1 | 2021

CeraNews | TO THE POINT

HEALTH ECONOMICS & POLICY | OUTCOMES RESEARCH | IMPLANT MATERIAL

Next Generation of Hip Arthroplasty Options?

Isn't technology wonderful? Vaccine engineering is rescuing the world from the pandemic of Covid-19. On a smaller scale, technology may bring about a revolution in the dusty old world of hip arthroplasty. Two ceramic hip resurfacing products are showcased in this edition of CeraNews – truly innovative devices, in a world where innovation is hard to achieve. The existential battle between conservatives and progressives has been resoundingly won by the conservatives over the last decade as quite a few of the recent 'improvements' achieved the opposite of improving things.
Large diameter metal-on-metal hip replacements were not a success and many patients had to suffer the consequences. Ceramic was the answer – to avoid any metal-related issues, ceramic femoral heads are now used in most hip replacements worldwide. But thanks to a few pioneers like Harlan Amstutz, who sadly died in May 2021, hip resurfacing has not gone away. Harlan will be sadly missed by his patients, many of whom were prominent athletes. Their return to top-level sport continues to make headlines, backed up by RCT data documenting the significant advantages for resurfaced hips. They enable a faster and more symmetric gait, while patients with THA appear to be slower, with the normal hip doing more of the work[1].

Professor Justin P Cobb
Imperial College London, UK

View the full editorial

Hip Resurfacing: Current limitations and new solutions

Hip resurfacing with metal implants is limited by restrictive patient selection. Using ceramic components allows to eliminate metal-related issues and opens new options for this tissue-sparing procedure. Thanks to the biocompatible material, hip resurfacing could again become a realistic choice for active patients with a good bone stock.

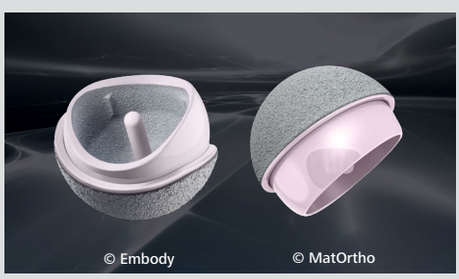
Understand the background

Case Reports: Back to high activity levels

An underwater photographer (42 years) and a climbing enthusiast (60 years) with severe hip problems received ceramic hip resurfacing implants. After successful surgeries, both returned to high activity levels very quickly, showing excellent scores in terms of function and gait analysis.
Case reports by: Mr Andrew Manktelow and Prof. Justin P Cobb

Comprehend the relevance

Biocompatibility for a tissue-sparing procedure



Just as in THA bearing couples, ceramics could be the (bio)logical alternative for hip resurfacing, too: It is the only material in hard-on-hard bearings proven in arthroplasty that does not release toxic metal ions. Currently, two ceramic-on-ceramic hip resurfacing systems are being tested clinically for safety and efficacy.

Check the evidence

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Stuttgart district court commercial register, no. 734826
VAT identification no. DE814031115

Responsible Editor: Dr. Henrich Mannel
Editorial Board: Prof. Justin P Cobb
Concept and Editing: Florence Petkow, Dr. Alessandro Alan Porporati

MT-00728-2106-EN-01

Next Generation of Hip Arthroplasty Options?

Professor Justin P Cobb
Imperial College London, UK

Dear colleagues,

Isn't technology wonderful? Vaccine engineering is rescuing the world from the pandemic of Covid-19. On a smaller scale, technology may bring about a revolution in the dusty old world of hip arthroplasty. Two ceramic hip resurfacing products are showcased in this edition of CeraNews – truly innovative devices, in a world where innovation is hard to achieve. The existential battle between conservatives and progressives has been resoundingly won by the conservatives over the last decade as quite a few of the recent 'improvements' achieved the opposite of improving things.

Large diameter metal-on-metal hip replacements were not a success and many patients had to suffer the consequences. Ceramic was the answer – to avoid any metal-related issues, ceramic femoral heads are now used in most hip replacements worldwide. But thanks to a few pioneers like Harlan Amstutz, who sadly died in May 2021, hip resurfacing has not gone away. Harlan will be sadly missed by his patients, many of whom were prominent athletes. Their return to top-level sport continues to make headlines, backed up by RCT data documenting the significant advantages for resurfaced hips. They enable a faster and more symmetric gait, while patients with THA appear to be slower, with the normal hip doing more of the work[1].

The two-incision approach to the hip has also failed the test of time, while the anterior approach to hip arthroplasty with or without a traction table now has a solid evidence base demonstrating quicker and easier recovery, allowing same-day or overnight surgery in selected patients. Metabolic markers of stress confirm the higher levels of function in the early postoperative period[2]. This elevation of hip arthroplasty to the ambulatory surgery centres will be a major economic driver, as patients can be treated safely at a lower cost.

A ceramic hip resurfacing which combines these two domains has the potential of giving us entirely new options. The muscle sparing approach, avoiding both metal-related issues and a femoral stem, are obviously attractive. However, there is a serious caveat: extended learning curves are well-documented for both the anterior approach and the hip resurfacing procedure. Combining them might even cause additional problems.

Again, new technology could contribute importantly to achieve good outcomes. Virtual Reality training in arthroplasty can support surgeons in acquiring new skills in arthroplasty faster and at a higher level[3]. A growing range of assistive technologies can help to ensure that the surgery's targets are achieved[4], reassuring both patients and their surgeons.

After a long 2020, the summer of 2021 has an optimistic feel: technology is overcoming the pandemic, and is also offering the prospect of a next generation of hip arthroplasty options. In my view, the future is looking rosy, well actually pink.

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1. Gerhardt D, Mors TGT, Hannink G, Van Susante JLC. Resurfacing hip arthroplasty better preserves a normal gait pattern at increasing walking speeds compared to total hip arthroplasty. *Acta Orthop.* 2019;90(3):231-236. doi:10.1080/17453674.2019.1594096.

2. Zhao HY, Kang PD, Xia YY, Shi XJ, Nie Y, Pei FX. Comparison of Early Functional Recovery After Total Hip Arthroplasty Using a Direct Anterior or Posterolateral Approach: A Randomized Controlled Trial. *J Arthroplasty.* 2017;32(11):3421-3428. doi:10.1016/j.arth.2017.05.056.

3. Logishetty K, Rudran B, Cobb JP. Virtual reality training improves trainee performance in total hip arthroplasty: a randomized controlled trial. *Bone Joint J.* 2019;101-B(12):1585-1592. doi:10.1302/0301-620X.101B12.BJJ-2019-0643.R1.

4. Cobb JP, Kannan V, Brust K, Thevendran G. Navigation reduces the learning curve in resurfacing total hip arthroplasty. *Clin Orthop Relat Res.* 2007;463:90-97. doi:10.1097/BLO.0b013e318126c0a5.

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Hip Resurfacing: Current Limitations and New Solutions

Medical implants have to comply with a steadily increasing multitude of regulations to demonstrate safety and performance. Metal-on-metal hip resurfacing arthroplasty (HRA) devices are associated with metal related pathologies, and due to the concerns related to their unique risks and problems identified in the medical device reporting systems and recalls, this type of implant is subject to increased scrutiny from regulatory bodies. To date there are two metal-on-metal HRA's approved by the FDA and three approved under a CE mark in Europe. Hip resurfacing with metal implants is still possible but is limited to well-selected patients and generally performs best in males. Use of ceramic in hip resurfacing avoids the metal-related pathologies observed with metal-on-metal hip resurfacing devices. Ceramic, a material with excellent biocompatibility, allows hip resurfacing to once again become a realistic option for patients with good bone stock.

Resurfacing as Alternative to Total Hip Arthroplasty

Hip resurfacing arthroplasty was developed as a bone and tissue-sparing alternative to total hip arthroplasty (THA) providing a more anatomical hip reconstruction. In the case of HRA revision, a primary THA device can be used, potentially delaying the total joint replacement in patients by decades. Until recently, only metal-on-metal (metal-on-metal) implants were available for HRA. Such HRA systems have been subject to metal (Cobalt Chromium Molybdenum, CoCrMo) related problems which may now cause surgeons to question their views on the existing and the potential advantages of this type of implant. In young male patients, HRA has yielded excellent results according to a study of the International Hip Resurfacing Group:

"Overall cumulative Kaplan-Meier survivorship was 88.9% at 22 years (95% CI: 88.3–89.5%). 2 HRA designs (…) led to inferior results while all others yielded similar survivorships. Excluding (these), implant survivorship in 11,063 cases was 95% at 10 years and 90% at 22 years. In men, implant survivorship was excellent: 99% at 10 years and 92.5% at 21 years. In females, implant survivorship was 90% at 10 years and 81.3% at 22 years. The overall revision rate was 3.6% with most common reasons for revision being implant loosening and adverse local tissue reactions. The best survivorship was found in patients with osteoarthritis (95% CI, 92.1–93.3% at 22 years), the poorest was among dysplastic hips (78.3%; 95% CI, 76.5–80.1% at 20 years, $p < 0.001$)."[1]

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Hip Resurfacing: Current Limitations and New Solutions (continued)

Conceptual advantages

The advantages of HRA are well documented with perhaps the most important being preserving of the structure of the femoral head and neck, more reliable restoration of leg length and offset than in THA, a more anatomical femoral loading with stress shielding consequently reduced and the potential to delay the need for a THA. The risk of early dislocation is lower by a factor of 2 to 4. In patients with HRA on one side and THA on the other, the HRA limb accepts more weight and pushes off with greater force in gait analyses. The 2014 guidance issued by the National Institute of Health and Care Excellence (NICE) of the UK considers (metal-on-metal) HRA suitable for patients whose life expectancy exceeds the expected lifetime of THA devices and who probably will need a revision procedure. Delaying the first full-fledged THA by up to 20 years or more results in a higher quality of life for the patient and significantly lowers the cost and risks of a later revision. As health care providers follow regulations and strive to avoid risks, these advantages are mainly reserved for young, active male patients. It is not apparent that HRA has a lower survival rate than a conventional THA in male patients with good bone stock at any age. Evidence now emerging also suggests that latent mortality is lower following HRA than THA in equivalent patients.

Ceramic options

The Australian Register Report of 2020 states that 'metal related pathology is the most common reason for revision after 7 years' for HRA. Using ceramic instead should therefore minimise the major risks and contraindications for HRA.

Ceramic components have the potential to make the advantages of HRA accessible to a wider range of patients including females. Today, two ceramic-on-ceramic HRA systems are in the process of clinical evaluation*. Both rely on BIOLOX®*delta* material which has been widely used in hip arthroplasty since 2003, defining a benchmark for ceramic materials in arthroplasty in general. Ceramic-on-ceramic HRA has the potential to change practice and outcomes of hip arthroplasty significantly.

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1. Van Der Straeten C. Hip resurfacing arthroplasty in young patients: international high-volume centres' report on the outcome of 11,382 metal-on-metal hip resurfacing arthroplasties in patients ≤50 years at surgery. *Hip Int.* 2020:1120700020957354. doi:10.1177/1120700020957354.

2. Logishetty, Kartik; Muirhead-Allwood, Sarah K.; Cobb, Justin P. Hip resurfacing – what is its role in modern orthopaedics? *Bone and Joint 360*, 9/1,4-9 2/2020.

Logishetty K, Muirhead-Allwood SK, Cobb JP. Hip resurfacing – what is its role in modern orthopaedics? *Bone & Joint 360*. 2020;9(1):4-9. doi:10.1302/2048-0105.91.360742.

3. Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip. *Technology appraisal guidance [TA304]*. Published February 26, 2014 www.nice.org.uk/guidance/ta304. Accessed June 10, 2021.

4. *FDA Executive Summary Memorandum - Metal-on-Metal Hip Implant Systems.* Prepared for the June 27-28, 2012 Meeting of the Orthopaedic and Rehabilitation Devices Advisory Panel. Gaithersburg Hilton, Gaithersburg, Maryland.

5. European Commission, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). *Opinion on The safety of Metal-on-Metal joint replacements with a particular focus on hip implants.* 2014. https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_042.pdf. Accessed June 10, 2021.

6. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). *Hip, Knee & Shoulder Arthroplasty: 2020 Annual Report*, Adelaide; AOA, 2020: 1-474. [Accessed from: https://aoanjrr.sahmri.com/annual-reports-2020].

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Ceramic Resurfacing: Addressing a Clinical Need

Mr. Andrew Manktelow Nottingham University Hospital, UK

Mr. Andrew Manktelow, Nottingham University Hospital, UK

Osteoarthritis of the hip remains a common and frequently debilitating condition. As the associated symptoms of pain, restricted mobility worsen and limit function, conservative treatments are no longer effective and a surgical solution may be required. Thankfully the outcomes of carefully planned and performed primary hip arthroplasty surgery are excellent. Our patients can expect a return to a sound level of function, without pain and with reliable longevity in the vast majority of cases. With the majority of hip arthroplasty surgery being performed in the mid to late 60s these outcomes will mean that many patients will not be confronted with the increased risks and concerns of revision surgery. The same cannot be said for our younger patients.

The best option in the surgical management of hip arthritis in younger and more active patients remains a point of contentious discussion. There are similar concerns in the management of other patients who wish to maintain, or indeed require, higher levels of physical activity, with a more physiological range of movement. These increasing demands can result in higher rates of dislocation and wear in traditional hip arthroplasty.

The theoretical benefits of a hip resurfacing procedure are well-rehearsed and include the potential preservation of femoral bone stock, a more physiological loading of the proximal femur, a safer range of movement and the opportunity for a relatively conservative revision to a stemmed arthroplasty. While technical developments in fixation and bearing surface tribology in more traditional procedures have undoubtedly improved outcomes, many patients are not able to return to their desired functional level and many of our younger patients will require revision surgery, potentially involving challenging implant removal and bone stock restoration as a result of wear and loosening.

While some metal on metal bearings have proved a clinical concern, many of the more disconcerting scenarios surrounded by the use of stemmed large head metal on metal bearings. Certain hip resurfacing designs resulted in higher levels of an abnormal reaction to metal wear debris than others and results in smaller sizes and in women were less reliable. Against that background the results of the two recognized metal-on-metal hip resurfacing bearings when using sound component design and metallurgy, alongside accurate component alignment, in carefully consented male patients with an adequate head size and sound bone quality, have remained sound.

The H1® (Embody Ltd.) and the ReCerf® (MatOrtho Ltd.) ceramic hip resurfacing devices are both undergoing Clinical Investigations approved by the UK Health Research Authority.

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Ceramic Resurfacing: Addressing a Clinical Need (continued)

Simultaneously the use of large head ceramic bearing couples in more traditional hip arthroplasty surgery has continued with sound clinical results. The opportunity to combine the benefits of a ceramic bearing coupled with the bone preservation and safer mobility of a hip resurfacing has significant potential benefits for our patients. Particularly if we are also able to bring that concept into the surgical management of hip arthritis in both men and women and in a wider range of head sizes.

The stated design concept behind the development of a ceramic hip resurfacing has been to deliver the potential benefits of hip resurfacing more safely to a wider group of our young and active patients. Aiming to improve clinical outcomes, maintain and increase longevity while ensuring that revision to a stemmed arthroplasty, if required, remains a reasonable option.

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MT-00728-2106-EN-01

Case Report 1: 60 Years Old High Activity Male Patient with Stated Concerns of Metal Sensitivity

Courtesy by: Mr. Andrew Manktelow, Nottingham University Hospital, UK

A 60 year old recently-retired consultant anaesthetist was seen with significant pain and restricted mobility associated with his arthritic left hip. His situation had progressed rapidly and by the time of his surgery he was experiencing significant discomfort with walking and had groin and proximal thigh pain at night and at rest after activity. Clinical examination revealed a fit and healthy male with a fixed flexion deformity in his left hip and a painful restriction in his available range of movement. Radiology confirmed significant degenerative wear in the hip with no cystic change or sinister concern. The patient was an extremely keen and active gentleman who amongst other activities, such as walking, yoga, training and cycling, was also a highly accomplished climber. He was very keen to return to all his recreational activities following surgery. In addition, he had a previously diagnosed metal sensitivity and reaction and was not happy to be considered for a metal-on-metal bearing for that reason.

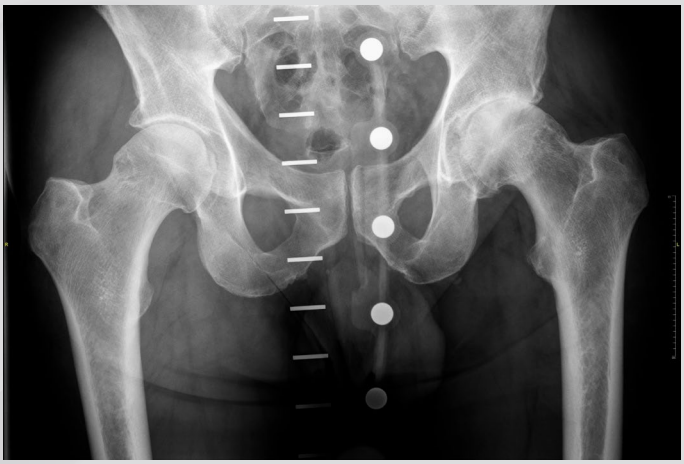

Fig 1: Radiograph showing severe osteoarthritis in the left hip with absent joint space and sclerosis with fixed adduction deformity giving rise to an apparent shortening in the left leg.

Concerned by the risk of instability whilst climbing, the options and possible benefits of considering a ceramic bearing and a hip resurfacing were discussed.

The ReCerf®, manufactured by MatOrtho Limited, is undergoing Clinical Investigation approved by the UK Health Research Authority.

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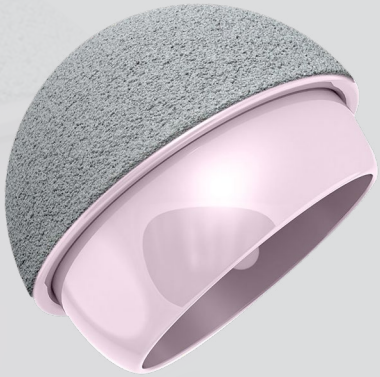
MT-00728-2106-EN-01

Case Report 1 (continued)

Following careful consent, including the relatively short follow-up for the ReCerf® device, a decision was taken to proceed with surgery.

At the time of surgery, via a standard posterior approach, using exactly the same exposure and release as required for a metal-on-metal hip resurfacing, a ReCerf® device was implanted. The 56mm colour-coded socket was implanted using a specifically-designed acetabular insertion device, used alongside the standard ADEPT® socket insertion handle and alignment jig. Socket position was targeted at between 35 and 40 degrees of abduction with anteversion matching the native socket and the transverse acetabular ligament, typically around 15 degrees.



ReCerf® Ceramic Hip Resurfacing
Courtesy: MatOrtho Limited

The standard ADEPT® medial referencing jig was used to position a guide wire into the femoral head and neck, determining bone preparation and component position. Again, the same instrumentation used for the ADEPT® device is used with ReCerf®. With preparation complete, a compatible and similarly colour-coded 50mm femoral component was cemented in place, using standard cement fixation and impaction technique to the established ADEPT® metal-on-metal device. (As such the ReCerf® concept uses of the majority of the ADEPT® metal-on-metal instrumentation and would therefore provide the surgeon with the opportunity to determine bearing surface material with flexibility intraoperatively.)

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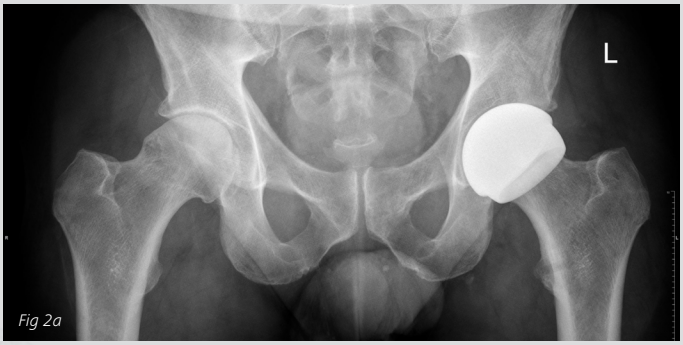
Case Report 1 (continued)



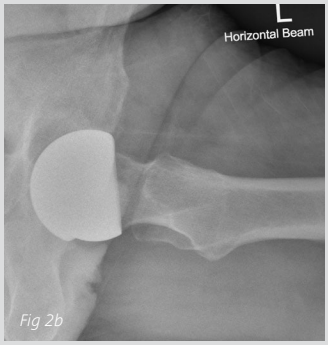


Fig 2a and 2b: Radiographs showing satisfactory AP and lateral postoperative appearances of a left ReCerf® Ceramic hip resurfacing.

The patient was managed comfortably on the ward over night and was comfortable and safe to be discharged the next day, on post op day 1, to continue with rehabilitation at home. Weightbearing was protected with two crutches for the first 3 weeks, then onto one crutch on the contralateral side proceeding to full weight bearing as tolerated by 6 weeks.

The patient's progress was reviewed initially at 6 weeks and again at 3 months. By 10 weeks the patient had already regained largely normal function, in part likely due to his strong drive and determination to return to his desired level of activity. In fact he had already re-started his climbing with confidence and control perhaps a little earlier than his surgeon would have advised, but without concern, as demonstrated in figure 3.

Fig 3: Courtesy Mr. A. Manktelow – With permission of the patient

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Case Report 1 (continued)

When asked about his experience and the decision to use the ReCerf® device the patient comments "I was very keen to have a resurfacing as I believe the risk of late dislocation is greatly reduced. I had always been fit and active until the arthritis curtailed my activities – even walking. My real passion is rock climbing where a high degree of hip mobility is essential".

This patient, alongside over 400 others who have received the ReCerf® device, continues to do well albeit at early follow-up. This exciting project to realise the advantages of hip resurfacing with ceramic bearings could herald a new dawn for the procedure with potential advantages for our young and active male and female patients. As with all hip surgery, attention to detail in patient selection, planning, exposure and implant alignment are crucial. However, as more long-term data becomes available, the ReCerf® design group hope that the ReCerf® device will provide a positive contribution to the surgical management of hip arthritis.

Mr. Andrew Manktelow is a Consultant Orthopaedic Surgeon at Nottingham University Hospitals NHS Trust in the UK. Andrew has a specialist hip interest with a tertiary referral practice for complex primary and revision cases. With regard to primary hip surgery, Andrew has a high-volume practice encompassing all hip pathology in patients with a wide age range. This case mix requires the use of different fixation and bearing surface options, dependent on patient demands, bone quality and morphology. Andrew has had a hip resurfacing practice for 20 years and has continued to perform this procedure in carefully selected patients. Andrew is Head of the Elective Orthopaedic Service in Nottingham, a previous President of the British Hip Society and is on the Council of the British Orthopaedic Association.

ReCerf® was developed in collaboration with an international surgeon team including Prof. Paul E. Beaulé (Canada), Mr. Andrew R. J. Manktelow (UK), Dr. Koen A. De Smet (Belgium) and Prof. William L. Walter (Australia)

Further reading: de Villiers D, Richards L, Tuke M, Collins S. Ceramic resurfacing: the future and challenges. *Ann Joint.* 2020;5(12):1-6. doi:10.21037/aoj.2019.12.11.

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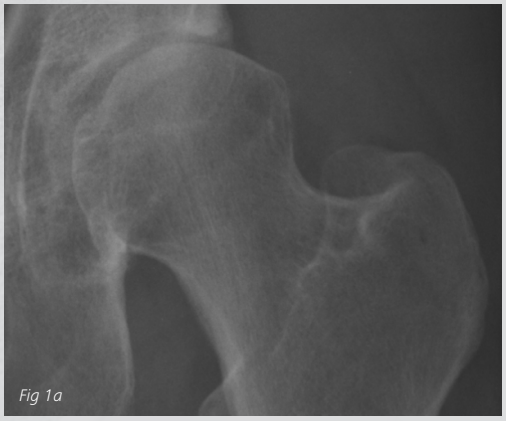
Case Report 2: 42 Years Old Female Patient with Dysplastic Hip

Courtesy by: Prof. Justin P Cobb, Imperial College London, UK

A 42 years old underwater photographer and ex dancer presented with a painful left hip now preventing exercise. On examination, she was fit and strong with pain on flexion and internal rotation of the hip.

Imaging revealed a dysplastic hip with superior and anterior subluxation and joint space loss (figures 1a and 1b).



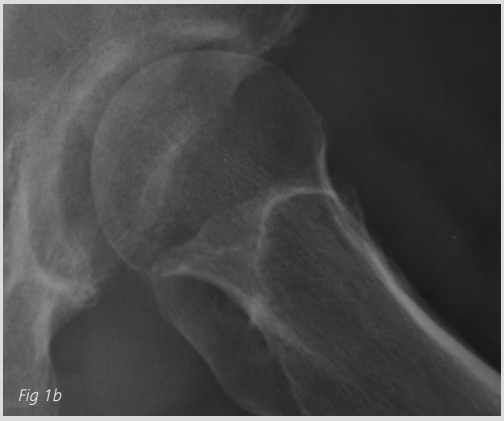
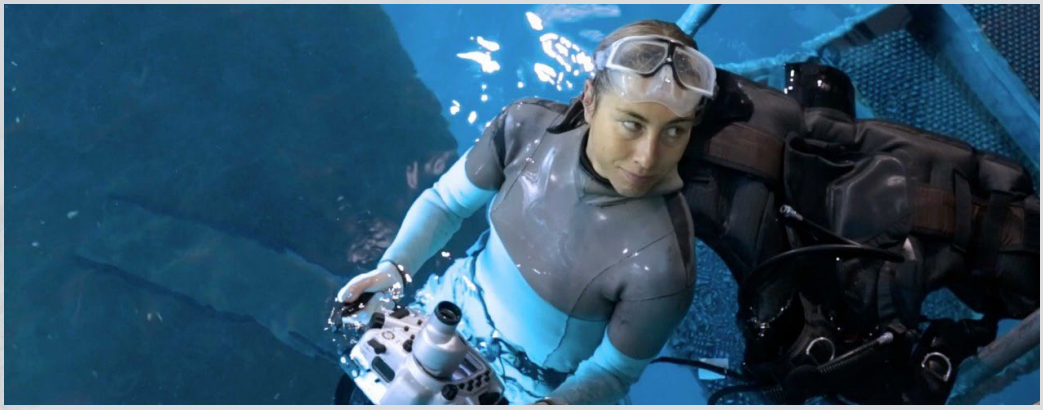


Fig 1a and 1b: Left dysplastic hip of a 42 years old under water photgrapher and ex dancer with pain and subluxation



Courtesy Prof. J. Cobb – With permission of the patient

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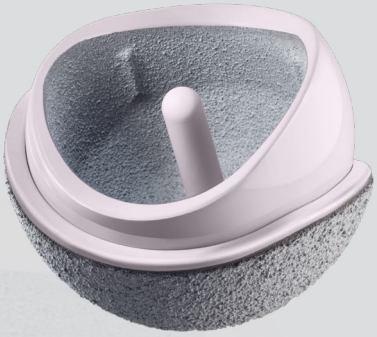
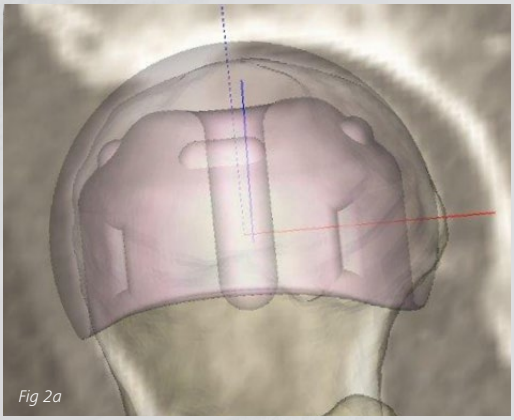
Case Report 2 (continued)



H1® Ceramic Hip Resurfacing
Courtesy: Embody Ltd

Planning using low dose CT[1] illustrated that the femoral head was best resurfaced with a 46mm diameter component (figures 2a and 2b).



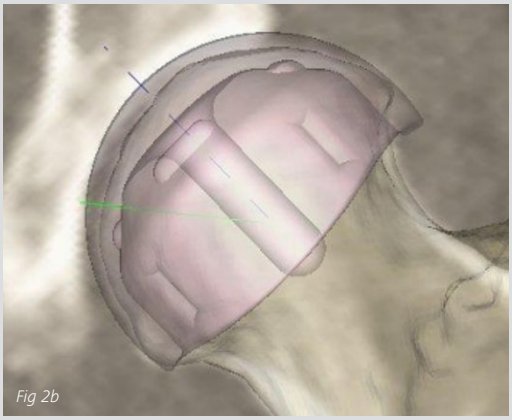


Fig 2a and 2b: Planned head position and orientation 135 degrees and neutral on neck by means of low dose CT[1]

The matching acetabular component could be inserted at 45 degrees of inclination and 15 degrees of anteversion providing good restoration of head coverage without psoas impingement (figures 3a and 3b).

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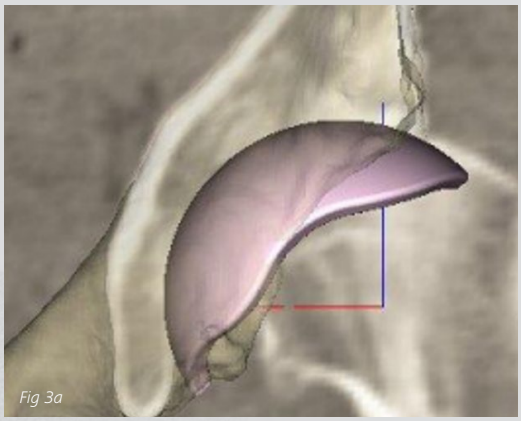


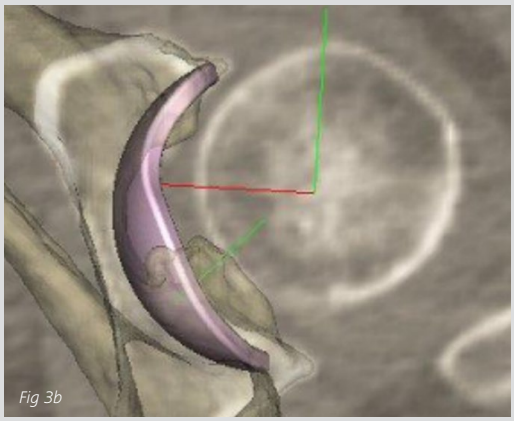
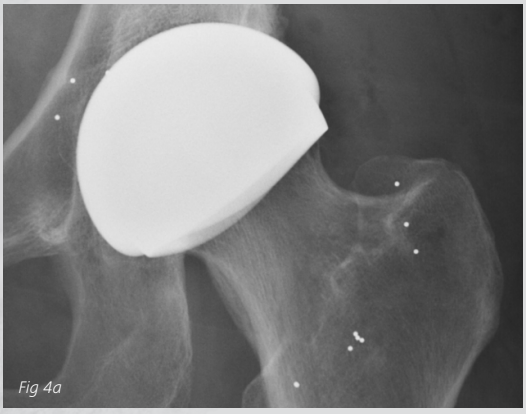


Fig 3a and 3b: Planned cup position and orientation 45 degrees inclination and 15 degrees anteversion by means of low dose CT[1]

At operation, the 46mm head was confirmed, maintaining femoral head bone-stock without compromise on the acetabular side. The single use reamer ensured stable press-fit without undue force.

X-rays taken postoperatively show the position and orientation achieved (figures 4a and 4b).



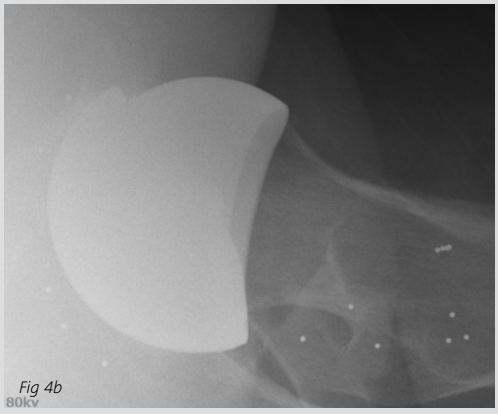


Fig 4a and 4b: Day 1 postop films with RSA beads showing achieved position and orientation

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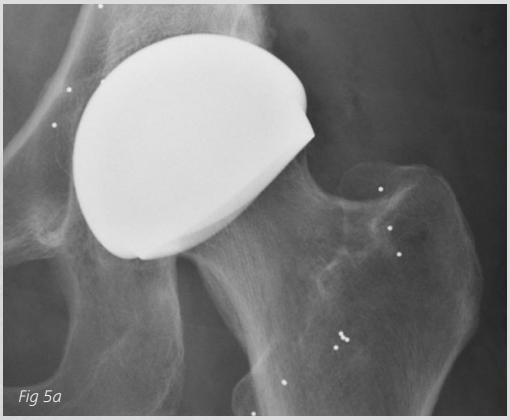
Case Report 2 (continued)

After 3 years the acetabular interface in mature, and both the femoral neck and periprosthetic pelvic bone is well maintained (figures 5a and 5b).



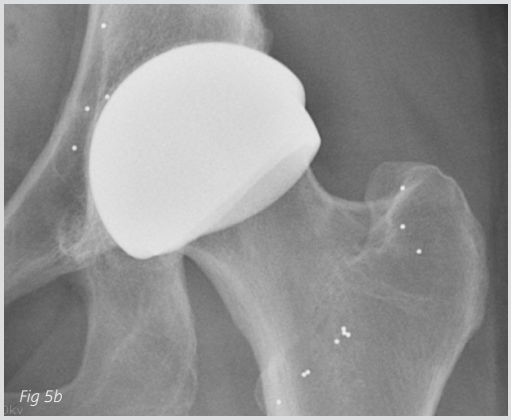


Fig 5a and 5b: Day 1 postop and 3 years postoperatively showing acetabular osseointegration and periprosthetic bone quality

In functional terms, the patient returned to work rapidly, both on land and underwater. Full marks were achieved with the Oxford Hip Score within 6 months after surgery, while substantial functional gains were still captured in the second postoperative year using personalized score Imperial Score, where 100% is the preoperative aspiration for each activity (figures 6a and 6b).

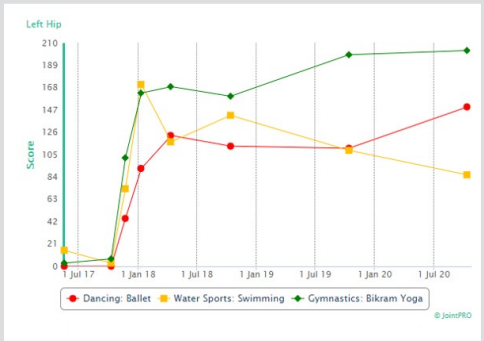


Fig 6a: Oxford Hip Score (Range 0-48; 48 = 100%)

Fig 6b: Imperial Score (Range 0-200; 100 = preop aspiration)

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Case Report 2 (continued)

Professor Cobb is the head of academic orthopaedic surgery at Imperial College London, working at King Edward VII Hospital for Officers and Charing Cross Hospital. He leads the MSk lab, a group of over 30 surgeons, engineers and scientists who recently moved into a new home: the Sir Michael Uren Hub in White City, West London. The research areas in the lab range from the nanostructure of bone through psi guides to device design and team VR training, Professor Cobb is a founder of Embody Orthopaedic, a spin-out from Imperial which is manufacturing the H1®. He is a civilian advisor in orthopaedics to the Royal Air Force, and is Orthopaedic Surgeon to Her Majesty the Queen.

Further reading: 1. Saracco A, Grassi A, Romagnoli M, et al. Reduced-dose computed tomography is the most accurate method to measure ceramic hip resurfacing cup version. *Eur J Radiol.* 2020;128:109040. doi:10.1016/j.ejrad.2020.109040.

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Making Resurfacing Biocompatible: The Ceramic Option

Removing metal from bearing surfaces eliminates the most important limitation of Hip Resurfacing Arthroplasty (HRA). Ceramic-on-ceramic bearing could be the (bio-) logical alternative: It does not release toxic metal ions and allows thin wall geometries necessary for HRA.

Ceramic-on-ceramic HRA devices have the potential to offer the advantages of metal-on-metal resurfacing devices like the Birmingham and Adept Hip resurfacing system without Cobalt and Chrome ion release. Currently, two ceramic-on-ceramic hip resurfacing systems are undergoing clinical evaluations in a trial for approval.*

Ceramic: A benchmark for bearing couples behaviour

Ceramic materials have a number of natural advantages when used as implant components in the human body. They resist practically any chemical reaction in physiological conditions; they exhibit excellent biological behavior and they show low immunological response. Further, specialized high-performance ceramics are highly resistant to wear with minimal production of wear debris, high fracture strength and toughness, and a very low immune response – all prerequisites for long-term survival of ceramic implants[1]. Ceramic materials coated with vacuum-plasma-sprayed titanium for cementless osseointegration are also compatible with MRI procedures[2].

Due to these technical attributes, surgeons around the world have opted for ceramic bearing components for millions of hip arthroplasty surgeries over the last four decades. Since its market introduction in the year 2003, the pink colored BIOLOX®*delta* ceramic has become the most widely used ceramic implant material in hip replacement defining a true benchmark in this field.

BIOLOX®*delta* is a zirconia-toughened alumina matrix composite ceramic with high fracture strength, excellent wear properties against both ultra high molecular weight polyethylene and importantly against itself. Its introduction opened up new horizons for making complex geometries and a wider range of orthopedic innovations possible.

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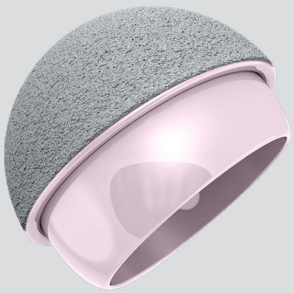
Making Resurfacing Biocompatible: The Ceramic Option (continued)

Fewer immune reactions, fewer bacterial infections



ReCerf® Ceramic Hip Resurfacing
Courtesy: MatOrtho Ltd.

The biocompatibility of alumina matrix composites like BIOLOX®*delta* has been proven clinically, in *in-vitro* studies and in *in-vivo* animal studies [6,7,8,9]. BIOLOX®*delta* particles do not stimulate inflammatory responses, do not cause DNA damage, nor oxidative stress in human cells in clinically relevant doses *i.e.* the material and its debris are neither cytotoxic nor genotoxic[6]. Furthermore, recent in-vitro studies and analyses of explants have demonstrated that bacterial adhesion on BIOLOX® ceramic surfaces is reduced in comparison to other bearing materials. Studies also show a reduced biofilm formation on BIOLOX® surfaces compared to metal and polymer surfaces[10,11].

Ceramic-on-ceramic HRA Systems

Due to very high fracture strength, toughness and wear resistance, BIOLOX®*delta* appears well-suited for use in hip resurfacing. Thin-walled ReCerf® acetabular cups made of this material have shown very high resistance to critical impact loads in a laboratory study under extreme conditions. All components passed a lateral fall simulated impact test without fracture and showed no visible damage. Eighty four percent of cups further survived a high velocity car crash simulated impact known to be sufficient to fracture the pelvis; beyond this loading some fractures of the cup edges could be produced[4].

H1® Ceramic Hip Resurfacing
Courtesy: Embody Ltd.

Both systems comprise monoblock femoral and acetabular components. These consist of BIOLOX®*delta* ceramics with vacuum-plasma-sprayed titanium and hydroxyapatite for cementless fixation. This type of textured surface is highly stable and biocompatible at the same time. It has been successfully used for decades on bone-facing surfaces of orthopaedic implants, enabling good primary fixation as well as long-term stability via osseointegration.[2] MatOrtho utilizes cement fixation for the ReCerf® HRA head to match the fixation method used for the majority of HRAs to date.

The H1® (Embody Ltd.) and the ReCerf® (MatOrtho Ltd.) ceramic hip resufacing devices are both undergoing Clinical Investigations approved by the UK Health Research Authority. H1® was implanted for the first time in 2017, ReCerf® in September 2018. The H1® has passed the phase safety study and patient enrollment has been concluded. The ReCerf® trial is underway with a number of implantations designated for special access by specialist surgeons under their local approval systems with all cases followed assiduously. To date 412 ReCerf® HRAs have been implanted.

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Making Resurfacing Biocompatible: The Ceramic Option (continued)

Resurfacing for smaller anatomies and women?

The reasons for data showing women to have lower implant survival with metal-on-metal HRA remain obscure. A number of reasons have been postulated and some high-volume surgeons have shown better outcome survival in women than men. There is little doubt that the reasons are multifactorial and it should be borne in mind that HRA was introduced to a large population concurrently with surgeon learning and wide indications for HRA being factors. Most HRA devices have fallen by the wayside during the demographic period with some performing very poorly more so than others and the BHR was for many of the early years forming a high volume of data. For many years this implant was only available in 4 mm size increments dictating a method of head size choice which consequently induced what is now recognised as undersizing in many cases. This will have led to greater difficulty for ideal placement and a strong possibility of neck impingement which is in turn associated with edge loading cup placement and increased metal ion release.

Thus, todays HRA geometry, sizing operative indications, and technique training is very different for which statistics will emerge in due course but needs to have a restart from about 10 years ago. There is little doubt however that removing metal ions will be of benefit for the technology. The articulating surfaces feature all the proven qualities of the BIOLOX®*delta* ceramic material. The most important are the lowest wear rate of all bearing materials, no metal ions, minimal wear debris generation, no polyethylene particles, superior lubrication and extremely low friction as well as precisely defined clearances. Ceramic materials are highly resistant to corrosion. As a result, issues that can lead to elevated wear rates and a high risk of adverse reaction to metal debris in metal-on-metal implants are ruled out by using a ceramic-on-ceramic bearing.

A change from metal to BIOLOX®*delta* was shown to maintain low wear under tests known to accelerate the wear rate of metal-on-metal. Wear tests simulating microseparation conditions in large diameter ceramic resurfacing bearings have reported low wear rates; 47 times lower than that reported for metal-on-metal bearings under these same adverse conditions: 'The low wear rate and highly biocompatible nature of this ceramic potentially offers an advantage over current meta-on-metal hip resurfacing designs and may represent the next generation of resurfacing devices'[5]. While there is currently limited data on these two implant devices it is possible that the indications may be widened clinically for what has been a restricted group more recently with metal-on-metal resurfacing devices including inclusion for smaller patients and women. With the use of ceramic-on-ceramic bearings, HRA could once again become a realistic option for patients with good bone stock in hip arthroplasty.

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1. Piconi C, Porporati A A. Bioinert Ceramics: Zirconia and Alumina. *Handbook of Bioceramics and Biocomposites.* doi:10.1007/978-3-319-09230-0_4-1. Springer International, 2015.

2. Hanawa T (2019) Titanium–Tissue Interface Reaction and Its Control With Surface Treatment. *Front. Bioeng. Biotechnol.* 7:170. doi:10.3389/fbioe.2019.00170.

3. Porporati A A, Piconi C, Mettang M, Deisinger U, Reinhardt C, Pitto R. Ceramics for artificial joints: The relevance of material biocompatibility. in: *Bioceramics.* https://doi.org/10.1016/B978-0-08-102999-2.00012- 0. Elsevier, 2021.

4. de Villiers D, Collins S. Resistance of a novel ceramic acetabular cup to critical impact loads. *J Engineering in Medicine* 2020. doi:10.1177/0954411920941383.

5. de Villiers D, Collins S. Wear of large diameter ceramic-on-ceramic hip bearings under standard and microseparation conditions. *Biotribology.* 2020; 21:100117. doi:10.1016/j.biotri.2020.100117.

6. Asif I M. *Characterisation and Biological Impact of Wear Particles from Composite Ceramic Hip Replacements. [PhD thesis].* Leeds, UK: University of Leeds; 2018. etheses.whiterose.ac.uk/20563. Accessed March 6, 2020.

7. Cunningham BW, Hallab NJ, Hu N, McAfee PC. Epidural application of spinal instrumentation particulate wear debris: a comprehensive evaluation of neurotoxicity using an in vivo animal model. *J Neurosurg Spine.* 2013;19(3):336-350. doi: 10.3171/2013.5.SPINE13166. Epub 2013 Jun 28.

8. Kretzer JP, Mueller U, Streit MR, et al. Ion release in ceramic bearings for total hip replacement: Results from an in vitro and an in vivo study. *Int Orthop.* 2018;42(1):65-70. doi:10.1007/s00264-017-3568-1.

9. Porporati AA, Piconi C, Mettang M, Deisinger U, Reinhardt C, Pitto R. 12 - Ceramics for artificial joints: The relevance of material biocompatibility. In: Osaka A, Narayan R, eds. Bioceramics From Macro to Nanoscale. *Elsevier Series on Advanced Ceramic Materials.* Elsevier; 2021. doi:10.1016/B978-0-08-102999-2.00012-0. Accessed November 10, 2020.

10. Pitto RP, Sedel L. Periprosthetic joint infection in hip arthroplasty: Is there an association between infection and bearing surface type? *Clin Orthop Relat Res.* 2016;474(10):2213-2218. doi:10.1007/s11999- 016-4916-y.

11. Lenguerrand E, Whitehouse MR, Beswick AD, et al. Risk factors associated with revision for prosthetic joint infection after hip replacement: a prospective observational cohort study. *Lancet Infect Dis.* 2018;18(9):1004-1014. doi:10.1016/S1473-3099(18)30755-2.

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