Title

Simultaneous (two surgeon) versus staged bilateral knee arthroplasty: an observational study of intra-operative and post-operative outcomes

Running Head: Bilateral knee arthroplasty

Authors

Dr Stephen D Gill^{a,b,c}, PhD, B Physio (Hons), stephen.gill2@deakin.edu.au,

Dr Leaha-Marie Hill-Buxton^c, MBBS, leaha.marie@outlook.com

Dr Stella May Gwini^d, PhD, stellamay.gwini@barwonhealth.org.au

Dr Stewart Morrison^c, MBBS, stewartmorrison@hotmail.com

Dr Brett Moreira^c, MBBS, brettcmor@gmail.com

Ms Sally Beattie^{a,c} RN, sallyb@barwonhealth.org.au

Dr Andrew Thomson^c, MBBS, FRACS (Orth),

andrewthomson@geelongortho.com.au

Professor Richard S Page^{a,b,c}, BMedSci, MBBS, FRACS (Orth),

richard.page@deakin.edu.au

^aBarwon Centre for Orthopaedic Research and Education (B-CORE), St John of God Hospital Geelong, VIC, Australia

^bSchool of Medicine, Deakin University, Waurn Ponds, VIC, Australia

^cOrthopaedic Department, University Hospital Geelong, Geelong VIC, Australia

^dResearch Directorate, Barwon Health, Geelong, VIC, Australia

Corresponding Author

Dr Stephen Gill

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Barwon Centre for Orthopaedic Research and Education (B-CORE)

St John of God Hospital Geelong

Myers St, Geelong, Australia, 3220

Email: Stephen.gill2@deakin.edu.au

Phone: +61 3 5226 8888

The corresponding author is not the recipient of a research scholarship. A summary of study was presented at the Australian Orthopaedic Association Annual Scientific Meeting 2019.

The manuscript includes four tables and one figure. The abstract has 241 words and the text has 2460 words (excluding abstract, acknowledgements, figure legends and references).

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Professor Richard S Page^{a,b,c}, BMedSci, MBBS, FRACS (Orth),
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^bSchool of Medicine, Deakin University, Waurn Ponds, VIC, Australia

^cOrthopaedic Department, University Hospital Geelong, Geelong VIC, Australia

^dResearch Directorate, Barwon Health, Geelong, VIC, Australia

Corresponding Author

Dr Stephen Gill

Barwon Centre for Orthopaedic Research and Education (B-CORE)

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Myers St, Geelong, Australia, 3220

Email: Stephen.gill2@deakin.edu.au

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TITLE

Simultaneous (two-surgeon) versus staged bilateral knee arthroplasty: an observational study of intra-operative and post-operative outcomes

ABSTRACT

Background

The advantages of simultaneous bilateral total knee arthroplasty (BTKA) remain controversial. This study investigated the effects of two-surgeon simultaneous (sim-BTKA) compared to separate-admission staged BTKA regarding intra-operative and post-operative outcomes and health service costs.

Methods

Patients underwent sim-BTKA or staged BTKA between 01/11/2008 and 30/06/2016. Data were extracted from a joint replacement registry and medical records. Median regression and Chi-squared tests were used for between-groups comparisons.

Results

Median hospital total length of stay (LOS) was five days less for sim-BKTA (n=122) than staged BTKA group (n=46) (7 vs 12; 95% CI 3.9, 6.1), and nine days less for inpatient rehabilitation (17 vs 26; 95% CI 3.7, 14.3). However, 80% of sim-BTKA patients went to inpatient rehabilitation (vs 27% following staged BKTA), so median total LOS was nine days less for staged BTKA (13 vs 22; 95% CI -12.8, -5.2). Total anaesthesia time was 135 minutes less for sim-BTKA ($p<0.001$), while staged BTKA required less blood transfusions ($p=0.001$). Complication rates were similar, except for superficial infections which were observed twice as often after staged BTKA (30% vs 15%, $p=0.048$). Twelve months following sim-BTKA and the first staged TKA, sim-BTKA had better WOMAC pain, stiffness and function scores ($p<0.05$). Average inpatient costs (hospital and rehabilitation) were \$6,388 less for sim-BTKA.

Conclusion

Sim-BTKA appears to be a comparatively safe alternative to staged BTKA. Sim-BTKA may be superior to staged BTKA due to faster improvements in pain and function and lower healthcare costs. How these results generalise to other health services requires further investigation.

Keywords

total knee arthroplasty; postoperative outcomes; health service utilisation;

INTRODUCTION

Symptomatic bilateral knee osteoarthritis is common, and has been reported in up to two-thirds of people requiring total knee arthroplasty (TKA).¹ Bilateral TKA (BTKA) is a surgical options for these patients.

The sequencing of BTKA occurs in three main ways: 1) separate-admission staged BTKA, 2) single-anaesthetic *sequential BTKA* in which knees are replaced one after the other, usually by the same surgeon, and 3) single-anaesthetic *simultaneous BTKA* (sim-BTKA), where arthroplasties are performed by two surgeons, each replacing a separate knee at the same time.^{2,}

³

The use of single-anaesthetic BTKA remains contentious with conflicting results between studies. Advocates of single-anaesthetic BTKA (either simultaneous or sequential) suggest several advantages over staged BTKA. Replacing both knees concurrently means that one untreated knee will not interfere with the patient's rehabilitation, resulting in faster return to optimum function while avoiding repeated anaesthesia and hospitalisation.⁴ Single-anaesthetic BTKA has been associated with lower total anaesthetic time, healthcare costs and revision rates compared to staged BTKA.⁵ However, the use of single-anaesthetic BTKA is debated due to the risk of complications.^{2, 6} Three systematic reviews reported higher 30-day mortality and blood transfusion rates in single-anaesthetic BTKA compared to staged BTKA, but

found no differences for cardiac complications, deep venous thrombosis and superficial infections, and mixed results for pulmonary embolisation, deep infection and neurological complications.^{5, 7, 8} However, none of the reviews differentiated between sim-BTKA and sequential BTKA.

Hu et al⁹ compared sim-BTKA and sequential BTKA and found sim-BTKA had fewer complications, shorter length of stay (LOS), lower hospital costs and similar functional outcomes. Given these differences, it is important to differentiate between the procedures when comparing outcomes to staged BTKA.

This study investigated the effects of sim-BTKA compared to staged BTKA regarding intra-operative and post-operative outcomes and health service costs.

MATERIALS and METHODS

Study design

Non-randomised longitudinal study.

Setting

The study was conducted at [removed for anonymous review] (UHG), a publicly funded 432 bed teaching hospital in Australia. Ten orthopaedic surgeons complete TKAs at the hospital, of whom nine also perform sim-BTKA. In 2015,

166 primary knee replacements were conducted at UHG, of which 16 (8 patients) were sim-BTKA.¹⁰

Participants

Eligible participants had undergone sim-BTKA or staged BTKA at UHG between 1 November 2008 and 30 June 2016. Dates corresponded to when electronic patient medical records were available, which was necessary to enable efficient data extraction. Revision TKA was excluded.

Sim-BTKA involved two surgical teams, each comprising a surgeon and registrar, completing a TKA on separate knees at the same time. The decision to complete sim-BTKA or staged BTKA was based on patient preference and the surgical and anaesthetic team's consideration of each patient's circumstances including comorbidities. The primary exclusion criteria for sim-BTKA was major cardiorespiratory disease, which was uncommon.

Postoperative care

Postoperative care for all patients following TKA was guided by the same protocol-driven care plans that informed peri-operative antibiotic therapy, analgesia, VTE prophylaxis, nursing care and rehabilitation. Patients whose social and mobility status prevented discharge to their usual accommodation went to the organisation's inpatient rehabilitation centre. Following discharge from inpatient care, all patients received outpatient rehabilitation under the

direction of Allied Health staff which ceased at the discretion of staff and patients.

Outcomes

Total inpatient length of stay (LOS, days) was the primary outcome, which was the summation of acute hospital and rehabilitation admissions for each patient.

Secondary outcomes were:

1. Acute hospital LOS (days)
2. Rehabilitation LOS (days)
3. Discharge destination (usual residence or rehabilitation)
4. Total anaesthetic time (minutes)
5. Proportion of participants requiring blood transfusion and volume transfused (units, packed red blood cells)
6. Complications (within 12 months of (each) operation)
 - a. Cardiac (acute myocardial infarction, pulmonary edema, cardiac arrest)
 - b. Infection (superficial, deep)
 - c. Neurological (peripheral or central nervous system)
 - d. Re-operation (any reason)
 - e. Deep vein thrombosis (confirmed on ultrasound)

- f. Pulmonary embolism (confirmed on computed tomography pulmonary angiogram)
- g. Acute renal failure (decline in renal function leading to a rise in serum creatinine and/or a fall in urine output)
- h. Readmission within 30 days of discharge
- i. Death (any cause)
7. Patient reported outcomes (PROMs; assessed preoperatively and 12 months following each operation; one questionnaire for both knees)
- a. Knee pain (WOMAC Likert scale¹¹)
 - b. Knee stiffness (WOMAC Likert scale¹¹)
 - c. Physical function (WOMAC Likert scale¹¹)
 - d. Satisfaction (Likert scale, investigator designed questionnaire)
8. Total inpatient costs¹² (Australian dollars, AUD)

Data collection

Eligible participants were identified using the organisation's joint replacement registry.¹³ The registry is a Human Research and Ethics Committee approved, 'opt-out' consent, prospective electronic database that contains preoperative, intraoperative and postoperative information on all patients undergoing joint replacement at the organisation.

PROMs were extracted from the registry. Remaining data were manually extracted from medical records by a study investigator (LMHB) who was trained

by senior investigators (SDG, SB). Medical record data were entered into a standardised template on REDCap, a password-protected electronic data collection and management tool.¹⁴

Participants' pre-operative health status were summarised with the Charlson Comorbidity Index (CCI)¹⁵ and American Society of Anesthesiologists (ASA) score.¹⁶ The CCI was calculated by extracting relevant information from each patient's medical record. The ASA score was copied from each patient's anaesthetic record.

Data analysis

Baseline characteristics were compared between groups using t-tests or Mann-Whitney U Tests (for continuous data) and the Chi-squared tests (for categorical data).

For PROMs, the primary analysis compared sim-BTKA at 12 months post-operation to staged BKTR at 12 months following the first TKA. Secondary analysis compared sim-BTKA at 12 months post-operation to staged BTKA at 12 months after the second TKA.

Comparisons for median LOS and anaesthetic time occurred using median regression and the estimates were reported as the median difference (staged BTKA minus sim-BTKA) with their 95% confidence intervals (CI). The likelihood of inpatient rehabilitation or receiving blood transfusion was assessed using Poisson regression with clustered sandwich estimators.¹⁷ The results were

reported as risk ratios (RR) with their 95% CIs. Complications were compared between groups using the Chi-squared test.

Analysis included all cases with available data. No imputation of missing data occurred. Data were collated and analysed using Stata Statistical Software version 14 (StataCorp 2015. College Station, TX: StataCorp LP). Tests were considered significant if $p < 0.05$.

Cost analysis

Prior to 1 July 2016, detailed costs per admission were not available; however, due to changes in financial reporting, comprehensive cost data were available after this date. Therefore, cost data between 1 July 2016 to 30 June 2018 were provided by the organisation's finance department and were used to estimate inpatient costs (hospital and rehabilitation) for study participants. Costs were determined using standardised governmental methods for attributing expenses during publicly funded inpatient care.¹² All labour costs for clinical and non-clinical staff and non-labour costs including prostheses, investigations, pharmacy and other equipment were included. Costs were provided per admission, not per day. Given that acute hospital costs are unevenly distributed throughout a patient's stay, with higher costs occurring near the day of surgery, calculating an average daily cost for acute admissions would misrepresent cost data, therefore an average cost per hospital admission was used to estimate costs for each participant in our study. However, costs

per day during rehabilitation are more evenly distributed throughout a patient's stay, so we used an average cost per day to estimate rehabilitation costs for each participant in our study.

Average hospital and rehabilitation costs for patients admitted between 01 June 2016 and 30 June 2018 were applied to the study dataset to estimate the cost per patient per admission, where:

Total inpatient cost per patient =

$$(\text{average cost per acute admission}) + (\text{average rehabilitation cost per day} \times \text{total number of days of rehabilitation})$$

No cost discounting was employed.

Ethical considerations

The organisation's Human Research Ethics Committee approved the study (ref 12/95).

RESULTS

Participant characteristics

During the study period, 122 patients underwent sim-BTKA and 46 patients underwent staged BTKA, indicating a preference towards sim-BTKA in our organisation. Participants' preoperative characteristics were similar between groups with respect to age, gender, Charlson Comorbidity Index and ASA Score ($p > 0.05$, see Table 1).

Surgeons and prostheses

Nine surgeons completed the staged BTKAs. The same surgeon replaced both knees for 39 patients (84.8%). The median time between staged BTKAs was 238 days (IQR 169-310 days). Nine surgeons and four senior registrars completed the sim-BTKAs. Eight of these surgeons also completed the staged BTKAs. The registrars completed six TKAs.

Length of stay and discharge destination

Median total LOS (hospital and inpatient rehabilitation) for staged BTKA (13 days) was nine days less (95% CI -12.8, -5.2) than sim-BTKA (22 days) (Figure 1). When only acute hospital admissions were considered, the median LOS for staged BTKA (both admissions combined) was five days more (95% CI 3.9, 6.1) than sim-BTKA. Following 80% of sim-BTKA surgeries, patients were discharged to inpatient

rehabilitation, compared with 27% for staged BTKA (Table 2, RR= 0.34; 95% CI 0.22, 0.53). However, LOS for inpatient rehabilitation was higher for staged BTKA than sim-BTKA (median difference = 9 days; 95% CI 3.7, 14.3).

Anaesthetic time and blood transfusions

Median total anaesthetic time was 135 minutes shorter (95% CI 120.8, 147.2) for sim-BTKA than staged BTKA (Table 2). Staged BTKA required blood transfusions about half as often as sim-BTKA (22% vs 53%; RR = 0.41; 95% CI 0.25, 0.69). The median blood units required was two (IQR 0-3) for sim-BTKA and zero for staged BTKA (IQR 0-2).

Complications

Complication rates were similar, except for superficial infections which were observed twice as often after staged BTKA (30% vs 15%, $p=0.048$, Table 2).

Pain and function

WOMAC data were unavailable for 40 sim-BTKA patients and 15 staged BTKA patients. The demographic characteristics of these patients were similar to those with data available. Twelve months following sim-BTKA or the first staged TKA, sim-BTKA had better knee pain, stiffness and physical function compared to staged BTKA (Table 3). Twelve months following sim-BTKA or the second TKA, sim-BTKA still had less pain and stiffness than staged BTKA (Table 3).

Similar proportions of patients in each group indicated they would 'definitely' have the operation again (sim-BTKA 56.0%; staged BTKA 62.9%) or 'definitely not' have the operation again (sim-BTKA 3.6%; staged BTKA 3.2%).

Cost analysis

Between 01 June 2016 and 30 June 2018, 54 and 16 patients underwent sim-BTKA and staged BTKA respectively. The average cost per person for acute hospital admission was \$26,465 (SD \$7,033) for sim-BTKA and \$35,894 (SD \$4,530) for both staged TKAs. Cost per day for inpatient rehabilitation was \$780 and \$781 for sim-BTKA and staged BTKA respectively. After applying these costs to our sample, and taking into account the different proportions of patients going to inpatient rehabilitation in each group, the average inpatient cost (hospital and rehabilitation) per patient was \$6,388 (14.8%) less for Sim-BTKA than staged BTKA (Table 4).

DISCUSSION

Sim-BTKA has been performed for more than 40 years, but controversy persists regarding its safety and benefits. Our study found that sim-BTKA was comparatively safe, cost-effective, and improved pain and function at faster rates than staged BTKA.

The current study is the first to our knowledge to provide empirical evidence that people undergoing sim-BTKA demonstrate faster functional

improvement and less pain than staged BTKA. Between group differences were most pronounced at 12-months, particularly for pain scores, equating to almost no pain for the sim-BTKA group compared to mild pain for the staged group. At 12 months following the second staged TKA, between-group differences were smaller and less clinically significant, suggesting that both groups eventually realise similar improvements.

Acute hospital LOS and total inpatient costs were lower for sim-BTKA than staged BTKA, which is consistent with other studies, including recent studies on single-anaesthetic BTKA that failed to distinguish between sim-BTKA and sequential BTKA.¹⁸⁻²⁶ Although a higher proportion of sim-BTKA patients are discharged to inpatient rehabilitation which extends inpatient costs,^{21, 22} acute hospital care is more expensive. Staged BTKA requires two operations and two acute hospital admissions which ultimately produces higher total costs.

Sim-BTKAs cost advantage is likely to diminish overtime with the trend towards shorter acute LOS following TKA.²⁷ However, outpatient costs should remain lower following sim-BTKA, as only one sequence of appointments and investigations are required compared to two sequences for staged BTKA.

Studies^{9, 25, 26, 28, 29} including ours, consistently show that sim-BTKA has lower total anaesthetic time than staged BTKA or less than double the anaesthetic time of unilateral TKA. In contrast, sim-BTKA has longer anaesthetic time than each individual staged BTKA (median 30minutes longer

in our study), and longer single-anaesthetic time can increase the risk of post-arthroplasty complications.³⁰⁻³³ Given that our study found similar complication rates between sim-BTKA and staged BTKA, longer single-anaesthetic time for sim-BTKA and longer total anaesthetic time for staged BTKA does not appear to effect post-operative complications for the outcomes we assessed.

Many studies in the last 10 years have compared single-anaesthetic BTKA with staged BTKA. Of these, studies using large datasets (n=5665 to 407,070 participants) have revealed inconsistent findings.^{21, 22, 34-39} Some studies have shown no differences in mortality or complication rates including revision surgery between single-anaesthetic BTKA and staged BTKA,^{34, 38 35, 39} whereas others have shown higher mortality^{21, 36} or cardiovascular complications for single-anaesthetic BTKA.^{36, 37} Some studies have shown lower complications such as infections for single-anaesthetic BTKA than staged BTKA,^{18, 34} which is partially consistent with a recent meta-analysis that found superficial infections occurred more often following staged BTKA than single-anaesthetic BTKA, but periprosthetic infections occurred at similar rates.⁴⁰ However, most single-anaesthetic BTKA studies fail to distinguish between sim-BTKA and sequential BTKA, and equivalent outcomes and costs for these procedures cannot be assumed.⁹ Therefore, most of these studies offer little specific evidence for comparing complication rates between sim-BTKA and staged BTKA.

Study strengths and limitations

To our knowledge, this is the first study since 1978²³ to directly compare functional outcomes following sim-BTKA with staged BTKA. Our surgeons who performed sim-BTKAs also performed the staged BTKAs, reducing the influence of different surgical techniques and prostheses in causing the between-group differences observed. However, unmeasured differences in techniques and prostheses in each group could have influenced intra-operative and postoperative outcomes. Evolution in intraoperative and postoperative care during the study period would have influenced both study groups, limiting the effect of care evolution on between group comparisons.

A primary limitation of the current study, and most other BTKA studies, is its retrospective non-randomised study design. Between group differences or similarities might represent differences in the participant characteristics rather than differences between the procedures. Although studies typically show that people receiving single-anaesthetic BTKA are younger and healthier,^{21, 34} such differences were not apparent in our study; however, unmeasured or unknown characteristics, such as BMI or certain comorbidities could have affected the results. The relatively small sample size limited the study's statistical power and ability to detect infrequent complications such as mortality; between-group differences might have become apparent with a larger sample. Cost data were not available prior to 1 July 2016; hence, costs for the participants in this study could not be directly determined, which might have

created inaccuracies in our cost analysis. Our costs and LOS might be different from other organisations, affecting the generalisability of our results.

Conclusions and recommendations

Sim-BTKA may be superior to staged BTKA as patients reported less joint pain and better physical function, and our health service incurred lower costs, with similar complication profiles between the procedures. Future studies are needed to confirm these findings at different health services while using prospective randomized study designs. Investigators are also encouraged to clearly delineate between sim-BTKA and sequential BTKA when reporting the effects of single-anaesthetic BTKA as these two groups may produce different peri-operative and post-operative outcomes.

Disclosure Statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Figure Legend

Figure 1: Median length of stay by BTKR technique. Note – median LOS for rehabilitation is only calculated among those discharged to rehabilitation (N=64 for sim-BTKR surgeries and N=25 for staged BTKR surgeries)

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Table 1: Participant characteristics

	Simultaneous BTKR (n=122)	Staged BTKR (n=46)		Comparison between Sim-BTKR and 1 st stage BTKR (p-value)
		1 st stage	2 nd stage	
Age (mean, SD)	70.6 (7.1)	70.7 (8.8)	71.5 (8.9)	0.904
Charlson Comorbidity Index (median, IQR)	1 [0, 2]	1 [0, 3]	1 [0, 3]	0.345
ASA: n(%)				
ASA I	7 (5.8)	1 (2.2)	0 (0)	0.682
ASA II	81 (66.9)	31 (67.4)	33 (71.7)	
ASA III & IV	33 (27.3)	14 (30.4)	13 (28.3)	
Gender – female: n(%)	76 (62.3%)	23 (50.0%)		0.149

Abbreviations: SD = standard deviation; IQR = interquartile range (25th & 75th percentiles)

Table 2: Discharge destination, blood transfusion volume, complications

	Simultaneous BTKR (n=122)	Staged BTKR (n=46)			(p-value)^a
		1st stage	2nd stage	Total (1st and 2nd stage)	
Discharged to rehabilitation: n (%)	97 (79.5)	13 (28.3)	12 (26.1)	25 (27.2) ^b	<0.001
Anaesthetic time (min)					
Median[IQR]	191 (175 – 210)	163 (145 – 188)	160 (145 – 175)	326 (296 – 350)	<0.001
Received blood transfusion : n (%)	64 (52.5)	9 (19.6)	11 (23.9)	20 (21.7) ^b	0.001
Amount of blood transfusion (units)					
Median [IQR]	2 [0 – 3]	0 [0 - 0]	0 [0 – 0]	0 [0 – 2]	0.039
Complications: n (%)					
Cardiac	27 (22.1)	3 (6.5)	5 (10.9)	8 (17.4)	0.564
Superficial infection	19 (15.6)	7 (15.2)	10 (21.7)	14 (30.4)	0.048
Acute renal failure	17 (13.9)	1 (2.2)	7 (15.2)	8 (17.4)	0.575
Deep infection	0 (0)	0 (0)	0 (0)	0 (0)	---
Neurological	5 (4.1)	1 (2.2)	0 (0)	1 (2.2)	>0.999
Readmission	8 (6.6)	3 (6.5)	0 (0.0)	3 (3.3) ^b	0.358
Re-operation	4 (3.3)	0 (0)	2 (4.4)	2 (4.4)	0.666
Death	1 ^c (0.8)	0 (0.0)	0 (0.0)	0 (0.0)	---

Abbreviations: IQR = interquartile range (25th & 75th percentiles)

^a compares simultaneous BTKR to staged BTKR 'total'

^b number of episodes where a patient was discharged to rehabilitation or readmitted, or the number of episodes with a blood transfusion. Hence denominator used for percentage is 92 episodes. For all other staged BTKR proportions, the denominator is 46.

^c due to metastatic lung cancer

Table 3: Comparison of WOMAC scores between sim-BTKR and staged BTKR

WOMAC domain	Simultaneous BTKR		Staged BTKR			Difference in WOMAC scores at 12 months post-op	
	Pre-op N=94	Post-op (12 months) N=82	Pre-op 1 st knee N=37	12 months Post-op		Simultaneous vs. 1 st staged TKR	Simultaneous vs. 2 nd staged TKR
				1 st knee (N=31)	2 nd knee (N=32)	p-value	p-value
Pain							
Median[IQR]	12 (10 – 14)	1 (0 – 3)	11 (10 – 13)	4 (0 – 10)	3 (0 – 9)	0.008	0.041
Function							
Median[IQR]	40 (34 – 47)	8 (3 – 17)	38 (33 – 46)	12 (5 – 33)	10 (3 – 30)	0.023	0.257
Stiffness							
Median[IQR]	5 (4 – 6)	2 (1 – 2)	5 (4 – 6)	2 (2 – 4)	2 (2 – 4)	0.002	0.002

Abbreviations: IQR= interquartile range (25th & 75th percentiles); BTKR = bilateral knee replacement; Diff = difference; CI = confidence interval

Table 4. Total average inpatient costs per person for sim-BKTR and staged BTKA

	Sim-BTKA, n=122	Staged BTKA, ^a n=46	Difference ^b
	Mean (SD)	Mean (SD)	(95% CI)
Health service cost (\$ AUD)	36,892 (6,515)	43,281 (12,509)	6,388 (3,462; 9,314)

^aboth surgeries combined, ^bDifference = (staged BTKA minus sim-BTKA)

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Author/s:

Gill, SD;Hill-Buxton, L-M;Gwini, SM;Morrison, S;Moreira, B;Beattie, S;Thomson, A;Page, RS

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