loss of wear resulting from the lack of motion reversal in flexion-extension simulation.

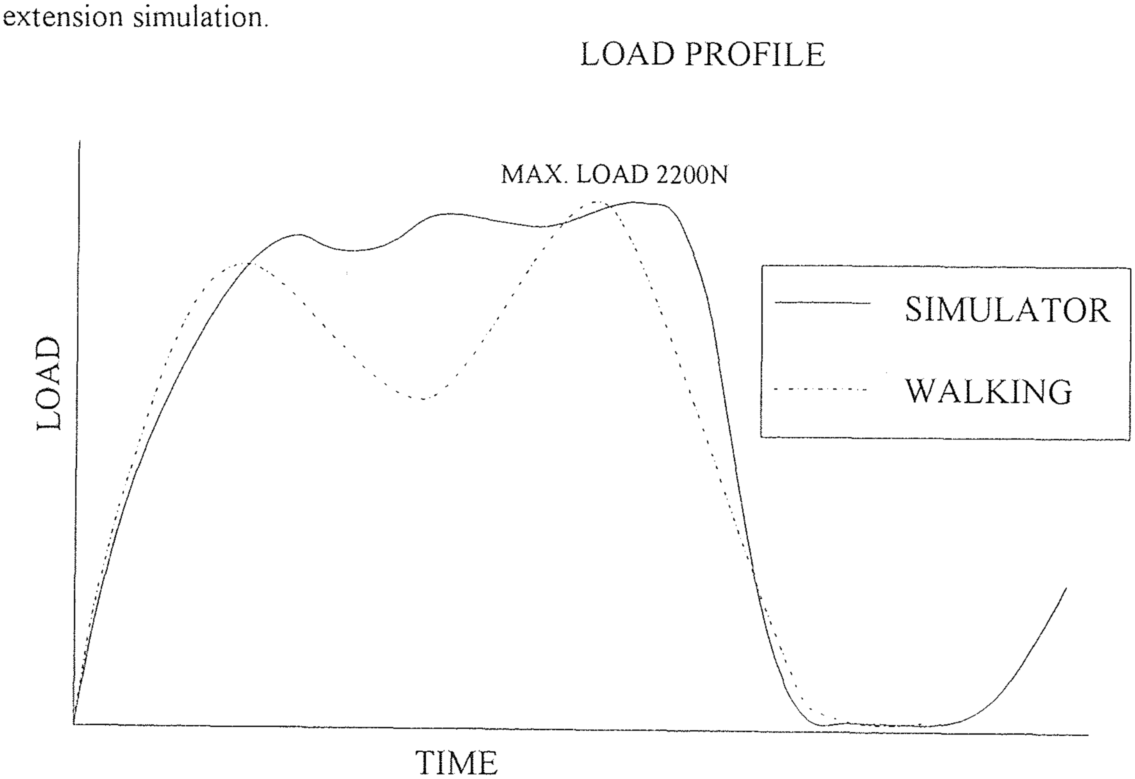

Figure 2.5. Comparison of normal walking profile and simulated load profile (17)

The retrieval of components for data acquisition were made at 0.5, 1.3, 3.6 and 5.0 million cycles. The bearing and control arm were then removed as assembled and photographed. All wear debris was then removed from the surface of the components. In cases where the wear debris formed a distributed film over the surface, a slight rubbing action was used to remove it. The components were then cleaned and rinsed in water. Prior to weighing each bearing, all components were wiped dry, forced air dried, and shelf dried for a minimum of 48 hours. The scale was monitored for changes and required to be stable for 24 hours. The scale used was an OHAUS E400 electronic scale with an accuracy to 0.01 grams and a maximum load of 200 grams. Each component was weighed three times and averaged. Reinforced Repro-Rubber molds were made of each bearing surface as evidence of bearing surface wear. These molds were then measured to obtain the dimensions of the tibial slots. An optical comparitor was used on the initial and final molds of each component at various cross-sections. Two cross-sections were measured on the initial molds while six equally spaced cross-sections on the final. A solid model was constructed from this data using Pro/ENGINEER.

2.2 Simulation II

Saline was also used as the cooling-lubrication fluid for the second simulation. Four Hylamer® and four UHMWPe bearings were initially soaked in saline for 72 hours, washed, and dried. The additional Hylamer® and UHMWPe bearings that were prepared, were needed as soak controls. Specimen weight is a major characteristic involved in determining wear, therefore the amount of water absorbed by each type of plastic may be significant. By inserting soak controls into one of the saline reservoirs, weight change due to absorption can be monitored.

All components were then mounted into the six station simulator where Hylamer® bearings were used in the odd numbered stations and UHMWPe bearings in the even numbered stations. The plastic portion of the conical bearings were all made of

UHMWPe. The simulator was configured to produce flexion from 0^{o} to 70^{o} and axial rotation of $+6^{o}$ to -6^{o} to simulates normal gait. The femoral mount is designed to produce an anterior-posterior motion of the bearing of about 1 cm. The test ran at 2 Hz with saline being sprayed between articulating surfaces. The Hydraulic Cylinder Subsystem load was set to vary from 0 to 2,200 N. For this test the load remains at 2,200 N for a third of a cycle and slowly drops to zero and remains there for the rest of the cycle.

The retrieval of components for data acquisition were made at 1.0, 2.5 and 5.0 million cycles. The test chamber was carefully opened such that the bearing and control arm remain on the femoral component. The bearing and control arm were then removed as assembled. The components were then cleaned and rinsed in water. Prior to weighing each bearing, all components were wiped dry, forced air dried, and shelf dried for a minimum of 48 hours. The scale was monitored for changes and required to be stable for 24 hours. For this simulation the scale used was an OHAUS Precision electronic scale which gives measurements in grams to three decimal places and maximum of 400 grams. Each component was weighed three times and averaged. After weighing each component, a dial gage was used to measure the height of various locations on each bearing surface (Figure 2.6 shows location of measurements). Three pin holes were placed on the sides of each tibial bearing prior to testing. These holes coincide with that of a custom holder. By using this holder, measurements were able to be taken from the same reference point. This data could then be used to determine height changes at various sections of the bearing at various intervals. The thickness of the lowest point on each condile (Figure 2.6 points #9 and #10) was measured using a micrometer. Each bearing was measured four times and averaged.

After testing was complete, the composition of each primary bearing surface was examined using a JEOL JSM-T300 Scanning Electron Microscope (SEM) and Kevex Analytical Software. The SEM does this by passing an electron beam across the surface of the sample where reflected electrons are then gathered and processed to produce an image. Each sample must be coated with a conductive material. This is achieved by placing each sample into a vacuum chamber where a carbon electrode is vaporized, coating the surface of the sample. The elemental analysis software then determines the attributes of the examined surface by determining the density of particles and the area on the sample. A plot shows the amount of each element present (Figure 2.7).

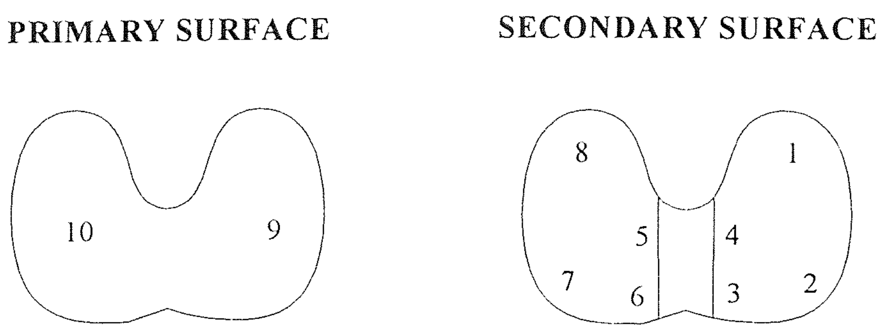

Figure 2.6. Location of height measurements on bearing surfaces

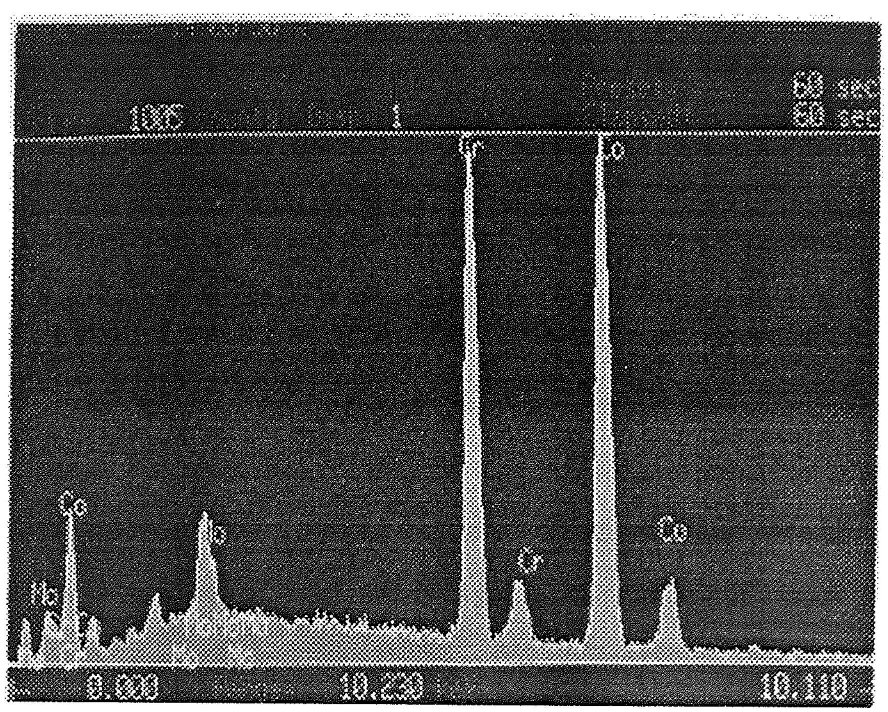

Figure 2.7. Plot generated by elemental analysis software of SEM examined surface

CHAPTER 3

RESULTS

3.1 Simulation I

Figure 3.1 shows the volumetric loss of each UHMWPe primary bearing throughout Simulation I. All bearings follow a common trend in volumetric loss up to 2.00 million cycles. However, between 2.00 and 3.60 million cycles, samples three and four break from this trend and begin to wear significantly more then the other samples. Samples three and four were accidentally switched during 2.00 million to 3.60 million cycles of testing. The average volumetric loss increases dramatically from 28.58 mm^3 to 119.69 mm^3 between 2.00 to 5.20 million cycles, respectively. Samples three and four have approximately 2, 3 and 5 times higher volumetric loss then the average of the remaining samples, at 2.00, 3.60 and 5.20 million cycles, respectively. At 5.2 million cycles, sample three has a volumetric loss of 364.42 mm^3 and sample four a loss of 192.93 mm^3 while the average volumetric loss of the remaining four samples is 40.19 mm^3.

Figure 3.2 shows the wear rate of each UHMWPe primary bearing throughout Simulation I. The average wear rate increases to 20.01 mm^3/million cycles at 2 million cycles then decreasing to 7.82 mm^3/million cycles at 3.60 million cycles and finally increases to a high of 49.12 mm^3/million cycles at 5.20 million cycles. Sample two follows this trend but at a different period. Peak wear rates of 14.29 and 13.40 mm^3/million cycles are found at 0.75 and 3.60 million cycles, respectively for sample two, instead of 2.00 and 5.20 million cycles as is found in the remaining samples. Once again an inconsistency is shown in samples three and four. At 5.20 million cycles, wear rates of 180.87 and 80.39 mm^3/million cycles are found in samples three and four, respectively. Sample five shows the only negative wear rate of -6.70 mm^3/million cycles at 3.60 million cycles.

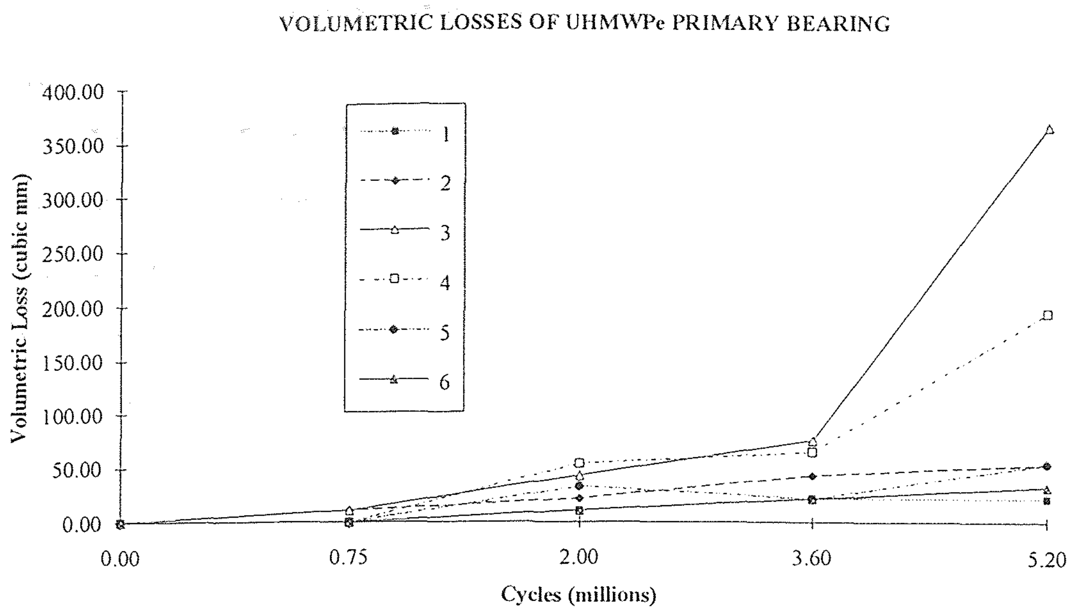

Figure 3.1. Volumetric loss of UHMWPe primary bearings from Simulation I

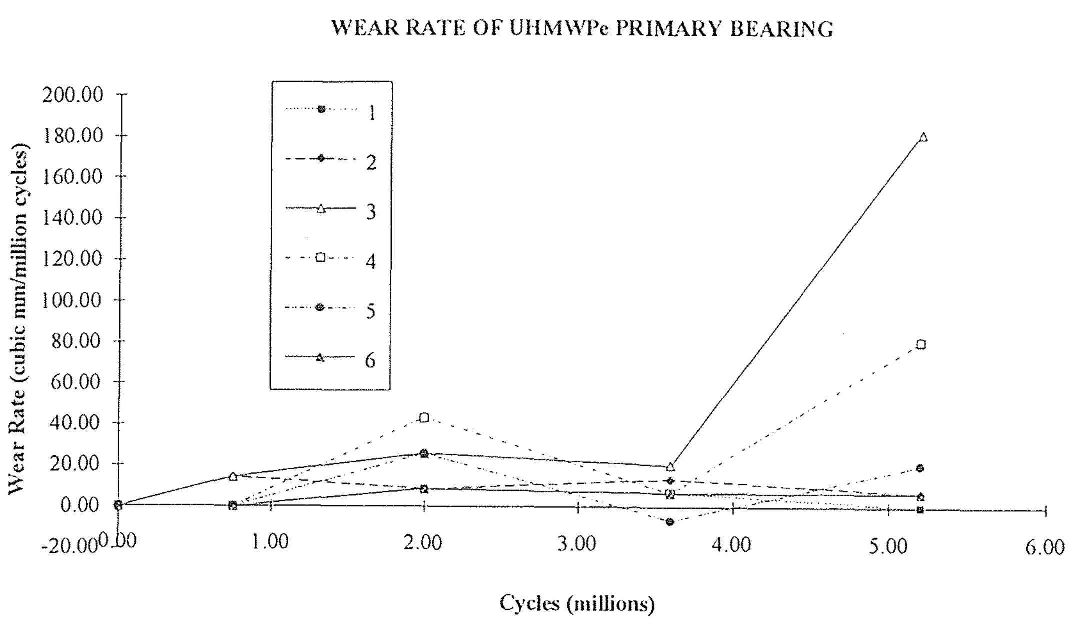

Figure 3.2. Wear rates of UHMWPe primary bearings from Simulation I

In order to measure the effect of lateral loading, the wear on the slot alone was measured. Repro-rubber molds were measured to obtain the dimensions of the tibial slots The results from the solid models, which were constructed using Pro/ENGINEER, are found on Table 3.1. Table 3.1 lists the volume of the bearing slots prior to testing and the volume following 5.20 million cycles as well as the change in volume. The change in volume was calculated by subtracting the initial volume from the final volume. Sample three had the greatest increase in slot volume of 30.25 mm^3. Sample five showed the least amount of change in slot volume at 15.67 mm^3 which is almost half that of sample three. The change in weight of each control arm was about 0.01 grams between intervals. This is within the accuracy of the scale, therefore rendering this data invalid.

Table 3.1. Change in volume of tibial bearing slot for each sample in Simulation I

Sample	Initial Volume (mm^3)	Final Volume (mm^3)	Change in Volume (mm^3)
1	1339.61	1360.27	20.66
2	1356.48	1374.69	18.21
3	1349.56	1379.81	30.25
4	1345.25	1361.39	16.14
5	1346.00	1361.67	15.67
6	1339.59	1362.63	23.04
Average	**1346.08**	**1366.74**	**20.66**

3.2 Simulation II

Figure 3.3 shows the volumetric loss of each UHMWPe primary bearing throughout Simulation II. A common trend is followed by all three samples up to 2.5 million cycles. However, sample one's volume loss increases dramatically from 5.36 mm^3 at 2.5 million cycles to 33.23 mm^3 at 5.0 million cycles, while samples two and three remain constant at 5.36 mm^3 and 0.00 mm^3, respectively, throughout the same period. Sample three shows no change in volume throughout the entire test.

Figure 3.4 shows the volumetric loss of each Hylamer® primary bearing throughout Simulation II. Samples one and two show no volumetric loss through the first million cycles. Sample two begins to wear slightly throughout the rest of the test, while samples one and three follow a common trend. Sample two has a volumetric loss of 4.29 mm^3 at 2.5 million cycles and then drops slightly to 3.22 mm^3 at 5.0 million cycles. The volumetric loss of samples one and three, however, continue to increase to a maximum of 20.36 mm^3 and 15.01 mm^3, respectively, at 5.0 million cycles.

Figure 3.5 shows the wear rate of each UHMWPe primary bearing throughout Simulation II. No common trend is seen by the three samples. Sample three has a constant zero wear rate throughout testing due to no observed volumetric loss (Figure 3.3). The wear rate of sample two shows no change during the first interval but rises to a maximum of 3.57 mm3/million cycles at 2.5 million cycles where it gradually returns to zero at 5.0 million cycles. Sample one begins to follow the same pattern at a different period but then increases dramatically to a maximum of 11.15 mm3/million cycles at 5.0 million cycles.

Figure 3.6 shows the wear rate of each Hylamer® primary bearing throughout Simulation II. A common trend at different magnitudes is followed by each of the three samples. The wear rate gradually increases to a maximum at 2.5 million cycles and then gradually decreases to a much lower value at 5.0 million cycles. At 2.5 million cycles, samples one, two, and three reach a maximum wear rate of 10.00, 2.86 and 5.72

mm^3/million cycles, receptively. Sample two's wear rate remains low and dips slightly negative to -0.43 mm^3/million cycles at 5.0 million cycles. Although sample one follows the common trend, a more erratic behavior is seen. As sample two, sample one shows no wear rate during the first million cycles, however, at 2.5 million cycles sample one shows a much higher wear rate then sample two.

Figure 3.7 compares the average volumetric loss of UHMWPe primary bearings and Hylamer® primary bearings throughout Simulation II. On average, the volumetric loss of UHMWPe is gradual, from 1.07 mm^3 at 1.0 million cycles to 3.57 mm^3 at 2.5 million cycles and slightly sharper to a maximum at 5.0 million cycles. The average volumetric loss of Hylamer® is similar to UHMWPe during the first million cycles but then sharply increases to 10.00 mm^3 at 2.5 million cycles. During the final interval, the volumetric loss of Hylamer® is again gradual as was during the first interval. Both materials show a 12.86 mm^3 maximum loss at 5.0 million cycles.

Figure 3.8 compares the average wear rates of UHMWPe primary bearings and Hylamer® primary bearings throughout Simulation II. The average wear rate of UHMWPe is gradual through the entire test. A maximum average wear rate of 3.72 mm^3/million cycles is reached at 5.0 million cycles. Hylamer®'s average wear rate is more erratic when compared to UHMWPe. For the first million cycles no distinction is seen between the two materials, however the average wear rate of Hylamer® quickly reaches a maximum of 6.19 mm3/million cycles at 2.5 million cycles while UHMWPe is only 1.67 mm^3/million cycles at the same interval. During the final interval, the wear rate of Hylamer® quickly decreases to 1.14 mm^3/million cycles while UHMWPe reaches a maximum.

Various height measurements were taken of each side of each primary bearing at each interval of Simulation II. This data is incomplete due to the deformation of the samples. Following the initial test interval, most of the bearings did not fit into the custom

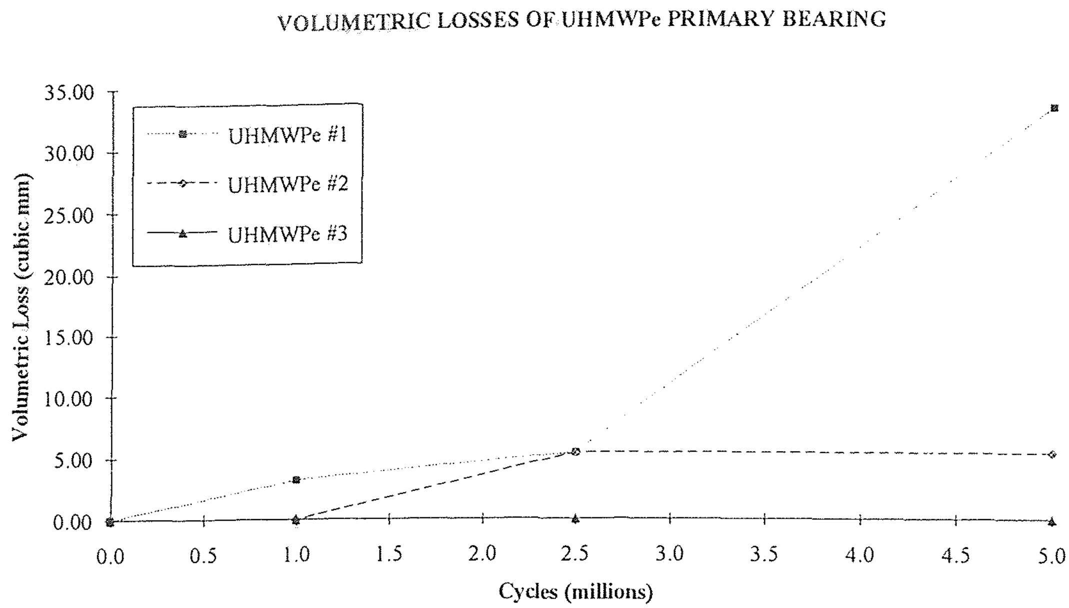

Figure 3.3. Volumetric loss of UHMWPe primary bearings from Simulation II

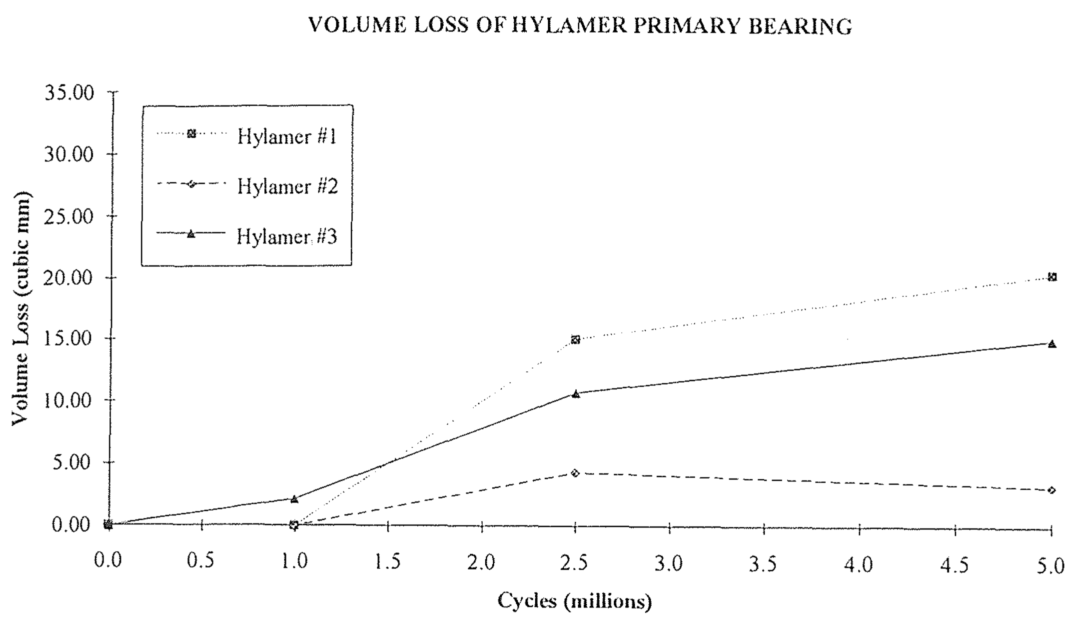

Figure 3.4. Volumetric loss of Hylamer® primary bearings from Simulation II

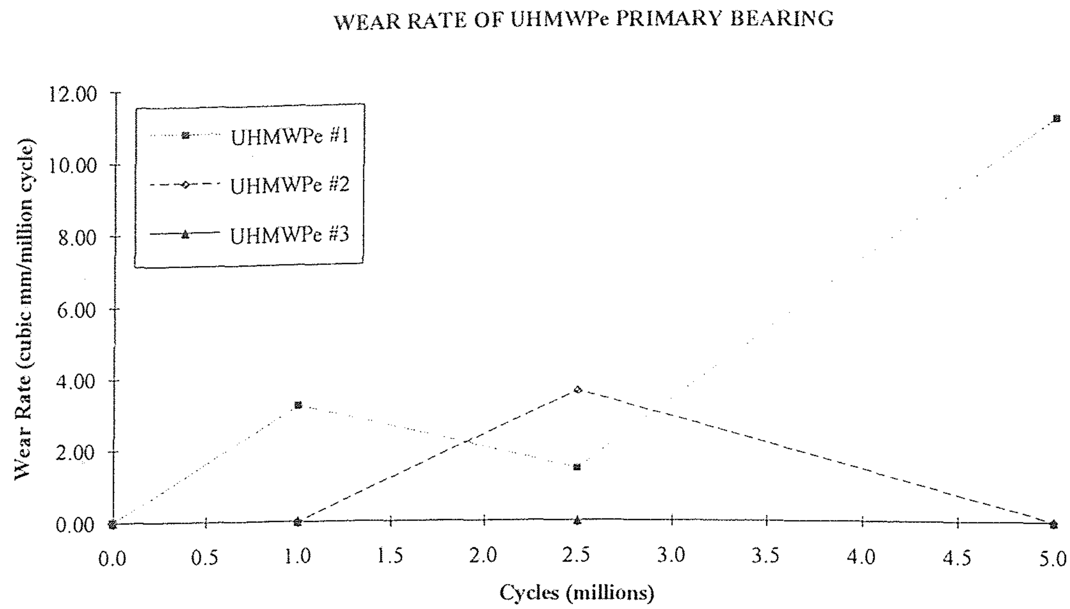

Figure 3.5. Wear rates of UHMWPe primary bearing from Simulation II

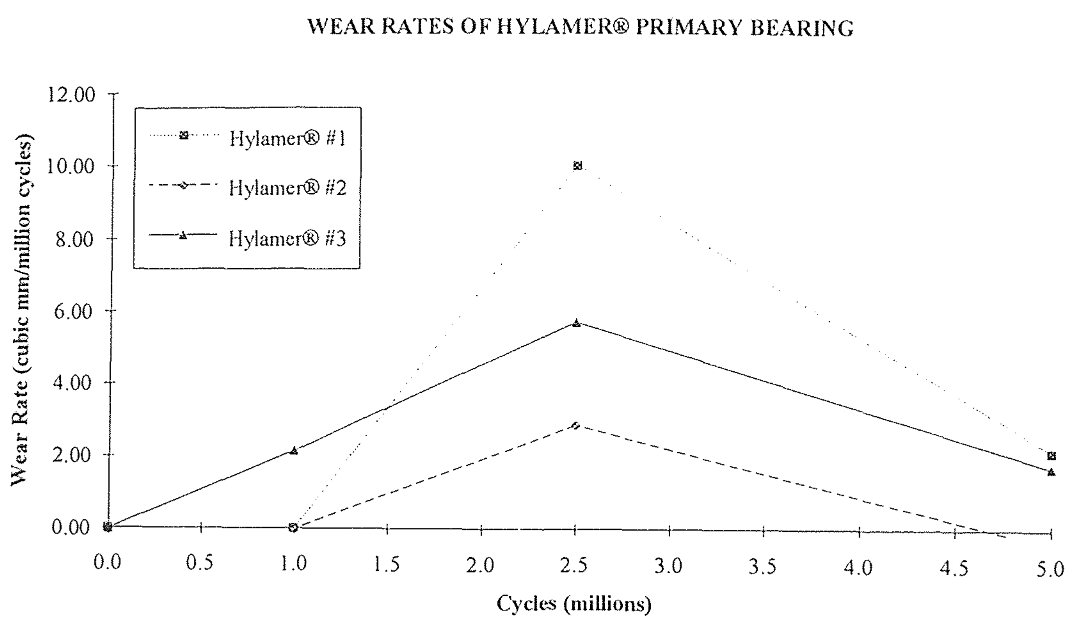

Figure 3.6. Wear rates of Hylamer® primary bearing from Simulation II

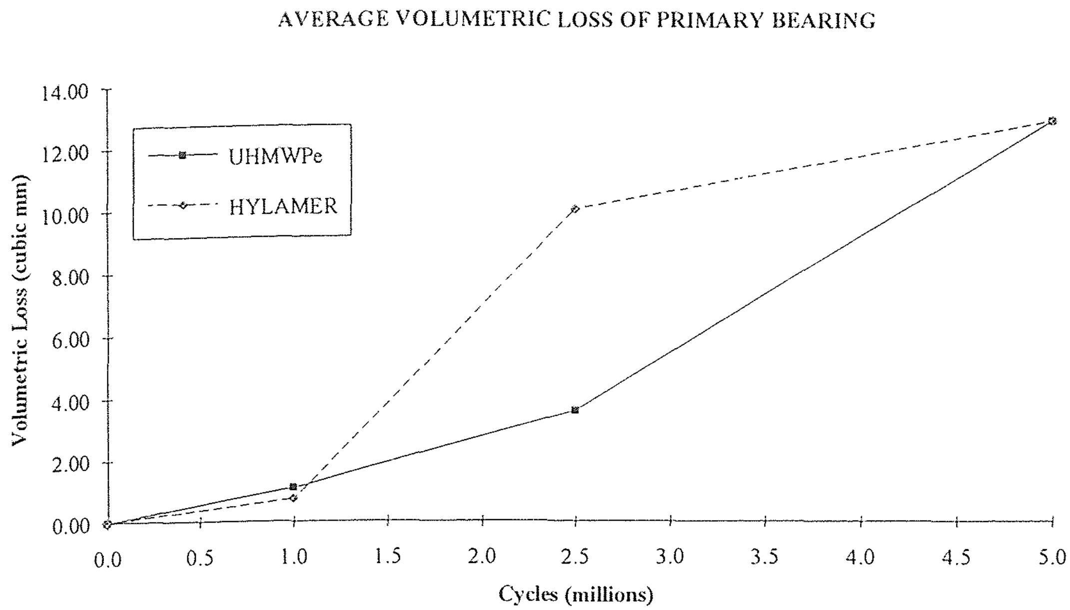

Figure 3.7. Average volumetric loss of UHMWPe and Hylamer® primary bearings

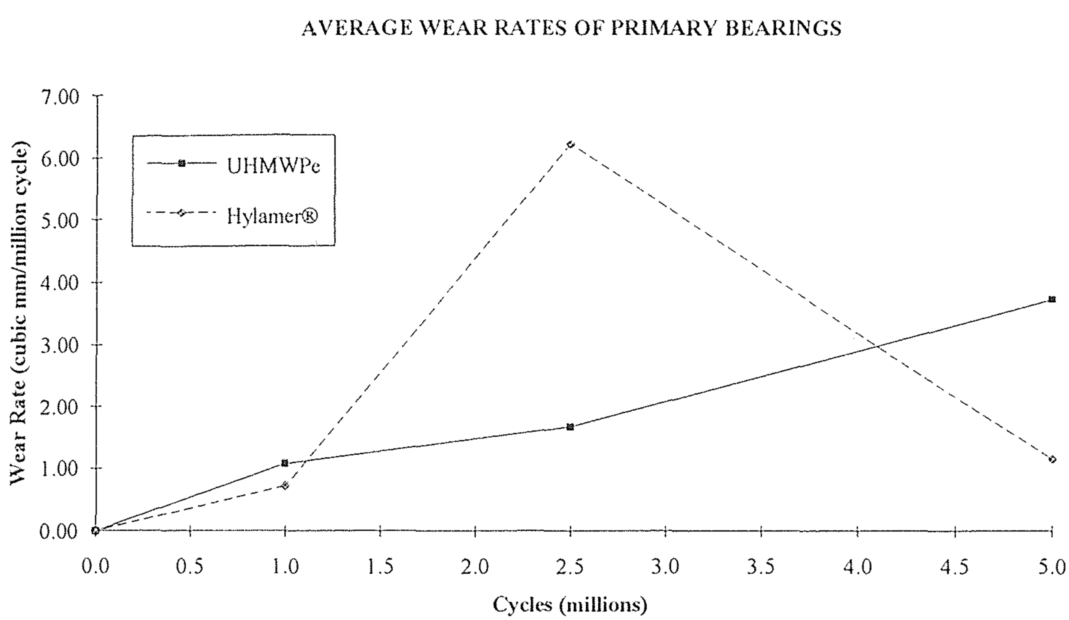

Figure 3.8. Average wear rates of UHMWPe and Hylamer® primary bearings

holder. However, the thickness of the lowest point on each condyle was measured at the end of testing (Table 3.2). The thickness of each condyle prior to testing was 0.245 in. (0.622 cm). The average thickness of each UHMWPe bearing decreased when the volume decreased. Hylamer® sample three is the thickest of the Hylamer® bearings at 5.0 million cycles, however a significantly higher volumetric loss is found when compared to sample two. Unlike UHMWPe sample one, Hylamer® sample one shows a significant decrease in thickness as well as volume when compared to the other Hylamer® samples. The decrease in thickness of Hylamer® sample one is noticeable to the naked eye.

Table 3.2. Average thickness of primary bearing condyles compared with volumetric loss of primary bearing for UHMWPe and Hylamer at 5.0 million cycles

	UHMWPe		Hylamer	
Sample	Thickness (cm)	Volume Loss (mm^3)	Thickness (cm)	Volume Loss (mm^3)
1	0.605	33.23	0.508	20.36
2	0.610	5.36	0.612	3.22
3	0.615	0.00	0.615	15.01

When visually examining some of the samples, small amounts of black streaks and light orange stains were noticed. These markings were more visible on the Hylamer® samples then on the UHMWPe samples, which may be due to Hylamer®'s solid white color. The primary surface of each sample was examined under a scanning electron microscope (SEM) for foreign substances and abnormalities. All surfaces were found clean of any metallic substances as well as abnormal markings. The streaks and stains were probably of an organic material and may have been caused by hydraulic fluid from the loading device or some lubricating oil entering the testing system.

CHAPTER 4

DISCUSSION

Much was learned from Simulation I that was used to improve the protocol of Simulation II. The accuracy of the instruments used to obtain results is vital to the credibility of test results. The electronic scale used for Simulation I was accurate to ± 0.01 grams. Some of the weight changes between consecutive intervals for each sample was about 0.01 grams which is within the accuracy of the scale. In Simulation II, the electronic scale used measured to an accuracy of ± 0.001 grams.

Since saline was used as a cooling-lubricating fluid, water absorption by the polymer must also be considered. Soak controls were used for Simulation II. Water absorption ranged from 0.003 grams to 0.006 grams for Hylamer® and 0.001 grams to 0.004 grams for UHMWPe during this test. This appears insignificant when compared to the weight of the bearings (about 20 grams). However, the change in weight between consecutive intervals was often less then 0.01 grams. Therefore, water absorption is significant to the weight change.

Saline was sprayed onto the knee system during testing while the soak controls were placed into the saline reservoir. Since the mechanism for the absorption of water is different between the control and the test, the possibility of error should be considered. The volume of the test samples change as they wear. This reduction in volume is insignificant to the amount of water absorbed due to the low magnitude of the volume loss and even lower magnitude of the water absorbed. However, since the bearing wear is measured by subtracting the actual weight of the bearing to the change in weight of the soak control, the accuracy of this value is to ± 0.002 grams. In order to improve the accuracy of the results, all values were weighed three times and averaged.

When examining the volumetric loss, there are times were wear increases sharply through one interval and then begins to level off through the next interval. This leveling off could be a sign of bedding in and increased congruence (19). If the knee prosthetic has a random motion bedding in will not occur. However, the motion of the knee system during testing consists of a semi-random motion with flexion-extension as well as axial rotation. This allows for slight bedding in to occur but it will not form a distinct groove or slot.

Periodically, a large increase in the bearings volumetric loss occur. This could be caused by mechanical error. The load was fluctuated hydraulically and was set prior to testing using an actuator. Each test station has an individual loading system. A slight variation in pressure between stations repeated over several thousand cycles could change the wear considerably. Misalignment of the bearing may occur due to mechanical loosening. A slight misalignment throughout an entire test interval could concentrate the load on a new section of the bearing. This in turn would cause the new rougher surface to begin a new wear cycle thereby increasing volumetric loss.

Another possible cause for a large increase in the bearings volumetric loss could be adhesive wear. A transfer film may form on the cobalt-chromium femoral component. Since the femoral components are not cleaned during testing, this film may remain or accumulate throughout the test. This thin layer of plastic could then become attached to the bearing and tear off plastic particles. The saline spray may reduce this effect by keeping the articulating surfaces cool and lubricated as well as filtering out an loose plastic particles.

Slight scratches were found on all the femoral components at the first examination interval of both tests. When examining retrievals from actual patients, this is rarely found (20). This may be due to the human bodies phenomenal filtration system. The faint scratches found in the test samples could be caused by three body wear. Although a filtration device was used, some particles may still enter the system. When the bearings were examined under a scanning electron microscope (SEM), no foreign particles were found. However, these particles may have been removed during the cleaning process or may have never been imbedded into the plastic and been filter out. The filters were changed periodically and were found to have a light orange discoloration during both tests. This discoloration was also seen in small amounts on some of the bearing surfaces of Simulation II. This is most likely some type of lubricating oil or hydraulic fluid that seeped into the system. When the stained section of the bearing was examined under the SEM, nothing was detected.

Samples three and four of Simulation I were accidentally switched during 2.00 million to 3.60 million cycles of testing. A dramatic increase in volumetric loss and wear rate began during this interval and continued to increase throughout the rest of the test. Also, excessive rust was found in station three at the 2.00 million cycle interval. This was caused by a blown gasket which was then replaced along with all filters and cooling-lubrication fluid. Sample three was found to have a significantly higher slot volume change when compared to the other five samples (Table 3.1). This too may have be caused by the excessive rust found in station three. Due to these known errors, these two samples should be discarded from the results. This change to the results shows a more gradual and predictable curve. Figures 4.1 and 4.2 compares the original data to the refined data (samples three and four discarded completely) of volumetric loss and wear rate, respectively. When comparing this data with that in Simulation II (Figures 4.3 and 4.4), both volumetric loss and wear rate throughout Simulation I are greater. This reinforces the fact that an off-centered load increases wear and wear rate.

Table 4.1 compares the total volumetric loss of each bearing with the increase in slot volume of the refined data. The primary and secondary surface wear which was calculated by subtracting the slot volume loss from the total volume loss are also tabulated (Table 4.1). It is shown that the bearing slots with higher volume loss, such as samples one and six, have a lower surface volume loss. Samples one and six have slot volume

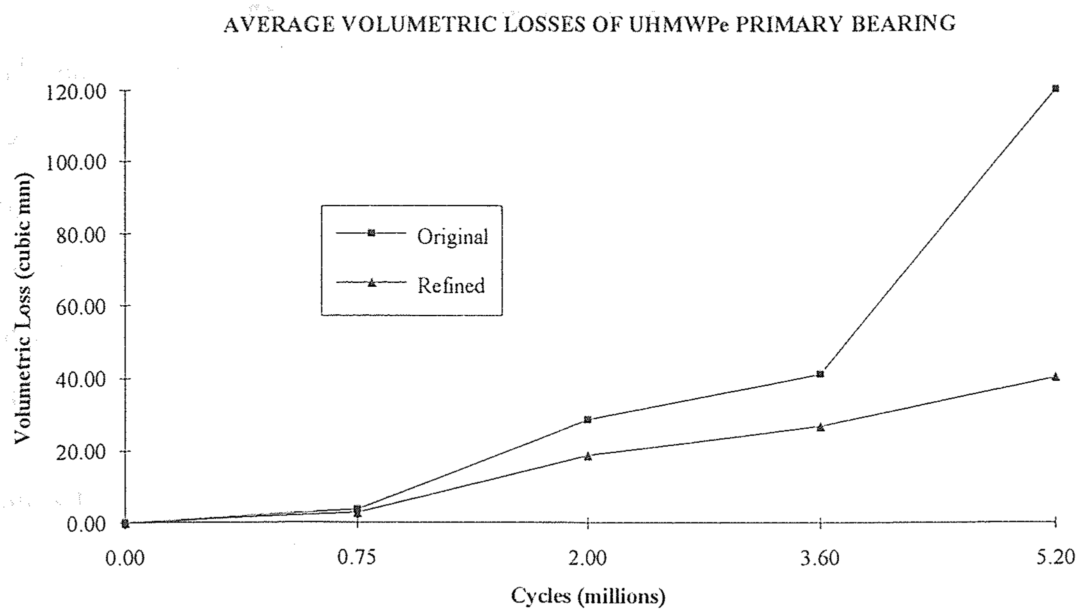

Figure 4.1. Average volumetric loss of original and refined data for Simulation I

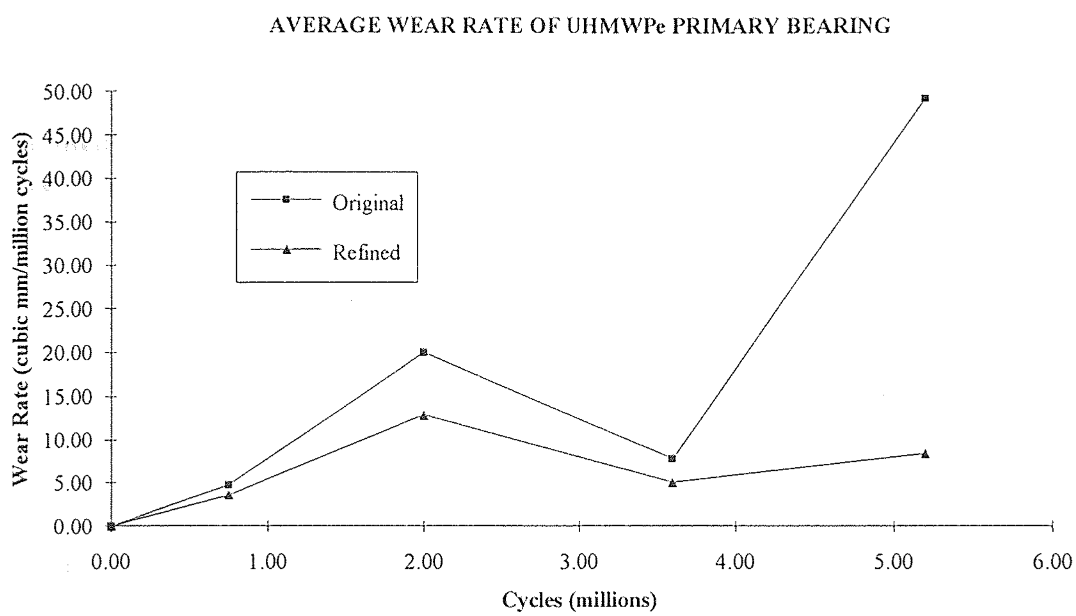

Figure 4.2. Average wear rate of original and refined data for Simulation I

losses of 20.66 mm^3 and 23.04 mm^3, respectively but only a surface volume loss of 0.78 mm^3 and 9.11 mm^3 respectively. However, samples two and five have slot volume losses of 18.21 mm^3 and 15.67 mm^3, respectively which is only slightly less then samples one and six but have a much greater surface volume loss of 35.38 mm^3 and 37.92 mm^3, receptively. This suggests that small amounts of wear at the slot may dramatically reduce the wear at the primary and secondary surfaces in turn reducing the total wear.

Table 4.1. Comparison of the volumetric loss at various locations of the bearing for the refined data in Simulation I

Sample	Total Volume Loss (mm^3)	Slot Volume Loss (mm^3)	Surface Volume Loss (mm^3)
1	21.44	20.66	0.78
2	53.59	18.21	35.38
5	53.59	15.67	37.92
6	32.15	23.04	9.11
Refined Average	**40.19**	**19.40**	**20.79**

When examining the volumetric losses of Simulation II, it is found that the volumetric loss begins to level off during the final interval (Figure 3.3 and 3.4). However, this does not occur with UHMWPe sample one. A dramatic increase in volume loss occurs. This indicates that some type of error has caused excessive wear in this sample during this interval. It is most likely that a mechanical error is responsible for this inconsistency. Figure 4.3 and 4.4 compare average Hylamer® and UHMWPe data as well as refined values of UHMWPe (discarding the last interval of UHMWPe sample one). It is shown that Hylamer® and UHMWPe have similar volumetric loss at 5.0 million cycles (Figure 4.3). However, if the refined data is used, UHMWPe has a considerably lower volumetric loss and wear rate after 1.0 million cycles.

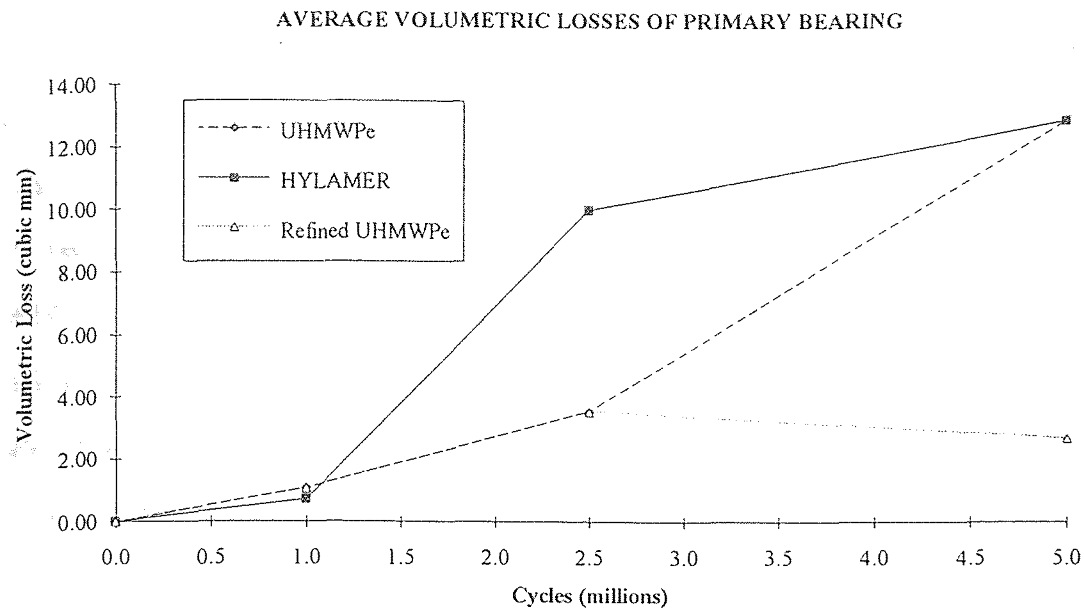

Figure 4.3. Average volumetric loss of original and refined data for Simulation II

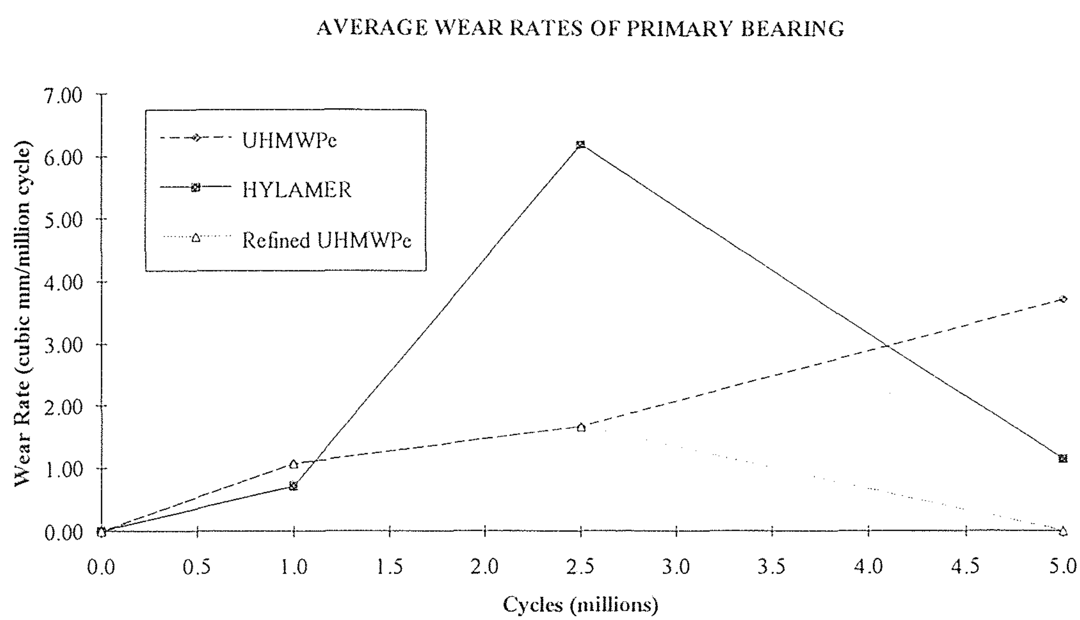

Figure 4.4. Average wear rate of original and refined data for Simulation II

Examination of the condyle thicknesses show that the UHMWPe bearings decrease in volume as the condyle thickness decreases, which is expected (Table 3.2). However, this does not occur in the Hylamer® bearings. Hylamer® sample three shows the least reduction in thickness but the third highest volumetric loss, with respect to all six samples. Also, Hylamer® sample one showed almost seven times more thickness reduction then UHMWPe sample one but only about 2/3 the volumetric loss. This indicates that significant amounts of wear occur in other sections of the bearing. The initial method of height measurements would have been more useful in finding a correlation between bearing thickness and volumetric loss. However, condyle thickness is beneficial when examining wear characteristics since the highest stress and greatest incongruency occurs between the bearing surfaces.

CHAPTER 5

CONCLUSION

The suggestion that Hylamer® did not wear greater than conventional UHMWPe was not borne out in this study. Hylamer®'s volumetric loss and wear rate were found to be considerable higher then UHMWPe. Hylamer®'s increase in crystallinity increases its yield strength and ultimate tensile strength. However, by increasing the crystallinity, stiffness is also increased. This increase in stiffness increases the contact stress which in turn increases the wear. Although a slight increase in strength is gained when using Hylamer®, wear resistance, an more important characteristic for total knee replacement systems, is reduced.

Further testing should be performed and testing methods improved. By increasing the testing cycles and number of test points, long term wear characteristics could be better predicted. Several thicknesses should be measured throughout the bearing at each interval to find a correlation between bearing thickness and volumetric loss.

APPENDIX A

Simulation I
Volumetric Loss of Primary Bearings

	Number of Cycles (x 10^6)				
	0.00	0.75	2.00	3.60	5.20
Component	Volume Loss (cubic mm)				
1	0.00	0.00	10.72	21.44	21.44
2	0.00	10.72	21.44	42.87	53.59
3	0.00	10.72	42.87	75.03	364.42
4	0.00	0.00	53.59	64.31	192.93
5	0.00	0.00	32.15	21.44	53.59
6	0.00	0.00	10.72	21.44	32.15
Average	**0.00**	**3.57**	**28.58**	**41.09**	**119.69**
Corrected	**0.00**	**2.68**	**18.76**	**26.80**	**40.19**

Simulation II
Volumetric Loss of Primary Bearings

	Number of Cycles (x 10^6)			
	0.0	1.0	2.5	5.0
	UHMWPe			
Component	Volume Loss (cubic mm)			
1	0.00	3.22	5.36	33.23
2	0.00	0.00	5.36	5.36
3	0.00	0.00	0.00	0.00
Average	**0.00**	**1.07**	**3.57**	**12.86**
	Hylamer			
Component	Volume Loss (cubic mm)			
1	0.00	0.00	15.01	20.36
2	0.00	0.00	4.29	3.22
3	0.00	2.14	10.72	15.01
Average	**0.00**	**0.71**	**10.00**	**12.86**

REFERENCES

1. Mow, Van C., and Hayes, Wilson C. *Basic Orthopaedic Biomechanics.* New York: Raven Press, (1991).

2. Pappas, Michael J.: "Wear in Metal-Plastic Joint Replacement". Mobile Bearing in Knee Replacement Meeting. February 1-2 (1993).

3. Peterson, C.D., Hillberry, B.M., and Heck, D.A.: "Component Wear of Total Knee Prostheses Using Ti-6Al-4V, Titanium Nitride Coated Ti-6Al-4V, and Cobalt-Chromium-Molybdenum Femoral Components". *Journal of Biomedical Materials Research.* vol. 22, pp. 887-903, (1988).

4. Dumbleton, John H.: "Wear and Prosthetic Joints". *Joint Replacement Arthroplasty.* vol. 6, pp. 47-57.

5. Buechel, FrederickF., and Pappas, Michael J.: "The New Jersey Low-Contact-Stress Knee Replacement System: Biomechanical Rationale and Review of the First 123 Cemented Cases". *Archives of Orthopaedic and Traumatic Surgery.* vol. 105, pp. 197-204, (1986).

6. Buechel, Fredrick F., and Pappas, Michael J.: "New Jersey Low Contact Knee Replacement System: Ten Year Evaluation of Meniscal Bearing". *Orthopaedic Clinics of North America.* vol. 20, pp. 147-177, April (1989).

7. Walker, Peter S.: "Requirements for Successful Total Knee Replacements". *Orthopaedic Clinics of North America.* vol. 20, pp. 15-21, January (1989).

8. Buechel, Fredrick F., and Pappas, Michael J.: "Biomechanics and Design Rationale; New Jersey LCS Knee Replacement System". Depuy Sales Training Seminars. (1993).

9. Buechel, Fredrick F., and Pappas, Michael J.: "LCS White Paper #1". *Biomedical Engineering.* November (1992).

10. Jones, S. M. G., Pinder, I. M., Moran, C. G., and Malcolm, A. J.: "Polyethylene Wear In Uncemented Knee Replacements". *The Journal of Bone and Joint Surgery.* vol. 74-B, pp.18-22, (1992).

11. Engh, Gerard A., Dwyer, Kimberly A., and Hanes, Cheryl K.: "Polyethylene Wear of Metal-Backed Components In Total and Unicompartmental Knee Prostheses". *The Journal of Bone and Joint Surgery.* vol. 74-B, pp. 9-17, (1992).

12. Buechel, Fredrick F., and Pappas, Michael J.: "LCS White Paper #2". *Biomedical Engineering.* November (1992).

13. Shaw, J. A., and Murray, D. G.: "Knee Joint Simulator". *Clinical Orthopaedics and Related Research.* vol. 94, pp. 15-23, (1973).

14. McLean, C. A. and Ahmed, A. M.: "Design and Development of Unconstrained Dynamic Knee Simulator". *Journal of Biomechanical Engineering.* vol. 115, pp.144-148, May (1993).

15. Szklar, O., and Ahmed, A. M.: "A Simple Unconstrained Dynamic Knee Simulator". *Journal of Biomechanical Engineering.* vol. 109, pp. 247-251, August (1987).

16. Yoshii : "Patellar Position and Tracking". *Clinical Orthopaedics and Related Research.* vol. 275, pp. 211-219, February (1992).

17. Pappas, Michael J. and Makris, George: "Simulation Study of the Lateral Loading Wear of the LCS A/P Glide Tibial Components". June 6 (1994).

18. Pappas, Michael J., Makris, George, and Buechel, Fredrick F.: "Wear in Prosthetic Knee Joints". Scientific Exihibit, 59th Annual Meeting of the AAOS, Washington D.C.. (1992).

19. McKellop, H., Clarke, I., Markolf, K., and Amstutz, H.: "Wear Characteristics of UHMW Polyethylene: A Method for Accurately Measuring Extremely Low Wear Rates". *Journal of Biomedical Materials Research.* vol. 12, pp. 895-927, (1978).

20. Pappas, Michael J., Makris, George, and Buechel, Fredrick F.: "Comparison of Wear UHMWPe Cups Articulating With Cobalt-Chromium and Titanium-Nitride Coated Titanium Femoral Heads". *Society of Biomaterials.* vol. 3, May (1990).

21. Pappas, Michael J.: "Wear in Metal-Plastic Joint Replacements". Presented at the Mobile Bearings in Knee Replacement Meeting, Redhill England. February (1993).

22. DePuy DuPont.: "Hylamer-M® in the AMK Total Knee System: Addressing the Issue of Polyethylene Destruction". *DePuy DuPont Orthopaedics.* (1992).

23. Wright, T.M. and Bartel, D.L.: "The Problem of Surface Damage in Polethylene Total Knee Componenets". *Clinical Orthopaedics and Related Research.* vol. 205, pp. 67-74, April (1979).

24. Pappas, Michael J., Makris, George, and Buechel, Fredrick 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. (1986).

25. 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, pp. 1041-1051, September (1986).

26. Rose, Robert M., Ries, Michael D., Paul, Igor L., Crugnola, Aldo M. and Ellis, Edward: "On the True Wear Rate Of Ultra High Molecular Weight Polyethylene in the Total Knee Prosthesis". *Journal of Biomedical Materials Research*. vol. 18, pp. 207-204, (1984).

27. 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).

28. Wright, Timothy M., and Rimnac, Clare M.: "Ultra-High-Molecular-Weight Polyethylene". *Joint Replacement Arthroplasty*. pp. 37-45.

29. 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).

30. Weightman, B., Isherwood, D.P. and Swanson, S.A.V.: "The Fracture of Ultra High Molecular Weight Polyethylene in the Human Body". *Journal of Biomedical Materials Research*. vol. 13, pp. 669-672, (1979).

31. Rostoker, B.: "Some New Studies of the Wear Behavior of Ultra High Molecular Weight Polyethylene". *Journal of Biomedical Materials Research*. vol. 10, pp. 303-310, (1976).