TREATMENT OF OSTEOARTHRITIS OF THE KNEE (NON-ARTHROPLASTY)

FULL GUIDELINE

Adopted by the American Academy of Orthopaedic Surgeons

Board of Directors

December 6, 2008

This Clinical Practice Guideline was developed by an American Academy of Orthopaedic Surgeons (AAOS) multi-disciplinary volunteer workgroup that included Orthopaedic surgeons, a family physician, and two physical therapists. It is based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This Clinical Practice Guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

This guideline and the systematic review upon which it is based were funded by the AAOS, with additional funding received from the Arthroscopy Association of North America (AANA) and the American Orthopedic Society of Sports Medicine (AOSSM). All panel members gave full disclosure of conflicts of interest prior to participating in the development of this guideline. The AAOS received no financial support from industry or other commercial sponsors to develop this guideline or the underlying systematic review.

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Disclosure Requirement

In accordance with AAOS policy, all individuals whose names appear as authors or contributors to Clinical Practice Guideline filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to voting on the recommendations contained within this Clinical Practice Guidelines.

Funding Source

This Clinical Practice Guideline was funded exclusively by the American Academy of Orthopaedic Surgeons who received no funding from outside commercial sources to support the development of this statement.

FDA Clearance

Some drugs or medical devices referenced or described in this Clinical Practice Guideline may not have been cleared by the Food and Drug Administration (FDA) or may have been cleared for a specific use only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.

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Summary of Recommendations

The following is a summary of the recommendations in the AAOS' clinical practice guideline, The Treatment of Osteoarthritis (OA) of the Knee. This guideline was explicitly developed to include only treatments less invasive than knee replacement (arthroplasty). This summary does not contain rationales that explain how and why these recommendations were developed nor does it contain the evidence supporting these recommendations. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. We are confident that those who read the full guideline and evidence report will also see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility. This summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient, physician and other healthcare practitioners.

Patient Education and Lifestyle Modification

Recommendation 1
We suggest patients with symptomatic OA of the knee be encouraged to participate in self-management educational programs such as those conducted by the Arthritis Foundation, and incorporate activity modifications (e.g. walking instead of running; alternative activities) into their lifestyle.

Level of Evidence: **II**
Grade of Recommendation: **B**

Recommendation 2
Regular contact to promote self-care is an option for patients with symptomatic OA of the knee.

Level of Evidence: **IV**
Grade of Recommendation: **C**

Recommendation 3
We recommend patients with symptomatic OA of the knee, who are overweight (as defined by a BMI>25), should be encouraged to lose weight (a minimum of five percent (5%) of body weight) and maintain their weight at a lower level with an appropriate program of dietary modification and exercise.

Level of Evidence: **I**
Grade of Recommendation: **A**

(*continued on next page*)

Rehabilitation

Recommendation 4
We recommend patients with symptomatic OA of the knee be encouraged to participate in low-impact aerobic fitness exercises.

Level of Evidence: **I**
Grade of Recommendation: **A**

Recommendation 5
Range of motion/flexibility exercises are an option for patients with symptomatic OA of the knee.

Level of Evidence: **V**
Grade of Recommendation: **C**

Recommendation 6
We suggest quadriceps strengthening for patients with symptomatic OA of the knee.

Level of Evidence: **II**
Grade of Recommendation: **B**

Mechanical Interventions

Recommendation 7
We suggest patients with symptomatic OA of the knee use patellar taping for short term relief of pain and improvement in function.

Level of Evidence: **II**
Grade of Recommendation: **B**

Recommendation 8
We suggest lateral heel wedges not be prescribed for patients with symptomatic medial compartmental OA of the knee.

Level of Evidence: **II**
Grade of Recommendation: **B**

Recommendation 9
We are unable to recommend for or against the use of a brace with a valgus directing force for patients with medial uni-compartmental OA of the knee.

Level of Evidence: **II**
Grade of Recommendation: **Inconclusive**

Recommendation 10
We are unable to recommend for or against the use of a brace with a varus directing force for patients with lateral uni-compartmental OA of the knee.

Level of Evidence: **V**
Grade of Recommendation: **Inconclusive**

(*continued on next page*)

Complementary and Alternative Therapy

Recommendation 11
We are unable to recommend for or against the use of acupuncture as an adjunctive therapy for pain relief in patients with symptomatic OA of the knee.

Level of Evidence: **I**
Grade of Recommendation: **Inconclusive**

Recommendation 12
We recommend glucosamine and/or chondroitin sulfate or hydrochloride not be prescribed for patients with symptomatic OA of the knee.

Level of Evidence: **I**
Grade of Recommendation: **A**

Pain Relievers

Recommendation 13
We suggest patients with symptomatic OA of the knee receive one of the following analgesics for pain unless there are contraindications to this treatment:

- Acetaminophen [not to exceed 4 grams per day]
- Non-steroidal anti inflammatory drugs (NSAIDs)

Level of Evidence: **II**
Grade of Recommendation: **B**

Recommendation 14
We suggest patients with symptomatic OA of the knee and increased GI risk (Age >= 60 years, comorbid medical conditions, history of peptic ulcer disease, history of GI bleeding, concurrent corticosteroids and/or concomitant use of anticoagulants) receive one of the following analgesics for pain:

- Acetaminophen [not to exceed 4 grams per day]
- Topical NSAIDs
- Nonselective oral NSAIDs plus gastro-protective agent
- Cyclooxygenase-2 inhibitors

Level of Evidence: **II**
Grade of Recommendation: **B**

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Intra-Articular Injections

Recommendation 15
We suggest intra-articular corticosteroids for short-term pain relief for patients with symptomatic OA of the knee.

Level of Evidence: **II**
Grade of Recommendation: **B**

Recommendation 16
We cannot recommend for or against the use of intra-articular hyaluronic acid for patients with mild to moderate symptomatic OA of the knee.

Level of Evidence: **I and II**
Grade of Recommendation: **Inconclusive**

Needle Lavage

Recommendation 17
We suggest that needle lavage not be used for patients with symptomatic OA of the knee.

Level of Evidence: **I and II**
Grade of Recommendation: **B**

Surgical Intervention

Recommendation 18
We recommend against performing arthroscopy with debridement or lavage in patients with a primary diagnosis of symptomatic OA of the knee.

Level of Evidence: **I and II**
Grade of Recommendation: **A**

Recommendation 19
Arthroscopic partial meniscectomy or loose body removal is an option in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus and/or a loose body.

Level of Evidence: **V**
Grade of Recommendation: **C**

Recommendation 20
We cannot recommend for or against an osteotomy of the tibial tubercle for patients with isolated symptomatic patello-femoral osteoarthritis.

Level of Evidence: **V**
Grade of Recommendation: **Inconclusive**

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Recommendation 21
Realignment osteotomy is an option in active patients with symptomatic unicompartmental OA of the knee with malalignment.

Level of Evidence: **IV and V**
Grade of Recommendation: **C**

Recommendation 22
We suggest against using a free-floating interpositional device for patients with symptomatic unicompartmental OA of the knee.

Level of Evidence: **IV**
Grade of Recommendation: **B**

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Peer Review

Participation in the AAOS guideline peer review process does not constitute an endorsement of this guideline by the participating organization.

Peer review of the draft guideline is completed by an outside Peer Review Advisory Panel. Outside Advisory Panels are convened for each AAOS guideline and consist of experts in the guideline's topic area. These experts represent professional societies other than AAOS and are nominated by the guideline workgroup prior to beginning work on the guideline. For this guideline, five outside peer review organizations were invited to review the draft guideline and all supporting documentation. All five societies participated in the review of the Treatment of Osteoarthritis (non-arthroplasty) guideline draft and three consented to be listed as a peer review organization in this appendix. Two organizations did not give explicit consent that the organization name could be listed in this publication. The organizations that reviewed the document and consented to publication are listed below:

The Arthroscopy Association of North America (AANA)
The American Orthopeadic Association (AOA)
The American Physical Therapy Association (APTA)

Participation in the AAOS guideline peer review process does not constitute an endorsement of the guideline by the participating organizations listed above.

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I. INTRODUCTION

OVERVIEW

This clinical practice guideline is based on a systematic review of published studies on the treatment of osteoarthritis (OA) of the knee in adults. It covers treatment up to, but not including, knee replacement. In addition to providing practice recommendations, this guideline also highlights gaps in the literature and areas that require future research.

This guideline is intended to be used by all appropriately trained surgeons and all qualified physicians considering treatment of OA of the knee. It is also intended to serve as an information resource for decision makers and developers of practice guidelines and recommendations.

GOALS AND RATIONALE

The purpose of this clinical practice guideline is to help improve treatment based on the current best evidence. Current evidence-based practice (EBP) standards demand that physicians use the best available evidence in their clinical decision making. To assist in this, this clinical practice guideline consists of a systematic review of the available literature regarding the treatment of osteoarthritis of the knee. The systematic review detailed herein was conducted between October 2007 and February 2008 and demonstrates where there is good evidence, where evidence is lacking, and what topics future research must target in order to improve the treatment of patients with OA of the knee. AAOS staff and the OA of the Knee physician workgroup systematically reviewed the available literature and subsequently wrote the following recommendations based on a rigorous, standardized process.

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

INTENDED USERS

This guideline is intended to be used by orthopaedic surgeons and all qualified physicians managing patients with OA of the knee. Typically, orthopaedic surgeons will have completed medical training, a qualified residency in orthopaedic surgery, and some may have completed additional sub-specialty training. Insurance payers, governmental bodies, and health-policy decision-makers may also find this guideline useful as an evolving standard of evidence regarding treatment of OA of the knee.

Diagnosis of OA of the knee is commonly made on the basis of signs and symptoms. Radiographic evidence is not necessary for the diagnosis of OA,[1] but rather can be used for confirmation if necessary by excluding other diagnoses including rare conditions such as osteochondritis dissecans, tumors, and other conditions. However, treatment for OA of

the knee is based on the assumption that decisions are predicated on patient and physician mutual communication with discussion of available treatments and procedures applicable to the individual patient. Once the patient has been informed of available therapies and has discussed these options with his/her physician, an informed decision can be made. Clinician input based on experience with both conservative management and surgical skills increases the probability of identifying patients who will benefit from specific treatment options.

PATIENT POPULATION

This document addresses the treatment of OA of the knee in adults (defined as patients 19 years of age and older). The guideline provides information on patient management post-diagnosis up to, but not including, knee replacement (arthroplasty). This guideline does not address patients diagnosed with rheumatoid arthritis or other inflammatory arthropathies.

INCIDENCE

OA of the knee incidence in the United States is estimated at 240 per 100,000 person years.[2, 3]

PREVALENCE

It is difficult to estimate the prevalence of osteoarthritis disease because there are no universally applicable criteria for its diagnosis.[2] Further, there is often no correlation between symptoms and clinical signs of OA of the knee.[2] The prevalence of symptomatic OA of the knee is estimated at 5%,[4] 17%,[5] and 12.1%.[6] Estimates vary by age group, five percent referring to adults who are 26 years and older, seventeen percent for adults 45 years and older, and twelve percent for adults 60 years and older.

BURDEN OF DISEASE

Osteoarthritis (of any joint) was the primary diagnosis in 11.1 million ambulatory care visits in 2004 and "an estimated 9.3 million adults had symptomatic OA of the knee in 2005."[2]

ETIOLOGY

Osteoarthritis results from an imbalance between breakdown and repair of the tissues of the synovial joint organ that occurs as a result of multiple risk factors including trauma and genetic predisposition.

RISK FACTORS

Occurrences of OA of the knee increase with age, especially for women. According to a number of studies, anywhere from 6% to over 13% of men, but between 7% and 19% of women, over 45 years of age are afflicted,[2] resulting in a 45% less risk of incidence for men.[3]

Additional factors that increase the risk of developing OA of the knee include genetics, excess body mass, specific occupations, repetitive knee bending or heavy lifting, and strong family history.[7]

EMOTIONAL AND PHYSICAL IMPACT OF OSTEOARTHRITIS OF THE KNEE

Olivera et al. [8] report that the incidence of OA of hand, hip, and knee increases with age, and women have higher rates of OA than men especially after age 50. Felson et al.[9] report that elderly persons with self-reported OA visit their physicians more often and experience more functional limitations than others in their age group. Current demographic trends, including the aging of the baby boomer population, the rise in rates of morbid obesity, and the higher recreational activity levels of our elderly population suggest that the emotional and physical impact of OA will continue to increase in the future.[2]

POTENTIAL BENEFITS, HARMS, AND CONTRAINDICATIONS

Individuals with OA of the knee often complain of joint pain, stiffness, and functional deficits. The aim of treatment is pain relief and improvement or maintenance of the patient's functional status. Long term results were often not available and adverse events varied by study (frequently they were not reported) in the literature available for this guideline. Most treatments are associated with some known risks, especially invasive and operative treatments. In addition, contraindications vary widely based on the treatment administered. Therefore, discussion of available treatments and procedures applicable to the individual patient rely on mutual communication between the patient and physician, weighing the potential risks and benefits for that patient.

II. METHODS

This clinical practice guideline and the systematic review upon which it is based evaluates the effectiveness of treatments for OA of the knee up to, but not including, knee replacement surgery. This section describes the methods used to prepare this guideline and systematic review, including search strategies used to identify literature, criteria for selecting eligible articles, grading the evidence, data extraction, methods of statistical analysis, and the review and approval of the guideline. The methods used to perform this systematic review were employed to minimize bias in the selection and summary of the available evidence.[10, 11] These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for treating OA of the knee.

This guideline and systematic review were prepared by the AAOS Treatment of Osteoarthritis of the Knee guideline workgroup with the assistance of the AAOS Guidelines Unit (Appendix I). When information from the literature was sparse or lacking, it was supplemented by the consensus opinion of the workgroup.

To develop this guideline, the workgroup held multiple teleconferences and participated in a two-day recommendation meeting at which the final recommendations were written and voted on. The resulting draft guidelines were then peer-reviewed, subsequently sent for public commentary, and then sequentially approved by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (see Appendix II for a description of the AAOS bodies involved in the approval process)

SIMULATED RECOMMENDATIONS

The workgroup began work on this guideline by constructing a set of simulated recommendations. These recommendations specify [what] should be done in [whom], [when], [where], and [how often or how long]. They function as questions for the systematic review, not as final recommendations or conclusions. Simulated recommendations are almost always modified on the basis of the results of the systematic review. These recommendations also form the guideline's scope and guide the searches for literature. These *a priori* simulated recommendations are inviolate in that, once specified, they cannot be modified, they must all be addressed by the systematic review, and the relevant review results must be presented in the final guideline. The *a priori* and inviolate nature of the simulated recommendations combats bias.

STUDY SELECTION CRITERIA

TYPES OF STUDIES

The physician workgroup also decided to exclusively use an Agency for Healthcare Research and Quality (AHRQ) evidence report, "Treatment of Primary and Secondary Osteoarthritis of the Knee", to address certain recommendations and a previously published clinical practice guideline to address certain other questions. Accordingly, the workgroup unanimously agreed to refer to the AHRQ evidence report [12] to address recommendations 12 and 16, and to refer to the OARSI guidelines [13, 14] to address

recommendations 1, 2, 3, 4, 11, 13, and 14. We addressed the remaining recommendations by conducting our own systematic reviews of the literature.

We developed *a priori* article selection criteria for our review. We first searched for published systematic reviews that examined the clinical effectiveness of treatments for OA of the knee, up to but not including knee replacement surgery. Except for one recommendation (recommendation 18), we included only these reviews when they were available. For recommendation 18, one of the two relevant systematic reviews[15] did not compare the treatment of interest to placebo, but the original studies did. Therefore, we included these original studies in our analysis.[16, 17] As a result of our searches for published systematic reviews, we use them to address recommendations 6, 7, 8, 9, 15, and 18.

We addressed the remaining recommendations (recommendations 5, 10, 16, 18, 19, 20, 21, and 22) with our own *de novo* systematic reviews of primary, published studies. When examining primary studies we analyzed the best available evidence regardless of study design. We first considered the randomized controlled trials identified by the search strategy. In the absence of two or more RCTs, we sequentially searched for prospective controlled trials, prospective comparative studies, retrospective comparative studies, and case-series studies.

ARTICLE INCLUSION CRITERIA FOR DE NOVO SYSTEMATIC REVIEWS

We developed *a priori* inclusion criteria that articles had to meet to be included in our *de novo* systematic reviews. Specifically, to be included in our systematic reviews an article had to be a report of a study that:

- Evaluated a treatment for OA of the knee
- Enrolled a patient population of at least 80% of patients with OA of the knee.
- Reported quantified results
- Was a full article, not a meeting abstract
- Was published in the peer-reviewed literature
- Was not a cadaveric, animal or in vitro study.
- Was not a letter, case report, historical article, editorial, or commentary
- Enrolled ≥ 10 patients in each of its study arms
- Enrolled a patient population of ≥ 80% or more of patients 19 years of age or older
- Was an English language article

- Was published in or after 1980 (older studies may not reflect current medical practice in OA Knee or pharmacology)

- Was not a retrospective chart review.

- Was prospective (for all recommendations except those pertaining to needle lavage, arthroscopy, osteotomy, and free-floating interpositional devices)

We also excluded some outcomes from consideration. With two exceptions, we included only patient-oriented outcomes and did not include surrogate/intermediate outcomes. Surrogate outcome measures are laboratory measurements or another physical sign used as substitutes for a clinically meaningful end point that measures directly how a patient feels, functions, or survives.[18] For a surrogate outcome be valid, it must be in the causal pathway between the intervention and the outcome and it must demonstrate a large, consistently measurable association with the outcome.[18] At the request of the AAOS physician workgroup we included two surrogate outcomes, range of motion and quadriceps strength. However, we considered these two outcomes only if all other study inclusion criteria were met and only if the study reported these surrogate outcome measures in conjunction with a patient-oriented outcome.

We only considered an outcome if ≥80% of the patients were followed for that outcome (for example, some studies reported short-term outcomes data on nearly all enrolled patients, and reported longer-term data on only a few patients. In such cases, we did not include the longer-term data).

For outcomes measured using "paper and pencil" instruments (e.g., the visual analogue scale, the Western Ontario and McMaster Osteoarthritis Index or WOMAC) we considered only results obtained using validated instruments.

MINIMAL CLINICALLY IMPORTANT IMPROVEMENT

Wherever possible, we considered the effects of treatments in terms of the minimal clinically important improvement (MCII) in addition to whether their effects were statistically significant. The MCII is the smallest clinical change that is important to patients, and recognizes the fact that there are some treatment-induced statistically significant improvements that are too small to matter to patients. The values we used for MCIIs are derived from the published literature. We used the effect sizes reported by Angst et al. for the MCII for pain (0.39) and function (0.37) for the WOMAC instrument.[19] We calculated the effect size for the MCIIs for stiffness (0.39) and the overall value (0.40) for the WOMAC instrument from the data reported by Angst et al.[19] We also used data from the same group to calculate the effect size for the MCIIs of the Short Form-36 (SF-36) for bodily pain (0.47), physical function (0.17), and a physical component summary score (0.26).[20] We used data reported by Tubach et al. to calculate the effect size for the MCIIs of the Visual Analog Scale (VAS) for pain (1.23) and global assessment (1.0).[21] For all calculated MCIIs, we standardized the effect size for an instrument by dividing the reported minimal clinically important difference between baseline and follow-up scores by the standard deviation of the mean baseline score.

The AHRQ report [12] that we used to address some recommendations also considered the MCII. The OARSI guidelines [13, 14] considered the MCII in data that addressed AAOS recommendation 14, but did not provide a quantitative definition of the MCII in data that addressed AAOS recommendations 11 and 13, and did not consider MCII in data that addressed AAOS recommendations 1, 2, 3, and 4. Where possible, we added the MCII to the data reported in the OARSI guidelines and included it for consideration by the workgroup.

We describe the results of studies and systematic reviews using terminology based on that of Armitage et al.[22] The associated descriptive terms we use in this guideline and the conditions for using each of these terms, are outlined in the following table:

Descriptive Term	Condition for Use
Clinically Important	Statistically significant and lower confidence limit > MCII
Possibly Clinically Important	Statistically significant and confidence intervals contain the MCII
Not Clinically Important	Statistically significant and upper confidence limit < MCII
Negative	Not statistically significant and upper confidence limit < MCII
Inconclusive	Not statistically significant but confidence intervals contain the MCII

LITERATURE SEARCHES

We searched for articles published up to February 22, 2008. Search strategies were reviewed by the workgroup prior to conducting the searches. All literature searches were supplemented with manual screening of bibliographies of all publications retrieved. A list of potentially relevant studies was also provided by the workgroup members. No such articles were included inasmuch as none met our inclusion criteria. We also searched the bibliographies of recent review articles for potentially relevant citations.

SEARCH FOR EXISTING SYSTEMATIC REVIEWS

The workgroup chose to use systematic reviews (rather than primary studies) to provide evidence and support when such reviews were available. We searched the following databases for these reviews:

- The Cochrane Database of Systematic Reviews (through February 22, 2008)
- PubMed (through February 22, 2008)

The study attrition diagram in Appendix III provides details about the inclusion and exclusion of these reviews, the search strategies we used are provided in Appendix IV, and a list of included systematic reviews can be found in the evidence tables. We included seven systematic reviews that considered thirty-four unique randomized controlled trials. (See Evidence Tables 1-5 in the separate Evidence Table document that accompanies this guideline and evidence report.)

SEARCH FOR RCTS AND OTHER STUDY DESIGNS

To identify primary studies for this guideline, we searched three electronic databases; PubMed, EMBASE, and CINAHL. The study attrition diagram in Appendix III provides details about the inclusion and exclusion of these studies, the search strategies we used are provided in Appendix IV, and a list of included studies can be found in the evidence tables.

We used a previously published search strategy [23] to identify relevant randomized controlled trials. In the absence of relevant RCTs, we modified the search strategy to identify studies of other designs. We sequentially searched for studies of other designs according to their level of evidence. If higher level evidence was available, we did not search for or include lower level evidence unless there was only one higher level study.

We conducted five recommendation-specific searches for primary articles. These were searches for literature on acupuncture, needle lavage, arthroscopy, osteotomy, and free-floating interpositional devices. Thirty-seven primary studies were included and ninety-two studies were excluded.

JUDGING THE QUALITY OF EVIDENCE

The quality of evidence was rated using an evidence hierarchy and an accompanying checklist for RCTs. This evidence hierarchy is shown in Appendix V.

Typically, randomized controlled trials were initially categorized as Level I studies, but the level of evidence was reduced by one level if there was a "No" or "Not Reported by Authors" to any of the following checklist items:

- Was randomization stochastic? (i.e. at the time of assignment to groups, did all patients have an equal probability of being assigned to any given group)
- Was there concealment of the allocation to groups?
- Were the patients, caregivers, or evaluators blinded?

Downgrading of Level I studies was not cumulative. If a study had more than one of the methodological flaws listed above it would only decrease by a single level. The downgrading of the formal level of evidence of a study indicates the discrepancy between claims of the study authors and the results of the critical appraisal process.

According to the AAOS Levels of Evidence, non-randomized controlled trials and other prospective comparative studies were initially categorized as Level II studies. Retrospective comparative studies and case-control studies were initially categorized as Level III studies and case-series studies/reports were categorized as Level IV studies.

We used the AMSTAR tool with additional criteria (Appendix VI) to rate the quality of systematic reviews.[24]

DATA EXTRACTION

Data elements extracted from studies were defined in consultation with the physician workgroup. Six reviewers completed data extraction independently for all studies.

Disagreements were resolved by consensus and by consulting the workgroup. Evidence tables were constructed to summarize the best evidence pertaining to each simulated recommendation. The elements extracted are shown in Appendix VII .

GRADING THE RECOMMENDATIONS

Following data extraction and analyses, each guideline recommendation was assigned a grade that was based on the total body of evidence available using the following system:

A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V) for or against recommending intervention.

I: There is insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Final grades were based upon preliminary grades assigned by AAOS staff, who took into account only the quality of the available evidence. Workgroup members then modified the grade using the 'Form for Assigning Grade of Recommendation (Interventions)' shown in Appendix VIII

CONSENSUS DEVELOPMENT

The recommendations and their grades of recommendation were voted on using a structured voting technique known as the nominal group technique.[25] We present details of this technique in Appendix IX. Each recommendation was constructed using the following language which takes into account the final grade of recommendation.

Guideline Language	Grade of Recommendation	Level of Evidence
We ***recommend***	A	Level I
We ***suggest***	B	Level II or III
option	C	Level IV or V
We are ***unable to recommend for or against***	I	None or Conflicting

STATISTICAL METHODS

When published studies only reported the median, range, and size of the trial, we estimated their means and variances according to a published method.[26]

We performed meta-analyses using the random effects method of DerSimonian and Laird.[27] Heterogeneity was assessed with the I-squared statistic.[28] All meta-analyses and effect size calculations were performed using STATA 10.0 (StataCorp LP, College Station, Texas) and the "metan" command.

Meta-regression was used in the analysis of studies concerning acupuncture. Regression analyses were performed using the permutation method of Higgins and Thompson [28] with 10,000 iterations. We used STATA 10.0 (StataCorp LP, College Station, Texas) and the "metareg" command to perform these computations.

We used the program TechDig 2.0 (Ronald B. Jones, Mundelein, Illinois) to estimate means and variances from studies presenting data only in graphical form.

For one study concerning acupuncture,[29] we imputed the standard deviation according to a published method.[30] For two additional studies concerning acupuncture, we used the baseline standard deviations and estimated the means from the mean change from baseline scores.[31, 32]

PEER REVIEW

The draft of the guideline and evidence report were peer reviewed for content by an expert outside advisory panel that was nominated by the physician work group *a priori* to the development of the guideline. In addition, the physician members of the AAOS Guidelines and Technology Oversight Committee and the Evidence Based Practice Committee also provided peer review of the draft document. Peer review was accomplished using a structured peer review form. (Appendix X) The draft guideline was sent to a total of 31 reviewers and 10 returned reviews. The disposition of all non-editorial peer review comments was documented and accompanied this guideline through the public commentary and the following approval process.

PUBLIC COMMENTARY

After modifying the draft in response to peer review, the guideline was subjected to a twenty-one day period of "Public Commentary." Commentators consist of members of the AAOS Board of Directors (BOD), members of the Council on Research, Quality Assessment, and Technology (CORQAT), members of the Board of Councilors (BOC), and members of the Board of Specialty Societies (BOS). Based on these bodies, up to 187 commentators had the opportunity to provide input into this guideline development process. Of these, 33 requested to review the document and 4 returned public comments.

THE AAOS GUIDELINE APPROVAL PROCESS

Following peer review, the final guideline draft was approved by the AAOS Guidelines Oversight Committee, the AAOS Evidence Based Practice Committee, the AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of

Directors. Descriptions of these bodies and dates of approval are provided in Appendix II.

REVISION PLANS

This guideline represents a cross-sectional view of current treatment and will become outdated when more sophisticated tests, more objective assessments, and more rigorous differential diagnoses are possible. Linkage to other disorders, genetic diagnosis, and occupational and human factors literature will contribute to our understanding of the early stages of OA of the knee and the means of differential treatment.

Because of the aging population, changing medical reimbursement practices by all payors and the high level of interest in this topic, the guideline will be revised in accordance with changing practice, rapidly emerging treatment options, new technology, and new evidence. It is anticipated that this guideline will be revised in 2012.

III. RECOMMENDATIONS AND SUPPORTING DATA

RECOMMENDATION 1

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

AAOS Level of Evidence: **Level II**
AAOS Grade of Recommendation: **B**

Rationale:

The OARSI guidelines, on which this recommendation is based, provide evidence from a single meta-analysis in regards to providing patient education and the impact of various self-management techniques (including changes in activity, exercise, and lifestyle modification) on patients with symptomatic OA of the knee.[13, 14] We evaluated this evidence as Level II.

This evidence shows that self management results in a statistically significant improvement in pain. The clinical importance of this effect cannot be determined. Although the effect is not large, it is possible that when distributed throughout a population, many patients might benefit from self-management. Enhancing this recommendation is that self-management is low cost and has few associated harms.

OARSI also reports that it was not possible to assess which specific aspects of self-management programs were the most effective,[14] making it difficult to recommend a specific program.

Supporting Evidence

Table 1. Summary of Evidence from OARSI for Self-Management

Outcomes	Comparison	ES (95% CI)	MCII
Pain relief*	Self-management vs. control	*d* = 0.06 (0.02, 0.10)	?

d = standard mean difference
ES = effect size
MCII = minimal clinically important improvement
? = cannot be determined/unknown

* Outcome measure is not defined by OARSI guidelines.

RECOMMENDATION 2

Regular contact to promote self-care is an option for patients with symptomatic OA of the knee.
AAOS Level of Evidence: **Level IV**
AAOS Grade of Recommendation: **C**

Rationale:
The OARSI guidelines, on which this recommendation is based, provide evidence from a single RCT about the regular contact of patients with symptomatic OA of the knee.[13, 14] The evidence was evaluated as Level IV. The AAOS workgroup initially considered the RCT evidence as a higher level but downgraded the evidence to Level IV because the results that are relevant to this recommendation are from a post-hoc subgroup analysis.

The results of this subgroup analysis suggest that regular telephone contact significantly reduces the amount of pain experienced by patients.[13, 14] The evidence from OARSI suggests this contact could be from lay personnel. Self-care is not defined in the OARSI document. The clinical significance of this finding cannot be determined because the MCII for the AIMS instrument (Arthritis Impact Measurement Scale) is unknown. The fact that telephone contact is of relatively low cost and has minimal (if any) associated harms supports this recommendation.

Supporting Evidence

Table 2. Summary of Evidence from OARSI for Regular Telephone Contact

Outcomes	Comparison	ES	MCII
Pain (AIMS)	Telephone contact vs. control	$d = 0.65$ ($p<0.01$)	?

d = standard mean difference
ES = effect size
NR = Not reported
MCII = minimal clinically important improvement
? = cannot be determined/unknown

* Outcome measure is not defined by OARSI.

RECOMMENDATION 3

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

AAOS Level of Evidence: **I**
AAOS Grade of Recommendation: **A**

Rationale:

The OARSI guidelines, on which this recommendation is based, provide evidence from two RCTs and a recent systematic review regarding the role of weight loss in patients with symptomatic OA of the knee.[13, 14] This evidence was evaluated as Level I because of the relevant studies were considered high quality, well designed RCTs.

Supporting this recommendation is that weight loss results in a possibly clinically important and statistically significant effect for functional improvement measured by the WOMAC function subscale (0.69; 95% CI 0.24, 1.14; MCII = 0.37).[13, 14] The effects of weight loss on other, relevant outcomes are less clear.

The effects of weight loss on pain cannot be determined because of uncertainties in the way pain was measured in the unique, relevant primary studies considered in the OARSI guideline. Accordingly, the results of studies that used the WOMAC to measure pain relief are negative because the MCII lies above the confidence intervals and the effect is not statistically significant (0.13; 95% CI -0.12, 0.38; MCII = 0.39).[13, 14] However, other studies reported in the OARSI guideline used an indeterminate method of measuring pain (making it impossible to know the MCII) and, although the effect is statistically significant (0.20; 95% CI 0, 0.39),[13, 14] we cannot conclude that the effect is not clinically important

Similarly, although weight loss has a statistically significant effect on physical disability (0.23; 95% CI 0.04, 0.42),[13, 14] the clinical importance of this effect cannot be determined because the MCII is unknown.

Finally, the effect of weight loss on knee stiffness as measured by the WOMAC stiffness subscale is inconclusive because the effect is not statistically significant and its confidence intervals contain the MCII (0.36; 95% CI -0.08, 0.80; MCII = 0.39).[13, 14]

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

Supporting Evidence

Table 3 (see next page)

Table 3. Summary of Evidence from OARSI for Weight Loss

Outcomes	Comparison	ES (95% CI)	MCII
Pain relief (WOMAC)	Weight loss diet vs. control	*d* = 0.13 (-0.12, 0.38)	0.39
Stiffness (WOMAC)	Weight loss diet vs. control	*d* = 0.36 (-0.08, 0.80)	0.39
Functional improvement (WOMAC)	Weight loss diet vs. control	*d* = 0.69 (0.24, 1.14)	0.37
Pain*	Weight loss diet vs. control	*d* = 0.20 (0, 0.39)	?
Physical disability*	Weight loss diet vs. control	*d* = 0.23 (0.04, 0.42)	?
d = standard mean difference ES = effect size MCII = minimal clinically important improvement ? = cannot be determined/unknown			

* Outcome measure is not defined by OARSI.

RECOMMENDATION 4

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

AAOS Level of Evidence: **I**
AAOS Grade of Recommendation: **A**

Rationale:

The OARSI guidelines on which this recommendation is based, provide evidence from a systematic review that included 13 randomized controlled trials on aerobic exercises (such as walking or cycling) in patients with OA of the knee.[13, 14] This recommendation was addressed by a systematic review of well-designed RCTs, making the evidence Level I.

The effects of aerobic exercises on pain relief (0.52; 95% CI 0.34, 0.70) and disability (0.46; 95% CI 0.25, 0.67)[13, 14] are statistically significant. Although the clinical importance of these effects cannot be determined, the relatively low cost and likely additional health benefits of exercise support this recommendation.

Supporting Evidence

Table 4. Summary of Evidence from OARSI for Aerobic Exercise

Outcomes	Comparison	ES (95% CI)	MCII
Pain relief*	Aerobic exercises vs. control	*d* = 0.52 (0.34, 0.70)	?
Disability*	Aerobic exercises vs. control	*d* = 0.46 (0.25, 0.67)	?

d = standard mean difference
ES = effect size
MCII = minimal clinically important improvement
? = cannot be determined/unknown

* Outcome measure is not defined by OARSI.

RECOMMENDATION 5

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

AAOS Level of Evidence: **V**
AAOS Grade of Recommendation: **C**

Rationale:

Individuals with OA of the knee often suffer from joint stiffness and may have loss of joint motion and limited muscle flexibility. We were unable to find any published studies that addressed the effects of motion/flexibility exercises in patients with OA of the knee. Therefore, this recommendation is based on expert opinion, which is Level V evidence.

The consensus of the AAOS workgroup is that range of motion and flexibility exercises are an option to address these impairments. The low cost of these exercises, the limited harms associated with them, and their potential benefits warrant this recommendation.

Supporting Evidence

We used expert opinion to support this recommendation. No studies investigating the use of range of motion or flexibility exercises were identified by our systematic literature searches.

RECOMMENDATION 6

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

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **B**

Rationale:

This recommendation was addressed by one Level II systematic review[33] that included nine RCTs that examined the effects of quadriceps strengthening on pain[34-42] and 10 RCTs[34-43] examined the effect of quadriceps strengthening on function. The systematic review concludes that quadriceps strengthening is effective. We supplemented the systematic review by performing our own meta-analyses. These analysis included an RCT[44] not included in the systematic review. The evidence is Level II because not all of the included RCTs were high quality, well designed trials.

The systematic review[33] that addressed this recommendation contained a meta-analysis that found that the effects of quadriceps strengthening on pain were statistically significant. The major shortcoming of this analysis was that it combined studies that measured pain in different ways, making it impossible to determine whether the effects were clinically important. Therefore, we performed our own meta-analysis of just those studies that used the WOMAC pain subscale. The results of this analysis suggest that quadriceps strengthening reduces pain by a statistically significant degree and is possibly clinically important. However, the results of this meta-analysis are difficult to interpret because of the presence of significant heterogeneity. When we omitted a single outlying trial (which found an unusually large effect) from the meta-analysis, there was no heterogeneity and the effect, although statistically significant, was not clinically important. This latter analysis strongly suggests that the effects of quadriceps strengthening on pain are statistically significant, but it is difficult to also conclude that they are not clinically important. This is because removal of a study from a meta-analysis simply because it is a statistical outlier is an *ad hoc* procedure. In light of this, and in light of the lack of harms associated with quadriceps strengthening, the evidence is sufficient to suggest the use of quadriceps strengthening.

The same systematic review[33] that reported a statistically significant effect on pain also reports that quadriceps strengthening improves function by a statistically significant degree. Again, due to the fact that the meta-analysis combined studies that used different scales, it was not possible to determine whether this effect was clinically important. Therefore, we conducted a *de novo* meta-analysis of only those studies that measured function using the WOMAC function subscale and included one RCT[44] not in the systematic review. The results of this meta-analysis, like that of our analysis on pain, suggest a statistically significant and possibly clinically important effect. However, due to the presence of heterogeneity, the results of this meta-analysis are difficult to interpret. We therefore conducted a subsequent meta-analysis of change scores and, again, found a statistically significant effect. However, we were unable to confirm the clinical importance of quadriceps strengthening. Nevertheless, these results do no obviate the effects of quadriceps strengthening on pain and, therefore, do not cause us to conclude that quadriceps strengthening is ineffective.

Supporting Evidence

The studies that addressed this recommendation ranged in duration from 8 weeks to 24 months, varied in their control group (no intervention or education), whether the programs were home-based or supervised, and used a variety of outcome measures. To measure pain, five studies in the systematic review used the WOMAC Pain subscale,[34-38] three used the Visual Analogue Scale (VAS),[39-41] and one used the Knee Pain Scale.[42] To measure function, seven studies used the WOMAC Function subscale,[34-38, 41, 43] two used the Dutch version of AIMS,[39, 40] and one used a physical disability questionnaire developed for the Fitness Arthritis and Seniors Trial (FAST).[42]

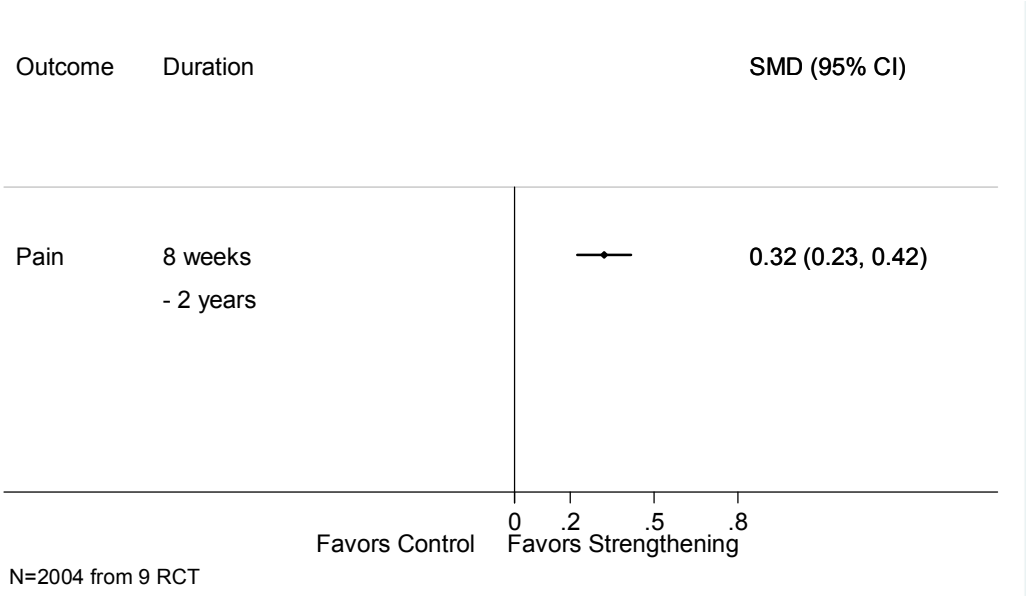
For the raw data addressing this recommendation, please see evidence tables: 6-7.
Figures relevant to this recommendation are Figure 1 - Figure 6.
Relevant study attrition diagram shown in Appendix III.

PAIN

Level of Evidence:
One Level II Systematic Review and one additional Level II RCT

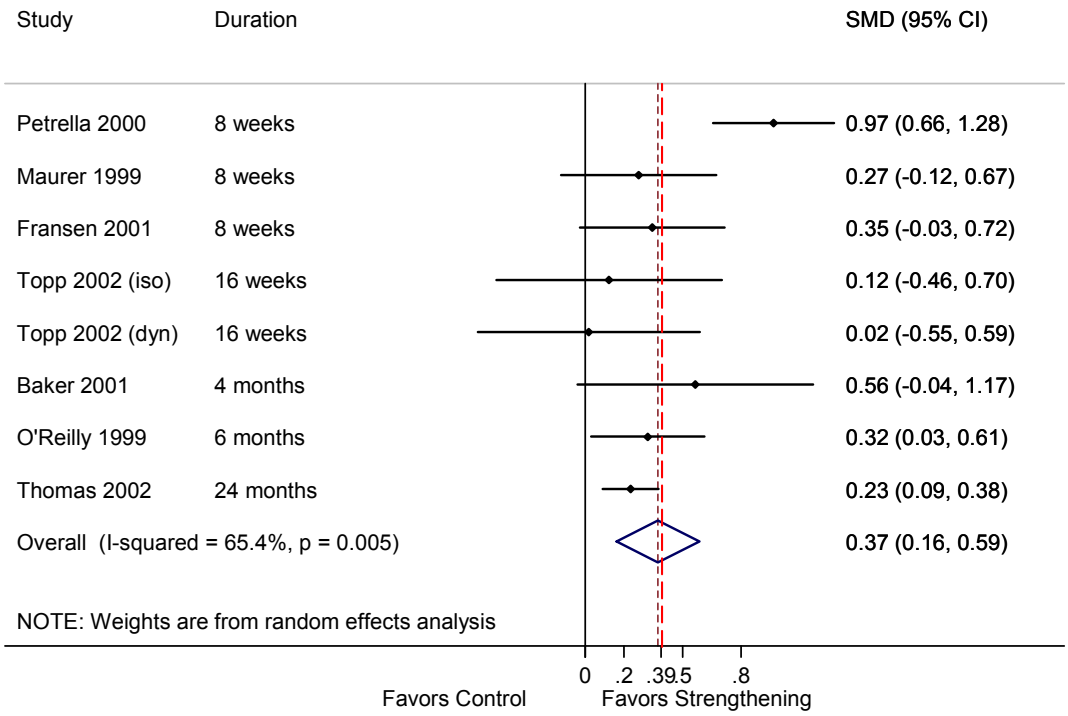
A meta-analysis conducted in the systematic review found a statistically significant effect (0.32; 95% CI 0.23, 0.42) of quadriceps strengthening on pain (Figure 1) but, because it combined different pain scales, the clinical importance of this effect cannot be determined. Consequently, we conducted our own meta-analyses (using a random effects model) of just those studies that reported pain on the WOMAC pain subscale. This analysis includes one RCT [44] not included in the systematic review. The first of these analyses (Figure 2) revealed a statistically significant and possibly clinically important effect (0.37; 95% CI 0.16, 0.59). However, this analysis was heterogeneous (I^2 = 65.4%), making the summary results difficult to interpret. The heterogeneity was due to the results of one trial [43] that found an unusually large effect and was a statistical outlier. Therefore, we conducted a second meta-analysis (Figure 3) that omitted this trial. The analysis was not heterogeneous (I^2 = 0.0%), and its results suggest that the effect of quadriceps strengthening is statistically significant but not clinically important (0.26; 95% CI 0.15, 0.37). The results of this meta-analysis are, nevertheless, equivocal because we were unable to discover why the study was an outlier. Omitting a study simply because it is an outlier is *ad hoc*.

Figure 1. Pain (systematic review Roddy et al. 2005)



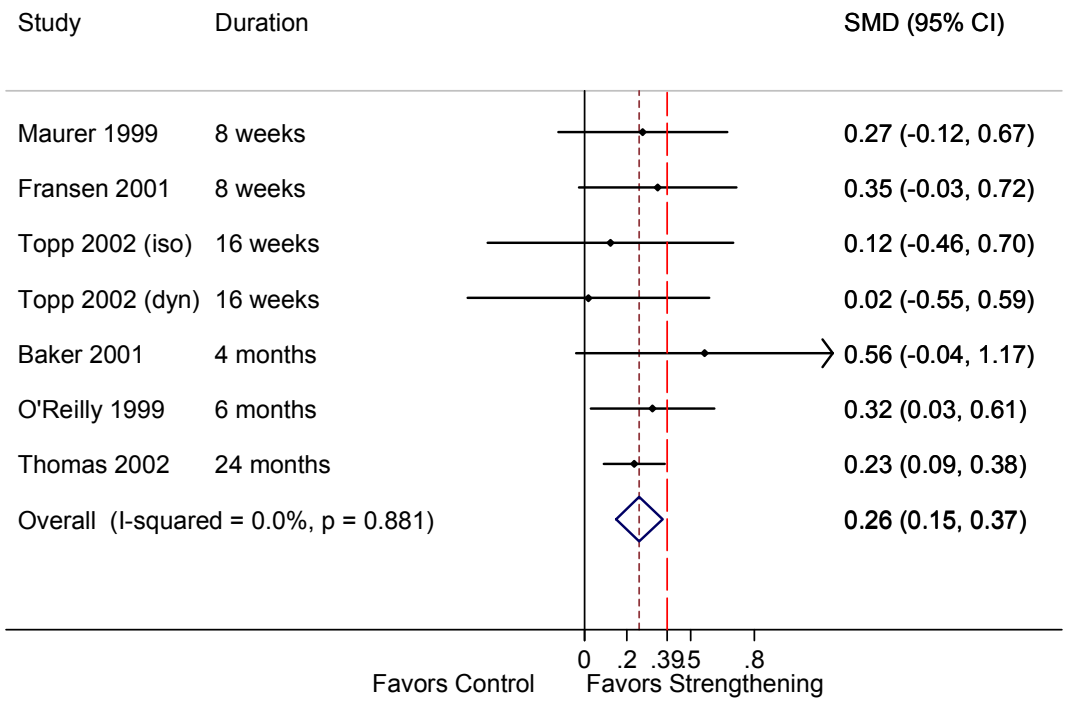
* 10th study [43] excluded from pain meta-analysis to reduce heterogeneity; all participants in this study were prescribed an NSAID, and the control group received a sham exercise program

Figure 2. AAOS Analysis: WOMAC Pain



*Longer Dashed line indicates MCII for WOMAC Pain
**Diamond represents summary statistic and associated 95% confidence interval
***SMD: standardized mean difference

Figure 3. AAOS Analysis: WOMAC Pain Excluding Petrella RCT



*Longer dashed line indicates MCII for WOMAC Pain

FUNCTION

Level of Evidence:

One Level II Systematic Review and one Level II RCT

The systematic review that addressed this recommendation found a statistically significant (0.32; 95% CI 0.23, 0.41) effect of quadriceps strengthening on function but combined multiple scales to measure the effect of quadriceps strengthening on disability. Because of this, the clinical importance of this effect again cannot be determined (Figure 4). To determine the clinical importance of quadriceps strengthening, we conducted a random effects meta-analysis of all quadriceps strengthening RCTs that utilized the WOMAC function subscale. Our analysis includes one RCT [44] not included in the systematic review. Figure 5 displays the results of this analysis, and shows that the effect was statistically significant and possibly clinically important (0.39; 95% CI 0.29,0.50), but it is difficult to interpret this summary statistic because of the presence of heterogeneity ($I^2 = 91.1\%$). This heterogeneity was due to one study.[43] In this study, there was a statistically significant difference between the treatment and control groups in function at baseline. In an attempt to account for this difference, we performed a meta-analysis of change scores. Figure 6 depicts the results of this analysis. The analysis exhibited no meaningful heterogeneity ($I^2 = 3.7\%$) and suggests that, although statistically significant, the results are not clinically important. Of note is that one can only accurately estimate the confidence intervals around change scores when the raw data are presented in all relevant articles or when the correlation between pre- and post-test scores is known. Neither quantity was published in the available studies, so we used the baseline standard deviation as a measure of the change score dispersion. This is a conservative assumption that will artificially widen the confidence intervals around the summary statistic. Because the MCII lies above these conservative confidence intervals, we can conclude that the effect of quadriceps strengthening on function in patients with OA of the knee is not clinically important.

Figure 4. Function (systematic review Roddy et al. 2005)

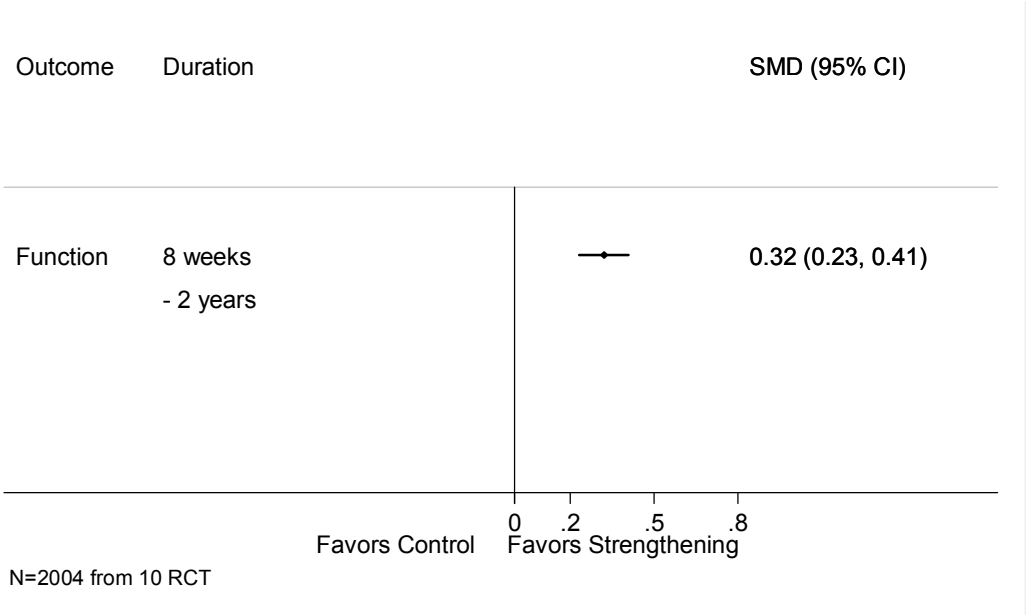
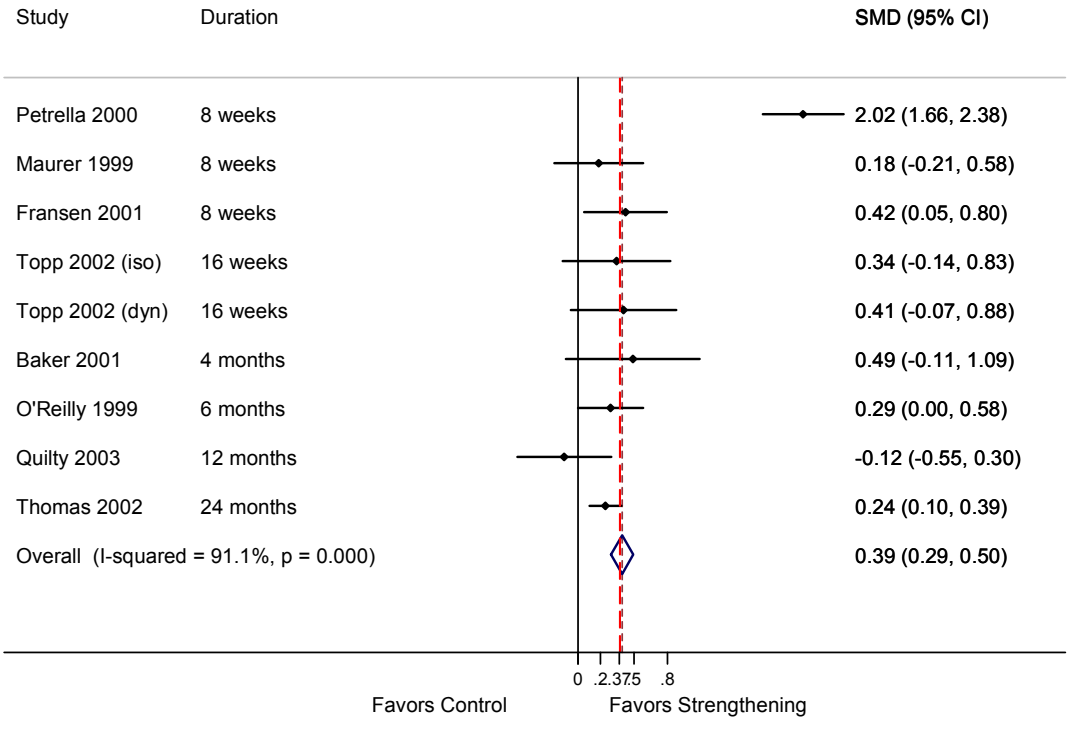
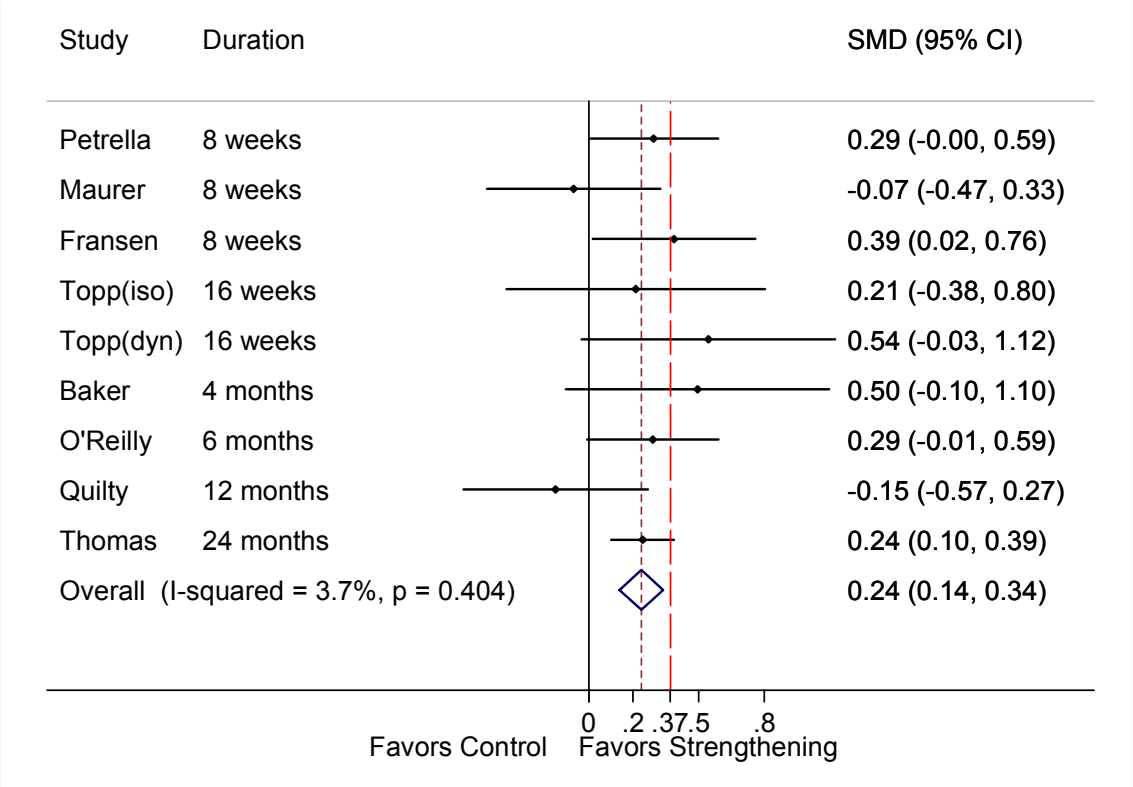


Figure 5. AAOS Analysis: WOMAC Function



*Petrella RCT: baseline difference in the outcome measure between the treatment and control groups
** Dashed line indicates MCII for WOMAC Function

Figure 6. AAOS Analysis: WOMAC Function Using Change Scores



*Longer dashed line indicates MCII for WOMAC Function

RECOMMENDATION 7

We suggest patients with symptomatic OA of the knee use patellar taping for short term relief of pain and improvement in function.

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **B**

Rationale:
One Level II Systematic Review[45] examined the use of patellar taping among patients with symptomatic OA of the knee. The review included one Level I RCT[46] and two Level II RCTs.[47, 48] The Level II RCTs did not conceal the allocation to groups. All three studies investigated taping to apply a medially directed force compared to sham taping and no taping. One study[47] also investigated taping to apply a laterally directed force. The systematic review concludes that medially directed taping produces a clinically meaningful change in chronic anterior knee pain or pain due to OA of the knee, and that there is insufficient evidence to determine the effectiveness of lateral taping.

The RCTs in the systematic review report statistically significant and possibly clinically important effects of medial taping on pain (as measured by the visual analogue scale) immediately and four days after the start of taping. There is some evidence that medial taping reduces pain on movement by an amount that is possibly clinically important, but this effect is only observed when taping is compared to no taping, and not when medial taping is compared to a sham.

Analysis of evidence in the systematic review does not suggest that lateral taping is effective.

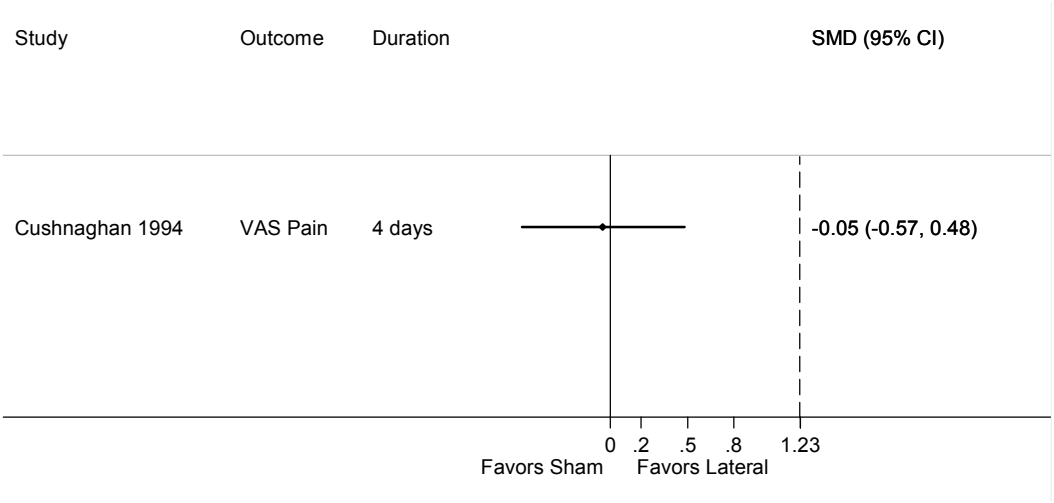
Supporting Evidence
For the raw data addressing this recommendation, please see evidence tables: 8-9.
Figures relevant to this recommendation are Figure 7 - Figure 9.
Relevant study attrition diagram shown in Appendix III.

PAIN: VISUAL ANALOG SCALE (VAS) - LATERALLY-DIRECTED TAPING

Level of Evidence:
One Level II Systematic Review

Figure 7 presents the effects of laterally-directed taping on pain measured by VAS. The results are negative inasmuch as the effect is neither statistically significant nor clinically important

Figure 7. Lateral vs. Sham Taping – Pain: VAS (systematic review Warden et al. 2008)



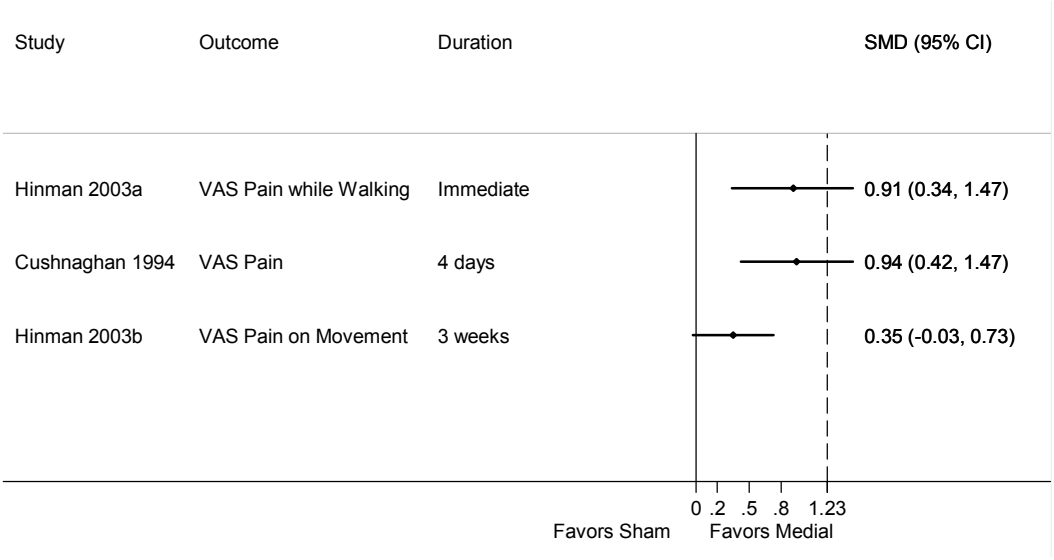
*Dashed line indicates MCII for VAS Pain

PAIN: VAS - MEDIALLY-DIRECTED TAPING

Level of Evidence:
One Level II Systematic Review

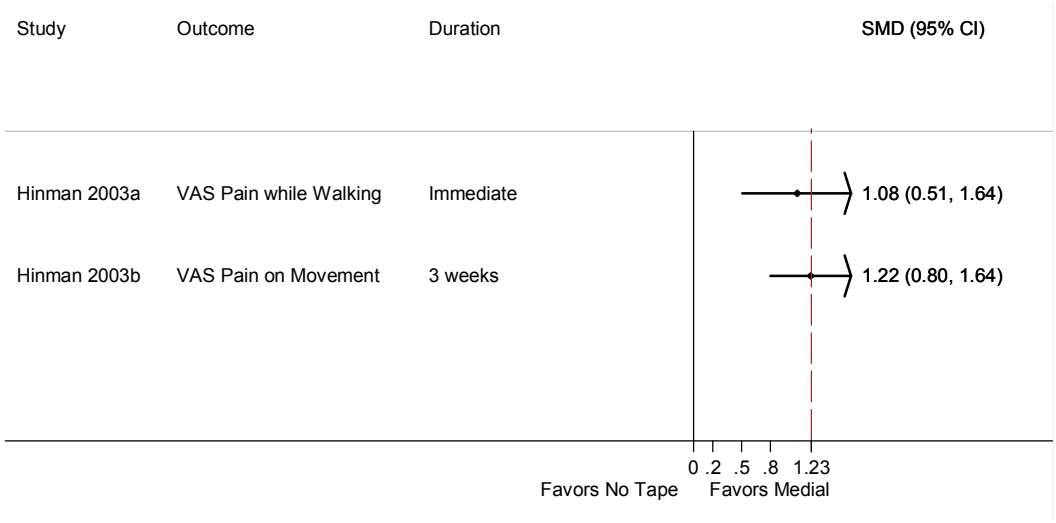
Figure 8 and Figure 9 present the effects of medially-directed taping on pain measured by VAS vs. sham and no taping, respectively. The MCII for VAS Pain is 19.9 mm,[21] which corresponds to a SMD of 1.23. When the comparison group is sham taping, the effect of medially-directed taping is statistically significant and possibly clinically important immediately and four days after taping. The effect is neither statistically significant nor clinically important three weeks after taping. When the comparison group is no taping (which is not as satisfactory of a control group as sham taping), the effect of medially-directed taping is statistically significant and possibly clinically important immediately, and three weeks after taping.

Figure 8. Medial vs. Sham Taping – Pain:VAS (systematic review Warden et al. 2008)



*Dashed line indicates MCII for VAS Pain

Figure 9. Medial vs. No Taping – Pain: VAS (systematic review Warden et al. 2008)



*Dashed line indicates MCII for VAS Pain

RECOMMENDATION 8

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

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **B**

Rationale:

This recommendation is addressed by one Level II Systematic Review[49] of three Level II RCTs that examined the use of lateral heel wedges among patients with symptomatic medial compartmental OA of the knee The three Level II RCTs were published in six separate articles.[50-55] Comparisons between lateral heel wedges and neutral heel wedges are investigated as well as comparisons between lateral wedged insoles and lateral wedged insoles with subtalar strapping. The systematic review concludes that there is only limited evidence for the effectiveness of lateral heel wedges and related orthoses.

The systematic review provides no evidence that lateral heel wedges are more effective than neutral heel wedges, when assessed with the WOMAC instrument for up to 24 months. The effects of lateral heel wedges on WOMAC function and stiffness are all statistically non-significant and trend in favor of the control group, and the all but one of the effects on WOMAC pain are statistically non-significant and similarly trend in favor of the control. The only statistically significant effect on WOMAC pain (at 6 months) again favors the control group (although the effect was not clinically important; Figure 10). No statistically significant effects of lateral heel wedges on patient global assessment (Figure 11) or analgesic intake (Figure 12) were found.

The systematic review provides no evidence that lateral heel wedges are more effective than subtalar strapped insoles when assessed by patient oriented outcome measures. Indeed, at 8 and 24 months, there were statistically significant effects on pain (as measured by the visual analogue scale) in favor of subtalar strapped insoles (the effect was not significant at 24 months; Figure 13). Statistically significant effects favoring strapped insoles were also found for the Lequesne index at 8 weeks and 12 months (but not at 24 months; Figure 14). The effects on pain were not clinically important, and the MCII is not known for the other outcomes.

These data suggest that there is no benefit to using lateral heel wedges, and there is the possibility that those who do not use them may experience fewer OA of the knee symptoms.

Supporting Evidence

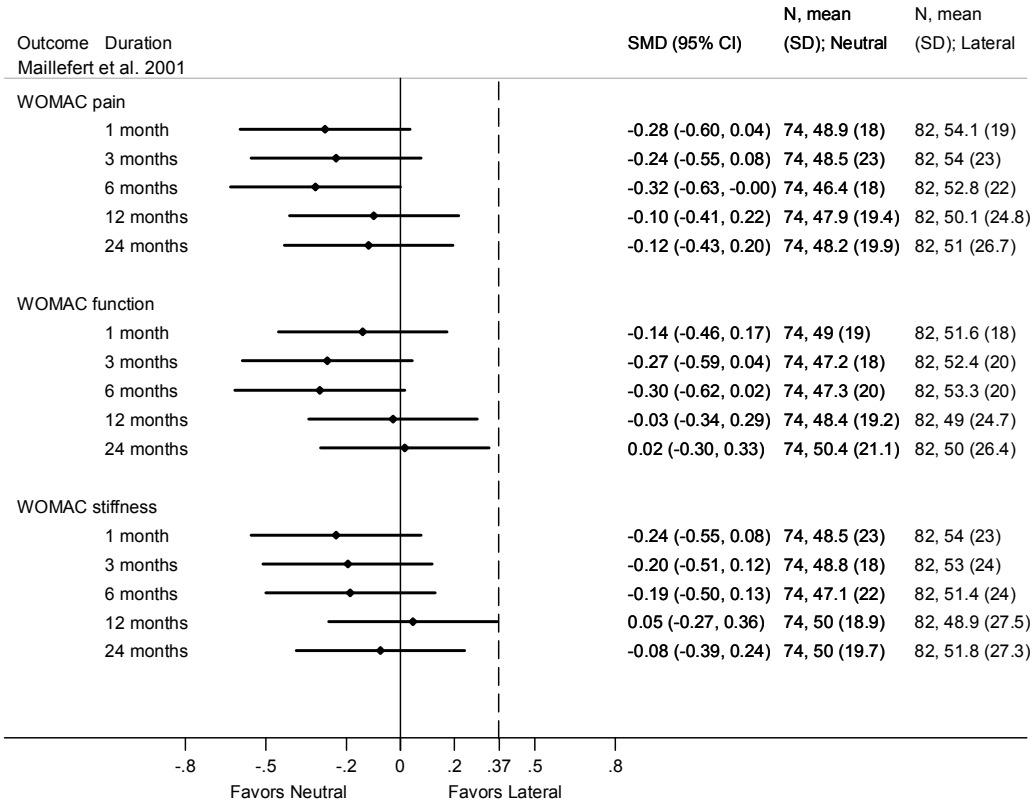
For the raw data addressing this recommendation, please see evidence tables: 10-11.
Figures relevant to this recommendation are Figure 10 - Figure 16.
Relevant study attrition diagram shown in Appendix III.

Figure 10 - Figure 12 display the results comparing lateral heel wedges to neutral heel wedges.

WESTERN ONTARIO MCMASTER QUESTIONNAIRE (WOMAC)

Level of Evidence:
One Level II Systematic Review

Figure 10. Lateral vs. Neutral Heel Wedge – WOMAC (systematic review Brouwer et al. 2008)

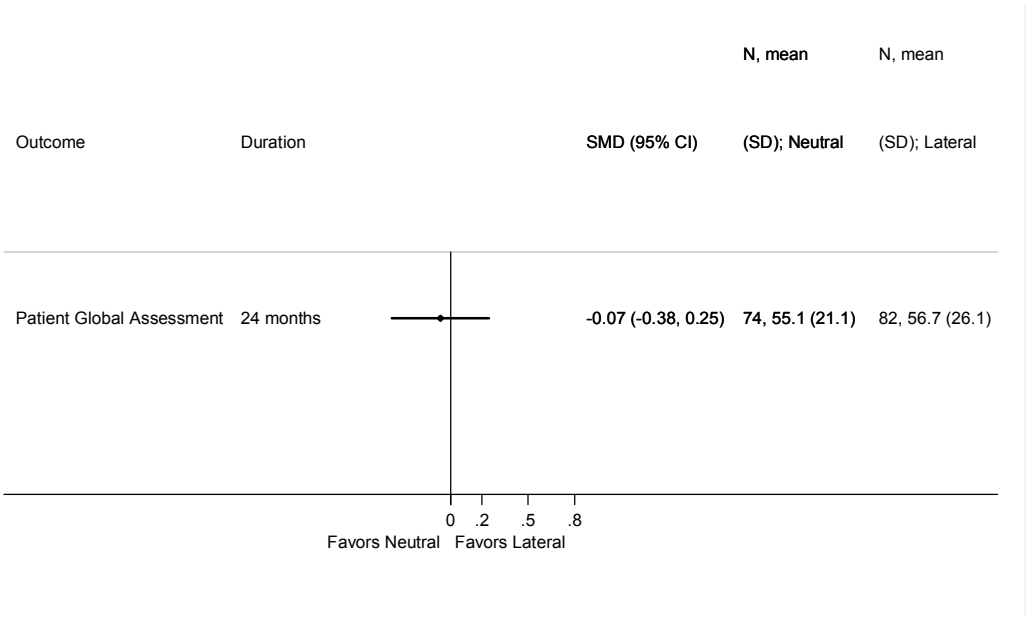


*Dashed line indicates MCII for WOMAC Function (0.37); MCII for Pain/Stiffness = 0.39

PATIENT GLOBAL ASSESSMENT

Level of Evidence:
One Level II Systematic Review

Figure 11. Lateral vs. Neutral Heel Wedge - Patient Global Assessment (systematic review Brouwer et al. 2008)



MEDICATION INTAKE

Level of Evidence:
One Level II Systematic Review

Figure 12. Lateral vs. Neutral Heel Wedge - Medication Intake (systematic review Brouwer et al. 2008)

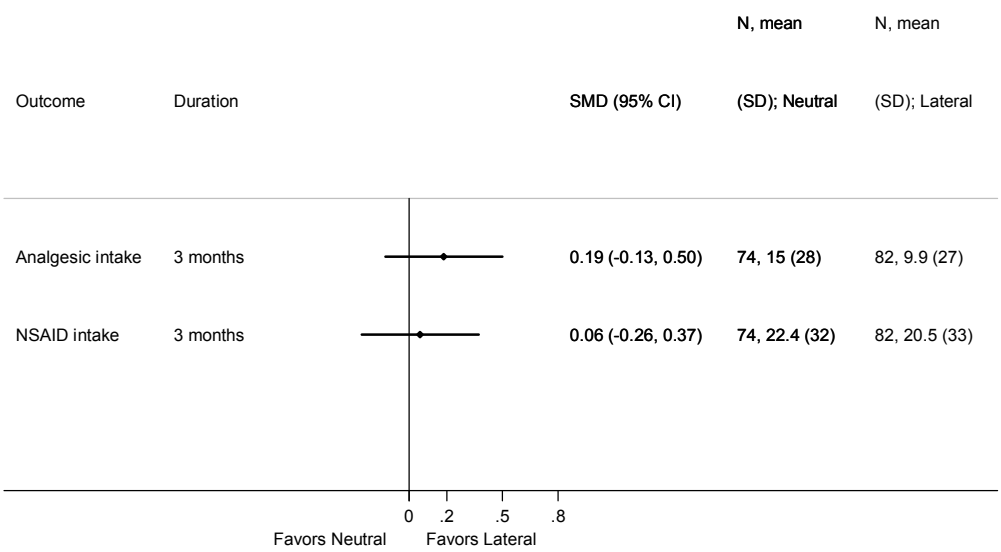
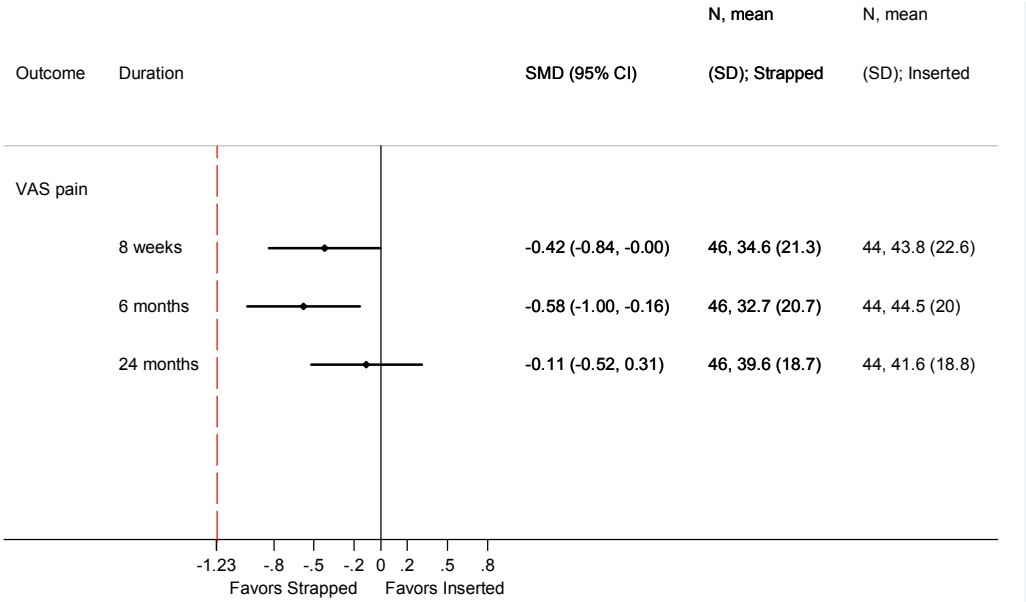


Figure 13 - Figure 16 display the results comparing inserted lateral wedged insoles to lateral wedged insoles with subtalar strapping.

PAIN: VAS

Level of Evidence:
One Level II Systematic Review

Figure 13. Traditional Inserted vs. Subtalar Strapped Insoles – Pain: VAS (systematic review Brouwer et al. 2008)



*Dashed line indicates MCII for VAS Pain

LEQUESNE INDEX

Level of Evidence:
One Level II Systematic Review

Figure 14. Traditional Inserted vs. Subtalar Strapped Insoles - Lequesne Index (systematic review Brouwer et al. 2008)

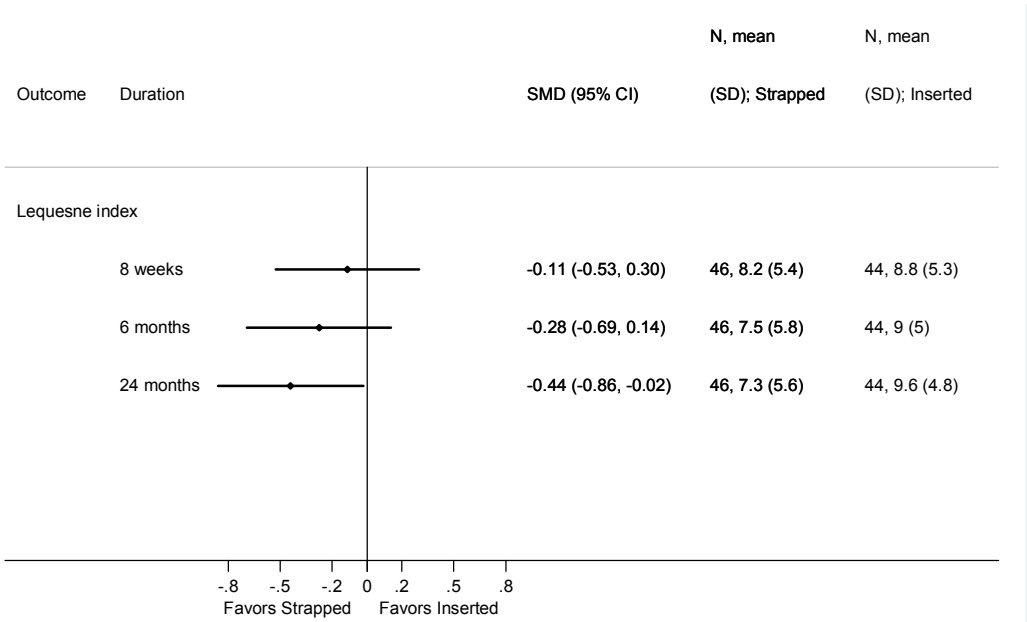
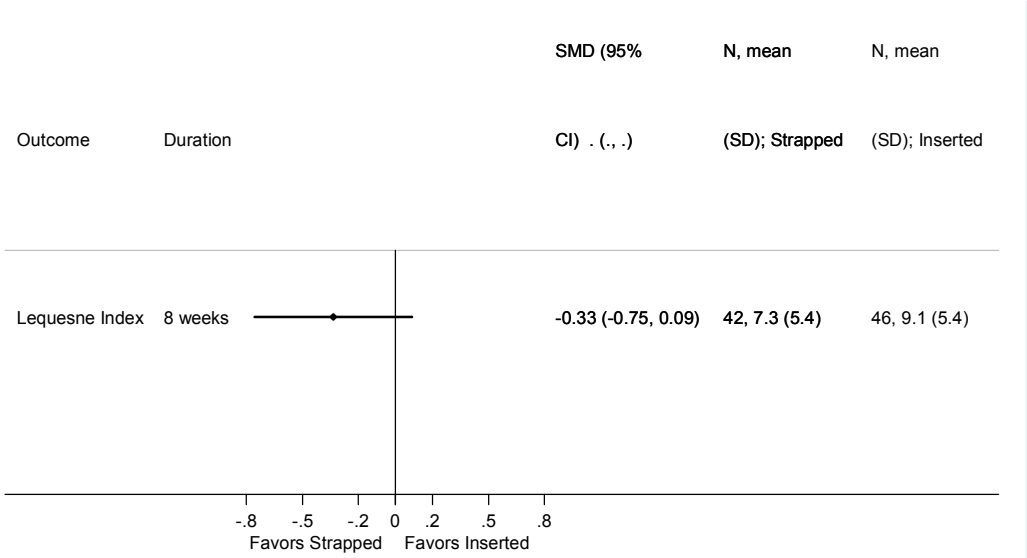


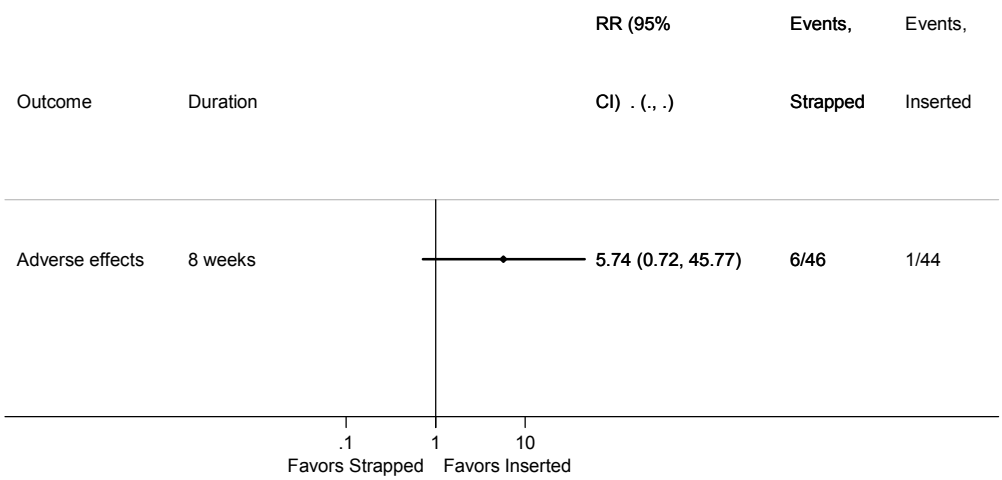
Figure 15. Sock-type Inserted vs. Subtalar Strapped Insole - Lequesne Index (systematic review Brouwer et al. 2008)



ADVERSE EFFECTS

Level of Evidence:
One Level II Systematic Review

Figure 16. Inserted vs. Subtalar Strapped Insoles - Adverse Effects (systematic review Brouwer et al. 2008)



*Adverse effects included popliteal pain, low back pain, and foot sole pain

RECOMMENDATION 9

We are unable to recommend for or against the use of a brace with a valgus directing force for patients with medial uni-compartmental OA of the knee.

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **Inconclusive**

Rationale:
One Level II Systematic Review[49] of two RCTs[56, 57] examined the use of braces among patients with medial uni-compartmental OA of the knee. The brace is applied with the intent to alter a varus malaligned knee and move the alignment of the knee in a valgus direction. One of the RCTs[57] included in the systematic review presented insufficient quantitative data for analyses. The systematic review concludes that there is only limited evidence for the effectiveness of knee braces.

The systematic review provides no evidence for improvement in pain measured by the Visual Analog Scale at 6 or 12 months. The effects are not clinically important and not statistically significant (Figure 17). The clinical importance of the effects of a brace on Walking Distance (Figure 19) and Quality of Life (Figure 21) cannot be determined and are not statistically significant at 6 or 12 months.

The qualitative results reported by the systematic review (for the study that did not adequately report quantitative data) indicate that patients in the brace group improved more on each outcome than patients that received either a neoprene sleeve or were in the control group.

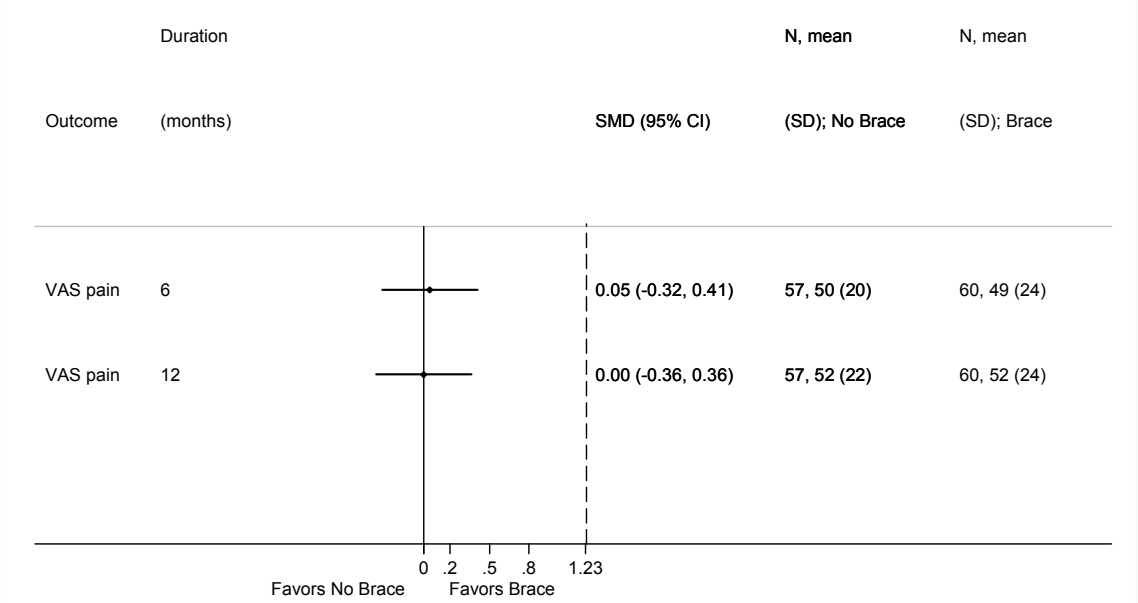
Supporting Evidence
For the raw data addressing this recommendation, please see evidence tables: 12-14.
Figures relevant to this recommendation are Figure 17 - Figure 21.
Relevant study attrition diagram shown in Appendix III.

Note: One[57] of the two RCTs included in the systematic review presented insufficient quantitative data for data extraction. See evidence tables 13 and 14 for details.

PAIN: VAS

Level of Evidence:
One Level II Systematic Review

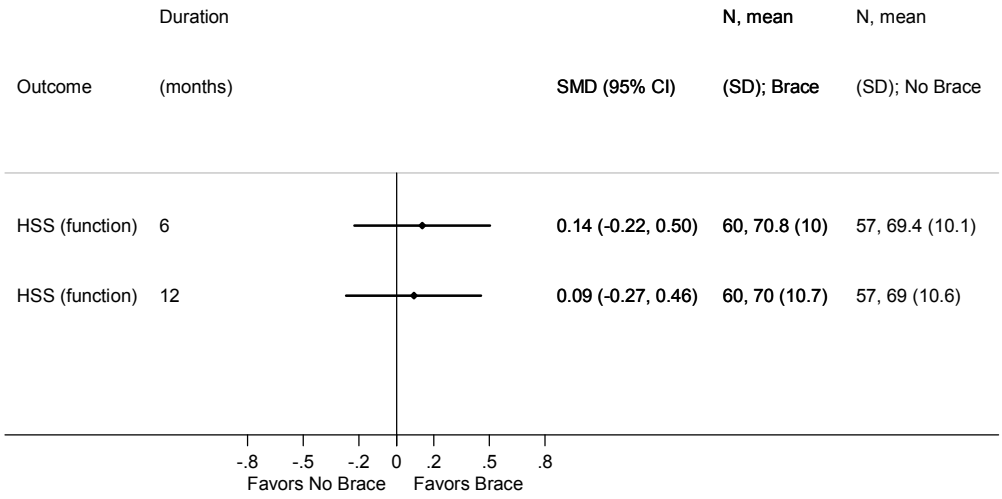
Figure 17. VAS Pain (systematic review Brouwer et al. 2008)



*81% of the study population had OA of the medial compartment; 19% had OA of the lateral compartment
**Dashed line indicates MCII for VAS Pain

HOSPITAL FOR SPECIAL SURGERY KNEE SCORE (HSS)
Level of Evidence:
One Level II Systematic Review

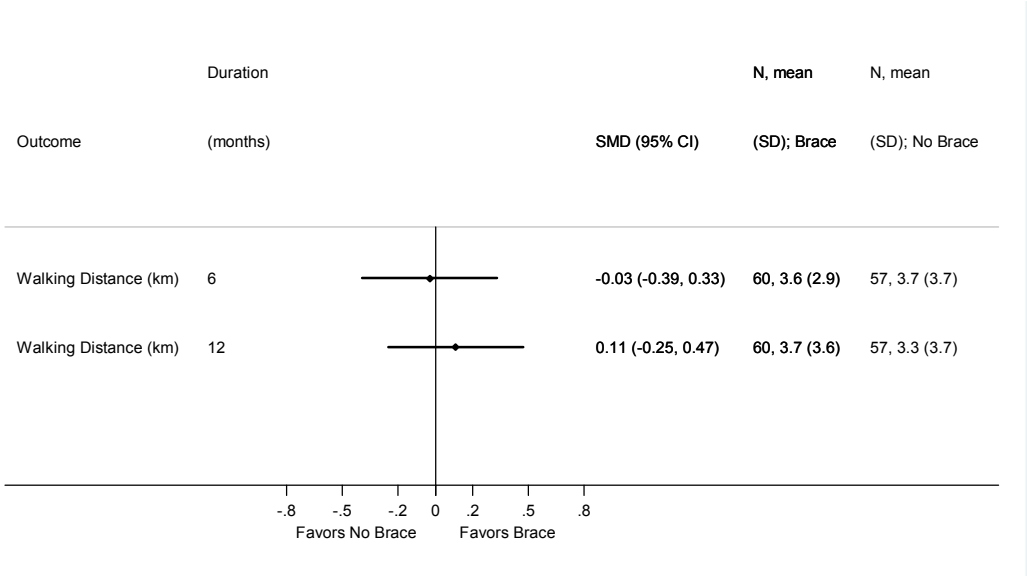
Figure 18. HSS (systematic review Brouwer et al. 2008)



*81% of the study population had OA of the medial compartment; 19% had OA of the lateral compartmental

WALKING DISTANCE (KM)
Level of Evidence:
One Level II Systematic Review

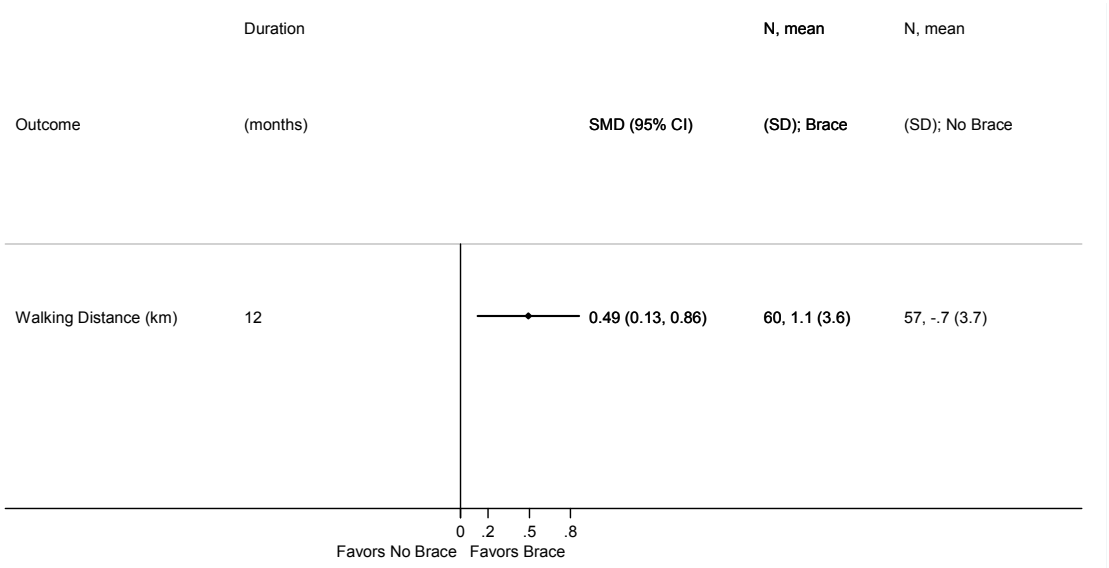
Figure 19. Walking Distance (systematic review Brouwer et al. 2008)



*81% of the study population had OA of the medial compartment; 19% had OA of the lateral compartmental

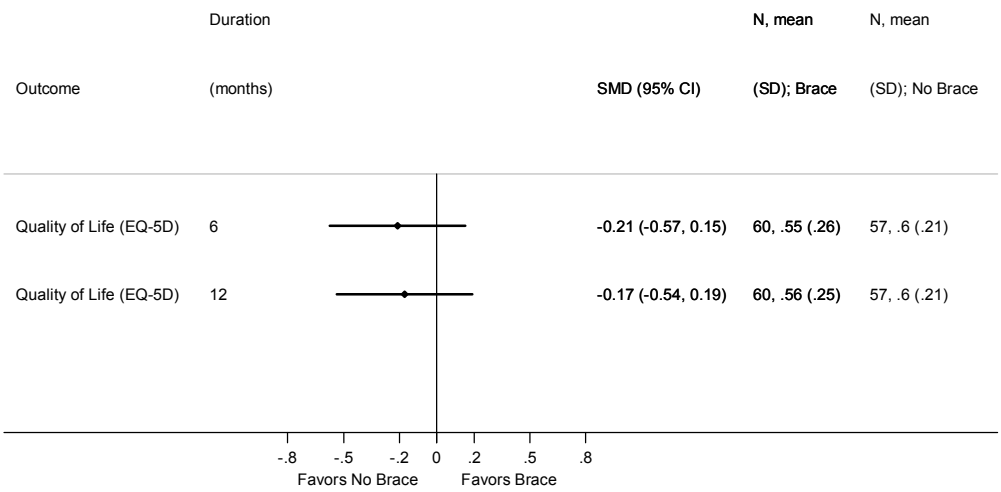
Because of between-group differences at baseline in walking distance, Figure 20 presents the effect size based on differences from baseline rather than the post-treatment values presented in Figure 19.

Figure 20. Walking Distance Change from Baseline (systematic review Brouwer et al. 2008)



QUALITY OF LIFE
Level of Evidence:
One Level II Systematic Review

Figure 21. Quality of Life (EQ-5D) (systematic review Brouwer et al. 2008)



*81% of the study population had OA of the medial compartment; 19% had OA of the lateral compartmental

RECOMMENDATION 10

We are unable to recommend for or against the use of a brace with a varus directing force for patients with lateral uni-compartmental OA of the knee.

AAOS Level of Evidence: **Level V**
AAOS Grade of Recommendation: **Inconclusive**

Rationale:

A knee brace, applied with the intent to alter a valgus malaligned knee and move the alignment of the knee in a varus direction, has been proposed as a treatment for individuals with symptomatic lateral tibiofemoral OA of the knee. No studies were identified by our systematic review processes, specific to patients with lateral tibiofemoral OA of the knee.

Supporting Evidence

No studies investigating the use of a brace with a varus directing force were identified by our systematic literature searches.

RECOMMENDATION 11

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

AAOS Level of Evidence: **I and II**
AAOS Grade of Recommendation: **Inconclusive**

Rationale:

This recommendation is addressed by the OARSI guidelines and six Level I and eight Level II RCTs. The OARSI guideline reports conflicting evidence, from two RCTs and one systematic review, regarding the symptomatic benefit of acupuncture in patients with OA of the knee.[13, 14] One RCT[58] and the systematic review[59] support the use of acupuncture and one RCT[60] does not support the use of acupuncture.

In an attempt to resolve these conflicting results, we conducted a *de novo* systematic review of previously published systematic reviews (Table F) and confirmed that their conclusions were conflicting. Consequently, we updated these reviews with our own, including performing a meta-analysis of results of all eligible RCTs on the use of acupuncture in patients with symptomatic OA of the knee.

Our meta-analysis suggests that the reported effects of acupuncture pain depend on study design and conduct. Accordingly, the largest effects on pain (Figure 22) and on function (as measured by the WOMAC function subscale; Figure 23) are found in studies that did not employ blinding, the smallest effects are found in studies that employed blinding and verified that patients were blinded, and intermediate effects are found in studies that employed blinding but did not verify that patients were blinded. Meta-regression reveals that these relationships are statistically significant, but also reveals that these relationships do not explain all of the differences between study results (Table 7). Further analyses showed that the effects of acupuncture on pain and function were not statistically significant in studies that verified that their patients were blinded. However, there remains a large amount of unexplained variance in this group of studies as well as in the other two groups. Thus, although our meta-analytic results suggest that the apparent effects of acupuncture are due to a placebo effect, the unexplained differences among study results do not conclusively prove this point. Because of this, and because of the conflicting conclusions of previously published systematic reviews, we agreed that currently available evidence about the benefits of acupuncture is inconclusive.

Supporting Evidence

For the raw data addressing this recommendation, please see evidence tables: 15-17.
Figures relevant to this recommendation are Figure 22 - Figure 103.
Relevant study attrition diagram shown in Appendix III.

PREVIOUSLY PUBLISHED ANALYSES

The results of previously published analyses on the effectiveness of acupuncture are shown in Table 5 (the OARSI guideline) and Table 6 (previously published systematic reviews.

Table 5. Summary of Evidence from OARSI for Acupuncture

Outcomes	Comparison	ES (95% CI)	MCII
Pain (WOMAC)	Acupuncture vs. sham	*d* = 0.51 (0.23, 0.79)	0.39
Stiffness (WOMAC)	Acupuncture vs. sham	*d* = 0.41 (0.13, 0.69)	0.39
Function (WOMAC)	Acupuncture vs. sham	*d* = 0.51 (0.23, 0.79)	0.37
d = standard mean difference ES = effect size MCII = minimal clinically important effect			

Table 6. Conclusions of Previously Published Systematic Reviews on Acupuncture in Patients with OA of the Knee

Systematic Review	Conclusion
Puett 1994 [61]	**?**
Ezzo 2001 [59]	↑
Ferrandez 2002 [62]	**?**
Kwon 2006 [63]	↑
White 2007 [64]	↑
Manheimer 2007 [65]	=
Bjordal 2007 [66]	↑ for EA, **?** for MA
? Inconclusive evidence = No clinical benefit ↑ Favors acupuncture EA electro-acupuncture MA manual acupuncture	

DE NOVO ANALYSIS

Figure 22 presents the results of the AAOS meta-analysis of 13 RCTs examining acupuncture's effect on pain among patients with OA of the knee vs. sham or non-sham control groups. Ten studies used the WOMAC pain subscale,[31, 32, 58, 60, 67-72] one used pain on VAS,[29] one used pain on the Numerical Rating Scale (NRS),[73] and one used Present Pain Intensity to measure pain.[74] Outcome durations ranged from 2-13 weeks.

Figure 23 presents the results of the AAOS meta-analysis of nine RCTs[31, 32, 58, 60, 67-71] examining acupuncture's effect on function among patients with OA of the knee (all nine utilized the WOMAC physical function subscale). Outcome durations ranged from 4-13 weeks.

The figures demonstrate that individual study results varied according to whether patients were blinded and whether the investigators attempted to determine that blinding was successful: studies that verified that efforts to blind patients were effective produced much smaller effects than studies that did not verify the effectiveness of patient blinding. Studies with no patient blinding found the largest effects.

Significant heterogeneity is present in both meta-analyses.

The results of our meta-regression on the effects of blinding status are shown in Table 7. There is a statistically significant association between the level of patient blinding and a study's effect size. This association applies to both pain ($p = 0.01$) and function ($p = 0.04$). While significant heterogeneity still remains in each model ($I^2 = 75\%$), blinding accounts for 50% and 44% of the between study variance in the pain and function models, respectively.

Figure 22. Acupuncture vs. Control - Pain

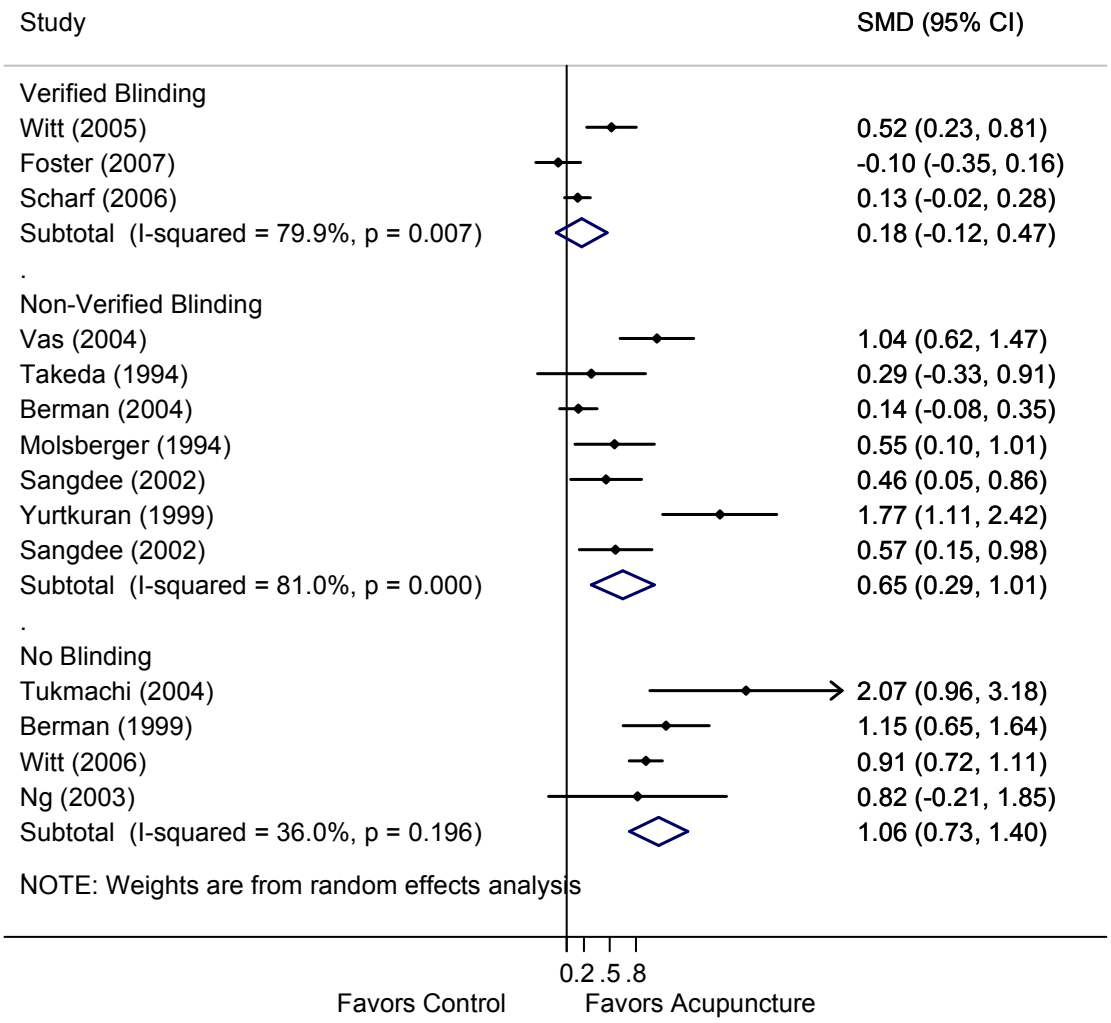
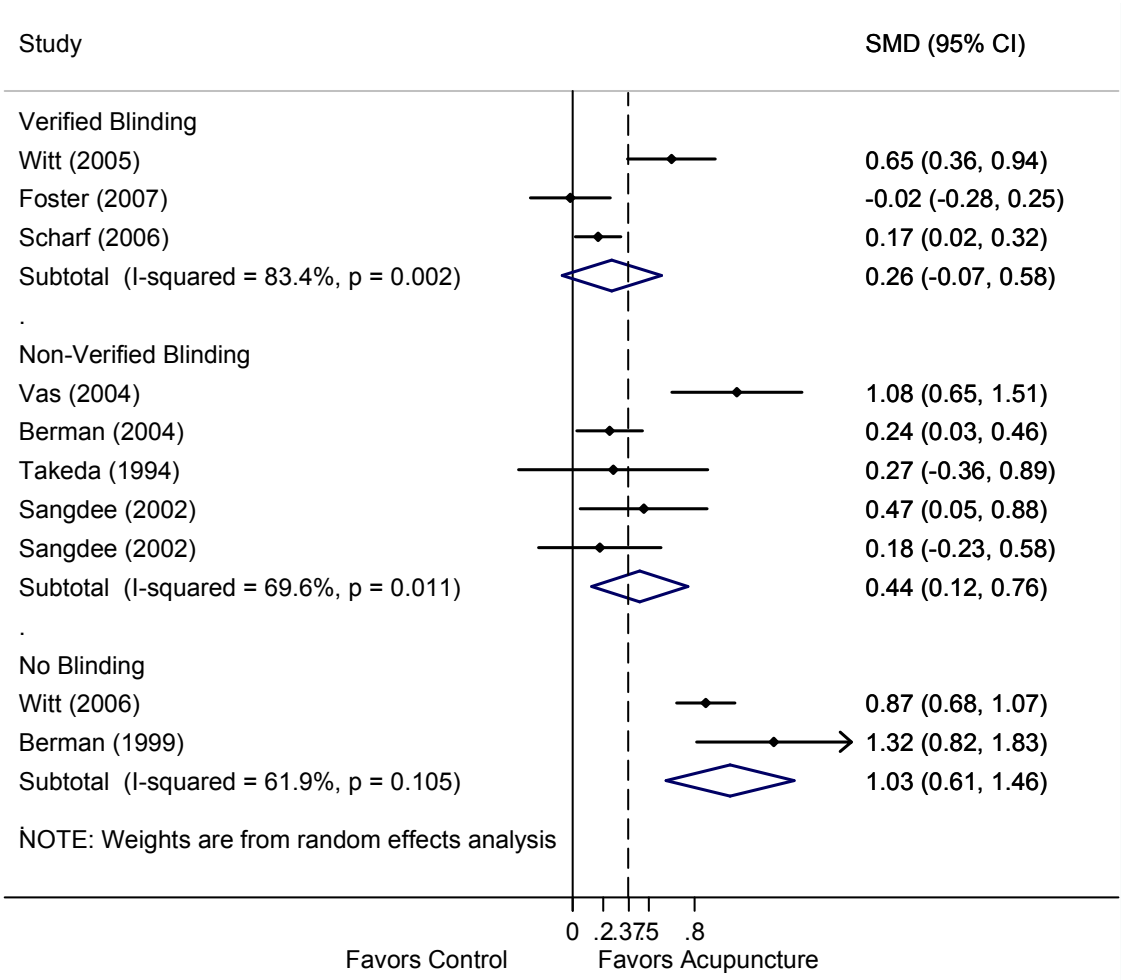


Figure 23. Acupuncture vs. Control - Function



*Dashed line indicates MCII for WOMAC Function

Table 7. Results of Meta-Regression of Effect of Level of Patient Blinding on Effect Size

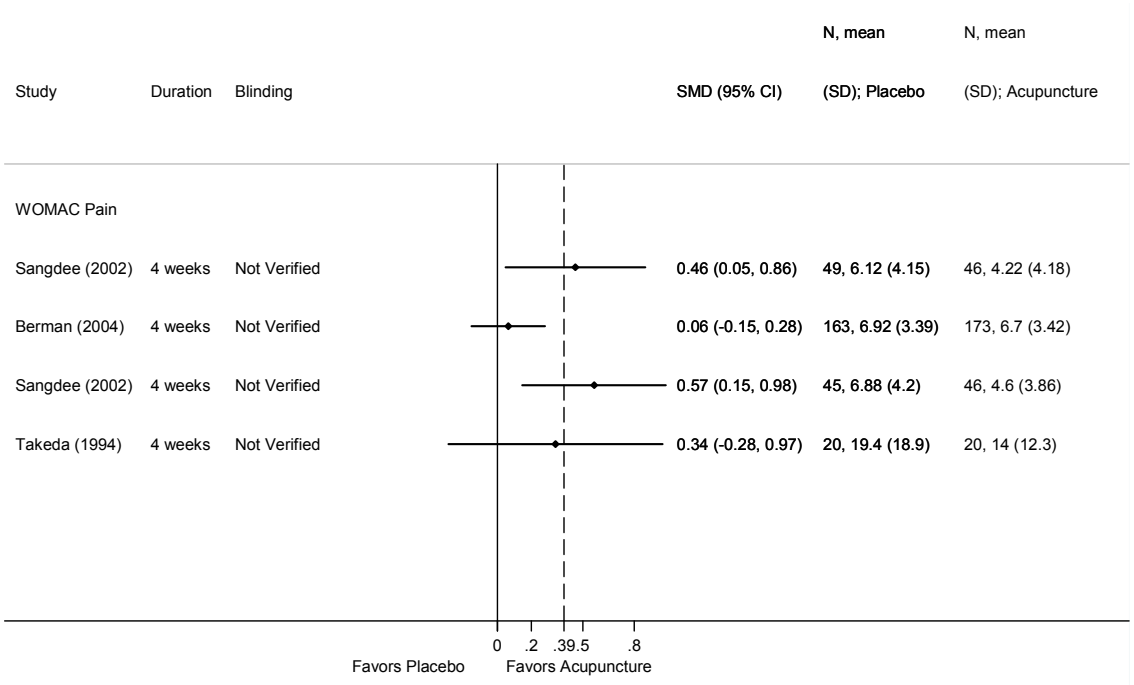
Outcome	p-value	% of Between-Study Variance Accounted For	Residual I^2
Pain	0.01	50.0%	74.7%
Function (WOMAC)	0.04	44.0%	74.9%

PAIN - WOMAC

Level of Evidence:
Four Level I RCTs and Six Level II RCTs

Figure 24 - Figure 28 present the results of acupuncture vs. placebo on the WOMAC Pain subscale for various durations. We did not perform a meta-analysis of these data because not all of the relevant studies verified that patients were blinded. Several studies (4 of 10) compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

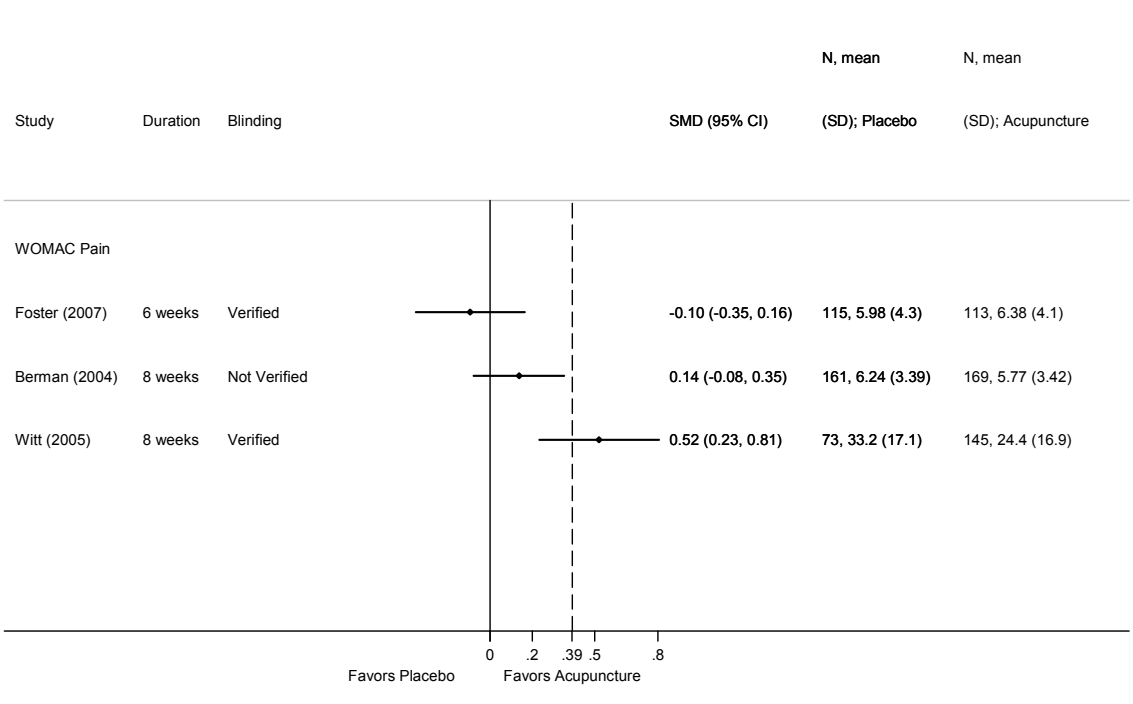
Figure 24. Acupuncture vs. Placebo - WOMAC Pain (4 weeks)



*Dashed line indicates MCII for WOMAC Pain

Data for WOMAC pain at 6-8 weeks. We did not perform a meta-analysis of these data because one study did not verify that patients were blinded.

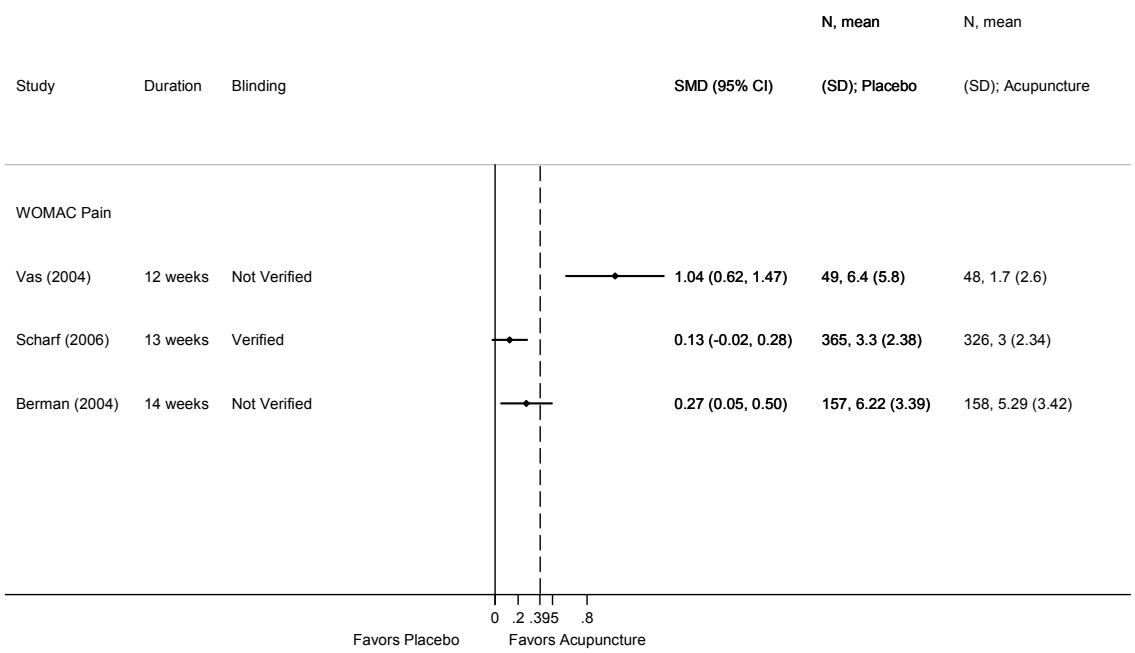
Figure 25. Acupuncture vs. Placebo - WOMAC Pain (6-8 weeks)



*Dashed line indicates MCII for WOMAC Pain

The effects of acupuncture on pain (as measured by the WOMAC) at 12-14 weeks are shown below. We did not perform a meta-analysis of these data because only one study verified that its patients were blinded.

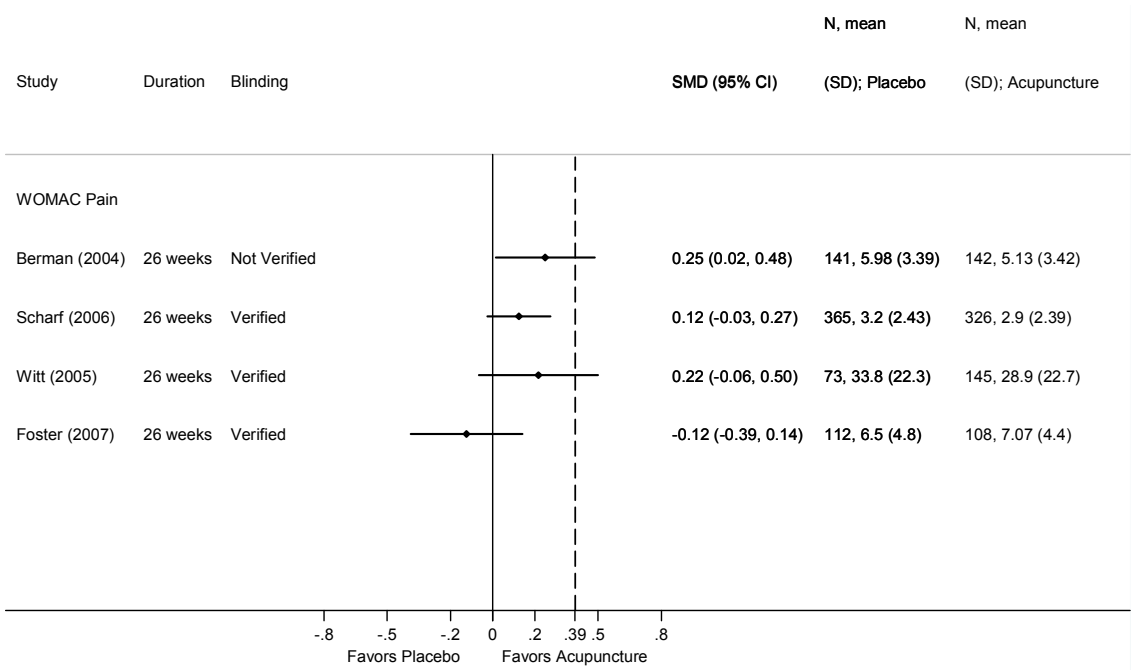
Figure 26. Acupuncture vs. Placebo - WOMAC Pain (12-14 weeks)



*Dashed line indicates MCII for WOMAC Pain

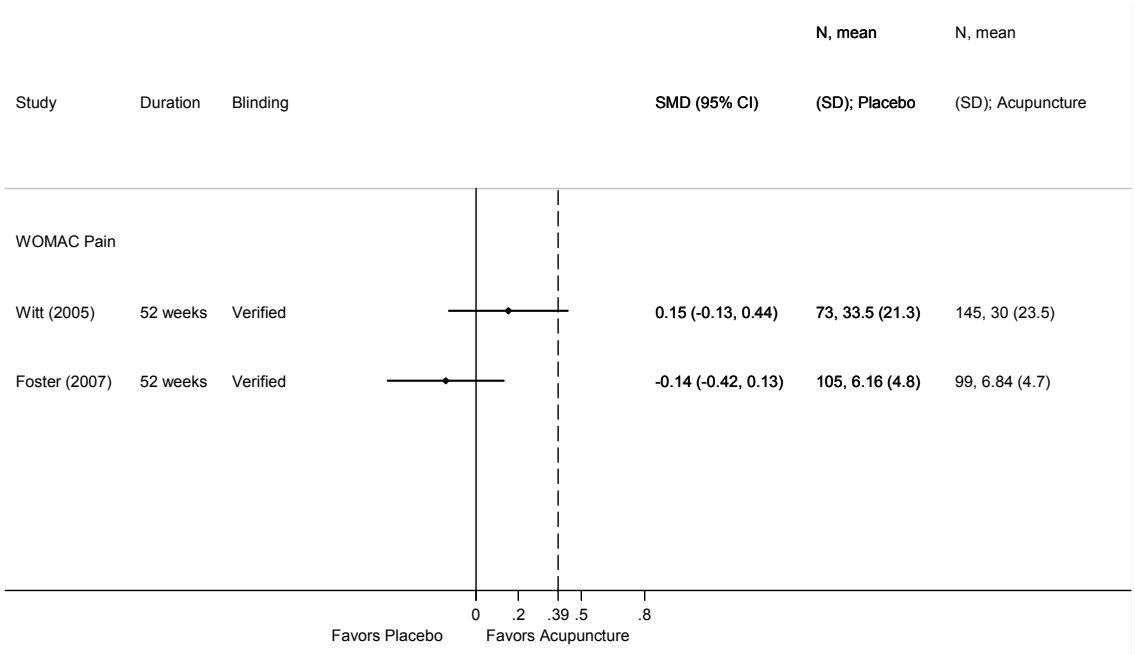
The effects of acupuncture on pain (as measured by the WOMAC) at 26 weeks are shown below. We did not perform a meta-analysis of these data because one study did not verify that its patients were blinded

Figure 27. Acupuncture vs. Placebo - WOMAC Pain (26 weeks)



*Dashed line indicates MCII for WOMAC Pain

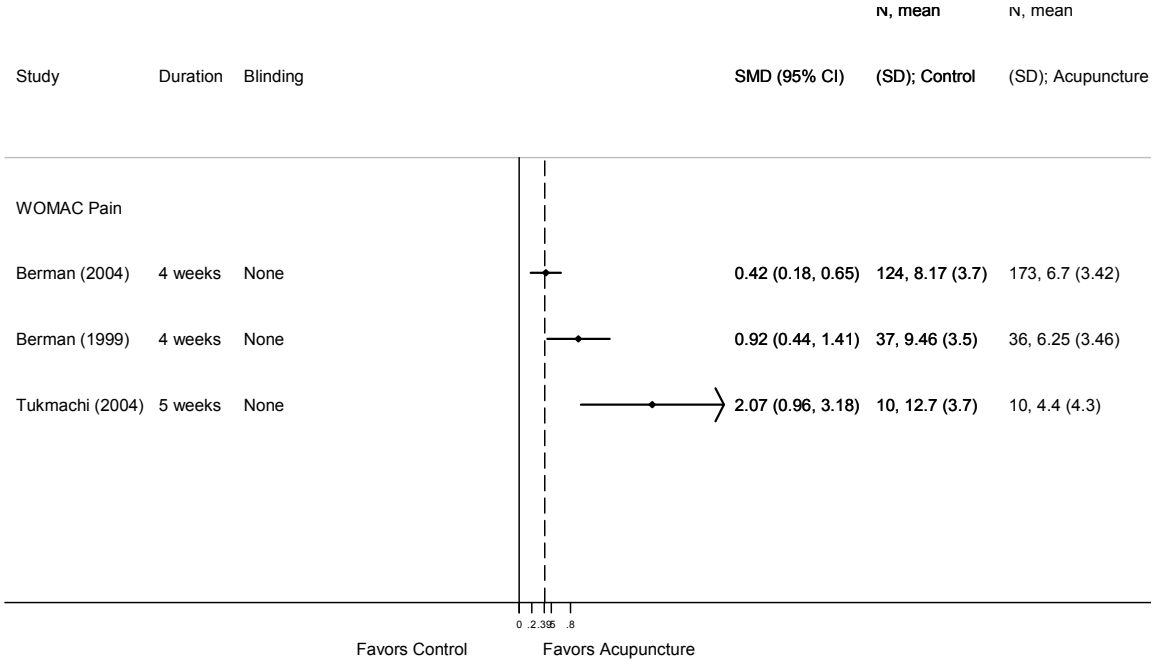
Figure 28. Acupuncture vs. Placebo - WOMAC Pain (52 weeks)



*Dashed line indicates MCII for WOMAC Pain

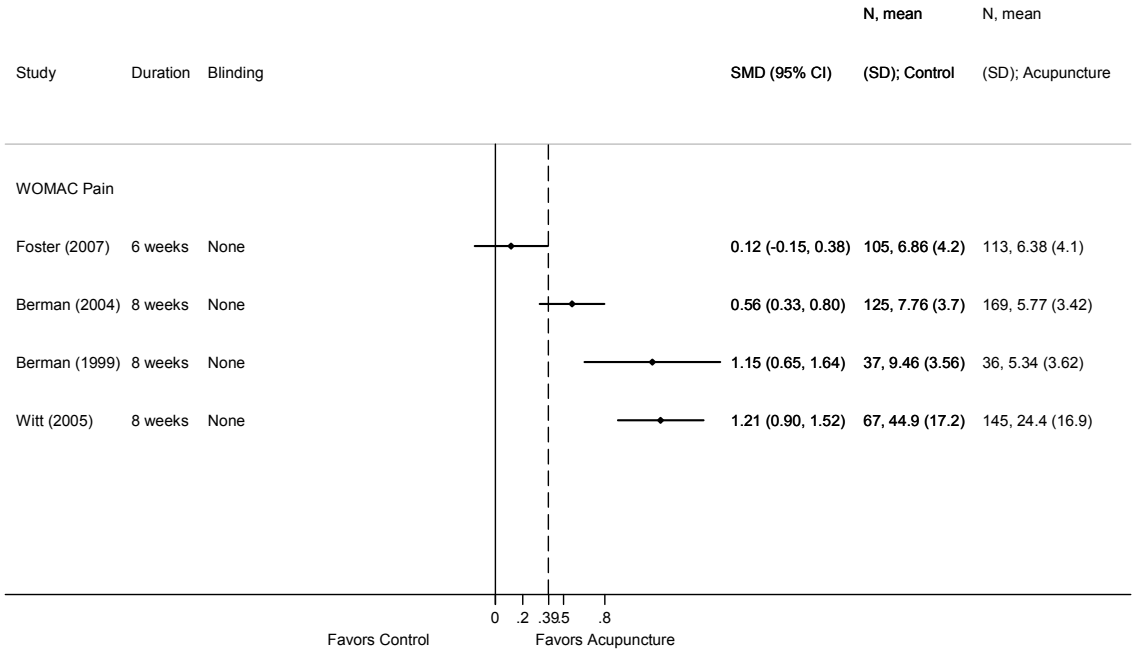
Figure 29 - Figure 33 present the results of acupuncture vs. non-sham control (wait list or usual care) on the WOMAC Pain Subscale. We did not perform meta-analyses of these data because the relevant studies did not blind their non-sham control group patients.

Figure 29. Acupuncture vs. Control - WOMAC Pain (4-5 weeks)



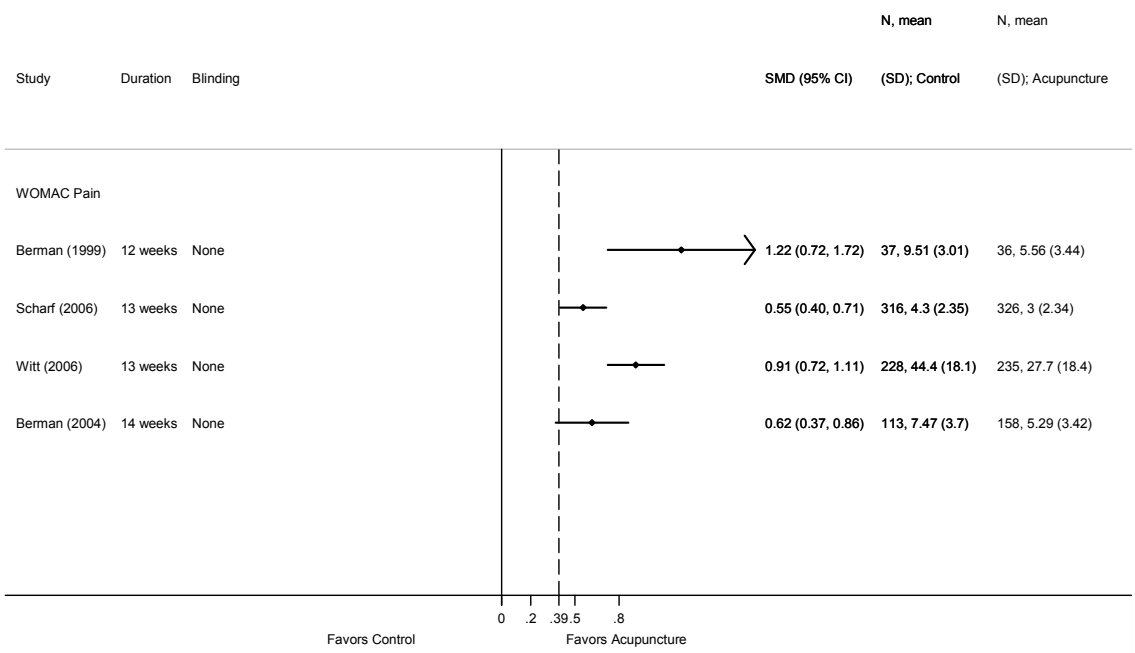
*Dashed line indicates MCII for WOMAC Pain

Figure 30. Acupuncture vs. Control - WOMAC Pain (6-8 weeks)



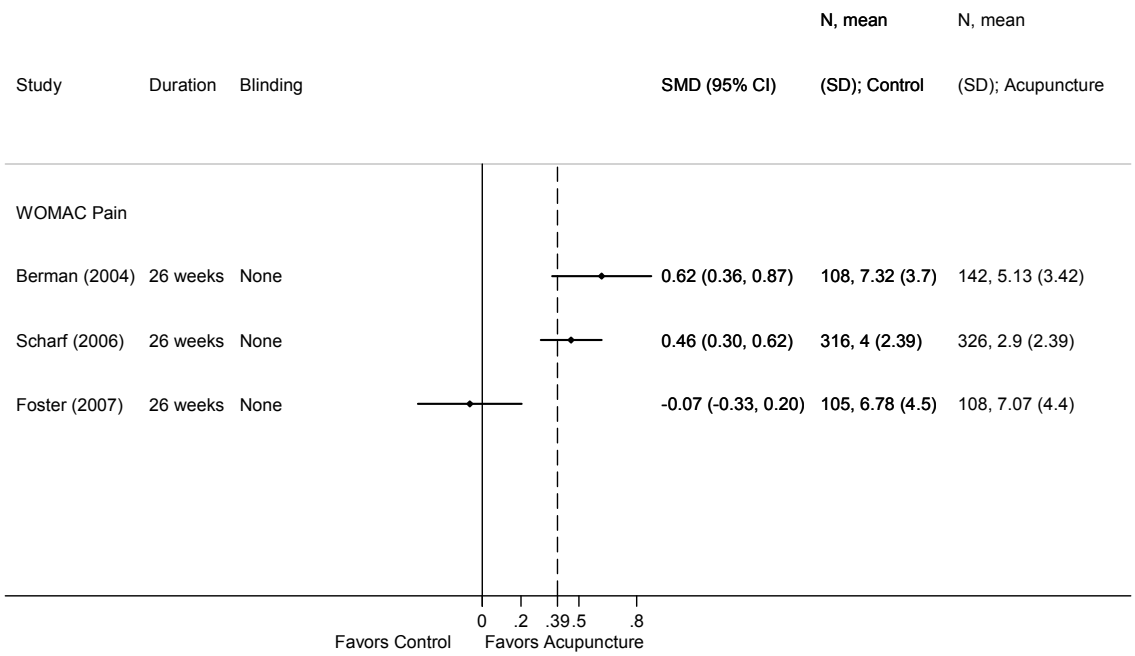
*Dashed line indicates MCII for WOMAC Pain

Figure 31. Acupuncture vs. Control - WOMAC Pain (12-14 weeks)



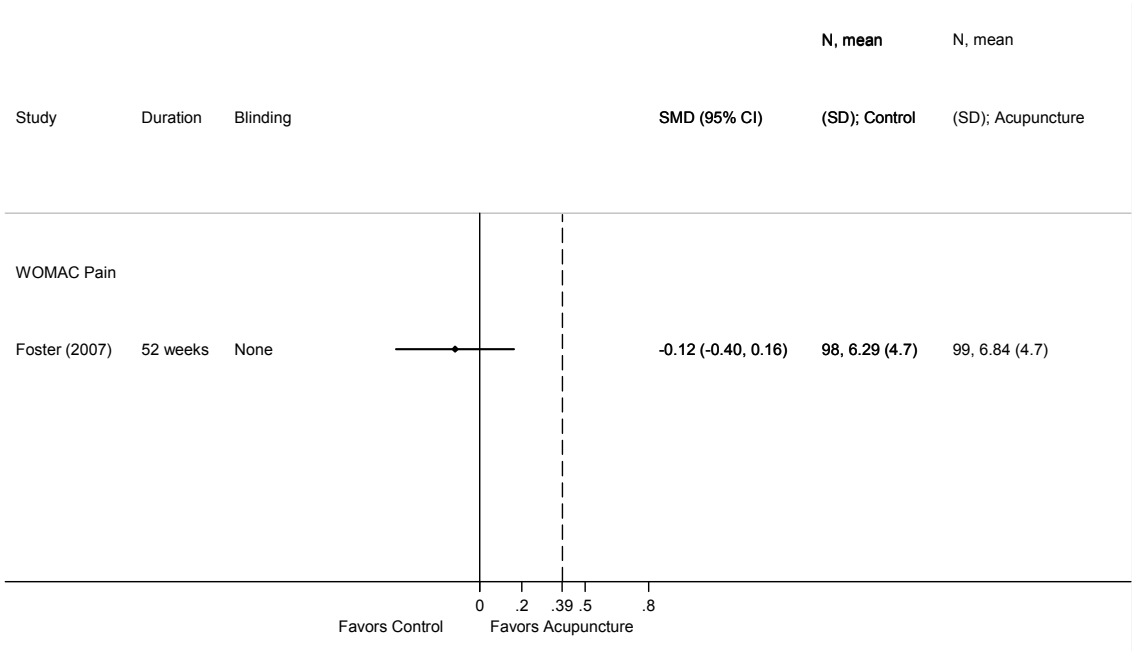
*Dashed line indicates MCII for WOMAC Pain

Figure 32. Acupuncture vs. Control - WOMAC Pain (26 weeks)



*Dashed line indicates MCII for WOMAC Pain

Figure 33. Acupuncture vs. Control - WOMAC Pain (52 weeks)

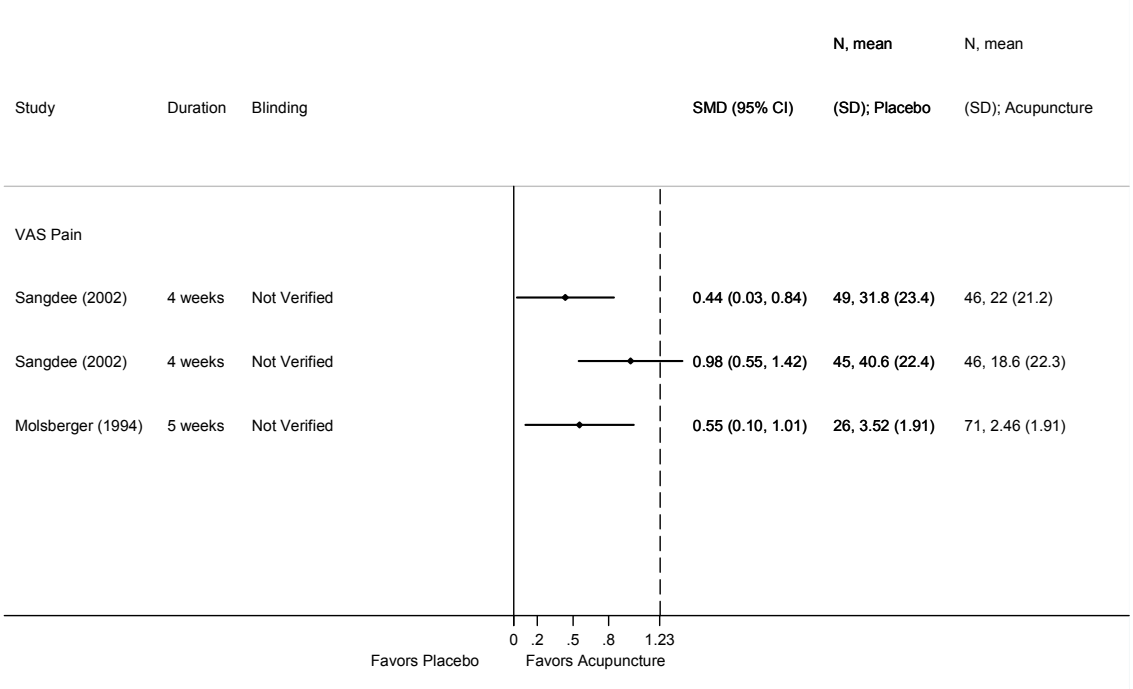


*Dashed line indicates MCII for WOMAC Pain

PAIN - VAS
Level of Evidence:
One Level I RCT and Three Level II RCTs

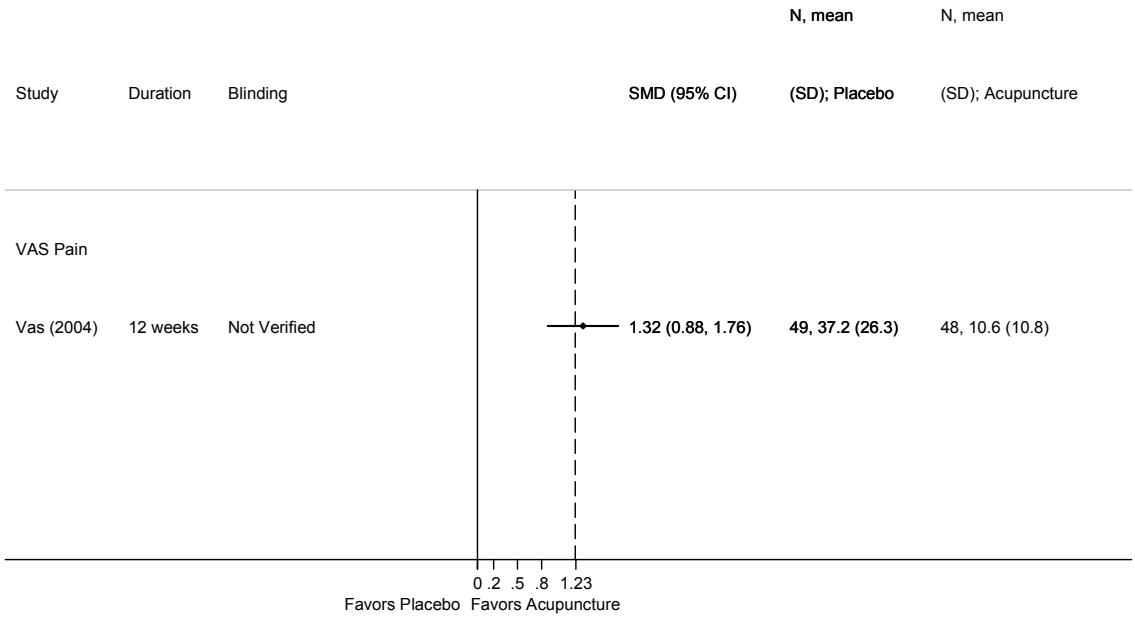
Figure 34 - Figure 35 depict the results of acupuncture vs. placebo on pain measured by VAS, while Figure 36 depicts the results of acupuncture vs. non-sham control. None of the relevant studies verified that their patients were blinded.

Figure 34. Acupuncture vs. Placebo - VAS Pain (4-5 weeks)



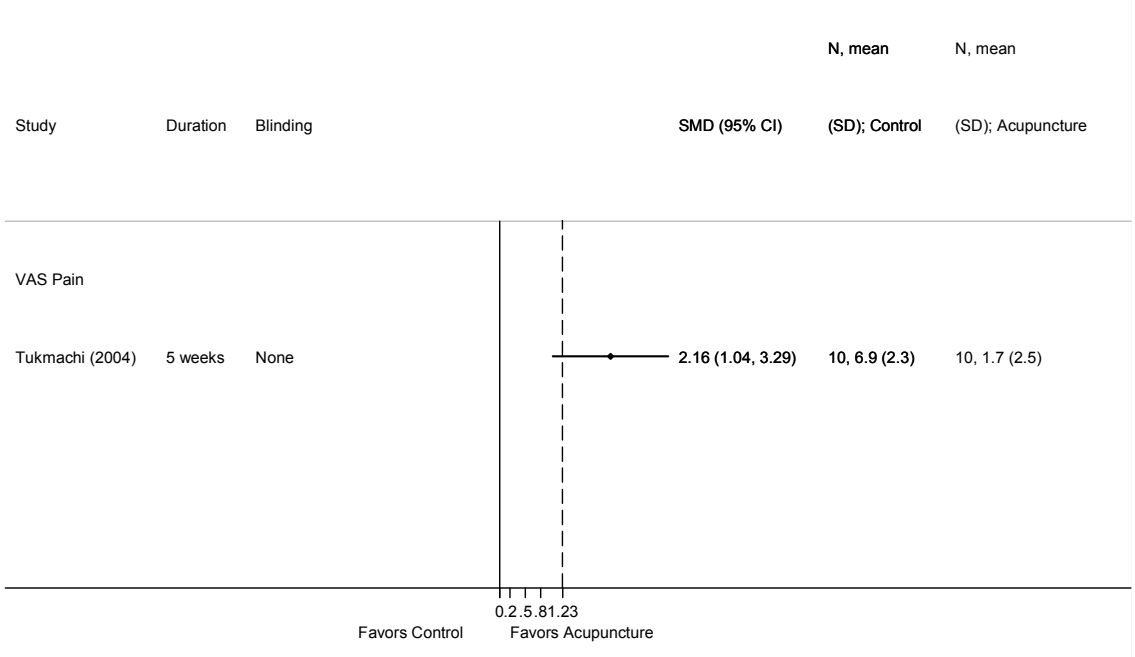
*Dashed line indicates MCII for VAS Pain

Figure 35. Acupuncture vs. Placebo - VAS Pain (12 weeks)



*Dashed line indicates MCII for VAS Pain

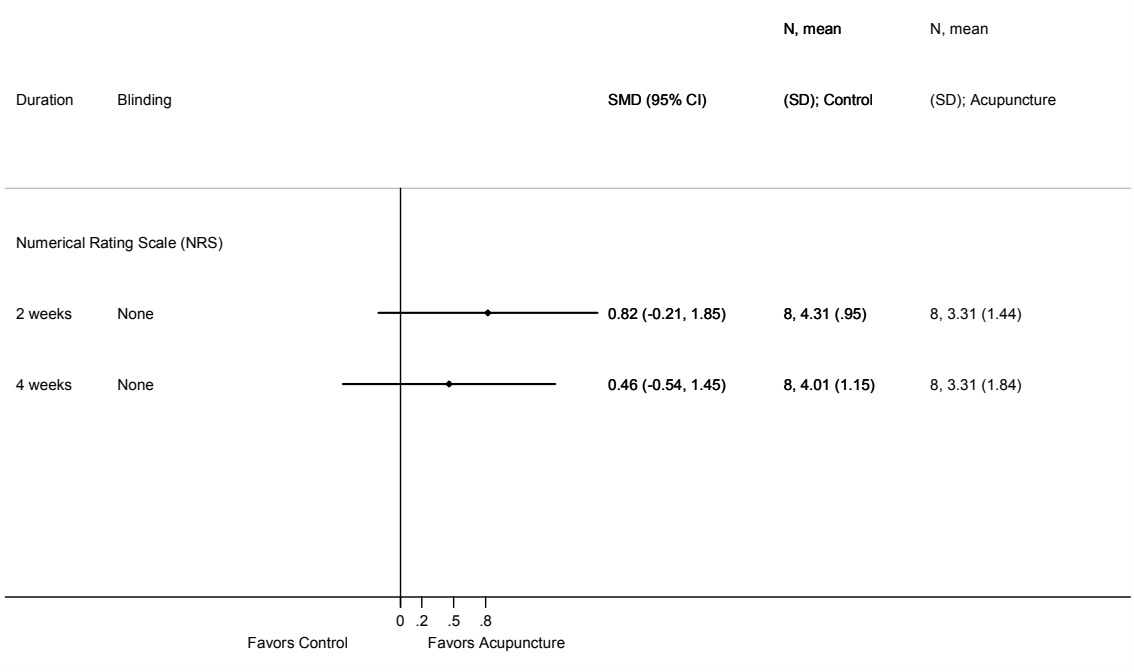
Figure 36. Acupuncture vs. Control - VAS Pain



*Dashed line indicates MCII for VAS Pain

PAIN - NRS
Level of Evidence:
One Level II RCT

Figure 37. Acupuncture vs. Control – NRS Pain (Ng et al. 2003)



PAIN INTENSITY - NRS
Level of Evidence:
One Level I RCT

Figure 38. Acupuncture vs. Placebo – NRS Pain Intensity (Foster et al. 2007)

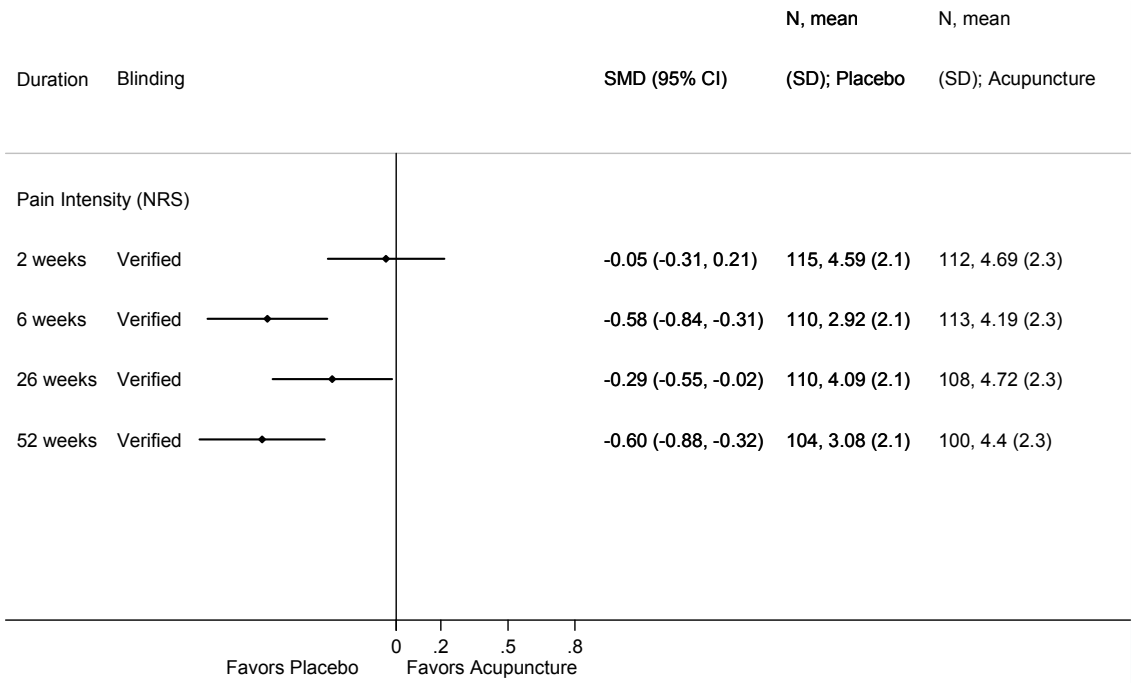
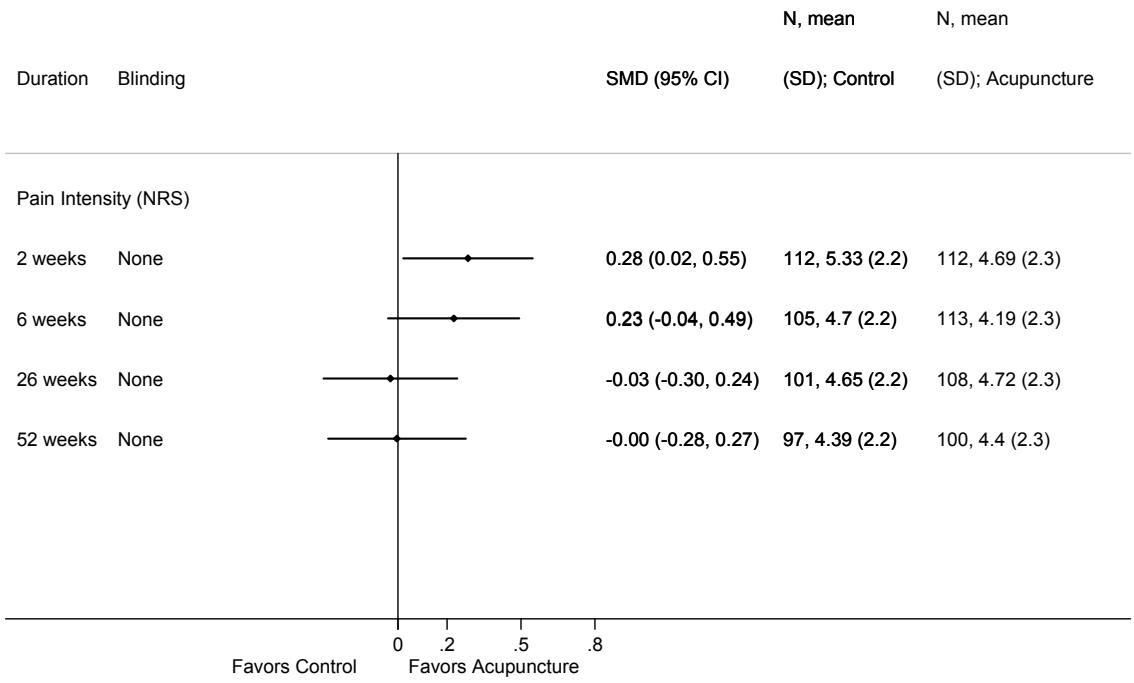


Figure 39. Acupuncture vs. Control – NRS Pain Intensity (Foster et al. 2007)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

PAIN UNPLEASANTNESS - NRS
Level of Evidence:
One Level I RCT

Figure 40. Acupuncture vs. Placebo – NRS Pain Unpleasantness (Foster et al. 2007)

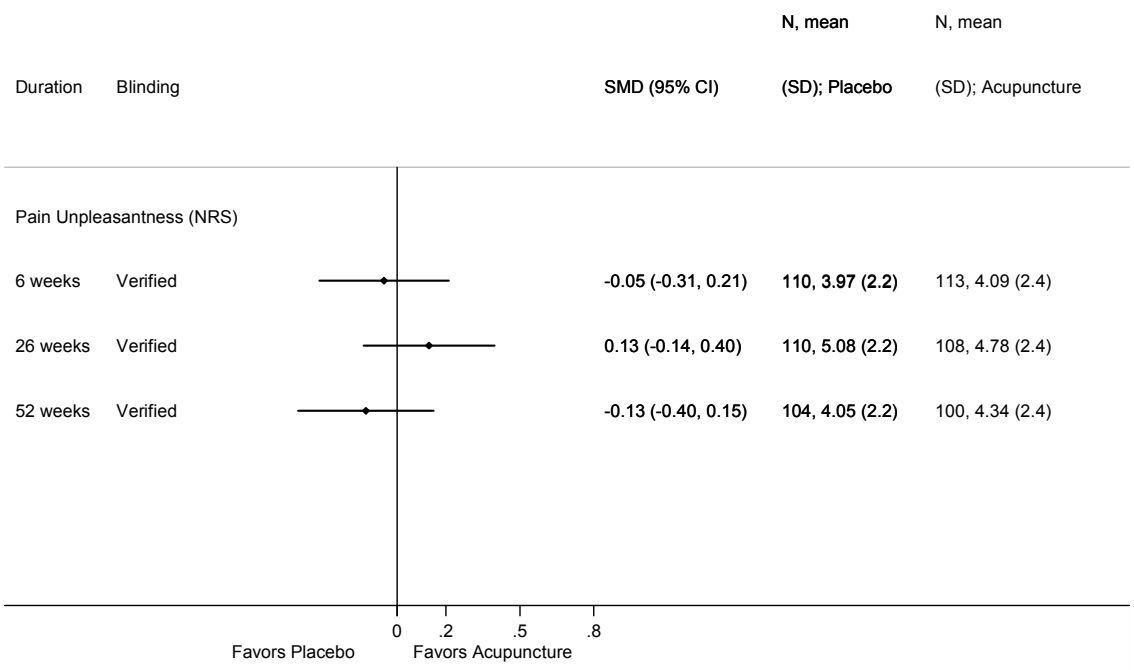
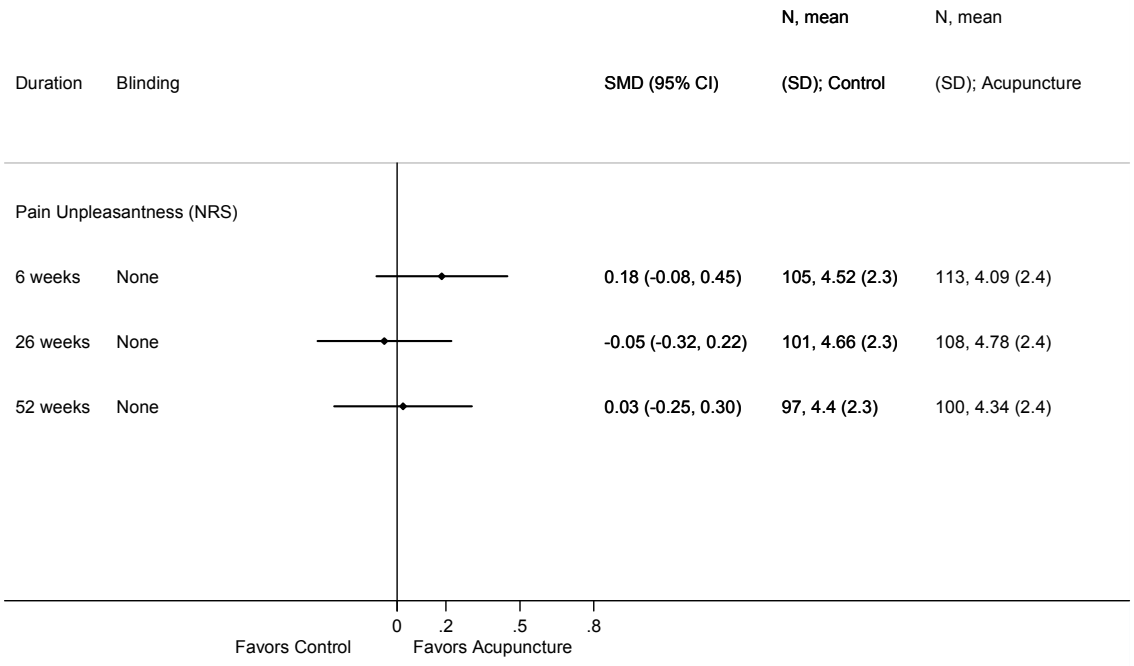


Figure 41. Acupuncture vs. Control - NRS Pain Unpleasantness (Foster et al. 2007)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

AFFECTIVE PAIN – SES
Level of Evidence:
One Level I RCT

Figure 42. Acupuncture vs. Placebo – SES (Schmerzempfindungs-Skala) Affective Pain (Witt et al. 2005)

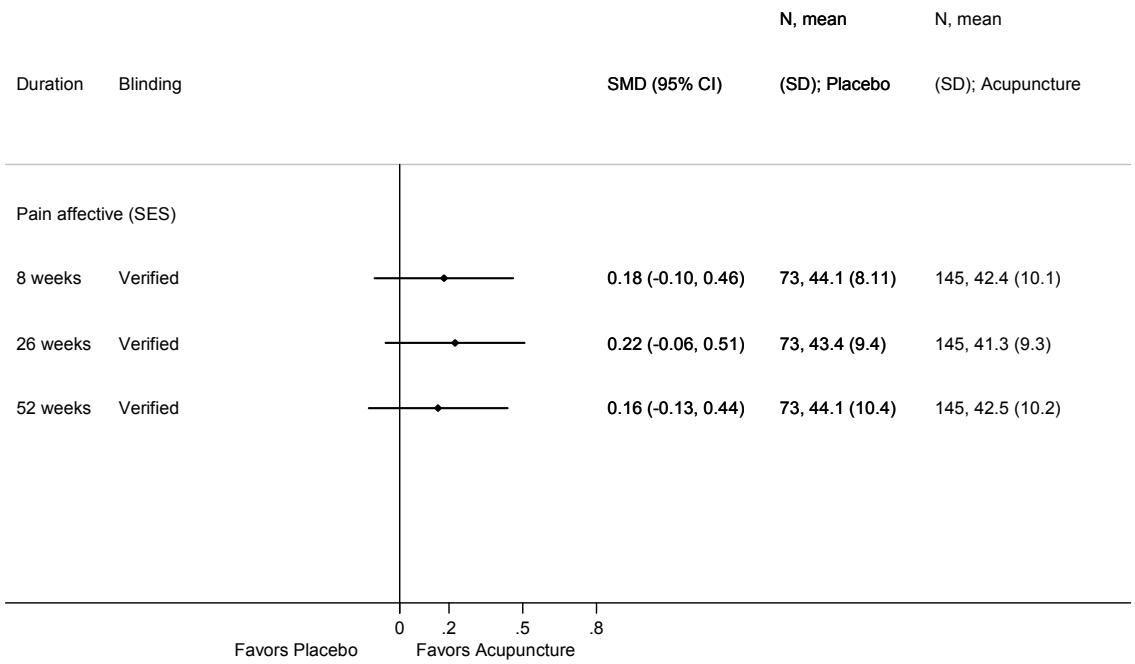
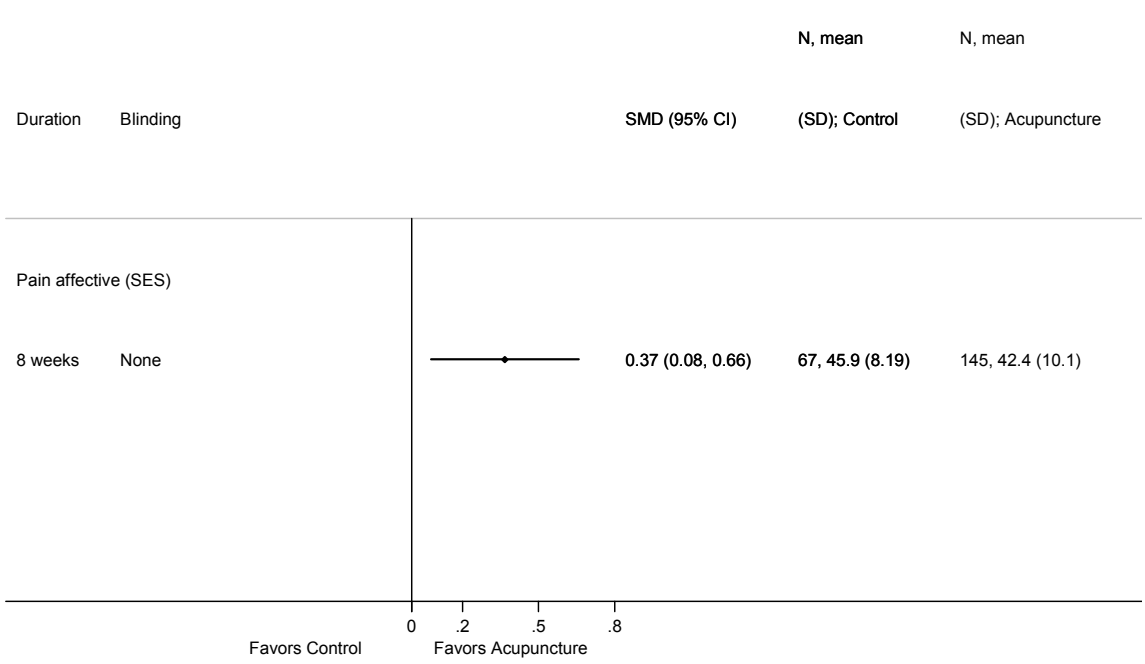


Figure 43. Acupuncture vs. Control - SES Affective Pain (Witt et al. 2005)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

SENSORIC PAIN - SES
Level of Evidence:
One Level I RCT

Figure 44. Acupuncture vs. Placebo – SES Sensoric Pain (Witt et al. 2005)

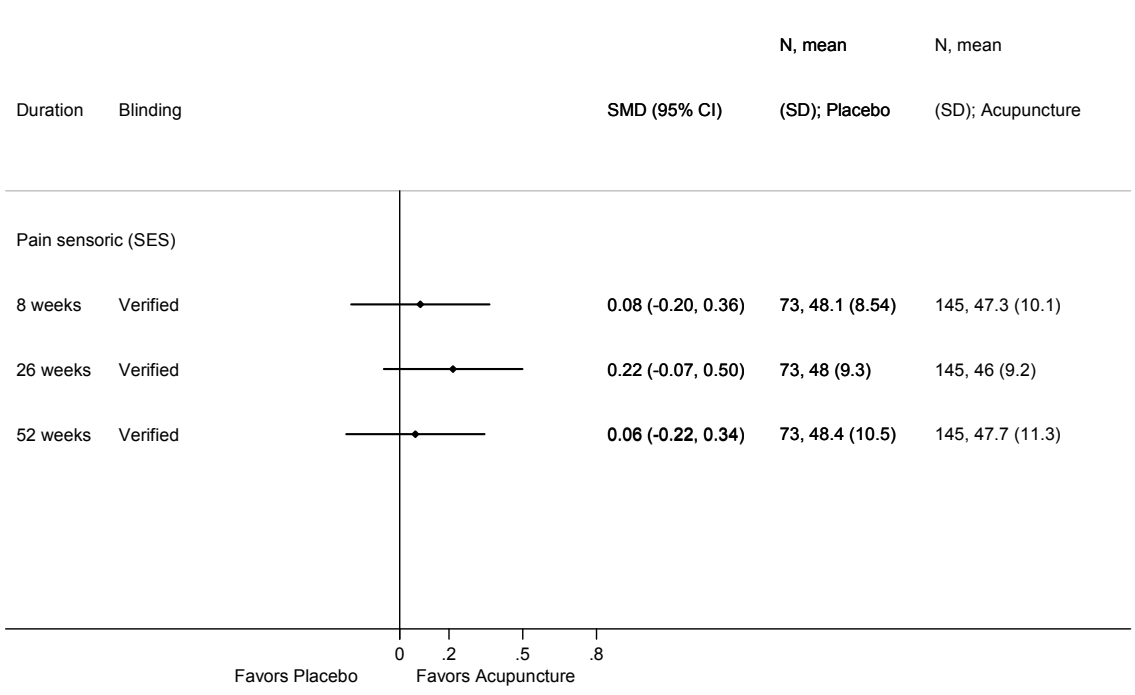
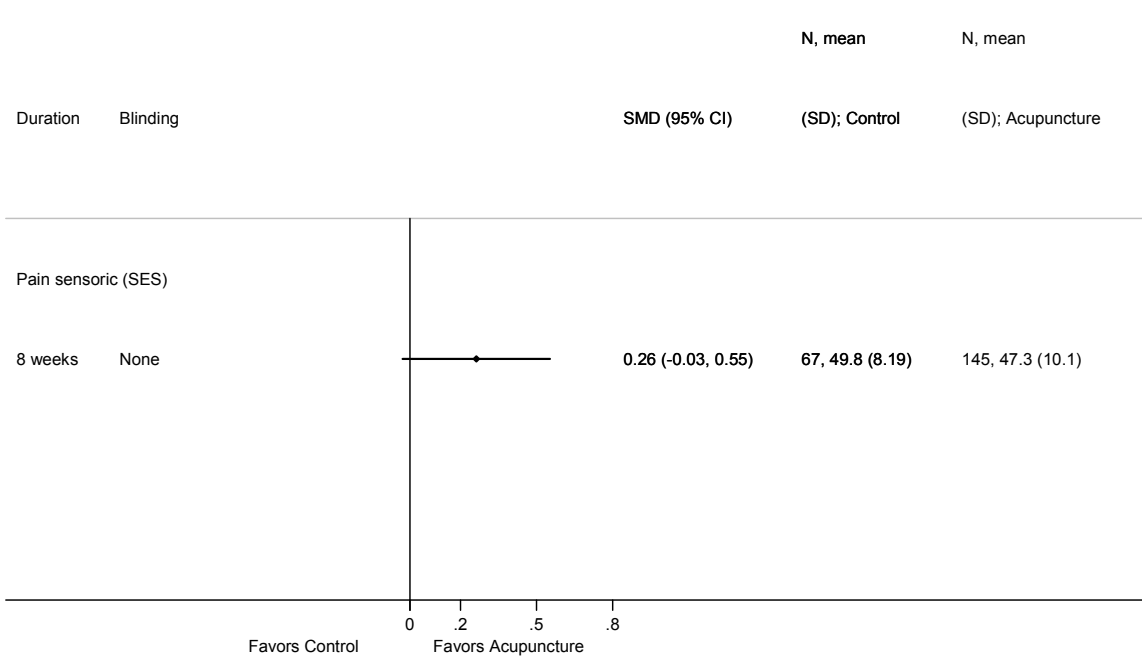


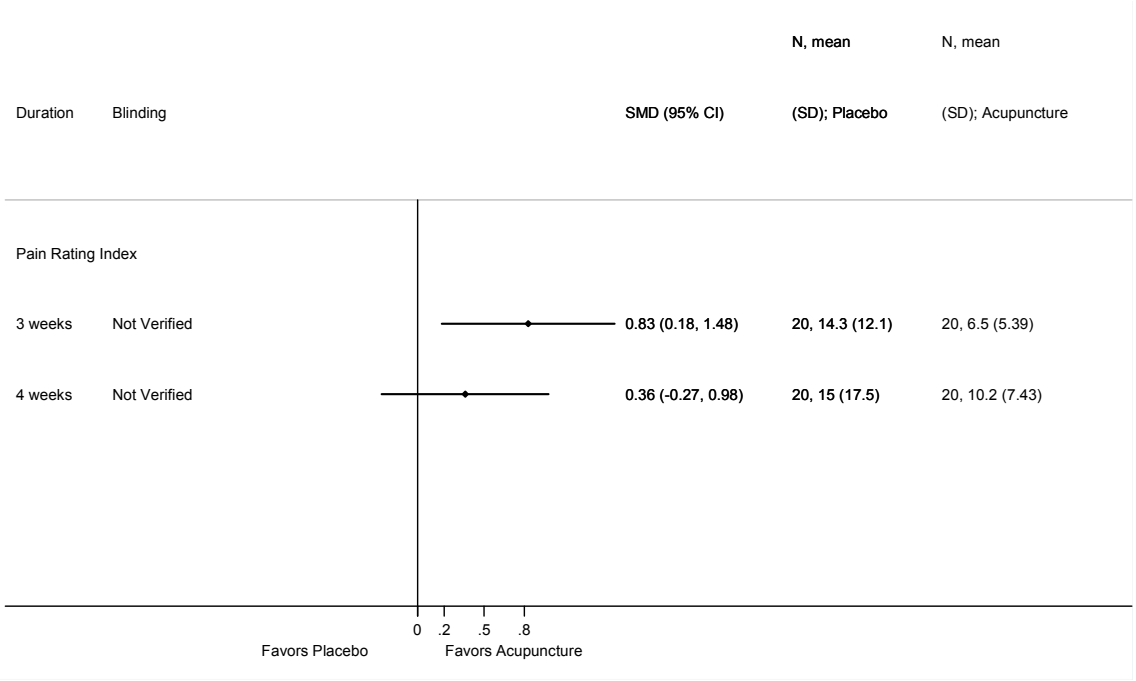
Figure 45. Acupuncture vs. Control – SES Sensoric Pain (Witt et al. 2005)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

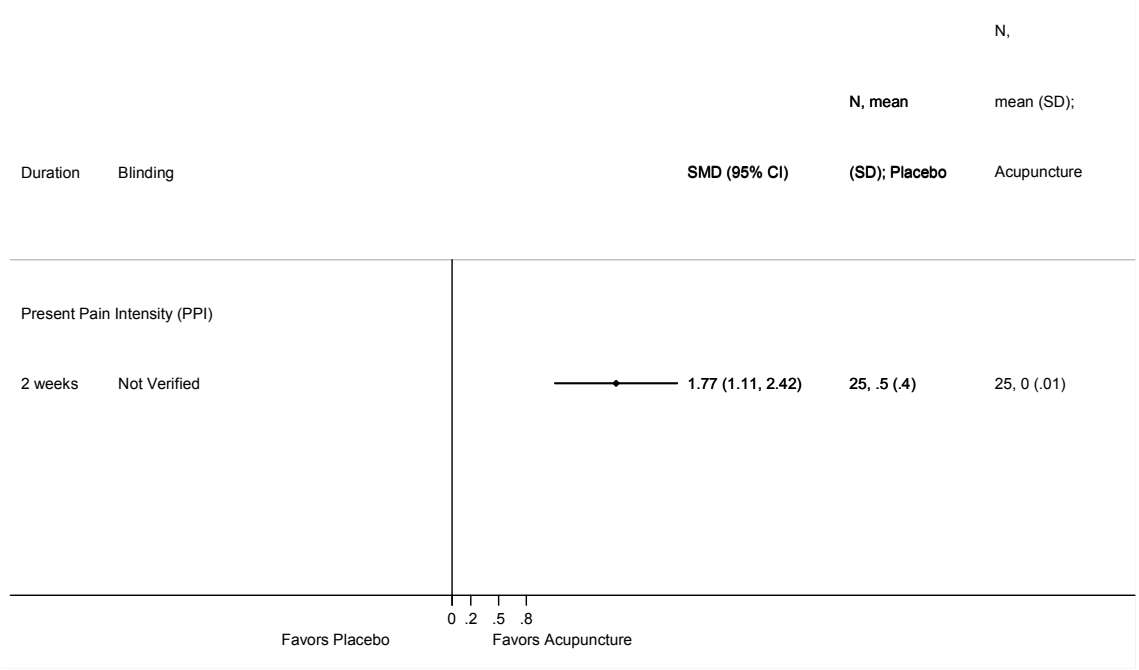
PAIN RATING INDEX
Level of Evidence:
One Level II RCT

Figure 46. Acupuncture vs. Placebo - Pain Rating Index (Takeda et al. 1994)



PRESENT PAIN INTENSITY
Level of Evidence:
One Level II RCT

Figure 47. Acupuncture vs. Placebo -Present Pain Intensity (Yurtkuran et al. 1999)



PAIN DISABILITY INDEX
Level of Evidence:
One Level I RCT

Figure 48. Acupuncture vs. Placebo - Pain Disability Index (Witt et al. 2005)

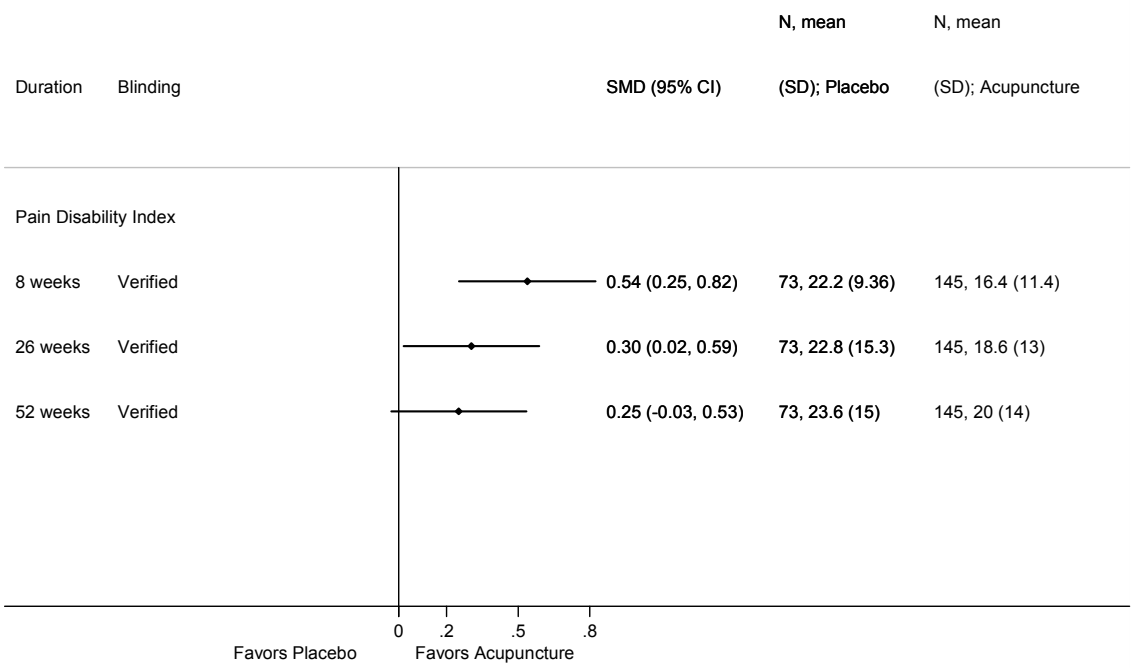
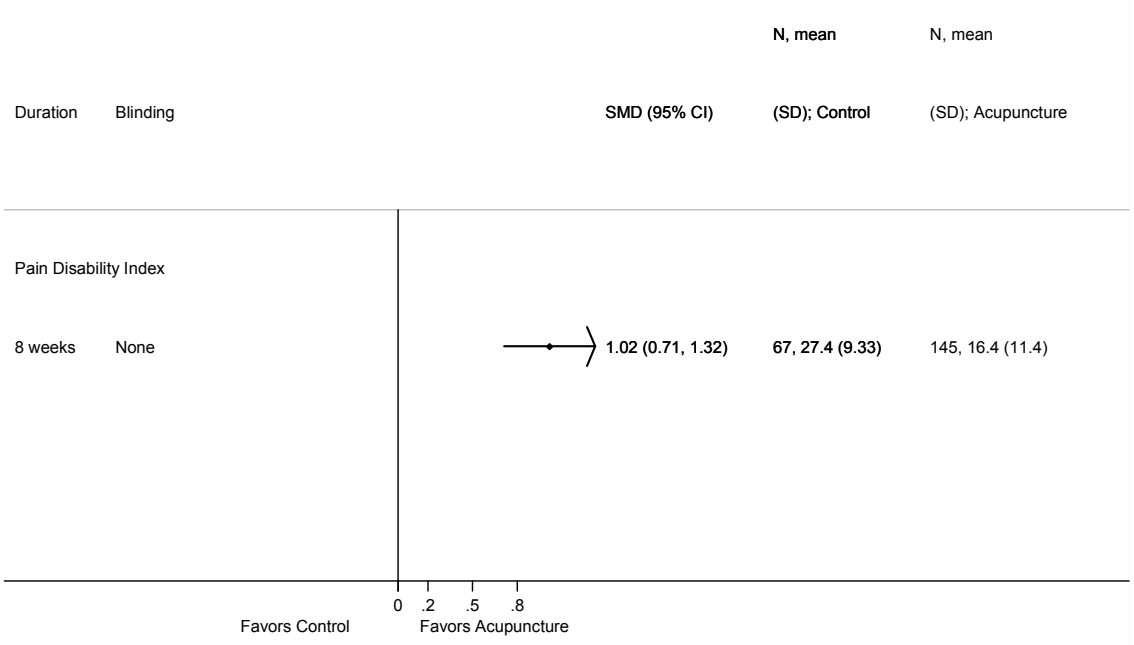


Figure 49. Acupuncture vs. Control - Pain Disability Index (Witt et al. 2005)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

LEQUESNE INDEX
Level of Evidence:
Two Level II RCTs

Figure 50. Acupuncture vs. Placebo - Lequesne Index

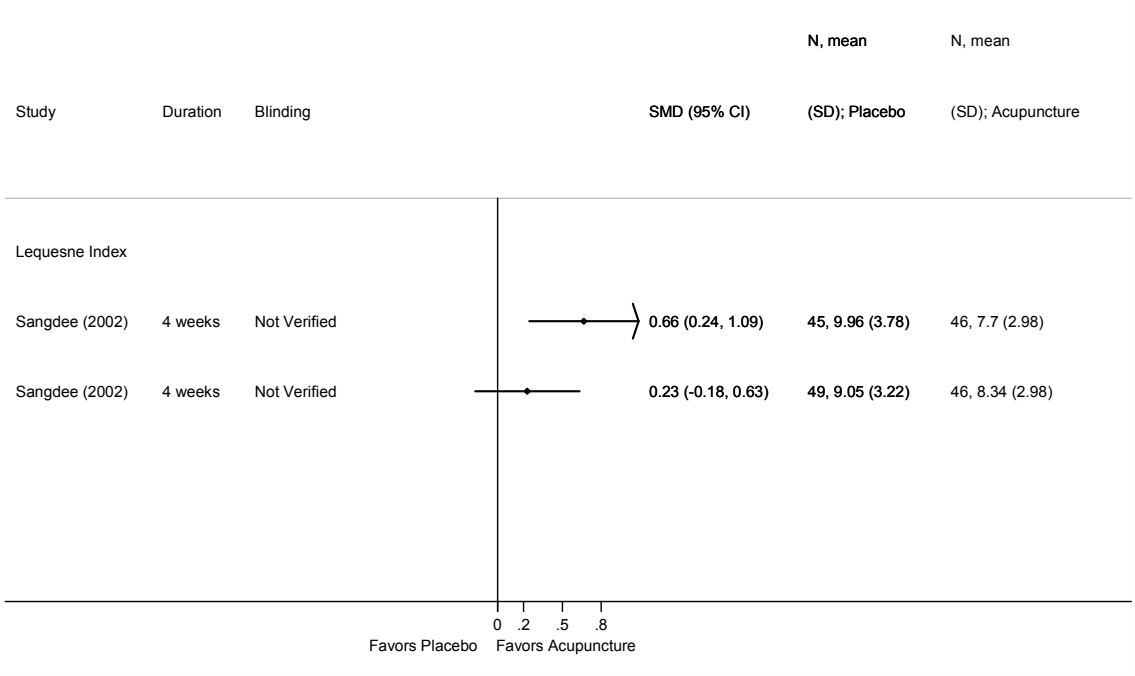
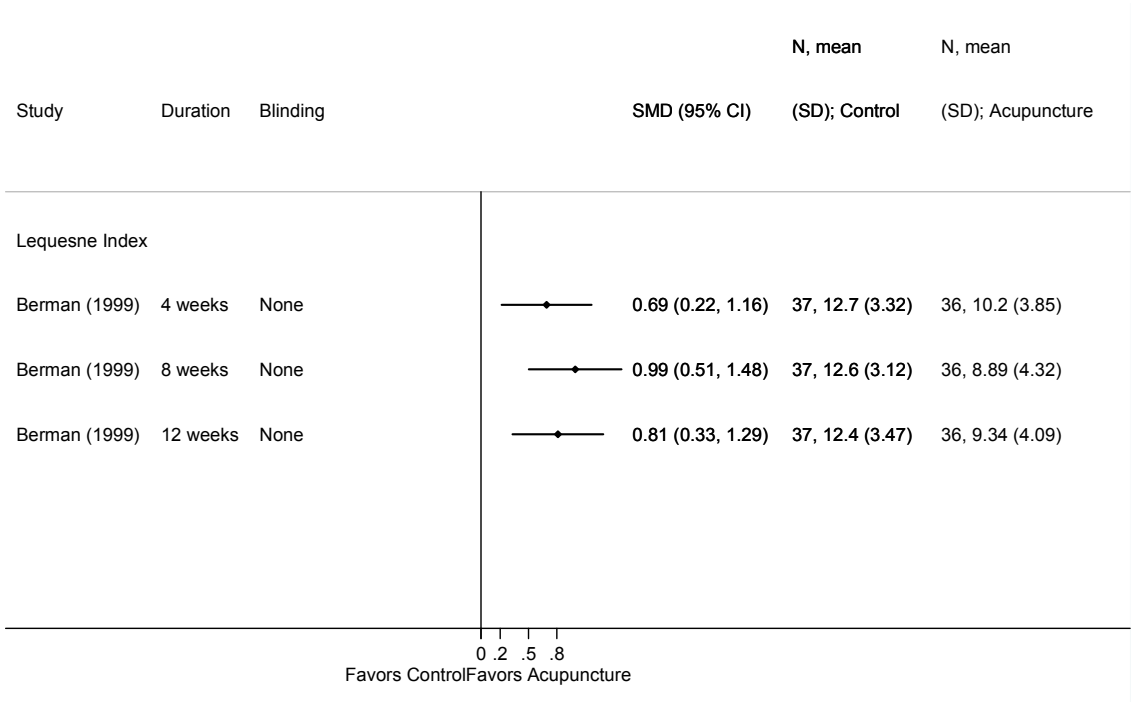


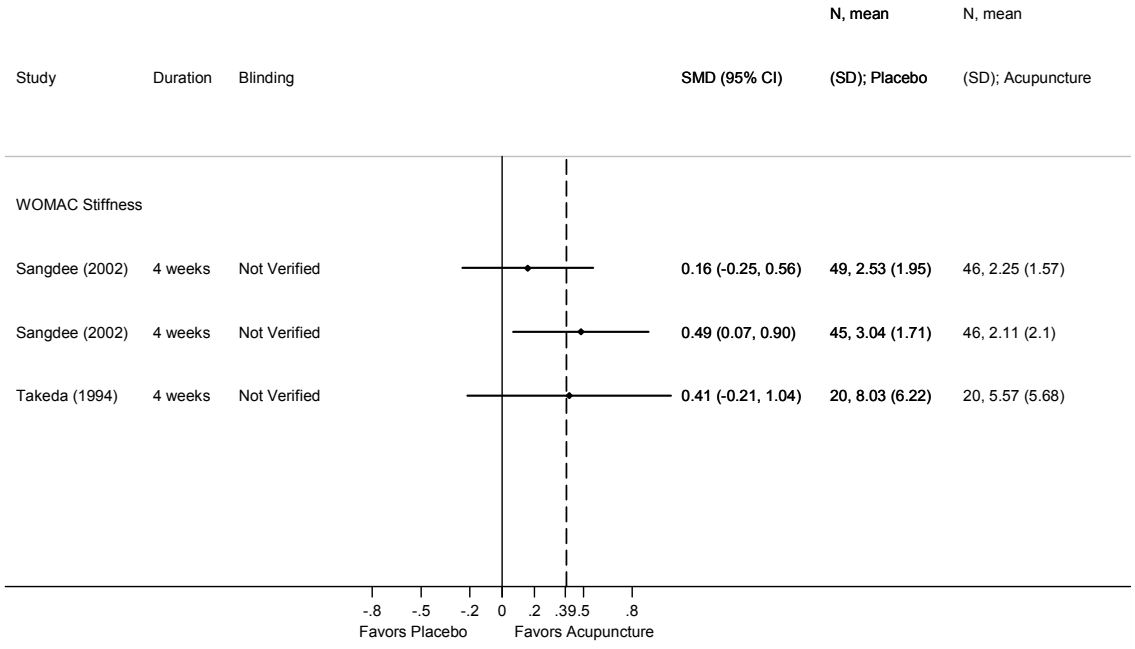
Figure 51. Acupuncture vs. Control - Lequesne Index



STIFFNESS - WOMAC
Level of Evidence:
Three Level I RCTs and Four Level II RCTs

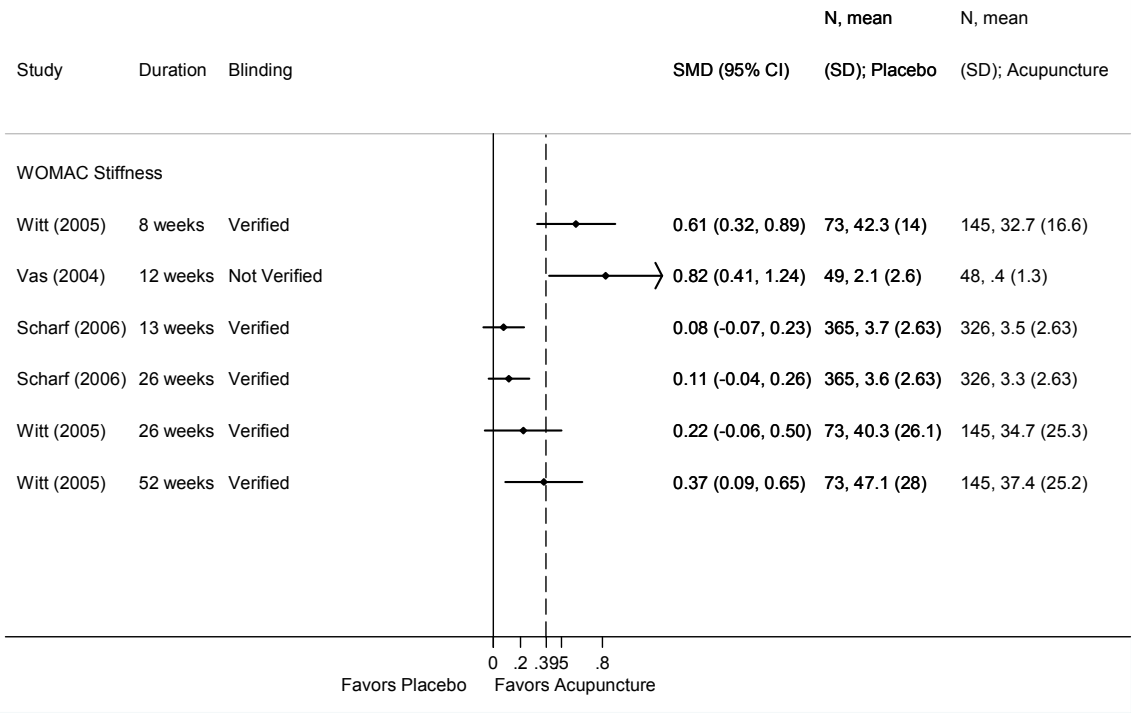
Figure 52 presents the results of two RCTs investigating acupuncture vs. placebo using the WOMAC Stiffness subscale at 4 weeks.[32, 69] Figure 53 presents the results of three RCTs investigating acupuncture vs. placebo using the WOMAC Stiffness subscale at all durations greater than 4 weeks,[58, 68, 70] while Figure 54 presents the results of four RCTs investigating acupuncture vs. non-sham control using the WOMAC Stiffness subscale at all durations.[58, 67, 68, 72] Several studies (2 of 7) compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

Figure 52. Acupuncture vs. Placebo - WOMAC Stiffness (4 weeks)



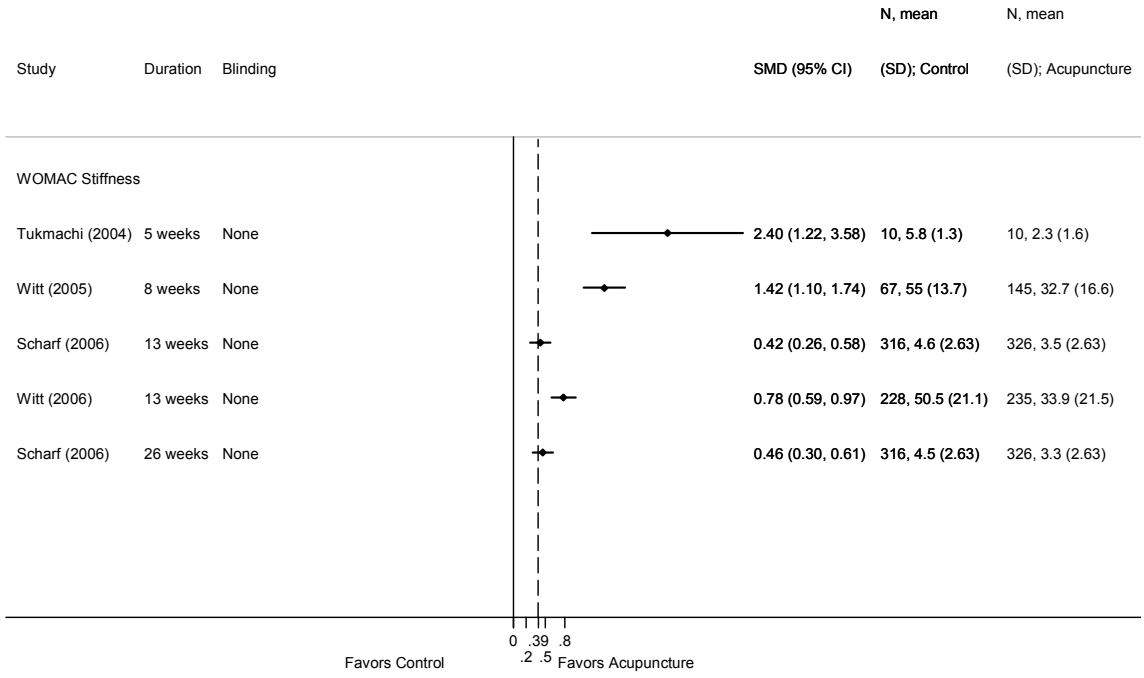
*Dashed line indicates MCII for WOMAC Stiffness

Figure 53. Acupuncture vs. Placebo - WOMAC Stiffness (8-52 weeks)



*Dashed line indicates MCII for WOMAC Stiffness

Figure 54. Acupuncture vs. Control - WOMAC Stiffness (all durations)

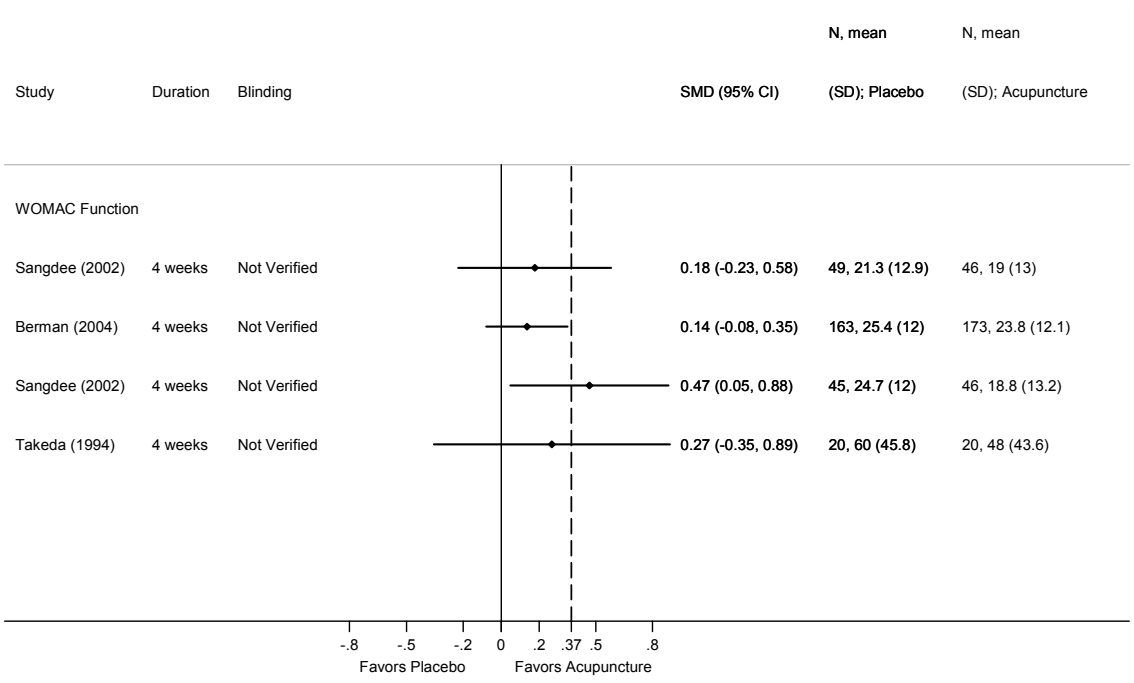


*Dashed line indicates MCII for WOMAC Stiffness

FUNCTION - WOMAC
Level of Evidence:
Four Level I RCTs and Five Level II RCTs

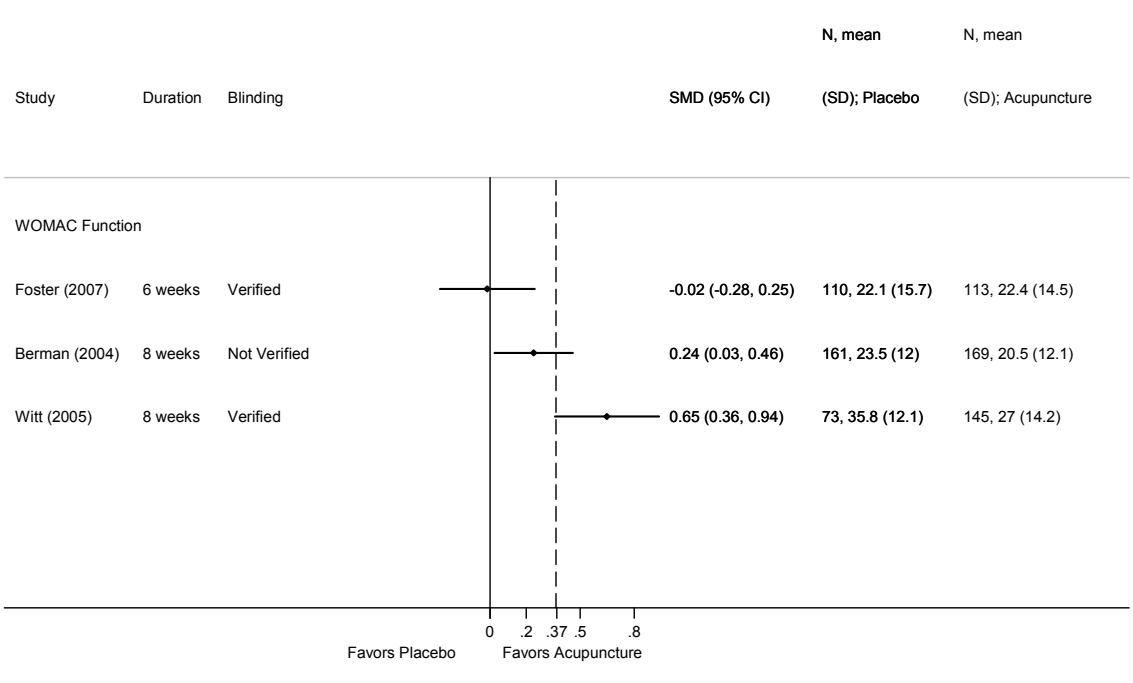
Figure 55 - Figure 59 present the results of trials comparing acupuncture to placebo at various durations on the WOMAC Function subscale.[31, 32, 58, 60, 68-70] Figure 60 - Figure 64 present the result of trials investigating acupuncture vs. non-sham control at various durations on the WOMAC Function subscale.[31, 58, 60, 67, 68, 71] We did not perform a meta-analysis of these data because not all of the studies verified that their patients were blinded. Several studies (4 of 9) compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

Figure 55. Acupuncture vs. Placebo - WOMAC Function (4 weeks)



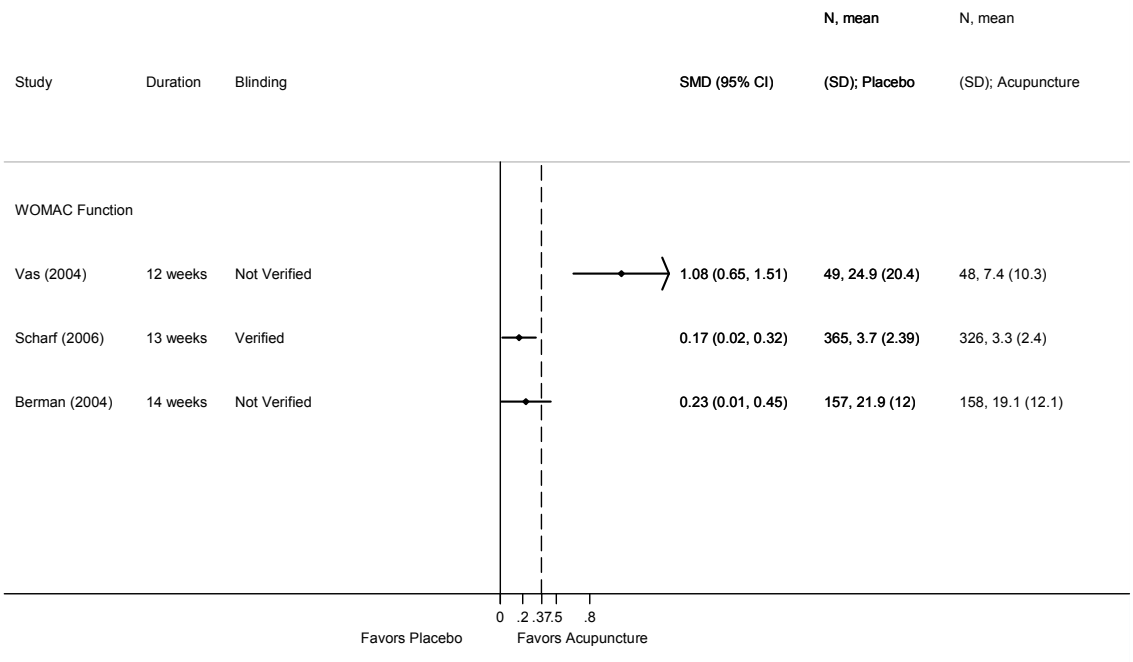
*Dashed line indicates MCII for WOMAC Function

Figure 56. Acupuncture vs. Placebo - WOMAC Function (6-8 weeks)



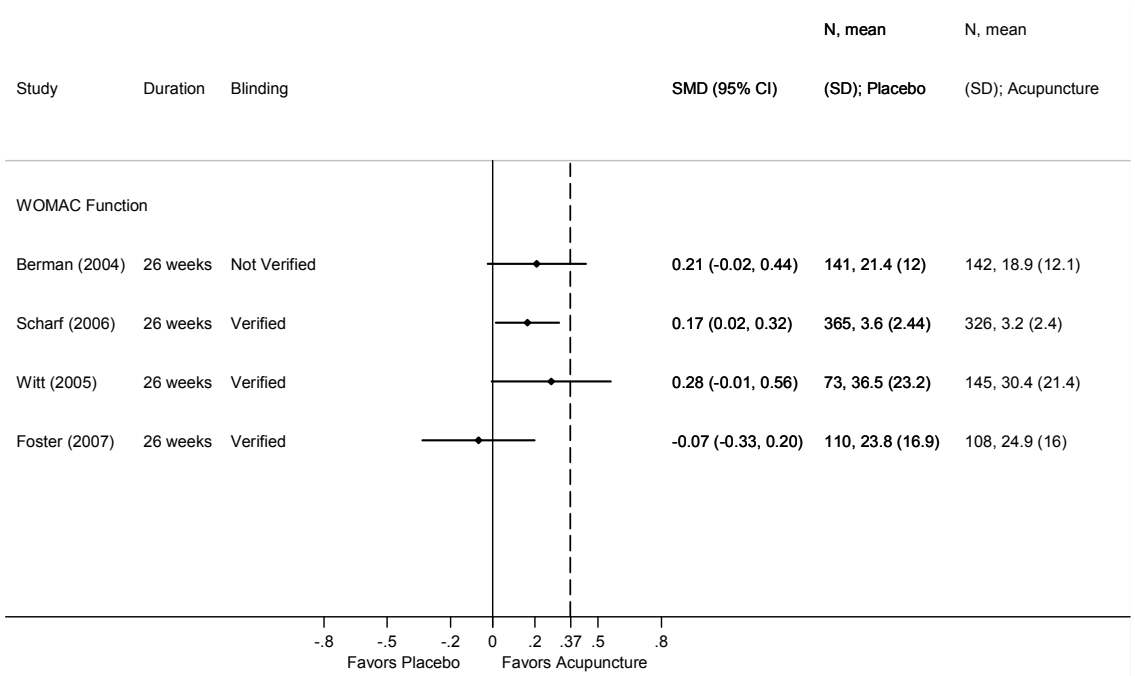
*Dashed line indicates MCII for WOMAC Function

Figure 57. Acupuncture vs. Placebo - WOMAC Function (12-14 weeks)



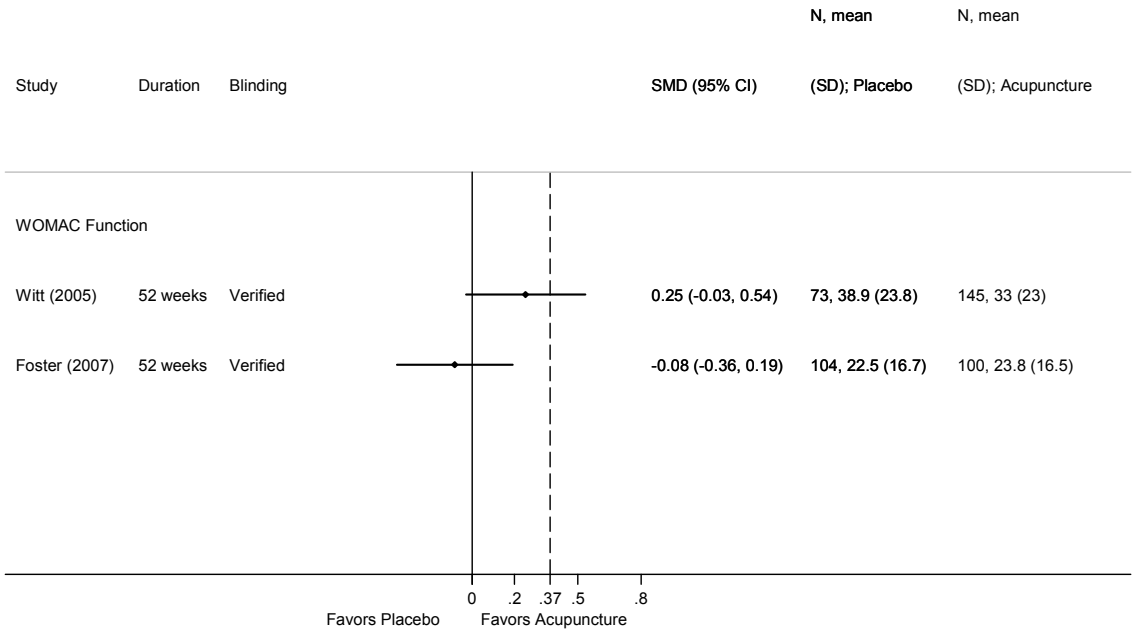
*Dashed line indicates MCII for WOMAC Function

Figure 58. Acupuncture vs. Placebo - WOMAC Function (26 weeks)



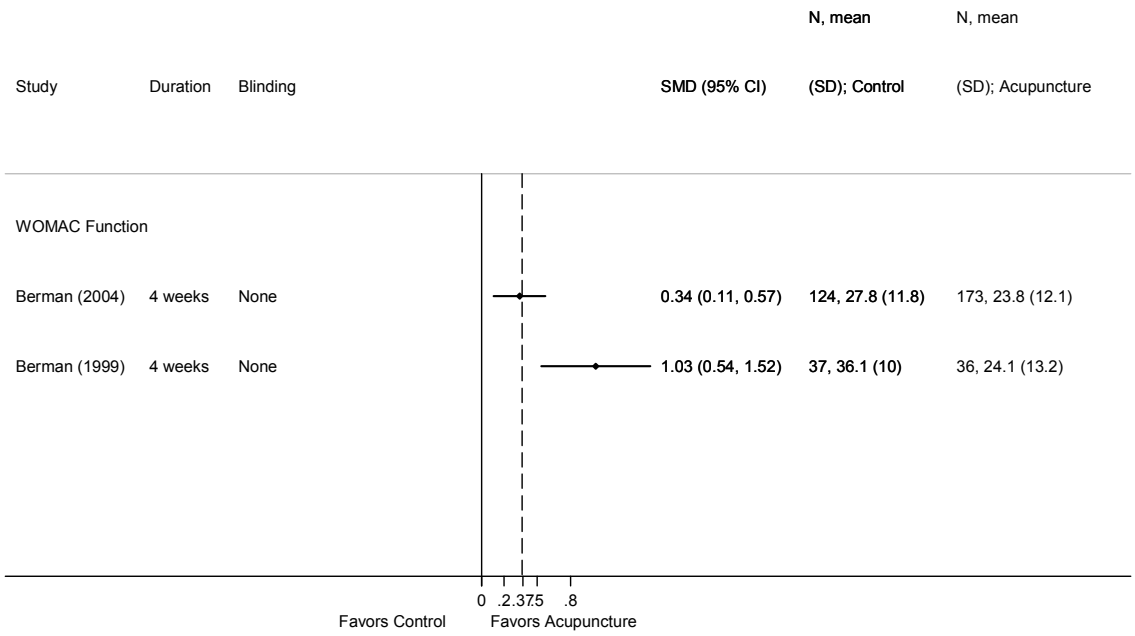
*Dashed line indicates MCII for WOMAC Function

Figure 59. Acupuncture vs. Placebo - WOMAC Function (52 weeks)



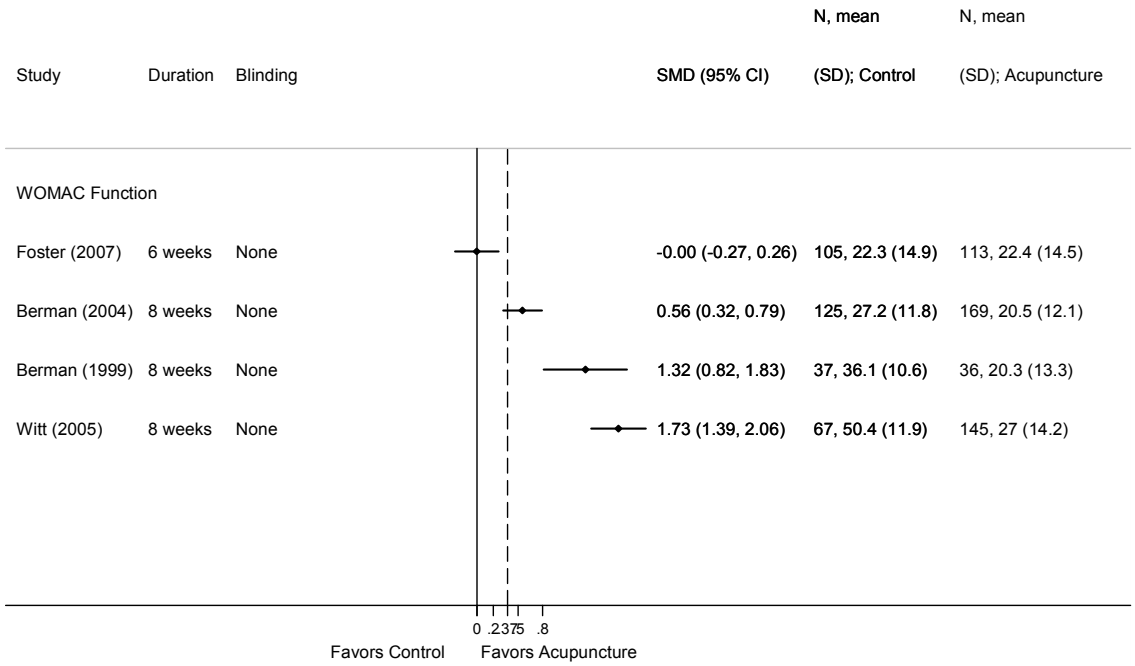
*Dashed line indicates MCII for WOMAC Function

Figure 60. Acupuncture vs. Control - WOMAC Function (4 weeks)



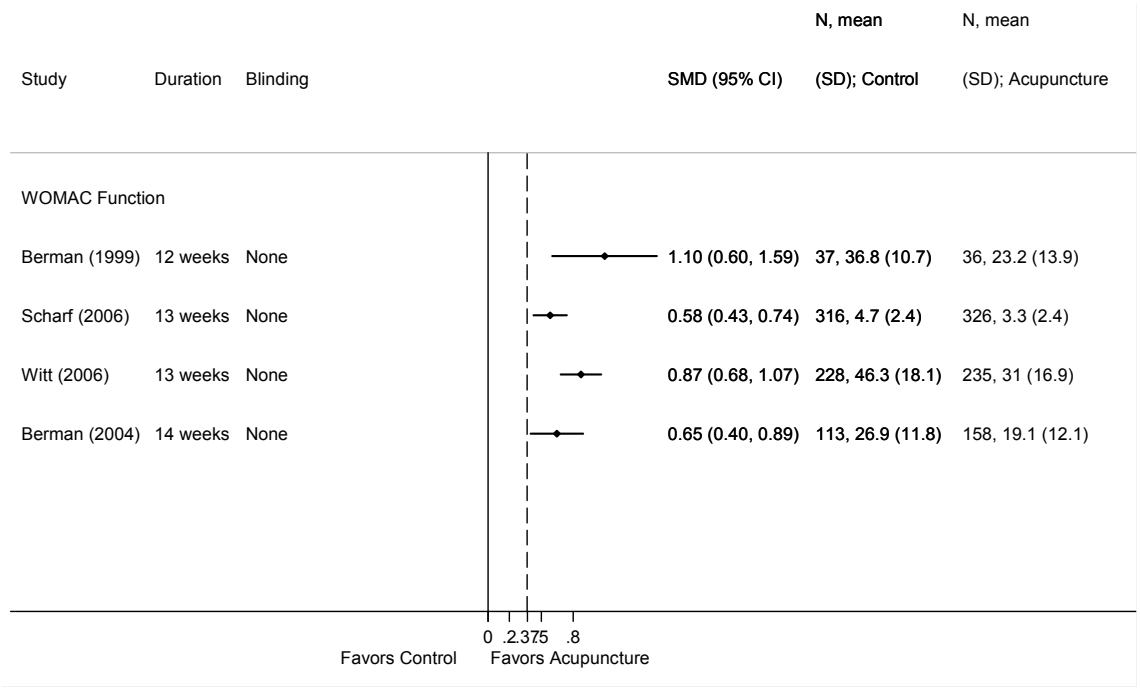
*Dashed line indicates MCII for WOMAC Function

Figure 61. Acupuncture vs. Control - WOMAC Function (6-8 weeks)



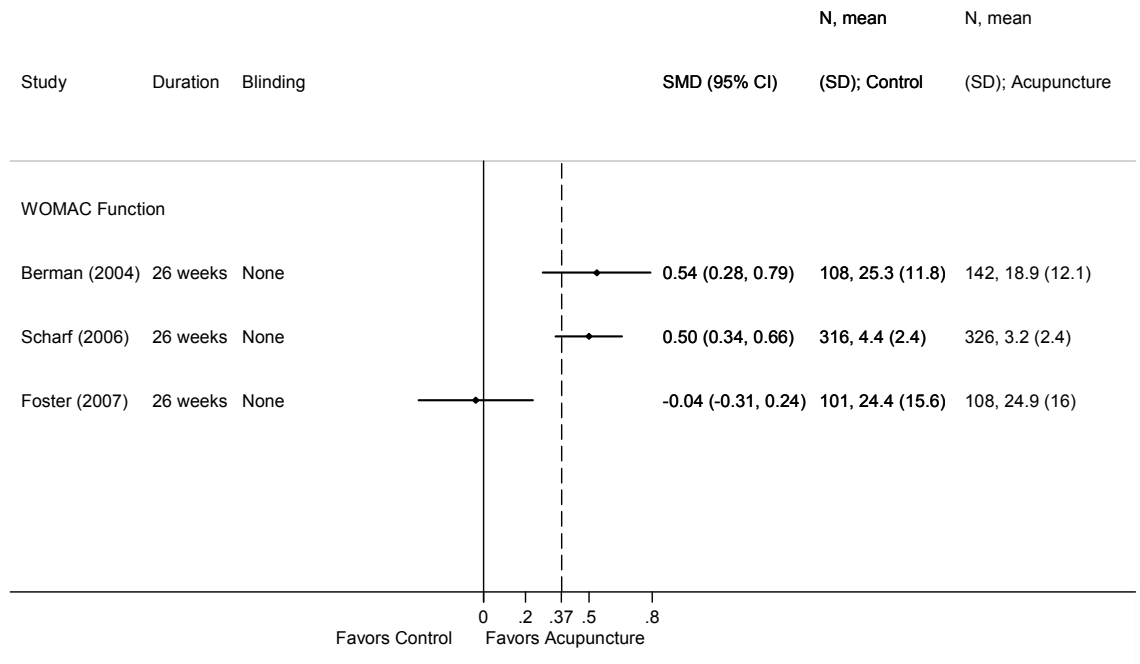
*Dashed line indicates MCII for WOMAC Function

Figure 62. Acupuncture vs. Control - WOMAC Function (12-14 weeks)



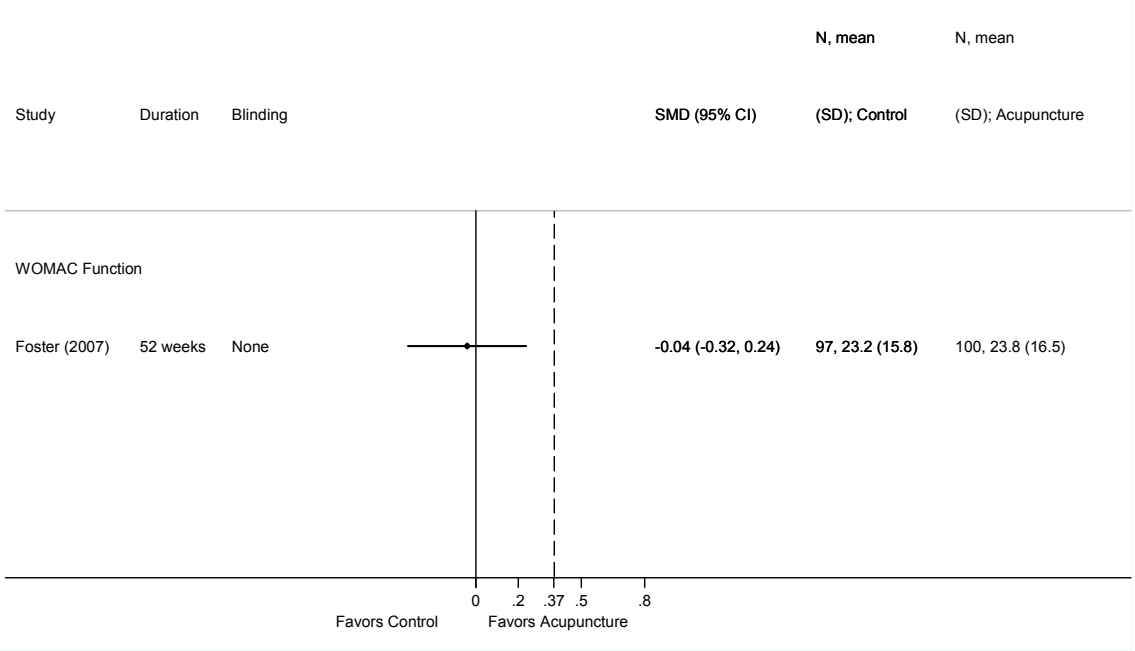
*Dashed line indicates MCII for WOMAC Function

Figure 63. Acupuncture vs. Control - WOMAC Function (26 weeks)



*Dashed line indicates MCII for WOMAC Function

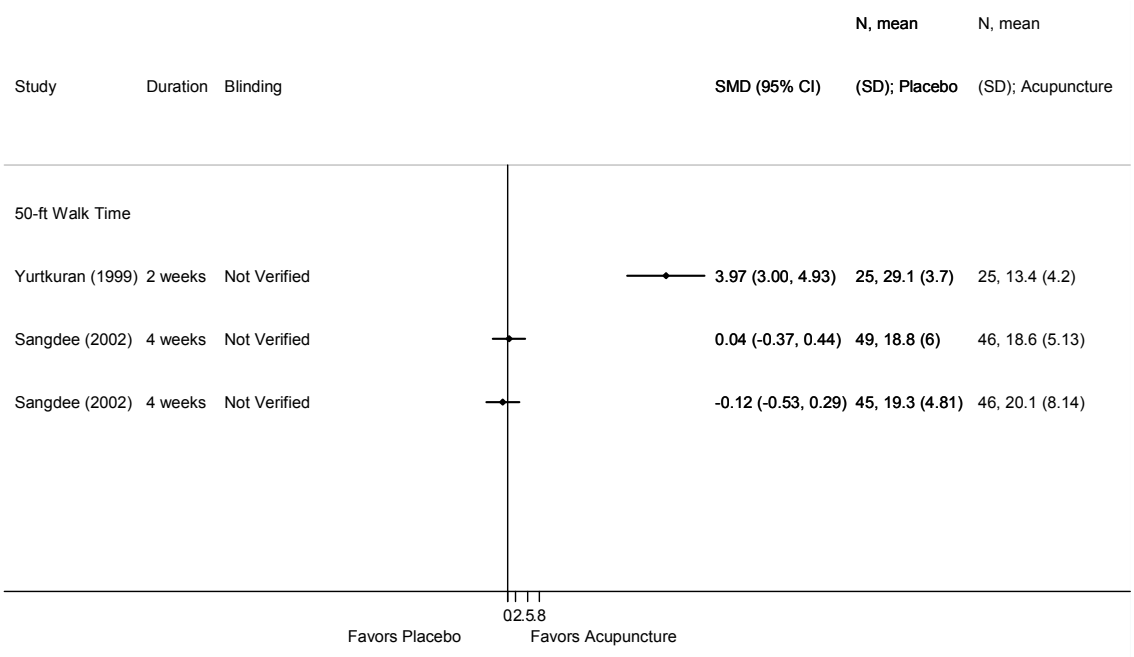
Figure 64. Acupuncture vs. Control - WOMAC Function (52 weeks)



*Dashed line indicates MCII for WOMAC Function

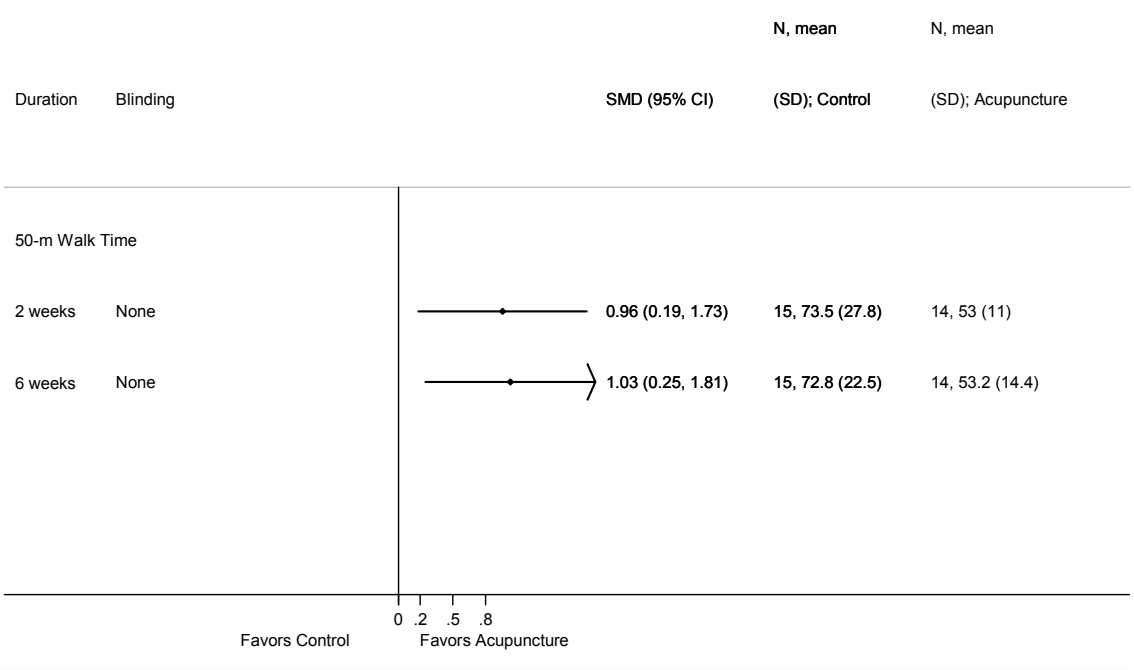
50-FT WALK TIME
Level of Evidence:
Two Level II RCTs

Figure 65. Acupuncture vs. Placebo - 50-ft Walk Time



50 METER WALK TIME
Level of Evidence:
One Level II RCT [75]

Figure 66. Acupuncture vs. Control - 50-m Walk Time (Christensen et al. 1992)



SIX MINUTE WALK DISTANCE
Level of Evidence:
One Level II RCT

Figure 67. Acupuncture vs. Placebo - 6-Minute Walk Distance (Berman et al. 2004)

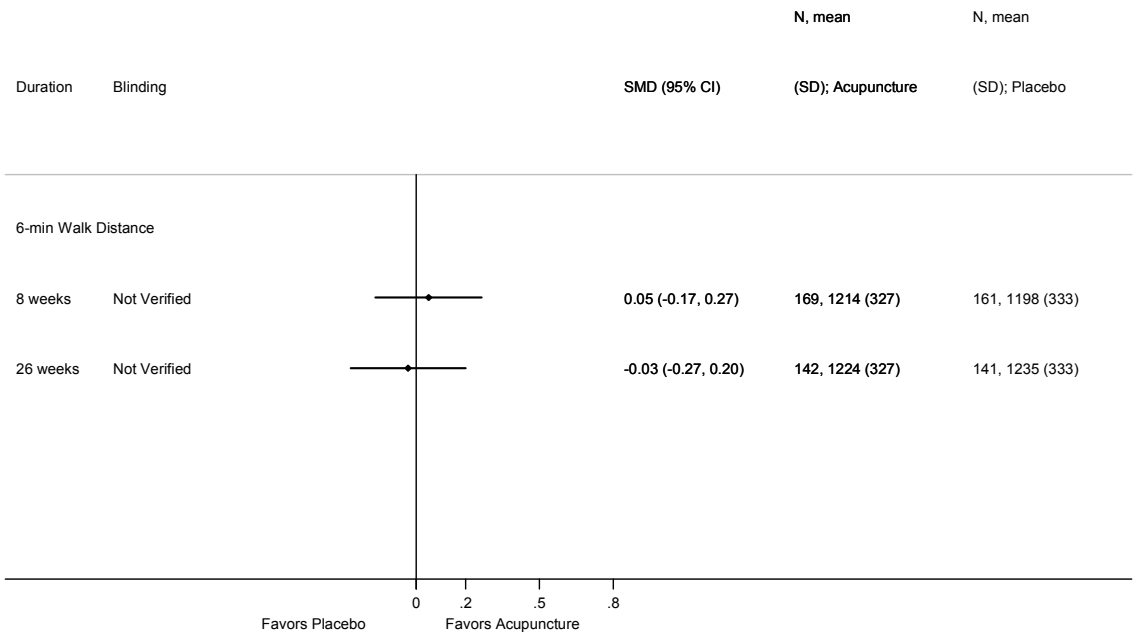
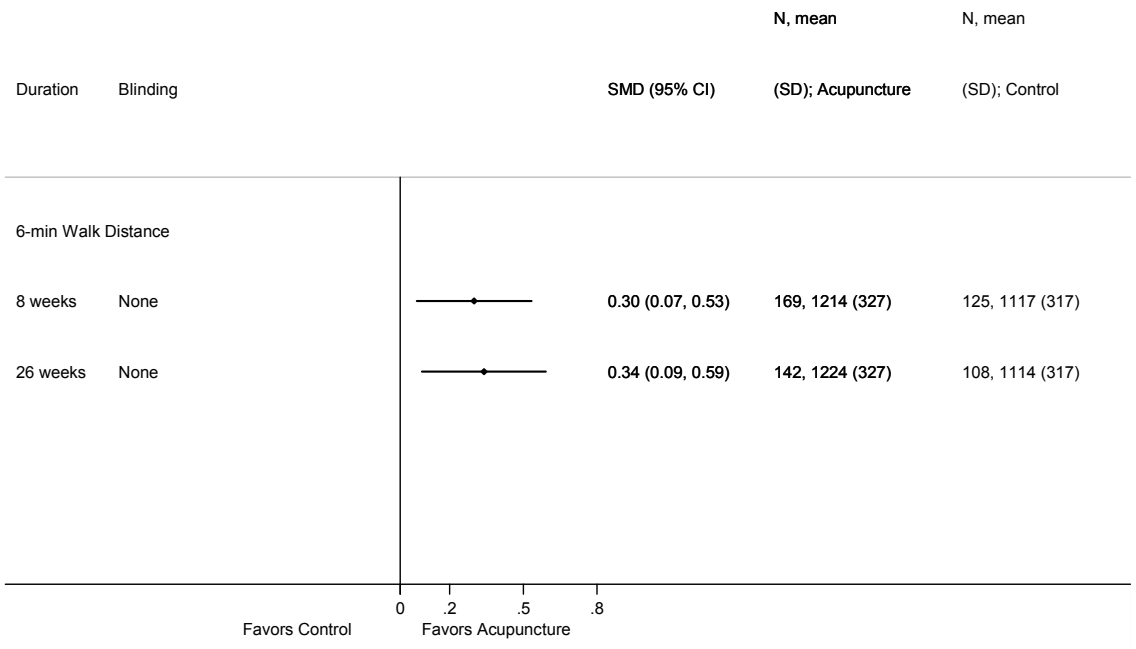


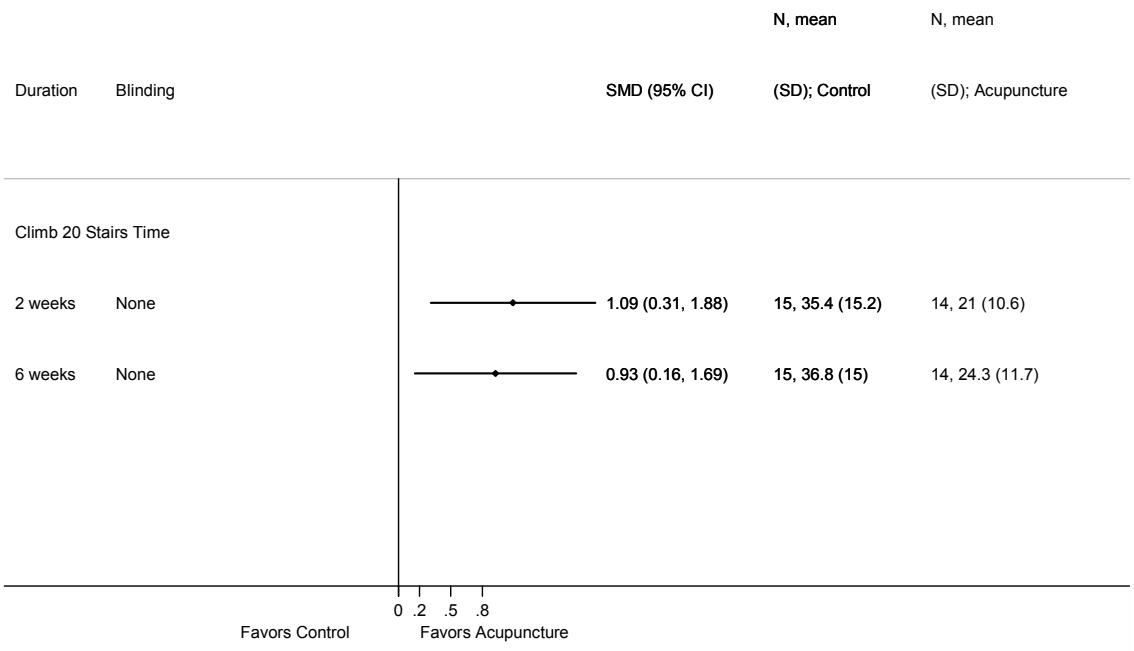
Figure 68. Acupuncture vs. Control - 6-Minute Walk Distance (Berman et al. 2004)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

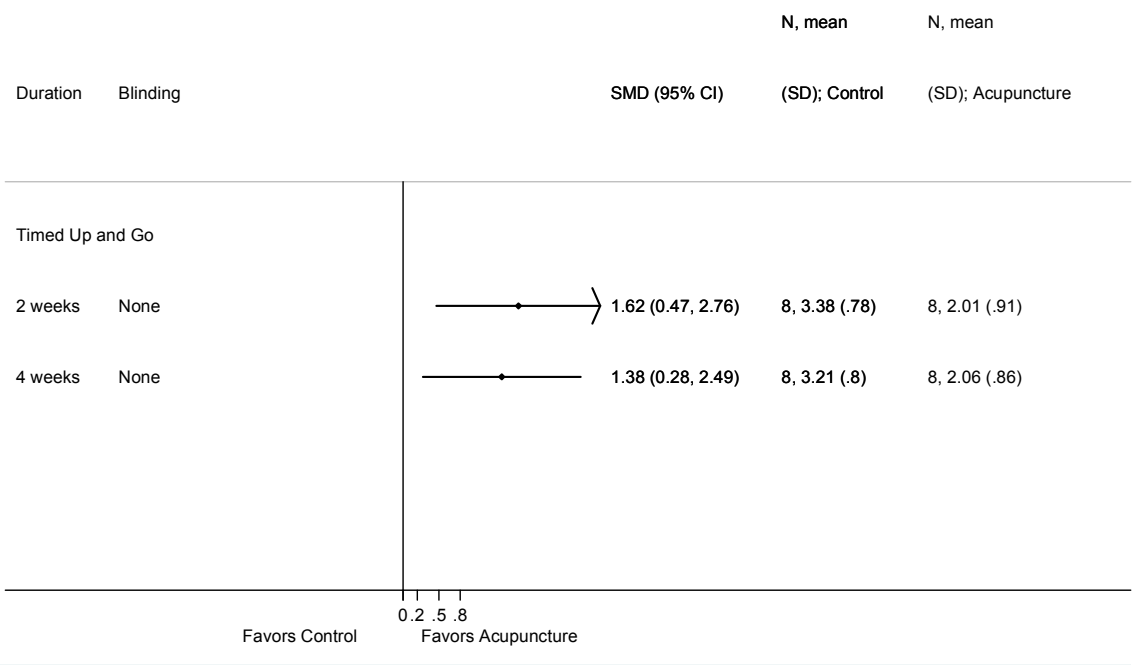
TIME TO CLIMB 20 STAIRS
Level of Evidence:
One Level II RCT

Figure 69. Acupuncture vs. Control - Climb 20 Stairs Time (Christensen et al. 1992)



TIMED UP AND GO
Level of Evidence:
One Level II RCT

Figure 70. Acupuncture vs. Control - Timed Up and Go (Ng et al. 2003)



SEVERITY OF MAIN FUNCTIONAL PROBLEM - NRS
Level of Evidence:
One Level I RCT

Figure 71. Acupuncture vs. Placebo – NRS Severity of Main Functional Problem (Foster et al. 2007)

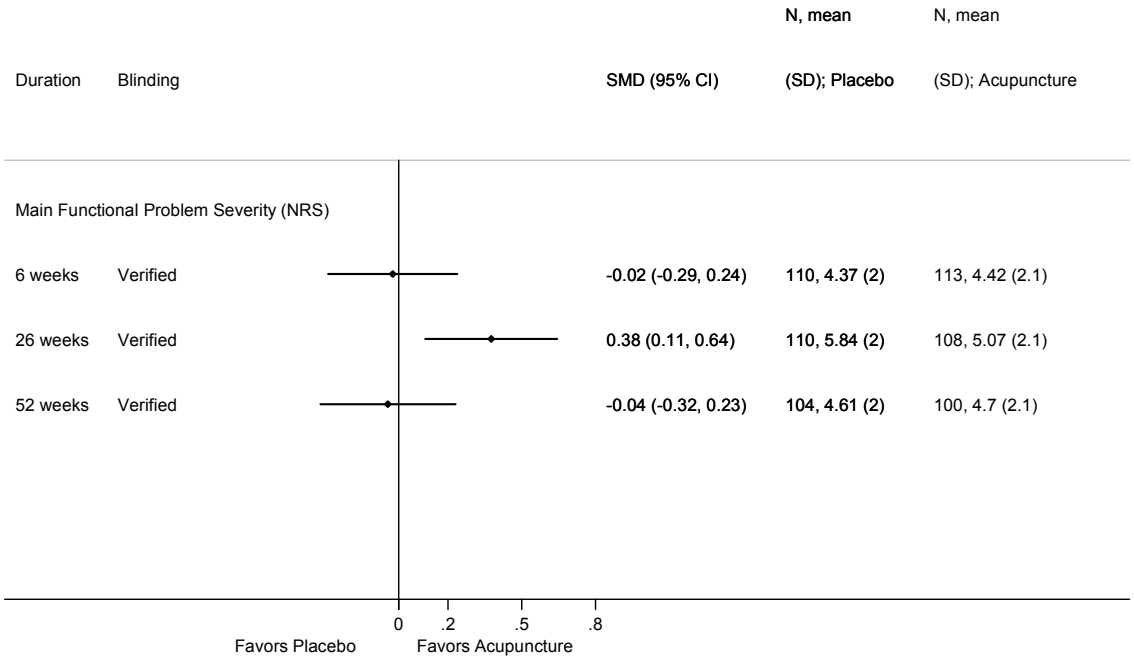
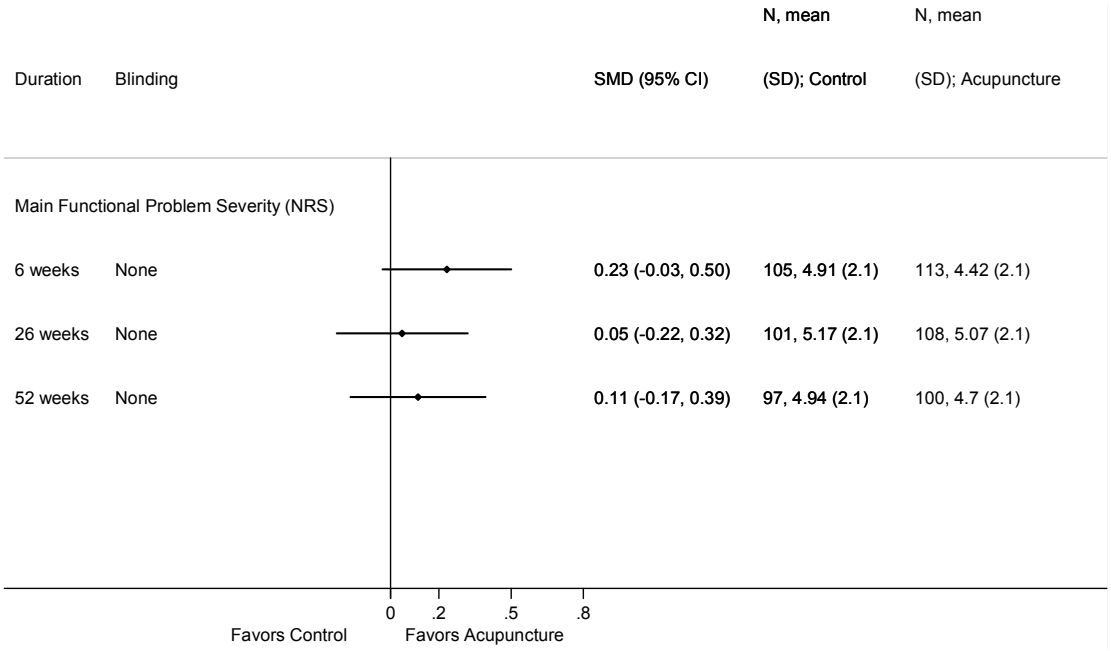


Figure 72. Acupuncture vs. Control - NRS Severity of Main Functional Problem (Foster et al. 2007)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

SF-12 PHYSICAL SCALE
Level of Evidence:
One Level I RCT

Figure 73. Acupuncture vs. Placebo - SF-12 Physical Scale (Scharf et al. 2006)

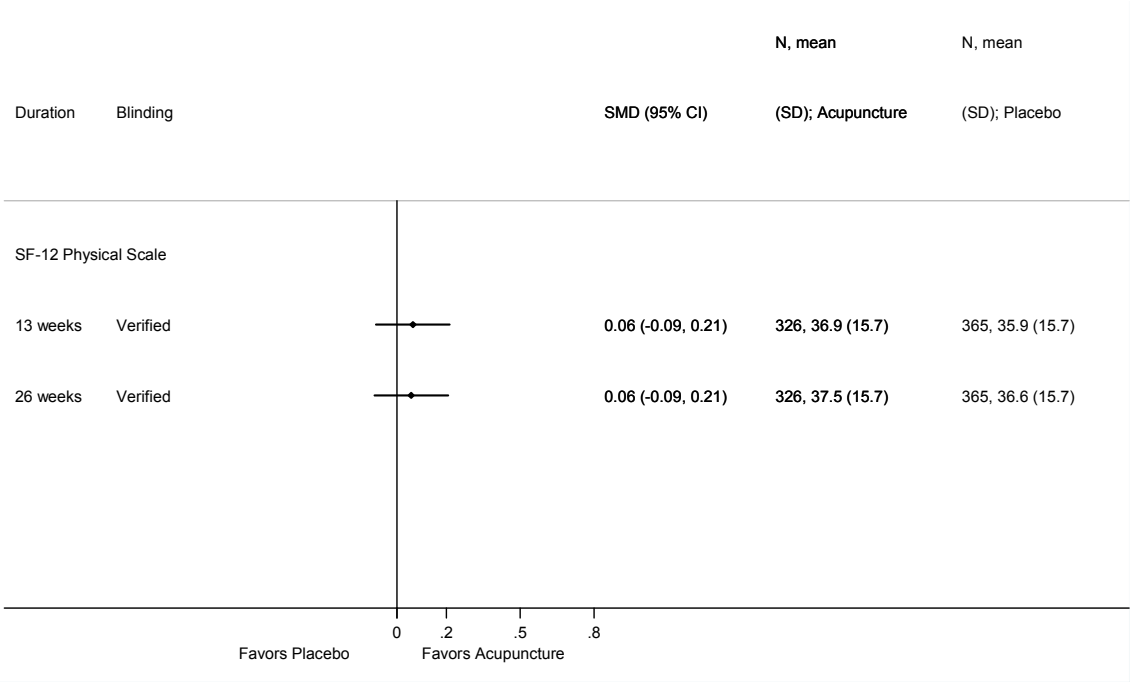
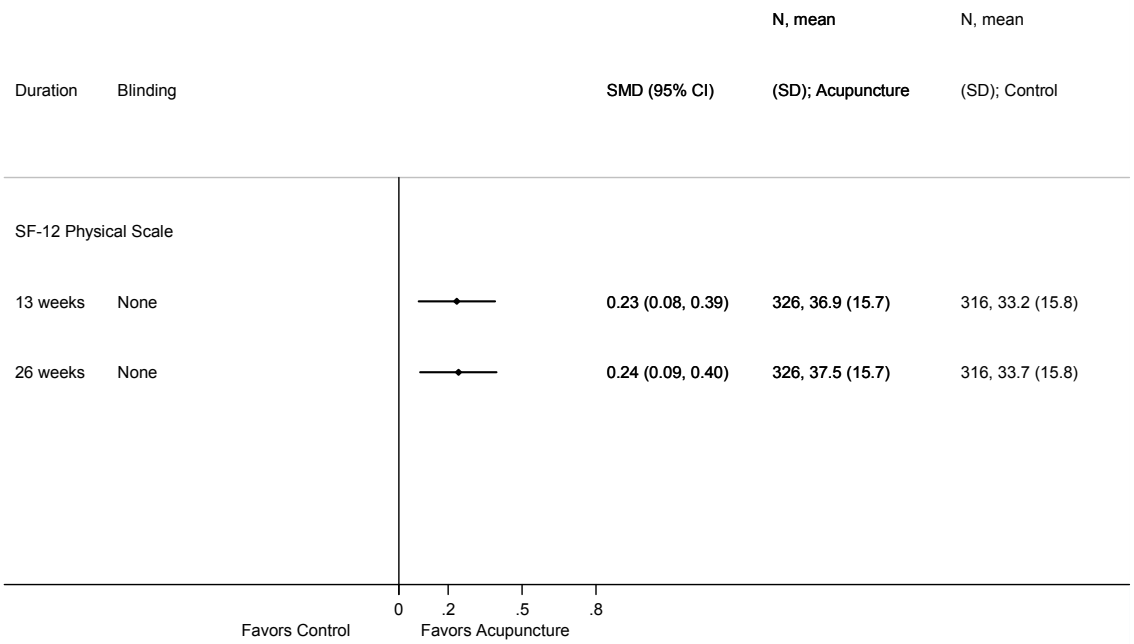


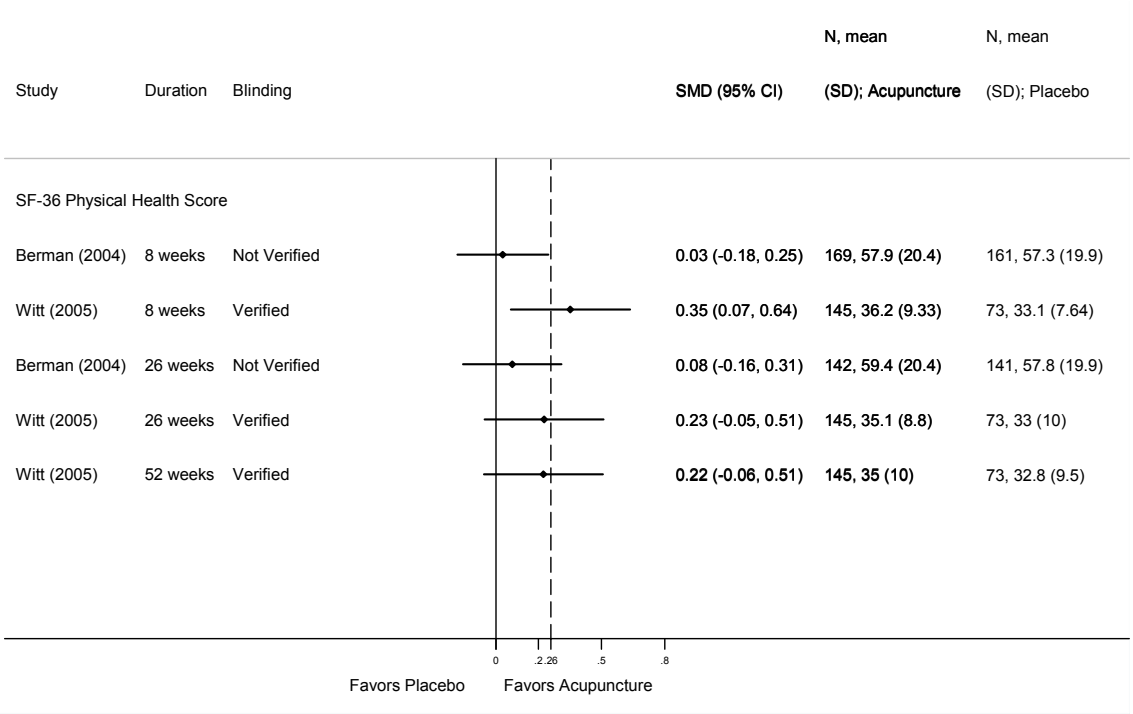
Figure 74. Acupuncture vs. Control - SF-12 Physical Scale (Scharf et al. 2006)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

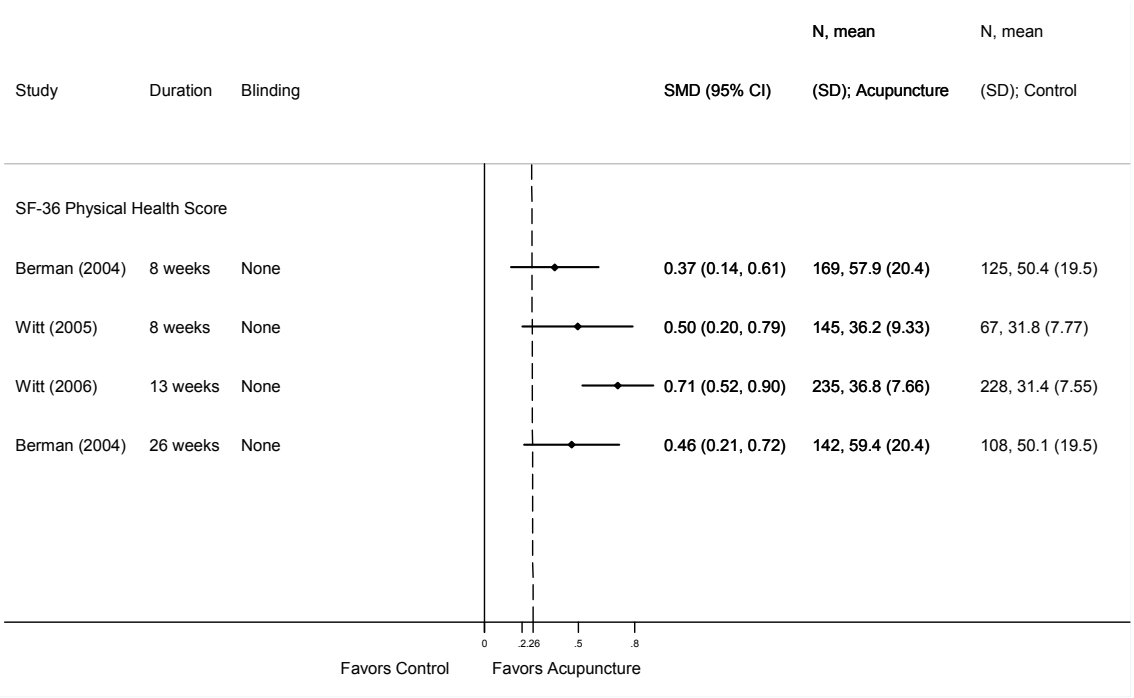
SF-36 PHYSICAL HEALTH SCALE
Level of Evidence:
One Level I RCT and One Level II RCT

Figure 75. Acupuncture vs. Placebo - SF-36 Physical Health Score



*Dashed line indicates MCII for SF-36 Physical Health

Figure 76. Acupuncture vs. Control - SF-36 Physical Health Score



*Dashed line indicates MCII for SF-36 Physical Health
**These studies compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

DEPRESSION - ADS
Level of Evidence:
One Level I RCT

Figure 77. Acupuncture vs. Placebo - Depression (Allgemeine Depressionskala-ADS) (Witt et al. 2005)

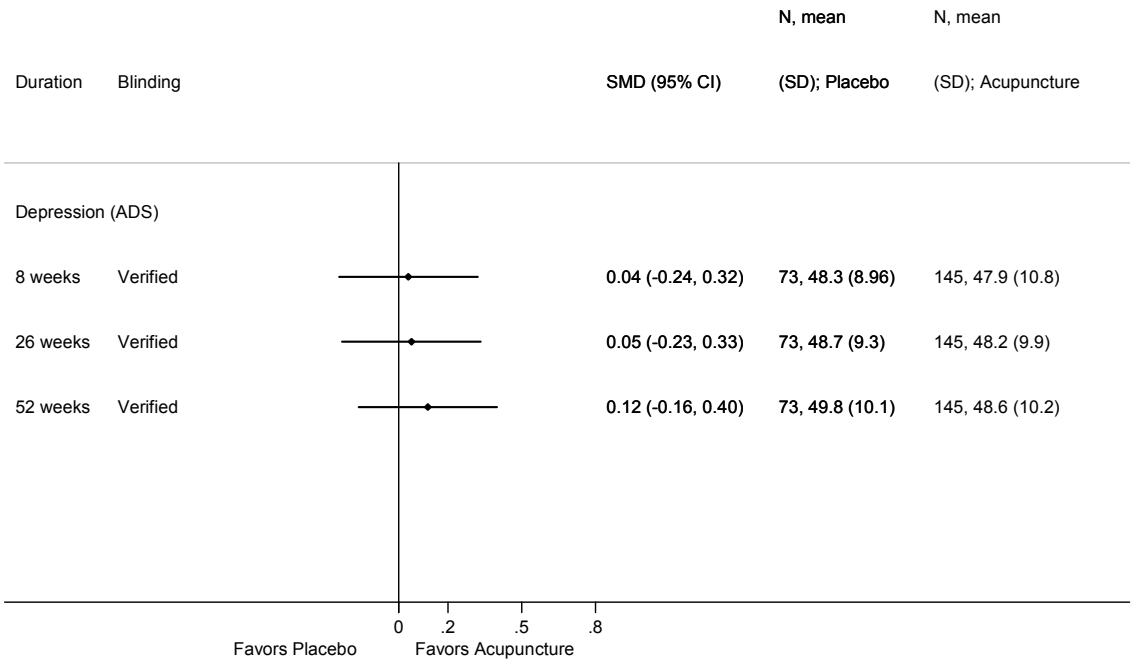
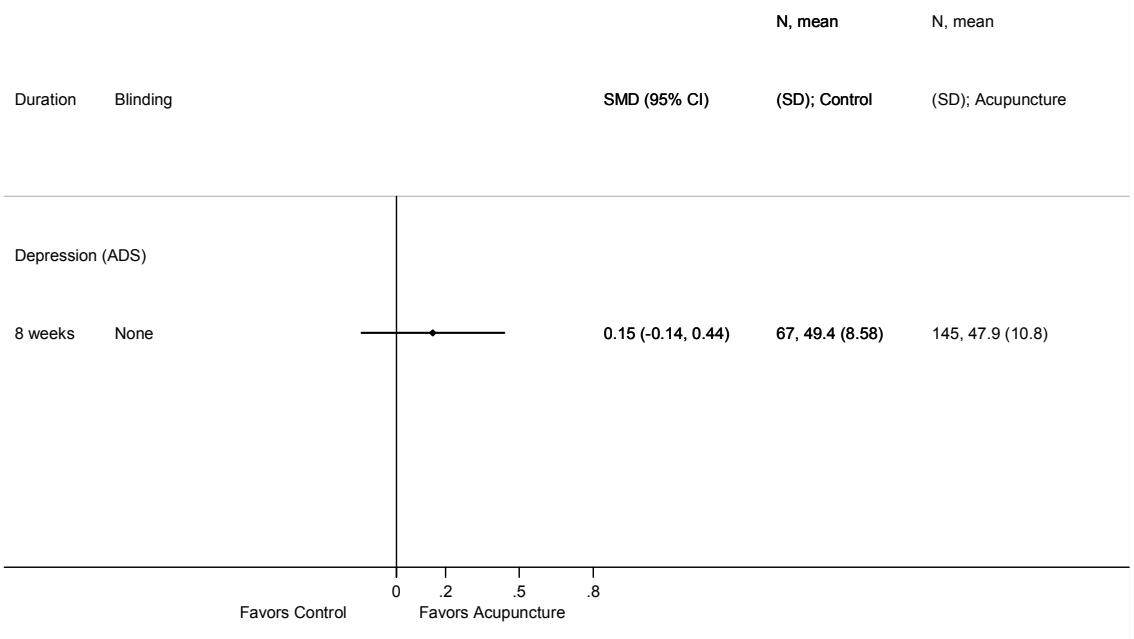


Figure 78. Acupuncture vs. Control - Depression -ADS (Witt et al. 2005)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

SF-12 MENTAL SCALE
Level of Evidence:
One Level I RCT

Figure 79. Acupuncture vs. Placebo - SF-12 Mental Scale (Scharf et al. 2006)

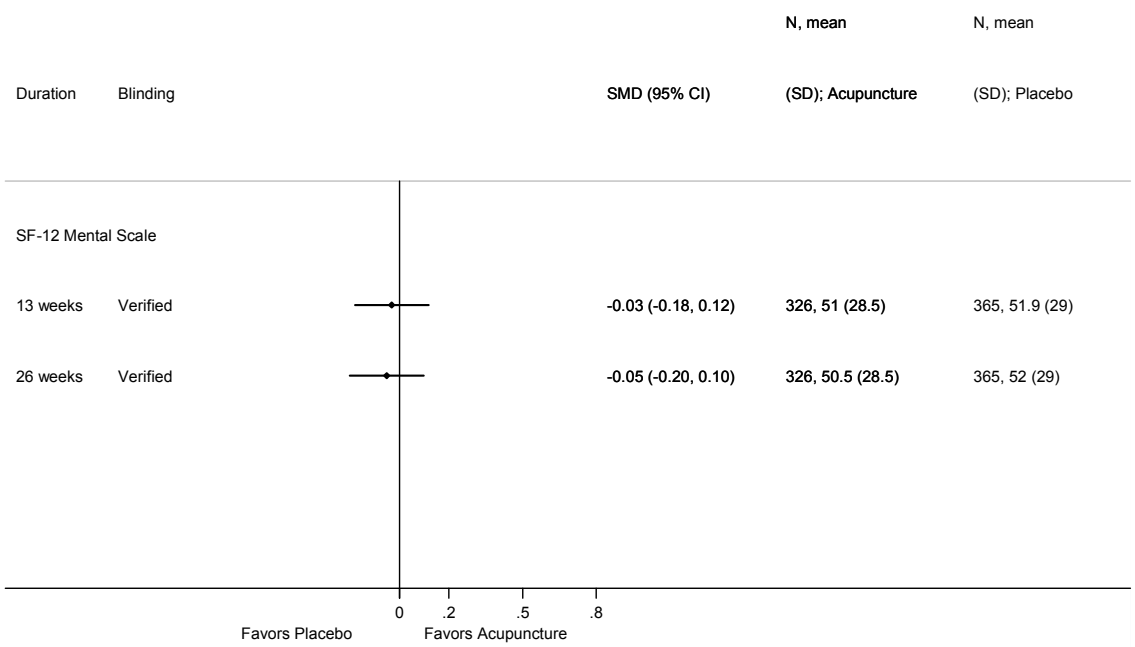
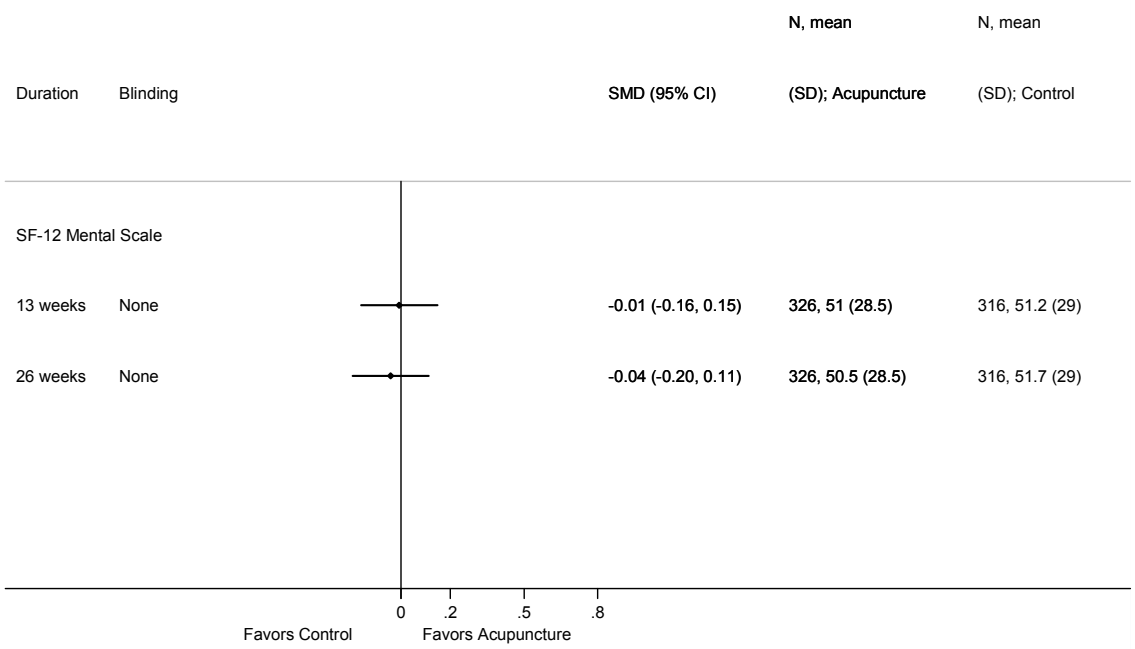


Figure 80. Acupuncture vs. Control - SF-12 Mental Scale (Scharf et al. 2006)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

SF-36 MENTAL HEALTH SCALE
Level of Evidence:
One Level I RCT

Figure 81. Acupuncture vs. Placebo - SF-36 Mental Health Score

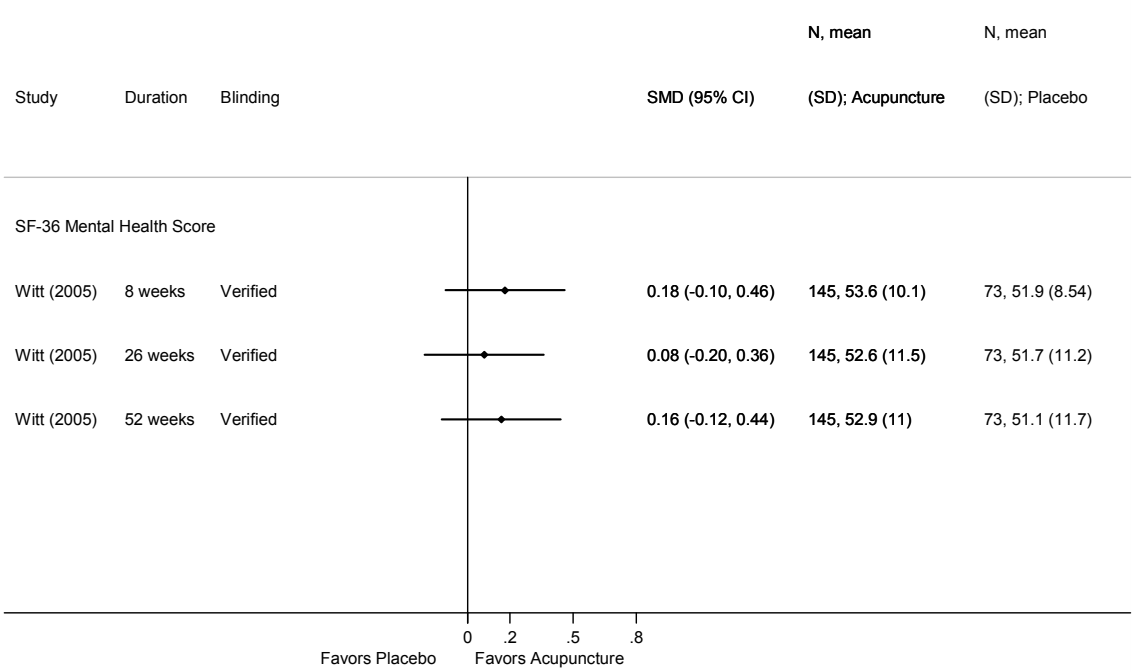
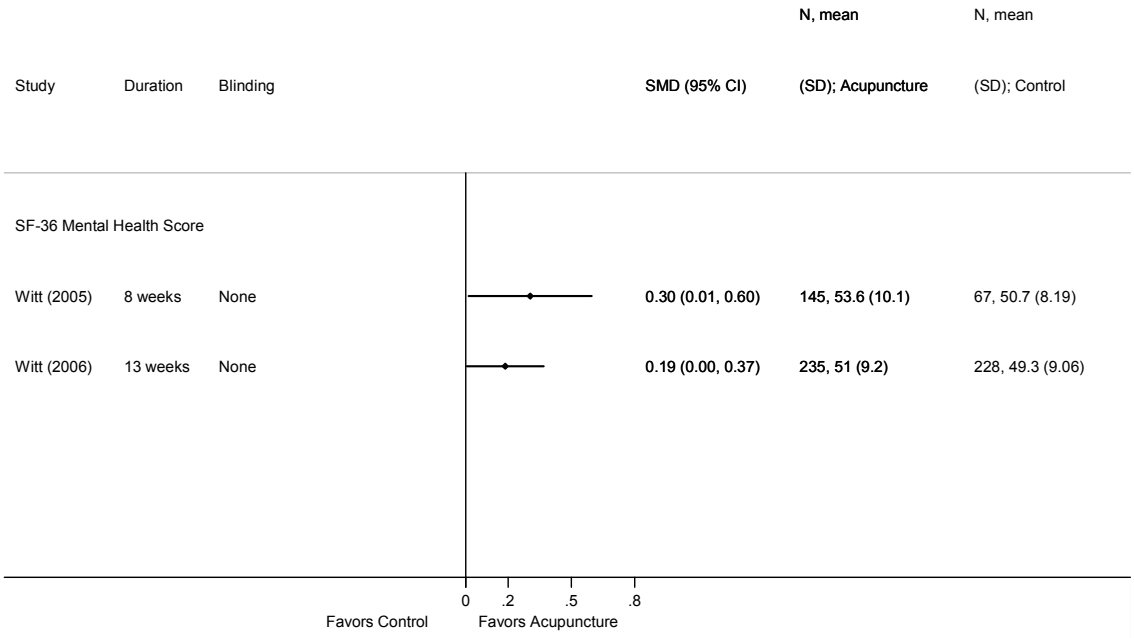


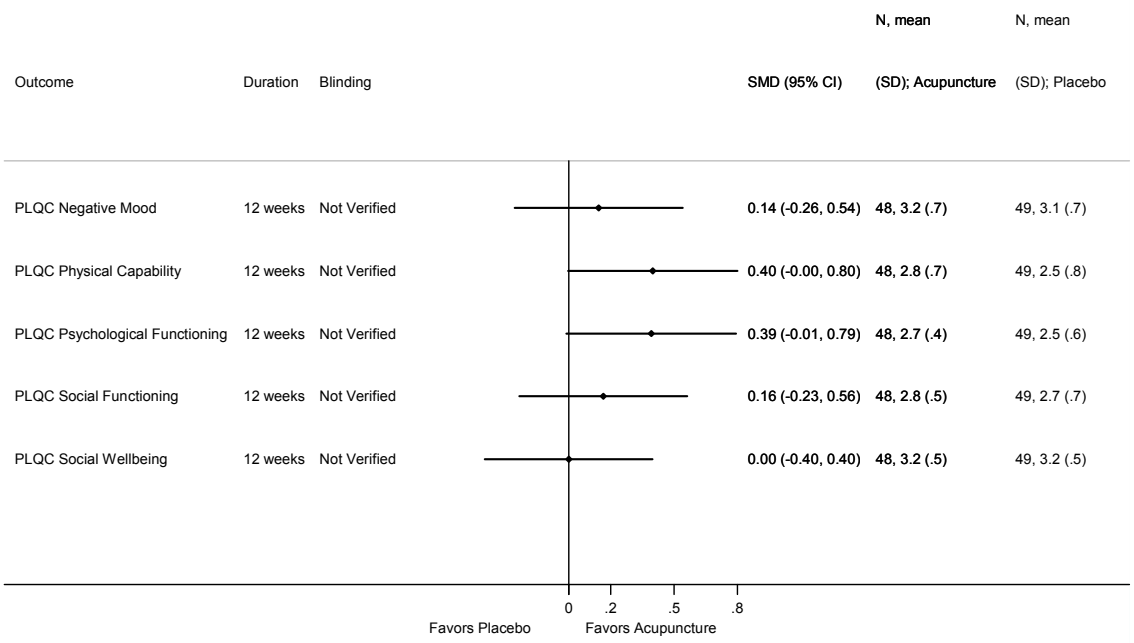
Figure 82. Acupuncture vs. Control - SF-36 Mental Health Score



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

PROFILE OF QUALITY OF LIFE IN THE CHRONICALLY ILL (PLQC)
Level of Evidence:
One Level I RCT

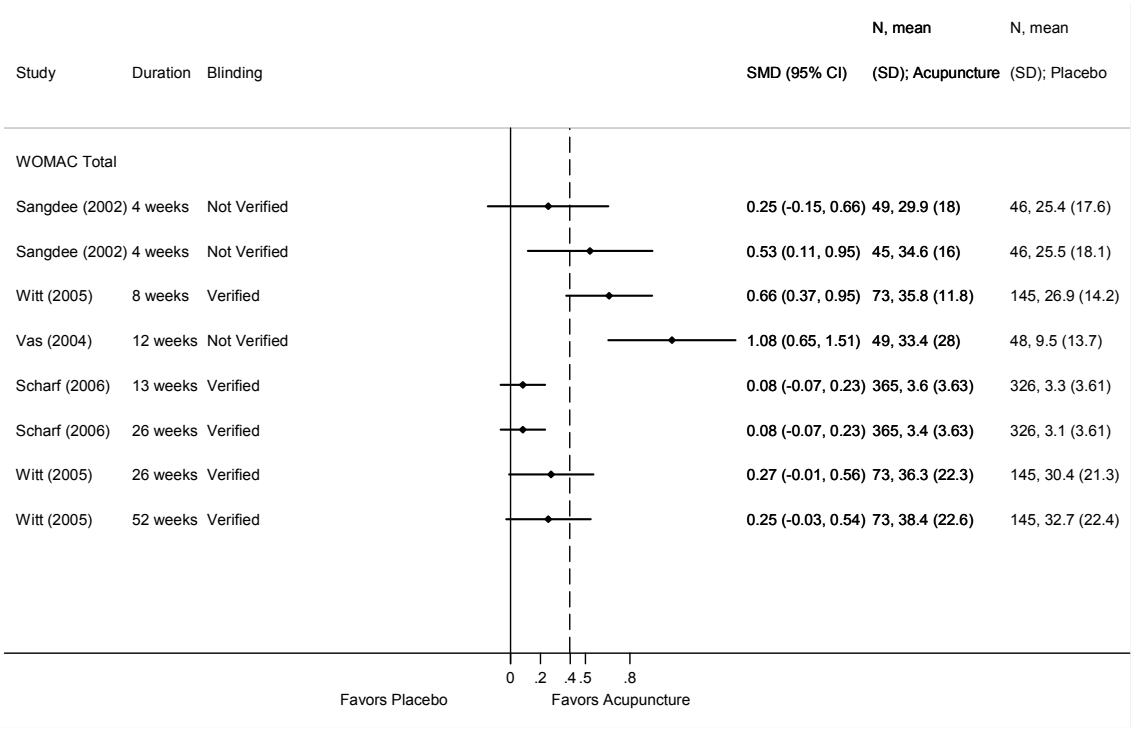
Figure 83. Acupuncture vs. Placebo – PLQC (Vas et al. 2004)



WOMAC - TOTAL
Level of Evidence:
Three Level I RCTs and Three Level II RCTs

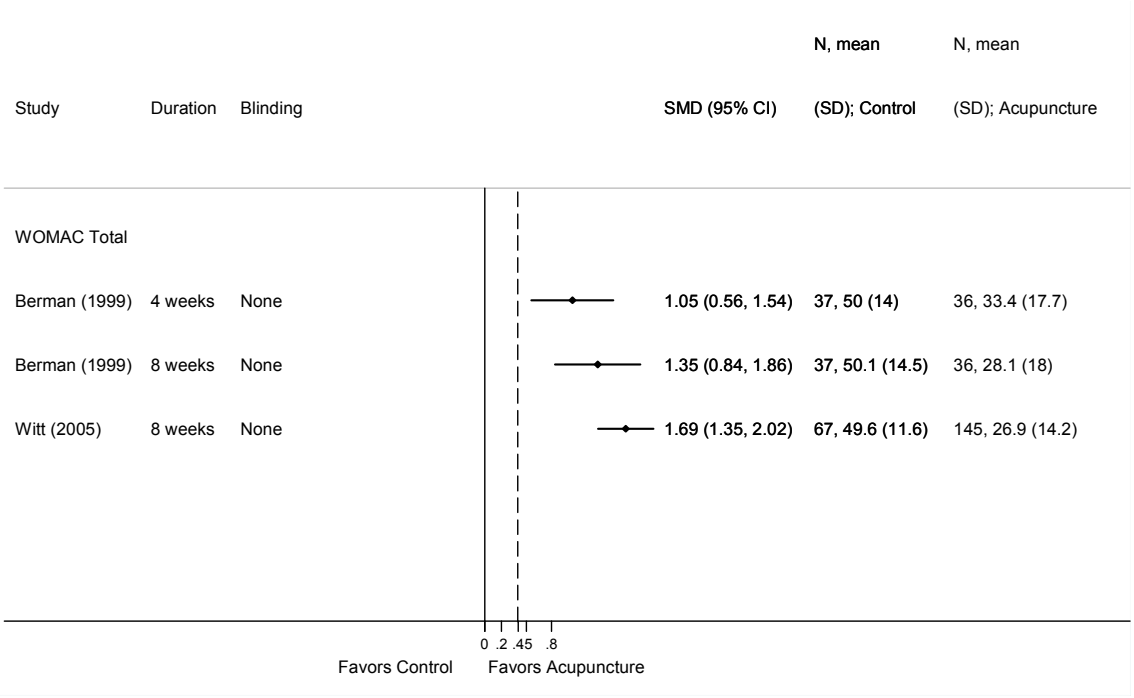
Several studies (2 of 5) compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

Figure 84. Acupuncture vs. Placebo - WOMAC Total



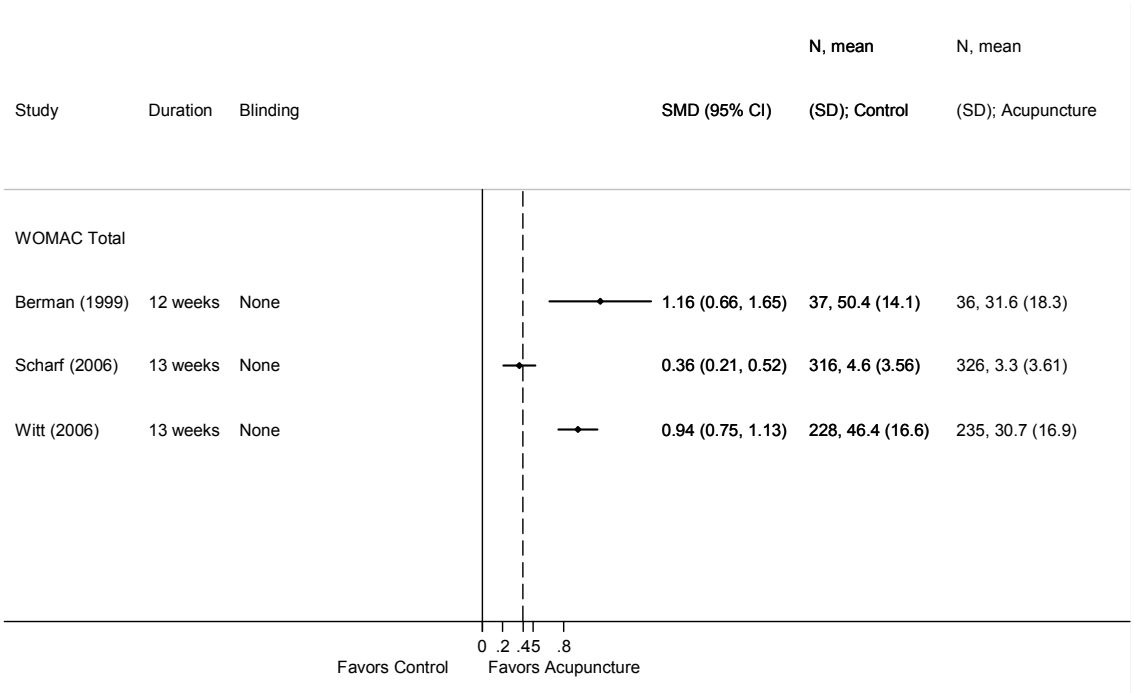
*Dashed line indicates MCII for WOMAC Total

Figure 85. Acupuncture vs. Control - WOMAC Total (4-8 weeks)



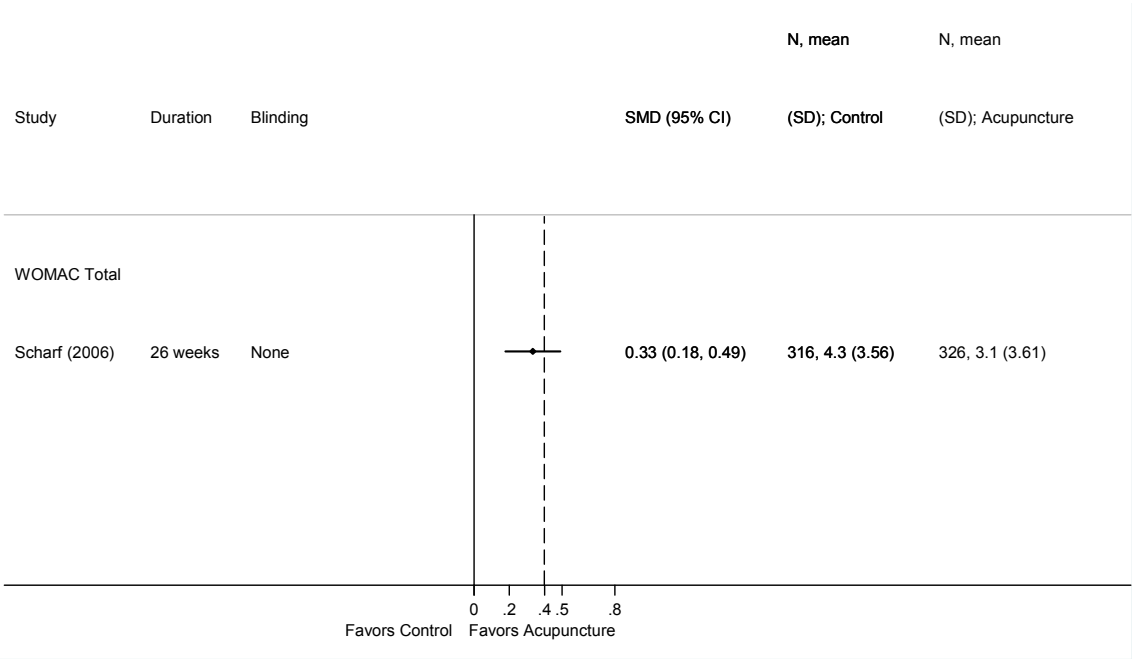
*Dashed line indicates MCII for WOMAC Total

Figure 86. Acupuncture vs. Control - WOMAC Total (12-13 weeks)



*Dashed line indicates MCII for WOMAC Total

Figure 87. Acupuncture vs. Control - WOMAC Total (26 weeks)



*Dashed line indicates MCII for WOMAC Total

PATIENT GLOBAL ASSESSMENT (CONTINUOUS)
Level of Evidence:
One Level II RCT

Figure 88. Acupuncture vs. Placebo -Patient Global Assessment (Berman et al. 2004)

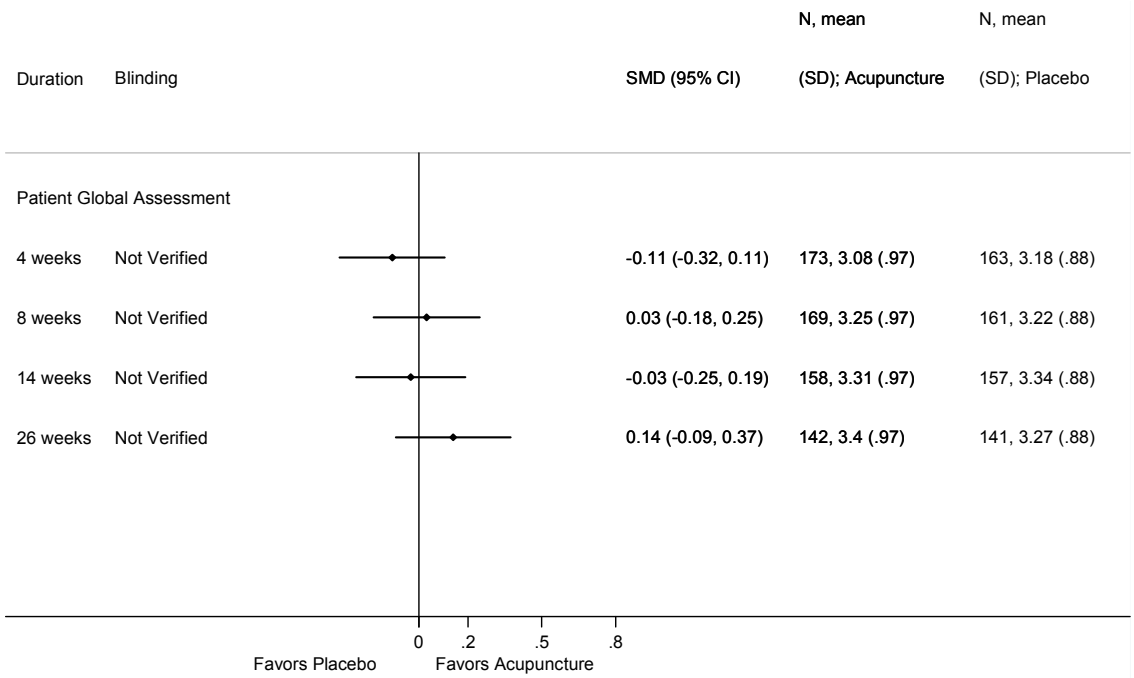
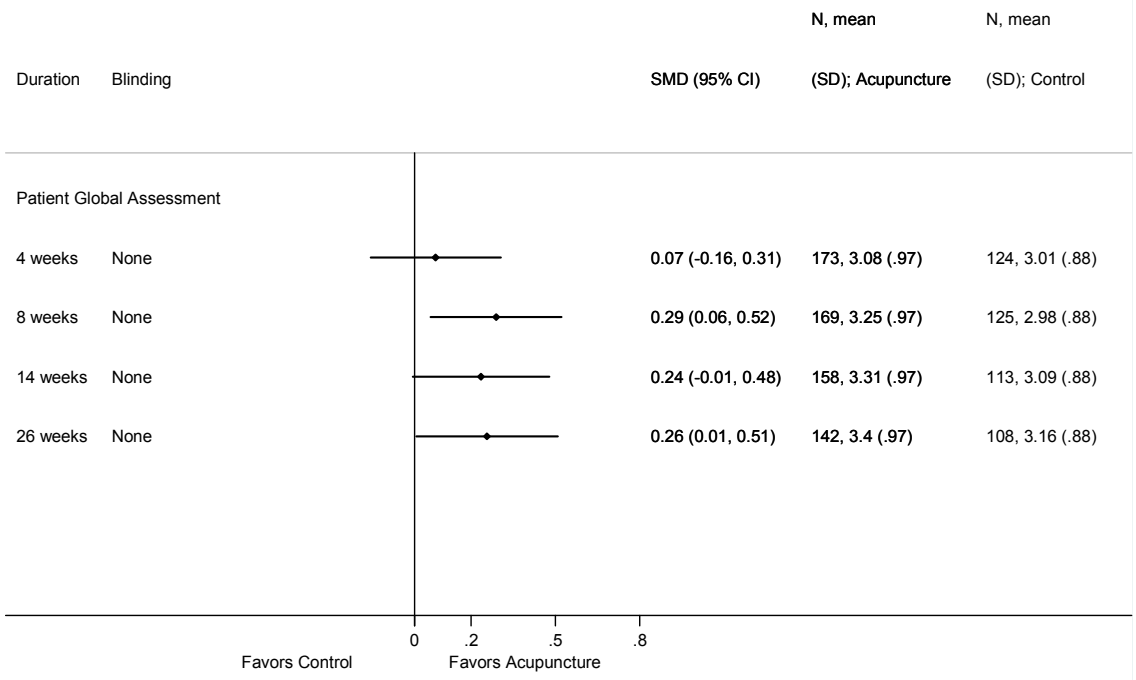


Figure 89. Acupuncture vs. Control -Patient Global Assessment (Berman et al. 2004)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

PATIENT GLOBAL ASSESSMENT (BINARY)
Level of Evidence:
One Level I RCT

Figure 90. Acupuncture vs. Placebo - Patient Global Assessment (Scharf et al. 2006)

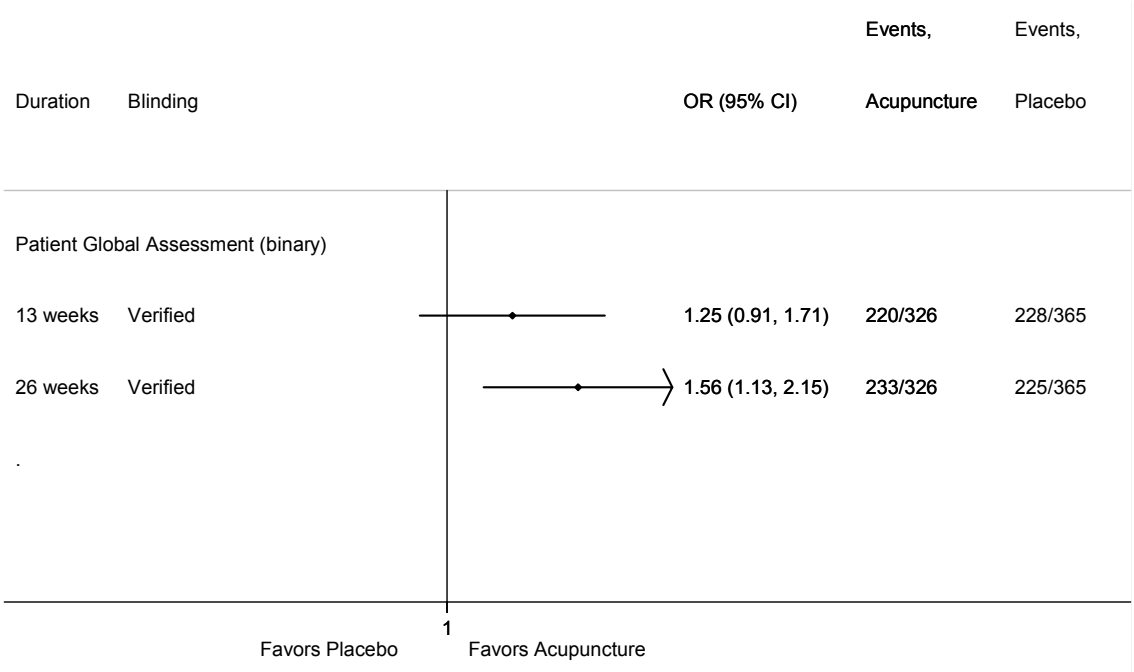
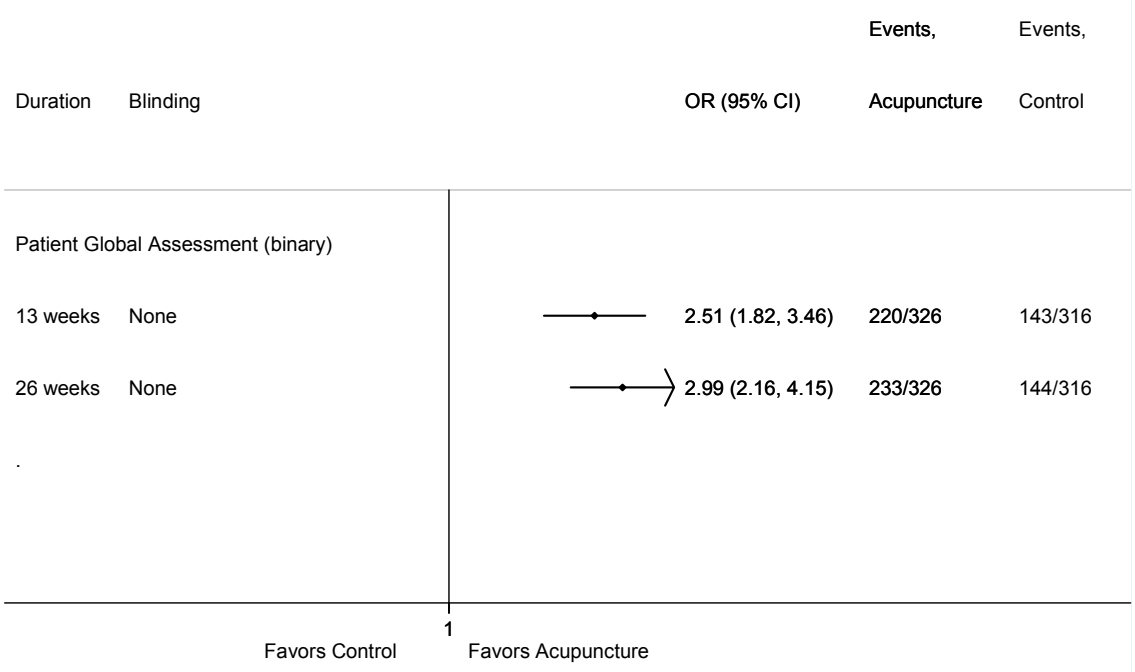


Figure 91. Acupuncture vs. Control - Patient Global Assessment (Scharf et al. 2006)



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

RESPONDERS
Level of Evidence:
Three Level I RCTs and Two Level II RCTs

Figure 92 - Figure 94 present results comparing the success rate of acupuncture vs. placebo at various durations. The definition of a responder varied by study, see evidence table 17 for details. Several studies (4 of 5) compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

Figure 92. Acupuncture vs. Placebo – Responders (4-13 weeks)

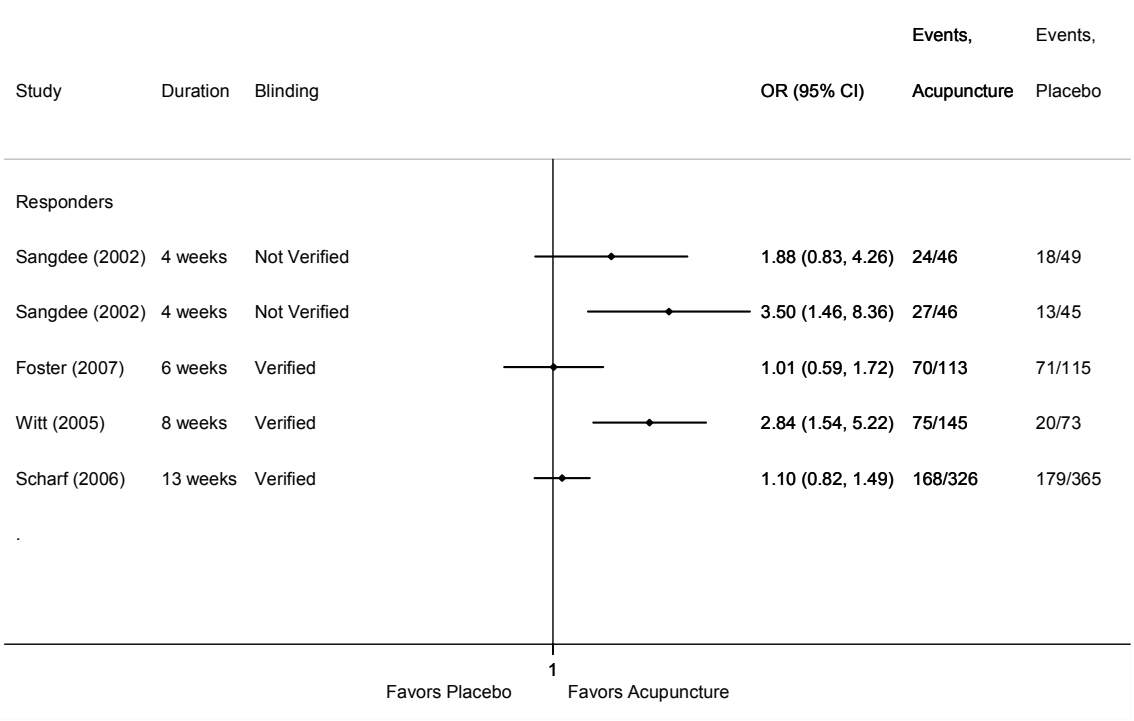


Figure 93. Acupuncture vs. Placebo - Responders (26 weeks)

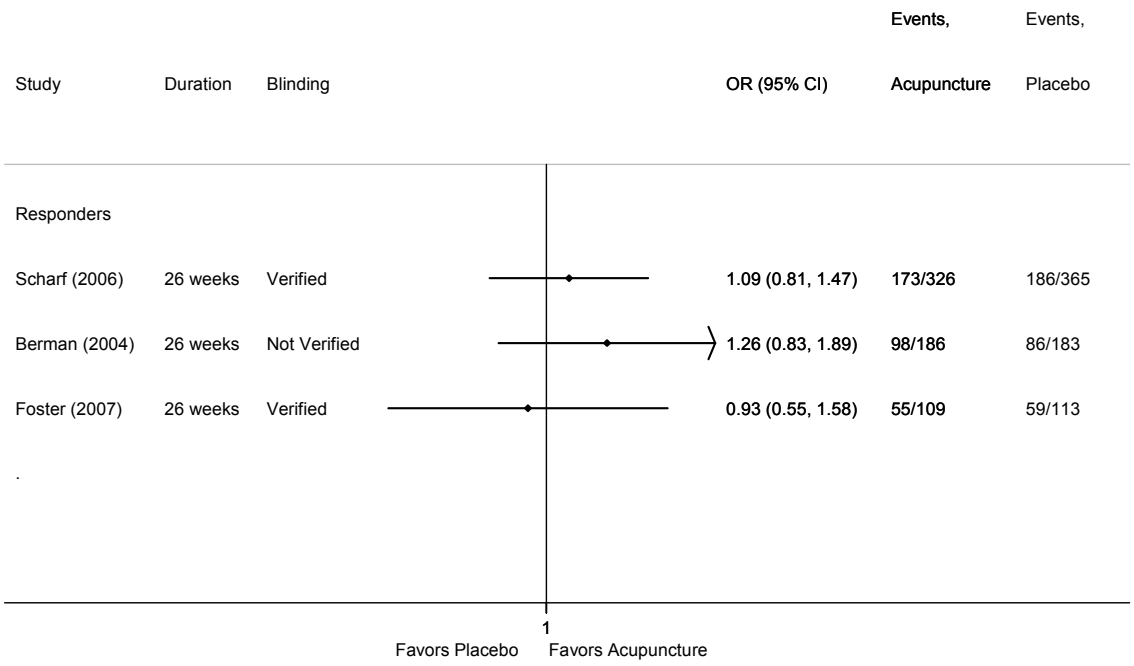


Figure 94. Acupuncture vs. Placebo - Responders (52 weeks)

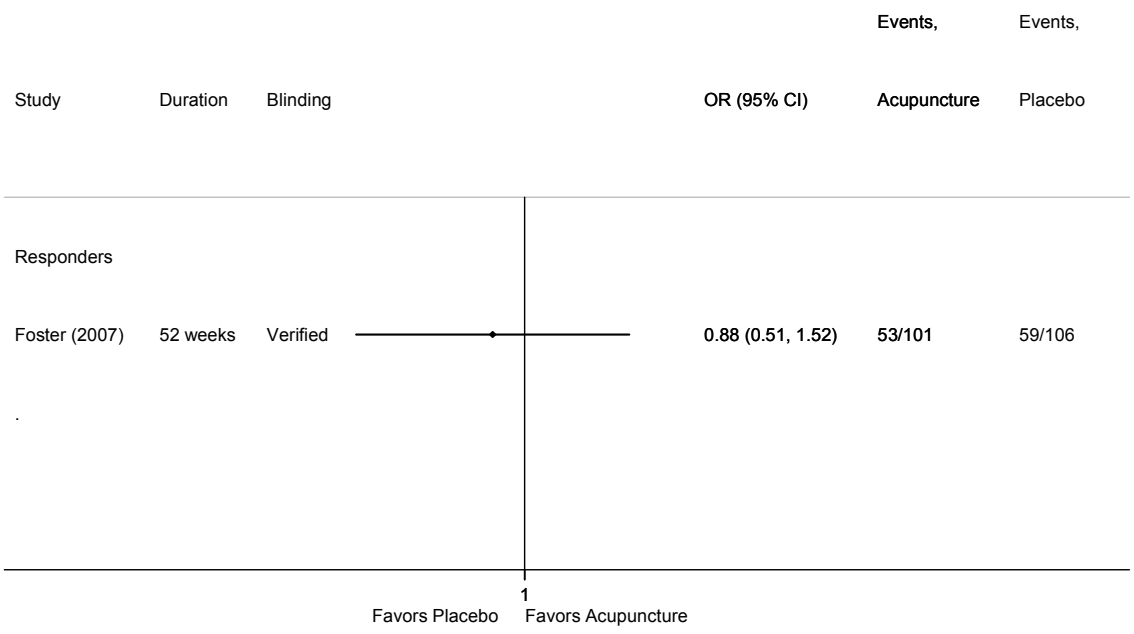


Figure 95. Acupuncture vs. Control – Responders (6-13 weeks)

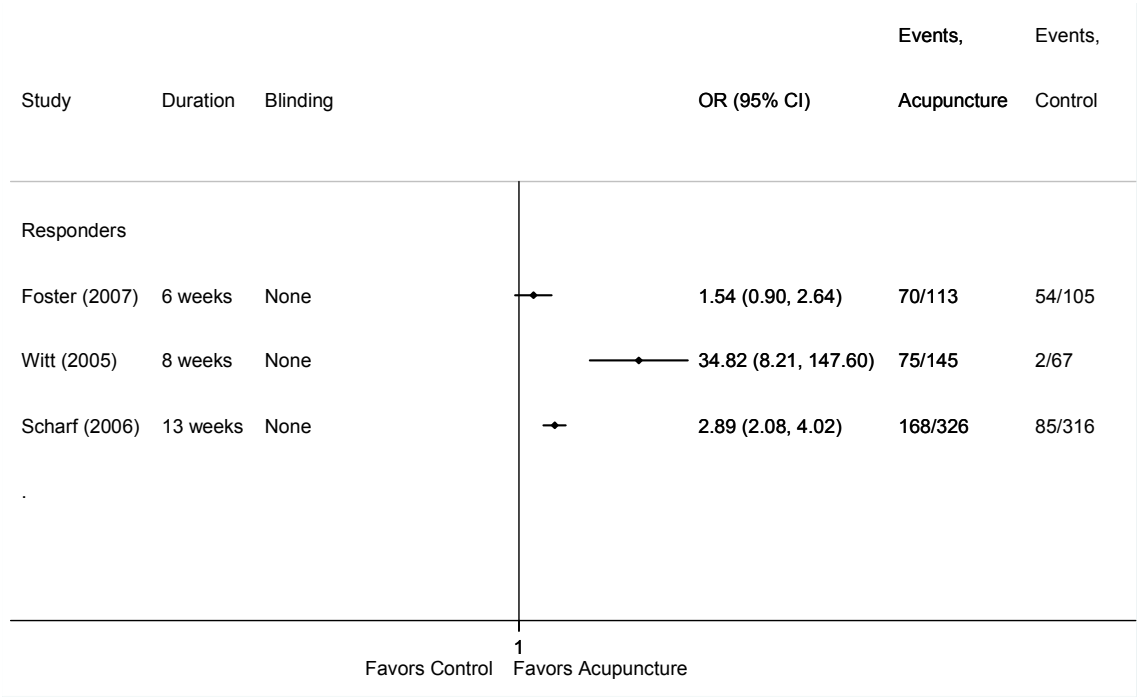


Figure 96. Acupuncture vs. Control - Responders (26 weeks)

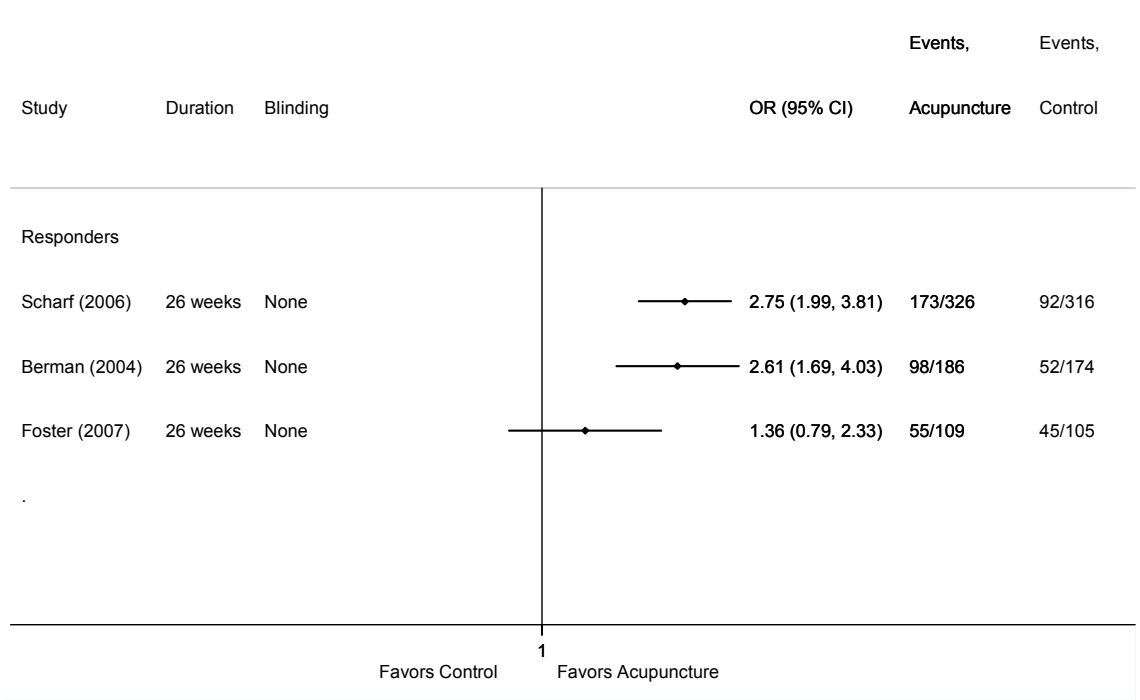
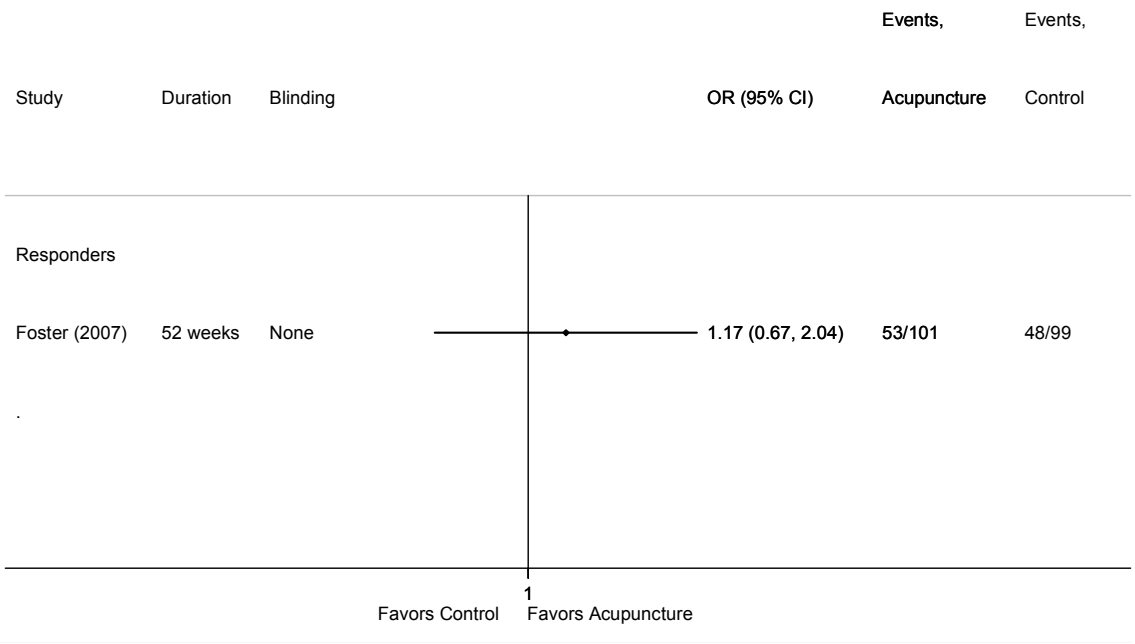
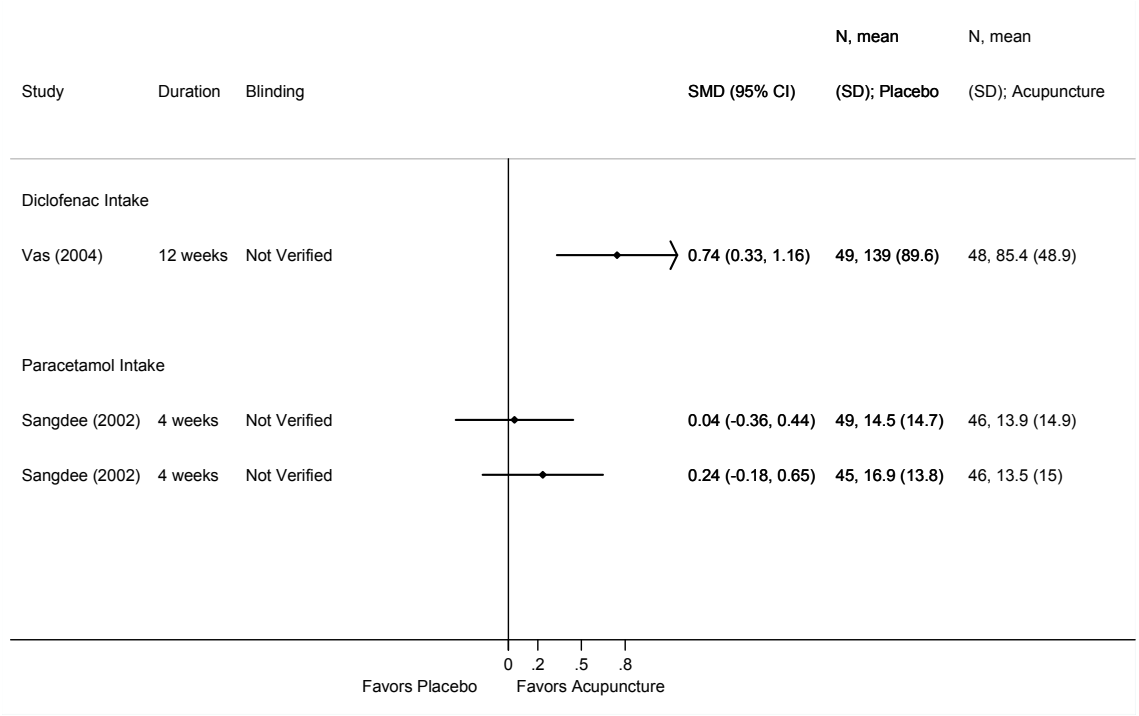


Figure 97. Acupuncture vs. Control - Responders (52 weeks)



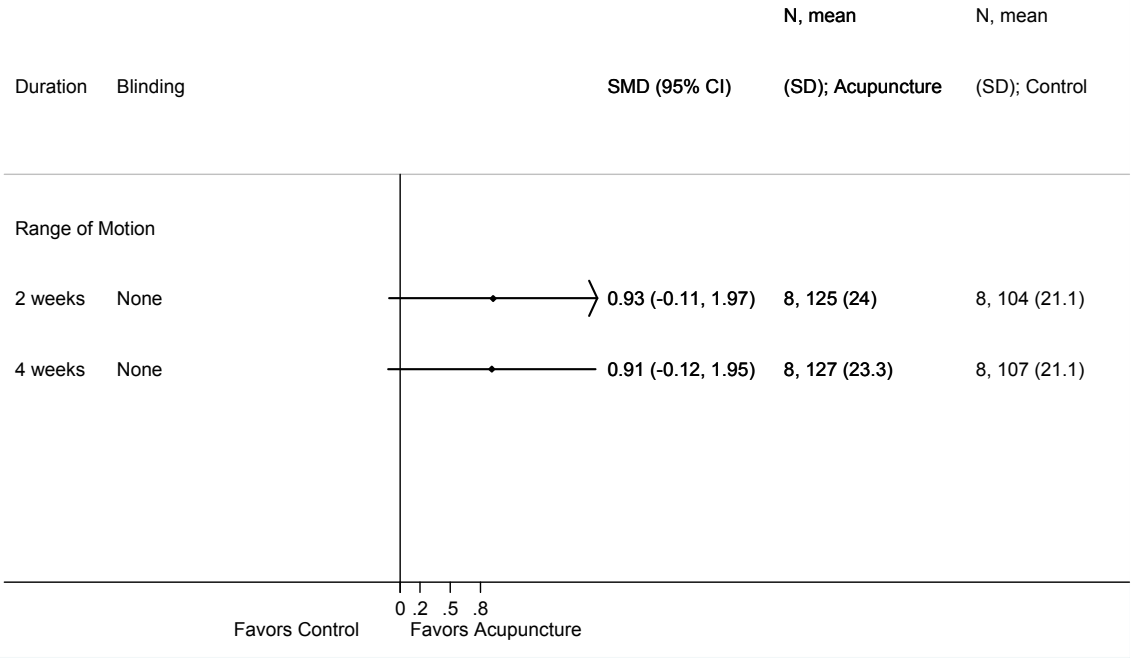
MEDICATION INTAKE
Level of Evidence:
One Level I RCT and One Level II RCT

Figure 98. Acupuncture vs. Placebo - Medication Intake



RANGE OF MOTION
Level of Evidence:
One Level II RCT

Figure 99. Acupuncture vs. Control - Range of Motion (Ng et al. 2003)



ADVERSE EVENTS
Level of Evidence:
Two Level I RCTs

Figure 100. Acupuncture vs. Placebo - Adverse Events

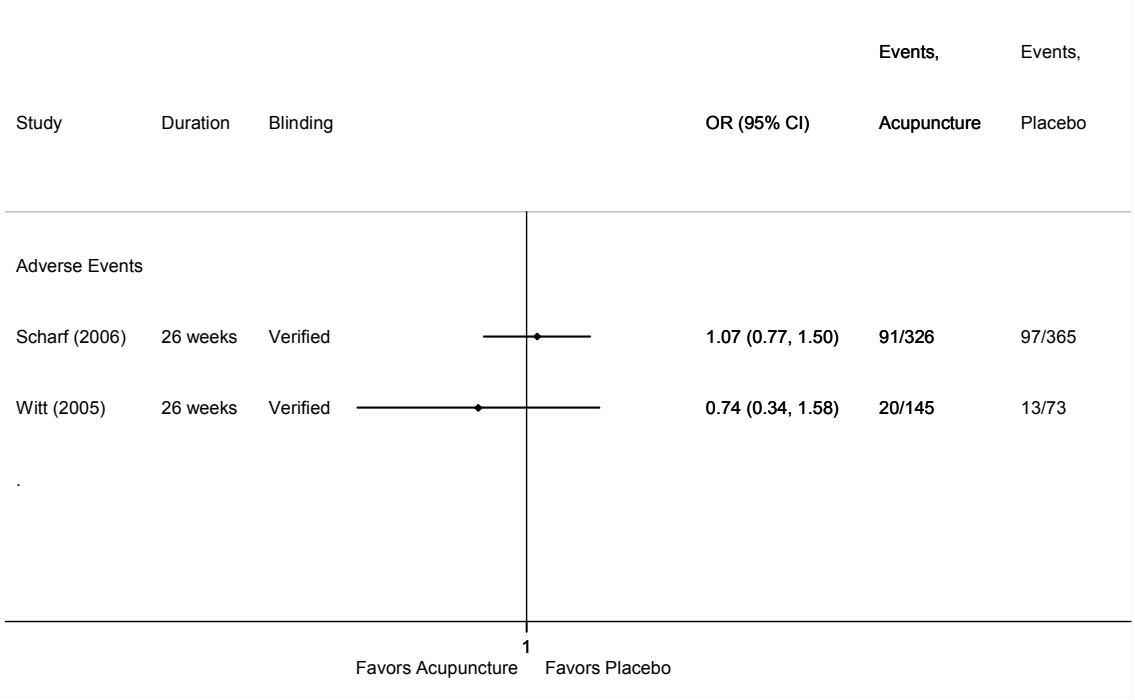
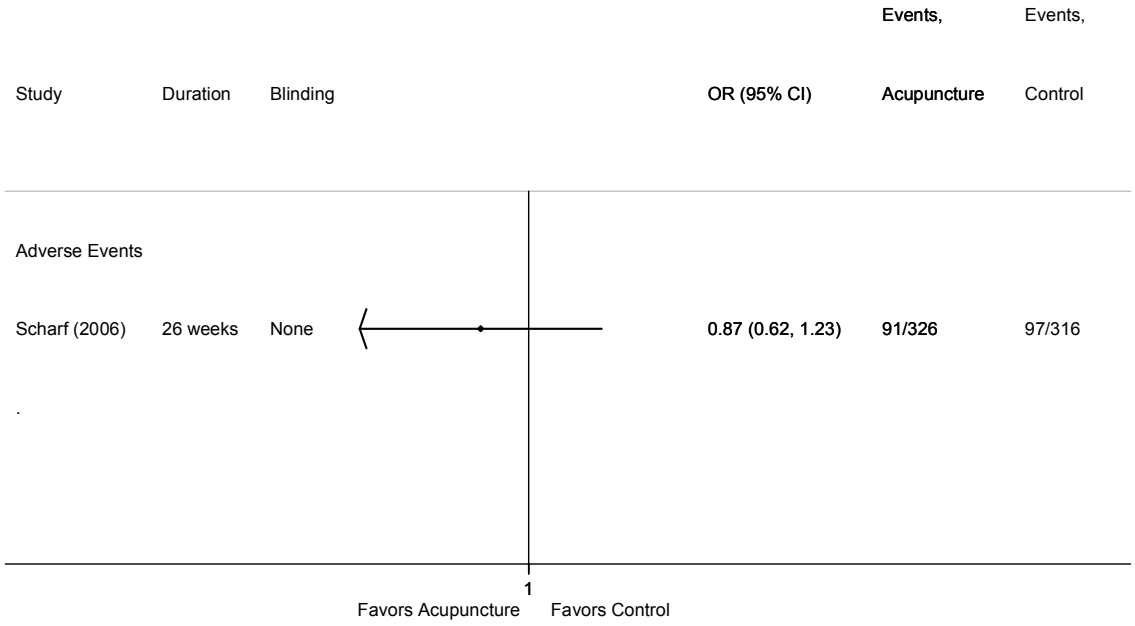


Figure 101. Acupuncture vs. Control - Adverse Events



*This study compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

SERIOUS ADVERSE EVENTS
Level of Evidence:
Two Level I RCT and One Level II RCTs

Figure 102 and Figure 103 present serious adverse events of acupuncture vs. placebo and non-sham control, respectively. Note that each study interpreted all adverse events as not related to the treatment.

Figure 102. Acupuncture vs. Placebo - Serious Adverse Events

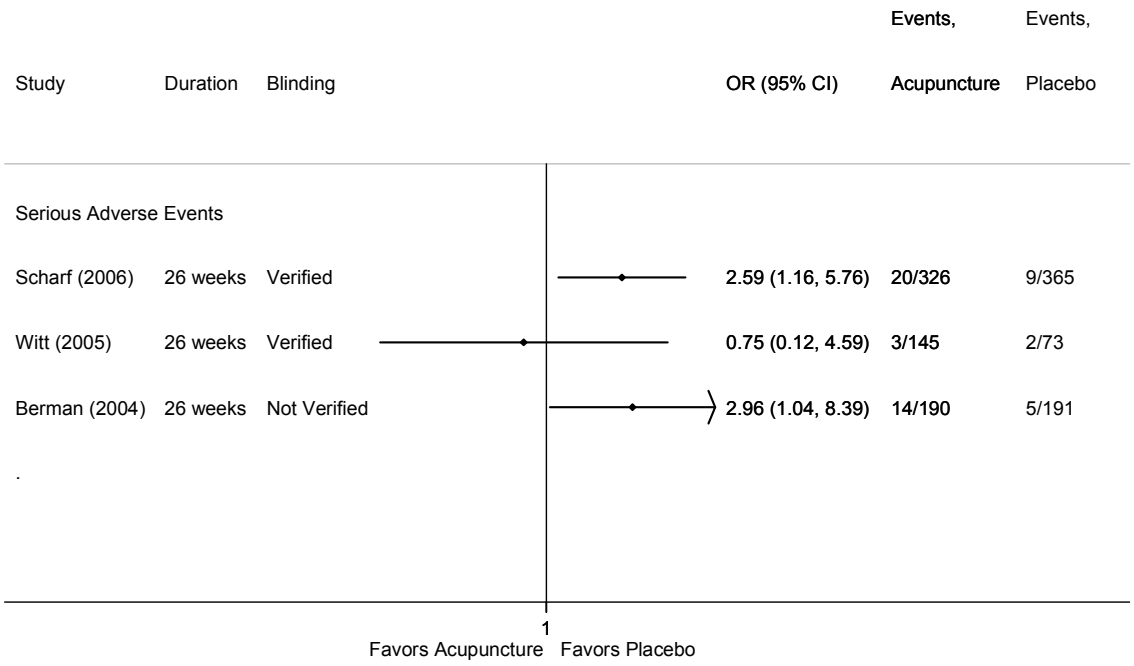
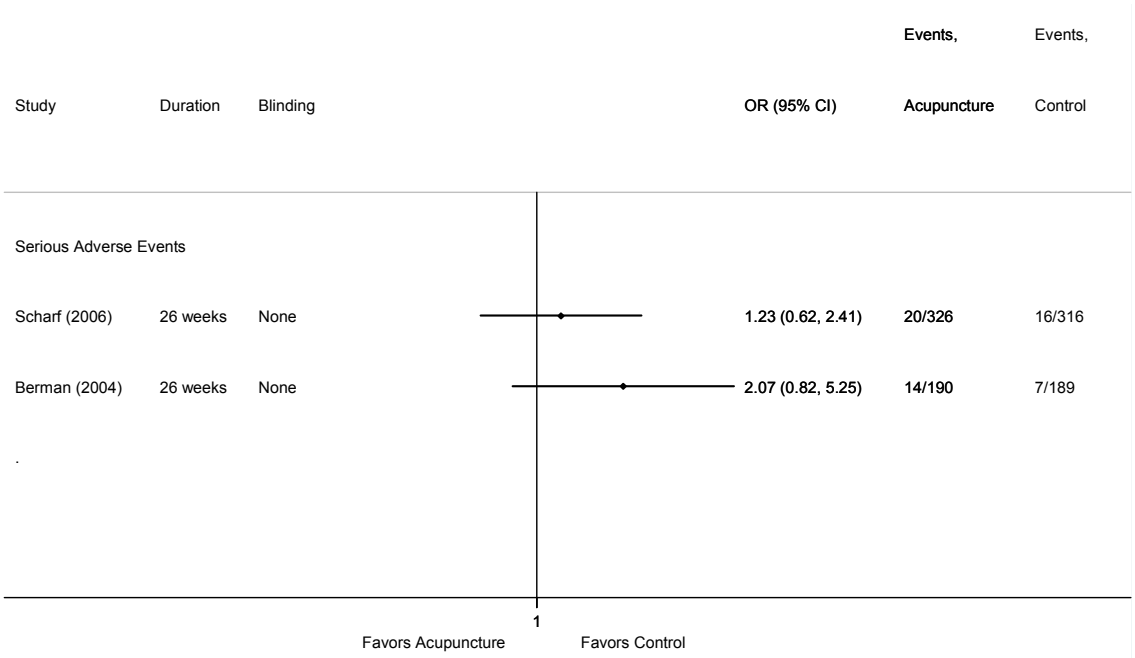


Figure 103. Acupuncture vs. Control - Serious Adverse Events



*These studies compared the acupuncture treatment group to both a placebo group and a non-sham control group. The level of blinding for a given study is specific to the comparison being made for each outcome; therefore, an individual study's level of blinding may vary in each figure.

RECOMMENDATION 12

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

AAOS Level of Evidence: **I**
AAOS Grade of Recommendation: **A**

Rationale:

This recommendation is based on an Agency for Healthcare Research and Quality (AHRQ) report[12] that provides evidence from one RCT and six systematic reviews (Table 8) on the use of glucosamine and/or chondroitin sulfate or hydrochloride among patients with symptomatic OA of the knee. We evaluated this evidence as Level I.

The AHRQ report states that "the best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination did not have any clinical benefit in patients with primary OA of the knee."[12] One of the six systematic reviews concluded no clinical benefit for glucosamine or chondroitin compared to placebo. The remaining five systematic reviews did not provide conclusions on the clinical importance; however, they conclude glucosamine and/or chondroitin are superior to placebo (Table 9).

The AAOS workgroup agreed that the AHRQ report presents a high quality systematic review of Level I evidence that demonstrates the best available evidence does not support prescribing glucosamine and/or chondroitin.

Supporting Evidence

This recommendation is addressed by the AHRQ Report,[12] and all of the quotations in this subsection are from that report:

"The best available evidence found that glucosamine hydrochloride, chondroitin sulfate, or their combination provide no clinical benefit in patients with primary OA of the knee. Five of six meta-analysis' concluded that glucosamine or chondroitin were superior to placebo. However, the MA (meta-analyses) results do not outweigh the GAIT results due to lower quality of the primary literature and small differences reported." (p.106)

"Glucosamine sulfate has been reported to be more effective than glucosamine hydrochloride, but the evidence is insufficient to draw conclusions." (p.106)

"In general, adverse events with glucosamine or chondroitin treatment were no greater than placebo." (p.107)

Table 8. Summary of Evidence from AHRQ Report - GAIT Results

Outcome*	Comparison	Result (n/N)	p-value**
20% decrease in WOMAC pain score	Glucosamine HCl vs. Placebo	64% (203/317)	p = 0.30
20% decrease in WOMAC pain score	Chondroitin Sulfate vs. Placebo	65.4% (208/318)	p = 0.17
20% decrease in WOMAC pain score	Glucosamine HCl + Chondroitin Sulfate vs. Placebo	66.6% (211/317)	p = 0.09
20% decrease in WOMAC pain score	Celecoxib vs. Placebo	70.1% (223/318)	p = 0.008

* 18% change in WOMAC pain is considered clinically important [19]
** p-value is from comparison to placebo

Table 9. Summary of Evidence from AHRQ Report - Review Conclusions

Systematic Review	Treatment Evaluated	Conclusion of Systematic Review
Bjordal 2006	Glucosamine or Chondroitin	No clinical benefit
Towheed 2006	Glucosamine	Statistically significant effect in favor of glucosamine
Poolsup 2005	Glucosamine	Glucosamine possesses moderate efficacy in improving symptoms
Richy 2003	Glucosamine or Chondroitin	Glucosamine and chondroitin are beneficial
Leeb 2000	Chondroitin	Significant efficacy of chondroitin on pain and function
McAlindon 2000	Glucosamine or Chondroitin	Glucosamine and Chondroitin may have efficacy and are safe

RECOMMENDATION 13

We suggest patients with symptomatic OA of the knee receive one of the following analgesics for pain unless there are contraindications to this treatment:

- Acetaminophen [not to exceed 4 grams per day]
- Non-steroidal anti inflammatory drugs (NSAIDs)

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **B**

Rationale:

The OARSI guidelines, on which this recommendation is based, provide evidence from three systematic reviews on the use of acetaminophen compared to placebo among patients with symptomatic OA of the knee.[13, 14] In addition, the OARSI guidelines provide evidence from four systematic reviews that examined the use of NSAIDs compared to placebo or acetaminophen. We categorized this evidence as Level II because of the lesser quality of included trials in the systematic reviews.

The evidence suggests statistically significant effects of acetaminophen on pain relief without any statistically significant risk of toxicity, when compared to placebo. The clinical importance of the effect on pain cannot be determined (Table 10).

NSAIDs appear to have a statistically significant effect on pain (Table 11), the clinical importance of which cannot be determined. NSAIDs also appear to reduce pain (as measured by the WOMAC subscale) significantly more than acetaminophen, but the effect is not clinically important (Table 11). Finally, NSAIDs have statistically significant and favorable effects on clinical response and patient preference as compared to acetaminophen, but a statistically significant increased risk of gastrointestinal complications. The clinical importance of these effects cannot be determined (Table 11).

Supporting Evidence
Table 10 and Table 11 (see next page)

Table 10. Summary of Evidence from OARSI for Acetaminophen

Outcomes	Comparison	ES (95% CI)	MCII
Pain*	acetaminophen vs. placebo	*d* = 0.21 (0.02, 0.4)	?
Pain*	acetaminophen vs. placebo	*d* = 0.13 (0.04, 0.22)	?
Toxicity*	acetaminophen vs. placebo	RR = 1.02 (0.89, 1.87)	?

d = standard mean difference
ES = effect size
MCII = minimal clinically important effect
? = cannot be determined/unknown

* Outcome measure is not defined by OARSI.

Table 11. Summary of Evidence from OARSI for NSAIDs

Outcomes	Comparison	ES (95% CI)	MCII
Pain*	NSAIDs/COX-2 vs. placebo	*d* = 0.32 (0.24, 0.39)	?
Pain**	NSAIDs/COX-2 vs. placebo	*d* = 0.23 (0.15, 0.31)	?
Pain	NSAIDs vs. acetaminophen	*d* = 0.20 (0.10, 0.30)	0.39
Clinical Response*	NSAIDs vs. acetaminophen	RR = 1.24 (1.08, 1.41)	?
Patient preference*	NSAIDs vs. acetaminophen	RR = 2.46 (1.51, 4.12)	?
GI Complications*	NSAIDs vs. acetaminophen	RR = 1.47 (1.08, 2.00)	?

d = standard mean difference
ES = effect size
MCII = minimal clinically important effect
? = cannot be determined/unknown

* Outcome is not defined by OARSI

** Analysis includes only trials that did not require patients to have a minimum flare of symptoms after treatment with NSAIDs was stopped before the trial

RECOMMENDATION 14

We suggest patients with symptomatic OA of the knee and increased GI risk (Age >= 60 years, co-morbid medical conditions, history of peptic ulcer disease, history of GI bleeding, concurrent corticosteroids and/or concomitant use of anticoagulants) receive one of the following analgesics for pain:

- Acetaminophen [not to exceed 4 grams per day]
- Topical NSAIDs
- Nonselective oral NSAIDs plus gastro-protective agent
- Cyclooxygenase-2 (COX-II) inhibitors

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **B**

Rationale:

The OARSI guidelines, on which this recommendation is based, provide evidence from eleven systematic reviews on the use of acetaminophen, topical NSAIDs, nonselective oral NSAIDs plus a gastroprotecive agent, or COX-II inhibitors among patients with symptomatic OA of the knee that have increased risk of GI complications.[13, 14] This evidence was evaluated as Level II because of the lesser quality of included trials in the systematic reviews.

The effectiveness of acetaminophen is discussed in Recommendation 13.

For topical NSAIDs, the evidence suggests a statistically significant effect on pain relief, stiffness, and function, but (Table 12) the clinical importance of these effects cannot be determined.

The effectiveness of nonselective oral NSAIDs and COX-II inhibitors is discussed in Recommendation 13. The evidence for oral NSAIDs included trials which investigated nonselective oral NSAIDs and COX-II inhibitors (Table 11 above).

Each of these regimens has a reduced relative risk for adverse GI events when compared with the isolated use of oral NSAIDs. The evidence does not demonstrate an advantage for any of these treatment regimens.[13, 14]

Supporting Evidence

See Table 10 and Table 11 in Recommendation 13.
See Table 12 next page.

Table 12. Summary of Evidence from OARSI for Topical NSAIDs

Outcomes	Comparison	ES (95% CI)	MCII
Pain* (1 week)	topical NSAIDs vs. placebo	*d* = 0.41 (0.16, 0.66)	?
Pain* (2 weeks)	topical NSAIDs vs. placebo	*d* = 0.40 (0.15, 0.65)	?
Pain* (≥ 4 weeks)	topical NSAIDs vs. placebo	*d* = 0.28 (0.14, 0.42)	?
Stiffness*	topical NSAIDs vs. placebo	*d* = 0.49 (0.17, 0.80)	?
Function*	topical NSAIDs vs. placebo	*d* = 0.36 (0.24, 0.48)	?

d = standard mean difference
ES = effect size
MCII = minimal clinically important effect
? = cannot be determined/unknown

* Outcome is not defined by OARSI

RECOMMENDATION 15

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

AAOS Level of Evidence: **II**
AAOS Grade of Recommendation: **B**

Rationale:

Intra-articular (IA) corticosteroid treatment in patients with symptomatic OA of the knee was examined in three Level II systematic reviews[15, 66, 76] which include lesser quality RCTs. A total of twelve unique RCTs comparing corticosteroid and placebo interventions were included in these reviews.[17, 77-87]

All three of the systematic reviews conclude that IA corticosteroids are effective for relieving pain in the short term (one week, 16-24 weeks,[76] at one week and continuing at two to three weeks,[15] and within 1-2 weeks[66]). The only systematic review that commented on whether these effects were clinically important concluded that the effects on pain at 1-2 weeks were not.[66] However, we were able to evaluate clinical importance using data from another systematic review.[15] The three RCTs considered in that review suggest possibly clinically important and statistically significant effects of intra-articular corticosteroids on pain (as measured by the VAS) one week after injection (Figure 105).

There is little evidence suggesting that intra-articular steroids have longer term benefits.

Supporting Evidence

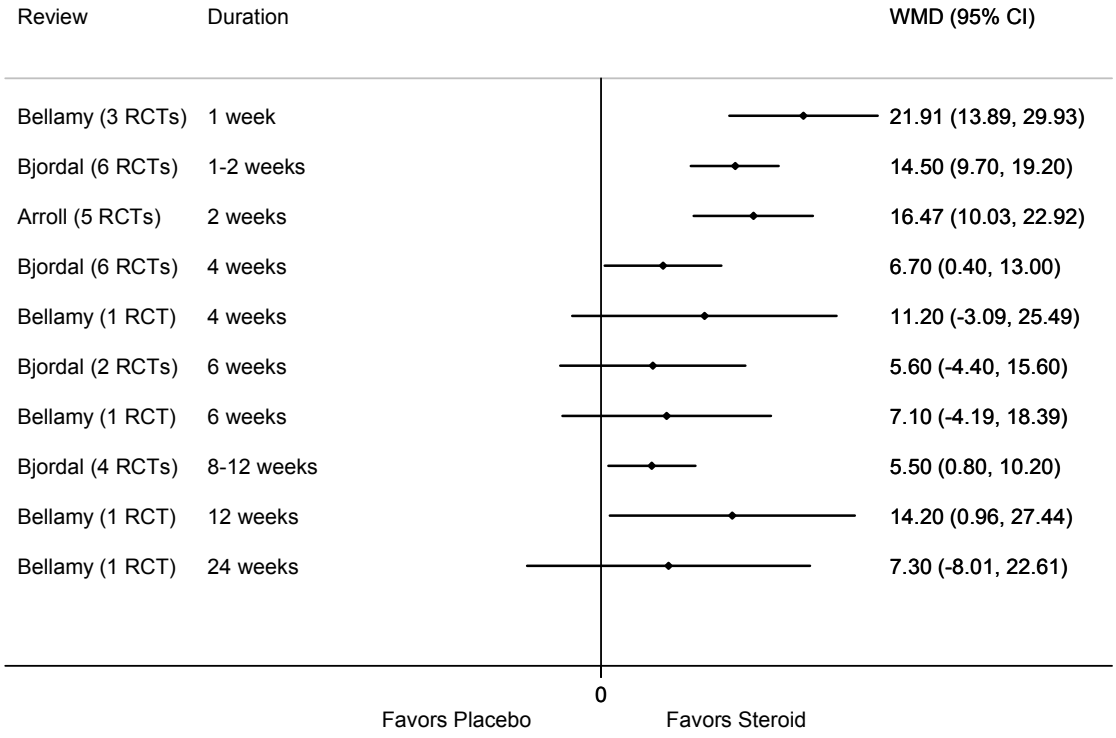
For the raw data addressing this recommendation, please see evidence tables: 18 – 19.
Figures relevant to this recommendation are Figure 104 – Figure 127.
The relevant study attrition diagram is shown in Appendix III.

PAIN: VAS

Level of Evidence:
Three Level II Systematic Review

All three previously published systematic reviews[15, 66, 76] assessed pain measured by VAS. A total of seven RCTs were examined within these systematic reviews, three of which were included in all three systematic reviews.[17, 79, 81]

Figure 104. WMD in pain measured by VAS (three systematic reviews: Arroll & Goodyear-Smith 2004, Bellamy et al. 2007, Bjordal et al. 2007)

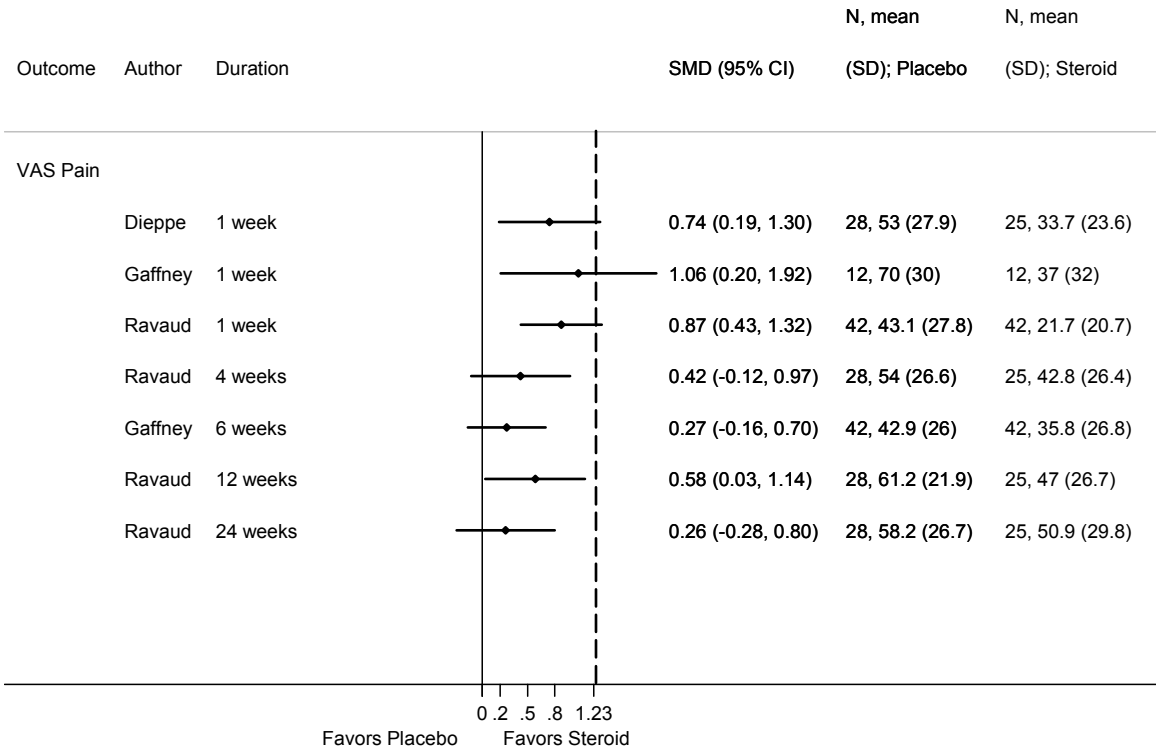


PAIN: VAS

Level of Evidence:
One Level II Systematic Review

One previously published systematic review[15] assessed pain measured by VAS. A total of three RCTs were examined.[17, 79, 81]

Figure 105. Pain measured by 100 mm VAS (systematic review Bellamy et al. 2007)



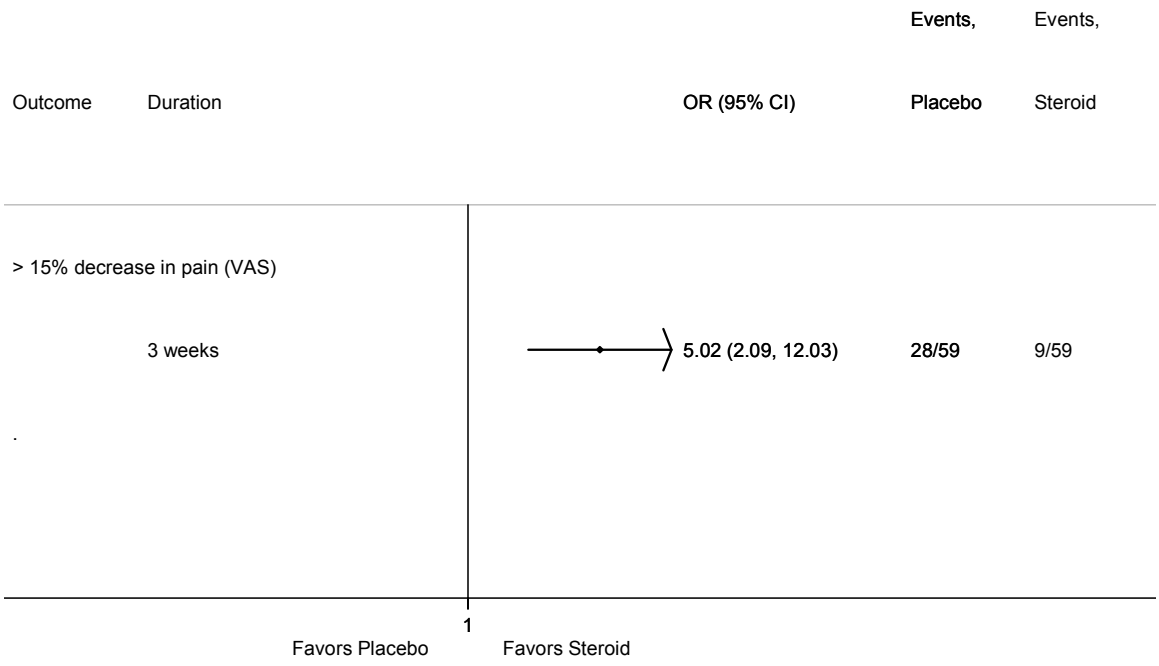
*Dashed line indicates MCII for VAS pain.

PAIN: >15% REDUCTION

Level of Evidence:
One Level II Systematic Review

One previously published systematic review,[15] reported one RCT[82] that examined the number of responders with a reduction in pain greater than fifteen percent three weeks post injection. Pain was assessed using VAS. Although a 15% reduction in pain was selected by the authors *a priori*, Tubach et al.[21] have reported a 40% reduction is necessary to be minimally clinically important.

Figure 106. Patients with greater than fifteen percent reduction in pain (systematic review Bellamy et al. 2007)

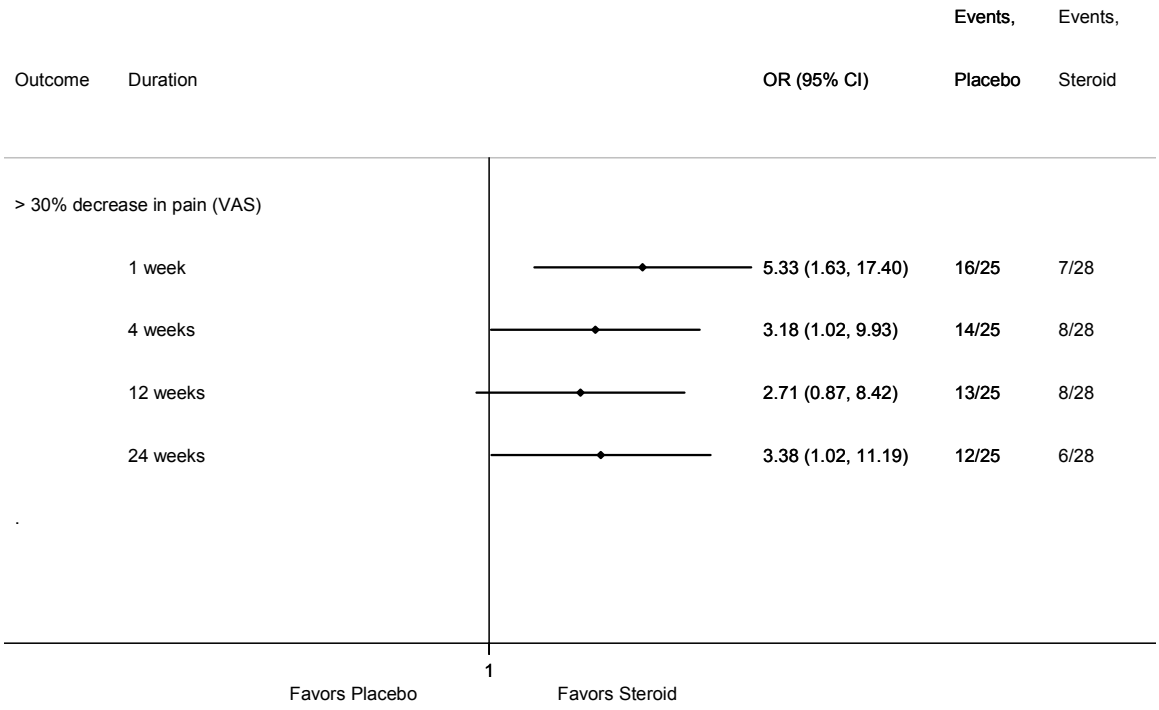


PAIN: >30% REDUCTION

Level of Evidence:
One Level II Systematic Review

One RCT[17] included in a previously published systematic review[15] examined the number of responders with a reduction in pain greater than thirty percent. Pain was assessed using VAS. Although a 30% reduction in pain was selected by the authors *a priori*, Tubach et al.[21] have reported a 40% reduction is necessary to be minimally clinically important.

Figure 107. Patients with greater than thirty percent reduction in pain (systematic review Bellamy et al. 2007)

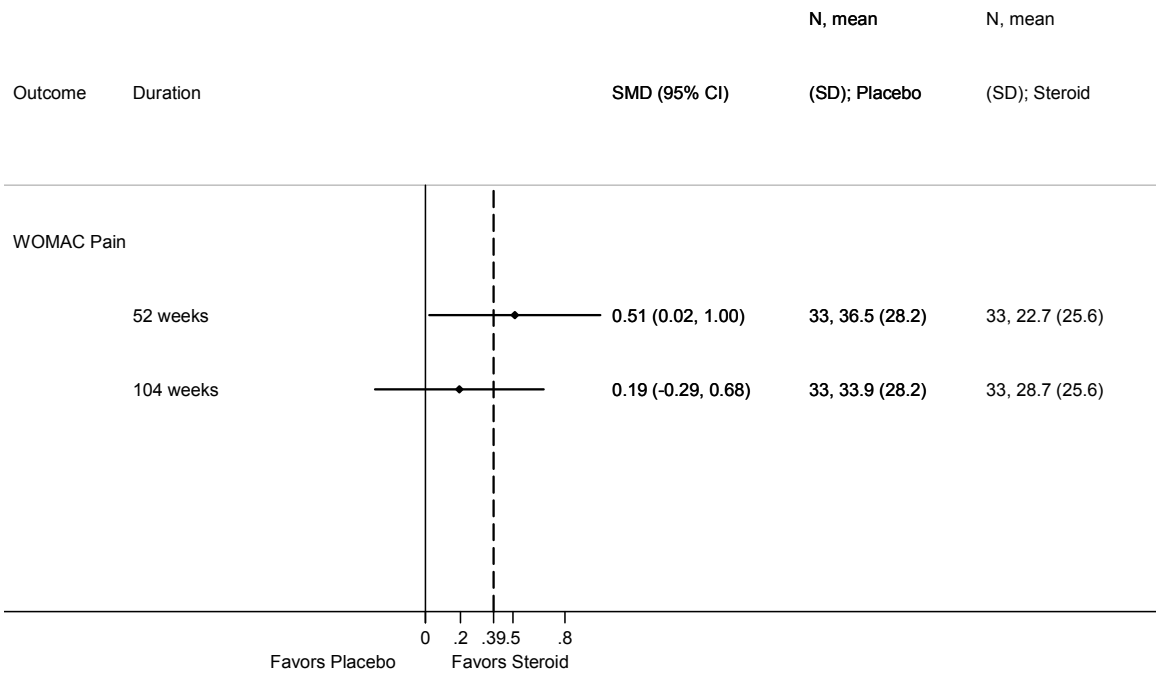


PAIN: WOMAC

Level of Evidence:
One Level II Systematic Review

One RCT[17] included in a previously published systematic review[15] assessed pain measured by WOMAC using a 100 mm VAS. To clarify the two year duration of study, the patient dose regimen is defined by the author either IA steroid or IA saline injections every three months over the course of the two year study for a total of eight injections.

Figure 108. WOMAC pain assessment measured by 100 mm VAS (systematic review Bellamy et al. 2007)



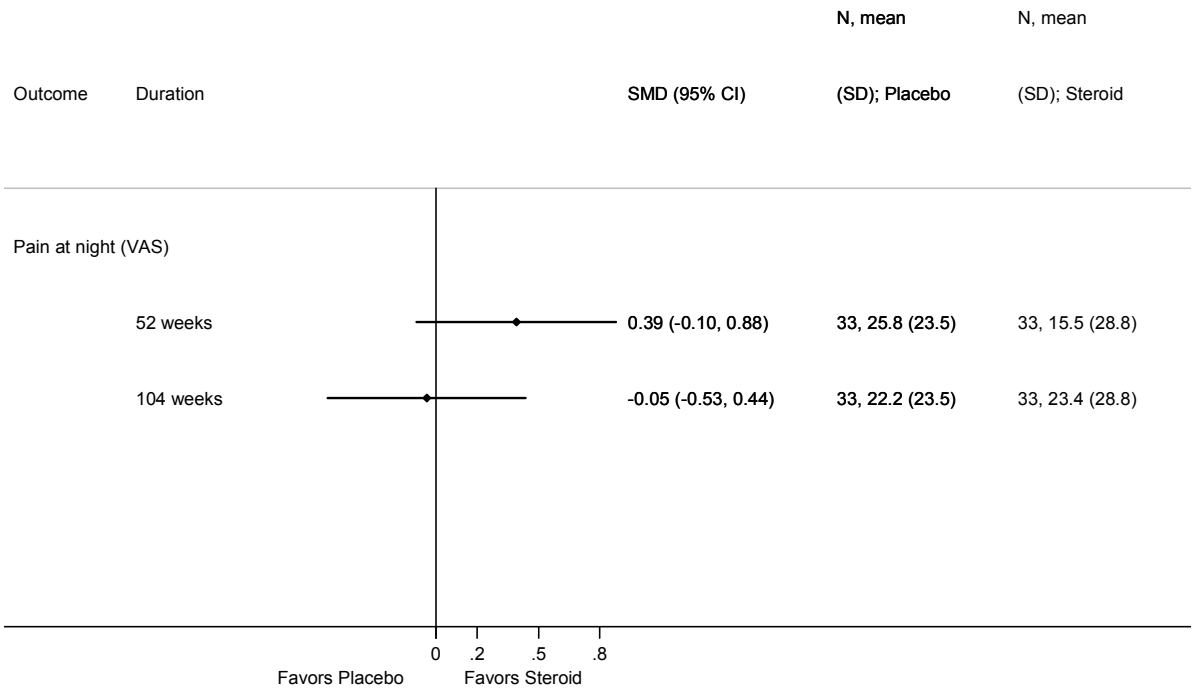
*Dashed line indicates MCII for WOMAC pain.

PAIN: AT NIGHT

Level of Evidence:
One Level II Systematic Review

One RCT[85] included in a previously published systematic review[15] assessed pain at night measured by a 100 mm VAS. To clarify the two year duration of study, the patient dose regimen is defined by the author either IA steroid or IA saline injections every three months over the course of the two year study for a total of eight injections.

Figure 109. Pain at night measured by 100 mm VAS (systematic review Bellamy et al. 2007)

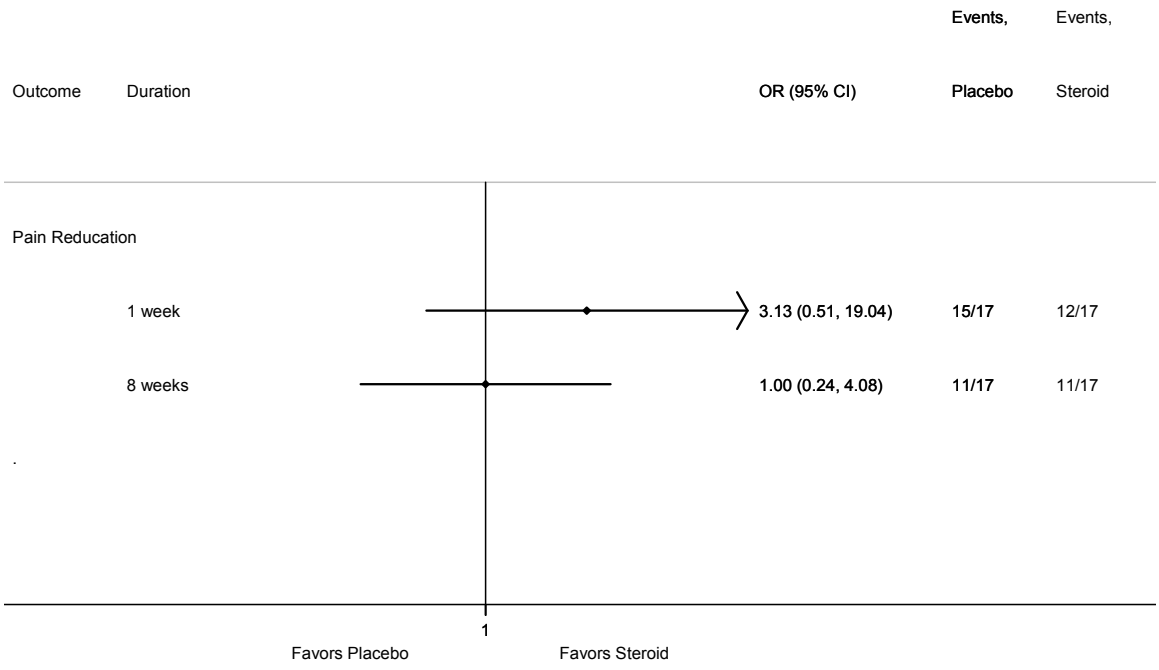


PAIN: REDUCTION

Level of Evidence:
One Level II Systematic Review

One RCT[80] included in a previously published systematic review[15] assessed the number of patients reporting a reduction in pain.

Figure 110. Patients reporting pain reduction (systematic review Bellamy et al. 2007)

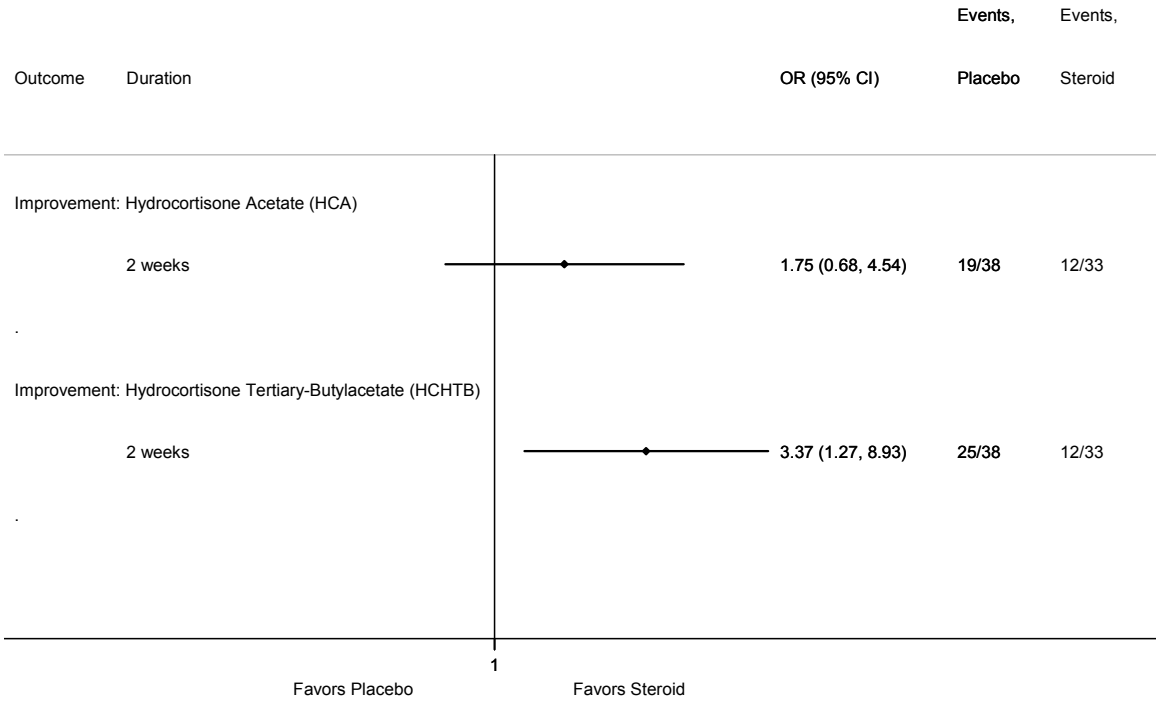


PAIN: IMPROVEMENT

Level of Evidence:
One Level II Systematic Review

One RCT[87] included in a previously published systematic review[15] examined the number of knees with improvement in pain two weeks post injection. Authors considered improvement as a participant rating symptoms less severe than the initial baseline assessment.

Figure 111. Knees with improvement after two weeks (systematic review Bellamy et al. 2007)

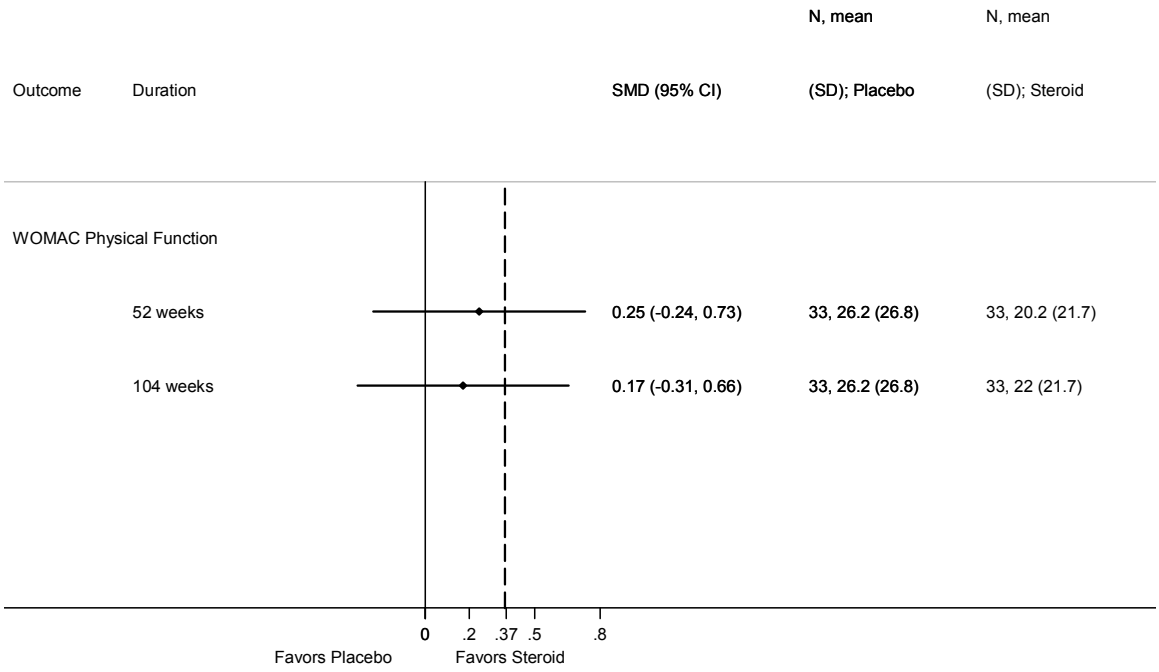


FUNCTION: WOMAC

Level of Evidence:
One Level II Systematic Review

One RCT[85] included in a previously published systematic review[15] assessed function measured by WOMAC using a 100 mm VAS. To clarify the two year duration of study, the patient dose regimen is defined by the author either IA steroid or IA saline injections every three months over the course of the two year study for a total of eight injections.

Figure 112. WOMAC physical function measured by 100 mm VAS (systematic review Bellamy et al. 2007)



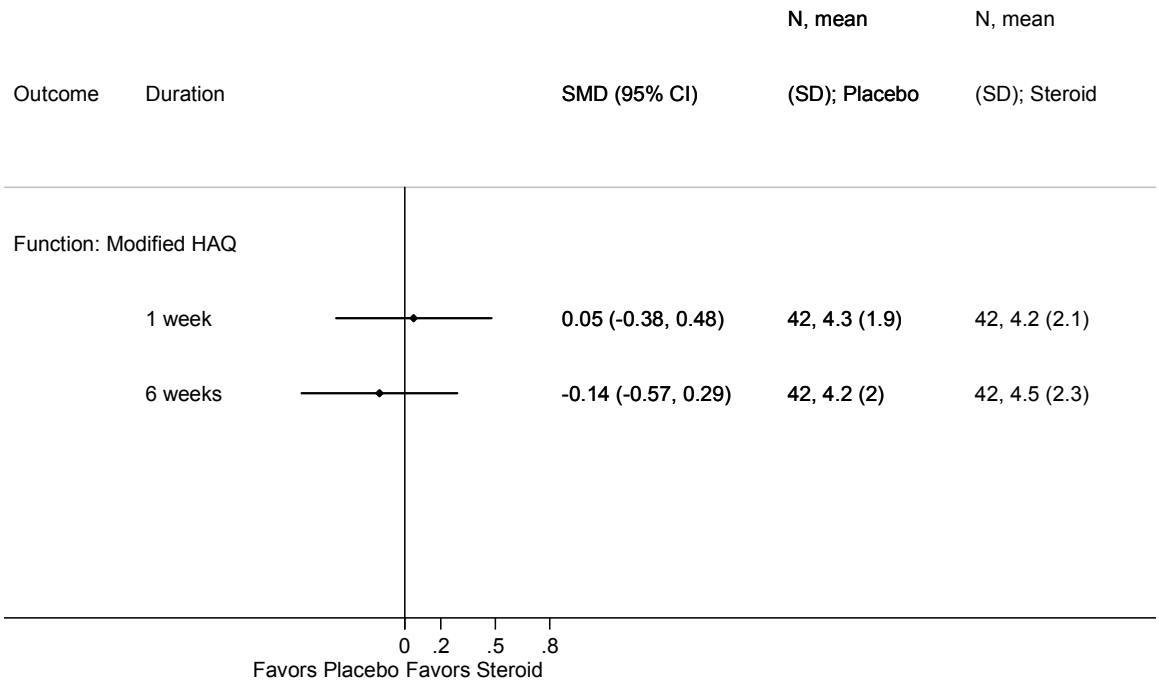
*Dashed line indicates MCII for WOMAC function.

FUNCTION: MODIFIED HEALTH ASSESSMENT QUESTIONNAIRE (HAQ)

Level of Evidence:
One Level II Systematic Review

One RCT[81] included in a previously published systematic review[15] utilized the Health Assessment Questionnaire (HAQ) modified for lower limb function. The HAQ is a five-dimension, patient-oriented measure assessing disability, pain, medication effects, costs of care and mortality.

Figure 113. Function measured by HAQ (systematic review Bellamy et al. 2007)

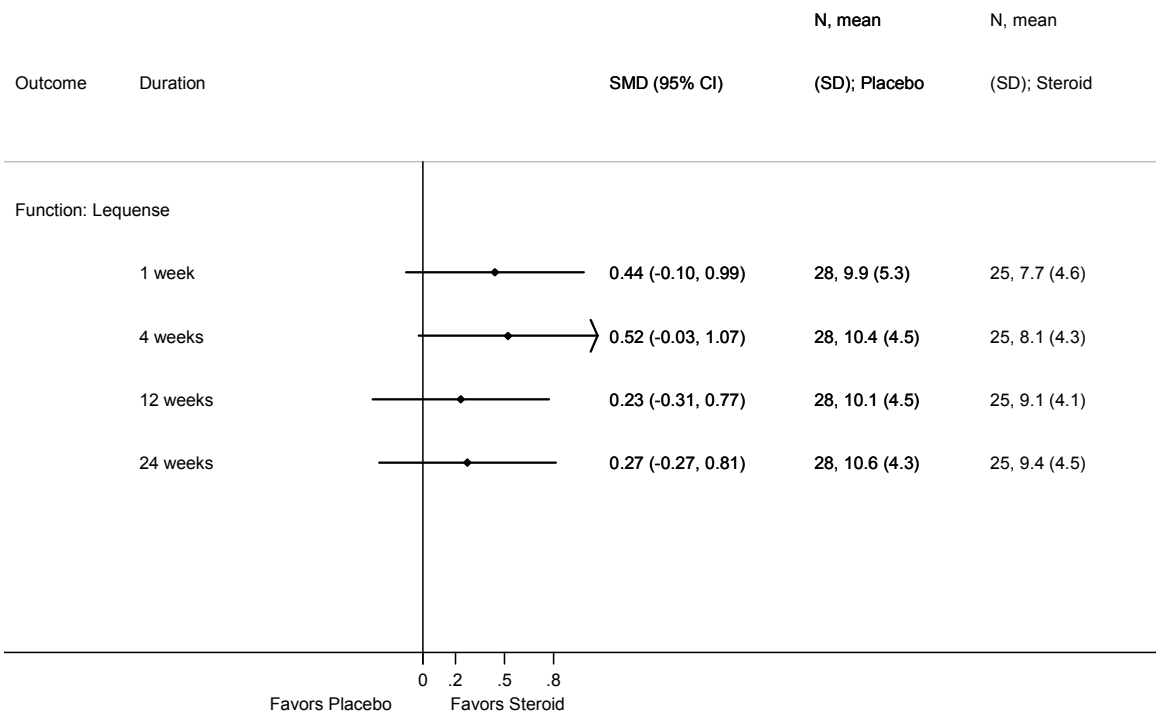


FUNCTION: LEQUESNE

Level of Evidence:
One Level II Systematic Review

One RCT[17] included in a previously published systematic review[15] assessed function as measured by the Lequesne Index. Scoring on the ten question Lequesne Index ranges from 0-24 with lower scores indicating less functional impairment.

Figure 114. Function measured by Lequesne Index (systematic review Bellamy et al. 2007)

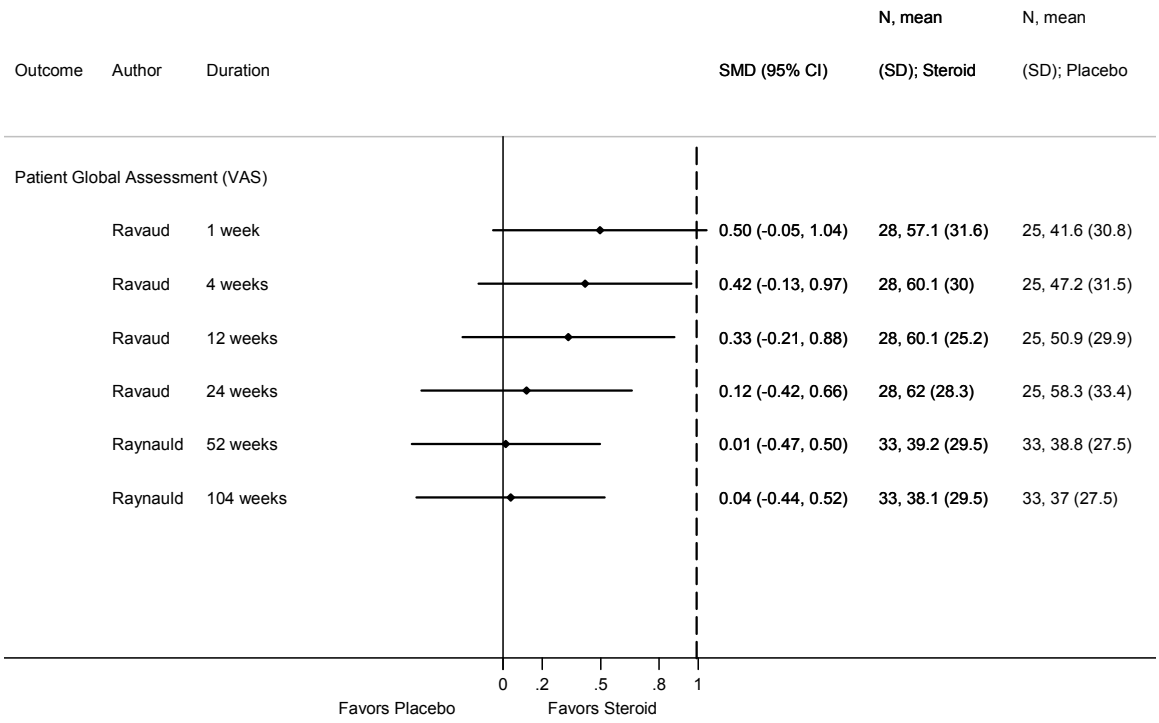


GLOBAL ASSESSMENT

Level of Evidence:
One Level II Systematic Review

Two RCTs[17, 85] included in a previously published systematic review[15] assessed patient global assessment measured by 100 mm VAS.

Figure 115. Global assessment measured by 100 mm VAS (systematic review Bellamy et al. 2007)



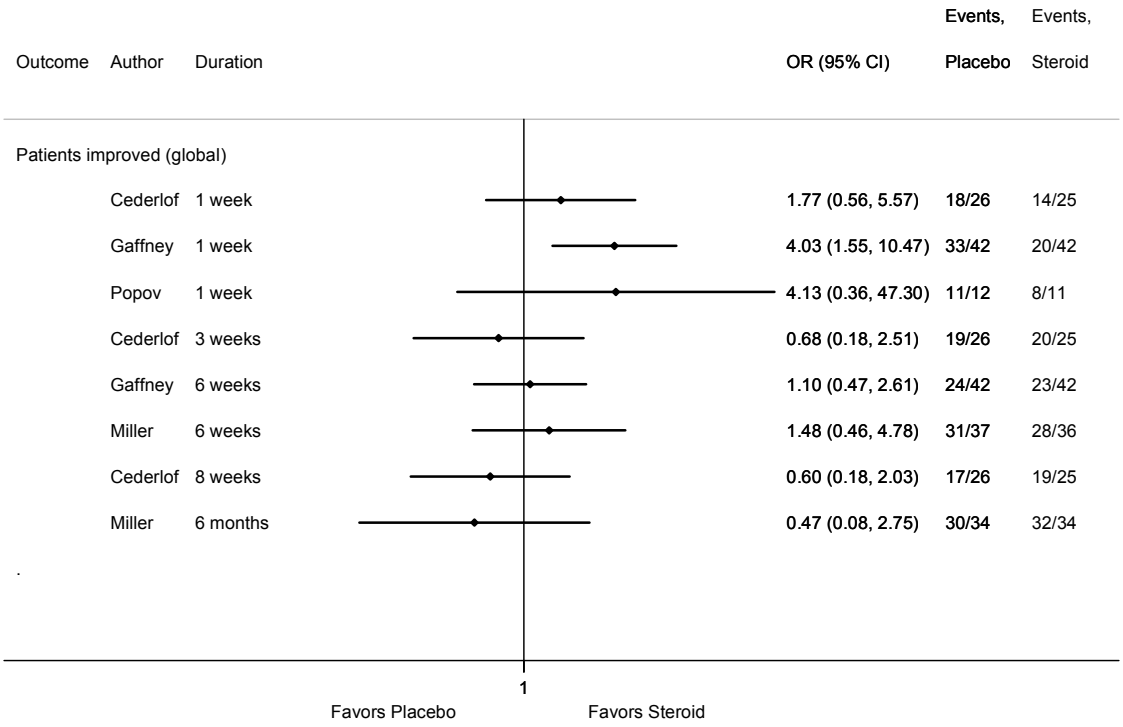
*Dashed line indicates MCII for global assessment (VAS).

GLOBAL ASSESSMENT: IMPROVEMENT

Level of Evidence:
One Level II Systematic Review

Four RCTs[78, 81, 83, 84] included in a previously published systematic review[15] examined patients with improved global assessment. All measurements utilized the 100 mm VAS.

Figure 116. Patients with improved global assessment (systematic review Bellamy et al. 2007)

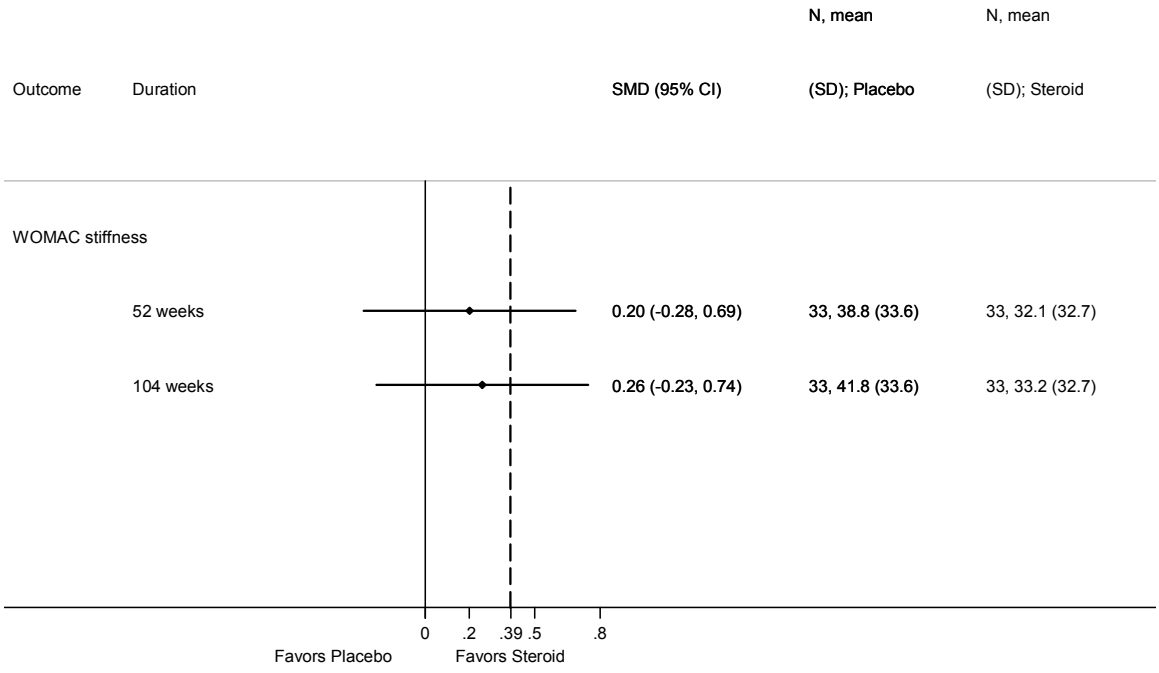


STIFFNESS: WOMAC

Level of Evidence:
One Level II Systematic Review

One RCT[85] included in a previously published systematic review[15] assessed stiffness measured by WOMAC using a 100 mm VAS. To clarify the two year duration of study, the patient dose regimen is defined by the author as either IA steroid or IA saline injections every three months over the course of the two year study for a total of eight injections.

Figure 117. WOMAC stiffness measured by 100 mm VAS (systematic review Bellamy et al. 2007)



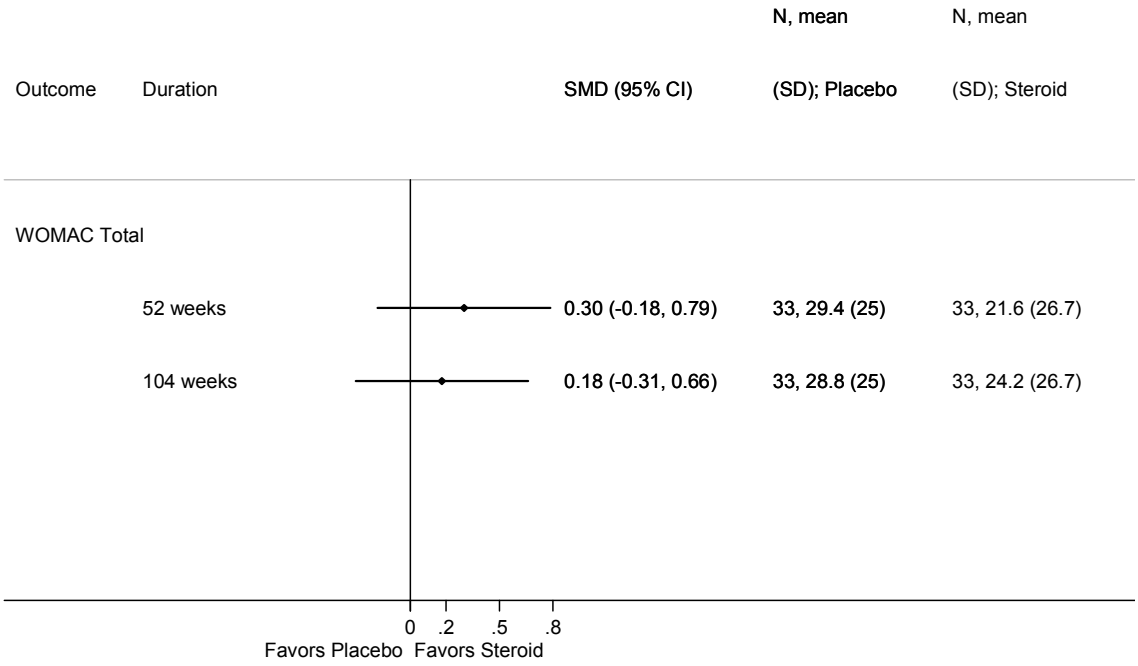
*Dashed line indicates MCII for WOMAC stiffness.

WOMAC TOTAL

Level of Evidence:
One Level II Systematic Review

One RCT[85] included in a previously published systematic review[15] examined total WOMAC score measured by 100 mm VAS. To clarify the two year duration of study, the patient dose regimen is defined by the author as either IA steroid or IA saline injections every three months over the course of the two year study for a total of eight injections.

Figure 118. Total WOMAC score measured by 100 mm VAS (systematic review Bellamy et al. 2007)

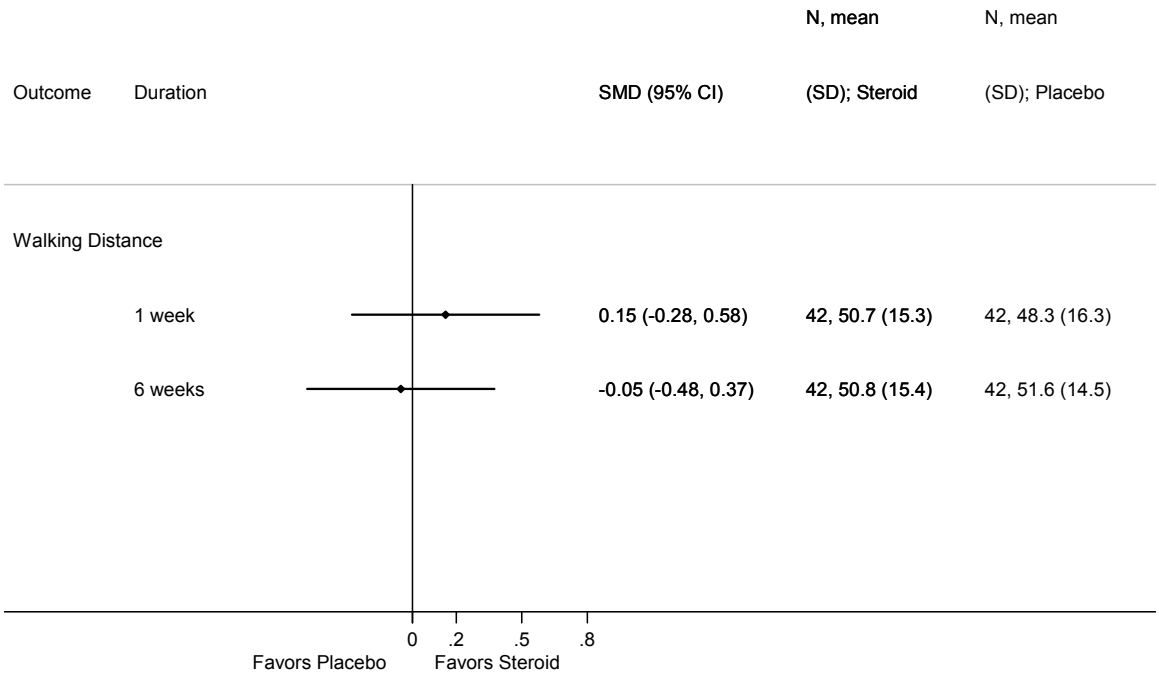


WALKING DISTANCE

Level of Evidence:
One Level II Systematic Review

One RCT[81] included in a previously published systematic review measured walking distance (in meters) over one minute.

Figure 119. Distance walked over one minute measured in meters (systematic review Bellamy et al. 2007)

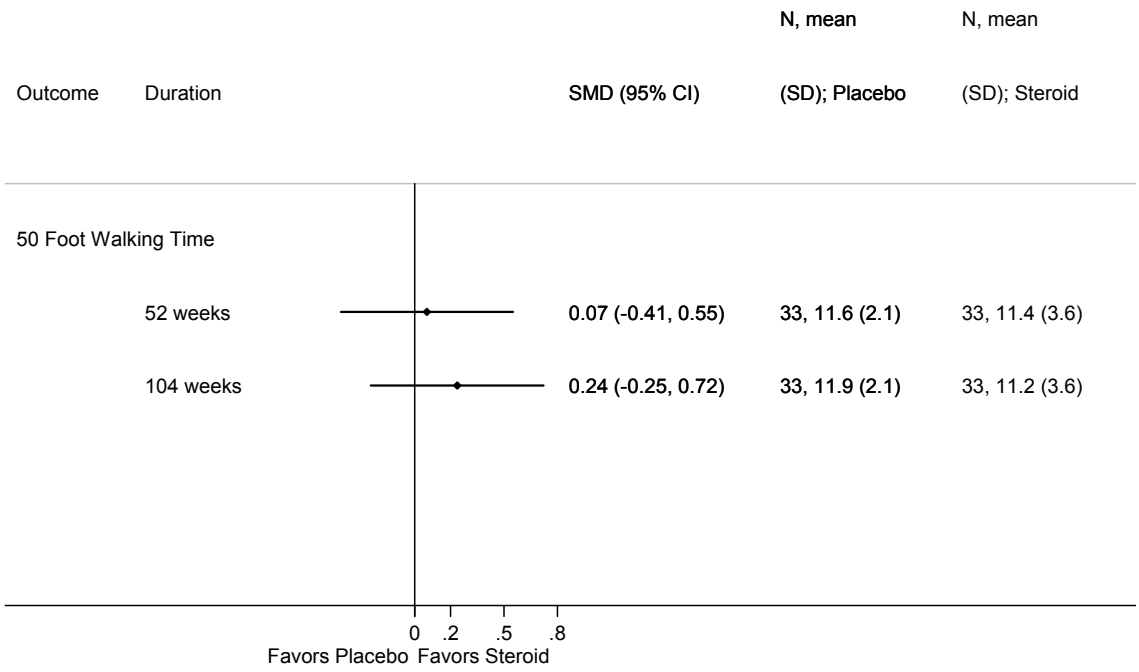


50-FOOT WALKING TIME

Level of Evidence:
One Level II Systematic Review

One RCT[85] included in a previously published systematic review[15] measured the time (in seconds) needed to walk fifty feet. To clarify the two year duration of study, the patient dose regimen is defined by the author as either IA steroid or IA saline injections every three months over the course of the two year study for a total of eight injections.

Figure 120. 50-foot walk time measured in seconds (systematic review Bellamy et al. 2007)

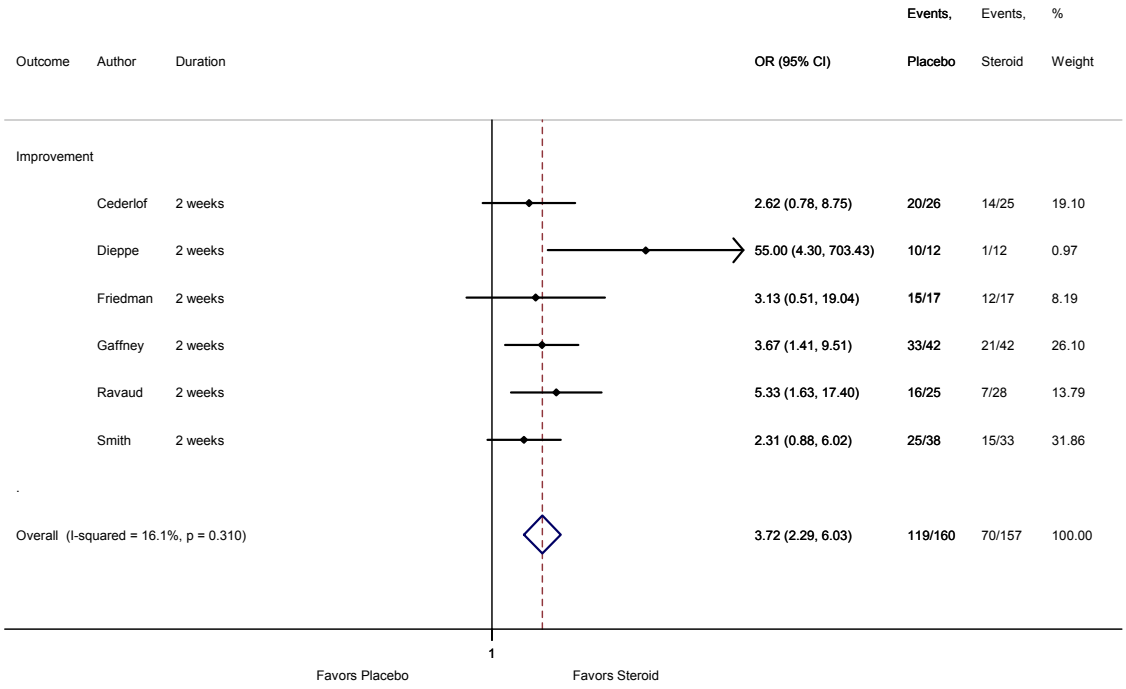


IMPROVEMENT

Level of Evidence:
One Level II Systematic Review

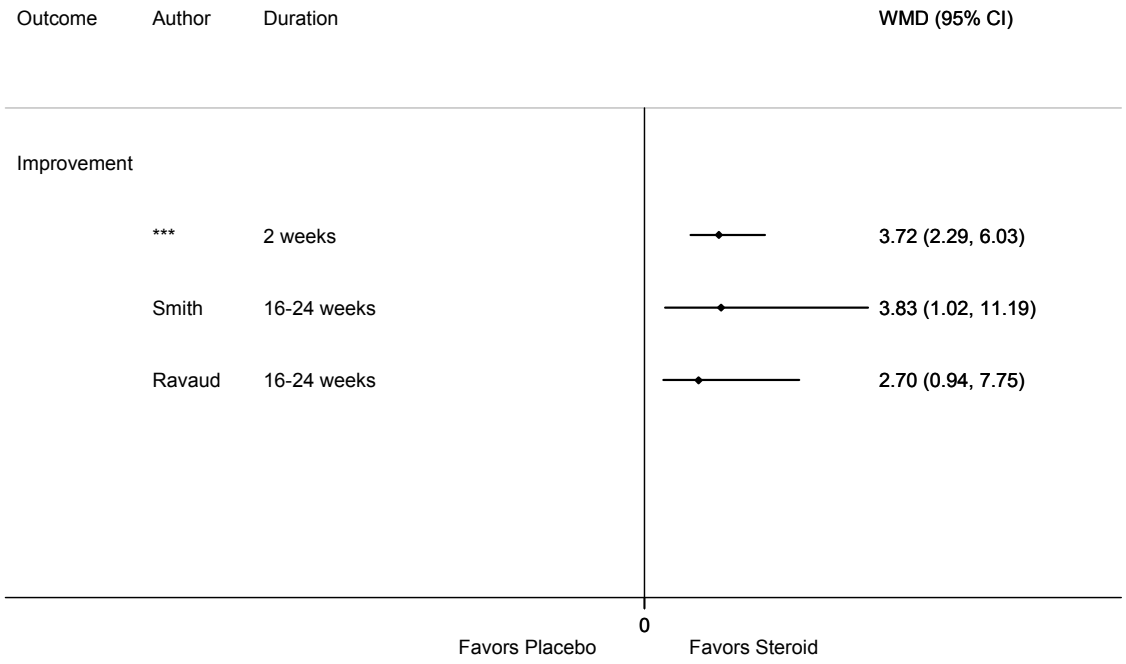
Six RCTs[17, 78-81, 86] included in a previously published systematic review[76] examined the number of knees with improvement. All six studies assessed at two weeks post injection and two of those studies also assessed sixteen to twenty-four weeks post injection.

Figure 121. Knees with improvement at two week duration shown as odds ratio (systematic review Arroll & Goodyear-Smith, 2004)



*Originally reported as risk ratios (RR) in the systematic review, odds ratios (OR) and the accompanying overall meta analysis statistic were calculated to maintain consistency through the guideline. Statistical significance and direction of effect are consistent with original systematic review.

Figure 122. Knees with improvement at all durations shown as weighted mean difference (systematic review Arroll & Goodyear-Smith, 2004)



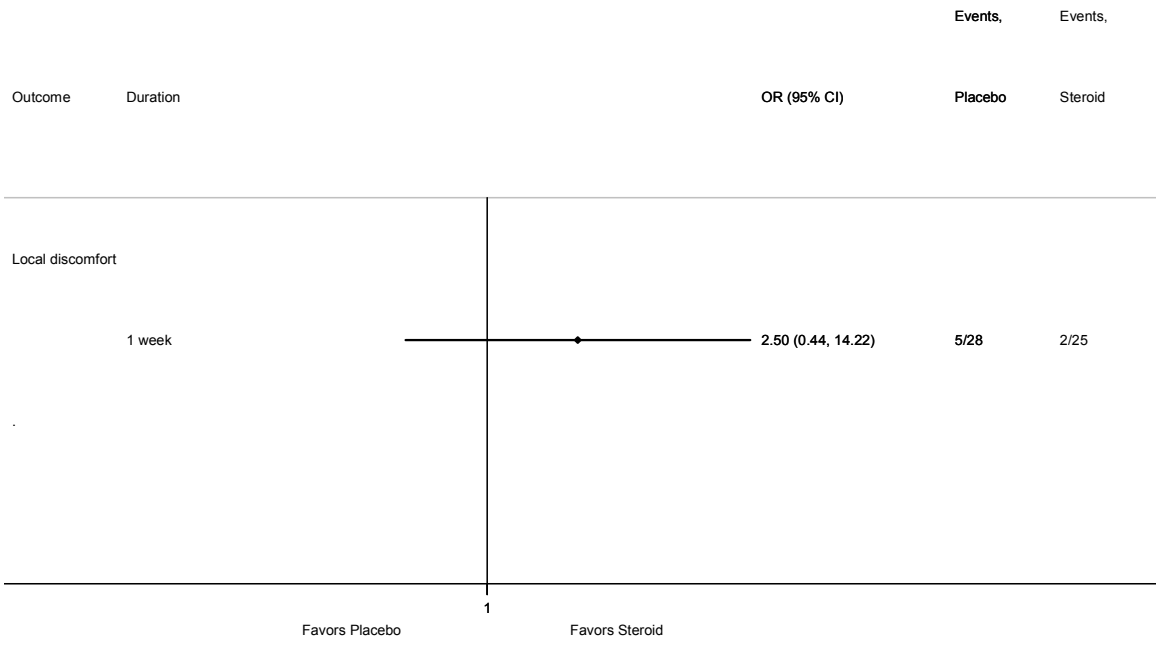
***WMD at two weeks is comprised of six RCTs shown in Figure 121.

LOCAL DISCOMFORT

Level of Evidence:
One Level II Systematic Review

One RCT[17] included in a previously published systematic review[15] examined the number of patients reporting local discomfort one week post injection. Patient ratings were made using a four-point scale.

Figure 123. Patients reporting local discomfort (systematic review Bellamy et al. 2007)

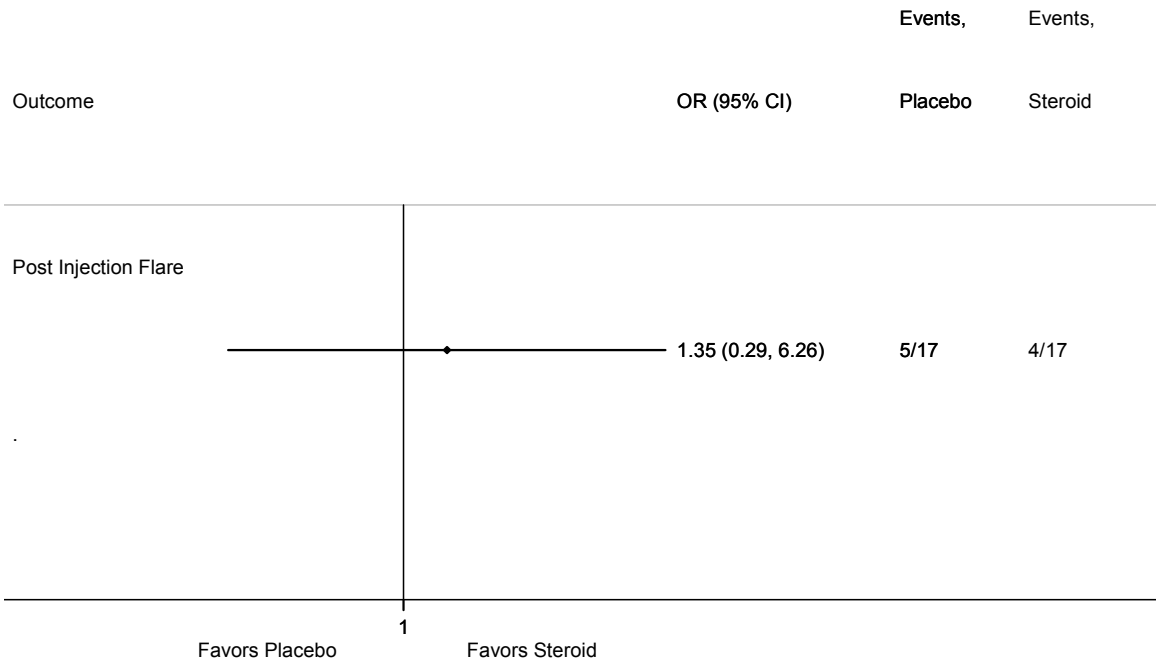


POST INJECTION FLARE

Level of Evidence:
One Level II Systematic Review

One RCT[80] included in a previously published systematic review[15] examined the number of patients experiencing post injection flare.

Figure 124. Patients with post injection flare (systematic review Bellamy et al. 2007)

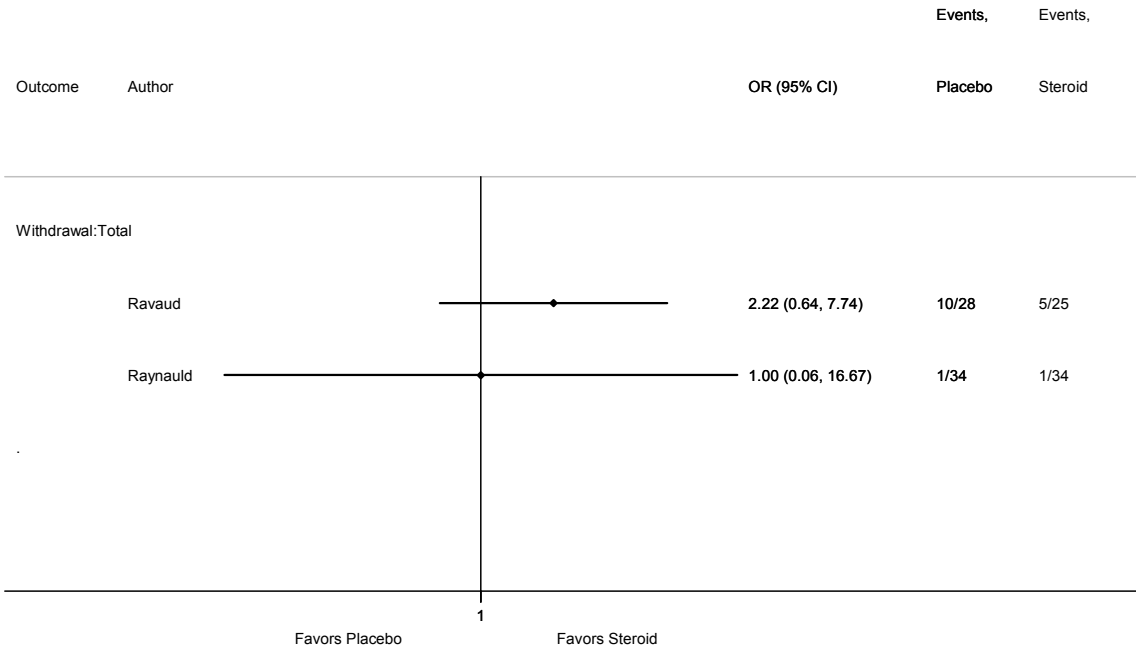


WITHDRAWALS: TOTAL

Level of Evidence:
One Level II Systematic Review

Two RCTs[17, 85] included in a previously published systematic review[15] examined the total number of withdrawals.

Figure 125. Total number of withdrawals (systematic review Bellamy et al. 2007)

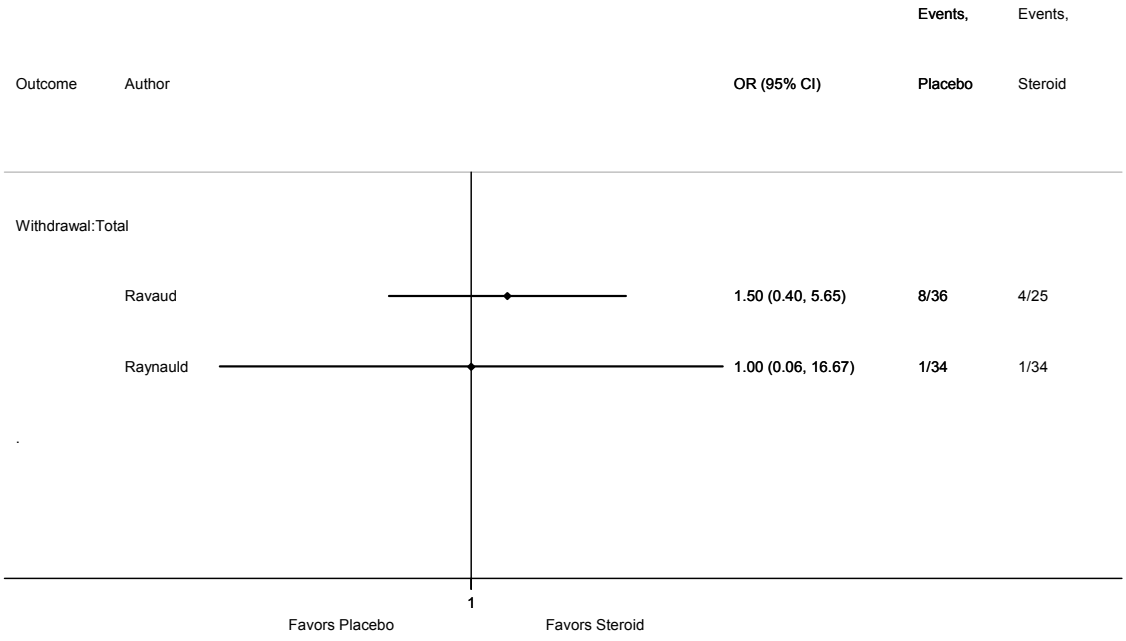


WITHDRAWALS: EFFICACY

Level of Evidence:
One Level II Systematic Review

Two RCTs[17, 85] included in a previously published systematic review[15] examined the total number of withdrawals due to lack of efficacy.

Figure 126. Total number of withdrawals due to lack of efficacy (systematic review Bellamy et al. 2007)

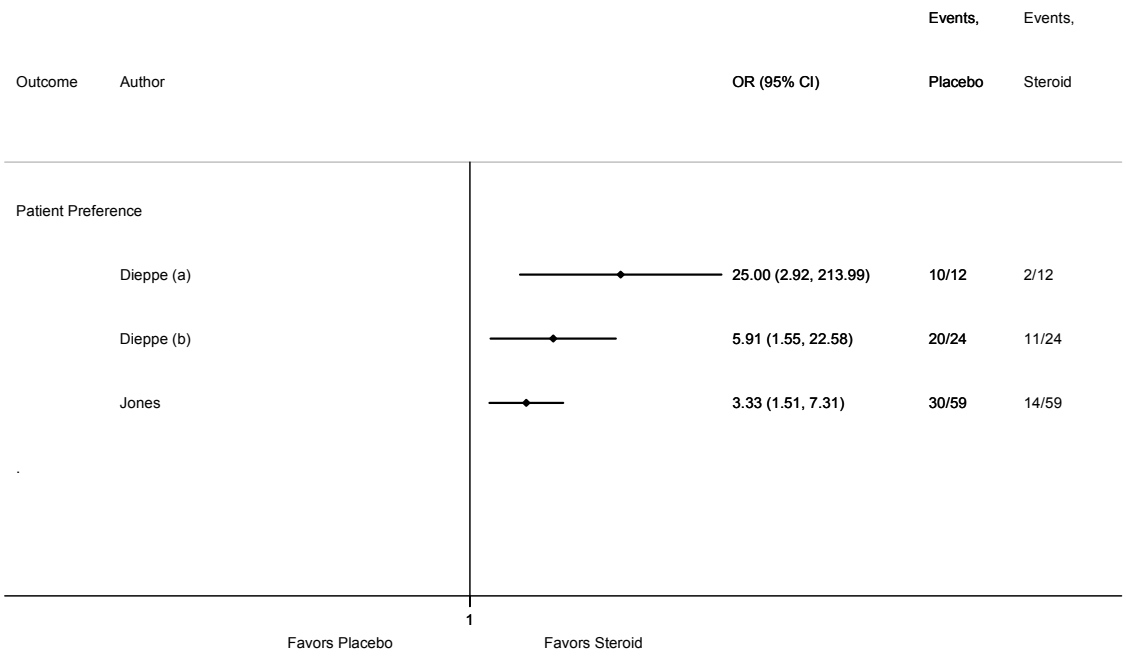


PATIENTS PREFERENCE

Level of Evidence:
One Level II Systematic Review

Two RCTs[79, 82] included in a previously published systematic review[15] examined the number of patients preferring steroid treatment.

Figure 127. Number of Patients preferring treatment (systematic review Bellamy et al. 2007)



RECOMMENDATION 16

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

AAOS Level of Evidence: **I and II**
AAOS Grade of Recommendation: **Inconclusive**

Rationale:

The Agency for Healthcare Research and Quality (AHRQ) report [12] upon which this recommendation is based provides evidence from 42 trials that examined the effectiveness of intra-articular hyaluronic acid (viscosupplementation) in patients with symptomatic OA. The AHRQ report explains that six meta-analyses and one additional RCT were considered in their review. This evidence was evaluated as Level I and II because some of the trials included in the AHRQ report were not well designed, high quality RCTs.

The AHRQ report states that "viscosupplementation generally shows positive effects" However, AHRQ further comments on these results, noting that they could have been influenced by "trial quality, potential publication bias, and unclear clinical significance (importance)." AHRQ also noted that the "pooled effects from poor-quality trials were as much as twice those obtained from higher ones (trials)."

The AAOS workgroup agreed that the AHRQ report presents a high quality systematic review of Level I and Level II evidence and graded this recommendation as inconclusive because of the conflicting evidence in pooled effects along with the unclear clinical importance of the results.

Supporting Evidence
This recommendation is addressed by the AHRQ report[12], and all quotations in this section are from that report:

"Results from 42 trials (N=5,843), all but one synthesized in various combinations in six meta-analyses, generally show positive effects of viscosupplementation on pain and function scores compared to placebo. However, the evidence on viscosupplementation is accompanied by considerable uncertainty due to variable trial quality, potential publication bias, and unclear clinical significance of the changes reported." (p. 2)

- "The pooled effects from poor-quality trials were as much as twice those obtained from higher-quality ones." (p. 2)
- "There is evidence consistent with potential publication bias. Pooled results from small trials (<100 patients) showed effects up to twice those of larger trials consistent with selective publication of underpowered positive trials. Among trials of viscosupplementation, those that have not been published in full text comprise approximately 25 percent of the total patient population."(p. 64)
- "Interpreting the clinical significance of pooled mean effects from the meta-analyses is difficult; mean changes do not quantify proportions responding. Numbers needed to treat cannot be calculated from mean changes." (p. 64)

"Trials of hylan G-F 20, the highest molecular weight cross-linked product, generally reported better results than other trials." (p. 64)

"Minor adverse events accompanying intra-articular injections are common, but the relative risk accompanying hyaluronan injections over placebo appears to be small. Pseudoseptic reactions associated with hyaluronans appear relatively uncommon but can be severe." (p. 65)

"In one trial, randomization was stratified by disease severity; all other subgroup results were obtained in post-hoc analyses. There was no evidence for differential effects according to subgroups defined by age, sex, primary/disease, BMI/weight, or disease severity. One positive post-hoc subgroup analysis found greater efficacy among older individuals with more severe disease, but was not confirmed in a subsequent trial."(p. 65)

RECOMMENDATION 17

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

AAOS Level of Evidence: **I and II**
AAOS Grade of Recommendation: **B**

Rationale:

AAOS conducted a systematic review that identified one Level I RCT[88] and 3 Level II RCTs[89-91] that studied needle lavage in patients with symptomatic OA of the knee. All three Level II RCTs were graded as such due to lack of patient and caregiver blinding and failure to conceal the allocation of patients to treatment groups. Two of the studies used a sham surgical control group while the remaining two studies compared needle lavage to either medical management or arthroscopic debridement.

Among all of the outcomes in all of the studies, only one was statistically significant at 12 or 24 weeks after needle lavage. Accordingly, the Level I RCT[88] (Figure 128) did not report a statistically significant effect of needle lavage on pain, function, 50-foot walking time, stiffness, acetaminophen use, tenderness, or swelling at 12 or 24 weeks. Dawes et al.[90] and Ike et al.[91] (Level II RCTs) did not find any statistically significant effects at 12 weeks. The only statistically significant finding was reported by Bradley et al.[88] and this was on quality of well-being at 24 weeks. In general, longer-term effects were also not statistically significant.

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

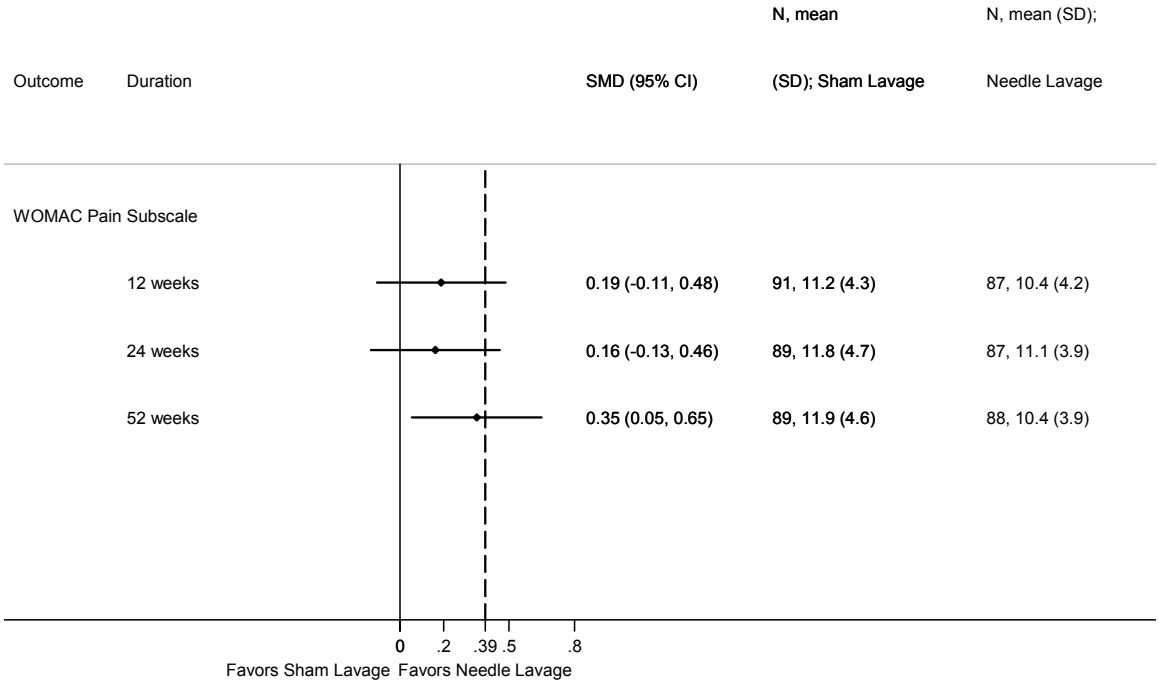
Supporting Evidence
For the raw data addressing this recommendation, please see evidence tables: 20 – 24.
Figures relevant to this recommendation are Figure 128 – Figure 152.
Relevant study attrition diagram shown in Appendix III.

PAIN: WOMAC

Level of Evidence:
One Level I RCT

One RCT by Bradley et al.[88] assessed knee pain using the Likert version of WOMAC.

Figure 128. Patient pain measured by WOMAC (Bradley et al. 2002)



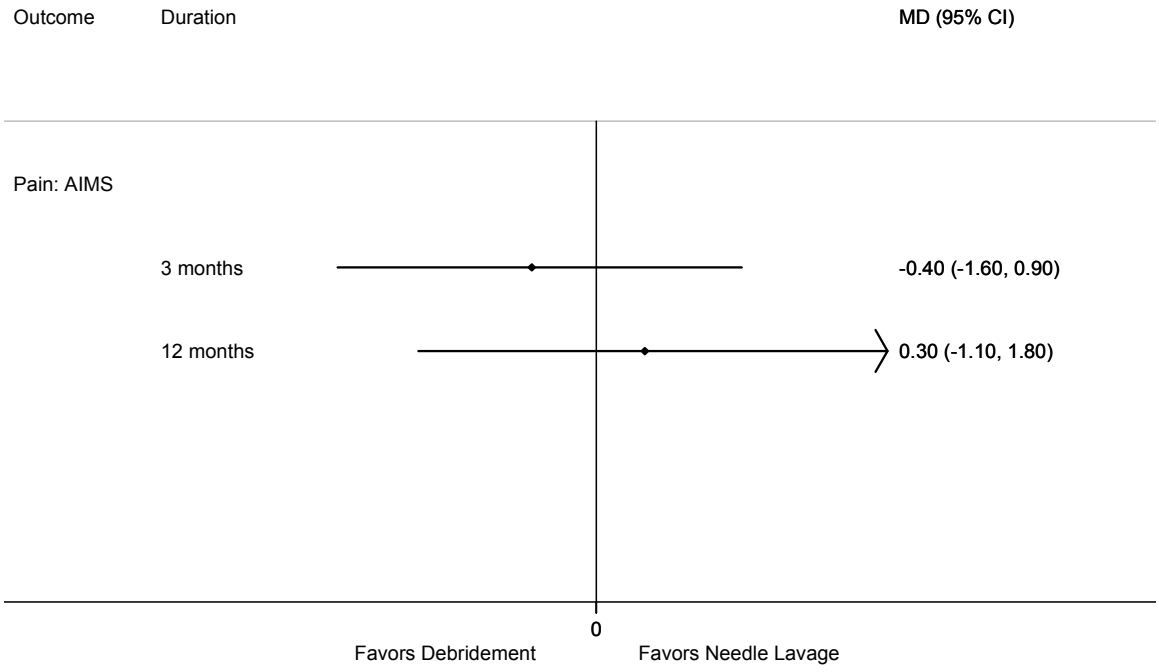
*Dashed line indicates MCII for WOMAC pain.

PAIN: ARTHRIS IMPACT MEASUREMENT SCALES (AIMS)

Level of Evidence:
One Level II RCT

Chang et al.[89] assessed pain as measured by AIMS.

Figure 129. Pain measured by AIMS (Chang et al. 1993)

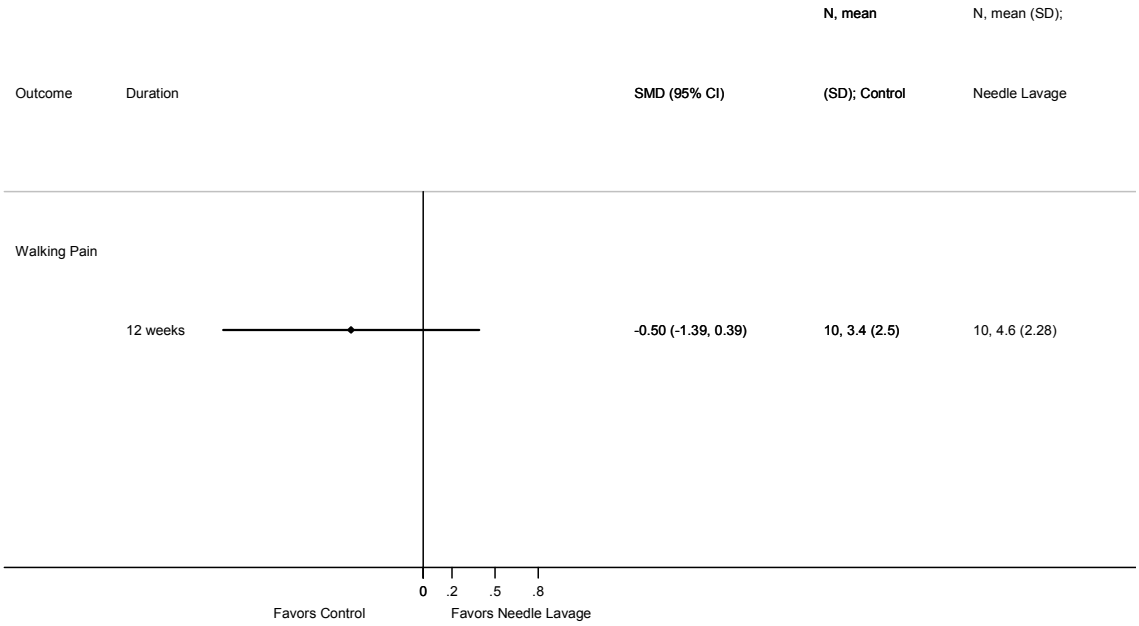


PAIN: WALKING

Level of Evidence:
One Level II RCT

The RCT by Dawes et al.[90] assessed pain as it related to walking using VAS.

Figure 130. Walking pain measured by VAS (Dawes et al. 1987)



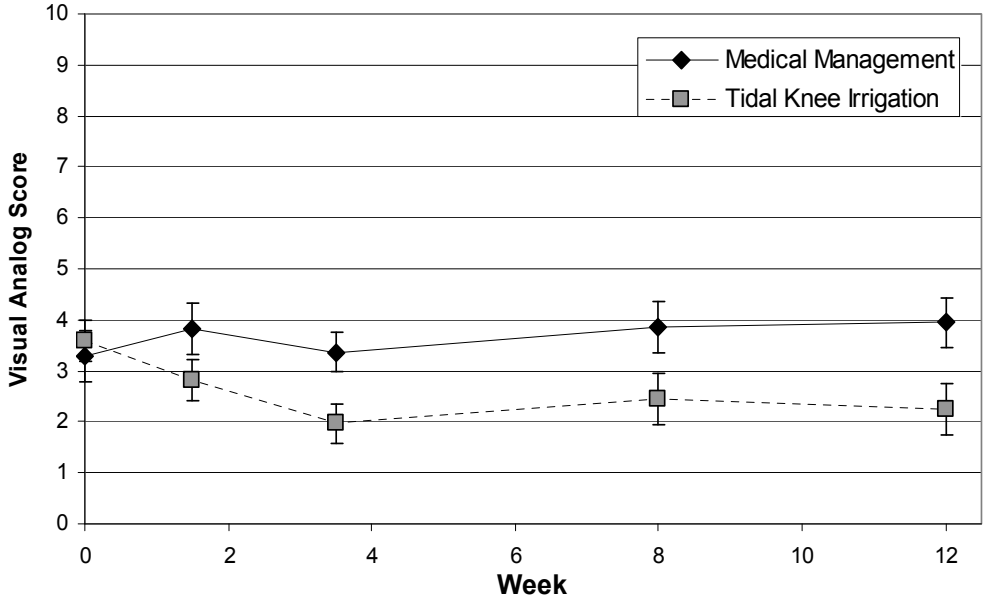
*95% confidence interval calculated using a standard deviation estimated from range[26].

PAIN: AFTER WALKING

Level of Evidence:
One Level II RCT

The RCT by Ike et al.[91] assessed pain as it related to walking using VAS. Authors report a statistically significant trend toward lower pain scores for patients receiving tidal knee irrigation using repeated measures analysis of variance ($p = 0.03$).

Figure 131. Pain after walking 50 feet measured by VAS (Ike et al. 1992)



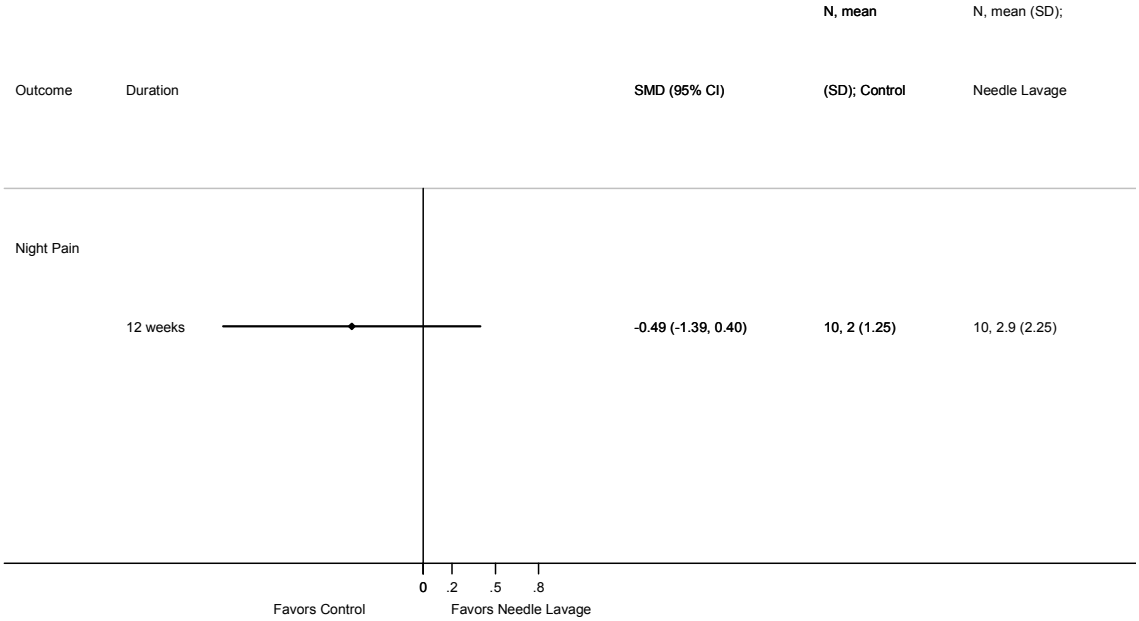
*Type of error dispersion shown in the graph is not noted by authors.

PAIN: AT NIGHT

Level of Evidence:
One Level II RCT

The RCT by Dawes et al.[90] assessed pain at night measured by VAS.

Figure 132. Pain at night measured by VAS (Dawes et al. 1987)



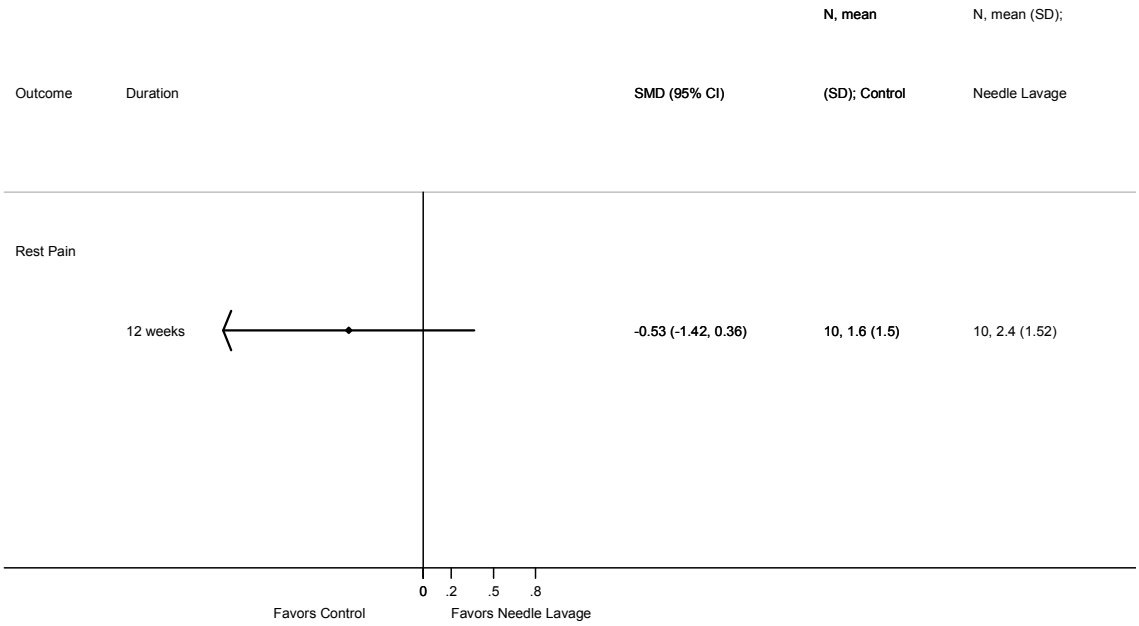
*95% confidence interval calculated using a standard deviation estimated from range[26].

PAIN: RESTING

Level of Evidence:
One Level II RCT

The RCT by Dawes et al.[90] assessed pain at rest measured using VAS.

Figure 133. Pain at rest measured by VAS (Dawes et al. 1987)



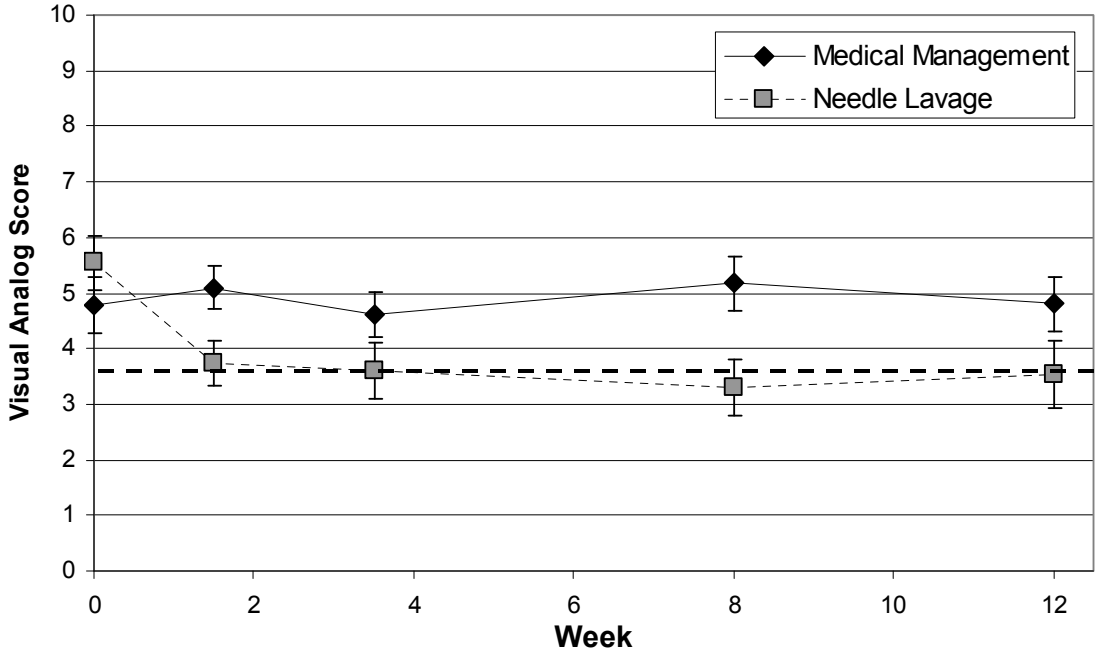
*95% confidence interval calculated using a standard deviation estimated from range[26].

PAIN: MOST INTENSE YESTERDAY

Level of Evidence:
One Level II RCT

Ike et al.[91] asked patients to assess the most intense knee pain on the day prior measured by VAS. Authors report a statistically significant trend toward lower pain scores for patients receiving tidal knee irrigation using repeated measures analysis of variance (p = 0.02).

Figure 134. Most intense pain yesterday measured by VAS (Ike et al. 1992)



*Type of error dispersion shown in the graph is not noted by authors.

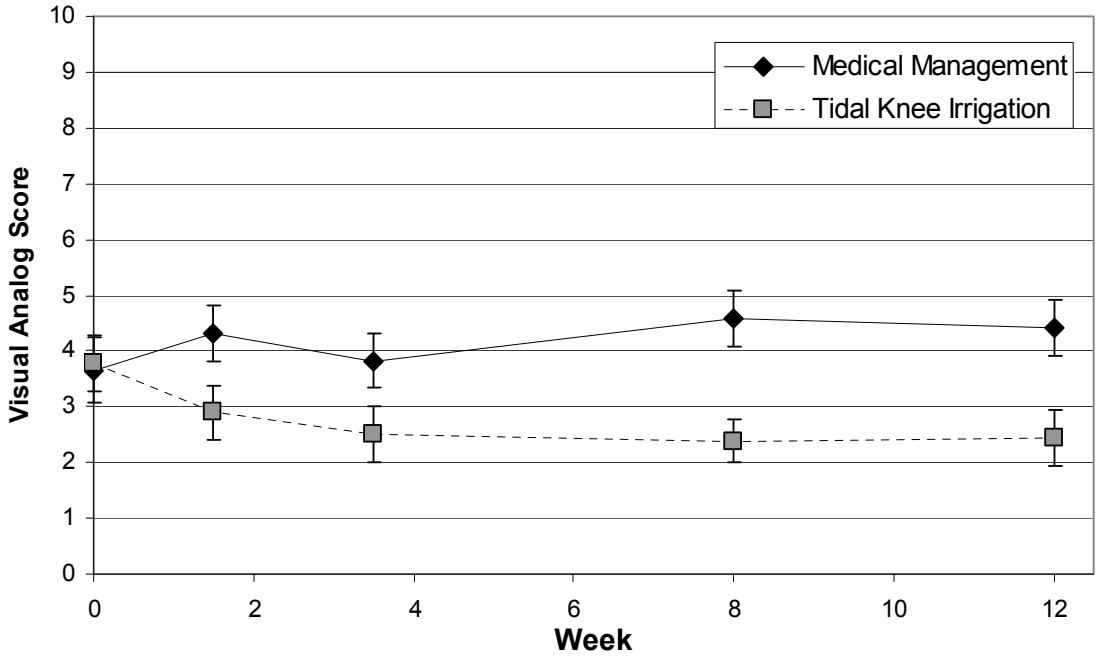
**Dashed line indicates MCII for VAS pain defined as a 20 mm decrease from baseline.

PAIN: AFTER STAIR CLIMB

Level of Evidence:
One Level II RCT

Ike et al.[91] asked patients to rate their pain after climbing four stairs measured by VAS. Authors report a statistically significant trend toward lower pain scores for patients receiving tidal knee irrigation using repeated measures analysis of variance ($p < 0.01$).

Figure 135. Pain after climbing four stairs measured by VAS (Ike et al. 1992)



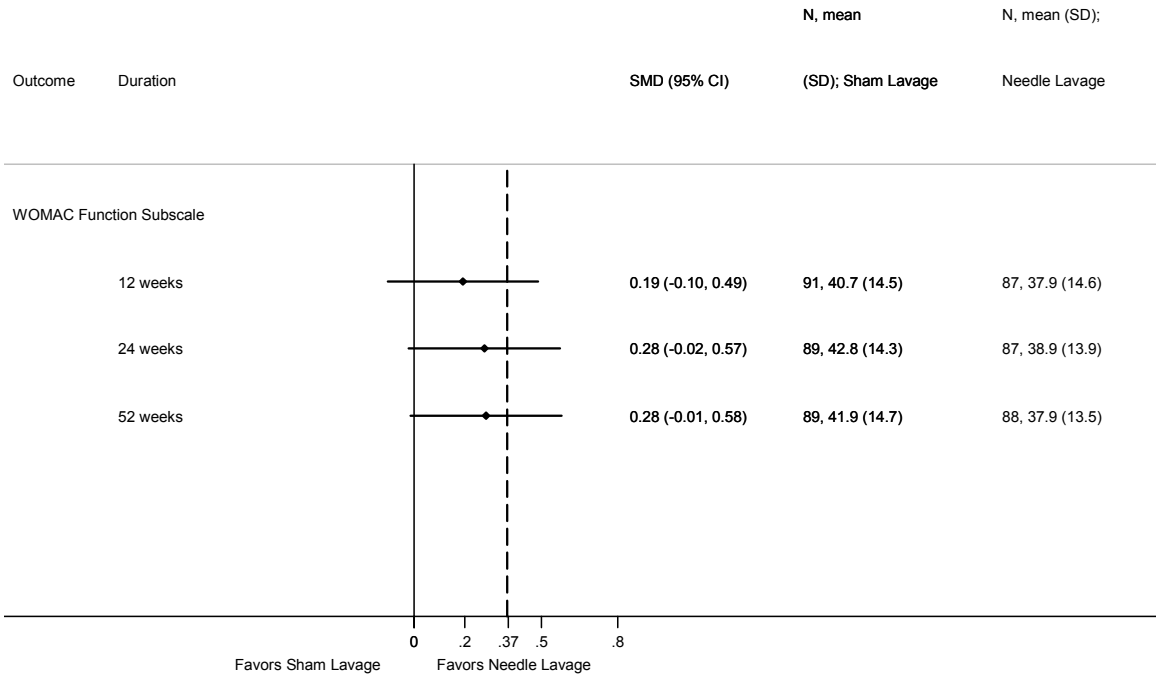
*Type of error dispersion shown in the graph is not noted by authors.

FUNCTION: WOMAC

Level of Evidence:
One Level I RCT

The RCT by Bradley et al.[88] assessed physical function using the Likert version of WOMAC.

Figure 136. Function as measured by WOMAC (Bradley et al. 2002)



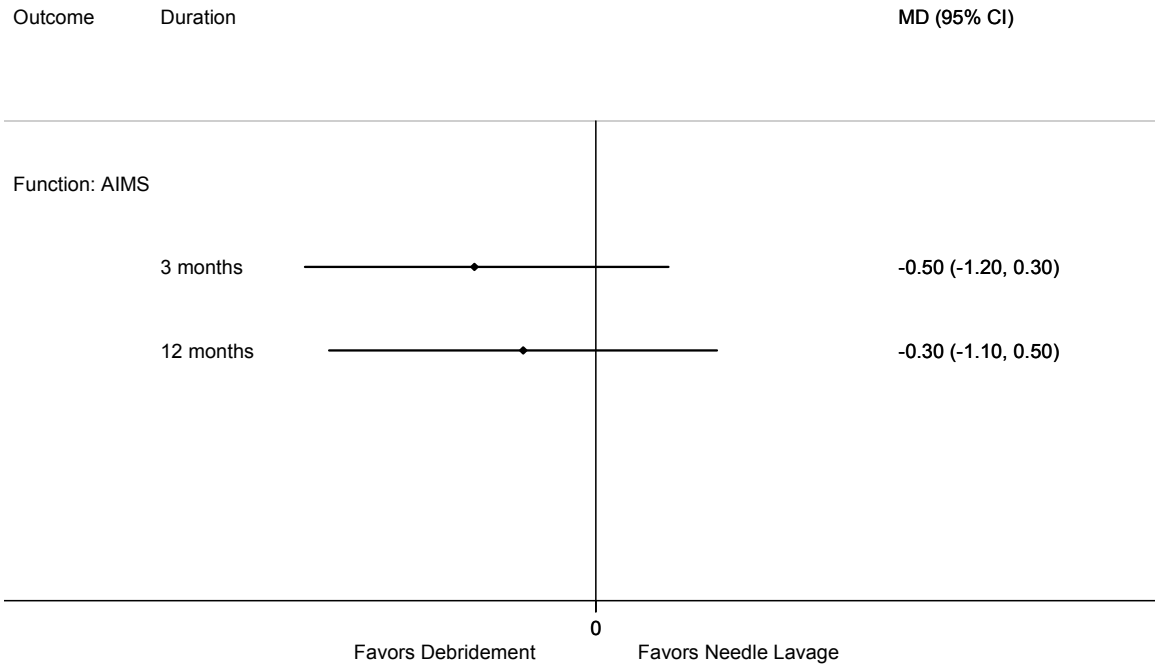
*Dashed line indicates MCII for WOMAC function.

FUNCTION: AIMS

Level of Evidence:
One Level II RCT

The RCT by Chang et al.[89] assessed function measured by AIMS.

Figure 137. Function measured by AIMS (Chang et al. 1993)

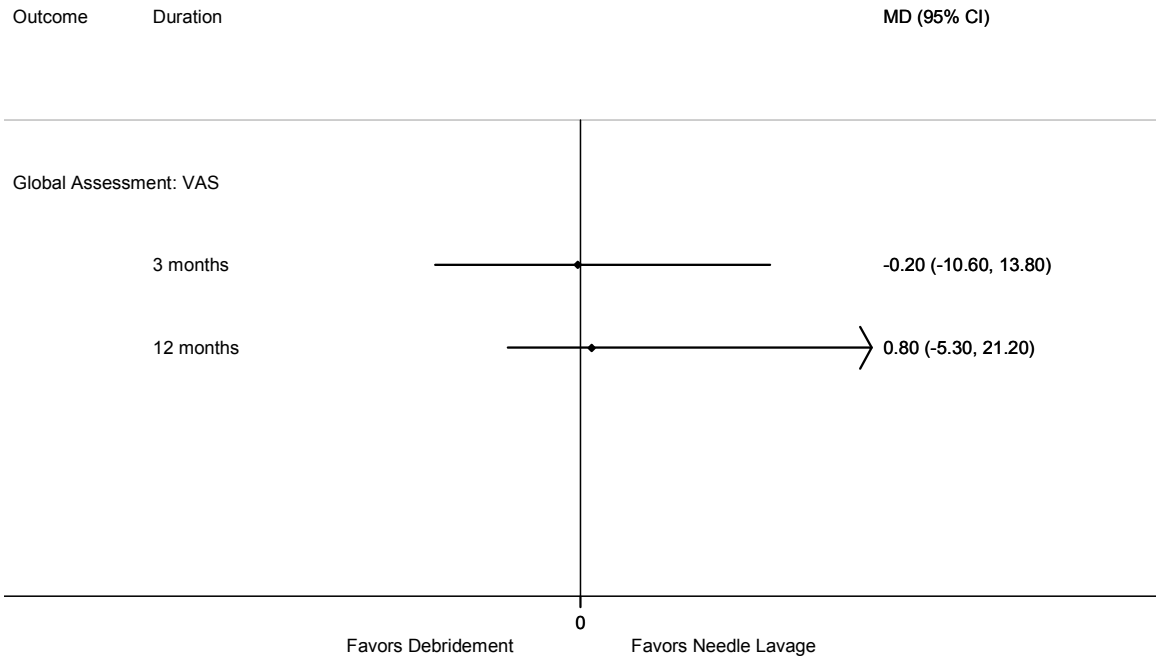


GLOBAL ASSESSMENT: VAS

Level of Evidence:
One Level II RCT

The RCT by Chang et al.[89] assessed global assessment measured by a 10-cm VAS.

Figure 138. Patient global assessment measured by 10-cm VAS (Chang et al. 1993)

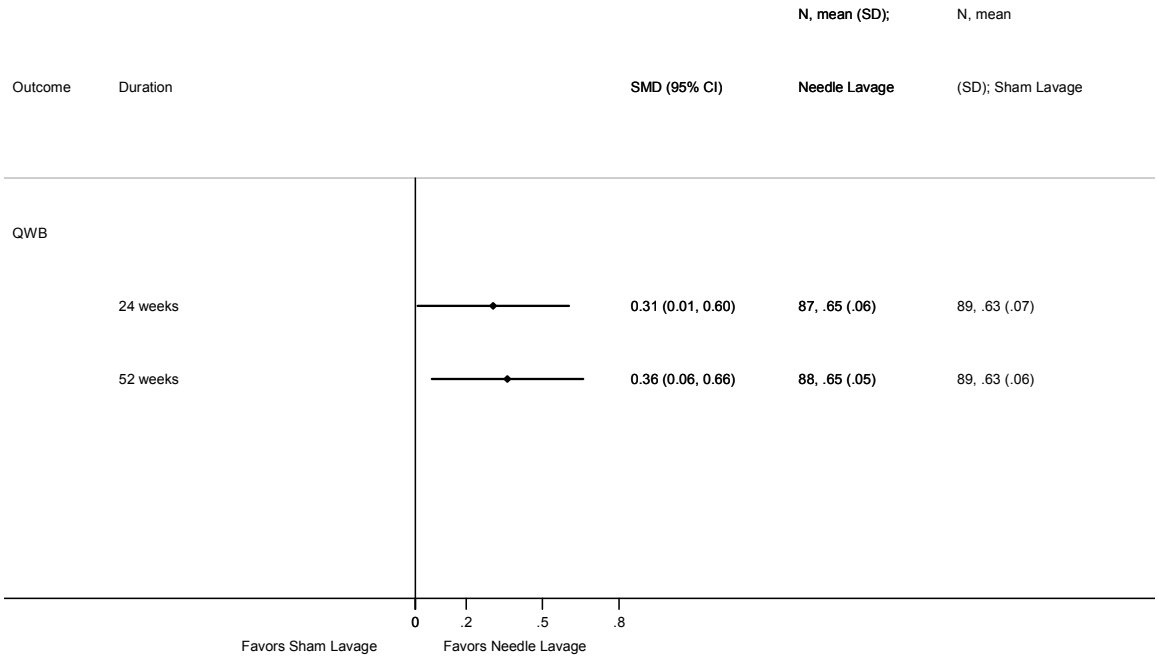


GLOBAL ASSESSMENT: QUALITY OF WELL-BEING (QWB)

Level of Evidence:
One Level I RCT

One RCT by Bradley et al.[88] examined patient global health status using the Quality of Well-Being (QWB) which assesses mobility, physical and social functioning. The QWB scale ranges from 0.0 (death) to 1.0 (optimal health). As such, a score of 1.0 represents complete freedom from symptoms.

Figure 139. Quality of well-being (Bradley et al. 2002)

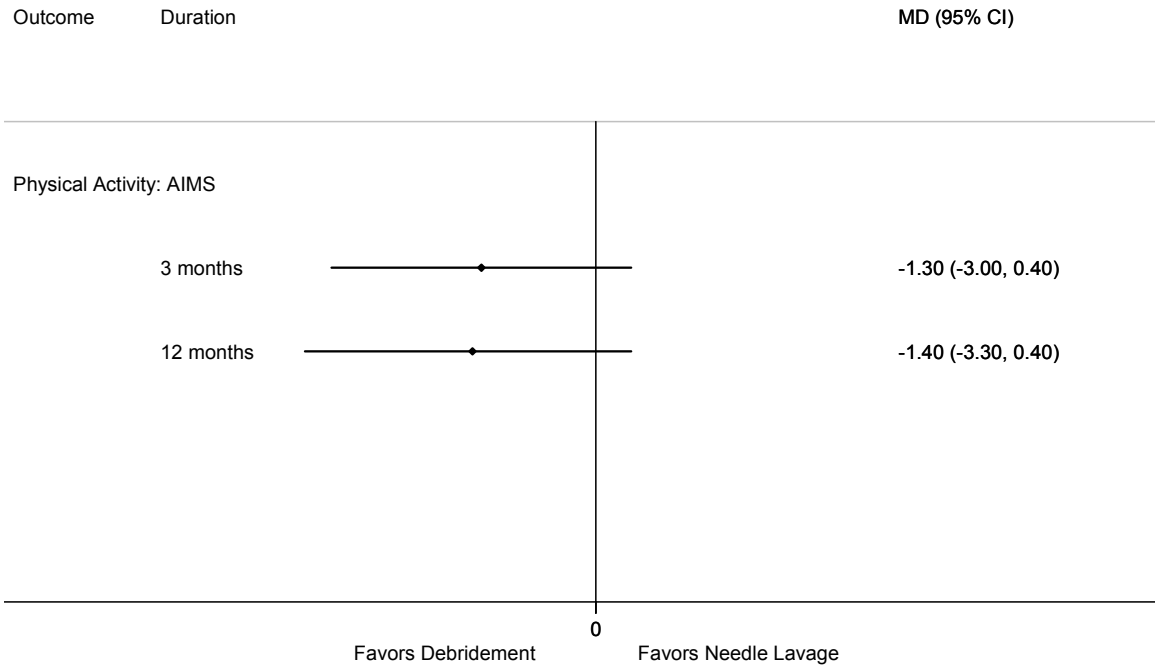


PHYSICAL ACTIVITY: AIMS

Level of Evidence:
One Level II RCT

The RCT by Chang et al.[89] assessed physical activity measured by AIMS.

Figure 140. Physical activity measured by AIMS (Chang et al. 1993)



50-FOOT WALK TIME

Level of Evidence:
One Level I RCT and one Level II RCT

One Level I RCT[88] and two Level II RCTs[89, 91] measured the time needed to complete a fifty-foot walk.

Figure 141. 50-foot walk measured in seconds (Bradley et al. 2002, Ike et al. 1992)

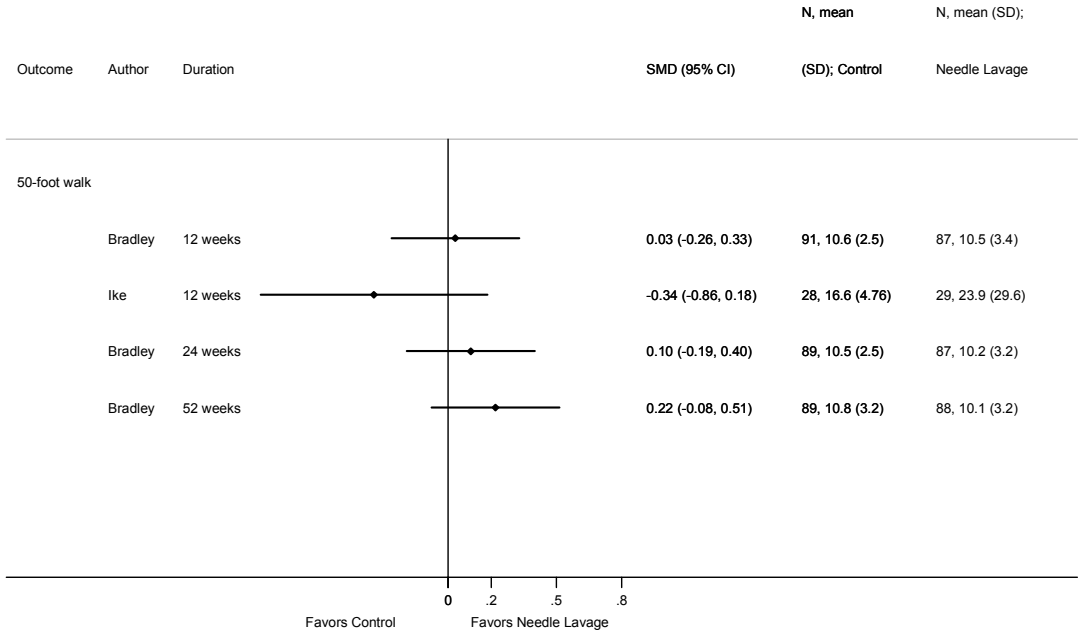
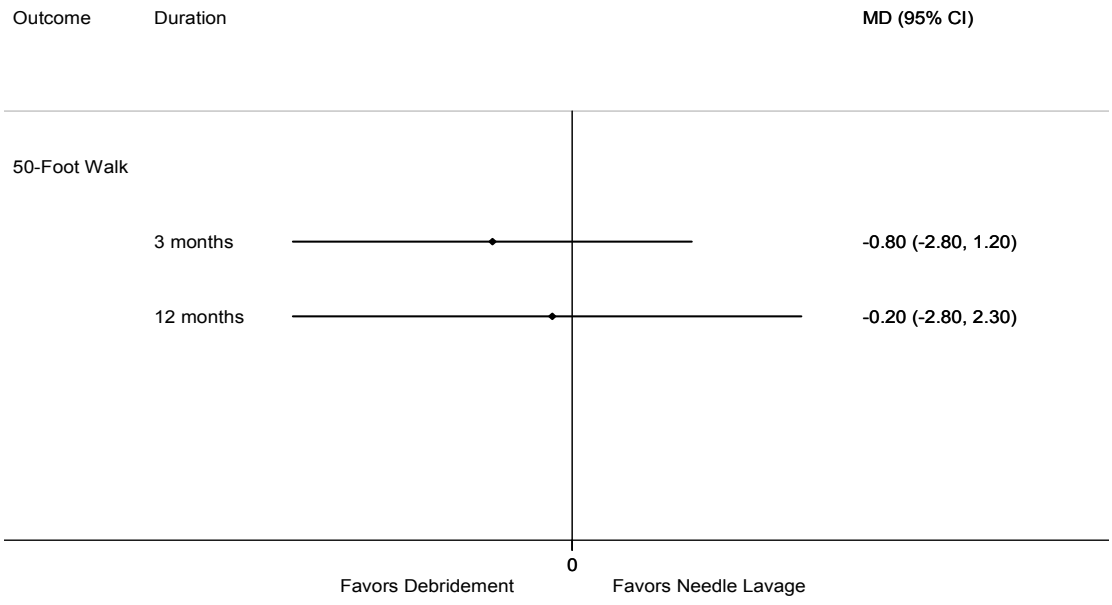


Figure 142. 50- foot walk measured in seconds (Chang et al. 1993)

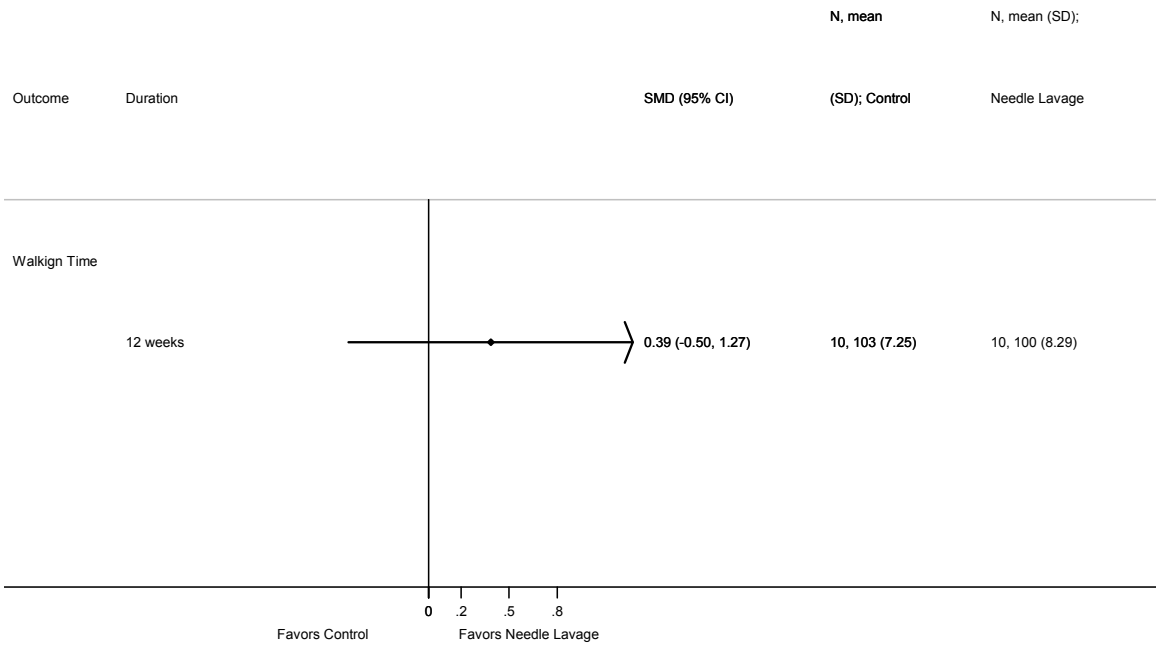


25-YARD WALK TIME

Level of Evidence:
One Level II RCT

Dawes et al.[90] measured the time needed to complete a twenty-five yard walk.

Figure 143. 50-foot walk measured in seconds (Dawes et al. 1987)



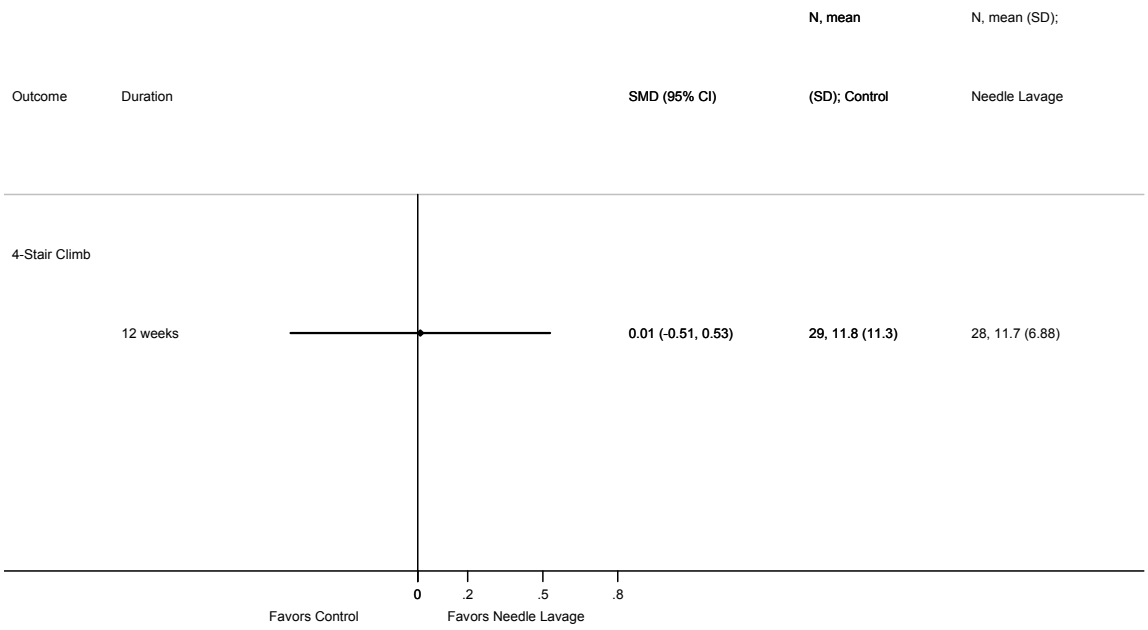
*95% confidence interval calculated using a standard deviation estimated from range[26].

4-STAIR CLIMB

Level of Evidence:
One Level I RCT

Ike et al.[91] assessed the number of seconds needed to climb four stairs.

Figure 144. Time needed to climb four stairs measured in seconds (Ike et al. 1992)

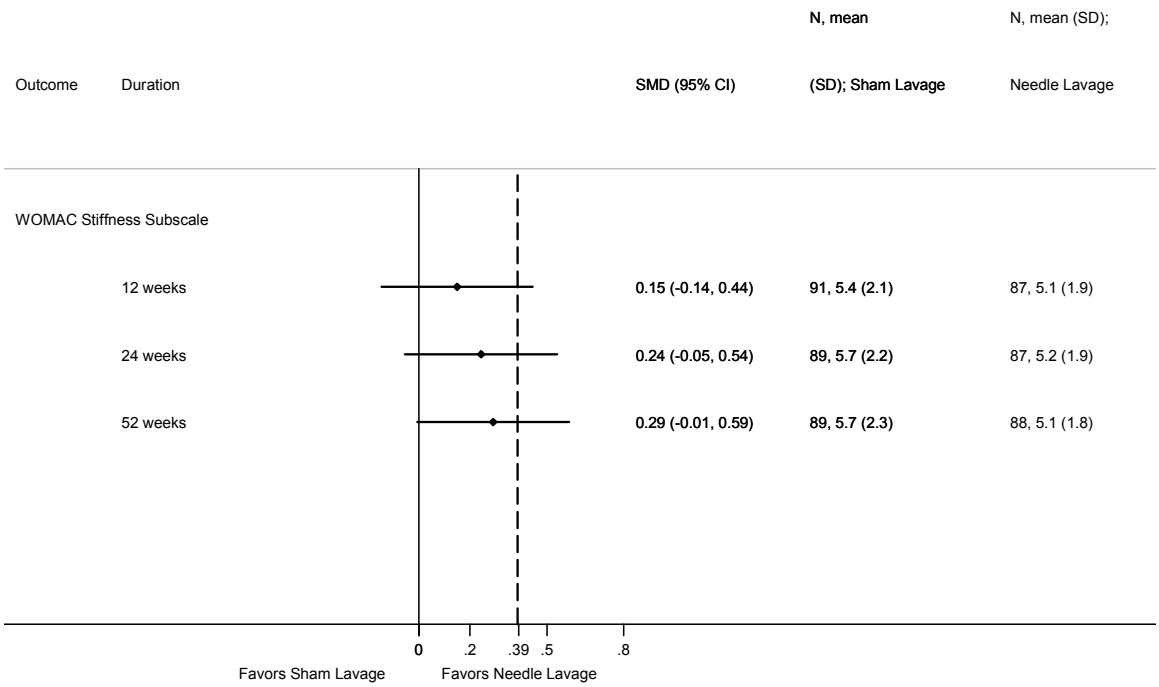


STIFFNESS: WOMAC

Level of Evidence:
One Level I RCT

Bradley et al.[88] assessed knee stiffness using the Likert version of WOMAC.

Figure 145. Stiffness as measured by WOMAC (Bradley et al. 2002)



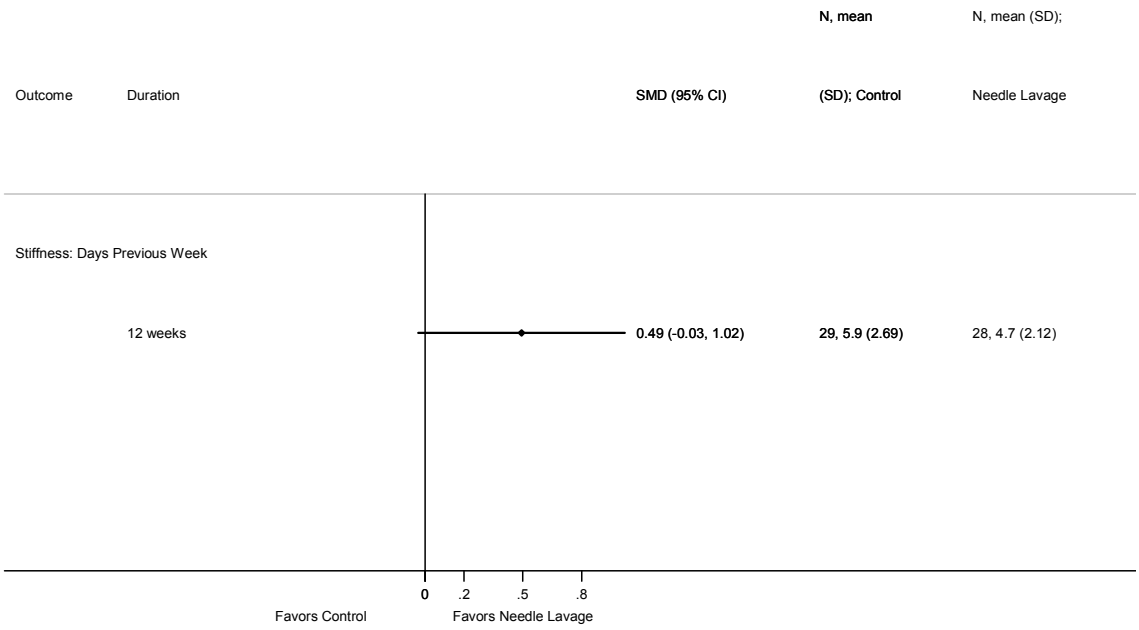
*Dashed line indicates MCII for WOMAC stiffness.

STIFFNESS: DAYS PREVIOUS WEEK

Level of Evidence:
One Level I RCT

Ike et al.[91] assessed the number of days in the previous week patients experienced knee stiffness.

Figure 146. Days with stiffness last week (Ike et al. 1992)

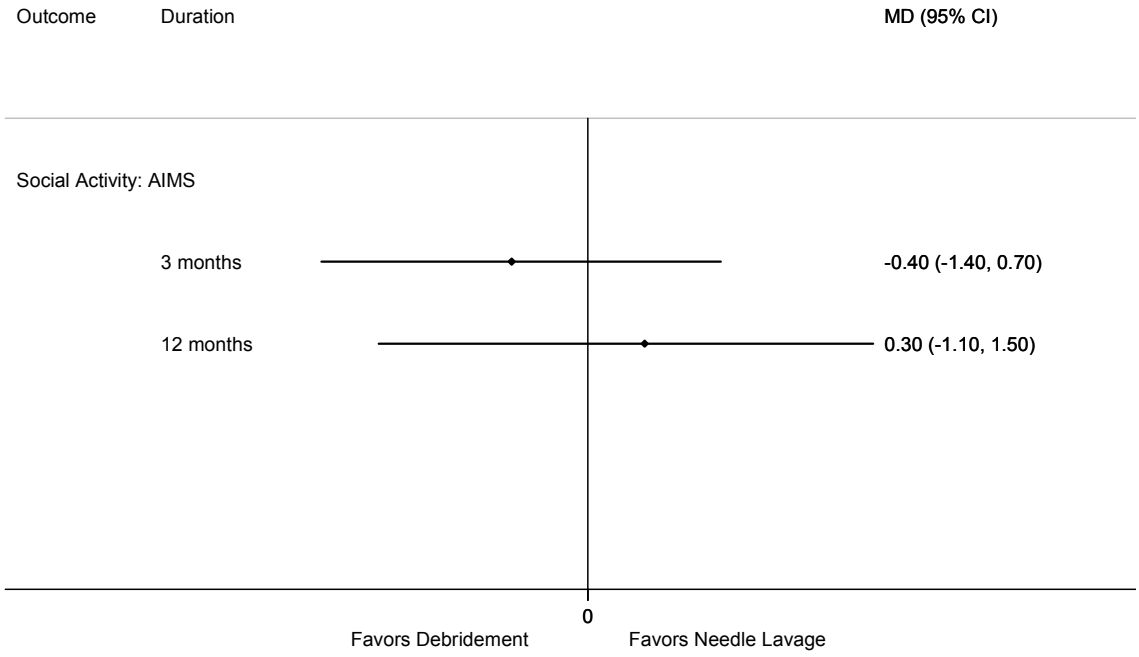


SOCIAL ACTIVITY: AIMS

Level of Evidence:
One Level II RCT

Chang et al.[89] assessed social activity as measured by AIMS.

Figure 147. Social activity measured by AIMS (Chang et al. 1993)

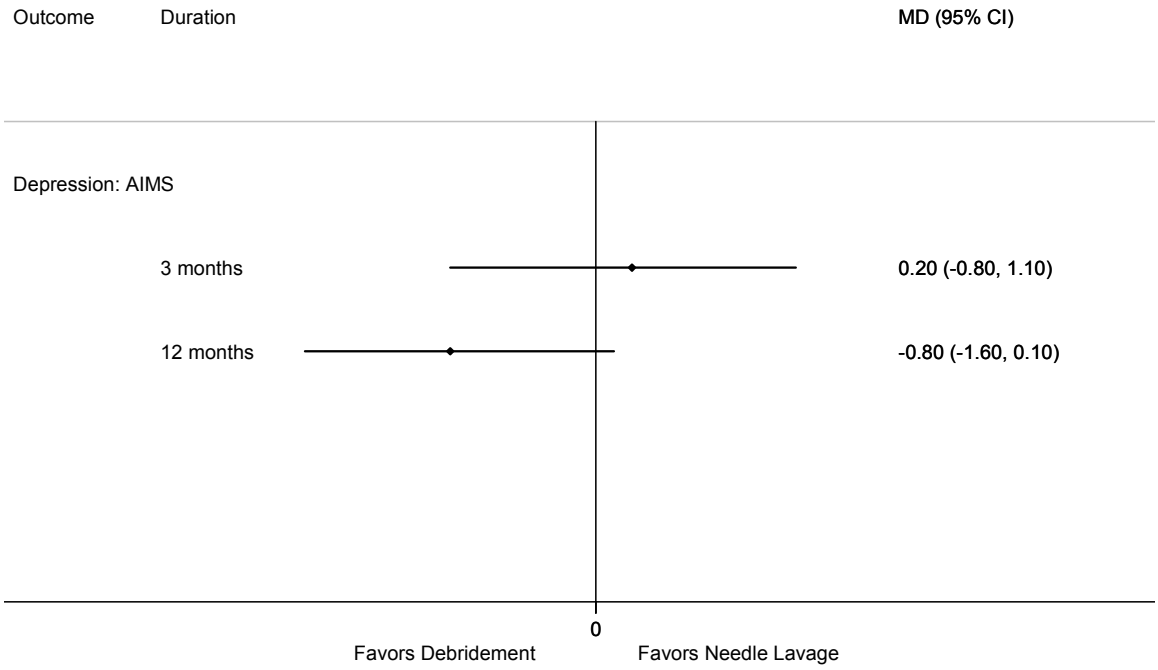


DEPRESSION: AIMS

Level of Evidence:
One Level II RCT

Chang et al.[89] assessed depression as measured by AIMS.

Figure 148. Depression measured by AIMS (Chang et al. 1993)

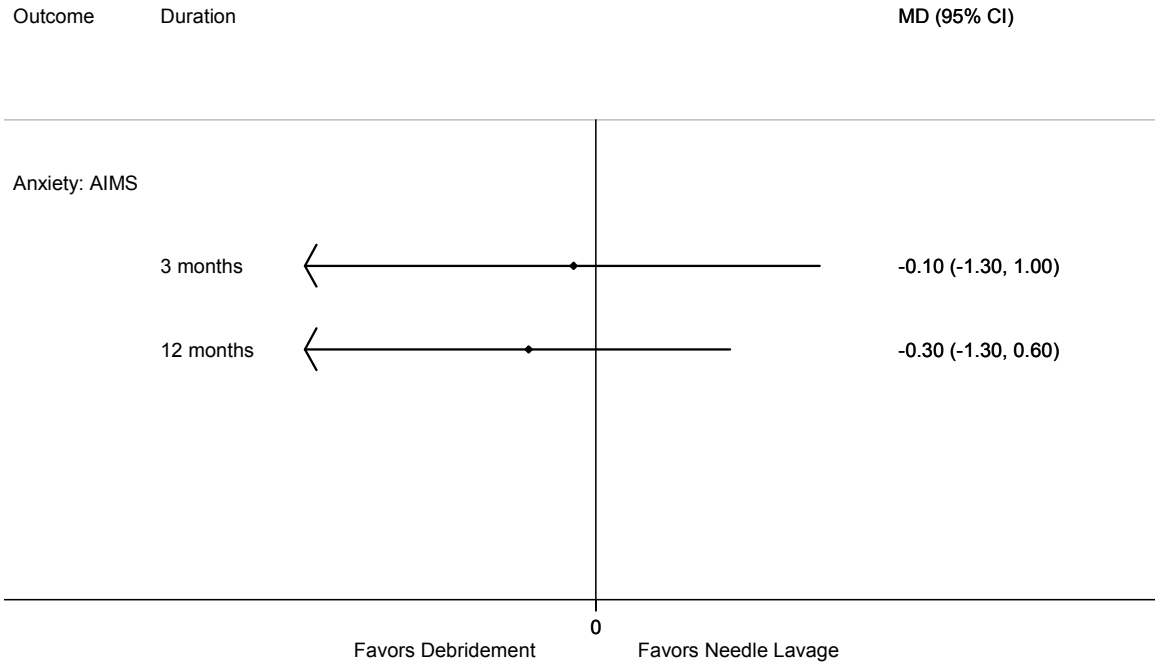


ANXIETY: AIMS

Level of Evidence:
One Level II RCT

Chang et al.[89] assessed anxiety as measured by AIMS.

Figure 149. Anxiety measured by AIMS (Chang et al. 1993)

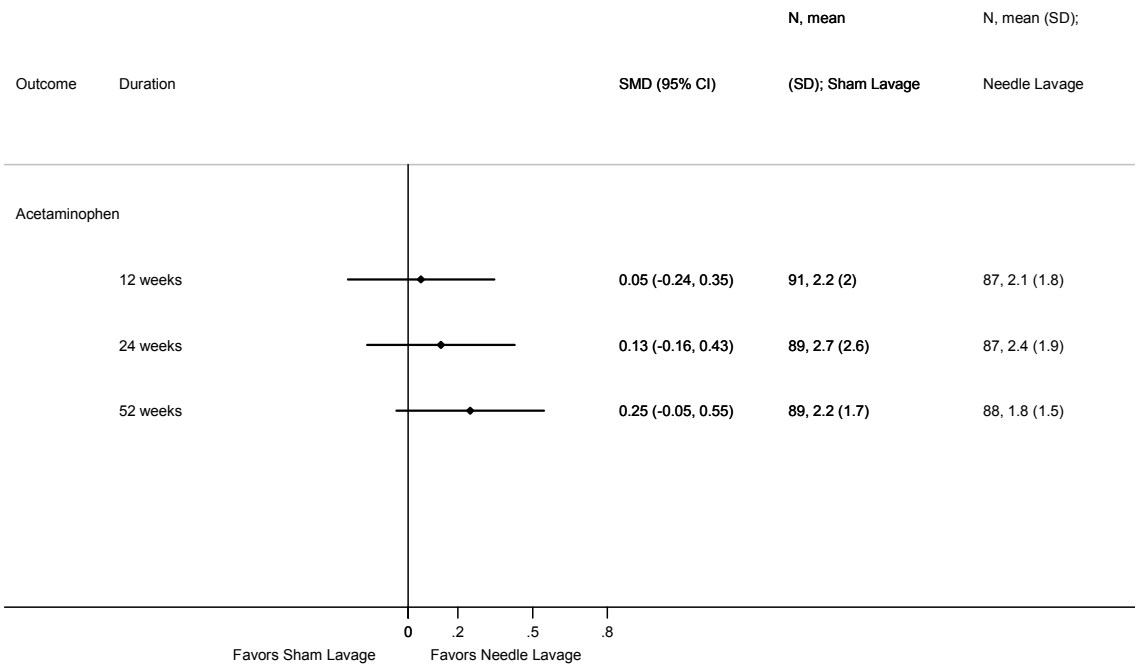


ACETAMINOPHEN USE

Level of Evidence:
One Level I RCT

Bradley et al.[88] assessed acetaminophen used measured by count.

Figure 150. Acetaminophen use measured by count (Bradley et al. 2002)

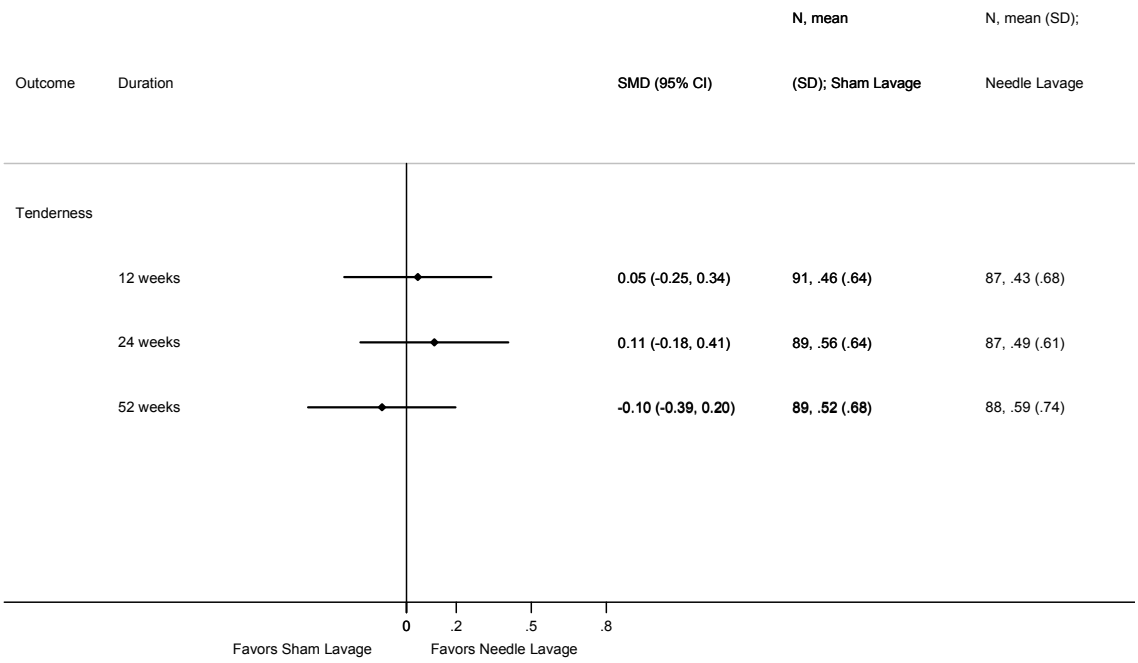


TENDERNESS

Level of Evidence:
One Level I RCT

Bradley et al.[88] included a physical examination for knee tenderness.

Figure 151. Knees with tenderness (Bradley et al. 2002)

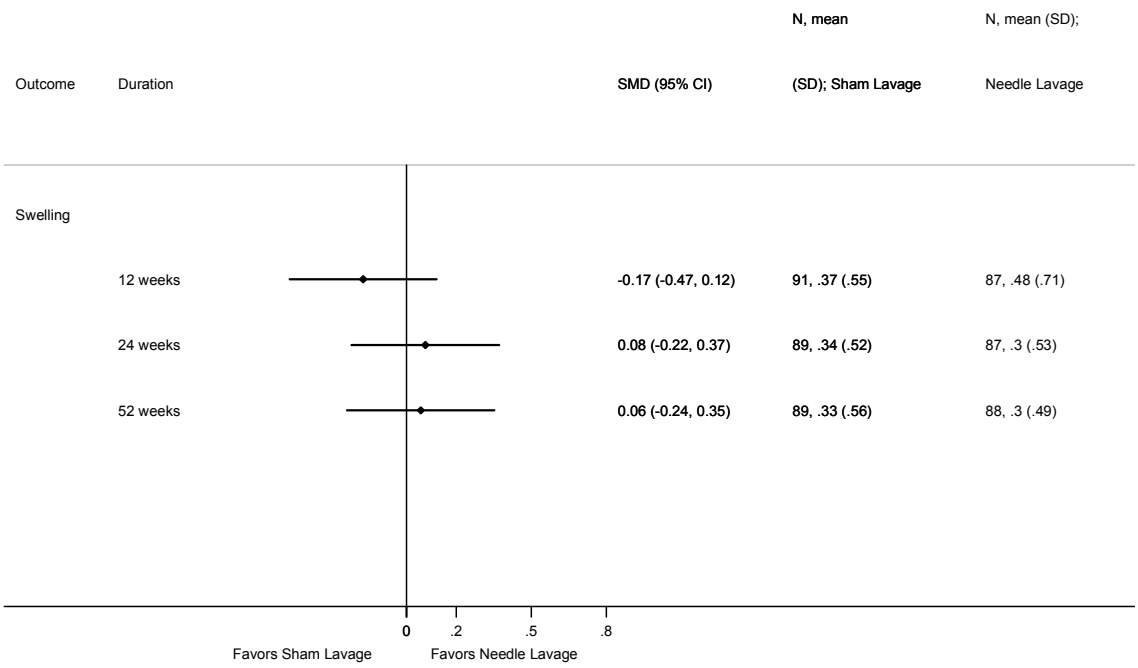


SWELLING

Level of Evidence:
One Level I RCT

Bradley et al.[88] included a physical examination for knee swelling.

Figure 152. Knees with swelling (Bradley et al. 2002)



RECOMMENDATION 18

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

AAOS Level of Evidence: **I and II**
AAOS Grade of Recommendation: **A**

Rationale:

One Level II Systematic Review[92] containing three RCTs[89, 93, 94] examined the use of arthroscopic debridement in patients with symptomatic OA of the knee. One of these RCTs[94] also included comparison of arthroscopic lavage alone to sham arthroscopic surgery (placebo), that was not reported by the systematic review. Our literature searches identified two additional Level II RCTs[16, 17] that investigated the differences between arthroscopic lavage alone and placebo.

The systematic review concluded that "[arthroscopic debridement] has no significant benefit for knee OA of undiscriminated cause."[92]

In the Level I RCT, the effects of arthroscopy with debridement or lavage were not statistically significant on the vast majority of patient oriented outcome measures for pain and function, at multiple time points from 1 week to 2 years after surgery. This RCT also found statistically significant effects in favor of the placebo group when compared to arthroscopic debridement on certain patient oriented outcomes (Figure 161, Figure 166). Similar results were found in the Level II RCTs.

We note that there may be limited applicability of the Level I RCT, which is called into question due to its limited population (largely male and veteran) and the number of potential study participants that declined randomization into a treatment group. However, additional evidence from the systematic review and the other RCTs we examined also support the lack of incremental benefit of arthroscopic debridement or lavage. In addition, surgical treatment subjects the patient to potentially increased risks (e.g. anesthetic complications, infection, and thrombophlebitis).

The AAOS workgroup agreed that the evidence for a lack of benefit, when considered with the increased risk due to surgery is sufficient to recommend against arthroscopic debridement and/or lavage in patients with a primary diagnosis of OA of the knee.

None of the evidence we examined specifically included patients who had a primary diagnosis of meniscal tear, loose body, or other mechanical derangement, and who also had a concomitant diagnosis of OA of the knee, and the present recommendation does not apply to such patients.

Supporting Evidence

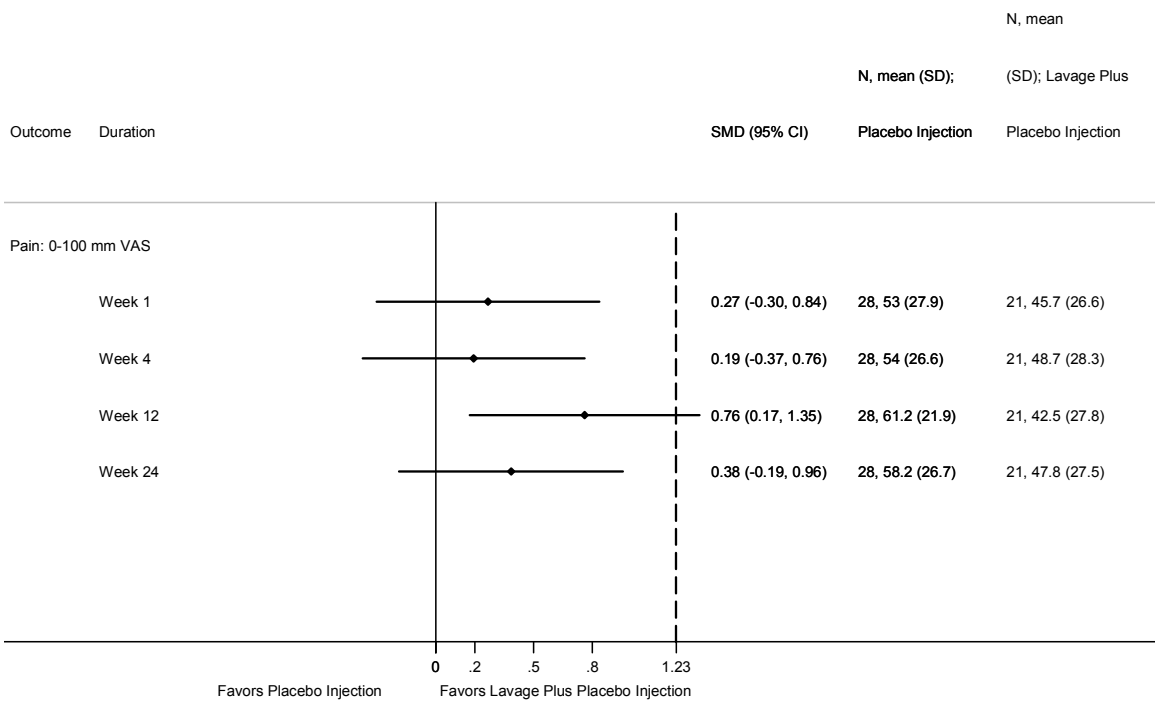
For the raw data addressing this recommendation, please see evidence tables: 25 - 31.
Figures relevant to this recommendation are: Figure 153 - Figure 173.
The relevant study attrition diagram is shown in Appendix III.

PAIN: 0-100 (VAS)

Level of Evidence:
One Level II RCT

Ravaudet al.[17] reported the outcome pain (measured by 100 mm VAS) comparing arthroscopic lavage versus placebo injection (see Figure 153).

Figure 153. Pain measured by 100 mm VAS – Lavage (Ravaud et al. 1999)



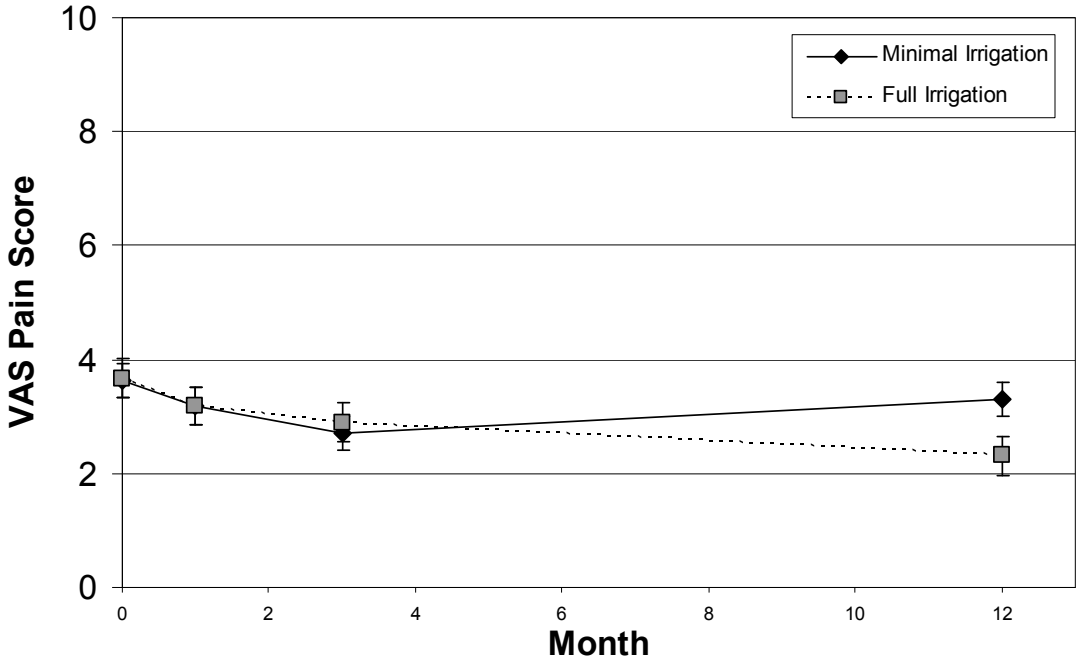
*Dashed line indicates MCII for VAS pain.

PAIN: 0-10 (VAS)

Level of Evidence:
One Level II RCT

Pain measured by 10 cm VAS was assessed by Kalunian et al.[16] (see Figure 154). Analysis of covariance examining mean change from baseline to twelve months was compared between the two groups (minimal vs. full irrigation). Authors note that the improvement in VAS pain was statistically significant ($p = 0.04$) favoring full irrigation including when controlling for significant covariates ($p = 0.02$).

Figure 154. Pain measured by 10 cm VAS – Lavage (Kalunian et al. 2000)



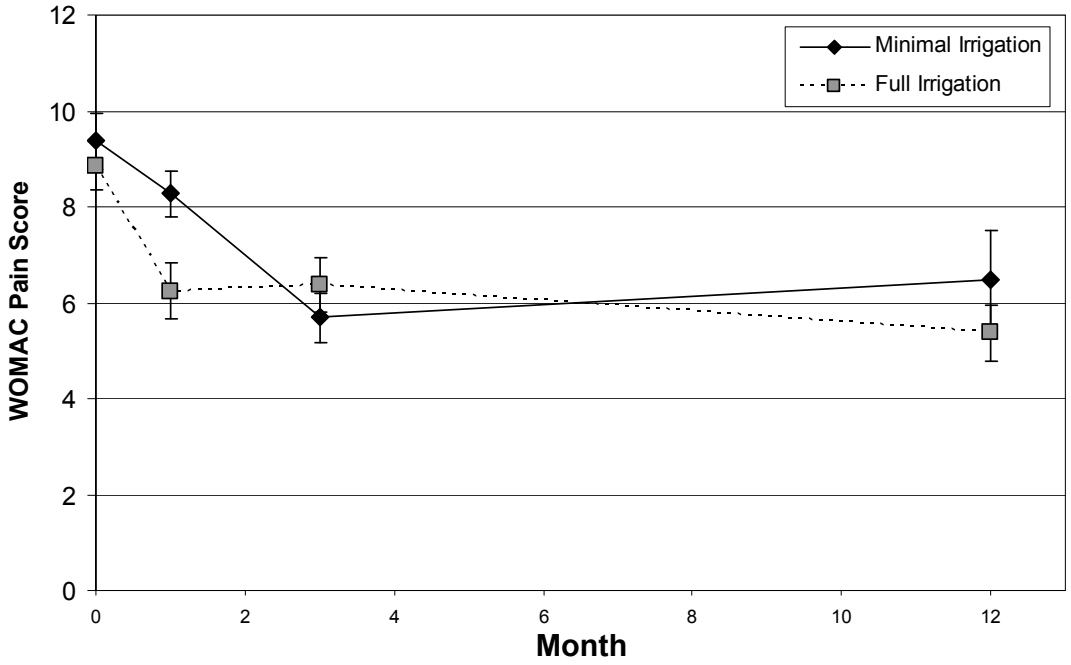
*Type of error dispersion shown in the graph is not noted by authors.

PAIN: WOMAC

Level of Evidence:
One Level II RCT

Kalunian et al.[16] assessed knee pain using the Likert version of the WOMAC. Analysis of covariance examining mean change from baseline to twelve months was compared between the two groups (minimal vs. full irrigation). Authors note that improvement in WOMAC pain was of borderline statistical significance ($p = 0.05$) favoring full irrigation and was statistically significant when controlling for significant covariates ($p = 0.04$).

Figure 155. Pain measured by WOMAC – Lavage (Kalunian et al. 2000)



*Type of error dispersion shown in the graph is not noted by authors.

PAIN: AIMS

Level of Evidence:
One Level I RCT and one Level II Systematic Review

Pain measured by AIMS was assessed by Moseley et al.[94] (see Figure 156) and by Chang et al.[89] in a Level II systematic review[92] (see Figure 157).

Figure 156. Pain measured by AIMS – Lavage (Moseley et al. 2002)

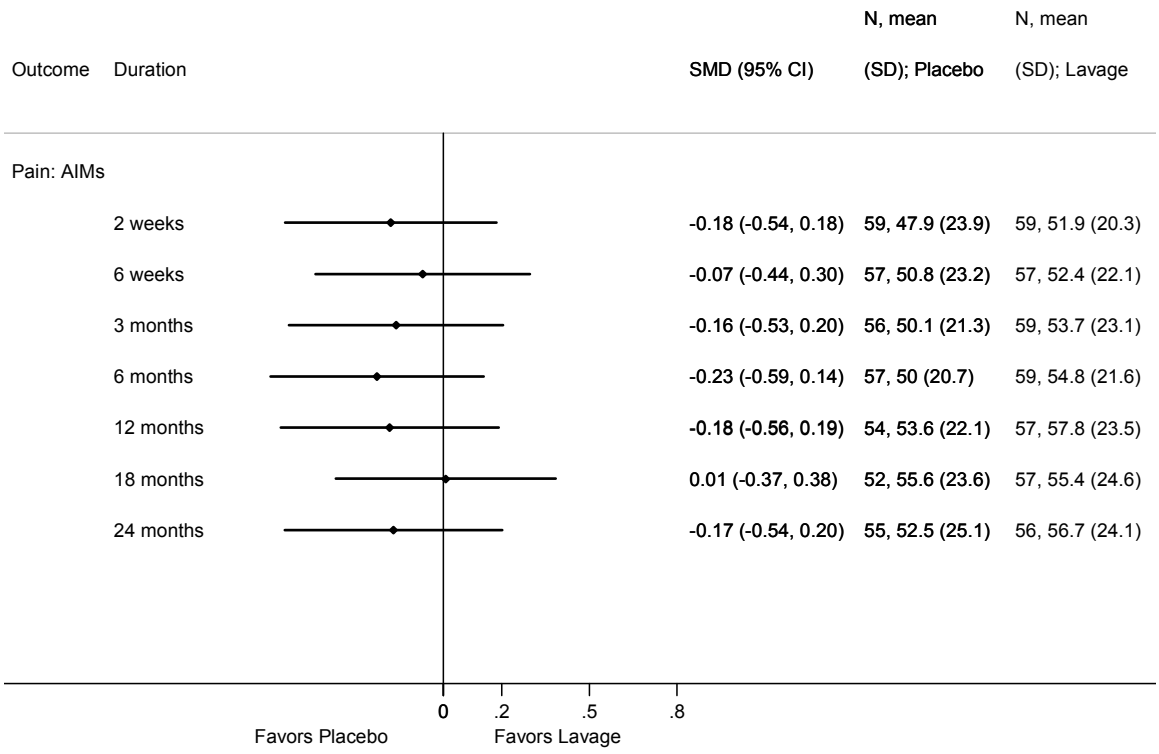
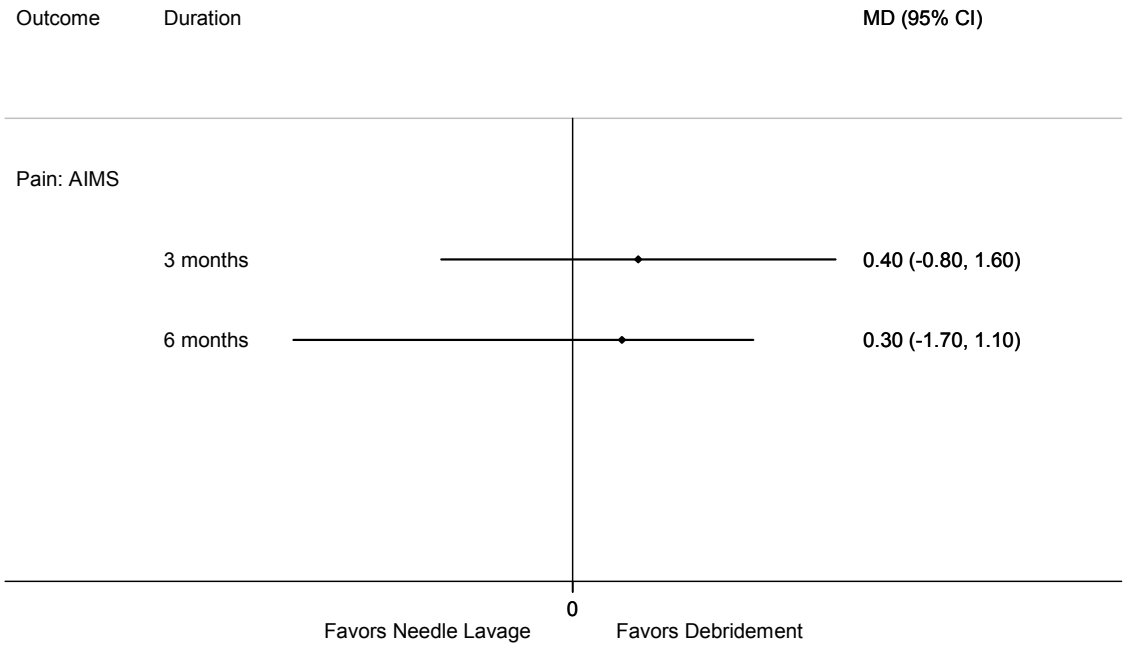


Figure 157. Pain measured by AIMS – Debridement (Chang et al. 1993 in Laupattarakasem et al. 2008)

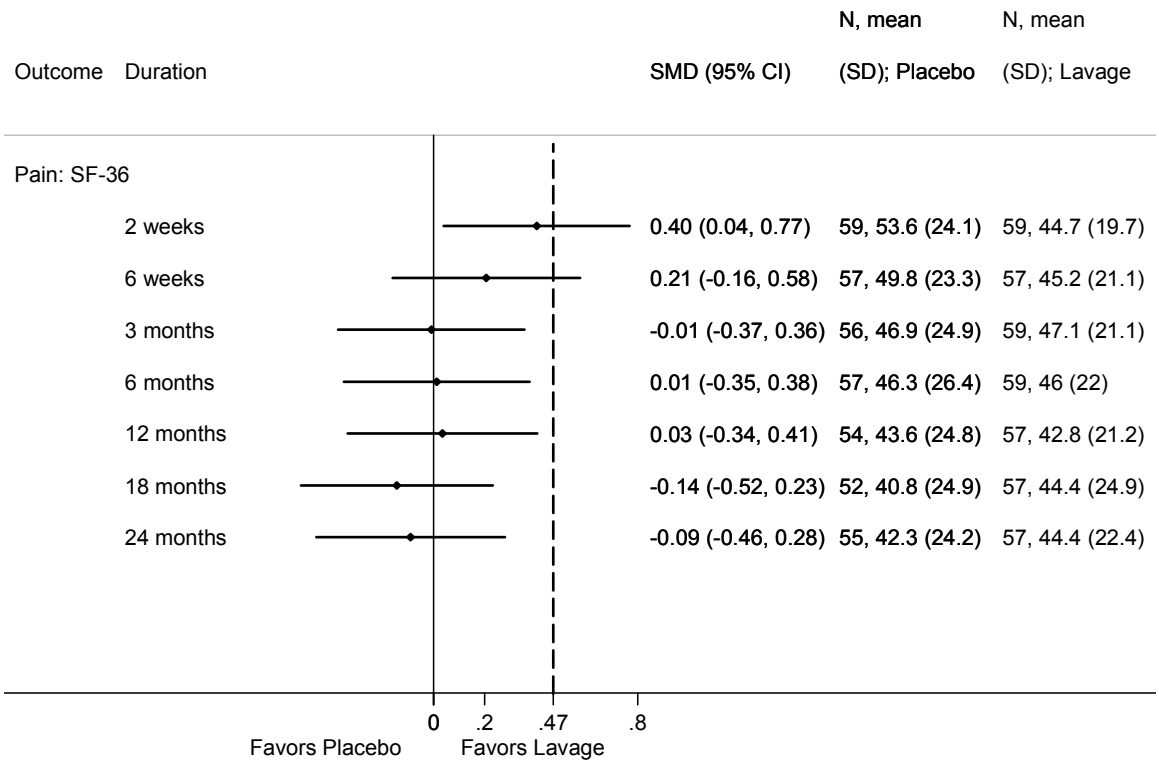


PAIN: SHORT FORM-36 HEALTH SURVEY QUESTIONNAIRE (SF-36)

Level of Evidence:
One Level I RCT

Moseley et al.[94] measured pain using SF-36.

Figure 158. Pain measured by SF-36 – Lavage (Moseley et al. 2002)



*Dashed line indicates MCII for SF-36 pain.

PAIN: KNEE SPECIFIC PAIN SCORE (KSPS)

Level of Evidence:
One Level I RCT and One Level II Systematic Review

Pain measured by the Knee Specific Pain Score (KSPS) was assessed by Moseley et al.[94] (see Figure 159). A Level II systematic review[92] examining debridement also included the Moseley RCT (see Figure 160; Figure 161).

Figure 159. Pain measured by KSPS – Lavage (Moseley et al. 2002)

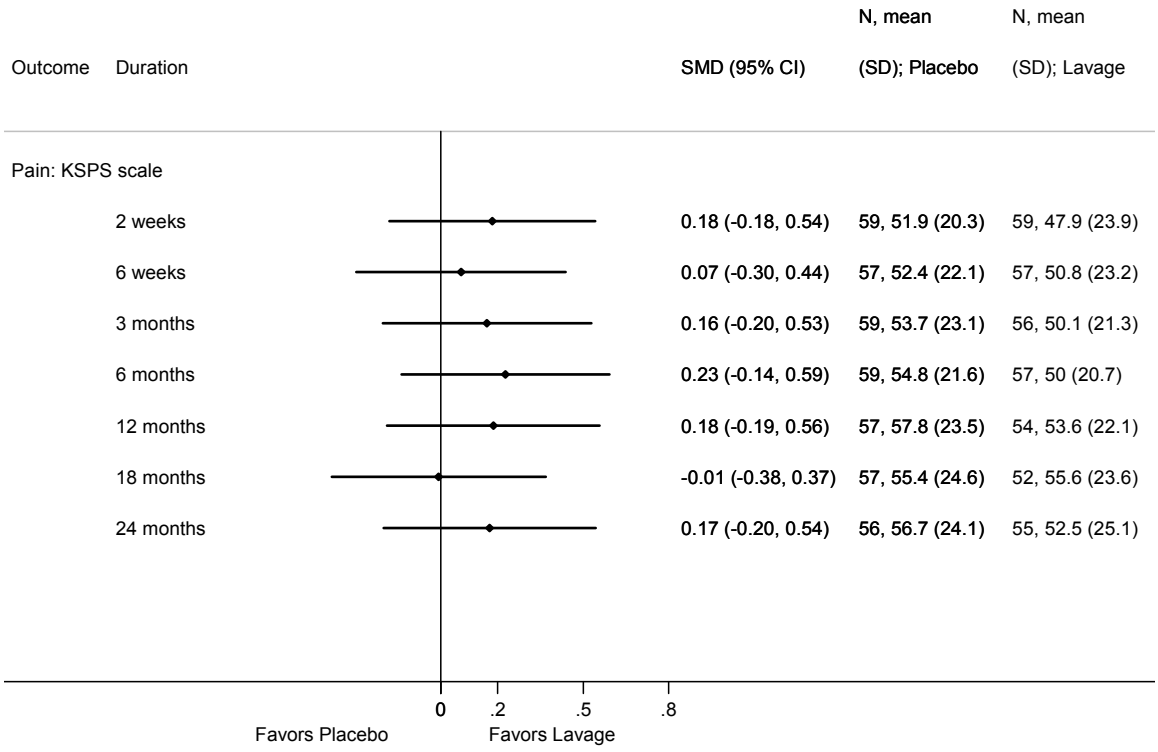


Figure 160. Pain measured by KSPS – Debridement & Lavage (systematic review Laupattarakasem et al. 2008)

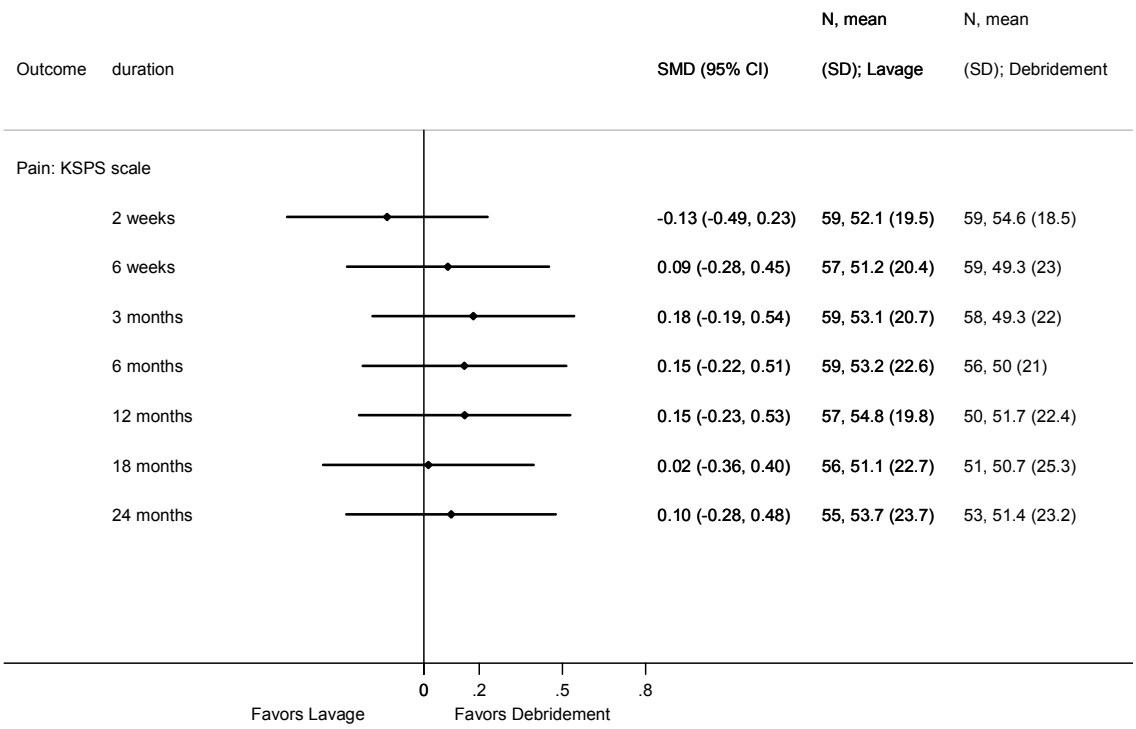
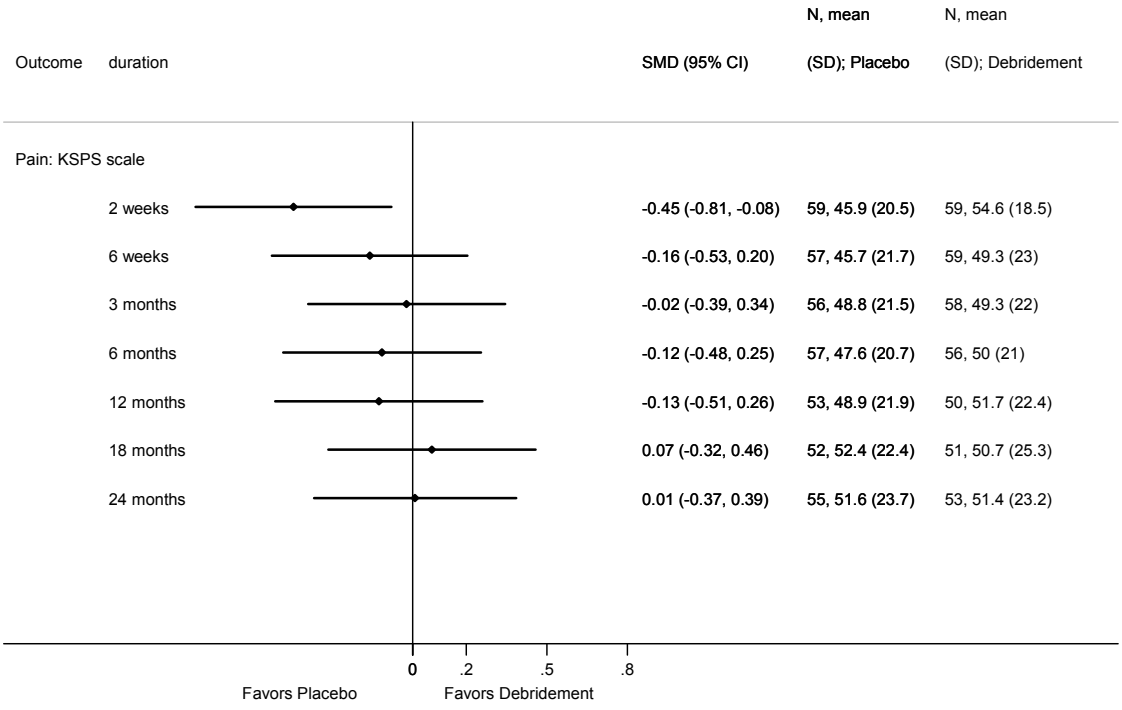


Figure 161. Pain measured by KSPS – Debridement (systematic review Laupattarakasem et al. 2008)

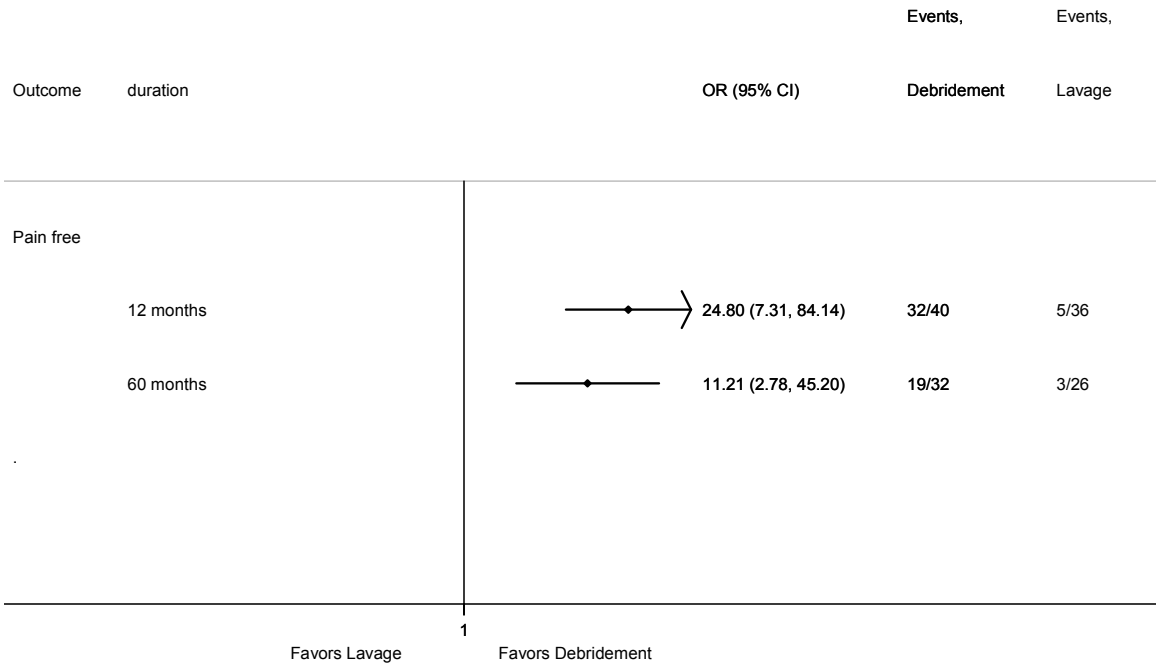


PAIN: FREE FROM

Level of Evidence:
One Level II Systematic Reviews

A Level II systematic review[92] included a RCT[93] assessing the number of patients reporting their knee to be free from pain.

Figure 162. Patients with pain free knees – Lavage & Debridement (systematic review Laupattarakasem et al. 2008)

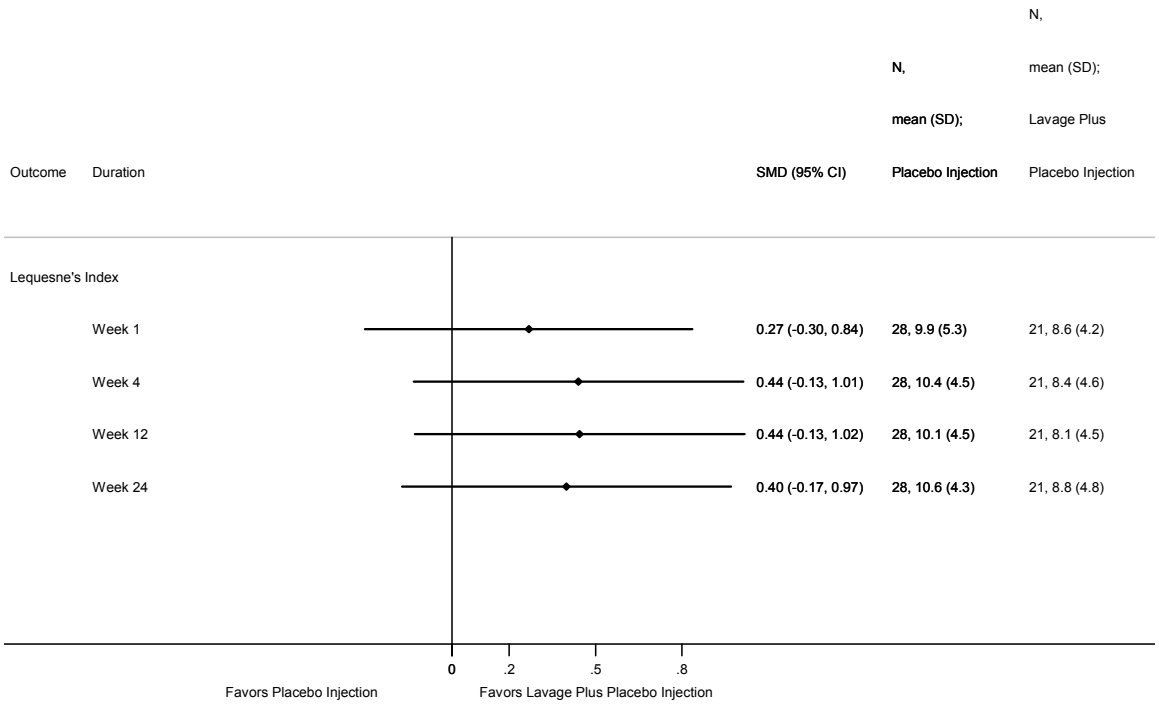


FUNCTION: LEQUESNE

Level of Evidence:
One Level II RCT

Function measured by Lequesne Index was assessed by Ravaud et al.[17] (see Figure 163).

Figure 163. Function measured by Lequesne Index – Lavage (Ravaud et al. 1999)

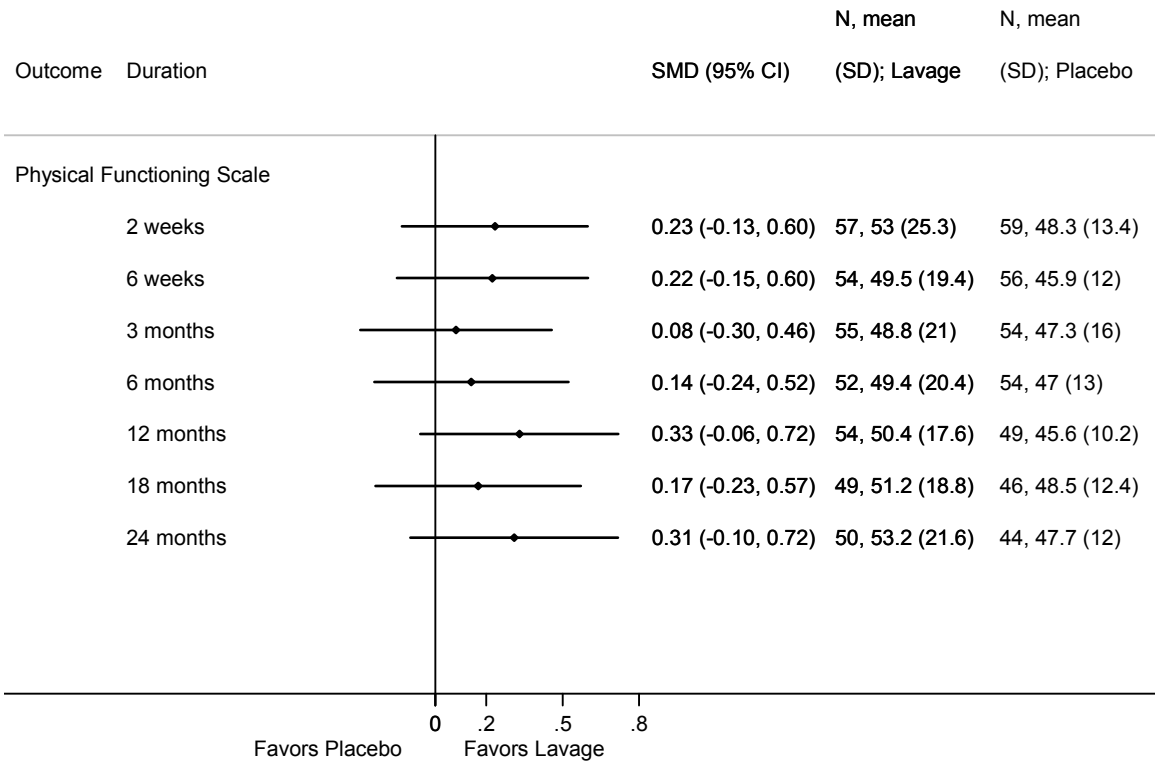


FUNCTION: PHYSICAL FUNCTIONING SCALE (PFS)

Level of Evidence:
One Level I RCT

Moseley et al.[94] devised a Physical Functioning Scale (PFS). Patients were required to walk 30 meters and to climb up and down a flight of stairs as quickly as possible with longer times indicating poorer function.

Figure 164. Physical Functioning Scale – Lavage (Moseley et al. 2002)

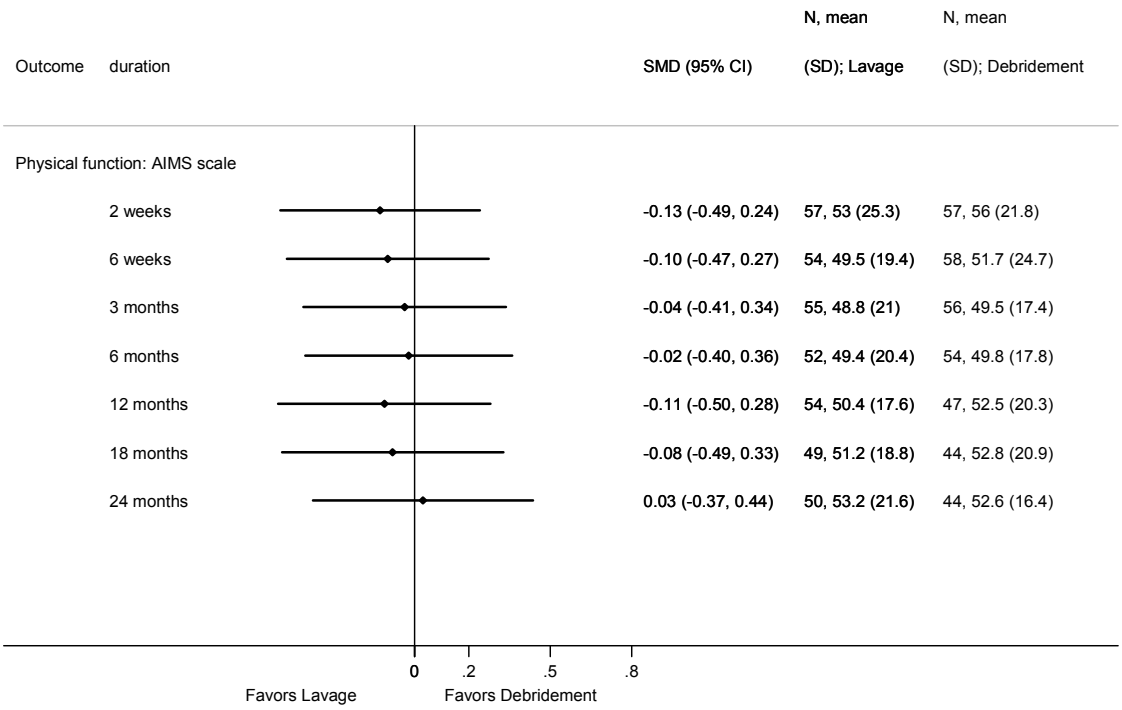


FUNCTION: AIMS

Level of Evidence:
One Level II Systematic Review

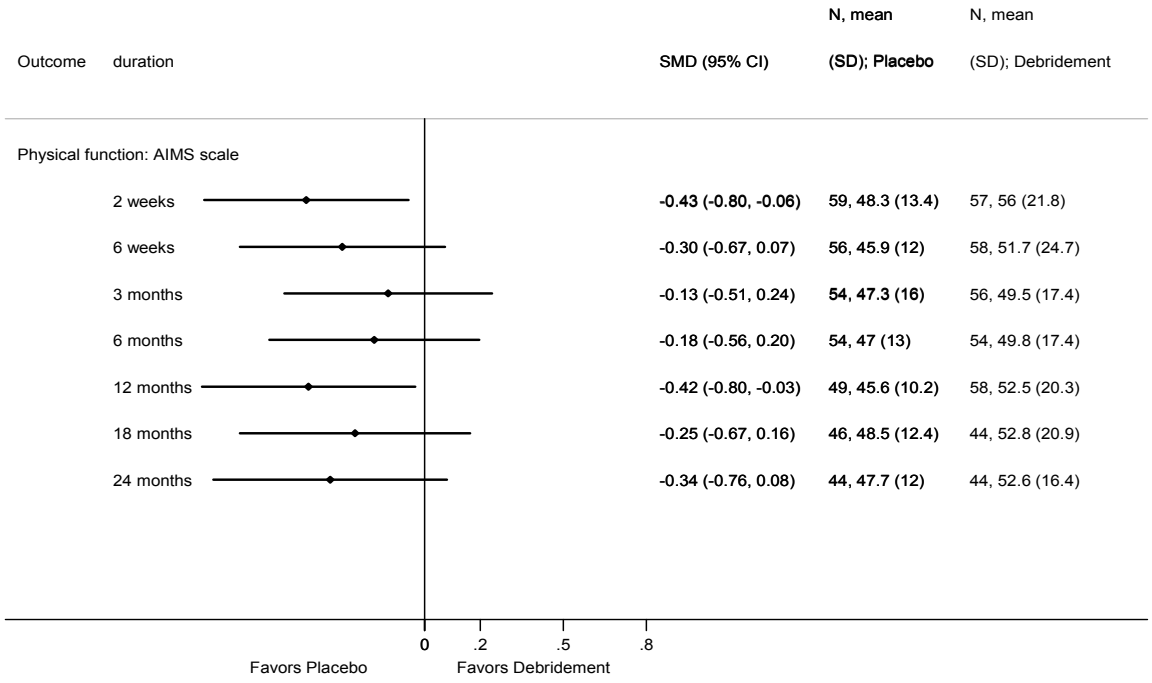
Function measured by AIMS was assessed in a Level II systematic review[92] which included two RCTs.[89, 94]

Figure 165. Physical function measured by AIMS – Debridement & Lavage (Moseley et al. 2002 in Laupattarakasem et al. 2008)**



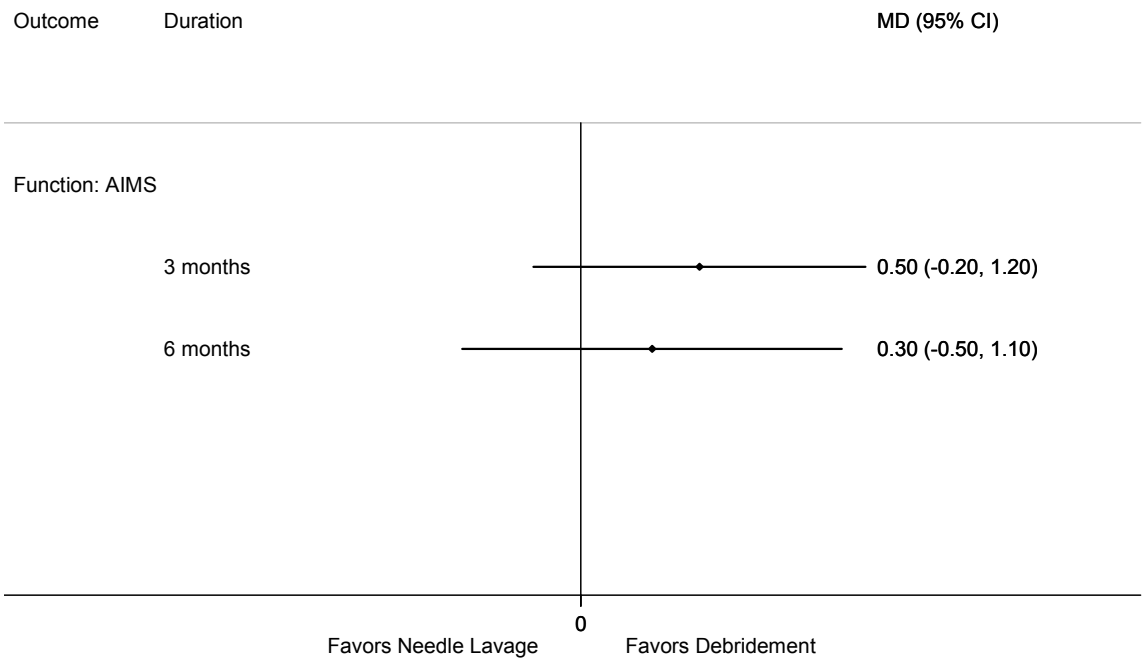
**Laupattarakasem et al (2008) report the above data as "Physical Function AIMS;" however, the data reported corresponds to the Physical Function Scale tabled in the original Moseley et al. (2002) study. This appears to be a labeling error on the part of Laupattarakasem et al. (Figure 164)

Figure 166. Physical function measured by AIMS – Debridement (Moseley et al. 2002 in Laupattarakasem et al. 2008)**



**Laupattarakasem et al (2008) report the above data as "Physical Function AIMS;" however, the data reported corresponds to the Physical Function Scale tabled in the original Moseley et al. (2002) study. This appears to be a labeling error on the part of Laupattarakasem et al. (Figure 164).

Figure 167. Physical function measured by AIMS – Debridement (Chang et al. 1993 in Laupattarakasem et al. 2008)

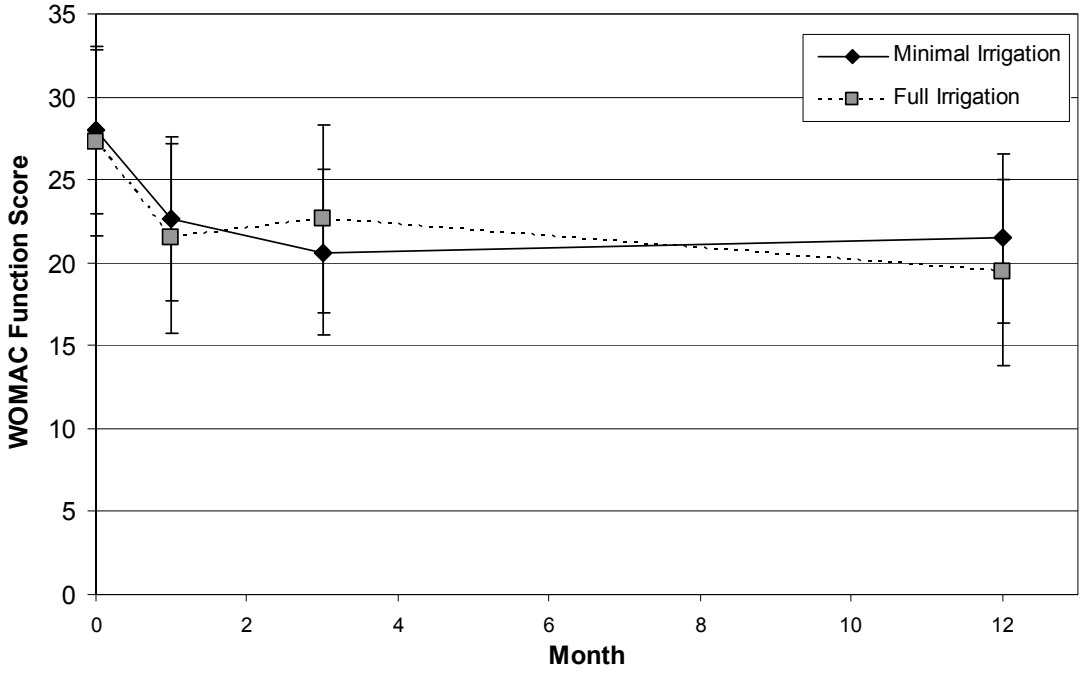


FUNCTION: WOMAC

Level of Evidence:
One Level II RCT

Kaluninan et al.[16] assessed knee function using the Likert version of the WOMAC. Analysis of covariance examining mean change from baseline to twelve months was compared between the two groups (minimal vs. full irrigation). Improvement in WOMAC function was not statistically significant when controlling for statistically significant covariates ($p = 0.15$). Authors do not note if WOMAC function is significant when not controlling for covariates.

Figure 168. Function measured by WOMAC – Lavage (Kalunian et al. 2000)



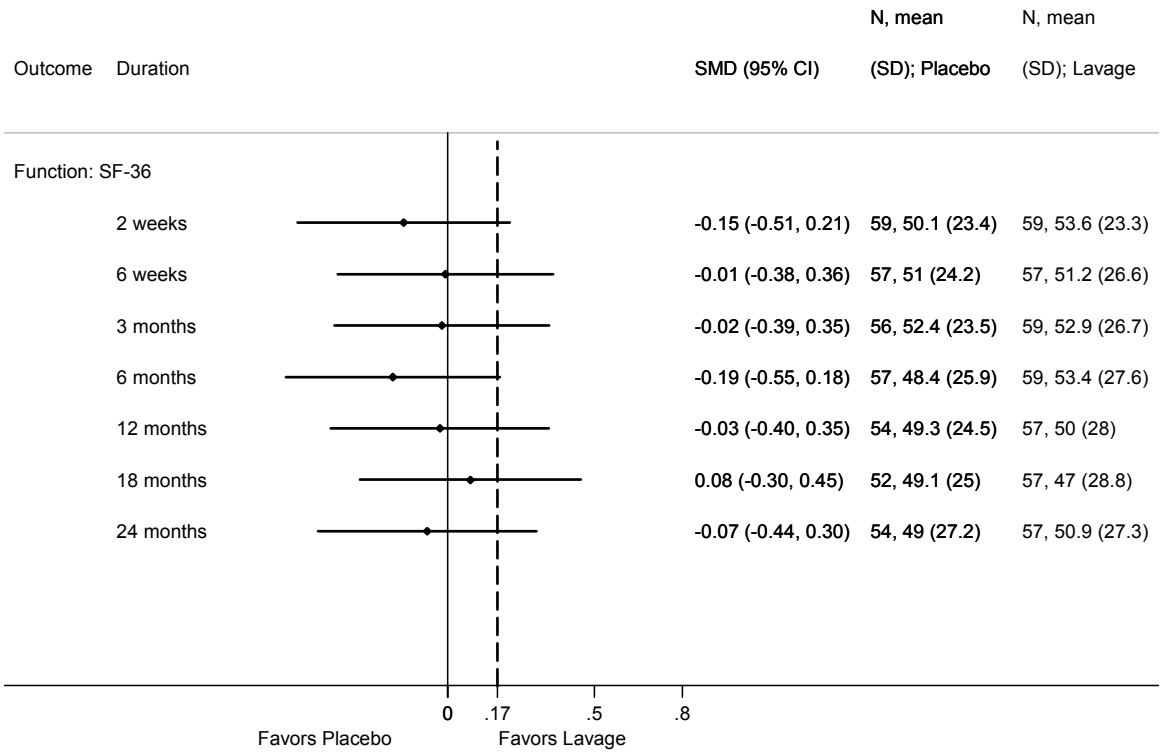
*Type of error dispersion shown in the graph is not noted by authors.

FUNCTION: SF-36

Level of Evidence:
One Level I RCT

Moseley et al.[94] assessed function as measured by SF-36.

Figure 169. Patient function measured by SF-36 – Lavage (Moseley et al. 2002)



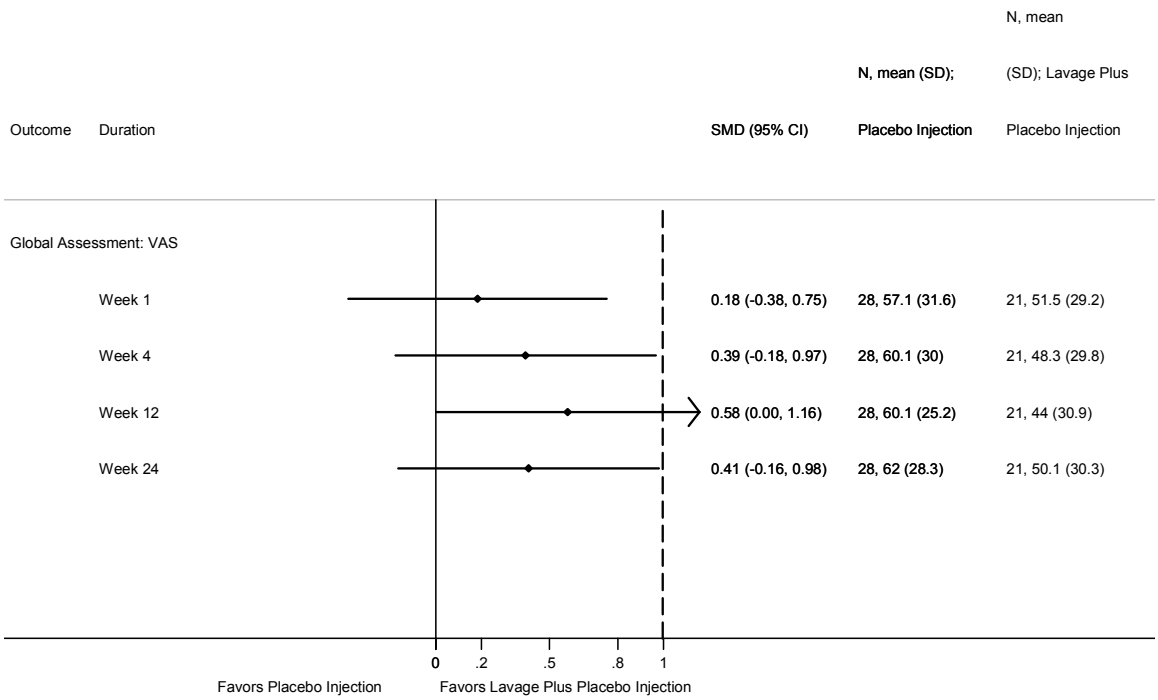
*Dashed line indicates MCII for SF-36 function.

GLOBAL ASSESSMENT (VAS)

Level of Evidence:
One Level II RCT

Global assessment measured by VAS was assessed by Ravaud et al.[17] (see Figure 170).

Figure 170. Global assessment measured by VAS – Lavage (Ravaud et al. 1999)



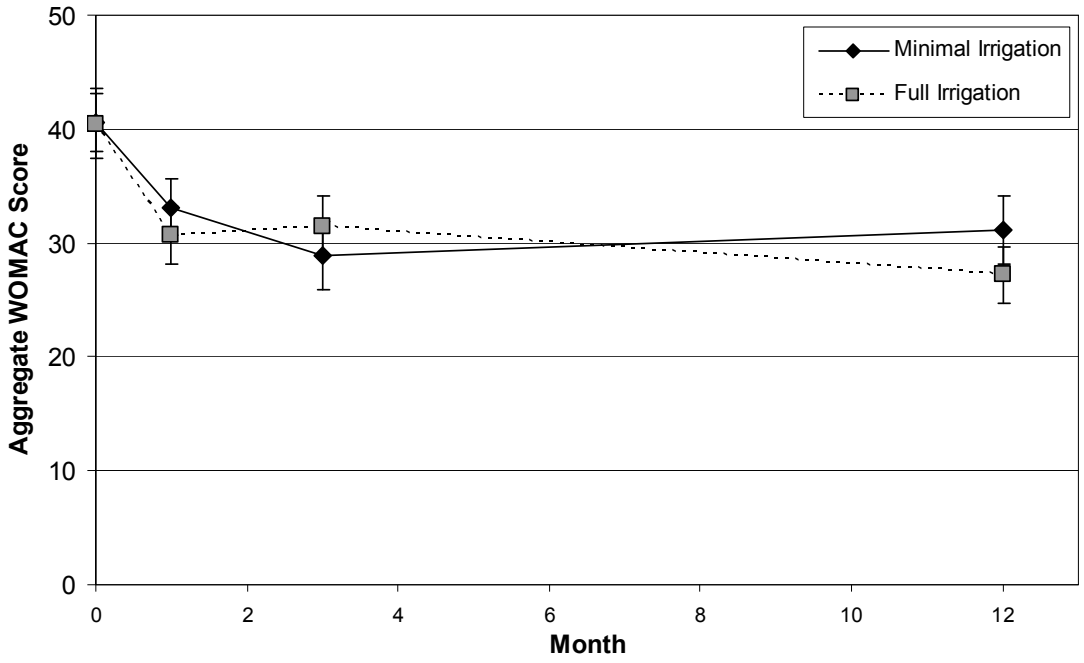
*Dashed line indicates MCII for global assessment (VAS).

AGGREGATE WOMAC

Level of Evidence:
One Level II RCT

Kalunian et al.[16] examined aggregate WOMAC scores defined as the sum of the pain, stiffness and function WOMAC subscores. Analysis of covariance examining mean change from baseline to twelve months was compared between the two groups (minimal vs. full irrigation). Authors note that the aggregate WOMAC score was not significant ($p = 0.13$) nor was it significant when controlling for significant covariates ($p = 0.10$).

Figure 171. Aggregate WOMAC – Lavage (Kalunian et al. 2000)



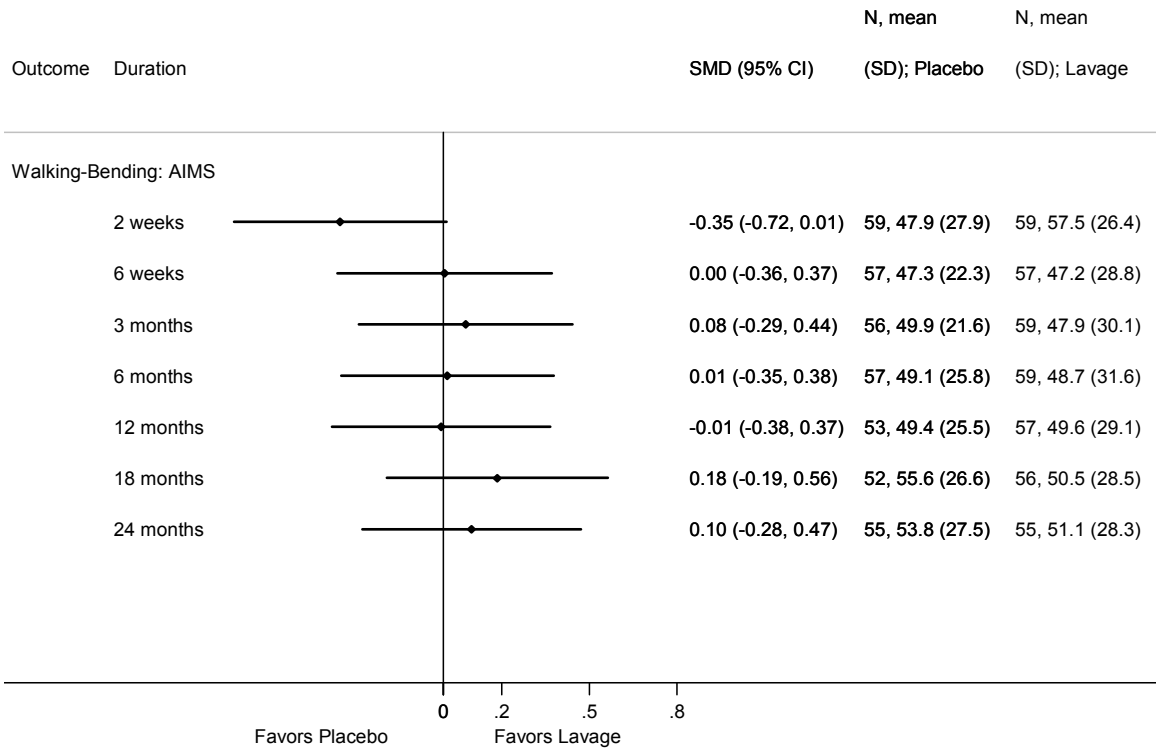
*Type of error dispersion shown in the graph is not noted by authors.

WALKING-BENDING (AIMS)

Level of Evidence:
One Level I RCT

Moseley et al.[94] assessed walking-bending as measured by AIMS.

Figure 172. Walking-bending measured by AIMS – Lavage (Moseley et al. 2002)

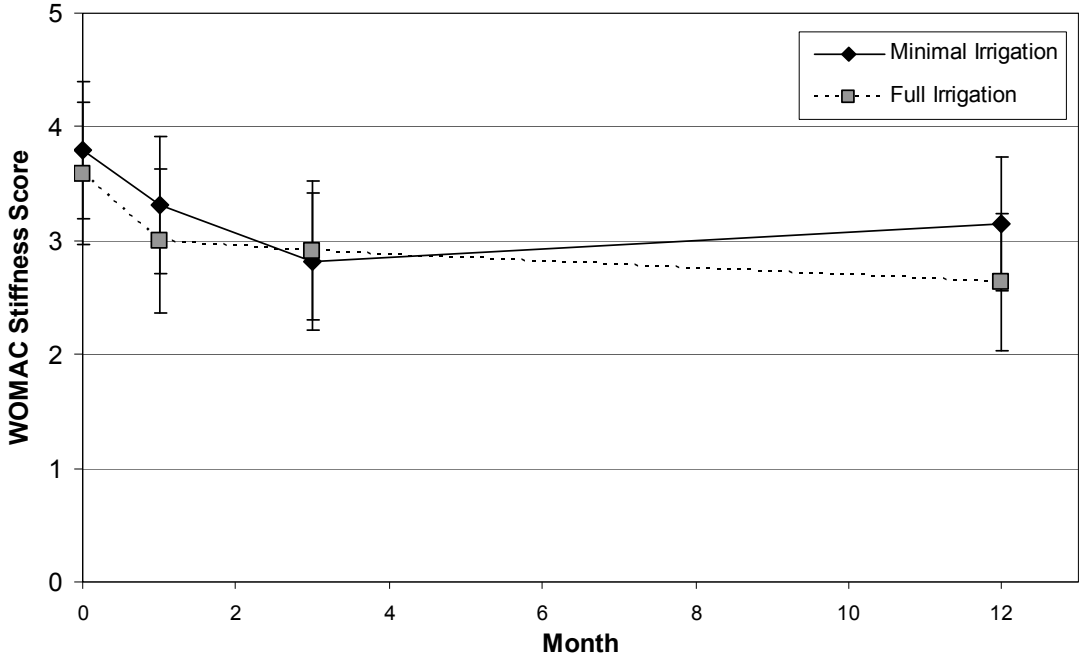


STIFFNESS: WOMAC

Level of Evidence:
One Level II RCT

Kalunian et al.[16] assessed knee stiffness using the Likert version of the WOMAC. Analysis of covariance examining mean change from baseline to twelve months was compared between the two groups (minimal vs. full irrigation). Authors note that improvement in WOMAC stiffness was not statistically significant ($p = 0.32$) nor was it significant when controlling for statistically significant covariates ($p = 0.22$).

Figure 173. Knee stiffness measured by WOMAC – Lavage (Kalunian et al. 2000)



*Type of error dispersion shown in the graph is not noted by authors.

RECOMMENDATION 19

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

AAOS Level of Evidence: **V**
AAOS Grade of Recommendation: **C**

Rationale:

Currently, arthroscopic partial meniscectomy and/or loose body removal are routinely performed in patients with symptomatic OA of the knee who also have primary signs and symptoms of a torn meniscus and/or a loose body. No studies were identified by our systematic literature review specific to this patient population. There is no evidence available to suggest that arthroscopic partial meniscectomy and/or loose body removal is or is not appropriate for a patient with a primary diagnosis of a torn meniscus and/or a loose body, in which OA of the knee is identified secondarily.

The expert opinion consensus of the AAOS workgroup is that arthroscopic partial meniscectomy or loose body removal is an option for patients with primary signs and symptoms a torn meniscus and/or loose body. Additional studies are warranted to look at the outcomes of arthroscopic surgery in this population.

Supporting Evidence:
No studies investigating the use of arthroscopic partial meniscectomy and/or loose body removal in patients with a primary diagnosis of a torn meniscus and/or intra-articular loose body and secondary OA of the knee were identified by our systematic literature searches.

RECOMMENDATION 20

We cannot recommend for or against an osteotomy of the tibial tubercle for patients with isolated symptomatic patello-femoral osteoarthritis.

AAOS Level of Evidence: **V**
AAOS Grade of Recommendation: **Inconclusive**

Rationale:

Osteotomy of the tibial tubercle has been proposed as a treatment for patients with isolated symptomatic patello-femoral OA of the knee. No studies were identified by our systematic review processes, specific to patients with isolated patello-femoral OA of the knee or of patients receiving an osteotomy of the tibial tubercle.

Supporting Evidence:
No studies investigating osteotomy of the tibial tubercle for patients with isolated patello-femoral OA were identified by our systematic literature searches.

RECOMMENDATION 21

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

AAOS Level of Evidence: **IV and V**
AAOS Grade of Recommendation: **C**

Rationale:

A systematic review investigated realignment osteotomy in patients with uni-compartmental knee OA with malalignment.[95] This review examined various osteotomy operative techniques, but did not specifically address the efficacy of realignment osteotomy. Instead it compared various realignment osteotomy operative techniques. This systematic review concludes that there is limited evidence for the efficacy of osteotomy.

To address efficacy, we examined five case series studies [96-100] and the baseline and follow up measurements within each treatment arm of six RCTs, comparing different operative techniques.[101-106] This evidence, including the pre- and post-operative data from RCTs, is considered Level IV because there is no comparison to a placebo or control group.

Clinically important and statistically significant differences from baseline (pre-operative) were found for pain, function, and stiffness as measured by the WOMAC instrument one year[104] after the procedure and for pain, symptoms, activities of daily living, function, and quality of life as measured by the Knee Injury and Osteoarthritis Outcome Score (KOOS) 2 years[96] after the procedure. Possibly clinically important and statistically significant differences from baseline were found for pain measured by VAS,[103] and the WOMAC instrument[104] one year after the procedure.

The remaining case series consistently shows statistically significant differences from baseline but cannot be evaluated for clinical importance. Complications or adverse events varied among surgical techniques reported by the case series evidence.

The AAOS workgroup agreed that the Level IV case series evidence suggested that realignment osteotomy had benefits that lasted up to two years after surgery. We did not analyze longer-term results because of loss of patients in the relevant studies. Additionally, the workgroup qualified this recommendation for “active” patients using Level V expert opinion.

Supporting Evidence

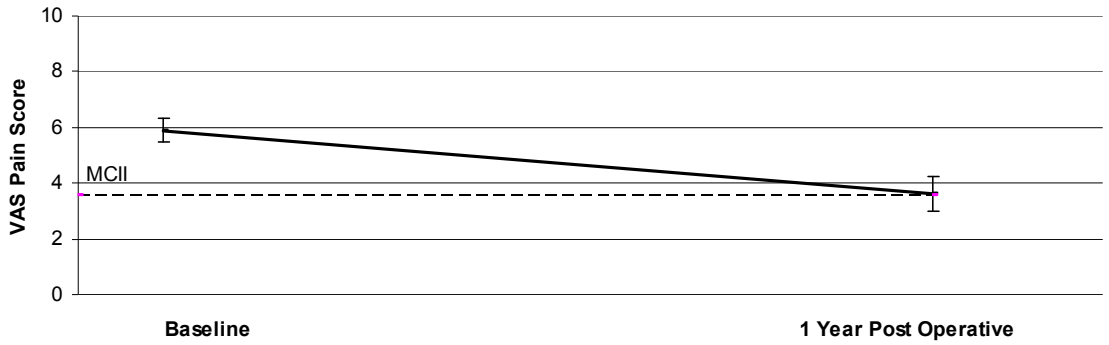
For the raw data addressing this recommendation, please see evidence tables: 32 - 35.
Figures relevant to this recommendation are Figure 174 – Figure 196.
The relevant study attrition diagram is shown in Appendix III.

PAIN: VAS

Level of Evidence:
Level IV case series evidence from one RCT

Brouwer et al.[103] presents level IV case series evidence examining pain using a Visual Analog Scale (VAS) at baseline and one year after closing wedge osteotomy or opening wedge osteotomy. Baseline and post procedure VAS pain mean scores within each group are shown in Figure 174 and Figure 175.

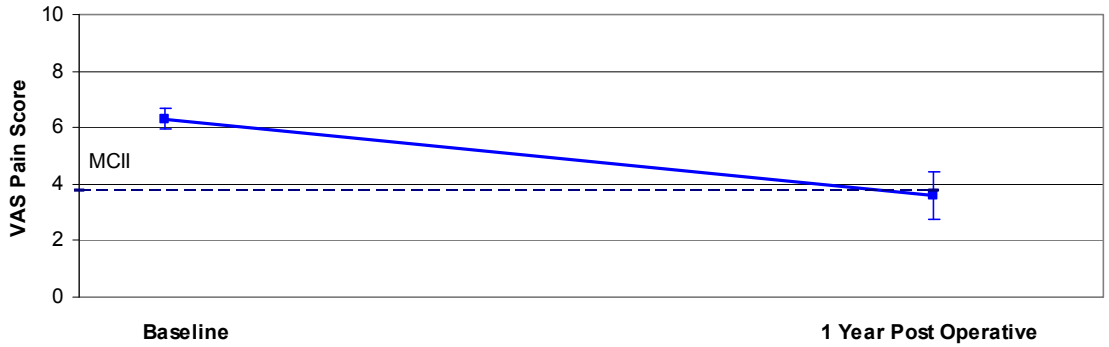
Figure 174: Mean VAS Pain Score in closing wedge HTO (Brouwer et al. 2006)



Change from baseline: $p<0.001$

95% confidence interval calculated from estimated standard deviation. [26]

Figure 175: Mean VAS Pain Score opening wedge HTO (Brouwer et al. 2006)



Change from baseline: $p<0.001$

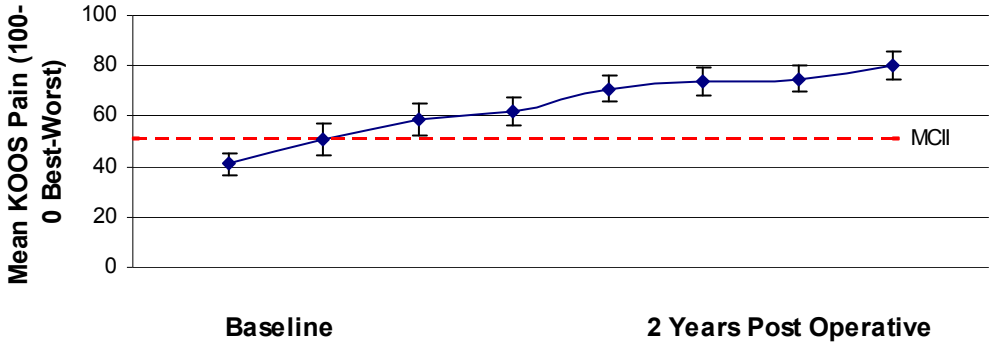
95% confidence interval calculated from estimated standard deviation. [26]

PAIN: KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)

Level of Evidence:
One Level IV case series study

Dahl et al.[96] measured pain at baseline and 2 years postoperatively in patients receiving hemicallotasis osteotomy using the pain subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS). Pain relief reached both clinical and statistical significance.

Figure 176: Mean KOOS Pain Score (Dahl et al. 2005)



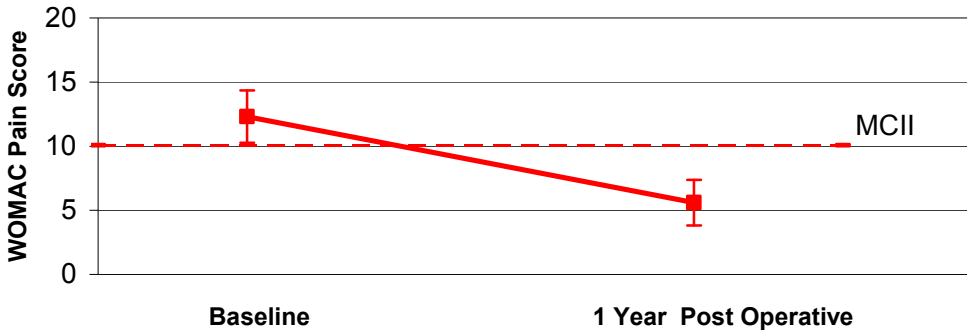
Change from baseline: $p < .001$

PAIN: WOMAC

Level of Evidence:
Level IV case series evidence from one RCT

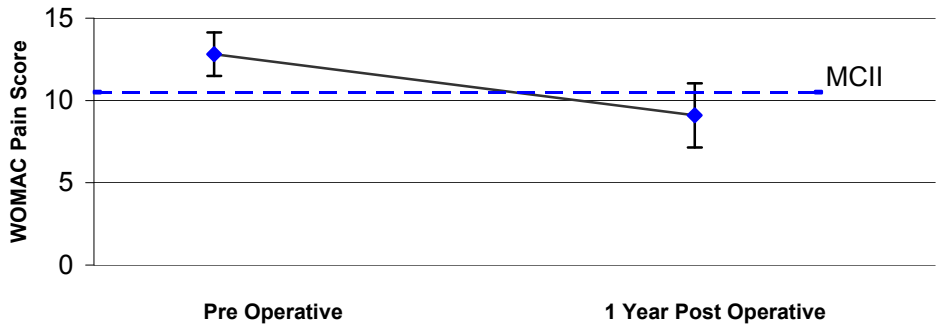
Adili et al.[104] reported the WOMAC pain scores in patients with Ilizarov or Coventry HTO at baseline and 12 months post surgery.

Figure 177 WOMAC Pain Score Ilizarov HTO (Adili et al.2002)



Change from baseline: p <.0001

Figure 178: Mean WOMAC Pain Score Coventry HTO (Adili et al. 2002)



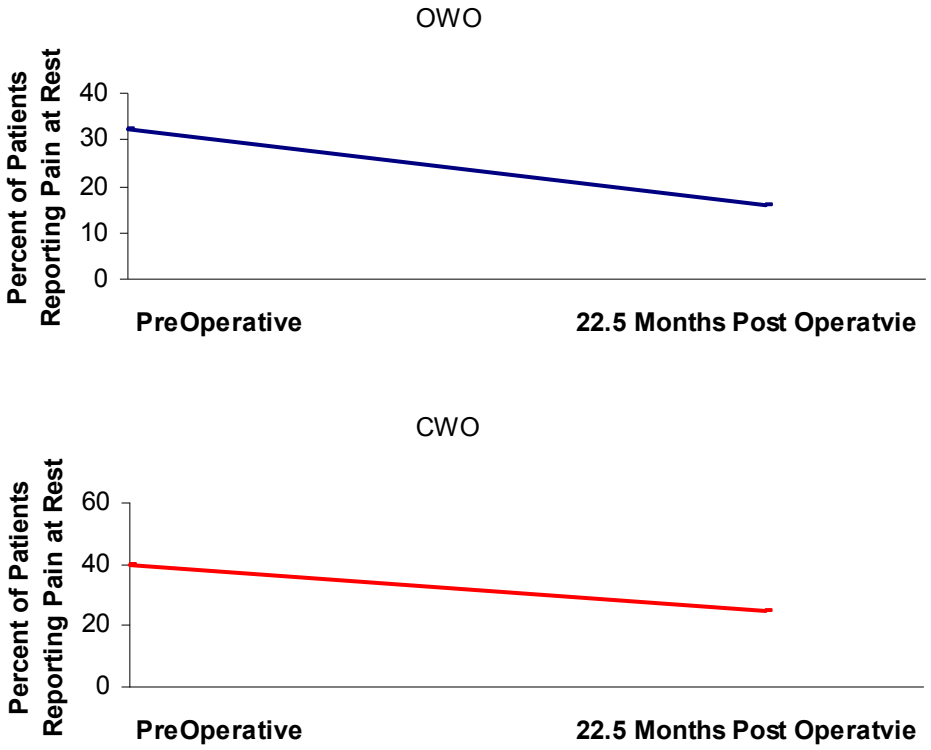
Change from baseline: p =.032

PAIN: PERCENT OF PATIENTS WITH PAIN AT REST AND WHILE WALKING

Level of Evidence:
Level IV case series evidence from one RCT

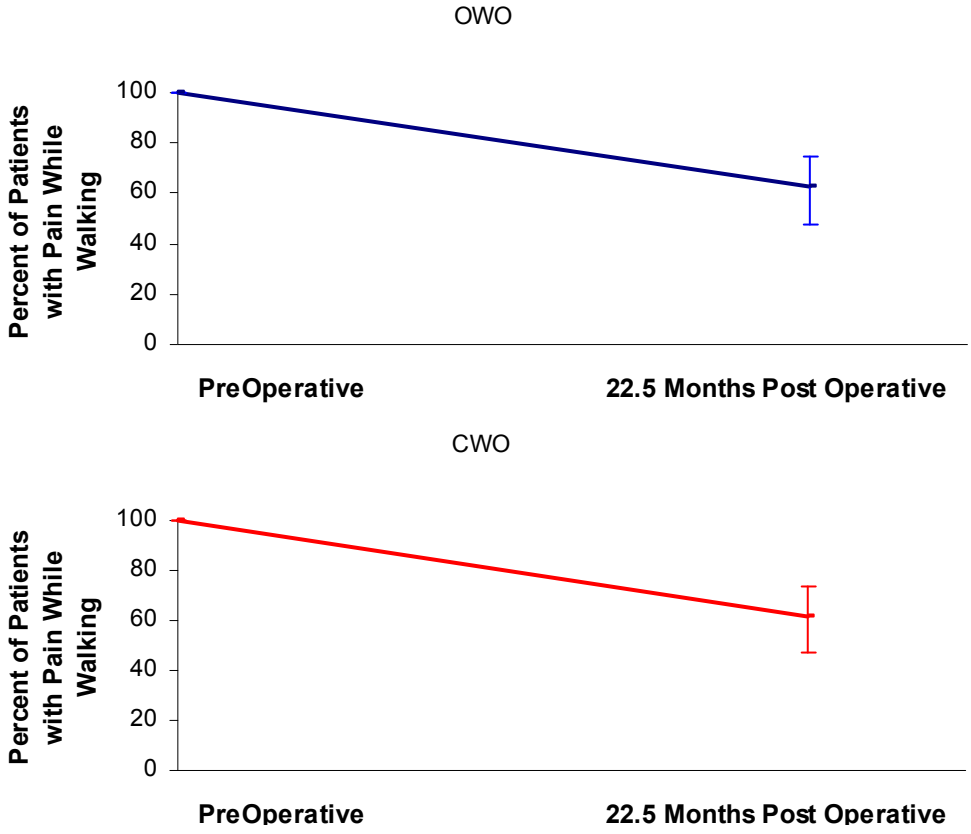
Hoell et al.[106] reported the percent of patients with pain while resting and pain while walking both before surgery and 22.5 months post surgery after receiving either opening wedge osteotomy or closed wedge osteotomy.

Figure 179: Percent of Patients with Pain at Rest (Hoell et al. 2004)



Change from baseline in both OWO and CWO groups: $p < .05$

Figure 180: Percent of Patients with Pain While Walking (Hoell et al. 2004)



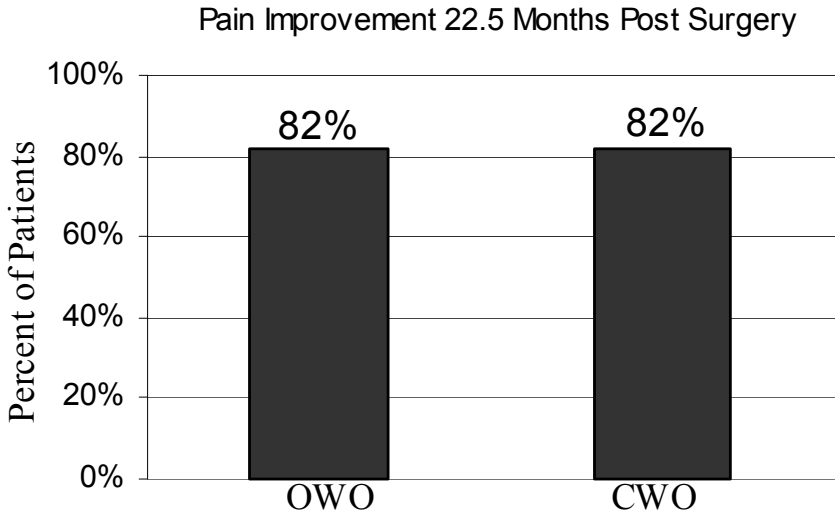
Change from baseline in both OWO and CWO groups: $p < .05$

PAIN: PERCENT OF PATIENTS WITH IMPROVEMENT IN PAIN

Level of Evidence:

Level IV case series evidence from RCT

Figure 181: Percent of Patients with Improvement in Pain. (Hoell et al. 2004)

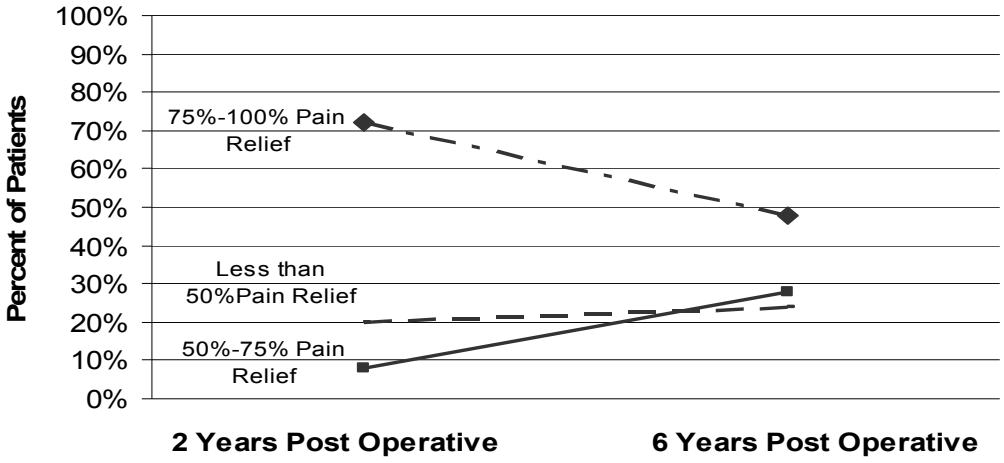


PAIN: PERCENT OF PATIENTS WITH REDUCTION IN PAIN

Level of Evidence:
One Level IV case series study

Devgan et al.[98] reported the percent of patients with 75-100%, 50-75%, or less than 50% reduction in pain at 2 years and 6 years.

Figure 182: Percent of Patients with Reduction in Pain using VAS Scale (Devgan et al. 2002)



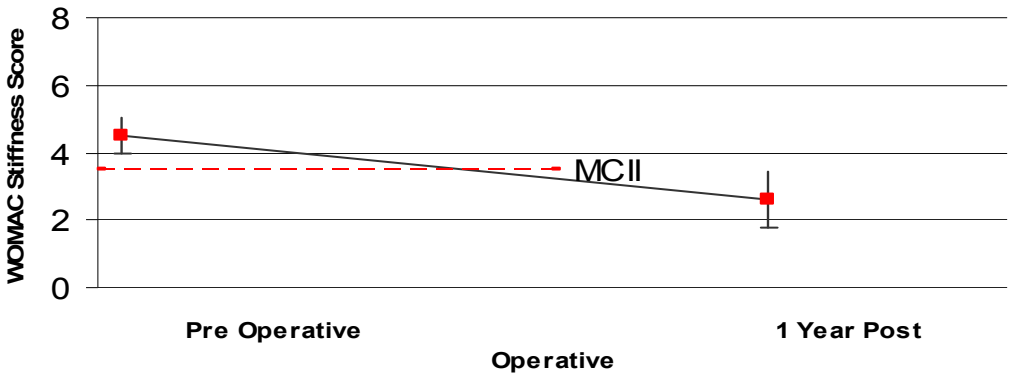
Change from 2 to 6Years is statistically significant in 75-100% pain relief group (OR = 2.78; CI = 1.22 - 6.39).

STIFFNESS: WOMAC

Level of Evidence:
Level IV case series evidence from one RCT

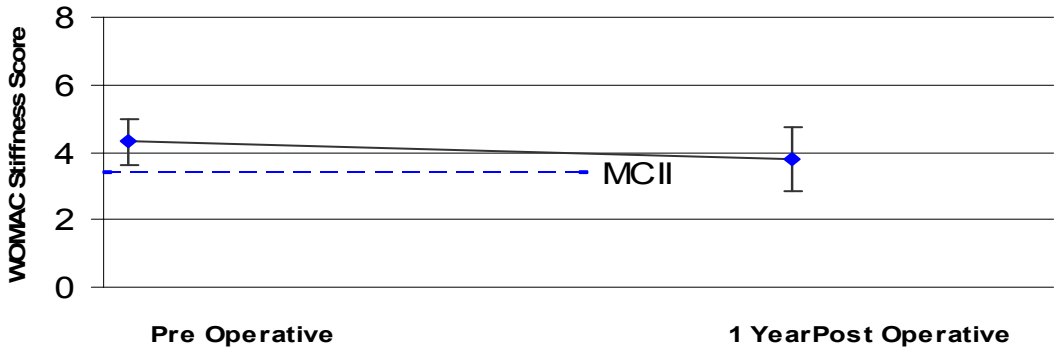
Adili et al.[104] reported the WOMAC stiffness scores in patients with Ilizarov or Coventry HTO at baseline and 12 months post surgery.

Figure 183: Mean WOMAC Stiffness Score Ilizarov HTO (Adili et al. 2002)



Change from baseline p = .003

Figure 184: Mean WOMAC Stiffness Score Coventry HTO (Adili et al. 2002)



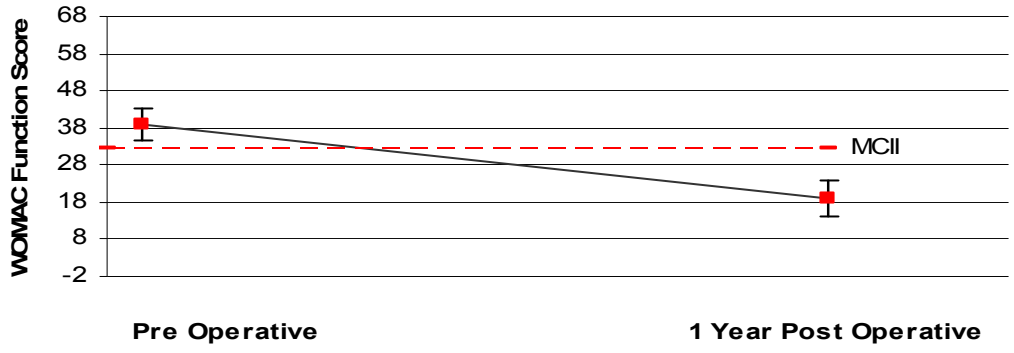
Change from baseline p=.48

FUNCTION: WOMAC

Level of Evidence:
Level IV case series evidence from one RCT

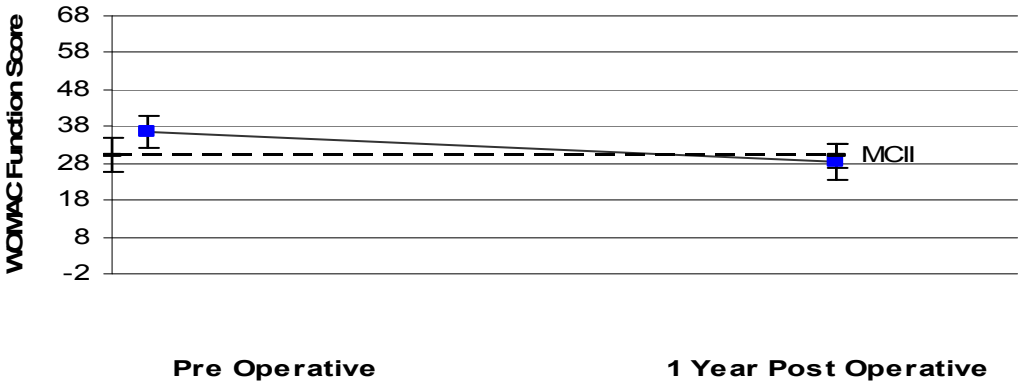
Adili et al.[104] reported the WOMAC function scores in patients with Ilizarov or Coventry HTO at baseline and 12 months post surgery.

Figure 185: Mean WOMAC Function Score Ilizarov HTO (Adili et al. 2002)



Change from baseline p <.001

Figure 186: WOMAC Function Score Coventry HTO (Adili et al. 2002)



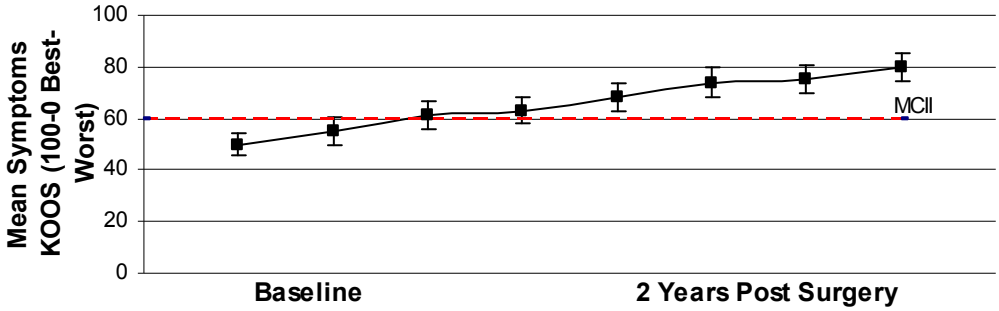
Change from baseline p =.02

SYMPTOMS: KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE

Level of Evidence:
One Level IV case series study

Dahl et al.[96] measured OA symptoms at baseline and 2 years postoperatively in patients receiving hemicallotasis osteotomy. Symptoms were measured using the symptom subscale of the Knee Injury and Osteoarthritis Outcome Score.

Figure 187: Mean Symptoms KOOS (Dahl et al. 2005)



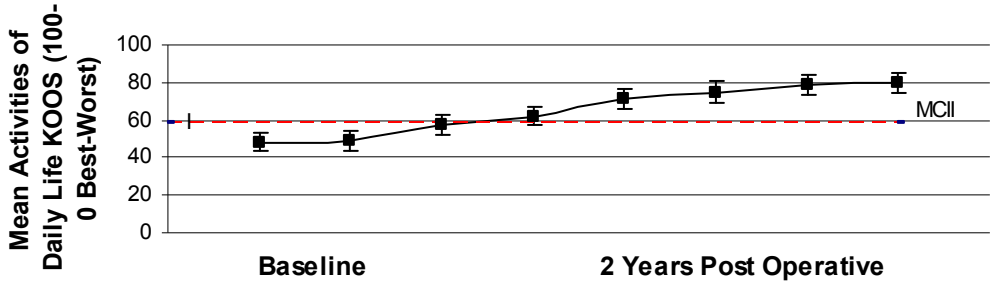
Change from baseline $p < .001$

ACTIVITIES OF DAILY LIFE: KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE

Level of Evidence:
One Level IV case series study

Dahl et al.[96] measured the level of activities of daily life (ADL) at baseline and 2 years postoperatively in patients receiving hemicallotasis osteotomy. ADL was measured using the activities of daily life subscale of the Knee Injury and Osteoarthritis Outcome Score.

Figure 188: Mean Activities of Daily Life KOOS (Dahl et al. 2005)



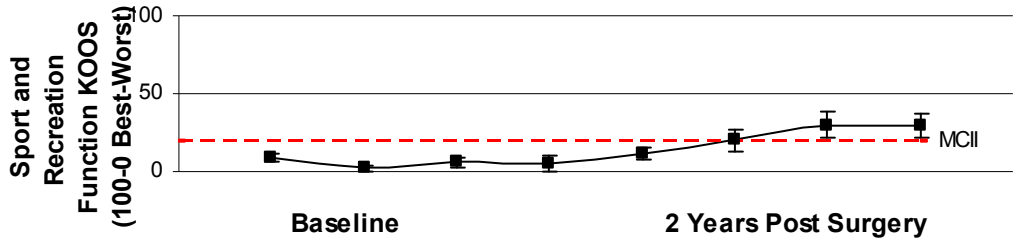
Change from baseline $p < .001$

SPORTS AND RECREATIONAL FUNCTION: KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE

Level of Evidence:
One Level IV case series study

Dahl et al.[96] measured the level of sports and recreational function at baseline and 2 years postoperatively in patients receiving hemicallotasis osteotomy.This was accomplished using the sports and recreational function subscale of the Knee Injury and Osteoarthritis Outcome Score.

Figure 189: Mean Sports and Recreational Function Score KOOS. (Dahl et al. 2005)



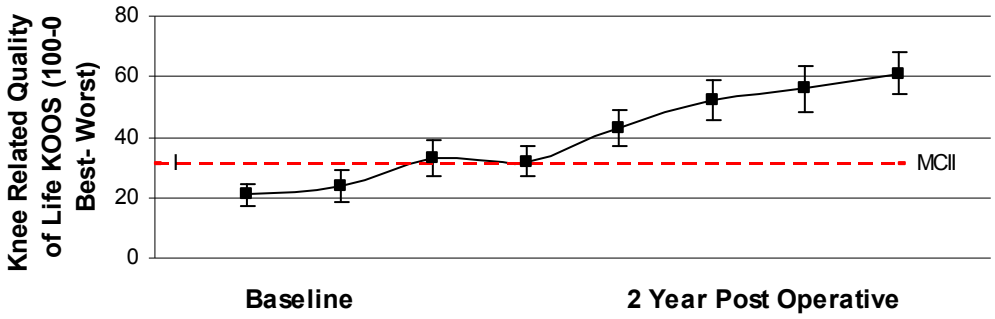
Change from baseline $p < .001$

KNEE RELATED QUALITY OF LIFE: KOOS

Level of Evidence:
One Level IV case series study

Dahl et al.[96] measured the knee related quality of life (QoL) at baseline and 2 years postoperatively in patients receiving hemicallotasis osteotomy. QoL was measured using the knee related quality of life subscale of the Knee Injury and Osteoarthritis Outcome Score.

Figure 190: Knee Related Quality of Life KOOS. (Dahl et al. 2005)



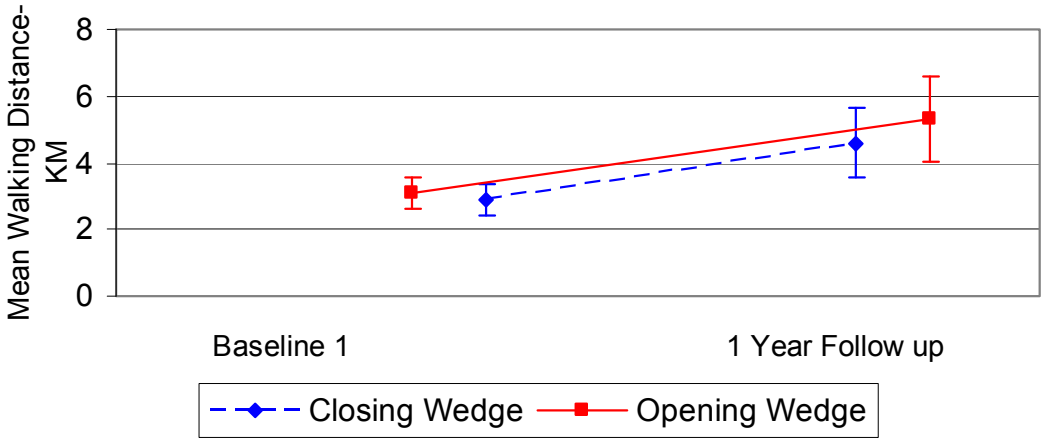
Change from baseline: $p < .001$

WALKING DISTANCE

Level of Evidence:
Level IV case series evidence from one RCT

Brouwer et al.[103] measured walking distance at baseline and one year post surgery. The author of this study did not provide a specific description of the test used to measure walking distance.

Figure 191: Mean Walking Distance (Brouwer et al. 2006)



Change from baseline: CW p = <.05 OW p<.05

95% confidence interval calculated from estimated standard deviation [26]

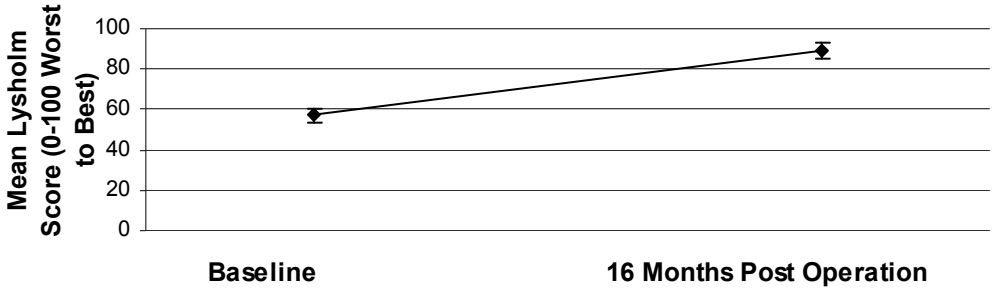
LYSHOLM SCORE

Level of Evidence:
One Level IV case series study and Level IV case series evidence from two RCTs

The Lysholm function score considers patient limp; squatting; walking; running and jumping; pain, swelling, and thigh atrophy.

Klinger et al.[99] reported the mean Lysholm score at baseline and 16 months postoperatively.

Figure 192: Mean Lysholm Score (Klinger et al. 2001)

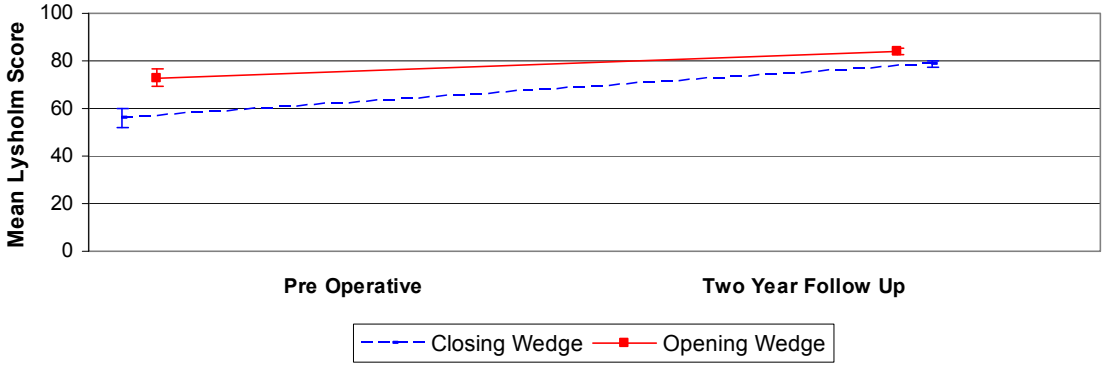


Change from baseline: $p < .05$

95% confidence interval calculated from estimated standard deviation and mean estimated from median [26].

Magyar et al.[105] examined the mean Lysholm scores before and two years following the procedure within both treatment arms.

Figure 193: Mean Lysholm Scores (Magyar et al. 1999)

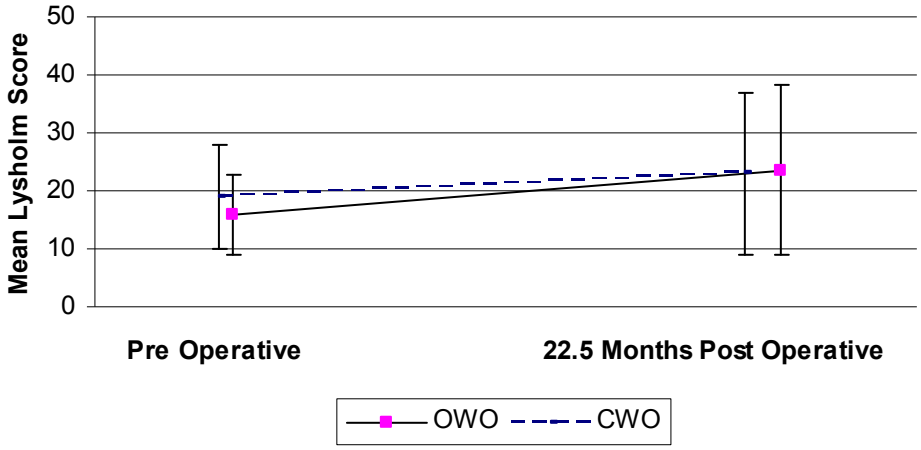


Change from baseline: HTO $p < .001$ HCO $p < .001$

95% confidence interval calculated from estimated standard deviation and mean estimated from median [26].

Hoell et al.[106] recorded the mean Lysholm score in both the opening wedge osteotomy group and closed wedge osteotomy group preoperatively and 22.5 months post operatively.

Figure 194: Mean Lysholm Score (Hoell et al. 2005)



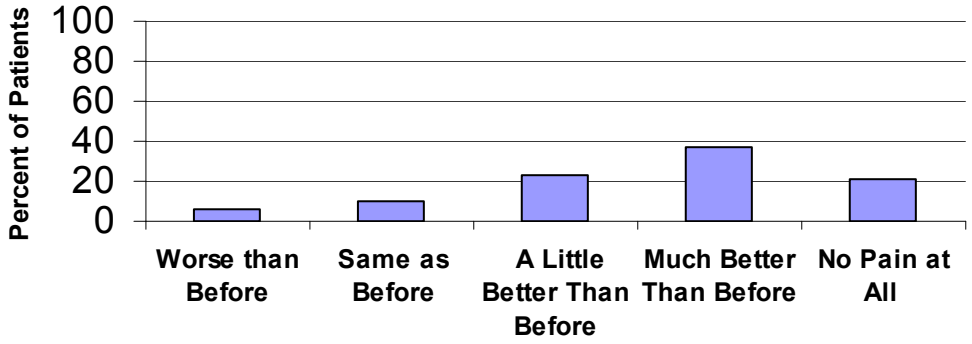
Change from baseline: OWO $p < .01$ CWO $p < .05$

PATIENT OPINION OF RESULTS

Level of Evidence:
Level IV case series evidence from one RCT

Myrnerts et al.[101] asked patients their opinion of the results of the operation at the final follow-up exam, 1 or 2 years after the surgery.

Figure 195: Patient Opinion of Results (Myrtnets et al. 1980)

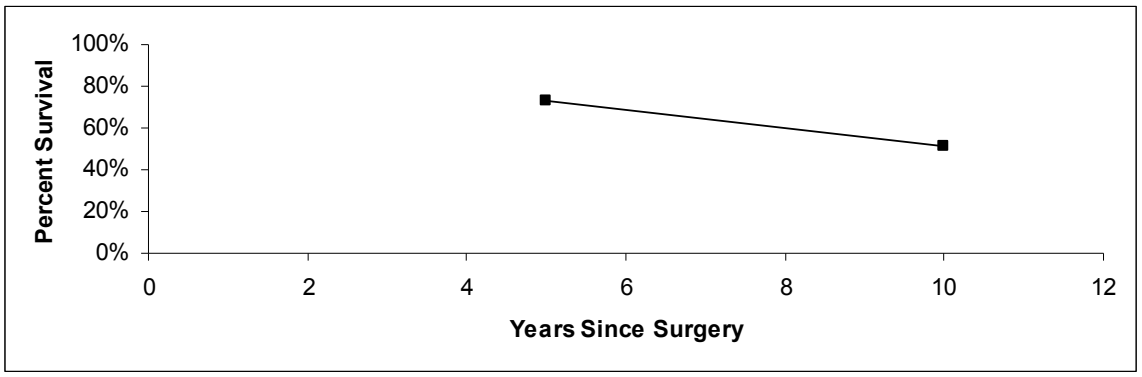


SURVIVAL

Level of Evidence:
One Level IV case series study

Naudie et al.[100] evaluated 106 osteotomies in 78 patients. The percent of survival of osteotomy at 5 and 10 years is reported in Figure 196

Figure 196: Percent Survival. (Naudie et al. 1999)



Statistically significant change in percent of survival from 5-10 years (OR= 2.57 95% CI= 1.44-4.53)

COMPLICATIONS OR ADVERSE EVENTS

Level of Evidence: IV

5 Level IV case series studies and Level IV case series evidence from 6 RCTs

Complications or adverse events reported by study authors varied considerably. Complication or adverse event rates ranged from 1 percent to 43 percent. Table 13 below shows complications or adverse events which exceeded 10 percent of the enrolled patients.

Evidence Table 40 contains all complications or adverse events reported in the eleven studies investigating osteotomy in patients with uni-compartmental knee OA with malalignment.

Table 13. Complications and Adverse Events exceeding 10% of Enrolled Patients

Complication or Adverse Event	Percentage of Patients	Study
Medial Joint Pain	43%	Adili et al. 2002 [104]
Removal of Osteosynthesis Material	41%	Brouwer et al. 2006 [103]
Minor Infection	40%	Adili et al. 2002 [104]
Grade 2 Pin Site Infection	33%	Magyar et al 1999 [105]
Pin/Wire Removal due to Infection	23%	Adili et al. 2002 [104]
Revised with Arthroplasty	20%	Naudie et al. 1999 [100]
Reoperation	18%	Myrnerts et al. 1980 [101]
Deep Vein Thrombosis	17%	Adili et al. 2002 [104]
Ankle Stiffness	17%	Adili et al. 2002 [104]
Loose Pin(s)	12%	Dahl et al. 2005 [96]
Grade 2 Pin Site Infection	10%	Dahl et al. 2005 [96]
Iliac Crest Morbidity	10%	Brouwer et al. 2006 [103]

RECOMMENDATION 22

We suggest against using a free-floating interpositional device for patients with symptomatic unicompartmental OA of the knee.

AAOS Level of Evidence: **IV**
AAOS Grade of Recommendation: **B**

Rationale:

Evidence from one published case series[107] and from the Australian Orthopaedic Association Joint Registry,[108-110] reporting the results of free-floating interpositional device surgeries performed between 2004 and 2006, addresses the use free-floating interpositional devices for treatment of unicompartmental OA of the knee. We categorized this evidence as Level IV evidence.

In 2007, the Australian Joint registry stated that they no longer use free-floating interpositional devices.[111]

The evidence demonstrates high reoperation rates in the patients followed in both series. Revision to total knee arthroplasty ranged from 32 percent at 2 years to 62 percent at 3 years. (Figure 201, Figure 202) The evidence demonstrates differences from baseline that are not clinically important and statistically significant for pain measured on VAS 2 years postoperatively (Figure 197). Differences from baseline on the Knee Society Function Score were statistically significant and remained "poor" post-operatively (Figure 199).

The AAOS workgroup upgraded this recommendation to grade B, based on the high revision rates in these series, and the potential harm associated with this intervention.

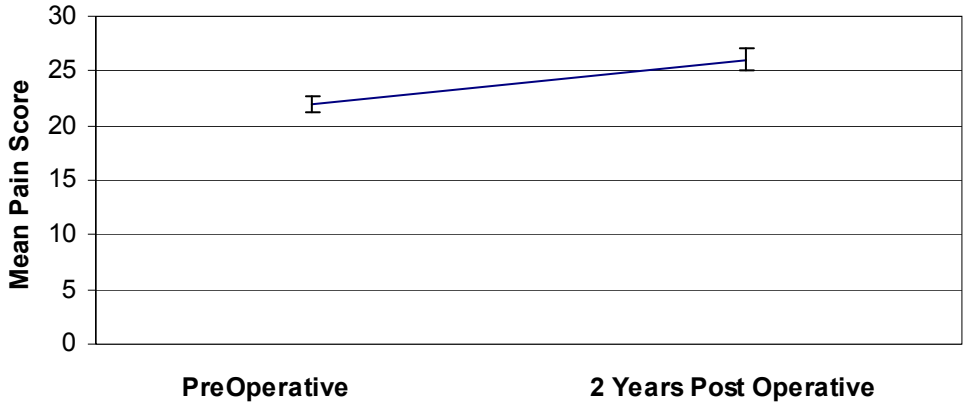
Supporting Evidence
For the raw data addressing this recommendation, please see evidence tables: 36 - 38.
Figures relevant to this recommendation are Figure 197 - Figure 202.
The relevant study attrition diagram is shown in Appendix III.

PAIN: VAS

Level of Evidence:
One Level IV case series study

Sisto et al.[107] measured pain using a VAS scale at baseline and at 24 months (range 22-26 months). A 19.9 mm change measured by VAS for pain is considered clinically important.[21]

Figure 197: Mean Pain Scores (VAS) (Sisto et al. 2005)



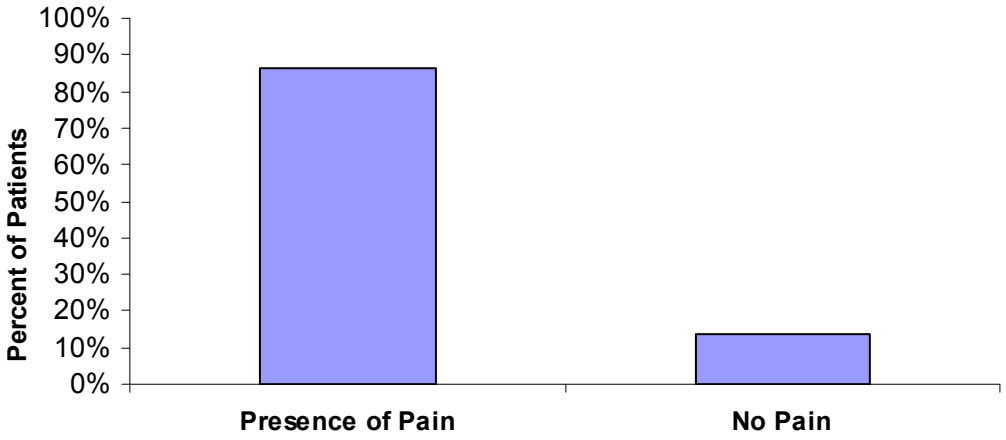
Change from baseline: p=.001

PAIN: PRESENCE WHILE WALKING

Level of Evidence:
One Level IV case series study

Sisto et al.[107] recorded the number of patients who complained of pain while walking 24 (range 22-26) months after surgery.

Figure 198: 26 Months Post-Operative Presence of Pain While Walking (Sisto et al. 2005)



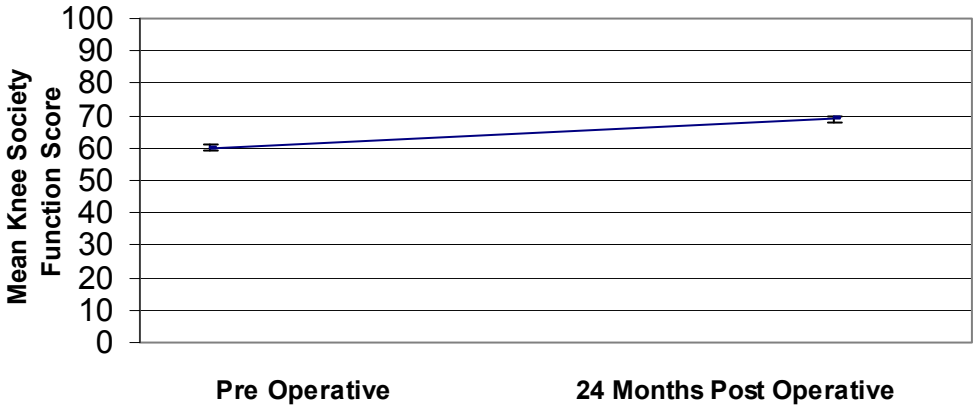
FUNCTION: KNEE SOCIETY SCORE

Level of Evidence: IV

One Level IV case series study

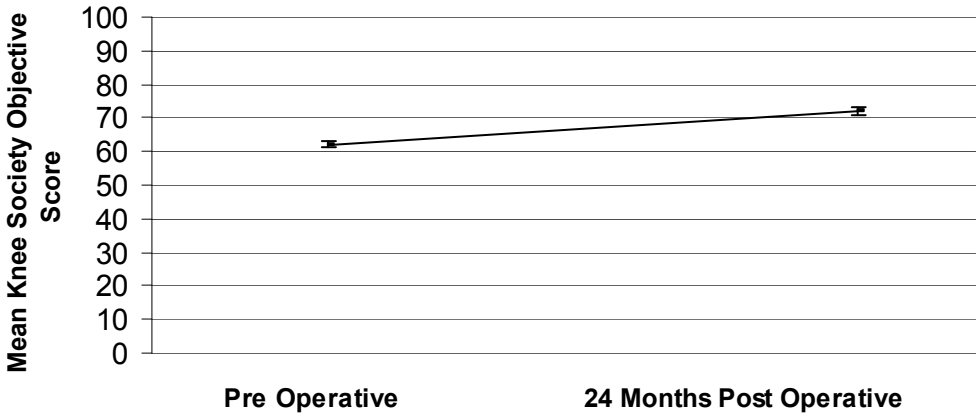
Sisto et al.[107] compare the pre and post surgery scores for both the Function and Objective Scores.

Figure 199: Mean Knee Society Function Score (Sisto et al. 2005)



Change from baseline: $p<0.001$

Figure 200: Mean Knee Society Objective Scores (Sisto et al. 2005)



Change from baseline $p<.0001$

REVISION RATE

Level of Evidence:
One Level IV case series study and Level IV evidence from joint registry data

Two case series report revision rate after free-floating interpositional device procedures. The Australian Joint Registry[110] reported 39 free-floating interpositional device procedures between 2004 and 2006. Sisto et al.[107] reported the revision rate of 37 free-floating interpositional devices arthroplasties in 34 patients.

Figure 201: Cumulative Percent of Revisions (Australian Joint Registry, 2006)

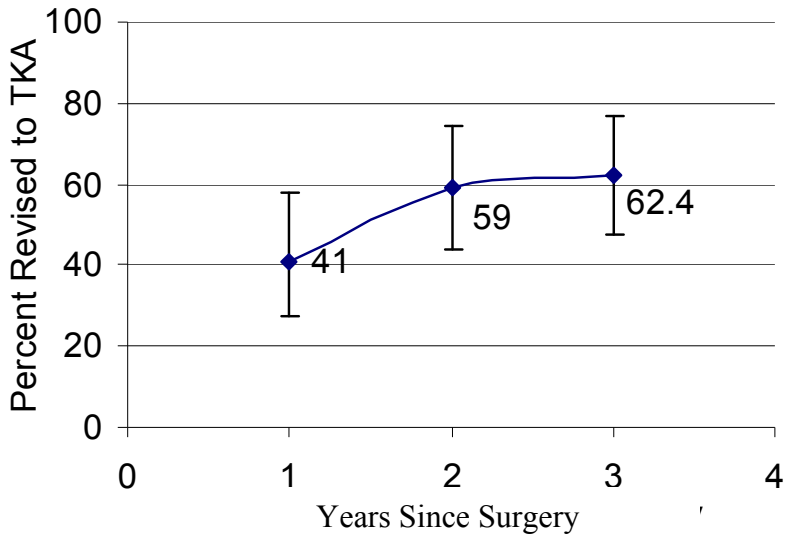
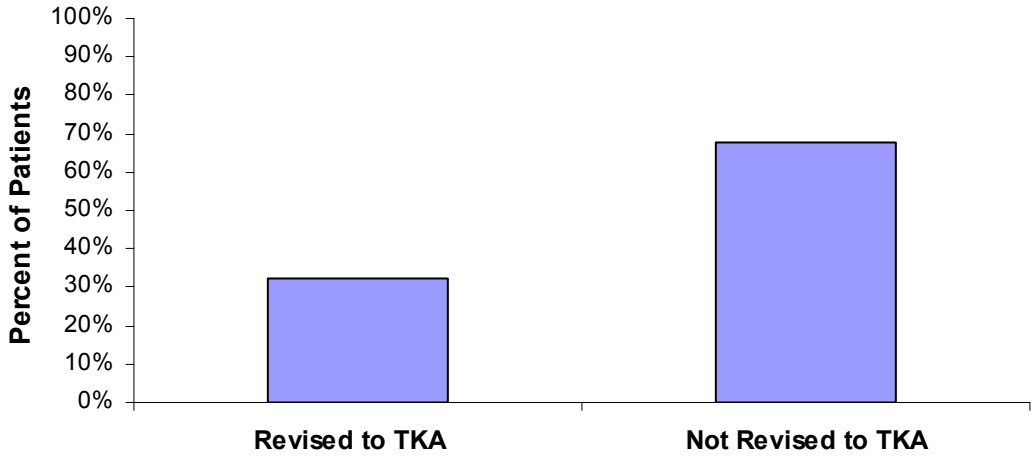


Figure 202: Percent Revised to TKA, (Sisto et al. 2005)



FUTURE RESEARCH

Many treatments for OA of the knee are addressed by randomized controlled trials. The quality of these trials is, in some cases, questionable. To achieve a high quality literature base, academic authors and scientists should invest their time and effort in studies designed to avoid bias. Techniques to limit bias include proper randomization and adequate, verified blinding of investigators, patients, and/or evaluators, wherever possible. Future studies should also include a priori power analysis to ensure clinically important improvements (improvement that matters to the patient). These studies should utilize patient oriented outcome measures (i.e. WOMAC, SF-36) whose key psychometric characteristics have been evaluated and validated. The use of validated patient oriented outcome measures will ensure that the measure of success of future studies is determined by minimal clinically important improvements.

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

IV.**APPENDIXES**

APPENDIX I
WORKGROUP

Conflict of Interest information for workgroup members is available in Appendix XI

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APPENDIX II
AAOS BODIES THAT APPROVED THIS CLINICAL PRACTICE GUIDELINE

Guidelines and Technology Oversight Committee
The AAOS Guidelines and Technology Oversight Committee (GTOC) consists of sixteen AAOS members. The overall purpose of this Committee is to oversee the development of the clinical practice guidelines, performance measures, health technology assessments and utilization guidelines.

Evidence Based Practice Committee
The AAOS Evidence Based Practice Committee (EBPC) consists of ten AAOS members. This Committee provides review, planning and oversight for all activities related to quality improvement in orthopaedic practice, including, but not limited to evidence-based guidelines, performance measures, and outcomes.

Council on Research, Quality Assessment, and Technology
To enhance the mission of the AAOS, the Council on Research, Quality Assessment, and Technology promotes the most ethically and scientifically sound basic, clinical, and translational research possible to ensure the future care for patients with musculoskeletal disorders. The Council also serves as the primary resource to educate its members, the public, and public policy makers regarding evidenced-based medical practice, orthopaedic devices and biologics, regulatory pathways and standards development, patient safety, occupational health, technology assessment, and other related areas of importance.

The Council is comprised of the chairs of the AAOS Biological Implants, Biomedical Engineering, Evidence Based Practice, Guidelines and Technology Oversight, Occupational Health and Workers' Compensation, Patient Safety, Research Development, and US Bone and Joint Decade committees. Also on the Council are the AAOS second vice-president, representatives of the Diversity Advisory Board, the Women's Health Issues Advisory Board, the Board of Specialty Societies (BOS), the Board of Councilors (BOC), the Communications Cabinet, the Orthopaedic Research Society (ORS), the Orthopedic Research and Education Foundation (OREF), and three members at large.

Board of Directors
The 17 member AAOS Board of Directors manages the affairs of the AAOS, sets policy, and determines and continually reassesses the Strategic Plan.

DOCUMENTATION OF APPROVAL

AAOS Workgroup Draft Completed	August 2008
Peer Review Completed	October 15, 2008
Public Commentary Completed	November 20, 2008
AAOS Guidelines and Technology Oversight Committee	November 24, 2008
AAOS Evidence Based Practice Committee	November 25, 2008
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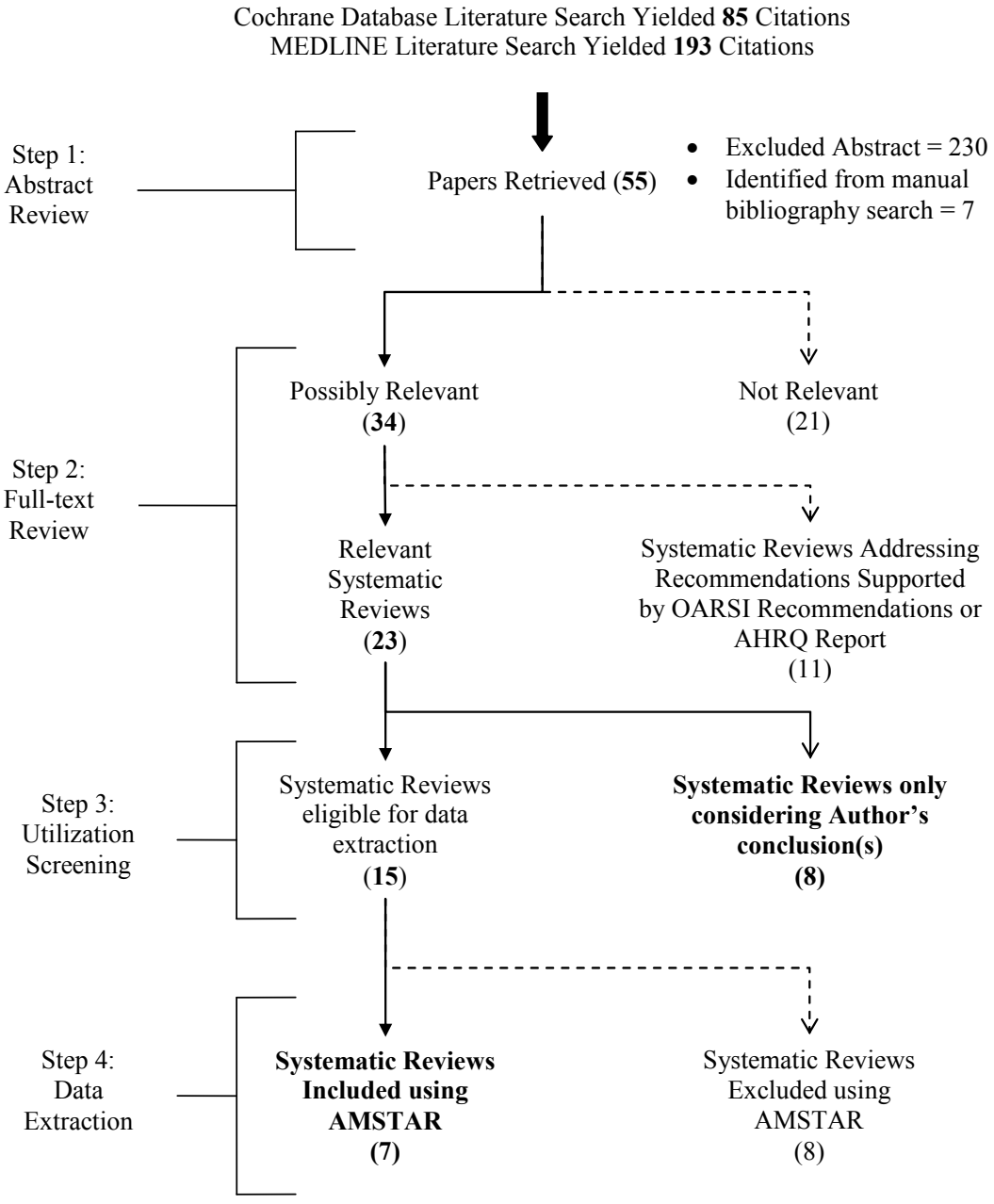
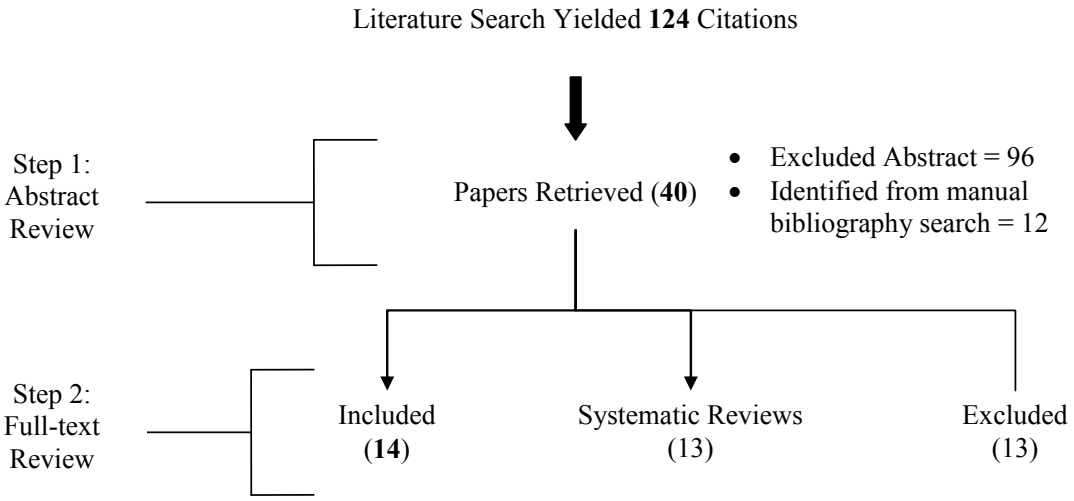
American Academy of Orthopaedic Surgeons Clinical Practice Guideline on the Treatment of Osteoarthritis of the Knee (Non-Arthroplasty). Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2008

APPENDIX III
STUDY ATTRITION FLOWCHARTS

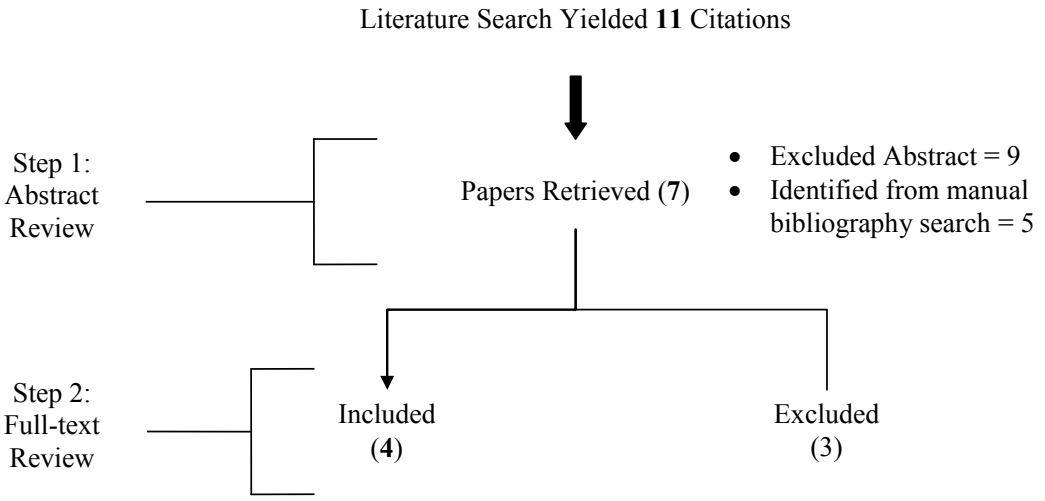
SYSTEMATIC REVIEWS



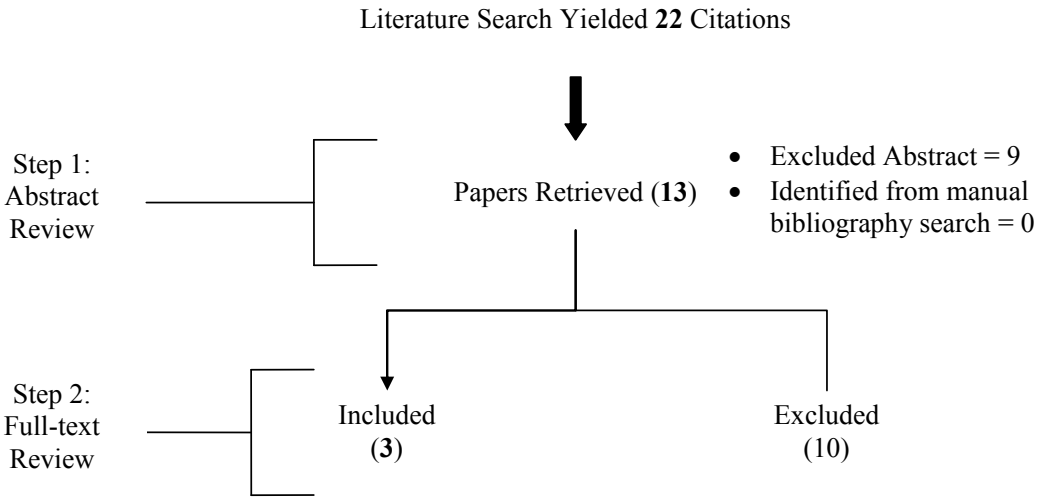
ACUPUNCTURE



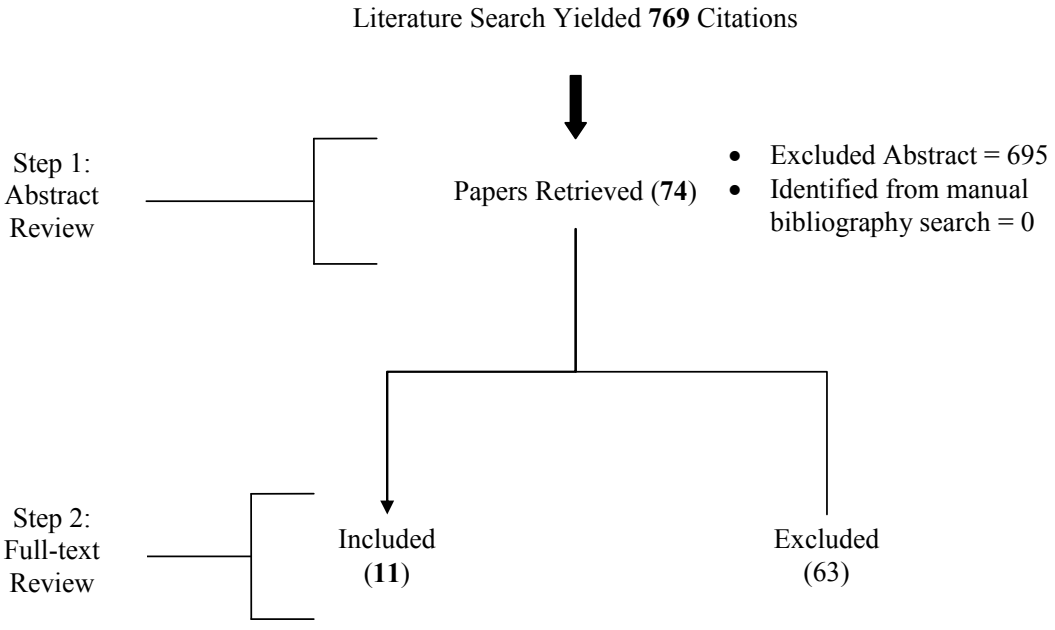
NEEDLE LAVAGE

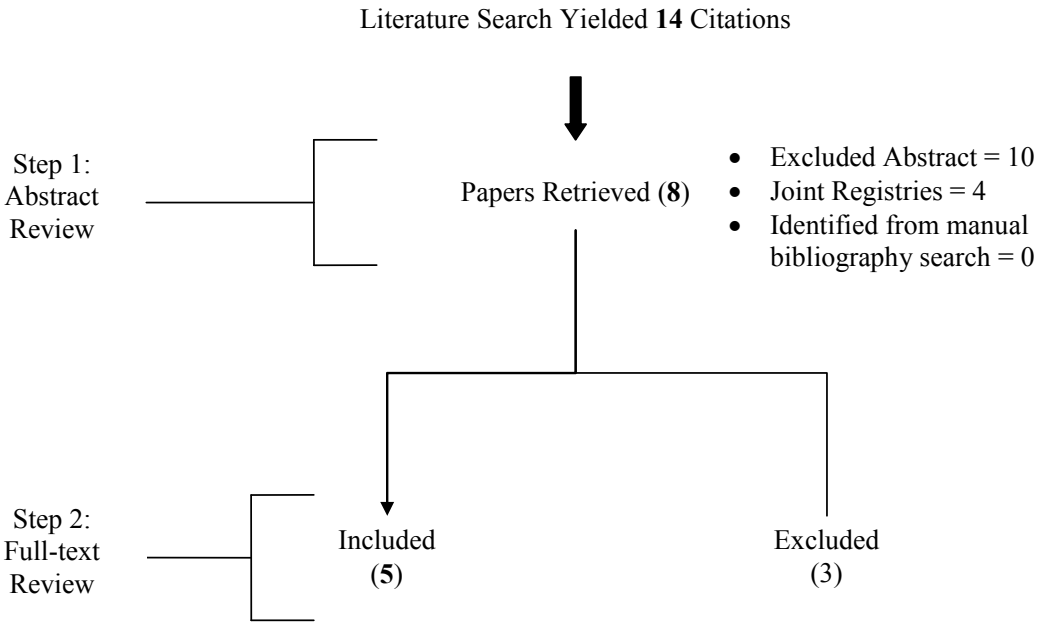


ARTHROSCOPIC LAVAGE AND/OR DEBRIDEMENT



REALIGNMENT OSTEOTOMY




Literature Search Yielded **14** Citations
Step 1:
Abstract
Review
Papers Retrieved (**8**)
Excluded Abstract = 10
Joint Registries = 4
Identified from manual bibliography search = 0
Step 2:
Full-text
Review
Included
(**5**)
Excluded
(3)

JOINT REGISTRIES

The following Joint Registries were searched for data pertaining to free-floating interpositional devices. Data was extracted from the highlighted registries.

National Joint Registries Reviewed

	2007	2006	2005	2004	2003	2002	2001	2000	1999
Australian National Joint Replacement Registry	Yes	Yes	Yes	Yes	NR	NR	NR	NA	NA
Canadian Joint Replacement Registry	NA	Yes*	NR	NR	NR	NR	NA	NA	NA
Norwegian Arthroplasty Register	NR	NR	NR	NR	NR	NR	NA	NA	NA
Sweedish Knee Arthroplasty Register	NA	NA	NA	NR	NR	NR	NR	NR	NR
Finish Arthroplasty Registry	NA	NR	NR	NR	NR	NR	NR	NA	NA
Romanian Arthroplasty Register	NA	NA	NA	NA	NA	NA	NA	NA	NA
New Zealand National Joint Registry 1999-2005 7 yr Report	NA	NA	NR	NR	NR	NR	NR	NR	NR
Scottish Arthroplasty Project	NR	NR	NR	NR	NR	NR	NA	NA	NA
National Joint Registry for England and Wales	NA	NA	NA	NA	NA	NA	NA	NA	NA

NR = Data on UniSpacer was not reported
NA = Report was not available
Yes = Reported Data

* Insufficient Data

APPENDIX IV
LITERATURE SEARCHES FOR SYSTEMATIC REVIEWS

The search for eligible literature began with a search for applicable systematic reviews. The search for systematic reviews was performed using the following databases. The full search strategies are displayed below:

- PubMed (from 1966 through February 22, 2008)
- The Cochrane Database of Systematic Reviews (through February 22, 2008)

All literature searches were supplemented with manual screening of bibliographies in publications accepted for inclusion into the evidence base. In addition, the bibliographies of recent review articles were searched for potentially relevant citations.

The search for systematic reviews using PubMed included the follow search strategy, with limits of publication dates 1966 to present, English language and humans:

> ("knee"[MeSH Terms] OR knee[Text Word]) AND ("osteoarthritis"[MeSH Terms] OR osteoarthritis[Text Word]) AND "humans"[MeSH Terms] AND English[lang] AND systematic[sb]

Our search for systematic reviews using the Cochrane Database of Systematic Reviews in Cochrane Reviews included the following search strategy:

> knee osteoarthritis AND (knee AND osteoarthritis)

Our initial search of PubMed and the Cochrane Database yielded 278 systematic reviews, of which 48 were retrieved and evaluated. Seven systematic reviews met all inclusion criteria.

LITERATURE SEARCHES FOR PRIMARY STUDIES

The literature searches for recommendations that were not addressed by existing systematic reviews were performed using the following databases. The full search strategies are listed below:

- PubMed
- EMBASE
- CINAHL

All literature searches were supplemented with manual screening of bibliographies in publications accepted for inclusion into the evidence base. In addition, the bibliographies of recent review articles were searched for potentially relevant citations.

ACUPUNCTURE

PubMed was searched using the following strategy:

> ("knee"[MeSH Terms] OR knee[Text Word]) AND ("osteoarthritis"[MeSH Terms] OR osteoarthritis[Text Word]) AND ("acupuncture"[MeSH Terms] OR ("acupuncture therapy"[TIAB] NOT Medline[SB]) OR "acupuncture therapy"[MeSH Terms] OR acupuncture[Text Word]) AND "humans"[MeSH Terms] AND English[lang] AND (Randomized Controlled Trial[ptyp] OR systematic[sb])

EMBASE was searched using the following strategy:

> (exp ACUPUNCTURE/ or acupuncture.mp.) AND (exp KNEE/ or knee.mp.) AND (osteoarthritis.mp. or OSTEOARTHRITIS/) limited to human and English language articles.

CINAHL was searched using the following strategy:

> (knee AND osteoarthritis AND acupuncture).mp. limited to English language clinical trials or systematic reviews.

NEEDLE LAVAGE

PubMed was searched using the following strategy:

> (needle lavage OR dual lavage OR closed lavage OR tidal irrigation) AND ("knee"[MeSH Terms] OR knee[Text Word]) AND ("osteoarthritis"[MeSH Terms] OR osteoarthritis[Text Word] OR gonarthritis[Text Word]) AND (randomized controlled trial[pt] OR clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR ("latin square"[tw]) OR placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies[mh] OR follow-up studies[mh] OR prospective studies[mh] OR cross-over studies[mh] OR control*[tw] OR prospective*[tw] OR volunteer*[tw]))

EMBASE was search using the following search strategy:

> ('needle lavage' OR (needle AND lavage) OR 'closed lavage' OR (closed AND lavage)) AND (osteoarthritis OR gonarthritis) , limited to English language

CINAHL was searched using the following strategy:

> ((closed AND lavage) OR (needle AND lavage)) AND (osteoarthritis OR gonarthritis)

ARTHROSCOPIC LAVAGE AND/OR DEBRIDEMENT

PubMed was searched for randomized controlled trials treating OA of the knee with arthroscopic lavage and/or debridement:

> (lavage OR debridement) AND ("knee"[MeSH Terms] OR knee[Text Word]) AND ("osteoarthritis"[MeSH Terms] OR osteoarthritis[Text Word] OR gonarthritis[Text Word]) AND ((English[lang])) AND ((Randomized Controlled Trial[ptyp]))

OSTEOTOMY

PubMed was searched using the following search strategy:

("osteotomy"[MeSH Terms] OR osteotomy[Text Word]) AND ("knee"[MeSH Terms] OR ("knee joint"[TIAB] NOT Medline[SB]) OR "knee joint"[MeSH Terms] OR knee[Text Word]) AND ("osteoarthritis"[MeSH Terms] OR osteoarthritis[Text Word] OR gonarthritis[Text Word]) AND English[lang] NOT "comment"[Publication Type] NOT "editorial"[Publication Type] AND (("1"[EDat]:"2008/02/22"[EDat]) AND (English[lang])) AND (("1"[EDat]:"2008/02/22"[EDat]))

EMBASE was search using the following search strategy:

(osteotomy and (knee and (osteoarthritis or gonarthritis))) limited to English Language

CINAHL was searched using the following strategy:

osteotomy AND (knee AND (osteoarthritis OR gonarthritis))

FREE-FLOATING INTERPOSITIONAL DEVICE

Pubmed, EMBASE and CINAHL were searched with the following strategy used for all databases:

'unispacer'

Using key terms "unispacer" "uni-spacer" and "UniSpacer" the following joint registries were searched:

Australian National Joint Replacement Registry
Canadian Joint Replacement Registry
Norwegian Arthroplasty Register
Swedish Knee Arthroplasty Register
Finish Arthroplasty Registry
Romanian Arthroplasty Register
New Zealand National Joint Registry 199-2005 7 yr Report
Scottish Arthroplasty Project
National Joint Registry for England and Wales

APPENDIX V
LEVEL OF EVIDENCE

Levels of Evidence For Primary Research Question[1]

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic Review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[2] of Level I studies
Level II	• Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[2] of Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[2] of Level III studies
Level IV	Case Series[8]	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called "cases"; e.g. failed total arthroplasty, are compared to those who did not have outcome, called "controls"; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

APPENDIX VI
RATING THE QUALITY OF SYSTEMATIC REVIEWS WITH AMSTAR

MAJOR FLAWS

QUESTION 1
If an a priori design is not utilized the systematic review does not meet the quality standards for inclusion in AAOS clinical practice guidelines.

QUESTION 3
If a comprehensive literature search is not conducted the systematic review does not meet the quality standards for inclusion in AAOS clinical practice guidelines.

QUESTION 6
If the characteristics of the included studies are not presented in aggregated form the systematic review does not meet the quality standards for inclusion in AAOS clinical practice guidelines.

QUESTION 7
If the scientific qualities of the individual studies is not assessed using a priori methods the systematic review does not meet the quality standards for inclusion in AAOS clinical practice guidelines.

SPECIAL RULES

QUESTION 9
If a meta-analysis is NOT performed then the answer should be "not applicable".

QUESTION 10
Answer not applicable if:

- question 9 is answered "not applicable"
- meta-analysis has less than 7 studies
- meta-analysis found heterogeneity

QUALITY RATING
To determine if a systematic review is applicable for use in an AAOS clinical practice guideline the AMSTAR results will be evaluated using the following system:

1. The systematic review must have "Yes" answers to 50% or more of the questions.
2. A question answered "not applicable" is ignored in determining item 1.
3. A question answered "can't answer" is given a half credit in determining item 1.

APPENDIX VII
DATA EXTRACTION ELEMENTS

The data elements below were extracted into electronic forms in Microsoft® Access. The extracted information includes:

Systematic Reviews

- Conclusions
- Inclusion/Exclusion Criteria
- Date Range for Included Articles
- Study Designs included
- Number of trials included in the review
- Number of Patients
- Types of Analyses used to evaluate the data
- Outcome measures used (See Types of Outcomes)

Study Characteristics (for all relevant outcomes in a study)

- methods of randomization and allocation
- use of blinding (patient, caregiver, evaluator)
- funding source/conflict of interest
- intention to treat analysis
- duration of the study
- number of subjects and follow-up percentage
- experimental and control groups
- a priori power analysis

Patient Characteristics (for all treatment groups in a study)

- patient inclusion/exclusion criteria
- co-interventions (if used) and co-morbidities (if present)
- measures of disease severity
- adverse events

Results (for all relevant outcomes in a study)

- outcome measure
- is the outcome measure patient-oriented? validated? objective/subjective?
- duration at which outcome measure was evaluated
- statistic reported (for dichotomous results)
- mean value and measure and value of dispersion (continuous results)
- statistical test used, value of test statistic, and p-value
- verification of calculations

APPENDIX VIII
FORM FOR ASSIGNING GRADE OF RECOMMENDATION (INTERVENTIONS)

GUIDELINE RECOMMENDATION_____

PRELIMINARY GRADE OF
RECOMMENDATION:_____

STEP 1: LIST BENEFITS AND HARMS

Please list the benefits (as demonstrated by the systematic review) of the intervention

Please list the harms (as demonstrated by the systematic review) of the intervention

Please list the benefits for which the systematic review is not definitive

Please list the harms for which the systematic review is not definitive

STEP 2: IDENTIFY CRITICAL OUTCOMES

Please circle the above outcomes that are critical for determining whether the intervention is beneficial and whether it is harmful

Are data about critical outcomes lacking to such a degree that you would lower the preliminary grade of the recommendation?

What is the resulting grade of recommendation?

STEP 3: EVALUATE APPLICABILITY OF THE EVIDENCE

Is the applicability of the evidence for any of the critical outcomes so low that substantially worse results are likely to be obtained in actual clinical practice?

Please list the critical outcomes backed by evidence of doubtful applicability:

Should the grade of recommendation be lowered because of low applicability?

What is the resulting grade of recommendation?

STEP 4: BALANCE BENEFITS AND HARMS

Are there trade-offs between benefits and harms that alter the grade of recommendation obtained in STEP 3?

What is the resulting grade of recommendation?

STEP 5 CONSIDER STRENGTH OF EVIDENCE

Does the strength of the existing evidence alter the grade of recommendation obtained in STEP 4?

What is the resulting grade of recommendation:

What is the resulting grade of recommendation?

NOTE: Because we are not performing a formal cost analyses, you should only consider costs if their impact is substantial.

APPENDIX IX
VOTING BY THE NOMINAL GROUP TECHNIQUE

Voting on guideline recommendations and performance measures will be conducted using a modification of the nominal group technique (NGT), a method previously used in guideline development.[25] Briefly each member of the guideline workgroup ranks his or her agreement with a guideline recommendation or performance measure on a scale ranging from 1 to 9 (where 1 is "extremely inappropriate" and 9 is "extremely appropriate"). Consensus is obtained if the number of individuals who do not rate a measure as 7, 8, or 9 is statistically non-significant (as determined using the binomial distribution). Because the number of workgroup members who are allowed to dissent with the recommendation depends on statistical significance, the number of permissible dissenters varies with the size of the workgroup. The number of permissible dissenters for several workgroup sizes is given in the table below:

Workgroup Size	Number of Permissible Dissenters
≤3	Not allowed. Statistical significance cannot be obtained
4-5	0
6-8	1
9	1 or 2

The NGT is conducted by first having members vote on a given recommendation/performance measure without discussion. If the number of dissenters is "permissible", the recommendation/measure is adopted without further discussion. If the number of dissenters is not permissible, there is further discussion to see whether the disagreement(s) can be resolved. Three rounds of voting are held to attempt to resolve disagreements. If disagreements are not resolved after three voting rounds, no recommendation/measure is adopted.

APPENDIX X
STRUCTURED PEER REVIEW FORM

Reviewer Information:

Name of Reviewer_____
Address_____
City_____ State_____ Zip Code_____
Phone _____Fax _____
E-mail_____

Specialty Area/Discipline: _____
Work setting: _____
Credentials: _____

May we list you as a Peer Reviewer in the final Guidelines? ☐ Yes ☐ No

Are you reviewing this guideline as a representative of a professional society? ☐ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline? ☐ Yes ☐ No

Reviewer Instructions
Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity, and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically to wies@aaos.org or fax the form back to Jan Wies at (847) 823-9769.

Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments y **Month, Day, Year**

	Please indicate your level of agreement with each of the following Statements, by placing an "X" in the appropriate box.			
	Very much agree	**Moderately agree**	**Moderately disagree**	**Very much disagree**
1. The recommendations are clearly stated	☐	☐	☐	☐
2. There is an explicit link between the recommendations and the supporting evidence	☐	☐	☐	☐
3. Given the nature of the topic and the data, all clinically important outcomes are considered	☐	☐	☐	☐
4. The guideline's target audience is clearly described	☐	☐	☐	☐
5. The patients to whom this guideline is meant to apply are specifically described	☐	☐	☐	☐
6. The criteria used to select articles for inclusion are appropriate	☐	☐	☐	☐
7. The reasons why some studies were excluded are clearly described	☐	☐	☐	☐
8. All important studies that met the article inclusion criteria are included	☐	☐	☐	☐
9. The validity of the studies is appropriately appraised	☐	☐	☐	☐
10. The methods are described in such a way as to be reproducible.	☐	☐	☐	☐
11. The statistical methods are appropriate to the material and the objectives of this guideline	☐	☐	☐	☐
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	☐	☐	☐	☐
13. Health benefits, side effects, and risks are adequately addressed	☐	☐	☐	☐
14. The writing style is appropriate for health care professionals and patients	☐	☐	☐	☐
15. The grades assigned to each recommendation are appropriate	☐	☐	☐	☐

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

Strongly recommend _____

Recommend (with provisions or alterations) _____

Would not recommend _____

Unsure _____

COMMENTS:
Please provide the reason(s) for your recommendation.

APPENDIX XI
CONFLICT OF INTEREST

All members of the AAOS workgroup disclosed any conflicts of interest prior to the development of the recommendations for this guideline. Conflicts of interest are disclosed in writing with the American Academy of Orthopaedic Surgeons via a private on-line reporting database and also verbally at the recommendation approval meeting.

Disclosure Items: (n) = Respondent answered 'No' to all items indicating no conflicts. 1=Board member/owner/officer/committee appointments; 2= Medical/Orthopaedic Publications; 3= Royalties; 4= Speakers bureau/paid presentations;5A= Paid consultant; 5B= Unpaid consultant; 6= Research or institutional support from a publisher; 7= Research or institutional support from a company or supplier; 8= Stock or Stock Options; 9= Other financial/material support from a publisher; 10= Other financial/material support from a company or supplier.

David Hunter, MD PhD: 2 (Osteoarthritis and Cartilage; Arthritis and Rheumatism); 7 (DJ Orthopaedics; Eli Lilly; Merck; National Institutes of Health; Pfizer; Stryker; Wyeth; AstraZeneca).

James J Irrgang, PhD: 1 (President, Orthopaedic Section of the American Physical Therapy Association); 2 (Arthritis Care and Research); 5B (Omeros); 7 (Biomet; Smith & Nephew).

Morgan H Jones, MD: 7 (Biomimetic; DePuy, A Johnson & Johnson Company; Regen Biologics; Small Bone Innovations; Stryker; TissueLink; ARS Arthro AG; Diapedia LLC; King Pharmacy; Arthrosurface; Apopharma).

Michael Warren Keith, MD: (n).

Bruce A Levy, MD: 7 (DePuy, A Johnson & Johnson Company).

Robert G Marx, MD: (n).

Elizabeth G Matzkin, MD: (n).

John C Richmond, MD: 1 (Arthroscopy Association of North America; Eastern Orthopedic Association; New England Baptist Hospital); 2 (Arthroscopy); 5A (Mitek; Stryker; Lifenet; Serica); 7 (Arthrex, Inc; Smith & Nephew).

Cheryl Rubin, MD: 1 (Arthroscopy Association of North America; Ramapo Valley Surgical Center).

Lynn Snyder-Mackler: (n).

Daniel Van Durme, MD: 2 (Annals of Family Medicine).

William Charles Watters III, MD: 1 (Bone and Joint Decade, U.S.A.; North American Spine Society; Intrisic Therapeutics; Work Loss Data Institute; American Board of Spine Surgery); 2 (The Spine Journal); 5A (Blackstone Medical; Medtronic Sofamor Danek; Stryker; Intrinsic Therapeutics; MeKessen Health Care Solutions); 8 (Intrinsic Therapeutics).

APPENDIX XII
EVIDENCE TABLES

See Evidence Tables Document (Evidence Tables.pdf)

Systematic Reviews Overview
Evidence Table 1. Characteristics of Included Systematic Reviews
Evidence Table 2. Systematic Reviews Included using AMSTAR
Evidence Table 3. Systematic Reviews Excluded using AMSTAR
Evidence Table 4. AMSTAR Results
Evidence Table 5. Relevant Systematic Reviews

Quadriceps Strengthening
Evidence Table 6. Primary Studies Included in Roddy et al. Systematic Review
Evidence Table 7. Analysis of Roddy et al Systematic Review

Patellar Taping
Evidence Table 8. Primary Studies Included in Warden et al Systematic Review
Evidence Table 9. Analysis of Warden et al Systematic Review

Lateral Heel Wedges
Evidence Table 10. Primary Studies Included in Brouwer et al Systematic Review
Evidence Table 11. Analysis of Brouwer et al. Systematic Review

Knee Braces
Evidence Table 12. Primary Studies Included in Brouwer et al. Systematic Review
Evidence Table 13. Analysis of Brouwer et al. Systematic Review
Evidence Table 14. AAOS Analysis of Kirkley et al.

Acupuncture
Evidence Table 15. AAOS Analysis - Included Studies
Evidence Table 16. AAOS Analysis - Excluded Studies
Evidence Table 17. AAOS Analysis - Results

Intra-articular Corticosteroids
Evidence Table 18. Primary Studies Included in Systematic Reviews
Evidence Table 19. Analysis of Systematic Reviews

Needle Lavage
Evidence Table 20. Included Studies
Evidence Table 21. Excluded Studies
Evidence Table 22. Results
Evidence Table 23. Design and Quality
Evidence Table 24. Patient Characteristics

Arthroscopic Debridement
Evidence Table 25. Primary Studies Included in Laupattarakasem et al. Systematic
Evidence Table 26. Analysis of Laupattarakasem et al. Systematic Review

Arthroscopic Lavage (AAOS Analysis)

Realignment Osteotomy

Free-Floating Interpositional Device

APPENDIX XIII

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