

Laboratory of Polymeric Bearing Modeling,
Characterization, and Simulation
Bioengineering Alliance of South Carolina
Department of Bioengineering, Clemson University Clemson, South Carolina

To,
Mr. Mark Ganaban
Ms Hyalogic LLC,
PO Box. 73736
Edwardsville, Kansas 6613

Dear Mr. Ganaban,

With reference to the conversation we had this morning about the possibility of using Synthovial Seven for our research studies, forwarding herewith the necessary information as you requested.

The Clemson University, South Carolina bioengineering program is one of the oldest in the world with a research emphasis on biomaterials, biomechanics, and cellular biology particularly for orthopedic and cardiovascular applications. The link <http://www.ces.clemson.edu/bio/> will provide you information of the faculty research interests and the facilities available in the department.

The department of bioengineering houses the Biotribology and the Vascular research laboratories headed by Professor Dr. Martine LaBerge. Dr. LaBerge's research expertise is focused on the tribological evaluation and characterization of natural and artificial surfaces used in the design of implants for orthopedic and vascular applications. The following two links will provide a comprehensive information of the facilities and the on going research in the two laboratories.

Biotribology Lab -<http://www.ces.clemson.edu/bio/research/biotri/biotri.htm>

Vascular Research Lab- <http://www.ces.clemson.edu/bio/research/vascular/vascular.htm>

The broad objective of the on going research is to replicate in vivo conditions in in-vitro simulations. The Biotribology Laboratory has two 4 station knee simulators. The simulators provide great flexibility in varying different parameters like the axial force and the flexion angle so as to mimic the human gait cycle. Wear tests are being conducted using the simulators for checking the wear rate and the wear patterns of the total knee joint replacement with bovine serum as an artificial lubricant. The laboratory has demonstrated that the rheology of Bovine Serum (BS) is very similar to normal synovial fluid with the exclusion of hyaluronic acid in BS. The published HA concentrations range from 1.07:1:0.28- 2.21:1:0.23 g/L for osteoarthritic (OA) fluid and 0.43:1:0.04- 0.64:1:0.42 g/L in periprosthetic fluid. Preliminary studies using bovine serum as lubricant and HA (1.5g/liter) have indicated a greater weight loss of the tibial plateau and higher wear rate compared to using bovine serum alone at 2 million cycles using the simulator.

We propose to use HA for the following two projects.

1. **Knee simulator studies:** To extend the results obtained from 2 million cycles using the simulator to 5 million cycles, so as to help develop a standard for the constituents for artificial lubricant in simulator testing. At the moment, the ASTM and ISO organizations are attempting to decide upon guidelines for lubricant formulation. It is our hope that our results will result in the inclusion of HA as a recommended additive in simulator testing worldwide.

2. **Fatigue crack propagation studies:** The objective of the proposed research being to quantify the effects of a physiological environment on the fatigue crack propagation of UHMWPE with a focus on hyaluronic acid and phospholipase, both molecules being present in the lubricant of artificial joints and degenerative joints. In this study, the combination of clinically relevant concentrations of these molecules will be analyzed in terms of their effects on crack growth. The study will help to determine the role of physiological factors on the fatigue process of UHMWPE and develop a better understanding of the relationship between the lubricating media and wear processes in vitro.

The molecular weight of your product Synthovial 7 TM -2.4 million Daltons being very close to our requirement of 2.3-2.6 million Daltons, prompted us to approach yourselves as a possibility of using it for future studies in the laboratory.

We would be highly obliged if you could provide us a sample of your product to conduct preliminary viscosity studies to determine the feasibility of using it for further studies.

If you require any further information, we would be more than happy to answer them

Thanking you in anticipation

Sincerely

Amit Aurora

Graduate Research Assistant Department of Bioengineering Clemson University, Clemson SC 29634.

c.c Dr. Martine LaBerge Mr. John Des Jardins