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CORR Insights®: Spectroscopic and Chromatographic Quantification of an Antioxidant-stabilized Ultrahigh-molecular-weight Polyethylene

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Where Are We Now?

Current implant technology primarily uses radiation-sterilized, pure ultrahigh-molecular-weight polyethylene (UHMWPE). This

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material, while more resistant to particle formation, in time, can still suffer from oxidation, leading to important changes in its material properties and potentially leading to increased wear and early failure. Oral and colleagues [1] documented a major improvement in oxidative resistance arising from blending vitamin E with the powder prior to polymerization. This approach increases oxidative resistance, but it can affect material properties depending on dose and synthesis technique. Biomet (Warsaw, IN, USA) was the first to market implants using vitamin E in the United States. The antioxidants, however, create a tradeoff with crosslink density that has to be compensated for with increased radiation dose, which can affect the immediate wear properties. The use of antioxidants, if safe, is likely to benefit patients through

increased lifespan of their implant components by preventing oxidation. Given the relative success of vitamin E, few other antioxidants have been evaluated for their effect on UHMWPE.

Where Do We Need To Go?

Vitamin E (α -tocopherol) has been reviewed and found to be safe in most in vitro testing. Patients with α -tocopherol allergy, however, might be sensitive to implants with this chemical doped in the powder. Systemic exposure and elution of vitamin E from these components appears to be low, although published in vitro reports do not cover the time frame of expected use (15–30 years). Other antioxidants may also improve the resistance of the material without affecting crosslink density or requiring additional radiation for crosslinking. Research in this field may prove challenging. Accelerated aging and testing provide good guesses as to material performance, but relative benefits from

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different antioxidant strategies might not be perceived for a decade or more depending on the eventual elution or inactivation of the dopants. Finally, the development of intellectual property in the United States surrounding the doping of orthopaedic implants with vitamin E means that this technology will be prevented from widespread market adoption for the immediate future. If other antioxidants can have beneficial effects on component lifespans, their development should be encouraged.

How Do We Get There?

Developing new materials for orthopaedic implants is a risky business. Expectations of these devices are high.

With patients living longer and healthier lives, an implant may need to function for 30 years or more without degradation of properties. Anticipating that type of behavior with in vitro and in vivo studies of limited duration is a significant engineering and scientific challenge. Studies like this one are a good first step at assessing toxicological and mechanical properties of potential dopants. They are a logical stepping-stone before moving into animal and wear studies with candidate materials. While there are undeniable patient benefits to improving oxidative resistance of orthopaedic materials, animal and in vitro wear data should be gathered prior to eventual human evaluation. There is a fine line between developing a new product and risking a patient's long-term outcome with unproven technology. For novel

antioxidants, there will be particular importance associated with clearly communicating the effects on immediate wear, long term oxidation, and overall implant performance to the orthopaedic community; these properties can be complex and interrelated. If the marketplace matures to provide more choices, it may be difficult for clinicians to make informed decisions in regards to nuanced performance differences between different antioxidant additives.

Reference

1. Oral E, Wannomae KK, Hawkins N, Harris WH, Muratoglu OK. α -Tocopherol-doped irradiated UHMWPE for high fatigue resistance and low wear. *Biomaterials*. 2004;25:5515–5522.