Université de Montréal

Hard-on-Hard Bearings in Total Hip Arthroplasty for Young Active and Patients with Osteoarthritis

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Résumé

Introduction

Le remplacement prothétique est le traitement ultime pour la dégénérescence avancée de la hanche. Cependant, l'usure prématurée des surfaces de frottement métal contre polyéthylène conventionnel (MoPc) réduit de façon importante sa longévité chez les patients jeunes et actifs. Pour surmonter ce problème, des surfaces de frottement alternatives ont été proposées, notamment les couples métal-métal (MoM) et céramique-céramique (CoC). Le but de cette étude est d'évaluer la survie à long terme de ces surfaces d'appui lors du remplacement total de la hanche (PTH) avec une articulation de petit diamètre MoM ou CoC et du resurfaçage de la hanche (RH) MoM.

Méthodes

La survie des implants a été évaluée à long terme dans deux études où les sujets ont été randomisées pour une PTH MoM 28 mm (99 hanches) ou un RH (104 hanches) dans l'étude 1 ou une PTH CoC (71 hanches) ou MoPc (69 hanches) dans l'étude 2. Les mesures d'efficacité principales comparés, au dernier recul, était le taux de révision, les taux de complications, score fonctionnels validés, et les signes radiographiques anormaux.

Résultats

Étude 1, après un suivi moyen de 15 ans, la survie avec révision pour toutes causes était de (89,2 % pour le RH versus 94,2 % pour la PTH MoM, p=0,292). Toutefois avec une révision aseptique comme critère d'évaluation, la survie était significativement plus élevée dans les PTH (97,4 % contre 89,2 % ; p=0,033). Les deux groupes ont obtenu des scores fonctionnels similaires. Étude 2, après un suivi moyen de 21 ans, la survie était significativement plus élevée (96,9% vs 73,6%, p<0,001) pour les PTH CoC versus MoPc. À l'évaluation radiographique, 13 % des MoPc étaient considérés descellées versus aucune CoC et 61 % des MoPc versus 6 % des CoC présentaient des signes d'ostéolyse (p<0,001). Les PTHs CoC avaient des scores moyens de WOMAC significativement plus élevés que le groupe MoPc (11.0 vs 19.4; p = 0.048).

Conclusion

L'utilisation de couples dur-dur MoM ou CoC en PTH ou RH ont offert une excellente survie et fonction à long terme chez une clientèle de sujets jeunes et actifs. En comparaison, le taux d'échec élevé du couple MoPc confirme qu'il doit être abandonné. Les résultats de cette étude doivent être

mis en perspective avec les résultats futurs des nouveaux couples métal contre polyéthylènes réticulés.
Mots-clés : arthroplastie totale de la hanche, resurfaçage de la hanche, céramique sur céramique, métal sur métal, survie randomisée, révision, complications.

Abstract

Introduction

Prosthetic replacement is the ultimate treatment for advanced hip degeneration. However, premature wear of the metal-on-conventional polyethylene (MoPc) bearing surfaces significantly reduces its longevity in young and active patients. To overcome this problem, alternative bearing surfaces have been proposed including metal-on-metal (MoM) and ceramic-on-ceramic (CoC) bearings. The aim of this study is to evaluate the long-term survival of these bearing surfaces during total hip replacement (THA) with a small diameter MoM or CoC bearings and hip resurfacing (HR) MoM.

Methods

Long-term implant survival was assessed in two studies where subjects were randomized to 28mm MoM THA (99 hips) or HR (104 hips) in Study 1, or CoC THA (71 hips) or MoPc (69 hips) in Study 2. The main outcome measures compared, at final follow-up, were revision rate, complications' rate, validated functional scores, and abnormal radiographic signs.

Results

Study I: after a mean of 15 years, survivorship with endpoint all-cause revision was 89.2% for HR versus 94.2% for MoM THA MoM ($p = 0.292$). However, with aseptic revision as an endpoint, survivorship was significantly higher in MoM THA (97.4%) compared to (89.2%) in HR ($p = 0.033$). Both groups achieved similar functional scores. Study II: after a mean follow-up of 21 years, survivorship was significantly higher in CoC (96.9%) versus (73.6%) in MoPc THAs ($p<0.001$). On radiographic evaluation, 13% MoPc were considered loose versus non in CoC, and 61% MoPc versus 6% CoC showed osteolytic signs ($p<0.001$). CoC had better mean WOMAC scores than MoPc (11.0 vs 19.4; $p = 0.048$).

Conclusion

Good long-term survival and function for HR and MoM 28-mm THA implants with similar overall rates of complications and revisions. CoC provided excellent results compared to MoPc at more than 20-year follow-up.

Keywords: total hip arthroplasty, hip resurfacing, ceramic-on-ceramic, metal-on–metal randomized survivorship, revision, complications.

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List Of Acronyms and Abbreviations

ANSM: Agence nationale de securité du médicament et des produits de santé

AOANJRR: Australian Orthopedic Association National Joint Replacement Registry

ARMD: ARMD: adverse reaction to metal debris

BHR: Birmingham Hip Resurfacing

CaO: calcium oxide

CoC: ceramic on ceramic

CoPxl: ceramic-on-highly crosslinked polyethylene

CoP: ceramic on polyethylene

CrCo : Chrome cobalt

HXLPE: highly cross-linked polyethylene

LDH: Large Diameter Head

MgO: magnesium oxide

MoM: metal on metal

MoP: metal on polyethylene

MoPc: metal on conventional polyethylene

MoPx: metal on cross linked polyethylene

MoPxl: metal-on-highly crosslinked polyethylene

NSAIDs: Non-steroidal anti-inflammatory drugs

OA: osteoarthritis

PE: polyethylene

PEc: Conventional polyethylene

RCTs: randomized control trials

R_{head}: radius of the femoral head

ROM: range of motion

THA: total hip replacement

HR: hip resurfacing

X-ray: x-rays

Ti: Titanium

UCLA: University of California, Los Angeles (UCLA) Physical Activity Scale

UHMWPE: ultra-high molecular weight polyethylene

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Inde

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Introduction

It is estimated that 37% of Canadians aged 20 or older have been diagnosed with arthritis reported osteoarthritis as their only form of the condition. Of these, 12% had pain in the hip; 29% in the knee, and 29% in both (1). Development of osteoarthritis (OA) involves progressive damage of articular cartilage (wear and tear), subchondral cysts, formation of osteophyte, periarticular ligamentous laxity, muscle weakness, and synovial inflammation (2). Finally, the hip joint becomes painful and stiff, resulting in reduction in quality of life and disability. Initially, the patient is treated with analgesic and anti-inflammatory drugs. If, however, symptoms persist, patients may also benefit from local intraarticular infiltrations of local anesthetics and anti-inflammatory drugs. However, osteoarthritis is a degenerative disease that progresses continuously, in the absence of an adequate response to conservative treatment, a total hip replacement (THA) is usually offered to patients in order to alleviate pain, regain mobility and improve quality of life (3).

THA is recognized as one of the most cost-effective surgeries. It provides pain relief and improved mobility when other treatment becomes ineffective (4, 5). Over the last 5 years, the number of hip and knee replacements performed in Canada has been steadily increasing. In 2017-2018, 58,492 hip replacements were performed in Canada, representing increases of 17.4% over a 5-year period(6).

Since introduction of modern THA in 1950s by Charnley (7), implants underwent several modifications, including bearing diameter, bearing surfaces' material, and shape of the components. THA is either conventional, consisting of a femoral stem and a head articulating against an acetabular cup (Figure 1) or can be a hip resurfacing (HR), consisting of a metal head cap and an acetabular cup (Figure 2). Fixation methods and bearing surfaces are the highest concerns in the design of such prostheses.

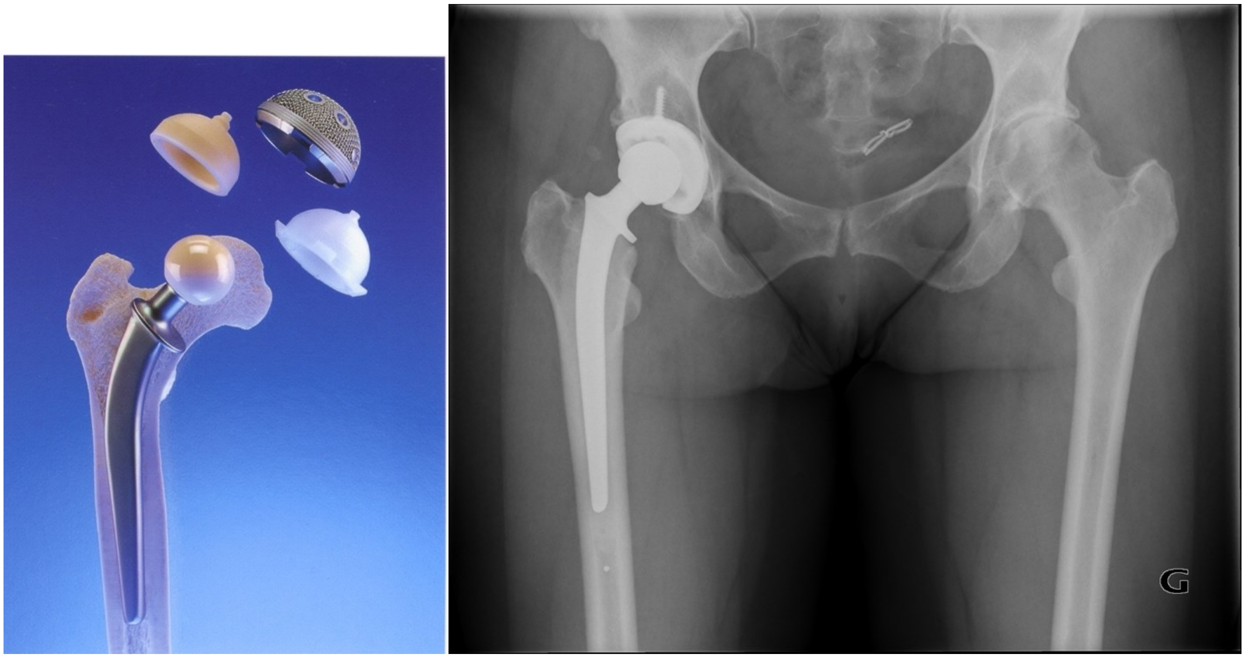

Figure 1. Conventional Total Hip Arthroplasty (THA)

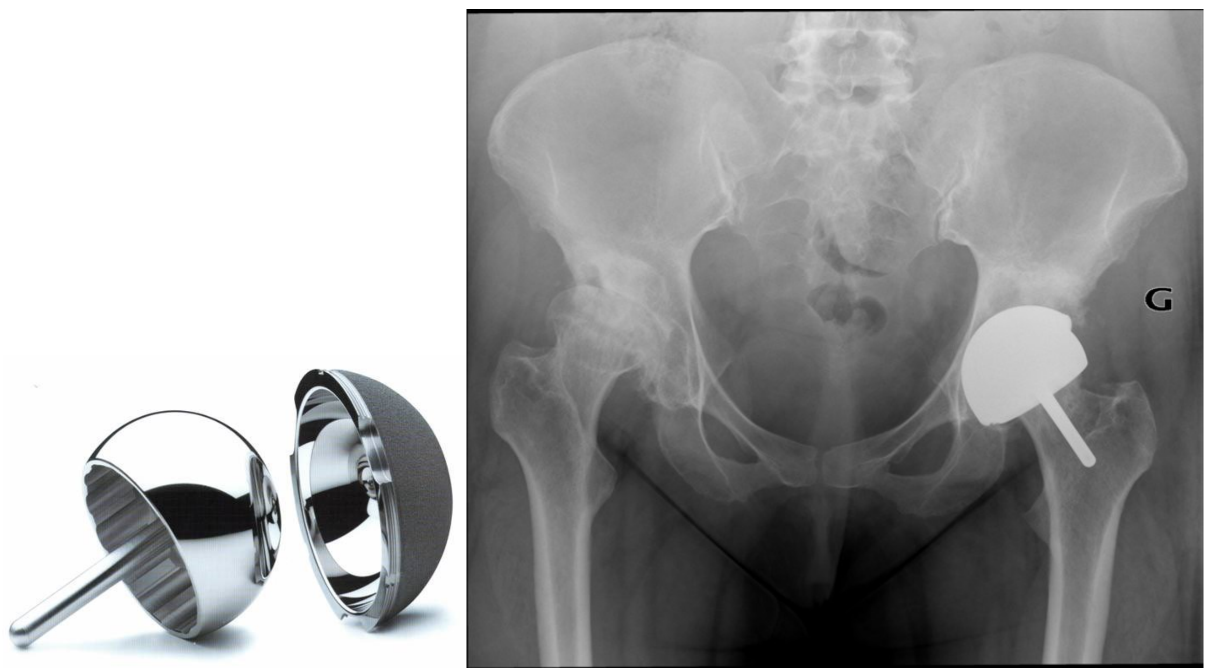

Figure 2. Hip Resurfacing

While primary THA is a highly effective treatment for degenerative hip disease, hip prostheses have a limited lifespan and might fail for a variety of reasons, requiring revision hip replacement surgery. Revision surgery is technically complex, requires specific training and places an increasing burden on the healthcare system. A recent study from Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) found that the lifetime risk of revision of hip replacement surgery approximately 35% for people in their 50s at the time of primary THA and decreases to 5% for those >70 years of age (8). The longevity of bearing surfaces in THA, especially in young and active patients, is still an important debate (9, 10). Metal on conventional polyethylene (MoPc) was linked to polyethylene wear during motion under load (11). The biological response to polyethylene debris leading to periprosthetic osteolysis and implant loosening (9, 12, 13), (14). The clinical manifestations of implant loosening are pain and functional limitations. When this happens, the patient must undergo a revision surgery. In Canada, the most common reported reason for revision was aseptic loosening (24.7%). Polyethylene wear-related biological reactions have attracted the attention towards alternative bearings (hard-on-hard bearings): ceramic-on-ceramic (CoC) and metal-on-metal (MoM) or newer highly crosslinked polyethylene (PXL). In addition to the better tribological properties offered by these alternatives, hip resurfacing (HR) has also offered proposed advantages including the conservation of hip biomechanics, better patient function and activity level after surgery, and less instability (15). When well-functioning implants are considered, HR has proven to yield better functional outcome scores when compared to THA mostly with highly demanding functions such as in sport and recreation (16). Technological advances continue to evolve in an attempt to improve longevity of THA, as well as decrease disadvantages to better meet patients' high functional demands and increased life expectancy. Assessing the efficacy of these new technologies requires a long-term clinical monitoring. There is a paucity of the literature reporting long term studies with high-quality evidence (RCTs) comparing hip prosthesis with different types of bearing surfaces. We believe that this study will provide the orthopedic community with the highest level of evidence of the long-term effects of the four different tested hip prostheses.

Chapter 1 LITERATURE REVIEW

1.1 OSTEOARTHRITIS OF THE HIP JOINT

Osteoarthritis (OA) can be primary or secondary caused by injuries, hip joint diseases during growth, inflammatory disease, such as Rheumatoid Arthritis or infection. The symptoms associated are pain and progressive ankylosis of the hip joint, gradually leading to a decrease in the patient's functional abilities. It is estimated that about 80% of those with osteoarthritis have some limitation in movement and up to a third of them will suffer severe disability (17).

1.1.1 Diagnosis of osteoarthritis of the hip:

Hip OA often can be diagnosed on clinical presentation alone. Imaging investigations can be useful both to confirm a diagnosis and to monitor disease evolution.

1.1.2 Classification of osteoarthritis of the hip:

Many classification systems for hip osteoarthritis have been proposed including the Tönnis classification (18, 19), Croft classification (20) as well as the Kellgren-Lawrence classification (Table 1) (21).

Grade	**Radiological finding**
0	Definite absence of x-ray changes of osteoarthritis
I	Doubtful joint space narrowing and possible osteophytic lipping
II	Definite osteophytes and possible joint space narrowing
III	Moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends
IV	Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone ends

Table 1. Kellgren-Lawrence Grading System for Osteoarthritis.

1.1.3 Management of osteoarthritis of the hip:

The American Academy of Orthopedic Surgeons (AAOS) has proposed an evidence based clinical practice guidelines to provide recommendations for diagnosis, treatment, and postoperative management of hip OA. The Appropriate Use Criteria (AUC) provide treatment recommendations on patient-specific level of the indications and classifications (Table 2) (22).

Indications	Classifications
Age	• Young (Approximately <40) • Middle-Aged (Approximately 40-65) • Elderly (Approximately >65)
Function-Limiting Pain	• Function-Limiting Pain at Moderate to Long Distances • Function-Limiting Pain at Short Distances • Pain at Rest or Night
Radiographic Evaluation	• Minimal OA • Minimal OA with acetabular dysplasia • Minimal OA with FAI • Moderate OA • Severe OA
Range of Motion Limitation	• Minimal • Moderate • Severe
Risk of Patient for Negative Outcome	• Modifiable risk factors present • No modifiable risk factors present

Table 2. Patient indications and classifications according to American Academy of Orthopedic Surgeons (AAOS)

Treatment (22):

(1) Assessment and optimization of risk factors

(2) Activity modification

(3) Assistive devices

(4) Oral medication management: non-opioid (i.e., NSAIDs and acetaminophen) or tramadol

(5) Intra-articular steroids injection

(6) Physiotherapy (as a non-surgical treatment)

(7) Arthroplasty

(8) Hip preservation surgery (osteotomies)

(9) Arthrodesis.

Total Hip Replacement:

Hip replacement surgery is an effective treatment in terms of pain relief and improving patient's hip mobility when conservative treatment becomes ineffective [2-5]. Total hip replacement is a surgical procedure where the worn cartilage and articulating femoral head of the hip joint is surgically removed and replaced with an artificial hip prosthesis in the form of an acetabular cup and a femoral stem coupled to an artificial femoral head. A hemispherical acetabular cup is fixed into the acetabulum after removing of worn cartilage. A femoral stem is inserted into the femoral medullary canal and secured with or without bone cement. An artificial femoral head is assembled to the neck of a femoral stem. Artificial femoral head is then reduced to articulate against the acetabular cup. (Fig. 2).

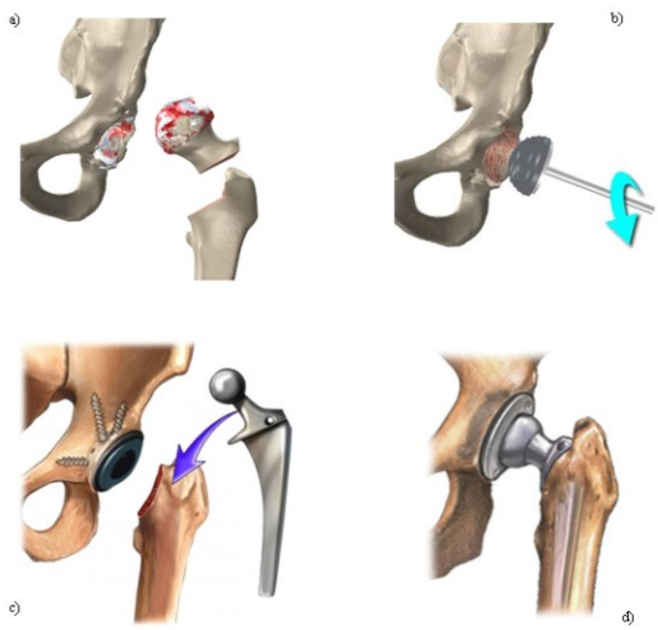

Figure 3. a) Section of the femoral neck. b) Acetabular preparation. c) Insertion of components. d) Component coupling

Hip Resurfacing:

The femoral head is not removed but is instead prepared and resurfaced with a metal cap with a short stem. The acetabulum is prepared as in conventional total hip replacement.

1.2 BEARING SURFACES

Wear has been widely recognized as the most important restraint to the long-term survivorship of hip implants (23).

1.2.1 Metal-on-Polyethylene:

Rational:

MoP is hard-on-soft bearing surface with a metallic femoral head articulating against PE acetabular component. MoPc has the highest wear rate of all bearing material combinations with a reported range of 0.1–0.2 mm/year (24). Clinical variables that influence polyethylene wear were reported by Devane and Horne (Table 2) (24). .

Ultra-High Molecular Weight Polyethylene (UHMWPE) was first introduced in 1962 by Charnley who developed the low-friction arthroplasty (25). Sterilization process of Pc by gamma irradiation in air was found to be responsible for the changes in its physical properties due to oxidation in response to free radical formation. Oxidation decreases resistance resulting in degradation and brittleness, and thus may increase wear (26). PE wear has a multifactorial nature and concerns multiple factors such as implant design, sterilization, packaging, material properties and patient's factors. Patient's related factors influencing PE wear include age, gender and activity level (27). Implant related factors include diameter of the femoral head, method of fixation, PE thickness and offset (Table 3) (28). Additionally, malpositioning of acetabular component accelerates PE wear either by impingement (29) or by edge loading caused by vertical orientation (30, 31). Conventional PE wear debris compromise implant fixation and periprosthetic bone stock. Aseptic loosening and periprosthetic osteolysis are widely recognized as the most serious challenges in hip arthroplasty. The biological response to wear particles were noticed to limit the longevity of joint replacements (32). Pc wear particles induce inflammatory responses by macrophage activation when their size falls within 0.3 µm to 10 µm (33). To improve the longevity of the prosthesis, Pc manufacturing and sterilization have seen several modifications. Most importantly, irradiation with an electron beam or with gamma radiation and thermal treatment to increase the number of cross-links across multiple polymer chains while preventing the formation of free radicals; precursors of oxidation-induced embrittlement (34, 35). The highly cross-linked polyethylene (HXLPE) is characterized by increased density and improved wear characteristics (36). The combination of a chrome-cobalt (CrCo) head with (HXLPE), has revealed a significant improvement in wear when compared with MoPc with a wear rate of 43–100% lower (34).

Factor	Increased wear	Reduced wear
Age	Young (< 50 yrs)	Older (> 50 yrs)
Activity level	High (2 m cycles/yr)	low
Head diameter	32 mm	26mm or 28mm
Fixation	Macro porosity	cement
PE thickness	< 8 mm	>8 mm
Offset	Non-restored	Restored

Table 3. Factors influencing PE wear (from Devane and Horne)

1.2.2 MoM THA:

Rational:

MoM is a hard-on-hard bearing surface with a metallic femoral head articulating against a metallic acetabular component. MoM bearings were initially engineered to be extremely smooth and hard; two properties reduce wear rate. The wear rate of MoM bearings is estimated to be 20-100 times lower than MoPc (37). Therefore, this led to a decrease in the incidence of osteolysis and subsequent failure, especially in younger, more active patients with long life expectancy (38). Larger diameter heads (LDH, >36 mm) MoM has evolved to provide better stability and range of movement (39). Unfortunately, such low rate of wear is not without disadvantages. Although most MoM THAs were successful, adverse reaction to metal debris (ARMD) has been reported as a form of soft tissue hypersensitivity reaction that is related to malfunctioning MoM (40-43) or more commonly to trunnionosis generated by the high frictional torque of LDH at trunnion-head modular interface (44, 45).

1.2.3 HR

Rational:

HR is a bone-preserving procedure. It involves removal and resurfacing of the diseased surfaces of the femoral head and the acetabulum with preservation of proximal femoral bone stock. Potential advantages of MoM HR are improved hip stability (46), reduced proximal femoral stress shielding (47), more optimal restoration of hip joint biomechanics and gait (48-50), return to high-demand sports activities (51, 52), and decreased morbidity if revision surgery is needed (53).

Risk factors for MoM HR failure included implant design, patient selection and surgical technique (54). However, HR should not be viewed as a single class of implants as the design differences between different systems account for the different results. Implants with low radial clearance and sub-hemispherical components with a small cup articular arc angle result in significantly higher possibility of edge loading and wear (55, 56).

Theoretically, the concept of HR is intuitive, and improved technology and better knowledge about risk factors may lead to its resurgence again. Some reports criticized the bone preservation hypothesis at the acetabular side compared to THA by the fact that more bone resection is needed to accommodate a large femoral head size (57).This criticism was later refuted by the fact that the amount of acetabular bone resection is not only dictated by the femoral head size but also the shell thickness and fine increments between sizes (58).

1.2.4 CoC Bearings:

Rational:

Alumina-on-alumina ceramic (Al_2O_3) bearings were first used by Boutin in 1970s (59). They were introduced to address the problems of friction and wear in MoM and MoP bearings surfaces (60). CoC bearings have shown by far the best performance in terms of wear between 0.002-0.005 mm/year versus 0.02 mm/year of CoPxl and 0.03–0.05 mm/year of a MoPxl (61, 62). CoC bearings offered greater scratch resistance, lesser wear debris production and has more resistant to damage by third-body particles than metal (63).

First-generation ceramics:

They were brittle composed of pure alumina made from industrial material. They possess poor microstructure with low density, inadequate purity, and large grain size (>5 um) because the long sintering process. Additionally, acetabular component was either cemented or press-fit which resulted in early failure. Poor mechanical properties and neck-liner impingement resulted in high fracture rates (64).

Second-generation ceramics:

In order to improve the strength, the average grain size was decreased, and porosity was lowered by adding calcium oxide (CaO) and magnesium oxide (MgO) during long sintering process (65).

Third-generation ceramics (BIOLOX® forte):

Changes have made to improve its mechanical properties. The ceramic underwent hot isostatic pressing to reduce grain size and the increase its density and purity. The fracture rate has substantially reduced to about 0.021%.

Fourth generation ceramics (BIOLOX® Delta)

Alumina matrix composite consists of 72.5% alumina, 25.5% zirconia and 2% mixed oxides (Strontium and chromium oxides) (66). It is more resistant to severe mechanical overloading as it prevents crack propagation.

Wear in CoC:

The wear particles from ceramic bearings are similar in size to wear particle from MoM bearings. However, in contrast to MoM, ceramic debris are biologically inert (67). In vitro volumetric wear rate for a modern 28mm CoC bearing is 0.1 mm^3 / years. However, when simulating edge loading and micro-separation, and increasing head size to 36mm, volumetric wear increased to 0.25mm^3 / year in CoC bearing and to 9 mm^3 / year with MoM bearings (68).

Concerns about CoC bearings:

1- Audible noise: *Clicking* and squeaking of CoC bearings were reported by several studies (69-74). The incidence of squeaking of CoC bearing is variable in literature with reported rates of 0.3%-24.6% (75). Squeaking has been attributed to disruption of fluid lubrication(76). Patient factors as well as component types and positions have also been linked to squeaking(73). Edge loading, stripe wear, impingement, and micro-separation have been association with squeaking. However, the long-term clinical significance of squeaking is still unknown (75, 77).

2- Ceramic Fracture: The risk of head fracture (0.004-1.4 %) is lower than the liner fracture (0.01-2 %) with higher risk in short neck 28-mm head (78, 79). Liner fracture has been linked to thin liner, improper engagement of the liner, damage of metal back or malorientation of acetabular component leading to impingement and edge-loading (74). Precision of surgical technique, with correct positioning and impaction of the ceramic liner and meticulous cleanliness of the Morse taper, is critical in reducing the fracture rate.

3- Edge loading and Stripe wear: Stripe wear has been observed with first and second generations CoC bearings and were linked to malorientation of acetabular components (80). The incidence of stripe wear which was reported in CoC implant retrieval studies varies from 52% (81) up to 83% (82). Stripe wear is a local area of wear near the edge acetabular liner and along the femoral head that resulted from edge loading. It is characterized as a long slender pattern of roughened damaged surface on the ceramic head.

4- The limited availability of sizes used to be another limitation of CoC use, However, recently, Biolox delta ceramic implants allowed the use of cups as small as 42mm with 28 mm head.

5- Cost remains the determining issue for ceramic bearings. However, the decreased lifetime revision cost could be an advantage when ceramic bearings are carefully selected according to patient age to recover the initial increase in expense of ceramic heads (83).

1.3 TRIBOLOGY OF BEARING SURFACES

Wear has been widely recognized as the most important restraint to the long-term survivorship of hip implants (23). Tribology is derived from the Greek terms for rubbing (τριβειν) and science (λογοσ). It is defined as a science of two interacting surfaces in relative motion. It encompasses friction, wear, lubrication, and related design aspects. Therefore, it is considered an important factor in the design and optimization of artificial joints.

1.3.1 Wear

Definition: Progressive loss of material from a surface due to relative motion at its contact interface with another surface (84).

Mechanisms:

The wear in joint replacement can be a combination of adhesive, abrasive, corrosive wear, or surface fatigue.

1. Adhesive wear

   Adhesive wear is the removal of material from a surface by hard irregularities (asperities) on the countersurface because of shearing of junctions between asperities. This contact is the real contact between bearing surfaces. Adhesive wear is the most common and least inevitable wear in bearing surfaces (85).

2. Abrasive wear

   Abrasive wear is the removal of material from a surface by hard particles (third body) entrapped between the two contact surfaces or due to a hard material groove into a softer surface.

3. Corrosive wear

   Corrosive wear result from a synergism between mechanical wear and chemical reaction of the material with the surrounding environment. The mechanical wear caused by friction result in removal of protective layer of metal (passivation layer) thus exposing the underlying metal susceptible to corrosion by surrounding body fluids (86).

4. Surface fatigue

   Surface fatigue wear is the removal of material due to repeated cyclic loading. It depends on the number of cycles, the amount of load applied and the friction acting at the surface during its lifetime.

1.3.2 Friction

It is the resistance to motion when one body move tangentially over another (87). Co-efficient of friction in ball-in-socket artificial hip joint is often modified by considering frictional torque (T) and the radius of the femoral head (R_{head}) and the resultant ratio is named as friction factor (f).

1.3.3 Lubrication

It is the interposition of a material most often a liquid between bearing surface to minimize interaction between them and thus reduces wear and friction (24).

The effectiveness of lubricant film depends on:

1- The lubricant film thickness.

2- The combined surface roughness of the bearing surfaces.

3- Sliding velocity and the pressure across the interface.

Chapter 2 OBJECTIVES AND HYPOTHESIS

2.1 SUMMARY OF THE PROBLEM

Degenerative hip disease represents a significant burden on health care. THA is recognized as one of the most cost-effective surgeries, however, limited by the implant survival. The biological response to polyethylene debris leading to osteolysis and aseptic loosening has been a major cause of failure of total hip arthroplasty. Over the years, the number of THA has been steadily increasing, especially in a younger population. The Australian Orthopedic Association National Joint Replacement Registry (AOANJRR) reports 13% cases for all primary THA are patients younger than 55 years (44). The activity levels and patients' expectations have drawn attention to more sustainable implant options. There is a perturbing correlation between younger age at initial surgery and lifetime risk of revision. Patients over 70 years have a 5% chance of revision surgery compared to 35% for patients younger than 55 years (88). Therefore, extensive research is being conducted to develop alternative bearing surfaces that have superior wear characteristics and thus increasing the longevity and safety of prosthesis. These bearing surfaces include CoC, MoM THA as well as HR. The advent of various bearing surfaces and their subsequent developments have seen the potential for very low wear, optimization of function in patient with highly demanding activities and increased implant longevity. However, the initial enthusiasm for these alternative bearing was subsequently investigated due to concerns about potential risks and associated complications. These risks are device failure, adverse reactions to metal debris generated, implant loosening, metal ion production, for MoM implants and ceramic fractures and production of audible noise for CoC implants.

Thus, several studies have been dedicated to the evaluate the performance of these alternate bearing surfaces. However, there is a paucity of long-term studies with a high level of evidence (RCTs) comparing HR to THA or THA with different bearings CoC, MoM or MoPc regarding implant survival, complication rates, functional scores, and radiographic outcomes over long term follow-up. The potential advantages of HR and THA with harder bearings are promising for a young and active population, particularly in terms of wear characteristics and longevity as well as stability and bone stock preservation.

2.2 OVERALL OBJECTIVE

The primary goal of this work is to evaluate the long-term clinical results HR and THA with alternate bearing in a young and active population.

Research perspectives and specific objectives

Two randomized studies were conducted by Dr Vendittoli as principal investigator.

Study 1

From July 2003 to January 2006, 203 hips were randomized to 28-mm MoM uncemented THA (99 hips) or hybrid MoM HR (104 hips).

Primary objective of this study was to compare the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score between the 2 groups.

Secondary objectives were to compare the revision rate and the complication rates, and to assess the radiographic findings between the 2 groups.

Early results of this study have been published (89, 90)

Study 2

From 1996 and 2001, 140 hips in 116 patients were randomized where 69 hips in 58 patients received MoPc and 71 hips in 68 patients received CoC bearing (91, 92)

Primary objective of this study was whether there was a difference in survivorship between MoPc and CoC THA.

Secondary objectives were to compare the rate of related complications, radiographic signs of wear and clinical scores between the 2 groups.

Early results of this study have been published (91, 92)

My work was to review these 4 cohorts of patients at a long-term FU and to test the following hypotheses.

2.3 HYPOTHESES

Study 1

HR would provide higher functional scores while the revision rates would be similar to 28 mm head MoM THA at the long- term follow-up.

Study 2

CoC bearing THAs have superior long term clinical results compared to MoPc THAs.

2.4 SPECIFIC OBJECTIVES

For study 1:

1- Primary objective is to evaluate the difference between HR and 28-mm MoM THA in term of clinical scoring systems at the last follow up.
2- Secondary objectives are:
   - To compare these results retrospectively with previously published clinical assessments when available and
   - To compare the radiographic outcomes, reoperation, and revision rates.

For study 2:

1- Primary objective is to evaluate the difference between MoPc and CoC THA in terms of survivorship, at more than 20 years postoperatively.
2- Secondary objective is
   - To compare related complications, radiographic signs of wear, and functional scores.

2.5 PRESENTATION OF ARTICLES

1- The first article (Chapter 4) presents the long-term outcomes of a randomized control trial compares clinical results of hip resurfacing to metal-on-metal THA. A total 203 hips were randomized to 28-mm metal-on-metal uncemented THA (99 hips) or hybrid HR (104 hips).

The rates of revision and the complications requiring reoperation at last follow up were the main outcome measures. In addition, patients' clinical results were also assessed with validated function scores and radiographic evaluation. Our results will allow us to hypothesize higher functional scores and similar rate of revision of HR compared to small head MoM-THA at the long-term follow-up.

This article was published on November 4, 2020, at Journal of Bone and Joint Surgery American Volume.

2- The second article (Chapter 5) presents the long-term outcomes of a randomized control trial compares the clinical results and implant survivorship of ceramic-on-ceramic to metal-on-conventional polyethylene THA after more than 20-year follow-up. A total 140 hips in 116 patients were randomized where Sixty-nine hips in 58 patients received MoP and 71 hips in 68 patients received CoC. Our results will allow us to hypothesize the superior long term clinical results CoC bearing THAs compared to MoPc THAs.

This article was published on December 11, 2020, at Orthopaedics & Traumatology: Surgery & Research Journal and received Best Paper Award at 14th European Hip Society (EHS) Congress 2021.

Chapter 3 MATERIAL, METHOD AND RESULTS

3.1 MATERIAL AND METHOD

3.1.1 THE COHORTS

In the first article (chapter 4), 203 hips between 18 and 65 years old were randomized to 28-mm metal-on-metal (MoM) THA (99 hips) or to HR (104 hips) between July 2003 and January 2006. The exclusion criteria were the presence of femoral deformity that prevented HR, previous hip arthrodesis, renal insufficiency, known or suspected metal allergy, or known or suspected osteoporosis of the hip were included in this study.

In the second article (chapter 5), a total of 140 hips in 116 patients with a mean age of 42 years were randomized to receive CoC or MoPc THA between 1996 and 2001. Sixty-nine hips in 58 patients received MoP and 71 hips in 68 patients received CoC. This included patients with degenerative hip joint disease, excluding patients < 18 years or > 70 years, active infection of the hip, severe osteoporosis compromising bone fixation of the implant, non-cooperative patient, severe instability of the hip, pregnancy, and acetabulum of < 50 millimeters diameter.

3.1.2 IMPLANTS

First article: Hip Resurfacing Compared to 28-mm Metal-on-Metal Total Hip Replacement at 15 Years of Follow-up.

The THA group received a CLS Spotorno grit-blasted titanium uncemented femoral stem, an Allofit uncemented acetabular cup, high carbon CrCo polyethylene sandwich acetabular insert with an internal diameter of 28 mm, Metasul CrCo 28 mm femoral head (Zimmer, Warsaw, Indiana, Using the 135 or 145° neck shaft angle stem with different head neck length (-4 mm, neutral, +4 mm and +8 mm) (Fig. 2a). The HR group received the hybrid Durom with high carbon CrCo femoral head and acetabular cup (Zimmer, Warsaw, Indiana, Fig. 2b).

The HR femoral component has a 4 mm wall thickness at the equator and 9 mm at the superior pole, a short alignment stem and internal recesses allowing controlled pressurization of cement to produce a mantle of 0.75 mm to 1.5 mm. The uncemented acetabular component subtended an angle of 165° and had a uniform thickness of 4 mm with an external titanium vacuum plasma-spray coating of 250 μm.

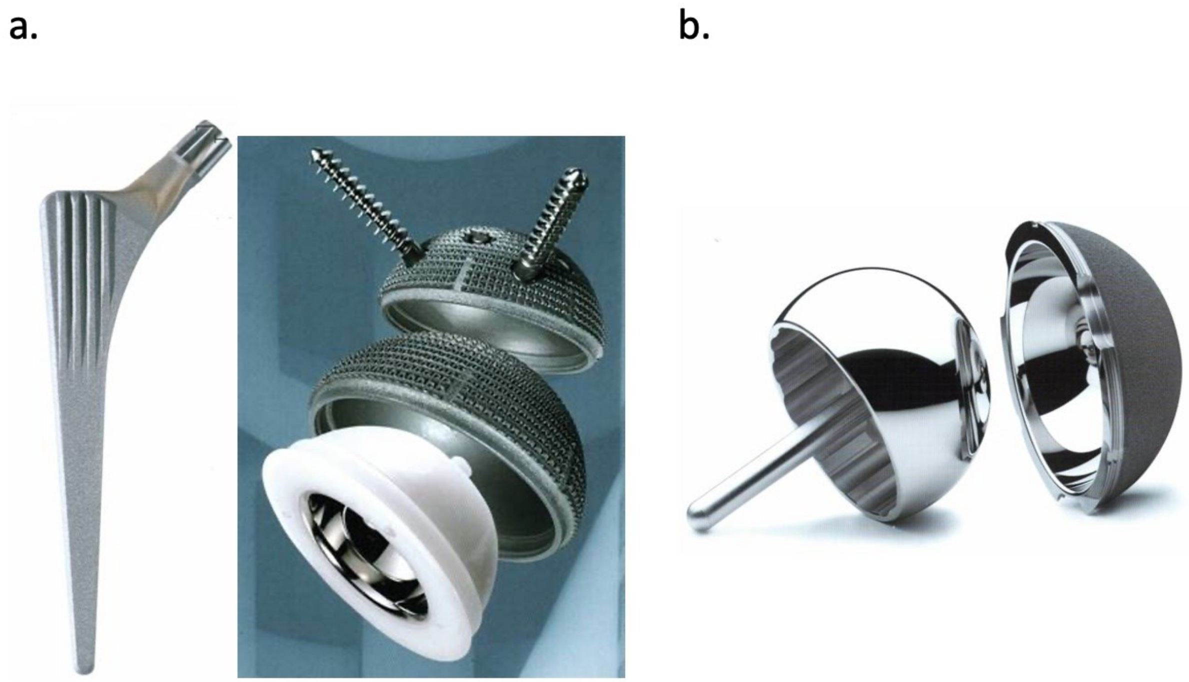

Figure 4. a. The CLS femoral stem (Zimmer, Warsaw, Indiana) and the Allofit acetabular cup (Zimmer, Warsaw, Indiana). b. The hybrid Durom HR system with wrought high carbon CrCo femoral head and acetabular cup ((Zimmer, Warsaw, Indiana).

Second article: Ceramic-on-Ceramic Total Hip Arthroplasty Is Superior to Metal-on-Conventional Polyethylene at 20 Years Follow-Up

A hybrid THA was implanted in all patients (Ceraver Osteal, Roissy, France) (fig 3). The cemented femoral implant has a smooth titanium (TiAl) surface covered by a layer of titanium oxide (TiO_2). It has a collar and a cervico-diaphyseal angle of 132°. The uncemented acetabular implant is made of titanium. Screw holes are available for supplementary primary fixation, and a titanium mesh covers the outer surface for secondary fixation.

The bearing surfaces were either an alumina insert with an alumina femoral head of 32 mm, or a polyethylene insert (Chirulen 1020, sterilized with ethylene oxide in 1996 and 1997, and with gamma irradiation in argon from 1997 to 2001) with a 28-mm stainless steel femoral head. The minimal acetabular shell size was 50 mm with alumina and 48 mm with polyethylene. No liner had an elevated lip.

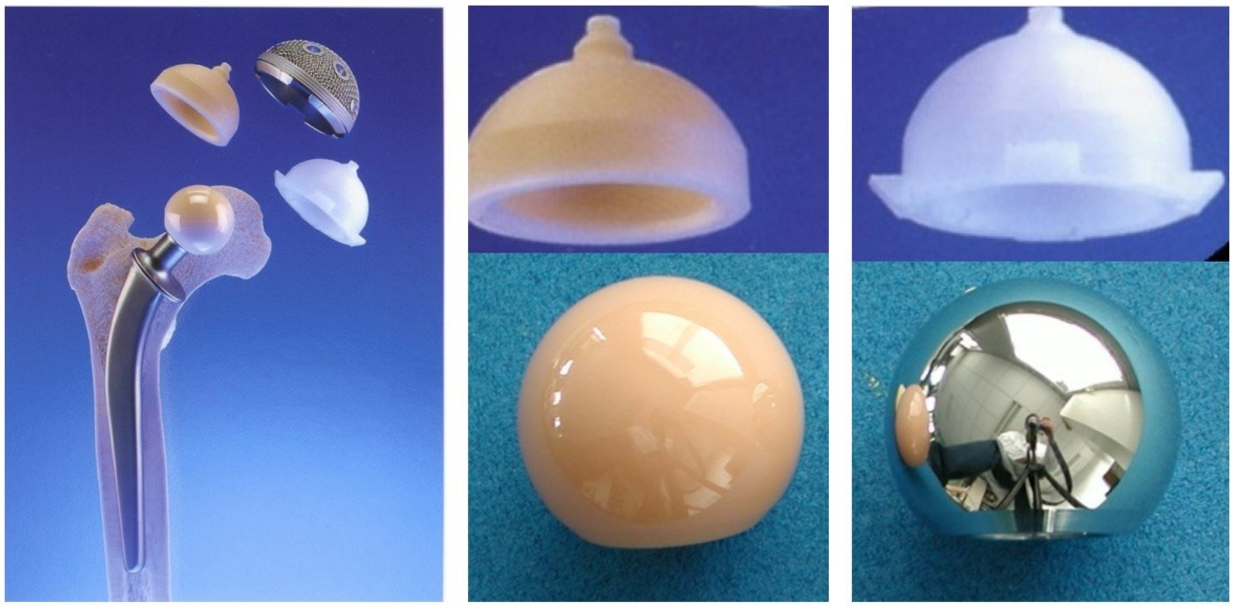

Figure 5. Ceraver Osteal cemented femoral stem and acetabular component. Patients were randomized to receive an alumina insert and a 32-mm alumina femoral head or a polyethylene insert and a 28-mm stainless steel femoral head.

3.1.3 CLINICAL SCORES

First article

WOMAC score(93), University of California, Los Angeles [UCLA] activity score (94), Forgotten Joint Score (95) and Patient-Joint Perception (96) were administered to patients at last follow-up and compared with previously-reported assessments carried out at 1, 2, and 5 years' follow-up, when available.

Second article

WOMAC score (93) and Joint Perception scores (97) were administered to patients at last follow-up.

Validated French version of the Hip disability and Osteoarthritis Outcome Score (HOOS-Fr) was used to obtain clinical scores (98). (HOOS-Fr): A self-administered Hip disability and Osteoarthritis Outcome Score questionnaire designed to further develop WOMAC. It contains 40 items and is used to evaluate patients with hip problems. Its five subscales are Pain (P), Symptoms (S), Activity limitations daily living (ADL), Function in sport and recreation (SP) and hip-related quality of life (QOL). The questionnaire generates a score out of 100. Zero indicates extreme symptoms and 100 represents no symptoms (98).

3.1.4 RADIOLOGICAL MEASUREMENTS

An anteroposterior (AP) radiograph of the pelvis with the legs in 15° of internal rotation and a cross-table lateral radiograph (whenever possible) of the operated hip were assessed at the last follow up compared with post-operative radiographs by coauthor (MS).

Cementless femoral stem loosening was considered definite in the presence of continuous lucent lines of more than 2 mm, stem fracture, or a change in component angulation of more than 5° or vertical subsidence of more than 5 mm when measured from the center of the femoral head to the most medial point of the lesser trochanter or to the tip of the greater trochanter (99). Cementless implant stability was evaluated according to criteria described by Engh et al. (100).

Cemented femoral stem loosening was considered definite in the presence of a continuous lucent line of more than 2 mm, cement fracture, stem fracture or vertical subsidence of more than 5 mm.

Acetabular loosening was considered definite in the presence of continuous radiolucency of more than 2 mm, component migration of more than 3 mm, component rotation, or the presence of broken screws (101).

Description of radiolucent line > 2mm and local osteolysis were done with the use of Gruen's zones for the femur (102) and Charnley-De Lee for the acetabulum (103). Osteolysis was defined as described by Zicat et al. as a focal area of radiolucency of more than 2 mm wide at the final follow-up that was not seen on the immediate postoperative radiographs (104). **Osteolysis** was recorded for either cavitary defect, or calcar resorption which seemed not to be a consequence of calcar remodeling. The vertical inclination of the acetabular component was measured in reference to a horizontal line between the teardrops and its height was measured from the distance between the inferior border of the cup and the inter-teardrop line.

Loosening of the femoral HR head was considered definite with the appearance of continuous lucent line around the cervical stem of more than 2 mm, a broken stem, or change in component angulation of more than 5° by taking the difference between femoral stem-shaft angle at the last follow-up and immediate postoperative radiographs. Stem–shaft angle was measured using the femoral stem axis and the line passing the center of the diaphysis (105). **Neck narrowing and heterotopic ossification** were also checked at the last radiographs. Narrowing of the femoral neck was defined as the progressive narrowing of both superior and inferior aspects of the femoral neck (106). Heterotopic ossification was recorded according to the Brooker et al classification (107).

3.1.5 STATISTICS

First article

Power analysis: The sample size calculation was based on minimum statistically and clinically significant differences of 5/100 on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in patients with unilateral hip arthroplasty (89, 90). With an expected rate of loss to follow-up of 15%, an estimated sample size of 76 cases in each group was needed to provide a power of 80% and standard deviation (SD) of 11.0 to detect a minimum statistically and clinically significant difference of 15% with an alpha error of 0.05.

Continuous variables are presented as mean with standard deviation (SD), and categorical variables as frequency and percentage. Categorical variables were analyzed with the chi-squared test, and Fisher's exact test when proportions were <5. Continuous variables were assessed with Kolmogorov Smirnoff test analyzed by a Student's t-test for data with normal distribution, and non-parametric Mann–Whitney tests and sign tests were used in the presence of asymmetrical distributions. Comparison within group (paired samples) between different follow-up assessments were performed with Related-Sample Wilcoxon Signed Rank Test for continuous variables and categorial paired samples were analyzed with the Related Sample McNemar Test. Implant survivorship was analyzed with the Kaplan-Meier estimator and compared with the Log Rank Test. The data were analyzed by SPSS version 25.

Second article

Power analysis: With an expected rate of loss to follow-up of 15%, an estimated sample size of 70 in each group was needed to provide a power of 80% to detect a clinically meaningful difference of 15% in revision rate with an alpha error of 0.05.

Continuous variables are presented as means (min-max; standard deviation [SD]) and categorical variables, as frequencies and percentages. For primary and secondary outcomes, the MoP and CoC groups were compared by Chi-square and Mann-Withney tests for categorical and continuous variables, respectively. Implant survivorship was evaluated by Kaplan-Meier method. As Kaplan-Meier approach was not designed to assess implant survivorship, it underestimates the implant survivorship in orthopaedic studies where a large number of patients die during follow-up (108). For that reason, deceased patients were not considered lost to follow-up in our Kaplan-Meier analysis. The significance level was defined as $p<0.05$. Statistical analyses were performed with SPSS 25.0 software (SPSS Inc., Chicago, IL, USA).

3.2 RESULTS

3.2.1 ARTICLE I (see CHAPTER 4)

In the previously published reports of RCT comparing HR to 28mm MoM THA (89, 90), we found improved biomechanical reconstruction with HR and no significant difference in acetabular bone resection, metal ion levels, clinical scores, or revision rates after mean follow-up of 8 years.

After mean follow-up of 15.0 years (14-16), 9 (4.4%) of the 203 hips were lost to follow-up and 15 (7.4%) deceased. The Kaplan-Meier survivorship with revision for any reason as the endpoint was 89.2% (95% CI, 82.3–96.1) for HR and 94.2% (95% CI, 89.3–99.1) for THA (p=0.292). Reasons for revision in THA included: 3 infections, 1 recurrent dislocation and 1 adverse reaction to metal debris (ARMD), and in HR: 2 ARMD and 7 femoral head loosening. With aseptic revision as the endpoint, the Kaplan-Meier survivorship was significantly higher in THA (97.4% versus 89.2%, p=0.033). No dislocation occurred in HR versus 4 in the THA (p=0.038) (Fig. 4&5).

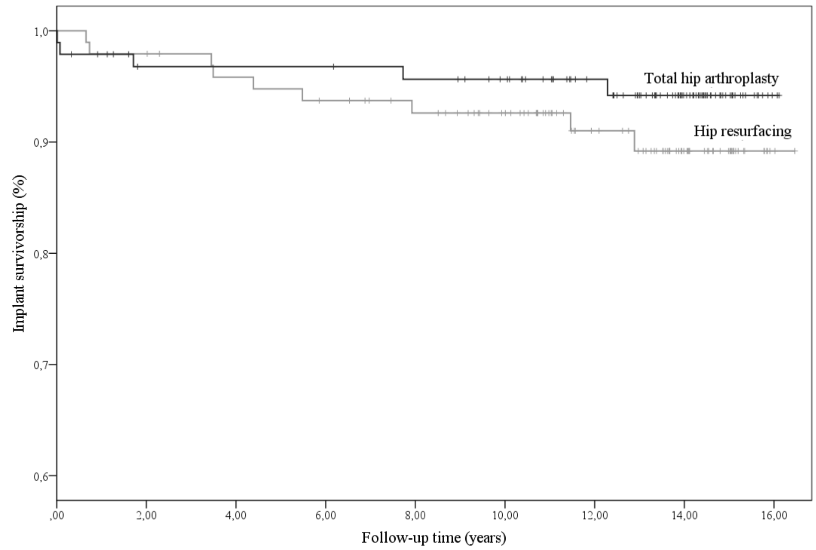

Figure 6. Kaplan Meier graph including early septic revision (p= 0.292).

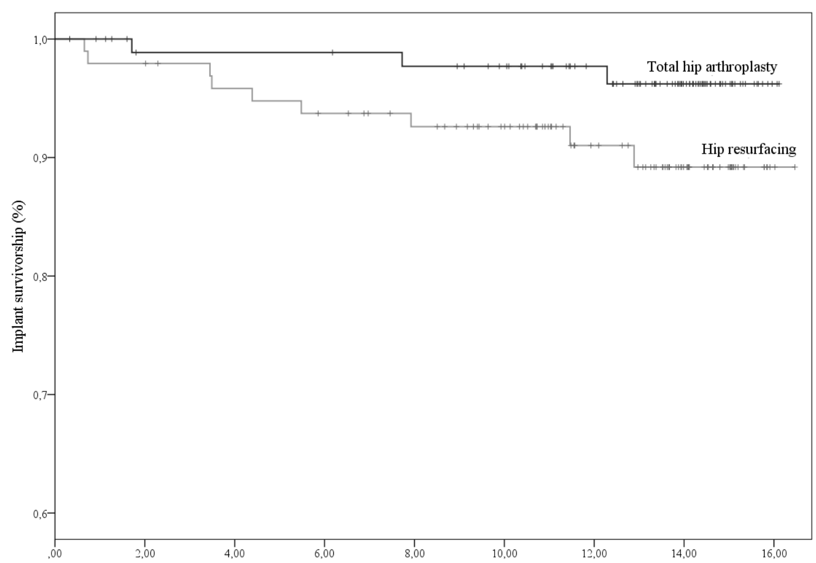

Figure 7. Kaplan Meier graph excluding early septic revision (p= 0.083).

Clinical Scores Evaluation

Both groups achieved similar mean WOMAC score (10.7 HR, 8.8 THA, p=0.749), Forgotten Joint Score (87.1 HR, 85.3 THA, p=0.410), UCLA activity score (6.3 HR, 6.4 THA, p=0.189), and overall Joint Perception (p=0.251).

Radiographic Evaluation

On radiographic evaluation, no implant was considered to be loose. Periprosthetic non-progressive (<2mm) radiolucent lines were observed in 40.5% of THA compared with 2.6% of HR (p<0.001).

3.2.2 ARTICLE II (see CHAPTER 5)

After a mean follow-up of 21 years (19 - 23), 40 patients (48 THAs; 34%) had died and 6 patients (6 THAs; 4%) were lost to follow-up. Aseptic revision rate was significantly higher in the MoPc group (17/69; 24.6%) versus CoC (2/71; 2.8%; p < 0.001). Kaplan-Meier survivorship estimator with revision for aseptic reasons was 73.6% (95% CI, 63.3 – 84.9%) for MoPc and 96.9% (95% CI, 92.8 - 100%) for CoC (p < 0.001) (Fig. 6).

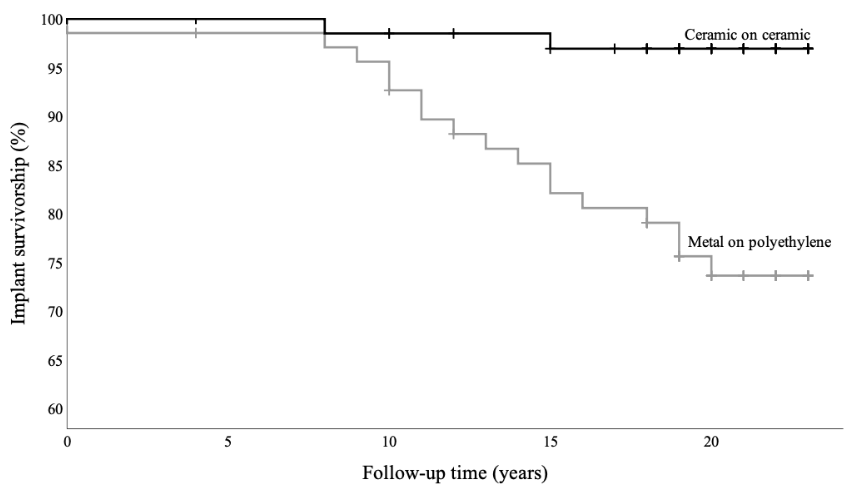

Figure 8. Kaplan-Meier survival curve with revision for aseptic loosening or severe wear as the endpoint.

Clinical Scores Evaluation

CoC had better mean WOMAC scores than MoPc (11.0 vs 19.4; $p = 0.048$). No ceramic fracture was observed (Fig. 7).

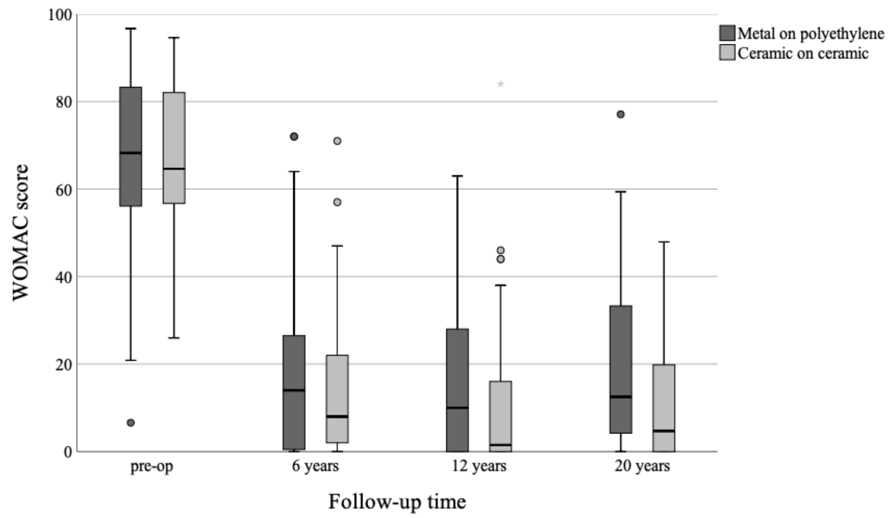

Figure 9. Box plots showing the pre-operative WOMAC scores in both groups (CoC and MoPc) and their post-operative values after a mean of 6 years, 12 years and 20 years. The boxes represent the median and interquartile range and the whiskers the data range.

Radiographic Evaluation

On radiographic evaluation, 13% (3/23) MoPc were considered loose versus no CoC, and 61% (14/23) MoPc versus 6% (2/33) CoC showed osteolytic signs ($p < 0.001$).

Chapter 4 ARTICLE 1: Hip Resurfacing Compared to 28-mm Metal-on-Metal Total Hip Replacement, A Randomized Study with Fifteen Years of Follow-up

Pascal-André Vendittoli, Maged Shahin, Charles Rivière, Alain Guy Roy, Janie Barry, Martin Lavigne

Abstract

Background:
Bone stock conservation, hip anatomy preservation, and greater stability are among the promoted advantages of hip resurfacing (HR). However, the disappointing failure of some implants nearly led to its abandonment. The aim of this study was to compare clinical scores and revision and complication rates after HR with those after total hip arthroplasty (THA).
Methods:
Two hundred and three hips were randomized to 28-mm metal-on-metal (MoM) THA (99 hips) or to HR (104 hips). Main outcome measures compared between groups were the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, the revision rate, and the complication rates. The radiographic findings were also assessed.
Results:
After a mean follow-up of 15 years (range, 14 to 16 years), 9 (4.4%) of the 203 patients were lost to follow-up and 15 (7.4%) had died. The Kaplan-Meier survivorship, with revision for any reason as the end point, was 89.2% (95% confidence interval [CI], 82.3% to 96.1%) for HR and 94.2% (95% CI, 89.3% to 99.1%) for THA ($p = 0.292$). The reasons for revision included infection (3 patients), recurrent dislocation (1 patient), and adverse reaction to metal debris (ARMD) (1 patient) in the THA group and ARMD (2 patients) and femoral head loosening (7 patients) in the HR group. With aseptic revision as the end point, the Kaplan-Meier survivorship was significantly higher in the THA group (97.4% versus 89.2%; $p = 0.033$). No dislocation occurred in the HR group compared with 4 in the THA group ($p = 0.058$). Both groups achieved a similar mean WOMAC score (10.7 in the HR group and 8.8 in the THA group; $p = 0.749$), Forgotten Joint Score (87.1 and

85.3, respectively; p = 0.410), University of California Los Angeles (UCLA) activity score (6.3 and 6.4, respectively; p = 0.189), and overall joint perception (p = 0.251).

Conclusions:

The specific HR and MoM 28-mm THA implants used in this study showed good long-term survival and function. The overall rates of complications and revisions were similar in both groups but were of different types. As it provides better femoral bone preservation and biomechanical reconstruction, HR may continue to have a role in selected patients when performed by experienced surgeons and using validated implants.

Level of Evidence: Therapeutic Level I.

Introduction

The use of metal-on-metal (MoM) bearings was reintroduced as an alternative to conventional polyethylene in total hip arthroplasty (THA) because of the biological response to polyethylene debris leading to osteolysis and aseptic loosening1. The early success of 28-mm MoM bearings led to the resurgence of the concept of hip resurfacing (HR)2. The potential advantages of MoM HR are improved hip stability3, reduced proximal femoral stress-shielding4, more optimal restoration of hip biomechanics and gait5-7, bone stock conservation, return to high-demand sports activities8,9, and decreased morbidity if revision surgery is needed10. These attractive benefits created a surge of popularity for HR as a solution for young and active patients liable to undergo revision during their lifetime.

Unfortunately, some HR designs showed unfavorable short-term results and were recalled8,9. Since then, there has been a considerable reduction in the use of HR. Risk factors for MoM HR failure included implant design, patient selection, and surgical technique11. Theoretically, the concept of HR is intuitive, and improved technology and better knowledge about risk factors may lead to its resurgence again.

In 2003, we conducted a randomized controlled trial (RCT) that included 219 patients to compare the clinical outcome between HR and 28-mm MoM THA12,13. We found improved biomechanical reconstruction with HR14, a higher rate of heterotopic bone formation in HR15, and no significant difference in acetabular bone resection16, metal ion levels17, clinical scores, or revision rates after a mean follow-up of 8 years13. To our knowledge, there are currently no long-term studies with a high level of evidence (RCTs) comparing HR and THA. Given the potential benefits of HR in restoring patient anatomy and biomechanics, and its potential advantage in patients with high-demand physical activity, it is important to report the long-term results of this study comparing the clinical and radiographic results at a mean follow-up of 15 years after HR and THA. Our main hypotheses were that HR would provide higher (+10 points) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores while the revision rates would be similar between groups13 at the long-term follow-up.

Materials and Methods

A detailed study protocol has been published previously[12,13]. From July 2003 to January 2006, 219 patients between 18 and 65 years old with degenerative hip disease and without femoral deformity that prevented HR, previous hip arthrodesis, renal insufficiency, known or suspected metal allergy, or known or suspected osteoporosis of the hip were included in this study. The cohort included all patients, representing a wide spectrum of pathologies without exclusion on the basis of sex, femoral head diameter, or other risk factors not known to increase failure rate at the time of study. All patients were operatively managed by 3 hip surgeons (A.G.R., M.L., and P.-A.V.) using the posterior surgical approach. The THA group received a CLS femoral stem (Zimmer) and an Allofit acetabular shell with a 28-mm Metasul chromium-cobalt (CrCo) bearing (Zimmer). The HR group received a hybrid Durom resurfacing implant (Zimmer) **(Fig. 1)**. Patient demographics are presented in **Table I**[13]. Ethics and scientific committee approvals were obtained from our institution, and informed consent was obtained from all participants.

Fig. 1: Postoperative anteroposterior pelvic radiograph of a 47-year-old man randomized for a CLS-Allofit 28-mm MoM total hip arthroplasty (Zimmer) in the right hip and a Durom HR implant (Zimmer) in the left.

TABLE I. Preoperative and Perioperative Data for Patients Who Received the Allocated Treatment

	THA	HR
No. of patients	99	104
Female sex *(no. [%])*	32 (32)	38 (37)
Right side *(no. [%])*	53 (53)	48 (46)
Diagnosis		
Osteoarthritis	78	81
Primary	39	32
Hip impingement	32	45
Protrusio	7	4
Posttraumatic arthritis	1	3
Legg-Calvé-Perthes	3	3
Hip dysplasia*	7	8
Crowe type I	5	4
Crowe type II	2	4
Osteonecrosis	2	3
Inflammatory arthritis	8	5
Rheumatoid arthritis	6	4
Ankylosing spondylitis	2	1
History of septic arthritis	0	1
Age[†] *(yr)*	50.7 ± 8.4 (24-65)	48.9 ± 9.0 (23-64)
Height[†] *(cm)*	171 ± 9.0 (150-195)	171 ± 7.8 (151-192)
BMI[†] *(kg/m^2)*	30.0 ± 6.8 (17.4-49.1)	26.6 ± 4.9 (17.6-42.0)

Acetabular vertical angle†	45.8° ± 5.8° (30°-55°)	47.6° ± 6.3° (31°-64°)
HR femoral component CCD angle†		142.5° ± 6.7° (130°-157°)

*According to the classification system of Crowe et al.[36].
† The values are given as the mean and the standard deviation, with the range in parentheses. BMI = body mass index, and CCD = cervicodiaphyseal angle.

All adverse events requiring reoperation were recorded. Clinical scoring systems (WOMAC score[18], University of California Los Angeles [UCLA] activity score[19], Forgotten Joint Score[20] [FJS], and patient joint perception[21]) were administered to patients at the last follow-up evaluation and compared with previously reported assessments carried out at the 1, 2, and 5-year follow-up evaluations, when available. Anteroposterior radiographs of the pelvis and cross-table lateral radiographs of the involved hip were assessed by 1 observer (M.S.) for the presence of radiolucent lines, osteolysis, or signs of definite implant loosening at the last follow-up, as previously described[13]. Data from all randomized hips of participants who received the allocated intervention were analyzed at the last follow-up, including those who had a reoperation or revision surgery, but excluding the hips in patients lost to follow-up or in those who had died.

Statistical Methods

Continuous variables are presented as the mean with the standard deviation (SD), and categorical variables are given as the frequency and percentage. Categorical variables were analyzed with the chi-square test and Fisher exact test when proportions were <5. Continuous variables were analyzed with a Student t test for data with a normal distribution, and nonparametric Mann-Whitney tests and sign tests were used in the presence of asymmetrical distributions. Comparison of within-group (paired-sample) differences between different follow-up assessments were performed with the related-sample Wilcoxon signed-rank test for continuous variables, and categorial paired samples were analyzed with the related-sample McNemar test. Implant survivorship was analyzed with the Kaplan-Meier estimator and compared with the log-rank test. The data were analyzed using SPSS software (version 25; IBM).

Results

At a mean follow-up of 15 years (range, 14 to 16 years), 9 patients were lost to follow-up and 15 had died **(Fig. 2)**.

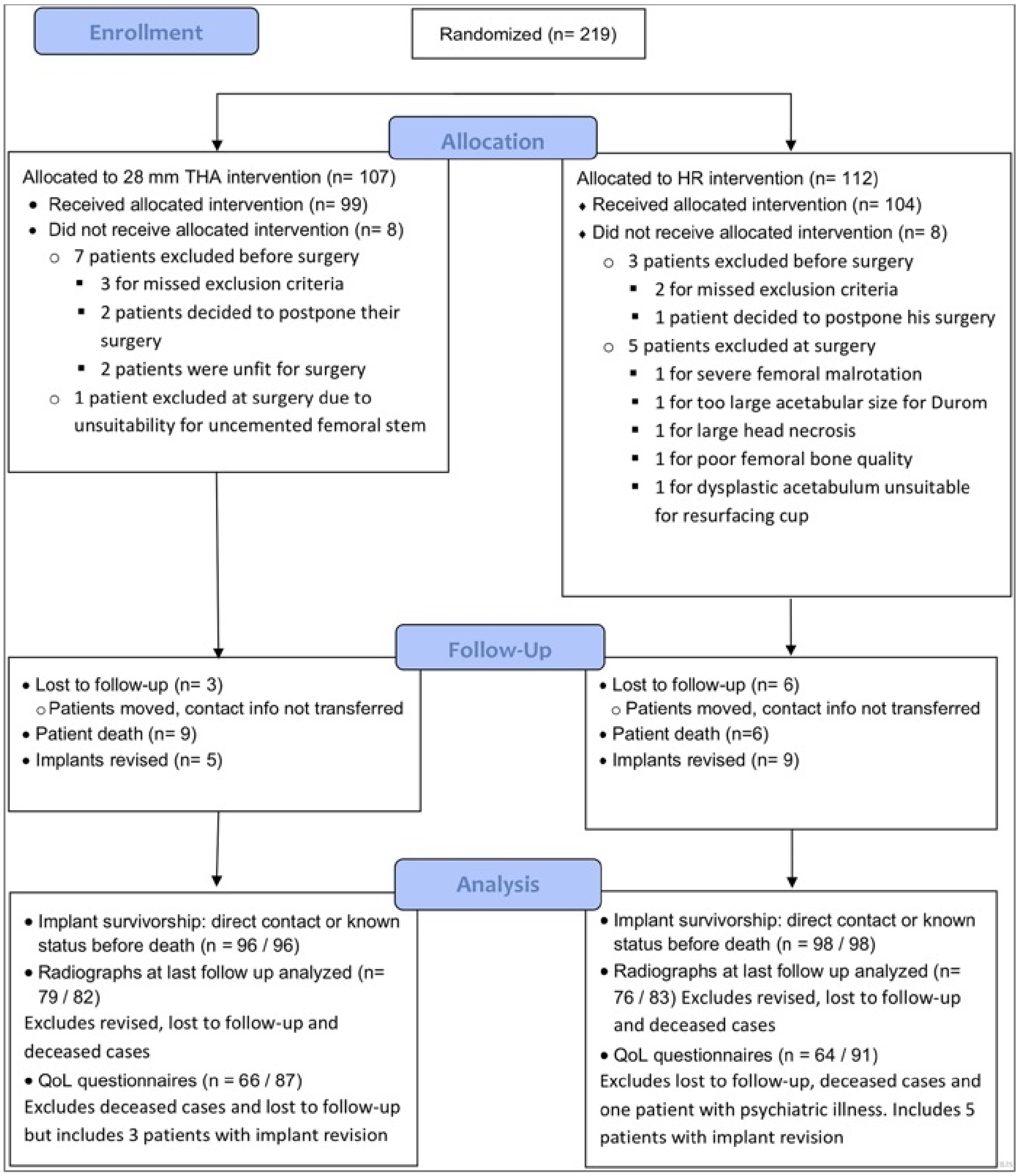

Fig. 2: Patient flow diagram. THA = total hip arthroplasty, HR = hip resurfacing, and QoL = quality of life.

Clinical Scores Evaluation

At the last follow-up, both groups achieved similar mean WOMAC, FJS, and UCLA activity scores **(Table II).** Only the UCLA total score achieved a significant difference (31.7 for HR and 33.2 for THA; p = 0.033). A significant deterioration in all scores was observed within each group between the 5-year and last follow-up evaluations (p = 0.001). Between the 1-year and 5-year evaluations, a significant improvement was observed only for the WOMAC (p = 0.012 for the HR group and p = 0.042 for THA; related-sample Wilcoxon signed-rank test). At the last follow-up, patient perception of the reconstructed hip was similar between the groups (p = 0.251; **Table III**), but more patients (60%) in the HR group perceived their reconstructed hip joint as "natural" than in the THA group (44%; p = 0.078). There was no difference between groups regarding reported pain around the hip joint (p = 0.996; **Table IV**).

TABLE II. Clinical Functional Scores

	1 Yr		5 Yr		Last Follow-up*	
	Score†	P Value	Score†	P Value	Score†	P Value‡
WOMAC		0.370		0.615		0.749
HR	7.9 ± 12.3		5.1 ± 9.5		10.7 ± 16.2	
THA	9.3 ± 10.2		5.8 ± 8.9		8.8 ± 11.8	
UCLA activity		0.049		0.035		0.189
HR	7.1 ± 1.7		7.5 ± 1.7		6.3 ± 2.0	
THA	6.6 ± 1.7		6.9 ± 1.8		6.4 ± 4.6	
UCLA total		0.054		0.177		0.033
HR	34.4 ± 5.3		35.5 ± 4.0		33.2 ± 6.5	
THA	33.4 ± 5.4		34.8 ± 4.0		31.7 ± 6.3	
FJS						0.410
HR	—		—		87.1 ± 16.4	
THA	—		—		85.3 ± 16.1	

*Data were available for 66 of 87 patients in the THA group and for 64 of 91 in the HR group (see Fig. 2).
†The values are given as the mean and the standard deviation.
‡Mann-Whitney test (non-normal distribution) for comparison of groups. A significant deterioration was detected within each group between the 5-year and last follow-up evaluations for WOMAC, UCLA activity, and UCLA total scores (p = 0.001; related-sample Wilcoxon signed-rank test). Between the 1-year and 5-year evaluation, a significant improvement was detected within each group only for WOMAC score (p = 0.012 for HR and p = 0.042 for THA; related-sample Wilcoxon signed-rank test).

TABLE III. Patient Perception of the Reconstructed Hip*

	1 Yr	P Value	5 Yr	P Value	Last Follow-up†	P Value‡
		0.242		0.908		0.251
Natural hip						
HR	45%		55%		60%*	
THA	51%		52%		44%*	
Artificial hip without limitation						
HR	26%		22%		12%	
THA	25%		21%		15%	
Artificial hip with minimal limitation						
HR	36%		22%		26%	
THA	24%		26%		35%	
Artificial hip with substantial limitations						
HR	4%		1%		2%	
THA	0%		1%		6%	
Nonfunctional hip						
HR	0%		0%		0%	
THA	0%		0%		0%	

*The difference between the groups was not significant at the 1-year (p = 0.242), 5-year (p = 0.908), and last (p = 0.251) follow-up evaluation.
†Data were available for 66 of 87 patients in the THA group and for 64 of 91 in the HR group (see Fig. 2).
‡At the last follow-up, the difference between the groups with respect to patient perception of the reconstructed hip as a "natural hip" did not reach a significant difference (p = 0.078).

TABLE IV. Self-Reported Pain Perception at and Around the Hip at Different Follow-up Periods*

	1 Yr		5 Yr		Last Follow-up	
		P Value		P Value	†	P Value
Pain at any site		0.124		0.254		0.996
HR	31%		36%		52%	
THA	41%		45%		52%	
Pain site						
Groin		0.862		0.745		0.344
HR	13%		6%		11%	
THA	14%		5%		17%	
Hip		0.551		0.488		0.520
HR	12%		24%		28%	
THA	15%		20%		33%	
Thigh		0.661		0.241		0.667
HR	4%		2%		6%	
THA	5%		6%		5%	
Buttock		0.370		0.838		0.023
HR	8%		13%		28%	
THA	12%		12%		12%	

*Data were available for 66 of 87 hips in the THA group and for 64 of 91 hips in the HR group (see Fig. 2).

Revision Surgeries (Table V)

Overall, revision rates were similar between the THA and HR groups (5.2% and 9.2%, respectively; p = 0.285), but the revision rate for aseptic loosening was significantly lower in the THA group (2.1% versus 9.2%; p = 0.008). At a follow-up of 15 years, the Kaplan-Meier survivorship estimate, with revision for any reason as the end point, was 89.2% (95% confidence interval [CI], 82.3% to 96.1%) for the HR group and 94.2% (95% CI, 89.3% to 99.1%) for the THA group (p = 0.292) **(Fig. 3-A)**. With aseptic revision as the end point, it was 89.2% (95% CI, 82.3% to 96.1%) for the HR group and 97.4% (95% CI, 93.9% to 100%) for the THA group (p = 0.033) **(Fig. 3-B)**. One patient in the THA group had an immediate postoperative dislocation because of a malpositioned acetabular component, and early component revision was performed without recurrence of dislocation. One patient in the THA group had adverse reaction to metal debris (ARMD) that resulted from impingement of a 28-mm + 7-mm skirted head on the acetabular metallic liner **(Figs. 4-A, 4-B, and 4-C)**. The ARMD soft-tissue damage caused recurrent dislocations, with both leading to revision surgery. Two deep infections developed in the THA group after postoperative joint lavage and debridement were performed for early infection. Both were cured with 2-stage revision. In a patient in the THA group, a late hematogenous infection of unknown origin (Staphylococcus aureus) was treated with 1-stage revision without recurrence. Revisions in the HR group were performed in 2 patients who had ARMD and in 7 patients who had femoral head loosening **(Figs. 5-A through 5-D)**. One ARMD resulted from edge-loading and increased wear due to acetabular component displacement with secondary fixation in an abduction angle of 75°. The other ARMD was diagnosed in a female patient at 96 months after implantation. She presented with delayed-onset groin pain, progressive femoral neck narrowing, elevated metal ions, and periarticular fluid collection. She had a 46-mm femoral implant in good position and an acetabular cup inclination of 50°. The femoral head loosening developed in the 7 patients (2 men and 5 women) in the HR group at an average at 63 months (range, 7 to 154 months) postoperatively. The mean femoral head diameter was 48.6 mm (range, 44 to 56 mm). During the revisions, 4 of 7 acetabular components were retained and matched with a large-diameter MoM femoral head on a primary femoral stem. For the THA revisions, both components were revised in 4 of 5 patients. The mean operative times for the HR and THA revisions were 117 and 166 minutes, respectively (p = 0.044).

TABLE V. Complications in Both Groups After a Mean Follow-up of 15 Years (Range, 14 to 16 Years)

	THA			HR			
	No.	Reoperation	Revision	No.	Reoperation	Revision	P Value
Early adverse events							
No. of cases analyzed	99			104			
Intraop. fracture							0.038
Acetabular fracture	0			2			
Proximal femoral fracture	4			0			
Deep vein thrombosis (clinically symptomatic)	3			1			
Neurapraxia	2			1			
Symptomatic leg-length discrepancy	1	1		1			
Superficial wound infection	2	4		1	1		
Adverse event occurrence up to last follow-up							
No. of cases analyzed	96			98			
ARMD	1		1	2		2	
Dislocation	4			0			0.058
Simple, without recurrence	2			0			
Recurrent dislocation	2*		1	0			
Femoral aseptic loosening	0			7		7	0.008
Femoroacetabular impingement (symptomatic)	0			2	1		
Heterotopic ossification (symptomatic)	0			4	1		
Deep infection†	3			0			0.119
Late chronic	2	2†	2	0			
Late hematogenous	1		1				
Periprosthetic fracture	1	1		0			0.495
Reoperations without revision	6	8		3	3		0.239
Revision procedures	5		5	9		9	0.285

*One patient had a revision for a dislocation secondary to ARMD (adverse reaction to metal debris).
*Two of these patients had a subsequent revision.

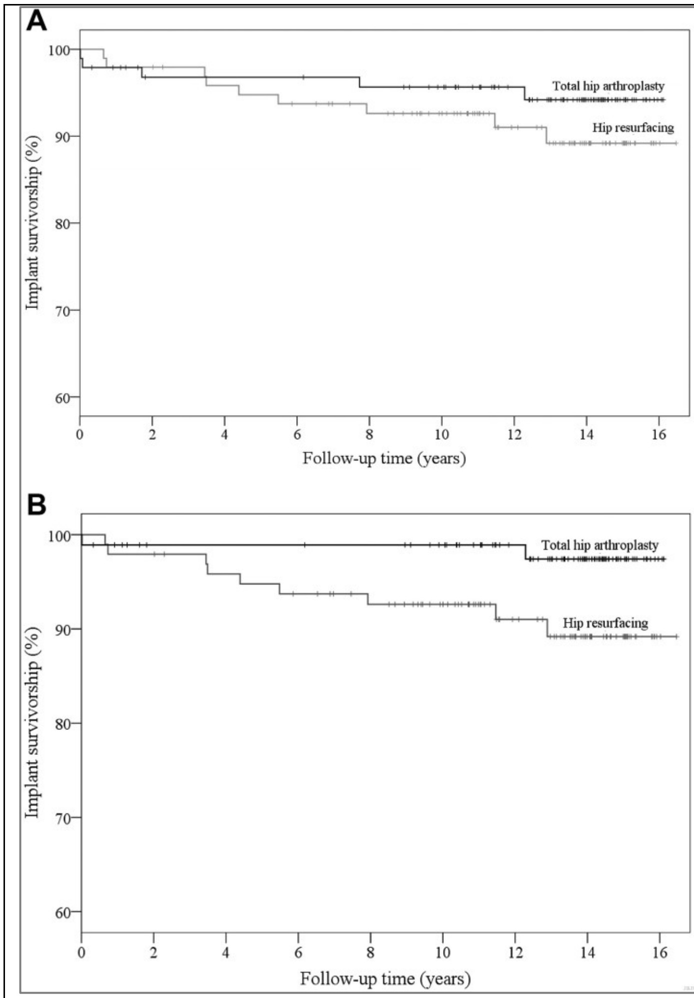

Fig. 3: Fig. 3-A: At a mean follow-up of 15 years, the Kaplan-Meier survivorship curve, with revision for all causes as the end point, was 89.2% (95% CI, 82.3% to 96.1%) for HR and 94.2% (95% CI, 89.3% to 99.1%) for THA (p = 0.292). **Fig. 3-B** At a mean follow-up of 15 years, the Kaplan-Meier survivorship curve, with aseptic revision as the end point, was 89.2% (95% CI, 82.3% to 96.1%) for HR and 97.4% (95% CI, 93.9% to 100%) for THA (p = 0.033).

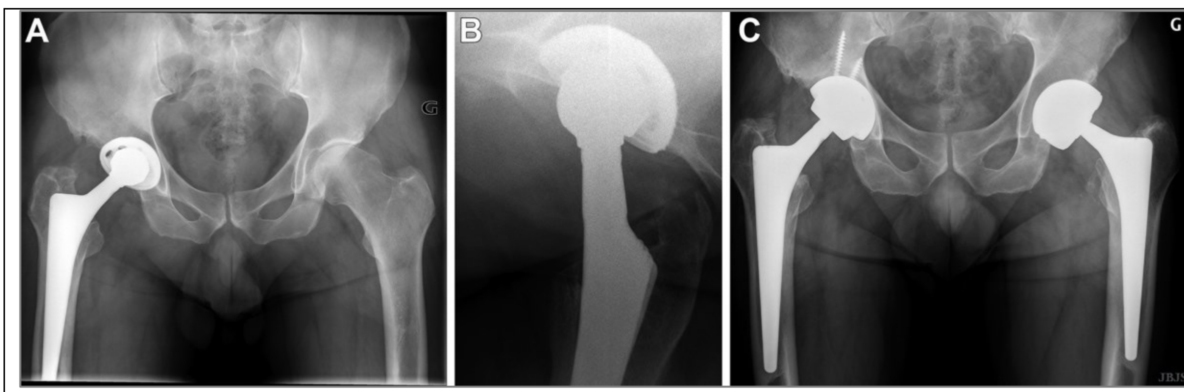

Fig. 4: Figs. 4-A, 4-B, and 4-C A 55-year-old man randomized for a 28-mm MoM THA (+7-mm skirted femoral head) in the right hip. Fig. 4-A Postoperative anteroposterior pelvic radiograph. Fig. 4-B True lateral hip radiograph showing the increased acetabular component anteversion and the proximity of contact between the head skirt and the acetabular metallic liner. On repeated contact between the CrCo skirt and the CrCo acetabular liner, the patient developed local ARMD and recurrent dislocations. Fig. 4-C Anteroposterior pelvic radiograph made after right hip revision. The femoral stem was retained while the

acetabular component was revised, reducing its anteversion and using a modular ceramic liner. Bearing diameter was increased to 40 mm with the appropriate modular ceramic liner and femoral head.

Reoperation without Revision and Other Adverse Events

There were no significant differences between the 2 groups with regard to reoperation rates without implant revision or any other adverse event rates (Table V). Four patients in the THA group experienced a dislocation compared with none in the HR group ($p = 0.058$). Two early dislocations were managed with closed reduction, without recurrence, and 2 required revision surgery, as described above.

Radiographic Evaluation

On radiographic evaluation, no implant was considered to be loose. Periprosthetic nonprogressive (<2 mm) radiolucent lines were observed in 40.5% of the patients who had THA, mostly in the proximal aspect of the femur, compared with 2.6% of the patients who had HR ($p < 0.001$). For THA, all radiolucent lines were located in femoral Gruen zones (1, 7, 8, or 14). These radiolucent lines represented the normal bone remodeling usually seen around this specific stem, as reported by Rivière et al.[22]. For HR, incomplete and nonprogressive radiolucent lines around the femoral metaphyseal stem in zones 1, 2, and 3, as described by Amstutz et al.[23], were evident in 2 patients. These were not associated with osteolysis or component migration. Bilateral nonprogressive femoral neck narrowing was observed in a female patient who had HR bilaterally. The prevalence of heterotopic ossification (HO) was significantly higher in the HR group than the THA group (40.8% compared with 24.1%; $p = 0.026$). Brooker grade-III and IV HO was observed in 9.2% of the hips in the HR group and 3.8% of the hips in the THA group ($p = 0.204$).

Discussion

The concept of HR is attractive, but there is a lack of long-term, high-quality evidence regarding its value in comparison with THA. In this RCT with an average follow-up of 15 years, the functional scores were similar between the groups. Both procedures showed low and similar overall revision rates (9.2% in the HR group compared with 5.2% in the THA group; $p = 0.285$). However, the types of complications requiring reoperation or revision were different between groups **(Table V)**. Infection and dislocation occurred only in the THA group, while femoral head loosening, and symptomatic HO were observed only in the HR group. When aseptic revision was the end point, THA had a significantly higher Kaplan-Meier survivorship estimate than HR (97.4% compared with 89.2%; p = 0.033).

Clinical Outcome Assessed by Functional Scores

At the last follow-up evaluation, we found no significant difference in the clinical scores between the 2 groups, except for the UCLA total score (Table II). This is slightly different from what we reported at a mean follow-up of 5 years, when a significantly higher mean UCLA activity score was seen with HR (7.5 versus 6.9 with THA; p = 0.035). In the current study, we observed a significant reduction in all scores over time in both groups (5 years versus the last follow-up, p = 0.001). Aging may explain this trend over time. In a systematic review comparing THA and HR, Hellman et al. found similar Harris hip scores (11 articles; p = 0.36), while the UCLA activity score was significantly higher for HR (9 articles; p < 0.001)[24]. The Swedish Hip Arthroplasty Register reported a case-control study comparing patient-reported outcome measures (PROMs) in HR and THA showing significantly better Hip disability and Osteoarthritis Outcome Score (HOOS) function in daily living and HOOS function in sports for HR, but no significant difference in HOOS quality of life, HOOS pain, HOOS symptoms, EuroQol-5 Dimensions (EQ-5D) index, hip pain, or satisfaction at 7 years postoperatively[25]. Most validated PROMs have some limitations. Some patients may have excellent FJS or WOMAC scores, while still perceiving their hip as being not "natural." Conversely, patients may feel that their hip is "natural," but they have suboptimal FJS or WOMAC scores[26]. In our study, 60% of patients in the HR group perceived their joint as "natural" versus 44% of those in the THA group (p = 0.078). Although not reaching significance, these results contrast with the midterm evaluation, in which we observed rates of 55% in the HR group compared with 52% in the THA group **(Table III)**[13].

Implant Survivorship

In this study, Kaplan-Meier survivorship curves, with revision for all causes as the end point, were similar for HR and THA (p = 0.292). Our results are consistent with the systematic review by Hellman et al. (12 articles involving 2,125 hips), in which they reported revision rates of 5.9% for HR versus 3.2% for THA (p = 0.18)[24]. Our study only had a power of 20% to detect a difference of 4% in the revision rate (9.2% in the HR group compared with 5.2% in the THA group). To reach a power of 80%, 635 patients per group would have been required. However, the types of complications requiring revision were different between the groups. When using aseptic revision as the end point, the Kaplan-Meier survivorship estimate significantly favored the THA (**Fig. 3-B**; $p = 0.033$). In the 2018 Australian Orthopaedic Association National Joint Replacement Registry annual report, which included a larger patient population and different implants, a higher cumulative percent revision was found in the HR group than in the THA group at 17 years (adjusted hazard ratio, 1.37; $p < 0.001$). Their most common reasons for HR revision were metal-related pathology (28%), loosening (24%), and fracture (18%). They identified female sex, increasing age, and small head size as risk factors for HR failure[27]. In our study, 7 HR revisions were performed for femoral loosening (2 men and 5 women with a mean head diameter of 48.6 mm). Aseptic loosening of the HR femoral component is most likely related to insufficient and/or improper initial fixation, fatigue failure of the underlying cement-bone interface, or femoral head osteonecrosis due to unfavorable cementing technique[10]. We believe that femoral head loosening in 2 of our HR patients was the result of poor patient selection as 1 patient was an osteopenic woman with a femoral head cyst of >1 cm3 and the other was a man with hemochromatosis. The Durom HR femoral implant was associated with a higher risk of femoral head loosening[28,29]. Improper implant design and cement mantle were linked to higher temperature and thermal bone damage during cement curing and may have led to femoral head necrosis and loosening[30-32]. Because of its poor performance, mostly related to loosening of the U.S. version of the acetabular cup (not used in the present study), the Durom HR components were recalled by the manufacturer in 2008[33].

We observed ARMD in 3 patients in this study: 1 secondary to impingement of the skirted head of the THA component on the acetabular metallic liner, 1 because of a malpositioned acetabular component of the HR implant, and 1 without obvious cause. These results support the good performance of the Metasul bearing used in the 28-mm femoral head THA component or HR implant. In fact, metal ion release with the Durom HR implant is low[13]. Despite the longer operative time and the wider exposure[12], no early postoperative infection occurred in the HR group, while 3 infections occurred in the THA group. One of these patients had psoriatic arthritis as an original diagnosis. Similarly, Hellman et al. reported a lower infection rate in the HR group (0.5%) than in the THA group (1.2%)[24].

Other Adverse Events and Reoperation

The prevalence of HO was significantly higher in the HR group ($p = 0.026$). Four patients in the HR group with HO were symptomatic, with 1 requiring resection[34]. The rate of HO in our patients was similar to that reported in a systemic review (3,799 HRs and 3,282 THAs), in which the overall prevalence was 26% to 58%, while the rate of severe HO was 4% to 7.6%[35]. The wider surgical dissection and formation of osseous debris during HR femoral head reaming are potential risk factors for HO. Hence, some authors have recommended meticulous surgical technique and have considered routine use of nonsteroidal anti-inflammatory drugs as prophylaxis against HO following HR[15].

No dislocation occurred in the HR group, whereas 4 patients in the THA group had dislocations (including 2 recurrent dislocations requiring revision surgery). The main factors favoring hip stability after HR are the preservation of hip anatomy (head size and proximal femoral 3-dimensional architecture). Hellman et al. also reported a lower rate of dislocation in the HR group than in the THA group (0.5% and 3.1%, respectively; $p = 0.03$)[24]. With use of cross-linked polyethylene and femoral head diameters of >28 mm, current rates of postoperative hip dislocation after THA may be lower than in the current study.

Study Limitations

This study is not registered as it was conducted before registration was common or required. Since most clinical results were self-reported, the patients' awareness of their treatment group (patients were not blinded to their prosthetic type) may have favorably biased the results toward the HR. Nevertheless, we observed no clinically relevant difference in clinical scores between the HR and THA groups. In addition, the number of enrolled patients limited the power of the study. We observed a trend favoring the HR group for some outcome scores (WOMAC, FJS, patient joint perception, and UCLA activity) and favoring the THA group for the implant survivorship. Although these differences might have become significant with a larger number of subjects, this might not have translated into clinically important differences. Last, the results of our study are implant-specific. At the time of the RCT, there was no long-term follow-up of highly cross-linked polyethylene, and the 28-mm MoM bearing was believed to be the most appropriate option to be compared with HR. The results of our study might have been different with a THA using cross-linked polyethylene combined with a femoral head that was >28 mm.

Conclusions

In the long term, MoM HR and a 28-mm femoral head THA implant showed similar functional outcome and overall implant survivorship, but THA had a significantly inferior aseptic revision rate. By providing better femoral bone preservation and more optimal hip biomechanics, HR remains an option for young and active patients, when performed in the appropriate patient by properly trained surgeons and using validated prostheses.

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Chapter 5 ARTICLE 2: Ceramic-on-Ceramic Total Hip Arthroplasty Is Superior to Metal-on-Conventional Polyethylene at 20-Year Follow-Up, A Randomized Clinical Trial

Pascal-André Vendittoli, Maged Shahin, Charles Rivière, Janie Barry, Pauline Lavoie, Nicolas Duval

Abstract

Background:

Metal-on-conventional polyethylene (MoPc) bearing wear-related biological reactions in total hip arthroplasty (THA) continue to raise concerns among young, active patients. Ceramic-on-ceramic (CoC) bearings may offer improved outcomes in this patient population.

Questions/purposes: The aim of this study was to determine if, more than 20years postoperatively, there is a difference between MoPc and CoC THA in terms of (1) survivorship, (2) related complications, (3) radiographic signs of wear, and (4) functional scores.

Hypothesis:

CoC bearing THAs have superior clinical results compared to MoPc THAs.

Patients and methods: A total of 140 hips in 116 patients with a mean age of 42years were randomised to receive CoC or MoPc THA between 1996 and 2001. Sixty-nine hips in 58 patients received MoP and 71 hips in 68 patients received CoC. Revision rate, WOMAC score, and radiological signs of osteolysis and loosening were compared at last follow-up.

Results:

After a mean follow-up of 21years (19-23), 40 patients (48 THAs; 34%) had died and 6 patients (6 THAs; 4%) were lost to follow-up. Aseptic revision rate was significantly higher in the MoPc group (17/69; 24.6%) versus CoC (2/71; 2.8%; $p<0.001$). Kaplan-Meier survivorship estimator with revision for aseptic reasons was 73.6% (95% CI: 63.3-84.9%) for MoPc and 96.9% (95% CI: 92.8-100%) for CoC ($p<0.001$). On radiographic evaluation, 13% (3/23) MoPc were considered loose versus no CoC, and 61% (14/23) MoPc versus 6% (2/33) CoC showed osteolytic signs

($p<0.001$). CoC had better mean WOMAC scores than MoPc (11.0 vs. 19.4; $p=0.048$). No ceramic fracture was observed.
Conclusion:
In this RCT, CoC bearings provided excellent results and were safer than MoPc bearings at more than 20-year follow-up. The long-term in vivo behaviour of CoC bearing makes it a great THA option for middle-aged patients and should be compared to newer polyethylene bearings.
Level of evidence: I.

1. Introduction

The longevity of bearing surfaces in total hip arthroplasty (THA) in young and active patients is still an important debate [1]. Polyethylene wear-related biological reactions have attracted the attention towards alternative hard-on-hard bearings Ceramic-on-ceramic (CoC) bearings offering a greater scratch resistance and lesser wear debris production, was linked to a reduction in wear-induced osteolysis, in the cumulative long-term risk of dislocation, and in the corrosion of the head-neck modular junction [1]. However, reports have raised concerns about the potential complications of CoC bearings, which include noises and component fracture [2-5].

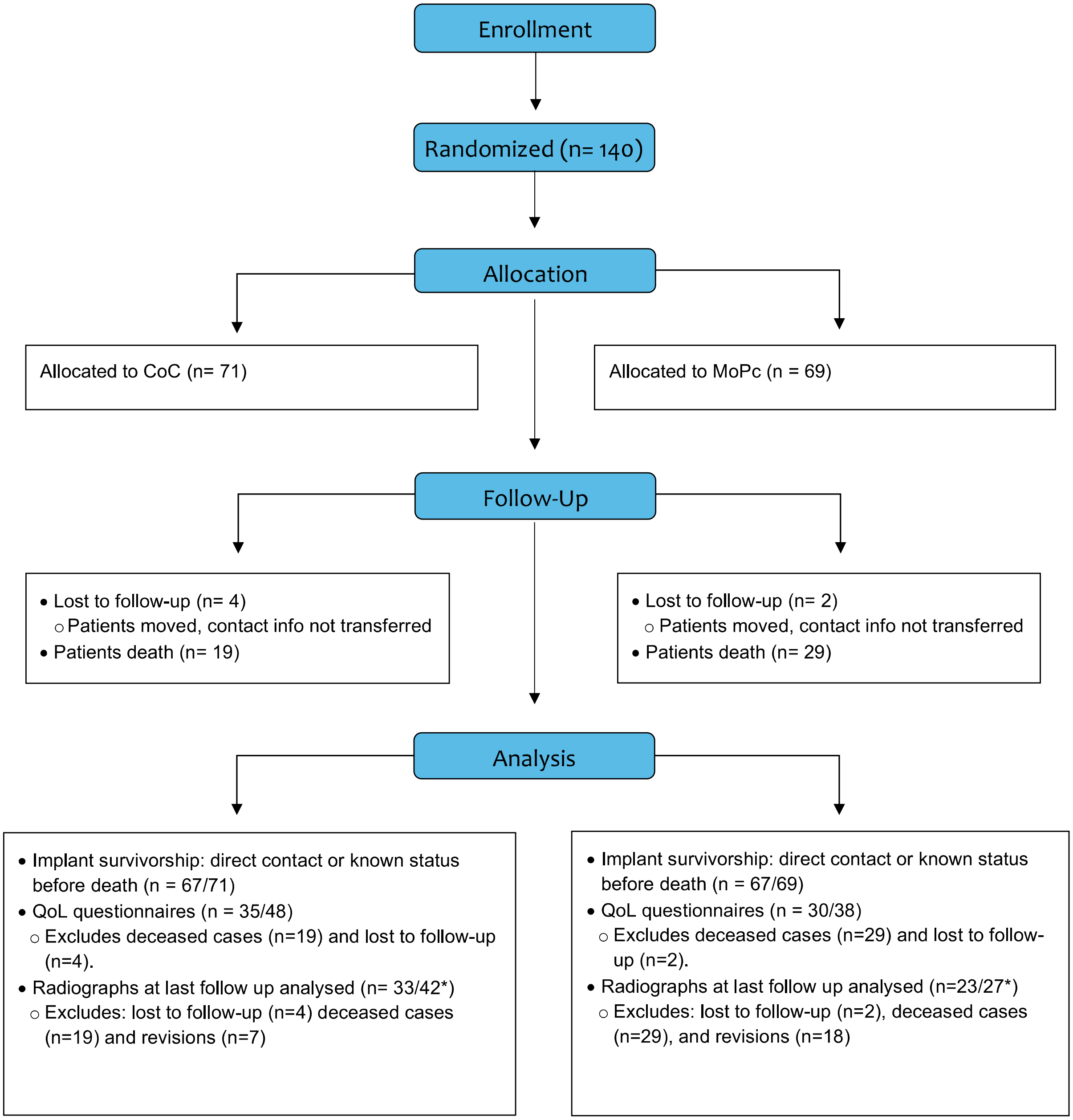
In 1996, we conducted a randomised control trial (RCT) comparing the clinical and radiological results of alumina-alumina to metal on conventional polyethylene (MoPc) bearings in 140 THAs. After a mean follow up of 12 years, we found a significantly higher revision rate in MoPc (11.6%) compared to CoC (1.4%) [6, 7]. All revisions in the MoPc group were related to polyethylene wear osteolysis. There is scarcity of long-term results of RCTs studying CoC bearings and heterogenicity of the published results [8, 9].

Evaluating our RCT COC and MoPc study groups, more than 20 years after implantation, we sought to answer the following questions: Is there a difference between MoPc and CoC THA in term of (1) survivorship, (2) related complications, (3) radiographic signs of wear, and (4) clinical scores. We hypothesised that CoC bearings have excellent long-term survival.

2. Patients and Methods

2.1 Patients

Between 1996 and 2001, 140 primary THAs in 116 patients aged less than 70 years with were randomised for CoC or MoPc bearing (69 MoPc and 71 CoC, Figure 1: patients' flow chart). Patients' demographics are presented in Table 1[6]. Ethics and scientific committee approvals were obtained from our institution, and informed consent was obtained from all participants. After a mean time after surgery of 21 years (19-23; 1.4), 40 patients (48 hips) were deceased from causes unrelated to their THA (7 MoPc and 1 CoC had undergone a revision of their THA before death) and 6 patients (6 THAs, 4%) have been lost to follow-up.



*One revised case died during the follow up in the CoC group and 7 in the MoP group

Fig. 1 Patients' flow chart [THA, total hip replacement (MoPc, Metal-on-Polyethylene conventional; CoC, Ceramic-on-Ceramic)]

Table I, Patient demographics data

	Metal on polyethylene	Ceramic on ceramic	p
Numbers randomised	69	71	
Gender			0.093
Male	38	30	
Female	31	41	
Age (years)	56.8	54.9	0.317
(Min-Max; SD)	29-70; 10.7	23-70; 12.5	
Side			0.986
Right	38	38	
Left	31	33	
Weight (Kg)	73.5	77.4	0.188
(Min-Max; SD)	45-107; 12.6	48-160; 21.5	
Diagnosis			0.869
Osteoarthritis	43	44	
Femoral head avascular necrosis	10	11	
Hip dysplasia	4	2	
Epiphysis pathology	4	1	
Inflammatory disease	8	12	
Tumour	0	1	

2.2 Methods

The same hybrid THA was implanted in all patients (Ceraver Osteal, Roissy, France, Figure 2). The cemented femoral implant has a smooth titanium alloy (TiAl) surface covered by a layer of Ti oxide. The uncemented acetabular implant (Cerafit®) is made of Ti. The bearing surfaces were either an alumina insert with an alumina femoral head of 32 mm for the CoC group, or a polyethylene insert (Chirulen 1020, sterilized with ethylene oxide in 1996 and 1997, and with gamma irradiation in argon from 1997 to 2001) with a 28-mm stainless steel femoral head for the MoP group. No liner had an elevated lip. An anterolateral approach was used in 122 hips, and a posterior approach was used in the remaining 18 hips. The femoral canal was prepared with rasp only, and we attempted to insert the largest possible implant. All stems were cemented with low-viscosity cement (Simplex®, Stryker), using a second-generation cementing technique. For more implant and surgical technique details, a detailed protocol of this RCT has been published previously [6, 7].

Fig 2 Ceraver Osteal, Roissy, France, cemented femoral stem and acetabular component.

2.3 Methods of Assessment

All adverse events requiring reoperation or revision during the follow-up period were recorded. WOMAC score [10] and Joint Perception scores [11] were administered to patients at last follow-up. Most recent anteroposterior (AP) radiographs of the pelvis and cross-table lateral radiographs of unrevised THA in living subjects were assessed by one observer (MS). Description of radiolucent line of more than 2mm and local osteolysis were done with the use of Gruen's zones for the femur [12] and Charnley-De Lee for the acetabulum [13]. Osteolysis was recorded for either cavitary defect, or calcar resorption which seems not to be a consequence of calcar remodeling. Implant stability was evaluated according to criteria described by Engh et al. [14]. The vertical inclination of the acetabular component was measured by reference to a horizontal line between the teardrops. Data from all randomized hips of participants who received the allocated intervention were analyzed, including those who had a reoperation or revision surgery.

2.4 Statistical analysis

Continuous variables are presented as means (Min-Max; SD) and categorical variables, as frequencies and percentages. For primary and secondary outcomes, the MoP and CoC groups were compared by Chi-square and Mann-Withney for categorical and continuous variables respectively. Implant survivorship was evaluated by Kaplan-Meier method. As Kaplan-Meier approach was not designed to assess implant survivorship, it underestimates the implant survivorship in orthopaedic studies where a large number of patients decease during follow-up[15]. For that reason, deceased patients were not considered lost to follow up in our Kaplan-Meier analysis. The significance level was defined as $p<0.05$. Statistical analyses were performed with SPSS 25.0 software (SPSS Inc., Chicago, IL, USA).

3. Results

Implant survivorship

Aseptic revision rate was significantly higher in the MoPc (17/69, 25%) than in CoC (2/71, 3%, $p<0.001$). The Kaplan-Meier survivorship estimator with revision for aseptic loosening or severe wear as the endpoint was 73.6% (95% CI, 62.8 – 84.4%) for MoPc and 96.9% (95% CI, 92.8 - 100%) for CoC ($p<0.001$. Figure 3). Mean time after surgery for aseptic revision was 12.9 (0-20; 5.0) years in MoPc and 11.5 (8-15; 5.0) years for CoC. Of the 17 aseptic MoPc revisions, one was for an intra operative acetabular fracture, discovered on the early postoperative radiograph, leading to early cup mobilisation. Other revisions were required for severe polyethylene wear and/or wear related implant loosening. Five of these had unipolar acetabular revisions and the other 11 had both components revised (Figure 4). One MoPc revision case had a polyethylene wear debris granulomatous pseudo-tumour causing crural nerve compression and axonotmesis. In the CoC group, the 2 revisions included both components; one was performed for a traumatic periprosthetic femoral fracture 15.3 years after surgery and the other one for femoral stem mechanical loosening after 8.4 years. Deep infection requiring 2 stages revision occurred in 5 CoC and in 1 MoPc. Four of the 6 infections developed during a short time period and were attributed to a sterilization problem at our centre, which was subsequently corrected.

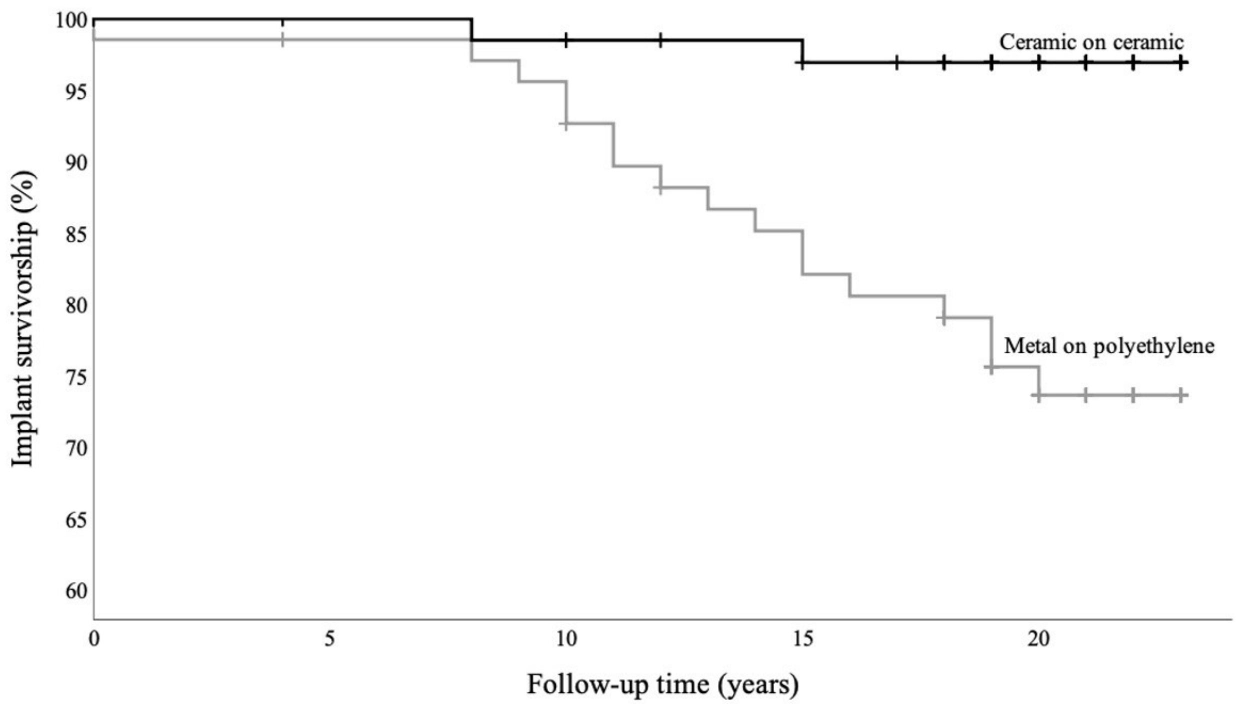


Fig 3 Kaplan-Meier survival curve with revision for aseptic loosening or severe wear as the endpoint was 73.6% (95% CI, 62.8 - 84.4%) for MoPc and 96.9% (95% CI, 92.8 - 100%) for CoC ($p < 0.001$).

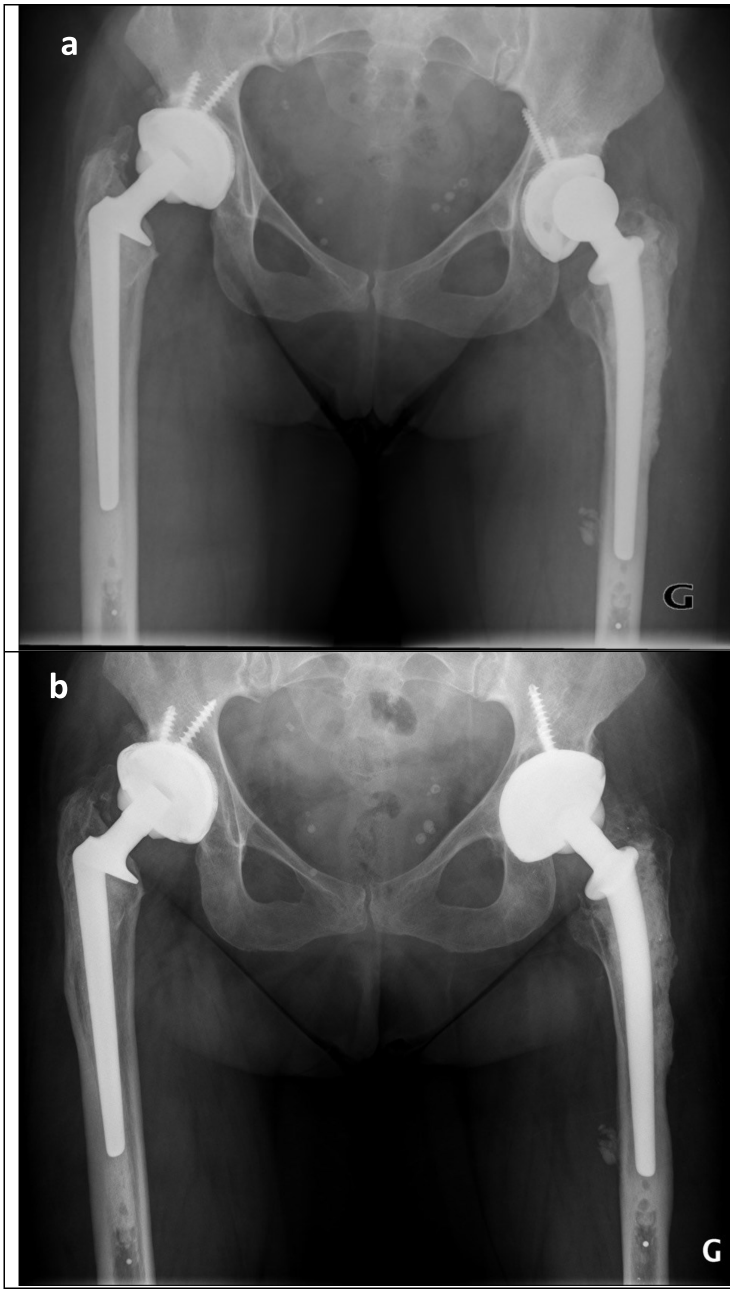


Fig 4 a) Anteroposterior pelvic radiograph of a 42-year-old woman with preoperative severe hip dysplasia 7 years after bilateral hip replacement. She was randomised for right CoC THA and left MoPc THA. Superior femoral head migration and polyethylene wear were observed on left hip radiograph (note the vertical cup position at 72°).
b) Last follow up anteroposterior pelvic radiograph in 2019 (15 years after left hip revision. Femoral stem was kept while the acetabular component was revised, reducing its abduction angle. Bearing diameter was increased to 32 mm with the appropriate modular ceramic liner and femoral head.

Other complications

Hip dislocation occurred in 3 MoPc THAs, 2 with a single episode, and 1 recurrent dislocation (still being treated conservatively). No ceramic component fracture was encountered.

Radiographic Analyses

Periarticular osteolysis signs (lytic zones or lucent lines) were observed in 60.9% MoPc (14/23) versus 6.1% (2/33) in CoC ($p<0.001$). Osteolysis signs were present at the pelvis in 13% MoPc (3/23) versus none in CoC and at the femur in 8.7% (2/23) MoPc versus none in CoC and 13% (3/23) of MoPc THAs were considered loose versus none in CoC.

Functional Scores

Pre-operative WOMAC scores were similar (67.3 vs 67.3 p=0.986, Figure 5). Although better WOMAC scores were obtained in the CoC group after 6.6 years (15.5 versus 19.7, p=0.435) and 12.3 years (10.7 versus 16.6, p=0.100), it did not reach a statistically significant difference. However, at last follow up, the WOMAC score was statistically better in CoC (11.0 vs 19.4 p=0.048). Moreover, significantly more CoC patients reported no limitation with their THA (68% versus 37%, p=0.013) but overall patient's Joint Perception results were not statistically significantly different (Table II).

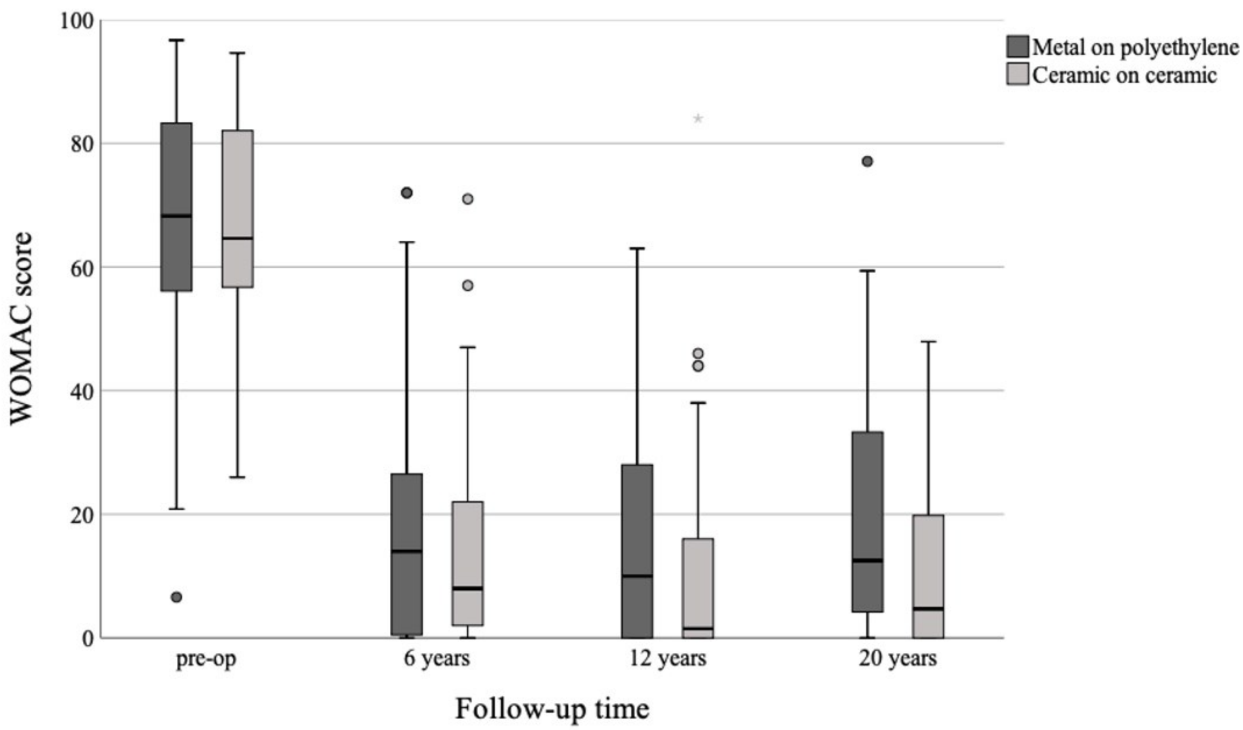


Fig 5 Box plots showing the pre-operative WOMAC scores in both groups (CoC and MoPc) and their post-operative values after a mean of 6 years, 12 years, and 20 years. The boxes represent the median and interquartile range and the whiskers the data range.

Table II. Perception questionnaire at last follow-up

	Metal on polyethylene	Ceramic on ceramic	P
Natural hip	33%	54%	0.073
Artificial hip without limitation	4%	14%	
Artificial hip with minimal limitation	52%	23%	
Artificial hip with significant limitations	11%	9%	
Non-functional hip	0%	0%	

Discussion

THA with MoPc has a high revision burden according to its usage (active patient and/or longer time in vivo). CoC articulation has been proposed as an alternative bearing since 1970s [16]. However, there is concern about long-term outcomes of ceramic-on-ceramic bearings. After more than 20 years, in the current study, in comparison to MoPc, CoC bearings THAs provided superior implant survivorship, no ceramic specific complications, and more favorable radiological and clinical outcomes. On their own, the clinical results of our CoC group are excellent and makes it a great option for the active middle-aged patients.

Implant survival

At 20-year follow up, our CoC group seldom required revision (2/71, 3%) for aseptic reasons, whereas MoPc were revised 8 times more (17/69, 25%). This represents excellent 20-year survival of 96.9% in CoC group (Kaplan-Meier estimate). Consistent with MoPc survival, recent evidence derived from pooled joint registry and case series of THA data suggests estimated survivorship for THA was 70% and 79% at 20 years, respectively [17]. Our findings correlate with a systematic review of RCTs and meta-analysis comparing THA with of 6 different bearings with more than 10 years follow up [8]. They reported a higher risk of revision of MoPc compared to CoC (RR 2.83; 95% CI=1.20 to 6.63). Similarly, a recent meta-analysis of RCTs looked at short to midterm survivorship of CoC, ceramic-on-cross-linked polyethylene (CoPxl) or MoPxl bearings in 2599 THAs, found that the three bearing surfaces performed significantly better than MoPc [18].

Causes of aseptic revisions:

Three revised MoPc had relatively vertical cup alignment that led to premature polyethylene wear (70.2°, 61.9° and 72.2° acetabular inclination angles). The mean acetabular angle of the revised

MoPc was 68.1° versus 49.6° for the unrevised cases. A significant increase in polyethylene linear wear was reported with cup inclinations greater than 55° [19]. Migaud et al. investigated the reasons and timing of revision in 238 CoC THAs and 1721 MoP THAs (77% were Pc). The most common causes for aseptic revision in MoP was cup loosening (41%), periprosthetic fracture (13%), and osteolysis (12%) versus cup loosening (17%) and dislocation (10%) in CoC [20]. After a short, mean follow up of 8.4 years, a meta-analysis included 5 RCTs (n=974 hips, 601 CoC and 373 MoPc), reported significant lower osteolysis and radiolucent lines with CoC (4.4% versus 18.1%, respectively; RR=0.22; 95% CI, 0.14–0.36; P<0.01) [21]. Another cause of THA revision is recurrent dislocation. Hernigou et al reported a cumulative risk of dislocation after 30 years of 13% with CoP versus 2% in CoC [22]. They related this difference to hip capsule distension and weakening as a result of polyethylene wear-induced inflammatory reaction. In our study, 3 MoPc had early dislocations (1 recurrent without revision) versus none in CoC. We did not encounter late dislocation in neither group.

Other complications and ceramic specific complications

With our CoC group of 2nd generation, no fracture was encountered. Similarly, Kang et al. reported no fracture of the ceramic bearing in 90 hips cohort of third generation alumina–on–alumina THA at 15 years [23]. In contrast, in a multicentre prospective study by Migaud et al., 16% (37/238) of CoC hips had ceramic-specific reasons for revision (ceramic breakage, squeaking, impingement, and incorrect ceramic insertion) [20]. They reported 5% fracture of ceramic component with both Alumina/Alumina and Delta/Delta ceramics. Most of these complications have been addressed by improvements in ceramic material that decreased the fracture risk to 0.16% in clinical studies [24]. Moreover, the introduction of larger diameter head CoC bearing with pre-assembled ceramic liner resulted in reduced risk of ceramic acetabular liner malposition, components' impingement (femoral neck against the ceramic rim), and increased range of movement and stability [25]. Using a monobloc acetabular component with a large-diameter head CoC in 276 THAs, our group found excellent functional outcomes with very low revision rates (0.4%) and no dislocations or implant fracture [26]. highly cross-linked polyethylene (HXLPE) liners, since its introduction has substantially lowered the wear rates in comparison to conventional polyethylene yet when combined with larger diameter heads, there have been concerns regarding the potential liner fracture (thin liners), and accelerated wear in the long-term [27, 28].

Clinical outcomes scores

In our randomized study, the patients were blind to their treatment group only for the first 12 months. At 6 y, 12 y and 20y CoC had higher scores but only reached a significant level at last follow up. At last follow up, we collected clinical scores of all available living patients (revised or not). So, the better WOMAC score of the CoC group at that timepoint may be linked to lower revision rate in that group and the inferior scores provided by the revised MoPc cases. In a meta-analysis of RCTs comparing different bearing combinations (31 studies) similar patient reported outcomes (PROMs) assessed by the Harris hip score, WOMAC, and Oxford hip score were found at short to midterm follow-up between the different bearings [9].

This study has some limitations. Firstly, we used MoPc as the control group because it was the gold standard when designing this study (1995). Systematic reviews have suggested reduced risk of osteolysis and revision in Pxl compared with Pc in THA [29]. On the other hand, a meta-analysis comparing the risk of revision for MoPc versus MoPxl THA of six registries suggested no significant difference of THA in young patients (HR, 1.20 [95% CI, 0.80 to 1.79]; p=0.384). While this may negatively impact the relevance of our study, our data remain of interest as representing the longest findings ever published from a RCT comparing CoC to MoPc bearing. In addition, taken apart, the results obtained in our CoC group are difficult to beat with an implant survivorship of 97% after 20 years. Moreover, none of the 2 revised CoC cases were performed for a bearing related reason. Last, as we recognize the importance of RCT registration in a publicly searchable clinical trial registry, we should mention that the current study was not registered in its design period 1994-95. At that time, such registration was not a common practice in orthopedic research.

Conclusion

By generating rare osteolysis and implant failure, alumina CoC bearing THA demonstrated excellent implant survivorship (97%) and to be safer than MoPc at 20-year follow up. The excellent in vivo long-term behavior of CoC THA makes it a great option for middle-aged patients and should be the point of comparison for long-term follow-up study with MoPxl THA.

Figures Legend

Figure 1 Patients' flow chart [THA, total hip replacement (MoPc, Metal-on-Polyethylene conventional; CoC, Ceramic-on-Ceramic)]

Figure 2 Ceraver Osteal, Roissy, France, cemented femoral stem and acetabular component.

Figure 3 Kaplan-Meier survival curve with revision for aseptic loosening or severe wear as the endpoint was 73.6% (95% CI, 62.8 – 84.4%) for MoPc and 96.9% (95% CI, 92.8 - 100%) for CoC (p<0.001).

Figure 4 a) Anteroposterior pelvic radiograph of a 42-year-old woman with preoperative severe hip dysplasia 7 years after bilateral hip replacement. She was randomised for right CoC THA and left MoPc THA. Superior femoral head migration and polyethylene wear were observed on left hip radiograph (note the vertical cup position at 72°).

b) Last follow up anteroposterior pelvic radiograph in 2019 (15 years after left hip revision. Femoral stem was kept while the acetabular component was revised, reducing its abduction angle. Bearing diameter was increased to 32 mm with the appropriate modular ceramic liner and femoral head.

Figure 5 Box plots showing the pre-operative WOMAC scores in both groups (CoC and MoPc) and their post-operative values after a mean of 6 years, 12 years, and 20 years. The boxes represent the median and interquartile range and the whiskers the data range.

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Chapter 6 DISCUSSION

6.1 PROBLEM

MoPc THA has been the gold standard for hip replacement surgery. Since the inflammatory response to conventional PE wear particles was established as the main cause of periprosthetic osteolysis and aseptic loosening, relentless efforts have focused primarily to increase the longevity of hip prosthesis through the development of more wear resistant bearing surfaces. Moreover, the foreseeable substantial increase in the need for THA, especially by a younger and generally more active patient population with higher functional demands, catalyzed the development of new hard-on-hard bearing technologies. The concept of new generation hard-on-hard bearings such as CoC and MoM have demonstrated lower friction and wear rates compared to MoPc surfaces (109). CoC bearings offer higher scratch resistance and almost negligible wear particle production. Additionally, ceramic particles are biocompatible; thus, they avoid the risk of wear-induced periprosthetic osteolysis. They also reported to have reduced cumulative long-term risk of dislocation and reduced corrosion at head-neck junction (110). Likewise, MoM bearings offered excellent tribological properties, with wear estimated at 5 to 7microns/million cycles (0.4 to 1 micron for alumina—alumina bearings). The estimated startup wear during the first two years of use is still 60 to 100-fold less than for MoPc bearings (111). HR adds several other attractive benefits including preservation of the femoral neck and avoidance of femoral canal violation, which facilitates future revision surgery. Other proposed advantages of HR include the preservation of the biomechanics of the hip, easier restoration of the length of the lower limbs and the rarity of dislocations (15). Furthermore, well-functioning MoM bearings presented a substantially reduced wear rates which in turn can lead to long term durability of the implant (39).

Despite the theoretical advantages of LDH MoM THA, such as joint stability and low bearing surface wear, unacceptably high failure rates related to trunnionosis, and malfunctioning implants outweigh their hypothetical advantages. These safety concerns related to MoM hip designs were also linked to implant design, patient selection and surgical technique (54). Consequently, elevated serum levels of metal ions have been found in patients with MOM bearings and were associated to possible local tissue reaction known as adverse reaction to metal debris (ARMD) (112).

Similarly, potential disadvantages of CoC bearings have been observed include higher cost, the inherent brittleness, and possible mechanical fractures of the ceramic liner and/or head, diminished intra-operative versatility related to neck length and liner (no elevated lip) and audible noises. Such concerns have been raised by several reports including noises and component fracture that might lead to catastrophic failure (71-74).

There is a lack high-quality evidence studies evaluating and comparing the long-term outcomes of different hard-on-hard bearings. To establish a true clinical value, we followed two RCTs (HR vs 28 mm MoM THA) and (COC vs MoPc) study groups for more than 16 and 20 years after implantation, respectively with the aim of answering the following question: Is there a difference in term of (1) survivorship, (2) related complications, (3) radiographic results, and (4) clinical scores.

6.2 HYPOTHESES

Chapter 4: we hypothesized that HR should provide significantly higher WOMAC score while the revision rates would be similar between groups at long-term follow-up

Chapter 5: we aimed to determine if, more than 20 years postoperatively, there is a difference in terms of (1) survivorship, (2) related complications, (3) radiographic signs of wear, and (4) functional scores. Thus, we hypothesized that CoC bearing THAs have superior clinical results compared to MoPc THAs.

6.3 SUMMARY OF MAIN RESULTS

6.3.1 IMPLANT SURVIVORSHIP

Comparing HR to 28mm MoM THA, the Kaplan-Meier survivorship estimate with aseptic revision as the endpoint was 89.2% (95% CI, 82.3–96.1) for HR vs 97.4% (95% CI, 93.9–100) for THA (p=0.033) at a follow-up of 15 years. Overall revision rates were similar between 28mm MoM-THA 5.2% and HR 9.2% (p=0.285) and the revision rate for aseptic loosening was significantly lower in THA (2.1% versus 9.2%, p=0.008).

Comparing MoPc THA to CoC THA, the Kaplan-Meier survivorship estimate with revision for aseptic loosening or severe wear as the endpoint was 96.9% (95% CI, 92.8 - 100%) for CoC and 73.6% (95% CI, 62.8 - 84.4%) for MoPc ($p<0.001$) at 11.5 years (8-15; 5.0) for the CoC group and 12.9 years (0-20; 5.0) for the MoPc group. The aseptic revision rate was significantly lower in the CoC group (2/71; 3%) than in the MoPc group (17/69; 25%; $p < 0.001$).

Our results demonstrated that the rate of aseptic revision for HR was inferior to both 28mm-MoM and CoC groups and was higher than MoPc. MoPc bearing was the worst performing bearing in term of THA longevity and aseptic loosening when compared to the other 3 surfaces. Finally, CoC demonstrated superior results in terms of increased longevity of the THA when compared with MoPc. In support to the previous results, a non-significantly higher rate of revision of 5.9% for HR versus 3.2% for THA was also reported in the systematic review by Hellman et al. (113). When comparing one of the best performing HR implants to THA procedures (CoC or CoPxl and MoPxl) in men younger than 65 years, results were in favor of THA in a study from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) that compared the risk of all-cause revision at 17 years for 4790 Birmingham Hip Resurfacings (BHR) and 2696 ≥ 32 mm-head THAs (CoC or CoPxl and MoPxl). At a mean follow-up of 11.9 years for the BHR and 9.3 years for the THAs group, revision rate was higher in patients with BHR 6.7% versus 3.4% in patients with THAs with the three different bearings (CoC or CoPxl and MoPxl (114). In fact, excellent survivorship of HR was reported in several studies, however, it was conditioned with meticulous patients' selection such as young men with a femoral head bigger than 48 mm, non-dysplastic acetabular morphology, and good bone quality (115, 116). Ten-year survivorship of HR might reach up to 99.7% when performed at high volume centers by experienced surgeons in properly selected patients (117). Several reports have demonstrated superiority of alternative bearing in term of survivorship when compared to conventional PE. The annual report of AOANJRR has also demonstrated the superiority of HXLPE, ceramics, and ceramicized metal (oxidized zirconium) in terms of THA survivorship when compared to conventional PE (44). This is also consistent with data from a pooled joint registry analysis that reported an estimated 20-year survival as low as 70%, and with data from a case series that reported an estimated recent 20-year survival of 79%, for MoPc THA (118).

Similarly, substantial evidence now suggests that MoM implants are associated with premature failure and lower survival rates compared to alternative bearings such as CoC and HXLPE with improved wear characteristics. Higher survivorship of CoC, CoPE, CoPxl and MoPxl bearings was reported in a systematic review and network meta-analysis of RCTs versus and inferior results for MoM and MoPE bearings (119). This evidence is also supported by a comparison meta-analysis of observational studies reporting higher survival rates of CoC when compared to MoM (120). In this context, anther observational study reported higher survivorship for aseptic loosening of CoC when compared to MoPc and MoM where the percentage of patients who were younger than 65 years was 70%, 58% and 9% for CoC, MoM and MoPc groups, respectively (121).

On the other hand, growing evidence supports the improved durability of HXLPE with promising results of low wear, osteolysis, and wear related loosening at mid-term follow-up in young patients (122-125). A systematic review and network meta-analysis of RCTs included 2599 THAs compared short to midterm survivorship of CoC to CoPxl, and MoPxl bearings in patients younger than 65 years found no significant difference in the risk of revision and the survivorship between the three different bearings. Authors has also reported that the three bearing surfaces performed significantly better than MoPc (126). Recent studies have reported 100% and 97.8% survivorship of HXLPE liners in young patients less than 50 years at an average 10 and 15 years of follow-up, respectively with no wear-related revision (127, 128). However, a study from the Australian Registry (AOANJRR) reported that the risk of revision for ARDM is 3.2 times in patients with 36-mm or larger metal heads compared to 32-mm or smaller in MoPxl THA (129). Finally, it should be also noted that the performance of HXLPE can be affected by different manufacturing processes of different producers (130).

6.3.2 THE RATES AND REASONS FOR REVISION DIFFERED ACCORDING TO THE HIP REPLACEMENT TYPE AND BEARING COMPONENT

The rates of aseptic revision were highest in MoPc (24.6%) followed by HR (9.2%) compared to CoC group (2.9%) and 28mm MoM THA (2.2%), respectively. Cause of aseptic failure differed according to the prosthesis and bearing surface. Bearing surface failure, osteolysis and implant loosening were the main reasons for revision in MoPc group compared to instability and ARDM induced by extra-articular impingement in MoM group, and traumatic periprosthetic fracture and mechanical stem failure in CoC group. However, the most common reason for aseptic revision in our HR was femoral head loosening.

Polyethylene wear related osteolysis was reported as the main reason of aseptic failure of THA by many authors. A study investigated the reasons and timing of revision in 238 CoC THAs and 1721 MoP THAs (77% were Pc) reported that the most common causes for aseptic revision in MoP were cup loosening (41%), periprosthetic fracture (13%), and osteolysis (12%), while the most common causes of revision in CoC were cup loosening (17%) and dislocation (10%) (131). Another study by Kim et al. reported a high rate of cup revision of about 16% due to polyethylene bearing wear, osteolysis and loosening in relatively active young patients with a minimum follow-up of 10 years (132).

Obviously, careful patient selection, meticulous surgical technique, and well-functioning implants are critical to successful outcomes of HR procedures. The most common reason of aseptic failure in our HR was femoral head loosening which is related to wrong HR indication such as female patients with a small femoral head diameter or preexisting femoral head pathology with poor bone quality. In concordance our results, Metal-related pathology (28%) and loosening (24%) were identified as the most common reason for revision of HR in the Australian Orthopedic Association National Joint Replacement Registry annual report when compared to THA group at 17 years. Female sex, small femoral head size and increasing age with poor bone quality were identified as risk factors for HR failure (44).

Unlike other reports where concerns related to aseptic failure of CoC THA are mainly related to components' fractures, the reason of aseptic revision in our CoC THA were not related to the bearing. In fact, the rate of ceramic fracture became considerably low with the improvement in ceramic materials and are mainly related to either trauma such as dislocation or technical surgical error such as mal-seated cups or mal-positioned component resulting in component impingement. (See ceramic specific complications under the adverse events section).

6.3.3 RADIOGRAPHIC EVALUATION

Periarticular osteolytic signs (lytic zones or lucent lines) among MoPc THAs were significantly more frequently observed 60.9% (14/23) compared with CoC THAs 6.1% (2/33) ($p < 0.001$). However, we observed no osteolysis in our MoM THA and HR. In accordance with our results, osteolysis has been reported in up to 60% of young, active patients with conventional polyethylene (133). Osteolytic signs were present at the pelvis in 13% (3/23) of MoPc THAs versus none CoC THAs, and at the femur in 8.7% (2/23) of MoPc THAs versus none of CoC THAs. Thirteen percent (3/23) of MoPc THAs were considered loose versus none of CoC THAs, HR and 28mm MoM THA. These results are also supported by several studies reporting no incidence of osteolysis with CoC bearings (70, 134, 135). The rarity of osteolytic lesions observed with CoC bearing is believed to be attributable to a lower concentration of ceramic wear particles in the periprosthetic tissue (136). A study from the Korean registry of two different types of ceramic bearing; Forte or Delta CoC reported no acetabular or femoral osteolysis up to 10 years of implantation (137). This is also in concordance with the long-term results of the studies involved young adults. A study of a large cohort of young patients with less than 50 years of age underwent cementless CoC THA reported no osteolysis at a mean of 13 years follow up (138). Similar to our results of MoM THA group, Innmann et al. reported no osteolysis in a cohort of young patients (less than 50 years) who received 28mm MoM THA after more than 18 year follow-up (139). A little different from our results, Higuchi et al. reported a high rate of periprosthetic osteolysis (14.5%) with small head MoM when compared to CoC (1.9%) and MoPxl (2.6%) bearings at a mean of 7.6 years follow up (140).

Periprosthetic non-progressive (<2mm) radiolucent lines appeared in 40.5% of THA around the uncemented stems, mostly in the proximal femur, compared with 2.6% of HR ($p<0.001$). For THA, all lucent lines were located in femoral Gruen zones (1,7, 8 or 14). These lucent lines represented the normal bone remodeling usually seen around this specific stem, as reported by Rivière et al (141).

Studies has reported no radiological evidence of osteolysis secondary to PE wear with newer HXLPE in young patient. A retrospective study observed no evidence of osteolysis in THAs where HXLPE coupled with different head materials (cobalt-chrome, ceramic, and oxidized zirconium (Oxinium)) with head diameters 26mm to 32mm in patients younger than 50 years after 15 years follow up (142). This evidence supports the findings of a study by Bryan et al. evaluated the clinical and radiographic outcomes of patients less than 50 years underwent cobalt-chrome small head (28mm-32mm) primary THA at a minimum of 10 years. They reported no osteolysis in patients with HXLPE THAs compared to 77% osteolysis in patients with conventional PE THAs . However, they reported a rate of dislocation leading to revision as high as 4.2% for the entire group which was attributed to small head diameters in their cohort (143). A complication that could be avoided by using LDHs. Nevertheless, LDH MoPxl bearings seem to have the same problem with LDH MOM. Reports have raised concern about ARMD associated with MoPxl which is likely due to fretting and corrosion at head-neck taper junction (144-146). Multiple studies have refuted this concern with the use of ceramic heads. A retrieval study of 52 ceramic head-trunnions matched to 52 CoCr head-trunnions demonstrated a lower median fretting and corrosion score in all zones in the ceramic group (147). Supporting these results, Eichler et al reported no radiographic signs of osteolysis or clinical signs of ARDM when they used serum Ti level as an indirect marker of trunnionosis in 57 patients with large-diameter CoC THAs over 5 years (148). To our knowledge no study has investigated the effect of LDH CoPxl regarding volumetric wear rate and osteolysis. Some studies reported that LDHs are associated with higher levels of volumetric wear (149, 150). A study by Lachiewicz et al of metal femoral heads coupled with first generation HXLPE reported that the mean annual volumetric wear produced by 36-mm heads is approximately twice that produced by 32-mm heads (149). Currently, there is no agreed on threshold regarding volumetric wear rates and osteolysis. Cross et al suggested that an annual volumetric wear of 40 mm^3 might not induce osteolysis (151). Assuming that this threshold is correct, increasing femoral head size is always associated with increased risk of volumetric wear and osteolysis may eventually develop. HXLPE bearings need to be followed up and evaluated for possible osteolysis on a long-term basis.

Incomplete non-progressive lucent lines around the femoral metaphyseal stem of HR were present in 2 cases and non-progressive femoral neck narrowing was seen in a female patient with bilateral HR. The reported incidence of femoral neck narrowing of more than 10% after HR varies from 0% to 59% (152). It has been found to be associated with valgus anatomic neck-shaft angle and female gender, shorter height, and small component size in men (106, 152). The significance of neck narrowing varied between reports, as some considered it a benign phenomenon and the narrowing stabilizes within 2 to 5 years (106) and other found to be associated with a higher incidence of failure and periprosthetic masses (ARDM) when compared to patients without neck narrowing (152). These findings added more limitations to the indications of HR.

6.3.4 FUNCTIONAL SCORES

All functional scores improved in the four groups at last follow-up. However, CoC group has achieved statistically better WOMAC score, and more patients reported no limitation with their THA when compared to MoPc. Also, more HR patients (60%) perceived their reconstructed hip joint as "natural" when compared to THA group (44%, p=0.078). Although, only a few studies have compared the influence of type of bearings on functional scores (153, 154), several studies have supported the concept that HR patients perform better in sports and high demand activities. A study by Oxblom et el reported that patients who underwent HR reported better postoperative functional outcomes at 7 years when compared to patients with conventional THA. They have reported a substantial difference in the most demanding functions (16). This observation is in accordance with the study by Haddad et al where HR resulted to better functional results regarding return to sports compared with conventional THA (155). Supporting this evidence, a systemic review comparing HR to different THA (CoC, MoM and MoP) reported slightly better or similar functional outcomes with HR when compared to THA (156).

Other functional advantage of HR is restoration of more physiological gait, walking speed and return to sporting activities when compared to conventional 28mm THA. When comparing gait pattern of HR and conventional THA, HR better preserves a normal gait pattern at increasing walking speeds compared to THA. This evidence is supported by the results of RCT conducted by Gerhardt et al. who analyzed pattern and mechanic of gait for HR and THA against controls at more than 5 years follow-up. They reported no significant difference was noted in any parameter between HR and THA at normal walking speeds, however, HR patients achieved normal gait pattern at higher walking speed, and a more physiological weight acceptance between the operated and unoperated limb, as well as preserved range of hip flexion during walking (48). This is also consistent with the results of a case control study reported that HR generates a more physiological gait during high walking speeds when compared to 32mm and 36mm THA (157). Regarding return to sports, the effect of sports on long term HR survival in a young and active patient (with mean age 51.9 years) was analyzed by Amstutz et al in a large cohort (806 hips). They used standardized activity scores, impact scores and hip cycle scores to assess whether return to sport has affected the implant survival. They observed survival rate of 95.3% at mean follow up of 10 years, with a wide range of sporting activities and they suggested that return to sport is safe after HR (158).

On the other hand, when comparing gait patterns of HR and LDH THA, LDH MoM THA has demonstrated similar functional outcomes and gait speeds at up to 1 year postoperative in a John Charnley Award winner study reporting the results of RCT comparing LDH THA and HR (159). Added to this, the indications of HR may be limited by challenging anatomy such as gender, small sized patients, hip dysplasia, and femoral and/or acetabular retroversion.

LDH THA seems to be a better solution for these patients who seek to return to highly demanding activity as it offers a supraphysiologic head-neck ratio resulting in a better range of motion and superior associated stability (46). An advantage makes LDH THA more forgiving regarding component positioning.

When comparing hip resurfacing to MoM LDH THA, despite the higher revision rate, MoM LDH THA offers better clinical scores than HR at 14-year follow-up of a randomized controlled trial (160). However, substantial evidence now suggests that LDH-MoM implants are associated with higher complication rates and premature failure than other alternatives. The unaccepted rate of trunnionosis demands an optimization of LDH-THA with new modular junction design and/or alternative bearing such as CoC. In this context, excellent clinical outcomes were reported in more than 90% of patients in a systemic review of LDH CoC THA with modular and monobloc ceramic liners (161). Supporting this evidence, Blakeney et al reported that 74% of patients perceived their reconstructed hips as natural in a study of large cohort of patients received monobloc acetabular component with LDH CoC THA at a mean of 67 months (162).

On the other hand, growing evidence supports the improved durability of HXLPE with promising results of low wear, osteolysis, and wear related loosening at mid-term follow-up (122-125).
A systematic review and network meta-analysis of RCTs compared short to midterm survivorship of CoC to CoPxl, and MoPxl bearings in patients younger than 65 years found no significant difference in the risk of revision and the survivorship between the three different bearings (126).

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6.3.5 ADVERSE EVENTS AND REOPERATRIONS NOT LEADING TO IMPLANT REVISION:

Dislocation

Dislocation following THA is the most common cause for revision surgery. Dislocation, however, is multifactorial and it seems to decrease with newer implant designs and meticulous surgical techniques. The rate of dislocation after primary THA ranges from 1.0% to 4.9%. In this study, hip dislocation was the most common adverse event 4% with 28mm MoM THA and MoPc. Compared to 0% with HR and CoC group. Similarly, a lower rate of dislocation with HR compared to THA (0.5% and 3.1%, respectively; p = 0.03) was reported in a systemic review by Hellman et al (113). The lower rate of dislocation with HR group is attributed to the increased jump distance with anatomical femoral head sizes. A systemic review by Neupane et al included 6 joint registries, one RCT and other observational studies of LDH-THA (36 mm or larger) with various bearing surfaces. Nine out of 20 studies reported 0% to less than 1% dislocation rate (163). This results are also supported by Australian Orthopedic Association National Joint Replacement Registry report that demonstrated a decrease in the cumulative incidence of dislocation at one year from 2.0% to 0.1% with increasing head size from 28 mm to 40 mm or bigger in CoC bearings (44). Supporting this evidence, anatomic head sizes have demonstrated to significantly lower the risk of dislocation in high-risk patients (0.5% vs 4.6%; P = 0.005) in a study comparing the rate of dislocation and revision for instability between 36-mm and anatomic femoral heads (LDH-MoM THA, dual-mobility bearings, and HR) in patients at high risk of dislocation over 10 years follow-up. Another retrospective review of large cohort of primary THAs reported a significantly higher rate of dislocation in small-diameter head (1.8%, 10 of 559) compared to the LDH THAs (0%, 0 of 248) at a mean follow-up of 5 years (164).

Large ceramic head sizes up to 48 mm were developed to reduce component impingement and increase stability along with optimized tribology to avoid the complications associated with LDH-MoM bearing. Metal ion release from the head-neck junction with ceramic heads is substantially lower than with metallic heads (165, 166). Added to this, the lowest revision rate for dislocation reported by the Australian registry is observed with ceramic head sizes 40 mm or larger (44).

Ceramic specific complications

Ceramic specific complications were rare in our study. We observed no ceramic component fracture in our study. Similarly, Kang et al. reported no fracture of the ceramic bearing in 90 hips of third-generation alumina–on–alumina THA at 15 years (135). In contrast, in a multicenter prospective study by Migaud et al., 16% (37/238) of CoC hips had ceramic-specific reasons for revision (ceramic breakage, squeaking, impingement, and incorrect ceramic insertion). They reported 5% fracture of ceramic component with both Alumina/Alumina and Delta/Delta ceramics (131).

A systematic review by Massin et al analyzed the ceramic fracture data from the ANSM (Agence nationale de securité du médicament et des produits de santé) and reported head fracture rates of 0–10% with the Forte ceramic (167). The improvements in ceramic material have substantially decrease the risk of ceramic fracture (168). In the Danish Arthroplasty Registry, the incidences of ceramic head and liner fractures were reported as inferior as 0.28% and 0.17%, respectively (169). Regarding the French ceramic experience, the reported rates of ceramic head fracture in the French literature has dropped from 0.18% with the Forte ceramic (third generation) to 0.0013% with the Delta ceramic (fourth generation) (167). However, the fracture rate of liners has remained stable at approximately 0.03 to 0.08%. Ceramic fractures are usually associated with an event like trauma or hip dislocation and more frequently to occur with cup mal-position such as more vertically positioned or excessive anteverted cups , or with mal-seated ceramic liner (170).

Therefore, the introduction of larger diameter head CoC bearing with pre-assembled ceramic liner has reduced the risk of ceramic liner fractures by avoiding ceramic acetabular liner malposition, components' impingement (femoral neck against the ceramic rim) and increasing the range of movement and stability (171). No ceramic fracture was reported in a large cohort by Blakeney et al where 276 hips with monobloc CoC LDH were reviewed at a mean of 5.6 years (162).

Noise generation

Another specific problem of hard-on-hard bearings is noise generation. Data for noise generation was spontaneously reported in routine clinical assessment, however, it was not systemically collected in our cohorts. There is no consensus regarding specific causes associated with squeaking. Also, the reported incidence of squeaking with CoC bearing in literature is very variable ranges from 0.5% to 36% (172-174). A high incidence of squeaking of 23% was reported by Blakeney et al in a large cohort of 276 hips received LDH CoC THAs with monoblock acetabular component. Squeaking was significantly associated with larger bearing diameter, younger age, higher functional scores. Functional scores and patient satisfaction were high despite squeaking (162). This observation is supported by Goldhofer et al (175) and differs from that of McDonnell et al (176), who reported a significantly higher incidence of squeaking with smaller bearing sizes. However, there was no significant differences regarding patient satisfaction or clinical outcomes between the patients with squeaking and silent hips. Blakeney et al attributed the association between squeaking and larger bearing sizes to the increased friction-induced vibrations caused by a greater head diameter resulting in disruption of fluid film lubrication. A phenomenon that may occur when moving the hip joint after a period of inactivity or by particular loading conditions with increased range (162). However, reported revision rate for squeaking is as low as 0.2%. It should be noted that the incidence of squeaking varies among different implants and is linked to femoral stem rigidity dictated by its design and material (177).

Adverse Reaction to Metal Debris

The rate of ARMD observed in our study was very low and was related to either extraarticular impingement in THA group or cup malposition in HR group. ARMD was commonly reported in literature because of trunnionosis at modular taper junctions. Increased frictional torque at the head-neck taper junction is one of the major factors contributing to fretting corrosion in LDH MoM THA (178, 179). It was previously thought that ARDM is only associated with MoM THA; however, reports have raised concern with MoPxl bearings about head-neck taper junction trunnionosis (144-146). The risk of revision for ARDM with 36mm or larger metal heads was more than three times that of 32mm or smaller in MoPxl THA in a study from the AOANJRR (129). The use of ceramic head can significantly reduce, but not eliminate, fretting and corrosion at the modular head-neck taper. A retrieval study evaluated the taper junction of 50 ceramic and 50 CoCr femoral heads (28–36 mm), reported less severe and lower extent of fretting and corrosion damage in the ceramic group ($p = 0.03$) (180). Supporting this evidence, a recent study reported no radiological nor biological signs (titanium serum levels) of trunnionosis with LDH ceramic bearing THA after 5 years. Therefore, there is no important wear and corrosion at the taper junction (148).

Heterotropic Ossification

Another concern for patients undergoing hip surgery is the development of heterotopic ossification (HO), especially HR who are younger, more active, and have high functional demands. Such complication might limit their hip movement and result in decreased functional their outcomes. The incidence of HO in this study was significantly higher in the HR group 40.8% compared to THA group 24%. This is consistent with the systemic review by Smith et al where they reported a similar overall incidence of HO with HR of 58% compared to THA (156). However, severe grades of HO (Brooker's III and IV) are of more clinical relevance and could be associated with pain and limited range of motion; 9% with HR group. This high incidence of HO with HR was attributed to the wider surgical dissection and formation of osseous debris during femoral head preparation in HR. A meta-analysis has shown that non-steroidal anti-inflammatory drugs (NSAIDs) can reduce HO formation by 59%, while gastrointestinal complications must be taken into account (181). Likewise, Rama et al. recommended meticulous surgical technique and the routine use of NSAIDs as prophylaxis against HO following HR (182). Selective cyclooxygenase (COX)-II blockers were demonstrated to be safer alternative for classical NSAIDs in prevention HO with respect to cardiovascular contraindications (183, 184).

6.3.6 LIMITATIONS OF STUDIES

For HR/ 28mm MoM THA

Firstly, since most clinical results were self-reported, patients' awareness of their treatment group (patients were not blind to their prosthetic type) may have favorably biased the HR. Nevertheless, we did not observe significant differences in clinical scores between HR and THA. Secondly, the number of enrolled patients limited the power of the study. We observed a trend favoring the HR group for some outcome scores (WOMAC, Forgotten joint, Patient joint perception and UCLA activity) and favoring THA group for the implant survivorship. Although these differences may have become statistically significant with a larger number of subjects, this may have not translated into clinically significant differences. Lastly, the results of our study are implant-specific, at the time of the RCT, there was no long term follow up of highly cross-linked polyethylene and the 28mm MoM bearing was believed to be the most appropriate option against HR. The results of our study may have been different with a THA using cross-linked polyethylene combined with a femoral head larger than 28mm.

For CoC THAs/ MoPc THAs

Firstly, we used MoPc as the control group because it was the gold standard when designing this study (1995). Systematic reviews have suggested a reduced risk of osteolysis and revision in Pxl compared with Pc in THA (185). On the other hand, a meta-analysis comparing the risk of revision for MoPc versus MoPxl THA of six registries suggested no significant difference of THA in young patients (HR, 1.20 [95% CI, 0.80 to 1.79]; p=0.384). While this may negatively impact the relevance of our study, our data remain of interest as representing the longest findings ever published from a RCT comparing CoC to MoPc bearing. The results obtained in our CoC group are remarkable with an implant survivorship of 97% after 20 years. Moreover, neither of the two revised CoC cases were performed for a bearing-related cause.

Secondly, sterilization method of Ceraver PE has changed during the period of our study. Ethylene oxide was used for the cases operated during the first 2 years of the study, followed by gamma irradiation in argon. However, the study design did not allow to compare performances of the two types of PE. Third, postoperative radiographs have limited sensitivity (62%) in detecting osteolysis when compared to computed tomography (100%). study with underestimates the extent of osteolysis compared to computed tomography, which is more sensitive (186). Regardless of imaging techniques, detection of osteolysis might be difficult in early years after implantation. However, the long-term follow up permit to identify osteolytic lesion over the years. Thirdly, no objective assessment was performed to validate the self-reported noises in our study. However, we could not find a detailed validation of questions regarding noises after THA in the current literature, and the definition of "squeaking" was proposed by Swanson et al. unwittingly if this definition was significant for the patients (187).

Chapter 7 CONCLUSIONS AND PERSPECTIVES

The concept of alternative bearing has always been an attractive subject that aims to improve survivorship of THA especially with the growing number of young and active patients with high functional demands. The importance of this concept has been established since the biological response to PEc wear particles was considered as the main cause of aseptic loosening and periprosthetic osteolysis. Hard on hard bearings have the potential advantages of improved implant tribology (lubrication, friction, wear), increased longevity, and reduced dislocation rates (188). However, there are concerns about the long-term results of MoM and CoC bearings as well as the unfavorable short-term results and recall of some HR designs that resulted in a considerable reduction in its use.

The long-term follow-up of these two RCTs has demonstrated from one side, a superior implant survivorship for the three hard-on-hard patient cohort in comparison to the MoPc group. Within the CoC, no ceramic-specific complication was observed. Comparing HR to THA, similar patients' functional scores were observed. Following our research results and comparing them to several other studies, HR may still have a role in selected patients when implanted by experienced surgeons and using validated implants as it provides better femoral bone preservation and biomechanical reconstruction. Our work suggests that hard-on-hard CoC THA, 28mm MoM THA or MoM HR are superior options to MoPc THA in middle-aged patients in term of survivorship, however a similar comparison with MoPxl THA is needed.

While the role of HR continues to be tempting in properly selected young patients for an excellent functional outcome, particularly returning to high demanding activity such as that required by competitive athletes, it may remain interesting to allowing for the LDH concept whilst avoiding MoM articulations. Obviously, the functional benefits of HR when extrapolated to LDH CoC THA should outweigh the concerns about adverse reaction to metal debris (ARMD) associated with MoM implants. LDH THAs could better replicate normal human anatomy leading to greater function and a more natural hip. LDH CoC bearings have shown early promising results. Although the high incidence of squeaking, it does not seem to be inconvenient to the patient.

On the other hand, studies have demonstrated promising results with HXLPE, coupling LDH with HXLPE may carry some potential disadvantages, either the trunnionosis with metal heads or volumetric wear with both meal and ceramic heads. Considering our results and that of several studies, THAs with lowest revision rates such as CoC coupled with large diameter heads could be a better choice, especially for young and active patients seeking implant durability. As aseptic loosening most commonly occurs with longer follow-up, there is a continuing need for high quality evidence (RCTs) of large population-based studies comparing clinical performance and survival of LDH-HXLPE THAs against CoC THAs.

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