MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY

Next-Generation Stabilization: Improving Joint Implant Efficacy and Durability

Using hindered amine light stabilizer has long-term benefits for implants.

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For years, metal-on-metal (MoM) bearings had been used for many orthopaedic joint reconstruction implants, particularly for total hip arthroplasty, which is one of the most common orthopaedic procedures. But new concerns about the biologic consequences of metal ion release from these bearings have emerged and are forcing the industry to explore alternative materials and technologies for this popular procedure.

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New Concerns for an Old Technology

In MoM hip implants, the friction that occurs between the metal head (femoral ball) and the acetabular liner (socket in the pelvis) creates wear debris. It occurs in all articulating joint implants. There is belief that metal ions cause various health issues and lead to elevated metal levels in the blood.

The wear particles generated by MoM hips go down in size to the nanometer scale. Due to their small particle size, the debris are more easily digested by cells, bound to proteins, and/or dissolved into body fluids. The metal implants can contain chromium and cobalt, to which many people are sensitive. Elevated chromium and cobalt levels have been seen in the testing of patient's serum and urine.[1] Total health effects remain inconclusive, but concerns persist.

While many of the biologic concerns associated with MoM hips have been evident for decades, high-profile MoM device failures have increased the pressures on industry and the medical community to find material alternatives that will offer the stability and longevity of MoM without the risks associated with ion generation. As a result, the future of MoM technology is unclear. Certain companies are already voluntarily pulling MoM from the market.

The most common alternative to MoM is metal on UHMWPE (ultrahigh molecular weight polyethylene), commonly referred to as metal on poly. The majority of hip implants are already made of metal on UHMWPE. It is expected that the decline in use and availability of MoM implants makes metal on polyethylene a natural alternative.

Improving on a Popular Poly Innovation

UHMWPE is a well-known biomaterial. With more than 40 years of clinical history in joint replacement devices, the material has excellent mechanical properties (toughness, fracture resistance and low coefficient of friction) and excellent biocompatibility. The very long entangled molecules and the low coefficient of friction gives the material good wear properties, making it long lasting as a bearing material. In addition, when crosslinked, the wear resistance is significantly improved.

Crosslinking is a process in which the UHMWPE is subjected to high levels of ionizing radiation such as gamma or E-beam radiation. Free radicals formed during irradiation initiate molecular combination reactions, resulting in longer molecules in a fixed network, which further improves the wear resistance. A material subjected to a radiation level of greater than 50 kilogray (kGy) is generally considered to be highly crosslinked. Gamma irradiation is commonly used to sterilize medical devices, but the dosage for sterilization is much lower.

Crosslinked UHMWPE is an improvement to joint reconstruction devices. The most obvious benefit lies in the significantly improved wear resistance measured on highly crosslinked UHMWPE. On average, a highly crosslinked poly device will have about nine times lower wear versus a noncrosslinked device. However, this difference comes at a cost, as the material loses fatigue and impact strength and will have residual free radicals present in the polymer. The wear resistance of the UHMWPE is directly related to the dosage level, meaning that the higher the gamma dose, the greater the wear resistance. However, the negative impact on the mechanical properties and concentration of residual radicals of the UHMWPE is also greater.

The residual radicals in the UHMWPE are a concern, because they can cause oxidation and premature aging of the material. Oxidation is a problem for UHMWPE materials because it destabilizes the polymer and can cause it to weaken over time, reducing the implant lifetime.

Fighting Oxidation

Stabilization technology can prevent or reduce the oxidation of UHMWPE and thereby protect the polymer for longer lifetime usage. Currently available stabilizing solutions include the blending of vitamin E into UHMWPE and soaking UHMWPE in a vitamin E solution. Vitamin E is a natural antioxidant and an effective free radical scavenger. It is a safe biocompatible additive, but it has also been observed to interfere with the crosslink efficiency of the UHMWPE polymer. The greater the concentration of vitamin E, the more it reduces the crosslink efficiency. This point is critical, because the crosslink efficiency is directly related to the wear properties of the UHMWPE. As vitamin E interferes with crosslinking, it reduces the crosslinking capability of the UHMWPE and thereby reduces the wear performance. In effect, there becomes a tradeoff between wear performance and oxidative stability using this technology.

Another stabilization method is thermal process treatment. This involves heating the polymer after crosslinking to remove residual free radicals. There are two approaches to thermal processing—remelting and annealing. Remelting involves heating the polymer above its melt transition temperature. This process quenches remaining free radicals, but also has a negative effect on the polymer by reducing the yield strength and ultimate strength of the polymer. Also, the fatigue strength is reduced significantly after remelting. Annealing is a heat treatment below the melt transition temperature. This process will not negatively affect the mechanical properties of the polymer, but it also will not remove all remaining free radicals.

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HALS Technology—Next Generation Stabilization

A new and effective stabilization technology makes use of a hindered amine light stabilizer (HALS). HALS is a known stabilizer in polymers for its long-term stabilization benefits in polymers that will be exposed to UV radiation. HALS can be blended into a solvent solution and then easily blended into the resin of the UHMWPE. The UHMWPE is then compression molded into bulk forms and machined into devices. The HALS stabilizer remains in very low part concentrations (parts per million) in the UHMWPE but yet has shown to be highly effective in stabilization.

HALS technology has the potential to transform the manufacturing of medical devices, and improve the safety, durability and cost efficiency of joint implants. It is an improvement over other stabilization methods because it does not interfere with the crosslinking efficiency or alter the mechanical properties of the UHMWPE.[2] As a result, device manufacturers do not need to change their manufacturing processes. In addition, HALS does not alter the color of the UHMWPE device. Vitamin E has a natural yellowish color and after processing will darken to a brownish-yellow, which has the appearance of something that is being oxidized.

In addition, HALS stabilizer regenerates itself. After scavenging a radical, it can turn back into the nitroxide form, which is again a radical scavenger. HALS is therefore not consumed like a phenolic stabilizer, such as vitamin E. A lower concentration can be applied since the technology has a longer stabilization lifetime than vitamin E. HALS technology can be applied to total hip, knee, shoulder, and ankle implants, or any application in which stabilization of UHMWPE is needed.

Conclusion

Stabilization is the next key development in UHMWPEs for joint replacement devices. HALS is poised to become the new standard because it stabilizes at least as effectively as vitamin E, does not interfere with the crosslink efficiency, is easy to process into UHMWPE, eliminates the need for thermal treatment, and saves costs.

Longer lasting implants should translate into cost savings to the healthcare system by reducing the need for revision surgery (the replacement of a device when the implant wears out). In joint replacement, the cost of surgery, recovery, and care outweigh the cost of the implant. Therefore, reducing the number of revision surgeries in the future will have a significant positive effect on the healthcare system.

References

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