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Fabrication and Wear Test of a Continuous Fiber/Particulate Composite Total Surface Hip Replacement

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FABRICATION AND WEAR TEST OF A CONTINUOUS FIBER/PARTICULATE

COMPOSITE TOTAL SURFACE HIP REPLACEMENT*

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SUMMARY

Continuous fiber woven E-glass/epoxy composite femoral shells having the same elastic properties as bone have been fabricated. These shells were coated with filled epoxy wear resistant coatings consisting of 1 to 64 micron particles of: Al_2O_3 , $Al_2O_3 + Cu$, and 18-8 stainless steel + Al_2O_3 in an epoxy matrix. The resulting femoral shells were wear tested dry against ultrahigh molecular weight polyethylene (UHMWPE) acetabular cups for up to 250 000 cycles on a total hip simulator. The best femoral shell tested was the one containing particles of 18-8 stainless steel + Al_2O_3 in an epoxy base. Articulation of this shell dry against UHMWPE for 250 000 cycles resulted in a friction force that was about 10 percent lower than that of the current total hip prosthesis, that is, a vitallium ball articulating dry with an UHMWPE cup. An UHMWPE acetabular cup when articulating with a vitallium ball showed a weight loss of 0.0004 g, while an UHMWPE cup when articulating with the 18-8 stainless steel + Al_2O_3 epoxy shell in the 250 000 cycle wear test showed a 0.0058 gram weight loss. Addition of graphite fibers to the UHMWPE acetabular cup and articulation with the 18-8 stainless steel + Al_2O_3 epoxy shell increased the friction force but reduced the surface damage to the UHMWPE. When femoral shells containing $Al_2O_3 + Cu$ particles in an epoxy matrix were run dry against UHMWPE for 42 000 cycles the friction force was continually increasing and there was evidence of more surface damage to the UHMWPE cup than when the shell contained particles of 18-8 stainless steel + Al_2O_3 .

INTRODUCTION

Most of the current artificial hip joints are composed of a metal femoral stem articulating with an ultrahigh molecular weight polyethylene (UHMWPE) acetabular cup. Both components are secured with acrylic bone cement. Problems of this design related to bone resorption, acrylic bone cement failure and loosening or fatigue of the metal stems (refs. 1 to 4) have led to interest in the cup or shell arthroplasty. This involves removal of bone from the femoral head and acetabulum and replacement with matching cups or shells (refs. 5 and 6). However, use of metal parts in

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this procedure may still lead to problems due to the mismatch in elastic properties between metal and bone. This problem has been solved by the analytical design of a continuous fiber epoxy composite femoral shell (ref. 7). The composite shell was designed to have the same elastic properties as bone, have adequate strength and be thin enough to require a minimum amount of bone resection. This design raises new questions related to the poor thermal conductivity, high coefficient of thermal expansion, low softening temperature and creep and wear of the epoxy composite. One possible solution would be to apply a relatively thin coating of a resin impregnated with particles that would make the surface harder and more wear resistant as well as change the thermal characteristics. The tribological characteristics of several filled epoxy wear resistant coatings sliding against UHMWPE in bench tests were found to be equivalent to that of 316 stainless steel sliding against UHMWPE (ref. 8).

Therefore, the objective of this investigation was to fabricate continuous fiber epoxy composite femoral shells having similar elastic properties as bone, apply appropriate wear resistant coatings and run wear tests of these shells articulating dry with UHMWPE acetabular cups in a total hip simulator. Results were compared to that of a standard vitallium ball articulating with an UHMWPE cup.

METHODS AND MATERIALS

Fabrication of the Epoxy/E-Glass Femoral Shells

The results of the analytical composite design (ref. 7) showed that it would take 10 to 12 layers of $0^\circ/90^\circ$ woven E-glass fibers to make a 2 millimeter thick epoxy composite shell. This was the same thickness metal shell that was found to require a minimum amount of bone resectioning (ref. 6). The epoxy/E-glass composite shell would have a factor of safety of 2.5 based on a tensor failure criterion when designed as an elastic spherical ball loaded against an elastic semi-infinite body. Thirty percent by volume of E-glass fibers and 70 percent by volume of epoxy would be required to give the shells similar elastic properties as bone.

The epoxy used consisted of a thermosetting resin, Araldite 6010,* and an aromatic diamine hardener, XU 205.* The epoxy was formed by mixing 100 parts to 32 parts by weight, respectively, of resin to hardener. The continuous fiber composite shells were formed by laying-up a $0^\circ/90^\circ$ woven E-glass** fabric (30 percent fibers by volume), layer by layer, on top of a 43.9 millimeter diameter spherical die. Flats were machined on two sides of the die to prevent rotation of the shells while being wear tested. Once the desired number of epoxy coated E-glass layers were obtained a two-piece female femoral mold, with an internal sphere cut in it, was clamped over the composite. This two-piece die butted up against a large nut threaded on the other end of the male femoral die. The nut served to preset the 2 millimeter distance between the male and female dies. The entire apparatus was then set in a nitrogen pressure chamber in an oven and a pressure of 1.02 MPa (150 psi) was applied to prevent void formation. The composite was gelled for 2 hours to 80°C (175°F) and then postcured for 4 hours at 150°C (300°F). The female femoral mold was removed and the outside radius

*Ciba-Geigy, Inc., Ardsley, New York.

**Woven fabric Style 1659, Burlington Glass Fabrics, Altavista, Virginia.

of the epoxy composite was reduced by 0.20 to 0.254 millimeter (0.008 to 0.010 in.) on a lathe. The outer surface was then coated with wear resistant coatings consisting of particles of either $Al_2O_3 + Cu$, or 18-8 stainless steel + Al_2O_3 all in an epoxy matrix. The female femoral mold was then repositioned on the shell and the entire apparatus set back in the oven. The coatings were cured in the same manner as the epoxy/E-glass shells. The final continuous fiber/particulate composite femoral shells were polished in the following sequence: wet 600 grit silicon carbide paper, 1 micron, 0.3 micron and 0.05 micron alpha-alumina polishing compound.

Fabrication of UHMWPE Acetabular Cups

The UHMWPE acetabular cups were compression molded in a two-piece male/female die. Two thermocouples, one in the male die and one in the female die, were used to monitor the compression molding temperature. The molding cycle appears in appendix A. UHMWPE polymer with and without graphite fibers was used. Five plain UHMWPE acetabular cups and one with 1:20 parts by weight of graphite fibers were molded.

APPARATUS

The total hip simulator (fig. 1) was designed to accept various designs of full-size total hip prostheses or a ball and socket test specimen and to simulate the motions (ref. 9), and the variable loads (refs. 9 to 11) encountered in the hip joint.

The femoral specimens were mounted in a fixture extending from the end of an oscillating shaft. The shaft oscillates up to $\pm 18^\circ$ and simulates the major extension and flexion of the hip joint in the sagittal plane of walking (see ref. 9). The shaft was driven by a variable speed direct current electric motor and worm gear box in unidirectional rotation. An eccentric was mounted on the output shaft of the gear box and was adjustable to give the desired extension and flexion. An adjustable length crank arm was connected on one end to the gear box eccentric that allows positioning of the ball in the sagittal plane. The other end of the crank arm was connected to a larger eccentric on the simulator drive shaft and drove the main shaft in oscillating motion. The femoral specimen was mounted on a bearing assembly in the femoral ball fixture perpendicular to the drive shaft. The inner bearing assembly holds the femoral ball. It has an arm extending radially from its center. The radial arm is restrained at the extended end and thus as the drive shaft oscillates the femoral specimen will oscillate in the transverse plane. For normal walking this oscillation is $\pm 7^\circ$ (ref. 9). The amount of internal and external rotation is determined by the restraining location on the radial arm.

The acetabular cup was mounted in a fixture that was stabilized with flexures. These flexures carry the load applied to the prosthesis assembly and permit the acetabular cup to move in a third motion $\pm 6^\circ$ (ref. 9) and simulate abduction and adduction motion of walking as encountered in the frontal plane. That simulated motion was a plane through the main drive shaft centerline. The motion was transmitted with a push rod driven by a cam on the main drive shaft. The cam was designed for the desired motion of the acetabular cup. The acetabular cup fixture has a special flexure suspension and force transducer that enables measurement of the friction force in the sagittal plane.

The load was applied by means of a hydraulic cylinder and hydraulic pump system through rods and main flexures. The hydraulic cylinder was controlled by a hydraulic servosystem and electronic programmer. A strain gage type load cell with two strain gage bridges was connected mechanically to the hydraulic cylinder. One of the bridge circuits served as an electrical feedback to the hydraulic servovalve and servocontroller amplifier. The second strain gage bridge was used to measure the load. The load strain gage bridge output was recorded on an oscillographic recorder.

PROCEDURE

The male die on which the femoral shells were formed was modified to fit the femoral ball fixture. The femoral shells and acetabular cups were then assembled (fig. 2) on the femoral ball fixture. The tests were run dry at room temperature (25°C) (77°F) to produce a worse case wear situation. The standard test was then run at a gait of 30 walking cycles per minute (60 steps/min) and a programmed load simulating walking. The loads ranged from 264 N (60 lb) to 2940 N (660 lb) and the load pattern was as shown in figure 3 for a single walking cycle. The friction force as a function of walking cycle was recorded at 2 hour intervals. The test was terminated after 42 000 cycles (approx. 24 hrs). Then a series of post-42 000 cycle friction tests were performed at constant loads ranging from 123 N (28 lb) to 2240 N (504 lb). Post-42 000 cycle wear test weight measurements were made on the acetabular cups.

During each walking cycle, the friction force at the ball-socket interface is continuously measured. A saw toothed curve normally results with one spike representing the maximum friction as the ball rotates in one direction and a second or negative spike representing the maximum friction as the ball rotates in the opposite direction. Normally, these curves are fairly symmetrical and therefore the maximum friction force is calculated by taking the peak to peak value and halving it.

The shells yielding the best results were then selected to run dry in a 250 000 cycle (approx. 1 week) wear test. The same gait and programmed load were used and the friction force was monitored. Pre- and post-test weight measurements were made on the acetabular cups. An optical microscope was used to study the wear surfaces of both the femoral shells and acetabular cups. Table 1 shows the test code, femoral shell code and material, and the acetabular cup code and material.

RESULTS

42 000 Cycle Wear Tests

The results of post-wear test friction measurements for femoral shells A, B, C, and D articulating dry against acetabular cups E, E, E and F, respectively, are shown in figure 4. For normal loads ranging from 125 N (28 lb) to 2240 N (504 lb) the friction force after the 42 000 cycle test was lowest in test D/E, that is, the (2:1) parts by weight 18-8 stainless steel/epoxy + (3:10) parts by weight Al_2O_3 /epoxy shell articulating with an UHMWPE acetabular cup. The friction force was highest for test B/E, the (1:2) parts by weight Al_2O_3 /epoxy + (1:5) parts by weight Cu/epoxy shell articulating with the UHMWPE acetabular cup. When a vitallium femoral ball, material A, was run with an UHMWPE cup, material E, the friction force was lower than in tests B/E, C/E, or D/F.

Figure 5 shows the maximum friction force as a function of time for all tests during the 42 000 cycle wear test. The friction force stabilized within 10 000 cycles for tests A/E, D/E, and D/F. The friction force during gait was lowest in test D/E, the (2:1) 18-8 stainless steel/epoxy + (3:10) Al_2O_3 /epoxy shell articulating with an UHMWPE cup. When the vitallium ball, material A, was run against the UHMWPE cup, material E, the friction force had the most stable profile. In tests B/E and C/E, the (1:2) Al_2O_3 /epoxy + (1:5) or (2:5) Cu/epoxy shells articulating with UHMWPE cups, the friction force was continually increased with time. When the copper content was doubled, the friction force (after 4000 cycles) increased about 20 to 30 percent.* Addition of 1:20 parts by weight of graphite fibers to the UHMWPE, acetabular cup F, and running dry against femoral shell D, the (2:1) 18-8 stainless steel/epoxy + (3:10) Al_2O_3 /epoxy shell, increased the friction force by about 40 percent compared to test D/E. During gait the friction force obtained when using femoral shell D was about 17 percent lower than when using material A in articulation against UHMWPE. Figure 6 shows the oscilloscope traces of both the programmed load and the friction force for all tests at the end of the 42 000 cycle wear test.

The acetabular cups from the 42 000 cycle tests were placed in a vacuum chamber, evacuated for a length of time for weight stabilization. They were then weighed in air at intervals prior to testing. This same procedure was followed after testing. The weights were averaged before and after the tests and subtracted to get the weight change. However, the standard deviation of the weight measurements was larger than the weight change for all 42 000 cycle wear tests, thus indicating no measurable wear.

Figure 7(a) to (d) shows femoral shells and acetabular cups after running for 42 000 cycles for tests A/E, B/E, C/E, and D/F, respectively. Femoral shells B, C and D were polished in the contact area. There was evidence in shells B and C, the Al_2O_3 + Cu/epoxy, of massive UHMWPE transfer and abrasion. The worn area in shells B, C, and D appeared to be in the form of a horseshoe around the polar cap. There was an area about 1.5 centimeters wide directly on the polar cap that was unpolished. The horseshoe extended downward from this about 1.5 centimeters. There was some visual evidence of flakes of abraded UHMWPE on the surface of the vitallium ball, material A. The worn area on shell D, from test D/F, was different from the others in that it extended directly across the polar cap. This area appeared to be covered with graphite, but there was no evidence of abrasion. The UHMWPE acetabular cups from tests B/E and C/E had some discoloration and scratches.

Figure 8 is a composite optical photograph in the polar cap area of acetabular cups from tests B/E, C/E, D/E, and D/F, respectively, after the 42 000 cycle wear test. When femoral shell B was run dry against acetabular cup E, there appeared to be adhesion in the polar cap area as seen in figure 8(a). When femoral shells C or D were run dry against material E the type of surface damage in the polar cap area appeared to be in the form of small parallel cracks (figs. 8(b) and (c)). The addition of graphite fibers to the UHMWPE increased its resistance to surface damage as can be seen in figure 8(d). Figure 9 is a composite optical photograph in the polar cap area

*Throughout this paper all percent changes are calculated as maximum-minimum/maximum x 100.

of femoral shells B, C, and D after, respectively, tests B/E, C/E, and D/E. There was little evidence of surface damage in this area to shells B or D. Shell C had some surface scratches.

250 000 Cycle Wear Test

Femoral specimens A and D were selected for continued testing against acetabular cup material E in 250 000 cycle wear tests. The maximum friction force from 42 000 to 250 000 cycles for test A/E was 121 ± 9 N and from test D/E it was 114 ± 2 N. There was very little damage to either specimen A, the vitallium ball, or its mating UHMWPE acetabular cup. However, there was evidence of abrasive wear on the UHMWPE cup after articulation against material D, the (2:1) 18-8 stainless steel/epoxy + (3:10) Al_2O_3 /epoxy shell. There was also evidence of scratches on the surface of shell material D. The weight loss of the UHMWPE cup from test A/E was 0.00044 ± 0.0001 g. The weight loss of the UHMWPE cup from test D/E was 0.0058 ± 0.0006 gram. A summary of friction and wear results for all tests appears in table 11.

DISCUSSION

Charnley (ref. 5) theorized that a larger diameter ball would produce higher frictional torques that might loosen the stem cup. However, according to these results a larger diameter ball may not necessarily produce this effect. For example, test D (44 mm diameter shell) had a friction force 17 percent lower than test A/E (22 mm diameter ball). Surface roughness, modulus, yield strength, hardness, etc., may also affect the friction force. Materials B and C had friction forces approximately 30 to 40 percent higher at a normal load of 2240 N than when shell D was run dry against the material E in post-42 000 cycle friction tests. The addition of 1:20 parts by weight graphite fibers to the UHMWPE, acetabular cup F, and running dry against shell D, increased the friction force approximately 10 to 20 percent between normal loads of 240 to 2240 N. Apparently the added graphite increased the ploughing component of friction, thus increasing the friction force. The friction force was reduced when the copper content was doubled (tests B/E and C/E). This increase in copper content have increased the thermal conductivity (see. ref. 8), and helped transfer heat away from the contact area. This in turn may have reduced the adhesive component of friction.

Figure 10 is a plot of the coefficient of friction versus normal load for post-42 000 cycle friction tests. The general trend was for the coefficient of friction to decrease with increasing load. The coefficients of friction based on an integrated average load of 1014 N during the 42 000 cycle wear tests for A/E, D/E and D/F were, respectively, 0.11, 0.094, and 0.17. Tests B/E and C/E yielded continuously increasing coefficients of friction throughout the tests. Again, material D articulating with material E had the lowest coefficient of friction.

During 42 000 cycle wear tests A/E, D/E, and D/F, the friction force reached a constant value within about the first 10 000 cycles (4 to 6 hrs). Apparently the tests (B/E and C/E) involving $(Al_2O_3 + Cu)$ /epoxy could not establish a run-in period. Probably the poor sliding characteristics of copper caused this. At the end of the 42 000 cycle wear test, the friction force for tests A/E and D/E were, respectively, 124 N and 97 N. During the

25 000 cycle wear test the friction forces for these same two tests were, respectively, 121 ± 9 N and 114 ± 7 N. This would seem to indicate a very small change in the friction force, hence, coefficient of friction up to 250 000 cycles. However, Amstutz (ref. 12) in a wear study of polymers sliding against SAE 4620 case hardened steel on an LFW-1 wear test machine, found that the coefficient of friction in mineral oil continually decreased up to 350 000 cycles. In a study of composite coated epoxy samples running dry against UHMWPE on an LFW-1 wear test machine (ref. 8) it was found that the friction force leveled off after the first 12 hours in a 48-hour wear test. These differences may be attributed to the different test conditions or test apparatus used.

In figure 6 there is a variation in the shade of the friction force traces as a function of the walking cycle for test A/E, compared to the other tests during the 42 000 cycle wear test. When the vitallium prosthesis was tested in figure 6(a), there is one peak at heel strike and one peak at toe-off. However, in all other tests there are three peaks of varying magnitude. It was noticed prior to testing that the fit between the shells and cups was a little too tight. The UHMWPE cups were then put back in the mold and stress relieved by cold compressing. This close fit may have caused the extra friction peak.

There were scratches, gouges and discoloration evident in acetabular cups from tests B/E and C/E and mild scratches and polishing in acetabular cups from tests A/E, D/E, and D/F. The mottled area in acetabular cups from tests B/E and C/E was yellowish-brown in color. This discoloration is probably due to copper deposits, or oxides of copper. This may indicate high adhesive forces removing copper from the shell or poor bonding of the copper to the epoxy. There was evidence of massive transfer of UHMWPE to the surfaces of shells B and C. However the surfaces of ball A and shell D in tests A/E and D/E were polished with few abrasive scratches. There was ample evidence of graphite transfer to the shell in test D/F in the 42 000 cycle wear test.

The type of surface damage observed under an optical microscope in the polar cap area of UHMWPE acetabular cups from the 42 000 cycle wear test varied from possible adhesion or abrasion to fatigue. Figure 8(a) shows a mottled area which could be the result of an adhesive wear process. This same effect was observed when an LFW-1 wear test machine was used (ref. 8). When the $(Al_2O_3 + Cu)/epoxy$ samples were run dry against UHMWPE for 42 000 cycles there appears to be cracks forming perpendicular to the direction of sliding (see fig. 8(b)). This same type of surface failure occurs when (18-8 stainless steel + Al_2O_3)/epoxy is used as seen in figure 8(c). The wear mechanisms of adhesion, abrasion and fatigue have been observed by other investigators. Walker et al. (ref. 13) observed abrasive wear and some cracks attributed to microfatigue in the two-piece UHMWPE total surface hip replacement. Rostoker, Chao and Galante (ref. 14) observed scratches and gouges, and surface cracks in tests done in vitro with a hip joint simulator. Weightman et al. (ref. 15) found cracks perpendicular to the direction of sliding when testing McKee-Farrar or Charnley-Muller prostheses on a total hip simulator. Therefore, the types of surface failure observed with conventional prostheses, that is, scratching (abrasion), gouges, adhesion and cracks were observed for the shells tested here.

Wear

There was some abrasion and polishing of the vitallium ball when run dry against UHMWPE for 250 000 cycles and a cup weight loss of 0.00044 gram. There was evidence of massive abrasion when the (18-8 stainless steel + Al_2O_3)/epoxy shell was run dry against the UHMWPE cup for 250 000 cycles. Powder or flakes of UHMWPE were found in the polar region of the acetabular cup. When these flakes were removed the resulting weight loss for the UHMWPE cup was 0.0058 gram. Since the UHMWPE has a density of 0.94 gm/cc and the sliding distance and integrated average load were, respectively, 1730 meters and 1014 N the wear rate for the acetabular cup in test D/E was $3.5 \times 10^{-15} \text{ m}^3/\text{N-m}$. * Test A/E yielded a wear rate of $1.5 \times 10^{-16} \text{ m}^3/\text{N-m}$. In a study by Brown, Atkinson, Dowson and Wright (ref. 16) the wear rate for UHMWPE sliding dry against surgical grade stainless steel in a pin-on disk wear test machine was $1.2 \times 10^{-16} \text{ m}^3/\text{N-m}$. Tanaka and Uchiyama (ref. 17) measured the wear of superhigh-molecular-weight polyethylene with a pin-on-disk apparatus. A calculated wear rate of about $5 \times 10^{-16} \text{ m}^3/\text{N-m}$ was reported. Similar experiments by Jones, et al. (ref. 18) yielded a higher wear rate ($1.6 \times 10^{-15} \text{ m}^3/\text{N-m}$). Obviously, more tests using a larger sample size and with a simulative joint lubricant would be needed to establish a reproducible wear rate for materials tested in this investigation.

BIOCOMPATIBILITY

The clinical use of any joint prosthesis demands biocompatibility of the materials employed. Some of the materials suggested, that is, UHMWPE epoxy, and acrylic bone cement have either been previously used as implant materials or have been shown to be relatively nontoxic in the as-cured or polymerized state when implanted in bulk form as reported by Lee and Neville (ref. 19), Hine et al. (ref. 20), and Escalles et al. (ref. 21). Toxicity of the fibers would be of less importance, to a certain extent, because of their encapsulation and subsequent isolation from tissue. However, in the event that a fiber would extrude into surrounding tissue, its tolerance should be examined. Quartz, a constituent of E-glass, was found to be well tolerated when implanted as a solid block subcutaneously (ref. 22). Aluminum-oxide has been found to be relatively biocompatible by Salzer et al. (ref. 23). An aluminum-oxide endoprosthesis was well tolerated in 12 tumor patients. Griss et al (ref. 24) found Al_2O_3 composites biologically acceptable, however Escalles et al. (ref. 21) found ceramics to present very poor tissue tolerance. Particles of 316 L stainless steel, which are commonly used prosthetic materials, could be substituted for the 18-8 stainless steel. This might prevent any problems related to the different types of steel as the 316 L stainless is now used in total hip prosthesis. Copper may be toxic as it is readily absorbed in the blood (ref. 24). When radioactive copper-64 or -67 was administered intravenously to 49 normal subjects, absorption was observed in 30 to 50 percent of the people tested. The toxic effects of copper in intrauterine devices is still under study (refs. 26 to 28). Possibly aluminum could be substituted for copper as its

*Although expressing wear rate in these units, implies a linear relationship between m^3/m and N_1 the authors do not have evidence to prove that this relationship is valid.

thermal conductivity is about the same as that for copper. At any rate, the final joint prosthesis would certainly have to be tested for tissue biocompatibility and checked for compliance with any ASTM Committee F-4 Standard for materials.

SUMMARY OF RESULTS

Continuous fiber woven E-glass/epoxy composite femoral shells having the same elastic properties as bone have been fabricated. These shells were coated with filled epoxy wear resistant coatings consisting of 1 to 64 micron particles of: $\text{Al}_2\text{O}_3 + \text{Cu}$, and 18-8 stainless steel + Al_2O_3 in an epoxy matrix. The resulting femoral shells were wear tested dry against ultrahigh molecular weight polyethylene (UHMWPE) acetabular cups up to 250 000 cycles on a total hip simulator. The major results were:

1. The femoral shell containing particles of 18-8 stainless steel and Al_2O_3 in an epoxy matrix articulating dry against an UHMWPE cup yielded the lowest friction force of all shells tested including a standard vitallium ball.

2. In a 250 000 cycle wear test, the wear rate of an UHMWPE cup articulating against a standard vitallium ball was $1.3 \times 10^{-16} \text{ m}^3/\text{N-m}$ while the rate for the 18-8 stainless steel + Al_2O_3 epoxy shell was $3.5 \times 10^{-15} \text{ m}^3/\text{N-m}$.

3. Addition of graphite fibers to the UHMWPE cup and articulation against the composite shell (18-8 stainless steel + Al_2O_3) caused an increase in the friction force but reduced surface damage to the cup.

4. Femoral shells containing particles of Cu and Al_2O_3 in an epoxy matrix articulating against UHMWPE cups yielded a continually increasing friction force and more cup surface damage than the 18-8 stainless steel and Al_2O_3 shell.

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APPENDIX A

Compression molding temperature-pressure sequence for UHMWPE cups:

1. Preheat molds to 121° C (250° F)
2. Preheat powder to 121° C (250° F)
3. Distribute powder evenly in female mold
4. Place male plunger in and pressurize to 5.2 Mpa (750 psi) and hold for 2 minutes
5. Reduce pressure to atmospheric
6. Repressurize to 6.9 Mpa (1000 psi) for 1 minute then lower to 3.5 Mpa (500 psi) and hold
7. Raise temperature to 216° ± 3° C (420° ± 5° F) and maintain pressure at 3.5 Mpa (500 psi)
8. Hold at 216° C (420° F) and 3.5 Mpa (500 psi) for 10 minutes.
9. Turn off heat and cool for about 15 minutes or until temperature reaches 177° - 163° C (350° - 325° F)
10. Then cool with frozen blocks* to 66° C (150° F) (at 149° C (300° F) repressurize to 6.9 Mpa (1000 psi))
11. Remove caps

*Aluminum blocks stored -29° C (-20° F).

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TABLE I. - TEST CODE, FEMORAL SHELL CODE AND MATERIAL,
AND ACETABULAR CUP CODE AND MATERIAL

Test code	Femoral shell code and material ^a	Acetabular cup code and material ^a (all cups unirradiated)
A/E	(A) Solid vitallium ball (Charnley) ^b	(E) UHMWPE (commercial)
B/E	(B) Epoxy/E-glass shell coated with (1:2) Al ₂ O ₃ / ^c epoxy + (1:5) Cu ^d /epoxy	(E) UHMWPE
C/E	(C) Epoxy/E-glass shell coated with (1:2) Al ₂ O ₃ /epoxy + (2:5) Cu/epoxy	(E) UHMWPE
D/E	(D) Epoxy/E-glass shell coated with (2:1) 18-8 stainless steel ^e /epoxy + (3:10) Al ₂ O ₃ /epoxy	(E) UHMWPE
D/F	(D) Epoxy/E-glass shell coated with (2:1) 18-8 stainless steel/epoxy + (3:10) Al ₂ O ₃ /epoxy	(F) (1:20) Graphite fibers ^f /UHMWPE

^aAll ratios are by weight.

^bBall diameter was 22 mm as compared to 44 mm (1.73 in.) for composite shells.

^c1 micron particles, Buehler Ltd., Evanston, Illinois.

^d16 micron particles, Cerac Inc., Menominee Falls, Wisconsin.

^e64 micron particles, Metco Inc., Westbury, Long Island, New York.

^fHercules, Inc., Wilmington, Delaware.

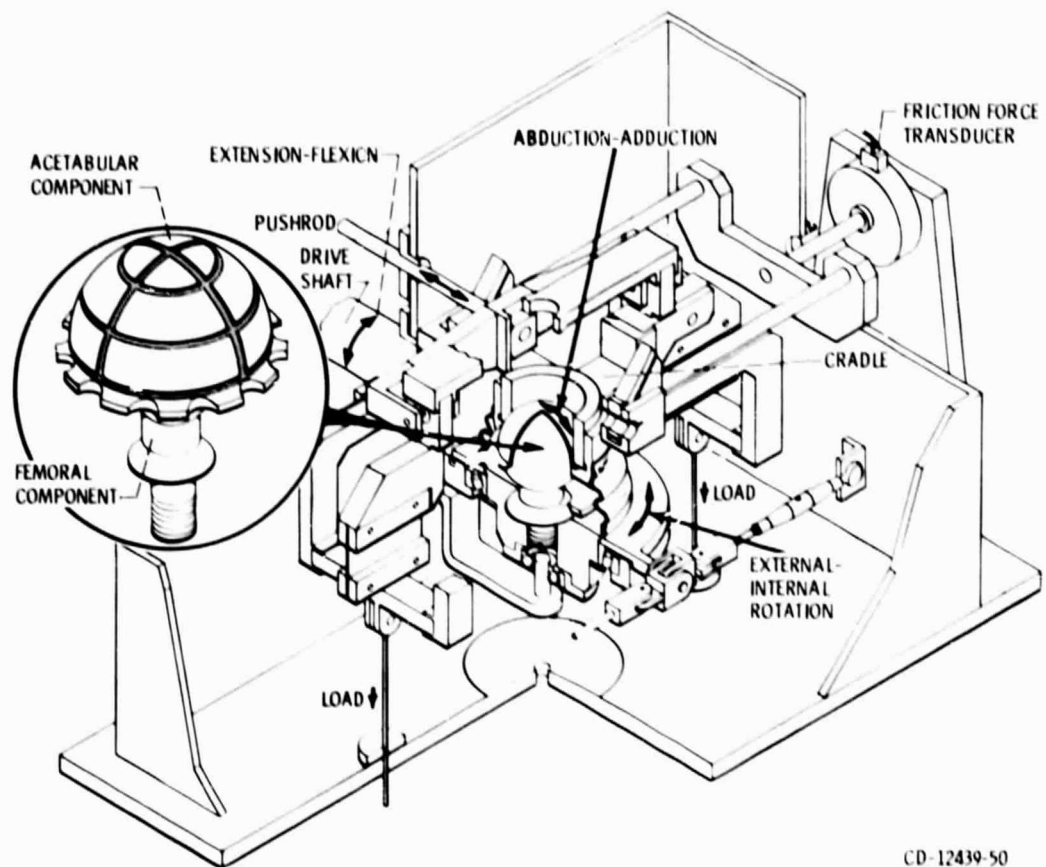
TABLE II. - SUMMARY OF RESULTS

Test	Maximum friction force, N		Coefficient of friction ^a during gait ^b	Wear rate ^a after 250 000 walking cycles, m ³ /N-m
	Variable load during gait ^b	Constant load (2240 N) post 42 000 cycle test		
A/E	114 (121) ^c	178	0.11	1.3x10 ⁻¹⁶
B/E	Continually increasing 163 at 4000 cycles 243 at 42 000 cycles	277	0.16-0.24	Not run
C/E	Continually increasing 119 at 4000 cycles 168 at 42 000 cycles	230	0.12-0.17	Not run
D/E	93 (114) ^c	161	0.094	3.5x10 ⁻¹⁵
D/F	168	203	0.17	Not run

^aBased on integrated average load of 1014 N.

^bDuring 42 000 cycle test.

^cDuring 250 000 cycle test.



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Figure 1. - Perspective and partial cutaway view of total hip simulator with prosthesis specimens showing direction of motion and load.

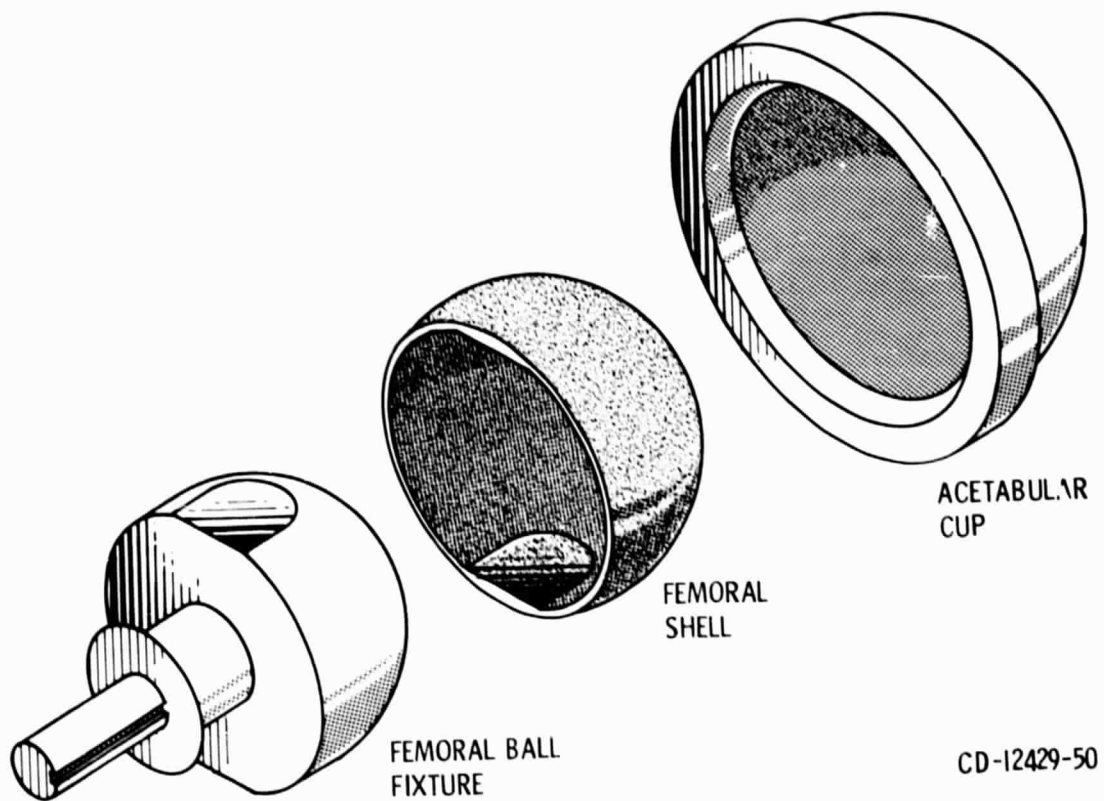


Figure 2. - Femoral ball fixture, femoral shell and acetabular cup of current design.

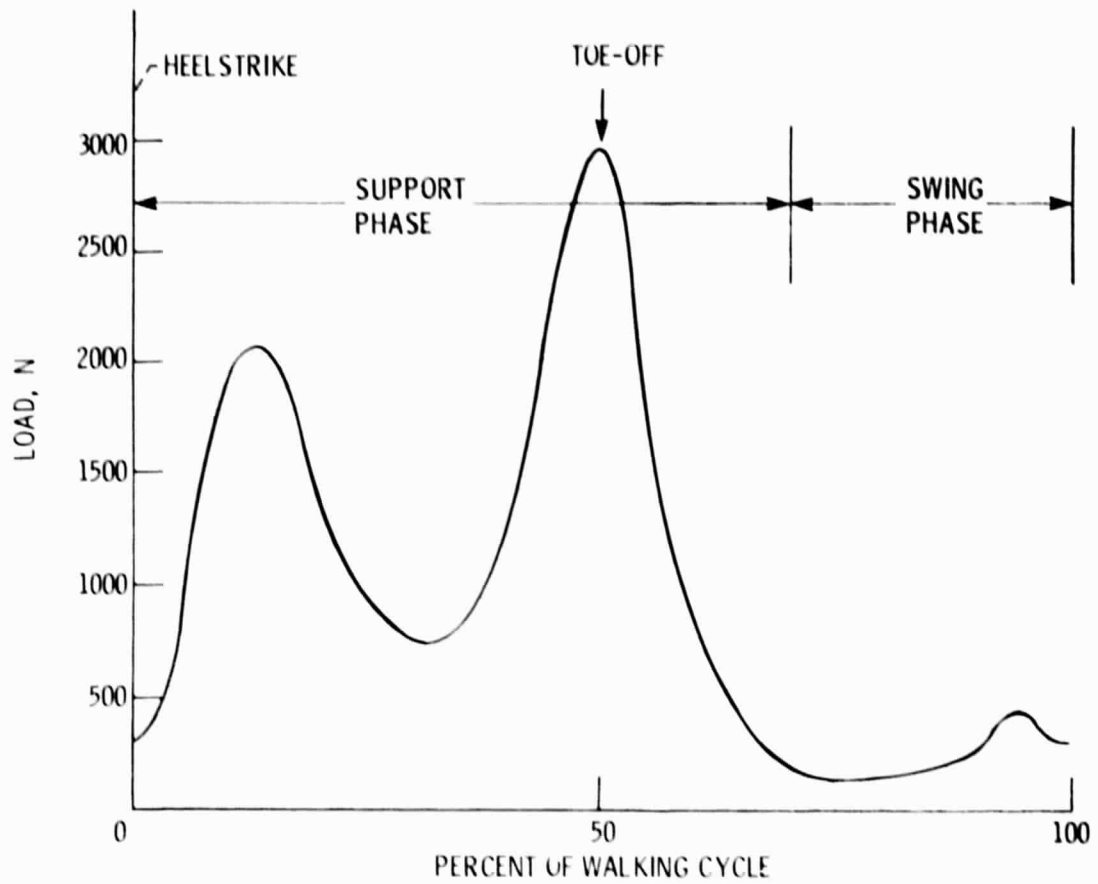


Figure 3. - Hip joint loads during gait.

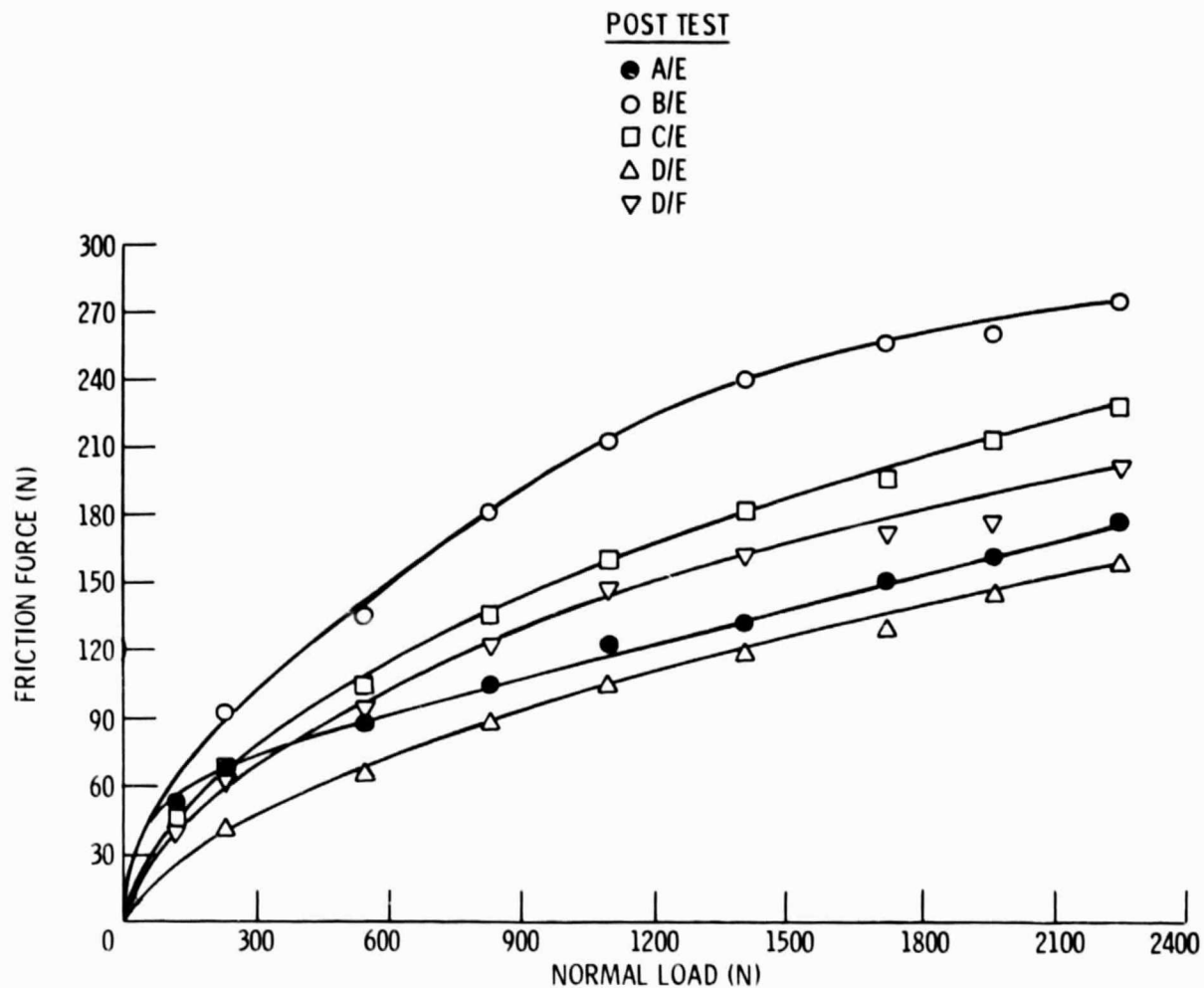


Figure 4. - Post 42 000 cycle friction force versus normal load.

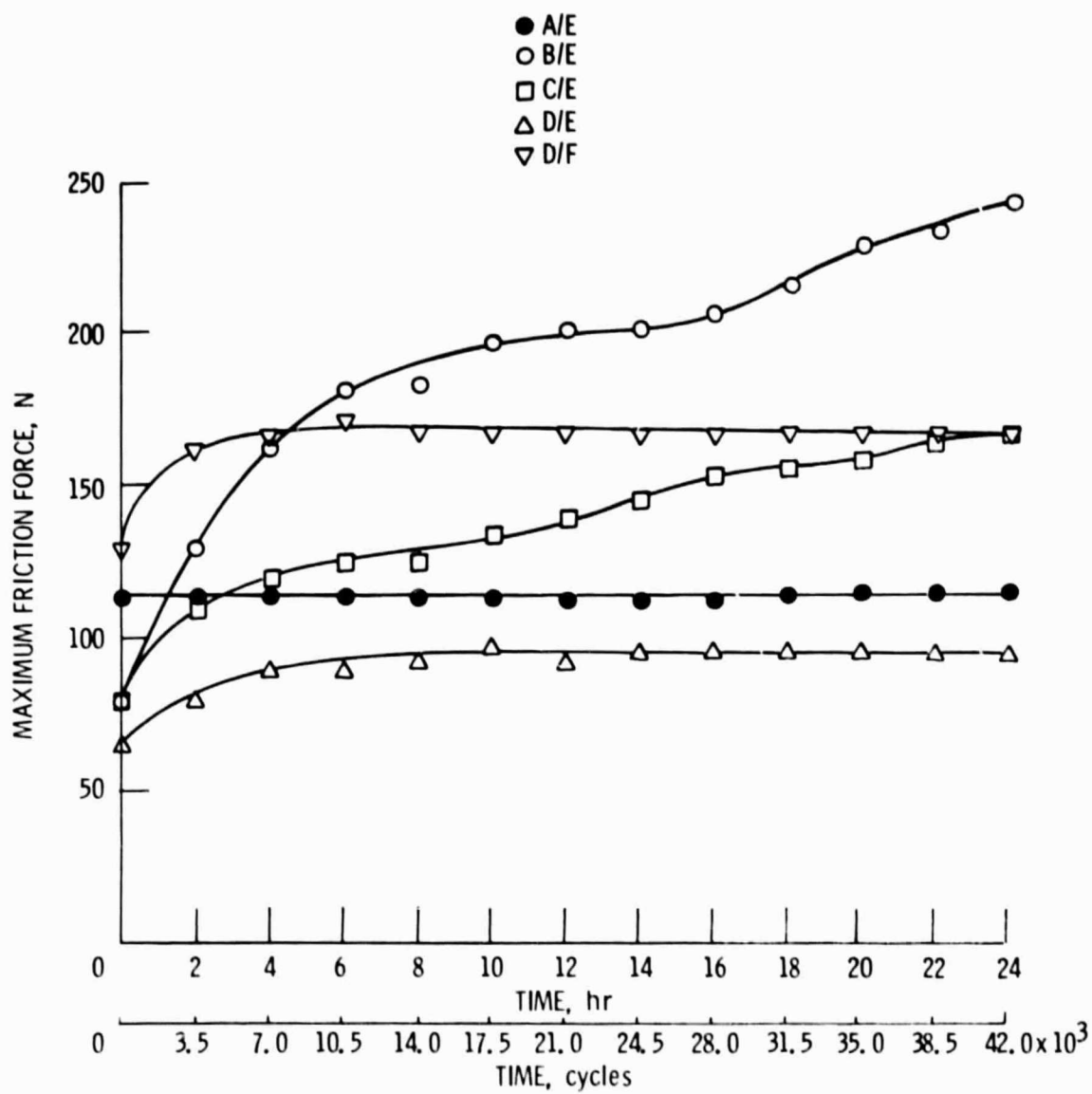


Figure 5. - Maximum friction force versus time during 42 000 cycle wear test.

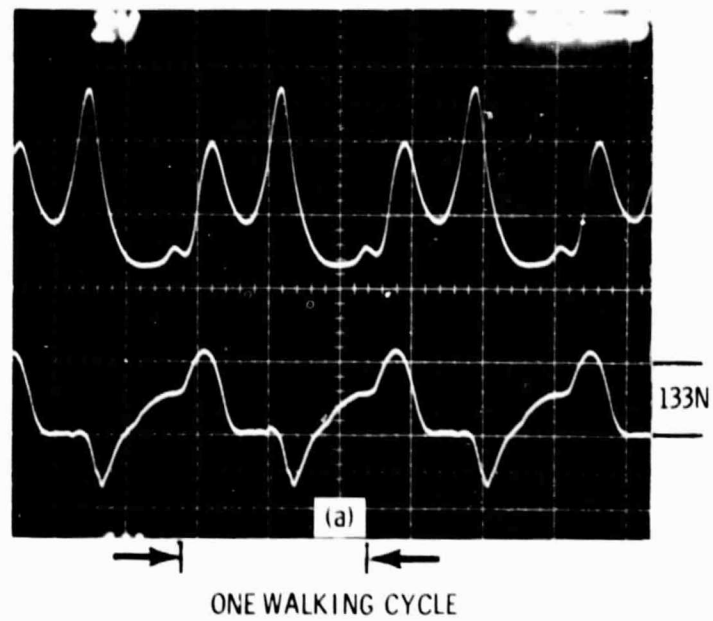


Figure 6. - Oscilloscope traces of programmed load and friction force for tests A/E, B/E, C/E, D/E, and D/F, respectively, at 42 000 cycles (24 hr).

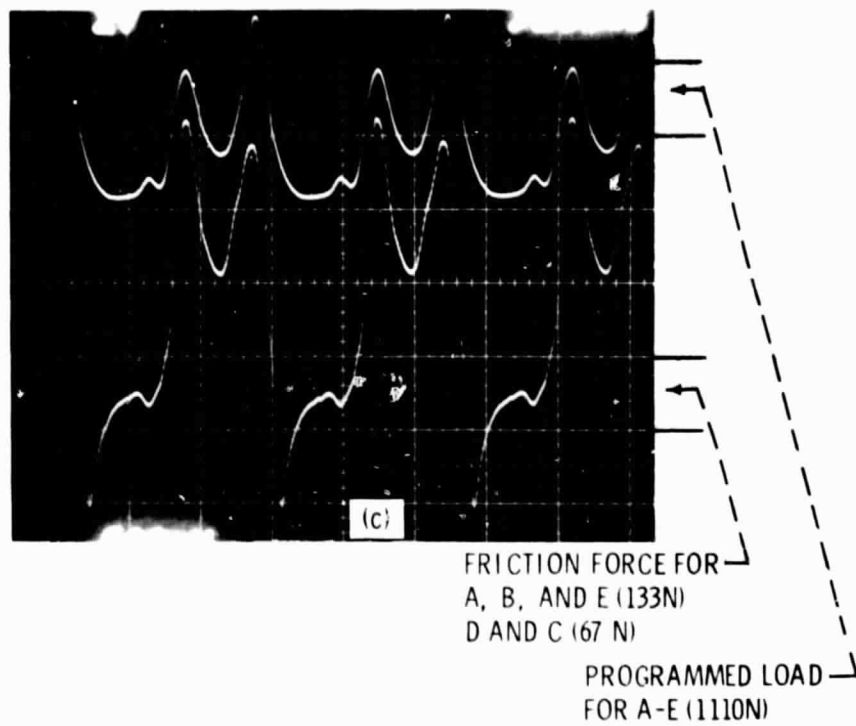


Figure 6. - Continued.

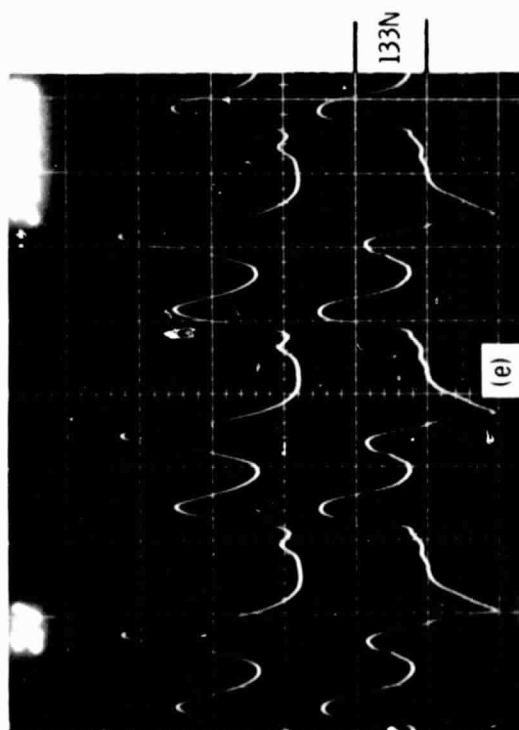
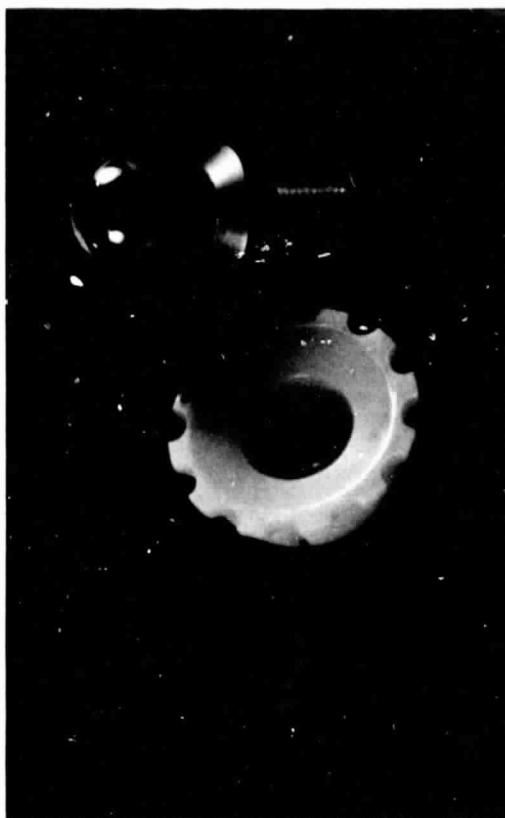
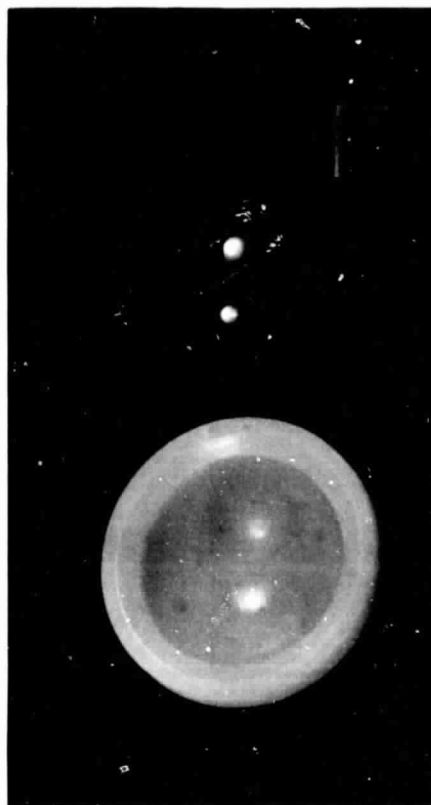


Figure 6. - Concluded.

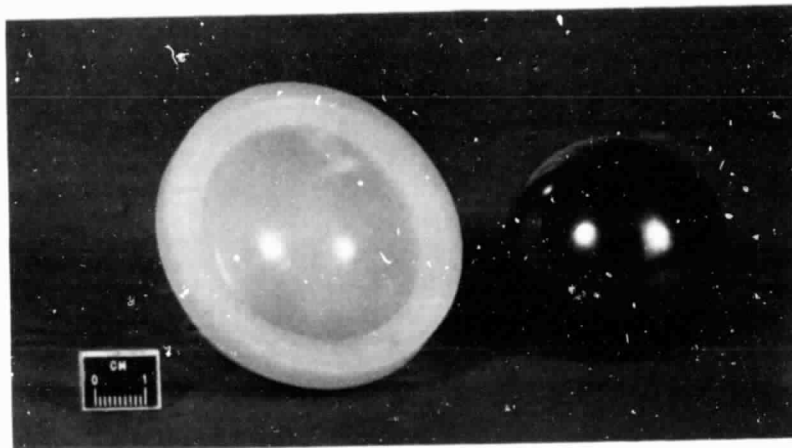


(a) TEST A/E.

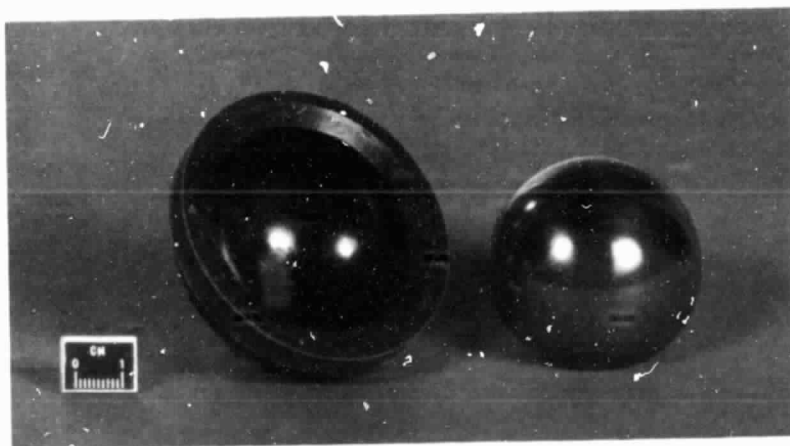


(b) TEST B/E.

Figure 7. - Femoral and acetabular specimens after 42 000 cycle wear test.



(c) TEST D/E.



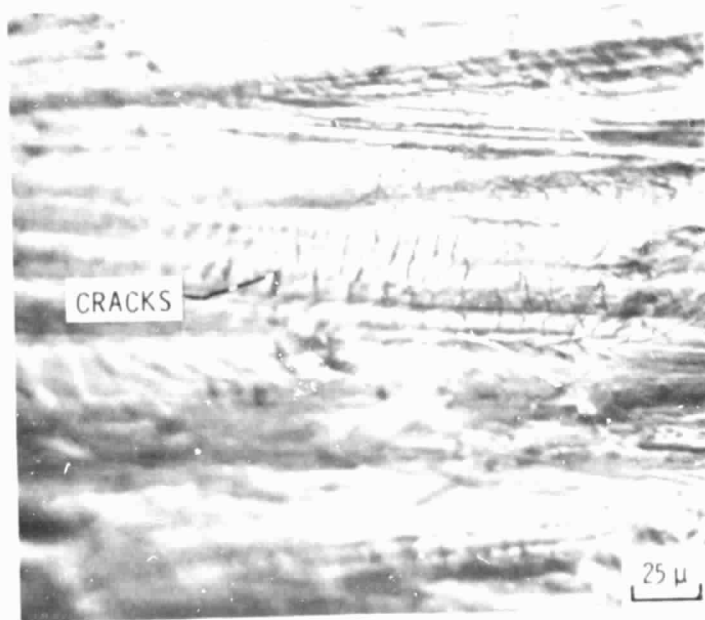
(d) TEST D/F.

Figure 7. - Concluded.

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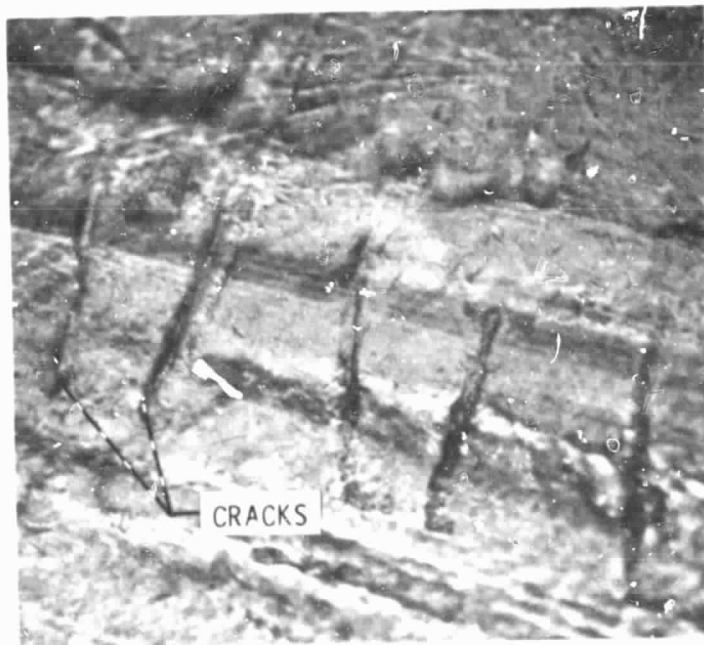


(a) B/E.

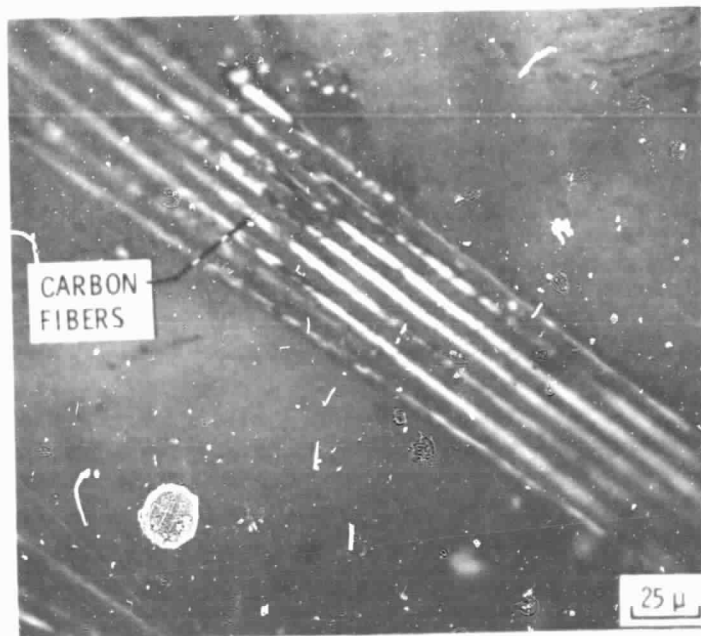


(b) C/E.

Figure 8. - Optical photograph of polar area in UHMWPE acetabular cups in tests B/E, C/E, D/E, D/F, respectively, after 42 000 cycles.

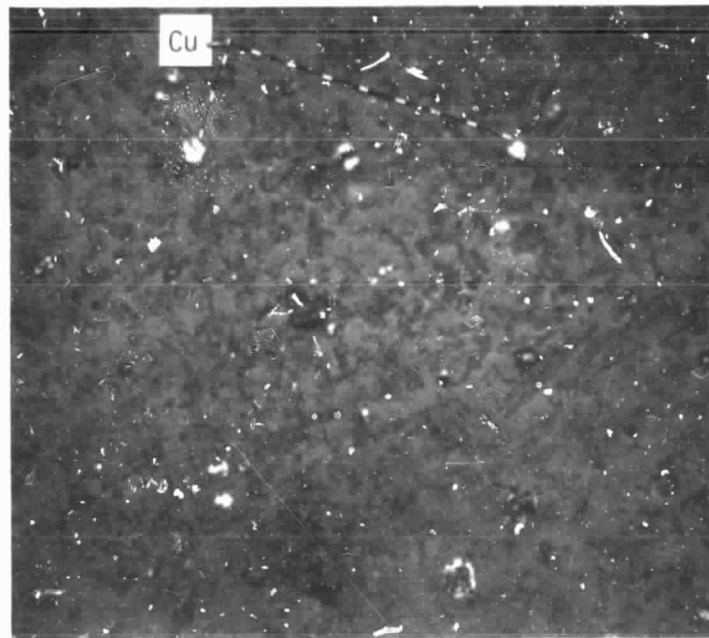


(c) D/E.

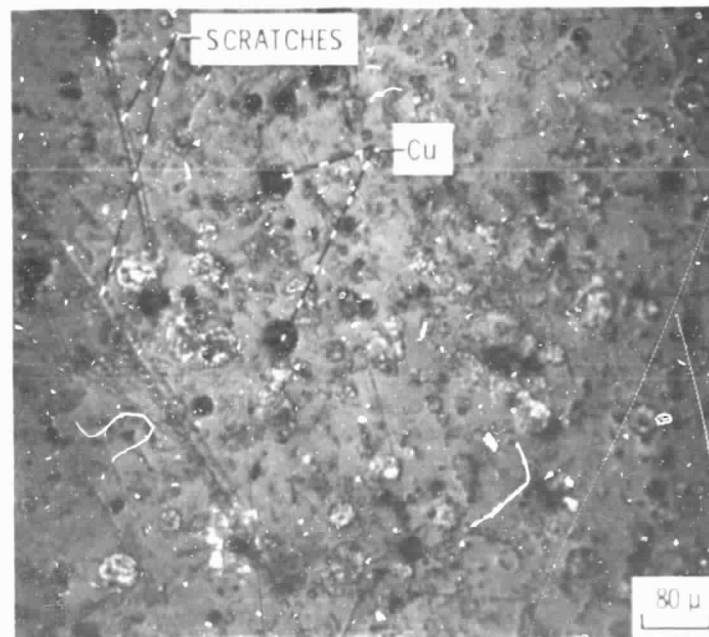


(d) D/F.

Figure 8. - Concluded.

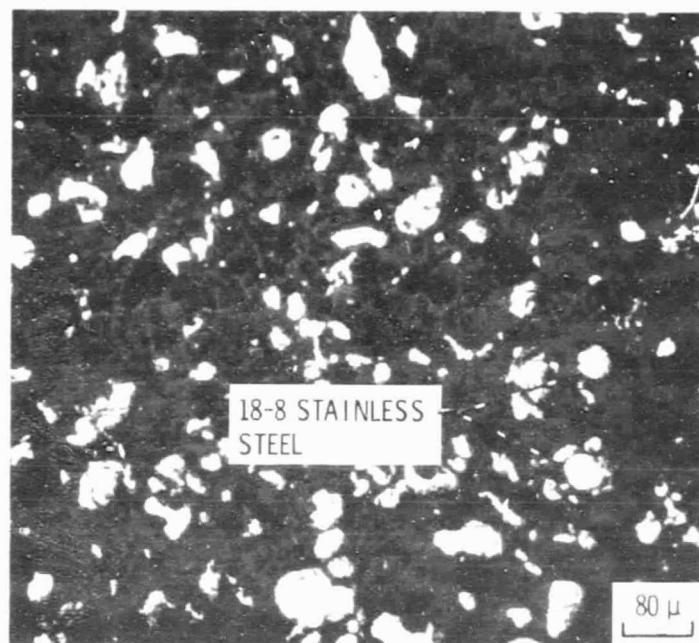


(a) SHELL B.



(b) SHELL C.

Figure 9. - Optical photograph of polar area on femoral shells B, and D, respectively, after 42000 cycle wear tests.



(c) SHELL D.

Figure 9. - Concluded.

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