Wear Particle Analysis of Supercritical Carbon Dioxide Sterilized UHMWPE from Total Knee Replacement Simulation

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Statement of Purpose: Recent evidence suggests that that supercritical carbon dioxide (SC-CO_2) may serve as a suitable sterilization alternative for many medical grade polymers [1]. For the case of ultra high molecular weight polyethylene (UHMWPE), alternatives to existing techniques that significantly affect the mechanical and/or wear properties of UHMWPE [2] could ultimately enhance the longevity of such materials. SC-CO_2 sterilization has been shown to deactivate many clinically relevant microbial strains [3], and it is effects on the long term wear rates of UHMWPE components are currently under investigation [4]. The current study investigates the morphology of SC-CO_2 and Gamma sterilized UHMWPE wear particulate from total knee replacement (TKR) simulation to more fully assess the potential this novel sterilization technique for clinical use.

Methods: The wear rates of two NexGen CR (Zimmer, Inc., Warsaw, IN) gamma sterilized (25 – 37 kGy) UHMWPE TKR inserts were compared to two NexGen CR SC-CO_2 sterilized UHMWPE TKR inserts utilizing force-controlled TKR wear testing simulation. SC-CO_2 sterilization was conducted utilizing a Thar R-250 supercritical fluid reactor (Thar Technologies, Inc, Pittsburgh, PA). The inserts were suspended over 1.3 ml of 1.5% H_2O_2 in a cotton pad, pressurized with CO_2 to 300 atm, and heated to 40º C for a duration of 2 hours, after which the system was depressurized over a period of 15 min. utilizing a back pressure regulator (conditions that completely deactivate a 6-log population of bacterial spores [3].

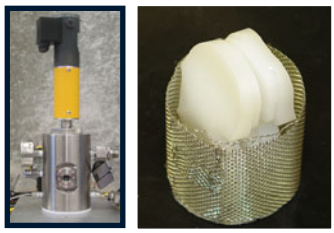

Figure 1. SC-CO_2 sterilization chamber and TKR inserts in stainless steel basket prior to placement in SC-CO_2 chamber

Following sterilization, the implants were subjected to 5 million ISO-14243 force-controlled gait cycles at 1 Hz on an Instron/Stanmore (Instron, Canton, MA) knee simulator. In vivo capsular constraints of 20N/mm and 0.27Nm/deg were utilized in conjunction with 500ml (per 0.5 million wear cycles of testing cycles) of 50% defined bovine calf serum (+0.2%NaN3). Statistical differences in average per/million load-soaked-corrected wear rates between gamma and SC-CO_2 sterilized implants were assessed using paired students t-tests (α=0.05).

Wear particle isolation from SC-CO_2 and Gamma UHMWPE lubricants at 1 and 4 million cycles was conducted using the hydrochloric acid (HCl) digestion method [5]. Serum samples were thawed, vortexed and then a 10 ml aliquot was removed and mixed with 50 ml of 37 vol% HCl. This mixture was heated and stirred to 60 ºC for 45 min. One ml of the resulting solution was then added to 100 ml of methanol. This solution was then vacuum filtered through a 0.2µm pore polycarbonate filter (Whatman, Middlesex, UK). Following filtration, the polycarbonate filters were sputter coated with platinum and imaged using a S-3400N scanning electron microscope (Hitachi-HTA, Schaumburg, Il) at 10,000X. Twenty representative images (12.5x10um field of view) were taken from each filter. Image-J (NIH) software was utilized to identify and estimate wear particle number and morphology through elliptical area fitting. Statistical differences were assessed with Kruskal-Wallis one-way ANOVA on Ranks with alpha = 0.05, and Tukey's analysis for multiple pairwise comparisons.

Results/Discussion: Particle size diameter ranges of 7.2-0.04um were found with over 788 particles being analysed for each specimen and time point. At the start of testing (1M) and at the end of testing (4M) no statistical differences ($p>0.05$) were noted between Gamma and SC-CO_2 UHMWPE wear particle morphology. Between 1M and 4M cycles of testing however, the Gamma and SC-CO_2 wear particles both statistically increased in average diameter and average area. Gamma vs. SC-CO_2 particles with less than 0.2um average diameter accounted for 77% vs. 76% of total particles measured at 1M and 87% vs. 81% at 4M, respectively.

Table 1. Wear Particle Morphology Data After TKR Simulation

	Average Area (um2)	Average Diameter (um)	Min/Max Average Ratio
Gamma 1M	0.1 ± 0.14	0.31 ± 0.18	0.73 ± 0.19
Gamma 4M	0.11 ± 0.14	0.34 ± 0.16	0.72 ± 0.19
SC-CO2 1M	0.12 ± 0.22	0.33 ± 0.21	0.73 ± 0.19
SC-CO2 4M	0.13 ± 0.22	0.35 ± 0.21	0.69 ± 0.22

Discussion: The analysis of wear particle morphology is a critical component in the assessment of biomaterial suitability for TKR bearing use. The results of this study show that SC-CO_2 sterilized UHMWPE tibial inserts produce wear particulate morphology that is not statistically different from that of Gamma sterilized inserts. The increasing particle size trend noted for each type of material could the hypothesized to be a product of metal counterface roughening over the course of testing. This study offers supporting evidence that SC-CO_2 shows promise as a method by which to sterilize UHMWPE bearing components.

References: [1] Destrubé, (2004) MS Thesis, Clemson University; [2] Kurtz, et. al (1999) Biomaterials, 20:1659-1688; [3] Hemmer et al, (2006) JBMR part B, App. Biomat. In Print; [4] DesJardins et. al (2005) SFB, pg. 222; [5] Niedzwiecki et. al (2001) JBMR; 56(2):245.

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