Minimum Ten Year Follow-Up of Highly Cross-linked Polyethylene Liners in Total Hip Arthroplasty
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Introduction:
Highly cross-linked polyethylene (HXLPE) has been introduced to decrease osteolysis secondary to polyethylene wear debris generation, thereby anticipating increasing long-term survivorship of the total hip arthroplasty (THA). The electron-beam irradiated cross-linked and melted polyethylene has been extensively evaluated in vitro. Muratoglu et al tested highly cross-linked polyethylene up to 27 million cycles using the Boston hip stimulator. That study documented both the reduction of secondary oxidation and improved wear of highly cross-linked polyethylene by gravimetric analysis compared with conventional polyethylene.

HXLPE is now one of the most widely utilized bearing surfaces for THA. The first patients to receive XLP were 10 years post-op as of December 31, 2008. This study, initiated at the time that the new highly cross-linked polyethylene was made clinically available, is the longest term clinical follow-up series on this material. After the initial introductory period, continued long-term follow-up and performance evaluation is needed. The purpose of this study is to report on the 10 year clinical and radiographic outcomes of the first group of patients implanted with one formulation of highly cross-linked polyethylene.

Methods:
An IRB approved cohort of three-hundred and twenty-two primary total hip replacements (299 patients) in which HXLPE liners (Longevity or Durasul, Zimmer Inc.) with either 22mm, 26mm, 28mm, or 32mm femoral heads will be ten years post-op as of January 2011. Currently, there are 29 patients (31 hips) with minimum 10 year radiographic follow-up. There were 13 females and 18 males with an average age of 55.4 years at surgery. Hips consisted of 28mm and 32mm head sizes. The clinical measures used to evaluate these were the Harris hip, EQ-5D, SF-36 functional scores, and UCLA activity scores. Of the 29 patients, 17 patients (17 hips) have minimum 10 year clinical follow-up. In addition to conventional plain radiograph assessment, the Martell method was used to measure head penetration over time.

The penetration rate was defined as the slope of the linear regression line of the plot of the femoral head penetration occurring between the initial post-operative film and each subsequent film. In order to separate the early bedding-in process and the true steady state wear rate, the slope of the linear regression line of the plot of the femoral head penetration occurring between the one year film and each subsequent film was determined. Statistical analysis was performed using the student’s t-test between head sizes in the HXLPE where significant differences were defined at p<0.05.

Results:
None of the HXLPE components showed radiographic loosening, failure or fracture. There were no osteolytic lesions around the cup or stem. Nor were any revisions performed for polyethylene wear or liner fracture. There were 21 hips with 28m head, and 10 hips with 32m heads. Clinical outcome scores were averaged: Harris Hip 82±0.3, EQ-5D 0.74±0.26, SF-36 physical activity scores 43±8.8, SF-36 mental score 54±2.8, and UCLA activity 6.4±2.6.

Femoral head penetration in the highly cross-linked polyethylene did not increase over time after the first year, nor did the scatter of the data increase with time (Figure 1). There was no significant difference in linear head penetration rates between the 28mm and 32mm femoral head sizes (23.3±34.0μm/year and 30.6±121.8μm/year respectively, p=0.80)

Figure 1. Steady state penetration of highly cross-linked polyethylene patients measured between one year and each follow-up radiograph.

Discussion:
Patients with highly cross-linked polyethylene continue to display no measureable wear at a 10 year follow-up. HXLPE with both 28mm and 32mm femoral head sizes had wear rates within the error detection of Hip Analysis Suite and were not significantly different than zero.

This long-term clinical and radiographic follow-up study of patients receiving primary THR using highly cross-linked polyethylene liners represents the largest series and longest follow-up period for this new bearing material. The clinical follow-up results are similar to what would be expected in a primary THR patient population. The radiographic results are excellent with no signs of peri-prosthetic osteolysis. The wear results continue to indicate very low wear in vivo with no signs of changes over time.

Significance: This is the longest term clinical report on the outcomes of THR patients receiving highly crosslinked polyethylene components.