INTRODUCTION

Oxidation issues in UHMWPE implants both in vitro and in vivo have been largely resolved in recent years thanks to new technologies for free radical elimination. Orthopedic community still faces the challenge of developing a bearing material with good material strength and wear resistance. The challenge is becoming an urgent need in view of the recent clinical retrieval studies showing surface cracks in some highly crosslinked UHMWPE implants. A new class of crosslinked UHMWPE has been recently introduced to the market by biomaterial suppliers based upon the concept of thermal crosslinking (TXL). In contrast to current grades of crosslinked UHMWPE where a post-radiation annealing, remelting, or vitamin-E diffusion process was employed at temperatures between 120 to 150°C for oxidation prevention, thermal crosslinking relies on reaction mechanisms proceeding at temperatures way above the melting point of UHMWPE for breakage and redistribution of radiation-induced crosslinks to obtain structurally uniform material. New free radicals are formed via C-C bond cleavage during thermal crosslinking which then inter-react into 3D crosslinks upon subsequent cooling. The crosslinking density of the resultant material is higher than its counterparts cited above at same radiation doses without any residual free radicals or oxidation potential. In this study, production blocks of thermally crosslinked UHMWPE were obtained and evaluated extensively for material properties listed in ASTM F648 and F2565. Alongside, knee simulator wear tests were also conducted to compare thermal crosslinking with remelting. The primary objective of this and related studies is to seek a well-balanced crosslinked UHMWPE between material strength and wear resistance.

METHODS

Production blocks of GUR1020 compression molded UHMWPE were obtained for systematic material property evaluation. Production certificate records showed that these blocks were first irradiated in air at 60 kGy followed by either remelting at 150°C or TXL at 260°C followed by slow cooling to room temperature. ASTM F648 and F2565 methods were adopted for structural material property evaluation. Table 1. The properties evaluated included tensile, Izod impact, density, swell ratio (F2214), and oxidation index (O1) and trans-vinylene-yield (TVI) profiles through the block thickness. Another batch of compression molded GUR1020 was irradiated in air at 60 kGy followed by either remelting at 150°C or thermal crosslinking at a temperature range between 170 and 240°C. Wear testing for both materials was conducted on a knee simulator (MTS, Eden Prairie, MN) following ISO 14243 using CoCrMo knee articulating couple (maximum axial load 2600 N, anterior/posterior translation 0 to 5.2 mm (posterior), internal/external rotation -1.9 to 5.7°, maximum flexion angle 58°; 1Hz.; Alpha Calf Fraction serum (Hyclone Labs, Logan, UT) diluted to 50% ). Statistical analysis was conducted on all data using t-tests with a p-value below 0.05 defined as significance.

RESULTS

Tensile yield, ultimate strength, elongation at break, Izod impact strength, and density data are presented in Table 1. Also listed are minimum requirements specified in ASTM F648 for the three medical grade virgin UHMWPE. Swell ratio, O1 (average), and TVI (average) data are shown in Table 2. Table 3 shows the knee wear test results.

DISCUSSION

From Tables 1 and 2, TXL at 260°C without radiation significantly reduced the swell ratio compared to the virgin polymer (11.0 vs. 14.25 reported in literature). However, the increased crosslinking level in TXL material did not significantly change the tensile yield, ultimate strength, or density. Elongation was slightly increased while Izod impact was slightly lower for TXL (both p<0.05). It has been theorized that crosslinks induced by thermal crosslinking are in the form of physical entanglements rather than chemical bonding. Such molecular network is desirable for improved wear resistance while maintaining material strength. As the radiation dose increased from 0 to 100 kGy for TXL materials (confirmed by TVI), swell ratio decreased from 11.0 to 3.1. In the meantime, ultimate tensile strength, elongation, and Izod impact decreased. Tensile yield decreased only slightly as it was primarily controlled by density which decreased slightly. It is important to note that all mechanical properties and densities of TXL materials irradiated up to 100 kGy still met the minimum requirements specified for the virgin polymers in F648. Earlier work has reported low to negligible wear for highly crosslinked TXL materials. Knee wear test results again confirmed the wear improvement by TXL (Table 3). At the same radiation dose of 60 kGy, TXL showed a wear rate of 10.4 mm/million cycle as compared to 13.9 mm/million cycle for remelting material (a reduction of about 25%). The authors attributed the improved wear in TXL over remelting to the increased overall crosslinking density and uniform distribution of crosslinks. Oxidation was negligible for all TXL.

CONCLUSION

Thermal crosslinking has produced UHMWPE materials with unique behaviors of wear resistance and material strength which often counteract in current technologies. Implant design engineers might be able to choose optimal crosslinking levels for achieving the clinical target of wear rate and fatigue strength using TXL.