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Preliminary report of clinical experience with metal-on-highly-crosslinked-polyethylene hip resurfacing

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Objectives

Modern metal-on-metal (MoM) hip resurfacing arthroplasty (HRA), while achieving good results with well-orientated, well-designed components in ideal patients, is contraindicated in women, men with head size under 50 mm, or metal hypersensitivity. These patients currently have no access to the benefits of HRA. Highly crosslinked polyethylene (XLPE) has demonstrated clinical success in total hip arthroplasty (THA) and, when used in HRA, potentially reduces metal ion-related sequelae. We report the early performance of HRA using a direct-to-bone cementless mono-bloc XLPE component coupled with a cobalt-chrome femoral head, in the patient group for whom HRA is currently contraindicated.

Methods

This is a cross-sectional, observational assessment of 88 consecutive metal-on-XLPE HRAs performed in 84 patients between 2015 and 2018 in three centres (three surgeons, including the designer surgeon). Mean follow-up is 1.6 years (0.7 to 3.9). Mean age at operation was 56 years (SD 11; 21 to 82), and 73% of implantations were in female patients. All patients were individually counselled, and a detailed informed consent was obtained prior to operation. Primary resurfacing was carried out in 85 hips, and three cases involved revision of previous MoM HRA. Clinical, radiological, and Oxford Hip Score (OHS) assessments were studied, along with implant survival.

Results

There was no loss to follow-up and no actual or impending revision or reoperation. Median OHS increased from 24 (interquartile range (IQR) 20 to 28) preoperatively to 48 (IQR 46 to 48) at the latest follow-up (48 being the best possible score). Radiographs showed one patient had a head-neck junction lucency. No other radiolucency, osteolysis, component migration, or femoral neck thinning was noted.

Conclusion

The results in this small consecutive cohort suggest that metal-on-monobloc-XLPE HRA is successful in the short term and merits further investigation as a conservative alternative to the current accepted standard of stemmed THA. However, we would stress that survival data with longer-term follow-up are needed prior to widespread adoption.

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Keywords: Hip arthritis, Young patients, Hip resurfacing, Arthroplasty, Implant survival

Article focus

- This paper presents a novel design of a metal-monobloc highly crosslinked polyethylene (XLPE) hip resurfacing arthroplasty (HRA).
- We report early complications and failures.
- We report clinical and radiological assessment.

Key messages

- No actual or impending failures were observed.
- The median Oxford Hip Score increased by 24 points, from 24 (interquartile range (IQR) 20 to 28) preoperatively to 48 (IQR 46 to 48) at the latest follow-up.
- Radiological adverse features are rare.

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Strengths and limitations

- These are preliminary early results.
- This resurfacing uses well-established materials in a novel design, with isoelasticity and less stress shielding.
- The design has potential for negligible metal ion release and associated adverse effects.

Introduction

Total hip arthroplasty (THA) is a successful treatment option for hip arthritis but long-term survivorship in young patients is not as good as in older patients.[1-4] The current generation of metal-on-metal (MoM) hip resurfacings (HRA) were developed to address the suboptimal performance of conventional metal-on-polyethylene (MoP) THA devices in young active patients.

Potential advantages of HRA include conservation of femoral bone stock and reduced rate of dislocation,[1] which allows safer movements at occupational and sporting activities, compared with THA. The SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) Report[5] and other reviews[6] and comparative studies[7-10] using patient-reported outcomes, gait analysis,[11] and occupational ability[12] suggest that HRA provide better functional outcomes than THA in well-selected young men. Other advantages include absence of multimodularity and better biomechanical reconstruction,[13] with less risk of limb-length error and better preservation of proximal femoral bone density.[14,15] Two reports[16,17] demonstrate reduced mortality in patients with MoM HRA in the medium term, compared with THA, which persisted after extensive adjustment for confounding, while others report no difference[18] in the early term, and no causality in the medium term.[19]

Risk factors for HRA revision include female sex and smaller sizes.[20-22] Implant design and accurate implant positioning are key[23,24] to preventing edge wear. One of the modes of failure from excess wear is termed pseudotumours. In this condition, a lymphocyte-dominated hypersensitivity is observed[25] histologically, which results often in soft-tissue and bony complications. A systematic review of pseudotumours showed an overall pooled prevalence of 0.4% (95% confidence interval (CI) 0.3 to 0.7) in all designs of MoM HRA combined.[26] Depending on the level of screening, it varied from 0.1% to 9.5%.

Following these observations, implant manufacturers have withdrawn MoM HRAs altogether or restricted them to men with large (> 48 mm) bearings. This leaves all women, and men with smaller hips, without a HRA option, leading to renewed research to find an alternative solution for patients in this demographic.

Modern ceramics and crosslinked polyethylene (XLPE) have dramatically improved arthroplasty bearing wear. Ceramic-on-ceramic (CoC) bearings show good implant survivorship,[27] but the issues[28] of liner chipping, aseptic loosening, and squeaking continue to cause concern.

Encouraging laboratory[29] and clinical results[30] over the past 15 years have established XLPE as a viable bearing counterface to metal and ceramic, making wear-induced osteolysis rare. Modern THA XLPE acetabular components consist of a thick XLPE liner fixed in a metal (usually titanium) shell through a locking mechanism. Encouraging results are reported with metal-on-XLPE (MoXLPE) HRAs using such two-piece components.[31,32] This construct, while acceptable in THA, has drawbacks in HRA, since increased overall component thickness leads to undesirable acetabular bone removal. Furthermore, locking mechanisms risk liner dissociation or XLPE failure, more so in a large-diameter construct with thin liners. A monobloc XLPE component with an integral fixation surface would eliminate those risks and maximize XLPE thickness. Historically, the Rob Mathys (RM) THA uncemented monobloc PE component with a porous fixation surface and its recent XLPE press-fit variant demonstrate good results. The original RM component shows a survival rate of 91% for all reasons and 99% for aseptic loosening at 10.7 years.[33,34]

The purposes of the study are: to explain the design features of the monobloc MoXLPE HRA component, coupled with a cobalt-chrome resurfacing femoral component; to assess early implant survival, clinical, and radiological results; to document complications and adverse events; and to present individual case studies.

Patients and Methods

Components. The acetabular component (Fig. 1) is a monobloc XLPE component with an integral porous titanium fixation surface. Great care has been taken in the design of these custom-made implants to ensure a minimum wall thickness of 3 mm at the periphery while exhibiting a positive variance in other regions owing to the custom nature of the design. At the pole, the thickness ranged from 5.16 mm to 6.99 mm.

The average pull-off strength of the titanium porous-coating-on-HXLPE is 16.3 Megapascals (MPa) (data on file; Jointmedica, Hallow, United Kingdom), which is slightly less than typical values for porous-coating-on-metal, reflecting the lower ultimate tensile strength of XLPE compared with metal.

Component articular angle is made greatest in the smaller components (163. 7° in the 48 mm outer diameter (OD) component) in order to allow maximum coverage in the smaller components, which are more prone to edge loading. It is progressively reduced in the larger components in order to minimize the risk of impingement.

The femoral head design is based on the existing Birmingham Hip Resurfacing (BHR; Smith & Nephew, Memphis, Tennessee), which has been in clinical use for over 20 years. Minor modifications to the internal geometry have been made addressing two decades of clinical observations. These include shortened stem length and

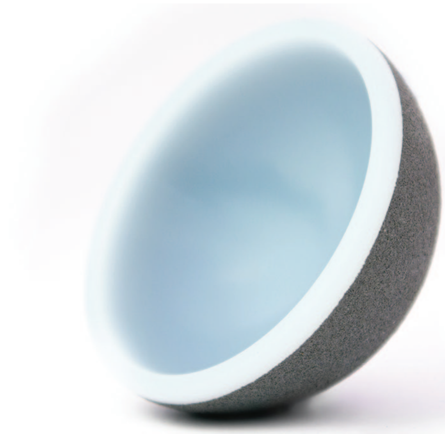

Fig. 1

The custom metal-on-crosslinked-polyethylene (MoXLPE) hip resurfacing device. Component sizes used in this cohort ranged from 48 mm to 60 mm outer diameter (OD). Implants were individually prescribed and manufactured for each patient, based on templating with calibrated plain radiographs. Thicker components (4 mm to 5 mm minimum thickness at periphery) were manufactured if there was a head-socket mismatch on templating.

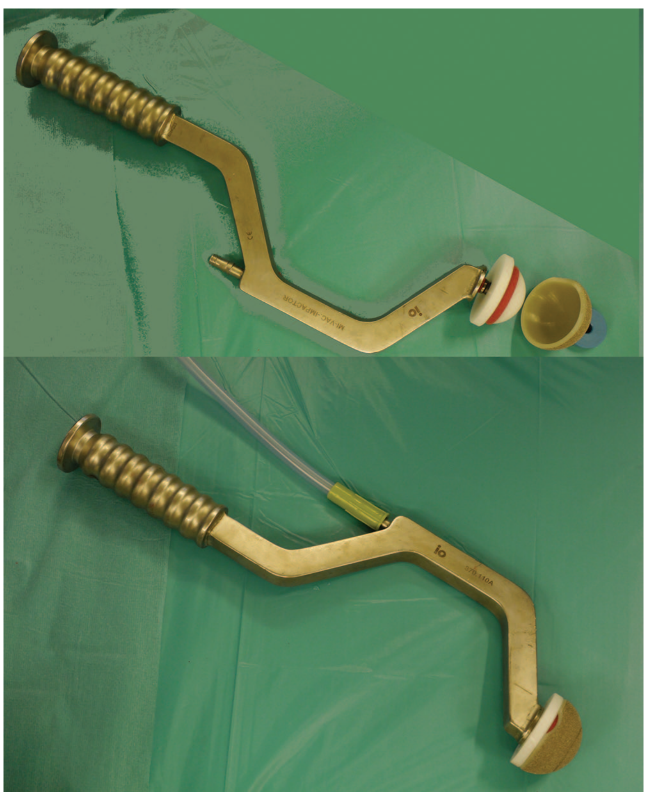

Fig. 2

Vacuum introducer to seat the component. The implant and introducer are coupled using 650 mm Hg negative pressure, through a size-specific implantation plate (supplied with the implant).

increased femoral component clearance against the prepared bone surface.

Patients. This is a cross-sectional, observational assessment of all MoXLPE HRAs performed by three surgeons (DJWM (the design surgeon), RBCT, and JPH) in three centres (BMI Hospital Edgbaston, Birmingham, United Kingdom; The Royal Orthopaedic Hospital, Birmingham, United Kingdom; and Freeman Hospital, Newcastle-upon-Tyne, United Kingdom) between April 2015 and June 2018. In this time period, there were 88 HRAs in 84 patients (four bilateral). Mean age at operation was 56 years (SD 11; 21 to 82), and 73% of implantations were in female patients (Table I).

Table I. Demographics of patients who underwent metal-on-crosslinked-polyethylene (MoXLPE) hip resurfacing arthroplasty (HRA)

Characteristic	Value
Sex, n (%)	
Male	23 (*27.3*)
Female	61 (*72.6*)
Mean age, yrs (SD; range)	56 (11; 21 to 82)
Location, n (%)	
United Kingdom	71 (*84.5*)
Overseas	13 (*15.4*)
Procedure, n (%)	
Primary procedure	85 (*96.5*)
Component revision	3 (*3.4*)
Indication (diagnosis)	
Osteoarthritis	83 (*94.4*)
Developmental dysplasia of the hip	1 (*1.1*)
Avascular necrosis	1 (*1.1*)
Revision of failed HRA	3 (*3.3*)
Mean component inclination angle, ° (SD; range)	38 (4.9; 24 to 47)
Head sizes used, n (%)	
42 mm	17 (*19.3*)
44 mm	16 (*18.2*)
46 mm	30 (*34.1*)
48 mm	8 (*9.1*)
49 mm*	1 (*1.1*)
50 mm	16 (*18.2*)

*ASR femoral component (DePuy, Warsaw, Indiana) retained at revision

Patients were contraindicated for conventional MoM HRA due to sex, femoral head size, or metal hypersensitivity issues, and were unsuited for a conventional THA due to young age or high activity needs. Those patients who had a history of metal allergy (such as to metal fashion accessories) were tested with lymphocyte transformation test (LTT) to ascertain reactivity against 20 different metals. All the patients were individually counselled, and detailed verbal and written informed consent was obtained.

Primary diagnoses included 83 primary osteoarthrosis, one Crowe grade 1 hip dysplasia, and one femoral head osteonecrosis. Three components were used in component revision procedures of previous MoM HRA. Revision component cases included one ASR (DePuy, Warsaw, Indiana) and one BHR, both revised for adverse reaction to debris. One BHR component was revised for aseptic loosening.

The posterior approach was used. A suction introducer is used for component implantation which is exactly the same introducer used on some CE-marked metal components.

The vacuum introducer-impactor is connected to a portable suction system capable of sustaining a maximum of 650 mm Hg. The components are supplied with



Fig. 3a Fig. 3b Fig. 3c

Radiological series of a 53-year-old female ballet dancer and yoga teacher: a) preoperatively; b) at two months; and c) at two years. She presented with right groin pain and a limp, affecting her quality of life and livelihood. She reported reacting to costume jewellery. A lymphocyte transformation test demonstrated a strong positive reaction to chromium. Total hip arthroplasty was offered, but the patient preferred a custom metal-on-crosslinked-polyethylene hip resurfacing arthroplasty. At one year, she had resumed all activities including ballet, pilates, and yoga. At two years, she works as a ballet teacher. Clinically and radiologically, there were no adverse features.

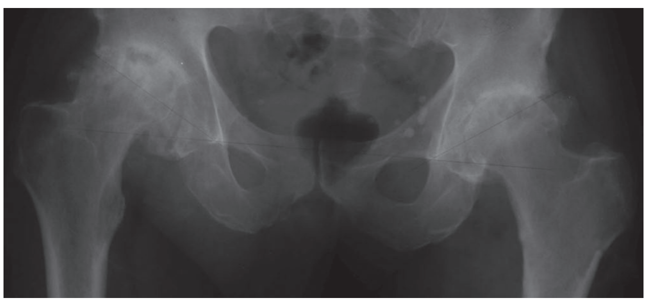
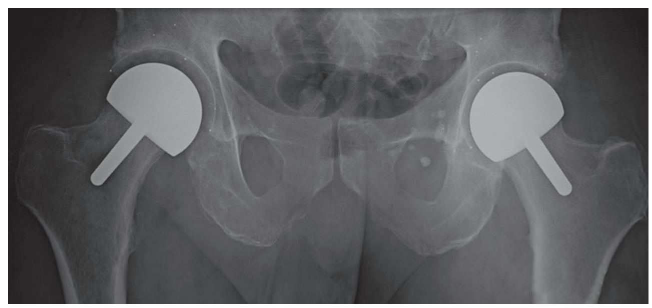

Fig. 4a Fig. 4b

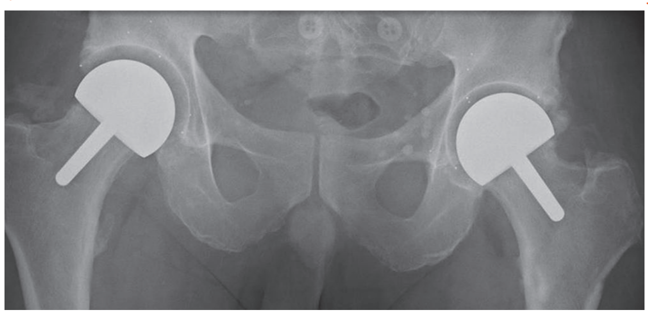

Fig. 4c

Radiological series of a 59-year-old male surgeon with an active lifestyle, including rowing, spinning, and gymnastics: a) preoperatively; b) at two months; and c) at one year. He presented with bilateral painful arthritic hips. He refused metal-on-metal hip resurfacing arthroplasty and total hip arthroplasty, and specifically requested a metal-on-crosslinked-polyethylene. Superolateral erosion creating secondary dysplasia required the use of a 10 mm inner diameter–outer diameter difference component on the right side. The more commonly used 6 mm sufficed on the left. At one year, he had returned to previous activity. A radiograph at one year showed grade I heterotopic ossification.

size-specific impaction plates. The correct plate is assembled with the introducer. The plate is then immersed in saline prior to coupling with the acetabular implant. This encourages a secure fit between implant and introducer. Ensuring the suction apparatus is set to its maximum setting, as soon as the instrument and implant are securely coupled, the component can be positioned and impacted in line with the preoperative plan (Fig. 2).

Stable primary fixation was achieved using 1 mm under-reaming and target component inclination of 40° and anteversion 20°. BHR technique was used for femoral head preparation and fixation.[35] Femoral component

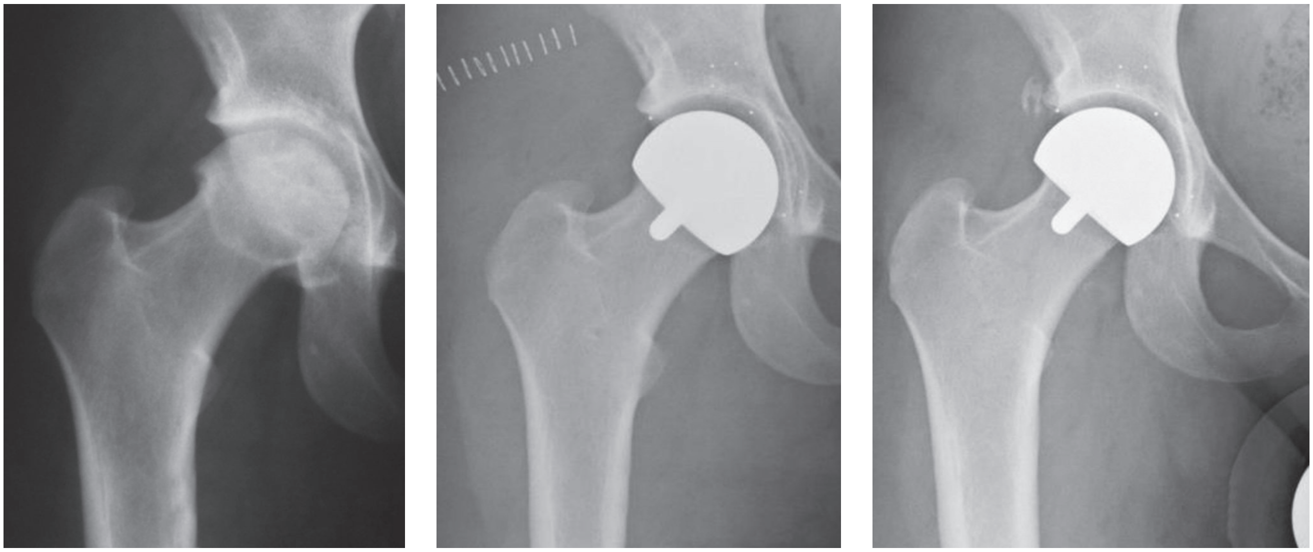

Fig. 5a Fig. 5b Fig. 5c

Radiological series of a 21-year-old female university student: a) preoperatively; b) at two days; and c) at one year. She presented with post-Perthes' disease bilateral painful hips, with her right hip being the most troublesome. Her presenting condition and young age made her an ideal candidate for a bone-conserving procedure. A custom crosslinked-polyethylene resurfacing was performed with 42 mm/48 mm components. At one year, she was back to sporting activity and has started a career.

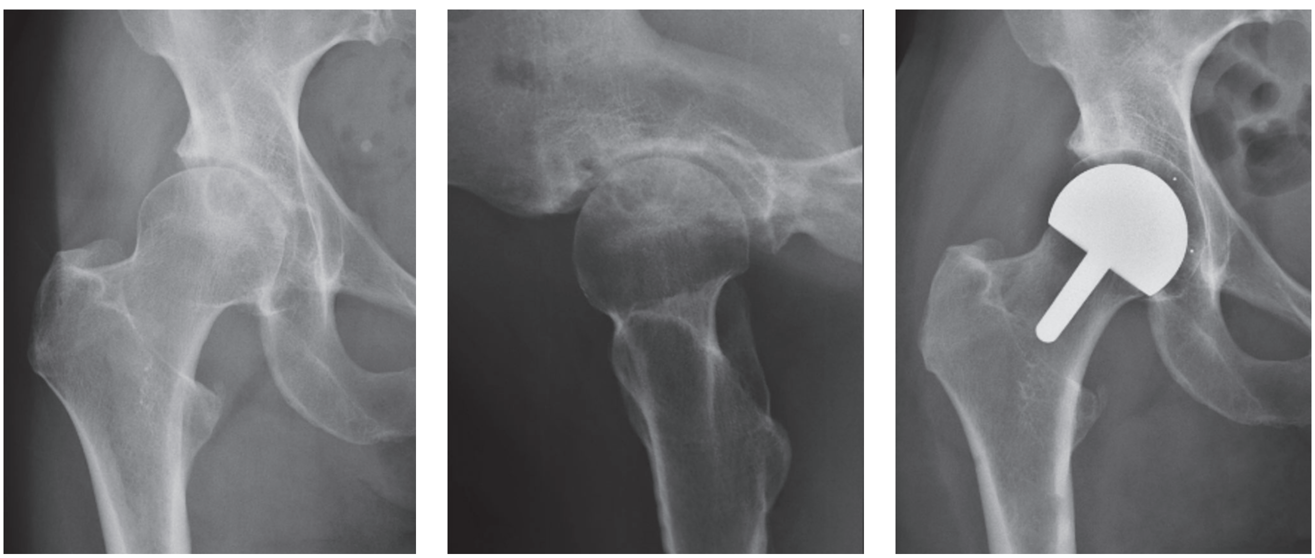

Fig. 6a Fig. 6b Fig. 6c

Radiological series of a 50-year-old female expedition travel agent and county golf coach: a) preoperatively; b) immediately postoperatively; and c) at three months. She was unable to work due to pain and requested a hip resurfacing, since her job required maintaining high activity levels. She returned to normal activity at work by three months.

implantation in neutral or mild valgus (not exceeding 5°) was achieved in all cases.

Postoperatively, full weightbearing with two elbow crutches was allowed for four weeks followed by one crutch or walking stick for a further four weeks. Patients in the United Kingdom were followed up at two months, one year, and two years with clinical and radiological assessment, as well as annual postal questionnaires between follow-ups. Further follow-up is planned at five, eight, and ten years. Those who could not attend clinics sent postal Oxford Hip Score (OHS) questionnaire responses and radiographs. Revision or impending revision of either component for any reason was taken as the endpoint for survival.

Radiological assessment was performed by an experienced consultant musculoskeletal radiologist blinded to the clinical result. Radiographs were assessed for component migration, radiolucencies or osteolysis, lucent lines,

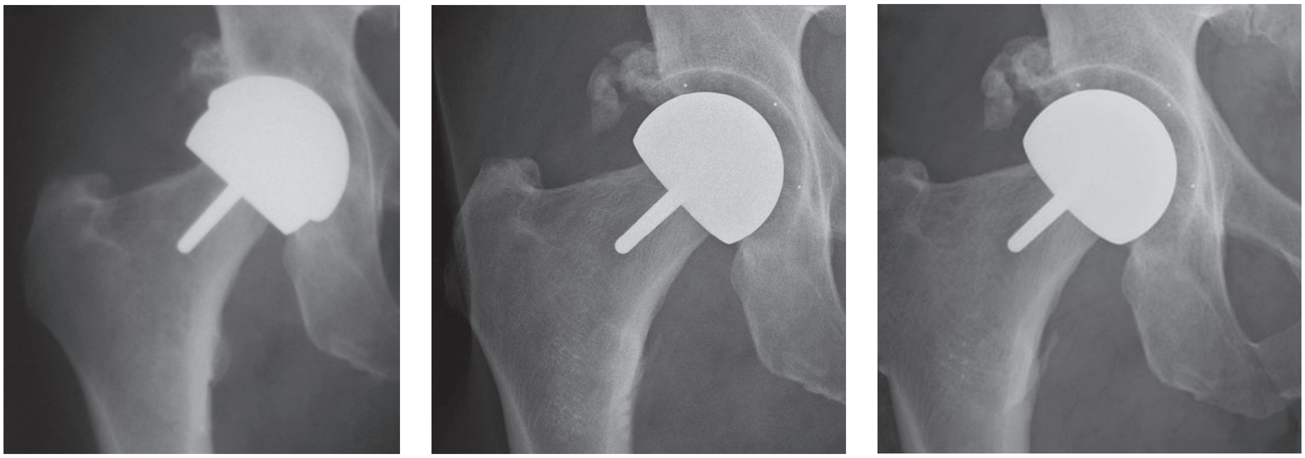

Fig. 7a Fig. 7b Fig. 7c

Radiological series of a custom crosslinked-polyethylene (XLPE) component used in the revision of a metal-on-metal (MoM) resurfacing component for a 63-year-old very active male patient: a) preoperatively; b) at two months; and c) at three years. An ASR (DePuy, Warsaw, Indiana) hip resurfacing arthroplasty (HRA) implanted nine years prior, presented with moderately elevated metal ions and a pseudotumour. He refused revision to a total hip arthroplasty as he wanted to continue his highly active lifestyle. He chose to undergo revision of his metal component to an XLPE component while retaining his well-fixed femoral component, converting his MoM HRA into a metal-on-XLPE HRA. Three years after the operation he continues in his active lifestyle.

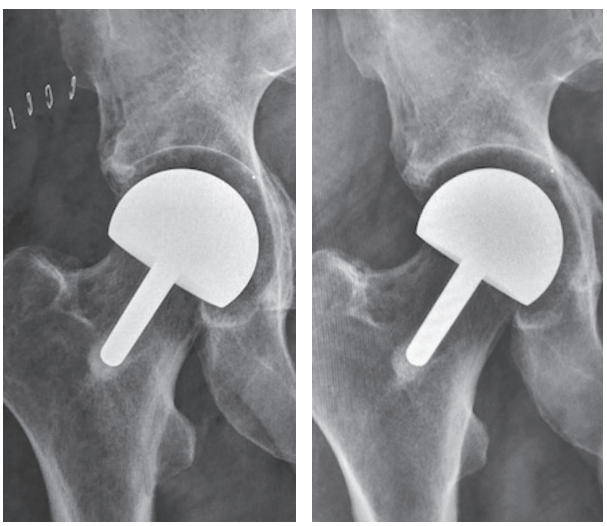

Fig. 8a Fig. 8b

Radiological series of revision of an existing Birmingham Hip Resurfacing (BHR; Smith & Nephew, Memphis, Tennessee) component in a 46-year-old male carpenter: a) postoperatively; and b) at one year. He had undergone a 46 mm/52 mm BHR 17 years earlier. Excess component inclination had resulted in high ions. Due to workplace demands, he was considered high-risk for a total hip arthroplasty. Revision to metal-on-crosslinked-polyethylene hip resurfacing arthroplasty using a 56 mm crosslinked-polyethylene component was performed while retaining the femoral component. He is pleased with the outcome and with reducing ion levels at 18 months.

loosening, femoral neck thinning, and any other adverse features. Shapiro–Wilk test was used for normality, and minimally important change (MIC) for clinically relevant improvement of OHS.[36]

Results

The mean follow-up of the 88 hips (84 patients) is 1.6 years (0.7 to 3.9), with 75 having reached one year or more follow-up; of these, 18 have longer than two years' follow-up. There has been no loss to follow-up, no actual or impending revisions, and no reoperations. No patient is reported deceased.

The median OHS changed from 24 preoperative (interquartile range (IQR) 20 to 28) to 48 (IQR 46 to 48) at latest follow-up (48 being the best possible score) giving a median difference of 24 for the whole group (the recommended group MIC is 11). For individual patients, the change varied from 11 to 38 points (the recommended individual MIC is 8), thereby demonstrating functional improvement in all patients individually and as a group.

No significant radiological change was noted in any patient (Figs 3 to 8), except one, a 48-year-old man. He had excellent initial recovery and continues to be very active with regular gym work. He returned to kite surfing at seven months postoperatively. He developed pain on flexion and internal rotation. Investigation showed a head-neck junction lucency suggesting partial femoral head avascular necrosis. His components are solidly fixed with no sign of migration or movement. Continued follow-up is in place.

The following adverse events were observed: a 46-year-old female patient developed transient postoperative femoral nerve palsy, which recovered from grade 0/5 power to grade 3/5 in three days, and fully recovered within six weeks. A 33-year-old female patient developed partial sciatic nerve palsy, which was recovering at the most recent follow-up. A 67-year-old male patient, who did not have a neurological deficit postoperatively, developed a partial common peroneal nerve deficiency (neurologically proven to be at the level of the fibular neck) after discharge home, probably due to a tight thromboembolism-deterrent stocking.

A 67-year-old female patient who had bilateral MoXLPE HRAs was found, on routine Doppler ultrasonography, to have a short-segment, asymptomatic, below-knee deep vein thrombosis (DVT) in the right mid-calf, which spontaneously resolved two weeks later without the need for anticoagulation. No other patient had symptomatic DVT, asymptomatic DVT, or pulmonary embolism.

Discussion

This is a preliminary report of a multicentre consecutive case series of a custom device that uses well-established bearing materials in a novel hip resurfacing component design (Figs 3 to 8. This study has a number of limitations. First, this series of custom devices were only available to three highly experienced hip resurfacing surgeons (having performed in excess of 1000 MoM HRAs each). Restricting device usage to experienced surgeons reduces the chances of learning curve problems distorting the assessment of device-related early failure issues,[37] and respects patient safety above everything else. Second, with a mean follow-up of 1.6 years, these results are at best preliminary. These early results indicate that further clinical investigation is worth pursuing. There are risks unique to MoXLPE HRA. Although polyethylene is not as brittle as ceramic, it is not as robust as metal. XLPE component breakage[38] has been occasionally reported. In most cases, this was due to problems with the mechanism that locks the XLPE insert to the metal shell. The fixation surface directly applied to XLPE in the current device avoids a coupling mechanism and eliminates that weak link. XLPE is not as stiff as metal, which raises the potential risk that, under pressure, it can deform, adversely affecting fixation. Neither of these have been observed in this series over three years. The most critical time for this to occur is in the early months, hence this preliminary report.

All these procedures have been entered in the National Joint Register of England and Wales and continue to be monitored therein. The Beyond Compliance Group of the Medicines and Healthcare Products Regulatory Agency has been consulted to advise on an early risk assessment of the technology.

There is increasing evidence[1-4] that the risk of revision of conventional hip arthroplasties varies with age at operation, with one recent report showing that the median time to revision for patients who had surgery younger than 60 years of age was 4.4 years.[3] The withdrawal of resurfacing devices from use in a large segment of this population group (women and men with small hip sizes) leaves them at increased risk of multiple lifetime revisions.

Scholes et al[39] reported implant survival of 96.8% (95% CI 94.2 to 99.4) at 15 years in a cohort of 226 patients who underwent a BHR aged less than 50 years. Furthermore, patients experienced and maintained significant improvements in health and hip function scores, and activity scales beyond ten years postoperatively, and were equal to, or exceeded, age- and sex-matched normative data in more than 80% of patients.[39]

In all the cases in the current series, the MoXLPE HRA has provided a conservative hip device in a young or active patient who would clearly benefit from it, but for whom such a device no longer exists. The variety of primary aetiologies (Figs 3 to 8) and revision situations treated in the series demonstrate the versatility of the device.

Like all HRAs, MoXLPE is also subject to the risks of femoral neck fracture and femoral head collapse. There are potential benefits of XLPE, including isoelasticity to normal bone and potential for less stress shielding in comparison with ceramic or metal components, which will be a subject for future research. Edge wear occurring in metal components, either due to poor design or poor positioning, leads to elevated ion levels and pseudotumours.[24] In ceramics, edge wear may lead to fractures or squeaking.[40] Wear of XLPE does not give rise to ions or metal-debris-related pseudotumours.

Bench testing to simulate the potential revision scenario of the Custom XLPE component gives the authors the confidence that, in such an unwelcome event, the insult to the patients will be minimized, as the implant can be effectively removed with standard acetabular reamers. It is reasonable to assume this advantage will result in minimal bone loss, and therefore potentially better revision outcomes, when compared with the removal of well-fixed uncemented metallic components.

In conclusion, the preliminary results in this small cohort of patients suggest that monoblock metal-on-XLPE HRA is a viable option for patients who may benefit from HRA, but for whom the option does not currently exist, and merits further investigation to see if it is advantageous over stemmed THA.

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