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Review

Ceramic-on-Metal Bearing in Total Hip Arthroplasty—Was It So Bad? A Narrative Review and a Critical Analysis of the Literature

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Abstract: Hip replacement has significantly improved the quality of life of patients with symptomatic hip osteoarthritis. Various bearings have been developed over the years. Each of these has advantages and disadvantages. On the one hand, Metal-on-Metal (MoM) has been associated with a high level of wear and metal ion release of chromium (Cr) and cobalt (Co). On the other hand, Ceramic-on-Ceramic (CoC) bearings, known to have a wear rate close to zero, have been associated with an increased risk of squeaking and component fracture. Ceramic-on-Metal (CoM), a hybrid hard-on-hard bearing, was proposed to overcome the CoC and MoM limits. Preliminary clinical and radiographical results have been described as favourable. Due to the failure of MoM and the increased risk of ion release and metal toxicity, CoM was withdrawn from the market without causing significant clinical complications. Data from the literature showed that CoM bearings are reliable and safe at medium- and long-term follow-up, if correctly implanted. In this narrative review, we analysed the real risks and benefits associated with the implantation of CoM bearings.

Keywords: ceramic-on-metal; hip replacement; hard-on-hard bearings

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1. Introduction

Hip arthroplasty (THR) has significantly improved the quality of life of patients with symptomatic osteoarthritis. Osteoarthritis is a degenerative joint disease that leads to a significant reduction in autonomy. It is typically characterized by pain, joint stiffness, reduced muscle tone, and a consequent reduction in physical capacity. The hip and knee are the most affected joints. Half of the world's over-65 population is affected by osteoarthritis, and 25% of these say they are unable to carry out normal daily activities. The European Project on Osteoarthritis (EPOSA) reported more accurate demographic data on this disease, involving six European countries (Germany, Italy, the Netherlands, Spain, Sweden, and the United Kingdom). This means that the prevalence of osteoarthritis is 30.4% [1].

In Italy, 40,775 hip prostheses were implanted in 2020 (data related to 7 regions), demonstrating that hip prosthetic replacement surgery is widespread and increasing in recent years [2].

Until the last century, degenerative pathologies of the hip joint were considered unavoidable events, associated with the advanced age of the patients. Few were the patients on whom surgery was performed to relieve the pain. The first attempts at arthroplasty date back to the end of the 1800s. The first difficulties emerged immediately, mainly relating to the wear of the interposition material and to the flare-up of joint stiffness and pain. In Italy, Carlo Marino Zuco (1946), Carlo Pais (1950), and Oscar Scaglietti (1952) performed the first surgical procedures, but with not very encouraging results. The first resurfacing prosthesis was introduced in the early 1950s by Charnley. The first-generation metal-on-polyethylene (MoP)-bearing resurfacing prostheses gave satisfactory short-term results. However, at longer follow-up, results were inconsistent. The importance of Charnley's work is also due to his contribution to the understanding of the biomechanics of the hip joint. In fact, in the 1950s, despite the introduction of acrylic cement and the development of prosthetic designs, the number of failures due to early mobilization of the implants was unacceptable [3].

In 1961, unbeknownst to Charnley, one of his assistants experimented with high-density polyethylene, demonstrating reduced wear. The same year, Charnley implanted the first high-density polyethylene (HMWP) prosthesis. The final dimensions judged optimal by Charnley were 22 mm for the head and 50 mm for the external diameter of the acetabular cup; thus, the concept of "low friction arthroplasty" was born [4].

The ceramic-on-ceramic (CoC) prosthesis by Mittelmeier dates back to 1974. The happy intuition of the CoC coupling, which is still today the best choice in terms of wear and friction coefficient, proved unsuccessful at the bone-ceramic acetabular interface. Also, in 1974, Bousquet was the first to use the ceramic-on-polyethylene (CoP) coupling. At the end of the 1970s, but above all during the 1980s, research in the prosthetic field intensified, and many models were created. In 1984, Muller re-evaluated the previously experimented MoM coupling [5].

MoM bearings have been used with conventional THR for many years, and early applications have shown promise [6]. The low wear potential of mechanically well-studied prostheses, no relevant risk of bearing fracture, and high design variability justified the application of MoM bearings even in hip resurfacing (HR) and large head hip arthroplasty (LH-THR) [7]. However, wear and corrosion of metal implants can release metal ions into the tissues around the hip and blood. Metal ion release can lead to "adverse reactions to metal debris" (ARMD) and potentially induce systemic adverse events (i.e., toxicity, teratogenicity, and carcinogenicity) [8].

According to current knowledge, patients with values higher than 7 μg/L must be carefully studied to evaluate their health risk and the possible indication for revision surgery. This is justified by the fact that the cut-off for the risk of ARMD is set at 7 μg/L, as indicated by the Medicines and Healthcare Products Regulatory Agency (MHRA) [9].

CoM was born to minimize complications associated with CoC and MoM, a novel hybrid hard-on-hard bearing where a ceramic femoral head articulates with a metal alloy liner. The theoretical advantage of this bearing is the lower risk of component breakage compared to CoC bearings and reduced acetabular wear, metal debris, and serum ion production compared to MoM bearings [10].

The measurement of serum Cr and Co ions plays an essential role in assessing the health risk in patients with hard-on-hard bearings, such as CoM and MoM. Therefore, the methods for carrying out the blood sampling and the analysis of the sample must be rigorous and reliable, and they must be aimed at avoiding contamination that could distort the results. In addition, it is mandatory to exclude the presence of other implanted medical devices containing metal ions and occupational exposure to metals, as well as the intake of particular beverages such as beer, before the sampling. The possible intake of supplements containing Cr should also be investigated. Venous blood samples should be collected using polypropylene tubes and 21-gauge stainless steel needles, preventing metal contamination. This is made possible through the use of particular devices, such as gloves, without powder or isopropyl alcohol for disinfection. All collection tubes must be free of traces of metal.

Inductively Coupled Plasma Mass Spectrometry is the technology mostly used to quantify Co and Cr. The analysis is conducted by switching between two acquisition modes: normal and cool plasma conditions. A certified reference material is usually used to verify accuracy [11].

From the 1980s onwards, the search for increasingly better coupling materials with low levels of wear led to the emergence of hard-on-hard couplings such as CoC. The latter is currently the coupling with the longest known duration and a wear rate close to zero. The fate of MoM was different; it was soon withdrawn from the market due to systemic and local complications linked to the release of Cr and Co ions. While the hard-on-hard CoM hybrid coupling has followed the fate of the MoM, it has been withdrawn from the market, as we will see, without causing significant complications to the patients.

The aim of this narrative review is to discuss evidence on CoM bearing in order to analyse the real risks connected to CoM implantation.

2. The Ceramic-on-Metal Bearing

THAs with CoC or MoM bearings have shown good mid-term and long-term results. However, these couplings have advantages and disadvantages. Ceramics are known for having very low wear rates and high biocompatibility of debris, but they are associated with squeaking and/or component fracture. On the other hand, the wear rate of the MoM bearing is much greater, especially in the case of implant mal-positioning. The excessive wear leads to the release of Cr and Co ions with local and systemic toxicity. For these reasons, a hybrid hard-on-hard bearing was introduced in the early 2000s: CoM. This bearing has advantages and, at the same time, fewer disadvantages compared to other hard-on-hard couplings. CoM coupling is in fact characterized by reduced adhesive and corrosion wear and reduced loss of metal ions because only one half of the implant is made of metal, with an expected longer survivorship. In addition, the risk of CoM bearing fracture and squeaking is lower than that of CoC. The first results at short- and medium-term follow-up for CoM were encouraging, showing a low risk of fracture, low release of Cr-Co ions, absence of squeaking, and excellent clinical and radiographic outcomes. The serum Cr-Co ion level was found to be mildly above baseline but lower than the MHRA threshold of 7 μg/L. CoM implants have not been widely adopted over the years, probably due to an increased awareness of the MoM risk of ARMD and metal ion systemic toxicity [10].

Additionally, the CoM bearing has another potential advantage: the liner can be thin, allowing for femoral heads of 36 mm. Indeed, it is known that the use of large-diameter heads improves the stability of the implant because the "Jump Distance" increases. The Jump distance is the degree of translation of the center of the femoral head required for hip dislocation. The wider the jump distance, the lower the risk of dislocation. The jump distance is used as a predictor of dislocation. For this reason, a large head diameter is an interesting option to reduce the risk of dislocation after total hip arthroplasty, as demonstrated by Scifert et al. [12] (Figure 1).

Furthermore, the CoM coupling also has the advantage of using a ceramic femoral head. In fact, it is known that the corrosion is lower at the morse taper when ceramic heads are implanted [13].

The 2017 British Joint Register (NJR) reported only 2156 hip prostheses implanted with CoM bearings. Most implants were performed between 2009 and 2010. But the rate of revision of CoM at 7 years of follow-up was 6.17%, significantly lower than the MoM revision rate (12.2%) [14].

(a) Laboratory studies

CoM is a bearing associated with high wear only if compared to CoC. The study by Affatato et al. evaluated the wear tendency of CoM hip bearings (three ball head diameters: 28, 32, and 36 mm), comparing them with CoC. The comparison with CoC is dictated by the fact that this is considered the gold standard for wear resistance. For this purpose, the weight loss over a standard wear simulation was monitored. In addition, electronic microscope evaluations were used to verify if any carbide removal from the metallic components triggered wear debris production, promoting abrasive third-body wear. After five million cycles, the results showed significantly greater wear in CoM compared with

CoC and significant greater wear for the 32 mm diameter compared with the 36 mm one. It was evident that the CoM coupling has a greater tendency to wear than the CoC [15].

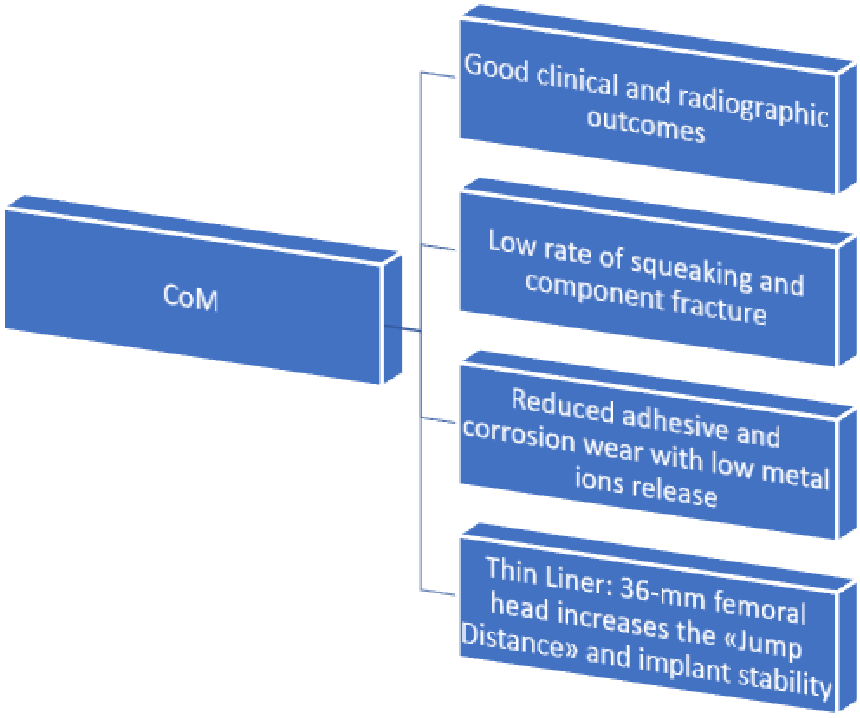

Figure 1. Advantages of CoM bearings.

On the other hand, in the laboratory studies conducted by Williams et al., friction, wear, and ion levels were lower in CoM bearings compared with MoM; CoM reported very similar wear to CoC and therefore significantly lower than MoM. If the components are not correctly implanted, and in the case of rim loading, all bearings showed increased wear, CoM reported lower wear and the absence of stripe wear compared with MoM bearings [16].

The laboratory studies carried out made it possible to study the wear mechanism in depth using electronic microscopy and the hip simulator. Surface profilometry is performed using a 2D contacting profilometer.

The areas of transfer on the ceramic heads are visualized using Scanning Electron Microscopy (SEM), while the transfer composition is assessed by EDX (energy dispersion of X-rays), with a reduced beam energy of 10 keV. Wear rates are determined with the help of the hip simulator, in which the explanted bearings are compared to three new CoM bearing components, applying a twin peak loading cycle with a peak load of 3 kN. In the hip simulator, the bearings are fixed in the anatomical position, then a Flexion—Extension movement to the head (Range of motion: $-15°$ to $30°$) and Internal—External rotation to the acetabulum (ROM: $\pm 10°$) are applied for 2 million cycles. Bearing surfaces are lubricated with 25% calf serum supplemented with 0.03% sodium ozide. The lubricant fluid is substituted approximately every 0.33 million cycles. Wear rates are reported as volumetric wear per million cycles (mm^3/million cycles) after being measured gravimetrically at 0.5, 1, and 2 million cycles and converted to volumetric wear (mm^3), considering the density of the metal alloy and ceramic material to be 8330 kg/m^3 and 4365 kg/m^3, respectively.

Isaac et al. reported their laboratory results: some evidence of transfer material was clearly shown on ceramic ball heads at visual inspection of the explanted bearings. 'Heavy' and 'light' metal transfers can be classified. On the other hand, there were also areas that had not changed following implantation. No rim damage was recorded during examination of the metal acetabular component, but only slight evidence of scratching within the bearing surface was evident. SEM was performed on both ceramic heads in the regions of visually observed 'heavy' material transfer. EDX analysis showed that a composition of Co and Cr elements was involved in the transfer material from the Co-Cr acetabular component to the ceramic ball head.

At 2 million cycles, the measured wear rate for CoM bearings was 0.047 mm^3/million cycles ($\pm$0.06). The mean wear rate when testing the explanted head and acetabular component was 0.15 mm^3/million cycles, the highest value, compared to the rate obtained from the test executed with the explanted head articulated with a new acetabular component, which was lower (0.034 mm^3/million cycles). The combination of explanted both heads with acetabular components presented a higher bedding—in wear—than the other bearings; but the steady-state wear was comparable with the other combination [17].

Exposure to higher levels of metal ions in the blood has raised doubts about whether these may be related to the risk of carcinogenicity, as known for MoM. Even when faced with metal ion blood levels only slightly above the limit, some authors wanted to study the risk of chromosomal alterations in patients carrying CoM bearing. Kazi et al. proposed the chromosomal analysis in the peripheral blood lymphocytes. Cytogenetic biomarkers (24-colour fluorescent in situ hybridization—FISH) were detected in all 46 chromosomes of the peripheral blood lymphocytes. Aneuploidy (gain or loss) and structural (break or translocation) chromosomal aberrations were searched for. Aneuploidy is characterized by an abnormality in the whole number of chromosomes (too many or too few) or by an alteration in the number of copies of chromosome segments. The 24-colour FISH analysis revealed a significantly increased incidence of breaks and losses. On the other hand, there was a significantly reduced incidence of gains. In addition, patients with unilateral or bilateral CoM hip arthroplasty were not different in terms of chromosomal aberrations. The result demonstrated the recurrence of chromosomal alterations in the blood of these patients, but the result can only be partially interpreted against CoM bearing. Pre-implantation chromosomal studies should have been performed on the same patients to demonstrate the direct correlation between the development of chromosomal alterations and high levels of metal ions in the blood [18]. Nowadays, the prosthetic release of metal ions in the blood is not clearly linked to cancer onset. Some authors reported a high rate of lymphatic and hematopoietic diseases, kidney, and prostate cancers [19,20]. On the other hand, other authors have not demonstrated any cancer link [21,22]. It could be essential to analyze this relationship in the correct epidemiological terms because more than 40 years are needed to prove the association, including for MoM (Table 1).

Table 1. Limits of CoM compared with CoC and MoM. (−: absence; +: little reported; ++: reported; +++: reported very frequently).

	CoM	**CoC**	**MoM**
Adhesive and corrosion wear	+	−	+++
Stripe wear	−	−	++
Fracture and component fracture	−	+++	−
Release of Chromium and Cobalt Ions	+	−	+++
Biocompatibility of debris	−	+++	−
Cancer onset due to metal toxicity	+(?)	−	+

(b) Clinical studies

The fate of the CoM coupling is closely linked to the MoM one and to the fear of causing similar risks to the health of patients. Despite the early withdrawal of this coupling from the market, the scientific evidence is often contradictory.

Cadossi et al. are one of the authors who demonstrated the opposite: Cr serum levels were significantly lower in the CoM-THA group than in the MoM-THA group (p50.02) at

3-year follow-up. So, CoM-THA patients are characterized by good clinical outcomes and a low release of Cr [23].

Similarly, 74 patients (85 hips) were followed up at a mean of 50 months by Yi et al. Radiographic evaluation did not show radiolucency, osteolysis, or loosening. On the other hand, serum metal ion levels were higher than the normal values of the unexposed population. But age, cup abduction angle, cup anteversion angle, acetabular version, bilateral arthroplasty, cup screw used, hip stem implant type, or femoral head size did not correlate with metal ion levels in the organic fluids [24].

Studies previously published by the authors of this manuscript demonstrated that patients with CoM couplings did not undergo revision if the components were well positioned, confirming previous results reported in many other scientific papers. The revision and failure (revision plus pseudotumor) rates recorded by the authors were, respectively, 3.2% and 4.8%. Our revision rate at long-term follow-up was similar to rates reported for other bearings used in hip replacements, 3.8–6.7% [25].

Like Yi et al., in our study, the values of blood ions showed higher values than in the general population, but still lower than the recognized levels of danger. Evidence from the data showed that correct positioning of the acetabular component plays a key role in wear and, consequently, blood ion levels. If correctly implanted, CoM bearings are reliable and safe at a mean 8-year follow-up. This implant is characterized by minimal rise of metal blood ions and involved neither systemic or local toxicity nor influenced clinical results [11].

CoM bearing and short femoral stems have been demonstrated to be safe and reliable at long-term follow-up, but the correct positioning of the implant components is essential to avoid complications [25].

Therefore, the CoM coupling did not entail particular risks for the patient even when associated with short stems, and this has been repeatedly confirmed in the literature. The need to analyze the safety of the hard-on-hard hybrid coupling in the implantation of short stems arises from the fact that the latter require careful techniques during implantation and therefore imperfect positioning is common, such as varus or valgus, undersized stem, or tendency towards leg-length discrepancy, especially in short first-generation stems. At a mean follow-up of 9 years, Mehta et al. reported a revision rate of 4.5% and metal ion levels above MHRA thresholds of 6.06% [26]. In 2017, Schouten published a study between CoM and MoM in 83 patients, demonstrating significantly lower values of blood metal ions in the CoM group, good clinical outcomes, and a low rate of implant revision [27].

Calcar atrophy and stress shielding are found to be relatively frequent in patients implanted with short femoral stems because of prosthetic stem design and modification of the load lines, and this is not correlated to the effect of metal ions on bone turnover. In addition, spot welds are evident in the patients treated with CoM and femoral short stem implants as analyzed by the authors of this paper and by other authors, confirming excellent fixation of the implants and optimal osseointegration. These results confirmed how short stems work well even at long-term follow-up, as recently described in the 2020 Australian Arthroplasty Register: revision rate at 15 years of 6.35%, better than 7.8% of other traditional stems, probably because of optimal load distribution across the metaphyseal region favoring proper osteointegration, regardless of the type of bearing used [27,28].

Hill et al. reported an important case-series: a total of 287 CoM THAs were performed in 271 patients (mean age 55.6 years at a mean follow-up of 34 months) with a five-year survival rate of 96.9% and higher than expected but not dangerous levels of metal ions in the blood [29].

Maurer-Ertl et al. proposed a case-series of 20 patients who underwent THA using a CoM bearing. Clinical outcomes were evaluated by standardized score systems (Harris Hip Score and WOMAC Score) and radiological examination on X-rays. Metal ion analysis was conducted on the patient's blood samples, and the collected ion values were then correlated to the positioning of the prosthesis components. The obtained mean ion concentrations for Co and Cr were 3.1 μg/L (range, 0.3–15.2 μg/L) and 1.6 μg/L (range, 0.1–5.5 μg/L), respectively, with maximum levels lower than the international accepted threshold for revision of MoM devices. The correlation analysis demonstrated a positive correlation between cup anteversion and Co and Cr blood levels. Routine follow-up with at least one obligatory evaluation of serum metal ion concentrations and a magnetic resonance imaging (MRI) scan once to exclude local soft tissue reactions is recommended [30].

Isaac et al. reported higher median ion blood levels in MoM bearings with respect to CoM. At 12 months of follow-up, Co and Cr concentrations were 0.08 μg/L and 0.22 μg/L, respectively, in CoM bearings and 0.48 μg/L and 0.32 μg/L in MoM joints, with a statistically significant difference for Cr levels ($p = 0.02$). In their study, the Author tested in a hip joint simulator different CoM bearings (one couple of explanted heads and acetabular components, one explanted head and a new acetabular component, and three new heads and acetabular components), and after one million cycles, all the wear rates were similar, with levels that were an order of magnitude less than those reported for MoM bearings. Two explanted ceramic heads from revision surgery revealed areas of thin metal transfer, and the explanted head and acetabular component presented higher bedding-in. Additionally, the Authors reported four outliers in each clinical group, correlated to component malposition [17].

Resuming all the published data on CoM bearings, the literature confirms good clinical radiographical and metal ion evidence that does not scientifically justify the withdrawal from the market, except for the fear of MoM failures.

3. Conclusions

In the case of a correctly positioned implant, CoM coupling is a safe and reliable bearing for medium- and long-term follow-up. Patients with CoM bearing carry a device that can release locally and systemically metal ions, so Cr and Co metal ions blood levels evaluation must be performed annually, even if asymptomatic. Repeated blood analysis and revision should be considered in cases of persistently high metal-ion blood values. Future studies with longer follow-up are necessary to understand when and how to revise these implants. Based on the available data, CoM coupling had been abandoned not because of the concrete risk of complications or failure but only for the unsuccess of MoM bearings and to avoid possible complaints and reimbursements.

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