Behavior of Hydroxyapatite-Coated Cementless Stems Placed With Coronal Malalignment in Primary Hip Arthroplasty. Long-Term Follow-Up Results

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ABSTRACT

Introduction: coronal malalignment of non-cemented stems remains controversial. It's been reported that femoral stems implanted with varus or valgus developed subsidence and lack of integration with femoral bone. The purpose of this study was to calculate prevalence of coronal malalignment in cementless, fully coated with hydroxialapatyte (HA) femoral stems focusing in their long-term clinical and radiographic outcomes. **Materials and Methods:** a retrospective study was performed, assessing 220 primaries total hip replacements with non-cemented, fully coated with HA, femoral stems between 2006 and 2009. Coronal alignment was assessed with hips antero-posterior views with 10º of internal rotation of lower limbs. We registered data about subsidence, proximal femoral osteolysis and cortical hipertrophy. Functional outcomes were assessed with Harris Hip Score (HHS). Free revision rate implant survival was calculated. **Results:** prevalence of femoral stems with malalignment was 32.3%. HHS showed an statistically significant increase after surgery (41.05 ± 6.5 versus 90.05 ± 2.5; p <0.01). There were 73.1% of femoral stems that achieved a bone stable fixation. We observed proximal femoral osteolysis in 3.0% of the patients and there were 3% of periprosthetic fractures. Free-revision survival rate was 100% at 10.9 years of follow-up. **Conclusion:** cementless, fully coated with HA femoral stems with varus/valgus malalignment achieves good long-term clinical and radiographic outcomes.

Keywords: Total hip arthroplasty; cementless femoral stems; coronal malalignment; hip revision.

Level of Evidence: IV

Comportamiento de los tallos no cementados recubiertos con hidroxiapatita colocados con alineación coronal inadecuada en la artroplastia primaria de cadera. Resultados del seguimiento a largo plazo

RESUMEN

Introducción: La mala alineación de los tallos femorales no cementados sigue siendo un tema controvertido. Algunos autores han comunicado una inadecuada osteointegración y hundimiento en los tallos en varo y otros no encontraron dichos efectos adversos, pese a la incorrecta alineación. Los objetivos de este estudio fueron determinar la prevalencia de tallos no cementados con cobertura total de hidroxiapatita en deseje coronal y mostrar los resultados clínicos-radiográficos a largo plazo. **Materiales y Métodos:** Estudio retrospectivo entre 2006 y 2009. Se analizaron 220 reemplazos totales de cadera primarios con tallos no cementados con cobertura completa de hidroxiapatita. La alineación coronal fue analizada con radiografías anteroposteriores de ambas caderas en 10º de rotación interna. Se registraron datos, como osteointegración, hundimiento, osteólisis femoral proximal e hipertrofia cortical. Para el análisis clínico se utilizó el *Harris Hip Score*. El análisis de supervivencia contempló la necesidad de revisión por cualquier causa. **Resultados:** La prevalencia de tallos en deseje fue del 32,3%, con mayoría de implantes en varo (73,3%). El *Harris Hip Score* tuvo un incremento estadísticamente significativo (41,05 ± 6,5 vs. 90,05 ± 2,5; p <0,01). El 73,1% de los tallos desarrollaron una fijación ósea estable. Se observó osteólisis femoral proximal en el 3% de los casos. Hubo un 3% de fracturas periprotésicas femorales. La supervivencia de la prótesis fue del 100% a los 10.9 años. **Conclusión:** Los tallos no cementados con cobertura total de hidroxiapatita toleran adecuadamente la alineación coronal en varo/valgo a largo plazo.

Palabras clave: Artroplastia total de cadera; tallos no cementados; deseje coronal; revisión de cadera.

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INTRODUCTION

The incorrect positioning of the prosthetic components constitutes a potential complication in total hip replacement (THA).[1] It is known that to obtain an optimal result in cemented THA, the entry site in the femoral canal must be precise and the positioning in the coronal and sagittal axes must be adequate, to avoid a heterogeneous thickness of the cement mantle around the stem.[2] Varus placement of the cemented femoral component is typically associated with cement mantle fracture, subsidence, and early mechanical loosening.[3,4] For uncemented stems, the effects of misalignment are still controversial. Probable complications would be represented by the higher incidence of intraoperative fractures, unstable fixation, early loosening, and postoperative thigh pain.[4-7] Some authors have published suboptimal osseointegration and instability due to implant undersizing in the varus-aligned cementless stems, due to the inadequate seating of the femoral component in the proximal femur.[8-10] However, other authors did not find such adverse effects, and obtained encouraging results, despite inadequate femoral positioning.[5,11]

The objectives of this study were to determine the prevalence of fully hydroxyapatite-coated cementless stems implanted in an inappropriate position in the coronal axis, emphasizing the clinical-radiographic outcomes, and to establish the long-term survival of the prosthesis in this group of patients.

MATERIALS AND METHODS

According to a retrospective analysis of the database of our Service, 681 primary THAs were performed between 2006 and 2009. In 255 (37.4%) THAs, a cementless femoral component was used; 220 (32.3%) cases corresponded exclusively to fully hydroxyapatite-coated stems (Corail, Depuy Synthes, Warsaw, Ind., USA) (Figure 1).

Figure 1. Corail® stem (cementless fixation). Titanium core with full Hydroxyapatite coating. Model without calcar support.

To determine the stems with inadequate coronal alignment, two observers independently carried out a radiographic analysis of the 220 THAs mentioned. Anteroposterior radiographs of both hips taken in the immediate postoperative period with 10° internal rotation of both lower limbs were used. The angle formed between the longitudinal axis of the stem and that of the femoral shaft was measured, and malalignment (varus or valgus) was considered if the angle was ≥2º.

The inclusion criteria were: Primary THA, use of a fully hydroxyapatite-coated cementless stem (Corail), inadequate positioning in the coronal plane, and a minimum follow-up of 10 years. The diagnoses that led to the arthroplasties are detailed in Table 1.

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Table 1. Preoperative diagnoses of the evaluated series.

Diagnoses	n (%)
Idiopathic coxarthrosis	58 (86.5%)
Osteonecrosis	5 (7.5%)
Coxarthrosis due to developmental dysplasia of the hip	3 (4.5%)
Coxarthrosis due to epiphysiolysis	1 (1.5%)

Surgical technique

All patients were operated on by the same surgical team, in a laminar airflow operating room, under hypotensive spinal anesthesia. The approach was always in the dorsal decubitus position, using a modified direct lateral approach.[12] First-generation cephalosporin was administered as prophylaxis half an hour before skin incision, and low-molecular-weight heparin was administered subcutaneously for 30 days, for thromboembolic prevention. Rehabilitation consisted of walking with a walker from the second day after surgery and then using two Canadian crutches from day 3 to the third week. From then on, they continued with a single crutch on the opposite side to the one operated on, to finally walk unaided from the sixth week after the surgery.

At the time of study closure, those patients who had not attended a follow-up visit in the last two years were contacted and asked to attend a personal interview. If this was not possible, they completed the interview via telephone. They were also asked to send a radiographic control.

Follow-up visits consisted of a physical examination and a radiographic examination (anteroposterior and lateral projection) at 3 and 6 weeks, and at 3 and 6 months after the procedure, and then an annual visit, if there were no complications.

The variables analyzed to characterize the population were: sex, age, diagnosis, femur type according to Dorr's classification,[13] bilaterality, type of cup used (Duraloc® and Pinnacle®, Depuy Synthes , Warsaw, Ind., USA), and friction torque used (ceramic-polyethylene, ceramic-ceramic, metal-metal).

For the clinical analysis, the *Harris Hip Score* [14] was used, which considers pain level, gait, range of motion, and functionality (performance in activities of daily life).

All measurements were carried out by two independent evaluators and, if consensus was not reached, they were reviewed by a senior author. Comparing the first radiograph after surgery with that of the last follow-up, the following aspects were studied:

1. *Stem osseointegration*: determined by evaluating endosteal condensation, defined as the formation of new bone at the implant-bone interface; fixation was classified as stable, fibrous stable, or unstable, according to the criteria of Engh et al.[15]

2. Subsidence: measured through the distance between the proximal angle of the lesser trochanter and the lateral shoulder of the femoral stem;[9] it was considered significant if it measured >2 mm.

3. *Appearance of proximal femoral osteolysis* (*stress shielding*).

4. *Formation of periosteal cortical hypertrophy*: defined as the increase in the femoral shaft diameter around the implant.

5. *Evidence of loosening around the prosthesis*: characterized by radiolucency around the stem, with cavities more than 5 mm long in the different areas of the proximal femur, as described by Gruen et al.[16]

Survivorship analysis considered the need for all-cause revision surgery; the requirement for revision due to femoral causes was segregated.

Statistical analysis

Categorical variables are described as frequencies and percentages, while continuous variables are expressed as average and standard deviation. Student's t test was used to analyze the numerical variables and compare the preoperative and postoperative values. Descriptive variables were analyzed with the chi-square test or Fisher's exact test. A p value <0.05 was considered statistically significant. All calculations were performed with the Graph Pad Prism 8.0 program.

FINDINGS

150 cases were excluded because they had an adequate alignment in the coronal plane and three because they did not comply with the minimum follow-up and it was impossible to locate them by telephone. The series consisted of 67 THAs in 58 patients (6 simultaneous bilateral THAs and 3 in two stages) with an average follow-up of 10.9 ± 0.8 years (range 10.0-12.7). The overall incidence of stems improperly placed in the coronal axis was 31.8% (70/220). The description of the patients is detailed in Table 2.

Table 2. Description of the patients included in the study

Features	Malalignment group n (%)
Sex	
Male	38 (65.5%)
Female	20 (34.5%)
Age (range)	62.8 ± 8.4 (40-71)
Side	
Right	32 (47.8%)
Left	35 (52.2%)
Diagnosis	
Idiopathic coxarthrosis	58 (86.5%)
Osteonecrosis	5 (7.5%)
Developmental dysplasia of the hip	3 (4.5%)
Coxarthrosis due to epiphysiolysis	1 (1.5)%
Femur type (Dorr[16])	
A	50 (74.6%)
B	17 (25.4%)
C	0 (0%)
Cup	
Duraloc®	30 (44.8)%
Pinnacle®	37 (55.2%)
Friction surface	
Ceramic-Polyethylene	64 (95.5%)
Ceramic-Ceramic	1 (1.5%)
Metal – Metal	2 (3.0%)

Clinical outcomes

At the last check-up, all had a good hip range of motion, walked unaided, and reported having returned to their daily and recreational activities without difficulty. None reported thigh pain after THA. A statistically significant increase in the *Harris Hip Score* was observed when comparing the values before and after surgery (41.05 ± 6.5 vs. 90.05 ± 2.5; $p < 0.01$).

Radiographic outcomes

Of the 67 THAs with a displacement in the coronal plane, ≥2° in relation to the longitudinal axis of the femoral shaft, 49 (73.3%) hips were varus with an average value of 2.5° ± 0.6 ° (range 2-4) and 18 (26.7%) were valgus, with an average of 2.7 ° ± 1.2 ° (range 2-7).

Regarding stem integration, radiographic signs of osseointegration were detected in 49 (73.1%) cases and fibrous stable union in 18 (26.9%) of the operated hips. The fixation of the sample cups was satisfactory in all cases.

Proximal femoral osteolysis was observed in two patients (3.0%): a stem with a 2° varus in the greater trochanter, with a follow-up of 11.5 years, and another hip with a 3° varus in the calcar, with 10.9 years of evolution (Figure 2). In both, there were no subsequent complications or evidence of radiographic progression.

Figure 2. A: Anteroposterior image of left THA, 11.5 years of evolution with a varus-aligned stem**.** Osteolysis is observed at the level of the greater trochanter. **B:** Anteroposterior image of right THA 11.9 years after surgery, showing osteolysis at the calcar level.

There were no cases of significant subsidence (>2 mm), periosteal cortical hypertrophy, or radiolucency around the implant compatible with loosening.

Complications

Intraoperative

Two (3%) periprosthetic femoral fractures occurred. When implanting a definitive femoral component with 2º valgus, a solution of continuity was generated in the calcar that required its extraction, fixation with a double wire loop, and reimplantation of the stem (Figure 3).

Figure 3. Postoperative follow-up after 10 years and 4 months of evolution of left THA. Intra-operative fracture treated with a wire loop. Stem with 2º valgus malalignment. A fragment of the greater trochanter can also be seen.

The patient evolved favorably, with good function and radiographic signs of stem stability, without subsidence at 10 years and 4 months of follow-up. The other case (3º valgus) was an untreated greater trochanteric fracture; the patient had a good clinical and radiographic evolution, despite having developed a nonunion.

One patient (1.7%) suffered intraoperative myocardial ischemia immediately after surgery and required urgent intervention by the cardiovascular surgery team. There were no cases of deep vein thrombosis or pulmonary thromboembolism.

Postoperative

Two patients (3%) presented anterior hip dislocation four and six months after surgery, respectively. One of the cases was of traumatic origin. Both required a bloodless reduction under general anesthesia; the evolution was favorable and the complication did not recur until the last follow-up (10.5 and 12.0 years of follow-up).

No cases of prosthesis infection or mechanical loosening of the femoral stem were detected.

In 12% (n = 8) of the arthroplasties, polyethylene wear was observed, manifested by the eccentricity of the femoral head of the prosthesis, without clinical repercussions in the last follow-up.

Considering the need for all-cause revision surgery, the medium-term survival of improperly placed coronal-plane Corail® stem THAs was 100%.

DISCUSSION

Based on our findings, incorrect positioning in the coronal plane of a fully hydroxyapatite-coated cementless femoral stem did not affect the long-term survival of the implant.

Varus alignment of the femoral stems is traditionally associated with poor outcomes.[17] Regarding cemented stems, different authors performed long-term analyses and reported failure rates of between 37.5% and 46% when implanted in varus. [4,18]

Similarly, Gill et al.[19] observed that the varus positioning of the femoral stem causes a thin cement mantle in the proximal medial and distal lateral cortices, generating a concentration of distal and lateral stress, which can cause a fracture of the cement mantle, loosening, and subsidence of the component, as well as periprosthetic femoral fracture due to lateral insufficiency.

For several years, cementless femoral fixation has become a globally accepted procedure with good outcomes in the medium and long term.[20] The behavior of femoral stem alignment in cementless implants varies according to the prosthesis design. In the first publications, Vresilovic et al.[9] obtained disappointing outcomes in cementless stems placed in varus. They observed that the misaligned implants had developed faulty osseointegration, with consequent failure of fixation. In another publication by Ries et al.[21] on the PCA® stem (Stryker-Howmedica, Mahwah, USA), varus implantation was associated with insufficient filling of the distal canal and poor stability at the tip of the stem. In another study, Mallory's group[8] analyzed a series of patients operated on with a plasma-sprayed titanium stem and found that it was necessary to revise two femoral implants due to a fixation failure caused by undersizing.

The survival of the prosthesis in the analyzed sample yielded an ideal result, there were no revision surgeries in the long-term follow-up. A possible explanation for the encouraging results of our series could be based on the design of the prosthesis, as well as the use of bone impaction rasps. Regarding the morphology of the implant, the proximal portion of the Corail® stem is quadrangular and wide, which allows a three-dimensional stabilization in the metaphyseal area, while the distal part is conical, a geometry that gives the proximal femur a decreasing stiffness gradient and prevents blockage of the distal medullary canal.[22]

The findings of this series are consistent with the work of Schneider et al.[23] who evaluated, in a multicenter study, 3,732 THAs with Spotorno® stem (Zimmer GmbH, Winterthur, Switzerland), with an average follow-up of 43 months. They found no correlation between stem alignment and prosthesis survival, implant migration, or the appearance of radiolucent lines around the prosthesis. The authors concluded that varus alignment of the cementless femoral component has no clinical or radiographic consequences, as does the cemented stem. Likewise, Min et al.[24] studied the clinical and imaging implications of femoral stem alignment. In 98 consecutive THAs using the same implant (Spotorno®) and an average follow-up of 7.7 years, they found 37% of femoral components were placed in varus/valgus in the coronal plane. They compared the clinical and radiographic outcomes with those of THAs with a neutral stem and did not obtain statistically significant differences. The fixation obtained was adequate in all cases and the bone response of the proximal femur was the same in both groups. They stated that the alignment of the cementless femoral implant does not compromise the clinical and radiographic evolution in the medium term. In another retrospective study of 125 primary THAs, De Beer's group[25] identified 16 cases with varus alignment (12.8%). They comparatively studied the clinical (*Harris Hip Score*) and radiographic (subsidence and loosening) results in 16 THAs with neutral alignment at four years of evolution and found no statistically significant differences. They suggested that, although varus alignment of the femoral stem is not recommended, this does not affect the evolution of THA in the medium term. Similarly, Khalily and Lester[5] examined 23 varus-aligned THAs using a titanium femoral stem (Alloclassic®, Zimmer GmbH, Winterthur, Switzerland), with a minimum follow-up of 5 years. All stems were clinically and radiographically stable at the last control. They emphasize that, although varus alignment may compromise the outcomes of some implants, the stem analyzed by them was reliable at 5 to 11 years of follow-up, despite the fact that it had been placed in the coronal axis.

The limitations of this study are its retrospective nature and the low number of cases analyzed. Among the strengths, we can mention that it is a series of patients treated in the same center, by the same surgical team, and with a considerable average follow-up.

CONCLUSION

In this series, the incorrect placement in the coronal plane of a fully hydroxyapatite-coated cementless stem did not affect its long-term clinical or radiographic behavior. We will continue monitoring these patients to identify potential complications.

Conflict of interests: The authors declare they do not have any conflict of interests.

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