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Primary Hip

Two-Year Results of Ceramic-on-Ceramic Hip Resurfacing in an International Multicenter Cohort

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ABSTRACT

Background: Hip resurfacing arthroplasty (HRA) is a bone-conserving alternative to total hip arthroplasty. We present the 2-year clinical and radiographic follow-up of a novel ceramic-on-ceramic HRA in an international multicenter cohort.

Methods: Patients undergoing HRA between September 2018 and January 2021 were prospectively included. Patient-reported outcome measures (PROMs) in the form of the Forgotten Joint Score, Hip Disability and Osteoarthritis Outcome Score Jr., Western Ontario and McMaster Universities Arthritis Index, Oxford Hip Score, and University of California, Los Angeles, Activity Score were collected preoperatively, and at 1 and 2 years postoperation. Serial radiographs were assessed for migration, component alignment, evidence of osteolysis or loosening, and heterotopic ossification formation.

Results: The study identified 200 patients who reached a minimum 2-year follow-up (mean 3.5 years). Of these, 185 completed PROMs follow-up at 2 years. There was a significant improvement in Hip Disability and Osteoarthritis Outcome Score ($P < .001$) and Oxford Hip Score ($P < .001$) between the preoperative, 1-year, and 2-year outcomes. Patients had improved activity scores on the University of California, Los Angeles, Active Score ($P < .001$), with 45% reporting a return to high-impact activity at 2 years. At 1 and 2 years, the Forgotten Joint Score was not significantly different ($P = .38$). There was no migration, osteolysis, or loosening of any of the implants. No fractures were reported over the 2-year follow-up, with only 1 patient reporting a sciatic nerve palsy. There were 2 revisions, 1 for unexplained pain at 3 months due to acetabular component malposition and 1 at 33.5 months for acetabular implant failure.

Conclusions: The ceramic-on-ceramic resurfacing at 2 years postoperation demonstrates promising results with satisfactory outcomes in all recorded PROMs. Further long-term data are needed to support the widespread adoption of this prosthesis as an alternative to other HRA bearings.

Hip resurfacing arthroplasty (HRA) provides an alternative arthroplasty option to total hip arthroplasty (THA) in the active patient who has intrinsically higher physical demands postsurgery [1,2]. A HRA preserves femoral bone stock, has a lower rate of dislocation [3], and a greater rate of return to impact activity compared to THA [4].

Metal-on-metal (MoM) HRA implants that are well implanted have very good long-term survival. However, adverse reactions to

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metal debris in MoM bearings are well-documented [5] and have resulted in a significant reduction in HRA performed worldwide. Ongoing concerns about the risk of metal toxicity [6] markedly limit their current use to a cohort of young male patients.

Alternative bearings for HRA would theoretically confer the benefits of resurfacing without exposing patients to the risk of metal ions, potentially expanding their use to a wider adult population. Ceramic bearings are well-proven in THA with excellent functional outcomes in large diameter ceramic-on-ceramic (CoC) THA [7], but there are very limited data supporting its use in HRA [8].

To our knowledge, we present the 2-year results of the largest case series to date of a CoC HRA (ReCerf, MatOrtho, Surrey, United Kingdom) in a large multinational multicenter cohort. We report the patient-reported outcome measures (PROMs), interval radiographic data, and complications in our series of the first 200 consecutive cases.

Methods

Patients

This multicenter prospective study included the first 200 consecutive cases of CoC HRA implantation. Surgery dates were between September 3, 2018, and August 15, 2020. Patients were recruited from 8 surgeon practices in 5 countries. The decision to resurface was made on the individual surgeon's assessment of the patient's age, activity level, and bony anatomy. Generally, patients under 55 who had expectations of returning to high-level functional or sporting activity were offered HRA over THA. All surgeons were established high-volume HRA resurfacing surgeons who had extensive experience in the ADEPT (MatOrtho, Surrey, United Kingdom) MoM HRA on which the ReCerf design was based.

Surgical Technique

A posterior approach preserving the capsule around the femoral neck [9] was used in the majority of the cases, and a small percentage (6 patients, 3%) used the Hueter-Anterior approach [10]. The femoral head was measured and prepared so that the prosthesis was aligned within the mid-axis of the femoral neck in both planes. In the coronal plane, some surgeons aimed for a slight valgus [11]. Care was taken to avoid notching. The socket was prepared to accommodate a cup 6 mm larger than the femoral component size. The definitive cup was then implanted before the femoral component was cemented using low-viscosity cement.

Implant Used

The ReCerf consists of 2 components (Figure 1) made from highly polished (Ra < 0.02 um) BIOLOX Delta Ceramic (CeramTec Gmbh, Plochingen, Germany). A cemented ceramic femoral component articulates with an uncemented ceramic monobloc acetabular component. There is a 6-mm differential between a coupled femoral and acetabular component across the size range. The femoral component has an internal stem proportionally sized to optimize load transfer to a patient's femoral head. The acetabular component achieves press-fit fixation using a DeltaFIX coating of plasma-sprayed titanium overlaid with a hydroxyapatite coating without the need for additional backside features.

Patient-Reported Outcome Measures (PROMs)

All patients completed PROMs in the form of the Oxford Hip Score (OHS), University of California, Los Angeles (UCLA) Activity Index, Forgotten Joint Score (FJS), and the Hip Disability and Osteoarthritis Outcome Score (HOOS). These were collected preoperatively, and at 6, 12, and 24 months postoperatively. The PROMs data and radiological data were collected prospectively until April 2023 to ensure a minimum follow-up of 2 years. This allowed for COVID-related delays in data collection. Surgical complications of any kind, including auditory and mechanical phenomena, were recorded and reported.

Radiographic Data

Anterior–posterior radiographs were collected from the local operating center and uploaded onto a central server, where they were assessed by an independent surgeon (DL) not involved in the implantation. The anterior–posterior radiographs were assessed at immediate and 2-year postoperative timeframes.

The acetabular cup inclination angle was measured as the angle between the line across the face of the acetabular component and the inter-tear drop line. In the absence of a radiographically visible femoral stem, a novel way of measuring the femoral neck shaft angle is described by the method outlined in Figure 2. Serial X-rays were also assessed for stress shielding, implant migration or loosening, femoral notching, and the presence of heterotopic ossification (HO).

Data Analyses

Survivorship analysis was performed with the Kaplan–Meier method. A student *t*-test was used to compare groups and a *P* value of < .05 was considered statistically significant.

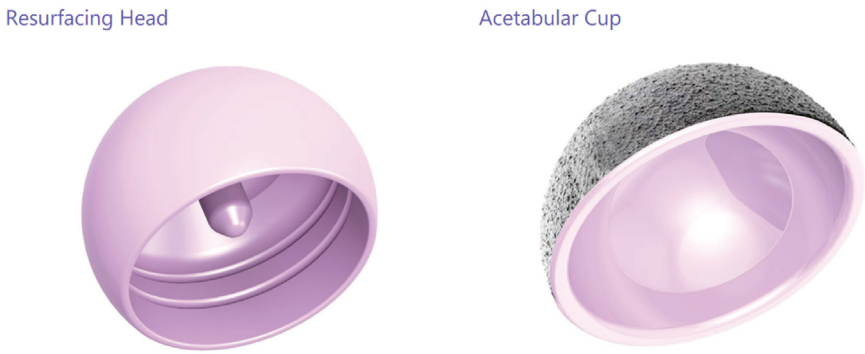

Fig. 1. ReCerf ceramic-on-ceramic HRA. HRA, hip resurfacing arthroplasty.

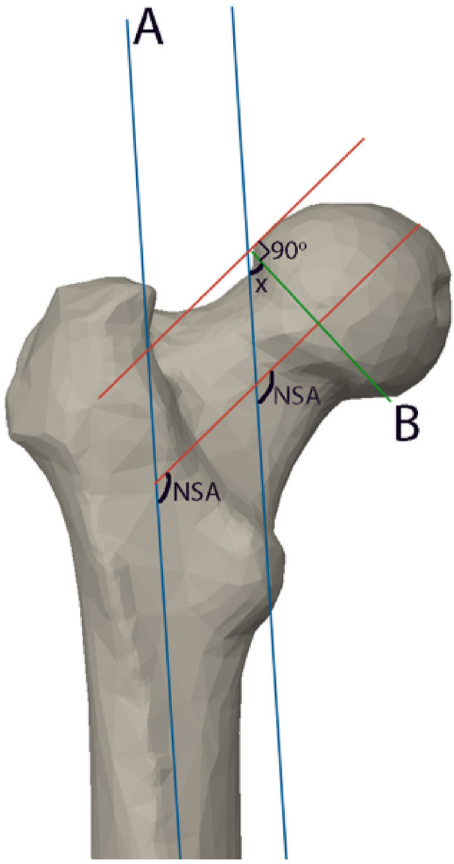

Fig. 2. Neck shaft angle = 90° + Angle X Where Angle X is defined as the angle between a line drawn across the face of the implant and a line drawn down the long axis of the femur.

Results

Demographics

A total of 200 hips (184 patients, 16 bilateral) were prospectively recruited across 5 countries, as detailed in Table 1. There were 109 men (55%) and 108 (54%) right-sided hip resurfacing operations. The mean age at the time of surgery was 50 years (range, 23 to 75). The mean preoperative body mass index was 26.8 (range, 19 to 42). The American Society of Anesthesiologists was grade 1 in 63%, grade 2 in 32%, and grade 3 in 5%. The mean follow-up was 42.5 months (3.5 years).

The most common indication for surgery was osteoarthritis in 95% (n = 190), followed by hip dysplasia in 3.5% (n = 7), inflammatory arthritis in 1% (n = 2), and osteonecrosis in 0.5% (n = 1). The implant size ranged from 40 to 60 mm, with the head size distribution by sex listed in Table 2. A 52-mm implant was the most common in men (30%) and a 48-mm was the most common in women (30%). There were 96 out of 200 (48%) who received a head implant size smaller than 50 mm.

Table 1
Breakdown of Patient Recruitment by Country and Surgeon.

Country	Surgeon Name	N by Surgeon	N by Country
Australia	Surgeon 1	41	137
Australia	Surgeon 2	62	
Australia	Surgeon 3	30	
Australia	Surgeon 4	4	
Canada	Surgeon 5	6	6
Belgium	Surgeon 6	43	43
South Africa	Surgeon 7	12	12
United Kingdom	Surgeon 8	2	2
Total		200	200

Table 2
Graph of Head Size Distribution According to Gender.

Size	Male	Female
Ø40 mm	0	1
Ø42 mm	0	8
Ø44 mm	2	26
Ø46 mm	6	22
Ø48 mm	4	27
Ø50 mm	23	6
Ø52 mm	33	1
Ø54 mm	21	0
Ø56 mm	12	0
Ø58 mm	6	0
Ø60 mm	2	0
Ø62 mm	0	0
Ø64 mm	0	0
Total	109	91

Patient-Reported Outcome Measures (PROMs)

An outline of the PROMs collected is summarized in Table 3.

The OHS score significantly improved from 21.8 preoperation to 43.5 at 6 months postoperation ($P < .01$). The OHS continued to improve between 6 months and 1 year ($P < .01$), but there was no significant difference between the scores at 1- and 2-year postoperation ($P = .3$) (Figure 3).

The UCLA score significantly improved from 4.8 preoperation to 7.3 at 6 months postoperation ($P < .01$). The UCLA score continued to improve between 6 months and 1 year (7.8 versus 8, $P < .01$), but there was no significant difference between the scores at 1- and 2-year postoperation ($P = .3$).

All subsections of the HOOS demonstrated improvement from preoperative to 6 months and again from 6 months to 1 year. The subsections of (1) sports and (2) quality of life continued to demonstrate statistically significant improvements from the 1 to 2-year timepoints.

The FJS improved from 73.9 at 6 months to 80.6 at 1 year postoperation ($P < .01$). The FJS at 1 and 2 years postoperation were not significantly different ($P = .35$).

Radiographic Results

Radiographs at 2 years (Figure 4) were obtained in 180 out of 200 cases. The mean acetabular cup inclination was 39°. There were 15 hips (8%) that had grade 1 HO and 1 (0.5%) had grade 2. There was no evidence of stress shielding. The mean femoral neck shaft angle was 137°, and small superior notches were seen in 8 patients (4%). There was no observed femoral or acetabular component migration or loosening visualized. There was no migration or osteolysis of any of the implants.

Survivorship

For all patients, the mean cumulative revision rate was 0.5% at both 1 and 2 years postoperation (95% confidence interval: 0.07 to 3.5) (Figure 5). No revisions were reported for men. For women, the mean cumulative revision rate was 1.1% at both 1 and 2 years postoperation (95% confidence interval: 0.16 to 7.55). There was no

Table 3
Patient-Reported Outcome Measure Data and Number of Complete Responders at Each Time Point in Row Below.

Patient-Reported Outcome Measure (Mean, Range, *n*)	Preoperative	6 mo	12 mo	24 mo
Oxford Hip Score	21.8 (4 to 47)	43.5 (15 to 48)	45 (22 to 48)	45.2 (9 to 48)
	194	171	178	178
University of California, Los Angeles Score	4.8 (1 to 10)	7.3 (2 to 10)	7.8 (2 to 10)	8 (2 to 10)
	154	155	161	177
HOOS Symptoms	41.6 (0 to 95)	84.9 (30 to 100)	87.8 (40 to 100)	88.7 (35 to 100)
	124	128	133	132
HOOS Pain	45.5 (3 to 90)	90.7 (23 to 100)	93 (45 to 100)	93.8 (50 to 100)
	124	128	133	131
HOOS Daily Living	50 (10 to 100)	90.8 (46 to 100)	93.8 (53 to 100)	94.8 (54 to 100)
	124	128	133	132
HOOS Sports	28.8 (0 to 81)	83.6 (0 to 100)	87.4 (0 to 100)	89.4 (6 to 100)
	164	169	178	180
HOOS Quality of Life	22.4 (0 to 88)	76.2 (0 to 100)	81.6 (19 to 100)	84.5 (13 to 100)
	165	169	178	180
Forgotten Joint Score	n/a	73.9 (0 to 100)	80.6 (0 to 100)	81.7 (6 to 100)
		126	131	128

HOOS, hip disability and osteoarthritis outcome score.

significant difference in survival between the total, men, and women cohorts ($P = .3$).

Complications

There was 1 patient who had a bilateral HRA who died during the follow-up period from a recurrence of tongue cancer. There were 2 cases of deep vein thrombosis in the operated limb that were managed according to the local anticoagulation policy. A superficial wound infection was treated with antibiotics. Another patient reported a postoperative sciatic nerve palsy that had improved, but not resolved at the most recent follow-up. There were 8 cases of squeaking (4%).

We report 2 cases of revision in women in our series. The first was a 49-year-old who was revised at 3 months for residual postoperative pain and an excessively anteverted cup. The revision work-up also revealed a symptomatic L5 sequestered disc. This case was felt to be a technical error and misdiagnosis leading to revision. The patient underwent an uncomplicated revision to THA. The second revision occurred in a 52-year-old at 33.5 months due to debonding of the titanium hydroxyapatite coating from the ceramic. The revision surgeon noted that the coating was easily removed using curettes without major underlying bone removal. A full failure investigation and retrieval analysis were carried out, and other cases implanted over a period of > 3 years were subjected to closer monitoring. No definitive cause for the debonding was found, and the mechanism has not been repeatable during aggressive and extensive in vitro testing. No further adverse events of this type have been reported in any other patients to date, and infrequent events like this have been published for devices with similar coatings [12–15].

Discussion

There remains an unmet clinical need for treatment options available to the young patient who has an arthritic hip. There is a growing body of evidence that demonstrates the superiority of resurfacing over THA in return for high-impact sports or physically demanding jobs [4,16]. There is also evidence of a near normalization of gait function [17], a lower incidence of postoperative dislocation, and an equivalent revision rate in young adults in HRA and THA [18,19].

Despite the theoretical advantages of HRA, the current generation of cobalt-chrome-molybdenum resurfacing implants still carries the risk of long-term local and systemic metal toxicity for patients [20]. This makes an alternative, more benign bearing surface attractive. The successful introduction of a new CoC HRA, especially in today's regulatory landscape, means that novel implants must follow the philosophy of being well-designed and well-implanted.

The resurfacing device utilized features key design characteristics of its predecessor, the well-performing Adept MoM HRA which has been on the market for 18 years. The current device has an optimal radial clearance specific to implant size and a constant Cup

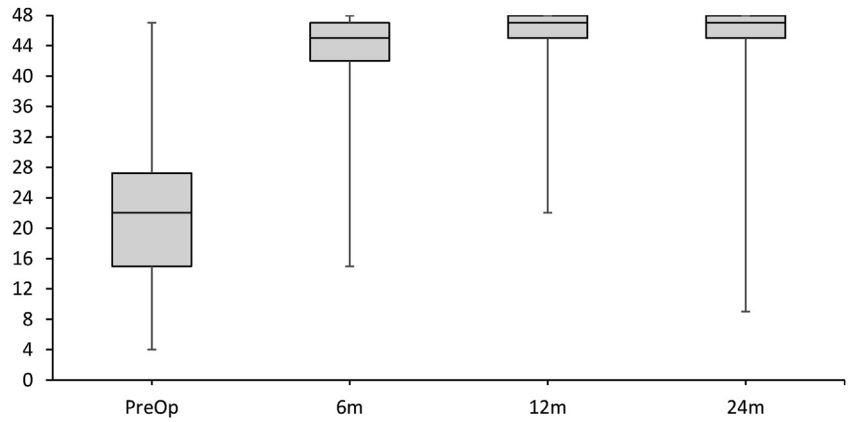

Fig. 3. Oxford Hip Score at 4 time points.

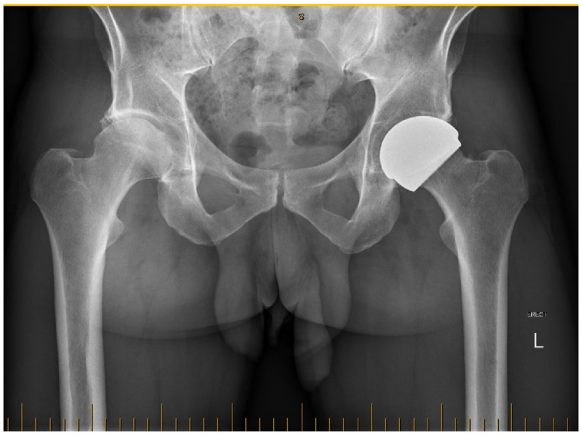

Fig. 4. Anterior–posterior radiograph of pelvis demonstrating a ceramic-on-ceramic hip resurfacing implant in situ.

Articular Arc Angle of 163°. These factors are well-demonstrated to be important to resurfacing implant performance and survival [21]. The device utilizes fourth-generation Biolox Delta, consisting of zirconia-toughened alumina. Alumina is an established articulating surface in THA [7,22] and has also been used in large-diameter bearings of up to 48 mm (Delta-Motion Finsbury Orthopaedics, Surrey, United Kingdom) [23], with excellent survivability and outcomes. Its use, however, in HRA has been very limited.

There have been historic studies detailing ceramic use in HRA-like implants [24–26], but to our knowledge, there has only been 1 other small case series of a CoC HRA [8]. Matharu et al. [8] reported early failures of their CoC implant in 5 patients. This implant featured a ceramic-polyurethane composite liner articulating against a cobalt-chromium femoral component that had a solid ceramic coating. The study reported universal failure and revision at a mean of 3 years. However, the very small study size and implant design meant the results should not be generalized.

To our knowledge, our study represents the largest case series to date of a modern CoC HRA implant. Our patient demographics demonstrate an expansion of the use of this device into a wider patient population [1] than possible with current MoM hip resurfacing devices. There were 91 out of 200 (46%) patients in our cohort who were women, and 96 out of 200 (48%) received a femoral implant smaller than a size 50 mm. These 2 factors have traditionally been linked with a higher risk of failure in MoM HRA. Registry data have consistently shown higher rates of failure of MoM HRA in women. This was thought to be a combination of smaller femoral head sizes [27], osteoporotic femoral necks, and a higher incidence of adverse reactions to metal debris [28].

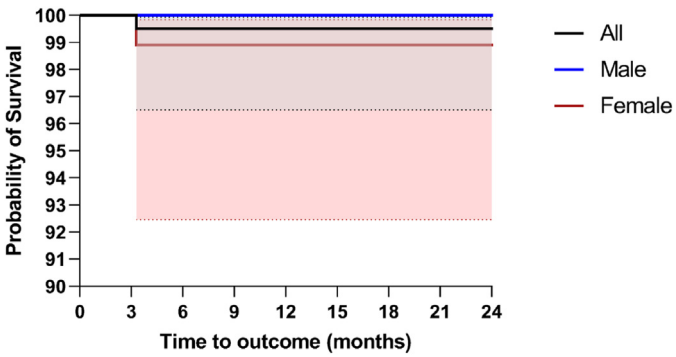

Fig. 5. Kaplan–Meier survivorship graph according to sex.

This device's all-ceramic construction negates concerns about metal ions. The cemented femoral component has a proportionally sized internal stem as opposed to a single-sized peg in the previous MoM HRA. A single-sized peg contributed a greater relative proportion of the overall stiffness in smaller femoral head sizes. Consequently, this increased stress shielding and subsequent fracture risk. The design protects against this and therefore allows the expansion of the implant's use to smaller patients. It will be interesting over time to assess if the use of a CoC bearing leads to a paradigm shift in the implant size.

Our PROMs data demonstrate significant early health gains. This cohort of patients reported excellent early analgesia (HOOS pain and HOOS symptoms) and overall improvement in hip function (OHS and FJS) by 6 months. At 2 years, the OHS increased by 23 compared to a minimum clinically important difference (MCID) of 9, the HOOS pain 48.3 compared to a MCID 33, and HOOS quality of life 62.1 3 compared to a 25 MCID [29]. Full return to play in high-impact sports took longer and continued to demonstrate statistically significant improvements at 1 year (UCLA) and even up to 2 years (HOOS Sports). Overall, after 2 years, 91 out of 200 (45%) of our patients reported engagement in frequent or occasional impact sports. These results are similar to previous studies looking at a return to higher-level sports in MoM HRA [4].

A UK-based randomized trial examined PROMs in THA and MoM HRA in patients who had a mean age of 56 years [30]. At 1-year postoperation, the mean OHS was 40.4 in the HRA group and 38.2 in the THA group. There was no statistically different change in OHS at the 5-year follow-up [31]. These scores are comparable to those of similar cohort undergoing CoC HRA, which had a mean OHS of 45 at 1-year postoperation. There are 2 Canadian studies that assessed the outcomes of MoM hip resurfacing with large head THA in patients <65 years [32,33]. In both studies, the UCLA score at 1 year significantly improved in both HRA (8 and 6.8) and THA (8.3 and 6.3) groups. Vendittoli et al. published results comparing HRA to THA using a 28-mm head, finding similar results at 1-year postoperation (UCLA score 7.1 with HRA and 6.3 with THA) [34]. These UCLA scores at 1 year are comparable to the mean 7.8 from our cohort undergoing CoC HRA.

Our radiological data confirm that the components were well-implanted, with no radiographic evidence of implant loosening or migration at 2-year interval films. The average inclination angle in this series was 39°, which is important in preventing edge loading and associated squeaking in CoC bearings [35]. The increased incidence of squeaking in progressively larger-diameter CoC bearings is well documented [36,37]. Our incidence of squeaking in 8 hips (4%) is slightly lower than published literature on larger diameter CoC THA [38,39].

We noted 16 cases of HO in our series, which is similar to the incidence to previous studies on HO in MoM HRA [40]. The patients in this series did not receive prophylactic nonsteroidal anti-inflammatory drugs or radiotherapy, although this has been suggested to reduce HO formation risk [41].

This case highlighted a potential limitation of this study relating to the early nature of the clinical and radiological follow-up. The implant-related revision occurred outside of the 2-year study window and underlines the importance of longer-term follow-up. However, the patient's symptomology started within the study period, and as such, the authors believe the 2-year mark to be sufficient to assess early outcomes.

In addition, the clinical results presented in this paper represent a series with extensive experience in HRA. The surgeons also had familiarity with the instrumentation from experience with the

precursor device. The authors recognize that these clinical results might not be easily translatable to a generation of younger hip surgeons with markedly less experience in HRA throughout training.

This study benefited from a high clinical and radiological follow-up rate despite the international nature of its cohort and the ongoing COVID pandemic. It also included a high number of non-designer surgeons that introduce heterogenicity into patient selection, surgical technique, and rehabilitation practice. Looking forward, future randomized controlled trials comparing modern CoC HRA to THA in young adults will be helpful in introducing novel resurfacing implants to the wider orthopaedic community, and results from the upcoming H1 trial are awaited.

In conclusion, the results of this resurfacing device, at 2 years postoperation are promising, with satisfactory outcomes in all recorded PROMs and radiological markers. Longer-term follow-up with increased patient numbers is required to restore surgeon confidence in HRA and expand the use of this novel HRA.

CRediT authorship contribution statement

David Lin: Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Data curation, Conceptualization. **Joshua Xu:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Patrick Weinrauch:** Writing – review & editing, Supervision, Investigation, Conceptualization. **David A. Young:** Writing – review & editing, Supervision, Investigation, Conceptualization. **Koen De Smet:** Writing – review & editing, Supervision, Data curation, Conceptualization. **Andrew Manktelow:** Writing – review & editing, Visualization, Supervision, Data curation, Conceptualization. **Paul E. Beaulé:** Writing – review & editing, Supervision, Methodology, Conceptualization. **William L. Walter:** Writing – original draft, Supervision, Resources, Formal analysis, Data curation, Conceptualization.

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