MINIMUM FIVE YEAR OUTCOME AND WEAR ANALYSIS OF LARGE DIAMETER FEMORAL HEADS ON HIGHLY-CROSS-LINKED POLYETHYLENE LINERS

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Introduction:
The introduction of highly cross-linked polyethylene in total hip replacement to minimize the occurrence of peri-prosthetic osteolysis secondary to wear debris also allowed the return to the use of larger diameter femoral heads. The added advantage to the use of larger diameter femoral heads is that they afford an increased range of motion, decreased implant impingement, and protection against dislocation. The specific aim of this clinical study is to perform a detailed follow-up and outcome study on a sub-group of patients who are at or around their 5 year follow-up anniversary. This represents the longest-term follow-up available of highly cross-linked polyethylene used with this revised concept of using a femoral head couple with larger diameters than have been used in the recent past. Our hypothesis was that total hip reconstructions with a femoral head 36mm or larger paired with XLPE would show acceptable clinical and radiographic results at a minimum of 5 years follow-up.

Methods:
Using our institutional registry, we prospectively followed a cohort of 124 patients (132 THAs) who had undergone primary THA with a 36-mm-millimeter or larger cobalt-chrome femoral head and either Durasul or Longevity liners (Zimmer; Warsaw, IN). After institutional review board approval was obtained, patients were prospectively enrolled in the current investigation. At a minimum 5-year follow-up, 13 THAs (12 patients) were excluded from the study because their liners were removed. Of these, 3 patients (3 THAs) had been revised for deep infection, 2 patients (2 THAs) had been revised for chronic instability, 1 patient (1 THA) had been revised due to a peri-prosthetic fracture, and 7 liners (6 patients) were removed due to a loose acetabular shell. In these 7 THAs, the acetabular components were revised due to an implant recall by the manufacturers, unrelated to the polyethylene. In addition, 15 patients (15 THAs) were deceased and 10 patients (11 THAs) were lost to follow-up. While the follow-up process is ongoing, the current, cohort consisted of 93 THAs (88 patients) who fit the inclusion criteria and had a hip history and/or questionnaire scores, and/or 5 year x-rays taken. This included 34 women and 59 men with an average age of 65.9 years (33-89 years). All patients had placement of a cementless titanium acetabular shell with fiber mesh coating (Trilogy, Zimmer Inc, Warsaw IN) or screw augmentation (Triology, Zimmer Inc, Warsaw, IN) with or without screw augmentation based on surgeon preference. The acetabular components had a median outer diameter measuring 56 mm (50-66). All THAs had placement of an electron beam ram extruded highly cross-linked polyethylene liner, with an inner diameter of 36 mm (Longevity, Zimmer Inc, Warsaw IN) or another formulation of electron beam ram extruded highly cross-linked polyethylene liner, with an inner diameter of 38 mm (DuraSul, formerly Centerpulse, Zimmer Inc, Warsaw, IN) of 36 and 38mm. These polyethylenes were manufactured using 10 Mrad and 9.5 Mrad irradiation respectively for cross-linking and subsequently re-melted to eliminate the resulting free radicals. Amongst the patients who had x-rays at a minimum of 5 years post primary THA, the median follow-up was 5.6 years (range 5.0-8.0). At latest follow-up, patients were assessed radiographically and clinically including Harris Hip score, UCLA activity score, EQ-5D, and SF-36 functional scores. Radiographic evaluation of femoral head penetration was performed using the Martell Hip Analysis Suite semi-automated digital measurement system.

Results:
Evaluation of radiographs showed no cases of osteolysis in either the pelvis or proximal femur. No acetabular cups or femoral stems failed due to aseptic loosening. Four patients have questionable signs of bone changes around the acetabular shell. These patients' radiographs will be independently reviewed by another physician and CT scans will be scheduled in order to reach a final determination. The median acetabular shell abduction and anteverision were 44 degrees (30-66 degrees) and 13 degrees (3-33 degrees) respectively for all THAs. There was no evidence of cup migration, screw breakage or eccentric wear on the liner. Regarding the femoral component, there were also no episodes of loosening, migration, osteolysis or fracture. The femoral head penetration rate into the electron beam XLPE was determined from the patients with acceptable radiographs. Currently, there are 24 patients with 36mm femoral heads, 4 with 38mm heads, and 2 with 40mm heads. There was no significant difference in the median total penetration rates between the 36 mm and 38 mm diameter femoral head groups, (0.056±0.10 and 0.060±0.05). Since there are currently only 2 patients in the 40mm head group, this group was not compared to the 36 and 38mm heads. Therefore the data of the two groups (36 and 38mm) were pooled into one large head group and treated as one population. The median total penetration rate for the large head group measured 0.05±0.09 mm/year. Figure 1 is a scatter plot of the penetration values measured from each radiograph compared to the initial post-operative radiograph. The penetration data was distributed around zero at all time periods. The slope of the linear regression line gave a total penetration rate which approximates zero, 0.003 mm/year, with an r² value of 0.0001, indicating that there was no correlation between the magnitude of femoral head penetration and time. The median femoral head penetration, which occurred during the first post-operative year, measured 0.59±1.04 mm/year. In contrast, the median steady state wear rate of the large head group, (occurring between the one year film and the longest follow-up), measured -0.009±0.15 mm/year. The steady state wear data was also distributed around zero at all time periods. The slope of the linear regression line gave a total steady state wear rate that approximates zero, -0.031 mm/year, with an r² value of 0.009, indicating that there was no correlation between the magnitude of polyethylene and time.

Figure 1 Scatter plot of the combined penetration data of the large head groups.
The patients who have currently submitted their outcome questionnaires (46 THAs) had a median HHS of 91.0 +/- 13.4; UCLA activity score of 6.0 +/- 1.9; SF-36 physical activity score of 48.8 +/- 11.3; SF-36 mental score of 57.8 +/- 8.1; and an EQ-5D score of 0.9 +/- 0.2. These scores are consistent with scores form patients with successful THR.

Conclusion:
The mid-term results on this prospective series of patients with THAs performed with a 36-millimeter or larger (36, 38, and 40mm) cobalt-chrome femoral head articulating with an electron beam XLPE showed excellent wear, clinical, and radiographic results. The use of larger diameter femoral heads is gaining more widespread acceptance both for patients who may be at increased risk for dislocation as well as for general use in younger and active patients. Their use allows patients the functional range of motion afforded to patients receiving large diameter metal on metal and surface replacements THA components.

The lack of early signs of osteolysis with the use of these large diameter femoral heads is encouraging. Continued and longer-term follow-up is needed to provide survivorship data.