INTRODUCTION: Previous studies have revealed that the annual wear rate in polyethylene articulations should be 0.1 mm or less to avoid future osteolysis. Highly Crosslinked polyethylene demonstrates 80-90% wear reduction in hip simulator testing, but the clinical documentation of this new polyethylene is still inadequate. In a previous radiostereometric study of a cemented cup we observed reduced penetration with the use of warm irradiated adiabatic melting (WIAM) polyethylene after 2 years. In this study we evaluated a highly cross-linked polyethylene used as insert in a porous and HA/TCP coated press-fit cup. Bilateral operations were done where one side was supplied with a highly cross-linked polyethylene liner and the other was provided with a conventionally gamma sterilized insert. Radiostereometric examinations were done up to 2 years after the operation.

METHODS: Thirty-one patients (11 male, 20 female) with bilateral primary or secondary arthrosis of the hip were studied (median age: 48 years: 29-70; weight: 75 kg: 51-97). All patients received bilateral hybrid THA (Spectron EF, Smith & Nephew; Trilogy, Zimmer Inc.). The Trilogy cups had 3 cluster holes for screw fixation and additional coating with a mixture of hydroxyapatite and tricalcium phosphate. The highly crosslinked PE was electron beam radiated to 10 Mrad at room temperature and melt-annealed at 150 degrees, sterilised by gas plasma. The conventional PE was compression moulded and sterilised by gamma irradiation (2.5 Mrad in Nitrogen). Twenty-eight mm cobalt-chromium heads were used. Surgery started on the most painful side, which was randomised to one of the two types of PE liner using closed envelopes. During the operation the surgeon inserted tantalum markers into the acetabulum and the liner on both sides. Radiostereometric examinations were done supine after 3-4 days, 3, 6 months, 1 and 2 years. The penetration of the femoral head center into the cup and the migration of the acetabulum and the liner on both sides. Radiostereometric examinations were done up to 2 years. The local ethical committee approved our study.

RESULTS: At present 42 hips in 21 patients have been evaluated with RSA up to 2 years. The mean (±S.E.) proximal penetration at 24 months was 0.08±0.01 mm for highly crosslinked PE and 0.21±0.02 mm for the conventional PE (p<0.001). During the second year the mean proximal penetration on the side with highly cross-linked PE was close to zero, whereas the control side showed a significant increase (crosslink/control:1±2 years p=0.002). The 3(D) total penetration at two years was 0.22±0.02mm and 0.32±0.03 mm respectively (p=0.01). The medial/lateral and anterior/posterior penetration was lower than 0.1 mm in both groups without significant differences (p>0.40). The medial/lateral, proximal/distal and anterior/posterior migration of the cup center and the rotations of the cup did not differ between the two types of PE (p>0.16) At 2 years the median Harris hip score was 100 for both hips.

DISCUSSION: In this study patients were operated bilaterally to reduce the influence of confounders. Previous studies have, however, suggested that the wear may differ between left and right sight in one and the same patient. Therefore randomisation was done to obtain an equal distribution study and control liners between the two sides. In both groups the proximal head penetration up to 1 year was about 0.1 mm probably reflecting plastic deformation and no true wear. The mechanical properties of highly cross-linked PE are different from those of conventional PE, but this difference did not have any influence on the early fixation of the cup. Our study could confirm previous studies indicating improved wear characteristics of highly crosslinked polyethylene in the clinical setting. The observation period is, however, short and our results cannot be directly transferred to other qualities of polyethylene processed to improve its wear resistance. We still recommend conservative use until a safety declaration can be issued for clinical routine praxis.

REFERENCES