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Unblinded Title Page

The Effects of Computer Navigation and Patient Specific Instrumentation on Risk of Revision, Patient Reported Outcomes, and Post-operative Mortality Following Primary Total Knee Replacement: An Analysis of National Joint Registry Data

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Abstract

Background

Computer navigation and patient specific instrumentation have been in use over the past two decades for total knee replacement (TKR) however their effects on implant survival and patient reported outcomes remain under debate. We aimed to investigate their influence on implant survival, Oxford Knee Score (OKS), health-related quality of life (EQ-5D-3L), intra-operative complications, and post-operative mortality across a real-world population, compared to conventional instrumentation.

Methods

Using National Joint Registry (NJR) data, an observational study including adult patients who underwent primary TKR for osteoarthritis between 2003 to 2020 was performed. The primary analyses were revision for all-causes and secondary analyses were differences in OKS and EQ-5D-3L at six months post-operatively, and mortality within one year post-operatively. Weights based on propensity scores were generated accounting for several covariates. A Cox proportional hazards model was used to assess revision and mortality outcomes. Generalised linear models were used to evaluate differences in OKS and EQ-5D-3L. Effective sample sizes (ESS) were computed and represent the statistical power comparable to an unweighted sample.

Results

Compared to conventional instrumentation, the hazard ratio (HR) across the 17-year follow-up for all-cause revision following TKR performed using computer navigation and patient specific instruments were 0.937 (95%CI 0.860–1.021, p=0.136, ESS 91,607) and 0.960 (95%CI 0.735–1.252, p=0.761, ESS 13,297), respectively. No differences were observed in OKS and EQ-5D-3L between conventional and computer navigated (-0.134, 95%CI -0.331 to -0.063, p=0.183, ESS 29,135, and 0.000, 95%CI -0.005 to 0.005, p=0.929, ESS 28,396 respectively) and patient

specific instrumentation TKR (0.363, 95%CI -0.104 to 0.830, p=0.127, ESS 4,412, and 0.004, 95%CI -0.009 to 0.018, p=0.511, ESS 4,285 respectively). Mortality within one year post-operatively was similar between conventional instrumentation and either computer navigation or patient specific instrumentation (HR 1.020, 95%CI 0.989–1.052, p=0.212, ESS 110,125).

Conclusions

Based on this large registry study, we conclude that computer navigated and patient specific instrumentation have no statistically or clinically meaningful effect on the risk of revision, patient reported outcomes, or mortality following primary TKR.

Level of evidence: II

Introduction

Total knee replacement (TKR) is a definitive treatment for patients suffering with end-stage osteoarthritis (1). Although improvements in several aspects of TKR surgery have been achieved over the years, there remain several unresolved challenges. Primary TKR survival rates are estimated to be 89.7% (95% confidence interval 87.5 to 91.5) at 20 years post-operatively and up to 20% of patients are dissatisfied with the outcome of their procedure (2, 3) (4). Commonly cited reasons include implant malalignment and soft tissue imbalance of the joint (5, 6).

These surgical errors can be addressed using computer assisted technologies including computer navigation and patient specific instruments. These technologies can improve the accuracy and reliability of implant positioning and target alignment compared to conventional instrumentation (7-10). They also avoid the use of intramedullary alignment rods that increase blood loss and can cause embolism of bone marrow contents into the systemic circulation that may influence post-operative mortality (11, 12). However, despite these theoretical advantages, it is unclear whether their use has helped improve revision rates, patient reported outcomes, or reduce mortality at a population level.

Previous studies that examined this topic using registry data did not account for confounding by indication through statistical techniques. They were also limited by small sample sizes, short follow-up periods, adjusted for few confounders, and focussed on a single implant and specific computer navigation system (13-15). Our study aimed to address these limitations. Using the National Joint Registry (NJR) and linked datasets for Patient Reported Outcome Measures (PROMs) and Mortality, we examined the effect of primary TKR performed using computer navigation and patient specific instruments compared to conventional technique on:

i) the risk of revision for all-causes

ii) differences in Oxford Knee Score and Health Related Quality of Life six months post-operatively

iii) mortality within 12 months post-operatively

iv) incidence of intra-operative complications

Methods

Study design and data sources

We performed an observational study using data from the NJR for procedures performed in England (16), National Health Service England (NHS) PROMs programme (17), and Office for National Statistics (ONS) death data (18). The NJR is a prospective register of primary and revision arthroplasty procedures. Data is contemporaneously submitted by the surgeon using a standardised form and has been mandatory in both the independent and public sectors since 2003 and 2011 respectively. Since April 2009, NHS funded patients undergoing elective primary TKR in England are asked to complete the Oxford Knee Score (OKS) and Health Related Quality of Life (EQ-5D-3L) patient-reported outcome questionnaires preoperatively and six months post-operatively (16). The OKS measures knee function and pain, while the EQ-5D-3L assesses quality of life across five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) (19, 20).

The base dataset consisted of 1,294,600 procedures performed between 1st April 2003 to 31st December 2020. All adult patients (≥18 years) who underwent primary TKR for osteoarthritis only were eligible. All computer navigation and patient specific instrumentation systems were eligible for inclusion; the NJR does not record information regarding the specific brand of computer assisted technology used during the procedure. Based on a suggested reporting framework for PROMs, we analysed pre- and post-operative questionnaires if completed by patients within 18 weeks prior to surgery and within six to twelve months after surgery, respectively (21). Patients who had died or underwent a revision procedure within twelve months of their initial procedure were excluded from the PROMs analyses, as inability to complete questionnaires or experiencing a revision procedure may confound their scores (21, 22).

Exposures and outcomes of interest

The exposures were conventional technique, computer navigation, and patient specific instrumentation TKR. Procedures were categorised under their respective groups based on the surgeon's selection of these available options when completing the Minimum Data Set form after each procedure. References to the term 'computer assisted technologies' throughout the text encompass both computer navigation and patient specific instrumentation.

The primary analysis was revision for all-causes following TKR performed using computer navigation and patient specific instrumentation compared to conventional technique.

Secondary analyses were conducted comparing computer navigation versus conventional technique due to the smaller sample size in the patient specific instrumentation group. These included revision for all-causes in patients aged over and under 60 years, for loosening/lysis, for prosthetic joint infection, and for causes other than loosening and prosthetic joint infection.

Additional secondary analyses were differences in patient reported joint function and health-related quality of life measured using OKS and EQ-5D-3L respectively at six months post-operatively, as well as mortality within one year.

Approximately 30% of TKR procedures within the NJR dataset lack body mass index (BMI) data, the majority of these occur in the early years of the NJR. Given this potential confounder, we explored the effects of missing data through sensitivity analyses that also considered this covariate for the comparisons revision for all-causes and PROMs (23, 24). We excluded patients from these analyses whose BMI values were outside the range of 15 to 65, considering such values erroneous. Due to variation in implant performance profiles we also conducted a sensitivity analysis restricting to the five most commonly used combination of prosthesis brands for the comparison revision for all-causes (16).

The mortality analysis involved grouping computer navigation and patient specific instrumentation TKR under one category (computer assisted technology) as both technologies avoid using intramedullary rods.
The occurrence of intra-operative complications among the three patient groups was also investigated.

Statistical analysis

Propensity scores were estimated using a logistic regression model approach with Sturmer weight trimming to improve the accuracy and precision of estimates. For revision outcomes, the covariates were age, sex, American Society of Anaesthesiologists (ASA) classification, operation funding, hospital setting (public or private), year of surgery, approach, surgeon case volume (defined as the mean number of procedures per year; analysed as a continuous measure and capped at 200 procedures/year), fixation, and patellar resurfacing. For PROMs outcomes, the latter two variables were substituted for pre-operative EQ-5D-3L and OKS scores as they have not been shown to influence these outcomes (25-27). For post-operative mortality, the covariates included age, sex, ASA classification, year of surgery, and fixation. Propensity score-based weights were generated for the patient groups. Standardized mean differences were examined prior to and following the construction of weights to assess for covariate imbalance between groups. These are computed by dividing the difference in the means of the variable in the two groups by an estimate of the standard deviation. Larger values indicate that the two groups are dissimilar, a commonly recommended threshold value is <0.1 (28). Kaplan-Meier estimates were used to analyse revision and post-operative mortality outcomes. The unit for survival analyses for revision and mortality outcomes was each primary procedure. For revision outcomes, cases were censored based on the date of the last follow-up (31st December 2020) or death, whichever occurred earlier. For outcome post-operative mortality, cases were also censored on the date of their revision event as reoperation may introduce confounding. A Cox proportional hazards model was used to assess for differences in revision risk and post-operative mortality. Proportionality was explored using flexible parametric modelling to decide the most appropriate approach and comparisons were performed using likelihood ratio testing (29). The data was modelled using restricted cubic splines with three knots to explore the possibility of a time varying effect of surgery with computer navigation and patient specific instrumentation. This model was compared to the equivalent model with no time-varying effect and found no significant difference (p=0.848). Hence, Cox proportional hazards models were used, with fixed effects for surgical technique (computer navigation, patient specific instrumentation or conventional surgery), sex, age, year of surgery, and surgeon case volume and stratified for ASA classification, approach, patellar resurfacing, fixation, operation funding and hospital setting to account for potential non-proportional hazards in these groups. For the PROMs analyses, the NHS Digital case mix adjustment methodology (version three) was used to estimate the expected post-operative scores (17). This accounts for several additional confounders amongst the population such as ethnicity. The difference between the expected and observed PROMs change scores between patient groups were analysed using a generalised linear model. The same statistical approaches were applied in the sensitivity analyses. Due to few events, an unadjusted analysis of intra-operative complications was performed using the Chi-squared test. Revision and mortality outcomes were expressed using hazard ratios (HR) while PROMs were expressed using their respective units. Effective sample sizes (ESS) are provided, reporting a comparable level of statistical power to an unweighted sample (30). 95% confidence intervals (CI) are presented and statistical significance was set at $p<0.05$. Analyses were carried out using Stata (version 16.1, StataCorp LP, College Station, Texas, USA, 1985–2019).

Results

Patient characteristics

The flow of patient data through to data analysis is shown in Figure 1. Table 1 presents the characteristics of the patient groups pre-weighting. Most procedures were performed using conventional technique (96.99% versus 3.01%). Median follow up time was longer for procedures performed using conventional instrumentation (6.34 years) and computer navigation (6.33 years) compared to patient specific instrumentation (4.52 years). The mean age and distributions of ASA and sex were similar across all patient groups. The medial parapatellar approach was used almost exclusively (93.79%) and implants were cemented for most procedures across all groups (95.84%). Patellar resurfacing was more common during procedures involving the use of patient specific instrumentation compared to computer navigation and conventional technique (46.1%, 41.1% and 38.7%, respectively).

In contrast to conventional and computer navigated TKR, a greater proportion of procedures performed using patient specific instrumentation were privately funded. BMI was similar between the groups, with data available for most procedures regardless of technique. However, availability of BMI data was relatively greater for procedures performed using patient specific instrumentation than computer navigation and conventional technique.

Table 2 details patients characteristics after weighting and their standardized mean differences.

Revision for all-causes

There were no differences observed in the revision rate for all-causes between conventional and computer navigated TKR (HR 0.937, 95%CI 0.860–1.021, p=0.136, ESS 91,607) (Figure 2). Similar results were found when comparing revision for all-causes between conventional and patient specific instrumentation TKR (HR 0.960, 95%CI 0.735–1.252, p=0.761, ESS 13,297) (Figure 3).

In the secondary analyses comparing conventional surgery and computer navigation, there were no differences in the revision rate for all-causes in patients aged below and over 60 years (HR 1.093, 95%CI 0.906–1.318, p=0.354, ESS 13,730, and HR 0.940, 95%CI 0.827–1.069, p=0.345, ESS 78,133, respectively) (Figures 4 and 5).

Revision for loosening, prosthetic joint infection, and other indications

There were no differences between conventional surgery and computer navigation when investigating revision risk for loosening/lysis (HR 0.914, 95%CI 0.771–1.084, p=0.301, ESS 91,607, Figure 6), prosthetic joint infection (HR 0.906, 95%CI 0.764–1.074, p=0.254, ESS 91,607, Figure 7), and for all other indications combined (HR 0.984, 95%CI 0.873–1.109, p=0.790, ESS 91,607, Figure 8).

OKS and EQ-5D

Univariable regression analyses using values from the weighted and case mix adjusted groups revealed no differences in the change in OKS and EQ-5D-3L scores following TKR performed using computer guidance and patient specific instrumentation compared to conventional technique (table 3).

Sensitivity analyses

The sensitivity analysis for revision risk for all-causes accounting for BMI in the model demonstrated similar results to the primary analysis (HR 0.976, 95%CI 0.876–1.088, p=0.665, ESS 59,599) (supplementary figure 1). Similar results were found in the sensitivity analysis restricting to the five most commonly used combination of prosthesis brands (HR 1.00, 95%CI 0.881–1.142, p=0.964, ESS 65,141) (supplementary figure 2).

Results of the sensitivity analyses accounting for BMI in the models comparing OKS and EQ-5D-3L between computer navigated and conventional TKR were similar to those of the primary analyses (supplementary table 1).

Post-operative mortality

Seven, 30, and 90-day cumulative unadjusted post-operative mortality were 0.04%, 0.05%, 0.10% versus 0.12%, and 0.22% versus 0.24%, among patients who underwent TKR using computer assisted technology and conventional technique, respectively. There were also no differences in mortality between these patient groups during the first year post-operatively (HR 1.020, 95%CI 0.989–1.052, p=0.212, ESS 110,125) (Figure 9).

Intra-operative complications

There were no statistically significant differences in intra-operative complications between groups (p=0.162) (Table 4). There was missing data for 66,925 procedures.

Discussion

This pragmatic study analysed several linked registry data sets and accounted for multiple covariates using propensity scoring statistical techniques to investigate differences in revision risk, OKS, EQ-5D, and post-operative mortality following TKR performed using computer navigation and patient specific instrumentation, compared to conventional technique. There were no differences found for all these investigated outcomes in the primary, secondary, and sensitivity analyses. The occurrence of intra-operative complications was also similar between groups. **Surgeons should reconsider using these technologies in TKR over conventional surgery in unselected cases if the rationale for their use is to improve any of the outcomes evaluated in this study.**

Our study findings are similar to those found in other countries' national registry data (31). McAuliffe et al. analysed the Australian Orthopaedic Association National Joint Registry (AOANJR) and compared patient groups who underwent TKR using image-derived instrumentation, computer navigation, and conventional technique (32). Their main analysis also showed no difference in all-cause revision between groups at a median of around two years follow-up. Similarly, Roberts et al. analysed the single most common computer assisted surgery system and implant in the New Zealand National Joint Registry and found no differences in revision rates in TKR performed between routine users of computer assisted surgery and conventional instrumentation at a mean 4.5 years follow up. They found comparable OKS scores between these groups at 6 months, 5 years, and 10 years post-operatively (33). The same authors also found no differences in mortality at 30 days and 6 months post-operatively between groups (34). In contrast, Harris et al. analysed the AOANJR dataset and found relatively higher mortality at seven, 30 and 90 days post-operatively in patients who underwent TKR using conventional technique compared to technology-assisted instrumentation (35).

The strengths of our study include the use of several linked, large datasets allowing a comprehensive investigation of multiple outcomes. We accounted for a range of important known confounders and mitigated confounding by indication through propensity scoring techniques. Furthermore, due to variations in the characteristics of patients managed by surgeons in different regions, additional adjustment for relevant confounders including deprivation, ethnicity, and a range of specific comorbidities were facilitated through the NHS Digital case mix adjustment methodology for the analyses of PROMs. Although there are nuances between the many computer assisted technology systems available for use, we did not restrict our analyses to particular systems and implants to ensure strong external validity of our results.

Our study has several limitations. We examined computer navigation and patient specific instrumentation in the broad sense, assessing their overall impact on outcomes at a population level. Individual technologies may differ within these groups and this may be better assessed in randomised trials. However, to understand the impact of the overall introduction of technology on a population, the registry approach gives a large volume of cases across a single large healthcare system. Despite this, revision events are rare and a post-hoc power calculation using the effective sample size and estimating event probability from the unweighted sample indicated a power of 0.69 for detecting a hazard ratio of 0.90, assuming equal allocation. Given our groups were not equal in size and the observed hazard ratio was greater than 0.90, we consider the analyses modestly underpowered to detect any potential difference in revision between conventional and computer navigated surgery. Analyses of registry data has recognised limitations, including potential for misclassification. While some procedures may have been erroneously categorised, this likely affects only a minority of cases and random regarding group allocation (36). Other residual confounding including alignment philosophy might influence revision and PROMs outcomes (37). Due to confidentiality and data governance policies, we received pseudo-anonymized data, which prevented the ability to account for patients who received a contralateral unicompartmental knee replacement or TKR during a separate visit to the operating room within the registry's data collection period. These factors may have affected the outcomes we investigated. In contrast, approximately 0.5% of patients underwent simultaneous bilateral TKR, making it unlikely that their effects significantly skewed the study's findings. Also, we were unable to account for any potential effects of prior non-arthroplasty knee surgery, as it was not possible to identify this subpopulation from the analysed datasets. This was mitigated by excluding patients from the analysis if the surgeon indicated that prior knee trauma was a contributing factor for the procedure. Lastly, although we compared mortality between groups, we could not investigate outcomes relating to morbidity including blood loss and venous thromboembolism, as this information is not recorded within the datasets.

Conclusions

Computer navigation and patient specific instrumentation did not confer revision, functional outcomes or post-operative mortality advantage. We are unable to exclude the possibility these technologies could benefit specific patient subpopulations and reduce revision risk at longer term endpoints. As computer assisted technology TKR is typically associated with higher costs, and based on our study findings showing absent differences, it seems unlikely that these technologies provide a cost-effective addition to practice. Future technologies, implant designs or different approaches to alignment or balancing may be required to improve outcomes, and should be accompanied by carefully planned research to ensure that the expense of introducing technologies brings tangible benefits to patients (38).

NOTES

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Data sharing

Access to data is available from The National Joint Registry (NJR), but restrictions apply to the availability of these data, which were used under license for the current study, and are therefore not publicly available. Data access applications can be made to the NJR Research Committee.

Ethical review statement

With support under Section 251 of the NHS Act 2006, the Ethics and Confidentiality Committee (ECC), (now the Health Research Authority Confidentiality Advisory Group) allows the NJR to collect patient data where consent is indicated as 'Not Recorded'. Before Personal Data and Sensitive Personal Data is recorded, express written patient consent is provided. The NJR records patient consent as either 'Yes', 'No', or 'Not Recorded'.

Conflicts of Interest

AM leads two studies (START:REACTS, about a shoulder device, and RACER-Knee, about robotic-assisted knee replacement) and is a co-investigator on another (RACER-Hip, about robotic-assisted hip replacement).

PW leads RACER-Hip (about robotic-assisted hip replacement).

These studies are funded by the UK National Institute for Health Research (NIHR), but for which Stryker, have funded treatment costs and some imaging and training costs.

JM is also a co-applicant for these three studies. For all of these studies, the full independence of the study team (AM, PW, and JM included) are fully protected by legal agreements agreed between the parties and approved by NIHR.

References

1. Carr AJ, Robertsson O, Graves S, Price AJ, Arden NK, Judge A, Beard DJ. Knee replacement. Lancet. 2012;379(9823):1331-40.
2. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res. 2010;468(1):57-63.
3. Williams DP, O'Brien S, Doran E, Price AJ, Beard DJ, Murray DW, Beverland DE. Early postoperative predictors of satisfaction following total knee arthroplasty. Knee. 2013;20(6):442-6.
4. James Lind Alliance. Hip & Knee Replacement for Osteoarthritis Top 10 2024 [Available from: https://www.jla.nihr.ac.uk/priority-setting-partnerships/hip-and-knee-replacement-for-osteoarthritis/top-10-priorities/.
5. Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. J Arthroplasty. 2009;24(4):560-9.
6. Huang NF, Dowsey MM, Ee E, Stoney JD, Babazadeh S, Choong PF. Coronal alignment correlates with outcome after total knee arthroplasty: five-year follow-up of a randomized controlled trial. J Arthroplasty. 2012;27(9):1737-41.
7. Hetaimish BM, Khan MM, Simunovic N, Al-Harbi HH, Bhandari M, Zalzal PK. Meta-analysis of navigation vs conventional total knee arthroplasty. J Arthroplasty. 2012;27(6):1177-82.
8. Onggo JR, Onggo JD, De Steiger R, Hau R. Robotic-assisted total knee arthroplasty is comparable to conventional total knee arthroplasty: a meta-analysis and systematic review. Arch Orthop Trauma Surg. 2020;140(10):1533-49.
9. Mannan A, Smith TO. Favourable rotational alignment outcomes in PSI knee arthroplasty: A Level 1 systematic review and meta-analysis. Knee. 2016;23(2):186-90.
10. Gong S, Xu W, Wang R, Wang Z, Wang B, Han L, Chen G. Patient-specific instrumentation improved axial alignment of the femoral component, operative time and perioperative blood loss after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2019;27(4):1083-95.
11. Lu K, Xu M, Li W, Wang K, Wang D. A study on dynamic monitoring, components, and risk factors of embolism during total knee arthroplasty. Medicine (Baltimore). 2017;96(51):e9303.
12. Church JS, Scadden JE, Gupta RR, Cokis C, Williams KA, Janes GC. Embolic phenomena during computer-assisted and conventional total knee replacement. J Bone Joint Surg Br. 2007;89(4):481-5.
13. Dyrhovden GS, Fenstad AM, Furnes O, Gothesen O. Survivorship and relative risk of revision in computer-navigated versus conventional total knee replacement at 8-year follow-up. Acta orthopaedica. 2016;87(6):592-9.
14. McAuliffe MJ, Beer BR, Hatch JJ, Crawford RW, Cuthbert AR, Donnelly WJ. Impact of Image-Derived Instrumentation on Total Knee Arthroplasty Revision Rates An Analysis of 83,823 Procedures from the Australian Orthopaedic Association National Joint Replacement Registry. JOURNAL OF BONE AND JOINT SURGERY-AMERICAN VOLUME. 2019;101(7):580-8.
15. Roberts TD, Frampton CM, Young SW. Outcomes of Computer-Assisted Surgery Compared with Conventional Instrumentation in 19,221 Total Knee Arthroplasties: Results After a Mean of 4.5 Years of Follow-Up. The Journal of bone and joint surgery American volume. 2020;102(7):550-6.
16. NJR Steering Committee. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man: 19th annual report Hemel Hempstead: National Joint Registry Centre, 2022 [updated 10th November 2022. Available from:

https://reports.njrcentre.org.uk/Portals/0/PDFdownloads/NJR%2019th%20Annual%20Report%202022.pdf.

17. NHS Digital. PROMs Methodologies 2024 [cited 2024 17th February]. Available from: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms/proms-methodologies#case-mix.

18. NHS Digital. ONS Mortality Data 2024 [cited 2024 17th February]. Available from: https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/linked-hes-ons-mortality-data.

19. EuroQol G. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy. 1990;16(3):199-208.

20. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. J Bone Joint Surg Br. 1998;80(1):63-9.

21. NJR Steering Committee. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man: 19th annual report. Hemel Hempstead: National Joint Registry Centre, 2022.

22. Scott CEH, Turnbull GS, Powell-Bowns MFR, MacDonald DJ, Breusch SJ. Activity levels and return to work after revision total hip and knee arthroplasty in patients under 65 years of age. Bone Joint J. 2018;100-B(8):1043-53.

23. Evans JT, Mouchti S, Blom AW, Wilkinson JM, Whitehouse MR, Beswick A, Judge A. Obesity and revision surgery, mortality, and patient-reported outcomes after primary knee replacement surgery in the National Joint Registry: A UK cohort study. PLoS Med. 2021;18(7):e1003704.

24. Giesinger JM, Loth FL, MacDonald DJ, Giesinger K, Patton JT, Simpson A, Howie CR, Hamilton DF. Patient-reported outcome metrics following total knee arthroplasty are influenced differently by patients' body mass index. Knee Surg Sports Traumatol Arthrosc. 2018;26(11):3257-64.

25. Prasad AK, Tan JHS, Bedair HS, Dawson-Bowling S, Hanna SA. Cemented vs. cementless fixation in primary total knee arthroplasty: a systematic review and meta-analysis. EFORT Open Rev. 2020;5(11):793-8.

26. Nam D, Lawrie CM, Salih R, Nahhas CR, Barrack RL, Nunley RM. Cemented Versus Cementless Total Knee Arthroplasty of the Same Modern Design: A Prospective, Randomized Trial. J Bone Joint Surg Am. 2019;101(13):1185-92.

27. Grela M, Barrett M, Kunutsor SK, Blom AW, Whitehouse MR, Matharu GS. Clinical effectiveness of patellar resurfacing, no resurfacing and selective resurfacing in primary total knee replacement: systematic review and meta-analysis of interventional and observational evidence. BMC Musculoskelet Disord. 2022;23(1):932.

28. Stuart EA, Lee BK, Leacy FP. Prognostic score-based balance measures can be a useful diagnostic for propensity score methods in comparative effectiveness research. J Clin Epidemiol. 2013;66(8 Suppl):S84-S90 e1.

29. Lambert PC, Royston P. Further development of flexible parametric models for survival analysis. The Stata Journal. 2009;9(2):265-90.

30. Burgette JM, Preisser JS, Rozier RG. Propensity score weighting: an application to an Early Head Start dental study. J Public Health Dent. 2016;76(1):17-29.

31. Bini SA. Rethinking the Value of Computer-Assisted Surgery: Commentary on an article by Timothy D. Roberts, MBChB, et al.: "Outcomes of Computer-Assisted Surgery Compared with Conventional Instrumentation in 19,221 Total Knee Arthroplasties. Results After a Mean of 4.5 Years of Follow-up". J Bone Joint Surg Am. 2020;102(7):e32.

32. McAuliffe MJ, Beer BR, Hatch JJ, Crawford RW, Cuthbert AR, Donnelly WJ. Impact of Image-Derived Instrumentation on Total Knee Arthroplasty Revision Rates: An Analysis of 83,823 Procedures from the Australian Orthopaedic Association National Joint Replacement Registry. Journal of Bone and Joint Surgery - American Volume. 2019;101(7):580-8.

33. Roberts TD, Clatworthy MG, Frampton CM, Young SW. Does Computer Assisted Navigation Improve Functional Outcomes and Implant Survivability after Total Knee Arthroplasty? J Arthroplasty. 2015;30(9 Suppl):59-63.

34. Roberts TD, Clatworthy MG, Frampton CM, Young SW. Does Computer Assisted Navigation Improve Functional Outcomes and Implant Survivability after Total Knee Arthroplasty? Journal of Arthroplasty. 2015;30(9 Supplement):59-63.
35. Harris IA, Kirwan DP, Peng Y, Lewis PL, de Steiger RN, Graves SE. Increased early mortality after total knee arthroplasty using conventional instrumentation compared with technology-assisted surgery: an analysis of linked national registry data. BMJ Open. 2022;12(5):e055859.
36. Baker PN, Jeyapalan R, Jameson SS. The value of national arthroplasty registry data in 2023. Bone Joint J. 2023;105-B(4):356-60.
37. Liu B, Feng C, Tu C. Kinematic alignment versus mechanical alignment in primary total knee arthroplasty: an updated meta-analysis of randomized controlled trials. J Orthop Surg Res. 2022;17(1):201.
38. McCulloch P, Altman DG, Campbell WB, Flum DR, Glasziou P, Marshall JC, Nicholl J, Balliol C, Aronson JK, Barkun JS, Blazeby JM, Boutron IC, Campbell WB, Clavien PA, Cook JA, Ergina PL, Feldman LS, Flum DR, Maddern GJ, Nicholl J, Reeves BC, Seiler CM, Strasberg SM, Meakins JL, Ashby D, Black N, Bunker J, Burton M, Campbell M, Chalkidou K, Chalmers I, de Leval M, Deeks J, Ergina PL, Grant A, Gray M, Greenhalgh R, Jenicek M, Kehoe S, Lilford R, Littlejohns P, Loke Y, Madhock R, McPherson K, Meakins J, Rothwell P, Summerskill B, Taggart D, Tekkis P, Thompson M, Treasure T, Trohler U, Vandenbroucke J. No surgical innovation without evaluation: the IDEAL recommendations. Lancet. 2009;374(9695):1105-12.

Figure legends

Figure 1: Flow diagram illustrating the process of inclusion and exclusion of procedure records

Figure 2: Revision for all-causes following primary TKR performed with computer navigation versus conventional technique

Figure 3: Revision for all-causes following primary TKR performed using patient specific instrumentation versus conventional technique

Figure 4: Revision for all-causes following primary TKR performed using computer navigation versus conventional technique in patients younger than 60 years

Figure 5: Revision for all-causes following primary TKR performed using computer navigation versus conventional technique in patients older than 60 years

Figure 6: Revision for loosening/lysis following primary TKR performed using computer navigation versus conventional technique

Figure 7: Revision for prosthetic joint infection following primary TKR performed using computer navigation versus conventional technique

Figure 8: Revision for indications other than loosening/lysis and prosthetic joint infection following primary TKR performed using computer navigation versus conventional technique

Figure 9: Mortality following primary TKR performed using computer assisted technology versus conventional technique

Supplementary figure 1: Revision for all-causes following primary TKR performed using computer navigation versus conventional technique when also accounting for BMI in the model

Supplementary figure 2: Revision for all-causes following primary TKR performed using computer navigation versus conventional technique when restricting to the top five most commonly used combination of prosthesis brands

Figure 3

Click here to access/download;Figure (TIFF or EPS only);Figure 3.tiff

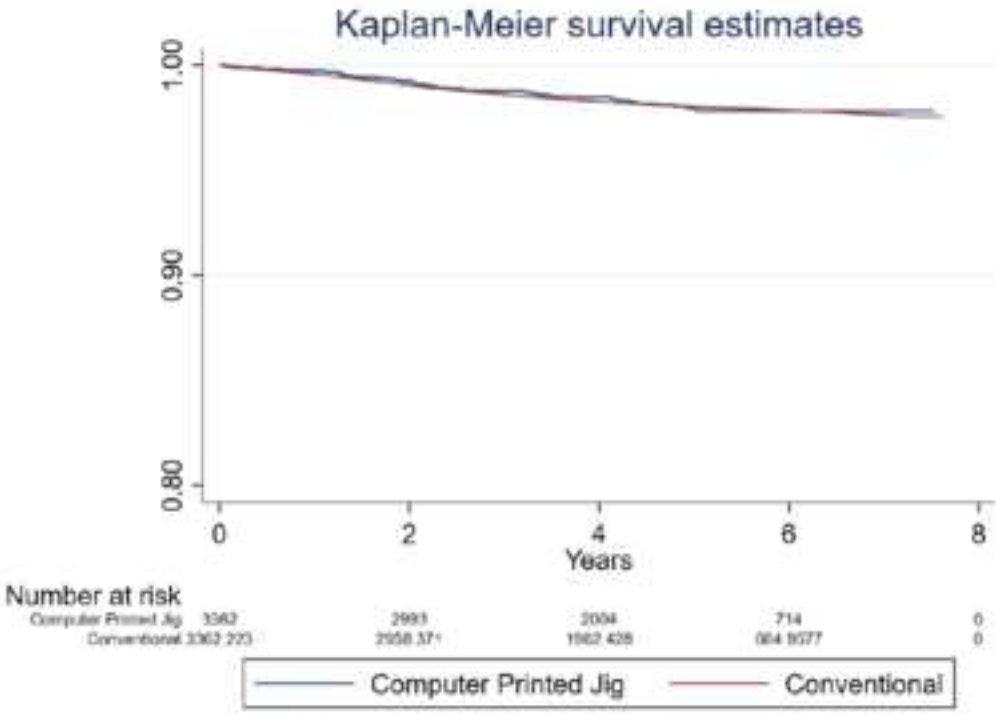


Figure 4

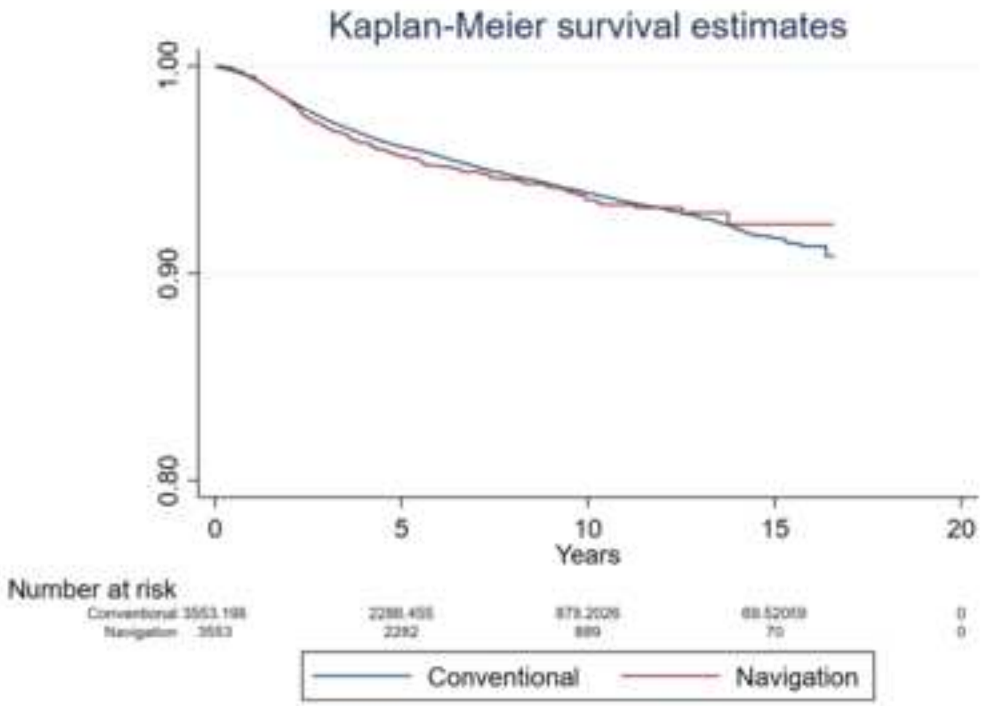
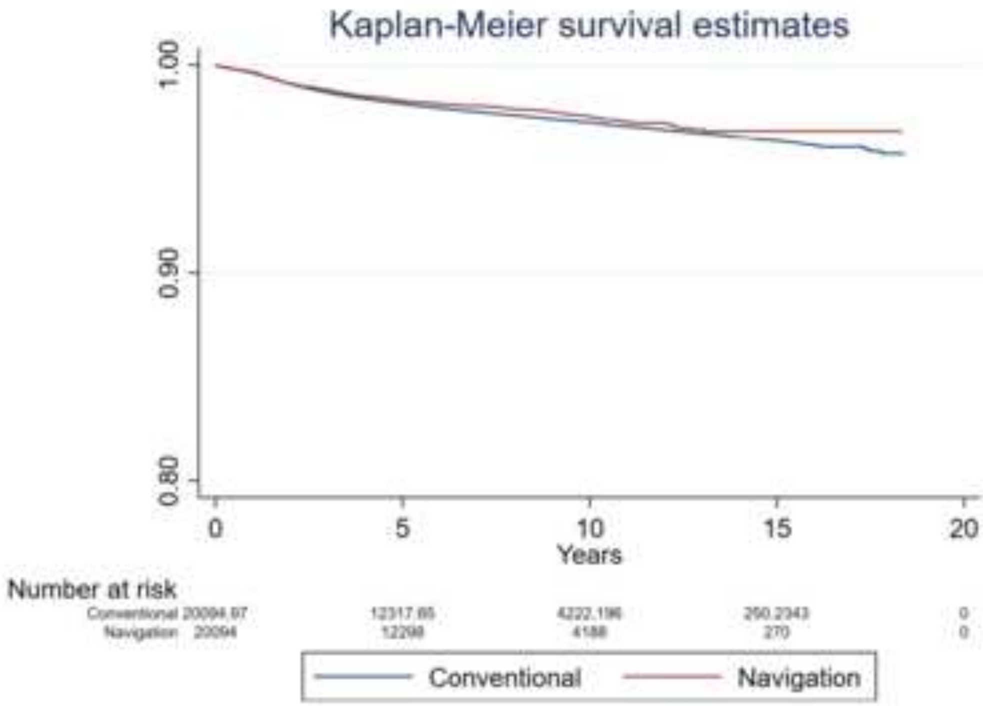

Kaplan-Meier survival estimates
1.00
0.90
0.80
0
5
10
15
20
Years
Number at risk
Conventional 3553.198 2288.455 879.2026 69.52059 0
Navigation 3553 2282 889 70 0
Conventional
Navigation

Figure 5

Click here to access/download;Figure (TIFF or EPS only);Figure 5.tiff



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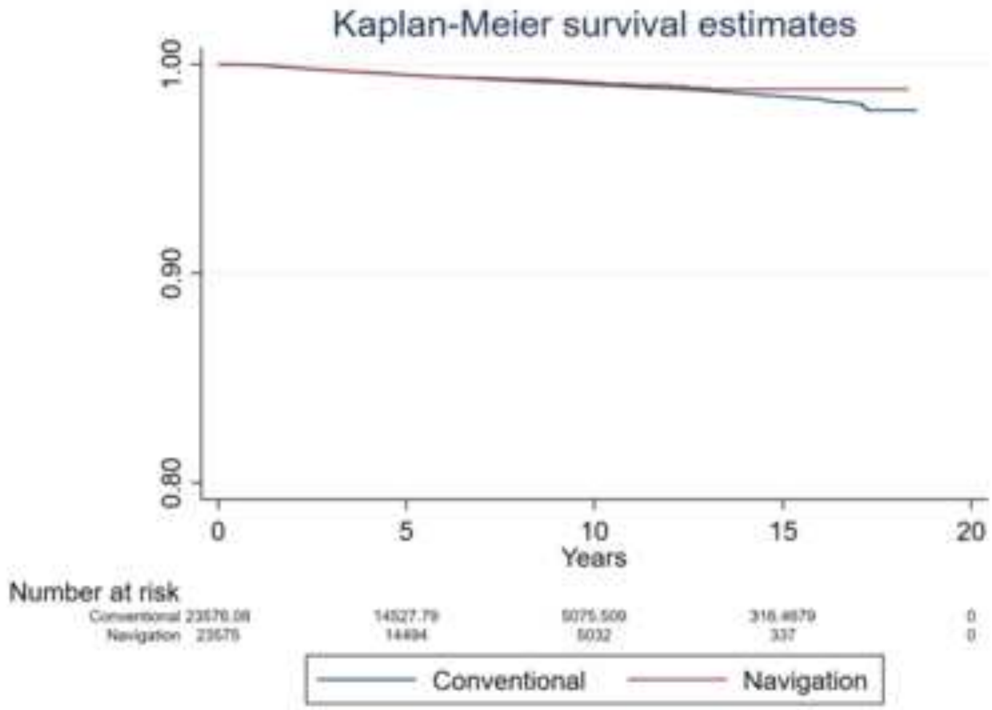

Figure 7

Click here to access/download;Figure (TIFF or EPS only);Figure 7.tiff

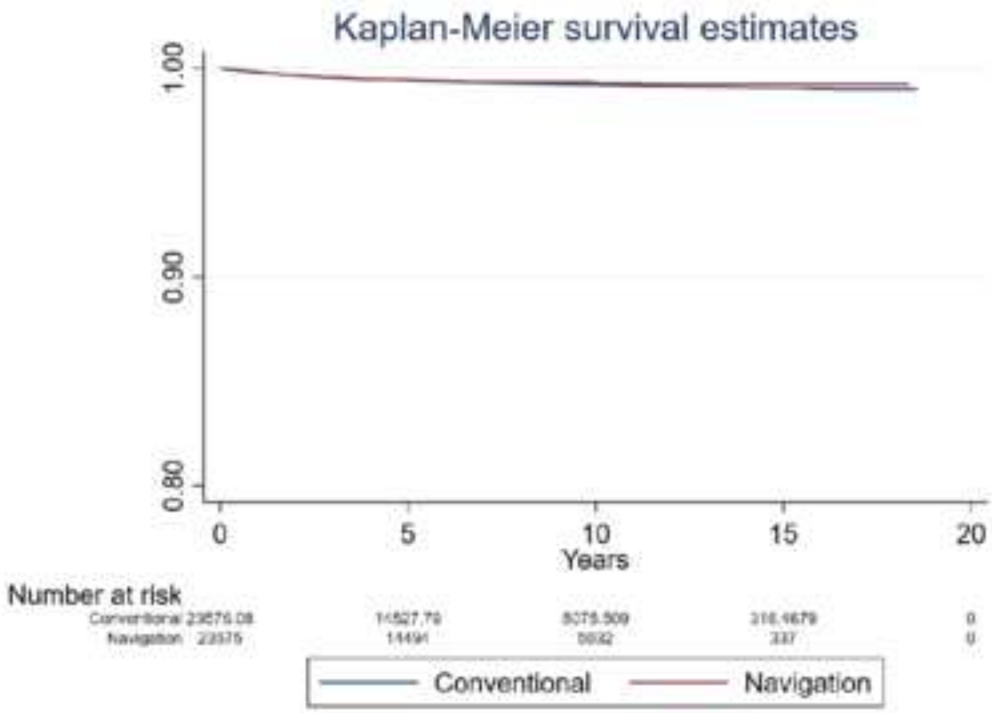

Figure 8

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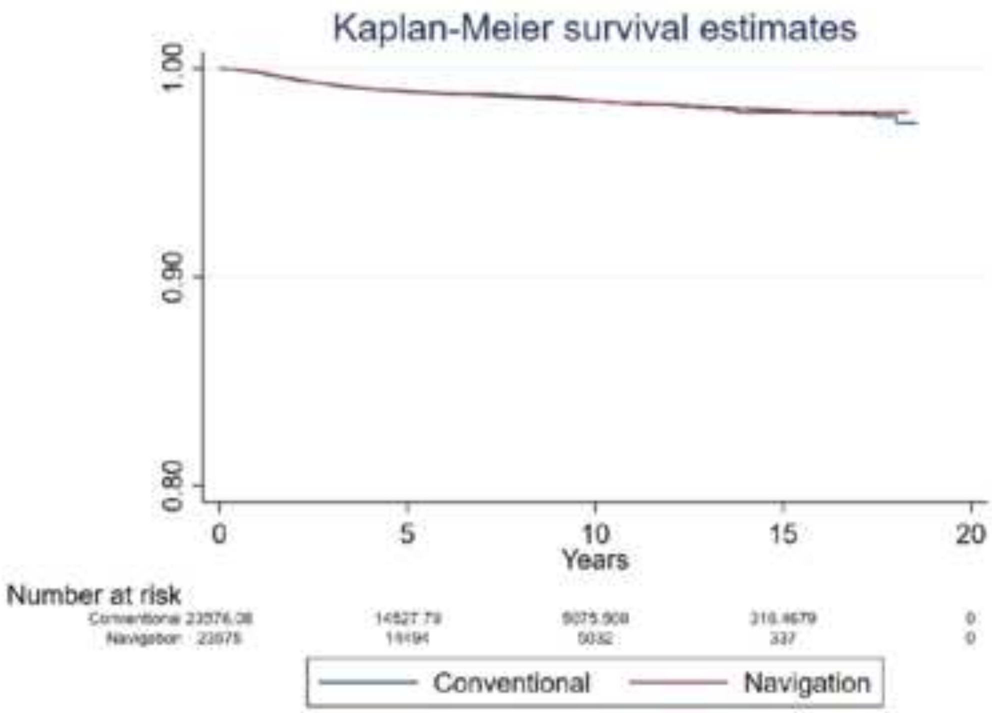


Figure 9

Click here to access/download;Figure (TIFF or EPS only);Figure 9.tiff

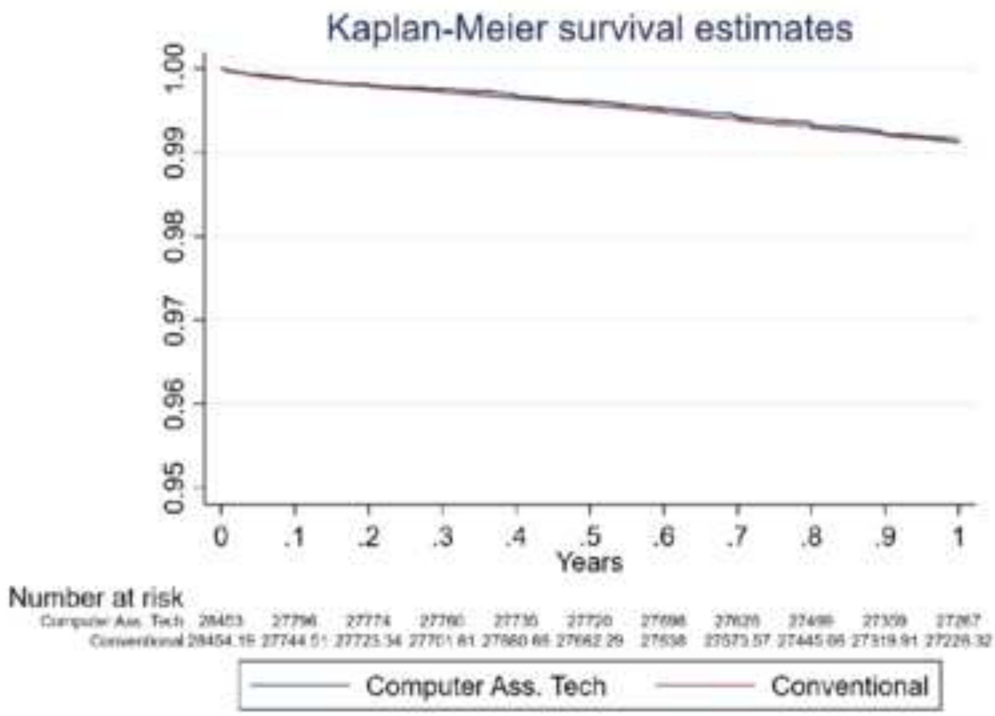
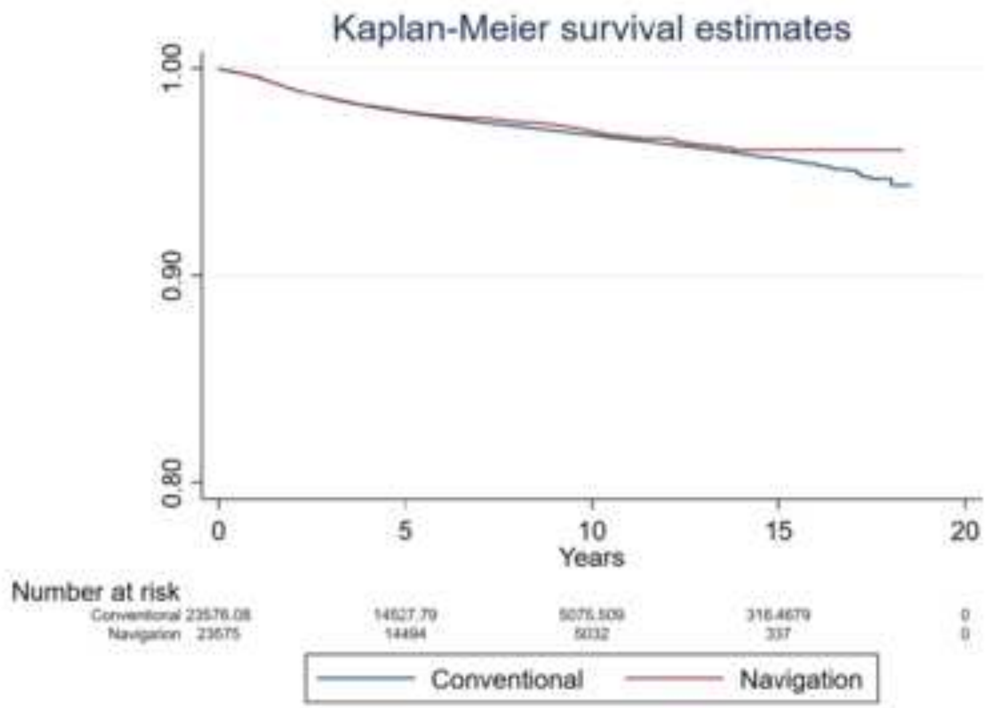


Figure 1


Knee procedure records received from NJR performed between 1 April 2003 and 31 December 2020 (n = 1,294,600)
Sequential exclusions:
- Age <18 years (n=13)
- Missing computer guided or robotic information (n=19,157)
- Implausible revision dates (n=159)
- Pre-April 2003 operation (n=36)
- Missing follow up data (n=225)
- Deceased on day of surgery (n=1,405)
- Missing sex information (n=12)
- Missing funding information (n=21,472)
- Indication not osteoarthritis only (n=47,226)
- Unclear knee surgery type (n=24,813)
- Unknown fixation (n=8,569)
- Missing hospital setting (n=60)
- UKR (n=106,709)
Subtotal exit (n=229,856)
Inclusions and exclusions, and accounting for missing data
Primary TKR eligible for analysis of revision (n=1,064,744)
Primary TKR eligible for analysis of OKS (n=362,959) and EQ5D (n=337,622) outcomes
Exclusions:
- Missing OKS (n=701,785)
- Missing EQ5D (n=727,122)
Propensity score weighting and Stürmer weight trimming
Primary TKR included in analysis comparing revision between conventional and computer navigation (n=873,278)
Primary TKR included in analysis comparing revision between conventional and patient specific instrumentation (n=421,457)
Primary TKR included in analysis comparing OKS (N=265,057) and EQ5D (n=261,307) between conventional and computer navigation
Primary TKR included in analysis comparing OKS (n=162,458) and EQ5D (n=158,389) between conventional and patient specific instrumentation

Figure 2



Kaplan-Meier survival estimates
1.00
0.90
0.80
0
5
10
15
20
Years
Number at risk
Conventional 23576.08 14527.79 5075.509 316.4679 0
Navigation 23575 14494 5032 337 0
Conventional
Navigation

Table 1

	Conventional surgery (n=1,031,950)	Computer navigation (n=27,161)	Standardised Mean Difference	Patient specific instrumentation (n=4,899)	Standardised Mean Difference
Number of revisions	25,020	643		86	
Median Observation Time (revision or censoring) (IQR)	6.34 years (3.61, 9.76)	6.33 years (3.48, 9.60)		4.52 years (2.90, 5.83)	
Mean age, years (SD)	70.3 (9.1)	69.5 (9.4)	-0.08	67.8 (9.5)	-0.26
Sex					
Female	589,684 (57.1%)	15,250 (56.1%)	0.02	2,589 (52.9%)	0.08
Male	442,266 (42.9%)	11,911 (43.9%)		2,310 (47.1%)	
Side					
Left	488,618 (47.3%)	12,867 (47.4%)	0.00	2,330 (47.6%)	-0.01
Right	543,332 (52.7%)	14,294 (52.6%)		2,569 (52.4%)	
ASA classification					

1	104,026 (10.1%)	3,144 (11.6%)	0.01	665 (13.6%)	-0.15
2	752,156 (72.9%)	19,008 (70.0%)		3,481 (71.1%)	
3	172,554 (16.7%)	4,939 (18.2%)		738 (15.1%)	
4	3,143 (0.3%)	68 (0.2%)		15 (0.3%)	
5	71 (0.0%)	2 (0.0%)		0	
Approach					
Medial parapatellar	967,904 (93.8%)	25,601 (94.3%)	-0.07	4,468 (91.2%)	0.03
Lateral parapatellar	8,400 (0.8%)	182 (0.7%)		73 (1.5%)	
Mid-Vastus	25,986 (2.5%)	865 (3.2%)		251 (5.1%)	
Sub-Vastus	11,000 (1.1%)	227 (0.8%)		53 (1.1%)	
Other	18,660 (1.8%)	286 (1.1%)		54 (1.1%)	
Fixation					
Cemented	989,363 (95.9%)	25,642 (94.4%)	0.05	4,770 (97.4%)	-0.05
Cementless	36,306 (3.5%)	1,437 (5.3%)		99 (2.0%)	
Hybrid	6,281 (0.6%)	82 (0.3%)		30 (0.6%)	

Patella resurfacing performed					
Yes	399,034 (38.7%)	11,173 (41.1%)	0.10	2,260 (46.1%)	0.17
No	632,916 (61.3%)	15,988 (58.9%)		2,639 (53.9%)	
Operation funding and hospital setting					
Public/Public	663,232 (64.3%)	19,278 (71.0%)	-0.03	2,027 (41.4%)	0.67
Public/Private	260,452 (25.2%)	4,210 (15.5%)		1,047 (21.4%)	
Private/Public	7,232 (0.7%)	322 (1.2%)		73 (1.5%)	
Private/Private	101,034 (9.8%)	3,351 (12.3%)		1,752 (35.8%)	
BMI					
Mean (SD)	30.9 (5.5)	30.9 (5.5)	0.02	30.5 (5.7)	-0.07
Complete responses (%)	67.3%	65.5%		79.0%	
Mean Surgeon	72.4 (43.9)	67.4 (35.4)	-0.16	71.4 (39.7)	-0.06

Operations per year					

Table 1: Pre-weighting characteristics of patients undergoing TKR

Table 2

	Conventional surgery versus computer navigation	Standardised Mean Difference	Conventional surgery versus patient specific instrumentation	Standardised Mean Difference
Effective Sample Size	91,607.16		13,296.78	
Mean age, years (SD)	69.8 vs 69.1 (9.1 vs 9.2)	0.00	68.6 vs 68.6 (9.3 vs 9.4)	0.00
Sex				
Female	56.7% vs 56.7%	0.00	54.7% vs 54.7%	0.00
Male	43.3% vs 43.3%		45.3% vs 45.3%	
Side				
Left	47.4% vs 47.6%	-0.00	47.4% vs 48.5%	-0.03
Right	52.6% vs 52.4%		52.6% vs 51.5%	
ASA classification				
1	9.6% vs 9.6%	0.01	8.5% vs 8.5%	-0.02
2	71.2% vs 71.2%		73.9% vs 73.9%	

3	18.9% vs 18.9%		17.2% vs 17.2%	
4	0.3% vs 0.3%		0.4% vs 0.4%	
5	0.0% vs 0.0%		0.0% vs 0.0%	
Approach				
Medial parapatellar	95.7% vs 95.8%	-0.03	90.4% vs 90.4%	0.01
Lateral parapatellar	0.5% vs 0.5%		1.6% vs 1.6%	
Mid-Vastus	2.5% vs 2.5%		6.1% vs 6.1%	
Sub-Vastus	0.6% vs 0.6%		1.2% vs 1.2%	
Other	0.6% vs 0.6%		0.7% vs 0.7%	
Fixation				
Cemented	97.0% vs 97.0%	-0.01	98.2% vs 98.2%	-0.01
Cementless	2.8% vs 2.8%		1.5% vs 1.5%	
Hybrid	0.2% vs 0.2%		0.3% vs 0.3%	
Patella resurfacing performed				
Yes	41.1% vs 41.2%	0.06	43.2% vs 43.2%	0.04
No	58.9% vs 58.8%		56.8% vs 56.8%	

Operation funding and hospital setting				
Public/Public	75.5% vs 75.5%	-0.01	55.6% vs 55.6%	0.03
Public/Private	13.8% vs 13.8%		28.3% vs 28.3%	
Private/Public	0.5% vs 0.5%		2.0% vs 2.0%	
Private/Private	10.2% vs 10.2%		14.2% vs 14.2%	
BMI				
Mean (SD)	31.1 vs 31.0 (5.6 vs 5.5)	0.00	31.3 vs 30.8 (7.2 vs 6.5)	-0.08
Complete responses (%)	68.3% vs 66.0%		78.4% vs 80.2%	
Mean Surgeon Operations per year	67.9 vs 67.9 (40.0 vs 34.8)	-0.03	73.6 vs 73.6 (41.5 vs 38.5)	0.00

Table 2: Post-weighting characteristics of the patients between the comparison groups

Table 3

	Conventional surgery versus computer navigation		Conventional surgery versus patient specific instrumentation	
	Conventional surgery	**Computer navigation**	**Conventional surgery**	**Patient specific instrumentation**
EQ5D: n (unweighted)	327,435	8,770	330,775	1,395
Weighted pre-operative and post-operative scores (SD)	0.415 (0.309) and 0.734 (0.252)	0.415 (0.310) and 0.730 (0.252)	0.462 (0.297) and 0.761 (0.238)	0.462 (0.295) and 0.761 (0.251)
Univariable# [ESS]	*	0.000 (95% CI -0.005 to 0.005; p=0.929) [28,396]	*	+0.004 (95% CI -0.009 to 0.018; p=0.511) [4,285]
OKS: n (unweighted)	352,113	9,342	345,915	1,447
Weighted pre-operative and	19.110 (7.590) and 35.529 (9.409)	19.111 (7.673) and 35.045 (9.555)	20.275 (7.540) and 36.503 (9.027)	20.276 (7.633) and 36.656 (9.011)

post-operative (SD)				
Univariable # [ESS]	*	-0.134 (95% CI -0.331 to -0.063; p=0.183) [29,135]	*	+0.363 (95% CI -0.104 to 0.830; p=0.127) [4,412]

Table 3: Pre- and post-operative OKS and EQ-5D scores, and regression analysis comparing conventional surgery to computer navigation and patient specific instrumentation. # weighted and case mix adjusted *indicates constant term in regression model

Table 4

	Conventional surgery (n=966,916)	**Computer navigation (n=25,270)**	**Patient specific instrumentation (n=4,899)**
None	961,913 (99.5%)	25,115 (99.4%)	4,872 (99.5%)
Fracture	1,435 (0.1%)	42 (0.2%)	9 (0.2%)
Patella Tendon Avulsion	351 (0.0%)	14 (0.1%)	6 (0.1%)
Ligament Injury	634 (0.1%)	18 (0.1%)	2 (0.01%)
Other	2,674 (0.3%)	82 (0.3%)	11 (0.2%)

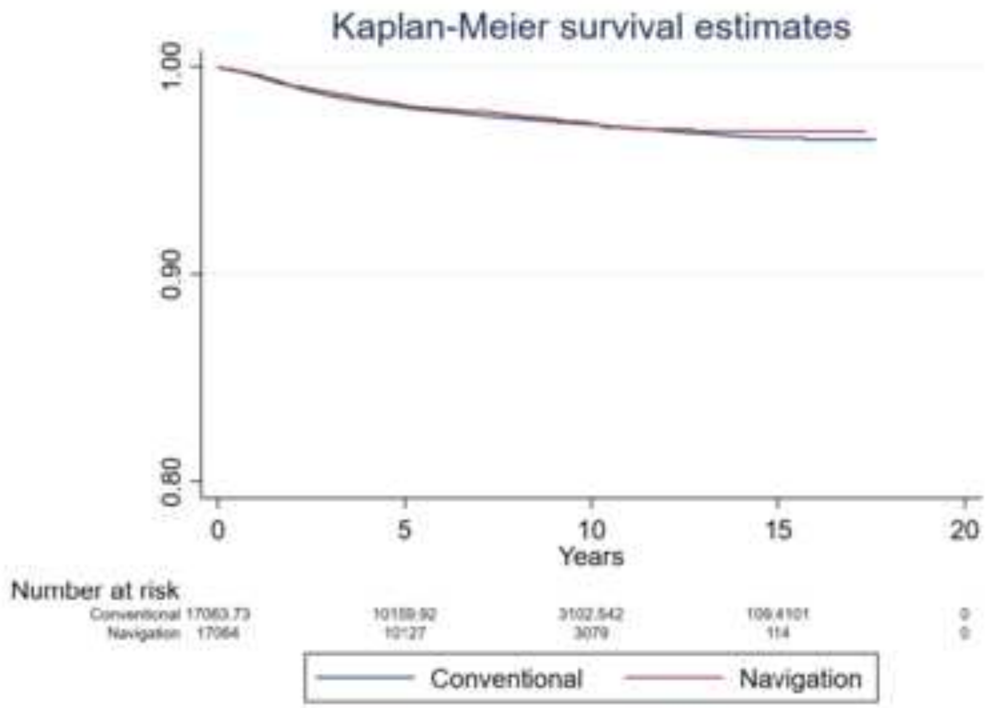
Table 4: Intra-operative complications that occurred among the three patient groups

Supplementary table 1

	Conventional surgery versus computer navigation	
	Conventional surgery	**Computer navigation**
	Mean (SD) or Mean (95% CI; p value)	**Mean (SD) or Mean (95% CI; p value)**
EQ5D: n (unweighted)	251,960	6,331
Pre-operative (weighted)	0.415 (0.308)	0.415 (0.308)
Post-operative (weighted)	0.736 (0.251)	0.733 (0.252)
Univariable (weighted and case mix adjusted) [ESS]	*	0.002 (-0.005 to 0.008; p=0.631) [20,150]
OKS: n (unweighted)	270,683	6,736
Pre-operative (weighted)	18.996 (7.479)	18.997 (7.464)
Post-operative (weighted)	35.414 (9.435)	35.211 (9.514)
Univariable (weighted and case mix adjusted) [ESS]	*	-0.023 (-0.255 to 0.210; p=0.848) [20,630]

Supplementary table 1: Pre- and post-operative OHS and EQ-5D-3L scores, and regression analysis comparing computer guidance and conventional surgery patient groups when accounting for BMI in the model. *indicates constant term in regression model

Supplementary figure 2



Supplementary figure 1