

Long-term clinical results of the Metasul metal-on-metal total hip arthroplasty: 12.6 years follow-up of 128 primary total hip replacements

Hendrik A. Zuiderbaan, Dennis Visser, Inger N. Sierevelt, Janine Penders, Jeanette Verhart, Diederik A. Vergroesen

Department of Orthopaedic Surgery, Spaarne Gasthuis, Hoofddorp - The Netherlands

ABSTRACT

Introduction: The purpose of the present study is to report the long-term clinical results of an uncemented total hip arthroplasty (THA) using a Metasul metal-on-metal (MoM) 28-mm bearing and to evaluate the long-term serum cobalt levels.

Methods: At an average of 12.6 years following primary THA, we retrospectively reviewed the clinical results of the first 116 consecutive patients (128 THAs) in our institution who underwent 28-mm Metasul MoM THA. Of the 78 patients who were able to visit our outpatient clinic, serum cobalt levels were evaluated.

Results: The overall survival rate of the cohort was 96.1% (95% confidence interval [CI], 93.2-99.6), 12.6 years (95% CI, 12.3-12.7 years) following surgery. 3 patients had undergone revision due to aseptic loosening of the stem and 2 patients sustained a periprosthetic fracture. The average modified Harris Hip Score was 90 (72-97) and the average Oxford Hip Score was 56 (48-60), representing both excellent outcome scores. The average serum cobalt of the entire cohort was 20.1 nmol/L (range 8.5-227.7 nmol/L). Serum cobalt levels of patients with a bilateral MoM THA were significantly higher (35.0 nmol/L, $p < 0.01$). No relation between serum cobalt levels, subjective outcome, radiolucent lines on radiographs and survivorship of the implant was noted.

Conclusions: Long-term results of the metasul MoM bearing articulation in THA seem to be excellent, although cobalt serum levels should be monitored closely.

Keywords: Cobalt, Metal-on-metal, Metasul, Total hip arthroplasty

Introduction

Uncemented total hip arthroplasty (THA) has been a successful treatment for patients with symptomatic osteoarthritis (OA) of the hip. Multiple reports, including data obtained from the various national registries, describe good to excellent long-term subjective outcome scores and survivorship of the implant. However, osteolysis remains the most dominant reason for revision surgery. Macrophage-induced bone resorption as a result of polyethylene wear, is the well-defined reason leading to osteolysis and subsequent aseptic loosening of the implant (1). Therefore, the minimisation of polyethylene wear plays a central role in the prevention of osteolysis and implant longevity.

In order to limit articular friction and polyethylene wear, the small diameter 28-mm metal-on-metal (MoM) THA was developed and introduced in the late 1980s. It was thought that

the wear-related osteolysis would reduce, due to the lower volumetric wear rate that would be produced. These potential advantages are confirmed by several mid- to long-term reports where an obvious reduced wear rate could be observed (2-4). However, concerns remain about the potential local biological and systematic adverse reactions of MoM designs as a result of metal debris caused by friction (5, 6). These concerns are justified and a result of the high percentage of pseudotumours and increased metallic blood serum levels among the MoM designs. The majority of these studies reporting these worrisome side-effects, are based on the larger diameter 36-mm MoM resurfacing hip designs. These reports have led to sceptical thoughts about the metal-on-metal bearing in hip replacement, not distinguishing between small diameter 28-mm total hip and the larger 36-mm diameter resurfacing hip designs. Since the long-term results of the 28-mm MoM THA are scarce, the purpose of the present study is to report the long-term clinical results of a large group of consecutive patients who underwent this type of THA. The 2nd goal of this study was to evaluate the serum cobalt values in this group, since there is limited mid- and long-term information about these levels following 28-mm MoM THA.

Accepted: August 5, 2017

Published online: October 14, 2017

Corresponding author:

Hendrik A. Zuiderbaan
Jozef Israëlskade 37d
1072RX Amsterdam, The Netherlands
aernoutzuiderbaan@hotmail.com

Materials and methods

Following institutional review board approval of our hospital, we retrospectively reviewed the first 136 patients

(150 THAs) that had undergone Metasul MoM THA from September 2002 to December 2003 (mean age 62.1 ± 6.8 years) in our hospital. All patients had undergone the identical cementless stemmed Metasul MoM THA. It consisted of a Zweymüller Alloclassic (Zimmer-GmbH) stem, an Allofit (Zimmer-GmbH) acetabular cup and a 28-mm Metasul Metal-on-Metal (Zimmer-GmbH) inlay. This second generation metal bearing consists of polyethylene insert with a cobalt-chrome metal inlay. Surgeries were performed by 5 surgeons who all have extensive experience in total hip replacement. An identical surgical straight lateral approach to the hip was performed in all cases according to the technique described by Hardinge (7).

Clinical and radiological follow-up

Between November 2014 and March 2015 all patients who had undergone primary THA in the previous mentioned inclusion period were contacted by telephone and invited for a follow-up visit in our clinic. Patients who underwent revision with the same type of implant during that time were excluded for this study. Furthermore, a sustained hip fracture was also considered a contraindication for this study since it is associated with a significant higher rate of dislocations (8). Patients who met the inclusion criteria were asked to fill out the Dutch validated version of the Oxford Hip Score (OHS) and the Harris Hip Score (HHS) (9, 10).

Radiographs of all included patients at final follow-up were analysed for the acetabular cup inclination and the potential detection of radiolucent lines. Acetabular cup inclination was measured on the weight-bearing anteroposterior (AP) views of the pelvis as the angle in degrees between a line drawn along the angle of the rim of the cup and the line drawn between the most inferior points of the ischial tuberosities. Radiolucencies around the stem were recorded according to the Gruen classification (11). DeLee and Charnley zone classification was utilised to score potential acetabular cup radiolucencies (12).

Serum cobalt analysis

Blood samples were taken from all patients who visited our outpatient clinic to assess the serum cobalt value at a minimum of 10 years following Metasul MoM THA implantation. According the guidelines set by the Dutch Orthopaedic Association, serum cobalt levels were measured by Atomic Absorption Spectroscopy and reported in nmol/l. The minimum detection limit for cobalt was 8.5 nmol/L. All values of cobalt below the detection limit were recorded as 8.5 nmol/L.

Statistics

SPSS 24.0 (IBM) was used to perform statistical analysis. Data analysis was mainly descriptive. Normally distributed data are presented as means and standard deviations. In case of non-normally and small sample sizes, data is presented as medians with interquartile ranges (IQR). Comparisons were evaluated by use of Student's t-tests or its non-parametric variant (Mann-Whitney U-test). Discrete variables are presented as numbers and proportions. Comparisons were

evaluated by use of χ^2 -tests. A p value <0.05 was considered as statistically significant. Implant survival was analysed using the Kaplan-Meier survival approach with revision of the femoral stem defined as endpoint. Patients lost to follow-up, or deceased with their prosthesis in situ were defined as censored.

Results

Patients

136 patients (150 THAs) who had undergone Metasul THA between September 2002 and December 2003 were contacted. The average age that patients underwent surgery was 62.1 years and the indications for their primary THA are displayed in Table I. At the time of final follow-up, 16 patients (18 THAs, 12%) had deceased. All deaths were unrelated to their total hip surgery. 4 patients were lost to follow-up because they moved away from the area. Of the remaining 116 patients (128 THAs) that were eligible for follow-up, 78 patients (85 THAs) were able to visit our outpatient clinic. Of the 38 patients (38 THAs, 28%) who were not able to visit, 20 patients (22 THAs, 15%) filled out the questionnaires.

Survival analysis

The average follow-up of the entire cohort (116 patients, 128 THAs) was 12.6 years (95% confidence interval [CI], 12.3-12.7). With revision for any reason as the endpoint, Kaplan-Meier survival analysis showed a survival rate of 96.1% (95% CI, 93.2-99.6) (Fig. 1). 5 patients had undergone revision surgery. Reasons for revision surgery were all stem related. 3 THAs were revised due to aseptic loosening of the stem. The remaining 2 patients underwent revision surgery after a sustained periprosthetic proximal femur fracture following a fall. Evaluating the survival of the implant, and thus excluding the 2 periprosthetic fractures, the survival rate was 97.7% (95% CI, 95.1-100).

Clinical and radiological outcome

The average acetabular cup inclination at final follow-up of all included patients was 40.7° (95% CI, 39.1-42.3). Radiolucent lines were observed in 5 patients (5 THAs, 6%). In contrast to the group without lucencies, the inclination of the acetabular cup differed significantly in the 5 patients with radiolucent lines (median 30° vs. 41° , $p < 0.01$) (Tab. II) (Fig. 2). No radiolucent lines surrounding the acetabular cup were observed.

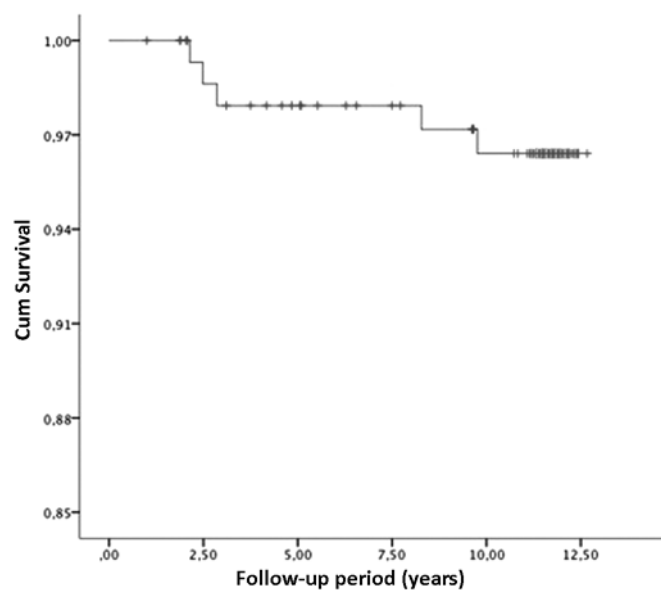
The median HHS was 84 (IQR 65-94) and the median OHS was 56 (IQR 48-60). Both presenting excellent outcome results 12.6 years following their THA.

Serum analysis

Of the 78 patients who were able to visit our outpatient clinic, 45 patients (58%) had a unilateral metasul MoM THA and 33 patients (42%) had a bilateral metasul MoM THA. The median serum cobalt of the entire cohort was 20.1 nmol/L (IQR 14.3-46.2). The median serum cobalt level in the unilateral metasul

TABLE I - The distribution of indications for primary total hip arthroplasty

Indication for surgery			Gender		
			Male	Female	Total
Indication for surgery	Osteoarthritis	Count	43	96	139
		% within gender	95.6%	91.4%	92.7%
	Rheumatic arthritis	Count	0	1	1
		% within gender	0.0%	1.0%	0.7%
	(Avascular) necrosis	Count	1	3	4
		% within gender	2.2%	2.9%	2.7%
	Hip dysplasia	Count	0	2	2
		% within gender	0.0%	1.9%	1.3%
	Other	Count	1	3	4
		% within gender	2.2%	2.9%	2.7%
Total		Count	45	105	150
		% within gender	100.0%	100.0%	100.0%

**Fig. 1** - Kaplan-Meier survivorship analysis for the entire cohort that underwent Metasul MoM THA between September 2002 and December 2003. The overall survival rate of the cohort was 96.1% (95% CI, 93.2-99.6), 12.6 years (95% CI, 12.3-12.7) following surgery.

MoM group was significantly lower (16.1 nmol/l, IQR 9.8-23.2) than the serum cobalt level in the bilateral group (35.0 nmol/l, IQR 20.2-69.3) ($p < 0.001$). The 7 patients that had elevated (85-170 nmol/L) and strongly elevated (>170 nmol/L) serum cobalt levels underwent additional CT-imaging (Tab. III). In 1 patient, an asymmetry of the soft tissues was found. A clear pseudotumour could not be clearly identified with an additional magnetic resonance imaging (MRI) scan. The patient was advised to visit the outpatient clinic for follow-up on regular basis. Of

TABLE II - Median (IQR) inclination angles and cobalt levels of patients with and without lucency. A significant more horizontal acetabular cup inclination was observed in the group with radiolucent lines. No relation was observed with the serum cobalt levels

	Lucency (n = 5)	Non-lucency (n = 80)	p value
Inclination (°)	30 (27-36)	41 (37-46)	<0.01
Cobalt (nmol/l)	13.1 (9.7-43.2)	20.9 (15.4-53.6)	0.28

the patients that underwent revision due to aseptic loosening, no serum cobalt levels were measured before revision surgery.

No relation between serum cobalt levels, clinical outcome scores, radiolucent lines and acetabular cup inclination was noted.

Discussion

In order to limit articular friction and associated polyethylene wear, MoM bearing articulations were introduced by McKee and Watsen-Farrar in the 1960s. Despite the theoretical advantages of these low friction MoM designs, the early reported revision rates were substantially higher than the metal-on-polyethylene (MoP) bearing designs (13). This led to the popularisation of MoP implants in the 1980s. Weber et al (14) stated that the high failure rate among the original MoM bearing designs, was a result of the improperly used materials and suggested that a well manufactured MoM hip design would lead to a dramatic decrease of articular friction. This led to the development and introduction of the metasul MoM articulation in the late 1980s. Good short- to medium-term results led to the popularisation of the implant. However, today long-term reports of the implant in relatively large



Fig. 2 - An example of a female patient 12 years following her THA surgery. The measured inclination of the acetabular cup is 33°. Please note the radiolucent lines in Gruen zones 1 and 7. The serum cobalt serum was slightly elevated according to the Dutch Orthopaedic Classification (40.9 nmol/l).

TABLE III - Patients stratified into cobalt categories according to the proposed classification of the Dutch Orthopaedic Association (25). In case of contralateral MoM prosthesis, cobalt levels were significantly higher compared to standard or no contralateral total hip arthroplasty ($p < 0.01$)

Category (nmol/L)	Total (n (%))	Contralat. MoM	Contralat. no MoM
Normal (<40)	55 (70)	17 (52)	38 (84)
Slightly elevated (40-85)	16 (20)	9 (27)	7 (16)
Elevated (85-170)	4 (6)	4 (12)	0 (0)
Strongly elevated (>170)	3 (4)	3 (9)	0 (0)

MoM = metal-on-metal.

groups of patients are scarce. Randelli et al (15) reported a 13-year survivorship of 94% in 149 cementless THAs. Recurrent dislocation was the main reason for revision surgery and aseptic loosening was found to play a minor role in implant failure that is comparable to our data. Another long-term report by Hwang et al (16) described the long-term result in a group of patients <50 years at 12.4 years follow-up. The overall survivorship rate of the 78 cementless metasul MoM THAs in their report was 98.7%. 2 patients were found to have

signs of acetabular osteolysis which led to a revision of the acetabular component in one case. This is in contrast to our data since we did not observe any lucencies surrounding the acetabular cup, nor were patients revised for acetabular cup loosening. Innmann et al (17) showed a substantial lower survivorship (90.9%) after 13 years. However, aseptic loosening was not found to play an important role since only 1 patient was revised for this reason. The last long-term report by Tardy et al (2) found an overall revision rate of 12.4% at 12.8 years follow-up. Cup loosening was found to be the reason for revision in 3 out of the 13 re-operated patients. Aseptic stem loosening was not observed at final follow-up. However, our data suggest that aseptic loosening of the stem in 3 out of 128 patients, is the dominant reason of implant failure. A total revision percentage of 3.9% was observed at an average of 12.6 years following surgery with good to excellent subjective outcome scores. Aseptic loosening of the cup was not found to play a role in implant failure. Based on our results, and supported by the previous mentioned long-term reports, it is suggested that implant loosening of the MoM THA designs plays a role in survivorship. However, evaluating revision percentages for loosening in other bearing designs show similar revision percentages (18). Based on our results we therefore conclude that the small diameter 28-mm MoM THA is not associated with accelerated implant loosening.

Radiolucent lines surrounding the THA can be suggestive of implant loosening. As displayed in Table II, radiolucent lines were observed in 5 patients at final follow-up. The presence of radiolucencies around the stem appeared to have a significant association with the inclination of the acetabular cup. The group with radiolucent lines around the stem had a significant more horizontal acetabular cup position ($p < 0.01$) in contrast to the group where the radiolucencies were absent. This finding may suggest that a too horizontal acetabular cup inclination should be avoided to reduce radiolucent lines surrounding the stem of MoM THA. However, all authors acknowledge that this finding may be potentially misleading since it is based on a relatively small group of patients containing only 5 patients. There is a necessity for future studies with a sufficient power containing larger groups of patients which will lead to a better understanding of this possible relation of cup inclination and radiolucent lines in 28-mm diameter MoM THA articulation. No relation of the acetabular cup position, cobalt serum levels, and subjective outcome scores were noted.

There is a lack of long-term reports which evaluate the relation of cobalt serum values and the position of the acetabular cup of the 28-mm Metasul THA. To our knowledge there is currently only 1 report that describes this relation (19). Brodner et al (19) evaluated the potential relation between acetabular cup inclination and serum cobalt levels in a small consecutive case series containing 20 THA patients. Although they did not find a significant overall association between cobalt serum levels and acetabular cup inclination, the authors found a 10- to 53.6-fold increased serum levels in the 3 patients with an acetabular cup inclination of 58°, 61° and 63° respectively. These findings are also found in the hip resurfacing literature where there is a clear association between increased whole blood metal concentrations and a relative more vertical acetabular cup position (20, 21). We were unable to repeat these findings. The possible explanation might be that

we had an average cup inclination of 40.7° (95% CI, 39.1-42.3). The only significant association we could find based on our cohort was that the average cobalt serum levels were significant higher in the group of patients who had two MoM THAs. Unfortunately, we are not able to explain the variation in cobalt serum levels, since potential relations between the previous mentioned various factors and serum cobalt levels cannot be proven by the data generated by this report.

Recently, local soft tissue reactions and potential toxic systematic adverse effects as a result of the metal debris caused by MoM articulations have led to sceptical thoughts about this type of bearing (5, 6). However, the majority of these reports are based on the larger diameter MoM hip designs. Several studies report a pseudotumor incidence of 20%-32.3% (22-24). None of the included patients in this group reported any toxic systematic adverse reactions due to elevated cobalt ions. This corresponds to a recent review, concluding that these toxic side effects only seem to occur in malfunctioning THAs. Although this was not noted in our group, the potential systematic adverse reactions should be monitored closely. Of the 78 patients who underwent serum cobalt evaluation, 30% presented with elevated cobalt levels (Tab. III). Furthermore, in the group that had undergone bilateral MoM THA, serum cobalt values were significantly higher than the unilateral group. Based on these results we recommend that patients with 28-mm MoM THAs should be monitored closely. Not only for pseudotumour evaluation, but especially for any potential systematic side-effects.

This study is not without limitations. First is the retrospective nature of this study. This made it unable to evaluate the prerevision cobalt serum levels of the 3 patients that were revised due to aseptic loosening and therefore draw any potential conclusions from this. Second, we report the results of a high-volume arthroplasty department. Therefore, results might not be duplicable in low-volume centres. Third, the rate of osteolysis might be underestimated since no routine computed tomography (CT) scan imaging was carried out in order to limit radiation exposure. Lastly, a substantial number of patients was lost in follow-up.

In conclusion, long-term results of the cementless Metasul MoM THA seem to be excellent with an overall survivorship rate 96.1% over a 12.6-year period with excellent outcome scores. However, based on this cohort, we recommend that serum cobalt should be monitored closely to evaluate any potential local and systematic adverse reactions. Especially in the group of who have a bilateral Metasul MoM THA. Future prospective and controlled studies are necessary to study the relationship and broad range of the cobalt serum levels and the possible relation on the clinical and radiographical outcomes of small diameter MoM THAs.

Disclosures

Financial support: None.
Conflict of interest: None.

References

- Harris WH. Wear and periprosthetic osteolysis: the problem. *Clin Orthop Relat Res.* 2001;393:66-70.
- Tardy N, Maqdes A, Boisrenoult P, Beaufils P, Oger P. Small diameter metal-on-metal total hip arthroplasty at 13 years - a follow-up study. *Orthop Traumatol Surg Res.* 2015;101(8):929-936.
- Dorr LD, Wan Z, Longjohn DB, Dubois B, Murken R. Total hip arthroplasty with use of the Metasul metal-on-metal articulation. Four to seven-year results. *J Bone Joint Surg Am.* 2000;82(6):789-798.
- Dastane M, Wan Z, Deshmane P, Long WT, Dorr LD. Primary hip arthroplasty with 28-mm Metasul articulation. *J Arthroplasty.* 2011;26(4):662-664.
- Zywił MG, Cherian JJ, Banerjee S, et al. Systemic cobalt toxicity from total hip arthroplasties: review of a rare condition Part 1 - history, mechanism, measurements, and pathophysiology. *Bone Joint J.* 2016;98-B:14-20.
- Zywił MG, Cherian JJ, Banerjee S, et al. Systemic cobalt toxicity from total hip arthroplasties: review of a rare condition Part 2. measurement, risk factors, and step-wise approach to treatment. *Bone Joint J.* 2016;98-B(1):14-20.
- Hardinge K. The direct lateral approach to the hip. *J Bone Joint Surg Br.* 1982;64(1):17-19.
- Dorr LD, Glousman R, Hoy AL, Vanis R, Chandler R. Treatment of femoral neck fractures with total hip replacement versus cemented and noncemented hemiarthroplasty. *J Arthroplasty.* 1986;1(1):21-28.
- Söderman P, Malchau H. Is the Harris hip score system useful to study the outcome of total hip replacement? *Clin Orthop Relat Res.* 2001;(384):189-197.
- Gosens T, Hoefnagels NH, de Vet RC, et al. The Oxford Heup Score: the translation and validation of a questionnaire into Dutch to evaluate the results of total hip arthroplasty. *Acta Orthop.* 2005;76(2):204-211.
- Gruen TA, McNeice GM, Amstutz HC. Modes of failure of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop Relat Res.* 1979;(141):17-27.
- DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop Relat Res.* 1976;(121):20-32.
- McKee GK, Watson-Farrar J. Replacement of arthritic hips by the McKee-Farrar prosthesis. *J Bone Joint Surg Br.* 1966;48(2):245-259.
- Weber BG. Experience with the Metasul total hip bearing system. *Clin Orthop Relat Res.* 1996;329(Suppl):S69-S77.
- Randelli F, Banci L, D'Anna A, Visentin O, Randelli G. Cementless Metasul metal-on-metal total hip arthroplasties at 13 years. *J Arthroplasty.* 2012;27(2):186-192.
- Hwang K-T, Kim Y-H, Kim Y-S, Choi I-Y. Cementless total hip arthroplasty with a metal-on-metal bearing in patients younger than 50 years. *J Arthroplasty.* 2011;26(8):1481-1487.
- Innmann MM, Gotterbarm T, Kretzer JP, et al. 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. *Int Orthop.* 2014;38(5):929-934.
- Meftah M, Klingenstein GG, Yun RJ, Ranawat AS, Ranawat CS. Long-term performance of ceramic and metal femoral heads on conventional polyethylene in young and active patients: a matched-pair analysis. *J Bone Joint Surg Am.* 2013;95(13):1193-1197.
- Brodner W, Bitzan P, Meisinger V, Kaider A, Gottsauner-Wolf F, Kotz R. Serum cobalt levels after metal-on-metal total hip arthroplasty. *J Bone Joint Surg Am.* 2003;85-A(11):2168-2173.
- Hart AJ, Buddhdev P, Winship P, Faria N, Powell JJSJ, Skinner JA. Cup inclination angle of greater than 50 degrees increases whole blood concentrations of cobalt and chromium ions after metal-on-metal hip resurfacing. *Hip Int.* 2008;18(3):212-219.

21. Langton DJ, Sprowson AP, Joyce TJ, et al. Blood metal ion concentrations after hip resurfacing arthroplasty: a comparative study of articular surface replacement and Birmingham Hip Resurfacing arthroplasties. *J Bone Joint Surg Br.* 2009;91(10):1287-1295.
22. Bisschop R, Boomsma MF, Van Raay JJ, Tiebosch AT, Maas M, Gerritsma CL. High prevalence of pseudotumors in patients with a Birmingham Hip Resurfacing prosthesis: a prospective cohort study of one hundred and twenty-nine patients. *J Bone Joint Surg Am.* 2013;95(17):1554-1560.
23. Bayley N, Khan H, Grosso P, et al. What are the predictors and prevalence of pseudotumor and elevated metal ions after large-diameter metal-on-metal THA? *Clin Orthop Relat Res.* 2015;473(2):477-484.
24. Bosker BH, Ettema HB, van Rossum M, et al. Pseudotumor formation and serum ions after large head metal-on-metal stemmed total hip replacement. Risk factors, time course and revisions in 706 hips. *Arch Orthop Trauma Surg.* 2015;135(3):417-425.
25. Nederlandse Orthopaedische Vereniging NO. Advies Metaal Op Metaal articulerende implantaten (MOM) van de Nederlandse Orthopaedische Vereniging 2015. <https://www.orthopeden.org/base/downloads/advies-mom-per-01-08-2015.pdf>. Accessed March 5th, 2014.