

Durability Testing of a Cementless Patella with a Chemically Crosslinked UHMWPE/Vitamin-E

Luis Alvarez¹(3A), Chris Gigliotti¹(3A), Zach Bryan¹(3A), Bo Gao¹(3A), Keith Wannomae²(3C), Orhun Muratoglu^{2,3}(1, 2, 3B, 4, 5, 7A)

¹Exactech, Inc., Gainesville, FL, ²Harris Orthopedics Laboratory, Massachusetts General Hospital, Boston, MA, ³Harvard Medical School, Department of Orthopedic Surgery, Boston, MA
Chris.Gigliotti@exac.com

INTRODUCTION: Cementless total knee arthroplasty continues to grow in popularity for patients who are younger and more active with the hope that long-term biological fixation may improve survivorship. Early generations of metal backed patella designs have demonstrated mixed results with failures attributed to separation of the UHMWPE from the metal backing, fracture of the metal backing, or complete wear-through of the bearing often times leading to metallosis [1-3]. Early catastrophic damage is also possible in cemented patellar components where the UHMWPE is often thicker and risk of articulation with the metal backing is not present [3,4]. This underscores the importance of designing cementless patellar components—often featuring a thinner UHMWPE layer than cemented all-polyethylene versions—in a way that maximizes the durability of the UHMWPE bearing. Chemical crosslinking UHMWPE with peroxides has demonstrated attractive properties of damage and wear resistance in previous studies [5,6]. Additionally, chemical crosslinking is particularly well suited for applications requiring UHMWPE over-molding, as it produces a highly crosslinked material during the molding process without the need for post-molding irradiation. This study aimed to compare the durability of GCPE metal-backed patella with one molded from chemically crosslinked antioxidant UHMWPE (Activit-E™). We hypothesized that the Activit-E material would demonstrate superior durability compared to GCPE.

METHODS: Two groups of additively manufactured patella metal backs of identical design were over-molded with GUR 1020 UHMWPE and Activit-E UHMWPE by a single manufacturer. Activit-E samples underwent customary high temperature melting subsequent to the molding process as previously described [7]. The GCPE samples were nitrogen flushed and vacuum packaged followed by gamma sterilization while the Activit-E samples were gamma sterilized under vacuum. All samples were aged for two weeks according to ASTM F2003 [8]. A simplified version of ISO 14243-5 described by Bryan et al. was used to compare durability of the patellar designs using an unrolled femoral component to linearly reciprocate against the patellar samples under applied axial load. A peak force of 2610N was applied for 50k cycles. The peak force was calculated using the minimum BW of 870N from §8.4 of ISO 14243-5:2019(E) along with Formula 4 from the standard. The inclined bearing ML force method (Method Two) detailed in §7.8 of ISO 14243-5:2019(E) [9], was used to generate the mediolateral shear force. This method results in a 10±1% ML shear force occurring continuously throughout the entire cycle. Patellofemoral rotation was converted to linear translation by determining the relationship between distance along the unrolled femoral component fixture and tibiofemoral flexion angle described in ISO 14243-5:2019(E). The resulting linear translation was approximately 20mm. Images and 3D scans of the patellar samples were taken before and after testing to evaluate damage. After completion of testing, the UHMWPE bearings were separated from the metal backs and oxidation index measurements were taken through the thickness of the bearings to determine whether oxidation occurred on the metal-opposing side of the polyethylene bearing.

RESULTS: All tested samples were able to complete 50k cycles with varying damage patterns as described in Table 1. After the first 3 samples of each group the load was increased to 125% of the original peak load for both an Activit-E patella and GCPE followed by a sample of Activit-E run at 150% peak load. The Activit-E patella samples exhibited less damage than the GCPE samples in that they showed no evidence of articular surface breakup at any load while the GCPE samples exhibited delamination, subsurface cracking, and breakup of the articular surface at all tested loads. Example images are shown in Figure 1.

Specimen	Number of Cycles Completed	Damage Pattern			Breakup of the Articular Surface	Maximum Backside OI	Maximum Articular OI
		Plastic Deformation	Subsurface Cracking	Delamination			
2610N Peak Applied Force							
Activit-E 1, 2, 3	50,000	X				0.089	0.097
GCPE - 1	50,000	X		X		0.295	0.291
GCPE - 2	50,000	X	X	X	X		
GCPE - 3	50,000	X	X		X		
3262.5N Peak Applied Force							
Activit-E - 4	50,000	X	X				
GCPE - 4	50,000	X	X	X	X		
3915 Peak Applied Force							
Activit-E - 5	50,000	X	X				

Table 1: Damage patterns observed for each sample at the given peak load.

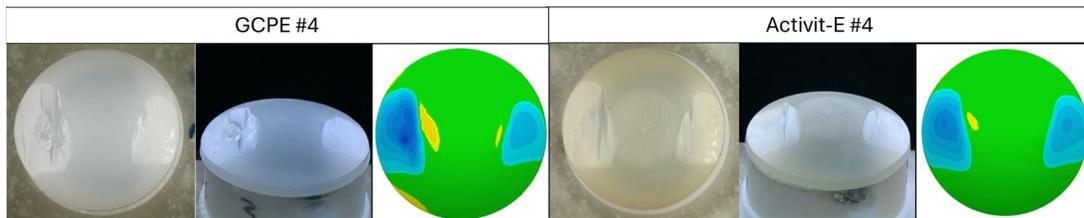


Figure 1: Damage patterns observed after testing.

DISCUSSION: The Activit-E samples demonstrated less damage as compared to conventional polyethylene samples. Oxidation index measurements indicate no appreciable oxidation in the Activit-E samples with relatively symmetric oxidation index profiles for the conventional samples when comparing the articular surface to the backside. This indicates the metal substrate may not fully prevent oxidation from occurring where the UHMWPE attaches to the metal backing. While the highly crosslinked nature of the Activit-E reduced the observed damage relative to the conventional samples, the addition of an antioxidant appears important to reduce oxidation on both the articular surface as well as the back side of the UHMWPE where attachment strength to the metal substrate is of critical importance.

SIGNIFICANCE/CLINICAL RELEVANCE: Peroxide crosslinked, vitamin-E stabilized UHMWPE shows enhanced durability and is a promising material for over-molding in cementless patellar components used in knee replacements.

REFERENCES: 1. Gustke et al. JOA, 2023 38(6). 2. Chan et al. JOA, 2017 32(8). 3. Joufflas et al. J Arthroplasty, 2023 38(6S). 4. Derr et al. J Arthroplasty, 2023 38 (5). 5. Alvarez et al. ORS 2024 no. 0893. 6. Schipper et al. Foot and Ankle Orth., 2024 9(4). 7. Alvarez et al. ORS 2024, no. 2433. 8. ASTM F2003-02 (2022). 9. ISO 14243-5: 2019(E)