Influence of Sterilization on Laser Sintered Polyamide Materials

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Disclosures: Sina Trik, Martin Bullemer, Monika Gessler, Laura J. Gilmour (Employees of EOS GmbH or EOS North America)

INTRODUCTION: The purpose of this study was to characterize the impact of Ethylene Oxide (EtO)-, Gamma-, and steam sterilization on laser sintered (EOS P395/6) polyamide 11 and 12 materials (EOS PA1101 and EOS PA2200). These materials are commonly used to create 3D printed patient specific cutting guides for orthopedic total knee, ankle or shoulder surgery. The hygienic requirements of these products include cleaning and sterilization post-processing steps. During post processing, the materials are exposed to physical, chemical and thermal stresses which can affect the ageing process. This study characterizes the effect of sterilization on mechanical tensile properties, density measurements and size accuracy of a laser sintered part.

METHODS: Flat tensile bars were created out of each material in two build space orientations: z-direction (vertical orientation in the build space) and xy-direction (horizontal orientation to the building space). Specimens were created to allow four groups for each material in the following sterilization conditions: as built, no sterilization (control), steam, EtO and gamma ray sterilization. All samples were built with a 50:50 virgin to recycled powder mix, at a layer thickness of 0.12mm. Sintering temperature was 175.5°C or 185°C for EOS PA2200 and EOS PA1101 respectively according to the manufacturer's specifications. Post processing included glass bead blasting at pressure of 3.9barr. Steam sterilization samples were cleaned and disinfected prior to sterilization up to a temperature of 85°C. The autoclave pressure/temperature process followed the manufacturer's recommendation (SHP LAV25). The entire process of cleaning, disinfection and sterilization was performed once, as is indicated for single use medical products, as well as a worst case condition of three cycles. One-cycle EtO sterilization time was 12 hrs., with 10 min. at 38°C and 69% humidity under vacuum, followed by gas concentration of 325-400 mg/L at 38°C. The final group was exposed to one-cycle of gamma ray sterilization as indicated for single-use medical devices at a maximum ray dose of 50kGy. Mechanical testing was conducted according to DIN EN ISO 527.

RESULTS SECTION: Elongation at break and tensile strength, size accuracy and density were reported for each group as compared to the control. Results are shown in Figures 1 and 2. The density results showed EOS PA1101 and 2200 remained steady at $\rho=1.00 g/cm^3$ and $0.79 g/cm^3$ respectively.

DISCUSSION: Mechanical properties of EOS PA1101 and 2200 were similar between as built and sterilized material. Size accuracy and density measurements did not change for any sterilization method indicating that the accuracy of the as built patient specific guide would be identical to the serialized guide. This is important for the inspection timing of a patient specific guide, since sterilization is often done as the last step of the process. It was also noted steam and EtO sterilization had no influence on the white color of the material, while gamma radiation discolored the EOS PA1101 and 2200 material slightly green and grey respectively.

SIGNIFICANCE/CLINICAL RELEVANCE: As more applications for laser based 3D printing are introduced to the medical field, it is important to understand the effect common methods of sterilization have on materials used for patient specific cutting guides.

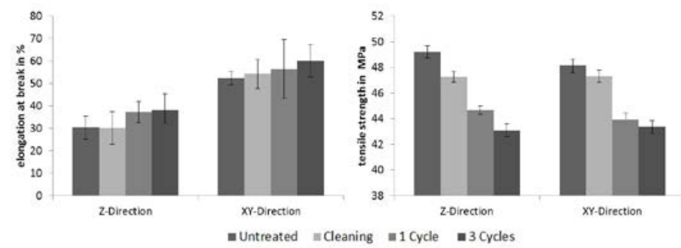

Figure 1a: Steam sterilization mechanical properteis EOS PA1101

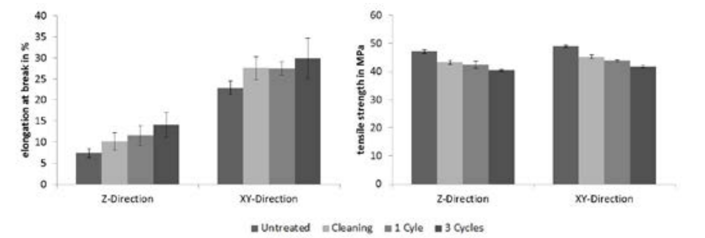

Figure 2a: Steam sterilization mechanical properteis EOS PA2200

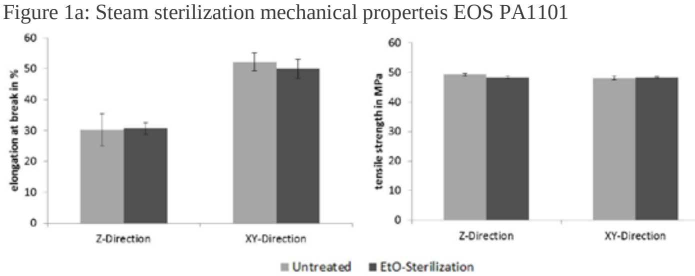

Figure 1b: EtO mechanical properties of EOS PA 1101

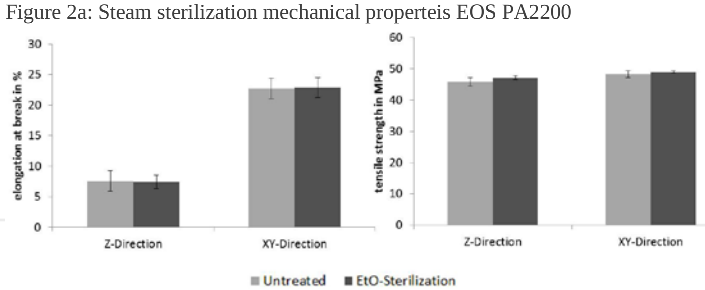

Figure 2b: EtO mechanical properties of EOS PA 2200

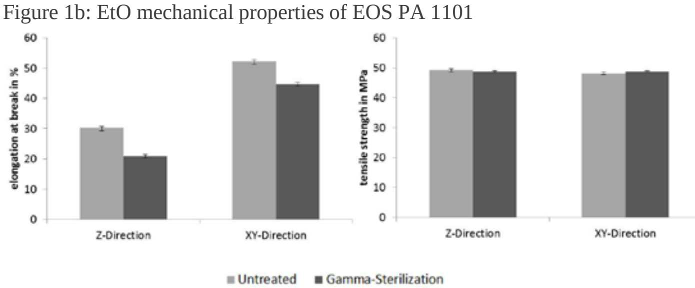

Figure 1c: Gamma sterilization mechanical properties of EOS PA1101

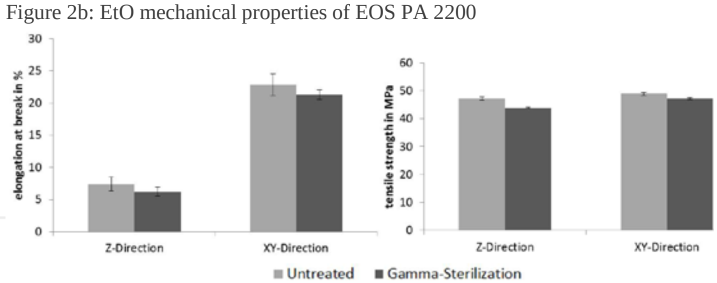

Figure 2c: Gamma sterilization mechanical properties of EOS PA2200