

Simultaneous or Staged Bilateral Knee Arthroplasty: A Rapid Review

Health Quality Ontario

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Evidence Development and Standards Branch at Health Quality Ontario

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All reports prepared by the Evidence Development and Standards branch at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Clinical questions are developed by the Evidence Development and Standards branch at Health Quality Ontario, in consultation with experts, end users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses; if none are located, the search is expanded to include randomized controlled trials and guidelines. Systematic reviews are evaluated using a rating scale developed for this purpose. If a systematic review has evaluated the included primary studies using the GRADE Working Group criteria (<http://www.gradeworkinggroup.org/index.htm>), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies in the systematic review are retrieved and the GRADE criteria are applied to a maximum of 2 outcomes. Because rapid reviews are completed in very short time frames, other publication types are not included. All rapid reviews are developed and finalized in consultation with experts.

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Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario's health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. The Evidence Development and Standards branch works with expert advisory panels, clinical experts, scientific collaborators, and field evaluation partners to conduct evidence-based reviews that evaluate the effectiveness and cost-effectiveness of health interventions in Ontario.

Based on the evidence provided by Evidence Development and Standards and its partners, the Ontario Health Technology Advisory Committee—a standing advisory subcommittee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario's Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Health Quality Ontario's research is published as part of the *Ontario Health Technology Assessment Series*, which is indexed in MEDLINE/PubMed, Excerpta Medica/Embase, and the Centre for Reviews and Dissemination database. Corresponding Ontario Health Technology Advisory Committee recommendations and other associated reports are also published on the Health Quality Ontario website. Visit <http://www.hqontario.ca> for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Evidence Development and Standards and its research partners review the available scientific literature, making every effort to consider all relevant national and international research; collaborate with partners across relevant government branches; consult with expert advisory panels, clinical and other external experts, and developers of health technologies; and solicit any necessary supplemental information.

In addition, Evidence Development and Standards collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This report was prepared by Health Quality Ontario or one of its research partners for the Ontario Health Technology Advisory Committee and was developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts and applicants to Health Quality Ontario. It is possible that relevant scientific findings may have been reported since the completion of the review. This report is current to the date of the literature review specified in the methods section, if available. This analysis may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: <http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations>.

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List of Abbreviations

AMSTAR	Assessment of Multiple Systematic Reviews
CI	Confidence interval
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
OR	Odds ratio
TKA	Total knee arthroplasty

Background

As legislated in Ontario's *Excellent Care for All Act*, Health Quality Ontario's mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Funding (QBF) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario's recommendations are intended to inform the Ministry of Health and Long-Term Care's Health System Funding Strategy.

For more information on Health Quality Ontario's Quality-Based Funding initiative, visit www.hqontario.ca.

Objective of Analysis

The objective of this analysis was to determine the safety of simultaneous bilateral knee arthroplasty compared to staged bilateral knee arthroplasty.

Clinical Need and Target Population

Individuals with osteoarthritis or rheumatoid arthritis of both knees may require replacement of the affected joints using bilateral knee arthroplasty. (1) Planned bilateral knee arthroplasty can be performed in a simultaneous or staged manner. (1)

Technology/Technique

Simultaneous bilateral knee arthroplasty refers to surgery conducted on both knees at the same time, with a single hospitalization and anaesthesia; it can be performed on both knees at once using 2 surgical teams or sequentially with 1 surgical team. *Staged bilateral knee arthroplasty* refers to a process involving 2 separate procedures and 2 hospitalizations. With staged bilateral knee arthroplasty, the interval between procedures can range from a few days to several months. Whether bilateral knee arthroplasty should be performed in a simultaneous rather than a staged manner remains controversial. (2;3)

Rapid Review

Research Question

What is the safety of simultaneous bilateral knee arthroplasty compared to staged bilateral knee arthroplasty?

Research Methods

Literature Search

Search Strategy

A literature search was performed on August 2, 2013, using Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid Embase, and EBM Reviews for studies published from January 1, 2007, to August 2, 2013. (Appendix 1 provides details of the search strategies.) Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Reference lists were also examined for any additional relevant studies not identified through the search.

Inclusion Criteria

- English-language full-text publications
- published between January 1, 2007, and August 2, 2013
- systematic reviews, meta-analyses, and health technology assessments
- bilateral knee arthroplasty population
- studies comparing simultaneous bilateral knee arthroplasty to staged bilateral knee arthroplasty
- 1 or more outcomes of interest

Exclusion Criteria

- studies comparing to unilateral knee arthroplasty

Outcomes of Interest

- mortality
- pulmonary embolism
- deep infection

Expert Panel

In April 2013, an Expert Advisory Panel on Episodes of Care for Hip and Knee Arthroplasty was struck. Members of the panel included physicians, personnel from the Ministry of Health and Long-Term Care, and representatives from community laboratories.

The role of the Expert Advisory Panel on Episodes of Care for Hip and Knee Arthroplasty was to contextualize the evidence produced by Health Quality Ontario and provide advice on the appropriate clinical pathway for hip and knee arthroplasty in the Ontario health care setting. However, the statements, conclusions, and views expressed in this report do not necessarily represent the views of Expert Advisory Panel members.

Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (4)

The quality of the body of evidence for each outcome was examined according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. (5) The overall quality was determined to be high, moderate, low, or very low using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that randomized controlled trials (RCTs) are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision, and publication bias—were then taken into account. Limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 main factors that may raise the quality of evidence were considered: large magnitude of effect, dose response gradient, and accounting for all residual confounding factors. (5) For more detailed information, please refer to the latest series of GRADE articles. (5)

As stated by the GRADE Working Group, the final quality score can be interpreted using the following definitions:

High	High confidence in the effect estimate—the true effect lies close to the estimate of the effect
Moderate	Moderate confidence in the effect estimate—the true effect is likely to be close to the estimate of the effect, but may be substantially different
Low	Low confidence in the effect estimate—the true effect may be substantially different from the estimate of the effect
Very Low	Very low confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Rapid Review

The database search yielded 139 citations published between January 1, 2007, and August 2, 2013 (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

Three systematic reviews with meta-analyses met the inclusion criteria. The reference lists of the included studies were hand-searched to identify other relevant studies, but no additional citations were identified. The 3 systematic reviews are summarized in Table 1.

Table 1: Summary of Systematic Reviews

Author, Year	Study Selection Criteria	Number of Studies Included	AMSTAR Score ^a
Fu et al, 2013 (6)	Inclusions: published 1965–2012; simultaneous bilateral TKA and staged bilateral TKA; osteoarthritis or rheumatoid arthritis in both knees; severe pain unrelieved by conventional therapy Exclusions: primary trauma or knee infection; TKA or revision surgery	18 retrospective comparative studies	5
Hu et al, 2011 (7)	Inclusions: published 1980–2010; mortality and morbidity of simultaneous bilateral TKA with staged bilateral TKA Exclusions: simultaneous and staged groups not in same article; data duplicated; demographic background not similar; usable data not reported	14 prospective or retrospective case-control studies	5
Restropo et al, 2007 (8)	Inclusions: published up to 2005, safety of simultaneous bilateral TKA versus staged bilateral TKA; any diagnosis Exclusions: none stated	18 studies (type not specified)	6

Abbreviations: AMSTAR, Assessment of Multiple Systematic Reviews; TKA, total knee arthroplasty.

^aMaximum possible score is 11.

Upon further review, the study by Restropo et al (8) was excluded, as it was the least recent and included unilateral total knee arthroplasty (TKA) in the staged bilateral TKA group. The remaining 2 studies had poor AMSTAR ratings with methodological flaws (Appendix 2). Given that both remaining studies had similar AMSTAR scores, Fu et al (6) was selected for inclusion in this rapid review, as it was the most recent and the most comprehensive.

Mortality

Mortality within 30 days after surgery was the primary endpoint reported in the review by Fu et al. (6). Thirteen of the 18 studies evaluated mortality, of which 7 provided estimable data for meta-analysis. Results from the studies and meta-analysis are presented in Table 2. Overall, the meta-analysis identified a significant increase in 30-day mortality among patients receiving simultaneous bilateral TKA compared to staged bilateral TKA ($P < 0.001$), but significant statistical heterogeneity was observed ($P = 0.009$). Although the methods stated that a random effects model would be used, the authors inappropriately used a fixed-effects model for this outcome. The GRADE for this body of evidence was very low.

Table 2: 30-Day Mortality With Simultaneous Bilateral TKA Compared to Staged Bilateral TKA

Author, Year	Number of Studies	Number of Patients (Simultaneous/Staged)	30-Day Mortality Findings	Summary Estimate for Mortality OR (95% CI)	I ² , %
Fu et al, 2013 (6)	7	26,169/77,951	5 studies found a nonsignificant difference between groups 2 studies found a significant increase in 30-day mortality with simultaneous bilateral TKA	2.25 (1.87–2.72)	73

Abbreviations: CI, confidence interval; OR, odds ratio; TKA, total knee arthroplasty.

A sensitivity analysis was conducted by the authors, and it identified the largest observational study as the primary source of statistical heterogeneity. Removal of this study resulted in a nonsignificant difference in mortality between the 2 groups (odds ratio, 1.35; 95% confidence interval, 0.98–1.85; $P = 0.07$) and no significant statistical heterogeneity ($I^2 = 3\%$). However, a clear explanation for the potential clinical heterogeneity was not identified, and no additional subgroup analyses were considered.

Overall, the analyses of mortality were likely biased toward healthier patients in the staged TKA group, as mortality rates were calculated based on the number of individuals who had completed 2 TKA surgeries, requiring patients to survive the first procedure to be included in the analysis.

Pulmonary Embolism

Results of the Fu et al (6) meta-analysis on pulmonary embolism are presented in Table 3. The authors found a significant increase in the risk of pulmonary embolism among patients receiving simultaneous bilateral TKA compared to staged bilateral TKA ($P = 0.005$). The authors stated that all included studies routinely used thromboprophylaxis, but no information regarding type or duration of therapy was provided. The start and total length of follow-up across studies was not provided, and may have differed between the simultaneous and staged groups. The GRADE for this body of evidence was very low.

Table 3: Pulmonary Embolism With Simultaneous Bilateral TKA Compared to Staged Bilateral TKA

Author, Year	Number of Studies	Number of Patients (Simultaneous/Staged)	Pulmonary Embolism Findings	Summary Estimate for Pulmonary Embolism OR (95% CI)	I ² , %
Fu et al, 2013 (6)	9	14,553/24,600	8 studies found a nonsignificant difference between groups 1 study found a significant increase in pulmonary embolism with simultaneous bilateral TKA	1.39 (1.11–1.76)	0

Abbreviations: CI, confidence interval; OR, odds ratio; TKA, total knee arthroplasty.

Deep Infection

A deep infection was defined by Fu et al (6) as any infection that occurred inside the knee joint and sometimes required removal of the prosthesis. Results from the meta-analysis on deep infection are presented in Table 4. Overall, there was a statistically significant decrease in deep infections among patients receiving simultaneous bilateral TKA compared to staged bilateral TKA ($P < 0.001$). The start and total length of follow-up was not provided, and may have differed between the simultaneous and staged groups. The GRADE for this body of evidence was very low.

Table 4: Deep Infection With Simultaneous Bilateral TKA Compared to Staged Bilateral TKA

Author, Year	Number of Studies	Number of Patients ^a	Deep Infection Findings	Summary Estimate for Deep Infection OR (95% CI)	I ² , %
Fu et al, 2013 (6)	7	38,743	No forest plot provided	0.52 (0.42–0.64)	0

Abbreviations: CI, confidence interval; OR, odds ratio; TKA, total knee arthroplasty.

^aThe number of patients in each group was not provided.

Limitations of Included Studies

The systematic review by Fu et al (6) and the studies included in the meta-analyses had potential methodological limitations that warrant caution in the interpretation of results. First, the assessment of simultaneous and staged bilateral surgery was limited to retrospective cohort studies, so that only observed—rather than planned—procedures were captured. This limitation may result in a bias toward healthier individuals, since those who had planned a staged TKA but did not complete the second procedure due to death or a serious complication would be misclassified as a unilateral TKA. (9) Additionally, no information was provided on how bilateral TKAs were identified in individual studies, or the period of time accepted or observed between staged bilateral TKAs.

The length of follow-up for pulmonary embolism and deep infection was not provided, and it is unclear whether these outcomes were assessed as cumulative events occurring after the first and second hospitalization in the staged bilateral TKA group, or if they were measured only after the second hospitalization. As a result, follow-up periods may differ between study arms or between individual studies.

Furthermore, no information on patient comorbidities was provided, and meta-analyses were conducted using raw data from the individual studies, eliminating any original analyses that may have adjusted for patient-level factors. Additionally, fixed- and random-effects models were inappropriately applied to the meta-analyses, and differed from the planned analyses outlined in the methods section of the review.

Conclusions

Based on 1 systematic review with methodological flaws, the following conclusions were made related to the safety of simultaneous bilateral TKA compared to staged bilateral TKA (very low quality of evidence):

- There was a significant increase in 30-day mortality.
- There was a significant increase in pulmonary embolism.
- There was a significant decrease in deep infections.

Acknowledgements

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Expert Panel for Health Quality Ontario: Episodes of Care for Primary Hip/Knee Replacement

Panel Member	Affiliation(s)	Appointment(s)
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Dr John Rudan	Queens University Kingston General Hospital	Head of Department of Surgery Orthopaedic Surgeon
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Dr David Backstein	Mount Sinai Hospital University of Toronto	Division Head of Orthopaedic Surgery Associate Professor
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Panel Member	Affiliation(s)	Appointment(s)
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Charissa Levy	GTA Rehab Network	Executive Director
Jane DeLacy	William Osler Health System	Executive Director Clinical Services
Kathy Sabo	University Health Network Toronto Western Hospital	Senior Vice President Executive Head

Appendices

Appendix 1: Literature Search Strategies

Limits: 2007-current; English

Filters: Meta-analyses, systematic reviews and health technology assessments

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to June 2013>, EBM Reviews - ACP Journal Club <1991 to July 2013>, EBM Reviews - Database of Abstracts of Reviews of Effects <2nd Quarter 2013>, EBM Reviews - Cochrane Central Register of Controlled Trials <June 2013>, EBM Reviews - Cochrane Methodology Register <3rd Quarter 2012>, EBM Reviews - Health Technology Assessment <3rd Quarter 2013>, EBM Reviews - NHS Economic Evaluation Database <3rd Quarter 2013>, Embase <1980 to 2013 Week 30>, Ovid MEDLINE(R) <1946 to July Week 4 2013>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <August 01, 2013>

Search Strategy:

-
- 1 exp Arthroplasty, Replacement, Knee/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or Arthroplasty, Replacement/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed (17811)
 - 2 exp knee arthroplasty/ use emez or exp Knee Prosthesis/ (34513)
 - 3 ((knee* adj2 (replacement* or arthroplast*)) or (knee* adj2 prosthes?s) or TKR).mp. (52919)
 - 4 or/1-3 (57031)
 - 5 exp Time Factors/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed (1054412)
 - 6 exp time/ use emez (510791)
 - 7 (bilateral* or simultan* or staged or sequen* or stagger* or synchron* or same day or double* or BTKA or STKA).mp. (5105252)
 - 8 or/5-7 (6498118)
 - 9 4 and 8 (8291)
 - 10 Meta Analysis.pt. (46030)
 - 11 Meta-Analysis/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed or exp Technology Assessment, Biomedical/ use mesz,acp,cctr,coch,clcmr,dare,clhta,cleed (55115)
 - 12 Meta Analysis/ use emez or Biomedical Technology Assessment/ use emez (85751)
 - 13 (meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*) or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab. (376467)
 - 14 ((health technolog* or biomedical technolog*) adj2 assess*).ti,ab. (4988)
 - 15 or/10-14 (430094)
 - 16 9 and 15 (240)
 - 17 limit 16 to english language [Limit not valid in CDSR,ACP Journal Club,DARE,CCTR,CLCMR; records were retained] (237)
 - 18 limit 17 to yr="2007 -Current" [Limit not valid in DARE; records were retained] (180)
 - 19 remove duplicates from 18 (139)

Appendix 2: Evidence Quality Assessment

Table A1: AMSTAR Scores of Included Systematic Reviews

Author, Year	AMSTAR Score	(1) Provided Study Design	(2) Duplicate Study Selection	(3) Broad Literature Search	(4) Considered Status of Publication	(5) Listed Excluded Studies	(6) Provided Characteristics of Studies	(7) Assessed Scientific Quality	(8) Considered Quality in Report	(9) Methods to Combine Appropriate	(10) Assessed Publication Bias	(11) Stated Conflict of Interest
Fu et al, 2013 (6)	5	✓	✓	✓	X	X	X	X	✓	X	X	✓
Hu et al, 2011 (7)	5	X	X	✓	X	X	X	X	✓	✓	✓	✓
Restrepo et al, 2007 (8)	6	✓	✓	✓	✓	X	X	X	X	✓	X	✓

Abbreviations: AMSTAR, Assessment of Multiple Systematic Reviews.

^aMaximum possible score is 11. Details of AMSTAR score are described in Shea et al. (4)

Table A2: GRADE Evidence Profile for Comparison of Simultaneous Bilateral TKA and Staged Bilateral TKA

Number of Studies (Design)	Risk of Bias	Inconsistency	Indirectness	Imprecision	Publication Bias	Upgrade Considerations	Quality
30-Day Mortality							
7 (observational)	Very serious limitations (-2) ^a	Serious limitations (-1) ^b	No serious limitations	No serious limitations	Undetected	None	⊕ Very Low
Pulmonary Embolism							
9 (observational)	Very serious limitations (-2) ^{ac}	No serious limitations	No serious limitations	No serious limitations	Undetected	None	⊕ Very Low
Deep Infection							
7 (observational)	Very serious limitations (-2) ^{ac}	No serious limitations	No serious limitations	No serious limitations	Undetected	None	⊕ Very Low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; TKA, total knee arthroplasty.

^aBased on the systematic review by Fu et al, (6) all included studies were retrospective cohorts with poor methodological quality. Data on patient comorbidities was not provided, and all meta-analyses were conducted based on raw data from the original studies, therefore not controlling for confounding and lacking adjustment in statistical analyses. Staged bilateral knee arthroplasties were biased toward individuals who survived the first surgery and had a second surgery, therefore not accounting for individuals who died prior to the second surgery or who did not adhere to the planned treatment.

^bSignificant statistical heterogeneity was observed in the meta-analysis, with no clear account of potential subgroups.

^cIt is unclear whether complications in the staged bilateral TKA group were measured from the first or second hospitalization, and therefore may be longer than in the simultaneous bilateral TKA group.

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