AAOS
American Academy of Orthopaedic Surgeons

TREATMENT OF CLAVICLE FRACTURES

Evidence-Based Clinical Practice Guideline

Adapted by:
The American Academy of Orthopaedic Surgeons Board of Directors
December 2, 2022

Endorsed by:

OTA Orthopaedic Trauma Association

American Shoulder and Elbow Surgeons 1982

American Society of Shoulder and Elbow Therapists

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Disclaimer

This clinical practice guideline (CPG) was developed by a physician volunteer clinical practice guideline development group based on a formal systematic review of the available scientific and clinical information and accepted approaches to treatment and/or diagnosis. This clinical practice guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's specific 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.

FDA Clearance

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

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SUMMARY OF RECOMMENDATIONS

Recommendations are formed when there is sufficient evidence by which to create a directional statement. This is defined as evidence from two or more high quality studies (i.e., a strong recommendation), two or more moderate quality studies (i.e., a moderate recommendation), or statements resulting in a strong or moderate strength following Evidence to Decision Framework upgrading and/or downgrading.

BONE STIMULATOR

Low-intensity pulsed ultrasound (LIPUS) should not be used for nonoperative management of acute midshaft clavicle fracture, as it does not result in accelerated healing or lower rates of non-union.

Quality of Evidence: Moderate

Strength of Recommendation: 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. Also requires no or only minor concerns addressed in the EtD framework.

HOOK PLATE vs. LATERAL LOCKING PLATE FOR LATERAL FRACTURE

Moderate evidence demonstrates that lateral locking plates may have fewer complications and better functional outcomes than hook plates for the treatment of lateral (Neer Type II) clavicle fractures in adults.

Quality of Evidence: Moderate

Strength of Recommendation: 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. Also requires no or only minor concerns addressed in the EtD framework.

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ISOLATED DISPLACED MIDSHAFT FRACTURE: OPERATIVE vs. NONOPERATIVE TREATMENT (ADULT)

Operative treatment of displaced midshaft clavicle fractures in adult patients is associated with higher union rates and better early patient-reported outcomes than non-operative treatment. However, practitioners may consider either operative or non-operative treatment as both are associated with similar long-term patient-reported outcomes and patient satisfaction.

Quality of Evidence: High

Strength of Recommendation: Strong ★★★★

Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention. Also requires no reasons to downgrade from the EtD framework.

NAILING vs. SINGLE PLATE

Surgical treatment of clavicle shaft fractures with an intramedullary nail or a single plate results in equivalent long-term clinical outcomes with similar complication rates. Plate fixation may be of benefit in the presence of fracture comminution.

Quality of Evidence: Moderate

Strength of Recommendation: 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. Also requires no or only minor concerns addressed in the EtD framework.

SUMMARY OF OPTIONS

Options are formed when there is little or no evidence on a topic. This is defined as low quality evidence or a single moderate quality study (i.e., a limited strength option), no evidence or only conflicting evidence (i.e., a consensus option), or statements resulting in a limited or consensus strength following Evidence to Decision Framework upgrading and/or downgrading.

NON-MODIFIABLE RISK FACTORS: AGE AND SEX

The non-modifiable risk factors age and sex do not predict patient reported functional outcomes following mid shaft clavicle fracture regardless of treatment modality.

Quality of Evidence: Low
Strength of Option: Limited ★★☆☆
Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

MODIFIABLE RISK FACTORS: SMOKING

Limited evidence suggests that smoking tobacco increases the rate of nonunion in clavicle fractures and leads to inferior clinical outcomes.

Quality of Evidence: Low
Strength of Option: Limited ★★☆☆
Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

DUAL PLATING

Dual plating of midshaft clavicle fractures in adults utilizing one 2.7-mm plate and a 2.7-mm or smaller plate may result in similar union rates and lower implant removal and secondary procedure rates than those seen with use of single 3.5-mm plates.

Quality of Evidence: Low
Strength of Option: Limited ★★☆☆
Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

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ANTERIOR vs. SUPERIOR PLATING

Anterior inferior plating of midshaft clavicle fractures in adults may lead to lower implant removal rates compared to superior plating.

Quality of Evidence: Low

Strength of Option: Limited ★★☆☆

Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

PRE-CONTOURED PLATE vs. NON-PRE-CONTOURED PLATE

Surgeons may use manufacturer-contoured anatomic clavicle plates for treatment of midshaft clavicle fractures in adults as they have lower rates of implant removal or deformation compared to other plates.

Quality of Evidence: Low

Strength of Option: Limited ★★☆☆

Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

RADIOGRAPH: SUPINE vs. UPRIGHT

Upright radiographs may be superior for demonstrating the degree of displacement in midshaft clavicle fractures when compared to supine radiographs.

Quality of Evidence: Low

Strength of Option: Limited ★★☆☆

Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

PREDICTORS OF NON-UNION FOLLOWING NONOPERATIVELY TREATED CLAVICLE FRACTURES

Increasing displacement and/or comminution in mid-shaft clavicle fractures may be associated with higher rates of non-union following non-operative treatment in adults.

Quality of Evidence: Low
Strength of Option: Limited ★★☆☆
Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

ISOLATED DISPLACED MIDSHAFT FRACTURE: OPERATIVE vs. NONOPERATIVE (ADOLESCENT ≤ 18 YEARS OLD)

In adolescent patients with displaced midshaft clavicle fractures, operative treatment may offer no benefit compared to non-operative treatment. Operative treatment is associated with similar union rates and substantial reoperation rates for implant removal.

Quality of Evidence: Low
Strength of Option: Limited ★★☆☆
Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

IMMOBILIZATION METHOD

In the absence of reliable evidence, it is the opinion of the work group that sling is preferred in most cases for immobilization of acute clavicle fractures as opposed to figure-of-eight brace.

Quality of Evidence: Consensus
Strength of Option: Consensus ★☆☆☆
There is no supporting evidence, or limited level evidence was downgraded due to major concerns addressed in the EtD framework. In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical opinion.

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LATERAL CLAVICLE FRACTURE: OPERATIVE vs. NONOPERATIVE TREATMENT

In the absence of reliable evidence, it is the opinion of the work group that displaced lateral fractures with disruption of the coracoclavicular ligament complex may benefit from operative repair.

Quality of Evidence: Consensus
Strength of Option: Consensus ★☆☆☆
There is no supporting evidence, or limited level evidence was downgraded due to major concerns addressed in the EtD framework. In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical opinion.

DEVELOPMENT GROUP ROSTER

VOTING MEMBERS

Melissa Wright, MD, Co-Chair
American Shoulder and Elbow Surgeons

Gregory Della Rocca, MD, PhD, FAAOS, Co-Chair
American Academy of Orthopaedic Surgeons

Jason Strelzow, MD, FAAOS
Orthopaedic Trauma Association (OTA)

Lisa Cannada, MD, FAAOS
American Academy of Orthopaedic Surgeons

Matthew Zens, DPT, SCS, MS, ATC
American Society of Shoulder and Elbow Therapists

Noah Raizman, MD, FAAOS
American Academy of Orthopaedic Surgeons

Benton Heyworth, MD, FAAOS
American Academy of Orthopaedic Surgeons

Scott Steinmann, MD, FAAOS
American Academy of Orthopaedic Surgeons

Ajay Srivastava, MD, FAAOS
American Academy of Orthopaedic Surgeons

David Carmack, MD, FAAOS
American Academy of Orthopaedic Surgeons

James Ostrander, MD
American Academy of Orthopaedic Surgeons

Aaron Chamberlain, MD, FAAOS
American Academy of Orthopaedic Surgeons

CONTRIBUTORS

Henry Ellis, MD, FAAOS, Oversight Chair
American Academy of Orthopaedic Surgeons

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AAOS STAFF

Jayson Murray, MA
Managing Director
Clinical Quality and Value, AAOS

Kaitlyn Sevarino, MBA, CAE
Director
Clinical Quality and Value, AAOS

Frank Casambre, MPH
Manager
Clinical Quality and Value, AAOS

Tyler Verity
Medical Research Librarian
Clinical Quality and Value, AAOS

Kevin Jebamony, MPH
Research Analyst
Clinical Quality and Value, AAOS

Kristine Sizemore, MPH
Research Analyst
Clinical Quality and Value, AAOS

Jennifer Rodriguez, MBA
Quality Development Assistant
Clinical Quality and Value, AAOS

INTRODUCTION

OVERVIEW

This clinical practice guideline is based on a systematic review of published studies examining the diagnosis and treatment of clavicle fractures. It provides recommendations that will help health care professionals integrate the current evidence for their clinical practices, and it highlights gaps in the literature in need of future research. This guideline focuses on the treatment of isolated clavicle fractures; additional considerations outside the scope of these guidelines are necessary for the treatment of clavicle fractures in the polytraumatized patient. This guideline is intended to be used by appropriately trained physicians and clinicians who treat clavicle fractures. It will also serve as an information resource for developers and applied users of clinical practice guidelines.

GOALS AND RATIONALE

The purpose of this clinical practice guideline is to evaluate the current best evidence associated with the treatment of isolated clavicle fractures. Evidence-based medicine (EBM) standards advocate for use of empirical evidence by physicians in their clinical decision making. To assist with access to the large resources of information, a systematic review of clavicle fracture literature was conducted between November 2021 and July 2022. This clinical practice guideline highlights where there is good evidence, where evidence is lacking, and what topics future research will need to target in order to help facilitate evidence-based decision making in the treatment of clavicle fractures. AAOS staff methodologists assisted the physician/clinician work group in evaluating the existing literature so that they could formulate the following recommendations based on a rigorous systematic process. Musculoskeletal care is provided in many different settings and by a variety of health care professionals. This guideline is an educational tool to guide qualified physicians and clinicians in making treatment decisions that improve the quality and efficacy of care. This guideline does not include all possible methods of care and does not intend to exclude other acceptable interventions similarly directed at obtaining favorable outcomes. The final decision to use a specific treatment is at the discretion of the treating health care professional and must be made after assessing all concerns presented by the patient, available diagnostic information, and consideration of locality-specific resources.

INTENDED USERS

This guideline is intended to be used by orthopaedic surgeons and other healthcare professionals treating isolated clavicle fractures. It is intended to serve as an information resource for health care professionals. In general, individual practicing physicians and clinicians do not have the resources required to complete a project of comparable scope and duration involving the evaluation of an extensive literature base. In April 2019, the AAOS adopted the use of the GRADE Evidence-to-Decision Framework into its clinical practice guideline development methodology. This framework enables work group members to incorporate additional factors into the strength of each recommendation and move away from the rigidity of previous AAOS recommendation language stems. The AAOS intends for this guideline to assist health care professionals engaged in the management of clavicle fracture patients not only with making shared clinical decisions with their patients but also in describing to patients why a selected intervention may represent the best available course of treatment. This guideline is not intended or authorized for use as a benefits determination document. It does not cover allocation of resources, business and ethical considerations, or other factors needed to determine the material value of orthopaedic care.

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PATIENT POPULATION

This guideline is intended for use with patients with an isolated clavicle fracture that has been diagnosed by a trained healthcare professional. It is not intended to guide the treatment of clavicle fractures in the polytraumatized patient where multiple other considerations impact treatment and where care should be at the discretion of an appropriately trained healthcare professional.

SCOPE

The scope of this guideline includes surgical and non-surgical interventions for clavicle fractures. These guidelines also offer information to help aid the treating healthcare professional in counseling patients regarding treatment options and expected outcomes.

During development of this clavicle fracture CPG, PICO questions related to the following topics warranted no evidence and were therefore not addressed in the final recommendations:

1. Timing of first follow-up radiographs after clavicle fracture.
2. Physical therapy for patients sustaining clavicle fracture and managed non-operatively.
3. Physical therapy for patients sustaining clavicle fracture and managed operatively.
4. Operative vs. non-operative management of fractures of the medial clavicle.
5. Use of locking screws during operative fixation of clavicle fractures.
6. Operative technique for treatment of distal (lateral) clavicle fractures.

ETIOLOGY

Clavicle fractures typically occur because of a direct blow to the shoulder. This can be due to a lower energy mechanism like a fall, or due to a higher energy event like a bicycle crash or motor vehicle collision.

INCIDENCE AND PREVALENCE

Clavicle fractures make up about 3-5% of all adult fractures. The incidence of clavicle fractures has been reported to be between 29 and 64 per 100,000 person-years in the last two decades, with higher incidences reported more recently[1,2,3]. Clavicle fractures occur in a bimodal age distribution with the first peak in incidence occurring during the second and third decades of life, making up nearly 1/3 of all clavicle fractures. A second peak of incidence occurs in the elderly population. A 2019 US private insurance claims database study reported that the rate of surgical intervention for clavicle fractures was 15.2%[2].

BURDEN OF DISEASE

Clavicle fractures impact men more often than women. They are common among contact athletes but occur after non-sports-related trauma as well.

With regard to economic burden of clavicle fractures, a systematic review of the literature has found that the mean overall cost per person of operative treatment of a clavicle fracture is around $10,000, while the cost for non-operative treatment averages closer to $8,000 USD[4]. The mean absence from work ranges from 8-193 days for patients receiving operative intervention and 24-69 days for those receiving non-operative treatment[4]. Data demonstrates that the cost-effectiveness of clavicle fracture treatment is largely driven by costs of operative treatment and lengths of absence from work.

EMOTIONAL AND PHYSICAL IMPACT

Clavicle fractures can result in long term negative functional consequences for the shoulder - particularly in the setting of fracture nonunion and malunion. Optimizing the treatment of clavicle fractures can reduce the negative physical and emotional impacts of the injury. It is the goal of these clinical practice

guidelines to help healthcare professionals to determine the ideal treatment for patients and counsel them appropriately.

POTENTIAL BENEFITS, HARM, AND CONTRAINDICATIONS

Clavicle fractures may be treated either non-operatively or operatively, with differing potential benefits and harms (depending on patient characteristics, such as age and occupation, as well as fracture characteristics, such as displacement).

Non-operative treatment of clavicle fractures has the benefit of avoiding surgical intervention and the associated risks of surgery. Non-operative treatment can allow for fracture healing and a return of function. However, while the harms of non-invasive treatments are typically lower than those associated with operative treatments, risks of non-operative treatment include delays in healing, time lost from work and wages, and nonunion or malunion, potentially impacting long term function. Non-operative treatment is rarely contraindicated, but situations such as open fractures and an unstable shoulder girdle often necessitate surgical intervention. Furthermore, certain clavicle fractures, particularly those with substantial shortening or displacement, may carry higher risk for future problems after non-operative treatment.

Operative treatment of clavicle fractures allows for anatomic reduction of the bone to expedite healing, reducing the risk of nonunion and allowing for long term improvement in function, particularly with displaced, comminuted, and shortened clavicle fractures. Operative treatment of clavicle fractures comes with risks inherent to surgical intervention including but not limited to bleeding, infection, and damage to nerves and blood vessels. While nonunion and malunion can be risks associated with operative intervention, they occur at rates lower than those seen after non-operative intervention. A substantial risk of operative treatment is re-operation, often for the removal of painful implants. Operative treatment is not indicated in minimally displaced fractures and may also be contraindicated by overall patient health and medical comorbidities.

The AAOS hopes that these clinical practice guidelines will help guide treating physicians to minimize harm and optimize benefit when selecting treatment methods for adult patients with isolated clavicle fractures.

METHODS

The methods used to perform this systematic review 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. To view the full AAOS clinical practice guideline methodology please visit https://www.aaos.org/quality/research-resources/methodology/ .

This clinical practice guideline evaluates the treatment of clavicle fracture and patient outcomes. 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.[1]

This clinical practice guideline was prepared by the AAOS Treatment of Clavicle Fracture Guideline physician development group (clinical experts) with the assistance of the AAOS Clinical Quality and Value (CQV) Department (methodologists). To develop this clinical practice guideline, the clinical practice guideline development group held an introductory meeting on November 14th, 2021, to establish the scope of the clinical practice guideline. As physician experts, the clinical practice guideline development group defined the scope of the

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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 Appendix I for search strategy).

LITERATURE SEARCHES

The systematic review begins with a comprehensive search of the literature. Articles considered were published prior to the start date of the search in a minimum of three electronic databases; PubMed, EMBASE, and the Cochrane Central Register of Controlled Trials. The medical librarian conducts the search using key terms determined from the guideline development group's PICO questions.

A CQV methodologist will review/include only primary literature but will supplement the electronic search with a manual search of the bibliographies of secondary literature sources, such as systematic reviews, as available. The methodologist will then evaluate all recalled articles for possible inclusion based on the study selection criteria and will summarize the evidence for the guideline work group who assist with reconciling possible errors and omissions.

A study attrition diagram is provided that details the numbers of identified abstracts, recalled and selected studies, and excluded studies that were evaluated in the CPG. The search strategies used to identify the abstracts is also included in the appendix of each CPG document.

DEFINING THE QUALITY OF EVIDENCE

The quality of evidence for a recommendation is determined by the quality and quantity of included literature for the statement. Statements with evidence from two or more "High" quality studies are considered to have "High Quality Evidence". Statements with evidence from two or more "Moderate" quality studies, or evidence from a single "High" quality study are considered to have "Moderate Quality Evidence". Statements with evidence from two or more "Low" quality studies or evidence from a single "Moderate" quality study are considered to have "Low Quality Evidence". Statements with evidence from one "Low" quality study or no supporting evidence are considered to have "Very Low Quality Evidence" or "Consensus" respectively.

DEFINING THE STRENGTH OF RECOMMENDATION

Judging the quality of evidence is only a steppingstone towards arriving at the strength of a CPG recommendation. An Evidence to Decision (EtD) Framework is applied to determine the strength of recommendation. It 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 data exists on critical outcomes.

Strength of recommendation expresses the degree of confidence one can have in a recommendation. As such, the strength expresses how possible it is that a recommendation will be overturned by future evidence. It is very difficult for future evidence to overturn a recommendation that is based on many high quality randomized controlled trials that show a large effect. It is much more likely that future evidence will overturn recommendations derived from a few small retrospective comparative studies. Consequently, recommendations based on the former kind of evidence are given a "strong" strength of recommendation and statements based on the latter kind of evidence are presented as options to the practicing clinician, rather than a directional recommendation, with either a "limited" strength or, in the event of no supporting or only conflicting evidence, a "consensus" strength.

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; however, the guideline development group had consensus (100% approval) when voting on every recommendation for this guideline. Any recommendation strength upgrade or downgrade based on the Evidence-to-Decision Framework requires a super majority (75%) approval of the work group.

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UNDERSTANDING THE QUALITY OF EVIDENCE AND STRENGTH OF STATEMENT

Table I. Level of Evidence Descriptions

Statement Strength	Evidence Quality	Statement Description	Strength Visual
Strong	High*	Evidence from two or more "High" quality studies with consistent findings recommending for or against the intervention. Or Rec is upgraded using the EtD framework.	
Moderate	Moderate*	Evidence from two or more "Moderate" quality studies with consistent findings or evidence from a single "High" quality study recommending for or against the intervention. Or Rec is upgraded or downgraded using the EtD framework.	
Limited	Low*	Evidence from two or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Or Rec is downgraded using the EtD framework.	
Consensus*	Very Low, or Consensus*	Evidence from one "Low" quality study, no supporting evidence, or Rec is downgraded using the EtD framework. In the absence of sufficient evidence, the guideline work group is making a statement based on their clinical opinion.	

*Unless statement was upgraded or downgraded in strength, using the EtD Framework

Table II. Interpreting the Strength of a Recommendation or Option

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

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.

Specialty societies relevant to the topic 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 Research and Quality Council (RQC), members of the Board of Councilors (BOC), 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, RQC, and EBQV so that they may review it and provide comment prior to being asked to approve the document. Based on these bodies, over 200 commentators have the opportunity to provide input into each CPG.

The chairs of the guideline work group, the manager of the AAOS CQV unit, and the Director of the AAOS CQV unit draft the initial responses to comments that address methodology. These responses are then reviewed by the chair and co-chair, who respond to questions concerning clinical practice and techniques. 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 CPG APPROVAL PROCESS

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

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REVISION PLANS

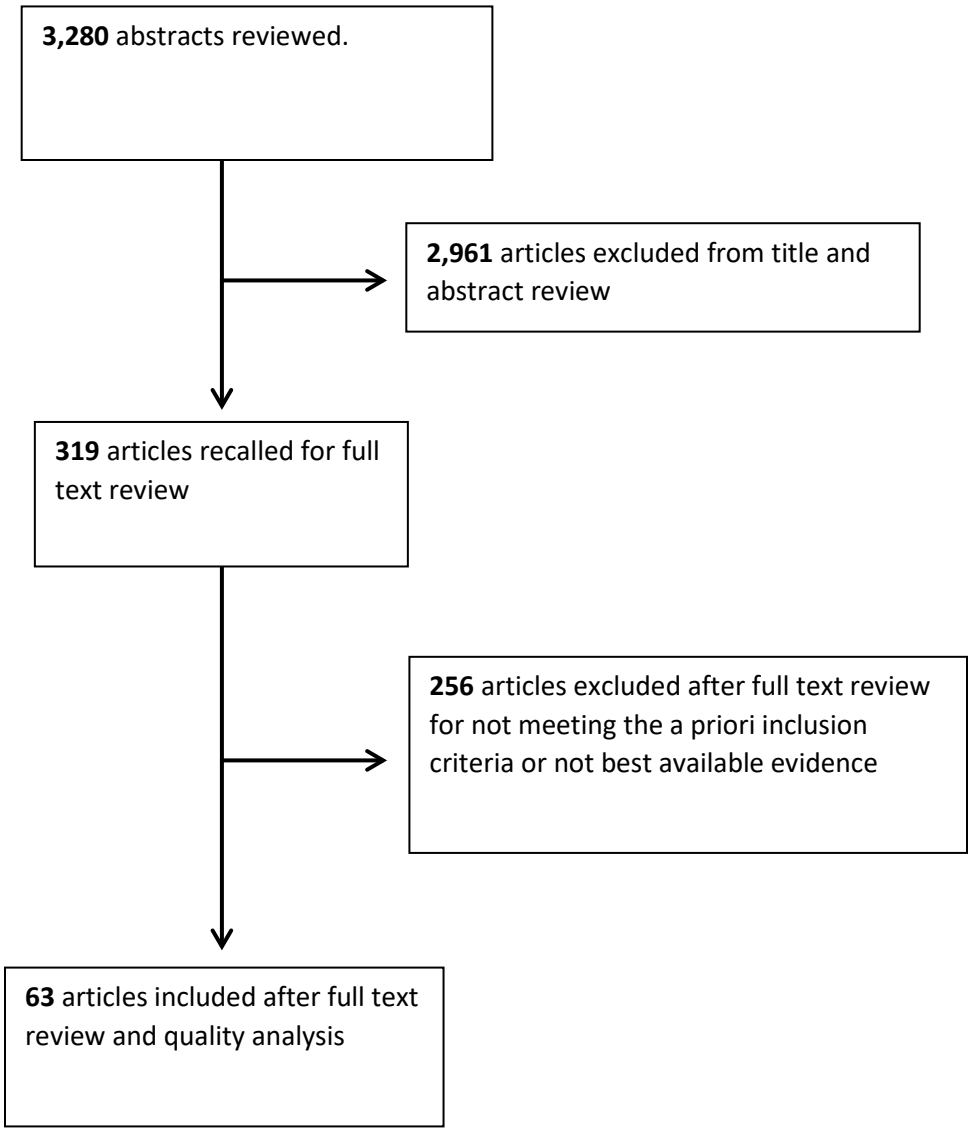
This clinical practice guideline represents a cross-sectional view of current treatment and may become outdated as new evidence becomes available. This clinical practice guideline will be revised in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology.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

CPG 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 clinical practice guidelines is announced by an Academy press release, articles authored by the clinical practice guideline development group and published in the Journal of the American Academy of Orthopaedic Surgeons, and articles published in AAOS *Now*. Most clinical practice guidelines are also distributed at the AAOS Annual Meeting in the Resource Center. The final guideline recommendations and their supporting rationales will be hosted on www.OrthoGuidelines.org.

Selected clinical practice guidelines are disseminated by webinar, the AAOS Learning Management System (LMS), Media Briefings, and by distributing them at relevant Continuing Medical Education (CME) courses and at the AAOS Resource Center.

Study Attrition Flowchart



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RECOMMENDATIONS

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Quality of Evidence: Moderate

Strength of Recommendation: 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. Also requires no or only minor concerns addressed in the EtD framework.

Rationale

There is limited evidence on treatment of clavicle fracture using low intensity pulsed ultrasound. One high-quality placebo-controlled trial (Lubbert 2008) was reviewed which investigated use of LIPUS in patients with acute midshaft clavicle fracture. It found that there was no difference in fracture healing, functional outcomes, or pain outcomes between the two groups.

Benefits/Harms of Implementation

There is no obvious benefit of low intensity pulsed ultrasound. However, it can cause unnecessary inconvenience to patients.

Outcome Importance

Clavicle fractures can be treated nonoperatively or surgically based on standard of care. Ultrasound usage is not necessary.

Cost Effectiveness/Resource Utilization

Low intensity pulsed ultrasound adds to significant financial burden to patient. Based on the evidence it doesn't seem to be cost effective.

Acceptability

There is no issue with acceptability of the outcome.

Feasibility

There is no issue with feasibility of the outcome.

Future Research

Further research is required in this area, as only one high-quality study was identified through the literature review. It's possible that medium intensity ultrasound may have different outcomes. High quality studies in

different age groups could shed some light on the possibility that ultrasound may have different effects in young versus older patients.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

HOOK PLATE VS. LATERAL LOCKING PLATE FOR LATERAL FRACTURE

Moderate evidence demonstrates that lateral locking plates may have fewer complications and better functional outcomes than hook plates for the treatment of lateral (Neer Type II) clavicle fractures in adults.

Quality of Evidence: Moderate

Strength of Recommendation: 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. Also requires no or only minor concerns addressed in the EtD framework.

Rationale

One randomized comparative trial (Wang 2020) evaluated the outcomes and complications following operative management of Neer Type II distal clavicle fractures treated with Hook plate versus Lateral Locking plate. Another study found no differences in objective outcomes of healing time, operative time, or blood loss between techniques but lower post-operative complication rates in the locking plate group (OR 5.64, 95% CI 1.37, 23.19) (Wang et al.). Additionally, subjective pain and outcomes scores (Constant, and UCLA) were significantly better in the locking plate techniques compared to the hook plate.

Benefits/Harms of Implementation

The choice of surgical plating technique for Neer Type II distal clavicle fractures appears to demonstrate a benefit with the use of lateral locking plates. A reduction in complications was demonstrated while providing similar rates of bony healing, comparable surgical time, and better patient reported outcomes.

Outcome Importance

Understanding the potential advantages and disadvantages of different surgical techniques for this potentially difficult surgical problem can improve complication rates and patient reported outcomes.

Cost Effectiveness/Resource Utilization

Based on the current evidence there is no recommendation that can be made related to cost/resource effectiveness on this topic. Given a substantial difference in complications between the two techniques the opportunity for cost analysis may be helpful to further analyze the global utility of each treatment.

Acceptability

The use of lateral locking plates requires minimal change to clinical practice as these are common plating techniques used throughout the body. Thus, the findings of this recommendation are likely to be acceptable amongst treating surgeons.

Feasibility

The surgical technique of lateral locked plating requires minimal if any major change in the surgical approach and definitive treatment technique and thus is feasible in most situations. The availability of lateral locking plates may be the only significant deterrent to the feasibility of this recommendation.

Future Research

Additional research is needed on this topic to further support or refute the findings of this study and to evaluate the cost effectiveness and ideal populations for the proposed techniques.

ISOLATED DISPLACED MIDSHAFT FRACTURE: OPERATIVE VS. NON-OPERATIVE TREATMENT [ADULT]

Operative treatment of displaced midshaft clavicle fractures in adult patients is associated with higher union rates and better early patient-reported outcomes than non-operative treatment. However, practitioners may consider either operative or non-operative treatment as both are associated with similar long-term patient-reported outcomes and patient satisfaction.

Quality of Evidence: High

Strength of Recommendation: Strong ★★★★

Evidence from two or more "High" quality studies with consistent findings for recommending for or against the intervention. Also requires no reasons to downgrade from the EtD framework.

Rationale

For those with displaced, mid shaft clavicle fractures, the exact amount of displacement and shortening to warrant consideration are not well-defined in the majority of studies. The referral to the guidelines of the COTS study 2007 are often discussed with displacement defined as no cortical contact between the two fragments. The studies which compared operative treatment with plate fixation versus non-operative treatment found an increased union rate with operative plate fixation (Ban 2021, Tamaoki 2017, COTS 2007). Additional studies that evaluated elastic stable intramedullary nailing (ESIN) also supported operative treatment for displaced midshaft clavicle fractures. The union rate not only was higher for operative treatment, but time to union was also faster (Chen 2011, Smekal 2009, Smekal 2011). There were superior functional outcomes earlier in the operatively treated group. For active patients and those who need to return to work with a displaced, midshaft clavicle fracture, operative fixation should be strongly considered.

Benefits/Harms of Implementation

Plate fixation and intramedullary nailing lead to higher union rates in adult patients. With any operative treatment, there is increased risk of infection and implant failure. The infection rates in all of the studies were low. There is increased need for surgery due to nonunion in the non-operatively treated group. There is increased need for reoperation for plate or EISN removal in the operatively treated group due to irritation and/or prominence of implant. Neither operative nor non-operative treatment was found to be superior in terms of cosmesis. At long-term follow-up, similar functional outcomes can be expected.

Outcome Importance

For displaced and shortened clavicle fractures, operative treatment with plate fixation was found to provide the best outcomes in terms of union rate.

Cost Effectiveness/Resource Utilization

Surgical fixation costs more in terms of overall costs and increased costs in the post operative period due to procedure costs for implant removal. With the need for operative conversion in non-operatively treated fractures to promote union, the delay in definitive management may affect the time to return to work and have economic consequences for the patient.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

Acceptability

Operative stabilization of displaced and/or comminuted mid shaft clavicle fractures is an acceptable treatment. There are more studies comparing plate fixation, but in comparing operative versus non-operative treatment, regardless of the type of implant, the union rate was superior and time to union was faster compared to non-operative treatment.

Feasibility

Operative treatment with a plate or intramedullary nailing can lead to a high union rate. The familiarity with plate fixation is the most likely reason for the greater number of studies analyzing this technique.

Future Research

Consistency in reporting the definition of displaced clavicle fractures in randomized studies should be sought. Mid- and long-term outcome studies would provide information on value of treatment over time in the adult population. Improved understanding or prediction of which patients are most likely to fail nonoperative or operative treatment will be useful to further tailor clinical decision-making. The determination of when non-operative treatment should be converted to operative stabilization would be useful in shared decision-making processes. It appears functional outcomes are similar at one year with either operative or non-operative treatment.

NAILING vs. SINGLE PLATE

Surgical treatment of clavicle shaft fractures with an intramedullary nail or a single plate results in equivalent long-term clinical outcomes with similar complication rates. Plate fixation may be of benefit in the presence of fracture comminution.

Quality of Evidence: Moderate

Strength of Recommendation: 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. Also requires no or only minor concerns addressed in the EtD framework.

Rationale

The literature (prospective and retrospective) generally supports that long-term clinical outcomes (> 1 year) are similar with the use of an intramedullary device versus single plate for fixation of displaced clavicular shaft fractures (Park 2020, Liu 2010, Zhang 2019, Anand 2021, Narsaria 2014). More comminution at the fracture site is however a clinical indication to use a clavicular plate, rather than an intramedullary device. The literature suggests better earlier clinical outcomes with the use of plates, presumably due to better stability early in the recovery phases after surgery (Anand 2021, Fuglesang 2018, van der Meijden 2015). The literature also suggests that hardware irritation/complications may be lower with the use of an intramedullary device when compared to a plate (Fuglesang 2018, Zhang 2019, Zehir 2016).

Benefits/Harms of Implementation

Benefits of these recommendations will potentially help surgeons avoid using an intramedullary device for a comminuted clavicular shaft fracture, when a better therapeutic choice would be a plate for clavicular shaft fracture with comminution. There are not potential clinical harms that could be created by following clinical recommendation of this guideline beyond the expected risks of surgical intervention.

Outcome Importance

Better clinical outcomes might be achieved by following this clinical guideline for the fixation of clavicular shaft fractures depending on fracture pattern simple versus comminuted).

Cost Effectiveness/Resource Utilization

At this time, the direct cost differences between intramedullary devices and plates for clavicular shaft fracture fixation are not known to this group. With respect to resource utilization, orthopedic surgeons would need clinical access to both intramedullary devices and plates for clavicular shaft fracture fixation. This might require more resources as hospitals would need to maintain inventories for both devices.

Acceptability

Clinically active orthopedic surgeons are probably more comfortable with plate fixation of clavicular shaft fractures at this time. Orthopedic surgeons may benefit from clinical training (sawbones, cadaver labs, etc.) to become more familiar with the use of intramedullary devices for clavicular shaft fracture fixation.

Feasibility

Clinical use of both intramedullary devices and plates is very reasonable for orthopedic surgeons who provide clinical surgical care for patients with clavicular shaft fractures.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

Future Research

Future research would include more long-term clinical outcome data (need for hardware removal, complications related to surgical procedure, patient reported outcomes, etc.) beyond twelve months.

OPTIONS

Low quality evidence, no evidence, or conflicting supporting evidence have resulted in the following statements for patient interventions to be listed as options for the specified condition. Future research may eventually cause these statements to be upgraded to strong or moderate recommendations for treatment.

NON-MODIFIABLE RISK FACTORS: AGE AND SEX

The non-modifiable risk factors age and sex do not predict patient reported functional outcomes following mid shaft clavicle fracture regardless of treatment modality.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

In general, non-modifiable factors and their effect on functional outcome after clavicle facture is not well studied. The effect of non-modifiable factors like age, gender, poly trauma, fall height, and hand dominance, fracture of shortening, and fracture displacement has been reported in the literature but no difference in functional outcome in these studied factors has been found.

One study reported no difference in outcomes based on age, sex, fracture type, and fracture shortening or displacement (Ban 2021). They reported better Constant scores at 6 weeks but no differences at 1 year. Another study did not find any differences in outcomes based on non-modifiable factors including age, sex, fracture shortening, hand dominance, or the diagnosis of diabetes (Chu 2018). Some studies reported no difference in outcome based on sex with either operative or non-operative treatment (Napora 2016, 2018). Finally, one study investigated high vs low energy mechanism, fall from height and the effect of hand dominance on clinical outcomes and found no difference (Nicholson 2020).

Benefits/Harms of Implementation

Nonmodifiable factors do not seem to affect patient reported outcomes therefore there is no significant benefit or harm of this recommendation.

Outcome Importance

Outcome does not go against standard of care. Surgical treatment of clavicle fracture is the preferred treatment in majority of significantly displaced fractures. Non-operative management could be a reasonable option in high-risk patients.

Cost Effectiveness/Resource Utilization

This recommendation does not have any effect on the financial aspect of clavicle fracture treatment.

Acceptability

Fracture treatment should be acceptable as it does not change the current standard of care.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

Feasibility

Operative and non-operative treatment are feasible. There is no additional barrier as a result of this recommendation.

Future Research

Research is lacking in this field. As non-modifiable factors cannot be changed, treatment methods should be calibrated based on relevant factors to achieve better outcomes. Well powered randomized controlled studies to identify factors that negatively impact functional outcomes are needed to help surgeons select an appropriate treatment strategy.

MODIFIABLE RISK FACTORS: SMOKING

Limited evidence suggests that smoking tobacco increases the rate of nonunion in clavicle fractures and leads to inferior clinical outcomes.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

Five low quality studies were examined, identifying smoking as the most common modifiable risk factor associated with poor outcomes (nonunion in surgical or non-surgical fixation). One study showed that non-union is an uncommon outcome in non-surgical treatment, however the risk of non-union was greatly increased by smoking (Liu 2015). Another non-surgical treatment study showed that smoking was the strongest risk factor for non-union (Murray 2013).

In two studies that analyzed both surgical and non-surgical treatment of clavicle fractures, ASES scores were assessed, demonstrating that smokers in each group had significantly lower ASES scores than those that did not smoke (Napora 2016, 2018). Smoking and unemployment led to overall poorer outcome in each of these studies as well. The final study also linked clavicle fracture non-union to smoking (Chu 2018).

Benefits/Harms of Implementation

Recognition of the risks of smoking on outcome following clavicle fracture may benefit surgeons as they counsel patients regarding expected outcomes.

Outcome Importance

Smoking is a modifiable risk factor that can be directly correlated to outcomes following a clavicle fracture which is critical to patient counseling and treatment decision making.

Cost Effectiveness/Resource Utilization

Not applicable to this recommendation.

Acceptability

No change to treatment is recommended.

Feasibility

As no change to treatment is recommended, feasibility is not applicable.

Future Research

Further research regarding other modifiable risk factors that may impact clavicle fracture treatment is needed.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

DUAL PLATING

Dual plating of midshaft clavicle fractures in adults utilizing one 2.7-mm plate and a 2.7-mm or smaller plate may result in similar union rates and lower implant removal and secondary procedure rates than those seen with use of single 3.5-mm plates.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

There were three low quality studies evaluating single versus dual plate fixation of midshaft clavicle fractures (Chen 2017, DeBaun 2020, Lee 2020). The studies evaluated differing aspects of clavicle fracture fixation. They compared results between dual mini fragment plates of multiple sizes (DeBaun 2020), dual plating with mini fragment and small fragment plates (Chen 2017), and finally two orthogonal mini-fragment plates (Lee 2020) compared to a single small fragment plate. The small fragment plate type, position, and fixation strategy (lag/neutralize/bridge/compression) was at the discretion of the operating surgeon in the studies with not all details reported (Chen 2017, DeBaun 2020), and not delineated (Lee 2020).

Lee (2020) did not find a significant difference in the need for hardware removal, but 8/89 small fragment plates were removed while no mini fragment plates were removed. Thus, the study favored mini fragment fixation regarding implant removal. This may not be applicable in the non-military population.

In Chen (2017) ten patients elected to undergo plate removal, with 7/10 being small fragment superior placement, favoring mini fragment dual plate fixation in terms of implant removal. DeBaun (2020) did not find a significant difference in hardware removal.

Benefits/Harms of Implementation

Any reoperation is considered a risk and the reoperation rate varied due to implant type and position. The use of multiple smaller plates rather than a single larger 3.5mm plate may benefit patients by providing similar union rates with a reduced rate of secondary procedures.

Outcome Importance

Dual plate fixation is an acceptable treatment for mid shaft clavicle fractures. There could be selection bias depending upon fracture type.

Cost Effectiveness/Resource Utilization

Higher rates of reoperation were noted for single implant fixation, leading to increased cost. In the one study that reported total operative time, those patients undergoing dual plate fixation took almost an hour longer in the operating room leading to increased cost. Formal cost analysis was not performed in any of the included studies.

Acceptability

These studies represent low quality studies with inconsistent operative details and outcomes. Consideration of dual plating techniques is likely acceptable to most orthopedic surgeons treating clavicle fractures as it within the current standards of care for treatment.

Feasibility

These studies may be useful when planning fixation for specific groups of patients in terms of counseling regarding hardware removal and union rate. Implementation of dual plating techniques in appropriate patients is likely feasible for most orthopedic surgeons as these implants are readily available in most hospitals similar to the single larger plates.

Future Research

Future studies are warranted on single versus dual plate fixation with controlled variables including type of plate, fracture type and positioning of plates. Details regarding duration of surgery and including patient reported outcome measures would be helpful. Large studies of diverse populations are necessary to assist in developing best practices on this topic.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

ANTERIOR vs. SUPERIOR PLATING

Anterior inferior plating of midshaft clavicle fractures in adults may lead to lower implant removal rates compared to superior plating.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

A single low-quality retrospective observational study (Serrano 2017) was included. There were 510 patients with mid-shaft clavicle fractures treated with either anterior-inferior (AI) plating or superior plating at the surgeon's discretion. The minimum follow up was 24 months. Regarding union rate and time to union, there was no difference between treatment groups. Similarly, regarding infection rate, there was no difference between treatment groups. Regarding implant removal for plate irritation, AI plating was preferred with superior plating carrying a 5 times greater odds ratio. Due to the decreased risk for a secondary intervention, this could be inferred to decrease the financial burden for the patient.

Benefits/Harms of Implementation

There is increased patient satisfaction assumed due to the decreased need for plate removal. Additionally, there are risks to a second operation so reducing the risk of a secondary operation is likely beneficial to patients.

Outcome Importance

There is no difference in union rate or time to union dependent upon plate position for mid shaft clavicle fixation. In addition, the infection rate is not different depending upon plate placement. However, rates of implant removal may vary depending on plate position and surgeons should be aware of this. The plate position for fixation should be at the discretion of the treating surgeon.

Cost Effectiveness/Resource Utilization

Due to decreased need for plate removal with anterior inferior plating, there is decreased burden on the health care system.

Acceptability

Either treatment is acceptable. The patient can be counseled regarding a low-quality study finding a lower need for plate removal and assumed increased patient satisfaction. Many orthopedic surgeons treating clavicle fractures likely already use both plate positions depending on fracture pattern and patient characteristics.

Feasibility

Either plate position should be feasible for most orthopedic surgeons treating clavicle fractures.

Future Research

Future research is needed to increase the number of studies with these two treatment interventions in direct comparison. Research should also focus on patient reported outcome measures to understand the relationship between satisfaction and plate removal.

PRE-CONTOURED PLATE vs. NON-PRE-CONTOURED PLATE

Surgeons may use manufacturer-contoured anatomic clavicle plates for treatment of midshaft clavicle fractures in adults as they have lower rates of implant removal or deformation compared to other plates.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

Two low quality studies were reviewed comparing pre-contoured and non-contoured plates for the treatment of clavicle fractures (Fang 2020, Rongguang 2016). Both studies demonstrated no significant differences in the rates of patient reports outcomes, or adverse events. Fang (2020) found pre-contoured plates offered a lower rate of implant deformity (0 vs. 11.3%) however implant removal rates, and clinical outcomes were similar between groups. Rongguang (2016) reported lower rates of hardware removal in the pre-contoured plate groups and those with high BMI.

Benefits/Harms of Implementation

Both pre-contoured and non-contoured plates offered similar functional outcomes across both studies. Rongguang (2016) suggested a reduced rate of implant removal which may provide the benefit of reduced incidence of revision surgery with no specific downside. Additionally, anatomically pre-contoured plates may be less likely to undergo deformity however the clinical significance of this was not demonstrated in either clinical study.

Outcome Importance

Further understanding of the utility of pre-contoured plates may provide insight into cost effective ways to manage this common pathology.

Cost Effectiveness/Resource Utilization

No evidence was presented in either study specific to cost effectiveness or resource utilization; however, given the higher rate of plate removal reported by Rongguang (2016). This is a future area of research need.

Acceptability

Both plate types (pre-contoured and non-contoured) use similar surgical techniques and would not require significant changes to established practices.

Feasibility

Anatomically pre-contoured plates are generally more expensive than non-pre-contoured plates. The availability of pre-contoured plates may be a significant deterrent to the feasibility of this recommendation in areas without access to such instrumentation.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

Future Research

Further high-quality studies evaluating the clinical, radiographic, and functional outcomes of patients treated with clavicle fractures are needed. Additionally, a cost effectiveness study would help to stratify the utility of these techniques.

RADIOGRAPH: SUPINE vs. UPRIGHT

Upright radiographs may be superior for demonstrating the degree of displacement in midshaft clavicle fractures when compared to supine radiographs.

Quality of Evidence: Low

Strength of Option: Limited ★★☆☆

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

Two low quality studies were reviewed demonstrating more displacement of midshaft clavicle fractures with upright compared to supine radiographs (Herman 2019, Malik 2017). Herman et al. found a higher proportion of displacement greater than 100% in the group with upright radiographs (52.1% vs 33.5%). Malik (2017) specifically measured the change in vertical and horizontal displacement on supine and upright radiographs taken within 2 weeks and found significantly more displacement in both planes in the upright group. The mean displacement ranged from 3.34 to 6.3 mm with use of upright films when compared to supine radiographs. Additionally, Herman et al. noted upright films more frequently lead to a change in treatment as a result of displacement when compared to supine imaging. Upright clavicle radiographs may provide more information regarding displacement compared to supine radiographs alone.

Benefits/Harms of Implementation

Patient positioning for upright versus supine radiographs is unlikely to cause notable harm or benefit to the patient. Upright radiographs are likely to show more displacement and may lead to changes in treatment secondary to displacement compared to supine radiographs.

Outcome Importance

Understanding the impact of positioning on displacement is important for the treating surgeon so that appropriate treatment and injury stratification can be determined.

Cost Effectiveness/Resource Utilization

No evidence related to cost or resource utilization is available on this topic. It is unlikely that there is a substantial difference between upright and supine radiographs as this is only a difference in patient positioning.

Acceptability

Little needed change in practice pattern makes this recommendation likely to be acceptable to most.

Feasibility

Alterations in position are feasible in most x-ray settings. Obtaining upright radiographs, once patient is able, can be performed in a subacute manner without clinically relevant changes in treatment.

Future Research

Continued understanding of the impact of displacement on clinical outcomes is necessary.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

PREDICTORS OF NON-UNION FOLLOWING NON-OPERATIVELY TREATED CLAVICLE FRACTURE

Increasing displacement and/or comminution in mid-shaft clavicle fractures may be associated with higher rates of non-union following non-operative treatment in adults.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

Four low quality observational studies examined the impact of various factors on the rate of nonunion for non-operatively treated midshaft clavicle fractures. Two studies found that comminution and displacement had a significant impact increasing the rate of nonunion (Liu 2015, Robinson 2004). One study found that comminution predicted delays in union at 6 and 12 weeks, but not by 24 weeks (Robinson 2004). Finally, one study found that comminution did not impact union rates (Rugpolmuang 2016). Based on the available evidence it is likely that comminution and displacement increase the risk of nonunion of a non-operatively treated midshaft clavicle fracture.

Benefits/Harms of Implementation

Understanding predictors of nonunion will benefit patients by providing the surgeon with more predictive information to help guide treatment. This can help minimize treatment delays and inappropriate treatment for patients.

Outcome Importance

Understanding predictors of nonunion with non-operative treatment of clavicle fractures is critical to patient counseling and treatment decision making.

Cost Effectiveness/Resource Utilization

Understanding predictors of nonunion can help lead to optimizing treatment for a patient earlier to reduce time off work while balancing complications.

Acceptability

Surgeons are likely to accept that there may be a higher risk of nonunion based on certain fracture characteristics, although this clinical practice guideline is not making treatment recommendations.

Feasibility

Guidelines regarding risk provide surgeons with information to help counsel patients and guide treatment but no treatment recommendations are provided here.

Future Research

Further research regarding outcomes is needed so that surgeons can make treatment decisions based on the risk of nonunion.

ISOLATED DISPLACED MIDSHAFT FRACTURE: OPERATIVE VS. NON-OPERATIVE TREATMENT [ADOLESCENT ≤ 18 YEARS OLD]

In adolescent patients with displaced midshaft clavicle fractures, operative treatment may offer no benefit compared to non-operative treatment. Operative treatment is associated with similar union rates and substantial reoperation rates for implant removal.

Quality of Evidence: Low

Strength of Option: Limited 

Description: Evidence from one or more "Low" quality studies with consistent findings or evidence from a single "Moderate" quality study recommending for or against the intervention. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.

Rationale

Two low-quality studies (Swarup 2011, Riiser 2021) comparing operative and non-operative treatment of clavicle fracture in adolescent patients (≤ 18 years old) met inclusion criteria. Both studies found no significant difference in patient reported outcomes between operative and non-operatively treated patients. Swarup (2021) found no significant difference between groups in QuickDASH, Numerical Rating Scales for pain, UCLA Activity Scale, PROMIS Pain Interference, and PROMIS Physical Function Upper Extremity, and Hospital for Special Surgery Pediatric Functional Activity Brief Scale (HSS Pedi-FABS). Eight of forty-three operatively treated patients required implant removal (Swarup 2011). Conducting a similar comparison, Riiser (2021) found no significant difference in QuickDASH or Oxford Shoulder Score. However, they did find that non-operative treatment was favored for cosmetic outcomes, pain, and patient satisfaction (Riiser 2021).

Benefits/Harms of Implementation

The decision for surgery in an adolescent patient should be based upon a shared decision-making model with the understanding that there is no difference in outcome measures once the fracture has healed. Surgery should be reserved for select cases in the older adolescents.

Outcome Importance

It is important to understand surgical treatment with a plate or intramedullary nail does not confer an advantage in functional outcomes. Displaced, midshaft clavicle fractures in adolescents heal regardless of what treatment method is chosen as no non-unions were reported in the two studies (Swarup 2021, Riiser 2021).

Cost Effectiveness/Resource Utilization

Operative treatment has a higher need for implant removal, thus increasing health care costs and the risks associated with additional surgery.

Acceptability

Families and patients need to be counseled they can expect similar functional results with surgery or without surgery and the studies favor a trend toward non-operative treatment providing a more favorable cosmetic result.

Feasibility

Guidelines regarding treatment risks and outcomes provide surgeons with information to help counsel patients and their families. No specific treatment recommendations are provided as similar outcomes are demonstrated regardless of how they are treated.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

Future Research

Due to the low number of studies on this topic, there is need for future research to provide best evidence to guide decision making. Research should be directed towards the older adolescents, age 14 –18.

IMMOBILIZATION METHOD

In the absence of reliable evidence, it is the opinion of the work group that sling is preferred in most cases for immobilization of acute clavicle fractures as opposed to figure-of-eight brace.

Quality of Evidence: Consensus
Strength of Option: Consensus ★☆☆☆

Description: Evidence there is no supporting evidence, or limited level evidence was downgraded due to major concerns addressed in the EtD framework. In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical opinion.

Rationale

A systematic review of literature yielded no studies that met inclusion criteria for this topic. Sling immobilization has been the mainstay of non-operative treatment in most studies evaluating non-operative treatment of clavicle fractures (Ahrens 2017, Smekal 2009, COT 2007, Ban 2021, Woltz 2018). Other modalities have included Collar and Cuff (Robinson 2013) and Figure-of-Eight bandage (Naveen 2017, Tamaoki 2017). However, these have been less studied overall compared to ORIF. A randomized trial for mid-shaft clavicle fractures treated non-operatively, demonstrated no improvement in function, reduced pain, and improved patient comfort/compliance with sling when compared to Figure-of-Eight (Ersen 2015). Simple Sling immobilization is easily applied, well tolerated, and cost effective.

Benefits/Harms of Implementation

Sling immobilization offers a simple, cost-effective technique for non-operative care. The risks, or harms of implementation are minimal for this specific intervention. The technique is ubiquitous with minimal opportunity for the generation of health disparities or access to treatment.

Outcome Importance

Identifying optimal immobilization strategies for patient comfort while maximizing outcomes is critical for patient satisfaction and improving the success of non-operative management when indicated

Cost Effectiveness/Resource Utilization

Sling immobilization is simple, and low cost with few significant risks compared to more complex or expensive immobilization methods

Acceptability

Surgeons and patients are likely to accept that sling immobilization may be optimal for non-operative management given its prevalence, simplicity of use and low cost.

Feasibility

Recommendations, even those with consensus only support, inform and help counsel patients regarding treatment. The use of sling immobilization is inexpensive and can be applied broadly across health care settings and environments.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

Future Research

Further research regarding the optimal immobilization method(s) including sling, collar and cuff or figure of eight sling, is needed so that surgeons can make evidence-based treatment decisions to optimize patient comfort, and outcome.

LATERAL CLAVICLE FRACTURE: OPERATIVE vs. NON-OPERATIVE TREATMENT

In the absence of reliable evidence, it is the opinion of the work group that displaced lateral fractures with disruption of the coracoclavicular ligament complex may benefit from operative repair.

Quality of Evidence: Consensus
Strength of Option: Consensus ★☆☆☆

Description: Evidence there is no supporting evidence, or limited level evidence was downgraded due to major concerns addressed in the EtD framework. In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical opinion.

Rationale
A systematic literature review yielded no studies that met inclusion criteria for this clinical practice guideline. Outside the inclusion criteria, limited reliable evidence exists to guide surgeons on the optimal treatment of lateral clavicle fractures. Overall multiple surgical techniques have been described with newer techniques associated with improved outcomes and reduced re-operation. The work group is of the opinion that given the available evidence supporting modern techniques of fixation and the established high risks of non-union, surgical management may be appropriate in selected patients with displaced lateral clavicle fractures.

Benefits/Harms of Implementation
Surgical management of lateral clavicle fracture with coracoclavicular ligament injury may reduce the risk of non-union and improve patient outcomes. However, given the lack of supportive literature at the current time careful consideration must be made to avoid unnecessary operative interventions in this patient population.

Outcome Importance
Further understanding of the utility of surgical management of the displaced lateral clavicle fracture with Coracoclavicular ligament disruption may provide insight into the clinical effectiveness and cost effectiveness of the technique

Cost Effectiveness/Resource Utilization
No evidence related to cost or resource utilization is available on this topic. This would be an important area of further research to guide thoughtful health policy and treatment decisions.

Acceptability
Little change is required to implement this recommendation; thus, it is likely to be acceptable to most.

Feasibility
Implementation of this recommendation requires little additional surgical change however, public health resources and the associated cost of treatment may make this less feasible in some health care settings. Additionally, novel treatment techniques described to address this injury may require additional expertise or knowledge prior to implementation.

Future Research
Continued understanding of the impact of displacement, and the role of treatment on clinical outcomes is necessary.

View background material via the CPG eAppendix 1
View data summaries via the CPG eAppendix 2

APPENDICES

Appendix I: References (*for Introduction and Included Literature*)

Introduction

1. Huttunen, Tuomas T. MD, PhD1,2,a; Launonen, Antti P. MD, PhD1; Berg, Hans E. MD, PhD3,4; Lepola, Vesa MD, PhD1; Felländer-Tsai, Li MD, PhD3,4; Mattila, Ville M. MD, PhD1,2,3,4. Trends in the Incidence of Clavicle Fractures and Surgical Repair in Sweden: 2001-2012. The Journal of Bone and Joint Surgery: November 2, 2016 - Volume 98 - Issue 21 - p 1837-1842 doi: 10.2106/JBJS.15.01284
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Included Literature

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e APPENDIX IV: GUIDELINE DEVELOPMENT GROUP DISCLOSURES

Prior to the development of this clinical practice guideline, clinical practice guideline development 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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VOTING MEMBERS' AND NON-VOTING OVERSIGHT CHAIRS' DISCLOSURES

Henry Bone Ellis Jr, MD, FAAOS

Submitted on: 08/05/2022

AAOS: Board or committee member ($0) Evidence Based, Quality, and Value (Self)

Orthopaediatric: Paid presenter or speaker ($0) Number of Presentations: 0

Pediatric Orthopaedic Society of North America: Board or committee member ($0)

Pediatric Research in Sports Medicine: Board or committee member ($0)

Smith & Nephew: Unpaid consultant N/A (Self)

Texas Orthopedic Association: Board or committee member ($0)

Melissa Wright, MD

Submitted on: 05/18/2021

American Shoulder and Elbow Surgeons: Board or committee member ($0)

Zimmer: Research support ($0)

Gregory John Della Rocca, MD, PhD, FAAOS, FACS

Submitted on: 06/04/2021

AAOS: Board or committee member ($0)

American College of Surgeons: Board or committee member ($0)

American Orthopaedic Association: Board or committee member ($0) N/A(Self)

AOTrauma: Board or committee member ($0) Committee member (Self)

Association of Bone and Joint Surgeons: Board or committee member ($0) Committee member (Self)

Geriatric Orthopaedic Surgery and Rehabilitation: Editorial or governing board ($0) N/A(Self)

Journal of Orthopaedic Trauma: Editorial or governing board ($0) n/a(Self)

Mergenet: Stock or stock Options Number of Shares: 14,500 N/A(Self)

Orthopaedic Trauma Association: Board or committee member ($0)

The Orthopaedic Implant Company: Stock or stock Options Number of Shares: 25,000 N/A(Self)

Wright Medical Technology, Inc.: IP royalties ($1,100) N/A(Self)

Jason Strelzow, MD, FAAOS

Submitted on: 05/17/2021

Acumed, LLC: Paid presenter or speaker ($1,500) Number of Presentations: 3 N/A(Self)

Acumed, LLC: Paid consultant ($5,000) N/A (Self)

American Society for Surgery of the Hand: Board or committee member ($0) N/A(Self)

BoneSupport: Paid consultant ($2,000) BoneSupport (Self)

Journal of Bone and Joint Surgery - American: Editorial or governing board ($0) JBJS Reviews (Self)

Journal of Hand Surgery - American: Editorial or governing board ($0) N/A(Self)

Orthopaedic Trauma Association: Board or committee member ($0) N/A(Self)

Stryker: Other financial or material support ($300) N/A(Self)

Lisa K Cannada, MD, FAAOS

Submitted on: 05/18/2021

AAOS Now: Editorial or governing board ($0) Editorial Board (Self)

Clinical Orthopaedic Society: Board or committee member ($0) Board of Directors (Self)

Journal of Bone and Joint Surgery - British: Editorial or governing board ($0) Editorial Board (Self)

Journal of Orthopaedic EXperience & Innovation: Editorial or governing board ($0) Editorial Board (Self)

Mid America Orthopaedic Association: Board or committee member ($0) Board of Directors, Chair Education Committee (Self)

Orthopaedic Trauma Association: Board or committee member; Board or committee member ($0) Practice Management Committee Member (Self)

Orthopedics: Editorial or governing board ($0) Editorial Board (Self)

Wolters Kluwer Health - Lippincott Williams & Wilkins: Editorial or governing board ($0) Journal of Orthopaedic Trauma EDitorial Board & Techniques in Orthopaedics Editorial Board (Self)

Matthew J Zens, DPT, SCS, MS, ATC

(This individual reported nothing to disclose); Submitted on: 06/04/2021

Noah Matthew Raizman, MD, FAAOS

(This individual reported nothing to disclose); Submitted on: 06/01/2021

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Benton E Heyworth, MD, FAAOS

Submitted on: 04/01/2021

Allosource: Other financial or material support ($0)

Imagen Technologies, Inc.: Stock or stock Options Number of Shares: 0

Pediatric Orthopaedic Society of North America: Board or committee member ($0)

Pediatric Research in Sports Medicine (PRISM): Board or committee member ($0)

Springer: Publishing royalties, financial or material support ($0)

Vericel: Other financial or material support ($0)

Scott P Steinmann, MD, FAAOS

Submitted on: 04/08/2021

Acumed, LLC: Paid consultant ($0) N/A(Family)

American Shoulder and Elbow Surgeons: Board or committee member ($0) (Self)

American Society for Surgery of the Hand: Board or committee member ($0) (Self)

Arthrex, Inc: IP royalties ($5,000) N/A (Self)

Arthrex, Inc: Paid consultant ($10,000) (Self)

Arthroscopy Association of North America: Board or committee member ($0) none (Self)

Biomet: IP royalties ($20,000) zimmer (Self)

Biomet: Paid consultant ($5,000) n/s(Self)

Journal of Hand Surgery - American: Editorial or governing board ($0) n/a(Self)

Journal of Shoulder and Elbow Surgery: Editorial or governing board ($0) (Self)

Orthopedics Today: Editorial or governing board ($0) n/a(Self)

Sonex: Paid consultant ($1,000) N/A(Family)

Stryker: Paid consultant ($0) N/A(Family)

Ajay Kumar Srivastava, MD, FAAOS

Submitted on: 06/01/2021

AAOS: Board or committee member ($0) EBQV Committee (Self)

David B Carmack, MD, FAAOS

(This individual reported nothing to disclose); Submitted on: 06/02/2021

James Ostrander, MD

(This individual reported nothing to disclose); Submitted on: 06/01/2021

Aaron Mark Chamberlain, MD, FAAOS

Submitted on: 09/23/2021

AAOS: Board or committee member ($0) Evidence-Based Quality and Value (Self)

American Shoulder and Elbow Surgeons: Board or committee member ($0) Fellowship Committee (Self)

Arthrex, Inc: Paid consultant ($0)

Johnson & Johnson: Paid consultant ($51,575) DePuy/Mitek(Self)

Zimmer: Research support ($0)

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