Fast fix or false hope? Polyethylene exchange in unstable primary unconstrained total knee arthroplasty

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Aims

Instability is a leading cause of revision after primary total knee arthroplasty (TKA). Isolated polyethylene exchange (IPE), typically involving increased insert thickness, is considered a fast and low-risk treatment option. However, evidence supporting its effectiveness remains limited. This study assesses outcomes and risk factors of IPE for secondary instability in unconstrained primary TKAs using data from the German Arthroplasty Registry (EPRD).

Methods

Patients with unconstrained primary TKA and subsequent IPE due to presumed instability were included. Polyethylene height increase served as a surrogate for instability severity. Cases with infection were excluded. Secondary patellar resurfacing (SPR) was analyzed as a potential influencing factor. Multivariate Cox regression and time-dependent analyses were used to identify predictors for re-revision, defined as any subsequent revision procedure.

Results

The study included 1,890 patients. IPE was performed on at a mean of 639 days (SD 521; 1 to 3343) after primary TKA, with a mean height increase of 3 mm (SD 2.2). The overall re-revision rate was 13.5%; 2.4% were due to periprosthetic joint infection. SPR was associated with lower revision risk (hazard ratio (HR) 0.50; 95% CI 0.37 to 0.68; $p < 0.001$). IPE one and two years after the index operation was associated with a decreased risk of subsequent revision (HR 0.33, 95% CI 0.20 to 0.55; HR 0.36, 95% CI 0.21 to 0.60). Polyethylene height increase > 3 mm was not associated with worse outcomes (< 3 mm HR 0.87, 95% CI 0.65 to 1.17; $p = 0.358$).

Conclusion

IPE can be a viable treatment for mild secondary instability following primary TKA, particularly with careful patient selection. SPR appears to improve implant survival and should be considered in cases with patellar pathology. Early-onset instability warrants critical evaluation, as it may indicate deeper underlying issues requiring component revision. These findings highlight the importance of an individualized surgical approach and underscore the need for thorough preoperative counselling to align treatment strategy with patient-specific risk factors and expectations.

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Take home message

- Polyethylene exchange represents a viable option for balanced instability, with five-year survival rates of 75% to 80% in the right indication.
- Early postoperative instability (< one year after index surgery) demands thorough evaluation, as it carries a higher risk of revision after polyethylene exchange.
- Secondary patellar resurfacing is recommended whenever patellar pathology is suspected.

Introduction

Total knee arthroplasty (TKA) has proven to be an effective treatment for alleviating pain and improving function in patients with end-stage osteoarthritis, achieving ten-year implant survival rates of up to 90%.[1] Despite these favourable long-term results, failure of the prosthesis remains an important clinical challenge, often leading to complex revision procedures. As primary TKA procedures continue to rise due to demographic and clinical factors, a corresponding increase in the number of revision surgeries is anticipated.[2]

Instability following primary knee arthroplasty represents one of the leading causes of both early and late postoperative revisions.[3] Recent registry studies report that 6.0% to 17.7% of all revisions are attributable to instability, while single-centre studies publish rates as high as 26%.[4,5] Several authors have proposed diagnostic algorithms to address this issue, emphasizing the importance of thorough preoperative assessment. Key considerations include mid-flexion instability, posterior offset, and joint line reconstruction, as well as prosthesis design and the degree of constraint.[4,6] Nonetheless, the question remains unresolved whether isolated polyethylene exchange (IPE), typically involving an increase in thickness by 2 mm or 4 mm and frequently combined with secondary patellar resurfacing (SPR), constitutes a viable therapeutic approach in cases of mild secondary instability following primary TKA.[7,8] Although several single-centre studies have addressed this issue, they often involve heterogeneous patient populations, limiting the statistical power of sub-group analyses.[7] Larger, multicentre studies are still lacking. While recent registry analyses have shed further light on this topic, they frequently include heterogeneous treatment methods, encompassing both polyethylene exchange and component revision.[9] In clinical practice, the choice between isolated inlay exchange and full component revision is often based on surgeon experience and subjective judgement, despite the significant implications for patient outcomes and healthcare resource use. Furthermore, current treatment guidelines provide limited direction, ranging from conservative management to complete TKA revision.[4,6] Importantly, patient satisfaction, which is already limited in a substantial proportion of primary TKA cases, has been shown to decline even further following revision procedures, highlighting the need for less invasive yet effective revision strategies.[10,11]

Therefore, the aim of this study is to analyze the outcomes of isolated polyethylene exchange revisions in unconstrained primary TKAs using data from a registry database.

Methods

The German Arthroplasty Registry (Endoprothesenregister Deutschland; EPRD)[12] was founded in 2012 by the German Society of Orthopedics and Orthopedic Surgery (DGOOC) cooperating with several statutory health insurances (AOK Bundesverband GbR, Verband der Ersatzkassen e.V. vdek) as well as the German Medical Technology Association (BVMed) as a register for hip and knee arthroplasties. Reporting to the EPRD is voluntary; however, due to the cooperation structure, the registry includes procedures of over 740 reporting hospitals, covering approximately 70% of all joint arthroplasties performed in Germany, both primary and revisions.[12]

Access to the insurance data of the two largest health insurers (AOK-B, vdek) ensures that revisions after the index case are recorded even if the hospital does not participate in the EPRD. This structure enables comprehensive follow-up of all registered patients and also grants access to further health-related data through the insurances.

Study design

In this cohort study, all patients aged 18 years and older receiving an IPE of primary, unconstrained TKA and a following revision were selected in the EPRD (2014 to 2024). For this study, only cases with both the primary implantation and a subsequent revision documented in the registry were included. All cases in which an infection was the cause for revision were excluded (due to the tenth International Classification of Diseases of the World Health Organization (ICD-10), T84.5 or M00).[13] Additionally, all cases which were labelled infectious in the voluntary classification conducted by the surgeon were excluded. Available data included the dates of both procedures, initial polyethylene height and the height difference for the second operation, surgical volumes for both primary and revision procedures at the centre, as well as patient comorbidities.

Patient characteristics

The final study cohort consisted of 1,890 patients with a mean follow-up of 1,028 days (SD 820; 100 to 3,651). A total of 257 patients eventually underwent a re-revision (13.6 %) after a mean of 487 days (SD 470; 2 to 2,170). All information on the cohort is shown in Table I.

Outcome

The endpoint of this study was a documented failure of the first revision due to all causes as well as the time between first revision and potential new surgery. Additionally, a distinction was made between periprosthetic joint infections (PJIs) and aseptic revisions as instability was the main focus of this study. Since the 'Operationen und Prozedurenschlüssel' (OPS) 301 codes of the re-revision were available, a more detailed endpoint analysis was possible.

Exposure variables and potential confounders

The main focus of this study was an increase in polyethylene height as an indication of instability. Since a complete implant documentation was available, the exact height difference between the two polyethylenes was calculated. Although this does not represent a definitive marker for the degree of instability, it was nevertheless included to allow for a more refined sub-group analysis. This decision was further

Table I. Patient data.

Variable	No re-revision (n = 1,633)	Re-revision (n = 257)	p-value*
Hospital size (revision), n (%)			0.008
0 to 15	533 (33)	108 (42)	
15 to 30	535 (33)	59 (23)	
30 to 60	324 (20)	52 (20)	
> 60	241 (15)	38 (15)	
Hospital size (primary), n (%)			0.037
0 to 200	599 (37)	115 (45)	
200 to 500	619 (38)	88 (34)	
> 500	415 (25)	53 (21)	
Unknown, n	0	1	
Polyethylene height difference, mm, n (%)			0.196
< 3	996 (61)	146 (57)	
≥ 3	637 (39)	111 (43)	
BMI, kg/m², n (%)			0.403
< 25	213 (14)	24 (11)	
25 to 30	463 (31)	74 (35)	
30 to 35	423 (29)	56 (26)	
> 35	373 (25)	60 (28)	
Unknown, n	161	43	
Sex, n (%)			0.498
Male	537 (33)	79 (31)	
Female	1,096 (67)	178 (69)	
Vital status, n (%)			0.503
Alive	1,566 (96)	244 (95)	
Deceased	67 (4.1)	13 (5.1)	
SPR (revision), n (%)			< 0.001
No	839 (54)	169 (71)	
Yes	723 (46)	70 (29)	
Unknown, n	71	18	
SPR (primary), n (%)			0.924
No	1,487 (91)	234 (91)	
Yes	146 (8.9)	23 (8.9)	
Mean primary polyetheylene height (SD)	8.62 (2.23)	8.60 (2.31)	0.873
Mean time to (first) polyethylene exchange (SD)	683 (570)	496 (445)	< 0.001
Mean age (at primary procedure), yrs (SD)	66 (10)	65 (10)	0.051

*Chi-squared test with simulated p-value (based on 2,000 replicates); Welch paired *t*-test.
SPR, secondary patellar resurfacing.

supported by registry studies demonstrating that greater inlay thickness is associated with an increased risk of revision.[14] Accordingly, inlay height differences were stratified into < 3 mm and ≥ 3 mm, this threshold was, based on the surgeons' intraoperative judgement, as the most frequent adjustments are typically 2 mm or 4 mm.

Procedures where SPR was conducted were included in the study, to identify this as a potential risk factor for a second revision. Based on the known annual number of primary arthroplasties performed at each hospital, centres were grouped into sub-categories (0 to 200, 200 to 500, and > 500). A similar classification was applied to the volume of revision arthroplasties per hospital (0 to 15, 15 to 30, 30 to 60, and > 60). Those variables will be named 'hospital size' in this analysis. Additionally, the time to the first revision was used to define early postoperative instability, with a cutoff set at one year following the primary operation.

Patient-specific factors included were age, sex, BMI in groups: under/normal weight (< 25 kg/m²), moderate overweight (25 to 30 kg/m²), overweight (30 to 35 kg/m²), and obese (> 35 kg/m²), American Society of Anesthesiologists (ASA) grade,[15] and comorbidities documented in the transferred health insurance data. Comorbidity was assessed using the Elixhauser Comorbidity index.[16]

Statistical analysis

For continuous variables, the mean and SD were calculated; for categorial variables, we report case numbers and frequencies. Differences between groups are assessed using *t*-tests for continuous variables and chi-squared tests for categorial variables. The time to a potential re-revision was visualized with Kaplan-Maier curves. We truncated follow-up at five years (1,825 days) and defined events as first re-revision within five years among patients alive at that time; others were censored. Kaplan-Meier curves were produced using the same time/event definition. We then fit Cox proportional hazards models on a complete-case dataset. Follow-up was administratively censored at five years to ensure stable estimation with sufficient numbers at risk and to avoid imprecise late survival estimates; deaths and losses to follow-up were treated as censoring. Because proportionality was not given for some predictors, we allowed age groups (< 60 years, 60 to 69 years, and ≥ 70 years) and time from primary to first revision (≤ one year, one to two years, and > two years) to have time-varying effects by fitting the model separately within three follow-up bands (0 to 1, 1 to 3, and 3 to 5 years). All other covariates were entered as time-invariant. We evaluated treatment clustering by comparing the frequency of SPR across polyethylene height strata and, as sensitivity analysis, tested an interaction term in the Cox model. Significance level was set to 0.05. All statistical analysis was performed with R v. 4.4.2 (R Foundation for Statistical Computing, Austria).

Results

The polyethylene exchange was conducted after a mean of 683 days (SD 570) for those without re-revision and 496 (SD 445) for those with revision after primary TKA. The mean polyethylene height was 8.6 mm (SD 2.1; 6 to 18) in both groups. Implantation of a SPR was conducted in 793 revisions. For patients with a re-revision, 29% had a SPR. Of all those who did not, 46% had a SPR. Revision due to PJI was necessary in 41 cases (2.4 %).

For Kaplan-Meier curves and the Cox proportional hazard model, deaths and end of available follow-up were

treated as censoring; follow-up was additionally administratively censored at five years.

The Cox proportional hazard model was run on complete cases only. Because of the many missing values for ASA and unlikely effect due to the known results from Table I, ASA was further excluded from the analysis. We included 1,686 patients in the model. We first ran a full model including the Elixhauser Comorbidity Score, polyethylene height difference, SPR, hospital size (primary and revision), age, sex, BMI and time to (first) polyethylene exchange. SPR use differed substantially by polyethylene height stratum: SPR was performed in 53.3% of cases with < 3 mm increase and in 29.6% with ≥ 3 mm increase ($p < 0.001$). As a sensitivity analysis, we included an interaction term. The SPR × thickness interaction was not statistically significant (likelihood ratio $p = 0.217$), suggesting no evidence of effect modification. To address non-proportional hazards, we split follow-up after the index revision into three bands (0 to one, one to three, and three to fiveyears) and estimated band-specific hazard ratios for age group and time from primary TKA to first IPE (≤ one, one to two, > two years). The Kaplan-Meier analysis is shown in Figure 1, the banded hazard ratios in Figure 2. Longer time from primary procedure to first revision was strongly protective in the first year after the index revision: compared with under one year, persons having one to two years have a hazard ratio (HR) of 0.33 (95% CI 0.20 to 0.55) and a HR of 0.36 (0.21 to 0.60) for more than two years; this attenuation was not evident in later bands (one to three years and three to five years). Age effects were modest: compared with 60 to 69 years, patients aged 70 years and older showed a lower hazard in years one to three (HR 0.49; 95% CI 0.26 to 0.91), whereas those younger than 60 years did not differ meaningfully (Figure 2). Among time-invariant covariates, SPR at revision was associated with a lower hazard of re-revision (HR 0.50; 95% CI 0.37 to 0.68), the Kaplan-Meier analysis is shown in Figure 3. A trend towards lower hazard was seen for larger primary hospital size (≥ 500 cases; HR 0.59; 95% CI 0.34 to 1.01). Higher patient comorbidity was independently associated with an increased risk of re-revision (HR 1.86, 95% CI 1.32 to 2.61; $p < 0.001$). No clear associations were observed for BMI group, sex, and polyethylene height difference (Figure 4). Overall hazard ratios are shown in Figure 5.

Discussion

The management of secondary instability following primary total knee arthroplasty remains a significant clinical challenge, particularly regarding the indication and effectiveness of IPE. Although this procedure is often considered a 'low-risk, potentially high-reward' intervention, robust clinical evidence supporting its efficacy is still lacking. Nevertheless, there is broad consensus that careful patient selection and thorough preoperative evaluation are essential prerequisites for a successful outcome. Several diagnostic and therapeutic algorithms for managing instability after TKA have been proposed.[4] Interestingly, isolated polyethylene exchange is typically not included in these recommendations.[7,8] On the contrary, it is explicitly cautioned against, as illustrated by the statement by Al-Jabri et al[4] in their meta-review: 'There is a temptation to simply insert a thicker polyethylene liner, […] and it is generally not recommended'. In contrast to these recommendations, registry data depict a different clinical practice. For example, Lewis et al[9] reported that isolated polyethylene exchange was the most commonly performed procedure for instability, accounting for 55% of cases (n = 2,605). However, they also demonstrated a re-revision rate of 24% over 14 years, with recurrent or persistent instability responsible for 32% of these subsequent procedures. In a similar manner, Choi et al[17] published a single-centre analysis showing a survival rate of 83% at five years after IPE with satisfying clinical results.

The data analyzed in this study consist of one of the largest IPE cohorts published up to date, with an observed revision rate of 13.5% during the follow-up period. The substantial sample size of this registry-based analysis allows for a more nuanced evaluation of individual clinical variables. SPR was identified as the strongest protective factor against subsequent re-revision (HR 0.50, 95% CI 0.37 to 0.68). Based on these findings, careful pre- and intraoperative assessment of the patellofemoral joint is strongly recommended in cases with suspected or evident patellar pathology. Additionally, as the polyethylene exchange leads to a subsequent joint line repositioning, intraoperative reassessment of patellar tracking should be routinely performed to mitigate the risk of secondary complications. It should be noted that in the presence of primary patellar pathology, postoperative patient satisfaction often remains limited despite surgical intervention. This observation is supported by the meta-analysis of Andronic et al,[18] who reported improved functional outcomes in only 53% of 293 patients, with merely 59% of 415 patients rating their postoperative result as subjectively satisfactory. However, the data found in this study should be considered with caution, as primary patellar resurfacing is generally not conducted in Germany.[19] In line with our findings of an increased risk for re-revision, if the first revision is conducted early, a registry study by Pardo et al[20] demonstrated that secondary patellar resurfacing is associated with an increased risk of re-revision if performed during the first two years after primary TKA.

Because SPR was less frequently performed in the ≥ 3 mm group, crude thickness-stratum comparisons may be confounded by concurrent SPR and underlying indication. We adjusted for SPR and found no evidence that the thickness association differed by SPR status. However, although SPR was associated with lower re-revision risk after adjustment, this finding may be influenced by confounding by indication and other unmeasured clinical factors not captured by the registry; therefore, the association should not be interpreted as causal.

In clinical practice, the indication for polyethylene exchange is often made in the context of a balanced, mild instability, which typically results in only a moderate increase in thickness (≤ 3 mm). This is also reflected in the present registry data, where an increase of 2 mm was by far the most frequently selected option (n = 794). Larger polyethylene differences are rarely used, as the clinical findings are generally associated with an extensive ligamentous insufficiency and are therefore considered to carry a potentially less favourable prognosis without component exchange.[9] However, the present study demonstrates that even in cases where a greater increase was chosen – which might suggest more severe preoperative instability – a comparable implant survival rate can be achieved (HR 0.89, 95% CI 0.65 to 1.17). These findings are in line with published data by Lewis et al,[9] where a

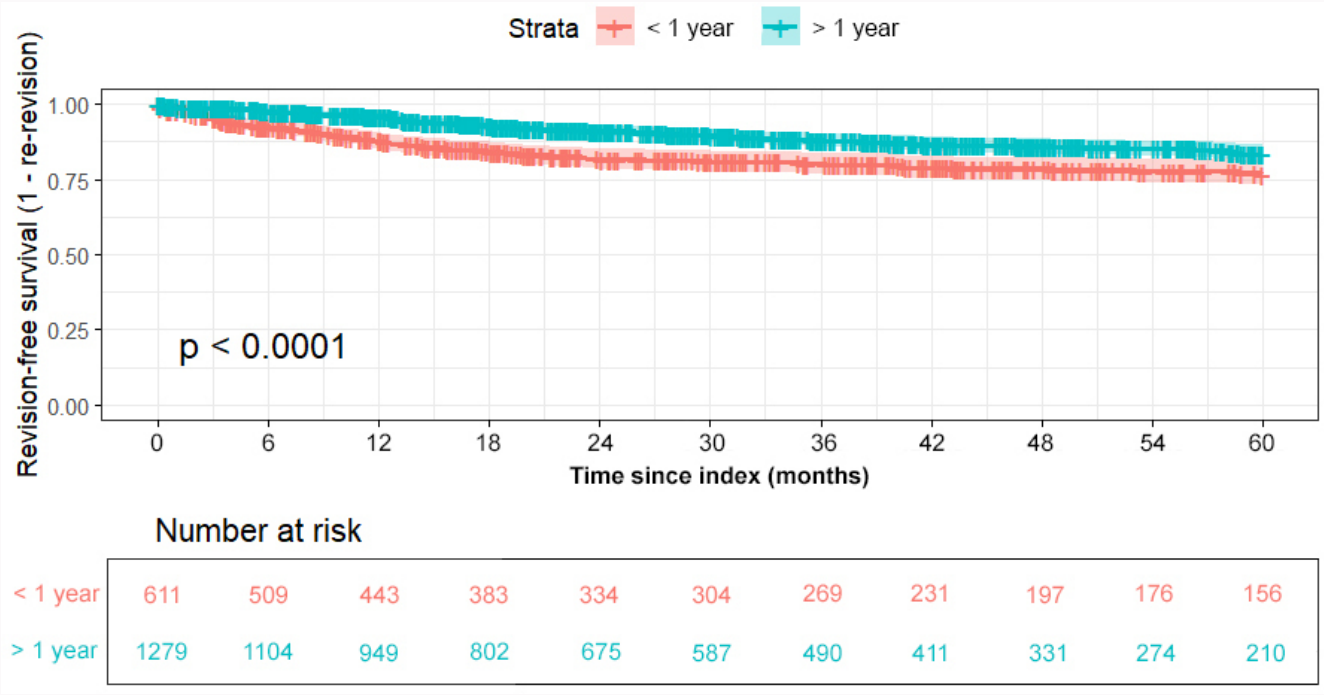

Fig. 1
Kaplan-Meier analysis, Strata: iIsolated polyethylene exchange conducted < one or > one year after primary arthroplasty.

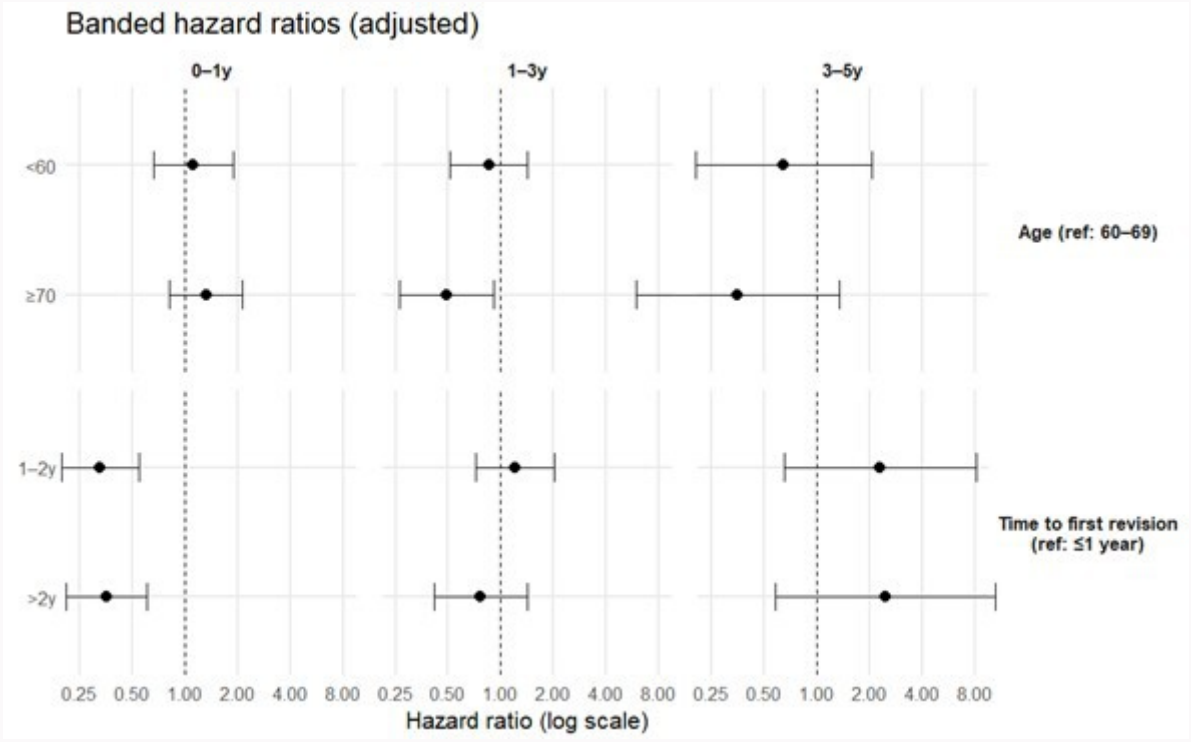

Fig. 2
Banded hazard ratios for 0 to one-; one to three, and three to five-year follow-up, Strata: age and time to first revision.

sub-group analysis was conducted for 1 mm to 3 mm, 3 mm to 5 mm, and > 5 mm increase (n = 333/359/136, respectively) showing no difference in revision rates. This highlights that with careful patient selection and precise surgical technique favourable long-term outcomes are attainable even in more complex scenarios. Notwithstanding, this analysis must be interpreted with caution, as the sub-group sizes differ considerably, potentially introducing bias and limiting the statistical power of direct comparisons (n = 1,088/591).

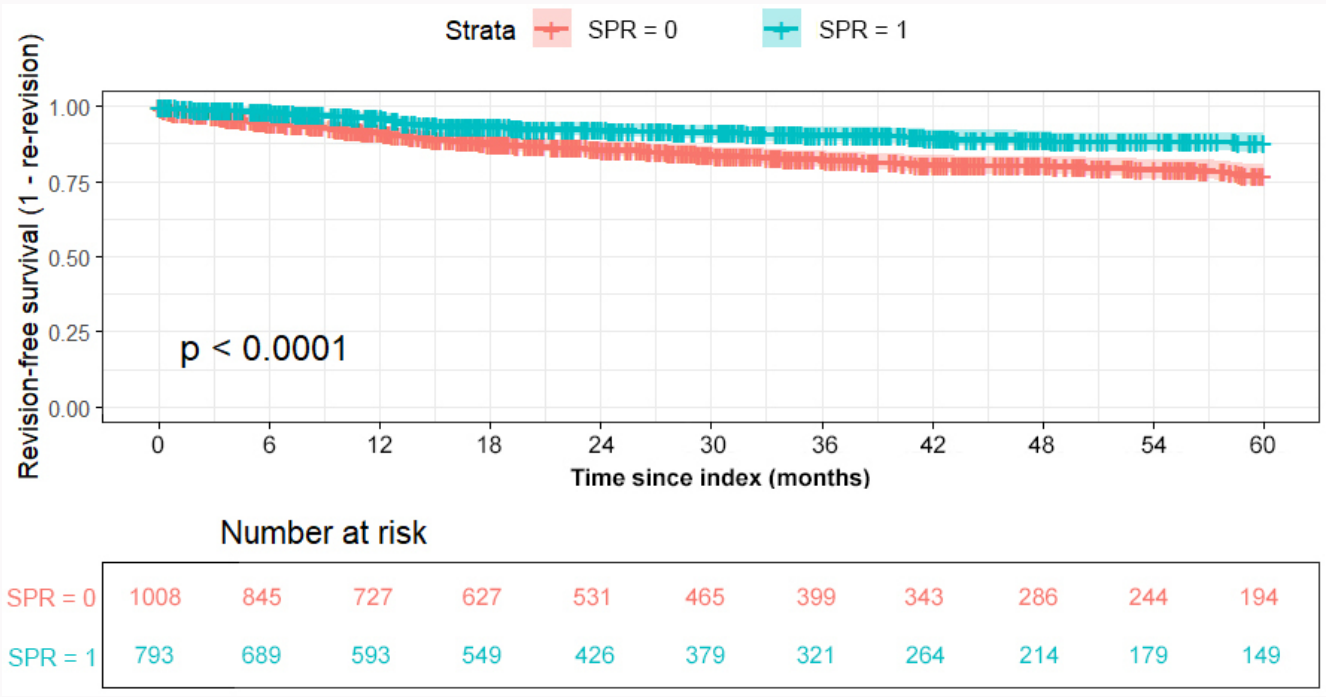

Fig. 3
Kaplan-Meier analysis, Strata: secondary patellar resurfacing (SPR) 0 = no; 1 = yes.

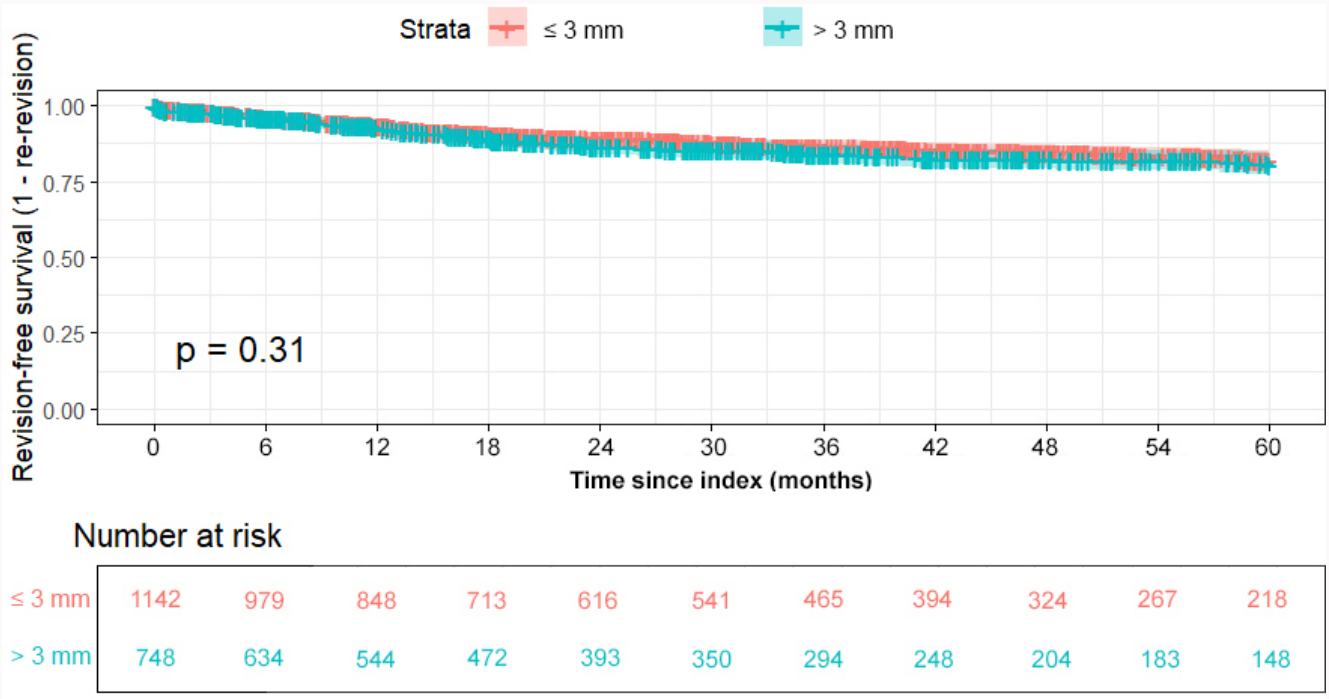

Fig. 4
Kaplan-Meier analysis, Strata: polyethylene height increase of < 3 mm vs ≥ 3 mm.

In contrast, the timing of the procedure appears to play a decisive role in clinical outcomes. In the first year after the index revision, patients whose had a longer time from first TKA to first revision (one to two years or > two years after the primary TKA) had a substantially lower failure hazard than those under one year (HR 0.33). This pattern suggests that early IPE may identify a higher-risk clinical scenario in which careful diagnostic work-up and consideration of alternative revision strategies are warranted. Importantly, this disadvantage of early cases attenuated over time, by years one to three and three to five after the index revision, differences were no longer significant, indicating that the excess risk is concentrated in the early postoperative period. These findings might support a more cautious approach to IPE when instability

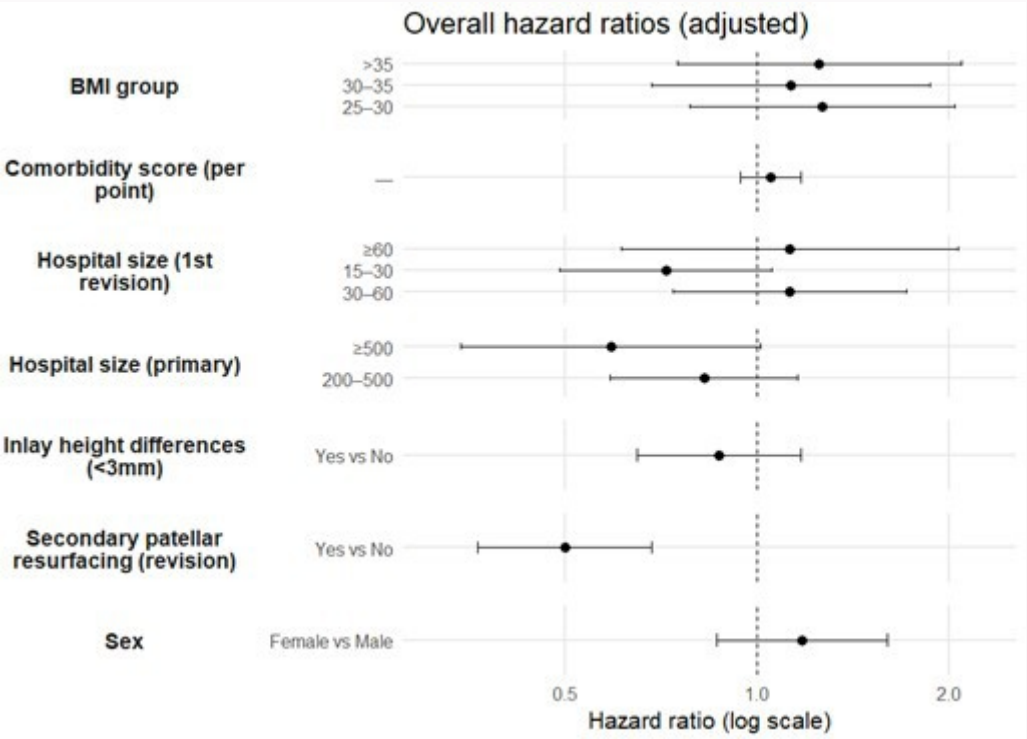

Fig. 5
Hazard ratios for the analyzed parameters.

occurs within the first postoperative year, whereas isolated polyethylene exchange appears more reasonable when instability presents after a longer interval, provided other causes are excluded and patient selection is careful. Previous studies on primary total knee arthroplasty have established that patient-specific factors, especially comorbidity burden, significantly influence revision risk.[21,22] Our results align with these findings, showing a markedly increased risk of revision in patients with higher comorbidities (HR 1.86, 95% CI 1.32 to 2.61; $p < 0.001$). This highlights the importance of thorough preoperative assessment and optimization of patient health before revision procedures.

In addition to timing and patient-related factors, structural and institutional factors, particularly the frequency with which revision procedures are performed, might impact treatment success. There appears to be a trend towards improved outcomes in clinics performing revision procedures more frequently (> 15/year), with statistical significance observed in the sub-group conducting 15 to 30 revisions per year (HR 0.57, 95% CI 039 to 0.83; $p = 0.003$). Although statistical significance was not reached for the number of primary arthroplasties performed in the initial implanting hospital, a similar trend was observed: patients who received their primary TKA in high-volume centres tended to have lower re-revision rates following polyethylene exchange. However, the extent to which this association for both primary and revision arthroplasty centres is influenced by patient selection or other unmeasured confounders cannot be determined from the available registry data.

This study is subject to several limitations inherent to registry-based analyses. First, the EPRD does not capture detailed clinical information such as intraoperative findings, radiological measurements, or standardized functional outcomes, which restricts the ability to fully contextualize surgical decision-making and postoperative results. Second, despite rigorous exclusion of infection-related cases, potential misclassification due to coding or reporting errors cannot be entirely ruled out. Third, sub-group analyses (e.g. stratification by polyethylene height or timing of revision) were based on unevenly distributed case numbers. Because some strata contained comparatively few events, sub-group estimates may be imprecise and underpowered to detect small-to-moderate differences. Additionally, although registry coverage in Germany is high, with approximately 70% of all procedures included, reporting remains voluntary and centre-specific factors such as surgeon experience or intraoperative techniques cannot be fully accounted for, which may confound the observed associations. Also, we could include data from 2014 to 2024, resulting in a potential limited follow-up time for primary surgery to first to a potential second revision. With a longer run of the EPRD, the study results should eventually be validated by longer follow-ups. Besides the inherent statistical and registry-related limitations, the clinical paremeters for an IPE must also be considered, as its indication is largely guided by the surgeon's experience and subjective judgement. As mentioned, multiple sub-types of instability exist, each requiring careful individual assessment. Given this complexity, it cannot be ruled out that in some cases, where a component revision would have been more appropriate, an IPE was performed instead, which naturally contributes to the higher observed risk of re-revision. Finally, the authors want to emphasize that the revision-free survival in no way reflects a satisfied patient, as already stated patient-reported outcome

measures are not available, therefore the results have to be interpreted with caution.

In conclusion, the outcomes after IPE depend on multiple factors, including the timing of instability, patient characteristics, and the surgical volume of the treating centre. While acceptable results can be achieved in most cases, early postoperative instability is linked to less predictable outcomes, highlighting the need for careful patient selection and individualized treatment planning. Detailed preoperative counselling is necessary to provide patients with realistic expectations regarding the benefits and limitations of the procedure. A structured shared decision-making process is important to align surgical objectives with patient goals and to minimize postoperative dissatisfaction.

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Data sharing
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