Effect of Chlorine Dioxide Terminal Sterilization on the Mechanical and Chemical Properties of UHMWPE Used in Total Joint Arthroplasty

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INTRODUCTION: Ultra high molecular weight polyethylene (UHMWPE) is the predominant bearing material used in modern total joint arthroplasty, where the stability of its mechanical properties post-sterilization is key in ensuring the long-term integrity of the implant. Currently, the main methods of sterilization within industry are radiation-energy based (i.e. gamma irradiation) or gas-sterilization based (i.e. ethylene oxide or gas plasma). With the growing need to replace ethylene oxide (EtO) with a more environmentally friendly and accessible sterilization method, chlorine dioxide gas sterilization has emerged as an alternative, low temperature, sterilant that may be a viable alternative [1]. This study provides an assessment of the impact that chlorine dioxide gas sterilization has on the mechanical properties of UHMWPE, pre- and post-sterilization.

METHODS: Two groups of medical-grade UHMWPE (GUR1020), one representing virgin ram extruded material (VIR) and one representing 90 kGy sequentially crosslinked and annealed ram extruded material (SXL), were assessed for mechanical and chemical stability at a non-sterilized (0X), one-time sterilized (1X), and two-time sterilized (2X) level. The material was machined into 1.5" thick preforms, packaged in an air-permeable pouch, and sterilized using a validated chlorine dioxide gas sterilization process. All three sterilization levels were assessed using the material tests and associated properties measured as listed in Table 1. Statistical hypothesis testing was performed using a one-way ANOVA test with α=0.05.

RESULTS: The results from material testing of all study groups are summarized in Table 2. There were no statistically significant differences between the levels of sterilization within the same group, per a one-way ANOVA test.

DISCUSSION: The results demonstrate that chlorine dioxide gas terminal sterilization has no statistically significant impact on the material properties of UHMWPE when compared to its non-sterilized version. While an increase in ultimate tensile strength and a decrease in work to failure were observed in both groups, the results were not statistically significant; additionally, any change in properties as a function of increasing sterilization cycle beyond two times would be beyond the scope of terminal sterilization for orthopedic devices, which are normally only sterilized with one cycle. Future studies on this sterilization technique may be performed to determine long term impact of the sterilization technique on the material, such as an expanded materials characterization including an accelerated aging study.

SIGNIFICANCE: This study shows that chlorine dioxide gas terminal sterilization is a potential viable alternative sterilization solution for UHMWPE that does not impact the baseline mechanical performance or chemical stability of the material.

REFERENCES:
[1] U.S. Food and Drug Administration. *Sterilization for Medical Devices*. 2025.

IMAGES AND TABLES:

Table 1. List of Materials Tests Performed with Associated Standard Procedures and Properties Measured

Test	Standard	Properties Measured
Tensile	ASTM D638	Elongation at Break (EoB) Ultimate Tensile Strength (UTS) Yield Strength (YS)
Izod	ASTM F648-A1	Izod Impact Strength (Izod)
FTIR	ASTM F2102 ASTM F2381	Oxidation Index (OI) Trans-Vinyl Index (TVI)
DSC	ASTM F2625	Surface Crystallinity ($X_{surface}$) Bulk Crystallinity (X_{bulk})
Crosslink Density	Based on Test Methods: ASTM D2765 ASTM F2214	Gravimetric Crosslink Density (XLD)
Small Punch	ASTM F2977	Ultimate Load (Ult Load) Ultimate Displacement (Ult Disp) Work to Failure (WtF)

Table 2. Summary of the Results of Testing, Average ± Standard Deviation

Group	EoB (%)	UTS (MPa)	YS (MPa)	Izod (kJ/m^2)	OI (n.u.)	TVI (n.u.)	$X_{surface}$ (%)	X_{bulk} (%)	XLD (mol/dm^3)	Ult Load (N)	Ult Disp (mm)	WtF (mJ)
VIR-0X	414 ± 14	62.2 ± 4.0	23.8 ± 0.1	154.1 ± 5.6	0.03 ± 0.1	n/a	54.6	56.2	n/a	60.2 ± 1.5	4.8 ± 0.0	250 ± 6
VIR-1X	430 ± 23	64.9 ± 6.3	23.8 ± 0.2	151.0 ± 2.4	0.03 ± 0.1	n/a	55.8	56.9	n/a	62.2 ± 3.1	4.8 ± 0.0	255 ± 8
VIR-2X	425 ± 25	65.6 ± 7.8	23.6 ± 0.2	153.6 ± 3.7	0.02 ± 0.1	n/a	54.8	55.5	n/a	60.7 ± 1.8	4.7 ± 0.1	243 ± 7
SXL-0X	255 ± 10	56.0 ± 3.8	24.6 ± 0.1	65.5 ± 0.7	0.05 ± 0.1	0.03	57.2	56.7	0.13	107.5 ± 2.4	5.1 ± 0.1	355 ± 15
SXL-1X	264 ± 15	57.4 ± 5.3	24.3 ± 0.2	66.6 ± 1.3	0.03 ± 0.0	0.03	57.0	57.1	0.15	104.5 ± 3.6	5.1 ± 0.3	337 ± 33
SXL-2X	266 ± 19	58.9 ± 5.8	24.4 ± 0.1	61.4 ± 1.1	0.05 ± 0.1	0.03	57.3	57.9	0.13	102.9 ± 4.8	4.7 ± 0.3	314 ± 32

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