Results with a cementless alumina-coated cup with dual mobility

A twelve-year follow-up study

F. Farizon, R. de Lavison, J.J. Azoulay, G. Bousquet*

Traumatology and Orthopaedic Centre, University Hospital Centre of Saint Etienne, Exercise G.I.P. Hôpital de Bellevue, Saint Etienne, France

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Abstract. *Between April 1980 and December 1981, 135 alumina-coated hemispherical cups were inserted without cement in patients with degenerative lesions. The cups were anchored by press fit and secured with a tripod attachment. The follow up was for over ten years. A bipolar polyethylene insert was used. Only one patient was lost to follow up in less than 2 years. Forty-four implants worked perfectly up to the time of death of the patients. Four cups were replaced, two after the patients sustained violent trauma, and there was an isolated instance of replacement of the insert only. The cumulative survival rate was 95.4% at 10 and 12 years follow up. The 78 surviving patients (85 cups) were examined, and radiographs were taken in 62 of them. Three patients showed clinical signs of deterioration and radiological signs of loosening, 2 others showed radiological signs of cup displacement without clinical symptoms. There was no evidence of osteolysis at the bone-cup interface in well functioning implants. These results confirm that cementless hemispherical cups survive well and demonstrate the value of a cup without holes for screws which can allow migration of polyethylene particles which might induce osteolysis of the adjacent ilium.*

Résumé. *135 cupules hémisphériques sans ciment à couverture d'alumine ont été mise en place entre avril 1980 et décembre 1981 au CHU de Saint Etienne pour pathologie dégénérative et suivie plus de dix ans. L'ancrage sous pression a été complétée par une fixation tripode. L'insert en polyéthylène est de type bipolaire. – Un cas a été perdu de vue avant*

deux ans. Quarante quatre ont parfaitement fonctionné jusqu'au décès du patient. Quatre changements de cupule ont eu lieu dont deux à la suite de traumatismes violents, ainsi qu'un changement isolé d'insert. La courbe actuarielle montre une survie cumulée de 95,4% à 10 et 12 ans. Les 78 patients survivants (85 cupules) ont été revus cliniquement et 62 radiologiquement. – Trois patients présentent des signes cliniques de dégradation avec une mobilisation de l'implant sur les radiographies. Deux autres patients présentent des signes de mobilisation radiologique de la cupule sans retentissement clinique. – Il n'y a pas d'ostéolyse ou de géodes à l'interface os-cupule. – Cette série confirme les bons résultats des cupules hémisphériques sans ciment à long terme. Elle montre l'intérêt d'une cupule sans orifice de vis surtout en zone portante qui favorise la migration des particules de polyéthylène au contact de l'ilion induisant l'apparition d'une ostéolyse.

Introduction

Many cemented acetabular implants require revision in the medium and long term for displacement and osteolysis around the prosthesis which can destroy the bone [5, 6, 11, 20, 23, 25]. These problems led to the development of cementless cups, anchored either with screws or by a press-fit [11, 18, 25, 28].

The complications associated with cemented cups prompted us to design and use, beginning in 1980, a press-fit cup anchored in all three spatial planes and coated with ceramic material (A1203) (Cupule Novae, SERF, 85 Chemin des Bruyères, F-69150 Decines).

Reprint requests to: F. Farizon, C.O.T., Hôpital Bellevue, F-42055 Saint Etienne Cedex 2, France

* Deceased

Our study is based on clinical and radiological evaluation of these implants with a 10 to 12 year follow-up.

Material and methods

The characteristics of the hemispherical cup, which is made of stainless steel and lined with a porous layer of alumina on its convex surface, have remained unchanged. This implant was described by Bousquet et al. and is made of plasma-sprayed alumina, which features porosity of 50 to 100 microns, is chemically inert and can become incorporated in bone [3].

Three mechanical anchoring devices are used to achieve stability when the cup is implanted; a 4.5 mm screw is inserted through an upper anchor clip into the ilium, and stainless steel pins are pressed into two holes in the socket (Fig. 1).

The metal cup is attached to a 22.2 mm femoral head by a bipolar retentive polyethylene connecting piece. The connecting cup has dual mobility, but movement tends to be in the small diameter. The double connection reduces the stress on the metal cup and improves the stability of the prosthesis [1].

The operations were carried out in an ordinary operating room by a team of orthopaedic surgeons whose experience varied widely. The approach was always posterolateral. In every case the tripod cup was fitted with a femoral implant without using cement. The cup was press-fitted after reaming to a diameter which was usually 1 to 2 mm smaller than that of the cup [3].

The diameter of the cups used ranged from 43 to 61 mm. Antibiotic prophylaxis was only given to some of the patients.

Between April 1, 1980, and December 31, 1981, 144 cups of this model were implanted consecutively, primarily to treat nontraumatic disorders.

Nine hips (6%) were excluded; five cups (3.3%) were removed for early sepsis before three years had elapsed. A poorly positioned cup which was retroverted by over 20° causing repeated dislocation and was replaced during the second post-operative year. Three cups were replaced in other centres during femoral repair for a fractured shaft of a modular prosthesis. Preoperative radiographs and the observation of the surgeons during these operations showed no cup displacement in the 3 cases.

We therefore followed 135 implants in 127 patients. At the time of operation, the average age of the patients was 63 years (range of 27 to 89 years). The procedure was performed on 64 right and 71 left hips, 66 in males and 69 in females. The most common diagnosis was primary degenerative joint disease (Table 1).

The survivors, who were studied more than 10 years after operation, were assessed by an examiner who was not the patient's surgeon.

The clinical records include data required by SICOT standards [13], but the advanced age of the patients at their last examination and their intercurrent disorders, made comparison of clinical criteria between the postoperative period, and the follow up over 10 years later, unreliable. We classed as failures patients who presented with groin or trochanteric pain and limited function.

Due to the length of the study and the many deaths which occurred during its course, we used an actuarial method of survival analysis to predict the failure rate for each period [8].

Three radiographs were taken routinely and we compared the postoperative films with those taken over 10 years later. The radiological measurements were performed using a specific, semi-automated input software program (Morphy Software® – ASM Informatique, 14 rue Sainte Catherine, 42000 Saint Etienne, France) on an Accugrid digitiser table (Num-

Fig. 1. Novae cup with dual-mobility system and head retention

Table 1. Preoperative diagnosis

Diagnosis	Number of cups
Primary osteoarthritis	90
Osteoarthritis secondary to dysplasia	19
Osteoarthritis secondary to congenital dislocation	10
Degenerative arthritis secondary to slipped capital femoral epiphysis	3
Post-traumatic arthritis	1
Rheumatoid arthritis	3
Sequelae of septic arthritis	4
Nontraumatic necrosis	3
Post-traumatic necrosis	2

onics®, 101 Commerce Drive, Montgomeryville, PA 18936 USA) connected to a desktop computer (IBM® Ambra 486, C.P.I. Ltd, PO Box 41, North Harbour, Portsmouth, Hampshire PO6 3AU, UK).

Our radiological analysis focused on socket migration and examination of the bone-prosthesis interface. We compared the position of the articular centre of the hip to the tear drop [29], and the inclination of the socket as described by Callaghan et al. [4], and changes in the postoperative orientation, the secondary onset of radiolucent lines or gaps and osteolysis in the different areas described by DeLee and Charnley [7]. We assessed the limitation of these different measurements which are related to variations in radiological incidence [19, 24].

Variations in inclination greater than 4° and migration of the articular centre of 3 mm or more were considered abnormal on correctly centred films. Radiolucent lines which developed gradually were also considered abnormal. The type of cup implant we used did not allow us to measure polyethylene wear in radiographs.

Results

Of the 127 patients (135 hips), 43 (with 44 cups) died during the course of the study without replacement of their implant; they were aged between 60 and 92 years. The cup remained in place for an average of 6.4 years (range 0 to 11.8 years) without clinical or radiological evidence of deterioration.

Table 2. Mechanical failures

Aetiology	Gender	Age	Years post op	Cause
CHD	F	44	1.5 years	Cup screw conflict (horizontal)
Secondary	F	56	4 years	Fall from standing position
Primary coxarthrosis	M	52	8 years	Fall from motorcycle
Post traumatic	M	36	10 years	Fall from a ladder

Fig. 2. Postoperative radiograph showing contact between the upper screw and the cup**Fig. 3.** Metallosis and secondary displacement 2 years after operation with broken screw**Table 3.** Survival analysis data for 135 THAs

Year-post op	No at start	Success	Lost	Died	Failed	No: at risk	Prop. failing	Cum. est. of sur	Confid. inter.
0 to 1	135	0	0	5	0	132.5	0.00	100	0.00
>1 to 2	130	0	1	3	0	128	0.00	100.00	0.00
>2 to 3	126	0	0	2	1	124.5	0.80	99.20	0.80
>3 to 4	123	0	0	2	1	121.5	0.82	98.38	1.14
>4 to 5	120	0	0	2	0	119	0.00	98.38	1.15
>5 to 6	118	0	0	2	0	117	0.00	98.38	1.16
>6 to 7	116	0	0	4	0	114	0.00	98.38	1.17
>7 to 8	112	0	0	6	0	109	0.00	98.38	1.20
>8 to 9	106	0	0	4	1	103.5	0.97	97.43	1.54
>9 to 10	101	0	0	6	1	97.5	1.03	96.43	1.85
>10 to 11	94	2	0	4	1	90.5	1.10	95.37	2.16
>11 to 12	87	47	0	4	0	84.5	0.00	95.37	2.23
>12 to 13	36	36	0	0	0	36	0.00	95.37	3.42

Prop.=proportion; CumEst of Surviv.=cumulative estimate of survival; Confid inter.=Confidence interval

Only one patient (1 cup) was lost to follow up before the end of the study because she left France a year after her operation.

Four implants in 4 patients (2.9%) were revised for mechanical failure following aseptic displacement of the cup (Table 2; Figs. 2, 3).

A fifth revision was done in a 69-year-old patient after operation for degenerative joint disease secondary to congenital dislocation of the right hip. She presented with a dislocation of the prosthesis during the tenth postoperative year secondary to wear of the polyethylene insert. The revision operation undertaken in our department involved changing the polyethylene insert without replacing the metal cup which was perfectly attached to the pelvis. Two years later, her clinical and radiological condition is

excellent, but she is classed as a failure in the actuarial study.

These revisions were not technically difficult and did not require bone grafting. If the above case is recorded as a failure, the survival analysis gives a total cumulative cup survival probability of 95.4% which remained unchanged from the tenth to the twelfth year (Table 3).

Clinical analysis of the 78 surviving patients (85 cups) showed that only one had deteriorated with painful symptoms and significant functional limitation after 4 years. Radiographs showed the cup had displaced vertically and medially, and this gradually progressed. The patient refused to undergo revision.

Two other cases show clinical signs of cup displacement with moderate groin pain, but no function-

Fig. 4. Postoperative radiograph

Fig. 5. The same cup 11 years later

Table 4. Changes over time in the post-operative bone-cup gaps

Post-op gaps	Areas	Number	Disappeared	Decreased	Stable	Increased
<2 mm	III	1		1		
	II-III	3		1	2	
	I-II-III	1	1			
<2 mm	III	4	1	2		1
	II-III	2	2			
	I-II-III	1	1			

Table 5. Radiolucent lines and migration of cups at last follow up

Case	Radiolucent lines		Migration/inclination			
	Zone	Thickness (mm)	Upward displacement (mm)	Medial (mm)	Cup angle (degree)	
					Post	F. Up
1	III	2	0	0	37°	38°
2	III	5	0	0	61°	60°
3	II-III	1	14	5	37,7°	28°
4	II-III	4	10	2	50°	54°
5		0	7	9	62°	68°
6	II-III	3	12,5	0,5	59°	64°

al disability; their radiographs showed migration of the cup.

Radiological analysis at more than 10 years after operation (average 11.4 years) showed that of the 62 cups, 61 had not had a further operation, including the patient who had a polyethylene insert changed. There were 30 women (33 hips) and 25 men (29 hips); their average age was 58.5 years (27–79 years) at the time of operation.

Analysis of the postoperative radiographs showed an average cup inclination of 50° (36–70°). At a later review, the inclination was 51° (28–72°).

Twelve patients presented with a space between bone and cup (Table 4). Their progress was good, with the gaps either disappearing (Figs. 4, 5) or becoming stable, except in one case where it widened. The latter was associated with a zone III gap which did not extend to the other areas. None of these pa-

tients had clinical signs of loosening of the cup. Radiographs showed no change in the position of the articular centre or in the inclination of the cup. On further reviews there were radiological changes in 6 patients (Table 5).

A radiolucent line, 2 mm or wider, appeared in 2 patients in zone III, but was not associated with clinical signs or radiological evidence of migration.

In the 4 other cases with migration of the cup there were radiolucent lines present in zones II and III in 3 patients; a fracture of the upper screw occurred in 2 cases.

Two cases had no clinical symptoms and 2 others had minimal pain during the first few steps or after long walks; two of the cups had been implanted vertically.

Although these 4 patients were not operated on again since they had few or no functional symptoms,

they were classed as failures as a result of displacement, 6.3% of the total seen at the final follow-up.

Discussion

The main early complication after hip arthroplasty, aside from infection, is dislocation of the prosthesis [15]. The intrinsic stability of this model reduces the number of dislocations [16]. Only one of our cases had a poor outcome due to an obvious technical failure.

The displacement of the cups increased over time, particularly after 10 years of implantation [10, 11, 12, 22] and decrease in bone structure often makes repair difficult.

In our study, among the 4 displaced cups needing revision during the first 12 years, only 2 cases could be attributed to a lack of stable anchoring, and they both had dysplasia sockets. A technical failure was present in one; in the two others, perfectly implanted cups displaced as a result of violent trauma; revision was simple.

We have had one fracture of the polyethylene insert which seemed linked to a manufacturing problem.

Our radiological study showed migration and inclination of the implant with few clinical symptoms in 6.3% of cases after 10 years.

The displacement of cups without cement does not create the large, overall radiolucent lines seen with cemented cups because the fibrous interface gradually collapses [9], and more bone is preserved. When we compared our results to those reported for cemented cups with more than 10 years of follow up, we found greater stability in our cases; Sutherland reported 29% radiological loosening [29], and Harris and Perrenberg 35.4% [11].

The appearance of an isolated radiolucent line in zone III in stable implants, which was present in 3 of our cases, may be due to localised osteolysis associated either with polyethylene wear particles or to an absence of loading in that area of the socket. These patients are relatively young and active; the osteolysis has so far not impaired the stability of their implant.

We did not find osteolysis in the area of the acetabular roof or its recesses. Lesions of this kind were discovered [27] in stable implants with screw holes in the upper polar region which encourage worn particles to migrate behind the implant [17]. The use of a large diameter (28 or 32 mm) femoral head accentuates this phenomenon through creep of the thin polyethylene [2, 14].

The bipolar insert of the Novae cup implant creates solid stability allowing the use of a 22.2 mm head. The polyethylene is over 8 mm thick. The implant does not have a hole in the load area of the cup which prevents migration of worn particles into the bone-implant interface.

Using survival analysis, the study of this cement-free cup shows stable results after 10 to 12 years of

implantation. The cup revisions before 10 years all resulted, except in one case, from either a technical problem or violent trauma. This confirms the encouraging long term results seen with hemispherical cups by press-fit and without the use of cement.

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