Wear of highly cross-linked cemented polyethylene cups and EtO-sterilized ultra-high molecular weight cemented polyethylene cups with Oxinium® or CoCr femoral heads: A randomized study of 150 hips using radiostereometric analysis

INTRODUCTION:
Highly cross-linked polyethylene acetabular cups and Oxinium® femoral heads were developed as an approach to reduce wear debris induced osteolysis. Laboratory tests have shown less wear with these new materials. The present RSA-study was performed to compare these new materials in vivo with conventional bearing materials used in articulations in total hip arthroplasty.

METHODS:
150 patients with a mean age of 70 years were randomized, single-blinded, to 5 groups.
The patients received either a cemented Charnley monoblock stainless steel femoral stem with a 22.2 mm head or a cemented Spectron EF femoral stem with a 28 mm head. The Charnley femoral stem artculated with a cemented Charnley Ogee acetabular cup and was used as a reference. The Spectron EF femoral stem was used with either cemented Reflection All-Poly EtO-sterilized ultra-high molecular weight polyethylene (UHMWPE) acetabular cups or cemented Reflection highly cross-linked polyethylene (XLPE) acetabular cups, combined with either Cobalt Chrome or Oxinium 28 mm femoral heads. The surgical technique was standardized and eight orthopedic surgeons or residents undergoing training in orthopedic surgery at the Department of Orthopedic surgery, Haukeland University Hospital, performed the operations. To avoid the influence of surgeon on the results, block randomisation was used to ensure that each surgeon operated an equal number of patients in the 5 groups.
The patients were followed up with repeated radiostereometric analysis (RSA) and clinical examinations (Harris Hip Score) for two years to assess the rate of penetration of the femoral head into the cup (wear of the polyethylene cups) and the clinical outcome. Femoral head penetration was calculated from the RSA-measurements along the 3 cardinal axes of the body. The cup wear results are presented as maximum total point motion (MTPM), which is the vector sum of the femoral head penetration in the 3 cardinal directions.
We used the student t-test for for independent samples to compare the femoral head penetration between the 5 groups at 2 years. When comparing RSA penetration at 6 and 24 months and Harris Hip Score preoperatively and at 2 years postoperative we used paired t-tests. We performed analysis of variance to detect any differences in Harris Hip Score at 2 years. Differences were regarded as being statistically significant if the p-value was less than 0.05. The study was approved by the regional Ethical Committee and performed under informed consent.

RESULTS:
At 2 years follow-up the mean MTPM (95 % Confidence Interval) for Charnley Ogee (n=25) was 0.20 mm (0.11-0.29). For the Spectron EF femoral stem used with Reflection All-Poly UHMWPE acetabular cups the mean MTPM (CI) at 2 years was 0.40 mm (0.23-0.57) when combined with Cobalt Chrome femoral head (n=23) and 0.50 mm (0.29-0.71) when combined with Oxinium femoral head (n=16). When using the Spectron EF femoral stem with Reflection XLPE combined with Cobalt Chrome (n=27) or Oxinium (n=24) femoral head the mean MTPM (CI) at 2 years was 0.19 mm (0.10-0.28) and 0.18 mm (0.07-0.29), respectively.
There were no differences in penetration between the Charnley/Ogee, XLPE/CoCr and XLPE/Oxinium groups (p=0.5-0.8). There was no statistically significant difference between the two Reflection All-Poly UHMWPE groups (p=0.09).
However the groups with Reflection all-poly cups had a statistically significant higher penetration than the three groups mentioned above (p<0.001).

DISCUSSION:
We found no significant increase in wear of Charnley Ogee after the bedding in period. This is contradictory to previous studies. However wear in these studies was not measured using radiostereometric analysis, but with conventional and less precise methods. Furthermore, wear in these studies was calculated as a mean over several years. It is possible that wear rates of the Charnley Ogee cup will accelerate after some years because of roughening of the articulating surfaces or aging changes to the polyethylene.
The groups with Oxinium femoral heads did not have less wear than the groups with Cobalt Chrome heads after 2 years follow-up. The roughening of the femoral heads with time may, according to in vitro studies, have less adverse effects on wear properties of the Oxinium heads than the Cobalt Chrome heads. Further follow-up is needed to evaluate the benefits, if any, of Oxinium femoral heads in the clinical setting.

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