

Hip total hybrid replacement with polished and tapered stem, modern cementing techniques and ceramic-ceramic bearings

Analysis of complications

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Abstract

Introduction: There are reports of excellent results with polished, cemented stems using modern techniques, even in young patients, although their combination with ceramic bearings has been scarcely reported. The aim of this study is to analyze results and complications in a series of hip arthroplasties with ceramic-ceramic bearings and cemented tapered polished stems, using second- and third- generation techniques.

Materials and Methods: We evaluated results and complications related to the ceramic-ceramic friction pair, and also survival in 277 patients who received hip arthroplasty with cemented tapered polished stems, in a state-of-the-art fashion, associated with a ceramic-ceramic friction pair. Average age was 56 years old; minimal follow-up was 6 years.

Results: We did not detect radiologic loosening neither did we detect migration nor radiolucencies. Infection rate was of 1.3%. The rate of complications supposedly caused by the ceramic couple was of 4%, and revision rate was of 1.4%. Seven-year survival, considering revision for any reason, was of 95.8% (95%CI= 94-99%) and, considering aseptic loosening, it was of 100%. All cases of dislocation caused metallic impregnation of the ceramic head, and this was the most frequent cause of revision. Sounds rates have been extraordinarily low compared to the other series of cementless fixation.

Conclusion: The association between modern cementing techniques and tapered and polished stems with ceramic bearings has proved to be an attractive surgical alternative with a seven-year survival rate of 95%, with no aseptic loosening.

Key words: Arthroplasty; hip; ceramic, complications.

Level of Evidence: IV

REEMPLAZO TOTAL DE CADERA HÍBRIDO CON TALLOS PULIDOS Y CÓNICOS, TÉCNICA DE CEMENTADO MODERNA Y SUPERFICIE CERÁMICA-CERÁMICA. ANÁLISIS DE LAS COMPLICACIONES

Resumen

Introducción: Se han logrado excelentes resultados con los tallos pulidos, cementados con técnicas modernas, aun en pacientes jóvenes, aunque su combinación con superficie cerámica solo se ha comunicado en forma aislada. El objetivo de este estudio es analizar los resultados y las complicaciones de una serie de artroplastias de cadera con superficie cerámica-cerámica, y tallos pulidos y cónicos cementados con técnicas de segunda y tercera generación.

Conflict of interests: The authors have reported none.

Materiales y Métodos: Se evaluaron los resultados, las complicaciones relacionadas con el par de fricción y la supervivencia de 277 pacientes tratados con artroplastias de cadera con tallos pulidos y cónicos cementados, en forma moderna, asociados a un par de fricción cerámica-cerámica. La edad promedio fue 56 años; y el seguimiento mínimo, de 6 años.

Resultados: No se detectaron aflojamientos radiológicos, migraciones, ni radiolucencias. La incidencia de infección fue del 1,3%. La incidencia de complicaciones por causas atribuibles a la cupla cerámica fue del 4%, y la de revisión, del 1,4%. La supervivencia a siete años, considerando revisión por cualquier motivo fue del 95,8% (IC95% 94-99%), y considerando el aflojamiento aséptico, del 100%. Todos los casos de luxación produjeron impregnación metálica de la cabeza cerámica y esta fue la causa más frecuente de revisión. La incidencia de sonidos ha sido excepcionalmente baja comparada con las de otras series con fijación no cementada.

Conclusión: La asociación de cementado moderno y tallos pulidos y cónicos con superficies cerámicas ha demostrado ser una alternativa atractiva con una supervivencia a siete años del 95%, sin aflojamientos asépticos.

Palabras clave: Artroplastia; cadera; cerámica, complicaciones.

Nivel de Evidencia: IV

Introduction

The ceramic-ceramic friction pair in total hip replacement has gained acceptance for “young” adult patients due to low rates of osteolysis, wear and fracture of the components.¹⁻³

Results with tapered polished stems using second-and third-generation surgical techniques have proved excellent at years 15, 25 and 30, even in young patients. The combination of both elements (ceramic friction pair and polished stems with modern cementing techniques) could be a cost-effective alternative for long survival with neither osteolysis nor wear.

Evidence of results with the aforementioned combination is scarce, because most publications about ceramic-ceramic deal with cementless arthroplasties.

As regards the ceramic-ceramic friction pair, there are reports of diverse complications, especially in the case of cementless fixation.⁴

Audible sounds are the most frequent complications directly related to the ceramic-ceramic couple, and they have been especially detected in series of cementless total arthroplasties.⁵⁻⁷

When it comes to acetabular cup designs with dorsal metallic shell, there are reports of high rates of peripheral debris and lack of coupling of the ceramic insert in a particular design with a dorsal metallic surface (Trident System™; Stryker Orthopaedics, Mahwah, NJ, USA), and also reports of metallic impregnation of the ceramic heads recovered during revision surgeries.^{1,6,8-10}

The aim of this work is to analyze medical and radiologic results and complications in a series of patients who received hybrid hip total arthroplasty with second- and third-generations cementing techniques, using ceramic-ceramic friction bearings, with a design of insert characterized by a dorsal metallic shell.

Materials and Methods

Between March, 2004, and December, 2007, we performed 303 hybrid hip total arthroplasties in 290 patients using the ceramic-ceramic friction pair. In 13% patients (4%), we performed bilateral arthroplasties, one of them in the same surgery.

Average follow-up was of 7.6 years (ranging from 6 to 9 years). Three patients passed away due to causes not associated with the procedure, whereas 10 patients (3%) were lost during follow-up.

The study population for the described time of follow-up was made up of 277 patients (290 hips). Average age at the time of surgery was 56 years old (ranging from 38 to 69). The study included 151 (54.5%) women and 126 (45.5%) men. Average BMI was 27.5 (ranging from 19 to 35). The most frequent diagnosis was osteoarthritis (Table 1).

All procedures were performed by the same surgical team at the same institution.

We applied the same surgical technique, using a posterior-lateral approach with systematic repair of the capsule and reinsertion of the external rotators. All patients received the same kind of implant. In the femur, we used a tapered polished cemented stem with distal centralizer (Exeter™, Osteonics, Stryker Inc., NJ, USA) implanted

Table 1. Patients’ pre-operative diagnosis

Diagnosis	n	%
Primary osteoarthritis	130	45%
Osteonecrosis	93	32%
Dysplasia	61	21%
Rheumatoid arthritis	6	2%
Total	290	

with a modern cementing technique. We used a third-generation technique in 204 hips (70%) including: bone cement mixing under vacuum, retrograde cement injection, distal plugging, pulsatile lavage of the femoral canal, stem pre-heating and proximal pressuring. In 86 cases, we used a second-generation cementing technique.

We used SimplexTM cement (Stryker Howmedica Osteonics, Mahwah, NJ, USA), without antibiotic (224 cases) and with antibiotic (tobramycin) (66 cases).

For acetabular cupping, we used elliptic cementless cups characterized by a greater peripheral diameter of 1.8 mm (peripheral auto-locking). Materials consist of titanium alloys covered by an external shell of hydroxyapatite. This system is ready to receive a ceramic insert supplied with a dorsal titanium shell that overlaps the ceramic rim and generates a metallic frame around the whole circumference. The cup has anti-rotator notches to ensure appropriate insert coupling; the insert is locked and stabilized as a Morse taper (Trident SystemTM, Stryker Orthopaedics, Mahwah, NJ, USA).

To guide the final position of the acetabular cups, we used anatomic markers. With ≤ 50 mm-diameter acetabular cups, we implanted 28 mm-diameter heads; with 52-56-diameter and >58 -diameter acetabular cups, we used 32- and 36-diameter heads respectively. We used 42 (14.4%) 28 mm-diameter heads, 197 (67.9%) 32 mm-diameter heads and 51 (17.5%) 36-diameter heads.

The postoperative protocol of antibiotic prophylaxis included an i.v. first generation cephalosporin divided into 4 doses in 24 hours. The anti-thrombotic therapy consisted of low-molecular-weight heparin as indicated by an institutional protocol based on the guidelines of the American College of Chest Physicians.¹¹

Patients were prescribed active mobilization in bed during the first post-operative 24 hours, and progressive weight bearing with canes as from the first 48 post-operative hours. Average time of hospitalization was 4.1 days (ranging from 2 to 13).

Medical follow-up

The medical follow-up included function, pain and life quality estimations measured by the Harris hip scale and the WOMAC self-estimation scale at reduced scale, validated in Spanish and converted from 1 into 100, in which 0 represents the worst result and 100, the best one.¹² The latter is incorporated into the system of records of digital medical histories at the institution. We recorded the values measured in such scales in the pre- and the post-operative periods; at weeks 3 and 6, at month 6, one year after the surgery and consecutively on a yearly basis until the end of the follow-up.

Radiologic follow-up

Radiologic evaluations were performed with the same intervals of time as the medical follow-up. We took anterior and lateral pelvic X-rays. In the post-operative radiologic evaluation of the femur we determined:

- a) The varus-valgus alignment in degrees, recording as positive (+) the varus and as negative (-) the valgus.
- b) The quality of the cement mantle as stated by the Barrack graduation scale¹³
- c) >1 mm progressive radiolucences in the seven Gruen zones
- d) osteolytic injuries

At final follow-up, we evaluated the fixation of the component as outlined by the Harris and McGann criteria.

In the acetabular cup, we documented: a) migrations, b) inclination and planar anterversion angles by the Widmer method,¹⁴ c) heterotopic ossifications using the Brooker classification,¹⁵ d) radiolucencies in the three zones described by De Lee and Charnley and e) osteolytic injuries.

Complications were classified as 1) general complications and 2) complications related to the friction pair and the design.

So as to identify audible sounds, we set out a questionnaire that was answered by 258 patients (260 hips); 120 of the patients were contacted by e-mail. If sounds were confirmed, the questionnaire asked about their intensity (low, moderate, and high), their frequency (isolated, continuous or intermittent) and the date sounds were heard for the first time after the surgery.

Statistical analysis

To estimate the likelihood of survival of the implants we used the Kaplan-Meier method. The end-points established were: revision of any of the components for any reason and revision for aseptic loosening or osteolysis. To compare the variables we used the t-test and the chi-square test. We established statistical significance for values of $p < 0.05$. Data were incorporated into a database and the statistical analysis was made using the version 15.0 of the SPSS program.

Results

Medical results

The average pre-operative score outlined by the Harris hip scale was of 40 (ranging from 18 to 57). At the end of the follow-up, the average score improved significantly to 89 (ranging from 68 to 97) ($p < 0.05$).

The score in the WOMAC scale increased from 39 (ranging from 11 to 54), in the pre-operative period, to 80 after the surgery, with statistically significant differences ($p < 0.05$).

After the surgery, function improved in all the patients, who were able to re-take work and leisure activities with no changes. Fifty of them (18%) somehow had to change at work or in leisure activities. Twelve patients (4%) reported mild or moderate pain at thigh level. In eight patients (3%), pain subsided spontaneously before the year and, in three patients (1%) before two years after the surgery. Two patients that suffered pain on the medial aspect of the thigh, what was interpreted as psoas-iliacus tendini-

tis, received bupivacaine and steroids infiltration, and the pain subsided definitely.

Another patient showed mild and intermittent thigh pain until the end of the follow-up. This group that suffered thigh pain showed statistically significant differences in the BMI average as compared to those who suffered no pain (27.2 vs. 29.8; $p < 0.05$).

At the end of the follow-up, 22 patients (8%) showed walking claudication or mild Trendelenburg. No patient required orthosis, and all of them were able to go up stairs, sit on chairs and dress without help.

Radiologic results

Two hundred and forty-two stems (83.4%) were aligned in neutral position; 36 (12.4%), in valgus and 12 (4%), in varus (Table 2).

As outlined by Barrack, the cement mantle was classified as: type A (99 stems, 34%); type B (173 stems, 60%); type C1 (15 stems, 5%) and type C2 together with type D (3 stems, 1%). (Table 3). We detected neither radiologic loosening nor progressive radiolucencies at the end of the follow-up.

In the acetabular cup, the average inclination angle was $43^\circ \pm 5^\circ$ (ranging from 31° to 57°). Average anteversion was $24^\circ \pm 7^\circ$ (ranging from 9° to 30°). We detected neither progressive radiolucent lines in nor migration of the acetabular cup. In two of them, we saw osteolytic injuries without migration.

At the end of the follow-up, nine hips (3%) showed Brooker grades 1 and 2 heterotopic calcifications.

General complications

Infection rate was of 1.3%. We recorded one acute infection and three chronic infections. We isolated negative coagulase *Staphylococcus aureus* in the patient with acute infection who, two weeks after the surgery, was treated with surgical toilette, change of the modular components and i.v. antibiotic therapy for 10 weeks. Chronic infections were diagnosed 11, 18 and 38 months after the surgery with isolation of methicillin-sensitive *Staphylococcus aureus* (one case) and methicillin-sensitive *Staphylococcus epidermidis* (two cases). All these cases were treated by two-time revision in both arthroplasty components and i.v. antibiotic therapy during six weeks or more. No patient showed medical signs of re-infection at the end of the follow-up.

Table 2. Femoral stem alignment*

Stem	n	%
Neutral	242	83.5%
Valgus	36	12.5%
Varus	12	4%

*Measures are in degrees in which 0° represents neutral position, varus degrees are positive and valgus degrees are negative.

Table 3. Evaluation of femoral cementing as stated by Barrack

Grade	n	%
A	99	34.1%
B	173	59.6%
C1	15	5.2%
C2/D	3	1.1%

Four patients showed persistent wound drainage. They received surgical evacuation of the hematoma plus lavage and debridement. Cultures were negative, and they did not show squeals.

One patient suffered crural palsy; recovery was partial at month six, with quadriceps weakness that showed when going up and down the stairs (WOMAC, 61; Harris, 72).

Complications related to the friction pair and the design

Three patients (1%) suffered dislocation events. All were subject to revision with the change of the two components. In the first case, the patient suffered two episodes of dorsal dislocation in the post-operative fourth week. The position of the acetabular component was 12° -anteversion and 54° -inclination. In the second episode, it was decided to revise the acetabular cup to increase anteversion and decrease inclination.

During the surgery, we saw signs of metallic impregnation in the ceramic head (Figure 1), that is why the change was made, increasing 4 mm the length of the femoral neck.

In the second case, dislocation took place at post-operative week six, and the position of the components was appropriate; however, due to the metallic impregnation we had detected in the first case, we decided to perform surgical exploration. Here we also saw signs of metallic impregnation in the femoral head, because of which we revised the ceramic modular components increasing 4 mm the length of the femoral neck.



Figure 1. Metallic impregnation of the femoral head and the ceramic acetabular insert after two dislocation events and closed re-setting.

In the third case, there were three dislocations; the first one took place at post-operative week four, the second one at post-operative month six (this one was re-set under general anesthesia); and the third one occurred at post-operative month nine. In the latter dislocation, out of our experience, it was also decided to perform surgical exploration, finding signs of metallic impregnation in the ceramic head. We changed the insert and the ceramic head and, to increase tension in soft tissues and avoid the collision between the surfaces, we decided to change the femoral component using a cement-on-cement technique. Sixteen months after the revision surgery, one patient showed an osteolytic injury in the acetabular cup, in the DeLee zone 1, without medical or radiologic signs of loosening. Four years after the surgery, this injury had not increased in size. There were no new dislocation episodes. In the other two patients, we did not detect osteolytic injuries, neither did we detect radiolucences nor signs of loosening.

In five hips (1.7%), we detected incomplete coaptation of the inferior pole of the ceramic insert in the immediate post-operative X-ray; in all cases we saw a similar image, characterized by incomplete settling of the inferior pole (Figure 2). No patient was subject to a second surgery. At the two-month radiologic follow-up, we saw spontaneous coaptation in all cases.

The relative risk of this complication occurring within the first 100 cases as compared to the group of the following cases was 4.3 (ranging from 1.6 to 11.2) ($p < 0.05$).

At the end of the follow-up (44-52 months; average 47.6), no patient with uncoupling of the ceramic insert

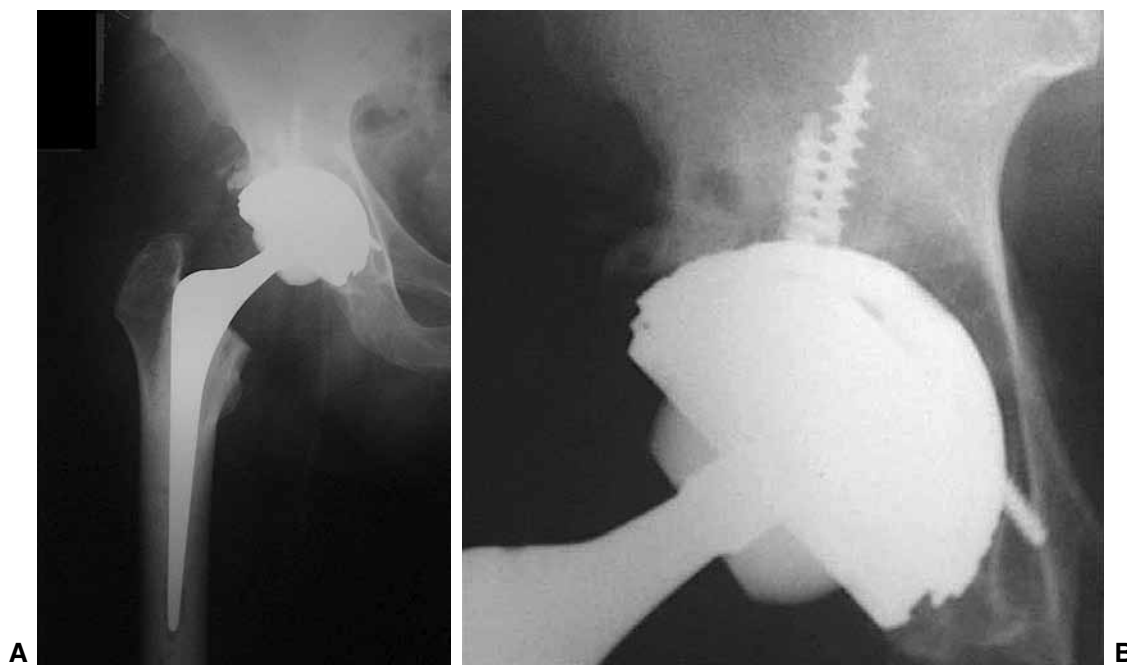
had radiologic or medical signs of prosthetic loosening; they did not show osteolytic injuries either.

One year after the surgery, one patient with BMI= 28 had the ceramic head fractured after a fall from standing height with lateral impact. It was a short modular neck (-4) (Figure 3A). We performed surgical revision changing both ceramic modular components by similar components, and we practiced total capsulectomy. Since the Morse taper in the femoral stem had been damaged (Figure 3B), we also changed the stem by cement-on-cement techniques using a thinner stem. After a three-year follow-up, the patient showed WOMAC scoring of 88, and we have not seen radiologic loosening signs in any component, neither did we see osteolytic injuries.

Following the protocol for identifying sounds, two patients confirmed sounds (0.7%). The first case was reported at one-year follow-up. Sound intensity was moderate, and the sound was intermittent, and it had been detected for the first time four months after the surgery. The sound could not be reproduced at the time of consultation.

The second case was reported for the first time by the specific questionnaire for detection of sounds. It was a low, intermittent sound, and it had been detected for the first time seven months after the surgery. It was possible to reproduce and record the sound at the time of consultation combining hip flexion-extension with hip rotation.

During the insertion of the ceramic components we did not detect peripheral debris. Complications rates related to the arthroplasty design and bearings were of 4%, even uncoupling of the ceramic insert and the fracture of the



▲ **Figura 2.** A. Post-operative X-ray. It shows uncoupling of the ceramic acetabular insert in the distal pole. B. Image of the uncoupling in the distal pole of the ceramic acetabular insert seen with greater magnification.



Figure 3. A. Remains of the fractured ceramic femoral head. B. Morse taper of the distorted femoral stem and the fractured femoral head.

femoral head. If we consider metallic impregnation due to hip dislocation as a complication related to the friction pair, the rate of revision due to causes directly linked to the ceramic-ceramic couple was of 1.4%. The summary of the complications is shown in Table 4.

Survival

Eight of the 277 patients (2.9%) who underwent follow-up as planned were subject to the revision of some component. Seven-year survival, considering as end-point the revision of any component for any reason, was of 95.8% (confidence interval [CI] of 95% from 94% to 99%).

If we consider as end-point the revision of any component for aseptic loosening or osteolysis, seven-year survival was of 100% (95%CI, from 95% to 100%). (Figure 4).

Discussion

Over the past 15 years, we have witnessed great progress in the manufacture of the ceramics and the design of the arthroplasty components that tend to improve resistance to fracture and general tribological conditions, and also the emergence of the so-called “third- and fourth-generation ceramics.”⁶ Resistance to wear found *in vitro* has been reproduced *in vivo* in some clinical trials, with a fracture rate of 1 in 10,000. These conditions have re-valued indications, especially among the youngsters. As regards complications, in 2006, Park et al.¹⁷ published a series of 357 hips with high rates of failure due to the fracture of the ceramic insert (1.7%), using a design of cups with a dorsal shell of high density polyethylene.

Table 4. Post-operative complications. Rates.

	Complications	n	%
General complications	Acute infection	1	0.3%
	Chronic infection	3	1%
	Persistent wound drainage	4	1.4%
	Crunal palsy	1	0.3%
Complications related to the friction pair and the design	Incomplete coaptation of the ceramic insert	5	1.7%
	Dislocation	3	1%
	Fracture of the ceramic head	1	0.3%
	Aseptic loosening	0	0%
	Audible sounds	2	0.7%

In this series, with dorsal-metallic-shell acetabular cups, there were no fractures of the ceramic inserts, something that coincides with other reports about the same design.^{3,18}

By means of this study, we were able to determine that the five cases of insert uncoupling (1.7%) occurred within the first 120 cases (4%). As from the fifth case, we paid particular attention to the implantation of the insert, making methodically sure about the appropriate clearing of soft tissues from the anchorage metallic surface, the energetic impaction of the insert and the careful checking of the final position of the ceramic insert, particularly the inferior pole after implantation. For the sake of trial, we started using systematically a curve periosteal elevator trying to uncouple the metallic distal end of the ceramic insert. This way, we proved the definite uncoupling of the ceramic insert in six more cases, after impaction, and we were able to verify the hampering presence of soft tissues remains only in three cases. In the six cases, we moved to the re-insertion of the insert, taking precaution against the aforementioned difficulties and verifying the definite coupling.

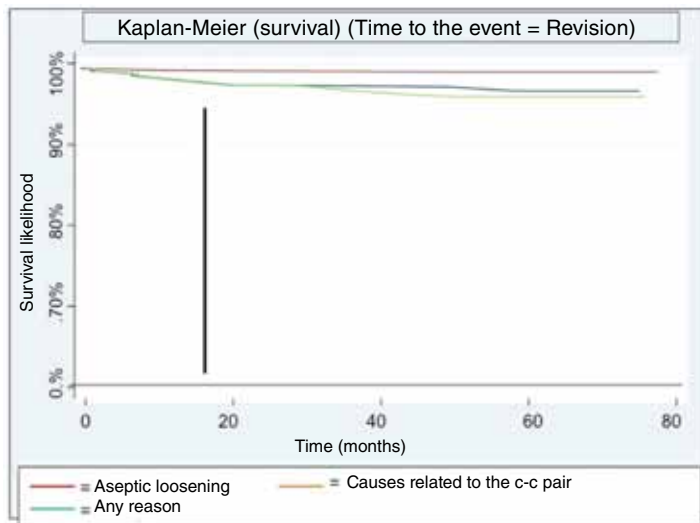
The relatively high risk (4,3) of this complication occurring within the first 100 cases suggest its strong association with the learning curve. None of these patients showed evidence of osteolysis, loosening or wear at the end of the follow-up.

In 2007, Langdown et al.⁸ published rates of 16% of incomplete anchorage of the insert. Later on, rates published were of 11% and 7%. Causal factors put forward were: possible deformation of the metallic cup at the time of inserting it in the acetabular cup, plus scarce visualization of the embedding distal pole of the insert due to the metallic frame it is surrounded by.

There are publications about isolated cases of metallic impregnation of the ceramic head occurred after hard setting maneuvers in acetabular cups with dorsal metallic shell.^{9,19} In the three cases of dislocation described in this series, we verified signs of metallic impregnation in the ceramic head. In all of them we performed arthroplasty revision, changing the ceramic modular components so as to decrease the risk of failure due to mode 3 wear.^{9,19}

From this series we conclude that dislocation is a complication that affects distinctively the ceramic-ceramic friction pair, since in all the cases we saw metallic impregnation of the head. These findings, plus the potential risk of failure due to wear by third body in young patients justifies exploration in all the cases that are characterized by more than one dislocation event, although causes are not directly linked to flaws in the orientation of the components and we are able to perform closed setting of the dislocation.^{9,19,20} It goes without saying that we have to avoid dislocation mastering pre-operative planning, the position of the components and post-operative education.

Rates of head fracture with second-generation ceramics have been of one in 10,000.³ It has been established



▲ Figure 4. Survival curves in the analyzed series.

that the increase in the rates of ceramic heads fracture is associated with the use of short modular necks.²¹ In the one fracture of ceramic heads in our series, the neck also was short.

Nowadays, audible sounds represent the complication directly associated with the ceramic-ceramic couple most frequently seen, with rates that range from 1% to 20%.^{4,5,7,22,23} Published series that report audible sounds have used most frequently both components of the cementless kind. The combination of an acetabular cup orientation characterized by excess of inclination and lack of anteversion, likely demographic variables and, especially, the metallic alloy and the specific design of the stem and the Morse taper represents the factors most frequently associated with the recording of audible sounds.^{5,7} There are also reports about the relationship between audible sounds and acetabular cups with metallic protecting rim.^{7,24}

It is worth mentioning that, in the series with ceramic-ceramic bearings and acetabular cups with metallic protecting rim, rates of audible sounds were of just 0.7%. Our personal hypothesis is that the cement that covers the femoral stem could modify the spread of the sound waves due to a high ratio of sound absorption and action as an acoustic isolator. Nowadays, there is research about this theoretical model using elements of applied acoustics.

As regards fixation, polished and tapered stems fixed with second- and third-generation cementing techniques have got excellent long-term survival rates.²⁵ Tendencies towards cementless fixation in some places of the world not always coincide with the evidence of results. A study including the database of the records in the four Nordic countries published in 2014 stated that survival rates for cemented fixation are greater than those for cementless fixation.²⁶ In a recent study that used state-of-the-art cementing techniques and the stem ExeterTM, reports were

of just 2% of aseptic loosening at year 25.²⁷ A revision of the results with the same stem in patients < 50 years-old showed a seventeen-year survival rate of 100%.^{27,28}

Conclusions

The combination of the three elements—state-of-the-art cementing techniques, polished tapered stems and

ceramic-ceramic bearings has showed a survival rate of 96% and 100% due to aseptic loosening, in an eight-year average follow-up. The low rates of complications related to the friction pair, which resulted in a revision rate of just 1.4% and low rates of audible sounds, are the factors that encourage the choice of the described technique, especially among patients with life expectancy >20 years.

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