



THE TREATMENT OF GLENOHUMERAL JOINT OSTEOARTHRITIS

GUIDELINE AND EVIDENCE REPORT

**Adopted by the American Academy of Orthopaedic Surgeons
Board of Directors
December 4, 2009**

This clinical practice guideline was developed by an American Academy of Orthopaedic Surgeons (AAOS) multi-disciplinary volunteer workgroup that included Orthopaedic surgeons and Orthopaedic sports medicine surgeons. It is based on a systematic review of the current scientific and clinical information and accepted approaches to treatment. 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.

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Disclaimer

This Clinical Practice Guideline was developed by an AAOS physician volunteer Work Group 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.

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 Guideline.

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First Edition

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The Treatment of Glenohumeral Joint Osteoarthritis

GUIDELINE AND EVIDENCE REPORT

Summary of Recommendations

The following is a summary of the recommendations in the AAOS' clinical practice guideline, The Treatment of Glenohumeral Joint Osteoarthritis. 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. The physician work group listed the recommendations below in order of patient care.

1. We are unable to recommend for or against physical therapy for the initial treatment of patients with osteoarthritis of the glenohumeral joint.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

2. We are unable to recommend for or against the use of pharmacotherapy in the initial treatment of patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

3. We are unable to recommend for or against the use of injectable corticosteroids when treating patients with glenohumeral joint osteoarthritis.

Strength of the Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

4. The use of injectable viscosupplementation is an option when treating patients with glenohumeral joint osteoarthritis.

Strength of the Recommendation: Limited

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

5. We are unable to recommend for or against the use of arthroscopic treatments for patients with glenohumeral joint osteoarthritis. These treatments include debridement, capsular release, chondroplasty, microfracture, removal of loose bodies, and biologic and interpositional grafts, subacromial decompression, distal clavicle resection, acromioclavicular joint resection, biceps tenotomy or tenodesis, and labral repair or advancement.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

6. We are unable to recommend for or against open debridement and/or non-prosthetic or biologic interposition arthroplasty in patients with glenohumeral joint osteoarthritis. These treatments include:
 - Allograft
 - Biologic and Interpositional Grafts
 - Autograft

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

7. Total shoulder arthroplasty and hemiarthroplasty are options when treating patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Limited

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

8. We suggest total shoulder arthroplasty over hemiarthroplasty when treating patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Moderate

Definition: A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

9. An option for reducing immediate postoperative complication rates is for patients to avoid shoulder arthroplasty by surgeons who perform less than two shoulder arthroplasties per year.

Strength of Recommendation: Limited

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

10. In the absence of reliable evidence, it is the opinion of this work group that physicians use peri-operative mechanical and/or chemical VTE (venous thromboembolism) prophylaxis for shoulder arthroplasty patients.

Strength of Recommendation: Consensus

Definition: A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

11. The use of either keeled or pegged all polyethylene cemented glenoid components are options when performing total shoulder arthroplasty.

Strength of Recommendation: Limited

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

12. In the absence of reliable evidence, it is the opinion of this work group that total shoulder arthroplasty not be performed in patients with glenohumeral osteoarthritis who have an irreparable rotator cuff tear.

Strength of Recommendation: Consensus

Definition: A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

13. We are unable to recommend for or against biceps tenotomy or tenodesis when performing shoulder arthroplasty in patients who have glenohumeral joint osteoarthritis.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

14. We are unable to recommend for or against a subscapularis trans tendonous approach or a lesser tuberosity osteotomy when performing shoulder arthroplasty in patients who have glenohumeral joint osteoarthritis.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

15. We are unable to recommend for or against a specific type of humeral prosthetic design or method of fixation when performing shoulder arthroplasty in patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

16. We are unable to recommend for or against physical therapy following shoulder arthroplasty.

Strength of Recommendation: Inconclusive

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

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For additional information concerning these processes and a complete list of individuals who participated in the peer review or public commentary processes of this document, please refer to the Appendices.

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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 of the glenohumeral joint in adults. 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 managing the treatment osteoarthritis of the glenohumeral joint. 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 glenohumeral joint. The systematic review detailed herein was conducted between November 2008 and June 2009 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 osteoarthritis of the glenohumeral joint. AAOS staff and the physician workgroup systematically reviewed the available literature and subsequently wrote the following recommendations based on a rigorous, standardized process.

Many different providers provide musculoskeletal care in many different settings. 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, all qualified physicians and/or healthcare professionals managing patients with glenohumeral joint osteoarthritis. 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 osteoarthritis of the glenohumeral joint.

Treatment for glenohumeral osteoarthritis 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 glenohumeral joint osteoarthritis in adults (defined as patients 19 years of age and older). The guideline provides information on patient management after diagnosis of osteoarthritis of the glenohumeral joint.

INCIDENCE

The incidence of glenohumeral joint osteoarthritis is more common in women and appears to increase with age.¹

PREVALENCE

Degenerative joint disease of the shoulder is relatively common.² The shoulder is, after knee and hip, the third most common joint to require surgical reconstruction.³

BURDEN OF DISEASE

“The estimated annual cost for medical care of arthritis and joint pain for patients with any diagnosis in 2004 was \$281.5 billion dollars. This is an average of \$7500 for each of the 37.6 million persons who reported having arthritis or joint pain.”³

ETIOLOGY

Arthritis of the glenohumeral joint can be the result of primary osteoarthritis, post-traumatic deformity, inflammatory arthritis, sepsis, or avascular necrosis.⁴

RISK FACTORS

The risk of shoulder arthritis is increased by a history of injury or surgery to the shoulder.¹

EMOTIONAL AND PHYSICAL IMPACT OF OSTEOARTHRITIS OF THE GLENOHUMERAL JOINT

Patients diagnosed with osteoarthritis of the shoulder experience pain, progressive loss of function and diminished quality of life.⁵

POTENTIAL BENEFITS, HARMS, AND CONTRAINDICATIONS

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 evaluate the effectiveness of treatments for osteoarthritis of the glenohumeral joint. 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, the methods used to define the strength of the evidence, and data extraction. The methods used to perform this systematic review were employed to minimize bias in the selection and summary of the available evidence^{6, 7}. These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for treating osteoarthritis of the glenohumeral joint.

An AAOS Glenohumeral Osteoarthritis physician work group prepared this guideline and the underlying systematic reviews with the assistance of the AAOS Clinical Practice Guidelines Unit (Appendix I) in the Department of Research and Scientific Affairs at the AAOS.

To develop the guideline, the work group met at an introductory meeting on November 22, 2008 to establish the scope of the guideline. Upon completion of the systematic review, the work group met again on June 27 and 28, 2009 to write and vote on the final recommendations and rationales for each recommendation. The resulting draft guidelines were then peer-reviewed, 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 (Appendix II).

FORMULATING PRELIMINARY RECOMMENDATIONS

The work group began work on this guideline by constructing a set of preliminary 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. Preliminary recommendations are almost always modified on the basis of the results of the systematic review. Once established, these *a priori* preliminary recommendations cannot be modified until the final workgroup meeting, they must be addressed by the systematic review, and the relevant review results must be presented in the final guideline.

STUDY INCLUSION CRITERIA

We developed *a priori* article inclusion criteria for our review. These criteria are our “rules of evidence” and articles that do not meet them are, for the purposes of this guideline, not evidence.

To be included in our systematic reviews (and hence, in this guideline) an article had to be a report of a study that:

- Evaluated a treatment for osteoarthritis of the glenohumeral joint.
- Was a full report of a clinical study and was published in the peer reviewed literature.

- Was an English language article published after 1965
- Was not a cadaveric, animal, *in vitro*, or biomechanical study
- Was not a retrospective case series, medical records review, meeting abstract, unpublished study report, case report, historical article, editorial, letter, or commentary
- Was the most recent report of a study or the report with the largest number of enrolled patients in a study with multiple publications
- Enrolled ≥ 10 patients in each of its study groups
- Enrolled a patient population comprised of at least 80% of patients with osteoarthritis of the glenohumeral joint,
- Reports quantified results
- Enrolled less than 20% of patients with: neurologic conditions, inflammatory arthropathy, AVN, rotator cuff arthropathy, infection.
- Study follow up must be at least 2 years (any surgical intervention). This criteria applies to Recommendations 5, 6, 7, 8, 11, 12, 13, 14, and 15.
- Must not be a revision shoulder arthroplasty.

When examining primary studies we analyzed the best available evidence. We first considered outcomes reported in randomized controlled trials. We then sequentially searched for outcomes reported in controlled trials, prospective comparative studies, and retrospective comparative studies. Finally, we searched for prospective case-series studies. Only outcomes of the highest level of available evidence are included. For example, if there are two Level II VAS Pain measures that address the recommendation, Level III, IV, or V VAS pain measures will not be included.

We included patient-oriented outcomes. As the term implies, patient-oriented outcomes are outcomes that matter to the patient. They tell clinicians, directly and without the need for extrapolation, that a diagnostic, therapeutic, or preventive procedure helps patients live longer or live better.⁸ Examples of patient-oriented outcomes include pain, function, and quality of life.

We also excluded some outcomes from consideration. We did not include surrogate 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.⁹ For a surrogate outcome to be valid it must be in the causal pathway between intervention and the outcome and it must demonstrate a large, consistently measurable association with the outcome.⁹

OUTCOMES CONSIDERED

Clinical studies often report many different outcomes. Again, we included only patient-oriented outcomes. We did not include surrogate outcomes. Radiographic results and radiolucency are examples of surrogate outcomes that were not included.

We only included data for an outcome if $\geq 50\%$ of the patients were followed for that outcome. For example, some studies report short-term outcomes data on nearly all enrolled patients, and report longer-term data on less than half of the enrolled patients. In such cases, we did not include the longer-term data. Additionally, we downgraded the Level of Evidence by one in instances where 50% to $\leq 80\%$ of patients were followed. For example, if an otherwise perfect randomized controlled trial reported data on all enrolled patients one week after patients received a treatment but reported data on only 60% of patients one year later, we would consider data from the later follow-up time as Level II evidence.

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 MCII are derived from published studies.

The values for the MCII for the majority of outcomes for glenohumeral joint osteoarthritis have not been reported in the literature. We could only report the minimally clinically important difference for the ASES overall score (See Figures 72 and 73; page 96 and 97). For Glenohumeral Joint Osteoarthritis, we were not able to identify any other MCII reported in the literature.

Table 1 MCII of Outcomes

Outcome Measure	Study	MCII	
		Points	Effect Size
American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)	Michener, et al. ¹⁰	6.4	0.379

When possible we describe the results of studies using terminology based on that of Armitage et al.¹¹ The associated descriptive terms we use in this guideline and the conditions for using each of these terms, are outlined in the following table:

Table 2 Description of Results with MCII

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 attempted to make our searches for articles comprehensive. Using comprehensive literature searches ensures that the evidence we considered for this guideline is not biased for (or against) any particular point of view.

We searched for articles published from January 1966 to June 2009. Strategies for searching electronic databases were constructed by the AAOS Medical Librarian. The search strategies we used are provided in Appendix III. We searched six electronic databases; PubMed, EMBASE, CINAHL, The Cochrane Library, The National Guidelines Clearinghouse and TRIP database.

All searches of electronic databases were supplemented with manual screening of bibliographies of all retrieved publications. We also searched the bibliographies of recent systematic reviews and other review articles for potentially relevant citations. Finally, a list of potentially relevant studies, not identified by our searches, was provided by the work group members. Medical management of osteoarthritis is covered by extensive literature; however, these studies were not limited to glenohumeral joint osteoarthritis.

The study attrition diagram (Appendix IV) provides details about the inclusion and exclusion of these studies.

DATA EXTRACTION

Data elements extracted from studies were defined in consultation with the physician work group. Three analysts completed data extraction independently for all studies. The work group audited the evidence tables. Disagreements about the accuracy of extracted data were resolved by consensus and consulting the work group. The elements extracted are shown in Appendix V.

The AAOS Guidelines Unit constructed evidence tables to summarize the best evidence pertaining to each preliminary recommendation. These tables are available as a supplemental document available on the AAOS website (<http://www.aaos.org/research/research.asp>). These evidence tables include complete lists of included and excluded articles, quality and design parameters of the included studies, and raw data extracted from the included studies.

JUDGING THE QUALITY OF EVIDENCE

Determining the quality of the included evidence is vitally important when preparing any evidence-based work product. Doing so conveys the amount of confidence one can have in any study's results. One has more confidence in high quality evidence than in low quality evidence.

We assessed the quality of the evidence for each outcome at each time point reported in a study. We did not simply assess the overall quality of a study. Our approach follows the recommendations of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) working group¹² as well as others.¹³

We evaluated quality on a per outcome basis rather than a per study basis because quality is not necessarily the same for all outcomes and all follow-up times reported in a study. For example, a study might report results immediately after patients received a given treatment and after some period of time has passed. Often, nearly all enrolled patients contribute data at early follow-up times but, at much later follow-up times, only a few patients may contribute data. One has more confidence in the earlier data than in the later data. The fact that we would assign a higher quality score to the earlier results reflects this difference in confidence.

We assessed the quality using a two step process. First, we assigned a Level of Evidence to all results reported in a study based solely on that study's design. Accordingly, all data presented in randomized controlled trials were initially categorized as Level I evidence, all results presented in non-randomized controlled trials and other prospective comparative studies were initially categorized as Level II, all results presented in retrospective comparative and case-control studies were initially categorized as Level III, and all results presented in case-series reports were initially categorized as Level IV (see Appendix VI). We next assessed each outcome at each reported time point using a quality questionnaire and, when quality standards were not met, downgraded the Level of evidence (for this outcome at this time point) by one Level (Appendix VI).

Assigning a Level of Evidence on the basis of study design plus other quality characteristics ties the Levels of Evidence we report more closely to quality than Levels of Evidence based only on study design. Because we tie quality to Levels of Evidence, we are able to characterize the confidence one can have in their results. Accordingly, we characterize the confidence one can have in Level I evidence as high, the confidence one can have in Level II and III evidence as moderate, and the confidence one can have in Level IV and V evidence as low.

DEFINING THE STRENGTH OF THE RECOMMENDATIONS

Judging the quality of evidence is only a stepping stone towards arriving at the strength of the guideline recommendation. Unlike Levels of Evidence (which apply only to a given result at a given follow-up time in a given study) strength of the recommendation takes into account the quality, quantity, and applicability of the available evidence. Strength of the recommendation also takes into account the trade-off between the benefits and harms of a treatment or diagnostic procedure, and the magnitude of a treatment's effect.

The strength of a recommendation expresses the degree of confidence one can have in a recommendation. As such, the strength expresses how possible it is that a recommendation will be overturned by future evidence. It is very difficult for future evidence to overturn a recommendation that is based on many high quality randomized controlled trials that show a large effect. It is much more likely that future evidence will overturn recommendations derived from a few small case series. Consequently, recommendations based on the former kind of evidence are rated as "strong" and recommendations based on the latter kind of evidence are given strength of recommendation of "limited".

This guideline contains preliminary recommendations that are supported by no data. Under such circumstances, work groups can issue opinion-based recommendations. We develop opinion-based recommendations *only if they address a vitally important aspect of patient care*. To ensure that an opinion-based recommendation is absolutely necessary, the AAOS has rules to guide the content of the rationales that underpin such recommendations. These rules are based on those outlined by the US Preventive Services Task Force (USPSTF) and can be found in Appendix VIII.

To develop the strength of a recommendation, AAOS staff first assigned a preliminary strength rating for each recommendation that took only the quality and quantity of the available evidence into account (see Table 3). Work group members then modified the preliminary strength rating using the ‘Form for Assigning Grade of Recommendation (Interventions)’ shown in Appendix VII. This form is based on recommendations of the GRADE Work Group¹² and requires the work group to consider the harms, benefits, and critical outcomes associated with a treatment. It also requires the work group to evaluate the applicability of the evidence. The final strength of the recommendation is assigned by the physician work group, which modifies the preliminary strength rating on the basis of these considerations.

Table 3 Defining the Strength of the Recommendation

Statement Rating	Description of Evidence Strength	Implication for Practice
Strong	<p>Evidence is based on two or more “High” strength studies with consistent findings for recommending for or against the intervention.</p> <p>A Strong recommendation means that the benefits of the recommended approach clearly exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a strong negative recommendation), and that the strength of the supporting evidence is high.</p>	<p>Practitioners should follow a Strong recommendation unless a clear and compelling rationale for an alternative approach is present.</p>
Moderate	<p>Evidence from two or more “Moderate” strength studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention.</p> <p>A Moderate recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.</p>	<p>Practitioners should generally follow a Moderate recommendation but remain alert to new information and be sensitive to patient preferences.</p>
Limited	<p>Evidence from two or more “Low” strength studies with consistent findings, or evidence from a single Moderate quality study recommending for or against the intervention or diagnostic.</p> <p>A Limited recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.</p>	<p>Practitioners should be cautious in deciding whether to follow a recommendation classified as Limited, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.</p>
Inconclusive	<p>Evidence from a single low quality study or conflicting findings that do not allow a recommendation for or against the intervention.</p> <p>An Inconclusive recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.</p>	<p>Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as Inconclusive and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.</p>
Consensus ¹	<p>The supporting evidence is lacking and requires the work group to make a recommendation based on expert opinion by considering the known potential harm and benefits associated with the treatment.</p> <p>A Consensus recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria.</p>	<p>Practitioners should be flexible in deciding whether to follow a recommendation classified as Consensus, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.</p>

¹ The AAOS will issue a consensus-based recommendation only when the service in question has virtually no associated harm and is of low cost (e.g. a history and physical) or when not establishing a recommendation could have catastrophic consequences.

Each recommendation was written using language that accounts for the final strength of the recommendation. This language, and the corresponding strength of recommendation, is shown in Table 4.

Table 4 AAOS Guideline Language

Guideline Language	Strength of Recommendation
<i>We recommend</i>	Strong
<i>We suggest</i>	Moderate
Is an <i>option</i>	Limited
We are <i>unable to recommend for or against</i>	Inconclusive
In the absence of reliable evidence, it is the <i>opinion</i> of this work group	Consensus

CONSENSUS DEVELOPMENT

Work group members voted on each recommendation and its strength using a structured voting technique that was a modification of the Nominal Group Technique (see Appendix VIII), a method previously used in guideline development.¹⁴ Voting on guideline recommendations was conducted by secret ballot.¹⁴ Briefly each member of the guideline work group 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 work group members who are allowed to dissent with the recommendation depends on statistical significance, the number of permissible dissenters varies with the size of the work group. If disagreements were not resolved after three voting rounds, no recommendation was adopted. Lack of agreement can be a reason that the strength of some recommendations may be labeled as “Inconclusive.”

For this guideline, the work group resolved all disagreements within three voting rounds and no recommendations were graded as “inconclusive” because of lack of agreement within the work group. Two consensus based recommendations were issued following the rules outlined in Appendix VIII.

STATISTICAL METHODS

When possible we report the results of the statistical analyses conducted by the authors of the included studies. In some circumstances, statistical testing was not conducted; however, the authors reported sufficient quantitative data, including measures of dispersion or patient level data for statistical testing. In these circumstances we used the statistical program STATA (StatCorp LP, College Station, Texas) to conduct our own analysis to interpret the results of a study. P-values < 0.05 were considered statistically

significant. When a statistical analysis was conducted, we noted if the analysis was that of the study authors or our own.

STATA was also used to determine 95% confidence intervals, using the method of Wilson, when authors of the included studies reported counts or proportions. The program was also used to determine the magnitude of the treatment effect. For data reported as means (and associated measures of dispersion) we calculated a standardized mean difference by the method of Hedges and Olkin.¹⁵ For proportions, we calculated the odds ratio as a measure of treatment effect.

We used G*Power 3 (Franz Faul, Universitat Kiel, Germany) to determine if a study was sufficiently powered to detect the MCII. In our power calculations, we used 80% power, 95% confidence intervals, and the number of patients per group. This allowed calculation of the minimal detectable effect size which was compared to the MCII effect size to determine if the study had enough power to detect the MCII.

PEER REVIEW

The draft of the guideline and evidence report were peer reviewed by outside specialty organizations that were nominated by the physician work group prior to the development of the guideline. Peer review was accomplished using a structured peer review form (see Appendix IX).

In addition, the physician members of the AAOS Guidelines and Technology Oversight Committee, the Evidence Based Practice Committee and the Chairpersons of the AAOS Occupational Health and Workers' Compensation Committee and the Medical Liability Committee were given the opportunity to provide peer review of the draft document.

We forwarded the draft guideline to a total of 34 peer reviewers and 17 returned reviews. The disposition of all non-editorial peer review comments was documented and the guideline was modified in response to peer review. The peer reviews and the responses to them accompanied this guideline through the process of public commentary and the subsequent approval process. Peer reviewing organizations and peer reviewing individuals are listed in this document if they explicitly agree to allow us to publish this information (Appendix X).

Peer review of an AAOS guideline does not imply endorsement. This is clearly stated on the structured review form (Appendix IX) sent to all peer reviewers and is also posted within the guideline (Appendix X). Endorsement cannot be solicited during the peer review process because the documents can still undergo substantial change as a result of both the peer review and public commentary processes. In addition, no guideline can be endorsed by specialty societies outside of the Academy until the AAOS Board of Directors has approved it. Organizations that provide peer review of a draft guideline will be solicited for endorsement once the document has completed the full review and approval processes.

PUBLIC COMMENTARY

After modifying the draft in response to peer review, the guideline was submitted for a thirty 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 185 commentators had the opportunity to provide input into the development of this guideline. Of these, one member returned public comments.

THE AAOS GUIDELINE APPROVAL PROCESS

In response to the non-editorial comments submitted during the period of public commentary, the draft was again modified by the AAOS Clinical Practice Guidelines Unit and physician work group members. The AAOS Guidelines and Technology Oversight Committee, the AAOS Evidence-based Practice Committee, the AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors approved the final guideline draft. Descriptions of these bodies are provided in Appendix II.

REVISION PLANS

This guideline represents a cross-sectional view of current treatment and/or diagnosis and may become outdated as new evidence becomes available. This guideline will be revised in accordance with this new evidence, changing practice, rapidly emerging treatment options, and new technology. This guideline will be updated or withdrawn in five years in accordance with the standards of the National Guideline Clearinghouse.

GUIDELINE DISSEMINATION PLANS

The primary purpose of the present document is to provide interested readers with full documentation about not only our recommendations, but also about how we arrived at those recommendations. This document is also posted on the AAOS website at <http://www.aaos.org/research/guidelines/guide.asp>.

Shorter versions of the guideline are available in other venues. Publication of most guidelines is announced by an Academy press release, articles authored by the workgroup and published in the Journal of the American Academy of Orthopaedic Surgeons, and articles published in *AAOS Now*. Most guidelines are also distributed at the AAOS Annual Meeting in various venues such as on Academy Row and at Committee Scientific Exhibits.

Selected guidelines are disseminated by webinar, an Online Module for the Orthopaedic Knowledge Online website, Radio Media Tours, Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

Other dissemination efforts outside the AAOS include submitting the guideline to the National Guideline Clearinghouse and distributing the guideline at other medical specialty societies’ meetings.

III. RECOMMENDATIONS AND SUPPORTING DATA

RECOMMENDATION 1

We are unable to recommend for or against physical therapy in the initial treatment of patients with osteoarthritis of the glenohumeral joint.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Despite an exhaustive review of the literature, there was insufficient evidence to make conclusions either in favor of or against the efficacy of physical therapy. This includes the modalities of massage, joint mobilization, joint manipulation, exercise, phonophoresis, iontophoresis, ultrasound, laser, acupuncture, and/or electrical stimulation, in the treatment of patients with osteoarthritis of the shoulder. Further, no studies of sufficient quality were found that addressed massage therapy, hydrotherapy, manual therapy and/or mobilization and manipulation.

Supporting Evidence

There were no studies of sufficient quality identified that examined the use of massage, joint mobilization, joint manipulation, exercise, phonophoresis, iontophoresis, ultrasound, laser treatments, acupuncture, and/or electrical stimulation. in patients with glenohumeral osteoarthritis. Further, no studies of sufficient quality were found that addressed massage therapy, hydrotherapy, manual therapy and/or mobilization and manipulation.

RECOMMENDATION 2

We are unable to recommend for or against the use of pharmacotherapy in the initial treatment of patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Conservative management of pain secondary to osteoarthritis frequently includes pharmacologic treatment. Non steroidal anti-inflammatories, acetaminophen, opioids, and over-the-counter supplements are routinely used. Despite an exhaustive literature review, there is insufficient evidence to support or refute the use of the pharmacologic treatments for shoulder arthritis.

Supporting Evidence

There were no studies of sufficient quality identified that examined the use of NSAID therapy, topical therapy, acetaminophen interventions, vitamin C and B interventions, chondroitin sulfate interventions, opium or narcotic therapy, oral corticosteroid interventions, or any herbal therapy in patients with glenohumeral osteoarthritis.

RECOMMENDATION 3

We are unable to recommend for or against the use of injectable corticosteroids when treating patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

There is no evidence to support or refute the use of intra-articular steroid injection for the treatment of osteoarthritis of the shoulder, whether performed with or without fluoroscopic, ultrasound or CT guidance.

Corticosteroid injections are used widely in clinical practice for patients with shoulder pain of all etiologies, and occasionally they are employed in conjunction with physical therapy as an initial treatment for patients with shoulder pain. Intra-articular injections are used for the treatment of osteoarthritis in other joints. The current literature does not support or refute the use of intra-articular steroid injection for the treatment of glenohumeral osteoarthritis

Supporting Evidence

There were no studies of sufficient quality identified that examined the use of injectable corticosteroids in the treatment of osteoarthritis of the shoulder.

RECOMMENDATION 4

The use of injectable viscosupplementation is an option when treating patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Limited**

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Currently we have one, industry supported, study⁵ that met the inclusion criteria supporting the use of intra-articular injection of sodium hyaluronate preparations in patients with shoulder pain. Hyaluronic acid injections have been evaluated in the treatment of shoulder osteoarthritis, demonstrating a statistically significant benefit in pain relief, range of motion and quality of life as measured by the VAS, SST, and UCLA outcome measures.

Supporting Evidence

Tables relevant to this recommendation are:

Table 5

Figures relevant to this recommendation are: Figure 1 through Figure 4

To address this study we included one Level IV study by Silverstein, et al.⁵ that assessed patients with osteoarthritis of the glenohumeral joint treated with viscosupplementation. Patients received three Hylan G-F 20 injections weekly for three weeks. One pain measurement (see Figure 1), two global health assessments (see Figure 2 and Figure 3) and one quality of life assessment (see Figure 4) are reported at the durations of 1, 3, and 6 months after the final injection. For each outcome measure, the change from baseline is statistically significant; however, these results are based on limited evidence.

VISCOSUPPLEMENTATION

Table 5 Results of viscosupplementation interventions

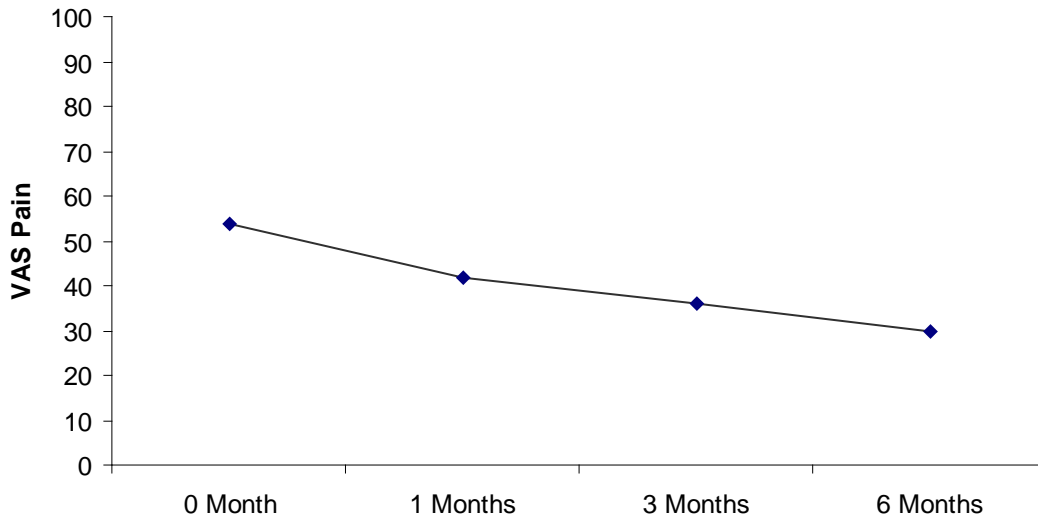
Authors	Outcome Domain	Outcome	LoE	Comparison	Duration			
					N	1	3	6
Silverstein, et al. 2007	Pain	VAS Pain	IV	Change from Baseline	25	•	•	•
	Global Assessment	UCLA			25	•	•	•
		SST- Number of "yes" responses			25	•	•	•
	Quality of Life	SST- Percent of patients able to sleep comfortably			25	•	•	•

- = Statistically significant improvement from baseline.
- VAS= Visual Analogue Scale
- UCLA= University of California at Los Angeles Shoulder Score
- SST= Simple Shoulder Test

PAIN- VAS

Twenty-six patients assessed pain using the Level IV VAS pain outcome measure at one and three months and twenty-five patients assessed pain at six months. Silverstein, et al.⁵ report a statistically significant improvement between 0 months and 1 month ($p=.01$), 0 months and 3 months ($p=.001$), and between 0 months and 6 months ($p=.001$).

Figure 1 Pain measured by VAS



Authors calculated paired t-test between 0 and 1 month, $p=.01$

Authors calculated paired t-test between 0 and 3 month, $p=.001$

Authors calculated paired t-test between 0 and 6 month, $p=.001$

Dispersion not reported by authors

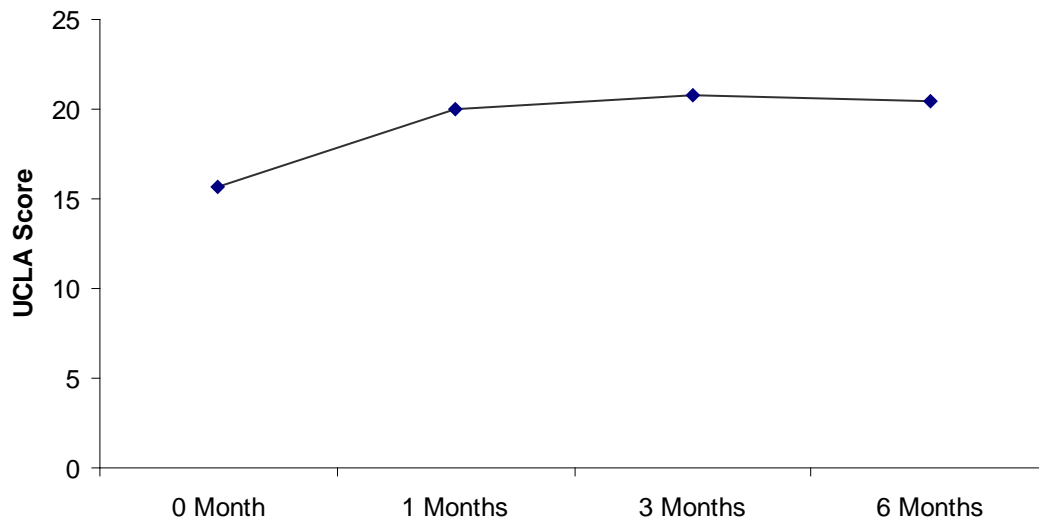
GLOBAL HEALTH ASSESSMENTS

Silverstein, et al.⁵ reported two Level IV global health assessments; UCLA (see Figure 2) and the SST (see Figure 3).

UCLA SCORE

The modified UCLA score consists of the sum of the individual scores for pain, function, motion, and strength as well as each individual score calculated for each visit. Silverstein, et al.⁵ report a statistically significant improvement between 0 months and 1 month ($p=.001$), 0 months and 3 months ($p=.001$), and between 0 months and 6 months ($p=.001$).

Figure 2 UCLA Score



Authors calculated paired t-test between 0 and 1 month, $p=.001$

Authors calculated paired t-test between 0 and 3 month, $p=.001$

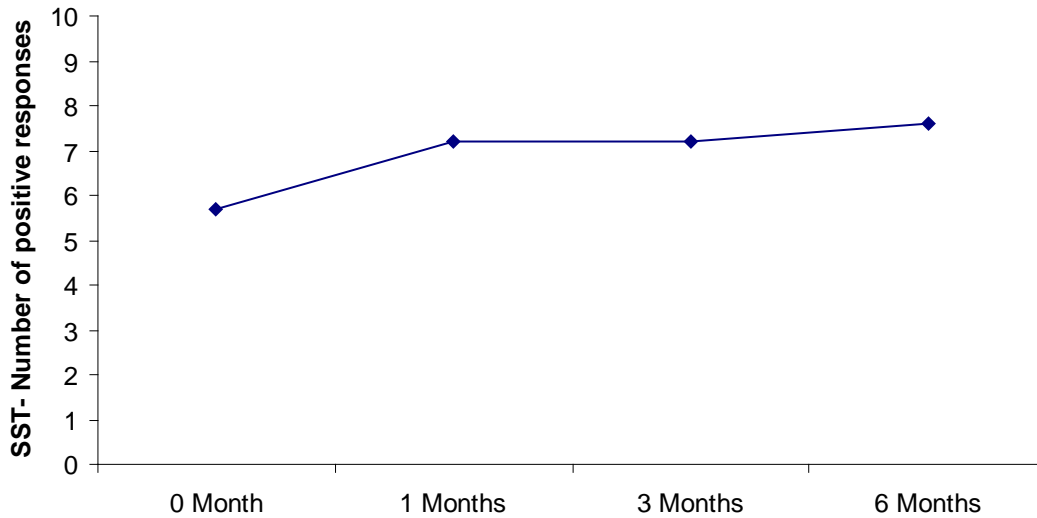
Authors calculated paired t-test between 0 and 6 month, $p=.001$

Dispersion not reported by authors

NUMBER OF POSITIVE RESPONSES-SST

The SST is a patient completed instrument that evaluates the patient's ability to complete eleven normal tasks of daily living with 11 "yes" or "no" questions and one question regarding the patient's ability to work. Silverstein, et al.⁵ analyzed two questions on the SST separately; therefore, the maximum score possible on the assessment is 10. Silverstein, et al.⁵ report a statistically significant improvement between 0 months and 1 month ($p=.012$), 0 months and 3 months ($p=.001$), and between 0 months and 6 months ($p=.001$).

Figure 3 Number of positive responses to SST questions



Authors calculated paired t-test between 0 and 1 month, $p=.012$

Authors calculated paired t-test between 0 and 3 month, $p=.001$

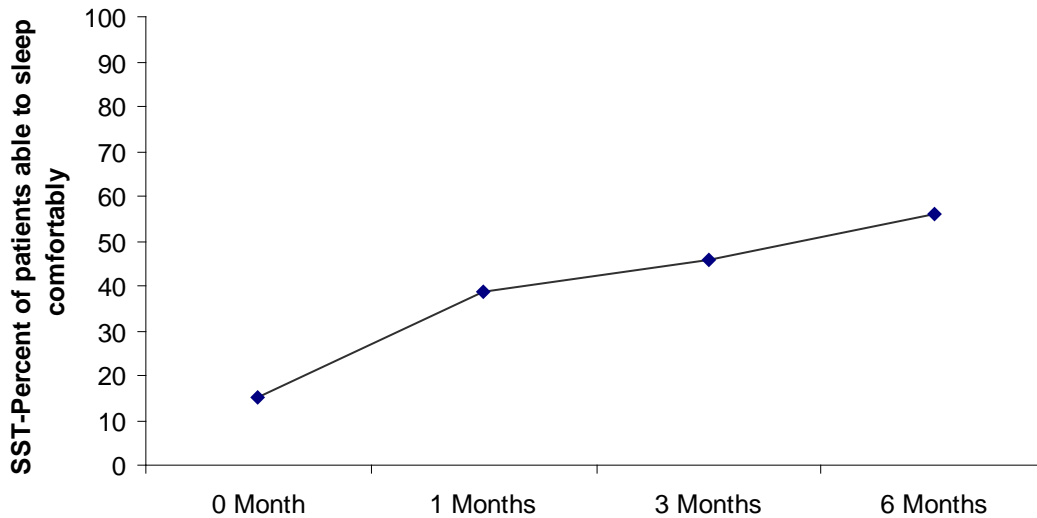
Authors calculated paired t-test between 0 and 6 month, $p=.001$

Dispersion not reported by authors

QUALITY OF LIFE -ABLE TO SLEEP COMFORTABLY- SST

Silverstein, et al.⁵ reported the SST ability to sleep question separately and reported a statistically significant improvement between 0 months and 1 month ($p=.01$), 0 months and 3 months ($p=.01$), and between 0 months and 6 months ($p=.001$).

Figure 4 Percent of patients able to sleep comfortably



Authors calculated paired t-test between 0 and 1 month, $p=.01$

Authors calculated paired t-test between 0 and 3 month, $p=.01$

Authors calculated paired t-test between 0 and 6 month, $p=.001$

Dispersion not reported by authors

RECOMMENDATION 5

We are unable to recommend for or against the use of arthroscopic treatments for patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

There is a concern for performing shoulder arthroplasty in patients under the age of 50 because of potential risk of increased prosthetic loosening and decreased survivorship of the prosthesis in this patient population. Patients with early stages of osteoarthritis may not have symptoms severe enough to warrant or be willing to undergo shoulder arthroplasty procedure. For this reason, arthroscopic options in the treatment of glenohumeral osteoarthritis are of interest. The role for arthroscopic surgical intervention in the treatment algorithm for osteoarthritis of the glenohumeral joint is inconclusive. Despite an exhaustive review of literature, there was insufficient evidence to make conclusions either in favor or against the efficacy of arthroscopic treatment, including glenohumeral debridement, capsular release, chondroplasty, microfracture, removal of loose bodies, biologic and interposition grafts, subacromial decompression, distal clavicle resection, biceps tenotomy or tenodesis, and labral repair or advancement in the treatment of the glenohumeral arthritis of the shoulder. This review was limited to the treatment of glenohumeral arthrosis and does not pertain to subacromial bursitis, acromio-clavicular arthrosis or impingement nor rotator cuff tendonopathy.

Supporting Evidence

There were no studies of sufficient quality identified examining arthroscopic debridement, capsular release, chondroplasty, microfracture, removal of loose bodies, biologic and interpositional grafts, subacromial decompression, distal clavical resection, biceps tenotomy or tenodesis, or labral repair or advancement in patients with osteoarthritis of the glenohumeral joint.

RECOMMENDATION 6

We are unable to recommend for or against open debridement and/or non-prosthetic or biologic interposition arthroplasty in patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

There is a concern for performing shoulder arthroplasty in younger patients because of potential risk of increased prosthetic loosening and decreased survival of the prosthesis. The role for open debridement and non-prosthetic and /or interposition arthroplasty in the treatment algorithm for osteoarthritis of the glenohumeral joint is inconclusive. Despite an exhaustive review of literature, there was insufficient evidence to make conclusions either in favor or against the efficacy of open debridement and non-prosthetic and /or interposition arthroplasty, including osteoarticular allograft, interpositional soft tissue allograft, and autograft in the treatment of the glenohumeral arthritis of the shoulder.

Supporting Evidence

There were no studies of sufficient quality identified examining open debridement and/or non-prosthetic or biologic interposition arthroplasty in patients with osteoarthritis of the glenohumeral joint.

RECOMMENDATION 7

Total shoulder arthroplasty and hemiarthroplasty are options when treating patients with glenohumeral joint osteoarthritis. (Please also see Recommendation 8)

AAOS Strength of Recommendation: **Limited**

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

The body of evidence^{4, 16, 17, 18, 19, 20, 21} supports the use of total shoulder arthroplasty or hemiarthroplasty for glenohumeral osteoarthritis. However, there is no reliable evidence for the use of humeral resurfacing in the existing literature for the treatment of glenohumeral joint osteoarthritis. Total shoulder arthroplasty or hemiarthroplasty provide significant improvements in pain, global health assessment, function, and quality of life scores^{4, 16, 17, 18, 19, 20, 21}. The majority of studies^{4, 18, 21} supported the use of hemiarthroplasty when performed in patients with naturally concentric glenoids or those reamed to concentricity.

Supporting Evidence

Tables relevant to this recommendation are: Table 6 through Table 9

Figures relevant to this recommendation are: Figure 5 through Figure 69

To determine the efficacy of total shoulder arthroplasty and hemiarthroplasty, we compared preoperative outcome measures to outcome measures after surgery^{4, 16, 17, 18, 19, 20, 21} (See Table 6 and Table 8). No studies of sufficient quality were found that addressed the efficacy of prosthetic resurfacing.

To determine which procedure is most effective, total shoulder arthroplasty was compared to hemiarthroplasty. This comparison is addressed in Recommendation 8.

TOTAL SHOULDER ARTHROPLASTY

TSA Efficacy

Table 6 Results of Total Shoulder Arthroplasty

Author	Outcome Domain	Outcome	LOE	Comparison	N	Duration					
						30-60 m	36 m	46 m	4.3 y	2 y	2.9 y
Raiss, et al. 2008	Pain	Pain- Constant and Murley	IV	Change from Baseline	21					•	
Iannotti, et al. 2003		Pain- VAS	V		95			•			
Orfaly et al. 2003		Pain -VAS	V		37				•		
Gartsman,et al. 2000		Pain- ASES	V		27			•			
Gartsman,et al. 2000		Pain-UCLA	V		27			•			
Raiss, et al. 2008	Global Assessment	Constant Score	IV	Change from Baseline	21					•	
Gartsman,et al. 2000		ASES	V		27			•			
Iannotti, et al. 2003		ASES	V		95				•		
Norris and Iannotti 2002		SST	V		94				•		
Worland, et al. 1998		UCLA Score	V		51						

Author	Outcome Domain	Outcome	LOE	Comparison	N	Duration					
						30-60 m	36 m	46 m	4.3 y	2 y	2.9 y
Gartsman,et al. 2000		UCLA Score	V		27		•				
Raiss, et al. 2008	Function	Activity-Constant and Murley	IV	Change from Baseline	21					•	
Raiss, et al. 2008		Power- Constant Murley	IV		21					•	
Raiss, et al. 2008		Mobility-Constant Murley	IV		21					•	
Boorman, et al. 2003		Physical function SF-36	V	Change from Baseline	91	•					
Gartsman,et al. 2000		Function-UCLA	V		27		•				
Orfaly et al. 2003		Function- VAS	V		37				•		
Norris and Iannotti 2002		Function- VAS	V		94			•			
Boorman, et al. 2003		Physical role function SF-36	V		91	•					
Gartsman,et al. 2000		Activities of Daily Living-ASES	V		27			•			
Gartsman,et al. 2000		Strenght- UCLA	V		27			•			

Author	Outcome Domain	Outcome	LOE	Comparison	N	Duration					
						30-60 m	36 m	46 m	4.3 y	2 y	2.9 y
Gartsman, et al. 2000		Motion-UCLA	V		27		•				
Fehringer, et al. 2002		Ability to lift eight pounds to shoulder level	V		102	•					
Fehringer, et al. 2002		Ability to lift one pound to shoulder level	V		102	•					
Fehringer, et al. 2002		Ability to place arm comfortably at side	V		102	•					
Fehringer, et al. 2002		Ability to place hand behind head	V		102	•					
Fehringer, et al. 2002		Ability to sleep comfortably	V		102	•					
Fehringer, et al. 2002		Ability to toss softball twenty yards overhand	V		102	•					
Fehringer, et al. 2002		Ability to toss softball twenty yards underhand	V		102	○					

Author	Outcome Domain	Outcome	LOE	Comparison	N	Duration					
						30-60 m	36 m	46 m	4.3 y	2 y	2.9 y
Fehringer, et al. 2002		Ability to tuck in shirt	V	Change from Baseline	102	●					
Fehringer, et al. 2002		Ability to work full time in a regular job	V		102	●					
Fehringer, et al. 2002		Ability to wash back of contralateral shoulder	V		102	●					
Fehringer, et al. 2002		Ability to place coin on shelf	V		102	●					
Fehringer, et al. 2002		Ability to carry twenty pounds at side	V		102	●					
Norris and Iannotti 2002		Ability to use arm	V		94			●			
Boorman, et al. 2003	Quality of Life	Mental health-SF-36	V	Change from Baseline	91	○					
Iannotti, et al. 2003		Quality of Life-VAS	V		95		●				
Boorman, et al. 2003		General health perception-SF-36	V		91	●					

Author	Outcome Domain	Outcome	LOE	Comparison	N	Duration					
						30-60 m	36 m	46 m	4.3 y	2 y	2.9 y
Iannotti, et al. 2003		Satisfaction- VAS	V		95			●			
Gartsman,et al. 2000		Satisfaction- UCLA	V		27			●			
Boorman, et al. 2003		Comfort- SF-36	V		91	●					
Boorman, et al. 2003		Emotional role function-SF-36	V		91	○					
Boorman, et al. 2003		Energy-SF-36	V		91	●					
Boorman, et al. 2003		Social Function SF-36	V		91	●					

●= statistically significant difference ○= no statistically significant difference

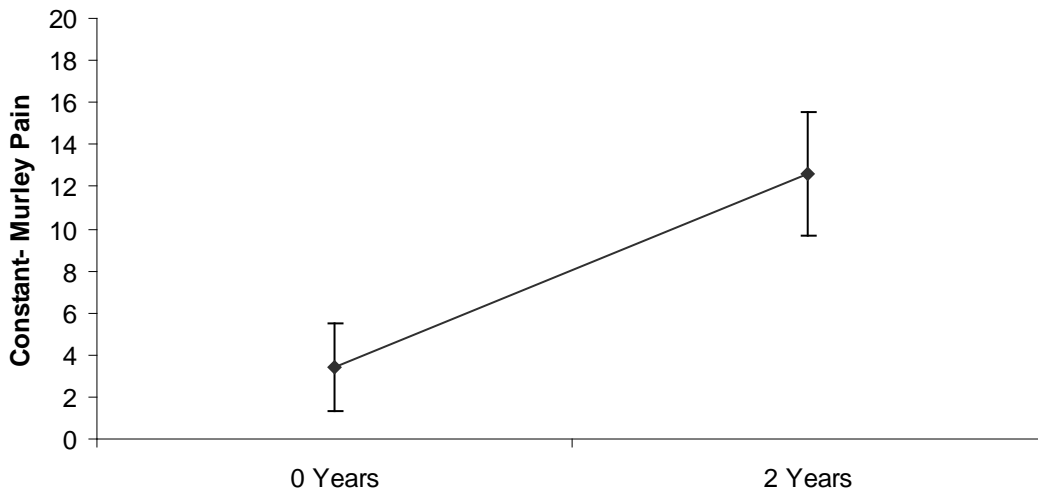
PAIN

One Level IV and four Level V pain outcome measures (please see Figure 5 through Figure 9) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with total shoulder arthroplasty. Patients completed a pain assessment at baseline and at least 2 years post operatively. The results of every pain measurement showed a statistically significant improvement from baseline. However, these results are based on limited evidence.

PAIN- CONSTANT AND MURLEY

Raiss, et al.¹⁶ reported a statistically significant improvement from baseline to 2 years ($p < .0001$).

Figure 5 Pain measured by Constant and Murley

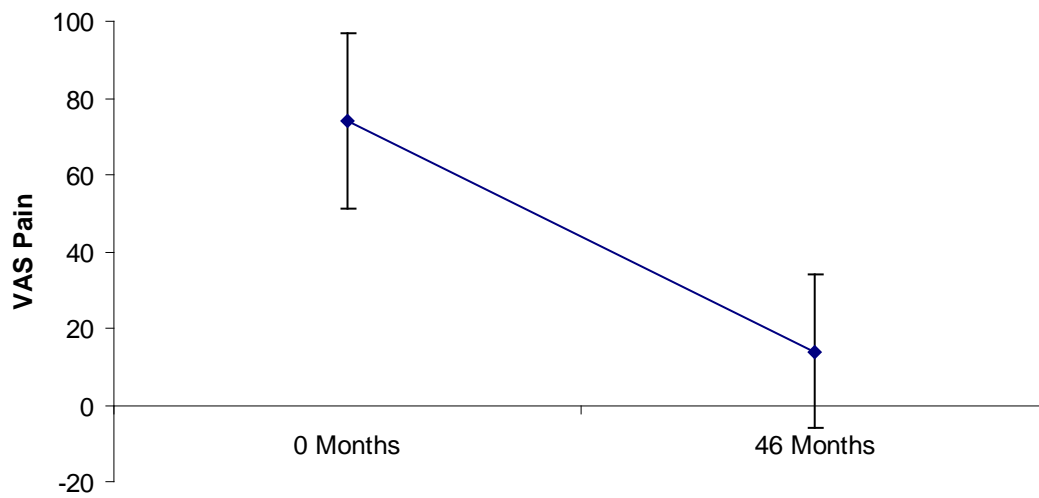


Author calculated t-test, ($p < .0001$)

PAIN-VAS

Iannotti, et al.¹⁷ reported a statistically significant improvement in VAS score from baseline ($p < .0001$).

Figure 6 Pain measured by VAS

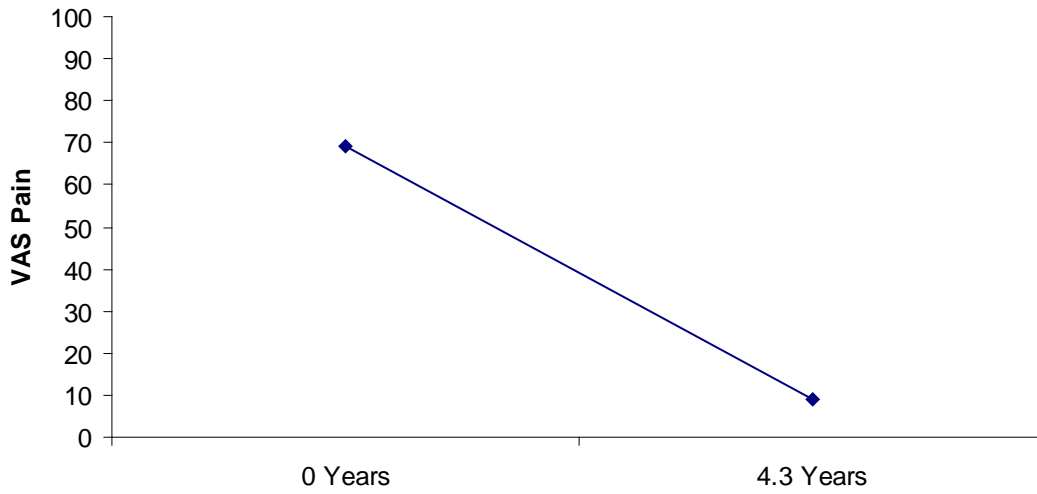


Author calculated t-test, ($p < .0001$)

PAIN-VAS CONTINUED

Orfaly, et al.⁴ did not report the statistical significance between the baseline value and the value 4.3 years post operative. Dispersion around either point estimate was not reported.

Figure 7 Pain measured by VAS



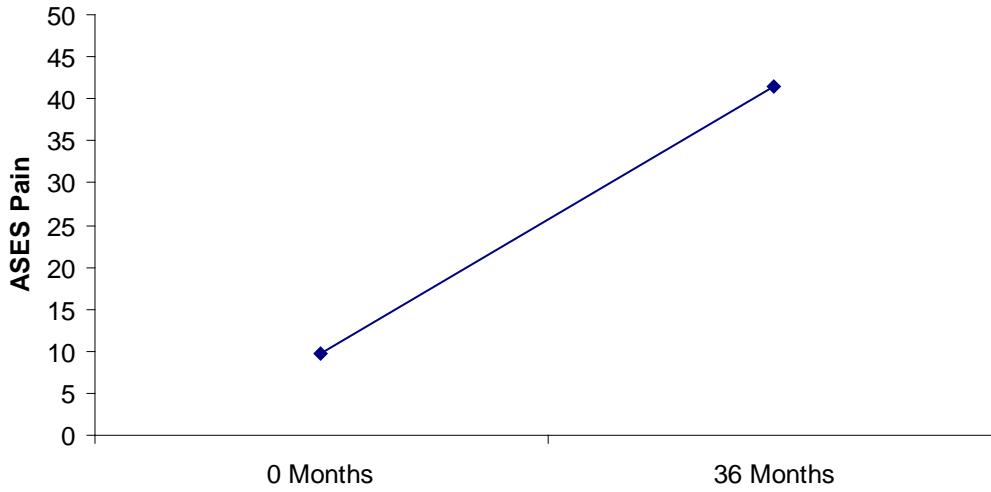
Authors did not report statistical significance

Authors did not report dispersion

PAIN- ASES

Gartsman, et al.¹⁸ reported a statistically significant improvement in ASES score from baseline ($p < .0005$).

Figure 8 Pain measured by ASES



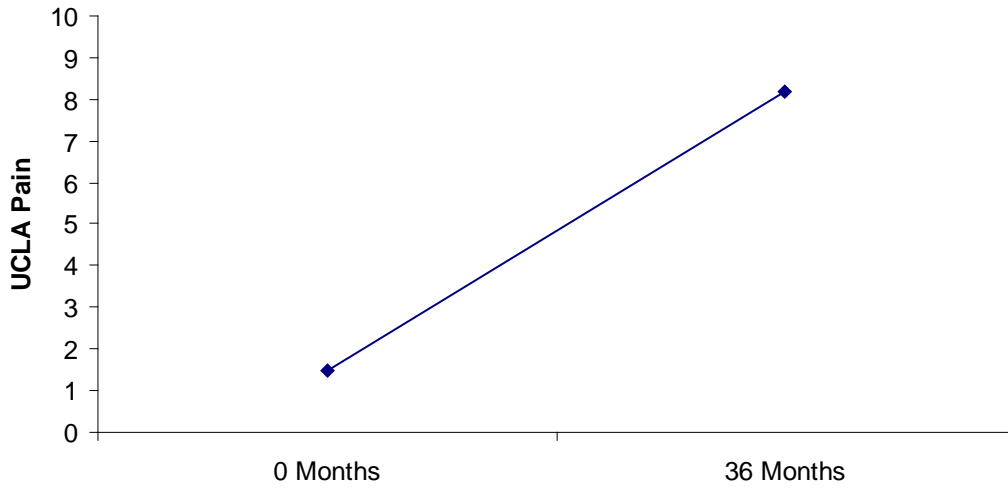
Author reported independent t-test, $p < .0005$

Authors did not report dispersion

PAIN- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 9 Pain measured by UCLA



Author calculated independent t-test, $p < .0005$

Authors did not report dispersion

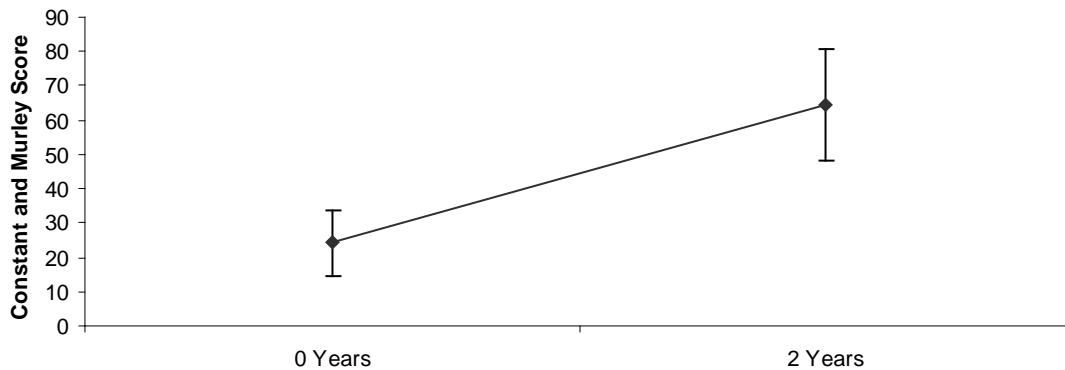
GLOBAL ASSESSMENT

One Level IV and four Level V global health assessments (please see Figure 10 through Figure 14) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with total shoulder arthroplasty. Patients completed a global health assessment at baseline and at least 2 years post operatively. The results of every pain measurement showed a statistically significant improvement from baseline. However, these results are based on limited evidence.

CONSTANT AND MURLEY SCORE

Raiss, et al.¹⁶ reported a statistically significant improvement from baseline to 2 years ($p < .0001$).

Figure 10 Constant and Murley Score

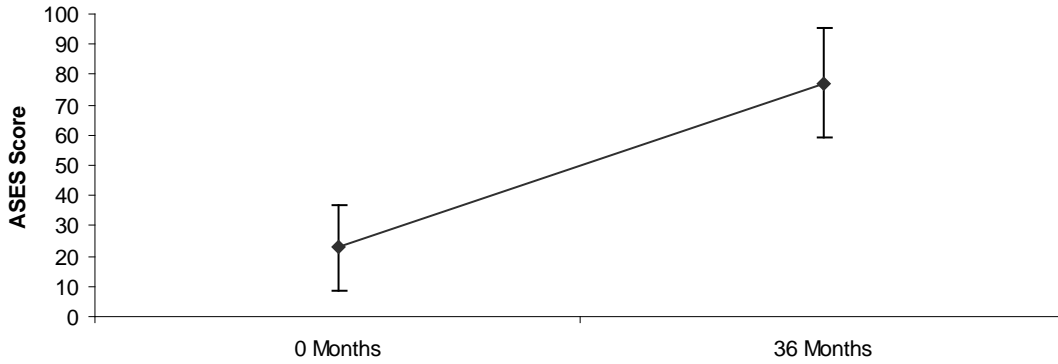


Author calculated t-test, $p < .0001$

ASES

Gartsman, et al.¹⁸ reported a statistically significant improvement in ASES score from baseline ($p < .0005$).

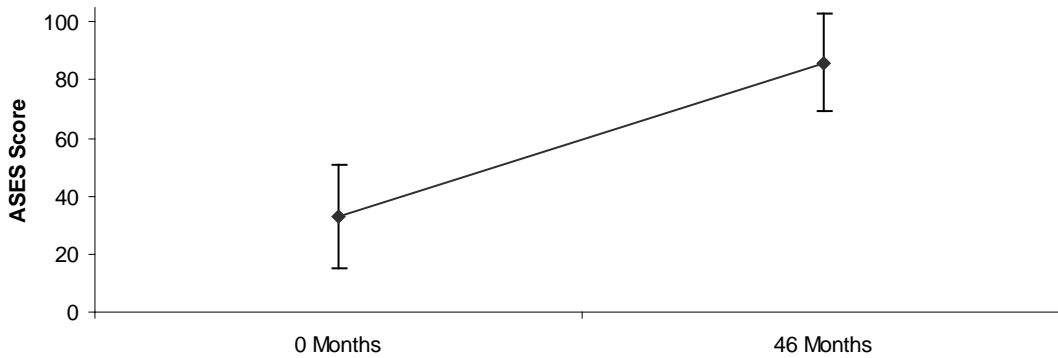
Figure 11 ASES Score



Author reported independent t-test, $p < .005$

Iannotti, et al.¹⁷ reported a statistically significant improvement in ASES score from baseline ($p < .0001$).

Figure 12 ASES Score

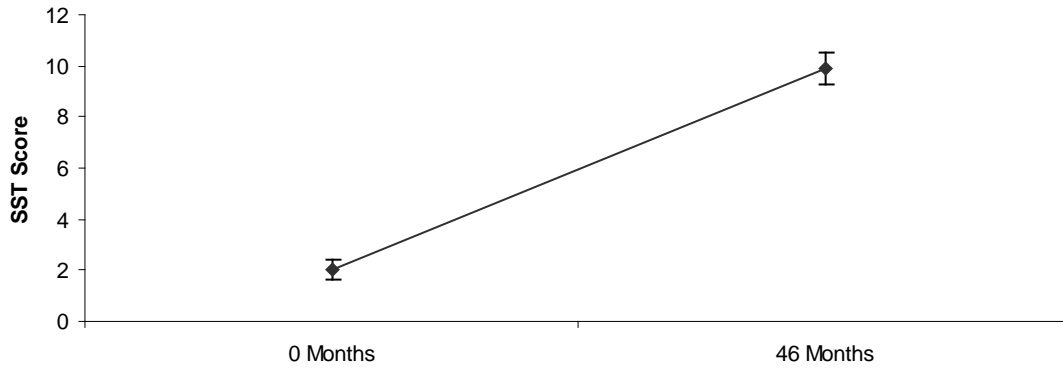


Author reported paired t-test, $p < .0001$

SST

Iannotti, et al.¹⁷ reported a statistically significant improvement in SST score from baseline ($p < .0001$).

Figure 13 SST Score

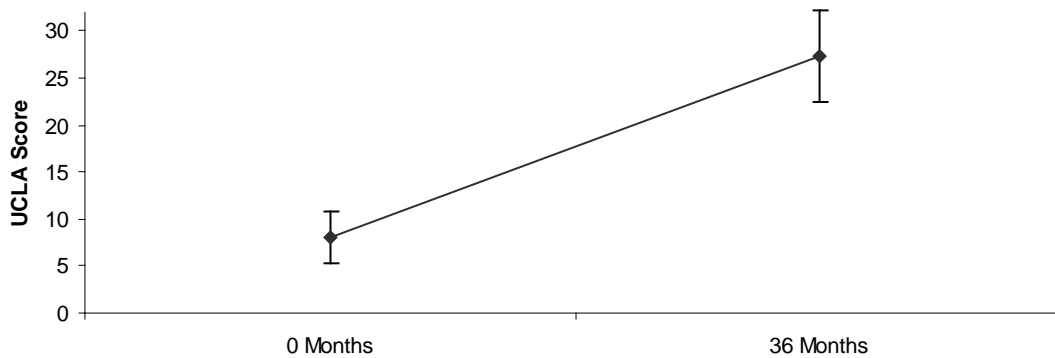


AAOS calculated paired t-test, $p < .0001$

UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 14 UCLA Score



Author calculated independent t-test, $p < .005$

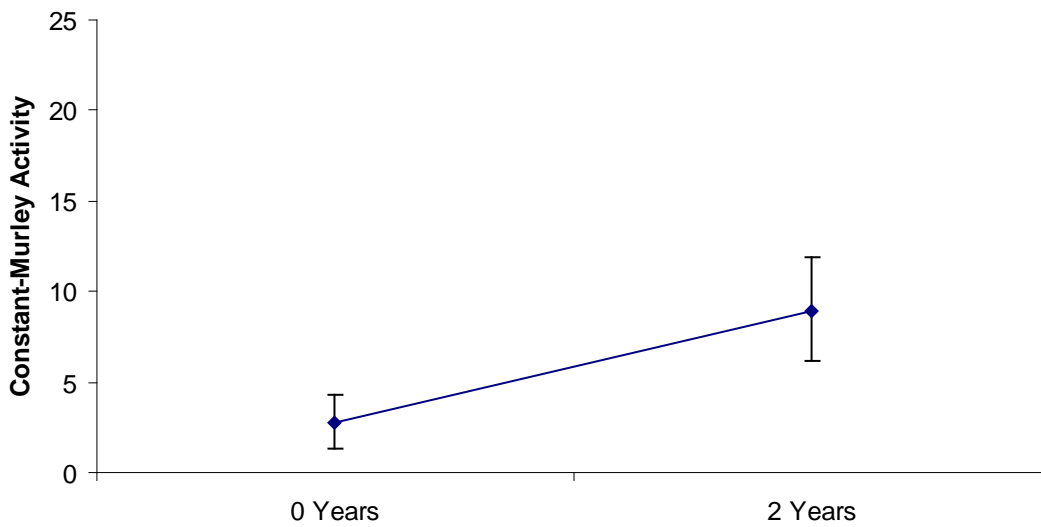
FUNCTION

Function outcome measures (please see Figure 15 through Figure 38) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with total shoulder arthroplasty.

ACTIVITY- CONSTANT MURLEY

Raiss, et al.¹⁶ reported a statistically significant improvement from baseline to 2 years ($p < .0001$).

Figure 15 Activity measured by Constant and Murley

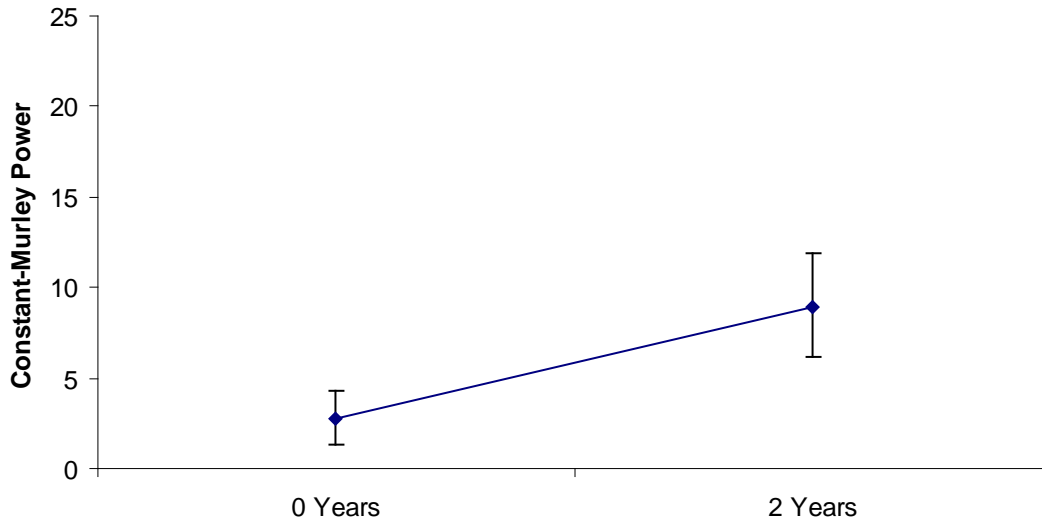


Author calculated paired t-test, $p < .0001$

POWER- CONSTANT AND MURLEY

Raiss, et al.¹⁶ reported a statistically significant improvement from baseline to 2 years ($p < .0001$).

Figure 16 Power measured by Constant and Murley

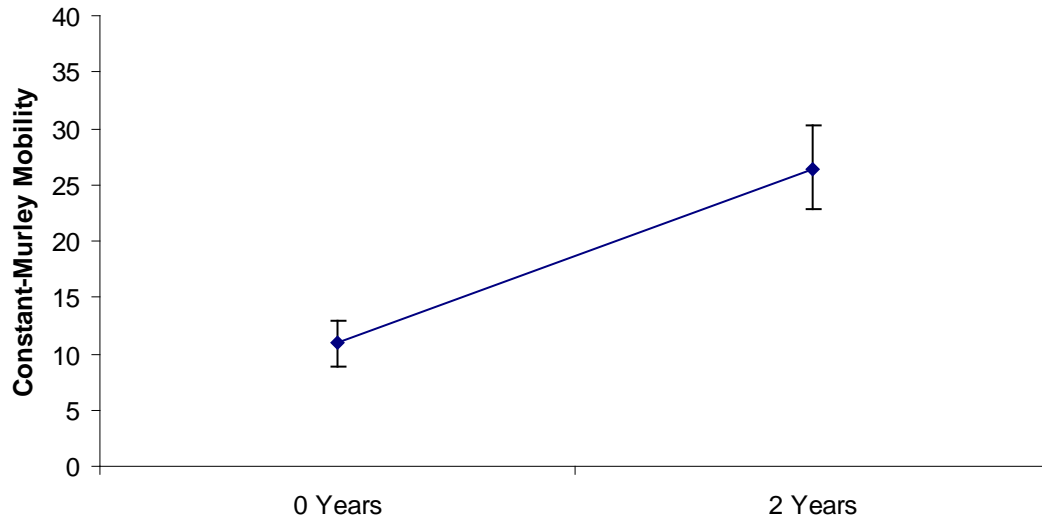


Author calculated t-test, $p < .0001$

MOBILITY- CONSTANT MURLEY

Raiss, et al.¹⁶ reported a statistically significant improvement from baseline to 2 years ($p < .0001$).

Figure 17 Mobility measured by Constant and Murley

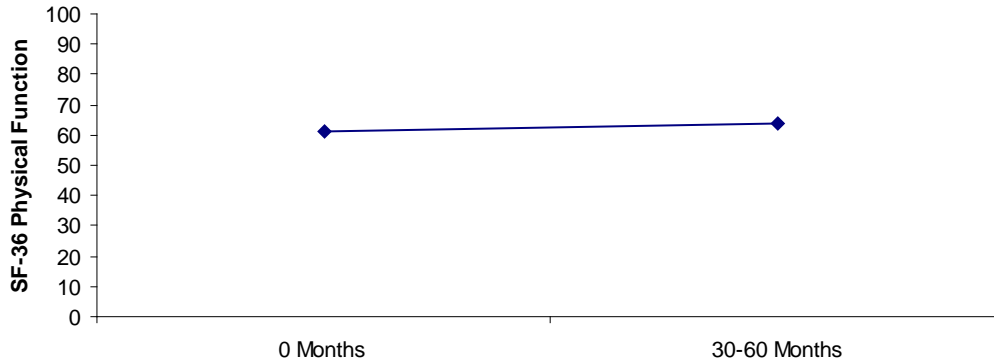


Author calculated t-test, $p < .0001$

PHYSICAL FUNCTION –SF-36

Boorman, et al.¹⁹ reported a statistically significant improvement in physical function from baseline at 30-60 months ($p<.01$). .

Figure 18 Physical function measured by SF-36



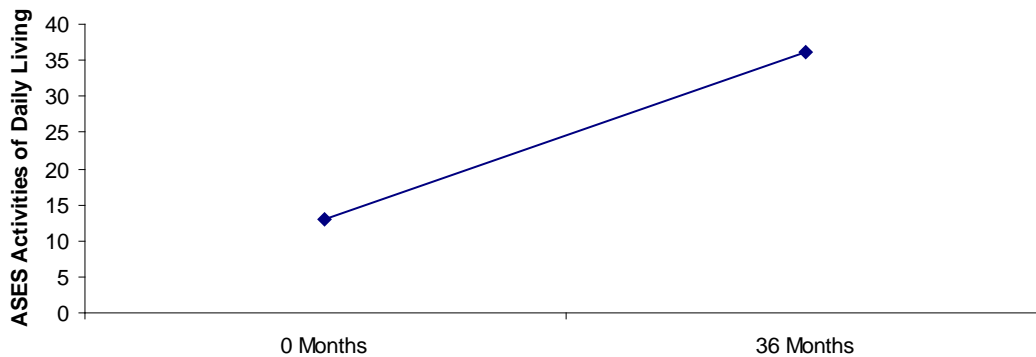
Author calculated paired t-test, $p<.01$

Dispersion not reported by authors

ASES ACTIVITIES OF DAILY LIVING

Gartsman, et al. reported a statistically significant improvement from baseline, ($p<.001$).

Figure 19 ASES Activities of daily living



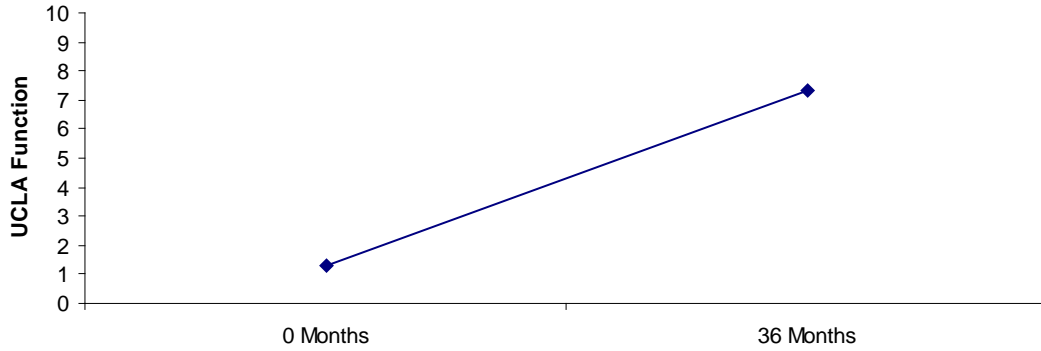
Author calculated t test, $p<.001$

Dispersion not reported by authors

FUNCTION- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 20 Function measured by UCLA



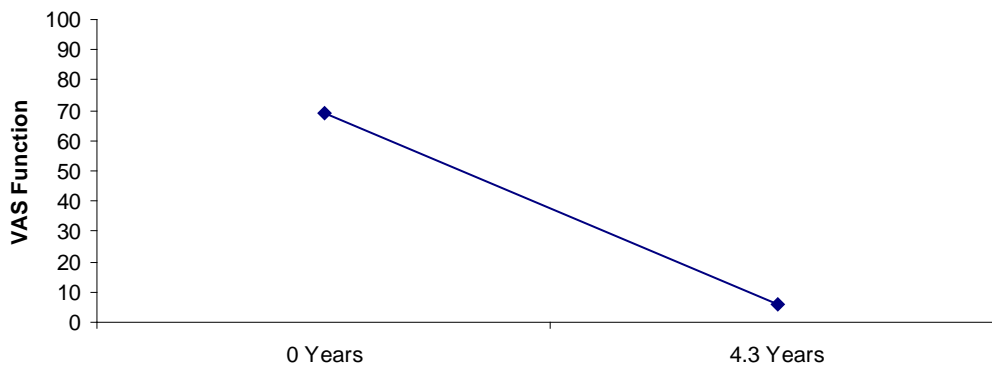
Author calculated independent t-test, $p < .0005$

Dispersion not reported by authors

FUNCTION-VAS

Orfaly, et al.⁴ did not report statistical significance or dispersion around either point estimate.

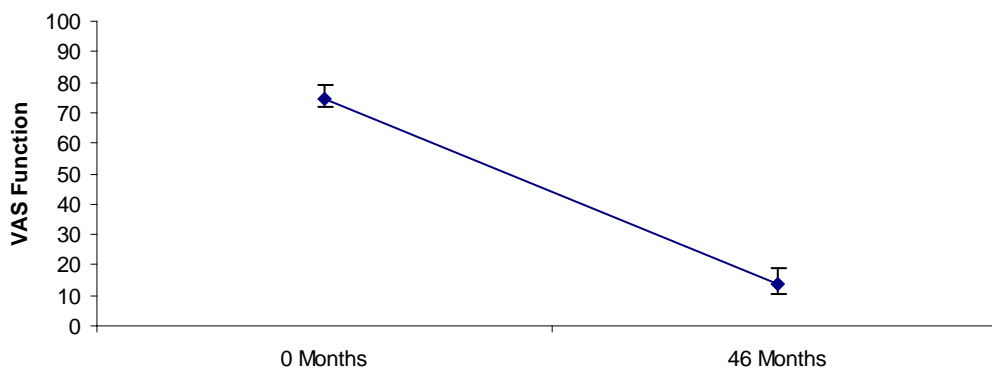
Figure 21 Function measured by VAS



Authors did not report statistical significance
Dispersion not reported by authors

Norris, et al.²² reported a statistically significant improvement in function from baseline to 46 months ($p < .001$)

Figure 22 Function measured by VAS

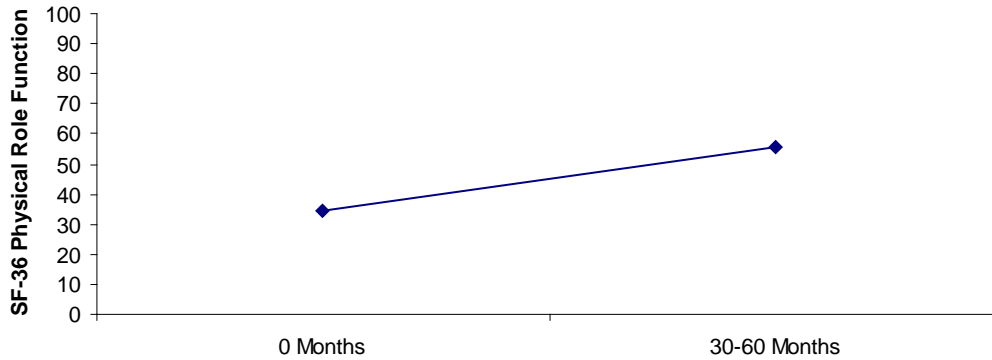


AAOS calculated paired t-test, $p < .0001$

PHYSICAL ROLE FUNCTION- SF-36

Boorman, et al.¹⁹ reported a statistically significant improvement in physical function from baseline to 30-60 months ($p < .01$).

Figure 23 Physical role function measured by SF-36



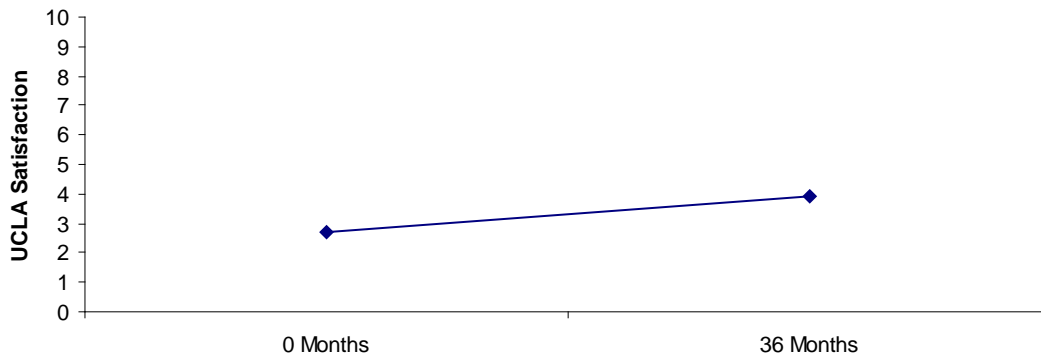
Author calculated paired t-test, $p < .01$

Dispersion not reported by authors

STRENGTH UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 24 Strength measured by UCLA



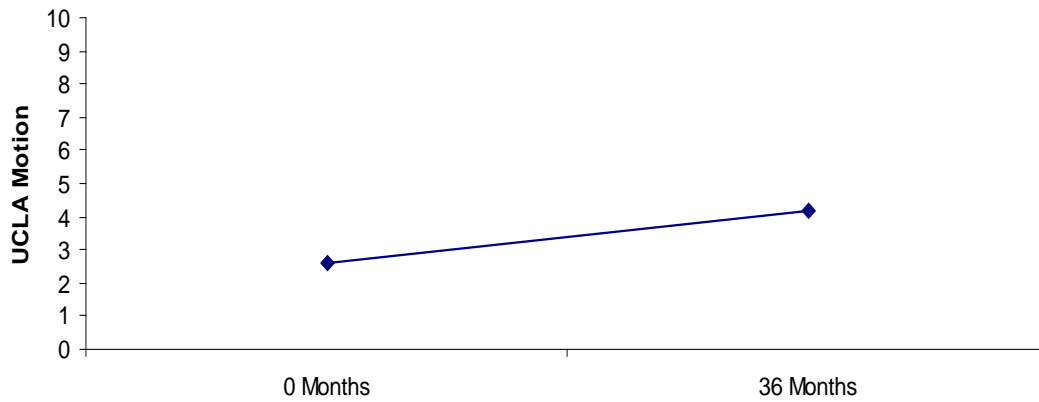
Author calculated independent t-test, $p < .005$

Dispersion not reported by authors

MOTION- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 25 Motion measured by UCLA



Author calculated independent t-test, $p < .005$
Dispersion not reported by authors

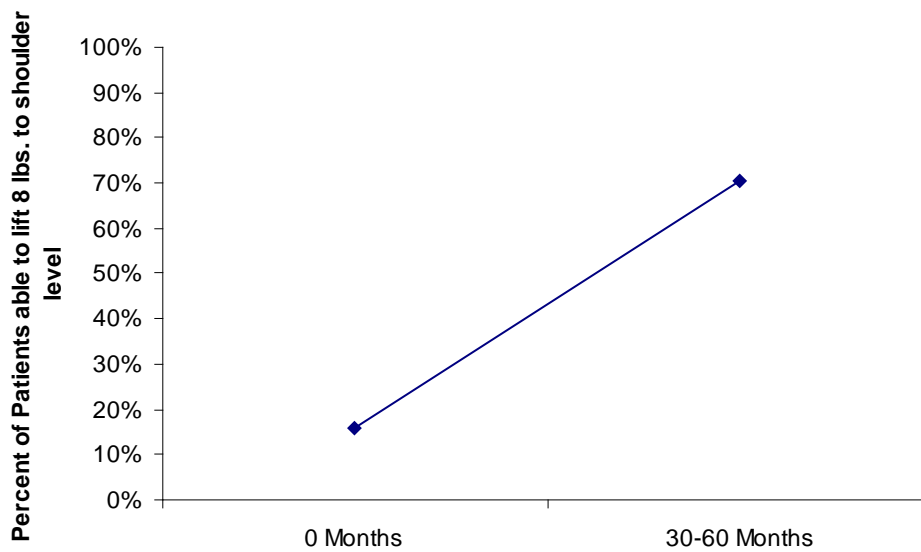
SST

Fehringer, et al.²⁰ compared the percent of patients with osteoarthritis of the glenohumeral joint able to complete each individual SST function assessment before surgery and 30-60 months after total shoulder arthroplasty (see Figure 27 through Figure 37)

ABILITY TO LIFT 8 LBS. TO SHOULDER LEVEL

Fehringer, et al.²⁰ The authors reported a statistically significant increase in the percent of patients able to lift the weight at 30-60 months when compared to the percent of patients able to lift the weight before surgery ($p<.01$).

Figure 26 Percent of patients able to lift 8 lbs to shoulder level



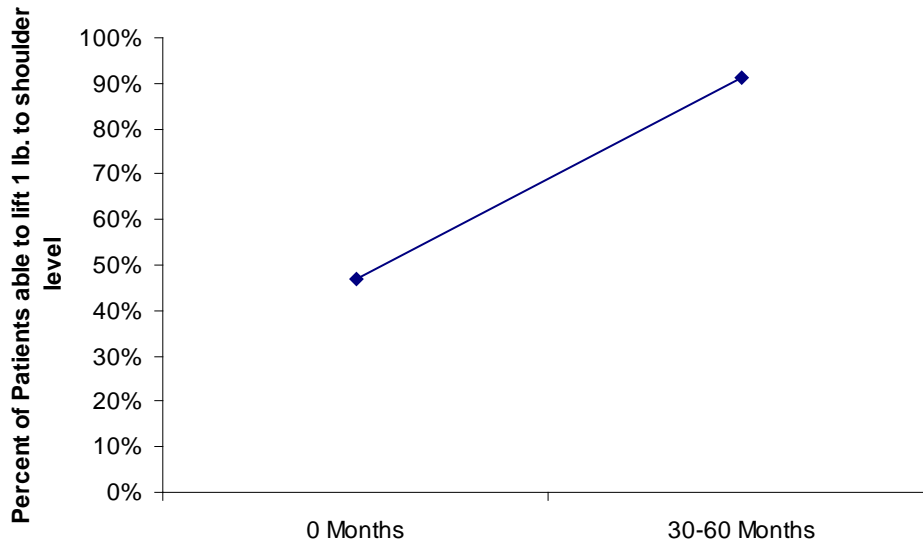
Author calculated chi-square test for paired observations, $p<.01$

Dispersion not reported by authors

ABILITY TO LIFT 1 LB. TO SHOULDER LEVEL

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to lift the weight at 30-60 months when compared to the percent of patients able to lift the weight before surgery ($p < .01$).

Figure 27 Ability to lift 1 lb to shoulder level



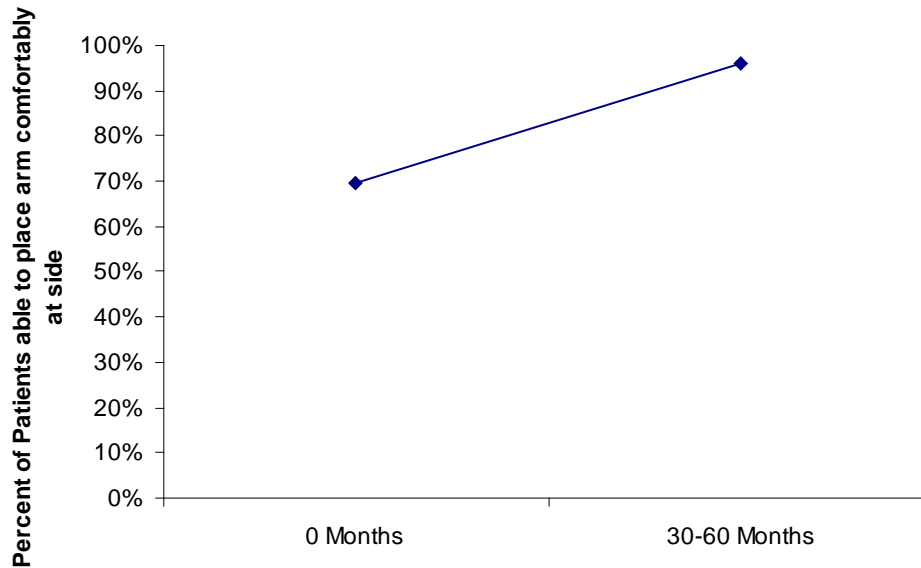
Author calculated chi-square test for paired observations, $p < .01$

Dispersion not reported by authors

ABILITY TO PLACE ARM COMFORTABLY AT SIDE

Fehringer, et al²⁰ T reported a statistically significant increase in the percent of patients able to place their arm at side at 30-60 months when compared to the percent of patients able to place their arm at side before surgery ($p<.01$).

Figure 28 Ability to place arm comfortably at side



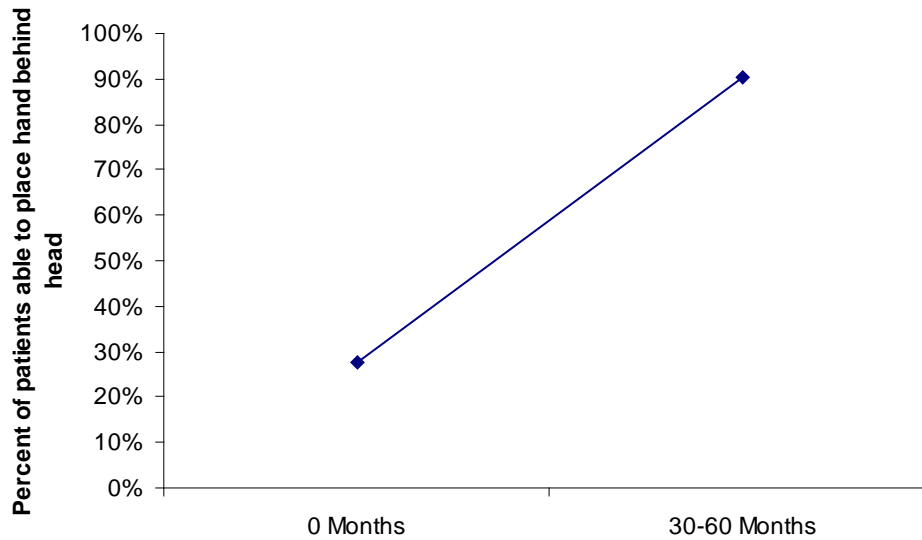
Author calculated chi-square test for paired observations, $p<.01$

Dispersion not reported by authors

ABILITY TO PLACE HAND BEHIND HEAD

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to place their hand behind head at 30-60 months when compared to the percent of patients able to place their hand behind head before surgery ($p < .01$).

Figure 29 Ability to place hand behind head



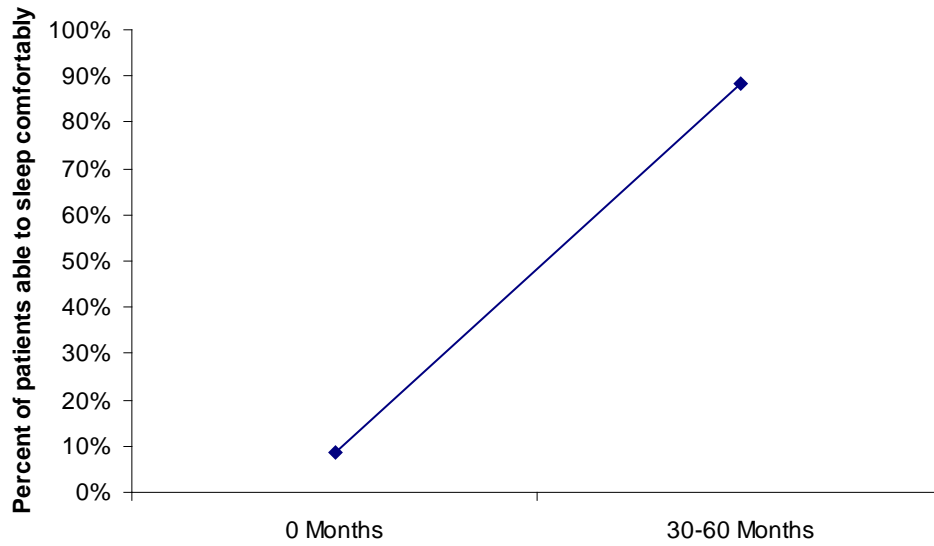
Author calculated chi-square test for paired observations, $p < .01$

Dispersion not reported by authors

ABILITY TO SLEEP COMFORTABLY

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to sleep comfortably at 30-60 months when compared to the percent of patients able to sleep comfortably before surgery ($p < .01$).

Figure 30 Ability to sleep comfortably

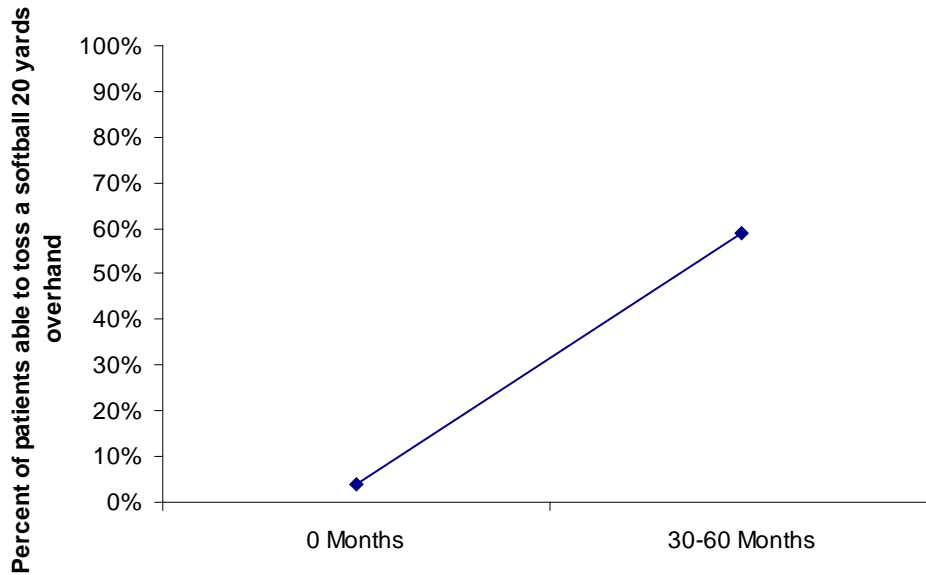


Author calculated chi-square test for paired observations, $p < .01$
Dispersion not reported by authors

ABILITY TO TOSS SOFTBALL TWENTY YARDS OVERHAND

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to toss a softball twenty yards overhand 30-60 months when compared to the percent of patients able to toss a softball twenty yards overhand before surgery ($p < .01$).

Figure 31 Ability to toss softball twenty yards overhand

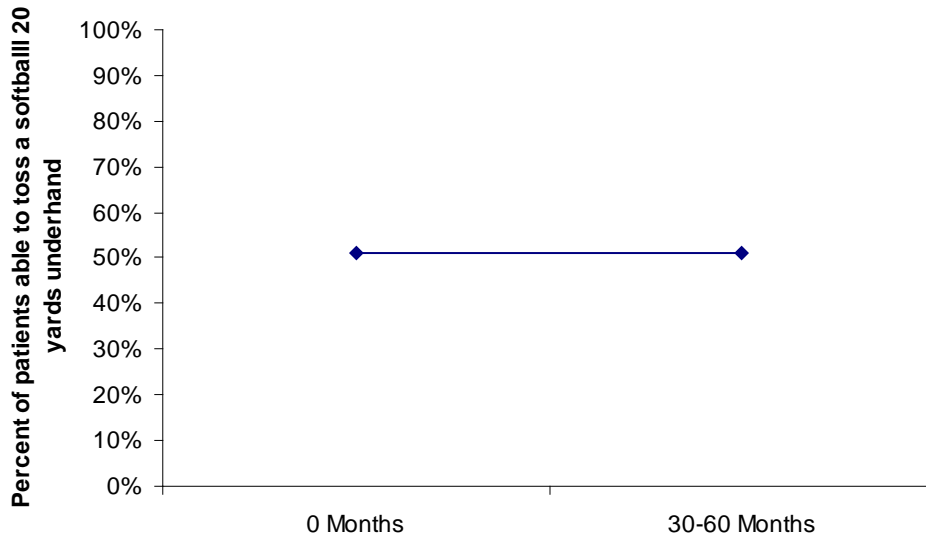


Author calculated chi-square test for paired observations, $p < .01$
Dispersion not reported by authors

ABILITY TO TOSS SOFTBALL 20 YARDS UNDERHAND

Fehringer, et al.²⁰ reported no statistically significant difference in the percent of patients able to toss a softball 20 yards underhand at 30-60 months when compared to the percent of patients able to toss a softball 20 yards underhand before surgery.

Figure 32 Ability to toss softball 20 yards underhand

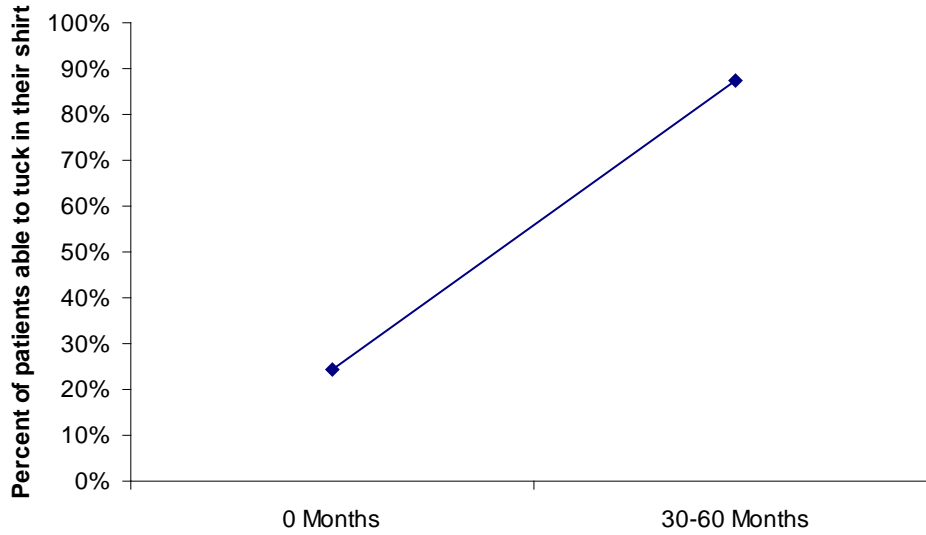


Author calculated chi-square test for paired observations, *ns*
Dispersion not reported by authors

ABILITY TO TUCK IN SHIRT

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to tuck in shirt at 30-60 months when compared to the percent of patients able to tuck in shirt before surgery ($p<.01$).

Figure 33 Ability to tuck in shirt

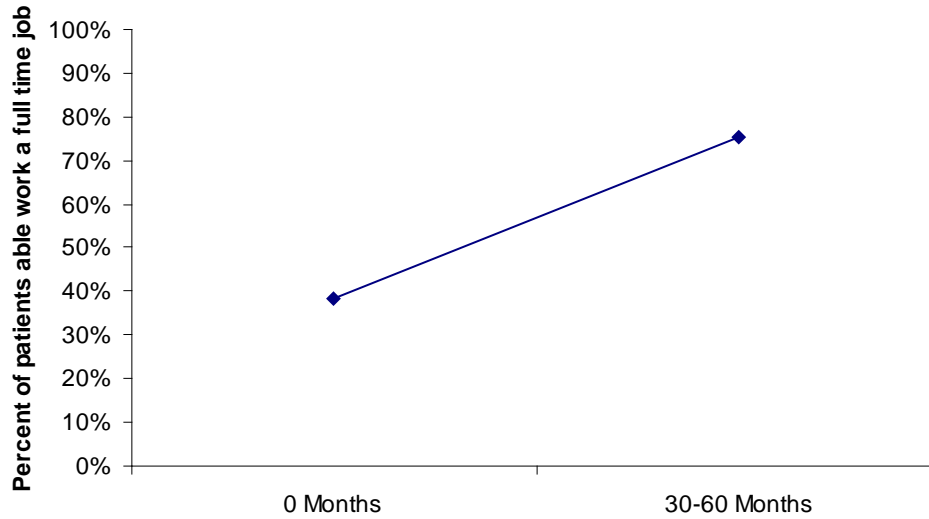


Author calculated chi-square test for paired observations, $p<.01$
Dispersion not reported by authors

ABILITY TO WORK A FULL TIME JOB

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to work a full time job at 30-60 months when compared to the percent of patients able to work a full time job before surgery ($p<.01$).

Figure 34 Percent of patients able to work a full time job



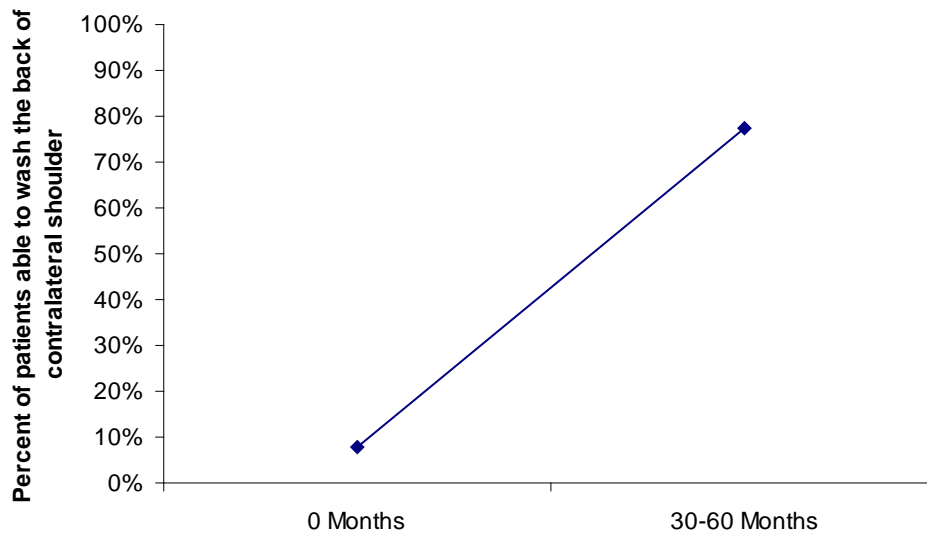
Author calculated chi-square test for paired observations, $p<.01$

Dispersion not reported by authors

ABILITY TO WASH THE BACK OF CONTRALATERAL SHOULDER

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to wash the back of the contra lateral shoulder at 30-60 months when compared to the percent of patients able to wash the back of the contra lateral shoulder before surgery ($p<.01$).

Figure 35 Percent of patients able to wash the back of the contra lateral shoulder

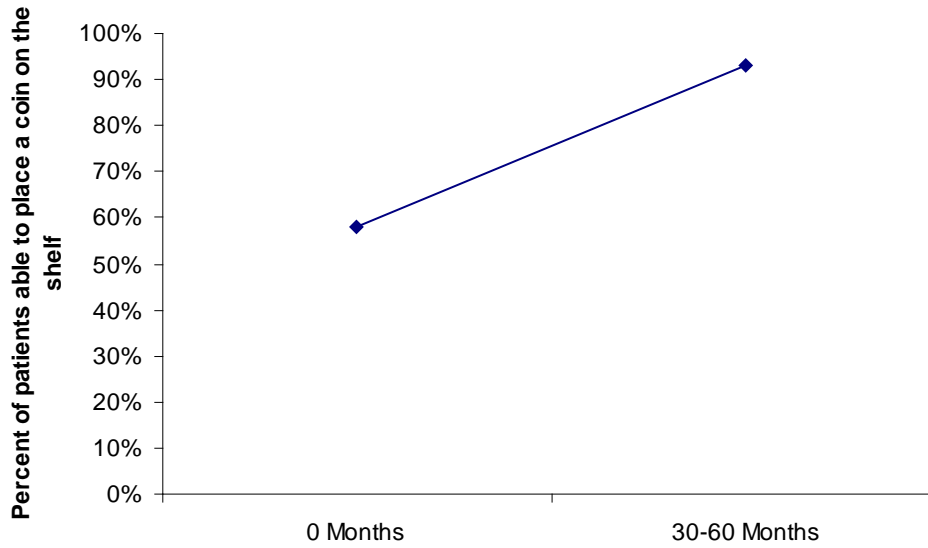


Author calculated chi-square test for paired observations, $p<.01$
Dispersion not reported by authors

ABILITY TO PLACE COIN ON SHELF

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to place a coin on a shelf at 30-60 months when compared to the percent of patients able to place a coin on a shelf before surgery ($p < .01$).

Figure 36 Percent of patients able to place coin on shelf

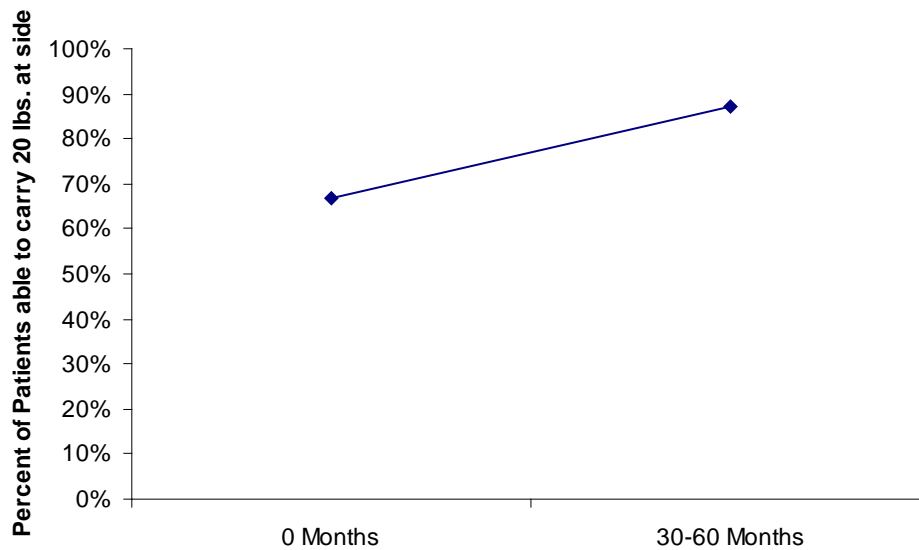


Author calculated chi-square test for paired observations, $p < .01$
Dispersion not reported by authors

ABILITY TO CARRY 20 LBS. AT SIDE

Fehringer, et al.²⁰ reported a statistically significant increase in the percent of patients able to carry 20 pounds at side at 30-60 months when compared to the percent of patients able to carry 20 pounds at side before surgery ($p < .01$).

Figure 37 Ability to carry 20 lbs. at side

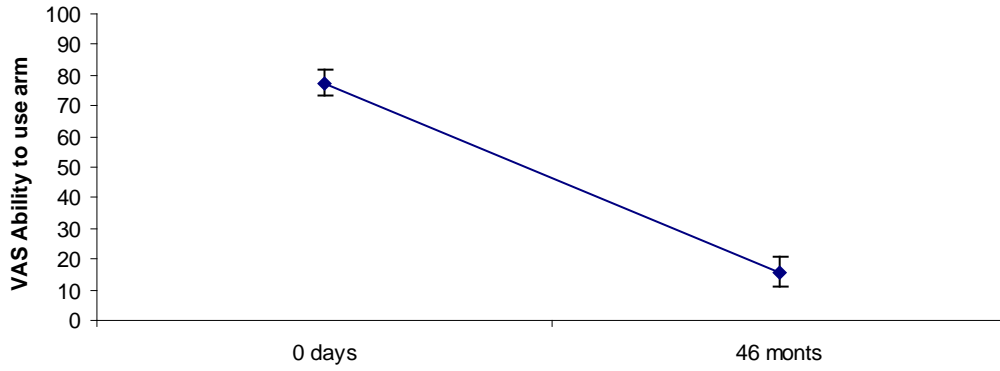


Author calculated chi-square test for paired observations, $p < .01$
Dispersion not reported by authors

ABILITY TO USE ARM

Norris and Iannotti compared the percent of patients able to use their arm before surgery and 46 months after surgery. There was a statistically significant difference ($p < .001$)

Figure 38 Ability to use arm



Author calculated t test, $p < .001$

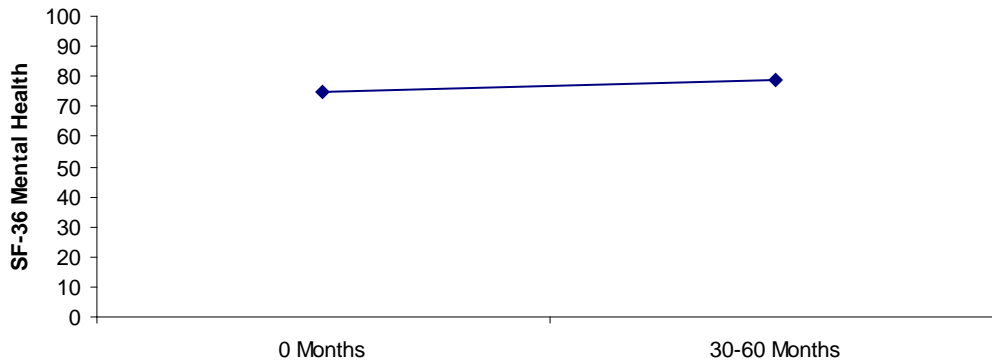
QUALITY OF LIFE

Nine Level V quality of life outcome measures (please see Figure 39 through Figure 47) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with total shoulder arthroplasty. Patients completed a quality of life assessment at baseline and at least 2 years post operatively. The results of seven quality of life measurements showed a statistically significant improvement from baseline. However, these results are based on limited evidence.

MENTAL HEALTH- SF-36

Boorman, et al.¹⁹ reported no statistically significant improvement in mental health from baseline to 30-60 months.

Figure 39 Mental Health measured by SF-36



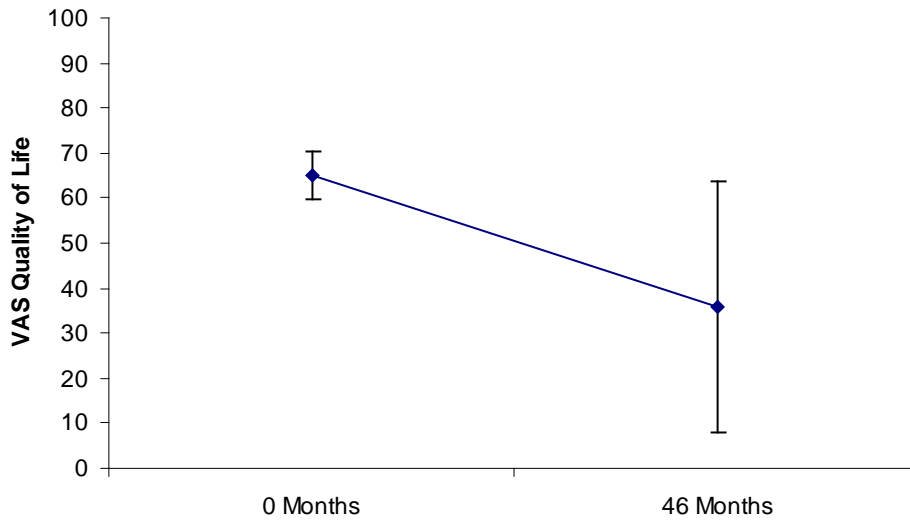
Author calculated paired t-test, $p < .01$

Dispersion not reported by authors

QUALITY OF LIFE- VAS

Iannotti, et al.¹⁷ reported a statistically significant improvement in VAS score from baseline ($p < .0001$).

Figure 40 Quality of Life measured by VAS

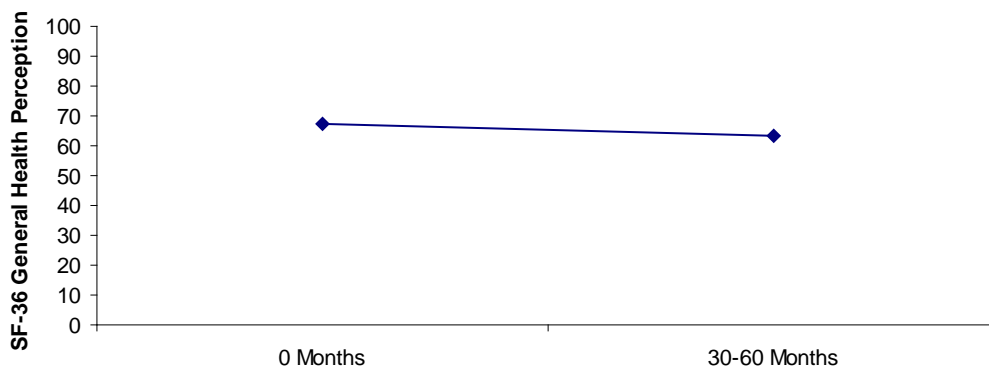


Author calculated paired t-test, $p < .0001$

GENERAL HEALTH PERCEPTION- SF-36

Boorman, et al.¹⁹ reported a statistically significant improvement in general health perception from baseline to 30-60 months ($p < .01$).

Figure 41 General health perception measured by SF-36



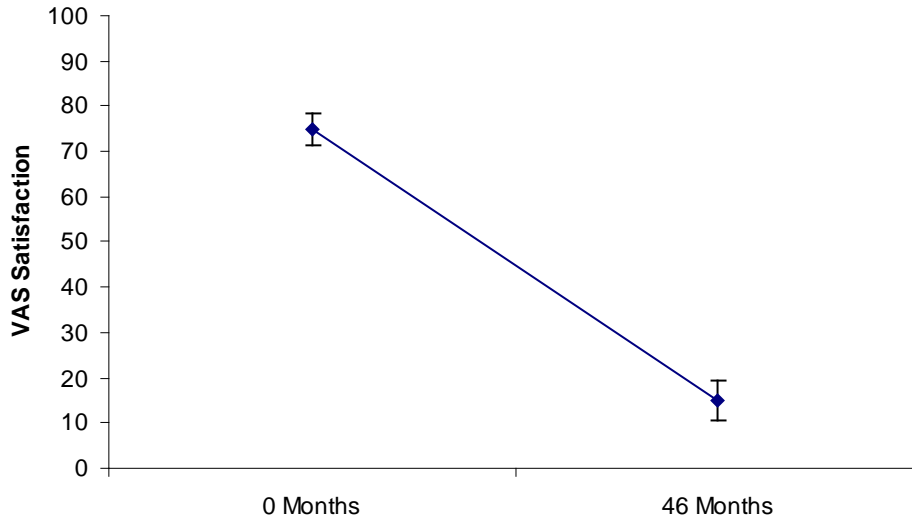
Author calculated paired t-test, $p < .05$

Dispersion not reported by authors

SATISFACTION-VAS

Iannotti, et al.¹⁷ reported a statistically significant improvement in VAS score from baseline ($p < .0001$).

Figure 42 Satisfaction measured by VAS

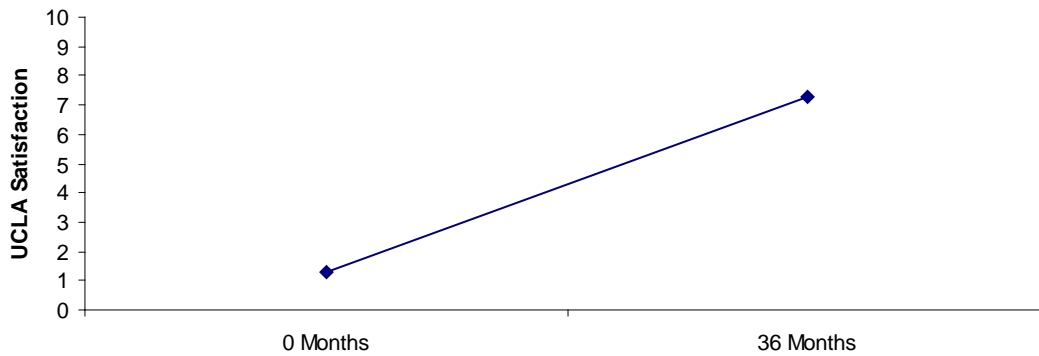


Author calculated paired t-test, $p < .0001$

SATISFACTION- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 43 Satisfaction measured by UCLA

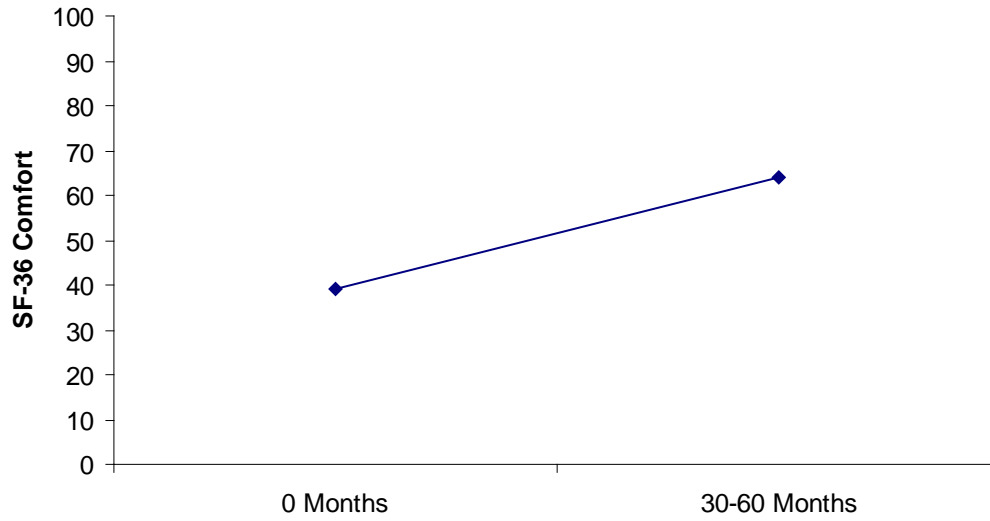


Author calculated independent t-test, $p < .005$
Dispersion not reported by authors

COMFORT- SF-36

Boorman, et al.¹⁹ reported a statistically significant improvement in comfort from baseline to 30-60 months ($p<.01$).

Figure 44 Comfort measured by SF-36



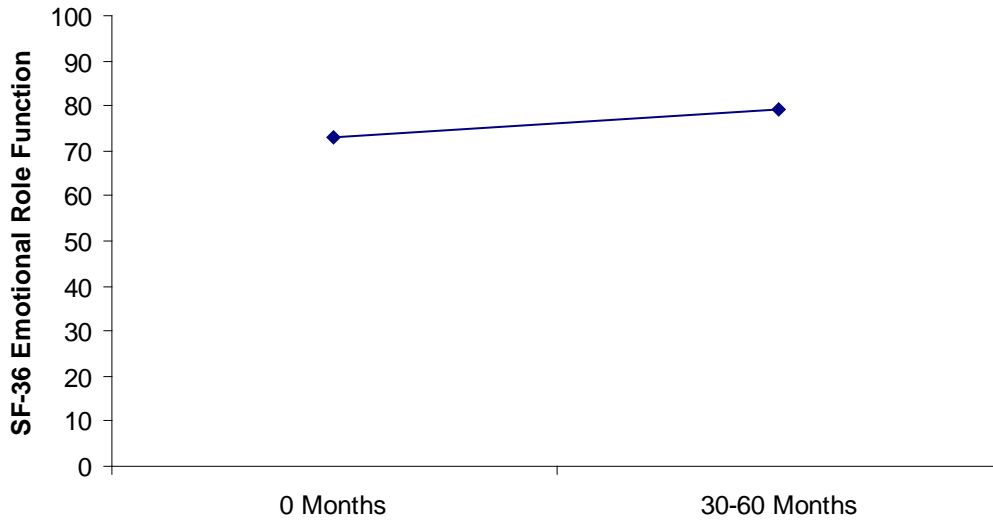
Author calculated paired t-test, $p<.01$

Dispersion not reported by authors

EMOTIONAL ROLE FUNCTION-SF-36

Boorman, et al.¹⁹ reported no statistically significant improvement in emotional role function from baseline to 30-60 months.

Figure 45 Emotional role function measured by SF-36



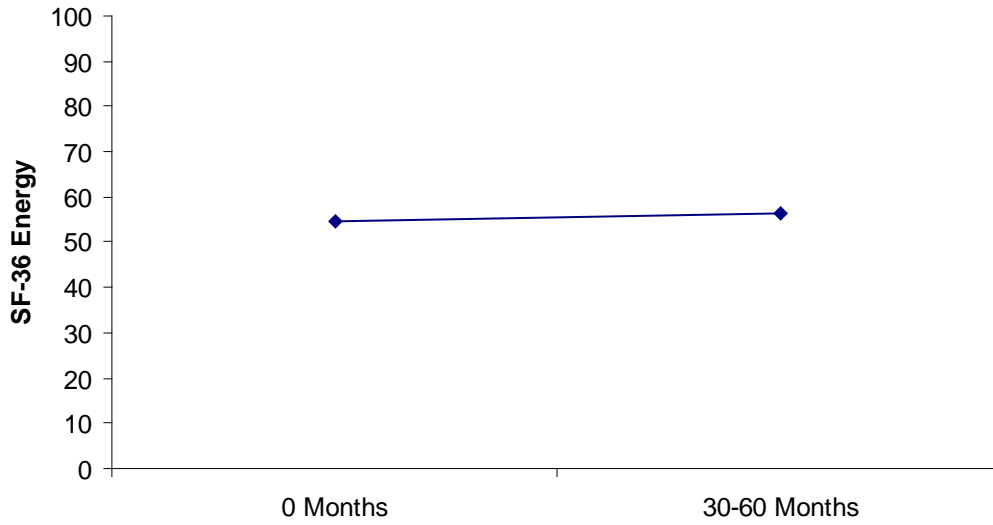
Author calculated paired t-test, not statistically significant

Dispersion not reported by authors

ENERGY- SF-36

Boorman, et al.¹⁹ reported no statistically significant improvement in energy from baseline to 30-60 months.

Figure 46 Energy-SF-36



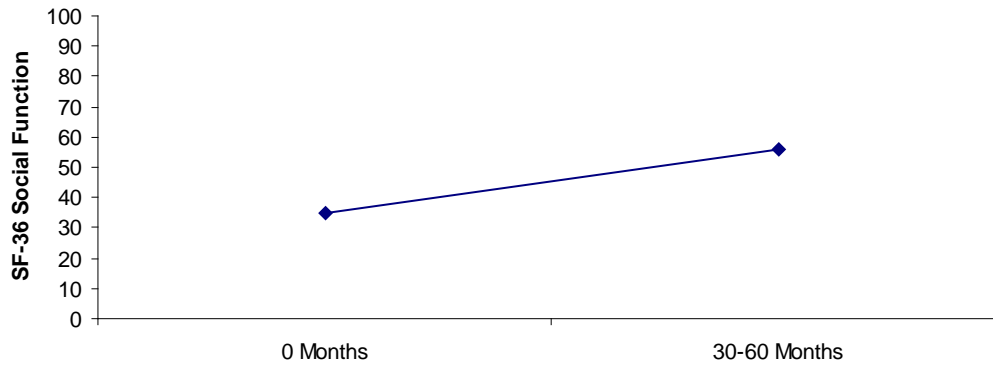
Author calculated paired t-test, not statistically significant

Dispersion not reported by authors

SOCIAL ROLE- SF-36

Boorman, et al.¹⁹ reported a statistically significant improvement in social role function from baseline to 30-60 months ($p < .01$).

Figure 47 Social Role Function SF-36



Author calculated paired t-test, $p < .01$

Dispersion not reported by authors

REPORTED ADVERSE EVENTS

Table 7 Reported Adverse Events for Total Shoulder

Author	Adverse Event	Treatment(s)	% of Patients	N	Action
Lo, et al. 2005	Nondisplaced fracture of the greater tuberosity	TSA	5%	20	Treated during surgery
Lo, et al. 2005	Fracture of the anterior-inferior corner	TSA	5%	20	Secured with a 3.- mm cannulated AO screw, and bone graft from the humeral head
Iannotti, et al. 2003	Periprosthetic fracture (Intraoperative)	TSA or Hemi	3%	128	1 patient- Decrease intensity of rehabilitation program and healed 1 patient-Stabilized with two cortical bone screws 1 patient-Stabilized immediately with a long-stem prosthesis and two cerclage wires 1 patient-Three operative procedures to achieve a successful union
Iannotti, et al. 2003	Glenoid fractures (Intraoperative)	TSA or Hemi	2%	128	1 patient- Humeral head replacement as well as reduction and fixation with a screw 1 patient- Stable after the glenoid component was cemented
Iannotti, et al. 2003	Fractures (Intraoperative)	TSA or Hemi	2%	128	No additional action
Iannotti, et al. 2003	Postoperative humeral head subluxation or dislocation	TSA or Hemi	4%	128	1 patient-Reoperation 1 patient-No surgery 3 patients-Follow up procedure unclear
Torchia, et al. 1997	Chronic posterior dislocation	TSA with Neer Prosthesis	3%	39	Reoperation
Orfaly et al. 2003	Symptomatic glenoid loosening	TSA	2%	37	Revision of the TSA to hemiarthroplasty with allograft placed in the glenoid defect
Iannotti, et al. 2003	Glenoid Loosening and Glenohumeral instability	TSA or Hemi	5%	128	Not Reported
Torchia, et al. 1997	Glenoid Component Loosening	TSA with Neer Prosthesis	8%	39	Reoperation

Author	Adverse Event	Treatment(s)	% of Patients	N	Action
Lo, et al. 2005	Anterior superior instability of the prosthesis	TSA	5%	20	No action
Gartsman, et al. 2000	Stiffness that was unresponsive to postoperative rehabilitation	TSA	4%	27	No Action
Gartsman, et al. 2000	Severe pain with an unclear source	TSA	4%	27	No Action
Iannotti, et al. 2003	Intraoperative transient radial nerve palsy	TSA or Hemi	1%	128	Resolved spontaneously after surgery
Raiss, et al. 2007	Transient brachial plexus palsy	TSA	4%	24	Resolved on it's own
Orfaly et al. 2003	Developed hematoma and a detachment of the subscapularis tendon	TSA or Hemi	2%	37	Evacuation of the hematoma and repair of the subscapularis
Orfaly et al. 2003	Developed a separation of the anterior deltoid origin after a trauma 1 year after surgery	TSA or Hemi	2%	37	Open repair
Torchia, et al. 1997	Sepsis	TSA with Neer Prosthesis	5%	39	Reoperation
Lo, et al. 2005	Infection	TSA	5%	20	Two operative debridements and intravenous antibiotics for 6 weeks

PREVIOUSLY PUBLISHED SYSTEMATIC REVIEWS

Two systematic reviews compare hemiarthroplasty to total shoulder arthroplasty. According to Radnay, et al.²³ “This systematic review of the literature and analysis provides a preponderance of evidence showing that for the treatment of primary glenohumeral osteoarthritis, total shoulder replacement significantly outperforms humeral head replacement with regard to pain relief, range of motion, and patient satisfaction.” (p. 400). Bryant, et al.²⁴ found, “the results of this study indicate that, at a short-term follow-up of two years, total shoulder arthroplasty provides more consistent improvement in function than hemi-arthroplasty for patients with primary osteoarthritis of the shoulder.” (p. 1995).

HEMIARTHROPLASTY (HHS)

HEMIARTHROPLASTY EFFICACY

Table 8 Results of Hemiarthroplasty- Pre and Post operative data

Authors	Outcome Domain	Outcome	LoE	Comparison	N	Duration				
						34 m	46 m	2 yr	4.3 yr	7.5 yr
Iannotti, et al. 2003	Pain	Pain VAS	V	Change from Baseline	33		●			
Wirth, et al. 2006		Pain VAS	V	Change from Baseline	49			●		○*
Orfaly, et al. 2003		Pain VAS	V	Change from Baseline	28				nr	
Gartsman,et al. 2000		Pain UCLA	V	Change from Baseline	24	●				
Gartsman,et al. 2000		Pain ASES	V	Change from Baseline	24	●				
Wirth, et al. 2006		Pain at Rest VAS	V	Change from Baseline	49			●		○*
Wirth, et al. 2006		Pain during Sleep VAS	V	Change from Baseline	49			●		○*
Gartsman,et al. 2000	Global Health Assessment	ASES Score	V	Change from Baseline	24	●				
Iannotti, et al. 2003		ASES Score	V	Change from Baseline	33		●			
Gartsman,et al. 2000		UCLA Score	V	Change from Baseline	24	●				
Gartsman,et al. 2000	Function	Function UCLA	V	Change from Baseline	24	●				
Orfaly, et al. 2003		Function VAS	V	Change from Baseline	28				nr	
Norris and Iannotti		Function VAS	V	Change from Baseline	32		●			
Wirth, et al. 2006		Shoulder function VAS	V	Change from Baseline	49			●		●
Gartsman,et al. 2000		Motion UCLA	V	Change from Baseline	24	●				
Gartsman,et al. 2000		Strength UCLA	V	Change from Baseline	24	●				
Gartsman,et al. 2000	Quality of Life	Activities of Daily Living VAS	V	Change from Baseline	24	●				
Iannotti, et al. 2003		Quality of Life VAS	V	Change from Baseline	33		●			
Wirth, et al. 2006		Quality of life VAS	V	Change from Baseline	49			●		○*

Authors	Outcome Domain	Outcome	LoE	Comparison	N	Duration				
						34 m	46 m	2 yr	4.3 yr	7.5 yr
Iannotti, et al. 2003		Satisfaction VAS	V	Change from Baseline	33		●			
Gartsman, et al. 2000		Satisfaction UCLA	V	Change from Baseline	24			●		
Wirth, et al. 2006		Work and Play VAS	V	Change from Baseline	49			●		○*

●= statistically significant improvement from baseline

Nr= Not Reported

* Change from 2.5 years

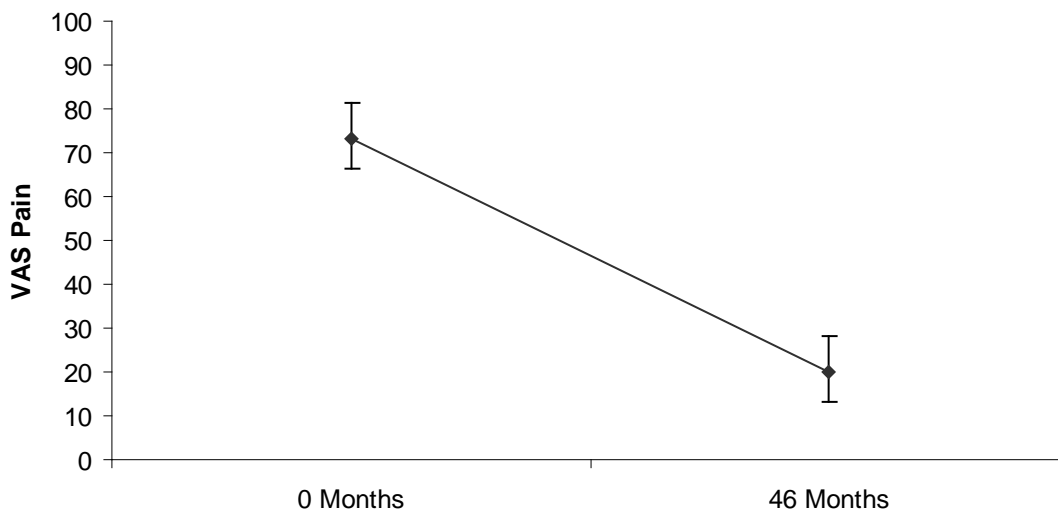
PAIN

Seven Level V pain outcome measures (please Figure 48 through Figure 54) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with hemiarthroplasty. Patients completed a pain assessment at baseline and at least 2 years post operatively. The results of every pain measurement showed a statistically significant improvement from baseline. However, these results are based on limited evidence.

PAIN- VAS

Patients completed the VAS pain assessment at baseline and at 46 months post operative. Iannotti, et al.¹⁷ reported a statistically significant improvement in VAS score from baseline ($p < .0001$).

Figure 48 Pain measured by VAS

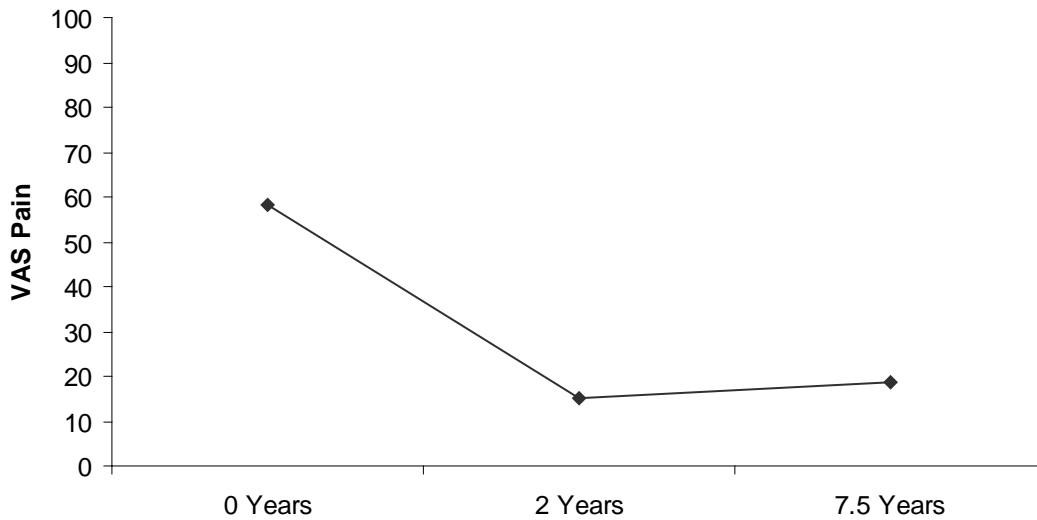


Authors reported paired t-test, $p < .0001$

PAIN-VAS CONTINUED

Wirth, et al.²¹ reported a statistically significant improvement between 0 days and 2 years ($p < .0001$) and between 0 days and 7.5 years ($p < .0001$). The improvement between two years and the final follow up was not statistically significant ($p = .45$), according to the authors.

Figure 49 Pain measured by VAS



0 days – 2 years author reported paired t-test ($p < .0001$)

0 days- 7.5 years author reported paired t-test ($p < .0001$)

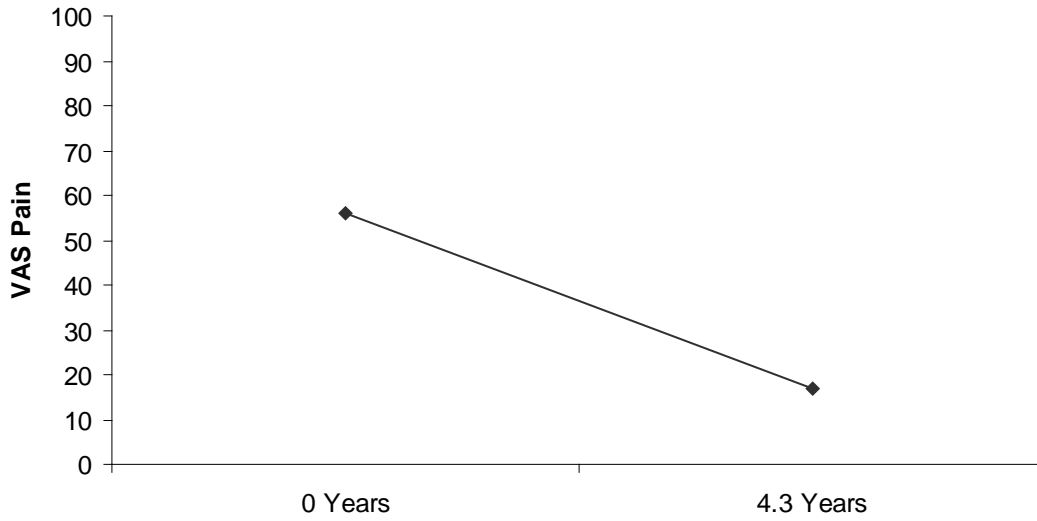
2 years- 7.5 years author reported paired t-test ($p = .45$)

Dispersion not reported by authors

PAIN-VAS CONTINUED

Orfaly, et al.¹⁹ did not report statistical significance between baseline and 4.3 years post operative. The author did not report dispersion around either point estimate.

Figure 50 Pain measured by VAS



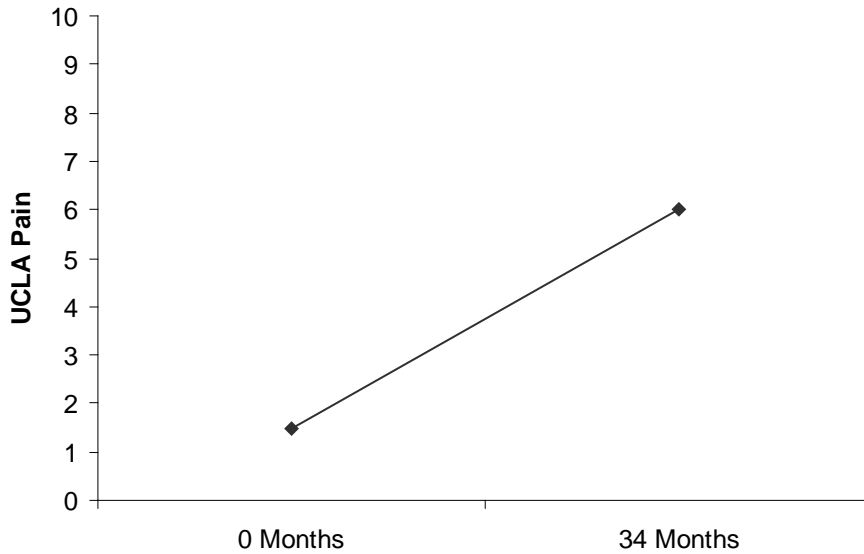
Authors did not report statistical significance

Dispersion not reported by authors

PAIN- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 51 Pain measured by UCLA

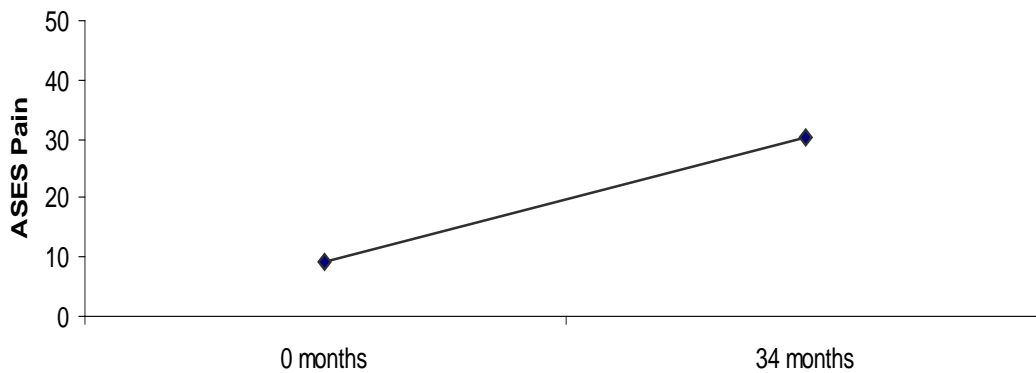


Author reported independent t-test, $p < .0005$

PAIN- ASES

Gartsman, et al.¹⁸ reported a statistically significant improvement in ASES score from baseline ($p < .0005$).

Figure 52 ASES Pain



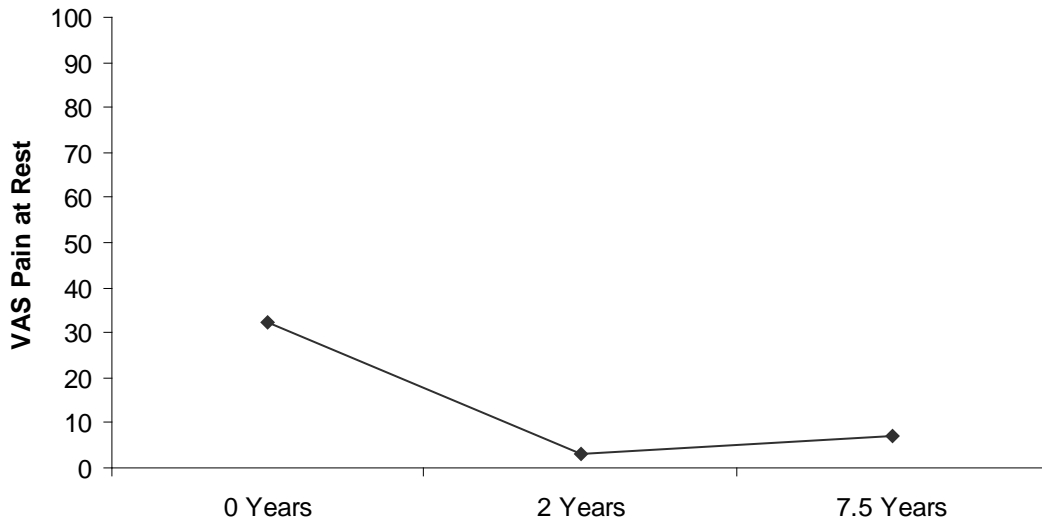
Author reported independent t-test, $p < .0005$

Dispersion not reported by authors

PAIN AT REST- VAS

Wirth, et al.¹⁷ reported a statistically significant improvement between 0 days and 2 years ($p<.0001$) and between 0 days and 7.5 years ($p<.0001$). The authors reported that the comparison between the two years and final follow up was not statistically significant ($p=.09$)

Figure 53 Pain at rest measured by VAS



0 days – 2 years- author reported paired t-test ($p<.0001$)

0 days- 7.5 years author reported paired t-test ($p<.0001$)

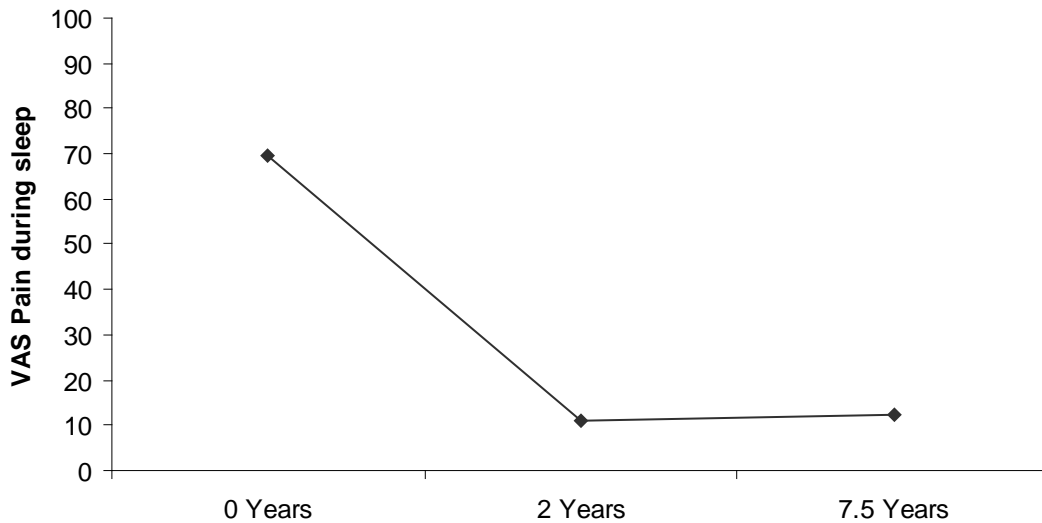
2 years- 7.5 years author reported paired t-test ($p=.09$)

Dispersion not reported by authors

PAIN DURING SLEEP- VAS

Wirth, et al.¹⁷ reported a statistically significant improvement between 0 days and 2 years ($p<.0001$) and between 0 days and 7.5 years ($p<.0001$). The authors reported the comparison between the two year and final follow up was not statistically significant ($p=.72$)

Figure 54 Pain during sleep measured by VAS



0 days – 2 years- author reported paired t-test ($p<.0001$)

0 days- 7.5 years author reported paired t-test ($p<.0001$)

2 years- 7.5 years author reported paired t-test ($p=.72$)

Dispersion not reported by authors

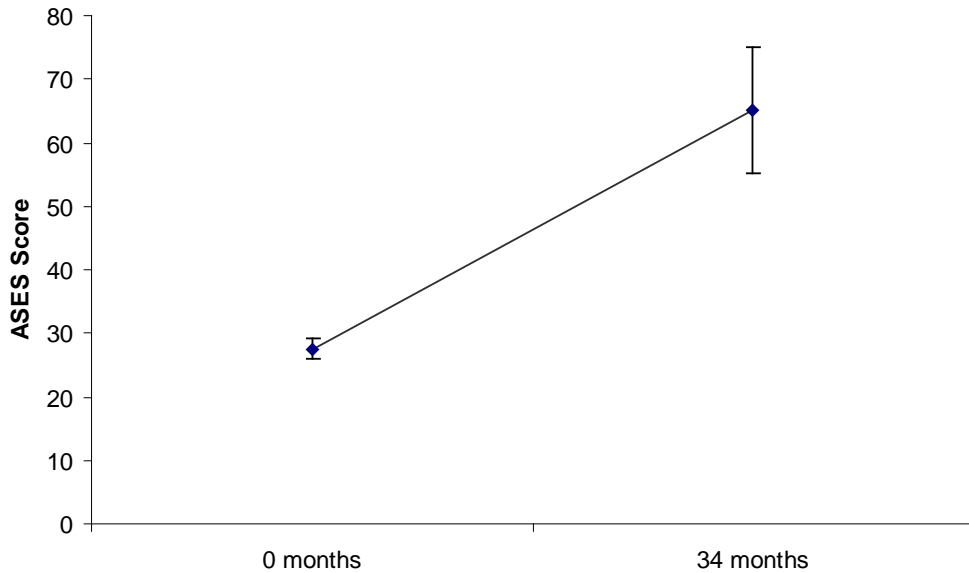
GLOBAL ASSESSMENT

Three Level V global assessment measures (please see Figure 55 through Figure 57) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with hemiarthroplasty. Patients completed a global assessment at baseline and at least 2 years post operatively. The results of every global assessment showed a statistically significant improvement from baseline. However, these results are based on limited evidence.

ASES CONTINUED

Gartsman, et al.¹⁸ reported a statistically significant improvement in ASES score from baseline ($p < .0005$).

Figure 55 ASES Score

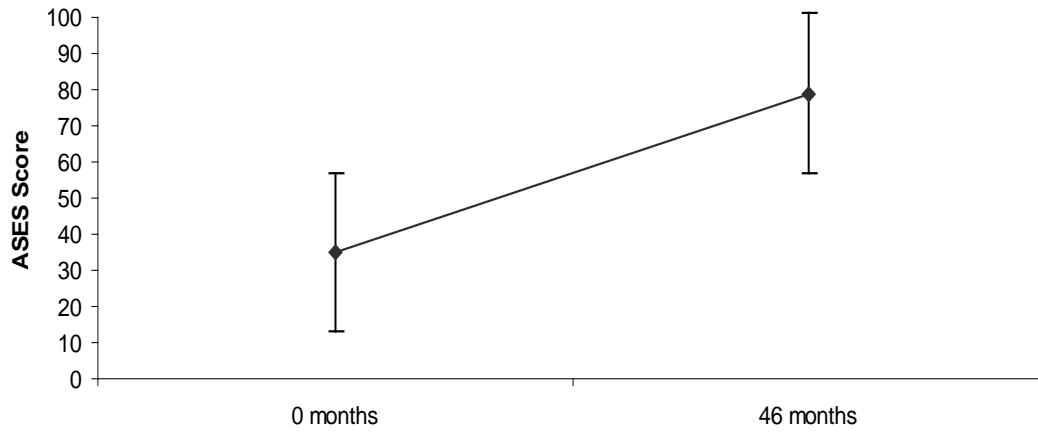


Author reported independent t-test, $p < .005$

ASES

Iannotti, et al.¹⁷ reported a statistically significant improvement in ASES score from baseline ($p < .0001$).

Figure 56 ASES Score

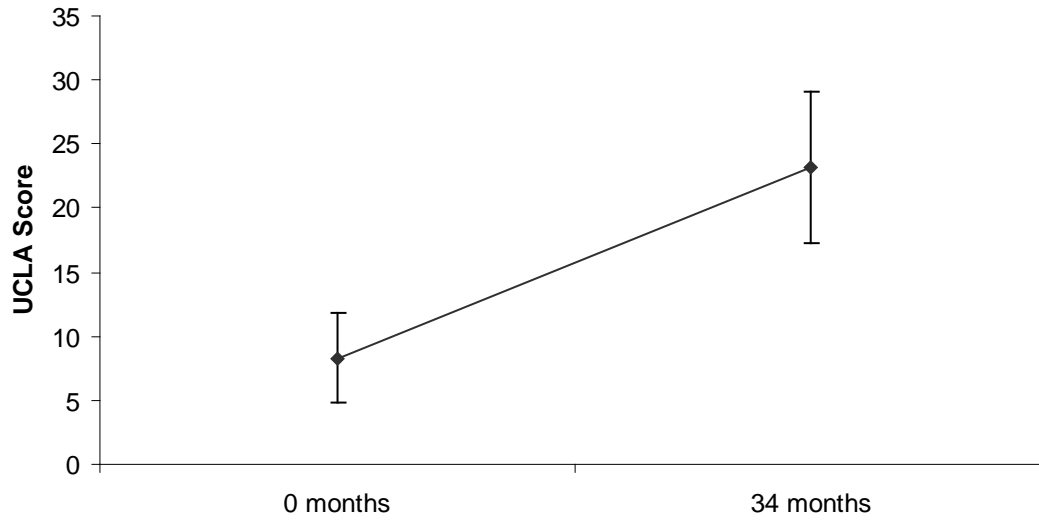


Author reported paired t-test, $p < .0001$

UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 57 UCLA



Author reported independent t-test, $p < .0005$

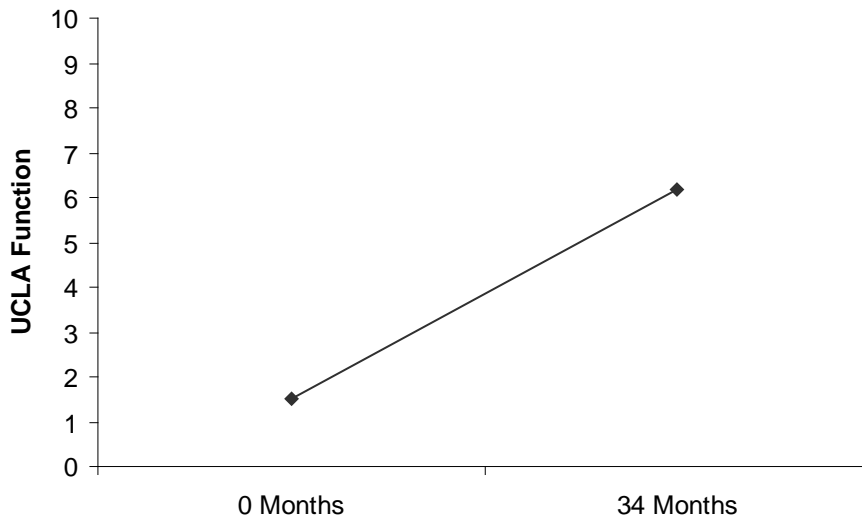
FUNCTION

Six Level V function outcome measures (please see Figure 58 through Figure 63) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with hemiarthroplasty. Patients completed a function assessment at baseline and at least 2 years post operatively. The results of four function assessment showed a statistically significant improvement from baseline. However, these results are based on limited evidence.

FUNCTION- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 58 Function measured by UCLA



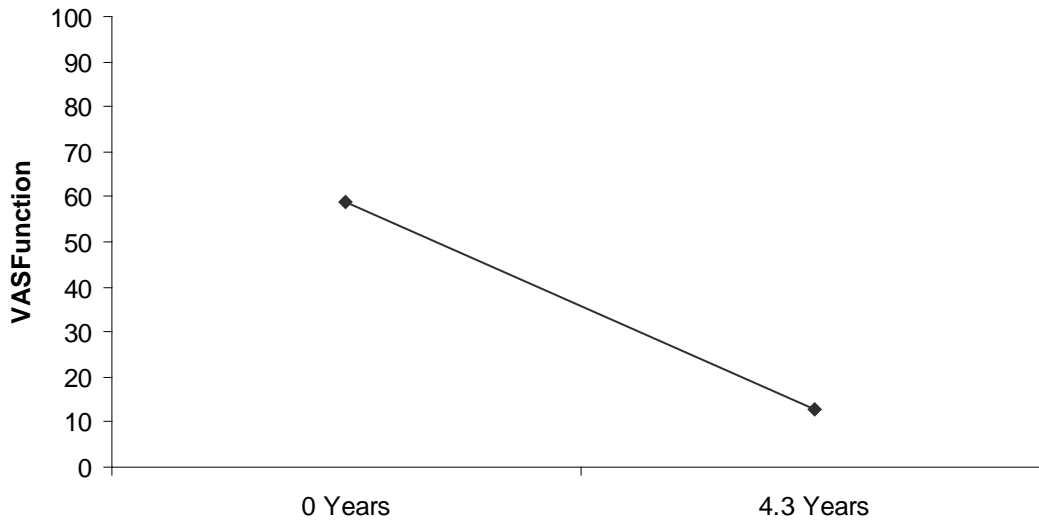
Author reported independent t-test, $p < .0005$

Dispersion not reported by authors

FUNCTION- VAS

Orfaly, et al.¹⁹ did not report statistical significance or dispersion around either point estimate.

Figure 59 Function measured by VAS

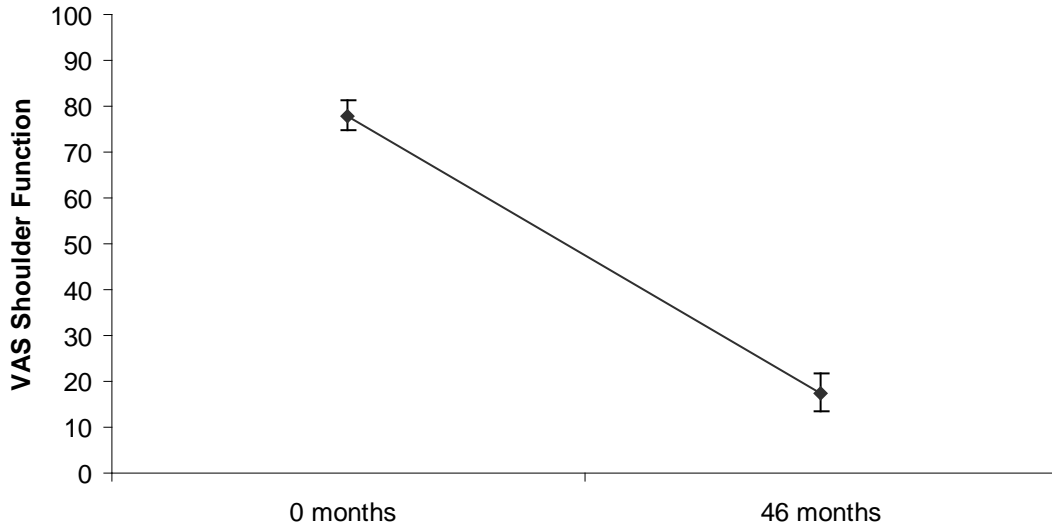


The authors did not report statistical significance
Dispersion not reported by authors

FUNCTION-VAS CONTINUED

Norris and Iannotti compared preoperative to postoperative VAS Function scores in patients with glenohumeral joint osteoarthritis. The authors found a statistically significant improvement in function scores at 46 months.

Figure 60 VAS Function

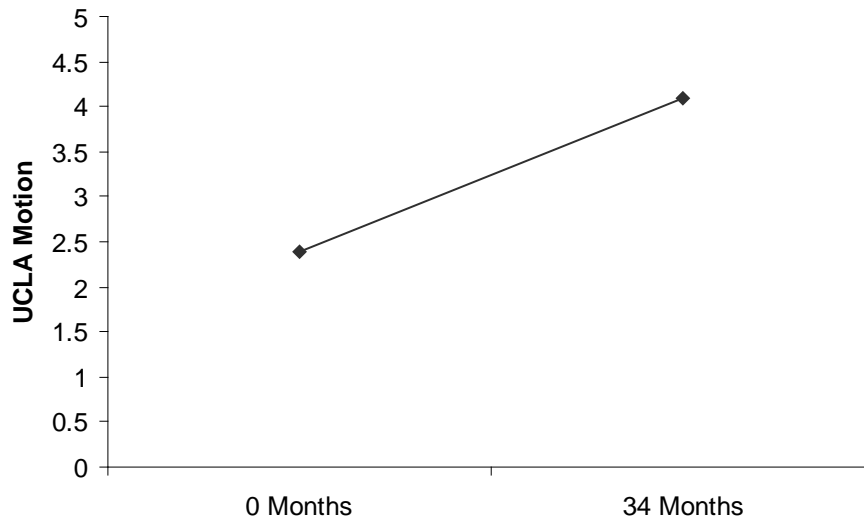


Author calculated t-test $p < .0001$
Dispersion reported as standard error of the mean

MOTION- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 61 Motion measured by UCLA



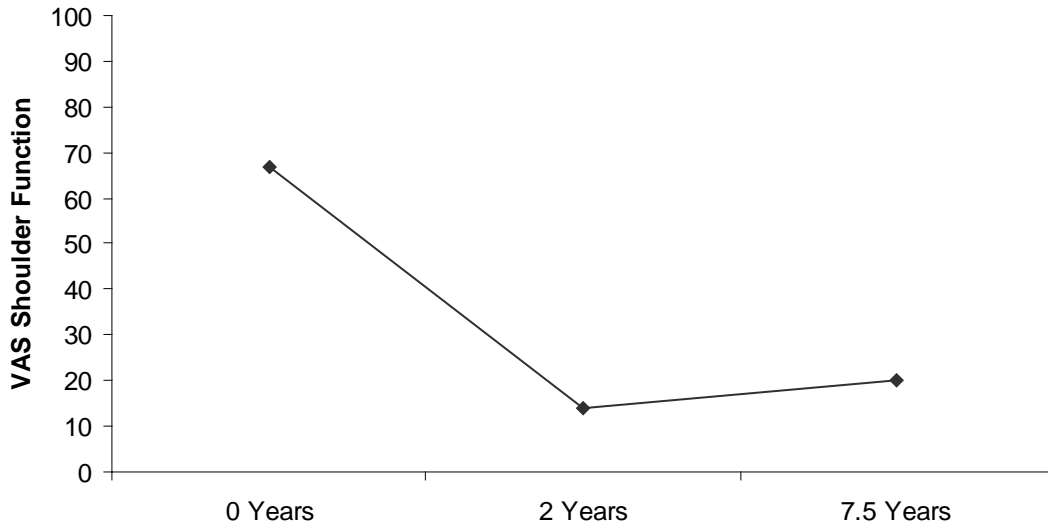
Author reported independent t-test, $p < .0005$

Dispersion not reported by authors

SHOULDER FUNCTION VAS

Wirth, et al.¹⁷ reported a statistically significant improvement between 0 days and 2 years ($p < .0001$) and between 0 days and 7.5 years ($p < .0001$). The authors reported the comparison between the two year and final follow up was not statistically significant ($p = .04$)

Figure 62 Shoulder function measured by VAS



0 days – 2 years- author reported paired t-test ($p < .0001$)

0 days- 7.5 years author reported paired t-test ($p < .0001$)

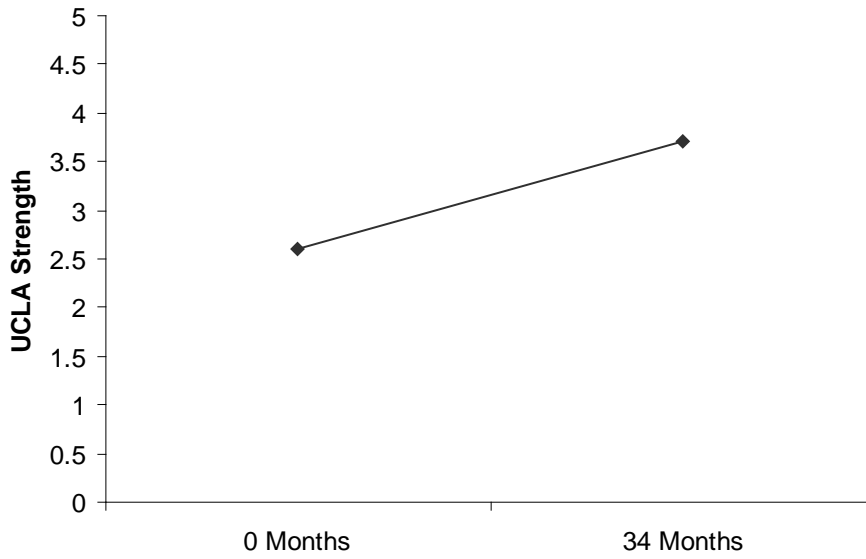
2 years- 7.5 years author reported paired t-test ($p = .04$)

Dispersion not reported by authors

STRENGTH- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 63 Strength measured by UCLA



Author reported independent t-test, $p < .0005$

Dispersion not reported by authors

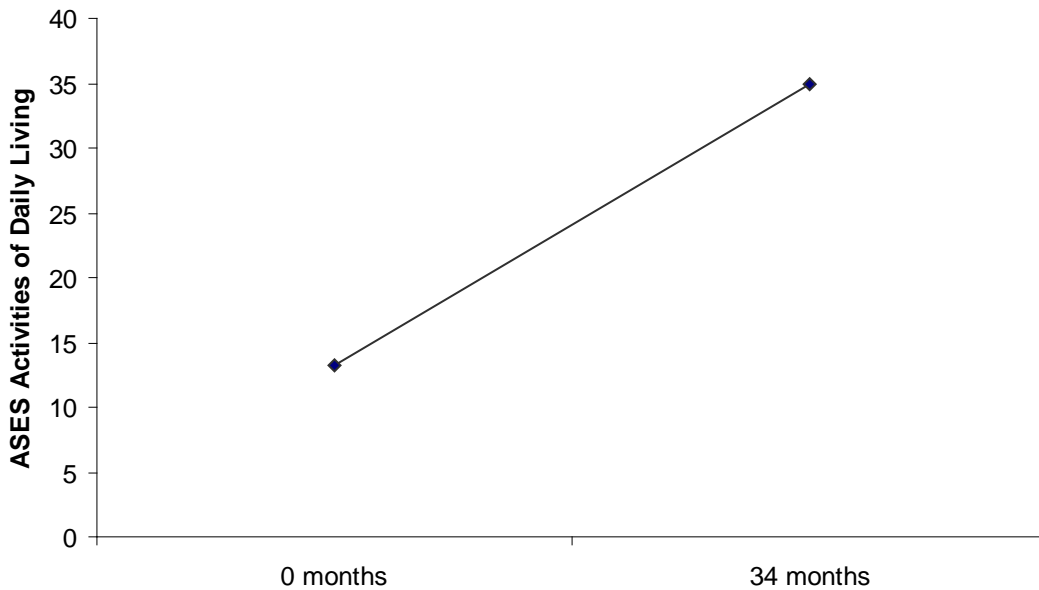
QUALITY OF LIFE

Six Level V quality of life measurements (please see Figure 64 through Figure 69) are reported in patients with primary osteoarthritis of the glenohumeral joint treated with hemiarthroplasty. Patients completed a quality of life assessment at baseline and at least 2 years post operatively. The results of all quality of life assessment showed a statistically significant improvement from baseline. However, these results are based on limited evidence

ACTIVITIES OF DAILY LIVING-ASES

Gartsman, et al.¹⁸ reported a statistically significant improvement in ASES score from baseline ($p < .0005$).

Figure 64 Activities of Daily Living measured by ASES

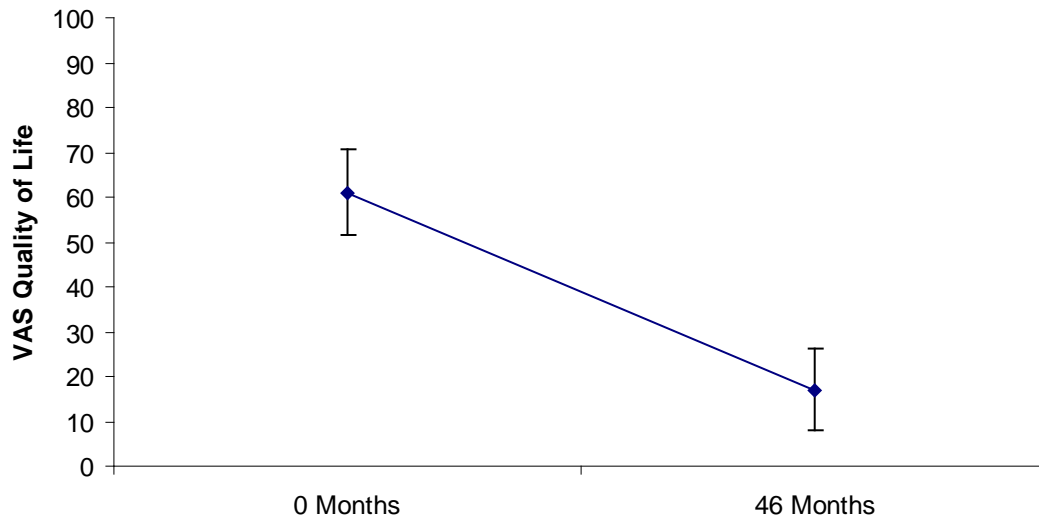


Author reported independent t-test, $p < .005$
Dispersion not reported by authors

QUALITY OF LIFE-VAS

Iannotti, et al.¹⁷ reported a statistically significant improvement in VAS quality of life score from baseline at 46 months ($p < .0001$)

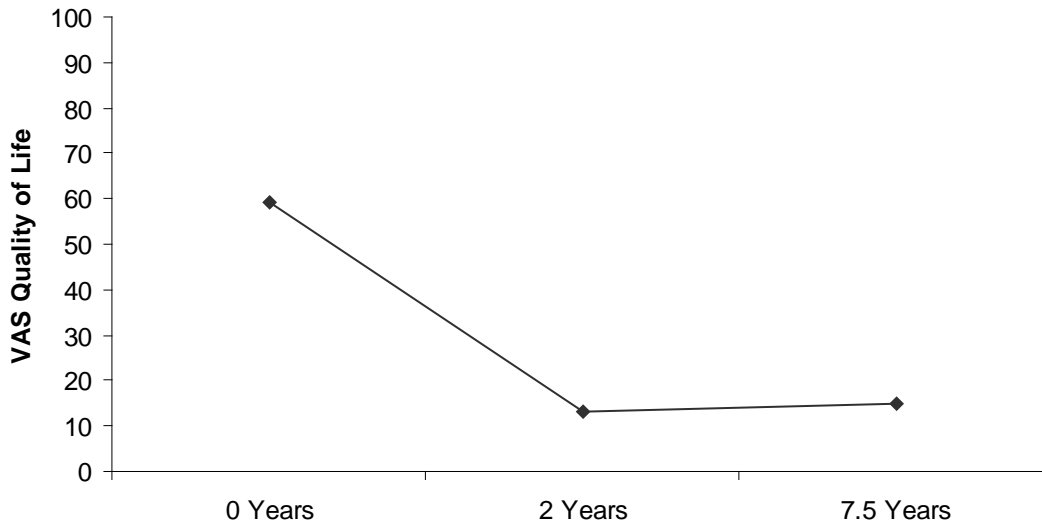
Figure 65 Quality of Life- VAS



Author reported t-test ($p < .0001$)

Wirth, et al.¹⁷ reported a statistically significant improvement between 0 days and 2 years ($p < .0001$) and between 0 days and 7.5 years ($p < .0001$) but that the comparison between the two year and final follow up was not statistically significant ($p = .84$)

Figure 66 Quality of Life measured by VAS



0 days – 2 years- author reported paired t-test ($p < .0001$)

0 days- 7.5 years author reported paired t-test ($p < .0001$)

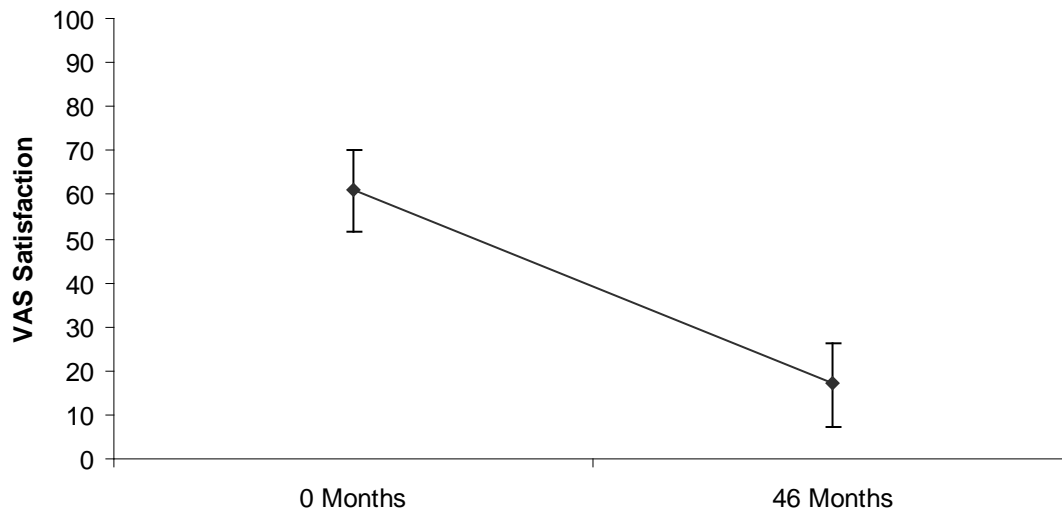
2 years- 7.5 years author reported paired t-test ($p = .84$)

Dispersion not reported by authors

SATISFACTION- VAS

Iannotti, et al.¹⁷ reported a statistically significant improvement in ASES score from baseline at 46 months ($p < .0001$).

Figure 67 VAS Satisfaction

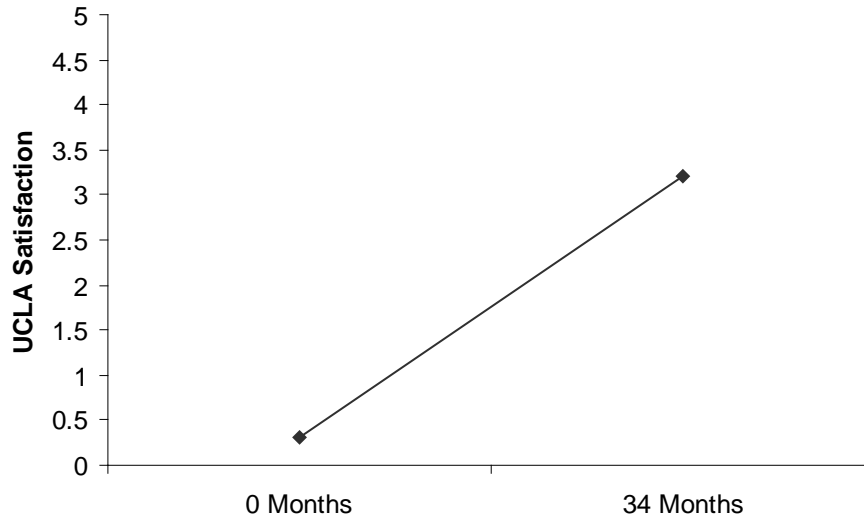


Authors reported paired t-test, $p < .0001$

SATISFACTION- UCLA

Gartsman, et al.¹⁸ reported a statistically significant improvement in UCLA score from baseline ($p < .0005$).

Figure 68 Satisfaction measured by UCLA



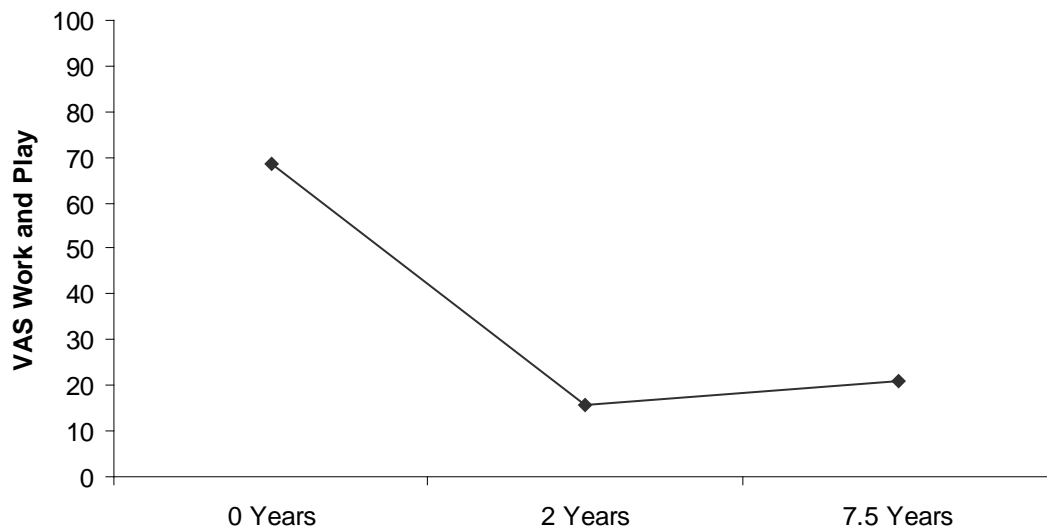
Author reported independent t-test, $p < .0005$

Dispersion not reported by authors

WORK AND PLAY-VAS

Wirth, et al.¹⁷ reported a statistically significant improvement between 0 days and 2 years ($p < .0001$) and between 0 days and 7.5 years ($p < .0001$). The authors reported the comparison between the two year and final follow up was not statistically significant ($p = .12$)

Figure 69 Work and Play measured by VAS



0 days – 2 years- author reported paired t-test ($p < .0001$)

0 days- 7.5 years author reported paired t-test ($p < .0001$)

2 years- 7.5 years author reported paired t-test ($p = .84$)

Dispersion not reported by authors

REPORTED ADVERSE EVENTS

Table 9 Reported Adverse Events Hemi arthroplasty

Author	Adverse Event	Treatment(s)	% Patients	N	Response to adverse event
Lo, et al. 2005	Intraoperative fracture	Hemi	10%	21	Treated during surgery
Cofield, et al. 1995	Humeral shaft fracture	Hemi	3%	35	Treated during surgery
Iannotti and Norris 2003	Periprosthetic fracture (Intraoperative)	TSA or Hemi	3%	33	Decrease intensity of rehabilitation program and healed Stabilized with two cortical bone screws Stabilized immediately with a long-stem prosthesis and two cerclage wires Three operative procedures to achieve a successful union
Iannotti and Norris 2003	Glenoid fractures (Intraoperative)	TSA or Hemi	2%	33	1 patient Humeral head replacement as well as reduction and fixation with a screw 1 patient Became stable after the glenoid component was cemented
Iannotti and Norris 2003	fractures (Intraoperative)	TSA or Hemi	2%	33	No additional action
Iannotti and Norris 2003	Glenoid Loosening and Glenohumeral instability	TSA or Hemi	5%	33	NR
Iannotti and Norris 2003	Postoperative humeral head subluxation or dislocation	TSA or Hemi	4%	33	1 patient Reoperation 1 patient No surgery 3 patients Follow up procedure unclear
Lo, et al. 2005	Superior migration of the humeral component with rotator cuff deficiency	Hemi	14%	21	No Action
Wirth, et al. 2006	Pain and migration of the humeral head	Hemi	2%	50	Revision surgery to total shoulder arthroplasty
Gartsman, et al. 2000	Increasing Pain and decreasing space between humeral head and the glenoid	Hemi	13%	24	Reoperation for resurfacing of the glenoid at 19, 39, and 48 months

Author	Adverse Event	Treatment(s)	% Patients	N	Response to adverse event
Lynch, et al. 2007	Pain and stiffness	Hemi	3%	35	Repeat concentric reaming of the glenoid 8 months after procedure.
Gartsman, et al. 2000	Stiffness that was unresponsive to postoperative rehabilitation	Hemi	4%	24	No Action
Wirth, et al. 2006	Postoperative subscapularis ruptures	Hemi	4%	50	Pectoralis major tendon transfer
Orfaly et al. 2003	Developed hematoma and a detachment of the subscapularis tendon	TSA or Hemi	2%	37	Evacuation of the hematoma and repair of the subscapularis
Orfaly et al. 2003	Developed a separation of the anterior deltoid origin after a trauma 1 year after surgery	TSA or Hemi	2%	37	Open repair
Iannotti and Norris 2003	Intraoperative transient radial nerve palsy	TSA or Hemi	1%	33	Resolved spontaneously after surgery
Wirth, et al. 2006	Idiopathic brachial plexus neuritis	Hemi	2%	50	NR
Cofield, et al. 1995	Hematoma	Hemi	3%	35	Surgical evacuation

RECOMMENDATION 8

We suggest total shoulder arthroplasty over hemiarthroplasty when treating patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Moderate**

Definition: A **Moderate** recommendation means that the benefits exceed the potential harm (or that the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the strength of the supporting evidence is not as strong.

Implications: Practitioners should generally follow a **Moderate** recommendation but remain alert to new information and be sensitive to patient preferences.

Rationale:

There were only two studies of sufficient quality to meet our inclusion criteria comparing total shoulder arthroplasty to hemiarthroplasty.^{18, 25} The largest of these studies reported that global health assessment scores and pain relief were statistically significantly better after total shoulder arthroplasty. Function and quality of life outcome measures in both studies showed no statistically significant differences between groups. No total shoulder arthroplasty required revision to hemiarthroplasty. However, 14% of patients treated with a hemiarthroplasty required revision to a total shoulder arthroplasty because of progressive glenoid arthrosis and pain. This difference in revision rates must be considered when contemplating shoulder arthroplasty and the possibility of a second operative exposure.

Supporting Evidence

Tables relevant to this recommendation are: Table 10 through Table 11

Figures relevant to this recommendation are: Figure 70 through Figure 88

We included two Level II studies, Gartsman, et al. (2000) and Lo, et al. (2005) that compare patients with glenohumeral osteoarthritis treated with either total shoulder arthroplasty or hemiarthroplasty.

Table 10 Summary Hemiarthroplasty versus TSA (Total Shoulder Arthroplasty)

Authors	Outcome Domain	Outcome	LoE	Comparison	N	Duration Months		
						24	35	46
Gartsman, et al. 2000	Pain	Pain ASES	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		●tsa	
Gartsman, et al. 2000		Pain UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		●tsa	
Gartsman, et al. 2000	Global Health Assessment	ASES	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		?	
Lo, et al. 2005		ASES	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	?		
Lo, et al. 2005		Constant and Murley	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Lo, et al. 2005		UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		

Authors	Outcome Domain	Outcome	LoE	Comparison	N	Duration Months		
						24	35	46
Gartsman, et al. 2000		UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		●tsa	
Gartsman, et al. 2000	Function	Function UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		○	
Gartsman, et al. 2000		Motion UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		○	
Gartsman, et al. 2000		Strength UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		○	
Gartsman, et al. 2000	Function	Activities of Daily Living ASES	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		○	
Lo, et al. 2005		Physical Component Scale SF-36	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Lo, et al. 2005	Quality of Life	Quality of Life WOOS	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		

Authors	Outcome Domain	Outcome	LoE	Comparison	N	Duration Months		
						24	35	46
Lo, et al. 2005		Physical Symptoms WOOS	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Lo, et al. 2005		Sports/Recreation/Work WOOS	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Lo, et al. 2005		Lifestyle WOOS	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Lo, et al. 2005		Emotions WOOS	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Lo, et al. 2005		Mental Component Scale SF-36	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	41	○		
Gartsman, et al. 2000		Satisfaction UCLA	II	Post Operative Score in Hemiarthroplasty group vs. Post Operative Score in Total Shoulder Arthroplasty	51		○	

?= not sufficiently powered to detect MCII; neither statistically or clinically significant ●= statistically significant difference ○= no statistically significant difference

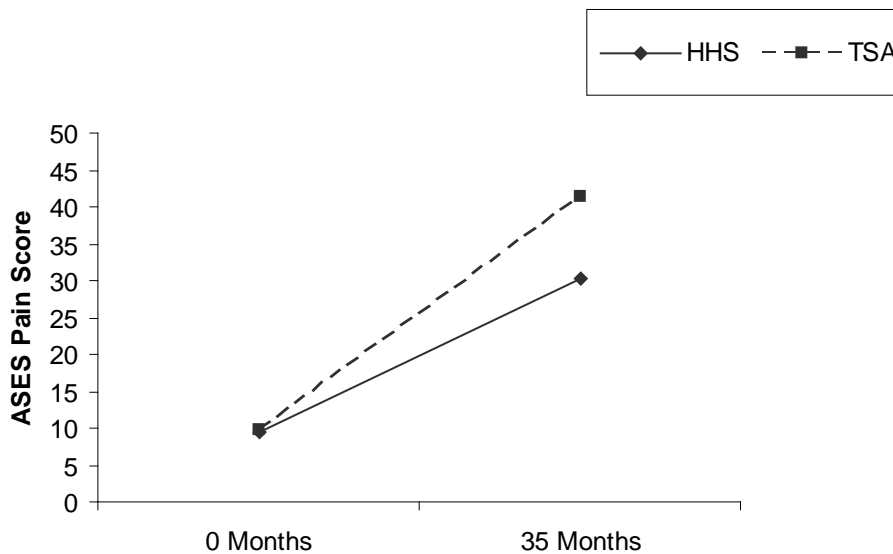
PAIN

Gartsman, et al.¹⁸ reported two Level II pain outcomes measurements, ASES and UCLA that assess treatment of osteoarthritis of the glenohumeral joint by hemiarthroplasty (HHS) (n=24) versus total shoulder arthroplasty (n=27). Patients assessed pain at thirty five months (range, 24-72 months). Both pain outcomes were statistically significantly in favor of TSA.

PAIN-ASES

Patients with osteoarthritis of the glenohumeral joint assessed pain using the ASES. Gartsman, et al.¹⁸ reported a statistically significant difference in pain relief, in favor of TSA, at thirty five months.

Figure 70 Pain measured by ASES



*Comparison of pain relief: author calculated independent t-test, $p=.002$

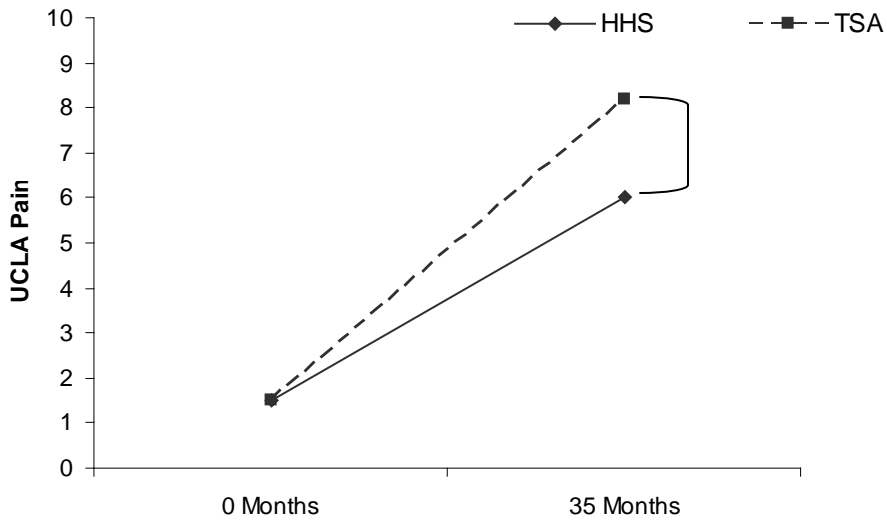
Dispersion not reported by authors

HHS= Hemiarthroplasty

PAIN-UCLA

Patients with osteoarthritis of the glenohumeral joint assessed pain using the UCLA. Gartsman, et al.¹⁸ reported a statistically significant difference in pain relief, in favor of TSA, at thirty five months ($p=.002$).

Figure 71 Pain measured by UCLA



*Author calculated independent t-test, $p=.002$

Dispersion not reported by authors

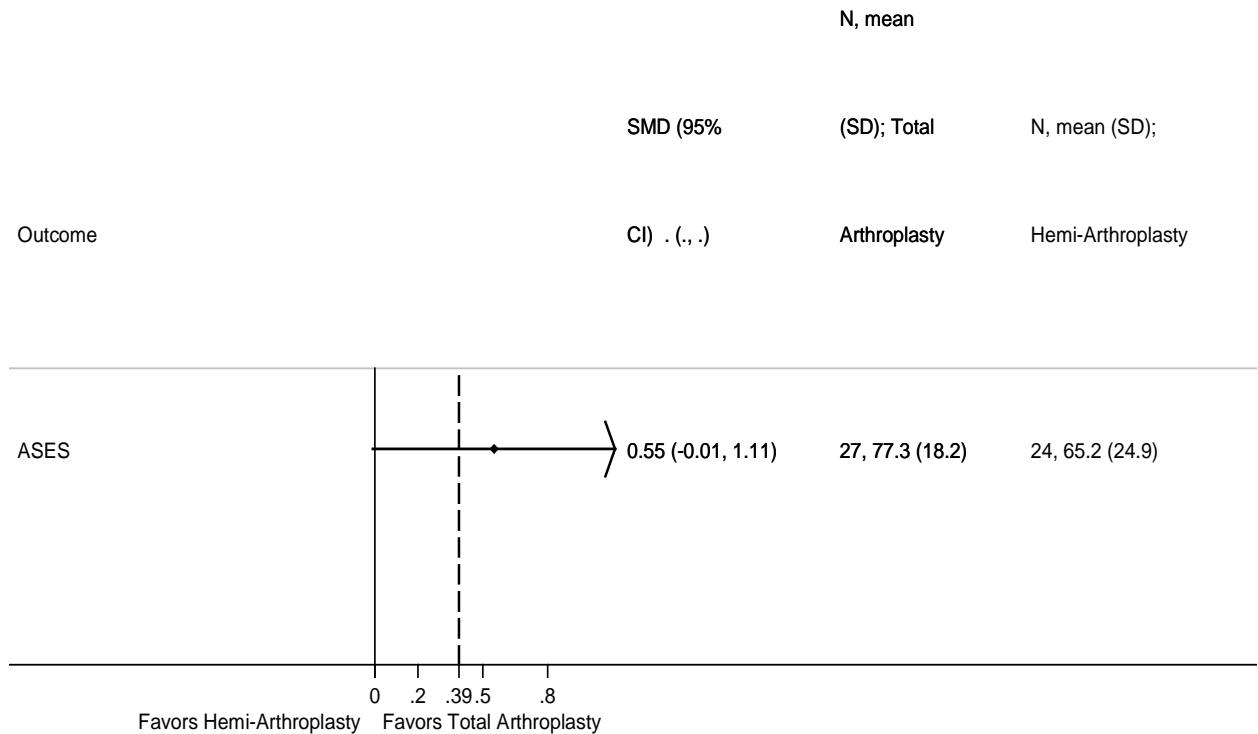
GLOBAL HEALTH ASSESSEMENT

Gartsman, et al.¹⁸ and Lo, et al.²⁵ reported five Level II global health outcome measures (see Figure 72 through Figure 76) that compared the overall health status of patients with glenohumeral joint osteoarthritis treated with hemiarthroplasty to patients treated with total shoulder repair. One measure showed a statistically significant difference between treatments, in favor of TSA (see Figure 75)

ASES

Gartsman, et al.¹⁸ compared ASES results of patients treated with total shoulder arthroplasty (n=27) to patients treated with hemiarthroplasty (n=24) using the ASES outcome measure. Patients completed the ASES scoring system at thirty five months (range, 24-72 months). The authors reported no statistically significant difference in ASES scores between the two groups. However, this study was not powered sufficiently to detect the MCII.

Figure 72 ASES Score



AAOS calculated effect size

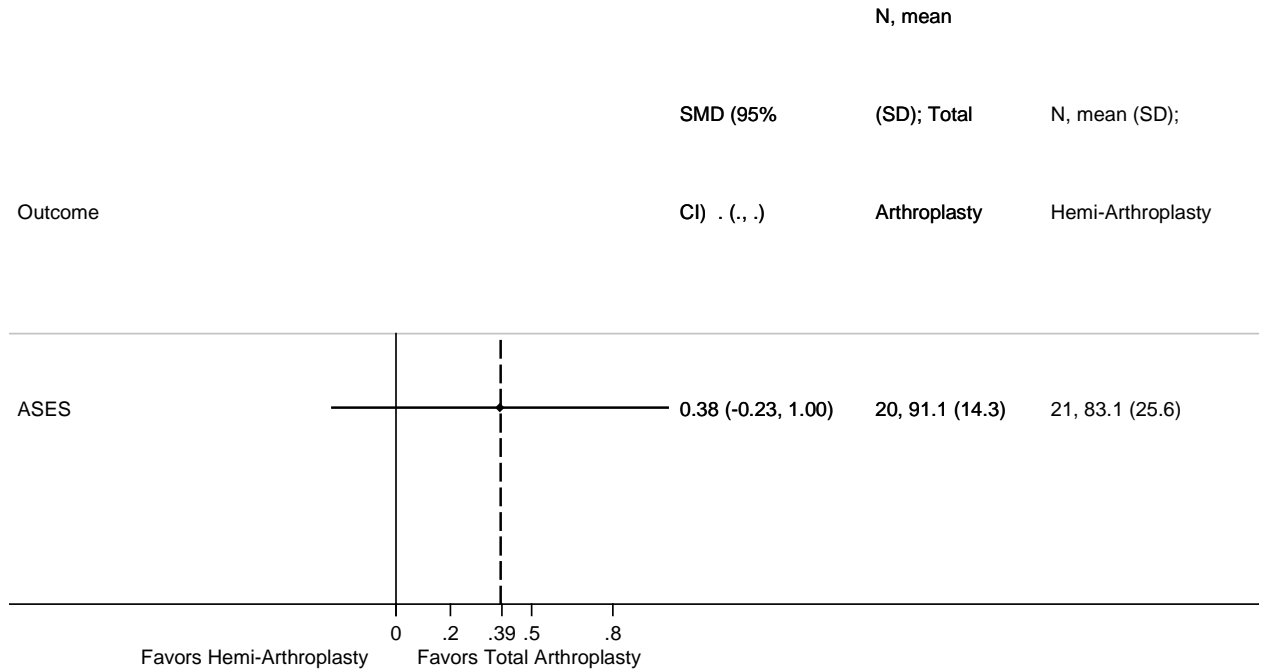
MCII indicated by dashed line

This study was not sufficiently powered to detect the MCII

ASES CONTINUED

Lo, et al.²⁵ compared patients treated with total shoulder arthroplasty (n= 20) to patients treated with hemiarthroplasty (n=21) using the ASES outcome measure. Patients completed the ASES scoring system at two years post operative. The authors reported no statistically significant difference in ASES scores between the two groups. However, this study was not powered sufficiently to detect the MCII

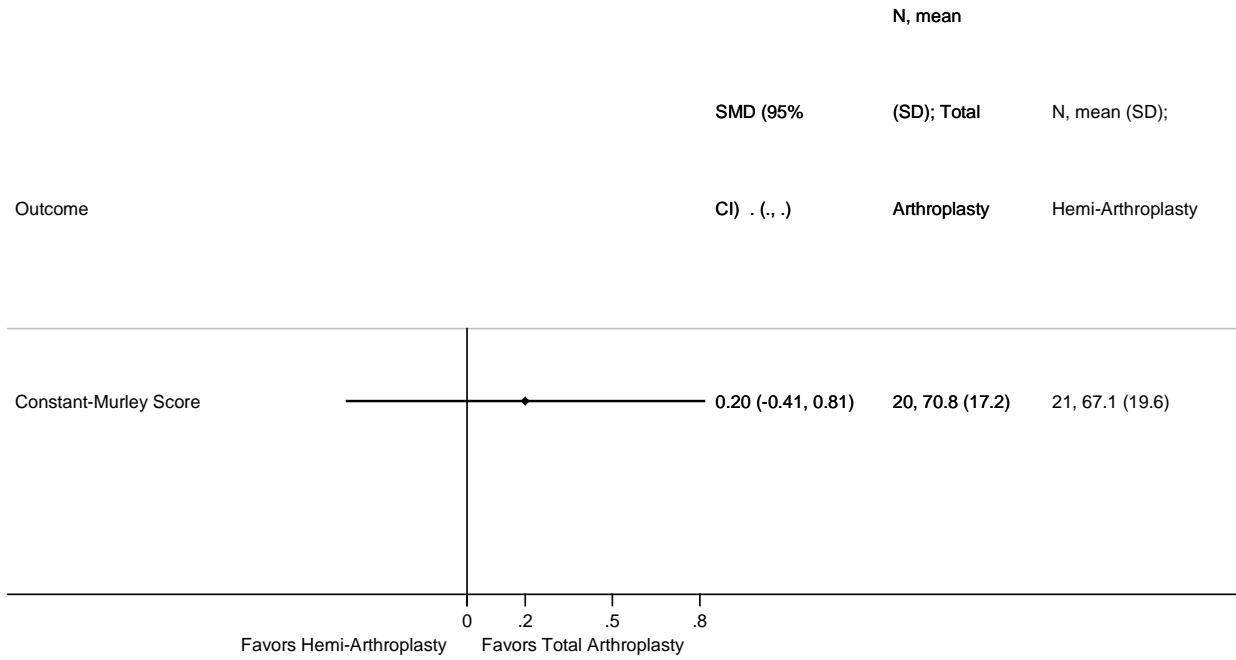
Figure 73 ASES Score



CONSTANT AND MURLEY SCORE

Lo, et al.²⁵ compared patients treated with total shoulder arthroplasty (n= 20) to patients treated with hemiarthroplasty (n=21) using the Constant and Murley outcome measure. Patients completed the Constant and Murley scoring system at two years post operative. The authors reported no statistically significant difference in Constant and Murley scores between the two groups.

Figure 74 Constant and Murley Score

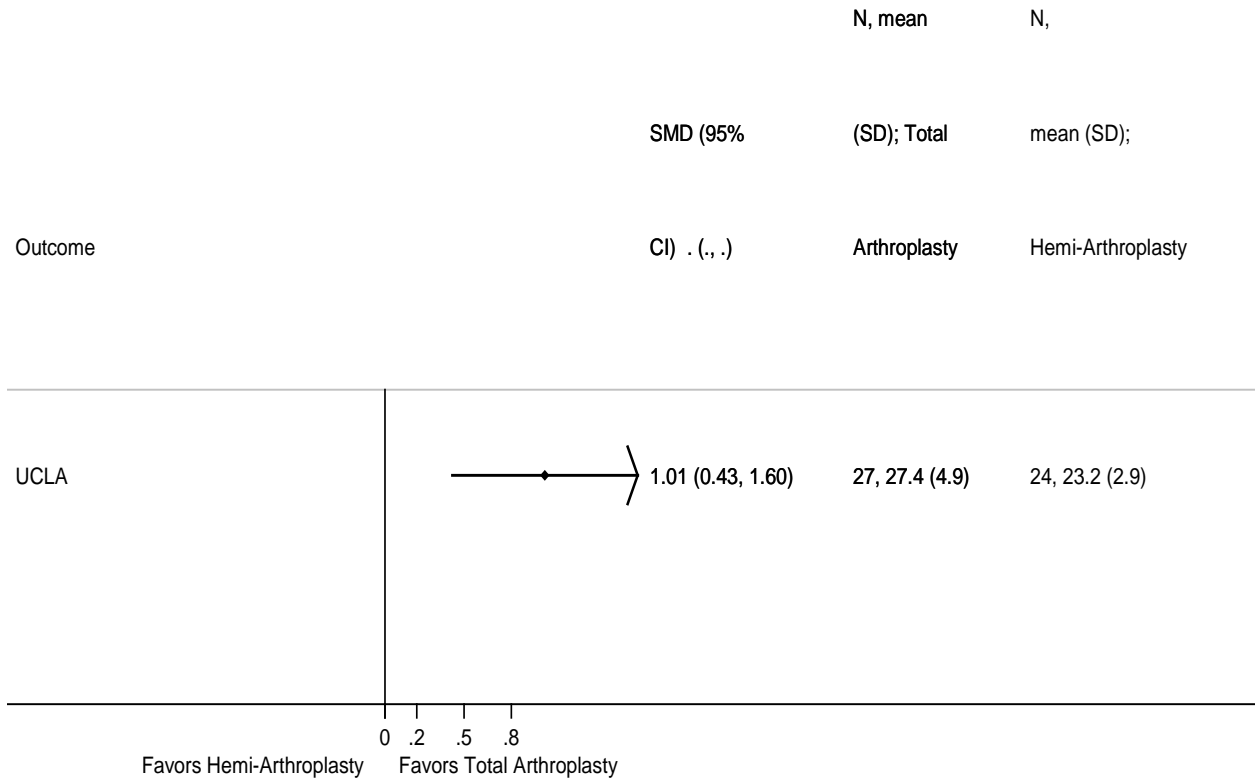


AAOS calculated effect size

UCLA TOTAL SCORE

Gartsman, et al.¹⁸ compared UCLA scores at thirty-five months (range, 24-72 months) postoperative of patients treated with total shoulder arthroplasty (n=27) to scores of those treated with hemiarthroplasty (n=24). Results were statistically significant in favor of total shoulder arthroplasty at two years.

Figure 75 UCLA Score

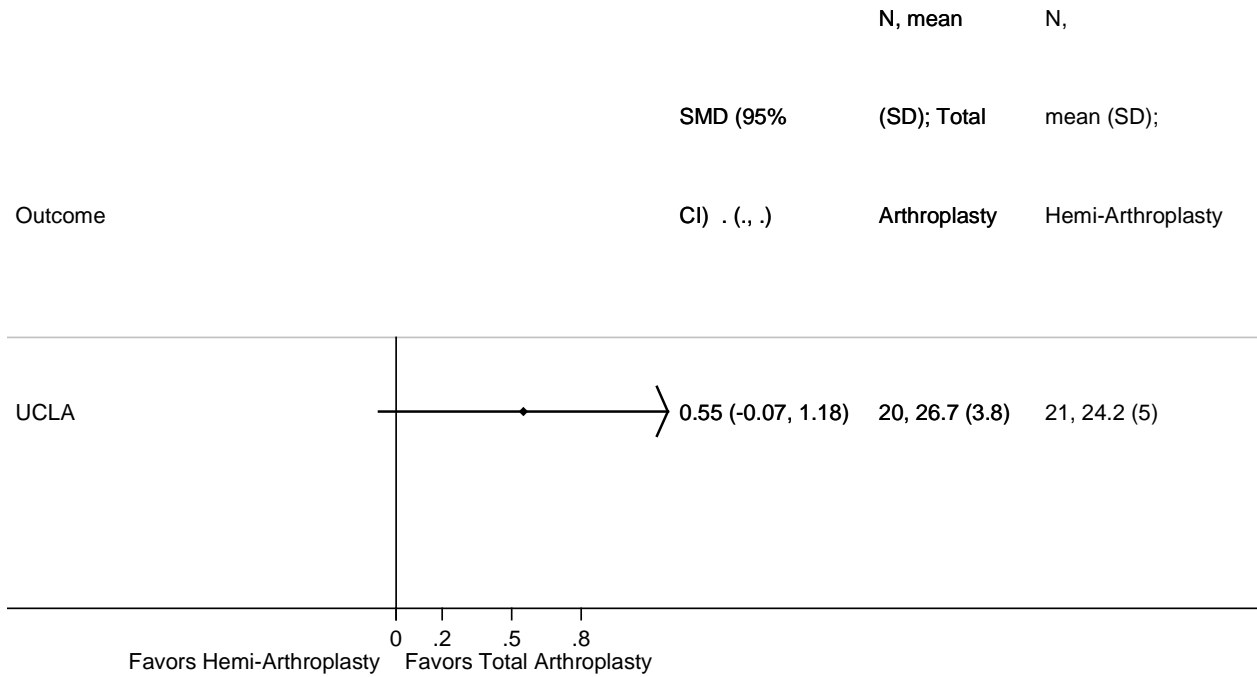


AAOS calculated effect size

UCLA TOTAL SCORE CONTINUED

Lo, et al.²⁵ compared patients treated with total shoulder arthroplasty (n=20) to patients treated with hemiarthroplasty (n=21) using the UCLA outcome measure. Patients completed the UCLA scoring system at two years post operative. The authors reported no statistically significant difference in UCLA scores between the two groups.

Figure 76 UCLA Score



AAOS calculated effect size

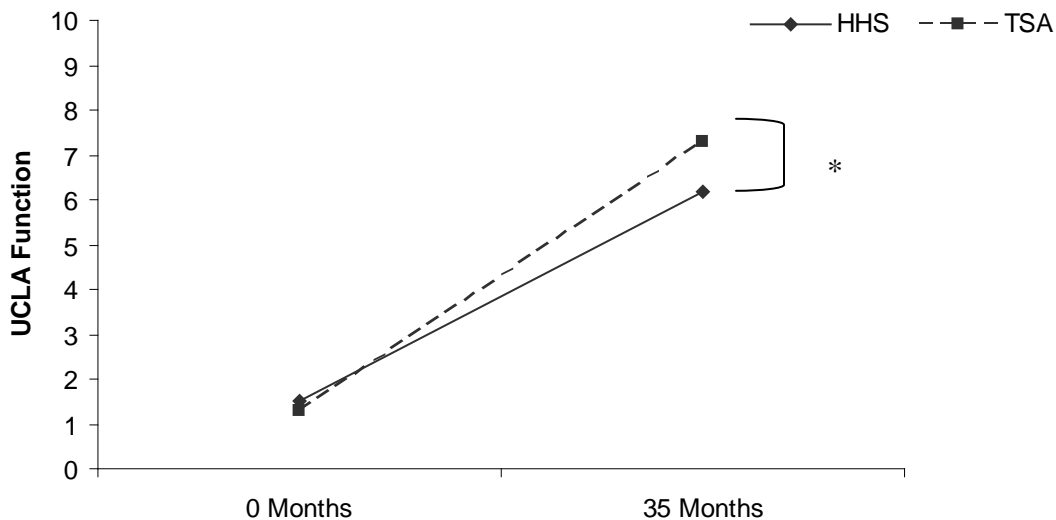
FUNCTION

Gartsman, et al.¹⁸ and Lo, et al.²⁵ report five Level II function outcome measures that compare patients treated with total shoulder arthroplasty to those treated with hemiarthroplasty. None of the results showed a statistically significant difference between groups.

FUNCTION- UCLA

Patients with osteoarthritis of the glenohumeral joint assessed function with the UCLA 35 months post operative (range 24-72 months). Gartsman, et al.¹⁸ compared results of the UCLA function assessment in patients treated with total shoulder arthroplasty (n= 24) to the results of those treated with hemiarthroplasty (n=27). Authors report no statistically significant difference between groups ($p=.097$).

Figure 77 Function measured by UCLA



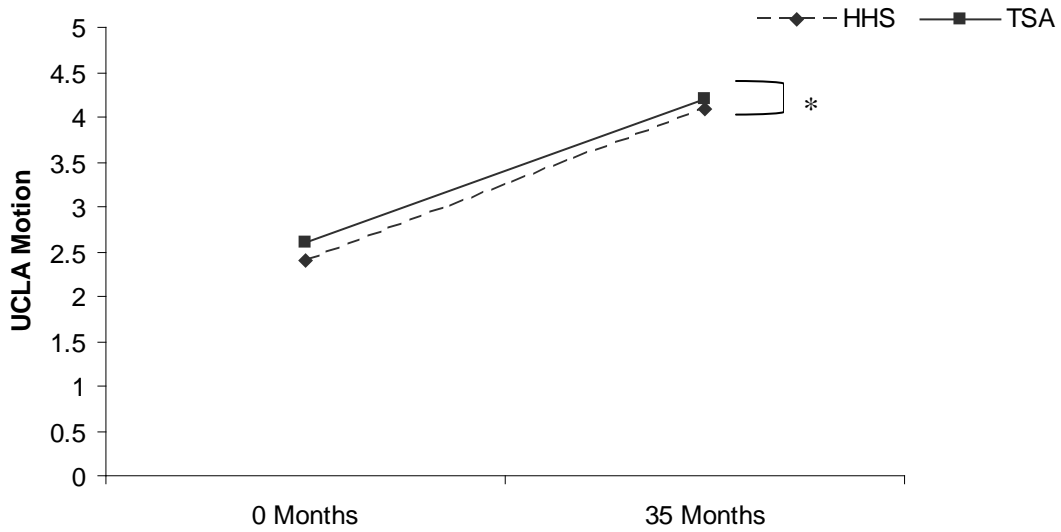
* Author calculated independent t-test, $p=.097$

Dispersion not reported by authors

MOTION-UCLA

Patients with osteoarthritis of the glenohumeral joint assessed motion with the UCLA assessment at 35 months post operative (range 24-72 months). Gartsman, et al.¹⁸ compared results of the UCLA motion assessment in patients treated with total shoulder arthroplasty (n=27) to the results of those treated with hemiarthroplasty (n=24). Authors report no statistically significant difference between groups ($p=.614$).

Figure 78 Motion measured by UCLA



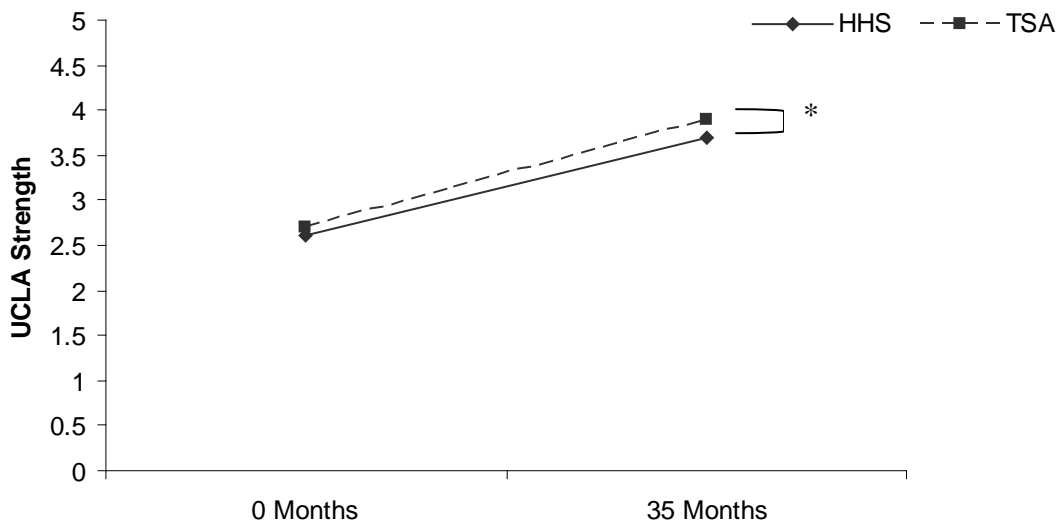
* Author calculated independent t-test, $p=.614$

Dispersion not reported by authors

STRENGTH-UCLA

Patients with osteoarthritis of the glenohumeral joint assessed strength with the UCLA assessment at 35 months post operative (range 24-72 months). Gartsman, et al.¹⁸ compared results of the UCLA strength assessment in patients treated with total shoulder arthroplasty (n=27) to the results of those treated with hemiarthroplasty (n=24). Authors report no statistically significant difference between groups ($p=.441$).

Figure 79 Strength measured by UCLA



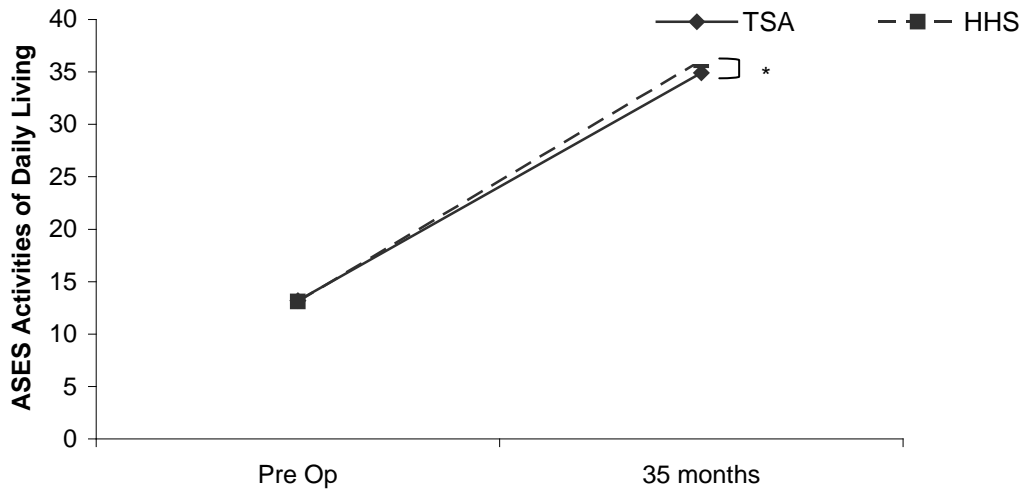
* Author calculated independent t-test, $p=.441$

Dispersion not reported by authors

ACTIVITIES OF DAILY LIVING- ASES

Patients with osteoarthritis of the glenohumeral joint assessed function with the ASES Activity of Daily Living assessment at 35 months post operative (range 24-72 months). Gartsman, et al.¹⁸ compared results of the ASES Activities of Daily Living assessment in patients treated with total shoulder arthroplasty (n= 27) to the results of those treated with hemiarthroplasty (n=24). Authors report no statistically significant difference between groups ($p=.723$).

Figure 80 ASES Activities of Daily Living



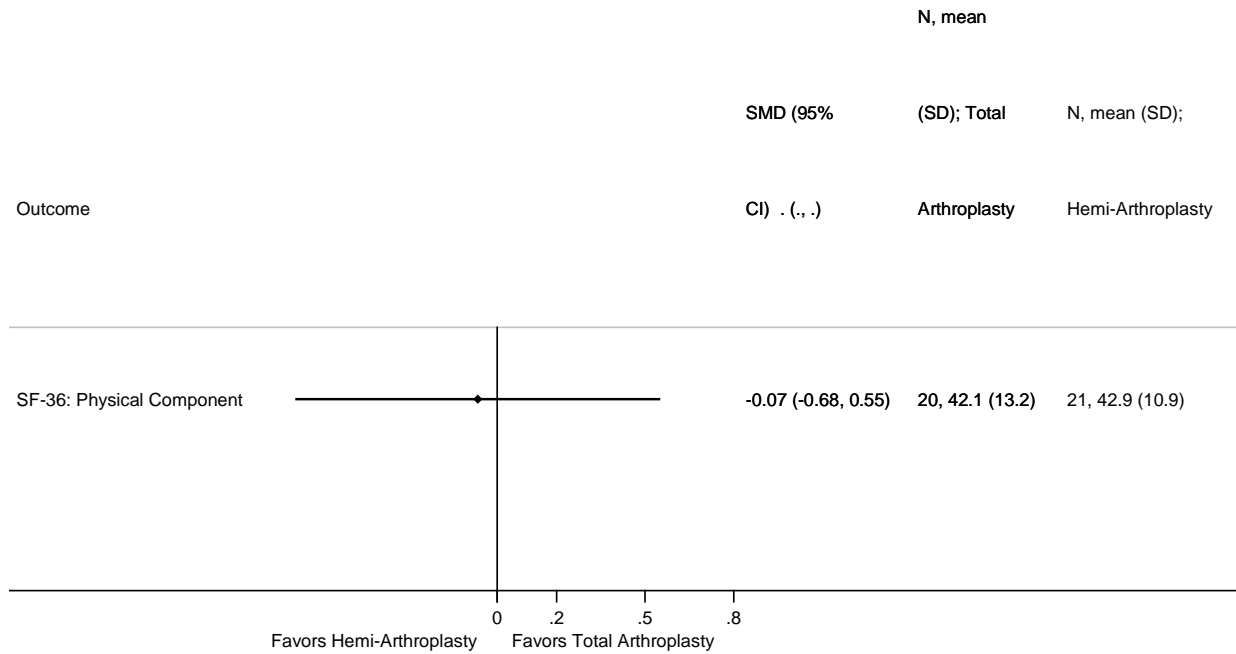
* Author calculated independent t-test, $p=.723$

Dispersion not reported by authors

SF-36 PHYSICAL COMPONENT

Patients with osteoarthritis of the glenohumeral joint assessed their physical status using the SF-36 physical component at two years post operative. Lo, et al.²⁵ compared SF-36 physical component results of patients treated with total shoulder arthroplasty (n=20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 81 SF-36 Physical Component



AAOS calculated effect size

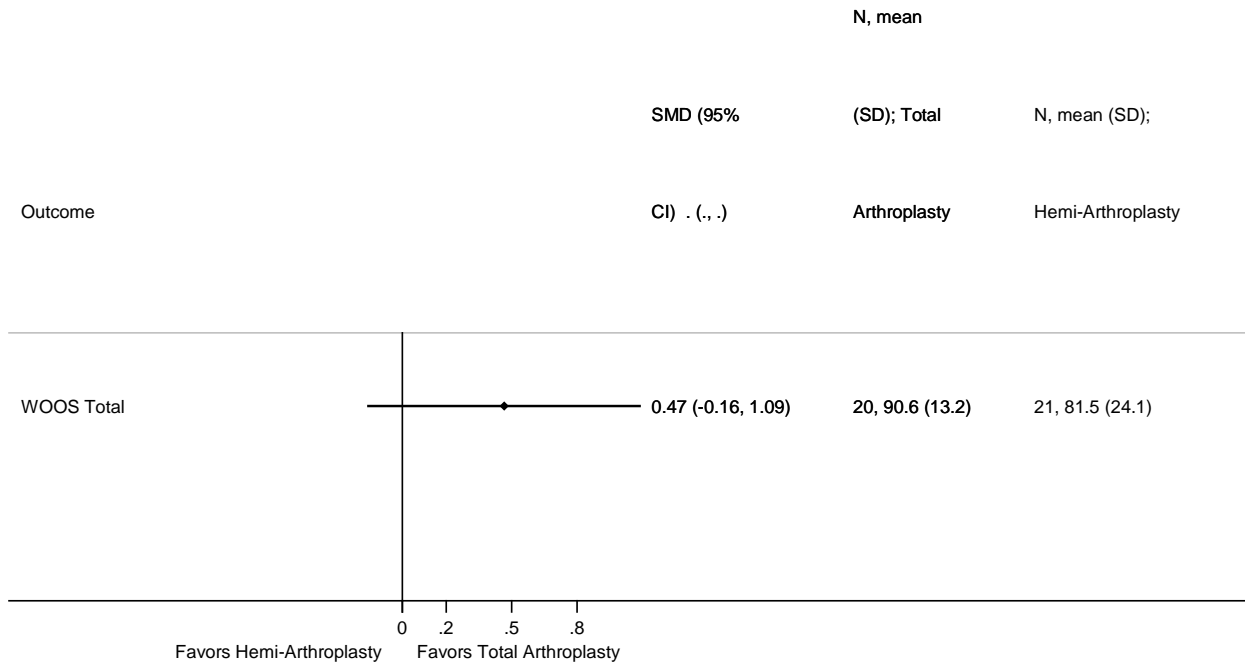
QUALITY OF LIFE

Gartsman, et al.¹⁸ and Lo et al report seven Level II quality of life outcome measures that compare patients with osteoarthritis of the glenohumeral treated with either TSA or HHS. None of the quality life outcome results showed a statistically significant difference between groups.

QUALITY OF LIFE- WOOS

Lo, et al.²⁵ compared WOOS quality of life results of patients treated with total shoulder arthroplasty (n=20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 82 Quality of Life measured by WOOS

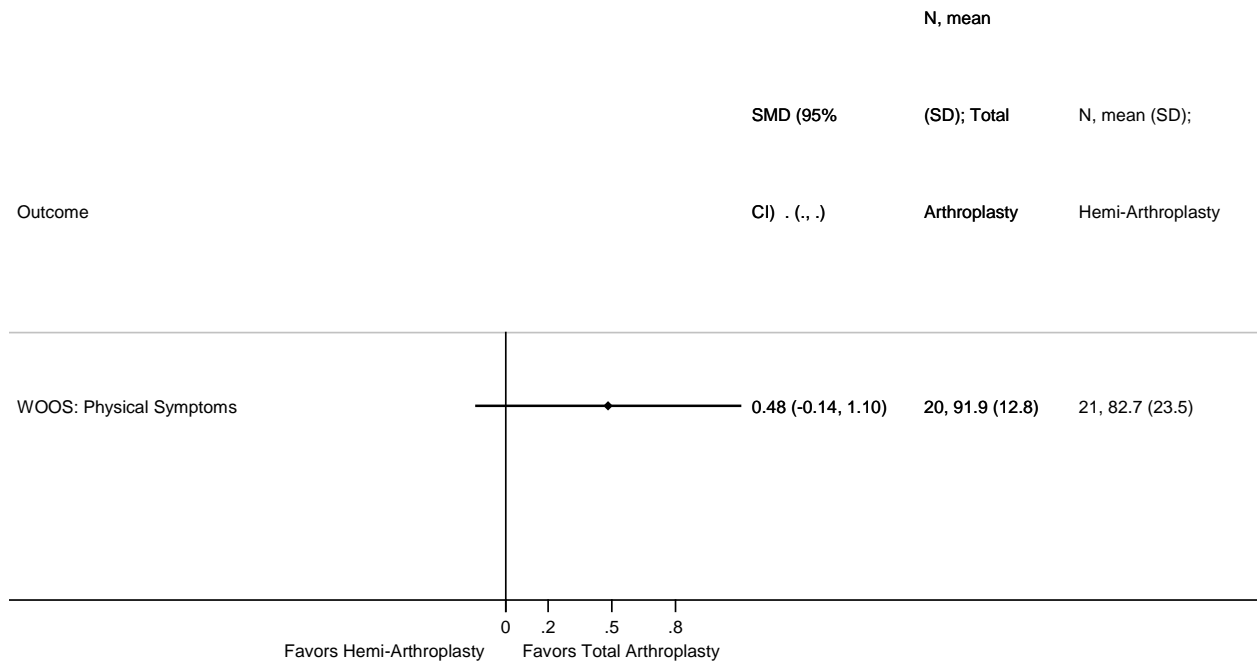


AAOS calculated effect size

PHYSICAL SYMPTOMS- WOOS

Patients with osteoarthritis of the glenohumeral joint assessed physical symptoms with the WOOS at two years post operative. Lo, et al.²⁵ compared WOOS physical symptom results of patients treated with total shoulder arthroplasty (n= 20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 83 Physical symptoms measured by WOOS

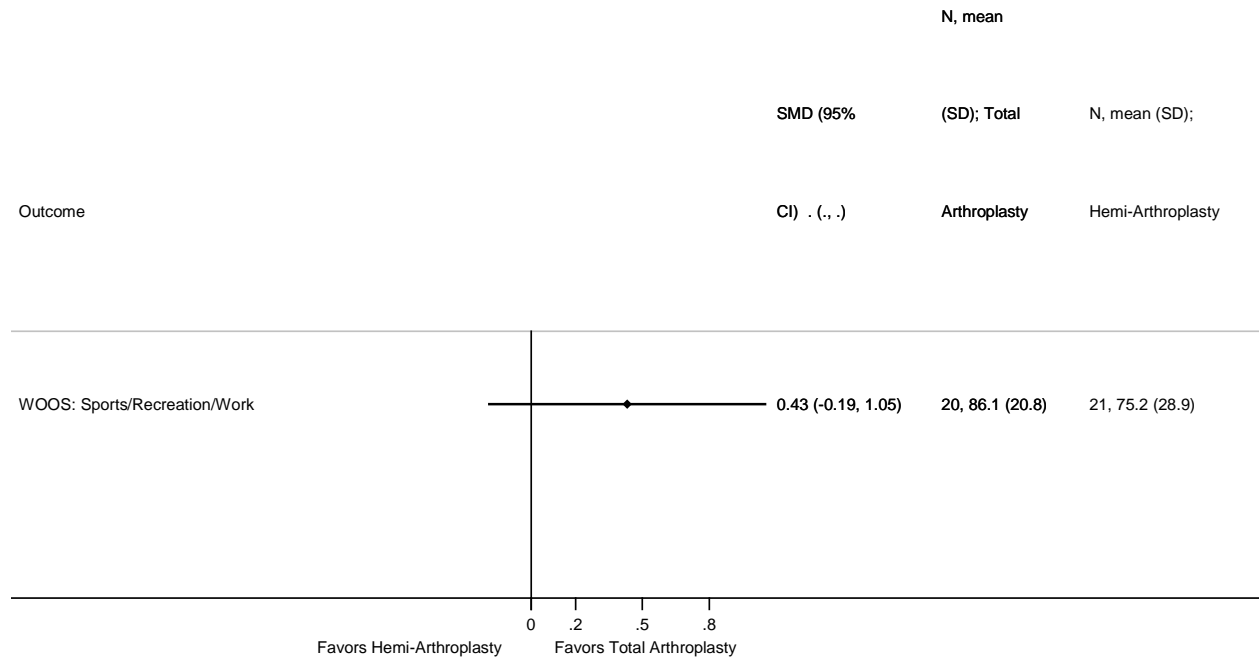


AAOS calculated effect size

SPORTS/RECREATION/WORK- WOOS

Lo, et al.²⁵ compared WOOS sports/recreation/work results of patients treated with total shoulder arthroplasty (n= 20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 84 Sports/Recreation/Work function measured by WOOS

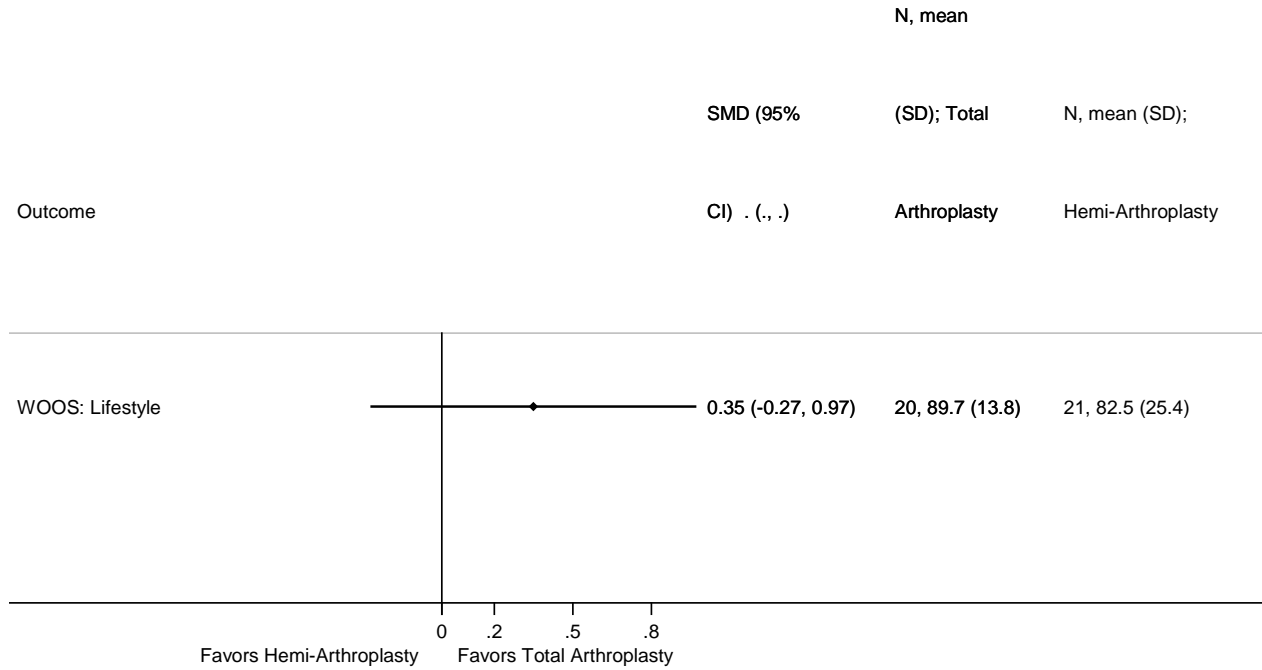


AAOS calculated effect size

LIFESTYLE- WOOS

Lo, et al.²⁵ compared WOOS lifestyle results of patients treated with total shoulder arthroplasty (n=20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 85 Lifestyle measured by WOOS

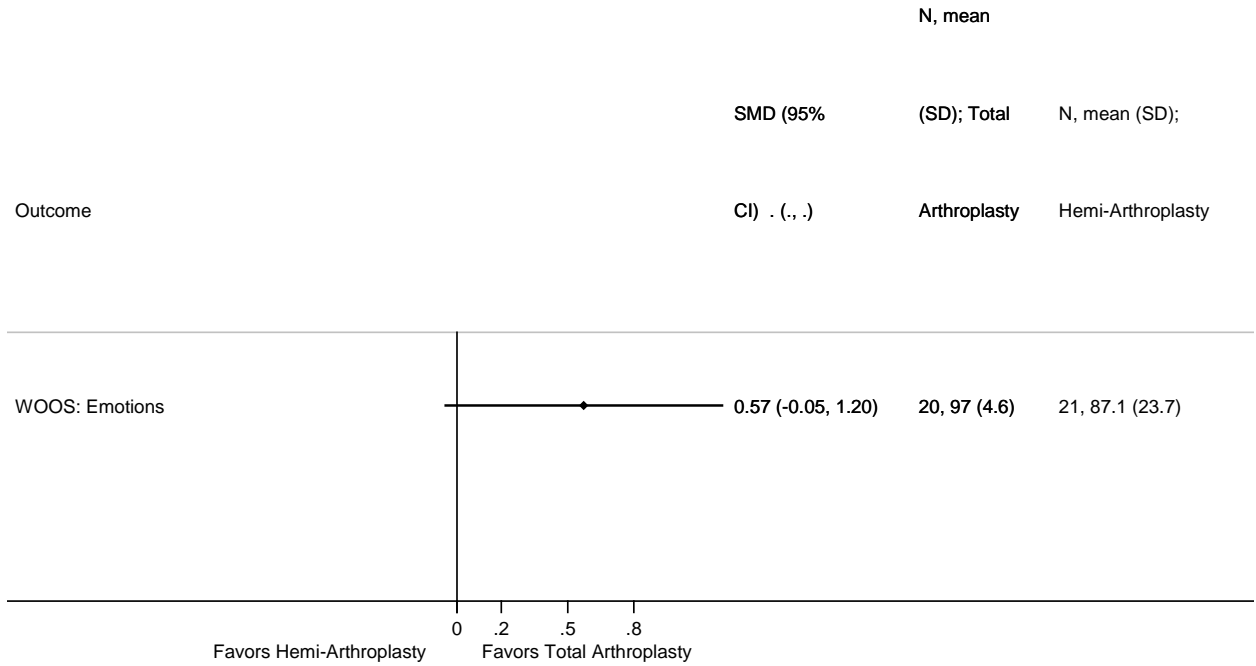


AAOS calculated effect size

EMOTIONS- WOOS

Lo, et al.²⁵ compared WOOS emotion results of patients treated with total shoulder arthroplasty (n= 20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 86 Emotions measured by WOOS

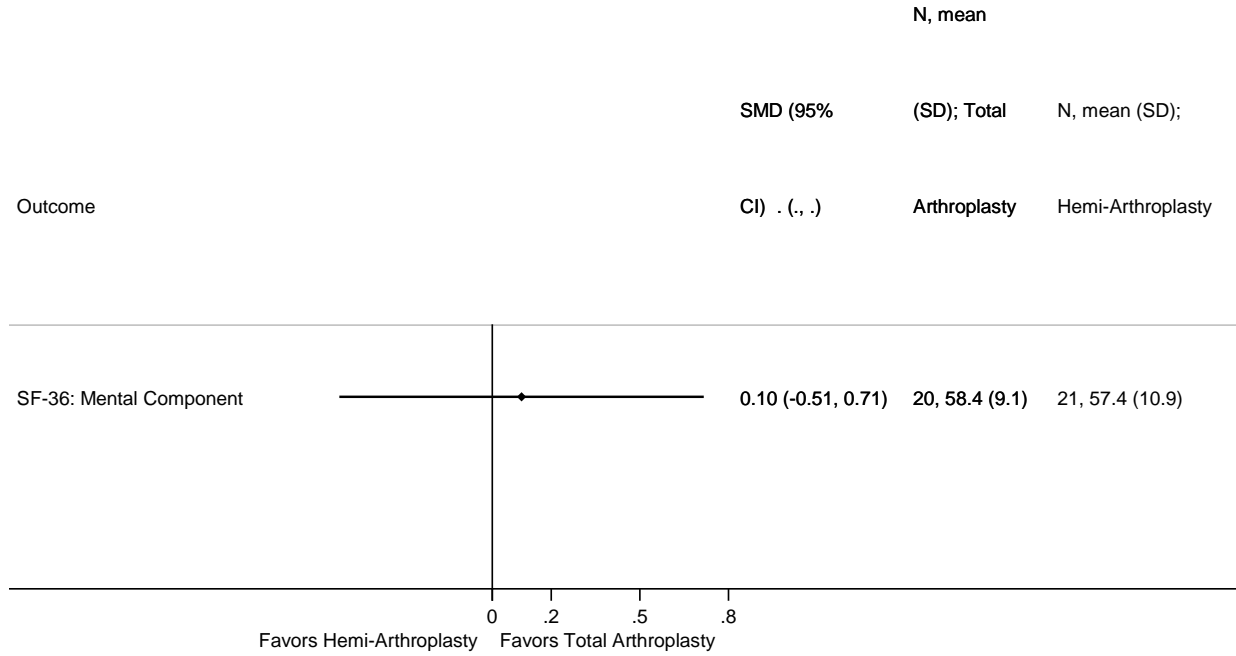


AAOS calculated effect size

SF-36 MENTAL COMPONENT

Lo, et al.²⁵ compared SF-36 mental component results of patients treated with total shoulder arthroplasty (n=20) to those of patients treated with hemiarthroplasty (n=21). The results at two years were not statistically significantly different between groups.

Figure 87 SF-36 Mental Component

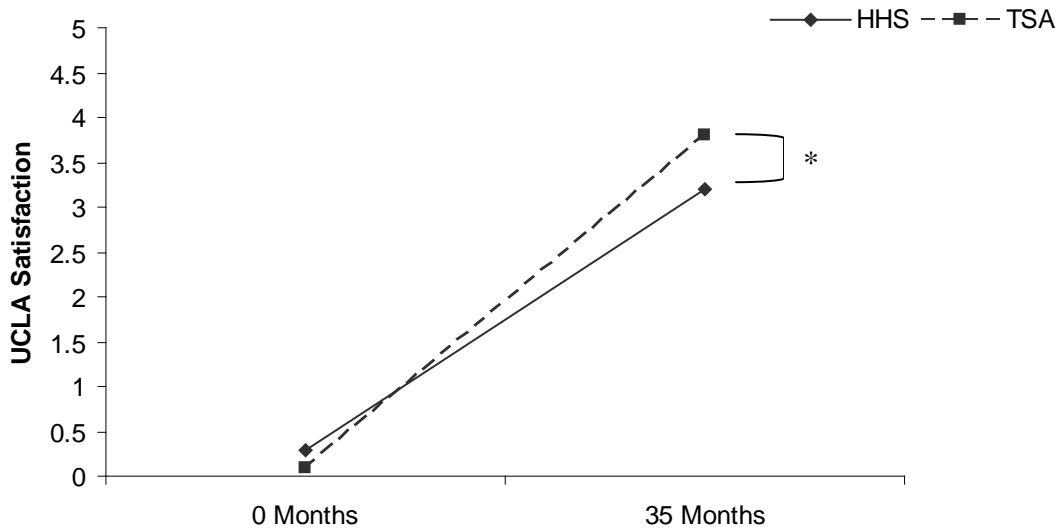


AAOS calculated effect size

SATISFACTION-UCLA

Gartsman, et al.¹⁸ compared results of the UCLA satisfaction assessment in patients treated with total shoulder arthroplasty (n=27) to the results of those treated with hemiarthroplasty (n=24). Authors report no statistically significant difference between groups ($p=.082$).

Figure 88 Satisfaction measured by UCLA



* Author calculated independent t-test, $p=.082$

Dispersion not reported by authors

ADVERSE EVENTS

Table 11 Adverse Events

Author	Adverse Event	HHS	N	Responsive Action to Event by Physician	TSA	N	Responsive Action to Event by Physician	% complications in TSA vs. HHS
Gartsman, et al. 2000	Pain and decreasing space between the humeral head and glenoid	14%	24	Reoperation for resurfacing of the glenoid	0%	27	Not applicable	●
Gartsman, et al. 2000	Severe pain	0%	24	Not applicable	4%	27	No additional surgery	○
Gartsman, et al. 2000	Stiffness that was unresponsive to rehabilitation	5%	24	No additional surgery	4%	27	No additional surgery	○
Lo, et al. 2005	Intraoperative Fracture	10%	21	Fixed during surgery	0%	20	Not applicable	●
Lo, et al. 2005	Nondisplaced Fracture of the greater tuberosity	0%	21	Not applicable	5%	20	Fixed during surgery	○
Lo, et al. 2005	Fracture of the anterior-inferior corner of the glenoid	0%	21	Not applicable	5%	20	Fixed during surgery	○

Author	Adverse Event	HHS	N	Responsive Action to Event by Physician	TSA	N	Responsive Action to Event by Physician	% complications in TSA vs. HHS
Lo, et al. 2005	Anterosuperior instability of the prosthesis at 6 months post surgery	5%	21	No additional surgery	0%	20	Not applicable	○
Lo, et al. 2005	Infection 2 weeks post surgery	0%	21	Not applicable	5%	20	Treated with two operative debridements two weeks after surgery and intravenous antibiotics for six weeks	○
Lo, et al. 2005	Superior migration of the humeral component with rotator cuff deficiency	5%	21	Revision	0%	20	Not applicable	○
Lo, et al. 2005	Progressive Glenoid Arthrosis	14%	24	Revision (16-19 months after initial surgery)	0%	20	Not applicable	●

Author	Adverse Event	Responsive Action to Event by Physician			Responsive Action to Event by Physician			% complications in TSA vs. HHS
		HHS	N		TSA	N		
Lo, et al. 2005	Fracture of the anterior-inferior corner of the glenoid	0%	21	Not applicable	5%	20	Fixed during surgery	○
Lo, et al. 2005	antero-superior instability of the prosthesis at 6 months post surgery	5%	21	No additional surgery	0%	20	Not applicable	○
Lo, et al. 2005	Infection 2 weeks post surgery	0%	21	Not applicable	5%	20	Treated with two operative debridements two weeks after surgery and intravenous antibiotics for six weeks	○
Lo, et al. 2005	Superior migration of the humeral component with rotator cuff deficiency	5%	21	Revision	0%	20	Not applicable	○
Lo, et al. 2005	Progressive Glenoid Arthrosis	14%	24	Revision (16-19 months after initial surgery)	0%	20	Not applicable	●

○ = No statistically significant difference between groups

● = Statistically significant in favor of total shoulder arthroplasty

RECOMMENDATION 9

An option for reducing immediate postoperative complication rates is for patients to avoid shoulder arthroplasty by surgeons who perform less than 2 shoulder arthroplasties per year.

AAOS Strength of Recommendation: **Limited**

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Two studies^{26, 27} reported increased early postoperative complication rates and increased length of stay when shoulder arthroplasty is performed by low volume surgeons. Low volume was defined as surgeons who perform less than two shoulder arthroplasties per year. Complications were only defined in one study and included mortality, wound dehiscence, early postoperative infection, pulmonary embolism, deep vein thrombosis, and “operative mishaps”. Complications following discharge were not assessed in either study when comparing the low volume and high volume surgeons. No patient outcome measurements or clinical assessments were reported in either study.

Supporting Evidence

Tables relevant to this recommendation: Table 12 through Table 17

Figures relevant to this recommendation: Figure 89 to Figure 93

We included two Level IV^{26, 27} studies that reported four outcome measures (please see Figure 89 through Figure 93).

Table 12 Summary of surgeon volume and arthroplasty outcome

Author	Outcome	Treatment	LoE	Comparison	N	Result
Hammond, et al 2005	Complication Rate	TSA or HHS	IV	High volume vs. Low Volume*	1868	●H
Hammond, et al 2005	Complication Rate	TSA or HHS	IV	Low volume vs. Medium Volume	1868	●H
Hammond, et al 2005	Complication Rate	TSA or HHS	IV	Medium volume vs. High Volume	1868	○
Jain, et al 2004	Complication Rate	TSA	IV	Low volume vs. High Volume	30046	●H
Jain, et al 2004	Complication Rate	TSA	IV	Medium volume vs. High Volume	30046	●H
Jain, et al 2004	Complication Rate	HHS	IV	Low volume vs. High Volume	30046	○
Jain, et al 2004	Complication Rate	HHS	IV	Medium volume vs. High Volume	30046	○
Hammond, et al 2005	Length of stay	TSA or HHS	IV	High volume vs. Low Volume*	1868	●H
Jain, et al 2004	Length of stay	TSA	IV	Medium volume vs. High Volume	30046	●H
Jain, et al 2004	Length of stay	TSA	IV	Low volume vs. High Volume	30046	●H
Jain, et al 2004	Length of stay	HHS	IV	Medium volume vs. High Volume	30046	●H
Jain, et al 2004	Length of stay	HHS	IV	High volume vs. Low Volume*	30046	●H
Jain, et al 2004	Nonroutine Discharge	TSA	IV	Medium volume vs. High Volume	30046	○
Jain, et al 2004	Nonroutine Discharge	TSA	IV	Low volume vs. High Volume	30046	○
Jain, et al 2004	Nonroutine Discharge	HHS	IV	Medium volume vs. High Volume	30046	●H
Jain, et al 2004	Nonroutine Discharge	HHS	IV	Low volume vs. High Volume	30046	●H
Jain, et al 2004	Mortality	TSA	IV	Medium volume vs. High Volume	30046	○
Jain, et al 2004	Mortality	TSA	IV	Low volume vs. High Volume	30046	○
Jain, et al 2004	Mortality	HHS	IV	Medium volume vs. High Volume	30046	○

Author	Outcome	Treatment	LoE	Comparison	N	Result
Jain, et al 2004	Mortality	HHS	IV	Low volume vs. High Volume	30046	○

●H = statistically significant in favor of High volume

○= not statistically significant

COMPLICATION RATE

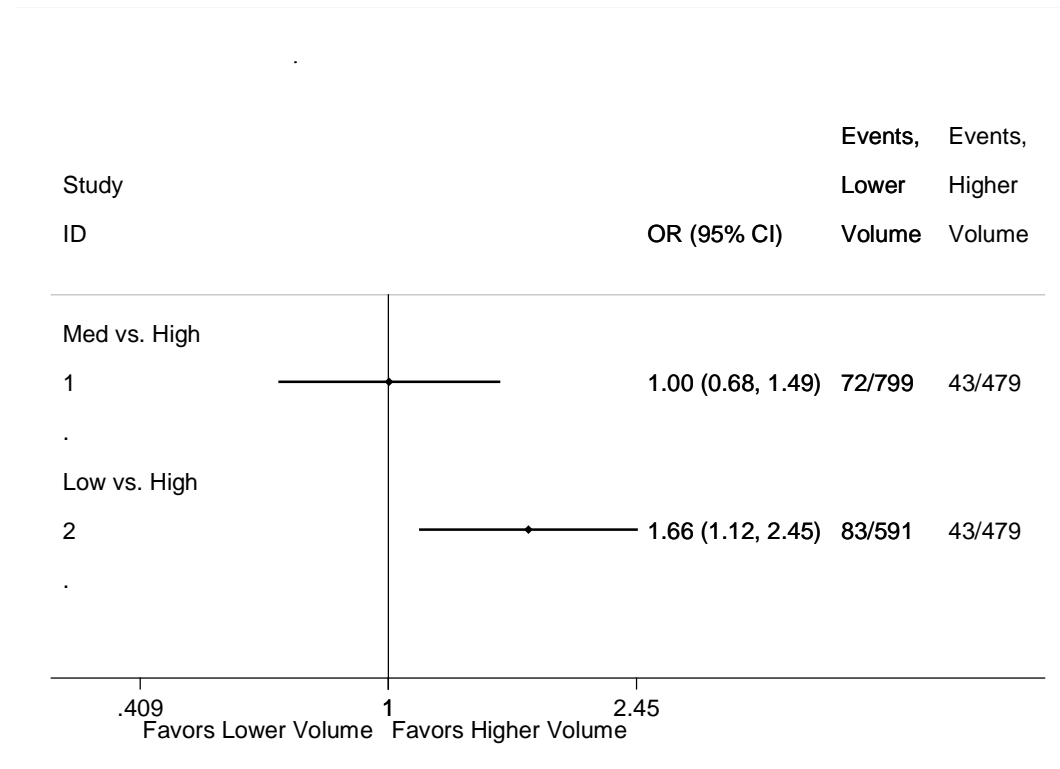
Hammond, et al.²⁷ and Jain, et al.²⁶ assessed the relationship between complication rate after total shoulder arthroplasty or hemiarthroplasty and individual surgeon experience.

Hammond, et al.²⁷ compared surgeon volume with complication rates. The authors categorized surgeons based upon total number of procedures performed during a seven year time frame (see Table 13) and compared surgeon volume with risk of complication. The authors reported a statistically significant difference in the risk of complications in surgeries performed by low volume surgeons when compared to high volume surgeons (statistics were adjusted for adjusted for: procedure, age, gender, race, marital status, co morbidities, diagnosis, insurance status, income, and hospital volume (see Figure 89).

Table 13 Surgeon volume classifications in 7 years

Category	Number of Arthroplasties Performed
Low Volume	1-5 Surgeries/7 years
Medium Volume	5-30 Surgeries/7 years
High Volume	Over 30 Surgeries/7 years

Figure 89 Risk of complication: high volume vs. low volume



AAOS calculated effect size

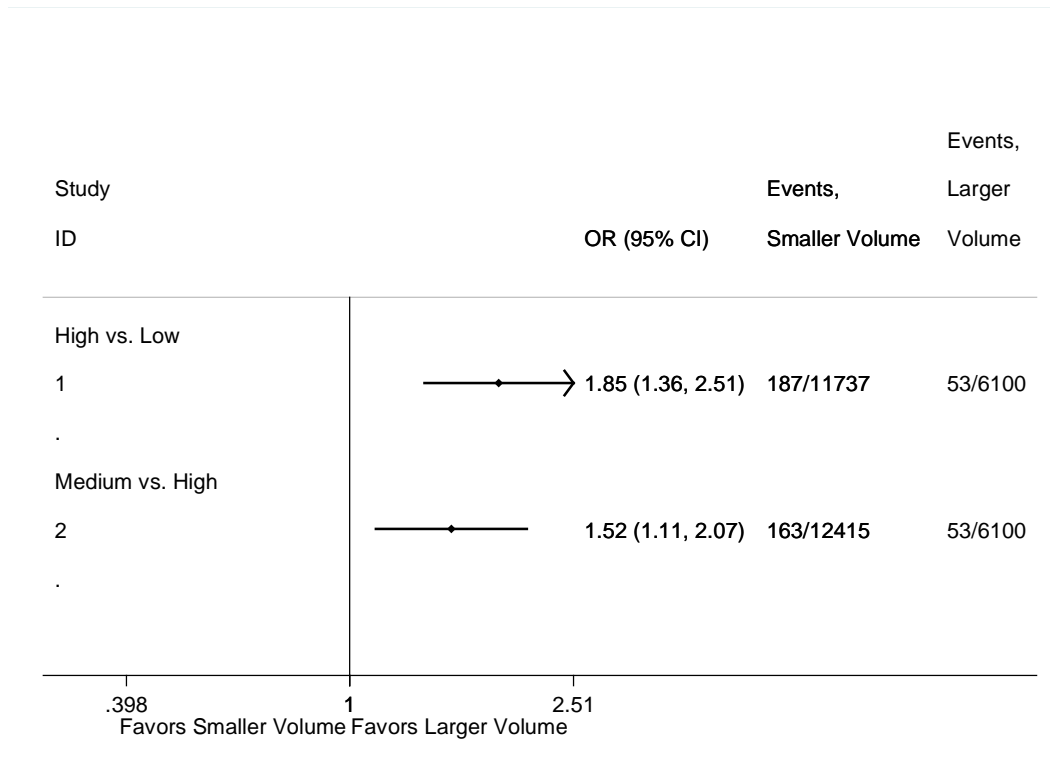
COMPLICATION RATE CONTINUED

Jain, et al.²⁶ compared patient in-hospital complication rate to the surgeon procedure volume; the authors categorized surgeons based upon total number of procedures performed during a one year time frame (see Table 13).

Table 14 Surgeon volume classification in 1 year

Category	Number of Arthroplasty Performed
Low Volume	< 2/year
Medium Volume	≥ 2 to < 5/year
High Volume	≥5/year

Figure 90 Surgeon volume compared with complications



AAOS calculated odds ratio

LENGTH OF HOSPITAL STAY

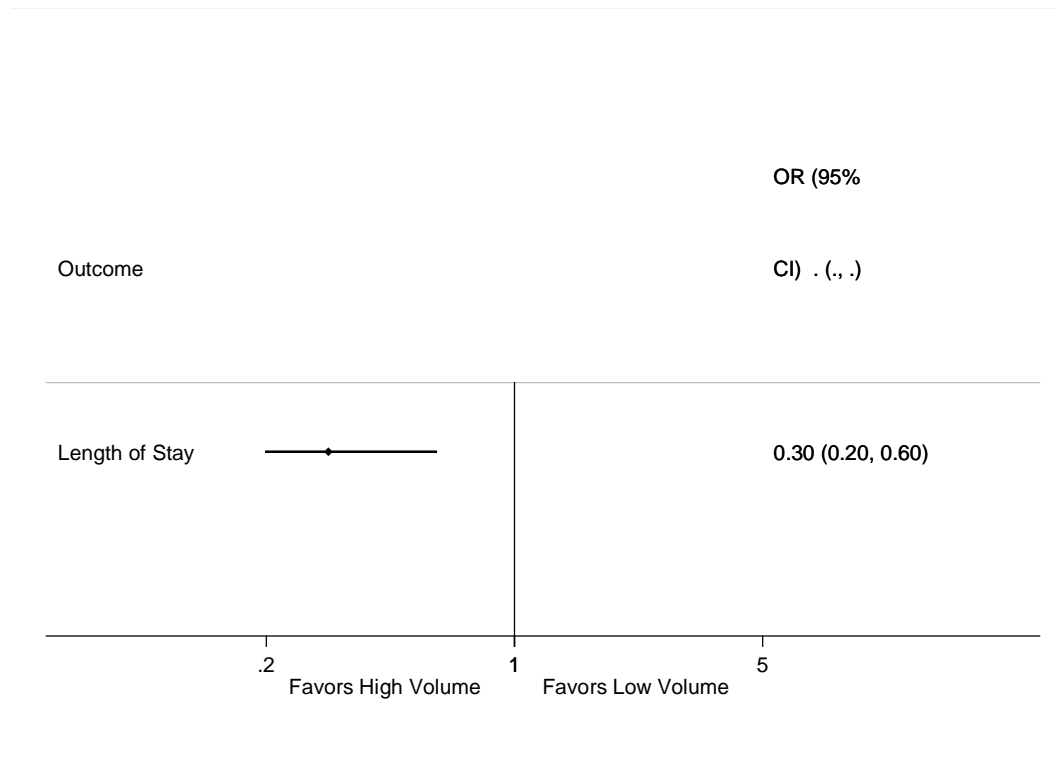
Hammond, et al²⁷ and Jain, et al²⁶ assessed the relationship between length of hospital stay after total shoulder arthroplasty or hemiarthroplasty and individual surgeon experience.

Hammond, et al.²⁷ compared surgeon volume with length of hospital stay (more than six days versus less than six days) and categorized surgeons based upon total number of procedures performed during a seven year time frame (see Table 15). Authors reported that patients of low-volume surgeons stayed in the hospital 1.4 days longer than high volume surgeons. The authors reported that high volume surgeons were three times more likely than low-volume surgeons to have patients with a hospital stay of less than six days (OR, 0.3 CI 0.2, 0.6) (statistics adjusted for: procedure, age, gender, race, marital status, co morbidities, diagnosis, insurance status, income, and hospital volume) .

Table 15 Surgeon volume classifications in 7 years

Category	Number of Arthroplasty Performed
Low Volume	1-5 Surgeries
Medium Volume	5-30 Surgeries
High Volume	Over 30 Surgeries

Figure 91 Length of hospital stay compared with surgeon volume



Jain, et al.²⁶ compared length of hospital stay after TSA or HHS with surgeon procedure volume. In both groups, the length of stay for patients treated by surgeons performing less than two surgeries was statistically greater than the length of stay for patients treated by surgeons performing more than five surgeries.

Figure 92 Length of hospital stay in TSA patients compared with surgeon volume

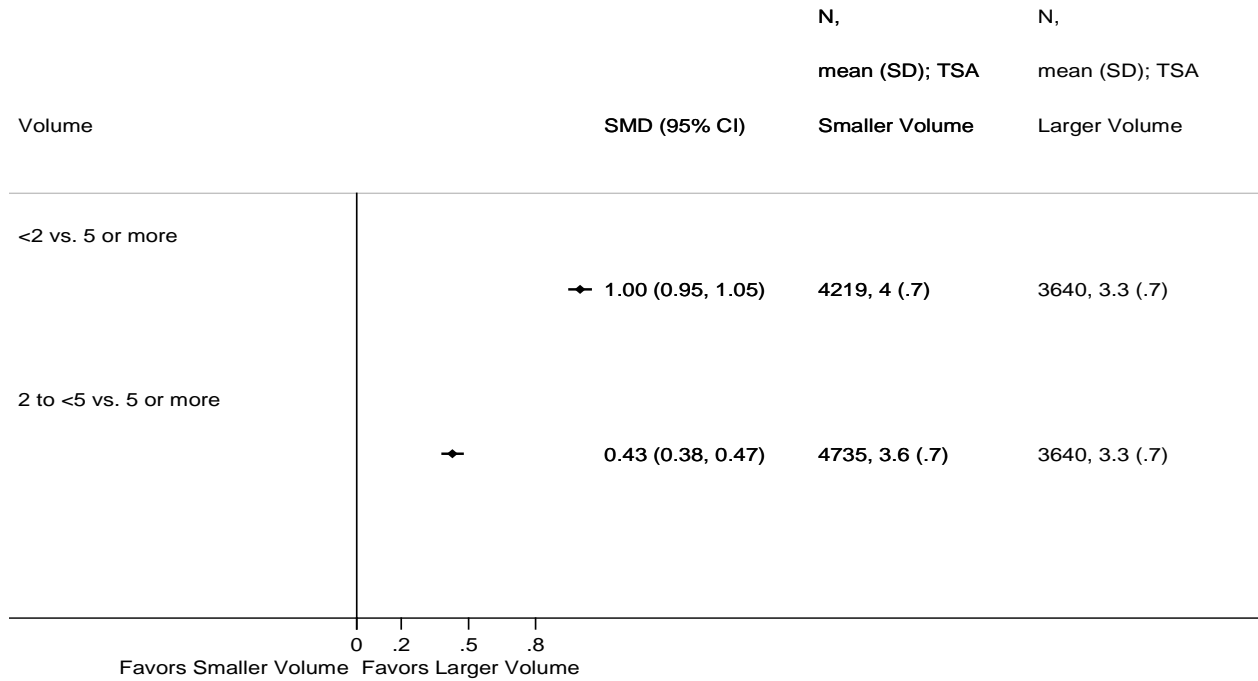
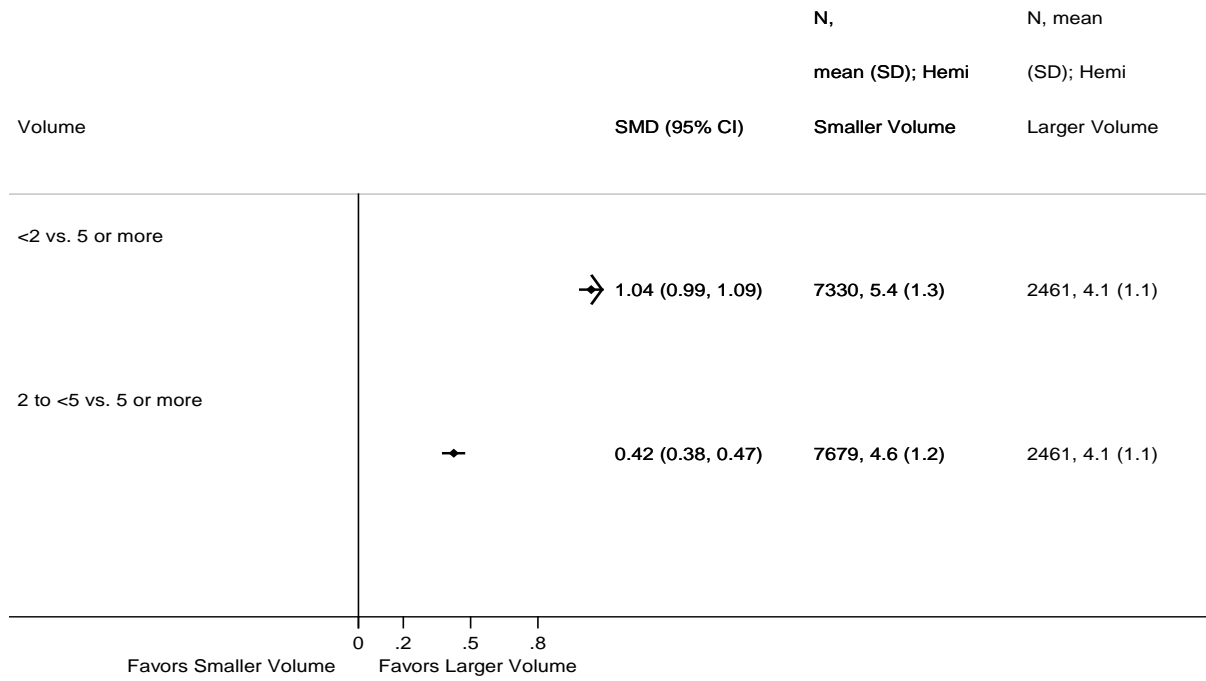


Figure 93 Length of stay for hemiarthroplasty patients compared with surgeon volume



NONROUTINE DISCHARGE

Jain, et al. ²⁶ compared percent of non routine patient discharges after TSA or HHS with surgeon procedure volume. Non routine discharge include: transfer to a short-term facility, skilled nursing facility, intermediate care facility, another type of facility, or home health care. Routine discharge includes patients discharged to home. The authors reported no statistically significant association between the percent of non routine discharge patients with procedure volume in the total shoulder arthroplasty group. However in the hemiarthroplasty group, the authors found a statistically significant association between surgeons who perform less than two procedures and surgeons who perform between two and five procedures when compared with surgeons who perform more than five and the percent of non routine discharges.

Table 16 Non routine discharge compared with surgeon volume

TSA Non routine Discharge		
Procedure Volume	Percent of Non routine Discharge	Adjusted Odds Ratio (95% Confidence Interval)
<2	30.9%	1.1 (0.8-1.4)
≥2 to <5	28.7%	.98 (0.8-1.2)
≥5	26.8%	1
HHS Non routine Discharge		
Procedure Volume	Percent of Non routine Discharge	Adjusted Odds Ratio (95% Confidence Interval)
<2	37.80%	1.3 (1.1-1.5)
≥2 to <5	38.10%	1.3 (1.1-1.6)
≥5	29.80%	1

MORTALITY

One author compared in hospital mortality rate with surgeon procedure volume, calculated per year for total shoulder arthroplasty and hemiarthroplasty separately. The authors reported no statistically significant association between the percent of mortalities with procedure volume in either the TSA group or hemiarthroplasty groups.

Table 17 Mortality compared to surgeon volume

TSA Mortality		
Procedure Volume	Percent of Mortality	Adjusted Odds Ratio (95% Confidence Interval)
<2	36.0%	4.4 (0.6-31.2)
≥2 to <4	32.0%	4.2 (0.6-29.6)
≥4	20.0%	1

HHS Mortality		
Procedure Volume	Percent of Mortality	Adjusted Odds Ratio (95% Confidence Interval)
<2	0.50%	0.9 (0.3-2.3)
≥2 to <4	0.36%	0.7 (0.2-1.9)
≥4	0.38%	1

RECOMMENDATION 10

In the absence of reliable evidence, it is the opinion of this work group that physicians use peri-operative mechanical and/or chemical prophylaxis to prevent VTE (venous thromboembolism) for the treatment of shoulder arthroplasty patients.

AAOS Strength of Recommendation: **Consensus**

Definition: A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Rationale:

Venous thromboembolism and pulmonary embolism are recognized potentially catastrophic complications faced by all patients who undergo shoulder arthroplasty. Despite the paucity of evidence to support or refute the use of embolic prophylaxis in shoulder arthroplasty patients, the consensus opinion of our work group is to employ its routine use. Mechanical prophylaxis for shoulder arthroplasty patients intra-operatively and during the immediate postoperative period places the patient at minimal additional risk or discomfort and may help prevent pulmonary embolism. Each patient should be assessed for the risk of pulmonary embolism and the addition of chemical prophylaxis considered if appropriate. The level of embolic risk must be weighed against the potential bleeding risk in these patients as well. We believe these actions are consistent with the current practice of most Orthopaedic surgeons. The AAOS has produced a guideline for the prevention of pulmonary embolus in lower extremity surgery, which can also serve as a reference; however, the risks for lower extremity surgery are reported to be higher than shoulder surgery.²⁸ As such these guidelines may not be applicable to this patient population.

Supporting Evidence

There were no studies of sufficient quality found that address this recommendation.

RECOMMENDATION 11

The use of either keeled or pegged all polyethylene cemented glenoid components are options when performing total shoulder arthroplasty.

AAOS Strength of the Recommendation: **Limited**

Definition: A **Limited** recommendation means the quality of the supporting evidence that exists is unconvincing, or that well-conducted studies show little clear advantage to one approach versus another.

Implications: Practitioners should be cautious in deciding whether to follow a recommendation classified as **Limited**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Rationale:

Studies have demonstrated that total shoulder arthroplasty provides improved outcomes in terms of pain relief and function (see Recommendation 7). The concept of performing a pegged or keeled glenoid has been studied extensively from a biomechanical standpoint, but limited data has been available regarding the clinical outcome, durability, and component stability when comparing the two types of resurfacing designs. As such, design considerations have long been considered an important variable when applied to the glenoid component.

One study²⁹ has evaluated the objective outcome and implant stability when comparing the keeled and pegged implant. The authors revealed there was no statistically significant difference between the designs in terms of pain relief and functional improvement in patients following total shoulder arthroplasty. The radiostereometric analysis performed at regular intervals during a two-year follow-up demonstrated greater micromotion in the keeled design group. Although this did not have an impact on short-term outcomes, this may suggest long-term implications with regards to implant loosening and progressive clinical symptoms.

Supporting Evidence

One study²⁹ examines clinical outcomes of both pegged and keeled glenoid components.

PEGGED

Strength of Recommendation: Limited

Tables relevant to this recommendation: Table 18

Figures relevant to this recommendation: Figure 94 through Figure 96

Three Level V outcome measures assess the efficacy of pegged glenoids.

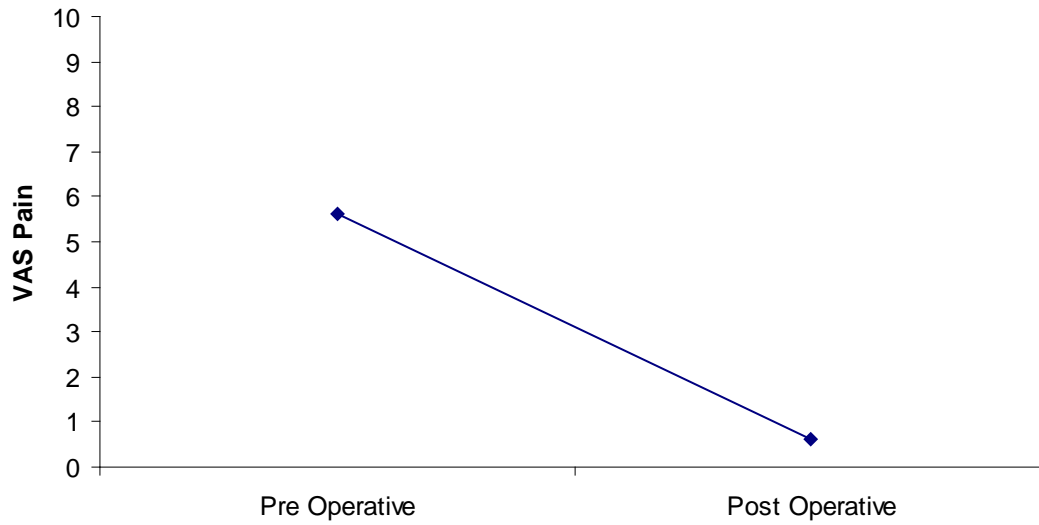
Table 18 Summary of results of pegged glenoid efficacy

Author	Outcome Domain	Outcome	LOE	Comparison	Post Operative
Nuttall, et al 2007	Pain	Pain VAS	V	Change from Baseline	●
Nuttall, et al 2007	Global Health Assessment	Constant-Murley Score	V	Change from Baseline	●
Nuttall, et al 2007		ASES Score	V	Change from Baseline	●

PAIN-VAS

Ten patients with osteoarthritis of the glenohumeral joint were treated with TSA and a pegged glenoid. Patients assessed their pain before surgery and at 2 years post operative. Nuttall, et al.²⁹ report a statistically significant improvement in pain from baseline to 2 years.

Figure 94 Pain measured by VAS



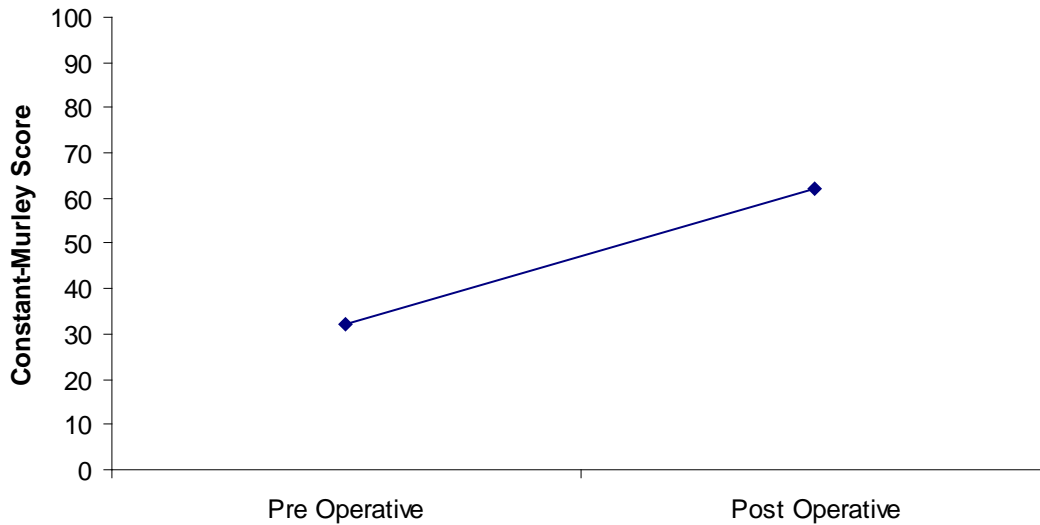
Author calculated paired t-test, $p < .001$

Dispersion not reported by authors

CONSTANT-MURLEY SCORE

Ten patients with osteoarthritis of the glenohumeral joint were treated with TSA and a pegged glenoid and assessed with the Constant-Murley score at 2 years post operative. Nuttall, et al.²⁹ report a statistically significant improvement in Constant-Murley score from baseline to 2 years.

Figure 95 Constant-Murley Score



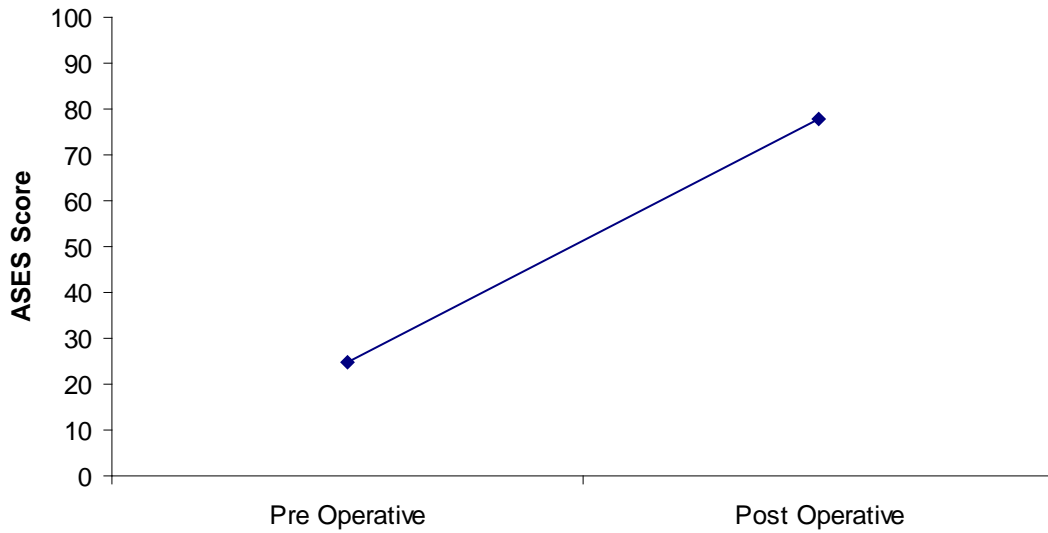
Author calculated paired t-test, $p < .001$

Dispersion not reported by authors

ASES SCORE

Ten patients with osteoarthritis of the glenohumeral joint were treated with TSA and a pegged glenoid and assessed with the ASES score at 2 years post operative. Nuttall, et al.²⁹ report a statistically significant improvement in Constant-Murley score from baseline to 2 years.

Figure 96 ASES Score



Author calculated paired t-test, $p < .001$

Dispersion not reported by authors

KEELED

Strength of Recommendation: Limited

Tables relevant to this recommendation: Table 19

Figures relevant to this recommendation: Figure 97 through Figure 99

Three Level V outcome measures assess the efficacy of the use of keeled glenoids.

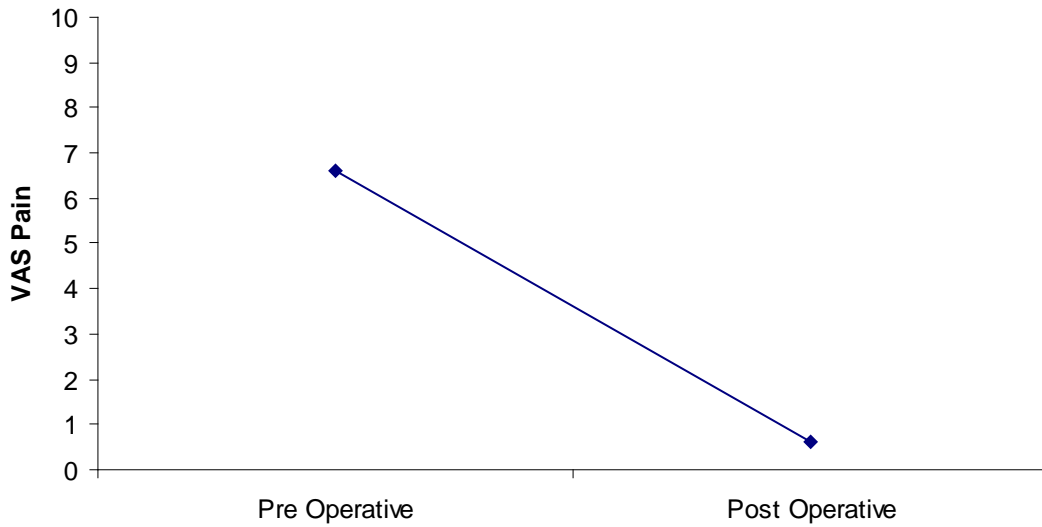
Table 19 Summary of results of keeled glenoid efficacy

Author	Outcome Domain	Outcome	LOE	Comparison	Post Operative
Nuttall, et al 2007	Pain	Pain VAS	V	Change from Baseline	●
Nuttall, et al 2007	Global Health Assessment	Constant-Murley Score	V	Change from Baseline	●
Nuttall, et al 2007		ASES Score	V	Change from Baseline	●

PAIN-VAS

Ten patients with osteoarthritis of the glenohumeral joint were treated with TSA and a keeled glenoid. Patients assessed their pain before surgery and at 2 years post operative. Nuttall, et al.²⁹ report a statistically significant improvement in pain from baseline to 2 years.

Figure 97 Pain measured by VAS



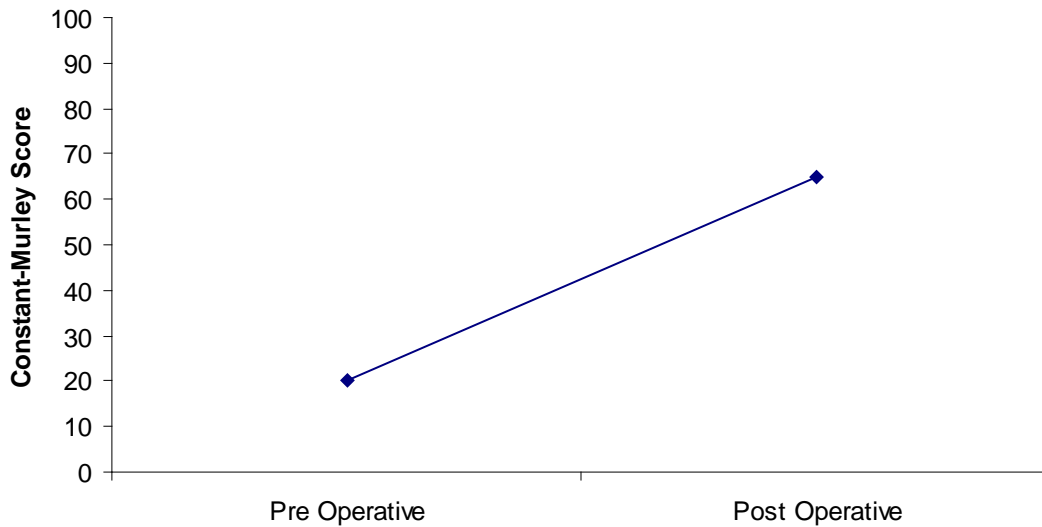
Author calculated paired t-test, $p < .001$

Dispersion not reported by authors

CONSTANT-MURLEY SCORE

Ten patients with osteoarthritis of the glenohumeral joint were treated with TSA and a keeled glenoid and assessed with the Constant-Murley score at 2 years post-operative. Nuttall, et al.²⁹ report a statistically significant improvement in Constant-Murley score from baseline to 2 years.

Figure 98 Constant-Murley



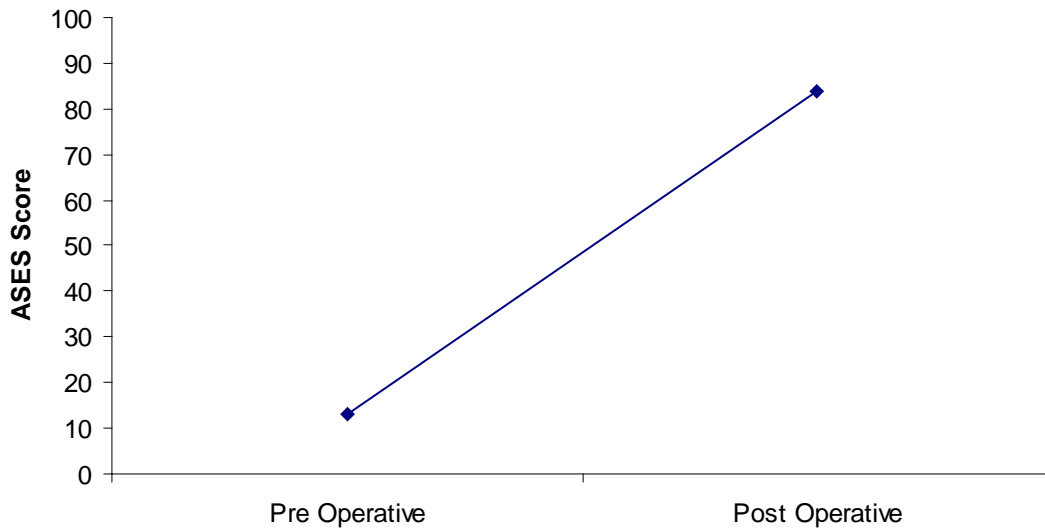
Author calculated paired t-test, $p < .001$

Dispersion not reported by authors

ASES SCORE

Ten patients with osteoarthritis of the glenohumeral joint were treated with TSA and a keeled glenoid and assessed with the ASES score at 2 years post operative. Nuttall, et al.²⁹ report a statistically significant improvement in Constant-Murley score from baseline to 2 years.

Figure 99 ASES



Author calculated paired t-test, $p < .001$

Dispersion not reported by authors

METAL BACK

There were no studies of sufficient quality identified which assessed cemented metal backed glenoid components.

SCREW FIXATION

There were no studies of sufficient quality identified which assessed screw fixation in glenoid components.

BONE IN GROWTH

There were no studies of sufficient quality identified which assessed bone in growth glenoid components.

TRABECULAR METAL

There were no studies of sufficient quality identified which assessed cemented trabecular metal glenoid components.

BIOLOGIC

There were no studies of sufficient quality identified which assessed biologic glenoid components.

PREVIOUSLY PUBLISHED SYSTEMATIC REVIEWS

One systematic review assessed glenoid components. Radnay, et al.²³ state, “TSR maintains low rates of glenoid loosening and significantly lower rates of revision surgery, especially when current all-polyethylene glenoid components are used.” (p. 401)
“Of the TSRs that used metal-backed glenoids, 6.8% required revision. However, the revision rate for loosening in TSRs with all-polyethylene glenoids was only 1.7%.” (p. 398)

RECOMMENDATION 12

In the absence of reliable evidence, it is the opinion of the work group that total shoulder arthroplasty not be performed in patients with glenohumeral osteoarthritis who have an irreparable rotator cuff tear.

AAOS Strength of Recommendation: **Consensus**

Definition: A **Consensus** recommendation means that expert opinion supports the guideline recommendation even though there is no available empirical evidence that meets the inclusion criteria.

Implications: Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus**, although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Rationale:

In the setting of an irreparable rotator cuff tear, glenoid component loosening is a potential complication of total shoulder arthroplasty due to the increased eccentric rim loading of the glenoid component that can occur. This has been termed the rocking horse phenomenon. Loosening and failure of the glenoid component can lead to pain and decreased function and may ultimately necessitate revision surgery. Currently, no reliable studies exist comparing clinical or radiographic results of total shoulder arthroplasty in patients with and without irreparable rotator cuff tears. Despite this, the current “best medical practice” is to perform total shoulder arthroplasty in patients with glenohumeral osteoarthritis who have intact or reparable rotator cuffs.

Supporting Evidence

No studies of sufficient quality have been identified which examine TSA in patients with glenohumeral osteoarthritis with and without an intact rotator cuff.

RECOMMENDATION 13

We are unable to recommend for or against biceps tenotomy or tenodesis when performing shoulder arthroplasty in patients who have glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Currently, some surgeons routinely sacrifice the biceps tendon at the time of arthroplasty and others preserve it, however these practice habits are either anecdotal or based on “experience”. Because of the paucity of the current body of literature and the variety of techniques used to address the biceps tendon at the time of shoulder arthroplasty, we are unable to support either routine biceps tenotomy or tenodesis.

Supporting Evidence

There were no studies of sufficient quality identified examining tenotomy or tenodesis when performing shoulder arthroplasty in patients with glenohumeral joint osteoarthritis.

RECOMMENDATION 14

We are unable to recommend for or against a subscapularis trans tendonous approach or lesser tuberosity osteotomy when performing shoulder arthroplasty in patients who have glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Non-healing or rupture of the subscapularis tendon repair following total shoulder arthroplasty is a recognized complication of the transtendinous approach. Deficiency of the subscapularis tendon can lead to poor results after total shoulder arthroplasty. Patients may complain of pain and difficulty with simple tasks like reaching the contralateral axilla or getting the arm behind the back to tuck in a shirt or reach into a back pocket. In addition, instability of the prosthesis, ranging from subluxations to overt dislocation, may occur. This has prompted some investigators to study osteotomy of the lesser tuberosity during surgical approach in shoulder arthroplasty. Lesser tuberosity osteotomy repair results in bone-to-bone healing, which may be more reliable than tendon-to-tendon or tendon-to-bone healing. While several studies have been published examining results of lesser tuberosity osteotomy following total shoulder arthroplasty in patients with glenohumeral osteoarthritis, they did not meet our inclusion criteria. Thus, the current available literature is insufficient to recommend for or against a lesser tuberosity osteotomy over a trans tendonous approach.

Supporting Evidence

There were no studies of sufficient quality identified examining subscapularis trans tendonous approach versus lesser tuberosity osteotomy in patients with glenohumeral joint osteoarthritis.

RECOMMENDATION 15

We are unable to recommend for or against a specific type of humeral prosthetic design or method of fixation when performing shoulder arthroplasty in patients with glenohumeral joint osteoarthritis.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Following Neer's original humeral design in the 1950's with monoblock stems in three sizes, over 70 different shoulder arthroplasty systems have been developed. Modern prosthetic design has evolved to include expanded sizes and increased modularity. Prostheses have become more anatomic, with features like variable neck-shaft angles and eccentric heads to allow the surgeon to more closely replicate the patient's normal anatomy. Surgeons can choose between prostheses designed for cemented or uncemented use. Purported advantages of one prosthetic design over another have been claimed. Despite this, no clinical studies of sufficient quality comparing different designs and fixation options were identified. Thus, the current available literature is insufficient to recommend for or against a specific type of humeral prosthetic design or method of fixation when performing shoulder arthroplasty in patients with glenohumeral osteoarthritis.

RECOMMENDATION 16

We are unable to recommend for or against physical therapy following shoulder arthroplasty.

AAOS Strength of Recommendation: **Inconclusive**

Definition: An **Inconclusive** recommendation means that there is a lack of compelling evidence resulting in an unclear balance between benefits and potential harm.

Implications: Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Inconclusive** and should exercise judgment and be alert to future publications that clarify existing evidence for determining balance of benefits versus potential harm. Patient preference should have a substantial influencing role.

Rationale:

Formal physical therapy has been a consistent recommendation following shoulder arthroplasty. Despite this common practice there are no high quality studies that address whether physical therapy improves outcomes following shoulder arthroplasty.

Supporting Evidence

There were no studies of sufficient quality identified examining physical therapy following shoulder arthroplasty in patients with glenohumeral osteoarthritis. There were seven studies that addressed Recommendations 7 and 8. Four of the seven studies reported that the patients underwent an exercise protocol following surgery, but did not separately examine the effect, if any of physical therapy. The comparison of arthroscopic surgery alone versus the results of surgery plus physical therapy has not been made; therefore, the benefit of physical therapy has not been determined.

FUTURE RESEARCH

The quality of scientific data regarding the treatment of glenohumeral osteoarthritis is unfortunately poor. One recommendation is made on the basis of moderate evidence, four recommendations are based on limited evidence and nine recommendations are inconclusive due to the lack of quality evidence. Two recommendations are based on the consensus of the work group after careful consideration of the lack of evidence and the harms associated with surgery.

In summary, we have no strong data to support any treatment for glenohumeral joint osteoarthritis and moderate and limited strength data to support surgery. Limited data suggests viscosupplementation may be a beneficial non operative treatment but we derive this data from one industry supported study. In addition, no high quality data currently exists to support pre or post operative physical therapy. Despite this, physical therapy is common practice. Clearly, we need high quality studies that address the benefits of preoperative physical therapy and whether physical therapy improves outcomes following shoulder arthroplasty.

Controversy will continue to exist regarding the optimal treatment of glenohumeral joint osteoarthritis until the quality of research improves. Treatment options for orthopaedic patients should be better grounded in quality data garnered from properly designed clinical trials designed with sufficient power to determine optimal treatments in every phase of disease progression.

Specific trials which would be helpful include the following:

1. Trials designed to evaluate the role and duration of non operative treatments in the initial management of patients diagnosed with glenohumeral joint osteoarthritis.
2. Trials designed to determine the optimal use and duration of pharmacotherapy, injected corticosteroids and viscosupplementation in the initial treatment of patients with glenohumeral joint osteoarthritis.
3. Trials designed to evaluate the role for arthroscopic surgical intervention in the treatment algorithm for osteoarthritis of the glenohumeral joint.
4. Trials designed to evaluate the role for open debridement and non-prosthetic and /or interposition arthroplasty in younger patients (<50 years old).
5. Trials designed to collect prospective data on resurfacing arthroplasty and to evaluate the indications for resurfacing would also be helpful.
6. Trials designed to evaluate the need for embolic prophylaxis, both mechanical and chemical, for all patients undergoing total shoulder arthroplasty. Ideally, this trial will be designed to clarify the level of embolic risk for patients while also weighing the potential bleeding risk in these patients.

7. The current body of literature also fails to address whether to use a subscapularis trans tendonous approach or lesser tuberosity osteotomy when performing shoulder arthroplasty in patients who have glenohumeral joint osteoarthritis. Trials to evaluate the efficacy of these techniques and patient prognostic factors would be useful.
8. Finally, formal physical therapy is a standard of treatment care following total shoulder arthroplasty. Trials to support the efficacy of post-operative physical therapy, by improved patient outcomes following total shoulder arthroplasty, must be done to validate this routine practice.

The future of the healthcare environment is being driven by patients who are better informed, by third party payors who are demanding proven treatment efficacy and cost efficiency and by pay for performance initiatives. The treatment of patients with glenohumeral joint osteoarthritis will require better high quality research to sustain treatment options in the future.

IV. APPENDIXES

APPENDIX I

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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) consist 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	July 10, 2009
Peer Review Completed	August 16, 2009
Public Commentary Completed	October 17, 2009
AAOS Guidelines and Technology Oversight Committee	November 16, 2009
AAOS Evidence Based Practice Committee	November 16, 2009
AAOS Council on Research, Quality Assessment, and Technology	November 19, 2009
AAOS Board of Directors	December 4, 2009

APPENDIX III

LITERATURE SEARCHES FOR PRIMARY STUDIES

The literature searches were performed using the following databases on January 28, 2009. The full search strategies are listed below:

- PubMed
- EMBASE
- CINAHL
- The Cochrane Library
- The National Guidelines Clearinghouse
- TRIP Database – Guidelines & Systematic Reviews

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.

PubMed was searched using the following strategy:

“glenohumeral arthritis”[tw] OR ((shoulder*[tiab] OR "Shoulder Joint"[mh] OR glenohumer*[tw]) AND (Osteoarthritis[mh:noexp] OR osteoarthriti*[tiab] OR Arthritis[mh:noexp] OR (arthriti*[tiab] AND (degenerat*[tiab] OR erosion[tiab] OR eroded[tiab]))) OR "Arthroplasty, Replacement"[mh:noexp] OR arthroplasty[tiab] OR "Joint Prosthesis"[mh:noexp] OR "Prostheses and Implants"[mh:noexp] OR resurfac*[tiab] OR hemiarthroplasty[tiab])) NOT ((“Shoulder Fractures”[majr] OR “Rotator Cuff/injuries”[majr] OR fractur*[ti] OR injur*[ti]) NOT (arthrit*[tw] OR osteoarthriti*[tw] OR periprosthetic[tiab] OR “Prosthesis Failure”[mh] OR “Postoperative Complications”[mh])) AND "1966"[PDat]:"2009"[PDat] AND "1"[EDat]:"2009/1/27"[EDAT] AND Eng[la] AND (human[mh] OR in process[sb] OR publisher[sb]) NOT (cadaver[mh] OR cadaver*[tw]) NOT (comment[pt] OR editorial[pt] OR letter[pt] OR addresses[pt] OR news[pt] OR "newspaper article"[pt] OR “historical article”[pt] OR "case reports"[pt] OR "retrospective case series"[tw])

EMBASE was searched using the following strategy:

'glenohumeral arthritis' OR (shoulder OR 'Shoulder'/de OR glenohumer*) AND ('Osteoarthritis'/de OR osteoarthriti* OR Arthritis/de OR 'Arthroplasty'/de OR 'Joint Prosthesis'/de) NOT ((injur*:ti OR fractur*:ti OR 'rotator cuff rupture'/mj OR 'rotator cuff injury'/mj) NOT (Osteoarthritis/de OR arthriti* OR osteoarthriti* OR 'prosthesis failure'/de OR periprosthetic OR 'postoperative complication'/de)) NOT 'retrospective case series' AND ([article]/lim OR [conference paper]/lim OR [review]/lim) AND [english]/lim AND [humans]/lim AND [embase]/lim NOT [27/01/2009]/sd NOT cadaver/de

CINAHL was searched using the following strategy:

(MM "shoulder" or shoulder) and (MM "osteoarthritis" or MM "arthritis" or osteoarthri* or MM "arthroplasty") not (PT "editorial" or PT "letter" or PT "case study" or MM "case studies")

The Cochrane Library was searched using the following strategy:

(shoulder OR glenohumeral) AND (arthrit* OR osteoarthri*)

The National Guidelines Clearinghouse was searched using the following strategy:

(shoulder OR glenohumeral) AND (osteoarthritis OR arthroplasty)

The TRIP Database – Guidelines and Systematic Reviews was searched using the following strategy:

(shoulder OR glenohumeral) AND (osteoarthritis OR arthroplasty)

NON OPERATIVE TREATMENT

Although the initial search strategy conducted included operative and non operative treatments, the paucity of non operative studies resulted in a unique search. This search was conducted on February 20, 2009 using the following strategy:

UPPER EXTREMITY PE/HEMORRHAGE FOLLOWING SHOULDER SURGERY

A separate search strategy was used on February 18, 2009 to identify studies related to upper extremity PE/hemorrhage following shoulder surgery.

PubMed was searched using the following strategy:

(shoulder[tw] OR rotator cuff[tw] OR glenohumeral[tiab] OR humerus[tw] OR glenoid[tw] OR "upper extremity" OR "upper extremities" OR "upper limb" OR "upper limbs") AND (arthroplasty[tw] OR hemiarthroplasty[tiab] OR arthroscopy[tw] OR surgery[sh] OR repair*[tiab]) AND (cerebral hemorrhage[mh] OR Venous Thrombosis[mh] OR Pulmonary Embolism[mh] OR "pulmonary embolism" OR Thromboembolism[Mesh:NoExp] OR thromboembol*[tiab] OR DVT[tiab] OR "deep vein thrombosis" OR "deep venous thrombosis" OR antithrombotic[tiab] OR warfarin[tw] OR aspirin[tw] OR heparin[tw] OR heparin[mh] OR enoxaparin[tw] OR dalteparin[tw] OR fondaparinux[tw] OR "Stockings, Compression"[mh] OR "compression stockings" OR "sequential compression devices" OR "sequential compression device") AND English[lang] AND (human[mh] OR in process[sb] OR publisher[sb]) AND "1966"[PDat]:"2009"[PDat]

EMBASE was searched using the following strategy:

(Shoulder OR 'rotator cuff' OR glenohumeral OR humerus OR glenoid OR 'upper extremity' OR 'upper extremities' OR 'upper limb' OR 'upper limbs') AND (arthroplasty OR hemiarthroplasty OR arthroscopy OR shoulder/dm_su OR repair* OR

'orthopedic surgery'/exp) AND ('thrombin inhibitor'/de OR 'deep vein thrombosis'/de 'postoperative thrombosis'/de 'thrombosis prevention'/de OR 'vein thrombosis'/de OR DVT OR thromboembol* OR 'deep vein thrombosis' OR 'deep venous thrombosis' OR 'venous thromboembolism' OR 'brain hemorrhage'/de OR 'lung embolism'/de OR 'pulmonary embolism' OR warfarin OR aspirin OR heparin OR enoxaparin OR dalteparin OR fondaparinux OR 'compression stockings' OR 'compression garment'/de OR 'sequential compression devices') AND [english]/lim AND [humans]/lim AND [embase]/lim

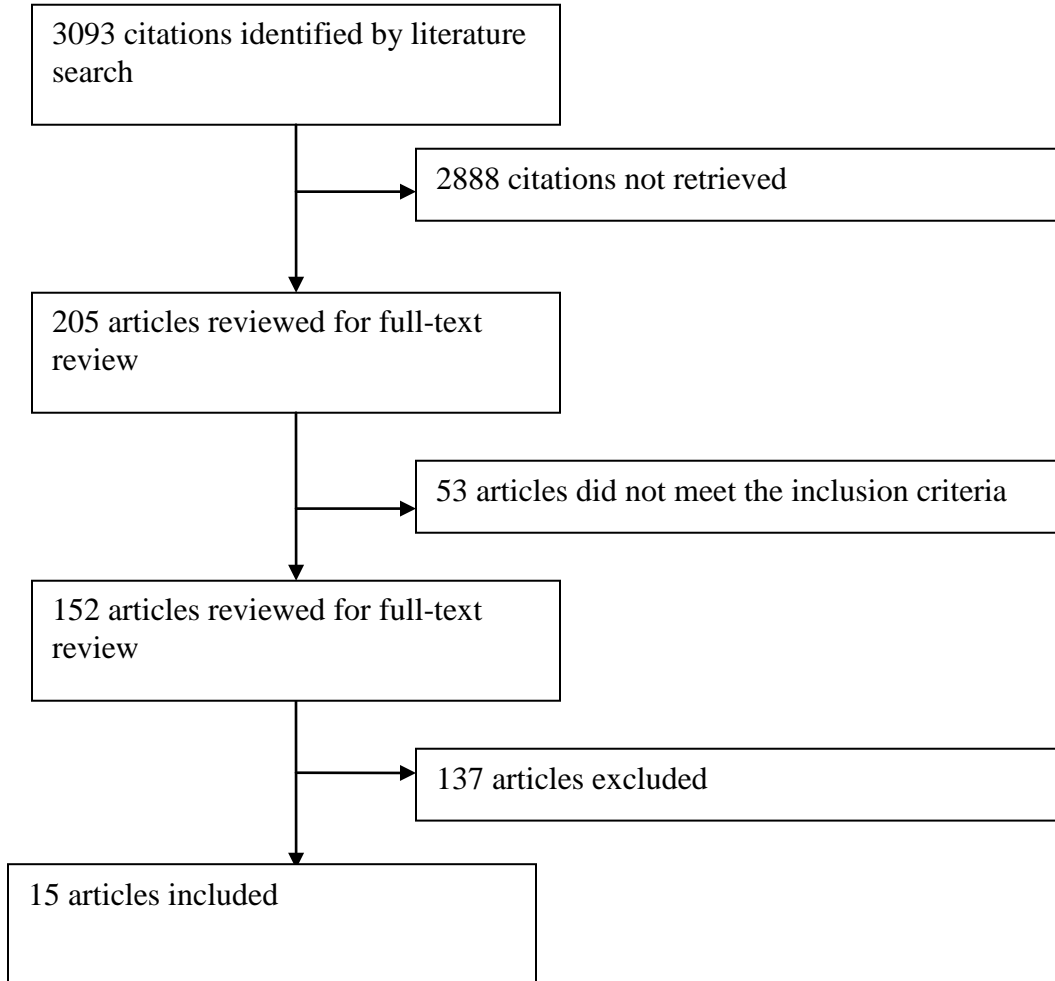
CINAHL was searched using the following strategy:

(shoulder OR "rotator cuff") AND (MM "cerebral hemorrhage" OR MM "venous thrombosis" OR MM "pulmonary embolism" OR thromboembol* OR DVT OR "deep vein thrombosis" OR "deep venous thrombosis" OR antithrombotic OR warfarin OR aspirin OR heparin OR MM "compression garments" OR "compression stockings" OR MM "compression therapy")

The Cochrane Library was searched using the following strategy:

(shoulder OR "rotator cuff") AND ("cerebral hemorrhage" OR "venous thrombosis" OR "pulmonary embolism" OR thromboembol* OR DVT OR "deep vein thrombosis" OR "deep venous thrombosis" OR antithrombotic OR warfarin OR aspirin OR heparin OR "compression stockings" OR "sequential compression devices")

**APPENDIX IV
STUDY ATTRITION FLOWCHARTS**



APPENDIX V

DATA EXTRACTION ELEMENTS

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

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
- 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
- age
- surgical complications
- adverse events

Results (for all relevant outcomes in a study)

- duration at which outcome measure was evaluated
- mean value of statistic reported (for dichotomous results)
- mean value of measure and value of dispersion (for continuous results)
- statistical test p-value

APPENDIX VI LEVEL OF EVIDENCE

Levels of Evidence For Primary Research Question¹

	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	<ul style="list-style-type: none"> High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals Systematic Review² of Level I RCTs (and study results were homogenous³) 	<ul style="list-style-type: none"> High quality prospective study⁴ (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) Systematic review² of Level I studies 	<ul style="list-style-type: none"> Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review² of Level I studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses Systematic review² of Level I studies
Level II	<ul style="list-style-type: none"> Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization) Prospective⁴ comparative study⁵ Systematic review² of Level II studies or Level I studies with inconsistent results 	<ul style="list-style-type: none"> Retrospective⁶ 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 review² of Level II studies 	<ul style="list-style-type: none"> Development of diagnostic criteria on consecutive patients (with universally applied reference “gold” standard) Systematic review² of Level II studies 	<ul style="list-style-type: none"> Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses Systematic review² of Level II studies
Level III	<ul style="list-style-type: none"> Case control study⁷ Retrospective⁶ comparative study⁵ Systematic review² of Level III studies 	<ul style="list-style-type: none"> Case control study⁷ 	<ul style="list-style-type: none"> Study of non-consecutive patients; without consistently applied reference “gold” standard Systematic review² of Level III studies 	<ul style="list-style-type: none"> Analyses based on limited alternatives and costs; and poor estimates Systematic review² of Level III studies
Level IV	Case Series ⁸	Case series	<ul style="list-style-type: none"> Case-control study Poor reference standard 	<ul style="list-style-type: none"> 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 VII
FORM FOR ASSIGNING STRENGTH OF RECOMMENDATION
(INTERVENTIONS)**

GUIDELINE RECOMMENDATION _____

PRELIMINARY STRENGTH 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 strength of the recommendation?

What is the resulting strength 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 strength of recommendation be lowered because of low applicability?

What is the resulting strength of recommendation?

STEP 4: BALANCE BENEFITS AND HARMS

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

What is the resulting strength of recommendation?

STEP 5 CONSIDER STRENGTH OF EVIDENCE

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

What is the resulting strength of recommendation?

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

APPENDIX VIII VOTING BY THE NOMINAL GROUP TECHNIQUE

Voting on guideline recommendations and performance measures is conducted using a modification of the nominal group technique (NGT), a method previously used in guideline development.¹⁴ 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.

OPINION-BASED RECOMMENDATIONS

Every guideline contains preliminary recommendations that are backed by little or no data. Under such circumstances, workgroups often want to issue opinion-based recommendations. Although doing so is sometimes acceptable in an evidence-based guideline (after all, expert opinion is a form of evidence), it is also important to avoid

constructing a guideline that liberally uses expert opinion; research shows that expert opinion is often incorrect.

We ask you to develop opinion-based recommendations *only if they address a vitally important aspect of patient care*. For example, constructing an opinion-based recommendation in favor of taking a history and physical is warranted. Constructing an opinion-based recommendation in favor of a specific modification of a surgical technique is seldom warranted. To ensure that an opinion-based recommendation is absolutely necessary, the AAOS has adopted rules to guide the content of the rationales that underpin such recommendations. These rules are based on those outlined by the US Preventive Services Task Force (USPSTF).³⁰ Specifically, rationales based on expert opinion must:

- **Not contain references to or citations from articles not included in the systematic review that underpins the original, preliminary recommendation.**
- **Not contain the AAOS guideline language “We Recommend”, “We suggest” or “treatment x is an option”.**
- **Contain an explanation of the potential preventable burden of disease.** This involves considering both the incidence and/or prevalence of the disease, disorder, or condition and considering the associated burden of suffering. A hypothetical opinion-based recommendation for a treatment of disease Y might begin by saying; “Each year, 10,000 patients are diagnosed with disease Y, and existing treatments for it are, at best, marginally effective. If untreated, these patients will eventually be unable to work.” To paraphrase the USPSTF,¹ when evidence is insufficient, provision of a treatment (or diagnostic) for a serious condition might be viewed more favorably than provision of a treatment (or diagnostic) for a condition that does not cause as much suffering. We (like the USPSTF) understand that evaluating the “burden of suffering” is subjective and involves judgment. This evaluation should be informed by patient values and concerns.

PLEASE NOTE THAT THE CONSIDERATIONS OUTLINED IN THIS BULLET MAKE IF VERY DIFFICULT TO RECOMMEND NEW TECHNOLOGIES. This is intentional. It is not appropriate for a guideline to recommend widespread use of a technology backed by little data and for which there is limited experience. Such technologies are addressed in the AAOS’ Technology Overviews.

When a preliminary recommendation addresses a new drug, device, treatment, or diagnostic, the final recommendation will most likely read that the group can neither recommend for or against the device, drug, or procedure addressed in the preliminary recommendation. In such cases, avoid making implied recommendations in the rationale. Avoid, for example, “Although treatment X appears to be promising, there is currently insufficient evidence to recommend for or against its use.”

- **Address potential harms.** Surgery has associated harms. Similarly, waiting for the results of a diagnostic test may cause anxiety, and harms may also accrue if there is a false positive test result (e.g., the patient may receive unnecessary treatment). In general, “When the evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television).”¹
- **Address apparent discrepancies in the logic of different recommendations.** Accordingly, if there are no relevant data for several preliminary recommendations and the workgroup chooses to issue an opinion-based recommendation in some cases but chooses not to make a recommendation in other cases, the rationales for the opinion-based recommendations must explain why this difference exists. Information garnered from the previous bullet points will be helpful in this regard.
- **Consider current practice.** The USPSTF specifically states that clinicians justifiably fear that not doing something that is done on a widespread basis will lead to litigation. The consequences of not providing a service that is neither widely available nor widely used are less serious than the consequences of not providing a treatment accepted by the medical profession and thus expected by patients.¹ When thinking about this, please remember that discussions of available treatments and procedures rely on mutual communication between the patient’s guardian and physician, and on weighing the potential risks and benefits for a given patient. The patient’s “expectation of treatment” must be tempered by the treating physician’s guidance about the reasonable outcomes that the patient can expect.
- **Justify, why a more costly device, drug, or procedure is being recommended over a less costly one** whenever such an opinion-based recommendation is made.

Work group members will write rationales for written recommendations on the evening of the first day of the final workgroup meeting. When the work group reconvenes on the second day of its meeting, it will vote on the rationales. The typical voting rules will apply (see checklist). If the work group cannot adopt a rationale after three votes, the rationale and the opinion-based recommendation will be withdrawn, and a “recommendation” stating that the group can neither recommend for or against the recommendation in question will appear in the guideline.

Discussions of opinion-based rationales may cause some members to change their minds about whether to issue an opinion-based recommendation. Accordingly, at any time during the discussion of the rationale for an opinion-based recommendation, any member of the work group can make a motion to withdraw that recommendation and have the guideline state that the work group can neither recommend for or against the recommendation in question.

Constructing opinion-based rationales requires a substantial amount of meeting time. Please consider this when deciding whether to issue such a recommendation. If the work group does complete all votes on all opinion-based rationales at its final meeting, the remaining work will have to be completed by teleconference. In order to meet the AAOS BOD mandated timelines, these teleconferences must occur no later than two weeks after the final work group meeting.

CHECKLIST FOR VOTING ON OPINION-BASED RECOMMENDATIONS

When voting on the rationale, please consider the following:

1. Does the recommendation affect a substantial number of patients or address treatment (or diagnosis) of a condition that causes death and/or considerable suffering?
2. Does the recommendation address the potential harms that will be incurred if it is implemented and, if these harms are serious, does the recommendation justify;
 - a. (a) why the potential benefits outweigh the potential harms and/or
 - b. (b) why an alternative course of treatment (or diagnostic workup) that involves less serious or fewer harms is not being recommended?
3. Does the rationale explain why the workgroup chose to make a recommendation in the face of minimal evidence while, in other instances, it chose to make no recommendation in the face of a similar amount of evidence?
4. Does the rationale explain that the recommendation is consistent with current practice?
5. If relevant, does the rationale justify why a more costly device, drug, or procedure is being recommended over a less costly one?

The work group will vote on each of the five questions listed above (four questions if question #5 is not relevant) using the nominal group technique. Failure to achieve consensus that every one of the above items ranks as a 7-9 means that the recommendation will be withdrawn and replaced by a recommendation stating that the work group cannot recommend either for or against the service addressed in the original recommendation.

APPENDIX IX

STRUCTURED PEER REVIEW FORM

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

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 weis@aaos.org or fax the form back to Jan Weis 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 by **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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. There is an explicit link between the recommendations and the supporting evidence	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Given the nature of the topic and the data, all clinically important outcomes are considered	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The guideline’s target audience is clearly described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The patients to whom this guideline is meant to apply are specifically described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The criteria used to select articles for inclusion are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The reasons why some studies were excluded are clearly described	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. All important studies that met the article inclusion criteria are included	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The validity of the studies is appropriately appraised	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. The methods are described in such a way as to be reproducible.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. The statistical methods are appropriate to the material and the objectives of this guideline	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Important parameters (e.g., setting, study population, study design) that could affect study results are systematically addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Health benefits, side effects, and risks are adequately addressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. The writing style is appropriate for health care professionals and patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. The grades assigned to each recommendation are appropriate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 X PEER REVIEW PANEL

Participation in the AAOS 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 Panel. Outside peer reviewers are solicited 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 work group prior to beginning work on the guideline. For this guideline, twelve outside peer review organizations were invited to review the draft guideline and all supporting documentation. Seven societies participated in the review of this guideline draft and all explicitly consented to be listed as a peer review organization in this appendix. The organizations that reviewed the document are listed below:

Arthroscopy Association of North America
American Academy of Family Physicians
American Academy of Physical Medicine and Rehabilitation
American Orthopaedic Society for Sports Medicine
American Physical Therapy Association
American Society of Shoulder and Elbow Surgeons
American Society of Shoulder and Elbow Therapists

Individuals who participated in the peer review of this document and gave their consent to be listed as reviewers of this document are:

Blair C. Filler MD	Jennifer Petrakis, DPT
Michael Heggeness MD	Charles Reitman MD
Michael W. Keith MD	John C. Richmond MD
Martin J. Kelley PT, DPT	Bryan L. Romig PT, DPT
John S. Kirkpatrick MD	Bruce Rougraff MD
John E. Kuhn MD	Kevin Shea MD
J. Mark Melhorn MD	Steven W. Strobe MD, MPH
Ariz R. Mehta MD	Russell Warren MD
David C. Morisette MD	Stephen Weber MD

Again, participation in the AAOS guideline peer review process does not constitute an endorsement of the guideline by the participating organizations or the individuals listed above.

PUBLIC COMMENTARY

A period of public commentary follows the peer review of the draft guideline. If significant non-editorial changes are made to the document as a result of public commentary, these changes are also documented and forwarded to the AAOS bodies that approve the final guideline.

For this guideline, members could submit public comments from September 17 to October 17, 2009. The physician members of the AAOS Board of Directors (BOD), Council on Research, Quality Assessment, and Technology (CORQAT) and members of the Board of Specialty Societies (BOS) and Board of Councilors (BOC) were given the opportunity to comment on this guideline.

Twelve members of the BOS requested that the guideline materials be forwarded to them for review. No BOS member returned comments. Six members of the BOC requested that the guideline materials be forwarded to them for review. No BOC member returned comments.

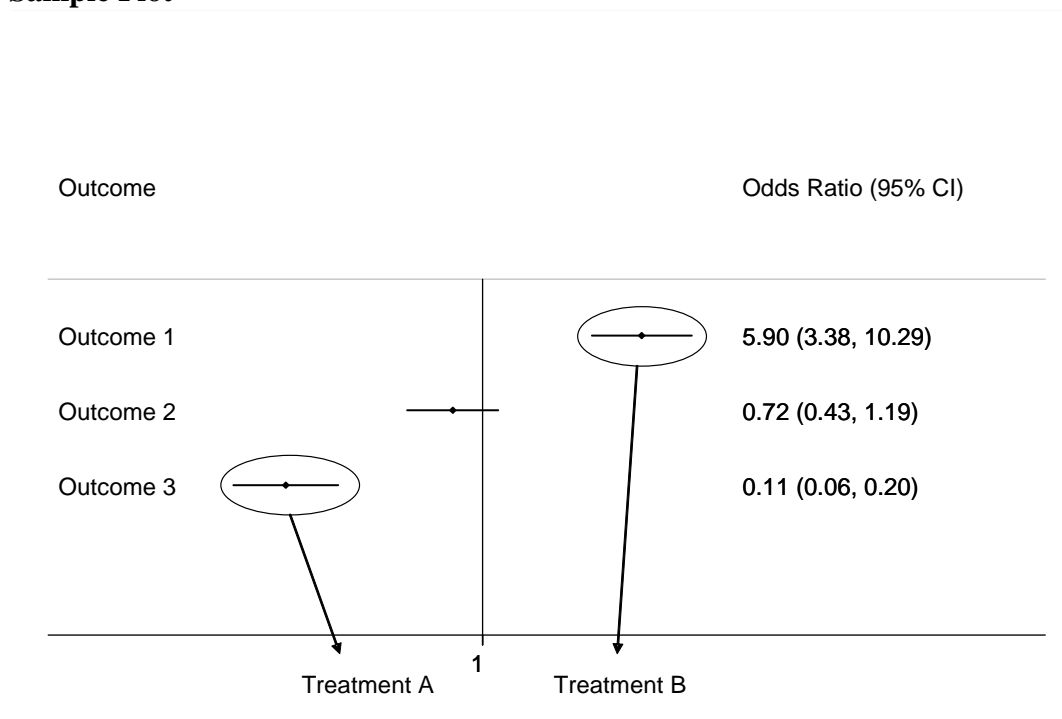
Participation in the AAOS guideline public commentary review process does not constitute an endorsement of the guideline by the participating organizations or the individual listed nor does it in any way imply the reviewer supports this document.

APPENDIX XI INTERPRETING THE FOREST PLOTS³¹



Throughout the guideline we use descriptive diagrams or forest plots to present data from studies comparing the differences in outcomes between two treatment groups. In this guideline there are no meta-analyses (combining results of multiple studies into a single estimate of overall effect), so each point and corresponding horizontal line on a sample plot should be viewed independently. In the example below, the odds ratio is the effect measure used to depict differences in outcomes between the two treatment groups of a study. In other forest plots, the point can refer to other summary measures (such as the mean difference or relative risk). The horizontal line running through each point represents the 95% confidence interval for that point. In this graph, the solid vertical line represents “no effect” where the Odds Ratio, OR, is equal to one. When mean differences are portrayed, the vertical line of no effect is at zero.

For example, in the figure below the odds of a patient experiencing Outcome 1 are 5.9 times greater for patients who received Treatment B than for patients who received Treatment A.. This result is statistically significant because the 95% Confidence Interval does not cross the “no effect” line. In general, the plots are arranged such that results to the left of the “no effect” line favor Treatment A while results to the right favor Treatment B. In the example below, the odds ratio for Outcome 1 favors Treatment B, the odds ratio for Outcome 3 favors Treatment A, and the odds ratio for Outcome 2 does not favor either treatment because the 95% CI crosses the “no effect” line (i.e. the difference is not statistically significant).

Sample Plot



DESCRIPTION OF SYMBOLS USED IN FIGURES AND TABLES

Symbol	Description
OR	Odds Ratio = The odds in Group B divided by the odds in Group A, where the odds is the probability of the outcome occurring divided by the probability of the outcome not occurring.
95% CI	95% Confidence Interval = A measure of uncertainty of the point estimate: if the trial were repeated an infinite number of times, then the 95% CI calculated for each trial would contain the true effect 95% of the time.
	An arrow in a forest plot indicates that the 95% confidence interval continues beyond the range of the graph.
	An open circle in a Summary of Evidence Table indicates that the result is not statistically significant.
● tsa	A filled-in circle in a Summary of Evidence Table indicates that the result is statistically significant in favor of the listed treatment (in this example, in favor of tsa = total shoulder arthroplasty)

APPENDIX XII 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.

Sara Edwards, MD (San Francisco, CA): (n). Submitted on: 10/14/2008.

Michael Q Freehill, MD (Edina, MN): 4 (Zimmer); 5A (Zimmer). Submitted on: 10/06/2008 at 03:12 PM.

Michael J Goldberg, MD: 2 (Journal of Pediatric Orthopedics; Journal of Children's Orthopaedics). Submitted on: 12/11/2007.

Rolando Izquierdo, MD (Crystal Lake, IL): 1 (Algonquin Road Surgery Center). Submitted on: 06/23/2008.

Michael Warren Keith, MD: (n). Submitted on: 10/10/2007 at 08:42 AM and last confirmed as accurate on 04/09/2008.

Walter Stanwood, MD (Duxbury, MA): 1 (Surgisouth, LLC); 5A (Arthrocare). Submitted on: 10/22/2008 at 03:44 PM.

Ilya Voloshin, MD (Rochester, NY): 5A (Arthrocare); 7 (Arthrex, Inc). Submitted on: 10/13/2008.

William Charles Watters III, MD: 1 (North American Spine Society; Work Loss Data Institute); 2 (The Spine Journal); 5A (Stryker; Intrinsic Therapeutics; McKessen Health Care Solutions). Submitted on: 10/09/2007 at 08:09 PM and last confirmed as accurate on 04/23/2008.

J Michael Wiater, MD (Beverly Hills, MI): 1 (American Shoulder and Elbow Surgeons; Michigan Orthopaedic Society); 2 (Journal of Bone and Joint Surgery - American; Journal of Shoulder and Elbow Surgery; Journal of the American Academy of Orthopedic Surgeons); 5A (Zimmer; American Academy of Orthopaedic Surgeons; Corather's Health Consulting, LLC); 7 (American Shoulder and Elbow Surgeons; William Beaumont Hospital Research Institute). Submitted on: 10/16/2008.

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.

**APPENDIX XIII
EVIDENCE TABLES**

See Evidence Tables Document (Evidence Tables.pdf)

APPENDIX IX REFERENCES

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