

# Treatment of Osteoarthritis of the Knee (Nonarthroplasty)

John Richmond, MD (Chair)  
 David Hunter, MD, PhD  
 Jay Irrgang, PT, PhD, ATC  
 Morgan H. Jones, MD  
 Bruce Levy, MD  
 Robert Marx, MD, MSc, FRCSC  
 Lynn Snyder-Mackler, PT, ATC,  
 SCS, ScD  
 William C. Watters III, MD  
 Robert H. Haralson III, MD,  
 MBA  
 Charles M. Turkelson, PhD  
 Janet L. Wies, MPH  
 Kevin M. Boyer  
 Sara Anderson, MPH  
 Justin St. Andre, MA  
 Patrick Sluka, MPH  
 Richard McGowan, MLS

## Abstract

The clinical practice guideline was explicitly developed to include only treatments less invasive than knee replacement (ie, arthroplasty). Patients with symptomatic osteoarthritis of the knee are to be encouraged to participate in self-management educational programs and to engage in self-care, as well as to lose weight and engage in exercise and quadriceps strengthening. The guideline recommends taping for short-term relief of pain as well as analgesics and intra-articular corticosteroids, but not glucosamine and/or chondroitin. Patients need not undergo needle lavage or arthroscopy with débridement or lavage. Patients may consider partial meniscectomy or loose body removal or realignment osteotomy, as conditions warrant. Use of a free-floating interpositional device should not be considered for symptomatic unicompartmental osteoarthritis of the knee. Lateral heel wedges should not be prescribed for patients with symptomatic medial compartmental osteoarthritis of the knee.

The work group was unable either to recommend or not recommend the use of braces with either valgus- or varus-directing forces for patients with medial unicompartmental osteoarthritis; the use of acupuncture or of hyaluronic acid; or osteotomy of the tibial tubercle for isolated symptomatic patellofemoral osteoarthritis.

## Overview and Rationale

The clinical practice guideline was approved by the American Academy of Orthopaedic Surgeons (AAOS) on December 6, 2008. It is based on a systematic review of published studies on the treatment of osteoarthritis (OA) of the knee in adults. The guideline was explicitly developed to include only treatments less invasive than knee replacement (ie, arthroplasty). In addition to providing practice recommendations, the guideline highlights gaps in the literature and areas that require future research.

The purpose of the clinical practice guideline is to help improve treat-

ment based on current best evidence. Current evidence-based practice standards demand that physicians use the best available evidence in their clinical decision making. To assist physicians, the guideline consists of a series of systematic reviews of the available literature on the treatment of OA of the knee in adults. These systematic reviews were conducted between October 24, 2007, and February 22, 2008; they identify areas of good evidence, show where evidence is lacking, and indicate topics that future research must target to improve treatment. AAOS staff and the Osteoarthritis of the Knee work group systematically reviewed the available literature and subse-

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quently wrote the recommendations based on a rigorous, standardized process.

Musculoskeletal care is provided in many different settings by many different providers. We created the guideline as an educational tool to guide qualified physicians through a series of treatment decisions in an effort to improve the quality and efficiency of care. The guideline should not be construed as including all proper methods of care or as excluding methods of care reasonably directed toward obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient as well as the needs and resources particular to the locality or institution.

The clinical practice guideline resulted in 22 specific recommendations in 8 separate categories: lifestyle modifications, rehabilitation, mechanical interventions, alternative therapies, pain relievers, intra-articular injections, needle lavage, and surgery. Each recommendation is graded based on the total body of evidence available to recommend for or against the intervention, using the following system:

A: Good evidence (consistent level I studies).

B: Fair evidence (consistent level II and III studies).

C: Poor-quality evidence (level IV or V).

Inconclusive: When there is insufficient or conflicting evidence.

Each recommendation was constructed using the following lan-

guage, which takes into account the final grade of recommendation: recommended, A; suggested, B; option, C; neither recommended nor not recommended, Inconclusive.

### Potential Harms and Contraindications

Individuals with OA of the knee often report joint pain, stiffness, and functional deficits. The goals of treatment are pain relief and improvement or maintenance of functional status. Long-term results were often not available, and adverse events varied by study (frequently they were not reported) in the literature available for the guideline. Most treatments are associated with some known risks, especially invasive and

Dr. Richmond is Chairman, Department of Orthopedic Surgery, New England Baptist Hospital, Boston, MA. Dr. Hunter is Chief, Division of Research, New England Baptist Hospital. Dr. Irrgang is Director of Clinical Research, Department of Orthopaedic Surgery, University of Pittsburgh, Pittsburgh, PA. Dr. Jones is Associate, Department of Orthopaedic Surgery, and Director, Surgical Sports Medicine Research, Sports Health Center, Cleveland Clinic, Cleveland, OH. Dr. Levy is Orthopaedic Surgeon, Departments of Orthopedic Surgery and Sports Medicine, Mayo Clinic, Rochester, MN. Dr. Marx is Orthopaedic Surgeon, Department of Orthopedic Surgery, Hospital for Special Surgery, New York, NY, and Professor, Orthopedic Surgery, Weill Medical College, Cornell University, New York. Dr. Snyder-Mackler is Physical Therapy Professor, Department of Physical Therapy, University of Delaware, Newark, DE. Dr. Watters is Orthopaedic Surgeon, Bone and Joint Clinic of Houston, Houston, TX. Dr. Haralson is Executive Director of Medical Affairs, AAOS, Rosemont, IL. Dr. Turkelson is Director of Research and Scientific Affairs, AAOS. Ms. Wies is Manager, Clinical Practice Guidelines Unit, Research and Scientific Affairs Department, AAOS. Mr. Boyer is Research Analyst, Guidelines, Research and Scientific Affairs Department, AAOS. Ms. Anderson is Research Analyst, Guidelines, Research and Scientific Affairs Department, AAOS. Mr. St. Andre at the time this guideline was being developed was Research Analyst, Guidelines, Research and Scientific Affairs Department, AAOS. Mr. Sluka is Research Analyst, Guidelines, Research and Scientific Affairs Department, AAOS. Mr. McGowan at the time this guideline was being developed was Medical Research Librarian, Research and Scientific Affairs Department, AAOS.

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surgical treatments. In addition, contraindications vary widely based on the treatment administered. Therefore, discussion of available treatments and procedures applicable to the individual patient rely on mutual communication between the patient and physician, weighing the potential risks and benefits for that patient.

## Methods

The methods used to develop the clinical practice guideline were designed to combat bias, enhance transparency, and promote reproducibility. Their purpose is both to give interested readers the ability to inspect all of the information the work group used to reach all of its decisions and to verify that these decisions are in accord with the best available evidence. The draft of the guideline was subject to peer review and public commentary. It was approved by the AAOS Evidence-Based Practice Committee, Guidelines and Technology Committee, Council on Research, Quality Assessment and Technology, and the Board of Directors. The methods used to prepare the guideline are detailed in the full clinical practice guideline, which is available at <http://www.aaos.org/research/guidelines/OAKguideline.pdf>.

Beyond the processes employed by the work group and the AAOS Guideline Unit in our own systematic review of the literature, the work group, to address certain questions, decided to utilize the evidence report "Treatment of Primary and Secondary Osteoarthritis of the Knee," prepared for the Agency for Healthcare Quality and Research (AHRQ),<sup>1</sup> and the previously published Osteoarthritis Research Society International (OARSI) treatment guidelines,<sup>2,3</sup> available at [www.oarsi.org](http://www.oarsi.org).

## Recommendations

### Recommendation 1

We suggest that patients with symptomatic OA of the knee be encouraged to participate in self-management educational programs, such as those conducted by the Arthritis Foundation, and incorporate activity modifications (eg, walking instead of running, alternative activities) into their lifestyle.

Level of Evidence: II

Grade of Recommendation: B

The OARSI guidelines, on which this recommendation is based, provide evidence from a single meta-analysis about the effect of education and self-management techniques (including changes in activity, exercise, and lifestyle modification) on patients with symptomatic OA of the knee.<sup>2,3</sup> Self-management results in a statistically significant improvement in pain, although the clinical importance of this improvement cannot be determined. The effect is not large, but it is possible that, with such pain improvement distributed throughout a population, many patients might be shown to benefit from self-management. Additionally, self-management is low in cost and has few associated harms. OARSI also reports that it was not possible to assess which specific aspects of self-management programs were the most effective,<sup>3</sup> thus making recommendation of a specific program difficult.

### Recommendation 2

Regular contact to promote self-care is an option for patients with symptomatic OA of the knee.

Level of Evidence: IV

Grade of Recommendation: C

The OARSI guidelines provide evidence from a single randomized controlled trial (RCT) about the regular contact of patients with symptomatic OA of the knee.<sup>2,3</sup> The AAOS work group initially considered the RCT evidence as being of a higher level

but downgraded the evidence to level IV because the results that are relevant to this recommendation are from a post hoc subgroup analysis. The results of this subgroup analysis suggest that regular telephone contact significantly reduces the amount of pain experienced by patients.<sup>2,3</sup> The evidence from OARSI suggests that this contact could be from lay personnel. Self-care is not defined in the OARSI document. The clinical significance of this finding cannot be determined because the minimally clinically important improvement (MCII) for the Arthritis Impact Measurement Scale (AIMS) instrument is unknown. The fact that telephone contact is of relatively low cost and has minimal, if any, associated harms supports this recommendation.

### Recommendation 3

We recommend that patients with symptomatic OA of the knee who are overweight (BMI >25) should be encouraged to lose weight (a minimum of 5% of body weight) and maintain their weight at a lower level with an appropriate program of dietary modification and exercise.

Level of Evidence: I

Grade of Recommendation: A

The OARSI guidelines provide evidence from two RCTs and a recent systematic review regarding the role of weight loss in patients with symptomatic OA of the knee.<sup>2,3</sup> This evidence was evaluated as level I because the relevant studies were considered to be high-quality, well-designed RCTs. Supporting this recommendation is that weight loss results in a possibly clinically important and statistically significant effect for functional improvement measured by the Western Ontario and McMaster Universities (WOMAC) function subscale (0.69; 95% CI, 0.24, 1.14; MCII = 0.37).<sup>2,3</sup> The effects of weight loss on other relevant outcomes are less clear. However, the ef-

fect of weight loss on functional improvement, combined with the fact that weight loss is likely to have health benefits that extend beyond OA of the knee, argues for this recommendation.

#### Recommendation 4

We recommend that patients with symptomatic OA of the knee be encouraged to participate in low-impact aerobic fitness exercises.

Level of Evidence: I

Grade of Recommendation: A

The OARSI guidelines provide evidence from a systematic review that included 13 RCTs on aerobic exercises (eg, walking, cycling) in patients with OA of the knee.<sup>2,3</sup> This recommendation was addressed by a systematic review of well-designed RCTs, making the evidence level I. The effect size of aerobic exercises on pain relief (0.52; 95% CI, 0.34, 0.70) and disability (0.46; 95% CI, 0.25, 0.67)<sup>2,3</sup> are statistically significant. Although the clinical importance of these effects cannot be determined, the relatively low cost and likely additional health benefits support this recommendation.

#### Recommendation 5

Range-of-motion/flexibility exercises are an option for patients with symptomatic OA of the knee.

Level of Evidence: V

Grade of Recommendation: C

Individuals with OA of the knee often suffer from joint stiffness and may have loss of joint motion and limited muscle flexibility. We found no published studies that address the effects of motion/flexibility exercises in patients with OA of the knee. Therefore, this recommendation is based on expert opinion, which is level V evidence. The consensus of the work group is that range-of-motion and flexibility exercises are an option to address these impairments. The low cost of these exercises,

the limited harms associated with them, and their potential benefits warrant this recommendation.

#### Recommendation 6

We suggest quadriceps strengthening for patients with symptomatic OA of the knee.

Level of Evidence: II

Grade of Recommendation: B

This recommendation was addressed by one level II systematic review<sup>4</sup> that included nine RCTs that examined the effects of quadriceps strengthening on pain<sup>5-13</sup> and no RCTs that examined the effect of quadriceps strengthening on function.<sup>5-14</sup> The systematic review concludes that quadriceps strengthening is effective. We supplemented the systematic review by performing our own meta-analyses. These analyses included an RCT<sup>15</sup> not included in the systematic review.

The evidence is level II because not all of the included RCTs were high-quality, well-designed trials. The systematic review<sup>4</sup> that addressed this recommendation contained a meta-analysis that found that the effects of quadriceps strengthening on pain and function were statistically significant. The major shortcoming of this analysis is that it combined studies that measured pain and function in different ways, thus making it impossible to determine whether the effects were clinically important. The results of our own meta-analysis on pain and function suggest a statistically significant and possibly clinically important effect. In light of this, and in light of the lack of harms associated with quadriceps strengthening, the evidence is sufficient to suggest the use of quadriceps strengthening.

#### Recommendation 7

We suggest that patients with symptomatic OA of the knee use patellar taping for short-term relief of pain

and improvement in function.

Level of Evidence: II

Grade of Recommendation: B

This recommendation of grade B is addressed by one level II systematic review<sup>16</sup> that examined the use of patellar taping among patients with symptomatic OA of the knee. The review included one level I RCT<sup>17</sup> and two level II RCTs.<sup>18,19</sup> The RCTs in the systematic review report statistically significant and possibly clinically important effects of medial taping on pain (as measured by the visual analogue scale) immediately and 4 days after the start of taping. There is some evidence that medial taping reduces pain on movement by an amount that is possibly clinically important, but this effect is observed only when taping is compared with no taping, not when medial taping is compared with a sham.

#### Recommendation 8

We suggest that lateral heel wedges not be prescribed for patients with symptomatic medial compartmental OA of the knee.

Level of Evidence: II

Grade of Recommendation: B

This recommendation is addressed by one level II systematic review<sup>20</sup> of three level II RCTs that examined the use of lateral heel wedges among patients with symptomatic medial compartmental OA of the knee. The three level II RCTs were published in six separate articles.<sup>21-26</sup> Comparisons between lateral and neutral heel wedges are investigated, as are comparisons between lateral wedged insoles and lateral wedged insoles with subtalar strapping. The systematic review concludes that there is only limited evidence for the effectiveness of lateral heel wedges and related orthoses. In addition, the possibility exists that those who do not use them may experience fewer symptoms from OA of the knee.

### Recommendation 9

We are unable to make a recommendation for or against the use of a brace with a valgus-directing force for patients with medial unicompartmental OA of the knee.

Level of Evidence: II

Grade of Recommendation: Inconclusive

This recommendation of Inconclusive is addressed by one level II systematic review<sup>20</sup> of two RCTs<sup>27,28</sup> that examined the use of braces among patients with medial unicompartmental OA of the knee. The brace is applied with the intent of altering a varus malaligned knee by moving the alignment of the knee in a valgus direction. One of the RCTs<sup>28</sup> included in the systematic review presented insufficient quantitative data for analyses. The qualitative results reported by the systematic review (for the study that did not adequately report quantitative data) indicate that patients in the brace group improved more on each outcome than did patients who received either a neoprene sleeve or were in the control group. The systematic review concludes that there is only limited evidence for the effectiveness of knee braces.

### Recommendation 10

We are unable to make a recommendation for or against the use of a brace with a varus-directing force for patients with lateral unicompartmental OA of the knee.

Level of Evidence: V

Grade of Recommendation: Inconclusive

A knee brace applied with the intent of altering a valgus malaligned knee by moving the alignment of the knee in a varus direction has been proposed as a treatment of individuals with symptomatic lateral tibiofemoral OA of the knee. No studies were identified by our systematic re-

view processes specific to patients with lateral tibiofemoral OA of the knee. Because of the absence of studies to address this treatment, this recommendation is level V.

### Recommendation 11

We are unable to make a recommendation for or against the use of acupuncture as an adjunctive therapy for pain in patients with symptomatic OA of the knee.

Level of Evidence: I

Grade of Recommendation: Inconclusive

This recommendation is addressed by the OARSI guidelines and by six level I and eight level II RCTs. The OARSI guidelines report conflicting evidence from two RCTs and one systematic review regarding the symptomatic benefit of acupuncture in patients with OA of the knee.<sup>2,3</sup> One RCT<sup>29</sup> and the systematic review<sup>30</sup> support the use of acupuncture; one RCT<sup>31</sup> does not. In an attempt to resolve these conflicting results, we conducted a de novo systematic review of previously published systematic reviews and confirmed that their conclusions were conflicting. Consequently, we updated these reviews with our own, including performing a meta-analysis of the results of all eligible RCTs on the use of acupuncture in patients with symptomatic OA of the knee.

Our meta-analysis suggests that the reported effects of acupuncture on pain depend on study design and conduct. Accordingly, the largest effects on pain and function are found in studies that did not employ blinding; the smallest effects are found in studies that employed blinding and verified that patients were blinded; and intermediate effects are found in studies that employed blinding but did not verify that patients were blinded. Further analyses showed that the effects of acupuncture on

pain and function were not statistically significant in studies that verified that their patients were blinded. However, there remains a large amount of unexplained variance in this group of studies as well as in the other two groups. Thus, although our meta-analytic results suggest that the apparent effects of acupuncture are to the result of a placebo effect, the unexplained differences among study results do not conclusively prove this point. Because of this, and because of the conflicting conclusions of previously published systematic reviews, we agreed that currently available evidence about the benefits of acupuncture is inconclusive.

### Recommendation 12

We recommend that glucosamine and/or chondroitin sulfate or hydrochloride not be prescribed for patients with symptomatic OA of the knee.

Level of Evidence: I

Grade of Recommendation: A

This recommendation is based on an AHRQ report that provides evidence from one RCT and six systematic reviews on the use of glucosamine and/or chondroitin sulfate or hydrochloride among patients with symptomatic OA of the knee.<sup>1</sup> We evaluated this evidence as level I. The AHRQ report states that “the best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination did not have any clinical benefit in patients with primary OA of the knee.”<sup>1</sup> One of the six systematic reviews concluded no clinical benefit for glucosamine or chondroitin compared with placebo. The remaining five systematic reviews did not provide conclusions on the clinical importance; however, they did conclude glucosamine and/or chondroitin are superior to placebo. The AAOS work group agreed that the AHRQ

report presents a high-quality systematic review of level I evidence demonstrating that the best available evidence does not support the prescribing of glucosamine and/or chondroitin.

### Recommendation 13

We suggest that patients with symptomatic OA of the knee receive one of the following analgesics for pain unless there are contraindications to this treatment: acetaminophen ( $\leq 4$  g/day) or nonsteroidal anti-inflammatory drugs (NSAIDs).

Level of Evidence: II

Grade of Recommendation: B

The OARSI guidelines provide evidence from three systematic reviews on the use of acetaminophen compared with placebo among patients with symptomatic OA of the knee.<sup>2,3</sup> In addition, the OARSI guidelines provide evidence from four systematic reviews that examined the use of NSAIDs compared with placebo or acetaminophen. We categorized this evidence as level II because of the lesser quality of included trials in the systematic reviews.

The evidence suggests that, compared with placebo, there are statistically significant effects of acetaminophen on pain relief without any statistically significant risk of toxicity. The clinical importance of the effect on pain cannot be determined. NSAIDs appear to have a statistically significant effect on pain, the clinical importance of which cannot be determined. NSAIDs also appear to reduce pain significantly more than does acetaminophen, but the effect is not clinically important. Finally, NSAIDs have statistically significant and favorable effects on clinical response and patient preference compared with acetaminophen, but they also have a statistically significant increased risk of gastrointestinal (GI) complications. The clinical impor-

tance of these effects cannot be determined.

### Recommendation 14

We suggest that patients with symptomatic OA of the knee and increased GI risk (ie, age  $\geq 60$  years, comorbid medical conditions, history of peptic ulcer disease, history of GI bleeding, concurrent use of corticosteroids and/or concomitant use of anticoagulants) receive one of the following analgesics for pain: acetaminophen (not to exceed 4 g per day), topical NSAIDs, nonselective oral NSAIDs plus gastroprotective agent; or cyclooxygenase-2 (COX-2) inhibitors.

Level of Evidence: II

Grade of Recommendation: B

The OARSI guidelines provide evidence from 11 systematic reviews on the use of acetaminophen, topical NSAIDs, nonselective oral NSAIDs plus a gastroprotective agent, or COX-2 inhibitors among patients with symptomatic OA of the knee who have increased risk of GI complications.<sup>2,3</sup> This evidence was evaluated as level II because of the lesser quality of included trials in the systematic reviews. The effectiveness of acetaminophen is discussed in the previous recommendation. For topical NSAIDs, the evidence suggests that there is a statistically significant effect on pain relief, stiffness, and function; however, the clinical importance of these effects cannot be determined. The effectiveness of nonselective oral NSAIDs and COX-2 inhibitors is also discussed in the previous recommendation. The evidence for oral NSAIDs included trials that investigated nonselective oral NSAIDs as well as COX-2 inhibitors. Each of these regimens has a reduced relative risk for adverse GI events compared with the isolated use of oral NSAIDs. The evidence does not demonstrate an advantage for any of these treatment regimens.<sup>2,3</sup>

### Recommendation 15

We suggest that intra-articular corticosteroids be used for short-term pain relief for patients with symptomatic OA of the knee.

Level of Evidence: II

Grade of Recommendation: B

Intra-articular corticosteroid treatment in patients with symptomatic OA of the knee was examined in three level II systematic reviews,<sup>32-34</sup> which include lesser quality RCTs. A total of 12 unique RCTs that compared corticosteroid and placebo interventions were included in these reviews.<sup>35-46</sup> All three of the systematic reviews conclude that intra-articular corticosteroids are effective for relieving pain in the short term (at 1 week and 16-24 weeks,<sup>34</sup> at 1 week and continuing at 2 to 3 weeks,<sup>32</sup> and within 1 to 2 weeks<sup>33</sup>). The only systematic review that commented on whether these effects were clinically important concluded that the effects on pain at 1 to 2 weeks were not.<sup>33</sup> However, we were able to evaluate clinical importance using data from another systematic review,<sup>32</sup> which suggested that clinically important and statistically significant effects of intra-articular corticosteroids on pain (as measured by the visual analogue scale) exist at 1 week after injection. There is little evidence suggesting that intra-articular corticosteroids have longer-term benefits.

### Recommendation 16

We cannot make a recommendation for or against the use of intra-articular hyaluronic acid for patients with mild to moderate symptomatic OA of the knee.

Levels of Evidence: I and II

Grade of Recommendation: Inconclusive

The AHRQ report<sup>1</sup> provides evidence from 42 trials that examined the effectiveness of intra-articular hyaluronic acid (ie, viscosupplementa-

tion) in patients with symptomatic OA. The AHRQ report explains that six meta-analyses and one additional RCT were considered in their review. This evidence was evaluated as levels I and II because some of the trials included in the AHRQ report were not well-designed, high-quality RCTs. The AHRQ report states that “viscosupplementation generally shows positive effects.”<sup>1</sup> However, the AHRQ report further notes that these results could have been influenced by “trial quality, potential publication bias, and unclear clinical significance (importance).”<sup>1</sup> The AHRQ report also noted that the “pooled effects from poor-quality trials were as much as twice those obtained from higher ones (trials).”<sup>1</sup> The AAOS work group agreed that the AHRQ report presents a high-quality systematic review of level I and level II evidence and graded this recommendation as inconclusive because of the conflicting evidence in pooled effects along with the unclear clinical importance of the results.

### Recommendation 17

We suggest that needle lavage not be used for patients with symptomatic OA of the knee.

Levels of Evidence: I and II

Grade of Recommendation: B

The AAOS conducted a systematic review that identified one level I RCT<sup>47</sup> and three level II RCTs<sup>48-50</sup> that studied needle lavage in patients with symptomatic OA of the knee. All three level II RCTs were graded as such because of lack of patient and caregiver blinding and failure to conceal the allocation of patients to treatment groups. Of all outcomes in all of the studies, only one was statistically significant at 12 or 24 weeks after needle lavage: quality of well-being at 24 weeks. In general, longer-term effects also were not statistically significant. Because of the lack

of demonstrated effect of needle lavage, we suggest that it not be used.

### Recommendation 18

We recommend against performing arthroscopy with débridement or lavage in patients with a primary diagnosis of symptomatic OA of the knee.

Levels of Evidence: I and II

Grade of Recommendation: A

One level II systematic review<sup>51</sup> containing three RCTs<sup>48,52,53</sup> examined the use of arthroscopic débridement in patients with symptomatic OA of the knee. The sole level I RCT<sup>53</sup> included comparison of arthroscopic lavage alone to sham arthroscopic surgery (placebo). Two additional level II RCTs<sup>35,54</sup> investigated the differences between arthroscopic lavage alone and placebo. The systematic review concluded that “[arthroscopic débridement] has no significant benefit for knee OA of undiscriminated cause.”<sup>51</sup>

In the level I RCT, the effects of arthroscopy with débridement or lavage were not statistically significant in the great majority of patient-oriented outcome measures for pain and function at multiple time points from 1 week to 2 years after surgery.<sup>53</sup> There may be limited applicability of the level I RCT, which is called into question because of its limited population (largely older male and veteran) and the number of potential study participants who declined randomization into a treatment group. However, additional evidence from the systematic review and the other RCTs we examined also support the lack of incremental benefit of arthroscopic débridement or lavage. In addition, surgical treatment subjects the patient to potentially increased risks (eg, anesthetic complications, infection, thrombophlebitis). None of the evidence we examined specifically included

patients who had a primary diagnosis of meniscal tear, loose body, or other mechanical derangement and who also had a concomitant diagnosis of OA of the knee, and the present recommendation does not apply to such patients.

### Recommendation 19

Arthroscopic partial meniscectomy or loose body removal is an option in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus and/or a loose body.

Level of Evidence: V

Grade of Recommendation: C

Currently, arthroscopic partial meniscectomy and/or loose body removal is routinely performed in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus and/or a loose body. No level I or II evidence is available to suggest that arthroscopic partial meniscectomy and/or loose body removal is or is not appropriate for a patient with a primary diagnosis of a torn meniscus and/or a loose body in whom OA of the knee is identified secondarily. The expert opinion consensus (level V evidence) of the AAOS work group is that arthroscopic partial meniscectomy or loose body removal is an option for patients with primary signs and symptoms of a torn meniscus and/or loose body. Additional studies are warranted to look at the outcomes of arthroscopic surgery in this population.

### Recommendation 20

We cannot make a recommendation for or against an osteotomy of the tibial tubercle for patients with isolated symptomatic patellofemoral osteoarthritis.

Level of Evidence: V

Grade of Recommendation: Inconclusive

No studies investigating osteotomy of the tibial tubercle for patients with isolated patellofemoral OA were identified by our systematic literature searches, thus making this recommendation that of expert opinion, level V. Osteotomy of the tibial tubercle has been proposed as a treatment of patients with isolated symptomatic patellofemoral OA of the knee.

### Recommendation 21

Realignment osteotomy is an option in active patients with symptomatic unicompartmental OA of the knee with malalignment.

Levels of Evidence: IV and V

Grade of Recommendation: C

A systematic review investigated realignment osteotomy in patients with unicompartmental knee OA with malalignment.<sup>55</sup> This review examined various osteotomy surgical techniques but did not specifically address the efficacy of realignment osteotomy. Rather, it compared various realignment osteotomy surgical techniques and concluded that there is limited evidence for the efficacy of osteotomy. To address efficacy, we examined five case series studies<sup>56-60</sup> and the baseline and follow-up measurements within each treatment arm of six RCTs,<sup>61-66</sup> comparing different surgical techniques. This evidence, including the preoperative and postoperative data from RCTs, is considered to be level IV evidence because there is no comparison to a placebo or control group. The AAOS work group agreed that the level IV case series evidence suggested that realignment osteotomy had benefits that lasted up to 2 years after surgery. We did not analyze longer-term results because of loss of patients in the relevant studies. Additionally, using level V expert opinion, the work group qualified this recommendation for “active” patients.

### Recommendation 22

We suggest not using a free-floating interpositional device for patients with symptomatic unicompartmental OA of the knee.

Levels of Evidence: IV

Grade of Recommendation: B

Evidence from one published case series<sup>67</sup> and from the Australian Orthopaedic Association National Joint Replacement Registry,<sup>68-70</sup> reporting the results of free-floating interpositional device surgeries performed between 2004 and 2006, addresses the use of free-floating interpositional devices for treatment of unicompartmental OA of the knee. We categorized this evidence as level IV evidence. In 2007, the Australian registry stated that it no longer uses free-floating interpositional devices.<sup>71</sup> The evidence demonstrates high secondary surgery rates in the patients followed in both series. Revision to total knee arthroplasty ranged from 32% at 2 years to 62% at 3 years. The AAOS work group upgraded this recommendation to grade B, based on the high revision rates in these series and the potential harm associated with this intervention.

### Future Research

Many treatments of OA of the knee are addressed by randomized controlled trials. The quality of these trials is, in some cases, questionable. To achieve a high-quality literature base, academic authors and scientists should invest their time and effort into studies designed to avoid bias. Techniques to limit bias include proper randomization and adequate, verified blinding of investigators, patients, and/or evaluators wherever possible. Future studies should also include a priori power analysis to ensure clinical improvement that matters to the patient. These studies should use patient-oriented outcome

measures (eg, WOMAC, Medical Outcomes Study 12-Item Short Form) whose key psychometric characteristics have been evaluated and validated. The use of validated patient-oriented outcome measures will ensure that the measure of success of future studies is determined by minimal clinically important improvements.

High-quality evidence for surgical treatment (up to but not including knee arthroplasty) of OA of the knee is generally lacking. The logistical difficulties and ethical concerns in conducting placebo-controlled studies of surgical interventions compromise the quality of these studies. To improve the quality of future studies of surgical treatments, the use of active, nonplacebo control groups should be considered. Surgical treatment of OA of the knee is often indicated in patients who exhibit symptoms unique from those of other pathologies (ie, loose body, meniscal tear) in addition to the symptoms from OA of the knee. Surgical treatment is also often indicated in patients with specific characteristics (ie, age, activity level, severity of OA). Investigators should develop rigorous patient-inclusion criteria to ensure that patients who typically receive the surgical intervention in clinical practice are adequately represented in the study population.

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