5-15 Year Follow-up of Hydroxyapatite-Coated Total Hip Replacements

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Purpose. This retrospective study was carried out to assess the survival of hydroxyapatite-coated total hip replacements (THR) implanted in our department.
Materials and methods. Of a total 136 patients we reviewed 154 THRs with 154 hydroxyapatite-coated stems and 144 hydroxyapatite coated cups with an evolution of 5-15 years. Each case was assessed clinically and radiologically using the information from the last control and the patients' clinical record. In the 24 cases that required replacement the causes of failure and reasons for review were assessed.
Results. The mean age of the patients at the time of surgery was 61 years. Intraoperative complications were seen in 10 cases and postoperative complications in 18. Replacements were performed of 7 isolated polyethylene components, 17 cups and 2 stems. The reasons for replacement were: polyethylene wear: 7 cases; cup loosening: 9 cases; cup loosening and polyethylene wear: 4 cases; dislocation: 3 cases; and infection: 1 case.
Conclusions. Hydroxyapatite-coated THRs, especially stems, deliver a long time survival that is at least comparable to that of other non-cemented implants. Compared to other types of fixation, hydroxyapatite offers long-term stable fixation and facilitates replacement in cases of failure.

Key words: *total hip replacement, hydroxyapatite, survival.*

Resultados de las prótesis totales de cadera recubiertas de hidroxiapatita con un seguimiento de 5-15 años

Objetivo. Hemos realizado un estudio retrospectivo para valorar la supervivencia de las prótesis totales de cadera recubiertas de hidroxiapatita implantadas en nuestro Servicio.
Material y método. En 136 pacientes se han revisado 154 prótesis totales de cadera con 154 vástagos recubiertos de hidroxiapatita y 144 cótilos recubiertos también de hidroxiapatita, con una evolución entre 5 y 15 años. Cada caso fue valorado clínica y radiológicamente con la información de la historia clínica y del último control. En los 24 casos que precisaron algún tipo de recambio se valoraron las causas del fracaso y el motivo de la reintervención.
Resultados. La edad media de los pacientes en el momento de la intervención fue de 61 años. Se presentaron complicaciones intraoperatorias en 10 casos y 18 en el posoperatorio. Se recambiaron 7 polietilenos aislados, 17 cótilos y 2 vástagos. Las causas de recambio fueron desgaste del polietileno (7 casos), aflojamiento del cótilo (9 casos), aflojamiento del cótilo asociado a desgaste del polietileno (4 casos), luxación (3 casos) e infección (1 caso).
Conclusiones. Las prótesis totales de cadera recubiertas de hidroxiapatita, y en especial los vástagos, ofrecen una supervivencia a largo plazo como mínimo comparable a la de otros implantes no cementados. Frente a otros tipos de anclaje, la hidroxiapatita ofrece una fijación estable a largo plazo y facilita el recambio en caso de fracaso.

Palabras clave: *prótesis total de cadera, hidroxiapatita, supervivencia.*

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Received: October 2005.
Accepted: March 2006.

The introduction of hydroxyapatite (HA) as an element that can be implanted in human beings and whose biological characteristics made it amenable to being used as coating for prostheses, opened up new horizons in prosthetic implantation methods.

At the end of the eighties in our Department we used to implant uncemented prostheses without HA. Although their metaphyseal incorporation was good and the long-term results were stable, they tended to cause diffuse thigh pain over a period of several months. Reports on the initial and short-term results of HA-coated prostheses did not show this effect, which led us to adopt those new designs in 1989, albeit timidly at the beginning. The emergence of new literature corroborating the both short and medium term advantages inherent in the above mentioned method of stabilization encouraged us to forge ahead with our decision to embrace HA-coated implants and now, many years on, we still uphold the same criterion, having implanted a total 270 cases.

Several studies have been performed to date on the chemistry and biological nature of HA and on the results of HA-coated prostheses[1,2]. Among them, we can mention studies showing a great increase in the rate at which it binds into metallic materials[2] and the firmness with which it incorporates into host bone[3].

More than fifteen years after having implanted the first HA-coated prosthesis in one of our patients, we decided to conduct a retrospective study in order to assess the results of this technology with a minimum follow-up of 5 years. The main goal of the study was to determine the survivorship of the implants as regards their incorporation and stability, a controversial matter between those who favor cementation and those who do not.

A review was carried out searching the patients' clinical records for such information as post-op and follow-up x-rays. Images showing the effect of total hip arthroplasty on the host bone were studied, paying special attention to *stress shielding* and to signs of bone-to-implant load transfer. We did not set about making an assessment of the results as regards range of motion or improvement in the patients' quality of life but we did take into account the presence of post-op pain or its reappearance in the medium or long term.

MATERIALS AND METHODS

Between January 1989 and December 1999 we implanted 144 cups and 154 stems, all of them part of HA-coated total hip prostheses in 79 females and 57 males with 18 bilateral cases. All operations were primary procedures, except for one 18-year-old Girdlestone procedure and one arthrodesis takedown in a 59 year-old patient who had undergone her arthrodesis during adolescence. At the time of making the study, 11 patients had died, three of them bilateral.

The approach used was Hardinge's direct lateral approach. Following the antibiotic regime prescribed in our hospital, a 1g dose of IV cephazolin was administered before surgery, followed by 1 g every 8 hours for three days. As from February 1996, this was changed for a single 2 g daily dose of IV cephazolin. In patients allergic to penicillin, a 600 mg dose of clindamycin was administered before surgery, followed by the same dose every 8 hours for three days. The etiology of the pathological process in the hip is reflected in Table 1. The prosthetic models implanted are reflected in Tables 2 and 3.

Table 1. Etiology of the patients in our series

Osteoarthritis	105
Necrosis	21
Rheumatic	9
Psoriatic	1
Traumatic	3
Perthes disease	1
Dysplasia	4
Paget's disease	1
Others	6
Girdlestone	1
Childhood disease	2

Table 2. Stem designs used in our study

Corail	119
Karey	13
Custom	9
Other	7
Kar	2
HG Anatomic	1
HG Multilock	3

Table 3. Cup designs used in our study

CBS	71
Atoll	38
Karey	13
Omega	7
Tropic	7
Other HAC-coated designs	7
IQL Aura	1

Most of the cups used were hemispherical impacted ones, their primary stability reinforced by means of 2-3 screws at the dome and 2 in the ischial and pubic areas. All prostheses used either a polyethylene-metal or a polyethylene-ceramic bearing surface. The heads used were ceramic (39 cases) and stainless steel (115 cases), with diameters of 28 mm in 137 cases, 32 mm in 15 and 22 mm in two cases.

The most frequently implanted stem designs were: Landos Corail (Landager, Chaumont, France) between 1989 and 1999 and Karey (Surgical Co. S.A.) from 1999 to the present. Both stems have a very similar trapezoidal design on two planes in the metaphyseal region and a straight tapering diaphyseal area with horizontal superficial macrostructures in the metaphysis and longitudinal ones in the diaphyseal region (there differ in their shape and distribution).

The most significant intraoperative complications were the following: presence of *coxa profunda* that required cancellous grafting in the acetabular floor (one case); difficulty to reduce the joint after implantation (6 cases of which one required a tenotomy); technical difficulties resulting from a dysplastic cup and a post-op flexion contracture in a patient with an 18-year-old Girdlestone procedure whose iliac crest had to be brought down 12 days later.

The postoperative protocol for the first few operated patients was bed-rest for 24 hours post-op. At the second day, the drainages were removed and sitting was allowed. Standing with partial weight-bearing as well as progressive walking were allowed at the third day. The use of crutches was mandatory until two months post-op. We progressively reduced the non weight-bearing period with use of two crutches to one month, followed by a further month with a single crutch. Currently some colleagues in our department even authorize immediate weight-bearing.

One of the authors reviewed the clinical records and the radiographs of all patients following the criteria laid down by Engh[4] (1987) for femoral loosening and by Hodgkinson[5] (1988) for acetabular loosening. For each prosthesis, a record was kept of the patient's personal details, the date of the procedure, data on the material implanted, any intraoperative complications, duration of the surgery, blood consumption, assessment of the implant's initial and final position, evaluation of the type of "seating" achieved, early and late postoperative complications, any reoperations, presence of radiological signs of loosening or other signs of failure.

THR survivorship was evaluated by means of the Kaplan-Meier survivorship analysis[6], taking as an endpoint the carrying out of a replacement and including confidence intervals of 95%[7]. Continuous variables have been expressed as mean values, and maximum and minimum values were also stated.

RESULTS

Patients' global mean age at the time of the primary surgery was 61.39 years (range: 18.7-83.5). Mean age among females was 60.62 (range: 18.74-83.58) and among males 62.49 (range: 29.34-78.32). Mean OR time was 107.94 minutes (range: 60-180) and blood consumption 1.35 units. Intraoperative complications occurred in 10 cases (6.5%) (Table 4); the number of immediate post-op complications was 16 (10.3%) and late complications were 2 (1.2%) (Table 5). Intercurrent processes appeared during the immediate post-op in 5 patients who presented with: skin eruption (one case), nephritic colic (one case) and fever unrelated to the hip (three cases). It should be mentioned that intraoperative fractures or fissures in the calcar occurred in the implantation of prosthetic designs that are no longer in use in our Department (HG Anatomic and HG Multilock). Furthermore, we currently undersize our stems.

Table 4. Intraoperative complications in our series

Greater trochanter lesion	2
Fracture of posterior rim during head dislocation	1
Foreign body excised at 20 days	1
Calcar fissure	2
Breakage of a screw in the cup	1
Diaphyseal fracture	1
Hypovolemic shock	2

Tabla 5. Postoperative complications

Dislocation in immediate post-op	2
Hematoma-hypocoagulability	2
Soft tissue infection	1
Dislocation at 2 months	2
Greater trochanter fracture caused by a banal fall at 5 days post-op	1
Pulmonary thromboembolism	2
Phlebitis	2
Abdominal distension	1
Bleeding of high digestive ways (stress ulcer)	2
Urinary retention	1
EHM-LPS Transient paresis	1
Death from heart arrest	1

EHM-LPS: extensor hallucis muscle-lateral popliteal sciatic

The two cases of dislocation we had during the immediate post-op period were resolved in a conservative way with bed-rest placing the limb in abduction and internal rotation once it had been reduced. The two cases of pulmonary thromboembolism occurred when the patients had already been discharged and were being satisfactorily treated in other hospitals with anticoagulant treatment.

On assessing the initial position of the implants, the cup was found to be in a correct position in 137 cases; in 4 cases it was considered to have been shifted into a vertical position, in one case it was anteverted, in one case it was retroverted and in one lateralized. The position of the stem was rated as correct in 146 cases; in 5 cases it was found to have moved into *valgus* and in 3 into *varus*. In narrow diaphyses the variability margin is very small, bur in wide medullary canals, if undersize stems are implanted, variability can be of several degrees.

A cup was considered to be positioned correctly if in an anteroposterior view it showed an inclination of between 40° and 50° with respect to a horizontal line drawn between the ischiums; a cup was considered verticalized if this inclination exceeded 50°. A stem was considered to be in *valgus* if its lateral metaphyseal area contacted the cortex of the base of the greater trochanter and its tip made contact with the medial diaphyseal area. A stem was considered to be in *varus* if it leant on the rest of the lower cortex of the neck and the calcar and its tip was in contact with lateral dyaphiseal cortex[8].

Of the total 154 cases, 14 were lost to follow-up (in 11 of these the patients died). So we were left with 140 prostheses in living patients. As far as the survivorship analysis is concerned, the date of death was considered in these patients the last control date.

Follow-up

When following up the patients and assessing the result of the hip prostheses we considered the possibility of evaluating the cups and the stems separately, but given the close connection between the causes of failure of both elements, we decided to conduct a joint evaluation.

Cups

Of the total 144 HA-coated cups, 24 had to be reoperated. Of the 120 remaining ones, 49 have to date had an evolution of more than 10 years and 66 have been implanted for 5-10 years. None of them showed signs of loosening at their last consultation, with a mean follow-up of 9.03 years (range: 0.05-15.65). Eleven patients died (14 cases), 5 of them with an evolution of less than 5 years, 3 between 5 and 10 years and 6 with over 10 years, one of these last ones had to be revised.

Stems

Of the 154 HA-coated stems implanted, 2 had to be revised: one after one month and the other at 2.5 years. Of the 152 remaining ones, 14 cases died and 138 are still in place with no signs of loosening. Of these 138 cases, 67 have had an evolution of between 10 and 15 years, and 66 have evolved 5-10 years. Mean stem evolution time is 9.15 years (range: 0.05-15.65).

Radiological study

Cups

The following findings have been made In the cups that until the time the study was carried out did not require a reoperation: 10 cases of osteolytic lines or cysts smaller than 1 cm; two additional cases present radiological signs of polyethylene wear; in 9 cases heterotopic calcifications have appeared. The cases that had to be revised are dealt with separately given their interest.

Stem

The following findings have been made in patients that required some sort of stem-related surgery: 3 cases of metaphyseal cavitation of less than 1 cm; 1 case of metaphyseal and trochanteric osteolysis greater than 1 cm; another three cases showed an interface image in the femoral shaft. In the cases that did not require revision, no stem showed radiolucent lines. In no case was stem subsidence observed. Osteopenia of the greater trochanter was found in 16 cases and of the calcar in 9 cases; 4 cases showed osteopenia of both the greater trochanter and the calcar. However, there is radiographic evidence of new cancellous bone formation at the level of the middle and distal third of the femoral stem; in the latter case the new bone formation was accompanied by the formation of a ledge in the majority of implants.

Analysis of cup and stem revisions

In 24 cases a revision of the cup was required. In two of them the femoral stem was also replaced in the same surgical act. The mean global follow-up time until reoperation was 6.63 years, but it was 7.13 years in cases in which only the acetabular component was approached (range: 0.05-13.96 years). For stems, mean global follow-up time until reoperation was 1.37 years. No isolated stem replacements have been carried out. These data indicate a survivorship of 83.3% (120/144) for acetabular components and of 98.7% (152/154) for femoral ones.

The main causes for acetabular revisions were: pure loosening (9 cases); loosening associated to polyethylene wear (4 cases); isolated polyethylene wear (7 cases); component malpositioning or dislocation (3 cases); infection (1 case). In the 7 cases of isolated polyethylene wear only the acetabular component was replaced.

If we consider the 24 cases in which cup revision was required (in isolation or together with the stem) the rescue procedure was performed before the first year in 2 cases, between 1 and 5 years in 5 cases, between 5 and 10 years in 12 cases and after 10 years in 5 cases.

If we analyze the reasons for the rescue surgery and the duration of the primary implant, we shall observe the following: revisions performed before the first year were motivated by dislocation or malpositioning; those carried out between 1 and 5 years were in 2 cases due to loosening and early wear in a verticalized cup, in one to low-grade infection and in only two cases to the loosening of an apparently well-positioned cup; those between 5 and 10 years were caused by pure loosening, wear and loosening resulting from cysts created by wear particles; all of those revised after 10 years' survivorship of the primary cup were due to poly wear.

Reoperations for isolated polyethylene cup wear were performed at 9.86 years (range: 7.29-13.96). The 13 cases of cup loosening, isolated or associated to PE wear, that occurred in correctly positioned implants, were found mainly in the Atoll (8/38), CBS (3/71) and Omega (2/7) designs, all of them hemispherical with surfaces with no macrostructuring. Cup mechanical failure rate, considered as loosening that may or may not be associated to PE wear, was 3.8%

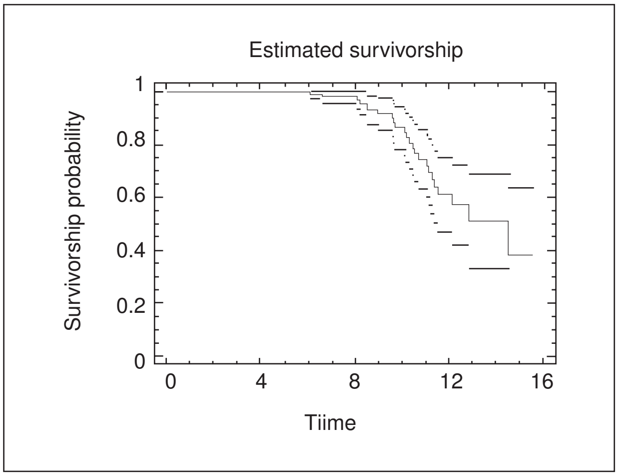

***Figure 1**. Cup survivorship analysis based on the Kaplan-Meier score (in years).*

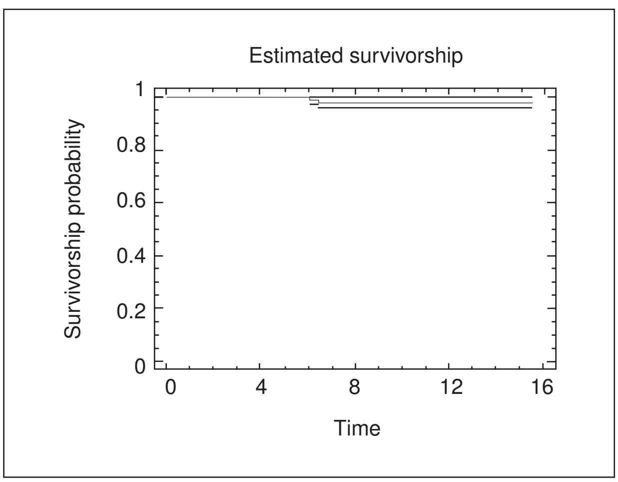

Figure 2. Stem survivorship analysis based on the Kaplan-Meier score (in years).

(20/144). Global 10-year survivorship for the whole series at 10 years, calculated by means of the Kaplan-Meier score, was 88.02 ± 3.86% (fig. 1).

In stems revisions were needed in one case because of adislocation at one month after surgery and in another because of low-grade infection. The first case revealed the malpositioning and consequential dislocation of the components. The indication for the primary procedure was a hip arhtrodesis takedown in a patient with significant ponderal overload and osteoarthritis in the lumbar region and the ipsilateral knee because of the lack of hip mobility. In the infected case, a two-stage replacement was carried out of all components, and a new Corail HAC-coated stem was implanted. Ten-year stem survivorship, calculated by means of the Kaplan-Meier score was 98.14 ± 1.3% (fig. 2).

***Figure 3.** Patient with bilateral hip dyslpasia who was implanted custom HA-coated prostheses of two different designs. The thicker stem caused a cortical hypertrophic reaction around it; this did not occur with the thinner design.*

The reappearance of pain in the medium and long term has traditionally been associated with the presence of complications, i.e. infection, loosening or the appearance of areas of wear-related osteolysis. Pain without associated loosening was only seen in one case in which a larger caliber stem design was used that occupied the whole of the diaphyseal cavity and caused cortical hyperthrophy (fig. 3).

The x-ray images of the fully loosened cups showed, apart from a change in orientation, peripheral radiolucencies greater than 2 mm. The presence of wear-related osteolysis was also detected both in the pelvic bone and in the femoral region of the greater trochanter and the metaphysis.

Seven prostheses that required revising the cup but which had a firmly anchored stem intraoperatively showed: 3 cases of metaphyseal cavitation of less than 1 cm and one case with cavitation greater than 1 cm. It should be emphasized that within the osteolytic cavity the stem's HA coating was still adhered to the metal, providing continuity to the medial cortices of the osteolytic lesion, and acting as a sealing mechanism that prevented the progression of osteolysis towards the metal/bone interface.

DISCUSSION

Tests carried out on the use of HA as a coating material for acetabular and femoral metal components have shown promising short and medium-term results in primary implants[9,10]as well as in revision cases[11]. Long-term results have also been encouraging, even in the first polyethylene cups that were directly coated with HA, a design now in disuse[12].

We believe that in our series the lack of thigh pain was related to the use of HA; conversely, the pain caused by cortical hypertrophy was connected to the THR design. Some studies show increased pull out strength in HA-coated components vis-à-vis non-HA-coated components as well as a HA-related promotion of osteogenesis to the extent that the latter can "jump" spaces of up to 2 mm13. Likewise, we should mention the study by Soballe according to which HA can induce the ossification of the fibrous membranes surrounding unstable implants[14,15].

The results of our study show as survivorship of HA-coated THRs comparable to that afforded by cemented and uncemented implants in the medium and long term. With respect to uncemented prostheses, they show a faster incorporation rate that does not cause thigh pain. After 10 years' follow-up, the results we provide cannot be easily compared with those of other studies given the existence of an overly high confidence interval. When the number of cases with more than 15 years' follow up in our study increases, we will be able to establish these comparisons.

In the large studies with large numbers of patients published by the Scandinavian hip registers, HA-coated THRs are used as a yardstick to compare the survivorship of cemented and uncemented (not HA-coated) hip prostheses in patients under 60 years of age16.The fact that, in spite of the variety of designs used, we only exchanged two out of a total 154 stems (one for malpositioning and the other for infection) seems indicate that the fact that most of them were metaphysially supported and fully HA-coated was what made their performance similar.

For a fair number of years now, we have observed that the use of HA makes it easy for the surgeon to prepare the site where the femoral stem is to be implanted, especially when the stem is straight and of a trapezoidal metaphyseal design. To appropriately place these stems, and achieve a sound long-term primary fixation of these components to perform a mechanical reaming until stable support is achieved in the medial cortex of the metaphyseal funnel and the femoral shaft. It is advisable to prepare the stem's recipient site by means of moderate broaching, avoiding rotation maneuvers, until perfect adjustment is achieved in the metaphyseal cancellous bone as well as sufficient final broach rotational stability. Contact between the cancellous bone and the prosthesis will promote the sealing of the area and thereby prevent PE debris from passing through[17]. Some prostheses that radiologically could be rated as oversized showed firm osteointegration and clinical performance. We currently consider it beneficial to leave 1-2 mm of the hardest endocortical cancellous bone intact since that way endocortical circulation is preserved; in addition, we believe that this cancellous bone has more osteogenic potential than the cortical bone.

As regards lavage, we consider that if the case has not been too laborious with multiple broach entries and exits brushing against the skin margins and potential contamination due to the length of the procedure, lavage may be counterproductive since it washes away growth factors and, when clots are removed there is an increase in bleeding. We believe that compacted cancellous bone helps stabilizing the stem and accelerates osteointegration since it bridges potential dead spaces between the stem and the bone.

With the current level of expertise in uncemented techniques, it seems clear that the fibrous membrane that forms around the smooth surfaces of uncemented prostheses offer a pathway for the migration of PE debris given the pumping effect caused by the alternation of positive and negative pressures created in the joint during weght-bearing[17,18]. This effect could send microparticles over a long distance – as far even as the femoral shaft. In circumferential porous-coated implants this situation is improved since in those cases the metal-bone interface is microscopic[19,20]. In a prosthesis that is securely positioned by means of a secure integration of the metal to the bone, as is the case in HA-coated implants, micromovements will be less as will also be this pumping effect, which will be circumscribed to the area that lies closest to the joint[17]. In HA-coated stems we have not observed this interface, rather, there is continuity between the metal, the coating and the bone.

The basic radiological sign of incorporation is the lack of interface lines or periprosthetic corticalization. In the periodic radiological tests images tend not to vary. One could debate whether microscopically, in the long term, when the HA-coating and the tricalcic phosphate have disappeared as a result of dissolution and fagocytosis, the bone will still remain so firmly attached to the metal. Nonetheless, even if this microscopic integration was not that intimate, we could conceive the creation of a bony mold so perfect that it prevents the prosthesis' mobility. To achieve this, the metal should have an adequate degree of roughness[21-25].

On some occasions, radiological studies on HA-coated THRs show some characteristic images. The areas of load transmission may reveal striations of the cortical bone, in the shape of a comb or of a group of prongs, indicating load transmission from the prosthesis to the bone[13]. This phenomenon is usually found in the acetabulum and in the metaphysis. The tip of the stem usually presents an image of bone condensation that has the shape of a ledge. In cases with good long-term evolution, this tends to be construed as a favorable sign.

The fact that in our series of primary HA-coated stems, mainly Landos Corail and Karey, we have hardly seen proximal bone atrophy due to *stress shielding* could be due to the fact that both are metaphyseal loading designs and, in both, the diaphyseal section is relatively short and tapered, which means that the area that could be affected by the *by passing* of loads becomes smaller. We have detected osteopenia either in the greater trochanter or the metaphysis more frequently in cases with a longer or thicker stem implanted in special cases such as those of obese or osteoporotic patients and in revisions, which have not been included in this series. In other prosthetic designs, calcar osteopenia tends to be the norm and is not related to whether there is HA-coating[26].

Stem failure tends to occur before the first year and is normally due to defective incorporation during the first few weeks or an acute low-grade infection. This lack of incorporation was seen In cases not included in this series owing to their short evolution period. Cases of late loosening occur after 10 years when the PE wear causes debris-related osteolysis, which in turn gives rise to proximal metaphyseal lesions which, depending on their extent, may compromise the stem's stability.

As in the case of stems, Impacted and screwed-in cups can undergo an early failure due to lack of incorporation or to infection. However, in general they tend to fail in the medium-term, particularly the hemispherical designs with a smooth surface (Atoll). When retrieved, they showed the disappearance of the HA-coating. The failure of these designs could probably be attributed, at least in part, to the fact that their surface is smooth[27]; for that reason they are no longer in use. Threaded cups, which offer solid primary fixation, have shown a good performance throughout the years. Cups with a textured periphery also seem to show good survival rates. In our view, although cups that are textured throughout their external surface may be considered the most stable in the long run, are a risky option given the great difficulty in retrieving them should the need arise.

To conclude, HA-coated THRs, particularly the HA-coated stems, have a similar and in some cases higher survivorship than uncemented THRs with no HA-coating[28]. We must wait until we have series with longer follow-ups in order to make the same claims about cemented prostheses. If we consider classical uncemented THRs, bone manipulation and OR time are reduced as is the incorporation time. In addition, there is no pain on the anterior aspect of the thigh. The weak link in HA-coated prostheses is the cup and the polyethylene component. For that reason, improvements in the bearing surfaces, whether ceramic-ceramic, metal-metal or containing some other new element, are critical[29] and manufacturers should produce rough surface implants to promote long-term stability[30].

In spite of all that was said above, we must remember that HA is not in itself a definitive fixation element. It is nevertheless an excellent accelerator and facilitator of incorporation thanks to its osteoinductive potential. This means that if the correct technique is applied, with maximum crystallinity and firm mechanical or chemical binding to an appropriately textured metal element, it can lead to durable implants in the long term.

ACKNOWLEDGEMENTS

To our colleagues in the Department Drs. J. Casanova Sallarés, M. Ribas Playan, S. Formiguera Sala and J. García Bonet. Without their help we would not have been able to produce this paper. We would also like to thank Dr. R Viladot Pericé for his help reviewing the manuscript.

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Conflict of interests: We, the authors, have not received any economic support to carry out this study. Nor have we signed any agreement with any commercial firm to receive benefits or fees. On the other hand, no commercial firm has provided nor will provide economic support to non-profit foundations, educational institutions or any of the other non-profit organizations that we are members of.