

# Clinical Outcome of the Metal-on-Metal Hybrid Corin Cormet 2000 Hip Resurfacing System

## An up to 11-Year Follow-Up Study

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**Abstract:** This report extends the follow-up for the largest center of the first multicenter US Food and Drug Administration investigational device exemption study on metal-on-metal hip resurfacing arthroplasty up to 11 years. A single surgeon performed 373 hip resurfacing arthroplasties using the hybrid Corin Cormet 2000 system. The Kaplan-Meier survivorship at 11 years was 93% when revision for any reason was used as an end point and 91% if radiographic failures were included. The clinical results demonstrate an acceptable failure rate with use of this system. Loosening of the cemented femoral components was the most common source of failure and occurred at all follow-up intervals. A learning curve that persisted for at least 200 cases was confirmed. All femoral neck fractures occurred before 6 months postoperatively. **Keywords:** hip resurfacing, hybrid fixation, hip arthroplasty, learning curve, femoral failure.  
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Hip resurfacing arthroplasty (HRA) with modern metal-on-metal devices has been performed in Europe and Australia since 1990. It has been accepted as an alternative to traditional total hip arthroplasty (THA), especially for young and active patients. According to the Australian registry in 2005, HRA comprised 8.9% of hip arthroplasties for all age groups and up to 29% of those for groups in which patients were younger than 55 years, which represented a rapid increase from 5.6% and 19.6%, respectively, in 2001 [1]. Previously published long-term follow-up survivorship rates have ranged from 33% up to 75% for standard metal-on-polyethylene bearing THA in young patients [2-5]. Total hip arthroplasties with improved ceramic-on-ceramic and second-generation metal-on-metal bearings have shown significantly improved outcomes in young patients [6-9]. At the same time, numerous studies have reported a high midterm success rate after metal-on-metal HRA [10-12]. In addition to offering a more durable alternative for young and active patients, other theoretical advantages of metal-on-metal HRA include

preservation of the proximal femur, reduced risk of dislocation, and greater retention of biomechanical characteristics of a normal hip joint.

The United States has a relatively short experience with metal-on-metal HRA. Although HRA devices are available worldwide, only a few manufacturers offer devices for HRA in the United States: the Birmingham hip resurfacing (Smith & Nephew, Memphis, Tenn), Corin Cormet 2000 (Corin, Cirencester, Gloucestershire, UK), and Conserve Plus (Wright Medical Technology, Arlington, Tenn) have received Food and Drug Administration (FDA) approval to be marketed in the United States for metal-on-metal HRAs by January 2011. The senior author (TPG) worked with Corin to plan, implement, and complete the first US FDA investigational device exemption study of metal-on-metal HRA devices. As the principal investigator and initial study site of this FDA trial, he performed nearly half of all the procedures that eventually led to FDA approval of the hybrid metal-on-metal Corin Cormet 2000 resurfacing device in July 2007. We now provide longer-term (up to 11 years) clinical and radiographic data on one of the first groups of patients who have undergone metal-on-metal HRA in the United States to better evaluate the durability of the Corin Cormet 2000 system and to assess the value of HRA in young patients.

### Material and Methods

Between January 2000 and March 2005, the senior author (TPG) performed 373 consecutive metal-on-

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Supplementary material available at [www.arthroplastyjournal.org](http://www.arthroplastyjournal.org).  
Submitted February 8, 2011; accepted June 25, 2011.  
The Conflict of Interest statement associated with this article can be found at [doi:10.1016/j.arth.2011.06.019](https://doi.org/10.1016/j.arth.2011.06.019).  
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0883-5403/2704-0007\$36.00/0  
[doi:10.1016/j.arth.2011.06.019](https://doi.org/10.1016/j.arth.2011.06.019)

metal HRAs in 329 patients. The demographic characteristics and diagnoses are listed in [Table 1](#). The study was approved by the institutional review board. All patients were requested to come back for follow-up visits at 6 weeks, 1 year, 2 years, and every other year. At the time of the latest follow-up, 3 patients (3 hips) had died of causes unrelated to their HRA. The original HRA in each of these patients was functioning well at the time of death. Because 143 (43%) of the 329 patients came from outside the state in which the senior author practiced, a variety of follow-up methods were used. A regular office visit was most frequently used. Alternatively, remote follow-up using an Internet or mail-in questionnaire, radiographs, and physical examination results by a local physical therapist was used. Finally, a phone interview by our medical team in combination with mail-in radiographs and physical examination results by a local physical therapist was used. The Harris hip score (HHS), UCLA activity score, and visual analog scale (VAS) pain score on the patients' normal and worst day, and the range of motion at the latest follow-up were collected. Anterior-posterior and lateral radiographs were evaluated for implant position and signs of migration, radiolucencies, and heterotrophic bone [13]. The nature and timing of all complications were recorded.

Corin Cormet 2000 implants are made of cast high-carbon cobalt-chromium. Uncemented fixation was used on the acetabular side; and cemented fixation, on the femoral side. No stems were cemented. Cysts were bone grafted before cementation. The femoral component had 3 evenly spaced longitudinal splines and was grit blasted on the undersurface of the component. The stem was tapered and polished. The acetabular component was equatorially expanded (a larger diameter at the rim than at the pole) with 2 small peripheral fins. It had a dual-coated bone ingrowth surface of plasma-sprayed titanium plus hydroxyl apatite. There were 5 femoral component sizes (40, 44, 48, 52, and 56) in 4-mm increments. There were a set of matching acetabular

components and a set of bridging cups (each bridging component had 2-mm extra wall thickness). In this study, the average size of femoral component used was  $50 \pm 4$  mm (range, 40-56 mm), the average acetabular component size used was  $56 \pm 4$  mm (range, 46-62 mm), and 14 bridging cups were used.

A posterior surgical approach was used in all of the cases [10]. The capsule was divided circumferentially, and a pocket was created under the abductors for the femoral head to allow access to the acetabulum. Surgical data are listed in [Table 2](#). After the operation, the patients were allowed to progress to full weight bearing as tolerated. No formal physical therapy was used postdischarge.

Kaplan-Meier survivorship curves were generated using femoral failures, acetabular failures, and all failures as end points. To evaluate the effect of the surgeon's experience, survivorship curves for all failures were generated for the first 100 cases, the second 100 cases, and the last 173 cases. To illustrate the timing of the 2 modes of femoral failure, a separate set of curves was generated comparing the 2 types of femoral failures. Paired *t* tests were performed to analyze the differences between preoperative and postoperative clinical scores. All of the data collection and data analysis including statistical analysis were performed using OrthoTrack (Midlands Orthopaedics, P. A., Columbia, SC) and JMP software (SAS Institute, Inc, Cary, NC).

## Results

The average duration of follow-up was  $8 \pm 1$  years (range, 6-11 years). The clinical outcomes including HHS scores, VAS pain scores, UCLA activity scores, and ranges of motion were summarized in [Table 3](#). Preoperatively, 108 hips had an average limb-length discrepancy of  $0.9 \pm 0.5$  cm (range, 0.5-4 cm); at the latest follow-up visit, 7 hips still had limb-length discrepancy, with an average discrepancy of  $1.0 \pm 0.6$  cm (range, 0.5-2 cm). There was a significant improvement in the average HHS from a preoperative value of  $52 \pm 10$

**Table 1.** Demographic and Diagnosis Data

	Average	Range
Age at surgery (y)	$50 \pm 9$	15-78
Weight (lb)	$193 \pm 44$	108-345
Body mass index	$28 \pm 5$	17-51
	Number	Percentage
Sex (N = 329 patients)		
Male	230	68%
Female	99	32%
Diagnosis (N = 373 hips)		
Osteoarthritis	274	73%
Avascular necrosis	43	12%
Dysplasia	29	8%
Rheumatoid arthritis	4	1%
Others	23	6%

**Table 2.** The Surgical Data for the Study Group

	Average	Range
Length of incision (in)	$5 \pm 2$	4-12
Operation time (min)	$105 \pm 15$	70-190
Estimated blood loss (mL)	$281 \pm 139$	15-1000
Size of acetabular component (mm)	$56 \pm 4$	46-62
Size of femoral component (mm)	$50 \pm 4$	40-56
	Number	Percentage
Anesthesia (N = 373 hips)		
Epidural	326	87%
General	33	9%
Spinal	8	2%
Combined	6	2%

**Table 3.** The Follow-Up Clinical Outcomes at the Latest Follow-Up of up to 11 Years Postoperatively

	Average	Range
Period of follow-up (y)	8 ± 1	6-11
VAS pain score on most days	0 ± 1	0-7
VAS pain score on the worst day	2 ± 2	0-10
UCLA activity score	7 ± 2	2-10
HHS	93 ± 11	37-100
Acetabular angle of inclination (°)	46 ± 8	17-66
Range of motion		
Contracture (°)	0 ± 0	NA
Flexion	108 ± 11	70-140
Abduction	53 ± 11	23-80
Adduction	31 ± 7	7-70
External rotation	40 ± 11	9-72
Internal rotation	30 ± 10	-20 to 70

(range, 23-76) to a postoperative score of  $93 \pm 11$  (range, 37-100) at the latest follow-up ( $P < .001$ ).

Twenty-one (6%) of the 373 hips required a revision of either the femoral component or the acetabular component, or both. Five were revised because of femoral neck fractures at an average of  $3.8 \pm 2.1$  months postoperatively; 7 for femoral component loosening at an average of  $39.1 \pm 27.5$  months postoperatively; 5 for acetabular component loosening at an average of  $48.5 \pm 30.5$  months postoperatively; 2 for late deep infections (5 months and 4 years); and 2 for an adverse wear reaction at 7 years postoperatively. In addition, there were 4 mildly symptomatic radiographically loose femoral components, where revision was offered but declined. There were 3 (0.8%) partial peroneal nerve palsies. There were no dislocations. There was 1 case of deep venous thrombosis, but no pulmonary emboli. There were no other serious medical complications.

Revision of 10 of 12 femoral failures was accomplished by a simple conversion to a stemmed large-bearing component with acetabular component retention. Three of 5 acetabular revisions were isolated with femoral retention. Both components were revised in the remaining 8 revisions. There was no evidence of adverse wear or osteolysis seen in any of these revisions except in the 2 cases in which "adverse wear reaction" was the preoperative diagnosis.

At the time of follow-up at 11 years postoperatively, Kaplan-Meier survivorship of the entire group was 93% using revision for any reason as the end point. If the 4 radiographic femoral failures are included, the survivorship was 91%. Separate Kaplan-Meier survival rates at 7-year follow-up for the first 100 cases, the second 100 cases, and the cases afterward were 93%, 93%, and 98%, respectively, when revision for any reason was used as the end point (Fig. 1A). The first 100 cases had a significantly higher failure rate compared with the last 173 cases ( $P = .03$ ), demonstrating that results improved with the surgeon experience. Eleven-year Kaplan-Meier

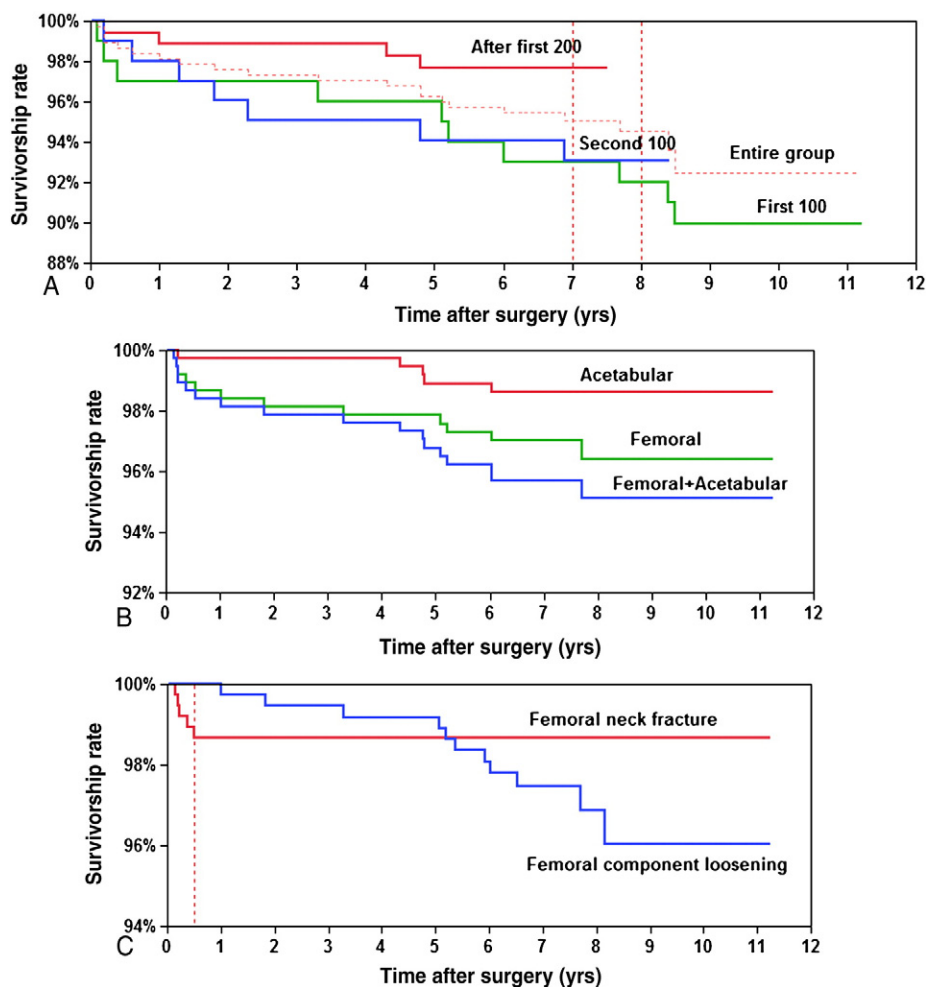
survivorship rate using causes of revision due to femoral component failure as the end point (7 loose, 5 fractures) was 96%; using causes of revision due to acetabular component failure (6 acetabular components revised) as the end point, 11-year survivorship was 99% (Fig. 1B). Both of these results leave 2 revisions for late infection and 2 revisions for adverse wear reaction unaccounted for. A separate pair of survivorship curves (Fig. 1C) was created to illustrate the timing of the 2 types of femoral failure: fracture (5) and loosening (7 revised, 4 additional radiographically loosening).

Except in the failed cases described above, no other radiolucencies were observed. Only 1 hip demonstrated a small area of osteolysis less than 1 cm in size. There were 9 cases in which reactive femoral stem lines of unclear significance were observed. There was 1 case in which the femoral stem was broken; but the femoral component remained stable for several years, and the patient was asymptomatic. Brooker class I heterotopic ossification was observed in 3 hips (0.8%) and Brooker class II was observed in 1 hip (0.3%) at the final follow-up. All 4 of these were seen in men.

## Discussion

Surgeons in the United States have been slow to adopt contemporary metal-on-metal HRA because of the high failure rates of metal-on-polyethylene HRA in 1980s and because of the well-documented long learning curve of hip surface arthroplasties [11,14-18]. The Birmingham hip resurfacing implant system was the first to receive FDA approval in the United States based on an unprecedented FDA decision to approve this implant on the basis of a single (developing) surgeon's personal foreign data in May 2006. The Corin Cormet 2000 was the first metal-on-metal HRA system to be approved based on the usual mechanism of a US-run multicenter FDA study in July 2007. The senior author was the lead investigator of this multicenter FDA trial and contributed approximately 40% of the cases of this FDA investigational device exemption study. Two previous studies reported the short-term clinical outcomes of this study [19,20]. At a minimum 2-year follow-up, 24 (7.1%) of 337 patients required a revision mainly because of femoral neck fracture or femoral component loosening; the HHS score of the HRA group was similar to that of the control THA group with a ceramic bearing surface. The senior author (TPG) had experience with only 20 cases of HRA before initiating this FDA study [12] and was therefore still learning this complicated surgical procedure. The purpose of this study was to report our midterm results of up to 11-year follow-up in the 373 HRAs performed by a single surgeon in his learning curve.

The overall implant survival using revision for any reason as the end point was 93% at 11-year follow-up. Back et al [21] demonstrated 99% survivorship after



**Fig. 1.** (A) Kaplan-Meier survivorship curves of the first 100 cases, the second 100 cases, and the cases afterward with use of revision for any reason as the end point. (B) Kaplan-Meier survivorship curves of the entire group with use of revision either for acetabular component failure or for femoral component failure as the end point. (C) Kaplan-Meier survivorship curves of the entire group with use of revision either for femoral neck fracture or for femoral component loosening as the end point.

metal-on-metal HRA at an average 3-year follow-up. McMinn et al [22] reported a cumulative survival rate of 95.2% at an average 9-year follow-up with the use of Birmingham hip resurfacing system; Amstutz et al [11] reported a 5-year survivorship rate of 95.2% for 1000 cases using the Conserve Plus system. Both Amstutz et al and McMinn et al were designing surgeons for the above implant systems with considerable experience with the procedure before undertaking their studies (Table 4; available online at [www.arthroplastyjournal.org](http://www.arthroplastyjournal.org)). If the current study was subdivided to 3 groups, the survivorship was 93% for the first 100 cases (group I), 93% for the second 100 cases (group II), and 98% for the remaining cases (group III) at 7-year follow-up postoperatively. This confirms the previous finding of other authors that a significant learning curve exists for HRA [11,17]. It is interesting to note that the results still improved after 200 cases, indicating that the learning curve may be much longer than we previously believed. The UCLA activity scores indicated that 47% were

functioning at a level 7 or above, which indicated that this cohort of patients had a high level of activity postoperatively as has been previously reported for HRA patients [23,24]. Therefore, direct comparison to studies of THA should be carried out with caution.

Femoral neck fracture was the most frequent early complication. All of these occurred before 6 months postoperatively. Although no femoral necks were notched, a 1.3% femoral neck fracture rate (5/373) was seen in 3 female and 2 male patients in the group. There were 2 cases in group I, 2 cases in group II, and only 1 case in group III, which translate to a 2%, 2%, and 0.6% femoral neck fracture rate for the respective groups. Other surgeons also showed that improved surgical experience could significantly reduce the rate of femoral neck fracture [17]. We found that femoral neck fracture always occurred within 6 months postoperatively (Fig. 1C). Therefore, a return to full sports activity should be delayed until the risk of femoral neck fracture is passed at 6 months postoperatively.

Loosening of the cemented femoral component (7 revised and 4 additional radiographically loosening; 2.9%) was the most common failure mode in this study; none of these 11 failures occurred before 12 months postoperatively. The possible modes of femoral loosening include osteonecrosis of the femoral head, poor cement interdigitation, inflammatory reaction toward cement, and cement fatigue failure. It is not possible to determine which of these is the source of failure in an individual case, although it is often presumed that osteonecrosis results in the earliest failures. A 2.9% failure rate of the femoral component due to aseptic loosening at 11 years indicates that cement seems to hold up reasonably well in this young and active cohort of resurfacing patients. We attribute this success to the favorable loading of cement through compression forces under a cemented femoral resurfacing component [25-27]. Although cement holds up reasonably well in femoral resurfacing, we found that it is the weakest link in the HRA construct in this study. We are therefore concerned that this problem will continue to worsen with longer follow-up as has been consistently demonstrated with previous cemented THA implants [28-30].

There were 5 cases of acetabular fixation failure (1.3%). Two of these were recognized within 2 years of surgery and therefore presumably represent failures of bone ingrowth. More concerning are the 3 cases of late fixation failure. This is typically an extremely uncommon mode of failure for uncemented acetabular components. The ingrowth surface was plasma spray titanium plus hydroxyapatite on the cobalt-chrome implant.

Although adverse wear reactions to metal debris have been reported at a higher rate in other studies [31], we experienced this problem in only 2 hips in 1 female patient at 8-year follow-up. In contrast to the Oxford report, revision in these 2 cases was straightforward without complication. In none of the other revisions that we performed did we encounter evidence of significant metallic wear debris or osteolysis. In contrast, revision of metal-polyethylene THA in young patients typically involves reconstruction of large osteolytic defects caused by reaction to polyethylene debris.

In summary, midterm follow-up of metal-on-metal HRAs with the Corin implant system demonstrates the following:

1. Survivorship of 93% at 11 years using revision as an end point, and 91% if all radiographic failures are included, in a young ( $50 \pm 9$  years old) and active (UCLA activity score  $7 \pm 2$ ) group of patients.
2. Seven-year survivorship improved with 200 cases of experience from 93% to 98%.
3. Loosening of cemented femoral components is the most common failure mechanism (2.9%).
4. All femoral neck fractures (1.3%) occurred before 6-month follow-up.

5. Adverse reaction to wear debris was a rare clinical problem at 6- to 11-year follow-up (0.5%).
6. Dislocations are rare with large metal bearings (0%).
7. Thromboembolic phenomena are rare in young patients undergoing HRA (1 deep vein thrombosis).

These data support the further study of this bone-preserving operation in young and active patients. Because of the extended learning curve, the use of this procedure is best limited to surgeons who specialize in this procedure. We suggest investigation of uncemented fixation as an alternative to cement for the femoral component to avoid late aseptic loosening of femoral components.

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## Appendix

**Table 4.** Comparison of Survivor Rates After Total Joint Arthroplasty Among Different Studies

Study	Type of Implant	Years Operations Performed	Mean Duration of Follow-Up (y)	No. of Hips	Age of Patients	Survival Rate		
						Total	Femoral	Acetabular
THA with long-term follow-up for all ages								
Berry et al	Charnley	1969-1971	25	2000	<40	63.7%	NA	NA
					40-49	62.0%	NA	NA
					50-59	75.9%	NA	NA
					60-69	86.9%	NA	NA
					70-79	92.6%	NA	NA
Nercessian et al			18.9 (range, 15.3-25.4)	98		73.5%	NA	NA
Valle et al			20.5 (range, 20-21.6)	124	51.5 (range, 23-77)	NA	68%	96%
THA with midterm follow-up for young patients								
Aldinger et al [2]	Combined	1985-1989	Range, 15-20	154	47 (range, 13-55)	≈48.7%	92%	56%
Eskelinen et al [3]	NA	1980-2003	15	2557	>54	65%-74%	67%-87%	53%-80%
Dorr et al [4]	Charnley	NA	16.2 (range, 13-20)	49	31.1 (range, 16-45)	33%	NA	NA
McAuley et al [5]	NA	NA	15	561	>50	60%	NA	NA
Devitt et al [32]	Charnley	1970-1978	18.1 (range, 16-25)	167	42.5 (range, 16-49)	75%	NA	NA
HRA with midterm follow-up for young patients								
Gundle et al [33]	Birmingham hip resurfacing	1999-2006	4.2 (range, 2-7.6)	610	51.8 (range, 16.5-81.6)	95.0%	NA	NA
Shimmin et al [34]	Birmingham hip resurfacing	1999-2001	5 (range, 4-6)	226	52 (range, 18-82)	97.8%	NA	NA
Fordyce et al [24]	Birmingham hip resurfacing	1999-2002	5.9 (range, 5-7.8)	110	54.5 (range, 35-75)	96.3%	NA	NA
McMinn et al [22]	Birmingham hip resurfacing	1997-2000	7.8 (range, 6-9.6)	110	47.2	95.2%	NA	NA
Amstutz [11]	Conserve Plus	1996-2006	5.6 (range, 1.1-11)	1000	50 (range, 14-78)	95.2%	NA	NA
Jaffe et al [7]	Hybrid Corin Cormet 2000	2001-2003	2.6 (range, 2-3)	337	50.1	92.9%	94.3%	98.8%
Current study [19]	Hybrid Corin Cormet 2000	2001-2005	8 (range, 6-11)	373	50 (range, 15-78)	93%	96%	98%