The Effect of ASTM F-2003 Accelerated Aging of UHMWPE on Specimen Weight Change

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Statement of Purpose: Wear testing of total knee replacement (TKR) systems provides an estimate of the overall functionality of implantable medical devices and provides a prediction of general damage and wear patterns during in vivo function. Often, the type of wear surface used in TKR is ultra-high molecular weight polyethylene (UHMWPE). The viable lifetime of these systems is dependent on the amount of wear induced in these surfaces, which is often assessed by measuring weight loss during wear testing in the laboratory [1]. UHMWPE is also known to suffer from the deleterious effects of oxidation during extended periods of shelf storage or implantation. In order to simulate the long-term effects of UHMWPE oxidation in the laboratory, an accelerated aging process is often employed. This allows researchers to assess possible deleterious effects of oxidation on samples in a period of weeks or months instead of the years typically required to reach long term stability [2].
The purpose of this study is to examine the gravimetric in UHMWPE specimens after the accelerated aging process, to determine if this process significantly effects the weight of these specimens. This study hypothesizes that the accelerated aging process causes a substantial increase in the initial weight of the UHMWPE samples.

Methods: Twenty UHMWPE tibial inserts were examined, over three separate wear testing studies (n=4, n=8, n=8), and included both PS and standard conforming UHMWPE insert designs. Prior to the start of wear testing, all tibial inserts were aged (ASTM F-2003) at an elevated temperature and oxygen pressure over a 14 day period to best represent a 5 year oxidation process that could occur in vivo. An oxygen bomb system capable of maintaining a temperature and pressure with high accuracy and precision was used. Initial conditions were set at 23±2° C and raised at a rate of 1.0±0.1° C/min until a temperature of 70° C was reached and an equilibrium pressure of 503 kPa was established [2]. In order to ascertain weight changes over time, the specimens were weighed immediately before the fourteen day aging process, and then weighed again hourly, daily, and weekly after the process. The specimens were stored under house vacuum in a dessicator for the duration of the study. Changes in all specimen weights were normalized to initial pre-testing values, and changes in specimen weight over the study were assessed for statically significance using paired student t-tests with α=0.05.

Results: Pre-aged UHMWPE insert weights averaged 23.53±1.82 (n=20, ±1 standard deviation) grams. Following the 14 day accelerated aging process, there was a statistically significant increase of 3.4±2.4 mg or 0.014±.010 weight % in UHMWPE weights (n=20, p=5E-9). Following this initial increase, UHMWPE weights slowly returned towards baseline values over time. Seven of the 20 samples decreased to steady state values by day 27, with the remaining specimens returning to near baseline values (paired t-test, P=0.04). Figure 1 show one n=8 test conducted, with Figure 1 with the specimen average returning to baseline values. The other two tests show similar increases and then the subsequent decreases in weight.

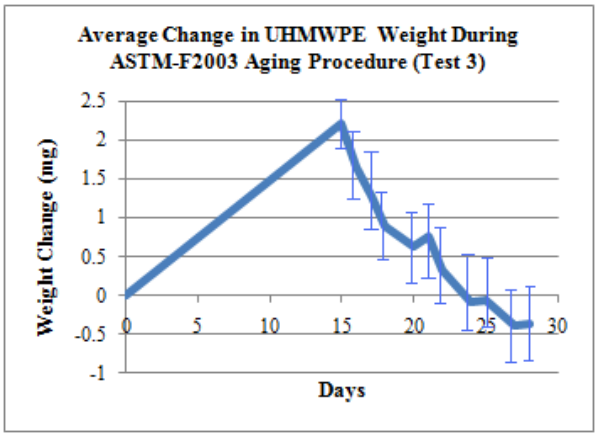

Figure 1. Test 3 containing 8 of 20 test samples of tibial inserts used in this study. Shown are the average values and standard deviations of those 8 samples.

Conclusions: We found that there was a substantial increase in the weights of the UHMWPE samples immediately following the accelerated aging process (ASTM F-2003). On average, it took between 22-27 days post-aging under vacuum conditions for the specimen weights to return to statistically similar pre-aging baseline values. Thus it follows that when the accelerated aging process is used for the artificial aging of UHMWPE bearing surfaces in wear testing, there should be a time period of at least three weeks to allow the UHMWPE to return to initial weights prior to continuing with any further testing involving the material. This gives adequate time for the weights to return to normal, and thus eliminates any subsequent skewing of data from further testing. All wear testing studies that utilize ASTM F-2003 should monitor post-aging weights to insure that baseline weight values have been achieved and do not therefore influence subsequent wear testing gravimetric measures.

References: [1] Buchanan F. Accelerated Ageing and Characterization of UHMWPE used in Orthopaedic Implants. www.azom.com, 11/5/2010
[2] "Standard Practice for Accelerated Aging of Ultra High Molecular Weight Polyethylene after Gamma Irradiation in Air," *ASTM F2003, American Society for Testing and Materials, 2008*

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