

JOINT TRAUMA SYSTEM CLINICAL PRACTICE GUIDELINE (JTS CPG)



Acute Extremity Compartment Syndrome (CS) and the Role of Fasciotomy in Extremity War Wounds (CPG ID: 17)

Guide providers in the evaluation and treatment of patients with extremity war wounds, including the role of prophylactic and therapeutic fasciotomy.

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GOAL

This CPG provides an overview of acute extremity Compartment Syndrome (CS) and present a standardized approach to guide providers in the evaluation and treatment of patients with extremity war wounds, including the role of prophylactic and therapeutic fasciotomy.

BACKGROUND

CS is a common, controversial, and disabling problem in extremity war injuries. Seven to 11% of civilian tibia fractures result in compartment syndrome.¹⁻⁵ A similar incidence can be expected in cases of fractures from non-battle injuries in deployed areas. In contrast, combat injuries often involve a higher overall trauma burden; extreme transfusion requirements; extensive soft tissue injuries; associated arterial injuries; multi-level limb trauma; and occur in remote locations. This results in fifteen percent of all military orthopaedic trauma casualties requiring at least one prophylactic or therapeutic fasciotomy.⁶

Recent research indicates proper detection of Compartment Syndrome (CS) is lifesaving and delay in diagnosis can be lethal.⁷ The operational definition of CS is a clinical syndrome wherein high pressure within a myofascial space reduces perfusion and decreases tissue viability. Therapeutic fasciotomy is indicated for established CS, and prophylactic fasciotomy is indicated when there is a substantial risk of compartment syndrome.⁸⁻¹⁰ Fasciotomy during the lag phase between injury and syndrome onset is prophylactic. Early detection is challenging, so prophylactic fasciotomy should be routine when compartment syndrome is likely. Prophylactic fasciotomy is most commonly indicated in patients with certain “at risk” fractures and in patients with prolonged ischemia or following limb reperfusion. Injury, treatment, and casualty variables affect risk (Tables 1 and 3) and may be interrelated.⁷⁻¹³ The difficulties associated with monitoring a patient’s physical exam during lengthy periods of transport must be considered in the decision to perform prophylactic fasciotomy, along with the inability to intervene surgically during Aeromedical Evacuation (AE).

The main factors are limb injury severity (particularly vessel injuries) and overall casualty injury severity (particularly shock) with a lesser factor being aggressive resuscitation (particularly >5 liters of crystalloid). Tissue edema and subsequent swelling due to injury maximizes in 1 to 2 days. Additional swelling from post-injury ischemia reperfusion (e.g., revascularization, shock, and tourniquet use) appears to delay the maximal time of limb swelling further; perhaps to 2 to 5 days post injury. High altitude (including normal AE aircraft cabin pressure), in and of itself, is not a contributor to compartment syndrome (Ritenour, et al). Compartment syndrome can lead to significant morbidity and mortality (Table 2). Surveys indicate surgeons with more training and experience, are more willing to perform fasciotomy. Once the decision is made to perform a prophylactic or therapeutic fasciotomy, a complete fasciotomy must be performed.¹⁴ There is evidence to support complete compartment release by full-length skin and fascial incisions as being superior to limited fasciotomy. Incomplete fasciotomy, a clearly preventable problem, risks worsened patient morbidity, mortality, and functional outcome.

EVALUATION

Tissue edema due to injury peaks at 24-48 hours, but vigilance should be maintained in the first week post-trauma, especially in cases requiring sequential surgical procedures, ongoing resuscitation, or in the presence of ischemia-reperfusion. The signs and symptoms of CS are the classic “5 P’s” which include: pain; palpably tense muscle compartments; paralysis; paresthesia’s or sensory deficit; and pulselessness.² Pain out of proportion to the injury or with passive stretch of a muscle group is the most important clinical finding, but is often obscured in combat casualties due to altered mental status, heavy sedation, and mechanical ventilation. Palpably tense compartments are thought to be specific but not sensitive; this clinical finding is also highly subjective. Paralysis and paresthesias are less useful acutely as they can also result from direct neural trauma. Pulselessness is a late

and ominous sign in civilian CS, but occurs more commonly in combat injuries, sometimes within minutes of an arterial injury or an expanding hematoma. The most common compartment syndrome is in the anterior leg.¹⁻² About 45% of all compartment syndromes are caused by tibia fracture. Open fractures, even with traumatic fasciotomy, have higher CS rates than closed fractures because they are more severe, with more swelling and more often injured arteries. The most commonly missed compartment syndromes are in the anterior and deep posterior compartments of the leg. The most commonly incompletely released compartments are also in the leg.¹

Pressure measurement has significant limitations and is not recommended for routine use in theatre. Emerging technologies, such as ultrafiltration catheters, may eventually allow continuous pressure monitoring while providing pressure relief by suctioning interstitial fluid.¹⁵ When monitoring patients for the development of CS, serial clinical examinations are repeated hourly when risk is high and less frequently when low. Provider experience and training improves detection. Documentation is important for later providers and performance improvement.

In one study, burns sustained in combat have been associated with an increased fasciotomy rate.⁷ In the absence of crush injury, fracture, multiple trauma, over-resuscitation, electrical injury, or similar indications, prophylactic fasciotomy on burned extremities may increase morbidity and mortality and are not indicated. (For additional information on escharotomy and fasciotomy in the management of patients with extremity burns, see [JTS Burn Care CPG](#)).¹⁶

TREATMENT

OPERATIVE INTERVENTION

CS requires immediate operative intervention. Once intra-compartmental pressure reaches a critical threshold, only surgical treatment can interrupt the cascade of events leading to ischemia and tissue necrosis. This should be accomplished as soon as possible, as irreversible tissue necrosis occurs within a few hours. Delayed or incomplete compartment release has been associated with increased mortality and need for amputation in military casualties.⁶ Therapeutic fasciotomy is performed for established compartment syndrome while prophylactic fasciotomy is performed for limbs at risk of developing CS.⁸⁻¹⁰ The decision to proceed with prophylactic fasciotomy is based on the pattern of extremity injury, the patient's physiological profile, and operational considerations. We recommend that any limb at risk of CS in an austere location, particularly when AE is anticipated or after extremity vascular repair, should undergo prophylactic fasciotomy when they reach a fixed surgical facility. This avoids missed compartment syndrome or delayed compartment release, especially during times of high battle rhythm. The difficulties associated with monitoring a patient's physical exam during lengthy periods of transport must be considered in the decision to perform prophylactic fasciotomy, along with the inability to intervene during AE. High altitude (including normal AE aircraft cabin pressure), in and of itself, is not a contributor to compartment syndrome.^{17,18}

DELAYED EVACUATION

Occasionally, casualties present with a compartment syndrome of prolonged duration (> 12 hours) due to delayed evacuation. This situation is associated with markedly increased risk of complications, including death and infection.¹² These casualties may be best treated with appropriate resuscitation, urine alkalization, mannitol use, and intensive support.¹⁹ Such conservative care has led to better outcomes than fasciotomy in casualties with closed injuries with mechanically crushed muscle.¹² Therefore, compartment syndromes with greater than 12 hours of warm ischemia with nonviable muscle should not routinely undergo fasciotomy.¹⁹ The role of amputation is currently unclear in this situation.

FASCIOTOMY

Once the decision is made to perform compartment release, a complete fasciotomy must be performed.^{14,20} This involves releasing all compartments in the affected anatomic region over their full length. In the calf/leg, the anterior, lateral, superficial posterior and deep compartments must be released through full length incisions. Although a one-incision approach is possible in expert hands, we feel that a two incision technique should remain the standard of care in combat.^{21,22} A frequent error by inexperienced surgeons is not releasing the deep posterior compartment of the calf/leg. In the forearm, the superficial and deep volar compartments must be released through an incision that extends from the lacertus fibrosus to the carpal tunnel. The dorsal compartment, when involved, is released through a separate incision. Incomplete fasciotomy can be secondary to failure to release a specific compartment or to short fascial incisions. The most commonly missed compartment syndromes are the anterior and deep posterior compartments of the calf/leg.⁷ The most common incompletely released compartments are also in the calf/leg.⁷ Incomplete fasciotomy is associated with worse outcomes; fortunately, improved surgical education has been shown to decrease the rate of fasciotomy requiring revision.^{7,23} There is no reported experience with fasciotomy performed by non-surgeons in austere locations. We would caution that attempting this procedure outside of an operating room setting is fraught with pitfalls, including uncontrollable bleeding and iatrogenic neurovascular injury. Wound vacuum dressings or laced vessel loops are both acceptable methods of initially covering the surgical wounds.

The common reasons for incomplete calf fasciotomy are:

- Improper identification of the septum dividing the anterior and lateral compartments. This can be avoided by making an initial transverse incision in the fascia overlying the septum, then deliberately opening the anterior and lateral compartments separately, creating a so called "H" incision.
- Incomplete development of the deep posterior compartment release by not deliberately taking the soleus muscle fibers off the posterior tibia. If performed correctly, the neuro-vascular bundle should be exposed in a fully decompressed deep posterior compartment.
- Fascial incisions are too short and do not cover the entire extent of the fascial compartment, either at the knee or ankle levels.

Passive stretch pain (e.g., ankle dorsiflexion), palpation of muscles for tenseness and pulse quality combined with an index of suspicion makes up the mainstay for clinical evaluation. Pressure monitoring by manometer does not reliably diagnose CS in theater, so the diagnosis remains a clinical, not a technological diagnosis. Since there is currently no sensitive or specific technique for establishing the diagnosis of compartment syndrome, a fasciotomy should be considered in a patient with significant mechanism of injury and clinical findings suspicious for compartment syndrome.

TREATMENT OF FOOT CS

Fasciotomy for treatment of CS of the foot remains controversial. While surgical release is generally supported in the literature, the sequelae of foot fasciotomy can, in many instances, result in more severe sequelae (infection, skin grafting, difficulty with shoe wear) than result from compartment syndrome itself (claw toe deformity). The surgeon must, therefore, carefully weigh the advantages and disadvantages prior to performing foot fasciotomies.

PERFORMANCE IMPROVEMENT (PI) MONITORING

POPULATION OF INTEREST

- All patients diagnosed with compartment syndrome
- All patients with limb AIS ≥ 3 or tourniquet time > 2 hrs

INTENT (EXPECTED OUTCOMES)

1. Compartment syndrome is diagnosed and treated prior to tissue necrosis.
2. When fasciotomy is indicated, a complete fasciotomy is performed.
3. Tourniquet times are documented.
4. The use of prophylactic fasciotomy is minimized.

PERFORMANCE/ADHERENCE METRICS

1. Number and percentage of patients diagnosed with compartment syndrome who receive fasciotomy performed at the same role of care (or have reason for delay documented).
2. Number and percentage of patients undergoing fasciotomy who require debridement of necrotic muscle in the affected limb.
3. Number and percentage of patients with tourniquet placed who have tourniquet times (placement and removal) documented.
4. Number and percentage of patients who undergo fasciotomy who do not have a diagnosis of compartment syndrome.

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.

REFERENCES

1. Shore BJ, Glotzbecker MP, Zurakowski D, et al Acute compartment syndrome in children and teenagers with tibial shaft fractures: incidence and multivariable risk factors. *J Orthop Trauma.* 2013 Nov; 27(11):616-21.
2. Radiographic predictors of compartment syndrome in tibial plateau fractures. Ziran BH, Becher SJ. *J Orthop Trauma.* 2013 Nov; 27(11):612-5.
3. Park S, Ahn J, Gee AO, Kuntz AF, Esterhai JL. Compartment syndrome in tibial fractures. *J Orthop Trauma.* 2009 Aug; 23(7):514-8.
4. McQueen MM, Duckworth AD, Aitken SA, et al Predictors of compartment syndrome after tibial fracture. *J Orthop Trauma.* 2015 Apr 9.
5. Shadgan B, Pereira G, Menon M, et al Risk factors for acute compartment syndrome of the leg associated with tibial diaphyseal fractures in adults. *J Orthop Traumatol.* 2014 Dec 28.
6. Kragh JF Jr, Wade CE, Baer DG, et al Fasciotomy rates in operations enduring freedom and iraqi freedom: association with injury severity and tourniquet use. *Orthop Trauma.* 2011 Mar; 25(3):134-9.
7. Ritenour AE, Dorlac WC, Fang R, et al. Complications after fasciotomy revision and delayed compartment release in combat patients. *J Trauma.* 2008; 64(2 Suppl):S153-61; discussion S161-2. Landstuhl cohort. Inadequate fasciotomy risks mortality. Surgeons should have this.
8. Mubarak SJ, Hargens AR. Compartment Syndromes and Volkmann's Contracture. Saunders, Philadelphia, 1981. First book on compartment syndrome, a dated classic.
9. US Army, Medical Research and Materiel Command. Compartment Syndrome: Diagnosis and Surgical Management DVD, 2008. 90 minutes, how to do surgery.
10. Office of The US Army Surgeon General, Health Policy and Services (HP&S) Directorate, All Army Action Order, Complications after fasciotomy revision and delayed compartment release in combat patients. 15 May 2007. Ritenour message.
11. Klenerman L. The Tourniquet Manual. London: Springer; 2003. The only book on tourniquets which increase the risk of compartment syndrome somewhat especially if used incorrectly such as a venous tourniquet.
12. Reis ND. Better OS. Mechanical muscle-crush injury and acute muscle-crush compartment syndrome: with special reference to earthquake casualties. *J Bone Joint Surg Br.* 87(4): 450-3, 2005. Late fasciotomy risks infection and mortality.
13. Walters TJ, Kragh JF, Kauvar DS, Baer DG. The combined influence of hemorrhage and tourniquet application on the recovery of muscle function in rats. *J Orthop Trauma.* 22(1): 47-51, 2008. Risk factors are interrelated.
14. Mubarak S, Owen C. Double-Incision Fasciotomy of the Leg for Decompression in Compartment Syndromes. *JBJS.* 59-A, No.2, March 1977.
15. Odland RM, Schmidt AH. Compartment syndrome ultrafiltration catheters: report of a clinical pilot study of a novel method for managing patients at risk of compartment syndrome. *J Orthop Trauma.* 2011 Jun;25(6):358-65.
16. Joint Trauma System, Burn Care, 11 May 2016.

17. McGill R1, Jones E, Robinson B, et al Correlation of altitude and compartment pressures in porcine hind limbs. *J Surg Orthop Adv.* 2011 Spring;20(1):30-3.
18. Kalns J, Cox J, Baskin J, Santos A, et al Extremity compartment syndrome in pigs during hypobaric simulation of aeromedical evacuation. *Aviat Space Environ Med.* 2011 Feb; 82(2):87-91.
19. Gerdin M, Wladis A, von Schreeb J. Surgical management of closed crush injury-induced compartment syndrome after earthquakes in resource-scarce settings. *J Trauma Acute Care Surg.* 2012 Jun 14.
20. Mathis JE, Schwartz BE, Lester JD, et al Effect of lower extremity fasciotomy length on intracompartmental pressure in an animal model of compartment syndrome: the importance of achieving a minimum of 90% fascial release. *Am J Sports Med.* 2015 Jan; 43(1):75-8.
21. Bible JE, McClure DJ, Mir HR. Analysis of single-incision versus dual-incision fasciotomy for tibial fractures with acute compartment syndrome. *J Orthop Trauma.* 2013 Nov; 27(11):607-11.
22. Maheshwari R, Taitsman LA, Barei DP. Single-incision fasciotomy for compartmental syndrome of the leg in patients with diaphyseal tibial fractures. *J Orthop Trauma.* 2008; 22:723–730.
23. Kragh JF Jr1, San Antonio J, Simmons JW, et al. Compartment syndrome performance improvement project is associated with increased combat casualty survival. *J Trauma Acute Care Surg.* 2013 Jan; 74(1):259-63.

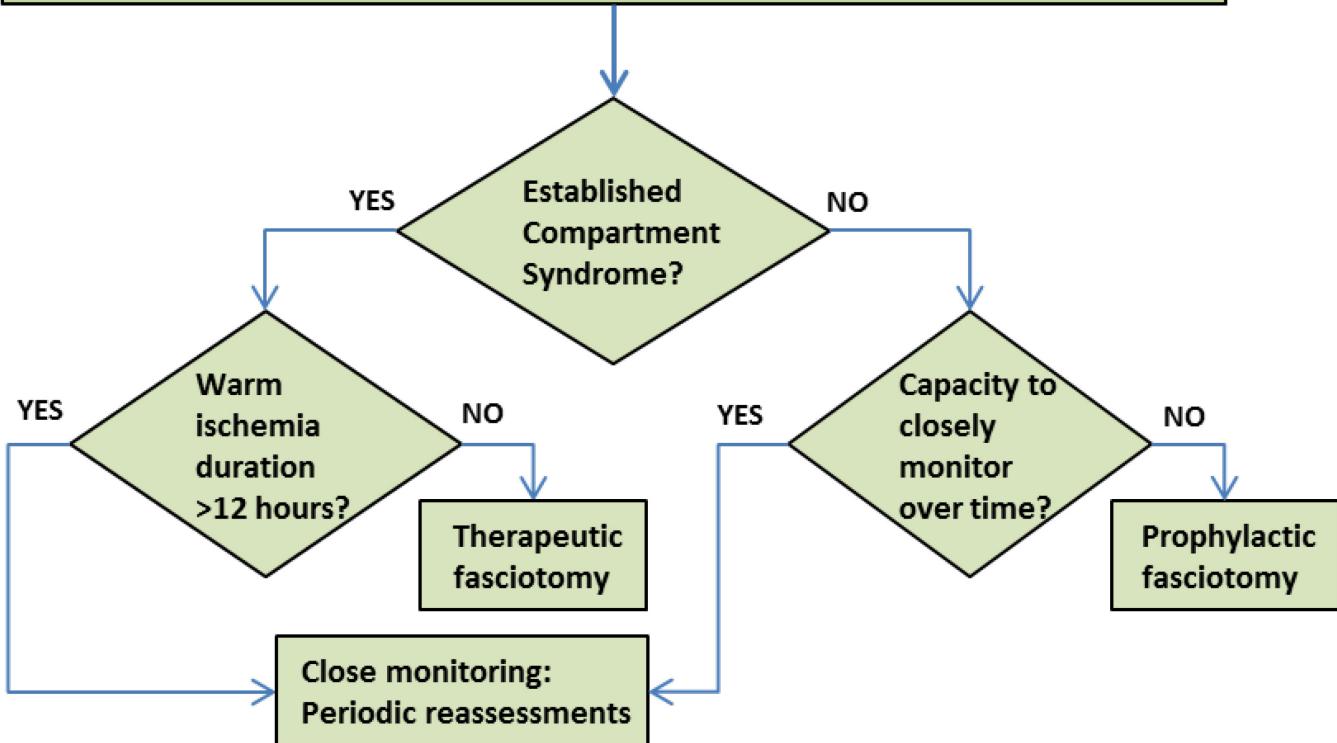
APPENDIX A: RISKS

Table 1. Risks for Acute Traumatic Compartment Syndrome	
Decreased Compartment Volume	<ul style="list-style-type: none"> • Tight cast or dressing, closure of prior fasciotomy, excess traction • External limb compression or crush particularly in obtunded or incapacitated casualty • Frostbite, burns or electric injury (may include escharotomy)
Increased Compartment Contents	<ul style="list-style-type: none"> • Edema accumulation: embolism, intravascular thrombosis, replantation, venous tourniquet, injections, extravasation, infiltration, ergotamine ingestion, ischemia-reperfusion, swelling, artery injury or spasm, revascularization procedures, prolonged arterial tourniquet use, shock hypoperfusion, angiography and catheterization, limbs positioned well above heart, mal-positioned joints (ankle dorsiflexion,) or stretched muscles • Prolonged immobilization and limb compression particularly with obtunded or drugged casualty, some surgical positioning • Hemorrhage, hemophilia, coagulopathy, anticoagulation, vessel injury • Large volume crystalloid resuscitation • Fractures particularly tibia fractures in adults, supracondylar humerus fractures in children displaced, comminuted, or open fractures increase hemorrhage, swelling, and CS risk • Popliteal cyst, long leg brace

Table 2. Morbidity Risk and Sequelae of Compartment Syndrome and Fasciotomy	
Potential Morbidity: Compartment Syndrome and Early Fasciotomy	<ul style="list-style-type: none"> • Skin scar, scaly skin, ulceration, tethered tendons • Postoperative arterial or graft thrombosis, thromboembolic disease • Wound infection, non-healing fasciotomy wounds • Limb swelling or chronic edema, shape change of limb, muscle hernia • Pain, paresis or paralysis, paresthesia • Coverage challenge: primary closure, delayed primary closure, skin graft, flap • Possible repair of arterial injury worsening ischemia-reperfusion injury
Potential Sequelae List: Compartment Syndrome with Late or Incomplete Fasciotomy	<ul style="list-style-type: none"> • Mortality, sepsis, multi-organ failure, acute kidney failure, • Myonecrosis, myoglobinemia, myoglobinuria, or rhabdomyolysis • Paresis or paralysis • Stiffness or contracture • Limb amputation, tissue loss, e.g., muscle debridement

APPENDIX B: ALGORITHM FOR CLINICAL DECISION MAKING ON COMPARTMENT SYNDROME IN A DEPLOYED SETTING**Risk Assessment for Extremity Compartment Syndrome**

Risk variables are listed in Table 1



APPENDIX C: COMPARTMENT SYNDROME HEALTHCARE RECORD DATA**Table 3. Healthcare Record Data in the Setting of Compartment Syndrome During War**

- Was the fasciotomy prophylactic (compartment syndrome absent) or therapeutic (compartment syndrome present)?
- When was the fasciotomy indicated and when was the injury?
- When was the procedure (to determine treatment lag)?
- Was the casualty able to be followed closely? If so, what was the clinical course? Was the casualty alert, intubated, or head injured?
- Was there a nerve injury or nerve block/regional anesthetic?
- What was the injury or risk factors (e.g., ischemia-reperfusion) that indicated the procedure?
- What are the sources of ischemia-reperfusion in the injury and care of this case?
- Associated injuries altering risk of compartment syndrome: shock, occult hypoperfusion, hypoxia, nerve dysfunction, impaired, obtunded, or uncooperative casualty, arterial injury or ischemia, fractures with soft tissue injury, over-resuscitation syndrome, coagulopathies (including hemophilia, etc.), hematoma formation, crush injury, capillary leak syndrome, and prolonged compression.
- What were the surgical findings and muscle compartment response to the procedure?
- What was the technique (dermotomy, fasciotomy, surgical approach, length of fasciotomy)?
- Was there retinaculotomy or epimysiotomy? List names of all compartments released.
- What delimited the fasciotomy extent, e.g., anterior leg fascia goes from the proximal tibial crest near Gerdy's tubercle to the anterior ankle extensor retinaculum (crural ligament)?
- List associated procedures: debridement, irrigation, fracture fixation, etc.
- Planned care: staged? Closure, repeat debridement, delayed primary, skin graft, or flap

APPENDIX D: COMPARTMENT DATA SHEET

Table 4. Data Sheet: Compartment Names, Main Muscles, and Diagnosis and Procedure Codes

Compartment	Main muscle(s)	Left or Right	Wound Notes, Compartment Syndrome (CS), Diagnoses, Indications, & Findings	Procedure(s) and Tissue Response to Procedure
			958.91: traumatic CS of upper extremity 958.92: traumatic CS of lower extremity 958.99: traumatic CS of other sites 958.90: CS, unspecified Prophylactic (CS absent) or therapeutic (CS present). Artery, vein, clot, & hematoma findings in compartment on exploration	83.12: fasciotomy of hand 83.14: fasciotomy, division of fascia 83.09: incision of fascia 86.09: escharotomy dermotomy, epimysiotomy Response: muscles bulged through fasciotomy, no bulge, pulse returned after absence
Deltoid	Deltoid			
Arm, Anterior	Biceps, Brachialis			
Arm, Posterior	Triceps			
Forearm, Volar	Flexors			
Forearm, Dorsal	Extensors			
Forearm, Mobile Wad	Brachioradialis			
Hand, Interossei	Interossei			
Hand, Central Palmar	Flexors			
Hand, Hypothenar	Digitii Minimi			
Hand, Thenar	Thumb Muscles			
Gluteus Maximus	Gluteus Maximus			
Gluteus Medius	Other Glutei			
Tensor Fascia Lata	Tensor			
Thigh, Anterior	Quadriceps			
Thigh, Posterior	Hamstrings			
Thigh, Adductor	Adductors			
Leg, Anterior	Tibialis Anterior			
Leg, Lateral	Peronei			
Leg, Deep Posterior	Tibialis Posterior			
Leg, Superficial Posterior	Gastrocnemius			
Foot, Interossei	Interossei			
Foot, Central	Flexors			
Foot, Lateral	Digitii Minimi			
Foot, Medial	Great Toe Muscles			
Iliacus	Iliacus, Psoas			

APPENDIX E: OPERATIVE NOTE TEMPLATE

Table 5. Operative Note Template for Dictation, Surgical Planning, or Data Collection

1. Patient	2. Surgeon
3. Date of Surgery	4. Anesthesia
5. EBL:	6. Tubes
7. Specimens	8. Complications
9. Implants, Devices	
10. Indication for operation:	
	a. Established compartment syndrome (therapeutic) b. Risk of compartment syndrome developing (prophylactic)
11. Preoperative wound appearance:	
	a. Size (volume of damaged tissue: large surgeon hand ~500ml) b. Depth, location, contamination material or matter
12. Preoperative imaging findings:	
	a. Soft tissue injury seen & fracture
13. Examination under anesthesia, fluoroscopy, and surgical exploration findings:	
	a. Distal pulse status b. Wound size, depth, location, contamination, materials or matter; burn eschar location and depth c. Vessel status, pulse, limb perfusion, capillary refill, congestion, edema, color of skin, warmth d. Clot presence, intravascular or extra vascular site, size (volume), location e. Hematoma presence f. Compartment hardness: soft, hard <ul style="list-style-type: none"> i. Epimysiotomy (if done by muscle name or compartment if known) ii. Retinaculotomy (if done by name, e.g., partial proximal ankle extensor) iii. Retinaculotomy extended from anterior leg compartment fasciotomy iv. Result of fasciotomy and procedure (distal perfusion and pulse; gap in fasciotomy edges on release in cm; bulging out of muscles in compartment) v. Compartments soft or hard vi. Muscle color, consistency, contractility, capacity to bleed
14. Patient condition, status, disposition and plan.	
15. Key note for air evacuation: "Patient has been monitored for X hours after injury/surgery and has not had progression of signs or symptoms of compartment syndrome."	

APPENDIX F: 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.