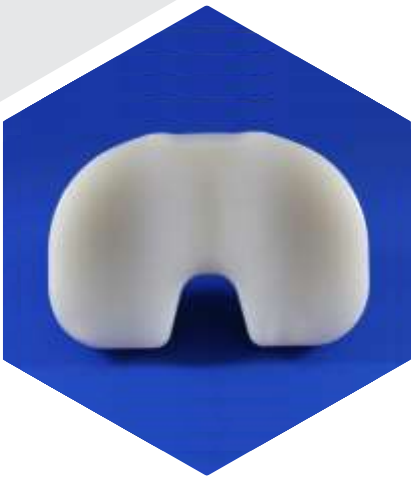
Cambridge Polymer Group



Highly Crosslinked UHMWPE for Hip & Knee Arthroplasties

Biomedical Material Development

Summary

In the mid 1990s, crosslinking ultra high molecular weight polyethylene (UHWMPE) by gamma irradiation was recognized to improve wear behavior when used in articulating joints such as hips and knees. A downside of radiation is the production of free radicals that can lead to oxidation. A discovery by Cambridge Polymer Group researchers and a scientist at Massachusetts General Hospital led to the development of a new processing method for highly crosslinked UHMWPE that utilized mechanical deformation to reduce free radical concentration.

This case study outlines the testing that demonstrated the efficacy of this technique. The test material was designated "CIMA," an acronym for Cold Irradiation Mechanical Annealing. Formulations were also prepared with added Vitamin E, an antioxidant, with the resulting material termed "eCIMA."

Experimental

CIMA and eCIMA were prepared by irradiating the samples with gamma radiation to specified doses > 50 kGy, and compressing the samples to targeted compression ratios, followed by thermal recovery at temperatures below the melting point of the UHMWPE.

The following analytical tests were conducted:

- Differential scanning calorimetry per **ASTM D2625**
- Tensile testing per **ASTM F648/D638**
- Swell ratio testing per **ASTM F2214**
- Pin-on-disk wear testing
- Oxidation index testing per **ASTM F2102** (after accelerated aging per **ASTM F2003** and after infusion in lipid and oxygen pressure aging)

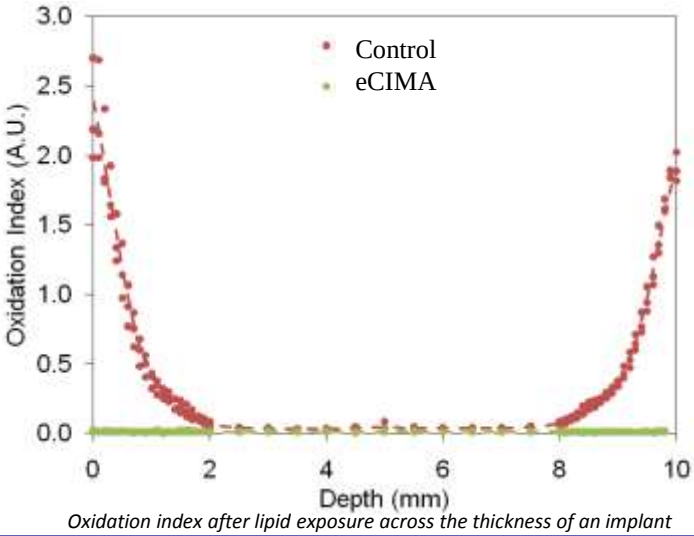
Test results were compared to irradiated and melted UHMWPE (Control), a technique used in first generation highly crosslinked UHMWPE.

Discussion

The eCIMA material showed a 10% increase in crystallinity vs. the control, which resulted in higher tensile strength while also showing a higher elongation at break. The swell ratio was comparable to the control showing the same amount of crosslinking, which was corroborated by the wear testing, which showed that the eCIMA material had the same wear rate as the control, which was 6-10 times lower than conventional UHMWPE. Lastly, the eCIMA showed very good oxidation stability when challenged with high pressure oxygen, elevated temperatures, and lipid oxidative challenges, exceeding the control by at least a factor of 5 in a screening test.

Analysis

These results demonstrated that the CIMA process is an effective technique for creating highly crosslinked UHMWPE showing good wear behavior, good mechanical properties, and good oxidation resistance, particularly when coupled with Vitamin E. Since this initial benchtop testing was performed, this patented material has been used successfully in the clinical field for several years in total hip and knee arthroplasty. The successful clinical results show the benefit of benchtop testing during development.



Oxidation index after lipid exposure across the thickness of an implant

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- Develop new materials
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- Create and execute experimental design
- Validate and verify manufacturing processes
- Perform root-cause analysis in product failures

Cambridge Polymer Group, Inc. was founded in 1996 to provide a cost-effective resource for testing, research and development to clients who need periodic access to Ph.D.-level scientists and their support structure. We have developed a host of testing methods and materials for our clients, which number more than 1,000.

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