Performance of Hylamer-M in Revision Total Knee Arthroplasty

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Introduction: Manufacturers have been modifying polyethylene in order to reduce wear and to increase implant longevity. Hylamer-M (DePuy, Warsaw, IN), an enhanced polyethylene with increased crystallinity, was developed for total knee arthroplasty in the early 1990s. The only reports in the literature concerning this product have been case reports of early failure due to significant osteolysis in the primary total knee replacements [1, 2]. In this study, we reviewed a series of patients who underwent revision knee arthroplasty surgery utilizing Hylamer-M polyethylene inserts and assessed the damage on retrieved components.

Methods: From 1994 to 2003 one hundred and twenty-one patients underwent revision total knee arthroplasty with implantation of a Coordinate® prosthesis and Hylamer-M® polyethylene insert (posterior-stabilized design, DePuy, Warsaw, IN). The Coordinate prosthesis comprises a polished cobalt chromium tibial base plate and a polished cobalt-chromium femoral component. Mean time to revision for the retrieved implants was 24 months. The sterilization technique for the retrievals at time of manufacturing was either gamma-in-air (2.5-4MRad) or gas-plasma.

There were 72 females and 49 males. The mean age at the time of surgery was 72 years (range, 42.6 - 89.1 years). The mean follow-up was 8.6 years (range, 3 - 13 years). The primary indications for revision knee surgery were aseptic loosening (n = 33), wear (n = 32), instability (n = 25), sepsis (n = 23), osteolysis (n = 3), periprosthetic fracture (n = 3), implant fracture (n = 2). All patients undergoing revision surgery for sepsis underwent a two-stage procedure.

The bearing surfaces (articular, post, and backside) of the seven retrieved Hylamer-M inserts were analyzed for evidence of surface damage [3]. A modified Hood-method was utilized [4] to report a damage score (DS). In this system the percentage damage, in ten percent intervals, is converted to a number from 0 to 10, with maximum damage scoring of 10. Each damage feature (burnishing, grooving, indentations, deformation, pitting, delamination, striations and stippling) was identified and the percentage of the surface area damaged in this manner was assigned a value using the grading system. Retrieved tibial inserts were graded under 10 - 40X magnification using a stereo light microscope (SZ-40, Olympus, Tokyo, Japan). Scanning electron microscopy (SEM) (JOEL 3400; Hitachi, Japan) was used to clarify articular surface damage that could not be categorized as pitting. Statistical analysis of all data was performed using the SPSS 14.0 (Chicago, IL) computer software package. Survivorship analysis was calculated using the Kaplan-Meier technique using revision surgery for any cause as an end point. Analysis of variance coupled with the Fisher's protected least-square-difference test post-hoc method (ANOVA and Fisher`s) was used to compare groups.

Results: Kaplan-Meier cumulative survival, using revision surgery as an endpoint, was 78.9% at 13 years (CI ± 19.44). Twelve knees have subsequently been re-revised at intervals ranging from 3 months to 10 years post-operatively, mean 19 months. Indication for further revision was instability (n = 7), recurrent sepsis (n = 4) and a loose femoral component (n = 1). No further revisions have been performed for wear or osteolysis.

The mean DS`s were 9.27 (range, 0 - 27), 3.29 (range, 0 - 14) and 5.82 (range, 0 - 23) for the articulating, post and backside surfaces respectively. The articular surface DS was significantly higher than post and backside DS ($p \leq 0.009$; ANOVA and Fisher`s). There was no difference between the amount of grooving and pitting damage observed ($p = 0.127$; ANOVA and Fisher`s). A characteristic surface pit under SEM revealed a granular surface feature inside the pit and detached fibrils around the pits periphery on gamma-in-air sterilized inserts, indicating a fatigue related wear mechanism. Pitting observed on gas-plasma sterilized inserts were identified as indentations due to third-body interactions, indicating an abrasion related wear mechanism. Delamination and cracking were not observed on the articulation, post or backside surface of the gas-plasma sterilized inserts.

Discussion: The inferior wear performance of gamma-in-air sterilized Hylamer-M was not surprising. However, damage features such as delamination and pitting due to surface fatigue were not observed on retrievals subjected to gas-plasma sterilization. These findings, therefore, suggest that the in-vivo wear performance of such Hylamer-M components may be comparable to conventional inertly treated polyethylene. Previous reports on Hylamer-M, outlining its potential for increased wear rates and early failure have been related to primary total knee arthroplasty with non-polished titanium tibial base plates [1, 2]. The revision rate in the present study was 10%, and survival was 79% at 10 years. Our results with Hylamer-M show comparable survival rates to conventional polyethylene reported in the literature for revision TKA [5, 6].

Conclusion: Patients with gamma-in-air sterilized Hylamer-M in their revision components should routinely be examined for severe wear and instability. Gas-plasma sterilization appeared to eliminate fatigue-related damage features on Hylamer-M, suggesting it to be a "safe" bearing material in the present revision component.

References: [1] Ahn et al, J Arthroplasty 2001;16(1):136-9; [2] Ries et al, J Arthroplasty 1996;11(8):974-976; [3] Gabriel et al, The Knee 1998;5:221-228; [4] Brandt et al, Combined ORS, 2004 2004:243; [5] Haleem et al, CORR 2004(428):35-9; [6] Gofton et al, CORR 2002(404):158-68.