

An Investigation of the Fatigue Induced Failure Modes of Fiber/Elastomer Composites as Bearing Surfaces in Total Hip Joint Prosthesis

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Goal Statement

This research represents a fundamental study of the failure mechanisms observed in fiber reinforced elastomeric bearing surfaces. The specific focus of this research is the failure of one or more of the bearing surfaces in a total hip joint replacement. The goal of this research is to develop a better fundamental understanding of all of the complex modes of failure in bearing surfaces which can then be used to design new materials with sufficient longevity for use in a total joint replacement or other bearing applications.

Abstract

It has been proposed to use elastomeric composites as artificial joints bearing surfaces to increase their fluid film lubrication and therefore reduce their failure attributed to wear mechanisms. The fluid generated between the surfaces supports part of the load and prevents direct contact of the bearing surfaces. However, permanent deformation or failure of elastomeric composites has been observed following debonding between fiber and matrix. It is hypothesized that heat generated at the contact between the elastomeric composite and the reciprocating counter part contributes significantly to failure of the elastomer. A preliminary study was conducted to determine the effectiveness of a tribological experimental model to verify this hypothesis. The coefficient of friction between UHMWPE and metal and an unreinforced polyurethane elastomer bearing against metal was measured using reciprocating motion. The next phase of this project will consist of using this experimental model to analyze the effect of friction on the failure of elastomeric composites composed of polyurethane matrix and fibers.

Introduction

Total joint replacements are performed to alleviate pain following the diagnosis of degenerative diseases such as rheumatoid arthritis and osteoarthritis. In a total joint replacement ultra high molecular weight polyethylene (UHMWPE) components are normally bearing against Cobalt-Chromium alloy, titanium alloy, or ceramic surfaces. UHMWPE debris resulting from the tangential motion between the components leads to implant loosening and retrieval.

Techniques have been proposed to reduce the wear rate of the implants such as the modification of the chemical and mechanical properties of UHMWPE and the use of soft layers to increase the lubrication of the bearing surfaces. ~~In fact, a thin, rigidly backed,~~ elastomeric layer allows the formation of a lubricant film in conditions where a very hard material such as steel would fail. However, experimental studies by the investigators [Chow et al, 1994; LaBerge et al, 1991; Leach et al, 1994; Leach et al 1994a] have demonstrated that severe fatigue stress concentrations occur in the layer and at the attachment edge of the coating which decrease the fatigue strength of these layers and their ability to withstand the applied fatigue stresses for a length of time comparable with the life of the bearing unit.

This NTC project uses as its basis the demonstrated hypothesis that the fatigue resistance of elastomeric coatings can be increased with composite technology using fibers and fabrics as reinforcements. During the past four months, preliminary data on the fabrication process of elastomeric composites have been gathered and the suitability of a tribological model for the study of elastomeric materials has been analyzed.

Materials and Methods

Based on its material properties and previous experience by the investigators in this type of application, Tecoflex™ was selected as the candidate elastomeric matrix material. Tecoflex™ is an aliphatic polyether polyurethane developed by Thermedics (Woburn, MA). Thermoplastic polyurethane elastomers, as a class of materials, are being investigated as articulating surfaces in the cushion-bearing concept of joint replacement (Auger, 1993).

Tecoflex™ is a medical grade material available in a wide range of properties and configurations; Tecoflex™ SG80A SG85A were the grades selected for this preliminary research because its elastic modulus most closely approximates values reported for articular tissues.

Fabrication and Characterization of Elastomeric Films

Films of Tecoflex™ SG80A and SG85A were fabricated using compression molding techniques. Prior to use, the Tecoflex™ pellets were dried in a forced-air oven according to the manufacturer's specifications. A compression molding technique was developed which allowed production of specimens up to 5 mm in thickness. Dried pellets of elastomer were placed in a 5" x 5" picture frame Teflon® mold which was then sandwiched between two 6" x 6" aluminum plates. A Teflon® release film (Wrightlon 5900; Airtech International; Carson, California) was used between the elastomer and the metal plates on both sides of the mold to prevent sticking. This unit was then placed between the platens of a Carver Hydraulic Laboratory Press (Model C; Menomonee Falls, Wisconsin). Light contact pressure was applied to the mold while the pellets were heated to 320 °F. Once this temperature was reached, the pressure was increased to 200 psi and these conditions were maintained for 30 minutes. Finally, the pressure was reduced and the elastomer was allowed to cool slowly in the mold under light contact pressure. Elastomeric films were allowed to set at room temperature for at least one week prior to use. Thickness and Shore A durometer (hardness) values were obtained from all samples to ensure uniformity of test specimens.

Compressive Testing of Elastomeric Films

The films were tested in compression using a Vitrodyne® 1000 Universal Materials Tester (Liveco; Burlington, VT). This system consists of a servomotor-driven linear actuator assembly mounted on a test stand, an interface controller box and a system-specific software program that runs on an IBM-AT compatible computer. The interface controller handles real-time control of the actuator motor and collection of data and is interfaced with the computer through an RS-232C serial port. This system has been expressly designed for use in testing biological materials, typically at low loads and strain limits.

The samples were mounted in a well and then placed under the actuator of the Vitrodyne® Tester. Indentation compression tests were performed on dry samples at 25 °C immersed in glycerine (100%). Indentation was accomplished using a highly-polished hemispherically-tipped indenter (diameter of 5 mm) which was mounted onto the test system actuator. Samples were indented at 1000 mm/sec using a full scale load of 10 lb. Time (s), load (gm),

and displacement (mm) were simultaneously recorded during the tests and saved as an ASCII file. The modulus of elasticity of the films of different hardness was calculated using Finkin's indentation model (Finkin, 1972) [1],

$$E = \frac{9PR}{16H^3} \left[\left(\frac{Rd}{H^2} \right)^{0.5} + 0.252 \left(\frac{Rd}{H^2} \right) + 0.1588 \left(\frac{Rd}{H^2} \right)^{1.5} + 0.2245 \left(\frac{Rd}{H^2} \right)^{2.0} + 0.3069 \left(\frac{Rd}{H^2} \right)^{2.5} + 0.2980 \left(\frac{Rd}{H^2} \right)^{3.0} \right]^{1.0} \quad [1]$$

where: R=radius of indenter, H=depth of penetration of indenter, P=load, E=modulus of elasticity, and d=thickness of the specimen.

Coefficient of Friction Measurement

a. Comparative Analysis

In order to compare the frictional behavior of the elastomeric films to materials used for orthopaedic bearing applications, a preliminary study was conducted to obtain preliminary data for the contact metal-UHMWPE. Thordon SXL, a polyurethane elastomer with a modulus of elasticity of 400 MPa, was also studied.

UHMWPE (DePuy-DuPont Orthopaedics, Warsaw, IN) was chosen for this study for two reasons. First, coefficient of friction values of UHMWPE bearing against metal are available in the literature and therefore can be compared to the values obtained for other materials bearing against metal. Secondly, since UHMWPE-metal coefficient of friction values are known, this material could serve as a control for the friction measuring system used in this study.

Two types of UHMWPE samples were tested and analyzed: (i) rough specimens and (ii) polished specimens. The rough specimens were simply used as received from DePuy-DuPont with a surface finish of that of implanted polyethylene. The root mean square (RMS) roughness of the rough polyethylene was estimated to be approximately 5 μm (Auger, 1993). The second set of polyethylene specimens were polished using a series of grit paper (120, 320, 600, 800, 1200) (Microcut Discs, Buehler, Lake Bluff, IL) to obtain a RMS of 350 nm. Roughness data were obtained with a non-contact profilometer with a 20X Mirau magnification head (TOPO, Wyko Corp., Tucson, AZ).

The second material used in this study (Thordon SXL, Thordon Bearings Inc., Burlington, Ontario, CN) was an elastomeric bearing which is made from thermosetting resins which are three dimensional, cross linked condensation polymers. It is a very hard, tough synthetic polymer alloy that has performance characteristics superior to most other bearing materials, including UHMWPE. Thordon is used in bearing applications for two reasons. First, Thordon is an elastomer and returns to its original shape after being stretched or deformed. Second, due to the basic characteristics of the material, Thordon has a high natural abrasion resistance. Rough and polished Thordon specimens were tested. The polished samples were polished using the same method described for the polyethylene to a RMS of 52 nm, while the rough samples had a RMS of 3.175 μm . The third type of material consisted of Tecoflex™ films (see above) compression molded on Thordon™.

Friction Testing

A reciprocating pin-on-plate friction table was used for friction testing (Figure 1) (Williams et al, 1993). Point contact was chosen to simulate the contact in the hip joint, which has a ball and socket configuration. A compressive static load of 150 g was applied on the chrome steel ball bearings, with a RMS of 8.962 nm, (0.5" diameter, Dixie Bearings Inc., Anderson, SC). A jig was designed to hold three ball bearings, equally spaced, which was attached to two force transducers with flexible threads. The force transducers were mounted on an external frame in order to prevent interference due to the reciprocating motion of the platform. The arrangement of the balls allowed the upper surface to be self-supported and thus avoids any interference resulting from mechanical constraints on the friction force measurements. Strain gages were mounted on the upper surface to provide a friction force transducer. The output from the strain gages was amplified, then collected and calibrated using an analog-to-digital converter (National Instruments) and a personal Macintosh IIsi computer with a data analysis software package (LabView II by National Instruments). The raw signal was filtered to remove vibrations not related to friction. The signals from the friction force transducers were compared before and after filtering. Before testing, the materials were cleaned using an oil removing detergent (Liqui-nox, Alconox Inc., New York, NY).

A Newtonian lubricant with a viscosity of 945 Cp (glycerine 100%) was placed between the two surfaces and they were brought together by lowering the jig onto the reciprocating platform. The magnitude of the velocity was set to sinusoidally vary from 0-212 mm/sec, by rotating the speed dial to the appropriate position. This velocity range produced an entraining velocity of 106 mm/s. The voltage output from the two forces transducers was amplified and used to determine the force required to hold the sample holder in place while the reciprocating plate moved. Since the applied force was known, the coefficient of friction could be determined.

The voltage values for the strain gauges were converted to force using the appropriate calibration curves. The coefficient of friction was determined by dividing the force measured by the transducer by the applied force. The static coefficient was chosen to be the highest coefficient of friction value obtained immediately after the strain gauges switched from one to the other, which corresponds to the value when motion begins. The kinetic coefficient of friction values were determined by taking the average of all coefficient values other than the static value. The instantaneous velocity at each sample time was calculated by dividing the change in distance by the change in time. The entraining velocity, which is the average of the highest and lowest instantaneous velocities, was 106 mm/s. Once the appropriate coefficient of friction and velocity values were determined, further data manipulation allowed plots of coefficient of friction vs. time, velocity, and load to be generated.

The friction coefficients were plotted against the period (time: 0, 1000, 2000, and 3000 cycles), velocity, and Sommerfeld number (Figure 1B). The Sommerfeld number in lubrication theory is a basic parameter defined as the ratio of viscous to pressure forces in a thin lubrication film ($S_o = \text{viscosity} \times \text{velocity} / \text{load}$).

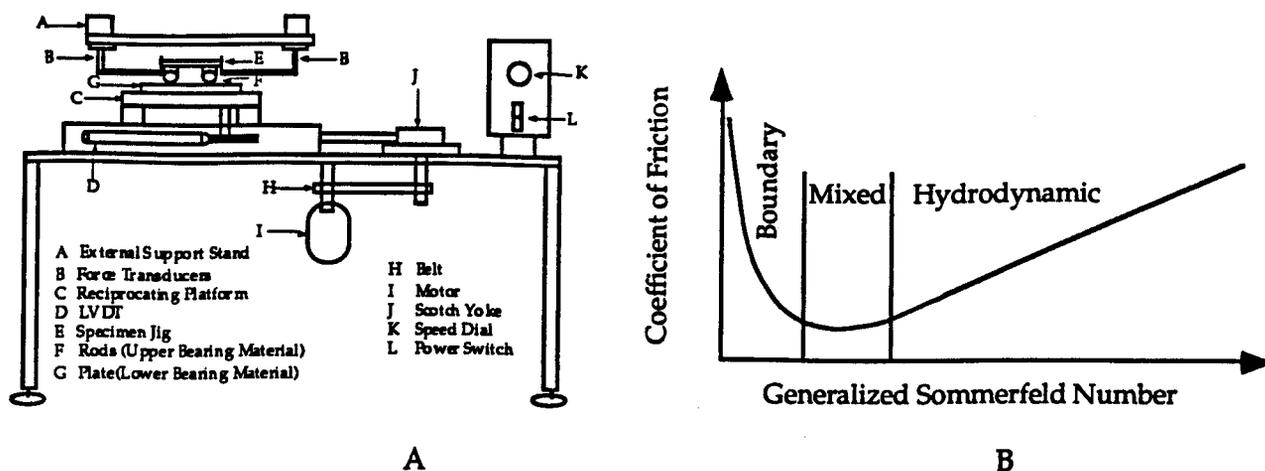


Figure 1. Schematic representation of the friction bench (A) and lubrication regimes for sliding surface pairs (B).

Composite Material Design and Experimental Variables

Since the goal of this research program is to characterize the frictional contribution to the failure modes of elastomeric composites due to fatigue loading, the most basic composite designs have been attempted: unidirectional $(0^\circ)_n$ and cross-ply $(0^\circ/90^\circ)_n$. During the past four months, an experimental set up has been chosen to fabricate the test composites as well as a fabrication technique. Lycra™ and polyester fibers have been investigated by our research group in the last year with satisfactory results. Composites have been built up layer by layer, using a combination of solution casting (Leach, 1994a) to apply the Tecoflex™ SG80A elastomeric matrix and a winding apparatus to control placement of the polyester and Lycra™ fibers. A schematic of the winding apparatus is shown in Figure 2.

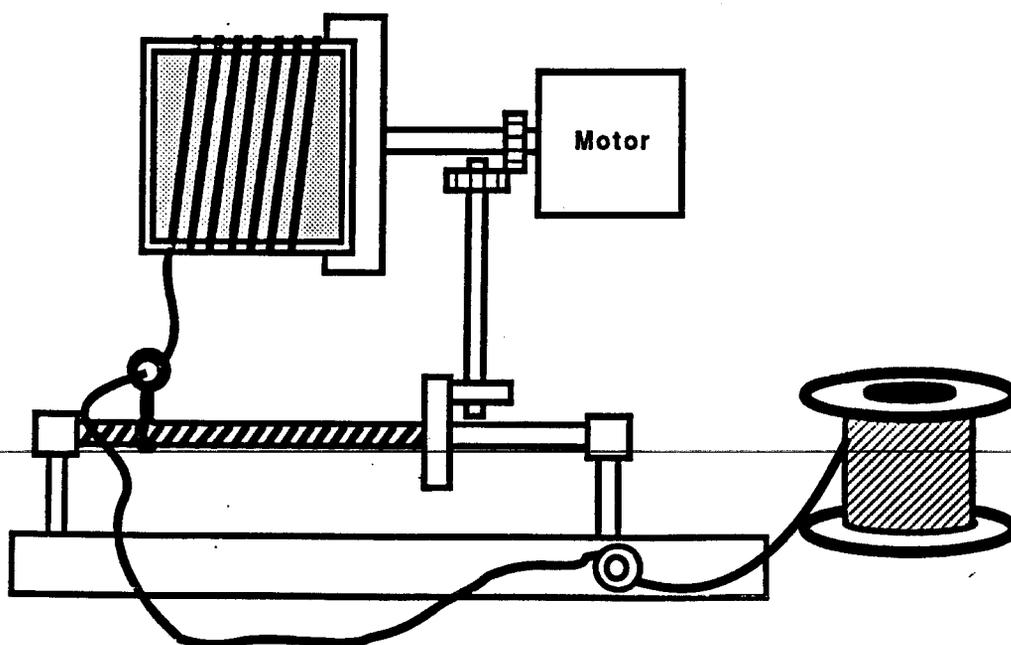


Figure 2. Schematic of winding apparatus used in fabrication of elastomeric composite materials. (from Leach, 1994)

Composite specimens have been fabricated as follows according to the method proposed by Leach (1994):

- 1) An elastomeric matrix layer of controlled thickness is applied to a plastic plate, approximately 8" x 8".
- 2) The frame is secured in the winding apparatus. Placement of the frame in the winding apparatus is adjusted to fabricate either unidirectional or cross-ply laminates. A guide is used to ensure that the frame was repeatably placed for each successive layer of fibers with a fiber spacing (within a range of 20-50 fibers/inch) corresponding to the desired fiber volume fraction.
- 3) The motor is started, which begins rotation of the frame and application of the fibers.
- 4) The frame is removed from the winding apparatus and another controlled thickness layer of matrix is applied, then allowed to dry.

This process is repeated until the composite thickness reaches approximately 2.5 mm. After application of the final layer of elastomeric matrix, the composite is allowed to set at room temperature for one week. The mechanical tribological properties of these fabricated composites will be characterized following a standard protocol. The actual fiber-volume fraction for composites will be determined using image analysis techniques.

Preliminary Results

This proposed research represents a fundamental study of the failure mechanisms observed in bearing surfaces. The focus of this research is the failure of one or more of the bearing surfaces in a total hip joint replacement. A significant percentage of the failure rate of approximately 25% of the 150,000 synovial joints replaced per year in the US is attributed to a high wear rate of the UHMWPE which causes implant loosening. Consequently, it is now clear that in order to improve the longevity of a total joint replacement, new materials and a better fundamental understanding of all of the complex modes of failure in bearing surfaces must be obtained.

The calculated modulus of elasticity based on Finkin's indentation model for each grade of Tecoflex™ assessed is shown in Table I. SG80A has modulus of elasticity value very similar to that of articular cartilage (6-10 MPa). However, based on a previous study by the investigators, unreinforced SG80A sustains a 40% permanent deformation after 1,000,000 cycle (cyclic compressive loading) while the permanent deformation of SG85A is 28% under the same conditions. SG95A and SG93A will be therefore assessed as test resins for the composites in this research.

Grade	Hardness	Young's Modulus (MPa)**
80A	80A	5.19±0.25
85A	85A	14.0±0.2
93A	93A	25.36 ±1.21

Table I. Physical data for Tecoflex™ elastomers.

Figures 3 and 4 show typical coefficient of friction vs period (time) curves for smooth UHMWPE and Thordon™. The coefficient of friction increases as a function of increasing velocity indicative of fluid film lubrication. The overall dynamic coefficient of friction is higher for the polyethylene-metal contact than for the Thordon™-metal contact demonstrating a possible advantage of deformable surfaces through elastohydrodynamic lubrication mechanism. No wear track or scratching were observed on the surfaces after testing. A significant decrease in coefficients of friction has been observed as a function of time (0 and 3000 cycles). Since Glycerine is a Newtonian fluid, its rheological properties should not vary as a function of shear rate and reciprocating motion. However, an increase in temperature could decrease its viscosity, thus possibly explaining the observed decrease in coefficient of friction with time. Even though more testing is presently in progress to confirm this argument, a priori, this model is consistent with the major objective of this project which is to determine the effect of heat generation on the failure of the elastomer-fiber composites

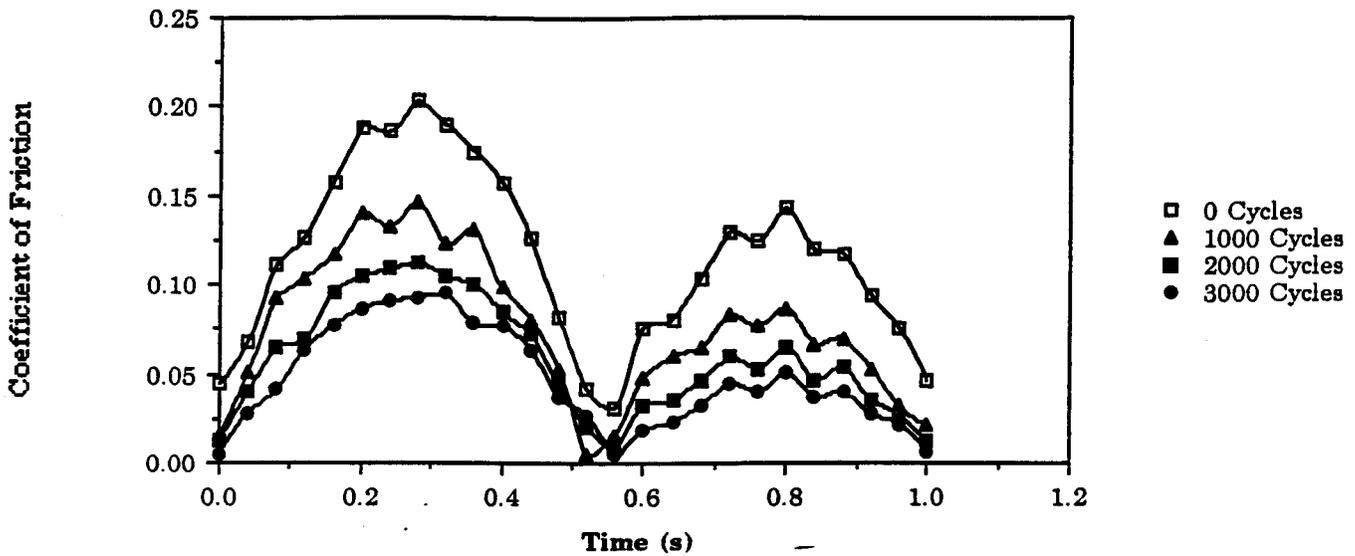


Figure 3. Coefficient of friction vs time curve for smooth UHMWPE (100% glycerine)

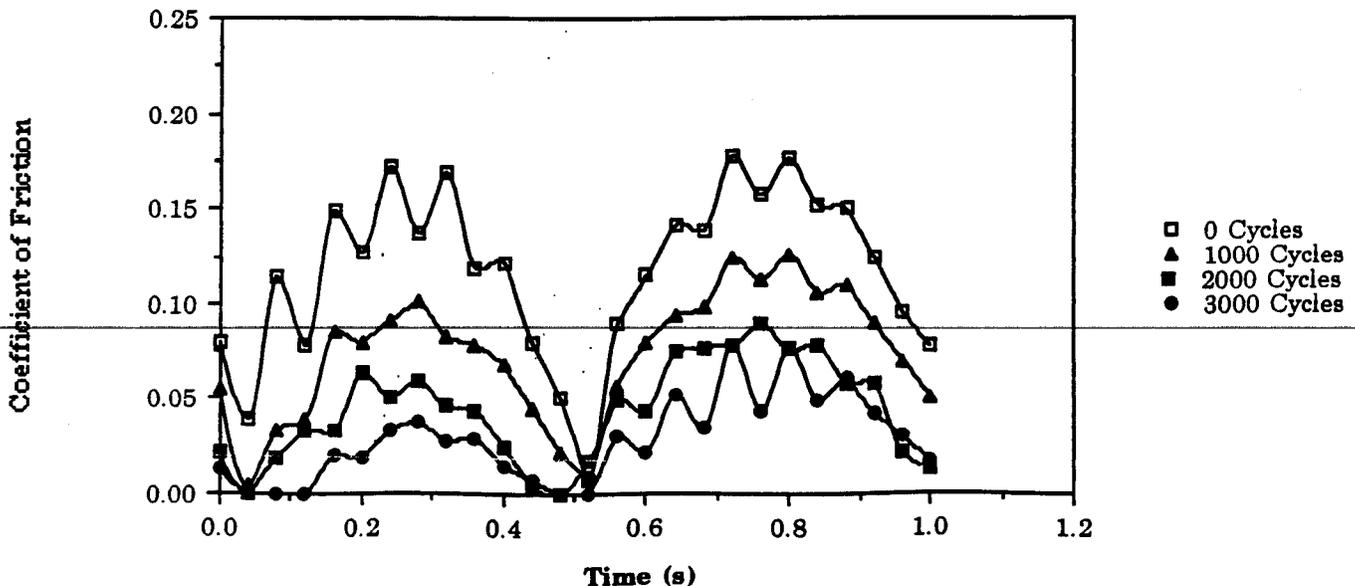


Figure 4. Coefficient of friction vs time curve for smooth Thordon™ (100% glycerine)

Work is currently in progress to instrument the tribological study point contact to measure the heat transfer during reciprocating motion and its effect of the composite. From these results the surface and subsurface temperature in the composite during reciprocating motion will be estimated.

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Additional Acknowledgment

National Institute of Health (Grant 1R15- AR41538-01)