MINIMUM THREE YEAR CLINICAL RESULTS WITH LARGE DIAMETER FEMORAL HEADS ON HIGHLY CROSS-LINKED POLYETHYLENE LINERS

++Orthopaedic Biomechanics and Biomaterials Lab, Massachusetts General Hospital Boston, MA 02114
ebragdon@partners.org

Introduction:
Osteolysis, secondary to polyethylene wear, is one of the major factors limiting the long-term success of total hip arthroplasty. Wear has historically dictated the use of femoral heads of 32 mm diameter or less. In the last 5 years, gamma sterilized in air and gamma sterilized in nitrogen UHMWPE have been supplanted in many centers by highly-cross-linked polyethylene (XLPE) and early laboratory and clinical studies have shown an even greater improvement in wear characteristics. This decrease in wear appears to be independent of head size with certain XLPE studied in vitro, whereas larger heads produce more wear when articulated with conventional UHMWPE. The added advantage of the use of larger diameter femoral heads is that they afford an increased range of motion, decreased implant impingement, and protection against dislocation. Although the alternate bearing surface options today are a marked improvement over conventional gamma sterilized ultra-high molecular weight polyethylene (UHMWPE), long-term clinical data on their performance is not yet available. The aim of this study was to perform a clinical and radiographic assessment of a group of patients receiving THRs with large diameter femoral heads using 36 mm, 38 mm or 40 mm femoral heads articulating against electron beam irradiated and melted highly-cross-linked polyethylene. Our hypothesis was that total hip reconstructions with a femoral head larger than 32 mm paired with XLPE would show acceptable clinical and radiographic results at a minimum of 3 years follow-up.

Methods:
Between March 2000 and March 2002, 76 primary THRs were performed on 71 patients with end stage degenerative joint disease of the hip. After institutional review board approval was obtained, patients were prospectively enrolled in the current investigation. Sixty-one hips (57 patients) fit the inclusion criteria. A total of 15 THRs (14 patients) were excluded from the study. Of those hips, the acetabular components were revised in 9 THRs due to an implant recall by the manufacturers, unrelated to the polyethylene, 1 THR was revised for sepsis, 1 for a femoral peri-prosthetic fracture and 1 for recurrent dislocation. Three patients died before the minimum 3 year follow-up. The final cohort consisted of 45 THRs (42 patients) with adequate follow-up who fit the inclusion criteria. This included 22 women and 20 men with an average age of 62.5 years (28-86 years). All patients had placement of a cementless titanium acetabular shell with fiber mesh coating (Trilogy, Zimmer Inc, Warsaw IN or Inter-op, formerly Centerpulse Inc, Zimmer Inc, Warsaw IN) with or without screw augmentation based on surgeon preference. The acetabular components had a median outer diameter measuring 56 mm (50-64). All THRs had placement of an electron beam ram extruded highly-cross-linked polyethylene liner, with an inner diameter of 36 mm or 40 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). 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. Patients were followed for a minimum 3 years (range 3-4.2, median 3.2 years). At last follow-up, patients were assessed radiographically and clinically including Harris Hip score, UCLA activity score, Western Ontario and McMaster University Osteoarthritis Index (WOMAC) 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. The median acetabular shell abduction and anteversion were 46 degrees (29-67 degrees) and 22 degrees (1-60 degrees) respectively for all THRs. 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.

Conclusion:
The femoral head penetration rate into the electron beam XLPE was determined from the patients with acceptable radiographs. There was no significant difference in the median total penetration rates between the 36 mm, 38 mm, or 40 mm diameter femoral head groups, (-0.12±0.22, -0.08±0.26, and 0.11±0.20 mm/year, p>0.34). Therefore the data of the three groups were pooled into one large head group and treated as one population. The median total penetration rate for the large head group measured -0.10±0.23 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, -0.060 mm/year, with an r² value of 0.02, 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 0.24±1.25 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 -0.06±0.41 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 approaches zero, -0.043 mm/year, with an r² value of 0.03, 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 had a median HHS of 91.5, UCLA activity score of 6, SF-36 physical activity score of 44.9, and WOMAC physical activity score of 3.5.

52nd Annual Meeting of the Orthopaedic Research Society
Paper No: 0186