



## Complete Summary

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### GUIDELINE TITLE

AAOS clinical guideline on osteoarthritis of the knee (phase II).

### BIBLIOGRAPHIC SOURCE(S)

American Academy of Orthopaedic Surgeons. AAOS clinical guideline on osteoarthritis of the knee (phase II). Rosemont (IL): American Academy of Orthopaedic Surgeons; 2003. 15 p. [75 references]

### GUIDELINE STATUS

This is the current release of the guideline.

**\*\* REGULATORY ALERT \*\***

### FDA WARNING/REGULATORY ALERT

**Note from the National Guideline Clearinghouse:** This guideline references a drug(s) for which important revised regulatory information has been released.

On April 7, 2005, after concluding that the overall risk versus benefit profile is unfavorable, the FDA requested that Pfizer, Inc voluntarily withdraw Bextra (valdecoxib) from the market. The FDA also asked manufacturers of all marketed prescription nonsteroidal anti-inflammatory drugs (NSAIDs), including Celebrex (celecoxib), a COX-2 selective NSAID, to revise the labeling (package insert) for their products to include a boxed warning and a Medication Guide. Finally, FDA asked manufacturers of non-prescription (over the counter [OTC]) NSAIDs to revise their labeling to include more specific information about the potential gastrointestinal (GI) and cardiovascular (CV) risks, and information to assist consumers in the safe use of the drug. See the [FDA Web site](#) for more information.

Subsequently, on June 15, 2005, the FDA requested that sponsors of all non-steroidal anti-inflammatory drugs (NSAID) make labeling changes to their products. FDA recommended proposed labeling for both the prescription and over-the-counter (OTC) NSAIDs and a medication guide for the entire class of prescription products. All sponsors of marketed prescription NSAIDs, including Celebrex (celecoxib), a COX-2 selective NSAID, have been asked to revise the labeling (package insert) for their products to include a boxed warning, highlighting the potential for increased risk of cardiovascular (CV) events and the well described, serious, potential life-threatening gastrointestinal (GI) bleeding associated with their use. FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA

determines pose a serious and significant public health concern. See the [FDA Web site](#) for more information.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

### DISEASE/CONDITION(S)

Osteoarthritis of the knee

### GUIDELINE CATEGORY

Evaluation  
Management  
Treatment

### CLINICAL SPECIALTY

Orthopedic Surgery  
Physical Medicine and Rehabilitation  
Rheumatology

### INTENDED USERS

Physicians

### GUIDELINE OBJECTIVE(S)

To guide qualified physicians through a series of diagnostic and treatment decisions in an effort to improve the quality and efficiency of care in patients with osteoarthritis of the knee

### TARGET POPULATION

Skeletally mature individuals with confirmed osteoarthritis of the knee for whom conservative treatment has been ineffective

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Evaluation**

1. Evaluation of patient (i.e., age, level of symptomology, impact of knee dysfunction or pain on quality of life, medical comorbidity, suitability for surgery)
2. Tests as indicated (magnetic resonance imaging [MRI] scan of knee; radiography of the knee)

### **Management/Treatment**

1. Patient education and counseling on surgical procedures (i.e., expected outcomes, potential for risks, and complications)
2. Surgical options:
  - Total joint replacement
  - Knee fusion
  - Arthroscopic debridement
  - Total knee arthroplasty
  - Tibial osteotomy
  - Unicompartmental arthroplasty of the medial compartment of the knee
  - Distal femoral varus osteotomy
  - Procedure to elevate the tibial tubercle or a patellectomy
  - Patellofemoral arthroplasty

## **MAJOR OUTCOMES CONSIDERED**

Efficacy of surgical treatment including:

- Quality of life
- Short-term and long-term success rates
- Patient satisfaction
- Pain relief
- Return of prior knee function (e.g., range of motion measurement, weight bearing, ambulation)

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

*Evaluation of Existing Guidelines:* A search of MEDLINE, the National Guidelines Clearinghouse and the American Medical Association's Clinical Practice Guidelines Directory (1999) was performed. Only one relevant guideline was located. The American College of Rheumatology Subcommittee on Osteoarthritis Guidelines: Recommendations for the medical management of osteoarthritis of the hip and knee: 2000 Update, was reviewed by the work group.

*Literature Review:* A search of MEDLINE was performed in order to update the literature used to develop the original guideline. English language peer reviewed journals from 1990 to 2000 with human studies of adults over 19 years of age were included.

## **NUMBER OF SOURCE DOCUMENTS**

75 articles were identified and reviewed

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

**Type I.** Meta-analysis of multiple, well-designed controlled studies; or high power randomized, controlled clinical trial

**Type II.** Well-designed experimental study; or low-power randomized, controlled clinical trial

**Type III.** Well-designed, non-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series

**Type IV.** Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies

**Type V.** Case reports and clinical examples

**Consensus/opinion** (*as it is used in bibliography of the original guideline*): Articles representing expert consensus and not meeting the rigid I-V measurement are noted to represent consensus/opinion.

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not applicable

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

*Consensus Development:* The work group participated in a series of conference calls and meetings in which information was extracted and incorporated into the original algorithm. Information from the literature was supplemented by the consensus opinion of the work group, when necessary. Multiple iterations of the guideline were then completed and reviewed by work group members. Modifications (when supported by references from the literature) were then incorporated by the work group chairman.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Strength of Recommendation**

The strength of the guideline recommendations for or against an intervention was graded as follows:

- A.** Type I evidence or consistent findings from multiple studies of types II, III, or IV
- B.** Types II, III, or IV evidence and findings are generally consistent
- C.** Types II, III, or IV evidence, but findings are inconsistent
- D.** Little or no systematic empirical evidence

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The guideline was reviewed and approved by various groups within the American Academy of Orthopaedic Surgeons (AAOS) including the Evidence Analysis Work Group, Evidence-Based Practice Committee, Council on Research and Scientific Affairs, Board of Councilors, and Board of Directors prior to publication.

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Definitions for the ratings of the strength of recommendation (A-D) and the levels of evidence (Type I-Type V) are provided at the end of the "Major Recommendations" field.

### **Diagnosis**

## **Osteoarthritis**

### *Definition of the Problem*

Osteoarthritis of the knee is an increasingly common problem due to a more active society, often leading to prior knee injuries, an increasingly elderly population, and a growing percentage of the population that is overweight. Osteoarthritis of the knee should be suspected when a patient presents with knee pain that has been longstanding, increases with activity, particularly weight bearing and stairs, and improves with rest. Onset of pain and dysfunction is often insidious. Deformity, fixed contracture, crepitance, and effusion are common findings. The differential diagnoses include inflammatory arthritis, bursitis or tendonitis, anterior knee pain, and internal derangement.

Patients entering Phase II of the guideline have failed to respond to conservative treatment. Pain, instability and function have not improved to a satisfactory level despite conservative treatment rendered, as outlined in Phase I of the guideline (see the National Guideline Clearinghouse (NGC) summary of the American Academy of Orthopaedic Surgeons [AAOS] guideline [AAOS Clinical Guideline on Osteoarthritis of the Knee](#)). This treatment may have included analgesics or nonsteroidal anti-inflammatory medications, activity modification including weight reduction, and therapeutic exercise. It may have included trial of durable medical equipment such as knee braces, ambulatory assistive devices, or orthoses. The patient may have undergone intra-articular injection in the knee with steroid or viscosupplementation.

### *Recommendations*

For patients with osteoarthritis of the knee presenting to a musculoskeletal specialist, conservative treatment measures should have been exhausted. The age of the patient, level of symptomology, impact of knee dysfunction or pain on quality of life, and medical comorbidity should be assessed. If there is a medical contraindication to surgery, conservative treatment should be continued. The diagnosis of neuropathic arthropathy should be considered. The role for surgical intervention, including arthroplasty, is not well defined for a neuropathic joint (**"D" Recommendation**).

If a patient without a medical contraindication to surgery or neuropathic joint remains dissatisfied with the outcome of conservative care and has significant knee dysfunction, pain, or both, surgical alternatives should be considered. Evaluation by an orthopaedic surgeon is appropriate. Referral by a rheumatologist or physiatrist to an orthopaedic surgeon is indicated.

### Previous Knee Infection or Osteomyelitis

For a patient with osteoarthritis that has failed to respond to conservative treatment and had a previous infection involving the knee, staged total knee replacement or knee fusion should be considered (**"D" Recommendation**). The choice to proceed with surgery, and between the two options, should be based on the patient's age, activity level, occupation, and a discussion. The discussion should include the natural history of the underlying condition including short- and long-term pain and physical impairment expectations with and without surgery.

The efficacy of the proposed surgical procedure should be discussed. The risks and possible complications of each treatment option and reasonable expectation and timeframe to accomplish the expected outcome should be discussed.

Total joint replacement is contraindicated in the presence of active infection. When there is a history of infection, preoperative aspiration is often indicated. The risk of infection remains 10% or greater when total knee arthroplasty is performed even in the presence of infection in the distant past ("**D**" **Recommendation**). In a young patient with history of chronic infection, knee fusion should be considered ("**D**" **Recommendation**). Good results have been reported in total knee arthroplasty in patients under 55 years of age ("**B**" **Recommendation**).

Knee fusion may be considered in young, active, high demand patients with isolated bi- or tri-compartmental degenerative arthritis, particularly when associated with severe knee instability.

#### Patients Without Significant Joint Space Narrowing

Weight bearing standing anterior to posterior (AP) radiographs of the knee should be taken ("**A**" **Recommendation**). A lateral view of the knee joint and view tangential to the patellofemoral joint should be obtained. A standing radiograph, taken from posterior to anterior, with the knee flexed 45 degrees can show loss of cartilage in the posterior aspect of the knee ("**A**" **Recommendation**).

If there is suspicion of avascular necrosis (AVN) involving the knee, a magnetic resonance imaging (MRI) scan may be performed. If MRI confirms the presence of avascular necrosis in older patients, with extensive involvement of the condyle, total knee arthroplasty is often indicated ("**B**" **Recommendation**). Younger patients with more localized involvement may be candidates for a lesser procedure ("**C**" **Recommendation**).

If avascular necrosis is not present and there is not significant joint space narrowing, arthroscopic debridement can be considered. Arthroscopic debridement may be indicated for the treatment of patients with degenerative arthritis with mechanical symptoms ("**B**" **Recommendation**). Neither arthroscopic lavage nor debridement is indicated for patients without mechanical symptoms ("**A**" **Recommendation**). Results of arthroscopic debridement in patients with mechanical symptoms are variable, but high success rates are reported when there is not gross malalignment or instability, there is some articular cartilage remaining, and symptoms are well localized ("**B**" **Recommendation**).

Abrasion or drilling has not been shown to have added benefit ("**C**" **Recommendation**). Careful patient selection is required. "For the subgroup of knees with loose bodies or flaps of meniscus or cartilage that are causing mechanical symptoms, especially locking, catching, or giving way of the joint, there is a consensus that arthroscopic removal of these unstable tissues improves joint function and alleviates symptoms." (Felson DT, Buckwalter J; Editorial: Debridement and lavage for osteoarthritis of the knee, *New Eng J Med*, 347(2):132-3.)

If arthroscopic debridement for osteoarthritis of the knee is considered, a discussion with the patient should include the natural history of the underlying condition including short- and long-term pain and physical impairment expectations with and without surgery. The efficacy of the proposed surgical procedure should be discussed. The risks and possible complications of each treatment option and reasonable expectation and timeframe to accomplish the expected outcome should also be discussed.

#### Bi-compartmental or Tri-compartmental Arthritis

Patients with bi- or tri-compartmental arthritis of the knee who have failed to respond to conservative treatment should be considered for total knee arthroplasty ("**A**" **Recommendation**). The decision to proceed with total knee arthroplasty is shared by the patient and surgeon, and is based largely on quality of life issues. The choice to proceed with surgery should be based on the patient's age, activity level, occupation and a discussion. The discussion should include the natural history of the underlying condition including short- and long-term pain and physical impairment expectations with and without surgery. The efficacy of the proposed surgical procedure should be discussed. The risks and possible complications of each treatment option and reasonable expectation and timeframe to accomplish the expected outcome should be discussed.

Total joint replacement is contraindicated in the presence of active infection. Good results have been reported in total knee arthroplasty in patients under 55 years of age ("**B**" **Recommendation**).

#### Medial Compartment Arthritis

Young, active patients with varus alignment that have failed to respond to conservative treatment should be considered for tibial osteotomy ("**A**" **Recommendation**). Prerequisites for predictable results from proximal tibial osteotomy include: a range of motion of 5 to 90 degrees or greater, maintenance of some articular cartilage medially, minimal involvement of the lateral and patellofemoral compartments, and no more than minimal instability or lateral subluxation.

Patients who are less active may be considered for unicompartmental arthroplasty of the medial compartment of the knee ("**B**" **Recommendation**). Pain should be well localized to the medial compartment, and radiographs should demonstrate minimal involvement of the lateral and patellofemoral compartments. Reasonable weight and a functionally intact anterior cruciate ligament are associated with favorable outcome.

Patients with predominantly medial compartment arthritis who are not candidates for a tibial osteotomy or unicompartmental arthroplasty may be candidates for total knee arthroplasty ("**A**" **Recommendation**).

A discussion with the patient should include the natural history of the underlying condition including short- and long-term pain and physical impairment expectations with and without surgery. The efficacy of the proposed surgical procedure should be discussed. The risks and possible complications of each

treatment option and reasonable expectation and timeframe to accomplish the expected outcome should also be discussed.

#### Lateral Compartment Arthritis

Young, very active patients with isolated narrowing of the lateral compartment may be candidates for a distal femoral varus osteotomy ("**B**" **Recommendation**). Distal femoral varus osteotomy is indicated when there is 10 degrees or more of tibiofemoral valgus, particularly when the joint line is oblique.

Patients who are not candidates for a distal femoral varus osteotomy may be candidates for total knee arthroplasty ("**A**" **Recommendation**) or, occasionally, unicompartmental arthroplasty of the lateral compartment ("**C**" **Recommendation**).

#### Isolated Patellofemoral Arthritis

Young, very active patients with symptoms and radiographic changes isolated to the patellofemoral joint may be considered for a procedure to elevate the tibial tubercle ("**D**" **Recommendation**) or a patellectomy ("**D**" **Recommendation**). The role of patellectomy is not well defined and indications are limited. Results of tibial tubercle elevation have been variable with a significant complication rate.

A patient who is not young or very active may be a candidate for total knee arthroplasty ("**B**" **Recommendation**). A patellofemoral arthroplasty may also be considered, but the role for this surgical procedure is not well defined and indications are limited ("**B**" **Recommendation**).

A discussion with the patient should include the natural history of the underlying condition including short- and long-term pain and physical impairment expectations with and without surgery. The efficacy of the proposed surgical procedure should be discussed. The risks and possible complications of each treatment option and reasonable expectation and timeframe to accomplish the expected outcome should also be discussed.

#### *Alternative Approaches*

Continued conservative care for osteoarthritis of the knee may result in continued pain, dysfunction, and limitation in function. This often results in a diminution in quality of life. The avoidance of the risk and discomfort of surgery, for some patients, is desirable. There is some evidence that a long delay before arthroplasty is performed may result in a slightly poorer outcome, possibly due to worsening of muscle function and joint motion ("**C**" **Recommendation**).

#### **Definitions:**

#### **Strength of Recommendation**

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**B.** Types II, III, or IV evidence and findings are generally consistent

**C.** Types II, III, or IV evidence, but findings are inconsistent

**D.** Little or no systematic empirical evidence

### **Levels of Evidence**

**Type I.** Meta-analysis of multiple, well-designed controlled studies; or high power randomized, controlled clinical trial

**Type II.** Well-designed experimental study; or low-power randomized, controlled clinical trial

**Type III.** Well-designed, non-experimental studies such as nonrandomized, controlled single-group, pre-post, cohort, time, or matched case-control series

**Type IV.** Well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies

**Type V.** Case reports and clinical examples

**Consensus/opinion** (as it is used in bibliography of the original guideline):  
Articles representing expert consensus and not meeting the rigid I-V measurement are noted to represent consensus/opinion.

### **CLINICAL ALGORITHM(S)**

A detailed algorithm is presented in the original guideline document on [Universe of Adult Patients with Osteoarthritis of the Knee -- Phase II](#).

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is specifically stated and identified for each recommendation (see the "Major Recommendations" field).

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

- Successful surgical treatment for osteoarthritis of the knee results in a significant, measurable improvement in quality of life. Arthroplasty procedures are associated with a high short-term and long-term success rate. Patient satisfaction is good; pain and function usually improve significantly. Ambulation is usually significantly improved following successful knee arthroplasty. The ability to kneel and squat may not be improved with total knee arthroplasty.

- Osteotomy procedures may be slightly less reliably successful and afford slightly less pain relief than arthroplasty procedures, but allow a young patient to remain active. This is important for relatively young patients with high occupational or recreational desires for knee function. Osteotomy procedures generally are associated with a significant short-term and medium-term improvement in quality of life.

## **POTENTIAL HARMS**

Risks and complications of surgery

## **CONTRAINDICATIONS**

### **CONTRAINDICATIONS**

Total joint replacement is contraindicated in the presence of active infection

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made by the treating physician after a full assessment of all circumstances presented by a patient, including the needs and resources of a particular locality or institution.

## **IMPLEMENTATION OF THE GUIDELINE**

### **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

### **IMPLEMENTATION TOOLS**

Clinical Algorithm

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
Living with Illness

### **IOM DOMAIN**

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### **BIBLIOGRAPHIC SOURCE(S)**

American Academy of Orthopaedic Surgeons. AAOS clinical guideline on osteoarthritis of the knee (phase II). Rosemont (IL): American Academy of Orthopaedic Surgeons; 2003. 15 p. [75 references]

### **ADAPTATION**

The guideline was adapted from the 1996 American Academy of Orthopaedic Surgeons (AAOS) Clinical Guideline on Knee Pain, originally developed by a multi-professional panel led by the AAOS Task Force on Clinical Algorithms in cooperation with the AAOS Committee on Clinical Policies, the American Association of Neurological Surgeons, the American College of Physical Medicine and Rehabilitation, the American College of Rheumatology, as well as individuals in other medical specialties including family practice.

### **DATE RELEASED**

2003

### **GUIDELINE DEVELOPER(S)**

American Academy of Orthopaedic Surgeons - Medical Specialty Society

### **SOURCE(S) OF FUNDING**

American Academy of Orthopaedic Surgeons

### **GUIDELINE COMMITTEE**

American Academy of Orthopaedic Surgeons (AAOS) Work Group

### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Revision Panel (1999-2003):* Greg Stocks, MD, *Chairman*; Doug Dennis, MD; J. Wesley Mesko, MD; John A. Cardea, MD; Charles R. Clark, MD

*Original authors (1996-1999):* Aaron Rosenberg, MD, *Chairman*; Steven F. Harwin, MD; Thomas Sculco, MD; Doug Dennis, MD; Don Reilly, MD; Howard Fuchs, MD; Chuck Bush Joseph, MD; Calvin Brown, MD; Robert Barrack, MD; Ray Wasielewski, MD; Michael Kelly, MD

### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American Academy of Orthopaedic Surgeons Web site](#).

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (800) 626-6726 (800 346-AAOS); Fax: (847) 823-8125; Web site: [www.aaos.org](http://www.aaos.org).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

- Universe of adult patients with osteoarthritis of the knee -- Phase II. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2004. 1 p.

Electronic copies: Available in Portable Document Format (PDF) from the [American Academy of Orthopaedic Surgeons Web site](#).

Print copies: Available from the American Academy of Orthopaedic Surgeons, 6300 North River Road, Rosemont, IL 60018-4262. Telephone: (847) 823-7186; (800) 346-AAOS. Fax: (847) 823-8125. Web site: [www.aaos.org](http://www.aaos.org).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on May 3, 2004. The information was verified by the guideline developer on May 13, 2004. This summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs).

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