Minimum ten-year results of a 28-mm metal-on-metal bearing in cementless total hip arthroplasty in patients fifty years of age and younger

Moritz M. Innmann · Tobias Gotterbarm · Jan Philippe Kretzer ·
Christian Merle · Volker Ewerbeck · Stefan Weiss ·
Peter R. Aldinger · Marcus R. Streit

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Abstract

Purpose Concerns have been raised in relation to metal-on-metal (MoM) articulations with catastrophic soft-tissue reactions due to metal debris. We reviewed how small head MoM articulations perform in primary uncemented total hip arthroplasty (THA) in young patients at a minimum of ten years.

Methods We retrospectively evaluated the clinical and radiographic results of the first 100 consecutive primary cementless THAs using the 28-mm Metasul MoM articulation in 91 patients younger than 50 years of age at the time of surgery.

Results After 13 years, survival for the endpoint revision due to any reason was 90.9 % and 98.9 % for revision due to aseptic implant loosening. The cumulative incidence of MoM related revisions was 1.2 %. Small proximal femoral osteolysis was found in 18 % of hips. No acetabular osteolysis or loosening was detected. Two hips showed signs of femoral neck impingement with severe damage to the neck.

Conclusions Early in the second decade, MoM-associated complications were rare using the 28-mm Metasul articulation,

and aseptic loosening was not a major mode of failure in this cohort of young patients.

Level of evidence Therapeutic Level IV.

Keywords Hip · Arthroplasty · Replacement · Young patient · Metal-on-metal · Bearing · Metasul

Introduction

Second generation MoM bearing surfaces have been reintroduced in order to avoid polyethylene (PE) wear-related complications [1] and have been in use for two decades [2]. MoM bearings have long been recognized as an attractive concept, particularly in young patients, who often regain their pre-operative level of activity [2]. However, over the past few years severe concerns have been raised in relation to mainly large head diameter MoM articulations with catastrophic soft-tissue reactions due to excess metal debris, with possible subsequent implant failure [2, 3]. In contrast, several studies report acceptable implant failure rates according to the NICE criteria [4] using the 28-mm head Metasul MoM articulation [5–9]. However, there are only few long-term data on the results of primary cementless THA using this articulation in young patients [6, 7]. Close monitoring routines have been proposed for patients with large head diameter MoM articulations, but it remains unclear if they are also necessary with small head diameter MoM articulations.

The purpose of the present study was (1) to evaluate the clinical and radiological results at a minimum of ten years in an independent series using the Metasul MoM articulation in patients aged 50 years or younger at the time of surgery, (2) to

M. M. Innmann · T. Gotterbarm · J. P. Kretzer · C. Merle ·
V. Ewerbeck · M. R. Streit (✉)

Department of Orthopaedic and Trauma Surgery, University of
Heidelberg, Schlierbacher Landstrasse 200a, 69118 Heidelberg,
Germany
e-mail: marcus.streit@arcor.de

S. Weiss

Department of Joint Replacement Surgery, ARCUS Kliniken
Pforzheim, Rastatter Strasse 17-19, 75179 Pforzheim, Germany

P. R. Aldinger

Department of Orthopaedic and Trauma Surgery, Orthopädische
Klinik Paulinenhilfe, Diakonieklinikum, Rosenbergstrasse 38,
70192 Stuttgart, Germany

evaluate the rate of bearing-type related revisions and (3) to compare our results with those reported in the literature.

Materials and methods

Patients

Between January 1995 and December 2001, 100 consecutive cementless THAs were performed in 91 patients aged 50 years or younger at the time of surgery, using the Metasul MoM articulation. At this time, indication for the MoM bearing was young patient age with a high expected level of physical activity after THA. Comorbidities, i.e. obesity, alcoholic disease or a history of cancer were not considered as exclusion criteria. Patients were followed prospectively with our institutional joint registry and retrospectively identified for inclusion into the study cohort. Informed consent was obtained from all patients prior to inclusion in the study. The institutional review board of the University of Heidelberg approved all procedures and the study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2008.

The study cohort included 61 male and 30 female patients. The mean age at surgery was 42 years (range, 21–50). Pre-operative study cohort data is given in Table 1. At a minimum of ten years, 11 patients (11 hips) had died with the endoprosthesis in situ due to causes related to their pre-operative comorbidities, and three patients (three hips) were lost to follow-up. Seven hips underwent revision, leaving 79 hips for review at a mean follow-up time of 12 years (range, ten to 15). Clinical and radiographic follow-up was available for 63 hips. Clinical follow-up only was available for 16 hips. The distribution of hips at final follow-up is shown in Fig. 1.

Surgical procedure

The procedures were performed by 13 different surgeons at our institution. A modified Watson-Jones or a transgluteal

Bauer approach was used with the patient in the supine position. Partial weight-bearing was recommended for six weeks. Intravenous third-generation cephalosporin (1.5 g cefuroxime) was administered peri-operatively. Low-molecular weight heparin (enoxaparin or nadroparin) was administered subcutaneously as anticoagulation therapy for six weeks postoperatively.

A Metasul (Zimmer, Warsaw, IN, USA), forged, high carbide ([C], 0.2–0.25 %) CoCr alloy sandwich MoM articulation was used in all hips. The 28-mm-diameter Metasul metal head was combined with the Metasul metal inlay (thickness 2.4 mm), embedded in an ultra-high-molecular weight PE sandwich which was inserted in the acetabular cup. An uncemented, press-fit titanium acetabular cup and a tapered uncemented stem were used in all hips.

Clinical and radiographic evaluation

Patients were evaluated clinically and radiographically at one, three, and five years postoperatively and every five years thereafter. The Harris hip score (HHS) [10] was assessed pre- and postoperatively, at a minimum of ten years.

Standard pelvis anteroposterior (AP) and lateral radiographs of the hip were evaluated by two different reviewers who were not involved in the surgery (M.M.I., M.R.S.). Acetabular radiolucent lines and osteolysis were described according to the zones established by DeLee and Charnley [11]. Osteolysis was defined as a lucent zone devoid of trabecular bone with a sclerotic border, not visible on the immediate postoperative radiographs [1, 12]. The acetabular component was considered to be loose if there was migration of >3 mm horizontally or vertically on serial radiographs, a circumferential radiolucent line or breakage of acetabular screws [12]. Femoral loosening was defined as progressive axial subsidence or varus or valgus tilting [13]. Femoral radiolucent lines or osteolysis were evaluated using the zones described by Gruen et al. [14].

Table 1 Demographics and diagnosis of the hips

Demographics and diagnosis	Male	Female	Total
Age, mean (SD)	41 (6.4)	44 (6.3)	42 (6.3)
Hips, no. (%)	67 (67 %)	33 (33 %)	100 (100 %)
Body mass index (kg/m ²), mean (range) OP	27 (19–38)	27 (19–38)	27 (19–38)
Right:left	27:40	12:21	39:61
Osteoarthritis, no. (%)			38 (38 %)
CDH, no. (%)			27 (27 %)
Avascular necrosis, no. (%)			18 (18 %)
Posttraumatic OA, no. (%)			6 (6 %)
Rheumatoid Arthritis, no. (%)			4 (4 %)
Other, no. (%)			7 (7 %)

Fig. 1 Distribution of hips at final follow-up

Statistical analysis

Kaplan-Meier survivorship analysis was used to determine survival rates with the use of two end points: revision for any reason and revision for aseptic loosening. Revision was defined as “an operation that involved removal and/or replacement of one or more components of a joint replacement”. Continuous variables were compared with the use of a two-sided Student’s t-test. We considered p-values of <0.05 to be significant. Graphpad Prism® Version 5.01 (Graphpad Software, La Jolla, CA, USA) was used to record and analyse the data.

Histologic examination

During revision procedures, specimens were retrieved from the hip capsule. Tissue samples were fixed in formalin and embedded in paraffin. Serially, sections (6 µm) were stained with routine protocols for hematoxylin and eosin and examined with standard microscopy with polarized and normal light.

Results

Revisions

After a minimum of ten years, seven hips had been revised (Table 2.) One hip was revised for late aseptic loosening of an undersized stem in a patient with posttraumatic osteoarthritis. In two hips, an isolated revision of the bearing was performed. In the first hip, the MoM articulation was exchanged to a metal-

on-PE bearing for persistent pain due to a metal hypersensitivity reaction as identified with histology. The patient had an excellent outcome after revision surgery (HHS 98 points). The second isolated revision of the bearing was performed ten years after primary THA for recurrent dislocation. Intra-operatively, ventral impingement between the femoral neck and the Metasul liner were obvious, where the neck of the stem showed a notch from impingement. The primary bearing was exchanged to a hooded 32-mm Metasul articulation. No further dislocation occurred after revision surgery in this patient. There was one impending revision due to isolated aseptic loosening of an undersized stem with late onset of pain and late progressive subsidence at 13 years postoperatively.

Clinical results

The mean total Harris hip score (HHS) showed a significant increase from 46 points (range, 18–77) pre-operatively to 92 points (range, 51–100) at the last follow-up ($p < 0.001$).

Radiographic results

After a minimum follow-up of ten years, no acetabular cup showed radiographic signs of loosening or periacetabular osteolysis. One undersized femoral component demonstrated radiographic evidence of definite loosening with late subsidence. In total, radiolucencies and/or osteolysis were detected in 27 hips. The distribution of radiolucent lines and osteolysis and their progression is presented in Table 3. All osteolytic lesions were small with a linear pattern and limited to the

Table 2 Revisions

Hip	Reason for revision	Revision procedure	Time to revision (years)
1	Infection	Two stage revision of cup and stem	3
2	Infection	Two stage revision of cup and stem	5
3	Late aseptic stem loosening	Isolated stem revision	6
4	Traumatic periprosthetic fracture	Isolated stem revision	8
5	Persistent pain/metal hypersensitivity	Isolated liner and head revision	8
6	Recurrent dislocation	Isolated liner and head revision	10
7	Acetabular implant failure	Cup, liner and head revision	12

Table 3 Osteolysis and radiolucencies

Location	Osteolysis n (%)	First appearance years postop (mean [range])	Progressive (%)	Radiolucencies n (%)	First appearance years postop (mean [range])	Progressive (%)
Acetabulum	0	-	-	5 (8 %)	3.2 (1.4–5.0)	0 %
Stem	11 (18 %)	3.2 (0.6–9.1)	80 %	16 (25 %)	2.3 (0.6–5.9)	64 %
Proximal (Gruen zones I/VII)	11 (18 %)	3.2 (0.6–9.1)	80 %	15 (24 %)	1.9 (0.6–3.6)	60 %
Distal (Gruen zones II–VI)	0	-	-	1 (1 %)	5.9	100 %

proximal femur (Gruen zones I/VII). In the hip revised for periprosthetic femoral fracture, no acetabular or femoral radiolucencies or osteolysis could be detected in a CT scan obtained immediately before revision surgery. One unrevised hip showed radiological signs of femoral neck impingement with severe damage to the neck of the stem (Fig. 2).

Survival analysis

At 13 years, the survival rate, using revision for any reason as the end point, was 90.9 % (95 % CI, 80.9–95.8 %; 24 hips at risk; Fig. 3). The survival rate with the end point being revision for aseptic implant loosening was 98.8 % (95 % CI, 92.5–99.8 %; 24 hips at risk; Fig. 4) and 100 % at 13 years, respectively. The cumulative incidence of MoM related revisions was 1.2 % (95 % CI, 1.6–8.0 %) at 13 years.

Histologic examination

Tissue samples from the hip revised for unexplained pain due to a suspected metal hypersensitivity reaction did not show macroscopic signs of metallosis. Microscopic examination

showed a mild foreign-body reaction to only few metal debris, located extracellularly, as well as stored intracellularly in diffusely distributed macrophages. Under polarized light, debris particles appeared granular, slightly birefringent, yellow or greenish. Only minor focal lymphocytic infiltration accentuated perivascularly with marginal high endothelial venules were detected. No lymph follicles or eosinophilic granulocytes were identified.

Discussion

Uncemented total hip arthroplasty in young and active patients has shown good to excellent long-term survivorship [15, 16], but it still has to be considered challenging, especially with regard to longevity. MoM bearings were introduced to reduce PE wear and therefore provide long-term survival. In the literature, the Metasul bearing has demonstrated excellent survival in young patients of 100 % at 12 and 99 % at 14 years, respectively [6, 7]. Similarly, minimum ten-year survival rates of 94 % and 99 %, have been reported for this articulation in older patients with uncemented THA [5, 8]. However, our cohort of young patients could not support these excellent results, demonstrating only an acceptable survival rate of 91 % for all revisions at 13 years. Very good survival for aseptic loosening as the endpoint and a low incidence for MoM related failures were observed in our study with the Metasul bearing. The prevalence of acetabular osteolysis in our series is

Fig. 2 Anteroposterior (a) and lateral left hip (b) radiographs of a 50-year-old woman at 11 years after THA for dysplasia of the hip. Note the high anteversion and inclination angle of the acetabular component and damage to the femoral neck (black arrow) presumably due to impingement of the neck at the metal insert

Fig. 3 Kaplan-Meier survivorship curve and 95 % CI with revision for any reason as the end point. Thirteen-year survival was estimated at 90.9 % (95 % CI, 80.9–95.8 %; 24 hips at risk)

Fig. 4 Kaplan-Meier survivorship curve and 95 % CI with revision for aseptic loosening as the endpoint. Thirteen-year survival was estimated at 98.9 % (95 % CI, 92.5–99.9 %; 24 hips at risk)

consistent with the low rate (0–1 %) reported in the literature for the Metasul bearing in uncemented THA [5–8]. Our rate of 18 % for small proximal femoral osteolysis is relatively high though not compromising any stem for aseptic loosening. This finding was consistent with the results of Randelli et al. [5] and Hwang et al. [7], reporting rates of 14 % and 9 % at a minimum of ten years. Both authors described the osteolytic lesions as focal or small, with a linear pattern, limited to Gruen zones I and VII, according to the findings in our series. The incidence and clinical relevance of proximal femoral osteolysis with the Metasul bearing still seems to be a controversial issue. Overall rates of osteolysis range from 0–14 % in uncemented THA at a minimum of ten years of follow-up [5–9]. Care must be taken when comparing the reported rates of osteolysis, as patient collectives are heterogeneous with respect to implant fixation [17] and design [5]. In contrast to the incidence of radiographic osteolysis, the revision rates related to osteolysis with a Metasul bearing in uncemented THA are low, ranging from 0–3 % for the cup and 0–1 % for the stem [5–8, 18].

The cumulative incidence of MoM related complications was low in our series (1.2 %). A single metal hypersensitivity reaction with persistent pain was found in one hip, which had to be revised. These findings are consistent with previous reports on the Metasul articulation with revision rates for persistent unexplained pain ranging from 0–3 % [5–9, 17, 18]. Eswaramoorthy et al. [9] associated persistent pain, leading to revision in two of 104 hips, to aseptic lymphocytic vasculitis associated lesions (ALVAL), in the context of a possible hypersensitivity reaction to metal debris [19]. Typical complications associated with large diameter head MoM bearings, like a high percentage of adverse reactions to metal debris resulting in implant failure, including metallosis, ALVAL and pseudotumor [2, 3], were not a major reason for revision in our study. Nevertheless, in synopsis of the clinical, radiographic and histological findings in the hip revised for persistent pain, the results were consistent with a metal hypersensitivity reaction, as described previously [7, 9, 19]. With the detection of perivascular lymphocytic infiltrations, high

endothelial venules, macrophages and only few metal debris particles, our histologic findings can be most likely interpreted as aseptic lymphocytic vasculitis associated lesions, possibly according to Willert et al. [19].

There are some limitations of the study that have to be acknowledged. First, the study design is retrospective; however, a high rate of follow-up (97 %) was obtained. No blood ion concentrations were measured and no routine CT-scan imaging was carried out due to additional radiation exposure, possibly underestimating the rate osteolysis [6, 18]. A potential bias of the present radiographic results cannot be excluded, as 20 % of the hips were not available for radiographic follow-up.

However, we believe that the results of the present study are important as a substantial number of uncemented THAs with Metasul bearings have been performed in young patients and it is still controversial how close these patients should be followed up, keeping in mind the catastrophic complications with large head diameter MoM articulations.

The present study describes an acceptable clinical outcome and implant survivorship with respect to the recommendations of the National Institute for Clinical Excellence, UK [4]. The results in this cohort of young patients compare favourably to the results reported for metal-on-conventional PE bearings in cementless THA in young patients [1]. The rate of complications related to the MoM bearing and the rate of revision for aseptic implant loosening or osteolysis was encouragingly low. Considering the data reported on uncemented THA with the Metasul articulation in young patients and the findings in the present series, we believe this bearing performs satisfactory [20] with good clinical outcome [21]. However, we are concerned by the following findings, namely, the high rate of small proximal femoral osteolysis in combination with slight asymptomatic progression, the rare but severe complication of metal hypersensitivity reactions and the finding of severe damage to the femoral neck due to impingement of the neck and the sandwich metal insert observed in two cases in this series. In this context, the small diameter hard-on-hard Metasul bearing seems to be less forgiving for impingement compared to soft-on-hard bearings like metal on PE. It remains unclear if the femoral neck might be at risk for breakage or the sandwich liner at risk for dissociation in the long term in these cases [22, 23]. The progression of radiolucencies and/or osteolysis may potentially be the result of accelerated metal or PE wear of the liner.

In conclusion we recommend a mandatory five-year follow-up routine in asymptomatic patients, though we believe strict follow-up routines as proposed for large head MoM prostheses [24] are not mandatory in asymptomatic patients.

Like many other surgeons, we abandoned the use of MoM bearings and advocate the use of alternative bearings like ceramic on highly cross-linked PE, as the local and systemic long-term effects are still not fully understood. Further investigations are mandatory to show whether late MoM reactions,

further progression of osteolysis or neck damage will occur in the long term.

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