NIH Consensus Development Conference on Total Knee Replacement

◆

December 8–10, 2003
William H. Natcher Conference Center
National Institutes of Health
Bethesda, Maryland

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Sponsored by:

♦ National Institute of Arthritis and Musculoskeletal and Skin Diseases
♦ Office of Medical Applications of Research

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Introduction

Background

Total knee replacement (TKR) has shown increasing success in relieving knee pain and improving joint function for patients suffering from knee problems due to injury, degenerative disease, and inflammation. Each year, approximately 300,000 TKR surgeries are performed in the United States for end-stage arthritis of the knee joint. As the number of TKR surgeries performed each year increases and the indications for TKR extend to younger patients, a review of available scientific information is necessary to enhance clinical decisionmaking and stimulate further research.

First used in the late 1950s, early TKR implants poorly mimicked the natural motion of the knee and resulted in high failure and complication rates. Advances in TKR technology within the past 10 years have enhanced the design and fit of knee implants, resulting in improved short- and long-term outcomes.

Despite the increased success of TKR, questions remain concerning which materials and implant designs are most effective for specific patient populations and which surgical approach is optimal for a successful outcome. Physical, social, and psychological issues may influence the success of TKR, and understanding patient differences could facilitate the decisionmaking process before, during, and after surgery, thereby achieving the greatest benefit from TKR. Particular attention also must be given to the treatment and timing options related to the revision of failed TKR surgery.

Conference Process

To address these questions, the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Institutes of Health Office of Medical Applications of Research are sponsoring a consensus development conference to explore and assess the current scientific knowledge regarding TKR. Specifically, the conference will address the following key questions:

- What are the current indications and outcomes for primary TKR?
- How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors affect the short- and long-term outcomes of primary TKR?
- Are there important perioperative interventions that influence outcomes?
- What are the indications, approaches, and outcomes for revision TKR?
- What factors explain disparities in the utilization of TKR in different populations?
- What are the directions for future research?

During the first 1½ days of the conference, experts will present the latest TKR research findings to an independent panel. After weighing all of the scientific evidence, the panel will prepare a consensus statement answering the questions above. On the final day of the conference,

the panel chairperson will read the draft statement to the conference audience and invite comments and questions. A press conference will follow, that afternoon, to allow the panel to respond to questions from the media.

The panel's draft consensus statement will be posted to the NIH Consensus Development Program's Web site—www.consensus.nih.gov—as soon as possible after the close of conference proceedings. The final statement will be posted 3 to 4 weeks later.

General Information

Conference sessions will be held in the Natcher Conference Center, National Institutes of Health, Bethesda, Maryland.

The conference may be viewed live via webcast at http://videocast.nih.gov. Webcast sessions also will be available after the conference.

The dining center in the Natcher Conference Center is located on the main level, one floor above the auditorium. It is open from 6:30 a.m. to 2:30 p.m., serving hot breakfast and lunch, sandwiches and salads, and snack items. An additional cafeteria is available from 7 a.m. to 3:30 p.m., in Building 38A, level B1, across the street from the main entrance to the Natcher Conference Center.

The telephone number for the message center at the Natcher Conference Center is (301) 594-7302.

Conference Sponsors

The primary sponsors of the conference are the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the Office of Medical Applications of Research (OMAR) of the National Institutes of Health (NIH), a component of the U.S. Department of Health and Human Services. The conference is cosponsored by the National Institute of Child Health and Human Development (NICHD), the U.S. Food and Drug Administration (FDA), the National Institute of Standards and Technology (NIST), and the Office of Research on Women's Health (ORWH), NIH.

The National Library of Medicine (NLM) and the Agency for Healthcare Research and Quality (AHRQ) provided additional support to conference development.

Financial Disclosure

Each speaker presenting at this conference has been asked to disclose any financial interests pertaining to this subject area. Please refer to the material in your participant packet for details.

Agenda

Monday, December 8, 2003

8:30 a.m.	Opening Remarks **Stephen I. Katz, M.D., Ph.D.** Director National Institute of Arthritis and Musculoskeletal and Skin Diseases National Institutes of Health

8:30 a.m.	Opening Remarks
		Stephen I. Katz, M.D., Ph.D.
		Director
		National Institute of Arthritis and Musculoskeletal and Skin Diseases
		National Institutes of Health

8:40 a.m.	Charge to the Panel
		Susan Rossi, **Ph.D., M.P.H.**
		Deputy Director
		Office of Medical Applications of Research
		National Institutes of Health

8:50 a.m.	Conference Overview and Panel Activities
		E. Anthony Rankin, M.D.
		Panel and Conference Chairperson
		Chief of Orthopaedic Surgery
		Providence Hospital

I. Current Indications and Outcomes

9:00 a.m.	Current Indications for Primary Total Knee Replacement
		Thomas S. Thornhill, M.D.
		John B. and Buckminster Brown Professor of Orthopaedic Surgery
		Harvard Medical School
		Orthopaedic Surgeon in Chief
		Brigham and Women's Hospital

9:20 a.m.	Known Complications of Primary Total Knee Arthroplasty
		Peter F. Sharkey, M.D., M.S.
		Associate Professor
		Department of Orthopaedic Surgery
		Rothman Institute
		Thomas Jefferson University Hospital

Monday, December 8, 2003 (continued)

9:40 a.m.   Expected Outcomes of Primary Total Knee Replacement
        Jeffrey N. Katz, M.D., M.S.
        Associate Professor of Medicine
        Division of Rheumatology, Immunology and Allergy
        Brigham and Women's Hospital

10:00 a.m.   Summary of Evidence on Predictors of Total Knee Arthroplasty Outcomes
        Robert L. Kane, M.D.
        Professor
        University of Minnesota School of Public Health
        Director, Minnesota Evidence-based Practice Center

10:20 a.m.   Discussion
        Participants with questions or comments for the speakers should proceed
        to the microphones and wait to be recognized by the panel chair. Please
        state your name and affiliation. Questions and comments not heard before
        the close of the discussion period may be submitted at the registration
        desk. Please be aware that all statements made at the microphone or
        submitted later are in the public domain.

II. Variables That Affect Short- and Long-Term Outcomes

10:50 a.m.   Effects of Patient and Surgical Factors on Total Knee Replacement
        Outcomes
        Joshua J. Jacobs, M.D.
        Crown Family Professor of Orthopaedic Surgery
        Rush Medical College

11:10 a.m.   The Effect of General Implant Design Factors on Outcomes
        in Primary Total Knee Replacement
        Timothy M. Wright, Ph.D.
        Senior Scientist, Hospital for Special Surgery
        Professor of Applied Biomechanics
        Department of Orthopaedic Surgery
        Weill Medical College of Cornell University

Monday, December 8, 2003 (continued)

11:30 a.m.   The Specific Effect of the Mobile Bearing Design on the Short- and Long-Term Outcomes of Primary Total Knee Replacement
Robert B. Bourne, M.D., FRCSC
Professor and Chairman
Division of Orthopaedic Surgery
Department of Surgery
London Health Sciences Centre
University of Western Ontario

11:50 a.m.   Discussion

12:20 p.m.   Lunch

1:30 p.m.   The Current Status of Unicompartmental Knee Arthroplasty
Richard D. Scott, M.D.
Professor of Orthopaedic Surgery
Harvard Medical School

1:50 p.m.   The Effect of Material Factors on the Short- and Long-Term Outcomes of Primary Total Knee Replacement
Clare M. Rimnac, Ph.D.
Associate Professor
Department of Mechanical and Aerospace Engineering
Case Western Reserve University

2:10 p.m.   The Effect of Knee Kinematics, Gait, and Wear on the Short- and Long-Term Outcomes of Primary Total Knee Replacement
Thomas P. Andriacchi, Ph.D.
Professor
Division of Biomechancial Engineering
Department of Mechanical Engineering
Stanford University

2:30 p.m.   Discussion

3:00 p.m.   Osteolysis: Etiology and Emerging Nonsurgical Treatments
Richard J. Looney, M.D.
Associate Professor of Medicine
Division of Rheumatology
Department of Medicine
University of Rochester

Monday, December 8, 2003 (continued)

3:20 p.m.	Osteolysis: Surgical Treatment **Gerard A. Engh, M.D.** Director, Knee Research Anderson Orthopaedic Research Institute
3:40 p.m.	Discussion

III. Medical Interventions That Influence Outcomes

4:10 p.m.	Medical Interventions That Influence Outcomes of Primary and Secondary Total Knee Replacement **E. Michael Keating, M.D.** Orthopaedic Surgeon Center for Hip and Knee Surgery
4:30 p.m.	Pre- and Postoperative Rehabilitation Interventions That Influence Outcomes of Primary and Secondary Total Knee Replacement **Victoria A. Brander, M.D.** Director, Northwestern Arthritis Institute Assistant Professor, Physical Medicine and Rehabilitation Northwestern University Feinberg School of Medicine
4:50 p.m.	Discussion
5:20 p.m.	Adjournment

Tuesday, December 9, 2003

IV. Indications, Approaches, and Outcomes for Revision Total Knee Replacement and Salvage Procedures

8:30 a.m.	Indications and Approaches for Revision Total Knee Replacement and Salvage Procedures **Chitranjan S. Ranawat, M.D.** Chairman, Department of Orthopaedic Surgery Lenox Hill Hospital
8:50 a.m.	Salvage Procedures for Failed Total Knee Replacement **Aaron G. Rosenberg, M.D.** Professor of Surgery Department of Orthopaedic Surgery Rush Medical College

Tuesday, December 9, 2003 (continued)

9:10 a.m.   Outcomes of Revision Total Knee Replacement and Salvage Procedures
                             for Failed Total Knee Replacement
                             Nizar N. Mahomed, M.D., Sc.D.
                             Smith and Nephew Chair in Orthopaedic Research
                             Associate Professor
                             Division of Orthopaedic Surgery
                             Department of Surgery
                             University Health Network
                             University of Toronto

9:30 a.m.   Functional Outcome Following Revision Total Knee Arthroplasty:
                             Meta-analysis
                             Khaled J. Saleh, M.D.
                             Associate Professor
                             Department of Orthopaedic Surgery
                             University of Minnesota School of Medicine
                             Minnesota Evidence-based Practice Center

V. Disparities in the Utilization of Total Knee Replacement

9:50 a.m.   Disparities and Potential Inequities in the Use of Total Joint Replacement
                             Maria E. Suarez-Almazor, M.D., Ph.D., M.Sc.
                             Professor of Medicine
                             Department of Health Services Research and Rheumatology
                             Baylor College of Medicine

10:10 a.m.   Disparities in Utilization of Total Knee Arthroplasty
                             Timothy J. Wilt, M.D., M.P.H.
                             Professor
                             Section of General Medicine
                             Center for Chronic Disease Outcomes Research
                             Minneapolis Veterans Affairs Medical Center
                             University of Minnesota
                             Co-Director, Minnesota Evidence-based Practice Center

10:30 a.m.   Patients' Perspectives: Qualitative Research Before and After Surgery
                             Paul A. Dieppe, M.D., FRCP, FFPH
                             Professor
                             Medical Research Council's Health Services Research Collaboration
                             Department of Social Medicine
                             University of Bristol

10:50 a.m.   Discussion

11:00 a.m.   Adjournment

Wednesday, December 10, 2003

9:00 a.m.   Presentation of the Consensus Development Statement

9:30 a.m.   Public Discussion
The panel chair will call for questions and comments from the audience on the draft consensus statement, beginning with the introduction and continuing through each subsequent section in turn. Please confine your comments to the section under discussion. The chair will use discretion in proceeding to subsequent sessions so that comments on the entire statement may be heard during the time allotted. Comments cannot be accepted after 11:30 a.m.

11:00 a.m.   Conference Adjourns
Panel meets in executive session to review public comment. Conference participants are welcome to return to the main auditorium to attend the press conference at 2 p.m.; however, only members of the media are permitted to ask questions during the press conference.

2:00 p.m.   Press Conference

The panel's draft statement will be posted to www.consensus.nih.gov as soon as possible after the close of proceedings, and the final statement will be posted 3 to 4 weeks later.

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Abstracts

The following are abstracts of presentations to the NIH Consensus Development Conference on Total Knee Replacement. They are designed for the use of panelists and participants in the conference and as a reference document for anyone interested in the conference deliberations. We are grateful to the authors, who summarized their materials and made them available in a timely fashion.

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Current Indications for Primary Total Knee Replacement

Thomas S. Thornhill, M.D.

The American College of Rheumatology has reported that total joint arthroplasty is one of the significant advances of the 20th century for the treatment of the arthritic patient. The evolution of total knee arthroplasty (TKA) has refined the procedure to relieve pain and restore function in over 95 percent of patients. Moreover, reported implant survival rates at 10 years are, in fact, superior to those for total hip arthroplasty. The early total knees were hinges and suffered from problems of loosening, infection, and inability to deal with patellofemoral arthritis. Total knees evolved from metal to plastic designs that either sacrificed, substituted, or preserved the posterior cruciate ligament. Each of these techniques has reported high survivorship at 5 to 10 years (Ranawat, Luessenhop, Rodriguez, 1997; Martin, McManus, Scott, et al., 1997; Schai, Thornhill, Scott, 1998). During this evolution, design problems have included polyethylene that was gamma irradiated in air, metal-backed patellae, and certain modular designs that lead to increased failure. The most important factors leading to successful TKA include proper patient selection and proper surgical technique.

The indications for TKA include destructive knee arthropathy, joint dysfunction, pain that cannot be controlled medically, and functional loss due to the arthritic knee. In 1996, Mancuso and colleagues surveyed orthopaedists in the New York area and noted variation among surgeons in the indications for TKA. In an unrelated study of octogenarians, Joshi (2003) and colleagues showed that TKA was of great help even though these patients with low demand might do well with a more standard prosthesis. In 2002, Fortin and coworkers reported on outcomes based on timing of hip and knee arthroplasty and concluded that patients with worse baseline functional status had poorer outcomes than a cohort who underwent arthroplasty with less functional impairment.

Selection of TKA for both inflammatory and noninflammatory arthritis of the knee must be considered in the context of other surgical procedures available for treatment of this condition. These procedures include arthroscopy for early meniscal damage, osteotomy, unicompartmental knee replacement, and total knee replacement (TKR). It also is important to ascertain how easily each of these procedures can be converted to a successful total knee, if needed. The studies of Gill and colleagues (1995), Levine and colleagues (1996), and others have compared the conversion to total knee of many of these procedures. The decision about which is the proper procedure depends on the extent of the arthritis, the diagnosis, associated conditions, the degree of deformity, and the patient's age and activities.

TKR patients are generally hospitalized for 4 to 5 days depending on the region and associated comorbidity. Many of these patients can go home, but some require a supervised rehabilitation facility. The proposed changes under the Centers for Medicare & Medicaid Services "75% Rule" may jeopardize many TKR patients by denying them access to needed rehabilitation facilities. Following rehabilitation, patients are permitted to walk, swim, golf,

garden, and even engage in recreational skiing and doubles tennis. It is not recommended that they jog or participate in repeated activities that involve impact loading.

TKA remains an important treatment option for the care of patients with severe inflammatory and noninflammatory arthritis. This procedure has proven invaluable in restoration of function and has had a strong economic impact in returning patients to work and independent living.

References

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Martin SD, McManus JL, Scott RD, Thornhill TS. Press-fit condylar total knee arthroplasty. 5- to 9-year follow-up evaluation. J Arthroplasty 1997;12(6):603–14.

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Known Complications of Primary Total Knee Arthroplasty

Peter F. Sharkey, M.D., M.S.

Total knee arthroplasty (TKA) is an extremely successful operation in terms of both outcome and durability. Success rates exceeding 90 percent, measured by patient satisfaction, have been reported. In addition, cemented knee implants have been shown to be durable beyond the second decade (Rand, Trousdale, Ilstrup, et al., 2003). Nonetheless, as with any operation, an inherent complication rate is associated with TKA, and complications can quite negatively influence the results of the procedure. Medical complications, including pulmonary embolism, myocardial infarction, arrhythmias, and congestive heart failure, have been reported to occur in 1 to 2 percent of cases after TKA (Mantilla, Horlocker, Schroeder, et al., 2002). Deep-vein thrombosis and pulmonary embolism are dreaded complications of TKA; however, significant morbidity or mortality associated with these complications is relatively rare (Fitzgerald, Spiro, Trowbridge, et al., 2001; Kim, Kim, 2002). Most authors agree that some form of thromboembolic prophylaxis is necessary following TKA (Reitman, Emerson, Higgins, et al., 2003). Aspirin, low-molecular-weight heparin, low-dose warfarin, and pneumatic compression boots all have been demonstrated to have a favorable risk-benefit profile and have been recommended for use in thromboembolic prophylaxis following TKA (Brookenthal, Freedman, Lotke, et al., 2001; Larson, MacMillan, Lachiewicz, 2001; Mesko, Brand, Iorio, et al., 2001; Westrich, Haas, Mosca, et al., 2000; Westrich, Menezes, Sharrock, et al., 1999).

Preoperative medical evaluation and clearance by a qualified internist are mandatory before surgical intervention. If significant underlying medical problems are suspected, surgery should be postponed until the patient's condition can be optimized. For patients with comorbidities, bilateral TKA may not be justified. Staged, sequential unilateral TKA has been shown to result in a lower complication rate in high-risk patients (Adili, Bhandari, Petruccelli, et al., 2001; Lane, Hozack, Shah, et al., 1997; Parvizi, Sullivan, Trousdale, et al., 2001). The benefits of improved surgical techniques, shorter surgical times, and earlier mobilization after TKA are accepted.

Surgical complications following TKA include infection, component failure, wound-healing problems, and nerve and vascular injuries. Infection occurs after 1 to 2 percent of cases, but the risk can be diminished with the use of prophylactic antibiotics (Tang, Chiu, Ng, et al., 2003), body-exhaust suits (Der Tavitian, Ong, Taub, et al., 2003), and "total joint rooms." Risk factors for infection include a history of multiple knee surgeries, immune-compromised patients, and long operating room times. Incision and drainage and long-term antibiotics often can successfully treat early infection, generally defined as infection present less than 2 weeks. Chronic infection usually requires revision surgery, with removal of components and staged reconstruction. Any patient with "suspicious pain" after TKA should be evaluated carefully for infection by checking a sedimentation rate, C-reactive protein, and aspiration. Nuclear scans are of questionable value (Peersman, Laskin, Davis, et al., 2001; Tsukayama, Goldberg, Kyle, 2003).

Mechanical problems following total knee arthroplasty include component loosening, polyethylene wear, malalignment, and instability (Sharkey, Hozack, Rothman, et al., 2002). These complications are often the result of surgical error. However, obesity, increased patient activity, and poor component design can contribute to the incidence of these failure modes (Deshmukh, Hayes, Pinder, 2002; Miric, Lim, Kahn, et al., 2002).

Patellar problems post TKA are particularly troublesome. Avascular necrosis of the patella, poor surgical technique, and increased patient activity can lead to patellar fracture and loosening. Meticulous surgical technique, with particular attention to patellar tracking, can result in a very low incidence of failure. Metal backing on the patellar component, although a good idea theoretically, has been shown to predispose the patellar component to early failure. The patella should be resurfaced using cemented all-polyethylene components. Young, heavy patients or highly active patients with very good range of motion are predisposed to patellar failure after TKA. In these high-risk patients, consideration should be given to not resurfacing the patella. Although this practice may result in more anterior knee pain following TKA, it lessens the risk of disastrous complications.

Delayed wound healing after TKA has been associated with prior surgery, malnutrition, rheumatoid arthritis, obesity, the use of steroids, and diabetes. Wound problems can be prevented by using existing incisions or, if the incision cannot be used, leaving at least a 7 cm skin bridge between the old incision and the new incision. Presurgical reconstruction using tissue expanders also may prevent disastrous wound-healing complications. In addition, judicious use of a lateral release is imperative; a lateral release has been associated with delayed wound healing. If a hematoma or persistent drainage is noted postoperatively, aggressive management with incision and drainage should be considered. Proactive management of these problems can prevent wound-healing issues. Furthermore, persistent drainage or hematoma may be a sign of infection, and early incision and drainage could prevent deep infection.

Vascular complications following TKA, while relatively rare, are obviously important (Ninomiya, Dean, Goldberg, 1999). Early recognition is critical before tissue necrosis occurs. With early recognition and treatment, good outcomes can be obtained. However, if the problem is not recognized early, compartment syndrome and tissue necrosis can occur with terrible consequences. Tourniquets should be avoided in high-risk patients (Eyres, Sharpe, Abdel-Salam, 1999). If a patient's pulses cannot be palpated preoperatively, then evaluation by a vascular surgeon should be considered.

Neural complications, usually peroneal nerve palsy, also have been reported after TKA (Schinsky, Macaulay, Parks, et al., 2001). Causes are variable but have been reported to include correction of severe deformities, such as the valgus knee or the knee with a severe flexion contracture. Compression of the nerve also can result in palsy. The use of epidural anesthesia is a risk factor since patients are not aware of the evolution of nerve palsy. The use of continuous passive motion (CPM), combined with epidural anesthesia, may potentiate this complication. Treatment should include prompt recognition, removing the dressing, CPM, and flexing the knee. If palsy occurs in conjunction with a hematoma, then evacuation should be performed.

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Expected Outcomes of Primary Total Knee Replacement

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"Outcomes" is a broad term that covers a wide range of results of surgery, some short term and others long term, some technical and others more global. The following classification will guide this discussion of total knee replacement (TKR) outcomes.

Table 1. Classification of the outcomes of TKR

Time Period	Broad Category	Specific Examples
Perioperative	Mortality Medical complications Surgical complications	 MI, DVT, PE, fat embolus, pneumonia Infection, fracture
Short term (i.e., 1–5 years)	Patient centered Complications	Pain, function, satisfaction, QOL Infection, early prosthesis failure
Long term (i.e., 10+ years)	Patient centered Surgical	Pain, function, QOL Mortality Late infection Prosthesis survival (loosening, osteolysis)

MI=myocardial infarction; DVT=deep vein thrombosis; PE=pulmonary embolism; QOL=quality of life

Perioperative Outcomes

A population-based study of the outcomes of TKR in the Medicare population analyzed data on 80,000 Medicare recipients who had primary TKR in U.S. hospitals in 2000 (Katz, Mahomed, Baron, et al., 2003). Algorithms based on validated Medicare claims were used to identify events occurring within the first 90 days following primary TKR. The data show 90-day mortality at 0.6 percent, MI at 0.8 percent, pneumonia requiring hospitalization at 1.4 percent, PE at 0.8 percent, and deep prosthetic infection at 0.4 percent. These data reflect the experience nationwide, not just in referral centers where a relatively small number of patients undergo the procedure.

The study examined the association between the annual TKR volume performed by the hospital and surgeon and the outcomes of surgery. As has been reported for total hip replacement (Katz, Losina, Barrett, et al., 2001) and many other procedures (Birkmeyer, Siewers, Finlayson, et al., 2002; Dudley, Johansen, Brand, et al., 2000; Halm, Lee, Chassin, 2002), high-volume centers tend to have lower rates of these adverse events following TKR compared with low-volume centers (Katz, Mahomed, Baron, et al., 2003).

Short-Term Outcomes of TKR

The literature on TKR outcomes includes many articles reported from referral centers and a small number of population-based and community-based reports. The distinction is important because in the United States only 20 percent of patients undergoing primary TKR receive surgery in centers that perform more than 200 cases per year in the Medicare population (Katz

JN, unpublished data), yet the vast majority of published reports are from such high-volume centers.

Callahan and colleagues (1994) reported a quantitative synthesis (meta-analysis) of the literature reported through 1992. These authors included 130 studies, which enrolled more than 9,000 patients. Sixty-three percent of the patients had osteoarthritis (OA) and one-third had rheumatoid arthritis (RA), compared with over 90 percent having OA in population-based samples (Katz, Mahomed, Baron, et al., 2003). Because the articles used a wide range of outcome measures, synthesis was difficult. Nevertheless, a synthesis of the literature demonstrated that 89 percent of patients had good or excellent outcomes.

Hawker and colleagues (1998) reported a cross-sectional study of the outcomes of primary TKR in three population-based cohorts (one in Indiana, one in Pennsylvania, and another across the entire United States) of Medicare recipients who had TKR between 1985 and 1989. Patients responded to a survey that elicited their current status in 1992 (2 to 7 years postoperatively) and their recalled status before TKR. The study had an 80-percent response rate. Knee pain improved dramatically in the cohort. Whereas 59 percent of respondents recalled severe pain on walking preoperatively, only 6 percent reported severe pain with walking at the time of the survey. Fifty-five percent of respondents reported no difficulty walking on flat ground at the time of the survey. Eighty-five percent of patients were satisfied with the results of surgery, 3.5 percent were neutral, and 11 percent were dissatisfied.

Heck and colleagues (Heck, Robinson, Partridge, 1998) performed a prospective community-based study of the outcome of TKR in patients cared for by 48 orthopaedic surgeons operating in 25 hospitals throughout Indiana. Of 563 patients referred for the study, one-half participated and provided 2-year followup data. Eighty-one percent of patients demonstrated improvement in physical functional status, measured with the SF-36 physical composite score. Eighty-eight percent of patients were satisfied with the results of surgery, 3 percent were neutral, and 9 percent were dissatisfied.

Robertsson and colleagues (2000) reported on patient satisfaction with surgery among patients in the Swedish Knee Arthroplasty Register. More than 25,000 patients were queried 2 to 17 years following primary TKR. Among patients operated on for OA, 83 percent were very satisfied or satisfied, and, among patients operated on for RA, 86 percent were very satisfied or satisfied.

Therefore, despite differences in study populations and methodology, there is striking consistency in the finding that about 85 percent of patients are satisfied with TKR (table 2).

Table 2. Satisfaction with the results of primary TKR

Author, Year	Design	Sample	N	Percent Satisfied With TKR
Hawker, 1998	Cross-sectional	Population based	1,750	85%
Heck, 1998	Prospective	Community based	291	88%
Robertson, 2000	Cross-sectional	National TKR registry	24,368	83%—OA 86%—RA

The indications of TKR are expanding to include older patients, younger patients, and patients with select comorbid problems, particularly obesity. Age does not appear to be associated with pain relief, functional status, and satisfaction with surgery (Hawker, Wright, Coyte, et al., 1998; Robertsson, Dunbar, Pehrsson, et al., 2000). Morbid obesity may be associated with a higher rate of complications (Winiarsky, Barth, Lotke, 1998). This risk factor can be modified by bariatric surgery before TKR in carefully selected patients (Parvizi, Trousdale, Sarr, 2000). There are no reports of differential outcomes of TKR in patients of different races, although this issue has received little formal study.

Long-Term Outcomes

Patient survival. Mortality 30 days following TKR was 0.21 percent in a Mayo Clinic series (Parvizi, Sullivan, Trousdale, et al., 2001) and 0.46 percent within 90 days in a single surgeon's practice (Gill, Mills, Joshi, 2003). Mortality at 90 days was 0.6 percent in a population-based cohort of Medicare beneficiaries (Katz, Mahomed, Baron, el al., 2003). Therefore, mortality in the perioperative period is well below 1 percent. In the meta-analysis of Callahan and colleagues (1994), approximately 1.5 percent of patients died per year of followup. Because older patients face a finite risk of death even without TKR, deaths should be compared with the number of expected deaths, adjusting for age and sex, with a standardized mortality ratio. In one small Japanese series (Ohzawa, Takahara, Furumatsu, et al., 2001) of 165 total knee replacements followed for 9 years, the standardized mortality ratio for patients with OA undergoing TKR was 0.11 (95-percent confidence interval [CI]: 0.02–0.40). A study from the United Kingdom of 936 patients with TKR (Khan, Emberson, Dowd, 2002) found a standardized mortality ratio in the first 3 postoperative months of 0.74 (95-percent CI: 0.29–1.53). These findings may simply reflect favorable selection; that is, patients selected for elective surgery are healthier than controls. However, it is possible that these orthopaedic procedures actually reduce mortality by permitting patients to be more active and to avoid potentially toxic pain medications. This is an important area for further research.

Prosthesis survival. The meta-analysis of Callahan and colleagues (1994) found that per year of followup, approximately 1 percent of patients with tricompartmental TKR underwent revision. A report from the Mayo Clinic on 11,606 patients followed as long as 20 years found a prosthesis survival of 91 percent at 10 years, 84 percent at 15 years, and 78 percent at 20 years (Rand, Trousdale, Ilstrup, et al., 2003). A report from the Hospital of Special Surgery that followed TKR recipients as long as 22 years reported annual failure rates of about 0.4 percent (Font-Rodriguez, Scuderi, Insall, 1997). Therefore, in these referral center series, over 90 percent of TKR patients survived without revision 10 years following surgery.

There is less information on the rates of revision in population-based cohorts. Revisions are difficult to identify using administrative data because of coding ambiguities. Heck and colleagues (Heck, Melfi, Mamlin, et al., 1998) used Medicare claims data to estimate a rate of revision between 1 and 4.2 percent after 4 years of followup. The wide range reflects the best- and worse-case scenarios, using their estimation procedures. Coyte and colleagues (1999) used similar procedures to estimate the rate of revision of TKR in an Ontario cohort and found that 4.3 to 8.0 percent were revised after 7 years. These estimates are gross, but they support the general

statement that revision rates appear to be no higher than 1 percent per year. The proportion of revisions due to mechanical loosening, osteolysis, and infection require further study.

Methodological Notes

Although reliable, valid, and responsive measures have been developed for assessing the outcome of TKR, these measures are not used consistently. Hence, it is difficult to synthesize results across reports. Furthermore, results are generally reported with mean scores at the group level. No standard measures of "success" exist at the individual level (such as a specified level of pain relief and functional improvement). Claims data are useful for determining rare outcomes such as complications, revisions, and death; however, claims data are intended for administrative purposes, not for clinical research. As a result, a number of frustrating limitations arise. For example, many administrative data systems do not distinguish right from left TKR, leaving ambiguity as to whether a revision reflects failure of the index or of the contralateral knee.

Future Research

The younger, more demanding patient with advanced knee OA remains a challenge. Although published data suggest excellent functional and symptomatic results in this group, with prosthesis survival exceeding 90 percent at 10 years, these individuals continue to represent a growing, challenging pool of TKR patients, for whom prosthesis design and patient selection could be further optimized. The outcome of TKR in racial and ethnic minorities also needs further study; we must define and implement structures and processes of care that enhance the success and accessibility of TKR. In addition, data on survival following TKR and total hip replacement raise the question of whether these procedures may actually improve the quantity as well as the quality of life. This is a critically important research question. Finally, the research base consists of isolated observations. Research on broad policy models of OA treatment and outcome that incorporate nonoperative and surgical therapy, as well as health services delivery strategies, would permit a clearer view of the consequences of interventions to manage patients with knee OA.

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Summary of Evidence on Predictors of Total Knee Arthroplasty Outcomes

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Total knee arthroplasty (TKA) is one of the most common orthopaedic procedures. In 2001, 171,335 primary knee replacements and 16,895 revisions were performed (Orthopedic Network News Online, 2002). Because these procedures are elective and expensive (Medicare paid approximately $3.2 billion in 2000 for hip and knee joint replacements) and because the prevalence of arthritis is expected to grow substantially as the population ages (Acheson, Collart, 1975; Peyron, 1986), these procedures are likely to come under increasing scrutiny.

Previous reports suggest that TKA improves functional status, relieves pain, and results in relatively low perioperative morbidity (Callahan, Drake, Heck, et al., 1994). However, the conclusions of consensus panels or surveys of health care providers suggest considerable disagreement about the indications and contraindications for the procedure (Tierney, Fitzgerald, Heck, et al., 1994; Wright, Coyte, Hawker, et al., 1995; Mancuso, Ranawat, Esdaile, et al., 1996; Coyte, Hawker, Croxford, et al., 1996; Wright, Hawker, Bombardier, et al., 1999; Malmlin, Melfi, Parchman, et al., 1998). However, these opinions are not entirely evidence based. This presentation summarizes the analysis of the literature prepared by the Minnesota Evidence-based Practice Center.

Literature Review

To address the question about the indications and outcomes of TKA, the National Library of Medicine staff conducted a systematic review of the literature published from 1995 to April 2003. Of the 3,519 references screened using our inclusion criteria (primary TKA studies, more than 100 knees per study, baseline data and postoperative outcomes data provided, experimental or quasiexperimental study design, English language, tricompartmental), 611 references either met the inclusion criteria or needed further screening of the full article to determine whether they met inclusion. Of these, 62 studies reported pre- and post-TKA functional data using at least 1 of the 4 established measures we relied on (Knee Society [KS] score, Hospital for Special Surgery [HSS] score, Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC], or SF-36). All but 15 studies were conducted in the United States or Canada. Whenever feasible, we present the analysis using both patients and knees. We conducted a meta-analysis of the functional outcomes data.

Patient Sample

On average, the patients were younger than 75 and very few of them were older than 85, about two-thirds were female, and about one-third were considered obese (BMI [body mass index] of 30 or higher). Nearly 90 percent of the patients had osteoarthritis. We did not

specifically address bilateral TKA, but we did separate analyses by numbers of knees and numbers of patients.

Summary of Major Findings

The basic observations can be summarized as follows:

- The average age of patients undergoing TKA in these reports was 70 years. No studies provided data on racial or ethnic status.
- The functional scores after TKA are consistently higher than before the procedure. The mean effect size (defined as the number of standard deviations of change from baseline scores) for the HSS studies is 3.91 for those with followup up to 2 years, 3.01 for those with followup of 2 to 5 years, and 2.97 for those studies with more than 5 years of followup. For the studies using KS, the mean effect size is 2.35 for those with followup of 0 to 2 years, 2.73 for those with followup of 2 to 5 years, and 2.67 for those with followup of 5 or more years. For WOMAC studies, the mean effect size for 0 to 2 years of followup is 1.62. The more generic SF-36 scores have the smallest mean effect size; for the studies with 0 to 2 years of followup, the mean effect size is 1.27.
- There is no evidence that age, gender, or obesity is a strong predictor of functional outcomes.
- Patients with rheumatoid arthritis show more improvement than those with osteoarthritis, but this finding may be related to their poorer functional scores at the time of treatment and hence the potential for more improvement.
- The revision rate through 5 or more years is 2.0 percent of knees and 2.1 percent of patients.
- Complications as defined by each investigator occurred in 5.4 percent of patients and 7.6 percent of knees. The vast majority of complications were "knee related" or deep venous thrombosis. Only 8 cardiovascular or pulmonary complications were reported in nearly 6,000 patients, suggesting that these adverse effects were not fully addressed in this literature.
- There is reason to suspect selection effects in both the type of patients referred for TKA and those reported in the literature and the attrition on followup. Therefore, these findings must be interpreted with caution as the basis for clinical practice. Some information on attrition rate was reported for 49 studies. Of these studies, the median percentage of subjects lost to followup was 2 percent, and the range was 0 to 28 percent. If death is added to the definition, the range increases to 0 to 56 percent with a median of 12 percent.

Discussion

We differentiated "indications for TKA" from "correlates or factors related to outcomes." The former addresses the factors needed to warrant TKA (or, conversely, the factors that contraindicate TKA because the procedure is ineffective or unnecessary or because it places the patient at unacceptably high perioperative risk). The latter addresses whether outcomes vary

according to clinical or demographic factors. To address indicators would require a design that compared the outcomes of persons with the potential indicator with and without surgical treatment. However, it is possible to examine the potential for contraindications by examining only those who receive arthroplasties.

The number of studies that employed any analytic technique examining the functional outcome in terms of at least one independent variable of interest was limited. Only 12 of the 69 studies used any analysis that directly assessed the relationship of these patient variables to a change in functional status.

Study Design Issues

The conclusions are tempered by the limitations of many of the designs of the studies included in the analysis. Undoubtedly, the candidates at highest risk were censored out. Although osteoarthritis does not seem to be a predictor of outcomes, the results seem to be somewhat better for rheumatoid arthritis, but few of these studies simultaneously controlled for other aspects of the patients.

Quality of the Evidence

Overall, the scientific quality of the current evidence is weak. Only a handful of studies employed any form of multivariate analysis. The outcomes of orthopaedic surgery, like most other treatments, are the results of the treatments interacting with the characteristics of the patients. Real understanding will come about only when the analytic techniques can address both sets of variables simultaneously. The analyses that come from such studies must employ sophisticated statistical methods to examine the effects of the patient characteristics on the outcomes of interest. Orthopaedic outcomes research has made considerable strides in the past decade. Much greater attention is now paid to using established outcomes measures. The next step in this progress is to employ more sophisticated research designs that incorporate patient characteristics into the analysis.

Research Recommendations

The current state of empirical work does not provide a strong basis for making clinical recommendations regarding indications for outcomes from TKA. As the pressure mounts for using more discrimination in identifying subjects for elective surgery, better information will be needed. The ideal study design to answer questions about indications for surgery remains a randomized clinical trial (RCT) in which persons with advanced arthritis (or other potential joint problems) are randomly assigned to medical management or joint replacement. However, given the enthusiasm for joint replacement and the generally positive effects on function, it might be difficult to recruit subjects for such RCTs, even without the prospect of sham surgery. Therefore, a major component of research into the effectiveness of joint replacement and the patient characteristics associated with better outcomes will be well-conducted observational studies.

More attention must be paid to the independent variables (or risk factors) associated with clinically relevant outcomes. Adequate research designs will require the use of multivariate analysis. To generate the sample size needed for multivariate analysis, these studies will likely have to be cooperative ventures. Such a plan would also broaden their representation. They will require systematic collection of data on potential indicators and risk factors and active followup to maintain the cohort, even when patients do not return for scheduled followup clinical visits.

A further concern is that much of the orthopaedic research to date has been sponsored by device manufacturers, who obviously have a stake in the results. More independently funded research might help to provide data that can be more readily adopted as the basis for evidence-based practice.

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Effects of Patient and Surgical Factors on Total Knee Replacement Outcomes

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A growing body of literature explores the relationship of patient- and surgical-specific factors to the clinical outcomes of total knee arthroplasty. This information comes from case series, implant registries, and government databases. Although many published studies address these issues, several of them are limited by small patient numbers and the short duration of followup. In addition, the findings from the myriad of studies available are often conflicting. The studies highlighted in this summary have been chosen primarily on the basis of the large numbers of patients involved and the long duration of followup.

Patient Characteristics

The patient characteristics that have been studied most frequently include the underlying diagnosis (e.g., osteoarthritis [OA], rheumatoid arthritis [RA], posttraumatic arthritis), age, and weight (body mass index [BMI]). Valuable, unique information on the effects of these parameters on outcomes comes from national implant registries, particularly from Scandinavian countries with relatively stable populations and national health systems. The advantage of registries is that large numbers of patients are available for study; the disadvantages are that the only available outcome measure is survivorship and that the populations are relatively homogeneous. Robertsson and colleagues (2001) reported on the Swedish Knee Arthroplasty Register, which included information on 41,233 total knee replacements (TKRs) performed between 1975 and 1997. Analysis of survivorship rates during those years revealed that the higher the age of the patients at the primary operation, the lower the revision rate. This relationship between survivorship and age also was apparent when the revision was done for loosening but not for infection. With regard to gender, the cumulative revision rate (CRR) did not differ between the sexes for OA, whereas men had a higher CRR for RA. In addition, men had a higher CRR when the revision was for infection.

The authors of the Swedish Knee Arthroplasty Register study also observed that the primary disease had an effect on the outcomes. After correcting for age, patients with TKRs for OA had 1.3 times the risk of revision for any reason (1.7 times for loosening) in comparison with patients with RA. However, patients with RA had 1.4 times the risk of revision for infection. In contrast, RA patients undergoing unicompartmental knee arthroplasty had 3.1 times the risk of revision as those undergoing TKR.

Furnes and colleagues (2002) reported on 7,174 primary TKRs performed between 1994 and 2000 in the Norwegian Arthroplasty Register. This study found statistically significant increases in the revision rate in patients undergoing surgery who were younger than 60 years old at the time of primary TKR. While there were no differences in survivorship between patients

with OA and those with RA, patients with posttraumatic arthritis had more revisions for infection, instability, and pain compared with those with primary gonarthrosis.

Vazquez-Vela Johnson and colleagues (2003) reported on 402 patients undergoing 562 primary cemented cruciate-retaining TKRs of one design carried out by a single surgical team. The most significant demographic factor associated with a lower 10-year survivorship was the age of the patient at the time of arthroplasty. Patients older than 60 had a survival rate of 99.1 percent, whereas patients younger than 60 had a survival rate of 82.4 percent. Gender also had a significant impact—women had a higher survival rate at 10 years than men (98.6 versus 94.5 percent, p = 0.042). BMI was shown to have a significant impact on survivorship as well. Patients with OA and a BMI higher than 30 had a survival rate of 92.7 percent, whereas patients with OA and a BMI lower than 30 had a survival rate of 98.4 percent (p = .0015). The highest survival rates at 10 years were observed in nonobese women with OA who were older than 60 years (99.4 percent), and the worst survival rates were seen in obese men with OA who were younger than 60 years (35.7 percent).

In an analysis of all hospitalizations in Ontario, Canada, between April 1984 and March 1991, Coyte and colleagues (1999) found that total knee revisions were relatively rare, with only 1,301 patients hospitalized for this reason during this time interval. The following patient factors were shown to be associated with longer survivorship: the diagnosis of RA, age greater than 55, and residence in a rural area. Gender and comorbidity (the Charlson index) were not shown to be associated with survivorship.

Another patient-related factor that has been discussed in the context of patient outcomes is activity level. Because there is very limited literature comparing quantitative estimates of activity level on TKR outcomes, patient age has been considered a surrogate. The generally poorer results of TKR in younger individuals are usually ascribed to the fact that these individuals are more active and place more demands on their prostheses, leading eventually to implant loosening. However, this assertion has not been proven in a rigorous fashion. Gait adaptations, common to patients following TKR (Andriacchi, Galante, Fermier, 1982), may influence the dynamics of the artificial knee joint. Hilding and coworkers (1996) reported that patients who walked with a higher peak flexion moment show increased tibial component migration that put them at risk for aseptic loosening.

Other patient-related factors that have been correlated to TKR outcomes, as determined by patient-completed health status forms, include psychosocial variables (Sharma, Sinacore, Daugherty, et al., 1996; Heck, Robinson, Partridge, et al., 1998), comorbidities (Wasielewski, Weed, Prezioso, et al., 1998), and preoperative functional status (Fortin, Penrod, Clarke, et al., 2002).

Surgical Technique

Surgical technique is arguably the most important determinant of TKR outcome. This statement is supported by the fact that surgeons who perform more than 20 TKRs annually have fewer complications than those who perform fewer than 20 (Heck, Robinson, Partridge, et al., 1998). Numerous facets of surgical technique may contribute to outcomes, many of which are

difficult to quantify or describe. Parameters that have been considered include alignment, surgical approach, method of fixation, and ligament balance.

As was the case for patient factors, valuable information on the effect of surgical factors can be obtained from national registries. Findings from the Swedish register (Robertsson, Knutson, Lewold, et al., 2001), for example, demonstrate a 1.4 times higher risk of revision of cementless tibial components compared with cemented components in patients with OA. The impact of other surgical variables cannot be ascertained from these registries because information on component alignment, surgical approach, and ligament balance is not recorded. In fact, there is extremely limited literature on the effect of these surgical parameters on short- or long-term TKR outcomes, whether measured by survivorship or patient-completed health status forms. Nonetheless, Sharkey and colleagues (2002) reported that 33 percent of the 212 total knee revision surgeries performed at one institution from 1997 to 2000 were required because of malalignment (12 percent) and instability (21 percent). In a study examining retrievals from an early cruciate retaining TKR design (Wasielewski, Galante, Leighty, et al., 1994), the authors correlated increased polyethylene wear to inadequate medial release, excessive posterior slope of the tibial component, elevation of the joint line, and patellar subluxation.

Restoration of the proper position of the tibiofemoral joint line has been shown to affect the outcome of posterior stabilized TKRs (Figgie, Goldberg, Heiple, et al., 1986). Malalignment and improper soft tissue balance are commonly reported and are known to cause elevated and eccentric loads between femur and tibia (Dorr, Conaty, Schreiber, et al., 1985). This situation increases the contact stresses tremendously, often resulting in accelerated wear (Collier, Mayor, McNamara, et al., 1991; Kilgus, Moreland, Finerman, et al., 1991; Wright, Hood, Burstein, 1982). Malrotation of the femoral and tibial components has been shown to affect the performance of the patellofemoral joint—the combined (tibial plus femoral) internal rotation correlated with the severity of the patellofemoral malfunction. Small amounts (1 to 4 degrees) of combined internal rotation were associated with maltracking, whereas large amounts (7 to 17 degrees) were associated with early patellar dislocation or late patellar component failure (Berger, Crossett, Jacobs, et al., 1998).

Additional clinical studies are needed to fill the gaps in our knowledge concerning the relationship between specific surgical factors and patient outcomes.

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The Effect of General Implant Design Factors on Outcomes in Primary Total Knee Replacement

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Replacing the knee joint with man-made implants requires that the resulting bone-implant system restore normal function and transfer large loads across the joint. The implants themselves must remain well fixed to the supporting bone and must resist wear and mechanical failure for decades. The challenge in total knee replacement design is to balance these competing goals. Ensuring normal function requires that the implant's surfaces not be overly constrained. However, reducing constraint usually means reducing conformity between the surfaces, leading to large stresses in the implant components that in turn increase the chance for wear and loosening. The effect of implant design factors on clinical outcomes can best be understood by considering how compromises between these goals are achieved.

Lessons From the Natural Knee Joint

The primary motion of the knee is flexion and extension as controlled by bony anatomy, muscle forces, and ligament constraints. The tibial plateaus are rather flat, and the femoral condyles have a large radius in extension and a smaller radius in flexion. As the knee is flexed, constraint provided by the posterior cruciate ligament (PCL) causes the femur to roll back on the tibia. The posterior translation combined with the condyles' smaller radii of curvature provides the knee with its large range of motion. Load is transferred across the joint with the aid of menisci and cartilage, which help distribute loads over a large contact area.

Other knee motions are considerably smaller. Large moments are created across the joint because of the side-to-side forces that occur with the ground during walking. The bicondylar nature of the knee allows it to resist these moments by redistributing the load shared by the two plateaus (Burstein, Wright, 2001). Little medial-lateral movement between the joint surfaces is required; rather, the compliant nature of the soft tissues provides for load redistribution.

As with most joints, the muscles that move the knee are at a mechanical disadvantage in resisting the loads that occur with daily activities. Muscle forces and, consequently, joint contact forces are quite large—as much as 4 times body weight during normal activities (Morrison, 1970). Transferring the contact loads into the supporting cancellous bone and then to the cortical shaft dominates the mechanical burden placed on the knee. In the proximal tibia, for example, the load is carried almost entirely by the cancellous bone near the joint and is gradually transmitted to the cortical bone as the cancellous bone stiffness decreases and the outer shell stiffness increases. To carry this load, the bone density is greatest beneath the plateaus, where the loads applied by the femoral condyles are greatest during activities of daily living. The lowest density bone is found in the region between the plateaus.

Knee Replacement Design

The motion provided by a knee replacement is controlled through the articular geometry of the femoral and tibial components. Combining curved surfaces in both the anteroposterior and medial-lateral directions (creating a toroidal shape) is a common method employed to provide adequate range of motion and appropriate constraint to knee replacements while at the same time minimizing contact stresses that might cause wear and implant loosening (Insall, Scott, Ranawat, 1979; Bartel, Bicknell, Wright, 1986).

Additional geometric constraints are used to control motion. For example, femoral rollback during knee flexion, and therefore a large range of motion, can be provided by substituting for the PCL through a post-and-cam mechanism (Insall, Lachiewicz, Burstein, 1982). Similarly, constraints to side-to-side translations and rotations can be controlled by more constrained post-and-cam combinations, an important consideration in treating patients with inadequate collateral ligaments and bony deformities (Donaldson, Sculco, Insall, et al., 1988).

Most contemporary knee replacements are modular; the tibial component consists of a metallic tray into which is fixed a polyethylene insert to serve as the articulating component. Modular components provide the surgeon with important intraoperative options, such as the level of constraint and the choice of cementless fixation. The metallic tray better distributes load to the underlying bone than an all-polyethylene component (Bartel, Burstein, Santavicca, et al., 1982); however, metal-backed components also incorporate another interface besides the joint surface at which wear and mechanical failure can occur (Rao, Engh, Collier, et al., 2002).

Mobile bearing knee designs intentionally include an additional moving interface. The bearing needed for function is separate from the bearing between the articular surfaces to attempt to have muscles and ligaments control more of the joint motion while simultaneously allowing for more conforming articular surfaces in fixed bearing designs, leading to lower contact stresses and presumably better wear resistance (Buechel, Pappas, 1986; O'Connor, Goodfellow, 1996).

Outcomes and Knee Design

Contemporary designs provide patients with a stable, flexible joint adequate for daily activities and with implants that remain fixed to the surrounding bone for decades (Aglietti, Buzzi, De Felice, et al., 1999). Design differences intended to address the compromise between function and wear often demonstrate equivalent clinical results (Clark, Rorabeck, McDonald, et al., 2001), although considerable evidence exists that design can adversely affect outcome, leading to premature catastrophic implant failure and osteolysis (Tsao, Mintz, McCrae, et al., 1993; Huang, Ma, Liau, et al., 2002). The role of specific design factors is difficult to discern because comparative studies of designs are rare and, even then, more than one important design factor often is different between the implants being studied. Thus, the benefit of specific design features often is established through preclinical testing and analyses (Sathasivam, Walker, 1999; Akagi, Ueo, Takagi, et al., 2002) in the hope that improved outcomes will occur as they are adopted.

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The Specific Effect of the Mobile Bearing Design on the Short- and Long-Term Outcomes of Primary Total Knee Replacement

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Total knee replacement (TKR) has revolutionized the care of patients with end-stage arthritic conditions of the knee. The success of total knee arthroplasty, an aging population, and increased public demand have led to dramatic increases in the number of knee replacements. In addition, a growing trend is to offer TKR to patients who are younger than 60 years of age. When TKR is offered to younger, more active patients, wear becomes an important issue (D'Lima, Trice, Urquhart, et al., 2001; Walker, Sathasivam, 1999). It is recognized that most total knee replacements have high contact stresses that often exceed the yield point of ultra-high molecular weight polyethylene (UHMWPE), resulting in significant wear (Bourne, Rorabeck, Finlay, et al., 1987; D'Lima Trice, Urquhart et al., 2001; Robinson, Mulliken, Bourne, et al., 1995). It is also recognized that most total joint replacements do not replicate normal joint kinematics, resulting in varying degrees of sliding at the articular surface that, in concert with high-contact stresses, can lead to increased wear (Goodfellow, O'Connor, 1986; Hirakawa, Bauer, Stulbert, et al., 1996; Jones, Skedros, Chan, et al., 2001; Schroeder-Boersch, 2001; Stiehl, Dennis, Komistek, et al., 1997; Stiehl, Dennis, Komistek, et al., 1999; Stiehl, Komistek, Dennis, et al., 2001; Stukenborg-Colsman, Ostermeier, Hurschler, et al., 2000).

Mobile bearing TKR has been proposed as a solution to many of these problems. Goodfellow and O'Connor (1986) first proposed the Oxford meniscal-bearing TKR as a more kinematically sound design. In the original Oxford implant, the medial and lateral tibiofemoral joints, but not the patellofemoral joints, were resurfaced, and the anterior and posterior cruciate ligaments (PCLs) were preserved. The four-bar linkage created by the anterior cruciate ligament (ACL) and the PCL directed the movement of the meniscal bearings forward in extension and backward in flexion. This meniscal-bearing design had the advantages of low contact stresses that might result in less fatigue wear, less constraint that might lead to less loosening, and a self-aligning potential that might lead to better range of motion and improved patellofemoral kinematics.

Buechel and Pappas (1990) developed the low contact stress (LCS) TKR. The LCS device resembled a condylar knee replacement that not only allowed replacement of the patellofemoral joint but also could be inserted with either a meniscal or rotating-platform configuration. Once again, these authors claimed the benefits of better kinematics, lower contact stresses, less constraint, and self-aligning principle.

Today, the Oxford TKR usually is used in unicompartmental knee arthroplasty mainly because the ACL is normal in only about one-third of arthritic patients (Bourne, Rorabeck, Finlay, et al., 1987). When the ACL was absent, a higher rate of aseptic loosening and bearing dislocation was noted (Bourne, Rorabeck, Finlay, et al., 1987; Goodfellow, O'Connor, 1986).

The LCS meniscal-bearing TKR also has been less successful than the rotating-platform version (Callaghan, Insall, Greenwald, et al., 2001; Callahgan, Squire, Goetz, et al., 2000; Collier, Mayor, McNamara, et al., 1991; Matsuda, White, Williams, et al., 1998). With the LCS meniscal design, bearing dislocation has been observed in 1.3 to 9.3 percent of patients (Buechel, Pappas, 1990; Callaghan, Squire, Goetz, et al., 2000; Sorrells, Stiehl, Voorhorst, 2001). Occasional catastrophic wear of the meniscal bearing also was observed, perhaps related to polyethylene that was sterilized by gamma irradiation and air. As such, the LCS rotating-platform TKR has been used much more commonly. Excellent 10-year survivorship has been reported with the LCS rotating-platform knee in 94 to 100 percent of patients (Callaghan, Insall, Greenwald, et al., 2001; Callaghan, Squire, Goetz, et al., 2000; Sorrells, Stiehl, Voorhorst, 2001).

Many unresolved issues remain for rotating-platform mobile bearing TKR (Draganich, Pottenger, 2000; Goodfellow, O'Connor, 1978; Kaper, Smith, Bourne, et al., 1999; Lewandowski, Askew, Lin, et al., 1997; Matsuda, Whiteside, White, et al., 1999; Polyzoides, Dendrinos, Tsakonas, 1996; Sathasivam, Walker, Campbell, et al., 2001; Stiehl, Voorhorst, 1999; Stiehl, Voorhorst, Keblish, et al., 1997; Stukenborg-Colsman, Ostermeier, Hurschler, et al., 2000; Walker, Sathasivam, 2000; Walker, Sathasivam, 1999). These issues include the femoral "J" curve that determines whether the tibial component will be fully congruent from –5 to 90 degrees flexion or gait congruent from 0 to 20 degrees. Another issue is the need for anteroposterior translation of the rotating platform. A third issue involves determining which rotating-platform implant is best and whether these mobile-bearing knee replacements are superior to fixed-bearing implants in terms of range of motion, kinematics, and wear.

Knee Range of Motion During Normal Gait

Knee range of motion during normal gait has been assessed at the London Health Sciences Centre at the University of Western Ontario. In healthy subjects, the mean knee flexion was about 8 degrees at heel strike, achieving a maximum knee flexion of 15 degrees at midstance and 10 degrees at toe-off. Because of preexisting flexion contractures, flexion in subjects scheduled for TKR differed: 16 degrees at heel strike, 17 degrees at midstance, and 19 degrees at toe-off. In the middle of the swing phase, the healthy patients had flexion of 65 degrees, whereas the subjects with arthritis had flexion of only 52 degrees.

Contact Area Studies

Contact area studies have demonstrated that gait-congruous mobile bearing TKRs have large areas of tibiofemoral contact only during gait and line-contact similar to fixed bearing TKRs at higher degrees of flexion. On the other hand, totally congruous mobile bearing knee replacements provide large areas of tibial femoral load bearing from 5 degrees hyperextension to 90 degrees flexion.

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Knee Wear Simulator Studies

Somewhat paradoxically, knee wear simulator studies have demonstrated gravimetric wear that was least for fixed bearing TKR, followed by rotate-only, then rotate, and translate rotating-platform implants.

Discussion

Rotating-platform TKR seems to provide equivalent clinical results to fixed-bearing TKR. Rotating-platform TKR also provides designing surgeons and orthopaedic companies to enhance the performance of TKRs, particularly for use in younger patients. Although attractive, the benefits of rotating-platform TKR need to be elucidated. If cross-linked polyethylene has a role in TKR, it might be with rotating-platform TKR in which contact stresses are lower and fatigue wear less of a problem. In addition, alternate-bearing surfaces for the femoral and tibial components may provide an increased advantage in rotating-platform knee replacements minimizing abrasive and adhesive wear.

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The Current Status of Unicompartmental Knee Arthroplasty

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Current Indications

In theory, unicompartmental knee arthroplasty (UKA) is an attractive alternative to osteotomy or total knee arthroplasty (TKA) in selected osteoarthritic patients. Advantages over osteotomy include a higher initial success, fewer early complications, a longer lasting result, better cosmetic alignment, the ability to do bilateral surgeries the same day, and easier conversion to TKA should that become necessary in the future (Hanssen, Stuart, Scott, et al., 2000; Kozinn, Scott, 1989; Thornhill, Scott, 1989). Advantages of UKA over TKA include the preservation of both cruciate ligaments, allowing more normal knee kinematics and a potentially higher level of performance. In addition, bone stock is preserved, providing the possibility for an easier revision should that become necessary in the future. Easier revision was not documented by an early series of failed UKAs but has been confirmed by several more recent reports (Levine, Ozuna, Scott, et al., 1996; McAuley, Engh, Ammeen, 2001).

Possible revision problems following tibial osteotomy include unusable previous incisions, poorly accessible prior hardware, joint line distortion, malunion, nonunion, patella baja, offset tibial shafts, deficient lateral tibial bone, and the potential for deficient medial tibial bone. Potential revision problems after TKA include the possibility of joint line distortion and patella baja. There also is the probability of deficient femoral bone, patellar bone, and both medial and lateral tibial bone. Revision problems following UKA should only consist of the possibility of deficient medial bone, depending on the amount of resection for the initial procedure or the mechanism of failure (if it involves loosening and subsidence of the tibial component).

The ideal patient for UKA has been described as an elderly sedentary individual with significant joint space loss isolated to either the medial or lateral compartment. Angular deformity should be no more than 5 or 10 degrees off a neutral mechanical axis. Ideal weight is below 180 pounds. Preoperative flexion contracture should be less than 15 degrees. At surgery, the anterior cruciate ligament is ideally intact and there is no evidence of inflammatory synovitis (Kozinn, Scott, 1989). Indications for the procedure are broadening today because of the availability of less invasive operative techniques and more rapid recovery with UKA (Romanowski, Repicci, 2002). Because of its conservative nature, the procedure is thought of as a conservative first arthroplasty in the middle-aged patient. Because of its less invasive nature with more rapid recovery and potentially less medical morbidity, it is considered the "last arthroplasty" in the octogenarian or older (Deshmukh, Scott, 2002).

Outcomes of UKA

Initial results reported for UKA in the 1970s were not as encouraging as they are today. This improvement is most likely due to lessons that had yet to be learned about patient selection, surgical technique, and prosthetic design. By the 1980s, reported results were improving, with postoperative range of motion much higher than that reported for TKA (Marmor, 1988; Scott, Santore, 1981). As longer followups were reported, results were obtained that were competitive with those reported for TKA. Through the first postoperative decade, revision rates were seen at approximately 1-percent failure per year or a 90-percent survivorship of the prosthesis at 10 years. Survivorship into the second decade appeared to slightly accelerate and be somewhat less than that reported for TKA (Deshmukh, Scott, 2001; Scott, Cobb, McQueary, et al., 1991). More recently, however, some 10-year results have been reported that have survivorship well over 95 percent at 10 years. These improved results most likely reflect the lessons learned about patient selection, prosthetic design, and surgical technique (Berger, Nedeff, Barden, 1999; Murray, Goodfellow, O'Connor, 1998). Modes of failure most often consist of problems with component wear or loosening or because of secondary degeneration of the opposite compartment. This latter complication is usually a late cause of failure but can occur early if the alignment of the knee is overcorrected by the surgical technique.

Factors That Influence Prosthetic Wear and Loosening

Polyethylene wear often is design related or accelerated by problems with surgical technique. A study has been reported that suggests that the wear pattern of the prosthesis reproduces the preoperative wear pattern of the arthritic knee (McCallum, Scott, 1995). This wear pattern for the varus knee is most often anterior and medial (White, Ludkowski, Goodfellow, 1991). Prosthetic designs and surgical technique must accommodate this wear pattern. For example, a UKA with conforming articulating topography often will result in excessive stresses imparted to the fixation interface because the conformity conflicts with the predetermined wear pattern of that individual knee. Fixed-bearing UKA prostheses must be nonconforming where the articulation is slightly round on the femoral side and mostly flat on the tibial side. Conforming articulations must be of the mobile-bearing type so that they can accommodate to the individual knee's wear pattern.

Similarly, placement of the femoral and tibial components should be such that this anterior and medial wear pattern should not be exaggerated. This favors placement of a medial femoral component slightly to the lateral side of the center of the condyle to centralize the articulation of the femoral component on the tibial component. In addition, the surgeon must avoid significant internal rotation of the femoral component because this situation will cause the leading edge of the femoral runner to articulate more toward the periphery of the tibial component and accentuate any abnormal wear pattern.

UKA as an Option in the Middle-Aged Patient

Although the classic selection criteria for UKA have emphasized the elderly patient as a candidate, the indications for UKA are rightfully being extended to a younger age group. The advantages of UKA in the middle-aged patient (especially female) are its high initial success,

few early complications, preservation of both cruciate ligaments, and easy future conversion (Deshmukh, Scott, 2002). As of this date, however, there are few reports in the literature on results of UKA in middle-aged patients (Engh, McAuley, 1999; Schai, Suh, Thornhill, et al., 1998), and their followup is relatively short. A soon-to-be-published report by Price and colleagues (2001) delivered at the American Academy of Orthopaedic Surgeons in 2001 revealed a survivorship of 92 percent in patients younger than age 60. The advent of less invasive surgery and operative techniques that allow more rapid recovery with less morbidity supports the concept of pursuing UKA in younger patients (Romanowski, Repicci, 2002). Caution should be used, however, in advocating this procedure for the young, heavy, athletic person because high levels of physical activity may be detrimental to the longevity of the procedure.

The Future

UKA is now being performed with increasing frequency throughout the world. This trend will most likely continue. Research must continue in the areas of ideal patient selection, prosthetic design, and surgical technique. Improvements in the durability of the polyethylene will enhance longevity. Mobile-bearing articulations may improve long-term polyethylene wear by providing increased surface conformity without constraint. Their routine use in the United States is hindered by current Food and Drug Administration regulations that require a minimum of 6 mm of polyethylene in the articulation. When combined with the thickness of the metal tray, composite thicknesses of mobile bearings in the United States approach 10 mm and prevent a conservative tibial resection. In Europe, polyethylene as thin as 3.5 mm is being used with good initial success. If research proves that this smaller thickness is sufficient in a mobile-bearing unit, it will allow a surgeon to remain conservative with the initial tibial resection, even in mobile-bearing designs.

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The Effect of Material Factors on the Short- and Long-Term Outcomes of Primary Total Knee Replacement

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Total knee replacements (TKRs) are typically composed of metallic components that articulate against an ultra-high molecular weight polyethylene (UHMWPE) component. While TKRs have been removed or revised due to failure of metallic components (Rimnac, Wright, Bartel, et al., 1991), the material of most concern with respect to its influence on both short- and long-term performance of TKRs is UHMWPE. One study reported that 25 percent of TKR revisions were related to UHMWPE damage and wear (Sharkey, Hozack, Rothman, 2002), exceeding the individual percentage of revisions attributed to loosening, instability, and infection. Osteolysis around TKRs, as a result of the generation of sub-micron-sized UHMWPE debris, also has become of increasing concern in the past 10 years (Peters, Engh, Dwyer, et al., 1992; Huang, Ma, Liau, et al., 2002).

In addition to patient factors, component geometry, and factors such as malalignment and abnormal kinematics, material factors affect the wear of UHMWPE tibial components. Therefore, efforts have been made to optimize UHMWPE component performance through consideration of resin type and manufacturing method (e.g., presence or absence of calcium stearate, compression molding, ram extrusion), sterilization method (e.g., gamma radiation in oxygen or low-oxygen environment, ethylene oxide gas, gas plasma), and modifications to the UHMWPE microstructure (crosslinking) (Kurtz, Muratoglu, Evans, et al., 1999).

Types of UHMWPE Wear Damage and Fracture

Wear damage occurs to the articulating surface of tibial and patellar components (Won, Rohatgi, Kraay, et al., 2000), to central cams and posts (Furman, Mahmood, Wright, et al., 2003), and to the backsurface of tibial components (Wasielewski, 2002). UHMWPE knee components can undergo adhesive, abrasive, and fatigue wear damage. Adhesive wear of tibial knee (and acetabular hip) components is believed to be related to the plastic flow behavior of UHMWPE (Kurtz, Rimnac, Pruitt, et al., 2000). Abrasive wear of UHMWPE components is related to the surface roughness of the counterface and also to the presence of third-body particulates (porous coating or bone cement debris). When third-body particulates are present, the wear of both conventional and crosslinked UHMWPE materials may be greatly increased compared with clean conditions (Widding, Scott, Jani, et al., 2003). The fatigue fracture behavior of UHMWPE is believed to affect pitting and delamination types of wear damage (Wright, Bartel, 1986). UHMWPE knee patellar components, condyles, and cams and posts of tibial components also can undergo gross fracture (Weightman, Isherwood, Swanson, 1979; Wright, Rimnac, Stulberg, 1992; Won, Rohatgi, Kraay, et al., 2000; Furman, Mahmood, Wright, et al., 2003; Hendel, Garti, Weisbort, 2003). This occurrence also is related to the fatigue and fracture strength of UHMWPE.

Influence of Resin Type, Manufacturing Method, and Sterilization Method

The potential deleterious effect of the additive calcium stearate was at one time controversial; however, the discussion is moot today because UHMWPE resins containing calcium stearate are no longer offered (Kurtz, Edidin, 2003). It is difficult to separate the influence of UHMWPE resin type and manufacturing method on component performance because these two variables often have been coupled (Won, Rohatgi, Kraay, et al., 2000). Subtle differences in the morphology and fatigue crack propagation behavior of compression-molding versus ram-extrusion UHMWPE have been reported (Pruitt, Bailey, 1998). Overall, it is unclear whether manufacturing method affects the performance of TKRs, although one clinical report of a single TKR design found that direct compression-molded tibial components had better long-term performance than ram-extruded and machined components (Weber, Worland, Keenan, et al., 2002). Regarding sterilization, retrieval studies of tibial knee components suggest that shelf aging and/or in vivo aging following gamma radiation sterilization in air can be detrimental to component performance (Collier, Sperling, Currier, et al., 1996). In particular, delamination in tibial knee components can be exacerbated by oxidative degradation (Bohl, Bohl, Postak, et al., 1999). Gross fracture also may be exacerbated by oxidative degradation (Wright, Rimnac, Stulberg, et al., 1992; Won, Rohatgi, Kraay, et al., 2000). Oxidative degradation of UHMWPE results in a decrease in fatigue crack propagation resistance (Baker, Hastings, Pruitt, 2000). Therefore, sterilization and processing methods have been modified to eliminate or substantially reduce oxidative degradation of UHMWPE. For example, UHMWPE components that are gamma radiation sterilized are now typically packaged in a low-oxygen environment. Poststerilization processes also are used now to consume free radicals and, thus, reduce oxidative degradation (Kurtz, Muratoglu, Evans, et al., 1999). Other forms of sterilization (ethylene oxide gas, gas plasma) do not affect the mechanical behavior of UHMWPE.

Influence of Modification of UHMWPE Microstructure

Highly crosslinked UHMWPEs, processed with a total dose ranging from 50 to 105 kGy, have been introduced for total hip replacement and TKR components to reduce wear (Kurtz, Muratoglu, Evans, et al., 1999; Muratoglu, Mark, Vittetoe, et al., 2003). In addition to radiation dose level, postirradiation thermal treatments (to reduce long-lived free radicals that could lead to oxidative degradation) also are employed. Crosslinking UHMWPE appears to be beneficial with respect to reduction of adhesive wear. Therefore, crosslinking UHMWPE may be beneficial for use in TKR components in terms of long-term performance. However, crosslinking adversely affects uniaxial ductility, and the uniaxial failure strain of UHMWPE decreases linearly with increasing radiation dose (Martell, Verner, Incavo, 2002). The choice of thermal treatment also affects the crystallinity and mechanical properties of highly crosslinked UHMWPE; the effect of these modifications on component performance is unknown. Crosslinking also leads to a reduction in fatigue and fracture resistance; therefore, its use in TKR components is of some concern because of the potential increased propensity for fracture. In this regard, one manufacturer uses a lower radiation dose (65 kGy) for crosslinked UHMWPE for knee components compared with the higher doses used for hip replacements; this lower dose presumably mitigates fracture risk. Also, crosslinked UHMWPE has not yet been introduced in cruciate-sacrificing tibial knee component designs with central posts, again possibly because of the concern of fracture.

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Directions for Future Research

With the continuing introduction of new UHMWPE formulations into clinical use, there is a need to develop a fundamental understanding of failure mechanisms in conventional and highly crosslinked UHMWPE materials so that material/design combinations of knee components at risk of in vivo fracture can be predicted. At present, total knee wear simulator testing is the primary method for preclinical verification of a TKR. Unfortunately, this method, at best, provides only some ranking of materials/designs with respect to wear resistance and provides even less guidance with respect to component fracture resistance. Furthermore, the ability to reliably predict stochastic failure and damage evolution in UHMWPE materials at the macroscale would assist in predicting failure events at the microscale. In this regard, a wear model that is based on polymer physics, as opposed to empirical observations, would be a valuable tool in modeling and predicting the performance of new and existing UHMWPE materials. The foundation for failure, damage, and wear theories for UHMWPE materials has been laid with the establishment of a physically based constitutive model for conventional and highly crosslinked UHMWPEs (Bergstrom, Rimnac, Kurtz, 2003). Continued efforts to improve preclinical predictions of the performance of TKR materials/designs and well-controlled retrieval analysis studies of in vivo performance of TKRs (to "close the design loop") are needed.

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The Effect of Knee Kinematics, Gait, and Wear on the Short- and Long-Term Outcomes of Primary Total Knee Replacement

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Introduction

The primary goals of total knee replacement (TKR) include restoring function and maintaining the long-term mechanical integrity of the device. An understanding of knee kinematics during ambulatory activities is fundamental to meeting both of these goals. In particular, short-term outcome depends on restoring ambulatory function during activities of daily living. Long-term failure modes, such as wear, fatigue failure, and loosening, are influenced by the kinematics of the joint because the cyclic mechanical demands on the joint depend on ambulatory function. This presentation examines the relationship between knee kinematics, patient function, and the mechanical factors that influence long-term wear failure modes of primary TKR.

Knee Kinematics and Ambulatory Function

The motion of the knee is complex and involves displacements with 6 degrees of freedom during most ambulatory activities. While the primary motion of the knee is flexion, the secondary displacements, including anterior-posterior (AP) translation, internal-external (IE) rotation, and abduction-adduction, play an important role in the overall function of the knee joint (Fukubayashi, Torzilli, Sherman, et al., 1982). During passive motion, the secondary displacements of the knee are coupled to knee flexion. Certain passive motions of the knee (screw-home; external tibial rotation with extension [Hallén, Lindahl, 1966] and femoral rollback; posterior movement of the femur with flexion [Andriacchi, Stanwyck, Galante, 1986]) have been characterized and are considered fundamental to normal knee function. The passive characteristics of the secondary movements of the knee have been related to the shape of the articular surfaces and ligament function (Wilson, Feikes, Zavatsky, et al., 2000). However, when extrinsic forces are present, the secondary motions are driven by the magnitude and direction of these forces because secondary motions such as AP translation or IE tibial rotation require relatively low forces to displace the joint from a neutral position (Markolf, Bargar, Shoemaker, et al., 1981; Markolf, Graff-Radford, Amstutz, 1978; Rudy, Sakane, Debski, et al., 2000). Therefore, during weight-bearing activities, the secondary displacements of the knee depend on extrinsic forces acting during a particular activity. Of course, the secondary displacements are contained within an envelope of passive limits of the joint (Blankevoort, Huiskes, de Lange, 1988).

The secondary displacements of the knee are extremely important to restoring normal function during activities of daily living. Two examples include stair climbing and squatting into deep flexion:

Stair Climbing. The ability to step up or down is required for restoring normal function following TKR. The AP displacement (secondary to flexion) of the knee has been shown to influence the ability of patients to ascend stairs in a normal manner (Andriacchi, Galante, Fermier, 1982.) Abnormal rollback was one explanation given for the reduced quadriceps moment associated with cruciate sacrificing because reduced rollback would shorten the lever arm of the quadriceps muscle (Andriacchi, Galante, Fermier, 1982). However, recent studies (Andriacchi, Dyrby, Johnson, 2003) demonstrate that the femur does not simply roll back with flexion during stair climbing. AP motion of the femur depends on the phase of the stair-climbing cycle. During the early swing phase, the femur moves forward with flexion as a result of the hamstring producing knee flexion. The femur begins moving posteriorly at approximately 45 degrees of flexion, probably as tension in the posterior cruciate ligament (PCL) increases. The results of the study suggest that restoring or replacing PCL function near 45 degrees of flexion is an important consideration in TKR.

Squatting Into Deep Flexion. The capacity for deep flexion is essential for activities of daily living for Indian, Middle Eastern, and Japanese cultures. However, even in Western cultures, a wide range of activities (recreational and occupational) requires deep flexion. Several recent studies (Andriacchi, Dyrby, Johnson, 2003; Hefzy, Kelly, Cooke, 1998) of deep flexion indicate the importance of IE during squatting into deep flexion. Squatting from a standing position requires approximately 150 degrees of flexion to a resting squat. Flexion between 0 and 120 degrees is accompanied by approximately 10 degrees of external rotation of the femur. However, between 120 and 150 degrees of flexion, the femur externally rotates an additional 20 degrees. Therefore, beyond 120 degrees of flexion, the knee requires substantial external rotation to achieve deep flexion. Currently, most designs of total knee arthroplasty can achieve 120 degrees of flexion. However, patients requiring deeper flexion will need the capacity for substantial rotation beyond 120 degrees.

Kinematics and Wear

Implant wear is the primary mechanical factor limiting the long-term outcome of TKR. The kinematics of the knee is a critical factor influencing wear at the joint (Wimmer, Andriacchi, 1997; Wimmer, Andriacchi, Natarajan, et al., 1998). Again, the secondary displacements are an important consideration in the outcome of TKR because these displacements have a substantial influence on wear.

Rolling Versus Sliding. Subtle variations in rolling, tractive rolling, and sliding motion and the direction of the pathway of motion can have substantial effects on the production of wear debris or cyclic fatigue of the ultra-high molecular weight polyethylene (UHMWPE) (Wimmer, Andriacchi, 1997). The degree of rolling and sliding can be quantified by the slip velocity. The magnitude of the interfacial slip velocity provides quantification of the rolling versus sliding behavior of the tibiofemoral joint when relative motion occurs. For pure rolling, the interfacial slip velocity approaches zero (Johnson, 1985; Johnson, Andriacchi, Laurent, 2000; Johnson,

Andriacchi, Laurent, et al., 2001). The absolute maximum slip velocities occur during swing phase just before heelstrike. A previous knee simulator study (Johnson, Andriacchi, Laurent, 2000) showed that the maximum wear rate was significantly greater when these slip velocities were incorporated as input to the simulator relative to studies in which the slip velocities were not applied. Therefore, the high slip velocities during heelstrike and during swing phase indicate the potential for sliding motion that can produce a greater volume of abrasive wear debris.

The considerable differences in the wear scar formation between retrieved and simulator-tested implants (Harman, DesJardins, Banks, et al., 2001) can be explained by differences between in vivo kinematics and the type of kinematics used in wear simulators. In addition, the variability of in vivo wear scar formation has been related to the variability of human gait after TKR (Wimmer, Nechtow, Kleingries, et al., 2003). Most of the variability in worn contact area can be explained by gait abnormalities of TKR patients. These abnormalities cause larger wear areas contributing to possibly higher wear rates. Since most TKR patients walk with an abnormal gait pattern, knee simulator input parameters should be reconsidered.

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Osteolysis: Etiology and Emerging Nonsurgical Treatments

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Inflammation in Periprosthetic Osteolysis

Early loosening may reflect poor surgical technique, infection, or mechanical overload. After several years of bone loss at the bone-prosthesis interface, osteolysis seems to be the critical process responsible for loosening. This osteolysis appears to result from an inflammatory reaction to particulate debris generated from the prosthesis. At the interface between the prosthesis and the bone, a membrane resembling the synovial membrane of joints and tendons is formed; this membrane is composed principally of fibroblasts and macrophages. The quest for more durable and wear-resistant materials, which will generate less wear debris, and other aspects of better implant designs continue to be areas of active investigation. However, several groups, including our own, have focused on the host response to wear debris, postulating that wear-debris-induced osteolysis is the major cause of prosthetic implant failure (Goldring, Jasty, Roelke, et al., 1986). In this model, wear debris generated from the prosthesis is phagocytosed by macrophages and initiates an inflammatory response that leads to the recruitment of activated osteoclasts and osteolysis at the bone-implant interface.

Potential Therapies

Currently, no drugs are specifically approved for the treatment of aseptic loosening of prostheses. However, the above paradigm for loosening (i.e., wear-debris-induced, tumor necrosis factor (TNF)-alpha-mediated inflammation resulting in osteoclast activation) suggests that three categories of drugs should be tested for their ability to prevent or treat loosening of prosthetic joints (Schwarz, Looney, O'Keefe, 2000).

The first category is the bisphosphonates. These drugs can inhibit osteoclasts, are effective, and are used widely to prevent or treat osteoporosis. A recent small clinical study showed that alendronate can reduce the periprosthetic bone loss that develops soon after total hip replacement. However, as the authors of that study point out, this early bone loss is probably secondary to stress shielding rather than to wear-debris-induced inflammation. Indeed, patients who had a total hip replacement more than 5 years previously or who were awaiting revision surgery for loosening did not have a similar increase in periprosthetic bone density when treated with alendronate. Unfortunately, periprosthetic osteolysis was not an endpoint in this study. The effects of bisphosphonates on inflammation-induced osteolysis also have been evaluated in patients with rheumatoid arthritis (RA). In three studies, the effects of bisphosphonates on radiographically evaluated erosions have varied but have been predominantly negative. In one small study (a total of 27 patients randomized to either 1,000 mg/day of pamidronate by mouth or placebo for a year), erosions in the treated group progressed less rapidly. However, no such effect was found in two larger studies (a total of 40 patients given 30 mg of pamidronate or

placebo intravenously each month for a year, and a total of 105 patients given 300 mg/day pamidronate or placebo by mouth for 3 years). In this study, spinal and femoral bone mineral density improved significantly in the treated group even though the erosions progressed. Although it is possible that the doses used were inadequate to block osteolysis, these studies in humans suggest that bisphosphonates may be less effective for use against inflammation-induced osteolysis than against generalized osteoporosis. On the other hand, a report on how zolendronate blocks bone resorption in a rabbit/carrageenan model of inflammatory arthritis indicates that bisphosphonates may be effective in some types of inflammation-induced osteolysis.

A second category of drugs for the treatment of prosthetic loosening comprises those designed to inhibit TNF, namely etanercept and infliximab. Both of these agents are potent inhibitors of synovial inflammation and both have been approved worldwide for the treatment of RA. Recent studies have shown that both can block erosions in this disease. Because of their effects on erosions in RA and on wear-debris-induced osteolysis in animals, these anti-TNF agents are the most promising medications available for the treatment of established loosening. However, they are very expensive and therefore should not be used to treat loosening until their efficacy is proven in clinical trials.

Finally, a third category of drugs to treat prosthetic loosening comprises the biologics being developed that interfere with RANK/RANK-ligand signaling. RANK (receptor activator of nuclear factor-kappaß) is a receptor on osteoclasts and osteoclast precursors that transmits a signal required during osteoclast and lymph node development. RANK-ligand (also known as OPGL, ODF, and TRANCE) is an agonist for RANK and is expressed on osteoblasts and activated T cells; it provides the essential signal for osteoclast differentiation and survival. Osteoprotegrin (OPG) is a natural decoy receptor that binds RANK-ligand and prevents it from interacting with RANK. The biologics being developed to inhibit osteoclasts include recombinant OPG and a soluble form of RANK. The potency of these molecules is best illustrated by the phenotype or transgenic mice that overexpress these factors and suffer from osteopetrosis. Preliminary studies in an animal model indicate that a soluble chimeric RANK-Fc molecule has no effect on inflammation but completely inhibits osteoclast induction and wear-debris-induced osteolysis in vivo. Therefore, these new RANK-based biologics, which are even more potent inhibitors of osteoclasts than the bisphosphonates, may offer another future approach to the treatment or prevention of periprosthetic osteolysis.

Need for Better Imaging Techniques

The development of three-dimensional (3-D) imaging now permits quantitative analysis of bone loss in the periacetabular region (Looney, Boyd, Totterman, et al., 2002). In association with other validated clinical and laboratory outcome measures, 3-D imaging will provide a comprehensive outcome measure of drug performance. This work provides an important basis for the development of clinical trials examining intervention in this complex disease process and is an important advance in our assessment of periprosthetic bone loss.

Pilot Study of Etanercept in Periacetabular Osteolysis (Schwarz, Boyd, Totterman, et al., 2003)

The cytokine TNF-alpha has been demonstrated to be central to this process and is considered to be a leading target for intervention. Unfortunately, even though the Food and Drug Administration (FDA)-approved TNF antagonists are available, such as etanercept, no reliable outcome measures exist to evaluate the efficacy of a drug to prevent periprosthetic osteolysis. To develop an effective outcome measure, we evaluated the progression of lesion size in 20 patients with established periacetabular osteolysis (mean 29.99 cm^3, range 2.9–92.7 cm^3) of an uncemented primary total hip replacement over 1 year, using a novel volumetric computer tomography (3D-CT) technique. We also evaluated polyethylene wear, urine N-telopeptides, and functional assessments (Western Ontario McMaster [WOMAC]) osteoarthritis index, SF-36 health survey, and Harris hip score) for comparison. At the time of entry into the study, baseline CT scans were obtained and the patients were randomized to etanercept (25 mg s.q., twice/week) and placebo in a double-blinded fashion. CT scans, urine, and functional assessments also were obtained at 6 and 12 months. No serious adverse drug-related events were reported, but one patient required revision surgery before completion of the study because of aseptic loosening. No remarkable differences between the groups were observed. However, the study was not powered to see significant drug effects. 3D-CT data from the 19 patients were used to determine the mean increase in lesion size over 48 weeks, which was 3.19 cm^3 (p < 0.0013). Analysis of the urine N-telopeptides and functional assessment data failed to identify a significant correlation with wear or osteolysis. In conclusion, volumetric CT was able to measure progression of osteolysis over the course of a year, thus providing a technology that could be used in therapeutic trials. Using the data from this pilot, we provide a model power calculation for such trials.

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Osteolysis: Surgical Treatment

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Implant Failure

When an implant fails because of wear and osteolysis, the surgeon must try to identify the underlying cause, particularly if the failure is premature (i.e., less than 10 years after implantation). The problem often can be identified and corrected with revision surgery.

Patient factors, surgical technique factors, and implant factors must be considered on a case-by-case basis. Patient factors, such as size and activity level, are largely out of the surgeon's control. If an error in surgical technique is evident, such as malalignment or instability, revision surgery must be directed to correcting the surgical error. If the underlying problem is with the implant design, fabrication, or sterilization, the deficiency must be eliminated with the revision implant.

To plan for the revision surgery, the surgeon must have knowledge of the implant system being revised. The operative report from the patient's primary arthroplasty is needed to identify the manufacturer and size of the implant. When retention of any of the primary components is contemplated, product identification labels provide the most reliable source of information. The labels should be obtained to determine whether acceptable modular parts are available from the manufacturer.

Surgical Options for Revision Total Knee Arthroplasty With Modular Components

Four surgical options exist for managing wear and osteolysis with modular components. These options include modular tibial insert exchange using standard inserts, tibial insert exchange using custom or modified inserts, tibial component revision, and full revision of both the femoral and tibial components.

Polyethylene Insert Exchange. When an implant fails prematurely for wear and osteolysis, materials issues must be evaluated. However, the influence of design, fabrication, and sterilization methods on wear-related factors is difficult to analyze. Clinical studies rarely contain information on the method of sterilization and shelf life, factors known to adversely affect the mechanical properties of polyethylene through oxidation (Bohl, Bohl, Postak, et al., 1999; McGovern, Ammeen, Collier, et al., 2002). Although manufacturers have abandoned this method of sterilization, the shelf lives of most implants in retrieval analyses and clinical outcome studies are unknown.

Modularity also may play a part in accelerated wear by contributing additional debris from backside insert wear and baseplate wear (Engh, Lounici, Rao, et al., 2001; O'Rourke, Callaghan, Goetz, et al., 2002; Wasielewski, Parks, Williams, et al., 1997). If the original insert

failed because of oxidation from a prolonged shelf life or because of a poor modular locking mechanism, the revision insert must not reintroduce the same deficiency. In this situation, simple insert revision is not an acceptable option.

Although insert exchange would appear to be an attractive revision option with anticipated low morbidity, the results have been discouraging. In one study, 48 knees managed with modular tibial insert exchange were followed for an average of 7.4 years (Engh, Koralewicz, Pereles, 2000). Six of 22 inserts (27 percent) exchanged because of severe wear of the primary insert failed fewer than 5 years after the exchange. When insert wear was not the primary reason for revision, only one implant failed insert exchange. Therefore, insert exchange did not address the problem of severe wear or a deficient modular locking mechanism. In addition, it is important to note that the shelf life of the new polyethylene insert was unknown and may have contributed to failure of the insert exchange.

Insert Exchange With a Modified Modular Tibial Insert. Modular interface wear may sometimes be secondary to a design issue with the tibial insert. In a study of tibial osteolysis by Peters and colleagues (1992), the high central tibial eminence of the polyethylene insert was noted to have severe wear from impingement on the intercondylar recess of the Synatomic femoral component. Removal of this eminence on a modified insert resulted in a successful outcome with insert exchange. Only 1 of 10 cases failed with this modified insert (Engh, Parks, Ammeen, 1994).

A second option in this surgical management category, with unpublished but reportedly successful outcomes, is to eliminate backside motion by stabilizing a modular insert with cement fixation. This technique is particularly applicable with posterior-stabilized total knee implants in which impingement and post wear have been identified as a potential source of wear debris and a cause of backside tibial insert wear. Although this approach does not eliminate the potential for post wear, it is hoped that it will eliminate backside wear.

If insert wear is due to malalignment, a custom implant can be fabricated to correct the problem. Up to 4 degrees of angular deformity can be corrected with such a modified insert.

Tibial Component Revision. If the tibial component is to be revised and the femoral component retained, the new tibial implant must have an intact and proven modular component locking mechanism. Otherwise, the surgeon should consider tibial component revision to a one-piece tibia or full revision to an implant with a more stable locking mechanism.

A tibial baseplate that reduces backside wear can provide an alternative to full knee revision. One option that does not eliminate backside motion but should reduce wear is the use of a polished cobalt chrome baseplate. I have managed 65 knees with osteolysis by converting an unpolished titanium tibial baseplate to a polished cobalt-chrome baseplate. Of 46 knees with minimum 2-year followup after tibial component re-revision (mean: 62 months [range, 25–189]), this procedure has been successful in 37 knees. The remaining nine knees required additional surgery.

Full Knee Revision. Specific results of full knee revision for management of wear and osteolysis have not been reported. In most total knee revision studies, the reported reason for

revision surgery was aseptic loosening, not wear and osteolysis. In many instances, full knee revision is the only option when an implant fails from wear and osteolysis, particularly if bone support is severely compromised and fracture has occurred, or is likely to occur, through an osteolytic bone defect. If the primary implant is obsolete and replacement parts for the primary system are not available, full revision is the only option. Similarly, if the polyethylene inserts available with the primary components were gamma irradiated in air with an unknown or unacceptable shelf life, all components must be revised. In addition, if the implant in situ has significant backside wear and a revision component is not available to minimize backside wear by an improved locking mechanism design, full revision is the only option.

At the Anderson Clinic, 124 full knee revisions have been performed secondary to wear and osteolysis. A total of 67 knees had osteolytic defects on both the femoral and tibial sides. A minimum 2-year followup (mean: 62 months [range, 24–159]) of 73 knees revealed that only 4 knees have undergone re-revision. In 30 knees, large osteolytic bone defects were repaired with allograft bone. Even though these knees had the most severe damage from wear debris, the outcome of revision surgery was most successful with full revision.

Conclusions

A variety of surgical options are available with revision arthroplasty to manage wear and osteolysis. As long as the underlying mechanism for accelerated wear is addressed and eliminated with the revision implant, the outcome of revision surgery is similar to revision surgery for other reasons. Although revision implants are considerably more expensive than primary components, the best results appear to be with full revision. Because revision implants have been available for only 10 years, longer followup is necessary to determine the durability of such components and to compare their outcome with that of primary total knee implants. In my practice, when I examined the clinical outcome according to the four surgical options for managing wear and osteolysis, the Knee Society clinical scores of my patients are relatively similar to each other and to the results with primary knees (table 1).

Table 1. Clinical outcomes by surgical option

Surgical Option	Mean Knee Society Clinical Score	Mean Knee Society Functional Score	Mean Arc of Motion
Insert Exchange	84 pts. (range, 40–99)	78 pts. (range, 0–100)	105° (range, 61°–124°)
Modified/Custom Insert Exchange	87 pts. (range, 65–100)	70 pts. (range, 45–100)	109° (range, 94°–130°)
Tibial Re-revision	82 pts. (range, 49–100)	67 pts. (range, 0–100)	100° (range, 0°–135°)
Full Revision	87 pts. (range, 45–100)	69 pts. (range, 0–100)	106° (range, 35°–140°)

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Medical Interventions That Influence Outcomes of Primary and Secondary Total Knee Replacement

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Several medical interventions can potentially affect outcomes of primary and secondary total knee replacement (TKR). Some of these interventions have been studied and reported in detail, and yet a definitive answer is still elusive. These medical interventions include blood management, type of anesthesia, deep vein thrombosis (DVT) prophylaxis, antibiotic prophylaxis, and pain management.

Blood Management

The use of allogeneic blood has been shown to be a risk that should be avoided if possible in primary and secondary TKR. It has been associated with immunomodulation and subsequent increased infections and length of hospital stay. The alternatives to allogeneic blood are autologous blood, salvage and reinfusion, hemodilution, and treatment of anemia with pharmaceuticals. All of these techniques have shown decreased allogeneic blood usage; however, no technique in regular use today has been able to decrease allogeneic use below 6 percent. One of the problems has been the lack of a consistently applied transfusion protocol. Another problem has been the overutilization and wastage of autologous blood. In addition, many questions still exist about the cost-effectiveness and the actual real cost of these techniques.

Anesthesia

A controversy still exists regarding the use of regional versus general anesthesia in TKR. Most studies comparing regional and general anesthesia have been done without the use of DVT prophylaxis in the general anesthesia arm. In these series, regional anesthesia has had fewer DVTs. The studies have been in high-risk general surgery populations. In one randomized prospective study of TKR patients, there was no difference in morbidity or DVT rate.

DVT Prophylaxis

Multiple agents have been studied for prevention of DVT and pulmonary embolus. These agents have been reasonably successful in the prevention of DVT, but a fatal pulmonary embolus rate of approximately 1 percent has been found in all the studies. The studies also have shown an increased risk of bleeding complications. In addition, some recent studies, not well controlled, have shown an increase in infection rate with the use of DVT prophylaxis.

Antibiotic Prophylaxis

The use of prophylactic antibiotics has been shown to be effective in decreasing infection rates post TKR. The use of antibiotics in cement has been shown to be effective in decreasing infection in European and Scandinavian studies. Usage in the United States has been hampered by lack of Food and Drug Administration (FDA) approval and worry about the development of resistant organisms in the patients developing infections.

Pain Management

Studies have been done to evaluate pain management after TKR. The studies have shown that adequate pain management is essential for rehabilitation. However, no single method has been shown to be both effective and risk free.

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Pre- and Postoperative Rehabilitation Interventions That Influence Outcomes of Primary and Secondary Total Knee Replacement

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Preoperative Physical Therapy and Exercise Programs

Patients with osteoarthritis (OA) exhibit significant physical impairments and functional limitations when compared with their peers who do not have OA. Studies have shown that exercise and physical therapy (PT) for knee OA provide benefit (Minor, Hewett, Webel, et al., 1989; Ettinger, Burns, Messier, et al., 1997). Exercise is recommended as an initial OA intervention by the American College of Rheumatology. Therefore, exercise prescription should be a part of the routine management of patients with knee arthritis. Exercise as a specific preoperative strategy has not been studied extensively. Most studies are limited by small sample size, lack of randomization, and failure to account for the numerous other perioperative interventions or patient-specific factors that affect outcome.

In a randomized, controlled trial, Deyle and colleagues (2000) compared PT to placebo (subtherapeutic ultrasound). The PT group exhibited significant improvements; 20 percent of the untreated patients went on to total knee arthroplasty (TKA) compared with only 5 percent of the therapy group. In a small prospective trial, Rodgers and colleagues (1998) reported that PT before TKA produced modest gains only in flexion strength and muscle area. D'Lima and coworkers (1996) assigned 10 patients to each of 3 preoperative groups (control, PT, and aerobic exercise). All three groups showed improvement after surgery, but there were no significant differences in ultimate outcome. Wang and coworkers (2002) randomized 28 patients scheduled for TKA to either PT or "routine" care. Gait characteristics were better in the exercise group. Therefore, although there are no large, controlled prospective trials of preoperative PT, available literature, anecdotal evidence, and data regarding positive effects of exercise in knee OA suggest that exercise should be a routine recommendation before total knee replacement (TKR) surgery. The overall efficacy of PT as well as specific PT treatments must be evaluated.

Preoperative Patient Education

Preoperative educational interventions are used increasingly to facilitate streamlined postoperative care. However, limited data are available to evaluate the impact of these programs. Daltroy and colleagues (1998) suggested that total joint replacement (TJR) patients who exhibit the most denial and the highest anxiety achieved the greatest benefit from preoperative education. Maurer and coworkers (1999) compared the effects of exercise versus patient education on pain and function. Exercisers improved more than those receiving education. In a prospective, observational study, Brander and colleagues (2003) reported that heightened preoperative anxiety and depression were associated with excessive pain and poor outcome after

TKA, suggesting that preoperative treatments of psychological impairments (such as self-efficacy training or treatment of depression) might be useful. Anecdotal evidence suggests that preoperative education may increase patient satisfaction and facilitate the discharge process. In summary, specific preoperative education may be useful, particularly in anxious patients. More research is needed to identify the most efficient forms of preoperative patient education.

Postoperative Rehabilitation Interventions

The goals of rehabilitation following TKA are to obtain rapid recovery of knee motion, strength, and independence. No research exists to support the use of any specific postoperative exercise protocols. Kramer and coworkers (2003) compared home exercise to outpatient PT after TKA and found no differences in overall outcome. In a randomized prospective trial, Hewitt and Shakespeare (2001) suggested that flexion-based exercises are superior to extension after TKA. The use of continuous passive motion (CPM) following TKA remains controversial. Although several studies suggest that CPM allows for greater early knee flexion, less pain, and fewer manipulations, studies are consistently unable to prove long-term benefit. One randomized, controlled trial (McInnes, Larson, Daltroy, et al., 1992) reported that although CPM increased flexion and decreased swelling and the number of manipulations, it did not affect pain, extension, strength, or outcome. However, CPM did result in cost savings as a consequence of fewer manipulations. Pope and coworkers (1997) prospectively randomized 53 patients to no CPM, CPM of 0 to 40 degrees, or CPM of 0 to 70 degrees. At 1 week, the patients in the 0 to 70 CPM category exhibited greater flexion but required more analgesics and had more blood loss. At 1 year, there were no significant differences. Kumar and colleagues (1996) prospectively compared CPM with early passive flexion of the knee (the "drop and dangle" exercise method). Compared with patients in the CPM group, patients in the drop-and-dangle group were discharged from the hospital 1 day earlier, had better extension range at 6 months, and had less wound drainage. Comparing CPM to home PT, Worland and colleagues (1998) reported no differences in outcome at 6 months, yet the costs for CPM were much lower than the costs for PT. In summary, no specific research supports the use of particular postoperative rehabilitation protocols. CPM may be a cost-effective intervention, facilitating early knee flexion after TKA but without apparent long-term significance. A subset of patients, such as those with very stiff or painful knees, might gain an advantage from CPM. Further study is needed to clarify this possibility.

Postacute Inpatient Rehabilitation Care

Since the introduction of diagnosis-related group (DRG)-based Medicare payments to acute care hospitals, length of hospital stay after TJR has been reduced dramatically through earlier mobilization of patients, streamlining care, discharging patients at lower functional levels, and transferring patients to DRG-exempt rehabilitation units. Several investigators have sought to predict the patients with TKA who might require prolonged inpatient care. In a retrospective study, Forrest and coworkers (1998) reported that only age and diabetes correlated with the need for inpatient rehabilitation after total joint arthroplasty (TJA). No prospective, randomized trials have evaluated differences in outcome between patients discharged to home and those sent for inpatient rehabilitation. Early transfer, by postoperative day (POD) three, to inpatient

rehabilitation has become a common clinical practice, the merits of which have been debated. Its proponents believe that patients at risk for poor recovery warrant aggressive inpatient rehabilitation to achieve their goals. Others argue that the practice is simply a cost-shifting maneuver. In a prospective, randomized controlled trial, Munin and colleagues (1989) sought to determine the effect of early transfer of high-risk patients to inpatient rehabilitation. Patients who were transferred at POD 3 compared with POD 7 exhibited shorter length of stay, lower total cost, more rapid achievement of goals, and equivalent 4-month outcomes. Mahomed and coworkers (2000) retrospectively surveyed TJA patients and found no differences between those who went to inpatient rehabilitation and those who went home. Therefore, further research on the utility of postacute inpatient care is imperative in light of the common utilization of inpatient rehabilitation services, the costs associated with this care, and the clear need for extended rehabilitative care in the most disabled patients.

Long-Term Exercise Guidelines for TKA Patients

Studies of individuals following TKA have demonstrated persistent physical impairments and functional limitations. These impairments should be used to guide prescription of specific rehabilitation interventions. Fuchs and colleagues (1999) described reduced proprioception after TKA. Berman and coworkers (1991) found reduced quadriceps strength 2 years following surgery. Huang and coworkers (1996) reported abnormal quadriceps-hamstring strength ratios more than 6 years after surgery. Lorentzen and colleagues (1999) described a loss of isometric flexion strength in the operated limb after surgery. Wilson and coworkers (1990) reported reduced knee range of motion during walking and stair descent but normal gait after TKA. The use of rehabilitation techniques similar to the treatment of patellofemoral pain syndrome (PFPS) might be extrapolated to the TKA population given the similarity of functional biomechanical deficits. Like PFPS patients, TKA patients experience impairments that include medial quadriceps insufficiency; inflexibility of the lateral retinacula, iliotibial band, hamstrings, and gastrocnemius muscles (which increase effective knee flexion or cause lateral tracking of the patella); gluteus medius and hip external rotator weakness (leading to medial rotation of the femur); imbalance of hip internal and external rotators; and excessive pronation of the foot. Rehabilitation methods can include incorporating taping of the patella, proper shoe orthotics, strengthening of the quadriceps (VMO) via a short-arc (<45 degrees of knee flexion) to minimize patellofemoral joint stress, and hip external rotator strengthening. Specific exercise strategies need further study.

The long-term impact of regular physical activity on prosthetic longevity is debated. The common belief is that regular physical activity, through imparting greater stress on the prosthetic joint, leads to more rapid wear and early failure. Most studies have not directly evaluated the impact of exercise on TKR longevity. Instead, assumptions are based on lab testing of implant materials, mathematical models, and clinical outcome studies in which age is used as a proxy for activity. All of these methods pose difficulties when extrapolated to the clinical setting. For example, the strength of in vitro testing is its incorporation of bone and material into the test; however, it offers only a very basic model of a much more complicated physiologic situation. Analytical estimates are similarly primitive, lacking contributions from other muscle groups and out-of-plane forces. Wide variations in activity among persons of specific age groups make activity assumptions based on age fairly invalid. Kuster and colleagues (2000) tested the

compressive forces generated during recreational activities. Using pressure-sensitive film, the researchers measured the amount of implant surface area that was loaded to the polyethelene "yield point." Cycling caused the least stress; power walking led to no overloaded areas. However, downhill hiking and jogging were associated with significant overloaded areas. In summary, regular exercise offers numerous health benefits; however, the effect of exercise on implant longevity, patient satisfaction, and quality of life after TKA requires further investigation.

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Indications and Approaches for Revision Total Knee Replacement and Salvage Procedures

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Indications

Approximately 5 to 10 percent of total knee arthroplasties require revision within 10 to 15 years (Emmerson, Moran, Pinder, 1996; Falatyn, Lachiewicz, Wilson, 1995; Malkani, Rand, Bryan, et al., 1995; Nafei, Kristensen, Knudsen, et al., 1996; Ranawat, Flynn, Saddler, et al., 1993; Rand, Ilstrup, 1991; Rinonapoli, Mancini, Azzara, et al., 1992; Ritter, Herbst, Keating, et al., 1994; Schai, Thornhill, Scott, 1998; Weir, Moran, Pinder, 1996; Whiteside, 1994). Revision surgery is most commonly indicated for the treatment of infection, mechanical loosening, and instability. Polyethylene wear has emerged as an important cause of the need for revisions, and more recently, modularity of implants and back-side wear have been found to be additional causes of osteolysis, especially with noncemented fixation. Contrary to the published data, revision for patellar loosening, fracture, or dislocation has been required in less than 1 percent of cases in the senior author's experience. Revision surgery is occasionally necessary to gain motion in patients with stiffness after knee replacement. The principles of revision knee arthroplasty are similar to those of primary surgery. These principles include obtaining a wide exposure, restoring the mechanical alignment in three planes, maintaining the joint line, balancing the ligaments and soft tissue, restoring the functioning quadriceps, achieving good cement fixation, and replacing any substantial bone loss with metal wedges or bone graft.

It is important to know the cause of failure before planning surgery. In most situations, the reason is obvious. Patients with ill-defined pain without any clear-cut evidence of infection may have low-grade sepsis. Definite diagnosis in these cases can be very difficult, and care must be taken in trying to ascertain the cause of pain before revision surgery. Referred pain from the spine should be ruled out before the decision to revise the implant is made.

Exposure

If there are multiple incisions, they require careful attention. The principle of maintaining a skin flap width-to-length ratio of 2 to 1 should be followed, and the surgeon must take care to avoid creating an "island of avascular skin." A lateral incision is preferred when multiple scars are present; a longitudinal straight incision can incorporate the old incision. A well-healed vertical or longitudinal incision, which can be lifted from the subcutaneous tissue, is best during surgery and does not interfere with healing. The skin should be felt to assess whether it is movable. If the scar adheres to the deeper structures or if split-thickness skin grafts were used in the past, consideration should be given to using a tissue expander in consultation with a plastic surgeon.

The skin flaps are undermined minimally on both sides to expose the quadriceps tendon. The tendon is entered on the medial side, leaving a few millimeters of tendon medially along with the vastus medialis for later closure. All of the scar tissue from the parapatellar gutters under the quadriceps is removed to free the quadriceps. The knee is exposed by releasing the soft tissue subperiosteally on the medial side of the proximal tibia, which is externally rotated as the sleeve is developed. The dissection is continued to the posteromedial aspect of the tibial condyle. Any scar tissue present in the region of the posterior cruciate ligament is excised from both the femur and tibia. The tibia is externally rotated and brought anterior to the femur with the knee flexed to 90 degrees.

Exposure in the Stiff Knee

When revision surgery is performed for stiffness, which is defined as preoperative flexion of less than 60 degrees, the following choices are available for exposure: V-Y plasty, quadriceps tendon snip, long tibial tubercle osteotomy, and subperiosteal sleeve dissection.

The V-Y plasty (Coonse, Adams, 1943; Insall, 1984) involves a standard medial parapatellar arthrotomy combined with a second incision that begins at the proximal end of the first and proceeds obliquely distally through the quadriceps tendon and lateral retinaculum, creating an inverted V. This technique provides excellent exposure but at the cost of disrupting the blood supply to the patella and distal quadriceps tendon as well as an increased incidence of extensor lag and weakness of extension (Aglietti, Buzzi, D'Andria, 1991; Trousdale, Hanssen, Rand, et al., 1993).

The quadriceps tendon snip is a later modification of the V-Y plasty with a shorter second limb directed obliquely and proximally from the proximal extent of the initial medial arthrotomy (Vince, 1993). This modification is less disruptive to the blood supply to the patella and quadriceps tendon but does not allow for adjustment of the quadriceps tension during closure.

The long tibial tubercle osteotomy involves an 8- to 10-centimeter osteotomy of the tibial tubercle (Whiteside, Ohl, 1990). Care is taken to preserve the lateral soft-tissue attachments to the fragment to maintain its blood supply because a major concern of this technique is healing of the osteotomy.

The preference is to use the subperiosteal sleeve dissection in combination with a lateral release. With this technique, there is a controlled lengthening and release of the soft tissue from the medial and posterior aspects of the tibia and also from the lateral aspect of the femur. The soft tissue is elevated subperiosteally off of the tibia, progressing further distally as necessary. Posteriorly, the insertion of the semimembranosus is sharply elevated. The lateral release involves clearing the lateral gutter of scar tissue and releasing the patellofemoral ligament. If the iliotibial band is tight, it is lengthened with multiple stab incisions. The posterolateral capsule, popliteus tendon, and lateral collateral ligament are released from the femur when necessary. This technique allows a wide exposure of the knee and increases the range of motion at the time of surgery to approximately 90 degrees. If it is still difficult to mobilize the patella after the subperiosteal sleeve dissection/lateral release, then a quadriceps snip is performed.

Removal of the Components

Removal of the tibial and femoral components involves opening the cement-bone interface. To do this, a combination of a high-speed burr (e.g., Midas Rex), oscillating saw, osteotomes, and a component extraction device (e.g., Big Bertha extractor) is used. The emphasis at this stage is on meticulous technique to preserve as much of the host bone as possible.

Results of Revision Total Knee Arthroplasty

Good or excellent results have been obtained on average in approximately 70 percent of patients (Fehring, Griffin, 1998; Friedman, Hirst, Poss, et al., 1990; Goldberg, Figgie, Figgie, et al., 1988; Jacobs, Hungerford, Krackow, et al., 1988; Murray, Rand, Hanssen, 1994; Rand, 1991; Rand, Bryan, 1988). These results are not as good as those obtained after primary total knee replacement, where good-to-excellent results are generally obtained in more than 90 percent (Colizza, Insall, Scuderi, 1995; Dennis, Clayton, O'Donnell, 1992; Goldberg, Figgie, Figgie, et al., 1988; Hanssen, Rand, 1988; Ranawat, Flynn, Saddler, 1993; Ranawat, Luessenhop, Rodriguez, 1997; Rinonapoli, Mancini, Azzara, et al., 1992).

Only a few studies have examined survivorship after revision total knee arthroplasty. Ritter and colleagues reported a 97-percent survival rate at 6 years using prosthesis removal as the endpoint (Ritter, Eizember, Fechtman, et al., 1991). Others did not find revision surgery to be as durable, with 8-year survivorships of 75 percent and 83 percent in two different studies (Haas, Insall, Montgomery, et al., 1995; Peters, Hennessey, Barden, et al., 1997). These latter results are inferior to those obtained after primary total knee arthroplasty, with 10- to 20-year survivorships of more than 90 percent in most reports (Emmerson, Moran, Pinder, 1996; Falatyn, Lachiewicz, Wilson, 1995; Font-Rodriguez, Scuderi, Insall, 1997; Malkani, Rand, Bryan, et al., 1995; Nafei, Kristensen, Knudsen, et al., 1996; Ranawat, Flynn, Saddler, et al., 1993; Rinonapoli, Mancini, Azzara, et al., 1992; Ritter, Herbst, Keating, et al., 1994; Schai, Thornhill, Scott, 1998; Weir, Moran, Pinder, 1996).

Salvage Procedures

Failure after revision total knee arthroplasty, which occurs infrequently, presents a difficult challenge; salvage may be the only available option. Salvage options include knee arthrodesis, resection arthroplasty, and above-knee amputation. Indications for knee arthrodesis include situations in which reimplantation is unlikely to be successful, such as multiple failed two-stage reimplantation, infection with antibiotic-resistant organisms, or infected knee arthroplasty with bone or soft-tissue loss, particularly extensor mechanism or collateral ligaments. Knee arthrodesis may be contraindicated in nonambulatory patients, severe uncontrollable infection, unreconstructable soft tissue or bone loss, or severe vascular insufficiency or in patients with severe ipsilateral hip or ankle or contralateral knee problems that would preclude adequate function after knee fusion. In these rare instances, consideration may need to be given to resection arthroplasty or above-knee amputation.

Conclusion

The principles of revision total knee arthroplasty are similar to those of primary surgery. These include restoring the joint line and mechanical alignment of the knee, soft-tissue balancing, and preserving bone stock. Surgery often is made more difficult in revision cases because of previous incisions raising concerns of skin vascularity; scarring obscuring normal anatomy; the necessity of component removal; lack of bone stock requiring bone graft or metal wedges; incompetence of soft tissue, including ligaments and patellar tendon, necessitating constrained components; and tendon augmentation. These factors make it even more critical during revision surgery that the surgeon maintain careful attention to detail with adherence to the general principles mentioned above. By doing so, good-to-excellent results can be obtained in more than two-thirds of the cases.

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Salvage Procedures for Failed Total Knee Replacement

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A Definition of Salvage Procedures

Salvage procedures are used when revision of the failed total knee is not possible; alternate procedures are employed to provide the patient with continued functional use of the limb. In most cases in which salvage procedures are required, infection is a prominent feature, and removal of the total knee arthroplasty (TKA) has been necessary before salvage. Advances in soft tissue transfers (Sanders, O'Neill, 1981), bone grafting, and transplantation, as well as a better understanding of the periprosthetic infection, have resulted in a much higher rate of revision for failed (and infected) TKAs. However, there are occasions when revision is ill advised and salvage procedures must be employed.

Indications

Heroic attempts at revision arthroplasty in the face of repeatedly failed TKAs may seem reasonable in some settings and unreasonable in others. The surgeon (and certainly the patient) facing the consequences of the failed arthroplasty must be aware of the potential risks and benefits of the various available interventions, specifically as related to the anatomic and physiologic attributes of the limb (including the condition of the soft tissue, the extensor mechanism, and the underlying bone stock as well as the neurovascular integrity of the limb), while considering factors unrelated to the knee itself, such as underlying health and expected longevity.

When reimplantation is contraindicated, salvage procedures are generally indicated (Johnson, Bannister, 1986; Windsor, Insall, Urs, et al., 1990). To decide between salvage and repeated attempts at reimplantation, the surgeon must be familiar with the prerequisites, indications, contraindications, and techniques of reimplantation (revision), as well as the salvage alternatives, which include amputation, resection arthroplasty, and arthrodesis.

Amputation

Amputation is certainly the most difficult alternative for the surgeon to contemplate. Amputation is indicated when (1) a limb is unsalvageable due to uncorrectable vascular insufficiency, (2) persistent pain is unresponsive to efforts at pain relief, (3) life-threatening infection is unresponsive to appropriate surgical and medical therapy, or (4) sufficient tissue loss has occurred to preclude the possibility of retaining a useful limb, and tissue restoration is deemed impossible or impractical. Unfortunately, above-the-knee amputation in this population frequently confines the patient to minimal ambulation (Lambregts, Hitters, 2002). The most common indications are vascular insufficiency (Smith, McGraw, Taylor, et al., 2001) or

persistent sepsis and severe soft tissue loss. A review of 18,442 knee replacements showed the prevalence of this complication: 67 (0.36 percent) of the knee replacements were eventually followed by amputation. Of these amputations, approximately two-thirds were due to progressive vascular disease and one-third were due to specific failures of the arthroplasty itself that were not amenable to limb salvage (Sierra, Trousdale, Pagnano, 2003).

Resection Arthroplasty

Resection arthroplasty or creation of a pseudarthrosis entails removal of the arthroplasty and immobilization of the joint while scar tissue fills the resection space. Resection arthroplasty is indicated in cases in which revision to a new arthroplasty is deemed impractical or impossible in a low-demand patient, usually with multiarticular joint involvement, where lack of knee joint motion resulting from fusion will hamper mobility and/or excessively stress adjacent joints. The few series of pseudarthrosis creation following failed TKA generally demonstrate poor results. In a series of 28 patients with knee resection arthroplasty, only 50 percent were functional ambulators; all of these patients required assistive devices for ambulation, and 17 percent required arthrodesis surgery (Falahee, Matthews, Kaufer, 1987). In a series of 15 patients, 12 were considered poor and 3 fair (Lettin, Neil, Citron, et al., 1990).

Arthrodesis

Unless a specific indication for resection arthroplasty is present, the bulk of data supports better function and pain relief with arthrodesis if revision to a new arthroplasty is deemed inappropriate (Brodersen, Fitzgerald, Peterson, et al., 1979; Chapchal, 1948; Fidler, 1983; Figgie, Brody, Inglis, et al., 1987). The disabilities and compensations from arthrodesis are well studied (Rud, Jensen, 1985). Contraindications are few and relative.

Techniques used (as well as the likelihood of success) depend on the amount of bone loss present and the presence or absence of continued sepsis (Rand, Bryan, 1986; Rand, Bryan, Chao, 1987). External fixation, which provides immediate stabilization of the knee following implant removal, has been well described (Manzotti, Pullen, Deromedis, et al., 2001; Brodersen, Fitzgerald, Peterson, et al., 1979; Fidler, 1983; Rand, Bryan, Chao, 1987). Internal fixation or intramedullary nailing requires a sterile fusion bed; therefore, most of these procedures are done as staged operations. In cases of severe bone loss, either vascularized autograft or allograft bone segments can be used to bridge extensive defects. Relatively straightforward anatomy above and below the knee and special arthrodesis nails are required. The use of these nails has greatly improved the likelihood of obtaining fusion in cases with significant bone loss (Waldman, Mont, Payman, et al., 1999; Incavo, Lilly, Bartlett, et al., 2000).

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Outcomes of Revision Total Knee Replacement and Salvage Procedures for Failed Total Knee Replacement

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Revision total knee replacement (TKR) is required when primary TKR failure leads to increasing pain and disability. The outcomes of revision TKR are evaluated using various metrics, including rates of re-revision, physician-derived measures of pain and function, patient-derived measures of pain and function, radiographic evaluations of implant functioning, and economic analyses. Salvage procedures are considered when revision TKR is not a feasible option. The outcomes of these procedures are measured in similar fashion to revision TKR.

The literature on revision TKR and salvage procedures is limited compared with the literature on primary TKR. The majority of reports are small case series from single tertiary referral centers with no control groups and limited length of followup. The outcomes are measured using a variety of instruments that make comparison between reports difficult. To simplify this discussion, the following topics will be covered separately:

- Revision of unicondylar knee replacement (UKR)
- Revision of primary TKR for aseptic failure
- Revision of revision TKR for infection
- Salvage procedures for failed TKR

Outcomes of Revision Unicondylar Knee Replacement

Few reports focus specifically on the outcomes of revision TKR for failed UKR. Some authors have suggested that a failed UKR can be revised to a TKR without much difficulty (Chakrabarty, Newman, Ackroyd, 1998). In a retrospective study of 48 knees, Lai and Rand (1993) had 81 percent good or excellent results at 5.4 years of followup. In a retrospective review of 29 patients, Barrett and Scott (1987) found that 66 percent had good to excellent outcomes at an average of 4.6 years. In a retrospective review, Padgett and coworkers (1991) showed that the technical aspects of revision of failed UKR present difficulties. They concluded that the results of revision TKR for a failed UKR were not as good as those for a primary TKR and in fact were similar to results of revision TKR after failed primary TKR.

Outcomes of Revision Primary TKR

In general, the reports on outcomes of revision for failed primary TKR show good results up to 5 years following surgery. The results beyond 5 years are less certain. They depend on the complexity of the revision as well as patient characteristics. Goldberg and colleagues (1988) looked at the results of revision TKR in 65 consecutive cases followed for an average of 5 years (range of 2 to 10 years) using a modified Mayo clinic knee rating scale. A variety of implants

were used, including total condylar, posterior stabilized, total condylar III, and kinematic rotating hinge prostheses. A good or excellent outcome was noted in only 46 percent of patients, a poor result or failure occurred in 42 percent of the cases, and infection occurred in 4.5 percent of patients. Friedman and coworkers (1990) reviewed 137 cases with an average followup of 5.2 years. They document a clinical success rate of 63 percent and a failure rate of 5.8 percent. Ritter and coworkers (1991), using survival analysis in a cohort of 37 cases, noted at 4 to 6 years post surgery a survival rate of 54 percent. Stuart and colleagues (1993) from the Mayo Clinic looked at 655 condylar revision TKRs done over a 10-year period. Of this cohort, 46 cases came to re-revision TKR. At an average followup of 7.5 years from re-revision, 52 percent were classified as failures. Gustilo and coworkers (1996) did a retrospective review of 56 consecutive revision TKRs followed for an average of 8.3 years. Using the Hospital for Special Surgery (HSS) knee scoring system, they had a good to excellent outcome of 73 percent.

Outcomes of Revision TKR for Infection

Revision TKR for infection is a challenging problem. The treatment options include (1) antibiotic suppression alone, (2) surgical debridement of the joint with retention of the prosthesis and antibiotics, (3) resection arthroplasty, (4) arthrodesis, (5) one-stage revision, (6) two-stage revision, and (7) amputation. The most successful functional results for the treatment of an infected TKR have been obtained from two-stage revisions. Wilson and colleagues (1990) reported that 15 of 20 patients undergoing revision TKR had no pain at a mean followup of 2.9 years. In a followup study of 34 cases, Windsor and colleagues (1990) reported that 76 percent had no pain or mild pain, 18 percent had moderate pain, and 6 percent had severe pain. They also reported that 69 percent had good to excellent results with a mean range of knee flexion of 87 degrees. Rosenberg and coworkers (1988), in a prospective study of 26 infected knees followed up for an average of 29 months, achieved 100-percent eradication of infection and 75-percent good to excellent outcomes based on the HSS score.

Outcomes of Salvage Procedures for Failed TKR

Salvage procedures for failed TKR can be grouped as (1) resection arthroplasty, (2) arthrodesis, and (3) amputation. The literature in this area is very limited (Donley, Matthews, Kaufer, 1991; Windsor, 1993; Kaufer, 1999). In general, pain relief and function following any of these salvage procedures is limited and far inferior to revision TKR. Salvage procedures are considered an option of last resort in patients with compromised soft tissues, severe bone loss, and severe medical comorbidities.

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Functional Outcome Following Revision Total Knee Arthroplasty: Meta-analysis

Khaled J. Saleh, M.D.

Objective

The objective of this study was to perform a systematic literature review to describe patient outcomes following revision total knee arthroplasty (TKA) using various global knee score (GKS) ratings.

Data Sources

A computerized literature search and bibliography review identified English-language articles published from 1966 through 2000.

Study Selection

A multistage assessment was used to determine articles containing data that met the objective of the study. In the first stage, abstracts were reviewed to identify articles that (1) reported any postoperative outcomes, (2) reported on revision knee procedures, and (3) had a study sample greater than five subjects. In the second stage, the articles were extracted and reviewed, and their bibliographies were examined for missed citations in the review articles retrieved. In the third stage of assessment, we included only study articles that reported outcomes using a GKS rating.

Analysis

Meta-analyses of GKSs were undertaken using a fixed-effects model with the assumption that the variances of each individual measurement were identical across studies. The variance of the overall estimate was then calculated under this model using the between-study variability.

Results

Fifty-eight articles with a total of 1,965 patients met the initial inclusion criteria. Forty-two articles comprising 45 unique patient cohorts and a total of 1,515 patients contained sufficient GKS data for analysis and were used in the meta-analyses. The mean patient age across the 45 patient cohorts was 66.6 years. Approximately 61 percent of the enrolled subjects were women, ranging from a minimum of 28 percent to a maximum of 82 percent. Osteoarthritis was the primary reason for the index knee replacement.

The preoperative averaged functional and clinical mean Knee Society (KS) score was 35.4 (95% confidence interval [CI]: 30.7–39.9), which significantly increased by a mean of 30.8 points (95% CI: 26.6–35.0) to 66.2 (95% CI: 61.6–70.2) postoperatively (p<0.0001). The preoperative mean Hospital for Special Surgery (HSS) score was 51.5 (95% CI: 48.9–54.1), and there was a significant mean increase of 28.3 points (95% CI: 25.3–31.2) to 79.8 (95% CI: 76.4-83.1) postoperatively (p<0.0001). No significant correlation was seen between the preoperative score and the amount of improvement in either the KS or the HSS studies. The percentage of subjects attaining excellent or good ratings was 72.7 percent (95% CI: 69.2–76.3) in studies reporting on cohorts in which some subjects had both knees revised, compared with 82.6 percent (95% CI: 79.1–86.1) in studies reporting on cohorts in which no subjects had multiple knees revised (p<0.05). The percentage of subjects attaining an excellent or good outcome increased steadily with longer followup to 60 months; thereafter, KS scores level off and HSS scores decline marginally. Articles in which a greater proportion of patients had the proximate cause for revision as infection reported a lower proportion of excellent or good outcomes than articles in which fewer patients had infections (67.5 percent [95% CI: 61.5%, 73.4%] versus 78.5 percent [95% CI: 74.7%, 82.3%]).

Conclusions

Revision TKA is a safe and effective procedure for failed knee replacements. The results appear to indicate that patients undergoing bilateral TKA revision are more severely affected preoperatively and attain lower functional outcomes than those undergoing single knee revision, although the magnitude of improvement is similar in both groups. Functional outcomes seem to improve with longer followup for at least 5 years. Difficulties in abstracting information due to inconsistent reporting of data in the original studies limited our ability to explore several variables that may affect outcomes.

Disparities and Potential Inequities in the Use of Total Joint Replacement

Maria E. Suarez-Almazor, M.D., Ph.D., M.Sc.

Variations in the utilization of total joint replacement (TJR) are well documented, both geographically and in populations differing on the basis of personal characteristics such as race or gender. Recent publications have examined these variations to elucidate whether they are clinically and socially appropriate or they represent inequitable health care. Equity refers to both the extent to which inequalities in health among groups of individuals at similar risk are minimized and the fairness with which health care is distributed (Aday, Begley, Lairson, et al., 1998). Differences in utilization among subgroups of patients do not necessarily imply inequity if they are due to variations in health status, differences in need under a social justice concept (e.g., need to work), or personal preferences. Yet, after these caveats, inequities in health care indeed exist on the basis of gender, race, age, education, income, and cultural beliefs. Are there inequities in the use of TJR? Geographic variations in utilization rates appear to be unrelated to clinical need. Variation in the utilization of health services can be a consequence of either over- or underutilization. For TJR, the data are scarce, but the limited evidence suggests that the procedure might be underutilized (Hawker, Wright, Coyte, et al., 2000).

A number of studies have found striking differences in the use of these procedures among ethnic groups (Dunlop, Song, Manheim, et al., 2003; Escalante, Barrett, del Rincon, et al., 2002; Escalante, Espinosa-Morales, del Rincon, 2000; Hoaglund, Oishi, Gialamas, 1995; Katz, Freund, Heck, et al., 1996; McBean, Gornick, 1994; Melzer, Guralnik, Brock, 2003; Oishi, Hoaglund, Gordon, et al., 1998; Wilson, May, Kelly, 1994). Whites are twice as likely to undergo TJR as African Americans or Hispanics. These differences cannot be attributed to the prevalence or severity of osteoarthritis (OA). Differences in the use of TJR across gender also have been documented. A Canadian study reported that women were three times less likely to receive TJR than males (Hawker, Wright, Coyte, et al., 2001). In addition, women appear to be more disabled by the time they are referred for surgery (Holtzman, Saleh, Kane, 2002). Education and income also have an impact on the use of TJR, and these variables appear to be independent of access to a health care system. In Canada, where universal health care exists, patients with low socioeconomic status appear to receive fewer TJRs despite greater need, compared with those with higher socioeconomic status (Hawker, Wright, Glazier, et al., 2002).

What factors may explain disparities in the utilization of TJR? It is clear that clinical need is not a factor. In the first National Health and Nutrition Examination Survey (NHANES I), African American women were at increased risk for radiologic OA compared with white women, whereas no differences were observed in men (Anderson, Felson, 1988). Studies evaluating disability in individuals with self-reported arthritis have shown varying results in relation to ethnicity, and there is some evidence that African American patients with OA report the same degree of pain and disability as their white counterparts and worse quality of life (Ang, Ibrahim, Burant, et al., 2003; Ibrahim, Burant, Siminoff, et al., 2002). Using defined radiologic criteria for

the prevalence of OA in the Framingham cohort, the overall prevalence in the cohort was similar in men and women, although more women had symptomatic disease (Felson, Naimark, Anderson, et al., 1987). Overall, the symptomatic burden and disability from OA appear to be at least as prevalent—and possibly more prevalent—in African Americans than in whites, females, and individuals with low socioeconomic status. Therefore, the disparities in TJR use cannot be explained by clinical need.

A number of factors may be critical in explaining these disparities, including issues related to equity and access, physician recommendations, patient perceptions and preferences, and the interaction between health care providers and patients.

Access to care often is cited as a major element in health care disparities. In TJR, these differences may be less relevant than for other conditions because most patients with OA are older than 65 years of age and eligible for Medicare. Nevertheless, patients with Medicare and supplemental insurance are more likely to undergo TJR than patients with Medicare alone (Dunlop, Song, Manheim, et al., 2003). Ethnic differences remain after controlling for access to care and even after adjusting for income. The relationship between race and income often is difficult to disentangle. Escalante and colleagues (2002, 2000) reported that race and poverty remained as independent variables associated with low use of TJR. Moreover, in Canada, where access to care is facilitated by a universal health care system, differences remain in the utilization of TJR between men and women and between those with low versus high education and income.

Ethnic and gender bias in recommendations by physicians has been documented. Physicians presented with patient scenarios were less likely to recommend cardiovascular procedures to African American women than to white men, despite similar descriptions of clinical status (Schulman, Berlin, Harless, et al., 1999). Hawker and colleagues (2000) reported that women with OA were less likely to have discussed TJR with their physicians than men with similar clinical status, although their willingness to have surgery was similar to that of men.

Patient preferences also may play an important role in TJR use. In a population-based survey, Hawker and colleagues (2001) reported that only 15 percent of the patients with severe knee or hip OA were definitely willing to undergo arthroplasty. African American veterans with OA were less likely than whites to consider TJR, had less understanding of the condition, and expected worse outcomes after surgery (Ibrahim, Siminoff, Burant, et al., 2002a; Ibrahim, Siminoff, Burant, et al., 2002b). The differences remained after adjusting for educational level, suggesting that other independent factors influenced these preferences. Historically, African Americans report less confidence in physician recommendations and medical interventions than other ethnic groups (Blendon, Scheck, Donelan, et al., 1995; Collins, Clark, Petersen, et al., 2002). Additional cultural differences may be crucial in determining these patient preferences. Ethnicity, gender, and religion can modify one's beliefs and attitudes regarding illness and healing. Ang and colleagues (2002) reported that African Americans with OA were half as likely as whites to hypothetically consider surgery, and the difference appeared to be partially mediated by their attitudes toward prayer. African Americans prayed more and perceived prayer to be helpful for their condition.

Finally, a factor that is becoming increasingly recognized as a determinant of health care use is the interaction between patients and their doctors. Physicians provide less information and

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do not encourage as much participation for African Americans compared with whites. Moreover, African Americans are more satisfied with care when paired with physicians from their own ethnic group. Gender differences in participation at the time of the medical encounter also have been reported (Kaplan, Gandek, Greenfield, et al., 1995). Research in this field is evolving, and it may provide an understanding of the issues surrounding patient decisionmaking regarding TJR.

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Disparities in Utilization of Total Knee Arthroplasty

Timothy J. Wilt, M.D., M.P.H.

Overview

Total knee arthroplasty (TKA) is one of the most common orthopaedic procedures. In 2001, 171,335 primary knee replacements and 16,895 revisions were performed (Orthopedic Network News Online, 2003). These procedures are elective and expensive (Medicare paid approximately $3.2 billion in 2000 for hip and knee joint replacements), and the prevalence of arthritis is expected to grow substantially as the population ages.

In collaboration with the Office of Medical Applications of Research and the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Agency for Healthcare Research and Quality (AHRQ) defined the scope of work for this AHRQ-TKA project to include an evidence report on the indications for primary TKA and revision TKA (Kane, Saleh, Wilt, et al., 2003). The findings of this report suggest that TKA improves functional status, relieves pain, and results in relatively low perioperative morbidity. However, based on conclusions from consensus panels or surveys of health care providers, there is considerable disagreement about the indications for the procedure, that is, which patients are most likely to benefit from TKA and, conversely, in which patients TKA is contraindicated or of low value.

Disparities in Utilization of TKA

The understanding of disparities in utilization of TKA is important. The *Healthy People 2010* initiative has made the reduction of racial and gender disparities a health care priority (Healthy People 2010, 2000). Previous work has suggested that use of TKA may vary according to gender, race or ethnic group, and possibly geographic region. However, it is not clear to what extent these reported variations are due to potential differences in the incidence or severity of arthritis, patient treatment preferences and knowledge, comorbid conditions, overall utilization rates within a geographic region, or provider or health system biases. For example, the incidence of osteoarthritis (OA) has been estimated to be about 1.5- to 2.0-fold higher in women than in men (Hawker, Wright, Coyte, et al., 2000). Similarly, radiologic signs of knee OA are higher in blacks than in whites or Hispanics (Hirsch, Cheng, Grigorian, et al., 2001). A greater understanding regarding whether disparities in TKA utilization exist and, if they do, what the causal factors are, could lead to improvements in health delivery and receipt whereby treatment would not be determined by a person's gender, race, or geographic location. Eliminating disparities would allow us to define the optimal rate of an effective TKA, that is, every patient who could benefit clinically from the procedure and who wanted it done would have it performed.

Identification and Analysis of the Evidence

The objective of this portion of the AHRQ-TKA report was to conduct a systematic review to determine the factors that explain disparities in the utilization of TKA in various populations. We conducted a search of English-language articles via PubMed from 1995 to 2003 and an accompanying bibliography review. The search resulted in 176 references of which 23 met preliminary inclusion criteria (primary TKA studies, more than 100 knees per study, gender and race data provided, experimental or quasi-experimental design). Of these studies, three met the inclusion criteria for analysis. Reference lists from the articles were searched. Three additional articles were found and were included in the analysis (total n = 6) (Dunlop, Song, Manheim, et al., 2003; Escarce, Epstein, Colby, et al., 1993; Hawker, Wright, Coyte, et al., 2000; Katz, Freund, Heck, et al., 1996; Peterson, Hollenberg, Szatrowski, et al., 1992; Wilson, May, Kelly, 1994). Several studies included both hip and knee replacement surgery. An additional article evaluating racial, ethnic, and geographic disparities in rates of TKA among Medicare patients was published after the completion of our full report (Skinner, Weinstein, Sporer, et al., 2003).

We conducted a qualitative summary of reported TKA rates according to gender, race, and geographic region. Most of the studies that address access relied on large administrative data sets that did not contain detailed clinical data on which to base the indications for knee surgery. However, some of these studies had at least some clinical information on the underlying problems of the sample being studied. Dunlop and colleagues (2003) used the Asset and Health Dynamics Among the Oldest Old (AHEAD) data set, which includes self-reported conditions such as arthritis. Hawker and coworkers (2000) identified persons with arthritis as the basis of their sample. Wilson and colleagues (1994) limited their study to Medicare beneficiaries with a diagnosis of OA.

Disparities Based on Gender, Race and Ethnicity, and Geographic Region

The conclusions with regard to the differential treatment of women are mixed, but the preponderance of evidence suggests that women are almost twice as likely to undergo TKA as men. The possibility that the higher rates of TKA in women may be due to the higher prevalence of arthritis among women does not apply to one study that examined only persons with arthritis. However, it is plausible that the severity or type of arthritis varied.

The evidence regarding nonwhite groups is quite consistent. Nonwhites undergo TKA about half as often as whites. Most analyses simply report the rate at which the procedures were performed, with no attention to the actual size or nature of the population at risk. The lower rates of TKA among blacks occurred despite a higher prevalence of OA in this group, suggesting that the prevalence of OA was not a mitigating factor.

In a study of Medicare patients by Skinner and colleagues (2003), TKA rates were significantly lower for black men than for non-Hispanic white men in nearly every region of the country. For the Hispanic population and for black women, racial or ethnic disparities at the national level were due in part to geographic differences rather than to differences in the rates for

various racial and ethnic groups within geographic areas. Residential segregation and low-income levels contributed to racial and ethnic TKA disparities.

Future Research Needs

The findings from this systematic review indicate that utilization rates in TKA vary according to gender, race and ethnicity, and geographic region. However, the available data present limitations that make it difficult to fully understand disparities of TKA in various populations. Future research is required to answer the following key questions (Lavizzo-Mourey, Knickman, 2003; Skinner, Weinstein, Sporer, et al., 2003):

- What is the "right" or optimal rate of TKA; that is, which patients are most likely to benefit from and desire TKA and, conversely, in which patients is TKA contraindicated or of low benefit?
- Are the observed gender, racial and ethnic, and geographic variations in TKA rates due to differences in (1) incidence or severity of arthritis, (2) presence and severity of comorbid conditions, (3) patient preferences or knowledge regarding the risks and benefits of TKA, (4) individual provider biases or stereotyping, or (5) barriers in health care delivery systems?
- What are effective, practical approaches that health care providers and systems can use to reduce TKA disparities?

Conclusions

The data sources to evaluate variation in access to TKA are limited in number and quality. However, the available information suggests that TKA access varies according to gender, race and ethnicity, and geographic region. Women and white individuals have higher rates of TKA than men and nonwhites. To reduce disparities, we need an understanding of factors associated with different TKA rates and methods.

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Patients' Perspectives: Qualitative Research Before and After Surgery

Paul A. Dieppe, M.D., FRCP, FFPH

Patients should be involved in the development of consensus statements about total knee joint replacement. People who have experienced a knee replacement can offer important insights to the indications and outcomes of the procedure, as well as disparities and directions for future research. As part of a major research program exploring the pathways to knee or hip replacement in the United Kingdom (UK), the Medical Research Council's Health Services Research Collaboration has used focus groups, patient surveys, and indepth interviews to help understand the views and experiences of people with severe knee joint arthritis and their attitudes about joint replacement.

Experience of Arthritis in Older People and Barriers to Surgery

Sanders and colleagues (2002) carried out indepth interviews with 27 people aged 51 to 91 years with severe arthritis of the hip and/or knee; they analysed the data thematically using the constant comparison technique. The researchers explored barriers to care within this group.

An important finding was that many older people perceive arthritis as an integral part of their lives and view severe symptoms as normal. This perception has made several of them reluctant to seek treatment. However, they also talked about the disruptive effect of symptoms on their lives and of their pessimism about what could be done about it. This negative view of treatments (including surgery) was another barrier to the utilization of appropriate health care, and physicians often reinforced these negative views.

Willingness To Undergo Surgery

An important determinant of discrepancies in the provision of knee replacement surgery is the varying willingness of patients to undergo the operation. Hawker and colleagues (2001) have done groundbreaking work on this issue in Canada. They compared the views of people in two areas of Ontario, one with relatively high rates of provision of joint replacement and one with a low rate of provision. Willingness to have surgery among people with severe arthritis was assessed through interviews at which information about risks and benefits was given in accordance with the usual practice of the surgeons. Of those individuals with potential need for surgery, only 14.9 percent in the high-rate area and 8.5 percent in the low-rate area were definitely willing to have surgery, emphasizng the importance of patient preferences. In the UK, Juni and coworkers (2003) found that willingness to undergo knee replacement is less than that for hip replacement given the same severity of symptoms.

Patients' Views on the Prioritization of Knee Replacement Surgery

Woolhead and colleagues (2002) undertook semistructured, indepth interviews with 25 patients awaiting primary knee replacement surgery. The researchers explored patients' views on prioritization for knee replacement as well as their expectations regarding surgery.

Patients thought that the criteria for a decision to operate should include the following:

- The combined length and severity of pain and immobility (the "area under the curve" of problems, rather than current pain or disability)
- A threat to paid employment
- The need to care for others
- Younger people rather than older people

Patients also thought that health care professionals placed too much emphasis on age, weight, and what they saw as excessive complaining by some patients.

Health care professionals often talk about the importance of patients' expectations, but most of the interviewees were either unable or unwilling to voice their expectations. Rather, they talked of their hopes (both ideal and pragmatic) and their fear of surgery.

Views of Patients With Knee Arthritis on Different Interventions and Research Priorities

Using focus groups to populate a questionnaire, Tallon and colleagues (2000) surveyed 112 people with knee osteoarthritis on symptoms, interventions, and research priorities. This work, and related studies with health care professionals as well as literature reviews (Chard, Tallon, Dieppe, 2000), has highlighted a mismatch between the priorities of patients and those of professionals and academics in the treatment of knee arthritis. It is not clear which group is "right."

Patients reported that one of their highest research priorities was the development of clear indications about who should and should not undergo surgery for knee arthritis. During focus groups and interviews, many patients expressed surprise that doctors did not know when it was best to do surgery during the course of arthritis.

Making Sense of Outcomes

An intervention such as a knee replacement is a major event in the life of an individual. The decision to endure such a procedure has to be rationalized (so you say it was a success), and after the event it is difficult to remember or imagine what one was like beforehand (so you must be better).
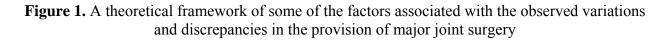
Woolhead (submitted for publication) went back to 10 of her interviewees 6 months after their surgery and explored their perceptions of the outcome through a second indepth interview. The patients struggled to understand the outcome and often described it in contradictory terms;

they presented both a public expression of a good outcome and private dismay at continuing symptoms and problems. These apparently contradictory accounts were consistent in the context of the informants' lives and represented adaptation or accommodation to a change in health status.
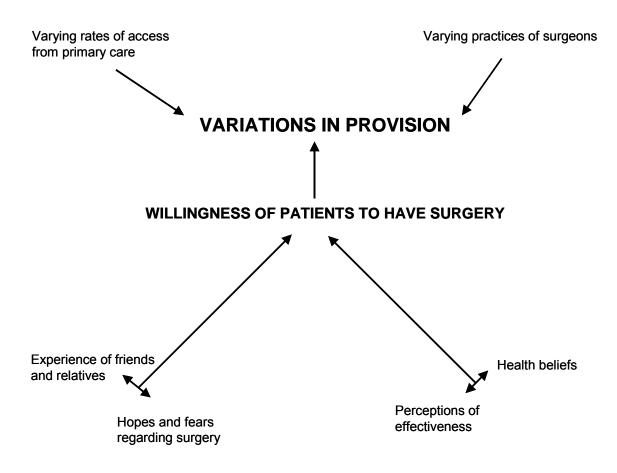
Other patient-centered work on outcomes has been undertaken by Carr and coworkers (2001), who stressed the importance of "response shift" over time, and Campbell and colleagues (2003), who observed that the results of standard self-report questionnaires on outcome often contradicted what people said during indepth interviews. Outcomes are not the simple issue that we would sometimes like to believe.

Conclusions

The following conclusions can be drawn from the research on patients' perspectives on total knee replacement:

- Patient perspectives must be taken into account.
- Patients' views of what is most important in health care and research often differ from the views of the professionals.
- Arthritis is often seen as a normal part of aging and not as a disease in need of an intervention. Health professionals may reinforce this view.
- Patients think that issues often ignored by professionals, such as a threat to paid employment and caring for others, should be major determinants of a decision to undergo surgery.
- Peoples' public expressions of a positive outcome after surgery may hide privately held views to the contrary.
- Willingness to undergo surgery varies and may be a major determinant of the observed variations in rates of delivery of knee surgery; the research reviewed here suggests a framework for thinking about disparities in provision, as outlined in the figure.

Figure 1. A theoretical framework of some of the factors associated with the observed variations and discrepancies in the provision of major joint surgery

Varying rates of access
from primary care

Varying practices of surgeons

VARIATIONS IN PROVISION

WILLINGNESS OF PATIENTS TO HAVE SURGERY

Experience of friends
and relatives

Health beliefs

Hopes and fears
regarding surgery

Perceptions of
effectiveness

Future Research Priorities

The following topics are areas for future research:

- Reasons for the varying, low rates of willingness to undergo surgery among people with severe arthritis should be explored.
- Other barriers to equitable provision, at both primary and secondary care levels, must be investigated further.
- More research is needed on what constitutes a "good" or a "bad" outcome.
- The determinants of a "bad" outcome must be understood so that people who are not going to benefit can be protected from surgery.
- Ways must be found to incorporate the views of patients into the development of policies and practice in joint replacement surgery.
- Patients should have a major say in the future research agenda.

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