Mechanical Properties of Ultra High Molecular Weight Polyethylene NIST Reference Material # 8456

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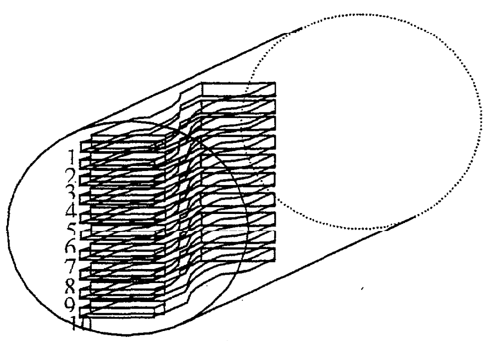
Introduction. The objective of this paper is to present the mechanical properties of Ultra High Molecular Weight Polyethylene (UHMWPE) Reference Material (RM) 8456, newly available from the National Institute of Standards and Technology. The UHMWPE RM that had previously been supplied by the Hospital for Special Surgery has been exhausted.

Materials and Methods. The UHMWPE used for RM 8456 was donated by Poly Hi Solidur, Inc., MediTECH Division (Production Code PG9981, Premium Grade Ultra High Molecular Weight Polyethylene, Virgin UHMWPE Raw Material Lot No. 332945, source identified as TICONA GUR 1050 ##). Type IV tensile specimens, 3.25 mm thick, were prepared according to ASTM D-638. Specimens were fabricated from test bars from each end and at 30.48 m intervals of a continuous production run of 304.8 m (1000 ft) for a total of 11 test bars. Ten test specimens were cut from each bar, spaced evenly across a bar, as shown in the figure, with specimens 1 and 10 from the outermost portion and specimens 5 and 6 from the innermost portion.

A randomized table for testing order and data recording was made. Randomization was done according to test bar



letter designations and was blocked according to the numerical specimen order within the test bars.

Young's Modulus: Note 15 of ASTM D 638 states: "Modulus of materials is determined from the slope of the linear portion of the stress-strain curve. For most plastics, this linear portion is very small, occurs very rapidly, and must be recorded automatically." The linear portion of the stress-strain curve for RM 8456 occurred at strains well below 0.5 %. Therefore, Elastic Modulus testing, was conducted by six repeated measurements on each specimen at peak strains between 0.15 % and 0.25 %. The protocol: 1) Specimen fixed in grips starting at a zero load, 2) Crosshead speed set at 50 mm/min, 3) Load cell and extensometer specifications as described in D 638, calibrated every 10 tests electronically, both before and after the testing session, with dead weights, 4) Data collection rate set at maximum for the instrument.

The modulus was compared at 1 %, 2 %, and 3 % strains. Ten specimens, which exhibited mean 0.3 %-strain Young's modulus values that were nearly identical, were chosen from the 110 specimens that were fabricated. These specimens were tested using the same instrument setup, but with a maximum strain limit of 3.5 %. One test was run on each specimen and the stress-strain curve was analyzed to determine the secant modulus between 0 % to 1 %, 0 % to 2 %, and 0 % to 3 % strain.

Yield strength, Ultimate Tensile Strength, and Elongation. Each characteristic was determined from destructive tests of all of the specimens. The yield point determination is not defined in ASTM D 638. Since every specimen exhibited a characteristic maximum load at yield, the yield point was determined as the highest zero-slope point on the load-deflection curve.

Results.

Table 1 Young's Modulus

Strain	Secant Modulus (Mean)	±	Standard Deviation
0 % to 1 %	945 MPa	±	19 MPa
0 % to 2 %	678 MPa	±	18 MPa
0 % to 3 %	532 MPa	±	12 MPa

The reported values and uncertainties for all properties are shown in Table 2, below. The expanded uncertainty is computed as U = 2u to approximate 95 % confidence interval.

Table 2

Property	Mean	u	U	Units
Young's Modulus	1258.	22.	44.	MPa
Yield Strength	23.56	0.33	0.66	MPa
Ultimate Strength	45.8	3.0	6.0	MPa
Elongation	460.	20.	40.	% (Percent)

Statistical Analysis:

The largest differences in properties were in specimen positions (SPs) 1 & 10 (see figure) and only small differences exist among test bars for SPs 2 through 9. Hence, the certified region excludes the outside 1 cm of the bar's diameter Properties were not significantly different within a bar. The uncertainty is computed and reported as the standard deviation of a single future predicted value at any single position chosen at random from the lot. The uncertainty of the certified values is:

$$u = \sqrt{S^2_{between} + S^2_{mean}}$$

$S^2_{between}$ is the variance that accounts for differences among positions on a single RM; S^2_{mean} is variance of the reported value as calculated from measurements on J (J=11 here) bars at each of 8 central positions.

Commercial materials identified are neither endorsed by NIST nor claimed by NIST to be superior to others.

Contact Stress Assessment in Conventional and Highly Crosslinked UHMWPE Acetabular Liners with Finite Element Analysis and Pressure Sensitive Film

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Introduction: A dominant long-term concern with total hip replacement (THR) is the wear associated with the use of ultra high molecular weight polyethylene (UHMWPE) and the resulting periprosthetic osteolysis[1-5] which may result in premature failure requiring further revision surgery. However, recent developments in the formulation and manufacture of UHMWPE have resulted in a highly crosslinked material that exhibits high resistance to wear[6-9] and holds promise to improve the bearing surfaces in total hip replacement. In addition to presenting a more wear resistant surface, selected ones of the newer, highly cross-linked UHMWPE also exhibit a lower modulus of elasticity, possibly resulting in an improved contact stress distribution. The aim of this work was to examine the stress distribution and magnitude under normal loading of the bearing surfaces in a representative THR, conducted with computer models using properties of conventional UHMWPE, which was gamma sterilized in nitrogen, and those of the recently developed, highly crosslinked UHMWPE treated with E-beam irradiation with subsequent melting and sterilization with ethylene oxide.

Materials and Methods: Stress distribution and magnitude in the acetabular component of a THR during simulated loading with a peak load of 3,000 Newtons (representing three times body weight of a patient weighing 1,000 Newtons or 225 pounds) during single leg stance were examined using finite element analysis (FEA) techniques and pressure sensitive film to compare two materials: 1) conventional ultra high molecular weight polyethylene (UHMWPE) after radiation with gamma rays to 2.5-4.0 MRad, and 2) a more highly cross-linked, melted UHMWPE sterilized with ethylene oxide. Three sizes of acetabular inserts with a nominal thickness of 3 mm were examined (28mm, 38mm and 46mm inside diameter). Nominal and worst case dimensions (at the limits of manufacturing tolerance) were employed in the FEA models to determine the sensitivity of contact and internal stress to these parameters. The head was loaded with 3,000 Newtons (674 lbs.) at an angle of 40° from the axis of symmetry. An exploded view of the model for the size 46/59 is shown in Figure 1. The cup inserts were modeled as elastic/plastic isotropic materials with properties based on measurements carried out under uniaxial compression. The properties used in the computation were piecewise linear approximations of true stress and true strain. The elastic moduli and Poisson's ratio in the linear range of the characteristics for the conventional UHMWPE were 873 MPa and 0.439 and for the highly cross-linked UHMWPE, 676 MPa and 0.425. The parameters adjusted to represent the worst-case conditions were the head, liner and shell diameters at the head/liner and liner/shell interfaces while all other dimensions were held constant. Adjustment of the dimensions within manufacturing tolerances was done to create a situation that would result in elevated stresses at contact interfaces of the THR. A worst-case condition, then, consisted of minimum femoral head diameter, maximum cup inside diameter, minimum cup outside diameter, and maximum shell inside diameter. The test matrix consisted of two materials (conventional and highly crosslinked polyethylene), two-dimensional configurations (nominal and worst case), and three THR sizes (28/41, 38/51 and 46/59) for a total of twelve simulations.

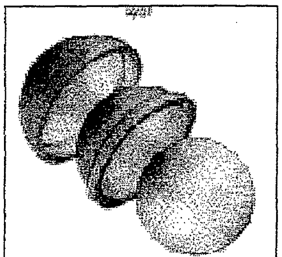
Figure 1 - Finite Element Model

In addition to the finite element analysis, contact stresses were measured experimentally with Fuji Film Prescale (Sensor Products, E. Hanover, N.J.). A 3 mm strip of Fuji Film Prescale was placed between the femoral head and the corresponding liner. The components were then loaded on an MTS servo hydraulic testing machine (Eden Prairie, Mn.) to a load of 3000 Newtons (674 lbs.) for a duration of two minutes. The acetabular liner was oriented to 40 degrees of abduction with respect to the horizontal and the load was applied in a vertical direction following the loading scheme used in the FEA stress calculations. The strips of Fuji Film were then analyzed using an FPD 305 Densitometer (Sensor Products) in the region of the strip that had the most intense color pattern. Therefore, the contact stress values reported here are the maximum encountered during loading. The Fuji Film contact stress measurements were carried out with all three sizes.

Results: Results of the FEA stress analysis at the head/liner interface for size 28/41 are illustrated in Figure 2. Von Mises stress contours for the same simulation are shown in Figure 3. The other two sizes exhibited similar relationships at lower stress levels. Contact pressure measurements with the Fuji Prescale Film are illustrated in Figure 4. Under every FEA test condition, the highly cross-linked UHMWPE experienced lower stress levels than the conventional polyethylene at the contact interfaces and throughout the volume of the cup. Using nominal dimensions, the stress distribution at the head/liner interface was evenly distributed around a central location in the direction of the load. Under worst-case dimensional conditions the stress levels were higher and the distribution was less uniform, with an additional area of elevated stress appearing closer to the rim of the liner at both the head/liner and liner/shell interfaces. FEA findings were consistent with pressure sensitive film data.

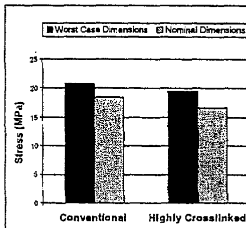

Figure 2 - Maximum Von Mises Stress (size 28/41)

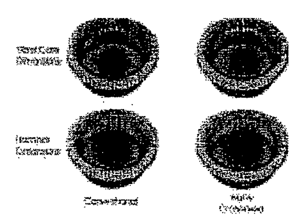
Figure 3 - Von Mises Stress Contours (size 28/41)

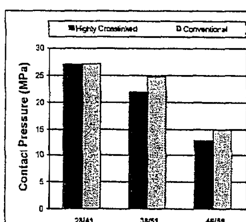

Figure 4 - Pressure Sensitive Film Measurements

Discussion: In summary, the newer highly cross-linked UHMWPE represents a material with clearly superior wear characteristics in vitro. Part of the improvement in wear characteristics may be due to the fact that the highly cross-linked UHMWPE has a lower modulus of elasticity, resulting in improved stress distribution. FEA modeling consistently shows the highly cross-linked UHMWPE to exhibit less stress than the conventional material at the critical interfaces under load, even when measured at the nominal thickness of 3 mm for the liner.

The small differences noted in the measurements of stress with the Fuji Prescale Film and the finite element analyses may be due to the following: (i): the material model used in the FEA is elastic-plastic with no viscoelasticity and (ii) the finite thickness of the Prescale Film may produce an altered stress distribution with edge effects.

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