

UHMWPE Fluid Absorption And Off-Gassing Following Supercritical CO₂ Sterilization

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Statement of Purpose: Supercritical carbon dioxide (SC-CO₂) processing is a promising sterilization technique for biomedical materials, with previous research showing that SC-CO₂ sterilization deactivates many clinically relevant microbial strains [1]. One collateral result of this process is the potential infusion of CO₂ into a porous material bulk. Ultra high molecular weight polyethylene (UHMWPE) is susceptible to fluid absorption, which can hamper the accurate gravimetric assessment of material weight loss during laboratory wear testing. The current study investigates the effect of SC-CO₂ processing on the long-term weight changes of UHMWPE, and compares these weight changes to SC-CO₂ sterilized UHMWPE tibial insert soaked control weight changes observed during total knee replacement (TKR) wear testing.

Methods: Sixteen (16) UHMWPE rectangular pucks (compression molded GUR 1050, 60x27x10mm) with outer surface areas (4980mm²) that approximated a TKR tibial insert were divided into four treatment groups of n=4. Group UV was left unsterilized and stored under vacuum at 25°C. Group UB was left unsterilized and immersed in 50% bovine serum (BS) (+0.2% NaN₃) at 37°C. The final two groups were sterilized using SC-CO₂ (+1.3ml 1.5% H₂O₂) in supercritical fluid reactor (Thar Technologies, Inc, Pittsburgh, PA) which was pressurized with CO₂ to 300 atm, and heated to 40° C for 2 hrs and then depressurized over 15 minutes. Group SV was then stored under vacuum at 25°C, and group SB was immersed in 50% BS (+0.2% NaN₃) at 37°C.

The rectangular specimens were then compared to the weight change trends of 4 UHMWPE unloaded soaked control tibial inserts (NexGen CR, Zimmer, Inc., Warsaw, IN) as part of a 5 million cycle TKR wear study. Two inserts were gamma-sterilized (25 – 37 kGy) and the other two were SC-CO₂ sterilized as listed above. All inserts were allowed a 7 day “off-gassing” period under vacuum before immersion in BS, with 0.5 million (~14 days) interval measurements of gravimetric changes over time. Statistical differences in average weight changes between rectangular specimen groups were assessed at specific time intervals using Students T-tests with $\alpha=0.05$.

Results: All SC-CO₂ sterilized pucks statistically increased in weight (84.2±1.5mg and 89.0±1.1mg, SV and SB groups respectively) immediately following SC-CO₂ processing. Rapid short-term (24 hrs) logarithmic weight loss rates were followed by slower long-term (24-300 hours) rates, with the absolute weights of the SV group eventually statistically intercepting with the unsterilized vacuum control group at 320.4±7.9 hours (p>0.05). The SB group statistically diverged from the SV group at 216 hours and plateaued at a positive weight gain of 2.4±0.3mg at 265 hours indicating a net absorption of BS lubricant during the off-gassing period. The UB group steadily increased in weight between 0-265 hours until it became statistically similar to the SB group.

The SC-CO₂ TKR UHMWPE inserts showed an average initial net loss of 7.8mg at 0.5 million cycles and then remained relatively unchanged to 5 million cycles. The gamma soaked controls steadily absorbed 0.7±1.5mg of BS per million cycles between 0-5 million cycles.

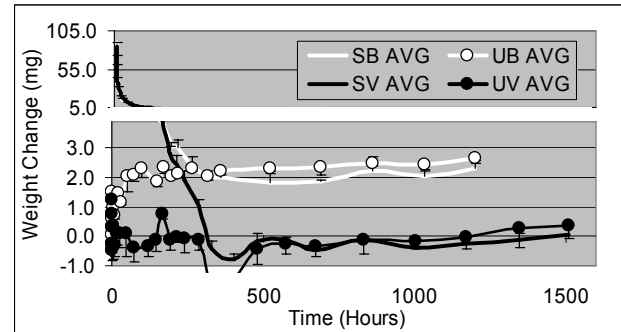


Figure 1. SC-CO₂ and unsterilized UHMWPE soaked control weight changes showing BS absorption and logarithmic off-gassing over time.

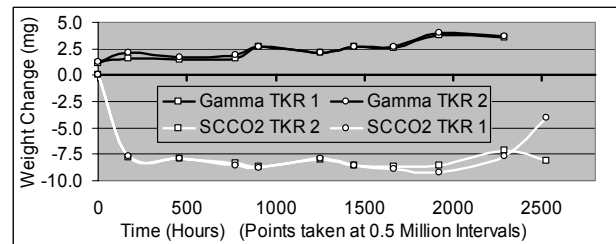


Figure 2. Gamma and SC-CO₂ TKR soaked control weight changes during 5 million cycle wear testing study.

Discussion/Conclusions: Experimental soaked controls are utilized in wear testing studies to quantify material fluid absorption weight gains that could potentially mask weight losses due to material wear. During TKR wear testing, the SC-CO₂ UHMWPE tibial inserts were shown to have a rate of 8.8±0.5mg/million cycles. The SC-CO₂ soaked control weight change of 7.8mg between 0-0.5 million cycles represented a potential 89% error in reported weight loss, had soaked controls not properly been employed. This study shows that SC-CO₂ sterilization significantly affects the weight of UHMWPE and that significant CO₂ off-gassing can continue to occur up to 340hrs (14 days) following sterilization. After complete SC-CO₂ specimen off-gassing, the material did not exhibit any characteristic lubricant uptake out to 87 days (4 million cycles). This observation indicates a characteristic change in UHMWPE absorption mechanisms from that of standard UHMWPE lubricant soaked controls and is a topic for future research.

References: [1] Spilimbergo, S. Biotechnol Bioeng 2003, 84(6): 627-38.

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