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Patellar resurfacing during primary total knee replacement is associated with a lower risk of revision surgery. An analysis using the National Joint Registry for England, Wales, Northern Ireland, and The Isle of Man

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Manuscripts

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3 **Patellar resurfacing during primary total knee replacement is associated with a lower**
4 **risk of revision surgery. An analysis using the National Joint Registry for England,**
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6 **Wales, Northern Ireland, and The Isle of Man**
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12 **Abstract**
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17 **Aims**
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19 There remains debate whether or not the patella should be resurfaced during total knee
20 replacement (TKR). For non-resurfaced TKRs, we estimated what the revision rate would
21 have been if the patella had been resurfaced, and examined the risk of re-revision following
22 secondary patellar resurfacing.
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31 **Methods**
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33 A retrospective observational study of the National Joint Registry for England, Wales,
34 Northern Ireland, and The Isle of Man was performed. All primary TKRs for osteoarthritis
35 alone between April 2003 and December 2016 were eligible (n=842,072). Patellar
36 resurfacing during TKR was performed in 36%. The primary outcome was all-cause revision
37 surgery. Secondary outcomes were (1) the number of excess all-cause revisions associated
38 with using TKRs without (vs. with) patella resurfacing, and (2) the risk of re-revision after
39 secondary patellar resurfacing.
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51 **Results**
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53 The cumulative risk of all-cause revision at 10-years was higher ($P<0.001$) in primary TKRs
54 without patellar resurfacing (3.54%, 95%CI=3.47-3.62) compared to those with resurfacing
55 (3.00%, 95%CI=2.91-3.11). Using flexible parametric survival modelling, we estimated one
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3 'excess' revision per 189 cases performed where the patella was not resurfaced by 10-years
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5 (equivalent to 2,842 excess revisions in our cohort). The risk of all-cause re-revision
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7 following secondary patella resurfacing was 4.6 times higher than the risk of revision after
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9 primary TKR with patella resurfacing (at 5-years from secondary patella resurfacing: 8.8% vs.
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11 1.9%).
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17 **Conclusions**

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19 Performing TKR without patella resurfacing was associated with an increased risk of revision.
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21 Secondary patella resurfacing led to a high risk of re-revision. This represents a potential
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23 substantial healthcare burden that should be considered when forming treatment guidelines
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25 and commissioning services.
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Introduction

Total knee replacement (TKR) is clinically-effective^{1, 2} and cost-effective³ for the treatment of pain and reduced function secondary to degenerative conditions, like osteoarthritis. The lifetime risk of undergoing TKR ranges from 10%-23% for women, and 6%-15% for men.^{4, 5} However after TKR, up to 34% of patients still experience persistent pain.⁶ When a TKR is performed, the patella can either be left alone, articulating against the trochlea of the femoral component, or resurfaced with a polyethylene implant.^{3, 7, 8}

There remains considerable debate as to whether the patella should be resurfaced or not during TKR. Proposed advantages of resurfacing include decreased anterior knee pain and fewer re-operations, whilst proposed disadvantages of resurfacing include increased risk of patellar fracture, tendon injury, dislocation, and component loosening.⁹ Data from 2004 to 2014 observed that in the United States, 82% of surgeons resurface the patella, compared with 35% in countries outside the United States (ranging from 59% in Australia to 2% in Sweden).¹⁰ A recent meta-analysis of ten overlapping meta-analyses (published between 2005 and 2015) reported similar patient function and pain outcomes between patellar resurfacing and non-resurfacing, but a greater risk of further surgery for patellofemoral problems when the patella was not resurfaced. None of the studies considered all-cause revision.¹¹ Registry data from Australia (data covering 1999-2016), New Zealand (data covering 1999-2015), Sweden (data covering 1975-2016) and Norway (data covering 1994-2016) report conflicting results regarding the effect of patellar resurfacing on revision rates.^{7,}

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If the patella has not been resurfaced, the patient may subsequently undergo a revision procedure because of persistent pain, known as secondary patellar resurfacing. The limited

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3 data available from small studies suggests this procedure is associated with relatively poor
4 levels of patient satisfaction (up to 64%), low rates of clinical improvement and may be
5 associated with further revisions.¹⁴⁻¹⁶
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12 We retrospectively assessed the use of patellar resurfacing in TKR in a large prospectively
13 collected cohort. We compared all-cause revision rates following primary TKRs according to
14 whether the patella had been resurfaced or not. We explored what the revision rates would
15 have been in the non-resurfaced TKR group if the patella had been resurfaced at primary
16 surgery. We also determined the effect of implant fixation and constraint on the risk of
17 secondary patellar resurfacing, and whether these effects were brand/design specific. Finally,
18 we determined the risk of re-revision following secondary patellar resurfacing.
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Methods

We conducted a retrospective analysis of prospectively collected, observational cohort data from the National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man. The NJR is the world's largest joint replacement registry and is mandatory. Unique patient identifiers permit linkage of primary and revision procedures, defined by components being removed, added or exchanged. The NJR achieves high levels of data capture (95%),¹⁷ and patient consent for data linkage (92%).¹⁷ Independent validation studies have reported that data completion and accuracy are excellent for procedures within the NJR.^{18, 19} For patients who die, date of death is obtained from the Personal Demographics Service and linked to the NJR data; anonymised data is then used for analysis.

Our initial cohort comprised all data-linked primary TKRs entered between 1st April 2003 (the start of the registry) and 31st December 2016, as described in the NJR 14th Annual Report (2017). Exclusion criteria included: uncertain knee type or unable to determine whether patellar resurfacing was performed at primary surgery, implantation for indications other than osteoarthritis alone, unicompartmental knee replacement or patellofemoral replacement (Figure S1).

The primary exposure of interest was whether a patient received a patellar resurfacing or not at primary TKR.

Other variables considered included: age at primary, sex, date of surgery, American Society of Anesthesiologists (ASA) grade (grouped for analysis as 1, 2, or 3-5), TKR fixation (cemented, cementless or hybrid), constraint (cruciate retaining (CR), posterior stabilised (PS) or others/uncertain), and brand.

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6 The primary outcome was all-cause revision surgery of the primary TKR defined as the
7 addition, modification or removal of any implant.¹⁷ Secondary outcomes were (1) the number
8 of excess all-cause revisions associated with the patella not being resurfaced at primary TKR,
9 and (2) the risk of subsequent revision after secondary patellar resurfacing compared with the
10 risk of revision after primary TKR with patellar resurfacing.
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19 **Statistical Analysis**

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21 Statistical survival models were used to compare the risk of first (all-cause) revision between
22 those with and without patellar resurfacing, measuring time from date of primary to revision
23 and censoring at 31st Dec 2016 or date of death.
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31 Kaplan-Meier estimates provided simple estimates of cumulative revision and subgroups
32 were compared with log-rank tests. The statistical package Stata version 15.0 was used
33 (Stata/SE 15.0 software, StataCorp LLC, Texas, 1985-2015) and a 5% level of significance
34 employed throughout.
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43 Given demographic differences between the two groups, we sought to estimate what the
44 survival in the group without patellar resurfacing might have been had they had their patella
45 resurfaced initially. We used Flexible Parametric Survival Modelling (FPM), as previously
46 described²⁰⁻²² and used in this context,²³ implemented in Stata (see above), to develop a
47 prediction model for revision in a 90% random sample of the primary TKRs where the patella
48 had been resurfaced (referred to below as the 'training set'). Predictor variables were age at
49 primary TKR (continuous), sex, ASA, year of primary, TKR fixation and constraint. A small
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3 number had missing/unavailable age or sex (Figure S1) but ASA and year of primary data
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5 were complete.
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The use of FPM offers more modelling flexibility than Cox Proportional Hazards regression.
In particular with respect to the assessment/modelling effects of predictors whose effects on
the baseline hazard (e.g. risk of revision surgery) vary with time (as opposed to having a
constant or ‘fixed’ proportional effect) and in making model predictions. Briefly the shape of
the baseline hazard is modelled via a restricted cubic spline function. Splines were classically
defined as flexible rulers that allowed fitting between multiple points that a straight line could
not achieve without requiring an excess of lines. Splines are flexible functions defined by
piecewise polynomials joined to form a smooth function. Knots are the points where the
created splines join. The restricted cubic spline function is fitted to the (log) cumulative
baseline hazard against the (log) time from the primary. Time-varying effects of predictors
are explored as spline function interactions with the baseline hazard. Here we first sought the
number of degrees of freedom ($df=1+\text{number of knots}$) to best model the baseline spline, then
added the predictor covariates, beginning with age and sex, then adding the other covariates,
assessing the effects of each using a combination of likelihood ratio tests and examination of
the Akaike and Bayesian information criteria to determine a prediction model. These methods
have been used previously and described in detail.²⁴

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49 The prediction model was applied to (i) the remaining 10% of TKRs in which the patella was
50 resurfaced (‘test set’) and (ii) the primary TKRs in which the patella was not resurfaced. In (i),
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52 a comparison between predicted and actual cumulative revision validated the model. In (ii),
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54 the prediction model estimated the cumulative revision that would have been expected had
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56 the patella been resurfaced at the primary surgery.
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6 The need for secondary patellar resurfacing was further explored in TKRs that had not been
7 resurfaced at the primary operation. Secondary patellar resurfacing is a single stage revision,
8 with no components other than a patella inserted and with no indications suggestive of other
9 types of revision.^{3, 7, 8} In the early phase of the NJR, secondary patellar resurfacing was
10 classified as a 'reoperation', as a distinct procedure from other types of revision. We included
11 the small number of secondary resurfacings (n=241) entered into the registry during this early
12 phase using this classification as long as they met the other parts of the definition above. The
13 risk of secondary resurfacing was compared between the three TKR constraint groups (CR,
14 PS or other/uncertain) using Cox proportional hazards regression models (with the
15 proportional hazards assumption checked graphically), censoring for other first revisions and
16 death. This was checked using a Fine and Gray model, which takes into account the potential
17 for competing risks, i.e. risks which preclude patients from undergoing the outcome of
18 interest (i.e. secondary patella resurfacing).²⁵ Therefore in this case we used the Fine and
19 Gray models to account firstly for revision for reasons other than secondary patella
20 resurfacing and secondly for death. Further comparisons were made between brands with
21 more than 1000 implantations of both CR and PS.
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44 Similar approaches were used to compare the all-cause re-revision rate following secondary
45 patellar resurfacing (in primary TKRs that had not initially had the patella resurfaced at the
46 primary operation) with primary TKRs in which the patella was resurfaced initially.
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Results

There were 842,796 primary TKRs eligible for inclusion (Figure S1) of which 724 were excluded due to missing/uncertain implant details at primary surgery. This left 842,072 primary TKRs (99.9%) for analysis. Patella components were recorded in 305,844 (36%), with the remaining 536,228 (64%) not receiving a patella component (Table 1).

Observed all-cause revision rates following primary TKRs with versus without patellar resurfacing

Following primary TKR, the cumulative risk of all-cause revision surgery was significantly higher in those without patellar resurfacing at the time of primary surgery compared to those with (overall logrank test $P < 0.001$). The respective Kaplan-Meier estimates at 10-years were 3.54% (95%CI: 3.47-3.62) and 3.00% (95%CI: 2.91-3.11) (Figure 1). The most common indications for revision in both groups were aseptic loosening and infection (Table S1).

The two groups differed in respect of factors known to be related to outcome (Table 1). These factors were accounted for in our models.

Development of a prediction model

A 90% random sample of the 305,788 primary TKRs with patellar resurfacing with age/sex known formed the 'training' model prediction set ($n=275,209$). The best fitting FPM had a baseline hazard fitted with 5 degrees of freedom, time-varying effects of age, sex and ASA (modelled with $df=5$, 5 and 1 respectively) and year of the primary as a 'fixed', categorical effect. Implant fixation and constraint were also added; both were statistically significant as 'fixed' effects ($P < 0.001$ for each), although the findings were little changed with these variables excluded.

Predictive model for cumulative risk of all-cause revision

Using the model obtained, out-of-sample predictions were made for the ‘test’ set of TKRs in which the patella had been resurfaced (10% random sample; n=30,579) and for the TKRs in which the patella had not been resurfaced (n=536,131 with age and sex known). Figure 2(a) shows the model-predicted outcomes for the two groups were broadly similar, any differences reflecting their small differences in demographic profile. Figure 2(b) adds the cumulative revision actually observed in these two groups (Kaplan-Meier). In the test set (in blue) the actual outcome was similar to that predicted by the model, thus validating the model, whereas for the group without patellar resurfacing (in red) the actual outcome was worse than had been predicted. Table 2 shows the model-predicted and actual cumulative revision risks for the two groups. This equates to one excess revision per 189 cases performed where the patella was not resurfaced by 10-years. This would represent approximately 2,841 excess revisions within 10-years of primary TKR in the studied cohort.

Effect of constraint and brand on risk of secondary patellar resurfacing

Amongst the first revisions recorded for the primary TKRs without patellar resurfacing, there were 2,246 (19.5%) performed for secondary patellar resurfacing. The risk of secondary patellar resurfacing was 17% higher in PS than CR implants (adjusted hazard ratio (HR)=1.17, 95%CI=1.06-1.29, P=0.002; Table S2). The Cox model shown here is cause-specific as it censors for ‘other revisions’ as well as deaths; however the occurrence of a revision for another indication may preclude a patient from having a secondary resurfacing. The Fine and Gray models shown (Table S2: right hand columns) address this by reporting subdistribution hazard rates (SHRs) which take into account the competing risk of being

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3 revised for another indication as well as death during follow-up; the findings were similar (16%
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5 increased risk of secondary patellar resurfacing with PS implants compared with CR).
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10 We also examined the risk of secondary patellar resurfacing between eight knee brands with
11 over 1,000 implantations of both CR and PS designs. This analysis included a total of
12 390,104 primary TKRs performed for osteoarthritis only where the patella was not resurfaced
13 at the primary TKR procedure (Table S3), of which 1,424 underwent secondary resurfacing.
14
15 Whilst there were overall differences between the brands in respect of the risk of secondary
16 patellar resurfacing (Figure S2: logrank $P < 0.001$) there was a significant interaction between
17 constraint and brand on secondary patellar resurfacing rate ($P < 0.001$, Cox proportional
18 hazards regression model adjusting for age, sex, ASA, year of primary and implant fixation)
19 indicating that the effect of constraint differed between these brands (Table S3). In the most
20 commonly implanted TKR (PFC Sigma Bicondylar), the risk of secondary patellar
21 resurfacing was significantly higher in PS designs compared with CR designs (adjusted
22 HR=2.28, 95% CI=1.93-2.69, $p < 0.001$) whereas for Vanguard the risk was lower (adjusted
23 HR=0.37, 95% CI=0.15-0.91, $p = 0.031$). The level of constraint was not significantly related
24 to secondary patellar resurfacing in the other TKR brands.
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45 **Risk of re-revision following secondary patellar resurfacing**

46 Of 2,246 TKRs that underwent secondary patellar resurfacing, 145 went on to have a further
47 revision for any cause. The cumulative revision rate following secondary patellar resurfacing
48 was higher than would be expected in a primary TKR where patellar resurfacing had been
49 performed. Using the 'training' set of the latter, a prediction model was developed using sex,
50 age, ASA and year of primary. This was used to predict cumulative revision in the 2,246
51 secondary patellar resurfacings and the test set of 30,579 primaries with patellar resurfacing
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3 (as model validation). Figure 3(a) shows the predicted revision for the two groups; Figure 3(b)
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5 demonstrates the revision rate following secondary patellar resurfacing was 4.6 times higher
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7 than would be expected (8.8% vs. 1.9% at 5 years).
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10 11 12 **Discussion**

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14 This large national registry study observed that 36% of TKRs in our registry underwent
15 patellar resurfacing during the primary surgery. This rate is lower than in the United States
16 and Australia but consistent with other countries.¹⁰ All-cause revision rates were higher in
17 TKRs without compared to those with primary patellar resurfacing. If all patients had
18 received patellar resurfacing initially, we predicted that nearly 3,000 excess revisions within
19 10-years could have been avoided. We also observed that in patients not undergoing patellar
20 resurfacing initially, the risk of secondary patellar resurfacing was associated with implant
21 constraint, and in some instances to implant brand. Finally, we demonstrated that all-cause
22 revision rates were over four-times higher following secondary patellar resurfacing compared
23 with primary TKR surgery with patellar resurfacing.
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40 Multiple meta-analyses of randomised controlled trials (RCTs) exist comparing patellar
41 resurfacing with non-resurfacing, with some showing improved results for patellar
42 resurfacing (better patient-reported outcome measures (PROMs), less anterior knee pain, and
43 fewer re-operations),^{9, 26} whilst others report no clinical benefits of patellar resurfacing over
44 non-resurfacing.²⁷ However most RCTs involved small cohorts (under 150 patients), with
45 short-term follow-up (under 3 years), and variable outcome reporting. Few studies were
46 appropriately powered to report on revision rates and/or PROMs.⁹ In smaller registry studies,
47 data from New Zealand, Sweden and Norway have demonstrated no difference in revision
48 rates following primary TKR with or without patellar resurfacing,^{8, 12, 13} although the New
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3 Zealand registry did observe better PROMs at 6-months and 5-years following TKR with
4 patellar resurfacing.⁸ By contrast, recent Australian registry data on 136,116 TKRs reported
5 higher revision rates in TKRs where surgeons performed no or infrequent patellar resurfacing
6 compared with those cases where surgeons regularly resurfaced.⁷ Our study, which is the
7 largest analysis on this topic to date, supports the Australian observations that the risk of
8 revision surgery is greater when TKR is performed without patellar resurfacing. Our findings
9 are also in agreement with the emerging evidence from NICE in the UK (based on RCT
10 data), in that the evidence presently supports patellar resurfacing over no resurfacing;
11 however trials are still needed to compare always versus selective patellar resurfacing.²⁸
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26 Our prediction models indicated that if all 536,228 TKRs without patellar resurfacing had
27 been resurfaced, 2,841 excess revisions within 10-years of primary TKR could have been
28 avoided. Revisions produce less predictable outcomes than primary surgery, and following
29 revision patients can have pain/disability, loss of function, and loss of participation in
30 society/employment.²³ Therefore this is likely to represent a substantial healthcare burden of
31 surgeons not resurfacing the patella in TKR (two-thirds of all cases in our registry). A formal
32 health economic analysis is beyond the scope of this paper, as this requires the capture of all
33 health care associated costs, not just the cost of primary implants and revision procedures.
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35 However, the best quality health economics study based on a UK RCT with 10-year follow-
36 up demonstrated that patella resurfacing was dominant (less costly and more effective) than
37 not resurfacing in primary TKR, even after considering the extra initial patellar component
38 costs.³ Over the 10-year trial follow-up period, patella resurfacing at primary TKR saved
39 £104 per patient compared with not resurfacing. The overall increased costs in the non-
40 resurfacing group were due to additional admissions and procedures needed over the 10-years.
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58 Therefore if all 536,228 TKRs without patellar resurfacing from the NJR were actually
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3 resurfaced, it is possible that savings of £55.8 million could be made over 10-years. Recent
4 updated guidelines from NICE support the notion that routine patellar resurfacing in primary
5 TKR is cost-effective,²⁸ however we encourage detailed studies including health-economic
6 analyses to explore this clinical strategy further.
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14 The risk of secondary patellar resurfacing was associated with implant constraint, being
15 higher in PS compared with CR implants. When we explored this finding further in the most
16 commonly used brands, we observed that the level of constraint was not related to secondary
17 patellar resurfacing within most brands (Figure S2). However in the most commonly
18 implanted TKR (PFC Sigma Bicondylar), the risk of secondary patellar resurfacing was
19 higher in PS (i.e. more constrained) designs compared with CR designs. This likely explains
20 why this effect was seen when analysing all TKRs regardless of brand. In another TKR brand
21 (Vanguard), the risk of secondary patellar resurfacing was lower in PS compared with CR
22 designs. Although other registries have explored the effect of constraint on outcomes
23 following TKR with and without patellar resurfacing,^{8, 29} we believe this is the first report to
24 specifically assess this issue in commonly used TKR brands worldwide. The design of the
25 knee prosthesis and the shape of the femoral groove (trochlea) that articulates with the patella
26 vary between brands and may also vary within brands according to constraint, which may be
27 associated with the risk of secondary patellar resurfacing. Depending on which brand is used,
28 the relationship between constraint and the risk of secondary patellar resurfacing seems to
29 vary. This has important implications for surgeons who do not perform patellar resurfacing at
30 primary TKR, as they must consider the brand being used and not just the level of constraint.
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56 In 2,246 TKRs without patellar resurfacing later undergoing secondary patellar resurfacing,
57 we observed that one in eleven required further revision within 5-years. This revision risk
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3 was 4.6 times higher than following a TKR with patellar resurfacing, and ultimately has cost
4 implications to the patient, healthcare system, and society. However it is acknowledged that
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6 only 1 in 189 cases where the patella was not resurfaced initially would need revision by 10-
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8 years, which may include secondary patella resurfacing. So the absolute risk of requiring a
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10 revision after a secondary patellar resurfacing is relatively small.
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17 Similar findings were reported in a smaller cohort from the Australian registry, with 4-year
18 revision rates of 15% following 566 secondary patellar resurfacings compared with 2.8%
19 following primary TKR with patellar resurfacing.³⁰ Small studies on patients undergoing
20 secondary patellar resurfacing suggest that in addition to the need for further operation, there
21 are relatively poor levels of patient satisfaction and clinical improvement.¹⁴⁻¹⁶ After TKR up
22 to 34% of patients still experience persistent pain.⁶ It is possible that some patients
23 undergoing secondary resurfacing for an indication such as patellar degeneration, have pain
24 arising from causes not related to the patella, therefore this subgroup are unlikely to gain
25 benefit from a secondary patellar resurfacing. The outcomes of secondary patella resurfacing
26 mean that it can not be considered to be a “benign” procedure and any surgeon
27 recommending this procedure should appropriately counsel their patients given the likely low
28 chance of improvement.
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47 This study uses a validated model in the largest cohort studied to date to ascertain what the
48 results of intervention would have been for patients receiving a TKR if the patella had been
49 resurfaced in all cases. Assessing an unselected population reduces the risk of sampling bias,
50 therefore improving study validity and generalisability. Furthermore, studies validating NJR
51 data have observed that when procedures were captured within the NJR the data completion
52 and accuracy were excellent.^{18, 19}
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5 Using observational data means causality cannot be determined. Revision rates can be
6 underestimated in the NJR,^{18, 19} although there is no reason to suspect any underreporting
7 would differ between the groups considered. It is acknowledged that the risk of secondary
8 patella resurfacing may be underestimated, as in some instances the tibial polyethylene insert
9 will also have been exchanged (e.g. if there was intraoperative evidence of wear or damage).
10 Such cases would then be classed as a revision rather than a secondary patella resurfacing.
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12 However these cases would still be captured within our analyses of all-cause revisions.
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24 PROMs were not assessed, nor were non-revision procedures (i.e. wound washouts, fixation
25 of fractures, and manipulations under anaesthetic), or complications not requiring further
26 surgery (i.e. conservatively treated fractures, and some infections), which are all important to
27 consider when comparing results between two different treatments. Although we were able to
28 assess the effect of implant constraint and brand on outcomes, data were not available within
29 the registry to assess other factors that may be associated with the risk of secondary patellar
30 resurfacing, such as trochlear geometry (which may vary between brands, and also may vary
31 within some brands according to the level of constraint), component position, and the native
32 patella (shape, thickness, condition). Furthermore it was outside the scope of this study to
33 perform a formal cost-effectiveness analysis, which will be useful when making decisions
34 about whether or not to perform patellar resurfacing in primary TKR.
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51 **Conclusions**

52 Performing TKR without patellar resurfacing is associated with an increased risk of future
53 revision procedures. This represents a potential substantial healthcare burden that should be
54 considered when forming treatment guidelines and commissioning services. Consistent with
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3 current NICE research priorities, we recommend that randomised trials to define the clinical
4 and cost effectiveness of patellar resurfacing in TKR are conducted. Surgeons electing not to
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6 perform primary patellar resurfacing must also be aware that there are significant differences
7
8 in outcomes between TKR brands and the level of constraint. Furthermore, clinicians should
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10 be aware that secondary patellar resurfacing is not a benign procedure as it has a high short-
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12 term re-revision rate, and thus patients should be counselled accordingly before undergoing
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14 such procedures.
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For Review Only

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Figure Legends

Figure 1 Kaplan-Meier estimates (with 95% CIs) of cumulative percentage all-cause revision rates for primary TKRs with and without patellar resurfacing (n=305,844 and n=536,228 respectively)

Figure 2

(a) Model predicted outcomes for the 'test' set of TKRs in which the patella had been resurfaced, and the model prediction results of what the revision rate would have been for TKRs in which the patella had not been resurfaced if the patella had been resurfaced initially

(b) Cumulative revision (Kaplan-Meier estimates with 95% CI) observed in the patellar resurfacing and non-patellar resurfacing TKR groups superimposed onto Figure 2(a)

Figure 3

(a) Model predicted outcomes for the 'test' set of TKRs in which the patella had been resurfaced, and for the TKRs undergoing secondary patellar resurfacing but assumed that the patella had been resurfaced initially (see text for model details)

(b) Cumulative (re-)revision actually observed in the secondary patellar resurfacing and non-patellar resurfacing TKR groups superimposed onto Figure 3(a)

Table 1 Patient demographics

		Number (%) implants with their patella resurfaced (unless indicated)			Total (n=842,796)
		Not resurfaced (n=536,228)	Resurfaced (n=305,844)	Not known (n=724)	
Age (y) at primary*	Median (IQR)	70 (64-76)	70 (64-77)	69 (61.5-75)	(n=842,644)*
	Mean (SD)	69.7 (9.1)	69.8 (9.2)	68.2 (9.8)	
Sex**	Male	244,739 (67.7%)	116,455 (32.2%)	342 (0.1%)	361,536 (100%)
	Female	291,489 (60.6%)	189,388 (39.4%)	382 (0.1%)	481,259 (100%)
ASA at primary	P1	60,773 (63.3%)	35,094 (36.6%)	115 (0.1%)	95,982 (100%)
	P2	389,776 (63.6%)	222,171 (36.3%)	529 (0.1%)	612,476 (100%)
	P3/P4/P5	85,679 (63.8%)	48,579 (36.2%)	80 (0.1%)	134,338 (100%)
Fixation	Cemented	493,881 (62.2%)	300,160 (37.8%)	675 (0.1%)	794,716 (100%)
	Uncemented	36,468 (92.2%)	3,053 (7.7%)	26 (0.1%)	39,547 (100%)
	Hybrid	5,879 (68.9%)	2,631 (30.8%)	23 (0.3%)	8,533 (100%)
CR/PS	CR	426,060 (68.5%)	196,364 (31.6%)	0 (0.0%)	622,424 (100%)
	PS/Constrain.	104,999 (49.8%)	106,013 (50.2%)	0 (0.0%)	211,012 (100%)
	Other/uncertain	5,169 (55.2%)	3,467 (37.0%)	724 (7.7%)	9,360 (100%)

* Omits 152 for whom age could not be validated

** Omits 1 with uncertain sex

Table 2 Kaplan-Meier estimates of cumulative revision rates for the 536,131 TKRs without and 30,579 with patellar resurfacing (test set), each compared with their predicted cumulative revision (in red), calculated from their age, sex, year of primary, PS/CR group and fixation using the data derived from the training set of 305,788 TKRs with a patellar component recorded.

	Number of primaries	Cumulative % revised		
		At 1 year	At 5 years	At 10 years
TKRs without patellar component	536,131	0.41 [0.39-0.43] <i>0.40</i>	2.31 [2.26-2.35] <i>1.89</i>	3.55 [3.47-3.62] <i>3.02</i>
TKRs with patellar resurfacing (test set*)	30,579	0.33 [0.27-0.40] <i>0.39</i>	1.80 [1.63-1.99] <i>1.85</i>	2.81 [2.52-3.12] <i>2.93</i>

*This was the subset of the TKRs with patellar resurfacing used to validate the predictive model (see Methods section)

Supplementary material

Figure S1 Flowchart of study selection criteria

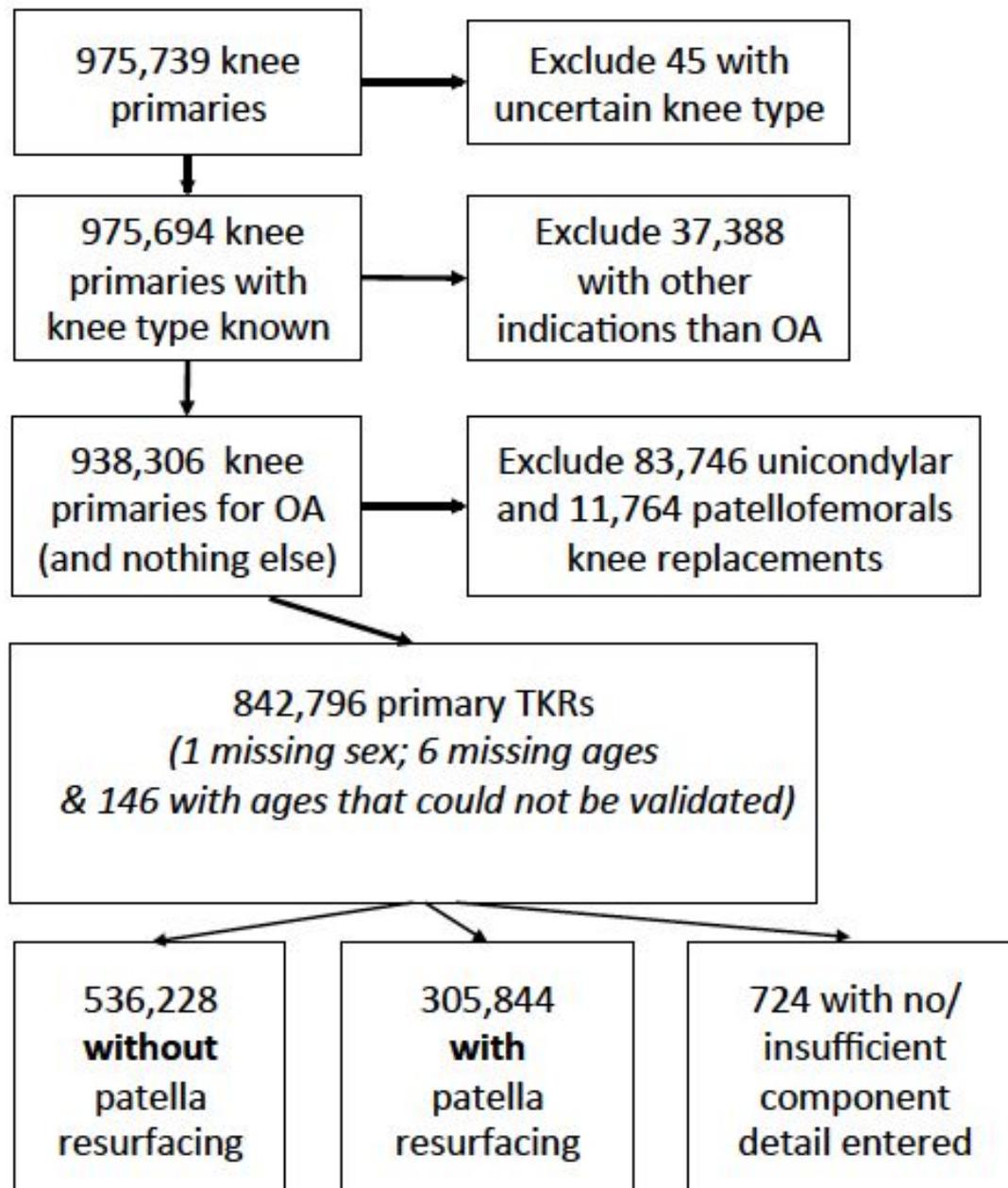


Table S1 Indications for TKR revision surgery (more than one indication for revision can be listed for each revised knee)

Patella resurfaced*	Number of cases	Number of revisions	Number of revisions excluding 3 with no stated indications	Number of revisions for each indication (% of revisions):					
				Aseptic loosening	Infection	Pain	Instability	Mal-alignment	Stiffness***
No	536,228	11,516	11,516	2,920 (25.4%)	2,573 (22.3%)	2,131 (18.5%)	1,805 (15.7%)	1,005 (8.7%)	953/11,507 (8.3%)
Yes	305,844	5,238	5,235	1,512 (28.9%)	1,543 (29.5%)	680 (13.0%)	965 (18.4%)	477 (9.1%)	458/5,228 (8.8%)
All cases*	842,072	16,754	16,751	4,432**	4,116**	2,811**	2,770**	1,482**	1,411/16,735***

Continued:

Patella resurfaced	Number of revisions for each indication (% of revisions):					
	Lysis	Implant Wear	Peri-prosthetic fracture	Dislocation /Subluxation	Implant fracture	Other indication
No	587 (5.1%)	485 (4.2%)	356 (3.1%)	346 (3.0%)	58 (0.5%)	2,106 (18.3%)
Yes	343 (6.6%)	277 (5.3%)	204 (3.9%)	160 (3.1%)	37 (0.7%)	436 (8.3%)
All cases*	930**	762**	560**	506**	95**	2,542**

*Uncertain cases had been excluded;
 **Based on 16,751 revisions where indication was stated;
 ***Based on 16,735 revisions, rather than 16,751, as this indication was not reported in MDS vs 1

Table S2 Effect of constraint on need for secondary patellar resurfacing in TKRs without patellar resurfacing at primary

Constraint	Number of primaries	Number first revisions classified as patellar resurfacings	Multivariable Cox ‘proportional hazards’ regression model to compare the 3 constraint groups with adjustment for age, sex, ASA, year of primary and fixation HR* [95%CI]	Fine and Gray model (‘other revisions’ regarded as competing risk) SHR** [95%CI]	Fine and Gray model (‘other revisions’ and ‘deaths without having been revised’ regarded as competing risks) SHR** [95%CI]
CR	426,060	1,720	1 [referent]	1 [referent]	1 [referent]
PS/Constrained	104,999	504	1.17 [1.06-1.29] P=0.002	1.16 [1.05-1.29] P=0.003	1.16 [1.05-1.28] P=0.003
Other/uncertain	5,169	22	0.88 [0.57-1.33] P=0.536	0.87 [0.57-1.32] P=0.515	0.86 [0.56-1.31] P=0.483
Total	536,228	2,246			

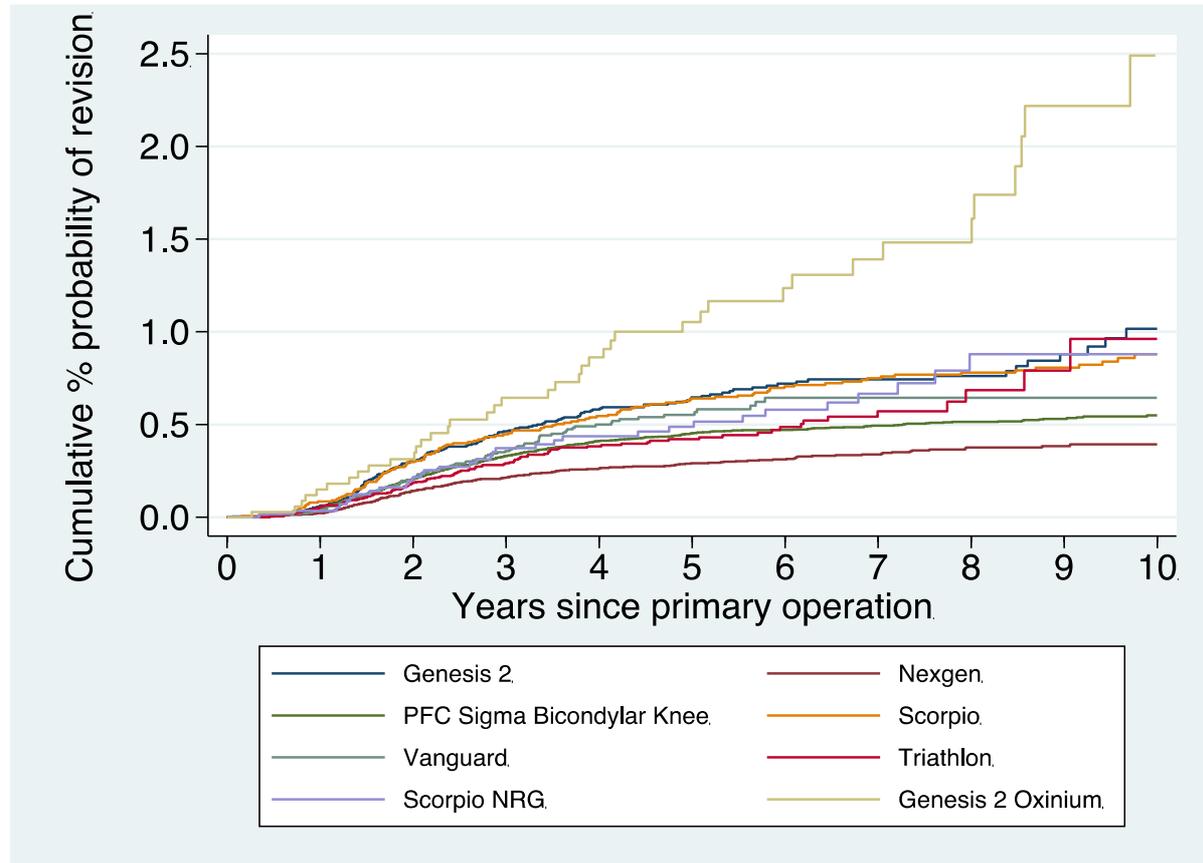
*HR=Hazard Rate ratio; **SHR=Subdistribution Hazard Rate ratio

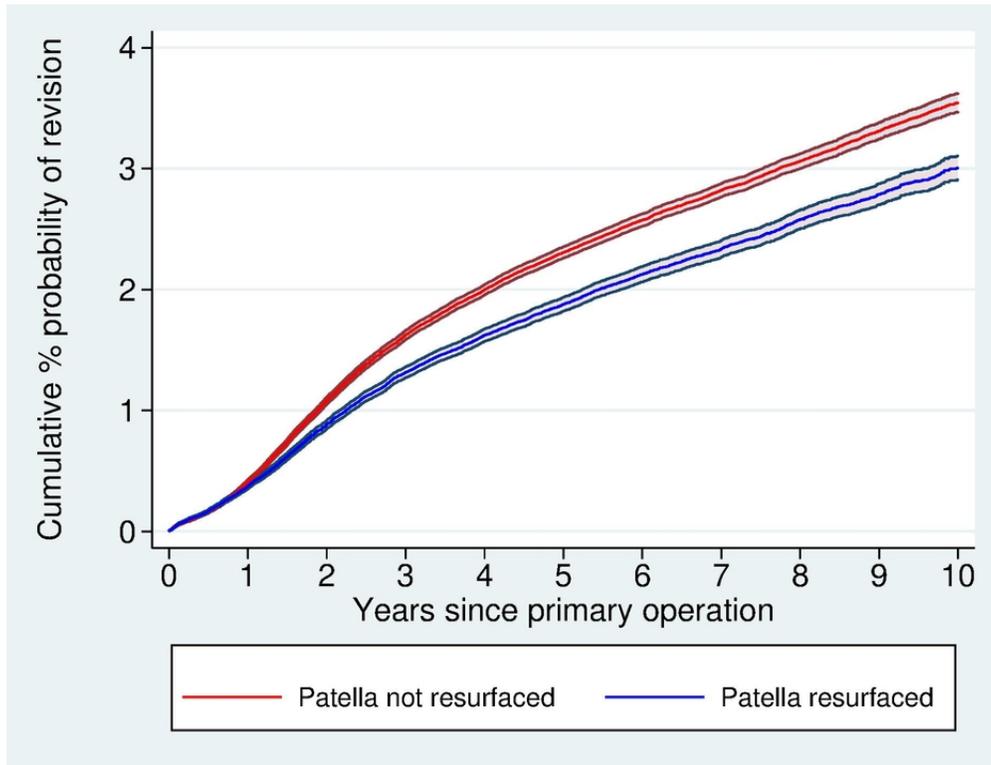
Table S3 Brand differences in the effects of constraint on risk of secondary patellar resurfacing calculated from a multivariable Cox Proportional Hazard regression model adjusting for age, sex, ASA, year of primary and fixation.

Brand	Number	Number with other/uncertain constraint (Excluded)	Number with CR or PS (Included)	Constraint		Differential effects of PS/Const vs CR (as referent) for each brand on risk of secondary patellar resurfacing, with adjustment for age, sex, ASA (P1/P2/P3+4+5), year of primary and fixation HR* [95%CI]
				CR Number (%)	PS Number (%)	
Genesis 2	31,848	106	31,742	24,749 (78.0%)	6,993 (22.0%)	1.22 [0.85-1.74] P=0.283
Nexgen	92,442	526	91,916	48,033 (55.3%)	43,883 (47.7%)	1.12 [0.86-1.46] P=0.412
PFC Sigma Bicondylar	168,892	958	167,934	138,662 (82.6%)	29,272 (17.4%)	2.28 [1.93-2.69] P<0.001
Scorpio	15,658	171	15,487	11,926 (77.0%)	3,561 (23.0%)	1.26 [0.83-1.92] P=0.274
Vanguard	31,569	370	31,199	27,356 (87.7%)	3,843 (12.3%)	0.37 [0.15-0.91] P=0.031
Triathlon	42,357	88	42,269	37,629 (89.0%)	4,640 (11.0%)	1.13 [0.66-1.94] P=0.663
Scorpio NRG	5,970	84	5,886	4,310 (73.2%)	1,576 (26.8%)	1.23 [0.58-2.53] P=0.579
Genesis 2 Oxinium	3,713	42	3,671	2,288 (62.3%)	1,383 (37.7%)	0.70 [0.35-1.39] P=0.305]

*HR=Hazard Rate Ratio

Figure S2 Kaplan-Meier estimates for secondary resurfacing for knee brands commonly implanted as both CR and PS designs (at least 1000 of each).

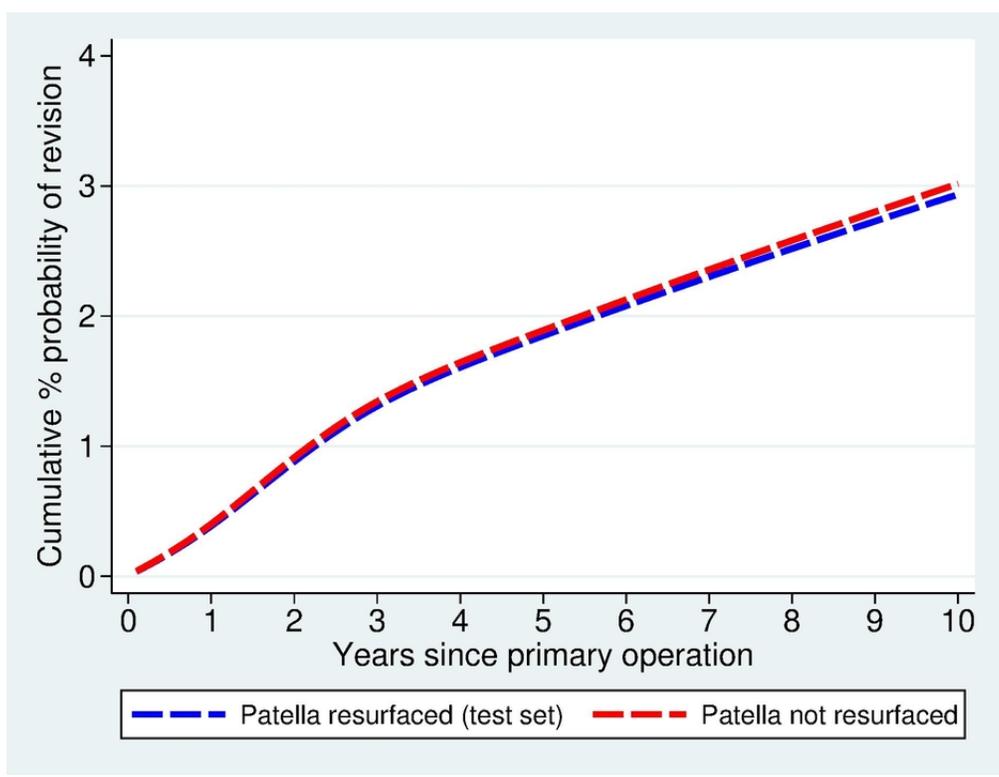




1. Kaplan-Meier estimates (with 95% CIs) of cumulative percentage all-cause revision rates for primary TKRs with and without patellar resurfacing (n=305,844 and n=536,228 respectively)

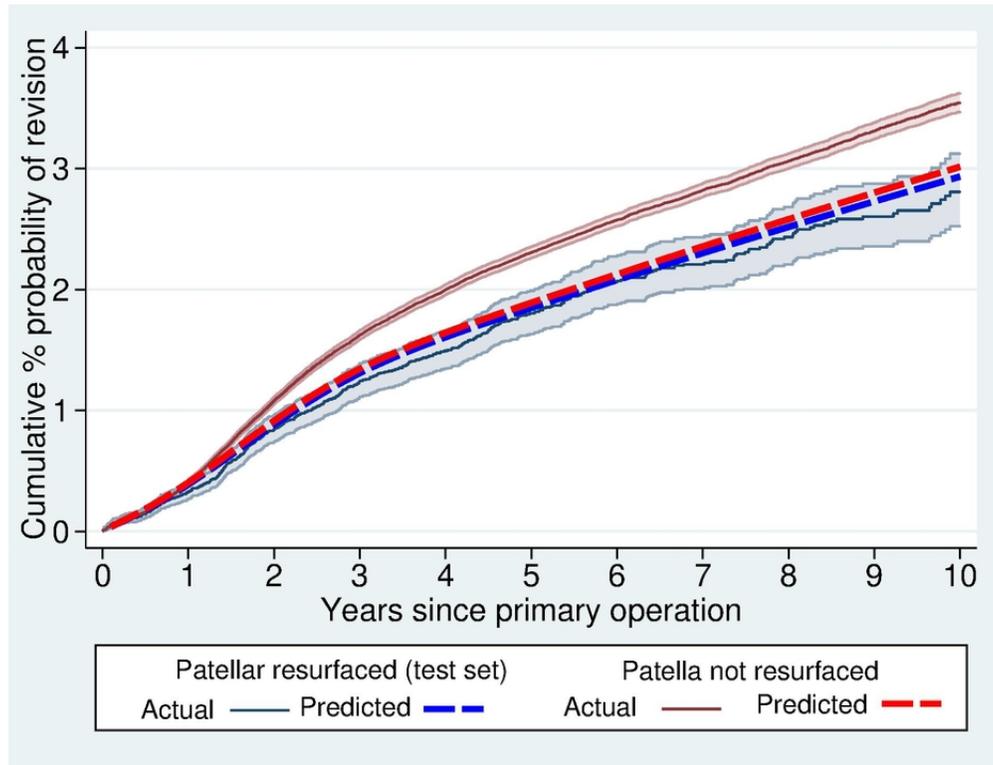
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2 (a) Model predicted outcomes for the 'test' set of TKRs in which the patella had been resurfaced, and the model prediction results of what the revision rate would have been for TKRs in which the patella had not been resurfaced if the patella had been resurfaced initially

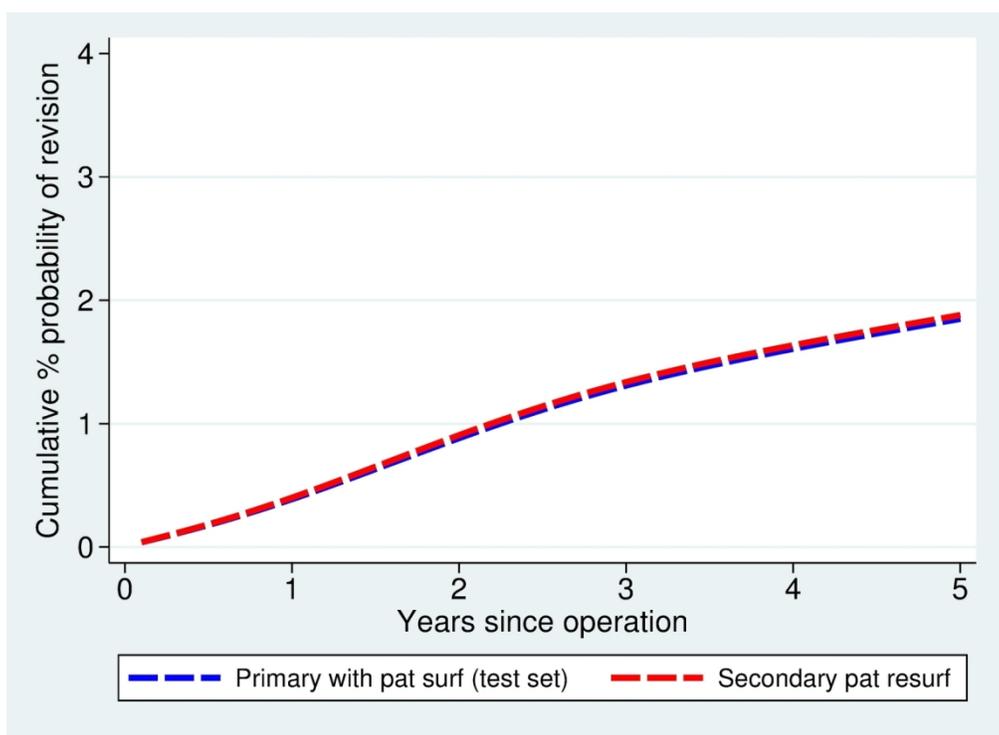
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2 (b) Cumulative revision (Kaplan-Meier estimates with 95%CI) observed in the patellar resurfacing and non-patellar resurfacing TKR groups superimposed onto Figure 2(a)

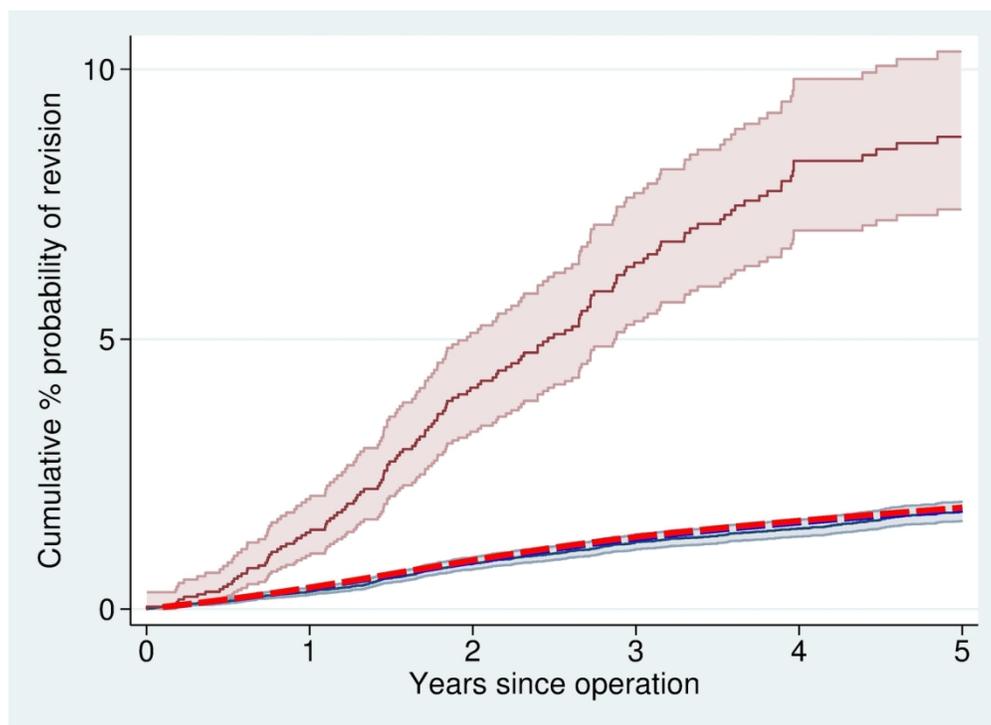
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3 (a) Model predicted outcomes for the 'test' set of TKRs in which the patella had been resurfaced, and for the TKRs undergoing secondary patellar resurfacing but assumed that the patella had been resurfaced initially (see text for model details)

139x101mm (300 x 300 DPI)



3 (b) Cumulative (re-)revision actually observed in the secondary patellar resurfacing and non-patellar resurfacing TKR groups superimposed onto Figure 3(a)

139x101mm (300 x 300 DPI)