Washington State Health Care Authority

Health Technology Assessment

HTA Evidence Report Arthroscopic Surgery of the Knee for Osteoarthritis

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Knee Arthroscopy for Osteoarthritis

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The information in this assessment is intended to assist health care decision makers, clinicians, patients and policy makers in making sound evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability

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1. APPRAISAL SUMMARY

Technology Background

Osteoarthritis (OA) is a common orthopedic condition characterized by articular degeneration within a joint. Clinical osteoarthritis is estimated to affect approximately 27 million people in the United States and the prevalence of OA of the knee may be as high as 37.4% of the population aged 60 and older (Lawrence 08). Primary OA of the knee refers to articular degeneration which has no obvious underlying etiology or predisposing cause. OA with an underlying cause such as metabolic (calcium crystal deposition), inflammatory (septic arthritis), anatomic abnormality, or trauma may be referred to as secondary OA. The distinction between primary and secondary disease is not always clear and the clinical presentation and symptoms of both classifications are may be similar (Doherty 1983).

The diagnosis of osteoarthritis is commonly based on a combination of symptoms and physical findings such as knee pain or stiffness and radiographic findings (Claessens 1990). Treatment for osteoarthritis of the knee is undertaken with the goals of reducing pain, maintaining mobility, and minimizing disability; medical management may include drug therapy, physical or occupational therapy, heat and cold application, surgical intervention, or weight loss.

Patients with knee osteoarthritis and symptoms that are refractory to drugs frequently receive arthroscopic interventions for diagnosis or treatment. Interventions such as debridement and lavage of the knee are carried out with the goal of delaying knee replacement arthroplasty. Although orthopedic guidelines list joint lavage and arthroscopic debridement as treatment options, their roles in managing OA of the knee remain controversial (Zhang 2008). In 1998, it was estimated that 650,000 knee arthroscopies were performed yearly (Moseley 2002). Knee arthroscopies can be performed under local, spinal, general or other types of anesthesia. Arthroscopies are considered by many to be minimally invasive procedures, but clinically significant adverse events have been reported. For example, the incidence of deep venous thrombosis (DVT) in patients undergoing knee arthroscopy has been reported to be from 0.6% to 17.9% depending on the diagnostic method used (Ramos 2007).

Objective of this Review

Knee arthroscopy for lavage and debridement in knee osteoarthritis is a high volume and high cost intervention and, as such, should be demonstrated to provide an acceptable benefit-risk ratio for patients through well-designed, conducted and evaluated RCTs.

The primary objective of the review is to provide an overview and quality assessment of a recently published systematic review and to provide an update to that review by systematically searching and appraising any significant new literature published since the review was completed in 2007.

Key Questions Addressed in this Report

For patients with osteoarthritis of the knee:

1. What is the evidence that arthroscopic lavage reduces pain and improves function?
2. What is the evidence that arthroscopic debridement reduces pain and improves function?
3. What is the evidence that either debridement or lavage reduces pain and improves function for any subpopulation of patients with osteoarthritis?
4. What is the evidence regarding adverse events from arthroscopic debridement and lavage?
5. What is the evidence regarding cost or cost-effectiveness of arthroscopic lavage or debridement?

Methods Summary

The methodology used in this review included a critical appraisal of the AHRQ review conducted by Samson (2007), Table 1. We also sought systematic reviews and RCTs dealing with efficacy and safety of arthroscopic debridement and lavage for knee osteoarthritis published after the search date of the AHRQ review. Additionally, we sought and appraised RCTs dealing with harms.

As a result of findings from this critical appraisal and review of subsequent evidence, this review is based heavily on one section of the AHRQ evidence report (Samson 2007) from the Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center, which is a well-conducted systematic review of three treatments for osteoarthritis (OA) of the knee: intra-articular injections of viscosupplements; oral glucosamine, chondroitin, or the combination; and, arthroscopic lavage and debridement (AHRQ Publication No. 07-E012) referred to in this report as "the AHRQ publication" (see Table 1 for critical appraisal of Samson 2007). It is also based on literature searches that update AHRQ publication along with an independent critical appraisal of the relevant studies published after the search date of the AHRQ publication (Tables 2-4), including a Cochrane review (Laupattarakasem 2008) (Table 3). We found no relevant efficacy studies published after the search date of the AHRQ publication. The 2008 Osteoarthritis Research Society International recommendations (guidelines) for the management of hip and knee Osteoarthritis (Zhang 2008) are also reviewed (Table 5). Implications from this evidence review are provided.

Summary Results

The key clinical questions are answered below based on the best-available efficacy and safety evidence. Evidence Grades Used in Brief (details found in Section III: Evidence Rating):

- **Grade A: Useful** — The evidence appears strong and sufficient to use in making health care decisions - no significant threats to validity were ascertained.
- **Grade B: Possibly useful** — The evidence appears potentially strong and is probably sufficient to use in making health care decisions - some threats to validity were identified.
- **Grade B-U: Possible to uncertain usefulness** — The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U. Health care decision-makers should be fully informed of the evidence quality.

- **Grade U: Uncertain validity and/or usefulness** — There is sufficient uncertainty that caution is urged regarding its use in making health care decisions. Delfini does not use such information to inform clinical decisions regarding efficacy.

Questions 1-3:

1. What is the evidence that arthroscopic lavage reduces pain and improves function?
2. What is the evidence that arthroscopic debridement reduces pain and improves function?
3. What is the evidence that either debridement or lavage reduces pain and improves function for any subpopulation of patients with osteoarthritis?

Conclusion

AHRQ Publication Findings: We agree with the authors of the AHRQ publication's efficacy conclusions that the evidence is insufficient to conclude that arthroscopy and lavage or debridement for treatment of osteoarthritis of the knee results in pain reduction or improved function for patients. This includes any subgroups of patients.

Review and Update Findings: Neither arthroscopic lavage nor debridement have been found to be superior to sham arthroscopy in well-designed and conducted randomized controlled trials (RCTs).

Searching yielded numerous studies of lavage and debridement for treatment of knee OA. No new studies since the AHRQ Publication met inclusion criteria. One additional systematic review was identified and evaluated for quality.

Only one study (Moseley 2002), Table 2, a possibly valid RCT, could be used as the foundation for our efficacy conclusion. The authors of this RCT evaluated the confidence intervals for the Knee-Specific-Pain Score (KSPS) at two years along with other measures of pain and function and determined that they did not include a clinically meaningful difference between either the debridement group and placebo or the lavage group and placebo group. This study provides possibly useful evidence that neither arthroscopic lavage nor debridement is more effective than a placebo (sham) procedure for treatment of knee OA.

Although the Moseley (2002) study has some threats to validity, we — as did the authors of the AHRQ publication (Samson 2007), Table 1 and the authors of a Cochrane review (Laupattarakasem 2008), Table 3 — consider it to be the best available valid and clinically useful efficacy evidence upon which arthroscopy decisions should be based. The AHRQ Publication (Samson 2007) reached the following conclusion based on the Moseley study: "Osteoarthritis of the knee is a common condition. Arthroscopy with debridement and lavage is widely used in the treatment of OA of the knee, yet the best available valid and clinically useful evidence does not clearly demonstrate clinical benefit. Uncertainty regarding clinical benefit can be resolved only by rigorous, multicenter RCTs. In addition, given the public health impact of OA of the knee, research on new approaches to prevention and treatment should be given high priority."

Conclusion Grade: B-U
Possible to uncertain usefulness — The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U. Health care

decision-makers should be fully informed of the evidence quality.

Reason for Grade

- Conclusion is based on a single RCT.
- The single RCT was graded B-U due to some threats to validity.

Question 4:

4. What is the evidence regarding adverse events from arthroscopic debridement and lavage?

Conclusion

AHRQ Publication Findings: The AHRQ publication reported extensive safety data from observational studies (see below). As mentioned in the AHRQ publication, confidence in the accuracy of adverse events data is extremely low when it is derived from observational studies. Observational data, however, provide useful indicators that should raise end users' awareness about safety concerns

Review and Update Findings: We found only Grade U study (uncertain efficacy and usefulness) information on adverse effects from RCTs evaluating arthroscopy with lavage and debridement for knee OA primarily because the trials focused on efficacy and did not formally measure safety events. RCT and observational data of uncertain validity and usefulness (Grade U), however, provide some indications about safety that should raise end users' awareness about potential harms. (Anesthesia risk information is not included in assessment below.)

Complication	Frequency	Source
Mortality	0.1% to 0.5%	Samson 2007
Stroke or MI	0.3%	Samson 2007
DVT	0.6% to 17.9%	Ramos 2007
Hemarthrosis	Up to 25%	Samson 2007
Infection	0.5% to 2%	Samson 2007

Conclusion Grade: B-U Based on Grade U Evidence

Possible to uncertain usefulness — The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U. Health care decision-makers should be fully informed of the evidence quality.

Reason for Grade

- Conclusion is based on weak evidence.

In order to reach risk-benefit conclusions, clinicians, patients and policy-makers are advised to consider the evidence on adverse events which is almost always weaker than evidence available for evaluating efficacy. This issue comes into sharp focus when evidence of clinical benefit from an intervention is lacking as is the case in arthroscopy with lavage and debridement for OA of the knee. Safety evidence on arthroscopy with lavage and debridement for knee OA is of

extremely poor quality. We reviewed RCTs of arthroscopic lavage or debridement for knee OA including those excluded by the AHRQ publication and sought RCTs that measured adverse events published after the AHRQ review. We found no useful information on adverse effects from RCTs that evaluated arthroscopy with lavage and debridement for knee OA, primarily because the trials focused on efficacy and did not formally measure safety events. Observational data, however, provide useful indicators that should raise end users' awareness about safety concerns:

- Case series data also suggest that arthroscopy may not be a low risk-procedure in knee lavage and debridement. (Table 85 in AHRQ publication, Samson 2007):
    - Mortality has been reported to be from 0.1% to 0.5% ;
    - A 0.3% rate of stroke or myocardial infarction has been reported;
    - A hemarthrosis rate of nearly 25% was reported in one case series;
    - Reports of infection have ranged from 0.5% to 2%;
- DVT as measured by clinical findings, ultrasound or venography in RCTs involving patients undergoing knee arthroscopy has been reported in a recent Cochrane review to be from 0.6% to 17.9% (Ramos 2007), Search Table 4. However, the applicability of this clinical trial data to patients undergoing knee lavage and debridement is limited because knee arthroscopy in this Cochrane review was performed for a wide array of indications in heterogeneous populations. Unfortunately, complications and subsequent interventions were not measured in three RCTs that evaluated the efficacy of knee arthroscopy with lavage and debridement for the treatment of OA (see Laupattarakasem 2008, Table 3);
- A large Canadian database study (Wai 2002), reviewed in the AHRQ publication reported that, for patients undergoing knee arthroscopy and lavage or debridement, the probability of complications was 1.9% overall. The probability of repeat arthroscopy was 2.8 percent within 1 year and 7.7 percent within 3 years. The probability of undergoing total knee arthroplasty was 9.2 percent within 1 year and 18.4 percent within 3 years. High tibial osteotomy was performed in 1.2 percent within 1 year and in 2.9 percent within 3 years. The probability of arthroplasty, osteotomy or repeated arthroscopy increased significantly with age;
- If general anesthesia is used, adverse events such as nausea and other more significant risks are incurred. If spinal anesthesia is used, the risks of leakage and spinal headache are incurred.

Question 5:

5. What is the evidence regarding cost or cost-effectiveness of arthroscopic lavage or debridement?

Conclusion

AHRQ Publication Findings: The AHRQ publication did not address the issue of cost or cost-effectiveness.

Review and Update Findings: We found only Grade U study (uncertain efficacy and usefulness) information on cost and cost-effectiveness. As noted below, this is likely because effectiveness has not yet been demonstrated.

- No useful economic modeling information was found in our MEDLINE searches.
- An economic model (Search Table 7. DARE, Record #2) was provided by The Medical

Advisory Secretariat Ministry of Health and Long-Term Care, Toronto. The authors were unable to conduct a full economic analysis because effectiveness was not demonstrated in the literature. They state that based on the Moseley (2002) trial, cost effectiveness is likely to be unfavorable. However, they provide an outline of considerations (e.g., hospital costs, non-hospital costs, discounting, etc. that may be useful in creating an economic model to inform cost estimates.

Conclusion Grade: U
Uncertain validity and/or usefulness — There is sufficient uncertainty that caution is urged regarding its use in making health care decisions.

Reason for Grade

- Conclusion is based on insufficient evidence.

2. Technology Background and Context

This section of the report describes the technology, provides relevant clinical background, and provides context for discussion by highlighting key implications and/or concerns raised by the clinical context, current practice standards, general state of research and evidence, or lack thereof. This section also provides information on other organizations that have considered the topic, including practice guidelines, other systematic reviews, and coverage policies. Finally, this section notes any current or ongoing research that may be relevant.

Clinical Background

Treatment for OA of the knee aims to alleviate pain and improve function in order to mitigate reduction in activity (American College of Rheumatology, 2000; Felson, 2006). However, most treatments do not modify the natural history or progression of OA, and thus are not considered curative. Nonsurgical modalities include education, exercise, weight loss, and various supportive devices; acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen; nutritional supplements (glucosamine and chondroitin); and, intra-articular viscosupplements. Guidelines for the medical management of osteoarthritis emphasize the role of both nonpharmacologic and pharmacologic therapies (American College of Rheumatology, 2000; Jordan, Arden, Doherty, et al., 2003). Initial management involves nonpharmacologic therapies, including education, exercise, various appliances and braces, and weight reduction. Acetaminophen is recommended as first-line pharmacologic therapy. If pain relief is inadequate with acetaminophen, analgesic-dose NSAIDs may be used (e.g., ibuprofen, naproxen). If symptom response to a lower NSAID dosage is inadequate, higher, anti-inflammatory, doses may be used. Intra-articular corticosteroid injection may be considered when relief from NSAIDs are insufficient or the patient is at risk from gastrointestinal adverse effects. Injection of corticosteroids is frequently limited to three to four times per year per joint because of concern about the possibility of progressive cartilage damage through repeated injection in the weightbearing joints (Neustadt, 1992).

If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Operative treatments for symptomatic OA of the knee include arthroscopic lavage and cartilage debridement, osteotomy, and, ultimately, total joint arthroplasty (Day, 2005). Surgical procedures intended to repair or restore articular cartilage in the knee, including abrasion arthroplasty, microfracture techniques, autologous chondrocyte implantation, and others, are appropriate only for younger patients with focal cartilage defects secondary to injury (Clarke and Scott, 2003)

The Technology

Knee joint lavage and arthroscopic debridement are commonly performed procedures in the treatment of knee OA. Answering questions relating to the evidence for efficacy and safety is important in order to ensure that meaningful health care improvements result from the use of these procedures. Arthroscopic lavage is a non-curative measure in which intra-articular fluid is aspirated and the joint is washed out, with the goal of removing inflammatory mediators, debris, or small loose bodies from the osteoarthritic knee. Articular debridement involves removal of cartilage or meniscal fragments, but the term does not have precise meaning and may variably include cartilage abrasion, excision of osteophytes and synovectomy. Debridement is intended to improve symptoms and joint function in patients with mechanical symptoms such as locking or catching of the knee. As pointed out in the AHRQ publication, lavage and debridement are often

performed during a single arthroscopic procedure, and it is difficult to attribute the success or failure of arthroscopy to a lavage or debridement. Arthroscopic lavage and debridement studies were included in this update and the previous AHRQ publication if arthroscopic treatment of OA involved lavage with or without debridement, and debridement was not specifically required to include procedures beyond nonabrasion chondroplasty and removal of loose bodies. Thus, neither the AHRQ publication nor this update included studies if they focused on arthroscopic meniscectomy, ligament or meniscus repair, abrasion chondroplasty or other arthroscopic procedures. Although arthroscopic knee lavage and debridement are frequently performed in an attempt to delay total knee replacement surgery, there is uncertainty about efficacy and the benefit-risk ratio of these interventions. The uncertainty of the current situation is reflected by the variation seen in clinical judgments regarding efficacy, health plan coverage decisions and inconsistencies between the best available valid and clinically useful evidence and clinical guideline recommendations. There are a number of clinical implications which derive from the current lack of a robust evidence base to inform conclusions regarding efficacy and safety.

Patient Implications

When substantial benefits for patients have not been demonstrated through valid RCTs, it is imperative for patients and others to be appropriately informed of the potential harmful effects of an intervention along with the concomitant interventions that accompany it. There is a high likelihood of many physicians not conveying accurate quantitative efficacy and safety information to patients. In addition to potential harms described above, long-term safety is unknown. This affects cost as well-- not only for the procedure, but also for costs resulting from caring for patients who experience harms. This procedure may have implications for time lost from work.

On the other hand, there is one case series, included in the AHRQ publication, (Table 83 in the AHRQ publication) which reported 90% patient satisfaction with symptom and function with a mean follow-up of approximately 4 years. We found three case series reporting satisfaction. In one case series (Fond 2002), the authors reviewed charts of 36 patients and rated patient satisfaction at 2 and 5 years. At 2 years, 32 patients were rated good to excellent satisfaction and 4 patients were rated as having poor satisfaction. At 5 years, there were 25 with good to excellent ratings, 3 fair and 8 poor results. In another case series (McGinley 1999), 77 patients were contacted for follow-up 10 or more years after arthroscopy and debridement. Patient satisfaction averaged 8.6 on a 0 to 10 scale. In a third case series of 194 patients (Harwin 1999), patients provided an answer to the questions, “Are you better?” “Are you unchanged?” or “Are you worse?” Answers were sought 2 to 15 years (mean, 7.4) following arthroscopy. Overall, 63.2% (129 knees) were better, 21.1% (43 knees) were unchanged, and 15.7% (32 knees) were worse after surgery.

The validity and usefulness of these case series are severely limited by the numerous confounders and biases present in case series including lack of comparison group, lack of blinding, placebo effect, to name just a few.

Clinical Practice Issues & Standards of Care

AD and lavage for OA of the knee are performed with great frequency, reported by Moseley (2002) to be approximately 650,000 per year in 1998, yet despite this frequency they remain controversial even among experts within the orthopedic community. For example, in the OARSI guidelines, the strength of recommendations by the guideline team on a scale of 0 to 100 (100

being strongest) was over 90 for weight loss, non-steroidal anti-inflammatory drugs, acetaminophen and total knee replacement, but only 60 for lavage and arthroscopic debridement. Controversy is frequent when there is uncertainty.

Difficult-to-change, costly and at times harmful guidelines or standards of care can be established when interventions are adopted without strong evidence of substantial net benefit for patients (Auerbach 2007).

Clinical guidelines groups may present evidence in such a manner that "upgrades the evidence" of benefit. This is likely to encourage overuse. For example, The Osteoarthritis Research Society International (OARSI) guidelines group awarded what they consider to be a high level (level Ib grade of evidence) to many studies which were actually considered to be of low quality by the authors of the AHRQ publication. Grade Ib evidence is defined by the OARSI group as a single RCT; however, this is not sufficient to be considered high quality evidence — RCTs must be valid and clinically useful. In contrast to the OARSI rating, the Moseley 2002 RCT (the only study identified as high quality by the AHRQ authors and grade B-U by our review) was not assigned an evidence grade at all by the OARSI group. Potential threats to validity were mentioned in the narrative text of the OARSI guideline (and conversely, no threats to validity were mentioned for the other RCTs given an Ib grade by them and considered low quality by the AHRQ publication authors). A striking example of upgrading of evidence by the OARSI group was the evaluation of the Livesley 1991 study which was rated as a grade Ib study by the OARSI group without any information about threats to validity, but yet was rated as poor by the authors of the AHRQ publication because of numerous threats to validity including the lack of randomization.

Clinical Practice Guidelines

We evaluated the 2008 Osteoarthritis Research Society International (OARSI) recommendations (guidelines) for the management of hip and knee Osteoarthritis (Zhang 2008) which in included a review of the literature and other guidelines. The methodology of determining the levels of evidence, however, was flawed and as a result, the evidence received higher quality ratings than those assigned by the authors of the AHRQ publication. Proposition 24 of the guideline applies to arthroscopic knee lavage and debridement and states:

The roles of joint lavage and arthroscopic debridement in knee OA are controversial. Although some studies have demonstrated short-term symptom relief, others suggest that improvement in symptoms could be attributable to a placebo effect." Arthroscopic debridement, a procedure that variably includes joint lavage, the removal of loose bodies, debris, mobile fragments of articular cartilage, unstable torn menisci and impinging osteophytes, has been extensively used in the treatment of OA knee for more than 70 years; and joint lavage is currently recommended as useful treatment for patients with knee OA in 3/3 treatment guidelines where this modality of therapy was considered. However, controversy regarding the efficacy and indications for these procedures in the management of knee OA continues. (See Table 5 for full critical appraisal).

Previous Systematic Reviews/Technology Assessments

This report is an update of a recently conducted (2007), well designed AHRQ systematic review. See Search Tables 3 and 4 for previous systematic reviews and Search Table 7 for previous technology assessments. These reviews provide no additional efficacy or safety data beyond that

contained in the AHRQ publication. Clinical Evidence (search date 6/20/08) contains no relevant systematic reviews.

Medicare and Representative Private Insurer Coverage Policies

The following information on coverage is taken from the Ontario Health Technology Advisory Committee report Arthroscopic Lavage and Debridement for Osteoarthritis of the Knee.

- The Centers for Medicare & Medicaid Services (CMS) published their decision in 2004. It states that the evidence is adequate to conclude that the two procedures are neither reasonable nor necessary for patients with OA of the knee. Their specific funding recommendations are as follows:
    - No coverage of lavage alone for patients with OA of the knee.
    - No coverage of debridement for patients with knee pain only or with severe OA.
    - All other indications of debridement for patients with OA of the knee will remain at contractor discretion.
- Aetna published their clinical policy bulletin in 2004 and concluded the following:
    - Arthroscopic lavage is considered experimental and investigational because its effectiveness is not established.
    - Arthroscopic debridement is considered experimental and investigational for persons with knee pain only or with severe OA.
- Aetna concluded that arthroscopic debridement may be considered medically necessary in people with mild to moderate disease with pain plus mechanical problems such as those due to loose bodies and meniscal tears.
- The CIGNA Health Care Coverage Position, with an effective date of April 15, 2004, stated the following: It does not cover any of the following treatments for OA as they are considered experimental, investigational, or unproven:
    - Lavage alone
    - Debridement for patients with knee pain only
    - Debridement for patients with severe OA
    - It does cover arthroscopic debridement (with or without lavage) for OA of the knee as medically necessary in the presence of all of the following:
    - Normal limb alignment or minimal malalignment of the joint is present
    - X-ray confirmation of no or minimal degenerative arthritis
    - Recent onset of symptoms or within one year of presentation
    - Documentation of at least one of the following conditions: mechanical symptoms (e.g., locking of the limb, giving way or catching), loose bodies, unstable flaps of articular cartilage, disruption of the meniscus, or impinging osteophytes

Ongoing Clinical Trials

Twenty-six potentially relevant ongoing clinical trials were identified. None of the trials focus on lavage or debridement; however they may be relevant for safety.

Research Issues and Recommendations

Knee arthroscopy for lavage and debridement in knee osteoarthritis is a high volume and high cost intervention and, as such, should be demonstrated to provide an acceptable benefit-risk ratio for patients through well-designed, conducted and evaluated RCTs.

We concur with the implications stated in the AHRQ publication (Samson 2007) and the Cochrane review (Ramos 2007), namely that further high quality research is urgently needed in specific population groups. In addition, we would like to emphasize the following points:

- To demonstrate that an intervention is likely to improve patients' health or quality of life requires valid evidence that meaningful patient benefits outweigh harms.
- Low quality evidence or clinical experience is insufficient for demonstrating improved patient outcomes and may result in significant harms and costs. Decision-makers, in the absence of high quality evidence, must make decisions based on many factors and this requires judgment. It is problematic to rank non-valid evidence above expert opinion because it may give the appearance that fatally flawed evidence is valid. Low quality evidence, because of confounding and biases, frequently falsely inflates reported study results.
    - It should be emphasized that obtaining valid study results is dependent upon good study methods. High quality studies for therapies require blinding of subjects and everyone working with the subjects or study data (double-blinding, sometimes referred to as triple-blinding) in order to decrease the likelihood of bias. Bias may be more likely to occur when evaluating subjective outcomes such as pain, satisfaction, and function in non-blinded studies, but it has also been reported with objective outcomes such as mortality. When dealing with subjective outcomes, it is critical to distinguish the effect of the intervention from the effect of the patient's expectation of the intervention. The only way to distinguish the effect of a patient's positive expectations of an operation from the intervention itself is to blind patients to the treatment they receive and randomize them to receive the intervention of interest or to receive a sham intervention (placebo). Lack of blinding may affect RCT results dramatically. Jüni (2001) reviewed four studies that compared results from double-blinded versus non-blinded RCTs and attempted to quantify the amount of distortion (bias) caused by lack of double-blinding. Overall, the overestimation of effect was approximately 14% (relative difference). The overestimation of effect may be much larger in some studies. The largest study included in the Jüni (2001) review assessed the methodological quality of 229 controlled trials from 33 meta-analyses and then analyzed, using multiple logistic regression models, the associations between those assessments and estimated treatment effects. Trials that were not double-blind yielded on average 17% greater effect, 95% CI (4% to 29%), than blinded studies (P = .01). Kjaergard (2001) reviewed fourteen meta-analyses involving 190 randomized trials from eight therapeutic areas and reported even greater distortion from lower quality studies. Compared with large trials, intervention effects were exaggerated in small trials with no double-blinding (ratio of odds ratios, 0.52 [CI, 0.28 to 0.96]; P < 0.01), translating into a 48% estimate of benefit when studies lack adequate double-blinding.

    - There is an urgent need for additional double-blind RCTs of arthroscopic lavage and debridement in various patient groups with OA of the knee to determine if there are —
        - Clinical benefits for clearly defined sub-population groups with OA of the knee. Studies should be conducted in patients with OA and mechanical symptoms, those without mechanical symptoms, those with mild and

moderate OA of the knee to determine if specific subgroups derive substantial clinical benefits from these interventions.

- Risk-benefit ratios for differing anesthetic strategies such as local versus spinal or general anesthesia and specifics of various concomitant interventions such as anticoagulation and use of tourniquets in patients at various risk levels should be determined.

3. Methods

The methodology used in this review included a critical appraisal of the AHRQ review conducted by Samson (2007), Table 1. We also sought to supplement and update this systematic review by searching for RCTs and RCTs dealing with efficacy and safety of arthroscopic debridement and lavage for knee osteoarthritis published after the search date of the AHRQ review. Additionally, we sought and appraised RCTs dealing with harms.

AHRQ Publication Methods

The AHRQ publication reviewers retrieved 23 studies of arthroscopy in knee OA. The authors sought and assessed systematic reviews, meta-analyses and RCTs published in full or in abstract along with other study designs. Primary outcomes were pain, function, quality of life and adverse effects. The authors searched MEDLINE (through March 29, 2007), EMBASE (through March 16, 2006), and Cochrane Controlled Trials Register (through November 27, 2006). EMBASE was updated with abbreviated searches through November 27, 2006. Additional sources were 2004–2006 conference proceedings of the American Association of Orthopedic Surgeons (AAOS), American College of Rheumatology (ACR) and the Osteoarthritis Research Society International (OARSI). Because there were few RCTs on arthroscopy or comparative outcomes, the authors also sought nonrandomized comparative trials and, for arthroscopy, administrative database analyses and case series (n>50). Of 1,842 citations, 451 articles were retrieved and 98 selected for inclusion for the three interventions they reviewed. Data from administrative database analyses and case series were not used to inform conclusions regarding efficacy of arthroscopic lavage and debridement, but were used in reporting adverse events.

The AHRQ publication's search strategy, criteria for study selection and approach to evaluating efficacy and safety are of high quality, but the inclusion criteria of information for efficacy published only as abstract, inclusion of studies with up to 20% loss to follow-up and use of non-randomized trials for comparative outcomes can increase the likelihood of drawing conclusions from non-valid studies. This is a potential limitation of the AHRQ publication methodology; however, it important to note that the authors did not end up drawing efficacy conclusions from studies with these limitations despite their inclusion criteria. The AHRQ Publication authors were careful to describe the limitations of database and other observational studies and appropriately utilized these studies in their evaluation of safety.

Methods: Details of Delfini Methodology

In keeping with acceptable evidence-based medicine practice, scientific information from valid and clinically useful secondary sources or secondary studies are utilized, where possible, as a basis for each review and updated with new valid and clinically useful information from primary sources published after the date of the search used for creating the secondary source. (A primary source is the report of an original research study. A secondary source is any source that utilizes primary research information.)

Sources

The Cochrane Database, Clinical Evidence, DARE and PubMed (MEDLINE) are systematically searched using a one- or two- part question (intervention and/or condition) with or without modifiers (e.g., acute, adult, etc.), depending on the project. Additional searches are often done

tailored to the project. MeSH (Medical Subject Headings) search terms are utilized when they exist.

Limits
Limits are applied in the search to filter out inappropriate study types. Study designs are matched to type of study question. For example, for interventions of prevention, screening and therapies, only randomized controlled trials are utilized for drawing cause and effect conclusions related to efficacy. For prognosis, cohort studies are sought.

Searching and Filtering
Several searches are usually performed applying variations to maximize potentially relevant studies. Details of the search include search date, search terms, limits (e.g., RCT or systematic review) and are documented, as are the number of hits and whether or not each reference is relevant. Titles and abstracts are evaluated to determine relevancy. Studies found to have fatal flaws identifiable within the title or abstract are excluded at this stage. Specific exclusion criteria are found in individual search tables included in review documentation. Generally exclusion criteria include the following at a minimum: studies not published in the English language, studies not relevant to the question, animal studies, editorials, opinion pieces, abstracts without full documentation of research, narrative reviews, studies published in supplements, observational studies for interventions, studies deemed not useful for clinical questions (see below for description).

- Clinically useful studies are defined as those with clinically meaningful size of benefits for pre-specified outcomes of importance to patients defined as mortality, morbidity, symptom relief, emotional and physical functioning and health-related quality-of-life.
- Studies reporting pre-specified intermediate outcomes are excluded unless a strong valid and useful chain-of-evidence has been established between intermediate markers and resulting clinically significant outcomes, as defined above, with clinically meaningful size of benefits.

Exceptions may be made as deemed necessary to support good EBM practice such as papers dealing with reports of harms, observations with all-or-none-results and certain public health interventions which may be deemed as having experimental characteristics or for which prognostic factors are so broad as to render confounding unlikely. For example, observational data may be convincing for emergency surgery for ruptured aortic aneurysms, the use of antibiotics in acute meningitis or results of public health water purification efforts. In these instances, many or all affected individuals were affected or died and, after the intervention, many or most were prevented from being affected or survived.

Critical Appraisal
All sources remaining after title and abstract evaluation are critically appraised using a critical evaluation checklist tool specific to the type of source and its category to identify threats to validity. For example systematic reviews (including meta-analyses) have a checklist specific for systematic reviews. Other secondary sources such as clinical guidelines are appraised using a more generic checklist for other secondary sources. Primary studies have their own set of critical appraisal questions depending upon their categorical area such as therapy or diagnostic testing.

Delfini critical appraisals are performed using the specific items in each tool (available at http://www.delfini.org/delfiniTools.htm and included in this document in 2.3 Study Findings — see tables) and also utilizing critical thinking and the application of general critical appraisal concepts.

Selected Secondary Sources

The critical appraisal process for secondary sources includes a number of elements, including a review of the systematic search methods employed and an assessment of whether the secondary source includes only valid and clinically useful primary sources. To assess the latter, the source is reviewed to determine whether critical appraisal of the content was performed, along with an assessment of the evidence-grading system. One or two of included primary studies considered to be of the highest quality are critically appraised for validity and usefulness as an audit by Delfini. If these studies pass the audit, one or two included primary studies of the lowest quality is evaluated as well. If these lower quality studies also pass, it is assumed that the authors have employed good critical appraisal techniques.

If the source passes an audit for validity and usefulness, the source's efficacy and safety conclusions are used in the Delfini evidence synthesis and new research published following the date of the source's search strategy is sought.

If the source does not pass the audit for validity and usefulness, but has utilized a sound search strategy and sound criteria for excluding efficacy studies lacking relevance, validity or for other problems, all the primary studies selected for inclusion by the source are critically appraised, and valid, useful studies form the basis of the Delfini review, which will then be updated with any new valid and clinically useful primary studies published after the date of the secondary source's search.

Primary Studies

All primary studies are critically appraised for validity and usefulness using a checklist designed by Delfini, the specific considerations chosen depending upon the studies' categorical type.

Evidence Grading

Individual conclusions, studies, summaries and/or recommendations are assigned a grade for the quality or strength of the evidence. Delfini Grades are Grade A (strong and appears sufficient for informing decisions), Grade B (potentially strong and probably sufficient for informing decisions), Grade B-U (might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B) and Grade U (uncertain validity and/or usefulness). See Delfini Evidence Grading Scale for detailed descriptions.

Our approach is to determine if a study is a Grade U study as efficiently as possible. Many studies are lethally flawed and frequently only one reviewer is needed to establish a Grade U. For studies and/or conclusions receiving higher grades, two reviewers may be utilized and consults obtained for complex reviews. Differences in outcomes from the reviewers' assessments are discussed until a consensus is reached, favoring a more conservative approach.

Table 1. *Delfini* Validity & Usability Grading Scale

Grade of Usability	Strength of Evidence Advice **Grades can be applied to individual studies, to conclusions within studies, a body of evidence or to secondary sources such as guidelines or clinical recommendations. General advice is provided below.**
● **Grade A: Useful**	The evidence is strong and appears sufficient to use in making health care decisions – it is both valid and useful (eg, meets standards for clinical significance, sufficient magnitude of effect size, physician and patient acceptability, etc.) Advice: Studies achieving this grade should be outstanding in design, execution and reporting with useful information to aid clinical decision-making, enabling reasonable certitude in drawing conclusions. For a body of evidence: Several well-designed and conducted studies that consistently show similar results • For therapy, screening, prevention and diagnostic studies: RCTs. In some cases a single, large well-designed and conducted RCT may be sufficient; however, without confirmation from other studies results could be due to chance, undetected significant biases, fraud, etc. In such instance the study might receive a Grade A, but the Strength of the Evidence should include a cautionary note. • For natural history and prognosis: Cohort studies
⊙ **Grade B: Possibly Useful**	The evidence appears potentially strong and is probably sufficient to use in making health care decisions - some threats to validity were identified Advice: Studies achieving this grade should be of high quality in design, execution and reporting with non-lethal threats to validity and with sufficiently useful information to aid clinical decision-making, enabling reasonable certitude in drawing conclusions. For a body of evidence: The evidence is strong enough to conclude that the results are probably valid and useful (see above); however, study results from multiple studies are inconsistent or the studies may have some (but not lethal) threats to validity. • For therapy, screening, prevention and diagnostic studies: RCTs. In some cases a single, large well-designed and conducted RCT may be sufficient; however, without confirmation from other studies results could be due to chance, undetected significant biases, fraud, etc. In such instance the study might receive a Grade A, but the Strength of the Evidence should include a cautionary note.

	• Also for diagnosis, valid studies assessing test accuracy for detecting a condition when there is evidence of effectiveness from valid, applicable RCTs. ▪ For natural history and prognosis: Cohort studies
O Grade B-U: Possible to uncertain usefulness	The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U. Study quality is such that it appears likely that the evidence is sufficient to use in making health care decisions; however, there are some study issues that raise continued uncertainty. Health care decision-makers should be fully informed of the evidence quality.
○ **Grade U: Uncertain Validity and/or Usefulness**	There is sufficient uncertainty that caution is urged regarding its use in making health care decisions. • Uncertain Validity: This may be due to uncertain validity due to methodology (enough threats to validity to raise concern – our suggestion would be to **not** use such a study in most circumstances) or may be due to conflicting results. • Uncertain Usefulness: Or this may be due to uncertain applicability due to results (good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. • Uncertain Validity and Usefulness: This is a combination of the above. • Uncertainty of Author: If the author has reached a conclusion that the findings are uncertain, doing a critical appraisal is unlikely to result in a different conclusion. The evidence leaves us uncertain regardless of whether the study is valid or not. Critical appraisal is at the discretion of the reviewer.

Efficacy of Treatments—Evidence Grading

For questions of efficacy of therapeutic interventions, screening or prevention, only valid and clinically useful results from grades A, B and B-U are utilized. Studies or conclusions receiving a Grade U are generally treated by Delfini as hypothesis-generating only. They are not used for drawing cause and effect conclusions, but are regarded as if the studies had never been conducted – meaning that Delfini believes it is completely reasonable to rely on clinical judgment in the absence of valid and clinically useful evidence published in the medical literature.

Safety—Evidence Grading

Delfini may utilize safety data from Grade U studies because safety information from RCTs may be limited. Data from selected low grade RCTs may have greater validity and usefulness than observational studies or case reports. However, Delfini may include observational data if potentially meaningful information arises during the course of a review — often this information is not systematically sought. Evaluating safety data is a complex process. Standards are often lower for using safety data than for using efficacy data and so there may be more uncertainty about the results. Therefore, conclusions about safety issues are worded carefully so that information drawn from potentially flawed data regarding safety is not presented as if it is based on stronger evidence than actually exists. Safety data may be poorly collected and reported and

may under-represent adverse events. There are also cautionary tales about overzealous application of weak safety evidence that may, ultimately, have caused more harms to patients than if the agent had continued to be available.

- Adverse events often occur infrequently, are often hard to find and usually not the topic of study.
- Systematic reviews of RCTs dealing with risks and harms of the intervention being reviewed should usually be sought.
  - There are potential limitations of RCTs and systematic reviews of RCTs that do not specifically focus on safety questions, e.g., when the RCTs —
    - May not have reported or fully reported adverse events;
    - May be of insufficient duration;
    - May have relied upon small populations (e.g., sampling error or power issues).
- Frequently, risks and harms are not pre-specified as outcome measures in RCTs, increasing the likelihood of chance findings.
  - We look for patterns in multiple studies and to review whether several of the safety outcomes are biologically related or if there is a dose-response relationship, which lends support that these are true safety concerns and not a result of chance findings;
  - Unless a study is powered for safety questions, lack of statistically significant differences may mean there is no difference or it may mean it is still unknown if there is a difference. Confidence intervals are useful in evaluating safety issues. For a valid study, the CI represents the range for which there is a 95% chance that the true answer lies. If the range includes a difference that is clinically meaningful, the study has not excluded the risk or harm.
    - Example: Authors report "The two groups did not differ in clinically relevant bleeding." PMID: 12049858. However, the CIs provide much more information: Absolute Risk Increase, (95% CI) = 1.3, (0.3 to 2.9) and since the true difference in bleeding between the two groups could be as great as 2.9% (i.e., clinically relevant) the authors' conclusion is misleading.
- Risks and harms may not be detected until long after completion of RCTs through observational reports. Therefore, long-term safety is frequently unknown.
- We incorporate observational information into safety reviews if potentially significant risks are detected following the publication of an RCT. We regard safety data from low quality RCTs with caution and generally consider the results as "signals" or "indicators" or observations from which we cannot conclude cause and effect associations and emphasize that the information is prone to bias, confounding and chance.
- FDA post-marketing safety data may also be useful to decision-makers.
- As with efficacy data, safety data is evaluated for quality. Although a study may be considered low quality overall, it may be sufficiently valid in one area, such as safety to include in a review; therefore, at times we grade individual study conclusions rather than assign a grade to the overall study.

- We urge clinicians to be aware of FDA recommendations.

4. The Evidence

This section includes an overview and summary conclusions related to the evidence, followed by a detailed analysis of the included studies.

As a result of findings from this critical appraisal and review of subsequent evidence, the evidence conclusions are based heavily on one section of the evidence report (Samson 2007) from the Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center, which is a well-conducted systematic review of three treatments for osteoarthritis (OA) of the knee: intra-articular injections of viscosupplements; oral glucosamine, chondroitin, or the combination; and, arthroscopic lavage and debridement (AHRQ Publication No. 07-E012) referred to in this report as "the AHRQ publication" (see Table 1 for critical appraisal of Samson 2007). It is also based on literature searches that update AHRQ publication along with an independent critical appraisal of the relevant studies published after the search date of the AHRQ publication (Tables 2-4). The 2008 Osteoarthritis Research Society International recommendations (guidelines) for the management of hip and knee Osteoarthritis (Zhang 2008) are also reviewed (Table 5). Implications from this evidence review are provided.

AHRQ Publication Overview

Well-conducted evidence-based reviews focus not on the number of relevant studies, but on study validity (closeness to truth) and clinical usefulness in order to draw conclusions about cause and effect associations. High quality medical science reduces clinical uncertainty by improving decision makers' ability to accurately predict benefits and risks of various interventions. The vast majority of the medical literature is not valid or clinically useful. This is especially true in the surgical literature where studies are frequently not well-designed and conducted. The goal of a quality evidence review is to systematically search for whatever potentially valid and clinically useful information is available, appraise the information obtained and summarize what is found to be valid and clinically useful information (with some exceptions made, such as for safety). Frequently much labor and thoughtfulness go into reviews for which no valid and clinically useful evidence exists. In such instances, it is important to point out that absence of evidence of benefit does not mean that an intervention does not work — it means there is continued uncertainty. In the case of arthroscopy of the osteoarthritic knee with lavage or debridement it is fortunate that efforts identified at least one study that may provide enough reliability to help inform clinical practice decisions. Otherwise, it is Delfini's position that studies not meeting sufficient acceptability criteria for validity and clinical usefulness be treated as hypothesis-generating only for efficacy and that the results should not be seen to be any more reasonable as guides for clinical practice than clinician judgment.

As noted in the methods section, the AHRQ publication reviewers retrieved 23 studies of arthroscopy in knee OA. The authors sought and assessed systematic reviews, meta-analyses and RCTs published in full or in abstract along with other study designs. Primary outcomes were pain, function, quality of life and adverse effects. The authors searched MEDLINE (through March 29, 2007), EMBASE (through March 16, 2006), and Cochrane Controlled Trials Register (through November 27, 2006). EMBASE was updated with abbreviated searches through November 27, 2006. Additional sources were 2004–2006 conference proceedings of the American Association of Orthopedic Surgeons (AAOS), American College of Rheumatology (ACR) and the Osteoarthritis Research Society International (OARSI). Because there were few RCTs on arthroscopy or comparative outcomes, the authors also sought nonrandomized

comparative trials and, for arthroscopy, administrative database analyses and case series (n>50). Of 1,842 citations, 451 articles were retrieved and 98 selected for inclusion for the three interventions they reviewed. Data from administrative database analyses and case series were not used to inform conclusions regarding efficacy of arthroscopic lavage and debridement, but were used in reporting adverse events.

The AHRQ publication's search strategy, criteria for study selection and approach to evaluating efficacy and safety are of high quality, but the inclusion criteria of information for efficacy published only as abstract, inclusion of studies with up to 20% loss to follow-up and use of non-randomized trials for comparative outcomes can increase the likelihood of drawing conclusions from non-valid studies. This is a potential limitation of the AHRQ publication methodology; however, it important to note that the authors did not end up drawing efficacy conclusions from studies with these limitations despite their inclusion criteria. The AHRQ Publication authors were careful to describe the limitations of database and other observational studies and appropriately utilized these studies in their evaluation of safety.

After careful review, we concur with the conclusions reached by the authors of the AHRQ publication. We have provided greater emphasis on the quantitative aspects of harms data in our summary fully acknowledging the significant limitations in the studies presenting adverse events data. Systematic reviews, RCTs and observational studies may all present flawed or biased adverse event data because of inadequate attention to identification of harms or measurements of harms, faulty data collection or reporting of data. Nevertheless, providing quantitative estimates of adverse events with the above caveats may be useful for clinicians, patients or policy-makers who are making decisions based on benefit-risk judgments.

We found no grade B evidence for efficacy or safety. We determined, as did the AHRQ publication authors (Samson 2007) and the authors of a Cochrane review (Laupattarakasem 2008), that the Moseley 2002 trial was of sufficient quality to inform conclusions regarding efficacy of arthroscopy with lavage and debridement for treatment of osteoarthritis of the knee. A search of DARE yielded several additional technology assessment reviews (Search Table 7) predating the AHRQ publication. Because the evidence reviewed in these documents was subsequently extensively reviewed in the AHRQ publication, these reports are not formally reviewed here.

Moseley (2002) concluded that, "The outcomes after arthroscopic lavage or arthroscopic débridement were no better than those after a placebo procedure." We assigned the Moseley 2002 a study grade of B-U which represents evidence that might be sufficient to use in making health care decisions. The grade of B-U evidence is used when there is sufficient uncertainty about validity or usefulness that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U which represents significant uncertainty. In grade B-U studies the quality the evidence is sufficient to use in making health care decisions. However, health care decision-makers should be fully informed of the evidence quality and degree of uncertainty determined by the reviewers.

Of the 23 articles on arthroscopy retrieved by the authors of the AHRQ publication all except Moseley (2002) were excluded for efficacy. Reasons for exclusion included the following: lack of inclusion criteria, incorrect study design, lack of primary data, narrative (not-systematic) review, and the intervention was other than arthroscopic debridement and lavage. A recent

Cochrane review also rated Moseley (2002) as the only relevant study of moderate quality (see Table 3).

We also reviewed the RCTs evaluated in the AHRQ publication for safety and have determined that the clinical trial safety data is not useful for informing safety decisions because the data is extremely limited. Adverse events were not prespecified as outcome measures, data collection and reporting appear to have been poorly done. The Cochrane review (Ramos 2007), Table 4, dealing with DVT following arthroscopy provides important but limited information on deep vein thrombosis following arthroscopy.

Evidence Search Results Post AHRQ Publication

Studies other than Moseley (2002) have been published (see critique of Laupattarakasem 08, Table 3). However, lethal threats to validity preclude drawing conclusions regarding efficacy. We found no other relevant efficacy studies published after the search date.

Evidence Summary: Efficacy

There is a paucity of valid, relevant evidence regarding the efficacy of knee arthroscopy and lavage or debridement for the treatment of osteoarthritis of the knee. At this time there is only one possibly useful study of arthroscopy with lavage and debridement for OA of the knee. This study is a randomized, double-blind, placebo-controlled trial (Moseley 2002), which studied 180 patients with knee arthritis (Table 2). This RCT found that arthroscopic lavage and debridement were not superior to sham arthroscopy for the treatment of knee OA. Although this study has some threats to validity, we, as did the AHRQ publication authors (Table 1) and Cochrane reviewers (Laupattarakasem 2008), Table 3, consider it the best available valid and clinically useful efficacy evidence upon which arthroscopy decisions should be based.

Evidence Summary: Safety

It is important to place strong emphasis on harms data. The evidence on harms in arthroscopy and debridement for the treatment of osteoarthritis of the knee is weak, coming from some RCTs with methodological problems such as inadequate reporting of adverse event details. Most of the harms data come from observational studies and case series.

We found one pertinent Cochrane review (Ramos 2007), Table 4, dealing with harms following arthroscopy published after the AHRQ publication. This review provides important information on deep vein thrombosis. A major limitation of this Cochrane review is that it included studies of knee arthroscopy performed for indications other than treatment of OA of the knee, and there was great heterogeneity in the populations, type of anesthesia and details of the procedure (eg, use of tourniquets). The AHRQ publication provides extensive adverse event data from observational studies. Major threats to validity found in observational studies are well-known. Nevertheless, consideration of adverse events is extremely important in clinical decision-making and almost always requires the consideration of evidence which is weaker than evidence available for evaluating efficacy. This issue comes into sharp focus when evidence of clinical benefit from an intervention is lacking as is the case with arthroscopy with lavage and debridement for OA of the knee. The available evidence on harms is suggestive that arthroscopy may not be a low risk-procedure:

- Mortality has been reported to be from 0.1% to 0.5% (Table 85 in AHRQ publication);
- A 0.3% rate of stroke or myocardial infarction has been reported (Table 85 AHRQ publication);

- DVT has been reported to be from 0.6% to 17.9% depending on the diagnostic method used (Ramos 2007);
- A hemarthrosis rate of nearly 25% was reported in one case series (Table 85 AHRQ publication);
- Infection has been reported to be from 0.5% to 2% (Table 85 AHRQ publication);

If general anesthesia is used, adverse events such as nausea and other more significant risks are incurred. If spinal anesthesia is used, the risks of leakage, spinal headache, etc. are incurred.

Evidence Summary: Economic Models

- No useful economic modeling information was found in our MEDLINE searches.
- An economic model (Search Table 7. DARE, Record #2) was provided by The Medical Advisory Secretariat Ministry of Health and Long-Term Care, Toronto. The authors were unable to conduct a full economic analysis because effectiveness was not demonstrated in the literature. They state that based on the Moseley (2002) trial, cost effectiveness is likely to be unfavorable. However, they provide an outline of considerations (e.g., hospital costs, non-hospital costs, discounting, etc. that may be useful in creating an economic model to inform cost estimates.

Study Findings

Table 1: AHRQ Publication: Secondary Study Critique

Systematic Review Study Details
Secondary Study Critique **AHRQ Publication: Study Validity & Evidence Usability Critique: Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157**
Reviewer: Michael E. Stuart MD **Outcomes:** **Primary Outcomes:** • Pain severity or intensity • Self-reported physical function • Patient global assessment • Quality of life. **Secondary Outcomes:** • Concomitant analgesic use. • Need for or time to total knee replacement or other surgeries.
Number of studies/ subjects included: 23 articles on arthroscopy were retrieved. 180 subjects included as best-available evidence.
Reported Results **Efficacy conclusions were based on the results of a single RCT (Moseley 2002). Other trials were mentioned in various contexts for thoroughness.** **Superiority analyses (Moseley 2002):** At no follow-up time did either the lavage or debridement groups achieve significantly better mean outcomes than placebo on any of the 6 efficacy outcomes. At 1 year, the placebo group had significantly better time to walk 30 meters and scale a flight of stairs than the debridement group. The mean number of seconds on the 1 year Physical Function Scale (± standard deviation [SD]) was 45.6 (± 10.2) in the placebo group and 52.5 (± 20.3) in the debridement group (p=0.04). **Equivalence analyses:** Of the 84 comparisons for equivalence, the minimal important difference was excluded from confidence intervals in 72. **Adverse Events:** Limited adverse events data were presented in the Moseley 02 study. The authors stated that there were only two minor complications: incisional erythema in one patient and in another, calf swelling with venography negative for thrombosis.
Authors' answers to key questions: **1. What are the Clinical Effectiveness and Harms of Arthroscopic Lavage and Debridement in Patients With Primary OA of the Knee?**

Systematic Review Study Details

Secondary Study Critique
AHRQ Publication: Study Validity & Evidence Usability Critique: Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157

- The best available valid and clinically useful evidence — a single placebo-controlled RCT — found arthroscopic lavage with or without debridement was not superior to placebo. The evidence base does not definitively show that arthroscopy is no more effective than placebo. But additional RCTs of high quality and with favorable outcomes would be necessary to refute the existing trial, which suggests equivalence between placebo and arthroscopy.
- Neither the placebo-controlled RCT, published by Moseley, O'Malley, Petersen, et al., in 2002, nor other studies distinguished between primary and secondary OA. However, due to the age of patients, it is likely most patients had primary OA.
- No other study besides Moseley, O'Malley, Petersen, et al. (2002) addressed the potential contribution of placebo effects to apparent improvement in outcomes after arthroscopy.
- The primary limitations of the Moseley, O'Malley, Petersen, et al. (2002) trial are lack of details describing the patient sample, the use of a single surgeon and enrollment of patients at a single Veterans Affairs Medical Center. These concerns call into question the generalizability of this trial's findings.
- Since OA of the knee affects a large population, uncertainty about arthroscopy's effectiveness should be resolved with further well-conducted and well-reported RCTs.
- Major methodologic shortcomings in non-placebo RCTs, an administrative database analysis and case series preclude resolution of uncertainties raised by the trial of Moseley, O'Malley, Petersen, et al. (2002).
- Evidence on the harms after arthroscopic lavage and debridement comes primarily from an administrative database analysis and case series reports. Potential harms include infection, prolonged drainage from arthroscopic portals, effusion, hemarthrosis, and deep vein thrombosis. To determine whether the risk of such harms is acceptable, it is important to establish whether the effectiveness of arthroscopic lavage and debridement surpasses placebo.

2. What are the Clinical Effectiveness and Harms of Arthroscopic Lavage and Debridement in Patients With Secondary OA of the Knee?

- The AHRQ publication identified no studies that enrolled patients with only secondary OA of the knee, or that reported separately on secondary OA of the knee. Therefore, no conclusions can be drawn about treatment outcomes in patients with secondary OA of the knee.

3. How do the Short-Term and Long-Term Outcomes of Arthroscopic Lavage and Debridement Differ by the Following Subpopulations: Age, Race/Ethnicity, Sex, Primary or Secondary OA, Disease Severity and Duration, Weight (Body Mass Index), and Prior Treatments?

- Subgroup analyses for mechanical symptoms, alignment and OA stage were performed in the placebo-controlled RCT by Moseley and colleagues. No differences in results were observed within subgroups. Thus, it cannot be concluded that arthroscopic lavage with or without debridement has effects greater than placebo for specific subgroups.
- Subgroup analyses were also performed in a quasi-experimental study, an administrative database and several case series. In these studies, different outcomes were observed according to age, presence of mechanical symptoms and severity of OA. However, since these studies

Systematic Review Study Details	
Secondary Study Critique **AHRQ Publication: Study Validity & Evidence Usability Critique: Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157**	

had substantial methodologic flaws, it cannot be concluded that arthroscopy has greater effectiveness in specific patient subgroups.

4. How do the Short-Term and Long-Term Outcomes of Arthroscopic Lavage and Debridement, Viscosupplements and Glucosamine/Chondroitin Compare for the Treatment of: Primary OA of the Knee; and Secondary OA of the Knee?

- A single RCT compared use of arthroscopic lavage and debridement with intra-articular Hyalgan®. This poor quality study analyzed data from only 32 patients, finding no significant differences between groups on 3 scales concerned with pain and function.
- This trial provides an inadequate evidence base to form conclusions about the comparative effects of viscosupplements and arthroscopy.
- No other comparative study, randomized or nonrandomized, addressed the relative effects of arthroscopic lavage and debridement, viscosupplements and glucosamine/chondroitin.

Authors' conclusions: "Osteoarthritis of the knee is a common condition. Arthroscopy with debridement and lavage is widely used in the treatment of OA of the knee, yet the best available valid and clinically useful evidence does not clearly demonstrate clinical benefit. Uncertainty regarding clinical benefit can be resolved only by rigorous, multicenter RCTs. In addition, given the public health impact of OA of the knee, research on new approaches to prevention and treatment should be given high priority."

Assessment: The AHRQ publication bases its efficacy conclusion on the best-available evidence, the trial of Moseley (2002). We agree with this approach and the AHRQ publication's conclusions. The AHRQ publication contains extensive information on adverse events which is of low quality, but provides a basis for making quantitative estimates of harms.

I. Systematic Review Validity Assessment	
1.	**Research Question:** Clearly stated and meaningful questions to the literature, determined in advance? **Assessment:** Key questions were appropriate
2.	**Clinical Significance of Question:** Do the research questions address morbidity, mortality, symptom relief, emotional and/or physical functioning or health-related quality of life? **Assessment:** Yes. Primary outcomes were pain, function, quality of life and adverse effects. The AHRQ publication provides extensive background information on the outcome measures.
3.	**Study Selection:** Explicit, documented and appropriate selection criteria chosen in advance for included studies that are sufficiently similar? For example, needs to specify study type (eg, RCT, cohort, etc.), population, methods, inventions or exposures and outcomes. **Assessment:** Authors sought and assessed systematic reviews, meta-analyses, and RCTs published in full or in abstract along with other study designs. Studies selected for informing conclusions were appropriate.
4.	**Study Design:** If this is a question of therapy, screening or prevention, and observational studies are used to answer questions of efficacy, ***Delfini*** suggests not using the review. **Assessment**: Authors were careful to provide caveats about using observational studies to draw conclusions about efficacy and based their conclusions on the single highest quality trial (Moseley, 2002).

Systematic Review Study Details	
Secondary Study Critique **AHRQ Publication: Study Validity & Evidence Usability Critique: Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157**	
5.	**Search Strategy:** Documented systematic and comprehensive search strategy that is well thought out and executed? **Assessment:** Excellent search strategy: The authors searched MEDLINE® (through March 29, 2007), EMBASE (through March 16, 2006), and Cochrane Controlled Trials Register (through November 27, 2006). EMBASE was updated with abbreviated searches through November 27, 2006. Additional sources were 2004–2006 conference proceedings of the American Association of Orthopedic Surgeons (AAOS), American College of Rheumatology (ACR) and the Osteoarthritis Research Society International (OARSI). Because few RCTs on arthroscopy or comparative outcomes were found the authors sought nonrandomized comparative trials and utilized an administrative database analyses and case series (n>50). Of 1,842 citations, 451 articles were retrieved and 98 selected for inclusion for the three interventions. Twenty-three articles on arthroscopy were retrieved.
6.	**Patient Population Assessment:** Is the population appropriate for this question? **Assessment:** Yes. Further studies including subjects with a range of severity of knee OA of are needed. Correspondents noted that over 40% of eligible subjects in the Moseley (2002) trial declined to participate (conceivably due to risk of being randomized to the placebo (sham) group). This may have created study groups not representative of the larger population, (i.e., a problem with external validity).
7.	**Critical Appraisal:** What is the quality of included studies? **Assessment:** The AHRQ publication used an approach to grading evidence (good, fair, poor) based on USPSTF system and a checklist for systematic reviews (Oxman and Guyatt). Our judgment is that — 1. The approach potentially allows for inclusion of non-valid primary studies because it does not consider • The effect of co-interventions; • Studies with up to 20% loss to follow-up can be classified as good quality evidence. 2. The approach used by the AHRQ publication potentially allows for inclusion of non-valid systematic reviews: • The following questions in our opinion are insufficient criteria for judging validity since the criteria are soft and up to the judgment of the reviewer, plus they don't specifically state to only use valid studies (which is an issue as many people utilize invalid evidence and others interpret "best available evidence" in such a way that they utilize invalid evidence in lieu of valid evidence): Question 5. Were the criteria used for assessing the validity of the included studies reported? Question 6. Was the validity of all the studies referred to in the text assessed using appropriate criteria? 3. Despite these methodological problems, the approach used by AHRQ publication did not result in drawing conclusions from non-valid efficacy studies in the arthroscopy review.

Systematic Review Study Details	
Secondary Study Critique **AHRQ Publication: Study Validity & Evidence Usability Critique: Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157**	
8.	**Missing Outcomes Data:** Assessment of how loss to follow-up is handled and is it done appropriately? **Your Assessment:** The highest quality study included in the review and the basis for conclusions regarding efficacy lost ~9% of subjects. The reviewers concluded that significant distortion of results did not occur.
9.	**Homo-/heterogeneity:** **Your Assessment:** N/A—The SR utilized only 1 RCT as the basis for conclusions.
10.	**Combining Results**: If results were combined, was it done in a reasonable and appropriate manner? **Your Assessment:** N/A
11.	**Weighting:** If weighting was employed, was a reasonable approach taken? **Assessment:** N/A
12.	**Author's Discussion**: Well executed sensitivity analyses, discussion of limitations, explanations of differences in studies and their results, etc.? **Your Assessment:** Excellent discussion including detailed analysis of studies, results, correspondence and implications.
13.	**Other Issues (e.g., potential conflict of interest):** **Assessment:** None
14.	**Author's Conclusion:** Conclusions are supported by the evidence? **Assessment**: After careful review, we concur with the conclusions reached by the AHRQ publication authors.
15.	**Transparency:** Is sufficient detail provided that enables a through quality assessment of this review and such that this review could be replicated? ▪ Does the review provide a list of the specific studies included for drawing conclusions? **Your Assessment:** Excellent transparency
16.	**Evidence Grade:** • **Quality of efficacy evidence for arthroscopy with lavage and debridement: Grade B-U**. Grade B-U evidence represents possible to uncertain usefulness. The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B (possibly useful) and the uncertainty is not great enough to fully warrant a Grade U (uncertain usefulness because of validity or applicability issues), i.e., there are some study issues that raise continued uncertainty. Health care decision-makers should be fully informed of the limitations of the evidence. • **Quality of safety evidence for arthroscopy with lavage and debridement: Grade U.** Grade U evidence represents sufficient uncertainty that caution is urged regarding use of the information in making health care decisions. Uncertainty may be due to methodologic flaws

Systematic Review Study Details	
Secondary Study Critique **AHRQ Publication: Study Validity & Evidence Usability Critique: Treatment of Primary and Secondary Osteoarthritis of the Knee. Evidence Report/Technology Assessment No. 157**	
	that threaten validity or to uncertain applicability of results (e.g., good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. Grade U evidence may be useful in understanding potential harms. Evaluating safety data is a complex process. Standards are often lower for using safety data than efficacy data and so there may be much uncertainty about the results. Conclusions about safety issues should be worded carefully so that information drawn from potentially flawed data regarding safety is not presented as if it is based on stronger evidence than actually exists.

Table 2. Moseley 2002. Delfini Group Primary Study Critique

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

Study Type

- Randomized
- Double-blind (patients and assessors of outcomes)
- Placebo-controlled through sham operation
- Superiority
- Equivalence (after superiority was not demonstrated)
- Single-center
- Single orthopedic surgeon

Funding Source
Details: Grant from Dept of Veterans Affairs

Pertinent Commentaries
- Useful letters, editorial

Aim

Details	To evaluate the efficacy of arthroscopy for osteoarthritis of the knee.
	▪ No remarks

Outcome Measures

Details	Primary Outcome(s) ▪ Pain in the study knee 24 months after the intervention, as assessed by a 12-item self-reported Knee-Specific Pain Scale (KSPS) created for the study
Details	Secondary Outcome(s) ▪ Two additional assessments of pain and three assessments of function at all time points. ▪ Pain: o Arthritis pain in general (i.e., not specifically in the study knee) was assessed by means of the four-item pain subscale of the Arthritis Impact Measurement Scales (AIMS2-P). o Body pain (i.e., not necessarily from arthritis and not necessarily in the knee) was assessed with the 2-item pain subscale of the Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36-P). ▪ The AIMS2-P and the SF-36-P scores were transformed into scores on a scale from 0 to 100. ▪ Physical function o The 5-item walking–bending subscale from the AIMS2 (AIMS2-WB), transformed into scores on a scale from 0 to 100, with higher

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

	scores indicating more limited function. o The 10-item physical-function subscale from the SF-36 (SF-36-PF), transformed into scores on a scale from 0 to 100, with higher scores indicating better function. o The Physical Functioning Scale (PFS) to record the amount of time in seconds that a patient required to walk 30 m (100 ft) and to climb up and down a flight of stairs as quickly as possible. Longer times indicate poorer functioning.
Threat	Problems identified
Threat?	o Problem: Several correspondents stated that the measurement instrument for primary outcome, the Knee Specific Pain Scale (KSPS), had not been validated. The authors published a study subsequently demonstrating that the scale had good psychometric qualities, and this is probably not a significant threat.

Definitions

	▪ No remarks

::PRIMARY STUDY DETAIL

Duration

Details	24 months
	▪ No remarks

Intervention

Details	**Lavage** • Diagnostic arthroscopy was performed. • The knee was lavaged with at least 10 liters of fluid. Anything that could be flushed out through arthroscopic cannulas was removed. • If a mechanically important, unstable tear in the meniscus (e.g., a displaced "bucket-handle" tear) was encountered, the torn portion was removed and the remaining meniscus was smoothed to a firm, stable rim. • No other débridement was performed. **Débridement** • Diagnostic arthroscopy was performed. • The joint was lavaged with at least 10 liters of fluid, rough articular cartilage was shaved (chondroplasty was performed), loose debris was removed, all torn or degenerated meniscal fragments were trimmed, and the remaining meniscus was smoothed to a firm and stable rim. No abrasion arthroplasty or

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

	microfracture was performed. Typically, bone spurs were not removed, but any spurs from the tibial spine area that blocked full extension were shaved smooth. **Placebo Procedure** • A standard arthroscopic débridement was simulated. Three 1-cm incisions were made in the skin. The surgeon asked for all instruments and manipulated the knee as if arthroscopy were being performed. • Saline was splashed to simulate the sounds of lavage. • No instrument entered the portals for arthroscopy. • Patients were kept in the operating room for the amount of time required for a débridement.
	▪ No remarks

N

Details	180
	▪ No remarks

Population As Actually Studied Per Baseline Characteristics, Inclusions & Exclusions

Details	General description of population studied: The subjects were all veterans, average age 52, 89%-97% male, ~60% White, 30% Black. Approximately 25% had severe arthritis.
	▪ No remarks
Threat	Problems identified
Threat	▪ Including subjects with severe arthritis may create an external validity problem.

Inclusions

Threat	Problems identified
Threat?	▪ Correspondents stated that patient selection should have been based on plain-film radiography during posterior-anterior flexion in a position of weight bearing and that some included patients had contraindications for arthroscopy, including patients presenting only because of pain, and those with nonreactive joints, multiple compartment involvement, angulatory deformities and noncompliance with non-weight-bearing for at least 1 month prior to arthroscopy. These do not appear to be major threats.

Exclusions

Threat	Problems identified
Threat?	▪ The participation rate (56 percent) was low which may have been due to subjects not wishing to be randomized to a sham group. It is possible that this

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

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	creates an issue with external validity.

Baseline Characteristics Analysis

	▪ No remarks

Diagnostic Issues

	▪ No remarks

Screening

	▪ No remarks

Randomization

+	▪ POSSIBLY ADEQUATE o Participants were stratified into three groups according to the severity of osteoarthritis (grade 1, 2, or 3; grade 4, 5, or 6; and grade 7 or 8). A stratified randomization process with fixed blocks of six was used. o Block randomization can be predicted at times.

Concealment of Allocation

?	▪ POSSIBLY ADEQUATE o "Sequentially numbered, stratum-specific envelopes containing treatment assignments were prepared and given to the research assistant. After the patient was in the operating suite, the surgeon was handed the envelope. The treatment assignment was not revealed to the patient." o Envelopes can be "gamed." o Use of research assistant, as described, might increase likelihood of adequate concealment.

Blinding

	▪ No remarks

Co-interventions/Concomitant Medication Usage

Threat?	▪ No report of concomitant co-interventions or concomitant medications.

Disallowed Medications

	▪ None reported.

Adherence

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

	▪ No remarks

Other Study Procedures

Note	▪ Sham group was sedated; lavage and debridement groups had endotracheal tube.

Measurement Methods

	▪ No remarks

Quality Control Procedures

	▪ No remarks
+	▪ Reporting of quality control measures

Deviations from Protocol

	▪ No remarks

Equivalence or Non-inferiority Trials

	▪ This study was designed as a superiority trial. However, when the investigators failed to show that arthroscopy was superior to placebo, they statistically tested for equivalence. They considered whether the 95 percent confidence intervals for the differences in outcome between each arthroscopic procedure and the placebo procedure included clinically important differences which were determined from the literature and the change in ratings of patients (their scores on a single-item scale that asked patients if their condition was the same somewhat better [or worse], or much better [or worse] than before surgery) and the standard error of measurement (the SD of the instrument multiplied by the square root of one minus its reliability coefficient). The minimal important differences used for the evaluation were as follows: A difference of 13.5 points on the KSPS, 10.0 on the AIMS2-P, 11.8 on the SF-36-P, 12.8 on the AIMS2-WB, 11.3 on the SF-36-PF, and 4.5 on the PFS. ▪
Caution	Cautions Regarding Equivalence and Non-Inferiority Studies ▪ It is controversial whether determining minimally important differences post hoc is valid because of the risk of a subjective and biased setting of the clinically relevant confidence intervals. The settings chosen by the authors in this study seem appropriate.

Statistical Analysis Methods

	▪ Use of Kaplan-Meier curves can be prone to bias. Full information is not reported.

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

Analysis Population & Analysis Commentary

	▪ No remarks

Safety Population

	▪ Lacks attention to safety.

ITT Analysis

Threat	Problems identified
Threat	▪ Intention-to-treat analysis was not done o 5% or more missing values in results – see below ▪ Lack of ITT in the equivalence analysis may have been reasonable because ITT analysis may create bias towards equivalence

Missing Values in Results

9% total 8.3% P 9.8% L 8.6% D	← Missing values in results percentage
Threat	Problems identified (consider percents to be approximations)

Other Confounders

	▪ No remarks

Quality of Research, Article and/or Reporting

	▪ No remarks

Other

Threat?	▪ External validity may be affected by single operator — however, surgeon seems highly expert so results for the intervention are possibly as good as can be.

Results Efficacy

- **Primary outcome:** At no point did either arthroscopic-intervention group have greater pain relief than the placebo group. Results were reported as mean values (with 95 percent confidence intervals) on the Knee-Specific Pain Scale. Assessments were made before the procedure and at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, 18 months, and 24 months after the procedure. Higher scores indicate more severe pain.).
    - There was no statistically significant difference in knee pain between the placebo group and either the lavage group or the débridement group at one year

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

(mean [±SD] KSPS scores, 48.9±21.9, 54.8±19.8, and 51.7±22.4, respectively; P=0.14 for the comparison with the lavage group, and P=0.51 for the comparison with the débridement group). At two years, the mean KSPS scores were 51.6±23.7, 53.7±23.7, and 51.4±23.2, respectively; P=0.64 and P=0.96, respectively. The weighted mean difference (WMD) for pain scores at two weeks was 2.5 (95% CI -4.4 to 9.4). The WMD was not statistically significant at any of the measurement points up to 24 months after the intervention.

- **Secondary outcomes**:
  - For physical function, at no time point did either of the arthroscopic intervention groups have significantly greater improvement (AIMS2) in function than the placebo group. The WMD difference at 24 months was -0.6 (95% CI -8.3 to 7.1) for physical function.
  - For scores on the subscale of the Arthritis Impact Measurement Scales (AIMS2-P) there were no statistically significant difference between the placebo group and either the lavage or debridement group at any time during the two years.
  - Scores on Physical Functioning Scale: There were no statistically significant differences between the placebo group and either the lavage or debridement group at any time during the two years except at two weeks when the difference between the placebo group and the debridement group was -7.7; (95% CI -14.3 to -1.1), P value 0.02.

- **Equivalence results**: The investigators considered whether the 95 percent confidence intervals for the differences in outcome between each arthroscopic procedure and the placebo procedure included clinically important differences which were defined as a difference of 13.5 points on the KSPS, 10.0 on the AIMS2-P, 11.8 on the SF-36-P, 12.8 on the AIMS2-WB, 11.3 on the SF-36-PF, and 4.5 on the PFS. In 72 of 84 comparisons the confidence intervals excluded the minimal important differences.

Results Safety

Minimal information reported: "Postoperatively, there were two minor complications and no deaths. Incisional erythema developed in one patient, who was given antibiotics. In a second patient, calf swelling developed in the leg that had undergone surgery; venography was negative for thrombosis."

Authors conclusions

"In this controlled trial involving patients with osteoarthritis of the knee, the outcomes after arthroscopic lavage or arthroscopic débridement were no better than those after a placebo

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

procedure."

"… If the efficacy of arthroscopic lavage or débridement in patients with osteoarthritis of the knee is no greater than that of placebo surgery, the billions of dollars spent on such procedures annually might be put to better use. This study has also shown the great potential for a placebo effect with surgery…"

Reviewers Comments Regarding Authors' Conclusions

Agree with conclusions. Further studies are needed to verify the results with attention to specific populations and concomitant interventions such as type of anesthesia, use of tourniquet, etc., but as of this writing this study represents the highest quality evidence available regarding the efficacy of arthroscopy with lavage and debridement for treatment of OA of the knee.

Overall Validity and Clinical Usefulness Summary	▪ Good efforts to blind subjects and those assessing outcomes ▪ Some potential question of validity of KSPS. ▪ Lacking full details regarding randomization and potential for predictability using block randomization. ▪ Potentially less than adequate concealment of allocation methods. ▪ No reporting of co-interventions. ▪ Sham group was sedated; lavage and debridement groups had endotracheal tube. ▪ Controversial to establish delta for equivalence analysis post hoc. ▪ Use of Kaplan-Meier curves — full information is not reported. ▪ Over 5% missing data points. ▪ No ITT analysis (which may be appropriate for equivalence, but not for superiority). ▪ Appears to lack formal measurement of safety outcomes. ▪ External validity potentially affected by inclusion of subjects with severe arthritis and other subject selection issues, single surgeon, single institution, "decline rate" of 44% of eligible subjects make generalization to other populations or subgroups questionable

Evidence Grades

- **Quality of efficacy evidence for arthroscopy with lavage and debridement: Grade B-U.**
  Grade B-U evidence represents possible to uncertain usefulness. The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B (possibly useful) and the uncertainty is not great enough to fully warrant a Grade U (uncertain usefulness because

Primary Study Critique

Study Reference: Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11; 347(2):81-8.

Reviewers: Michael E. Stuart, Sheri A. Strite

of validity or applicability issues), i.e., there are some study issues that raise continued uncertainty. Health care decision-makers should be fully informed of the limitations of the evidence.

- **Quality of safety evidence for arthroscopy with lavage and debridement: Grade U.** Grade U evidence represents sufficient uncertainty that caution is urged regarding use of the information in making health care decisions. Uncertainty may be due to methodologic flaws that threaten validity or to uncertain applicability of results (e.g., good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. Grade U evidence may be useful in understanding potential harms. Evaluating safety data is a complex process. Standards are often lower for using safety data than efficacy data and so there may be much uncertainty about the results. Conclusions about safety issues should be worded carefully so that information drawn from potentially flawed data regarding safety is not presented as if it is based on stronger evidence than actually exists.

Table 3. Cochrane Laupattrarakasem 2002.

Delfini Critique. Secondary Study. Cochrane Database of Systematic Reviews: Arthroscopic debridement for knee osteoarthritis.

Date: 6/10/08 **Study Reference:** Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23;(1):CD005118. Review.
Reviewer: Michael E. Stuart MD

Study Type: Systematic Review

Study Aim: To identify the effectiveness of arthroscopic debridement (AD) in knee OA on pain and function.

Systematic Review Study Details
Secondary Study Critique: Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.
Outcomes: **Primary Outcomes:** 1. Reduction of knee pain. 2. Improvement of knee functions. **Secondary Outcomes:** 1. Time to next major intervention (e.g., total knee arthroplasty) indicating failure of the treatment or censoring due to end of the study or dropout. 2. Amount (doses, frequencies and types) of non steroidal anti-inflammatory (NSAIDs) and/or analgesics used as rescue therapies in parallel with the treatment and control. 3. Post-operative morbidities or complications. 4. Other outcomes according to the authors' reports.
Number of studies/ subjects included: 3 articles on arthroscopy were included. 288 subjects randomized, 271 included.
Reported Results Results of the three trials were individually described due to differences of the comparison groups and heterogeneity of the clinical and methodological aspects, which precluded meta-analysis of results. **AD versus closed needle lavage** Chang 1993 (rated as at high risk of bias) reported that, after controlling for baseline differences, the adjusted mean Arthritis Impact Measurement Scales (AIMS) pain scores were 5.0 in the arthroscopic debridement (AD) group and 5.4 in the lavage group with no statistically significant weighted mean difference (WMD-0.4, 95%CI -1.6 to 0.8) at three months of follow-up. The adjusted mean AIMS pain scores at 12 months of follow-up were 5.3 in the AD group and 5.0 in the lavage group with no statistically significant difference (WMD 0.3, 95% CI -1.1 to 1.8) **AD versus lavage** Moseley 2002 (rated as at moderate risk of bias) presented results from a total of 163 patients who completed the trial at 24 months. The pain scores showed a decrease from the baseline of approximately 10 points in both the AD and lavage groups at two weeks after the intervention. The

Systematic Review Study Details

Secondary Study Critique:
Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.

WMD for pain scores was 2.5 (95% CI -4.4 to 9.4). After that the pain scores fluctuated less than 5 points at each measurement and the WMD was not statistically significant at any of the measurement points up to 24 months after the intervention. The WMD difference at 24 months was -0.6 (95% CI -8.3 to 7.1) for physical function. The authors reported that 79.7% of participants in the AD group and 88.5 % of patients in the lavage group used analgesics (prescribed and non-prescribed). [Note from Delfini Reviewers: Analgesic use reported here is baseline; not 24 months post-intervention.]

AD versus wash-out
Hubbard 1996 (rated as at high risk of bias) reported a significant difference in pain relief with a relative risk of 5.76 (95% CI 2.52 to 13.18) between debridement and washout at one year follow-up. A significant difference in pain relief of 5.15 (95% CI 1.71 to 15.49) between debridement and washout at five years follow-up was also reported. Physical function measured as mean modified Lysholm scores were presented without standard deviations for each subgroup for pain relief (success or failure). The scores were similar for each comparable pain relief subgroup. The higher mean scores were seen in the success groups with 61 for debridement versus 63 for washout at one year follow-up, and 58 for debridement versus 59. For washout at five years follow-up. Lower mean scores were seen in the failure groups, with 33 for debridement versus 35 for washout at one year and five year follow-up.

AD versus placebo
Moseley 2002 found a large decrease of 19 points from the baseline in the placebo group at two weeks after the intervention. The WMD for pain was 8.7 (95% CI 1.7 to 15.8), indicating a statistically significant result in favor of the placebo group for pain reduction and the number-needed-to-harm was 5. The WMD at each subsequent measurement point was not statistically significant up to 24 months after the intervention. For physical function the WMD for function at two weeks was 7.7 (95% CI 1.1 to 14.3), indicating that the AD group experienced significantly worsening of function, with a number-needed-to-harm of 6. A second statistically significant result was found at 12 months follow-up, with a WMD of 6.9 (95% CI 0.4 to 13.4) and the number-needed-to-harm of 9. The authors reported that 79.7% of participants in the AD group and 91.7% in the placebo group used analgesics. [Note from Delfini Reviewers: Analgesic use reported here is baseline; not 24 months post-intervention.]

Adverse Events
None of the trials measured postoperative complications or subsequent interventions. Moseley 2002 stated that incisional erythema occurred in one patient and in another, calf swelling was found and the patient had negative venography for thrombosis.

Authors' Conclusions
Although the authors included results for the three studies, their major conclusions are based on Moseley 2002. The authors conclude that there is gold level evidence (Moseley 2002) that AD has no significant benefit in knee OA. They also concluded that controversial or areas of uncertainty remain to be addressed, (e.g., there may be groups of patients or levels of severity of disease for which the intervention may be effective).

Systematic Review Study Details	
Secondary Study Critique: Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.	
	The authors also state in their conclusions based on Hubbard 1996 that AD provides more successful results for localized lesions on the medial femoral condyle than arthroscopic washout, but point out that the study was of lower methodological quality. (Note: the Hubbard 1996 study was rated as high risk of bias).
	Reviewers' Comments on Authors' Conclusions The authors make no statement about the clinical benefit of knee lavage in OA. We agree with their conclusions about AD based on Moseley 2002.
I. Systematic Review Validity Assessment	
17.	**Research Question:** Clearly stated and meaningful questions to the literature, determined in advance? **Assessment:** Appropriate
18.	**Clinical Significance of Question:** Does the research question address morbidity, mortality, symptom relief, emotional and/or physical functioning or health-related quality of life? **Assessment:** Yes
19.	**Study Selection:** Explicit, documented and appropriate selection criteria chosen in advance for included studies that are sufficiently similar? For example, needs to specify study type (eg, RCT, cohort, etc.), population, methods, inventions or exposures and outcomes. **Assessment:** Authors sought and assessed randomized controlled trials (RCTs) or controlled clinical trials (CCTs) assessing effectiveness of AD compared to another surgical procedure, including sham or placebo surgery and other non-surgical interventions, in patients with a diagnosis of primary or secondary OA of the knees, who did not have other joint involvement or conditions requiring long term use of non-steroidal anti-inflammatory drugs (NSAIDs).
20.	**Study Design:** If this is a question of therapy, screening or prevention, and observational studies are used to answer questions of efficacy, ***Delfini*** suggests not using the review. **Assessment**: No observational studies were included.
21.	**Search Strategy:** Documented systematic and comprehensive search strategy that is well thought out and executed? **Assessment: Authors** searched the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 2, 2006); MEDLINE (1966 to August, 2006); CINAHL (1982 to 2006); EMBASE (1988 to 2006) and Web of Science (1900 to 2006) and screened the bibliographies, reference lists and cited web sites of papers.
22.	**Patient Population Assessment:** Is the population appropriate for this question? **Assessment:** Yes.
23.	**Critical Appraisal:** What is the quality of included studies? **Assessment:** (1) Selection bias (randomization and allocation concealment)

Systematic Review Study Details	
Secondary Study Critique: Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.	
	Authors assessed the possibility of selection bias for each trial, using the following criteria: (A) adequate concealment of allocation: such as telephone randomization, consecutively numbered, sealed opaque envelopes; (B) unclear whether adequate concealment of allocation: such as list or table used, sealed envelopes, or study does not report any concealment approach; (C) inadequate concealment of allocation: such as open list of random-number tables, use of case record numbers, dates of birth or days of the week; (D) concealment of allocation not used. (2) Performance bias (blinding of participants, researchers and outcome assessment) They assessed performance bias for each trial, using the following criteria: (2.1) blinding of participants -yes: such as patients did not know which procedure they received -no: such as patients knew which procedure they received -unclear: no information (2.2) blinding of outcome assessment -yes: such as investigators measured pain among the patients without awareness of the interventions they received; -no: such as pain was measured from the patients among the treatment groups -unclear: investigators measured pain among the patients similarly (3) Attrition bias (loss of participants, for example, withdrawals, dropouts, protocol deviations) They assessed completeness to follow up using the following criteria: (A) less than 5% loss of participants; (B) 5% to 9.9% loss of participants; (C) 10% to 19.9% loss of participants; (D) more than 20% loss of participants. (4) Sample size calculation (A) adequate explanation of sample size calculation: such as all information related to sample size calculation were available (B) unclear whether the sample size was calculated or no available information (C) inadequate explanation of sample size calculation: such as some information related to sample size calculation were available (D) not calculated Low risk of bias was defined as those receiving an 'A' rating for selection bias, attrition bias and sample size calculation, and 'yes' for blinding of participants and outcome assessment. Moderate risk of bias was defined as those receiving at least one 'B' or 'C' rating for selection bias, attrition bias, sample size calculation , or 'unclear' for blinding of participants or outcome assessment.

Systematic Review Study Details	
Secondary Study Critique: Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.	
	High risk of bias was defined as those receiving at least one ' D' or 'No rating' for selection bias, attrition bias, sample size calculation, and blinding of participants or outcome assessment. The evidence of review was graded according to the Cochrane Musculoskeletal Group Method Guidelines (Maxwell 2006) as the following: Platinum level The Platinum ranking is given to evidence that comprises a published systematic review that has at least two individual controlled trials each satisfying the following: • Sample sizes of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome. • Blinding of patients and assessors for outcomes. • Handling of withdrawals >80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable). • Concealment of treatment allocation. Gold level The Gold ranking is given to evidence if at least one randomized clinical trial meets all of the following criteria for the major outcome(s) as reported: • Sample sizes of at least 50 per group. If they do not find a statistically significant difference, they are adequately powered for a 20% relative difference in the relevant outcome. • Blinding of patients and assessors for outcomes. • Handling of withdrawals > 80% follow up (imputations based on methods such as Last Observation Carried Forward (LOCF) acceptable). • Concealment of treatment allocation. Silver level The silver ranking is given to evidence if randomized trial does not meet the above criteria. Silver ranking would also include evidence from at least one study of non-randomized cohorts who did and did not receive the therapy or evidence from at least one high quality case-control study. A randomized trial with a 'head-to-head' comparison of agents is considered Silver level ranking unless a reference is provided to a comparison of one of the agents to placebo showing at least a 20% relative difference. Bronze level The bronze ranking is given to evidence if there is at least one high quality case series without controls (including simple before/after studies in which the patient acts as their own control) or if it is derived from expert opinion based on clinical experience without reference to any of the foregoing (for example, argument from physiology, bench research or first principles).
24.	**Missing Outcomes Data:** Assessment of how loss to follow-up is handled and is it done appropriately? **Your Assessment:** The Moseley 2002 study used as the basis for conclusions regarding efficacy

Systematic Review Study Details	
Secondary Study Critique: Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.	
	lost ~9% of subjects and did not do an ITT analysis. The reviewers did not recalculate results imputing missing data.
25.	**Homo-/heterogeneity:** **Your Assessment:** Significant heterogeneity. Therefore the reviewers reported study results individually.
26.	**Combining Results**: If results were combined, was it done in a reasonable and appropriate manner? **Your Assessment:** N/A
27.	**Weighting:** If weighting was employed, was a reasonable approach taken? **Assessment:** N/A
28.	**Author's Discussion**: Well executed sensitivity analyses, discussion of limitations, explanations of differences in studies and their results, etc.? Assessment: The authors state that, although direct comparison with placebo is important, in future studies researchers investigating a similar research question should compare alternative treatment options to increase the number of options for people with knee OA who have not responded to conservative treatments. They also point out that although Moseley 2002 reported results contrary to most previous studies, that the previous studies were observational and case series and do not represent strong evidence.
29.	**Author's Conclusion:** Conclusions are supported by the evidence? **Assessment**: Conclusions based on Moseley 2002 (see Results above) are supported by evidence.
30.	**Transparency:** Is sufficient detail provided that enables a through quality assessment of this review and such that this review could be replicated? ▪ Does the review provide a list of the specific studies included for drawing conclusions? **Your Assessment:** Good transparency
31.	**Evidence Grade:** • **Quality of efficacy evidence for arthroscopy with lavage and debridement: Grade B-U.** Grade B-U evidence represents possible to uncertain usefulness. The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B (possibly useful) and the uncertainty is not great enough to fully warrant a Grade U (uncertain usefulness because of validity or applicability issues), i.e., there are some study issues that raise continued uncertainty. Health care decision-makers should be fully informed of the limitations of the evidence. • **Quality of safety evidence for arthroscopy with lavage and debridement: Grade U.** Grade U evidence represents sufficient uncertainty that caution is urged regarding use of the information in making health care decisions. Uncertainty may be due to methodologic flaws that threaten validity or to uncertain applicability of results (eg, good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or

Systematic Review Study Details	
Secondary Study Critique: Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23 ;(1):CD005118. Review.	
	other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. Grade U evidence may be useful in understanding potential harms. Evaluating safety data is a complex process. Standards are often lower for using safety data than efficacy data and so there may be much uncertainty about the results. Conclusions about safety issues should be worded carefully so that information drawn from potentially flawed data regarding safety is not presented as if it is based on stronger evidence than actually exists. In the authors' plain text summary they state there may be a small risk of infection and venous thromboembolism but provide no study data.

Table 4. Cochrane Ramos. Secondary Study:

Cochrane Database of Systematic Reviews: Ramos 2007. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy.

Date: 6/10/08 **Study Reference:** Ramos J, Perrotta C, Badariotti G, Berenstein G. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD005259. DOI: 10.1002/14651858.CD005259.pub2.
Reviewer: Michael E. Stuart MD

Study Type: Systematic Review

Study Aim: Evaluate the effectiveness and safety of thromboprophylaxis to reduce the incidence of DVT in patients undergoing knee arthroscopy?

Systematic Review Study Details	
Secondary Study Critique Ramos J, Perrotta C, Badariotti G, Berenstein G. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD005259. DOI: 10.1002/14651858.CD005259.pub2.	
Outcomes: **Primary Outcomes:** • Proximal and distal deep vein thrombosis (DVT) events clinically, venographically or sonographically diagnosed. • Pulmonary embolism (PE) diagnosed by ventilation/perfusion (V/Q) lung scan, spiral computed tomography (CT), or pulmonary angiography. • Death related to embolic events. **Secondary Outcomes:** • Reported side/adverse effects.	
Number of studies/ subjects included: 4 trials/527 subjects were included.	
Reported Results • Overall there were three distal DVTs in the low molecular weight (LMWH) and one pulmonary embolus (PE) compared to 20 DVTs in those who received "no treatment" yielding an incidence of 4.4%. • In the four studies, all but one of the thrombotic events were distal DVTs. • There was one event of pulmonary embolism in one study. One study reported no thrombotic events.	
I. Systematic Review Validity Assessment	
1.	**Research Question:** What is the effectiveness and safety of thromboprophylaxis to reduce the incidence of DVT in patients undergoing knee arthroscopy? **Assessment:** Because answering this question is likely to provide information about adverse events in patients undergoing knee arthroscopy, it may be useful for estimating adverse events in patients undergoing arthroscopy for OA of the knee.
2.	**Clinical Significance of Question:** Does the research question address morbidity, mortality, symptom

Systematic Review Study Details	
Secondary Study Critique Ramos J, Perrotta C, Badariotti G, Berenstein G. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD005259. DOI: 10.1002/14651858.CD005259.pub2.	
	relief, emotional and/or physical functioning or health-related quality of life? **Assessment:** The authors used both clinical and intermediate outcome measure such as proximal and distal DVT events clinically, venographically or sonographically diagnosed; pulmonary embolism diagnosed by V/Q lung scan, spiral computed tomography (CT), or pulmonary angiography; death and adverse events. Judgment is required in interpreting surrogate outcome measures.
3.	**Study Selection:** Explicit, documented and appropriate selection criteria chosen in advance for included studies that are sufficiently similar? For example, needs to specify study type (e.g., RCT, cohort, etc), population, methods, inventions or exposures and outcomes. **Assessment:** Authors sought publications describing (or which might describe) RCTs or CCTs (controlled clinical trials) of mechanical or pharmacological interventions used to prevent DVT in patients undergoing knee arthroscopy.
4.	**Study Design:** If this is a question of therapy, screening or prevention, and observational studies are used to answer questions of efficacy, Delfini suggests not using the review. **Assessment**: No observational studies were included.
5.	**Search Strategy:** Documented systematic and comprehensive search strategy that is well thought out and executed? **Assessment:** Search strategy was appropriate for the clinical question: Searched The Cochrane Peripheral Vascular Diseases (PVD) Group Specialized Register (last searched 25 October 2006) and the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library (searched Issue 4, 2006) for all publications describing (or which might describe) RCTs or CCTs of mechanical or pharmacological interventions used to prevent DVT in patients undergoing knee arthroscopy utilizing the following databases:1) MEDLINE from 1966 to October 2006 using the search terms "thrombotic "[in all fields] AND arthro* [in all fields] AND prophy* [in all fields] OR preven* [in all fields], AND Hepar*'[in all fields] combined with the MEDLINE search strategies for randomized controlled trials; (2) EMBASE from 1980 to October 2006; (3) Lilacs from 1988 to October 2006. In addition, we searched the reference lists of identified studies, and articles and abstracts of international meetings of Orthopedics, Hematology and Thrombosis journals from the year 1998 to 2004. Authors contacted specialists known to be involved in phlebology and interested in post thrombotic syndrome for details of unpublished and ongoing trials. There were no restrictions on language.
6.	**Patient Population Assessment:** Is the population appropriate for this question? **Assessment:** Predominantly male (average 70%) adults (trial mean ages from 31 to 44 years); History of previous DVT was an exclusion criterion and potential risk factors were taken into account in 2 studies. The type of knee arthroscopy intervention performed varied across studies: anterior cruciate ligament (ACL) reconstruction, partial meniscectomy and diagnostic procedures. In two studies risk factors such as use of tourniquet and type of anesthesia were taken into account.
7.	**Critical Appraisal:** What is the quality of included studies? **Assessment:**

Systematic Review Study Details	
Secondary Study Critique Ramos J, Perrotta C, Badariotti G, Berenstein G. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD005259. DOI: 10.1002/14651858.CD005259.pub2.	
	Types of studies Randomized clinical trials (RCTs) and controlled clinical trials (CCTs), whether blinded or not (ie, double blinded, single blinded or unblinded). **Quality Assessment** Two evaluators independently evaluated concealment of allocation, blinding, intention-to-treat analysis, completeness of follow-up. 2 studies were of acceptable quality, 2 were of low quality because of no description of the allocation methods and how randomization was achieved, no information on inclusion and exclusion criteria and lack of intention-to-treat analysis. Adverse event definitions were not clear. However, sensitivity analysis excluding lower quality studies did not alter results. Threats to validity in considering efficacy: • Single or non-blinding; • Lack of appropriate stratification of the arthroscopic intervention; • Few details regarding randomization; • No details or weak methods for concealing allocation; • Many patients were low-risk making it difficult to apply results to patients with knee OA; • Lack of intention-to-treat analysis. **Assessment**: Although the quality of the RCTs was low, the review provides limited quantitative information about the incidence of DVT following arthroscopy.
8.	**Missing Outcomes Data:** Assessment of how loss to follow-up is handled and is it done appropriately? **Assessment:** One higher quality study lost 8% in the intervention group and 2% in the control group and the other higher quality study lost 7%. Sensitivity analysis excluding lower quality studies did not alter results.
9.	**Homo-/heterogeneity:** Authors used a test of heterogeneity (chi-square) to assess potential differences between trials and did not find significant heterogeneity in any of the comparisons. I^2 statistic was 0.0% in all included studies. **Assessment:** N/A—The systematic review utilized only 1 RCT as the basis for conclusions.
10.	**Combining Results**: If results were combined, was it done in a reasonable and appropriate manner? **Assessment:** N/A
11.	**Weighting:** If weighting was employed, was a reasonable approach taken? **Assessment:** N/A
12.	**Author's Discussion**:

Systematic Review Study Details	
Secondary Study Critique Ramos J, Perrotta C, Badariotti G, Berenstein G. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD005259. DOI: 10.1002/14651858.CD005259.pub2.	
	Assessment: Helpful discussion including results of previous studies: • The authors reviewed a previous meta-analysis that reported an incidence of DVT following arthroscopy of 3.1% to 17.9%. • The authors state in their discussion based on their literature review that the incidence of PE in distal asymptomatic DVT varies between 1.6% and 21% and may be related to the patient risk factors. • The patients included in this review may be at different risk than patients undergoing arthroscopic debridement and lavage for treatment of knee OA.
13.	**Other Issues (e.g., potential conflict of interest):** **Assessment:** None
14.	**Author's Conclusion:** No strong evidence was found to conclude thromboprophylaxis is effective to prevent thromboembolic events and safe, in people with unknown risk factors for thrombosis undergoing knee arthroscopy. **Assessment**: The major value of this study is the harms data. The populations studied may be at different risk than OA patients undergoing knee arthroscopy for lavage and debridement. Nevertheless, this study provides limited evidence about incidence of DVT following arthroscopy.
15.	**Transparency:** Is sufficient detail provided that enables a through quality assessment of this review and such that this review could be replicated? ▪ Does the review provide a list of the specific studies included for drawing conclusions? **Your Assessment:** Good transparency
16.	**Evidence Grade:** • **Quality of efficacy evidence: N/A. This study was not used for efficacy.** • **Quality of safety evidence: Grade U.** Grade U evidence represents sufficient uncertainty that caution is urged regarding use of the information in making health care decisions. Uncertainty may be due to methodologic flaws that threaten validity or to uncertain applicability of results (e.g., good methodology, but questions due to effect size, applicability of results when relating to biologic markers, or other issues). These latter studies may be useful and should be viewed in the context of the weight of the evidence. Grade U evidence may be useful in understanding potential harms. Evaluating safety data is a complex process. Standards are often lower for using safety data than efficacy data and so there may be much uncertainty about the results. Conclusions about safety issues should be worded carefully so that information drawn from potentially flawed data regarding safety is not presented as if it is based on stronger evidence than actually exists.
17.	**Implications:** The following data may be useful in clinical decision-making but the following estimates do not come from high quality scientific studies. • It may be reasonable to estimate the incidence of DVT following arthroscopy to be between 3.1% to 17.9%. • The incidence of PE in patients with distal asymptomatic DVT has been reported to be between

Systematic Review Study Details	
Secondary Study Critique Ramos J, Perrotta C, Badariotti G, Berenstein G. Interventions for preventing venous thromboembolism in adults undergoing knee arthroscopy. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD005259. DOI: 10.1002/14651858.CD005259.pub2.	
	1.6% and 21% and may be related to patient risk factors and details of the interventions.

Table 5. OARSI Guideline:
Clinical Practice Guideline Critique (Tool Adapted for Review)

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
Reviewer: Michael E. Stuart MD

Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
RELEVANCE & SIGNIFICANCE ISSUES				
1. Is this information relevant to your patients? What is the topic and to what population does it apply? Review age, gender, severity, etc. **Comments:** Controversial and patients require clear benefit/risk/uncertainty information	X			*Are patients markedly different from **yours**? If so, the test of relevance may not have been met.*
2. Are the expected outcomes clinically significant and will they provide reasonable estimates of benefit, especially given that benefit is likely to be smaller than that which is demonstrated in research settings? **Comments:** Insufficient evidence to conclude there are clinically significant benefits, and this set of recommendations suggests there is valid evidence of benefit.			X	*Look for things that matter to patients: morbidity, mortality, symptom relief, functioning, quality of life and satisfaction. Avoid proxy markers if there is no proof of meaningful benefit.*
3. How will the quality improvement project impact outcomes in your setting? ♦ Prevalence of risk factors/disease in your population ✓ Health Status ✓ Benefits / Harms / Risks/ Uncertainties / Alternatives compared to current practice ♦ Patient Satisfaction ♦ Professional Satisfaction ♦ Utilization / Cost (see #4) **Comments:** Uncertainties regarding benefits, harms. Utilization/Cost are significant concerns with lack of			X	*IOM Framework Considerations: Care that is – safe, effective, patient-centered, timely, efficient, equitable.* *When evaluating organizational impacts, mitigate the "silo" effect of department budgeting by considering cost and benefit across the entire organization.*

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
Reviewer: Michael E. Stuart MD

Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
evidence. There is insufficient evidence to conclude that patients will benefit, and there are documented harms from arthroscopy. Question 4.-6 N/A				
VALIDITY ISSUES				
7. How current is this document? **Comments:** Search included guidelines published through January 2007.				*QI projects should be reviewed at least every two years and kept current in the event of major new information.*
8. Is the development process described (Explicit EB, EB, Consensus, Variation, Benchmarking, No Description)? **Comments**: Combined evidence-based and consensus process with strength of recommendations (SOR) developed using a visual analogue scale after guideline members reviewed: (a) The list of accepted propositions in which the level of the research evidence for each proposition was indicated according to the evidence hierarchy (b) The results of the authors' critical appraisal of existing guidelines (c) A summary of the systematic analysis of the research evidence from 2002 to 2006 including details of quality scores, effect size for pain, function and stiffness, the NNT, the RR or OR and the cost per QALY for each modality of treatment proposed where these were available, and (d) A first draft of the guideline manuscript. **Comments:** Although this guideline attempted to review all existing guidelines for OA of the knee, a major weakness is the methodology used for establishing levels of evidence (LOE). This allows for the possibility of "upgrading" of the evidence. LOEs were based on the Oxman and Guyatt method for systematic reviews and the Jadad scale for randomized controlled trials (RCTs). The Oxman and Guyatt approach allows for inclusion of non-valid **primary studies** because it does not provide for evaluation of co-			X	

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
Reviewer: Michael E. Stuart MD

Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
interventions and allows up to 20% loss to follow-up in its rating of good quality evidence. In our opinion the Oxman and Guyatt approach allows inclusion of non-valid **systematic reviews**. The following questions allow for the possibility of including non-valid systematic reviews since the criteria are soft and up to the judgment of the reviewer, plus they don't specifically state to only use valid studies (which is an issue as many people utilize invalid evidence and others interpret "best available evidence" in such a way that they utilize invalid evidence in lieu of valid evidence): #5. Were the criteria used for assessing the validity of the included studies reported? #6. Was the validity of all the studies referred to in the text assessed using appropriate criteria? The Jadad scale for evaluating RCTs has been criticized widely for several deficiencies: • The Jadad scale consists of three items, and up to two points are given for randomization, two for double blinding and one for description of withdrawals and dropouts. An overall score between zero and five is assigned. A score of three is commonly regarded as adequate trial quality. The Jadad scale is problematic in that: o Points can be awarded merely for reporting rather than giving appropriate attention to methodological quality; o For randomization, the scale addresses explicitly the sequence generation, but not concealment of allocation of the sequence; o The scale does not address intention-to-treat analysis among many other considerations. Therefore, randomized trials with an appropriate randomization sequence, but with no concealment of allocation, with large numbers of dropouts that are well described, using only a per-protocol analysis and having other biases such as differences between groups, may be scored as of the highest methodological quality (five points).				

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
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Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
Studies have shown low interrater agreement of ratings of the Jadad scale, particularly for withdrawals and dropouts, where kappa values below zero. Agreement that is worse than that expected by chance have been reported.				
9. Who developed the improvement? Were epidemiologic and clinical perspectives used to develop the improvement? Were other disciplines and perspectives represented as needed? **Comments:** Sixteen experts from four medical disciplines (primary care, rheumatology, orthopaedics and evidence-based medicine) from two continents and six countries (USA, UK, France, Netherlands, Sweden and Canada) developed the guideline. See number 8. for major concerns.				*Sponsors and developers may bring a biased perspective. Lack of sponsor information may be of concern.* *A rigorous development process can help mitigate bias. At a minimum development should involve clinical and epidemiologic expertise.*
10. Does the document disclose the strength of evidence upon which the recommendations/options are based? ♦ Search strategy ♦ Selecting and evaluating articles ✓ Grades of evidence ✓ Methods of each study (design, conduct, analysis, conclusions) ✓ Methods for ensuring validity and usefulness of information used. (**Note**: it is recommended to audit the quality of the appraised information by selecting, from the included studies, a study considered to be of the highest quality and one of the lowest and performing a critical appraisal as double-check.) ♦ Synthesis of the evidence ♦ Are you comfortable that the developers utilized the best available evidence?			X	*Does the improvement meet tests for scientific relevance and validity? Is the evidence used the best available?*

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
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Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
Comments: Search strategy was reasonable. Strength of recommendations were made based on clinical experience and a system (Jadad scale) for establishing levels of evidence that has been shown to "upgrade" low-grade RCTs. Level of evidence Ib can be achieved by a single RCT without assurance of validity. The evidence synthesis may be misinterpreted as providing valid evidence of benefit. For example, the OARSI guidelines group awarded what they consider to be a high level (level Ib grade of evidence) to many studies which were actually considered to be of low quality by others. Grade Ib evidence is defined by the OARSI group as a single RCT; however, this is not sufficient to be considered high quality evidence — RCTs must be valid and clinically useful. In contrast to the OARSI rating, the Moseley 2002 RCT (the only study identified as high quality by a Cochrane systematic, our review and critical appraisal by others was not assigned an evidence grade at all by the OARSI group. Potential threats to validity were mentioned in the narrative text of the OARSI guideline (and conversely, no threats to validity were mentioned for the other RCTs given a Ib grade by them). A striking example of upgrading of evidence by the OARSI group was the evaluation of the Livesley 1991 study which was rated as a grade Ib study by the OARSI group without any information about threats to validity, but yet was rated as poor by an Agency for Healthcare Research and Quality (AHRQ) publication because of numerous threats to validity including —ironically — the lack of randomization.				
DECISION SUPPORT ISSUES				
11. Do the key messages meet our patients' needs? **Comments:** No. Patients need clear statements regarding the lack of valid evidence and quantitative data demonstrating the likelihood of benefit. Harms are not addressed in this guideline document, and readers cannot			X	

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
Reviewer: Michael E. Stuart MD

Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
draw risk-benefit conclusions. Proposition 24 of the guideline (replicated below) refers to fatally flawed evidence in support of arthroscopic knee lavage and debridement. "The roles of joint lavage and arthroscopic debridement in knee OA are controversial. Although some studies have demonstrated short-term symptom relief, others suggest that improvement in symptoms could be attributable to a placebo effect." "Strength of Evidence: (SOR): 60% (95% CI 47-82) Arthroscopic debridement, a procedure that variably includes joint lavage, the removal of loose bodies, debris, mobile fragments of articular cartilage, unstable torn menisci and impinging osteophytes, has been extensively used in the treatment of OA knee for more than 70 years; and joint lavage is currently recommended as useful treatment for patients with knee OA in 3/3 treatment guidelines where this modality of therapy was considered. However, controversy regarding the efficacy and indications for these procedures in the management of knee OA continues. For many years evidence for the efficacy of arthroscopic joint lavage and debridement in knee OA rested on the clinical outcomes observed in uncontrolled cohorts as is the case for the majority of surgical interventions (LoE III). In such studies 50-80% of patients were typically recorded as having decreases in knee pain lasting from 1 to 5 years. One RCT, which compared articular debridement and lavage alone in 76 knees with medial compartment knee OA, found that 80% of the debridement group and 14% of the washout group were pain free at 1 year, with 59% of the debridement group and 12% of the washout group remaining free from knee pain after 5 years (LoE Ib). A second prospective comparative study compared arthroscopic debridement with non-operative medical treatment in 70 patients. After 2 years 75% of the operated patients and 16% of the medically treated patients had improvements using the HSS177 knee rating score.				

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
Reviewer: Michael E. Stuart MD

Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
RCTs comparing tidal knee irrigation with standard medical therapy, and joint lavage plus physiotherapy with physiotherapy alone both demonstrated statistically significant reduction in pain in the lavage groups at 3 months and this was still evident at 1 year in the latter trial (LoE Ib). However a good quality, placebo- controlled RCT in which 180 patients with knee OA were randomly assigned to receive arthroscopic debridement, arthroscopic lavage or placebo (sham) surgery with a skin incision and simulated arthroscopy showed no significant differences between the groups in the primary end point (pain on a self-reported 12-item knee specific pain scale) at 24 months, or in any of the other secondary outcome measures of pain and function at any time point." "The effect size for pain and function were 0.09 (95% CI -0.27, 0.44) and -0.10 (95% CI -0.45, 0.26) for arthroscopic lavage, and -0.01 (95% CI -0.37, 0.35) and -0.09 (95% CI -0.27, 0.45) for arthroscopic debridement. This is one of only a very few placebo-controlled RCTs of surgical procedures in which sham surgery has been undertaken. Clearly surgery does have very powerful placebo effects and the investigators emphasized, as have others, that the power of placebos should never be underestimated. Although much of the controversy that followed the publication of this study related to the ethical and practical issues of undertaking blinded placebo-controlled trials of surgical procedures, it was also criticized on methodological grounds relating to the design of the study, the documentation of clinical and operative features, the outcome measures employed and the statistical analysis, as well as a failure to undertake a subset analysis to see whether any subgroups of patients who were deriving benefit from arthroscopic debridement were being lost in the pooled analysis. A recent review of published studies concluded that there was some evidence to suggest that arthroscopic debridement of meniscus tears in patients with OA and arthroscopic debridement of knees with low-grade OA may have limited utility (LoE III)."				
12. Are the important recommendations/options (with			X	

Date: 06/10/08 Study Reference: Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008; 16:137-62. PMID: 18515155
Reviewer: Michael E. Stuart MD

Purpose: Technology Assessment: Arthroscopic lavage and debridement for osteoarthritis of the knee

CONSIDERATIONS	CONCERNS			*SIDEBAR*
	None	Minor	Major	
benefits, risks, uncertainties, alternatives, costs of each choice) provided? ♦ Symptom relief ♦ Morbidity, mortality ♦ Function ♦ Quality of life **Comments:** No. Risk information is absent.				
13. Choice: Does the improvement accommodate differing patient values and preferences? **Comments:** No.			X	

CONCLUSIONS & YOUR JUDGMENT

14. Are any limitations described? Yes: no patient participation.

15. Are there ethical issues to be considered?

Yes. Patients and providers should be provided with information based on valid and clinically useful evidence.

17. Should this intervention be accepted?

Comments: No.

- Insufficient evidence to conclude efficacy.
- Concern regarding the risk-benefit ratio for patients.
- Significant costs without predictably improved patient outcomes.

5. APPENDIX

Keys to Reading this Report

Online Document Navigation
In Microsoft Word, navigation to report sections can be accomplished via Word's Document Map feature: View > Document Map.

Important Abbreviations Used:
AD: Athroscopic debridement
AIMS-P: Arthritis Impact Measurement Scales-Pain
CI: Confidence interval
DARE: Database of Abstracts of Reviews of Effects
DVT: Deep vein thrombosis
FDA: Food and Drug Administration
KSPS: Knee-Specific Pain Score
MeSH: Medical Subject Heading
OA: Osteoarthritis
OARSI: The Osteoarthritis Research Society International
PMID: PubMed-Indexed for MEDLINE. This may be referred to as a PubMed Identification number and may be used in the PubMed search window to locate a manuscript.
RCT: Randomized controlled trial
WMD: weighted mean difference

References (See Search Tables for excluded study references)

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Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11;347(2):81-8.

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Wai EK, Kreder HJ, Williams JI. Arthroscopic debridement of the knee for osteoarthritis in patients fifty years of age or older: utilization and outcomes in the Province of Ontario. J Bone Joint Surg Am 2002;84-A(1):17-22.

Zhang W, Moskowitz RW, Nuki G, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage 2008;16:137-62. PMID: 18515155

Reference 2: Ongoing Clinical Trials

Methods
Search Source: clinicaltrials.gov
Search Terms: knee and arthroscopy
Date: 06/26/08

Delfini Note: While these studies may represent the most relevant to this topic, none of them clearly focuses on debridement or lavage. They may be relevant for safety information, however.

1 Not yet recruiting
HTO With and Without Arthroscopy
Condition: Medial Compartment Osteoarthritis of the Knee
Intervention: Procedure: Arthroscopy

2 Recruiting
Arthroscopy in the Treatment of Degenerative Medial Meniscus Tear
Condition: Degenerative Tear of the Medial Meniscus of Knee
Interventions: Procedure: Operative (partial arthroscopy); Procedure: Conservative (diagnostic arthroscopy)

3 Completed
A Multicentre, Double-Blind, Double-Dummy, Randomised Study of the Analgesic Efficacy and Safety of Valdecoxib Compared to Diclofenac Sodium in Patients Undergoing Knee Arthroscopy for Anterior Cruciate Ligament (ACL) Reconstruction
Condition: Pain, Postoperative
Interventions: Drug: valdecoxib; Drug: diclofenac

4 Not yet recruiting
F18-Flouride PET/CT in Acute Knee Injury
Condition: Knee Injury
Intervention:

5 Completed
Auricular Acupuncture for Pain Relief After Ambulatory Knee Arthroscopy
Condition: Postoperative Pain
Intervention: Procedure: Auricular acupuncture

6 Recruiting
Traumeel S for Reduction of Post Operative Pain Following Arthroscopy
Condition: Post-Operative Pain
Interventions: Drug: Traumeel S: intra-operative irrigation + oral ingestion; Drug: Placebo

7 Recruiting
Study Into the Effect of Ibandronate for the Treatment of Bone Marrow Edema in Relation to Spontaneous or Non-Traumatic Osteonecrosis of the Knee: A Randomized Double-Blind,

Placebo-Controlled Trial
Conditions: Osteonecrosis of the Knee; Bone Marrow Edema of the Knee
Interventions: Drug: Ibandronate IV; Drug: Placebo

8 Completed
Effect of Celecoxib Versus Placebo Before and After Knee Surgery on the Overall Use of Analgesics After Surgery
Condition: Arthroscopy
Interventions: Drug: Celecoxib; Other: Placebo

9 Active, not recruiting
Prospective Multicenter Randomized Controlled Trial of ChondroCelect® (in an Autologous Chondrocyte Transplantation Procedure) vs Microfracture in the Repair of Symptomatic Defects of the Knee
Condition: Articular Cartilage Lesion of the Femoral Condyle
Interventions: Drug: ChondroCelect; Procedure: Characterized Chondrocyte Implantation

10 Recruiting
Comparison of Autologous Chondrocyte Implantation Versus Mosaicoplasty: a Randomized Trial
Condition: Knee Chondral or Osteochondral Defect
Interventions: Procedure: Autologous chondrocytes transplantation; Procedure: Mosaicoplasty

11 Completed
Effect of Celecoxib Versus Placebo Before and After Knee Surgery on Overall Use of Analgesics After Surgery
Condition: Arthroscopy
Interventions: Other: Placebo; Drug: Celecoxib

12 Recruiting
Trial Comparing BST-CarGel and Microfracture in Repair of Articular Cartilage Lesions in the Knee
Condition: Knee Injuries
Interventions: Device: BST-CarGel; Device: BST-CarGel

13 Terminated
PROCRIT and Short-Term Outcomes in Orthopedic Surgery
Conditions: Surgery, Arthroscopy; Anemia
Intervention: Drug: epoetin alfa

14 Completed
Medical and Economical Evaluation of Computer-Assisted Reconstruction of the Anterior Cruciate Ligament (ACL)
Conditions: Knee Injuries; Anterior Cruciate Ligament; Arthroscopy
Intervention:

15 Recruiting

Meniscal Repair: A Randomized Prospective Trial of FAST-FIX vs. Meniscal Suturing
Condition: Torn Reparable Meniscus
Intervention: Procedure: Meniscal repair

16 Completed
Surgery Versus no Surgery for OA of the Knee
Condition: Osteoarthritis
Interventions: Procedure: Arthroscopic Surgery of the Knee; Procedure: the best available non-surgical treatment alone

17 Recruiting
In Vivo Arthroscopic Behavior of the Infrapatellar Plica of the Knee
Condition: Patellofemoral Pain Syndrome
Intervention: Procedure: observation of the behavior of the infrapatellar plica

18 Suspended
Efficacy Study of Continuous Intraarticular Infusion in Patients Undergoing Arthroscopic Knee and Shoulder Operations
Conditions: ACL Repair; Meniscectomy; Bankart Repair
Intervention: Drug: Bupivacaine

19 Not yet recruiting
Comparing Knee Cartilage Surgery Versus Standard Physical Therapy in Treating People With a Meniscal Tear and Osteoarthritis
Condition: Osteoarthritis
Interventions: Procedure: Arthroscopic partial menisectomy; Other: Standard physical therapy; Other: Postoperative rehabilitative physical therapy

20 Recruiting
Efficacy and Safety of OMS103HP in Patients Undergoing Allograft Anterior Cruciate Ligament (ACL) Reconstruction
Condition: Knee Injuries
Interventions: Drug: OMS103HP; Drug: Vehicle

21 Recruiting
Efficacy and Safety of OMS103HP in Patients Undergoing Autograft Anterior Cruciate Ligament (ACL) Reconstruction
Condition: Knee Injuries
Interventions: Drug: OMS103HP; Drug: Vehicle

22 Recruiting
Safety of OMS103HP in Patients Undergoing Anterior Cruciate Ligament (ACL) Reconstruction
Condition: Knee Injuries
Interventions: Drug: OMS103HP; Drug: Vehicle

23 Recruiting
Intraarticular Opioids Vs Glucocorticosteroids in Gonarthritis
Condition: Rheumatic Disease

Interventions: Drug: intraarticular morphine; Drug: intraarticular dexamethasone

24 Recruiting
Treatment of Chondral Lesions Concomitant With Partial Meniscectomy
Conditions: Partial Meniscectomy; Chondral Lesions
Interventions: Device: Mechanical Shaver; Device: Paragon T2

25 Completed
Effect of Rofecoxib and a Narcotic Analgesic to Treat Pain Following Arthroscopic Surgery.
Condition: Pain, Postoperative Arthroscopy.
Interventions: Drug: MK0966 / Duration of Treatment: 1 Days; Drug: Comparator: acetaminophen (+) hydrocodone bitartrate / Duration of Treatment: 1 Days; Drug: Comparator: placebo (unspecified) / Duration of Treatment: 1 Days

26 Not yet recruiting
Clinical Use of Andante SmartStep System in Gait Rehabilitation
Conditions: Ankle Injuries; Femoral Neck Fractures
Intervention: Device: SmartStep(tm) biofeedback device

IX. Search Strategies and Tables

Search Table 1. RCT Debridement Update Search

Category	Description
Clinical question or focus	Debridement osteoarthritis knee
Source	PubMed
Terms	debridement osteoarthritis knee
MeSH	Yes for intervention, condition
Limits	RCTs
Details	(("osteoarthritis, knee"[MeSH Terms] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "knee osteoarthritis"[All Fields] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "osteoarthritis knee"[All Fields]) AND ("debridement"[MeSH Terms] OR "debridement"[All Fields])) AND Randomized Controlled Trial[ptyp]
Date of Search	6/15/08
Total Yield	9
Number of studies critically appraised	1
Number of studies included in review Efficacy:1 Safety:0	Adverse events not measured. Complications mentioned in some studies

Ref #	Reference: RCT Debridement Update	AHRQ Publication Notes	Delfini Notes: R=retrieve; E=exclude
1.	Bradley JD, Heilman DK, Katz BP, Gsell P, Wallick JE, Brandt KD. Tidal irrigation as treatment for knee osteoarthritis: a sham-controlled, randomized, double-blinded evaluation. Arthritis Rheum. 2002 Jan;46(1):100-8.	E: narrative review excluded by AHRQ publication	R: efficacy and safety Excluded after review: not arthroscopic irrigation
2.	Forster MC, Straw R. A prospective randomised trial comparing intra-articular Hyalgan injection and arthroscopic washout for knee osteoarthritis. Knee. 2003 Sep;10(3):291-3. PMID: 12893153	Rated poor quality by AHRQ	R: safety Excluded after review: no measurement adverse events
3.	Hempfling H. Intra-articular hyaluronic acid after knee arthroscopy: a two-year study.	E: non-relevant study question	R: safety Retrieved. " No side effects or adverse

Ref #	Reference: RCT Debridement Update	AHRQ Publication Notes	Delfini Notes: R=retrieve; E=exclude
	Knee Surg Sports Traumatol Arthrosc. 2007 May;15(5):537-46. Epub 2006 Dec 23. PMID: 17187274		events were observed for either treatment procedure."
4.	Hubbard MJ. Articular debridement versus washout for degeneration of the medial femoral condyle. A five-year study. J Bone Joint Surg Br. 1996 Mar;78(2):217-9. PMID: 8666628	E: excluded by AHRQ, non-relevant study question	R: safety Retrieved. Excluded after review: no measurement adverse events
5.	Knutsen G, Engebretsen L, Ludvigsen TC, Drogset JO, Grøntvedt T, Solheim E, Strand T, Roberts S, Isaksen V, Johansen O. Autologous chondrocyte implantation compared with microfracture in the knee. A randomized trial. J Bone Joint Surg Am. 2004 Mar;86-A(3):455-64. PMID: 14996869		E: non-relevant study question
6.	Merchan EC, Galindo E. Arthroscope-guided surgery versus nonoperative treatment for limited degenerative osteoarthritis of the femorotibial joint in patients over 50 years of age: a prospective comparative study. Arthroscopy. 1993;9(6):663-7. PMID: 8305102	Included in AHRQ efficacy review, rated as poor quality	R: safety Retrieved. Excluded after review: no measurement adverse events
7.	Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11;347(2):81-8. Summary for patients in: J Fam Pract. 2002 Oct;51(10):813. PMID: 12110735	Not included in AHRQ publication	E : Review of RCT
8.	Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for	I= Included by AHRQ	Retrieved; see full critique

Ref #	Reference: RCT Debridement Update	AHRQ Publication Notes	Delfini Notes: R=retrieve; E=exclude
	osteoarthritis of the knee. N Engl J Med. 2002 Jul 11;347(2):81-8. PMID: 12110735		
9.	Uluçay C, Altintaş F, Ugutmen E, Beksaç B. [The use of arthroscopic debridement and viscosupplementation in knee osteoarthritis] Acta Orthop Traumatol Turc. 2007 Nov-Dec;41(5):337-42. Turkish. PMID: 18180567	E=non-relevant question	E: non-English

Search Table 2. RCT Lavage Update Search

Category	Description
Clinical question or focus	Lavage osteoarthritis knee
Source	PubMed
Terms	Lavage osteoarthritis knee
MeSH	Yes for intervention, condition
Limits	RCTs
Details	((("irrigation"[TIAB] NOT Medline[SB]) OR "irrigation"[MeSH Terms] OR lavage[Text Word]) AND ("osteoarthritis, knee"[MeSH Terms] OR knee osteoarthritis[Text Word])) AND Randomized Controlled Trial[ptyp]
Date of Search	5/6/08
Total Yield	12
Number of studies critically appraised	1 (duplicate — in lavage search)
Number of studies included in review Efficacy: 1 (duplicate — in lavage search) Safety: 0	Adverse events not measured. Complications mentioned in one trial (duplicate study not counted).

Ref #	Reference: RCT Lavage Update	AHRQ Notes	Delfini Notes: R=retrieve; E=exclude
1.	Ayral X, Gicquere C, Duhalde A, Boucheny D, Dougados M. Effects of video information on preoperative anxiety level and tolerability of joint lavage in knee osteoarthritis. Arthritis Rheum. 2002 Aug;47(4):380-2. PMID: 12209483	E: outcome not focus of project	E: outcome not focus of project
2.	Bradley JD, Heilman DK, Katz BP, Gsell P, Wallick JE, Brandt KD. Tidal	E: narrative review excluded by AHRQ	R: efficacy and safety

Ref #	Reference: RCT Lavage Update	AHRQ Notes	Delfini Notes: R=retrieve; E=exclude
	irrigation as treatment for knee osteoarthritis: a sham-controlled, randomized, double-blinded evaluation. Arthritis Rheum. 2002 Jan;46(1):100-8. PMID: 11817581		Excluded after review: not arthroscopic irrigation
3.	Dawes PT, Kirlew C, Haslock I. Saline washout for knee osteoarthritis: results of a controlled study. Clin Rheumatol. 1987 Mar;6(1):61-3. PMID: 3581699	E: excluded by AHRQ	R: efficacy and safety Excluded—not arthroscopic irrigation
4.	Frías G, Caracuel MA, Escudero A, Rumbao J, Pérez-Gujo V, del Carmen Castro M, Font P, González J, Collantes E. Assessment of the efficacy of joint lavage versus joint lavage plus corticoids in patients with osteoarthritis of the knee. Curr Med Res Opin. 2004 Jun;20(6):861-7. PMID: 15200744	E: excluded by AHRQ, non-relevant study question	R: safety Retrieved. Excluded. Rejected after full text review—not arthroscopic lavage
5.	Hempfling H. Intra-articular hyaluronic acid after knee arthroscopy: a two-year study. Knee Surg Sports Traumatol Arthrosc. 2007 May;15(5):537-46. Epub 2006 Dec 23. PMID: 17187274	E: non-relevant study question	Duplicate study. Retrieved. "No side effects or adverse events were observed for either treatment procedure."
6.	Kalunian KC, Moreland LW, Klashman DJ, Brion PH, Concoff AL, Myers S, Singh R, Ike RW, Seeger LL, Rich E, Skovron ML. Visually-guided irrigation in patients with early knee osteoarthritis: a multicenter randomized, controlled trial. Osteoarthritis Cartilage. 2000 Nov;8(6):412-8. PMID: 11069725	E=Excluded by AHRQ, non-relevant question	R: safety Retrieved. No adverse events reported;
7.	Maillefert JF, Hudry C, Baron G, Kieffert P, Bourgeois P, Lechevalier D, Coutaux A, Dougados M. Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis: a prospective randomized controlled study. Osteoarthritis Cartilage. 2001 Nov;9(8):738-45. PMID: 11795993	E=non-relevant question	E : non-relevant
8.	Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic	I= Included by AHRQ	Retrieved; full critique Included in efficacy conclusions

Ref #	Reference: RCT Lavage Update	AHRQ Notes	Delfini Notes: R=retrieve; E=exclude
	surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11;347(2):81-8. PMID: 12110735		
9.	Pham T, Maillefert JF, Hudry C, Kieffert P, Bourgeois P, Lechevalier D, Dougados M. Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis. A two-year prospective randomized controlled study. Osteoarthritis Cartilage. 2004 Jan;12(1):46-55. PMID: 14697682	E=non-relevant question	E : non-relevant
10.	Ravaud P, Moulinier L, Giraudeau B, Ayral X, Guerin C, Noel E, Thomas P, Fautrel B, Mazieres B, Dougados M. Effects of joint lavage and steroid injection in patients with osteoarthritis of the knee: results of a multicenter, randomized, controlled trial. Arthritis Rheum. 1999 Mar;42(3):475-82. PMID: 10088770	E=excluded by AHRQ, non-relevant question	R:safety; retrieved full text. "No severe adverse reactions were observed in any of the treatment groups."
11.	Smith MD, Wetherall M, Darby T, Esterman A, Slavotinek J, Roberts-Thomson P, Coleman M, Ahern MJ. A randomized placebo-controlled trial of arthroscopic lavage versus lavage plus intra-articular corticosteroids in the management of symptomatic osteoarthritis of the knee. Rheumatology (Oxford). 2003 Dec;42(12):1477-85. Epub 2003 Jul 16. PMID: 12867587	E=excluded by AHRQ, procedures other than lavage or debridement	R for safety; retrieved full text. Safety data not measured. "Three subjects required further sutures of arthroscopy portals because of leakage of synovial fluid."
12.	Wu CW, Morrell MR, Heinze E, Concoff AL, Wollaston SJ, Arnold EL, Singh R, Charles C, Skovrun ML, FitzGerald JD, Moreland LW, Kalunian KC. Validation of American College of Rheumatology classification criteria for knee osteoarthritis using arthroscopically defined cartilage damage scores. Semin Arthritis Rheum. 2005 Dec;35(3):197-201. PMID: 16325660	E=not RCT	E: non-relevant

Search Table 3. Secondary Studies Lavage

Category	Description
Clinical question or focus	Lavage osteoarthritis knee
Source	PubMed
Terms	Lavage osteoarthritis knee
MeSH	Yes for intervention, condition
Limits	Systematic Reviews
Details	((("irrigation"[TIAB] NOT Medline[SB]) OR "irrigation"[MeSH Terms] OR lavage[Text Word]) AND ("knee osteoarthritis"[Text Word] OR "osteoarthritis, knee"[MeSH Terms] OR osteoarthritis knee[Text Word])) AND systematic[sb]
Date of Search	5/6/08
Total Yield	10
Number of studies/sources critically appraised	3
Number of studies included in review	3 (2 systematic reviews included in efficacy review, 1 guideline included in review)

Disposition: Secondary Studies Lavage

Source	Author Yr PMID: Secondary Studies Lavage	Source Search Date	Search & Exclusions Acceptable ?	Audit of Quality of Included Studies	Disposition/ Reason
PubMed	Laupattarakasem PMID: 18254069	MEDLINE (1966 to August, 2006); CINAHL (1982 to 2006); EMBASE (1988 to 2006) and Web of Science (1900 to 2006)	Yes	1 grade B-U study	▪ Include in systematic review ▪ Use only Moseley 2002 for efficacy conclusions (as did Cochrane) ▪ Other studies were judged as low quality and not reviewed
PubMed	Samson PMID: 18088162	MEDLINE through March 2007	Yes	▪ 1 grade B-U study	▪ Include in systematic review ▪ Use only Moseley 2002 for efficacy conclusions (as did Cochrane)

Source	Author Yr PMID: Secondary Studies Lavage	Source Search Date	Search & Exclusions Acceptable ?	Audit of Quality of Included Studies	Disposition/ Reason
					▪ Grade U studies were used for safety
PubMed	Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, Dougados M, Hochberg M, Hunter DJ, Kwoh K, Lohmander LS, Tugwell P. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008 Feb;16(2):137-62. PMID: 18279766	1945 to October 2005	No	▪ Failed audit	R: Guideline summary ▪ Critically appraised secondary source but not used for conclusions

Total Search Yield: Secondary Sources Lavage

Ref #	Reference: Secondary Studies Lavage	Delfini Notes: E: Exclude R: Retrieve
1.	Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Intraarticular corticosteroid for treatment of osteoarthritis of the knee. Cochrane Database Syst Rev. 2005 Apr 18;(2):CD005328. Review. Update in: Cochrane Database Syst Rev. 2006;(2):CD005328. PMID: 15846755	E: superseded by Bellamy PMID: 16625636
2.	Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Intraarticular corticosteroid for treatment of osteoarthritis of the knee. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD005328. Review. PMID: 16625636	R: Safety — E: not relevant
3.	Boutron I, Tubach F, Giraudeau B, Ravaud P. Methodological differences in clinical trials evaluating nonpharmacological and pharmacological treatments of hip and knee osteoarthritis. JAMA. 2003 Aug 27;290(8):1062-70. PMID: 12941679	E: not relevant
4.	Gentelle-Bonnassies S, Le Claire P, Mezieres M, Ayral X, Dougados M. Comparison of the responsiveness of symptomatic outcome measures in knee osteoarthritis. Arthritis Care Res. 2000 Oct;13(5):280-5. PMID: 14635296	E: not relevant
5.	Laupattarakasem W, Laopaiboon M, Laupattarakasem P,	R: efficacy & safety

Ref #	Reference: Secondary Studies Lavage	Delfini Notes: E: Exclude R: Retrieve
	Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23;(1):CD005118. Review. PMID: 18254069	Include for efficacy
6.	Samson DJ, Grant MD, Ratko TA, Bonnell CJ, Ziegler KM, Aronson N. Treatment of primary and secondary osteoarthritis of the knee. Evid Rep Technol Assess (Full Rep). 2007 Sep;(157):1-157. Review. PMID: 18088162	R: efficacy & safety NOTE: AHRQ 2007 Review Include for efficacy and safety
7.	Siparsky P, Ryzewicz M, Peterson B, Bartz R. Arthroscopic treatment of osteoarthritis of the knee: are there any evidence-based indications? Clin Orthop Relat Res. 2007 Feb;455:107-12. Review. PMID: 17279040	E: not relevant
8.	Vad VB, Bhat AL, Sculco TP, Wickiewicz TL. Management of knee osteoarthritis: knee lavage combined with hylan versus hylan alone. Arch Phys Med Rehabil. 2003 May;84(5):634-7. PMID: 12736873	R: safety R: efficacy only if lavage demonstrated efficacy in other studies — E: not relevant
9.	Waddell DD. Viscosupplementation with hyaluronans for osteoarthritis of the knee: clinical efficacy and economic implications. Drugs Aging. 2007;24(8):629-42. Review. PMID: 17702533	E: not relevant
10.	Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, Dougados M, Hochberg M, Hunter DJ, Kwoh K, Lohmander LS, Tugwell P. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008 Feb;16(2):137-62. PMID: 18279766	R: Guideline summary Critically appraised secondary source but not used for conclusions

Search Table 4. Secondary Studies Debridement

Category	Description
Clinical question or focus	Debridement osteoarthritis knee
Source	PubMed
Terms	Debridement osteoarthritis knee
MeSH	Yes for intervention, condition
Limits	Systematic Review
Details	(("debridement"[MeSH Terms] OR debridement[Text Word]) AND ("osteoarthritis, knee"[MeSH Terms] OR knee osteoarthritis[Text Word])) AND systematic[sb]
Date of Search	5/8/08
Total Yield	8
Number of studies critically	All duplicated in Table 3. Secondary Studies Lavage

Category	Description
appraised	
Number of studies included in review	All duplicated in Table 3. Secondary Studies Lavage

Disposition: Secondary Studies Debridement

Source	Author Yr PMID: Secondary Studies Debridement	Source Search Date	Search & Exclusions Acceptable ?	Audit of Quality of Included Studies	Disposition/ Reason
	All duplicates - see Table 3. Secondary Studies Lavage				

Total Search Yield: Secondary Sources Debridement

Ref #	Reference: Secondary Studies Debridement	Notes
1.	Glass GG. Osteoarthritis. Dis Mon. 2006 Sep;52(9):343-62. Review. No abstract available. PMID: 17142123	E
2.	Hochberg MC, Altman RD, Brandt KD, Clark BM, Dieppe PA, Griffin MR, Moskowitz RW, Schnitzer TJ. Guidelines for the medical management of osteoarthritis. Part II. Osteoarthritis of the knee.American College of Rheumatology. Arthritis Rheum. 1995 Nov;38(11):1541-6. PMID: 7488273	E
3.	Lane NE, Thompson JM. Management of osteoarthritis in the primary-care setting: an evidence-based approach to treatment. Am J Med. 1997 Dec 29;103(6A):25S-30S. Review. PMID: 9455966	E
4.	Laupattarakasem W, Laopaiboon M, Laupattarakasem P, Sumananont C. Arthroscopic debridement for knee osteoarthritis. Cochrane Database Syst Rev. 2008 Jan 23;(1):CD005118. Review. PMID: 18254069	Duplicate see Table 3
5.	Ohnsorge JA, Maus U, Weisskopf M, Laskin RS. Arthroscopy and knee osteoarthritis: only a placebo effect?] Z Orthop Ihre Grenzgeb. 2006 May-Jun;144(3):241-3. German. No abstract available. PMID: 16821165	E
6.	Samson DJ, Grant MD, Ratko TA, Bonnell CJ, Ziegler KM, Aronson N. Treatment of primary and secondary osteoarthritis of the knee. Evid Rep Technol Assess (Full Rep). 2007 Sep;(157):1-157. Review. PMID: 18088162	Duplicate see Table 3
7.	Siparsky P, Ryzewicz M, Peterson B, Bartz R. Arthroscopic treatment of osteoarthritis of the knee: are there any evidence-based indications? Clin Orthop Relat Res. 2007 Feb;455:107-12. Review. PMID: 17279040	E

Ref #	Reference: Secondary Studies Debridement	Notes
8.	Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, Dougados M, Hochberg M, Hunter DJ, Kwoh K, Lohmander LS, Tugwell P. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008 Feb;16(2):137-62. PMID: 18279766	Duplicate see Table 3

Search Table 5a. Adverse Effects Update Knee Lavage / Debridement Search I

Category	Description
Clinical question or focus	Lavage osteoarthritis knee
Source	PubMed
Terms	osteoarthritis knee arthroscopy AND (adverse OR complication*)
MeSH	Yes, see below
Limits	(("2007/03/29"[PDAT] : "2007/06/01"[PDAT]) AND English[lang])
Details	(("osteoarthritis, knee"[MeSH Terms] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "knee osteoarthritis"[All Fields] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "osteoarthritis knee"[All Fields]) AND ("arthroscopy"[MeSH Terms] OR "arthroscopy"[All Fields])) AND (adverse[All Fields] OR (complication[All Fields] OR complication/associations[All Fields] OR complication/death[All Fields] OR complication/diagnosis[All Fields] OR complication/extension[All Fields] OR complication/flap[All Fields] OR complication/lethality[All Fields] OR complication/morbidity[All Fields] OR complication/mortality[All Fields] OR complication/problem[All Fields] OR complication/renal[All Fields] OR complication/reoperation[All Fields] OR complication/revision[All Fields] OR complication/sequelae[All Fields] OR complication/side[All Fields] OR complication'[All Fields] OR complication"[All Fields] OR complication's[All Fields] OR complicationed[All Fields] OR complicationes[All Fields] OR complicationfree[All Fields] OR complicationis[All Fields] OR complicationless[All Fields] OR complicationn[All Fields] OR complicationof[All Fields] OR complications[All Fields] OR complications/100[All Fields] OR complications/1000[All Fields] OR complications/11[All Fields] OR complications/4[All Fields] OR

Category	Description
	complications/471[All Fields] OR complications/51[All Fields] OR complications/73[All Fields] OR complications/adverse[All Fields] OR complications/caused[All Fields] OR complications/chronic[All Fields] OR complications/clotting[All Fields] OR complications/comorbidities[All Fields] OR complications/complaints[All Fields] OR complications/death[All Fields] OR complications/delivery[All Fields] OR complications/dhf[All Fields] OR complications/disabilities[All Fields] OR complications/diseases[All Fields] OR complications/errors[All Fields] OR complications/failures[All Fields] OR complications/graft[All Fields] OR complications/incidence[All Fields] OR complications/infections[All Fields] OR complications/interventions[All Fields] OR complications/malfunction[All Fields] OR complications/malpositions[All Fields] OR complications/mediastinitis[All Fields] OR complications/mortality[All Fields] OR complications/number[All Fields] OR complications/outcomes[All Fields] OR complications/patient[All Fields] OR complications/patient/yr[All Fields] OR complications/person[All Fields] OR complications/pneumonia[All Fields] OR complications/problems[All Fields] OR complications/psychology[All Fields] OR complications/reoperations[All Fields] OR complications/repairs[All Fields] OR complications/respiratory[All Fields] OR complications/sepsis[All Fields] OR complications/sequelae[All Fields] OR complications/side[All Fields] OR complications/subsequent[All Fields] OR complications/switching[All Fields] OR complications/symptoms[All Fields] OR complications/toxicity[All Fields] OR complications/underlying[All Fields] OR complications/unfavorable[All Fields] OR complications'[All Fields] OR complications"[All Fields] OR complications2[All Fields] OR complications4[All Fields] OR complicationsin[All Fields] OR complicationsp6n[All Fields] OR complications such[All

Category	Description
	Fields])) AND (("2007/03/29"[EDAT] : "2008/06/01"[EDAT]) AND English[lang])
Date of Search	6/1/08
Total Yield	9
Number of studies judged relevant	0 after abstract review
Number of studies included in review	0

Studies: Yield and Disposition

Ref #	Reference: Adverse Effects Update Knee Lavage / Debridement I	Delfini Notes	Not Retrieve Duplicate Exclusion Other (specify)	Retrieve Efficacy	Retrieve Safety	Retrieve Other (specify)
1.	Budsberg SC, Bergh MS, Reynolds LR, Streppa HK. Evaluation of pentosan polysulfate sodium in the postoperative recovery fromcranial cruciate injury in dogs: a randomized, placebo-controlled clinical trial.Vet Surg. 2007 Apr;36(3):234-44.PMID: 17461948		E: not relevant			
2.	Christiansen SE, Jacobsen BW, Lund B, Lind M. Reconstruction of the medial patellofemoral ligament with gracilis tendonautograft in transverse patellar drill holes.Arthroscopy. 2008 Jan;24(1):82-7. Epub 2007 Nov 5.PMID: 18182207		E: not relevant			
3.	Cohen M, Amaro JT, Ejnisman B, Carvalho RT, Nakano KK, Peccin MS, Teixeira R, Laurino CF, Abdalla RJ. Anterior cruciate ligament reconstruction after 10 to 15 years: associationbetween meniscectomy and				R; review of full text: no mention of adverse events	

Ref #	Reference: Adverse Effects Update Knee Lavage / Debridement I	Delfini Notes	Not Retrieve Duplicate Exclusion Other (specify)	Retrieve Efficacy	Retrieve Safety	Retrieve Other (specify)
	osteoarthrosis.Arthroscopy. 2007 Jun;23(6):629-34.PMID: 17560477					
4.	Emerson RH Jr, Higgins LL. Unicompartmental knee arthroplasty with the oxford prosthesis in patients withmedial compartment arthritis.J Bone Joint Surg Am. 2008 Jan;90(1):118-22.PMID: 18171965		E: not relevant			
5.	Ilahi OA, Stein JD, Ho DM, Bocell JR, Lindsey RW. Arthroscopic findings in knees undergoing proximal tibial osteotomy.J Knee Surg. 2008 Jan;21(1):63-7.PMID: 18300675				R: Full text review: 1/32 experienced partial wound dehiscence (mentioned, but not relevant as completely different procedure)	
6.	Kubota C, Kobayashi S, Miyazaki T, Kokubo Y, Yayama T, Uchida K, Sato R,Bangirana A, Baba H. Exceedingly large femoral condyle intraosseous ganglion cyst following hightibial osteotomy.J Orthop Sci. 2007 Nov;12(6):592-6. Epub 2007 Nov 30. No abstract available.PMID: 18040643		E: not relevant			
7.	Samson DJ, Grant MD, Ratko TA, Bonnell CJ, Ziegler KM, Aronson N. Treatment of primary and secondary osteoarthritis of		D			

Ref #	Reference: Adverse Effects Update Knee Lavage / Debridement I	Delfini Notes	Not Retrieve Duplicate Exclusion Other (specify)	Retrieve Efficacy	Retrieve Safety	Retrieve Other (specify)
	the knee.Evid Rep Technol Assess (Full Rep). 2007 Sep;(157):1-157. Review.PMID: 18088162					
8.	Sladden MJ, Mortimer NJ, Elston G, Newey M, Harman KE. Staphylococcal scalded skin syndrome as a complication of septic arthritis.Clin Exp Dermatol. 2007 Nov;32(6):754-5. Epub 2007 Aug 22. No abstract available.PMID: 17714529		E: not relevant			
9.	Zietz PM, Selesnick H. The use of hylan G-F 20 after knee arthroscopy in an active patient populationwith knee osteoarthritis.Arthroscopy. 2008 Apr;24(4):416-22.PMID: 18375273				R for safety: full text review no information regarding safety of arthroscopy	

Search Table 5b. Adverse Effects Update Knee Lavage / Debridement Search II

Category	Description
Clinical question or focus	Lavage osteoarthritis knee
Source	PubMed
Terms	Lavage osteoarthritis knee
MeSH	Yes for intervention, condition
Limits	RCTs
Details	((("irrigation"[TIAB] NOT Medline[SB]) OR "irrigation"[MeSH Terms] OR lavage[Text Word]) AND ("osteoarthritis, knee"[MeSH Terms] OR knee osteoarthritis[Text Word])) AND Randomized Controlled Trial[ptyp]
Date of Search	5/6/08
Total Yield	12
Number of studies judged relevant	0
Number of studies included in	0

Category	Description
review	

Ref #	Reference: Adverse Effects Update Knee Lavage / Debridement II	AHRQ Notes	Delfini Notes: R=retrieve; E=exclude
1.	Ayral X, Gicquere C, Duhalde A, Boucheny D, Dougados M. Effects of video information on preoperative anxiety level and tolerability of joint lavage in knee osteoarthritis. Arthritis Rheum. 2002 Aug;47(4):380-2. PMID: 12209483	E: outcome not focus of project	E: outcome not focus of project
2.	Bradley JD, Heilman DK, Katz BP, Gsell P, Wallick JE, Brandt KD. Tidal irrigation as treatment for knee osteoarthritis: a sham-controlled, randomized, double-blinded evaluation. Arthritis Rheum. 2002 Jan;46(1):100-8. PMID: 11817581	E: narrative review excluded by AHRQ	R: efficacy and safety Excluded after review Not arthroscopic irrigation
3.	Dawes PT, Kirlew C, Haslock I. Saline washout for knee osteoarthritis: results of a controlled study. Clin Rheumatol. 1987 Mar;6(1):61-3. PMID: 3581699	E: excluded by AHRQ	R: efficacy and safety Excluded—not arthroscopic irrigation
4.	Frías G, Caracuel MA, Escudero A, Rumbao J, Pérez-Gujo V, del Carmen Castro M, Font P, González J, Collantes E. Assessment of the efficacy of joint lavage versus joint lavage plus corticoids in patients with osteoarthritis of the knee. Curr Med Res Opin. 2004 Jun;20(6):861-7. PMID: 15200744	E: excluded by AHRQ, non-relevant study question	R for safety; Retrieved. Excluded. Needle lavage, no safety data reported.
5.	Hempfling H. Intra-articular hyaluronic acid after knee arthroscopy: a two-year study. Knee Surg Sports Traumatol Arthrosc. 2007 May;15(5):537-46. Epub 2006 Dec 23. PMID: 17187274	E: non-relevant study question	R=retrieve safety Retrieved. " No side effects or adverse events were observed for either treatment procedure." Exclude: adverse events not measured
6.	Kalunian KC, Moreland LW, Klashman DJ, Brion PH, Concoff AL, Myers S, Singh R, Ike RW, Seeger LL, Rich E, Skovron ML. Visually-guided irrigation	E=Excluded by AHRQ, non-relevant question	R= safety and efficacy Retrieved. No adverse events

Ref #	Reference: Adverse Effects Update Knee Lavage / Debridement II	AHRQ Notes	Delfini Notes: R=retrieve; E=exclude
	in patients with early knee osteoarthritis: a multicenter randomized, controlled trial. Osteoarthritis Cartilage. 2000 Nov;8(6):412-8. PMID: 11069725		reported;
7.	Maillefert JF, Hudry C, Baron G, Kieffert P, Bourgeois P, Lechevalier D, Coutaux A, Dougados M. Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis: a prospective randomized controlled study. Osteoarthritis Cartilage. 2001 Nov;9(8):738-45. PMID: 11795993	E=non-relevant question	E
8.	Moseley JB, O'Malley K, Petersen NJ, Menke TJ, Brody BA, Kuykendall DH, Hollingsworth JC, Ashton CM, Wray NP. A controlled trial of arthroscopic surgery for osteoarthritis of the knee. N Engl J Med. 2002 Jul 11;347(2):81-8. Summary for patients in: J Fam Pract. 2002 Oct;51(10):813. PMID: 12110735	E= Excluded by AHRQ, lacking primary data	E
9.	Pham T, Maillefert JF, Hudry C, Kieffert P, Bourgeois P, Lechevalier D, Dougados M. Laterally elevated wedged insoles in the treatment of medial knee osteoarthritis. A two-year prospective randomized controlled study. Osteoarthritis Cartilage. 2004 Jan;12(1):46-55. PMID: 14697682	E=non-relevant question	E
10.	Ravaud P, Moulinier L, Giraudeau B, Ayral X, Guerin C, Noel E, Thomas P, Fautrel B, Mazieres B, Dougados M. Effects of joint lavage and steroid injection in patients with osteoarthritis of the knee: results of a multicenter, randomized, controlled trial. Arthritis Rheum. 1999 Mar;42(3):475-82. PMID: 10088770	E=excluded by AHRQ, non-relevant question	R for safety Exclude: steroid injections
11.	Smith MD, Wetherall M, Darby T, Esterman A, Slavotinek J, Roberts-Thomson P, Coleman M, Ahern MJ. A randomized placebo-controlled trial of arthroscopic lavage versus lavage plus intra-articular corticosteroids in the management of symptomatic osteoarthritis of the knee. Rheumatology	E=excluded by AHRQ, procedures other than lavage or debridebment	R for safety E: steroids

Ref #	Reference: Adverse Effects Update Knee Lavage / Debridement II	AHRQ Notes	Delfini Notes: R=retrieve; E=exclude
	(Oxford). 2003 Dec;42(12):1477-85. Epub 2003 Jul 16. PMID: 12867587		
12.	Wu CW, Morrell MR, Heinze E, Concoff AL, Wollaston SJ, Arnold EL, Singh R, Charles C, Skovrun ML, FitzGerald JD, Moreland LW, Kalunian KC. Validation of American College of Rheumatology classification criteria for knee osteoarthritis using arthroscopically defined cartilage damage scores. Semin Arthritis Rheum. 2005 Dec;35(3):197-201. PMID: 16325660	E=not RCT	E Non-relevant

Search Table 6. Cost/Economics Debridement/Lavage PubMed

Category	Description
Clinical question or focus	Economic analysis arthroscopic debridement lavage OA knee
Source	Medline PubMed
Terms	osteoarthritis knee arthroscopic debridement AND (economic OR cost)
MeSH check	Yes for osteoarthritis, irrigation, econcomics
Limits	none
Details	(("osteoarthritis, knee"[MeSH Terms] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "knee osteoarthritis"[All Fields] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "osteoarthritis knee"[All Fields]) AND arthroscopic[All Fields] AND ("debridement"[MeSH Terms] OR "debridement"[All Fields])) AND (("economics"[MeSH Terms] OR "economics"[All Fields] OR "economic"[All Fields]) OR ("economics"[Subheading] OR "economics"[All Fields] OR "cost"[All Fields] OR "costs and cost analysis"[MeSH Terms] OR ("costs"[All Fields] AND "cost"[All Fields] AND "analysis"[All Fields]) OR "costs and cost analysis"[All Fields]))
Date of Search	6/20/08
Total Yield	5
Number of studies critically appraised	0 — All excluded after abstract review for lack of relevant economic or cost information
Number of studies included in review	0

Ref #	Reference: Cost/Economics Debridement/Lavage	Delfini Notes	Not Retrieve Duplicate Exclusion Other (specify)	Retrieve Efficacy	Retrieve Safety	Retrieve Other (specify)
1.	Day B. The indications for arthroscopic debridement for osteoarthritis of the knee. Orthop Clin North Am. 2005 Oct;36(4):413-7. Review. PMID: 16164946	Non-relevant	E			
2.	Gilbert JE. Current treatment options for the restoration of articular cartilage. Am J Knee Surg. 1998 Winter;11(1):42-6. Review. PMID: 9533054	Non-relevant	E			
3.	Krystallis CT, Kirkos JM, Papavasiliou KA, Konstantinides PA, Kyrkos MJ, Kapetanos GA. Arthroscopic debridement of the osteoarthritic knee under local anaesthesia. Acta Orthop Belg. 2004 Jun;70(3):260-7. PMID: 15287406	Non-relevant	E			
4.	Stone KR, Walgenbach AW, Freyer A, Turek TJ, Speer DP. Articular cartilage paste grafting to full-thickness articular cartilage knee joint lesions: a 2- to 12-year follow-up. Arthroscopy. 2006 Mar;22(3):291-9. Erratum in: Arthroscopy. 2006	Non-relevant	E			

Ref #	Reference: Cost/Economics Debridement/Lavage	Delfini Notes	Not Retrieve Duplicate Exclusion Other (specify)	Retrieve Efficacy	Retrieve Safety	Retrieve Other (specify)
	Apr;22(4):A16. PMID: 16517314					
5.	Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, Bierma-Zeinstra S, Brandt KD, Croft P, Doherty M, Dougados M, Hochberg M, Hunter DJ, Kwoh K, Lohmander LS, Tugwell P. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008 Feb;16(2):137-62. PMID: 18279766	Non-relevant	E			

Search Table 7. DARE Search

Category	Description
Clinical question or focus	Arthroscopic debridement /lavage OA knee
Source	DARE
Terms	Arthroscopy knee osteoarthritis
Date of Search	6/20/08
Total Yield	7
Number of studies critically appraised	0
Number of studies included in review	1: Record #2 Contains economic model

DARE Search Records
Record #1 Duplicate: not retrieved TTL: Treatment of primary and secondary osteoarthritis of the knee AUT: Samson DJ, Grant MD, Ratko TA, Bonnell CJ, Ziegler KM, Aronson N.

DARE Search Records

XSO: Rockville: Agency for Healthcare Research and Quality (AHRQ)
XSE: Evidence Report/Technology Assessment No. 157
PUB: Agency for Healthcare Research and Quality (AHRQ)
XYR: 2007
PAG: 270
XPT: Systematic review
XST: This is a publication undertaken by a member of INAHTA. For further information please contact the agency using the contact details in Correspondence Address field.
XAO: "Systematic review of outcomes of three treatments for osteoarthritis (OA) of the knee: intra-articular viscosupplementation; oral glucosamine, chondroitin or the combination; and arthroscopic lavage or debridement." (Structured abstract)
XTI: Drug therapy, Surgery
XSD: Systematic review
XRR: Viscosupplementation trials generally report positive effects on pain and function scores compared to placebo, but the evidence on clinical benefit is uncertain, due to variable trial quality, potential publication bias, and unclear clinical significance of the changes reported.

The Glucosamine/Chondroitin Arthritis Intervention Trial (GAIT), a large (n=1,583), highquality, National Institutes of Health-funded, multicenter RCT showed no significant difference compared to placebo. Glucosamine sulfate has been reported to be more effective than glucosamine hydrochloride, which was used in GAIT, but the evidence is not sufficient to draw conclusions. Clinical studies of glucosamine effect on glucose metabolism are short term, or if longer (eg, 3 years), excluded patients with metabolic disorders.

The best available evidence for arthroscopy, a single sham-controlled RCT (n=180), showed that arthroscopic lavage with or without debridement was equivalent to placebo. The main limitations of this trial are the use of a single surgeon and enrollment of patients at a single Veterans Affairs Medical Center.

No studies reported separately on patients with secondary OA of the knee. The only comparative study was an underpowered, poor-quality trial comparing viscosupplementation to arthroscopy with debridement.
XCL: Osteoarthritis of the knee is a common condition. The three interventions reviewed in this report are widely used in the treatment of OA of the knee, yet the best available evidence does not clearly demonstrate clinical benefit. Uncertainty regarding clinical benefit can be resolved only by rigorous, multicenter RCTs. In addition, given the public health impact of OA of the knee, research on new approaches to prevention and treatment should be given high priority.
CO1: United States
KWO: Osteoarthritis,-Knee/th [therapy]
XAC: 32007000601
XID: 23 November 2007
XLA: English
XUR: http://www.ahrq.gov/clinic/tp/oakneetp.htm
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32007000601

Record #2

DARE Search Records

Retrieved: included in review for economic modeling

TTL: Arthroscopic lavage and debridement for osteoarthritis of the knee
AUT: Medical Advisory Secretariat
XSO: Toronto: Medical Advisory Secretariat (MAS)
PUB: Medical Advisory Secretariat (MAS)
XYR: 2005
XPT: Report
XST: This is a publication undertaken by a member of INAHTA. For further information please contact the agency using the contact details in Correspondence Address field.
CO1: Canada
KWO: Osteoarthritis,-Knee; Arthroscopy; Irrigation; Debridement; Knee-Joint
XAC: 32006000508
XID: 10 May 2006
XLA: English
XUR: http://www.health.gov.on.ca/english/providers/program/mas/mas_mn.html
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32006000508

Record #3
Retrieved
Excluded: superceded by Samson 2007
%%%%
TTL: Therapeutic arthroscopy for the management of osteoarthritis of the knee. Systematic review
AUT: Hodgkinson B, Merlin T, Graves S, Cleland L, Hiller J E
XSO: Adelaide: Adelaide Health Technology Assessment (AHTA) on behalf of Medical Benefits Fund
PUB: Adelaide Health Technology Assessment (AHTA) on behalf of Medical Benefits Fund
XYR: 2004
XPT: Report
XST: This is a publication undertaken by a member of INAHTA. For further information please contact the agency using the contact details in Correspondence Address field.
CO1: Australia
KWO: Arthroscopy; Osteoarthritis,-Knee/su [surgery]; Outcome-Assessment-(Health-Care); Review-Literature
XAC: 32006000579
XID: 16 May 2006
XLA: English
XUR: http://www.public-health.adelaide.edu.au/consult/health_techn_assess.html
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32006000579

Record #4
Not retrieved: superceded by Samson 2007
%%%%
TTL: Arthroscopic lavage for knee osteoarthritis

DARE Search Records

AUT: Allgood P
XSO: London: Bazian Ltd (Editors), Wessex Institute for Health Research and Development, University of Southampton
XSE: STEER: Succint and Timely Evaluated Evidence Reviews 3(3)
PUB: Bazian Ltd, Wessex Institute for Health Research and Development (WIHRD)
XYR: 2003
PAG: 10
XPT: Review
XST: This is a publication undertaken by a health technology assessment organisation. For further information please contact the agency using the contact details in the Correspondence Address field.
XAO: This study aims to assess the effects of arthroscopic lavage, with or without debridement, in people with osteoarthritis of the knee.
XTI: Surgery
XSD: Review
XCL: We found one good quality randomised controlled trial that was directly relevant to the question. It found that arthroscopic debridement and lavage did not improve pain and function compared with placebo in people with knee osteoarthritis. We found limited evidence that full arthroscopic lavage improves pain compared with low volume lavage in people with mild knee osteoarthritis. We found limited evidence that arthroscopic debridement improves pain compared with arthroscopic lavage in people with osteoarthritis of the medial femoral condyle only. We found no evidence that arthroscopic lavage or debridement improves patient reported pain, function or disability compared with non-arthroscopic treatments.
CO1: United Kingdom
KWO: Osteoarthritis,-Knee; Arthroscopy; Irrigation; Debridement
XAC: 32004000058
XID: 26 January 2004
XLA: English
XUR: http://www.wihrd.soton.ac.uk/projx/signpost/welcome.htm
DBN: HTA
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=32004000058

Record #5
Excluded: non-relevant
%%%%
TTL: Evaluation of acute knee pain in primary care
AUT: Jackson J L, O'Malley P G, Kroenke K
XSO: Annals of Internal Medicine
XYR: 2003
VOL: 139(7)
PAG: 575-588
XCC: This review set out to determine the role of radiological procedures in evaluating the causes of acute knee pain. Only a single radiological technique, magnetic resonance imaging, was evaluated. The conclusions drawn by the authors were recommendations for practice, based on a limited number of studies of unclear quality. The results of this review must therefore be treated with caution.
XST: This record is a structured abstract written by CRD reviewers. The original has met a set

DARE Search Records

of quality criteria. Since September 1996 abstracts have been sent to authors for comment. Additional factual information is incorporated into the record. Noted as [A:....].
XAO: To determine the role of radiological procedures in evaluating causes of acute knee pain.
XSI: Studies evaluating the accuracy of history, physical examination and imaging tests were eligible for inclusion. The included studies evaluated the diagnostic accuracy of physical examination or magnetic resonance imaging (MRI). The decision rules used to inform when to order a plain radiography film were Pittsburgh knee rules, Weber and colleagues' rule, Ottowa knee rules, and Fagan and Davies' rule. The clinical examination techniques evaluated were the Lachman Test, Anterior Drawer Test and Pivot Test.
XNE: Inclusion criteria relating to the reference standard were not reported. The included studies used arthroscopy or arthrotomy as the reference standard.
XPA: Studies of people with acute knee pain, defined as beginning less than one week before the person seeks medical attention, were eligible for inclusion. No details of the participants in the included studies were given.
XOA: To be eligible for inclusion, the sensitivity and specificity, or sufficient data for their calculation, had to be reported.
XSD: Inclusion criteria relating to the study design were not reported. The review included both retrospective and prospective studies evaluating decision rules; no further details were given. No details of the design of studies evaluating physical examination and MRI were reported.
XSS: MEDLINE was searched from 1966 to October 2002; the search strategy is available online (accessed 21/09/2005). See Web Address at end of abstract. The bibliographies of retrieved studies were also checked.
XVC: Study quality was assessed using an adapted McMaster method. The criteria included: an explicit outcome definition; an explicit definition of findings to predict outcome; blinded assessment; reporting of intra-observer agreement, age and gender of population, details of the study site, and mathematical modelling technique used; a test of miscalculation rate; and the effects of clinical use prospectively tested. The authors did not state how the papers were assessed for quality, or how many reviewers performed the quality assessment.
XDC: The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.
XDE: Two reviewers extracted the data, with any disagreements resolved by consensus. Data were extracted to calculate the sensitivity and specificity; alternatively, the sensitivity and specificity reported in the study were used if there was insufficient information to calculate them. Receiver operating characteristic (ROC) curves were fitted for each study. The prevalence for each diagnosis was based on data from the National Ambulatory Medical Care Survey.
XNS: The review included 129 studies. Of these, 5 evaluated the accuracy of decision rules (n=3,039), 35 revaluated physical examination and 89 evaluated MRI. There were insufficient study details to determine the sample sizes for studies evaluating physical examination and MRI.
XCS: The fitted ROC curves were used to estimate the summary sensitivity and specificity. The summary test sensitivity was taken from the point on the fitted ROC curve corresponding to the median specificity. Confidence intervals for sensitivity and specificity were calculated from the fitted ROC curves, at the median specificity based on the standard deviation of the fitted line.
XDS: The authors did not investigate heterogeneity statistically, and did not provide sufficient details to determine whether clinical heterogeneity was present. The authors stated that subgroup analyses were conducted to investigate the effect of study quality.
XRR: MRI (89 studies).

DARE Search Records

The summary estimate for the sensitivity of MRI for detecting meniscal, posterior collateral ligament, anterior cruciate ligament tears, and cartilage damage ranged from 75 to 87%. The specificity for detecting these lesions ranged from 80 to 93%.

Decision rules (5 studies).

The sensitivity ranged from 95 to 100% and the specificity from 24 to 79%. The authors stated that the Ottawa knee rules were most thoroughly validated in 2 studies by the same authors, which reported a sensitivity of 100% and specificities of 49% and 54%.

Physical examination (35 studies).

The sensitivities for detecting meniscal, anterior cruciate ligament and posterior collateral ligament tears ranged from 74 to 81%. The sensitivity for detecting other cartilaginous damage was 51%. The specificity was between 92 and 96% for all lesions except medial meniscus lesions.
XCO: No.
XCL: The authors' conclusions were specific recommendations for practice.
XCM: The review question seemed clear, stating that the authors were evaluating radiological techniques. However, only one radiological technique (MRI) was evaluated. Other non-radiological techniques (decision rules and physical examination) were also included, although not discussed fully in the narrative.

Overall, the inclusion criteria were very poorly defined. A very limited search was undertaken, resulting in the potential for publication bias which the authors did not investigate. In addition, the authors did not specify whether any language restrictions were applied. There was very limited information on the methodology of the review; therefore, it was unclear whether methods to eliminate error and bias were employed. Study quality was assessed and was mentioned briefly in the narrative. However, details of the criteria used were absent, the effects of study quality were not fully explored, and the results of the subgroup analysis (which the authors reported had been undertaken) were not reported.

Insufficient details of the included studies were reported. The conclusions drawn by the authors were recommendations for practice, which were based on a limited number of inadequately described studies of unclear quality. Therefore, the results of this review may not be reliable and must be treated with caution.
XIM: Practice: The authors made several recommendations. In particular, the Ottawa decision rules should be used for deciding when to obtain a plain film to assess for knee fractures; a physical examination should be sufficient to decide whether patients with potential meniscal and ligament injuries should be referred; and the use of clinical criteria rather than plain films for evaluating osteoarthritis. The authors did not recommend the use of plain films for the diagnosis of pseudogout.

Research: The authors did not state any implications for further research.
XOP: This additional published commentary may also be of interest. Trinh K. Review: several diagnostic aids have moderate to high accuracy for detecting abnormalities in acute knee pain. Evid Based Med 2004;9:57.

DARE Search Records

KWO: Arthralgia/et [etiology]; Arthrography/st [standards]; Diagnosis,-Differential; Fractures,-Cartilage/ra [radiography]; Knee-Injuries/di [diagnosis]; Knee-Joint/ra [radiography]; Ligaments,-Articular/in [injuries]; Magnetic-Resonance-Imaging; Menisci,-Tibial/in [injuries]; Osteoarthritis/di [diagnosis]; Physical-Examination/st [standards]
XAC: 12003008663
XID: 30 September 2005
XLA: English
XPR: 14530229
XUR: http://www.annals.org/cgi/content/full/139/7/575
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=12003008663

Record #6
Excluded: non-relevant
%%%%
TTL: Viscosupplementation for the treatment of osteoarthritis of the knee
AUT: Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G
XSO: Cochrane Database of Systematic Reviews: Reviews
PUB: John Wiley & Sons, Ltd
XYR: 2006
VOL: Issue 2
XST: This is a regularly updated Cochrane review. Please see the Cochrane Library for the full version.
XAO: To assess the effects of viscosupplementation in the treatment of OA of the knee. The products were hyaluronan and hylan derivatives (Adant, Arthrum H, Artz (Artzal, Supartz), BioHy (Arthrease, Euflexxa, Nuflexxa), Durolane, Fermathron, Go-On, Hyalgan, Hylan G-F 20 (Synvisc Hylan G-F 20), Hyruan, NRD-101 (Suvenyl), Orthovisc, Ostenil, Replasyn, SLM-10, Suplasyn, Synject and Zeel compositum).

Osteoarthritis (OA) is the most prevalent chronic joint disorder worldwide and is associated with significant pain and disability.
XSS: MEDLINE (up to January (week 1) 2006 for update), EMBASE, PREMEDLINE, Current Contents up to July 2003, and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched. Specialised journals and reference lists of identified randomised controlled trials (RCTs) and pertinent review articles up to December 2005 were handsearched.
XVC: RCTs of viscosupplementation for the treatment of people with a diagnosis of OA of the knee were eligible. Single and double-blinded studies, placebo-based and comparative studies were eligible. At least one of the four OMERACT III core set outcome measures had to be reported (Bellamy 1997).
XDE: Each trial was assessed independently by two reviewers for its methodological quality using a validated tool. All data were extracted by one reviewer and verified by a second reviewer . Continuous outcome measures were analysed as weighted mean differences (WMD) with 95% confidence intervals (CI). However, where different scales were used to measure the same outcome, standardized mean differences (SMD) were used. Dichotomous outcomes were analyzed by relative risk (RR).
XRR: Seventy-six trials with a median quality score of 3 (range 1 to 5) were identified. Follow-up periods varied between day of last injection and eighteen months. Forty trials included

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comparisons of hyaluronan/hylan and placebo (saline or arthrocentesis), ten trials included comparisons of intra-articular (IA) corticosteroids, six trials included comparisons of nonsteroidal anti-inflammatory drugs (NSAIDs), three trials included comparisons of physical therapy, two trials included comparisons of exercise, two trials included comparisons of arthroscopy, two trials included comparisons of conventional treatment, and fifteen trials included comparisons of other hyaluronans/hylan. The pooled analyses of the effects of viscosupplements against 'placebo' controls generally supported the efficacy of this class of intervention. In these same analyses, differential efficacy effects were observed for different products on different variables and at different timepoints. Of note is the 5 to 13 week post injection period which showed a percent improvement from baseline of 28 to 54% for pain and 9 to 32% for function. In general, comparable efficacy was noted against NSAIDs and longer-term benefits were noted in comparisons against IA corticosteroids. In general, few adverse events were reported in the hyaluronan/hylan trials included in these analyses.
XCL: Based on the aforementioned analyses, viscosupplementation is an effective treatment for OA of the knee with beneficial effects: on pain, function and patient global assessment; and at different post injection periods but especially at the 5 to 13 week post injection period. It is of note that the magnitude of the clinical effect, as expressed by the WMD and standardised mean difference (SMD) from the RevMan 4.2 output, is different for different products, comparisons, timepoints, variables and trial designs. However, there are few randomised head-to-head comparisons of different viscosupplements and readers should be cautious, therefore, in drawing conclusions regarding the relative value of different products. The clinical effect for some products, against placebo, on some variables at some timepoints is in the moderate to large effect-size range. Readers should refer to relevant tables to review specific detail given the heterogeneity in effects acr oss the product class and some discrepancies observed between the RevMan 4.2 analyses and the original publications. Overall, the analyses performed are positive for the HA class and particularly positive for some products with respect to certain variables and timepoints, such as pain on weight bearing at 5 to 13 weeks postinjection.In general, sample-size restrictions preclude any definitive comment on the safety of the HA class of products; however, within the constraints of the trial designs employed no major safety issues were detected. In some analyses viscosupplements were comparable in efficacy to systemic forms of active intervention, with more local reactions but fewer systemic adverse events.In other analyses HA products had more prolonged effects than IA corticosteroids. Overall, the aforementioned analyses support the use of the HA class of products in the treatment of knee OA.
XAC: 10000005321
XID: 5 June 2006
XUR:
http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD005321/frame.html
DBN: DARE
RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=10000005321

Record #7
Excluded: non-relevant
%%%%
TTL: Surgical approaches for osteoarthritis
AUT: Gunther J P
XSO: Best Practice and Research in Clinical Rheumatology
XYR: 2001

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VOL: 15(4) PAG: 627-643 XST: This study has been evaluated by a health economist for CRD. This study is not an economic evaluation and has not received an abstract. It is considered to be a review article and the bibliographic details are included here for information. CO1: Germany KWO: Adolescent; Adult; Arthroplasty,-Replacement,-Hip; Arthroplasty,-Replacement,-Knee; Arthroscopy; Bone-Malalignment/su [surgery]; Female; Humans; Male; Middle-Aged; Osteoarthritis,-Hip/su [surgery]; Osteoarthritis,-Knee/su [surgery]; Osteotomy; Randomized-Controlled-Trials; Treatment-Outcome XAC: 22001001982 XID: 21 November 2001 XLA: English DBN: NHS EED RUR: http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?ID=22001001982

Search Table 8. Satisfaction Lavage Search

Category	Description
Clinical question or focus	Patient satisfaction lavage
Source	PubMed
Terms	lavage osteoarthritis knee patient satisfaction
MeSH	Yes
Limits	None
Details	("irrigation"[MeSH Terms] OR "irrigation"[All Fields] OR "lavage"[All Fields]) AND ("osteoarthritis, knee"[MeSH Terms] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "knee osteoarthritis"[All Fields] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "osteoarthritis knee"[All Fields]) AND ("patient satisfaction"[MeSH Terms] OR ("patient"[All Fields] AND "satisfaction"[All Fields]) OR "patient satisfaction"[All Fields])
Date of Search	5/8/08
Total Yield	3
Number of studies critically appraised	0
Number of studies included in review	0
Comments:	All studies are fatally flawed because of methodology: case series data with numerous biases and confounders.

Primary Studies: Yield and Disposition

Ref #	Reference: Satisfaction Lavage	Delfini Notes E: exclude R: retrieve
1.	McLaren AC, Blokker CP, Fowler PJ, Roth JN, Rock MG. Arthroscopic débridement of the knee for osteoarthrosis. Can J Surg. 1991 Dec; 34(6):595-8. PMID: 1747839	E: not satisfaction
2.	Moseley JB Jr, Wray NP, Kuykendall D, Willis K, Landon G. Arthroscopic treatment of osteoarthritis of the knee: a prospective, randomized, placebo-controlled trial. Results of a pilot study. Am J Sports Med. 1996 Jan-Feb; 24(1):28-34. PMID: 8638750	E: not relevant
3.	Vad VB, Bhat AL, Sculco TP, Wickiewicz TL. Management of knee osteoarthritis: knee lavage combined with hylan versus hylan alone. Arch Phys Med Rehabil. 2003 May; 84(5):634-7. PMID: 12736873	E: Not satisfaction

Search Table 9. Satisfaction Debridement Search

Category	Description
Clinical question or focus	Patient satisfaction debridement
Source	PubMed
Terms	Debridement osteoarthritis knee patient satisfaction
MeSH	Debridement; osteoarthritis, knee; patient satisfaction
Limits	none
Details	("debridement"[MeSH Terms] OR "debridement"[All Fields]) AND ("osteoarthritis, knee"[MeSH Terms] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "knee osteoarthritis"[All Fields] OR ("osteoarthritis"[All Fields] AND "knee"[All Fields]) OR "osteoarthritis knee"[All Fields]) AND ("patient satisfaction"[MeSH Terms] OR ("patient"[All Fields] AND "satisfaction"[All Fields]) OR "patient satisfaction"[All Fields])
Date of Search	5/8/08
Total Yield	13
Number of studies critically appraised	0
Number of studies included in review	0
Comments	All studies are fatally flawed because of methodology: case series data with numerous biases and confounders.

Ref #	Reference: Satisfaction Debridement	Delfini Notes: E: exclude R: retrieve
1.	Belickas J, Vitkus L, Fiodorovas M, Pocius G. Efficiency of arthroscopic treatment in the knee osteoarthritis] Medicina (Kaunas). 2003;39(11):1082-9. Lithuanian. PMID: 14646462	E: non-English
2.	Dervin GF, Stiell IG, Rody K, Grabowski J. Effect of arthroscopic débridement for osteoarthritis of the knee on health-related quality of life. J Bone Joint Surg Am. 2003 Jan;85-A(1):10-9. PMID: 12533566	R: retrieved Outcome measures were the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) which measures pain, stiffness and physical function, and the Short Form-36 (SF-36), which measures functional status, general well-being, and overall health assessment. Dealt with pain, function E: Did not deal with patient acceptance or satisfaction
3.	Fond J, Rodin D, Ahmad S, Nirschl RP. Arthroscopic debridement for the treatment of osteoarthritis of the knee: 2- and 5-year results. Arthroscopy. 2002 Oct;18(8):829-34. PMID: 12368778	R. retrieved Case series from chart review (36 patients). Outcome measures: The modified Hospital for Special Surgery (HSS) scoring scale was used as an objective scoring method for preoperative and postoperative symptoms. The level of patient satisfaction was also recorded. The subjective results (level of satisfaction) at 2 years were 32 good to excellent results and 4 poor results. At the 5-year follow-up, there were 25 with good to excellent results, 3 fair results, and 8 poor results. Grade U
4.	Harrison MM, Morrell J, Hopman WM. Influence of obesity on outcome after knee arthroscopy. Arthroscopy. 2004 Sep;20(7):691-5. PMID: 15346109	E: not satisfaction
5.	Harwin SF. Arthroscopic debridement for osteoarthritis of the knee: predictors of patient satisfaction. Arthroscopy. 1999 Mar;15(2):142-6.	R: retrieved Case series (194 patients). Patients provided subjective assessment regarding the outcome of their operation. The patients,

Ref #	Reference: Satisfaction Debridement	Delfini Notes: E: exclude R: retrieve
	PMID: 10210070	at the time of review, were asked: "Are you better? Are you unchanged? or Are you worse?" Results: Follow-up ranged from 2 to 15 years (mean, 7.4 years). Overall, 63.2% (129 knees) were better, 21.1% (43 knees) were unchanged, and 15.7% (32 knees) were worse after surgery. Grade U
6.	McGinley BJ, Cushner FD, Scott WN. Debridement arthroscopy. 10-year followup. Clin Orthop Relat Res. 1999 Oct;(367):190-4. PMID: 10546614	R: retrieved Case series 77 patients were contacted for follow-up 10 or more years after arthroscopy and debridement. Patient satisfaction averaged 8.6 on a 0 to 10 scale. Grade U
7.	McLaren AC, Blokker CP, Fowler PJ, Roth JN, Rock MG. Arthroscopic débridement of the knee for osteoarthrosis. Can J Surg. 1991 Dec;34(6):595-8. PMID: 1747839	R: case series Not satisfaction
8.	Moriya H, Sasho T, Sano S, Wada Y. Arthroscopic posteromedial release for osteoarthritic knees with flexion contracture. Arthroscopy. 2004 Dec;20(10):1030-9. PMID: 15592231	E: non-relevant
9.	Moseley JB Jr, Wray NP, Kuykendall D, Willis K, Landon G. Arthroscopic treatment of osteoarthritis of the knee: a prospective, randomized, placebo-controlled trial. Results of a pilot study. Am J Sports Med. 1996 Jan-Feb;24(1):28-34. PMID: 8638750	E: non-relevant
10.	Spahn G, Heinecke K, Gross G, Tepper W. Arthroscopic joint debridement for gonarthrosis: influence of degree of chondral damage and muscle weakness on results] Z Orthop Ihre Grenzgeb. 2004 Jan-Feb;142(1):60-5. German. PMID: 14968386	E: non-English
11.	Uluçay C, Altintaş F, Ugutmen E, Beksaç B. The use of arthroscopic debridement and viscosupplementation	E: non-English

Ref #	Reference: Satisfaction Debridement	Delfini Notes: E: exclude R: retrieve
	in knee osteoarthritis] Acta Orthop Traumatol Turc. 2007 Nov-Dec;41(5):337-42. Turkish. PMID: 18180567	
12.	van den Bekerom MP, Patt TW, Rutten S, Raven EE, van de Vis HM, Albers GH. Arthroscopic debridement for grade III and IV chondromalacia of the knee in patients older than 60 years. J Knee Surg. 2007 Oct;20(4):271-6. PMID: 17993066	E: non-relevant
13.	Vojtassak J, Seliga J. High tibial osteotomy and debridement of the knee joint in treatment of varotic gonarthrosis. Bratisl Lek Listy. 2001;102(10):470-2. PMID: 11802295	E: non-relevant

Public Comments and Responses

The Knee Arthroscopy for Osteoarthritis Report reviewing and updating AHRQ's 2007 Systematic report, also subject to public comment and response was posted June 30, 2008 through July 11, 2008 for public comment period.

The Health Technology Assessment Program received no public comment responses on the draft report. No comments were forwarded to the vendor for response.

Internal clarity and formatting revisions were completed.