PPD Meditech Direct Compression Molded Polyethylene

Mechanical, Physical, and Tribological Properties and Clinical Performance

By

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BioVera LLC Technical Report

Title: PPD DCM UHMWPE – Mechanical, Physical, and Tribological Properties and Clinical Performance

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Executive Summary

The purpose of this report is to summarize publicly available information on the physical, mechanical, and tribological properties and clinical results for PPD-MediTech's direct compression molded (DCM) polyethylene and monoblock products. The information was gathered via literature searches of the worldwide web (www) and the web sites of several journals and professional societies. All relevant papers, book chapters, and abstracts were downloaded, printed, and reviewed.

PPD began direct compression molding GUR 1020 polyethylene for the orthopaedic industry in 1996. The first commercialized PPD-molded product was the Hedrocel Monoblock Acetabular Cup (Implex, 1997), which is currently marketed as the Zimmer Trabecular Metal Monoblock Cup. In late 1998, the Hedrocel Monoblock Tibia and Patella were commercialized by Implex. In 2002, Zimmer commercialized the NexGen CR and LPS Trabecular Metal Monoblock Tibial and Patellar implants. All monoblock products commercialized by Implex and Zimmer have been molded by PPD, packaged in nitrogen gas, and sterilized with 30 kGy of gamma radiation. Between 1998 and 2000, Implex researched, patented, and received FDA 510K clearance for cross-linked polyethylene products (60 kGy, 190F, N_2) using PPD's DCM GUR 1020.

The published mechanical and physical properties show that PPD's DCM GUR 1020 to meet or exceed ASTM and ISO standards for medical grade polyethylene. A review and comparison of this data shows PPD's DCM polyethylene to maintain higher ductility and lower crystallinity and density than ram-extruded and sheet-molded polyethylene materials subjected to 60 kGy of gamma radiation. This suggests (beneficial) maintenance of the amorphous phase of PPD-molded UHMWPE. Hip wear testing (ASTM F-1714, 28mm CoCr heads) showed PPD's DCM polyethylene (30 kGy in nitrogen) to wear at a linear rate of 0.032 mm/million cycles (18.3 mg, 20.3mm^3 per million cycles). When cross-linked at 60 kGy at 190^o F in nitrogen, the hip wear rate was 0.004 mm/million cycles (2.1 mg, 2.3mm^3 per million cycles). In comparison, identically processed (60 kGy, 190^o F) and wear tested Perplas (now Orthoplastics) molded GUR 1020 sheet wore at three times the rate of PPD's DCM GUR 1020 cups (6.6 versus 2.1

mg/million cycles). Hip wear simulation testing by Li et al showed cross-linked PPD DCM GUR 1020 to wear less than Stryker's Crossfire and DePuy's Marathon polyethylene materials. Li et al also showed PPD's standard (30 kGy, N_2) DCM GUR 1020 to have the lowest wear of all standard (single dose of gamma radiation, 30 kGy) materials, including Biomet's Arcom polyethylene. The wear rates measured for both standard and cross-linked PPD DCM cups were found to be substantially lower than the clinical threshold for osteolysis, which is considered to be 0.1 mm/year (million cycles).

The theoretical performance advantages of monoblock technology, defined here as direct compression molding of UHMWPE into a porous metal substrate (tibial base plate, patellar base, acetabular shell) were measured via mechanical and tribological testing and finite element analyses. This work showed the potential for backside polyethylene wear to be eliminated, more normalized load transfer to bone (reduced stress shielding), and enhanced mechanical stability (for the tibial implant). Since 2005, published clinical evidence has validated the theoretical advantages of monoblock technology and PPD's direct compression molded polyethylene. Five independent research groups have shown post-operative zone II polar gaps to reliably fill-in for the DCM monoblock cup, and the Mayo Clinic has shown maintenance of substantially higher bone density in all radiographic zones. For the monoblock tibia, two independent RSA studies have shown less medial-lateral lift-off and reliable biological fixation. These clinical findings were in part attributed to the advantages of monoblock technology.

The most remarkable finding of this work is the universally reported excellent clinical results with PPD's DCM GUR 1020 polyethylene. With nearly 12 years of clinical history and numerous published abstracts and papers, there are zero reported cases of osteolysis. In terms of survivorship, the DCM monoblock tibia and acetabular cup have 100% survivorship with the end points defined as revision for osteolysis and/or radiographic evidence of osteolysis. There is no other polyethylene product or implant system marketed in the history of orthopaedics that can make this claim after ten years of widespread, high-volume clinical use. This remarkable clinical record is the most reliable indicator of the high quality and wear-resistance of PPD's DCM GUR 1020 polyethylene, and supports its continued use in orthopedic total joint replacement products.