The Effect of 2nd Generation Barrier Packaging on Polyethylene for Total Disc Replacement

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Introduction: Previous studies have shown that the ultra-high molecular weight polyethylene (UHMWPE) used in total disc replacement (TDR) will oxidize during shelf storage and following implantation for components gamma sterilized in air and in first-generation barrier packaging. Specifically, the areas that readily have access to bodily fluids and tissues (i.e. the rim of the Charité TDR) oxidize more than regions that are shielded, such as the domed regions of the core. Prior to 1997, gamma sterilization in air was used for the Charité TDR. After 1997, first-generation, polymeric barrier package was used to prevent oxidation on the shelf; however, this packaging was found to be permeable to air. DePuy Spine (Raynham, MA) currently produces the Charité TDR and the polyethylene is now gamma sterilized in an impermeable metal foil-based package. However, the extent of oxidation in UHMWPE TDRs sterilized in this manner remains poorly understood.

Methods and Materials: We analyzed the oxidation, oxidation potential, and dome penetration of 58 Charité UHMWPE cores. 54/58 cores were implanted for 7.4y (Range: 1.8–16.3y). Four never implanted cores (3 Link and 1 DePuy) were removed from their original packaging and used as controls. In addition to pain and facet arthrosis, the retrieved TDRs were revised for migration (n=3), lateral subluxation (n=1), osteolysis (n=1), and/or subsidence (n=12). 15/54 (28%) were implanted before 1997, and therefore were gamma sterilized in air. 6/54 (11%) were identified as Link components that were gamma sterilized in first generation polymeric packaging (Inert 1). 5/54 (9%) were identified as DePuy Spine components and were therefore gamma sterilized in an impermeable metal foil-based package (Inert 2). We could not trace the sterilization method in 28/54 retrievals by Link.

Dome penetration was measured directly using a micrometer (accuracy: 0.001 mm). A penetration rate was calculated by dividing the dome penetration by the implantation time. To assess oxidation, 200 µm slices were taken from the domed regions that are shielded, such as the domed regions of the core. Prior to 1997, gamma sterilization in air was used for the Charité TDR. After 1997, first-generation, polymeric barrier package was used to prevent oxidation on the shelf; however, this packaging was found to be permeable to air. DePuy Spine (Raynham, MA) currently produces the Charité TDR and the polyethylene is now gamma sterilized in an impermeable metal foil-based package. However, the extent of oxidation in UHMWPE TDRs sterilized in this manner remains poorly understood.

Figure 1: Regional oxidation for UHMWPE Charité cores.

Figure 2: Regional oxidation potential for UHMWPE Charité cores.

Figure 3: Dome penetration rate is negatively correlated with implantation time.

Results: The first-generation polymeric packaging cores exhibited dome and rim oxidation of magnitudes similar to cores that were gamma sterilized in air (p ≥ 0.2; ANOVA with Student’s T-test, Figure 1). The cores in metal foil based packaging had lower oxidation than both the gamma air group and the first generation group at both the dome (p ≤ 0.03) and the rim (p ≤ 0.001). The rim was more oxidized than the dome in the gamma air (mean OI difference = 3.8; p < 0.0001) and first generation cores (mean OI difference = 3.3; p = 0.03). The foil-based packaging cores, however, had similar oxidation values at the dome and rim (mean OI difference = 0.2; p = 0.3). The foil-based packaging had lower hydroperoxide values at both the dome and rim than the gamma air and first generation cores (p < 0.01; ANOVA with Student’s T-test, Figure 2). The hydroperoxide index was elevated at the rim compared to the dome in all groups (p ≤ 0.03). Dome penetration was similar across all groups (p = 0.8; Wilcoxon Test). Dome penetration rate was negatively correlated with implantation time (Spearman’s Rho = -0.58, p < 0.0001, Figure 3) but not dome oxidation or hydroperoxide content (p > 0.24).

Discussion: To the authors’ knowledge this is the first study comparing historical, 1st, and 2nd generation barrier packaging for polyethylene of the same TDR design. Our data support the hypothesis that oxidation is greater in the historical and first generation packaging, than for the metal foil-based packaging. The metal foil-based packaging had lower OI and HI than both the aforementioned sterilization methods. This is consistent with other types joint replacement where the efficacy of barrier packaging varies by method. While oxidation remained low at both the dome and rim for the foil-based cores, this group was also only implanted for 2.7 years, on average. It remains to be seen how in vivo oxidation will progress after more substantial implantation times.

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References: