EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session I:** Overview from EWI I / Research Updates
PRESENTATION	**#1:** United States Army Institute of Surgical Research (USAISR) Orthopaedic Trauma Research Program (OTRP)Update
SPEAKER	Joseph C. Wenke, PhD

The FY2006 Defense Appropriations bill designated $7.5M to establish the Orthopaedic Trauma Research Program in an effort to improve treatment and outcomes of battlefield extremity injuries. The OTRP is part of the part of the Medical Research and Materiel Command (MRMC) medical research program and is administered by the US Army Institute of Surgical Research in Fort Sam Houston, TX. Input from the first Extremity War Symposium, military orthopaedic surgeons, civilian clinician-scientists and experts in the field was used to develop the request for proposals that defined the purpose of the OTRP and the research areas of interest. These areas include bone regeneration, soft tissue healing, prevention of wound infection, improving irrigation/debridement techniques, prevention of heterotopic ossification, and epidemiology of current battle-related injuries. Strongest consideration was placed on proposals that could improve patient care of battlefield-injured warriors within five years by providing an improved treatment, product, or change of guidelines. One hundred pre-proposals were submitted, and seventy-five of these were invited to submit full proposals. Sixty proposals were received by the May 9, 2006 deadline and were evaluated and scored by a review panel. Ultimately, fourteen protocols were selected for funding. Several of these protocols proposed multi-year funding which will require the investigators reach yearly milestones to receive continual funding. It is anticipated that the $6.8M funded for FY2007 will only allow a few new projects to be funded in addition to funding those protocols that successfully meet the criteria for continuation funding. The OTRP is different from other Congressional set-aside research projects that are intended to improve treatment and outcomes of battlefield injuries. Instead of having the resources designated to fund a specific project, the OTRP has a competitive funding process. Proposals are peer-reviewed on the degree of 1) military relevance, 2) military impact, and 3) scientific merit. This process ensures that research projects that have the highest chance to improve treatment of battlefield injuries are funded and is felt to be the best use of resources.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session I:** Overview From EWI I / Research Updates
PRESENTATION	**#2:** National Center for Medical Rehabilitation Research (NCMRR): Updates on Prosthetics and Assistive Technologies
SPEAKER	Michael Weinrich, MD

Investigator Initiated Research

- Investigators set directions
- No fixed priorities
- Competitive review
- R01, R21, R03 (research grant), K (career development), R41 (SBIR) mechanisms
- > 80% of NIH funding
- Deadlines 3x/yr

Current Projects of Note

- Amputation Surgery and Prosthetic Education (James, U Michigan)
- Do Amputees Benefit from Rehabilitation Services? (Stineman, U Pennsylvania)
- EMG propagation in planar muscles for prosthetic control (Kuiken, Northwestern)
- BMP and FGF signaling in mammalian digit regeneration (Muneoka, Tulane)
- Computerized prosthetic alignment system (Boone, Cyma)
- High-performance transcutaneous port (Cahn, Biomedical Strategies)
- A low-cost upper-extremity prosthesis for under-served populations (Veatch, Ada Technologies)
- Career training in bladder control neural prosthesis (Gustafson, Case Western)

Resources

- Program officers
  - Dr. Louis Quatrano quatranl@mail.nih.gov
  - Dr. Nancy Shinowara shinowan@mail.nih.gov
  - Dr. Michael Weinrich mw287k@nih.gov
- CRISP http://crisp.cit.nih.gov/
- Office of Extramural Research http://grants1.nih.gov/grants/oer.htm
- Tutorial http://www.niaid.nih.gov/ncn/grants/default.htm

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session I:** Overview From EWI I / Research Updates
PRESENTATION	**#3:** Update on National Institutes of Health (NIH) Research: National Institute of Arthritis and Musculoskeletal and Skin Diseases
SPEAKER	James S. Panagis, MD, MPH

The National Institutes of Health (NIH) is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. Composed of 27 institutes and centers, the goals of the agency are as follows:

1. foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health;
2. develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
3. expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
4. exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

1. in the causes, diagnosis, prevention, and cure of human diseases;
2. in the processes of human growth and development;
3. in the biological effects of environmental contaminants;
4. in the understanding of mental, addictive and physical disorders; and
5. in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

Although research related to musculoskeletal trauma is supported by several of its Institutes and Centers, the focal point for this research at the NIH is the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The mission of the NIAMS is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases. Through its Extramural and Intramural Research Programs, the NIAMS supports a broad range of basic science and clinical research in the area of musculoskeletal trauma. In addition, it supports an even larger portfolio of related research in the areas of regenerative medicine, and in bone, cartilage and connective tissue, muscle, and skin biology.

The purposes of this presentation are to briefly review this portfolio, discuss ongoing initiatives in the area of musculoskeletal trauma, and to state our willingness to establish collaborative activities/partnerships to support further research in this important area.

For more information, please visit: http://www.nih.gov/about/researchadvances.htm.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	Session I: Overview from EWI I / Research Updates
PRESENTATION	**#4:** Department of Defense Appropriations for Extremity War Injuries
SPEAKER	Kathryn M. Pontzer, JD

Prior to 2004, the American Academy of Orthopaedic Surgeons (AAOS) had not actively pursued musculoskeletal research funding issues within the Department of Defense. In 2004, the AAOS secured language in the fiscal year (FY) 2005 Defense Appropriations bill to make "orthopaedic extremity trauma research" one of the 21 research priorities in the Peer Reviewed Medical Research Program. The appropriations bill included $50 million in funding to be distributed through a competitive grant process, to fund research on these priorities. This language was the first step in laying the foundation to work with key members of the House and Senate Defense Appropriations Subcommittee to ensure that the need for expanded orthopaedic trauma research would be recognized and addressed in future years.

In 2005, the AAOS Office of Government Relations greatly expanded its efforts to obtain federal funding through the Department of Defense Appropriations bill for military orthopaedic trauma research. In the FY 2006 Defense Appropriations bill, Congress appropriated $7.5 million specifically earmarked to establish the Orthopaedic Extremity Trauma Research Program (OETRP) at the U.S. Army Institute of Surgical Research (ISR) in Ft. Sam Houston, Texas. ISR is responsible for administering this program, which now funds intramural and extramural peer-reviewed orthopaedic trauma research. The original request of the AAOS was $25 million.

Last minute conferencing between House and Senate Defense appropriators resulted in $6.8 million to fund OETRP in FY 2007. This reduction was largely driven by the Senate. Senator Ted Stevens (R-AK), Chair (now Ranking Member) of the Senate Defense Appropriations Subcommittee, who was an outspoken advocate for the program, was required by the full Appropriations Committee to cut $9 million more from his Defense budget for domestic programs. The House had recommended $9 million to fund OETRP.

Despite this cut back, the OETRP was one of the highest funded programs in the 299 line items under the "Medical Technology" and "Advanced Medical Technology" programs of the Army under Title IV, Research, Development, Test and Evaluation of the Defense Appropriations Act of 2007, H.R. 5631. Also, while the AAOS-supported program received a reduction in funding, it is interesting to note that there was a marked increase in funding for orthopaedic-related research between FY 2006 and 2007 directed to specific universities. Funding for orthopaedic research in FY 2007 now approaches $30 million with the bulk of this funding going to research earmarked for specific institutions at the request of individual Members of Congress.

As the AAOS prepares to lobby for FY 2008 funding, 14 grants are currently funded under the OETRP. But the opportunity for significant advancement in orthopaedic exists, inasmuch as the OETRP received over 60 grant proposals for the initial $7.5 million in funding for FY 2006. With this funding program in place, the AAOS continues to work closely with military orthopaedic surgeons at ISR, Brooke Army Medical Center, Walter Reed Army Medical Center and elsewhere, to identify gaps in musculoskeletal trauma research and to use this information to advocate for an increased federal commitment. These funds are critical to support the previously funded multi-year grants and to fund additional intramural and extramural orthopaedic trauma research priorities.

This presentation will review the new 110th Congress, specifically the Defense Appropriation Subcommittee members, and discuss strategy for outreach to key legislators using the information on the OETRP grants to convey critical research needs and successes.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session I:** Overview from EWI I / Research Updates
PRESENTATION	**#5:** The Military Orthopaedic Trauma Registry
SPEAKER	LTC H. Michael Frisch, MD

The MOTR (Military Orthopaedic Trauma Registry) was created to be a comprehensive database specific for war injuries by modifying internationally accepted classifications and then using it as a basis for a Joint Military Orthopaedic registry. As with any classification, to be useful it must consider the severity of the injury and serve as a basis for treatment and evaluation of the results. It has to be designed to maximize reliability, accuracy, and validity, while minimizing variability. It also has to have the flexibility to capture retrospective and prospective data. The classification and evaluation of Extremity War Injuries is complicated not only by the severity of the injuries but by the fact that patients have often sustained multiple overlapping injuries. Other unique factors which must be considered include: Massive Soft Tissue Wounds, Cavitation, Contamination, Burns, Segmental Defects, and Amputations. While the structure and design of the registry is crucial to its utility, without proper support and defined protocols of use the registry full potential will not be realized. Abstracters, registrars, and computer programmers must be fully trained in, funded, and dedicated to the maintenance of the registry. To facilitate both multi-center and multi-specialty research, the MOTR will be linked to the JTTR (Joint Theater Trauma Registry).

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session II:** Field Hemostatic Techniques and Their Overall Implication on Extremity Wound Management
PRESENTATION	**#6:** The Scope of Wounds Encountered in Casualties from The Global War on Terrorism
SPEAKER	CDR Michael Mazurek, MD

The injuries seen in our current conflict demonstrate a broad scope of wounds that range from the simple and straight forward, that can be managed with non-operative wound care only, to the more dramatic extremity injuries requiring amputation or multiple bony and soft tissue procedures for limb salvage. The majority of wounds are minor and can be managed non-operatively, overall data from OIF supports this since greater that 50% of those wounded return to duty. Thanks, in part, by the use of body armor, "up-armored" vehicles, intense training of our Marines, Sailors and Soldiers, and surgical capability within minutes of the battlefield, survivability of those wounded in Operation Iraqi Freedom (OIF) is at roughly 90%. Much like we are seeing extremity trauma in the civilian trauma center that was not survivable prior to the advent of automobile crumple zones, airbags, seatbelt laws, and maturation of our Trauma Systems, extremity battlefield trauma is too increasing in complexity and severity. Therefore the spectrum of injury we see in our current conflict ranges from minor wounds to previously fatal wounds requiring multiple procedures for soft tissue and bony defects or multiple prosthetic challenges.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session II:** Field Hemostatic Techniques and Their Overall Implication on Extremity Wound Management
PRESENTATION	**#7:** Emergency Tourniquet Use to Stop Bleeding in Major Limb Trauma
SPEAKER	COL John F. Kragh, Jr., MD

The Thomas splint was the only first aid device shown to decrease mortality in limb injured patients until now. The number one cause of preventable battlefield death is isolated limb hemorrhage, and about half of preventable deaths fall into this category. Overall, 10% of battlefield deaths are from isolated limb exsanguination, and this is from the Vietnam War.

Recent introductions of tourniquets and changing doctrine has led to apparent reductions in prehospital deaths from limb exsanguination in recent wars, but the problem has not been completely eradicated. Tourniquets used in selected patients have saved lives on the battlefield, and anecdotal evidence is currently being replaced with cohort data of greater rigor. Preliminary analysis shows that early use of tourniquets is associated with a lower mortality than later use and that prehospital use is better than hospital use. Palsy and amputation rates from tourniquet use are about 1% each. Due to the lack of quality data and persistent conventional wisdom of the tourniquet as a method of last resort, fielding of tourniquets of soldiers from some nations has been absent or slow. The filling of specific knowledge gaps regarding tourniquet use should help resolve the controversies regarding their use, fielding, development, and risks of morbidities. Few organizations, research universities or corporations are involved in combat casualty care research, and yet the opportunity to address important topics such as whether first aid devices are associated with improved mortality can in theory be studied in war's epidemics of casualties. However, the difficulties in doing clinical research in normal settings are complicated in wartime. The work is hard yet the gain is large. Further work needs to include a cohort matched study design to see if tourniquets are lifesaving in a more rigorous study. Longer follow up of patients with tourniquets may help measure the risks of emergency use.

During the first Emergency War Injury symposium of the American Academy of Orthopaedic Surgeons in 2006, the word tourniquet was mentioned rarely, but the data indicate that they are powerful lifesaving devices worthy of study. Orthopaedic surgeons are the subject matter experts to whom emergency providers and patients turn toward to ask questions about tourniquet use and risks. The body of knowledge regarding emergency tourniquet use rests on the foundation of science regarding operating room tourniquet use, and the body of knowledge regarding emergency tourniquet use requires further development through clinical and translational research.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session II:** Field Hemostatic Techniques and their Overall Implication on Extremity Wound Management
PRESENTATION	**#8:** Application of HemCon® in Battlefield Extremity Trauma: A Preliminary Report on the Chitosan-Based Hemostatic Dressing: Experience in Current Combat Operations
SPEAKER	John B. Holcomb, MD **Co-Investigators:** Ian Wedmore MD, John G. McManus, MD, and Anthony E. Pusateri, PhD

Background: Hemorrhage remains a leading cause of death in both civilian and military trauma patients. The HemCon® chitosan-based hemostatic dressing is approved by the U.S. Food and Drug Administration (FDA) for hemorrhage control. Animal data have shown the HemCon® dressing to reduce hemorrhage and improve survival. The purpose of this article is to report preliminary results of the hemostatic efficacy of the HemCon dressing used in the prehospital setting on combat casualties.

Methods: A request for case information on use of HemCon® dressings in Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) was sent to deployed Special Forces combat medics, physicians and physician assistants**.**

Results: Forty-eight uses of the HemCon® dressing were reported and reviewed by two U.S. Army physicians. Four of the 48 cases were determined duplicative resulting in a total of 44 combat uses. Dressings were utilized externally on the chest and abdomen in 19 cases, on extremities in 23 cases and on neck or facial wounds in 2 cases. In 66% of cases dressings were utilized following gauze failure and were 100% successful. In 42 (95%) of the cases, the use of the HemCon® dressing resulted in cessation of bleeding or improvement in hemostasis. Dressings were reported to be most useful on areas where tourniquets could not be applied to control bleeding. The dressings were reported to be most difficult to use in extremity injuries where they could not be placed easily onto or into the wounds. No complications were reported.

Conclusion: The HemCon® dressing appears to be an effective hemostatic agent for prehospital combat casualties.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session II:** Field Hemostatic Techniques and their Overall Implication on Extremity Wound Management
PRESENTATION	**#9:** Application of QuikClot™ in Battlefield Extremity Trauma
SPEAKER	CAPT Peter Rhee, MC, USN

Whether in the field and or the hospital, expedient hemorrhage control is of paramount importance in management of trauma. The US military has recently developed and tested a number of local hemostatic agents designed to facilitate rapid hemorrhage control. One of these products, approved by the Food and Drug Administration (FDA) for external use and fielded by the US Military is a manufactured granular mineral zeolite called QuikClot™. This inert mineral product composed of oxides of silicon, aluminum, sodium, and magnesium and small amounts of quartz. It acts as molecular sieve and rapidly adsorbs water in a non-chemical, physical reaction. While this process generates heat, the primary mechanism effecting hemostasis appears to be the rapid concentration of platelets and clotting factors which promotes rapid clot formation. Although this product is being sold and distributed, its' clinical use and efficacy has not yet been reported. This case series describes the first 103 documented clinical use of this local hemostat.

Methods: The uses have been reported by a variety of personnel including civilian and military use. Documented cases utilizing a self reporting survey sheet submitted by the users and first hand detailed interviews with the users when possible.

Results: There were 103 documented cases of QuikClot™ use: 69 by the US Military in Iraq, 20 by civilian trauma surgeons and 14 by civilian first responders. There were 83 cases involving application to external wounds and 20 cases of intracorporeal use by military and civilian surgeons. All field applications by first responders were successful in controlling hemorrhage. The overall efficacy rate was 92% with eight cases of ineffectiveness noted by physicians in morbid patients with massive injuries when the QuikClot™ was used as a last resort. These reported failures were felt to be due to the coagulopathic state of the patient from massive resuscitation or the inablility to get the product directly to the source of hemorrhage. When the QuikClot™ was applied on responsive patients the heat generated by the exothermic reaction caused mild to severe pain and discomfort. There were three cases of burns caused by the heat generated by the QuikClot™ application with one case requiring skin grafting. There was one major complication from intracorporeal use due to scar formation from a foreign body reaction.

Conclusions: QuikClot™ has been used effectively used by a wide range of providers in the field and hospital to control hemorrhage. The overall efficacy was 92% but the field experience by various providers was 100%. The QuikClot™ is approved for use on uncontrolled external hemorrhage but there have been 20 cases of intracorporeal use for uncontrollable life threatening hemorrhage that was not amendble to conventional therapy. Ineffectiveness of QuikClot™ has been reported in coagulopathic patients where it was felt that QuikClot™ could not be applied directly to the bleeding source. While some complications have been reported, its ultimate complication rate is not yet fully known. As with any tool available for medical use, there are appropriate circumstances where it is useful and circumstances where it is not. Obtaining training prior to use would be preferred whenever possible.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session II:** Field Hemostatic Techniques and their Overall Implication on Extremity Wound Management
PRESENTATION	**#10:** Fibrin Sealant Dressings
SPEAKER	MAJ Martin A. Schreiber, MD FACS

Hemorrhage is the leading cause of preventable death both on the battlefield and in civilian trauma deaths. During the last decade, the field of advanced hemorrhage control has exploded resulting in a number of products that have proven superiority over the traditional agents that have been used for centuries. The purpose of this presentation is to discuss the composition, delivery and uses of representative products that contain fibrin and/or thrombin.

The dry fibrin sealant dressing (DFSD) is composed of lyophilized human thrombin and fibrinogen imbedded in a vicryl mesh. The dressing delivers a high concentration of coagulation factors to the site of injury and it is absorbable theoretically obviating the need for a second operation if it is left in place to control bleeding. DFSD has been shown to be effective in coagulopathic and non-coagulopathic animal models utilizing Grade V liver injuries, aortic injury and femoral arterial injury. There has been limited use in humans. DFSD can be carried by medics in the field and it has been applied to a combat victim.

The first fibrin sealant approved in the United States was Tisseel®. Tisseel® is composed of human fibrinogen and thrombin from pooled plasma donors as well as bovine aprotinin. Its preparation requires stirring and warming for up to 20 minutes making it less ideal as an agent for unplanned emergencies. Tisseel® is FDA approved for cardiopulmonary bypass, splenic injury and colostomy closure. It can be applied utilizing a syringe applicator or with a spray device.

Evicel® is an entirely human-based product made up of fibrinogen and thrombin. It can be stored for up to 2 years at -18C but it then requires thawing into liquid form prior to use. It can also be stored for 30 days at 2-8C and it can then be used immediately with minimal preparation. Evicel® is indicated as an adjunct to hemostasis in liver resection surgery when standard techniques have failed. It has been shown to reduce the time to hemostasis in patients undergoing liver resection compared to standard topical agents. Evicel® can be applied with a syringe device or sprayed on diffuse surfaces using a pressure regulator.

The final product to be discussed is FloSeal®. Floseal® is composed of a gelatin matrix made from bovine collagen that consists of microgranules that are cross-linked with glutaraldehyde. This matrix is mixed with thrombin prior to application and it is rapidly available for use. Thrombin enhances clotting and the granules swell approximately 20% producing a tamponade effect. Floseal® has been shown to accelerate the time to hemostasis after cardiac and vascular surgery when compared to gelfoam and thrombin. It is applied using a syringe applicator.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session II:** Field Hemostatic Techniques and their Overall Implication on Extremity Wound Management
PRESENTATION	**#11:** Frontline Experience with Field Hemostatic Measures
SPEAKER	CAPT Frank K. Butler, Jr., MD

Combat medics in the U.S. military are currently trained to manage extremity trauma on the battlefield using the measures outlined in the Tactical Combat Casualty Care guidelines contained in the Sixth Edition of the Prehospital Trauma Life Support Manual. The Care under Fire guidelines call for the combat medic to stop life-threatening external hemorrhage using a tourniquet for hemorrhage that is anatomically amenable to tourniquet application. Once care has moved into the Tactical Field Care phase, the medic is directed to assess for discontinuation of tourniquets once bleeding is controlled by other means. These means include direct pressure combined with the hemostatic agents HemCon® and QuikClot™. Before releasing a tourniquet on a patient who has been resuscitated for hemorrhagic shock, the combat medic should assure a positive response to resuscitation efforts (i.e. a peripheral pulse normal in character and normal mentation if there is no associated traumatic brain injury).

Multiple reports from medics and physicians have documented that tourniquets are working well and saving lives on battlefields in the Global War on Terror. Additionally, failure to use tourniquets in some casualties has resulted in deaths that were potentially preventable. Tourniquets are particularly valuable when the casualty's unit is still actively engaged with hostile forces, when the casualty is experiencing life-threatening hemorrhage from more than one extremity, and when multiple casualties are sustained. Reported complications from battlefield tourniquet use have been few and limited to peripheral neuropathies. Most of the reported experience has been with the Combat Application Tourniquet. This device has worked well after a few problems with the windlass breaking in early models. Adequate training in tourniquet use for deploying combatants is critical to successful use in combat. Key training points include: 1) the need for ALL combatants to carry tourniquets and be trained in their use; 2) the need for the tourniquet to be carried in a location on the battle gear that affords immediate access if needed; 3) what wounds are appropriate for tourniquet use; 4) what wounds are NOT appropriate for tourniquet use; 5) the correct location for the tourniquet in relationship to the wound; 6) when to remove the tourniquet; 7) when NOT to remove the tourniquet; 8) not to intermittently loosen the tourniquet while applied; 9) HOW to remove the tourniquet when it is appropriate to do so; and 10) instruction and practice in applying the Combat Application Tourniquet.

Both HemCon® and QuikClot™ have been shown to be effective in controlling life-threatening hemorrhage and should be carried by all combatants. These agents are most valuable for controlling hemorrhage in sites that are not amenable to tourniquet use, but are also useful when trying to remove tourniquets from extremity wounds. HemCon® should be used as the agent of first choice because it does not produce the painful exothermic reaction seen with QuikClot™. QuikClot™ should be held in reserve for cases in which the hemorrhage is not well-controlled with HemCon®.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session III:** Early Debridement
PRESENTATION	**#12:** Principles and Techniques of Debridement
SPEAKER	COL Roman Hayda, MD

Debridement, a seemingly simple surgical procedure, is much more complex and controversial in actual practice. War wounds are associated with a high degree of contamination and tissue injury requiring expert debridement to reduce the risk of infection. Explosive weapons in particular drive foreign material from the munition and the surrounding environment deep into the soft tissues and bone. In addition, tissues to include muscle, fat, and even bone may be extensively devitalized by high energy weapons such as machine guns. Regardless of its historical origins, debridement has come to signify the excision of devitalized tissue and removal of foreign material to prevent infection. It is invariably linked to the process of irrigation of the wound to further reduce infection. The most effective and efficient process of debridement should lead to the significant reduction of infection while maximizing the function of the limb upon healing.

The process of debridement involves inspecting the wound, enlarging its margins, and removing devitalized and foreign material. The most efficient debridement is thorough and does not rely on serial visits to the operating theater. At the conclusion of debridement, the injury should be ready for definitive treatment and healing.
In practice the surgeon is faced with a number of choices: which wounds require debridement; how is the limb and its tissues investigated; how much tissue should be removed under ideal conditions; and what is the minimum that should be debrided under less than ideal conditions? These questions hinge on the concept of zones of injury. There exists a transitional zone of injury which is not clearly necrotic but is not normal. Depending on local and systemic factors, this transitional zone may recover or necrose. The management of the wound and of the patient influences the fate of this transitional zone and has a significant impact on patient outcome. While most wounds are recommended for formal surgical management including some requiring extensive dissection into cavities and along tissue planes, some wounds can be superficially cleansed and allowed to heal.

The assessment of tissue vitality is still dependent on very subjective visual and tactile inspection. Muscle is evaluated by its color, contractility, consistency and capacity to bleed. Skin, fat and fascia are similarly evaluated. Finally, bone which is stripped of soft tissue, unless it is "critical" to reconstruction such as those containing significant articular segments, is recommended for removal. The subjective nature of these evaluations leads to variable practice by surgeons affecting how extensively wounds are opened, how much tissue is removed, and ultimately affect patient outcome.

Recent investigations have demonstrated that standard methods of irrigation may traumatize tissues while also further imbedding foreign material. The clinical relevance of these studies is not yet clear. The optimal method of irrigation in terms of fluid type, amount and delivery method or additives remain under investigation, and are important in the effective reduction of infection.

Improving outcomes and minimizing complications in treating war injured will rely on standardizing the following: wound assessment; technique of debridement; frequency and interval for reinspection: and optimization of recovery of the transitional zone. Practice, research and guidelines should be aimed at improving objective criteria for debridement and its techniques.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session III:** Early Debridement
PRESENTATION	**#13:** Indications for Primary Amputation: The Ultimate Debridement
SPEAKER	MAJ Greg M. Osgood, MD

Protection of vital organs through the universal use of body armor has been a significant advancement in modern armed conflict. Soldiers survive significant high energy ballistic and blast trauma but commonly sustain severe injuries to exposed limbs. Injuries include open fractures, catastrophic soft tissue damage, neurovascular disruptions, near amputations, and extensive burns. Patients in Level 2 and Level 3 combat hospitals present challenging decisions to orthopaedic surgeons who may not have extensive experience in limb salvage and primary trauma amputation. Expanding on civilian research and further examining current indications for acute amputation of mangled extremities may help establish more concrete guidelines for wartime surgeons.

One generalized indication for acute amputation is the attempt to decrease polytrauma patient mortality. At Level 2 and 3 facilities multispecialty trauma teams evaluate the impact of the mangled extremity on patient resuscitation. The general trauma surgeon may recommend amputation based on the limb's metabolic load on the patient's physiological reserves in the setting of polytrauma. Rising serum lactate in acidosis, acute anemia secondary to uncontrolled hemorrhage, warm ischemia time, and other resuscitation indices may provide life saving justification for primary amputation in the under-resuscitated patient. Rules for acute amputation based on physiological parameters, however, are lacking; such indications would assist the field surgeon greatly when struggling to resuscitate a patient with a mangled extremity.

A second category of amputation indications includes those factors that may increase reconstruction morbidity or impair functional recovery during salvage. Limb salvage indices were originally developed to provide guidelines for early mangled extremity care. Recent literature has suggested, however, that these algorithms are poor predictors of success through either amputation or reconstructive procedures. The combat orthopaedic surgeon, like the civilian trauma orthopaedist, evaluates the amount of bone loss, the severity of soft tissue injury (muscle damage, arterial disruption, tibial nerve continuity, and soft tissue coverage), the likelihood of salvage complications (infection, nonunion, and poor function), and the anticipated protracted course of functional recovery, when considering extremity amputation. Here, the orthopaedic surgeon's trauma training and experience play critical roles in early decision making. The LEAP study has examined the validity of these relative amputation indications among civilians, however, those patients differ from injured soldiers in injury, demographic, and socioeconomic characteristics. These differences may impair extrapolation of LEAP study results to combat casualty outcomes.

The indications for acute amputation for extremity war injuries remain imprecise and subjective despite recent studies performed on civilian patients. The LEAP study provides insufficient guidelines for early management of severe extremity war injuries prior to arrival at the Level 5 trauma center, but supplies a framework for future combat casualty research. A high incidence of severe upper extremity injury mandates dedicated investigation into the predictors of successful reconstruction or amputation of upper extremity wounds. Further evaluation of surgeons' front line decision making may determine useful physiological parameters and wound characteristics that advocate acute life saving amputation in the field. Rigorous retrospective review of casualties from current conflicts in Iraq and Afghanistan may, in the near future, yield reliable clinical determinants of successful limb reconstruction and amputation.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session III:** Early Debridement
PRESENTATION	**#14:** Secondary Debridement
SPEAKER	LTC H. Michael Frisch, MD

The importance of debridement or excision of Extremity War Injuries has been recognized by military surgeons throughout history. The technique of debridement / excision was standardized during WWI at Inter-Allied Surgical Conference in1917 and included: extension of the wound, excision of the skin margin, exploration of all layers, and excision of nonviable muscle. These principles were developed in a pre-antibiotic era with the ultimate goal of removing both contamination and devitalized tissue which could serve as a potential culture medium thereby reducing the risk of infection. These principles and techniques have not changed though and are still the basis by which both civilian and military surgeons treat wounds.

While the current trend in the civilian trauma care is toward immediate primary closure and fracture fixation after the initial debridement, the severity of Extremity War Injuries often prohibit this approach and require serial debridements. The treatment of Extremity War Injuries is essentially a balance between the excision of nonviable tissue to prevent an infection and the preservation of viable tissue to facilitate reconstruction. A grey zone is created by the dynamic nature of the tissue within the wound and the process of demarcation. The transfer of energy by ballistic and blast injuries to tissues creates a zone of injury which can be further divided into the permanent cavity, the zone of extravasation, and the zone of concussion. The degree of tissue damage as well as it ability to recover is variable between these zones and results in a demarcation of the tissue within the wound over time.

Since the Extremity War Wounds are contaminated and will demarcate over time resulting in additional nonviable tissue, it is generally recommended to perform serial or secondary debridements until the wound has stabilized to prevent an infection from developing after definitive closure or fixation. Several factors will affect the need to perform a secondary debridement. Intrinsic factors are those which directly relate to the patient and his wound and extrinsic factors are outside influences which can have an effect. Intrinsic factors can be further subdivided into systemic and local. Systemic being the physiologic status of the patient: his ability to perfuse and maintain tissue viability and his ability to resist infection. Local factors being the nature of the wound itself and level of contamination. Extrinsic factors are those which interfere with the patient receiving timely and appropriate care. The surgeon must take all these factors into consideration when deciding upon the need for a secondary or serial debridement. Inherent to the topic of secondary debridement is the question of how to objectively assess the adequacy of debridement, viability of tissue, and the level of contamination.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session IV:** Early Stabilization
PRESENTATION	**#16:** Overview of Bone Stabilization Issues
SPEAKER	COL Roman Hayda, MD

Fracture treatment, both open and closed, presents a unique challenge to the war surgeon. These fractures are frequently open, complex and sustained in remote locations with limited resources for care. It is imperative for the war surgeon to thoroughly understand these injuries, the biomechanical and physiologic principles of treatment as well as the constraints of the tactical environment for optimal treatment.

In previous conflicts casting, splinting, and traction for definitive care were the mainstays of fracture treatment. However, the evolution of orthopaedic technology has allowed for the evolution of techniques of bony stabilization. Currently, external fixation has become the mainstay of initial treatment of long bone fractures and periarticular injury of war casualties. Although there are clear advantages to this method, its limitations and complications must be acknowledged.

External fixation is almost the ideal fracture management tool for the austere environment. With a relatively small inventory, frames can be placed to effectively stabilize almost all long bone injuries and the pelvis. By achieving bony stabilization limb alignment and length can be maintained while allowing for wound inspection. Knowledge of critical anatomy and biomechanical principles allows for safe and effective treatment in most all situations. The minimally invasive technique and minimal internal implant burden also assists in mitigating infection. Effective external fixation of the appendicular skeleton lessens ongoing soft tissue injury, assists in pain management and facilitates transport.

Most of these frames are used only in transport being changed to other forms of internal or external fixation when the casualty reaches their definitive care facility. It is rare that the frame placed in theater becomes the definitive form of fracture care. However, given logistical and operational constraints how much stabilization is required to allow for transport between the very austere level 2 facility and level 3 and subsequently between level 3 and level 5? Development of appropriate guidelines will assist in creating frames that are effective and economical for their intended purpose while not limiting the options for definitive care.

The pins provide the critical interface for this device. However, they can also be associated with nerve and vessel injury. Pin track infections can be especially problematic if the pin is close to the fracture site. Methods to decrease pin infections and soft tissue injury must be included to optimize the application of external fixation.
Fractures around the shoulder but especially the hip have presented challenges to the use of external fixators. Although the frame provides traveling traction, the combined weight and the long lever arm of the extremity is very demanding of the frame construct. Additionally, fixation into the pelvis is more difficult to achieve especially in the field environment. Although outright frame failures have not been observed when spanning the hip, its shortcomings in stabilization, pain control and transport warrant discussion and consideration of alternate methods.

Splints and K-wires are also forms of excellent bony stabilization especially in the upper extremity and the foot even in mutilating injury. These methods must be included the orthopaedic war surgeon armamentarium. Guidelines and technical tips for bony stabilization using external fixation, k-wires splint and other methods in the austere environment will assist the war surgeon to implement the optimal tool for the given clinical and tactical situation.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session IV:** Early Stabilization
PRESENTATION	**#17:** Principles of External Fixation for Damage Control / Austere Environment
SPEAKER	David Teague, MD

The care of high energy extremity trauma in civilian trauma centers has changed dramatically in the last 10-15 years. Attention to the integrity of the soft tissue envelope surrounding periarticular injuries, in particular, led to many staged protocols for management of these complex fractures, the hallmark of which was the liberal use of bridging external fixation. The emphasis on temporizing measures allowed the controlled surgical planning and technical execution that these difficult fractures require for limb and function preservation. The damage control movement for management of multiply injured patients likewise led to reassessments of the wisdom of prolonged exhaustively definitive surgical management of all long bone injuries at the time of presentation. The convergence of these two developments currently has generated a heightened awareness for the patient's overall status, with particular attention to manage limbs effectively without causing additional and preventable damage to the patient's pulmonary injuries and traumatic brain injuries. Utilizing the team approach, with leadership from the general surgery trauma chief and input from the neurosurgeon, the orthopedic team can logically plan the best extremity management interventions in staged fashion.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session IV:** Early Stabilization
PRESENTATION	**#18:** Realities of External Fixation in the Field: Options and Technical Tips
SPEAKER	MAJ Greg M. Osgood, MD

External fixation of extremity injuries has become the foundation of in-theater orthopaedic surgery. Compact sterile packaging of standard instrumentation for field use has simplified external fixator application at Level 1 and Level 2 echelons of care. Effective unilateral frames are assembled close to the forward line of battle; patients arrive at Level 3 facilities with successful early fracture stabilization and wound management. Simple frames have facilitated timely injury debridement, wound care, pain control, and patient transport. Some lingering deficits in combat external fixator application, however, require recognition.

Certain fracture patterns present significant challenges to applying effective fracture stabilization through external fixation in the field. Acetabulum fracture dislocations, proximal humerus fractures, pertrochanteric femur fractures, and subtrochanteric femur fractures are especially difficult to stabilize with simple external fixation. Internal fixation options are available at most Level 3 facilities, but they expose soldiers to the significant risk of infection. Consequently, internal fixation is usually reserved for Level 5 care.

External fixators are applied at Level 2 hospitals under austere conditions. Close to the front lines, these facilities usually lack fluoroscopy and have field hospital operating tables that can impair the optimal use of fluoroscopy. Although effective fracture stabilization is usually achieved in this setting, suboptimal pin placement and incomplete fracture reduction can result. Definitive fracture care once the patient reaches a Level 5 facility may be facilitated by improved operating conditions at Level 2 centers.

Most orthopaedic surgeons deploying to war do not routinely evaluate wounds comparable to those that modern combat is delivering to the field hospital. Guidelines for unfamiliar operative techniques, including effective external fixator application for complex high energy bony and soft tissue wounds, will improve early patient care and assist definitive management. These guidelines should address not only optimal techniques of fracture stabilization and the safe placement of fixator pins, but also should discuss the effect of Level 2 and 3 surgeons' decisions on definitive fracture fixation and the impact of frame application on wound care and patient transport. Wartime soft tissue wounds are challenging for orthopaedic surgeons who do not take call at major trauma centers. More extensive use of established trauma training facilities, available to all services, may supplement exposure of surgeons to complex orthopaedic injuries and recent technical advancements prior to deployment.

Level 5 facilities are employing dynamic multiplanar external fixation for definitive fracture management more frequently as experience with this technique builds and as evidence emerges supporting limb salvage procedures. A field surgeon's consideration of these techniques during the primary unilateral external fixator application may improve the conversion to more dynamic multiplanar frames once the patient is evacuated. The use of multiplanar fixation at Level 3 and 4 facilities requires further consideration as physician experience at these centers expands.

Simple external fixator use in the field has advanced early patient care; however, specific improvements in military application will further enhance definitive fracture management. Future developments should include additional consideration for difficult fracture patterns, standardized protocols for pin care, upgrades in forward operating conditions, the forward employment of multiplanar fixator systems, and advanced guidelines for external fixator application in the field.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session IV:** Early Stabilization
PRESENTATION	**#19:** Impact of Initial Fixation on Definitive Care Options
SPEAKER	LTC Romney C. Andersen, MD **Co-Investigators:** LCDR Jonathan A. Forsberg, MD and LCDR John Keeling, MD

The recent conflict in Iraq has produced over 46,880 casualties evacuated to the United States for definitive care. Initial (battlefield) care consists of aggressive resuscitation, a thorough surgical debridement, external fixation of fractures followed by neurovascular intervention to include fasciotomies. External fixation is applied in an expedient fashion, often without the use of fluoroscopy. It is not uncommon that the initial external fixator configuration and fasciotomy locations complicate the definitive fixation options. In fact, several aspects of initial orthopaedic care have significant ramifications regarding definitive fixation at the tertiary care military medical center.

Transition from an external fixator to an intramedullary device is controversial in this patient population and many reports show relatively high rates of infection. Data presented at the Society of Military Orthopaedic Surgeons (SOMOS) demonstrated over a 10 % infection rate for conversion of tibial fractures treated initially with external fixation to an intramedullary device. The initial pin placement generally dictates that new pins be placed through a new skin incision to avoid pin tract infections. Therefore, it is desirable that the stabilization and transport frame not use the most desirable pin sites, leaving them available for definitive fixation, if necessary. Pins should also be placed through normal skin whenever possible as it allows for easier VAC ™ placement throughout the serial debridement process.

Early intramedullary fixation is an attractive option as civilian trauma centers report acceptable infection rates. Our patient population demands thorough and adequate serial debridement procedures prior to any type of internal fixation, particularly intramedullary nailing. In our experience, early intramedullary fixation has resulted in several cases of deep, intramedullary osteomyelitis that are difficult to treat and result in a high degree of morbidity and prolonged convalescence. In rare instances, amputations were necessary to successfully eradicate this type of infection.

Reconstruction of bony defects requires a highly individualized and innovative approach. We have found autograft, particularly useful, especially in the patient with multiple extremity injuries and a single impending amputation. All viable tissue is maintained as it affords the possibility of bony and even ostomyofasciocutaneous autograft, affectionately known as "spare parts surgery." Occasionally, bony tissue has been preserved subcutaneously for a short time following amputation, for delayed reconstruction of an osseous defect. On several occasions, we have noted that amputated tissue that could have been used for a complex reconstruction was discarded that could have aided in reconstruction.

Inaccurately placed fasciotomy wounds often make definitive fixation difficult. In general, incisions should be made longitudinally in line with the bone, with definitive fixation in mind. Fasciotomies placed too close together can lead to necrosis of the skin bridge between the incisions. Appropriately placed fasciotomies allow for a more predictable approach, not only for fixation, but for rotational muscle flaps as well.
The use of factor VII has been called into question regarding its potential implication in deep vein thromboses and pulmonary emboli. Several surgical cases in our institution have had to be delayed secondary to these complications. Attempts to review this data have not been successful as records from overseas are often incomplete and do not usually include information regarding Factor VII dosing.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session V:** Principles of Post-Op Wound Management and Evacuation Considerations
PRESENTATION	**#20A:** Dressings/Splinting and Pain Management During Air Evacuation of Acutely Injured Patients
SPEAKER	Lt Col Tracy L Popey, MD

The care of acutely injured patients in an air evacuation environment presents unique challenges not encountered when caring for patients on the ground. The nature of these injuries in the current combat theaters frequently combines both blast and blunt components, resulting in a wide range of soft tissue and bony injuries.

The type of dressing and provisional bony stabilization must be individualized to each patient. Space constraints as well as general environment preclude routine changing of dressings in flight; thus dressings should be able to contain expected wound drainage for at least 12 hours. Options for dressings include standard dry or wet-to-dry dressings, antibiotic-impregnated bead pouches, or negative pressure dressings. Bead pouches have not generally been used forward of US-based facilities for American service members. Splinting options generally include plaster splints versus use of external fixators. Decisions regarding this choice must take into account inherent bony stability of the underlying injury as well as the potential need to assess/access soft tissue wounds. The use of traction which requires any type of swinging weight is not possible.

Pain management, even on the ground, can be a complex issue. Add in stressors of flight to include decreased partial pressure of oxygen, noise, vibration, lack of humidity, immobility, thermal issues (usually too cold, but sometimes too hot), and it becomes an even bigger problem. Options available to the treating physician are much better at this time than they were at the beginning of the conflict. Oral narcotics with parenteral boluses remain the mainstay of treatment, but are no longer the only choices. We now have available to us the possibility of patient-controlled analgesia (PCA) for in-flight use. The PCA can be administered intravenously or into a nerve sheath through a peripheral nerve catheter. Key to providing adequate pain relief in flight is to recognize that pain medication requirements during air evacuation are frequently double or triple what they are on the ground. Early concerns about the possibility of peripheral nerve blocks impeding recognition of impending compartment syndrome, have, thus far, turned out to be unrealized.

This presentation reviews some of the unique features of caring for injured patients in the current US air evacuation system as well as the pros and cons of various dressing/splinting and pain management options available for use during the transport of acutely injured patients by fixed wing aircraft, thus enabling the treating physician to choose the optimal combination for each patient. Many factors must be considered, and, while techniques and options have improved greatly over the last few years, there is still room for much improvement.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session V:** Principles of Post-Op Wound Management and Evacuation Considerations
PRESENTATION	**#20B:** Development of a New Antibiotic Bead System
SPEAKER	CAPT D. C. Covey, MD

There is a need to more effectively address the high incidence of infection seen in military personnel sustaining battlefield injuries in Iraq and Afghanistan. Their wounds are usually caused by explosive munitions or high velocity bullets, and often have extensive contamination. These wounds are left open for delayed or secondary surgery, and typically undergo multiple irrigation and debridement procedures prior to closure. Although parenteral antibiotics are initiated at the first or second echelon of care, levels within injured tissues are often not adequate to prevent infection. This leaves wounds susceptible to resistant strains of bacteria, including *Acinetobacter baumannii*, an organism often cultured from wounds sustained in Iraq.

Orthopaedic literature has indicated that polymethylmethacrylate (PMMA) antibiotic-impregnated bead pouches have efficacy for treatment of large contaminated musculoskeletal wounds by an ability to achieve bactericidal antibiotic levels in local tissues. Since there is no FDA-approved, sterile, off-the-shelf antibiotic bead product available, beads are usually made *ad hoc* during surgery. However, the time and resources necessary to make PMMA antibiotic beads by battlefield surgical teams usually obviates their early use. To meet the battlefield need, antibiotic bead spacers are being developed and readied for FDA clearance. The beads consist of a PMMA core containing barium sulfate (for radiopacity) enclosed in a polymer coating that delivers tobramycin that can elute for up to 72 hours. This FDA-approved drug eluting polymer technology has been used in over 2 million vascular implants. The beads in development are 7 mm in diameter, spaced 7 mm apart, and connected by a strong, non-absorbable suture that is likewise coated with the drug eluting polymer and the entire construct also performs a spacer function to keep the wound and its interstitial spaces open to help minimize bacterial colonization. After bead placement in the wound an occlusive dressing is applied and the beads may remain *in situ* for up to 72 hours. Current plans are for 100 beads per sterile blister package. The beads have been evaluated in desert-like conditions, and have remained stabile in temperatures in excess of 150° F without evidence degradation of the beads or drug delivery polymer coating.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session V:** Principles of Post-Op Wound Management and Evacuation Considerations
PRESENTATION	**#21:** Role of Negative Pressure Therapy in Combat Trauma
SPEAKER	CDR Joel D. Stewart, MD and LTC Romney Andersen, MD

The first goal of this presentation is to review the basic science and theoretical benefits of negative pressure therapy. Briefly it allows temporary soft-tissue coverage, contains the wound, removes contaminants and dead tissue, prevents desiccation of tissues, and resuscitates demarcating tissue.

The next goal is to review the relative indications for negative pressure therapy. Specifically one published and one pending article specific to military uses of negative pressure therapy and new basic science research pertaining to high energy wounds and tissue resuscitation will be reviewed.

The next topic will be the stepwise application of negative pressure dressings specifically to reduce maceration and to obtain seals in difficult areas and around external fixator pins.

Next, there will be a discussion of the Navy experience with improvised systems onboard the USNS Comfort.

Finally, new ideas regarding the use of negative pressure therapy in combat; as well as ideas for investigation of the role of negative pressure therapy in transportation of patients.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session V:** Principles of Post-Op Wound Management and Evacuation Considerations
PRESENTATION	**#22A:** Initial Management of Traumatic Limb Injury for Air Evacuation
SPEAKER	COL John V. Ingari, MD

The purpose of this paper is to delineate the initial management of traumatic limb injuries sustained in a combat zone with particular emphasis how that management is affected by the rapid air evacuation out of the war zone.

Approximately 70 percent of all traumatic combat injuries incurred during Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) is orthopaedic injury to the extremities.[1] Penetrating trauma from blast injury was the most common mechanism of injury, followed by gunshot wounds as the second most common etiology. The initial management of these traumatic limb injuries required efficiency, thoroughness, and meticulous attention to detail to maximize limb salvage. Particular focus on the patient's subsequent rapid air evacuation (Air Evacuation), often within 24 hours of initial injury, to Landstuhl Germany via a six hour jet aircraft flight, had to be added to the surgeon's decision making processes in order to optimize viable limb salvage.

Initial management of traumatic limb injury included a history to determine the mechanism of injury and other co-existing trauma, followed by standard resuscitation protocols. The next decision facing the surgeon was to decide between efforts at limb salvage vs. amputation. When possible, a second surgeon's opinion was offered prior to amputations. Limb salvage was preferred over amputation for initially viable extremities and was greatly facilitated by the use of external fixators to span open fractures with significant soft tissue loss.

Irrigation and debridement, with emphasis on thorough debridement of all devitalized tissues and foreign materials was performed in theater. Those limbs determined to be clearly non-viable due to severe soft tissue and bony injury, typically from a blast mechanism, were amputated immediately. With respect to the subsequent anticipated six hour air evacuation flight, fasciotomies were done "early and often" in limb salvage efforts, to maximize subsequent limb viability. The several hours of patient recumbency and relative immobilization, coupled with ongoing fluid resuscitation during air evacuation, had to be added to the equation of the potential of developing compartment syndrome in a traumatized limb. Less than five percent of patients arriving at Landstuhl required fasciotomy for evolved compartment syndrome during transport from Iraq, owing to the "early and often" policy of performing fasciotomies in theater. No primary skin closure was done in theater, and a "ridiculously bulky" dressing covering open wounds was placed prior to transport. Wound care and dressing placement was greatly aided by the use of external fixators placed in theater. In addition, the external fixator provided the requisite limb immobilization and enhanced patient comfort to allow patient transport from theater hospital, to ambulance or bus, and finally onto the aircraft for evacuation out of the theater.

1. Mazurek, M.T. and J.R. Ficke, The scope of wounds encountered in casualties from the global war on terrorism: from the battlefield to the tertiary treatment facility. J Am Acad Orthop Surg, 2006. 14(10 Suppl): p. S18-23.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session V:** Principles of Post-Op Wound Management and Evacuation Considerations
PRESENTATION	**#22B:** Air Evacuation Considerations: Impact of Partial Pressure Environment on Acute Trauma
SPEAKER	COL Elisha Powell, IV, MD

DISCLAIMER: *The views expressed in this presentation are those of the speakers and do not represent those of the Armed Services, the Department of Defense or the U.S. Government.*

Injured and ill patients are being aeroevacuated out of the combat zone much faster than 10 to 15 years ago. The average time for patients to be transported to Germany and on to the United States has decreased from 10-14 days during Operation Desert Storm to three days. The doctrine has changed from stable patient care to critical patient care; move sicker patients sooner rather than holding them in hospitals near or in the combat zone. Critical Care Air Transport Teams (CCATT) have been a huge advance with increased critical care patient movement. New advances, as well as challenges, have arisen from this revolutionary change in how we transport and care for acutely injured patients in the partial pressure environment.

Aeroevacuation challenges, advances, and opportunities include negative pressure wound management in the air, the challenge of compartment syndromes in aeromedical transport, and deep vein prophylaxis in throughout the aeroevacuation system. Negative pressure wound therapy has revolutionized the treatment of soft tissue wounds resulting from both traumatic and non-traumatic causes but is only now being studied in the aeromedical system. Extremity compartment syndromes as we transport injured patients rapidly to Germany and back to the United States has been identified an area for improvement. Blast injury seen in the combat theater today is a unique injury mechanism not often seen in the civilian environment. High-explosive (HE) blast effect may cause increased risk of DVT/PE formation in combat casualties. The Joint Theater Trauma System (JTTS) staff has developed a clinical practice guideline for patients at highest risk to include those undergoing emergency trauma surgical procedures with major orthopedic surgery/injuries of the extremities, spine, and pelvis, and those with ongoing coagulopathy, or with a prohibitive risk of bleeding. Lovenox, Sequential Compression Devices, and IVC filters are all options with the guideline. DVT and PE can be greatly reduced in 90% or more of surgical and trauma patients without additional risk factors by use of this systematic preventive strategy.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session VI:** Next Phase of Guideline Development
PRESENTATION	**#23:** Proposal for Changes to Emergency War Surgery Manual
SPEAKERS	COL James Ficke, MD, and LTC James Keeney, MD

Major treatment principles for the management of high energy musculoskeletal trauma seen with combat injury have remained largely unchanged in the past decade. Aggressive debridement of devitalized soft tissue, large volume irrigation of open wounds, liberal use of fasciotomy for the treatment of evolving compartment syndromes and vascular shunting to restore limb perfusion remain critical for successful reconstruction and avoidance of infection. Provisional stabilization of long bone and pelvic fractures using external fixation techniques has become the method of choice prior to evacuation out of theater.

Although these principles are constant, the experiences obtained by U.S. military orthopaedic surgeons during OIF/OEF support modification of details, and some techniques, in the current Emergency War Surgery Manual.

Guillotine amputations are no longer a preferred technique. Soft tissue for reconstruction is often at a premium, and efforts to preserve viable tissue for coverage are advocated. The section on amputation commits several pages on transportation casting, which has not been effective, given current rapid evacuation capabilities. Circumferential casting is also no longer recommended. Splints provide adequate support during transport and allow for easier access for soft tissue and compartment assessment. External fixation has also been used more extensively and additional techniques (e.g. proximal femur; hindfoot; spanning knee/elbow) should be illustrated. Additionally, techniques for safe fasciotomy of the upper extremity should be included, as many upper extremity compartment syndromes have occurred.

An electronic version of the text could incorporate more extensive use of visual support, including digital photography of the injuries encountered and short video clips of surgical techniques.

The development of a mature theater of operations during a prolonged occupation in OIF/OEF has resulted in the extension of military health care resources to the host nation population. While the provision of definitive care for local nationals is not the focus of the current EWI symposium, an update to the EWS manual could include a discussion of surgical treatment considerations for host nation injured. Surgical techniques on soft tissue coverage, including regional rotational flaps, in particular, would be a valuable resource. An additional chapter of this nature should include a strong discouragement against a broader application of these techniques on U.S. and coalition injured. The surgeon should also be instructed to consider their facility capability and individual experience when utilizing these techniques on host nationals.

The treatment of combat extremity injury remains centered around provisional stabilization and rapid aeromedical transport to Echelon IV and V facilities for definitive care. While the majority of the treatment principles covered in the Emergency War Surgery manual are still maintained, there are some significant areas where the experiences of military orthopedic surgeons in OIF/OEF should be represented in a revised edition of the manual in the near future.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session VI:** Next Phase of Guideline Development
PRESENTATION	**#24:** Development of Preparatory Courses
SPEAKER	CAPT Daniel Unger, MD

They say those who fail to learn from the mistakes of history are doomed to repeat them. This has been especially true with regard to the treatment of combat musculoskeletal injuries. We have relearned lessons over and over with each military conflict as though it was the first. The development of a standardized Military War Extremity Surgery Course which addresses the historical lessons of combat casualties and establishes basic treatment principles and basic skills requirements would seem to be a basic requirement for any orthopedic surgeon deploying to a combat theater or austere environment. However, there are currently disjointed training opportunities that are not standardized nor consistently applied. Each service has a Trauma Training Center which focuses primarily on Level I civilian trauma care. There are combat medical training courses, such C4, Emergency War Surgery Course and the Combat Extremity Surgery Course. There are however no mandatory training requirements nor consistent updates to course material. Topics for discussion in this session include;

- Should there be a separate, standardized Military War Extremity Surgery Course that closely follows the principles established by the EWI II?
- Should this be mandatory training for every military orthopedic surgeon and how often should these principles and skills be refreshed/updated?
- Who should be responsible for the course content and updated relevance?
- What funding opportunities are available (DMRTI)?
- Do these war extremity surgical principles (triage, damage control, field tourniquet use) transfer to the civilian orthopedic surgeon who may be volunteering in foreign countries or potentially involved in the treatment of victims of future terrorist attacks (24)?
- Should this be a single course or combined for both civilian and military.

These types of severe, high energy and explosive injuries will continue to occur for the foreseeable future and beyond. Our current civilian and military training programs do not address or prepare the average orthopedic surgeon to handle these types of injuries and we have again repeated historical mistakes and relearned lessons the hard way. This is an opportunity to break that cycle and arm those with the knowledge and skills to effectively handle combat casualties.

EXTREMITY WAR INJURIES II:
DEVELOPMENT OF CLINICAL RESEARCH PRINCIPLES

SESSION	**Session VI:** Next Phase of Guideline Development
PRESENTATION	**#25:** Evidence-Based Clinical Practice Guidelines
SPEAKER	Charles M. Turkelson, PhD

Clinical practice guidelines and, particularly evidence-based clinical practice guidelines, have come into increasing use over the last two decades. At the end of 2006, the National Guidelines Clearinghouse, an on-line compendium of evidence-based guidelines compiled by the Agency for Healthcare Research and Quality (AHRQ), contained guidelines from approximately 118 professional societies as well as 17 guidelines from the U.S. Dept. of Defense, and 18 guidelines from the U.S. Veterans Health Administration.

Evidence-based guidelines are prepared according to a specific, scientific protocol. This protocol is designed to combat bias, and increase transparency and reproducibility. An evidence-based protocol typically includes; (1) framing key questions according to a specific format (i.e., specifying the patients, interventions, comparisons, and outcomes of interest), (2) retrieving, insofar as is practical, all available research on a given topic (as opposed to selecting research that supports a particular point of view), (3) retrieving published articles according to specific criteria, (4) ascertaining one's confidence in the findings of available research (i.e., assessing study quality), (5) considering the degree to which published techniques and patients are like the techniques and patients in which one is interested, (6) using well-defined voting rules for determining whether a recommendation should be incorporated into the guideline and, (7) expressing the degree of confidence (i.e., assigning a grade) in the recommendations contained in a guideline. The rigor by which evidence-based guidelines are prepared often means that such guidelines have greater stature than a traditional literature review.

Preparing clinical practice guidelines, and particularly evidence-based guidelines, is not without disadvantages. Preparing them can be labor-intensive, slow, and expensive. Therefore, one usually undertakes guideline development when there is: (1) variation in diagnosing and/or treating the health problem, (2) there are no existing, well-done guidelines on the topic, (3) there is high individual or population morbidity, mortality, or disability, (4) the health problem carries a high unit or aggregate cost, (5) the public or political demand for the guideline is high, and/or (6) there is sufficient existing research.

"Sufficient existing research" does not imply that one must only consider evidence from randomized, controlled trials. Guidelines usually incorporate the best *available* evidence, not the best *possible* evidence. However, because the best available evidence might be of relatively low quality, we might have relatively little confidence in it and in the recommendations derived from it. We express this reduced confidence by using a relatively low grade of recommendation. "Sufficient existing research" also does not imply that every recommendation in a guideline be based on experimental evidence. Expert opinion is a form of evidence, and is commonly used when there are no relevant published research findings. Indeed, nearly every guideline contains some recommendations based on expert opinion.

Evidence-based clinical practice guidelines are increasingly used and supported by professional societies and government (including military) bodies. When prepared with appropriate rigor, evidence-based clinical practice guidelines can meet the highest levels of scientific integrity, even when those guidelines contain recommendations based on expert opinion. However, the challenges in preparing such guidelines must also be considered.