White Paper

Summary of BioPoly® RS Material Stability Testing

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Background: BioPoly® RS material is a microcomposite of crosslinked hyaluronan (HA) and UHMWPE. During the manufacturing process, HA is incorporated into UHMWPE and subsequently crosslinked in situ, creating the raw material for BioPoly®. Implants are direct compression molded from this material so that the final state is fully consolidated BioPoly®. Since both UHMWPE and crosslinked HA can be susceptible to degradation over time when implanted in the body, the stability of this material was tested. Material stability was determined through serial exposure to oxidative (accelerated aging), enzymatic (concentrated hyaluronidase), and material (fatigue) degradative mechanisms. These mechanisms, which are present concurrently in vivo were performed sequentially to simulate these conditions, and the effects were assessed in order to evaluate implant material stability.

Methods: BioPoly® RS and UHMWPE implants were made according to validated manufacturing processes and designated for use as test samples to characterize the stability of the BioPoly® RS material. All specimens were EO sterilized prior to testing. Baseline material testing was completed to assess material properties of control samples and the remaining test samples were exposed to accelerated aging conditions in an oxygen bomb for 14 days, soaked in a concentrated hyaluronidase enzyme solution for 14 days, and subjected to compressive fatigue for 10 million cycles. Final material testing was completed to compare the mechanical, material, and implant functional properties of the test samples to baseline control samples.

Results: Material testing showed that even after being subjected to accelerated aging and enzyme degradation, the BioPoly® material had retained its hydrophilic properties as measured by contact angle. As expected, the results also indicate that BioPoly® is significantly more hydrophilic than UHMWPE. The locking mechanism that secures the BioPoly® material on a titanium stem was also tested and the results indicate that the implant locking mechanism greatly exceeded the required acceptance criteria after being exposed to the severe testing conditions. Additionally, material strength was measured, and there were no significant differences observed between the baseline and post-stability test groups.

Conclusions: The testing showed that the BioPoly® RS material is stable and is not detrimentally affected by subjecting implants consecutively to the severe conditions of oxidative degradation (accelerated aging), enzymatic degradation (hyaluronidase), and mechanical fatigue (physiologic compressive).