

First knee for pain and function versus second knee for quality of life

a registry study of patient-reported outcomes following staged bilateral knee arthroplasty in Australia

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Aims

The aim of this study was to describe and compare joint-specific and generic health-related quality of life outcomes of the first versus second knee in patients undergoing staged bilateral total knee arthroplasty (BTKA) for osteoarthritis.

Methods

This retrospective cohort study used Australian national arthroplasty registry data from January 2013 to January 2021 to identify participants who underwent elective staged BTKA with six to 24 months between procedures. The primary outcome was Oxford Knee Score (OKS) at six months postoperatively for the first TKA compared to the second TKA, adjusted for age and sex. Secondary outcomes compared six-month EuroQol five-dimension five-level (EQ-5D-5L) domain scores, EQ-5D index scores, and the EQ visual analogue scale (EQ-VAS) between knees at six months postoperatively.

Results

The cohort included 635 participants (1,270 primary procedures). Preoperative scores were worse in the first knee compared to the second for all instruments; however, comparing the first knee at six months postoperatively with the second knee at six months postoperatively, the mean between-knee difference was minimal for OKS (-0.8 points; 95% confidence interval (CI) -1.4 to -0.2), EQ-VAS (3.3; 95% CI 1.9 to 4.7), and EQ-5D index (0.09 points; 95% CI 0.07 to 0.12). Outcomes for the EQ-5D-5L domains 'mobility', 'usual activities', and 'pain/discomfort' were better following the second TKA.

Conclusion

At six months postoperatively, there were no clinically meaningful differences between the first and second TKA in either the joint-specific or overall generic health-related quality of life outcomes. However, individual domain scores assessing mobility, pain, and usual activities were notably higher after the second TKA, likely reflecting the cumulative improvement in quality of life after both knees have been replaced.

Take home message

- Following staged bilateral total knee arthroplasty, the final outcomes are nearly identical for each knee, but patients reported ongoing pain and problems with mobility and usual activities after the first procedure, which resolved following the second procedure.
- The likelihood that patients will report greater quality of life after their second knee is replaced is useful information for clinicians to impart to patients.

Introduction

Total knee arthroplasty (TKA) is an effective surgery for the treatment of knee pain and loss of function, most commonly due to osteoarthritis (OA). In Organisation for Economic Cooperation and Development (OECD) countries, TKA rates increased by 40% on average between 2007 and 2017, and are projected to increase further due to population ageing and increasing obesity rates, both of which are associated with osteoarthritis.¹ At the initial clinical presentation, approximately 30% of patients have bilateral knee OA, and following unilateral TKA, 40% of patients have the second knee replaced within eight years.^{2,3} Bilateral TKA (BTKA) can be performed either simultaneously during a single hospital admission or staged over two separate admissions. Data from several countries indicate that staged BTKA procedures are most common. In Canada, 9% of all TKA surgeries between 2006/7 and 2013/4 were staged bilateral (to a maximum of one year apart), an increase of 29% during that period, compared to 2% simultaneous BTKA, a figure which was steady during the study period.⁴ In the UK, 98.7% of BTKAs are staged.⁵ Of 980,419 TKA procedures performed in Australia between 2003 and 2021, 25.6% were bilateral, with 5.5% simultaneous and 17.3% with six or more months between procedures.⁶

A number of studies, including seven systematic reviews, have compared simultaneous with staged BTKA, but the predominant focus has been peri- or postoperative complications, length of stay, costs, or in the case of staged BTKA, the optimal timing of the second surgery.⁷⁻¹² Little attention has been given to patient-reported outcome, such as pain, function, or quality of life. These outcomes are commonly captured using validated generic or disease-specific questionnaires.

The growth in staged BTKA has coincided with increasing interest in patient-reported outcomes following the second knee arthroplasty. To date, only small, single-centre studies have examined patient-reported outcomes in first versus second TKA.¹³⁻¹⁸ The aim of this study is to describe and compare patient-reported outcomes of the first versus second knee in patients undergoing staged BTKA for OA using data from a national joint replacement registry.

Methods

Study design, data sources, and ethics approval

This was a retrospective cohort study using individual-level data from two registry sources: the Arthroplasty Clinical Outcomes Registry National (ACORN) from January 2013 to January 2018, and the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) from July 2018 to January 2022.^{19,20} Ethical approval for this study was granted by the Hunter New England Human Research

Ethics Committee (reference no. 12/11/21/5.02). Using an opt-out verbal consent process, patients provided informed consent to participate in ACORN after being provided the approved patient information sheet. The AOANJRR collection of joint replacement and patient-reported outcome measures (PROMs) data are approved by the Commonwealth of Australia as a Federal Quality Assurance Activity (F2022L00986) Part VC of the Health Insurance Act, 1973 and Part 10 of the Health Insurance Regulations 2018. All AOANJRR studies are conducted in accordance with ethical principles of research (the Helsinki Declaration II).²¹ All patients undergoing joint arthroplasty in Australia provide consent for routine AOANJRR data collection on an opt-out basis. Additional informed consent was obtained from all participants in the PROMs programme.

Data collection

The ACORN database captured data on all elective hip and knee arthroplasties at ten sites in Australia from 2013 to 2018, with follow-up to 2019. For ACORN, trained registry staff collected demographic, anthropometric, medical history, and PROMs data from patients at the preadmission appointment. Six months after surgery, patients were contacted by telephone to collect postoperative PROMs data.

The AOANJRR, established in 1999, records data on all knee arthroplasties in Australia. In 2018, the AOANJRR began capturing PROMs at 44 sites across Australia (currently 202 sites) using a purpose-built electronic data capture system, Real time Automated Platform for Integrated Data capture (RAPID).²² RAPID was custom designed by the Information Communication Technology Team at the South Australian Health & Medical Research Institute (SAHMRI), which is where the AOANJRR is housed. Once recruited and registered by trained hospital staff at participating sites, patients logged in to RAPID to complete consent forms and preoperative questionnaires. At six-month follow-up, patients received automatic email or text reminders, followed by telephone contact if required. Following registration and consent, preoperative data are captured from 97.8% of patients and postoperative data from 79% of patients.²² All ACORN PROMs data were integrated into RAPID following manual review and data quality audit. Data checking ensured > 99% completeness and 94% to 96% accuracy.

Participants

All adults undergoing elective primary or revision TKA and with the cognitive ability to respond to PROMs were eligible for inclusion in the registries. Participants were eligible for entry into this study if they underwent elective staged primary BTKA in Australia between 2013 and 2021, with a gap between the first and second procedures of six to 24 months; and were aged 18 years or older at the time of the first procedure. The gap between procedures was chosen to prevent overlap between procedures for PROMs collected at six months postoperatively, and to restrict the cohort to people who likely already had bilateral disease at initial presentation. Participants were excluded if they had undergone revision or unicompartmental knee arthroplasty, opted out of either registry, or had incomplete baseline or six-month data for the Oxford Knee Score (OKS).^{23,24}

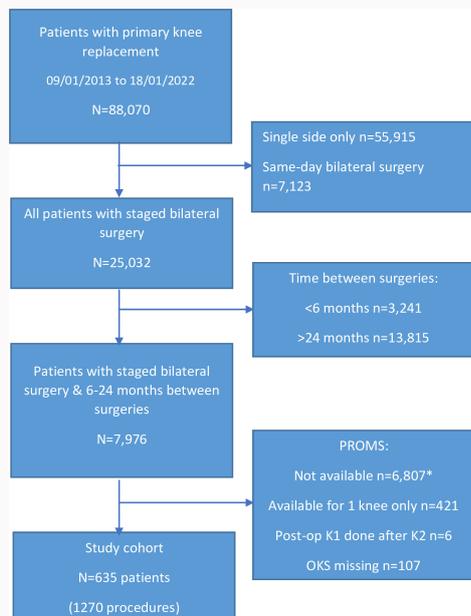


Fig. 1

Study cohort. *Patient-reported outcome measures (PROMs) were implemented as a pilot project with staged implementation at a limited number of sites. Once implemented, 97.8% of patients completed preoperative and 79% completed postoperative data. OKS, Oxford Knee Score.

Instruments

The OKS is a valid and reliable 12-item questionnaire developed to measure knee pain and function for people undergoing knee arthroplasty.²⁴ It is scored from 0 (worst pain, least function) to 48 (no pain, best function). The minimal clinically important difference (MCID) is a measure used to denote the smallest change that is noticeable by a patient and/or would warrant a change in management.²⁵ The MCID for the OKS is five points;^{26,27} a difference of less than five points is not considered to be clinically meaningful.

The EuroQol five-dimension (EQ-5D) comprises two generic standardized instruments designed to measure patient-reported health status: the five-dimension five-level (EQ-5D-5L) and the EQ-visual analogue scale (EQ-VAS).²⁸ The EQ-5D-5L assesses five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression using five levels of response (no problems, slight problems, moderate problems, severe problems, extreme problems/unable to do), returning frequencies of people at each level in a domain. The EQ-5D index has a maximum value of 1 (representing full health) while 0 is the health state equivalent to death; values below 0 represent health states worse than death. The estimated MCID for the EQ-5D index in knee arthroplasty has been estimated from 0.20 to 0.28.²⁹ The EQ-VAS is a scale on which a patient rates their current health 'today' from 0 (the worst imaginable health) to 100 (the best imaginable health), with an estimated MCID between 6.4 and 15 points.^{30,31}

Primary and secondary outcomes

The primary outcome for this study was the difference in the OKS at six months after the first TKA, compared to the second TKA. Secondary outcomes were the difference in six-month EQ-5D domain scores, EQ-5D index, and the

Table I. Participant characteristics at baseline by operative side with Australian Orthopaedic Association National Joint Replacement Registry total knee arthroplasty cohort (from 1999 to 2022).

| Characteristic | NJRR*† | | |
|----------------------------------|------------|---------------------------|----------------|
| | First side | Second side (n = 886,536) | |
| Mean age, yrs (SD) | 66.9 (8.6) | 68.1 (8.6) | 68.5 (9.2) |
| Mean BMI, kg/m ² (SD) | 34.0 (7.2) | 34.6 (7.8) | Obese† 58% |
| Female, n (%) | 399 (63) | 399 (63) | 495,840 (55.9) |
| ASA grade, n (%) | | | |
| I | 22 (3.5) | 14 (2.2) | 28,948 (5.6) |
| II | 334 (53) | 313 (49) | 280,706 (54.1) |
| III | 269 (43) | 303 (48) | 203,310 (39.2) |
| IV | 4 (0.6) | 5 (0.8) | 5,564 (1.1) |
| Primary diagnosis, n (%) | | | |
| Osteoarthritis | 623 (98) | 629 (99) | 867,113 (97.8) |
| Other inflammatory arthritis | 2 (0.3) | 3 (0.5) | 4,464 (0.5) |
| Rheumatoid arthritis | 10 (1.6) | 3 (0.5) | 10,223 (1.2) |

*Source: AOANJRR Demographics of Hip, Knee and Shoulder Arthroplasty: Supplementary Report

†Source: AOANJRR Hip, Knee & Shoulder Arthroplasty: 2023 Annual Report; BMI is provided in categories only in this report.

ASA, American Society of Anesthesiologists; NJRR, National Joint Replacement Registry; SD, standard deviation.

EQ-VAS for the first TKA compared to the second TKA. We selected the OKS as primary outcome, as it is joint-specific and is the more commonly used PROM in the context of TKA.³² In addition, indication for surgery is based on joint-specific rather than general health instruments.

Statistical analysis

Characteristics of the study cohort, including age, sex, BMI, primary diagnosis, and American Society of Anesthesiologists grade (ASA; a preoperative risk-stratification based on comorbidities)^{33,34} were reported descriptively. At baseline and six months postoperatively, the OKS, EQ-VAS, and EQ-5D index were described by procedure (first or second TKA) using mean and standard deviation (SD). Six-month PROM scores for the first TKA versus the second TKA were compared using linear regression models with generalized estimating equations. This was to account for the correlation between first and second procedure within patients. Models were adjusted for age and sex. Differences between sides are reported as the second side score minus the first side score and presented with 95% confidence intervals (CIs). The EQ-5D domains were dichotomized into 'no problems' and 'any problems' (the latter category grouped 'slight problems', 'moderate problems', 'severe problems', and 'extreme problems/unable to do') and reported as the proportion of patients who responded 'no problems' for each procedure at baseline and six months, without adjustment, and compared using chi-squared tests. The EQ-5D index was calculated using published Australian

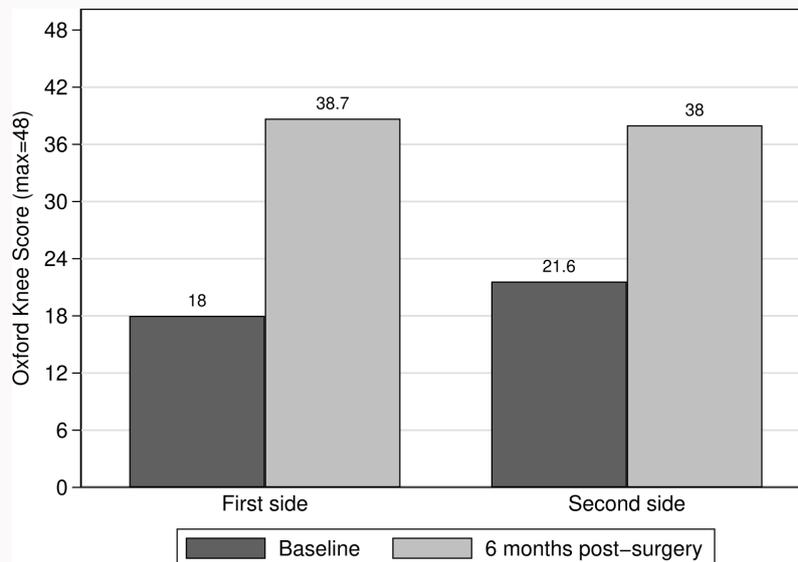


Fig. 2
Mean Oxford Knee Score at baseline and six months post-surgery by operative side.

preference weights.³⁵ Inclusion criteria restricted the primary outcome (OKS) to people with complete data at both timepoints; for the other PROMs, missing data were addressed using casewise deletion. The study used a convenience sample extracted from two large databases covering multiple sites across Australia over an eight-year period; as such, no sample size calculations were undertaken. All data analyses were conducted using SAS software version 9.4 (SAS Institute, USA). All tests were two-tailed at the 5% level of significance.

Results

Study cohort

Between 9 January 2013 and 18 January 2022, 88,070 patients underwent elective primary TKA at sites collecting PROMs (Figure 1). Patients were excluded if they underwent a single TKA only ($n = 55,915$), same-day bilateral surgery ($n = 7,123$), bilateral surgeries with $< six$ ($n = 3,241$) or > 24 ($n = 13,815$) months between sides, if PROMs were not available ($n = 6,807$) or were available for one side only ($n = 421$), if the OKS was missing at one or both timepoints ($n = 107$), or if PROMs data for the first side were collected after the second side ($n = 6$), leaving 635 patients who met the eligibility criteria and were included in the analysis (Figure 1). Table I includes demographic information for the entire primary knee arthroplasty cohort from the Australian Orthopaedic Association National Joint Replacement Registry for comparison.^{6,20}

Participant characteristics

Over 98% of the study cohort had a primary diagnosis of OA, and 63% were female. The mean age at the time of first TKA was 66.9 years (SD 8.6) and mean BMI was 34.0 kg/m² (SD 7.2). The comorbidity burden increased slightly between procedures, with 43% and 48% of the study cohort categorized as ASA grade III at the time of the first and second TKA procedures, respectively. Mean time between procedures was 13.9 months (SD 4.6), with a range of six to 24 months. There were no differences in baseline characteristics among people who were excluded

due to missing OKSs ($n = 107$) and those included in the study cohort; the study cohort was also similar to the entire primary total knee arthroplasty cohort ($n = 886,536$; Table I).^{6,20}

Outcome data

The mean preoperative OKS was worse for the first side (18.0 points (SD 8.0) vs 21.6 (SD 8.3)), but by six months postoperatively the OKS was better after the first TKA, with an adjusted mean difference between sides at six months of -0.8 points (95% CI -1.4 to -0.2 ; Figure 2).

Baseline and six-month EQ-5D-5L scores for the first and second procedures are provided in Table II.

While the mean preoperative EQ-VAS was worse before the first TKA (65.2 (SD 21.4) vs 70.7 (SD 18.4)), by six months post-surgery the adjusted mean difference between sides was 3.3 points (95% CI 1.9 to 4.7; Figure 3).

The mean EQ-5D index was 0.29 (SD 0.38) before the first TKA and 0.43 (SD 0.34) before the second TKA. Six months after surgery, it had increased to 0.70 (SD 0.27) and 0.79 (SD 0.23), respectively, with a between-side adjusted mean difference of 0.09 points (95% CI 0.07 to 0.12; Figure 4).

All EQ-5D domains were worse at baseline and at six months postoperatively for the first TKA, but all domains showed substantial improvement following the first and second TKAs. Improvement in the 'mobility', 'usual activities', and 'pain/discomfort' domains was greater following the second TKA, compared with the first TKA (Figure 5).

Discussion

In this study of patient-reported outcomes following staged bilateral TKA, there were no clinically meaningful differences in the six-month OKS, EQ-VAS, or EQ-5D index for the first TKA compared to the second TKA procedure. Worse preoperative scores for the first TKA meant that a greater magnitude of pre- to postoperative change in OKS, EQ-VAS, and EQ-5D index was observed for the first TKA. There were notable differences, however, in the EQ-5D-5L domains assessing pain, mobility,

Table II. EuroQol five-dimension five-level scores at baseline and six months post-surgery, by operative side.

| Dimension | Baseline, n (%) | | 6 mths post-surgery, n (%) | | p-value* |
|------------------------------|-----------------|-------------|----------------------------|-------------|----------|
| | First side | Second side | First side | Second side | |
| Mobility | | | | | < 0.001 |
| No problems | 18 (2.9) | 39 (6.2) | 236 (37) | 375 (59) | |
| Slight problems | 66 (11) | 124 (20) | 171 (27) | 161 (25) | |
| Moderate problems | 269 (43) | 276 (44) | 165 (26) | 81 (13) | |
| Severe problems | 256 (41) | 189 (30) | 62 (9.8) | 13 (2.0) | |
| Unable to do | 15 (2.4) | 5 (0.8) | 1 (0.2) | 5 (0.8) | |
| Personal care | | | | | 0.048 |
| No problems | 274 (44) | 315 (50) | 493 (78) | 515 (81) | |
| Slight problems | 144 (23) | 152 (24) | 97 (15) | 85 (13) | |
| Moderate problems | 152 (24) | 131 (21) | 29 (4.6) | 29 (4.6) | |
| Severe problems | 48 (7.7) | 27 (4.3) | 15 (2.4) | 3 (0.5) | |
| Unable to do | 6 (1.0) | 8 (1.3) | 1 (0.2) | 2 (0.3) | |
| Usual activities | | | | | < 0.001 |
| No problems | 39 (6.3) | 73 (12) | 290 (46) | 379 (60) | |
| Slight problems | 123 (20) | 188 (30) | 196 (31) | 169 (27) | |
| Moderate problems | 254 (41) | 247 (39) | 106 (17) | 68 (11) | |
| Severe problems | 160 (26) | 109 (17) | 36 (5.7) | 16 (2.5) | |
| Unable to do | 48 (7.7) | 16 (2.5) | 7 (1.1) | 3 (0.5) | |
| Pain/discomfort | | | | | < 0.001 |
| No pain | 6 (1.0) | 20 (3.2) | 149 (23) | 256 (40) | |
| Slight pain | 52 (8.3) | 109 (17) | 210 (33) | 246 (39) | |
| Moderate pain | 269 (43) | 284 (45) | 187 (29) | 101 (16) | |
| Severe pain | 231 (37) | 192 (30) | 76 (12) | 25 (3.9) | |
| Extreme pain | 66 (11) | 28 (4.4) | 13 (2.0) | 7 (1.1) | |
| Anxiety/depression | | | | | 0.585 |
| Not anxious/depressed | 263 (42) | 321 (51) | 481 (76) | 493 (78) | |
| Slightly anxious/depressed | 167 (27) | 169 (27) | 98 (15) | 100 (16) | |
| Moderately anxious/depressed | 123 (20) | 107 (17) | 41 (6.5) | 29 (4.6) | |
| Severely anxious/depressed | 58 (9.3) | 26 (4.1) | 11 (1.7) | 8 (1.3) | |
| Extremely anxious/depressed | 12 (1.9) | 9 (1.4) | 3 (0.5) | 4 (0.6) | |

*Chi-squared test for association between side and postoperative score.

and usual activities, with higher scores evident following the second TKA compared with the first TKA.

Consistent with our findings, previous studies have reported comparable postoperative OKSs for bilateral TKAs at various follow-up intervals and less postoperative improvement after the second TKA due to better preoperative scores.¹³⁻¹⁶ As most patients would have the worst knee replaced first, larger improvements in pain and function after the first TKA may be expected. A recent systematic review reported inferior outcomes for the second TKA in five of seven studies, based on less postoperative improvement after the second TKA.³⁶ However, absolute postoperative outcome scores were similar between the bilateral TKAs in all included

studies, with the between-knee difference in OKS at six or 12 months postoperatively ranging from -0.6 points (indicating a 'better' outcome for the first knee) to 1.7 points (indicating a 'better' outcome for the second knee), well short of the accepted MCID estimate of five points.²⁶ The review reported similar postoperative outcomes to our study, with no meaningful difference in OKS between sides at six months.

Although previous studies have reported knee-specific PROM scores for people undergoing staged bilateral TKA, little is known about changes in generic PROM scores following staged procedures. In contrast to the similar OKSs at six months following the first and second TKA, we found that a greater proportion of patients reported 'no problems' in the

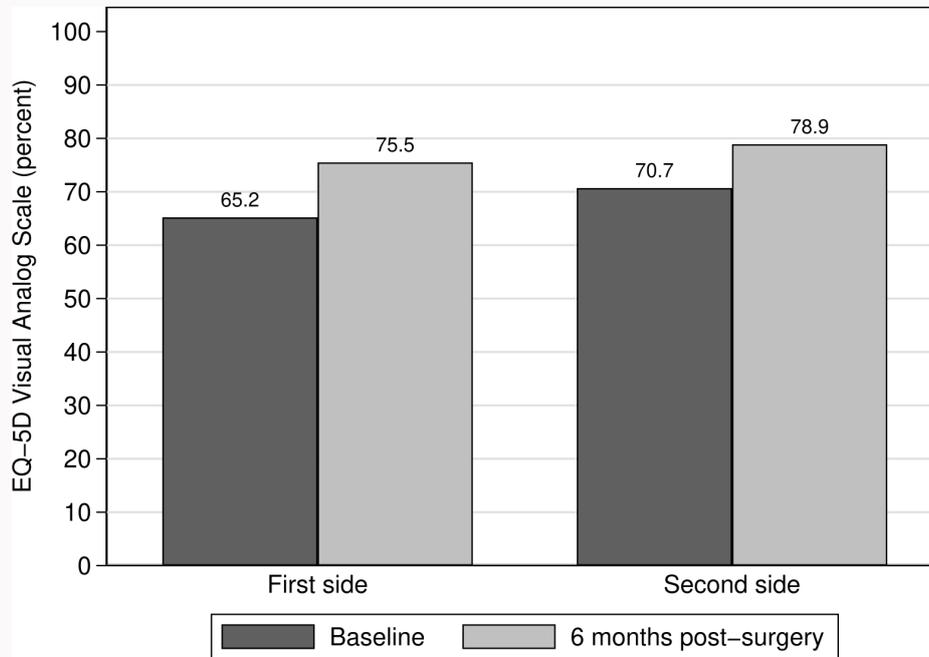


Fig. 3 Mean EuroQol five-dimension (EQ-5D) visual analogue scale (VAS) scores at baseline and six months post-surgery, by operative side.

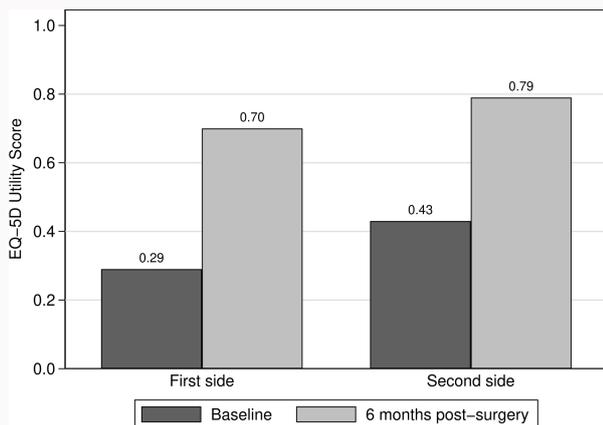


Fig. 4 Mean EuroQol five-dimension (EQ-5D) index score at baseline and six months' post-surgery by operative side.

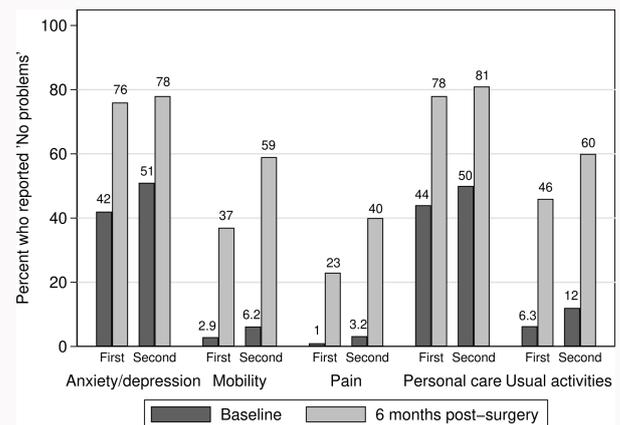


Fig. 5 EuroQol five-dimension (EQ-5D) domains at baseline and six months post-surgery by operative side – percentage of patients who report 'no problems'.

EQ-5D domains of mobility, pain, and usual activities following the second TKA, compared with the first TKA. This may be explained by patients still having one symptomatic knee impacting their overall pain, function, and mobility following the first procedure, which is then addressed by the second procedure.

While we did not assess whether there was any relationship between the time between procedures and PROMs, a previous study by Abram et al¹³ found no association between the interval between procedures and postoperative OKS results. In that study, participants had a mean 23 months (1 to 74) between procedures. Another study of 306 patients with one to 12 months between procedures found no association between surgical interval and any outcomes (complications, 90-day readmission, and OKS at two years postoperatively).³⁷

This study is not without limitations. Because the first TKA is assumed to be undertaken on the worst knee, the first and second TKAs are not directly comparable although our within-subject design accounts for other potential confounders. Patients are inevitably older for the second procedure, though we have limited this by restricting this study to staged procedures that were between six and 24 months apart. While postoperative data were collected only at six months, most improvement in pain, function, and quality of life is evident by this time.³⁸ Strengths of this study include use of a large, high-quality representative database, meaning the data are representative of the Australian TKA population and likely generalizable to other high-income countries based on the average age and BMI, sex, and high proportion with a diagnosis of osteoarthritis.³⁹ Both data sources have high

accuracy due to ongoing quality assurance and data audit processes with > 99% completeness in ACORN. During the AOANJRR PROMS pilot phase, PROMs data were captured in the electronic system for 10,204 of 19,699 (51.8%) primary procedures. Of the 51.8% with PROMs data, 97.8% of patients completed preoperative and 79% completed postoperative data.^{22,40} Data from this study were taken from the pilot phase of the PROMs project.⁴¹ Another strength is the concomitant use of joint-specific plus generic PROMs instruments.

In conclusion, despite many studies assessing hospital or clinical outcomes, little attention has been given to patient-reported outcomes following staged bilateral TKA. In this study, we found that despite the final outcomes being near-identical, patients reported ongoing pain and problems with mobility and usual activities after the first procedure that resolved following the second procedure. The generic quality of life instrument detected nuanced improvements beyond that of the joint-specific assessment, reinforcing the need for complementary PROMs to comprehensively assess outcomes in this population. The likelihood that patients will report greater quality of life after their second knee is replaced is useful information for clinicians to impart to patients.

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Data sharing

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

Ethical review statement

Ethical approval for this study was granted by the Hunter New England Human Research Ethics Committee (reference no. 12/11/21/5.02). AOANJRR collection of joint replacement and PROMs data are approved by the Commonwealth of Australia as a Federal Quality Assurance Activity (F2022L00986) Part VC of the Health Insurance Act 1973 and Part 10 of the Health Insurance Regulations 2018. All AOANJRR studies are conducted in accordance with ethical principles of research (the Helsinki Declaration II). All patients undergoing joint replacement in Australia provide consent for routine AOANJRR data collection on an opt-out basis. Additional informed consent was obtained from all participants in the PROMs programme.

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