10 year outcomes of ceramic on ceramic bearing versus metal on polyethylene bearing: a randomised controlled trial in patients under 65 years undergoing total hip arthroplasty

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INTRODUCTION:

To compare the long term clinical and radiological outcomes of patients receiving a ceramic head on a ceramic bearing, as part of a hybrid total hip arthroplasty (THA) construct, compared to patients receiving a metal on polyethylene bearing as part of a fully cemented THA construct.

METHODS:

In this single centre trial for which ethical approval was received via the North and East Devon Regional Ethics Committee (04/Q2102/127), we randomly assigned 303 hips in 290 adult patients under the age of 65, undergoing unilateral or staged bilateral THA. 156 hips were randomised to a ceramic on ceramic bearing with uncemented cup (CoC group: Alumina ceramic head on a ceramic liner; Trident® system, © Stryker, Kalamazoo, MI, USA), whereas the remaining 147 hips were randomised to a metal on Ultra High Molecular Weight (UHMW) polyethylene bearing surface with a cemented cup (MoP group: metal head in a cemented polyethylene socket; Exeter™ Contemporary™ Flanged Cup, © Stryker, Kalamazoo, MI, USA). All patients were implanted with a cemented Exeter V40 stem (© Stryker, Kalamazoo, MI, USA). 13 patients underwent staged bilateral THAs (no simultaneous THAs were performed): in 6 patients both sides were randomised to CoC; in 2 patients both sides were randomised to MoP; 5 patients were randomised to both groups. Patients and research staff were blinded to the allocations, but the surgeons were unblinded. Patients were followed-up at 10-years and at standardised timepoints (2 and 5 years) prior to this.

The primary outcome measure was the incidence of re-operation for any cause. Secondary outcomes included patient reported outcome measures (PROMs) using Harris, Oxford, EQ-5D-5L and modified Charnley hip scores along with routine complications of THA and incidence of noise (audible squeak / click) questionnaire. No patient was lost to follow-up at 10 years of follow-up.

RESULTS:

The mean age of the patients was 57.5 years (SD 6.1 years; Range: 28 to 65 years). 133 hips were male and 169 involved the right side. Primary osteoarthritis was the commonest diagnosis for THA (283 hips), followed by dysplasia (7 hips), idiopathic avascular necrosis of the femoral head (5 hips), spondyloarthropathy (3 hips) and other causes (5 hips). Baseline characteristics and pre-operative scores were well balanced between groups (age: $p=0.166$; gender: $p=0.903$; laterality: $p=0.353$; pre-operative scores: $p>0.05$).

Pre-operative PROMs across groups showed Oxford Hip Score (OHS) was 19.9 (4-41). Harris Hip Score (HHS) was 17.3 (0-44) for pain, and 26.9 (4-47) for function. EQ-5D-5L was 0.44 (0.24-0.85), whereas the EQ VAS was 72.4% (20-100). No significant difference in pre-operative PROMs were observed between groups.

At 10-years follow-up, 18 hips (6.2%) had deceased all from causes unrelated to their THA and with no difference in rate between groups ($p=0.722$) [10 hips from the CoC group (time of operation to death: 6.5 years (SD 2.32 years; Range 2.0-9.8 years)); 8 hips from the MoP group (time of operation to death: 7.7 years (SD 3.05 years; Range 1.0-10.4 years))]. None of these had revisions of their THA prior to death.

9 revision THAs were performed on patients involved in this study (9/303; 3.0%) with no significant difference between groups. In the CoC group, a total of 4 hips were revised (4/156 = 2.6%), 2 for implant neck fractures (at 9.0 and 9.5 years respectively), 1 for infection and 1 periprosthetic fracture. In the MoP group, there were 5 hips revised (5/147 = 3.4%), 3 for infection, 1 for aseptic loosening of the cup and 1 for chronic pain (no evidence of radiological loosening or infection). There was no significant difference between other THA complications such as dislocation, venous thromboembolism, etc. ($p=0.484$).

At a minimum of 10 years of follow-up, significant improvement was noted in PROMs in both groups (p<0.005 for all PROMs). Mean post-operative OHS was 41.5 (SD 9.1; 9-48) in the CoC group, compared to 39.8 (SD 10.6; 4-48) in the MoP group (p=0.143). Across both groups, Harris Hip Score (HHS) was 37.8 (SD 9.8; 0-44) for pain, and 40.4 (SD 8.8; 7-47) for function again with no significant difference in improvement between groups (comparing the two groups: p=0.234 and p=0.135 respectively).

Modified Charnley score was 5.4 for pain (SD 1.3; 0 to 6), 5.3 for function (SD 1.5; 0 to 6) and 5.2 for range of movement (SD 0.9; 0 to 6) (comparing the two groups: p=0.340, p=0.264 and p=0.278 respectively). EQ-5D-5L was 0.78 (0.25 to 1.00), whereas the EQ VAS was 78% (25 to 100) (comparing the two groups: p=0.128 and p=0.174 respectively).

Regarding the patient's perception of noise (audible squeak / click) generated from their hip, this was significantly more common in the CoC group (p=0.026) with 36 patients (23.1%) describing some noise from their THA compared to 16 (10.7%) in the MoP group [CoC group: always noisy 1 patient / hips (0.7%), frequently noisy 6 (4.3%), occasionally noisy 19 (13.5%), rarely noisy 10 (7.1%), never noisy 104 (73.8%); MoM group: always 0 patient / hips, frequently 0, occasionally 8 (6.0%), rarely 8 (6.0%), never 117 (87.3%)]. No hip was revised due to noise or squeaking.

Kaplan-Meier survival (revision operation for any cause) was 97.3% (95% CI: 94.8 to 99.8%) for the CoC group and 96.2% (95% CI: 92.9 to 99.5%) for the MoP group (Log rank test: p=0.689) (Figure 1).

DISCUSSION AND CONCLUSION:

This study demonstrates no difference, at a minimum of 10 years, in the clinical outcomes of patients younger than 65 years of age receiving a THA using a ceramic on ceramic bearing and those receiving a metal on UHMW polyethylene bearing. Increased noise was reported in the ceramic on ceramic group but this did not lead to any revision procedures. A metal on polyethylene cemented cup has a lower incidence of noise, without an increased risk of re-operation and complications, with an additional benefit of being less costly.

Figure 1: Survival function estimated by the Kaplan-Meier method. Censoring (time of death or time the patient was last seen) is indicated by vertical marks, whereas the dips in the survival curve represent the failures/revisions.