Optimization of Outcomes Following Limb Salvage of Combat-Related Lower Extremity Trauma

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Declaration

I, Daniel Stinner, declare that

(a) the submitted material as a whole is not substantially the same as published or unpublished material that I have previously submitted, or am currently submitting, for a degree, diploma, or similar qualification at any university or similar institution;
(b) that I have stated clearly which parts of the work or works submitted have previously been submitted for any such qualification; and
(c) where the work submitted includes work conducted in collaboration with others, I have provided a written statement on the extent of my individual contribution to the material and the conditions and circumstances under which the work was carried out. This statement has been signed by the lead/corresponding author for each of these works.

Index of Published Works for Consideration

Study Number	Reference
Study 1 (Appendix 1)	Temporary External Fixation Is Safe in a Combat Environment. Possley DR, Burns TC, Stinner DJ, Murray CK, Wenke JC, Hsu JR, Skeletal Trauma Research Consortium. J Trauma 2010;69:S135-S139.
Study 2 (Appendix 2)	Outcomes of Internal Fixation in a Combat Environment. Stinner DJ, Keeney JA, Hsu JR, Rush JK, Cho MS, Wenke JC, Ficke JR, Skeletal Trauma Research Consortium. J of Surgical Orthopaedic Advances 2010;19(1):49-53.
Study 3 (Appendix 3)	Return to Duty Rate of Amputee Soldiers in the Current Conflicts in Afghanistan and Iraq. Stinner DJ, Burns TC, Kirk KL, Ficke JR. J Trauma 2010;68:1476-1479.
Study 4 (Appendix 4)	Prevalence of Late Amputations during the Current Conflicts in Afghanistan and Iraq. Stinner DJ, Burns TC, Kirk KL, Scoville CR, Ficke JR, Hsu JR, Late Amputation Study Team. Mil Med 2010;175(12):1027-1029.
Study 5 (Appendix 5)	Descriptive Characteristics and Amputation Rates With Use of Intrepid Dynamic Exoskeleton Orthosis. Hill O, Bulathsinhala L, Eskridge SL, Quinn K, Stinner DJ. Military Medicine 2016;181(S4):77-80.
Study 6 (Appendix 6)	Bedigrew KM, Patzkowski JC, Wilken JM, Owens JG, Blanck RV, Stinner DJ, Kirk KL, Hsu JR. Can an Integrated Orthotic and Rehabilitation Program Decrease Pain and Improve Function After Lower Extremity Trauma. Clin Orthop Relat Res 2014;472:3017-3025.
Study 7 (Appendix 7)	Stinner DJ, Wenke JC, Ficke JR, Gordon W, Toledano J, Carlini A, Scharfstein DO, MacKenzie EJ, Bosse MJ, Hsu JR. Military and Civilian Collaboration: The Power of Numbers. *Mil Med* 2017;182(3/4):10-17.

Statement of Candidate's Contribution to Published Work

Contributions of the candidate	Corresponding author in agreement	
Paper 1: Temporary External Fixation Is Safe in a Combat Environment. Daniel Stinner identified the need for this review in concert with Joseph Hsu. He assisted with the literature review to create the grading criteria for potential, minor, and major complications. He assisted with data collection and review of radiographs. Finally, his effort was critical in interpretation of the results and manuscript preparation in conjunction with his co-authors.	D Possley	x
Paper 2: Outcomes of Internal Fixation in a Combat Environment. Daniel Stinner and James Ficke identified the clinical need for this review. He performed the literature review, wrote the protocol, obtained permission from the local institutional review board, created the CRFs, and performed the data collection, which included travel to Landstuhl, Germany to ensure accuracy of data retrieved. He performed the data analysis and interpretation of the results. Finally, he wrote the manuscript in liaison with his co-authors.	D Stinner	x
Paper 3: Return to Duty Rate of Amputee Soldiers in the Current Conflicts in Afghanistan and Iraq. James Ficke developed the clinical question. Daniel Stinner performed the literature review, wrote the protocol, obtained permission from the local institutional review board, created the CRFs, and performed the data collection. He performed the data analysis with the assistance of a statistician, and he interpreted the results. Finally, he wrote the manuscript in liaison with his co-authors.	D Stinner	x

Paper 4: Prevalence of Late Amputations during the Current Conflicts in Afghanistan and Iraq. Daniel Stinner and Joseph Hsu developed the clinical question. Daniel Stinner performed the literature review, wrote the protocol, obtained permission from the local institutional review board, created the CRFs, and performed the data collection. He performed the data analysis with the assistance of a statistician, and he interpreted the results. Finally, he wrote the manuscript in liaison with his co-authors.	D Stinner	x
Paper 5: Descriptive Characteristics and Amputation Rates With Use of Intrepid Dynamic Exoskeleton Orthosis. Owen Hill led this study. Daniel Stinner clinical expertise was used to collect all of the injury characteristics and diagnosis codes of the 624 patients under review and assigned each to one of seven groups that he created. This was of paramount importance because he created groups that were all clinically relevant. Upon completion of the data analysis, Daniel Stinner contributed in writing several portions of the manuscript and provided significant leadership in the editing of the overall manuscript to ensure that the message conveyed was clinically relevant.	O Hill	x
Paper 6: Can an Integrated Orthotic and Rehabilitation Program Decrease Pain and Improve Function After Lower Extremity Trauma. Joseph Hsu, Johnny Owens, and Ryan Blanck are responsible for the development of the custom PDAFO and RTR-CP. Daniel Stinner served as the principal investigator for the POSITIVE study (prospective observational study) following short term outcomes of patients in the program from 2013-2016. For this study, he assisted with performing the annual continuing literature review, updating the CRFs, patient recruitment/enrollment, and data collection. He assisted with interpretation of the data and critical editing of the manuscript.	K Bedigrew	x

Paper 7: Military and Civilian Collaboration: The Power of Numbers. Daniel Stinner developed the research question in collaboration with Joseph Hsu. He also served as his site's (one of the MTFs) principal investigator both assisting in administrative approval and patient enrollment of the studies examined. He also acquired the registry data and worked closed with Anthony Carlini and Dan Scharfstein, two METRC statisticians, to perform the data analysis. Finally, he led the data interpretation in conjunction with Joseph Hsu and led the manuscript writing effort.	D Stinner	x

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Finally, my wife and children deserve the largest thanks of all. Thank you for all your love and continued support. I certainly could not have done any of this without you.

Abbreviations

ADL	Activities of daily living
AFO	Ankle-foot-orthosis
CIV	Civilian Trauma Centre
DoDTR	Department of Defense Trauma Registry
DMDC	Defense Manpower Data Center
EMED	Expeditionary Medical Encounter Database
FSST	Four square step test
JTTR	Joint Trauma Theater Registry
ICD-9	International Classification of Diseases-9th Edition
IDEO	Intrepid Dynamic Exoskeleton Orthosis
ISS	Injury Severity Score
LEAP	Lower Extremity Assessment Project
METRC	Major ExtremityTrauma Research Consortium
MDR	Military Health System Data Repository
MTF	Military Treatment Facility
NJ	New Jersey
PDAFO	Passive Dynamic Ankle-Foot-Orthosis

PTOA	Post-traumatic osteoarthritis
RTD	Return to Duty
RTR-CP	Return-to-Run Clinical Pathway
S3	Surgical Scheduling System
SMFA	Short Musculoskeletal Form Assessment
SSI	Surgical site infection
SSWS	Self-selected walking speed
UK	United Kingdom
US	United States
USA	United States of America
VAS	Visual analog scale
VR-12	Veterans Rand 12 item health survey

CHAPTER 1

MANAGEMENT OF COMBAT-RELATED LOWER EXTREMITY INJURIES

1.1 Introduction

Following the terrorist attacks on 11 September 2001, the United States quickly found itself at war in Afghanistan starting on 7 October 2001 and later in Iraq in 2003. In 2019, nearly eighteen years later, US forces remain actively engaged in combat operations in both regions. In fact, since the start of conflicts in Iraq and Afghanistan nearly 2 million service members have been deployed, of which, over 6,000 have sustained orthopaedic injuries as a result of combat trauma.[1] While there are unfortunate effects of these conflicts, including many casualties, their protracted nature has allowed the investigation of the epidemiology and management of injury and wounding patterns.

The Joint Trauma System was created in 2004 in an effort to improve the care and optimize outcomes of the combat-wounded.[2] The Joint Theater Trauma Registry (JTTR), now known as the Department of Defense Trauma Registry (DoDTR), was launched prior to the establishment of the Joint Trauma System to record all US military patients evacuated through military medical facilities and their subsequent surgical procedures during evacuation. The JTTR can contain as many as 450 data elements for each patient. Between 2003 and 2008, there were over 23,000 patients recorded on this registry.[3,4]

During the early conflicts, Owens et al. (2008) used JTTR data to report on injuries sustained by a US Brigade Combat Team; injury patterns were similar to previous conflicts with the extremities sustaining the highest proportion of injuries (55%, 3,575/6,609).[5] Owens et al. (2007) found that 82% of all casualties within this US Brigade Combat Team (1281/1566 casualties) sustained an injury to the extremities. However, the mechanism of injury most commonly seen was blast or explosion (81%), which was much higher than reported in any prior conflicts.[6] These data are similar to a more recent report of UK combat casualties from 2003 to 2012, where it was noted that the extremities were most often injured (6,074/14,071; 43% total injuries) and most often the result of a blast injury (65%).[7] Similar to the US report, over three-quarters (1813/2348; 77%) of UK combat casualties in Afghanistan sustained an extremity injury.[8] In addition to the high prevalence of extremity injuries seen in the combat-injured during the recent conflicts, blast injuries, which have been the most common mechanism of injury, are typically very high energy and result in severe, life changing injuries.[9–11]

While the majority of combat wounds to the extremities are soft-tissue wounds (53%, 1895/3575), fractures comprise over a quarter of all extremity injuries (26%, 915/3575).[6] One observational study following 4,122 service members' in Iraq over a four year period found the incidence of fracture to be 11.4 per 1,000 combat years,[12] with the tibia and fibula being the most common fractures, which accounted for 48% (216/454) of lower extremity fractures.[6] These data were echoed by Chandler et al. (2017) who found that tibia and fibula fractures were the most common fractures in a UK cohort, with open tibia fractures accounting for 65% (159/244) of all tibia fractures.[8] Unlike civilian trauma which sees a higher percentage of closed fractures as opposed to open fractures, over 80% (758/915) of combat-related fractures are open.[6,13] This, again, demonstrates the severity of injuries sustained in combat. High energy lower extremity trauma has been common throughout these conflicts and, as a result, has become the focus of significant research in combat casualty care.[13–15]

1.2 Patterns of Combat Injury

During the early stages of the conflicts in Afghanistan and Iraq, physicians noted patterns emerging from the volume of combat injuries. Those soldiers that were commonly on patrol by foot were either receiving gunshot injuries to the extremities or what has become referred to as dismounted (i.e. on foot and not mounted in a vehicle), blast injuries. These injuries would commonly result in severe foot and lower limb injuries, often not salvageable.[10,16] Those soldiers mounted in vehicles had a characteristic pattern of injuries when exposed to an under-vehicle blast,[9,10] as this mechanism of injury often resulted in severe

foot and ankle trauma. As the conflicts persisted, the clinical care and reconstruction capabilities of the military surgeons, both in the combat environment and at larger tertiary military treatment facilities, continued to improve whereby severe limb injuries were being successfully salvaged.

1.2.1 Hindfoot Injury

Open calcaneus fractures account for fewer than 8.5% of all calcaneus fractures in the civilian population, but they occurred more frequently (43%, 122/283) during the recent conflicts.[17] Calcaneal fractures caused as a result of an under-vehicle blast also had a high association with concurrent tibia and fibula fractures (67%) and spine fractures (30%).[9] Those sustaining foot and ankle injuries as a result of an improvised explosive device had a primary amputation rate of 15% (13/89), and another 8% (7/89) underwent early amputation following medical evacuation.[10] In another series of combat-related open calcaneus fractures, a quarter of patients (11/40) underwent early amputation, which occurred prior to medical evacuation out of the area of combat operations. Ultimately, in this small patient cohort followed up over a mean of 33 months, 45% of patients (18/40) underwent amputation as a result of their injury.[9] This is a higher rate than typically observed in the civilian setting; the highest amputation rate after open calcaneus fracture was 14% (6/43) in one of the largest case series published.[18]

1.2.2 Tibia Fracture

As Owens et al. (2007) reported, the tibia was the most commonly fractured bone in the lower extremity in the combat injured, accounting for half (218/454; 48%) of all lower extremity fractures.[6] In one series of 244 combat-related tibia fractures, 65% were open fractures.[8] In another series of tibia fractures definitively treated at a tertiary referral centre for combat injuries, 82% were Gustilo-Anderson type III open tibia fracture.[19] These more severe injuries are typically seen much less frequently in the civilian trauma setting.[13] Due to the severity of these injuries, as many as 17% of combat-related type III open tibia fractures undergo early amputation (within 90 days of injury), which is comparable to amputation rates in the civilian setting for similar severe open fractures.[20,21]

1.2.3 Limb Amputation

In one of the first reports on amputations from the recent conflicts, Stansbury et al. found that between 2001 and 2006, US soldiers sustained 423 major limb amputations, defined as proximal to the wrist or ankle joint. This accounted for 7.4% of all major limb injuries at

the time.[22] In one study, using a deployed cohort of nearly 2 million service members, Belmont et al. (2013) found the rate of amputation to be 0.52 per 1,000 service members per year.[1] In a UK cohort, Chandler et al. found that 11% (205/1813) of UK soldiers with extremity injuries sustained a major limb amputation with approximately half having multiple amputations. In a more comprehensive analysis of 1,631 US soldiers with major limb amputations, Krueger et al. found transtibial amputations were the most common (n=683; 42%) with 30% (n=366) sustaining multiple limb amputations.[23]

1.3 Conclusion

The extremities are the most commonly injured body region in modern combat. The most common mechanism is blast injury and there are high rates of severe open fractures and amputation. Due to the severity of the injuries, a significant amount of resources were being utilized to care for these injured service members.[24] Despite efforts, many soldiers were medically retired or separated from the service because of "unfitting conditions" as a result of injuries sustained.[25]

Early in the Afghanistan and Iraq conflicts, there was limited guidance describing the management of high energy lower extremity trauma. Much of the clinical management of these injuries lacked a sound scientific basis as these are uncommon in the civilian setting and only through the recent creation of civilian trauma networks has quality research begun.[13,26,27] The next chapter explores early interventions in the care of combat-related extremity injuries in an effort to identify best practice for their management.

CHAPTER 2

AN ASSESSMENT OF EARLY TREATMENT OF COMBAT-RELATED EXTREMITY FRACTURES

2.1 Introduction

In order to understand the evolution of combat-related extremity care, the basics of combat care are firstly described. When a service member is injured in a combat operation, he or she is provided buddy-aid by another service member or medic within the unit on the battlefield (Role 1). Typically, for extremity care, this would include immediate/emergency care such as application of a pressure dressing, tourniquet, or providing basic limb immobilization/splinting in the field setting. They would then be rapidly transported to a higher level of care (Role 2). At the Role 2, which is designed to be a mobile surgical capability that can operate out of tent-like structures or fixed facilities, a forward surgical team, which typically consists of a 20-person team (composed of one orthopaedic surgeon, general surgeons, nurse anaesthetists, critical care nurse, and additional staff), can provide basic resuscitation and damage control surgery. These Role 2 medical units were spread throughout the area of combat operations in Afghanistan and Iraq. This was in an effort to provide every combat-injured service member with life and limb-stabilising surgical care within one hour of injury, based on evidence demonstrating improved outcomes after receipt

of appropriate surgical and resuscitative care within one hour of injury, termed the "Golden Hour."[28] In addition, these Role 2 facilities have limited holding capabilities which requires an injured service member to be immediately transferred once stabilised to a Role 3 facility (field hospital with similar capabilities to civilian trauma centres, with surgical subspecialists, a blood bank, physical therapy, laboratory, and radiographic services). From there, American soldiers would be evacuated through Landstuhl, Germany (Role 4), prior to returning to a military medical centre in the continental United States. Definitive management and rehabilitation of combat injuries would typically not occur until arrival at one of the military medical centres in the United States.[29]

Initial emergency surgical care is typically provided at the Role 2 or Role 3 facilities. Common procedures for extremity injury includes debridement and irrigation of soft tissue injuries and open fractures and external fixation of long bone fractures.[30] The existing guidelines for the management of combat-related long bone fractures consider transportation casts and temporary external fixation as acceptable means of initial treatment prior to evacuation out of the area of combat operations.[31,32] However, there were reports of surgeons performing definitive fixation in the combat environment, at Role 3 facilities, prior to evacuation.[33] This practice was concerning due to a number of reports documenting the high rate of deep surgical site infection (SSI) and osteomyelitis in patients with severe injuries.[34–36] Deep SSIs are serious complications, often requiring reoperation and prolonged treatment, and are a risk factor for major limb amputation.[20,21]

From these concerns rose frequent debates throughout the first half of the conflicts in Afghanistan and Iraq regarding the appropriate initial management of combat-related extremity fractures. An early cadaveric study demonstrated that external fixator pins could be placed without radiographic assistance, offering support for external fixation within the austere environment.[37] Whilst there was a growing body of evidence describing the benefit of temporary external fixation of long bone fractures in polytrauma patients in the civilian setting,[38,39] there were limited outcome data from the combat environment. There were some reports of external fixators used in Croatia and Somalia for the treatment of combat-related extremity fractures from the mid- 1980s and early 1990s. However, these reports were mostly small cases series, focused on definitive treatment using external fixators, or descriptions of the ease of application in the field environment. These reports lacked assessment of associated complications.[40–42]

Temporary external fixation in the combat environment has the distinct advantage of achieving fracture stability during medical evacuation. It also allows for acute wound

management as many of these injuries have large soft tissue wounds. For these reasons, it was standard practice during early years of the Afghanistan and Iraq conflicts for US military medical forces to perform temporary external fixation of long bone fractures prior to medical evacuation to the US.[43] Alarmingly, one of the initial reports of external fixation applied prior to evacuation was in a small cohort of combat-injured UK service members deployed in Afghanistan, where 13 of 15 external fixators applied required revision or complete removal due to complications. The most common complication was instability of the external fixator (10/13). As a result, the authors concluded that external fixation was of limited benefit when treating military injuries.[44] This report was controversial when compared to earlier literature and current practice of external fixation use for combat injuries. Although alarming, the results are not unsurprising given the significant challenges with placing external fixation in the combat environment. First, intra-operative fluoroscopy and/or radiographs were typically not available in the field setting. In addition, external fixator pins often had to be placed using a hand drill, which presents additional challenges. As a result, there was a need for a rigorous evaluation of the application of external fixations performed in the combat environment.

2.2 The Safety of Temporary External Fixation in the Combat Environment

2.2.1 Study 1 [Appendix 1]

Temporary External Fixation Is Safe in a Combat Environment. Possley DR, Burns TC, Stinner DJ, Murray CK, Wenke JC, Hsu JR, Skeletal Trauma Research Consortium. J Trauma 2010;69:S135-S139.

It was in the above context of clinical uncertainty regarding the safety of external fixation in the combat environment that we undertook a critical evaluation of the early management of combat-related extremity injuries. The initial step was to evaluate the safety of external fixators used in the temporary stabilization of severe open tibia fractures, graded as Gustilo-Anderson type III fractures.[45] Type III open fractures are those with significant soft tissue damage and periosteal stripping, those requiring soft tissue coverage, and/or an open fracture with an associated vascular injury requiring repair. We chose this fracture type for several reasons. First, open lower limb fracture was relatively common during the ongoing conflicts. Second, external fixation of these injuries was typically preferred over placement of a transportation cast or splinting due to the associated soft tissue wounds. Finally, these severe lower limb fractures always lacked inherent stability, even upon fracture reduction.

2.2.2 Development of a Classification Scheme

In order to evaluate the application and outcomes associated with application of external fixation in the combat environment, whereby intra-operative fluoroscopy is mostly unavailable, I determined potential factors that could be evaluated by any observer reviewing radiographs and medical records. These factors were determined after literature review and were grouped into categories by the research team based on their perceived severity.

Major complications comprised documented complications as a result of external fixator placement that resulted in either patient harm, or the need for significant revision fixation, i.e. mechanical failure. Pin track osteomyelitis was defined as positive bone cultures and those treated for presumptive osteomyelitis with six weeks of intravenous antibiotics at any point during the follow-up period. Deep wound infection or septic arthritis was defined as positive deep wound cultures without positive bone cultures. Minor complications were those complications requiring a minor intervention, i.e. pin removal or addition of bars or pins to increase stability. At the time, there were little data in the published literature describing over-penetration of external fixator pins. The external fixator pins commonly used by US and UK forces in combat operations was the Hoffmann (Stryker Howmedica Osteonics, Rutherford, NJ, USA) 5mm apex-pin, which has a distance of 6mm from the tip to the first threads. I chose to allow for over-penetration to be no more than three additional threads beyond the far tibial cortex. This equated to approximately 9mm. Topp et al. (2003), found that mean overpenetration of external fixator pins when fluoroscopy was not used in cadavers, was 13mm with a mean distance to neurovascular structures from the tip of the pin of 10.2 mm.[37] I therefore chose a range of 'shallow pin over-penetration' to be 9-25mm. Potential complications consisted of pins being placed within 25mm (approximately one inch) of the fracture, which is typically considered to be within the fracture hematoma, thus increasing the risk of infection at the fracture site.[46] The remaining 'Potential Complications' are all technical findings that could be observed on radiographs that were considered risk factors for a 'Major Complication.' For example, if a pin was placed within 14mm of the tibial plateau, which could have been intra-articular but did not result in septic arthritis (deep SSI), this was considered a 'Potential Complication.' If the same pin did result in the development of septic arthritis (deep SSI), it was considered a 'Major Complication.'

Table 1. Complications of temporary external fixator placement

Potential Complications
Pins within 1 inch of the fracture site
Loss of fracture reductions
Deep pin overpenetration ≥ 26mm
Soft-tissue pin placement (no cortical purchase)
Intra-articular pin placement (≤ 14mm from the tibial plateau or ≤ 10mm from the tibial plafond)
Minor Complications
Pin track infection necessitating pin removal
Shallow pin overpenetration (9mm – 25mm)
Frame instability requiring additional bars or pins
Major Complications
Neurovascular injury because of frame application
Mechanical frame failure
Pin track osteomyelitis
Septic arthritis because of intra-articular pin placement

This was a retrospective study whereby all patients with Gustilo-Anderson type III open tibia fractures who had a temporary external fixator applied in the area of combat operations (Iraq/Afghanistan) and were subsequently medically evacuated to Brooke Army Medical Center in San Antonio, TX between March 2003 and June 2007 were eligible for inclusion. Patients who sustained a tibia fracture were identified by searching the JTTR using ICD-9 codes. These patients were then cross-referenced with the Brooke Army Medical Center's Surgical Scheduling System (S3). We then performed a radiograph and medical record review identifying 45 consecutive patients with a total of 55 Gustilo-Anderson type III open tibia fractures. Two patients were excluded because of different treatment pathways. Patients were managed with temporary external fixation for a mean of 30 days (range, 5-135 days) before conversion to definitive fixation. The mean follow-up was 2.2 years after initial

external fixator application (range, eight months to five years). Ultimately, 53 total external fixator constructs in 43 patients (10 with bilateral tibia fractures) were included in the analysis with a total of 228 external fixator pins. Successful frame application was defined as the absence of major or potential complications, ie. risk factors for major complications, at latest follow-up (Table 1). While not performed during this study, as with the development of any new classification system, future research would benefit from determining its inter- and intra-observer reliability.

2.2.3 Key Findings from Study 1

We found no major complications recorded in the hospital medical records or observed on radiographic review. Minor complications occurred in 27/53 (51%) external fixator constructs and potential complications occurred in 12/53 (23%) constructs. Minor complications occurred in 28/228 (12%) external fixator pins and potential complications occurred in 21/228 (9%) pins inserted. Using our defined criteria, 77% of 53 external fixators applied in the field were successfully placed without any recorded potential or major complications. Despite this, 23% of external fixators had potential complications, i.e. risk factors for a major complication, although none occurred. In addition, because there were no major complications reported, we concluded that temporary external fixation was a safe means of stabilizing long bone fractures during the conflicts in Iraq and Afghanistan given the limitations within the environment. As a result, this review led to recommendations incorporated into the Joint Trauma System's Clinical Practice Guidelines for extremity fracture management in the austere environment.[47] In addition, surgical tips and techniques to avoid the complications observed have been incorporated into the Combat Extremity Surgical Course, which US military orthopaedic surgeons are required to attend every three years. This demonstrates successful dissemination of this work into military medical practice.

2.3 The Safety of Internal Fixation Performed in a Combat Environment

2.3.1 Study 2 [Appendix 2]

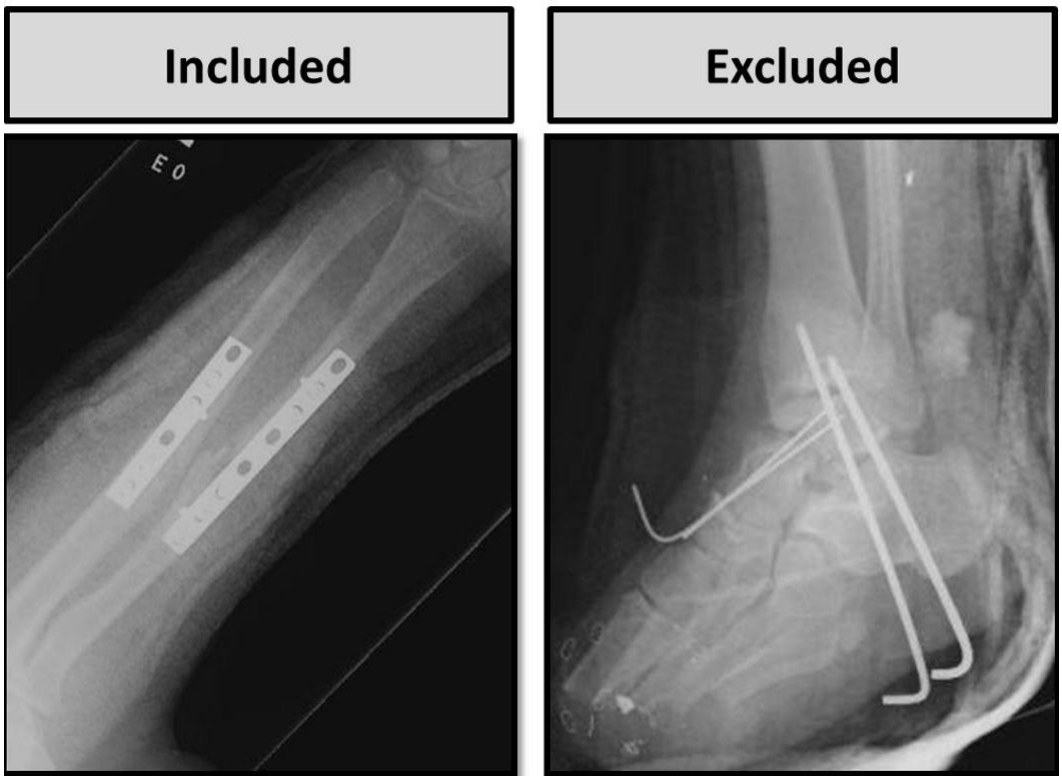
Outcomes of Internal Fixation in a Combat Environment. Stinner DJ, Keeney JA, Hsu JR, Rush JK, Cho MS, Wenke JC, Ficke JR, Skeletal Trauma Research Consortium. J of Surgical Orthopaedic Advances 2010;19(1):49-53.

Internal fixation undertaken in the area of combat operations was of concern, because of limited availability of surgical instruments and radiologic support, as well as concerns over

levels of sterility within field hospitals. Despite this, the occasional patient would be medically evacuated after definitive internal fixation was performed within the combat environment. In order to ensure optimal initial care was delivered, given the increased risk of SSI following combat-related musculoskeletal injury,[34,36] I sought firstly, to determine the number of patients having internal fixation performed in the combat environment and secondly, to describe the outcomes of these patients.

In order to identify eligible patients, I first identified all ICD-9 Procedural Codes relevant to internal fixation of extremity fractures (Appendix 8). Permission was obtained to search these codes within the JTTR from the US Army's Institute of Surgical Research, San Antonio, TX, USA. Inclusion and exclusion criteria were established. Ultimately, all service members who underwent internal fixation of an extremity, spine, or pelvic fracture prior to medical evacuation out of Iraq or Afghanistan were included. The initial search of the JTTR identified 124 eligible patients between 2001 and 2008. I developed Case Report Forms (CRFs) which included injury, treatment, and follow-up data (Appendix 9). I then reviewed all medical records and radiographs to ensure internal fixation was performed in the combat region prior to medical evacuation. Ultimately, 47 patients met inclusion criteria (Figure 1). Three patients had internal fixation performed on multiple fractures (two each). The remaining 77 patients were excluded because they were incorrectly coded (Figure 1). The mean follow-up was 17 months (range 2 weeks-5 years; median 15 months). Important findings in this cohort were that the most common mechanism of injury was blunt trauma (n=34; 68%), the mean (standard deviation) Injury Severity Score (ISS) was 11.4 (SD 1.1) (range, 4-34), and only one-third of the fractures were open. This was in direct contrast to the overall burden of combat-related extremity injuries during the conflicts where blast and penetrating mechanisms were most common; and open fractures are more prevalent, comprising as much as 82% of all fractures.[6] In addition, with a mean ISS of 11.4, it is clear that the majority of these patients were not the typical polytrauma patient that would commonly undergo damage control orthopaedics at a Role 2 or Role 3 facility.

Figure 1. Radiographic examples of fracture fixation. A fracture that was included and one that was excluded are shown. The talar neck fracture dislocation on the right was excluded because the method of fixation included wires that penetrated the skin.



2.3.2 Key Findings from Study 2

The three most common injuries recorded in these 47 patients (50 fractures) were 1) proximal femur fractures (which are difficult to stabilize with external fixation unless the hip is spanned with the external fixator extending from the pelvis to the femur, making transport more challenging), 2) forearm fractures, and 3) ankle fractures (Table 2). Thus, these injuries were not the characteristic injuries sustained during the recent conflicts, such as type III open tibia or open calcaneus fractures described in chapter 1.

Table 2. Injury characteristics of fractures that underwent internal fixation.

Fracture (total)	Closed (34)	Open (16)	Total (50)
Ankle	10	0	10
Clavicle	0	1	1
Hip	10	4	14
Forearm	6	8	14
Humerus	0	2	2
Patella	2	0	2
Spine	0	1	1
Talus	4	0	4
Tibia	2	0	2

Most of the fractures (39/50; 78%) that underwent definitive fixation prior to medical evacuation healed without the need for further intervention. There was one post-operative infection (2%), which occurred four weeks after surgery, one intra-operative complication, and two patients with missed injuries that required additional surgical intervention (4%) (Table 3).

Table 3. Additional procedures performed following medical evacuation.

Fracture Location	Open/ Closed	A/O Classification	Reason for Additional Procedures	Additional Procedures Performed
Ankle	closed	44B	1. Sub-optimal placement of syndesmosis screw was not through the syndesmosis 2. Medial malleolus fracture not fixed	1. Revision syndesmosis ORIF 2. ORIF medial malleolus fracture
Ankle	closed	44B	1. Medial clear space widening 2. Post-operative infection	1. Syndesmosis ORIF 2. Debridement and irrigation (2)
Hip (femoral neck)	closed	31B	1. Nonunion, hardware failure	1. Total Hip Arthroplasty (1 year after initial fixation)
Hip (femoral neck)	open	31C	1. Iliac artery bypass graft	1. Augmentative hip-spanning external fixator
Forearm	closed	22C	1. Delayed union	1. Bone graft (10 weeks after initial fixation)
Forearm	open	22B	1. Symptomatic hardware	1. Hardware removal (1 year after initial fixation)
Forearm	open	23C	1. Delayed union	1. Revision ORIF with bone graft (6 weeks after initial fixation)
Patella	closed	comminuted	1. Symptomatic hardware	1. Hardware removal (Date unknown)
Hip (Subtrochanteric)	closed	32A	1. Symptomatic hardware	1. Hardware removal (2 years after initial fixation)
Tibia (Tibial Plateau)	closed	41B	1. "Improved fixation"	1. Revised to buttress plate

Whilst these results are in line with outcomes that might be anticipated in a definitive or civilian setting,[48,49] this series is too small for making definitive statements about safety

(especially regarding uncommon events such as deep SSI). In addition, patient-reported outcome measures were not measured. However, these were infrequent occurrences on the US Joint Trauma Theater Registry, which at the time of my search, held data on over 23,000 injured service members.[3] Therefore, this was the largest military cohort available. The data were consistent with the use of internal fixation undertaken in the combat environment, in certain limited circumstances, being relatively safe provided the appropriate surgical facilities and resources are available.

2.4 Conclusion and Impact on the Management of Combat-Related Extremity Injuries

My assessment of the early treatment of combat-related extremity fractures suggested that the initial management within the area of combat operations was good. External fixators were being applied safely in most cases. Whilst internal fixation was being performed on a select few patients, surgeons were mostly performing internal fixation in appropriate cases, which resulted in acceptable outcomes regarding infection and secondary operations. Given our successful evaluation of temporary external fixation, it has remained the standard for surgical stabilization of long bone injuries in the combat environment, except in relatively unusual situations such as proximal femoral fractures.[32]

This chapter described the early treatment of combat-related extremity trauma; the next chapter will explore patient outcomes in those with severe lower extremity injuries, through examination of the recovery trajectory, examining return to military duty. In addition, I will describe an emerging problem: the decision to undergo late amputation after perceived failed limb salvage.

CHAPTER 3

EVALUATION OF OUTCOMES AFTER COMBAT-RELATED LOWER EXTREMITY TRAUMA

3.1 Introduction

When a service member sustains a severe lower limb injury in combat, usual management is either limb salvage or amputation. Many clinical decision tools and scoring systems have been developed to help the clinician decide whether a severely injured limb should be amputated or not; none of these tools accurately predict functional recovery following limb salvage.[50,51] To make the decision more difficult, the best available data reporting outcomes of amputation versus limb salvage following high energy civilian trauma found no difference in outcomes at both two and seven years following injury.[52,53] As a result, the orthopaedic surgeon is left to their own clinical judgement. For the injured service member, this assessment occurs at each step of the medical evacuation pathway, and often continues throughout the reconstructive process.

Many factors, from both the surgeon and the patient perspective, influence the decision to reconstruct or amputate a severely injured lower limb. Clinical factors include the severity of injury (both to the bone and soft tissues), hemodynamic status at time of presentation, patient comorbidities, and viability of the terminal extremity, among others. While many of these factors may influence the decision to amputate or reconstruct a severely injured lower limb from the orthopaedic surgeon's perspective, other factors may play a significant role in the decision-making process from the patient perspective. For example, limb salvage often has a lengthy recovery process and patients often undergo more operations than those undergoing early amputation for similar injuries.[20] In addition, during the early years of the conflicts in Afghanistan and Iraq, there was a specific amputee advanced rehabilitation program with dedicated resources and state-of-the-art prosthetics, while no such program existed at the time for those undergoing limb salvage.[54] Furthermore, those injured in combat who sustained an amputation were easily identified and openly supported by the public due to the absence of a limb, whereas those undergoing limb salvage following combat injury were often much more difficult to identify due to the presence of all of their limbs. Finally, prior to 2008 there were significant differences in financial compensation to the injured service member where the service member with an amputation received more compensation than the service member undergoing limb salvage.[55]

While there are various factors that influence the decision to amputate or reconstruct a severely injury lower limb, early in the conflicts in Iraq and Afghanistan, there were little data describing long-term outcomes of these patients to help guide the decision-making process. Typically, data published at the time consisted of small case series describing a single surgical team's experience and outcomes focused on fracture union or infection.[30] As a result, there was a need for a better description of short and longer term clinical and patient-reported outcomes for these patients.

3.2 Assessment of Clinical Outcomes Following Combat-Related Amputation and Limb Salvage.

3.2.1 Study 3 [Appendix 3]

Return to Duty Rate of Amputee Soldiers in the Current Conflicts in Afghanistan and Iraq. Stinner DJ, Burns TC, Kirk KL, Ficke JR. J Trauma 2010;68:1476-1479.

One commonly accepted outcome measure after injury or healthcare intervention is return to work. Within the military, this is referred to as 'returning to duty' (RTD). Following

a severe injury, a service member is required to undergo a Physical Evaluation Board (PEB) assessment of their ability to remain on active duty. During their recovery process, one of their first questions is often, "when will I be able to return to my unit?" In other words, they want to return to work to 're-join the fight' and help their 'team.'

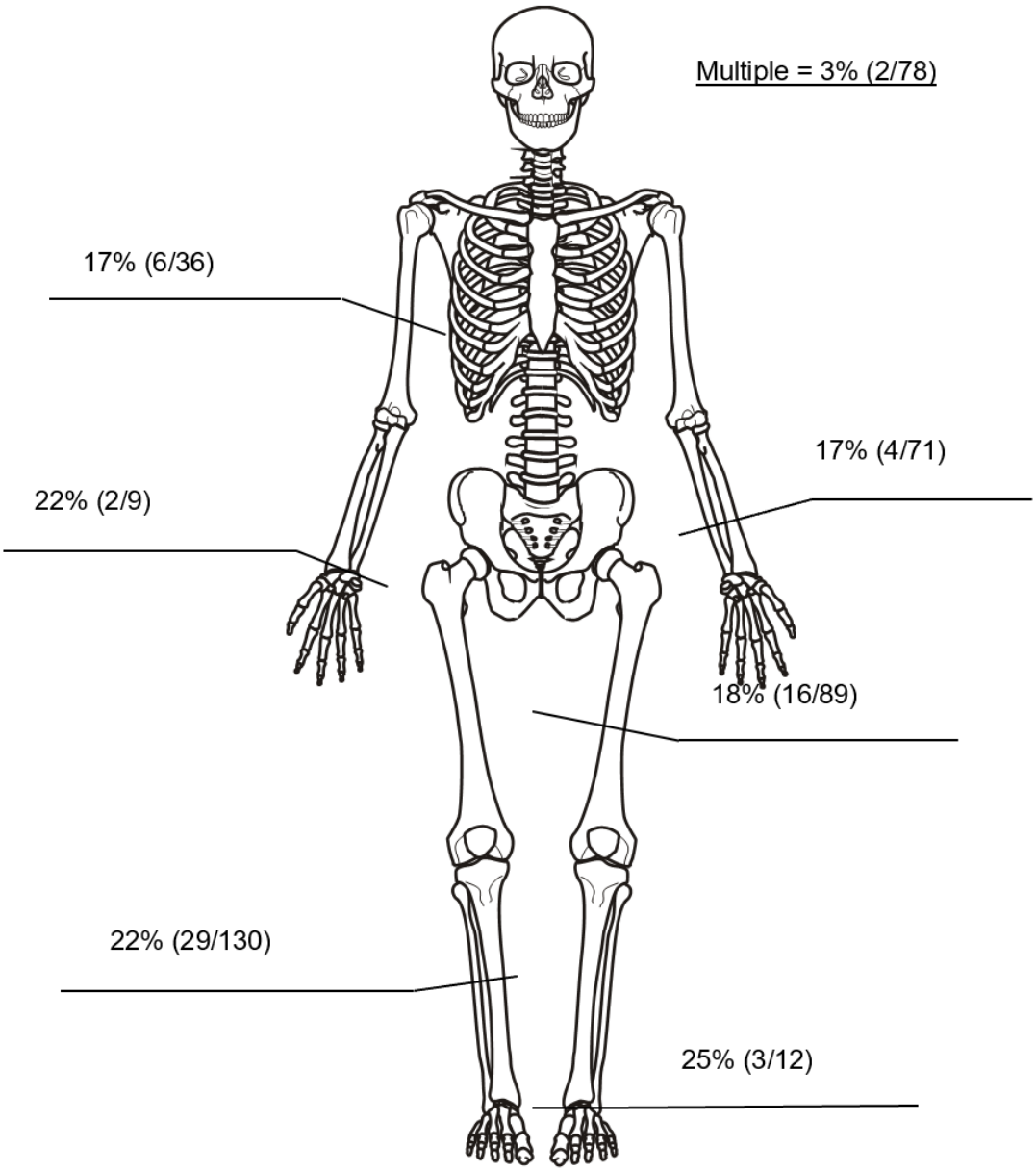
After the Gulf War (Operation Desert Shield and Operation Desert Storm: August 1990 to February 1991), Kishbaugh et al. (1995) reported that only 2% of military amputees (11/469) returned to duty. It is important to note that of this cohort of those returning to duty, six personnel had partial hand amputations. The authors concluded that returning to duty after any amputation was rare.[56] During the recent conflicts, those with traumatic amputations were becoming a recognized cohort as they accounted for 2% of all battle injuries and 7% of major limb injuries.[22] Major limb amputations were occurring at rate of just over 2 per 1,000 personnel deployed per year.[1] As of 2015, there were over 1600 US military service members with a combat-related amputation from the recent conflicts in Iraq and Afghanistan.[57] For these reasons, and because I could compare the current RTD rate of amputees to those of a previous conflict, I chose to investigate rates of RTD in the amputee population.

This study was a retrospective review using the established PEB database, maintained in San Antonio, TX, USA, which receives approximately 5,000 new cases per year,[58] to identify those who presented to the PEB after they sustained a combat-related major limb amputation. These patients had amputations defined as at or proximal to the wrist in the upper extremity and at or proximal to the ankle in the lower extremity. All entries logged between October 2001 and June 2006 were eligible. If a service member is unable to return to active duty when they have reached the point of maximal medical improvement, as determined by their treating physician, they are referred for an evaluation by the PEB. Due to the severity of their injury, all amputees must be referred for a PEB. The service members identified in the PEB database were then cross-referenced with those entered into the Military Amputation Database, which was a separate registry of all combat-related amputees maintained by Walter Reed Army Medical Center in Bethesda, Maryland. While this database often lacked the PEB final disposition, it contained additional patient specific information not found in PEB. The electronic medical records of all combat-related amputees identified were then reviewed at a minimum of two years post-amputation to confirm patient demographics, injury characteristics, and PEB final disposition (either returned to duty or separated from service).

3.2.2 Key Findings from Study 3

Of the 395 service members identified with major limb amputations, 65 returned to duty (17%). Officers and senior enlisted personnel returned to duty at a higher rate than junior enlisted personnel (35%, 23%, and 7%, respectively). The mean age of service members returning to duty was four years older than those who separated from the service (31 vs. 27 years). Finally, while the overall RTD rate following major limb amputation was low, 22% of those with an isolated transtibial amputation, which was the most common amputation level, returned to duty compared to only 3% of those with multiple major limb amputations (Figure 2).

Figure 2. Personnel returning to work by site of amputation, as proportion (%) of those with amputation at that level. (Total Amputees=395)



3.2.3 Comparison of Key Findings to Prior Studies and other Injury Patterns

These data were immediately incorporated into clinical practice within the military to help decision-making when counselling injured patients, i.e. whether to perform an early amputation or attempt limb salvage, when put in the context of other injury patterns. These are important data when comparing to the previous study by Kisbaugh et al. (1995) who, using the same PEB database, reported a return to duty rate of 2% following amputation. In this previous study, over half of the patients that returned to duty had partial hand amputations, which were excluded in the current analysis.[56] If partial hand and partial foot amputations were included in the current analysis, the overall RTD rate would be higher than 17%. In addition to knowing the current RTD rate of amputees following combat-related injuries, it is also helpful to know the RTD rate of other comparable injuries for data to be considered in context.

In a separate publication, we (Cross et al. 2012) performed a retrospective review of combat-related Gustilo-Anderson type III open tibia fractures in a US military cohort.[59] We found that the overall RTD rate was 18% (21/115), but this improved to 22% for isolated type III open tibia fractures (17/76).[59] Interestingly, this is a similar RTD rate to that found for those with isolated transtibial amputations.[60] However, only 13% (4/32) of those with a type III open tibia fracture that subsequently went on to amputation after an initial attempt at limb salvage returned to duty.[59] Sheean et al. (2014) examined RTD following combat-related hindfoot injury and found an overall RTD rate of 20% (24/122), but of those with a hindfoot injury that went on to amputation, the RTD rate was 12% (7/57).[61] While the RTD rates are similar among severe injuries to the lower extremity, the overall low RTD rate highlights that there is room for improvement. Furthermore, the difference in RTD rates between limb salvage and acute amputations compared to those undergoing amputation after an attempt at limb salvage raises some concerns.

3.3 Defining an Emerging Problem: The Late Amputation

As a result of the conflicts in Afghanistan and Iraq and a new young amputee cohort, the US military established an Amputation Rehabilitation Program. This program gave new amputees access to state-of-the-art rehabilitation facilities, including cutting edge prosthetics and peer-support. As a result, many amputees excelled in their rehabilitation and exceeded traditional recovery expectations. For example, studies have demonstrated that the metabolic demands of transtibial amputees is between 9-33% greater than nondisabled individuals. However, a recent study by Esposito et al. (2014) showed that the metabolic demand of

amputees treated at these advanced rehabilitation facilities was equivalent to able-bodied controls when walking at the same velocity.[62]

During this same period, the Lower Extremity Assessment Project (LEAP) Study Group[52,53] began publishing the findings of their prospective observational study comparing outcomes of those undergoing limb salvage or amputation following high energy civilian lower extremity trauma. In 545 patients, they found no evidence of a difference between groups using the patient-reported Sickness Impact Profile, when assessed at two and seven years after injury.[52,53] However, they did find that several non-treatment related factors affected outcome, such as poor social-support network and low self-efficacy.[53] These are typically areas where many in the military excel, given the structure of the military and inherent support systems.

Several follow-on studies from the LEAP Study Group showed that many patients have a perceived need for vocation, mental health, and other support services following high energy trauma and these are not met during the first year of recovery.[63] What makes this worse is that those with a perceived need for physical therapy following lower extremity trauma who do not receive it, have worse outcomes.[64] This may explain why a retrospective cohort study (n= 324) by Doukas et al. (2013) comparing combat-injured amputees and limb salvage patients found that amputees tended to have better functional outcomes than limb salvage patients.[11] Whilst this study was ongoing, military amputees had a rehabilitation pathway that included a multitude of vocational, mental health, and social support programs and resources. During this same period, there was no structured rehabilitation program for the limb salvage patients. In a retrospective comparison of combat-injured limb salvage patients, early amputees and late amputees, Melcer et al. (2013) found that those undergoing early amputation improved in several areas, including psychiatric diagnoses. However, it is important to note that they also had more access to rehabilitative services as evident by having a greater number of outpatient visits for psychiatry, occupational therapy, and physical therapy.[65]

It was not uncommon for limb salvage patients to be discouraged during their recovery process, whether due to functional limitations or complications, and to consider undergoing late amputation. Due to growing concerns about the number of late amputations occurring long after initial injury, we investigated this further.

3.4 The Prevalence of Late Amputations Following Combat Injury

There have been over 1,600 US military service members who have sustained a combat-related amputation during the conflicts in Iraq and Afghanistan.[57] Many of these amputations are performed in the days immediately following injury, but some occurred months to years after initial injury. In order to gain a better understanding of the trajectory of recovery after traumatic injury, we investigated the pattern and occurrence of late amputations.

3.4.1 Study 4 [Appendix 4]

Prevalence of Late Amputations during the Current Conflicts in Afghanistan and Iraq. Stinner DJ, Burns TC, Kirk KL, Scoville CR, Ficke JR, Hsu JR, Late Amputation Study Team. Mil Med 2010;175(12):1027-1029.

A retrospective review of the Military Amputee Database was conducted to identify all combat-related amputations from October 2001 to June 2006. Electronic medical records and radiographs were reviewed to confirm demographic, injury, and amputation information, including time from injury and level of amputation. At the time, there was no consensus definition for a 'delayed' or 'late' amputation. The LEAP Study Group compared civilian patients who sustained high energy lower extremity trauma who had an amputation at four time intervals; within 24 hours, between 24 hours after injury and hospital discharge, between the first hospitalization and three months after injury, and greater than three months after injury. Patients who had their amputation more than three months after injury had worse outcomes at two years.[66] I chose to define 'late amputation' as those occurring more than three months following injury for this reason and the fact that it allowed adequate time for initial limb reconstruction.[66] Out of the 348 lower extremity amputees identified from the database within the time period studied, 53 (15%) of the amputations fulfilled the definition of late, with over half of these occurring more than one year following their injury (Table 4).

Table 4. Time between injury and late amputation.

Time to Amputation	Amputees, *n* (%)
3-6 months	8 (15%)
6-12 months	17 (32%)
12-24 months	19 (36%)
> 24 months	9 (17%)

3.4.2 Key Findings from Study 4

There were several key results learned from this study. Firstly, the prevalence of late amputation (15%) within the cohort of combat-related amputations was higher than previously reported in the current conflicts. While the authors did not define late amputation, Stansbury et al. reported early in the Iraq and Afghanistan conflicts that 95% (404/423) of all combat-related amputations were traumatic, i.e. acute. In our study, more than half of the late amputations occurred more than one year post-injury (53% ≥ 12 months). This correlates with a more comprehensive study subsequently performed by Krueger et. al (2012) that reported a mean of 473 days after injury in those undergoing late amputation.[23] Finally, we found that 70% (37/53) of those undergoing late amputation had a transtibial amputation, similar to that reported by Kruger et al. (92/127, 72%).[23]

As discussed previously, in the combat-injured military cohort, the transtibial amputation can be an extremely functional level. While data at the time was limited, amputees did anecdotally appear to have better functional outcomes. However, one must remember that early in the conflicts, the limb salvage patients had limited access to advanced rehabilitation resources, which have been associated with improved outcomes.[63,64,67]

3.5 Conclusion: The Evolving Problem Defined

I found that 17% of amputees returned to duty, higher than reported a decade earlier (2%), using the same PEB database.[56,60] I also found that when comparing similar injuries, i.e. isolated transtibial amputation to isolated type III open tibia fracture, a similar proportion returned to duty (22%).[59] Despite this, the number of late amputations was alarmingly high. While this could be due to multiple factors to include the development of deep SSIs,[20] one concern was the discrepancy in rehabilitation and resources between patient populations. In the next chapter I present an investigation of a novel custom passive dynamic ankle-foot-orthosis (PDAFO) that, when coupled with an advanced rehabilitation program, may improve outcomes in those with severe lower extremity injuries.

CHAPTER 4

OPTIMIZATION OF OUTCOMES FOLLOWING LIMB SALVAGE

4.1 Introduction

In response to the perceived improved outcomes observed in military amputees when compared to limb salvage patients, a multidisciplinary rehabilitation program for limb salvage patients was developed in 2009. This program would eventually be referred to the Return to Run Clinical Pathway (RTR-CP), as the common goal for patients was the ability to run again. While there were noticeable similarities between this program and the military's Amputee Rehabilitation Program, there were several distinct differences due to the nature of the injuries (retained limb vs. amputation). This program centred around the custom passive-dynamic-ankle-foot-orthosis (PDAFO), also referred to as the Intrepid Dynamic Exoskeleton Orthosis or IDEO™. This device was developed to offload the injured hindfoot or tibia, which is often the pain generator in these patients, and to restore function while minimizing pain with activity. The orthosis was coupled with an intense rehabilitation program, the RTR-CP. This program was developed with a sports medicine approach, thus focusing on strength, plyometrics, power, and agility.

Initially, the rehabilitation program was designed for patients undergoing complex limb reconstruction with ringed external fixators. Phase one of rehabilitation would begin whilst wearing the fixator. Once the frame was removed, patients were fitted with the custom PDAFO and commenced on a more advanced phase, with a goal of progressing to running and returning to a high level of function. Owens et al. (2011) reported on the first ten patients to complete the program, all with severe lower extremity fractures, eight of which returned to running and all returned to some form of advanced functional activity.[68]

One important aspect of the RTR-CP is that it is multidisciplinary. Some initially believed that the success seen was only due to the new custom PDAFO. However, as subsequent data would prove, the success of the PDAFO was dependent on other elements, most notably, the physical therapy program. In evaluating the first 146 patients to receive the custom PDAFO, Blair et al. (2014) found that 31 patients did not participate in the physical therapy program while 115 completed the program after receiving the PDAFO. The return to duty rate for those who received the PDAFO only was 13% compared to over 50% for those receiving the device and completing the rehabilitation program.[69] At the time of this study, the typical program duration was a minimum of four weeks of daily (Monday-Friday) physical therapy sessions after receiving the brace. Subsequent efforts have been made to scale this down to make it more generalizable.

These initial reports suggested success with the new custom PDAFO when used in conjunction with the RTR-CP, but this device had to be compared to braces that were already commercially available for patients with these injury patterns. A small comparative study by Patzkowski et al. (2012) was performed comparing functional outcomes of patients using the new custom PDAFO to two other commonly used, commercially available ankle-foot-orthoses, the Allard BlueROCKER® and the Posterior Leaf Spring, as well as to no brace. Eighteen patients underwent a testing session completing a series of validated functional measures. The order of brace used for each testing session was randomised. Performance was significantly (statistically) better in all functional measures tested (four square step test, timed stair ascent, self-selected walking speed, and 40 yard dash) except the sit-to-stand five times test for the PDAFO compared to each of the commercially available braces and to no brace. Perhaps more importantly, the majority of patients (17/18) also preferred the custom PDAFO over the other braces tested.[70]

4.2 Need for Prescriptive Referral Guidance for a Custom Orthosis and Rehabilitation Program

In addition to the small clinical series being published on this new PDAFO and the RTR-CP, a variety of biomechanical studies were being performed to understand the biomechanics of the brace and to evaluate avenues for optimisation.[71–73] However, through all of this, there was little published literature describing the characteristics and injury patterns in patients who would likely benefit from the new orthosis and rehabilitation program used in the military setting.

4.2.1 Study 5 [Appendix 5]

Descriptive Characteristics and Amputation Rates With Use of Intrepid Dynamic Exoskeleton Orthosis. Hill O, Bulathsinhala L, Eskridge SL, Quinn K, Stinner DJ. Military Medicine 2016;181(S4):77-80.

As previous reports have shown, to include my research described in Chapter 3, late amputations account for up to 15% of combat-related amputations.[20,23,74] Additionally (in a paper not included in this thesis), we (Huh et al., 2011) showed that those with late amputation (11/213) following a combat-related type III open tibia fracture required more reoperations (mean=three reoperations for those going on to late amputation, two reoperations for early amputation, and only one for successful limb salvage).[20] In addition, they had higher rates of deep SSI (73% (8/11) for late amputation) compared to those undergoing early amputation (15/36; 42%) or successful limb salvage (34/166; 21%).[20] This demonstrates the severity of these injuries and complicated limb-reconstruction trajectory.

While, at the time, the benefits of the new custom PDAFO were described in limited case reports and case series, the specific injury patterns that benefit from the brace had yet to be defined. We undertook an epidemiologic study to identify patterns of device prescription and correlation with subsequent amputation, which was defined as a treatment failure. This retrospective study was based on data extraction from multiple medical and defense registries: the Expeditionary Medical Encounter Database (EMED), Defense Manpower Data Center (DMDC), Military Health System Data Repository (MDR), and patient records at the Center for the Intrepid. Multiple sources were utilized to ensure the most robust patient cohort receiving the custom PDAFO, as each data source did not represent the entire cohort that received the brace. The aim was to identify all patients prescribed the PDAFO between 2009, which was when the brace was first developed, and 2014 at the Center for the Intrepid. At the time, nearly all custom PDAFOs were being prescribed at the Center for the Intrepid, San Antonio, TX. Variables extracted from databases included patient demographics, military characteristics, initial primary referral diagnosis, and date of initial evaluation at the Center

for the Intrepid. If the patient had an ICD-9 code or procedure code for amputation that occurred following initial evaluation at the Center for the Intrepid, they were considered a treatment failure. A total of 624 eligible patients were identified. Due to inconsistencies in the medical records, only 533 patients had a clear referral diagnosis and were included in the analysis of amputation by diagnostic category. Using the referral diagnosis, I grouped injury patterns for the referral diagnosis into injury types or categories. The seven injury types were: 1) nerve injury below the knee, 2) tibia (excluding pilon fracture), 3) ankle (pilon fracture, ankle post-traumatic osteoarthritis, and ankle fusion), 4) hindfoot (hindfoot PTOA, fusion), 5) midfoot/forefoot, 6) soft tissue (compartment syndrome, Achilles tendon injury), and 7) other. These are shown in Table 5 and the percentages for each category going on to subsequent amputation are shown in Table 6.

Table 5. Referring injury diagnosis, *n*=533.

Injury	Description	*n* (%)
Ankle	Pilon fracture, post-traumatic osteoarthritis, fusion	139 (25)
Tibia	Fracture, excludes pilon fracture	96 (18)
Nerve injury below knee	Functional deficit below knee	91 (16)
Hindfoot	Post-traumatic osteoarthritis, fusion	79 (14)
Soft tissue	Compartment syndrome, Achilles tendon injury, quadriceps injury	33 (6)
Midfoot/Forefoot	Foot pain, midfoot/forefoot post-traumatic osteoarthritis, toe amputation	21 (4)
Other	Osteomyelitis, late effects of fracture, nerve injury above the knee	93 (17)

Table 6. Amputations per Injury Type.

Injury Type	Amputated (*n*, %)
Ankle	19 (14%)
Nerve injury below knee	13 (14%)
Other	19 (20%)
Tibia	22 (23%)
Hindfoot	21 (27%)
Soft tissue	9 (27%)
Midfoot/Forefoot	6 (29%)

4.2.2 Key Findings from Study 5

This retrospective record review study yielded good quality information on the variety of referral diagnoses of patients who had plateaued through traditional rehabilitation programs and were subsequently referred for the custom PDAFO. Specifically, I determined that most patients being prescribed the custom PDAFO had either an ankle injury (n=139; 25%), tibia injury (n=96; 18%), nerve injury resulting in a functional deficit below the knee (n=91; 16%), or hindfoot injury (n=79; 14%). In addition, I found that fewer than 20% (121/624) of patients prescribed the custom PDAFO went on to late amputation. While this rate may seem high, it is important to note that it was common practice at the time for clinicians to refer patients to receive a custom PDAFO and participate in the RTR-CP who were considering amputation as a result of functional limitations and/or chronic pain. Many of these patients may have already made up their mind that they wanted an amputation, but we would not comply until they had attempted the RTR-CP. This is of importance when considering the fact that over half (64/121) of the patients that went on to amputation had the procedure within three months of referral for the custom PDAFO. This is barely enough time to receive the brace and complete the program, which together is a minimum of eight weeks. What we can glean from these data is that those with ankle injuries and nerve injuries resulting in functional deficits below the knee had the lowest rates of late amputation, (n=19; 14%) and (n=13; 14%), respectively. Furthermore, those with midfoot/forefoot injuries, soft tissue injuries, and hindfoot injuries were the most likely to go on to late amputation with all three categories having a late amputation rate of greater than 25%. These results have helped to guide current prescriptive patterns and are being used to further delineate injury patterns where the custom PDAFO is likely to be effective.

4.3 Need to Improve the Quality of Data Describing Outcomes of Those Receiving a Custom PDAFO and Participating in the Military Rehabilitation Programme (RTR CP)

4.3.1 Study 6 [Appendix 6]

Can an Integrated Orthotic and Rehabilitation Program Decrease Pain and Improve Function After Lower Extremity Trauma. Bedigrew KM, Patzkowski JC, Wilken JM, Owens JG, Blanck RV, Stinner DJ, Kirk KL, Hsu JR. Clin Orthop Relat Res 2014;472:3017-3025.

To further study the effect of the RTR-CP and custom PDAFO, we began a prospective, longitudinal, cohort study. A case report form was created to prospectively

record data for each testing session (appendix 10). Patients were included if they were active duty military with a functional deficit of the lower extremity related to: muscle weakness; a nerve injury; volumetric muscle loss; or significant pain preventing a return to normal function and full rehabilitation participation. In addition, they had to have completed all planned surgical interventions on their injured extremity and must be willing to complete the RTR-CP. The final study group consisted of 84 patients with a heterogenous group of lower extremity injuries (Table 7). Patients were also grouped into one of two groups based on time of entry into the program in relation to their injury. The 'Late Entry' group was defined as beginning the program more than two years following injury (n=31) and the 'Early Entry' group was defined as entering the program within two years of injury (n=53). Reasons for functional limitations at entry into the program included lower extremity weakness (87%), mechanical pain (80%), stiffness (64%), neuropathic pain (52%), and muscle loss (25%).

Table 7. Lower extremity diagnoses.

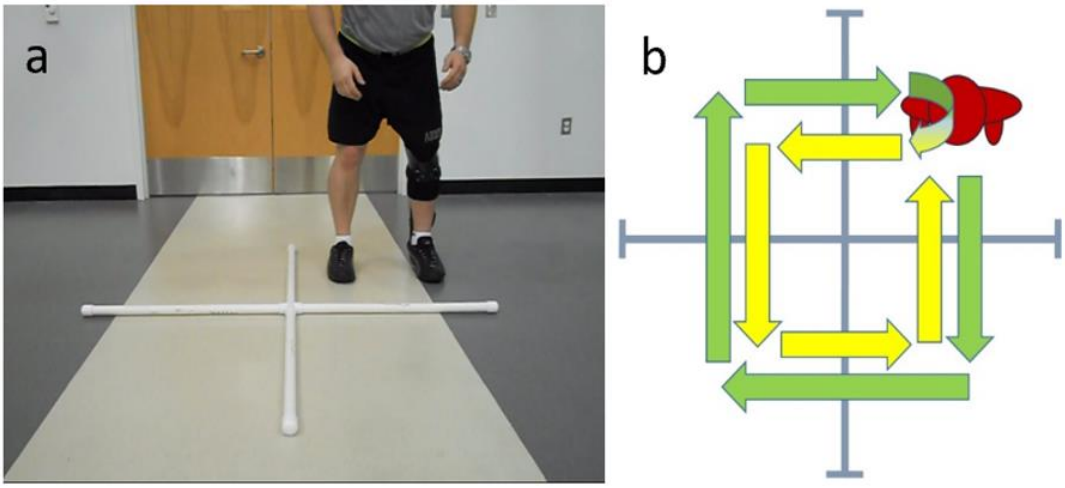
Diagnoses	Patients (%)
Fractures	58 (69%)
Femur	2 (2%)
Tibia (diaphyseal)	20 (24%)
Tibial plafond/ankle	23 (27%)
Hindfoot (talus/calcaneus)	29 (35%)
Midfoot/Forefoot	12 (14%)
Nerve injury	53 (63%)
Proximal to the knee	8 (15%)
Distal to the knee	45 (85%)
Osteoarthritis	6 (7%)
Post-traumatic	5 (6%)
Degenerative	1 (1%)

For this cohort study, all patients completed an initial month of physical therapy targeting strength training, functional movement, and core muscle strengthening while their custom PDAFO was being fabricated. The goal of the program was to prepare the patient for the four weeks of therapy using the custom PDAFO. After receiving the custom PDAFO, patients then had an additional month of physical therapy focused on correct use of the device to maximize energy storage and return during both high- and low-impact activities. Physical performance measures and validated patient-reported outcome measures were completed at week 0 (start of the program), week 4 (before receiving the custom PDAFO), and week 8 (conclusion of the four weeks of training with the custom PDAFO) (Appendix 10). Patient-reported outcome measures included the Short Musculoskeletal Function Assessment (SMFA), the Veterans Rand 12 (VR-12), and visual analogue pain scale (VAS). Physical performance measures tested included the four square step test (Figure 3), the timed stair ascent, self-selected walking speed, and the 20-meter shuttle run (Table 8). All of these measures, except the 20-meter shuttle run, have been validated in a young, healthy active-duty military population.[75] Three trials of each physical performance measure were performed at each time interval.

Table 8: Description of the Physical Performance Measures Tested at Week 0, Week 4, and Week 8.

Physical Performance Measure	Description
Four Square Step Test	The Four Square Step Test (FSST) is a dynamic test of balance and mobility.[76,77] The test measures an individual's ability to move forward, backward, and laterally over an obstacle measuring approximately one inch in height. The subject begins in one quadrant and steps forward into the next quadrant, brings the second foot into the same quadrant, then moves laterally, backwards, and laterally again, each time bringing both feet into the respective quadrant before stepping off to the next quadrant. Once the individual is back at the starting point, they repeat the cycle in reverse as shown in the figure 3. The patient is allowed one practice followed by three timed trials.
Timed Stair Ascent	The Timed Stair Ascent is an objective measure of mobility and power. The patient is instructed to ascend 12 stairs as fast as possible while touching each stair with alternating feet without use of the handrail. The patient is timed from the start of the test to the point at which both feet have reached the 12th step.[75]
Self-Selected Walking Speed	The self-selected walking speed is a general test of mobility. Patients were instructed to walk 25 meters at a comfortable pace. The middle 15 meters was timed and the patient's speed calculated.
20-Meter Shuttle Run	The 20-meter shuttle run assesses a patient's power and ability to change pace. To complete the shuttle run, patients were instructed to move to a cone 10 meters away and return as quickly as possible.

Figure 3. Four Square Step Test. A patient can be seen preparing to start the four square step test (a). The patient will step into each quadrant with both feet before progressing to the next quadrant until the patient returns to the starting quadrant (following the green arrows) and then the process is repeated in reverse (yellow arrows) (b).



4.3.2 Key Findings from Study 6

Patients improved in all four physical performance measures over time (Table 9). Patient-reported outcome measures improved after completion of the program, including all subcategories of the SMFA (except arm), pain scores, and physical quality of life (Table 10).

Table 9. Physical Performance Measures at Week 0, Week 4, and Week 8. Mean ± SD (standard deviation) for healthy controls and MDC_{95} (minimal detectable change 95% confidence interval) provided for reference.[75]

Physical Performance Measure	Week 0	Week 4	Week 8	Mean ± SD for Healthy Controls	MDC_{95} Test-Retest Reliability
Four Square Step Test	10.9 s	9 s	6.7 s	5.7 ± 1.0 s	1.41 s
20m Shuttle Run	1 m/s	1.6 m/s	2.6 m/s	Not available	Not available
Self Selected Walking Speed	1.1 m/s	1.2 m/s	1.5 m/s	1.51 ± 0.17 s	Not available
Timed Stair Ascent	8.1 s	7.47 s	4.82 s	2.82 ± 0.37 s	0.37 s

Table 10. Patient-reported outcome measures for the combined cohort (*n*=84).

Patient-Reported Outcome Measure	Week 0	Week 4	Week 8
Short Musculoskeletal Function Assessment			
Daily Activities	36	35	23
Emotional Status	48	46	37
Mobility	42	42	30
Function	33	32	23
Bothersome	36	35	23
Arm	5	5	5
Visual analog pain scale			
Pain scale rating	3.9	3.8	2.7
Veteran Rand 12-item Health Survey			
Mental component score	48	48	51
Physical component score	27	29	37

The late entry group (31/84), also improved in all physical performance measures, function, pain scores and physical quality of life. (Appendix 6, Table 4). This is an important finding because patients' functional outcomes with the injuries similar to those captured in this study typically plateau within one year of injury.[76,77] In other words, patients that have reached their peak of functional recovery through traditional rehabilitation, can still improve in both physical performance and in patient-reported outcomes when receiving the custom PDAFO and the intensive rehabilitation programme.

Finally, the PDAFO and accompanying rehabilitation program were developed out of a need to improve outcome following severe lower extremity trauma to minimize the number of patients going on to late amputation when they are dissatisfied with their functional recovery. At enrolment in this study, 50 of the 84 patients were considering an amputation, being unable to run/jump (n=74), having mechanical pain (n=72), and weakness (n=57) cited as the most common reasons. At the conclusion of the program, only 9 patients were considering amputation.

4.4 Conclusion: Improved Function Following Lower Extremity Trauma

While early outcomes during the recent conflicts seemed to favour amputation over limb salvage, the development of the custom PDAFO and RTR-CP may have levelled the playing field. Most patients considering amputation were satisfied after receiving their custom device and rehabilitation. Despite these initial improvements, we found that there were broad

injury patterns where patients were more likely to fail treatment and proceed on to late amputation, such as those with hindfoot injuries. In the next chapter, I will conclude the thesis by reviewing limitations of the work presented thus far and considering issues for future research to optimize outcomes following high energy lower extremity trauma.

CHAPTER 5
CONCLUSION

5.1 Introduction

As described in the previous chapter, we found that a custom device and intensive rehabilitation led to improved outcomes in patients with lower extremity trauma. However, these studies had limitations.[78] This chapter firstly begins with a discussion of the methodological limitations and concludes with how future research could be improved.

5.2 Methodological Limitations of the Studies Presented

While the assumption is made that the registries used throughout these studies are of high quality, there are limitations with each. Table 11 reviews the different registries used in these studies, highlighting their strengths and weaknesses. The one recurring weakness is that not all data could be obtained from any single registry. For example, for studies three (Appendix 3) and five (Appendix 5) multiple databases were queried, and the findings were verified by independent medical record review. In addition, the casualty specific registries from the recent conflicts in Afghanistan and Iraq (EMED and JTTR/DoDTR) contain little orthopaedic injury detail, which also required subsequent independent medical record review.

Table 11. Databases utilized in studies 1 – 5.

Database	Number of Entries	Comments
DMDC	35 million	Contains the most accurate records with regard to service and rank for military service members. Catalogues all personnel in the military for purposes of healthcare, retirement funding, and administrative needs. This database is limited in that it only provides patient specific demographics with regard to age, service, and rank for purposes of the presented studies.
EMED	> 100,000	Maintained by US Naval Health Research Center. Data is continuously abstracted from casualty medical records from military providers at forward deployed treatment facilities in the combat zone. This data is limited in that it typically only includes injury specific information prior to medical evacuation back to the US. Level of orthopaedic injury detail is limited.
JTTR/DoDTR	> 132,000	Prospective data entry of all combat casualties has been consistent since 2003. There are up to 450 data fields per casualty. This data is limited in that it typically only includes injury specific and initial treatment information prior to medical evacuation back to the US. Level of orthopaedic injury detail is limited.
Military Amputee Registry	~ 400	Database maintained by a single individual at a single military treatment facility from 2001-2006, but attempted to include all US military amputees. As a result, it was limited in the completeness of data fields, and current data.
MDR	> 10 million	Contains records of all healthcare encounters at all US military medical facilities (> 260 health care facilities). While this database is very robust, it is limited by the data input. For example, all diagnoses had to be verified by personal review of the medical records to ensure accuracy in the studies presented.
PEB Database	Began in 1981, between 5,000 and 6,000 cases entered annually.	PEBs occur at 3 separate sites within the country and data is stored centrally. This data is very robust and accurate as it includes the PEB findings to include disability ratings.

There are also several confounding variables that are consistent through these studies as they are comprised of active duty military service members. First, the mean age was typically < 30 years and over 90% of the service members included were male. Second, while not reported within these studies, it is generally accepted that the military service members engaged in combat operations are healthy and without significant medical comorbidities. These factors impact the ability to compare outcomes to civilian populations. For example, while a 2% SSI rate following internal fixation of extremity fractures may be similar to that seen in a civilian population, a military cohort is likely to be younger and healthier, thus may underestimate the true risk of infection following internal fixation in an austere environment.

Several biases have also been introduced within the studies presented. In study one (Appendix 1), measurement bias may have resulted in false measurements for pin penetration as electronic radiographs were used, which may not have been calibrated appropriately. In addition, the inter- and intra-reliability of the new classification scheme was not assessed, which should be considered in future research. In determining the sample for study two (Appendix 2), I found that many of the fractures were coded incorrectly (coded with internal fixation procedure codes when this was not performed). This introduced the potential for misclassification bias. I attempted to mitigate this bias by personally reviewing radiographs and medical records of all patients to ensure the study population only consisted of those who underwent internal fixation in the area of combat operations. In study three (Appendix 3), selection bias may have resulted in a higher proportion of senior enlisted and officers returning

to duty. The fact that senior enlisted and officers tend to have less physically demanding jobs and more leadership/managerial roles may have led to these results. For similar reasons, this potential for selection bias may have also been present in study four (Appendix 4) where although officers made up a small proportion of the overall amputee population, they comprised a much higher proportion of those with late amputations. Misclassification bias was again present in the study by Hill et al. (2016, Study 5, Appendix 5). Using multiple databases to obtain service member diagnoses for referral for the custom PDAFO was necessary to ensure the most robust patient cohort. However, these databases often had incorrect diagnoses listed. We attempted to overcome this bias by performing independent medical record review to confirm the diagnosis for the referral and I personally reviewed 10% of all diagnoses to ensure they were placed into appropriate injury type categories. Channelling bias was also likely present as many of the patients prescribed the IDEO™ at the Center for the Intrepid were encouraged by their physician to attempt the RTR-CP prior to performing a late amputation. Evidence of this exists in the fact that 54% of the amputations that occurred in the population that was prescribed the IDEO™ occurred within three months of referral, which was barely enough time to complete the full program. As a result, this likely resulted in an inflation in 'treatment failures,' i.e. amputation. One of the key findings from study six (Appendix 6) was that 41/50 patients were no longer considering amputation after completing the device and rehabilitation program. Given the significant time commitment throughout the eight-week program, response bias may have been introduced, thus resulting in an overestimation of program's influence on the service member considering subsequent amputation.

Several of the studies also consisted of small study populations with a heterogenous group of injuries that made specific analyses difficult. Despite including all internal fixation cases performed in the area of combat operations over a seven-year period, only 50 total fractures were included. While this descriptive study resulted in a heterogenous group of injuries including everything from forearm to ankle fractures, it was the largest series to date describing outcomes in this population. Although the study by Bedigrew et al. (Study 6, Appendix 6) was a prospective observational study where inclusion criteria could be rigorously controlled, it also had a patient cohort that consisted of various injuries. Despite work described in the previous chapter, the ideal patient population that would benefit from the PDAFO and RTR-CP has yet to be clearly delineated.[79] As such, we chose to be inclusive in our study design, which did make comparisons across specific injury patterns difficult due to their smaller individual numbers. Furthermore, while the results were promising, the rehabilitation program was isolated to a single centre and, at the time we published, the program had yet to be replicated at other sites.

There were also several weaknesses within the statistical analyses performed in the studies presented. As mentioned, study two (Appendix 2) had a small sample size which also lacked a control group. As a result, only descriptive statistics were presented. In addition, in several of the studies (Studies 1, 3, and 4; Appendices 1, 3 and 4, respectively) multiple statistical tests were performed on a single data set. It is important to recognize that when this is done without properly accounting for it in the analysis it increases the likelihood of a Type 1 error, obtaining a false positive result. Unfortunately, this occurs commonly in orthopaedic publications.[80] However, there are ways to mitigate this, i.e. applying a Bonferroni correction, which should be incorporated into the analysis in future studies when multiple statistical tests are performed on a single data set.

Finally, while the studies presented were often the first and/or largest series to date describing outcomes of a specific population, service personnel with combat-related lower extremity trauma, they are limited due to their relatively small numbers. As a result, several of the studies included patients with limited follow-up (i.e. study two, Appendix 2), but I felt this was necessary as the sample size was already very small to begin with. In addition, while follow-up of one year would be ideal, when trying to identify post-surgical complications, specifically surgical site infections which often present within thirty days of surgery, I felt that a shorter length of follow-up was acceptable for inclusion. Furthermore, the majority of evidence currently available to guide our treatment of these severe combat-related extremity injuries is based on Level IV data generated from small studies, such as these presented, which often lack a comparison group.[81] Despite the high percentage of severe injuries seen at military treatment facilities compared to those that are less severe, the overall numbers are modest. An alternative approach, moving forward, would be to partner with civilian trauma centres to perform higher quality research to help guide future treatment of combat-injured patients. This concept has been challenged due to the concern that civilian trauma centres do not have the same representative injuries as those arising as a result of combat.

5.3 Direction of Future Extremity-Related Combat Casualty Care Research

5.3.1 Study 7 (Appendix 7)

Military and Civilian Collaboration: The Power of Numbers. Stinner DJ, Wenke JC, Ficke JR, Gordon W, Toledano J, Carlini A, Scharfstein DO, MacKenzie EJ, Bosse MJ, Hsu JR. *Mil Med* 2017;182(3/4):10-17.

It was in this setting, understanding the limitations of our existing research, that we recognized the need to partner with civilian trauma centres to conduct higher quality research to identify optimal care of the combat-injured. The Major Extremity Trauma Research Consortium (METRC) was established in 2009 to help build infrastructure within the orthopaedic trauma community in the US and to establish research priorities set by the US Department of Defense. This consortium, which is similar to the major trauma networks in the UK, initially began with four military treatment facilities and 21 civilian trauma centres.

This study consisted of two parts. The first was to compare registry data, collected at each site over one year, to determine the number of injuries treated that are comparable to military-specific injuries. Patients were prospectively entered within the registry if they were aged 18 and 84 years with a surgically treated fracture. Hip fractures in patients over 60, wrist, hand, ankle, clavicle, patella, and foot fractures (other than talus, calcaneus, and crush mechanism) were excluded.

The second part of the study compared actual enrolment data into the first three METRC studies to demonstrate the need for civilian collaboration. These studies were the FIXIT trial (two arms, prospective randomised and observational, comparing two treatment options for severe open tibia fractures: internal fixation with plate or nail and circular external fixation), the OUTLET trial (prospective observational, comparing outcomes in patients undergoing limb salvage or amputation for severe distal tibia, ankle, and/or foot injuries), and the BIOBURDEN trial (prospective observational, characterising bacteria present at the time of wound closure in serve open extremity wounds).

5.3.2 Key Findings from Study 7

There were 875 fractures that met inclusion criteria from the four military treatment facilities and 14,362 fractures from the 21 civilian trauma centres. Overall, 35% (303/875) were open fractures treated at the military treatment facilities compared to 22% (3,188/14,362) at the civilian trauma centres (Table 12).

Table 12. METRC Registry Data Comparing Fracture Types and Anatomic Locations (MTF=Military Treatment Facilities (n=4), CIV=Civilian Trauma Centres (n=22)).

	MTF		CIV		Percentages	
Fracture Location	**Closed**	**Open**	**Closed**	**Open**	**%Open MTF**	**%Open CIV**
Humerus	53	32	1186	301	37.6%	20.2%
Radius/Ulna	61	50	1077	478	45.0%	30.7%
Pelvis/Acetabulum	52	7	1918	74	11.9%	3.7%
Femur	97	31	2860	591	24.2%	17.1%
Tibia	132	103	3126	1441	43.8%	31.6%
Foot	65	23	777	222	26.1%	22.2%

As described throughout this thesis, severe open fractures, such as type III open fractures are of specific relevance to the military. Whilst a higher percentage of these fractures were treated at the military treatment facilities compared to civilian trauma centres (18% vs. 10%), they only accounted for a modest 160 fractures compared to the 1,475 fractures treated at civilian trauma centres (Table 13).

Table 13. METRC Registry Data Comparing Severity of Fractures (MTF=Military Treatment Facilities (n=4), CIV=Civilian Trauma Centres (n=22)).

	n, %	
Injury Type	**MTF**	**CIV**
All Open I/II	86, 10%	1639, 12%
All Open III	160, 18%	1475, 10%

Finally, to further demonstrate the potential benefit from collaboration with a civilian trauma network to conduct combat-relevant extremity trauma research, we found that only 6% (68/1,199) of patients were enrolled in the three prospective studies at military treatment facilities compared to 1,131 enrolled at the civilian trauma centres. This not only demonstrates the challenge of doing prospective research relevant to combat-related extremity trauma, but also highlights the benefit of partnering with civilian trauma centres moving forward.

5.4 Ongoing and Future Research

5.4.1 Identification of the optimal patient cohort for the PDAFO and RTR-CP

Hill et al. (2016, Study 5, Appendix 5) found that the three patient groups most likely to go on to late amputation were those with midfoot/forefoot injuries, soft tissue injuries, and hindfoot injuries.[79] To better delineate the benefit, or lack thereof, seen with the PDAFO and RTR-CP for specific diagnoses within the broad categories assigned by Hill et al. (2016), follow-on work has focused on the groups that seemed to perform worse with a higher percentage going on to late amputation after completion of the rehabilitation program. I began by evaluating outcomes of patients with a hindfoot fusion, which included those with an isolated subtalar fusion or an ankle fusion, after receiving the PDAFO and completing the RTR CP. In this study by Sheean et al. (2016, not included in this thesis), we found that statistically significant improvements in all physical performance measures were observed in both groups and that those with isolated subtalar fusions also had improvement in patient-reported outcomes (function, quality of life and pain). We concluded that the treatment program was a good option for improving function in patients following hindfoot and/or ankle fusion.[82] The success rate for other foot injuries has yet to be determined.

I also turned my attention to those with 'soft tissue injury' because these patients also had a higher rate of subsequent amputation (27%) after using the PDAFO.[79] One subset of patients within this cohort are those with nerve injuries proximal to the knee that result in functional deficits to the lower extremity. In another publication not included in this thesis, I evaluated a small cohort of 30 patients with nerve injuries proximal to the knee.[83] Those patients with isolated foot drop demonstrated improvements in all physical performance measures tested. Those with globally poor ankle function improved in all physical performance measures and in some patient-reported outcomes. This small series suggests that people with proximal nerve injuries may benefit from the custom device and rehabilitation program.

5.4.2 Is treatment with this custom PDAFO and RTR-CP generalizable to other institutions?

While these study findings suggest promising improvements in physical performance and patient-reported outcomes in those receiving this customised intervention, they only describe the experience of a single institution. In addition, much of the prior work was limited due to short term follow-up. To build upon the growing body of work evaluating the custom

PDAFO and RTR-CP, a larger multi-centre, prospective observational study was developed that addressed key weaknesses of earlier studies. Three geographically separated centres participated and follow-up was extended to one year.[84] In addition, several modifications were made to the overall RTR-CP program to make it more generalizable, i.e. fewer physical therapy sessions, etc.

In another study not included with this thesis, we recently reported the results of this multi-centre prospective observational study.[85] Of the 81 patients recruited, Potter et al. (2018) found that the patients attended a mean of 9.1 ± 3.1 physical therapy sessions. At the completion of the RTR-CP, there were improvements in all physical performance measures tested, except the Self-Selected Walking Speed. Satisfaction with the PDAFO device was evaluated using the OPUS (Orthotics and Prosthetics Users' Survey) and this was very high at the completion of the program (85/100) with some attenuation over time, at six (73%) and 12 months (72%). Only four of the 81 patients (5%) included in the analysis proceeded to amputation, for chronic pain. An important finding was that patient-reported outcomes continued to improve after completion of the rehabilitation programme, at the six and 12-months follow-up time points.[85]

Potter el al. (2108) demonstrated that the fabrication of the custom PDAFO and replication of the RTR-CP could be undertaken at other sites while demonstrating similar improvements in both function (physical performance measures) and patient-reported outcomes. In addition to its spread to multiple sites within the US, a similar version of the PDAFO and RTR-CP is now being used in the UK.[86]

5.5 Summary

Combat brings with it many challenges to be overcome, not just by the soldier, but also by the surgeon. Operating in an austere environment offers a unique set of challenges not commonly seen in clinical practice in established hospital settings. As the conflicts escalated resulting in many combat-injured with extremity trauma, questions arose as to the ideal methods of care for these high energy injuries. External fixation was found to be a safe intervention on the battlefield.[87] While there was significant concern regarding internal fixation performed in the area of combat operations, my investigations found that surgeons were performing internal fixation for appropriate indications.[88] As treatment algorithms evolved,[32] patients would ultimately undergo their definite reconstruction after leaving the area of combat operations. For a growing number undergoing limb salvage, dissatisfaction with their level of function and pain led them to pursue late amputation.[20,74] Although return

to duty rates were similar among isolated below-the-knee amputees and type III open tibia fractures,[59,60] other reports comparing outcomes of patients from the recent conflicts seemed to favour the below knee amputee when compared to the limb salvage patient.[11,89]

With a growing number of patients electing to pursue late amputation, there was a need for an intervention that could improve outcomes in the limb salvage patient population. With the development of a custom device and an intensive rehabilitation program, I found functional improvements in physical performance measures and patient-reported outcomes in those with severe lower extremity trauma.[82,83,90] These results have subsequently been replicated at multiple sites, to include the UK, and are impacting many patients who have suffered life-changing injuries.[85,86]

5.6 Future Work

As the body of literature builds supporting the use of this custom passive dynamic ankle-foot-orthosis coupled with the return-to-run clinical pathway, further research must continue to explore the diagnoses that will benefit from the intervention. Future work should also be focused on brace optimization or modification for specific injury patterns that more commonly result in treatment failure with the current orthosis design. A partnership with civilian trauma centres is necessary to achieve the numbers needed to perform future high-quality randomised controlled trials to evaluate the effect of individual components of the complex program (i.e. compare brace alone to rehabilitation only). One caution when developing future prospective randomized controlled trials evaluating new (or unfamiliar) surgical techniques or treatment algorithms is the concern that individual surgeon or institutions' biases may subsequently bias the results of the study. This could be mitigated through cluster randomization where patients are randomized to a treatment based on the skillset or particular resources that a surgeon or institution has. Finally, alternative treatment strategies should be investigated as well, and studies should incorporate health economics to obtain robust cost-effectiveness data.

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To Whom it May Concern:

This letter is confirming Daniel Stinner's roll as a co-author for the manuscript titled, "Temporary External Fixation Is Safe in a Combat Environment." Mr. Stinner helped to identify the need for this review. He assisted with the literature review to help create the grading criteria for potential, minor, and major complications. He also assisted me with data collection and review of radiographs. Finally, his effort was critical in interpretation of the results and manuscript preparation in conjunction with myself as the lead author and the rest of our co-authors. I have worked with Mr. Stinner extensively over the previous 10+ years and am pleased that he selected our manuscript as his manuscript that begins his thesis. I wish him success in his application for a PhD by publication.

I would be happy to answer any questions related to Daniel's involvement in this manuscript or other work that we have done together at [redacted] or [redacted]

Respectfully,

[redacted]

Daniel Possley DO, MS

Cornerstone Orthopaedics & Sports Medicine

www.drpossley.com

CORNERSTONE
Orthopaedics & Sports Medicine, P.C.

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
U.S. ARMY HEALTH READINESS CENTER OF EXCELLENCE
3630 STANLEY ROAD
JBSA FORT SAM HOUSTON, TEXAS 78234-6100

MCCS-D 17 March 2017

MEMORANDUM FOR: Members of the Warwick University Admissions Panel

SUBJECT: Dr. Daniel Stinner and the Intrepid Dynamic Exoskeleton Orthosis (IDEO) manuscript

1. It is with great enthusiasm that I comment on Dr. Daniel Stinner's contribution to our co-authored paper entitled "Descriptive Characteristics and Amputation Rates with use of Intrepid Dynamic Exoskeleton Orthosis."

2. We sought to describe the injury characteristics and amputation rates of patients who have received an IDEO, but needed to ensure that our results made sense from a clinical perspective. I asked for Dr. Stinner's assistance in two specific areas: 1) Categorizing injury characteristics into clinically relevant groups and 2) Ensuring the appropriate clinical message was conveyed.

3. Dr. Stinner took all of the injury characteristics and diagnosis codes of the 624 patients under review and assigned each to one of seven groups that he created. This was of paramount importance because he created groups that were all clinically relevant. In other words, injuries that behaved and were treated the same way were grouped together. This allowed us to apply broad strokes to try and identify which patients do well with an IDEO and which still go on to late amputation and to see if failure correlates with their injury characteristic or diagnosis code.

4. Upon completion of the data analysis, he contributed in writing several portions of the manuscript and provided significant leadership in the editing of the overall manuscript to ensure that the message conveyed was clinically relevant.

5. Dr. Stinner demonstrated exceptional performance in many facets of this research effort. He has robust knowledge of clinical medicine, orthopedic surgery, epidemiology, statistics, measurement analysis, and synthesizing scientific evidence.

6. Overall, I think that you would be extremely hard pressed to find someone with all the attributes and abilities that Dr. Stinner possesses, and I feel he will be an outstanding addition to your program. He is a person with unlimited potential.

7. For further questions, please feel free to contact me directly at [redacted]

Owen T. Hill, PhD
Lieutenant Colonel, SP Corps
U.S. Army

STANFORD
SCHOOL OF MEDICINE
Stanford University Medical Center

Katherine M. Bedigrew, M.D.
Clinical Instructor
Department of Orthopaedic Surgery
450 Broadway Street
Mailcode 6342
Redwood City, CA 94063
Office: (650) 721-7628

Members of the Warwick University Admissions Panel,

I am writing to describe Mr. Daniel Stinner's contribution to our paper titled "Can an Integrated Orthotic and Rehabilitation Program Decrease Pain and Improve Function After Lower Extremity Trauma." Mr. Stinner did much of his initial research on amputees, but became interested in limb salvage as he found more and more limb salvage patients were going on to amputation. The Intrepid Dynamic Exoskeletal Orthosis (IDEO) offered limb salvage patients an alternative to amputation, which peaked his interests. He became involved in this program as a trainee in San Antonio, TX which involved actively collecting data and enrolling patients into the POSITIVE study, which was a prospective observational study following the outcomes of these patients. As a trainee, he would attend the clinic with his mentors Mr. Kevin Kirk and Mr. Joseph Hsu, where he would evaluate these patients and assist in recording patient data. When he completed his training in 2013, he took over the program providing continued leadership for this prospective observational study, which has now enrolled over 260 patients and has obtained patient reported functional outcomes and physical performance measures to objectively quantify the effect of the IDEO on recovery after lower extremity trauma.

Mr. Stinner's specific involvement was instrumental in this manuscript and included assistance in data collection, data analysis, and editing of the final manuscript. I would be happy to answer any additional questions at [redacted] or [redacted]

Sincerely,

[redacted]

Katherine Bedigrew, MD

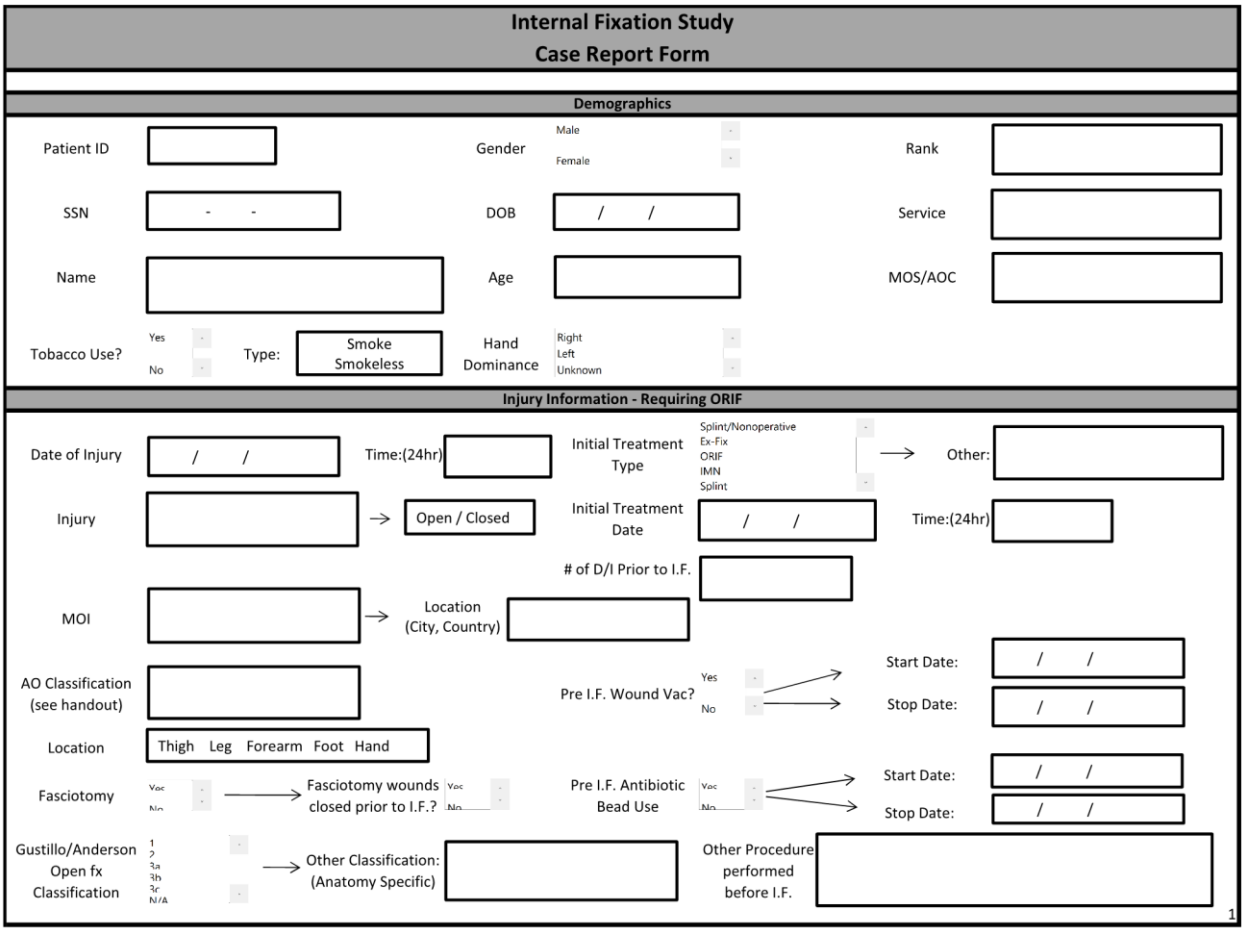
Appendix 8 ICD-9 Procedure Codes relevant to internal fixation, Study 2

Procedure Code	Description
78.40	Other repair or plastic operations on bone, unspecified site
78.41	Other repair or plastic operations on bone, scapula, clavicle, and thorax [ribs and sternum]
78.42	Other repair or plastic operations on bone, humerus
78.43	Other repair or plastic operations on bone, radius and ulna
78.44	Other repair or plastic operations on bone, carpals and metacarpals
78.45	Other repair or plastic operations on bone, femur
78.46	Other repair or plastic operations on bone, patella
78.47	Other repair or plastic operations on bone, tibia and fibula
78.48	Other repair or plastic operations on bone, tarsals and metatarsals
78.49	Other repair or plastic operations on bone, other bones
78.50	Internal fixation of bone without fracture reduction, unspecified site
78.51	Internal fixation of bone without fracture reduction, scapula, clavicle, and thorax [ribs and sternum]
78.52	Internal fixation of bone without fracture reduction, humerus
78.53	Internal fixation of bone without fracture reduction, radius and ulna
78.54	Internal fixation of bone without fracture reduction, carpals and metacarpals
78.55	Internal fixation of bone without fracture reduction, femur
78.56	Internal fixation of bone without fracture reduction, patella
78.57	Internal fixation of bone without fracture reduction, tibia and fibula
78.58	Internal fixation of bone without fracture reduction, tarsals and metatarsals
78.59	Internal fixation of bone without fracture reduction, other bones
79.30	Open reduction of fracture with internal fixation, unspecified site
79.31	Open reduction of fracture with internal fixation, humerus

79.32	Open reduction of fracture with internal fixation, radius and ulna
79.33	Open reduction of fracture with internal fixation, carpals and metacarpals
79.34	Open reduction of fracture with internal fixation, phalanges of hand
79.35	Open reduction of fracture with internal fixation, femur
79.36	Open reduction of fracture with internal fixation, tibia and fibula
79.37	Open reduction of fracture with internal fixation, tarsals and metatarsals
79.38	Open reduction of fracture with internal fixation, phalanges of foot
79.39	Open reduction of fracture with internal fixation, other specified bone
79.90	Unspecified operation on bone injury, unspecified site
79.91	Unspecified operation on bone injury, humerus
79.92	Unspecified operation on bone injury, radius and ulna
79.93	Unspecified operation on bone injury, carpals and metacarpals
79.94	Unspecified operation on bone injury, phalanges of hand
79.95	Unspecified operation on bone injury, femur
79.96	Unspecified operation on bone injury, tibia and fibula
79.97	Unspecified operation on bone injury, tarsals and metatarsals
79.98	Unspecified operation on bone injury, phalanges of foot
79.99	Unspecified operation on bone injury, other specified bone
81.40	Repair of hip, not elsewhere classified
81.47	Other repair of knee
81.49	Other repair of ankle
81.83	Other repair of shoulder
81.85	Other repair of elbow
81.00	Spinal fusion, not otherwise specified
81.01	Atlas-axis spinal fusion
81.02	Other cervical fusion, anterior technique
81.03	Other cervical fusion, posterior technique
81.04	Dorsal and dorsolumbar fusion, anterior technique

81.05	Dorsal and dorsolumbar fusion, posterior technique
81.06	Lumbar and lumbosacral fusion, anterior technique
81.07	Lumbar and lumbosacral fusion, lateral transverse process technique
81.08	Lumbar and lumbosacral fusion, posterior technique
84.71	Application of external fixator device, monoplanar system
84.72	Application of external fixator device, ring system
84.73	Application of hybrid external fixator device

Appendix 9 Case Report Forms, Study 2



Internal Fixation Study
Case Report Form

Demographics

Patient ID

Gender: Male / Female

Rank

SSN - -

DOB / /

Service

Name

Age

MOS/AOC

Tobacco Use? Yes / No

Type: Smoke / Smokeless

Hand Dominance: Right / Left / Unknown

Injury Information - Requiring ORIF

Date of Injury / /

Time:(24hr)

Initial Treatment Type: Splint/Nonoperative / Ex-Fix / ORIF / IMN / Splint → Other:

Injury → Open / Closed

Initial Treatment Date / /

Time:(24hr)

# of D/I Prior to I.F.

MOI → Location (City, Country)

AO Classification (see handout)

Pre I.F. Wound Vac? Yes / No

Start Date: / /

Stop Date: / /

Location: Thigh Leg Forearm Foot Hand

Fasciotomy: Yes / No → Fasciotomy wounds closed prior to I.F.? Yes / No

Pre I.F. Antibiotic Bead Use: Yes / No

Start Date: / /

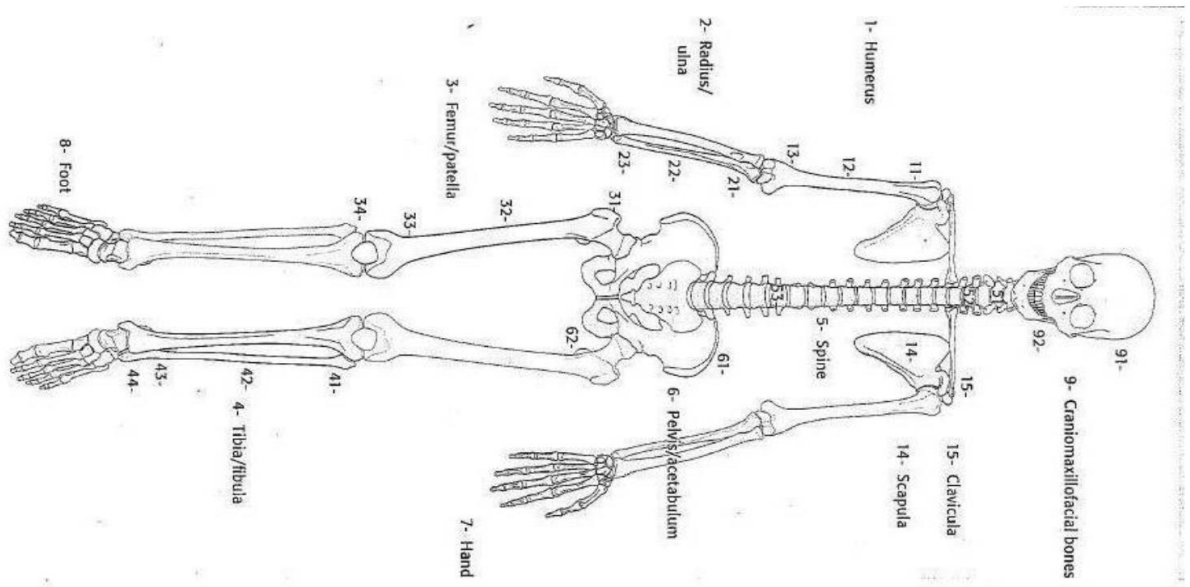
Stop Date: / /

Gustillo/Anderson Open fx Classification: 1 / 2 / 3a / 3b / 3c / N/A → Other Classification: (Anatomy Specific)

Other Procedure performed before I.F.

1

AO Classification Skeleton

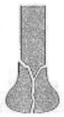


2

AO Type

3

Definitions of fracture types for long-bone fractures in adults
Exception to this are fractures of the proximal humerus (11-), proximal femur (31-), malleoli (44-), subtrochanteric fractures (32-)

Segment	Type		
	A	B	C
1 Proximal			
	Extraarticular No involvement of displaced fractures extending into the articular surface	**Partial articular** Part of the articular component is involved, leaving the other part attached to the meta-/diaphysis	**Complete articular** Articular surface involved, metaphyseal fracture completely separates articular component from the diaphysis
2 Diaphyseal			
	Simple One fracture line, cortical contact between fragments exceeds 90% after reduction	**Wedge** Three or more fragments, main fragments have contact after reduction	**Complex** Three or more fragments, main fragments have no contact after reduction
3 Distal			
	Extraarticular No involvement of displaced fractures extending into the articular surface	**Partial articular** Part of the articular component is involved, leaving the other part attached to the meta-/diaphysis	**Complete articular** Articular surface involved, metaphyseal fracture completely separates articular component from the diaphysis

Injury Information

Ipsilateral Injuries
- Upper Extremity
- Lower Extremity

Contralateral Injuries
- Upper Extremity
- Lower Extremity

Other Nonorthopaedic Injuries

Spine Injury

Pelvis Injury

ISS

Head Injury?
- Yes
- No

GCS @ time of fixation

Internal Fixation

Fixation Performed

Date of ORIF / /

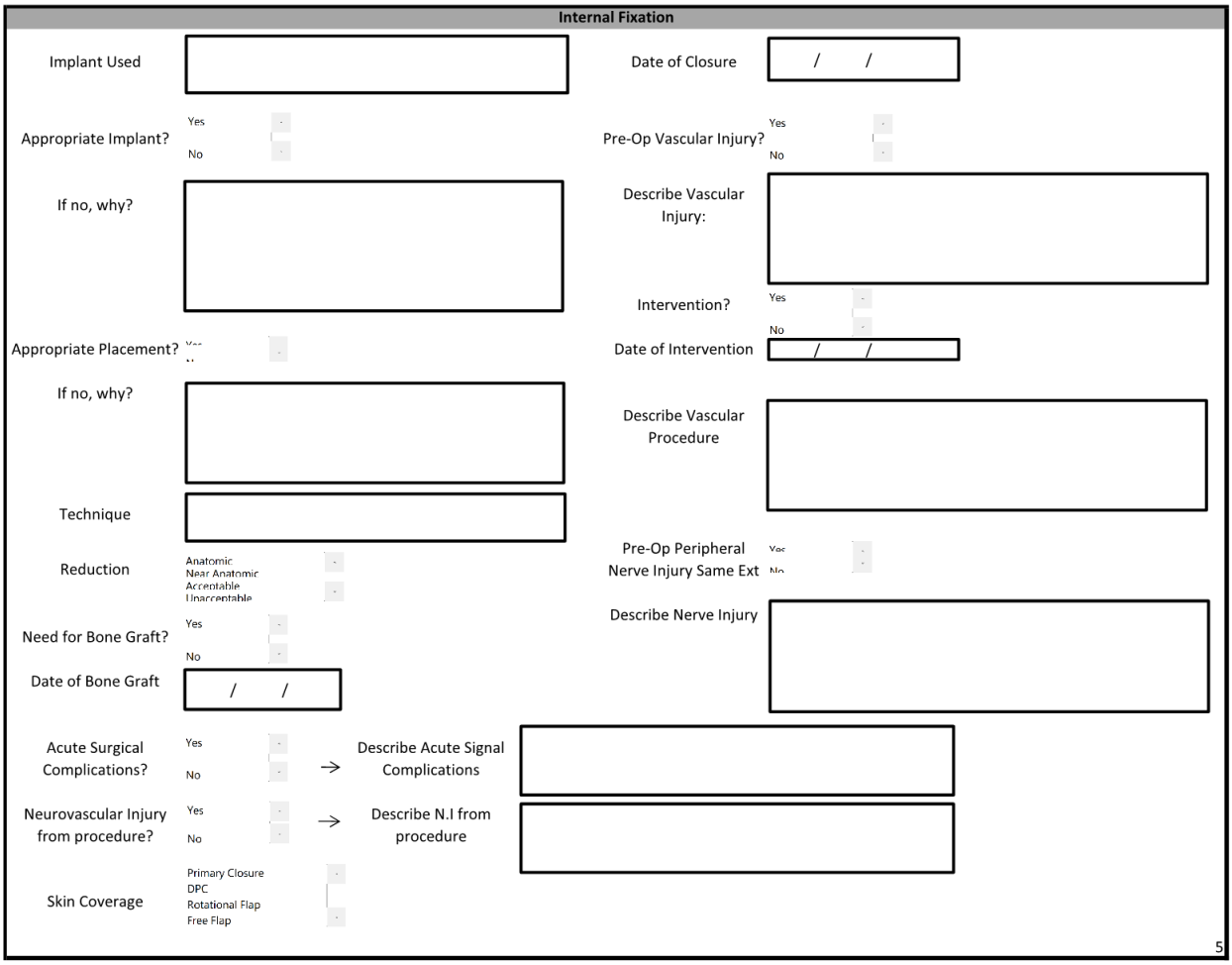
Location of Internal
- Level I
- Level II
- Level III
- Level IV
- Level V

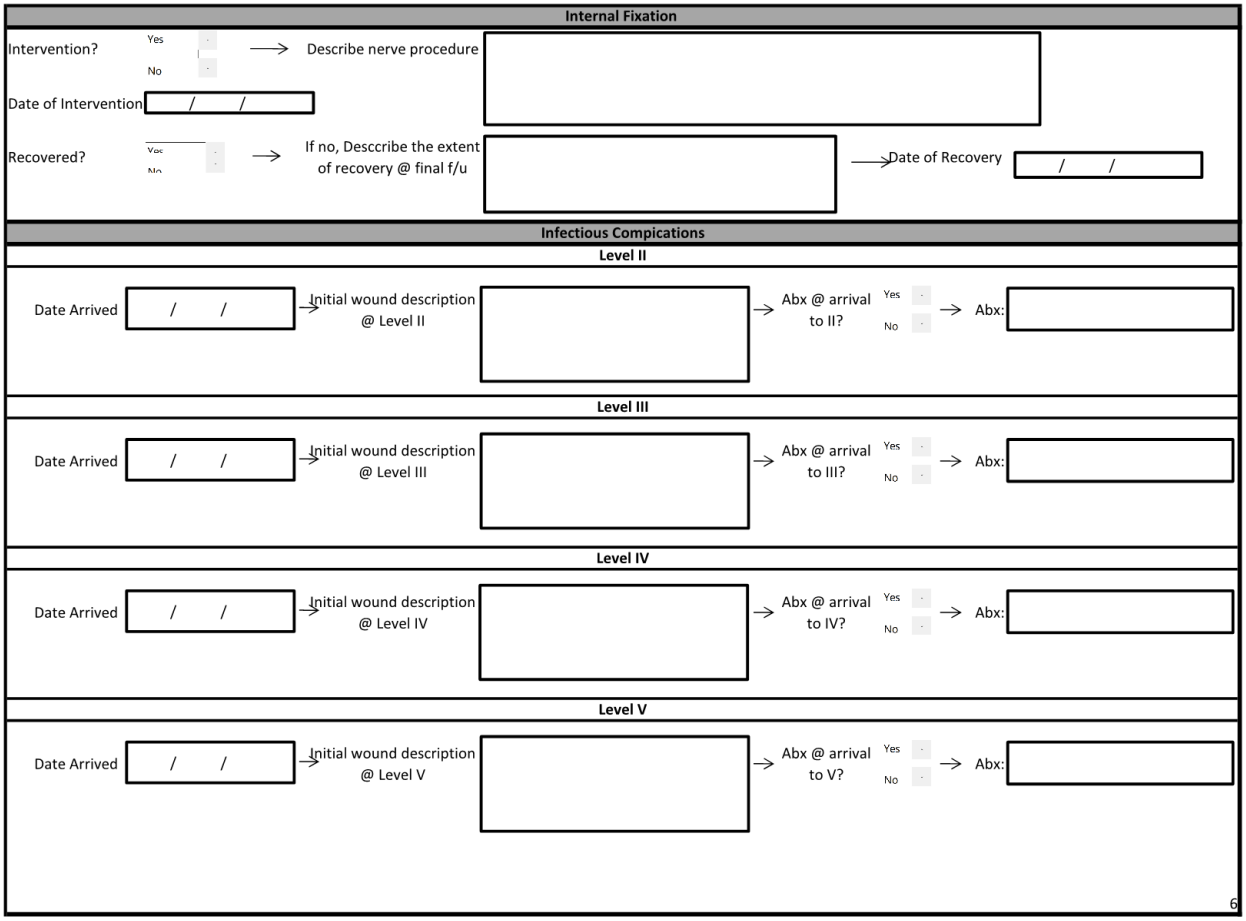
Specific Location (Unit, City, Country)

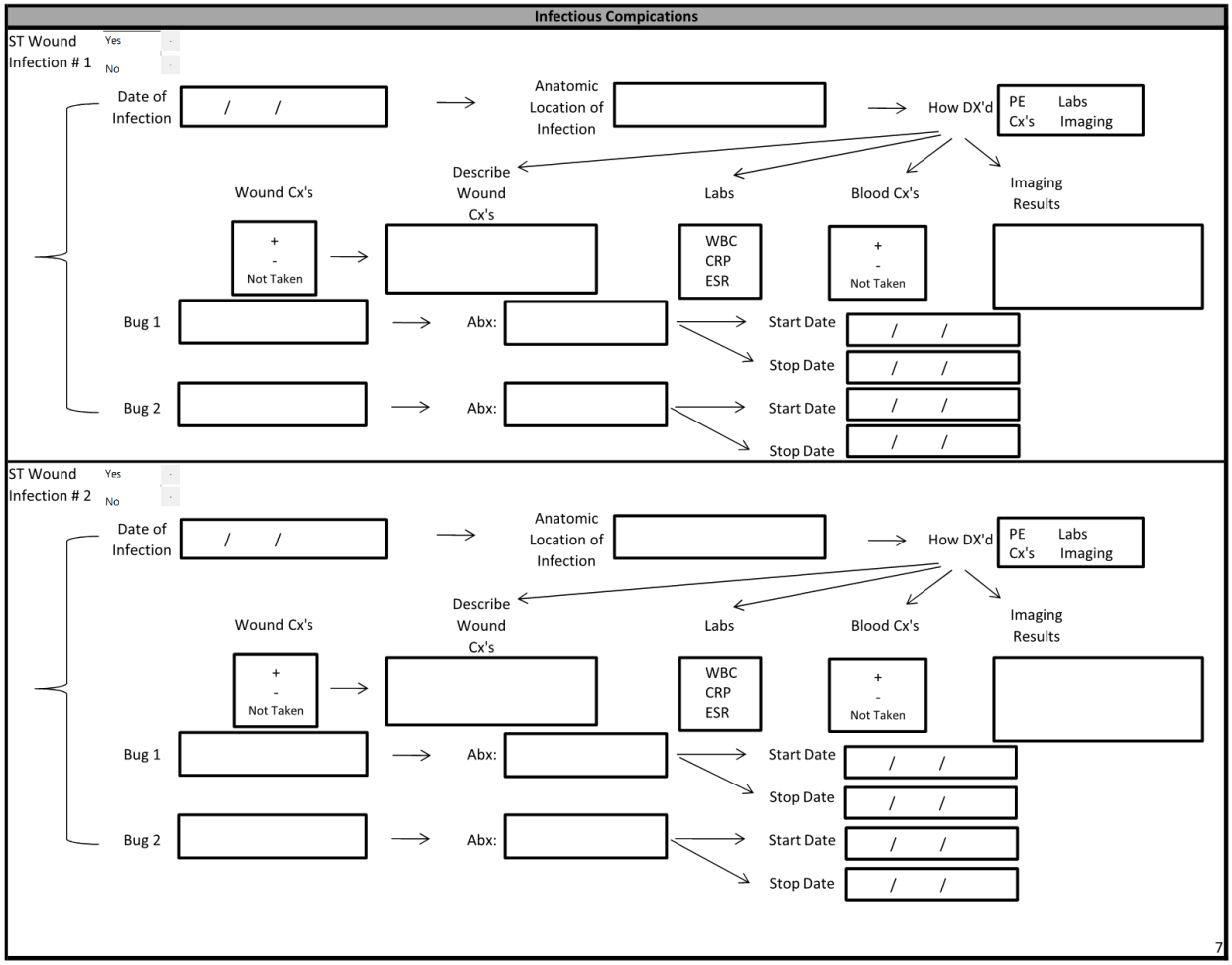
Surgeons
1
2
3

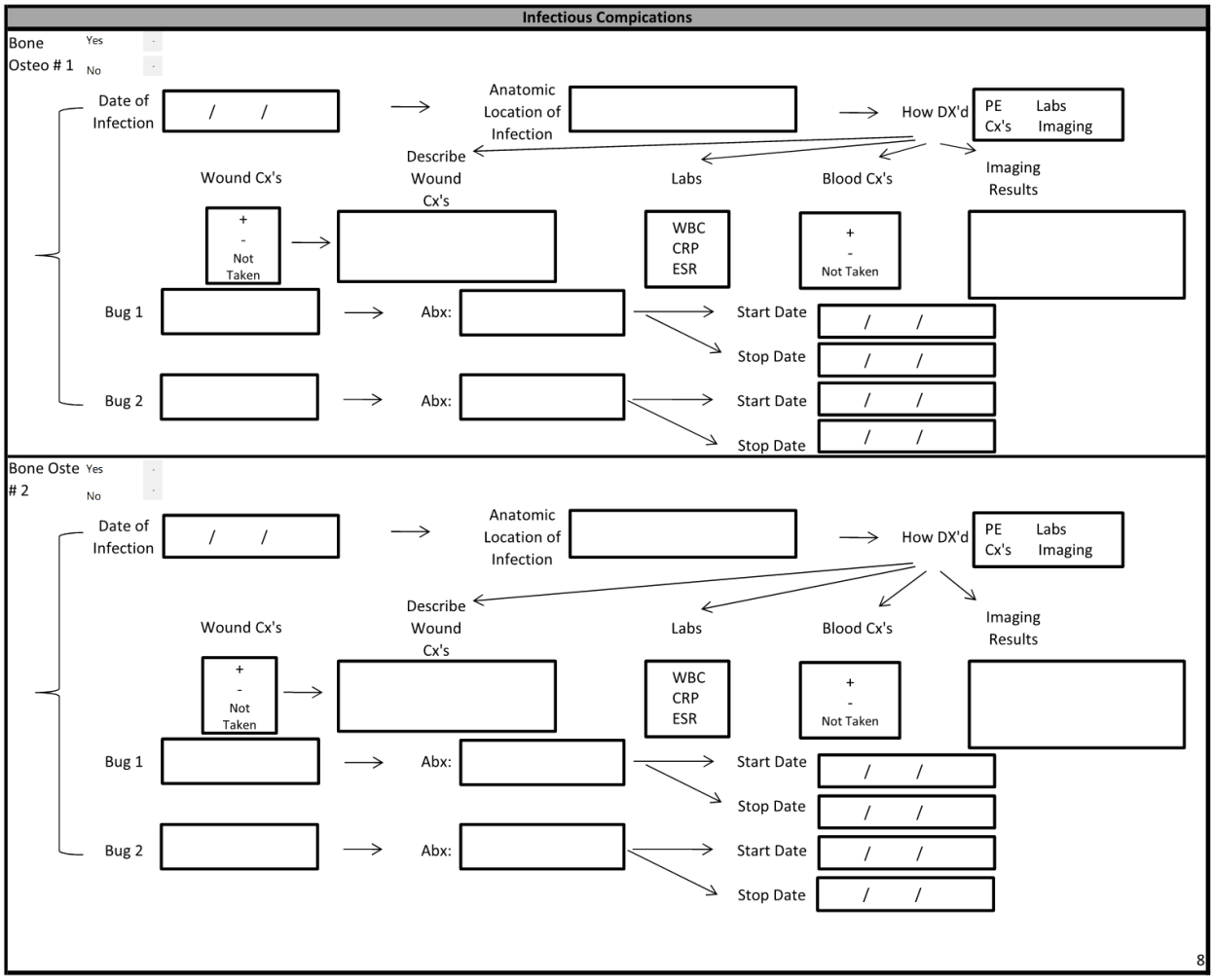
Stated Indication for Internal Fixation

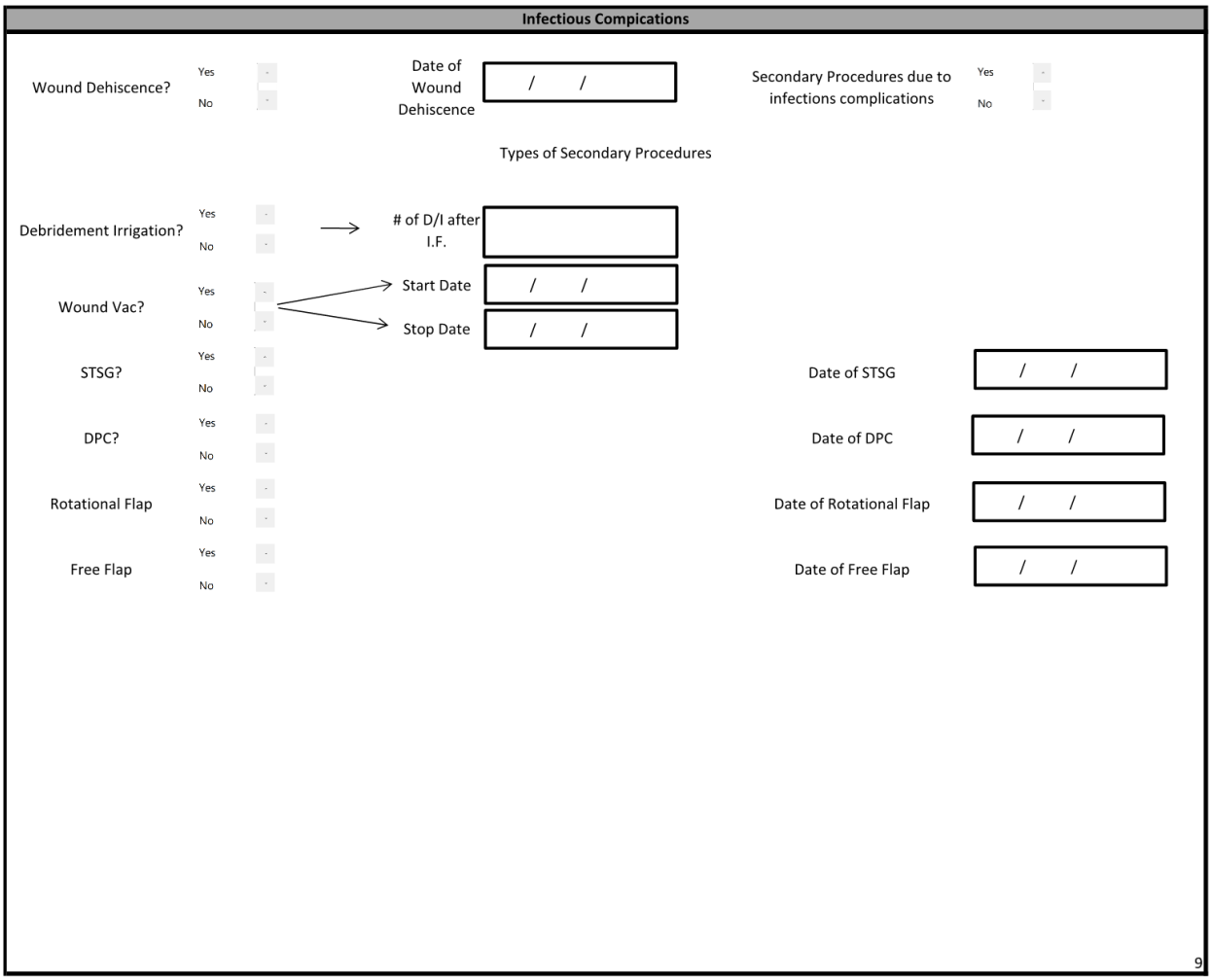
4


Internal Fixation
Implant Used
Date of Closure
/ /
Appropriate Implant?
Yes
No
Pre-Op Vascular Injury?
Yes
No
If no, why?
Describe Vascular Injury:
Intervention?
Yes
No
Appropriate Placement?
Date of Intervention
/ /
If no, why?
Describe Vascular Procedure
Technique
Reduction
Anatomic
Near Anatomic
Acceptable
Unacceptable
Pre-Op Peripheral Nerve Injury Same Ext
Describe Nerve Injury
Need for Bone Graft?
Yes
No
Date of Bone Graft
/ /
Acute Surgical Complications?
Yes
No
Describe Acute Signal Complications
Neurovascular Injury from procedure?
Yes
No
Describe N.I from procedure
Skin Coverage
Primary Closure
DPC
Rotational Flap
Free Flap
5


Internal Fixation
Intervention?
Yes
No
Describe nerve procedure
Date of Intervention
/ /
Recovered?
Yes
No
If no, Desccribe the extent of recovery @ final f/u
Date of Recovery
/ /
Infectious Compications
Level II
Date Arrived
/ /
Initial wound description @ Level II
Abx @ arrival to II?
Yes
No
Abx:
Level III
Date Arrived
/ /
Initial wound description @ Level III
Abx @ arrival to III?
Yes
No
Abx:
Level IV
Date Arrived
/ /
Initial wound description @ Level IV
Abx @ arrival to IV?
Yes
No
Abx:
Level V
Date Arrived
/ /
Initial wound description @ Level V
Abx @ arrival to V?
Yes
No
Abx:
6


Infectious Compications
ST Wound Infection # 1
Yes
No
Date of Infection
/ /
Anatomic Location of Infection
How DX'd
PE
Labs
Cx's
Imaging
Describe Wound Cx's
Wound Cx's
Labs
Blood Cx's
Imaging Results
+
-
Not Taken
WBC
CRP
ESR
Bug 1
Abx:
Start Date
Stop Date
Bug 2
ST Wound Infection # 2
7


Infectious Compications
Bone Osteo # 1
Yes
No
Date of Infection
/ /
Anatomic Location of Infection
How DX'd
PE
Labs
Cx's
Imaging
Describe Wound Cx's
Labs
Blood Cx's
Imaging Results
Wound Cx's
+
-
Not Taken
WBC
CRP
ESR
+
-
Not Taken
Bug 1
Abx:
Start Date
Stop Date
Bug 2
Abx:
Start Date
Stop Date
Bone Oste # 2
Yes
No
Date of Infection
/ /
Anatomic Location of Infection
How DX'd
PE
Labs
Cx's
Imaging
Describe Wound Cx's
Labs
Blood Cx's
Imaging Results
Wound Cx's
+
-
Not Taken
WBC
CRP
ESR
+
-
Not Taken
Bug 1
Abx:
Start Date
Stop Date
Bug 2
Abx:
Start Date
Stop Date
8


Infectious Compications
Wound Dehiscence?
Yes
No
Date of Wound Dehiscence
/ /
Secondary Procedures due to infections complications
Yes
No
Types of Secondary Procedures
Debridement Irrigation?
Yes
No
# of D/I after I.F.
Wound Vac?
Yes
No
Start Date
/ /
Stop Date
/ /
STSG?
Yes
No
Date of STSG
/ /
DPC?
Yes
No
Date of DPC
/ /
Rotational Flap
Yes
No
Date of Rotational Flap
/ /
Free Flap
Yes
No
Date of Free Flap
/ /
9

Internal Fixation

Required Revision? Yes / No

Date of Required Revision / /

# of subsequent hospitalizations due to I.F.

Reason for Revision

Describe procedure:

Additional Revisions

1.Date:
1.Procedure:

1.Reason/Description:

_____

2.Date:
2.Procedure:

2.Reason/Description:

_____

3.Date:
3.Procedure:

3.Reason/Description:

Date of Union / /

Physical Therapy/OT? Yes / No

Pre-op ROM

VAS @ final f/u

Most recent ROM

Date of final f/u / /

10

Additional Comments

11

Appendix 10 Case Report Forms, Study 6

POSITIVE

Use of an Integrated Orthotic and Rehabilitation Initiative for Treatment of Lower Extremity Musculoskeletal Disorders

Please fill out all the information below to the best of your knowledge:

Demographics

Subject #_____ Date of Visit _____ Gender: ☐ Male ☐ Female Current Age_____

Smoker: ☐ Yes ☐ No Home duty station_____

Injury

Date of Injury:_____ Rank at injury:_____ MOS at injury:_____

Traumatic Brain Injury: ☐ Yes ☐ No If yes: ☐ Mild ☐ Moderate ☐ Severe

Diagnosis at time of injury: (Check all that apply)

Fracture: ☐ Hip ☐ Femur ☐ Knee ☐ Tibia ☐ Ankle ☐ Talus ☐ Calcaneus ☐ Hindfoot

Compartment Syndrome: ☐ Thigh ☐ Lower Leg ☐ Foot

Spinal cord Injury: ☐ Yes ☐ No If yes: Level:_____

Other:_____

Mechanism of Injury: (Check all that apply)

Explosion: ☐ IED ☐ RPG/Grenade ☐ Mortar ☐ Landmine ☐ Motor Vehicle Accident ☐ Gun Shot Wound ☐ Fall

☐ Blunt ☐ Penetrating ☐ Burn ☐ Crush Injury

☐ Combat ☐ Non-Combat

Surgery

of procedure(s) to leg/legs receiving the IDEO:_____ # of hospitalizations from your injury on the IDEO leg:_____

Functional Capabilities

Do you need assistive device(s) to walk? ☐ Yes ☐ No If yes: ☐ Foot and Ankle brace (AFO) ☐ Cane

Are you able to run? ☐ Yes ☐ No If yes, can you run for at least a mile? ☐ Yes ☐ No

Are you able to jump? ☐ Yes ☐ No

Do you play sports? ☐ Yes ☐ No

Which sports:_____

Occupational Capabilities

Duty status after injury: ☐ Return to duty ☐ COAD ☐ PEB ☐ MEB ☐ Separated/retained

Deployment MOS_____

Can you stand continuously for at least an hour? ☐ Yes ☐ No

Can you move with a load weighing at least 20lbs? ☐ Yes ☐ No

POSITIVE

Use of an Integrated Orthotic and Rehabilitation Initiative for Treatment of Lower Extremity Musculoskeletal Disorders

IDEO

Fill if receiving IDEO on LEFT leg	Fill if receiving IDEO on RIGHT leg
Desired amputation: ☐ Yes ☐ No Level: ☐ Above Knee ☐ Below Knee ☐ Through Knee Reason: ☐ Pain (Leg/Ankle) ☐ Weakness ☐ Limited Activity ☐ Nerve pain (Burning/Tingling) Other:_____	Desired amputation: ☐ Yes ☐ No Level: ☐ Above Knee ☐ Below Knee ☐ Through Knee Reason: ☐ Pain (Leg/Ankle) ☐ Weakness ☐ Limited Activity ☐ Nerve pain (Burning/Tingling) Other:_____
Major amputation on right leg? ☐ Yes ☐ No Level: ☐ Above Knee ☐ Below Knee ☐ Through Knee Partial foot amputation? ☐ Yes ☐ No	Major amputation on left leg? ☐ Yes ☐ No Level: ☐ Above Knee ☐ Below Knee ☐ Through Knee Partial foot amputation? ☐ Yes ☐ No
Peripheral nerve injury ☐ Yes ☐ No Numbness: ☐ Yes ☐ No If yes: ☐ Whole foot ☐ Part Foot ☐ Leg & Foot Weakness: ☐ Yes ☐ No If yes: ☐ Thigh ☐ Calf ☐ Shin (drop foot) ☐ Foot	Peripheral nerve injury ☐ Yes ☐ No Numbness: ☐ Yes ☐ No If yes: ☐ Whole foot ☐ Part Foot ☐ Leg & Foot Weakness: ☐ Yes ☐ No If yes: ☐ Thigh ☐ Calf ☐ Shin (drop foot) ☐ Foot
Nerve Pain (burn & tingling) ☐ Yes ☐ No If "Yes", location: ☐ Leg ☐ Foot	Nerve Pain (burn & tingling) ☐ Yes ☐ No If "Yes", location: ☐ Leg ☐ Foot
Decreased motion to joints: ☐ Yes ☐ No If "Yes", location: ☐ Knee ☐ Ankle ☐ Foot	Decreased motion to joints: ☐ Yes ☐ No If "Yes", location: ☐ Knee ☐ Ankle ☐ Foot
Did you have a circular external fixator? ☐ Yes ☐ No	Did you have a circular external fixator? ☐ Yes ☐ No
Foot/Ankle deformity ☐ Yes ☐ No If "Yes", location: ☐ Ankle ☐ Midfoot ☐ Forefoot ☐ Calcaneus ☐ Heel ☐ Talus	Foot/Ankle deformity ☐ Yes ☐ No If "Yes", location: ☐ Ankle ☐ Midfoot ☐ Forefoot ☐ Calcaneus ☐ Heel ☐ Talus
Muscle Loss (loss of function due to removal of muscle due to trauma or surgery: ☐ Yes ☐ No Location: ☐ Thigh ☐ Calf ☐ Shin ☐ Foot % Absent_____	Muscle Loss (loss of function due to removal of muscle due to trauma or surgery: ☐ Yes ☐ No Location: ☐ Thigh ☐ Calf ☐ Shin ☐ Foot % Absent_____
Soft Tissue Coverage needed: ☐ Yes ☐ No Type: ☐ Free Flap ☐ Splint thickness skin graft ☐ Shortened the leg with circular ex-fix Location_____	Soft Tissue Coverage needed: ☐ Yes ☐ No Type: ☐ Free Flap ☐ Splint thickness skin graft ☐ Shortened the leg with circular ex-fix Location_____

POSITIVE

Use of an Integrated Orthotic and Rehabilitation Initiative for Treatment of Lower Extremity Musculoskeletal Disorders

IDEO

Fill if receiving IDEO on LEFT leg	Fill if receiving IDEO on RIGHT leg
Post Traumatic Osteoarthritis (pain at a joint with weight bearing/activity): ☐ Yes ☐ No Joint(s) affected: ☐ Knee ☐ Ankle ☐ Back part of foot ☐ Middle/front of foot	Post Traumatic Osteoarthritis (pain at a joint with weight bearing/activity): ☐ Yes ☐ No Joint(s) affected: ☐ Knee ☐ Ankle ☐ Back part of foot ☐ Middle/front of foot
Fusion: ☐ Yes ☐ No If "Yes": ☐ During initial hospital stay ☐ After initial hospital discharge Location: ☐ Ankle only ☐ Subtalar ☐ Triple arthrodesis (back of foot but not ankle) ☐ Tibia/talus/calcaneus(entire back of foot and ankle)	Fusion: ☐ Yes ☐ No If "Yes": ☐ During initial hospital stay ☐ After initial hospital discharge Location: ☐ Ankle only ☐ Subtalar ☐ Triple arthrodes (back of foot but not ankle) ☐ Tibia/talus/calcaneus(entire back of foot and ankle)
Infection ☐ Yes ☐ No Location: ☐ Tibia (shin) ☐ Talus/Calcaneus (heel) ☐ Middle/front of foot Was treatment successful ☐ Yes ☐ No	Infection ☐ Yes ☐ No Location: ☐ Tibia (shin) ☐ Talus/Calcaneus (heel) ☐ Middle/front of foot Successful ☐ Yes ☐ No
Has it been 6 months and has your bone not healed yet? (Nonunion) ☐ Yes ☐ No Location_____ Did you require surgery for this? ☐ Yes ☐ No Successful ☐ Yes ☐ No	Has it been 6 months and has your bone not healed yet? (Nonunion) ☐ Yes ☐ No Location_____ Did you require surgery for this? ☐ Yes ☐ No Successful ☐ Yes ☐ No

Thank you for your time and participation

POSITIVE

Use of an Integrated Orthotic and Rehabilitation Initiative for Treatment of Lower Extremity Musculoskeletal Disorders

Trail Times ***For official use only***

Subject #_____ Date of Visit_____ Visit Description_____

Trial	SSWV - Level	Stair Climb	FSST	20 Meter Shuttle Run
	Sec. 1/100	Sec. 1/100	Sec. 1/100	Sec. 1/100
1				
2				
3				

Comments

Any major events (i.e. infection, need for additional surgery, etc.) in the patient's care since last study visit?

Appendix 11 Publications

(h-index=21, Total Citations: 1423)

Peer-Reviewed

1. Tribble DR, Lewandowski LR, Murray CK, Petfield JL, Warkentien T, Krauss Margot, Potter BK, Stinner D and the Trauma Infectious Disease Outcomes Study Group. Osteomyelitis Recurrence with Open Femur Fractures among Combat Casualties from Iraq and Afghanistan. J ORTHOP TRAUMA [In Press].
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3. Dunderdale CM, Chalupa RL, Potter BK, Burns TC, Hsu JR, Stinner DJ. Tobacco may not affect outcomes in combat related severe open tibia fractures. JBJS JOURNAL OF ORTHOPAEDICS FOR PHYSICIAN ASSISTANTS [In Press].
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Schmitz MR, Slaugh M, Song DJ, Stinner DJ, Tintle SM, Tucker CJ, Waltz RA, Wilson K. Current Concepts Review: Patient Reported Outcomes in Orthopaedics. J BONE JOINT SURG AM 2018;100(5):436-442.

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