

## **Evaluation of Vitamin E Diffused Highly Crosslinked Polyethylene Wear and Porous Titanium Coated Shell Stability: A Seven-Year Randomized Control Trial using Radiostereometric Analysis**

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**Introduction:** Vitamin-E diffused, highly-crosslinked polyethylene (VEPE) and porous titanium-coated (PTC) shells were introduced in total hip arthroplasty (THA) to reduce the risk of aseptic loosening. Radiostereometric analysis (RSA) is the gold-standard for the assessment of in vivo implant performance. The purpose of this study was to use RSA to: (1) evaluate the in vivo wear properties of VEPE, (2) assess the stability of PTC shells, and (3) report their clinical outcomes at 7-years.

**Methods:** Eighty-nine patients were enrolled into a prospective study. All patients received a PTC shell and were randomized to receive a VEPE liner (N=44) or a moderately-crosslinked polyethylene liner (ModXLPE) (N=45). RSA was used to measure polyethylene wear and cup migration. Differences in wear were assessed while adjusting for BMI, activity level, acetabular inclination, anteversion, and head size. Plain radiographs were assessed for radiolucency, and patient-reported outcome measures (PROMs) were administered at each follow-up.

**Results:** Seventy-three patients (82%) completed the 7-year visit. RSA quality metrics were excellent (mean condition number= $28 \pm 1$ , mean error= $0.19 \pm 0.01$  mm). Median 7-year linear penetration was  $-0.07 \pm 0.16$  mm and  $0.00 \pm 0.22$  mm for the VEPE and ModXL cohorts, respectively ( $p=0.116$ ). PROMs ( $p=0.310-0.807$ ) and radiolucency incidence ( $p=0.330$ ) were not different between the polyethylene cohorts. The average shell migration rate was  $0.04 \pm 0.09$  mm/yr. At 7-years, patients with radiolucency (34%) demonstrated greater migration (mean difference:  $0.6 \pm 0.2$  mm;  $p < 0.001$ ). Disease-specific PROMs were lower for patients with radiolucency and greater migration ( $p=0.009-0.045$ ). No implants appeared loose based on plain radiographic evaluation, and none were revised for aseptic loosening.

**Conclusions:** This is the first RCT to report 7-year RSA results for VEPE. All wear rates were below the previously-reported osteolysis threshold of 0.1 mm/yr. PTC shells demonstrated acceptable primary stability through 7 years as indicated by low migration and lack of failures due to aseptic loosening. Patients with acetabular radiolucency were associated with higher shell migration and lower PROMs.