This report may be used, in whole or in part, as the basis for development of clinical practice guidelines and other quality enhancement tools, or a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

AHRQ is the lead Federal agency charged with supporting research designed to improve the quality of health care, reduce its cost, address patient safety and medical errors, and broaden access to essential services. AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes; quality; and cost, use, and access. The information helps health care decisionmakers—patients and clinicians, health system leaders, and policymakers—make more informed decisions and improve the quality of health care services.

Evidence Report/Technology Assessment
Number 86

Total Knee Replacement

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-02-0009, Task Order #2

Prepared by:
Minnesota Evidence-based Practice Center, Minneapolis, Minnesota

Investigators
Robert L. Kane, MD
Khaled J. Saleh, MD, MSc, FRCSC
Timothy J. Wilt, MD, MPH
Boris Bershadsky, PhD
William W. Cross III, BA
Roderick M. MacDonald, MS
Indulis Rutks, BS

AHRQ Publication No. 04-E006-2
December 2003

This document is in the public domain and may be used and reprinted without permission except those copyrighted materials noted for which further reproduction is prohibited without the specific permission of copyright holders.

Suggested Citation:
Kane RL, Saleh KJ, Wilt TJ, Bershadsky B, Cross WW III, MacDonald RM, Rutks I. Total Knee Replacement. Evidence Report/Technology Assessment No. 86 (Prepared by the Minnesota Evidence-based Practice Center, Minneapolis, MN). AHRQ Publication No. 04-E006-2. Rockville, MD: Agency for Healthcare Research and Quality. December 2003.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This report on Total Knee Replacement was requested and funded by the Office of Medical Applications of Research, National Institutes of Health. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Acting Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Barnett S. Kramer, M.D., M.P.H.
Director, Office of Medical Applications of Research
National Institutes of Health

The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services of a particular drug, device, test, treatment, or other clinical service.

Acknowledgments

We would like to thank the people who worked on the abstractions themselves including: Tyler Bailey; Jesse Botker; Kevin Bozic, MD; Kevin Broder; Gideon Burstein, MD; Jason J. Caron; Stephanie Cintora; Todd Gengerke; Brad Hilger; Richard Iorio, MD; Craig Israelite, MD; William Macaulay, MD; Charles Nelson, MD; and Alexander W. Stricker III. We also wish to thank William M. Woodhouse for his role as data manager and Krystal Wiesenberg for data entry. Marilyn Eells was responsible for editing and formatting the report.

Structured Abstract

Context: The projected growth in the population with arthritis is likely to expand the future demand for elective arthroplasty. At present, there is no strong empirical base for the indicators in current use for what criteria should be used to identify potential candidates for Total Knee Arthroplasty (TKA)[a]; nor is there professional consensus around such indications. An NIH consensus conference has been planned to address these questions. This report summarizes the literature as part of the background for that conference.

Objectives: A systematic review of the literature was undertaken to address four questions:

1. What are the current indications for, and outcomes from, primary total knee replacement?
2. How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors, affect the short-term and long-term outcomes of primary total knee replacement?
3. Are there important perioperative interventions that influence outcomes?
4. What are the indications, approaches, and outcomes for revision total knee replacement?
5. What factors explain disparities in the utilization of total knee replacement in different populations?
6. What are the directions for future research?

Data Sources: The primary TKA literature search was performed by the National Library of Medicine, which searched PubMed from 1995 to April 2003. The access search was done using PubMed and covering the period from 1990 through April 2003. The literature search on revisions was done in two stages. A prior Medline search covering the period from 1996 through 2000 was the basis for a meta-analysis. An updated search using PubMed covered 2001 through April 2003.

Study Selection: The nature of this topic required heavy reliance on observational studies. The major criteria for identifying studies for inclusion in the indications for TKA search required that they address primary TKAs, have at least pre and post surgery data using at least one of four standard functional measures (Knee Society [KS] score, Hospital for Special Surgery [HSS] score, WOMAC, or SF-36), have a sample size of at least 100 total knee replacements, be published in English, and utilize tricompartment TKA. Sixty-two studies met the full inclusion criteria. The selection of studies on access required that they examine the relationship of at least gender or race to the performance of primary TKAs. Six articles were included. The same inclusion criteria applied to primary TKAs were applied to the update of the TKA revision study. Fourteen articles met the criteria.

[a] We use the term total knee arthroplasty instead of total knee replacement because the abbreviation is frequently confused with total knee revision.

Data Extraction: Data were abstracted by trained abstractors using a standardized abstraction tool that had been pilot tested and reviewed by the Technical Expert Panel. For the indicators search, the original abstractions were reviewed to assure reliability. All articles meeting the inclusion criteria were independently re-reviewed by each of the three principals. Information related to study and patient characteristics, baseline and followup functional status measures, perioperative complications, and revision rates were extracted using a standardized abstraction tool that had been pilot tested. The access data was abstracted by a subset of the original abstractors using another standardized tool. The TKA revision update was abstracted by an abstractor and one principal using a modification of the primary TKA tool.

Data Synthesis: Both TKA and total knee arthroplasty revision (TKAR) are associated with improved function. The strongest evidence exists over a followup period of up to two years, but the studies that extend to five and even ten years of followup show positive results as well. The average age of patients undergoing TKA in these reports was 70 years with few over aged 85. Two -thirds were female, one third were considered obese, and nearly 90% had osteoarthritis. No studies provided data on racial/ethnic status. The mean effect size (expressed as numbers of standard deviations) is considered large in magnitude and varies from 1.6 to 3.9 depending on the functional measure used and the duration of followup. There is no evidence that age, gender, or obesity are strong predictors of functional outcomes. Patients with rheumatoid arthritis show more improvement than those with osteoarthritis, but this may be related to their poorer functional scores at the time of treatment and hence the potential for more improvement. The revision rate through five or more years is 2.0% of knees and 2.1% of patients. Complications as defined by the investigator occurred in 5.4% of patients and 7.6% of knees. Patients with rheumatoid arthritis show more improvement than those with osteoarthritis. With regard to access, nonwhites receive TKAs less often than whites despite higher rates of osteoarthritis. Women receive TKAs more often than men, but the pattern is not as consistent as with race. TKA revisions are associated with consistent improvement in function on an order of magnitude similar to primary TKAs.

Conclusions: In general, the outcomes research on TKAs emphasizes before and after studies that are variations on case series of various techniques and prostheses with little attention to the role of other factors or to attrition. Although demographic and clinical factors are recorded, they are rarely used in the analysis. A consistent body of evidence suggests substantial improvement in function associated with TKA and TKAR. The follow-up periods vary but the mean is greater than five years. More informed decision making about indicators for TKAs will require stronger research designs. These need to be planned as prospective studies with multivariate analysis. Such analyses will require larger samples and more consistent and comprehensive data collection than was found in this review.

Contents

Evidence Report

Chapter 1. Introduction 1

Chapter 2. Methods and Analytic Framework 11
- TKA Indicators 12
- TKA Access 13
- TKA Revisions 13

Chapter 3. Results 17
- Baseline Characteristics of Patients 17
- What is the Magnitude of Effect of Primary TKA? 18
- Revisions and Complications 19
- What are the Correlates of Functional Outcomes? 20
- Does Access to TKA Vary with Race and Gender? 21
- Total Knee Arthroplasty Revisions (TKAR) (Summary and Update of the Systematic Review by Saleh et al., 2002) 22
  - Does TKAR improve GKS and is this improvement related to preoperative disease severity? 23
  - Do patients undergoing multiple TKARs have more severe disease as judged by preoperative GKS scores compared with single TKAR cohorts? 23
  - Do outcomes vary between multiple and single TKAR groups as measured by KS or HSS? 24
  - What proportion of TKAR subjects attain excellent/good (E/G) results postoperatively as measured by GKS? Do results vary between the multiple and single knee cohorts, length of followup, or presence of infection as the proximate cause for revision? 24
  - What is the complication rate following TKAR? 24
  - Updated findings of the TKAR report 25

Chapter 4. Discussion 75
- Research Recommendations 77
  - Lessons Learned 78
- Research Agenda 80

References and Included Studies 83

Listing of Excluded Studies 89

List of Acronyms/Abbreviations 115

Appendixes

Appendix A. Measurement Scales
Hospital for Special Surgery score (HSS) 121
Knee Society (KS) score 123
Western Ontario and MacMaster University (WOMAC) Osteoarthritis Index 131
Appendix B. Technical Expert Panel Members and Reviewers 135
Appendix C. Exact Search Strings
Search Strings for Total Knee Arthroplasty (TKA) Scores 139
Search Strings for Total Knee Arthroplasty Access 141
Search Strings for Total Knee Arthroplasty Revisions 142
Appendix D. Abstracting Form 145
Appendix E. Functional Outcome Following Total Knee Arthroplasty Revision: A Meta Analysis (Saleh et al.) 163
Appendix F. Evidence Tables
Evidence Table 1. Primary TKA studies with at least a pre/post design 187
Evidence Table 2. Basic information for calculating revision rates 197
Evidence Table 3. Basic information for calculating complication rates 201

Tables

Table 1 Studies of beliefs about indications, referrals, and thresholds for total knee arthroplasty 4
Table 2 Summary of studies of clinical agreement about patient factors for either referral or surgery (set at >90% for significant agreement) 8
Table 3 Descriptive statistics on 62 studies 27
Table 4 Mean followup duration according to functional assessment scale (in months) 28
Table 5 Weighted baseline and followup scores for TKA outcomes measures 29
Table 6 Functional outcomes by measure and followup interval based on number of subjects 30
Table 7 Functional outcomes by measure and followup interval based on number of knees 37
Table 8 Meta analysis for HSS 42
Table 9 Meta analysis for KS 43
Table 10 Meta analysis for WOMAC 45
Table 11 Meta analysis for SF-36 46
Table 12 Revision rates after primary TKAs 47
Table 13 Assessmentg of TKA prostheses and surgical procedures 48
Table 14 Asessment of TKA procedures/programs 55
Table 15 Complications: Prevention of Venous Thrombosis (VT)/Pulmonary Embolism (PE) studies 57
Table 16 Complications: Prevention of infection studies 59
Table 17 Complications: Tourniquet studies 60
Table 18 Number of studies that include potential correlates of function 61

Table 19 TKA outcomes scores based on age, gender, BMI-index/obesity, and type of arthritis 62
Table 20 TKAR studies using multiple regression modeling 63
Table 21 Gender/racial disparities in total knee arthroplasty studies 65
Table 22 Summary of race and gender effects on TKA rates 67
Table 23 Updates on total knee revision studies 68
Table 24 Potential study questions 81

Figures

Figure 1 TKA article inclusion/exclusion flow chart 15
Figure 2 Mean increase in Knee Society scores (postoperative less preoperative scores) as a function of postoperative followup (months) for subjects undergoing TKA revision surgery 72
Figure 3 Mean increase in Hospital Special Surgery scores (postoperative less preoperative scores) as a function of postoperative followup (months) for subjects undergoing TKA revision surgery 72
Figure 4 Proportion of subjects undergoing TKA revision surgery in each cohort self-rated as excellent or good as a function of postoperative followup (months) 73

Appendixes and Evidence Tables are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm