Impact of Sterilization Techniques on Polymer-Coated Silicon for Renal Replacement Applications

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Background:
Silicon nanopore membranes, functionalized with hemocompatible polymer-based coatings, show promise as a filter for an implantable renal replacement system. However, there is a paucity of information regarding how sterilization, necessary for clinical application, affects these membranes and their function. We aim to characterize the effects of five standard sterilization modalities on coated substrates.

Methods:
Solid 1 x 1cm silicon chips were coated with polyethylene glycol (PEG) or poly-sulfobetaine methacrylate (pSBMA) and then exposed to one of five sterilization modalities (autoclave, dry heat (160 °C for 120 minutes), ethylene oxide (EtO), hydrogen peroxide (Sterrad®) and x-ray). Uncoated and non-sterilized membranes served as controls. The surface coatings were analyzed by contact angle, x-ray photoelectron spectroscopy (XPS), ellipsometry and ELISA for albumin adsorption.

Results:
After sterilization the presence of PEG and pSBMA was confirmed by contact angle and XPS. Autoclave was the only technique that caused a significant decrease in the thickness of the PEG layer (Δ0.327nm, $p = 0.0013$). For pSBMA, each sterilization technique caused a significant decrease in thickness except EtO. X-ray resulted in the largest decrease in pSBMA thickness (Δ3.192nm, $p = 0.019$). Moreover, compared to non-sterilized substrates, x-ray had the largest increase in albumin adsorption, particularly for pSBMA-coated silicon (+12.86%, $p = 0.0018$).

Conclusions:
Sterilization of coated silicon wafers alters their surface chemistry and likely their biocompatibility. While in most cases the alterations appear to be relatively equivalent without major differences, x-ray, particularly of pSBMA-coated membranes, appears to be least favorable as it had the largest effect on protein adsorption and polymer thickness. Understanding the impact of sterilization on silicon substrates is essential to ensuring efficacy and hemocompatibility of implantable renal replacement systems.