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Survivorship of uncemented PE/metal acetabular components in young patients. Prospective study with an 8-13 year follow-up

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Abstract
Introduction: Although young patients with total hip prostheses are known to have a greater functional demand, there are few prospective studies on uncemented cups with a metal/polyethylene (PE) bearing surface.
Purpose: To assess the outcome and the survivorship of acetabular components in young patients with a minimum 8-year follow-up, as well as the factors leading to cup mechanical failure.
Materials and methods: Prospective study of 42 primary uncemented total hip arthroplasties with a metal/PE bearing surface, in 34 patients with a mean age of 52.5 years (range: 28-60), and initial diagnosis of primary osteoarthritis in 61% of cases. The Harris score was used for the functional assessment. Digitalized radiographs and computer image analysis were used to study the positioning and the incorporation of the components, as well as PE wear rates.
Results: Mean postoperative follow-up was 11 years (range: 8-13). Functionally, 36 cases (85.7%) had a satisfactory outcome. Radiologically there was one case of stem instability and 4 cases of acetabular instability, which had to be revised; there was also one case of a deep infection. Thirty-one cases (73.8%) showed some degree of PE wear, with a mean annual linear loss of 0.20 ± 0.09 mm. Aggregate PE survivorship at 11 years was 25% (95% CI: 37.1-64.5). The wear was more intense in the younger patients (p=0.05), in the more obese ones (p = 0.04) and in verticalized cups (p=0.01); no statistically signi cant relationship was found (p>0.05) with gender, previous diagnosis, neck length or use of acetabular screws. The cases with the greatest wear showed a higher incidence of periacetabular osteolysis (p=0.001).
Conclusions: Although the percentage of satisfactory results has been acceptable, the high incidence of survivorship-shortening PE wear would seem to preclude the use o fan uncemented metal/PE acetabular component in patients younger than 60 years of age, especially if they are obese.

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PALABRAS CLAVE
Cadera;
Desgaste;
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Artroplastia total no cementada;
Recubrimiento poroso proximal

Supervivencia del componente acetabular no cementado con par polietileno-metal en pacientes jóvenes: estudio prospectivo con seguimiento de 8 a 13 años

Resumen

Introducción: los jóvenes con prótesis totales de cadera presentan una mayor demanda funcional, a pesar de lo cual son escasos los estudios prospectivos sobre cotilos no cementados con par de fricción metal-polietileno.

Objetivo: evaluar los resultados y supervivencia del componente acetabular en pacientes jóvenes con seguimiento mínimo de 8 años, así como los factores que influyen en su fallo mecánico.

Material y método: estudio prospectivo de 42 prótesis totales de cadera primarias no cementadas y par de fricción metal-polietileno, en 34 pacientes con media de edad de 52,5 (intervalo, 28-60) años, y diagnóstico inicial de artrosis primaria en el 61%. Para la valoración funcional se empleó la escala de Harris. Radiológicamente se estudió la posición y la integración de los componentes y el desgaste del polietileno sobre radiografías digitalizadas y análisis informático de imágenes.

Resultados: El seguimiento postoperatorio medio fue de 11 (8-13) años. Funcionalmente hubo 36 (85,7%) casos de resultado satisfactorio. Radiológicamente hubo 1 caso de inestabilidad del vástago y 4 acetabular que requirieron revisión quirúrgica, así como otro caso de infección profunda. Algún grado de desgaste de polietileno se detectó en 31 (73,8%) casos con una pérdida lineal media anual de 0,270,09 mm. La supervivencia acumulada del polietileno fue a los 11 años del 25% (intervalo de confianza del 95%, 37,1-64,5). Dicho desgaste fue mayor en los más jóvenes (p = 0,05), más obesos (p = 0,04) y en cotilos verticalizados (p = 0,01); no hubo relación significativa (p40,05) con el sexo, diagnóstico previo, longitud del cuello ni colocación de tornillos acetabulares. Los casos con mayor desgaste presentaron mayor incidencia de osteólisis periacetabular (p = 0,001).

Conclusiones: aunque el porcentaje de resultados satisfactorios ha sido aceptable, la gran incidencia de desgaste del polietileno que acorta su supervivencia desaconseja utilizar un componente acetabular no cementado con par polietileno-metal en pacientes de menos de 60 años de edad, sobre todo si son obesos.

Introduction

Several Studies have been published on the results of uncemented total hip replacement in young patients.[1-3] However, the number of prospective studies on the subject is limited and most of them have a small sample size, which has stood in the way of providing clinical evidence of their performance over time. Uncemented porous-coated acetabular components, as well as metal-polyethylene bearing surfaces, have afforded good results,[4,5] but mechanical failure has been reported in young patients[6-8] due to diverse factors, generally attributed to their higher functional demands and expectations, which result in excessive polyethylene wear.

It must be considered that polyethylene wear is a result of natural evolution. Soon after implantation and withstanding the first loads, the material experiences a certain initial deformity because of the penetration of the metal head into the softer polyethylene material. It is considered that this bedding-in process occurs in the first 18 months after implantation.[9]

Our purpose was to prospectively evaluate the results and the survivorship of uncemented acetabular cups, in a polyethylene-metal bearing configuration, in uncemented total hip arthroplasty in patients under 60 years of age over a mean 8-year follow-up period. We also analyzed the factors that could result in mechanical failure.

Materials and methods

Between 1993 and 1997 a prospective study was carried out of 256 Perfecta (Orthomet, Minneapolis) type total hip prostheses, with uncemented acetabular and femoral components and polyethylene-metal bearing surfaces.

The inclusion criteria for our study were: a primary prosthesis in patients ≤60 years of age, without previous surgery on the affected hip and with minimal follow-up of 8 years. Thirty-eight patients (48 prostheses) complied with the requirements; of these 2 had died and another 2 were lost to follow-up before 8 years' post-op. So our sample shrank to 34 patients (42 prostheses), 8 patients (23.5%) had a bilateral arthroplasty.

There were 18 males (53%) and16 females (47%), with a mean age at the time of surgery of 52.5 (range: 28-60) years. They had a mean body mass index of 27.7 (range:

23.9-37.8). Preoperative diagnosis was primary osteoarthritis in 26 (61,9%) cases, avascular necrosis in 13 (30.9%) and post-traumatic sequela in 3 (7.2%).

The prosthesis implanted was a Perfecta (Orthomet, Minneapolis), with an anatomic titanium alloy femoral stem with porous coating in its proximal third, and a hemispherical extensively coated titanium alloy cup with ns and 4 screw holes. The polyethylene used for the insert was Duramer® ultra-high molecular weight polyethylene (UHMWPE). The insert had an upper lip of 10°, was gamma sterilized and had 6 positions for cup anchorage. In all cases, the bearing couple was metal-polyethylene, with a 28 mm CrCo head; available with 0, 4 and 8 mm neck options. The cup was always impacted and its size corresponded to that of the last reamer used. The available sizes ranged between 46 and 62 mm, the most usually implanted one was the 50 mm cup in 18 cases (42.9%). The cup was screwed in in 40 (95.%) cases, depending on the surgeon's assessment of the primary stability obtained following impaction, and always with 2 diverging screws in the upper quadrant (g. 1). The size of the femoral stem corresponded to the last metaphyseal reamer used, with appropriate press- tting of the 7 sizes available (range: 9-18 mm). The most frequently used stem was the 13.5 mm one, in 17 (40.5%) cases.

In all cases, a direct lateral approach (Hardinge) was used. Antibiotic and antithrombotic prophylaxis protocols were applied.

Postoperatively, sitting was allowed at 24 hours and partial weightbearing with crutches at 3 days from surgery.

All patients were evaluated postoperatively both clinically and radiologically at 6 weeks, 3 and 6 months and then annually. The data from the last evaluation were used for assessing the results.

For the preoperative and postoperative evaluations, the Harris Hip Score was used.[10] Results were considered excellent if the score was above 85 points; good if the score was between 70 and 84; fair for scores between60 and 69, and poor for scores under 59 points.

For the radiographic evaluation we standardized the x-ray views to be obtained: digitized pelvic anteroposterior standing lms to be viewed on a screen and processed with image-based computer software

Femoral stem stability was evaluated on the basis of the criteria laid down by Engh[11] for uncemented stems. According to these criteria, uncemented stems are classi ed into stable stems with bony incorporation, stables stems with brous incorporation and unstable stems.

For the acetabular cup[12] we measured inclination, radiolucencies, osteolysis and migration. Stability was classi ed[13] as stable with bony incorporation, stable with brous incorporation and unstable.

Acetabular polyethylene wear was measured with a computer software (Autocad 2007) applied to digital radiography. Since wear is caused by penetration of the prosthetic head into the polyethylene, we measured the change in the position of the center of the femoral head with respect to the center of the acetabulum. The value for the 6 weeks' post-op x-ray was considered the "zero" position. Wear was calculated on the basis of the migration of the center of the head from the starting point.[14] Three radiographic measurements were taken and the mean value was calculated. Polyethylene wear was considered to exist if linear displacement was greater than 1 mm. Volumetric wear[15] was calculated by applying the $V=ø?r^{2}?z$ formula, where V stands for volumetric wear, r for the femoral head radius and z for linear wear.

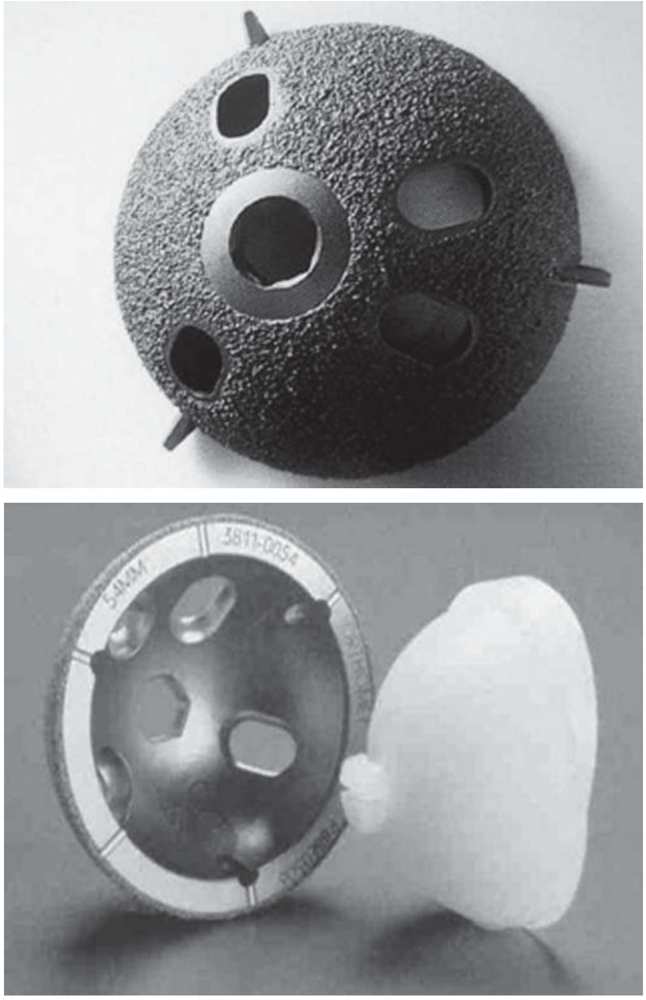

Figure 1 Porous-coated acetabular component and polyethylene insert of the Perfecta Hip System (Orthomet).

For the statistical analysis, the SPSS computer software was used. For the qualitative variables, the χ^2 test with Yates' correction was used, and for the quantitative ones the paired and independent-sample versions of Student's "t" test as well as Spearman's correlation coef cient. For survivorship analysis we used the Kaplan-Meier method, considering as endpoints surgical revision of the prosthesis for any reason and, at the acetabular level, cup revision or polyethylene wear. P values ≤ 0.05 were considered signi cant.

Results

Mean post-operative follow-up was 11 (8-13.2) years. Mean pre-op score on the Harris scale was 48.1 (17-62), which increased signi cantly (p=0.001) at the last post-operative

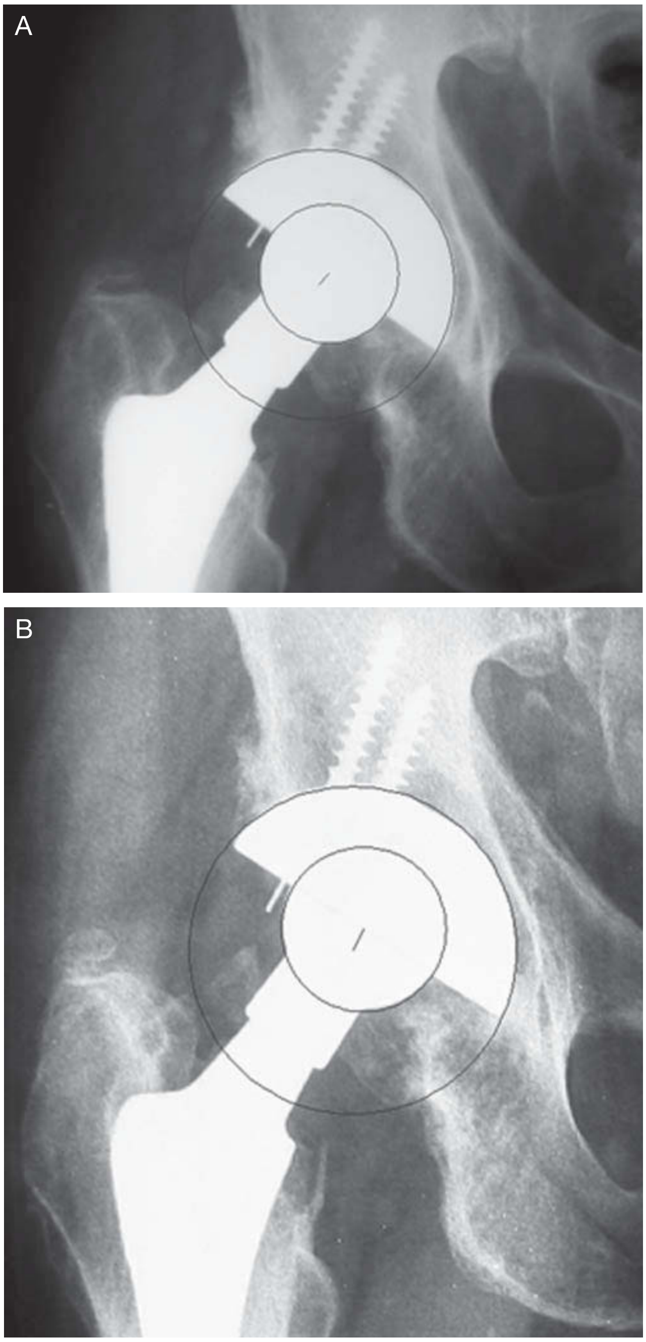

Figure 2 52 year-old male. Body mass index (BMI): 25.71. A: Radiograph at 6 weeks. Initial distance between centers: 2.54 mm. B: Follow-up: 9.92 years; nal displacement between centers: 4.34 mm; linear wear: 1.80 mm; annual wear, 0.18 mm.

follow-up visit to 85.3 (53-100). There were 21 (50%) hips with excellent results; 15 (35.7%) with good results and 6 (14.3%) with poor results. The latter required surgical revision: 5 because of mechanical problems and 1 because of an infection.

As regards femoral stems, 38 (92.6%) were considered stable with bony incorporation, 2 (4.8%) stable with brous incorporation and 1 (2.6%) unstable. There were no cases of femoral osteolysis. One case presented with subsidence of the stem and required surgical revision at 58 months. Another 2 cases presented with non-progressive radiolucencies and did not need to be revised because their last score on the Harris Hip Score was between 82 and 91 points.

At the last x-ray review, mean cup inclination was 41.9° (30°-82°). There were 37 (90.2%) stable cups with bony incorporation; the other 4 (9.8%) were instable and required surgical revision between 95 and 124 months after the primary procedure. Unstable acetabuli presented with associated polyethylene wear and in 2 cases the cup was too steep. All cups were xated by means of screws. A certain degree of osteolysis was identi ed in 8 (19.5%) cups, 6 at the level of the ischium and another 2 around the screws. Although these did not require surgical revision, all showed polyethylene wear o fan annual average of 0.24±0,05 mm. The 2 cases in which screws were not used, did not present with acetabular osteolysis.

On the whole, 31 (73.8%) cases showed polyethylene wear of more than 1 mm, with a mean linear wear rate of 2.32±1.12 mm, representing a mean yearly rate of 0.2±0.09 mm, and a mean volumetric wear rate of 106.65±65.93 µl (g. 2). Polyethylene wear was signi cantly higher in younger patients (r=?0.45; p=0.05), in those with a bone mass index over 30 (p=0.04) and when cup inclination was steeper (r=0.4; p=0.01). Likewise, cases with periacetabular osteolysis experienced more polyethylene than those with wear but no osteolysis (p=0.001). On the other hand, there was no signi cant dependence on preoperative diagnosis (p=0.08), sex (p=0.86), femoral neck length (p=0.64) or the use of acetabular screws (p=0.56) (table 1).

As regards complications, in the immediate post-op period there was once dislocation, which was treated by means of closed reduction and obtained a nal clinical score of 94. There was one deep infection that required a revision procedure at 50 months from the rst surgery. Furthermore, as mentioned above, there were 5 surgical revisions prompted by mechanical failure; one of them caused by femoral stem subsidence and the other 4 by acetabular loosening or polyethylene wear.

All of this means that general survivorship of the prosthesis for any cause at 11 years was 85.7% (95% con dence interval, range: 84.7–96.7).

To calculate isolated survivorship of the acetabular component, we disregarded the 2 revision surgeries, undertaken because of infection and stem-related problems, and selected acetabular revision or detection of polyethylene wear as our endpoint. We obtained a survivorship of 25% (95%CI, range: 37.1–64.5) (g. 3).

Discussion

The cobalt-chromium/ultra-high molecular weight polyethylene bearing is the most widely used one for hip arthroplasty. Polyethylene insert wear is the main cause of osteolysis and of decreased implant survivorship. Such wear is multifactorial and depends on factors related with the patient, the design of the components and the surgical technique.[16,17]

Table 1 Data for linear polyethylene wear

Factors	PE wear*	P
Age		0.05 (r=?0,45)
<50 years	0.21	
>50 years	0.17	
Sex		0.86
Male	0.19	
Female	0.2	
Body mass index		0.04
<30	0.19	
>30	0.25	
Previous diagnosis		0.08
Osteoarthritis	0.19	
Necrosis	0.22	
Fracture	0.2	
Ácetabular angle		0.01 (r=0,4)
<50°	0.17	
>50°	0.24	
Femoral neck length		0.64
0 mm	0.2	
4 mm	0.2	
8 mm	0.21	
Screw use		0.56
Yes	0.2	
No	0.2	
Osteolysis		0.001
Yes	0.24	
No	0.19	

*Mean annual wear of the polyethylene insert.

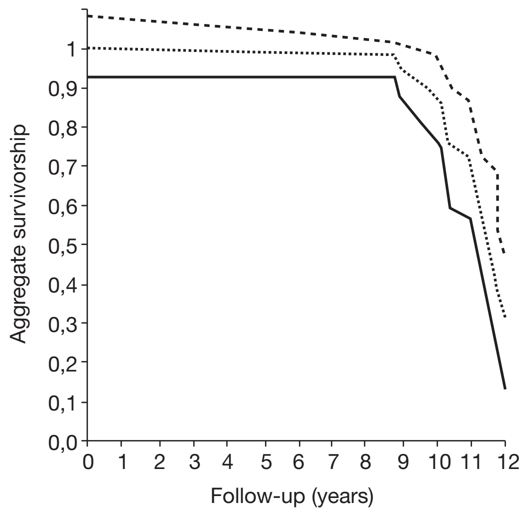

Figure 3 Survivorship function for acetabular components with a 95% confidence interval (Kaplan-Meier).

Radiologic measurement of polyethylene wear by means of a computer program has its limitations. We tried to minimize errors by standardizing the performance of radiographs as far as the types of views taken, the way the patient is positioned, use of digitized images to accurately convert relative measurement values into real values, and use of computerized measurements to reduce intra-and inter-observer error. Furthermore, although in line with other authors[14,18-20] our technical measurement error was 0.2 mm, we extended it considering a potential error in linear measurements of 1 mm. There is no consensus as to whether the measured wear could vary if the x-ray exam is performed with the patient standing or in the supine position.[18,19] The same as other authors,[12,21,22] to calculate polyethylene wear we took as "zero" position the radiograph taken 6 weeks postoperatively and considered the study of wear on radiographs with a minimum 8 years post-op, although other authors consider that wear could start becoming apparent at 2 years,[14,18,19] since the penetration of the prosthetic femoral head into the polyethylene liner occurs during the first 18 months because of the plasticity of the components.

In our study, there was some degree of polyethylene liner wear in 73.8% of cases, with an annual mean of 0.2±0.9 mm. However, not all of these had clinical repercussions. In their study of Harris Galante type I uncemented acetabular components, Crowther et al[12] report wear only in 27.1% of cases, with an annual mean of 0,,5±0,1 mm; the study comprised 56 patients with a mean age of 37 years and mean follow-up of 11 years, Bur there authors use standard plates and performed their measurements with an electronic device. Fahandezh-Saddi et al,[17] in their series of 68 patients with Duraloc type uncemented acetabular components and AML uncemented stems also found, after a mean 10 years' follow-up, a low incidence (16.6%), even if in their case mean patient age was 65 years. They used standard plates and no not specify the type of manual measurement device used. Kim et al,[23] in a study of 64 patients with a Duraloc cup, a mean age of 43 years, and 9.4 years' follow-up, found linear polyethylene wear of 0.1±0.01 mm a year, but they deducted from this figure the wear of the first 3 years post-op since they attributed it to the bedding-in process, which is something we did not do in our own study as that type of wear, albeit natural, effectively reduces the thickness of the polyethylene component.

The patient's activity level has a greater effect on polyethylene liner wear than the length of follow-up of the prosthesis, which means that younger patients, characterized by higher functional demand levels, will be prone to more wear. In line with other authors, in our series we found that the younger the patient, the more severe the polyethylene wear.[12,17,18,24]

Gamma sterilization and vacuum packing of ultra-high molecular weight polyethylene increases the strength of the polyethylene material. Nevertheless, it is known that long-term storage significantly reduces such strength.[25,26] In the present study we were not able to determine the length of storage of polyethylene so as to ascertain this factor's influence on wear.

Appropriate placement of prosthetic components is fundamental for correct load transfer. In our study, cups that were placed too steeply experienced more polyethylene liner wear than those where acetabular inclination was correct, which is in line with the findings of other authors.[17,27] The use of acetabular screws in controversial with respect to whether they result in increased polyethylene liner wear as a result of particle migration through the screw holes. In patients with good bone quality, impaction of a hemispherical cup should provide sufficient stability, making the use of screws unnecessary, which would constitute a protective factor against polyethylene wear.[27] In our study, we did not find a relationship between the use of screws and increased polyethylene liner wear.[12,17,28,29]

The size of the femoral head exerts a direct influence on polyethylene liner wear. Jasty et al[30] compared the wear caused by 28 mm and 32 mm heads in 128 components retrieved from autopsies or revision surgery. They came to the conclusion that for each millimeter increase in head diameter, there is a 10% increase in polyethylene wear. Fahandezh-Saddi et al[17] reported more intense wear when 32 mm heads were used. In all our cases, we used 28 mm femoral heads in order to minimize the influence of the head diameter variable on polyethylene liner wear. The neck length used has not shown itself to be significantly related to polyethylene liner wear, a finding also reported by Crowther et al.[12] However, Urquhart et al[31] found more wear in the cases in which he used a long 14 mm neck as a way of reducing the neck diameter/femoral head ratio. Match between head and taper should be as close as possible so as to reduce the number of wear particles released.

Osteolysis occurred in 19.5% of cases, always on the acetabular side. Our study confirms that polyethylene line wear is significantly more severe in cases with osteolysis. In addition, together with other authors[12,27,29] we found that 0.2 mm/year is the threshold above which wear must be construed to be derived from osteolysis. Only in 2 cases was osteolysis present in the area around the screws and absent from the femoral side. In patients with radiologic osteolysis we recommend performance of a CT-scan to detect smaller osteolytic lesions that cannot be observed in plain films.[32]

To conclude, alter a mean follow-up of 11 years, the clinical result of porous coated total hip replacement was satisfactory in 85.7% of cases and radiological component incorporation succeeded in 90.2% of cases in the cup and 92.6% in the stem in patients under 60 years of age. Nevertheless, the fact that 73.8% of cases showed some degree of polyethylene liner wear alerts us to a higher incidence of osteolysis, clinical impairment and the need of surgical revision in the future.

Conflict of interests

The authors have not received any financial support in the preparation of this article. Nor have they signed any agreement entitling them to receive benefits or fees from any commercial entity. Furthermore, no commercial entity has paid or will pay any sum to any foundation, educational institution or other non-profit-making organization to which they may be affiliated.

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