

EUROMEDITERRANEAN BIOMEDICAL JOURNAL 2022,17 (3) 7-11

(FORMERLY: CAPSULA EBURNEA)

Case report

OXIDIZED ZIRCONIUM-NIOBIUM (OXINIUM) BALL HEAD: SYSTEMATIC REVIEW AND CASE REPORT OF LOCAL AND SYSTEMIC REACTIONS TO CATASTROPHIC FAILURE

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ARTICLE INFO

Article history: Received 12 Oct 2021 Accepted 26 Nov 2021 Published 08 Jan 2022

Keywords:

Oxinium, Total hip arthroplasty,
Surface-Oxidized ZirconiumNiobium Alloy ball head, wear,
polyethylene liner breakage,
systematic review

ABSTRACT

Total hip arthroplasty is a very common procedure. The research for low wear bearings is still on. Surface-Oxidized Zirconium-Niobium Alloy (OxZr) is one of the materials born with this goal. We report the case of an OxZr femoral head undergoing rapid in situ wear following the dislocation of the polyethylene liner and direct contact with the metal back. Slow progressive pain, pseudotumor and limping were progressively observed. Histologically, only a fibrous reaction containing metal debris without relevant features of inflammation was observed. Nevertheless, OxZr debris evocated a slow scarce cellular inflammatory reaction and no systemic toxicity, as also reported in the literature. In case of repeated dislocations or suspected breakage of the liner, we recommend close follow-up and prompt revision.

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1. Introduction

Total hip arthroplasty (THA) is a common major surgical procedure that is often performed in patients affected by hip osteoarthritis, avascular necrosis or developmental hip dysplasia (DCA). The number of implanted hip prostheses is growing worldwide: in Europe, more than a total of 100,000 hip arthroplasties were performed during 2015, recording an increase of 3.5% over the previous year. Low wear rate is a key element for long-term THA survival, minimising osteolysis and subsequent aseptic loosening of the implant.

The relevance of the wear of polyethylene (PE) liners coupled to metallic femoral heads has been well known for a long time. As a consequence, several technologies were developed to improve its tribological behaviour. Several types of cross-linked PE (XLPE) and vitamin-E-doped PE were produced.

Ceramic coatings of different types (e.g. TiN, TiNbN, CrN, ZrN, Diamond-Like-Carbon) were applied on metallic ball heads to improve finish and scratch resistance of the surface [1].

OxiniumTM (Smith & Nephew, Memphis, TN) was introduced with this aim in the early 1990s. It is an ASTM B531 alloy (nuclear –grade Zircadyne 702 Zr-Nb alloy) treated to obtain a monoclinic zirconia (ZrO2) layer on its surface. This process yields a material with a 5-micron thick ceramic surface on a core of metal [2]. This external surface is more resistant to abrasive scratching than the one of cobalt-chrome femoral heads, reducing the potential for abrasive wear, leaving a metal core to retain strength and flexibility [3]. Due to the hardness of the surface zirconia layer, OxiniumTM is today available as femoral heads for hip replacements or as femoral components for knee replacements, coupled to XLPE components.

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In July 2014, Smith & Nephew (S&N) stated that nearly 1 million Oxinium TM implants (both knees and hips) have been sold and implanted successfully worldwide. One critique is that the 5 μ m – thick oxide layer can be easily damaged in case of joint dislocation leaving the soft metal core of the ball head exposed [1].

We conducted a systematic review of the literature to evaluate the implant survival and the incidence of complications, also in comparison with other bearings. We have also reported our experience on the severe consequences which can take place in the case of damaging the surface of an OxZr femoral head after the breakage of the highly cross-linked polyethylene (XLPE) liner.

2. Methods

We conducted a systematic review according to PRISMA statement using the PubMed/MEDLINE database and Google Scholar [4]. No limits were applied for publication date. Only articles available in English and in full-text were included. All databases were examined from their inception up to June 30, 2021. Databases were queried with terms "total" AND "hip" AND "arthroplasty" AND "Oxinium" OR "Oxidized" AND "zirconium". Inclusion criteria were: clinical studies, studies about outcomes and survival rate of OxZr femoral head compared or not with other materials, studies published before June 30,2021 (end of our search).

Studies about knee replacements, case reports and pre-clinical studies were excluded.

Two independent reviewers screened studies for eligibility. A first screening was based on titles and abstracts. Selected studies were screened again based on the full text. Disagreement between the two reviewers was discussed and solved.

One reviewer extracted data from selected manuscripts and collected them in an electronic spreadsheet (Excel, Microsoft Corporation, Redmond, WA, USA). The following data were extracted from the full text of each included study: authors, year of publication, study design (prospective or retrospective), number of patients, patients' age and gender, surgical indication, implant survivorship and complications. Data were extracted by one author and checked by another. The primary outcome considered was implant survivorship. Complications were also analysed.

Descriptive statistics were used to summarize findings across all studies included.

3. Results

The search of electronic databases resulted in 150 studies. After screening, removing duplicates and eligibility assessment, 12 studies were included in the review. Study characteristics are reported in Table 1.

Selected studies included a total of 1,370 patients, with the mean age of 59.2 years. 11 selected studies compared polyethylene-oxidized zirconium with other bearings. End-stage primary osteoarthritis was the most frequent indication for hip replacement. Hip instability and infection were the most common complications, rarer was aseptic loosening of the components. When reported, implant survival was more than 90% in all the studies at a mean follow-up of 6.4 years (Table 2).

Authors/ Year of Publication	Type of study	Number of Patients	Gender (M=male; F=female)	Mean Follow-Up (years)	Mean Age (years)
Petis et al. 2016 ⁵	Retrospective Cohort	622 (311 for oxidized group)	312 M, 310 F	8.2 for cobalt-chrome Group; 7.8 for oxidized zirconium group	54.8
Teeter et al. 2018 6	Retrospective Cohort	36 (18 for oxidized group)	20 M, 16 F	5.4 for cobalt-chrome group 5.2 for oxidized zirconium group	59.9
Karidakis et al. 2015 ⁷	Prospective Cohort	199 (104 for oxidized groups)	81 M, 118 F	9	71
Zaoui et al. 20158	Prospective Randomized	100 (50 for oxidized groups)	44 M, 56 F	CPE groups: 7 HXLPE groups: 6	62
Jassim et al. 2015 ⁹	Prospective Randomized	401 (268 for oxidized groups)	152 M, 249 F	5	63
Morison et al. 201410	Randomized Controlled Trial	80 (43 for oxidized groups)	42 M, 38 F	6.8	52
Garvin et al. 2015 ¹¹	Retrospective Cohort	87 (43 for oxidized group)	40 M, 47 F	12	42
Sato et al. 2012 ¹²	Retrospective Cohort	393 (315 for oxidized groups)	Not Reported	6.3 for CPE group; 11.9 for HXLPE group	60.7
Jonsson et al. 2015 ¹³	Prospective Randomized	120 (39 for oxidized groups)	35 M, 85 F	5	70
Lewis et al. 200814	Prospective Randomized	100 (50 for oxidized zirconium groups)	52 M, 48 F	2	51
Sobti et al. 2019 ¹⁵	Retrospective Cohort	104	Not Reported	8.8	63.8
Samer et al. 201816	Prospective Randomized	50 (25 for oxidized zirconium group)	27 F, 23 M	2.01	60.6

Table 1. Studies characteristics. (CPE: conventional polyethylene; HXLPE: high cross-linked polyethylene)

Authors	Indication	Implant Survivorship	Complications	
Petis et al. ⁵	Primary osteoarthritis; Osteonecrosis; Inflammatory arthritis; Posttraumatic arthritis; Acetabular/femoral dysplasia; Slipped capital femoral epiphysis	98.7%	2 infections, 1 aseptic loosening. 1 hip instability 1 periprosthetic fracture	
Teeter et al. 6	Osteoarthritis Not Reported		Not Reported	
Karidakis et al. 7	Osteoarthritis Not Reporte		1 infection, 1 hip instability, 1 leg length discrepancy	
Zaoui et al. 8	Osteoarthritis	Not Reported	None	
Jassim et al. 9	Osteoarthritis, avascular necrosis, trauma, rheumatoid Not Reported Arthritis		7 hip instabilities, 2 infections	
Morison et al. 10	Osteoarthritis	94.1% (cumulative)	1 infection, 1 hip instability	
Garvin et al. 11	Osteoarthritis, Hip dysplasia, Avascular necrosis, Inflammatory arthritis, Posttraumatic arthrosis, Slipped capital femoral epiphysis, Legg- Calvé-Perthes disease, Coxa vara	Not Reported	None	
Sato et al. 12	Primary osteoarthritis; Rheumatoid arthritis; Osteonecrosis	Not Reported	8 cup aseptic loosening, 1 hip instability, 2 neck fracture of the stem (cumulative)	
Jonsson et al. 13	Primary or secondary hip osteoarthritis	Not Reported	5 infections (cumulative)	
Lewis et al. 14	Osteoarthritis; Advanced avascular necrosis; Developmental hip dysplasia; Rheumatoid arthritis	98%	2 hip instabilities, 1 infection	
Sobti et al. 15	Osteoarthritis	100%	1 calcar fracture, 1 periprosthetic fracture	
Samer et al. 16	Osteoarthritis	100%	None	

Table 2. Indications, implant survival and complications reported in the selected studies about Oxidized Zirconium. (Cumulative: complications and implant survival reported were not subdivided between groups)

Our experience

A 60-year-old woman affected by bilateral osteoarthritis secondary to hip dysplasia, underwent a left THA in April 2000. A 46 mm cup with a conventional PE + 20 elevated liner (Reflection - S&N, Memphis, TN) associated with a conic stem (Cone Prosthesis – Protek, Berna, Switzerland) and a 28 mm/-4 mm alumina head (Biolox Forte – CeramTec, Plochingen, Germany) were implanted.

In 2001, she underwent THA on the right side that was revised in 2003 because of periprosthetic joint infection. In June 2007, aseptic loosening and mobilization of the cup occurred on the left side and a new revision was planned. The visual inspection reported signs of intraoperative metallosis. A TMT 48 mm cup (Trilogy Cluster-holed shell with Longevity PE liner) and an OxiniumTM 32 mm/ +8mm head were implanted. The postoperative period occurred regularly without any complication and the patient performed clinically and radiographically well until 2014 when she fell and reported a right side inferior pubic ramus fracture, conservatively healed. After that in 2015, she referred to a left mild tight pain and a troublesome metallic noise from the hip associated with an increasing limb length shortening, that over the time reached about 2 cm. The X-Ray showed liner wear with eccentricity of the femoral head and heterotopic ossifications classified as Brooker 2-3. The metal back and the stem resulted bony stable (Engh and Hodgkinson criteria) without any sign of osteolysis [17]. Blood examinations were obtained: erythrocyte sedimentation rate (ESR: 5 mm; reference values: 0-15) was normal while C-reactive protein (CRP: 5.7 mg/dl; reference values: < 1) was elevated. No local signs of infection or abnormalities in blood metal ions (Co, Cr) were present. In 2016, the patient executed an ultrasound-guided joint aspiration that was negative for infection, while the X-Ray showed metallosis extended from the trochanteric side to the femoral and inguinal area. (Figure 1A). The CT scan revealed a lobulated widespread pseudotumor with metallic density (Hounsfeld Unit 1800-2500) (Figure 1B). Femoral head and liner substitution was proposed but the patient decided to wait one more year.

In 2017, re-revision surgery was performed. Intraoperatively an abundant dark jelly mass was found and debrided until it was reasonably possible. (Figure 1C/1D) At histological examination, the material, retrieved intraoperatively, showed the presence of abundant dense fibrous tissue containing few cells and comminute metallic debris, frequently agglomerated in coarse clusters. (Figure 2A). Few fibroblasts, occasional small capillary vessels and macrophagic-like cells were also observed. No necrosis nor acute or chronic inflammatory cells or giant cells were observed (Figure 2B). Immunohistochemistry for CD68 confirmed the macrophagic nature of the majority of cells dispersed among the fibrous tissue (Figure 2C/2D). On clinical examination, no pathologies have been found that can cause deficiency of the immune response or disorders of the nervous system, such as diabetes, rheumatic diseases, etc. The PE liner was broken in the upper external elevated rim and disengaged. The OxiniumTM head was severely abraded and deformed in a "coin shaped" fashion, allowing the view of the taper top that was eroded in the upper posterior portion due to contact with the metal back (Figure 3).

A volumetric assessment of the damaged head revealed the loss of 7927mm³. Bone loss was found in the acetabular roof, in the posterior wall and in the trochanteric region.

Overall, the cup and the stem were stable. In consideration of the poor bone stock and of the stability of the implant (cup and stem), it was decided to leave them on site. A new XLPE liner 10° elevated was cemented inside the metal back after drilling micro perforations to achieve a rougher surface. A revision titanium sleeve (Bioball®, Merete Medical, Berlin, Germany) was applied on the damaged neck associated to a new

28 mm BIOLOX delta head (CeramTec). Bone loss was compensated with homologous bone graft. After surgery the patient was evaluated at serial follows up (1-3-6-12-24 months).

Radiographically there were no improvements, and the dense metallic shadow persisted on site. Clinically, the patient quickly improved in pain and range of motion, and returned to walk without adjuvants. Results were durable (2 years of Follow-Up).

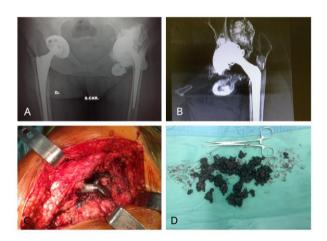


Figure 1. Preoperative radiograph (A): large and irregular joint opacification from the trochanteric side to the femoral and inguinal area. Preoperative CT scan (B): lobulated pseudotumor with metallic density; Intra-operative view (C): extensive metallosis of periprosthetic tissues; Periprosthetic tissues (D): a dark jelly mass which was debrided until it was possible.

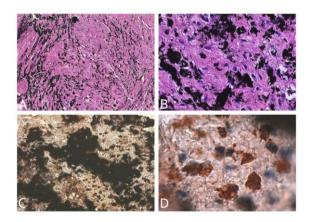


Figure 2. Histologic specimen of periprosthetic tissue stained with hematoxylin and eosin at 10X magnification (A): presence of fibrous tissue, with few cells, containing comminute metallic debris; At 40X magnification (B), few fibroblasts, macrophages and small vessels are visible; Immunohistochemistry for CD68 at 20X and 40X magnification (C-D): the presence of few macrophages is confirmed, some of which contain debris. No signs of acute inflammation or necrosis.



Figure 3. Pictures of the retrieved polyethylene liner and OxZr head: the breakage of the liner to which its mobilization has followed is clearly visible. The comparison with a new 32mm ball head demonstrates the advanced state of wear and the loss of sphericity.

4. Discussion

Despite the wide spread of hip prosthesis, minimizing the bearing wear is among the key factors for a long survival of a hip arthro-prosthesis. The aim of surface treatments on ball heads is to decrease the bearing wear compared with CoCr ball heads. The hardness of the OxiniumTM ball head surface, due to the oxide layer, is similar to that of zirconia ceramics but the scratch resistance of the surface is much lower. When the outer layer is damaged, the metal soft core is exposed undergoing accelerated wear. The review of the literature conducted shows that the use of OxZr femoral heads is safe, if the prosthetic implant is well positioned. The OxZr-polyethylene bearing did not show at a medium-term follow-up a significant increase in the failure rate; indeed, the implant survival was always above 90% [5,10,14-16].

On the other hand, since 2007, the literature is reporting cases of damage to the surface of OxiniumTM ball heads after dislocation or during closed joint reduction. Kop et al. report three cases of severe damage of OxiniumTM femoral heads after joint dislocation. This author points out that while in CoCr heads the damage is mainly due to abrasion and scratching, the damage of OxiniumTM is due to plastic flow of the substrate which has a relatively low hardness (HV 285) in comparison with CoCr alloy (HV ~ 420) and Titanium alloy (HV 350) [18]. In 2009 Jaffe et al. reported the analysis of OxiniumTM heads retrieved after closed reduction for joint dislocation, observing the damage of the surface layer [19].

Intraoperative damage of OxiniumTM ball heads was reported by McCalden et al., who observed the exposure of the zirconium alloy and flaking of the coating on scratch sides due to the intraoperative contact with the rim of the socket during joint reduction [20].

Moussa et al. remarked the different behaviour between Oxinium[™] femoral heads explanted for recurrent dislocation and femoral heads retrieved during revision surgery for other reasons. They analysed 59 Oxinium[™] femoral heads retrieved from 2006 to 2013 at the Hospital for Special Surgery (New York, NY), observing substantially more damage in the ball heads explanted for recurrent dislocation (p<0.001).

This was likely due to the impact between the shell and the femoral head during dislocation, leading to the damage and the detachment of the zirconium dioxide layer and increasing of the surface roughness in Oxinium™ femoral heads [21].

On the other hand, the case reported by Tribe et al. is a clear example of the consequences of the in-situ damage of an OxiniumTM femoral head after liner dislocation. The retrieval analysis showed that fracture of the superior rim of the polyethylene liner had caused the failure of the locking mechanism. This allowed the liner to rotate, leaving the OxiniumTM femoral head articulating with the metal-back. The patient reported a noisy hip, then X-Ray demonstrated eccentric wear of the liner, flattening of the metallic head and opacification of soft tissues due to metallosis. At revision, heavy metallosis and absence of tissue necrosis can be found in the synovia with the liner cracked and disengaged [22].

Our case has many correspondences with the one reported by Tribe et al. In fact, even our patient did not report any episodes of dislocation, progressively developing moderate pain and shortening of the limb. Therefore, very likely, the trigger was the dislocation of the XLPE liner (4mm), may be consequent to the indirect trauma occurred one year before, in the absence of severe wear. The direct articulation of the OxiniumTM femoral head with the metal acetabular shell led to the damage of the 5-micron surface layer. The exposed soft core of the femoral head led to local development of extensive metallosis. The histological study showed no tissue necrosis. In fact, it has been demonstrated that zirconium and niobium induce a diffuse but not necrotizing reaction and result in limited systemic toxicity, opposite to cobalt-chrome femoral heads [9]. Pazzaglia et al. reported severe systemic damage following the release of chromium and cobalt for significantly less wear of the femoral head [23].

OxiniumTM heads have been in clinical use for a long time, with very good clinical records. Nevertheless, a significant body of clinical evidences show that the damage of the surface oxide layer in an OxiniumTM femoral head may increase the wear leading to osteolysis and loosening of the implant. In the most severe cases, as in the one that we reported in this paper, the contact between the head and the metallic socket may lead to severe wear of the head, with metallosis due to the release of a large mass of metallic debris to the periprosthetic tissues, which appears to be nontoxic systemically in the absence of tissue necrosis. Overall, the tissue and systemic reactions to zirconium-niobium alloy debris appear less severe than the ones observed in the case of severe wear of cobalt-chrome bearings. However, we recommend a strict monitoring of the implants, especially in case of joint laxity or following episodes of joint dislocation treated with closed reduction, and to propose revision surgery in a short time in case of suspected damage of the OxiniumTM femoral head.

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