Clinical, Wear and Oxidative Performance of Long-Term Duration™ Polyethylene Acetabular Retrievals

Medel, F.J.[1]; Mateo, J.[2]; Canales, V.[3]; Panisello, J.J.[2]; Piñol, M.[4]; Gómez, J.[5]; Martín, C.[2]; Peleato, P.[6]
[1]Dpt. Mechanical Engineering, University of Zaragoza-ICMA (Spain)
[2]Deparment of Orthopaedic Surgery and Traumatology. Miguel Servet University Hospital (Zaragoza; Spain)
[3]Deparment of Orthopaedic Surgery and Traumatology. Royo Villanova Hospital (Zaragoza; Spain)
[4]Department of Organic Chemistry. University of Zaragoza-ICMA (Spain)
[5]Deparment of Orthopaedic Surgery and Traumatology. Lozano Blesa Clinic University Hospital (Zaragoza; Spain)
[6]Deparment of Orthopaedic Surgery and Traumatology. Hospital of Barbastro (Huesca; Spain)
fjmedel@unizar.es

Introduction: Duration™ Stabilized Polyethylene (Stryker Howmedica) has been the precursor of modern highly crosslinked polyethylenes in total hip joint arthroplasty [1]. Duration™ Polyethylene was subjected to gamma sterilization in low-oxygen blisters and post-irradiation annealing to promote crosslinking and free radical recombination [1-2]. Thus, Duration™ components were anticipated to exhibit enhanced oxidative stability and increased crosslink density -and therefore superior wear resistance- than historical, gamma-irradiated in air, components. Previous studies have reported lower *in vitro* and radiographic wear rates for Duration™ acetabular inserts [3-4]. However, it is unclear whether the wear reduction, with its potential benefit to bone stock, and the oxidative stability of Duration™ are maintained after long-term implantation. Our objective was to assess the clinical, wear and oxidative performance of Duration™ polyethylene acetabular inserts retrieved after long-term implantation.

Methods and Materials: As part of our multicenter retrieval program, 12 Anatomique Benoist Girard (ABG; Stryker Howmedica) polyethylene acetabular liners were collected after revision surgery (4 historical, ABG I, and 8 Duration™, ABG II, polyethylene). The cementless, hydroxyapatite coated, ABG hip prosthesis was one of the first systems to evolve from a historical to a moderately crosslinked (Duration™) polyethylene component [1, 3-7]. Clinical information was available for both patient cohorts, including implantation times, patient demographics, revision reason and the incidence of osteolysis. All the acetabular retrievals were clean and photodocumented. Loaded (superior) and unloaded (inferior) regions of the polyethylene liners were identified by visual inspection. The thicknesses of both superior and inferior regions were mapped using a digital point micrometer (resolution 0.001 mm). Femoral head penetration was computed as the difference between the average inferior and superior thicknesses. FTIR oxidation analysis was carried out on polyethylene sections (150-200 microns thick) microtomed from the retrieved acetabular inserts. To avoid the interference of absorbed lipids, polyethylene sections underwent heptane extraction (6 hours) prior to oxidation assessment. Maximum oxidation indexes were calculated per ASTM F2102 at the rim, bearing and backside of the acetabular liners. Additionally, crystallinity contents were computed from infrared spectra to evaluate changes in microstructure triggered by oxidative chain scission. Crystallinity percentages were obtained applying the following formula:

$$\%C = \frac{\frac{A_{1897}}{A_{1303}}}{\frac{A_{1897}}{A_{1303}} + 1}$$

where A_{1897} and A_{1303} represent the areas under the peaks centered at the corresponding absorption frequencies [8]. As a measure of the progression of recrystallization processes, a recrystallization percentage was defined as the difference between the crystallinity percentages at the most and least oxidized areas for the regions of interest.

Results: Historical, ABG I, polyethylene liners were implanted for an average of 18.2 (14.0 – 21.3) years, whereas Duration™, ABG II, polyethylene components were *in vivo* a mean of 12.3 (4.3 – 18.5) years. Reasons of revision of ABG I liners included polyethylene wear (n=1), pain (n=1), osteolysis (n=1), and loosening (n=1). In the case of retrieved ABG II acetabular inserts, loosening (n=3), pain (n=1), periprosthetic fracture (n=1), abscess (n=1), osteolysis (n=1) and polyethylene wear (n=1) motivated the revision surgery. Evidence of osteolysis was reported in three (n=3) of the patients implanted with historical ABG I acetabular liners and in five (n=5) of the patients implanted with Duration™ polyethylene components. All the historical polyethylene acetabular liners exhibited either rim damage or delamination near the loaded region of the insert. On the contrary, ABG II liners exhibited no sign of rim damage or delamination, except for one case. Historical ABG I polyethylene liners had higher femoral penetration (0.10 ± 0.05 mm/year) than Duration™ ABG II inserts (0.07 ± 0.06 mm/year). However, the difference in femoral penetration was not statistically significant (p=0.35; Student´s t-test). Oxidation results confirmed higher average maxima indexes for historical polyethylene in rim and bearing regions (Figure 1), although these differences were not statistically significant, except for the bearing inferior region (p=0,0013). Nevertheless, some Duration™ acetabular retrievals exhibited high oxidation (OI > 3) at the rim near loaded areas and generally

increasing oxidation with implantation time (Figure 2). According to our FTIR crystallinity data, historical retrievals exhibited higher average crystallinity maxima in all regions. Likewise, recrystallization percentages were also higher in historical polyethylene retrievals (Table 1)

Discussion: Lower femoral penetration and the general absence of rim and delamination damage suggest Duration™ polyethylene inserts achieved superior wear resistance than historical components even in the long-term. However, this difference in wear performance was not significant as the power of our dataset was 14% and the least significant number of samples was 51. In addition, reasons of revision and the lower incidence of osteolysis in patients implanted with the Duration™ (ABG II) acetabular inserts also point out the deleterious effects of polyethylene wear were mitigated to some extent. Regarding oxidation, historical and Duration™ polyethylenes appear to have a similar behavior, as no significant differences were found in maxima FTIR oxidation indexes, except for the bearing inferior region. These findings suggest the post-irradiation annealing was not effective in providing Duration™ polyethylene liners with improved oxidative stability compared to historical components. However, FTIR crystallity data indicate that recrystallization processes were dominant in historical, but not in Duration™ retrievals, even taking into account the difference in implantation time. The annealing strategy was also believed to promote additional crosslinking in Duration™ polyethylene, which could hinder microstructure rearrangements triggered by oxidation. Overall, Duration™ components appear to succeed as far as wear-related properties are concerned, but its success is limited regarding oxidative stability and oxidation-induced microstructure changes.

Acknowledgements: This study was funded by University of Zaragoza (Project JIUZ-2014-TEC-10) and Diputación General de Aragón (Project T40-Grupo Consolidado de Investigación en Biomateriales). We thank José Alberto Villuendas (Stryker Iberia) for his support to the retrieval program and María Povar and Encarna Sánchez for their technical assistance.

References:

[1] Manley M. *Highly Cross-Linked and Annealed UHMWPE.* In: *UHMWPE Biomaterials Handbook (Third Edition)*
[2] Sun et al. *Non-oxidizing polymeric material.* United States Patent No.: 6,174,934 B1. Jan 16, 2001.
[3] Geerdink et al. *Acta Orthopaedica* (2006) 77 (5): 719–725.
[4] Geerdink et al. *Clin Orthop Relat Res* (2009) 467:979–984.
[5] Gallo et al. *International Orthopaedics (SICOT)* 2010; 34:19–26.
[6] Herrera et al. *The Journal of Arthroplasty* 2013; 28: 1160-1166.
[7] Herrera et al. *BioMed Res Int* 2015; Art. ID 386461: 1-13.
[8] Medel, Rimnac and Kurtz. *J Biomed Mater Res* 2009; 89A: 530–538.

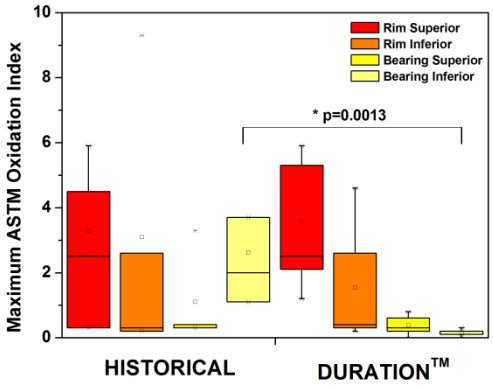

Figure 1. Maximum ASTM oxidation indices of historical and Duration™ polyethylene retrievals

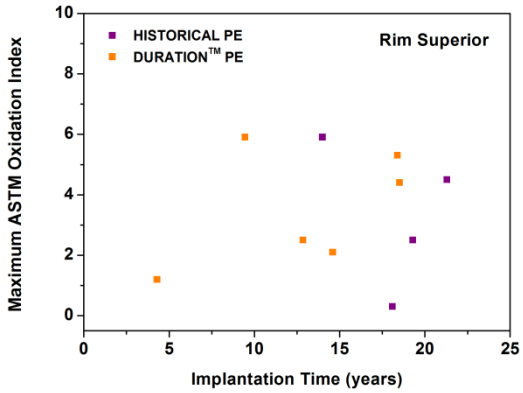

Figure 2. Evolution of oxidation with implantation time for acetabular polyethylene retrievals.

RECRYSTALLIZATION (%)				
	Rim Superior	**Rim Inferior**	**Bearing Superior**	**Bearing Inferior**
Historical	10,4 ± 6,8	18,3 ± 11,0	16,7 ± 9,7	6,7 ± 4,7
Duration™	6,0 ± 8,1	7,0 ± 7,5	7,0 ± 9,0	4,5 ± 5,9

Table 1. Recrystallization percentages in retrieved historical and Duration™ polyethylene acetabular liners.