Wear of ultra-high molecular weight polyethylene and polytetrafluoroethylene in a hip simulator

A dose-response study of protein concentration

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ABSTRACT – Charnley's laboratory wear studies of non-gamma sterilized polytetrafluoroethylene (PTFE) and polyethylene (PE) found that the PTFE to PE wear-rate ratio of 250:1 was much higher than the in-vivo wear ratio of 20:1. Tests of PTFE and PE in our laboratory showed a wear ratio of 150:1, using bovine serum as the lubricant and 190:1 with water as the lubricant.

Our hypothesis was that the wear-rates of PTFE and PE cup materials were related to the concentration of protein in the serum. We studied the wear behavior of PTFE and PE cups in varied protein concentrations, using 4 femoral head sizes to validate the clinical range reported by Charnley.

The PTFE wear-rates increased with increasing protein concentration and conversely, PE wear-rates decreased with increasing protein concentration. This inverse relationship made it possible to bring the wear ratio closer to the desired clinical wear ratio. We found that the clinically relevant PTFE/PE wear ratio corresponded to 3–10 mg/mL of protein in bovine serum.

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The discrepancy between wear-rates measured in vitro and those measured in vivo was first noted by Charnley (1976). Charnley found that polytetrafluoroethylene (PTFE) lubricated in biological fluids (bovine synovial fluid or water with 0.5% gelatin) wore 250 times more than polyethylene (PE) in the laboratory. However, the wear ratio in vivo was only 20:1.

Charnley's PTFE/PE wear-rate ratio of 20:1 was based on 6-year results prior to 1969 with non-gamma sterilized implants (Charnley 1976). Gamma sterilization was begun by Chas. F. Thackray Ltd. in March 1967 (Wroblewski, personal communication (2000)). Charnley's set of 39 PTFE cases included active and inactive patients, but excluded PTFE cups, which had worn completely through. The latter were probably those with the highest wear-rates. Analysis showed that active patients had wear-rates 1.6–2.6 times higher than Charnley's basis for his PTFE/PE wear ratio (Charnley et al. 1969, Oparaugo et al. 1998, Wang 1999). Therefore, the PTFE/PE wear ratio could range from 20:1 to 53:1.

Contemporary simulator studies, using bovine serum as the lubricant, have shown PE wear-rates lower than the clinical rates (Livermore et al. 1990, Kabo et al. 1993, Saikko, 1993, Callaghan et al. 1995, Bragdon et al. 1996, Clarke et al. 1997, McKellop et al. 1997, Jasty et al. 1997) and PTFE wear-rates 4 times higher than the clinical rates (Clarke et al. 1995, Good et al. 1996). Water-lubricated tests of both materials showed wear-rates much lower than the clinical rates (Saikko 1993, Clarke et al. 1995, Good et al. 1996, Phipatanakul et al. 1998). All such in vitro studies

maintained the high PTFE/PE wear ratio, as first described by Charnley.

However, Charnley's PTFE revision cups showed that volumetric wear increased linearly with head-diameter (Charnley 1976). This same head-size effect has now been reported clinically for PE cups (Livermore et al. 1990, Jasty et al. 1997). The ball-size effect for both PTFE and PE has been duplicated in the laboratory with serum lubrication (Good et al. 1996, Clarke et al. 1997). However, in water-lubricated tests the wear-rates were 4 times lower than clinical and the ball-size effect was lost (Good et al. 1996, Phipatanakul et al. 1998).

Because of the greater wear-rates of PTFE lubricated with 100% serum, and the near zero wear-rates in water, it was hypothesized that there was a dose-response to the serum/protein concentration (SPC). Contemporary studies of 32 mm head sizes also have shown that proteins in the serum play an integral part in the lubrication of PE (Polineni et al. 1997, Wang et al. 1998). Therefore, both PTFE and PE of 4 sizes were tested in various percentages of serum/protein concentrations to determine whether the PTFE/PE wear ratio could be matched in the laboratory, while maintaining the ball-size effect.

Material and methods

PTFE acetabular cups were machined from virgin extruded bar-stock and PE acetabular cups were machined from GUR 4150 extruded bar-stock (Hospital for Special Surgery; Bennett et al. 1996). 3 wear-cups and 1 soak-control cup were used per diameter (22.25 mm, 28 mm, 32 mm and 42 mm) with matching CoCr femoral heads (Protek Inc., Berne, Switzerland). Neither PE nor PTFE cups were sterilized.

The cups were arranged inverted in a multi-channel hip simulator (Shore Western Manufacturing Inc., Monrovia, CA). De-ionized water was used to dilute the bovine serum (Hyclone Laboratories, Logan, Utah; 100% serum = approximately 70 mg/mL total protein) and each test-chamber held approximately 250 mL of lubricant. A 10% solution of EDTA and sodium azide was added to the serum lubricants in the PE tests. All tests were run with a physiological or sinusoidal load-profile at a maximum load of 2 kN. The test frequency was 1 Hz. Lubricant temperature was monitored, but not controlled. Wear was determined by the weight-loss method, using a Sartorius microbalance (Model RC #167). The weight changes due to fluid-sorption (soak specimens) were subtracted from the weight of the wear specimens to determine net wear. The precision among the 3 wear cups of each size was determined using 95% confidence limits.

5–12 wear measurements (events) were performed per wear test, and linear regression analysis was used to estimate the wear-rate (weight loss per million cycles). Each PE test totaled approximately 2.2 million cycles and ran for a minimum of 3 days per event. The PTFE tests ran for 1 day per event with each test running approximately 339,000 cycles. The lubricant solution was replenished because of evaporation in the PE tests but was not necessary for the PTFE tests. Fresh lubricant was used for each event and at the end of each event, the lubricant and debris were collected for future analysis.

Volumetric wear-rates were calculated using the specific density of PTFE, certified as 2.16 mg/mm^3 (Coast Plastics Inc.) and PE, certified as 0.94 mg/mm^3 (Hospital for Special Surgery). The Volumetric Wear Index (VWI) was used to relate the increase in wear of any size of femoral head relative to the Charnley 22.25-mm size (Clarke et al. 1995). Scanning electron microscopy (SEM; Phillips Scanning Electron Microscope, UCR, Riverside, CA) was performed on the surfaces of the acetabular surfaces.

Results

PTFE wear-rates continuously increased with increasing serum/protein concentration and the ball-size effect of increased wear with increasing head-size was maintained (Figure 1, Table 1). The wear-rates at 3 mg/mL protein concentration increased from 2000 mm^3/Mc for 22 mm to 4000 mm^3/Mc for 42 mm and then all wear-magnitudes doubled by 70 mg/mL protein concentration for all ball sizes.

The PE wear-rates at 3 mg/mL protein concentration were in the range of 35–60 mm^3/Mc and at

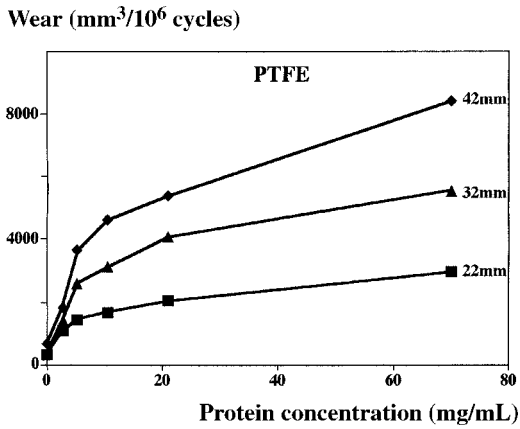

Figure 1. Dose-response curve of PTFE acetabular cups articulating on CoCr femoral heads in various protein concentrations (70 mg/mL protein = 100% serum).

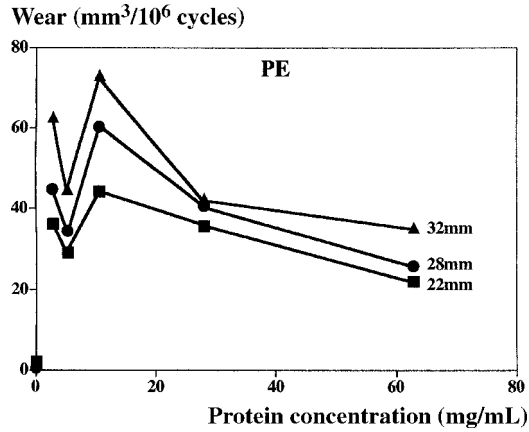

Figure 2. Dose-response curve of UHMWPE acetabular cups articulating on CoCr femoral heads in various protein concentrations (70 mg/mL protein = 100% serum).

Table 1. Volumetric wear-rates ($mm^3/10^6$ cycles) of PTFE/CoCr in 0, 3, 5, 10, 21, 63 and 70 mg/mL of protein (70 mg/mL protein = 100% serum)

	PTFE wear-rates ($mm^3/10^6$ cycles) in various protein concentrations			
Protein mg/mL	22-mm wear	32-mm wear	42-mm wear	Precision 95%CI
0	305	305	650	71
3	1056	1406	1810	4
5	1415	2587	3622	4
10	1670	3100	4580	5
21	2013	4055	5376	3
63	2792 [a]	5300 [a]	NA	NA
70	2949	5603 [a]	6430	3

[a] Extrapolated using rate of increase in wear from 5 to 70 mg/mL protein (15.7 and 30.3 $mm^3/10^6$cycles protein concentration for 22 mm and 32 mm, respectively).

Table 2. Volumetric wear-rates ($mm^3/10^6$ cycles) of UHMWPE/CoCr in 0, 3, 5, 10, 21, 63 and 70 mg/mL of protein (70 mg/mL protein = 100% serum)

	UHMWPE wear-rates ($mm^3/10^6$ cycles) in various protein concentrations			
Protein mg/mL	22-mm wear	32-mm wear	42-mm wear	Precision 95%CI
0	1.9	0.6	1.6	306
3	36	45	63	16
5	29	35	45	13
10	44	60	73	12
28	36	40	42	9
63	22	26	35	13

63 mg/mL protein, wear-rates decreased to 21 and 35 mm^3/Mc for 22 and 32 mm, respectively (Table 2, Figure 2). All tests with serum/protein lubricant maintained the ball-size effect.

The PTFE/PE wear ratio was lowest, 22:1, at 3 mg/mL protein concentration increasing to 150:1 at 63 mg/mL protein concentration. The ratio was highest (191:1) with water lubrication (Table 3). SEM studies of the PE acetabular cup surfaces showed no pitting.

Discussion

The choice of lubricant can significantly affect the results and validity of in-vitro testing (McKellop et al. 1992, Cooper et al. 1993, Derbyshire et al. 1994, Clarke et al. 1995, Wang et al. 1996, Liao et al. 1999). However, laboratories and standards organizations cannot agree as to which lubricant to use for in-vitro testing. The International Standards Organization (ISO) specifies 25% calf serum, diluted with de-ionized water (ISO 14242-5). The American Society for Testing and Materials (ASTM) designates "...bovine blood serum; however, another suitable lubrication medium may be used if validated" (ASTM F04-22-10). Still other

Table 3. Volumetric wear-rate ratios of PTFE to UHMWPE in 0, 3, 5, 10 and 63 mg/mL of protein concentration (70 mg/mL protein = 100% serum)

Protein mg/mL	22 mm	32 mm
0	161	191
3	29	22
5	49	58
10	38	42
63	138	150

laboratories continue to use water for laboratory testing (Saikko 1995, Wroblewski et al. 1996, Saikko and Pfaff 1998).

In water-based tests, PTFE and PE were at their lowest wear-magnitudes with 0.6 mm^3/Mc for PE and 305 mm^3/Mc for PTFE. From 3 to 10 mg/mL protein concentration, the PTFE wear-magnitudes increased dramatically and then from 10 to 70 mg/mL protein concentration, the wear-magnitudes continued to increase, but at a lower rate. In contrast, the PE wear-magnitudes showed a decreasing trend from 3 to 63 mg/mL protein concentration, which was also reported by Wang et al. (1998) and Liao et al. (1996). In all serum-lubricated tests, both PTFE and PE exhibited increased wear with increased head-diameter, which was consistent with previous studies (Good et al. 1996, Clarke et al. 1997, Bragdon et al. 1998).

Due to this divergent wear-performance in the two polymers, the PTFE/PE wear-ratio was only within the clinical relevant range from 3 to 10 mg/mL protein concentration (Table 3). Liao et al. (1996) expressed concern over the surface-pitting seen with the naked eye on the acetabular cup in low concentrations of serum. However, his study was complicated by the use of zirconia heads which are known to worsen the serum-degradation effects (McKellop et al. 1992) and the small amount of lubricant in each test chamber. With lubricant volumes greater than 200 mL pitting was not seen with the naked eye or with SEM in this study or in that by Wang et al. (1998), using CoCr heads.

Wang et al. (1999) showed that a serum (65 mg/mL) lubricant volume of 100 mL caused less wear and more protein precipitate for sterilized PE than 200 or 400 mL of lubricant. Wear of UHMWPE increased by 30% from 200 mL to 400mL of serum. Thus, using a physiological range of 21 mg/mL of protein concentration (Decker et al. 1959, Kushner and Somerville 1971, McCarty1979, Altman and Gray 1984) and doubling the lubricant volume can result in a clinical PTFE/PE wear-ratio. Therefore, we see no objection to using protein concentrations between 3 and 30 mg/mL, with lubricant volumes greater than 200mL in hip simulators.

Conclusions

1. When 3–70 mg/mL protein concentrations were used, PTFE wear-magnitudes increased and PE wear-magnitudes decreased in the hip simulator model. The PE wear-magnitudes peaked at 10 mg/mL protein concentration and the PTFE wear-rates were in the clinical range from 3 to 10 mg/mL.

2. In all serum-lubricated studies, both polymer materials had the highest wear-rates with the largest head-size.

3. The PTFE/PE ratio was within a physiological range between 3 and 10 mg/mL protein concentration.

4. In water lubrication, both PTFE and PE wear-rates were at their lowest and the PTFE/PE wear-ratio was highest.

5. Thus, the wear-rates of both PTFE and PE were dose-dependent on the protein concentration in the lubricant.

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