

Serum Composition Affects the Fluid Uptake and Wear of Polyethylene in Total Knee Simulator Testing

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Introduction: Simulator wear testing of knee implants should subject the polyethylene (PE) bearing surface to a clinically relevant lubricant [1 - 4]. However, the effects of certain factors that define the characteristics of the lubricant, such as osmolality and hyaluronic acid (HA) have only received minor recognition in wear testing. The purpose of the present study was to investigate whether serum composition affects the weight gain and, most importantly, the simulator wear rate of PE inserts.

Materials and Methods: A six-station (three left side, three right side) displacement-controlled knee simulator (AMTI, Waltham, MA) was used to conduct a wear test for a total of 5.5 million cycles (Mc), following ISO guidelines [2]. The tested knee implant was of cruciate retaining design (AMK, DePuy, Warsaw, IN). The gas-plasma sterilized PE inserts (10mm, GUR 1050) were pre-soaked in distilled water at 37°C until saturation occurred after 70 days. Alpha calf serum (ACS) was supplied in Fe²⁺-supplemented form by HyClone (Logan, UT). It was diluted with various liquids to a protein concentration of 19 ± 2 g/l (Table 1). In test 1, the serum was diluted with phosphate-buffered saline solution (PBS) on both sides. In test 2, the serum on the left side was diluted with PBS and 1.5 g/l of HA (Lifecore Biomedical, Inc.; MW = 1.78 MDa) [3]. In test 2, the serum on the right side was diluted with distilled water (DW). All implants remained at their original wear station throughout wear testing.

Table 1: Test protocol.

Test	Mc	Dilutive Liquids	
		Left side implants	Right side implants
1	0 - 3.5	ACS + PBS	ACS + PBS
2	3.5 - 5.5	ACS + PBS + HA	ACS + DW

An antibiotic-antimycotic was periodically added to the test to retard bacterial growth. Also, EDTA (20mM) was added to bind Fe²⁺ and inhibit calcium deposition. To determine the clinically relevant osmolality compared with the different calf serum dilutions, synovial fluid from 20 patients was measured (Table 2) using an osmometer (model 5520, Wescor, Logan, UT).

The paired-samples Students t-test was utilized to compare the fluid uptake prior to testing. A general linear model (GLM) coupled with the Fisher's LSD test as the post-hoc method was used to compare wear rates from individual tests.

Table 2: Osmolality measurements.

Medium	n	Osmolality [mmol/kg]
Synovial fluid	20	301 ± 4.00
ACS + DW	3	145 ± 2.00
ACS + PBS	3	312 ± 1.00
ACS + PBS + HA	3	321 ± 2.64

Results: The fluid uptake between the left and right side implants was not different after the pre-soaking period

(p=0.312, paired samples-test). There was a weight gain from 0 - 1 Mc (Fig.1).

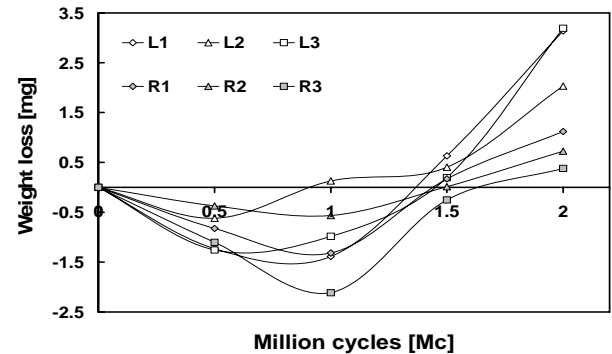


Figure 1: PE wear during the first 2Mc.

The PE wear rate of the left side implants increased significantly (p = 0.002, GLM and Fisher's LSD) by a factor of 2 when HA was added to the serum (4.72 ± 0.52 mg/Mc vs. 9.57 ± 1.90 mg/Mc) (Fig 2). The PE wear rate of the right side implants increased significantly (p = 0.020, GLM and Fisher's LSD) by a factor of 2.3 when PBS was replaced with DW in the serum (1.18 ± 0.19 mg/Mc vs. 2.79 ± 0.39 mg/Mc).

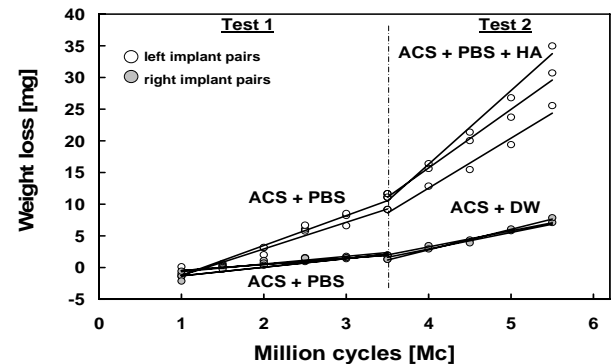


Figure 2: Weight loss from 1- 5.5Mc.

Discussion: The change in osmolality between the pre-soaking fluid and the actual test fluid was probably responsible for the weight gain during the first Mc. Under the present conditions, the amplifying effect of adding HA, on the PE wear was only 29% of that report by Desjardins et al [4] (2 vs. 6.88). There was no adverse effect on the PE wear of the high Fe²⁺ concentration in the serum (at the time of the testing, non-iron supplemented ACS was not available from the serum manufacturer). It appeared that PBS maintains the integrity of specific protein constituents in the calf serum, leading to improved boundary lubrication.

References: [1] Kitano T. J Biomech. 2001;34:1031. [2] ISO 14243-3 (2004). [3] Mazzucco DC. CORR. 2004; 429:17. [4] DesJardins J. IMechE[H]. 2005;220(5)609.