#1059 - Clinical Study / Free Papers

Vitamin E diffused THA liners show no less head penetration after 5 years postoperatively compared to HXLPE in a randomized controlled trial

Orthopaedics / Pelvis, Hip & Femur / Joint Replacement - Primary

Kristian Kjærgaard[1], Ming Ding[1], Carsten Jensen[2], Charles Bragdon[3], Henrik Malchau[3], Christina M. Andreasen[4], Ole Ovesen[4], Christian Hofbauer[5], Søren Overgaard[4]

1. Orthopaedic Research Laboratory, Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Department of Clinical Research, University of Southern Denmark, Odense, Denmark
2. Institute of Regional Health Research, University of Southern Denmark, Odense, Denmark
3. Harris Orthopaedic Laboratory, Massachusetts General Hospital, Boston, United States
4. Orthopaedic Research Laboratory, Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Department of Clinical Research, University of Southern Denmark, Odense C, Denmark
5. Department of Orthopaedic Surgery, Vejle Hospital, Vejle, Denmark

Keywords: Hip, Vitamin E, RSA, Clinical Trial, E-Poly, Radiostereometric Analysis

Background
Total hip arthroplasty (THA) is a successful procedure to reduce pain and increase function and quality of life for the majority of patients who suffer from hip osteoarthritis. However, in the long term, failure due to aseptic loosening may occur. Aseptic loosening is associated with increased wear of polyethylene liners, and wear may be reduced by using oxidatively stabilised liners utilising vitamin E to achieve oxidative stability.

Objectives
Primary objective: To compare femoral head penetration into the liner between a) vitamin E diffused highly cross-linked polyethylene (vE-PE) THA liners and conventional highly cross-linked polyethylene (XLPE) liners and b) 32 mm and 36 mm femoral heads. Secondary objective: To compare cup migration between a) vE-PE and XLPE liners and b) 32 mm and 36 mm femoral heads. Exploratory objective: To compare change in patient-reported outcomes (PRO) between 32 mm and 36 mm femoral heads.

Study Design & Methods
This was a factorial clinical trial with 2×2 intervention groups. Patients with hip osteoarthritis were randomly assigned to receive vE-PE or XLPE liner with a femoral head size of 32 or 36 mm (4 combined intervention groups). Head penetration and cup migration were measured using radiostereometric analysis (RSA) at baseline, 3, 12, 24, and 60 months postoperatively. Patient-reported outcome measures (EQ-5D, Harris Hip Score, and UCLA Activity Score) were assessed at baseline, 3, 12, 36, and 60 months. Adverse events were assessed using a nation-wide registry. Powered as a parallel-group design, we aimed to include 100 patients. Outcomes were analysed using linear mixed method analyses.

Results
Of 220 screened patients, 126 were included in this study, 117 received allocated intervention, and 94

were still enrolled after 5 years.
Primary outcome: Head penetration was similar between liner materials and head sizes at 5 years, vE-PE versus XLPE -0.093 mm (95% CI: [-0.209, 0.023], p = 0.12), and 36 mm versus 32 mm 0.042 mm (95% CI: [-0.076; 0.159], p = 0.49), respectively.
Secondary outcome: No difference in cup migration at 5 years was found, vE-PE versus XLPE 0.059 mm (95% CI: [-0.262; 0.380], p = 0.72), and 32 mm versus 36 mm 0.042 mm (95% CI: [-0.283; 0.367], p = 0.80).
Exploratory outcome: No difference in patient-reported outcome measures was found.
Adverse events: No trial subjects received revision surgery during their trial participation.

Conclusions
No difference in head penetration was found from baseline to 5 years between vE-PE and XLPE liners, or between 32 and 36 mm heads.