THE IMPACT OF LUBRICANT PROTEIN CONCENTRATION ON THE OUTCOME OF HIP JOINT SIMULATOR TESTING

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Introduction : Bovine serum is widely used as a lubricant in laboratory hip simulator testing of prostheses. The presence of proteins in the serum has been identified as the critical constituent that is responsible for reproducing clinically similar wear surface and wear debris morphologies for UHMWPE. In recent years, it was realized that the protein concentration of the serum used may significantly affect the wear mechanisms and wear rates of the UHMWPE [1,2,3]. It was proposed that the protein concentration in the lubricant must be controlled within the human synovial fluid range in order to accurately predict clinical wear performance in the laboratory [1]. This study presents further experimental evidence to substantiate this argument.

Materials and Experimental Method : 32 mm I.D. and 60 mm O.D. acetabular cups were machined from extruded GUR4150 UHMWPE and PTFE rods. The UHMWPE cups were sterilized by gamma irradiation at 2.5 Mrads in air while the PTFE cups were left unirradiated. A multi-station and multi-axis hip joint simulator (MTS, Eden Prairie, MN) was used to evaluate the wear performance of the UHMWPE and PTFE cups. 32 mm diameter CoCr femoral heads were used as the counterface. The following conditions were used in the simulator test: anatomical positioning of the components., Paul-type load with 2450 N maximum and 50 N minimum, and cross-shear motion. Various water-based lubricants with different protein concentrations were used. These ranged from pure water (protein concentration: 0 mg/ml) to 100% regular bovine serum with 65 mg/ml protein concentration.. Approximately 400 ml lubricant was used for each chamber. Lubricant was changed every 250,000 cycles. The test was run for one million cycles and the wear rate was defined as volume loss per million cycles.

Results : Fig. 1 and Fig. 2 show the wear rate as a function of lubricant protein concentration for UHMWPE and PTFE, respectively. The UHMWPE cups showed no measurable wear (< 2 $mm^3/10^6$ cycles) with pure water lubrication and a maximum wear rate of 95 $mm^3/10^6$ cycles at a protein concentration of 10 mg/ml. Further increases in protein concentration beyond 10 mg/ml caused a gradual drop in the wear rate. The PTFE cups, on the other hand, showed a wear rate of 1786 $mm^3/10^6$ cycles at 0 mg/ml protein concentration and 2947 $mm^3/10^6$ cycles at 10 mg/ml. The wear rate continued to increase as the protein concentration increased to 65 mg/ml. Therefore, the wear rates of UHMWPE and PTFE responded to the increase in protein concentration very differently. The wear rate ratios between PTFE and UHMWPE are plotted in Fig. 3 as a function of protein concentration. A ratio of more than 800 was obtained at 0 mg/ml protein concentration, it dropped drastically to about 20 at 5 mg/ml and then increased to 31 at 10 mg/ml. The ratio continued to increase as the protein concentration increased beyond 10 mg/ml. At 65 mg/ml, the PTFE/UHMWPE wear ratio reached 131.

Discussion and Conclusions: The fact that the wear rates of UHMWPE and PTFE responded to increasing lubricant protein concentration in opposite ways indicates that protein concentration in the lubricant plays a critical role in the accuracy and validity of hip joint simulator testing. Average clinical wear rates of Charnley's 22 mm PTFE sockets ranged approximately from 2.0 mm/year to 3.72 mm/year (760 to 1413 $mm^3/10^6$ cycles) with 2.0 mm/year representing sockets that were not worn through and 3.72 mm/year representing all sockets including those that were worn through [4]. Average clinical wear rates for Charnley's UHMWPE sockets (22 mm) ranged from 0.07 mm/year [5] to 0.20 mm/year (30 to 80 $mm^3/10^6$ cycles) [6]. Therefore, the clinically relevant PTFE/UHMWPE wear ratios are in the range from 10 to 53. The hip simulator wear rate ratios that fall within this clinical range are those obtained with lubricants that contain 5 mg/ml to 25 mg/ml proteins. The protein concentration of human synovial fluids falls within the range between 20 mg/ml and 35 mg/ml [7]. Since regular bovine serum contains about 65 mg/ml to 75 mg/ml proteins, which not only doubles the protein concentration of synovial fluid but also drastically exaggerates the PTFE/PE wear ratio, it must be diluted by at least 50% prior to being used as a proper lubricant.

References: [1] A. Wang, et al., 24th Annual Meeting of Society For Biomaterials, 1998, p. 218. [2] I. Clarke and A. Wang, in Oonishi (ed.), Wear of Total Hip Arthroplasty, Elsevier, 1998. [3] P. Liao, et al., 5th World Biomat Cong., 1996, p.871. [4] J. Charnley, et al., Med. and Biol. Engrg., 7, 1969, 3-39. [5] M. J. Griffith, et al., Clin. Orthop., 137, 1978, 24-36. [6] R. M. Hall, Proc. Instn Mech. Engrs., Part H: Eng. in Med., Vol. 210, 1996, 197-207. [7] H. Saari, et al., J. Rheum., 20(1), 1993, p. 87.

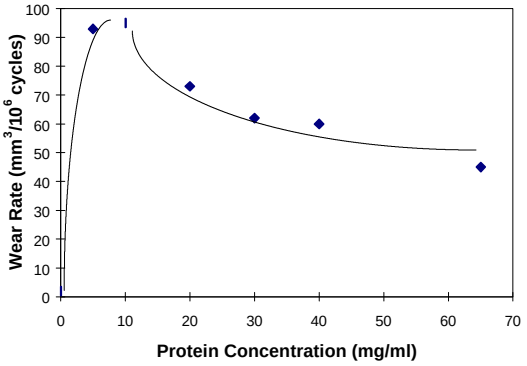

Fig. 1: Wear rate of UHMWPE cups vs. lubricant protein concentration.

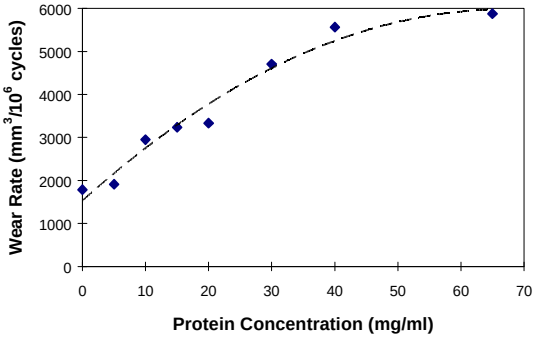

Fig. 2: Wear rate of PTFE cups vs. lubricant protein concentration.

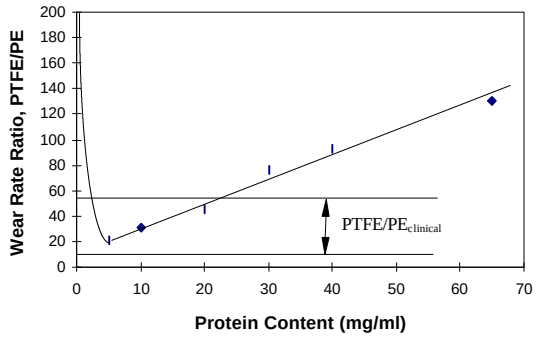

Fig. 3: Wear rate ratio PTFE/PE vs. lubricant protein concentration.

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