

HYDROXYAPATITE-COATED STEMS WITH METAPHYSEAL AND DIAPHYSEAL PRESS-FIT. ELEVEN-YEAR FOLLOW-UP RESULTS

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We report the 11-year follow-up results of 52 unilateral primary hip arthroplasties performed with hydroxyapatite-coated stems. The femoral prosthesis used was a collarless titanium alloy implant, with proximal circumferential hydroxyapatite coating and increased distal thickness to fit the proximal diaphyseal region of the femur.

Clinical evaluation was performed using the Merle d'Aubigné Hip Score. Anteroposterior and lateral radiographs were obtained and compared with previous postoperative films. Radiographic evaluation was carried out following Engh's criteria for uncemented implant fixation and using Livermore's method for measurement of polyethylene wear. At the end of the follow-up period, excellent and good clinical results were recorded in 40 arthroplasties (77%). The incidence of thigh pain at one year was 32.7%, but it decreased to 4.2% after the first postoperative year. The 11-year survival rate was 92.3%. Seven arthroplasties were revised because of aseptic loosening of the cup in one case, aseptic loosening of the stem, in one case, septic loosening of the stem in one case, periprosthetic fracture in two cases and polyethylene wear in three cases. Forty-two (87.5%) of the nonrevised stems met the criteria for radiographic osseointegration. Cortical hypertrophy was observed around the mid-part and tip of the stem in 22 patients of the series. This sign tends to be related to thigh pain ($p < 0.1$). Calcar osteolysis was present in 8 cases. There was only one case of distal femoral osteolysis. We found a strong and significant relationship between long-term wear rates and the occurrence of osteolysis ($p < 0.001$). We concluded that thigh pain is in relation to the distal diameter of the stems and significantly decreases after the first postoperative year. There was a low incidence of oste-

olysis in our series in comparison with other series of noncemented implants with 32-mm femoral heads and with similar follow-up.

Keywords : arthroplasty ; hip ; prosthesis design ; hydroxyapatite.

Mot-clés : arthroplastie ; hanche ; prothèse ; hydroxyapatite.

INTRODUCTION

The decade of the 1980's was considered by many hip surgeons to be the decade of cemented versus cementless arthroplasties (9).

Uncemented total hip arthroplasty was introduced because earlier series of cemented hip prostheses produced a high failure rate after 10 years, especially in younger and more active patients (4, 21, 23). In an attempt to find a better method of fixation, new cementless implant designs with porous or hydroxyapatite coating were introduced to achieve bone ingrowth. The expected advantages of biologic fixation were greater longevity and less bone loss if revision is needed (22).

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The cementless hip replacement alternative has been received with enthusiasm in our country. The indications for uncemented components have expanded during the last years, and they are now more frequently implanted than cemented prostheses in most orthopedic centers in Spain.

Nevertheless, earlier reports about cementless hip arthroplasty described a high rate of thigh pain (1.5% to 16%) and limp (5% to 28%), at 1 to 2 years after surgery (22).

The exact cause of thigh pain in uncemented arthroplasty is not well understood, but possibilities include a mismatch between the modulus of elasticity of the bone and that of the prosthesis, endosteal irritation, stress transfer to the tip of the femoral component, poor fixation with micromotion of the stem tip and gross loosening (1, 10).

From January 1989 to June 1990, 68 patients underwent 76 primary uncemented total hip arthroplasties at "San Cecilio" University Hospital in Granada. The femoral components had hydroxyapatite coating and a thick stem to fill the diaphyseal canal. The aim of the present study was to analyze the clinical and radiographic evolution of these implants after 11 years' follow-up.

MATERIALS AND METHODS

The original study group consisted of the first 68 consecutive patients in whom a total of 76 hydroxyapatite-coated total hip prostheses were implanted for primary or secondary osteoarthritis. All operations were performed between January 1989 and June 1990. Patients with bilateral arthroplasties (eight cases), and those lost to follow-up (seven cases) were excluded. One patient died from an unrelated cause, seven years after operation. The results of the present study were therefore based on 52 unilateral total hip arthroplasties.

The mean age of the patients at the time of operation was 65.3 years (range, 45 to 76 years). Thirty-four of the total hip arthroplasties (65.4%) were in men and 18 (34.6%) in women. There was bilateral hip disease in 16 cases (31%), and 5 patients (9.6%) had polyarticular involvement.

The diagnoses were: primary osteoarthritis (34 cases; 65.4%), avascular necrosis of the femoral head (16 patients, 30.8%), and sequels of proximal femoral epiphysiolysis (2 cases).

The arthroplasty combined an Opti-fix porous-coated cup and Ti-fit collarless stem (Smith and Nephew Richards; Memphis, Tennessee) made of a titanium alloy. The Ti-fit femoral component was a proportionally sized straight stem with a Morse tapered neck. The modular design accepted four different neck lengths in four different head diameters. The stems were available in diameters ranging from 9 to 17 mm and in progressively increasing lengths from 115 to 170 mm. The proximal third had a plasma-spray hydroxyapatite coating and a double wedge shape in the frontal and sagittal planes. This coating had a thickness of 200 ± 50 micrometers, a purity of 98% and a porosity of 20%. The mid-portion and distal part had a rounded rectangular shape for maximum contact and stability. The stem extended down to the isthmus area to achieve a tight fit and neutral positioning of the stem. During the femoral broaching, the canal had to be widened with a rigid medullary reamer to achieve a better contact with the distal part of the stem. A 32-mm metallic femoral head was used in all patients.

All arthroplasties were done by, or under direct supervision of the senior investigator (MAHH). All the patients were operated using the lateral approach described by Hardinge. No trochanteric osteotomy and no bone grafting was carried out. Routine prophylactic antibiotics (2 g cefamandol before and 12 hours after the surgical procedure) and antithromboembolic (5000 U. heparin, every 12 hours, for 15 days) regimens were employed. Postoperatively, the patients were limited to partial weight-bearing for six weeks. Clinical and radiographic follow-up was performed after six weeks, three months, six months, and yearly thereafter.

Clinical analysis was based upon the Merle d'Aubigné and Postel (18) scoring system, which scores three parameters: pain, range of motion and walking, from 0 to 6 points each. The incidence and evolution of thigh pain, the complications and survival of the implants were also recorded. A subjective evaluation of pain in the thigh graded the pain in four categories: thigh pain absent, mild and intermittent, moderate with functional restriction and severe.

Radiographic assessment included anteroposterior and lateral radiographs. A detailed radiographic analysis was performed retrospectively by two of us (OONS and MPL), who were not involved in the index operation or in the clinical follow-up and who were blinded to the presence or absence of pain in the thigh.

The preoperative radiographs were assessed for bone quality, with use of the integrated scheme for cortical and trabecular bone evaluation of Engh and Bobyn (6)

Table I. — Preoperative quality of bone protocol(6). The cortical index is the ratio between the bicortical diameter (C) and the width of the medullary canal (M), 10 cm distal to the lesser trochanter. It is a measure of cortical bone quality.

Radiographic bone quality score		
1. Cortical index : C/M		
Excellent	> 2.1	4 points
Good	1.9 – 2.1	3 points
Fair	1.7- 1.9	2 points
Poor	< 1.5 – 1.7	1 point
2. Trabecular Index of Singh (Intertrochanteric region) : 3 points maximum.		
3. Add 1 point in case of male patient, age under 50 years or diagnosis different from rheumatoid arthritis.		
POOR (1 -5)		GOOD (6 - 10)

(table I). The postoperative radiographs were evaluated for the stability and fixation of the femoral component according to Engh's criteria (7) for noncemented implants (table II), amount of head penetration and the occurrence of osteolysis. The linear wear was measured by the method of Livermore *et al.* (13), using only anteroposterior radiographs of the pelvis. To examine the relationship between 11-year true wear rates and osteolysis, we grouped patients into three categories according to whether the wear rate was less than 0.1 mm/year, between 0.1 and 0.2 mm/year, or greater than 0.2 mm/year.

Statistical analysis was performed in the Department of Biostatistics of the School of Medicine of the University of Granada. Survivorship analysis according to Kaplan and Meier was used. The comparison of the radiographic variables in the presence or absence of thigh pain was carried out using the Chi-square test. Chi-square analysis was also used to determine if there was a significant difference in the presence or absence of osteolysis among the three groups. The value of alpha (level of significance) was set at 0.05.

RESULTS

Early complications in the series included two superficial infections (3.8%) and four deep vein thromboses (7.7%). No femoral fractures, dislocations or neurovascular injuries were recorded.

Seven arthroplasties had been revised at the end of the follow-up period (fig. 1), because of aseptic loosening (two years postoperatively ; revision of both components), periprosthetic fracture with loosening of the femoral component (four years postoperatively ; revision of the stem), deep joint infection with septic loosening of the cup (two-step revision of both components in the fifth postoperative year), aseptic loosening of the stem (six years postoperatively ; revision of the stem) and in 3 cases owing to periacetabular osteolysis (11 years

Table II. — Engh's stability scale for uncemented prostheses (7)

		Fixation/stability score		<i>Undetermined</i>		
Fixation scale	Proximal third appearance.			0	None	+ 5.0
	Lines/Lucencies	Extensive. $\geq 50\%$	- 5.0			
	Spot Welds	Absent.	- 2.5	0	Present	+ 5.0
				Fixation Score		
Stability scale	Distal two-thirds appearance.			0	None	+ 5.0
	Lines/Lucencies	Extensive. $\geq 50\%$	- 3.5			
	Pedestal	Present	- 3.5	0	Absent	+ 2.5
	Calcar modeling	Hypertrophy	- 4.0	0	Atrophy	+ 3.0
	Interface deterioration.	Present	- 2.5	0	Absent	+ 2.5
	Lines/Lucencies					
	Migration	Present	- 5.0	0	Absent	+ 3.0
Particle shedding	Present	- 5.0		0	None	+ 1.0
				Stability Score		

CATEGORIES	< - 10 Unstable	- 10 to 0 Suboptimum but stable	0 to + 10 Ingrowth suspected	> + 10 Bone ingrowth
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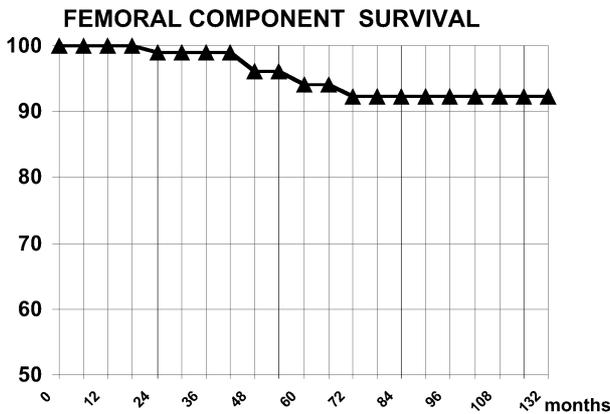


Fig. 1. — Eleven-year survival curve for Ti-fit stems

postoperatively, only head and cup revision without stem exchange).

The functional results of the remaining 48 femoral components at the time of the most recent follow-up examination were classified as excellent for nine patients (18.7%), good for 31 (64.6%) and fair for eight (16.7%), according to the Merle d'Aubigné scoring system (18).

At one year, moderate-to-severe thigh pain was present with 17 (32.7%) of the 52 hips. Nevertheless, the incidence of thigh pain decreased abruptly after the first postoperative year, and at the end of the follow-up only two patients out of 48 functioning stems (4.2%) had significant pain in the thigh (fig. 2). On the other hand, groin pain increased progressively and was present in six patients (12.5%) at the end of the follow-up.

We found that 40 patients (76.9%) had a preoperative good quality of bone, and 12 (23.1%) a poor quality assessed with use of Engh and Bobyn's criteria (table I).

Twenty-two of the 52 initial hip replacements (42.3%) showed a radiographic picture characterized by moderate calcar atrophy and cortical hypertrophy around the distal two-thirds of the stem (fig. 3). These changes became evident between nine months and two years after surgery, and remained unchanged in successive radiographs to the end of the follow-up.

Calcar atrophy was present in 69.2 % of the cases. The prevalence of cortical hypertrophy was

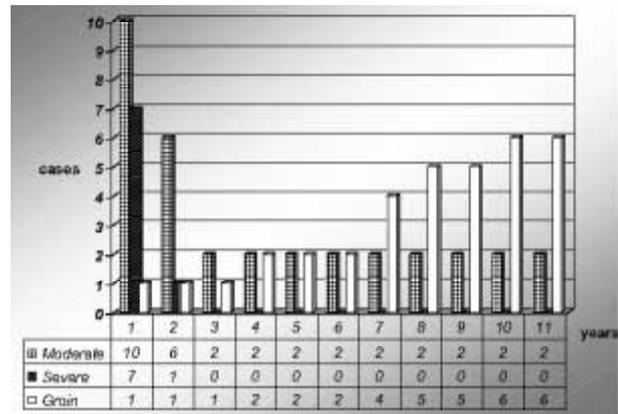


Fig. 2. — Pain prevalence during follow-up. Thigh pain is graded as moderate and severe. Groin represents groin pain.

42.3% (22 patients). Heterotopic ossification (HO) was present in 23.1% of the patients, and two had Brooker grade III HO. No subsidence and no complete radiolucent lines were identified, except around the stem that had loosened. Incomplete and nonprogressive radiolucent lines were seen in 16 cases (30.8%). Two femoral components were associated with slight pedestal formation. Eight of the 48 stable hips (16.7%) had evidence of osteolysis confined to Gruen zone 1 or 7 or to the acetabulum with correlation to polyethylene wear (fig. 4). There was only one case of intramedullary or distal osteolysis in surviving stems. Three patients have undergone reoperation for bone grafting of the acetabulum and cup substitution. We found a strong and significant relationship between long-term wear rates and the occurrence of osteolysis ($p < 0.001$). Osteolysis did not develop in any of the 28 hips with a wear rate of less than 0.1 mm per year (table III).

The fixation-stability score for the 48 surviving femoral components at the end of the follow-up reflected bone ingrowth in 42 hips (87.5%), four probable ingrowth (8.3%) and two probable fibrous but stable fixation (4.2%).

There was no significant association between the analyzed radiographic variables and the clinical outcomes of pain in the lower limb, except cortical hypertrophy, with a high incidence in patients with thigh pain (table IV).



Fig. 3. — *a.* Immediate postoperative radiograph of a primary Ti-fit stem. *b.* Two-year radiographic control. Moderate calcar atrophy and midstem cortical hypertrophy can be seen.

Table III. — Relation between osteolysis and bead shedding and wear rate for the 48 surviving hips at 11-year follow-up

HEAD PENETRATION (mm)	CASES	OSTEOLYSIS		BEAD SHEDDING	
		Cases	Percentage	Cases	Percentage
< 0.1 mm/year	28	0	0	0	0
0.1 – 0.2 mm/year	16	4	25	0	0
> 2mm/ year	4	4	100	3	75
Chi-square test		p < 0.001			

DISCUSSION

During the first postoperative year thigh pain affected more than 30% of the patients of the series, and for this reason we abandoned this prosthesis design.

The reported prevalence of associated pain in the thigh in noncemented total hip replacement ranges between 2% and 40% (10, 12, 20, 22). The higher rates (30% and 40%) belong to series of porous-coated stems (1, 10, 12, 16). Nevertheless, we must consider other design factors to understand the

Table IV. — Radiographic findings and pain in the thigh

	Pain in the Thigh				Chi2 Test p value
	Yes		No		
	Cases	Percentage	Cases	Percentage	
Total number of hip prostheses	17		35		
Poor bone quality	5	29.1	7	20.0	0.68562
Spot welds	6	35.3	15	42.8	0.2576
Pedestal	2	11.8	0	0	0.19334
Cortical hypertrophy	11	64.7	11	31.4	0.076024
Radiolucencies	7	41.2	9	25.7	0.41623
Heterotopic bone	5	29.1	7	20.0	0.68562



Fig. 4. — Eleven-year postoperative radiographic control. Femoral head in eccentric position because of polyethylene wear. Periacetabular osteolysis. Spot welds around midportion of the stem. No distal osteolysis can be seen on the femoral side.

thigh pain in relation to hip arthroplasty. McAuley *et al.* (16) reported only 13 cases from a series of 507 porous-coated stems, i.e. a 2.6% prevalence of thigh pain, in contrast to percentages previously reported.

Karrhölml *et al.* (11) reported thigh pain at the two-year follow-up evaluation, in two of 23 patients who received a hydroxyapatite-coated Ti-fit stem. Their clinical results did not differ significantly between these patients and those with a Ti-fit cemented stem regarding pain scores at two years' follow-up.

Dlima *et al.* (2) published a prospective study of a series of 200 stems with identical design (100 inserted with bone cement and 100 without cement) and concluded that cemented fixation was associated with a 3% rate of thigh pain while non-cemented implants had a 40% rate of thigh pain. The same authors (3) reported one year later, a 6% thigh pain incidence with the same hydroxyapatite-coated implants.

The relation between the distal diameter of the stem and cortical hypertrophy is well known (9, 23, 24). The presence of thigh pain in well-fixed implants in the series, and association with aggressive bone remodeling (calcar atrophy and distal cortical hypertrophy) are consistent with stress transfer to the tip of the femoral component and the hypothesis of endosteal irritation as a cause for thigh pain. An increased width of the cortical bone at the distal end of the stem was found by Karrhölml *et al.* (11) in 15 of 23 patients with the same

hydroxyapatite-coated Ti-fit femoral implant. On the other hand, the 87.5% rate of radiographic bone ingrowth rules out loosening as cause of the phenomenon (12).

At present, we prefer exclusively metaphyseal fit and low rigidity implants to avoid such aggressive bone remodelling. Nevertheless, the 11-year clinical outcomes and survival analysis of the Ti-fit femoral component are good. The incidence of early thigh pain is a concern, but similar to other series (12, 17), it decreased abruptly after the first postoperative year. The percentage of bone ingrowth fixation was 87.5%, and aseptic loosening of the stem was recorded as cause of revision in only two cases.

Osteolysis has been found with loose and well-fixed cemented and cementless femoral and acetabular implants (14, 15, 19). The use of a 32-mm femoral head is associated with increased volumetric wear, but osteolysis in our series had a low incidence in comparison with other series of noncemented implants with 32-mm femoral heads and with similar follow-up (5, 8).

Absence of distal endosteal lysis except in one case, along with correlation with calcar erosion to polyethylene wear, suggests that early circumferential bony ingrowth afforded by the hydroxyapatite coating prevents distal endosteal access to polyethylene debris at medium-term follow-up (2, 12).

Regarding thigh pain, the main conclusion drawn from this series is that a femoral component with a proximal circumferential hydroxyapatite coating can provide stable fixation for as long as 11 years after implantation and can seal the canal from distal osteolysis.

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SAMENVATTING

P. HERNÁNDEZ CORTÉS, O. O. NÁJERA SAGASTUME, F. MESA RAMOS, M. PAJARES LÓPEZ, M. A. HERNÁNDEZ HERNÁNDEZ. Resultaten na 11 jaar van een femorale stem met meta- en diaphysaire fixatie en hydroxy-apatietbekleding.

De schrijvers beschrijven de resultaten na 11 jaar, van primaire totale heupprothese met een femorale stem die proximaal rondom bekleedt is met hydroxy-apatiet en distaal vrij volumineus is om in de femorale schaft steviger te vatten. De klinische evaluatie gebeurde volgens de score van Merle d'Aubigné.

De evaluatie van de röntgenbeelden in longitudinale richting gebeurde volgens de criteria van Engh voor cementloze protheses. Voor de polyethyleen slijtage werd de Livermore methode gebruikt. 40 THP waren excellent of goed (77%). Dijpijn was frekwent in het eerste jaar : 32.7%, maar daalde vervolgens tot 4.2%. De survival rate na 11 jaar was 92.3%. Zeven arthroplasties werden hernomen : aseptische loosening van de cup in één geval, van de schaft in eveneens één geval, septische loslating in een derde geval, drie gevallen van polyethyleen slijtage en tenslotte een geval van een periprosthetische fractuur. Osteointegratie tradt op voor 42 of 87.5% van de niet hernomen femorale stems. Corticale bothypertrofie tegenover het middendeel en het uiteinde van de stem werd gezien bij 22 patiënten. De correlatie

met dijpijn was niet statistisch significant ($p < 0.1$). Calcar osteolyse werd 8 maal vastgesteld. Eénmaal trad osteolyse op ter hoogte van de schaft. Het optreden van osteolyse is duidelijk gebonden aan polyethyleen slijtage ($p < 0.01$). De schrijvers menen dat de dijpijn moet worden in verband gebracht met de stemdiameter. Ze vermindert sterk na het eerste jaar. Het concept van de gebruikte stem : hydroxyapatiet proximaal en volumineuze doormeter distaal, verzekert een stevige fixatie op korte en middellange tijd. De overlevingsbeperking van een heupprothese lijkt in deze omstandigheden in eerste instantie de polyethyleenslijtage.

RÉSUMÉ

P. HERNÁNDEZ CORTÉS, O. O. NÁJERA SAGASTUME, F. MESA RAMOS, M. PAJARES LÓPEZ, M. A. HERNÁNDEZ HERNÁNDEZ. Résultats à 11 ans d'une tige fémorale à fixation métaphysaire et diaphysaire et à revêtement d'hydroxyapatite.

Les auteurs rapportent les résultats à 11 ans d'une série de 52 arthroplasties primaires de la hanche avec une tige fémorale à revêtement d'hydroxyapatite. Ce composant en alliage de titane, sans collerette d'appui avait dans sa partie proximale un revêtement circonférentiel d'hydroxyapatite ; son diamètre distal important visait à lui assurer une fixation dans la partie proximale de la diaphyse fémorale.

L'évaluation clinique a été faite sur base du score de Merle d'Aubigné, les radiographies de face et de profil ont été comparées de façon longitudinale. L'évaluation radiologique s'est faite sur base des critères de Engh pour la fixation des implants sans ciment ; l'usure du polyéthylène a été mesurée par la méthode de Livermore. Au recul, des résultats cliniques excellents et/ou bons ont été notés pour 40 arthroplasties (77%). A un an, il y avait 32,7% de douleur de cuisse, mais ce taux est descendu à 4,2% après la première année. La survie à 11 ans était de 92,3%. Sept arthroplasties ont été reprises. La raison était un descellement aseptique de la cupule dans un cas, un descellement aseptique de la tige dans un autre, un descellement septique de la tige dans un autre encore, une fracture périprothétique dans un cas, et l'usure du polyéthylène dans trois cas. L'aspect radiologique était celui d'une ostéointégration dans 42 des tiges non reprises (87,5%). Il existait une hypertrophie corticale en regard de la partie moyenne et de l'extrémité de la tige chez 22 patients. Cet aspect était corrélié, mais de façon non significative, avec la douleur de

cuisse ($p < 0,1$). On notait une ostéolyse du calcar dans 8 cas. Il y avait un seul cas d'ostéolyse distale au niveau du fémur. Les auteurs ont observé une relation forte et significative entre l'usure du polyéthylène à long terme et la survenue d'une ostéolyse ($p < 0,01$). Ils concluent que la douleur de cuisse est en rapport avec le diamètre distal de la tige et qu'elle diminue nettement après la première année. La conception de cette tige, avec son

revêtement circonférentiel d'hydroxyapatite, lui assure une fixation stable à moyen terme et à long terme ; le facteur principal qui limite la longévité de ces prothèses reste l'usure du polyéthylène. Le taux d'ostéolyses dans cette série est cependant plus bas que dans d'autres séries d'implants non cimentés avec tête de 32 mm, au même recul.