

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



Amputation: Evaluation and Treatment (CPG ID: 07)

To provide standardization of optimal care for the performance of wound management and life-saving amputations that will ensure preservation of maximum limb length, promote healing of viable tissues, and facilitate optimal rehabilitative function.

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TABLE OF CONTENTS

Background	2
Decision to Amputate	2
Evaluation and Treatment	2
Post-Operative Management	3
Aeromedical Evacuation Considerations	4
Performance Improvement (PI) Monitoring.....	5
Population of Interest	5
Intent (Expected Outcomes)	5
Performance/Adherence Metrics.....	5
Data Source	5
System Reporting & Frequency.....	5
Responsibilities.....	5
References	5
Appendix A: Additional Information Regarding Off-label Uses n CPGs	7

BACKGROUND

The extent of the “zone of injury” is dependent upon the mechanism of injury (i.e. blast, gunshot and crush injuries), as well as the co-morbidities and physiologic status of the casualty. Factors such as severe blood loss with massive resuscitation, burns, compartment syndrome, tourniquet use, and contamination load often extend the actual amount of tissue damage beyond that which is apparent on initial visual inspection.¹ Amputation terminology includes traumatic amputations which are immediate extremity amputations caused by the wounding mechanism itself. Primary amputations are those performed by a surgical team after evaluation of the mangled extremity, with the decision not to pursue limb salvage for whatever reason. Secondary amputations can occur early (within 90 days) or late (after 90 days), with the latter referring to those amputations occurring after an initial attempt at limb salvage has been undertaken. Most commonly, primary and early secondary amputations are performed for vascular injuries not amenable to repair or resulting in prolonged limb ischemia, nerve injuries not compatible with a functional extremity, or extensive nonviable tissue with potential for uncontrolled sepsis. Late secondary amputations are generally performed due to patient preference or major complications (e.g., flap failure, recurrent osteomyelitis, persistent poor function or pain) of attempted limb salvage. Current consensus regarding extremity amputation following battle-injury is to preserve limb length and vascularity, facilitate adequate wound drainage, and achieve eventual coverage and closure of the amputation wound.²

DECISION TO AMPUTATE

Although a number of scoring systems to predict the need for amputation exist,³ none is widely accepted or validated in the combat trauma population. Intact or the potential to restore perfusion (by vascular repair or shunt) may be the first determinant. If perfusion can be restored, any decision regarding amputation for nerve or bone loss can potentially be deferred until later, with the structurally unstable limb for transport by splinting or external fixation. Given the time sometimes required to restore perfusion, amputation may be necessary and a Damage Control procedure in a massively injured patient.

EVALUATION AND TREATMENT

1. Thorough **inspection of the wounds** with liberal use of surgical wound extension is necessary to inspect all levels of tissue including examination of fascial planes. If available, continuous wave Doppler examination and diagnostic arteriography can be used as adjuncts in cases where distal perfusion is a concern.⁴
2. **After early control of active hemorrhage** is achieved, gross decontamination, followed by a meticulous sharp debridement using a scalpel and/or scissors should be a starting point for nearly all wartime penetrating wounds. Removal of all nonviable tissue, including skin, fat, fascia, muscle, and bone, is essential to reduce the load of contamination and necrotic tissue in the wound and is the hallmark of an adequate debridement. The adjunct of irrigation or lavage with normal saline is also important to decrease bacterial count and soiling. This can be accomplished using various devices such as pulse lavage using a battery powered system or gravity irrigation using genitourinary tubing or bulb/syringe. Published clinical data is inconclusive as to which irrigation method is superior (see Initial Management of War Wounds JTS CPG for additional information). Assurance of hemostasis is important prior to evaluation for dressing or closure.⁵
3. **In the setting of an extremity amputation**, appropriate vascular structures should be ligated proximal to the bone resection but as distal as possible to ensure adequate tissue perfusion. Vascular structures should be separated from nerves prior to ligation.

4. **The amputation should be performed at the most distal level which provides viable bone and soft tissues for later closure.** In select instances close to the proximal joint (e.g. knee, elbow), preservation of viable bone length in the absence of adequate viable soft tissue coverage is advocated in order to preserve options for either late free tissue transfer coverage and amputation level salvage or disarticulation. Ipsilateral fractures proximal to the level of viable tissue should be initially stabilized and should not be a determining factor for amputation level. These fractures can be stabilized with external fixation, splinting, or pins to facilitate evacuation.⁶
5. Be prepared to **accept atypical skin and tissue flaps** so long as the tissue is viable.
6. **Do not perform primary closure of traumatic amputations.** All wounds must be left open and re-evaluated with serial irrigation and debridement's as the zone of injury declares itself.
7. **Avoid open circular or guillotine amputations.** These techniques are antiquated, sacrifice viable soft tissue and relegate the casualty to more proximal revision, and are not that much faster than the open, length-preserving length of initial amputation advocated. All amputations should be performed at the most distal level practicable with re-evaluation of the open amputation site within the first 24 hours.^{7,8}

POST-OPERATIVE MANAGEMENT

1. **Soft dry dressing should be applied around the amputation site and extremity.** Circumferential wraps with gauze rolls and ace wraps must be applied in a figure of eight fashion without excessive compression.
2. The limb **may be placed in a splint or bivalve cast** to prevent joint contractures and provide soft tissue support when necessary. There should be simple access for wound inspection.
3. In the **event of the short skin flaps**, skin traction to prevent soft tissue retraction is an option.
4. **Avoid placement of pillows under the knee** so as to prevent contractures when dealing with amputations below the knee.
5. **Negative Pressure Wound Therapy (NPWT) device using Reticulated Open Cell Foam (ROCF)** material, have recently been shown to be an alternate strategy and valuable adjunct in the overall management of amputation wounds.⁹ The Vacuum Assisted Closure (VAC) device has been the primary NPWT device used within the DoD. Recent clinical studies support the use of the VAC as a soft tissue wound management adjunct in appropriately prepared wounds as a bridge to delayed closure, flap coverage, or coverage with a split thickness skin graft. In appropriately debrided and prepared wounds the VAC has been shown to increase the rate of granulation and decrease bacterial colonization leading to effective amputation coverage and or closure.¹⁰ Use of NPWT/ROCF should be considered only after complete wound debridement and hemostasis have been achieved. The VAC ROCF sponge should cover the open wound bed and be set to -125 mm Hg continuous pressure.⁴

NOTE: Use of VAC dressings has recently been demonstrated to be safe in patients during strategic aeromedical evacuation.

The efficacy and long-term sequelae of NPWT/ROCF is not yet fully established, however; current clinical experience has been largely favorable. Surgeons who elect to employ this wound coverage method as part of their overall wound management strategy should be thoroughly familiar with the VAC system and its correct use.

6. There are **disadvantages to the use of NPWT** in the management of combat-related amputations: they are bulky for transport and can easily occlude or leak, resulting in ineffective therapy or the machine

shutting down automatically during transport. Additionally, NPWT can macerate tissue, obliterate soft tissue planes, and there is concern for a potential role in the pathogenesis of heterotopic ossification.

7. **NPWT/ROCF dressings can be left in place for 24 to 48 hours** depending upon the extent and acuity of the wound. More extensive and acute soft tissue wounds should have the VAC dressing removed with further irrigation and debridement on shorter intervals (every 24 hours) compared to less extensive wounds (greater than every 24 hours). Initiation of delayed primary closure from the ends of the wound may be started during these repeat debridements and irrigation with re-application of smaller VAC dressing sponges.
8. **Coordinate dressing changes/repeat debridement with evacuation schedule** to avoid extended periods without wound care or inspection. Given the extent of many soft tissue wounds dressing changes and repeat debridements should be performed in the operating room affording the patient the comfort of conscious sedation or general anesthesia and the surgeon access to the full array of equipment necessary to perform adequate debridement. Also, reapplication of the VAC dressing may be more complete and effective if performed in the operating room with the support of operating room and anesthesia teams.

AEROMEDICAL EVACUATION CONSIDERATIONS

Due to the requirement to move the coalition patient with traumatic amputation to Role 4 facilities usually out of theater, early and safe transport of these patients should involve consideration of the following factors.

1. **Concomitant injury management** is crucial during flight. Additional orthopedic injuries should be stabilized and structurally sound for transport. Limbs should be splinted and positioned to decrease the possibility of post traumatic contractures.
2. If **adequate tissue perfusion** is a concern, supplemental oxygen should be given to increase oxygen tissue delivery.
3. **Large wounds or wound vacuums** can add an area of increased heat loss. Take preventative measures to reduce risk of hypothermia.
4. **Flight stresses** include movement and vibration which can increase pain during transport. It is likely that pain medication requirements will increase during these times. Evaluate analgesia protocols as well as the patient's analgesia needs and response to pain medications.
5. **Do not remove drains or wound vac** in the immediate period prior to aeromedical evacuation. Coordinate dressing change timing with the patient movement schedule.
6. **Patients with multiple trauma** require Deep Vein Thrombosis prophylaxis if anatomically feasible and not contraindicated. Refer to [The Prevention of Deep Vein Thrombosis-Inferior Vena Cava Filter CPG, 02 Aug 2016 \(ID:36\)](#) for specific guidance.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

All patients with diagnosis of limb amputation or limb amputation procedure code.

INTENT (EXPECTED OUTCOMES)

1. Amputation wounds are not closed at the initial operation
2. Circular/guillotine amputation is avoided (viable soft tissue is preserved).
3. Repeat debridement/dressing change within 48 of first debridement/amputation procedure.

PERFORMANCE/ADHERENCE METRICS

1. Number and percentage of patients in the population of interest who have amputation wounds left open at initial operation (closed flap amputation at first procedure = non-adherence).
2. Number and percentage of patients in the population of interest who have documentation that all viable soft tissue is preserved at the initial operation.
3. Number and percentage of patients in the population of interest who have their dressing change/repeat debridement in <48 hours of initial amputation/procedure.

DATA SOURCE

- Patient Record
- Department of Defense Trauma Registry (DoDTR)

SYSTEM REPORTING & FREQUENCY

The above constitutes the minimum criteria for PI monitoring of this CPG. System reporting will be performed annually; additional PI monitoring and system reporting may be performed as needed.

The system review and data analysis will be performed by the JTS Chief and the JTS PI Branch.

RESPONSIBILITIES

It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.

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APPENDIX A: ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of “off-label” uses of U.S. Food and Drug Administration (FDA)–approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e. “off-label”) uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing “investigational new drugs.” These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. Some command requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGS

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that use by DoD health care practitioners or considers it to be the “standard of care.” Rather, the inclusion in CPGs of off-label uses is to inform the clinical judgment of the responsible health care practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible health care practitioner within the practitioner-patient relationship.

ADDITIONAL PROCEDURES**Balanced Discussion**

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including in an appendix an appropriate information sheet for distribution to patients, whether before or after use of the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.