# Clinical and Radiographic Outcomes of 139 Hips with Articular Surface Replacement Total Hip Arthroplasty*

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**ABSTRACT:** **Background:** The articular surface replacement (ASR) total hip arthroplasty (THA) was recently recalled from the market due to high failure rates. This modality was used frequently by surgeons at our medical center.

**Objectives:** To assess the clinical and radiographic outcomes in patients following the surgery and determine the revision rate in our cohort.

**Methods:** Between 2007 and 2010 139 hips were operated on and evaluated in our clinic. All patients underwent a clinical interview, function and pain evaluation, as well as physical examination and radiographic evaluation. When necessary, patients were sent for further tests, such as measuring cobalt-chromium levels and magnetic resonance hip imaging.

**Results:** With an average follow-up of 42 months the revision rate was 2% (3/139). Patients reported alleviation of pain (from 8.8 to 1.7 on the Visual Analog Scale, $P < 0.001$), good functional outcomes on the Harris Hip Score, and improved quality of life. Overall satisfaction was 7.86 on the reversed VAS. For patients who required further tests, clinical and radiographic outcomes were significantly poorer than for the rest of the cohort. Average blood ion levels were high above the normal (cobalt 31.39 ppb, chromium 13.32 ppb), and the rate of inflammatory collection compatible with pseudotumors on MRI was 57%.

**Discussion:** While our study favors the use of the ASR implant both clinically and radiographically, some patients with abnormal ion levels and inflammatory collections on MRI might require revision in the future.

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**KEY WORDS:** articular surface replacement (ASR), total hip replacement, pseudotumor, cobalt-chromium levels

Metal-on-metal total hip arthroplasty first appeared in the 1960s. Early designs were mostly inferior to the traditional Charnley THA. Second-generation metal-on-metal THA was introduced in the late 1980s and became widespread in the mid-1990s, with the promise of lower wear rates [1]. Large-head metal-on-metal THA designs gained popularity in the last decade, mostly due to their theoretical advantages over traditional designs; these include lower wear rates, and improved stability, durability and range of motion [2-5]. However, recent studies have shown that large-head metal-on-metal THA fail earlier than other THA designs [6]. One specific large-head metal-on-metal bearing, the articular surface replacement by DePuy, had an alarming abnormal proportion of early failures [7,8]. Subsequently, Johnson & Johnson recalled this implant in August 2010 [9]. The ASR implant was one of the most popular implants used by surgeons in the Adult Reconstructive Unit of our department. We sought to examine the clinical outcomes of this surgical procedure in our practice.

## PATIENTS AND METHODS

### THE ASR CLINIC

Once Johnson & Johnson announced the ASR recall notice, the Israel Ministry of Health instructed hospitals to summon all patients with the ASR implant for clinical evaluation by a joint specialist. Altogether, 125 patients with 139 hips were operated on by senior surgeons of the Adult Reconstruction Unit of the Orthopedic Division. All operations took place between 2005 and 2010 in three medical centers: two private medical facilities (61%) and one university-affiliated medical center (39%).

The clinic was designated to conduct a follow-up on patients and their hip function, and in cases of need to continue the blood ion workup and magnetic resonance hip imaging. The physicians examining the patients were all senior surgeons in the Adult Reconstruction Unit of the Orthopedic Division of our center.

Data collected for each patient included:

- **The medical interview:** basic history and demographics, review of the surgery report (including surgical approach, cup size, stem type), revision rate, pain level assessment using the Visual Analog Scale (0 = no pain, 10 = severest pain) for preoperative hip pain levels and postoperative pain, patient satisfaction assessed with modified VAS (0 = not satisfied,

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VAS = Visual Analogue Scale
THA = total hip arthroplasty

ASR = articular surface replacement

10 = very satisfied), Harris Hip Score for subjective pain and function assessment [10], and the 12-item short-form health survey questionnaire for quality of life assessment [11]

- **Physical exam:** range of hip motion (adduction, abduction, flexion internal and external rotation), and special exams (limb length discrepancy and Trendelenburg test)

**Table 1.** Demographics, and clinical and radiographic outcomes in patients with articular surface replacement total hip arthroplasty

| | | N | Average (SD) | |
|---|---|---|---|---|
| **Demographics and surgical data** | | | | |
| Age (yr) | | 125 patients | 67.6 (10.83) | |
| Gender (Male/Female) | | 125 patients | 46%/54% | |
| Follow-up (mos) | | 124 hips | 41.93 (13.8) | |
| Operation side | Right | 139 hips | 68 | |
| | Left | | 43 | |
| | Bilateral | | 14 | |
| Femoral head size (mm) | | 120 hips | 45.35 (4.08) | |
| Acetabular implant size (mm) | | | 51.94 (3.17) | |
| Femoral stem size (mm) | | | 11.5 (2.15) | |
| **Outcome** | | | | |
| | | 139 hips | 2% | |
| **Subjective (Patients') Assessement** | | | | |
| Pain (Visual Analogue Scale) | Preoperative | 122 hips | 8.8 (1.7) | $P < 0.001$* |
| | Postoperative | | 1.7 (2.2) | |
| Satisfaction rate (reverse Visual Analogue Scale) | | 122 hips | 7.86 (3.4) | |
| Harris Hip Score | Average | 111 patients | 82.45 (19.41) | |
| | Excellent (90–100) | 57 patients | 97.18 (2.74) | |
| | Good (80–90) | 19 patients | 85.58 (2.46) | |
| | Fair (70–80) | 4 patients | 76.25 (3.5) | |
| | Poor (< 70) | 31 patients | 54.26 (11.66) | |
| SF-12 Physical component (range 14–69) | | 111 patients | 41 (12) | |
| SF-12 Mental component (range 19–68.9) | | 111 patients | 49 (13) | |
| **Objective (clinician) assessment** | | | | |
| Range of motion (degrees) | Abduction | 127 hips | 42.33 (8.3) | |
| | Adduction | | 22.01 (5.2) | |
| | Flexion | | 101.57 (9.4) | |
| | Internal rotation | | 19.67 (11.3) | |
| | External rotation | | 36.04 (10.9) | |
| Gluteal weakness (positive Trendelenburg sign) | | | 6.2% | |
| Leg length difference (> 0.5 cm) | | | 7.8% | |
| **Radiographic assessment** | | | | |
| Osteolysis | | 122 hips | 4% | |
| heterotopic ossification | | | 2% | |
| Inclination angle antero-posterior radiograph (degrees) | | | 45.6 (6.7) | |

*Compared with paired samples *t*-test

- **Radiographic assessment based on the most recent hip radiograph:** inclination angle in the antero-posterior pelvic radiograph [12], and assessment of endosteal lysis, heterotropic ossification, leg length discrepancy, and anatomic restoration. All radiographs were analyzed by joints specialists.

The examiner assessed whether the patient required additional follow-up, such as blood ion levels (cobalt and chromium), special imaging (MRI) or another follow-up visit. The decision was made by the surgeon according to Ministry of Health instructions based on the Medicines and Healthcare products Regulatory Agency (MHRA) safety alert, April 2010 [13]. Blood tests and imaging were recommended when: a) patients had symptoms associated with the ASR implant, b) radiological features associated with adverse outcomes including component position or small component size, c) patient or surgeon concern regarding the metal-on-metal bearing, and d) concern about patients with higher than expected rates of failure.

Blood ion levels were sent for analysis to an international laboratory (Trace Elements Unit, Southhampton General Hospital, Southhampton; SAS Trace Element Laboratory, Charing Cross Hospital, UK).

MRI imaging was performed with the metal artificial reduction sequence (MARS). Patients were evaluated for stability of the prosthesis, soft tissue reactions, and fluid collection formation, specifically fluid collections with a thick, low signal intensity wall compatible with "pseudotumor" arising from or located adjacent to the joint. All MRI scans were evaluated by a senior radiologist specializing in musculoskeletal MRI.

## STUDY DESIGN AND STATISTICAL ANALYSIS

This was a retrospective analysis of prospective data collected in the clinic and approved by the institutional review board. All data were analyzed with SPSS for Windows Version 17.0 (SPSS Inc, Chicago, IL). Descriptive statistics included mean, standard deviation and frequencies. Paired *t*-test was used to compare pre- and postoperative pain levels. Independent samples *t*-test was used to compare patients who required additional follow-up with those who did not.

## STUDY POPULATION

Surgery was performed on 139 hips in 125 patients and examined in the ASR clinic; 46% of the patients were male and 54% female. The average age was 67.6 years (age limits 32–90 years). Average follow-up was 42 months (SD 13.8 months) [Table 1].

## SURGICAL PROCEDURE

Fourteen patients had bilateral procedures; 68 patients were operated on their right hip and 43 on their left. Ninety-nine percent of the procedures were performed with the standard

posterior approach to the hip. Average femoral head size was 45.3 mm, acetabular implant size was 51.94 mm and femoral stem size 11.5 mm on average [Table 1]. All procedures were performed by three senior joint surgeons. We were unable to retrieve surgical data for 19 hips (13%).

## RESULTS

### CLINICAL OUTCOMES

The overall revision rate in our study was 2% (3/139). One patient had two revisions, at 1 and 3 years after the primary surgery. The etiology was pain due to a suspected pseudotumor. The second patient had the revision 3 years postoperatively and the etiology was snapping hip. The third patient had the revision 3 years post-surgery and the pain was caused by adhesions adjacent to the hip joint.

Patient satisfaction on the reverse VAS (0–10) was 7.86. The average Harris Hip Score was 82.45, with 51% of patients ranking their hip function as excellent (> 90 points).

The SF-12 life quality questionnaire rated 41 (range 14–69) for the physical component and 49 (range 19–68.9) for the mental component. These questionnaires (SF-12, Harris Hip Score and satisfaction VAS) were completed by 111 patients (89%).

Pain levels on VAS (0–10) were 8.8 for preoperative hip pain compared with 1.7 for postoperative hip pain ($P < 0.001$). Data regarding pain levels were available for 122 hips (87.7%) [Table 1].

Postoperative hip range of motion was in the normal range with a mean 101.57° flexion (SD 9.4°), 42.33° abduction (SD 8.3°), 22.01° adduction (SD 5.2°), 36.04° external rotation (SD 10.9°) and 19.67° internal rotation (SD 11.3°) [Table 1].

Additional physical examination tests showed a positive Trendelenburg test in 6% of the patients and leg length discrepancy (> 0.5 cm) in 7.8% [Table 1].

### RADIOGRAPHIC OUTCOMES

Of the 122 hips with available radiograph 5 (4%) showed signs of osteolysis and 2% had signs of heterotopic ossification. The mean inclination angle on the anterior posterior hip radiograph was 45.6° (range 33–70°) [Table 1].

### ADDITIONAL TESTS

Blood ion levels were measured in 32 patients (25.6%). Fourteen hips required MRI (10%). The group that required additional testing showed poorer results in all clinical outcome scales including: Harris Hip Score (67.8 ± 21 vs. 87.83 ± 15.5, $P < 0.0001$), difference between post- and preoperative pain levels (5.9 ± 2.57 vs. 7.49 ± 2.41, $P = 0.0025$), satisfaction VAS score (5.26 ± 3.92 vs. 8.68 ± 2.77, $P < 0.0001$), and SF-12 physical and mental components. This group also had poorer range of hip motion and higher inclination angle on anteroposterior radiograph [Table 2]. When comparing clinical and radiographic outcomes for patients with abnormal follow-up tests to those with normal follow-up test, the only significant difference was in the SF-12 mental component (39.25 ± 14.8 vs. 51.23 ± 11.97, $P = 0.032$) [Table 3].

SF-12 = short form (12 items)

VAS = visual analogue scale

**Table 2.** Analysis of variables associated with additional follow-up required for ASR patients

| | Patients not requiring additional follow-up | | Patients requiring additional follow-up | | |
|---|---|---|---|---|---|
| | Average (SD) | N | Average (SD) | N | *P* value* |
| Pain improvement (VAS) | 7.49 (2.41) | 92 hips | 5.9 (2.57) | 30 hips | 0.0025 |
| Harris Hip Score | 87.83 (15.58) | 81 patients | 67.8 (21) | 30 patients | ‹ 0.0001 |
| Satisfaction (reverse VAS) | 8.68 ( 2.77) | 81 patients | 5.26 (3.92) | 30 patients | ‹ 0.0001 |
| SF-12 Physical | 43.16 (12.78) | 82 patients | 34.54 (10.34) | 29 patients | 0.0014 |
| SF-12 Mental | 50.75 (10.28) | 82 patients | 43.8 (14.85) | 29 patients | 0.0068 |
| Inclination angle (degrees) | 44.89 (6.61) | 93 hips | 47.89 (6.73) | 29 hips | 0.035 |
| Sum of range of motion (degree) | 224.4 (25.2) | 95 hips | 210.93 (34.18) | 32 hips | 0.0191 |

*Compared with independent samples *t*-test

VAS = visual analog scale (0–10), VAS = preoperative pain on VAS-postoperative pain on VAS

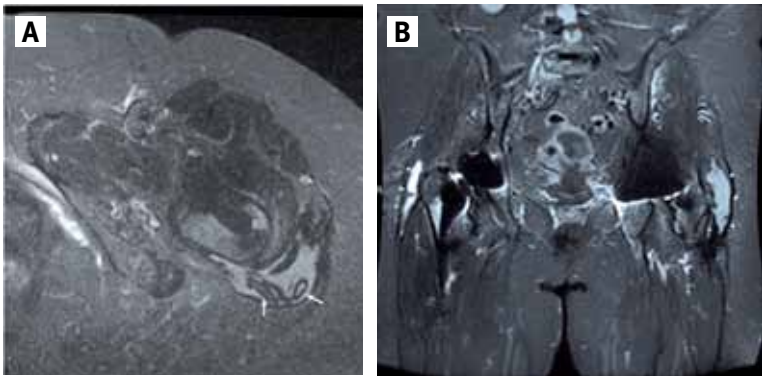
**Table 3.** Analysis of variables associated with abnormal findings in additional follow-up for ASR patients (blood ion levels or MRI)

| | Patients without abnormal follow-up findings | | Patients with abnormal follow-up findings | | |
|---|---|---|---|---|---|
| | Average (SD) | N | Average (SD) | N | *P* value* |
| Pain improvement (VAS) | 5.83 (2.85) | 12 hips | 5.94 (2.46) | 18 hips | 0.911 |
| Harris Hip Score | 72.41 (24.25) | 12 patients | 64.72 (19.78) | 18 patients | 0.348 |
| Satisfaction (VAS) | 4.41 (4.39) | 12 patients | 5.83 (3.58) | 18 patients | 0.339 |
| SF-12 Physical | 38.01 (13.08) | 11 patients | 32.42 (7.92) | 18 patients | 0.161 |
| SF-12 Mental | 51.23636 (11.97) | 11 patients | 39.25 (14.88) | 18 patients | 0.0324 |
| Inclination angle (degrees) | 45.63 (4.38) | 11 hips | 49.27 (7.61) | 18 hips | 0.161 |
| Sum of range of motion (degrees) | 213.75 (32.1) | 12 hips | 209.25 (36.06) | 20 hips | 0.721 |

*Compared with independent samples *t*-test

VAS = visual analog scale (0–10), VAS = preoperative pain on VAS-postoperative pain on VAS, HHS = Harris hip score

**Figure 1.** Magnetic resonance images of pseudotumor in a patient after left hip replacement with articular surface replacement




**[A]** Axial view, showing low signal intensity fragments compatible with metal debris within the pseudotumor (arrows)

**[B]** Coronal view, showing a small collection on the right, where polyethylene on metal hip replacement was performed. The difference in the intensities between the collections is shown (arrow heads)

Blood ion levels were high on average, with cobalt levels averaging 31.39 ppb (SD 56.6) and chromium level 13.32 ppb (SD 25.3). Sixteen patients (50%) had cobalt level above normal (> 7 ppb, according to the traditional limits [7]). Chromium levels were higher than normal (> 7 ppb) in 9 patients (28.1%).

### MRI RESULTS

MRI examinations were performed for 14 hips (12 patients). In eight hips, a collection compatible with inflammatory reaction was demonstrated [Figure 1]. The average size of the collection was 156 $cm^3$ (range 4.99–335 $cm^3$). Average cobalt level for patients with a collection was 59.65 ppb (SD 63.8) and chromium level 30.74 ppb (SD 31.63) compared with cobalt 62.11 (SD 113.3) and chromium 28.07 (SD 53.28) for patients without collections. These differences were not significant.

## DISCUSSION

The main reason for the popularity of the large-head metal-on-metal bearing was the potential advantages that this implant offered: minimal wear and osteolysis in young active patients [14], improved hip stability, and reduced dislocation rate [2-5]. However, recent publications and data from large population-based registries [6,15] showed that the opposite was true and that these articulations fail more rapidly than other designs. In addition, this implant design is susceptible to accelerated wear and loosening [16-18]. Other concerns regarding the large-head metal-on-metal implants were adverse events related to its use, specifically adverse soft tissue reactions [8] such as metallosis, hypersensitivity, pseudotumor formation and aseptic lymphocytic vasculitis-associated lesions [19].

There should be a clear distinction between large-head and traditional small-head metal-on-metal bearing as the latter do not suffer the same high failure rate as the former. However, recent evidence from the National Joint Registry of England and Wales, of 31,171 patients with metal-on-metal bearing of any size, showed its inferiority to ceramic-on-ceramic bearing in terms of failure rate [6].

Several studies have shown that the articular surface replacement total hip arthroplasty failed more than other designs. Langton et al. [8] reported a 48.8% failure rate at 6 years, Garen et al. [7] reported a 12% revision rate at 2 years follow-up, and data from the Australian Joint Registry showed a revision rate of 9.3% at 5 years [15]. Subsequently, the implant was recalled by Johnson & Johnson in August 2010. Since the implant was very popular (over 93,000 sold [9]), the ongoing litigation around the ASR might prove costly.

The etiology of the ASR THA early failures is still unknown but is largely attributed to implant design flaws [7]. One hypothesis is the functional articular surface theory [20]. According to this theory when the functional articular surface is reduced the implant is more susceptible to wear. The ASR design includes a less than hemispherical cup, and rims of the acetabular cup serve as handles for the insertion tool, all leading to a smaller functional articular surface. Another design issue is that of the acetabular component, which is sub-hemispheric and thin at the rims, thus contributing to poor fixation to the acetabulum and higher rate of osteolysis [21].

Our experience with 139 hips with large-head metal-on-metal ASR THA in a follow-up of 42 months showed lower revision rates than previously reported. Hip pain diminished significantly, and postoperative hip function and quality of life were similar for other THA [22]. In accord with these outcomes, patient satisfaction with the operation was high. Additionally, our study showed abnormal follow-up test results (MRI and ion levels) specifically among patients who were either symptomatic or concerned about recent publications regarding the ASR implant. Blood ion levels of cobalt and chromium measured high above the normal, 31.39 ppb and 13.32 ppb, respectively. MRI scans revealed a high proportion of abnormal findings, specifically a prevalence of 55% of pseudotumors. This prevalence is similar to recent findings by Hart and co-researchers [23].

Our study has several limitations. This was a retrospective analysis of prospectively collected data. Some of the questionnaires had a retrospective component that might expose the study to recall bias. The surgeries were performed by only three surgeons but in different medical centers, and some of the examiners collecting the data were the surgeons performing the operation. The clinical follow-up was relatively short. Special blood and imaging tests were performed only in patients requiring them and not for the whole cohort.

Our cohort presents better clinical outcomes with the use of the ASR THA than recently reported, specifically with regard to the revision rate. Since evidence for the early failure of this design is overwhelming, we largely attribute our good results to the relatively short-term follow-up. Other hypotheses explaining our results are better patient selection and intraoperative decision making, i.e., the final type of implant used was decided upon intraoperatively. The factor that guided the surgeon's intraoperative decision to use the ASR implant was good acetabular bone stock. An additional explanation for our results might be the surgeons' experience: all surgeries were performed by three surgeons with a high volume of THA, specifically ASR THA.

While low revision rates were noted in our study compared to recent publications, a high proportion of the patients required additional evaluation. Patients who required additional follow-up tests (MRI or blood ion levels) showed poorer results, both clinically and radiographically. High ion level is known to correlate with future revision [24] as well as pseudotumors [25]. Possibly, this group will undergo revisions in the future, thus significantly elevating our cohort revision rates.

## CONCLUSIONS

Our study evaluated the clinical and radiographic performance of the ASR THA system in light of recent reports of a high revision rate. Our study included 139 hips with the ASR implant and an average follow-up of 42 months. Initial results have yet to match previously published data with a 2% revision rate. Extra careful follow-up of this cohort is imperative in light of higher than normal ion level and pseudotumors on MRI, which might elevate the revision rate in the future.

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