DEGRADATION OF THROUGH-THICKNESS MECHANICAL PROPERTIES OVER TIME IS MORE SEVERE THAN PREVIOUSLY ESTIMATED USING INDIRECT MEASUREMENT TECHNIQUES

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Introduction. Degradation of ultra-high molecular weight polyethylene (UHMWPE) following gamma sterilization in air is now widely recognized to be a limiting factor in the longevity of total joint replacement components. Accelerated aging techniques have been developed to evaluate the resistance of UHMWPE to degradation [1-3]. Although the physical and chemical properties of UHMWPE following gamma sterilization have been studied exhaustively after natural and accelerated aging, only recent advances in miniature specimen testing techniques [4-8], such as the small punch test, have enabled direct mechanical characterization of orthopaedic components.

Consequently, the purpose of this study was to compare the mechanical behavior of GUR 1120 tibial components after five and ten years of natural shelf aging with tibial components that had been subjected to accelerated aging. This study also addressed the following research question: to what extent does gamma sterilization in air, followed by five and ten years of aging on the shelf, degrade the mechanical behavior of tibial inserts inhomogeneously through the thickness of the component?

Methods. This study consisted of eight knee implants of the same design and manufacturer. Three groups of implants were machined from compression molded sheet stock and sterilized with a standard dose of gamma radiation (in air) in 1988 (n=2), 1993 (n=2), and 1998 (n=4), respectively. Two of the freshly irradiated implants were subjected to 4 weeks of accelerated aging in air at 80° C (0.1°C/min initial heating rate).

Mechanical testing was conducted using the small punch test to measure the large-deformation mechanical behavior of the UHMWPE under multi-axial loading conditions [4,5]. Disk-shaped test specimens (500 µm thick, 6.4 mm diameter) were machined from two cylindrical cores taken perpendicular to the articulating surface of each condyle. Forty-seven mechanical tests were performed on material starting from within 25 µm of the articulating surface (n=23) and at a depth of 1.5 to 2.0 mm (n=24). Through-thickness FTIR and DSC was also conducted to characterize the oxidation and crystallinity of the implants to complement mechanical testing results. Oxidation index was calculated from the FTIR spectra by normalizing the area under the carbonyl absorbance peak by the reference peak area at 1460-1470 cm^{-1}. Analysis of variance was performed using SAS Version 6.12 to evaluate the following factors: location (surface and subsurface), age (unaged, artificially aged, aged 5 years, aged 10 years), and age-location interaction.

Results. The small punch load-displacement behavior for undegraded UHMWPE typically displayed an initial peak load (during initial bending of the disk-shaped specimen), followed by a drawing phase under equibiaxial tension (Fig. 1). However, degradation was associated with progressive reduction of the ductile drawing phase, as illustrated by the 10-year shelf aged materials (Fig. 1). In addition to the loss of ductility, the 10-year aged UHMWPE also showed a substantial decrease in the initial peak load, when compared with unaged controls (Fig. 1). Aging significantly affected the small punch test measures of initial load, ultimate load, ultimate displacement, and work to failure for the GUR 1120 (Table 1, $p < 0.0001$). Furthermore, a significant age-location interaction was observed for the initial load ($p < 0.0001$), ultimate load ($p < 0.006$), ultimate displacement ($p < 0.003$), and work to failure ($p < 0.004$). Natural aging resulted in subsurface degradation of the mechanical properties for the GUR 1120. At a depth of 1.5 to 2.0 mm, the average initial peak load after 10 years of natural aging was 47% lower than the unaged controls; the ultimate load was 85% lower; the ultimate displacement was 53% lower; and the work to failure was 78% lower.

In contrast with the mechanical behavior, the oxidation index decreased monotonically through the thickness of the inserts. The accelerated aging protocol only mechanically degraded the surface (Table 1, Fig. 1). However, the mechanical behavior at the surface following the accelerated aging was bounded by the subsurface mechanical behavior following 5 and 10 years of natural aging (Fig. 1).

Discussion. This study is novel in its exploration of long-term degradation to the large-deformation mechanical behavior of GUR 1120 tibial components following five and ten years of post-irradiation aging in air. The accelerated aging protocol mechanically degrades the surface (but not the subsurface) regions of GUR 1120 tibial components to an extent bounded by the subsurface mechanical behavior of 5 and 10 years of natural aging. The results of this study, in particular the decrease in initial peak load after long-term aging, suggests the hypothesis that severe degradation is accompanied by deleterious changes to not only the ultimate properties (i.e., strength and ductility), but also the polymer yield behavior. Reductions of the yielding and plastic flow behavior of UHMWPE have important clinical implications, especially for highly stressed tibial components, which may be subjected to macroscopic large deformations during *in vivo* loading and may exhibit fatigue damage, such as pitting or delamination. We hypothesize that a primary cause of fatigue wear observed in retrievals may be the heterogeneous degradation of mechanical properties through the thickness of the implant.

The small punch test method, which has been extensively validated for wear-tested components and short-term retrieved implants [4,5,9], was found to be a reproducible method for directly measuring the mechanical behavior of the severely degraded UHMWPE even after 10 years of shelf aging. We found that scalar measures of oxidation, such as the oxidation index, did not appear to be related to the mechanical behavior beneath the articulating surface. This study establishes miniature specimen mechanical testing techniques as an invaluable and particularly sensitive tool for validation of proposed accelerated aging methods for UHMWPE.

References: [1] Sun et al., Polym. Repr., 35,1994; [2] Sanford et al.,1995 ORS,119; [3] Furman et al.,1998 ORS,102; [4] Kurtz et al., Biomaterials, 18:1659-1663,1997. [5] Kurtz et al., 1998 SFB, 125. [6] Sutula et al., CORR, 319: 28-40, 1995. [7] Collier et al., CORR, J Arthroplasty, 11: 377-389, 1996. [8] White et al., CORR, 331:164-71, 1996; [9] Edidin et al., 1998 SFB, 220.

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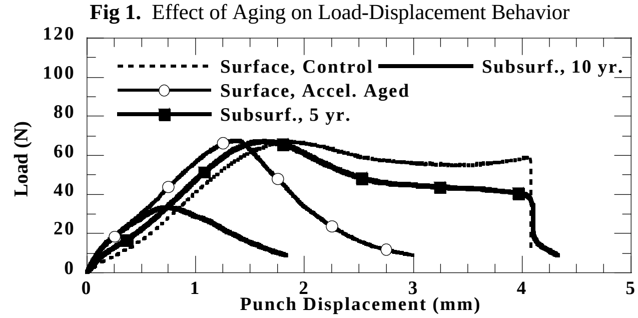
Table 1. Summary of Small Punch Testing Results

Year Gamma Sterilized	Specimen Location	Initial Peak Load (N)	Ultimate Load (N)	Ultimate Displ. (mm)	Work to Failure (mJ)
1998	Surface	64.6±2.9	55.1±2.1	4.11±0.04	191±8
1998	Subsurface	64.9±3.1	60.9±3.4	4.07±0.08	196±13
1998-AA	Surface	62.5±8.5	17.7±12.1	2.20±1.57	78±71
1998-AA	Subsurface	70.3±1.0	65.4±1.8	4.06±0.04	207±5
1993	Surface	72.6±1.5	56.7±6.2	4.13±0.20	214±17
1993	Subsurface	69.7±1.3	39.0±3.7	4.11±0.15	190±5
1988	Surface	58.1±7.7	22.5±16.9	2.64±0.32	99±29
1988	Subsurface	34.7±1.7	8.9±0.0	1.91±0.12	43±4

AA: Components subjected to 4 weeks of Accelerated Aging at 80°C

Fig 1. Effect of Aging on Load-Displacement Behavior



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