

Does Sterilization and Consolidation Method Influence Wear Debris morphology for Cross-linked Polyethylene?

S. Donde¹; S. Buell¹; R. Baez¹; L. Herrera¹

¹Stryker, Mahwah, NJ

INTRODUCTION

- Sequentially cross-linked and annealed polyethylene (X3, Stryker, Mahwah, NJ) is a highly cross-linked ultra-high molecular weight polyethylene (UHMWPE) that has been available on the market for hip and knee total joint replacements with a successful clinical history^{1,2}.
- This polyethylene is GUR 1020 processed with gamma irradiation to 30 kGy followed by annealing in three sequential steps for a final irradiation dosage of 90 kGy³.
- Sterilization processes used in the industry include gas plasma sterilization (GP) and ethylene oxide gas sterilization (EtO).
- Compression molding (CM) and ram extrusion (RE) are two common consolidation methods for UHMWPE.
- The purpose of this study was to examine whether wear debris generated from knee and hip wear simulation tests are morphologically similar regardless of consolidation and sterilization method processes.**

MATERIALS AND METHODS

- Knee and hip wear evaluation was conducted following a walking cycle as per ISO 14243-3 for knees and ISO 14242-3 for hips^{4,5}.
- Used serum samples were collected at 0.5 million cycle intervals for both hips and knees and processed for debris isolation using an acid digestion method⁶.
- Random fields of view for each material were collected using a Quanta 650 Field Emission Electron Microscope and 200 particles were identified for wear debris morphology analysis for both CM-GP X3 and RE-EtO X3 polyethylene for knees and hips.
- Statistical analysis was performed on wear debris dimensions using the Student's t-test ($p < 0.05$).

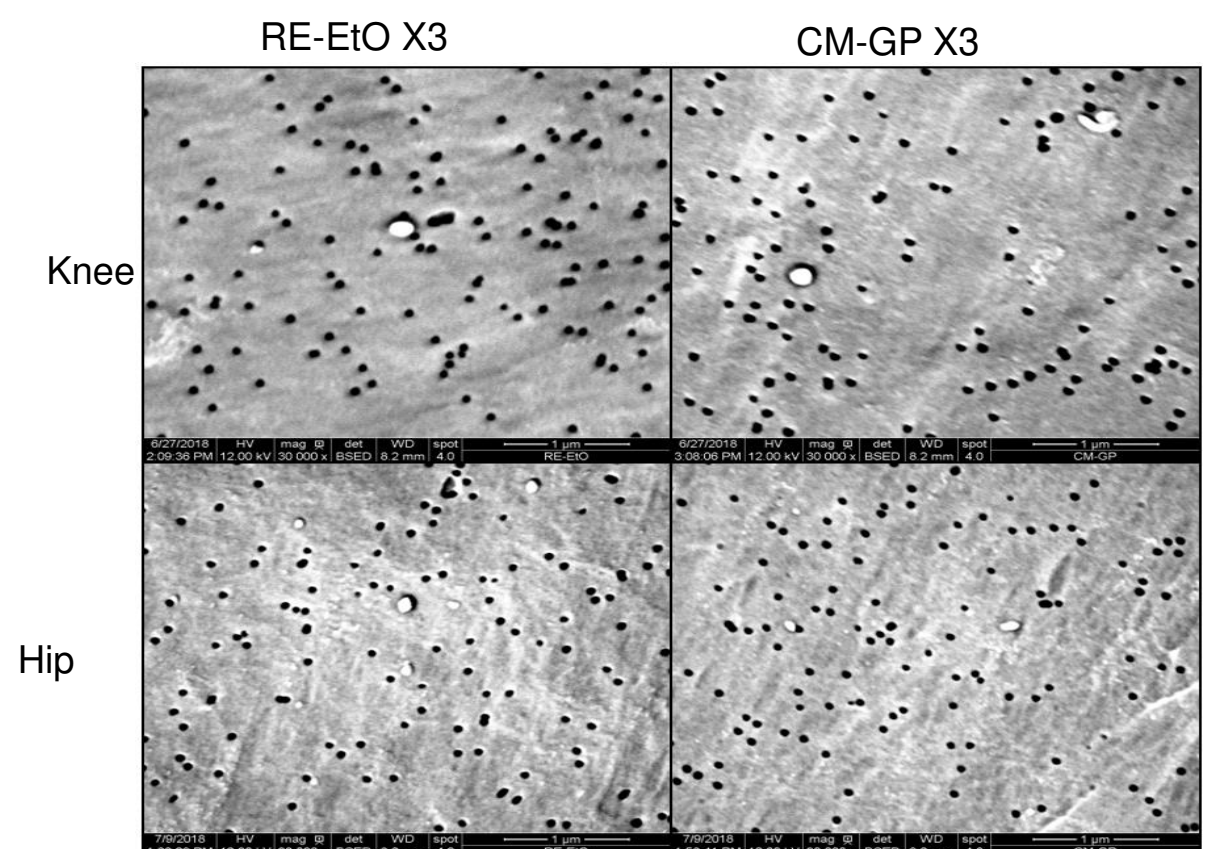
RESULTS

Wear Debris Morphology

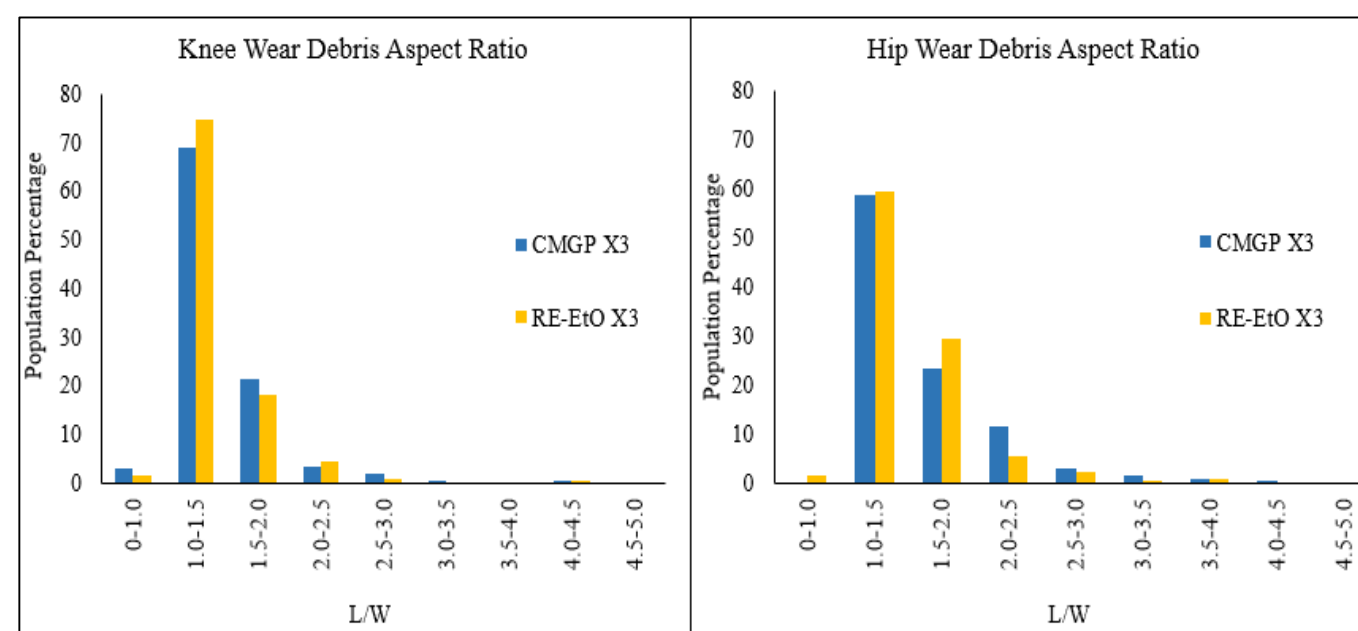
	Knee (X3)		Hip (X3)	
	RE-EtO	CM-GP	RE-EtO	CM-GP
Average Length (μm)	0.19 +/- 0.12	0.15 +/- 0.09	0.13 +/- 0.06	0.11 +/- 0.05
Average Width (μm)	0.14 +/- 0.07	0.11 +/- 0.06	0.09 +/- 0.03	0.07 +/- 0.03
Average ECD (μm)	0.18 +/- 0.10	0.14 +/- 0.08	0.12 +/- 0.05	0.10 +/- 0.04

No significant difference in average length, average width, or average ECD between RE-EtO X3 and CM-GP X3 groups.

Scanning Electron Microscope (SEM) image depicting similar morphology in knee and hip wear debris



Aspect ratio distribution for knee wear debris (left) and hip wear debris (right)



DISCUSSION

- Results showed no significant difference in wear debris morphology for X3 material, regardless of consolidation and sterilization methods.
- X3 RE with EtO sterilization did not have a significant effect on the wear debris morphology of the inserts when compared to X3 CM with GP sterilization regardless of device.

Austin, TX
February 2-5, 2019

ORS
Orthopaedic Research Society

Poster # 1011
Stryker # X3-POS-13_19617