

Limb Salvage or Early Amputation

Evidence-Based Clinical Practice Guideline

Adapted by:

The American Academy of Orthopaedic Surgeons Board of Directors
December 6, 2019

Endorsed by:



Dynamic. Decisive. Dedicated.



ORTHOPAEDIC
— TRAUMA —
ASSOCIATION

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Disclaimer

This clinical practice guideline 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 this clinical practice guideline filed a disclosure statement as part of the submission process. All panel members provided full disclosure of potential conflicts of interest prior to voting on the recommendations contained within this clinical practice guideline.

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First Edition

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SUMMARY OF RECOMMENDATIONS

BURDEN OF INJURY

Other Injury Burden


Time₀ and Time₁

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

Strength of Recommendation: Moderate 

Description: Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD framework.

B. 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  (upgraded)

Description: Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD framework.

Severe HELET Injury

Time₁ and Beyond

C. 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 

Description: Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD framework.

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  (upgraded)

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.

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 

Description: Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD framework.

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 

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.

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 ★★☆☆

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.

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 ★★☆☆

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.

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 ★★★☆

Description: Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD framework.

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  (upgraded)

Description: Evidence from two or more “Moderate” quality studies with consistent findings, or evidence from a single “High” quality study for recommending for or against the intervention. Also requires no or only minor concerns addressed in the EtD framework.

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 

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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INTRODUCTION

OVERVIEW

This clinical practice guideline is based on a formal systematic review of published studies addressing treatment of severe lower limb trauma below the distal femur by either amputation or attempted limb salvage. In addition to providing clinical practice recommendations, this guideline also highlights limitations of the current literature and areas that require future research. This clinical practice guideline is focused on the care of adult trauma patients.

Advances in the treatment of severe high-energy trauma lower extremity trauma (HELET) have significantly improved the surgeon's ability to enter and progress patients through a successful limb salvage treatment pathway. The selection of the appropriate patient and/or injury burden for limb salvage efforts, however, remains controversial. The LEAP Study found that, on average, patients with severe high-energy lower extremity trauma below the distal femur had similar functional outcomes at 2 and 7 years, regardless of whether they were treated with amputation or limb salvage. (Bosse et al, 2002) The study recommended that, when possible, limb salvage should be considered, given the similar outcomes and a healthcare cost advantages to limb salvage. (MacKenzie et al, 2004).

However, recent research from military combat casualties have further challenged our concept of best patient selection for limb salvage. The METALS study, published in 2013, retrospectively reviewed 324 patients with complex lower extremity combat injuries. After adjusting for covariates, the amputation patients had better functional outcomes scores compared to the reconstruction patients. (Doukas, JBJS 2013) Severe injuries to the foot and ankle might present the surgeon and patient with a greater challenge than a complex diaphyseal tibia fracture. For example, a sub-study from the LEAP cohort found that patients with injuries that foot and ankle injuries required treatment with ankle arthrodesis and/or flaps had an outcome worse than a transtibial amputation. (Ellington et al, 2013) Likewise, Dickens et al reported on 89 combat injured patients with 102 open calcaneus fractures. Forty-three limbs were amputated, and these patients reported improved pain and activity levels than those in the salvage cohort.

Limb salvage scoring strategies have been developed to assist the surgical team with the selection of limb reconstruction or amputation treatment. (ref – Limb salvage scores) Studies in both civilian and military lower extremity trauma patients, however, have failed to support clinical validity for the scores. (Bosse et al, 2005; Hsu et al, 2017) Surgeons making treatment decisions and recommendations need to consider the physiologic status of the patient as well as the feasibility of limb salvage - with an outcome expected to be at least as good as a transtibial amputation. Ischemia time, contamination, tissue loss, nerve trauma and the regional and systemic injury burden are factors that weigh into the treatment decision. At all times, patient survival needs to be prioritized over a limb salvage effort.

For the purpose of this guideline, the decision-making opportunity is defined in two time points – Time Zero and Time 1+. Time zero is the initial surgical contact, in close proximity to the time

of injury. Time 1+ represents all future evaluations that provide information that further supports or alters the initial treatment decision.

Following severe lower extremity trauma, patients are challenged with psychosocial distress and access to rehabilitation and prostheses and orthoses. These services are critical, but often difficult to obtain based on a patient's insurance status.

GOALS AND RATIONALE

The purpose of this clinical practice guideline is to help improve treatment selection for patients with severe lower limb trauma based on the current best evidence. The clinical practice guidelines included in this report are based on the results of a formal systematic review of the available literature related to the amputation or limb salvage treatment decision in adult trauma patients that was completed by the AAOS staff using a rigorous, standardized process that was conducted between June 2018 and June 2019. A work group consisting of military and civilian musculoskeletal trauma and limb salvage surgeons, vascular surgeons, general surgery trauma surgeons, plastic surgeons and rehabilitation experts and AAOS staff skilled in constructing clinical practice guidelines subsequently agreed upon the following recommendations after determining the evaluation and treatment options informed by good evidence. The work group also reviewed gaps in evidence-based practice and suggested future research directions to improve the initial and subsequent evaluation and decision-making elements for limb salvage or amputation following severe lower extremity trauma.

Musculoskeletal care is provided in diverse settings by providers of differing backgrounds and experience. This guideline is intended as an educational tool to aid qualified Orthopaedic trauma providers' decision making and improve the quality and efficiency of care. This guideline should not be construed as including all proper methods of care or excluding methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment must be made in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

A particular challenge in constructing this guideline is the fact that the topic does not lend itself to prospective randomized clinical trials. The only absolute indication for an amputation at Time Zero is the inability to restore or maintain limb perfusion. Retrospective and prospective longitudinal studies are inherently impacted by both surgeon and patient treatment decision bias. In the era of shared decision-making, for example, patients with severe injuries that are expected to have dismal outcomes under limb salvage can and do refuse amputation despite appropriate counseling.

INTENDED USERS

This guideline is intended for orthopaedic surgeons and other surgical providers and rehabilitation specialists who partner in the care of patients with severe lower extremity trauma. In the civilian setting, the majority of patients with high energy lower extremity fractures that demand a limb salvage versus amputation decision are treated at Level 1 trauma centers by

orthopaedic trauma specialists. In a far forward military setting, appropriately skilled orthopaedic and general surgeons will provide the Time Zero assessment and initial care.

PATIENT POPULATION

This document 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.

BURDEN OF DISEASE

Due to the limitations of existing databases, as well as controversies regarding the definition of overt limb salvage versus “routine” lower extremity trauma, there are no good data to accurately capture the prevalence or incidence of limb threatening lower extremity trauma. We do know that approximately 2 million individuals in the United States are living with limb loss, with nearly ½ of those being due to trauma and a substantial majority of trauma-related amputations involving the lower extremity. (Ziegler-Graham et al Arch Phys Med Rehabil 2008)

RISK FACTORS

Risk factors associated with severe high energy lower limb trauma include transition to amputation for patients initially placed into the limb salvage pathway and conditions common to both treatments, to include infection, additional tissue loss, venous thromboembolism, post-traumatic stress disorder, chronic pain syndrome and heterotopic ossification. Fracture non-union, soft tissue reconstruction failure, post-traumatic arthritis and chronic limb edema/swelling are specific to the limb salvage cohort.

EMOTIONAL AND PHYSICAL IMPACT

The emotional impact of trauma-related limb threatening injuries and amputations cannot be overstated. While amputations have historically been considered to have greater psycho-emotional impact, injuries requiring either treatment strategy can be devastating. Likewise, the implications for physical function, health-related quality of life, and disability or return to work status can be severely and adversely affected by either treatment.

POTENTIAL BENEFITS, HARMS AND CONTRAINDICATIONS

Limb salvage for a patient/injury with a functional performance outcome expected to be worse than that of an amputation, or where the limb salvage attempt adds significant risk to the patient’s life, should be avoided. If possible, access to rehabilitation and prostheses should be determined for civilian patients prior to offering a non-emergent amputation, as a limb reconstruction might be the only avenue to guarantee retention of ambulatory potential in these cases.

Patients placed into or electing to pursue the limb salvage pathway need to understand that this treatment decision is dynamic. If, at Times 1+, major complications develop or additional clinical information becomes available, the continued pursuit of limb salvage versus amputation decision must be re-addressed.

The relatively recent, strong emphasis on shared-decision making might not be indicated for each patient and/or injury pattern. If offered a “chance” for limb salvage, medically naive or emotional patients will often opt for salvage. The treatment team needs to consider the “feasibility versus advisability” of limb salvage in the most severe cases and appropriately assist the patient in the selection of the best long-term treatment option.

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.

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 for management of acute compartment syndrome. To view the full AAOS clinical practice guideline methodology please visit <https://www.aaos.org/additonalresources/>

This clinical practice guideline evaluates the decision factors important for limb salvage or early amputation. 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 Limb Salvage and Amputation Clinical Practice 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 October 3, 2018 to establish the scope of the clinical practice guideline. As the physician experts, the clinical practice guideline development group defined the scope of the clinical practice guideline by creating PICO Questions (i.e. population, intervention, comparison, and outcome) that directed the literature search. The AAOS Medical Librarian created and executed the search (see [Appendix VII](#) for search strategy).

Best Evidence Synthesis

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

Literature Searches

The medical librarian conducted a comprehensive search of MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials based on key terms and concepts from the clinical practice guideline development group’s PICO questions (Appendix IV). Bibliographies of relevant systematic reviews were hand searched for additional references. All databases were last searched on February 6, 2019 with limits for publication dates from 1990 to present and English language. The full search strategies are reported in Appendix VII.

Defining the Strength of the Recommendations

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

Voting on the Recommendations

The recommendations and their strength were voted on by the guideline development group members during the final meeting. If disagreement between the guideline development group occurred, there was further discussion to see whether the disagreement(s) could be resolved. Recommendations can be 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.

Interpreting the Strength of Evidence

Table I. Strength of Recommendation Descriptions





Strength of Recommendation	Overall Strength Of Evidence	Description of Evidence quality	Strength Visual
Strong	Strong	Evidence from two or more “High” quality studies with consistent findings for recommending for or against the intervention. Also requires no reasons to downgrade from the EtD framework	
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. Also requires no or only minor concerns addressed in the EtD framework.	
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. Also, higher strength evidence can be downgraded to limited due to major concerns addressed in the EtD Framework.	
Consensus	No reliable evidence	There is no supporting evidence, or higher quality 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.	

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

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

Review Period

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

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

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

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

Again, the AAOS asks for comments to be assembled into a single response form by the specialty society and for the individual submitting the review to provide disclosure of potentially conflicting interests. The review stage gives external stakeholders an opportunity to provide evidence-based direction for modifications that they believe have

been overlooked. Since the draft is subject to revisions until its approval by the AAOS Board of Directors as the final step in the guideline development process, confidentiality of all working drafts is essential.

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

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

alongside the guideline document throughout the remainder of the approval processes and final publication.

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

The AAOS Clinical Practice Guideline Approval Process

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

Revision Plans

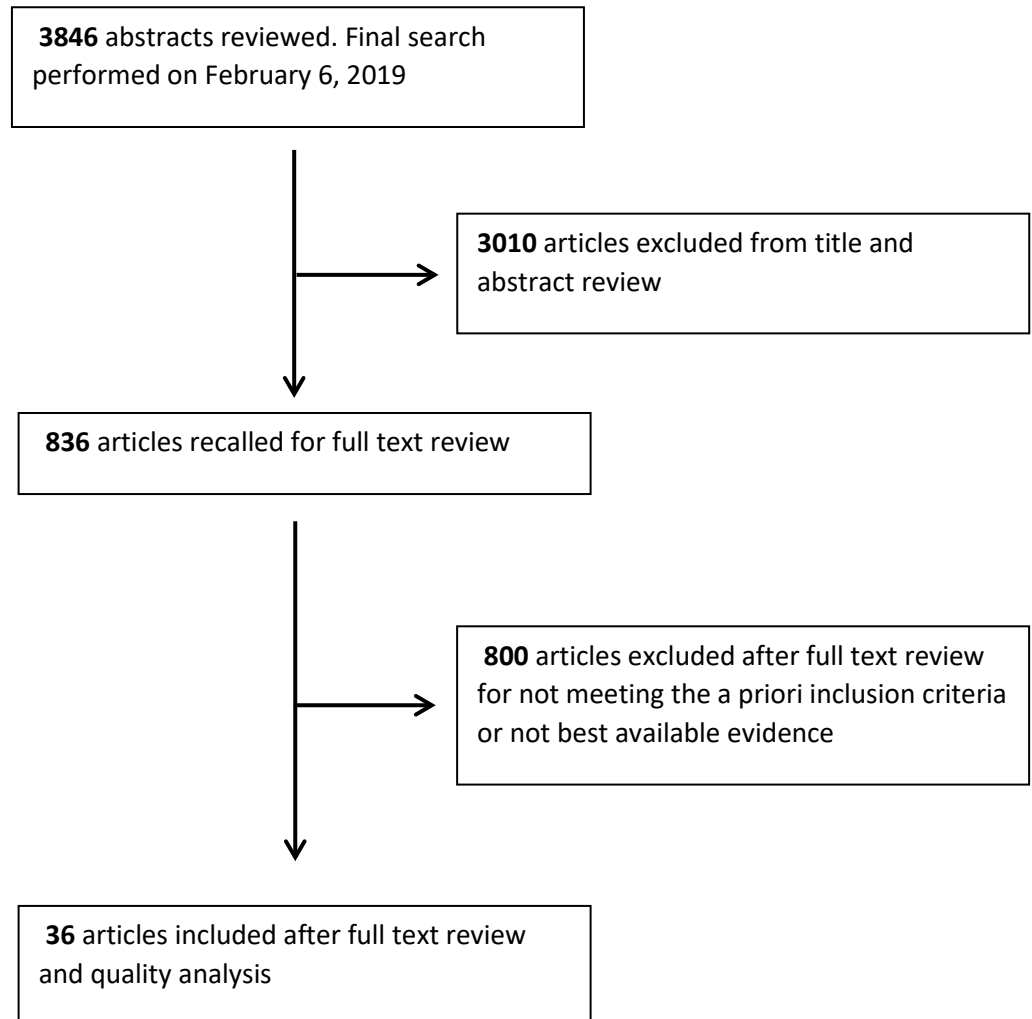
This clinical practice guideline represents a cross-sectional view of current treatment and may become outdated as new evidence becomes available. This clinical practice guideline will be revised in accordance with new evidence, changing practice, rapidly emerging treatment options, and new technology.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

Clinical Practice Guideline 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 various venues such as on Academy Row and at Committee Scientific Exhibits. The final guideline recommendations and their supporting rationales will be hosted on www.OrthoGuidelines.org.

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

Study Attrition Flowchart



RECOMMENDATIONS

BURDEN OF INJURY

Non-Limb Specific Injury Time₀ and Time₁

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

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.

B. 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 ★★★★★ (upgraded)

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.

Limb Specific Injury Time₁ and Beyond

C. 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 ★★★★★

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 that the poly-trauma patient with combined lower extremity injuries require limb salvage attempts. In the study from Webster (2018), in a military population of high ISS greater than 26 and bilateral and

unilateral amputation, patients with pelvic fractures had increased mortality. Additionally, those with bilateral lower extremity amputations had a higher risk of death.

In Allami (2017), in veterans with ankle-foot injuries, having additional injuries was a determinant of poorer mental health and poorer PCS scores. In the study from Laferrier (2010) in a population of military polytrauma patients, an increasing number of combat injuries (including bilateral limb loss, traumatic brain injury) is associated with higher odds of wheelchair use. Laferrier also found that in patients with bilateral lower-limb loss compared to those with unilateral limb loss, there was also a higher odds of wheelchair use. In the study by Hutchison (2014) in subjects with military related amputees, having multiple amputations was associated with an increased odds of PE and VTE. Additionally, in the study by Bennett (2018) in a military population with injuries to the foot and ankle, having coexisting talar and calcaneal fractures was found to be associated with lower AAOS F&A scores but the same was not seen for fractures of the mid-foot.

BENEFITS & HARMS:

In the acute setting, standard ATLS trauma resuscitation, and operative or non-operative management of the trauma patient injuries is paramount. The patient's injuries are triaged based on addressing life-threatening injuries (providing a stable airway, oxygenation) and stopping bleeding. Initial "Damage Control" trauma techniques are deployed (Damage Control Trauma Surgery and Damage Control Resuscitation). Damage control trauma and orthopedic surgery in the setting of a lower extremity injury may require re-establishing blood flow to the extremity, which can be a temporary vascular shunt, and external fixation.

IMPORTANT/PRIORITY OUTCOMES:

The priority at this point is survival of the patient.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

The cost of survival is high. The cost of a survivor with an amputation is higher.

ACCEPTABILITY:

High

FEASIBILITY:

High

FUTURE RESEARCH:

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.

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 ★★★★★ (upgraded)

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:

STRENGTH OF EVIDENCE: Moderate

O’toole (JBJS-AM; 2008) determined that the presence of anxiety or depression at 2 years after injury decreased patient satisfaction. MacKenzie (JBJSn-AM; 2005) found that patients with low self-efficacy had worse Sickness Impact Profile (SIP) scores. Melcer (JOT; 2013) showed that lower extremity trauma amputees had greater odds of mood disorders. Furthermore, PTSD risk was lower in amputees versus non-amputees. Bosse (N Engl J Med; 2002) concluded that amputees and non-amputees had higher SIP scores if they had poor self-efficacy and a poor social support network.

BENEFITS & HARMS:

Screening and treatment of psychosocial risk factors can increase patient satisfaction after amputation or limb salvage. Failure to address these risk factors have been shown to result in poor SIP scores, functional outcome, and patient satisfaction.

OUTCOME IMPORTANCE:

Identification and proper referral for psychosocial risk factors can help improve outcomes in all lower extremity trauma patients regardless of whether they receive amputation or limb salvage.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

Bhatnagar (J Rehabil Res Dev; 2015) demonstrated presence of PTSD resulted in higher prosthetic costs as well as cost associated with psychiatric treatment in amputees.

ACCEPTABILITY:

This recommendation is acceptable to all civilian and military lower extremity trauma patients undergoing amputation or limb salvage

FEASIBILITY:

This recommendation is feasible in trauma centers with proper referral services. The application of these services to provide psychosocial support will not affect surgical decision making and operative treatment.

FUTURE RESEARCH:

View background material via the [LSA CPG eAppendix](#)

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.

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 ★★☆☆

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:

Available evidence demonstrates the importance of psychosocial factors (e.g. anxiety, depression, Self-efficacy) on outcomes (O’Toole 2008, MacKenzie 2005) and indicates improvement through structured behavioral health intervention could improve outcomes. Further, improved psychosocial adjustment is associated with greater physical mobility. (Wen 2018)

Available evidence suggests a beneficial effect of physical therapy after severe high energy lower-extremity trauma. Individuals whose legs were salvaged after limb-threatening trauma to the lower limb, and had an unmet need for physical therapist directed care as determined by a physical therapist, have decreased odds of improvement in multiple domains of care as compared to patients whose needs were met (Castillo 2008).

In military service members, a structured clinical pathway including multi-disciplinary rehabilitative care (e.g. PT, OT, behavioral health) and a custom carbon fiber dynamic orthosis yielded significant improvements in physical mobility, patient reported outcomes and return to work (duty) following limb trauma. (Blair 2014, Potter 2018, Hsu 2017)

BENEFITS & HARMS:

The benefits of participation in a structured rehabilitation program (e.g. PT, OT, behavioral health) following high energy lower extremity traumatic injury are improved psychological and functional outcomes. Physical or psychological risks associated with receiving care from a qualified provider are limited. Participation in a structured rehabilitation program requires both transportation and dedicated time. Risks associated with an inability to access rehabilitative care include decreased functional and psychological outcomes.

IMPORTANT/PRIORITY OUTCOMES:

Priority outcomes include pain, the ability to complete essential activities of daily living, psychosocial state, the ability to return to full employment and the ability to participate in activities in the community.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

The financial cost and resource utilization associated with participation in therapist driven structured rehabilitative programs are outweighed by benefits in improved physical mobility, function, participation and psychosocial state. Logistical concerns and costs for individuals with limited resources are a primary consideration.

View background material via the [LSA CPG eAppendix](#)

ACCEPTABILITY:

High

FEASIBILITY:

Moderate (Dependent on payor status, policy and patient resources)

FUTURE RESEARCH:

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.

Additional Rationale References

1. Hsu, J.R., Owens, J.G., DeSanto, J., et. al. Patient Response to an Integrated Orthotic and Rehabilitation Initiative for Traumatic Injuries: The PRIORITI-MTF Study. *J Orthop Trauma* 2017; 31:S56-S62.
2. Potter, B.K., Sheu, R.G., Stinner, D., et. al. Multisite Evaluation of a Custom Energy-Storing Carbon Fiber Orthosis for Patients with Residual Disability After Lower-Limb Trauma. *J Bone Joint Surg Am.* 2018; 100(20): 1781-1789.

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 ★★☆☆

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.

RATIONALE:

The evidence suggests that plantar sensation or an observed tibial nerve transection is not an absolute, major, or unique factor for early amputation. In 2005, Bosse et al. (as part of the LEAP study) identified 55 patients with an insensate extremity (lack of plantar sensation) after lower extremity trauma. They found the presence of an insensate foot at the time of presentation did not adversely affect limb salvage at both 12- and 24-months post injury. More recently Bennett et al. in 2018, found in a cohort of 77 patients’ neurologic deficit also did not impact functional recovery.

BENEFITS & HARMS:

Given the available procedures for nerve reconstruction and/or innervated free tissue transfer, nerve injury alone should not predicate salvage versus amputation. However, a known nerve injury (e.g. transection, avulsion, crush, segmental injury) identified at presentation will result in a more complicated reconstructive process for the patient with lower limb trauma. The work group recommends future salvage decisions outside of the acute presentation should be shared with the patient incorporating the risks and benefits of salvage versus amputation. Possible negative sequelae of salvage include lack of motion, lack of sensation and debilitating neuropathic pain.

IMPORTANT/PRIORITY OUTCOMES:

Priority outcomes include a sensate, mobile, stable and nonpainful limb.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

As an independent factor, there is no direct impact on cost effectiveness/resource utilization.

ACCEPTABILITY:

High (not sure)

FEASIBILITY:

High (not sure)

FUTURE RESEARCH:

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

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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.

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 ★★☆☆

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.

RATIONALE

Immediate massive skin and soft tissue loss, and necrosis of crushed or ischemic tissue after injury requiring debridement(s), is not an absolute indication to perform early amputation. Loss of dynamic tissues such as muscle and tendon may compromise function, but anatomic redundancy, compensation, allografts, tendon transfers and bracing can maintain or restore function even in the face of major losses. Massive skin defects can also be managed with free tissue transfers, autografts and allografts and an increasing number of bioengineered membranes. Negative-pressure wound therapy provides temporizing capabilities, promotes intrinsic biologic healing processes and may improve surgical repair success.

Crush injury releasing products of necrosis into the circulatory system may cause renal compromise, multi-system organ failure, circulatory collapse, and death. Despite performing timely surgical intervention or amputation when these problems manifest clinically, irreversible organ damage or death may result. The decision to pursue limb salvage instead of immediate amputation at the time of severe crush injury will sometimes result in avoidable organ loss or death, but these negative outcomes cannot be predicted in an individual patient at the time of injury.

In 2005, MacKenzie et al (as a part of the LEAP study), analyzed 397 patients and showed volumetric muscle loss was associated with a worse Sickness Injury Profile (SIP) score at 84 months after injury, but did not adversely affect limb salvage.

Crush and/or blunt injury was investigated by SM Melton in 1997, TN Hutchison in 2014, and EE Low in 2017, and showed no impact on limb salvage versus amputation. There was a significantly increased risk of pulmonary embolism (PE) (Hutchison) and need for amputation revision (Low) in the 2014 and 2017 studies, which had 1003 and 2314 patients, respectively.

T. Melcer et al (2017) studied 625 patients with lower limb blast injury and showed no impact on limb salvage. Pain and subsequent osteoarthritis were more common in this type of injury, but they found no increases in PE, infection, or osteomyelitis. Penetrating injury did raise the risk of VTE (Hutchison, 2014)

A. Jain in 2013 looked at lower extremity de-gloving injuries in 40 patients who underwent amputation. This injury type had no significant impact on amputation infection rates.

BENEFITS & HARMS:

Massive muscle and soft tissue loss may complicate or prolong the limb salvage pathway. Ultimate functional outcome may be compromised by the loss of muscle/tendon units and other mechanically important structures.

Cost data clearly show a successful limb salvage patient incurs significantly lower lifetime medical costs compared to amputation.

Some patients with massive soft tissue injury who do not undergo immediate amputation will ultimately have permanent organ failure, septic shock, and/or death. At time zero, there are no factors which can prospectively identify these patients.

OUTCOME IMPORTANCE:

Patients who undergo successful limb salvage will retain a useful extremity, with significantly less lifetime medical expense.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

Successful limb salvage in the setting of severe soft tissue injury may result in higher short-term costs related to multiple surgical procedures, wound management, and prolonged hospitalization. Lifetime medical expenses will be lower compared to amputation.

ACCEPTABILITY:

Pursuing limb salvage in cases of massive soft tissue loss/injury may strain resources at initial point of care, especially in mass-casualty scenarios. Temporizing measures for massive soft tissue injury may be unavailable. Time zero medical personnel may fear being judged retrospectively in cases of ultimate fatality or permanent organ damage in massive crush injuries.

FEASIBILITY:

Adequate resources for massive soft tissue injuries need to be available at initial point of care. These include temporizing coverage options (negative pressure dressings, allograft or engineered tissue coverings) and personnel skilled in wound management using these techniques.

FUTURE RESEARCH:

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.

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 ★★☆☆

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.

RATIONALE

Six low quality studies examined the effect of various vascular injury on patient outcomes. One study (Asensio, 2006) found that both coagulopathy in the operating room and having two or more hard vascular signs were significantly associated with higher odds of mortality. Hard signs of vascular injury can include the absence of distal pulses, expanding hematoma, palpable thrill, audible bruit and pulsatile bleeding. Additionally, a decrease in the number of patent arteries in the lower leg, was found to be associated with a higher risk of complications in patients as well as a higher risk of take-backs and a higher risk of an increase in total flap failures (Stranix, 2017). Another study (Doucet, 2011) looking at limb ischemia also found it to be predictive of failure of limb salvage. Three additional studies (Jain, 2013, Bennett, 2018, and Melton, 1997) examining ischaemic vascular injury, vascular injury and vein injury, failed to find significance between these factors and infection in the residual limb, AAOS F&A score, and secondary amputation respectively.

The evidence suggests that neither hard signs of vascular injury, nor duration of limb ischemia are absolute factors in the decision as to whether to pursue limb salvage or amputate the injured extremity. However, there is a consensus among the panel that a direct relationship exists between the duration of ischemia and adverse extremity outcomes, including amputation. Therefore, the panel recommends that steps be taken to promptly identify arterial injury and limb malperfusion and to limit the duration of extremity ischemia to a practical minimum. The panel also recommends performance of measures such as extremity fasciotomy and debridement of non-viable tissue to reduce the negative impact of ischemia and reperfusion injury.¹ Additionally, attempts at limb salvage should not be continued in extremities that are unable to have perfusion maintained or restored. Both the available evidence and common sense are clear that when unable to restore or preserve limb perfusion, continued limb salvage efforts are inappropriate and ill-advised

Arterial injury and extremity ischemia leads to adverse effects including injury to and death of skeletal muscle, peripheral nerves and other soft tissue components. Preclinical research demonstrates that hemorrhagic shock worsens the effect of extremity ischemia and reduces the neuro-muscular ischemic threshold to less than 3 hours.² Recent clinical study from U.S. civilian trauma centers also demonstrates that minimizing the duration of extremity ischemia (to less than 3 hours) is associated with higher rates of limb salvage.³

Pre-clinical and retrospective human study of military and civilian patients confirms the utility of temporary vascular shunts as a damage control adjunct in restoring extremity perfusion.^{4,5} In this setting temporary vascular shunts perform best (i.e. stay patent) within a 4-6 hour time window and then are removed at the time of definitive vascular repair. Evidence suggests that vascular shunts are more effective in larger, more proximal

extremity vessels, but that they cause no harm when placed as a damage control maneuver in smaller, more distal vessels.⁴ Clinical consensus is that the use of temporary vascular shunts can be used in certain extremity injury scenarios to limit ischemia and extend the window of successful limb salvage.⁶

Clinical outcomes studies demonstrate that approximately 30-40% of patients who have successful extremity salvage experience poor limb function and diminished quality of life (e.g. chronic pain, limited mobility and need for additional operations).⁷⁻⁹ Approximately 10-15% of patients who have successful limb salvage during the early phases of care elect to have a secondary amputation of the affected limb in the months and years following injury – most commonly due to chronic pain, recurrent infection or limited function/mobility.⁷⁻⁹

Additional Rationale References:

1. Percival TJ, Rasmussen TE. Reperfusion strategies in the setting of extremity vascular injury with ischemia. *Brit J Surg* 2012;99(Suppl 1):66-74.
2. Hancock HM, Stannard A, Burkhardt GE, Williams K, Dixon P, Cowart J, Spencer JR, Rasmussen TE. Hemorrhagic shock worsens neuromuscular recovery in a porcine model of hind limb vascular injury and ischemia/ reperfusion. *J Vasc Surg* 2011;53(4):1052-62.
3. Alarhayem AQ, Cohn SM, Cantu-Nunez O, Eastridge BJ, Rasmussen TE. Impact of time to repair on outcomes in patients with lower extremity arterial injuries. *J Vasc Surg*. 2019 May;69(5):1519-1523. doi: 10.1016/j.jvs.2018.07.075.
4. Rasmussen TE, Clouse WD, Jenkins DH, Peck MA, Eliason JL, Smith DL. The use of temporary vascular shunts as a damage control adjunct in the management of wartime vascular injury. *J Trauma* 2006;61(1):15-21.
5. Subramanian A, Verduyck G, Dente C, Wyrzykowski A, King E, Feliciano DV. A decade's experience with temporary intravascular shunts at a civilian level I trauma center. *J Trauma*. 2008 Aug;65(2):316-24; discussion 324-6.
6. Gifford SM, Aidinian G, Clouse WD, Fox CJ, Jones WT, Zarzabal L, Michalek JE, Propper BW, Burkhardt GE, Rasmussen TE. Effect of temporary vascular shunting on extremity vascular injury: an outcome analysis from the GWOT vascular initiative. *J Vasc Surg* 2009;50(3):549-55.
7. Scott DJ, Arthurs ZM, Stannard A, Monroe HM, Clouse WD, Rasmussen TE. Patient-based outcomes and quality of life after salvageable wartime extremity vascular injury. *J Vasc Surg* 2014;59(1): 173-179.
8. Perkins ZB, Yet B, Glasgow S, Marsh W, Tai NRM, Rasmussen TE. Long-term, patient-centered outcomes of Lower Extremity Vascular Trauma. *J Trauma Acute Care Surg*. 2018 Jul;85(1S Suppl 2):S104-S111.
9. Sharrock AE, Tai N, Perkins Z, White JM, Remick KN, Rickard RF, Rasmussen TE. Management and outcome of 597 wartime penetrating lower extremity arterial injuries from an international military cohort. *J Vasc Surg*. 2019 July 70(1):224-232.

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 ★★★★★

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 high quality (MacKenzie, 2006) and three moderate quality (Bosse, 2002; MacKenzie, 2004, 2005) studies revealed significantly worse physical, psychosocial, and overall function measures on the Sickness Index Profile (SIP) among recent and current smokers versus never smokers. Despite the focus of this literature on smoking specifically, the work group recommends cessation of all forms of nicotine given that it is the active ingredient that contributes most to the majority of negative physiological side effects. Physicians should recommend nicotine education/cessation (abstinence of nicotine) for all patients with high energy lower limb trauma and engage in shared decision-making with patients as there is moderate evidence to suggest that smoking/nicotine has a detrimental effect.

BENEFITS/HARMS:

It is well known that smoking has been linked to a multitude of other health risks including, but not limited to multiple cancers, cardiac and pulmonary diseases, PVD, wound complications (including infection), slower bone healing and nonunion, etc. Hence, smoking/nicotine cessation may have multitude of positive effects on outcomes without having any known risks among patients with severe lower extremity trauma regardless of treatment strategy.

IMPORTANT/PRIORITY OUTCOMES:

Successful limb salvage and achieving optimal overall outcomes while minimizing costs/complications are ideal for both patients and health care systems. These ideals will more likely be realized when patients are able to successfully quit smoking/nicotine use.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

Smoking/nicotine cessation has the potential to significantly decrease the costs associated with complications and improve quality of life outcomes in patients with severe lower extremity trauma regardless of treatment strategy. Smoking/nicotine cessation programs are often covered comprehensively by insurers, and thus, little out-of-pocket expense to patients. Therefore, it is likely that smoking/nicotine cessation would prove cost-effective over a life-time to both patients and health care systems.

ACCEPTABILITY:

Most patients, even smokers and users of other nicotine products, will acknowledge that smoking/nicotine may lead to poor general health, and thus, would accept the notion that continued smoking/nicotine use may lead to worse outcomes after severe lower extremity injury.

FEASIBILITY:

There is no evidence to suggest recommending one technique over another for achieving successful smoking/nicotine cessation. Discussion of various techniques is beyond the scope of this paper.

FUTURE RESEARCH:

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.

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 ★★☆☆ (upgraded)

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:

A prospective study from the LEAP group (Bosse 2001) used five injury severity scoring systems (MESS, LSI, PSI>>) to prospectively evaluate 556 patients with lower extremity injuries. At six months from the time of injury 407 patients remained in the limb salvage group. They found that each scoring system was highly specific for amputation, but not sensitive. They concluded that a low score could be used to predict a limb salvage patient, but that a high score could not be used to predict the need for an amputation. This study was not included in the references for the CPG as it did not assess difference in outcomes, however, is relevant to the use of lower extremity injury severity scores at time of injury. While the panel agrees these scores should not be used to guide treatment, they can be useful when used in a descriptive manner and to provide a framework when discussing treatment options with the patient and family.

The same group (Ly, 2008) prospectively evaluated the same five scoring systems to predict outcome following limb salvage using the Sickness Impact Profile (SIP) at 6 months and 2 years after injury. They found that none of the scores were predictive of either the SIP at 6 and 24 months or of the change in SIP between 6 and 24 months. They concluded that these scoring systems should not be used to predict functional outcome following successful limb salvage in patients who sustain a high energy lower-extremity trauma.

A study of 155 military patients with type III open tibia fractures reported that 110 patients underwent successful limb salvage and 45 eventually required amputation. The average MESS scores for these two cohorts were 5.3 and 5.8, respectively; more importantly, MESS scores demonstrated specificity of 87.8% for predicating amputation, but a sensitivity of only 35% and positive predictive value of only 50% for scores ≥ 7 . The authors concluded that MESS scores were neither adequately “sensitive nor accurate for predicting amputation” (Sheean 2014).

BENEFITS & HARMS:

Given that lower extremity scores have not been shown to predict outcomes or the need for amputation or limb salvage, the benefit of implementing this recommendation will be that fewer patients will receive an upfront

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amputation based on a high extremity specific score such as the MESS or LSI. This should reduce the number of unnecessary amputations. It is possible that a patient with a high MESS, LSI or PSI score may ultimately require an amputation due to other factors and each patient should be evaluated on a case by case basis.

IMPORTANT/PRIORITY OUTCOMES:

Priority outcomes include preventing unnecessary amputations based on tools that have been shown to have a low sensitivity to predict need for amputation.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

As an independent factor, there is no direct impact on cost effectiveness/resource utilization.

ACCEPTABILITY:

High

FEASIBILITY:

High

FUTURE RESEARCH:

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.

Additional Rationale References:

1. Bosse, M.J., MacKenzie, E.J., Kellam, J.F., et. al. A Prospective Evaluation of the Clinical Utility of the Lower-Extremity Injury-Severity Scores. *J Bone Joint Surg Am.* 2001; 83(1):3-14.
2. Sheean, A.J., Krueger, C.A., Napierala, M.A., Stinner, D.J., Hsu, J.R. Evaluation of the Mangled Extremity Severity Score in Combat-Related Type III Open Tibia Fracture. *J Orthop Trauma.* 2014; 28(9):523-6.

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 ★★☆☆

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.

RATIONALE:

Bennett, PM et. al. (2018) performed a study of 114 combat-wounded patients followed for a median of 5 years who sustained 90 fractures. The authors report that, “The median Short-Form 12 physical component score (PCS) of 62 individuals retaining their limb was 45 (IQR 36 to 53), significantly lower than the median of 51 (IQR 46 to 54) in patients who underwent delayed amputation after attempted reconstruction. [...] Regression analysis identified three variables associated with a poor F&A score: negative Bohler’s angle on initial radiograph; coexisting talus and calcaneus fracture; and tibial plafond fracture in addition to a hindfoot fracture. The presence of two out of three variables was associated with a significantly lower PCS compared with amputees.”

Bevevino, AJ, et. al performed a study of 155 open calcaneus fractures treated with a “median follow-up 3.5 years and an amputation rate 44%.” Authors employed an “artificial neural network designed to estimate likelihood of amputation, using information available on presentation. For comparison, a conventional logistic regression model was developed with variables identified on univariate analysis. [...] Decision curve analysis indicated the artificial neural network resulted in higher benefit across the broadest range of threshold probabilities compared to the logistic regression model.”

Ellington and his colleagues in the LEAP Study Group evaluated the 2-year results of patients with mangled foot and ankle injuries that were treated with “limb salvage surgery that required free tissue flaps for wound closure compared with a similar [group of patients with foot and ankle injury who] underwent early below-knee amputation (BKA).” They evaluated the SIP score (the higher the score, the greater is the disability) and other functional outcome measures such as walking speed, number of rehospitalizations for injury-related complications, time to full weight bearing, the visual analog pain scale, and return to work at 2 years. Their conclusion was that patients with severe foot and ankle injuries who require free tissue transfer or ankle fusion have SIP outcomes that are significantly worse than BKA with the typical skin flap design closure

Dickens, JF et. al. performed a “retrospective review of 102 combat-related open calcaneal fractures.” Multivariate Cox proportional-hazards regression identified that “blast” being the mechanism of injury and the location and larger size of the open wound, “were predictive of eventual amputation.”

BENEFITS & HARMS:

Desirable anticipated effects are large: the lifetime costs and quality of life for accurate and predictable decision-making are substantial. The undesirable effects consist of amputation OR limb salvage decisions that increase costs, reduce quality, but are largely mitigated with shared decision-making and are lower relative to the desirable effects. Precision in decision making somewhat clearly outweighs the risks.

OUTCOME IMPORTANCE:

Shared decision making has very little downside, and this question is foundational to the entire Practice Guideline; Evidence is sufficient for this relatively discrete set of injury variables to improve arrival at data-based decision making

COST EFFECTIVENESS/RESOURCE UTILIZATION:

Consideration of prolonged treatment processes includes implant and surgical costs; hospitalizations; recovery duration as well as lifetime disability; emotional and behavioral care costs as well as prostheses/ orthoses.

ACCEPTABILITY:

There will continue to be stakeholders who will refute the available literature for risk to benefit ratio, the costs, and the importance of outcomes.

Potential moral objections to intervention are low in that autonomy and shared decision-making mitigates other ethical principles such as no maleficence, beneficence, or justice.

FEASIBILITY:

Development of a decision tool is feasible to implement and highly important to surgeons and facilities where these injuries are only occasional. This is a sustainable intervention and permits autonomy for providers as well as patients. Barriers include dissemination across various specialties and disciplines

FUTURE RESEARCH:

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.

Additional Rationale References:

Bevevino, A.J., Dickens, J.F., Potter, B.K., Dworak, T., Gordon, W., Forsberg, J.A. A model to predict limb salvage in severe combat-related open calcaneus fractures. *Clin Orthop Relat Res.* 2014; 472(10): 3002-9.

CONSENSUS STATEMENTS

Disclaimer

This companion consensus statement document was developed by a multidisciplinary physician volunteer guideline development group based expert opinion. This companion consensus statement document is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

Insurance payers, governmental bodies, and health-policy decision-makers may also find this guideline useful as a summary of the current research regarding management of osteoarthritis of the hip. This document is not intended for use as a stand-alone benefits determination document. Making these determinations involves many factors not considered in the present document, including available resources, business and ethical considerations, cost/benefit analysis, risk/harms analysis, and need.

Methodology

Per current AAOS methodology, guideline development groups have the option to create companion consensus statements for any clinical practice guideline (CPG) PICO questions which return no evidence after the systematic literature review is conducted.

Companion consensus statements are created using the following steps:

- 1) Prior to the final meeting and after the final/updated literature search for a guideline/systematic review topic, AAOS staff provides a list of any PICO questions which did not return relevant literature to the guideline development group (GDG).
- 2) An electronic form is sent to the GDG member(s) assigned to the PICO question of interest. The form contains the original PICO question and an open response box for them to input a consensus recommendation that reflects their clinical experience and expertise. If more than one GDG member is assigned to the PICO question of interest, they each submit a preliminary consensus statement independently. The submitted preliminary consensus statement must remain within the conceptual parameters of the original question.
- 3) The oversight chair and chairs of the guideline/systematic review retain the right to edit, or request edits to, the preliminary statement if they feel the statement commented on items outside the scope of the original PICO question.
- 4) The submitted preliminary consensus statements are reviewed/approved by the GDG at the final meeting and the chairs of the guideline/systematic review will lead a discussion regarding the preliminary recommendation and any work group suggested edits. The GDG is allowed to edit the preliminary consensus statements during the discussion if necessary. Final edits must be motioned and approved by a majority of work group members (60% of group must approve edits).

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.

RATIONALE

The complexity of psychosocial and medical variables relevant to lower limb amputation and lower limb salvage patients inhibit the ability to provide the direct impact of orthotics/prosthetics. However, appropriately crafted and fitted Orthotics/prosthetics are intertwined with the patient's quality of life, return to work, physical functioning, residual limb skin health, and pain. The holistic approach to treating, managing, and supporting the patient's desired level of function after a lower limb amputation or salvage procedure requires regular adjusting or replacing of orthotics/prosthetics for the patient to maintain optimal physical function and health.

BENEFITS & HARMS:

Patients' with comfortably fitting orthotics/prosthesis trend towards longer periods of orthotic/prosthesis use and higher rates of return to work. Residual limb skin health is an omnipresent challenge; appropriately fitted and maintained prosthesis are essential to preserving the residual limb skin health and potentially preserving future limb length.

COST EFFECTIVENESS:

Evidence indicates increased lifelong cost with lower limb amputation primarily as a result of prosthesis maintenance and replacements. There is no indication that poorly fitting or maintained prosthesis/orthotics are cost effective, improve compliance, reduce residual limb skin health complications, or improve the patient's function and quality of life; appropriately fitted, maintained, and regular orthotic/prosthesis replacement is more likely to support the holistic treatment and improve the physical function of lower limb amputee and lower limb salvage patients.

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.

RATIONALE

Immediate massive skin and soft tissue loss, and necrosis of crushed or ischemic tissue after injury requiring debridement(s), is not an absolute indication to perform immediate amputation. Loss of dynamic tissues such as muscle and tendon may compromise function, but anatomic redundancy, compensation, allografts, tendon transfers and bracing can maintain or restore function even in the face of major losses. Massive skin defects can also be managed with autografts and allografts and an increasing number of bioengineered membranes. Negative-pressure wound therapy provides temporizing capabilities, promotes intrinsic biologic healing processes and may improve surgical repair success.

Crush injury releasing products of necrosis into the circulatory system may cause renal compromise, multi-system organ failure, circulatory collapse, and death. Despite performing timely surgical intervention or amputation when these problems manifest clinically, irreversible organ damage or death may result. The decision to pursue limb salvage instead of immediate amputation at the time of severe crush injury will sometimes result in avoidable organ loss or death, but these negative outcomes cannot be predicted in an individual patient at the time of injury.

In 2005, MacKenzie et al (as a part of the LEAP study), analyzed 397 patients and showed volumetric muscle loss was associated with a worse Sickness Injury Profile (SIP) score at 84 months after injury, but did not adversely affect limb salvage.

Crush and/or blunt injury was investigated by SM Melton in 1997, TN Hutchison in 2014, and EE Low in 2017, and showed no impact on limb salvage versus amputation. There was a significantly increased risk of pulmonary embolism (PE) (Hutchison) and need for amputation revision (Low) in the 2014 and 2017 studies, which had 1003 and 2314 patients, respectively.

T. Melcer et al (2017) studied 625 patients with lower limb blast injury and showed no impact on limb salvage. Pain and subsequent osteoarthritis were more common in this type of injury, but they found no increases in PE, infection, or osteomyelitis. Penetrating injury did raise the risk of VTE (Hutchison, 2014)

A Jain in 2013 looked at lower extremity de-gloving injuries in 40 patients who underwent amputation. This injury type had no significant impact on amputation infection rates.

BENEFITS & HARMS:

Massive muscle and soft tissue loss may complicate or prolong the limb salvage pathway. Ultimate functional outcome may be compromised by the loss of muscle/tendon units and other mechanically important structures.

Cost data clearly show a successful limb salvage patient incurs significantly lower lifetime medical costs compared to amputation.

Some patients with massive soft tissue injury who do not undergo immediate amputation will ultimately have permanent organ failure, septic shock, and/or death. At time zero, there are no factors which can prospectively identify these patients.

OUTCOME IMPORTANCE:

Patients who undergo successful limb salvage will retain a useful extremity, with significantly less lifetime medical expense.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

Successful limb salvage in the setting of severe soft tissue injury may result in higher short-term costs related to multiple surgical procedures, wound management, and prolonged hospitalization. Lifetime medical expenses will be lower compared to amputation.

ACCEPTABILITY:

Pursuing limb salvage in cases of massive soft tissue loss/injury may strain resources at initial point of care, especially in mass-casualty scenarios. Temporizing measures for massive soft tissue injury may be unavailable. Time zero medical personnel may fear being judged retrospectively in cases of ultimate fatality or permanent organ damage in massive crush injuries.

FEASIBILITY:

Adequate resources for massive soft tissue injuries need to be available at initial point of care. These include temporizing coverage options (negative pressure dressings, allograft or engineered tissue coverings) and personnel skilled in wound management using these techniques.

FUTURE RESEARCH:

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.

Comorbidities

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.

RATIONALE

Consensus opinion was reached by the work group based on the argument that limiting surgical exposures (early amputation) would likely minimize complications and increase cost-effectiveness in patients with severe and/or multiple comorbidities (COPD, PVD, CHF, valvular disease, ESRD, liver failure, dementia, etc.) who may not tolerate multiple surgeries when pursuing limb salvage.

BENEFITS & HARMS:

Minimizing the numbers of surgeries in patients with severe comorbidities will potentially minimize the risk of perioperative complications including, but not limited to death, re-admissions, increased length-of-stay (LOS), wound complications, infection/sepsis, VTE, and serious cardiopulmonary and renal complications. Certainly, overestimating the number and/or severity of comorbidities at time zero could lead to premature amputation outside the purview of life-over-limb scenarios.

IMPORTANT/PRIORITY OUTCOMES:

Death, re-admissions, increased LOS, wound complications, infection/sepsis, VTE, and serious cardiopulmonary and renal complications are all well-known negative outcomes that surgeons seek to avoid in attempting to provide high quality care and increased quality of life for their patients. Additionally, they have become well-known metrics by which health care organizations are benchmarked for quality of care.

COST EFFECTIVENESS/RESOURCE UTILIZATION:

Literature supports that lifetime costs of amputation are higher for young patients with diminishing costs approaching that of limb salvage when performed in patients with decreased life expectancy. Under the assumption that patients with severe and/or multiple comorbidities would more likely be older and experience more complications with attempted limb salvage, appropriate early amputation may be the more cost-effective strategy among these patients.

ACCEPTABILITY:

Some people groups may approach the limb salvage versus amputation dilemma with a “limb salvage at all cost” philosophy. However, it is believed that most patients will choose an interactive, rationalized decision-making approach when presented with reasonable evidence and medical facts about their pre-existing health by their surgeon in order to make the most appropriate choice for them.

FEASIBILITY:

Outside of the life-over-limb scenario, informed medical decision-making is the standard of care. Taking into account the type, number, combination, and/or severity of comorbidities and their potential effects on outcomes will promote this process.

FUTURE RESEARCH:

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.

APPENDICES



Appendix I – References for Included Literature

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Appendix II - 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.

Non-Voting Oversight Chairs' and Voting Members' Disclosures

Oversight Chair – Non-Voting Members

Benjamin J Miller, MD Submitted on: 04/02/2018

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

Musculoskeletal Oncology Research Initiative: Board or committee member (\$0)

Musculoskeletal Tumor Society: Board or committee member (\$0)

Work Group – Voting Members

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Orthopaedic Implant Company: Stock or stock Options Number of Shares: 0

Benjamin Kyle Potter, MD Submitted on: 07/12/2018

Biomet: Unpaid consultant

Clinical Orthopaedics and Related Research: Editorial or governing board (\$5,000) Deputy Editor(Self)

Journal of Orthopaedic Trauma: Editorial or governing board (\$0)

Journal of Surgical Orthopaedic Advances: Editorial or governing board (\$0)

Society of Military Orthopaedic Surgeons: Board or committee member (\$0)

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American Orthopaedic Foot and Ankle Society: Board or committee member (\$0)

James R Ficke, MD Submitted on: 04/11/2018

AAOS: Board or committee member (\$0)

American Orthopaedic Association: Board or committee member (\$0)

Journal of Southern Orthopedic Association: Editorial or governing board (\$0)

Orthopaedic Research and Education Foundation: Board or committee member (\$0)

Orthopedics Today: Editorial or governing board (\$0)

Southern Orthopaedic Association: Board or committee member (\$0)

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

Andrew Robert Fras, MD (This individual reported nothing to disclose); Submitted on: 08/13/2018

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Exelixis (EXEL): Stock or stock Options Number of Shares: 0

Guided Therapeutics (GTHP): Stock or stock Options Number of Shares: 0

Johnson & Johnson: Stock or stock Options Number of Shares: 0

Musculoskeletal Transplant Foundation: Other financial or material support (\$0)

PayMD: Unpaid consultant

Stroma Inc: Unpaid consultant

Synthes: Stock or stock Options Number of Shares: 0

Michael S Pinzur, MD Submitted on: 05/14/2018

AAOS: Board or committee member (\$0)

AAOS Atlas of Amputations: Editorial or governing board (\$0)

American Orthopaedic Foot and Ankle Society: Board or committee member (\$0)

Foot and Ankle International: Editorial or governing board (\$0)

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

Stryker: Paid consultant (\$0)

Jason M Wilken, PhD, PT (This individual reported nothing to disclose); Submitted on: 10/02/2018

Rosanna Lisa Wustrack, MD (This individual reported nothing to disclose); Submitted on: 06/01/2018

Appendix III – PICO Questions Used to Define Literature Search

1. In adult patients (17-65yrs) with high energy lower extremity trauma, what patient/injury factors indicate immediate amputation is necessary to prevent sepsis, organ failure, non-viable extremity, or death?
2. In adult patients (17-65yrs) with high energy lower extremity trauma, what patient/injury characteristics indicate an amputation should be considered to allow improved outcomes as compared to limb salvage?
3. In adult patients (17-65yrs) with high energy lower extremity trauma, what environmental factors (Insurance, rehabilitation/clinical pathway/return to run, custom dynamic orthosis, prosthesis, etc.) affect the decision to amputate when considering outcomes as compared to limb salvage?

Appendix IV – Literature Search Strategy

Database: PubMed

Interface: NCBI (<https://www.ncbi.nlm.nih.gov/pubmed>)

Date Searched: Feb. 6, 2019

LINE	SEARCH SYNTAX
#1	"Lower Extremity"[mh] OR "lower extremity"[tiab] OR "lower extremities"[tiab] OR "lower limb"[tiab] OR "Bones of Lower Extremity"[mh] OR "hip"[tiab] OR "knee"[tia-b] OR "femur"[tiab] OR femoral[tiab] OR fibula[tiab] OR fibular[tiab] OR tibia[tiab] OR tibial[tiab] OR patella[tiab] OR acetabulum[tiab] OR acetabular[tiab] OR metatarsal[tiab] OR tarsal[tiab] OR leg[tiab] OR foot[tiab] OR ankle[tiab]
#2	"Wounds and Injuries"[mh] OR trauma[tiab] OR traumatic[tiab] OR injury[tiab] OR injuries[tiab] OR injured[tiab] OR avulsion[tiab] OR mangled[tiab]
#3	(#1 AND #2) OR "Lower Extremity/injuries"[mh] OR "Bones of Lower Extremity/injuries"[mh]
#4	"Amputation"[mh] OR "Limb Salvage"[mh] OR amputation[tiab] OR amputations[tiab] OR amputated[tiab] OR disarticulation[tiab] OR hemipelvectomy[tiab] OR hemipelvectomies[tiab] OR "limb salvage"[tiab] OR "salvaged limb"[tiab] OR "limb loss"[tiab]
#5	#3 AND #4
#6	(Adolescent[mh] OR Child[mh] OR Infant[mh] OR Aged[mh]) NOT Adult[mh]
#7	(animal[mh] NOT human[mh]) OR cadaver[mh] OR cadaver*[ti] OR ((comment[pt] OR editorial[pt] OR letter[pt] OR "historical article"[pt]) NOT "clinical trial"[pt]) OR addresses[pt] OR news[pt] OR "newspaper article"[pt] OR pmcbook OR "case report"[ti] OR "case reports"[pt]
#8	(1990:3000[pdat]) AND English[la]
#9	#5 NOT (#6 OR #7)
#10	#9 AND #8

Database: Embase

Interface: Elsevier (<https://embase.com>)

Date Searched: Feb. 6, 2019

LINE	SEARCH QUERY
#1	'lower limb'/exp OR 'bones of the leg and foot'/exp OR 'lower extremity':ti,ab OR 'lower extremities':ti,ab OR 'lower limb':ti,ab OR 'leg':ti,ab OR 'ankle':ti,ab OR 'knee':ti,ab OR 'hip':ti,ab OR 'femur':ti,ab OR 'femoral':ti,ab OR 'fibula':ti,ab OR 'tibia':ti,ab OR 'acetabular':ti,ab OR 'acetabulum':ti,ab OR 'metatarsal':ti,ab OR 'tarsal':ti,ab OR 'hindfoot':ti,ab OR 'calcaneus':ti,ab OR 'talus':ti,ab OR 'foot':ti,ab
#2	'injury'/de OR 'avulsion injury'/exp OR 'battle injury'/exp OR 'blunt trauma'/de OR 'crush trauma'/exp OR 'leg injury'/exp OR 'multiple trauma'/exp OR 'missile wound'/exp OR 'gunshot injury'/exp OR trauma:ti,ab OR traumatic:ti,ab OR injury:ti,ab OR injuries:ti,ab OR injured:ti,ab OR avulsion:ti,ab OR mangled:ti,ab
#3	'amputation'/de OR 'disarticulation'/exp OR 'foot amputation'/exp OR 'leg amputation'/exp OR amputation:ti,ab OR amputations:ti,ab OR amputated:ti,ab OR disarticulation:ti,ab OR hemipelvectomy:ti,ab OR hemipelvectomies:ti,ab OR 'limb salvage'/exp OR 'limb salvage':ti,ab OR 'salvaged limb':ti,ab OR 'limb loss':ti,ab OR 'limb sparing':ti,ab
#4	#1 AND #2 AND #3
#5	('in vitro study'/exp OR 'nonhuman'/de OR 'cadaver'/de OR 'animal experiment'/exp) NOT 'human'/exp
#6	('embryo'/exp OR 'fetus'/exp OR 'juvenile'/exp OR 'aged'/exp) NOT 'adult'/exp
#7	'abstract report'/de OR 'book'/de OR 'editorial'/de OR 'editorial'/it OR 'note'/de OR 'letter'/it OR 'case study'/de OR 'case report'/de OR 'conference abstract'/it OR 'chapter'/it OR 'conference paper'/it OR 'conference review'/it
#8	#4 NOT (#5 OR #6 OR #7) AND [1990-2019]/py AND [english]/lim

Database: Cochrane Central Register of Controlled Trials (CENTRAL)

Interface: Wiley (<https://www.cochranelibrary.com/central>)

Date Searched: Feb. 6, 2019

LINE	SEARCH QUERY
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#1	[mh "Lower Extremity"] OR "lower extremity":ti,ab OR "lower extremities":ti,ab OR "lower limb":ti,ab OR [mh "Bones of Lower Extremity"] OR hip:ti,ab OR femur:ti,ab OR femoral:ti,ab OR fibula:ti,ab OR tibia:ti,ab OR tibial:ti,ab OR patella:ti,ab OR acetabulum:ti,ab OR acetabular:ti,ab OR metatarsal:ti,ab OR tarsal:ti,ab OR leg:ti,ab OR foot:ti,ab OR ankle:ti,ab
#2	injur*:ti,ab OR trauma*:ti,ab OR avulsion:ti,ab OR mangled:ti,ab
#3	[mh "amputation"] OR [mh "limb salvage"] OR amputation*:ti,ab OR amputated:ti,ab OR disarticulation:ti,ab OR hemipelvectomy*:ti,ab OR "limb salvage":ti,ab OR "salvaged limb":ti,ab OR "limb loss":ti,ab
#4	#1 and #2 and #3 not "conference abstract":pt with Publication Year from 1990 to 2019, in Trials

Appendix V – Inclusion Criteria

Customized Inclusion Criteria

- Study must be of a *lower extremity trauma* injury
- Study must be published in or after **1990**
- Study should have **10 or more patients** per group
- Consider all follow-up times

Standard Inclusion Criteria For All CPGs

- Article must be a full article report of a clinical study (studies using registry data can be included in a guideline if it is published in a peer-reviewed journal and meets all other inclusion criteria/quality standards).
- Retrospective non-comparative case series, medical records review, meeting abstracts, historical articles, editorials, letters, and commentaries are **excluded**.
- Confounded studies (i.e. studies that give patients the treatment of interest AND another treatment without appropriate sub-analysis or statistical adjustment) are **excluded**.
- Case series studies that have non-consecutive enrollment of patients are **excluded**.
- Controlled trials in which patients were not stochastically assigned to groups AND in which there was either a difference in patient characteristics or outcomes at baseline AND where the authors did not statistically adjust for these differences when analyzing the results are **excluded**.
- All studies of “Very Low” quality of evidence (e.g. Level V) are **excluded**.
- Study must appear in a peer-reviewed publication
- For any included study that uses “paper-and-pencil” outcome measures (e.g. Composite measures, SF-36, etc.), only those outcome measures that have been validated will be included
- For any given follow-up time point in any included study, there must be $\geq 50\%$ patient follow-up (if the follow-up is $>50\%$ but $<80\%$, the study quality will be downgraded by one Level)
- Study must be of humans
- Study must be published in English
- Study results must be quantitatively presented
- Study must not be an in vitro study
- Study must not be a biomechanical study
- Study must not have been performed on cadavers

We will only evaluate surrogate outcomes when no patient-oriented outcomes are available.

Best Available Evidence

When examining primary studies, we will analyze the best available evidence regardless of study design. We will first consider randomized controlled trials identified by the search strategy. In the absence of two or more RCTs, we will sequentially search for prospective controlled trials, prospective comparative studies, retrospective comparative studies, and prospective case-series studies. Only studies of the highest level of available evidence are included, assuming that there were 2 or more studies of that higher level. For example, if there are two high quality studies that address the recommendation, moderate and low studies addressing the same procedure and outcomes are not included.