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Link to published version (if available):
10.2106/JBJS.17.00039

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Implications of Introducing New Technology

Comparative Survivorship Modeling of Metal-on-Metal Hip Replacements and Contemporary Alternatives in the National Joint Registry

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Disclosure: This work was funded by a grant from the Healthcare Quality Improvement Partnership of the National Joint Registry for England, Wales and Northern Ireland; this grant included funding for the salary of the one of the authors (L.P.H.). The partnership and registry had no role in the design of the study; collection, analysis, and interpretation of data; or writing of the manuscript. The views expressed represent those of the authors and do not necessarily reflect those of the National Joint Registry Steering Committee or Healthcare Quality Improvement Partnership, who do not vouch for how the information is presented. In addition, on the Disclosure of Potential Conflicts of Interest forms, which are provided with the online version of the article, one or more of the authors checked “yes” to indicate that the author (or the author’s institution) had a relevant financial relationship, in the biomedical arena outside the submitted work; and “yes” to indicate that the author had other relationships or activities that could be perceived to influence, or have the potential to influence, what was written in this work. (http://links.lww.com/XXXXXXX).
**Background:**

New medical technologies are often used widely without adequate supporting data, a practice that can lead to widespread catastrophic failure such as occurred with metal-on-metal (MoM) hip replacements. We determined both how revision rates would have differed if, instead of receiving MoM hip replacements, patients had received existing alternatives and the subsequent cumulative re-revision rates of the patients who did receive MoM hip replacements compared with alternatives.

**Methods:**

This study is a population-based longitudinal cohort study of patient data recorded in the National Joint Registry (NJR) for England, Wales and Northern Ireland between April 2003 and December 2014. We ascertained implant failure rates separately among stemmed MoM total hip replacement (THR) and hip-resurfacing procedures and, using flexible parametric survival modeling, compared them with the failure rates that would have been expected had existing alternatives been used. We used Kaplan-Meier survivorship analysis to compare cumulative re-revision of patients who received stemmed MoM primary replacements that failed and of those who underwent hip resurfacing that failed with those whose non-MoM THRs had failed.

**Results:**

In all, 37,555 patients underwent MoM hip resurfacing, with a 10-year revision rate of 12.6% (95% confidence interval [CI]: 12.2% to 13.1%) compared with a predicted revision rate of 4.8% if alternative implants had been used. The 32,024 stemmed MoM THRs had a 19.8% (95% CI: 18.9% to 20.8%) 10-year failure rate compared with an expected rate of 3.9% if alternatives had been used. For every 100 MoM hip-resurfacing procedures, there were 7.8 excess revisions by 10 years, and for every 100 stemmed MoM THR procedures, there were 15.9, which equates to 8,021 excess first revisions. Seven-year re-revision rates were 14.9% (95% CI: 13.8% to 16.2%) for stemmed non-MoM THRs, 18.0% (95% CI: 15.7% to 20.7%) for MoM hip resurfacing, and 19.8% (95% CI: 17.0% to 23.0%) for stemmed MoM THRs.

**Conclusions:**

This study highlights the consequences of widespread and poorly monitored adoption of a medical technology. Over 1 million MoM hip prostheses were implanted worldwide. The excess failure on a global scale will be enormous. This practice of adopting new technologies without adequate supporting data must not be repeated.

**Level of Evidence:**

Therapeutic **Level III.** See Instructions for Authors for a complete description of levels of evidence.
New technologies are constantly being introduced into medical practice. These technologies undergo extensive preclinical testing, but once in clinical use they are often not effectively evaluated. Initial published data are usually from inventors and manufacturers and therefore may not be generalizable. One prominent example is metal-on-metal total hip replacements (MoM THR). Over 1 million of these devices were implanted worldwide before National Joint Registry (NJR) data from England and Wales first demonstrated unacceptably high failure rates\(^1,2\). These findings were also noted in Australia, Spain, Italy, the U.S., and Nordic countries\(^3,4\).

Stemmed MoM THR and hip-resurfacing implants became popular between 2003 and 2008 because surgeons believed that these would have lower failure rates than existing alternatives, particularly in younger patients, in whom wear and failure rates are higher with established types of hip replacement\(^5\). This belief was based on tribological laboratory observations that MoM bearings had very low wear rates\(^6,7\). In addition, lower wear rates would allow the use of larger femoral heads, which would decrease the risk of dislocation\(^8\). By 2008, approximately one-third of all hip replacements being performed in the U.S. and 14% of all hip replacements being performed in England and Wales were MoM\(^9\). Randomized studies comparing MoM hip resurfacing with THR were underpowered to determine whether there were any significant differences between the interventions, and the results of these studies appeared late in the course of introducing the MoM technology\(^10-12\). Unfortunately, both MoM hip resurfacing\(^1\) and MoM stemmed THR\(^2,13\) went on to fail at much higher rates than the alternatives did. The usage of such implants subsequently declined to <1% of all hip replacements performed in England and Wales in 2014\(^9\). However, the NJR has recorded nearly 70,000 MoM hip replacements implanted between April 2003 and December 2014\(^9\).

We believe that health-care systems worldwide were essentially involved in a large-scale uncontrolled trial without understanding the long-term implications or the potential impact on failure rates of the joint prostheses implanted and on the patients who received them. The present analysis had 2 arms, stemmed MoM and resurfacing MoM prostheses. It is well documented elsewhere that the failure mechanisms and outcomes differ between these 2 arms\(^1,2\), but neither stemmed MoM nor resurfacing MoM has been a clinical success. We wished to ascertain the consequences of using MoM hip prostheses by determining the excess revision rate attributable to MoM hip-resurfacing and MoM THR prostheses implanted during this period. We achieved this aim by modeling what the outcomes would have been in patients who received MoM hip replacements (assessing stemmed MoM and hip resurfacing separately) if the technology had never been introduced and instead patients had received the alternative technologies in use (non-MoM hip replacements) according to age, sex, and diagnosis leading to hip replacement. We compared this information with the actual outcomes that these patients experienced to determine the excess failure rates. Lastly, we determined the re-revision rate for hips that had been revised and we documented the reasons for revision of all first revision procedures.

**Materials and Methods**

The base dataset was 708,311 linked primary hip replacements performed in England and Wales between April 1, 2003, and December 31, 2014, and described in the 12th Annual Report of the NJR\(^14\). The Data Quality Audit suggests that in recent years approximately 3% of primary replacements and 5% of revisions were not recorded in the NJR\(^15\). In addition, annual implant sales in England and Wales have corresponded extremely well with the recorded number of arthroplasties performed. Approximately 10% of recorded procedures have been lost because of linkage issues, as no suitable person-level identifier could be found.
Around half of these losses are because patients declined to give consent for their data to be held.

Implants were divided into 3 groups: stemmed THRs with MoM bearings (n = 32,024), MoM hip-resurfacing protheses (n = 37,555), and all other stemmed THRs with other combinations of bearing surfaces (non-MoM; n = 626,314). The bearing-surface combination implanted could not be established in 11,977 cases because of missing information, and a further 441 cases were excluded because some ambiguity was found in the data recorded in the NJR. Table 1 illustrates that the proportions of stemmed MoM THRs and hip-resurfacing procedures rose to peaks at 2008 and 2006, respectively, and both subsequently fell.

First, we sought to compare the outcomes of the stemmed MoM THRs and MoM hip-resurfacing procedures with the stemmed THRs with non-MoM bearing surfaces and, for the stemmed MoM THRs and MoM hip-resurfacing procedures, to compare actual outcomes with outcomes expected had other bearing-surface combinations been used instead of the MoM bearing. The 12,418 implants with uncertain bearing surfaces (1.8%) were excluded, leaving 695,893 cases available for analysis. Second, we wished to ascertain whether the hips that were revised required re-revision.

**Statistical Methods**

The primary outcome of interest for this analysis was the time elapsed from the primary procedure to the first recorded linked revision procedure. We used survival methods to account for censoring, with either the date of December 31, 2014, or the date of death if the patient had died before then. The maximum potential follow-up available was 11.75 years.

We developed a prediction model from a 90% random sample of the stemmed non-MoM set (the training set), retaining the remaining 10% for model validation (the test set).

Predictors used in the model were sex, continuous age in years at the primary operation (as 4 restricted cubic splines), and the reason for the primary procedure (osteoarthritis [OA] only, other indication [with or without OA], and any trauma, with any trauma overriding all other indications). For the modeling, we used flexible parametric survival modeling\(^{16,17}\) as implemented in Stata (version 14; StataCorp)\(^{14}\), which accommodates time-varying effects of the predictor variables. The latter time-varying effects were assessed using likelihood ratio tests and examination of the Akaike and Bayesian information criteria (AIC and BIC, respectively).

Proportional hazards regression models can be expressed on the natural logarithm of the cumulative hazards (ln{H} scale as ln{H(t|x')} = ln{Ho(t)} + x'β, where x' are covariates in the model and β is a vector of their coefficients (to be determined). In flexible parametric survival modeling, the logarithm of the baseline cumulative hazard (ln{Ho(t)}) is modeled as a restricted cubic spline function of the logarithmically transformed time from the primary procedure (ln(t)) as fully described by Lambert and Royston\(^{17}\). The methodology allows time-varying effects of the model covariates to be explored by forming interactions between them and the spline function for the baseline hazard; splines with fewer knots can be used for these effects than for the baseline\(^{17}\).

The developed model was used to make out-of-sample cumulative revision predictions for the other 3 groups: the stemmed non-MoM THR test set (to validate the model), the stemmed MoM THR implants, and the MoM hip-resurfacing implants. For each of these groups, the actual cumulative revision estimates (Kaplan-Meier estimates) were compared with those predicted from the model. For the stemmed MoM THR and the MoM hip-resurfacing groups, the predicted cumulative revision would be the expected results had
the patients been managed in the same way as those who received the stemmed non-MoM implants, allowing for age, sex, and indication.

Fixation was not included in the prediction model. The decision to use MoM implants would, by definition, have been constrained to uncemented or hybrid fixation. Had other bearing surfaces been used instead, it would not necessarily follow that they would have had the same method of fixation. Similarly, head size was not included in the prediction. First, all resurfacing prostheses would have had large heads (diameter, ≥36 mm) by definition and, second, where a stemmed MoM THR was used with a large head, it would not follow that a large head would have been used if a different bearing-surface combination had been used.

In the hips that were revised, we then used Kaplan-Meier survivorship analysis to estimate the cumulative re-revision by year from first revision.

Results

A summary of the variables for analysis, with comparisons among the various subgroups, is shown in Table II. The numbers with missing data were small and were similarly distributed in the subgroups. In total, there were no data available on the indication for the primary procedure for 61 implants, the age was missing (not validated because the National Health Service number was not traced) for 341 implants, and the patient sex was not available for 6 implants.

Outcome in terms of time to revision is known to depend on the sex and age of the patient. Among the stemmed non-MoM THRs, cumulative revision (Kaplan-Meier estimate) was progressively worse where there were “other indications” for the primary procedure or “any trauma” than when the indication was “OA [osteoarthritis] only” (see Appendix). However, these differences are seen in univariate analyses (see Appendix) and may reflect the interrelationships between these factors and the age and sex of the patient.

For prediction of outcome, we used age, sex, and risk group (reason for the primary procedure). A series of exploratory analyses on the stemmed non-MoM THR training set (data not shown; n = 563,354 cases with complete information) suggested that 3 knots (i.e., 4 degrees of freedom) would give a satisfactory fit for the baseline hazard. Sex, age, and risk group all had time-varying effects, with respective degrees of freedom of 1, 2, and 2. Out-of-sample prediction based on this model for the 3 groups (the stemmed non-MoM THR test set, the stemmed MoM THRs, and the MoM hip-resurfacing group) are plotted in Figure 1. This modeling shows the predicted outcomes if stemmed and resurfacing MoM implants had not been used in these specific patients. These predicted outcomes suggest that slightly worse cumulative revision results would be expected for MoM hip resurfacing and stemmed MoM THRs than for the stemmed non-MoM THRs, probably reflecting the fact that these groups were more heavily weighted to men and to younger patients. In Figure 2, the actual cumulative revision rates (Kaplan-Meier) with pointwise 95% confidence intervals (CIs) have been added. For stemmed MoM THRs and MoM hip resurfacing, the actual results were much worse than expected a priori, with stemmed MoM THRs showing a more marked difference. These rates contrasted with those for the stemmed non-MoM THR test set, in which the cumulative revision rates were close to their expected values, validating the model.

Table III documents the actual cumulative revision rates for the stemmed non-MoM THR test set, the stemmed MoM THRs, and the MoM hip-resurfacing group compared with their expected cumulative revision rates estimated from the model. It can be seen that, for every 100 stemmed MoM THR implants, there were 15.9 (19.8 – 3.9) excess revisions by 10 years. Similarly, for every 100 MoM hip-resurfacing procedures, there were 7.8 (12.6 – 4.8) excess revisions by 10 years. Finally, Figure 3 (as well the Appendix) shows the re-revision rates of the hips that were revised during the study period. Seven-year re-revision rates were 14.9% (95% CI: 13.8% to 16.2%) for stemmed non-MoM THRs, 18.0% (95% CI: 15.7% to
20.7%) for MoM hip resurfacing, and 19.8% (95% CI: 17.0% to 23.0%) for stemmed MoM
THRs.

“Adverse reaction to metal debris” as an option for the reason for revision was not
added to the minimum data set of the NJR until 2008. Thirty-three percent of resurfacing
revisions and 46% of stemmed MoM revisions were performed for adverse reaction to metal
debris from 2008 until December 2014, compared with only 2% of the revisions performed
on non-MoM THRs. The reasons for revision are outlined in the Appendix.

Discussion

Our model predicts that every 100 MoM hip-resurfacing procedures performed would
result in 7.8 additional revision hip replacements within 10 years and every 100 stemmed
MoM THRs, in 15.9 additional revision hip replacements within 10 years. In all, 32,024
stemmed MoM THRs and 37,555 MoM hip-resurfacing prostheses were implanted between
April 2003 and December 2014, resulting in a prediction of 8,021 excess first revisions
within 10 years of implantation. Data capture in the early years of the NJR was incomplete
and, thus, our numbers are an underestimation of this problem. MoM hip replacement
prostheses are still being implanted worldwide in 2017. In all, 790 resurfacing and 67
stemmed MoM THR procedures were recorded in the NJR in 2014 even though the
unacceptably high failure rates for these devices were published in The Lancet in 20121,2.

Furthermore, of the MoM hip replacements that have been revised (either to non-
MoM or MoM prostheses) in England and Wales, nearly 1 in 5 required re-revision within 7
years. This rate is greater than that for stemmed non-MoM THRs, and the difference becomes
more marked with time. Many surgeons were attracted to resurfacing as revision of the
femoral component is much easier than revision of a stemmed femoral component because
the integrity of the femoral metaphysis and diaphysis is preserved. However, the data
presented show that these so-called easier revisions lead to higher re-revision rates, most
likely explained by the fact that there were different reasons for first revision between the
groups as well as the fact that, in some first revisions following resurfacing procedures, an
MoM articulation was maintained when only 1 component was revised.

The personal and societal costs of revision hip surgery are enormous. Both the failure
of the implant and the subsequent revision cause the patient pain, loss of function, and loss of
participation in society. The hospital costs of each revision episode are approximately
$16,800 (£12,000)19. In total, 8,021 excess first revisions over 10 years will thus cost the
National Health Service in England and Wales approximately $140 million (£100 million).
Furthermore, there are the additional costs of second and subsequent revisions and follow-up
appointments, including blood tests for cobalt and chromium levels, magnetic resonance
imaging (MRI), and ultrasound (as recommended by the Medicines & Healthcare products
Regulatory Agency for MoM hip replacements) and the cost of treating disability and pain as
well as lost employment.

MoM hip prostheses have been used extensively worldwide. It is estimated that over 1
million have been implanted20 and, at their peak, they accounted for approximately one-third
of the hip replacements performed in the U.S.21. Our patients are similar in age, diagnosis,
body mass index, and sex to those in most registries, and the implants used are manufactured
by the same companies. Our results are thus likely to be generalizable to other health-care
settings outside of the U.K. Simply comparing failure rates between patients who underwent
MoM THRs and those who did not would not be valid, as the groups vary considerably
according to age and sex, factors that are on the causal pathway of hip failure. It is well
established that failure rates after stemmed MoM replacement procedures are proportional to
prosthetic head size1 and, after resurfacing MoM, inversely proportional to head size2. If the
MoM procedures had been confined to only small-diameter stemmed articulations and large-diameter resurfacing, then the results would have been better.

Our model appears to be valid as it accurately predicted the actual failure in the test set of non-MoM hip replacements and thus the predictions for the 2 MoM groups are likely to be correct. Furthermore, the modeling is particularly pertinent as it allows us to compare the outcomes with the outcomes most likely had the patients received the same prostheses as those who did not receive MoM implants but who were of the same age and sex and had the same diagnosis and were treated in the same health-care setting contemporaneously. If the same analysis were to be performed in another health-care setting, such as the U.S., then the outcome of the modeling would be slightly different because of differences in practice, such as greater usage of uncemented implants.

A major strength of this analysis is the large cohorts involved, allowing us to determine associations between the choice of implant at the time of the primary procedure and the subsequent risk of revision surgery and also allowing us to construct a robust model using patient age, sex, and diagnostic reason for the hip replacement to predict the outcome had MoM options not been available. Although data-capture rates in the NJR are very high, in the early years of the registry, data capture was not complete. We have no reason to believe that this incomplete data capture would have differed between the different types of hip replacement, and therefore these data can be considered to be missing at random and to not affect the results observed. Inherent in the establishment of any registry is the fact that capture will initially be incomplete until the registry is fully established. This issue is mitigated by the fact that we are looking at time to revision from primary procedures recorded in the registry. Therefore, any revisions not recorded in the early years are most likely to be of primary operations that were performed prior to the establishment of the registry and thus have no bearing on this analysis. The 13th Annual Report shows that only 3% of the revisions recorded in 2003 were of primary procedures recorded in the NJR, rising to 41% in 2015.

It is important to note that the 6th Annual Report, published in 2009, clearly showed much higher failure rates with MoM resurfacing with only 3 years of follow-up, which may have contributed to the rapid decline in usage of these implants in England and Wales after 2009.

In conclusion, this study highlights the consequences of the rapid and widespread introduction of medical technology without adequate knowledge or understanding of the potential long-term outcomes. It was not necessary to implant over 1 million of these devices before the outcomes were ascertained. The post-market surveillance requirements of the regulators were insufficiently stringent to ensure early detection of potentially adverse outcomes. We have used the example of MoM hip replacements, but the principle of effective regulation and post-market surveillance applies to devices in all branches of medicine. We are hopeful that lessons will be learned to guide the introduction of implants and devices into clinical practice in the future.

Appendix

Tables showing the relationship between patient sex, age, and reason for the primary operation; the relationship between sex, age, and fixation in patients with stemmed non-MoM THR implants; the numbers of first revisions and re-revisions, by implant type; the risk of re-revision, by time since first revision; reasons for the first revision, by implant type; and the main reasons for revision, by time since the primary operation; and a figure showing the cumulative percentage probability of revision for stemmed non-MoM THR implants, by indication for the primary operation, are available with the online version of this article as a data supplement at jbjs.org.
NOTE:
The authors wish to thank Professor Paul Dieppe for invaluable advice during the preparation of this manuscript.
References


Fig. 1
Graph showing the model-predicted cumulative percentage probability of revision. Out-of-sample prediction was made using the model developed from the training set, with age, sex, and reason for the primary procedure (risk group) as the predictors. There were 563,354 cases with complete information in the training set; the respective prediction-group sizes were 62,589 cases in the stemmed non-MoM THR test set (black dashed line), 32,009 cases in the stemmed MoM THR group (red dashed line), and 37,533 cases in the MoM hip-resurfacing group (blue dashed line).

Fig. 2
Graph showing the model-predicted cumulative percentage probability of revision compared with the actual cumulative percentage revision. The model-predicted cumulative percentage probability of revision for the stemmed non-MoM THR test set is shown with the black dashed line; for the stemmed MoM THR group, with the red dashed line; and for the MoM hip-resurfacing group, with the blue dashed line. The actual cumulative percentage revision is shown with solid lines (Kaplan-Meier with 95% CI [shading]).

Fig. 3
Graph showing the cumulative percentage probability of re-revision, grouped by type of primary hip replacement: stemmed non-MoM THR test set (black line), stemmed MoM THR group (red line), and MoM hip-resurfacing group (blue line). The respective numbers at risk for re-revision for these 3 groups at 0, 2, 4, 6, and 8 years after the first revision are shown below the graph.
<table>
<thead>
<tr>
<th>Year of Primary Op.</th>
<th>Stemmed THR Implants*</th>
<th>All Other Bearing Surfaces</th>
<th>MoM Resurfacing*</th>
<th>Implants with Uncertain/Ambiguous Bearing Surfaces*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003 (from April 1)</td>
<td>303 (2.1%)</td>
<td>12,192 (84.5%)</td>
<td>1,415 (9.9%)</td>
<td>514 (3.6%)</td>
<td>14,424</td>
</tr>
<tr>
<td>2004</td>
<td>861 (3.1%)</td>
<td>23,558 (84.1%)</td>
<td>2,860 (10.2%)</td>
<td>734 (2.6%)</td>
<td>28,013</td>
</tr>
<tr>
<td>2005</td>
<td>2,525 (6.3%)</td>
<td>32,343 (80.5%)</td>
<td>4,262 (10.6%)</td>
<td>1,051 (2.6%)</td>
<td>40,181</td>
</tr>
<tr>
<td>2006</td>
<td>4,518 (9.5%)</td>
<td>36,758 (77.3%)</td>
<td>5,121 (10.8%)</td>
<td>1,153 (2.4%)</td>
<td>47,550</td>
</tr>
<tr>
<td>2007</td>
<td>6,977 (11.5%)</td>
<td>45,892 (75.8%)</td>
<td>6,217 (10.3%)</td>
<td>1,436 (2.4%)</td>
<td>60,522</td>
</tr>
<tr>
<td>2008</td>
<td>8,084 (12.1%)</td>
<td>51,305 (76.7%)</td>
<td>5,953 (8.9%)</td>
<td>1,508 (2.3%)</td>
<td>66,850</td>
</tr>
<tr>
<td>2009</td>
<td>5,726 (8.4%)</td>
<td>56,345 (83.1%)</td>
<td>4,439 (6.5%)</td>
<td>1,294 (1.9%)</td>
<td>67,804</td>
</tr>
<tr>
<td>2010</td>
<td>2,406 (3.4%)</td>
<td>63,624 (90.6%)</td>
<td>2,725 (3.9%)</td>
<td>1,458 (2.1%)</td>
<td>70,213</td>
</tr>
<tr>
<td>2011</td>
<td>395 (0.5%)</td>
<td>69,428 (94.8%)</td>
<td>1,846 (2.5%)</td>
<td>1,551 (2.1%)</td>
<td>73,220</td>
</tr>
<tr>
<td>2012</td>
<td>118 (0.2%)</td>
<td>75,535 (97.7%)</td>
<td>1,066 (1.4%)</td>
<td>602 (0.8%)</td>
<td>77,321</td>
</tr>
<tr>
<td>2013</td>
<td>44 (0.1%)</td>
<td>77,595 (98.1%)</td>
<td>861 (1.1%)</td>
<td>588 (0.7%)</td>
<td>79,088</td>
</tr>
<tr>
<td>2014</td>
<td>67 (0.1%)</td>
<td>81,739 (98.3%)</td>
<td>790 (1.0%)</td>
<td>529 (0.6%)</td>
<td>83,125</td>
</tr>
<tr>
<td>Total</td>
<td>32,024 (4.5%)</td>
<td>626,314 (88.4%)</td>
<td>37,555 (5.3%)</td>
<td>12,418 (1.8%)</td>
<td>708,311</td>
</tr>
</tbody>
</table>

*The values are given as the number of implants, with the percentage in parentheses.
TABLE II Comparison of Variables of Interest for Analysis Across Groups

<table>
<thead>
<tr>
<th></th>
<th>Stemmed MoM THR</th>
<th>MoM Hip Resurfacing</th>
<th>Stemmed Non-MoM THR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of cases</strong></td>
<td>32,024</td>
<td>37,555</td>
<td>626,314</td>
</tr>
<tr>
<td></td>
<td>32,024</td>
<td>37,555</td>
<td>626,314</td>
</tr>
<tr>
<td></td>
<td>32,024</td>
<td>37,555</td>
<td>626,314</td>
</tr>
<tr>
<td></td>
<td>32,024</td>
<td>37,555</td>
<td>626,314</td>
</tr>
<tr>
<td><em><em>Males</em> (50.3%)</em>*</td>
<td>16,114 (50.3%)</td>
<td>26,413 (70.3%)</td>
<td>237,916 (38.0%)</td>
</tr>
<tr>
<td></td>
<td>23,654 (37.8%)</td>
<td>214,262 (38.0%)</td>
<td>23,654 (37.8%)</td>
</tr>
<tr>
<td><strong>Median age at primary op. (IQR)† (yr)</strong></td>
<td>64 (57 to 71)</td>
<td>55 (49 to 60)</td>
<td>70 (63 to 77)</td>
</tr>
<tr>
<td><strong>Indication for primary op.</strong></td>
<td>28,174 (88.0%)</td>
<td>34,169 (91.0%)</td>
<td>561,390 (89.6%)</td>
</tr>
<tr>
<td>OA only*</td>
<td>28,174 (88.0%)</td>
<td>34,169 (91.0%)</td>
<td>561,390 (89.6%)</td>
</tr>
<tr>
<td>Other indication*</td>
<td>2,762 (8.6%)</td>
<td>3,051 (8.1%)</td>
<td>40,861 (6.5%)</td>
</tr>
<tr>
<td>Any trauma*</td>
<td>1,084 (3.4%)</td>
<td>330 (0.9%)</td>
<td>24,011 (3.8%)</td>
</tr>
<tr>
<td><strong>No. of cases with missing indication‡</strong></td>
<td>4</td>
<td>5</td>
<td>52</td>
</tr>
</tbody>
</table>

*The values are given as the number, with the percentage in parentheses. †IQR = interquartile range. ‡For 61 implants, no data were available on the indication for the primary operation.
TABLE III Comparison Between Actual Cumulative Percentage Probability of Revision and the Model-Estimated Cumulative Percentage Probability of Revision Had Patients Not Received MoM Prostheses

<table>
<thead>
<tr>
<th>Cumulative Percentage Probability of Revision*</th>
<th>Stemmed Non-MoM THR, Test Set</th>
<th>Stemmed MoM THR</th>
<th>MoM Hip Resurfacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time since primary op.</td>
<td>Actual</td>
<td>Estimated</td>
<td>Actual</td>
</tr>
<tr>
<td>1 yr</td>
<td>0.64 (0.58-0.71)</td>
<td>0.7</td>
<td>1.0 (0.9-1.1)</td>
</tr>
<tr>
<td>3 yr</td>
<td>1.3 (1.2-1.4)</td>
<td>1.4</td>
<td>3.3 (3.1-3.5)</td>
</tr>
<tr>
<td>5 yr</td>
<td>1.8 (1.7-1.9)</td>
<td>2.0</td>
<td>7.4 (7.2-7.8)</td>
</tr>
<tr>
<td>7 yr</td>
<td>2.4 (2.2-2.6)</td>
<td>2.5</td>
<td>12.7 (12.3-13.1)</td>
</tr>
<tr>
<td>10 yr</td>
<td>3.5 (3.2-3.9)</td>
<td>3.3</td>
<td>19.8 (18.9-20.8)</td>
</tr>
</tbody>
</table>

*The values are given as the actual cumulative percentage probability of revision (Kaplan-Meier), with the 95% CI in parentheses, and as the model-estimated cumulative percentage probability of revision (interpolated flexible parametric survival modeling estimates) had patients not received MoM prostheses, by time since the primary operation.