

Management of Glenohumeral Joint Osteoarthritis

Evidence-Based Clinical Practice Guideline

Adopted by: The American Academy of Orthopaedic Surgeons Board of Directors March 23, 2020

Endorsed by:









Please cite this guideline as:

American Academy of Orthopaedic Surgeons. Management of Glenohumeral Joint Osteoarthritis Evidence-Based Clinical Practice Guideline. www.aaos.org/gjocpg. Published March 23, 2020.

Disclaimer

This Clinical Practice Guideline was developed by an AAOS physician volunteer Clinical Practice Guideline development group based on a systematic review of the current scientific and clinical information and accepted approaches to management of rotator cuff injuries. 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 the 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.

Funding Source

This clinical practice guideline was funded exclusively by the American Academy of Orthopaedic Surgeons who received no funding from outside commercial sources to support the development of this document.

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SUMMARY OF RECOMMENDATIONS

HYALURONIC ACID

Strong evidence supports that there is no benefit to the use of hyaluronic acid in the treatment of glenohumeral joint osteoarthritis.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

PROGNOSTIC FACTORS (BMI: BODY MASS INDEX)

Strong evidence suggests that obese patients with glenohumeral osteoarthritis do not experience an increase in the rate of early post-operative complications.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

PROGNOSTIC FACTORS (GENDER/SEX)

Strong evidence supports that gender/sex is not associated with better or worse post-operative outcomes.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

PROGNOSTIC FACTORS (COMORBIDITIES)

Strong evidence suggests that patients with glenohumeral joint osteoarthritis who have more comorbidities experience higher rates of early post-arthroplasty complications.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

TOTAL SHOULDER ARTHROPLASTY

Strong evidence supports that anatomic total shoulder arthroplasty demonstrates more favorable function and pain relief in the short- to mid-term follow-up when compared to hemiarthroplasty for the treatment of glenohumeral osteoarthritis.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

GLENOID COMPONENTS – PEGGED OR KEELED

Strong evidence supports that the clinician may utilize pegged or keeled glenoid components in patients with glenohumeral joint osteoarthritis and a well-functioning rotator cuff. Pegged components demonstrate less radiolucent lines, but the effect on clinical outcomes and survivorship are unclear.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

PROGNOSTIC FACTORS (AGE)

Moderate evidence supports that older age at the time of surgery is associated with lower revision rates.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

PROGNOSTIC FACTORS (SMOKING)

Moderate evidence suggests that smoking is associated with inferior post-operative outcomes.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

PROGNOSTIC FACTORS (PRE-OPERATIVE FUNCTION)

Moderate quality evidence suggests that, while both higher and lower pre-operative functioning patients with glenohumeral joint osteoarthritis will likely experience improvement following arthroplasty, patients with higher pre-operative function may experience less functional improvement.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

PROGNOSTIC FACTORS (DEPRESSION)

Moderate evidence suggests that depression is associated with inferior post-operative outcomes in patients with glenohumeral joint osteoarthritis undergoing arthroplasty.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

GLENOID COMPONENTS – METAL-BACKED CEMENTLESS

Moderate evidence supports that surgeons not use metal-backed cementless glenoid components.

Strength of Recommendation: Moderate (upgraded)

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

TOTAL SHOULDER ARTHOPLASTY -- SUBSCAPULARIS PEEL, TENOTOMY, LESSER TUBEROSITY OSTEOTOMY

Moderate evidence supports that surgeons can utilize subscapularis peel, lesser tuberosity osteotomy, or tenotomy when performing shoulder arthroplasty.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

HEMIARTHROPLASTY – STEMS

Limited evidence supports that clinicians may utilize stemmed, stemless or resurfacing prosthesis for patients with glenohumeral joint osteoarthritis undergoing total or hemi-arthroplasty.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

SUMMARY OF CONSENSUS STATEMENTS

There is no evidence or only conflicting supporting evidence for the following recommendations. In the absence of reliable evidence, the systematic literature review development group is making a recommendation based on their clinical opinion.

PRE-OPERATIVE PHYSICAL THERAPY

In the absence of reliable evidence, it is the opinion of the work group that physical therapy may benefit select patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Consensus

POST-OPERATIVE PHYSICAL THERAPY

In the absence of reliable evidence, it is the opinion of the work group that clinicians may prescribe physical therapy in patients following shoulder arthroplasty.

Strength of Recommendation: Consensus

INJECTABLE BIOLOGICS

In the absence of reliable evidence, it is the opinion of the work group that injectable biologics, such as stem cells or platelet-rich plasma, cannot be recommended in the treatment of glenohumeral osteoarthritis.

Strength of Recommendation: Consensus

ALTERNATIVE NON-SURGICAL TREATMENTS

In the absence of reliable evidence, the work group cannot recommend for or against the use of the following:

Acupuncture Dry needling Cannabis Cannabodiol (CBD) oil Capsaicin Shark cartilage Glucosamine and chondroitin Cupping Transcutaneous Electrical Nerve Stimulation (TENS) Strength of Recommendation: Consensus

OPIOID PAIN MEDICATION

In the absence of reliable evidence, it is the opinion of the work group that opioids not be prescribed as routine and long-term pain management of glenohumeral osteoarthritis.

Strength of Recommendation: Consensus

NON-PROSTHETIC SURGICAL OPTIONS

In the absence of reliable evidence, it is the opinion of the work group that non-prosthetic surgical options may or may not provide short-term benefit for patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Consensus

RADIOGRAPHS

In the absence of reliable evidence, it is the opinion of the work group that patients with glenohumeral osteoarthritis undergoing arthroplasty should be imaged with axillary and true AP (Grashey view) radiographs, with advanced imaging performed at the discretion of the clinician.

Strength of Recommendation: Consensus

CEMENTED STEMS

In the absence of reliable evidence, it is the opinion of the work group that either cemented or cementless stems can be utilized in the treatment of patients with glenohumeral joint osteoarthritis and a well-functioning rotator cuff.

Strength of Recommendation: Consensus

ANATOMIC/ REVERSE TOTAL SHOULDER ARTHROPLASTY

In the absence of reliable evidence, it is the opinion of the workgroup that clinicians may use either anatomic total shoulder arthroplasty (TSA) or reverse TSA for the treatment of glenohumeral joint osteoarthritis in select patients with excessive glenoid bone loss and/or rotator cuff dysfunction.

Strength of Recommendation: Consensus

GLENOID COMPONENTS – POLYETHYLENE-METAL OR ALL-POLYETHYLENE

In the absence of reliable evidence, it is the opinion of the workgroup that clinicians may use polyethylene-metal hybrid glenoid components or all-polyethylene components during total shoulder arthroplasty for treatment of glenohumeral joint osteoarthritis.

BICEPS TENODESIS AND TENOTOMY

In the absence of reliable evidence, it is the opinion of the workgroup that clinicians may consider concomitant biceps tenodesis or tenotomy during shoulder arthroplasty.

Strength of Recommendation: Consensus

TRANEXEMIC ACID

In the absence of reliable evidence, it is the opinion of the workgroup that utilization of tranexamic acid during shoulder arthroplasty may result in reduced blood loss and reduced risk of blood transfusion.

Strength of Recommendation: Consensus

SUPRASPINATUS TEARS

In the absence of reliable evidence, it is the opinion of the workgroup that, for patients with small isolated, repairable supraspinatus tears, clinicians can perform anatomic total shoulder arthroplasty.

Strength of Recommendation: Consensus

DISCHARGE

In the absence of reliable evidence, it is the opinion of the workgroup that same-day discharge is an option after shoulder arthroplasty in select patients.

Strength of Recommendation: Consensus

CRYOTHERAPY

In the absence of reliable evidence, it is the opinion of the workgroup that either continuous cryotherapy or cold packs can be used following shoulder arthroplasty.

Strength of Recommendation: Consensus

MULTIMODAL PAIN MANAGEMENT

In the absence of reliable evidence, it is the opinion of the workgroup that multimodal pain management strategies or non-opioid individual modalities can provide added benefit for postoperative pain management following shoulder arthroplasty.

Strength of Recommendation: Consensus

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INTRODUCTION

OVERVIEW

This clinical practice guideline is based on a systematic review of published studies for the treatment of glenohumeral joint osteoarthritis. This guideline aims to provide practice recommendations based on the best available evidence, highlight the limitations in the current literature, and suggest areas for future research. The often-repeated qualifier, "In the absence of reliable evidence", should not be understood as there is no evidence, but that the evidence in the literature did not meet our minimum inclusion criteria (e.g. animal studies, cadaver studies, case series, etc.).

This guideline was developed for all qualified and appropriately trained health care professionals involved in the management of glenohumeral joint osteoarthritis. It is intended as an information resource to guide decision making and assist developers of future practice guidelines and treatment recommendations.

GOALS AND RATIONALE

Clinical practice guidelines provide evidence-based treatment recommendations derived from a systematic review of the best current available evidence in the literature. The goal of this guideline is to summarize the areas where there is good evidence and poor evidence in the management of glenohumeral joint osteoarthritis and identify areas where evidence of any kind is lacking. AAOS staff and the physician and physical therapy work group predetermined specific questions of interest for this patient population, systematically reviewed the currently available literature, and developed the current recommendations based on the strength or weaknesses of the results of this review.

This guideline was created as a tool to assist physicians, surgeons and other health care professionals that care for patients with glenohumeral joint osteoarthritis in developing an understanding of levels of evidence that exist for a range of common diagnostic and treatment practices. It is by no means a replacement for appropriate clinical judgement regarding any specific treatment modality or procedure and each patient should be managed based on their needs and resources available to the individual healthcare provider.

INTENDED USERS

Healthcare professionals other than orthopaedic surgeons, including but not limited to, geriatricians, adult primary care physicians, adult medicine specialists, physical therapists, occupational therapists, physician assistants, nurse practitioners, physiatrists, who routinely see this patient population in various practice settings may also benefit from this clinical practice guideline. The treatment of glenohumeral joint osteoarthritis is based on informed decision making between the patient and the healthcare provider. Discussion of available nonsurgical and surgical treatments provides a thorough outline of all of the options so an informed decision can be made. Clinician input based on medical knowledge, conservative management and surgical experience as well as skill, all influence the successful identification of who will benefit from specific treatment options.

This guideline is not intended for use as a benefits determination document.

PATIENT POPULATION

This document addresses the management of patients with glenohumeral joint osteoarthritis. It is not intended to address management of glenohumeral joint arthritis from etiologies other than

osteoarthritis (i.e. rheumatoid arthritis, inflammatory arthritis, post traumatic arthritis, avascular necrosis, rotator cuff tear arthropathy, capsulorrhaphy arthropathy, post-infectious arthropathy, etc.).

BURDEN OF DISEASE

Chronic shoulder pain can result in significant dysfunction, disability, and increased health care costs. Shoulder pain has been reported as one of the most commonly affected joints for chronic pain, affecting 22.3 million in patients over 18 years of age in 2015.(Weinstein et al., Burden of Musculoskeletal Disease) It is estimated that shoulder pain affects 5-21% of the adult population in the United states and glenohumeral joint arthritis affects nearly a third of the world's population over the age of 60.^{10,22} (Singh et al 2010) The economic burden for the management of glenohumeral joint osteoarthritis is directly correlated with duration of conservative management, surgical costs, perioperative complication rates, as well as implant survivorship, and need for revision shoulder arthroplasty. As the population ages, so to does the disease burden of patients needing treatment for glenohumeral joint osteoarthritis. The reported annual increase of procedural volume from 2007 to 2015 has been estimated between 192% to 322%. Correspondingly, this will also result in an increased revision burden of approximately 4.5 to 7%. (Day et al JSES 2010)

The 2016 Agency for Healthcare Research and Quality reported a mean of 66,185 patients discharged from the hospitals across the United States (mean length of stay 1.7 days) with a diagnosis of primary glenohumeral joint osteoarthritis (IDC-10 codes M19.01, M19.011, M19.012, M19.019). The average hospital charge was \$64,332 for each patient's hospital encounter. The presented data in this report does not specifically state the reason for hospitalization, however, it is reasonable to assume that these patients underwent shoulder arthroplasty. From this data set it is clear that surgical treatment of shoulder glenohumeral joint osteoarthritis is a large health care burden.

ETIOLOGY

Glenohumeral joint osteoarthritis is characterized by progressive humeral head cartilage loss, adaptive changes to the subchondral bone, development of inferior humeral head osteophytes. These changes result in subsequent biomechanical change of the glenohumeral joint, joint space narrowing, posterior humeral head subluxation followed by progressive posterior glenoid bone loss. Although it has been hypothesized that there may be a genetic predisposition to disease progression, primary glenohumeral joint osteoarthritis has no specific causative factor that explains the etiology of the disease process other than the degenerative process that naturally occurs as a result of aging.

INCIDENCE AND PREVALENCE

Glenohumeral joint osteoarthritis is more common in women and increases with age. Primary glenohumeral joint osteoarthritis can occur over a broad age range, it is most commonly seen in patients >60 years of age. Radiographic data has found a prevalence rate of 94% in women and 85% in men over the age of 80 years.³⁰ (Hashemi et al) Furthermore, Kerr et al (AJR 1985) reported a 20% incidence of idiopathic glenohumeral joint osteoarthritis in patients over the age of 60 who presented for shoulder symptoms. While the true incidence and prevalence of glenohumeral joint osteoarthritis cannot be estimated currently, it is important to recognize it is common.

RISK FACTORS

Age is the biggest risk factor for the development of primary glenohumeral joint osteoarthritis. While there are many known causes of secondary glenohumeral joint arthritis, the cause of primary osteoarthritis is largely unknown.

EMOTIONAL AND PHYSICAL IMPACT

Primary symptomatic glenohumeral joint osteoarthritis is characterized by progressive loss of function and pain. Rozencwaig et al, JBJS 1998 demonstrated that an increased number of medical comorbidities correlated with worse shoulder function demonstrated by lower preoperative simple shoulder test scores as well as worse functional and comfort components on the Short Form-36 parameters. Unfortunately, the results of this study cannot correlate disease severity with functional status or symptoms.

POTENTIAL BENEFITS, HARMS, AND CONTRAINDICATIONS

There are risks associated with both surgical and non-operative treatment of glenohumeral joint osteoarthritis. These risk factors increase based on the invasiveness of the treatment modality. Risks include but are not limited to infection, functional limitations, stiffness, neurovascular injury, deep venous thrombosis, pulmonary embolism, anesthesia complications, etc. The risks of complications are influenced by the providers' choice of treatment as well as patients underlying medical comorbidities. Contraindications are based on the specific treatment as well as patient related factors.

FUTURE RESEARCH

Risk factors for implant survivorship of total shoulder arthroplasty need further investigation with high-quality, well-designed studies that have long term follow-up. Numerous factors have been found to contribute to implant failure such as stability of glenoid fixation, preservation of glenoid subchondral bone, severity of eccentric glenoid wear, excessive glenoid retroversion, proper surgical technique, and magnitude of posterior humeral head subluxation. Unfortunately, the current literature does not provide enough high-quality evidence to develop definitive treatment recommendations to direct implant selection (i.e. anatomic total shoulder arthroplasty, hemiarthroplasty, reverse total shoulder arthroplasty).

Areas in need of additional high-quality research include the efficacy of physical therapy and other non-surgical treatment modalities as an alternative to arthroplasty, and preoperative physical therapy (prior to shoulder arthroplasty). If and how home based versus formal outpatient physical therapy impacts clinical outcome is also of interest, as is the impact of preoperative narcotic use. There are many areas of intervention that are commonly used in the management of glenohumeral joint osteoarthritis with little to no evidence-based data to support their use.

Preoperative surgical planning using thin slice (<1mm cuts) 3-D CT scan with planning software has become an area that has gained significant popularity. Yet to date, there is no supporting evidence that the use of these advanced imaging modalities and software has an impact on clinical and functional outcomes, complication rates or implant survivorship. High quality well designed multicenter prospective cohort studies and randomized trials are needed to provide evidence to the impact of this technology.

The availability of more advanced imaging has been accompanied by an increasing understanding of the surgical challenges created by significant posterior glenoid bone loss. Concomitantly, surgeons have expanded the indications for the use of reverse total shoulder arthroplasty in glenohumeral osteoarthritis with complex glenoid wear even in the presence of an intact rotator cuff. To date there have been no high-quality studies demonstrating improved clinical outcome, and/or implant survivorship, when reverse total shoulder arthroplasty as opposed to anatomic total shoulder arthroplasty in these challenging situations. Well-designed prospective cohort or randomized trials are needed to support evidence-based recommendations.

Additional References:

Rozencwaig, R., van Noort, A., Moskal, M.J., Smith, K.L., Sidles, J.A., Matsen, F.A., The correlation of comorbidity with function of the shoulder and health status of patients who have glenohumeral degenerative joint disease. *J Bone Joint Surg Am.* 1998;80(8):1146-53.

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Singh, J.A., Sperling, J., Buchbinder, R., McMaken, K., Surgery for shoulder osteoarthritis. *Cochrane Database Syst Rev.* 2010;10:CD008089.

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Weinstein, S.I., Yelin, E.H., Watkins-Castillo, S.I., Burden of Musculoskeletal Diseases in the US (BMUS)- 4th edition: Prevalence of Select Musculoskeletal Conditions: pgs 1-8 Available at http://www.boneandjointburden.org.

METHODS

The methods used to perform this clinical practice guideline were employed to minimize bias and enhance transparency in the selection, appraisal, and analysis of the available evidence. These processes are vital to the development of reliable, transparent, and accurate clinical recommendations for management of Glenohumeral Joint Osteoarthritis. To view the full AAOS clinical practice guideline methodology please visit the <u>eAppendix 1</u> or <u>https://www.aaos.org/additonalresources/</u>.

This clinical practice guideline evaluates the effectiveness of approaches in the management of Glenohumeral Joint Osteoarthritis. The AAOS approach incorporates practicing physicians (clinical experts) and methodologists who are free of potential conflicts of interest relevant to the topic under study, as recommended by clinical practice guideline development experts.

This clinical practice guideline was prepared by the AAOS Management of Glenohumeral Joint Osteoarthritis Clinical Practice Guideline Physician Development Group (clinical experts) with the assistance of the AAOS Clinical Quality and Value (CQV) Department (methodologists). To develop this systematic literature review, the systematic literature review development group held an introductory meeting on January 26, 2019 to establish the scope of the systematic literature review. As the physician experts, the systematic literature review development group defined the scope of the clinical practice guideline by creating PICO Questions (i.e. population, intervention, comparison, and outcome) that directed the literature search. The AAOS Medical Librarian created and executed the search (see eAppendix 1 for search strategy).

BEST EVIDENCE SYNTHESIS

We included only the best available evidence for any given outcome addressing a recommendation. Accordingly, we first included the highest quality evidence for any given outcome if it was available. In the absence of two or more occurrences of an outcome at this quality, we considered outcomes of the next lowest quality until at least two or more occurrences of an outcome had been acquired. For example, if there were two 'moderate' quality occurrences of an outcome that addressed a recommendation, we did not include 'low' quality occurrences of this outcome. A summary of excluded articles can be viewed in eAppendix 1. All of the detailed data for each recommendation can be found via eAppendix 2.

LITERATURE SEARCHES

The medical librarian conducted a comprehensive search of PubMed, Embase, and the Cochrane Central Register of Controlled Trials based on key terms and concepts from the systematic literature review development group's preliminary recommendations. Bibliographies of relevant systematic reviews were hand searched for additional references. All databases were last searched on June 7, 2019 with limits for publication dates from 2000-2019 and English language.

DEFINING THE STRENGTH OF THE RECOMMENDATIONS

Judging the strength of evidence is only a steppingstone towards arriving at the strength of a systematic literature review recommendation. The strength of recommendation (Table 1) also takes into account the quality, quantity, and the trade-off between the benefits and harms of a treatment, the magnitude of a treatment's effect, and whether there is data on critical outcomes. Table 2 addresses how to interpret the strength of each recommendation.

VOTING ON THE RECOMMENDATIONS

The recommendations and their strength were voted on by the guideline development group members during the final meeting. If disagreement between the guideline development group

occurred, there was further discussion to see whether the disagreement(s) could be resolved. Recommendations were approved and adopted in instances where a simple majority (60%) of the guideline development group voted to approve; Please see appendix for voting breakdown.

INTERPRETING THE STRENGTH OF EVIDENCE Table 1. Strength of Recommendation Descriptions

Strength	Overall Strength of Evidence	Description of Evidence Quality	Strength Visual
Strong	Strong	Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.	****
Moderate	Moderate	Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.	****
Limited	Low or Conflicting Evidence	Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.	****
Consensus	No Evidence	There is no supporting evidence. In the absence of reliable evidence, the systematic literature review development group is making a recommendation based on their clinical opinion.	****

1 Table II. Clinical Applicability: Interpreting the Strength of a Recommendation

Strength of Recommendation	Patient Counseling (Time)	Decision Aids	Impact of Future Research
Strong	Least	Least Important, unless the evidence supports no difference between two alternative interventions	Not likely to change
Moderate	Less	Less Important	Less likely to change
Limited	More	Important	Change possible/anticipated
Consensus	Most	Most Important	Impact unknown

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REVIEW PERIOD

Following the final meeting, the CPG draft undergoes a 3-week review period for additional input from external content experts. Written comments are provided on the structured review form. All reviewers are required to disclose their conflicts of interest.

To guide who participates, the CPG work group identifies specialty societies at the introductory meeting. Organizations, not individuals, are specified.

The specialty societies are solicited for nominations of individual reviewers approximately six weeks before the final meeting. The review period is announced as it approaches, and others interested are able to volunteer to review the draft. The chairs of the guideline work group review the draft of the guideline prior to dissemination.

Some specialty societies (both orthopaedic and non-orthopaedic) ask their evidence-based practice (EBP) committee to provide review of the guideline. The organization is responsible for coordinating the distribution of our materials and consolidating their comments onto one form. The chair of the external EBP committees provides disclosure of their conflicts of interest (COI) and manages the potential conflicts of their members.

Again, the AAOS asks for comments to be assembled into a single response form by the specialty society and for the individual submitting the review to provide disclosure of potentially conflicting interests. The review stage gives external stakeholders an opportunity to provide evidence-based direction for modifications that they believe have been overlooked. Since the draft is subject to revisions until its approval by the AAOS Board of Directors as the final step in the guideline development process, confidentiality of all working drafts is essential.

The CPG is also provided to members of the AAOS Board of Directors (BOD), members of the Council on Research and Quality (CORQ), members of the Board of Councilors (BOC), and members of the Board of Specialty Societies (BOS) and members of the Committee on Evidence-Based Quality and Value (EBQV) for review and comment. The CPG is automatically forwarded to the AAOS BOD and CORQ so that they may review it and provide comment prior to being asked to approve the document. Members of the BOC and BOS are solicited for interest. If they request to see the document, it is forwarded to them for comment. Based on these bodies, over 200 commentators have the opportunity to provide input into each CPG.

The chairs of the guideline work group and the manager of the AAOS CQV unit drafts the initial responses to comments that address methodology. These responses are then reviewed by the chair and cochair, who respond to questions concerning clinical practice and techniques. The Senior Manager of Clinical Quality and Value may provide input as well. All comments received and the initial drafts of the responses are also reviewed by all members of the guideline development group. All proposed changes to recommendation language as a result of the review period are based on the evidence. Final revisions are summarized in a report that is provided alongside the guideline document throughout the remainder of the approval processes and final publication.

The AAOS believes in the importance of demonstrating responsiveness to input received during the review process and welcomes the critiques of external specialty societies. Following final approval of the guideline, all individual responses are posted on our website http://www.aaos.org/quality with a point-by-point reply to each non-editorial comment. Reviewers who wish to remain anonymous notify the AAOS to have their names de-identified; their comments, our responses, and their COI disclosures are still posted.

THE AAOS CLINICAL PRACTICE GUIDELINE APPROVAL PROCESS

This final clinical practice guideline draft must be approved by the AAOS Committee on Evidence-Based Quality and Value Committee, the AAOS Council on Research and Quality, and the AAOS Board of Directors. These decision-making bodies are described in <u>eAppendix 1</u>. Their charge is to approve or reject its publication by majority vote.

REVISION PLANS

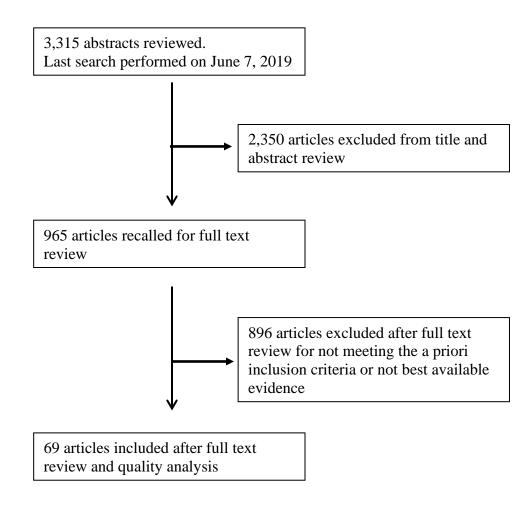
This clinical practice guideline represents a cross-sectional view of current treatment and may become outdated as new evidence becomes available. This clinical practice guideline will be revised in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology. This clinical practice guideline will be updated, re-issued, or withdrawn in five years.

SYSTEMATIC LITERATURE REVIEW DISSEMINATION PLANS

The primary purpose of the present document is to provide interested readers with full documentation of the best available evidence for various procedures associated with the topic of this review. Publication of most systematic literature reviews is announced by an Academy press release, articles authored by the systematic literature review development group and published in the *Journal of the American Academy of Orthopaedic Surgeons*, and articles published in *AAOS Now*.

Selected clinical practice guidelines are disseminated by webinar, AAOS Online Learning, the Orthopaedic Video Theater (OVT), Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

STUDY ATTRITION FLOWCHART



RECOMMENDATIONS

HYALURONIC ACID

Strong evidence supports that there is no benefit to the use of hyaluronic acid in the treatment of glenohumeral joint osteoarthritis.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

There were 2 randomized- controlled studies that were evaluated. In Blain et al, an industry sponsored study, it did not meet its primary endpoint as there was no difference in pain scores at 13 weeks when comparing hyaluronic acid to phosphate-buffered saline solution. Kwon et al, was also an industry sponsored study and Food and Drug Administration Investigational Device Exemption (G060225) that was established to assess the safety and effectiveness of 3 weekly intra-articular injections of HA compared with saline. The patients enrolled in the study consisted of mixed pathologies in addition to glenohumeral osteoarthritis. Neither visual analog scores nor outcome measures in Rheumatoid Clinical Trials-Osteoarthritis Research Society International (OMERACT-OARSI) met statistical significance at 26 weeks. In addition, injections were given blindly and with minimal patients receiving ultrasound or fluoroscopic injections.

Two other studies by the same author (DiGiacomo et al) were reviewed and were of lesser quality.

Strength of Evidence (quality of evidence):

Strong

Cost Effectiveness/Resource Utilization:

There is added cost without any benefit.

PROGNOSTIC FACTORS (BMI)

Strong evidence suggests that obese patients with glenohumeral osteoarthritis do not experience an increase in the rate of early post-operative complications.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

Several high-quality studies have addressed BMI as a risk factor for early postoperative complications with none demonstrating significant differences with non-obese patients undergoing shoulder arthroplasty for glenohumeral osteoarthritis.

Bernstein D et al (2017) utilized a logistical regression model of data from the America College of Surgeons National Surgical Quality Improvement Program (NSQIP) to identify factors associated with increased risk of adverse events and re-admissions within 30 days of surgery. BMI was not found to predict an increased risk of these complications.

Chalmers et al (2014) failed to demonstrate an increase in complication rates, transfusion rates, intraoperative blood loss or surgical time based on BMI. However, a post-hoc analysis by the authors suggested that this study was underpowered to assess this association.

Jiang et al (2016) again queried the NSQIP database and found that while surgical time was increased for patients with greater BMI, 30-day complication and re-admission rates were not increased.

Strength of Evidence (quality of evidence):

Strong

Benefits & Harms:

There is benefit in providing access to shoulder arthroplasty to obese patients as an option for treatment of glenohumeral osteoarthritis in face of the lack of increase in early postoperative complications.

Cost Effectiveness/Resource Utilization:

Considerable resources can be expended in attempts to modify high BMI to improve surgical risk. Other significant health benefits from treating obesity notwithstanding, shoulder arthroplasty for glenohumeral osteoarthritis appears not to be affected by BMI in early complication rates.

Future Research:

While early postoperative complication rates have not been demonstrated to be increased in obese patients undergoing shoulder arthroplasty for glenohumeral arthritis, the effect of BMI on other factors such as long-term complications (e.g. late infection, prosthetic loosening, dislocation, rotator cuff tear) and pain and functional outcomes remain to be demonstrated in high quality studies.

PROGNOSTIC FACTORS (GENDER/SEX)

Strong evidence supports that gender/sex is not associated with better or worse post-operative outcomes.



Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

Numerous studies have not found any significant difference in outcomes between men and women undergoing TSA for osteoarthritis. Equivalent outcomes can be expected between both genders/sexes undergoing TSA for OA. Patients can be counseled that their outcome from TSA for OA is not gender/sex specific, and that men and women can expect similar outcomes.

Strength of Evidence (quality of evidence): Strong

Benefits & Harms:

Outcome Importance: This should serve to eliminate any gender/sex-based biases towards (or against) either gender/sex in performing TSA for osteoarthritis.

Future Research:

Future studies should continue to evaluate post-operative outcomes for TSA in osteoarthritis, with one of the variables examined to include gender/sex-based differences. There has been a movement towards gender/sex specific implants. Current data would suggest this may not be needed in the shoulder given the similar outcomes, future studies could further assess this.

Additional References:

- 1. Rasmussen, J.V., Amundsen, A., Sørensen, A.K.B., et.al. Increased use of total shoulder arthroplasty for osteoarthritis and improved patient-reported outcome in Denmark, 2006-2015: a nationwide cohort study from the Danish Shoulder Arthroplasty Registry. *Acta Orthop.* 2019;90(5):489-494.
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- 7. Baumgarten, K.M., Chang, P.S., Dannenbring, T.M., Foley, E.K., Does total shoulder arthroplasty improve patients' activity levels? *J Shoulder Elbow Surg*. 2018;27(11):1987-1995.
- 8. Merolla, G., Cerciello, S., Marenco, S., Fabbri, E., Paladini, P., Porcellini, G., Comparison of shoulder replacement to treat osteoarthritis secondary to instability surgery and primary osteoarthritis: a retrospective controlled study of patient outcomes. *Int Orthop*. 2018;42(9):2147-2157.
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- 10. Mahony, G.T., Werner, B.C., Chang, B., Grawe, B.M., et. al. Risk factors for failing to achieve improvement after anatomic total shoulder arthroplasty for glenohumeral osteoarthritis. *J Shoulder Elbow Surg*. 2018;27(6):968-975.
- 11. Simovitch, R., Flurin, P.H., Wright, T., Zuckerman, J.D., Roche, C.P., Quantifying success after total shoulder arthroplasty: the substantial clinical benefit. *J Shoulder Elbow Surg*. 2018;27(5):903-911.
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- 13. Dowdle, S.B., Glass, N., Anthony, C.A., Hettrich, C.M., Use of PROMIS for Patients Undergoing Primary Total Shoulder Arthroplasty. *Orthop J Sports Med.* 2017;5(9):2325967117726044.
- 14. Kilian, C.M., Press, C.M., Smith, K.M., et. al. Radiographic and clinical comparison of pegged and keeled glenoid components using modern cementing techniques: midterm results of a prospective randomized study. *J Shoulder Elbow Surg*. 2017;26(12):2078-2085.
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PROGNOSTIC FACTORS (COMORBIDITIES)

Strong evidence suggests that patients with glenohumeral joint osteoarthritis who have more comorbidities experience higher rates of early post-arthroplasty complications.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

There is a growing body of literature examining the role comorbidities play in post-operative outcomes in shoulder arthroplasty, although it should be noted there is variability in some of the results. Two high quality studies (Bernstein 2017 and Chalmers 2014) showed that patients with medical comorbidities were at increased risk for complications and hospital re-admission.

One high quality study (Chalmers et al) noted significantly higher Charlson Comorbidity Index (CCI) scores in those with post-operative complications, both in overall complications and those deemed to be surgical, although it should be noted the majority of complications were classified as "minor" in this study. Another high-quality study (Bernstein et al) demonstrated that elevated BUN and creatinine were associated with adverse events in TSA, while elevated BUN, elevated creatinine, low platelets, and hypertension requiring medications was associated with TSA and unplanned readmission.

A moderate quality study (Mahony et al) has suggested that patients with diabetes do not show as much improvement following anatomic TSA, with the authors noting that patients with diabetes were more likely to undergo further surgery in within two years of shoulder arthroplasty or fail to obtain a minimal clinically important difference in ASES scores.

Strength of Evidence (evidence quality): Strong

Benefits & Harms:

As the demand for shoulder arthroplasty increases, it is imperative surgeons understand those patients who will likely best succeed after shoulder arthroplasty and have the fewest complications and readmissions. No harm would come to patients by taking into account these risk factors.

Cost Effectiveness/Resource Utilization:

This information allows surgeons to stratify which patients will do best with surgery, potentially reducing revision rates and readmissions following shoulder arthroplasty.

Future Research:

Future research is needed to better clarify these risk factors and to determine if outcomes following shoulder arthroplasty can be more accurately predicted.

TOTAL SHOULDER ARTHROPLASTY

Strong evidence supports that anatomic total shoulder arthroplasty demonstrates more favorable function and pain relief in the short- to mid-term follow-up when compared to hemiarthroplasty for the treatment of glenohumeral osteoarthritis.



Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

There were 2 high quality (Gartsman et al. 2000 & Lo et al. 2005), one moderate quality (Mann et al. 2014), and 13 low quality (Garcia et al. 2016, Edwards et al. 2003, Iannotti et al. 2003, Virk et al. 2018, Razmjou et al. 2014, Gowd et al. 2019, Krukenberg et al. 2018, Werthel et al. 2018, Rasmussen et al. 2018, Levy et al. 2004, Clinton et al. 2007, and Orfaly et al. 2003, Schairer et al. 2014) studies evaluating and comparing the outcomes of anatomic total shoulder arthroplasty to hemiarthroplasty.

Gartsman et al. 2000, performed a prospective randomized trial and found significantly better pain relief (p=0.002), internal rotation (p=0.003) and lower revision rates (3 subjects in hemiarthroplasty group underwent reoperation for conversion tot total shoulder arthroplasty) with anatomic total shoulder arthroplasty. Both ASES and UCLA scores were also significantly better for the anatomic total shoulder arthroplasty group.

Lo et al. 2005, performed a prospective randomized double-blind study comparing anatomic total shoulder to hemiarthroplasty. The total shoulder arthroplasty group had better postoperative ASES, UCLA, WOOS quality of life, Constant scores at two years follow up but these values did not reach statistical significance. There were 4 patients in the hemiarthroplasty group considered as failures 3 of which due to progressive glenoid erosion and one due to rotator cuff deficiency with poor function and increased pain. Two went on to revision surgery and conversion to anatomic total shoulder arthroplasty.

Meta-analysis was performed favoring anatomic total shoulder arthroplasty with regards to improvement in ASES score (Gartsman et al. 2000, Iannotti et al. 2003, Lo et al. 2005, Razmjou et al. 2014, Virk et al. 2018), functional scale (Clinton et al. 2007, Gowd et al. 2019, Lo et al. 2005, Virk et al. 2018), pain scale (Garcia et al. 2016, Iannotti et al. 2003, Lo et al. 2005, Virk et al. 2018), range of motion (specifically external rotation)(Virk et al. 2018, Razmjou et al. 2014), patient satisfaction (Edwards et al. 2003, Garcia et al. 2016, Gowd et al. 2019, Werthel et al. 2018) and lower complication rate (Garcia et al. 2016, Mann et al. 2014, Werthel et al. 2018).

Longer follow-up is needed to determine if these findings maintain over time especially related to implant survivorship, patient reported outcomes, pain, function, and quality of life. Additionally, prior studies did not adequately stratify patients by parameters that are now understood important such as glenoid morphology type and rotator cuff integrity.

Strength of Evidence (quality of evidence):

Strong

Benefits & Harms:

There are no harms with implementation of this recommendation.

Outcome Importance:

Methods to optimize predictable postoperative outcomes following shoulder arthroplasty will decrease complication rates, increase implant survivorship as well as patient function improvements and satisfaction.

Cost Effectiveness/Resource Utilization:

Evidence based decisions regarding implant choice will ideally result in decreased long term costs by decreasing the need for revision surgery, decrease need for prolonged treatment with physical therapy and decreased risk of long-term pain related issues.

Acceptability:

Anatomic total shoulder arthroplasty is already an acceptable commonly used procedure for the treatment of glenohumeral joint arthritis.

Feasibility:

Again, anatomic total shoulder arthroplasty is a well-established surgical treatment for glenohumeral joint arthritis.

Future Research:

Additional research is needed to determine long term follow-up of the outcomes of shoulder arthroplasty. Currently, the studies which have met inclusion criteria for this document as well as that are available are at best medium-term follow-up. Although there are case series in the literature with >10-year follow-up this is not sufficient to make evidence-based decisions regarding treatment. It is important to understand the long-term outcomes, survivorship as well as consequences of failure from issues such as glenoid failure (i.e. bone loss, erosion, implant loosening), rotator cuff pathology, humeral implant failure or stress shielding.

GLENOID COMPONENT – PEGGED OR KEELED

Strong evidence supports that the clinician may utilize pegged or keeled glenoid components in patients with glenohumeral joint osteoarthritis and a well-functioning rotator cuff. Pegged components demonstrate less radiolucent lines, but the effect on clinical outcomes and survivorship are unclear.

Strength of Recommendation: Strong

Description: Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention.

RATIONALE:

There were two high quality (Edwards et al. 2007, Gartsman et al. 2000) and two low quality (Throckmorton et al. 2010, Lazarus et al. 2002) studies which met inclusion criteria. These studies demonstrated that pegged components have a lower incidence of postoperative radiolucent lines. There was no significant difference in either functional outcomes, pain, or patient reported outcome measures. There was also no significant difference in the incidence of glenoid component loosening, radiographic failure or need for revision surgery between groups. The included studies have only short-term follow-up (2 years). Longer follow-up is needed to demonstrate if there will be a clinically significant difference between pegged and keeled glenoid components. Additionally, identifying if glenoid component type will influence implant survivorship can only be determined with long term follow-up (>10 years). Given the current evidence, it is at the discretion of the surgeon as to which implant to use based on comfort with surgical technique to reproducibly achieve a successful outcome. Furthermore, the pegged constructs studied are not the implants commonly in use today.

Strength of Evidence (quality of evidence):

Strong

Benefits & Harms:

There are no risks associated with the use of either glenoid component as they are already standard practice for use during anatomic total shoulder arthroplasty. These decisions are currently being made at the discretion of the surgeon.

Outcome Importance:

Implant survivorship and predictability of the clinical outcome following anatomic total shoulder arthroplasty will result in lower incidence of reoperation, longer duration of pain relief, and maintained shoulder function.

Cost Effectiveness/Resource Utilization:

Evidence based decision making on type of glenoid component utilized for anatomic total shoulder arthroplasty should result in longer survivorship. Methods to prevent need for reoperation/ revision shoulder arthroplasty decreases cost and health care resources often required for an extended period of time due to the increased complexity associated with revision surgery. Pegged and keeled glenoid components have similar cost so currently either implant does not add additional expense. View background material via the GJO CPG eAppendix 1

View data summaries via the GJO CPG eAppendix 2

Acceptability:

Currently both pegged and keeled glenoid components are used frequently during anatomic total shoulder arthroplasty therefore there should be no issues implementing this recommendation as it does not influence a change in clinical practice.

Feasibility:

This recommendation does not impact a change in clinical practice recommendation therefore until further evidence is available continued use of either pegged or keeled glenoid components is appropriate.

Future Research:

Most important future research is high quality investigation with either prospective randomized trials or prospective cohort studies to establish long term (>10 year) follow-up of these implants is critical to determine survivorship/ failure rates, clinical and functional outcomes.

PROGNOSTIC FACTORS (AGE)

Moderate evidence supports that older age at the time of surgery is associated with lower revision rates.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

RATIONALE:

One moderate quality study (Robinson et al 2018) and two low quality studies (Odquist et al 2018, Rispoli et al 2006) have evaluated the outcomes of patients who underwent hemiarthroplasty for the treatment of glenohumeral joint osteoarthritis. All three of these studies were retrospective reviews of hemiarthroplasty patients of institutional (Robinson et al, Rispoli et al) or national (Odquist et al) database registries. All three studies used Cox proportional hazards regression model to determine the factors associated with survival defined as time from the index procedure free from any revision surgery. The findings of all three studies demonstrate that older age was associated with a decreased risk of revision surgery. The study by Odquist et al had a minimum follow-up of 5 years after the index procedure and the Robinson et al study, which was a continuation of the same patient cohort as the Rispoli et al study which was published at an earlier time point, had a mean follow-up duration of 17 years. The most common reason for revision surgery in the study by Robinson et al was due to glenoid arthrosis and glenoid erosion was cited as one of the most common reasons for revision in the study by Odquist et al.

Strength of Evidence (quality of evidence): Moderate

Benefits & Harms:

There are no known harms associated with implementing this recommendation.

Outcome Importance:

The reader should understand that this association between older age and lower revision rate was identified in only 3 studies all of moderate to low quality and is in reference to patients undergoing hemiarthroplasty for the treatment of glenohumeral joint osteoarthritis. In addition, the surgeon should understand that multiple studies have shown an association between better patient reported outcomes and total shoulder arthroplasty over hemiarthroplasty for glenohumeral joint osteoarthritis.

Future Research:

Further prospective studies are needed to determine the effect of age on survivorship after shoulder arthroplasty in not only the setting of hemiarthroplasty but total and reverse shoulder arthroplasty.

PROGNOSTIC FACTORS (SMOKING)

Moderate evidence suggests that smoking is associated with inferior post-operative outcomes.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

RATIONALE:

Literature analysis regarding smoking history and shoulder arthroplasty revealed one high quality (Bernstein et al 2017) and two low quality studies (Leschinger et al 2017, and Wells et al 2018) resulting in a moderate level of evidence supporting the detrimental effect on postoperative patient outcomes and higher complication rates. Two additional studies by Althoff et al 2019, and Hatta et al did not satisfy the inclusion criteria for this CPG, though are relevant for discussion. Althoff et al in their analysis of the American College of Surgeons NSQIP found an increased risk of overall surgical complications specific to wound healing and surgical site infection. Hatta et al concluded that both current and former smokers had significantly higher risk of periprosthetic infection in comparison with nonsmokers. Additionally, current smokers demonstrated a higher risk of postoperative fractures than both former smokers and nonsmokers.

Strength of Evidence (quality of evidence): Moderate

Benefits & Harms:

Smoking (tobacco consumption) remains a national health concern with widespread effects on patient health, not necessarily specific to outcomes and complications associated with shoulder arthroplasty for GJO. Patient counseling, behavioral modification, and medication regimens may reduce perioperative usage of tobacco products and reduce complications rates after shoulder arthroplasty.

Future Research:

Future high-quality studies are required to compare the early and late complications associated with shoulder arthroplasty in smokers versus non-smokers.

Additional References:

- 1. Althoff, A.D., Reeves, R.A., Traven, S.A., Wilson, J.M., Woolf, S.K., Slone, H.S., Smoking is associated with increased surgical complications following total shoulder arthroplasty: an analysis of 14,465 patients. *J Shoulder Elbow Surg.* 2019; 1-6.
- 2. Hatta, T., Werthel, J.D., Wagner, E.R., et. al. Effect of smoking on complications following primary shoulder arthroplasty. *J Shoulder Elbow Surg*. 2017;26(1):1-6.

PROGNOSTIC FACTORS (PRE-OPERATIVE FUNCTION)

Moderate quality evidence suggests that, while both higher and lower pre-operative functioning patients with glenohumeral joint osteoarthritis will likely experience improvement following arthroplasty, patients with higher pre-operative function may experience less functional improvement.

Strength of Recommendation: Moderate

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

RATIONALE:

One moderate quality study (Mahony et al 2018) and one low quality study (Somerson et al 2017) have evaluated the outcomes of patients with GJO undergoing shoulder arthroplasty and determined a relationship between the level of preoperative function and its correlation to postoperative function as determined by patient-reported outcomes (PRO). The study by Mahony et al was a retrospective review of prospectively collected data on 459 patients who underwent total shoulder arthroplasty (TSA) at minimum 2 years follow up. They identified a subgroup of 41 patients (8.9%) who failed to reach the minimal clinically important difference (MCID) on ASES scores (less than 16.1point change preop to postop) and analyzed these patients for factors associated with this unsatisfactory outcome. They identified a higher baseline preoperative ASES score as one such factor in their multi-variate analysis. Additional factors for poor response after TSA included prior shoulder surgery, rotator cuff tear at the time of arthroplasty and diabetes.

Similarly, Somerson et al analyzed prospectively collected data from a series of 101 patients who had undergone ream and run hemiarthroplasty surgery for factors associated with clinical outcomes at a minimum of 2 years follow up. They determined that a lower simple shoulder test (SST) score preoperatively was associated with a more significant improvement in the postoperative score using multivariate statistics. It must be noted that the purpose of the study was to determine patient and surgical factors associated with humeral component medialization and whether the outcomes were associated with this potential medialization if/when it occurred.

Outcome Importance:

The strength of the recommendation is low; however, this guideline demonstrates that high functioning patients with GJO (which are usually younger and more active patients wishing higher levels of function) remain a challenging patient population as there appears to be a "ceiling" effect in terms of their functional improvement after shoulder arthroplasty. This information is important to understand when counseling these patients regarding their expected outcomes after shoulder arthroplasty.

Future Research:

Further study is needed in this area of clinical outcomes after shoulder arthroplasty to help advance our understanding of this ceiling effect of higher functioning patients with glenohumeral joint osteoarthritis.

PROGNOSTIC FACTORS (DEPRESSION)

Moderate evidence suggests that depression is associated with inferior post-operative outcomes in patients with glenohumeral joint osteoarthritis undergoing arthroplasty.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

RATIONALE:

There was one high quality study (Werner et al 2017) which evaluated the outcomes of patients with glenohumeral joint osteoarthritis who underwent total shoulder arthroplasty. The authors performed a retrospective analysis of a cohort of 88 patients from their prospectively collected institutional database who had a diagnosis of depression and underwent total shoulder arthroplasty for osteoarthritis. They compared this group to an age and gender/sex-matched control group without depression in a 2:1 ratio (control group N=176). Their results showed that the while the depression group had significant improvement in their outcome scores (SF-12, ASES Score, Marx Activity Score, and custom satisfaction questionnaire) at a minimum of 2-year follow-up, the degree of improvement in ASES, SF-12 and satisfaction scores was significantly less when compared to the cohort of patients without depression. However, this difference in improvement did not achieve clinical importance. The authors concluded that patients with depression should be counseled about the impact of their diagnosis on outcomes after total shoulder arthroplasty but that patients should not be excluded from surgical treatment just because of their depression.

Strength of Evidence (quality of evidence): Moderate

Benefits & Harms:

There are no known harms associated with implementing this recommendation.

Cost Effectiveness/Resource Utilization:

Healthcare institutions and health insurance payors continue to move toward incorporating patient reported outcomes and patient satisfaction scores into compensation and reimbursement formulas. Therefore, identifying patient factors, such as depression, that has a significant impact on these outcome measures becomes important.

Future Research:

Further prospective studies on the diagnosis of depression and its effect on patients undergoing shoulder arthroplasty are needed. The study cited here examined depression as a discrete variable but was not able to distinguish between severity of depression and its effect on outcomes measures. Also, further work should evaluate whether the treatment of depression might affect the outcomes for these patients to determine if there is an ability to modify/improve outcomes if patients' depression is treated appropriately.

GLENOID COMPONENT – METAL BACKED CEMENTLESS

Moderate evidence supports that surgeons not use metal-backed cementless glenoid components.

Strength of Recommendation: Moderate (upgraded)

Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

RATIONALE:

Evidence to Decision Framework: Recommendation upgraded from limited to moderate because of a very low reported survivorship rate;

Different modes of failure have been observed with metal backed as compared to all polyethylene components. These include gross loosening and catastrophic implant failure resulting in severe glenoid bone lose, rapid polyethylene backside wear with metal on metal contact and significant metal debris. Metal backed cementless glenoid components have been abandoned due to poor outcomes, high revision rates and catastrophic glenoid implant failure. Gauci et al. 2018, reported a 70% failure rate with need for revision surgery and 24% survivorship at 12 years for cementless metal backed glenoid components. This is compared to 74% survivorship in the cemented polyethylene glenoid group. Modes of failure reported included polyethylene wear with metal on metal contact, instability, and rotator cuff failure. Those with preoperative posterior humeral head subluxation with a biconcave retroverted glenoid (Walch B2) were most at risk for metal backed glenoid implant failure. Clitherow et al. 2014, also reported 4.4 times higher revision rate of uncemented metal backed glenoid implants as compared to cemented all polyethylene components (P<0.001) at mean follow-up of only 3.5 years. The results from the Australian National Joint Registry Page et al.⁶⁰ also supports these findings with revision rate of 17.9% for uncemented metal backed glenoid components (Hazard Ratio 4.77; 95%CI 4.10-5.55, P<0.001) compared to 3.7% for cemented glenoid components. This data has led to most implant companies in the united states removing metal backed cementless glenoid components from the market.

Strength of Evidence (quality of evidence): Limited

Benefits & Harms:

76% failure rate; studies report ceasing use because of unfavorable outcomes.

Outcome Importance:

Critical to have knowledge of poor results associated with uncemented metal backed glenoid components.

Cost Effectiveness/Resource Utilization:

Avoidance of use of any implant with a high failure rate will prevent increased costs and additional resources need to correct these issues.

Acceptability:

This data is well known and currently metal backed cementless glenoid implants are not used.

Feasibility:

Already part of standard practice not to use as well as understanding of failures of metal backed glenoid.

Future Research:

Future studies are needed to develop and design new glenoid implants if metal backed cementless implant concept is to be pursued with a goal of improving the survivorship of the glenoid.

TOTAL SHOULDER ARTHROPLASTY - SUBSCAPULARIS PEEL, LESSER TUBEROSITY **OSTEOTOMY, TENOTOMY**

Moderate quality evidence supports that surgeons can utilize subscapularis peel, lesser tuberosity osteotomy, or tenotomy when performing shoulder arthroplasty.

Strength of Recommendation: Moderate



Description: Evidence from two or more "Moderate" quality studies with consistent findings, or evidence from a single "High" quality study for recommending for or against the intervention.

RATIONALE:

The subscapularis tendon must be mobilized to gain exposure to the glenohumeral joint. Several studies have described subscapularis dysfunction following repair of a subscapularis tenotomy just medial to the lesser tuberosity or a detachment of the subscapularis from the lesser tuberosity (subscapularis peel). Deficiency of the subscapularis can lead to poor results after shoulder arthroplasty. Patients may complain of pain and difficulty with functional tasks such as tucking in a shirt or reaching the back pocket. This has prompted 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. Two high quality studies (Lapner, et al. 2012, 2013), analyzing the same cohort and 2 lower quality studies resulted in no clinically significant differences among the three surgical techniques.

Strength of Evidence (quality of evidence): Moderate

Future Research: Current studies report follow up at 12- and 24-months post-op. Future studies should investigate longer term comparison of the three surgical techniques.

HEMIARTHROPLASTY - STEMS

Limited evidence supports that clinicians may utilize stemmed, stemless or resurfacing prosthesis for patients with glenohumeral joint osteoarthritis undergoing total or hemi-arthroplasty.

Strength of Recommendation: Limited

Description: Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for against the intervention or diagnostic or the evidence is insufficient or conflicting and does not allow a recommendation for or against the intervention.

RATIONALE:

Four low quality studies (Odquist et al. 2018, Rasmussen et al. 2018, Lebon et al. 2014, Fourman et al. 2019) met inclusion criteria to make evidence-based recommendations related to the outcome of stemmed, stemless, and resurfacing humeral components. Rasmussen et al. reported Finnish registry data and compared stemmed to stemless (metaphyseal fixation) anatomic total shoulder arthroplasty demonstrating that male gender/sex and previous surgery were the only risk factors related to increase risk of revision surgery. Implant type did not influence outcome at final follow up with 6-year survivorship (95.3% stemless and 95.8% stemmed). Most common indication for revision was infection. Fourman et al. compared resurfacing to stemmed humeral implant hemiarthroplasties and demonstrated no difference with regards to ASES, function, or patient satisfaction, but statistically significant (p<0.05) better pain relief for the stemmed group (this did not reach MCID). Similarly, Lebon et al. compared stemmed with resurfacing hemiarthroplasty and found significantly higher revision rate in the resurfacing group due to glenoid wear (9.8% resurfacing group; 0% hemiarthroplasty group). There was no statistically significant difference in Constant score, subjective shoulder value, Quick-DASH, pain, or range of motion between groups.

The data from these low-quality studies provides early information that any of these implants are reasonable and safe options but should be used with caution as there is no long-term outcome studies.

Strength of Evidence (quality of evidence):

Limited

Benefits & Harms:

There are no additional harms or risks associated with this recommendation as all of these humeral options are currently being used.

Outcome Importance:

Guidance with regards to the best and most reliable implant option will help surgeon's choice the implant that can reliably/ predictably provide successful outcome with low risk of the need for reoperation from implant failure.

Cost Effectiveness/Resource Utilization:

As with any implant related recommendation the goals for successful treatment options with low risk of component related failure. Avoidance of the need for revision surgery will keep costs down and keep the need for utilization of additional future health care resources minimized.

Acceptability:

These implants are already in use clinically, this recommendation does not impact a change in practice until future well-designed high-quality studies are performed.

Feasibility:

There is no change in practice recommendation associated with this statement therefore as all of these humeral options are being used it will alter current treatment.

Future Research:

High quality studies with long term follow up (>10 years) directly comparing stemmed, stemless, and humeral resurfacing for both hemiarthroplasty as well as anatomic total shoulder arthroplasty are needed to determine if one implant type provides better outcome, pain relief, and survivorship.

CONSENSUS STATEMENTS

PRE-OPERATIVE PHYSICAL THERAPY

In the absence of reliable evidence, it is the opinion of the work group that physical therapy may benefit select patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Consensus

RATIONALE:

One low quality case series (Chinese) reported on multimodal treatment including PT, NSAIDs, injections (cortisone and/or sodium hyaluronate), and education at the discretion of the treating physician. N = 129; at 3 months alone PT not effective so added a multi-modal treatment approach 84 /86 received rehabilitation/formalized PT services added to other interventions and 69% found the PT component to be helpful.

Initial improvement at 3 months after multi-modal intervention, then worsening, then better at 12 months which was sustained at 36 months. Outcomes assessed included VAS, SST, SF-36.

Expert opinion from book chapter by Patrick St. Pierre and Mark Frankle: "Shoulder Rehabilitation: Is there a role for home therapy?" In: Physical Therapy: Theories, Practices and Benefits, ISBN: 978-1-61122-418-4

Editor: James P. Bennett ©2011 Nova Science Publishers, Inc.

"Formal PT is used in most patients before surgery is considered, and often is effective in decreasing pain, restoring function, and obviating the need for surgical intervention."

The workgroup discussed that young patients with GJO who are not good candidates for arthroplasty due to concerns for implant survivorship, and older patients who are not surgical candidates due to co-morbidities may benefit from physical therapy to aid in optimizing mobility and function, and minimizing pain.

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

Physical therapy may be beneficial for shoulder patients to improve mobility, strength and function for patients with GJO. Overzealous therapy may increase pain in this population. Benefits may be appreciated over a long course of care and may be of a greater advantage to patients who are not candidates for shoulder arthroplasty.

Cost Effectiveness/Resource Utilization:

Therapy services pose an expense to third party payers as well as to patients for deductibles/copayments. Often there is a visit limit for rehabilitation services therefore if surgery is being considered, therapy may best be reserved for post-operative rehabilitation needs.

Future Research:

The efficacy of formal physical therapy for GJO needs to be studied in a more systematic fashion with long term follow up.

Additional References:

- 1. Guo, J.J., Wu, K., Guan, H., et. al. Three-Year Follow-up of Conservative Treatments of Shoulder Osteoarthritis in Older Patients. *Orthopedics*. 2016;39(4):e634-41.
- St. Pierre, P., & Frankle, M. (2011). Shoulder Rehabilitation: Is there a role for home therapy? In J.P. Bennet (Ed) *Physical Therapy: Theories, Practices and Benefits*. Hauppauge, NY: Nova Science Publishers, Inc.

POST-OPERATIVE PHYSICAL THERAPY

In the absence of reliable evidence, it is the opinion of the work group that clinicians may prescribe physical therapy in patients following shoulder arthroplasty.

Strength of Recommendation: Consensus

RATIONALE:

Physical therapy following shoulder arthroplasty has been a common recommendation. However, there are no high quality studies addressing the frequency of physical therapy visits, the specific exercise recommendations, nor the timeframe for the introduction of exercises. One low quality study (Mulieri, et al) found no difference in outcome between formal physical therapy and a physician directed home program. However, this study did not define the formal physical therapy program and compliance with either program was not measured.

Strength of Evidence (quality of evidence):

No reliable evidence

Future Research:

Future studies should evaluate the effect of physical therapy on outcomes following shoulder arthroplasty. A comparison of post-operative exercise protocols, number and timing of physical therapy visits, and method of delivery of physical therapy (physical therapist, physician, video) should be performed.

INJECTABLE BIOLOGICS

In the absence of reliable evidence, it is the opinion of the work group that injectable biologics, such as stem cells or platelet-rich plasma, cannot be recommended in the treatment of glenohumeral osteoarthritis.

Strength of Recommendation: Consensus

RATIONALE:

There is lack of evidence of the utilization of biologics in the treatment of osteoarthritis of the glenohumeral joint. Biologics refers specifically to platelet rich plasma and cells derived from bone marrow aspirate or adipose cells. There was consensus from the panel that better standardization and high-quality evidence from clinical trials is needed to provide definitive evidence on the efficacy of biologics in glenohumeral OA. Carr and Rodeo provide some clarity in the misuse of terms such as stem cells and related to biologics and provide basic science on its potential benefit for different shoulder pathologies. It further stresses the importance of high-quality studies needed in this area of orthopedics. Additionally, Murray et al provide specifications for minimum requirements for reporting clinical studies involving PRP and MSCs. This may help to provide comparisons between the different cell therapies and its effect on shoulder pathologies such as glenohumeral arthritis.

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

Currently there is no evidence supporting the benefit of these interventions and the potential harm is that seen with all unregulated injectables.

Cost Effectiveness/Resource Utilization

The marketing of injecting biologics has and continues to outpace the science. There is a significant cost to patients without any current scientific evidence proving efficacy in glenohumeral arthritis. **Future Research:**

High-quality studies are needed in the use of biologics for the treatment of glenohumeral osteoarthritis.

Additional References:

- 1. Carr, J.B., Rodeo, S.A., The role of biologic agents in the management of common shoulder pathologies: current state and future directions. *J Shoulder and Elbow Surg.* 2019;28: 2041-2052.
- 2. Chu, C.R., Rodeo, S., Bhutani, N., et. al. Optimizing clinical use of biologics in orthopaedic surgery: consensus recommendations from the 2018 AAOS/NIH U-13 conference. *J Am Acad Ortho Surg.* 2019;27(2):e50-e63.

3. Murray IR, Geeslin AG, Goudie EB, Petrigliano FA, LaPrade RF. Minimum Information for Studies Reporting Biologics in Orthopaedics (MIBO): Platelet Rich Plasma and Mesenchymal Stem Cells. *J Bone Joint Surg Am* 2017;99(10):809-19.

ALTERNATIVE NON-SURGICAL TREATMENTS

In the absence of reliable evidence, the work group cannot recommend for or against the use of the following:

Acupuncture Dry needling Cannabis Cannabodiol (CBD) Oil Capsaicin Shark Cartilage Glucosamine and Chondroitin Cupping Transcutaneous Electrical Nerve Stimulation (TENS)

Strength of Recommendation: Consensus

RATIONALE:

Data regarding the use of complementary and alternative medicines (CAMs^{*}) for the management of GJO is lacking. The peer reviewed literature does not provide credible evidence that the above modalities provide benefit or harm to patients with GJO. In view of these deficiencies, we cannot support or restrict the usage of the above alternative treatment options when managing symptomatic GJO.

*CAMS: acupuncture, dry needling, cannabis, CBD oil, non-prescription pain patches, capsaicin, shark cartilage, glucosamine and chondroitin, cupping

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

Unable to assess due to lack of evidence from peer reviewed literature

Future Research:

Randomized controlled trials comparing complementary and alternative medicines to accepted medications and/or control group (placebo) would provide helpful data substantiating non-inferiority. Potential barriers to comparative studies include, but are not limited to, state and federal laws and regulations, funding, and heterogeneity of study design (i.e. number of treatment arms, dosages and durations of treatment, power analysis, patient reported outcomes).

OPIOID PAIN MEDICATION

In the absence of reliable evidence, it is the opinion of the work group that opioids not be prescribed as routine and long-term pain management of glenohumeral osteoarthritis.

Strength of Recommendation: Consensus

RATIONALE:

Only low-quality studies have evaluated the use of narcotic pain medication in the treatment for glenohumeral joint osteoarthritis in the preoperative setting. However, other literature is widely available that evaluates the impacts of these medications in the treatment of arthritis of other joints, in other orthopaedic settings and for other medical conditions.

Thompson et al (2019) showed that chronic opioid use in the pre-operative setting was an indicator for poor outcomes following anatomic TSA. The authors noted worse outcome scores, motion, and strength in those patients taking narcotic medications prior to surgery. They also suggested that while patients on narcotic medications could improve with anatomic TSA, it is not to the same degree as to those not on opioid medications prior to surgery.

Another study (Morris et al 2017) reported higher rates of sleep disturbance in those patients using narcotic pain medications prior to surgery, with sleep disturbance patients noting worse Constant pain, Constant activity, and WOOS index scores.

Recent CDC guidelines regarding the use of opioids for joint pain and arthritis recommend:

Many adults with arthritis are prescribed opioids,3 but there is a lack of evidence of their longterm effectiveness when used for chronic conditions such as arthritis. Safer options exist to help manage arthritis pain.

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

There is no harm in reducing the prevalence of opioid use in our society, given the current high rates of addiction and narcotic pain medication use. The recommendation to avoid routine use of opioids for the long-term management of glenohumeral osteoarthritis may benefit patients as it serves to increase the focus on modalities and interventions with greater proven benefit.

Cost Effectiveness/Resource Utilization:

With high rates of patient use, it would seem to be cost effective to reduce the utilization of these medications. However, the costs of alternative medications and required treatment programs must be taken into account.

Acceptability:

Patients on long term opioids may find it difficult to wean off narcotic pain medications, although recommendations should be readily accepted by treating physicians.

Feasibility:

While treating physicians are gaining insight into the dangers of prescribing narcotic medications, it is necessary to educate patients regarding the potential adverse impacts of these pain medications, including their apparent lack of efficacy as well as their potential for dependency and addiction.

Future Research:

Future research is required to determine the best pain management regimens for those with glenohumeral joint osteoarthritis who have yet to undergo surgery.

NON-PROSTHETIC SURGICAL OPTIONS

In the absence of reliable evidence, it is the opinion of the work group that non-prosthetic surgical options may or may not provide short-term benefit for patients with glenohumeral joint osteoarthritis.

Strength of Recommendation: Consensus

RATIONALE:

Several non-arthroplasty options exist for young patients with glenohumeral joint osteoarthritis. These options include arthroscopic debridement with capsular release, axillary nerve release, humeral osteoplasty, microfracture, osteochondral allograft, and biologic resurfacing with various tissue allografts. All of these options have small case series reports of the clinical outcomes relating the success and or failures of these methods of joint preservation surgery. These options therefore should be used with caution and although not found to cause significant adverse postoperative complications the results are mixed. Skelley et al. reported only minimal temporary pain relief and 42.4% of the cohort went on to total shoulder arthroplasty at an average of 8.8 months following the arthroscopic procedure. Additionally, 60.6% of patients reported they were not satisfied with the outcome. In contrast, Mitchell et al. reported 5 year follow up on what the authors termed the "CAM" (complete arthroscopic management) procedure which included humeral chondroplasty, capsular release, synovectomy, humeral osteoplasty, axillary nerve neurolysis, subacromial decompression, loose body removal, microfracture, and biceps tenodesis. The authors reported that 26% of patients went on to total shoulder arthroplasty at a mean of 2.6 years (range 6 months-8.2 years). Five-year survivorship was 76.9%. Risk factors associated with failure of this procedure included Walch type B2 or C glenoids (P=0.006), joint space narrowing resulting in <2mm of joint space remain on the true AP radiograph. Additionally, 2 patients required additional surgery one underwent revision capsular release for stiffness at 5.6 months and the other underwent a revision CAM procedure at 7.9 years. There were no reported intraoperative or postoperative complications.

Little has been published on the outcomes, survivorship, or complications associated with microfracture or osteochondral allograft reconstruction.

Biologic resurfacing of the glenoid has been reported as an option using either lateral meniscus allograft or human acellular dermal tissue matrix. Strauss et al. reported intermediate term follow up of this procedure and found clinical failure rate of 51.2%. The group that lateral meniscus allograft use utilized had a failure rate of 45.2% at mean of 3.4 years, and those with human acellular dermal tissue matrix interposition had a failure rate of 70% at an average of 2.2 years. The cohort had early postoperative improvements in ASES, VAS pain scores, simple shoulder test and range of motion, but these improvements were short lived. Lo et al. reported the results of hemiarthroplasty supplemented with glenoid biologic resurfacing using acellular human dermal allograft and found 81% of patient were satisfied or very satisfied with the results at an average follow up of 60 months. 9.1% of patients went on to revision surgery with conversion to anatomic total shoulder arthroplasty. Additionally, there were 11% who had poor function postoperatively but did not go on to revision surgery. Although this modification of the procedure does involve hemiarthroplasty the results seem to be improved as compared to isolated glenoid interposition.

Strength of Evidence (quality of evidence):

No reliable evidence

Benefits & Harms:

Providing non-arthroplasty surgical options to young patients may be beneficial to this difficult patient population. Risks and benefits of these procedures must be discussed with the patients to determine who would best be suited for these types of joint preserving options.

Outcome Importance:

Given the current literature a lot of work remains to determine the efficacy of these joint preserving nonarthroplasty surgical treatment options.

Cost Effectiveness/Resource Utilization:

These options are often expensive and time consuming with prolonged recovery, especially the interposition arthroplasty techniques. With the relatively high failure rates and needs for future revision surgery the value of these options still is to be determined.

Acceptability:

To be determined.

Feasibility:

There are several surgeons performing these operations, but due to poor evidence to the efficacy of this outcomes of these procedures is yet to be determined.

Future Research:

Future studies are needed to provide strong high-quality evidence to support the use of these surgical techniques.

Additional References:

- Millett, P.J., Fritz, E.M., Frangiamore, S.J., Mannava, S. Arthroscopic Management of Glenohumeral Arthritis: A Joint Preservation Approach. J Am Acad Orthop Surg. 2018;26(21):745-752.
- Mitchell, J.J., Horan, M.P., Greenspoon, J.A., Menge, T.J., Tahal, D.S., Millett, P.J. Survivorship and Patient-Reported Outcomes After Comprehensive Arthroscopic Management of Glenohumeral Osteoarthritis: Minimum 5-Year Follow-up. *Am J Sports Med.* 2016;44(12):3206-3213.
- 3. Strauss, E.J., Verma, N.N., Salata, M.J., et. al. The high failure rate of biologic resurfacing of the glenoid in young patients with glenohumeral arthritis. *J Shoulder Elbow Surg.* 2014;23(3):409-19.
- 4. Lo, E.Y., Flanagin, B.A., Burkhead, W.Z.. Biologic resurfacing arthroplasty with acellular human dermal allograft and platelet-rich plasma (PRP) in young patients with glenohumeral arthritis-average of 60 months of at mid-term follow-up. *J Shoulder Elbow Surg.* 2016;25(7):e199-207.
- 5. Skelley, N.W., Namdari, S., Chamberlain, A.M., Keener, J.D., Galatz, L.M., Yamaguchi, K. Arthroscopic debridement and capsular release for the treatment of shoulder osteoarthritis. *Arthroscopy*. 2015;31(3):494-500.

RADIOGRAPHS

In the absence of reliable evidence, it is the opinion of the work group that patients with glenohumeral osteoarthritis undergoing arthroplasty should be imaged with axillary and true AP (Grashey view) radiographs, with advanced imaging performed at the discretion of the clinician.

Strength of Recommendation: Consensus

RATIONALE:

Pre-operative evaluation of patients undergoing shoulder arthroplasty helps to define osseous anatomy, pathology and potential component positioning. In addition to other radiographic projections, well-positioned True AP (Grashey) and axillary radiographs will evaluate glenohumeral cartilage space narrowing, joint congruity and joint subluxation. Axillary radiographs will also provide information on glenoid morphology and bone stock. If there are clinical concerns for rotator cuff compromise, MRI, ultrasound or CT arthrogram could be considered. While utilization of pre-operative planning with 3D CT imaging with or without patient-specific instrumentation has been shown to improve accuracy of desired implant position, there is inadequate data to determine how this affects long term clinical outcomes.

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

Ordering physicians should be mindful of radiation doses associated with pre-operative planning CT examinations.

Future Research:

High quality evidence is needed to evaluate if improved clinical outcomes are associated with more accurate arthroplasty component positioning.

CEMENTED STEMS

In the absence of reliable evidence, it is the opinion of the work group that either cemented or cementless stems can be utilized in the treatment of patients with glenohumeral joint osteoarthritis and a well-functioning rotator cuff.

Strength of Recommendation: Consensus

RATIONALE:

Historically, shoulder arthroplasty began with the use of cemented humeral stems and over time implant design has progressed where cementless (press fit) humeral stems are now more commonly used. Each implant design and implantation fixation/technique has its own inherent issues and risks of complications. Cemented humeral stems result in longer surgical times due to cement placement and make for a more difficult revision for implant extraction. Cementless humeral stems can result in proximal humerus stress shielding and subsequent bone loss depending on method of fixation/ bone ongrowth. At the time this clinical practice guideline was developed, there were no high quality studies which met inclusion criteria to guide evidence-based treatment recommendations.

Uy et al. performed a systematic review and meta-analysis comparing cemented to cementless humeral components and found no significant difference in revision rates (2.3% cementless, 1.8% cemented) when controlling for variable follow up rates. It is unknown if all of the reported revisions were strictly related to complications from the humeral stem. Radiographic loosening was reported 1.4% cemented group and 3.8 cementless group. Wurthel et al. reported 98.0% for cemented and 92.4% for cementless 20-year survivorship for humeral loosening. The authors concluded that both types of fixation provide >90% long term survival. Litchfield et al.⁴⁰ performed a prospective double-blind randomized trial comparing cement to uncemented fixation of humeral stems. The authors found statistically significant improved strength, forward elevation as well as WOOS for the cemented group at two-year follow-up, and significantly less operative time for the uncemented group. There was no difference between groups for ASES or SF-12 at two years. Interestingly, subgroup analysis demonstrate any difference between groups.

Strength of Evidence (quality of evidence):

No reliable evidence

Benefits & Harms:

There are no adverse risks related to the use of either cemented or cementless (press fit) humeral stems.

Outcome Importance:

As with all component related questions/statements, the most important factor is clinical outcome, function, and implant survivorship. The data needs to be strengthened in the literature to provide strong evidence-based recommendations.

Cost Effectiveness/Resource Utilization:

Both implant choices have demonstrated cost effectiveness given the success and longevity of the humeral side of the reconstruction. Determinations still need to be established as to which fixation method will

make for more straightforward revision with less risk of proximal humeral bone loss and improved predictable outcomes following revision surgery.

Acceptability:

Both cemented and cementless (press fit) fixation has already been established and has been used clinically for several years. There should be no issues to overcome regarding these treatment methods even with consensus recommendation.

Feasibility:

The consensus statement does not change current clinical practice.

Future Research:

Well-designed high-quality studies are needed to provide data to support an evidence-based guideline regarding cement and cementless humeral stems for shoulder arthroplasty with long term follow-up. These studies should focus on long term patient reported outcomes as well as humeral related complications.

Additional References:

- Uy, M., Wang, J., Horner, N.S., et. al. Cemented humeral stem versus press-fit humeral stem in total shoulder arthroplasty: a systematic review and meta-analysis. *Bone Joint J.* 2019;101-B(9):1107-1114.
- 2. Werthel, J.D., Lonjon, G., Jo, S., Cofield, R., Sperling, J.W., Elhassan, B.T., Long-term outcomes of cemented *versus* cementless humeral components in arthroplasty of the shoulder: a propensity score-matched analysis. *Bone Joint J.* 2017;99-B(5):666-673.

ANATOMIC OR REVERSE TOTAL SHOULDER ARTHROPLASTY

In the absence of reliable evidence, it is the opinion of the workgroup that clinicians may use either anatomic total shoulder arthroplasty (TSA) or reverse TSA for the treatment of glenohumeral joint osteoarthritis in select patients with excessive glenoid bone loss and/or rotator cuff dysfunction.

Strength of Recommendation: Consensus

RATIONALE:

Despite the increasing use of reverse total shoulder arthroplasty in the treatment of glenohumeral osteoarthritis (GJO), there are limited studies comparing anatomic to reverse total shoulder arthroplasty for the treatment of GJO with an intact rotator cuff. Kiet et al. 2015, Steen et al. 2015, and Wright et al. 2019, all performed comparison studies between anatomic and reverse total shoulder arthroplasty finding no significant difference in patient reported outcomes, complication rates, visual analog pain scores, range of motion, and incidence of revision surgery. All three studies concluded that either method is both safe and effective for the treatment of glenohumeral joint arthritis. Reverse total shoulder arthroplasty can be used for the treatment of glenohumeral joint osteoarthritis with significant associated rotator cuff dysfunction and/or severe glenoid deformity.

Strength of Evidence (quality of evidence):

No reliable evidence

Benefits & Harms:

Anatomic and reverse total shoulder arthroplasty are safe and effective methods for treatment of glenohumeral joint arthritis.

Outcome Importance:

Given the increased utilization of reverse total shoulder arthroplasty it is important to understand the safety, outcomes, and survivorship of these implants as compared to anatomic total shoulder arthroplasty.

Cost Effectiveness/Resource Utilization:

Although no difference in short term outcomes have been reported, Steen et al.76 found reverse total shoulder arthroplasty to be approximately \$7274 more expensive then anatomic total shoulder arthroplasty at the time of the authors publication (2015). These costs must be weight with the issues associated with anatomic total shoulder arthroplasty such as glenoid loosening and rotator cuff failure neither of which have been an issue with reverse total shoulder arthroplasty.

Acceptability:

Both anatomic and reverse total shoulder arthroplasty are being used in clinical practice for the treatment of this patient population.

Feasibility:

Anatomic and reverse total shoulder arthroplasty are both commonly used for the treatment of glenohumeral joint arthritis therefore this recommendation does not result a change in clinical practice recommendations.

Future Research:

There is a need for future high-quality prospective cohort and/or randomized clinical trials comparing the outcomes, survivorship, and complications associated with anatomic and reverse total shoulder arthroplasty. The results of these investigations will provide evidence-based recommendations as to which patients would be more appropriate for each implant type.

Additional References:

- 1. Kiet, T.K., Feeley, B.T., Naimark, M., et. al. Outcomes after shoulder replacement: comparison between reverse and anatomic total shoulder arthroplasty. *J Shoulder Elbow Surg.* 2015;24(2):179-85.
- Wright, M.A., Keener, J.D., Chamberlain, A.M., Comparison of Clinical Outcomes After Anatomic Total Shoulder Arthroplasty and Reverse Shoulder Arthroplasty in Patients 70 Years and Older With Glenohumeral Osteoarthritis and an Intact Rotator Cuff. J Am Acad Orthop Surg. 2019.

GLENOID COMPONENTS – POLYETHYLENE-METAL OR ALL POLYETHYLENE

In the absence of reliable evidence, it is the opinion of the workgroup that clinicians may use polyethylene-metal hybrid glenoid components or all-polyethylene components during total shoulder arthroplasty for treatment of glenohumeral joint osteoarthritis.

Strength of Recommendation: Consensus

RATIONALE:

Recently, methods for improved glenoid fixation have been designed in order to decrease loosening rates and need for revision surgery. Hybrid glenoid polyethylene components include cages as well as addition of trabecular metal. Friedman et al. compared cemented all polyethylene glenoid implants to hybrid cage glenoid implants and found lower rates of aseptic loosening (1.3% hybrid vs 3.8% all polyethylene), as well as significantly lower revision rates in the hybrid cage group (2.5% vs 6.9%, P=0.0088). The authors did report 1.3% incidence of articular surface dissociation. Nelson et al. reported 5-year outcomes of hybrid glenoid component with a central porous titanium post and cemented peripheral pegs. The authors found 2.2% incidence of glenoid failure requiring revision and 20% classified as at risk for loosening. Overall concluding low rate of mechanical failure and successful clinical outcomes as measured by ASES score as well as functional range of motion. Finally, Watson et al. reported the results of trabecular metal backed glenoid components. The authors reported 25% rate of radiographic metal debris, 1 catastrophic failure and 11% revision rate at 2-year follow-up. The authors concluded that this implant should be used with caution. It is clear that many new hybrid options are become available for clinical use with good clinical outcomes as relatively low complication rates.

Strength of Evidence (quality of evidence):

No reliable evidence

Benefits & Harms:

Early studies demonstrate that at short term follow up hybrid glenoid components have been safe with low complication and revision rates.

Outcome Importance:

Functional and patient reported outcomes related to the use of hybrid glenoid components as well as safety profile with survivorship, modes of failure and incidence of revision surgery as compared to standard all polyethylene glenoid implants.

Cost Effectiveness/Resource Utilization:

Cost analysis investigation still remains to be performed as commonly newer technology can be more expensive.

Acceptability:

These implants are becoming increasing more popular for clinical use so there seems to be no barriers to implementation for the use of these glenoid components.

Feasibility:

Hybrid glenoid components are already used in clinical practice for treatment of glenohumeral joint osteoarthritis during anatomic total shoulder arthroplasty.

Future Research:

Future high quality comparative long-term outcomes studies need to be performed to determine the impact of hybrid glenoid fixation on implant survivorship. This data can provide guidance as to which patients should be indicated for the use of hybrid glenoid components during anatomic total shoulder arthroplasty. Additionally, can follow the influence of glenoid deformity as well as rotator cuff pathology on outcomes and implant survivorship.

Additional References:

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BICEP TENODESIS AND TENOTOMY

In the absence of reliable evidence, it is the opinion of the workgroup that clinicians may consider concomitant biceps tenodesis or tenotomy during shoulder arthroplasty.

Strength of Recommendation: Consensus

RATIONALE:

There was only one low strength investigation that looked at biceps tenodesis at the time of total shoulder arthroplasty for primary osteoarthritis. As biceps tendon pathology has been associated with pain in patients with osteoarthritis, we believe that clinicians can consider an adjunct biceps tenodesis or tenotomy at the time of shoulder arthroplasty.

Strength of Evidence (quality of evidence):

No reliable evidence

Future Research:

High quality evidence is needed to evaluate if improved clinical outcomes are associated with biceps tenodesis or tenotomy at the time of shoulder arthroplasty.

TRANEXAMIC ACID

In the absence of reliable evidence, it is the opinion of the workgroup that utilization of tranexamic acid during shoulder arthroplasty may result in reduced blood loss and reduced risk of blood transfusion.

Strength of Recommendation: Consensus

RATIONALE:

While the topic of tranexamic acid (TXA) use in the setting of shoulder arthroplasty has been studied, high quality evidence does not currently exist on its use in the setting of patients with glenohumeral joint osteoarthritis (OA) undergoing surgical treatment. Thus, only a consensus level recommendation is made here. However, a number of clinical studies¹⁻⁷ have shown a reduction in perioperative blood loss with the use of TXA in patients undergoing primary shoulder arthroplasty (anatomic and reverse total shoulder). Two recent meta-analysis^{8,9} which included all but one of the aforementioned clinical studies (3 randomized controlled trials and 3 retrospective cohort studies) concluded that administration of TXA was associated with a significant reduction in the postoperative change in hemoglobin concentration, drain output, total blood loss and a trend toward reduction in rate of blood transfusions. A total of 680 patients were included in the meta-analysis and combined both primary anatomic and reverse shoulder arthroplasty and there was marked heterogeneity of TXA regimens used in each study.

Benefits & Harms:

Tranexamic acid treatment appears to be associated with reduction in perioperative blood loss after primary shoulder arthroplasty and the benefits of decreasing blood loss after surgery are apparent. At the same time, tranexamic acid use in patients appears to be safe. A recent meta-analysis⁹ of 680 patients undergoing primary shoulder arthroplasty (3 Level I and 3 Level III studies) found no significant difference in the overall complication rate nor the rate of thromboembolic events between the TXA and non-TXA groups.

Cost Effectiveness/Resource Utilization:

Tranexamic acid is known to be a very inexpensive drug that is highly cost-effective.¹⁰

Future Research:

Further study is needed to determine the optimal dosing and route of administration of TXA. The studies that have been performed to date have included varying drug doses and frequency and have also differed in mode of administration (intravenous or topical). Additionally, the majority of the studies have pooled together both anatomic and reverse shoulder arthroplasty and more data is needed to determine its efficacy in each alone. Additionally, while there is no evidence of increased complication to date, including any increased risk of thromboembolic phenomenon, future studies on the safety of TXA use in shoulder surgery is needed.

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SUPRASPINATUS TEARS

In the absence of reliable evidence, it is the opinion of the workgroup that for patients with small isolated, repairable supraspinatus tears, clinicians can perform anatomic total shoulder arthroplasty (TSA).

Strength of Recommendation: Consensus

RATIONALE:

None of the studies derived from the literature search for GJO specific to repairable rotator cuff tears and anatomical total shoulder arthroplasty met the criteria for CPG inclusion. These studies were not included for multiple reasons including inadequate sample size (less than 20 patients per group), etiology for reconstruction, and lack of comparison group. However, several studies have indicated favorable results regarding anatomic total shoulder arthroplasty in the setting of a repairable rotator cuff tear. Simone et al reported the greatest improvement in forward elevation after anatomic TSA in ten patients that demonstrated a small rotator cuff tear. Complications only occurred in patients with medium and large rotator cuff tears (instability, glenoid component loosening, and periprosthetic fracture). Iannotti et al reported on thirteen shoulders that exhibited a repairable full-thickness tear of the supraspinatus tendon with anatomic TSA. These tears did not affect the overall American Shoulder and Elbow Surgeons score, pain relief or patient satisfaction. Rispoli and colleagues in their case series similarly did not find that isolated supraspinatus tendon tears affected shoulder-specific outcome parameters during shoulder arthroplasty when performed for the treatment of primary osteoarthritis. In contradistinction, Livesey et al noted a poor result in 31% of patients that underwent concomitant rotator cuff repair and anatomic TSA, underscoring the challenges that this clinical scenario presents.

Strength of Evidence (quality of evidence):

No reliable evidence

Benefits & Harms:

In the setting of GJO with a rotator cuff tear, surgeons must make a critical decision to proceed with anatomical shoulder arthroplasty with rotator cuff repair versus reverse shoulder arthroplasty. The potential for revision of failed anatomic TSA due to rotator cuff insufficiency must be weighed against the risks of increased complication rates after primary reverse shoulder arthroplasty.

Outcome Importance:

It is important to determine the safety of anatomic shoulder arthroplasty in the setting of a repairable rotator cuff tear as a platform based anatomic arthroplasty may be readily converted to a reverse total shoulder. This option provides the practitioner and patient more options than immediately proceeding to reverse total shoulder.

Cost Effectiveness/Resource Utilization:

Evidence-based decisions regarding implant choice should ideally result in decreased long term costs by reducing the need for revision surgery, decreasing the utilization of higher cost reverse total shoulder arthroplasty, and improving long-term pain and return to work.

Acceptability and Feasibility:

Anatomic total shoulder replacement and open rotator cuff repair are familiar and well-accepted by orthopaedic surgeons. These implants and surgical techniques are widely available and reproducible.

Future Research:

Future high-quality studies are necessary to directly compare patients with GJO with an intact rotator cuff versus those with repairable small (< 1 cm) supraspinatus tendon tears when performing anatomic total shoulder arthroplasty with respect to patient reported outcomes, complications, and revision rates.

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DISCHARGE

In the absence of reliable evidence, it is the opinion of the workgroup that same-day discharge is an option after shoulder arthroplasty in select patients.

Strength of Recommendation: Consensus

RATIONALE:

Same day discharge following shoulder arthroplasty, either from the PACU of an inpatient facility or from an ambulatory surgical center, is a viable option for select patients following surgery. There is no convincing evidence to suggest that same day discharge following shoulder arthroplasty is not a safe option. Engagement of the surgeon and each individual patient is required to determine if the patient is a suitable candidate for same day discharge without an undue increase in peri-operative risks.

There have been several studies (Leroux et al. 2016, Brolin et al. 2017, Fournier et al. 2019, Leroux et al. 2018, Charles et al. 2019) which have examined the safety, efficacy, complication rate, and incidence of readmission following outpatient shoulder arthroplasty.

Fournier et al. developed a validated patient selection algorithm for proper patient selection as to who would be appropriate candidates for outpatient shoulder arthroplasty. Stratification was based on age and cardiopulmonary comorbidities with an endpoint of complications, adverse events, and hospital admission. Using this selection algorithm there were no hospital readmissions for cardiopulmonary events within 90 days, and the authors noted a 5% acute complication rate.

Charles et al., Leroux et al. 2018, Brolin et al., Leroux et al 2016. all reported results of outpatient shoulder arthroplasty demonstrating no significant difference with regards to major or minor complication rates and readmission rates when compared to the inpatient setting. This data provides supporting evidence that in the appropriate patient population this is a safe and cost-effective practice. Patient selection is key to success and the patients most at risk for dissatisfaction with pain control postoperatively are those who have been taking chronic narcotic pain medication preoperatively.

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

It is possible that same day discharge in patients who are not good candidates could result in increased risk of uncontrolled postoperative pain or medical complications. Most important considerations would be concern for cardiopulmonary or thromboembolic events which would require intervention and or readmission, postoperative wound problems, or increased need for reoperation. Patients may also have increased rates of return to the emergency department or hospital re-admission.

Outcome Importance:

Given the increasing utilization of shoulder arthroplasty shown by several recent studies, demonstrating the efficacy of same day discharge will better help surgeons meet this future demand.

Cost Effectiveness/Resource Utilization:

This will likely prove to be a cost-effective endeavor when compared to current post-operative protocols with patients staying 1-2 days following surgery. It may be that utilization of a Surgical Care Program Manager, while an initial added expense, is required to ensure that safe and effective patient centered care can be provided across the continuum.

Feasibility:

The impact upon physician and hospital reimbursement will need to be explored to see if wider adoption of same day discharge is feasible.

Future Research:

Further research is needed to determine those patients who are the best candidates for same day discharge following shoulder arthroplasty, as well as to better understand which patients are most at risk for emergency room visit or readmission/hospitalization following outpatient shoulder arthroplasty.

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CRYOTHERAPY

In the absence of reliable evidence, it is the opinion of the workgroup that either continuous cryotherapy or cold packs can be used following shoulder arthroplasty.

Strength of Recommendation: Consensus

RATIONALE:

There was one randomized control trial (Noyes et al- refer below) comparing continuous cryotherapy versus ice pack in 40 patients that did not demonstrate a significant difference in pain scores, quality of sleep or narcotic use. This study was a mix of patients who received both anatomic and reverse shoulder arthroplasty and was not exclusive to patients who received shoulder arthroplasty for glenohumeral osteoarthritis.

Strength of Evidence (evidence quality):

No reliable evidence

Benefits & Harms:

Uncommon potential harm entails prolonged ice pack exposure leading to skin burn.

Cost Effectiveness/Resource Utilization:

Cold therapy units may not be covered by insurance and may add cost to the patient.

Feasibility:

It is feasible for patients to manage post-operative swelling with cold therapy units or ice packs.

Future Research:

More high-quality evidence is needed focusing on the effectiveness of cold therapy units in patients who receive anatomic shoulder arthroplasty for osteoarthritis.

Additional References:

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MULTIMODAL PAIN MANAGEMENT

In the absence of reliable evidence, it is the opinion of the workgroup that multimodal pain management strategies or non-opioid individual modalities can provide added benefit for postoperative pain management following shoulder arthroplasty.

Strength of Recommendation: Consensus

RATIONALE:

Mclaughlin et al performed a prospective study comparing standard opioid based versus multimodal pain management in patients who received elective or revision shoulder arthroplasty (anatomic or reverse). Opioid use in the multimodal cohort was lower on all days evaluated and there was a shorter length of stay with the multimodal group (1.44 vs 1.91days). There was no difference in 30- or 90-day ED visits.

Strength of Evidence (quality of evidence):

No reliable evidence

Benefits & Harms:

Reduction in opioid use reduces risks of side effects of medications as well potential risk of opioid diversion.

Future Research:

Future high-quality studies may focus on multimodal pain management after elective shoulder arthroplasty.

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GUIDELINE DEVELOPMENT GROUP DISCLOSURES

Prior to the development of this clinical practice guideline, group members disclose conflicts of interest (COI). They disclose COIs in writing to the American Academy of Orthopaedic Surgeons via a private on-line reporting database and also verbally at the recommendation approval meeting.

Disclosure Items: (n) = Respondent answered 'No' to all items indicating no conflicts. 1 = Royalties from a company or supplier; 2 = Speakers bureau/paid presentations for a company or supplier; 3A = Paid employee for a company or supplier; 3B = Paid consultant for a company or supplier; 3C = Unpaid consultant for a company or supplier; 4 = Stock or stock options in a company or supplier; 5 = Research support from a company or supplier as a PI; 6 = Other financial or material support from a company or supplier; 7 = Royalties, financial or material support from publishers; 8 = Medical/Orthopaedic publications editorial/governing board; 9 = Board member/committee appointments for a society.

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AAOS: Board or committee member (\$0) CPG(Self) BMC Musculoskeletal Disorders: Editorial or governing board (\$0) (Self) DePuy, A Johnson & Johnson Company: Paid presenter or speaker (\$1) Number of Presentations: 1 N/A(Self) DePuy, A Johnson & Johnson Company: Paid consultant (\$0) N/A(Self) DePuy, A Johnson & Johnson Company: Research support (\$1) N/A(Self) Heraeus: Unpaid consultant N/A(Self) Innomed: IP royalties (\$0) Design royalties(Self) Johnson & Johnson: Stock or stock Options Number of Shares: 25 N/A(Self) Pacira Pharmaceuticals: Paid consultant (\$1) N/A(Self) Procter & Gamble: Stock or stock Options Number of Shares: 38 N/A(Both) Zimmer: Paid presenter or speaker (\$1) Number of Presentations: 1 N/A(Self) Zimmer: Paid consultant (\$0) Consulting(Self) Zimmer: Stock or stock Options Number of Shares: 20 N/A(Self) Zimmer: Research support (\$1) N/A(Self)

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WORK GROUP VOTING RESULTS

All recommendations received unanimous votes in favor of creation except:

- I. BMI Recommendation
 - 1 opposed
- II. Pre-Op Function Recommendation
 - 3 opposed
- III. Hemiarthroplasty; Stemmed vs (Stemless) Resurfacing Recommendation
 - 1 opposed