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

P.-A. VENDITTOLI, M. LAVIGNE, A.-G. ROY, D. LUSIGNAN

Orthopaedic Service, Maisonneuve-Rosemont Hospital (University of Montreal affiliated Hospital), Montreal, Quebec - Canada

ABSTRACT: The purpose of this prospective randomised study is to compare the early clinical results of the metal-on-metal hip resurfacing to metal-on-metal THA. Two hundred and ten hips were randomised between August 2003 and January 2006 (191 subjects). One hundred and two hips were implanted with an uncemented titanium tapered stem, and an uncemented titanium acetabular component and 28 mm metal-on-metal bearing (THA group) and 103 hips received a hybrid metal-on-metal surface replacement arthroplasty (SRA group). No significant difference was found with the WOMAC or Merle d'Aubigné-Postel scales. However, a significantly higher activity level was found in the SRA group (UCLA score 6.3 versus 7.1, p= 0.037) and a greater percentage of the SRA patients returned to heavy or moderate activities at one - year postoperatively (72% versus 39%, p=0.007). No patient in either group presented with thigh pain one year after surgery. Both techniques present similar complication rates (0.15). This study supports the theory of better functional recovery in the short-term favouring the SRA when compared to THA. The clear benefit of surface replacement arthroplasty over THA is proximal femoral bone preservation. However, the long term survivorship of the SRA will determine the real value of the theoretical advantage. (Hip International 2006; 16 (suppl 4): S73-81)

KEY WORDS: Total hip arthroplasty, Surface replacement arthroplasty, Randomised trial, Taper stem, Metal bearing

INTRODUCTION

Although total hip arthroplasty (THA) has demonstrated a satisfactory clinical outcome in elderly patients, the same results have not been duplicated in the younger patient. In male patients younger than 55 years, THA failure approaches 33% at 16 year follow-up (1). With new technology being available, metal-on-metal total resurfacing of the hip joint has gained in popularity (2). Compared to THA, total hip resurfacing may present many advantages such as less bone is sacrificed, the femoral canal is not violated, hip biomechanics is preserved, leg length management is easier, dislocation of the joint is rare, and the potential for easier revision is increased (3, 4).

The few short-term clinical data reported in the literature for the new generation resurfacing implants demonstrate excellent outcomes (5). Survivorship of the implant seems to match THA for the same age group (5). Despite enthusiasm about modern, hybrid metal-on-metal total hip resurfacing, there is no direct comparative study with THA published in the literature (6). The main objective of this study is to compare the early clinical results of the metal-on-metal hip resurfacing to THA.

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Fig. 1 - *The CLS femoral stem (Zimmer, Winterthur, Switzerland) and the Allofit acetabular cup (Zimmer, Winterthur, Switzerland).*

Fig. 2 - *The hybrid Durom hip surface replacement system with wrought high carbon chrome-cobalt femoral head and acetabular cup (Zimmer, Winterthur, Switzerland).*

MATERIALS AND METHODS

Study population

Subjects, from 18 to 65 years of age with degenerative hip joint disease who were candidates for both metal-metal THA and SRA were recruited for study. Patient exclusion criteria was proximal femoral deformity preventing SRA implantation, hip arthrodesis, renal insufficiency, known or suspected metal allergy, osteopenia or osteoporosis of the hip. The study protocol was approved by the research ethics and scientific committees of our institution. All subjects who participated in the study gave written informed consent.

Study design

In this prospective study, patients were randomly assigned to two treatment groups (THA or SRA). For each surgeon (P.-A.V, M.L, A.-G.R) a block randomisation table was created with Statistical Package for the Social Sciences (SPSS®, version 10.04, SPSS Inc., Chicago, IL, USA).

Intervention

A posterior approach was used for both groups. Incision length was left to the surgeon's discretion. Standard instruments were used for all the operations. The external rotators were completely released while exposing, and reattached with trans-osseous sutures when closing. In the SRA group the posterior approach included a circumferential capsulotomy, a partial elevation of the gluteus minimus from the supra acetabular bone and, when necessary to increase femoral mobilisation, a complete release of the gluteus maximus femoral tendon was performed.

The THA group received the CLS femoral stem (Zimmer, Winterthur, Switzerland, Fig. 1), the Allofit acetabular cup (Zimmer, Winterthur, Switzerland, Fig. 1), a wrought high carbon chrome-cobalt polysandwich insert and 28 mm femoral head (Metasul, Zimmer, Winterthur, Switzerland, Fig. 1). Using the 135 or 145° neck shaft angle stem with different head neck length (-4 mm - +8 mm), surgeons took care to reproduce as possible the patient leg length and offset. The SRA group received the hybrid Durom with wrought high carbon chrome-cobalt femoral head and acetabular cup (Zimmer, Winterthur, Switzerland, Fig. 2).

Postoperatively, weight bearing as tolerated was allowed in the THA group and protected weight bearing for three to four weeks was advised for the SRA group. All patients were discharged home, and discharge was allowed once the patient could walk safely more than 50 m, climb stairs, transfer to and from the bed safely, and perform exercise programmes independently.

Outcome measures

Clinical function was evaluated, preoperatively, at three, six, and 12 months follow-up with the Western Ontario McMaster osteoarthritis index (WOMAC) (7), Merle d'Aubigné-Postel (8, 9) and UCLA activity score (10). Other measures included incision length, surgical time, surgical blood loss, different complications rates (dislocation, fracture, etc.), patient satisfaction and length of hospital stay.

Radiographic analysis

All radiographs were scanned at 300 dpi with a high-resolution optical scanner (Vidar VXR-12, Herndon, VA, USA) and analysed with Imagika™ software (View Tech, CMC Corp., NJ, USA). Patient diagnosis was classified by consensus of three ortho-paedic surgeons on the basis of clinical history, available laboratory tests and radiographs. To differentiate the hip impingement subgroup, lateral radiographs of the hip joint were examined carefully according to Nötzli et al (11). Acetabular dysplasia was diagnosed with an acetabular index of more than 20° and a center edge angle of Wiberg (12) of less than 20°. Dysplasia cases were subdivided according to the Crowe classification (13).

Statistical analysis

Student's t-test and the chi square test were used for continuous and categorical variables, respectively. Analyses were performed by Statistical Package for the Social Sciences (SPSS® 14.0 software, SPSS Inc., Chicago, IL, USA). The degree of statistical significance was defined as $p<0.05$.

RESULTS

Two hundred and ten hips (191 subjects: 163 with unilateral hip replacement, 15 with one of two hip replacements randomised in the study, and 16 with bilateral hip replacement randomised in the study; seven with bilateral THA, six with bilateral SRA and three with both) were randomised between August 2003 and January 2006. One hundred and three hips were randomly assigned to the THA group and 107 to the SRA group. Demographic data were comparable between groups (Tab. I). However, there was a difference in the average BMI between the groups (THA: 29.6 range 17.4 to 49.1, SRA: 27.2 range 17.6 to 44.9) ($p < 0.01$).

Four patients randomised for a SRA were excluded during surgery. Two were converted to a large head THA during surgery (Durom acetabular cup implanted with a modular Durom femoral head on a CLS stem). The first patient presented with extensive head necrosis which may have compromised the component fixation. The second patient had severe femoral neck retroversion which was not suitable for an anatomical reconstruction with a SRA. The third patient required a 73 mm acetabular cup, not available in the Durom SRA system. In the fourth patient, the surgeon had to use supplemental acetabular screw fixation to obtain primary fixation in moderate acetabular dyplasia. One patient randomized for uncemented THA presented with very poor proximal femur bone quality and during surgery the surgeon decided to use a cemented stem. One hundred and three SRA and 102 THA are left for pre- and postoperative data analyses.

Perioperative data comparison is presented in Table II. One revision was performed for recurrent dislocation secondary to a malpositioned acetabular component in the THA group. Two revisions were performed in the SRA group for femoral head aseptic loosening (one at six months and one at nine months post op). During revision of these two cases, the surgeon implanted an uncemented tapered primary stem (CLS, Zimmer, Winterthur, Switzerland) and a large metal head that matched the well fixed Durom (Zimmer, Winterthur, Switzerland) acetabular component. Two early deep infections occurred in the THA group. Patients were washed, debrided, and given intravenous antibiotics for six weeks with no recurrence of the infection to date (more than 18 months post lavage). In SRA, femoral

TABLE I - PATIENT DEMOGRAPHICS BY GROUP (N=HIPS)

	THA	SRA	p value
No.	103	107	
Sex (male/female)	70/33	67/40	0.416
Side (right/left)	51/52	51/56	0.845
Diagnosis			0.152
Osteoarthritis	78	81	
Primary	39	31	
Impingement hips	32	45	
Protrusio	7	5	
Perthes	3	3	
Hip dysplasia	7	10	
Crowe 1	5	6	
Crowe 2	2	4	
Osteonecrosis	2	3	
Post trauma	2	3	
Inflammatory arthritis	11	5	
Rhumatoid arthritis	9	4	
Ankylosing spondylitis	2	1	
Post septic arthritis	0	2	
Age in years	50.6	49.1	0.199
(min-max)	(24-65)	(23-64)	
Height in cm	172	172	0.999
(min-max)	(150-195)	(151-192)	
BMI	29.6	27.2	0.01
(min-max)	(17.4-49.1)	(17.6-44.9)	

BMI - body mass index.

TABLE II - PERIOPERATIVE DATA BY GROUP

	THA	SRA	p value
No.	102	103	
Surgical time in minutes	85	101	<0.001
(min-max)	(50-155)	(61-185)	
Incision length in centimetres	14.5	17.2	<0.001
(min-max)	(60-352)	(103-300)	
Total blood loss in millilitres	482	524	0.382
(min-max)	(100-3300)	(100-2200)	
Transfusion rate	9.7%	4.7%	0.193
Length of hospital stay in days	6.1	5.0	0.01
Rehabilitation at home (vs. rehab center)	82%	91%	0.06
Complications rate	13%	7%	0.151
Intra-op acetabular fissure (uneventful)	0	2	
Intra-op proximal femoral fissure (uneventful)	4	0	
Deep vein thrombosis (clinically symptomatic)	2	2	
Neurapraxia (sciatic)	2	1	
Early deep infection without recurrence	2	0	
Dislocation			
Traumatic without recurrence	2	0	
Recurrent dislocation	1	0	
Aseptic loosening	0	2	

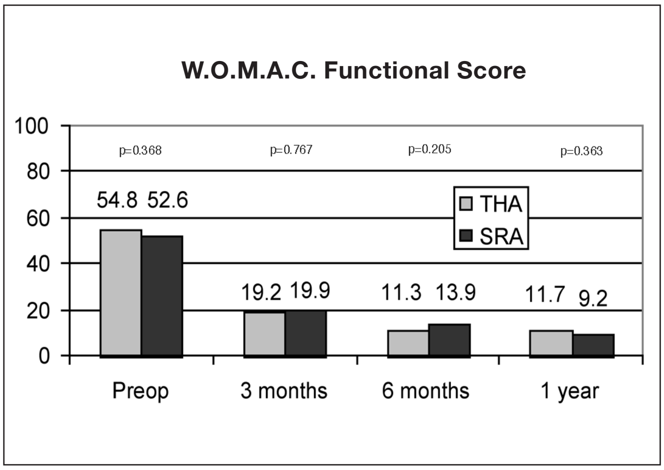

Fig. 3 - WOMAC score preoperative and at 3 months, 6 months and 1 year postoperative for the THA group and the SRA group.

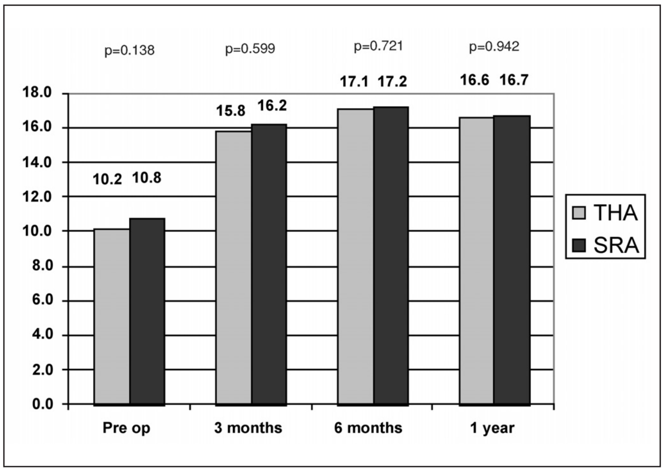

Fig. 4 - *Merle d'Aubigné Postel score preoperative and at 3 months, 6 months and 1 year postoperative for the THA group and the SRA group (maximum score = 18).*

TABLE III - RADIOGRAPHIC EVALUATION OF BOTH GROUPS*

	THA	SRA	p value
Acetabular vertical angle in degrees (min, max)	45.3 (30, 55)	47.3 (31,64)	0.05
SRA femoral component CCD angle (min, max)		142.6 (130, 157)	
SRA CCD angle modification from pre-op value/ (min, max)		7.8 (-6, 19)	
Preoperative leg length discrepancy in millimetres (min, max)*	-1.3 (-15.5, 9.7)	-1.6 (-14.6, 4.0)	0.536
Postoperative leg length discrepancy in millimetres (SD, min, max)*	3.0 (3.6, -6.0, 12.9)	-1.8 (2.6, -9.9, 5.9)	<0.001
Leg length discrepancy correction (post – pre) in millimetres (min, max)*	1.8 (-12.3, 10.7)	0.1 (-5.8, 5.5)	0.001
Preoperative femoral offset in millimetres (min, max)	34.5 (12.7, 47.9)	33.7 (17.1, 51.9)	0.443
Postoperative offset in millimetres (min, max)	39.0 (26.2, 54.0)	33.8 (10.2, 47.0)	<0.001
Offset correction (post – contra lateral) in millimetres (SD, min, max)*	4.2 (4.0, -6.9, 11.6)	-2.8 (3.3, -13.9, 6.7)	<0.001

*for valid measurement, these data exclude contralateral deformed cases and bilateral arthroplasties, n=145, 69 SRA and 76 THA.

neck notching of 1 mm occurred in six cases and 2 mm in two cases (total: n = 8/103, 8%). Seven of the notches were located at the antero-superior part of the femoral neck and one was in the posterior area. Most of the notches were in remodelled osteophytes, not in the native femoral neck. No neck fracture was seen in the SRA group. Results of the radiographic analysis are presented in Table III.

No significant difference was found between groups with the WOMAC and the Merle d'Aubigné-Postel scale (Figs. 3 and 4) and patient satisfaction was very high in both groups (98 % very satisfied or satisfied). More SRA

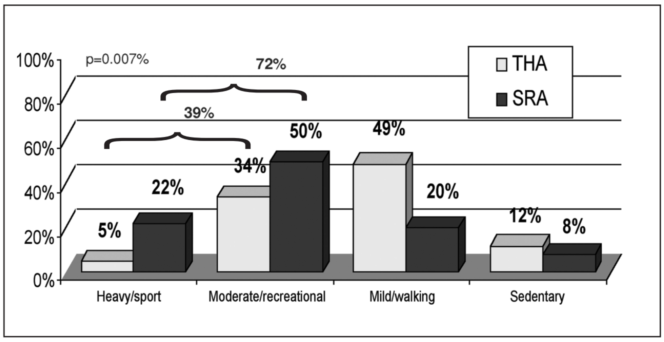

Fig. 5 - *Patients activity level 1 year after surgery for the THA and SRA groups.*

patients returned to heavy or moderate activities at one-year postoperatively (72% vs 39%, p= 0.007, Fig. 5). Of the subjects working pre-operatively, more SRA patients returned to work at one year following surgery (THA 14/21, 66% vs SRA 26/27, 96%, p=0.02). A statistically significant difference was found between the two groups using the UCLA activity score at the one year post op evaluation (THA, 6.3 and SRA 7.1, p=0.037). At one year post op, no patient in either group reported thigh pain at rest or during activities.

DISCUSSION

Despite the strong enthusiasm, many unanswered questions remain regarding metal-metal hip resurfacing. To be able to really appreciate the value of SRA, it must be compare to the gold standard treatment for hip degeneration (THA) utilising multiple outcome measures. In theory, the long-term survivorship of THA should exceed the patient's life expectancy. In the occurrence of a failure before patient death, the implant should be easily revisable and, the substituted THA composite should still offer good clinical function. To meet these expectations hip resurfacing with metal-on-metal bearing surfaces was reintroduced (14). Comparison of implant survivorship between THA and SRA is crucial but will be possible only with a follow-up of more than 10 years. Currently, there are also many other issues differentiating THA and SRA that can be compared including surgical technique, early complication rate, postoperative recovery, biomechanical hip joint restoration, clinical function, patient satisfaction, and presence of thigh pain.

In order to clarify the differences between SRA and THA with regards to those issues, we undertook a randomised study in August 2003. The primary strength of this study is the randomised design which reduces selection bias.

Perioperative results

In our study, surgical time and incision length were significantly longer in the SRA group. Keeping the femoral head, to obtain good acetabular exposure and be able to decrease the acetabular component abduction angle to near 45°, the surgeon must perform greater soft tissue releases (circumferential capsulotomy, gluteus maximus femoral insertion, and quadratus femoris) and use a longer skin incision (2.7 cm longer in SRA). Bone cement was only used for SRA femoral fixation so most of the surgical time difference (+16 min) could be attributable to the cement curing time (approximately 12 min).

Complications involving THA and SRA

The most frequent early complications reported for THA are dislocation at 3-4% (15, 16), intraoperative femoral fissure or fracture at 2% (17) and infection at 1%. In SRA, the frequently reported complication is femoral neck fracture at 1-2% (2). Our results in a group of 102 THA and 103 SRA are in accordance with the reported literature rates. However, one must note while both procedures present similar complication rates (SRA 7% vs THA 13%, p=0.151) they include different complication types. Uncemented tapered THA implants offer great clinical results (18, 19) but may be at increased risk of causing femoral fissure or fracture during implantation in comparison to cemented stems. In comparison, in the SRA group, we had fissures on the acetabular side. This could be explained by the stiffer acetabular component used in the SRA group (made of chromium and cobalt with a wall thickness of 4 mm) which need a strong press fit fixation in absence of the supplemental screw fixation option. Although the difference isn't significant, two infections occurred in the THA group and none in the SRA group. Possibly the antibiotic cement used in the SRA group (versus uncemented implant in the THA group) successfully prevented infection. Contrary to most reports, no patient sustained a femoral neck fracture in our SRA group (2). Careful patient selection and precise component positioning using the Durom alignment jig may have contributed to the absence of femoral neck fracture. This is also our continuing experience for patients we implanted with the Durom implant (no evidence of neck fracture in more than 200 cases). We observed different dislocation rates between groups (THA 3% vs SRA 0%). Since the femoral head/neck ratio for SRA (1.2-2.0) is lower or equal to THA (2.0, 28 mm head with 14 mm neck), this may not explain the difference. We believe that the main factor for hip stability after SRA is hip capsular healing in conjunction with its anatomical head size. Once the hip capsule is healed, because of the large volume to displace, SRA dislocation is impossible without a complete disruption of the capsule. In comparison, a 28 mm head may dislocate with slight capsular stretching.

Biomechanical restoration

Optimum hip biomechanical reconstruction is often associated with better functional outcome and a lower complication rate (20). Contrary to two recently published papers (non randomised) (21, 22), on a subgroup of the present study we found that hip biomechanical reconstruction was better achieved with SRA implants (n= 104, SRA 49 vs THA 55) (23). In the present paper, with the entire cohorts (n=145 patients with unilateral hip replacement or non deformed contra lateral proximal femur, SRA 69 vs THA 76), we found similar results. Surface replacement arthroplasty is more precise and reproducible allowing leg length and offset preservation/restoration within a narrower range of value. However, the potential for correction of severe preoperative deformity (leg length or offset) is limited with SRA in comparison to THA.

Bone conservation

Because of the high probability of revision surgery in the young and active adult, SRA of the hip is a promising surgical treatment for hip degeneration. In most surgery, femoral head and neck sizes dictate the acetabular component size (24). Some surgeons suggested that this limitation favours the selection of larger acetabular component size which may lead to more acetabular bone resection, in comparison to a standard THA (25). However, in the patient cohorts presented in this study, using specific SRA implants and following careful surgical planning and technique, we were able to remove similar amounts of acetabular bone in comparison to THA (average acetabular component size: 54.9 mm versus 54.7 mm, p=0.770) (24).

Clinical results

With validated functional scales including the WOMAC and the Merle D'Aubigné Postel scoring systems, we were not able to identify any significant difference between the two groups up to one year postoperative (Figs. 3 and 4). The scores obtained by these young and active cohorts of patients might cause a ceiling effect of these scales such that, if most patients obtain near maximal scores, it is difficult to demonstrate a difference between groups (26). However, using more specific scores such as the UCLA activity score, we were able to find a statistical significant difference between the two groups (THA, 6.3 and SRA 7.1, p=0.037). Surface replacement arthroplasty patients had a statistically significant shorter length of hospital stay (6.1 vs 5.0 days p=0.001). Of the subjects working preoperatively, more SRA patients had returned to work at 1 year after their surgery (THA 14/21, 66% versus SRA 26/27, 96%, p=0.02). These findings are in contradiction with the greater soft tissue dissection performed in SRA versus THA. Factors influencing positively the SRA outcome may be the absence of diaphyseal femoral invasion/fixation, improved proprioception, larger metal-metal femoral head size, and better biomechanical reconstruction.

A proposed advantage of SRA is better proximal femoral bone load transfer (27) and the absence of thigh pain. Low thigh pain rate is of primary importance when treating young and active patients. In THA, the thigh pain rate depends on the type of femoral implant fixation (cemented or not) and the stem design (18, 28). As reported by other authors (19), our THA patients (with CLS tapered femoral component, Zimmer, Winterthur, Switzerland) did not report any thigh pain after one year of follow-up. Regarding postoperative thigh pain, using this specific THA stem, it was then impossible to demonstrate any advantages for SRA.

Early failures

Three revisions were performed during the short follow-up of this study (minimum 6, maximum 40 months). One acetabular component in the THA group was repositioned at one week postoperative for recurrent dislocation secondary to an originally malpositioned component. Two SRAs were revised at six and nine months postoperatively for femoral aseptic loosening. One of the SRA patients had haemochromatosis disease which is recognised to be associated to a higher aseptic loosening rate in THA (29). The other failed femoral head had a cystic lesion measured to be 2 cm^2. Beaule et al found a significant relation between the presence of femoral head cystic lesion larger than 1 cm and a higher failure rate (4). These failures emphasize the importance of careful pre operative patient selection. At revision surgery, we found the two femoral head components were almost completely filled with cement. Overzealous head lavage and cement pressurisation may ultimately be the underlying reason for these two failures. Both femoral components were easily revised with a non-cemented primary femoral component and patients recovered similar to the primary THA group.

CONCLUSION

In our study THA and SRA results had similar satisfaction rates in young patients suffering from hip joint degeneration, but seems to offer better functional performance regarding activity level and capacity to return to work. Both techniques present different types of complications but similar rates of overall occurrence of complications. Surface replacement arthroplasty has a clear benefit over THA in proximal femoral bone preservation, but the long term survivorship of the SRA will determine the real value of this advantage.

Address for correspondence:
Pascal-André Vendittoli, MD
5345 boul L'Assomption, suite 55
Montreal, Québec, H1T 4B3, Canada
e-mail: pa.vendittoli@videotron.ca

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