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The morphology of UHMWPE wear debris generated by a hip joint simulator

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ABSTRACT

THE MORPHOLOGY OF UHMWPE WEAR DEBRIS GENERATED BY A HIP JOINT SIMULATOR

by
Aaron P. Essner

The size, quantity and shape of total hip replacement wear debris may identify wear mechanisms as well as play a role in osteolysis. Characterization of wear particles generated from a hip joint simulator was conducted followed by comparison with literature reported in vivo results. The effect of counterface material and lubricant type on particle morphology was assessed. Biomaterial pairs including UHMWPE articulated against CoCr, Alumina and Zirconia were considered. Deionized (D.I.) water and bovine serum were used as lubricants. Particles generated from Alumina/UHMWPE in serum were slightly larger than those for CoCr and Zirconia against UHMWPE in serum. Particle shape for these materials in serum were similar, with two types including a round or egg shaped submicron one and an elongated fibrous 1-2 micron one. Particles from CoCr against UHMWPE in D.I. water were flake like in shape and in the millimeter size range with some in the 5 micron range as well. The water condition produced particles dissimilar to the others. Literature reported clinical findings supported the particle types and sizes generated under serum while those generated in water were not supported in the literature. The in vitro simulator was found to accurately reproduce in vivo wear mechanisms under serum lubrication based on debris characterization results.

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by
Aaron P. Essner

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THE MORPHOLOGY OF UHMWPE WEAR DEBRIS GENERATED BY A HIP JOINT SIMULATOR

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CHAPTER 1

INTRODUCTION

1.1 Objectives

Wear has become a major concern in the use of prosthetic hip replacements. Results from joint simulators used to study wear have been questioned regarding the type of wear mechanisms they produce. It is therefore the objective of this study to characterize wear debris produced in a hip joint simulator and use this information to assess the validity of a simulator. This can be accomplished through comparison of particle morphology with in vivo findings reported in the literature. If valid, the simulator would be expected to produce a similar particle morphology to in vivo findings. In addition the effects of lubricant and counterface material will also be considered. A process of particle isolation has been developed for this purpose.

1.2 Introduction

In today's society technology has advanced to the point where replacement of the joints of the body is possible, with dates reported as early as 1939 [1]. In fact total joint replacement (TJR) and especially total hip replacement (THR) has become somewhat common. The need for replacement surgery stems from several medical problems including joint disease such as osteoarthritis. Trauma from automobile accidents or sports injuries for example is another factor necessitating THR [2]. Functionality is usually restored and pain relieved but long term success has been variable and is of concern. However, despite the progress that has been made today's prosthetic joint implants are not ideal and problems often develop among patients. These problems include adverse tissue reactions that can lead to loosening and eventual failure of the implant, especially in total hip replacements [3,4,5,6,7,8,9]. Particle debris released from

wear has been implicated as playing a role in implant failure through loosening and pain [3,4,5,6,7,8,9]. Recent attention from the joint replacement field has been focused on this problem, and a probable cause has been identified which will be described later.

A total hip replacement involves two components, usually composed of two separate materials. These components are a femoral stem with a spherical head, and an acetabular cup usually including a liner and an outer shell. Materials generally associated with these components include CoCr (cobalt chrome), Ti (titanium), ceramics and stainless steel as well as UHMWPE (ultra high molecular weight polyethylene) [2]. The hip stem and outer shell are generally metal and the acetabular cup liner is generally a polymer. A head, usually CoCr, is fitted on the stem with a radius matching that of the cup liner and the two components are mated together forming an articulating surface. A ball and socket joint is formed allowing a wide range of motion. The most common arrangements seen clinically are a CoCr or Ti stem with a UHMWPE shell liner and a CoCr shell [2]. The stem usually takes an anatomical form while the cup is usually a semi-sphere with a convex outer surface and a concave inner surface.

1.3 Wear

Wear and wear debris have become important factors in long term clinical success of THRs [10]. When any two surfaces come in contact with each other under motion and loading, wear is experienced [11]. Wear can take many forms but generally involves the removal of surface material from one or both of the articulating surfaces. Although wear can take place on both of the surfaces involved, the majority of the wear is experienced by the softer of the two materials, which is usually UHMWPE [12]. Wear has been clinically identified to varying degrees on the articular surface of UHMWPE but may also occur on the outer non-articulating part of the UHMWPE liner [13,14,15,16,17,18]. Regardless of source location the removed material often takes the form of small particles

and it is these particles that have been identified as a possible biological instigator for THR failure. It has been proposed that wear products in the form of small wear debris can induce tissue reaction [3,4,5,6,7,8,9]. A hypothesized process for implant failure due to wear particle debris will be described below, but the underlying mechanisms for the generation of the particles will be described first. The specific mechanisms whereby material is removed are still under heavy investigation but several commonly suspected mechanisms will be outlined here.

Adhesion, abrasion, fatigue, penetration, delamination and brittle fracture have all been suggested as wear mechanisms in THRs [11,13,14,15]. For various reasons including geometry and loading as well as material properties, abrasion ,adhesion and fatigue seem to be the most likely mechanisms [13].

Abrasion is a wear mechanism due to three body wear, caused by contaminant or third body particles being trapped between the articular surfaces [11,14]. The result of this wear mechanism is the scratching often seen on wear surfaces. Under this mechanism material may be removed from the softer polymer surface if a third body hard particle becomes trapped between surfaces under loading and motion. The hard particle would generally be pushed into or across the polymer by the harder articular surface causing plowing, cutting and gouging which have been seen clinically [12,13,14,18]. Wear debris from the polymer could be produced as a result of this process.

Adhesion is a wear mechanism that involves the microscopic surface of one material adhering to the surface of another at contact points between interfering asperities [11,13,14]. These asperities are microscopic protrusions characteristic of the surface roughness of a material. Adhesive wear usually results in a film of the softer material being transferred to the harder counterface. This is due to stronger bonding at the articular interface between the two materials than within the bulk of the softer polymer material itself [11]. The result is a shear induced tearing and removal of polymer bulk

material onto the counterface or even onto a preexisting film. If lubrication is present transfer films do not appear to form to the classical extent, that is on a large scale or the macro level. A fair degree of lubrication may be assumed in the THR application, leading to the further assumption that a pure adhesive wear mechanism is probably not acting. In fact Nusbaum has indicated that adhesive wear would generate rather large wear particles in the 1 mm range [13]. Since these were not observed it was again concluded that pure adhesion probably does not occur under normal lubricated conditions for the current application.

A form of adhesion, on a micro rather than macro level may be present nonetheless. If the lubrication mode was a boundary one occurring due only to molecular films of lubricant attached to each surface, a significant degree of asperity contact could still occur [11]. This is because the lubricant film would not be thick enough to prevent the larger and taller asperities of each surface from contacting. The overall result would be a partial adhesive wear mechanism and the subsequent formation of particles. These particles could form if the polymer contact area adheres to a counterface asperity. Articulation would cause a shearing motion and the polymer could undergo elastic and plastic deformation with eventual shear rupture and subsequent particle release at the adhesive junction. This action may not occur due to one contact between asperities but may take many repeated contacts as provided by cyclic articulation

Adhesion of some type could also occur at sights of imperfections such as protrusions or folds on the polymer surface if the lubricant film were to break down at these contact spots. Surface irregularities such as machining marks and material pile ups due to abrasion could provide these imperfections resulting in areas predisposed to adhesion assisted particle formation [14,19]. These irregularities would provide high spots on the polymer surface where contact with the counterface would be ensured. Partial adhesion of the polymer contact area to the counterface due to insufficient lubrication could occur

as described above. Release of the particles could be caused by shear or tensile rupture due to ductile failure. Fluid shear from the lubricant may be important as well.

A fatigue mechanism may also contribute to wear and its subsequent debris. In this mechanism surface cracks could result from elastic tensile stresses placed on the polymer surface [13]. It was suggested debris generated from such a mechanism may be large [13]. Surface cracking has been noted clinically and could be the consequence of a fatigue type mechanism [20]. Other researchers did not see cracking however so the role of a pure fatigue mechanism is questionable [12,18]. Nonetheless, if fatigue took place particles could be produced at junctions where several cracks crossed with debris size depending on crack geometry.

Even though the role of pure fatigue is debatable several fatigue related wear mechanisms have been proposed. An abrasion assisted fatigue mechanism was suggested by Nusbaum for instance [13]. Another type of fatigue mechanism has been suggested by Wang et al.. [21]. Under contact, plastic deformation occurs in the softer material in regions of surface asperity contact. If the contact is lubricated and a cyclic motion is enacted, the asperity contact points may be seen to undergo a process of plastic strain accumulation, also called plastic ratcheting. A particle would probably not result from a single asperity contact due to limitation of true adhesion by the lubricant. It would therefore take repeated asperity contacts to accumulate enough strain to cause particle generation through material failure. Repeated asperity contact is provided under cyclic articulation conditions. In this model strain would simply accumulate in a region until rupture and subsequent particle release occurred. This theory also suggests that a rippled effect would form on the wear surface and particle generation would be on the scale of the ripple spacing, most likely micron in size. The existence of the ripples was confirmed by scanning electron microscopy of a worn cup surface. These surface ripples could be considered as articulation generated imperfections and could therefore be sites

predisposed to the same type of adhesion assisted particle generation method already described.

A surface appearance similar to Wang's ripples was noted by Rostoker et al. who called them folds [12]. A theory regarding the formation of this surface phenomenon including particle release was described. Particle formation may start initially as elastic deformation of the UHMWPE due to local contact with the counterface surface roughness asperities. Deformed material can then create a bulge around the local contact area. If a shearing motion is then enacted, the material bulge would be further deformed in the direction of motion as the counterface alternately slips and adheres to it. Cold flow could cause a fold to form. Further motion and subsequent deformation would then result in fold thinning and formation of a film. Adhesion to the counterface during further shearing translation could eventually cause the thin folded material to yield and tear away from the substrate forming a wear particle. This type of mechanism would depend heavily on adhesion though, which has already been questioned.

True wear in THRs is probably a combination of adhesion, abrasion and fatigue and possibly other mechanisms. The appearance or dominance of a certain type of mechanism probably depends on clinical, design and patient factors. One fact is common to wear regardless of the mechanism however. Wear debris and wear particles are inevitably produced as a consequence of two materials coming in contact under load and motion. Much of the literature has implicated this debris in the failure of THRs as will be described below.

1.4 Biological Response

Failure is often caused by aseptic loosening, migration of the implant, pain and or infection, all of which have been associated with polymeric wear debris [3,4,9]. It has been suggested that particles may be completely benign, but evidence has been presented

that indicates tissue reaction and loosening may result from the presence of wear debris particles [3,4,5,6,7,8,9]. Particles of UHMWPE have been suggested as the dominant type of wear debris found clinically so it is these particles in particular that are drawing attention [12].

The failure of THRs due to aseptic loosening is caused by a loss of fixation within the bone of the femur or acetabulum. Loosening has been explained biologically as bone destruction at the implant/bone interface due to foreign body reaction [4]. This destruction leaves a once press fit with less support allowing the implant to move or migrate, with the loss of fixation defined as aseptic loosening. The destruction of bone stock has been termed bone resorption or osteolysis. It is in the development and progress of osteolysis that particulate debris, especially UHMWPE debris, has been suspected. An adverse biological inflammatory reaction may be enacted in tissue surrounding an implant due to the presence of wear products in a concentrated amount [3,4,5,6,7,8,9]. Purely mechanical loosening theories specifying stress phenomena such as stress shielding or possibly over stressing of the bone around an implant have been proposed, but there is much evidence supporting the primary role of a biological mechanism [4]. Factors important to the mechanism of loosening enacted by wear debris have been found in the literature as described below.

Particles of UHMWPE have been identified within joint capsule and implant interfacial tissue [3,4,6,7,8,9]. These particles have been seen both extracellularly and intracellularly, usually in association with foreign body inflammatory response cells called macrophages [3,4,6,7,8,9]. There are two types of macrophages, both mononucleated histiocytes and multinucleated giant cells, and particles are usually found within the histiocytes and surrounded by the giant cells [3,6,7,8,9]. The size of the particle seems to have relevance on whether it will be engulfed or surrounded [5,7].

There also appears to be a link between the amount of UHMWPE debris and number of histiocytes present [3].

Factors common among researchers from the literature included identification of the presence of macrophages, both mononucleated histiocytes and multinucleated giant cells, in association with the presence of UHMWPE wear debris [3,6,7,8,9]. These cells have been associated with an inflammatory response leading to loosening [3,5,6]. In fact macrophages have been linked to the osteolytic process [3,4,5,6]. This link has been established through the identification of osteolytic inducing enzymes released by the macrophage cells [5]. These enzymes may include collagenase, prostaglandin E2 and interleukin-1 [3]. Despite its high biocompatibility, engulfed UHMWPE particles appear to be able to stimulate a bone resorption process, most likely through these enzymes [5,6]. It is for this reason that particle size is important. Small particles that cells are able to engulf may cause the cell to release these enzymes and for this reason may be more detrimental than larger particles. In addition to the size, both shape and quantity of particles present seem to be important [5,6,7].

It is an inevitable consequence of articulation to generate wear and wear particles. It can be assumed that any debris generated will end up in tissue around the implant. It can also be assumed that some of this debris will eventually be carried to the lymph nodes, and possibly enter the blood stream where it can travel throughout the entire body [6,9]. The fact that debris has been found in the lymph nodes indicates that the body does have some type of particle removal system. The ability of this system to remove particles may be limited however, indicating the relevance of particle quantity [5,22]. Amounts of particles in excess of the removal system's output would remain in the area near the implant.

A biological process of loosening due to particulate debris has been outlined by Pizzoferrato and is as follows [7]; Wear particles are first phagocytosed by fibrous joint

capsule cells which is followed by drainage through the joint capsule to the lymphatic system. If too many particles are present for removal on the internal capsule surface a granulation tissue reaction is enacted. Necrosis or tissue death then occurs in the granulation tissue contacting the implant surface. The necrotic tissue is formed into masses causing further granulation tissue response. Particles released from the necrotic masses help fuel the cycle as well. Eventually, the granulation tissue can no longer store all the particles and necrotic tissue so additional granulation tissue forms within the fibrous tissue layer found at the bone/implant interface. This additional granulation tissue may form within the bone marrow as well. Bone resorption occurs and once solid bone is replaced with soft granulation tissue. A loss off rigid bone occurs with the resulting loss of bony implant fixation. Loosening is the end result.

Adverse biological tissue response and osteolysis have been attributed to particles of bone cement, ceramic and metal as well, but in many studies the common denominator among cases of loosening was the presence of UHMWPE [4,5]. Thus debris induced loosening can occur in the absence of bone cement, metal or ceramic indicating the importance of UHMWPE wear in the long term fixation of THRs. Material selection, implant design, clinical protocol and post-operative drug treatment are all under consideration as possible solutions to the problem. These factors may help limit debris generation or control tissue reaction, but the exact mechanisms of biological response to foreign body particulate debris must first be explained before a solution can be proposed. Such an explanation would require exact knowledge regarding particle size and shape as well as quantity.

In addition to providing insight into the loosening problem, particle collection and characterization may also help define some of the wear mechanisms acting in specific cases [23]. In fact, measurement of wear debris has been suggested as a possible wear assessment method adding to the importance of debris collection techniques [12,23].

Total wear must equal the amount of particle debris produced. Collection and characterization of debris may also help evaluate in vitro simulation. In vitro simulation has been found to produce similar wear evidence to in vivo samples, so wear debris may help in confirming this finding [12]. The importance of wear debris collection and analysis has thus been established.

The goals of this paper therefore are described as follows. The main goal is collection and characterization of UHMWPE wear debris from an in vitro hip simulator. Debris will be collected from different material pairs to determine if debris from each condition is similar. In addition, comparison of this debris with results found in the literature will be conducted. In this way the ability of an in vitro simulator to duplicate in vivo wear mechanisms can be assessed. Identification of the wear mechanisms acting in vitro may also be possible. The effect of lubricant on the wear mechanisms and their particles will also be considered. Determination of total quantity of particles will not be discussed here however.

1.5 Particle Isolation and Characterization

A search of the literature was performed to establish in vivo as well as other in vitro findings regarding particle size and shape. These findings comprise the standard that the current study will be compared against. Most of the studies found in the literature were histologic in nature, involving light microscopy techniques, although some also used scanning electron microscopy. (SEM) Most used samples of tissue recovered from areas near THRs during revision surgery. Standard techniques for preparing histologic specimens including fixation of tissue samples were used in most cases.

Willert and Semlitsch identified particles in revision tissue with polarized light microscopy [24]. Particle sizes from 0.5 μm to 50 μm were reported with some ranging to 100 μm. Small particles were described as elongated platelets and granules, while

larger ones were said to be splinters, threads, plates and spears. Maloney et al. identified needle like particles 0.1 μm to 10 μm in size with an average of 1-3 μm [25]. Submicron particles were also identified. Shanbhag et al. used a sedimentation and digestion technique to isolate UHMWPE particles [26]. Verification that the particles were indeed UHMWPE was provided by energy dispersive x-ray spectroscopy (EDX) as well as fourier transform infrared spectrometry (FTIR). These techniques involve compositional elemental analysis of the specimen. In the case of EDX analysis, the particles were shown to be similar in basic elemental composition to the SEM carbon stub background. This would be expected if the particles were a polymer since the most frequent basic element contained in its molecular chains is carbon. FTIR showed a spectrum with UHMWPE as the dominant peak. Size was measured from SEM micrographs and was reported as 0.1-2.0 μm with a dumbbell or spherical shape. Clusters 20-50 μm in diameter consisting of smaller particles were also seen. Some cigar shaped longer particles 20-200 μm long with a width of 1-3 μm were reported as well. Schmalzried et al. used polarized light microscopy for histological samples of revision tissue to report filamentous and needle like particles several microns in size [27]. Boynton et al. and Revell et al. both used a similar procedure to Schmalzried with Boynton reporting small and large shards of UHMWPE and Revell describing granules, rectangles, ovoids and flakes up to 50 μm in largest dimension [28,29]. In another paper Revell et al. described literature findings including granules, spears, splinters and threads with some occasional large shavings [30]. The description also included large flakes to fine dust. Sizes were 0.5 to 50 μm in diameter. Bullough and Cooper et al. processed tissue recovered from revisions and used polarized light to describe their findings [5,9]. Bullough saw threadlike particles 1 μm wide and 4-10 μm long while Cooper described large particles up to 80 μm in size. In another study Maloney et al. used a similar method and found submicron to 25 μm sized particles with an average of 0.6 to 0.7 μm [31].

Several additional investigators from the literature also chronicle particle identification. Savio et al. performed an extensive literature search regarding wear debris and summarized in vivo findings with two particles types [16]. Small ones in the 1-5 μm range were granular, round, filamentous, and needle like. Larger ones were 5-25 μm up to 200 μm in the shape of fibres, flakes, spears splinters, and needles. Savio also described in vitro simulator findings reported in the literature. Under these conditions submicron sized particles were often present with some degree of clustering noted. Granular and needle like debris in the 1-50 μm span was reported under bovine serum lubricated joint simulator conditions. Large flakes and particles in the millimeter size range have also been reported. Rose et al. also reported on findings from an in vitro joint simulator [23]. Particles were collected from bovine serum lubricant by denaturing with KOH followed by filtration and ultrasonic ejection into an isoproponal density gradient column. The particles were found to cluster in a layer between 0.93 g/cm^3 and 0.96 g/cm^3 isoproponal solutions. Debris on the order of 1 mm was noted and particles were found to be larger than 100 μm and smaller than 10 μm in general. The goal of the study was volumetric measurement based on areal fractions so no shapes were reported.

Two additional reports regarding particles were reported in detailed papers by Shanbhag et al. and Campbell et al. [32,33]. Shanbhag used a process of digestion, sedimentation and centrifuging on tissue obtained from revision surgery. The composition of the debris recovered was verified as UHMWPE with EDX and FTIR. Spheroids 0.1 to 2 μm in mean dimension were noted as well as fibrils 0.2 to 0.3 μm wide and up to 10 μm long. Cigar shaped particles 20 to 200 μm long and 1 to 3 μm wide were also described. Clustering of the smaller particles was observed. An analysis was also conducted on a base resin sample for UHMWPE (GUR 415) obtained from the manufacturer. This analysis showed small spherules and fibrils, which were shapes found in the wear debris, further confirming the material as UHMWPE. Campbell et al. also

processed tissue obtained from joint revision surgery [33]. The method used was very similar to the one developed for current study as will be described in the next section. Rounded particles 0.07 to 6.3 μm in diameter and elongated particles 0.57 to 12.2 μm in length were found. Most spherical particles were submicron and most elongated ones were in the 0.5 to 3 μm length range generally less than 0.25 μm wide. The fibrous particles were often noted to have "heads". Both FTIR and differential scanning calorimetry (DSC) confirmed the particle material as UHMWPE. DSC did this by applying heat to the material at a specific rate. The melting point indicates what material is present based on reference values.

CHAPTER 2

MATERIAL AND METHODS

The first step in this study was to determine a source for wear particles. Since the particles are generated due to the articulation of THRs, an in vitro hip simulator was selected as a source of particles. The simulator used was electro-servo-hydraulic in nature and provided for the articulation of an artificial joint femoral head against an acetabular cup insert.

The simulator was constructed by MTS systems and was digitally controlled. A detailed paper describing the simulator can be found in the literature but a brief description will be given here [34]. The system consisted of a load frame accommodating eight separate stations with control provided by a remote panel. A schematic of the simulator is shown in Figure 1, and overall operation is similar to that developed by McKellop and Clarke [35]. Figure 2A is a schematic of one station and shows a spigot for fixation of the head above the test chamber. The chamber houses the acetabular cup and is fixed to a rotation block by a bearing. This block has an inclination of 23° and is rigidly fixed to the load shaft. This configuration allows a single shaft to provide simultaneous biaxial motion comprised of rotation and axial loading. Loading is provided by a linear actuator through which the shaft passes, while rotation is imparted to all eight individual station shafts by a motor and planetary gear system. Each station shaft thus loads and rotates each block and the rotation block bearing allows the block to turn without subsequent chamber rotation which is prevented by an anti-rotation pin. Motion of the chamber is provided by the angled face of the rotation block. As the block rotates along with the shaft the angled face causes the chamber to oscillate in an oval motion. The cup was seated in a polyurethane mold which was fixed within the chamber by several dowel pins. A steel collar provided additional support. This is shown in

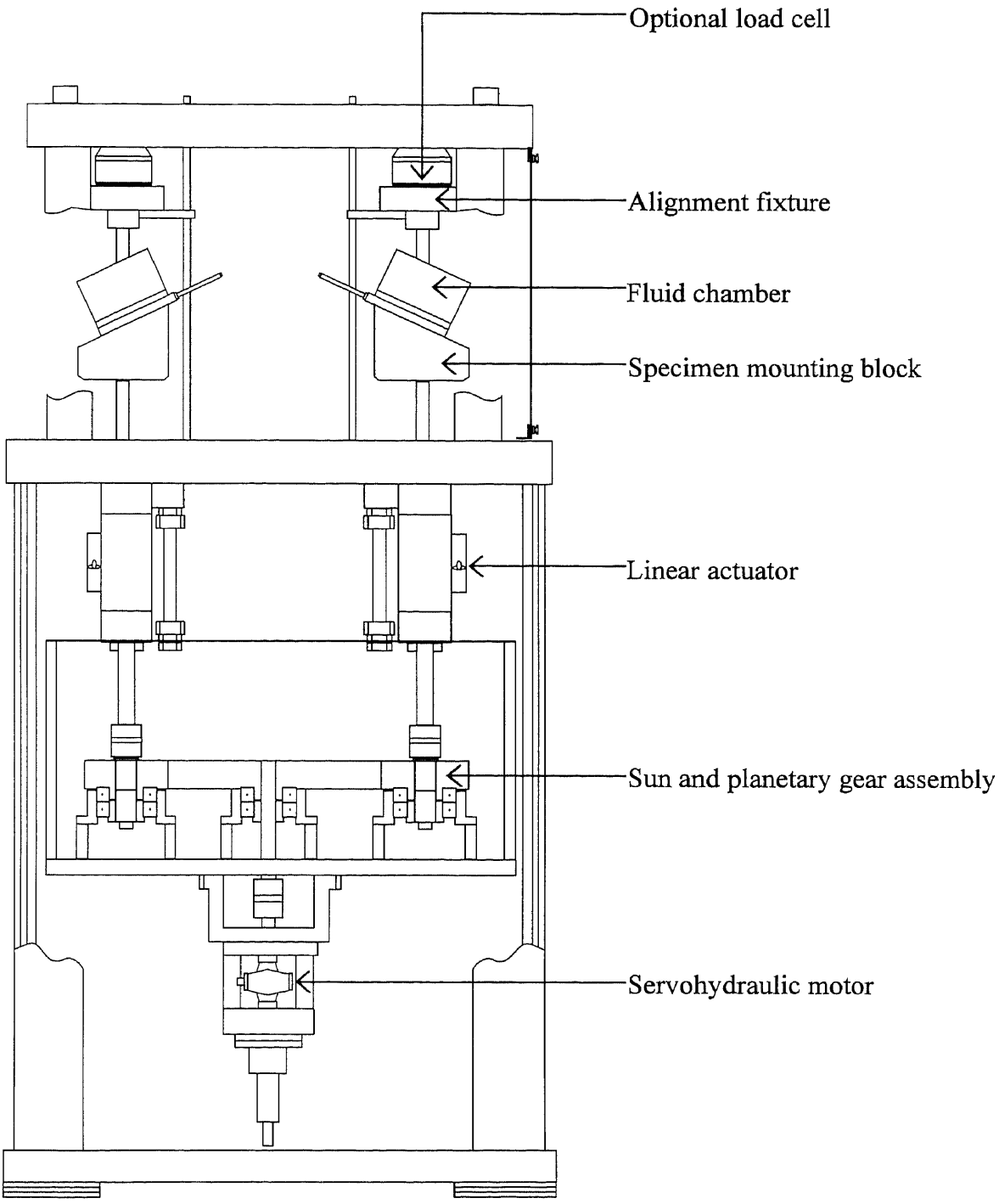


Figure 1. Schematic of MTS/Howmedica Hip Joint Simulator

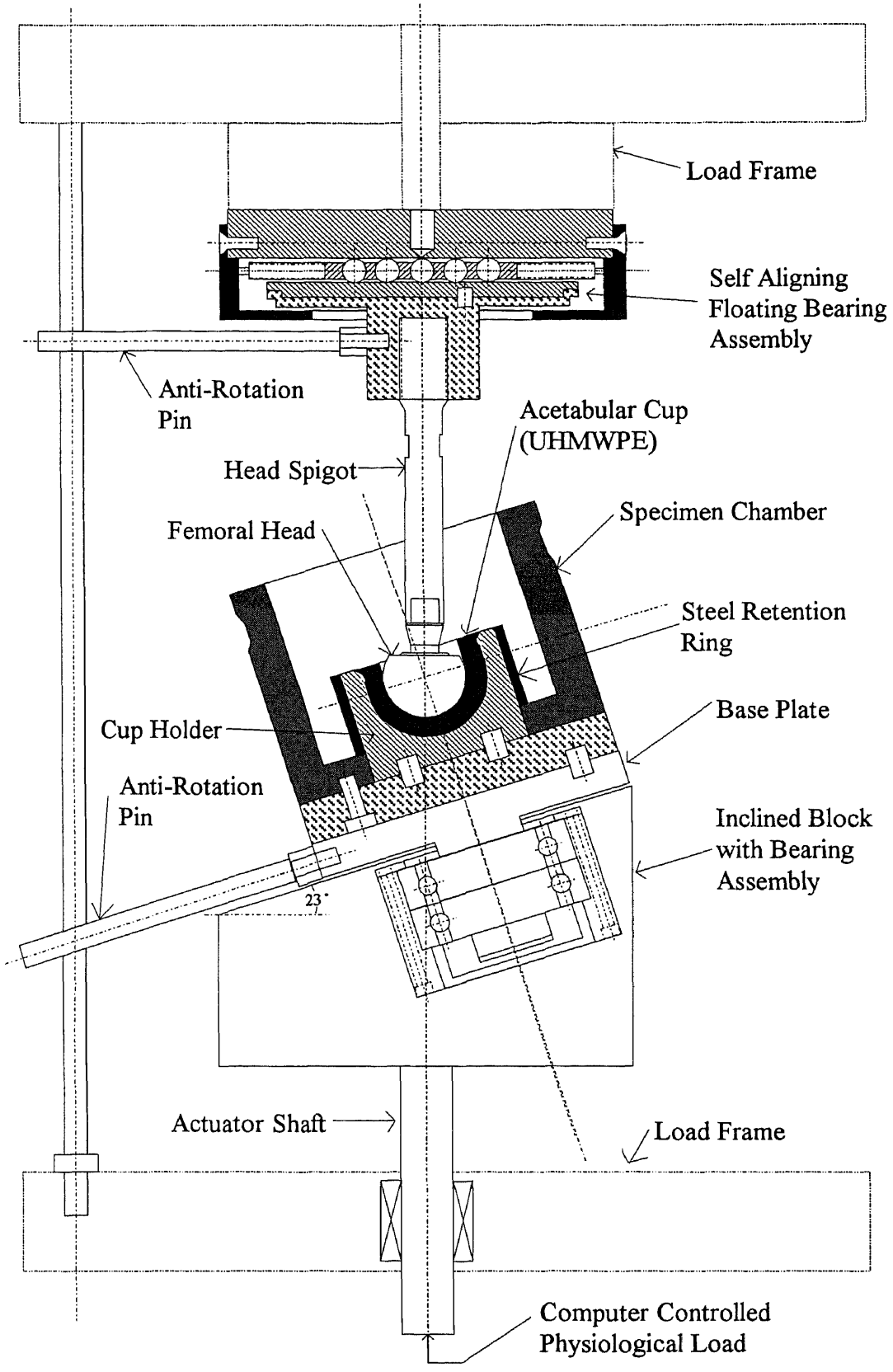


Figure 2A. Schematic of Simulator Showing a Blow Up of the Head/Cup Interface

Figure 2B. Thus articulation follows the same oval motion that the chamber experiences. The head spigot above the chamber is mounted to a floating load bearing, allowing for self alignment. All loading and motion is caused from the load shaft below however, so this point may be considered fixed.

The loading profile used for testing was the physiologic Paul curve with a maximum peak load of 2450 N (550 lbs) and a minimum of 90 N (20 lbs) [36]. This is shown in Figure 3. A frequency of 1 Hz was used for the rotational speed. All heads and cups used were 32 mm in diameter. The heads, cups and test chambers were all ultrasonically cleaned for 30 minutes in a soap solution followed by an additional 30 minutes in deionized (D.I.) water prior to use. The heads and cups had standard industry surface finishes and were unworn prior to use.

The simulator fixturing provided a specimen chamber that was filled with bovine calf serum. (0.3% sodium azide added as an anti-bacterial agent) It was the bovine serum lubricant that was collected as a source of wear debris particles.

A protocol for removing any wear debris present in the serum was developed based partly on an ASTM draft document for particle collection, and partly on methods found in the literature [23,33,37,38]. Serum for several material pairs was first collected. Material pairs of interest included CoCr heads as well as ceramic heads of two types (Alumina and Zirconia) articulated against UHMWPE. In addition CoCr articulated against UHMWPE in a de-ionized water bath was also of interest. The UHMWPE cups used for the trials were machined from an industry standard material (Poly Hi GUR 415). The CoCr heads used were of Vitallium® alloy and the ceramic ones were manufactured by Morgan Matroc Ltd.

All tubes, vials, glassware and tools used were first cleaned ultrasonically in an appropriate cleaning solution (Micro) for 30 minutes and then rinsed and ultrasonically cleaned for an additional 30 minutes in 0.2 μm filtered D.I. water. They were then triple rinsed with 0.2 μm filtered D.I. water before use. All solutions and water used in the

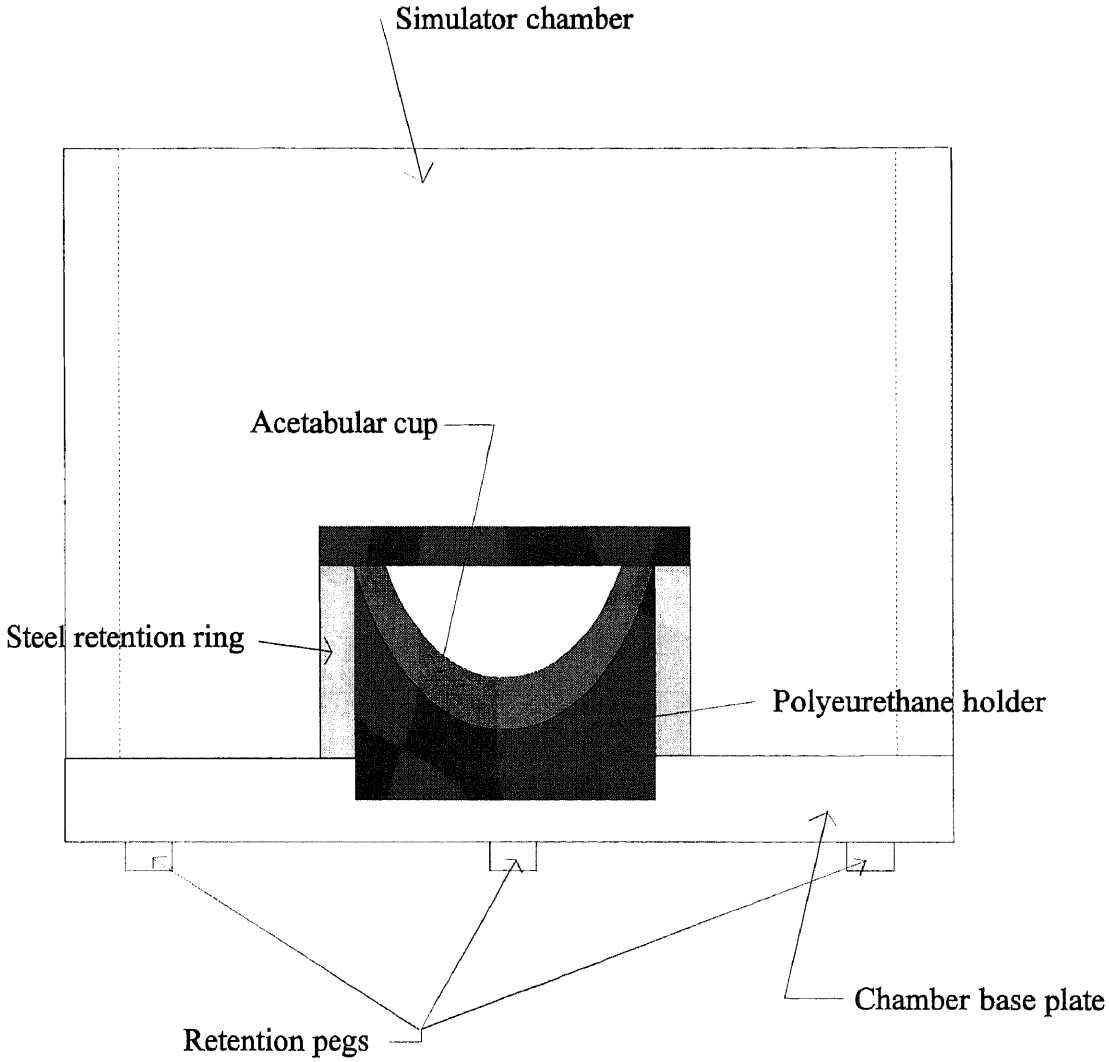


Figure 2B. Schematic Showing Specimen Chamber for Simulator

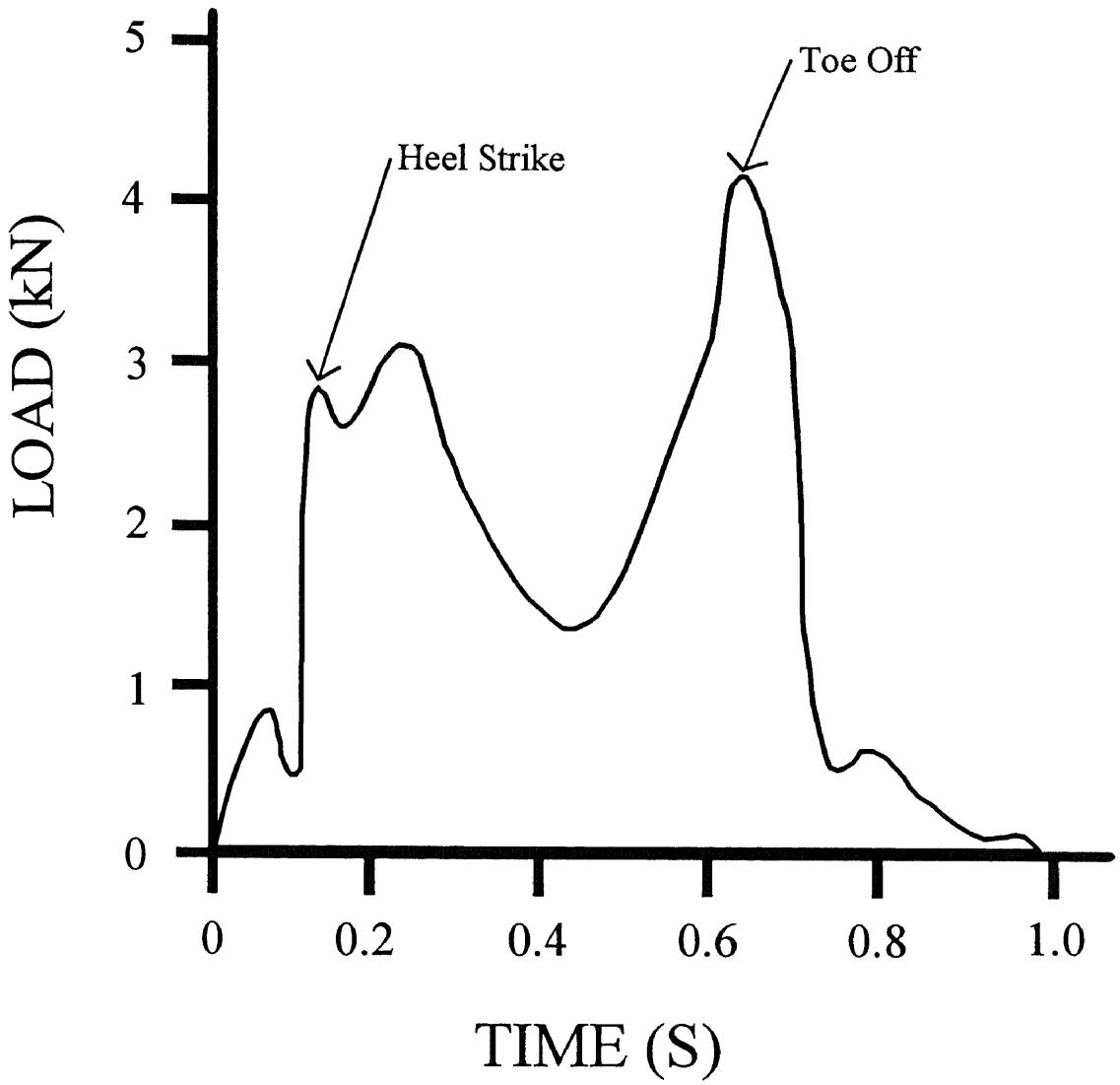


Figure 3. Loading Profile Used for Simulator Testing (Reference [34])

protocol were first filtered through 0.2 μm filters. The filters used for sample deposition were also the same 0.2 μm Nuclepore polycarbonate filters used for all filtering. These filters were used based on their regular and consistent pore structure. Preliminary trials found cellulose filters to be unacceptable due to the irregular surface and hole structure exhibited under SEM analysis. For this reason the Nuclepore filters were selected. Careful cleaning of all apparatus and use of a clean work station were necessary to reduce chances of sample contamination. This was deemed important as expected particle size was sub micron meaning samples could easily be contaminated by air borne dust or debris.

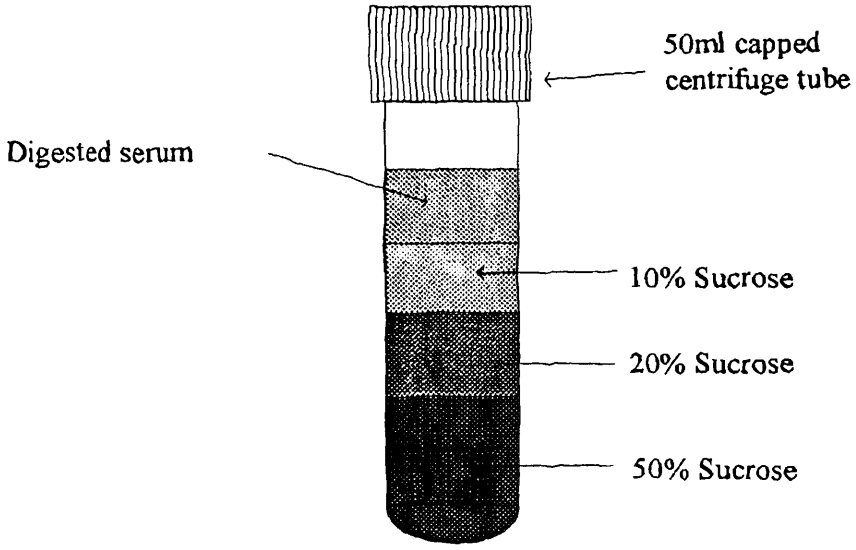
UHMWPE in bovine serum:

1) Approximately 250 ml of serum was collected from an individual hip simulator chamber surrounding one femoral head articulated against one acetabular cup. The serum was collected after a 250,000 cycle interval.

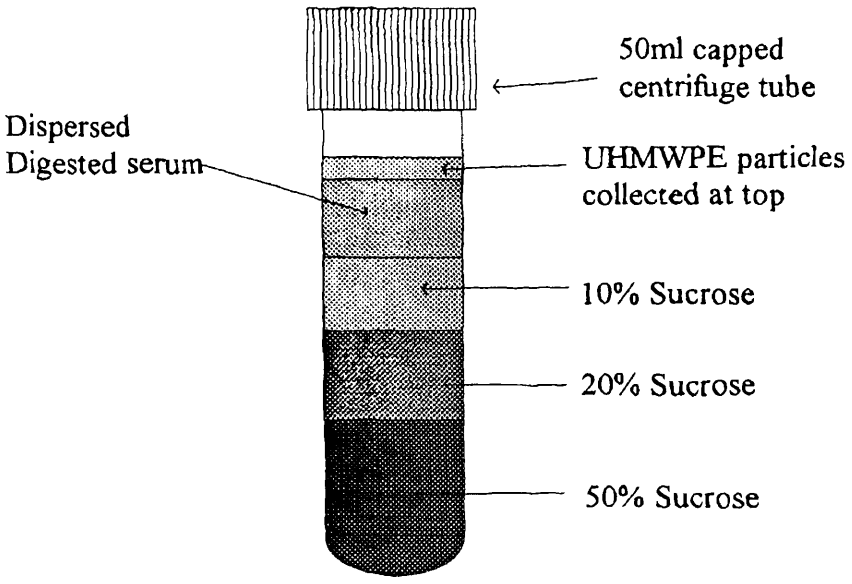
2) The serum was diluted with twice as much 5N KOH (0.2 μm filtered Potassium Hydroxide). This solution was heated to 65°C and stirred on a stirrer/hotplate for 6 hours. The purpose of this step was to digest the serum and remove cellular and protein material.

3) Sucrose solutions with concentrations of 10%, 20% and 50% were prepared and then filtered through 0.2 μm Nuclepore Polycarbonate filters. A variable gradient consisting of 10 ml of each of these solutions was then prepared in 50 ml Pyrex capped centrifuge tubes. Figure 4A shows a depiction of the gradient.

4) A 15 ml quantity of the digested serum was then placed on top of the gradient. The tubes were then placed in a Beckman CS-6 centrifuge and centrifuged at 3600



A. Pre-Centrifuge



B. Post-centrifuge

Figure 4. Schematic of Particle Separation Sucrose

RPM for 6 hrs. Since UHMWPE has a density of about 0.93 g/cm^3, it was lighter than all the sucrose solutions and centrifuging allowed and UHMWPE particles to migrate to the very top of the gradient.

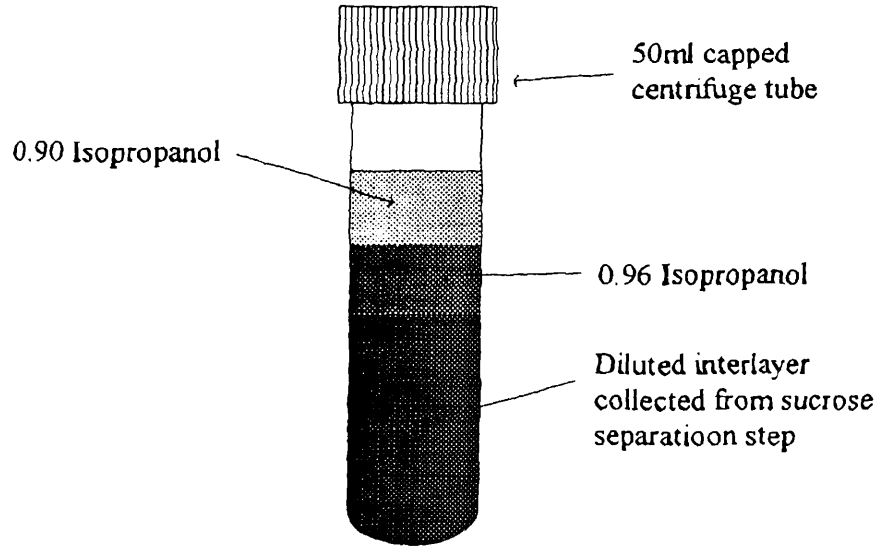
5) After the tubes were removed from the centrifuge, the top layer of the gradient was collected by pipette and was placed into cleaned 50 ml glass capped vials. This top layer generally had an opaque appearance compared to the other layers in the tube. This is illustrated in Figure 4B. The remainder of the original sucrose gradient was discarded.

6) Next 25 ml of hot filtered water was added to the vials containing the top layer. These were then agitated in Cole-Parmer heated ultrasonic cleaner for 1hr at 60°C to remove any adhering sucrose.

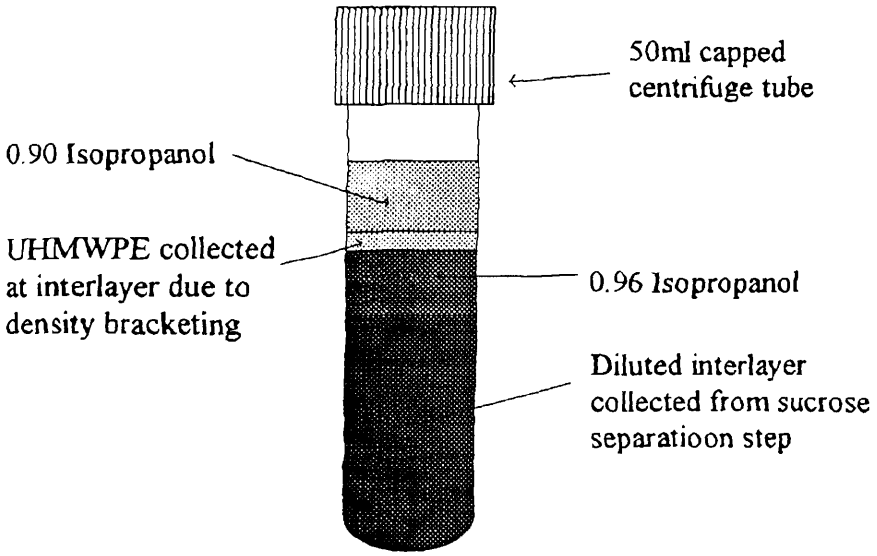
7) The vial contents were then transferred to clean centrifuge tubes and topped with 3 ml each of 0.90 g/cm^3 and 0.96 g/cm^3 0.2 μm filtered isopropanol solutions. These values bracket the density of the UHMWPE. A depiction is shown in Figure 5A.

8) The vials were again placed in the centrifuge and run at 3600 RPM for 2 hrs. This allowed any UHMWPE particles to collect as an interlayer between the two isopropanol layers.

9) The interlayer containing the UHMWPE particles at the interface of the two isopropanol solutions was collected. This region appeared opaque or white in color. It was collected by pipette and placed in clean vials for characterization.



A. Pre-Centrifuge



B. Post-centrifuge

Figure 5. Schematic of Particle Separation Isopropanol Gradient

Figure 5B shows an example of this. Filtered water was added to dilute the interlayer. The remainder of the isopropanol gradient was discarded.

10) Several drops of solution were then placed in the center of a prepared 0.2 μm Nuclepore polycarbonate filter. This is shown in Figure 6. Two filters were used to prevent the primary filter from adhering to the Gelman Analyslide filter holders used. At least two separate samples were prepared for each trial. The covered filter holders were then placed in a Sanpla Dry Keeper auto desiccator for drying.

11) Several days were allowed for complete drying, after which SEM samples were prepared. This was accomplished by carefully cutting the debris deposit area from the filter and placing it on a 0.5 inch round aluminum SEM stub. Adhesion to the stub was provided by a conductive carbon tab. At least two samples were prepared from separate filters. This SEM preparation step was carried out under aClean Room Products Class 100 tabletop clean station. Appropriate clean procedures were followed (gloves etc.).

12) Characterization of the particles was conducted using a software controlled Phillips XL - 40 Scanning Electron Microscope. All samples were first gold coated at 80 mV for 180 seconds in a Bal-Tec SCD 050 sputter coater. Figure 7 shows a schematic of one of these samples. Characterization involved visual identification of particles, including description of approximate size and shape. Estimating the total number of particles present was difficult due to varying degrees of dilution among the various samples.

During characterization SEM micrographs were taken for all samples depicting various fields of view. Each individual micrograph contains information on the specific

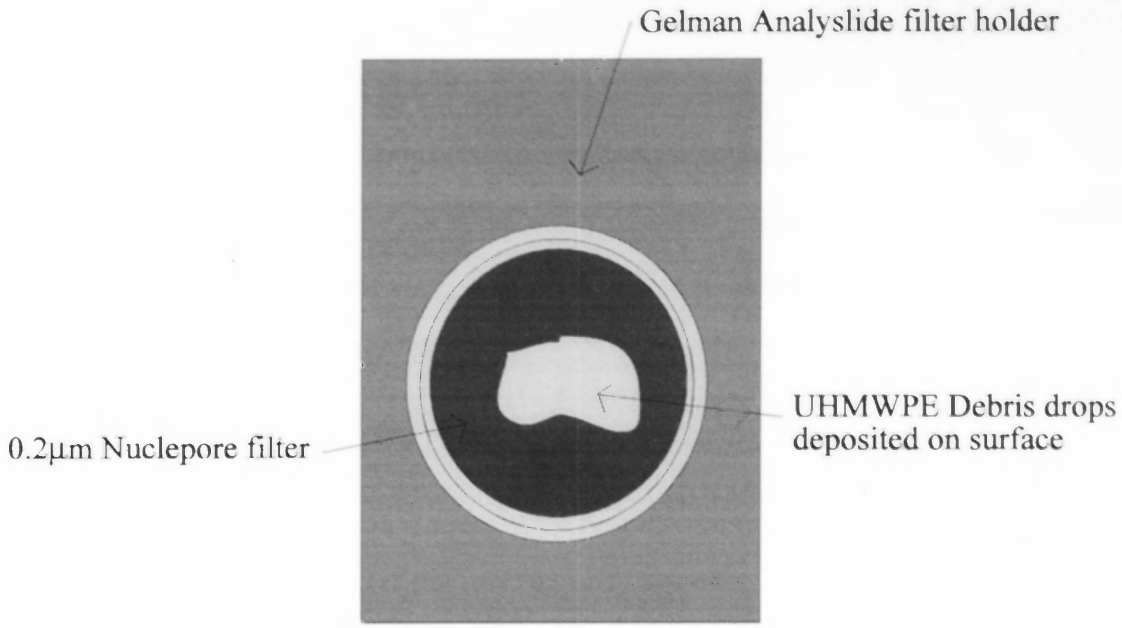


Figure 6. Schematic of filter holder with filter and UHMWPE debris deposited on it

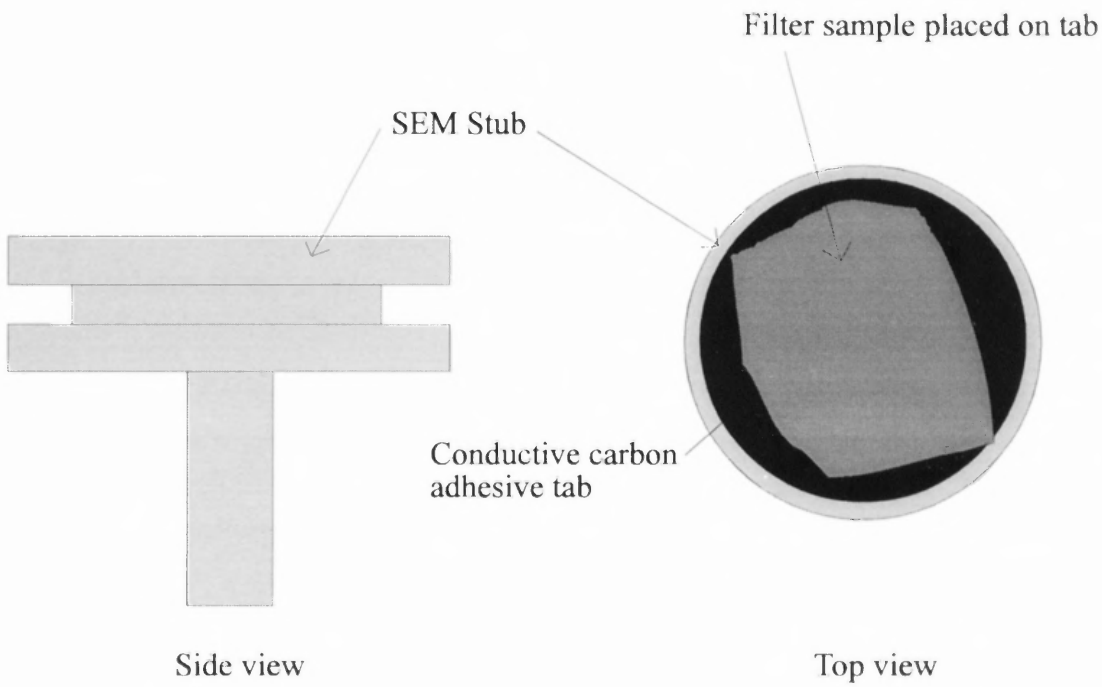


Figure 7. Schematic of SEM stub with debris sample

scale and magnification shown. The scale allows for comparison of particle size of different samples.

A protocol similar to the one already outlined was used for the CoCr - UHMWPE in de-ionized water trial. In fact all steps were identical with the exception of the KOH digestion step. This step was unnecessary and was omitted, as no cellular or protein material was present in the water lubricant.

CHAPTER 3

RESULTS AND DISCUSSION

3.1 Trial 1 - UHMWPE-CoCr in Serum

A standard material pair used in THRs, CoCr against UHMWPE, was used as the standard control for comparison. purposes. This trial proved to be very successful, yielding a vast number of microscopic particles. These are shown in Figures 8A-8Z (see APPENDIX A). These figures show micrographs of the observed particles. The background surface shown is the actual surface of the 0.2 μm filter used for particle collection. The round dark spots that can be noted are the holes in the surface of the filter. Note the very regular and smooth appearance of the filter surface. This allows for easy identification of any particles collected. The particles appear as lighter colored irregular objects resting on the surface.

The micrographs show many small UHMWPE particles, some only just larger than the filter pores. The shapes are quite variable, although two general types can be seen. One of these is comprised of smaller spherical shaped particles (type 1). Some of these appear to be nearly round while others are more oblong or egg shaped with some appearing particularly elongated. These smaller particles are generally much smaller than 1 μm in their longest dimension, with the vast majority even smaller than 0.5 μm. This is shown by comparing the particles to the scale present at the bottom center of each micrograph. Indeed some particles appear to be small enough to just about fit through the filter pores.

The second particle type (type 2) is somewhat larger than the first. These particles generally appear to be 1 μm or larger in their largest dimension, with many in the 2 μm range. The shape of these particles is somewhat different than the smaller ones. These particles appear elongated in shape with their length much larger than their width. The width of these thread like particles can be seen to be smaller than 1 μm in many cases.

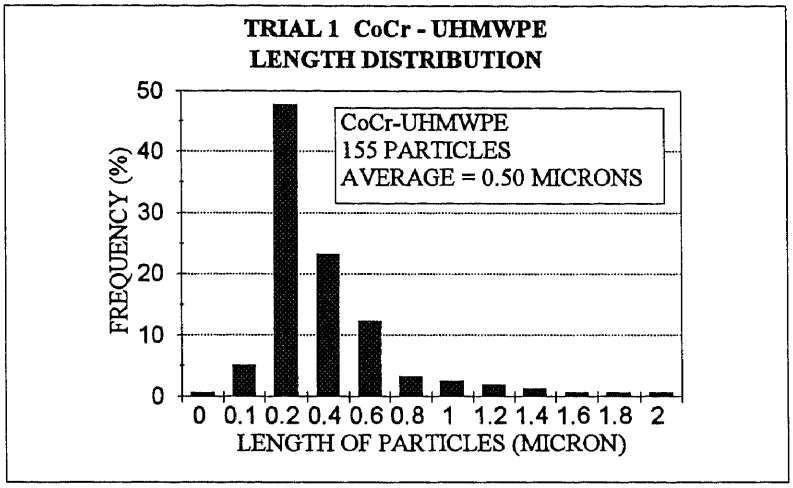
These particles could also be described as shards, fibres or possibly needles. Many appear to have a "head" or a larger bulb shape on one end. Some are curled and some show regions of necking along their length. The micrographs show slightly less of this type of particle.

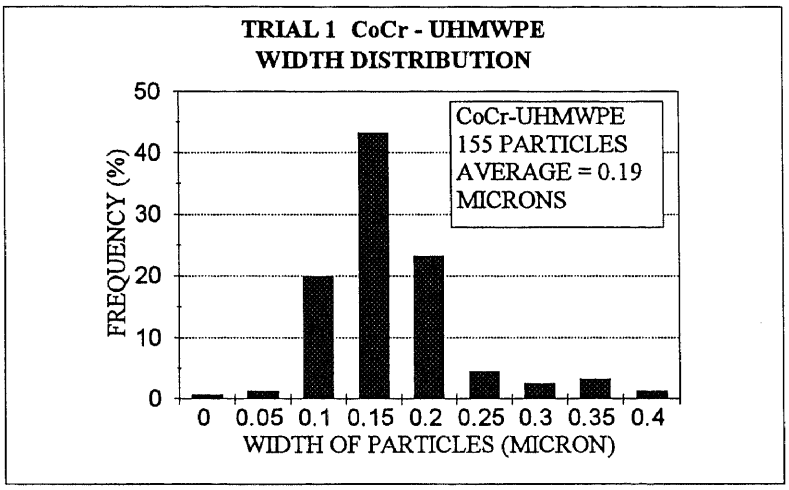
A quantitative determination of size was made by enlarging several randomly selected micrographs that contained a dense population of particles. The micrographs selected were all recorded at a magnification of 20000x and all were then enlarged by 200x. Individual particles were randomly selected on the enlarged micrographs and measured from edge to edge using a digital Mitutoyo caliper. The length was measured as the longest dimension and the width was measured as the widest area of the shortest dimension. The results are shown in Figure 9. This figure shows frequency distributions for the length, width and aspect ratio (l/w) of 155 particles. The average length was seen to be 0.496 μm, with a width of 0.192 μm and an aspect ratio of 3.00. This indicates that an average particle was submicron in size with an elongated shape.

3.2 Trial 2 - UHMWPE-Alumina in Serum

Ceramics have been suggested as alternates to standard CoCr for use in THRs. Increased hardness and improved surface wetability are two reasons for this suggestion, and these factors among others have been hypothesized to cause lower wear rates than CoCr [2]. The performance of these materials regarding wear particle generation is also important however. Improved wear performance may not be the only qualifying factor for alternates to CoCr. If a greater number of smaller particles were produced despite a lower wear rate, possible increased risk of aseptic loosening would also become a deciding factor. For this reason the size and type of wear debris produced by ceramics was analyzed. Alumina against UHMWPE will be discussed first.

The standard protocol already outlined was followed with results pictured in Figures 10A-10N (see APPENDIX B). The interlayer collected from the final centrifuging step





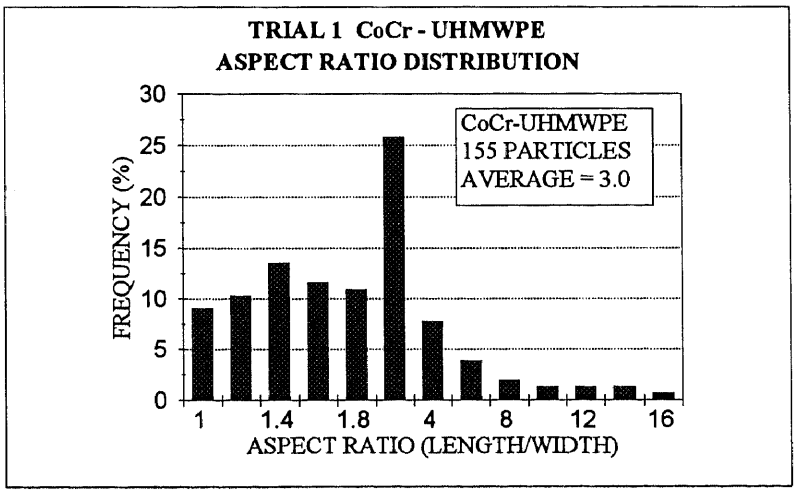


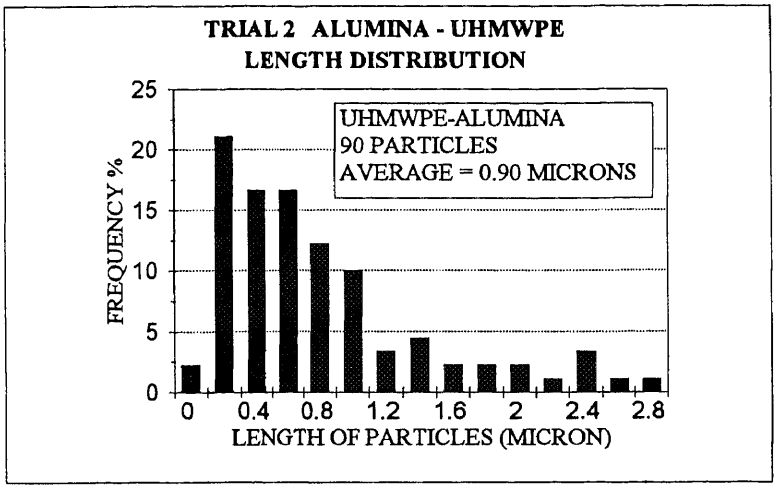
Figure 9. Frequency Distributions for Trial 1

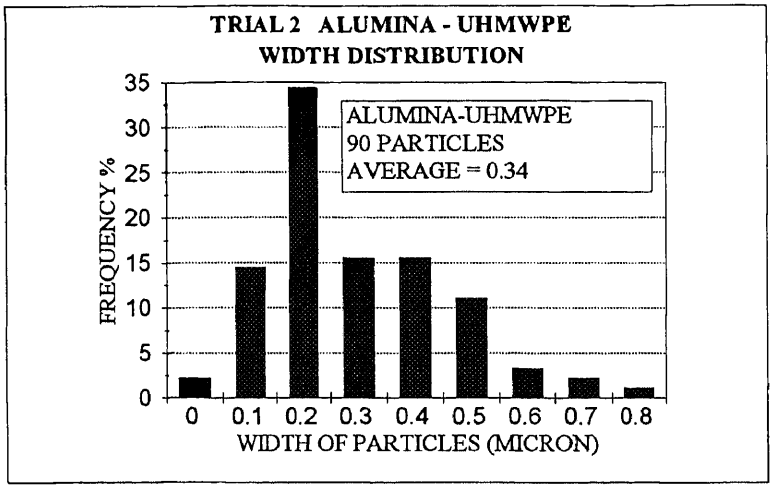
was apparently very diluted as the particles seen were somewhat spread out on the filter surface. The particles observed were similar to those seen for the CoCr control. Two separate particles types were again noted. These included the same small spherical type 1 particles as well as the larger fibrous type 2 particles. The smaller ones were egg shaped or elongated ovals, with a size range of 0.2 μm to about 0.75 μm in largest dimension. These smaller particles appeared to have a slightly less smooth or regular surface than that of the control. The second larger type of particle was also present with similar thread or shard like shapes. The size of theses appeared to range from 1 to 5 μm, with all smaller than 10 μm and they were observed to be curled in some cases. A "head" was also present on some of them, as well as regions of necking. This second particle type was generally larger than the corresponding type seen with the control. It is interesting to note that some of the larger particles (Figure 10N) actually appeared to be agglomerates or collections of smaller particles stuck or fused together. This was generally not observed for the control, which demonstrated reasonable distinction between individual particles.

The approximate average size of a Trial 2 particle was also determined using the same measurement technique already described. Micrographs with a magnification of 10000x were selected and enlarged 200x. A total of 90 particles were randomly selected from several micrographs. The average length of a particle was found to be 0.903 μm, with a width of 0.337 μm and an aspect ratio of 2.97. Frequency distributions are shown in Figure 11. Although these particles averaged a larger size than the control, the average shape was similar if the aspect ratios are considered. This value again indicates the average particle was about 3 times longer than it was wide.

3.3 Trial 3 - UHMWPE-Zirconia in Serum

A second ceramic counterface material other than alumina was also considered as it has received similar attention in wear reduction attempts. This material was zirconia. A full





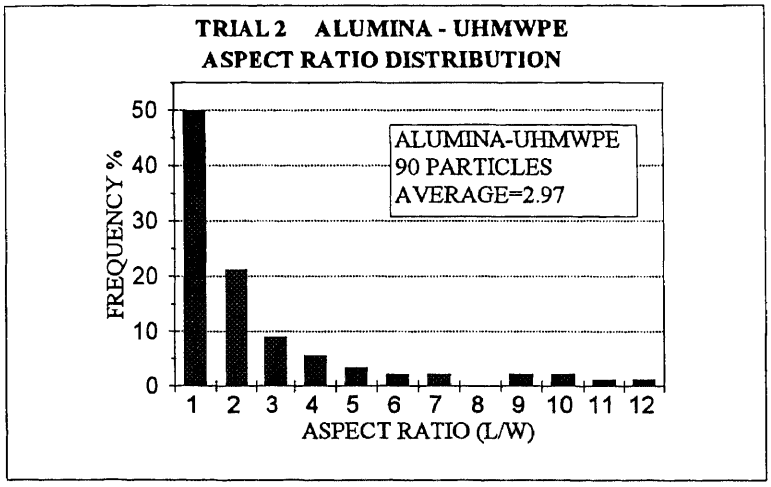
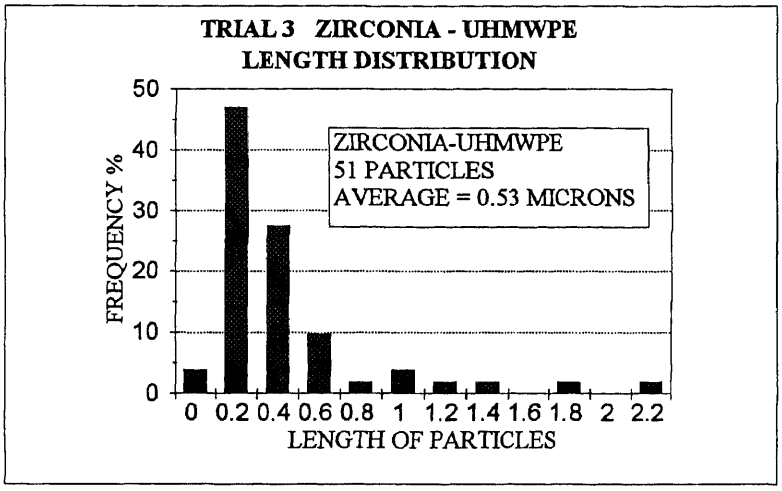
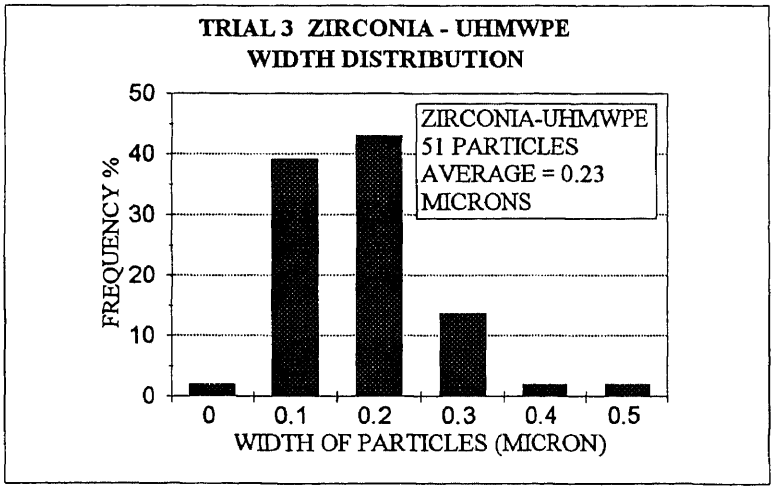


Figure 11. Frequency Distributions for Trial 2

trial was run on serum collected from UHMWPE-zirconia articulation and figures 12A-12M show results (see APPENDIX C). This trial was successful yielding vast numbers of particles. The two particle types already mentioned were again observed. The type 1 particles were observed to be generally smaller than 0.5 μm in largest dimension although some slightly larger ones were noted. All were less than 1 μm in size and many were similar in size to the 0.2 μm pores in the filter surface. The shape of these particles was somewhat regular, displaying a generally oval or egg like shape. They could also be described as pebbles. They were generally seen to posses smooth edges. The second particles type was present as well. These were again shard like or fibrous in shape with a size range of 1 to 5 μm in length. Width was generally less than 0.5 μm. These particles had a less regular shape when compared to the smaller ones and some were noted to be bent and slightly curled. Some necking was also noted with these particles appearing "sperm like". Some particles had the head or bulbous region noted on particles from the other trials. Some larger particles appeared to be clusters of smaller particles as well.

The same approximate sizing method used for the previous trials was again applied to the current one. Several micrographs with a magnification of 20000x were randomly selected and enlarged to 200x. A total of 52 particles were randomly selected and measured yielding and average length of 0.531 μm, an average width of 0.231 μm and an average aspect ratio of 2.27. (Frequency distribution is shown in Figure 13). These sizes are similar to the control although the aspect ratio is lower. This indicates these particles were not as elongated in shape on average. The larger particles noted here appeared similar to the control type 2 particles so the difference must have resulted from the type 1 particles. If these are examined they do not appear as elongated as the control type 1 particles. They instead appear to be slightly more spherical. Clustering was also noted for this trial and this was not seen in the control. The Trial 3 particles were also smaller on average than the Trial 2 ones. On an individual basis particles of both types from both trials appear to be similar. The Trial 3 type 1 particles do appear somewhat smoother





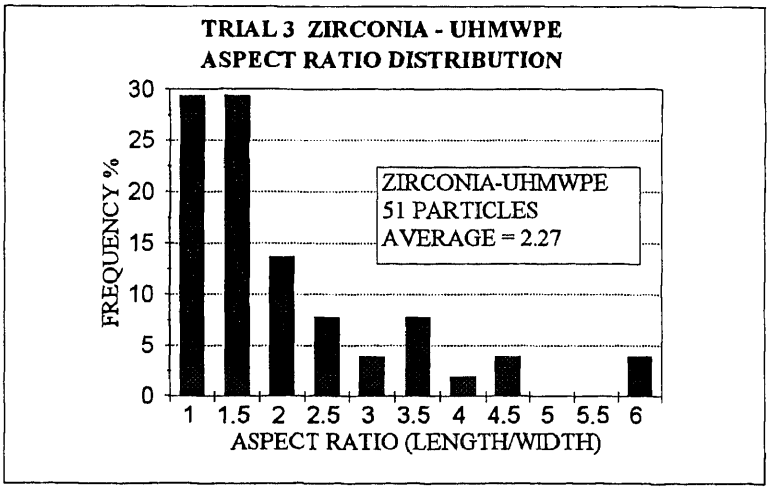


Figure 13. Frequency Distributions for Trial 3

however. A lesser degree of clustering was observed with the Trial 3 particles as well. This clustering may have contributed to the overall larger measured size for the Trial 2 particles. The morphology appears similar.

3.4 Trial 4 - UHMWPE-CoCr in D.I. Water

A trial was conducted on UHMWPE articulated against CoCr in de-ionized water. This was carried out to determine what effect changing lubricant would have on particle generation. The digestion step described in the protocol was omitted for this trial since no protein or cellular material was present to require denaturing or digestion. All other steps were followed however.

The results for this particular trial were somewhat different than the others. During the final isoproponal centrifuging step large pieces of debris could be seen in the interlayer. The micrographs for this trial showing some of these large pieces can be found in Figures 14A-14Z (see APPENDIX D). Several large particles on the order of millimeter size were noted, ranging from 0.5 mm to 2 mm in largest dimension. These particles appear as flakes or sheets of material. Several close ups are shown in figures 14G-14J. The surfaces of these large flakes appear to have cracks and pits as well as pieces of smaller debris adhering to them. If the apparent cracks are closely examined it can be seen that the flakes appear to be comprised of many thin sheets of material pressed together. At least some portion of each large flake is rolled over on itself as well, providing an exposed edge for examination. When the edge is observed the thin layer composition is particularly apparent. As already noted these giant flakes of material were visible by unassisted eye.

A second type of particle not clearly visible was also found. When the surface of the filter was observed many smaller flake like particles were found. These smaller particles appear similar to the small particles adhering to the giant flakes. Sizes for these as shown by the scale in each micrograph are generally around 2-3 μm in largest dimension. These

smaller particles were not as prevalent as the small particles noted in the previous trials, probably due to the fact that the giant flakes would account for most of the wear experienced by the articular surface. A cluster of the small flakes up to 20 μm wide was also noted. Submicron particles were only occasionally seen and one cigar shaped shard was seen as well. An insufficient number of small particles was found to enable the same rough sizing estimate used in the other trials but based on visual observations the overall particle size for this trial was somewhat larger than the others with a probable average of about 2 μm in length. This of course excludes the giant flakes. The predominant shape was also somewhat different from all other trials consisting almost exclusively of flat flake like particles.

3.5 Verification

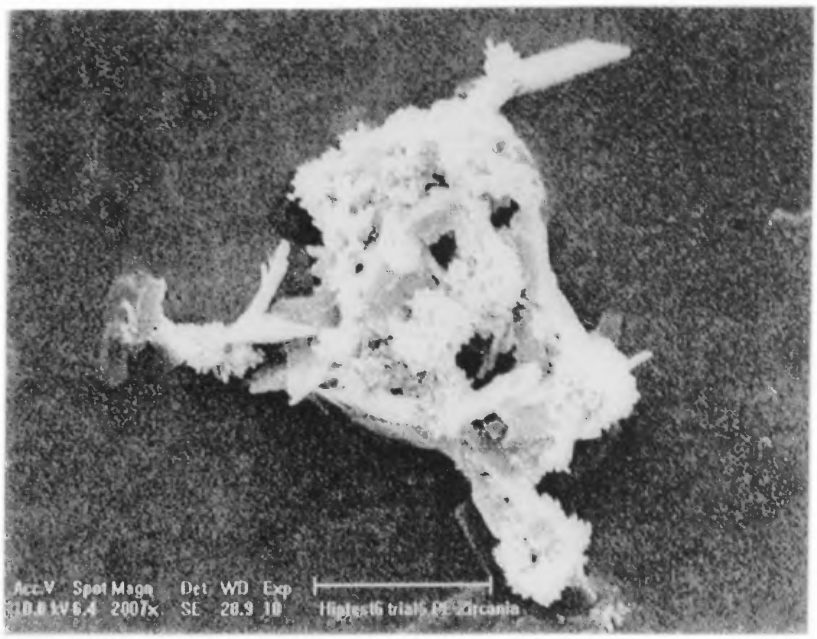
Several verification steps were carried out to determine whether the particles observed in the above trials were actually UHMWPE. As an initial precaution all equipment was thoroughly cleaned and rinsed with filtered water to eliminate contaminants. All pipetting steps and sample preparation was carried out under a Clean Room Products class 100 laminar flow clean station to reduce risk of airborne contamination. These steps should have acceptably reduced contamination risks. Active verification was also conducted.

During the Trial 3 experimental run an interesting development was observed. Upon the final centrifuging step a white spot of material was observed to collect at the bottom of the tube. This step used an isopropanol bracket to collect the UHMWPE particles as an interlayer. This interlayer was observed toward the top of the tube and was treated as already described. Since the spot of material appeared at the bottom of the tube it could not be the lighter UHMWPE seen in the interlayer. A sample of the bottom material was collected and deposited on a filter for analysis, and the same SEM preparations steps used for all trials was followed.

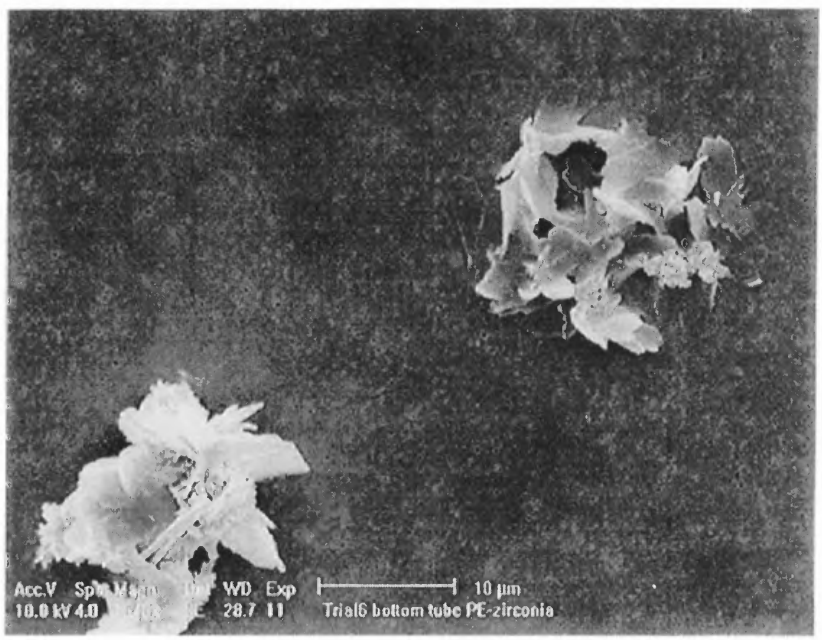
Results from the analysis of the bottom spot are shown in Figures 15A-15E. These figures show a large quantity of flake like particles in the 10 μm range. Many of these have an appearance similar to crumpled pieces of paper. Histological studies have shown that bacteria and other cells will often display this appearance when dried without prior fixation. Since the serum lubricant used is known to contain cellular as well as bacterial material it is assumed that these particles are actually dehydrated cells. This condition could easily be induced during the filter drying step. Since the interlayer that the UHMWPE particles were collected from was within the expected density range, and since these particles did not resemble the artifact particles just described it was assumed that the presumed UHMWPE particles were actually UHMWPE.

A further verification was provided by an EDX or energy dispersive X-ray analysis conducted during SEM characterization. This was accomplished by focusing the microscope on one particular particle and changing the detection mode to x-ray. A Sun Sparcstation equipped with image analysis software was used to display basic chemical element spectrum data. This process was conducted on one of the artifact particles described above. Results are shown in Figure 16. Spectrum peeks can be noted for carbon, gold and calcium. Carbon is a basic element contained by all organic matter and this peek was expected. The prominent gold peek results from the gold coating applied for conduction purposes. The calcium peek was interesting however. Calcium is a material present in biological cells so this information may confirm suspicions regarding the biological nature of the artifact cells.

The same EDX analysis was also conducted on particles of the Trial 1 UHMWPE against CoCR control. The results for this are shown in Figure 17. Peeks can be noted for carbon and gold with a slight one for oxygen. No calcium peak can be seen however. In addition the artifact particles did not show any oxygen peak. These differences clearly indicate a separate chemical composition for each particle type. The large gold peek was present in both but it is interesting to note that the carbon peek for the suspected

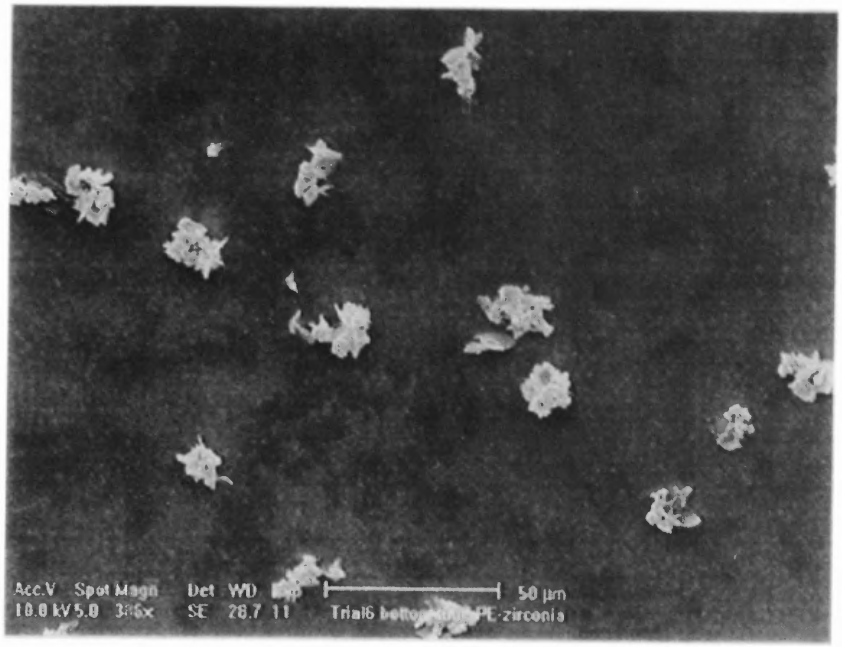


A



B

Figure 15 . Micrographs of Trial 3 (Zirconia-UHMWPE) Artifact Particles



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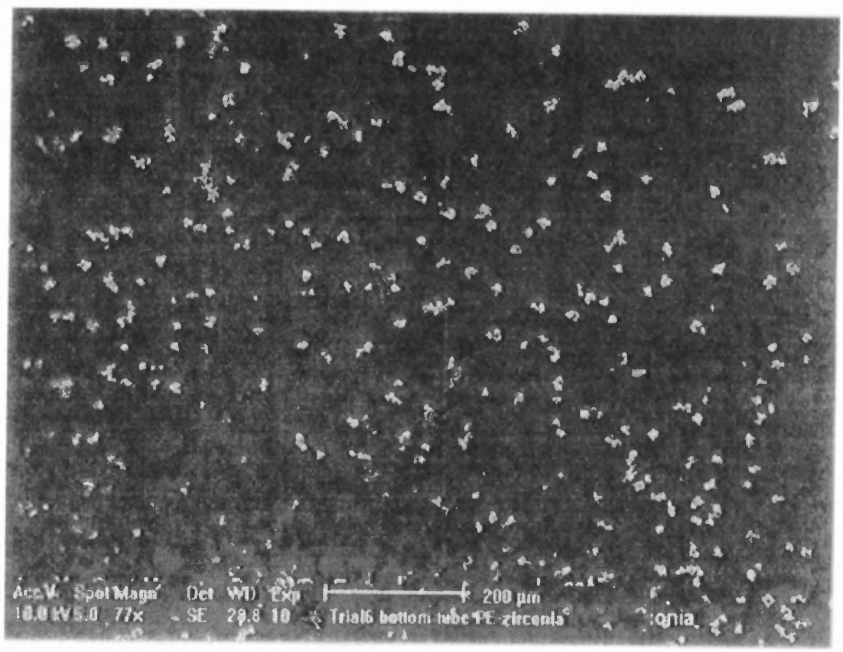

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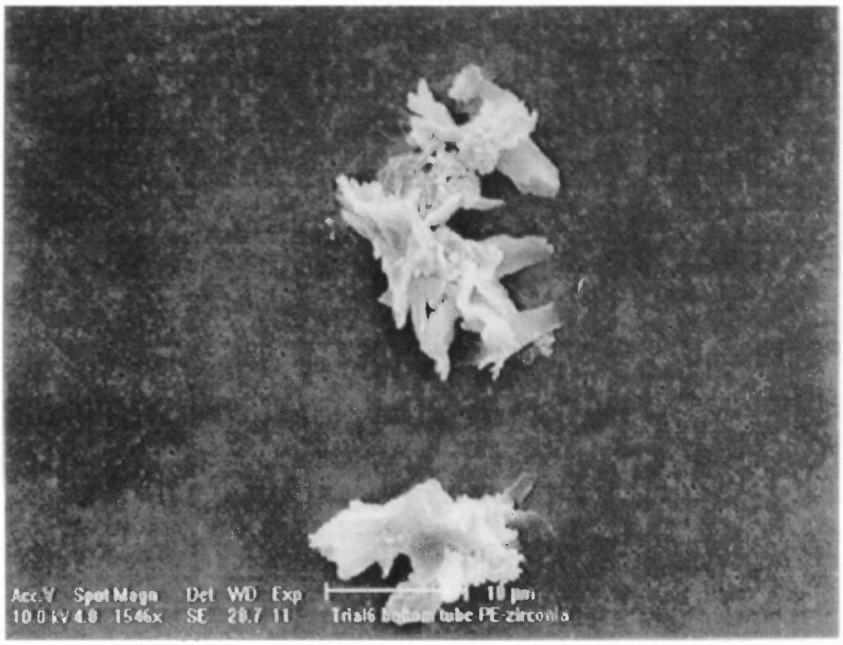
Figure 15 (Cont'd). Micrographs of Trial 3 (Zirconia-UHMWPE) Artifact Particles



E

Figure 15 (Cont'd). Micrographs of Trial 3 (Zirconia-UHMWPE) Artifact Particles

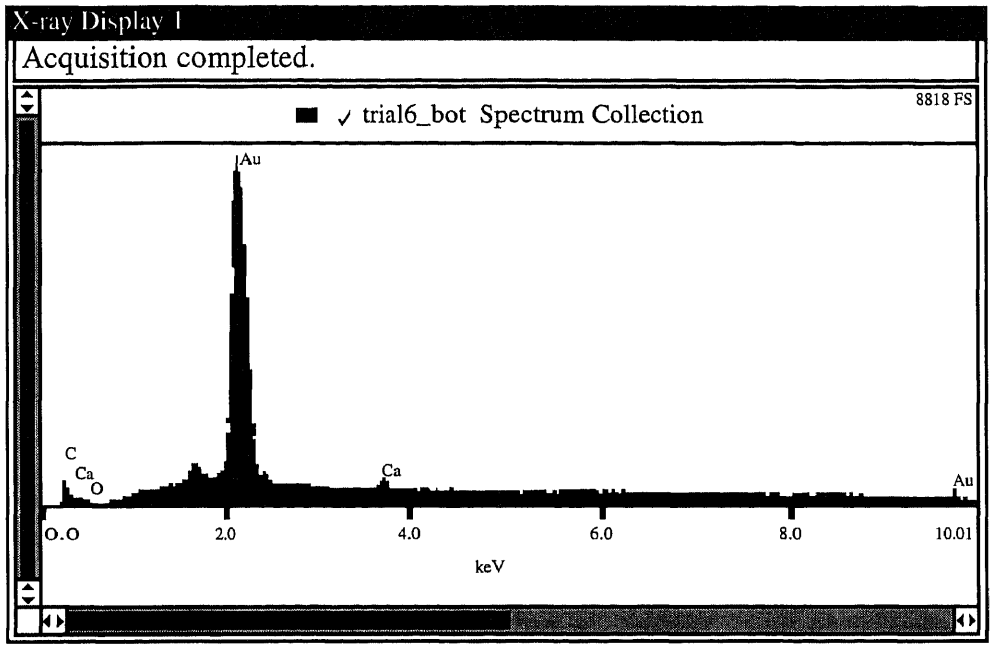


Figure 16. EDX Spectrum for Trial 3 Artifact Particle

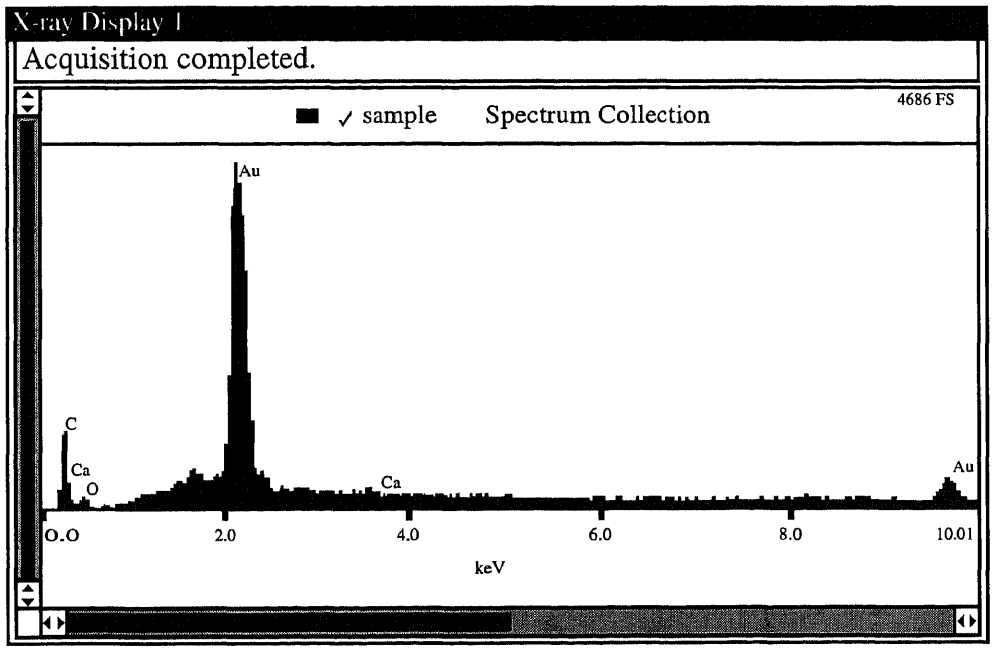


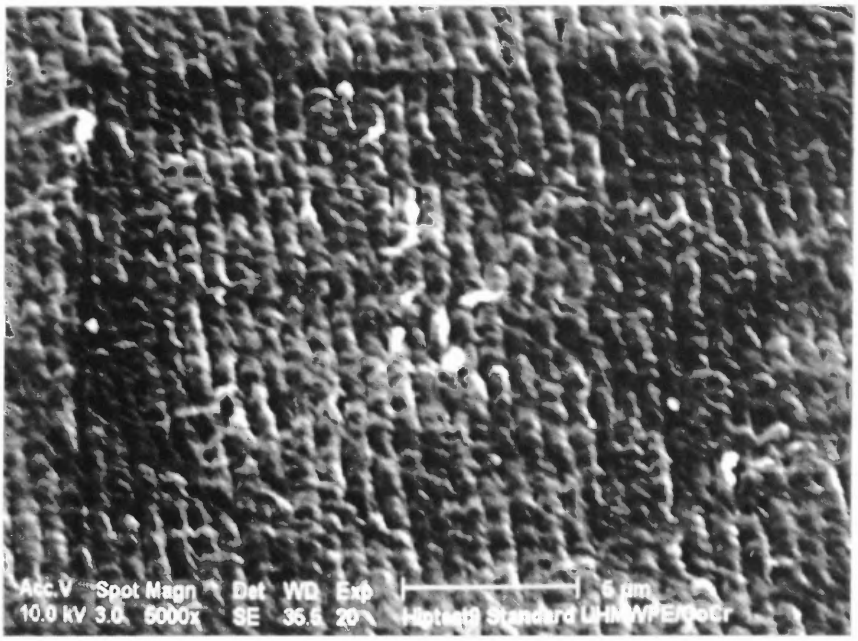
Figure 17. EDX Spectrum for Trial 1 UHMWPE Particle

UHMWPE particles was somewhat larger. This may reflect the high carbon content in the polymer chains further supporting the assumption that these particles were UHMWPE.

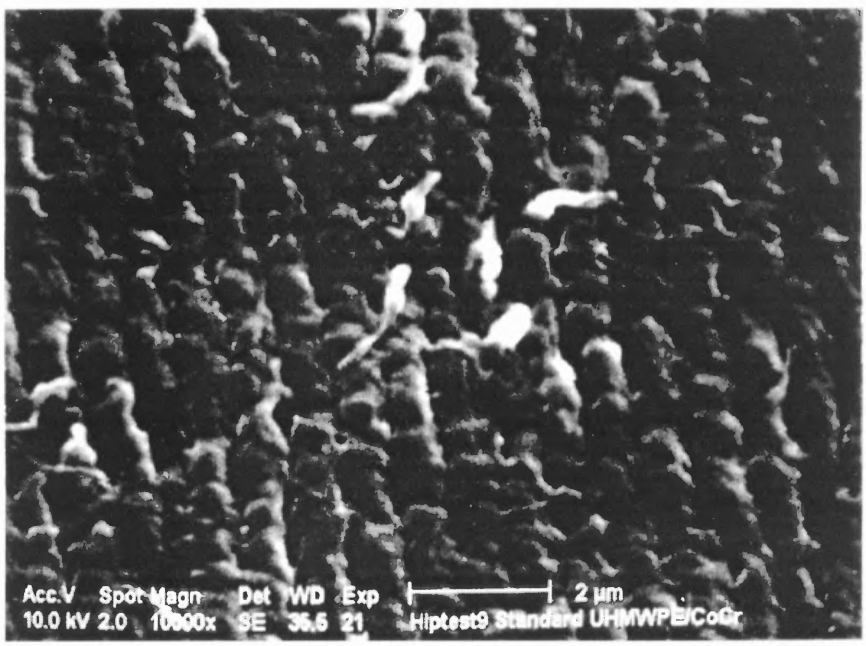
A final confirmation was found by conducting an SEM analysis on the cup from the Trial 1 control. The cup was prepared by removing the section that experienced articulation. This portion was then ultrasonically cleaned for 30 minutes in a soap solution followed by an addition 30 minutes in D.I. water. The section was then placed in a vacuum chamber for 30 minutes to ensure drying. It was then placed on a SEM stub mount using a conductive carbon adhesive tab and conductive carbon paint. The sample was then gold coated and analyzed with results shown in Figures 18A-18F. These figures show features of the wear surface reflecting wear mechanisms. Of particular interest is the appearance of particles emanating from various points on the cup surface. These forming particles appear very similar to those seen in the above trials. It can thus be safely assumed that the particles collected above were indeed UHMWPE shed from the cup surface.

3.6 Comparison to Literature Findings

In the literature a great deal of support for the present study can be found. Particles with shapes of flakes, ovoids, spheres, shards, threads, granules, spears, splinters and platelets were all reported. These descriptions are consistent with the types of particles described in this study. In addition the literature reported observance of clusters of smaller particles, as was seen here. Sizes reported ranged from 0.1-100 μm with many researchers finding sizes from 0.1 μm to 2 μm being common. This is within the size range of particles found here. Some investigators reported the larger particles up to 100 μ m, and particles of this size were generally not found in this study. This may be due to shortcomings of polarized light microscopy which cannot resolve individual smaller particles. Clusters of small particles may be reported as larger ones. Some researchers

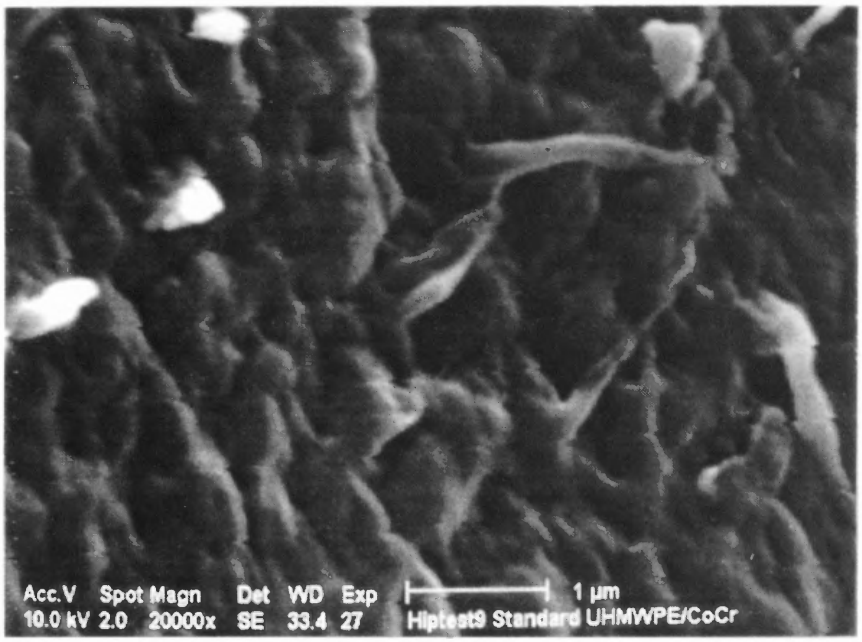


A



B

Figure 18 . Micrographs of Trial 1 Cup Surface Showing Forming Particles



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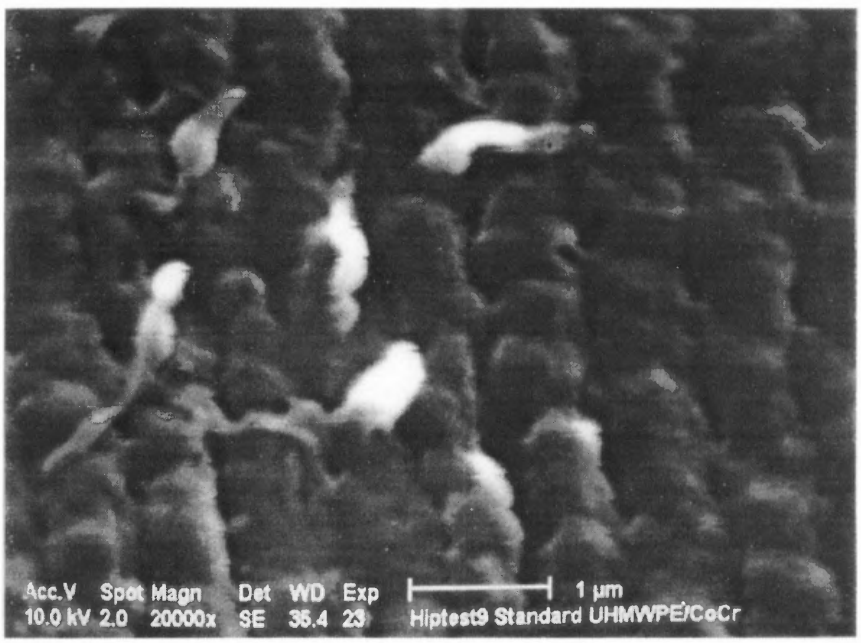

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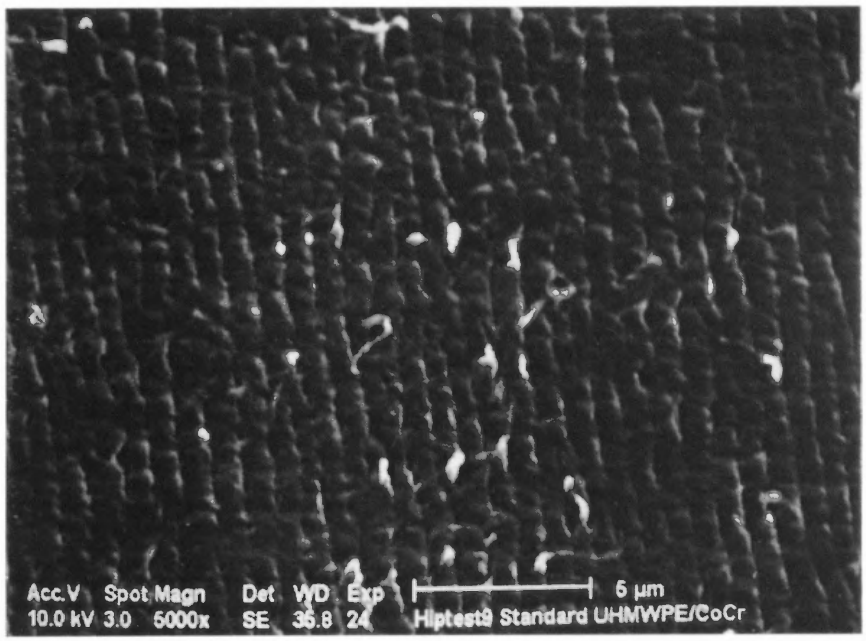
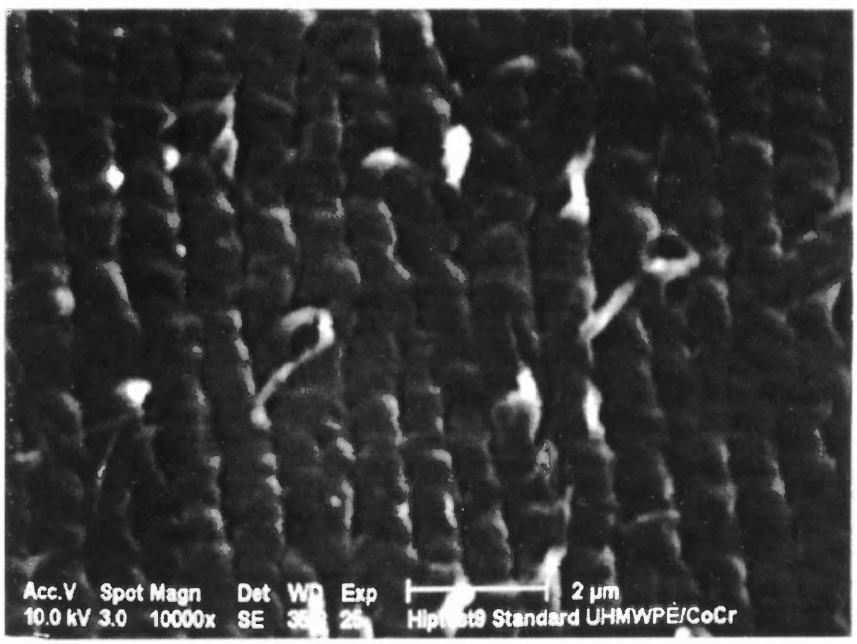
Figure 18 (Cont'd). Micrographs of Trial 1 Cup Surface Showing Forming Particles



E



F

Figure 18 (Cont'd). Micrographs of Trial 1 Cup Surface Showing Forming Particles

used scanning electron microscopy to identify particles and sizes for those studies were generally reported to be smaller than light microscopy values. These SEM studies report sizes similar to those reported here. An exception to the general particle size was the water trial, which yielded very large particles. Some investigators did report particles in the millimeter range. (specific literature references can be found in the introduction.)

Some of the size variation found in the literature may be due to experimental method differences. Many of the studies found in the literature were histological in nature depending on polarized light microscopy to identify the UHMWPE particles. Light microscopy probably does not afford the magnifications that are necessary to accurately identify and classify the UHMWPE particles. Over-estimations of size could easily occur at low magnification due to the clustering even seen in this study. Magnifications of 10000x and over are probably necessary to clearly identify and characterize particles. In addition the polarized light microscopy depends strongly on the birefrigence of polymer materials including UHMWPE. Some error could be introduced if other polymers were present during analysis.

Perhaps the most striking findings from the literature were reported by Shanbhag et al. and Campbell et al. [32,33]. Shanbhag reported spheroids 0.1 to 2 μm in mean dimension as well as fibrils 0.2 to 0.3 μm wide and up to 10 μm long. Smaller particles grouped in clusters were also observed. Campbell et al. used a method very similar to the one described in the current study, although DSC and FTIR were carried out [33]. Both rounded particles 0.07 to 6.3 μm in diameter and elongated particles 0.57 to 12.2 μm in length were found. Many submicron spherical and 1-3 μm elongated particles were reported. The elongated ones often had "heads". These findings strongly parallel current ones with shape and size being nearly identical to particles found from the serum lubricated trials. Even the same clustering and "head" formation was found. These two studies also involved DSC and FTIR confirmation of material. Since the size and shape resemblance is so striking it can be assumed that current particles are indeed UHMWPE.

CHAPTER 4

CONCLUSION

4.1 Conclusions

Wear particles were collected from several different material pairs, with one pair under two lubrication conditions. This was done to determine the shape and a rough size of particles generated from each of these couples. The importance of characterizing these particles has already been described, and this was the major goal of this study. An important aspect of this characterization was comparison of the particles from the various pairs, but comparison of these particles with those reported in the literature is also crucial.

The three material pairs considered under serum lubrication were noted to produce particles of two separate types. Furthermore, the type 1 smaller spherical particles observed were quite similar for all three pairs. The smallest ones were usually around 0.2 μm in size with a similar egg like shape. A second larger particle type was also observed for all three trials, generally with the same fibrous shape. Some difference in size of these particles was found however. The control particles were mostly in the 2 μm length range while the alumina ones ranged from 1-5 μm with some up to 10 μm in length. The zirconia ones also ranged from 1-5 μm with most in the 1-2 μm length range. Thus the control and zirconia type 2 particles were similar, while the alumina ones were slightly larger. All showed some curling, necking and asymmetry with the particle generally having a head.

The average sizes were quite similar for the control and zirconia trials while the alumina trial exhibited a larger average size. Aspect ratio was not similar for the control and zirconia trials though, with the zirconia particles not as elongated as the controls or the alumina ones. The average size data must be considered carefully however. Measurement error could have easily occurred due to the rough method used. At the high

magnifications used distinct particle edges were not always easily discernible due to focus problems. The average sizes reported also represent both large and small particles meaning that frequency of each type can be a factor. In addition clustering was seen among the particles from the ceramic UHMWPE material couples. This clustering leads to the observation of larger particles that are really agglomerates of smaller ones. All of these factors can easily skew measurement data. Overall impression is that there was reasonable similarity among trials with the exception of the UHMWPE/CoCr water trial (Trial 4).

The appearance of the water lubricated debris was strikingly different than the other debris. The overall size of this debris was larger and the shape was unique. Two types of debris were found as in the other trials, but the general structure of each type was similar unlike the other trials. The only discerning fact here was a gross size difference. Large particles were several millimeters in size while small ones were several microns. The large flakes appeared to be composed of many thin layers with the these layers possible generating or even being generated by the smaller flakes. No similarities were found between this trial and the others with the major difference being the alternate water lubricant.

The similarity of serum lubricated particles is an interesting point. Due to the differing surface hardness, and in the case of the ceramics, grain size, differences in particle type were expected [16]. Due to the fine grain size and surface finish of ceramics many fine particles were expected. Furthermore they were expected to be submicron and debris of this nature was seen. The spherical shape and small size of these type 1 particles was anticipated based on the fine surface features noted on the wear surface. The literature had also reported elongated fibrous particles so some of these were also expected. What was unexpected was that all counterface materials under serum lubrication would produce similar shaped particles of both types. This indicates that similar wear mechanisms inducing particle formation were occurring for all the material

types except the water trial. Due to the differing particle geometry, a different wear mechanism must have acted for the water trial.

The two distinct serum debris types indicate that at least two separate dominant wear mechanisms were probably acting. Suggestions include an adhesion assisted tensile instability mechanism and a critical strain mechanism, i.e. a plastic strain accumulation induced micro extrusion mechanism. Some descriptions of these were included in the introduction. The smaller spherical particles could be formed due to cyclic strain accumulation leading to ductile failure of micro asperities as a result of cumulative plastic deformation. The larger particles that were fibrous in shape could be due to an adhesion assisted tensile instability mechanism. For the latter mechanisms the surface "ripples" or folds and other surface defects could be pulled into fibrous wear debris by surface traction leading to elongated thin particles. These particles could experience the necking observed in the trials prior to rupture and removal from the substrate. This possible necking or yielding occurrence could also result in the head seen on some particles. During debris generation the particle could originate as a protrusion of material. Necking could cause the resulting particle to have a thin tail and a larger head due to the initial material protrusion. Curling seen in these particles could result from residual stresses.

The obvious difference in the water lubricated particles implies that a different wear mechanism was acting. Because all particles observed from Trial 4 were similar in shape and morphology with size being the only difference, it can be concluded that one type of wear mechanism was probably dominant under water lubrication. The particles observed are typical of transfer film phenomenon as observed for a true adhesive wear mechanism [11]. Therefore, under the water lubricated case true adhesion was allowed to occur resulting in a transfer film. These films often undergo a process of growth and back transfer and may shed pieces altogether. This must be the current case as millimeter size pieces were found. The film starts due to surface adhesion and grows as additional material is separated from the polymer substrate. This could occur on a microscopic level

leading to sequential growth as a thin layer is added due to additional articulation. A process such as this could account for the laminated structure observed in the film particles.

Trial 4 also indicates that the lubricant properties must be vastly different between water and serum. One investigator even stated the need for using serum as opposed to water for wear simulation testing based on coefficient of friction [23]. Bovine serum as an in vitro wear testing lubricant apparently has the ability to interfere with true adhesion where water does not. This may be due to long chain organic molecules present in the serum. These molecules can attach themselves to either articular surface resulting in a weak bond and a boundary lubrication film. These molecules and the resulting lubricant film can then separate the micro-asperities on the two articular surfaces to some extent. This would reduce local adhesion. Since D.I. water does not contain these molecules, no such separation is provided, resulting in more local contact among micro-asperities leading to increased adhesion and formation of a transfer film. It is interesting to note that the literature rarely reports the observance of transfer films in vivo and in fact indicates that true adhesion most likely does not act in vivo [13]. For this reason it can be concluded that deionized water as an in vitro simulator lubricant is inadequate and may reduce accuracy and validity of this type of testing.

The literature generally supports the current findings. Particles of distinct types appear to be present under serum lubricated conditions, most likely due to varying wear mechanisms. The shape and size of the debris reported under in vivo conditions was strongly similar to debris found in this study. This is especially true if findings by Shanbhag et al. and Campbell et al. are considered [32,33]. The general support by the literature does not only simply show similar particles but more importantly indicates the validity of using an in vitro hip simulator to duplicate in vivo wear and particle generation mechanisms. The wear mechanisms that produced the particles in the serum lubricated trials of this study must have been identical to those that produced the in vivo

THR wear particles in Shanbhag's and Campbell's studies. This is an important finding for future research. In vitro simulators can thus be used to accurately duplicate in vivo wear conditions aiding in the development and evaluation of new materials with improved wear and debris production characteristics.

4.2 Summary

In summary the conclusions that can be drawn from this study are as follows:

1.) Wear debris produced in vitro for zirconia, alumina and CoCr articulated against UHMWPE in serum are similar in shape and morphology.

2.) There does not appear to be a statistically significant difference in size for serum lubrication generated debris. (Slight average size differences were probably caused by measurement error or particle clustering.)

3.) At least two separate dominant wear mechanisms appeared to be acting for serum conditions in the current study, probably some type of adhesion assisted tensile instability mechanism and a critical strain mechanism.

4.) Water lubrication caused a different shaped larger particle to be produced compared to serum.

5.) Water lubrication probably allowed true adhesion and a subsequent transfer film to develop.

6.) Water lubrication does not reproduce in vivo wear mechanisms reported in the literature.

7.) The current findings regarding serum lubricated particle shape and rough size appear to be closely supported in the literature.

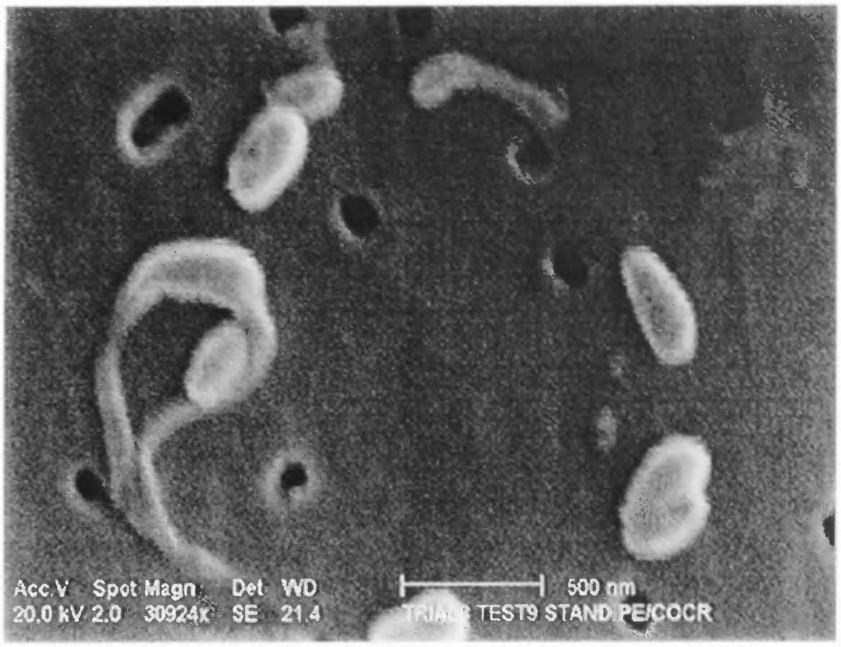
8.) In vitro THR joint simulators can accurately reproduce in vivo wear mechanisms if test parameters including lubricant closely resemble in vivo conditions.

9.) In vitro simulation is a reliable analytic tool for evaluating improved materials provided lubrication is similar to in vivo conditions.

If the long term success of TJRs, especially THRs is to be positive, the mechanism of loosening must be thoroughly understood. Paramount to this understanding is the role of wear debris and the effect of material, size, shape and quantity. Use of the above methods may be a valuable screening tool in the development of new materials. Wear debris collection and analysis must be a part of the evaluation of any THR articular material.

APPENDIX A

Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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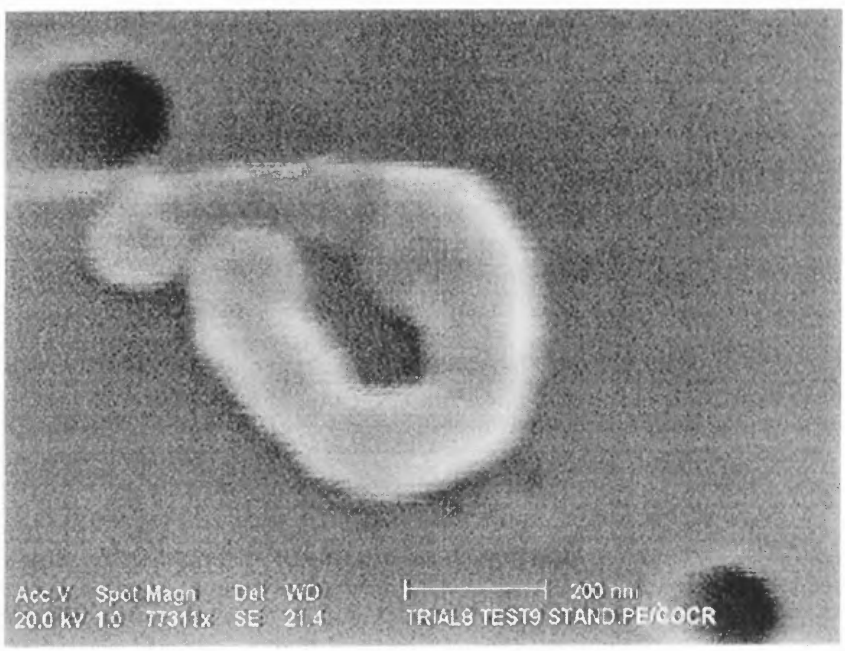
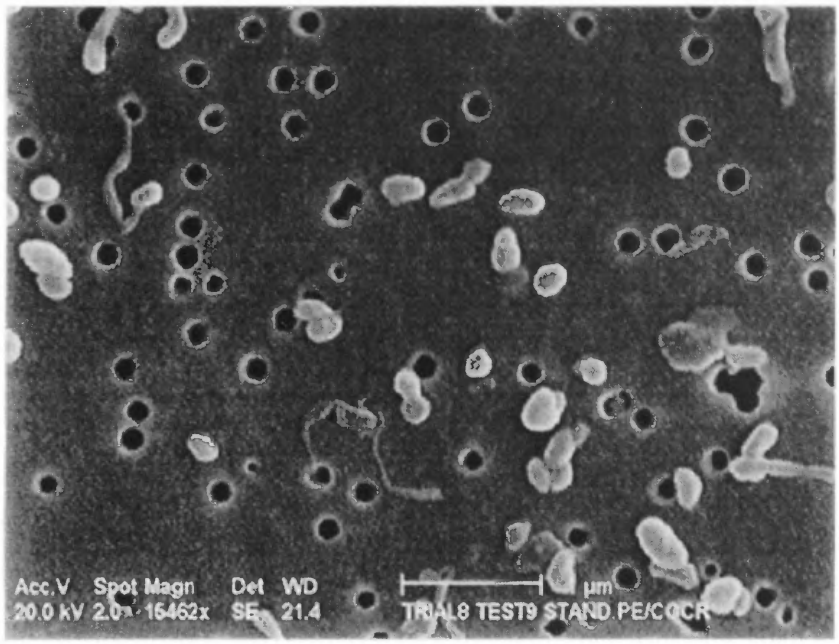


B

Figure 8. Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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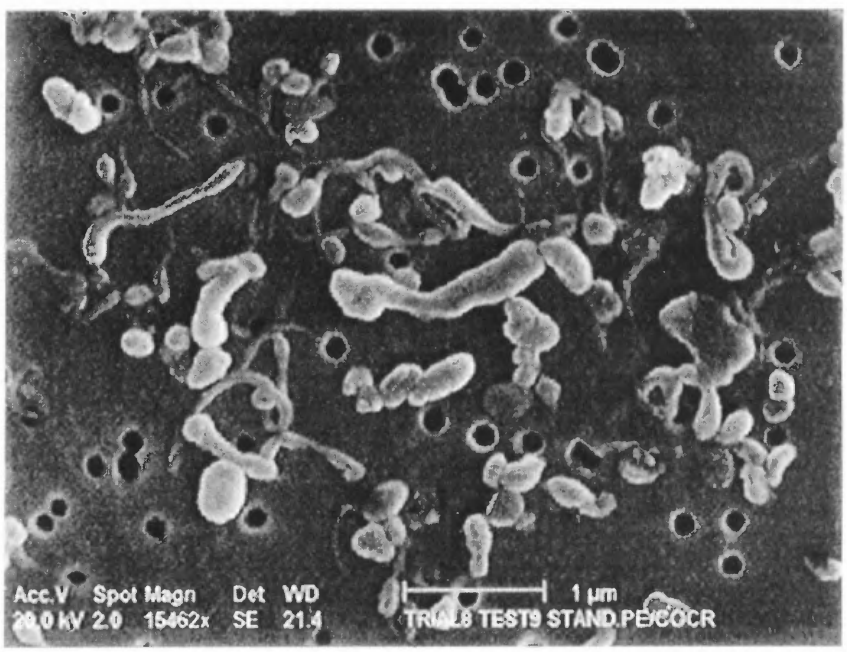

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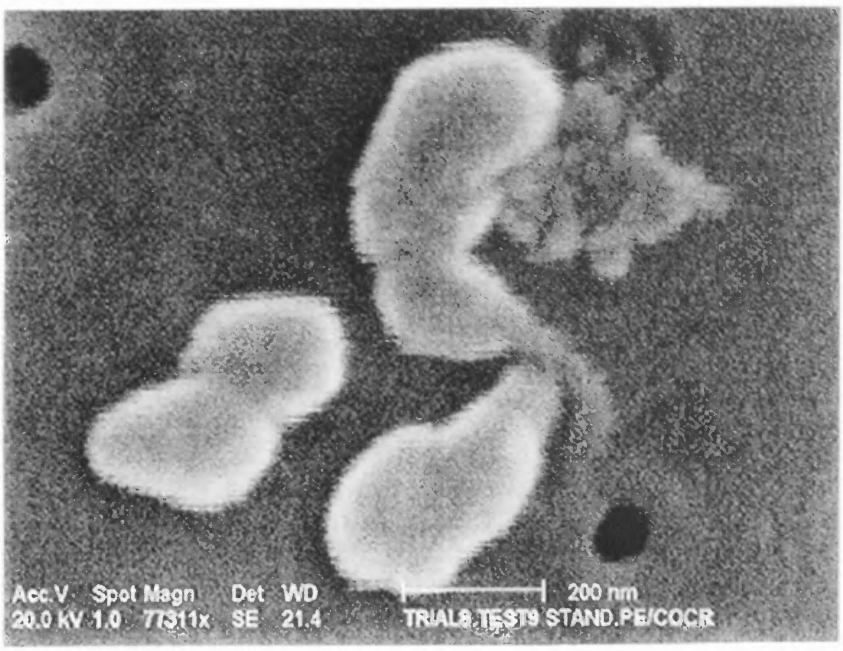
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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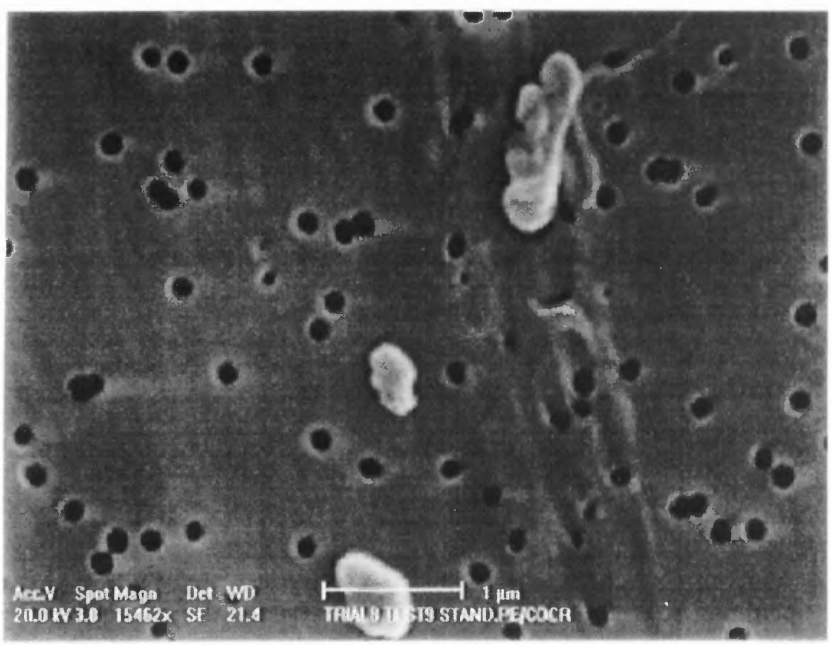

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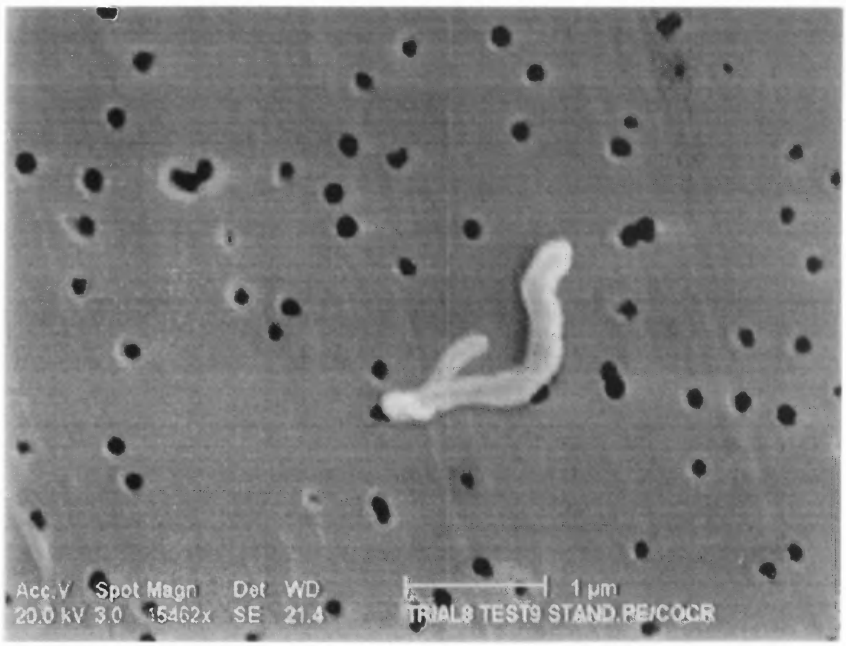
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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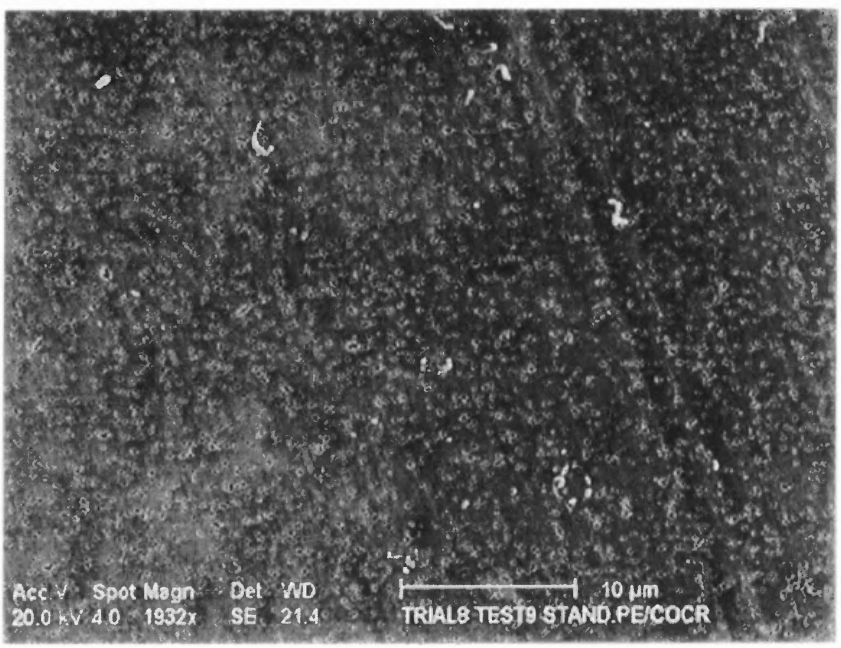

H

Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles

I

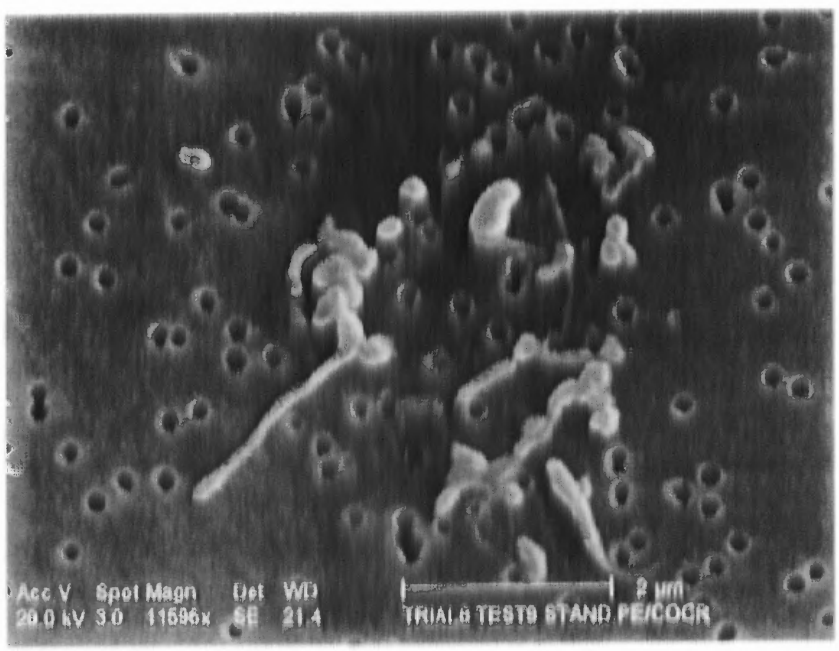

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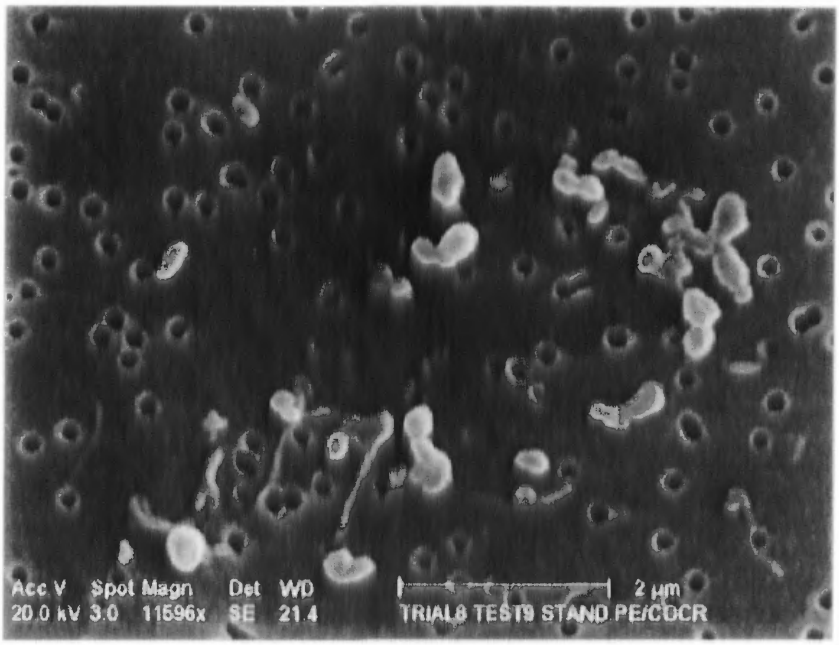
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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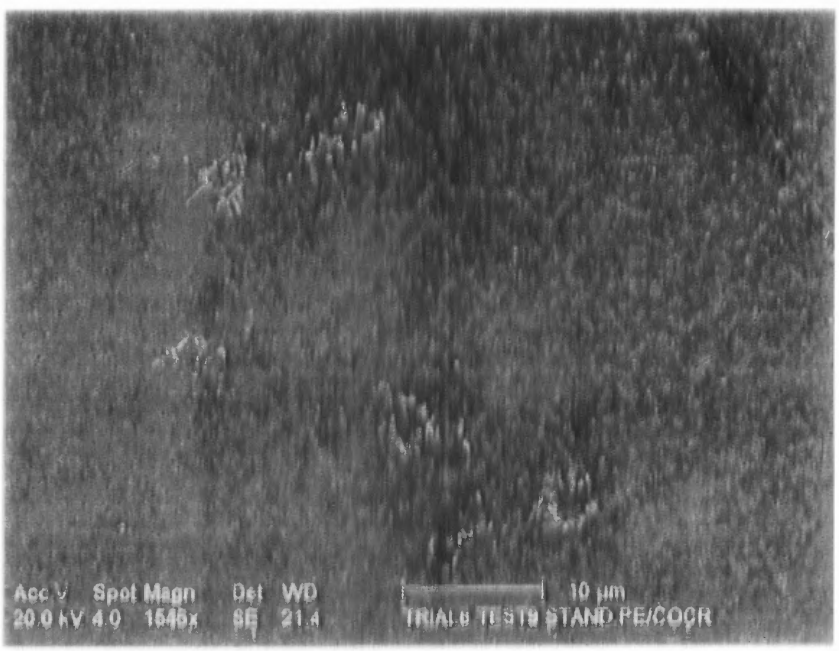

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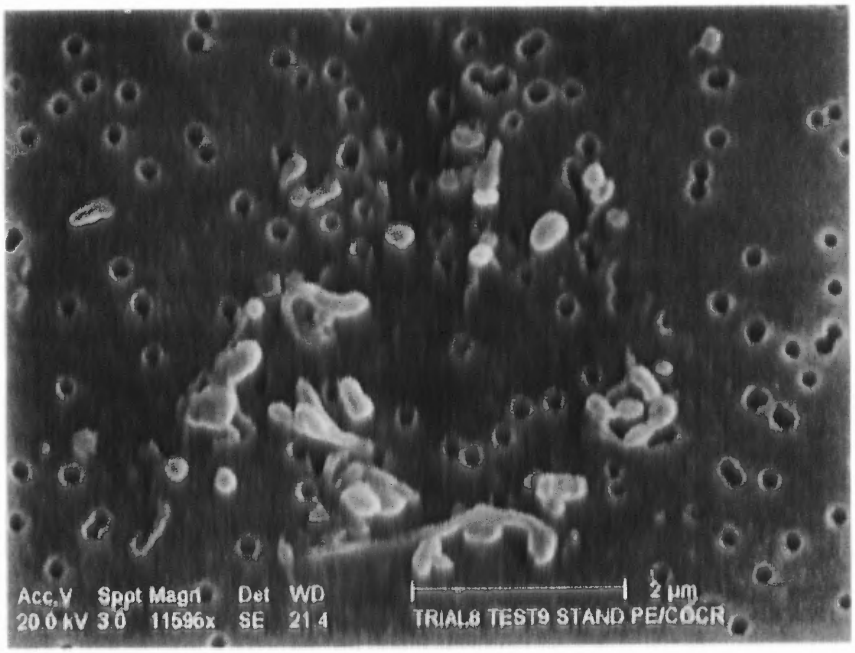
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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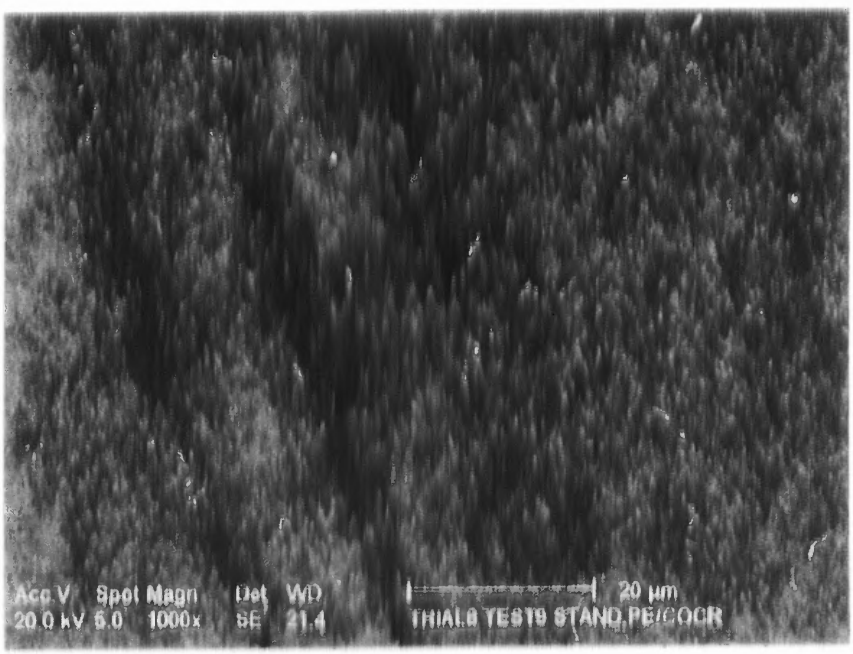

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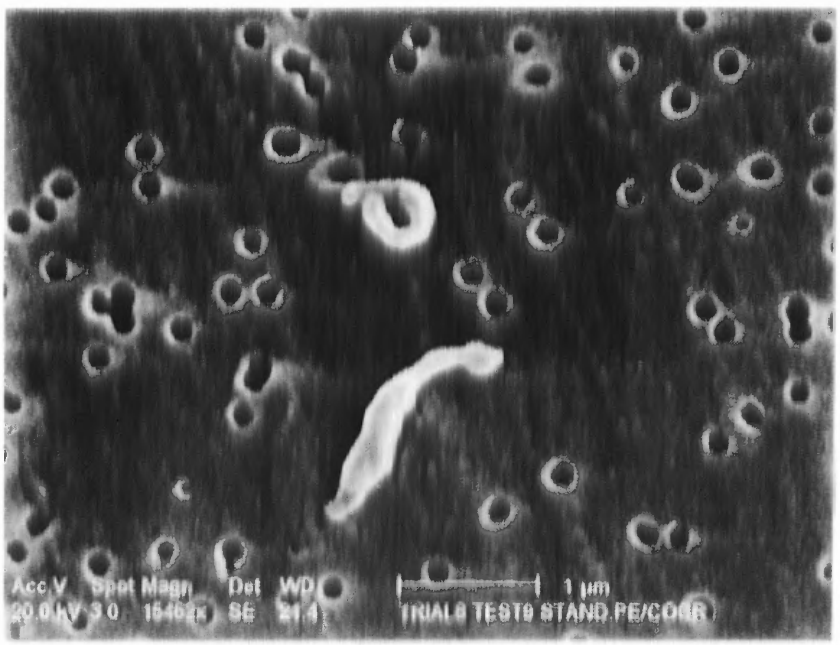
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles

O



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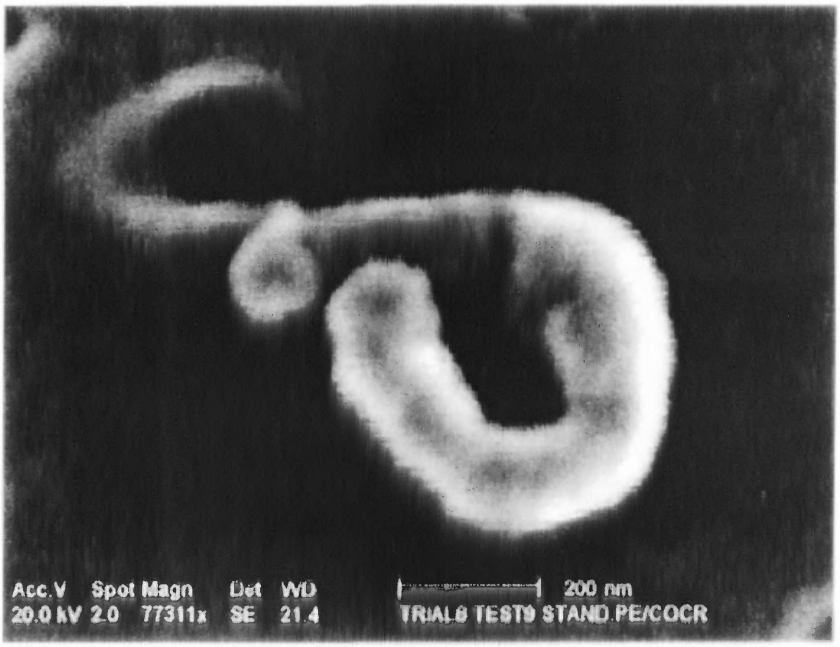

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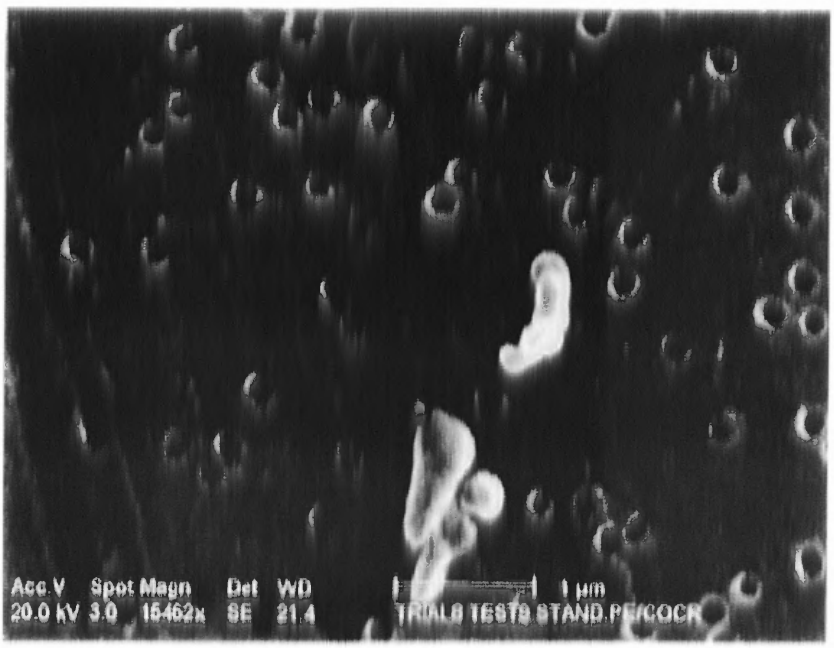

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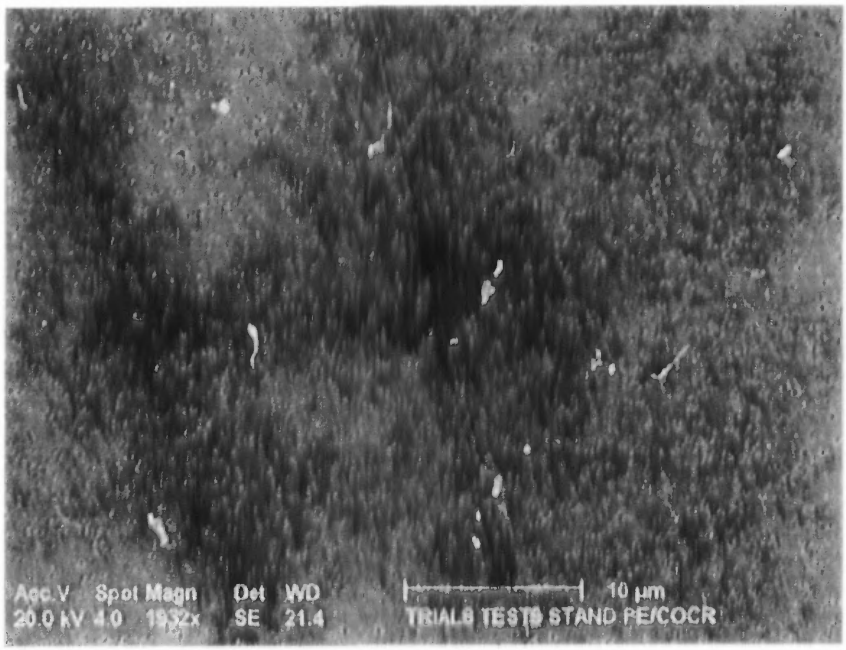
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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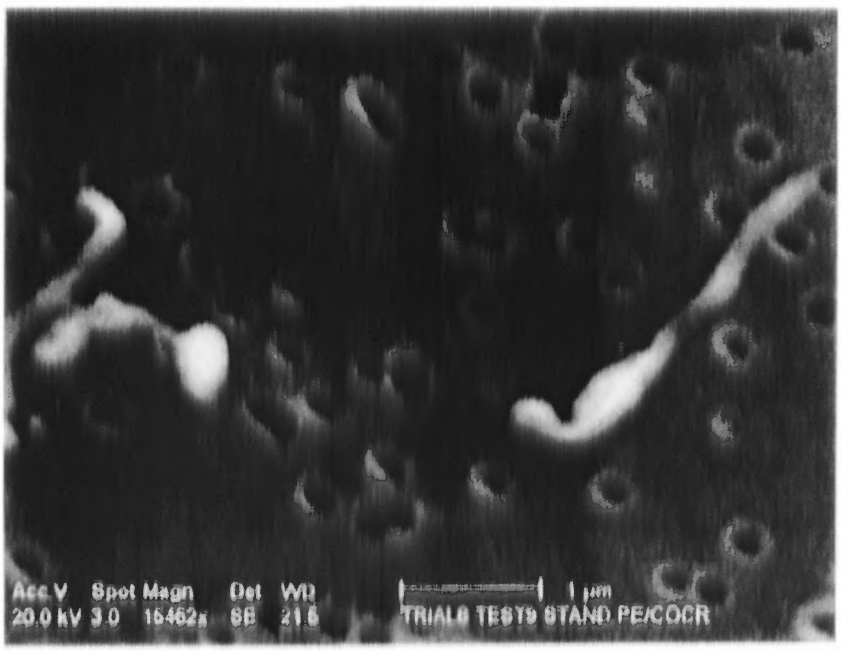

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Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles

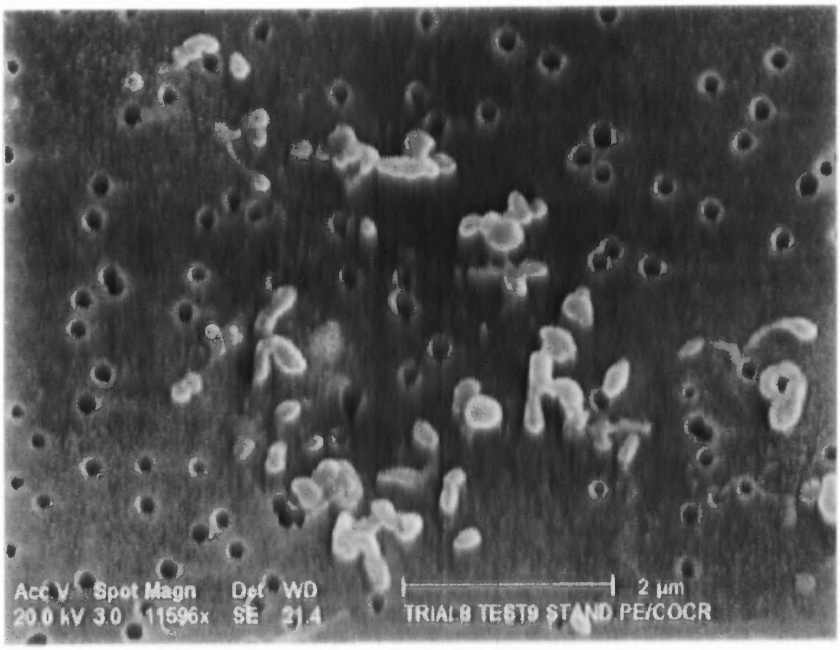

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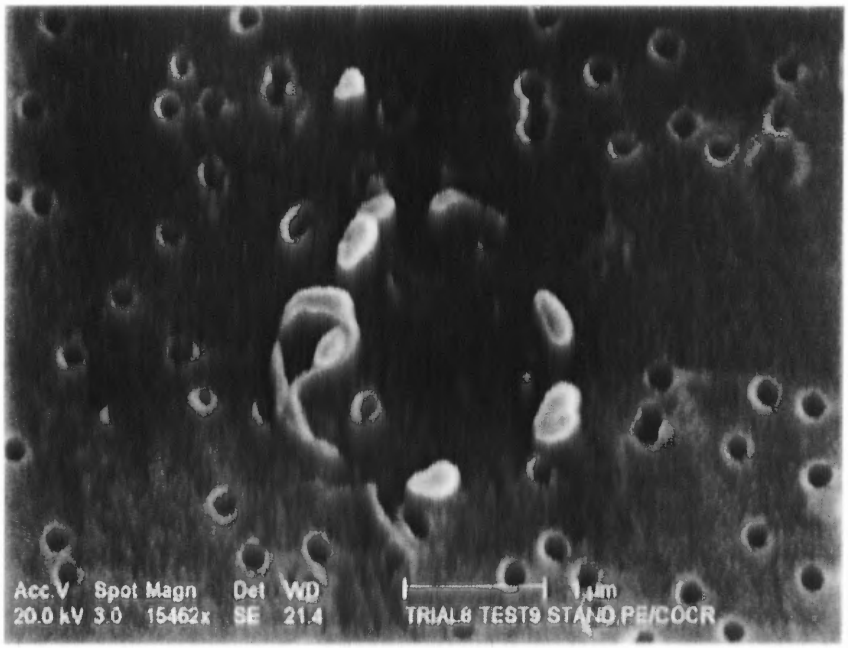
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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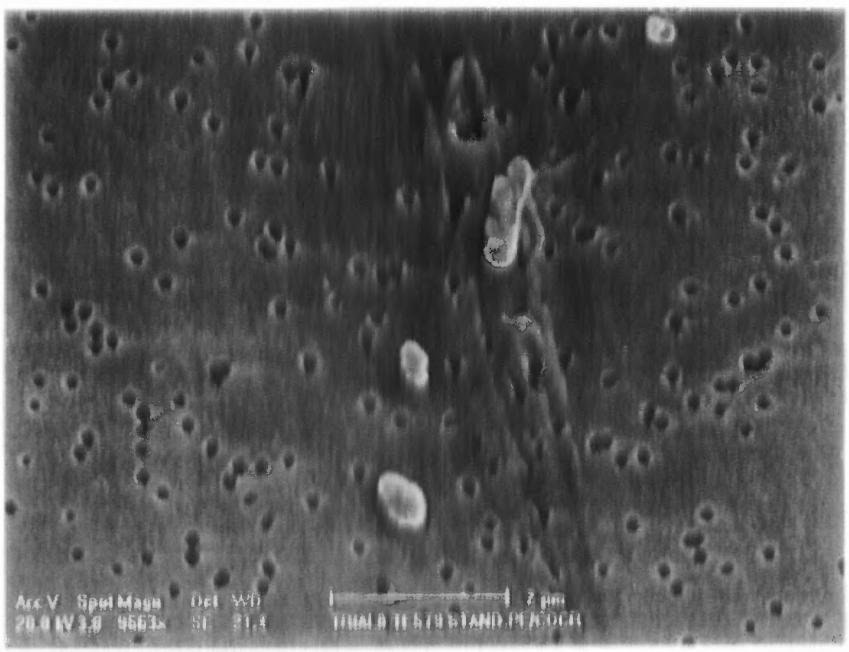

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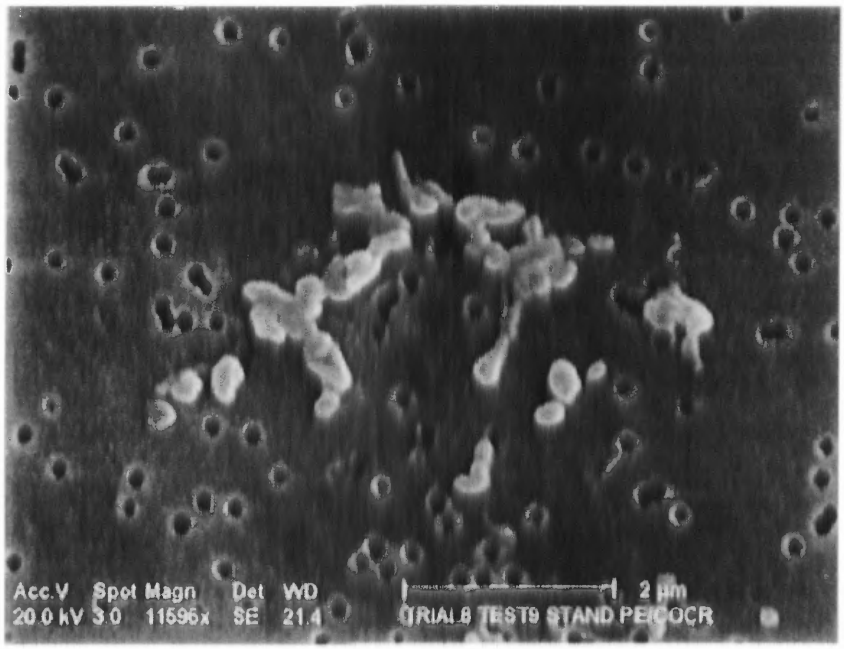
Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles



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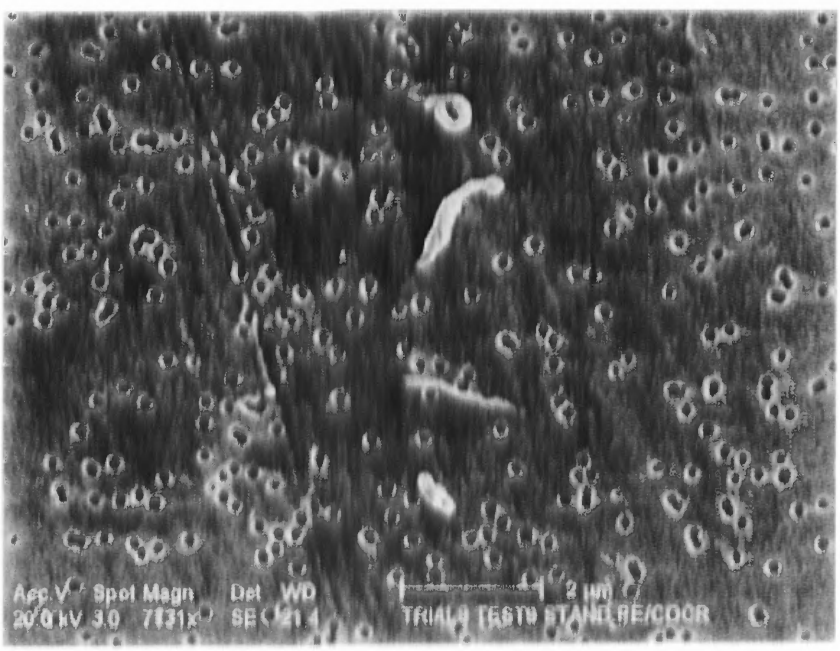
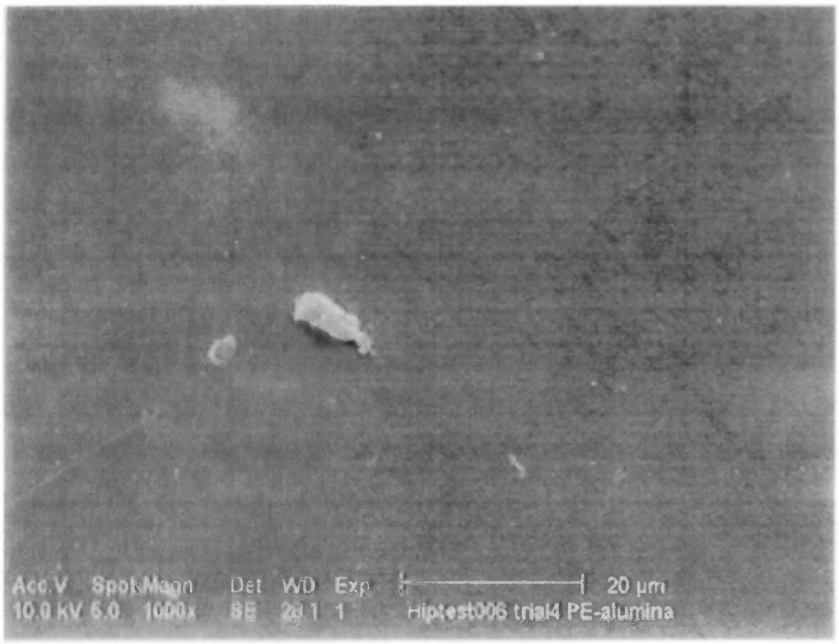


Z

Figure 8 (Cont'd). Micrographs of Trial 1 (CoCr-UHMWPE) Wear Particles

APPENDIX B

Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles



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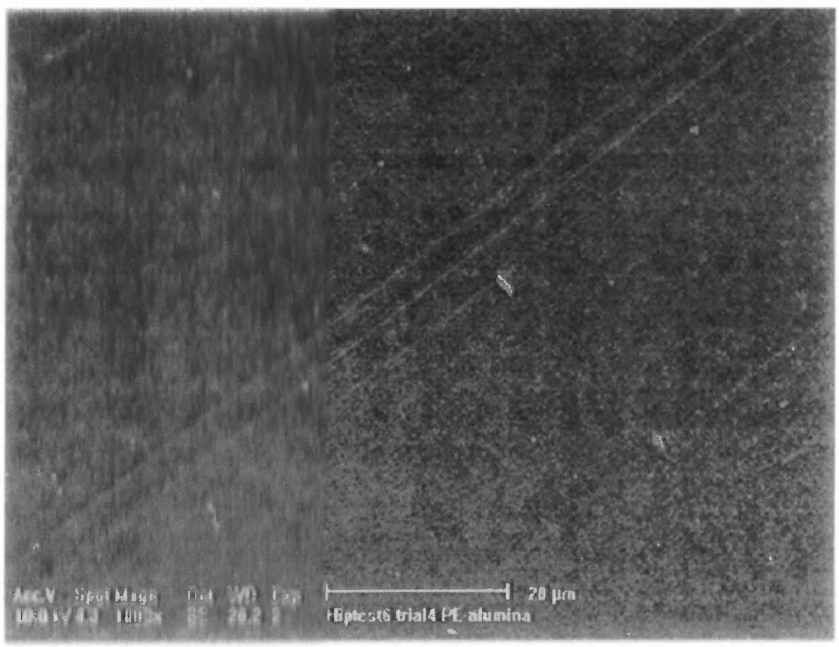
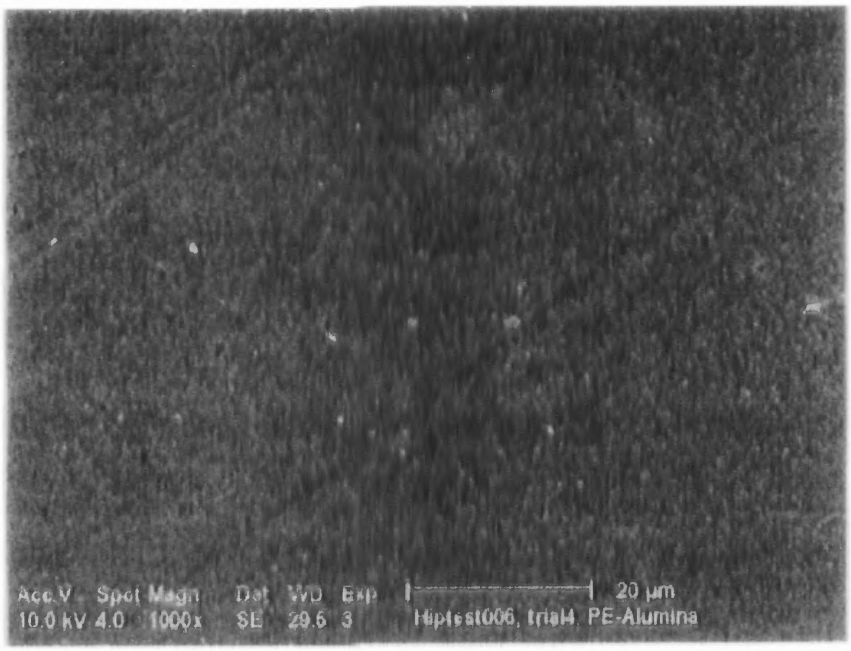


B

Figure 10. Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles



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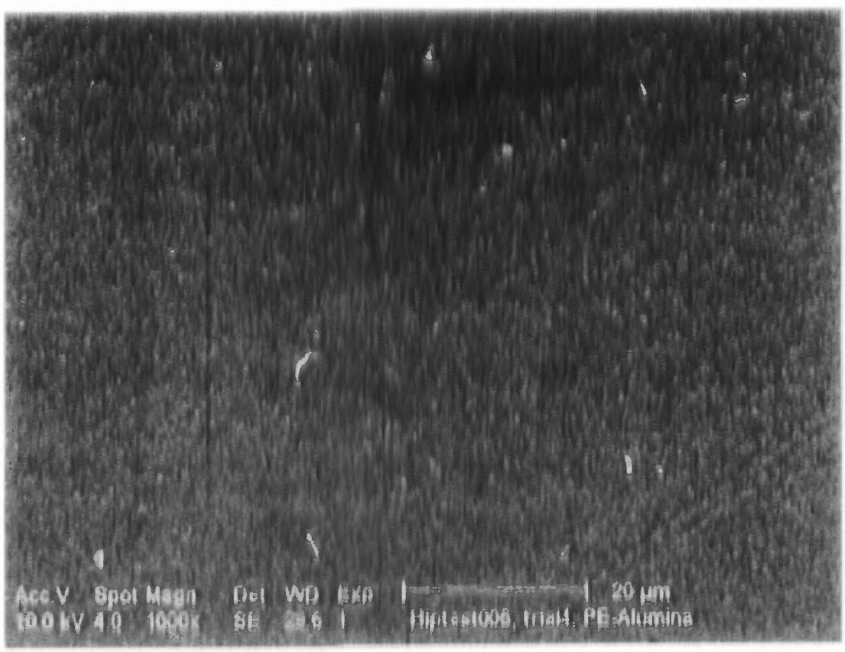


D

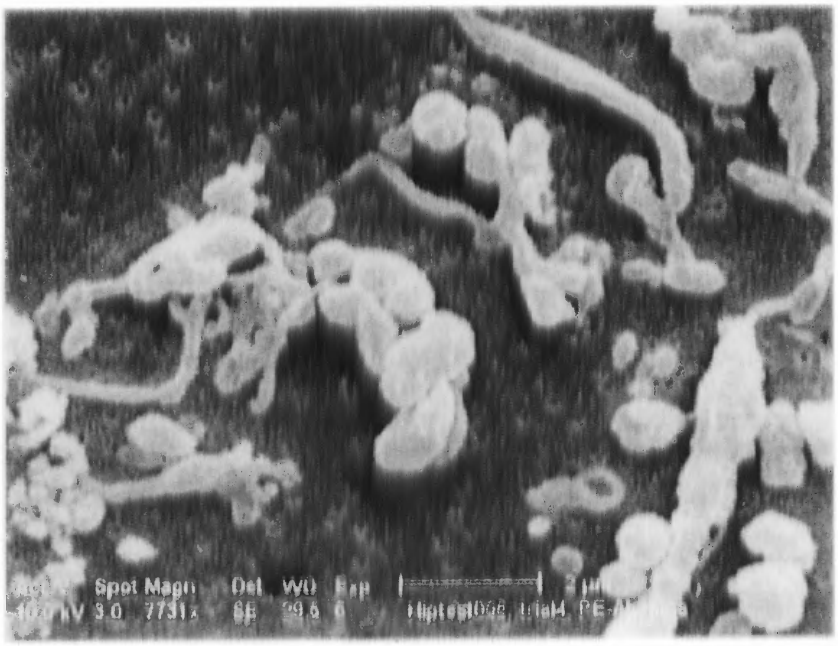
Figure 10 (Cont'd). Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles

E

F

Figure 10 (Cont'd). Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles

G



H

Figure 10 (Cont'd). Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles

I

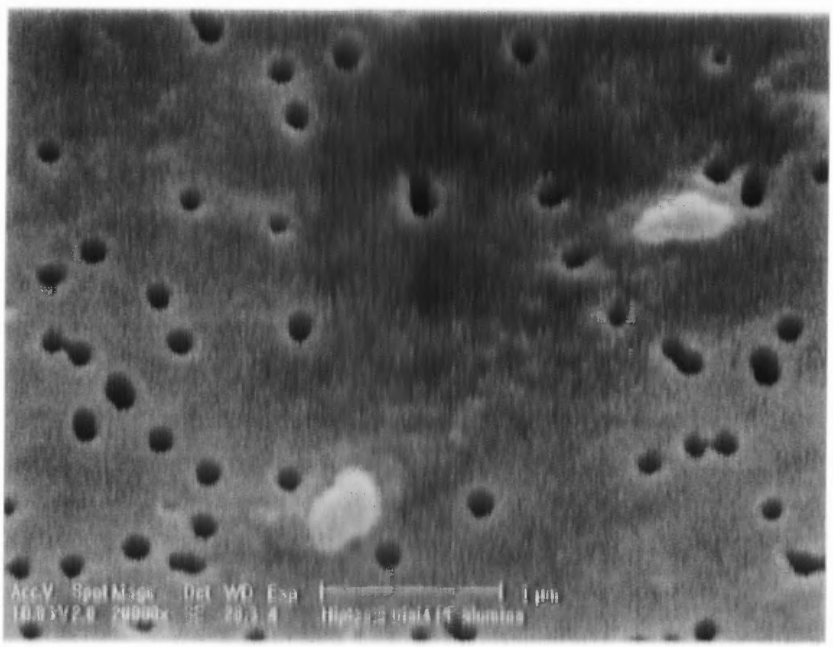


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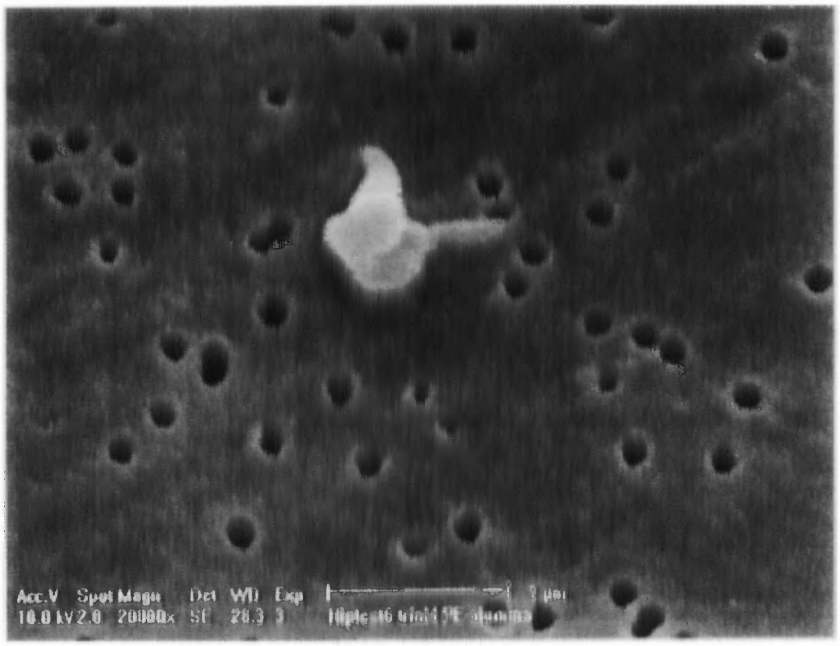
Figure 10 (Cont'd). Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles



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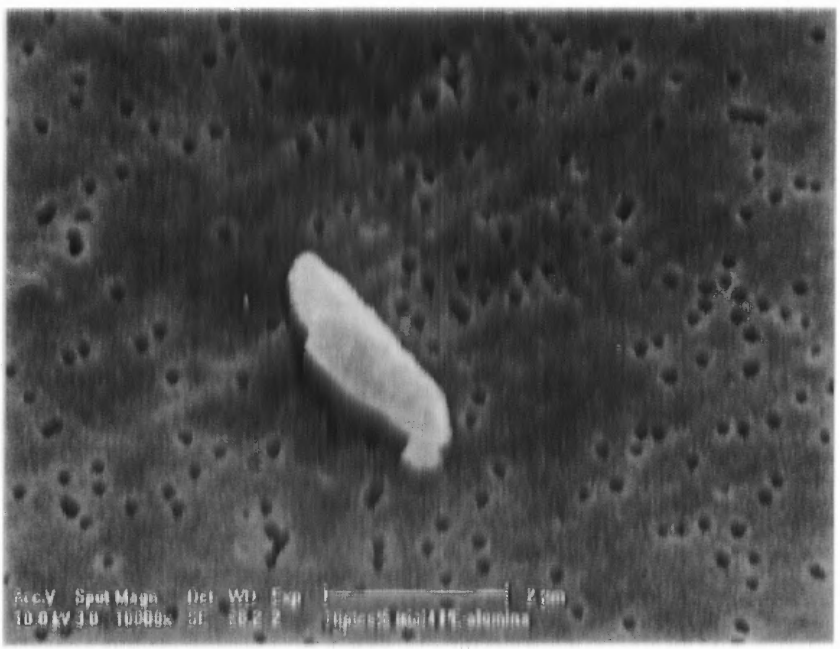

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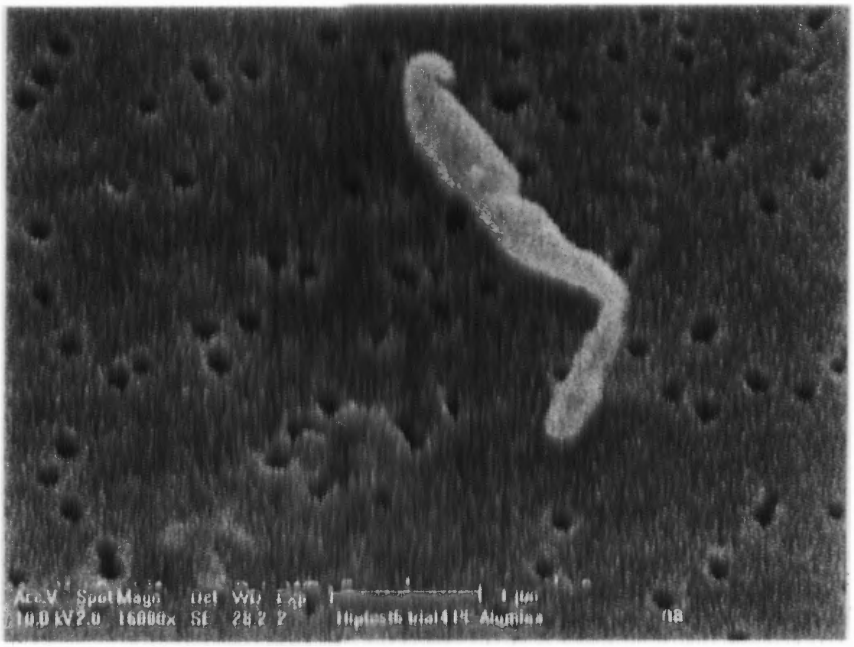
Figure 10 (Cont'd). Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles



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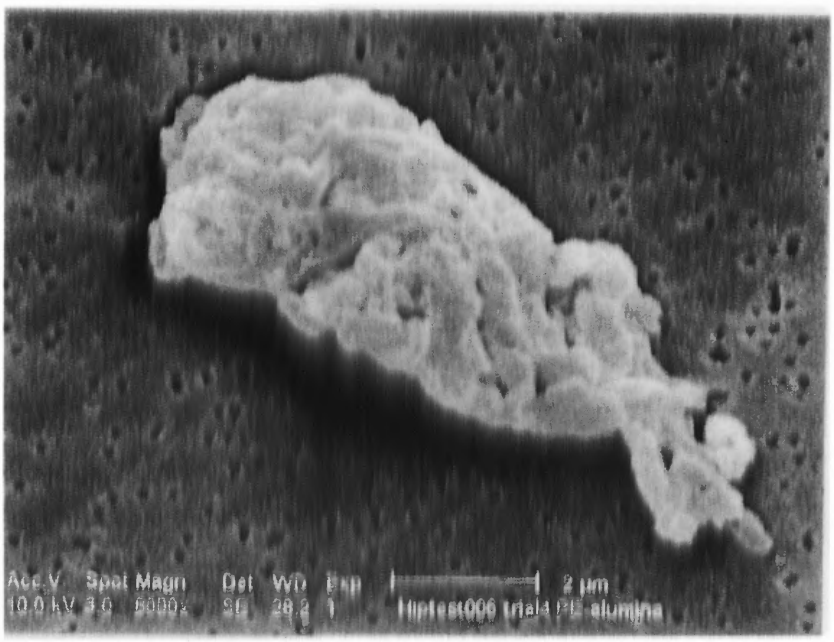

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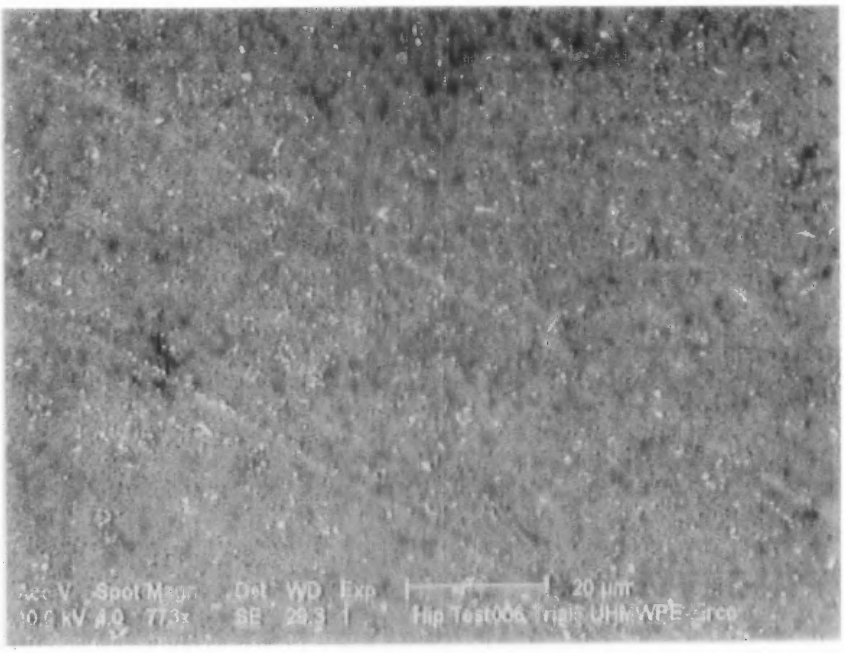
Figure 10 (Cont'd). Micrographs of Trial 2 (Alumina-UHMWPE) Wear Particles

APPENDIX C

Micrographs of Trial 3 (Zirconia-UHMWPE) Wear Particles



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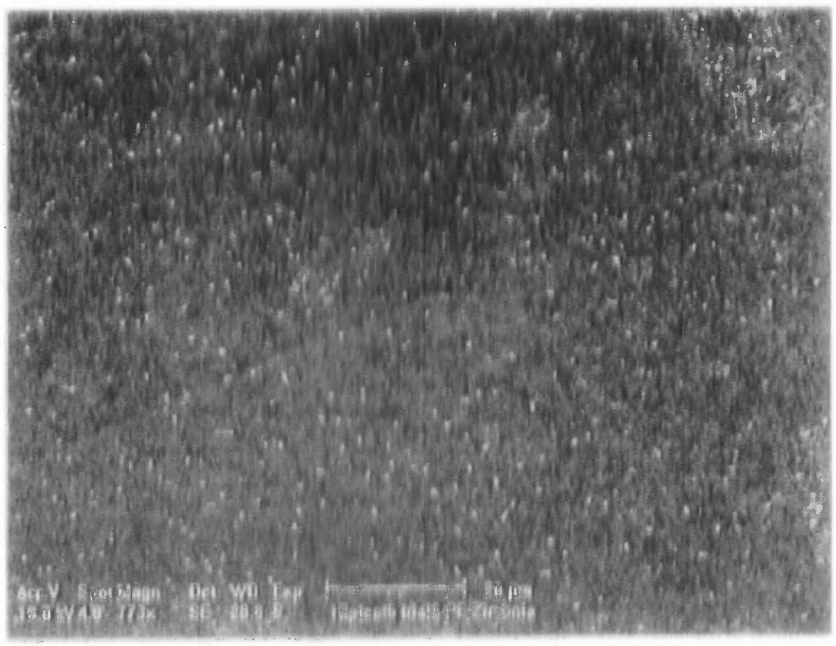
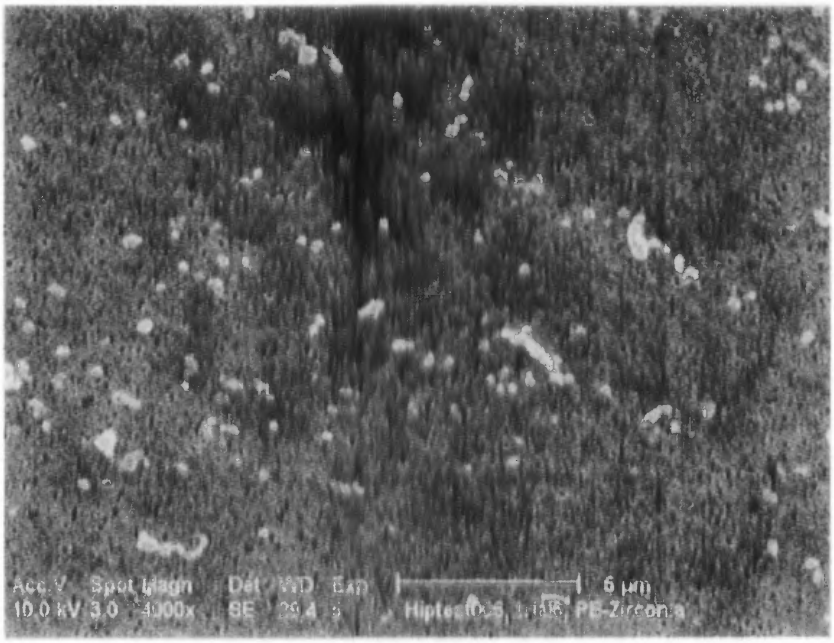


B

Figure 12. Micrographs of Trial 3 (Zirconia-UHMWPE) Wear Particles



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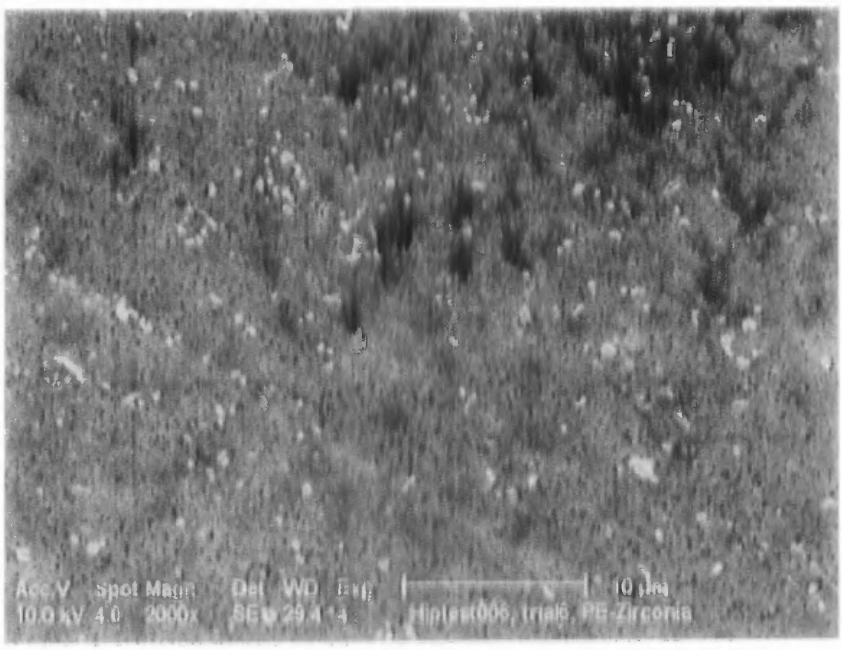
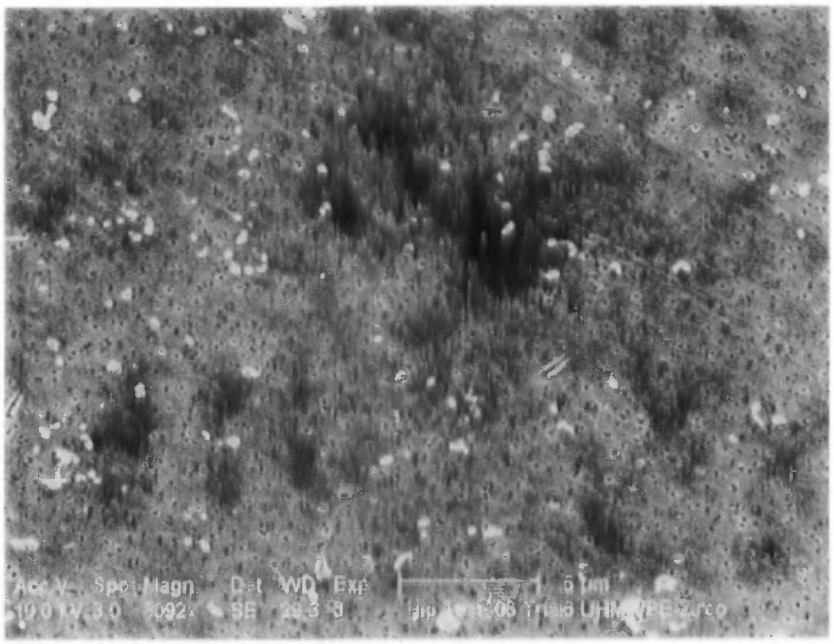


D

Figure 12 (Cont'd). Micrographs of Trial 3 (Zirconia-UHMWPE) Wear Particles



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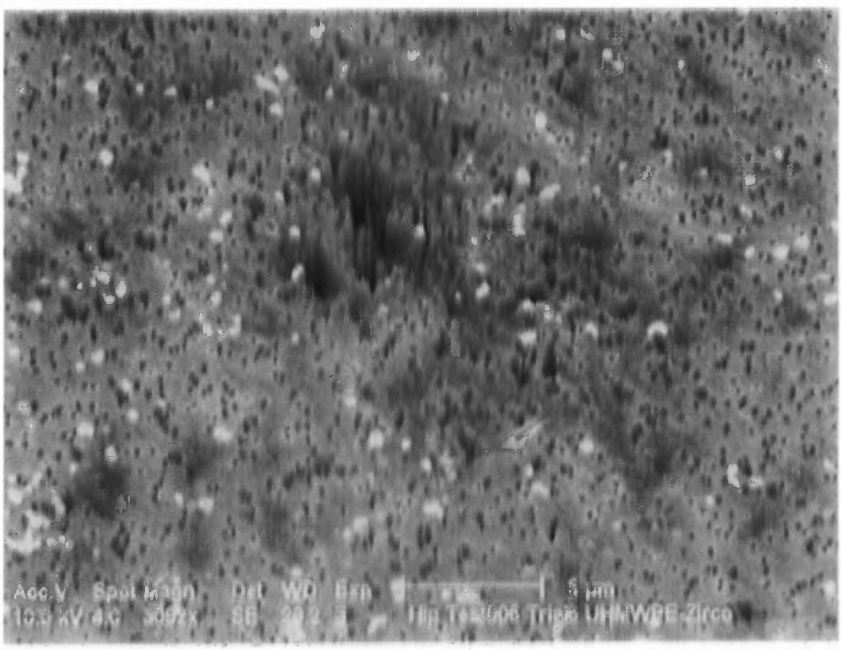
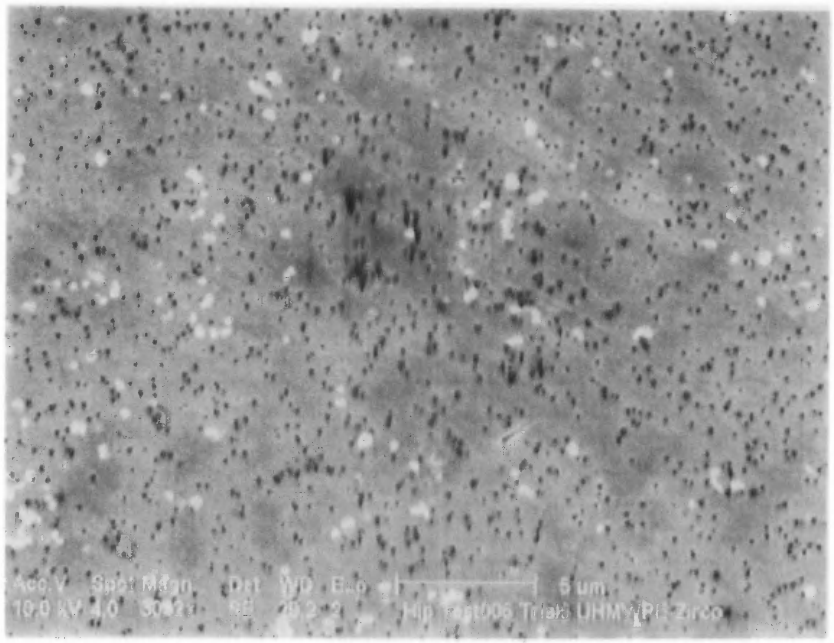


F

Figure 12 (Cont'd). Micrographs of Trial 3 (Zirconia-UHMWPE) Wear Particles



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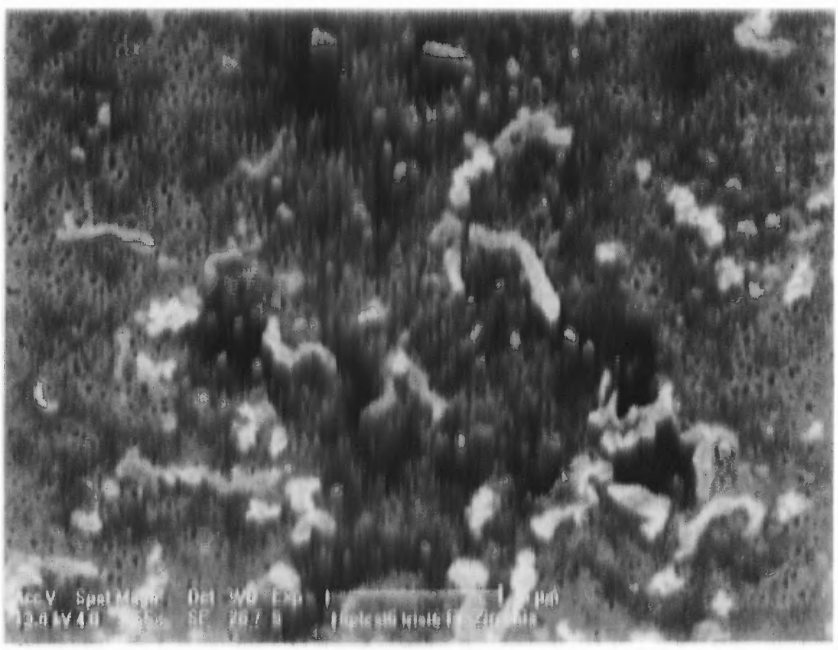

H

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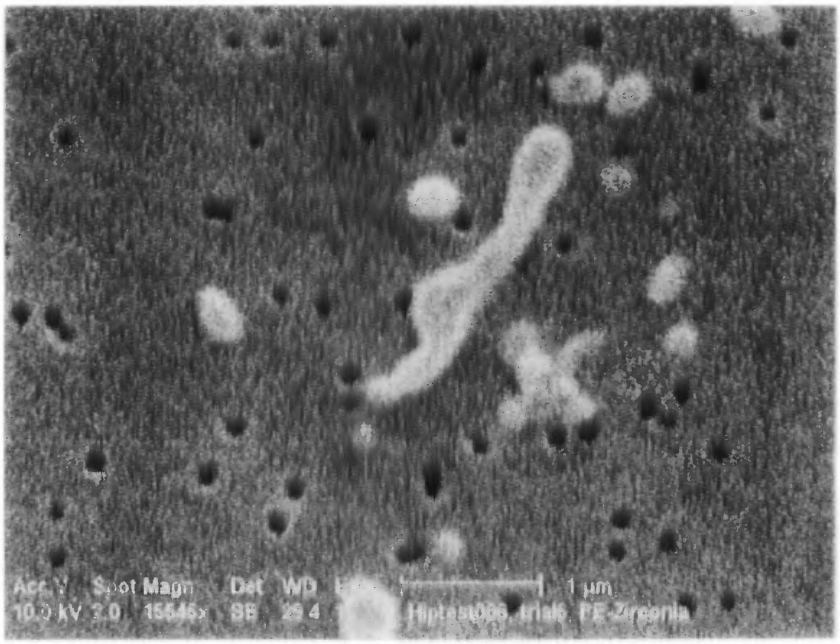

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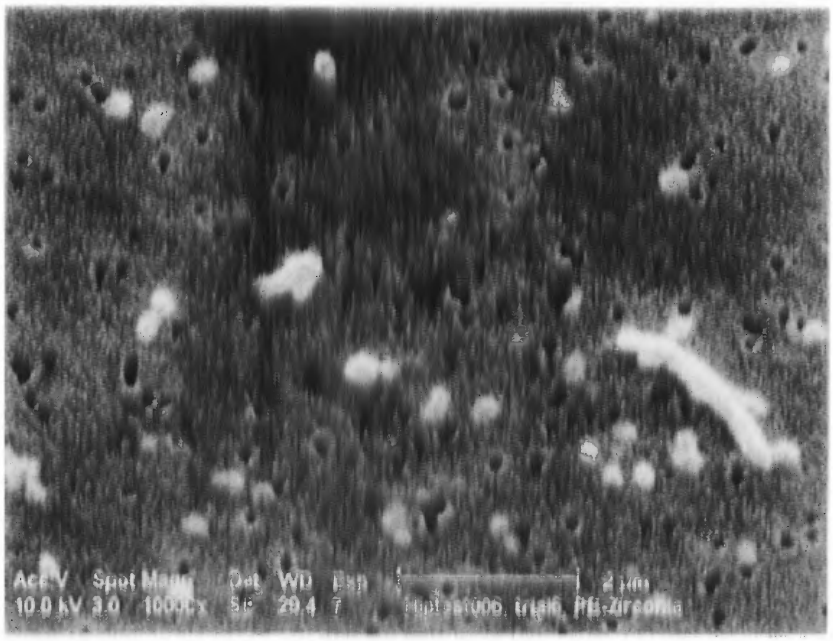

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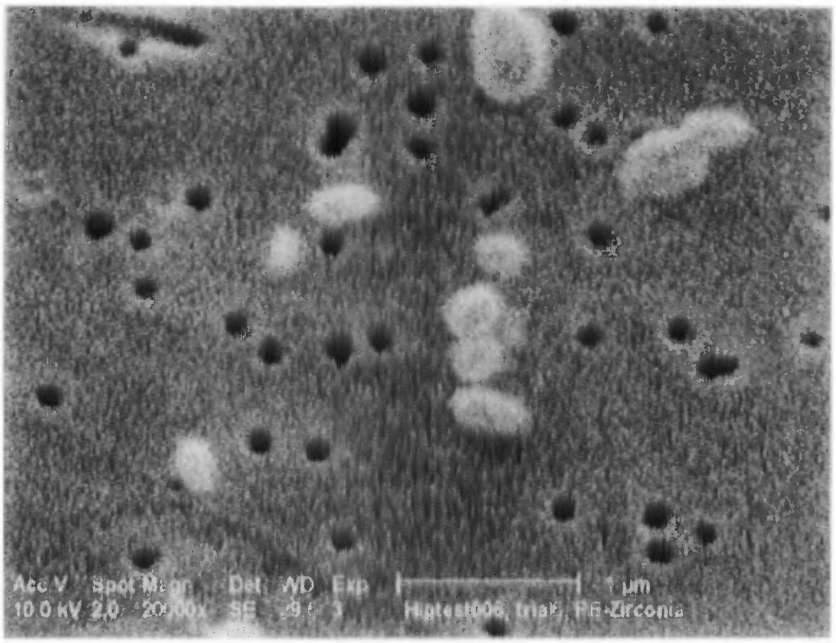

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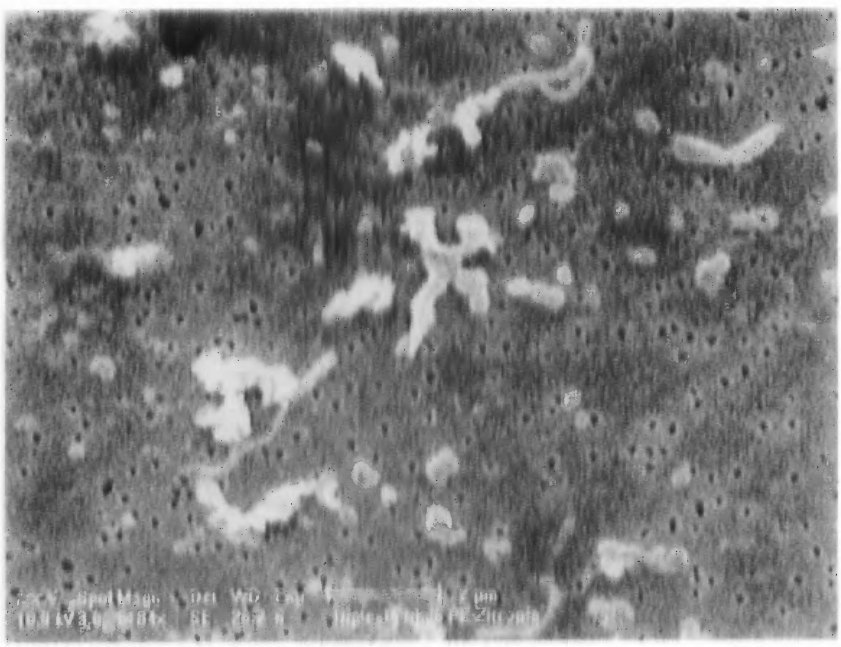

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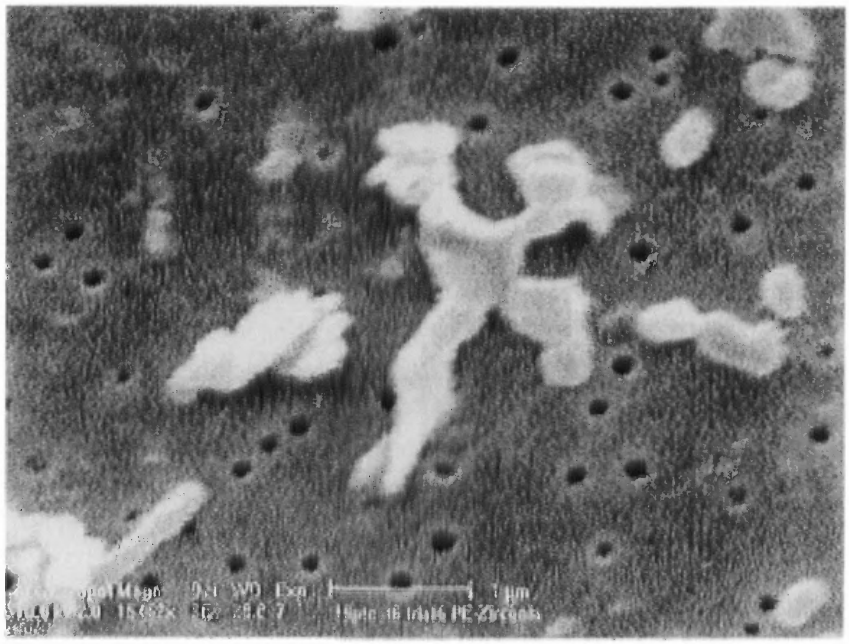
Figure 12 (Cont'd). Micrographs of Trial 3 (Zirconia-UHMWPE) Wear Particles

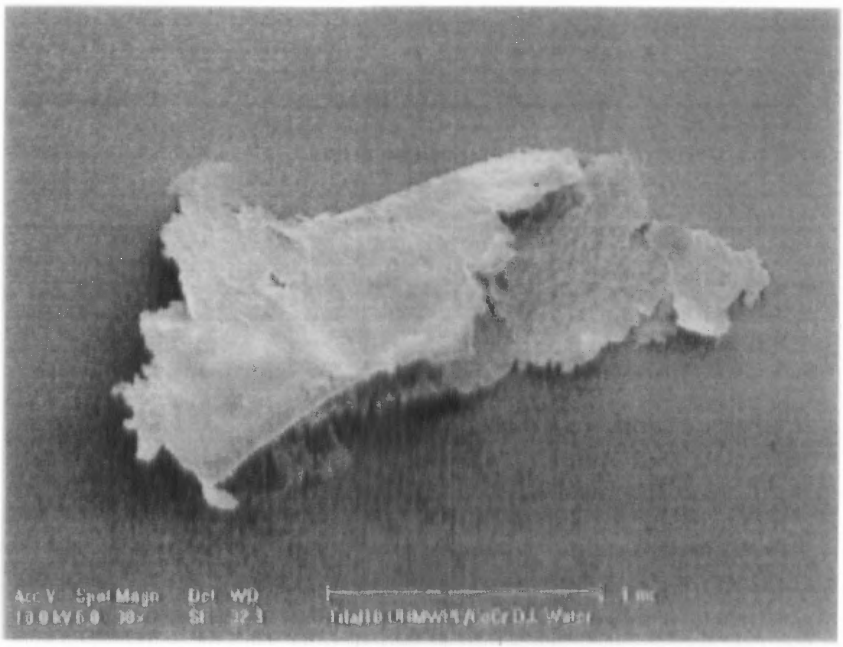


M

Figure 12 (Cont'd). Micrographs of Trial 3 (Zirconia-UHMWPE) Wear Particles

APPENDIX D

Micrographs of Trial 4 (CoCr-UHMWPE in DI Water) Wear Particles



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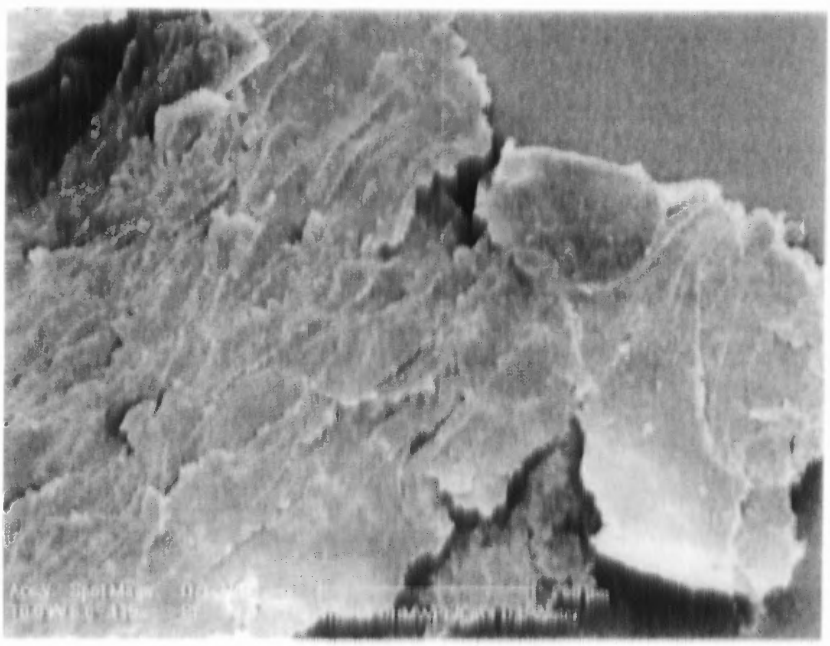
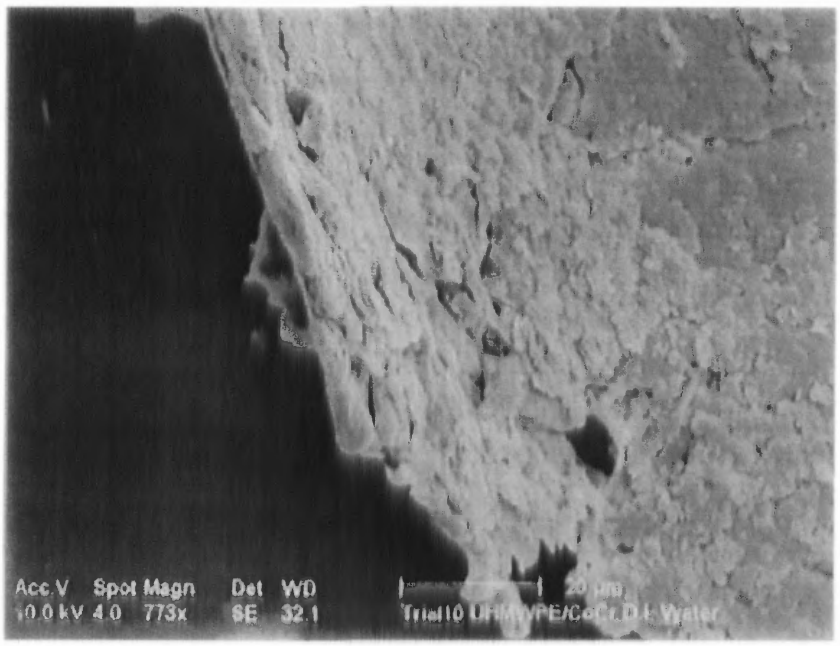


B

Figure 14. Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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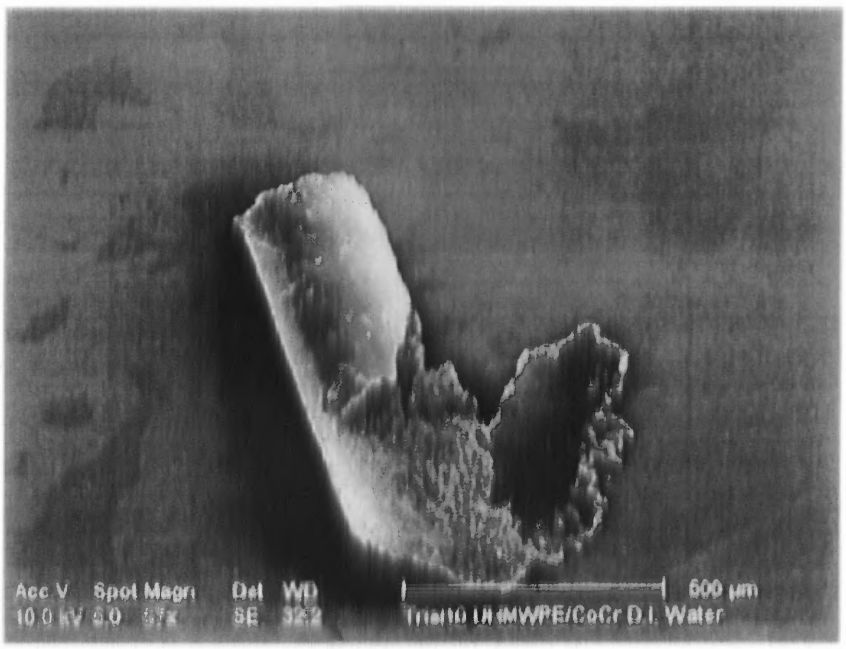
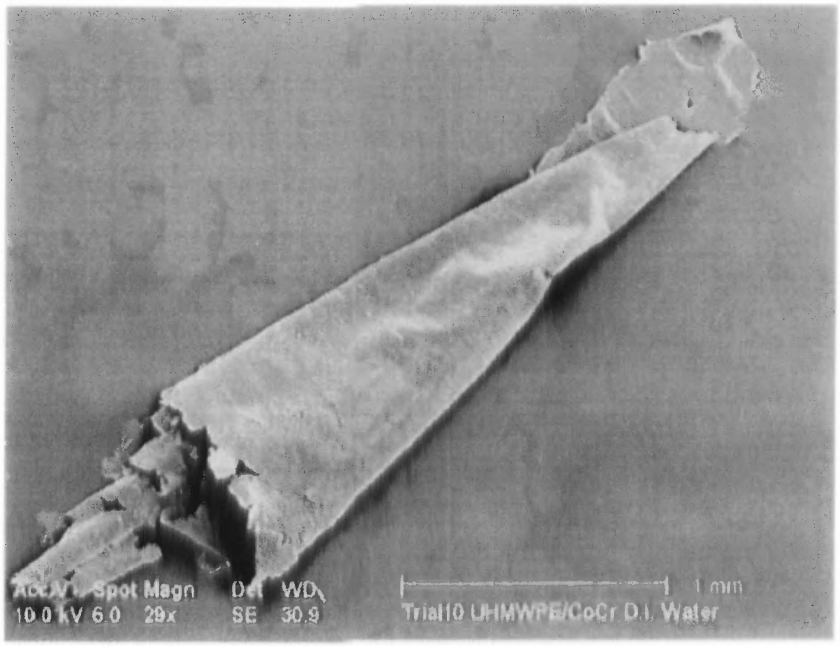


D

Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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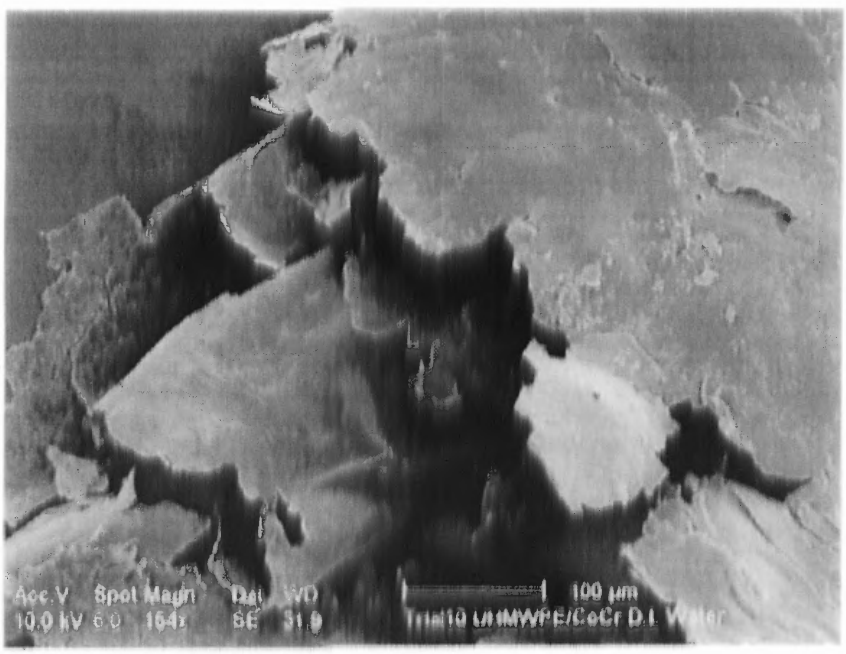

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Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles

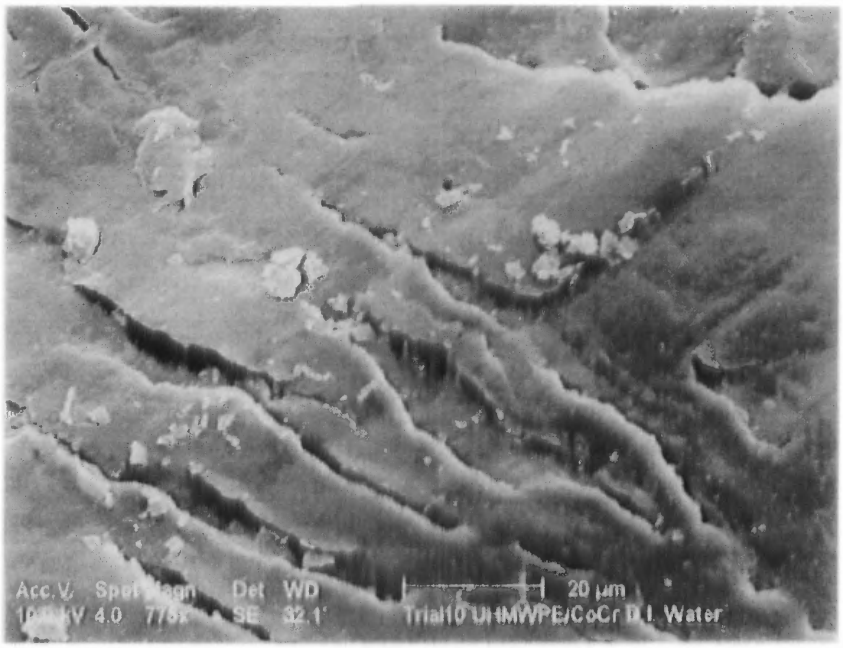

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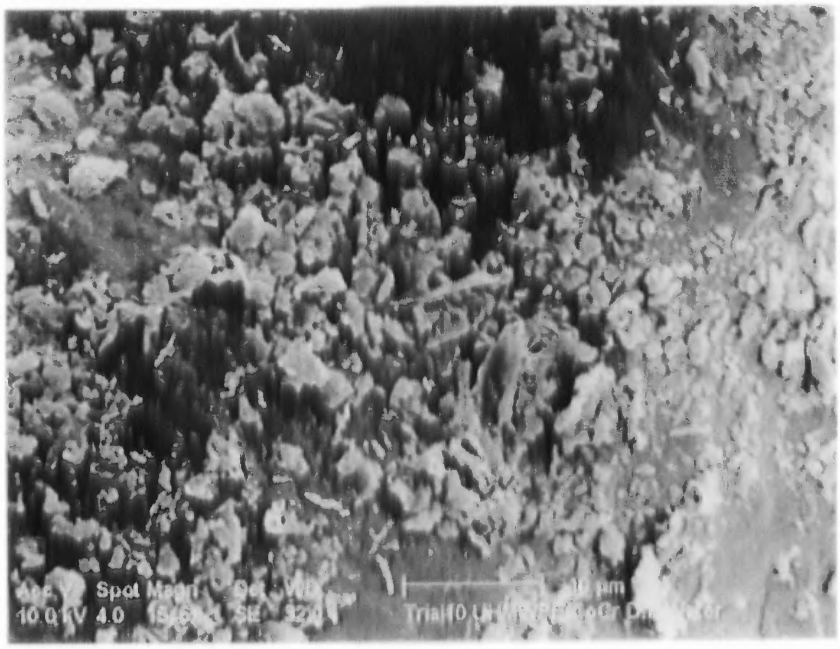
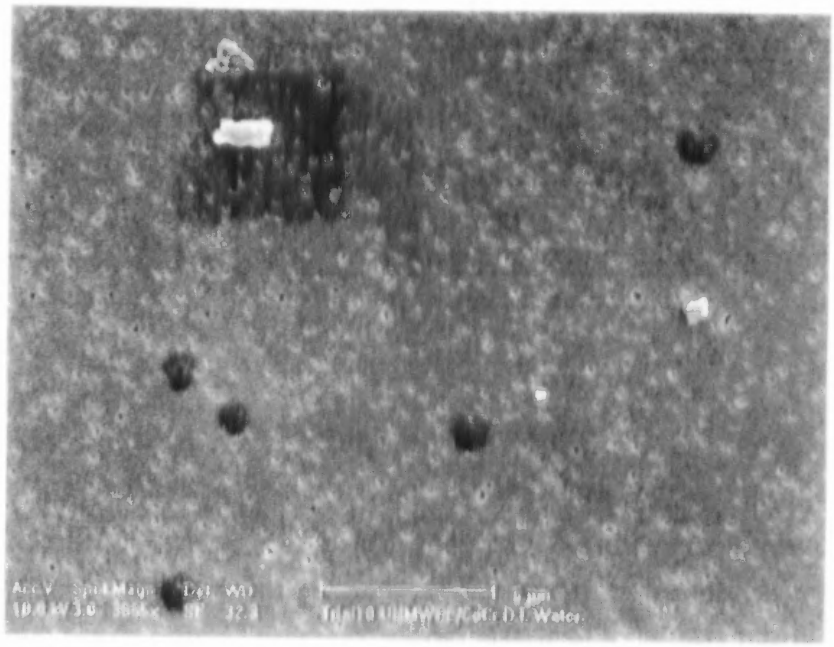
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



I

J

Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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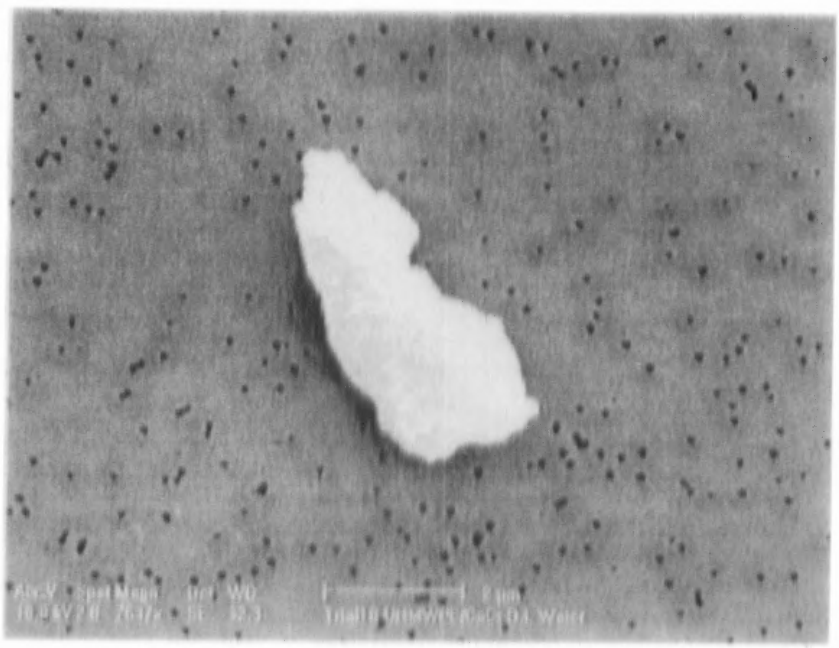
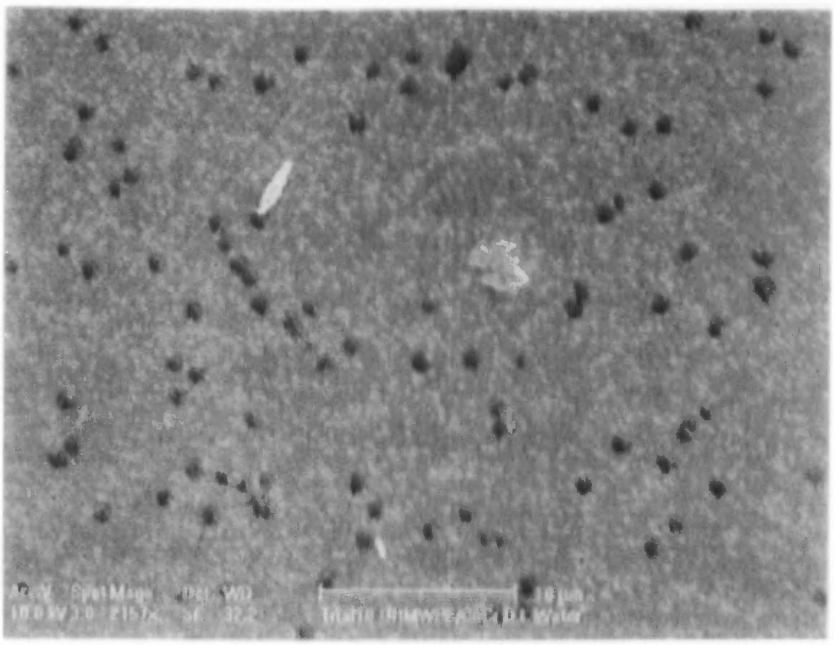


L

Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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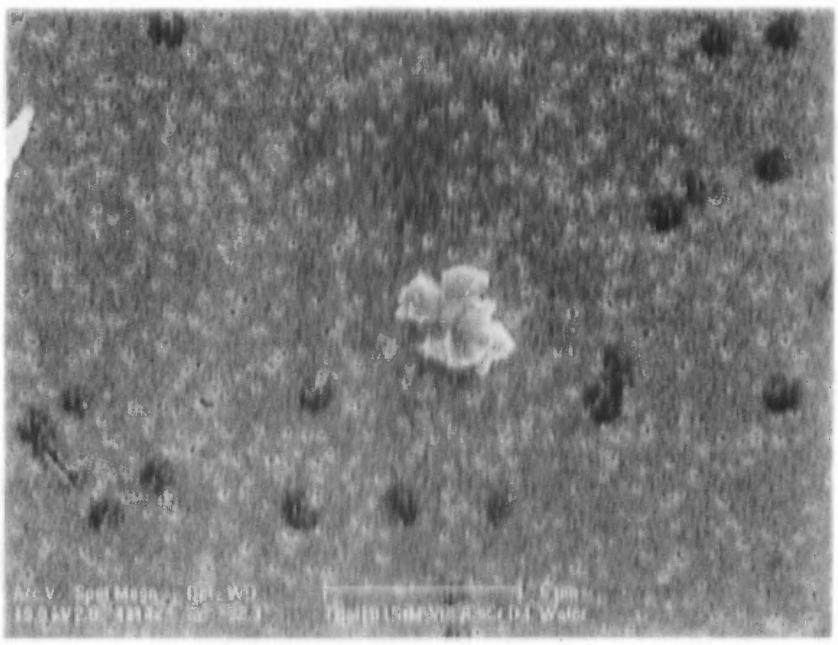

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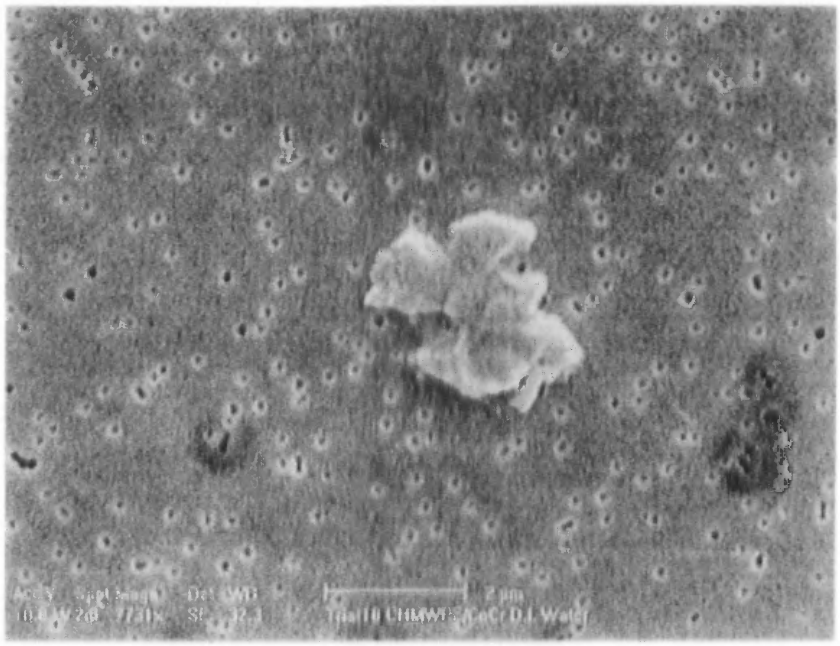
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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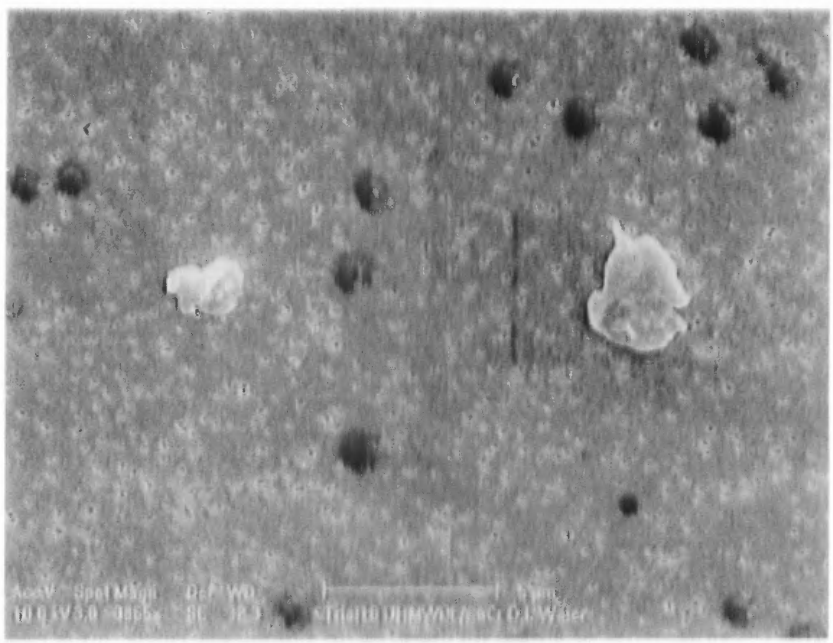

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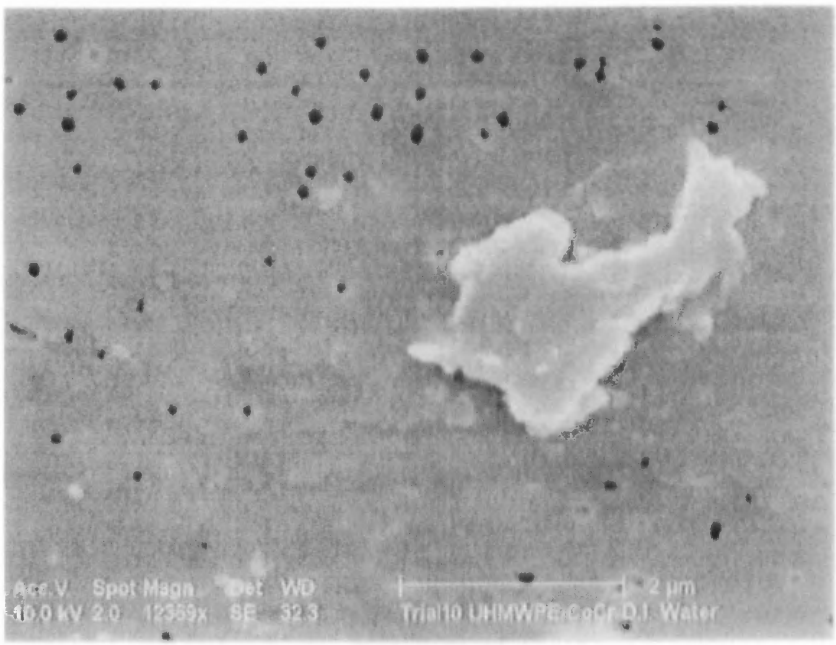
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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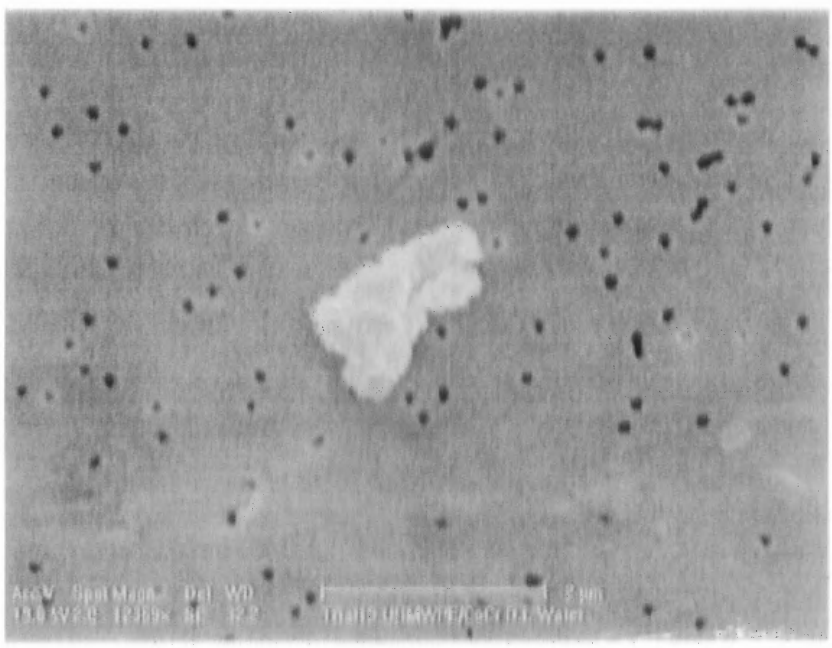

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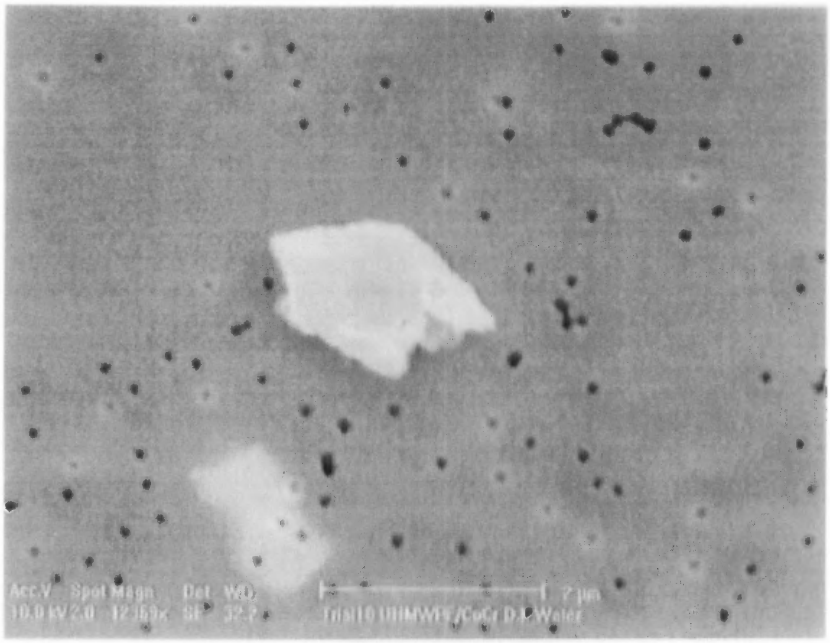
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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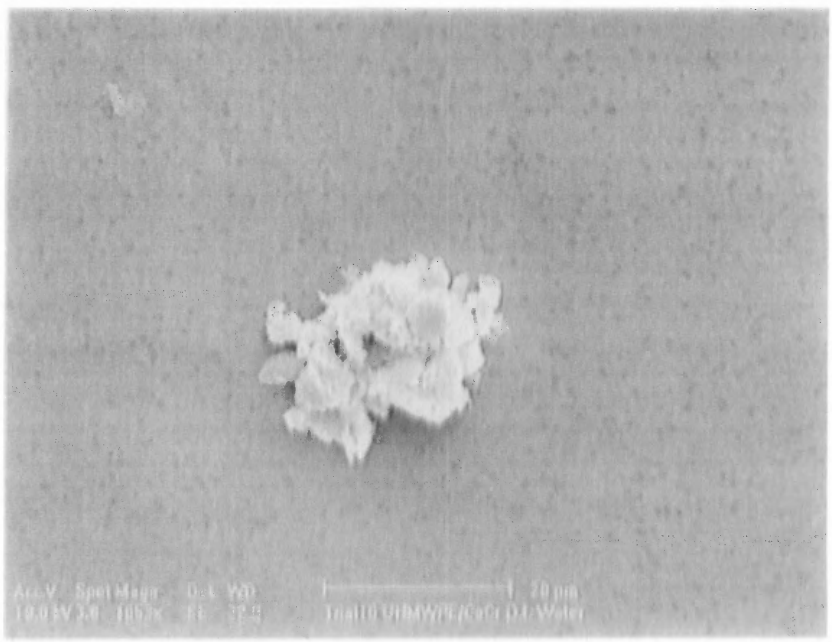

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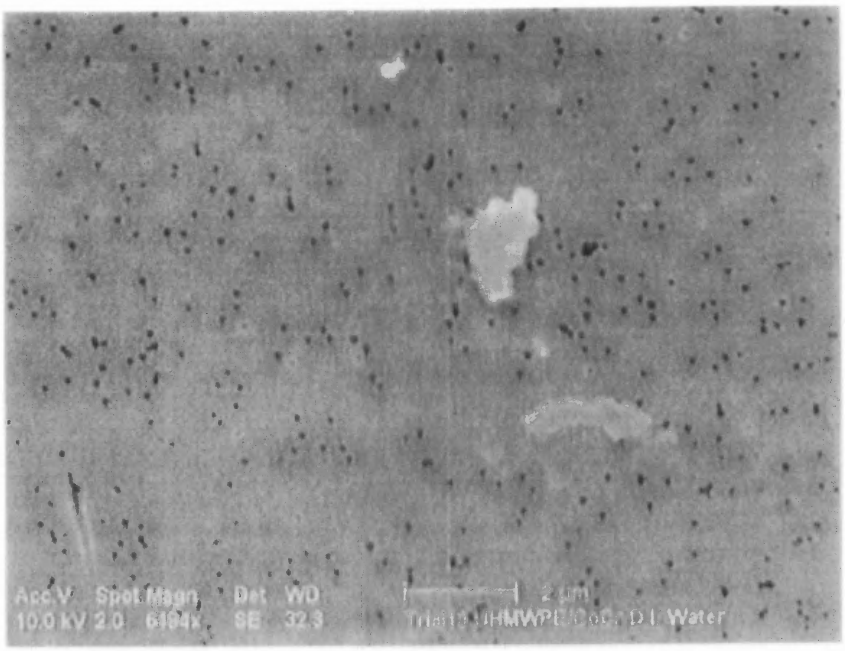
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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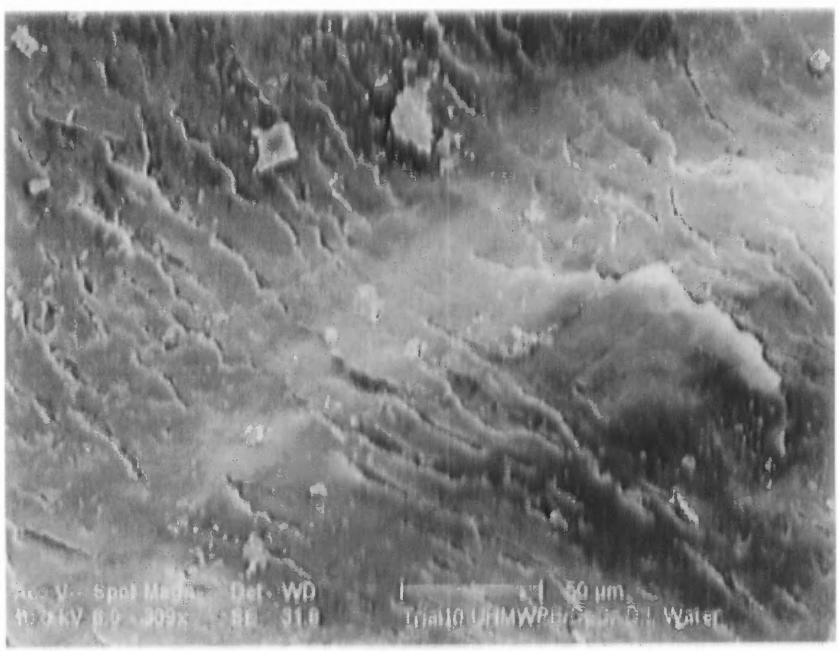

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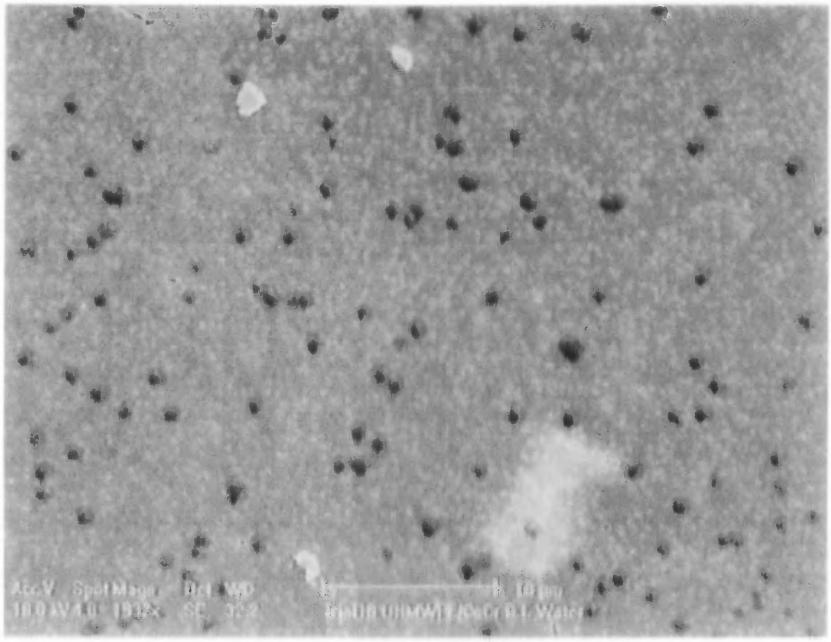
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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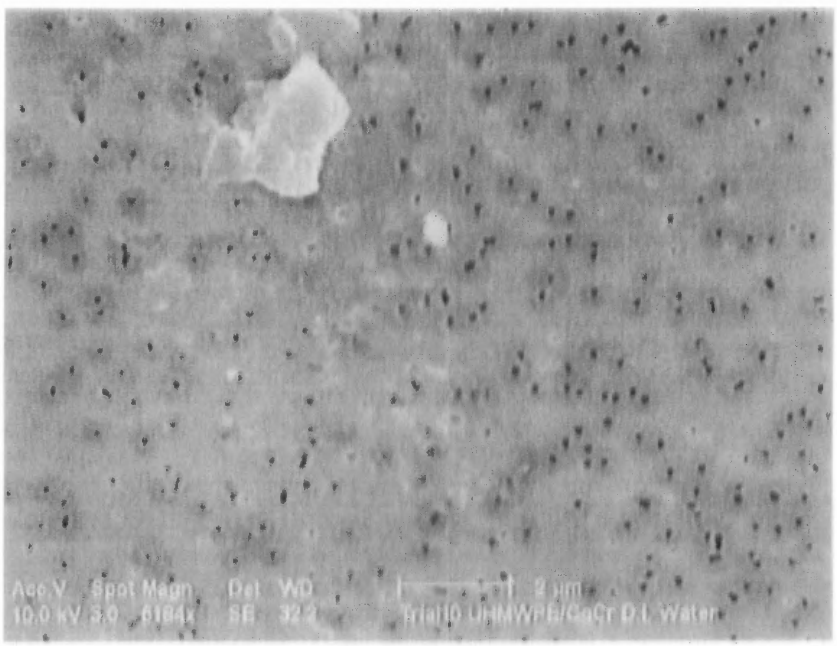

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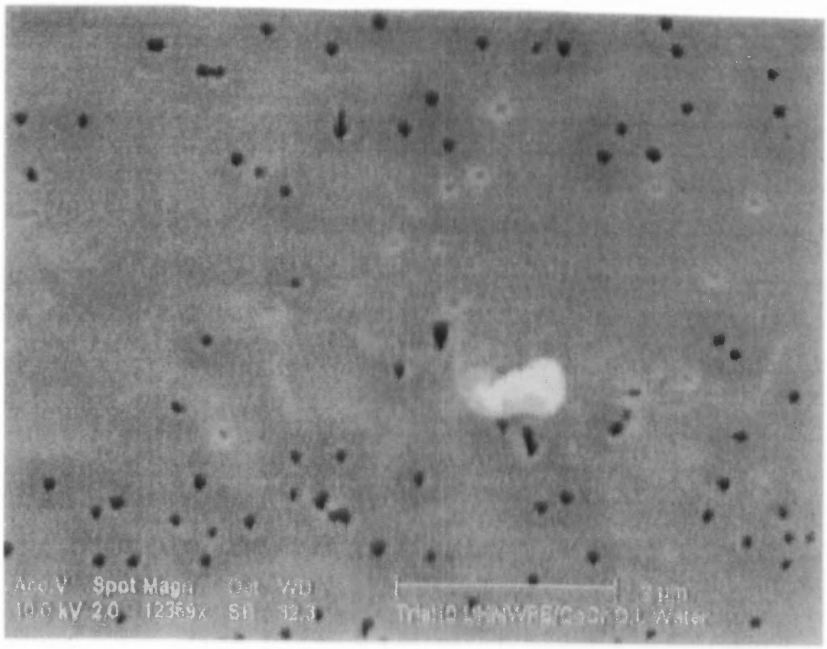
Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles



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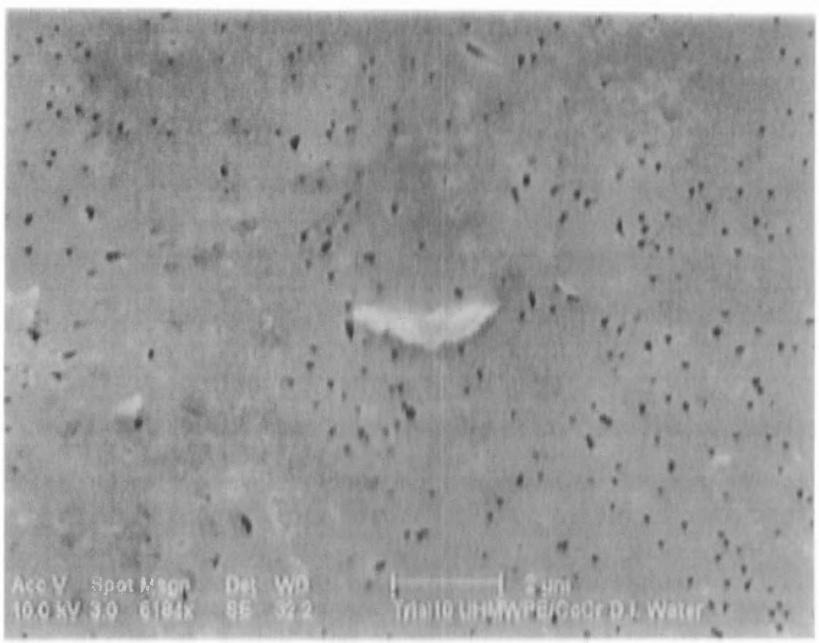

Z

Figure 14 (Cont'd). Micrographs of Trial 4 (CoCr-UHMWPE in D.I. Water) Wear Particles

REFERENCES

[1] Coleman, R.F., Herrington, J., and Scales, J.T., "Concentration of wear products in hair, blood and urine after total hip replacement," *British Medical Journal* , Vol 1, Mar. 1973, pp. 527-529.

[2] Dumbleton, J.H., "Wear and prosthetic joints," Joint Replacement Arthroplasty, Bernard F. Murray Ed., Churchill Livingstone, New York, 1991, pp.47-59.

[3] Kim, K.J., Wilson, S.C., D'Antonio, J.A., McClain, E.J., and Rubash, H.E., "High amounts of polyethylene debris in the membranes from bipolar endoprostheses," *Orthopaedic Transactions*, Vol 16 (3), Winter 1992-1993.

[4] Clarke, I.C., Campbell, P., and Kossovsky, N., "Debris mediated osteolysis - a cascade phenomenon involving motion, wear, particulates, macrophage induction and bone lysis," Particulate Debris from Medical Implants: Mechanisms of Formation and Biological Consequences, ASTM STP 1144, K.R. St. John Ed., American Society for Testing and Materials, Philadelphia, 1992, pp. 7-26.

[5] Cooper, R.A., McAllister, C.M., Bordon, L.S., and Bauer, T.W., "Polyethylene debris induced osteolysis and loosening in uncemented total hip arthroplasty: a cause of late failure," *Journal of Arthroplasty,* Vol 7 (3), Sept. 1992, pp. 285-290.

[6] St. John, K.R. (Ed), Particulate Debris from Medical Implants: Mechanisms of Formation and Biological Consequences, ASTM STP 1144, American Society for Testing and Materials, Philadelphia, 1992.

[7] Pizzoferrato, A., "Evaluation of the tissue response to the wear products of the hip joint endo-prosthesis," *Biomaterial Medical Devices and Artifical Organs*, Vol 7 (2), 1979, pp. 257-262.

[8] Rae, T., "Action of wear particles from total joint replacement prostheses on tissues," D. Williams Ed., Biocompatibility of Implant Materials, Sectos Publishing, London, 1976.

[9] Bullough, P.G., "Tissue reaction to wear debris generated from total hip replacement," *The Hip* , Vol 1, 1973, pp. 80-91.

[10] Kabo, J.M., Gebhard, J.S., Loren, G., and Amstutz, H.C., "In vivo wear of polyethylene acetabular components," *Journal of Bone and Joint Surgery* [Br], Vol 75 (2), Mar. 1993, pp. 254-258.

[11] Hutchings, I.M., Tribology: Friction and Wear of Engineering Materials, CRC Press, London, 1992.

[12] Rostoker, W., Chao, E.Y.S., and Galante, J.O., "The appearances of wear on polyethylene. A comparison of in vivo and in vitro wear surfaces," *Journal of Biomedical Materials Research*, Vol 12, May 1978, p. 317-335.

[13] Nusbaum, H.J., Rose, R.M., Paul, I.L., Crugnola, A.M., and Radin, E.L., "Wear mechanisms for ultra high molecular weight polyethylene in the total hip prosthesis," *Journal of Applied Polymer Science*, Vol 23, 1979, pp. 777-789.

[14] Jasty, M., and Smith, E., "Wear particles of total joint replacements and their role in periprosthetic osteolysis," *Current Opinion in Rheumatology*, Vol 4 (2), Apr. 1992, pp. 204-209.

[15] Dumbleton, J.H., "The clinical significance of wear in total hip and knee prostheses," *Journal of Biomaterial Applications*, Vol 3 (1), Jul. 1988, pp. 3-32.

[16] Savio, J.A. III, Overcamp, L.M., and Black, J., "Size and shape of biomaterial wear debris," *Clinical Materials*, Vol 15, 1994, pp. 101-147.

[17] Huk, O.L., Bansal, M., Betts, F., Lieberman, J.R., Huo, M.H., and Salvati, E.A., "Generation of polyethylene and metal debris from cementless modular acetabular components in total hip arthroplasty," *39th Annual Meeting, Orthopaedic Research Society*, Feb. 15-18, 1993, San Francisco, pp. 506.

[18] Jasty, M., Bragdon, C.R., Lee, K.R., Hanson, A.E., and Goetz, D.D., "Wear of polyethylene cups in THR: analysis of 159 cups retrieved at revision surgery or autopsy," *39th Annual Meeting, Orthopaedic Research Society*, Feb. 15-18, 1993, San Francisco, pp. 291.

[19] Wang, A., Polineni, V.K., Essner, A., Stark, C., and Dumbleton, J.H., "A tensile instability model for the wear of UHMWPE cups," To be submitted to *Journal of Material Science. Materials in Medicine.*, 1995.

[20] Fisher, J., Cooper, J.R., Dowson, D., Issac, G.H., and Wroblewski, B.M., "Wear mechanisms and sub-surface failure in UHMWPE acetabular cups," *39th Annual Meeting, Orthopaedic Research Society*, Feb. 15-18,1993, San Francisco, pp. 509.

[21] Wang, A., Stark, C., and Dumbleton, J.H., "The role of cyclic plastic deformation in the wear of UHMWPE acetabular cups," Submitted to *Journal of Biomedical Materials Research*, in press, 1995.

[22] Langkamer, V.G., Case, C.P., Heap, P., Taylor, A., Collins, C., Pearse, M., and Solomon, L., "Systemic distribution of wear debris after hip replacement: a cause for concern," *Journal of Bone and Joint Surgery* [Br], Vol 74B (6), Nov. 1992, pp.831-839.

[23] Rose, R. M., Schneider, H., Ries, M., Paul, I., Crugnola, A., Simon, S. R., and Radin, E. L, "A method for the quantitative recovery of polyethylene wear debris from the simulated service of total joint prostheses," *Wear*, Vol 51, Nov. 1978, pp.77-84.

[24] Willert, H.G., and Semlitsch, M., "Tissue reactions to plastic and metallic wear products of joint endoprostheses," S. Gschwend, H. Devrunner Eds., Total Hip Prosthesis, Hans Huber, Bern, 1976.

[25] Maloney, W.J., Smith, R.L., Huene, D., and Rubash, H., "Characterization of in vivo wear particles isolated from membranes around failed cementless total hip replacements," *Implant Retrieval Symposium of the Society for Biomaterials*, St. Charles Il, Sept. 17-20, 1992, pp. 28.

[26] Shanbhag, A.S., Jacobs, J.J., Glant, T.T., Gilbert, J.L., Black, J., and Galante, J.O., "Characterization of wear particles retrieved from failed uncemented total hip arthroplasty," *Implant Retrieval Symposium of the Society for Biomaterials*, St. Charles Il, Sept. 17-20, 1992, pp. 29.

[27] Schmalzried, T.P., Jasty, M., Burke, D.W., Rosenberg, A., Campbell, P.A., Kilgus, D., Amstutz, H.C., and Harris, W.H., "Periprosthetic bone loss: the role of polyethylene wear debris and the concept of the effective joint space," *Orthopaedic Transactions*, Vol 16 (3), Winter 1992-1993.

[28] Boynton, E., Waddell, J.P., Morton, J., and Gardiner, G.W., "Aseptic loosening in total hip implants: the role of polyethylene wear debris," *Canadian Journal of Surgery,* Vol 34 (6), Dec. 1991, pp. 599-605.

[29] Revell, P.A., Weightman, B., Freeman, M.A.R., and Roberts, V., "The production and biology of polyethylene wear debris," *Archives of Orthopaedic and Trauma Surgery,* Vol 91, May 1978, pp. 167-181.

[30] Revell, P.A., "Tissue reaction to joint prostheses and the products of wear and corrosion," C.L. Berry Ed., Bone and Joint Disease: Current Topics in Pathology, Springer-Verlag, Berlin, 1982, pp. 73-101.

[31] Maloney, W.J., Smith, R.L., Huene, D., and Rubash, H., "Particulate wear debris: characterization and quantitation from membranes around failed cementless femoral replacements," *39th Annual Meeting, Orthopaedic Research Society,* Feb. 15-18, 1993, San Francisco, pp. 294.

[32] Shanbhag, A.S., Jacobs, J.J., Glant, T.T., Gilbert, J.L., Black, J., and Galante, J.O., "Composition and morphology of wear debris in failed uncemented total hip replacement," *Journal of Bone and Joint Surgery* [Br], Vol 76B (1), Jan. 1994, pp. 60-67.

[33] Campbell, P., McKellop, H., Yeom, B., Grigoris, P., Salovey, R., and Amstutz, H.C., "Isolation and characterization of UHMWPE particles from periprosthetic tissues," *The 20th Annual Meeting of the Society for Biomaterials*, Mar. 1994, Boston, pp. 227.

[34] Mejia, L.C., and Brierley, T.J., "A hip wear simulator for the evaluation of biomaterials in hip arthroplasty components," *Biomedical Materials and Engineering,* Vol 4 (4), 1994, pp.259-271.

[35] McKellop, H., and Clarke, I., "Evolution and evaluation of materials screening machines and joint simulators in predicting in vivo wear phenomena," P. Ducheyne, G. Hastings Eds., Functional behavior of orthopaedic materials Vol II: Applications, CRC Press, Boca Raton, 1984, pp. 51-85.

[36] Paul, J.P., "Forces transmitted by joints in the human body.", Lubrication and wear in living and artificial human joints., The Institution of Mechanical Engineers, Proceedings 1966-67, Vol 181, Part 3J, London, pp 8-15.

[37] "Recovery of Particulate from tissue," Draft ASTM Document, Task Force F04.16.05, Technical Contact: Pat Campbell, Joint Replacement Institute, 2400 S. Flower St, Los Angeles, CA. 90007.

[38] Campbell, P., Ma, S., and Belcher, G., "A method for metal and particle isolation from periprosthetic tissues," *39th Annual Meeting, Orthopaedic Research Society*, Feb. 15-18, 1993, San Francisco, pp. 494.

[39] Amstutz, H.C., Campbell, P., Kossovsky, N., and Clarke, I.C., "Mechanism and clinical significance of wear debris induced osteolysis," *Clinical Orthopaedics and Related Research*, (276), Mar. 1992, pp. 7-18.

[40] Bennett, N.E., Wang, J.T., Manning, C.A., and Goldring, S.R., "Activation of human monocyte/macrophages and fibroblasts by metal particles; release of products with bone resorbing activities," *Transactions of the Orthopaedic Research Society,* Vol 18 (1), 1991, pp. 188.

[41] Bobyn, J.D., Collier, J.P., Mayor, M.B., Mctighe, T., Tanzer, M., and Vaughn, B.K., "Particulate debris in total hip arthroplasty: problems and solutions," Scientific Exhibit, AAOS Meeting, San Francisco, 1993.

[42] Bosch, P., Kristen, H., and Zweymuller, K., "An analysis of 119 loosenings in total hip endoprostheses," *Archives of Orthopaedic and Traumatic Surgery,* Vol 96, 1980, pp. 83-90.

[43] Campbell, P., Schmalzried, T., and Amstutz, H.C., "Wear debris induced osteolysis as a cause of TJR failure," *Implant Retrieval Symposium of the Society for Biomaterials*, St. Charles Il, Sept. 17-20, 1992, pp. 19.

[44] Crugnola, A., Schiller, A., and Radin, E., "Polymeric debris in the synovium after total joint replacements: histological identification," *Journal of Bone and Joint Surgery,* Vol 59A (7), Oct. 1977, pp. 860-861.

[45] DiCarlo, E.F., and Bullough, P.G., "The biological responses to orthopaedic implants and their wear debris," *Clinical Materials*, Vol 9 (3-4), 1992, pp. 235-260.

[46] Harley, J.M., and Boston, D.A., "Acetabular cup failure after total hip replacement," *Journal of Bone and Joint Surgery* [Br], Vol 67B, Mar. 1985, pp. 222-224.

[47] Harris, W.H., "Aseptic loosening in total hip arthroplasty secondary to osteolysis induced by wear debris from titanium alloy modular femoral beads," *Journal of Bone and Joint Surgery* [Am], Vol 73A (3), Mar. 1991, pp. 470-472.

[48] Huo, M.H., Salvati, E.A., and Buly, R.L., "Wear debris in cemented total hip arthroplasty," *Orthopaedics*, Vol 14 (3), Mar. 1991, pp. 335-340.

[49] Jasty, M., Jiranek, W., and Harris, W.H., "Acrylic fragmentation in total hip replacements and its biological consequences," *Clinical Orthopaedics*, Vol 285, Dec. 1992, pp. 116-128.

[50] Lombardi, A.V. Jr, Mallory, T.H., Vaughn, B.K., and Drouillard, P., "Aseptic loosening in total hip arthroplasty secondary to osteolysis induced by wear debris from titanium alloy modular femoral beads," *Journal of Bone and Joint Surgery* [Am], Vol 71A (9), Oct. 1989, pp. 1337-1342.

[51] Maguire, J.K. Jr, Coscia, M.F., and Lynch, M.H., "Foreign body reaction to polymeric debris following total hip arthroplasty," *Clinical Orthopaedics and Related Research*, (216), Mar. 1987, pp. 213-223.

[52] Margevicius, K.J., Bauer, T.W., McMahon, J.T., Brown, S.A., and Merritt, K., "Isolation and characterization of debris in membranes around total joint prostheses," *Journal of Bone and Joint Surgery,* Vol 76A (11), Nov. 1994, pp.1664-1675.

[53] Pazzaglia, U.E., and Pringle, J.A.S., "Bone resorption in vitro: macrophages and giant cells from failed total hip replacement versus osteoclasts," *Biomaterials*, Vol 10, May, 1989, pp. 286-288.

[54] Wang, A., Sun, D.C., Stark, C., and Dumbleton, J.H., "Wear mechanisms in total joint replacements," Submitted to *Wear*, in press, Apr. 1995.

[55] Willert, H.G., Bertram, H., and Buchhorn, G.H., "Osteolysis in alloarthroplasty of the hip. The role of ultra high molecular weight polyethylene wear particles, " *Clinical Orthopaedics and Related Research*, (258), Sept. 1990, pp. 95-107.