



MoM total hip replacements in Europe: a NORE report

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- The purpose of this paper is to determine the prevalence of metal-on-metal (MoM) total hip replacement (THR) in European registries, to assess the incidence of revision surgery and to describe the national follow-up guidelines for patients with MoM THR including resurfacings.
- Eleven registries of the Network of Orthopaedic Registries of Europe (NORE) participated totalling 54 434 resurfacings and 58 498 large stemmed MoM THRs.
- The resurfacings and stemmed large head MoM had higher pooled revision rates at five years than the standard total hip arthroplasties (THA): 6.0%, 95% confidence interval (CI) 5.3 to 6.8 for resurfacings; 6.9%, 95% CI 4.4 to 9.4 for stemmed large head MoM; and 3.0%, 95% CI 2.5 to 3.6 for conventional THA.
- The resurfacings and stemmed large head MoM had higher pooled revision rates at ten years than the standard THAs: 12.1%, 95% CI 11.0 to 13.3 for resurfacings; 15.5%, 95% CI 9.0 to 22 for stemmed large head MoM; and 5.1%, 95% CI 3.8 to 6.4 for conventional THA.
- Although every national registry reports slightly different protocols for follow-up, these mostly consist of annual assessments of cobalt and chromium levels in blood and MRI (MARS) imaging.

Keywords: metal-on-metal total hip replacement; joint registry

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Introduction

Metal-on-metal (MoM) bearings have been used since the early years of total hip replacement (THR). Early historical MoM prostheses from the 1960s, 1970s and 1980s include the McKee Farrar hip and the Ring hip prostheses.¹ They can be considered the first generation of metal-on-metal total hip replacement (MOM-THR). Their metal-on-polyethylene (MoP) counterpart was Charnley's low friction arthroplasty.¹ The Charnley MoP prosthesis had lower rates of early aseptic loosening than the first-generation MoM-THR and thus became the preferred bearing over MoM.¹⁻⁴

Around the turn of the millennium, a second generation of MoM-THR, including resurfacings, was introduced with the claim of reduced wear and superior implant survival, especially in high demanding young patients due to better metal alloys and hardening methods.⁵⁻⁷ Initially, second-generation MoM-THR showed good outcomes in younger patients.⁸ However, subsequent reports were more concerning with higher revision rates and occurrence of pseudo-tumours and ARMD (Adverse Reaction to Metal Debris).⁹⁻¹¹

Due to wear and corrosion, hip replacements with MoM bearings may produce small metallic particles.¹² These metallic fragments may lead to local adverse effects (e.g. pseudo-tumours) and there are some authors who believe that they may cause systemic adverse effects (e.g. nephrotoxicity, cardiotoxicity, carcinogenicity), structural changes in the visual pathways and basal ganglia with associated higher mortality rates at long-term follow-up. However, there are others who refute this suggestion.¹³⁻¹⁸

Acknowledging these findings, the MoM total hip arthroplasty (THA) and many resurfacing prostheses systems were recalled by their manufacturers and the use of MoM bearings decreased dramatically. Only a limited number of resurfacing brands are still available, and some manufacturers limit the use of their prostheses to male patients.^{19,20} By the time the MoM bearings were recalled from the market, a large number of patients had already been treated with MoM-THR. Several registries and organizations have advised against its use.²¹⁻²³

For all patients who had a MoM hip implanted and knowing the possible adverse effects on their health, it is generally agreed that it is of utmost importance to closely monitor patients with MoM bearings on a regular basis.^{11,18,19}

National Joint Arthroplasty registries play an important role as they enable identification of patients with MoM-THR, they enable assessment of the prevalence of MoM bearings and they enable monitoring of the incidence of revision surgery. The purpose of this paper is to determine the prevalence of MoM-THR in European registries, to assess the incidence of revision surgery and to describe the national follow-up guidelines.

Methods

All participating registries of the Network of Orthopaedic Registries of Europe (NORE) were approached for participation. The NORE is a platform within the EFORT and aims to improve international collaboration and research in orthopaedics with a focus on medical device surveillance. All NORE registries were contacted by email to complete a web-based survey. After four, eight and 12 weeks, a reminder was sent by email.

The web-based survey consisted of 28 items on demographic information of patients with resurfacings, stemmed large head MoM and standard (non-MoM) THA, on incidence of primary revision surgery, on incidence of revisions of revisions, on brands of MoM used and on guidelines for the follow-up of patients with MoM-THR.

Of the 24 European registries participating in NORE, 12 registries completed the online survey. One of the responding registries, the Latvian Arthroplasty Register (LAR), did not record any details on MoM implants and was therefore excluded from the analyses, leaving the results from 11 registries for the analyses.

Participating registries (in alphabetical order)

Danish Hip Arthroplasty Register (DHR), Denmark

The DHR started in 1995 and includes 1424 resurfacings and 2142 stemmed large head MoM implants. This registry has been cross-linked with the national patient registry of Denmark.

The Finnish Arthroplasty Register (FAR), Finland

The FAR started in 1980 and includes 5224 resurfacing and 13982 stemmed MOM implants. This registry has been cross-linked to the cancer registry.

Geneva Arthroplasty Registry (GAR), Switzerland

The GAR started in 1996 and includes 81 resurfacings and 92 stemmed large head MoM implants. This registry has not been cross-linked to any other registry.

Landelijke Registratie Orthopedische Implantaten (LROI), The Netherlands

The Dutch LROI registry started in 2007 and includes 2872 resurfacing and 7079 stemmed MOM implants. This registry has not yet been cross-linked with any other registry in The Netherlands.

The Norwegian Arthroplasty Register (NAR), Norway

The NAR started in 1987 and includes 485 resurfacing and 97 stemmed MOM implants. This registry has been cross-linked with other registry databases such as the Norwegian Patient Register, the cancer registry, HUNT (health study) and the Twin register.

National Joint Registry of England Wales and Northern Ireland (NJR)

The NJR started in 2003 and includes 38402 resurfacing and 30793 stemmed MoM implants. This registry has been cross-linked with the British cancer, heart failure and GPRD registries.

Register of Prosthetic Orthopaedic Implants (RIPO), Emilia-Romagna, Italy

The RIPO started in 2000 and includes 835 (local) and 1805 (extra-regional) hip resurfacing implants and 4663 stemmed MoM implants. The information of this registry has been linked with medication and discharge registries.

Catalan Arthroplasty Registry (RACat), Catalunya, Spain

The RACat started in 2005 and includes 604 resurfacings, of which 554 were primary, and 492 large head MoM implants (of which 470 were primary). This registry has not been cross-linked to any other registry.

Romanian Arthroplasty Register (RAR), Romania

The RAR includes 442 resurfacing implants from 2002 until 2016 and 76 stemmed MOM implants from 2006 to 2013. The RAR has not been cross-linked with any other registry.

Table 1. Demographics

| | Resurfacing | | | | Stemmed large head MoM | | | | Standard THA | | | |
|-------|-------------|----------|--------|-----------|------------------------|----------|--------|-----------|--------------|----------|--------|-----------|
| | n | Mean age | SD age | Women (%) | n | Mean age | SD age | Women (%) | n | Mean age | SD age | Women (%) |
| NJR | 38402 | 55.0 | | 29.2 | 30793 | 64.0 | | 49.9 | | | | |
| RIPO | 2637 | 52.7 | 10.9 | 26.0 | 2354 | 62.7 | 11.3 | 39.0 | 65938 | 69.2 | 10.4 | 62.0 |
| LROI | 2872 | 53.9 | 8.0 | 33.9 | 7073 | 65.4 | 10.4 | 64.3 | 193127 | 69.6 | 10.6 | 67.2 |
| NAR | 485 | 52.8 | 8.3 | 23.9 | 97 | 54.1 | 9.9 | 29.9 | 60760 | 68.8 | 11.3 | 66.6 |
| FAR | 5224 | 54.1 | 8.7 | 32.1 | 13982 | 61.7 | 10.1 | 44.4 | 322497 | 67.6 | | 66.3 |
| RAR | 442 | 44.1 | 12.3 | 31.4 | 76 | 42.6 | 12.1 | 26.0 | 83435 | 62.5 | 13.5 | 54.5 |
| VJRR | | | | | 355 | 52.0 | 11.0 | 44.5 | 37018 | 58.0 | 12.9 | 59.5 |
| DHR | 1424 | | | | 2142 | | | | 160000 | 70F, 67M | | 60.0 |
| RACat | 604 | 52.2 | 8.8 | 10.5 | 492 | 54.1 | 10 | 20.2 | 24196 | 69.9 | 11.5 | 54.5 |
| GAR | 81 | 48.1 | | 22.2 | 92 | 51.9 | | 25 | 3083 | 71.9 | | 61.5 |
| SHAR | 2263 | 49.5 | | 23.6 | 1042 | 51 | | 31.3 | 265986 | 68.5 | | 57.8 |
| Total | 54434 | | | | 58498 | | | | 1216040 | | | |

MoM, metal-on-metal; THA, total hip arthroplasty; NJR, National Joint Registry of England Wales and Northern Ireland; RIPO, Register of Prosthetic Orthopaedic Implants, Emilia-Romagna, Italy; LROI, Landelijke Registratie Orthopedische Implantaten, The Netherlands; NAR, The Norwegian Arthroplasty Register; FAR, The Finnish Arthroplasty Register; RAR, Romanian Arthroplasty Register; VJRR, Vreden Joint Replacement Register, Russia (regional registry); DHR, Danish Hip Arthroplasty Register; RACat, Catalan Arthroplasty Registry; GAR, Geneva Arthroplasty Registry; SHAR, Swedish Hip Arthroplasty Register

Swedish Hip Arthroplasty Register (SHAR), Sweden

The SHAR started in 1979 and includes 2263 resurfacings and 1042 stemmed large head MoM implants. This registry has been cross-linked with the national patient register of the national board of health and welfare.

Vreden Joint Replacement Register (VJRR), Russia (regional registry)

The VJRR registry includes 355 stemmed MoM implants starting from 2007. It did not include any resurfacings. This registry has not been cross-linked to any other registry.

Statistics

Standard descriptive statistics were used where appropriate. For calculating the pooled revision rates for resurfacings, large head stemmed MoM and standard THA (non-MoM) a random effects model was used in R statistics; package metafor.²⁴ An example of the data transfer form is provided in the appendix (Table S1).

Results

Demographics of MoM prostheses

The demographics are presented in Table 1. In total, 54 434 resurfacings and 58 498 stemmed large head MoM-THAs have been implanted in the included registries.

Patients with MoM-THR were younger than patients with standard THA. Within the MoM-THR patients with resurfacings were the youngest. The mean age of the resurfacing patients was in the range of 44.1 years in the RAR to 55 years in the NJR. The mean age of the patients with stemmed large head MoM implants were in the range of 42.6 years in the RAR to 65.4 years in the LROI. The mean age of patients with a standard MoP-THA was in the range of 58 years in the VJRR to 71.9 years in the GAR.

There were more females in the non-MoM-THR group. Within the MoM-THR group there were more females in the stemmed large head MoM group, so the resurfacing group comprised mostly males. The percentage of females in the resurfacing group was in the range of 10.5% in the RACat to 33.9% in the LROI. The percentage of females in the stemmed large head MoM group was in the range of 20.2% in the RACat to 64.3% in the LROI. The percentage of females in the standard THA group was in the range of 54.5% in the RACat and RAR to 67.2% in the LROI.

In RIPO, 7.0% of the included prostheses had MoM bearings (3.7% resurfacing and 3.3% stemmed large head MoM implants). In the LROI (Netherlands) database, 95.1% were non-MOM prostheses, 3.5% were stemmed large head and 1.4% were resurfacing prostheses. In the NAR registry (Norway), the proportion of prostheses with MoM bearings was 0.8% for resurfacing and 0.2% for stemmed large head MoM implants. In the RAR registry (Romania), the proportion of prostheses with MoM bearings was 0.5% for resurfacing and 0.09% for stemmed large head MoM implants. The FAR (Finland) had the largest component of stemmed large head prostheses in its registry (4.1%) and 1.5% resurfacings. The VJRR (regional) had no resurfacing prostheses included in the registry and 0.95% of the total registry was stemmed large head MoM implants. The DHR (Denmark) registry included 0.9% resurfacings and 1.3% stemmed large head MoM implants. In the RACat registry, 4.3% of included prostheses had MoM bearings (2.4% resurfacings and 1.9% stemmed large head MoM implants). In the GAR (Geneva), 5.3% of the included prostheses had MoM bearings (2.5% resurfacings and 2.8% stemmed large head MoM implants). In the SHAR (Sweden), 1.2% of the included prostheses had MoM bearings (0.8% resurfacings and 0.3% stemmed large head MoM implants).

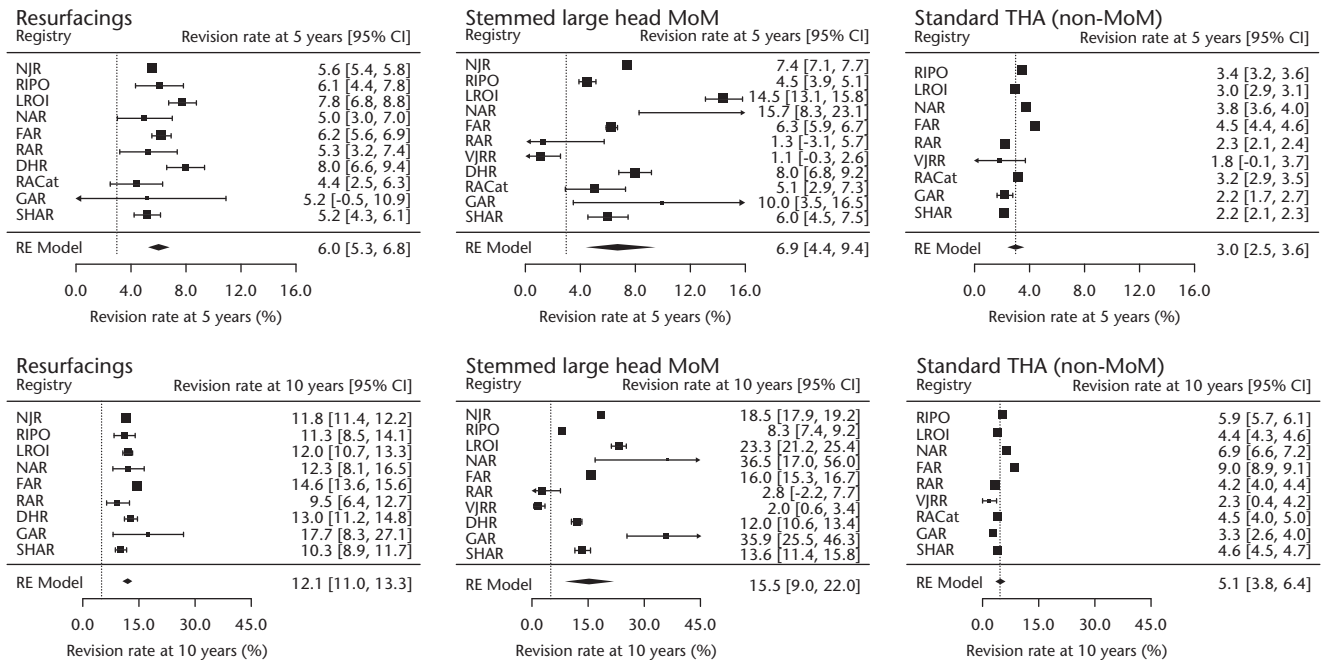


Fig. 1 Meta-analyses depicting the pooled revision rates for resurfacings, stemmed large head metal-on-metal (MoM) and standard total hip arthroplasty (THA) at five- and ten-years follow-up.

Brands used

The ASR MoM prosthesis was used by every included registry (both the ASR XL for THR and the DePuy ASR for hip resurfacing). In addition, in every registry, the Birmingham Hip Resurfacing prosthesis (BHR) was used, except for the GAR.

For stemmed large head MoM prostheses, a large variety of brands was used.

Although manufacturers expect surgeons to use all components of the same manufacturer, almost all included registries report off-label mix-and-match prostheses, except for the GAR. The NAR and RAR reported that these mix-and-match prostheses consist of the use of BHR acetabular cups in stemmed large head MoM implants.

Primary revisions

Five-year revision rates

The resurfacings and stemmed large head MoM implants had higher pooled revision rates at five years than the standard THA (Fig. 1): 6.0%, 95% confidence interval (CI) 5.3 to 6.8 for resurfacings; 6.9%, 95% CI 4.4 to 9.4 for stemmed large head MoM implants; and 3.0%, 95% CI 2.5 to 3.6 for standard THA. For the stemmed large head MoM implants, the five-year revision rates varied greatly between the registries from 1.1% for the VJRR to 15.7% for the NAR.

Ten-year revision rates

The resurfacings and stemmed large head MoM implants had higher pooled revision rates at ten years than the

standard THA (Fig. 1): 12.1%, 95% CI 11.0 to 13.3 for resurfacings; 15.5%, 95% CI 9.0 to 22 for stemmed large head MoM implants; and 5.1%, 95% CI 3.8 to 6.4 for standard THA. For the stemmed large head MoM implants, the ten-year revision rates varied greatly between the registries from 2.0% for the VJRR to 36.5% for the NAR.

Revisions of revisions

Five registries provided information regarding revisions of revisions; NJR, NAR, FAR, RACat and GAR.

In NJR, the proportion of patients needing a second revision at five years were comparable between resurfacing (11.5%) and standard non-MoM-THA (cemented 11.3%, uncemented 11.8%). The incidence of second revisions in stemmed large head MoM was higher with 13.8%.

The NAR included 97 persons with stemmed large head MoM implants of which 36.5% needed revision. Of these revised prostheses, 24% needed a second revision.

For resurfacing prostheses, this was 18.6%; in non-MoM-THA, 20.4% of the patients needing a revision underwent additional revision surgery between 2004 and 2014.

In the FAR, revisions of revisions were similar between resurfacing (13.7%) and stemmed MoM implants (12.2%). For standard non-MoM-THA, 20.24% of the revisions needed a second revision; however, the reported follow-up time was longer.

The RACat reported that out of 26 stemmed large head MoM revisions, one needed another revision. For

Table 2. Follow-up protocol.

| Follow-up protocol | | | | | |
|--------------------|---------------------|--|-------------------|-----------------|------------|
| | Minimum follow-up | Frequency | Co Serum levels | Cr Serum levels | MRI (MARS) |
| NJR | Lifetime of implant | MHRA guidelines | 7 ppb | 7 ppb | Yes |
| RIPO | Lifetime of implant | Resurfacing: 5 years Resurfacing at risk: 1 year MoM: 1 year | 7 ppb | 7 ppb | Yes |
| LROI | Lifetime of implant | Every 2-3 years | 1 ppb = 17 nmol/L | 0-40 nmol/L | Yes |
| NAR | Lifetime of implant | 'Written guidelines' | 7 ppb | 7 ppb | No |
| RAR | No | | No | No | No |
| VJRR | 2 years | | No | No | No |
| FAR | Lifetime | Every 2-3 years | Yes | Yes | Yes |
| DHR | Lifetime | 1, 2, 5, 7-8, 10, 15 years | 7 ppb | 134.5 nmol/L | Yes |
| RACat | 5 years-lifetime | Annual | 5 uL | 5 uL | yes |
| GAR | Lifetime | Every 2 years; more frequently if symptomatic | 2 ug/L | 2 ug/L | Yes |
| SHAR | No | Annual | 5 ug/L | 5 ug/L | Yes |

MoM, metal-on-metal; MHRA, Medicines and Healthcare products Regulatory Agency; NJR, National Joint Registry of England Wales and Northern Ireland; RIPO, Register of Prosthetic Orthopaedic Implants, Emilia-Romagna, Italy; LROI, Landelijke Registratie Orthopedische Implantaten, The Netherlands; NAR, The Norwegian Arthroplasty Register; FAR, The Finnish Arthroplasty Register; RAR, Romanian Arthroplasty Register; VJRR, Vreden Joint Replacement Register, Russia (regional registry); DHR, Danish Hip Arthroplasty Register; RACat, Catalan Arthroplasty Registry; GAR, Geneva Arthroplasty Registry; SHAR, Swedish Hip Arthroplasty Register

resurfacing, the incidence of re-revisions increased up to 10.7% and in standard THA the incidence of re-revision is 7.6%.

The GAR reported the all-cause second revision at five years to be 16.3% for MOM and 7% for non-MoM implants.

Follow-up guidelines

All the included registries continue to track MoM implants in the registries even if the use of MOM prosthesis has been discontinued.

The follow-up protocol of included registries is presented in Table 2.

The American Food and Drugs Administration (FDA) recommends performing these visits at least every two years for asymptomatic patients and every six months for patients with symptoms.²⁵ The European SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks) advises screening symptomatic patients annually, but leaves the frequency of asymptomatic patients to local protocols.

NJR

NJR is part of the British Orthopaedic Association (BOA) and the Medicines and Healthcare products Regulatory Agency (MHRA) 'Expert Advisory Group' (EAG) who first issued guidelines in 2012 and which have been regularly reviewed since then. Besides, orthopaedic surgeons and regulators the advisory group contains expert physicians representing all the disciplines whose patients could be affected by metal toxicity (cardiologists, endocrinologists, neurologists, nephrologists, etc.). For instance, patients who received stemmed MoM prostheses with a femoral head diameter of ≥ 36 mm are followed annually for the

lifetime of the prosthesis and have cobalt and chromium blood levels regularly measured. The EAG has set the level of acceptable cobalt and chromium at 7 ppb.

They recommend MRI (MARS) scans whenever patients are symptomatic or have high metal ion levels.^{26,27}

RIPO

RIPO follows the guidelines as recommended by EFORT and the European Commission. Patients with resurfacing are assessed yearly for the first five years. Then, they leave the surveillance process unless they are at risk (females, small head, malposition of the cup). All patients with stemmed large head MoM implants are screened annually. The assessment consists clinical evaluation, Rx and blood cobalt and chromium dosage (with a threshold of 7 ppb). If clinical, radiological or hematic data are abnormal, data are confirmed in a short follow-up (2 to 6 months) and eventually MRI (MARS) or dual-energy CT are performed.

LROI

The Dutch LROI stated '*Patients that have received MoM should be followed up conform our protocol as long as the MOM is in situ. In case of no clinical problems and with repeated low serum cobalt levels, these FU moments can be scheduled each 2/3 years. In case of rising metal levels, these FU moments should be increased. FU should consist of anamneses with special attention to local and systemic effects of metal-debris, radiograph of the hip with specific attention to the position and osteolysis. Blood Co and Cr should be checked. If necessary renal function should be checked as well. In case of complaints or abnormalities seen during FU, the investigation should be extended with MARS-MRI or CT.*'²⁸

NAR

The NAR states in the survey that there are 'written guidelines' according to which they perform follow-up of MoM patients: 'hospitals have a duty to regularly monitor all patients with MoM prostheses with a diameter of > 32 mm for the rest of their lives, as recommended by the Norwegian National Advisory Unit on Arthroplasty and Hip Fractures (<http://nrlweb.ihelse.net/> or <http://www.haukeland.no/nrl/>) and in line with similar recommendations in other countries.'

DHR

The DHR registry evaluates patients at risk at one, two, five, seven to eight and ten years and from then on every five years for the presence of pseudo-tumours, cobalt and chromium and have a threshold of 7 ppb (119 nMol/L) for cobalt and 134.5 nMol/L for chromium. Patients with pain may have an MRI on the indication pseudo-tumour.

RACat

Patient follow-up depends on the implant. Different follow-up guidelines were undertaken depending of the Co/CL levels, the presence or absence of symptomatology in the patient and the type of prosthesis (resurfacing or conventional MoM). Furthermore, among resurfacing prostheses, the prosthesis model (ASR or non-ASR) is considered, and among conventional prostheses, the head size.

Future

The problem of MoM prostheses is acknowledged by all registries included in this study.

Representatives of RIPO, NAR, RACat and GAR expected that the number of revisions in this specific patient group will rise in the future, whereas the rest of the registries think this will stay the same as it is now.

Conclusion

Patients with MoM-THR tended to be younger than patients with standard THA and there were more men in the MoM groups than in the standard THA group.

For the 11 included registries, the five-year and ten-year revision rates of resurfacings and stemmed large head MoM implants were higher than the revision rates of the standard THA. There was considerable between-registry variation in the five-year and ten-year revision rates of the stemmed large head MoM implants, whereas this was not the case for the revision rates of the resurfacings and standard THA. This between-registry variation needs further study to help identify patients at risk of revision in the stemmed large head MoM group.

Although every national registry reports slightly different protocols for follow-up, these mostly consist of annual

assessments of cobalt and chromium levels in the blood and MRI (MARS) imaging.

Most registries express their concerns regarding increased problems for patients with MoM prostheses, giving ground for a more integrated European approach in the follow-up protocol of MoM-bearing patients.

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ICMJE CONFLICT OF INTEREST STATEMENT

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LICENCE

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