A Comparison of Clinical Results of Hip Resurfacing Arthroplasty and 28mm Metal on Metal Total Hip Arthroplasty: A Randomised Trial with 3-6 Years Follow up.

Short Title: Randomized Trial Comparing Hip Resurfacing and Total Hip Arthroplasty

Authors:

Pascal-André Vendittoli, MD, MSc, FRCS(C)

Muthu Ganapathi, MBBS, MSc, FRCS, FRCS (ortho)

Alain G. Roy MD, FRSC(C)

Daniel Lusignan RN

Martin Lavigne, MD FRCS(C)

[1] Surgery Department of Maisonneuve Rosemont Hospital, University of Montreal, Montreal, Quebec, Canada

Please address all correspondence to:

Pascal-André Vendittoli
5415 boul L'Assomption
Montreal, Québec,
Canada
H1T 2M4
E-Mail: pa.vendittoli@videotron.ca
Tel: (514) 252-3823
Fax: (514) 252-0115

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Abstract

Two hundred and nine hips were randomized to receive either a 28-mm total hip athroplasty (THA, 100 hips) or hybrid hip resurfacing (HR, 109 hips). At 1 and 2 years post-operatively, patients with HR achieved statistically significantly better WOMAC functional scores. However, differences in scores were of slight clinical relevance with a difference of 2.2/100 and 3.3/100, at 1 and 2 years respectively (p=0.007). After an average follow-up of 56 months (range 36-72) there were similar re-operation rates 7/100 THA and 6/109 HR (p=0.655) and revision rates 2/100 THA and 4/109 HR (p=0.470). However, the types of complications were different. Higher early aseptic loosening rate was found in HR and long-term survival analysis of both patient cohorts is necessary to determine whether the potential bone preservation advantage offers by HR will overcome its earlier higher failure rate.

Key words: hip, arthroplasty, resurfacing, metal, randomised, clinical

Introduction

Total Hip Arthroplasty (THA) has demonstrated satisfactory survivorship and clinical outcome in older patients with fewer functional demands. However, implant failure remains a problem in younger subjects[1]. THA may also be associated with femoral stem-related thigh pain, leg length inequality, instability and reduced range of motion (ROM)[2-6].

Improvements in metal-on-metal (MoM) bearings have led to renewed interest in hip resurfacing (HR)[7-9]. The most obvious, attractive benefits of HR are preservation of the femoral neck and the avoidance of femoral canal violation, making future revision surgery easier[10,11]. Other proposed advantages include the conservation of hip biomechanics[12], easier leg length preservation[12] and rarity of dislocation[13]. Also, wear may be reduced with larger MoM bearings which, in turn, may lead to long-term implant durability[14].

To better assess whether there are real clinical benefits of HR in comparison with THA, we undertook a randomized controlled trial. Our main hypothesis was that HR subjects would demonstrate significantly better results on the Western Ontario McMaster osteoarthritis index (WOMAC)[15,16] at one and two years after surgery. We have published incomplete 1 year data[17] and different secondary early outcomes based on this study, including comparisons of biomechanical reconstruction[12], acetabular bone resection[18], and heterotopic bone formation[19]. The present paper reports the clinical and radiological results at a minimum 3-year follow-up.

Materials and Methods

Patients:

Ethics and scientific committee approvals were obtained from our institution for this study and informed consent was obtained for all participants. Patients presenting with degenerative hip joint disease between the ages of 18 and 65 years, who did not present one of the following exclusion criteria: proximal femoral deformity preventing HR, hip arthrodesis, renal insufficiency, known or suspected metal allergy and osteopenia or osteoporosis of the hip were recruited by 3 orthopaedic surgeons. Women above age 50 years were sent for pre-operative Dexa scan of the proximal femur. A T score of less than –1.0 was considered a contraindication to the HR procedure.

Group Allocation

Participants were randomly assigned to 2 treatment groups: 28-mm THA and HR. A randomization table (block of 5) for each surgeon was created with the Statistical Package for the Social Sciences (SPSS®, version 10.04, SPSS Inc., Chicago, IL, USA). Both surgeons and patients were kept blinded to the randomization group until the morning of surgery. All follow-up assessments were made by a research nurse not blinded to the treatment group.

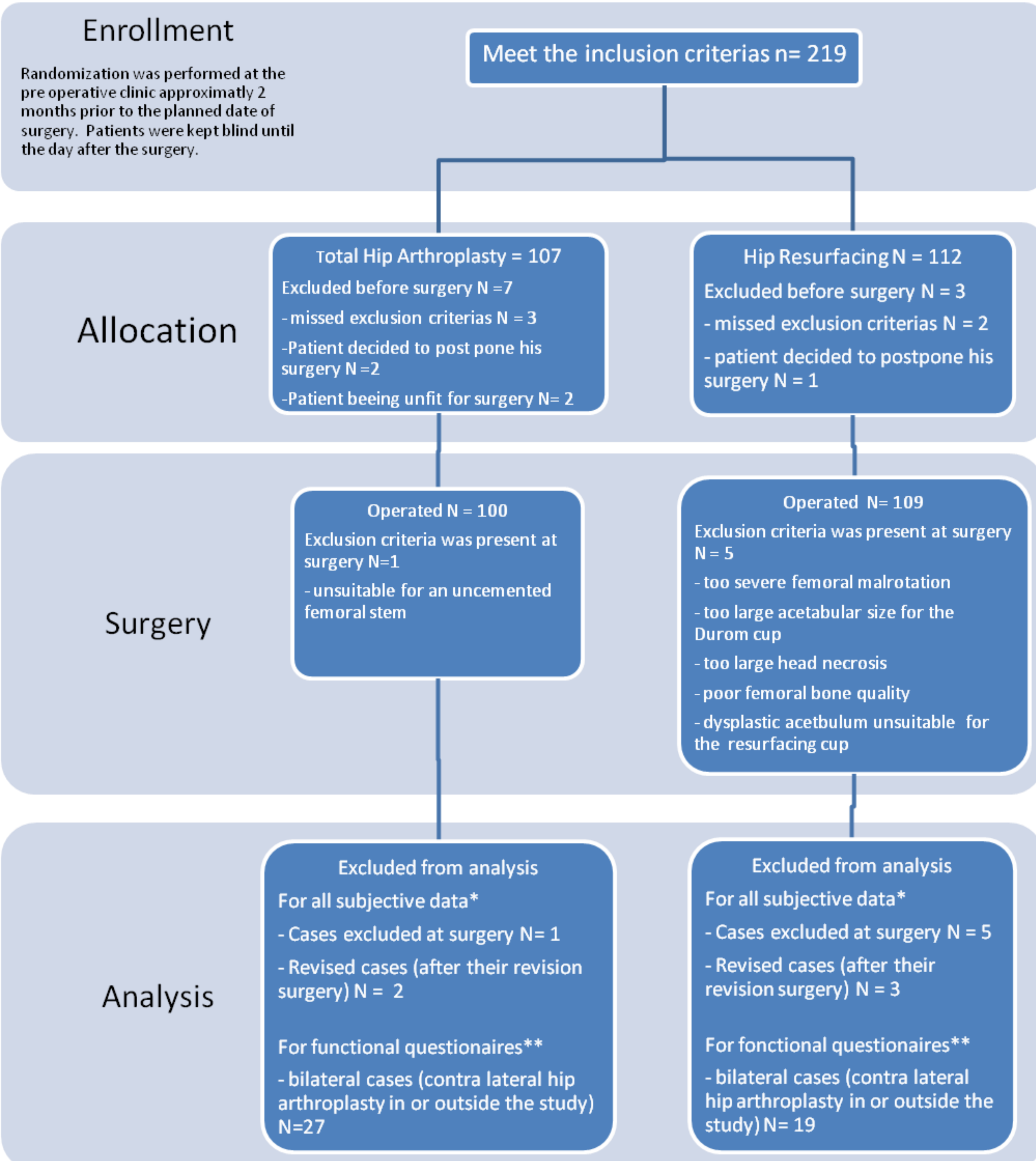
Sample size calculation

The main outcome measure of the present paper was the WOMAC[15,16,20,21] score in subjects with unilateral hip arthroplasty at 1 or 2 years post-operatively. Sample size calculation was based on a minimum statistically and clinically significant difference of 5/100. For Student's t-test with an alpha error of 0.05, a power of 80% and a standard deviation (SD) of 11.0 (our own unpublished data on a similar patient group), the required sample size was 76 cases in each prosthesis group. Two hundred and ten cases needed to be recruited to allow for an anticipated rate of 20% bilateral arthroplasty at 1 or 2 years and 15% loss to follow-up or withdrawal.

Study Groups

Two hundred and nineteen hips were recruited between July 2003 and January 2006 (see Figure 1 for flow diagram). Ten cases were excluded before surgery (3 in the HR group and 7 in the 28-mm THA group). The reasons for exclusion were: exclusion criteria missed at selection, patients unfit for surgery, and patients deciding to postpone their surgery. Two hundred and nine hips in 192 subjects were therefore operated (100 THA and 109 HR). The demographic data on both groups were comparable (Table 1)[22]. The planned implants could not be used in 5 hips originally randomized for HR. A summary of the peri-operative data on subjects not excluded at surgery is presented in Table 2[22].

Figure 1: Flow diagram of cases progressing through phases of the trial.



* Subjective data: patient satisfaction, patient perception of the reconstructed joint, reported pain (all operated hips were included in the complication and radiographic analyses)

** Functional questionnaires include: W.O.M.A.C., Merle d'Aubinié score, UCLA activity score and activity level. All other outcome measures include all operated cases and were excluded after a revision.

Table 1: Peri-operative data by group (all subjects who had a surgical procedure).

	THA	**HR**
N	100	109
Sex (Male/Female) Female percentage	68 / 32 32%	69 / 40 37%
Side (Right/Left) Right side percentage	53 / 47 53%	49 / 60 45%
Diagnosis		
Osteoarthritis Primary Impingement hips Protrusio	78 39 32 7	84 34 45 5
Perthes	3	3
Hip dysplasia Crowe 1 Crowe 2	7 5 2	10 6 4
Osteonecrosis	2	3
Post trauma	2	3
InflammatoryArthritis Rhumatoid arthritis Ankylosing spondylitis	8 6 2	5 4 1
Post septic arthritis	0	1
Age in years (min –max; SD)	51.0 (24-65; 8.6)	49.2 (23-64; 9.0)
Height in cm (min-max; SD)	172 (150 – 195; 9.6)	172 (151 – 192; 10.0)
BMI (min – max,; SD)	30.0 (17.4 – 49.1; 6.8)	27.0 (17.6 – 44.9; 5.3)

THA: total hip arthroplasty
HR: Hip resurfacing
Min: minimum
Max: maximum
SD: standard deviation of the mean
BMI: body mass index

Table 2: Peri-operative data by group (all subjects who had implanted one of the studied implant).

	THA	**HR**	**p value**
N	99	104	
Surgical time in minutes (min – max, SD)	87 (55 -173, 24.1)	101 (70 – 180, 18.1)	<0.001
Incision length in centimetres (min – max, SD)	15.1 (8.1 – 35.2, 5.0)	17.2 (10.3 – 30.0, 3.4)	0.004
Total blood loss in millilitres (min – max, SD)	543 (150 – 3300, 467.2)	529 (100 – 2100, 262.7)	0.792
Transfusion rate	9.7%	4.0%	0.107
Length of hospital stay in days	6.1	5.0	0.004
Rehabilitation at home vs rehab center	82%	91%	0.06
Acetabular vertical angle in degrees (min, max)	45.3 (30, 55)	47.3 (31-64)	0.05
HR femoral component CCD angle (min-max)		142.6 (130-157)	

THA: total hip arthroplasty
HR: Hip resurfacing
Min: minimum
Max: maximum
SD: standard deviation of the mean

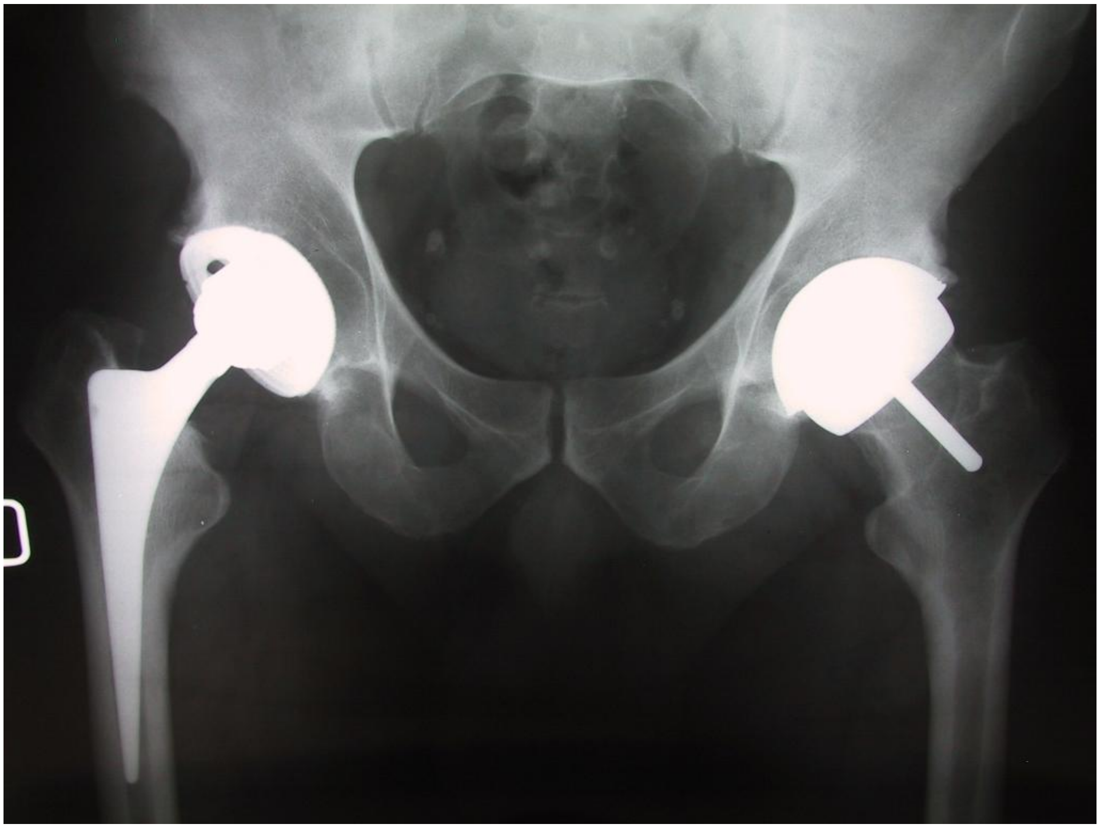
Seventeen patients underwent bilateral procedures: 6 bilateral THA, 6 bilateral HR, and 5 THA on one side and HR on the other side. Eighteen subjects already had a contralateral THA at randomization (10 in the THA group and 8 in the HR group). This left 72 THA and 85 HR patients with unilateral arthroplasty available to fill the functional questionnaires (Figure 1). Post-operative data at each follow-up included all unrevised cases for that follow-up period (patients being re-operated for other reasons were included).

Intervention

All procedures were performed with standard instruments and peri-operative antibiotic coverage. A posterior approach was used; the incision length was at the discretion of each surgeon. The external rotators and the posterior capsule were released during exposure and then re-attached with trans-osseous sutures at closure. Only for HR group, complete release of the gluteus maximus tendon insertion, circumferential capsulotomy and partial elevation of the gluteus minimus from the supra acetabular bone were performed in addition. The gluteus maximus tendon was repaired at closure.

All hips in THA group received a titanium, uncemented CLS-Spotorno™ femoral stem and Allofit™ acetabular cup with a 28 mm Metasul™ chrome-cobalt insert and femoral head (Zimmer, Warsaw, IN, USA; Figure 2). Implant options included 135 or 145 degree neck-shaft angle and neck lengths from -4 mm to +8 mm. The HR group received a hybrid Durom™ HR (Zimmer, Warsaw, IN; Figure 2), with a cemented femoral component and an uncemented acetabular component. Femoral head preparation included drilling of any sclerotic area and routine pulse lavage. Cementing was done with a low-viscosity cement with tobramycine (Simplex, Styker, Allendale, NJ) at approximately 4 minutes. The post-operative protocol included low-molecular weight heparin for 3 weeks, weight-bearing as tolerated for the THA group, and 3 to 4 weeks of protected weight-bearing for the HR group. Range of motion was restricted to 90 degrees of flexion and no internal rotation in the THA group for a period of 6 weeks. No range of motion restrictions were recommended in the HR group. Muscle strengthening and aerobic exercises were part of the post-operative protocol for both groups.

Figure 2 Antero-posterior radiograph of a patient who received a THA on his right hip and a HR on his left hip, both part of the study.



Outcome Measures

Functional:

WOMAC questionnaires were filled pre-operatively and at 3, 6, 12 and 24 months by the patients. Secondary outcomes included the Merle d'Aubigné-Postel scale[23], UCLA activity score[24] and functional tests, such as the "hop test" and "step test". For the "hop test", the patients were asked to hop on the operated limb for 10 repetitions. The "step test" consisted of climbing and stepping down a 35-cm high step with the operated limb (10 times). Both tests were graded as "very easy", "easy", "difficult" or "impossible" by the patients.

Radiographic:

Antero-posterior radiographs of the pelvis and a lateral radiograph of the hips were taken at each follow-up visit and compared with the immediate post-operative radiographs. All radiographs were scanned at 300 dpi with a high-resolution optical scanner (Vidar VXR-12, Herndon, VA, USA) and analyzed with Imagika™ software (View Tech, CMC Corp., NJ, USA). Signs of definite femoral stem loosening included a continuous lucent line of more than 2 mm, stem fracture, subsidence of more than 5 mm or change in component angulation of more than 5 degrees[25,26]. Signs of definite acetabular loosening included continuous radiolucency of more than 2 mm, component migration of more than 3 mm, component rotation, or the presence of broken screws[27].

Statistical analysis

Repeated-measures ANOVA was performed on WOMAC scores at 12 and 24 months as the within-subjects effect, and type of surgery as the between-subjects effect. Another repeated-measures ANOVA of WOMAC scores at 3, 6, 12 and 24 months and the same between-subjects effect was conducted to assess the effect of time over a longer period and to evaluate if there was a difference between groups at an early stage. In both cases, the analysis were undertaken with transformed scores (ln(x+1) instead of x) to correct non-normality of the data. For Merle d'Aubigné-Postel scores, the data were continuous and approximately normal before surgery, but could not be considered as continuous after surgery, becoming more and more "concentrated" on maximum values with time (at 24 months, more than 90% of subjects had a score of 17 or 18). To allow a sufficient number of subjects per cell, the scores were categorized as 16 or less or 17-18. Hence, a t-test was performed to compare the 2 groups before treatment, and chi-square tests were employed for the post-op data. Repeated-measures ANOVA was performed to compare UCLA scores for the 2 groups at 12 and 24 months. The study's power to find a statistically significant difference in UCLA activity score of 1.0/10 at 1 or 2 years was 95%. To compare the 2 groups for other results, Student' t test and the chi square test were used for continuous and categorical variables, respectively. Continuous variables are presented as mean ± SD, and categorical variables, as frequency and percentage. The data were analyzed by SPSS® 15.0 software (SPSS Inc.). The degree of significance was defined as $p<0.05$ for the main outcome.

Funding

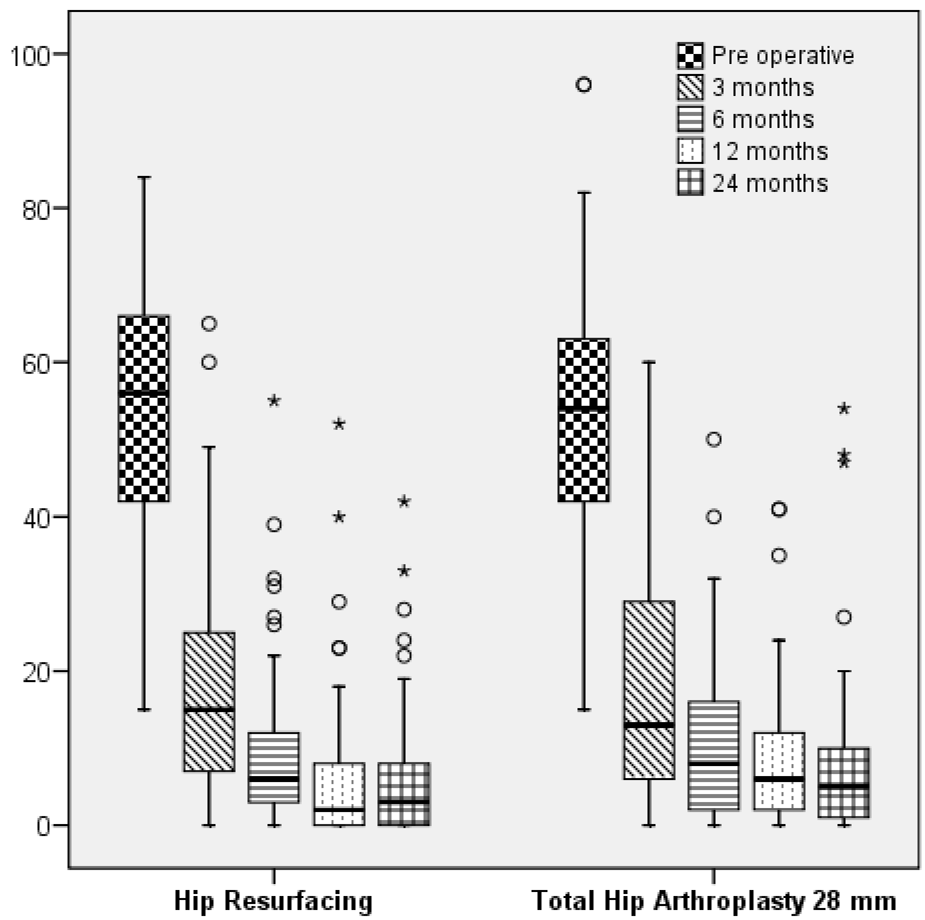
This study was funded by Zimmer, Warsaw, Indiana, USA

Results

Clinical outcome:

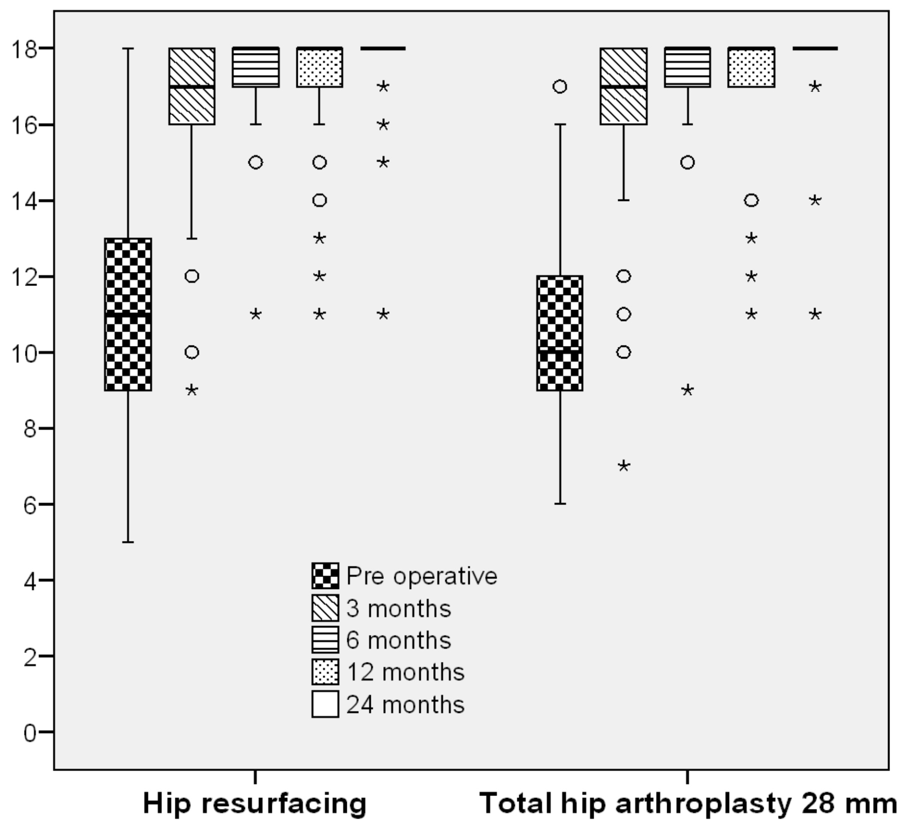
At pre-operative evaluation, no significant differences were found between the 2 groups on WOMAC scores: 54.4 (SD 18.3) versus 52.7 (SD 15.4) for THA and HR ($p=0.548$, Figure 3). At 12 and 24 months post-surgery, WOMAC scores were 10.2 (SD 10.7) and 9.0 (SD 11.9) for the THA group versus 8.0 (SD 13.2) and 5.7 (SD 8.6) for the HR group. Comparing WOMAC scores between groups at 12 and 24 months a significant difference was found between the two groups ($p=0.007$). Comparing WOMAC scores between groups including the 3, 6, 12 and 24 months scores, a significant improvement over time was observed for both groups ($p<0.001$). Scores variations for both groups during the follow ups was significantly different ($p=0.049$). This difference indicates that the scores of the 2 groups did not vary the same way with time: the 2 groups had close scores at 3 and 6 months, but between 6 and 12 months, the decrease in mean score was larger in the HR group. (The mean score for THA also declined, but at a slower rate.) Between 12 and 24 months, both mean scores declined at roughly the same rate, so the difference between the means stayed more or less similar. Further analysis pointed to a significant difference (for both groups) on scores between 3 and 6 months ($p<0.001$) and between 6 and 12 months ($p=0.001$) but not between 12 and 24 months ($p=0.916$). So a plateau was probably obtained between 12 and 24 months.

Figure 3 : Box plot chart of pre- and post-operative WOMAC scores for subjects with unilateral THA or HR. Data flagged by “o” are outliers (being more than 1.5 to 3.0 times the interquartile range over the third quartile), and data indicated by “*” are extreme values (more than 3 times the interquartile range over the third quartile).



For Merle d’Aubigné-Postel scores, no difference was found between groups, with a p-value of 0.351 (mean 10.4 (SD 2.5) for THA and mean 10.8 (SD 2.8) for HR; Figure 4). For the post-op data, there were no significant differences (p-values for 3, 6, 12 and 24 months were respectively 0.931, 0.427, 0.269 and 0.878). At 2 years, THA and HR had mean Merle d'Aubigné-Postel scores of 17.5 (SD 1.3) and 17.5 (SD 1.3).

Figure 4 : Box plot chart of pre- and post-operative Merle d'Aubigné-Postel scores for subjects with unilateral THA or HR. Data flagged by "o" are outliers (being more than 1.5 to 3.0 times the interquartile range over the third quartile), and data indicated by "*" are extreme values (more than 3 times the interquartile range over the third quartile).



Similar percentages of patients returned to heavy or moderate activities: 80% (59/74) for HR versus 75% (52/69) for THA (p=0.531) at 12 months, and 97% (70/72) for HR and 92% (60/65) for THA (p=0.192) at 24 months. On the UCLA activity scale, THA and HR had scores of 6.7 (SD 1.7) versus 7.2 (SD 1.9) at 12 months, and 7.1 (SD 1.6) versus 7.5 (SD 1.8) at 24 months. UCLA activity scores at 12 and 24 months showed no significant difference between groups (p=0.094). Moreover, scores for both groups did not significantly improved between 12 and 24 months (p=0.181). The percentage of subjects performing high-impact activity (UCLA score of 10) – 7% (5/70) for THA versus 15% (11/75) for HR at 12 months (p=0.148) and 11% (7/61) for THA versus 18% (12/67) for HR at 24 months (p=0.306) – did not reach statistical significance.

Including all operated cases where HR or THA was implanted and not revised (THA 98, HR 101), patient satisfaction was very high in both groups at 24-month follow-up, with 99% of very satisfied or satisfied patients in both groups (97/98 and 100/101). Among those working pre-operatively, more subjects in the HR group returned to their previous full time work at 1 year post-surgery: 95% (80/84) versus 83% (59/71) (p=0.013). However, at 2 years post-surgery, this difference was no longer present: 95% (76/80) versus 94% (63/67) (p=0.796). No significant differences were found regarding patients' perception of their reconstructed hip joint (Table 3). We were also unable to demonstrate any significant difference between the 2 groups with specific functional tests, such as the "hop test" or "step test" and the presence of Trendelenburg's sign (Table 4).

Table 3: Patients' perception of their reconstructed hip joint

	1 year follow up			2 years follow up		
	THA	HR	p	THA	HR	p
N	93	98		89	93	
			0.247*			0.471*
Natural hip	51%	45%		58%	53%	
Artificial hip without limitation	25%	26%		21%	20%	
Artificial hip with minimal limitation	25%	26%		19%	27%	
Artificial hip with significant limitations	0%	4%		1%	0%	
Non functional hip	0%	0%		0%	0%	

THA: total hip arthroplasty
HR: hip resurfacing
*Regrouping the 4 categories in 2: "hip without limitation" and "hip with limitation", Pearson Chi-Square p values are 0.451 and 0.291 for one and two years.

Table 4: Trendelenburg sign and Hop and Step tests

	6 months follow up			1 year follow up			2 years follow up		
	THA	HR	p	THA	HR	p	THA	HR	p
Number of hips	87	98		92	98		86	87	
Trendelenburg sign			0.587			0.452			0.414
Positive	12%	9%		2%	4%		2%	4%	
Hop test			0.296			0.152			0.268
Very easy	53%	62%		61%	76%		70%	78%	
Easy	24%	19%		27%	16%		17%	17%	
Difficult	16%	16%		7%	3%		5%	2%	
Impossible	7%	2%		5%	5%		8%	2%	
Step test			0.202			0.185			0.268
Very easy	45%	60%		54%	68%		70%	78%	
Easy	28%	18%		25%	20%		17%	17%	
Difficult	18%	15%		13%	6%		5%	2%	
Impossible	9%	6%		8%	5%		8%	2%	

THA: total hip arthroplasty
HR: hip resurfacing

Complications

There was no significant difference regarding reported pain/discomfort at any site for both groups for all follow up periods (Table 5). However in 4 HR cases (versus 0 in the THA) significant groin pain required investigation or treatment. Two HR had persisting femoro-acetabular impingement related pain. One underwent a successful femoral neck osteoplasty; for the other one, pain decreased over time to an acceptable level with conservative treatment. The 2 other painful HR patients had grade 3 Brooker HO. One had a successful surgical resection and the other one preferred conservative treatment. Pain reported at all other pain sites did not mandate treatment or affect patients' daily activities. Evaluating if the pain was related to different activities: walking, raising from a chair, at rest, put on shoes, climbing stairs, sexual intercourse and at night, no significant differences were found between the two groups at any period except raising from a chair at 6 months (THA 8%, SRA 21%, p=0.012).

Table 5: Pain at and around the hip at different follow up periods

	6 months follow up			1 year follow up			2 years follow up		
	THA	SRA	p	THA	SRA	p	THA	SRA	p
N	92	99		92	98		91	95	
Hip pain (any site)	24%	36%	0.071	41%	31%	0.124	20%	14%	0.265
Pain sites									
Groin	17%	22%	0.396	14%	13%	0.862	11%	10%	0.919
Greater trochanter area	17%	19%	0.731	15%	12%	0.551	7%	7%	0.836
Thigh	13%	8%	0.305	5%	4%	0.661	4%	2%	0.377
Buttock	9%	16%	0.157	12%	8%	0.370	3%	6%	0.432

While none of the patients in the HR group reported squeaking, it was present in 2 patients in the THA group who were able to reproduce it by loading the adducted and flexed hip joint. The squeaking noise was never heard during normal daily activities and finally disappeared after 2 years. Occasional clicks were encountered in 4 HR between 1 to 3 months after surgery and occurred during normal activities (standing, climbing stairs, etc.). All clicks disappeared at 3 to 6 months post-operatively.

At a mean of 56 months (range 36-72), 6 HR and 7 THA underwent a re-operation (Table 6). Revision surgery was performed in 4 HR for femoral head collapse at 6, 9, and 42 (2 cases) months after surgery. One female patient had a cyst involving >25% of the femoral head (Figure 5A-D), the second was a male patient with haemochromatosis, and the last two cases were a female and a male without particular risk factors. The four failed femoral components were revised without difficulty to an uncemented, tapered primary stem (CLS, Zimmer) and a large metal head that matched the well-fixed acetabular component. One patient with a HR developed painful grade 4 heterotopic ossification, who was unsatisfied with his hip ROM, was re-operated to remove ectopic bone at 27 months post-operatively. The final HR case was re-operated to relieve groin pain from persistent femoro-acetabular impingement caused by inadequate restoration of head-neck offset[28].

Table 6 Complications in both groups after an average follow up of 56 months (range 36 - 72 months)

	THA	HR	p*
Number of operated hips	100	109	
Complications			
Intra op acetabular fracture (uneventful)	0	2 (2%)	
Intra op proximal femoral fracture (uneventful)	4 (4%)	0	0.038
Deep vein thrombosis (clinically symptomatic)	3 (3%)	1 (1%)	
Neurapraxia (sciatic)	2 (2%)	1 (1%)	
Deep infection	5 (5%)	0	0.02
Early without recurrence	4 (4%)	0	
Chronic	1 (1%)	0	
Dislocation	4 (4%)	0	0.038
Simple, without recurrence	2 (2%)	0	
Recurrent dislocation	2 (2%)	0	
Femoral aseptic loosening	0	5 (5%)	0.030
Symptomatic leg length discrepancy	1 (1%)	0	
Symptomatic femoro acetabular impingement	0	2 (2%)	
Symptomatic heterotopic ossification	0	2 (2%)	
Total reoperations	7 (7%)	6 (6%)	0.655
Total revisions	2 (2%)	4 (4%)	0.470

*p-value were not reported when Chi square tests presented cells under n=4.

THA: total hip arthroplasty

HR: Hip resurfacing

THA cases where surgical intervention was needed are the following:

- 4 early deep infection without recurrence
- 1 chronic deep infection (1 revision)
- 1 recurrent dislocation (1 revision)
- 1 symptomatic leg length discrepancy

HR cases where surgical intervention was needed are the following:

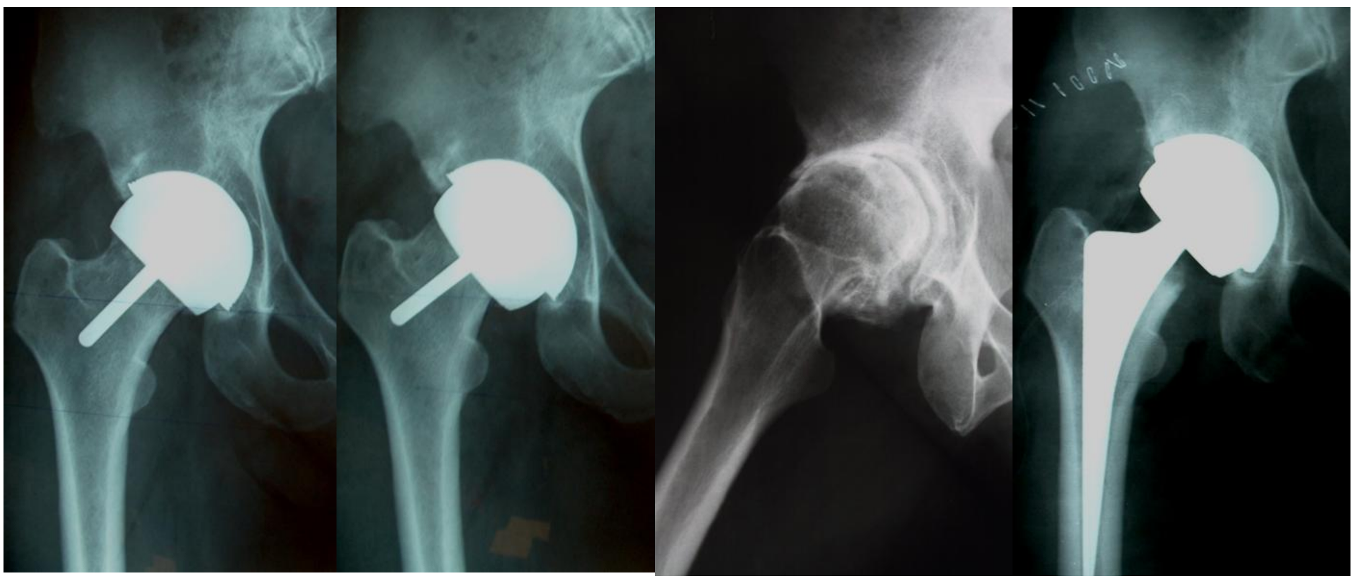
- 4 femoral aseptic loosening (4 revisions)
- 1 symptomatic femoro acetabular impingement
- 1 severe heterotopic ossification (Brooker grade 3-4)

Figure 5 A) Early post-operative antero-posterior radiograph of a right HR

B) Antero-posterior radiograph at 6 months follow-up showing varus angulation of the femoral component.

C) Pre-operative lateral radiograph of the proximal femur presenting a large head cyst in the anterior part.

D) Antero-posterior hip radiograph after the patient was revised with a modular large metal head femoral stem, keeping the acetabular component in place.



The seven re-operations in the THA group included: four early, deep infections that were debrided without further recurrence of infection. One chronic, late infection 18 months after surgery that needed 2-stage revision. One dislocation caused by acetabular component malposition which was treated with early revision of the acetabular component (too vertical and anteverted). The last re-operation occurred in a patient with persisting symptomatic leg length discrepancy, which was managed successfully by distal femoral shortening osteotomy. Three dislocation treated with closed reduction occurred in the THA group without recurrence. No patient in either group required a shoe lift for limb length discrepancy at the latest follow-up.

Radiographic analysis

At last follow-up (mean 56 months, range 36-72), none of the acetabular components were considered to be loose. Femoral neck narrowing of more than 10% was observed in only one HR asymptomatic patient. No migration or radiolucent line was seen in THA and HR cases, except for 2 HR which were considered loose at last follow-up. These femoral components presented a complete radiolucent line around the femoral stem and progressive varus tilt with telescoping (migration along the stem axis). Even if both subjects were asymptomatic, they were considered a radiographic failure, and are under regular review.

Discussion

Despite recent enthusiasm for HR, many unanswered questions remain. Adverse outcomes specific to HR include femoral neck fractures[29], femoral head avascular necrosis[30], persisting femoro-acetabular impingement[28], higher severe grades of heterotopic bone formation[19,31], and patients with extremely high metal ion levels[32,33]. Moreover, relevant radiolucent lines around stem and neck narrowing have been encountered, but their clinical significance is not clear[34,35].

Patient selection for HR procedure favours young, active males with primary osteoarthritis. Most recent reports on HR, therefore, involve a bias in patient selection and, thus, outcome after HR cannot be truly compared to reports on outcome after THA. A randomized study represents the most optimal design for appreciating the true value of HR in comparison to THA[36].

Comparison of implant survivorship between THA and HR is crucial to evaluate the long-term benefits of these procedures, but this will only be possible with long-term follow-up. In the present report, we asked whether there were important differences between HR and THA in terms of functional outcomes at 1 or 2 years post surgery. We also compared complication, re-operation and revision rates and radiographic analysis. As a primary outcome measure, we selected a validated functional score: WOMAC. Although a statistically significant difference was found, this study failed to show a clinically significant difference between the 2 treatment groups at 1 or 2 years after surgery. When using validated functional scales, such as the WOMAC, the scores obtained by such young and active patients can cause a ceiling effect of these scoring systems so that when most of them reach near maximal scores, it becomes difficult to demonstrate a clinical difference between the groups[37]. To overcome this potential ceiling effect, we analyzed the scores with a more specific questionnaire, the UCLA activity score, without finding a statistically significant difference between groups. The study's power to find a statistically significant difference in the UCLA activity score of 1.0/10 was 95%.

On the other hand, gait laboratory investigations may represent a more precise evaluation of functional outcome after hip arthroplasty, as some recent studies showed that HR patients performed better than THA subjects in the early post-operative period[38-40]. Although we did not undertake such gait analyses for all subjects in the current study, we used more demanding functional tests, such as the "hop test", the "step test" and Tredelenburg's sign, to differentiate both study groups, but we were unable to find a significant difference between them (Table 4). The "hop test" and "step test" require good postural balance as well as excellent muscle strength and control. Moreover, the "step test" requires good hip ROM (flexion).

In light of this study's inability to demonstrate a clear difference in functional outcome despite the multiple outcome measures, such a difference would certainly be of slight clinical relevance.

Study limitation

Patient awareness of their treatment group is a study limitation. Comparison in a double-blind trial would eliminate potential biases in patient and evaluator perceptions about the type of arthroplasty, although we feel that this would have been to the advantage of the HR group which did not clearly perform better in the study. Blinding patients implies either that both groups would have had to follow the same post-operative restriction protocol: no restriction (HR) or the posterior approach to hip restrictions (THA). By imposing THA restrictions on all, it could be argued that HR patients could not achieve their full potential. On the other hand, fearing dislocation, we felt that it would have been inappropriate to expose THA patients to an unrestricted protocol.

Regarding other outcome measures

Among subjects who were working prior to their surgery, more of them in the HR group returned to their previous full time work at 1-year post-surgery: 95% (80/84) versus 83% (59/71) ($p=0.013$). However, at 2 years post-surgery, this difference was no longer apparent: 95% (76/80) versus 94% (63/67) ($p=0.796$). Patient perception of their reconstructed hip was similar for both groups, with only about half of them considering their articulation as a "natural hip": 58% HR and 53% THA at 2 years (Table 3).

Surgical technique-related outcome

Patient selection was a significant factor affecting the ability to complete the surgical procedure[41]. In 5 hips randomized to HR, the planned procedure was abandoned because of technical difficulties. Surgeons should caution patients about this possibility and should have instruments available to convert the procedure to a THA.

Early complication rate

The most frequent early complications reported in the literature for THA are dislocation (3-4%)[3,42], intra-operative femoral fissure/fracture (2%)[43] and infection (1-2%). In HR, the main reported complication is femoral neck fracture (1-2%)[29]. In our study, we observed a comparable complication rate. However, intra-operative complications were different for both procedures. Four minor femoral fissures were noted intra-operatively in our THA group and were treated with cerclage wire and reinsertion of the stem. All fractures healed with protected weight-bearing, without stem subsidence at last follow-up. In contrast, minor fissures occurred on the acetabular side in 2 cases from the HR group. This could be explained by the stiffer acetabular component deployed in HR. Strong press fit is also required in the absence of the supplemental screw fixation option.

Four hips in the THA group dislocated, and 1 patient needed re-positioning of the acetabular cup. No dislocation was encountered in the HR group. Since the femoral head/neck ratio for HR (1.2-2.0) is lower than or equal to THA (2.0, 28-mm head with 14-mm neck), the head/neck ratio itself cannot explain the difference in the dislocation rate. The main factor favouring hip stability after HR is anatomical head size imposing greater jump distance, and once the hip capsule has healed, because of the large volume to displace, HR dislocation becomes almost impossible without complete capsule disruption.

Contrary to most reports, no patient sustained a femoral neck fracture in our HR group[29]. Careful patient selection and precise femoral component positioning with the alignment jig may have contributed to the absence of femoral neck fracture (no neck shaft angle below 130 degrees)[22]. However, 4 cases of femoral head collapse needed revision surgery. One failure was clearly due to poor patient selection. The femoral head bone of a female patient was osteopenic with a cyst greater than 1 cm[44]. The other was a male patient with haemochromatosis, a disease known to be associated with femoral head necrosis and a high failure rate in THA[45]. In these 2 cases, the retrieved heads were almost filled with cement. Overzealous jet lavage and cyst cement penetration might have been sources of the problem. Femoral head collapse is a specific complication related to the HR procedure. The above cases underlie the importance of careful patient selection, and better understanding of a favourable cementing technique is needed for short- and mid-term success of HR[44].

Pain

A proposed advantage of HR is better proximal femoral bone load transfer[46] and the absence of thigh pain. A low thigh pain rate is of primary importance when treating young and active patients. Only 4 patients in our THA group and 2 in the HR group reported occasional activity related to thigh pain at 2-year follow-up. In this randomised study, we did not find increased groin pain rate in HR versus THA subjects. However, in 4 HR cases, groin pain intensity mandated investigation or treatment versus 0 in the THA group. Pain in these cases was related to specific complications associated with HR: severe HO and persisting femoro-acetabular impingement[19,28].

Implant stability and survivorship

Radiographic evaluation at the latest follow-up showed stable components in all except 2 HR cases (migrated femoral component). These cases could be considered as "loose", but are asymptomatic and are being monitored. Lucent lines on the femoral side were not seen in any other HR. These observations are very different from those reported by Pollard et al. in 52 Birmingham HRs at a mean follow-up of 61 months (52-71 months)[34]. They found component migration in 10% (5/52) and lucent lines in 58% (30/52), around the stem and extending beyond 1 cm or more proximally. On the acetabular side, no continuous and/or progressive lucent lines were seen in our 2 groups. In a recent poster presentation by Dorr et al. (Metal-on-metal total hip arthroplasty using the Durom cup, 2009 AAOS annual meeting, Las Vegas, Nevada, USA) reported a very high rate of pain and secondary fixation failure (30/206 revised and further 29/206 radiographically loose after a follow up of 1.1 to 2.4 years) with the US version of the Durom^{TM} acetabular component. It is important to note that the Ti coating has been modified for the US version, and the results of the present study should be considered to represent the "worldwide" Durom^{TM} version.

Conclusion

In this randomized clinical study comparing HR and 28 mm THA in young patients suffering from hip joint degeneration, HR provided better early functional results but similar results were obtained at a follow-up of 2 years. Although both techniques had similar complication rates, the complications were of a different nature. Higher early aseptic loosening rate was found in HR and long-term survival analysis of both patient cohorts is necessary to determine whether the potential bone preservation advantage offers by HR will overcome its earlier higher failure rate.

Figure Legend

Figure 1 Flow diagram of cases progressing through phases of the trial.

Figure 2 Antero-posterior radiograph of a patient who received a THA on his right hip and a HR on his left hip, both part of the study.

Figure 3 Box plot chart of pre- and post-operative WOMAC scores for subjects with unilateral THA or HR. Data flagged by "o" are outliers (being more than 1.5 to 3.0 times the interquartile range over the third quartile), and data indicated by "*" are extreme values (more than 3 times the interquartile range over the third quartile).

Figure 4 Box plot chart of pre- and post-operative Merle d'Aubigné-Postel scores for subjects with unilateral THA or HR. Data flagged by "o" are outliers (being more than 1.5 to 3.0 times the interquartile range over the third quartile), and data indicated by "*" are extreme values (more than 3 times the interquartile range over the third quartile).

Figure 5 A) Early post-operative antero-posterior radiograph of a right HR.

B) Antero-posterior radiograph at 6 months follow-up showing varus angulation of the femoral component.

C) Pre-operative lateral radiograph of the proximal femur presenting a large head cyst in the anterior part.

D) Antero-posterior hip radiograph after the patient was revised with a modular large metal head and uncemented femoral stem, keeping the acetabular component in place.

REFERENCES

1. Malchau H, Herberts P, Eisler T, Garellick G, Soderman P. The Swedish Total Hip Replacement Register. *J Bone Joint Surg Am 2002;84-A Suppl 2:2-20.*
2. Lavernia C, D'Apuzzo M, Hernandez V, Lee D. Thigh pain in primary total hip arthroplasty: the effects of elastic moduli. *J Arthroplasty 2004;19-7 Suppl 2:10-6.*
3. Yuan L, Shih C. Dislocation after total hip arthroplasty. *Arch Orthop Trauma Surg 1999;119-5-6:263-6.*
4. Kluess D, Martin H, Mittelmeier W, Schmitz KP, Bader R. Influence of femoral head size on impingement, dislocation and stress distribution in total hip replacement. *Med Eng Phys 2007;29-4:465-71.*
5. Graehl PM. Leg-length discrepancy after total hip arthroplasty. *J Am Acad Orthop Surg 2006;14-5:319; author reply*
6. Parvizi J, Tarity TD, Slenker N, Wade F, Trappler R, Hozack WJ, Sim FH. Proximal femoral replacement in patients with non-neoplastic conditions. *J Bone Joint Surg Am 2007;89-5:1036-43.*
7. Amstutz HC. Hip resurfacing arthroplasty. *J Am Acad Orthop Surg 2006;14-8:452-3.*
8. Treacy RB, McBryde CW, Pynsent PB. Birmingham hip resurfacing arthroplasty. A minimum follow-up of five years. *J Bone Joint Surg Br 2005;87-2:167-70.*
9. Grigoris P, Roberts P, Panousis K, Bosch H. The evolution of hip resurfacing arthroplasty. *Orthop Clin North Am 2005;36-2:125-34, vii.*
10. Thomas BJ, Amstutz HC. Revision surgery for failed surface arthroplasty of the hip. *Clin Orthop Relat Res 1982-170:42-9.*
11. Beaule PE, Amstutz HC, Le Duff M, Dorey F. Surface arthroplasty for osteonecrosis of the hip: hemiresurfacing versus metal-on-metal hybrid resurfacing. *J Arthroplasty 2004;19-8 Suppl 3:54-8.*
12. Girard J, Lavigne M, Vendittoli PA, Roy AG. Biomechanical reconstruction of the hip: a randomised study comparing total hip resurfacing and total hip arthroplasty. *J Bone Joint Surg Br 2006;88-6:721-6.*
13. Shimmin AJ, Bare J, Back DL. Complications associated with hip resurfacing arthroplasty. *Orthop Clin North Am 2005;36-2:187-93, ix.*

14. Rieker CB, Schon R, Konrad R, Liebentritt G, Gnepf P, Shen M, Roberts P, Grigoris P. Influence of the clearance on in-vitro tribology of large diameter metal-on-metal articulations pertaining to resurfacing hip implants. *Orthop Clin North Am 2005;36-2:135-42, vii.*

15. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol 1988;15-12:1833-40.*

16. McGrory BJ, Harris WH. Can the western Ontario and McMaster Universities (WOMAC) osteoarthritis index be used to evaluate different hip joints in the same patient? *J Arthroplasty 1996;11-7:841-4.*

17. Vendittoli PA, Ganapathi M, Duval N, Lavoie P, Roy A, Lavigne M. Randomised controlled trial comparing two methods of acetabular cup positioning during total hip arthroplasty. *Hip Int 2007;17-3:137-42.*

18. Vendittoli PA, Lavigne M, Girard J, Roy AG. A randomised study comparing resection of acetabular bone at resurfacing and total hip replacement. *J Bone Joint Surg Br 2006;88-8:997-1002.*

19. Rama KR, Vendittoli PA, Ganapathi M, Borgmann R, Roy A, Lavigne M. Heterotopic ossification after surface replacement arthroplasty and total hip arthroplasty: a randomized study. *J Arthroplasty 2009;24-2:256-62.*

20. Bellamy N. Pain assessment in osteoarthritis: experience with the WOMAC osteoarthritis index. *Semin Arthritis Rheum 1989;18-4 Suppl 2:14-7.*

21. Laupacis A, Bourne R, Rorabeck C, Feeny D, Wong C, Tugwell P, Leslie K, Bullas R. The effect of elective total hip replacement on health-related quality of life. *J Bone Joint Surg Am 1993;75-11:1619-26.*

22. Vendittoli PA, Lavigne M, Roy AG, Lusignan D. A prospective randomized clinical trial comparing metal-on-metal total hip arthroplasty and metal-on-metal total hip resurfacing in patients less than 65 years old. *Hip International 2006;16-2 (suppl 4):S73-S81.*

23. Merle d'Aubigné R. Cotation chiffrée de la fonction de la hanche. *Revue de chirurgie orthopédique 1990;76:371-4.*

24. Amstutz HC, Thomas BJ, Jinnah R, Kim W, Grogan T, Yale C. Treatment of primary osteoarthritis of the hip. A comparison of total joint and surface replacement arthroplasty. *J Bone Joint Surg Am 1984;66-2:228-41.*

25. Harris WH, McCarthy JC, Jr., O'Neill DA. Femoral component loosening using contemporary techniques of femoral cement fixation. *J Bone Joint Surg Am 1982;64-7:1063-7.*

26. Malchau H, Karrholm J, Wang YX, Herberts P. Accuracy of migration analysis in hip arthroplasty. Digitized and conventional radiography, compared to radiostereometry in 51 patients. *Acta Orthop Scand 1995;66-5:418-24.*

27. Massin P, Schmidt L, Engh CA. Evaluation of cementless acetabular component migration. An experimental study. *J Arthroplasty 1989;4-3:245-51.*

28. Lavigne M, Rama KR, Roy A, Vendittoli PA. Painful impingement of the hip joint after total hip resurfacing: a report of two cases. *J Arthroplasty 2008;23-7:1074-9.*

29. Shimmin AJ, Back D. Femoral neck fractures following Birmingham hip resurfacing. *J Bone Joint Surg Br 2005;87-4:463-4.*

30. Lavigne M, Kalhor M, Beck M, Ganz R, Leunig M. Distribution of vascular foramina around the femoral head and neck junction: relevance for conservative intracapsular procedures of the hip. *Orthop Clin North Am 2005;36-2:171-6, viii.*

31. Back DL, Smith JD, Dalziel RE, Young DA, Shimmin A. Incidence of heterotopic ossification after hip resurfacing. *ANZ J Surg 2007;77-8:642-7.*

32. Boardman DR, Middleton FR, Kavanagh TG. A benign psoas mass following metal-on-metal resurfacing of the hip. *J Bone Joint Surg Br 2006;88-3:402-4.*

33. Allan DG, Trammell R, Dyrstad B, Barnhart B, Milbrandt JC. Serum cobalt and chromium elevations following hip resurfacing with the Cormet 2000 device. *J Surg Orthop Adv 2007;16-1:12-8.*

34. Pollard TC, Baker RP, Eastaugh-Waring SJ, Bannister GC. Treatment of the young active patient with osteoarthritis of the hip. A five- to seven-year comparison of hybrid total hip arthroplasty and metal-on-metal resurfacing. *J Bone Joint Surg Br 2006;88-5:592-600.*

35. Hing CB, Young DA, Dalziel RE, Bailey M, Back DL, Shimmin AJ. Narrowing of the neck in resurfacing arthroplasty of the hip: a radiological study. *J Bone Joint Surg Br 2007;89-8:1019-24.*

36. Howie DW, McGee MA, Costi K, Graves SE. Metal-on-metal resurfacing versus total hip replacement-the value of a randomized clinical trial. *Orthop Clin North Am 2005;36-2:195-201, ix.*

37. Marx RG, Jones EC, Atwan NC, Closkey RF, Salvati EA, Sculco TP. Measuring improvement following total hip and knee arthroplasty using patient-based measures of outcome. *J Bone Joint Surg Am 2005;87-9:1999-2005.*

38. Nantel J, Termoz N, Centomo H, Lavigne M, Vendittoli PA, Prince F. Postural balance during quiet standing in patients with total hip arthroplasty and surface replacement arthroplasty. *Clin Biomech (Bristol, Avon) 2008;23-4:402-7.*

39. Mont MA, Seyler TM, Ragland PS, Starr R, Erhart J, Bhave A. Gait analysis of patients with resurfacing hip arthroplasty compared with hip osteoarthritis and standard total hip arthroplasty. *J Arthroplasty 2007;22-1:100-8.*

40. Nantel J, Termoz N, Vendittoli PA, Lavigne M, Prince F. Gait patterns after total hip arthroplasty and surface replacement arthroplasty. *Arch Phys Med Rehabil 2009;90-3:463-9.*

41. Schmalzried TP, Silva M, de la Rosa MA, Choi ES, Fowble VA. Optimizing patient selection and outcomes with total hip resurfacing. *Clin Orthop Relat Res 2005;441:200-4.*

42. Phillips CB, Barrett JA, Losina E, Mahomed NN, Lingard EA, Guadagnoli E, Baron JA, Harris WH, Poss R, Katz JN. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *J Bone Joint Surg Am 2003;85-A-1:20-6.*

43. Taylor MM, Meyers MH, Harvey JP, Jr. Intraoperative femur fractures during total hip replacement. *Clin Orthop Relat Res 1978-137:96-103.*

44. Beaule PE, Dorey FJ, LeDuff M, Gruen T, Amstutz HC. Risk factors affecting outcome of metal-on-metal surface arthroplasty of the hip. *Clin Orthop 2004-418:87-93.*

45. Lunn JV, Gallagher PM, Hegarty S, Kaliszer M, Crowe J, Murray P, Bouchier-Hayes D. The role of hereditary hemochromatosis in aseptic loosening following primary total hip arthroplasty. *J Orthop Res 2005;23-3:542-8.*

46. Kishida Y, Sugano N, Nishii T, Miki H, Yamaguchi K, Yoshikawa H. Preservation of the bone mineral density of the femur after surface replacement of the hip. *J Bone Joint Surg Br 2004;86-2:185-9.*