

MANAGEMENT OF HIGH BILATERAL AMPUTATIONS

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<input type="checkbox"/> Minor Changes (or)	<input type="checkbox"/> Changes are substantial and require a thorough reading of this CPG (or)	
<input checked="" type="checkbox"/> Significant Changes	Proctoscopy for perineal injury; PI monitoring plan added	

- 1. Goal.** To review indications for and the procedures associated with the initial management of bilateral lower extremity amputations with associated pelvic/perineal injuries.
- 2. Background.** Bilateral lower extremity amputations with associated pelvic/perineal injuries represent one of the most challenging cohorts of surgical patients from management of the initial injury through final reconstruction. These injuries are associated with an increased incidence of morbidity and mortality. Survival is initially dependent upon hemorrhage control and massive resuscitation protocols. Later risks for mortality include sepsis and multisystem organ dysfunction. These injuries can broadly be divided into two categories; those with a perineal/pelvic floor injury and those without. There are few counterparts in civilian trauma. An organized aggressive continuum of surgical care by general surgeons and orthopaedists is critical to optimize outcomes.
- 3. Evaluation and Treatment.**
 - a. Initial Resuscitation.** These patients typically arrive in extremis shortly after injury. Tourniquets are often in place on all injured extremities. Due to profound shock and associated upper extremity amputations, IV access may not be obtained in the field. Rapid placement of IO (intra-osseous) lines is sometimes a useful adjunct to begin resuscitation prior to venous access. Large bore central venous access should be considered early and placed by an experienced proceduralist. This injury pattern mandates immediate activation of massive transfusion protocols, the preferential use of fresh blood (< 21 days old), minimal use of crystalloid products, and early consideration for the use of fresh whole blood (FWB), if blood resources are limited. (refer to Damage Control Resuscitation CPG)
 - b. Role of Resuscitative Thoracotomy.** Occasionally these patients arrive with CPR in progress. When signs of life are present, consideration of resuscitative thoracotomy should be given according to established clinical practice guidelines. Outcome data from OIF suggest a reasonable survival rate in properly selected patients.^a Another alternative described with exsanguination in civilian extremity injuries is the use of a brief period of CPR with concomitant massive blood product resuscitation before resorting to a resuscitative thoracotomy. Joint Theater Trauma Registry Review in autumn 2011 suggests the mortality associated with bilateral high amputations, pelvic injury and emergency department thoracotomy is very high (>90%). Experienced military surgeons debate the optimal approach to prevent ongoing hemorrhage in this population – thoracic, distal aortic or bilateral iliac proximal vascular control.

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- c. Triage Considerations. These patients consume massive amounts of blood products and utilize multiple surgical assets to include operative teams, equipment and operative hours. In the multiple casualty scenario, consideration of a balance between resources and surgical assets should be considered prior to proceeding with resuscitative thoracotomy.
 - d. Preoperative Studies. Useful preoperative studies may include CXR, AP Pelvis, FAST, and DPL, but should not delay surgical control of hemorrhage. Expeditious CT of the head may be considered in patients displaying lateralizing signs consistent with severe TBI requiring operative intervention, but should not degrade resuscitation or delay surgical hemorrhage control.
4. **Operative Approach.**
- a. Prioritization and Surgical Teams. The initial operative goal is hemorrhage control and control of contamination. Due to the nature of these injuries, this is best achieved using a team of general surgeons and orthopaedists working concurrently on the patient (if available). For example, two surgeons can achieve proximal control and address intra-abdominal injuries while a second team focuses on the amputations. A third team can be utilized to address upper extremity injuries, if present. This approach maximizes efficiency and limits prolonged physiologic insult to a severely injured patient. Prior to operation, the most critical procedures (i.e., proximal hemorrhage control, control of contamination, completion amputations, bladder repair and potential colonic diversion) should be listed, keeping in mind reasonable parameters to terminate surgery.
 - b. Proximal Vascular Control. The level of proximal vascular control is dictated by several clinical variables: previous resuscitative thoracotomy, associated pelvic disruption, level of tourniquet placement and level of amputation(s). Typically vascular control should be achieved at the most distal level possible, including control via a retroperitoneal approach or in the groin. A strategy of walking the clamps down in patients with massive pelvic injuries is prudent. This involves laparotomy, infra-renal aortic control, and movement of control distal to the internal and external iliacs. In the case of pelvic floor injuries with open pelvic wounds and active posterior bleeding, temporary control of the internal iliacs is prudent. This can be achieved with vascular clamps, vessel loops, Rumel tourniquets, or vascular clips. The benefit of achieving hemorrhage control must be balanced against the risk of ischemic tissue at the site of injury and subsequent infection and diminished wound healing. An attempt to reperfuse the internal iliacs should be made at the index or subsequent procedure. Ligation of both internal iliac arteries is to be avoided if at all possible; in cases of ongoing pelvic hemorrhage despite pelvic packing and angiographic embolization if available, bilateral internal artery ligation may be necessary.
 - c. Role of Proximal Diversion. In patients with an obvious need to divert the fecal stream due to pelvic disruption or an open pelvic fracture, stapled interruption of the sigmoid colon at the pelvic brim should be performed early to facilitate pelvic exposure and vascular control. Formal colostomy should be delayed until subsequent operative procedures.
 - d. Orthopedic Considerations. It is common for these patients to present with traumatic bilateral lower extremity amputations at various levels from transtibial amputations to very high transfemoral amputations, often with extremely complex soft tissue blast

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wounds up to and including the perineal and gluteal region. Associated traumatic amputation of the non-dominant upper extremity is also common. The most challenging cases involve open pelvic ring and peri-acetabular fractures and dislocations. Initial orthopaedic resuscitative involvement entails assuring that extremity hemorrhage control is sufficient with tourniquets. Often after the onset of the massive transfusion protocol, patients can bleed through in-place field tourniquets; in this case, they require placement of additional field tourniquets or pneumatic ones (if available) to control bleeding until optimized in the operating theater. Quick examination of the pelvic ring should be performed to address stability. Pelvic fractures can be stabilized with the use of clamped sheets or commercial pelvic binders centered over the trochanters.

Index operative procedures should be prioritized with surgical team leader. ***Hemorrhage control of traumatic amputated limbs and peri-pelvic sources is the priority.*** Pelvic and perineal packing is helpful for tiny vessel hemorrhage control and cases with continued oozing due to coagulopathies. In the multilevel amputee, limb length is inversely proportional to later energy expenditure. Revision amputations should occur at the most distal viable level with double ligation of all named vessels in an open, length-preserving fashion. Atypical rotational flaps are greatly preferred over guillotine-style or open circular amputations. Care should be given to salvaging healthy tissue for flap coverage, even if it is an atypical anterior rotational flap in the face of destroyed posterior tissue. When necessary, pelvic ring stabilization with external fixation is preferable to binders due to proximity of wounds and serial debridements that will be required. ASIS or AIIS pins are both appropriate, with the latter offering the greatest reduction control but the demands of available fluoroscopy and surgeon experience. Consideration should be given for later orthopaedic pelvic incisions so as to appropriately divert the location of colonic and urinary streams. External fixation of long bone fractures should be accomplished during the index procedure when possible. Smaller bone and joint fractures can be addressed if the patient remains stable, otherwise they are cared for after the initial operative resuscitation.

- e. Soft tissue Debridement. Adequate initial surgical debridement is critically important. These blast wounds are typically complex and extensive. They may be grossly contaminated with dirt, fragment debris, clothing and foliage. Wounds should be incised with well-planned incisions to extend the zone of injury to healthy tissue. Systematic debridement of nonviable skin, subcutaneous tissue, fascia, muscle, periosteum and bone is critical to reduce the bioburden and later risk of sepsis. With subsequent debridements, these blast wounds tend to evolve; if tissue is questionable and not contaminated it should be maintained and addressed at later surgical interventions. However, since the timing of the next operation (at the next echelon of care) is unpredictable, avoid leaving marginally viable tissue behind as many of these complex wounds will develop progressive necrosis. When present, pelvic/perineal and pelvic wounds need to be similarly addressed.
- f. Associated Vascular Injuries. This injury pattern appears to be associated with iliac vein injury. When possible these injuries should be shunted or repaired rather than ligated. Unless easily repairable, arterial injuries in these critically injured patients should be managed initially with shunting followed by formal repair at subsequent operation. Care should be taken to avoid exclusion of the profunda femoris during shunting or repair, in order to perfuse the soft tissue and muscle.

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- g. Associated GU Injuries. Injuries to the ureters, urethra, bladder, scrotum, penis, and prostate are common. These should be addressed if feasible with a focus on hemorrhage control, urinary control or diversion, and preservation of tissue for later reconstruction. See urologic trauma management CPG for specific recommendations.
- h. Associated (Occult) Rectal Injuries. Computerized Tomography alone may not always accurately exclude penetrating distal rectal injury in the setting of multiple perineal or perirectal fragmentation wounds with scatter artifact and random trajectories. Therefore, fragmentation wounds to the perineum and perianal regions should in general prompt proctoscopic examination of the distal rectum even if digital rectal examination in the emergency room is negative for blood. This may be difficult in the supine position and may be readily completed in the supported lateral position. Completion of the proctoscopic exam should be done prior to completing laparotomy as colonic diversion may be indicated even if there is no other strict indication based on the proximity of blast wounds to the fecal stream. If clot or active bleeding is identified on proctoscopic examination, the distal sigmoid colon/proximal rectum should be divided and matured at a subsequent operation into an end colostomy once the patient stabilizes up-range. Distal rectal wash out is not always necessary unless there is bulky retained stool in the presence of a suspected penetrating injury.
- i. Consideration of Prone Positioning. In most patients, the posterior soft tissue injuries can be addressed with elevation of the amputated stumps or with the patient in a lateral position after the supine portion of the case has been completed. However, certain injury patterns have a large posterior element. In these cases it is sometimes necessary to prone the patient during the index procedure for either hemorrhage control or debridement of deep blast wounds in the gluteal and low back region. This decision should not be made lightly and can often be deferred to secondary procedures. When undertaken, the use of a Jackson table can facilitate a safe transition to the prone position. Unstable pelvic ring injuries should be stabilized prior to proning a patient as this position can exacerbate pelvic volume widening and hemorrhage. Alternatively, lateral positioning with a bean bag could be considered.
- j. Temporary Abdominal Closure. Liberal use of temporary abdominal closure with delayed stoma maturation is advised.
- k. Wound Dressings. Traumatic wounds should not be definitively closed until multiple adequate debridements have been performed. By nature, the extensive soft tissue destruction and degree of contamination in these wounds make them infected until proven otherwise and a continuum of surgical debridements is necessary to prepare wounds for closure or coverage. If necessary and in the face of clean viable tissue, incisions made to extend the zone of wounds to healthy levels can be loosely approximated to prevent massive skin retraction. The preferred initial wound dressings include wet-to-dry, Dakin's soaked gauze, antibiotic bead pouches or negative pressure wound therapy.

5. Perioperative Management.

- a. Need for Radiologic Imaging. These injuries are associated with a significant transfer of energy to the casualty resulting in high risk for associated injuries of a blunt and

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penetrating nature. Once the patient is physiologically stabilized, complete imaging including “Pan Scan” CT and plain film examination should be obtained to evaluate for occult injury.

- b. Need for Repeated Debridements. It is important to appreciate the phenomenon of wound evolution and the expectation that the soft tissue will evolve with respect to extent and tissue viability over the course of several days. In the acute phase (<72 hours from injury) wounds should be frequently inspected in the operation room (every 24 hours). In the later, sub-acute phase (3-7 days from injury) wounds may require less frequent treatment based on the presence of viable tissue and absence of ongoing contamination. Multiple debridements are routinely required and the massively injured, physiologically deranged patient should not undergo excessive surgical procedures during the initial operation other than those required to control hemorrhage and gross contamination. See the Initial management of War Wounds CPG for further guidance.
- c. Role of systemic and Topical Antibiotics. Initial antibiotic selection should avoid empiric broad spectrum coverage but rather focus on narrow spectrum antibiotics (such as first generation cephalosporins) and the liberal use of topical delivery with Dakin’s soaked gauze or antibiotic beads. See Guidelines to Prevent Infection in Combat-Related Injuries CPG for specific recommendations.
- d. Role of VTE Prophylaxis. These patients are at very high risk of developing proximal deep vein thrombosis (DVT) and associated pulmonary embolus (PE). The presence of lower extremity amputation does NOT reduce this risk. In fact, patients with lower extremity amputations may actually be at higher risk for development of DVT and PE than those with similar injury severity without lower extremity amputation. It is recommended that these patients be started on appropriate DVT/PE prophylaxis as soon as coagulopathy is reversed. If contraindications to prophylactic anticoagulation persist, prophylactic IVC filter placement should be strongly considered. See Prevention of Deep Venous Thrombosis CPG for further recommendations.
- e. Transfer of Care. The down-range surgeon should make every effort to coordinate dressing changes and necessary repeat debridements in anticipation of required patient transport up-range. Given the propensity for wounds to evolve in their acute phase, the down-range surgeon must maintain a low threshold to perform additional debridement prior to evacuating the casualty if the patient would otherwise undergo an unacceptable interval between debridements. Given the unpredictable nature of the air evacuation system and to optimize timing of subsequent serial debridements, the patient should remain NPO for flight so that they are prepared for the next operation.

6. Performance Improvement (PI) Monitoring.

- a. Intent (Expected Outcomes).
 - 1) All patients at high risk for rectal injury are evaluated to eliminate the chance of missed injury
 - 2) All patients who undergo laparotomy have temporary abdominal closure to reduce chance for compartment syndrome and facilitate abdominal re-look and washout uprange.

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- 3) All patients receive or are considered for VTE prophylaxis as soon as clinically able.
- b. Performance/Adherence Measures.
 - 1) Proctoscopic examination was performed and documented during the index operation in these patients with fragmentation wounds to the perineum and perianal areas.
 - 2) In these patients undergoing laparotomy for vascular control and/or presence of intraabdominal injury, temporary abdominal closure was employed at the index operation.
 - 3) Appropriate VTE prophylaxis was initiated in a timely fashion or, if not, adequate documentation as to why not exists in the medical record and physician note.
- c. Data Source.
 - 1) Patient Record
 - 2) Joint Theater Trauma Registry (JTTR)
- d. 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 Joint Theater Trauma System (JTTS) Director, JTTS Program Manager, and the Joint Trauma System (JTS) Performance Improvement Branch.

7. **Responsibilities.** It is the trauma team leader's responsibility to ensure familiarity, appropriate compliance and PI monitoring at the local level with this CPG.
8. **References.**
 - a. Edens JW, Beekley AC, et al. Longterm outcomes after combat casualty emergency department thoracotomy. *J Am Coll Surg.* 2009 Aug;209(2):188-97.
 - b. Dorlac WC, DeBakey ME, Holcomb JB, et al. Mortality from isolated civilian penetrating extremity injury. *J Trauma.* 2005 Jul;59(1):217-22
 - c. Wisner DH, Victor NS, Holcroft JW. Priorities in the management of multiple trauma: intracranial versus intra-abdominal injury. *J Trauma.* 1993 Aug;35(2):271-6; discussion 276-8.
 - d. Dubose J, Inaba K, et al. Bilateral Internal Iliac Artery Ligation as a Damage Control Approach in Massive Retroperitoneal Bleeding After Pelvic Fracture. *J Trauma.* 2010 May 20. [Epub ahead of print]
 - e. Urologic Trauma Management CPG.
 - f. Labler L, Trentz O. The use of vacuum assisted closure (VAC) in soft tissue injuries after high energy pelvic trauma. *Langenbecks Arch Surg.* 2007 Sep;392(5):601-9.
 - g. Initial Management of War Wounds CPG.
 - h. Guidelines to prevent Infection in Combat-Related Injuries CPG.
 - i. Prevention VTE CPG.

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Approved by CENTCOM JTTS Director,
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Opinions, interpretations, conclusions, and recommendations are those of the authors
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APPENDIX A

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

1. 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.

2. 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.

3. 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.

4. Additional Procedures.

- a. 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.
- b. 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.
- c. 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.