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ORIGINAL STUDY

Results of Conserve Plus Hip Resurfacing : prospective clinical, radiographic and ion study

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We report the 3- to 5-year clinical, radiographic and serum ion level results of a prospective consecutive cohort of 42 hip resurfacing arthroplasties using the Conserve Plus implant in 39 male patients that were operated on by a single surgeon in a community hospital. Average age was 53 years (range 34-67) at surgery. There was one revision for a subcapital neck fracture. There were no surgery related complications. The survival of the implant was 95%. Clinical evaluation showed excellent results with a modified Charnley score of 17.6/18, Harris Hip Score of 96.2/100, WOMAC of 95.1/100, Oxford Score 15.3, and UCLA-Activity Score of 8/10. Radiographic analysis showed no implant at risk, no migration or signs of loosening, no neck narrowing and no osteolysis at final follow-up. Average cup inclination angle was 43.5° with 2 outliers (34° and 57°). Ion level study showed average cobalt in serum 1.04 µg/l (range 0-4) for the whole group, 0.7 µg/l (range 0-3) in patients with unilateral resurfacing and 2.0 µg/l (range 0-4) in patients with bilateral resurfacing. All patients had ion levels within the safe zone. This independent series of Conserve Plus HRA confirms good results at short- to mid-term with excellent wear characteristics. Results for avascular necrosis were equal to those for osteoarthritis.

Keywords : hip resurfacing ; ion levels ; clinical and radiographic results ; conserve plus.

INTRODUCTION

Total Hip Replacement (THR) gives excellent results with proven long term results in the elderly, but with concerns regarding its longevity in the younger population. Improvements in bearing designs have led to a resurgence of metal-on-metal (MoM) Hip Resurfacing. The advantages of hard-on-hard bearings regarding wear characteristics have to be outweighed against its possible disadvantages. While ceramic-on-ceramic exhibits the lowest wear rate, with excellent biocompatibility of ceramic trace elements, there is still the concern of ceramic fracture and instability due to the reduced head size. MoM Hip Resurfacing Arthroplasty (HRA) offers the advantage of recreating normal anatomy with preservation of proximal femoral bone stock, but there are concerns over the higher

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failure rate in the short term and over the toxicity of its wear products, metallic ions of which cobalt and chrome are the most important (*9*). Furthermore, there have been concerns over differences in results regarding the different brands on the market. Data from several registers show that HRA is performing well in a selected group of male patients and is probably superior in the young adult male population (*8*). The Conserve Plus HRA has been in use for over 15 years and the originator has published excellent results with up to 12 years of follow-up (*2*). Reports from independent centers are however scarce, and few studies have investigated ion levels in normal functioning individuals. It has also been suggested that MoM might have a higher prevalence of heterotopic ossification (HO) (*5*), and that results for avascular necrosis might be inferior (*4*). The purpose of the study was to evaluate the results of RHA performed by an independent surgeon in a community hospital, both clinically and radiographically. Also we wanted to evaluate the wear characteristics and hence the durability and possible longevity of the implant by evaluating the amount of cobalt in serum after the run-in period. Our follow-up includes the reporting of audible squeeking or clicking, the incidence of HO, and analysis of leg-length. In short, in-depth analysis of results of HRA.

MATERIAL AND METHODS

After approval of the Ethical Committee of the hospital, a prospective study was set up to evaluate the results of all HRA implanted in our hospital. Criteria for HRA in our department are male patients, with normal renal function, normal anatomy of the affected hip without significant leg length discrepancy, normal bone quality, suffering from debilitating pain due to osteoarthritis, avascular necrosis or posttraumatic osteoarthritis, and consenting to MoM THR. All patients operated on between January 2009 and January 2011 that were planned for HRA were entered in this prospective cohort study, and patients were consented for blood testing after a minimum of one year FU. The implant used was Conserve Plus (MicroPort Orthopaedics, Arlington USA), consisting of a 6 mm acetabular press-fit cobalt-chrome shell and a cemented femoral component. All surgeries were performed by the senior author (JS) in a standard operating room, wearing SteriShield protection (Stryker, USA). Simplex + tobramycin bone cement (Stryker Orthopaedics, USA) was used for all femoral components. The posterolateral approach was used for all patients and patients received a course of IV cefazoline during 24 hours (3 × 1 g). Preoperative planning was performed using a software planning system (Impax, Agfa Health Care, Belgium). Postoperatively a multimodal Venous Thrombo-Embolism (VTE) prophylaxis protocol was used with mechanical compression devices at night (AV-Impulse Foot Pumps, Covidien, Ireland) and aspirine or low molecular weight heparines (enoxaparine 40 mg) daily for 4 weeks. Patients received indomethacine during 5 days, starting the night before surgery, with omeprazole 20 mg orally as a protective measure. All patients were followed regularly at 6 weeks, 1, 3 and 5 years postoperatively and were evaluated clinically and radiographically. Patients had blood samples taken for analysis of cobalt in serum using Atomic Absorption Spectroscopy (AAS). Blood samples were taken in a standardized manner by a trained laboratory assistant and AAS was used in a ISO-certified laboratory. Detection limit for cobalt ions was 0.5 μg/l. At least one sample was taken after a minimum FU of one year, after the running-in phase. Clinical scores were performed independently by a physiotherapist (FL) and consisted of University of California at Los Angeles (UCLA) Activity Score (min 0-max 10), Oxford Score (min 48-max 12), Harris Hip Score (%), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (%) and modified Charnley Score (min 0-max 18). Patients were graded according to Charnley being grade A (one hip affected), B (both hips affected) or C (other joint involvement affecting the clinical scores) and were specifically asked for any presence of squeeking or clicking. X-ray evaluation consisted of AP-pelvis and lateral hip. X-rays were evaluated for component positioning and possible migration, evaluation of implant-bone interface, leg-length, the presence of HO according to Brookers classification, and the presence of lytic lines and osteolysis. The fate of all implants was known.

RESULTS

Forty-three HRA were performed in 40 patients over a 2-year period. Diagnosis for HRA was idiopathic or posttraumatic osteoarthritis in 31 hips, avascular necrosis in 10 hips, rheumatoid arthritis in 1 hip, and post septic arthritis chondrolysis in 1 hip. All patients have attended their 6-week FU

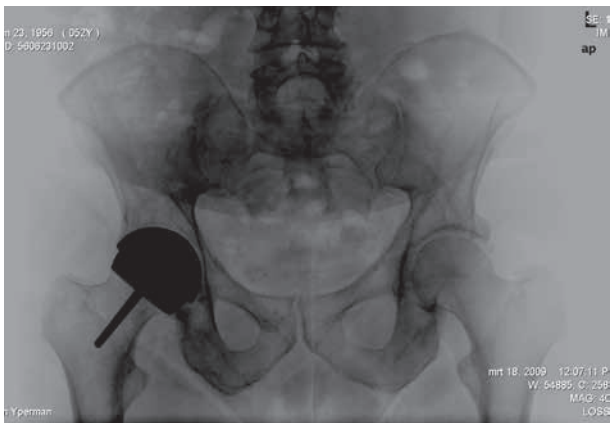

Fig. 1. — The Conserve Plus HRA. AP X-ray 3 year post surgery.

appointment. There were no complications in this series. One patient was excluded from the study because of the presence of a contralateral ASR HRA with elevated ion levels and presence of a failing ASR implant (diagnosis RA). This left 42 hips in 39 patients for evaluation. There were 2 patients lost to follow-up, but they could be contacted by telephone and had a well-functioning hip implant. This meant that the fate of all implants was known. One patient suffered a subcapital hip fracture after a fall one month after surgery, and he was converted to a THR with retention of the acetabular shell. One patient with a unilateral HRA was revised in another center for "hip pain" 9 months after surgery. The acetabular implant was in normal anteversion and 46° abduction angle without any radiological abnormality. The femoral component showed no abnormalities and he was classified as Brooker 1 at 6 months postop. He was known with hemisacralisation of the L5 transverse process and diagnosed with SI-joint pathology for which he received intermittent manual therapy with success. Diagnosis for revision was "intermittent pain in the groin and around the posterior hip region". No clear diagnosis was made at revision. The retrieved implant was not examined. All other implants (40/42) are in situ at present and functioning well. The overall survival rate was 95%. The revision rate for aseptic loosening was 0% at 5 years.

There were 35 patients for evaluation. All of these were clinically evaluated and had X-rays as per protocol. Four patients refused blood testing. This meant there were 35 patients with 38 HRA for clinical and radiographic evaluation and 31 patients with 34 implants for metal ion evaluation.

Clinical evaluation showed excellent results at a mean of 4 years (range 3-5 years). There were 28 Charnley category A patients, 5 category B and 6 category C patients. The patient reported average Oxford outcome score was 15.3 (range 12-21, where 12 is the maximum and best score), and all patients were satisfied with their hip implant. The average Harris Hip Score was 96.2 (range 100-82), the average modified Charnley Score was 17.6 (range 18-16), the average WOMAC-score was 95.1 (range 100-78). The average UCLA Activity Score was 8/10, with most patients scoring between 8-10, but 3 patients having a lower score due to cardiac or neurologic problems. None were limited by their HRA. No patient reported squeeking. There were no differences in clinical outcome in regard to the diagnosis for THA.

Radiographic evaluation showed that all implants were stable over time. There were no radiolucencies observed, and no signs of osteolysis was seen up to a maximum of 5 year follow-up. The average cup angle was 43.5° with only 2 out of 42 cups being outliers (34° and 57° respectively). The first outlier had a cobalt in serum of 2 μg/l ; the second outlier had also a cobalt level of 2 μg/l having bilateral THA. The femoral component had an average head-neck shaft angle of 135°. There were 30 hips with Brooker grade 0 (79%), 5 hips with grade 1 (13%), 3 with grade 2 (8%), and none with grade 3 or 4. There was one patient with symptomatic heterotopic ossification (grade 2) ; the others were asymptomatic. There were no differences in the radiographic outcomes in regard to the diagnosis. We observed no patient with significant neck narrowing up to date. Leg length was within 1 mm of normal anatomy in 34/38 hips (89%) ; in 2/38 the affected limb was lengthened by 4 and 7 mm respectively ; in 2/38 the limb was shortened by 8 and 10 mm respectively.

The average cobalt in serum was 1.04 μg/l (range 0-4 μg/l), with no patient showing an increase in values over time. Eighteen patients had undetectable levels of cobalt. The average level of cobalt of

unilateral THA was 0.7 μg/l (range 0-3 μg/l). The average level of cobalt of bilateral THA was 2.0 μg/l (range 0-4 μg/l).

One patient suffered from intermittent psoas tendonitis and groin pain after strenuous manual labor. His cobalt in serum was 3 μg/l and unchanged at 1 and 3 year follow-up. He had further investigations with normal ESR, CRP and complete normal X-ray, Tc99 bone scintigraphy and MRI following Metal Artefact Reduction Sequence (MARS-) protocol. This patient was originally treated for Femoro-Acetabular Impingement and had a postoperative septic arthritis with subsequent chondrolysis. It is unclear if his tendonitis and intermittent groin pain is related to the original diagnosis or to the implant.

Fig. 2. — The Conserve Plus HRA (Courtesy of Microport, Inc.).

DISCUSSION

In this study we have shown favorable results with the Conserve Plus HRA up to 5 years of follow-up. The results regarding survivorship are in line with those from the originator (*2*), and with those reported by Nam *et al* (*10*) showing survival of the implant in 94 to 97% at medium term. Medium term results of Birmingham Hip Replacement (BHR) show revision risk of around 2% (*8*). The published series from the originators of the BHR and Conserve Plus both show excellent long term survival of HRA : 88,5% at ten years for the Conserve Plus (*2*), and 95,8% at 15 years for the BHR (*4*). An independent study showed a 97,4% survival of the BHR at ten years (*3*), but 7% of patients were lost to follow-up. Also inclusion criteria and gender ratio might have influenced the results. The National Joint Registry data show a higher risk of revision for the Conserve Plus than the BHR (relative risk 2,03) (*8*), but the only comparative study between these 2 implants showed similar survival rates : 96,9% for Conserve Plus and 96,4% for BHR at 5 years (*10*). Pailhé *et al* showed in a systematic review that BHR, Conserve Plus and Cormet showed the best results for HRA, and all these implants meet the NICE-criteria (*11*). No differences in functional results could be found between these implants. It has been shown that female gender are at greater risk for revision after HRA (*8*).

Failure criterion is often revision of the implant for whatever reason. This criterion is not necessarily impartial because the sensitivity of the revision rate for clinical failure is not identical between HRA and THR. For hips with a poor functional outcome, only 12% of THR is being revised, as compared to 63% of HRA with a similar score. Registry data show revision rates of +/- 5% for HRA and +/- 4% for THR at medium term, but lower revision rates for HRA in men under age 55. Analysis of the English register showed that mortality in men was statistically lower for the BHR HRA in comparison to the uncemented THA group (*11*).

Subcapital hip fractures have been described after HRA, but its incidence is low (0.5-1%) (*11*). In our institution we have seen only 2 fractures over a period of 9 years, having performed well over 300 HRA procedures over that period. The incidence is well below 1%. In this series there was one fracture that was converted to a big ball femoral head THR and this patient is functioning well up to date (58 months FU). At the present time we do not advocate conversion to big femoral head MoM THR.

Besides subcapital hip fractures, another reason for failure is advanced reaction to metal debris (ARMD). Its incidence varies in the literature, also because of the difficulty in diagnosis. The largest

study on this topic from Langton *et al* studied the incidence of ARMD in a group of 4226 hips from 3 high volume surgeons in different centers (*9*). The found 58 failures with ARMD in this group, and their median cobalt and chrome levels were significantly higher than the control group. Survival analysis showed a failure rate due to ARMD of 9,8% for the ASR at 5 years, < 1% for the Conserve Plus at 5 years, and 1,5% for the BHR at 10 years. None of our patients have presented with ARMD up to date. One explanation might be that we have no patients with accelerated wear rates in our series. Real allergy to metal is rare and seems to be more prevalent in women.

Some authors have drawn the attention to the presence of groin pain after HRA. The group from Beaulé found its incidence to be as high as 18%, but declining with time (*7*). Its origin still has to be elucidated to date. We had 2 patients with groin pain, but could not find any abnormality. One patient was revised within one year in another center (see above). The second patient had psoas tendonitis, but only apparent after strenuous manual labor. This patient had a Harris Hip Score of 91 and a UCLA Activity Score of 9/10. His preoperative diagnosis was chondrolysis due to previous septic arthritis, which might explain the suboptimal result. Cup position was normal with good anteversion and no signs of psoas impingement. He declined psoas infiltration so far ; his MRI was normal with no signs of fluid collection of soft tissue reaction. It is important that surgeons are aware of the occurrence of "unexplainable groin pain" after HRA, as well as knowing the benign course over time of this problem, since patients might otherwise be offered revision THR inappropriately. A wait-and-see policy is advocated for as long as possible. Usually symptoms are mild and transient (*7*).

Psoas impingement has been described more frequently after HRA en big femoral head THR, and is often due to cup mal positioning. Lack of anteversion and/or anterior overhang of the metal shell is the main cause. We observed no such cases in this series.

We found no incidences of squeeking. Squeeking has been reported up to 6% in HRA, with Conserve Plus having the lowest incidence (0.75%) *(De Smet K. Unpublished data)*. Clicking and squeeking in MoM HRA is usually very mild and not disturbing to patients. It is rarely reported in the literature.

The activity scores were high in this series (8/10), as one can expect in a patient population of this age with well functioning implants. Nevertheless the measured ion levels were very low. Systemic levels of chromium and cobalt ions in whole blood, serum, or urine reportedly correlate with levels measured in joint fluid and with the linear and volumetric wear of the femoral component (*12*). During the run-in phase of MoM HRA the ion levels rise to peak levels approximately 9 to 12 months followed by a leveling-off or a slow decrease of the systemic Cr and Co concentrations once the lower wear steady-state phase is reached. Therefore ion levels should be measured after the implant is in use for more than one year, and they can be used as surrogate markers for accelerated wear, as shown by Van Der Straete, *et al* (*12*). Our results (0,7 μg/l for unilateral and 2,0 μg/l for bilateral HRA) favor well and are in line with other published data (*1,12*). Amstutz showed a median serum cobalt level of 1,06 μg/l for unilateral Conserve Plus HRA in 18 randomly selected patients (*1*). Bilateral HRA have a higher amount of serum metal ions, a fact that was confirmed in our series. All patients had cobalt levels well within the safe zone as described by Van Der Straeten *et al* (4 μg/l for unilateral HRA and 5 μg/l for bilateral HRA). One can expect that these values further decrease with time, as has been shown clearly by the study by Van Der Straeten *et al* (*13*), and by the study by Amstutz *et al* (*1*). In fact our results show an extremely low wear rate of the implant as reflected by a very low average cobalt level of 0,7 μg/l for unilateral HRA. Cobalt levels of Conserve Plus HRA are lower than those of BHR : the data from the De Smet series show statistically lower ion levels for Conserve Plus and Durom compared to ASR and BHR (*12*).

Heterotopic ossification is not being reported in many studies regarding HRA. In a series of 122 HRA patients, Geller reported a 75% incidence of HO (40% grade I, 20% grade II and 5,5% grade III) (*5*). In contrast to the study from Geller *et al*, we didn't find a high incidence of HO in our series. In fact our results show a very low rate of HO (13%

grade 1 and 8% grade 2), with the vast majority (79%) showing no signs of HO at all. This might be due to our protocol where all patients receive 100 mg of indomethacine for 5 days, starting the night before surgery.

We observed no cases of neck narrowing, and also no cases with aseptic loosening. The reported incidence of aseptic loosening is very low for BHR and Conserve Plus ; for all HRA +/- one third of revisions is for aseptic loosening (*11*).

One advantage of HRA is the very low rate of postoperative dislocation. In this series the dislocation rate was 0%. Another perceived advantage of HRA is the ability to better recreate the normal anatomy of the patient. It is well known that leg length inequality after conventional THR is of particular concern and lengthening more than 10 mm can lead to subjective dissatisfaction after surgery. In our series none had a leg length discrepancy of more than 10 mm, and in fact 89% of our HRA hips were within 1 mm of the normal anatomy.

The observed clinical VTE-rate in this series was 0% with a multimodal VTE-prophylaxis protocol. The total VTE-rate has been described to be in the order of 3-4%. Our numbers are too small to draw firm conclusions, but it has been proven that a multimodal protocol is safe and effective. Mechanical prophylaxis and early mobilization have been shown to decrease the clinical VTE-rate.

This study has several strengths. The study is performed in an independent center, and is single surgeon. All clinical scores are obtained by an independent physician. The fate of all implants is known and there is a complete clinical and radiographic analysis, supplemented with almost complete ion level data. Also the report includes data on the incidence of HO, leg length and the occurrence of possible squeeking. Weakness of the study is the small sample size, the relatively short follow-up time, and the absence of a control group.

In conclusion this consecutive prospective single surgeon series shows very good results of HRA with the Conserve Plus hybrid implant. The initial failure rate is low and the clinical data show excellent results in this high demand patient population. Most failures are seen in the first year. Subcapital hip fracture is a clear failure, but atypical groin pain is actually not ! Surgeons should be aware of the occurrence of atypical groin pain, and the benign course over time of this problem. We caution against overzealous revisions for "groin pain" in the absence of objective abnormalities of the implant and the surrounding tissues. The observed wear rates are extremely low and well below the safety threshold, and no adverse reactions were seen to date. We believe that this procedure is an excellent choice for the active male patient with hip osteoarthritis or avascular necrosis, provided that correct positioning of the implant is ensured and an implant is being used with a proven track record. In that setting, ARMD is a rare phenomenon, functionality very high and patient satisfaction to be expected. The use of indomethacine and meticulous operative technique ensures a low rate of heterotopic ossification. We advocate regular follow-up of these patients and further long-term data should be obtained to verify if these implants will last over time.

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