UHMW-PE IN JOINT RECONSTRUCTION

History

UHMW-PE [Ultra High Molecular Weight Polyethylene] has been used as bearing material in Orthopedic Joint Reconstruction since 1960s. The material has inherent properties like very high wear resistance, extremely high impact strength, excellent sliding properties and an outstanding resistance to chemicals. It is a biocompatible material resistant to all common sterilization processes.

Properties

As a polyethylene, UHMW-PE has a unique molecular structure. High volume Polyethylenes such as LDPE and LLDPE [Low Density Polyethylene and Linear Low Density Polyethylene, respectively] have linear chain architectures with a molecular weight of typically 50,000 g/mol. HDPE [High Density Polyethylene] is a linear polymer with a molecular weight of up to 200,000 g/mol. UHMW-PE surpasses the molecular weight of general purpose and high volume Polyethylenes by far: it has a molecular weight of 5,000,000 to 10,000,0000 g/mol according to the Margolies Equation used to characterize UHMW-PE.

In general, the higher the molecular weight, the higher the melt viscosity of the material and the higher the difficulty to process the material from its powdery origin as resin to

solid form, like plate or blocs which can be machined to Orthopedic Implant components like tibia inlay or acetabular cups.

In addition, with increased molecular weight the wear resistance of UHMW-PE increases. However, as a tradeoff the impact strength continues to decrease once the optimum of 5,000,000 g/mol is achieved.

All commercially available UHMW-PEs available today are based on two resins:

5,000,000 g/mol – Type 1 per ISO 5834
9,000,000 g/mol – Type 2 per ISO 5834

Note: UHMW-PE weights per Margolies Equation.

FIGURE 1: Implantable UHMW-PE [mol. weight of 5,000,000 and 9,000,000 g/mol] in Hip and Knee Joint Reconstruction Devices

ISO 5834 [and ASTM F648] are standards to characterize UHMW-PE and its properties for resin as well as molded shapes: Implants for surgery – Ultra-high-molecular-weight polyethylene.

These standards provide good normative references for physical properties of molded shapes [ISO 5834, part 2] as well as resin characteristics such as elongational stress, viscosity number, limits of contamination, ash and trace elements and particulate matter

[ISO 5834, part 1]. However, important details on e.g. agents being used or allowed in molding processes, heat treatments using Nitrogen or other Inert Processes, clean room conversion are not yet fully addressed or covered in these standards.

Process

Manufacturing methods to convert UHMW-PE from powder to solid state are compression molding and ram-extrusion. Today, the majority of Orthopedic Implant Manufacturers around the globe are using compression molded UHMW-PE due to performance and homogeneity, and this for both, cross-linked and standard UHMW-PE. The preference for compression molded material was supported by studies conducted in 1990s encouraged by Standardization Committees such as ASTM to improve the quality of biomaterials being used.

FIGURE 2: State-of-the-Art compression molding of UHMW-PE biomaterials in certified clean room.

Despite its good inherent wear resistance the performance of UHMW-PE has – until late 1990s – been deemed

the weak and limiting factor when used as bearing material in Orthopedic Implants.

This is when Orthopedic Companies and Converters began developing higher wear resistant UHMW-PE by means of using irradiation [such as e-beam or gamma irradiation] to cross-link UHMW-PE molecules. The cross-links lead to increased wear performance being initially proven in wear simulator testing in the 1990s. The tradeoff is some decrease in physical/mechanical properties as a result of chain scission also induced by the irradiation process being used to cross-link UHMW-PE, in particular impact strength is reduced. Today, cross-linked UHMW-PE is well established and recognized for its markedly improved wear resistance supported by clinical study results in the last almost 15 years. The usage of cross-linked UHMW-PEs as bearing materials in hips in the U.S. is estimated to exceed 70 % – with many different formulations being used basically, differentiated by cross-linking doses or by secondary thermal treatment [e.g. anneal versus re-melt for free radial elimination]. With more clinical follow-up needed cross-linked UHMW-PEs – eventually being cross-linked at lower dose – are penetrating the use as material of choice for knees as well.

Performance and innovation

A critical factor for UHMW-PE allowing the material to be used in implants with a life time of 25 to 30 years and plus is oxidation. As a polyolefin, any polyethylene is susceptible to oxidation. This pertains to standard as well as to cross-linked UHMW-PE. In addition, the risk of oxidation increases with cross-linking due to free radicals generated in the material by the radiation treatment [in both, e-beam and gamma irradiation].

Base materials such as compression-molded UHMW-PE, e.g. heat treated under Nitrogen to prevent oxidation, are available today to minimize risk of oxidation. In addition, not just the post compression molded heat treatment to stress

relieve material, also the post irradiation heat treatments to eliminate/reduce free radical are offered to be performed under Nitrogen/Inert Atmosphere. These capabilities, however, are not (yet) mandatory per ISO or ASTM standards characterizing UHMW-PE.

The development focus of the last 3 to 5 years has been centered around oxidative stability of the UHMW-PE using antioxidant additives such as Vitamin E or inorganic antioxidants. Some products have meanwhile become commercially available and FDA cleared for PMA. The expectation is that antioxidant blended UHMW-PE in combination with cross-linking will be the "golden standard biomaterial" used as bearing in Joint Reconstruction for the next decades. In addition, even similar to UHMW-PE, materials with conversion and cross-linking advantages are being explored as future materials for flexibility as well as cost reasons – with promising performance indications.

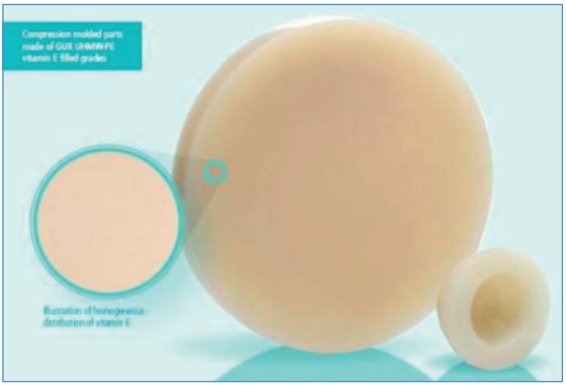

FIGURE 3: Antioxidant/Vitamin E blended UHMW-PE biomaterial for implants [source: Ticona – GUR® 1020 E medical grade UHMW-PE resin producer, incl. Vitamin E blended versions].

Partner

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