7-Year Radiographic And Clinical Follow-Up Of Vitamin E-Diffused Polyethylene Liners In Total Hip Arthroplasty: Findings From A Prospective, International, Multicenter Study Of 977 Patients

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Background

The success of total hip arthroplasty (THA) with metal-on-polyethylene implants is due in part to crosslinked polyethylene (XLPE). While XLPE has shown negligible in vivo wear through 12 years, in vitro studies suggest its potential for long-term oxidation and embrittlement. As a result, a new generation of XLPE, infused with the antioxidant vitamin-E (VEPE), was introduced in 2007. VEPE was hypothesized to result in reduced liner wear, and eventually a lower rate of aseptic loosing. Radiostereometic analysis data of small patient cohorts have suggested favorable polyethylene wear of VEPE compared with XLPE, but larger studies to ensure that VEPE is safe and has expected clinical performance are lacking.

Objectives

To document the safety and non-inferiority of VEPE liners, this study compared acetabular liner wear and patient reported outcome measures (PROMs) between VEPE and XLPE liners in THA patients from a prospective, international, multicenter study with 7-year follow-up.

Study Design & Methods

A prospective, international, multicenter study was initiated in 2007. This study was

prospectively designed to investigate radiographic and clinical outcomes in VEPE and XLPE liners. 17 centers across 8 countries (USA, Mexico, Norway, Sweden, Denmark, the Netherlands, UK, and Spain) enrolled 977 patients. Patients received either a VEPE or XLPE liner. Centers were randomly assigned to implant combinations.
At each follow-up visit (preoperative, postoperative, 1-, 3-, 5-, 7-, and 10-years), the Harris Hip Score (HHS), a pain numerical rating scale (NRS), and a satisfaction NRS (0 = very satisfied; 10 = dissatisfied) were collected. Revisions were also recorded. PROM scores were compared using Mann-Whitney U tests at 1- and 7-years.
Anterior posterior hip radiographs were measured for femoral head penetration into the liner (liner wear) using the Martell Hip Analysis Suite software and previously defined methods.

Results

The proportion of eligible patients with data at each visit was: postoperative (94.3%); 1-year (85.5%); 3-year (82.2%); 5-year (80.9%); 7-year (75.4%).
Mean femoral head penetration into the liner through 7-years was statistically significantly lower for the VEPE group than for the XLPE group (-0.0079 vs 0.037 mm/year; $p = 0.0026$). There was no difference in mean HHS at the 1-year (VEPE: 90.3 vs XLPE: 89.1, $p = 0.163$), or 7-year visits (VEPE: 88.5 vs XLPE: 90.4, $p = 0.843$).
There was no difference in mean Pain NRS at the 1-year (VEPE: 1.11 vs XLPE: 1.01, $p = 0.902$), or 7-year visits (VEPE: 1.23 vs XLPE: 1.18, $p = 0.826$).
Both the VEPE and XLPE patients were highly satisfied in the result of their surgery at the 1-year (VEPE: 1.10 vs XLPE: 1.12, $p = 0.908$) and 7-year visits (VEPE: 1.31 vs XLPE: 1.04, $p = 0.680$).
At 7-year follow-up, none of the 977 hips were revised due to liner wear or failure.

Conclusions

This study is the first prospective, international, multicenter comparison of both radiographic and clinical 7-year outcomes between VEPE and XLPE liners, in which patients were randomized by center to liner type.
At 7-year follow-up, both VEPE and XLPE liners showed low liner wear; however, VEPE liners were found to have statistically significantly less liner wear. Nonetheless, PROM analyses indicated no statistically significant differences in hip function or pain between patients with either liner type.
We conclude that THA performed with VEPE liners is a safe treatment with non-inferior clinical outcomes. These findings are promising while we await studies documenting the proposed longer-term benefits of VEPE for reduced rates of revisions due to aseptic loosening.