Seroma and Osteolysis with BP Hip Resurfacing

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Abstract

Background: Hip resurfacing arthroplasty (HRA) has more engineering challenges compared to total hip replacement (THR): (1) The larger femoral head has much greater frictional torque, (2) Just one acetabular component matches the femoral component, so implant prominence and impingement are common, (3) The polyethylene is necessarily thin and vulnerable to wear and deformation, (4) The functional demands are higher, (5) The HRA operative procedure is demanding and intolerant of flaws, (6) Osteolysis and seroma formation are more common with HRA compared to THR.

Patients ask for HRA and when the femur is blocked by incarcerated implants, infection, or deformity they should. Also, the higher functional performance of HRA attracts patients, but this outcome cannot be promised. Bone retention with HRA attracts patients, particularly the young, the metal sensitive and those for whom prior THR on the other side did not work out. Because of demands on the bone, the implants, and surgical technique, the HRA outcomes are not as predictable as THR but can be better.

Methods: This study is about osteolysis--the biggest challenge for polyethylene HRA. Osteolysis has been reduced -- but not eliminated -- with highly cross-linked polyethylene. The Buechel-Pappas (BP) design has remained constant through all seven companies that have manufactured the implant since its inception in 1981. The BP has been the only polyethylene HRA implant available consistently for the last 20 years. This study is also about seroma formation. Seromas and osteolysis occur unpredictably because of individual genetic and immune response variation among patients. The retained large femoral head and neck create more intrarticular pressure leading to seroma formation.

Results: Osteolysis was identified in patients with the BP HRA. Seromas occurred in many patients but often resolved over time. All components were placed without cement using sintered beads or plasma spray. The patients ranged in age from 20 to 79 years. Radiolucent osteolytic cystic lesions appeared in 5.1% of patients after 1 to 14 years (mean, 5 years). Osteolysis and seroma formation were more common with the larger implant dimensions, typically used in men. The osteolytic areas were 2 to 12 cm. The components usually remained well fixed. Sixty-one-percent of osteolysis patients had revision surgery, for a revision rate of 3.1%. Seromas do not have a reliable resolution strategy. Osteolysis and seroma formation are not related to the amount of polyethylene wear but rather to the reaction to wear debris. The granulation tissue in the osteolytic areas contained numerous activated macrophages. Patient specific genetic factors, age and gender drive the inflammatory immunologic response to the wear particles.

Conclusion: Osteolysis and seroma occur with the BP HRA. The incidence has become less with highly cross-linked polyethylene, but it is still more common compared to THR. It comes from polyethylene wear debris and the osseointegration coatings. Seroma formation and osteolysis remain unpredictable and unsolved issues that await a biologic solution. Polyethylene is the future of HRA and is safer than either metal or ceramic.

Introduction

With the end of the availability of the Birmingham Hip Resurfacing after 20 years, there is more interest again in polyethylene for HRA. Because of the high demand on the polyethylene and how thin it must be, osteolysis has always been the major barrier to the success for polyethylene HRA [2, 4-6]. Osteolysis in the context of implants refers to loss of the supporting bone. Osteolysis is also seen in 48% of THRs when studied by computed tomographic (CT) scan or magnetic resonance imaging (MRI) [16]. It was also a common cause of failure with early cemented implants and conventional polyethylene. Osteolysis may be less common with highly cross-linked polyethylene.

Early investigators thought osteolysis was from cement breakdown that caused a foreign body reaction. As cement techniques improved or cement went away, osteolysis was more often associated with wear of the polyethylene-bearing surface [9]. Osteolysis can be silent and associated with a good clinical outcome. It can also progress rapidly and become painful (Fig 1.).

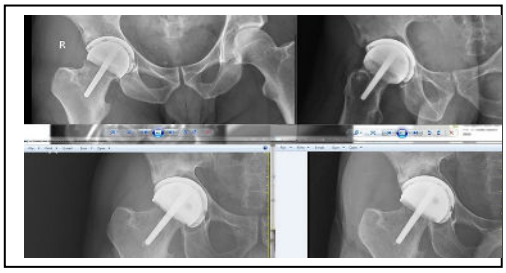


Fig. 1. These radiographs show the progression of osteolysis around a BP HRA over 3 years in a very active 44-year-old man.

Many cases need revision surgery. Both the incidence and progression of osteolysis is unpredictable.

The histology of osteolysis demonstrates fibrous tissue with foamy histiocytes, activated macrophages and scattered giant cells. There can be extensive osteoclastic bone resorption. Lymphocytes, plasma cells, and polymorphonuclear cells are rare indicating metal sensitivity is not likely. On high-power examination, the histiocytes contain foreign bodies within the cytoplasm. When examined under polarized light, particles of polyethylene and metal are seen. The presence of metal debris in the tissues is important: (1) Metal particles accelerate wear as they become trapped in the articulating surface, (2) phagocytosis of metal particles is a potent stimulator of osteolysis, and (3) metal particles are generated by corrosion or sometimes from shear forces from frictional torque or impingement. (4) Metal sensitivity has been offered as an explanation for osteolysis but is not likely because of absence of lymphocytes [9]. Also, it is common for patients to experience osteolysis in just one of two hips, even if identical implants are used.

Osteolysis is more common and more serious for HRA patients compared to THR patients for 5 reasons: (1) The enlarged articulation with HRA compared with THR generates much greater frictional torque, (2) The surfaces are subjected to much greater stress, (3) The patients are typically younger and more active, (4) The femoral neck is large, and (5) Underlying dysplasia and limited choice of implant dimensions make implant impingement a much more common and relevant issue in HRA compared to THR.

Very large fluid collections, described as seromas, are common with HRA and can be associated with osteolysis. Most seromas resolve over time, but some persist and become very large. Both osteolysis and seroma

formation are seen much more commonly when imaging includes CT or MRI (Figs. 2, 3).

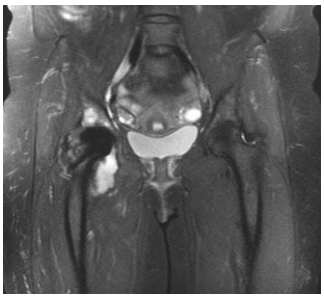


Fig. 2. This MRI shows a seroma and osteolysis in a 33-year-old woman with wear of the polyethylene liner 14 years after surgery.

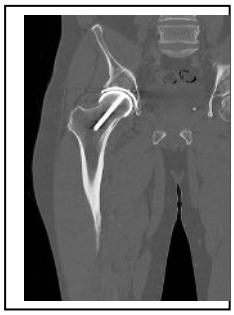


Fig. 3. This CT shows a large seroma without osteolysis or polyethylene wear 9 years after surgery in a very active 50-year-old man.

Methods

Osteolysis can lead to a poor outcome in HRA. There have been many implants used for HRA. All early HRA implants disappeared from lack of continued success due to osteolysis, loosening, impingement, avascular necrosis and femoral neck fracture [6]. Bearing surface wear has been cited as the explanation for many failures. There has been an evolution through different polyethylenes, metal and, most recently, ceramics. There has been no consistently successful bearing surface for HRA. We know polyethylene can work. It can have a low incidence of osteolysis, as there were few cases of osteolysis using Stryker X3 polyethylene in the small sizes 40 and 44 mm [17]. This study is concerned only with polyethylene and the BP prosthesis because it has been the only consistently available HRA over the last 20 years. [2, 4-6, 18].

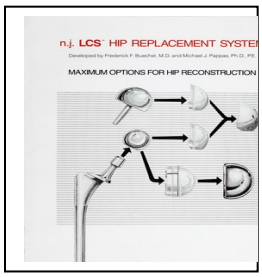
Polyethylene has been the most common bearing surface for both THR and HRA. Intermittent success interspersed with significant failures have been the story for HRA [6]. Sometimes, even the early designs and early (conventional) preparations of polyethylene proved successful for over 40 years.

Only the Buechel-Pappas HRA has been in continuous use for over 45 years. Also, only the Buechel-Pappas (also called the BP, New Jersey Conservative Hip, or BioCore 9) has been used long enough to make truly long-term observations. It will take many years for the implants currently in clinical trials to demonstrate superior safety (Polymotion).

Fred Buechel, an orthopedic surgeon, and Mike Pappas, an engineer, designed the BP HRA. It did not work well in their hands. Buechel and Pappas were best known for designing the LCS mobile-bearing knee. They also designed implants for the shoulder and ankle in addition to a THR and bipolar hip. Dr. Pritchett designed a more effective BP technique, more effective instruments and used the improved polyethylene [18, 19]. The BP results were better that the other HRA implants as demonstrated in the American Joint Replacement Registry. The less than hemisphere shape of the BP acetabular component copies the cemented Indiana Conservative hip. The femoral component is anatomically shaped. The BHR and Conserve femurs have flat-topped femurs and copy the Townley.

Manufacturing History

The BP started at DePuy. Because of the success of the LCS knee, there was interest in an LCS hip (Fig. 4).



Technique guide for the LCS New Jersey Hip System. It includes HRA, THR, and bipolar replacements.

This interest was short lived. Neither HRA nor mobile bearing total hips became popular. Buechel and Pappas used the royalties they received from DePuy, for their LCS knee, to begin their own implant development. At the same time Richard (Nik) Nikolaev, an innovator and implant sales representative, left DePuy to run Protek for Professor Maurice Mueller. I met him first in Phoenix, AZ in 1982. Nik worked closely with Buechel and Pappas and was the catalyst for commercializing the use of titanium nitride ceramic coatings [1, 14].

The first BP resurfacing implants came from Depuy (Warsaw, IN) and the second from Endomedics (Redbank, NJ). They were sintered bead cobalt-chrome and were used from 1981-1988. In 1988, Protek, under the leadership of Mr. Nikolaev, took over development, testing, and compliance of the BP acetabular component and self-aligning bipolar implants. Nikolaev changed the implants from sintered beads to plasma spray and changed the cobalt chromium to titanium. In 1989, the implants became titanium-nitride coated. In 1989, Professor Mueller sold Protek to Sulzer. The BP resurfacing implants and self-aligning bipolar were then turned over directly to Drs. Buechel and Pappas. They formed Endotec, Inc.

In 1994, the acetabular polyethylene locking mechanism was changed and protected by a new patent [3]. Also in 1994, sintered beads became an option again. The FDA clearance for cementless use of a BP design was granted. There have been no design changes in the BP since 1994. The implants were consistently TiN coated but are offered with either sintered beads or plasma spray.

Current FDA Status

The Food and Drug Administration's (FDA) status for HRA (Class III) is more strict than for THR (Class II). Companies offering resurfacing implants are smaller and more likely not to meet the regulatory burden; they subsequently withdraw from providing implants or have their implants recalled. With the end of the Birmingham Hip Resurfacing, there is no fully FDA-cleared HRA in the USA. The only resurfacing implants are the off-label BP implants or clinical trials. Clearly, this is not sustainable because of imperative cases such as blocked femurs.

Endotec continuously offered the current BP hip resurfacing as a 3-part FDA class II device starting in 1989 (Fig. 5).

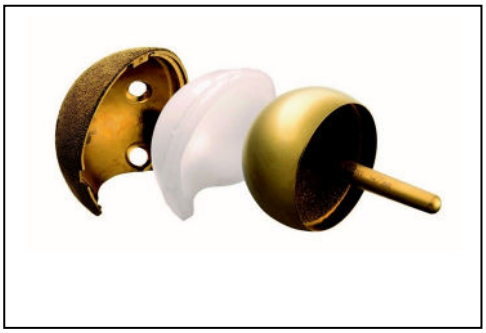


Fig. 5. This is a photograph of the cementless titanium nitride-coated 3-part BP HRA from Endotec.

On January 3, 2005, all 2-part resurfacing implants became class III devices [8]. This eliminated all prior HRA implants except the 3-

part BP. In 2024, the FDA after auditing, inspecting and continuous registration of the BP implants for 35 years as 3-part Class II device decided, without notice, that the BP was also a class III device. There was no restriction on the class II use of the components as a total hip replacement or femoral hemiarthroplasty. Also in 2024, the FDA warned the use of plasma spray and highly cross-linked polyethylene were manufacturing changes requiring additional FDA clearance. A warning was given and additional testing was performed. The implants passed all testing. Endotec and a successor company (Synovo Production) stopped producing implants.

The polyethylene initially used for the BP was 415. It became 1050 in 2005. After 2007, the BP was offered both with highly cross-linked 1020 and conventional 1050. The FDA clearance was for ASTM standard F648-84, not a specific polyethylene. All of the polyethylene used has met the standard. Also, the polyethylene used has always been the same as two of the larger manufacturers and was not made by any of the BP manufacturers.

Class III implants inherently have more risk compared to Class II and require a controlled study to obtain Premarket Approval (PMA) for use. These PMA studies are too time consuming and costly to be practical. The BP implant has several peer-reviewed publications. It accounts for 1/3 of the HRA cases in the American Joint Replacement Registry (Pritchett cases). There is also a patient-specific database with a mean 9-year follow-up.

Starting February 17, 2026, Real World Evidence will be used by the FDA for clearance. Studies such as Truveta, based on actual patient experience and documented in the patients' Electronic Medical Records provide the needed information. This Real World Evidence is more valid scientifically and more useful compared to the extensive laboratory testing used previously. Clearly, if implants are to be tested, they need to be real life, actually used retrievals, not laboratory specimens [1].

Premarket Approval (PMA) studies have not been reliable predictors of future outcomes anyway because the stringent controls on patient and surgeon enrollment, during the PMA, are not consistent with real world use. Plus, the follow up is too short. The BHR pulled all the smaller sizes in 2015 after their performance did not match the predictions.

It is important to note that FDA warnings and voluntary recalls are not final determinations. They are cautionary statements based on potential rather than proven issues. Patients rely on these FDA posts after surgery when they have problems. Patients consistently say they do not want the FDA to stand in the way of their getting HRA.

The FDA website warnings circulate on the internet and in Artificial Intelligence (AI). They are often interpreted as facts. The FDA does not reliably take their posts down after the implants are established as reasonably safe and effective by Real World or other Testing Evidence. There may be changes ahead, as Signature Orthopaedics from Australia obtained the rights to the Zimmer Recap, designed by Tom Gross, MD. They will be offering this metal-on-metal device on a Class II off-label basis in the USA starting toward the end of 2026.

BP Manufacturers

Almost all orthopedic implants have just a single manufacturer. Occasionally a highly successful implant, such as the Charnley Hip or Neer Shoulder and now potentially the Recap, will have a second manufacturer. The BP has had 7 manufacturers, including DePuy, where the BP was part of the LCS hip line.

The companies offering the BP HRA are:

Depuy 1981-1983

Endomedics Inc. 1984-1988

Protek Inc. 1988-1989

Endotec Inc. 1989-2009 (NJ and FL)

Endotec Inc. 2009-2019 (FL and CA operated by Korean Bone Bank and successors)

Synovo Production Inc. 2020-2024 (CA operated by Woo Joo Kim and not affiliated with Synovo Preserve)

BioCore 9 2022-2026 (NJ operated by Makris, Matalak and Dr. Buechel)

Pathophysiology of Osteolysis

The genetic factors driving the immune response to the metal wear debris with the Birmingham Hip Resurfacing have been well worked out using the Orthotype Algorithm. It is based on certain HLA genotypes [10]. Similar work will be able to predict the inflammatory immunologic response to polyethylene. Modifying the genetic susceptibility to osteolysis in mice has been possible by gene transfer.

Particle induced macrophage activation is induce by the wear debris particles. A complex network of inflammatory mediators mediates the process of bone resorption. These are Tumor Necrosis Factor, IL-6, IL1 and the RANK pathway chemokines. These inflammatory mediators respond to the specific genes that are upregulated in certain individuals. In some settings, trauma or infection can also induce the genomic upregulation or genome instability. Colony Stimulating factor upregulates the RANK pathway and the proinflammatory cytokines necessary for osteolysis. Both trauma and

inflammation or infection are behind conditions such as pigmented villonodular synovitis, which has parallels to osteolysis.

Of 51 specimens that were sent to pathology, the tissue look mostly like rheumatoid arthritis.

There has been some interest in modulating osteolysis with immunosuppressives such as rapamycin. We have had some success in treating osteolysis with Tymlos, which is a parathyroid hormone-related protein analog. This is a bone building medication requiring a daily subcutaneous injection

Osteolysis Results

Starting in 2012 BP resurfacing implants in this study were examined for the presence of osteolysis. The clinical outcomes were excellent in 95%. Some of the excellent results were in cases where osteolysis and seromas were also present. Osteolysis was seen in 5.1%. It occurred from 1 to 14 years following HRA. The patients were highly active (mean UCLA activity score 8 out of 10). They were also young (mean age 47 years). The larger femoral head diameters of 47 mm or greater accounted for almost all cases. Early return to function was the strongest patient factor for osteolysis development. All cases of seroma formation were associated with high early activity. The extent of osteolysis and seroma formation is not directly related to the amount of polyethylene wear.

Summary of Osteolysis Literature Following BP HRA

Dr. Beuchel performed 25 cases from 1983-1988; 10 developed osteolysis (mean 33 months, range, 12 to 54 months). The osteolysis was attributed to both the cobalt-chrome sintered bead implant and thin conventional polyethylene [2].

Dr. Buechel performed 60 cases from 1990 to 1995 after the implant became titanium-nitride coated titanium. At a follow-up of 8 to 60 months, the failure rate was 5% mostly from wear and osteolysis. The revision rate of these cases, however, became 49% by 18 years [4, 5].

Prasad, et al, performed 25 BP HRAs from 1989 to 1994; 17 were revised for osteolysis or femoral neck fracture (mean, 4 years, 10 months) [15].

Pritchett performed 216 cases from 2008 to 2012. The acetabular diameter in these cases was smaller (mean of 45.5 mm). Also, Pritchett used the BP acetabular component in revision cases paired with a variety of cobalt chromium femoral components including the Townley (BioPro), Conserve (Wright Medical), Birmingham (Smith and Nephew) and, most commonly, the Recap (Zimmer). Osteolysis was seen in 3% of these cases. Some of these were metal-on-metal revisions for metallosis including the above and the Corin and ASR [19].

BP cases starting in 2012 are entered in into the American Joint Replacement Registry when it started. They were also entered into an Institutional Review Board approved study in Seattle. One of the significant issues in HRA is that individual surgeon results have driven the narrative rather than a registry. The registry results are not collected by the surgeon and are an excellent source of independent information.

The osteolysis incidence was 3.2% in the AJRR. BP cases after 2019 except for revision from metal-on-metal, were all with the BP femoral component and the mean articular dimension was 49 mm. The osteolysis incidence was 5.1 %. Revisions were performed in 61% of patients with osteolysis for an osteolysis revision rate of 3.1%.

Revision to THR was the most common. This reduces the frictional torque and allows better access for bone grafting. Some cases were

treated with bearing surface exchange and retention of the HRA acetabular shell with grafting through the holes in the shells (Figs. 6 and 7). The outcomes have been positive in 90% of revisions.

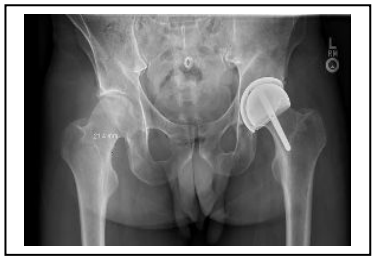


Fig. 6a. This AP pelvis radiograph shows a well-placed BP HRA in an active 40-year-old man.

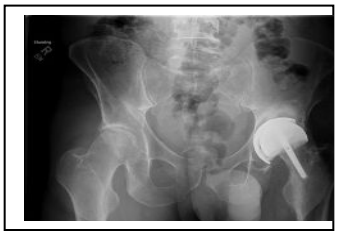
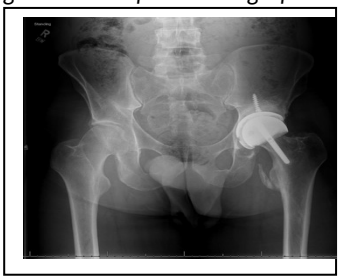


Fig. 6b. This AP pelvis radiograph shows polyethylene wear and osteolysis 6 years later.

Fig. 6c. This AP pelvis radiograph shows the acetabular component has been removed and revised with screw fixation and bone grafting.



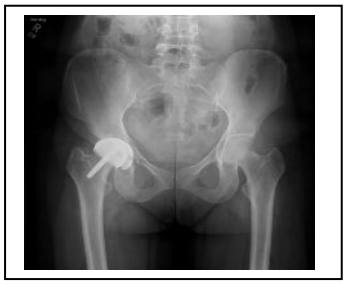


Fig 7a. This AP pelvis radiograph shows polyethylene wear and osteolysis 10 years after a BP HRA in a 37-year-old female athlete.

Fig. 7b. This AP radiograph shows revision of the polyethylene liner and graft placement through the fixation holes of the acetabular shell.

Seroma Formation

Seroma formation is more common in HRA compared to THR. This is inevitable because the retained femoral head and neck increase the intra-articular pressure. Seromas are often associated with osteolysis. A seroma is pocket of clear fluid that forms within the body after surgery. Seromas form from disruption of the lymphatic channels. The surgically created dead space leads to the accumulation of lymphatic, inflammatory, and exudative fluids. Seromas can be perpetuated by their inflammatory response of wear debris from the joint. Seromas are difficult surgical complications to resolve. The seroma fluids prevent tissue adhesion. Seromas are known for their persistence. Aspiration, compression, and surgical intervention have inconsistent success [20].

Seroma formation has been associated with increased activity in the early postoperative period following HRA. Seroma formation was found to be associated with nearly all cases of osteolysis in this series. Polyethylene liners from 47 mm and above accounted for 91% of cases. Sclerotherapy with doxycycline has been suggested as a treatment [7]. In persistent cases, a coxoperitoneal shunt has been suggested [12]. The Trebay Medical Shunt to relieve elevated synovial fluid pressure around failed total hip replacements was not a suc 90's and has not bee .

The ble treatment stra as are usually not pai port pain. Repeated

aspirations are discouraged. The correct surgical response is a measured one and based on specific and extensive prior HRA experience. It does not parallel THR treatment. Osteolysis is treated with anti-inflammatory medications, bone-building supplements, and activity modulation.

Discussion

Osteolysis can occur on just one side of bilateral identically implanted implants. It has occurred around a THR but not an HRA when a patient has one of each. Osteolysis can occur with or without screw holes and with both ceramic-coated titanium and cobalt chromium implants. Osteolysis occurs with both sintered bead and plasma spray coatings.

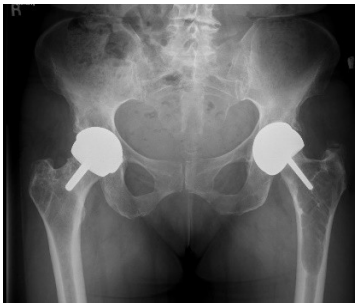


Fig 8. This AP Pelvis Radiograph shows a 65 year-old woman 20 years following a BHR on the Right and Conserve Plus on the left. There is severe femoral osteolysis on the left and significant acetabular stress shielding on the right.

Osteolysis runs a variable course. It can be aggressive and it also can remain limited. Osteolysis is more common in patients who are more active and with larger size implants. Osteolysis is not tied to any one manufacturer, implant design, or method. Osteolysis is much more common in HRA compared to THR. It can be seen with limited wear and, occasionally does not occur even with complete wear through [13]. Only the frequency of osteolysis has become less with highly cross-linked polyethylene. The severity of osteolysis is not less compared to conventional polyethylene. The value of highly cross-linked polyethylene is its greater ability to reduce wear and provide a more consistent outcome. Conventional polyethylene is capable of very long-term survivorship with some resurfacing cases lasting 40 years. Conventional polyethylene is just not as predictable. In the end is not the material but the genome driven host response.

It is critical to distinguish adverse wear from the normal bedding in of the polyethylene. An experienced observer is needed. The polyethylene often looks thinner in the anterior/superior position in a normal case after 2 years. HRA sockets are not THR sockets and they may be look vertical and less covered due increased anteversion as the surgeon struggles to get anterior coverage for a larger and thinner shell than a THR surgeon would choose. Patients are often not helped by surgeons who are not familiar with polyethylene HRA commenting on the acetabular component selection and placement.

Predicting when osteolysis might occur is not possible. It can occur early and in association with a large seroma. It can also occur many years later. It is difficult to treat. It usually responds well to revision surgery. Seromas can persist for years (mean, 4 years) but usually subside after a time. Patients find seromas extremely frustrating. Without ready explanations and reliable treatment, it is rare to find a patient who accepts a seroma well--once they are aware of it. Most seromas go undetected for both HRA and THR. THR surgeons and other physicians who are not familiar with polyethylene HRA are often not helpful in supporting patient acceptance and understanding seromas. Particle Panic is common.

Osteolysis and seroma formation remain problems in need of a solution. Understanding and controlling the personalized patient driven

mediators driving seroma and osteolysis formation are the future keys to successful management of these two important complications. Polyethylene remains a safer acetabular bearing surface than either ceramic or metal for HRA. Metal on Metal implants can have stress shielding and metal reactions. Ceramic on Ceramic has noise and can have fracture or stress shielding. Polyethylene has been the solution for failed metal-on-metal resurfacing or ceramic on ceramic [17]. Polyethylene is not perfect but it is the future of HRA.

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