Early Follow-up of a Long-term Registry-based Multicenter Total Hip Replacement Outcome Study: Vitamin E Doped Polyethylene Liner and Porous-Titanium Coated Acetabular Shells

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Introduction: The number of total joint arthroplasties (TJA) is increasing, necessitating an efficient method of evaluating patient outcomes and implant performance. Arthroplasty registries facilitate evidence-based quality monitoring and treatment enhancement by providing feedback to surgeons and implant manufacturers. Registries permit documentation, surveillance and evaluation of treatments, ensuring that inferior methods are eliminated. Implementation of a joint registry intends to reduce the incidence of revision procedures and improve patient outcomes. Consequentially the economic burden associated with revision surgery decreases, improving cost-effectiveness of TJA. Early clinical outcome through multicenter collaborations is important to document that there are no detrimental effects of new developments.

In vitro studies show that vitamin E doping of highly cross-linked polyethylene improves wear performance, retention of mechanical properties, and heightens resistance to oxidation due to the anti-oxidative properties of vitamin E. A porous titanium construct for biological fixation was developed for orthopedic use on acetabular shells. Long-term follow-up of these materials is important to ensure both early and late material performance in vivo. The purpose of this registry-based observational multicenter study is to prospectively monitor vitamin E doped polyethylene (VEPE) liners and porous titanium construct (PTC) acetabular shells compared to un-doped medium cross-linked polyethylene (XLPE) liners and plasma sprayed (PS) shells in patients.

Methods: Seventeen centers from the USA, Sweden, Denmark, Norway, UK, Spain, Mexico, and the Netherlands have recruited 977 patients into a prospective 10 year clinical and radiographic total hip replacement outcome study. Patients received either a PTC or PS shell (Regenerex or Ring-Loc, Biomet, respectively) with either a VEPE or XLPE liner (E1 or ArcomXL, Biomet, respectively). Patient demographics and surgical data were collected and stored via a web-based registry. Patients will be followed once preoperatively and at 6-10 weeks, 1, 3, 5, 7, and 10 years postoperatively. At each interval, 3 radiographs were obtained (anterior/posterior hip, anterior/posterior pelvis, and shoot-thru lateral), 5 surveys were completed (Harris hip score, case mix indicator, UCLA activity score, SF-36, and EQ-5D), and all data were added to the web-based registry. All postoperative complications and revisions were also collected via the web-based registry. Radiographs were measured for cup and stem position, as well as femoral head penetration into the liner, and to determine if any radiolucent lines were present at any of the postoperative intervals. The surveys over time monitor changes in the general and disease specific health and activity of the patients. Finally, complications and revisions are recorded throughout the study period.

Results: There have been 977 surgeries with a diagnosis of primary or secondary osteoarthritis. The average age at surgery was 62±9 years, 50% of the patients were male, and 90% were white. Eleven percent of the cases were done with an anterior approach, 32% with an anterolateral approach, and 56% with a posterolateral approach. There have been 15 dislocations in 11 patients and 13 revisions (4 for periprosthetic fracture, 1 septic revision, 6 for instability, and 2 for implant mismatch at the original surgery). Ten patients have died due to causes unrelated to the operation. The distribution of patients within the follow-up intervals is 2 at postop, 321 at 1 year, 572 at 3 years, and 82 at 5 years. There are 920 patients with postoperative AP pelvis films read for cup positioning where 60% have abduction within the 30° to 45° range, 73% have anteversion within the 5° to 25° range, and 45% of patients fall within both the abduction and anteversion windows (Figure 1). Wear analysis of AP pelvis films with Martell method from post-op to 3year showed a penetration rate at 0.01 mm/year for XLPE and a penetration rate of 0.003 mm/year for VEPE with no significant difference between them (p=0.43). Radiolucency readings around the shells showed a trend with minor non-continuous radioluencies at post-op in the PS shells, which disappeared by 3 years. The PTC shells tended to have an appearance of radioluencies at 1 year which diminished by 3 years. Regardless of the appearance of radioluencies, both cup types show stability through 3 years and into 5 years. Steady improvement was seen in all patient reported surveys
from the pre-to post-operative time periods at all centers ($p<0.0001$).

**Discussion:** Large scale multicenter registry studies permit analysis of rare complications, for which a local registry may not achieve sufficient statistical power. This study increased the rate of enrollment for this large cohort to assess specific components in a prospective manner while enabling the comparison of various surgical techniques and patient demographics. Our local registry model was expanded to a global model to facilitate this large scale 10 year monitoring study.

Short-term follow-up of these VEPE liners and PTC acetabular shells provide encouraging clinical and radiographic results with few intra- and post-operative complications despite the number of patients outside the ideal cup positioning window. The detected differences in the appearance of radiolucencies might be explained by the different levels of surface roughness in the shells. PTC shells have a rougher surface design which can cause soft tissue to adhere, and the inability to seat the shell on the bone across the hemisphere may be related to the appearance of radiolucencies. Surgical differences between centers also have to be taken into account as some centers ream the acetabulum line-to-line and others under-ream by 1 mm. Patient reported outcomes suggest improvement in physical function, activity, and health related quality of life across the centers after surgical treatment. While there do not appear to be any obvious early adverse effects from doping the liners with vitamin E or coating the cups with porous titanium, continued follow-up is required to determine if the use of these implants will result in less osteolysis and loosening.

**Significance:** This 17 center registry-based long-term clinical evaluation of vitamin E doped polyethylene liners and porous titanium coated acetabular shells in total hip replacement patients is highly effective in prospectively monitoring these new materials and patient outcomes. Early clinical and radiographic outcomes with both materials are encouraging.

**Acknowledgments:**

![Cup position for all 17 centers](image)

**References:**

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