

Lessons learned from early clinical experience and results of 300 ASR[®] hip resurfacing implantations

T Siebel^{1*}, S Maubach¹, and M M Morlock²

¹ Orthopaedic Department, Knappschafts Krankenhaus Püttlingen, Püttlingen, Germany

² Biomechanics Section, TUHH Hamburg University of Technology, Hamburg, Germany

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Abstract: Between August 2003 and April 2005, 300 ASR[®] metal-on-metal resurfacing hip endoprostheses were implanted by the first author and a fellow surgeon. The mean age at surgery was 56.8 years (18–75.9 years) and mean body mass index was 27.6 kg/m² (range, 19–41 kg/m²). The mean follow-up time was 202 days. The mean Harris hip score improved from 44 pre-operatively to 89 at 3 months post-operatively. In total, eight (2.7 per cent) cases [five neck fractures (1.66 per cent) and three cup revisions (1 per cent)] were revised. Two neck fractures occurred within a group of seven cases of femoral neck notching detected post-operatively; one neck fracture occurred out of two cases of incomplete seating of the femoral implant. A significantly higher ($p < 0.001$) failure rate was observed for patients who had undergone a previous osteosynthesis of the proximal femur (three revisions in a group of 15 patients). Revision cases had a significantly greater body mass index ($p = 0.031$). A learning curve was evident from the reduction in revisions from 5 in the first 100 surgical procedures to 2 in the next 100 and 1 in the last 100. These results show the importance of accurate surgical technique and careful patient selection for fourth-generation hip resurfacing implants,

Keywords: resurfacing, fourth generation, hip, revision, ASR

1 INTRODUCTION

Resurfacing implants are being used in rapidly growing numbers. The high rate of early failure of 'second-generation' implants, such as the Wagner cup [1–5], is the reason why this type of implant has been largely abandoned in recent years. Whereas in the second generation of implants the combination of a polyethylene (PE) cup and metal head was used, the third generation of resurfacing implants introduced a metal-on-metal (MOM) combination. The lower volumetric wear [6] and less biologically active metal debris have eliminated the catastrophic failure rates due to osteolysis, initiated by the mass of PE debris particles produced by the former generation of implants [7–8]. Long-term clinical results have been much better for third-generation MOM resurfacing implants [9]. Failure mechanisms of the

MOM implant generation have been found to be due to osteonecrosis [10] and femoral neck fracture [11, 12]. Additionally, the mechanical failure mechanisms of the bone–cement interface [13] and the fatigue failure of the bone in the head and neck regions [14, 15] have been discussed.

The latest 'fourth'-generation of resurfacing implants has been further improved by modifications in the design to preserve maximum bone by using thinner implant walls (especially on the acetabular side). Taking the ASR[®] system (Depuy International Ltd, Leeds, UK) as an example, the head geometry has a 3° inside taper (in comparison with the parallel-sided design of third-generation implants) to improve seating and to minimize the risk of disturbing the femoral neck. The pin of the femoral implant has been made thinner, to avoid stress shielding, and should be over-reamed. Implant diameters are available in 2 mm increments to improve the possibility of bone preservation. The diametral bearing clearance (between head and cup) has been reduced to 110 µm, on average, to minimize metal wear,

*Corresponding author: Orthopaedic Department, Knappschafts Krankenhaus Püttlingen, In der Humes, Püttlingen, Germany D-66346. email: orthopaedie@kk-puettingen.de

especially during the bedding-in phase, by attempting to optimize the lubrication regime for fluid-film lubrication [16]. The uncemented cup is covered with a Duofix® surface (hydroxyapatite layer 30–50 µm thick on a Porocoat® surface with an average pore size of 250 µm). Fins or screw fixation of the cup have been avoided to optimize the subhemispherical press fit and full seating of the implant.

The aim of this study was to assess the early clinical results for a new fourth-generation resurfacing hip replacement.

2 METHODS

2.1 General comments

Between August 2003 and April 2005, 300 patients were treated with an ASR® resurfacing implant (Depuy International Ltd, Leeds, UK) at the Orthopaedic Department of the Knappschafts hospital, Püttlingen, Germany. The implantations were performed by two surgeons (the first author and a fellow surgeon). All 300 patients were included in this prospective study and completely followed up, consisting of 108 female and 192 male subjects. The average age at the time of surgery was 56.8 years (18–76 years) with an average body mass index (BMI) of 27.6 kg/m² (range, 19–41 kg/m²). The mean follow-up time was 202 days (standard deviation (SD), 155 days). The majority of patients were treated with cup implants with a 56 mm outside diameter. Sixty-six patients underwent a pre-operative clinical examination, which was repeated at 3 months. The follow-up for these patients was 115 days (SD, 25 days).

2.2 Patient selection

The optimal indication for resurfacing was taken to be a case of valgus coxarthrosis with a large head-to-neck diameter ratio (greater than 1.2). This implies a large head with a relatively narrow neck of the femur. Only patients having caput–collum–diaphysis (CCD) angles in the range 130–145° were treated with a resurfacing implant.

Additional indications were mild dysplastic coxarthrosis and post-traumatic deformations. Borderline indications were head necrosis (only included in the case of a sclerotic repair stage). Patients older than 65 years at the time of surgery, patients who had undergone previous osteosynthesis of the ipsilateral hip, and cases of suspected osteoporosis were pre-operatively checked by dual X-ray absorptiometry scan for the bone quantity of the femoral neck. If the result indicated a bone age below 65

years, the patients were included; otherwise they were treated with a standard endoprosthesis. The BMI was not a criterion for patient selection.

A manifest osteoporosis, coxa vara, a previous infection, a malfunction of the kidneys or cysts more than 30 per cent of the femoral head diameter, a small head-to-neck ratio (below 1.1), and a very short neck (for example, in case of severe Perthes disease) were criteria for exclusion of an ASR® implantation.

2.3 Intra-operative procedure

A single shot of antibiotic (second-generation cephalosporin) was administered prophylactically. The dorsal approach with an incision length of 10–12 cm was used. The external rotators (Mm. piriformis, gemelli, obturatorius internus et externus) and the M. quadratus femoris were detached and an L-shaped incision of the capsule was made. Those structures were refixed by sutures after implantation. The uncemented subhemispherical acetabular component was implanted with a press fit by underreaming the acetabulum by 1 mm, according to the manufacturer's recommendation. Acetabular osteophytes were fully removed. Acetabular or femoral head cysts were resected and grafted with spongy bone harvested from the reaming residue. After reaming the head, areas of sclerotic bone were drilled to improve cement penetration. Before cement application, suction was applied to the femur through the central guiding hole in the femoral head. The trabecular bone of the head was cleaned by jet lavage to increase interdigitation of the cement. A small amount of low viscosity vacuum-mixed cement was applied by 'finger packing' to the reamed head to create a thin cement layer, which minimizes the polymerization temperature. The resurfacing head was fully seated by manual force, to avoid microfractures in the bone. Non-bridging femoral osteophytes on the femoral neck were removed. Bridging osteophytes were left untouched, since they may be load-bearing structures. This is critical in prevention of neck fractures. Immediately after implantation the hip was reduced, a single drainage was applied, structures refixed, and the wound closed.

Post-operatively heparin was administered as a low-molecular-weight thrombosis prophylactic as part of the standard surgical procedure. Weight bearing was allowed on the first day after surgery, according to pain levels, using two crutches during walking for a minimum of 4 weeks. The patients were advised that no activities involving external rotation against resistance or deep flexion with simultaneous internal rotation were permitted for a period of 6 weeks. High-impact sports activities such as jogging, tennis,

Table 1 Continuous demographic variables for the patients in the study (revision and non-revision cases)

Variable	Revision	<i>n</i>	Mean	SD	Minimum	Maximum	Significance
Age (years)	No	292	56.8	8.4	18.0	75.9	<i>p</i> = 0.553
	Yes	8	55.0	9.1	36.1	65.4	
	All	300	56.8	8.4	18.0	75.9	
Height (m)	No	292	1.72	0.08	1.50	1.90	<i>p</i> = 0.011
	Yes	8	1.79	0.08	1.70	1.90	
	All	300	1.72	0.08	1.50	1.90	
Weight (kg)	No	292	81.1	13.7	52.0	127.0	<i>p</i> = 0.001
	Yes	8	97.8	17.3	70.0	124.0	
	All	300	81.5	14.0	52.0	127.0	
BMI (kg/m ²)	No	292	27.5	3.9	19.0	39.0	<i>p</i> = 0.032
	Yes	8	30.6	5.8	25.0	41.0	
	All	300	27.6	4.0	19.0	41.0	

or skiing were not recommended for a minimum of 6 months (remodelling period of the neck).

2.4 Analysis

Patients were contacted by telephone for this study and questioned qualitatively about their satisfaction (yes/no). Harris hip score and UCLA score were assessed pre-operatively and at 3 months post-operatively for a group of 66 patients. Factors considered for all 300 patients were age, height, mass, and BMI as continuous variables. Gender, previous surgery of the proximal femur, notching of the femoral neck due to reaming (assessed from post-operative X-rays), and grade head necrosis (in a sclerotic repair stage) were treated as nominal variables. The data were analysed statistically using 'SPSS 12.1 for Windows' (SPSS Inc., USA). Nominal variables were analysed using a χ^2 test and continuous variables using one-way analysis of variance. A learning curve was analysed by comparing the number of revisions for consecutive surgeries. The surgeries were grouped in units of 50. A Kaplan–Meier survival analysis was also performed with 'days after surgery without revision' as the time variable. A stepwise discriminant analysis was performed with revision as the dependent variable and all patient demographics as independent variables. Type II error probability was set to 5 per cent ($\alpha = 0.05$) for all tests.

3 RESULTS

The mean follow-up time for all patients was 202 days (SD, 155 days). Overall, eight patients of 300 operated on (2.8 per cent) had to be revised. No deep-wound infection or clinically apparent thrombo-embolism was observed.

The mean 3 month follow-up time was 114 days

(SD, 25 days). The pre-operative Harris hip score of 44 ± 11 points (mean \pm SD) increased to 89 ± 13 at 3 months post-operatively ($n = 66$). The UCLA score improved from 4.0 ± 1.5 points pre-operatively to 6.1 ± 1.2 points at 3 months post-operatively ($n = 66$). Most patients contacted by phone ($n = 234$) were satisfied with the result of the surgery (94.5 per cent answered 'yes').

The statistical analysis showed a significantly higher risk of revision in the case of greater BMI ($p = 0.032$), weight ($p = 0.001$), and height ($p = 0.011$) but there was no significant effect of age ($p = 0.553$) (Table 1). There was a trend for higher risk of failure in men ($p = 0.160$; male, 3.6 per cent; female, 0.9 per cent).

In total, five neck fractures (four male and one female) were observed. All these occurred within a

Table 2 Nominal variables for successful and revision cases

		Number of revisions		Total number
		No	Yes	
Gender	Male	185 96.4%	7 3.8%	192
	Female	107 99.1%	1 0.9%	108
Notching	No	282 97.9%	6 2.1%	288
	Maybe	5 100.0%	0 0.0%	5
	Yes	5 71.4%	2 28.6%	7
Previous surgery	No	280 98.2%	5 1.8%	285
	Yes	12 80.0%	3 20.0%	15
Necrosis	No	264 97.8%	6 2.2%	270
	Yes	28 93.1%	2 6.7%	30

time frame of 4 months post-operatively. Two of these fractures was observed to be in a group of seven cases in which definite notching of the femoral neck was observed post-operatively by X-rays (Figs 1 and 2, and Table 2). A further five cases were judged to be 'maybe' notched post-operatively by X-ray examination.

One of two cases of incomplete seating of the head and consequent exposure of reamed bone at the head–neck interface (judged by post-operative X-ray examination) was suggested as the reason for a further neck fracture (Fig. 3). Neck fractures occurred in two cases of 15 patients who had undergone a previous osteosynthesis of the proximal ipsilateral femur (Fig. 4). Incomplete seating of the femoral implant showed a trend for increased risk of failure, while previous surgery and intra-operative notching increased the risk of a revision surgery significantly

($p < 0.001$ for each variable). In all these failures the head remained within the cup after fracture. After resection of the femoral neck a conventional stem with an ASR® XL revision head (Depuy International Ltd, Leeds, UK) was implanted.

The pre-operative diagnosis of a necrosis in a sclerotic repair stage showed an increased but non-significant ($p = 0.164$) risk of post-operative failure within the short-term follow-up period.

In one case an incorrectly implanted cup with excessively steep inclination had subsided in the trabecular bone, resulting in contact of the head with the acetabular bone. This painful implantation was repositioned (Fig. 5). A non-compliant patient who suffered from Parkinson's disease experienced a post-operative luxation, leading to surgical replacement of the cup in maximal anteversion. In one case a synovectomy was performed owing to persistence of

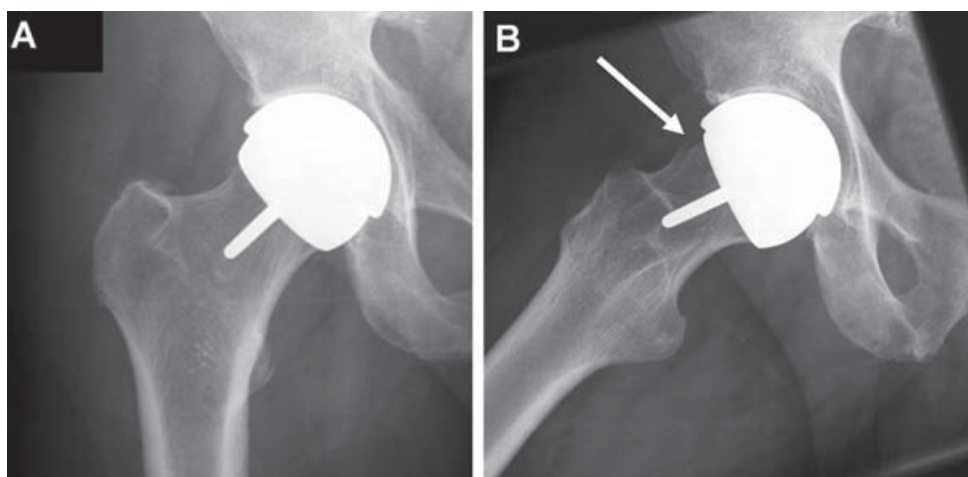


Fig. 1 A 54-year-old patient (coxarthrosis) with clear notching of the superior aspect of the neck (arrow): (A) anterior–posterior view; (B) medial–lateral view

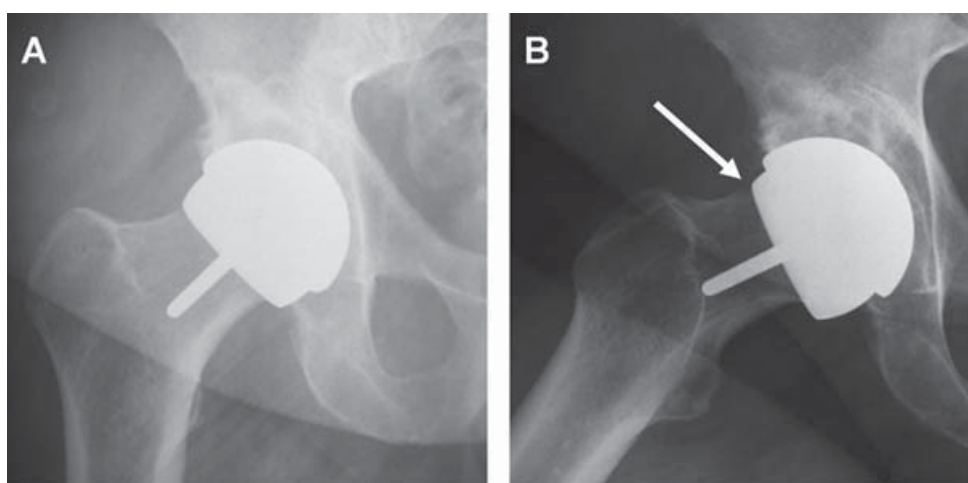


Fig. 2 A 61-year-old patient (osteoarthrosis) with notching of the superior aspect of the neck (arrow): (A) anterior–posterior view; (B) medial–lateral view

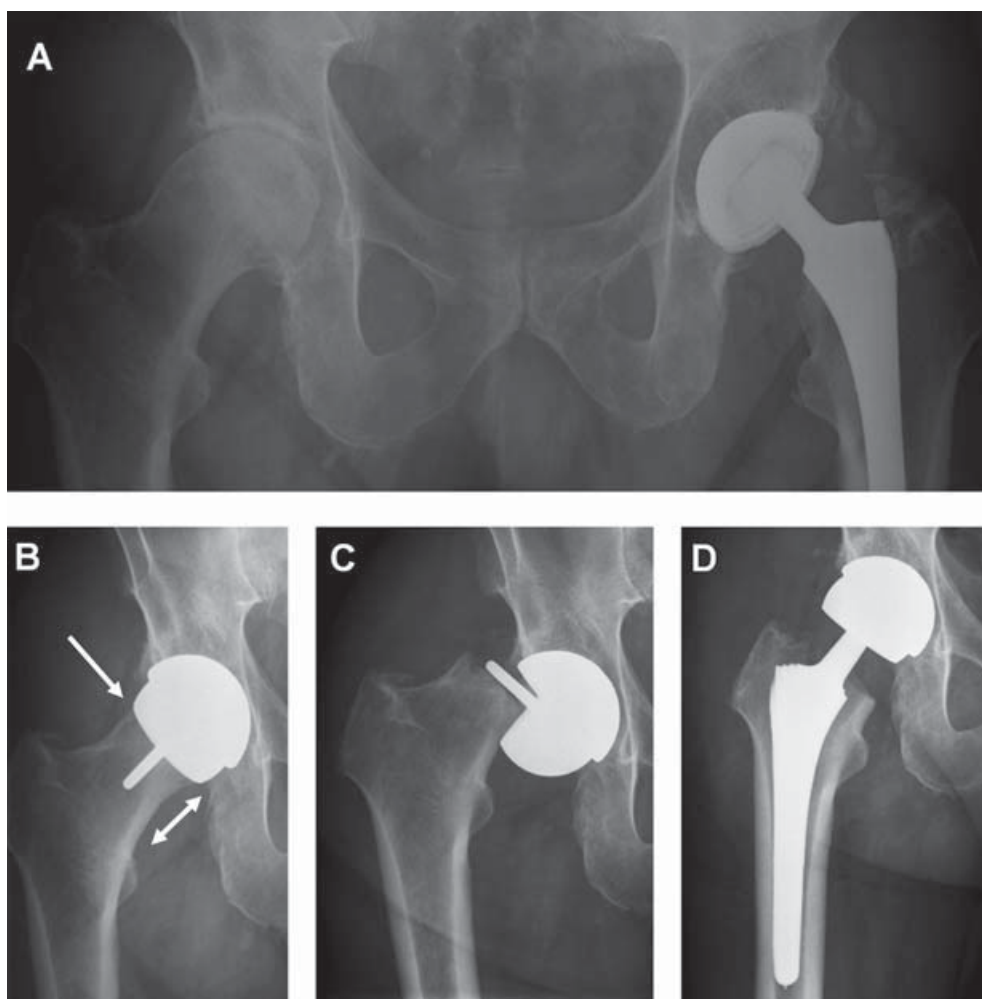


Fig. 3 A 62-year-old patient with coxarthrosis: (A) pre-operative X-ray; (B) post-operative X-ray showing incomplete seating of the femoral component (double-ended white arrow). A notch was evident at the supero-lateral head-neck junction (white arrow); (C) a 3.5 months post-operative X-ray showing fracture of the neck at the head-neck junction; it should be noted that this patient used two crutches and was non-weight bearing; (D) revision with a standard stem with a replacement large-diameter head articulating with the original cup

pain post-operatively. A single case of persistent peroneal palsy was reported, resulting from irritation of the ischiaticus nerve.

A learning curve was evident, with revisions starting at 5 per cent for the first 100 cases, decreasing to 2 per cent in the next 100 and to 1 per cent for

the last 100 patients (Table 3). This, however, was only a trend ($p = 0.308$). It should be noted that follow-up time was longer for the earlier cases.

The Kaplan–Meier analysis indicated a predominant failure frequency for the femoral neck fractures within the first 100 days after surgery (Fig. 6). The

Table 3 The learning curve parameterized by the number of failures for consecutive groups of 50 surgical cases. The number of surgical cases in the groups is not always 50 because of the problem of contacting some patients

		Value for the following number of surgical cases						Total
		1–50	51–100	101–50	151–200	201–250	251–300	
Revisions	No	48	47	48	50	49	50	274
	Yes	2 (4.0%)	3 (6.0%)	2 (4.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	8 (2.7%)
	Total	50	50	50	50	50	50	300

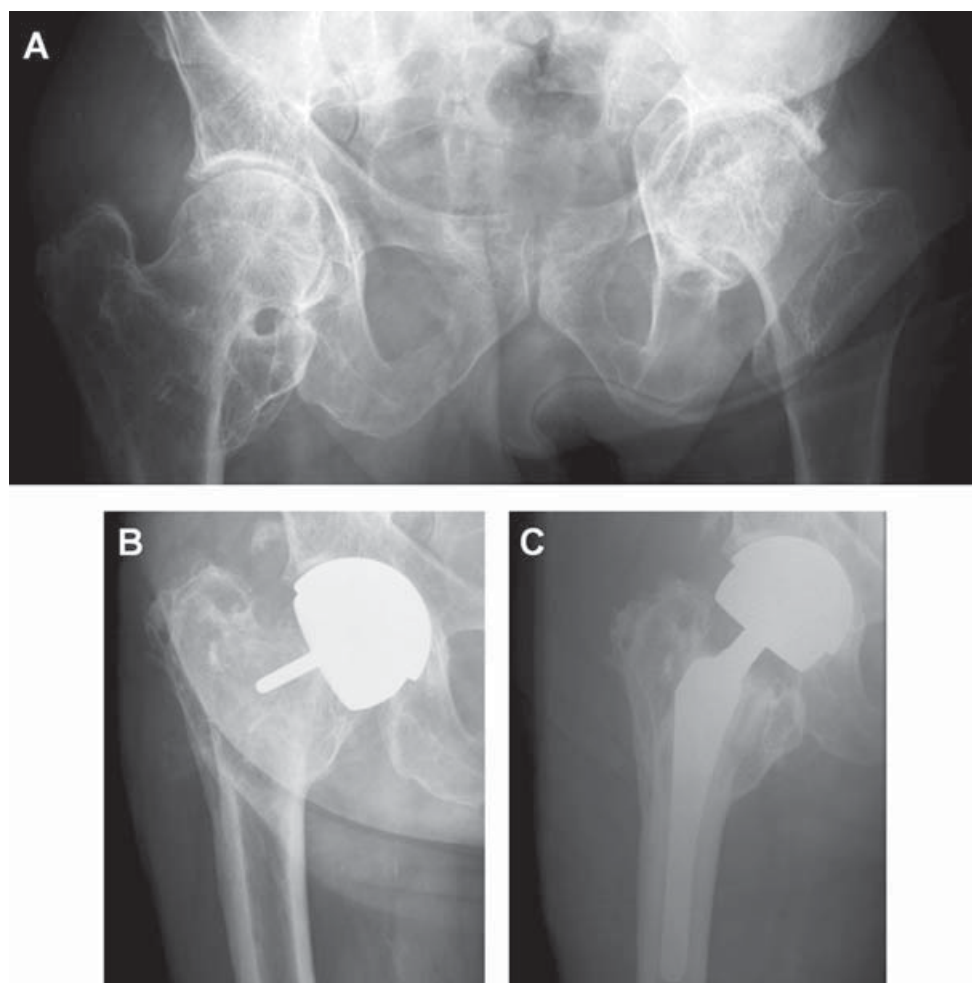


Fig. 4 A 56-year-old male with coxarthrosis 8 years after amputation of the left leg (above-knee amputation) and osteosynthesis of the right proximal femur: (A) pre-operative X-ray; (B) fracture of the femoral neck at the head–neck junction 2.5 months post-operatively; (C) revision with a standard stem with a replacement large-diameter head articulating with the original cup

discriminant analysis showed prior surgery to be the variable with the highest predictive value followed by notching and the body weight of the patient ($p < 0.001$ for each variable). The discriminant equation based on these three variables correctly classified 95 per cent of the cases. However, only four of the eight revision cases were classified correctly, indicating that other factors not addressed in this study influenced the results. These factors might include other surgical errors, trauma during surgery, or as yet unknown factors.

4 DISCUSSION

It is to the credit of Derek McMinn that hybrid hip resurfacing has been reintroduced with a MOM bearing. Whereas former generations failed by foreign-

body granulomas of the PE debris [3, 4] or loosening of cemented acetabular components [27], the third-generation MOM combinations have resulted in good middle- and long-term survival rates [7, 8]. The advantages of hip surface replacement are the well-preserved CCD and torsion angles of the femoral neck, the preservation of femoral bone (which could simplify revision surgery), and the good functional outcome. Surgical trauma to the bone would appear to be reduced in comparison with uncemented stem implantations. Whether the risk of fat embolism is reduced in comparison with a conventional stem implantation remains to be investigated. A notable disadvantage of hip resurfacing is that it cannot be used to correct varus deformity or abnormal anteversion or leg length discrepancy.

In the current study of 300 ASR[®] implantations the major reasons for revision surgery were apparently



Fig. 5 A 55-year-old patient with coxarthrosis after valgus osteotomy. The 3 month post-operative X-ray shows steep cup inclination. Revision was necessary owing to pain from subsidence into the acetabulum

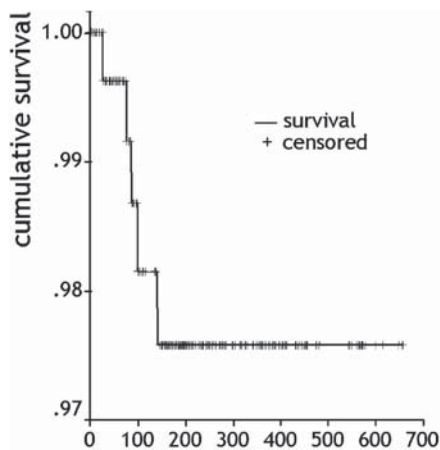


Fig. 6 Survival analysis according to the Kaplan–Meier method considering only femoral neck fractures as failures. The mean follow-up time for the 300 cases in this diagram was 202 days

caused by technical implantation errors and patient selection. To minimize the risks of neck fracture the head component was implanted according to the recommendation of Amstutz and co-workers [18] with a CCD angle above 130° to reduce neck loading. The rate of femoral neck fracture of 1.66 per cent in this study is comparable to published results for other MOM implants [19–22]. One of two cases with radiologically observed incomplete seating of the femoral component fractured (Fig. 3) because the trabecular bone was not stabilized by full coverage of the implant. To achieve full seating of the femoral implant, using hand pressure, rather than a mallet, to reduce the risk of microfractures [23] in the bone is recommended. The present authors favour a thin

cement layer to minimize tissue necrosis, which can be caused by excessive temperatures during cement polymerization. However, the risk of mechanical failure of the bone–cement interface (long-term failure) remains to be addressed [13]. Elimination of the potential problems with the cement layer with the introduction of cementless femoral head components [19] also remains to be addressed in long-term clinical studies.

It appears to be crucial that any notching of the femoral neck is avoided, since this was associated with two of the neck fractures in this study (Figs 1 and 2), as previously reported by Beaulé *et al.* [24]. The seven examples of neck notching observed in this study are similar to cases observed by Amstutz and Kody [25]. The conservative post-operative convalescence regime for subjects who indicated femoral neck notching at an early stage was not successful in preventing fracture in this study, in contrast with the work of Cossey *et al.* [26]. Previous osteosynthesis of the proximal femur was shown to increase the risk of early failure significantly (Fig. 4).

All fractures occurred within an early post-operative time frame of 4 months, which is a phenomenon that has been described by other workers and is still poorly understood [21, 26].

In the case of neck fracture the ASR[®] cup remained in place and after resection of the fractured neck a conventional stem with a large XL metal resurfacing revision head component was implanted to retain the low-wear advantages of MOM [6, 7, 27] and the reduced risk of luxation [25]. This approach is justified by retrieval studies indicating that the cup remains undamaged in the process of neck fracture [23]. A second (minor) bedding-in period has to be expected.

Luxation (multiple) of an ASR[®] hip occurred in one patient with Parkinson's disease who slept on the non-treated side with a deeply flexed hip joint. After multiple repositionings and conservative treatment with a brace, the joint was revised by repositioning the cup with 30° anteversion. Duijsens *et al.* [26] reported one luxation after 114 hip resurfacing implantations. In their study, three hips with unexplainable pain were reported and it was found that a high BMI was significantly related to a higher failure rate. Both findings are supported by the present study. In one case a hip was revised for unexplainable pain. The histological findings were not conclusive.

The mean Harris hip score of 89 points at 3 months after surgery and the low rate of early failures are encouraging for the short-term performance of the ASR[®] implant. To reduce the risk of notching, an improvement in the design of the reamer guide

instrumentation would be desirable, perhaps involving a navigation system. The steep learning curve from 5 per cent revisions for the first 100 implantations to 2 per cent for the next 100 cases and a final revision rate of 1 per cent indicate that this type of implant should be used only by skilled surgeons. The two surgeons in this study had previous experience with more than 100 third-generation implantations and still exhibited a learning curve. Better instruments, additional surgeon training, and navigation will hopefully reduce the learning curve effect in the future. In the light of the results of the present study it is emphasized that the following aspects should carefully be considered prior to selecting a patient for surface replacement of the hip:

- (a) overweight;
- (b) prior surgery to the proximal femur;
- (c) varus deformity;
- (d) abnormal torsion of the head;
- (e) cranio-lateral cysts larger than 1 cm² especially at the head-neck junction;
- (f) head-neck ratio smaller than 1.1.

This study should be viewed as an indication that careful patient selection and correct implantation technique are crucial for the success of hip resurfacing surgery.

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