A Novel Ceramic Coating for Reduced Metal Ion Release in Metal-on-Metal Hip Surgery

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INTRODUCTION: Data from the National Joint Registry of England and Wales (NJR) has shown that hip replacements with metal-on-metal (MoM) bearings, have significantly higher revision rates compared to metal-on-polyethylene (MoP). According to the NJR approximately 20% of MoM hip replacements are likely to need revision 10–13 years post-surgery, and larger head sizes (≥ 36 mm) are associated with a higher risk. In contrast, MoP implants are revised in less than 4% of patients at 10 years. Advantages in the use of larger MoM bearings include improved range of motion, reduced risk of revision and in the case of resurfacing devices, conservative bone-preserving surgery where less resection of femoral host bone is required. The hard-on-hard MoM articulation also has the potential to decrease volumetric wear and ultimately reduce the incidence of wear particle mediated osteolysis leading to implant failure. Continued wear of MoM bearings can result in the release of metal debris into the surrounding tissues, something that has in some patients been associated with adverse local tissue reactions (ALTR). Importantly, *in vitro* hip simulators failed to predict clinical issues identified with certain designs of MoM bearings. For this reason, we have developed an ovine total hip arthroplasty model where the metal ion release and biological response can be measured. The acetabular cup components were deliberately malpositioned in order to generate adverse wear conditions. The aim of our study was to use this model to investigate a 4th generation ceramic (SLC) coating, which may improve the wear performance and reduce metal ion release from MoM articulating components. Its performance was measured against non-coated MoM and MoP bearing combinations. Our hypothesis was that an SLC coating applied to the femoral head and acetabular cup surfaces would result in a reduction in volumetric wear, a decrease in blood chromium and cobalt ion levels and reduce any potential ALTRs.

METHODS: Ethical approval was granted and all procedures were carried out in compliance with the UK's Home Office Regulations (Animals Scientific Procedure Act 1986). Total hip replacement surgery was performed on 15 skeletally mature Charolais rams. Components were fixed using bone cement and acetabular cups were placed in a mal-aligned position in order to increase the wear of the bearing. Implants were included into one of 3 experimental groups: 1) MoM articulating surfaces coated with a SLC ceramic coating (SLC-MoM), 2) uncoated MoM surfaces (MoM) and 3) a metal on polyethylene (MoP) bearing. 3 sets of implants (comprising a femoral head, acetabular shell and femoral stem) in each group were investigated and each remained *in vivo* for 13 months. Once fully recovered from surgery, animals were exercised 5 times a week. Bearing surface and taper measurements to assess surface roughness (R_a and R_z) and volumetric wear were obtained pre- and post operatively using a Co-ordinate Measuring Machine (CMM), a Taylor Hobson Roundness machine, an Optical 3D Surface Profilometry Microscope and a Scanning Electron Microscope (SEM). Blood chromium (Cr) and cobalt (Co) metal ion levels were measured pre-operatively and at 2 and 4 weeks, and 4, 6, 12 and 13 months post surgery. At 13 months and following euthansia, an MRI was performed to investigate pathological changes in tissue structure where joint effusion, capsule thickness and the presence of any periprosthetic mass was noted. In order to investigate metal debris bio-distribution, samples of synovial tissue, the testes, spleen, heart, brain, kidney, liver, lung and bladder wall were obtained. Tissues were processed for histological analysis and graded using an ALVAL scoring system where scores of 0 (normal tissue) – 10 (ALVAL) were applied. Mann Whitney U tests were used for statistical analysis where $p<0.05$ was considered significant.

RESULTS: Although surface roughness of the SLC coated components were significantly increased (0.131 ± 0.055 µm) when compared with a polished metal surface (0.015 ± 0.001 µm) (in both femoral heads and acetabular cups) ($p = 0.046$), scanning electron microscopy showed the coating to be durable with no signs of delamination, coating loss or adverse reactions. Results also showed that post-retrieval, the R_a and R_z values increased in the MoM group when compared with retrieved MoP femoral heads. SEM demonstrated areas of multiple scratches on the heads and cups of retrieved components in the MoM and MoP groups, however scratches were not evident on the SLC surfaces. No significant differences in R_a and R_z values were seen when taper surface roughness was compared between groups and when pre-implantation data was compared with post-retrieval results. The SLC coating significantly lowered levels of chromium and cobalt metal ions within blood over the 13 month period (Figures 1 and 2). A pre-operative chromium ion level of 0.24 ± 0.03 ppb significantly increased to 0.81 ± 0.30 ppb in the uncoated MoM implants ($p = 0.001$) at 13 months post surgery. No significant increase was found in the SLC-MoM (0.21 ± 0.03 ppb) and MoP (0.21 ± 0.02 ppb) groups. Significantly lower levels of Cr were measured in both the SLC-MoM group ($p = 0.010$) and MoP group ($p = 0.046$) when compared with uncoated MoM bearings at 13 months. A significantly increased level of Cr was measured in the MoM group when compared with the SLC-MoM group at 1 ($p = 0.029$), 3 ($p = 0.024$), 6 ($p = 0.013$), 12 ($p = 0.019$) and 13 ($p = 0.010$) months post operatively. A pre-operative Co level of 1.19 ± 0.20 ppb increased to 2.72 ± 1.54 ppb in the uncoated MoM group at 13 months post-op, however this value was not significant. A significantly increased level of cobalt was measured in the MoM group when compared with the SLC-MoM group at 6 ($p = 0.042$), 12 ($p = 0.011$) and 13 ($p = 0.011$) months post operatively. Histological assessment showed no metallic debris within tissues and organs except for debris observed within synovial tissue immediately adjacent to the implant bearing in all experimental groups. Metallosis was observed in both the MoM and SLC-MoM groups however a significantly lower ALVAL score was measured in the SLC-MoM group (3.88) when compared with MoM components (6.67) ($p = 0.010$). ALVAL results also showed no significant difference when SLC-MOM components were compared to MoP (5.25). MRI analysis showed no tissue abnormalities in any of the three groups investigated.

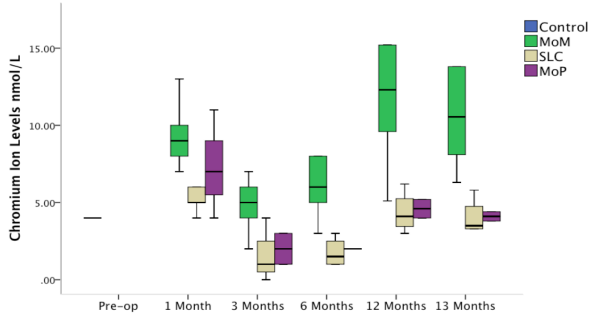

Figure 1: Pre- and post-operative Cr ion levels.

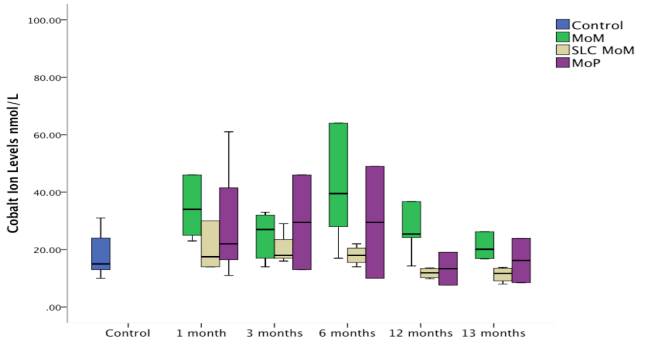

Figure 2: Pre- and post-operative Co ion levels.

DISCUSSION: *In vitro* hip simulators failed to predict problems with MoM bearings *in vivo*. This study successfully used a repeatable and reproducible accelerated total hip replacement ram model to study the effects of the wear and toxicity of released debris from different implant bearing materials *in vivo*. This study showed a SLC coating to be durable with no signs of delamination, coating loss or adverse reactions. A significant reduction in Cr and Co ion release and a decrease in the incidence of ALVAL were achieved following the application of this 4th generation ceramic coating onto the articulating surfaces in metal-on-metal hip replacement surgery.

SIGNIFICANCE: The use of a 4th generation ceramic coating has reduced the metal ion release from the underlying substrate and offers the potential opportunity to increase the survival of metal-on-metal bearing implants.

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