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METRC

Major Extremity Trauma and Rehabilitation Consortium

Clinical Practice Guideline for Limb Salvage or Early Amputation

Adopted by the American Academy of Orthopaedic Surgeons (AAOS) Board of Directors

December 6, 2019



The Major Extremity Trauma and Rehabilitation Consortium in collaboration with the American Academy of Orthopaedic Surgeons 2019 Clinical Practice Guideline on Limb Salvage or Early Amputation

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WHAT IS A CLINICAL PRACTICE GUIDELINE?

Clinical Practice Guideline

A clinical practice guideline is a series of recommendations created to inform clinicians of best practices, based on best available evidence



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GOALS AND RATIONALE OF A CLINICAL PRACTICE GUIDELINE



- Improve treatment based on current best evidence
- Guides qualified physicians through treatment decisions to improve quality and efficiency of care
- Identify areas for future research

CPG recommendations are not meant to be fixed protocols; patients' needs, local resources, and clinician independent medical judgement must be considered for any specific procedure or treatment

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WHAT IS EVIDENCE-BASED MEDICINE?

Evidence-Based Medicine is a Combination of:

- *Individual Clinical Experience*
- *Best External Evidence*
- *Patient Values and Expectations*



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WHAT IS EVIDENCE-BASED MEDICINE?

Evidence-Based Medicine

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence from clinical care research in the management of individual patients



Haynes, Sackett et al, 1996

Transferring evidence from research into practice

Sacket et al, 1996, BMJ

EBM: what it is and isn't

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IOM STANDARDS FOR DEVELOPING TRUSTWORTHY GUIDELINE



- Establish Transparency
- Management of Conflict of Interest
- Guideline Development Group Composition
- Clinical Practice Guideline-Systematic Review Intersection
- Establish Evidence of Foundations for and Rating Strength of Recommendations
- Articulation of Recommendations
- External Review
- Updating

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CLINICAL PRACTICE GUIDELINE PROCESS FLOWCHART

1. Select CPG Topic

2. Formulate Work Group (WG):
Representatives from AAOS/BOS/BOC/Other Organizations as appropriate
WG members may have no relevant FCOI

3. Seek Input on Question Topics:
From patients, AAOS members, Key Informant Panel (a panel of content experts precluded from WG participation due to FCOI).

4. In-Person Intro Meeting:
Formulate PICO Questions, Set Inclusion Criteria
(Completed by WG)

5. Literature Search and Review:
Conduct systematic literature search, appraise quality of studies (staff); WG members review included literature for their assigned recommendations

6. In-Person Final Meeting:
Develop Final Recommendations; Review quality appraisals and evidence tables. Assign a grade/rating for each based on evidence (WG). Completed both prior to and during final in-person meeting.

7. Review Period:
(3 weeks)
Nominated Specialty Society Representatives, AAOS BOD, AAOS CORQ, AAOS EBQV, AAOS BOC and BOS, Key Informant Panel

8. Response to Revew and Revisions:
Chairs and AAOS Staff review and respond to review; revise the draft as needed; any revisions to recommendation language requires WG approval

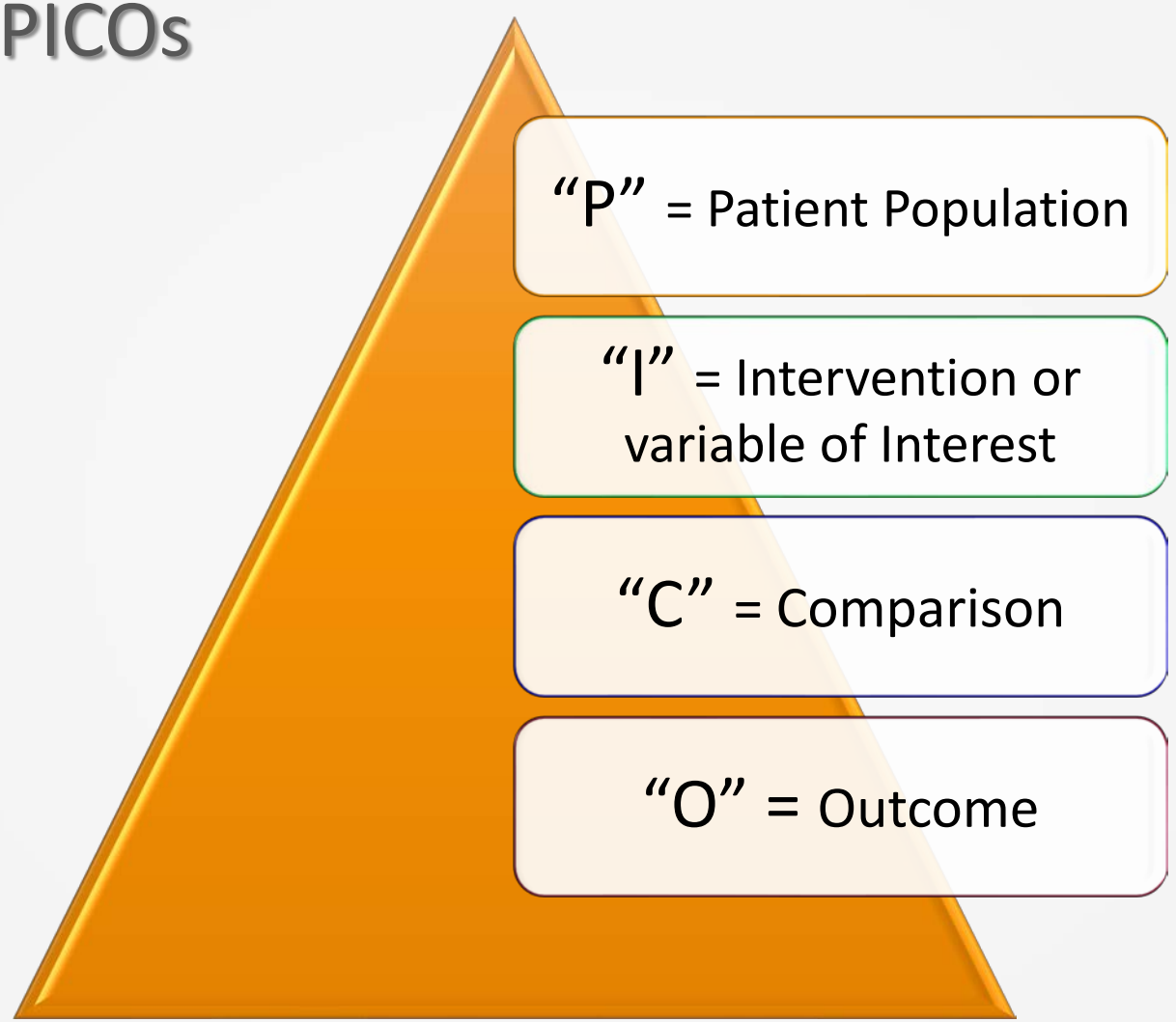
9. Approval Process:
The final CPG is reviewed and approved by the WG, EBQV, CORQ, and the AAOS Board of Directors

10. Communication, Dissemination, and Implementation

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FORMULATING PICOs



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INCLUSION/EXCLUSION CRITERIA

Standard inclusion criteria include:

- Must study humans
- Must be published in English
- Must be published in or after 1966
- Can not be performed on cadavers

Work group members define additional exclusion criteria based on PICO question



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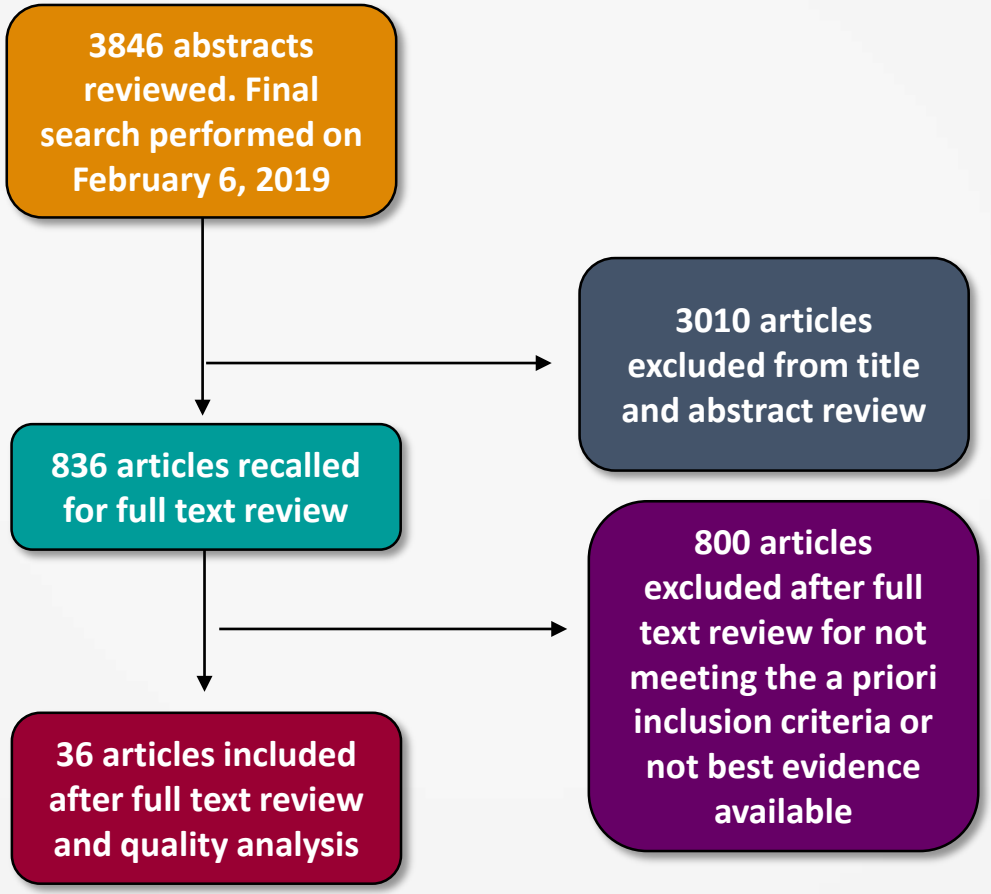
LITERATURE SEARCHES

- Databases used:
  - MEDLINE
  - EMBASE (Excerpta Medica dataBASE)
  - Cochrane Central Register of Controlled Trials
- Search using key terms from work group's PICO questions and inclusion criteria
- Secondary manual search of the bibliographies of all retrieved publications for relevant citations
- Recalled articles evaluated for inclusion based on the study selection criteria



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RESULTS OF QUALITY ASSESSMENT: STUDY ATTRITION FLOWCHART



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BEST EVIDENCE SYNTHESIS

Include only highest quality evidence for any given outcome if available

If there are fewer than two occurrences of an outcome of this quality, the next lowest quality is considered until at least two occurrences have been acquired.



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ASSESSING QUALITY OF EVIDENCE



- All included studies undergo a quality assessment.
- Each study's design is evaluated for risk of bias and receives a final quality grade, depending on the number of study design flaws.
- Study quality tables are made available to the work group in the final data report and the final publication of the guideline

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STRENGTH OF RECOMMENDATIONS

STRENGTH	OVERALL STRENGTH OF EVIDENCE	OVERALL STRENGTH OF EVIDENCE	STRENGTH VISUAL
STRONG	STRONG	Two or more HIGH Strength Studies with consistent findings for recommending for or against the intervention*	
MODERATE	MODERATE OR STRONG	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	LIMITED, MODERATE OR STRONG	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*	
CONSENSUS	NO RELIABLE EVIDENCE	In the absence of reliable evidence, the guideline work group is making a recommendation based on their clinical Opinion*	

*Recommendation strength can be upgraded or downgraded based on the application of the EtD framework.

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Incorporating the GRADE Evidence to Decision Framework into Recommendation Strengths

- Benefits and Harms
- Certainty of Evidence
- Outcome Importance
- Cost Effectiveness
- Acceptability and Feasibility



WORDING THE FINAL RECOMMENDATIONS

GUIDELINE LANGUAGE	STRENGTH OF RECOMMENDATION
In patients with [condition], X is recommended for…	**STRONG**
In patients with [condition], X is suggested for…	MODERATE
In patients with [condition], X is an option for…	LIMITED
In the absence of reliable evidence, it is the ***opinion*** of this guideline work group that…	CONCENSUS

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TRANSLATING RECOMMENDATIONS IN A CPG

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	More	Possible / Anticipates
Consensus	Most	Most Important	Impact unknown

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FINAL MEETING

The work group is charged with:

- Review of data summaries
- Final recommendation language
- Rationale and risk/harm construction
- Future research

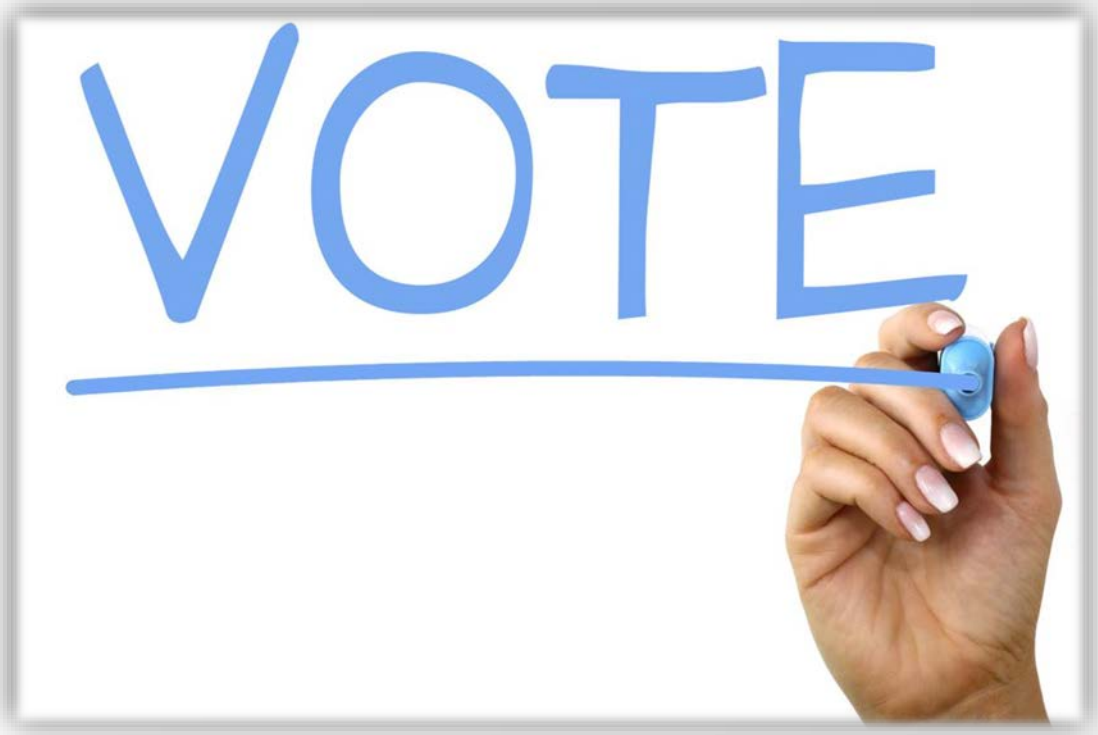


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VOTING ON THE RECOMMENDATIONS

- Recommendations and recommendation strengths voted on by work group during final meeting
- Approved and adopted by simple majority (60%) when voting on every recommendation
- If disagreement, further discussion to whether the disagreement could be resolved



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REVIEW PERIOD



- Specialty societies are solicited for nominations of reviewers approximately six weeks prior to final meeting
- CPG is also provided to:
  - **AAOS Board of Directors**
  - **AAOS Council on Research and Quality**
  - **AAOS Committee on Evidence-Based Quality and Value**
  - **AAOS Board of Councilors**
  - **AAOS Board of Specialty Societies**
  - **200 commentators have the opportunity to provide input into each CPG.**
- Recommendation changes required a majority vote by work group
- A detailed report of all resulting revisions is published with the guideline document

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CLINICAL PRACTICE GUIDELINE FOR LIMB SALVAGE OR EARLY AMPUTATION OVERVIEW



- Based on a systematic review of published studies
- Addresses the decision factors important to the selection of amputation or limb salvage of adult patients with severe lower extremity trauma distal to the femur.
- This guideline addresses limb salvage or early amputation in all settings. However, there are many military applications to these recommendations as well.
- Highlights limitations in literature and areas requiring future research.
- Trained orthopaedic surgeons and other surgical providers and rehabilitation specialists who partner in the care of patients with severe lower extremity trauma are the intended users.

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BURDEN OF INJURY - *Non-Limb Specific Injury - Time0 and Time1*

- The Physician team should evaluate overall burden of injury and patient physiology when considering if initial limb salvage is advisable.

Strength of Recommendation: Moderate 

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BURDEN OF INJURY - *Non-Limb Specific Injury - Time0 and Time1*

- In the absence of reliable evidence, the workgroup suggests the physician team should prioritize patient survival in the limb reconstruction vs. amputation decision. Limb specific damage control (i.e. temporizing) measures or immediate amputation should be considered when further attempts at definitive salvage will increase risk of mortality.

Strength of Recommendation: Moderate 

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BURDEN OF INJURY - *Limb Specific Injury – Time1 and Beyond*

- Physicians should consider the cumulative injury burden (soft tissue, vascular, nerve, bone, joint) of the limb when counseling patients on anticipated outcomes of and making recommendations on when to pursue limb salvage or amputation treatment.

Strength of Recommendation: Moderate 

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PSYCHOSOCIAL FACTORS

- Clinicians should screen all patients with high energy lower extremity trauma for psychosocial risk factors (e.g. depression, PTSD, anxiety, low self-efficacy, poor social support) affecting patient outcomes..

Strength of Recommendation: Strong 

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REHABILITATION

- Clinicians should recommend patients with high energy lower extremity trauma injuries participate in a rehabilitation program (e.g. PT, OT, behavioral health) to improve psychological and functional outcomes.

Strength of Recommendation: Moderate 

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NERVE INJURY

- The evidence suggests plantar sensation or an observed nerve transection is not a factor in the decision for limb salvage vs. amputation.

Strength of Recommendation: Limited 

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MASSIVE SOFT TISSUE AND MUSCLE DAMAGE- Time1

- Limited evidence suggests that these etiologies may lead to increased risk of adverse events or decreased functional outcomes:

  Crush
  Blunt
  Blast
  Penetrating
  Degloving
  Volumetric muscle loss/soft tissue loss

Strength of Recommendation: Limited 

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VASCULAR INJURY/LIMB ISCHEMIA

- The evidence suggests that neither hard signs of vascular injury nor duration of limb ischemia are absolute factors in the decision for limb salvage vs. amputation. However, the panel recognizes that prolonged ischemia is detrimental and the interval to reperfusion should be kept to a practical minimum. The duration of lower extremity ischemia is directly correlated with adverse events.

Strength of Recommendation: Limited 

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SMOKING

- Physicians should not consider a patient's smoking/nicotine use as a critical decision making factor at time zero; Physicians should recommend nicotine education/cessation (abstinence of nicotine) for all patients with high energy lower limb trauma as there is moderate evidence to suggest that smoking/nicotine use has a detrimental effect on outcomes for both amputation and limb salvage.

Strength of Recommendation: Moderate 

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LOWER EXTREMITY INJURY SCORES

- Physicians should not utilize extremity specific scores to select limb salvage vs. amputation, or to predict outcomes for patients with high energy lower extremity trauma.

Strength of Recommendation: Moderate 

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AMPUTATION/LIMB SALVAGE

- Injury patterns requiring ankle arthrodesis or foot free tissue transfer may be an indication for amputation in the non-acute phase and should be addressed in shared decision making with the patient.

Strength of Recommendation: Limited 

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ORTHOTICS/PROSTHETICS

In the absence of reliable evidence, it is the consensus of the work group that all patients with lower extremity amputation be fitted with an appropriate prosthesis.

Likewise, all lower extremity limb salvage patients with residual deficits should be evaluated for and/or fitted with an appropriate orthosis.

These conditions are lifelong and require periodic reevaluation and device adjustments and/or replacement.

Strength of Recommendation: Consensus 

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MASSIVE MUSCLE DAMAGE – Time0

In the absence of reliable evidence, the workgroup suggests massive muscle damage requiring extensive debridement is not an absolute factor in the decision for limb salvage vs. amputation.

Strength of Recommendation: Consensus



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CORMORBIDITIES

In the absence of reliable evidence, it is the opinion of the work group that pre-existing comorbid conditions should be considered in the decision of limb salvage vs amputation.

Strength of Recommendation: Consensus



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FUTURE RESEARCH

- The identification of patient characteristics and injury patterns that are best treated by amputation or limb salvage (given that salvage is feasible) is an on-going priority. Also critical is the development and validation of educational materials that will assist the treating team and the patient engaging in an evidence-supported, shared-decision making process. Rehabilitation is important to maximize the recovery from these injuries, but access to rehabilitation services is often a challenge in the civilian patient, particularly those requiring or treated with amputation. Research is needed to determine alternative pathways designed to address these patients. Lastly, patients in the limb salvage pathway are often faced with motor deficits, weakness, foot and ankle joint stiffness or arthrodesis. The impact of including a dynamic orthosis as part of the rehabilitation strategy requires more investigation.

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FUTURE RESEARCH – BURDEN OF INJURY

- This injury pattern is not amenable to randomized control study as it would be considered unethical to attempt limb salvage in a patient who is dying from another injury.

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FUTURE RESEARCH – PSYCHOSOCIAL FACTORS

- Current literature has shown that negative psychosocial factors results in poorer outcomes and satisfaction in both amputation and limb salvage. Long term studies are necessary to determine which factors are most important to address and what specific interventions are most effective.

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FUTURE RESEARCH – REHABILITATION

- Additional studies examining the specific association between the type (e.g. PT, OT, behavioral health interventions) and volume of care (number and duration) and resulting outcomes are needed. These data would help optimize the care pathway following traumatic limb injury, particularly in the context of multi-system or multi-limb injury, community reintegration/participation and training to use prosthetic and/or orthotic devices.

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FUTURE RESEARCH – NERVE INJURY

- High powered studies evaluating the impact of the level of nerve injury (with or without reconstruction) on functional outcomes are needed. Long-term outcome studies determining the return of sensation and motor function after reconstructive nerve procedures (e.g. nerve repair, graft, transfer and free soft tissue transfer) are also needed to help set patient and physician expectations in the care of the threatened limb.

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FUTURE RESEARCH – MASSIVE SOFT TISSUE AND MUSCLE DAMAGE – TIME1

- Studies of attempted limb salvage patients who progress to septic shock, permanent organ damage, and death should focus on predictive tools and clinical and laboratory findings which identify failing limb salvage situations, where timely conversion to amputation prevents organ death and/or patient demise. Studies which look at mechanism of injury, specific and quantifiable anatomic structure soft tissue damage or loss in lower extremity injury, may allow identification of patients at initial presentation who have predictable bad outcomes.

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FUTURE RESEARCH – SMOKING

- Defining the incidence of specific complications directly related to smoking/nicotine use for both limb salvage and amputation will enable more detailed physician-patient counseling. Additionally, defining the risk of failure of limb salvage specifically related to smoking/nicotine use could be a powerful adjunct for educating patients undertaking this strategy.

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FUTURE RESEARCH – LOWER EXTREMITY SCORES

- Developing a more sophisticated tool for surgeons that incorporates available patient characteristics that has a better sensitivity and specificity in identifying patients who would benefit from an immediate amputation using the body of research from the LEAP studies.

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FUTURE RESEARCH – AMPUTATION/LIMB SALVAGE

- Foremost will be implementation and validation of this toolkit/ guideline approach. Generalizability and acceptance criteria can be readily developed/ modified and need to be part and parcel of the roll out.

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FUTURE RESEARCH – MASSIVE MUSCLE DAMAGE – TIME0

- Studies of attempted limb salvage patients who progress to septic shock, permanent organ damage, and death should focus on predictive tools and clinical and laboratory findings which identify failing limb salvage situations, where timely conversion to amputation prevents organ death and/or patient demise. Studies which look at mechanism of injury, specific and quantifiable anatomic structure soft tissue damage or loss in lower extremity injury, may allow identification of patients at initial presentation who have predictable bad outcomes.

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FUTURE RESEARCH – CORMORBIDITIES

- Studies focused on understanding the specific type, number, combination, and/or severity of comorbidities effects on a multitude of outcomes will allow us to make more definitive future recommendations with regards to their influence on the decision for limb salvage versus amputation.

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ACKNOWLEDGEMENTS:

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PLEASE CITE CLINICAL PRACTICE GUIDELINE AS:

American Academy of Orthopaedic Surgeons Evidence-Based Clinical Practice Guideline for Limb Salvage or Early Amputation http://www.orthoguidelines.org/topic?id=1029. Published December 7, 2019.

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OrthoGuidelines

Easier access to AAOS Guidelines:

- Sort Alphabetically by Topic
- Sort Recommendations by Strength
- (*Strong, Moderate, Limited, Consensus)*
- Sort by Stage of Care
- Search Across ***all*** CPGs via a Single Keyword Search

Easier Access to Individual Recommendations:

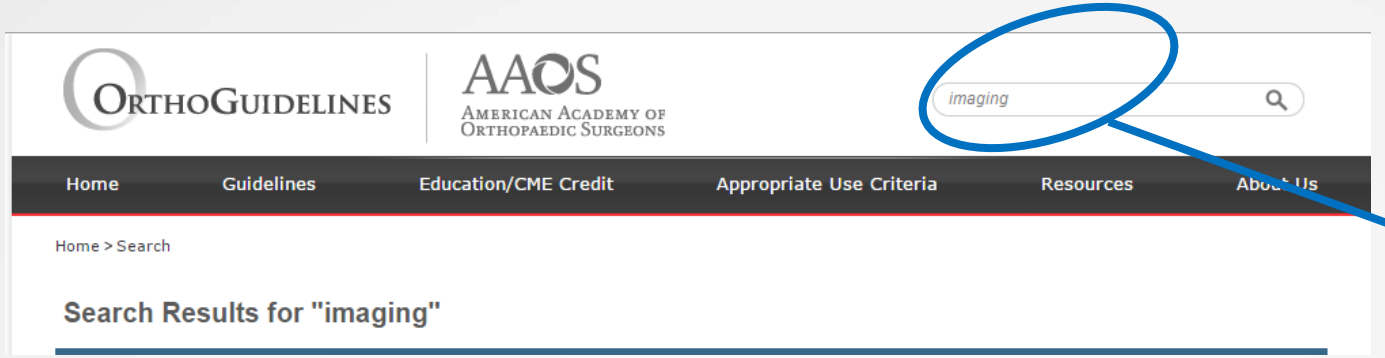
- View recommendations via shortened titles
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Clinical Practice Guidelines Now Available on Your Smartphone

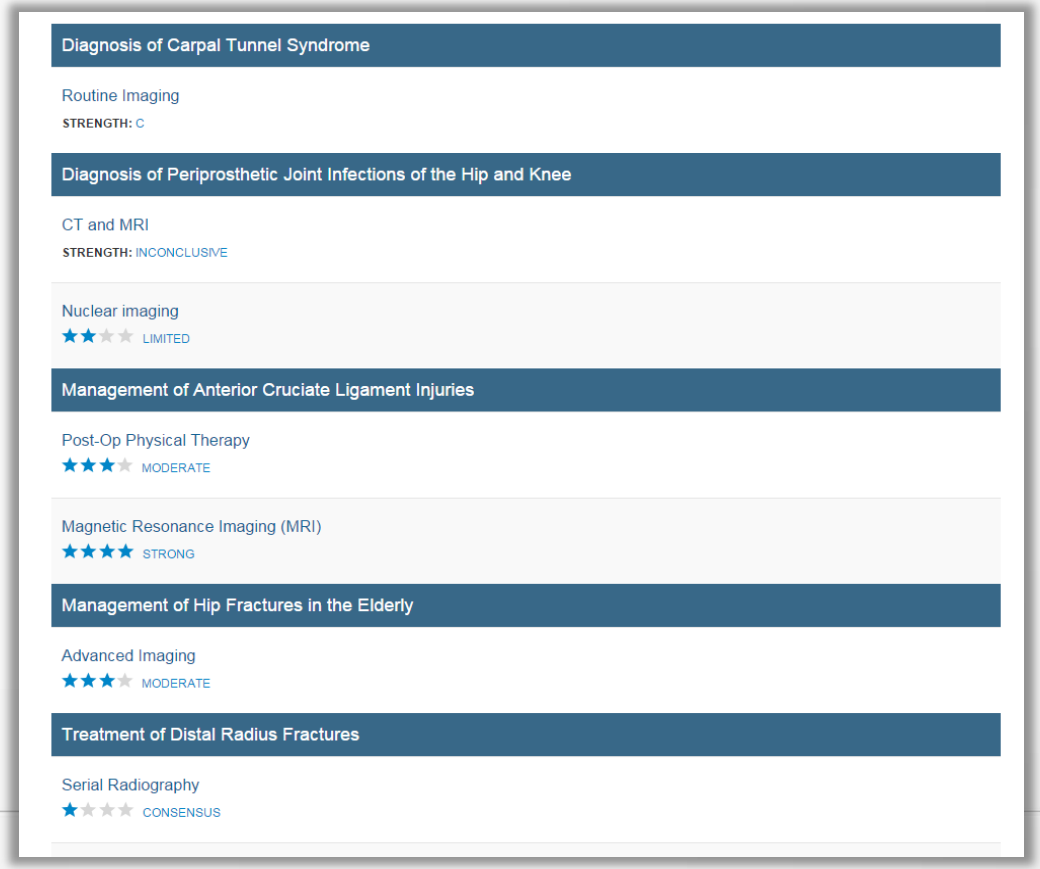
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Imaging

Search across all CPG and AUC Via a Single Keyword Search



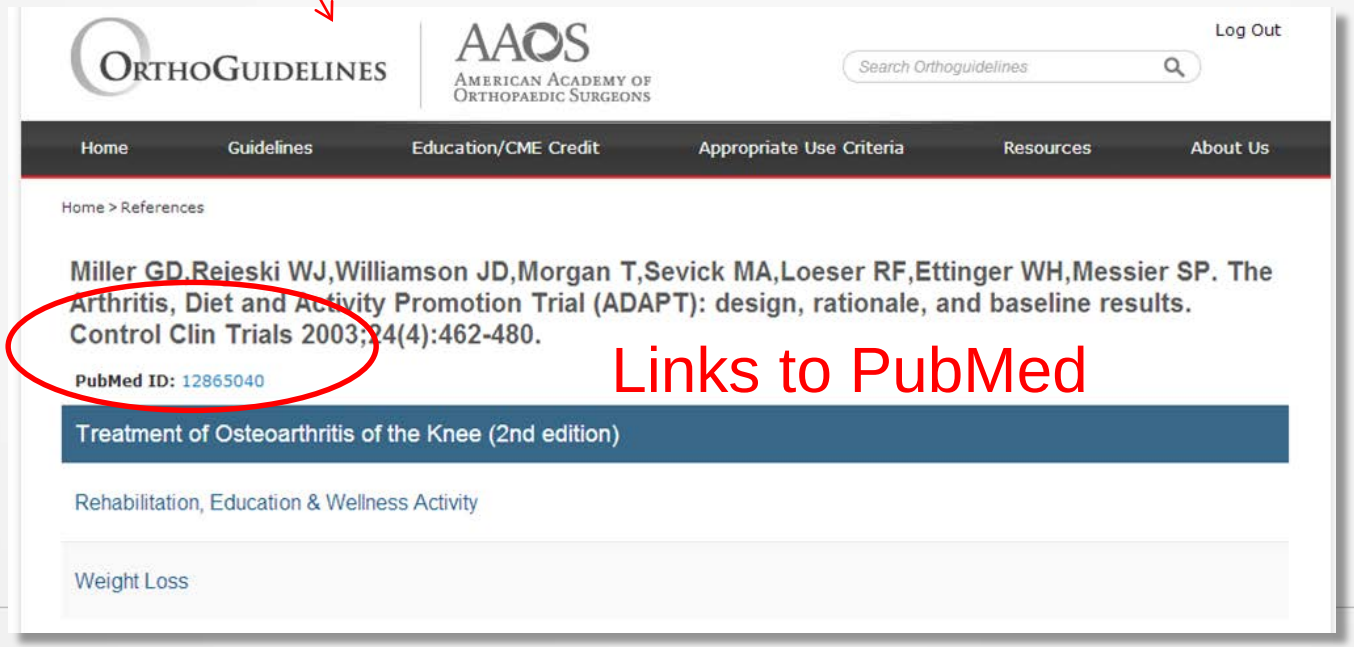
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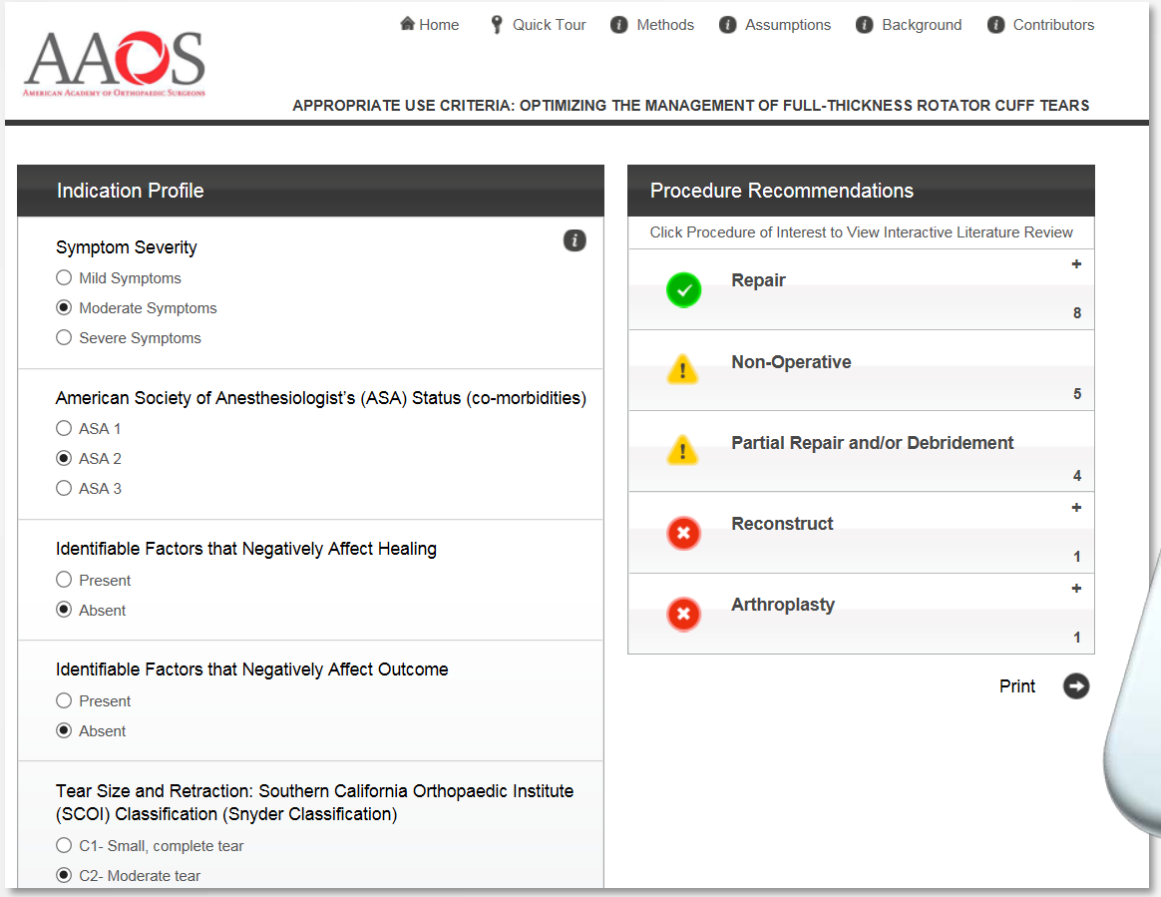
References provided for each recommendation

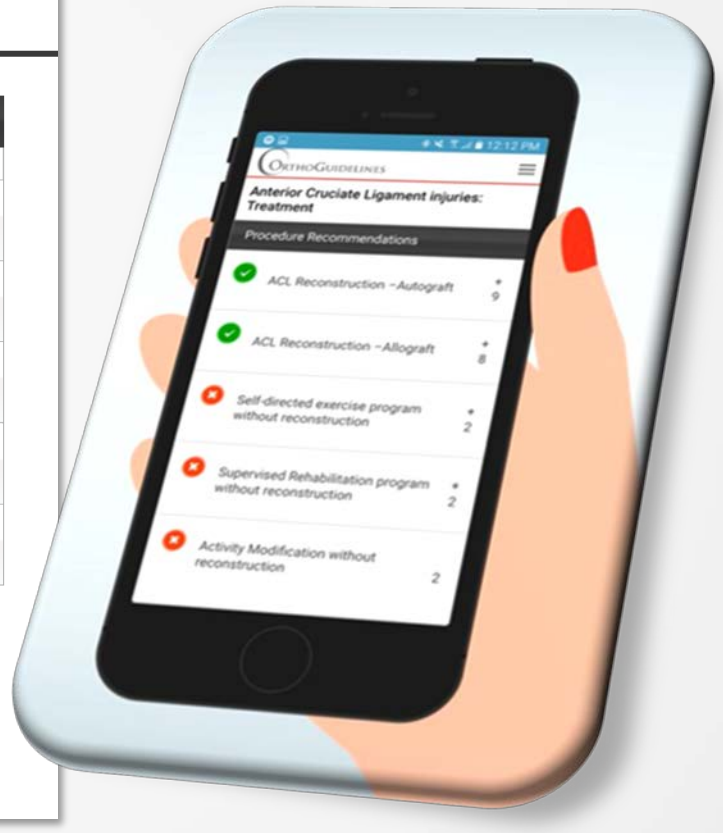
Miller GD,Rejeski WJ,Williamson JD,Morgan T,Sevick MA,Loeser RF,Ettinger WH,Messier SP. The Arthritis, Diet and Activity Promotion Trial (ADAPT): design, rationale, and baseline results. Control Clin Trials 2003;24(4):462-480.

(20) Lorig K, Lubeck D, Kraines RG, Seleznick M, Holan HR. Outcomes of self-help education for patients with arthritis. Arthritis Rheum 1985;28:680-685



Appropriate Use Criteria Tool

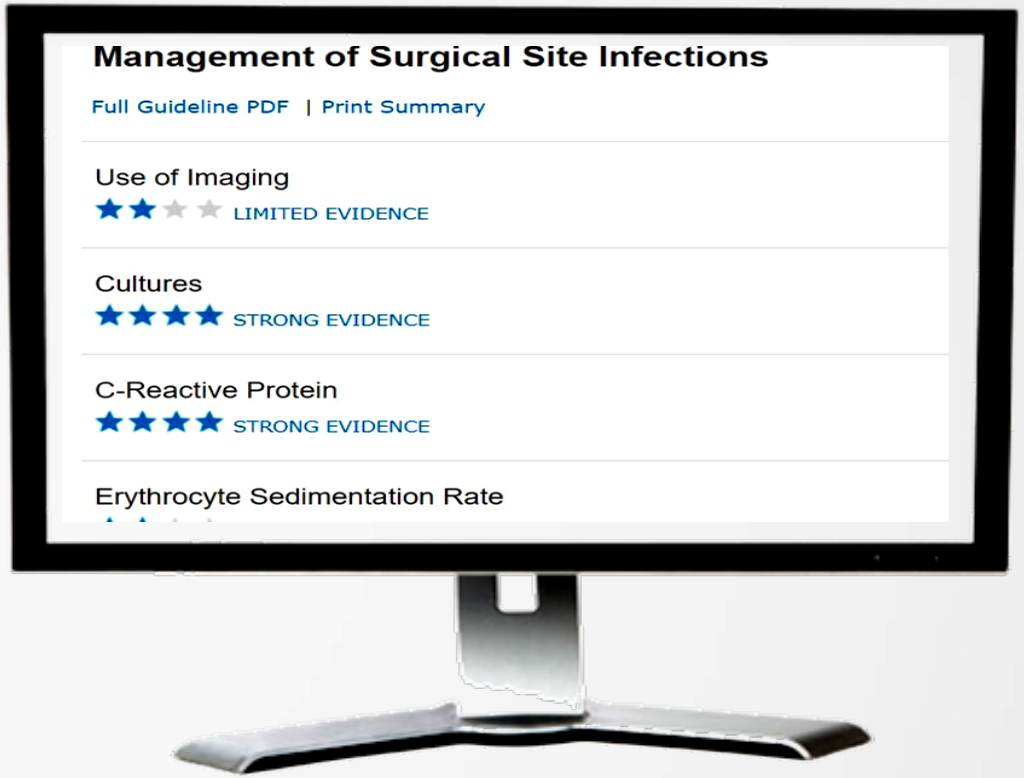




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PUBLISHED CLINICAL PRACTICE GUIDELINES

- Acute Achilles Tendon Rupture
- Acute Compartment Syndrome
- Anterior Cruciate Ligament Injuries
- Carpal Tunnel Syndrome
- Diagnosis and Prevention of Periprosthetic Joint Infections
- Distal Radius Fractures
- Glenohumeral Joint Osteoarthritis
- Hip Fractures in the Elderly
- Limb Salvage or Early Amputation
- Osteoarthritis of the Hip
- Osteoarthritis of the Knee (Arthroplasty)
- Osteoarthritis of the Knee (Non-Arthroplasty)
- Osteochondritis Dissecans
- Pediatric Developmental Dysplasia of the Hip in infants up to Six Months
- Pediatric Diaphyseal Femur Fractures
- Pediatric Supracondylar Humerus Fractures
- Psychosocial Factors Influencing Trauma Recovery
- Prevention of Orthopaedic Implant Infections in Patients Undergoing Dental Procedures
- Rotator Cuff Injuries
- Surgical Site Infections
- VTE Disease in Patients Undergoing Elective Hip & Knee Arthroplasty
- Tranexamic Acid in Total Joint Arthroplasty (Endorsement)
- Use of Imaging Prior to Referral to a Musculoskeletal Oncologist (Endorsement)



For additional information, please visit
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