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ORIGINAL STUDY

Comparative study between patients with osteonecrosis and osteoarthritis after hip resurfacing arthroplasty

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The purpose of this study was to compare the clinical outcomes of osteonecrosis (ON) and osteoarthritis (OA) patients after metal-on-metal hip resurfacing arthroplasty (HRA). We retrospectively reviewed our database and identified a study group of 122 HRA cases with the primary diagnosis of ON. A control group of 122 OA cases were randomly selected by a computer program to match the surgical date, gender and the femoral component type and size with the study group. We compared the results between these two groups and also compared the clinical outcome between cemented and uncemented HRA in ON cases. Overall survivorship, using any revision as an endpoint, was 88% for ON, compared to 100% for OA at ten years. There were no femoral failures in 47 uncemented femoral cases. Our study suggests that HRA may not be suitable for everyone, such as ON patients.

Keywords : hip resurfacing ; hip surface replacement ; osteonecrosis ; osteoarthritis ; metal-on-metal.

INTRODUCTION

It is estimated that roughly 600,000 patients in the United States suffer from osteonecrosis (ON) of the femoral head, with an average incidence of 10,000 to 20,000 new cases each year, especially in patients between the ages of 30 and 60 (*31*). Treatment results for core decompression, bone grafting, femoral osteotomy, hemi resurfacing, total hip arthroplasty (THA), and hip resurfacing arthroplasty (HRA) have been mixed (*19,22,31*). Non-surgical and hip preserving treatment options have been suggested for patients with early stages of ON whereas end-stage diagnoses commonly necessitate arthroplasty (*12,35*). THA failure rates for ON range from 3% to 48% at midterm follow-up (*30,33*). THA failure rates are generally acknowledged to be higher for ON than osteoarthritis (OA). Also, patients with ON are typically much younger than most other THA patients. These factors make choosing the appropriate surgical treatment difficult (*19,22,34*) and make preservation of the femoral head an important goal for ON patients (*4,22,30*).

Although high early failure rates with the Durom® (Zimmer, Warsaw, IN, USA) and ASR® hip resurfacing system (DePuy, Leeds, UK) due to design flaws have led to recalls in last few years (*21,28,29*), numerous studies have reported excellent survival rates with other metal-on-metal HRA implants in young, active patients with a broad spectrum of diagnoses (*10,17,24,25,36*). Several recent studies have reported mid-term implant

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survival rates of at least 93% following bone preserving HRA in patients with ON as a primary diagnosis, often outperforming THA survivorship in these ON patients (2,4,25). Additional evidence suggesting that more nearly-normal function can be achieved with HRA (27) makes this an attractive alternative for young active patients with ON.

Most previous studies of HRA for ON have reported on hybrid devices featuring uncemented acetabular and cemented femoral components (26,32). Promising early results with uncemented femoral resurfacing components have been reported (13,23). Because the vascular supply to the femoral head is tenuous and easily impaired during surgical exposure, many surgeons fear that bone ingrowth fixation into a porous femoral component may not be reliable. However, we have previously demonstrated that stable femoral fixation can be routinely achieved (13,14). Cases of femoral head ON may represent the most challenging cases to treat with HRA because of the loss of femoral bone required for implant fixation. Often, large femoral head defects remain after nonviable bone is debrided in surgery. These can be filled with cement or with bone graft. Filling large defects with cement leads to more thermal damage to the femoral head. This has been reported to increase the risk for femoral neck fracture and component loosening (20). Some studies have suggested that increased cement penetration into the femoral head, and thicker cement mantle thickness between the femoral head and component are risk factors contributing to early failures in hybrid prostheses (6,8,9).

We addressed two questions. First, were our results different in patients with ON as compared to OA ? Second, is cemented or uncemented femoral fixation superior in ON patients ? We have noticed that the base of the femoral head is always viable and bleeding even after the hip is exposed by a posterior approach. Indeed, the area surrounding the necrotic bone in ON cases often appears hyperemic, possibly due to the body's healing response to the avascular bone. Although there were large necrotic areas of bone in most cases of ON, we suspected that there was adequate remaining viable bone on which to achieve stable porous implant fixation. We wanted to know whether it was more successful to fix the implant with cement on the remaining viable bone and fill these defects with cement or whether it was better to gain stable fixation on the viable bone with a fully porous coated implant and fill the defects with bone graft.

MATERIAL AND METHODS

From May 2001 to Feb 2010, 1973 HRA cases were performed by a single surgeon (TPG). One hundred and twenty-two cases (122/1973 ; 6.2%) in 101 patients (73 male *vs.* 28 female ; 89 cases in male patients *vs.* 33 cases in female patients) with a primary diagnosis of osteonecrosis were identified in the entire group and were designated as the study group. During the same period of time, 1533 cases with the primary diagnosis of osteoarthritis were identified in 1290 patients (1003 male vs. 287 female) in our database. A control group of 122 osteoarthritis cases was randomly selected using a computer algorithm that matched the surgical date, gender, femoral component size and implant type. The entire ON study group was compared to a matched OA study group. At the same time, we subdivided this study group into the cemented and the uncemented study groups. Then, the ON subgroups were compared with each other.

Demographic information and osteonecrosis grade according to Ficat's definition are listed in Table I (11). Three HRA devices were used during this study : the hybrid Corin Cormet 2000 (Corin Group, Cirencester, Gloucestershire, United Kingdom) was employed in 44 cases (36%) ; the hybrid Biomet ReCap®-MagnumTM (Biomet®, Warsaw, Indiana, USA) in 31 cases (25%) ; and the fully porous coated Biomet Recap®-MagnumTM (Biomet®, Warsaw, Indiana, USA) in 47 cases (39%). Both hybrid Corin Cormet 2000 and hybrid Biomet Recap hip resurfacing system utilize uncemented fixation on the acetabular side and cemented fixation on the femoral side. The fully porous coated Biomet Recap hip resurfacing system employs uncemented fully porous fixation on both the acetabular and femoral sides. Clinical and radiographic assessments were recorded in the database prospectively. Institutional review board (IRB) approval was obtained for the present study.

All procedures were performed through the posterior approach (16). In all cases, standard resection of the head for femoral resurfacing using standard instrumentation was performed. Then, all loose necrotic bone was removed and any cystic soft tissue was also removed. Well-fixed necrotic bone was drilled with a 1/8-inch drill. The resulting defect was filled with cement when

Table I. – Demographics and diagnoses of the osteonecrosis and osteoarthritis groups

Variables	ON Group	OA Group	P-Value
# of Cases	122	122	–
Age at surgery (yrs)	44 ± 11	52 ± 7	< 0.0001*
Weight (kg)	188 ± 33	189 ± 40	0.72
BMI (kg/m²)	27 ± 4	28 ± 5	0.5
T-score	0 ± 2	0 ± 1	0.63
Gender (male)	89	89	0.95
Diagnosis			< 0.0001*
Osteoarthritis	–	122	–
AVN (I)	31	–	–
AVN (II)	3	–	–
AVN (III)	39	–	–
AVN (IV)	49	–	–

ON : osteonecrosis ; OA : osteoarthritis. * Statistically significant difference.

this was the method of implant fixation, but was filled with acetabular reamings when the femoral component was uncemented.

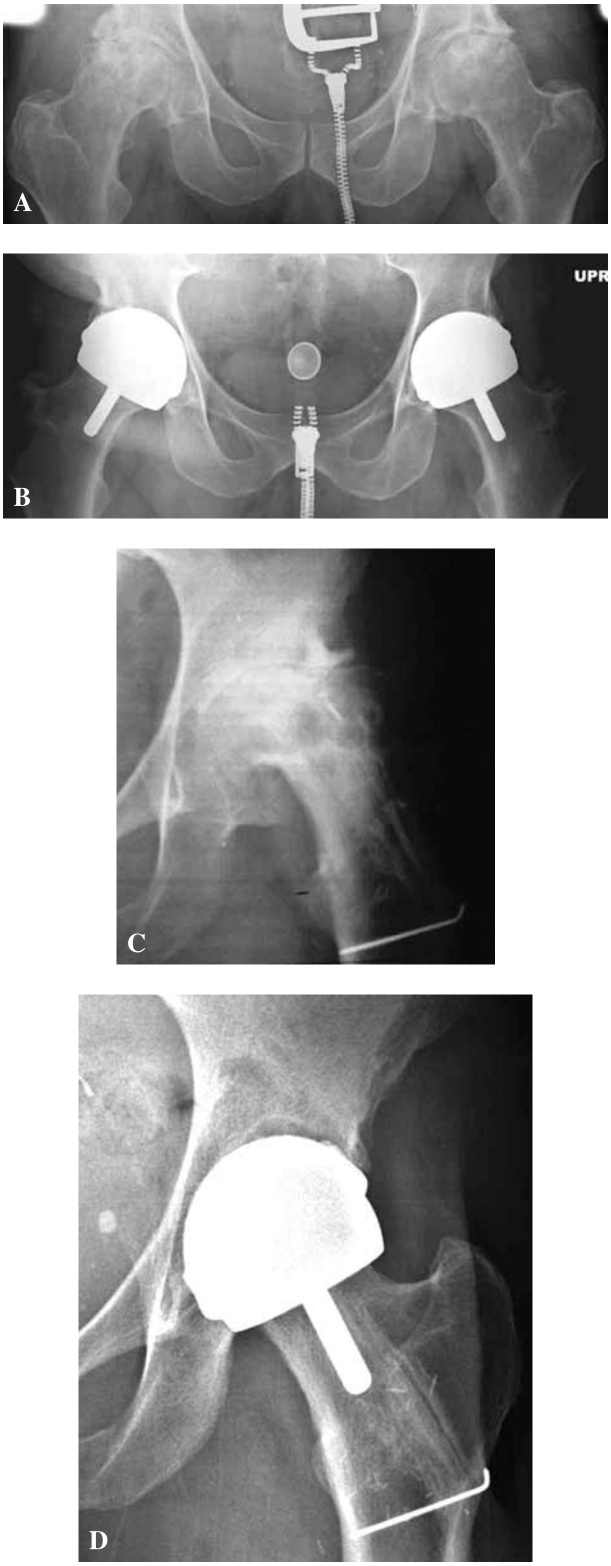
Postoperatively, weight bearing was advanced as tolerated. Crutches were typically used for two weeks and a cane for two weeks thereafter. Physical therapy was not utilized after hospital discharge. Return to unlimited activity was allowed after six months. Clinical and radiographic evaluations were requested at six weeks, one year, two years, and every other year thereafter. Clinical evaluation included the calculation of postoperative Harris hip score (HHS), UCLA activity score, and visual analogue scale (VAS) pain scores on regular and worst days. Physical examinations testing strength and range of motion (ROM) were only required at six weeks and one year postoperatively for remote follow-up patients unless complications were observed ; physical examinations were performed for all patients seen in the office for follow-up (*18*). All complications and failures were prospectively recorded and entered into the database. Standing and supine anterior-posterior (AP) pelvis (Fig. 1) and lateral radiographs were analyzed to assess component positioning and radiolucencies.

Statistical Analysis

All statistical analyses were performed with the use of OrthoTrack (Midlands Orthopaedics, P.A., Columbia, SC, USA) and JMP® (SAS, Cary, NC, USA). Paired *t*-tests were used to compare the preoperative and postoperative clinical outcomes in the study. Standard *t*-tests were performed for numeric variables to calculate the statistical difference between two groups. *Chi*-square analyses were utilized for categorical variables to calculate the statistical difference between these two groups. ASA score, UCLA activity score, VAS pain scores on regular days and on worst days were treated as ordinal variables in the statistical analyses. *Kaplan-Meier* survivorship curves were generated to estimate the survival rates. Furthermore, univariable proportional hazard regression models were generated in order to identify the most significant factors contributing to the survival rate of the femoral component for osteonecrosis patients after HRA. Then, a multivariable proportional hazard regression model based on the results of the previous univariable models was generated to identify the actual significant factors affecting the survival rate of the femoral component. The level of significance was defined at $p < 0.05$.

RESULTS

The average follow up duration was 6 ± 3 years (range : 2 to 12 years) for both groups. The ON study group had a significantly higher overall failure rate (9/122 ; 7.4%) than the OA control group (0/122, 0%) ($p = 0.0003$) (Table II). Ten years after the primary surgery, the Kaplan-Meier survivorship rate, using any revision as an endpoint, was 88% for



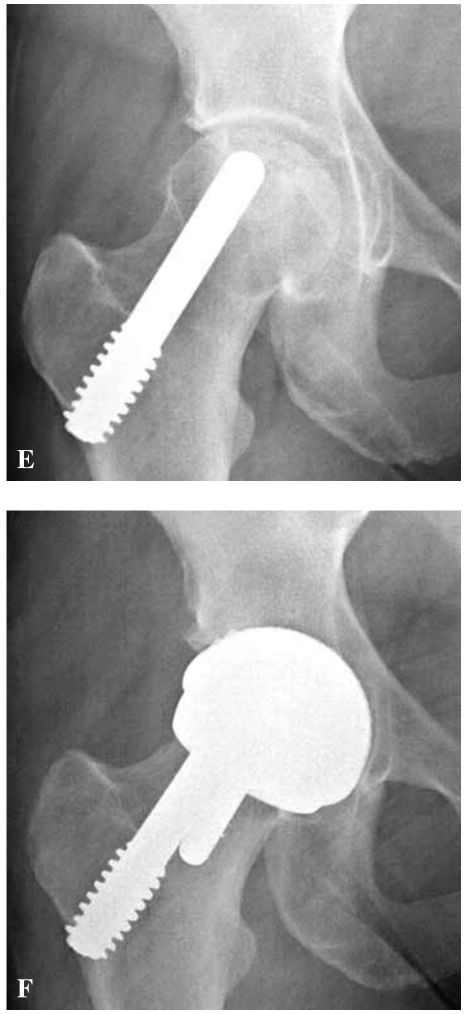


Fig. 1. — Case 1 : 57-year-old man with Ficat stage IV ON of both hips : (A) pre-operative radiograph showing extensive head involvement on the right ; (B) 3 years post-operative standing radiograph after bilateral uncemented HRA with the AIA of 31° for the right hip and the AIA of 37° for the left hip. Case 2. - 29-year-woman with Ficat stage IV ON : (C) pre-operative radiograph showing extensive head involvement after failed free fibula graft ; (D) 4 years post-operative standing radiograph after uncemented HRA with the AIA of 43° and leg lengths equalized.
Case 3. - 46-year-old woman with each Ficat stage IV ON after failed Implex rod. (E) pre-operative radiograph with well fixed Implex rod ; (F) 2 years postoperative uncemented HRA with AIA of 36°.

Table II. — Summary of failures and complications

Variables	ON Group	OA Group	P-Value
Case #	122	122	–
Complications	2 (1.6%)	3 (2.5%)	0.65
Sciatic nerve palsy	0	1	0.24
Deep infection (cured)	0	1	0.24
Superficial infection (cured)	1	0	0.24
Intertrochanteric fracture	1	1	1
Modes of Failure	9 (7.4%)	0	0.0003*
Acetabular component loosening	2	0	0.09
Femoral component loosening	4	0	0.02*
Dislocation	1	0	0.24
Deep infection	1	0	0.24
Psoas tendonitis	1	0	0.24

* Statistical difference.

ON and 100% for OA. The most common failure type for the study group was loosening of cemented femoral components. It occurred in four (4/122, 3.3%) ON cases and accounted for 44% (4/9) of all ON failures. All were treated with femoral revision using an uncemented stem and a jumbo femoral head to match the existing resurfacing acetabular component. Two failures (2/122 ; 1.6%) were caused by acetabular component loosening : one at five years was revised to a THA ; the other one at eight years had only an acetabular component revision (still HRA). One (1/122 ; 0.8%) had recurrent dislocations and was revised elsewhere. One had a deep infection two years post-operatively and was revised to THA. The last one was due to psoas tendonitis eight years after the primary surgery and was converted to THA.

For the study group, univariate proportional hazard analyses identified Ficat stage of osteonecrosis ($p < 0.0001$) and femoral fixation method (cemented/uncemented) ($P < 0.0001$) as potential significant factors that may increase the femoral failure rate for ON patients after HRA (Table III). Multivariate proportional hazard analysis based on these two variables confirmed that both Ficat stage of osteonecrosis ($p = 0.004$, risk ratio : 2) and femoral fixation method ($p < 0.0001$, risk ratio : 122) were significant factors that affect the femoral failure rate, and that femoral fixation method was the most significant factor. All four femoral component failures (4/75 ; 5.3%) occurred in the cemented group and none (0/47 ; 0%) in the fully porous coated group ($p = 0.046$). Using only revision of the femoral component for any reason as the end point, the survival rate for the cemented group was 96% at four years after the surgery, and 100% for the fully porous coated group (Fig. 2). The survival rate for the cemented group was 92% at 10 years after the surgery.

There were two complications in the study group and three in the control group ($p = 0.65$). In the study group, one significant superficial infection occurred one month postoperatively and was cured with debridement and antibiotics. Also, one intertrochanteric fracture occurred 5.5 years postoperatively and was successfully repaired. In the control group, there was one deep infection, 6 weeks postoperatively, which was cured with debridement and antibiotics, one intertrochanteric fracture that occurred two years post-operatively and was successfully repaired, and one sciatic nerve palsy.

The clinical and radiographic information at the latest follow-up visits are summarized in Table IV. The average postoperative HHS score in this study was significantly improved compared to preoperative scores ($p < 0.001$). The patients in both groups

Table III. — Results of univariate analyses and multivariate analysis with use of Cox proportional hazard regression models

Variables	P-Value	Hazard Risk	95% Confidence Interval	
Univariate analysis				
Age	0.095	0.987	0.973	1.002
BMI (<29/> = 29)	0.135	1.349	0.910	1.981
Gender (male/female)	0.350	1.212	0.814	1.850
American Society of Anesthesiologists (ASA) score	0.337	1.647	0.852	3.436
Size of Femoral Components (< = 48/> 48)	0.07	1.402	0.972	2.031
Stage of Osteonecrosis (I,II,III,IV)#	< 0.0001*	3.634**	2.243	5.985
Femoral Fixation Method (Cemented/Uncemented)	< 0.0001*	134.241	39.466	842.189
Multivariate analysis				
Stage of Osteonecrosis (I,II,III,IV)	0.004*	2.481	1.476	4.192
Femoral Fixation Method (Cemented/Uncemented)	< 0.0001*	122.251	34.63	783.118

*Statistically different
The most significant difference is between Ficat I and Ficat IV, which is listed here.

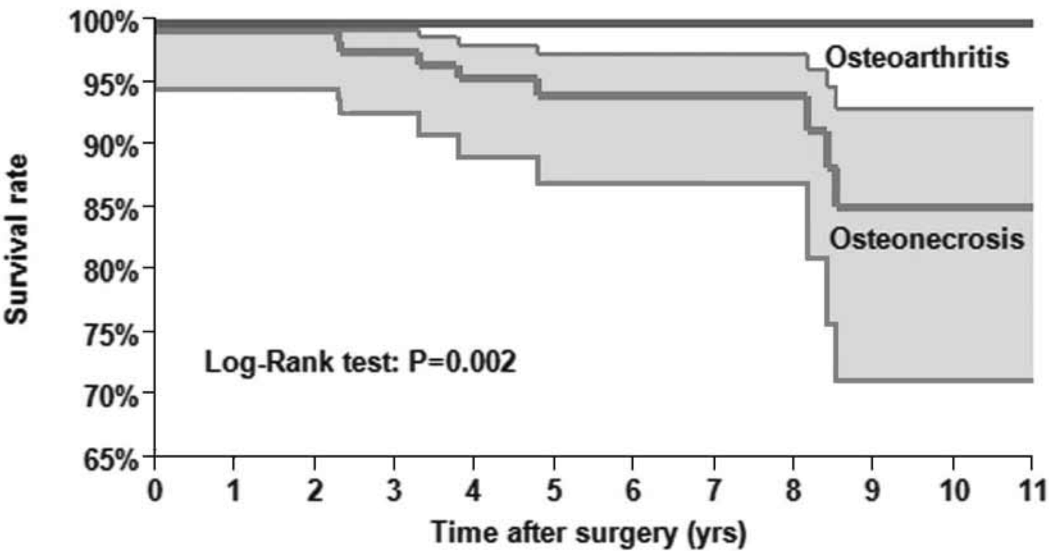


Fig. 2. — Kaplan-Meier survivorship curves of the osteonecrosis and osteoarthritis groups using revision of any component for any reason as the end point.

resumed active lifestyles after the surgery with an average UCLA activity score of 6.6 ± 2 for the study group and 7.3 ± 2 for the control group (p = 0.02). The average VAS on regular day was 0.5 ± 2 for the study group and 0.2 ± 1 for the control group (p = 0.03). The average acetabular inclination angle (AIA) for the study group was 43 ± 6 with only one case having AIA ≥ 55° and it was 44 ± 8 for the control group with 6 having AIA ≥ 55°. With the exception of the failed cases, there was no

Table IV. — Clinical and radiographic data

Variables	Osteonecrosis Group	Osteoarthritis Group	P-Value
Deceased	2	1	0.48
Preoperative			
HHS	50 ± 13	55 ± 12	0.0005*
Postoperative			
Clinical Data			
HHS	96 ± 12	98 ± 6	0.13
UCLA Activity Score	6.6 ± 2	7.3 ± 2	0.02*
VAS Pain : Regular Days	0.5 ± 2	0.2 ± 1	0.03*
VAS Pain : Worst Days	1.8 ± 3	1.0 ± 2	0.008*
Radiographic Data			
AIA (°)†	43 ± 6	44 ± 8	0.3
Radiolucency	0	0	1
Osteolysis	0	0	1

* Statistically different.
† AIA, Acetabular Inclination Angle.

radiolucency or osteolysis observed in either group. There were no adverse wear failures.

DISCUSSION

We found that the overall failure rate for ON at average follow-up of 6 ± 3 years was worse than for a matched group of OA (7.4% vs 0%, p = 0.003). Kaplan-Meier survivorship at 10 years for ON was also worse at 88% compared to 100% for OA. Primarily, this was due to loss of femoral fixation in the ON study group (4/122 = 3.3%). All femoral failures were due to loosening. There were no femoral neck fractures in either group. When we analyzed the femoral failures in the ON study group, we found that cement fixation of the femoral component (as opposed to uncemented) was the most significant independent risk factor (p < 0.0001), followed by increased Ficat stage of ON (p = 0.004). There were no femoral failures in the 47 uncemented femoral components.

This is the largest report of HRA for osteonecrosis published so far. Our 93.3% success rate in 122 cases with an average follow-up of 6 years (range : 2 to 12 years) is consistent with the survival rates reported in other studies (Table V). No other studies have compared the results with ON directly to OA. No other studies have investigated the use of uncemented femoral fixation.

In one study, 111 HRAs were performed in 85 patients with a mean age of 39 years and produced a 95% success rate at an average 5-year follow-up for patients with osteonecrosis of the femoral head (*7*). In a longer follow-up duration study, Amstutz *et al* reported a 94% survivorship rate at 8 years in 85 HRAs performed in patients with a mean age of 40 years having end-stage osteonecrosis as the indication for arthroplasty ; metal-on-metal HRA in patients diagnosed with osteonecrosis produce similar survival rates compared to those treated for other diagnoses but did not demonstrate this with data (*2*).

Several studies have investigated problems related to the cementation of components in HRA. One retrieval analysis study in 2006 first reported the difficulties in femoral component cementation during HRA procedures, emphasizing the significant variance in the method and timing in cement application (*8*). Excessive application of cement when fixing HRA components has also been known to cause thermal necrosis as a result of the heat produced throughout cement curing (*20*). In most cases

Table V. — Literature comparison of outcomes of hip resurfacing arthroplasty for osteonecrosis with use of hybrid HRA prostheses

Study	Prosthesis	Dates of Procedure	Primary Diagnosis	Patient Cohort		Avg FU Duration	Survivorship†	
				Hips	Female		FU (yrs)	Rate
Bose *et al.* (*9*)	Birmingham	2000-2005	ON	96	15.5%	5.4	5.4	95.4%
Amstutz *et al.* (*3*)	Conserve Plus	1996-2006	ON	85	18.6%	7.6	8	93.9%
Aulakh *et al.* (*5*)	NA	1997-2002	ON	101	23.2%	7.5	7	97.7%
Beaulé *et al.* (*6*)	Conserve/Conserve Plus	1996-2002	ON	84	18.0%	4.9		
Mont *et al.* (*27*)	Conserve Plus	2000-2003	ON	42	30.6%	3.2	3.2	94.5%
Current Study	Corin Cormet 2000/ Biomet Hybrid/Biomet Fully Porous-Coated	2001-2010	ON	122	28.0%	5.8	6	93.3%

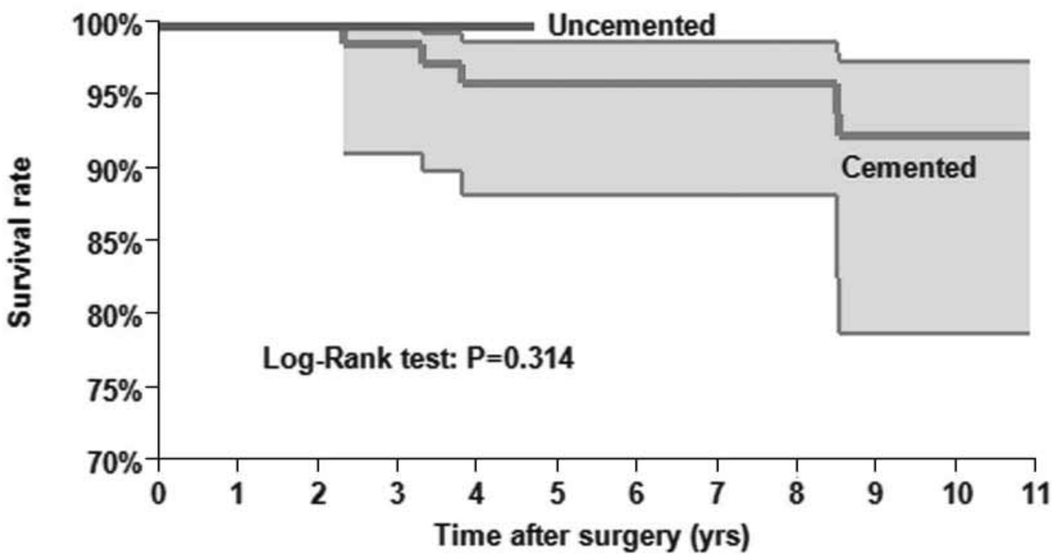


Fig. 3. — Kaplan-Meier survivorship curves of the osteonecrosis subgroups using revision of the femoral component for any reason as the end point. (Uncemented : Biomet Recap/Magnum uncemented implants ; Cemented : Biomet Recap hybrid and Corin Cormet 2000 hybrid implants with cemented femoral component).

of osteonecrosis, large areas of dead bone are removed and are then filled with cement. In our experience, the defects in ON are not amenable to bone grafting because they are segmental. Therefore, large boluses of cement are required which increase the thermal necrosis in the remaining viable surrounding bone. Although cement techniques have been modified (*1,3,9*), there is no evidence that any particular cement technique can decrease the rate of femoral failures in HRA. On the other hand, for OA patients, there are usually no large defects that require cement. When cysts are present, one study has shown that filling these cysts during cementation results in a higher femoral failure rate (*5*). However, the cysts in OA are usually cavitary and could be bone grafted instead of cemented. In a recent larger study, we have shown that cases of OA with cysts treated with bone grafting prior to cementation does not increase the femoral failure rate (*15*). We have therefore suspected that the excess cement required when fixing femoral components in ON is the likely reason that the failure rate is higher. There are two possible methods to avoid using the large excess quantities of cement in these cases. The segmental defect could be filled with a bulk structural allograft, which could be fixed to the remaining viable head prior to cementation. Or the defect could be filled with compacted acetabular reamings prior to implanting an uncemented femoral component that is completely porous coated. This porous coating achieves a press-fit on the remaining viable host bone. We have decided to investigate the latter strategy.

No other studies have reported results for a completely uncemented HRA system in ON. Using the Biomet fully porous-coated device produced a 100% survival rate at a follow-up of up to four years in 47 patients. We demonstrate statistically significant increased the success rate of the uncemented femoral component and our analysis also indicates that cement fixation is the most significant risk factor for failure of HRA in ON cases. Therefore, these preliminary results suggest that uncemented HRA may be capable of producing improved outcomes for patients with osteonecrosis that are similar to those for OA.

The following limitations of our study are noted. Although overall results for our 122 cases of ON are equivalent to other studies of HRA in ON, our data using the Biomet fully porous-coated uncemented HRA device are only early results. To be certain that uncemented fixation is truly superior to hybrid fixation for patients with osteonecrosis, longer-term follow-up will be necessary. Second, our results are representative of only a small percentage of our entire patient cohort and may limit an effective comparison ; however, numerous studies have reported clinical outcomes following HRA in patients with osteonecrosis for study groups containing fewer patients than in the present study (*2,4,7*).

We conclude :

1. The overall failure rate and survivorship for HRA in ON is worse than in OA, mostly due to failure of cemented femoral fixation.
2. Uncemented femoral fixation *may* offer a better method of fixation than cement in ON cases at short-term follow-up.
3. Results for uncemented HRA in ON at 4 years are equivalent to those for OA.
4. Femoral neck fracture is rare after HRA in ON and OA.
5. There is a greater risk for failure in cemented HRA with increasing Ficat stage of ON.

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