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14. ABSTRACT

The U.S. Air Force Medical Service presented the fifth annual Air Force Medical Research Symposium coordinated by the Air Force Medical Support Agency's Research and Development Division (AFMSA/SGRS). The symposium was held 24-26 August 2010 at the Doubletree Hotel Washington DC – Crystal City, Arlington, VA. The symposium featured two half-days of plenary sessions, one and a half days of scientific presentations, and a poster session. It was organized into four tracks to include: Operational & Medical, Enroute Care, Force Health Protection, and Nursing. These proceedings are organized into five volumes to include one that provides a general overview and all presentation and poster abstracts; the other four each address a specific track. Volume 3 contains abstracts and presentation slides for the Enroute Care Track.

15. SUBJECT TERMS

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Proceedings of the 2010 AFMS Medical Research Symposium
Volume 3. Enroute Care Track Abstracts and Presentations

Volume 3 of 5

Proceedings of the 2010 AFMS Medical Research Symposium
Volume 3. Enroute Care Track Abstracts and Presentations

Edited by: Dr. Welford C. Roberts

Held
24-26 August 2010
at the
DoubleTree Hotel Washington DC – Crystal City
300 Army Navy Drive
Arlington, VA 22202

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Proceedings of the 2010 AFMS Medical Research Symposium Introduction

The U.S. Air Force Medical Service presented the fifth annual Air Force Medical Research Symposium coordinated by the Air Force Medical Support Agency's Research and Development Division (AFMSA/SGRS). The symposium was held on 24-26 August 2010 in the Washington D.C. area at the Doubletree Hotel Washington DC – Crystal City in Arlington, VA. The symposium featured two half-days of plenary sessions, one and a half days of scientific presentations, and a poster session.

The symposium was organized into several tracks to include Operational & Medical, En-route Care, Force Health Protection, and Nursing, as follows:

- The Operational & Medical Track focused on patient care and treatment in garrison, expeditionary care during contingency operations, and enhancing performance of airman in challenging environments.
- The En-route Care Track addressed science and technology targeted at the continuum of care during transport from point of injury to definitive care to include medivac, aeromedical evacuation, critical care air transport, patient staging, and patient safety.
- The Force Health Protection Track focused on prevention of injury and illness and the early recognition or detection of emerging threats for in-garrison or deployed operations. Topics of interest include research in bio-surveillance, infectious disease, emerging threats (pandemic response), protective countermeasures, disaster response/consequence management, toxicology/health risks (e.g., particulates nanomaterials, radiation, etc.), monitoring disease trends, other areas of preventive medicine, public and environmental health relevant to the military workforce.
- The Nursing Track focused specifically on evidence based practice.

These proceedings are organized into five volumes, as follows:

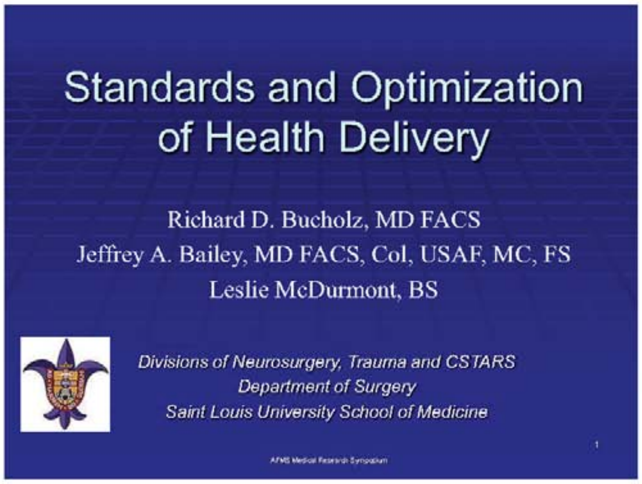
- Volume 1. This volume is a general overview of the entire 2010 Air Force Medical Research Symposium and includes abstracts of all the oral presentations and posters. First presented is the symposium's opening plenary session, followed by the abstracts from the four technical tracks, and then the closing plenary session. The abstracts associated with the poster session are in the last section of these proceedings. The agenda for the overall symposium is in Appendix A, attendees are listed in Appendix B, and continuing education information is in Appendix C of this volume. Appendices D-L are copies of presentation slides from the plenary sessions.
- Volume 2. This volume contains abstracts and presentation slides for the Operational & Medical Track.
- Volume 3. This volume contains abstracts and presentation slides for the En-route Care Track.
- Volume 4. This volume contains abstracts and presentation slides for the Force Health Protection Track.
- Volume 5. This volume contains abstracts and presentation slides for the Nursing Track.

Optimal User Interface for Remote En-Route Care Patient Monitoring

CSTARS- Cincinnati

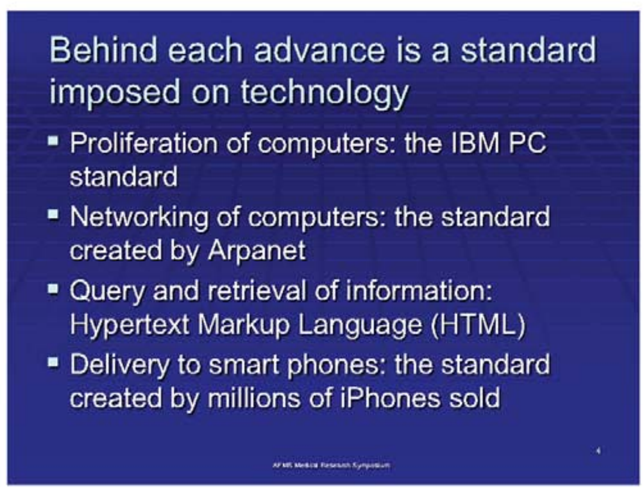
Richard D. Bucholz, MD

Introduction: The U.S. Army Medical Research and Materiel Command recommends operating rooms are developed that "design and test the optimal User Interface (UI) for surgeons, anesthesiologists, and nurses to input and access clinical data. The optimal UI will support multi-mode access, where clinicians are able to use mobile devices, internet browser access to intranets, and adequate remote access through secured internet connections." The Saint Louis University (SLU) Advanced Neurosurgical Innovation Center provides test-bed capacity to translate technology from bench to simulated test-bed, to the field. **Methods:** Multimodal technology developed at SLU (SLU, U.S. Pat No. 6,928,490) will provide a networking infrastructure to permit variable-bandwidth testing of medical device telemedicine in collaboration with existing USAF C-STARS simulation laboratory facilities at SLU. **Results:** (1) Create a shielded space manifested by a firewall-protected wired and wireless network, (2) Provide life support networked and controlled by the system, (3) Develop display devices to provide visualization for the surgeon as well as any other required participants to enable experts to remotely participate in a given intervention, (4) Enhance plasticity by removing cumbersome set-up tasks and allowing unprecedented connectivity between devices. (5) Allow rigorous documentation and archiving of all information generated within a continuum of care. **Conclusion:** This proposal will develop and test technology to integrate medical communication within a shielded environment, allow remote projection of medical and surgical expertise and control over variable bandwidth networks with secure encrypted remote command, and allow monitoring en route from far forward locations to the final definitive care facility.


Standards and Optimization of Health Delivery
Richard D. Bucholz, MD FACS
Jeffrey A. Bailey, MD FACS, Col, USAF, MC, FS
Leslie McDurmont, BS
Divisions of Neurosurgery, Trauma and CSTARS
Department of Surgery
Saint Louis University School of Medicine


Disclosures
Royalty on intellectual property: Medtronic
Financial interest: Medical Operating Networks LLC


Technology has impacted every facet of our lives
We interact with computers for almost every task
Networked computers allow near instantaneous communication across the planet
Almost any data source can be queried by a networked computer
This ability to connect and share information is continuously available on smart phones


Behind each advance is a standard imposed on technology
Proliferation of computers: the IBM PC standard
Networking of computers: the standard created by Arpanet
Query and retrieval of information: Hypertext Markup Language (HTML)
Delivery to smart phones: the standard created by millions of iPhones sold

Disruptive technologies must be standardized to make them useful

- Initial chaos caused by new paradigm has to be organized for everyday use
- A healthcare example:
  - Images produced by scanners from different companies were not compatible
  - Prevented review of medical images across platforms
  - Professional pressure created the DICOM standard
  - PACS systems could not exist without DICOM
- A lesson to be learned throughout medicine

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Production *and* display of health information needs standards

- Imaging frequently needs expert intervention
  - Ultrasound images require positioning, selection of depth, gain
  - Quality of MRI highly dependent on settings
- Particularly true of information obtained in the operating and emergency rooms
  - Positioning of microscopic or endoscopic images
  - Navigation to a critical point within the patient
- A standard must include bidirectional control and sharing of *all* information sources

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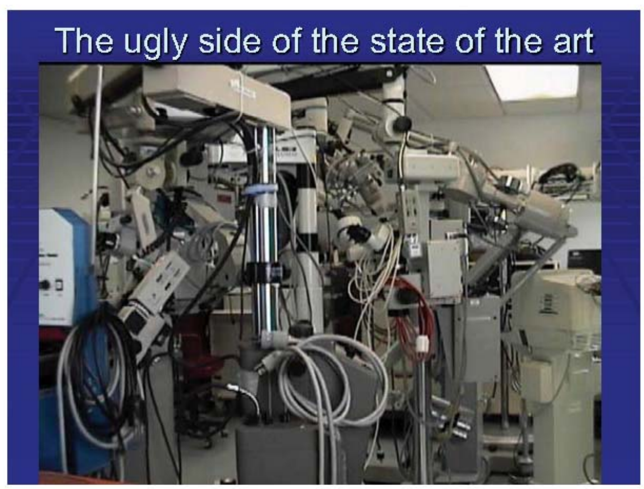
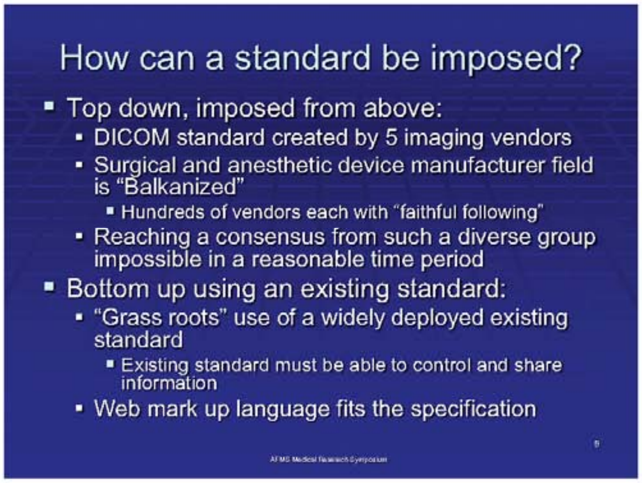
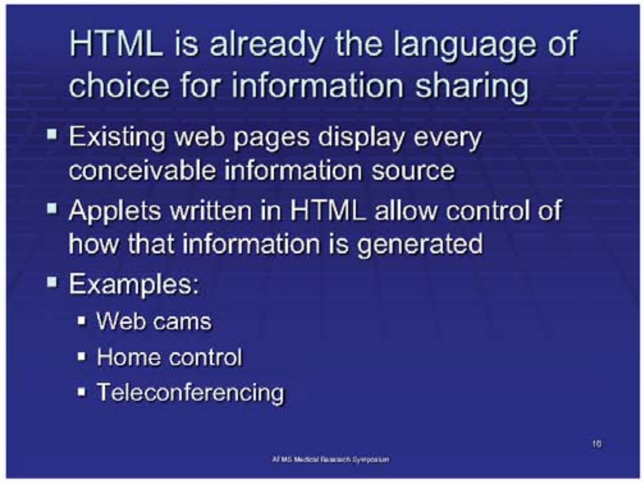
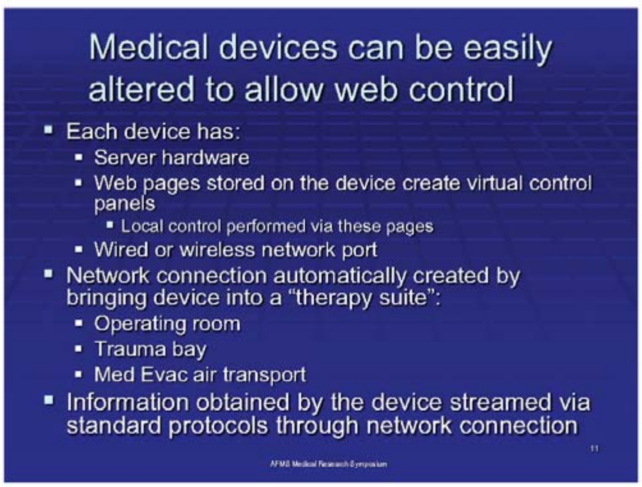
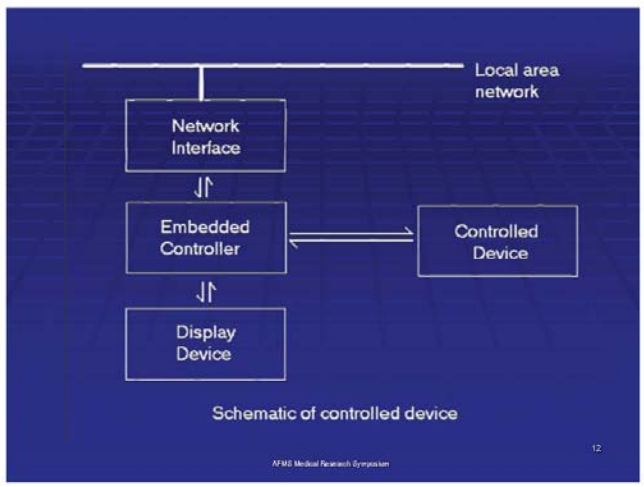
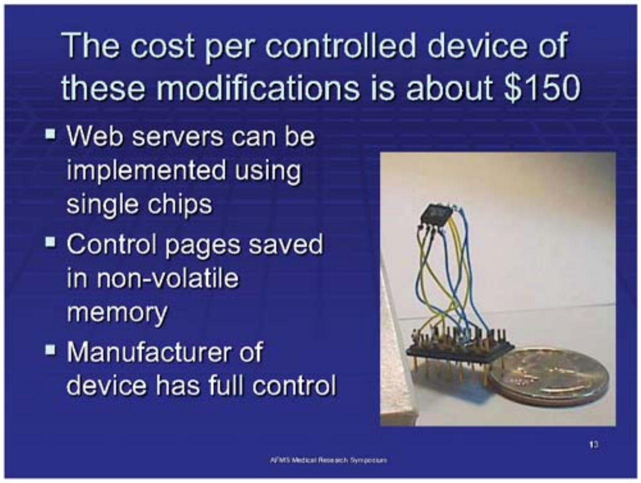



How can a standard be imposed?
Top down, imposed from above:
DICOM standard created by 5 imaging vendors
Surgical and anesthetic device manufacturer field is "Balkanized"
Hundreds of vendors each with "faithful following"
Reaching a consensus from such a diverse group impossible in a reasonable time period
Bottom up using an existing standard:
"Grass roots" use of a widely deployed existing standard
Existing standard must be able to control and share information
Web mark up language fits the specification


HTML is already the language of choice for information sharing
Existing web pages display every conceivable information source
Applets written in HTML allow control of how that information is generated
Examples:
Web cams
Home control
Teleconferencing


Medical devices can be easily altered to allow web control
Each device has:
Server hardware
Web pages stored on the device create virtual control panels
Local control performed via these pages
Wired or wireless network port
Network connection automatically created by bringing device into a "therapy suite":
Operating room
Trauma bay
Med Evac air transport
Information obtained by the device streamed via standard protocols through network connection


Local area network
Network Interface
Embedded Controller
Controlled Device
Display Device
Schematic of controlled device


The cost per controlled device of these modifications is about $150
Web servers can be implemented using single chips
Control pages saved in non-volatile memory
Manufacturer of device has full control
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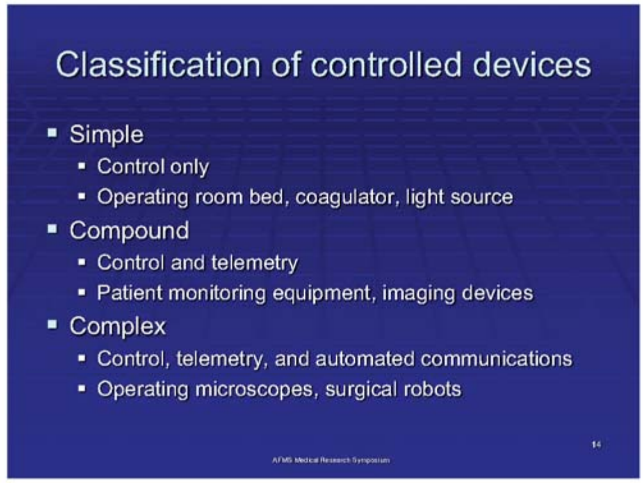
Classification of controlled devices
Simple
Control only
Operating room bed, coagulator, light source
Compound
Control and telemetry
Patient monitoring equipment, imaging devices
Complex
Control, telemetry, and automated communications
Operating microscopes, surgical robots
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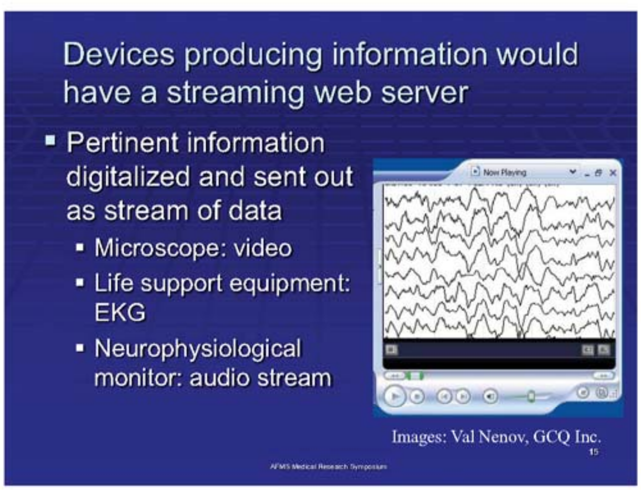
Devices producing information would have a streaming web server
Pertinent information digitalized and sent out as stream of data
Microscope: video
Life support equipment: EKG
Neurophysiological monitor: audio stream
Now Playing
Images: Val Nenov, GCQ Inc.
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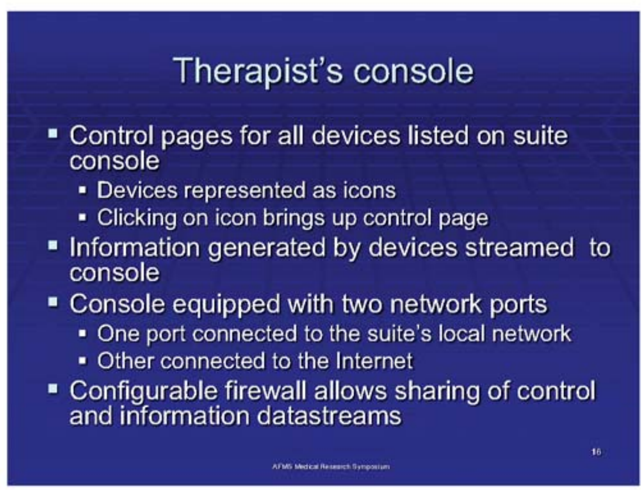
Therapist's console
Control pages for all devices listed on suite console
Devices represented as icons
Clicking on icon brings up control page
Information generated by devices streamed to console
Console equipped with two network ports
One port connected to the suite's local network
Other connected to the Internet
Configurable firewall allows sharing of control and information datastreams
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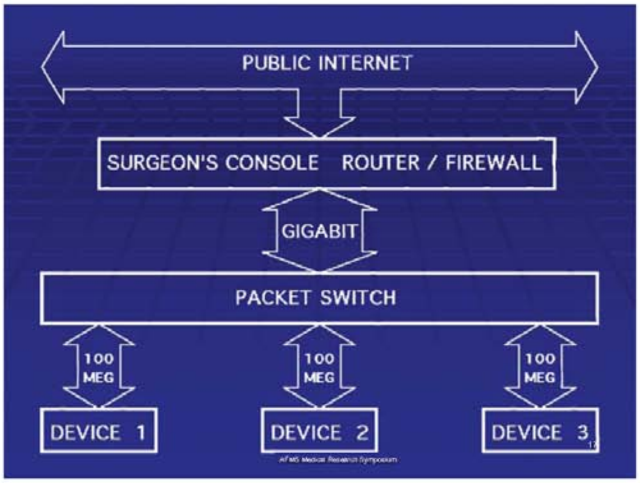

PUBLIC INTERNET
SURGEON'S CONSOLE ROUTER / FIREWALL
GIGABIT
PACKET SWITCH
100 MEG
100 MEG
100 MEG
DEVICE 1
DEVICE 2
DEVICE 3

Possible therapist's consoles
LCD touch panel on wheels
Plasma screen on wall
Head mounted display
Smartphone
Any device capable of displaying and interacting with a web page
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The problem of multiple computerized devices in one OR
Stereotaxis, Inc. 2006
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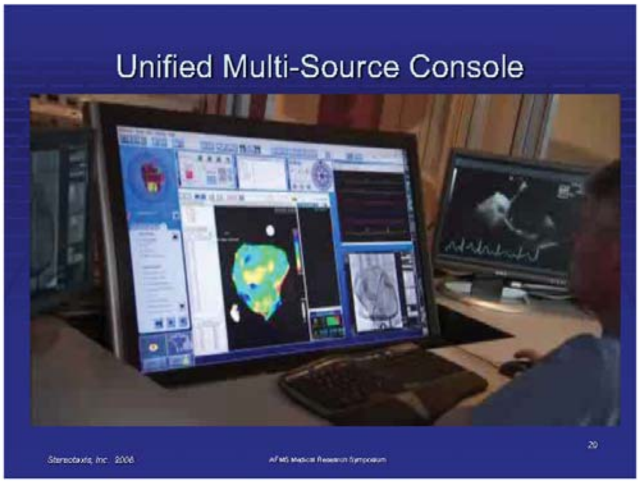

Unified Multi-Source Console
Stereotaxis, Inc. 2006
AFMS Medical Research Symposium
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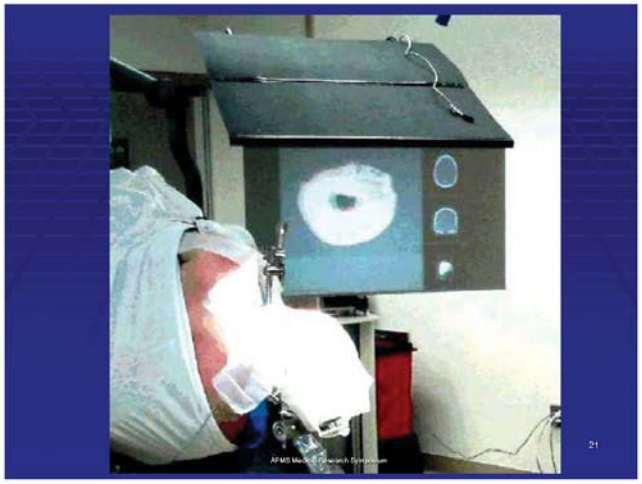
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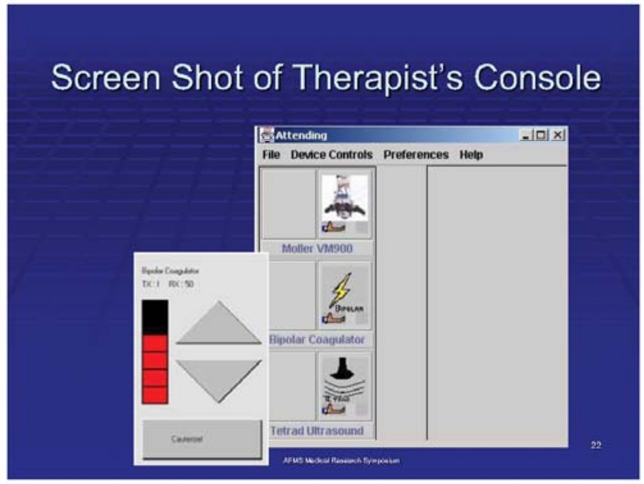
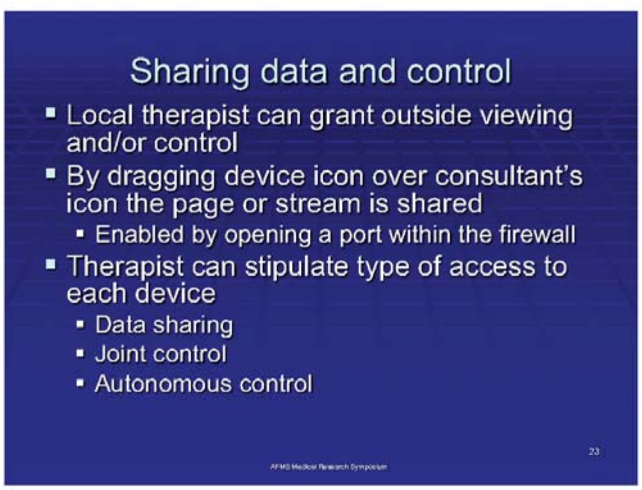

Screen Shot of Therapist's Console
Attending
File Device Controls Preferences Help
Moller VM900
Bipolar Coagulator
Tetrad Ultrasound
22


Sharing data and control
Local therapist can grant outside viewing and/or control
By dragging device icon over consultant's icon the page or stream is shared
Enabled by opening a port within the firewall
Therapist can stipulate type of access to each device
Data sharing
Joint control
Autonomous control
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Attending
File Device Controls Preferences Help
Moller VM900
Allow
Deny
bucholz
Requests Device List
Bipolar Coagulator
Tetrad Ultrasound
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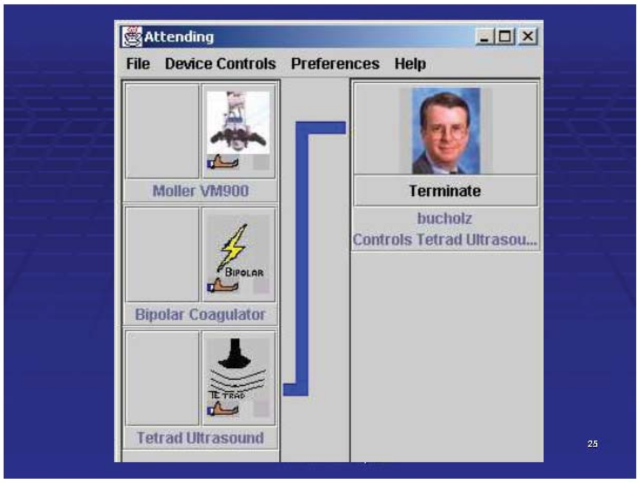

Remote workstation is simply any computer

- Requirements:
  - Network connection (wired or wireless)
    - Characteristics of connection will determine image quality and speed
  - Minimal hardware and software requirements
    - Compatible browser
    - Appropriate video codes
  - Microphone and webcam for bidirectional communication
- Almost any current laptop can be used

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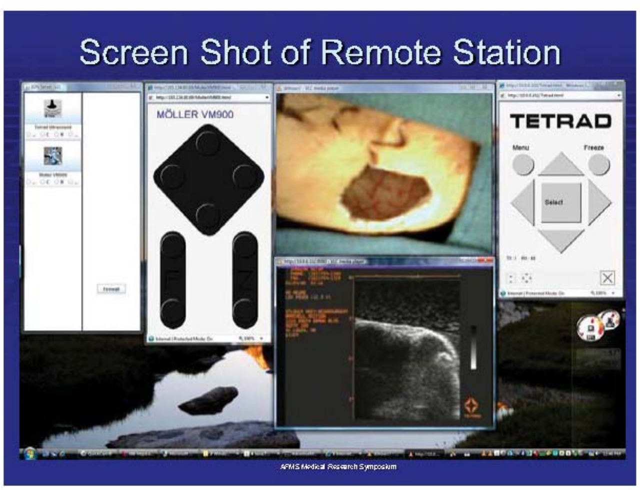

Example: brain electrode insertion

- Indicated for treatment of movement disorders
- Electrode location determined by imaging and intraoperative recording
- Position confirmed using intra-operative imaging
- Expertise required:
  - Interpretation and registration of images
  - Interpretation of electrode recordings

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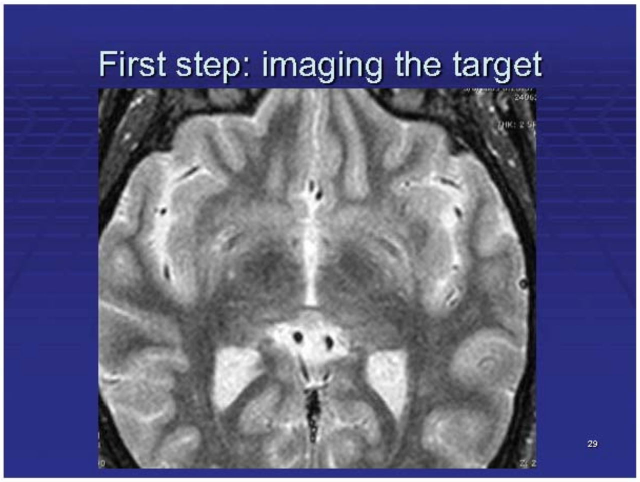
First step: imaging the target
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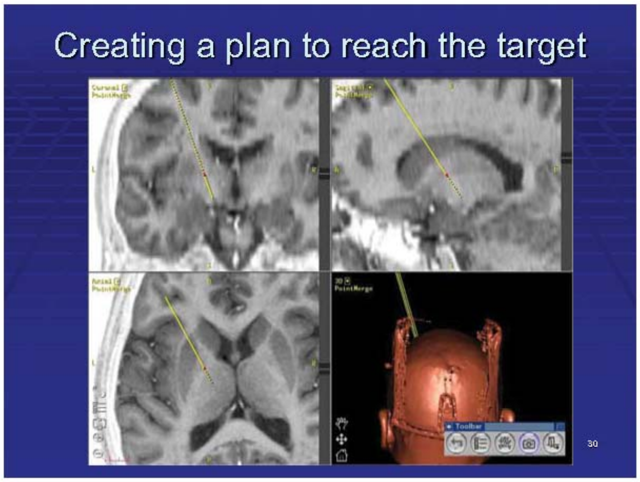
Creating a plan to reach the target
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Registering navigational system to anatomy in the operating room
31


Navigating electrode to target
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Fine tuning position based on neurophysiological recordings
33


Replacing recording lead with stimulator lead and confirming position
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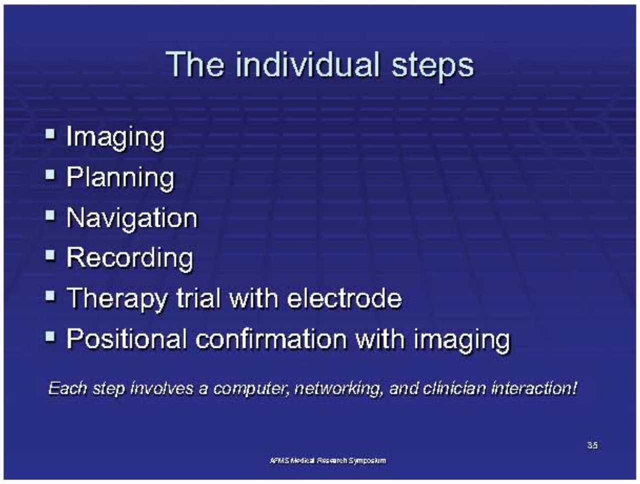
The individual steps
▪ Imaging
▪ Planning
▪ Navigation
▪ Recording
▪ Therapy trial with electrode
▪ Positional confirmation with imaging
Each step involves a computer, networking, and clinician interaction!
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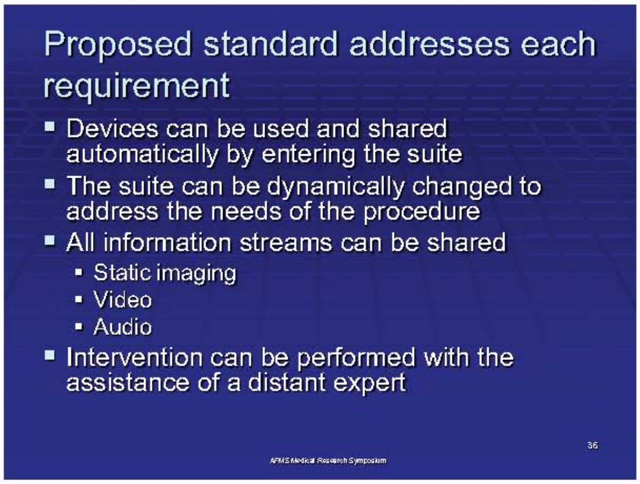
Proposed standard addresses each requirement
▪ Devices can be used and shared automatically by entering the suite
▪ The suite can be dynamically changed to address the needs of the procedure
▪ All information streams can be shared
▪ Static imaging
▪ Video
▪ Audio
▪ Intervention can be performed with the assistance of a distant expert
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The proposed solution places no requirements on "therapy suite"
Operating rooms are expected to allow any procedure
An open heart procedure can follow a craniotomy in the same room
Few hospitals can dedicate rooms to a single purpose
Devices are set up according to surgeon's preferences
These preferences may change during the procedure
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The standard can be used in the ED and in the field
One cable connection for multiple data streams
Consultant can monitor and control any device used within the suite
Video stream viewable by nursing and anesthesia
Control of complex diagnostic equipment would be simplified
Expertise can be projected into a local ED, ambulance, or Med evac aircraft
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Military services are a perfect place to start
Frequently encounter complex situations with time critical interventions
Situations often preclude experts to be "on the ground"
Our experience with CSTARS is a model of remote expertise projection
We would like to propose a test bed for medical evacuation
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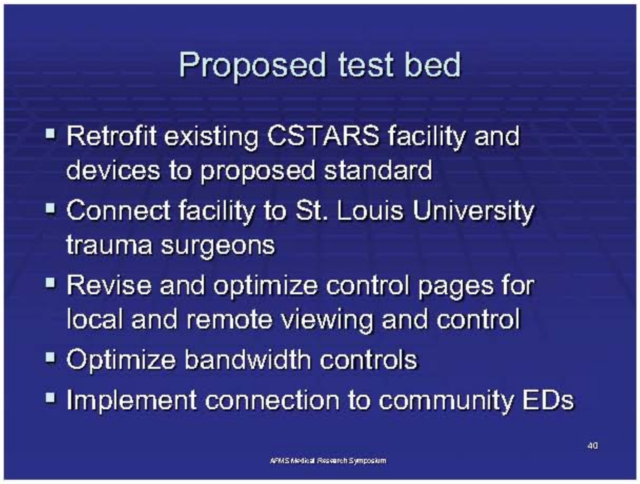
Proposed test bed
Retrofit existing CSTARS facility and devices to proposed standard
Connect facility to St. Louis University trauma surgeons
Revise and optimize control pages for local and remote viewing and control
Optimize bandwidth controls
Implement connection to community EDs
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Once test bed perfected:
Implement between CSTARS facilities
Network multiple community hospitals
Implement web based medical expertise panel to provide teleconferencing
Implement on evacuation aircraft to project expertise anywhere you can fly
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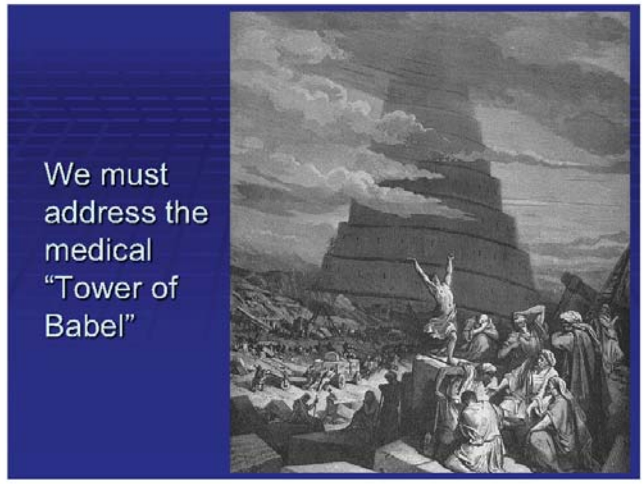

We must address the medical "Tower of Babel"

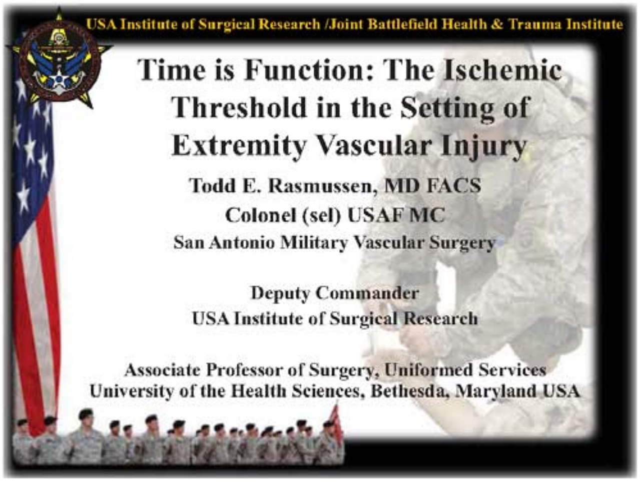
Vascular Injury Rates from the Wars in Iraq and Afghanistan

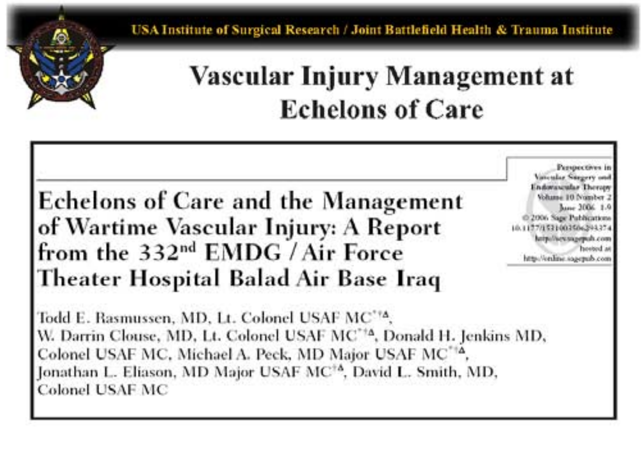
59th Medical Wing (MDW)/SSSOGV

Todd E. Rasmussen MD, Joseph M. White MD, W. Darrin Clouse MD Gabriel E. Burkhardt MD, Adam Stannard MRCS Brian J. Eastridge MD, Lorne H. Blackbourne MD

The Institute of Surgical Research, Fort Sam Houston, Texas and the Uniformed Services University of the Health Sciences, Bethesda, Maryland

OBJECTIVE: The rate of vascular injury in WWII, Korea and Vietnam was 2-3%; however, not since Vietnam has the epidemiology of this injury pattern in war been possible. This study objective is to report the burden of vascular injury over 7 years of recent combat. METHODS: The Joint Theater Trauma Registry was queried (2002-2009) for vascular injury in US Troops and groups defined. Group 1 (specific): Troops having sustained specific vascular injury and Group 2 (operative): Troops having undergone a designated operation for vascular injury. RESULTS: Group 1 included 1,597 Troops injured in Iraq (OIF) (n=1,417) and Afghanistan (OEF) (n=180). Mechanism included explosive (75%), gunshot (24%) and other (1%) with explosive more common in OIF than OEF (p<0.05). During this period, 13,076 battle related injuries occurred resulting in a specific rate of 12% (1,597/13,076) which was higher in OIF than OEF (13% vs. 9% respectively; p<0.05). Of Group 1, 60% (n=940) sustained injury to major or proximal vessels and 40% (n=630) to minor or distal vessels: categorized as arterial 64%, venous 16% or combined 20%. Group 2 comprised 1,212 Troops revealing an operative injury rate of 9% (1,212/13,076) and included ligation (n=660; 54%) or repair (n=552; 46%). The “died of wounds” rate was 6.2% in OIF and 7.2% in OEF (p =0.64). CONCLUSION: The rate of vascular injury recorded in modern combat is 5 times previously reported. Differences in vascular injury burden related to theater of war, mechanism of injury and combat operational tempo can be discerned and anticipated.


USA Institute of Surgical Research /Joint Battlefield Health & Trauma Institute
Time is Function: The Ischemic Threshold in the Setting of Extremity Vascular Injury
Todd E. Rasmussen, MD FACS
Colonel (sel) USAF MC
San Antonio Military Vascular Surgery
Deputy Commander
USA Institute of Surgical Research
Associate Professor of Surgery, Uniformed Services University of the Health Sciences, Bethesda, Maryland USA


USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Vascular Injury Management at Echelons of Care
Echelons of Care and the Management of Wartime Vascular Injury: A Report from the 332nd EMDG / Air Force Theater Hospital Balad Air Base Iraq
Todd E. Rasmussen, MD, Lt. Colonel USAF MC*†Δ, W. Darrin Clouse, MD, Lt. Colonel USAF MC*†Δ, Donald H. Jenkins MD, Colonel USAF MC, Michael A. Peck, MD Major USAF MC*†Δ, Jonathan L. Eliason, MD Major USAF MC†Δ, David L. Smith, MD, Colonel USAF MC
Perspectives in Vascular Surgery and Endovascular Therapy
Volume 10 Number 2
June 2006 1-9
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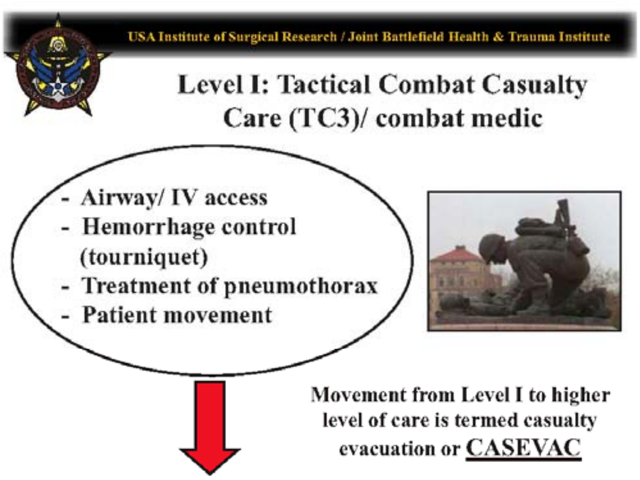
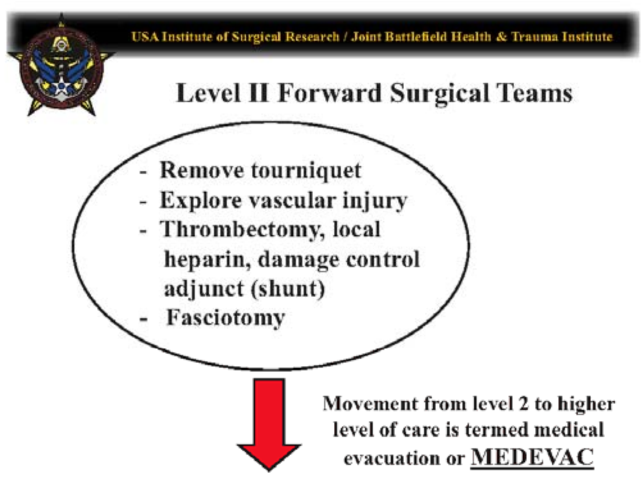
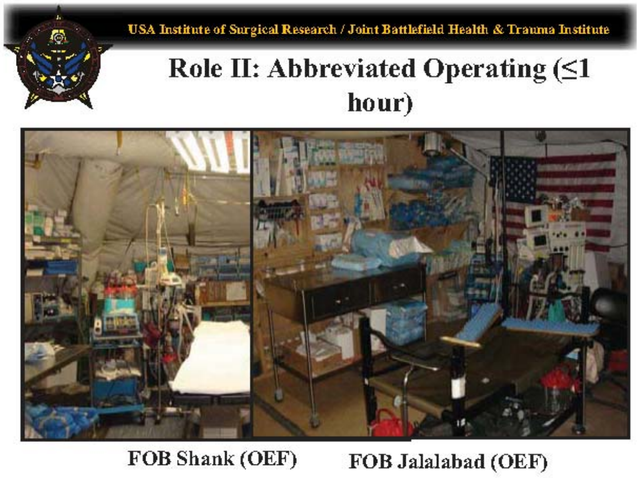
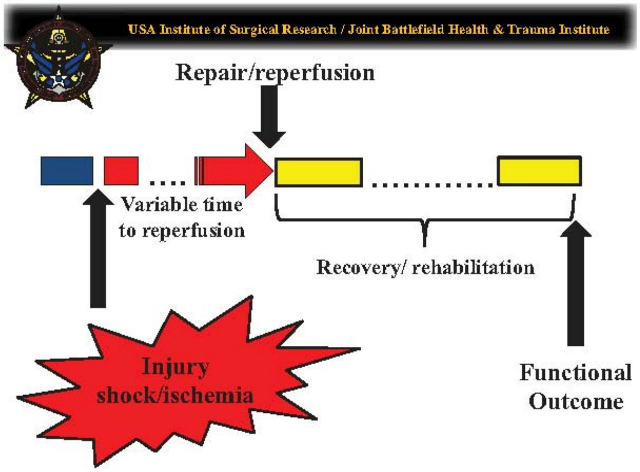
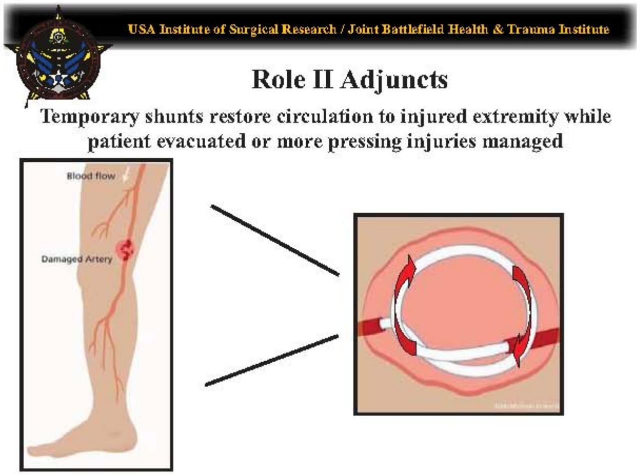
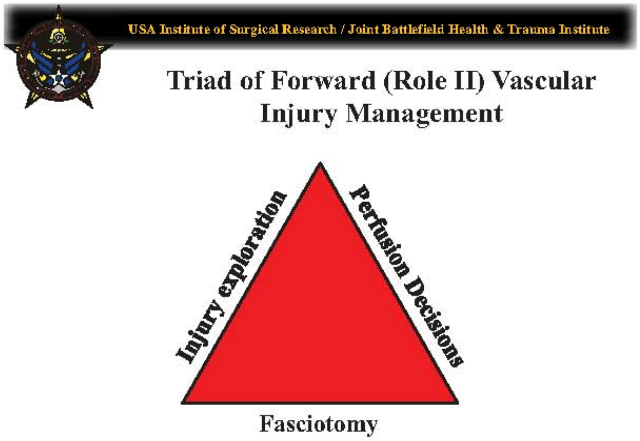

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Level I: Tactical Combat Casualty Care (TC3)/ combat medic
- Airway/ IV access
- Hemorrhage control (tourniquet)
- Treatment of pneumothorax
- Patient movement
Movement from Level I to higher level of care is termed casualty evacuation or CASEVAC

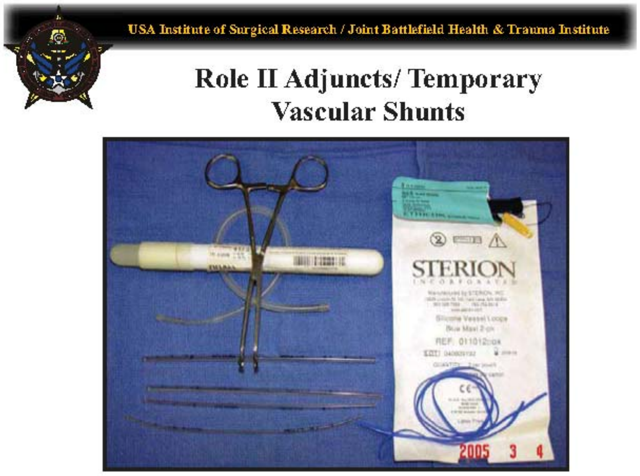

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Level II Forward Surgical Teams
- Remove tourniquet
- Explore vascular injury
- Thrombectomy, local heparin, damage control adjunct (shunt)
- Fasciotomy
Movement from level 2 to higher level of care is termed medical evacuation or MEDEVAC

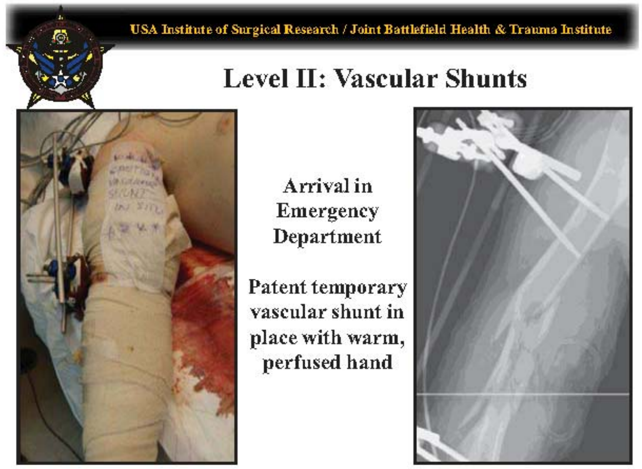

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Role II: Abbreviated Operating (≤1 hour)
FOB Shank (OEF)
FOB Jalalabad (OEF)


USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Repair/reperfusion
Variable time to reperfusion
Recovery/ rehabilitation
Injury shock/ischemia
Functional Outcome

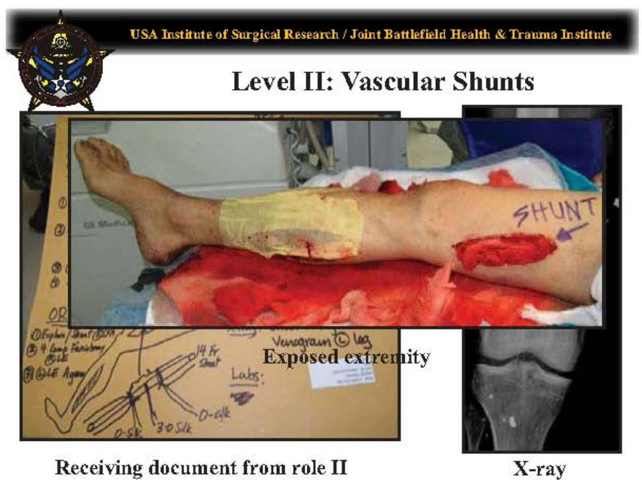

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Role II Adjuncts
Temporary shunts restore circulation to injured extremity while patient evacuated or more pressing injuries managed
Blood flow
Damaged Artery

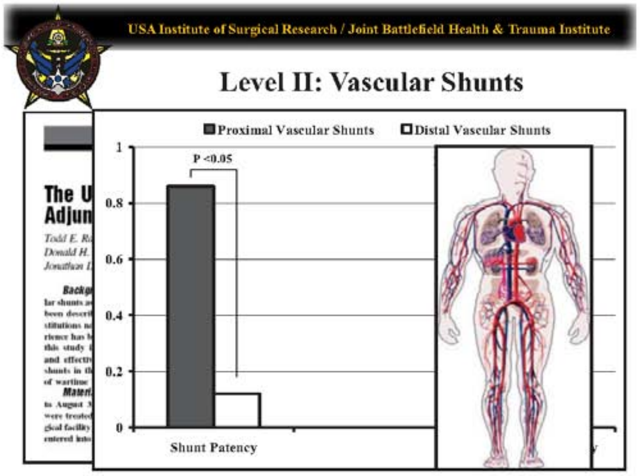

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Triad of Forward (Role II) Vascular Injury Management
Injury exploration
Perfusion Decisions
Fasciotomy

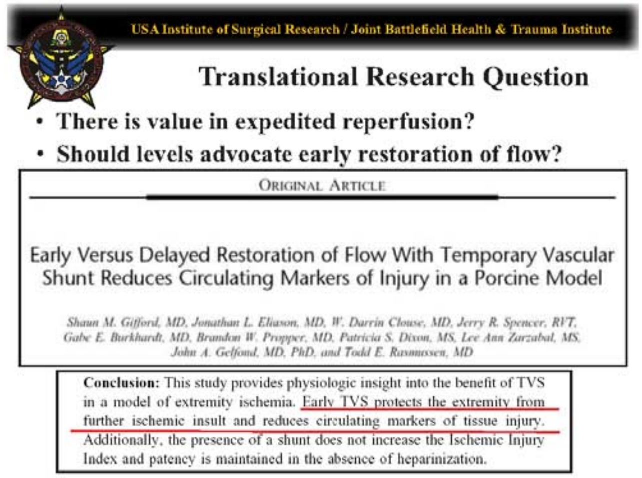

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Role II Adjuncts/ Temporary Vascular Shunts
STERION
2005 3 4

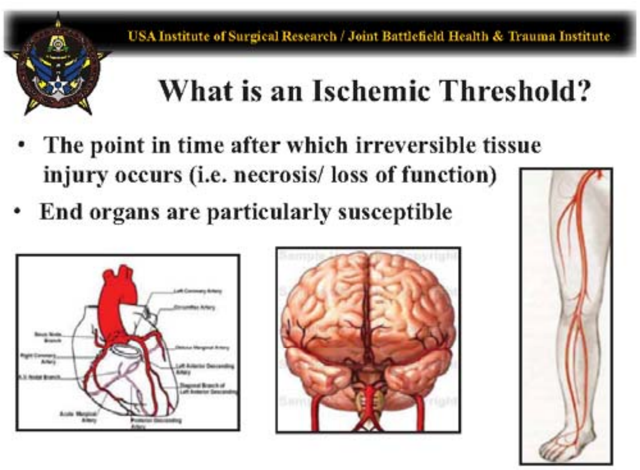

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Level II: Vascular Shunts
Arrival in Emergency Department
Patent temporary vascular shunt in place with warm, perfused hand

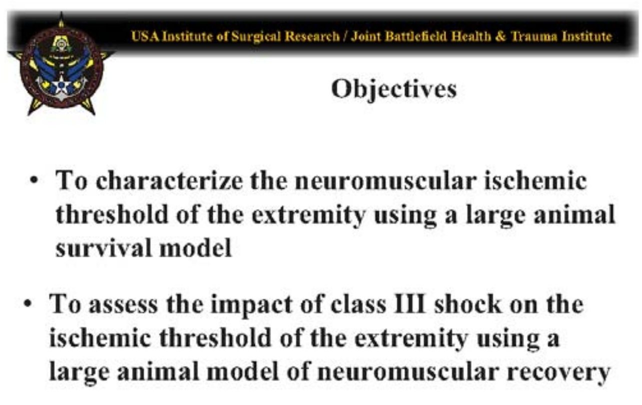

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Level II: Vascular Shunts
Javid shunt in
therapy (VAC™)

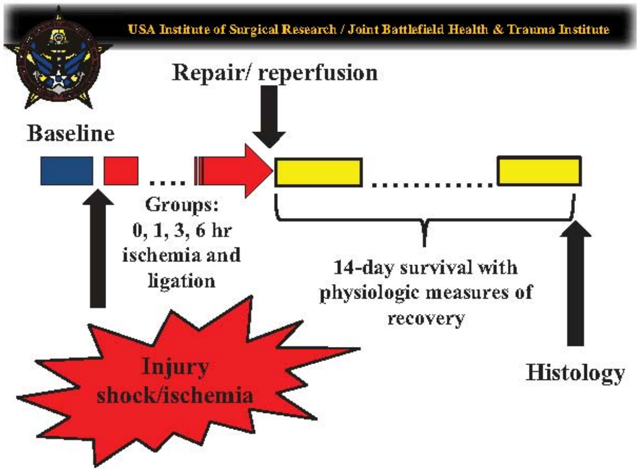

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Level II: Vascular Shunts
SHUNT
Exposed extremity
Receiving document from role II
X-ray

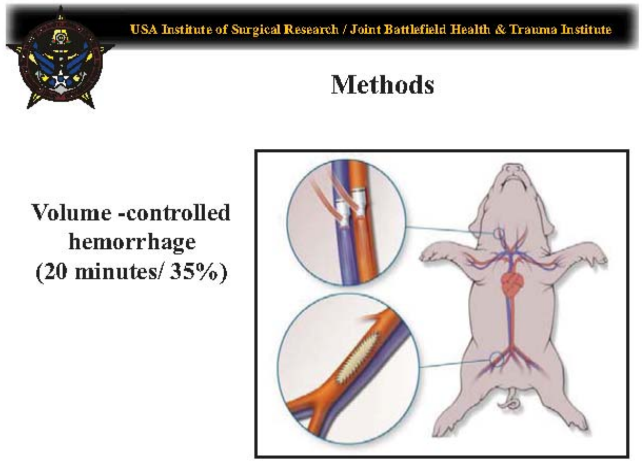

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Level II: Vascular Shunts
Proximal Vascular Shunts
Distal Vascular Shunts
P <0.05
1
0.8
0.6
0.4
0.2
0
Shunt Patency

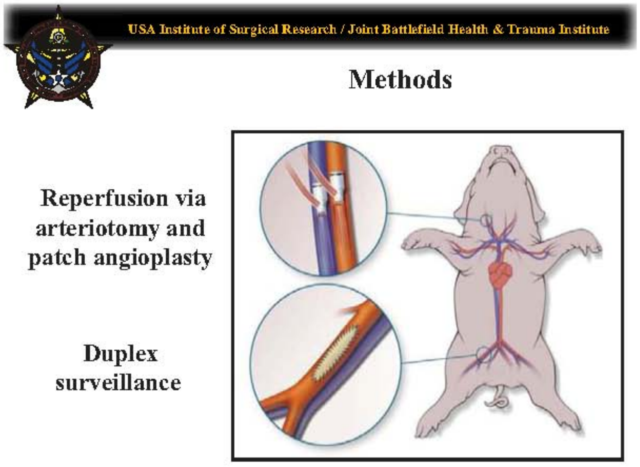

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Translational Research Question
There is value in expedited reperfusion?
Should levels advocate early restoration of flow?
ORIGINAL ARTICLE
Early Versus Delayed Restoration of Flow With Temporary Vascular Shunt Reduces Circulating Markers of Injury in a Porcine Model
Shaun M. Gifford, MD, Jonathan L. Eliason, MD, W. Darrin Clouse, MD, Jerry R. Spencer, RVT, Gabe E. Burkhardt, MD, Brandon W. Propper, MD, Patricia S. Dixon, MS, Lee Ann Zarzabal, MS, John A. Gelfond, MD, PhD, and Todd E. Rasmussen, MD
Conclusion: This study provides physiologic insight into the benefit of TVS in a model of extremity ischemia. Early TVS protects the extremity from further ischemic insult and reduces circulating markers of tissue injury. Additionally, the presence of a shunt does not increase the Ischemic Injury Index and patency is maintained in the absence of heparinization.


USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
What is an Ischemic Threshold?
The point in time after which irreversible tissue injury occurs (i.e. necrosis/ loss of function)
End organs are particularly susceptible

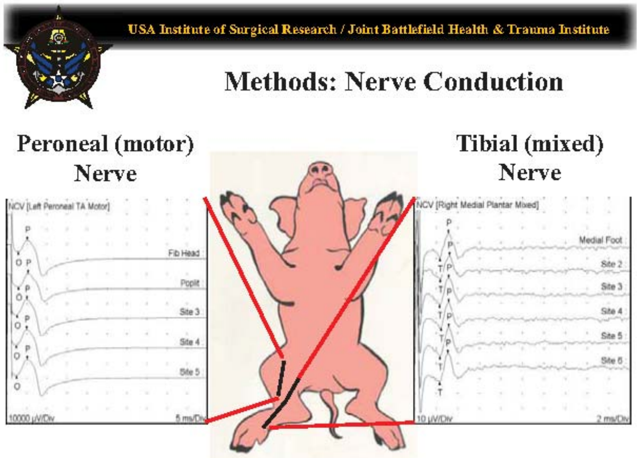

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Objectives
To characterize the neuromuscular ischemic threshold of the extremity using a large animal survival model
To assess the impact of class III shock on the ischemic threshold of the extremity using a large animal model of neuromuscular recovery

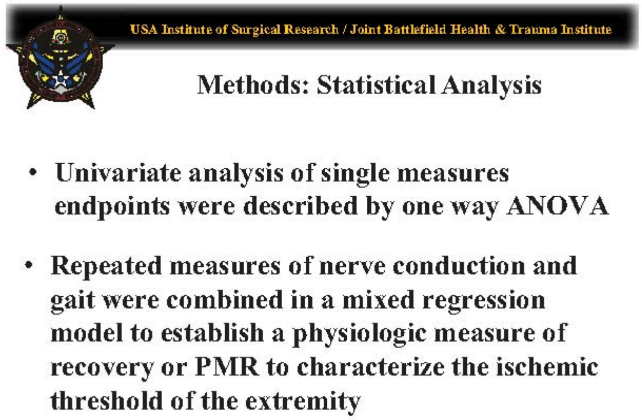

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Repair/ reperfusion
Baseline
Groups:
0, 1, 3, 6 hr
ischemia and
ligation
14-day survival with
physiologic measures of
recovery
Histology
Injury
shock/ischemia

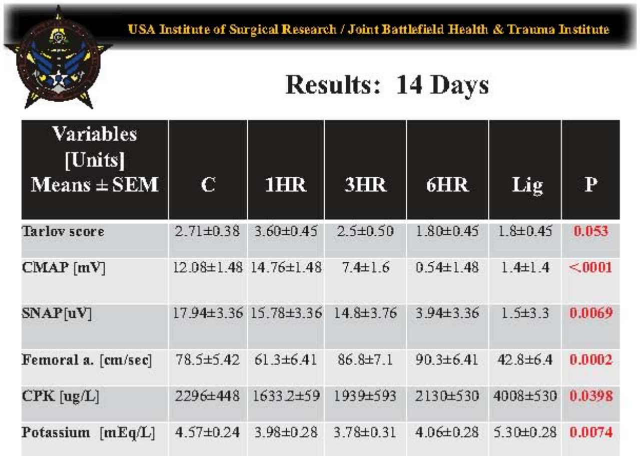

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Methods
Volume -controlled
hemorrhage
(20 minutes/ 35%)


USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Methods
Reperfusion via
arteriotomy and
patch angioplasty
Duplex
surveillance

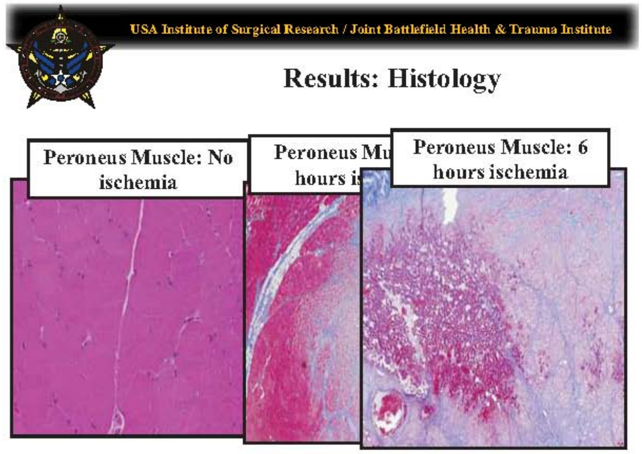

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
Methods
Modified Tarlov Score:
0 - Insensate, paralyzed limb
1 - Able to sit
2 - Stands, unable to bear weight
3 - Walks, with gait/ posture abnormality
4 - No gait or posture abnormality

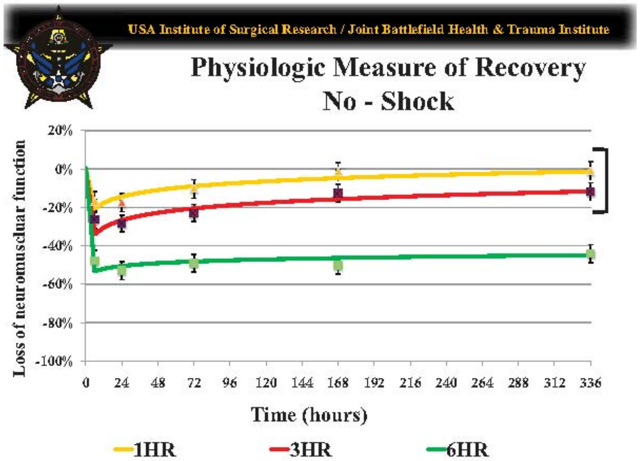


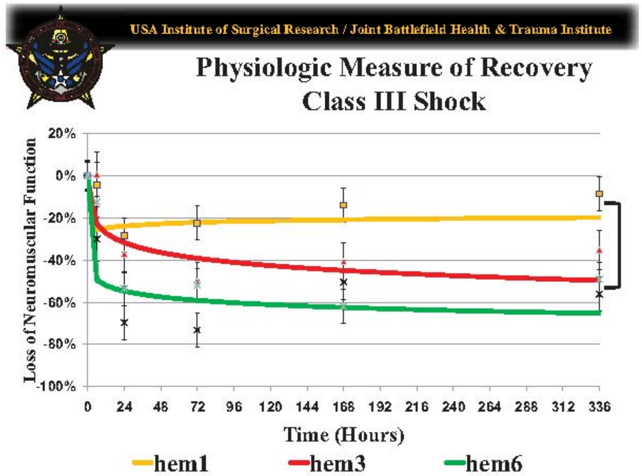




Variables [Units] Means ± SEM	C	1HR	3HR	6HR	Lig	P
Tarlov score	2.71±0.38	3.60±0.45	2.5±0.50	1.80±0.45	1.8±0.45	0.053
CMAP [mV]	12.08±1.48	14.76±1.48	7.4±1.6	0.54±1.48	1.4±1.4	<.0001
SNAP[uV]	17.94±3.36	15.78±3.36	14.8±3.76	3.94±3.36	1.5±3.3	0.0069
Femoral a. [cm/sec]	78.5±5.42	61.3±6.41	86.8±7.1	90.3±6.41	42.8±6.4	0.0002
CPK [ug/L]	2296±448	1633.2±59	1939±593	2130±530	4008±530	0.0398
Potassium [mEq/L]	4.57±0.24	3.98±0.28	3.78±0.31	4.06±0.28	5.30±0.28	0.0074







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Summary

- This experiment demonstrates the feasibility of combined hemorrhagic shock and extremity ischemia/reperfusion in a large animal survival model
- The presence of class III hemorrhagic shock compounds the impact of extremity ischemia reducing the ischemic threshold of the limb to less than three hours

USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute

Conclusion

- Strategies to improve functional limb salvage following extremity vascular injury in the setting of shock should include early restoration of flow within 60 minutes (i.e. time is tissue…)
- Further investigation is warranted to assess impact of interventions such as temporary vascular shunts, therapeutic reperfusion and fasciotomy on outcomes measures in this model


USA Institute of Surgical Research / Joint Battlefield Health & Trauma Institute
"For Combat Wounded..."

Direct Vascular Control Results in Less Physiologic Derangements than Aortic Crossclamping in a Porcine Model

Brooke Army Medical Center (BAMC) - Working with 59 Medical Wing (MDW)/SSSOGV

Capt Nick Markov

OBJECTIVE: Establishing vascular control during resuscitation in patients with end stage, non-compressible extra-thoracic torso hemorrhage remains debated. Currently, guidelines recommend emergency department thoracotomy (EDT) with aortic clamping although trans-abdominal aortic control and direct vascular control of the injury are potential alternatives. The objective of this study is to introduce an animal model of extra-thoracic torso hemorrhage and to compare the effectiveness of various methods of initial open vascular control. STUDY DESIGN: Animals (Sus Scrofa) (mean weight=80.9 kg) were randomized into 3 groups all of which had class III shock established via hemorrhage from an iliac artery injury prior to exploration with temporary vascular shunting. Group 1: EDT with thoracic aortic clamping (N=6), Group 2: intra-abdominal supra-celiac aortic clamping (SCC; N=6), and Group 3: direct vascular control (DVC) of bleeding site without aortic clamping (N=6). All groups were subsequently resuscitated and monitored for 6 hours with repeated measures of central perfusion, cerebral perfusion, and end organ function at standardized time points. RESULTS: There was no difference in mortality among the groups and no TVS failures. Central aortic pressure, carotid flow and trans-cranial brain oximetry all demonstrated increases in Groups 1 and 2 after application of the aortic clamp relative to Group 3 ($p<0.05$). During resuscitation, serum lactate levels were higher in Group 1 compared to Groups 2 and 3 (6.85 vs. 3.08 and 2.15, respectively; $p<0.05$) and serum pH in Group 1 reflected greater acidosis than Groups 2 and 3 (7.24 vs. 7.36 and 7.39, respectively; $p<0.05$). Groups 1 and 2 required significantly more intravenous fluid than Group 3 (2,166ml and 1,833ml, vs. 500ml respectively; $p<0.05$) and significantly more vasopressors were used in Groups 1 and 2 compared to Group 3 (52.1mcg and 43.5mcg vs. 10.3mcg, respectively; $p<0.05$). CONCLUSION: This study reports a novel model of non-compressible extra-thoracic torso hemorrhage comparing the effectiveness of EDT to SCC and DVC. Although EDT and SCC increased central and cerebral perfusion, DVC resulted in less physiologic derangement. Clinical studies evaluating DVC are warranted and require further investigation.

AFMS 2010

Direct vascular control results in less physiologic derangement than aortic cross clamping in a porcine model of non-compressible torso hemorrhage

Capt Nickolay Markov MD, Capt Joseph M. White MD, Lt Col Jeremy W. Cannon MD, Major John S. Oh MD, Lt Cdr Adam Stannard MRCS, Jerry R. Spencer RVT, Col (sel) Todd E. Rasmussen MD

San Antonio MilitaryVascular Surgery & The US Army Institute Of Surgical Research, Fort Sam Houston, Texas
The Uniformed Services University of the Health Sciences, Bethesda, Maryland

Background

Causes of Death in U.S. Special Operations Forces in the Global War on Terrorism

2001–2004

John B. Holcomb, MD, Neil R. McMullin, MD,* Lisa Pearse, MD,† Jim Caruso, MD,† Charles E. Wade, PhD,* Lynne Oetjen-Gerdes, MA,† Howard R. Champion, FRCS,‡ Mimi Lawnick, RN,* Warner Farr, MD,§ Sam Rodriguez, BS,§ and Frank K. Butler, MD‖*

Background: Effective combat trauma management strategies depend upon an understanding of the epidemiology of death on the battlefield.

Methods: A panel of military medical experts reviewed photographs and autopsy and treatment records for all Special Operations

survivable injuries. Structured analysis identified improved methods of truncal hemorrhage control as a principal research requirement.

Conclusions: The majority of deaths on the modern battlefield are nonsurvivable. Improved methods of intravenous or intracavitary, noncompressible hemostasis combined with rapid evacuation to surgery may increase survival.

Definition

"A constellation of injuries not amenable to control by external compression, which without intervention would likely result in death or significant morbidity as a result of hemorrhagic blood loss including trunkal vascular injury and high grade organ injuries"

Background

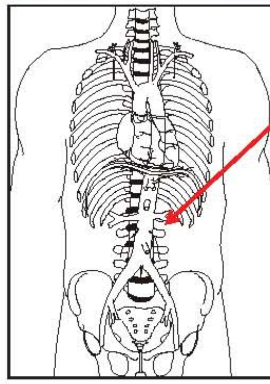
- Improvements in personal protective equipment and combat casualty care have resulted in improved survivability compared to previous conflicts
- Extremity vascular trauma is amenable to pre-hospital control
- 85% of battlefield deaths are due to exsanguination
- Currently non-compressible haemorrhage can only be controlled by surgical intervention

Background

- Optimal surgical approach to non-compressible extra-thoracic torso hemorrhage following penetrating injury in civilian and military setting is unknown

» 1. Seamon MJ et al. Emergency department thoracotomy: still useful after abdominal exsanguination? *J Trauma.* 2008; 64(1): 1-7.
» 2. Edens JW et al. Long term outcomes after combat casualty emergency department thoracotomy. *Journal of the American College of Surgeons.* 2009; 209(2):188-97.

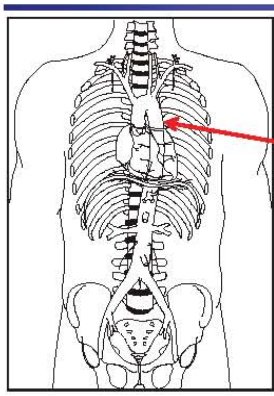
Background



- Traditional approach to the patient with profound shock and hemoperitoneum is laparotomy (i.e. primary laparotomy) and control of the vascular injury

Primary laparotomy:
- 6/11 (55%) survived OR
- 4/11 (36%) survived to discharge

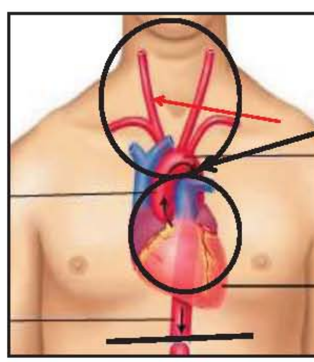
Background



- Alternatively, pre-laparotomy thoracotomy with aortic cross-clamp can be performed (i.e. resuscitative thoracotomy):
  - 11/29 (38%) survived OR
  - 7/29 (24%) survived to discharge

Ledgerwood AM, Kazmers M, Lucas CE. The role of thoracic aortic occlusion for massive hemoperitoneum. *J Trauma* 1976; 16(8):610-15

Background



- Resuscitative thoracic aortic occlusion
  1. Occlude aorta distal to left subclavian artery
  2. Existing cardiac stroke volume and "central pressure" maintained to myocardium and brain
  3. Bleeding distal to aortic occlusion temporized or stopped

Background

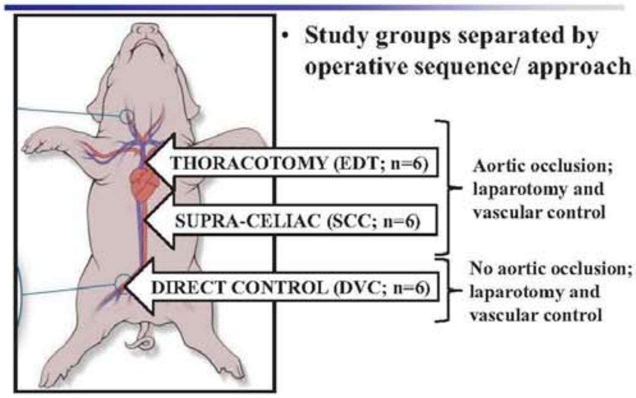
- Advantages of laparotomy and direct vascular control:
  - Analogous to "scoop and run"
  - Avoids time needed for thoracotomy (i.e. "additional pre-operative procedure")
  - Avoids the morbidity of violating the thoracic cavity
- Disadvantages of laparotomy and direct vascular control :
  - Prolonged global hypoperfusion

Objective

- To introduce a translatable, large animal model of extra-thoracic torso hemorrhage (class III/IV shock) allowing examination of the effectiveness of resuscitative aortic occlusion
- To compare the effectiveness of traditional methods of vascular control using hemodynamic measures of central and cerebral perfusion and circulating markers of physiologic derangement

Methods: Study Design

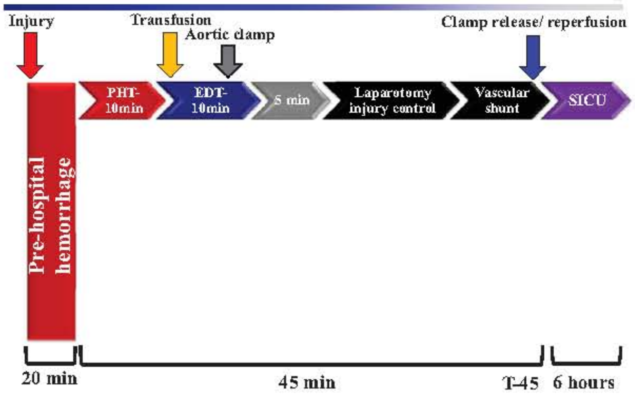
- Study groups separated by operative sequence/ approach



Methods: Surgical Approach

- 8.5 Fr sheath into right iliac artery to simulate vascular injury / hemorrhage
- Group 1 (EDT): Thoracic aortic occlusion through left anteriolateral thoracotomy
- Group 2 (SSC): Supra-celiac aortic occlusion through laparotomy and lateral to medial visceral rotation
- Group 3 (DVC): Direct vascular control without proximal aortic vascular occlusion

Methods: Study Flow Chart



Hemorrhage

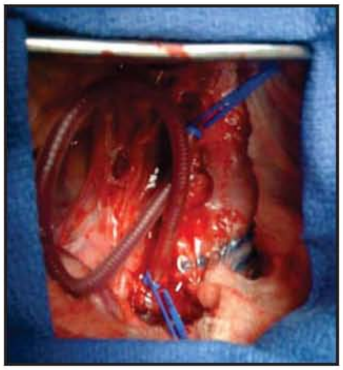
- Hemorrhage shock established by volume and rate controlled hemorrhage
- Hemoperitoneum was simulated by the infusion of 2 liters of 0.9% into the peritoneal cavity.
- 0.15ml/kg/min of ongoing hemorrhage was added prior to temporary vascular control.

Methods: Resuscitation

- Whole blood resuscitation was used (20% of total blood volume) (resuscitation consisted of shed blood)
- The blood pressure was titrated to a goal mean central pressure of 60 mmHg using intravenous fluid boluses (IVFB)
- Norepinephrine (8mg/250ml concentration) was titrated to obtain and maintain the goal central pressure

Methods: Injury Control/ Extremity Reperfusion

- Temporary vascular shunt in iliac artery injury site to control injury and restore perfusion during 6 hour ICU or resuscitation phase



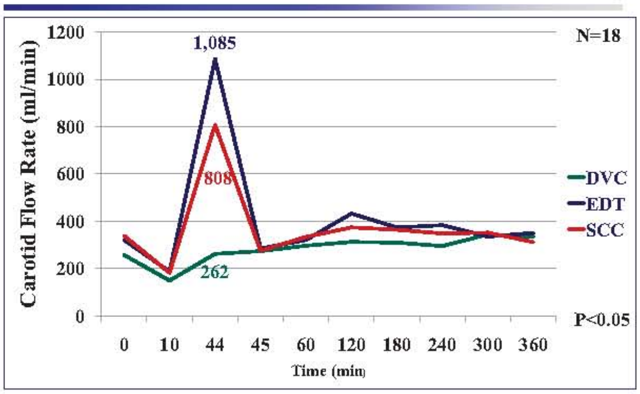
Methods: Statistical Analysis

- Group means of single measures were compared by analysis of variance
- Geometric means were compared for measures which appeared to be more normally distributed after log-transformation
- For repeated measures, group comparisons were conducted using a mixed model with autoregressive first order covariance structure treating time as a categorical factor

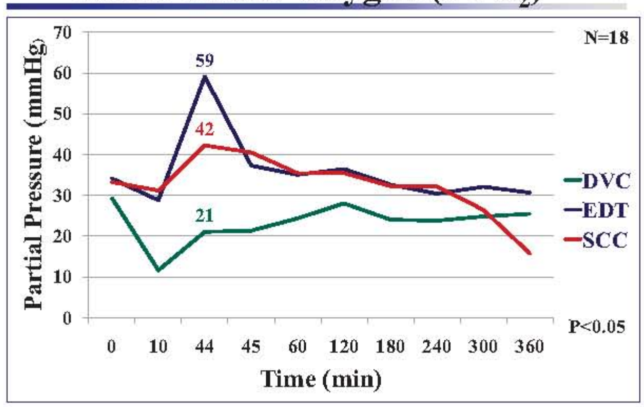
Methods: Physiologic Endpoints

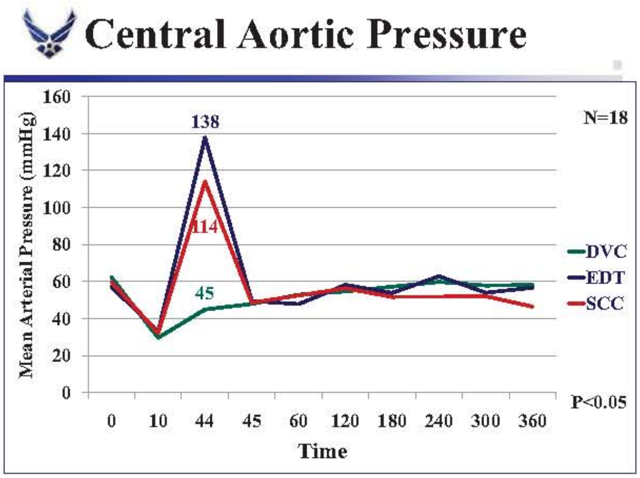
- Carotid flow rate (transonic flow probe; Transonic Systems Inc.)
- Partial pressure of brain tissue oxygenation (LICOX; Integra)
- Intravenous fluid bolus requirements
- Norepinephrine requirement

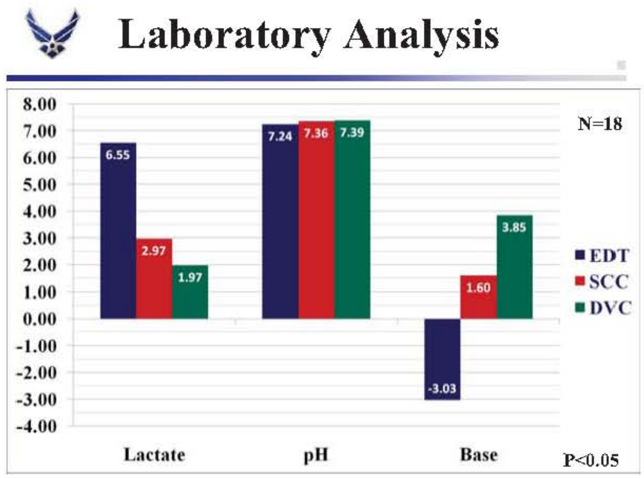
Results: Carotid Flow

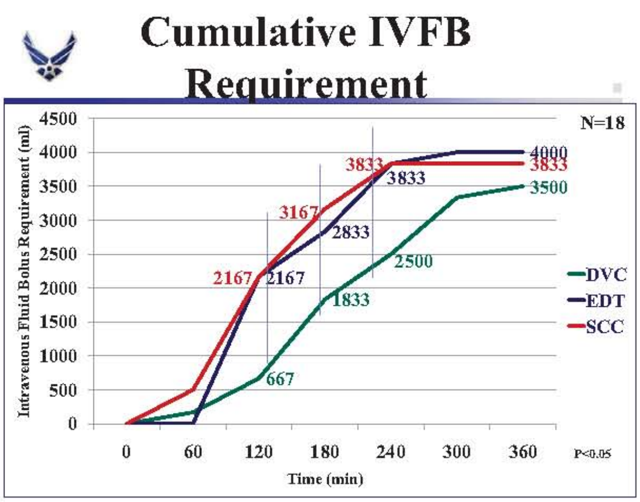


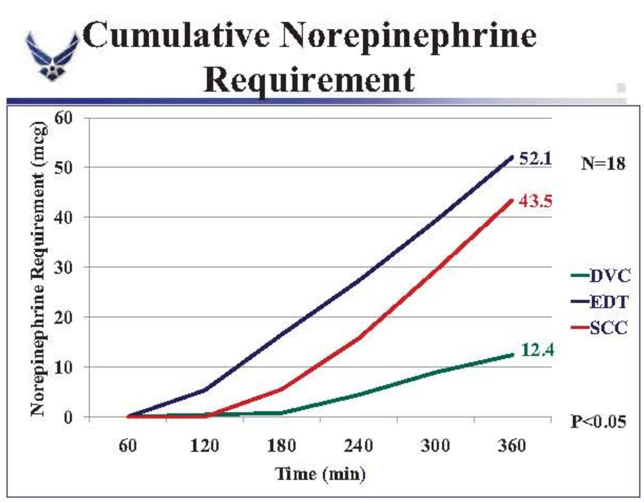
Partial Pressure of Brain Tissue Oxygen (PbO_2)




Central Aortic Pressure
Mean Arterial Pressure (mmHg)
160
140
120
100
80
60
40
20
0
138
114
45
N=18
DVC
EDT
SCC
P<0.05
0 10 44 45 60 120 180 240 300 360
Time


Laboratory Analysis
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
-1.00
-2.00
-3.00
-4.00
6.55
2.97
1.97
7.24
7.36
7.39
-3.03
1.60
3.85
N=18
EDT
SCC
DVC
Lactate
pH
Base
P<0.05


Cumulative IVFB Requirement
Intravenous Fluid Bolus Requirement (ml)
4500
4000
3500
3000
2500
2000
1500
1000
500
0
N=18
4000
3833
3833
3833
3500
3167
2833
2500
2167
2167
1833
667
DVC
EDT
SCC
0 60 120 180 240 300 360
Time (min)
P<0.05


Cumulative Norepinephrine Requirement
Norepinephrine Requirement (mcg)
60
50
40
30
20
10
0
52.1
43.5
12.4
N=18
DVC
EDT
SCC
P<0.05
60 120 180 240 300 360
Time (min)

Limitations

- Our model represented a relatively short reperfusion period without long-term survival data.
- Our model's overall survival rate was much greater than the anticipated survival demonstrated in the literature of 5-15%.
  - » Edens JW et al. Longterm outcomes after combat casualty emergency department thoracotomy. *Journal of the American College of Surgeons.* 2009; 209(2):188-97

Summary

- **This study reports a model of extra-thoracic torso hemorrhage allowing assessment of surgical approaches to resuscitative aortic occlusion and injury control**
- **Resuscitative aortic occlusion via open thoracotomy increases central aortic pressures and brain perfusion to levels greater than baseline**
- **Resuscitative aortic occlusion via open thoracotomy results in physiologic derangements including acidosis with greater fluid and pressor requirements**

Summary

- **Laparotomy with direct vascular control results in prolonged central aortic hypotension but is associated with less physiologic derangement than open thoracotomy with aortic clamping**
- **Ideal method of resuscitative aortic occlusion would achieve maintenance of central aortic pressure and cerebral flow in a less invasive manner, minimizing physiologic derangement**

Hemorrhagic Shock Worsens Neuromuscular Recovery in a Porcine Survival Model of Ischemia/Reperfusion Injury

59th Medical Wing (MDW)/SSSOGV

Capt Heather Hancock MD, Lt Cdr Adam Stannard MRCS, Jerry Spencer RVT, Capt Gabriel Burkhardt MD, LTC Todd Rasmussen MD: San Antonio Military Medicine Consortium, University of Texas Health Science Center at San Antonio, and the Uniformed Services University of the Health Sciences Bethesda, MD

BACKGROUND**: Current pre-hospital damage control strategies have increased survival to surgical care, resulting in an increased burden of severely injured salvaged limbs and emphasis on the functional outcomes of salvaged limbs. The objective of this study is to characterize the additive effect of hemorrhagic shock in a novel porcine survival model of functional limb outcomes.** METHODS**: Groups of 6 animals were randomized to iliac artery repair after progressive times of ischemia. 35% total blood volume was removed at a controlled rate creating Class 3 shock. An earlier arm used the same groups without hemorrhage and was used for comparison. Animals were monitored for 14 days to serially collect markers of functional recovery.** RESULTS**: Immediate Iliac repair and 1 hour ischemia animals had full functional recovery by the end of the observation period with minimal histologic evidence of remaining muscle and nerve damage, equivalent to controls without hemorrhage. Following 3 hours of ischemia, functional recovery was delayed and impaired, with moderate to severe degeneration of nerves and muscle noted on histology. Animals undergoing 6 hours of ischemia with the addition of hemorrhage had minimal EMG response and suffered severe systemic inflammation. Histological outcomes demonstrated nearly complete muscle and nerve degeneration. Significant mortality differences were noted when comparing delayed reperfusion groups (3, 6, ligation) with early repair.** CONCLUSION: **Results suggest a detrimental impact on the ischemic threshold already defined in a non-hemorrhagic model. It is likely that this model more accurately represents the critically ill combat casualty and as such will more reliably inform clinical practice.**

AFMS Virginia 2010

Hemorrhagic Shock Compounds Ischemia/ Reperfusion Injury in a Porcine Hind Limb Model

Capt Heather M. Hancock, MD
Lt Cdr Adam Stannard, MRCS
Capt Gabriel E. Burkhardt, MD
Jerry R. Spencer RVT
Col (sel) Todd E. Rasmussen, MD

San Antonio Military Vascular Surgery, Lackland AFB, TX,

The University of Texas Health Science Center
San Antonio, TX

The Uniformed Services University of the Health Sciences Bethesda, MD

Background

- Extremity trauma is the most common combat related injury
- Life threatening injuries may delay management of extremity vascular injuries
- Adjuncts such as temporary vascular shunts and fasciotomy extend the window of opportunity for repair

Rasmussen TE, Clouse WD. J Trauma 2006
Clouse WD, Rasmussen TE. J Am Coll Surg 2007
Clouse WD, Rasmussen TE. J Vasc Surg 2008
Gifford SM, Rasmussen TE . J Vasc Surg 2009

Background

- Clinical dogma proposing tolerance of 6 hours of extremity ischemia has been challenged with efforts to improve quality limb salvage
- Irreversible muscle and nerve injury may occur within 3 hours of hind limb ischemia

Schratzberger et al. Nature 2000
Chervo et al. J Surg Res 1989
Labbe et al. J Surg Res 1988

- Effects of graded ischemia during the acute reperfusion period suggest benefit with early restoration of flow

Gifford SM Rasmussen TE J Trauma 2009
Burkhardt GE Rasmussen TE J Trauma 2010

Background

- Vascular injury rates in the wars in Iraq and Afghanistan are 5 times that previously reported in wartime
- Changes in military doctrine have now positioned initial surgical care within 60 minutes of injury
- Recent burden of extremity vascular injury has led to a reprisal of efforts to improve quality or functional limb salvage

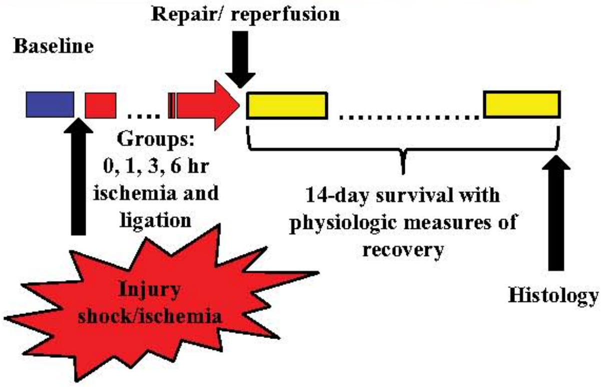
Background

- To advance functional or quality limb salvage a better understanding of the ischemic threshold of the limb is required
- To date models are small animal with limited ability to translate to large vessel injury and few include survival with physiologic measures of nerve and muscle function or recovery
- The impact of hemorrhagic shock on the ischemic threshold of the extremity is unknown

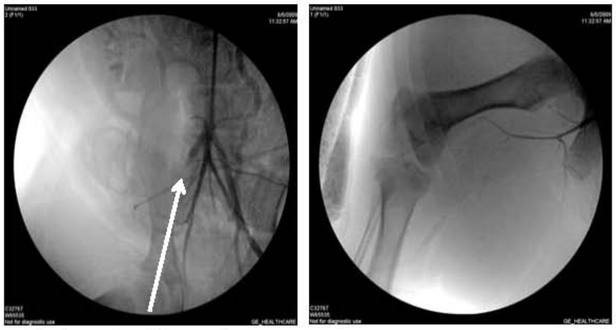
Objective

- Describe a large animal survival model of concomitant hemorrhagic shock and hind limb ischemia and reperfusion
- Characterize the impact of class III shock on the ischemic threshold of the extremity using a large animal model of neuromuscular recovery

Methods: Model Overview



Methods: Occlusion

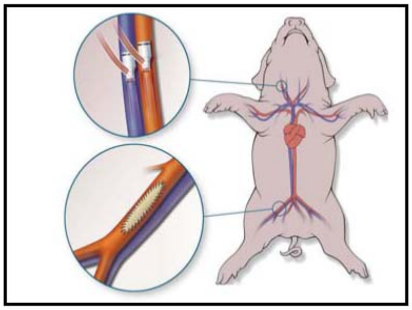


Ischemia: iliac artery occlusion

Absence of axial flow

Methods: Hemorrhage

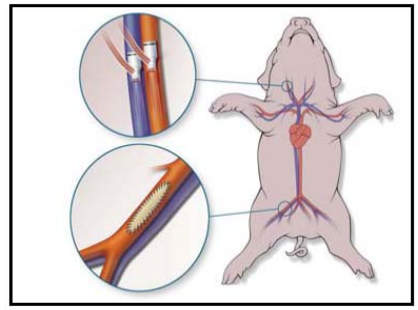
Volume -controlled hemorrhage (20 minutes/ 35%)



Methods: Repair

Reperfusion via arteriotomy and patch angioplasty

Duplex surveillance

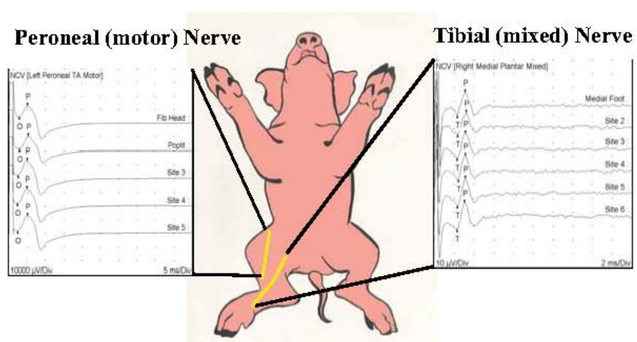


Methods: Gait Testing

Modified Tarlov Score:

- 0 - Insensate, paralyzed limb
- 1 - Able to sit
- 2 - Stands, unable to bear weight
- 3 - Walks, with gait or posture abnormality
- 4 - No gait or posture abnormality

Methods: Nerve Conduction



Methods: Histology

Muscle Degeneration

0 - No involvement

1 - 1% - 25% of cross sectional area affected

2 - 26% - 50% of cross sectional area affected

3 - 51% - 75% of cross sectional area affected

4 - 76% - 100% of cross sectional area affected

Nerve Degeneration

0 - No degeneration

1 - Minimal degeneration

2 - Moderate degeneration

3 - Severe degeneration

Methods: Statistical Analysis

- Univariate analysis of single measures endpoints were described by one way ANOVA, with significant variables further analyzed with subgroup t-test comparisons
- Repeated physiologic measures of nerve conduction and gait (CMAP, SNAP, NCV, Tarlov) were combined to generate a composite measure of neuromuscular recovery used to characterize the ischemic threshold of the extremity

Methods: Statistical Modeling

- Group comparison of repeated measures described via a mixed model with autoregressive 1st order covariant structure

Physiologic Model of Recovery (PMR)

$$Y = B_0 + B_1(1/(t+0.01)) + B_2(\ln(t+1))$$

Y is physiologic extent of recovery, B are coefficients derived from sum of least squares of observed data points and t is time

Results: Baseline

Variables Means (SD)	Control N=5	1 Hr N=5	3 Hr N=6	6 Hr N=6	Ligation N=6
Wt [kg]	84 (12)	80 (7)	78 (3)	82 (7)	82 (7)
HR [beats/min]	89 (5)	81 (10)	86 (8)	83 (8)	87 (4)
MAP [mmHg]	72 (3)	64 (3)	65 (3)	65 (5)	69 (9)
Hb [g/dL]	10 (1)	9 (1)	10 (1)	9 (0.4)	10 (1)
Lac [mmol/L]	1.2 (0.2)	1.1 (0.3)	1.0 (0.1)	1.0 (0.2)	1.0 (0.3)

Results: Baseline

Variables Means (SD)	Control N = 5	1 Hr N = 5	3 Hrs N = 6	6 Hrs N = 6	Ligation N = 6
Tarlov Score	4	4	4	4	4
CMAP [mV]	14 (2)	14 (3)	16 (5)	17 (5)	14 (5)
SNAP [uV]	25 (6)	20 (8)	25 (7)	20 (7)	21 (4)
NCV [m/sec]	42 (8)	41 (5)	45 (4)	42 (2)	44 (4)
Duplex Velocity [cm/sec]	78 (21)	81 (9)	81 (14)	85 (20)	72 (13)

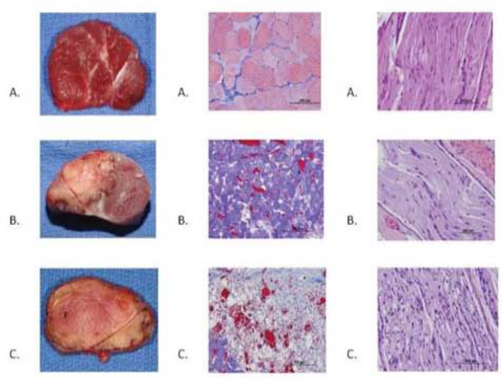
Results: Final

Variables Means ± SE	Control N = 5	1 Hr N = 5	3 Hrs N = 4/6	6 Hrs N = 5/6	Ligation N = 5/6	P
Tarlov Score	3.4 ± 0.4	3.6 ± 0.4	2.5 ± 0.4	1.8 ± 0.4	1.8 ± 0.4	0.005
CMAP [mV]	12 ± 1.5	15 ± 1.5	7.4 ± 1.7	0.5 ± 1.5	1.4 ± 1.5	<.0001
SNAP [uV]	18 ± 3.4	16 ± 3.4	15 ± 3.8	3.9 ± 3.4	1.6 ± 3.4	0.007
Duplex [cm/sec]	77 ± 6.7	61 ± 6.7	87 ± 7.5	90 ± 6.7	43 ± 6.7	0.0004

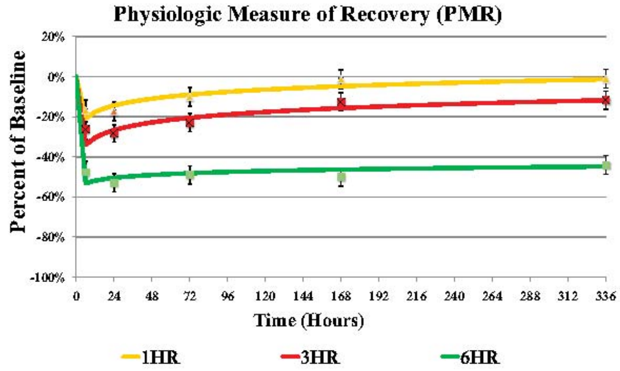
Results: Final

Variables Means ± SE	Control N = 5	1 Hr N = 5	3 Hrs N = 4/6	6 Hrs N = 5/6	Ligation N = 5/6	P
Hb [g/dL]	8.9 ± 0.3	9.4 ± 0.3	9.1 ± 0.4	8.5 ± 0.3	9.4 ± 0.3	0.35
AST [IU/L]	43 ± 11	42 ± 11	49 ± 12	48 ± 11	78 ± 11	0.14
Lactate [mmol/L]	0.9 ± 0.2	0.6 ± 0.2	0.8 ± 0.2	0.7 ± 0.2	0.7 ± 0.2	0.86
CPK [ug/L]	2145 ± 532	1633 ± 532	1940 ±594	2131 ± 532	4009 ± 532	0.04
K [mEq/L]	4.6 ± 0.3	4.0 ± 0.3	3.8 ± 0.3	4.1 ± 0.3	5.3 ± 0.3	0.01

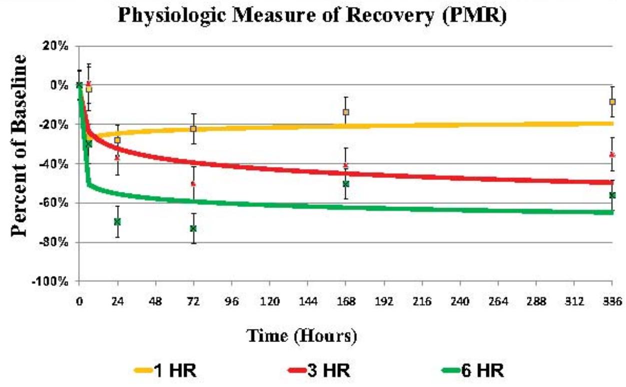
Results: Histology



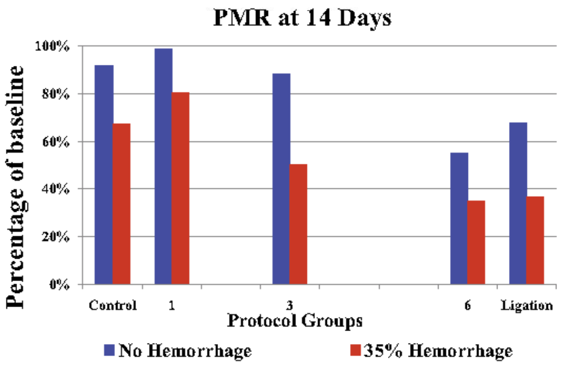
Results: PMR No Hemorrhage



Results: PMR Hemorrhage



Results: Study Comparison



Summary

- This experiment demonstrates the feasibility of combined hemorrhagic shock and extremity ischemia/reperfusion in a large animal survival model
- This experiment confirms and extends a previous report using this physiologic measure of recovery which includes nerve conduction and gait assessment in the absence of hemorrhage
- The presence of class III hemorrhagic shock compounds the impact of extremity ischemia reducing the ischemic threshold of the limb to less than three hours

Conclusion

- Strategies to improve functional or quality limb salvage following extremity vascular injury in the setting of shock should include early restoration of flow within 60 minutes
- Further investigation is warranted to assess the impact of interventions such as temporary vascular shunts, therapeutic reperfusion and fasciotomy on the outcome measures in this model

Acknowledgements

59th Clinical Research Squadron

Veterinary Pathologist
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Jackie Duncan

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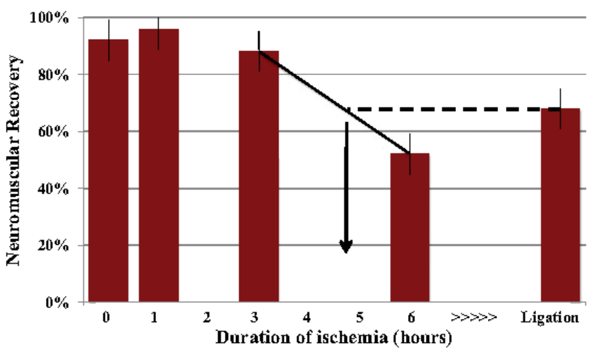
Richard Keaton
Anthony Edwards
Brittany Georoffe
Anthony Medina

Neurologist
Nathan Summers MD

Results: Ischemic Threshold

Estimation of the Ischemic Threshold



Quality of limb salvage following wartime extremity vascular injury: results of a novel patient-based outcomes study

UK Research Fellow Working with 59th Medical Wing (MDW)/SSSOGV

Adam Stannard, Gabe Burkhardt, Barbara Keltz, Chantel Porras, Rebecca Ivatury, Shaun Gifford, Todd Rasmussen, 59th Clinical Research Training Division, Wilford Hall Medical Center, 2200 Bergquist Drive , Bldg 4430, Lackland AFB, TX 78236-5300

BACKGROUND**: As efforts are increasingly directed beyond statistical, to quality limb salvage, following extremity vascular injury, a patient-based outcomes measure is needed. The objective of this study is to describe a novel questionnaire, designed to assess quality of limb (QOL) in a cohort of combat wounded with limb threatening injuries.** METHODS**: Clinical records from the Joint Trauma Theatre System (JTTS) were reviewed for a cohort with extremity vascular injuries between 2002 and 2009. A 21-point questionnaire addressing limb outcome (limb status, pain, functional impairment, satisfaction with current limb) was completed. Patient responses were stratified on a 30-point scale with 0 representing the poorest limb quality.** RESULTS**: Contact was made with 104/256 (41%) of patients and survey responses for QOL questionnaire from 45 (45%). Eighty-seven percent (39/45) of respondents had lower limb injuries. Nine patients with lower extremity injury (23%) had an amputation and all could mobilize with a device. Lower limb salvage was 76% at 28 months, although 91% reported the extremity did not work normally (77% specifying pain with ambulation). Ninety-one percent report function adequate to enable walking; 53% required daily analgesia for their extremity injury and 32% report they would be better off having had an amputation. Six respondents had upper extremity injuries with no amputations, 100% reported neurologic disability; 1 respondent would have preferred amputation. Overall 48% of the cohorts were separated with disability benefits and 52 % remain active duty with a profile.** CONCLUSION**: Results from this study demonstrate that patient-based outcomes following extremity vascular injury are limited by secondary amputation, pain and neurologic dysfunction. A novel QOL questionnaire aimed to better characterize functional limb salvage may allow correlation between in-theater strategies and long-term function.**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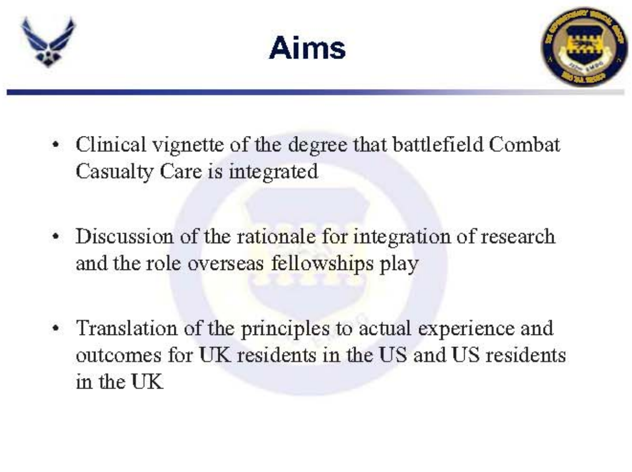
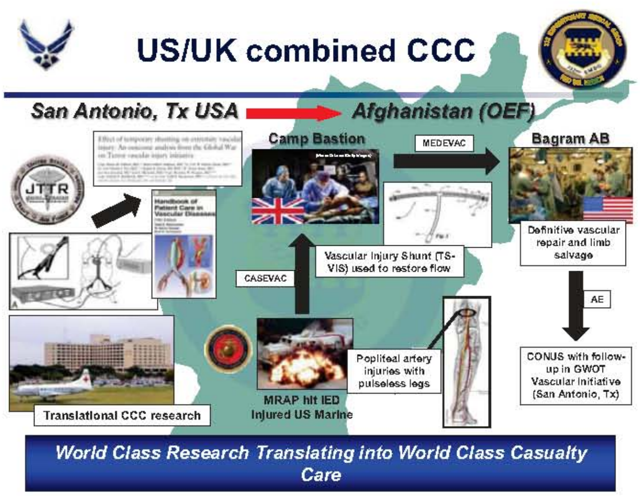
TRANS-ATLANTIC
OVERSEAS FELLOWSHIPS
Surgeon Lieutenant Commander
Adam Stannard
Royal Navy


Aims
Clinical vignette of the degree that battlefield Combat Casualty Care is integrated
Discussion of the rationale for integration of research and the role overseas fellowships play
Translation of the principles to actual experience and outcomes for UK residents in the US and US residents in the UK


US/UK combined CCC
San Antonio, Tx USA
Afghanistan (OEF)
Camp Bastion
MEDEVAC
Bagram AB
JTTR
Definitive vascular repair and limb salvage
Vascular Injury Shunt (TS-VIS) used to restore flow
CASEVAC
AE
Popliteal artery injuries with pulseless legs
CONUS with follow-up in GWOT Vascular Initiative (San Antonio, Tx)
MRAP hit IED
Injured US Marine
Translational CCC research
World Class Research Translating into World Class Casualty Care


Rationale for integrated CCC research
Almost a decade of sustained conflict
US and UK CCC reconfiguring to provide mutual support
Both face a common evolving battlefield

Rationale for integrated CCC research

- Historical conflicts resulted in medical advances
- The first prolonged conflicts in the era of evidence based medicine
- Use the opportunity to attain the greatest benefit

Rationale for integrated CCC research

- Maximum benefit is to be gained combining research endeavors
- Defines the questions and streamlines research
- Research fellows provide the focus for talent on both sides of the Atlantic

Rationale for integrated CCC research

- Two countries divided by a common language, but in the future not definitions?
- Alignment of focus begins with research
- Fellows can provide contacts in their own nation

Rationale for integrated CCC research

- Fellowships traditionally mainly benefitted the individual
- The main beneficiary is CCC
- How can we qualify that?

Clinical output UK resident in US program

- My experiences working within the vascular research group at Wilford Hall
- Started October 2009 to complete September 2010

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QUALITY OF LIMB SALVAGE FOLLOWING WARTIME EXTREMITY VASCULAR INJURY: RESULTS OF A NOVEL PATIENT-BASED OUTCOMES STUDY

Surg Lt Cdr Adam Stannard RN, Capt Gabe Burkhardt USAF, Barbara Keltz, Chantel Porras, Rebecca Ivatury, Capt Shaun Gifford USAF, Lt Col Todd Rasmussen USAF

Clinical output UK resident in US program

- On return to the UK plan to develop a similar system
- Increased numbers
- Differences
- Comparison

R C D M

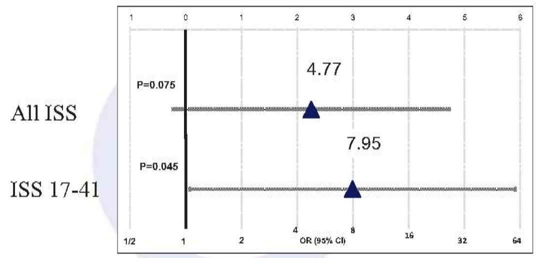
BATTLEFIELD NON-COMPRESSIBLE HAEMORRHAGE: A CONTEMPORARY EXPERIENCE

Stannard A, Rasmussen TE, Williams K, Midwinter M, Tai NR

Academic Department of Military Surgery & Trauma
Royal Centre for Defence Medicine
Birmingham
59th MDW, Lackland AFB, San Antonio, Texas

Method – Data Analysis

Results



- In ISS 17-41
  - Non-compressible mortality = 75% versus 34% for compressible

Discussion

- Assuming equivalent efficacy of a pre-hospital non-compressible haemorrhage control intervention to tourniquet in pre-hospital management of compressible haemorrhage, number to treat to save a mortality is 3 in the ISS range 17-41
- Efficacy will not be equivalent, but due to low number to treat, impact is still likely to be significant

Conclusion

- Non-compressible injury has a mortality and for most medical intervention is not possible
- Potential for significant intervention in a minority of casualties if earlier hemorrhage control
- Further corroborative analysis is required
  - Extending UK dataset
  - Applying US JTTR to address non-compressible haemorrhage

Clinical output UK resident in US program - MD

- In the UK an MD is a higher medical degree based upon a thesis
- Usually takes 2 years in the UK to complete research : Completed in Wilford Hall in less than 1 year
- Benefit is high degree of academic scrutiny and feedback to the group

Clinical output UK resident in US program - MD

- Basis of MD has 2 parts
- Clinical – Quality of limb
- Basic science – Therapeutic reperfusion

Clinical output UK resident in US program - MD

- Delivery of pharmacological agents at the time of reperfusion to reduce the effects of ischemia reperfusion injury
- Erythropoietin (EPO) and Statin (Lovastatin)
- Aim is to extend period before irreversible damage is done

Clinical output UK resident in US program – Additional output

- Defining torso vascular anatomy to produce a nomogram-tape for fluoroscopy-free aortic balloon insertion
- Assisted with several additional protocols within the lab and manuscript production
- Written 3 lab based protocols and 2 clinical protocols for continuing research

Clinical output UK resident in US program – Additional output

- Facilitated US fellowship to the UK
- Brought some new ideas to the OR
- Worked to perpetuate fellowships in both directions

US resident fellowship in the UK

Objectives:

1. Participate in the United Kingdom trauma system and observe UK Combat Casualty Care
2. Continue international collaborative efforts to improve Combat Casualty Care research
3. Observe physician directed pre-hospital care

US resident fellowship in the UK

- Association of Surgeons of Great Britain and Northern Ireland
- Royal Centre for Defence Medicine
- Headley Court
- Porton Down
- The Royal London Hospital
- MOST
- Military Surgery

US resident fellowship in the UK - ASGBI

- Largest UK surgical conference - international
- Defence Medical Services involvement
- Combat Casualty Care session
- Trauma session


US resident fellowship in the UK - RCDM
Receiving hospital for injured UK personnel
Opportunities to see and be involved with UK continuing care
Academic departments
UK JTTR

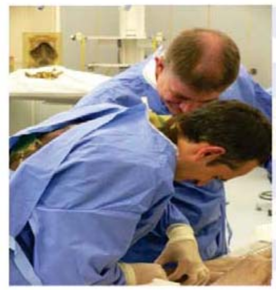

US resident fellowship in the UK – Headley Court
Centre for UK military rehabilitation (CFI)
Presentations transfer of ideas
Meeting UK rehabilitating service personnel


US resident fellowship in the UK – Porton Down
Porton Down
Salisbury
UK military centre of biomedical research
Potential for reciprocal lab based research in the future


US resident fellowship in the UK – Royal London

US resident fellowship in the UK – Royal London

US resident fellowship in the UK – MOST course



- Military Operational Surgical Training
- Part of pre-deployment training for UK doctors involved In CCC
- Held at the Royal College of Surgeons in London in partnership with Joint Medical Command

US resident fellowship in the UK – MOST course

- Multi-disciplinary, multi-surgical specialty, including theatre staff
- Scenario-based cadaveric dissection and Simman 3G simulation
- Contemporaneous wounding patterns updated 6/12

US resident fellowship in the UK – MOST course

- Live link to deployed surgical team
- Cooperation between academic departments and Royal College
- Mandatory for deployment
- US faculty on next course?

Summary

- US and UK CCC is increasingly integrated
- Integration of research endeavors focuses talent on clinical problems from slightly differing perspectives strengthening the outcome
- Research fellows provide a physical link and future resource to both sides of the Atlantic

Thank you

- To the US Air Force for providing the opportunity
- MG Travis
- Lt Col Rasmussen
- Dr Niemeyer
- Fellow residents and colleagues

Questions?

UK Poster US Poster

Traveling Fellowship to the United Kingdom as an adjunct to general surgical research and training

59th Medical Wing (MDW)

Lt Cdr Adam Stannard

Military medical missions spanning two mature theaters of conflict require flexible deployment of personnel and resources. International collaboration with allies operating in established facilities in Iraq and Afghanistan generates synergy in patient management, resource utilization, and research development. The impact of these relationships on the education of future physicians and surgeons has not previously been described. The objective of this traveling fellowship is to describe the utility of a brief structured orientation to military medicine and research within the United Kingdom.

Between 12 April and 14 May 2010, as a senior general surgical trainee, I participated in an exchange with the United Kingdom under the mentorship of several senior UK military consultants. In addition to presenting our group's research at two international meetings, I was invited to participate in the Military Operational Surgery Training (MOST) course. I completed a structured observership at the Royal London Hospital which included exposure to physician driven pre-hospital health care delivery, and operative management of trauma at a level I facility. Injured UK troops recovering at the leading military rehabilitation center in the UK (Headley Court) were interviewed, as were physicians involved in their care to describe functional limb salvage using patient based outcomes measures.

A brief structured exchange within the UK military medical system serves as a productive and meaningful adjunct to my military medical education. Research collaboration with respect to quality of limb outcomes may enable a more comprehensive assessment of the impact of surgical interventions following severe extremity injuries.

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QUALITY OF LIMB SALVAGE FOLLOWING WARTIME EXTREMITY VASCULAR INJURY: RESULTS OF A NOVEL PATIENT-BASED OUTCOMES STUDY

Surg Lt Cdr Adam Stannard RN, Capt Gabe Burkhardt USAF, Barbara Keltz, Chantel Porras, Rebecca Ivatury, Capt Shaun Gifford USAF, Lt Col Todd Rasmussen USAF

Background

- Extremity trauma dominates in contemporary conflicts
- Enhanced battlefield survivability relative to historic comparators
- Burden of extremity injury and its long term sequelae are high to individuals and health providers

Background

- **Traditionally limb outcome endpoints have focused on amputation rates**

	Limb Salvage	Setting
DeBakey	46%	World War II
Hughes, Rich et al	>80%	Korea to Vietnam
D'Sa	>90%	Northern Ireland

Background

Type of amputation	Definition
Traumatic	Amputation as a direct result of the mechanism of injury, at the time of injury
Primary	Amputation performed at initial surgical assessment/intervention
Secondary	Any amputation performed following a surgical decision for limb salvage

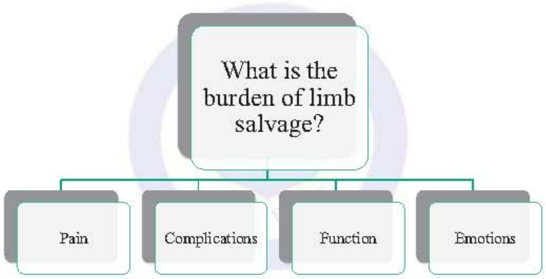
Background

Type of amputation	Definition
Primary	Limb Salvage 85%
Secondary	Limb salvage 78%

Background

- Is limb salvage rate the best measure of outcome success in limb threatening vascular injury?


Background



Background

- Recent shift in emphasis to functional limb salvage rather than anatomical limb salvage
- Adjuncts to traditional techniques for early restoration of blood flow such as Temporary Vascular Shunts are being increasingly used to improve functional limb salvage

Background

But…

Background

But…

Background

- No mechanism to assess the quality of functional limb salvage in combat casualties with limb threatening vascular injury

Background

- Questionnaires exist to assess quality of life and limb function
- Short Form 36
- Venous Insufficiency (CIVIQ) and Lower limb Ischemia
- Musculoskeletal Functional Assessment

Objectives

- Develop a performance improvement system
- Detailed vascular database
- Quality of limb questionnaire
- Assess quality of life in limb threatening vascular injury

Methods: The GWOTVI Database

- Basis of casualty identification is the Joint Theater Trauma Registry, held at the ISR
- Key staff are the vascular nurse specialists who staff the GWOTVI

Methods: The GWOTVI Database

- Casualties added as specific clinical project searches have been set up
- Electronic records mined
- Patient contact established

Methods: Quality of Limb Questionnaire

- Novel questionnaire
- 21 questions
- Covering:
  - Limb Status
  - Pain
  - Functional impairment
  - Limb Satisfaction

Methods: Quality of Limb Questionnaire

- Administered with SF-36 to casualties on the GWOTVI database injured between 2002 -2009
- Postal, Telephonic and Electronic methods of administration

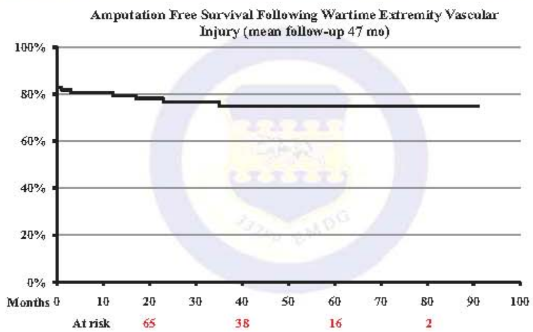
Results – Response Rate

267 extremity vascular injuries → Contact made (n=161; 60%) → Survey response (n=99; 61%)

Data From: GWOT Vascular Initiative

Median time injury to survey = 47 mo

Results – Amputation rate



Results – Limb injuries

- Lower limb 80%
- Limb salvage 78%
- Reasons contributing to amputation
  - Vascular 6
  - Infection 6
  - Bone 7
  - Neurological 6
- Upper limb 20%
- Limb salvage 100%

Results – Limb injuries

Bone injury

Secondary Amputation	Fracture	81 %
	No Fracture	19 %
Salvage	Fracture	49 %
	No Fracture	51 %

p=0.012

Nerve injury

Secondary Amputation	Nerve Injury	24 %
	No Nerve Injury	76 %
Salvage	Nerve Injury	41 %
	No Nerve Injury	59 %

p=0.14

Results – Lower limb injuries

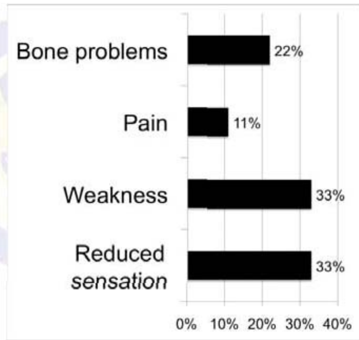
- 91% of those with salvaged lower limbs reported the limb was not normal

Results – Lower limb injuries

- 95% reported function sufficient to walk
- 67% require daily pain medications (33% in lower limb amputees)
- 27% felt that they would be better off with an amputation and prosthesis

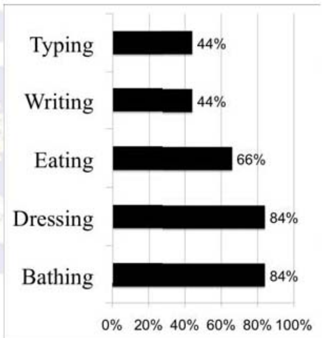
Results – Upper limb injuries

- 89% of those with salvaged limbs reported the limb was not normal



Results – Upper limb injuries

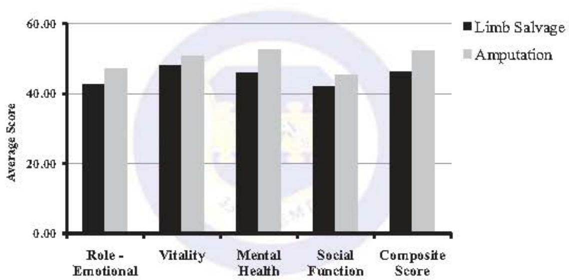
- 84% reported being able to use their arm in some way
- 28% require daily pain medication
- 21% better off with an amputation and prosthesis



Results – Scores

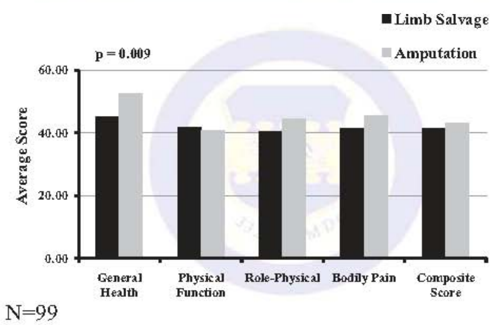
Score/Group	Overall (Mean)	Limb Salvage (Mean)	Amputee (Mean)	Limb Salvage Vs Amputee
ISS Injury Severity Score	16.7	16.0	19.6	p=0.12
MESS Mangled Extremity Severity Score	5.2	5.0	5.7	p=0.15
SF-36 Physical	42.1	41.9	43.1	p=0.53
SF-36 Mental	47.6	46.3	52.6	p=0.07

Results – SF-36 Physical



N=99

Results – SF-36 Mental



N=99

Results – SF-36 correlations

- Injury Severity Score (ISS) does not correlate with SF-36 Quality of Life in this series
- Mangled Extremity Severity Score (MESS) has a weak correlation with SF-36 Mental Composite Score in this series

Discussion

- The most common injury pattern on the battlefield is to the extremities
- The overall injury severity and limb specific injury severity reaching surgical intervention is greater than in previous conflicts
- Of all extremity injuries, it is those with a vascular component, which provide the greatest opportunity for impact on outcome

Discussion

- Amputation rates are similar to previous conflicts and close to the best civilian series
- We can clearly define the secondary amputation rates, their temporal nature and indication
- A system which allows us to look beyond crude amputation statistics has been developed to better assess outcome

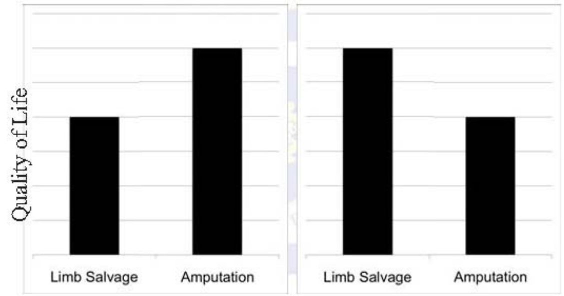
Discussion

- Limb salvage is not a panacea for extremity trauma, for some there is a price to pay “The Burden of Limb Salvage”
- At what level does the “cost” of limb salvage exceed its benefit?

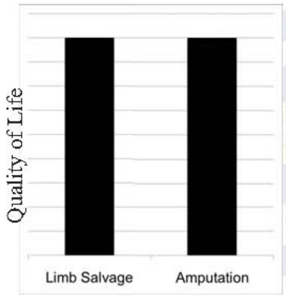
Discussion

- The bar that limb salvage must clear is the quality of Life and Limb afforded by amputation

Discussion



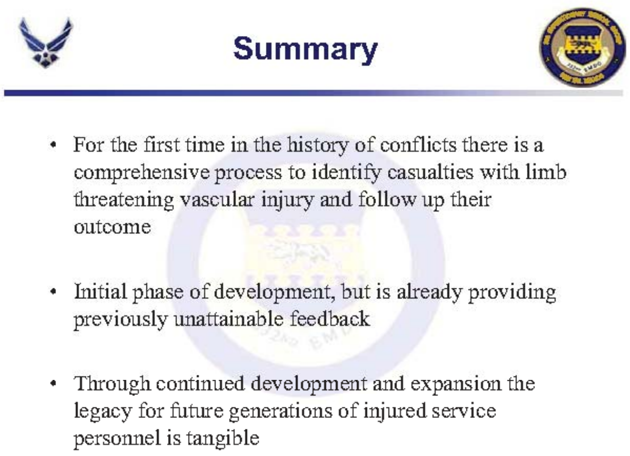
Discussion

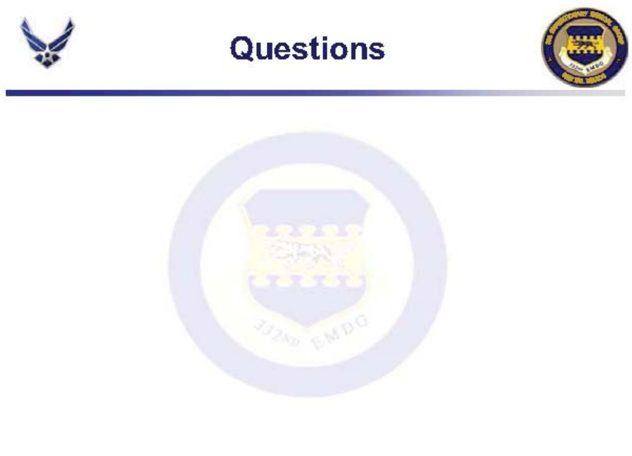


- Currently there is parity on the whole
- Some trends in favor mentally towards amputation
- Nothing clearly significant

Discussion

- We are pushing to improve outcomes from limb salvage through mitigation of ischemia-reperfusion injury
- There is also the challenge of limb re-implantation to be addressed in the future


Summary
For the first time in the history of conflicts there is a comprehensive process to identify casualties with limb threatening vascular injury and follow up their outcome
Initial phase of development, but is already providing previously unattainable feedback
Through continued development and expansion the legacy for future generations of injured service personnel is tangible


Questions

Enhancement in Communication of Performance Improvement Events within a Global Military Trauma System

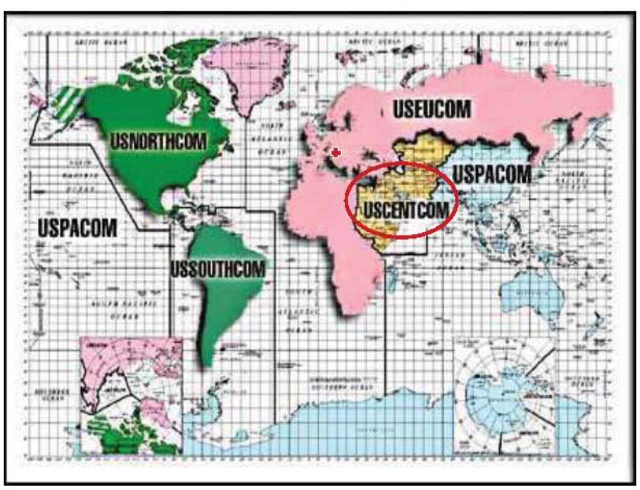
Landstuhl Regional Medical Center

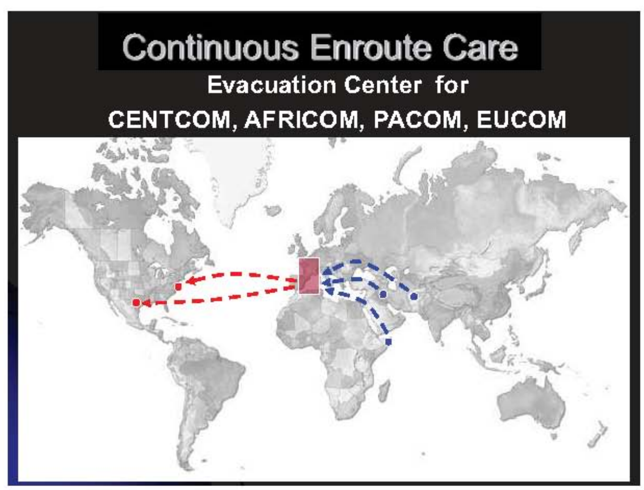
Kathleen Martin

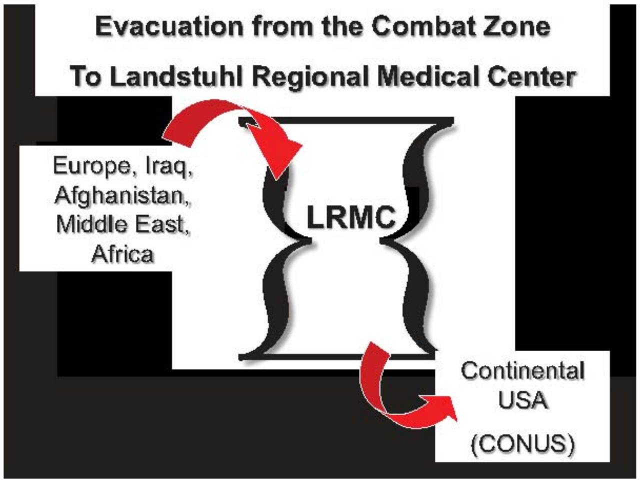
LRMC is the first military hospital outside the combat zones of Iraq (OIF) and Afghanistan (OEF) and concurrently indentifies performance Improvement (PI) events/ complications (E/C) related to downrange, enroute, and interfacility care. E/C identified in transit between OIF/OEF-LRMC-USA for evacuees accompanied by Critical Care Air Transport Teams (CCATT) are referred to the CCATT Pilot Unit. Aeromedical (AE) E/C are referred to the Air Force AE system PI Director, enhancing communication between ground and flight providers. Urgent issues are communicated verbally and weekly aggregate reports are sent to Joint Theater Trauma System (JTTS) downrange, CCATT and AE liaisons. In 2008, 1230 patients arrive to LRMC; 313 via CCATT and 724 via AE. PI E/C were captured concurrently and entered in the trauma registry by the Trauma Coordinators. There were 148 (12%) E/C identified and referred to JTTS; 28 (5%) to CCATT: 15 (<1%) to AE. In 2009, 1191 patients arrive to LRMC; 299 via CCATT and 813 via AE. There were 337 (28%) E/C identified and referred to the JTTS; 34 (7%) to CCATT; 11 (<1%) to AE. Communication of E/C occurred daily via secure DSN phone lines, encrypted email and video-teleconferencing. Communication of PI E/C is a challenge due to varied provider demographics, multi-service/national providers, distance across 3 continents, and in the complexity of effective PI. LRMC is the epicenter for bidirectional communication and utilizes technology, trauma PI/registry taxonomy in all interfaces despite distances and diversity, to leverage enhancements. This is an ideal arena to employ a true inclusive trauma system.

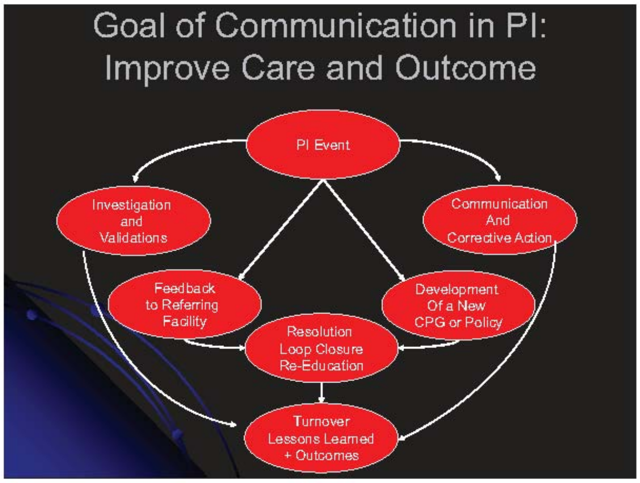

ENHANCEMENTS IN COMMUNICATION OF PERFORMANCE IMPROVEMENT EVENTS WITHIN A TRI-CONTINENT MILITARY TRAUMA SYSTEM
Kathleen Martin, MSN, RN
Trauma Program Nurse Director
Landstuhl Regional Medical Center, Germany
Joint Theater Trauma System


Background
United States Army Hospital
Landstuhl, Germany
1955
Landstuhl Regional Medical
Center, Germany
2006

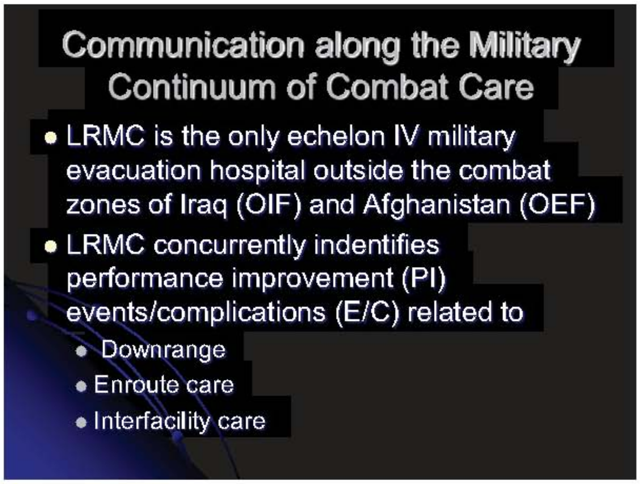

USEUCOM
USNORTHCOM
USPACOM
USCENTCOM
USPACOM
USSOUTHCOM


Continuous Enroute Care
Evacuation Center for
CENTCOM, AFRICOM, PACOM, EUCOM


Evacuation from the Combat Zone
To Landstuhl Regional Medical Center
Europe, Iraq, Afghanistan, Middle East, Africa
LRMC
Continental USA
(CONUS)


Goal of Communication in PI: Improve Care and Outcome
PI Event
Investigation and Validations
Communication And Corrective Action
Feedback to Referring Facility
Development Of a New CPG or Policy
Resolution Loop Closure Re-Education
Turnover Lessons Learned + Outcomes


Communication along the Military Continuum of Combat Care
LRMC is the epicenter for bidirectional communication of clinical information
LRMC utilizes technology, trauma performance improvement, trauma registry taxonomy in all interfaces
Challenges of distances and diversity are managed to leverage enhancements.
This is an ideal arena to employ a truly inclusive trauma system

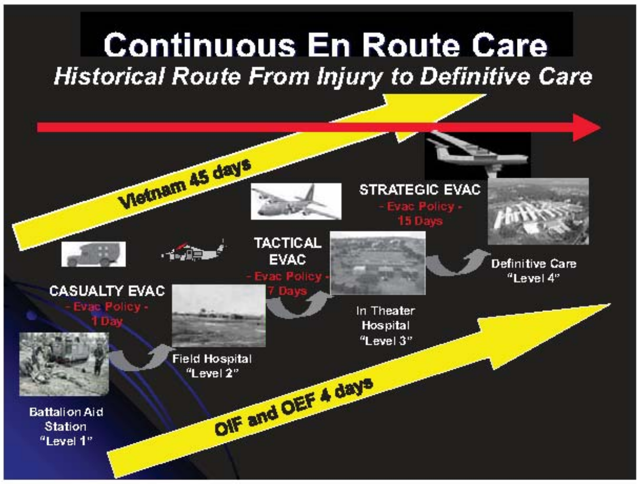

Communication along the Military Continuum of Combat Care
LRMC is the only echelon IV military evacuation hospital outside the combat zones of Iraq (OIF) and Afghanistan (OEF)
LRMC concurrently indentifies performance improvement (PI) events/complications (E/C) related to
Downrange
Enroute care
Interfacility care

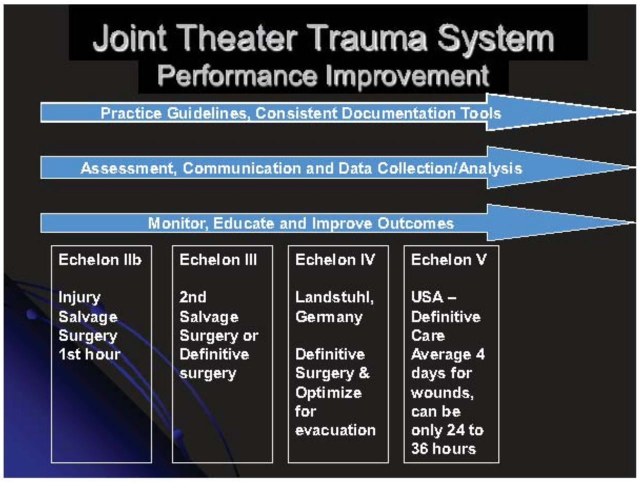
Events

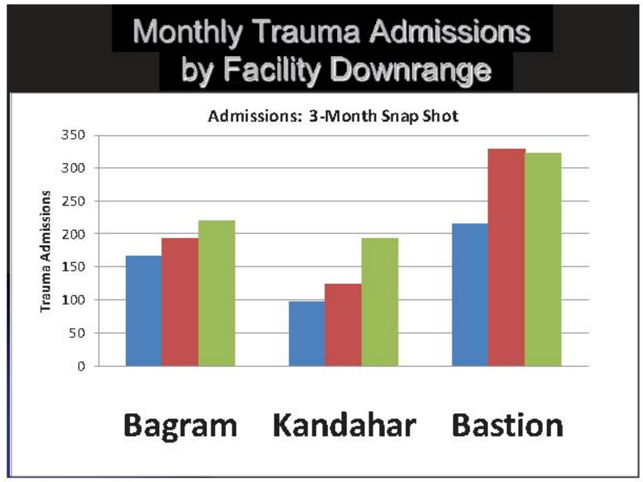
- 'Events' may be system or process related
- Defined across the continuum
  - Lack of documentation/films not available
  - Compartment release not adequate
  - C-spine not evaluated
  - Post splenectomy immunizations not given
  - Variance from JTTS practice guidelines
  - Missed injuries/delay in diagnosis
  - Burn flow sheet not utilized
  - Trauma team not activated from flight

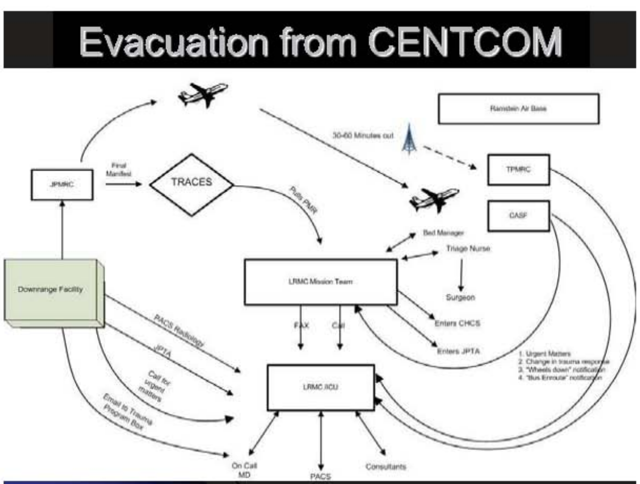
Complications

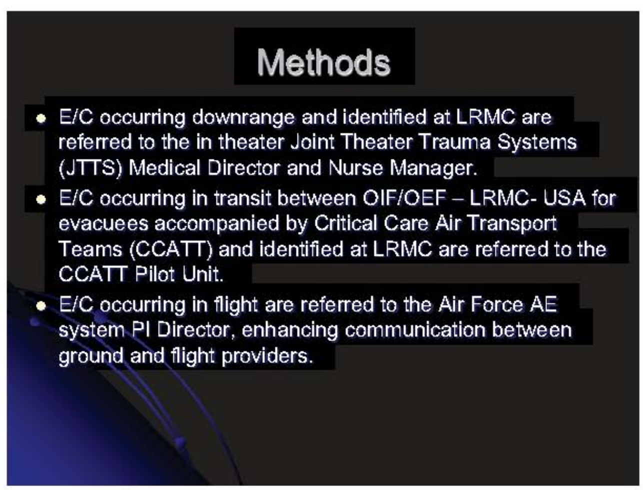
- Complications are patient specific
- Defined across the continuum
  - DVT
  - PE
  - Coagulopathy
  - Aspiration pneumonia
  - Sepsis
  - Coagulopathy
  - VAP vs CrAP
  - Wound infections

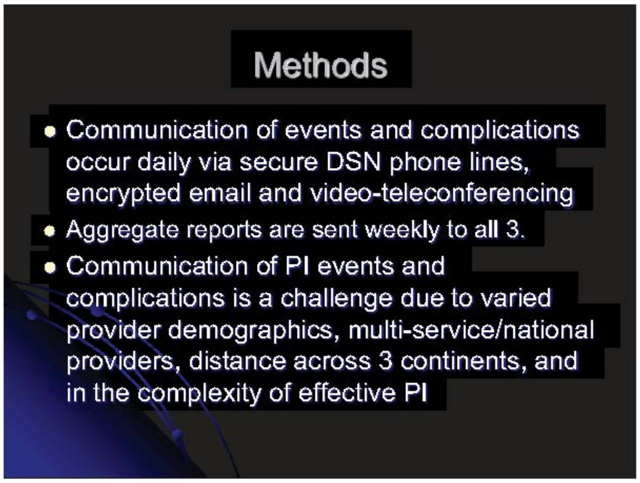


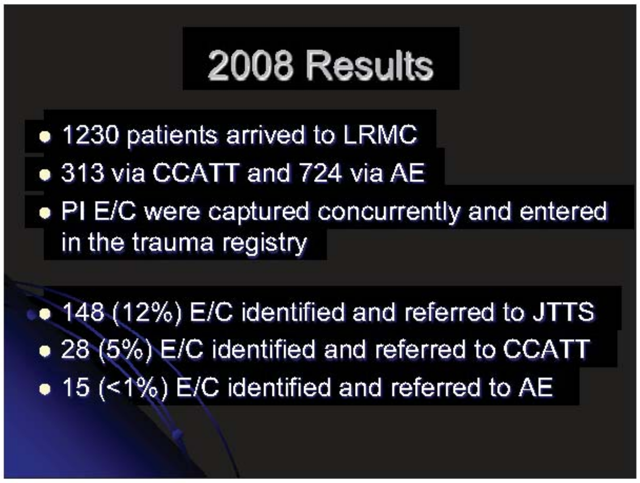

Joint Theater Trauma System
Performance Improvement
Practice Guidelines, Consistent Documentation Tools
Assessment, Communication and Data Collection/Analysis
Monitor, Educate and Improve Outcomes
Echelon IIb
Injury Salvage Surgery 1st hour
Echelon III
2nd Salvage Surgery or Definitive surgery
Echelon IV
Landstuhl, Germany
Definitive Surgery & Optimize for evacuation
Echelon V
USA – Definitive Care
Average 4 days for wounds, can be only 24 to 36 hours

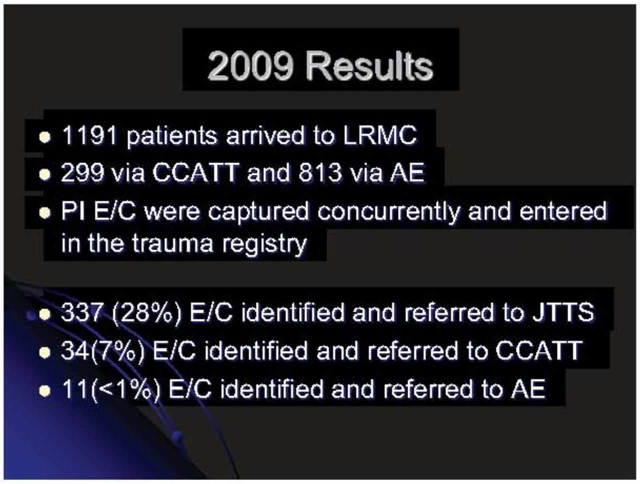

Monthly Trauma Admissions by Facility Downrange
Admissions: 3-Month Snap Shot
Trauma Admissions
350
300
250
200
150
100
50
0
Bagram
Kandahar
Bastion

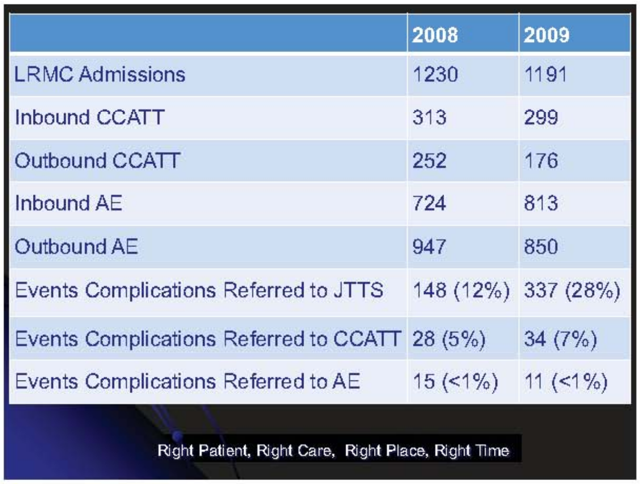

Evacuation from CENTCOM
Ramstein Air Base
30-60 Minutes out
JPMRC
Final Manifest
TRACES
Pulls PMR
TPMRC
CASF
Bed Manager
Triage Nurse
Surgeon
Downrange Facility
LRMC Mission Team
FAX
Call
Enters CHCS
Enters JPTA
PACS Radiology
JPTA
Call for urgent matters
Email to Trauma Program Box
LRMC ICU
On Call MD
PACS
Consultants
1. Urgent Matters
2. Change in trauma response
3. "Wheels down" notification
4. "Bus Enroute" notification


Methods
E/C occurring downrange and identified at LRMC are referred to the in theater Joint Theater Trauma Systems (JTTS) Medical Director and Nurse Manager.
E/C occurring in transit between OIF/OEF – LRMC- USA for evacuees accompanied by Critical Care Air Transport Teams (CCATT) and identified at LRMC are referred to the CCATT Pilot Unit.
E/C occurring in flight are referred to the Air Force AE system PI Director, enhancing communication between ground and flight providers.

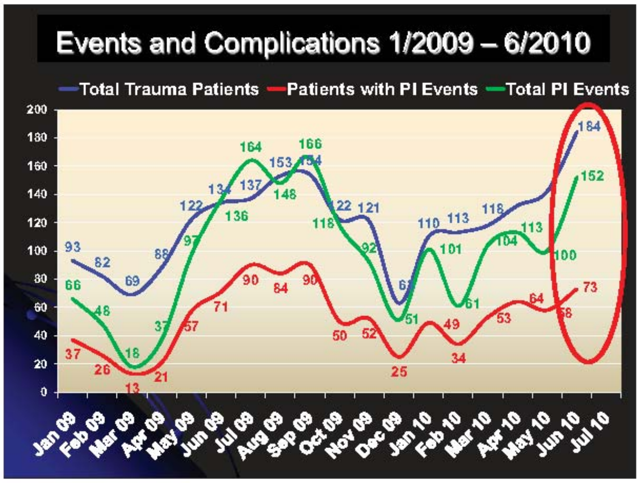


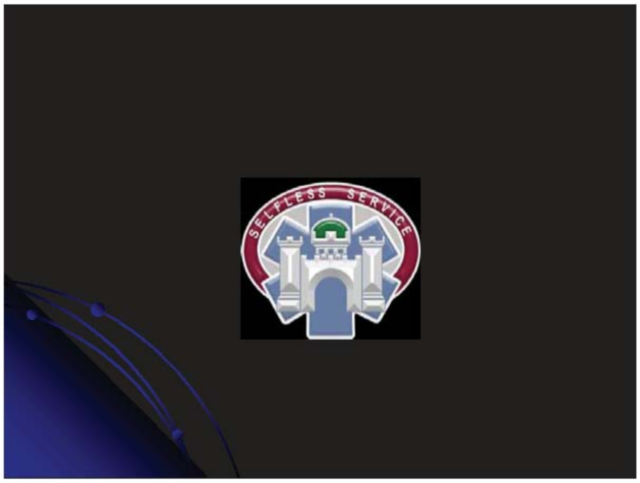


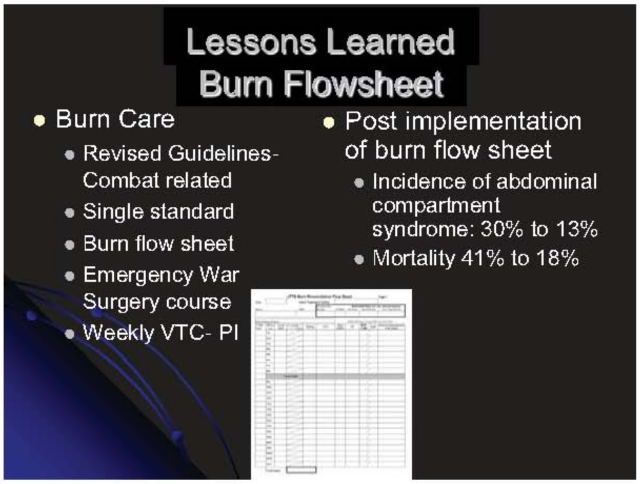




	2008	2009
LRMC Admissions	1230	1191
Inbound CCATT	313	299
Outbound CCATT	252	176
Inbound AE	724	813
Outbound AE	947	850
Events Complications Referred to JTTS	148 (12%)	337 (28%)
Events Complications Referred to CCATT	28 (5%)	34 (7%)
Events Complications Referred to AE	15 (<1%)	11 (<1%)


Events and Complications 1/2009 – 6/2010
Total Trauma Patients
Patients with PI Events
Total PI Events
200
180
160
140
120
100
80
60
40
20
0
Jan 09
Feb 09
Mar 09
Apr 09
May 09
Jun 09
Jul 09
Aug 09
Sep 09
Oct 09
Nov 09
Dec 09
Jan 10
Feb 10
Mar 10
Apr 10
May 10
Jun 10
Jul 10


SELFLESS SERVICE


Lessons Learned
Burn Flowsheet
Burn Care
Revised Guidelines- Combat related
Single standard
Burn flow sheet
Emergency War Surgery course
Weekly VTC- PI
Post implementation of burn flow sheet
Incidence of abdominal compartment syndrome: 30% to 13%
Mortality 41% to 18%


Lessons Learned
mild Traumatic Brain Injury
Traumatic Brain Injury
Outpatient Screening
Inpatient Screening
Global Algorithm
100% Capture
Initial screen
Military Assessment of Concussion Evaluation score (MACE)
Neurology evaluation
Exertion testing if asymptomatic at rest
Referral to TBI sites in United States
LRMC Traumatic Brain Injury Program
Inpatient Screening Questionnaire


Lessons Learned
Critical Care Air Transport Teams


Military Trauma System
Communication for Optimal Outcomes
Trend
Education
Guideline/Protocol
Refer Up the Chain
of Command
Doctrine
Joint Trauma
System
Development
Integrated
Communication
Network
Ongoing
Education
Training &
Knowledge
Process
Development
Evidence
Based
Practice
Concurrent
Issue
Identification
Concurrent
Feedback
Across
Echelons
COMBAT
CASUAL TY CARE
COMMUNICATION
CONTINUUM

Local Hemostatic Agents in a Survival Model of a Lethal Porcine Liver Injury

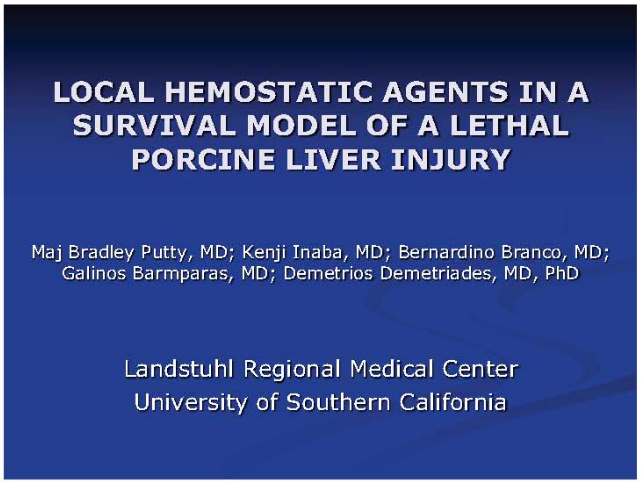
86th MDS

Maj/Dr. Bradley Putty

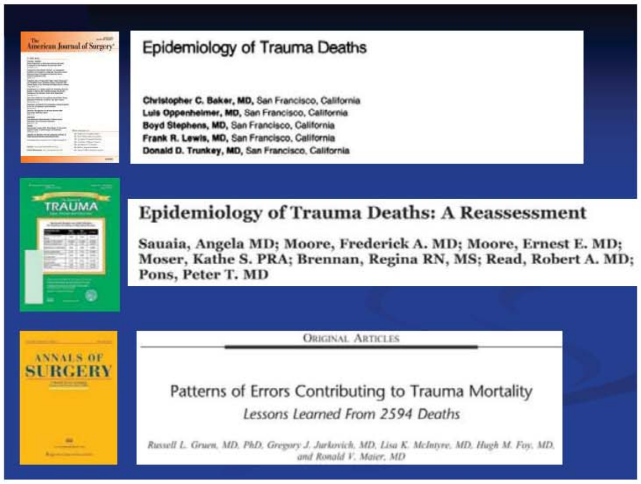
Rapid control of bleeding presents a major challenge in the severely injured trauma patient who may present with hypothermia and coagulopathy. Uncontrolled bleeding is the leading cause of combat-related death. The liver is the most commonly injured solid organ, and high grade injuries are difficult to treat. When the bleeding is resistant to standard techniques of control, the surgeon may be aided by the use of advanced topical hemostatic agents. The long term efficacy and safety of using such materials on the liver is unknown.

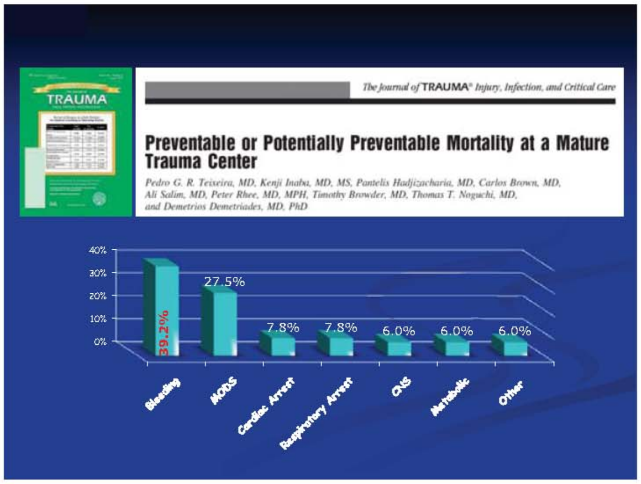
A survival model of a lethal liver injury in swine was employed to test commercially available advanced hemostatic agents against standard gauze dressing to determine if their use results in a durable decrease in blood loss and mortality. Following induction of hypothermia and a controlled 35% hemorrhage, the animals received a standardized grade IV liver injury. They were randomized to receive packing with plain gauze either alone or with a hemostatic agent (Celox(tm), Celox(tm) Gauze, or QuikClot® COMBAT GAUZE(tm)-the only topical hemostatic currently approved in-theater), with blood loss measured after 15 minutes and 2 days at repeat operation. Observation continued for two weeks before sacrifice with histologic evaluation for delayed effects on the liver and other major organs.

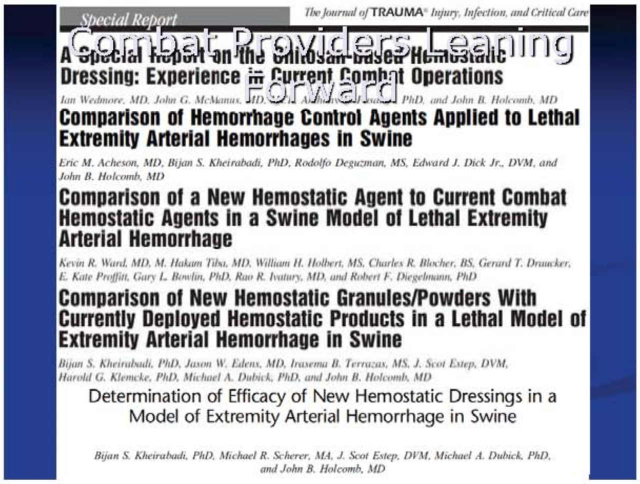
Of the agents tested, Celox(tm) and Celox(tm) Gauze were associated with the greatest 48 hour and 2 week survival, while Combat Gauze(tm) was associated with the highest mortality at 48 hours and 2 days. Celox(tm) appears to be associated with adhesion formation.


LOCAL HEMOSTATIC AGENTS IN A SURVIVAL MODEL OF A LETHAL PORCINE LIVER INJURY
Maj Bradley Putty, MD; Kenji Inaba, MD; Bernardino Branco, MD; Galinos Barmparas, MD; Demetrios Demetriades, MD, PhD
Landstuhl Regional Medical Center
University of Southern California


Uncontrolled Bleeding is a Major Cause of Preventable Death


The American Journal of Surgery
Epidemiology of Trauma Deaths
Christopher C. Baker, MD, San Francisco, California
Luis Oppenheimer, MD, San Francisco, California
Boyd Stephens, MD, San Francisco, California
Frank R. Lewis, MD, San Francisco, California
Donald D. Trunkey, MD, San Francisco, California
TRAUMA
Epidemiology of Trauma Deaths: A Reassessment
Sauaia, Angela MD; Moore, Frederick A. MD; Moore, Ernest E. MD; Moser, Kathe S. PRA; Brennan, Regina RN, MS; Read, Robert A. MD; Pons, Peter T. MD
ANNALS OF SURGERY
ORIGINAL ARTICLES
Patterns of Errors Contributing to Trauma Mortality
Lessons Learned From 2594 Deaths
Russell L. Gruen, MD, PhD, Gregory J. Jurkovich, MD, Lisa K. McIntyre, MD, Hugh M. Foy, MD, and Ronald V. Maier, MD


TRAUMA
The Journal of TRAUMA Injury, Infection, and Critical Care
Preventable or Potentially Preventable Mortality at a Mature Trauma Center
Pedro G. R. Teixeira, MD, Kenji Inaba, MD, MS, Pantelis Hadjizacharia, MD, Carlos Brown, MD, Ali Salim, MD, Peter Rhee, MD, MPH, Timothy Browder, MD, Thomas T. Noguchi, MD, and Demetrios Demetriades, MD, PhD
40%
30%
20%
10%
0%
39.2%
27.5%
7.8%
7.8%
6.0%
6.0%
6.0%
Bleeding
MODS
Cardiac Arrest
Respiratory Arrest
CNS
Metabolic
Other



Special Report

The Journal of TRAUMA® Injury, Infection, and Critical Care

A Special Report on the Chitosan-based Hemostatic Dressing: Experience in Current Combat Operations

Ian Wedmore, MD, John G. McManus, MD, ... PhD, and John B. Holcomb, MD

Comparison of Hemorrhage Control Agents Applied to Lethal Extremity Arterial Hemorrhages in Swine

Eric M. Acheson, MD, Bijan S. Kheirabadi, PhD, Rodolfo Deguzman, MS, Edward J. Dick Jr., DVM, and John B. Holcomb, MD

Comparison of a New Hemostatic Agent to Current Combat Hemostatic Agents in a Swine Model of Lethal Extremity Arterial Hemorrhage

Kevin R. Ward, MD, M. Hakam Tiba, MD, William H. Holbert, MS, Charles R. Blocher, BS, Gerard T. Draucker, E. Kate Proffitt, Gary L. Bowlin, PhD, Rao R. Ivatury, MD, and Robert F. Diegelmann, PhD

Comparison of New Hemostatic Granules/Powders With Currently Deployed Hemostatic Products in a Lethal Model of Extremity Arterial Hemorrhage in Swine

Bijan S. Kheirabadi, PhD, Jason W. Edens, MD, Irasema B. Terrazas, MS, J. Scot Estep, DVM, Harold G. Klemcke, PhD, Michael A. Dubick, PhD, and John B. Holcomb, MD

Determination of Efficacy of New Hemostatic Dressings in a Model of Extremity Arterial Hemorrhage in Swine

Bijan S. Kheirabadi, PhD, Michael R. Scherer, MA, J. Scot Estep, DVM, Michael A. Dubick, PhD, and John B. Holcomb, MD

Application of a Granular Mineral-Based Hemostatic Agent (QuikClot) to Reduce Blood Loss After Grade V Liver Injury in Swine

Anthony E. Pusateri, PhD, Angel V. Delgado, MS, Edward J. Dick, Jr, DVM, Raul S. Martinez, John B. Holcomb, MD, and Kathy L. Ryan, PhD

The Journal of TRAUMA® Injury, Infection, and Critical Care

Advanced Hemostatic Dressing Development Program: Animal Model Selection Criteria and Results of a Study of Nine Hemostatic Dressings in a Model of Severe Large Venous Hemorrhage and Hepatic Injury in Swine

Anthony E. Pusateri, PhD, Harold E. Modrow, PhD, Richard A. Harris, DVM, MS, John B. Holcomb, MD, John R. Hess, MD, MPH, Robert H. Mosebar, MD, Thomas J. Reid, MD, PhD, James H. Nelson, PhD, Cleon W. Goodwin, Jr., MD, Glenn M. Fitzpatrick, PhD, Albert T. McManus, PhD, David T. Zolock, PhD, Jill L. Sondeen, PhD, Rhonda L. Cornum, PhD, MD, and Raul S. Martinez, BS

Effect of a Chitosan-Based Hemostatic Dressing on Blood Loss and Survival in a Model of Severe Venous Hemorrhage and Hepatic Injury in Swine

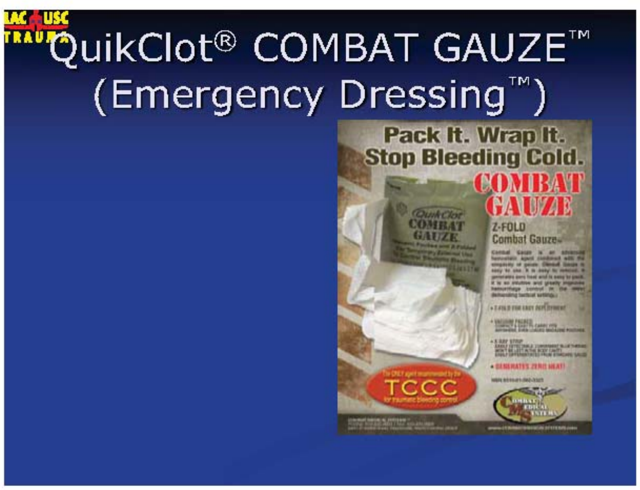
Anthony E. Pusateri, PhD, Simon J. McCarthy, PhD, Kenton W. Gregory, MD, Richard A. Harris, DVM, MS, Luis Cardenas, Albert T. McManus, PhD, and Cleon W. Goodwin, Jr., MD

Background: Hemorrhage is a leading cause of death from trauma. An advanced hemostatic dressing could aug- stasis, resuscitation volume, and 60-minute survival were quantified.

Results: Posttreatment blood loss and two of even in the chitosan and gauze groups (p = 0.04), respectively. Hemostasis was improved in the chitosan group (p

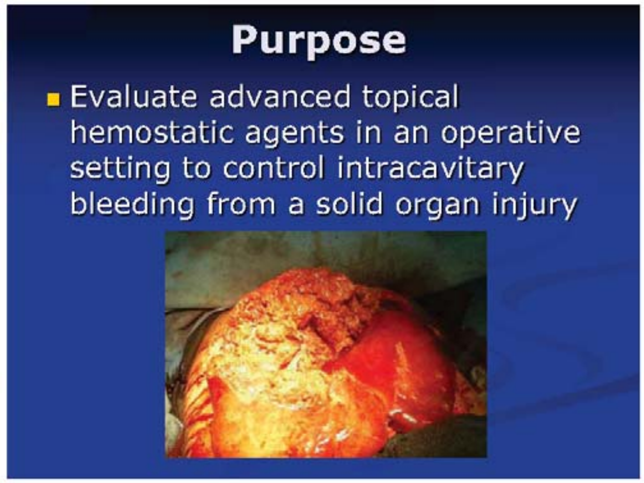

Celox™ Gauze
CELOX GAUZE

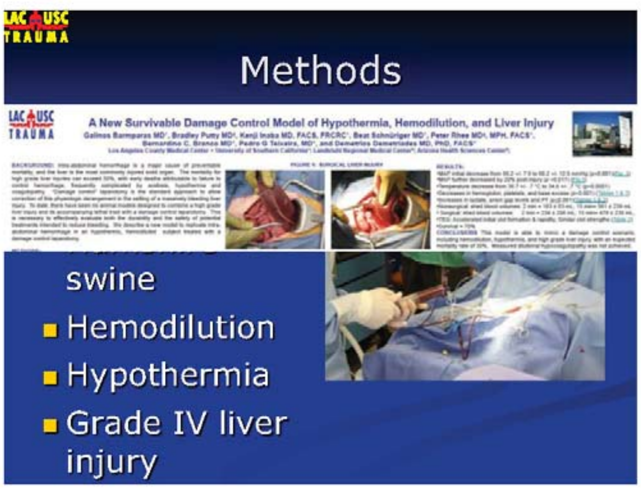

QuikClot® COMBAT GAUZE™
(Emergency Dressing™)
Pack It. Wrap It.
Stop Bleeding Cold.
COMBAT GAUZE
Z-FOLD
Combat Gauze
TCCC


QuikClot® COMBAT GAUZE™
(Emergency Dressing™)
Pack It. Wrap It.
Stop Bleeding Cold.
COMBAT GAUZE
Z-FOLD
Combat Gauze
TCCC

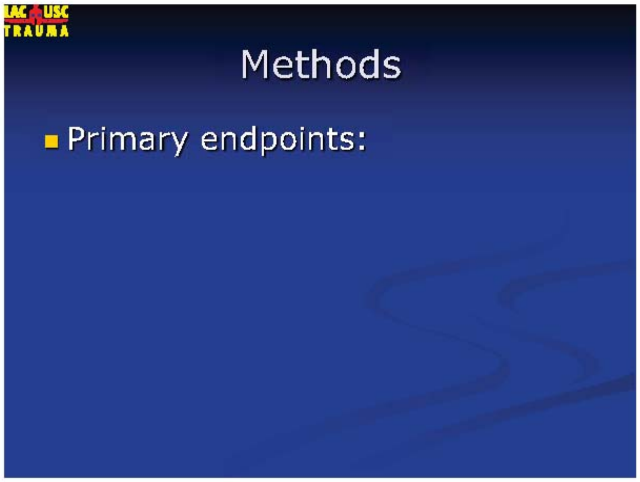

QuikClot® COMBAT GAUZE™
(Emergency Dressing™)
The ONLY agent recommended by the
TCCC
for traumatic bleeding control.

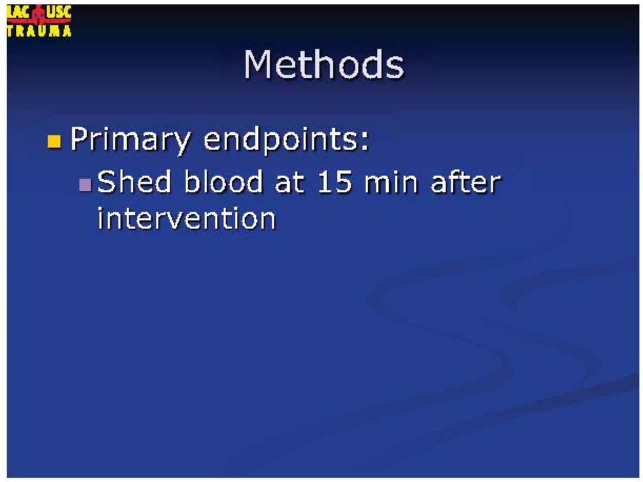

LAC USC TRAUMA
QuikClot® COMBAT GAUZE™ /Emergency Dressing™
QuikClot COMBAT GAUZE
QuikClot Emergency Dressing

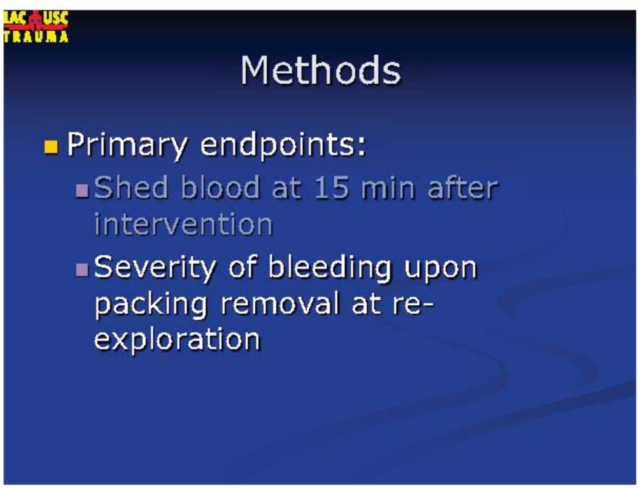

Purpose
Evaluate advanced topical hemostatic agents in an operative setting to control intracavitary bleeding from a solid organ injury

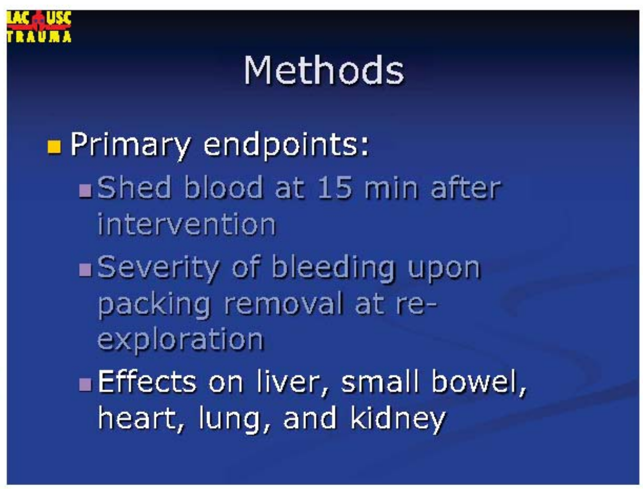

LAC USC TRAUMA
Methods
A New Survivable Damage Control Model of Hypothermia, Hemodilution, and Liver Injury
swine
Hemodilution
Hypothermia
Grade IV liver injury

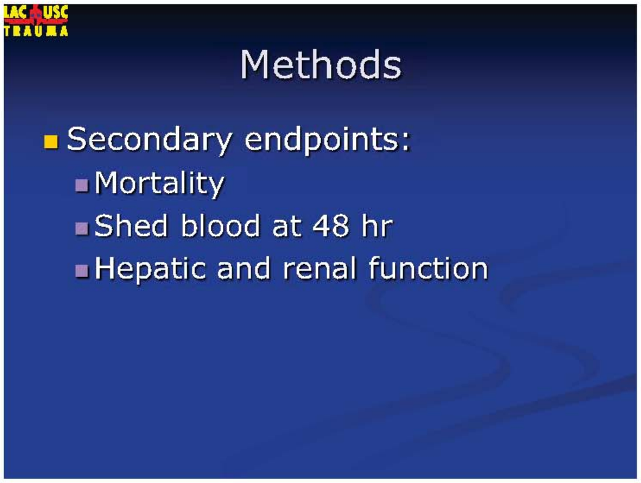

LAC USC TRAUMA
Four Arms
Plain gauze
Celox™
Celox™ Gauze
QuikClot® Combat Gauze™
Gauze Sponges
Gauze Sponges

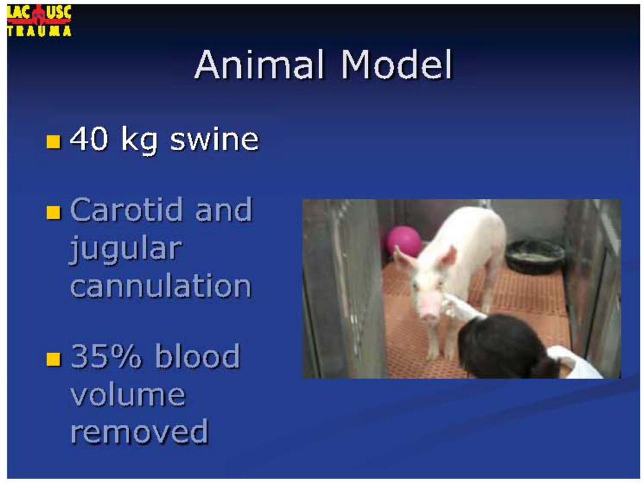

LAC USC TRAUMA
Methods
Primary endpoints:

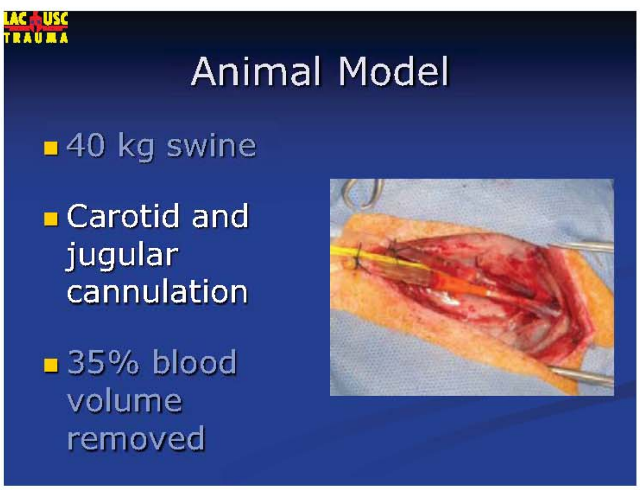

LAC USC TRAUMA
Methods
Primary endpoints:
Shed blood at 15 min after intervention

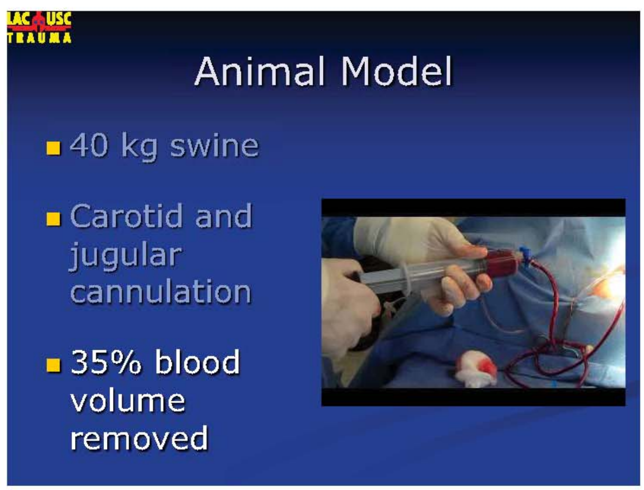

LAC USC TRAUMA
Methods
Primary endpoints:
Shed blood at 15 min after intervention
Severity of bleeding upon packing removal at re-exploration

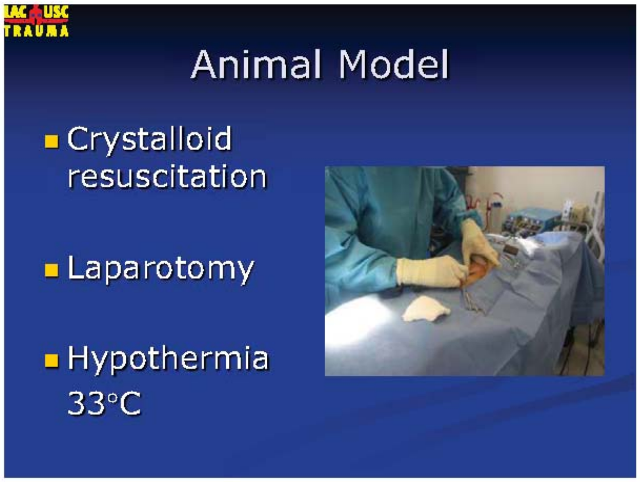

LAC USC TRAUMA
Methods
Primary endpoints:
Shed blood at 15 min after intervention
Severity of bleeding upon packing removal at re-exploration
Effects on liver, small bowel, heart, lung, and kidney

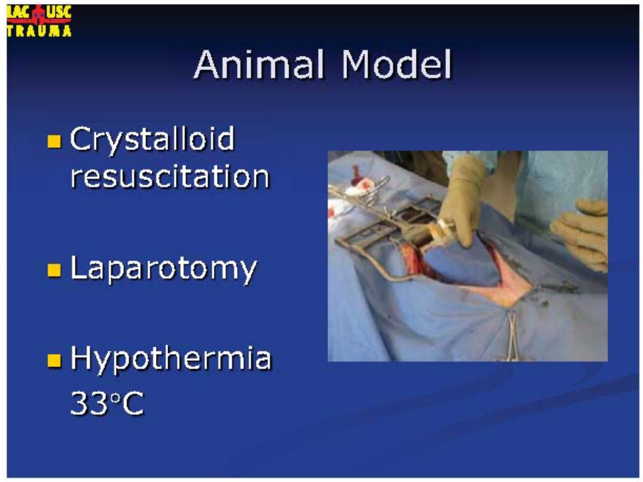

LAC USC TRAUMA
Methods
Secondary endpoints:
Mortality
Shed blood at 48 hr
Hepatic and renal function

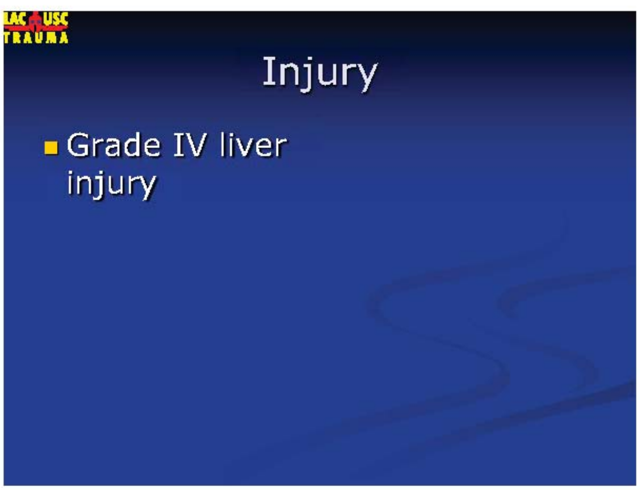

LAC USC TRAUMA
Animal Model
40 kg swine
Carotid and jugular cannulation
35% blood volume removed

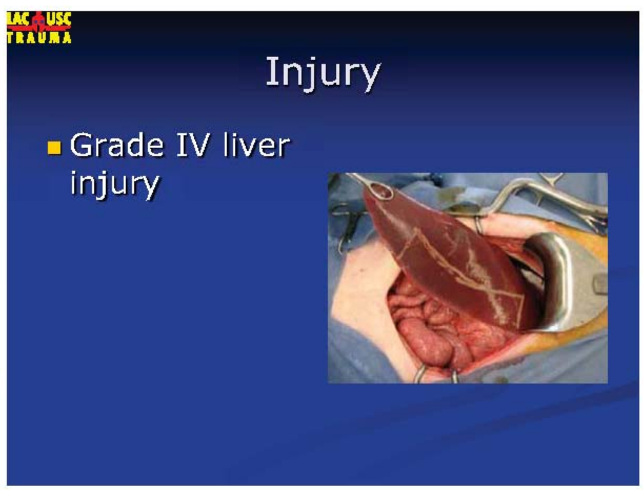

LAC USC TRAUMA
Animal Model
40 kg swine
Carotid and jugular cannulation
35% blood volume removed


LAC USC TRAUMA
Animal Model
40 kg swine
Carotid and jugular cannulation
35% blood volume removed


LAC USC TRAUMA
Animal Model
Crystalloid resuscitation
Laparotomy
Hypothermia 33°C

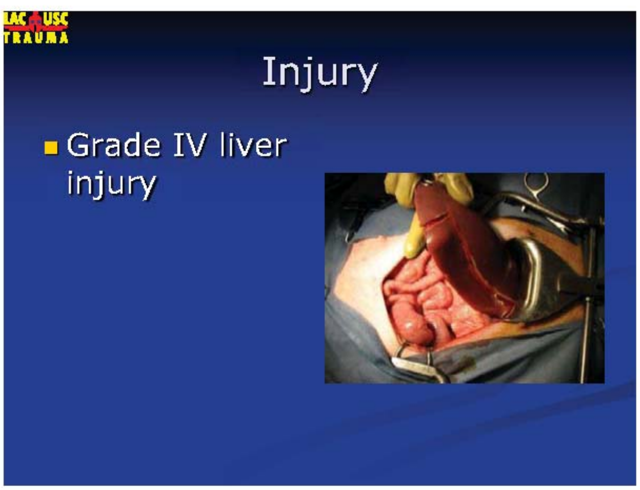

LAC USC TRAUMA
Animal Model
Crystalloid resuscitation
Laparotomy
Hypothermia 33°C

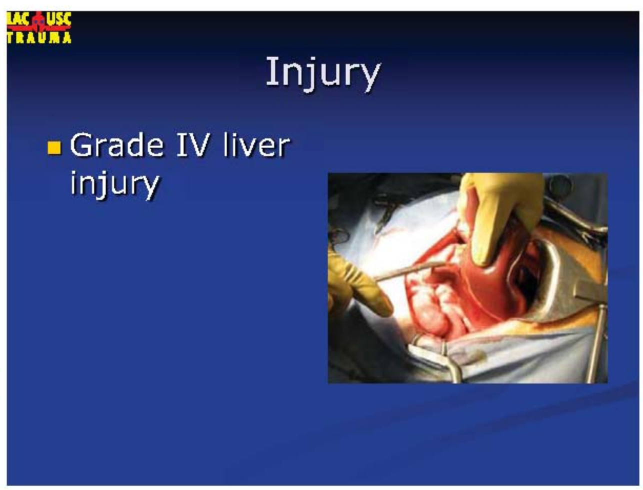

LAC USC TRAUMA
Injury
Grade IV liver injury

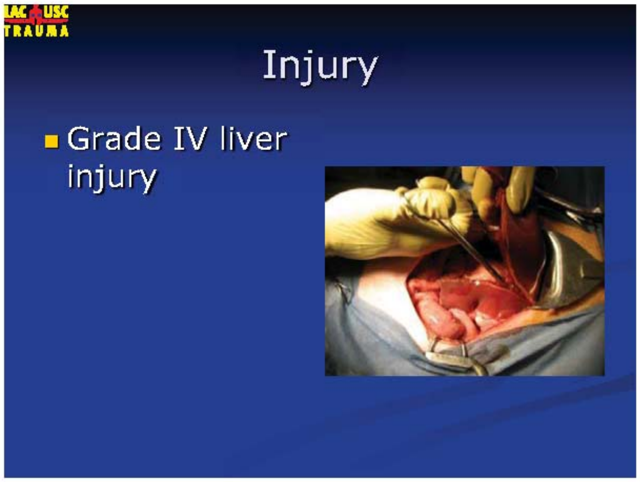

LAC USC TRAUMA
Injury
Grade IV liver injury

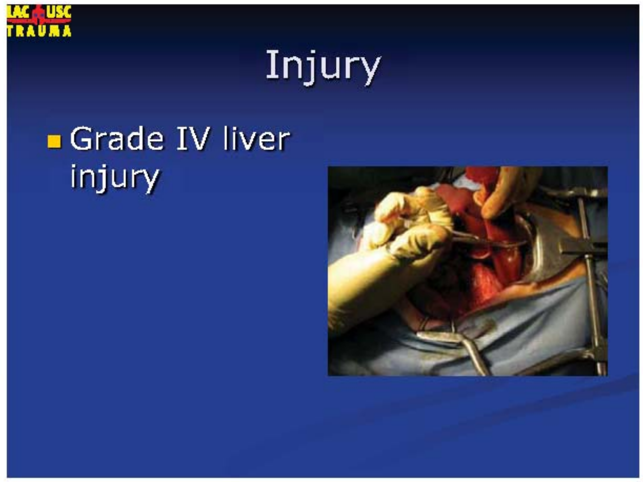

Injury
Grade IV liver injury


Injury
Grade IV liver injury


Injury
Grade IV liver injury


Injury
Grade IV liver injury


Injury
Grade IV liver injury


Injury
Grade IV liver injury


Quantitative blood loss 2 min


Injury
Grade IV liver injury
Quantitative blood loss at 2 min
Randomization

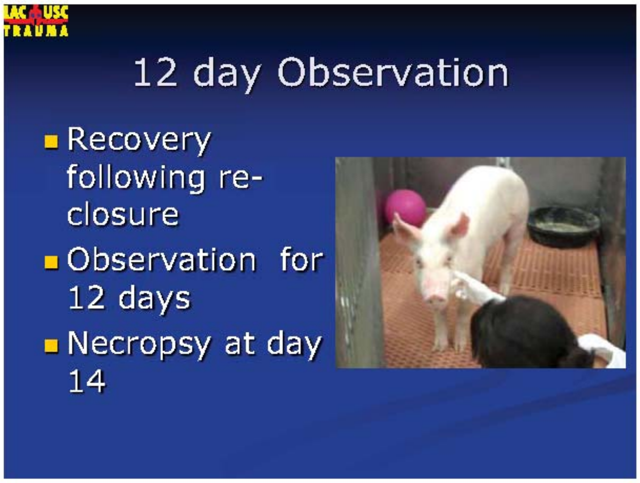

Treatment & "Damage Control"
Hemostatic packing for 15 min

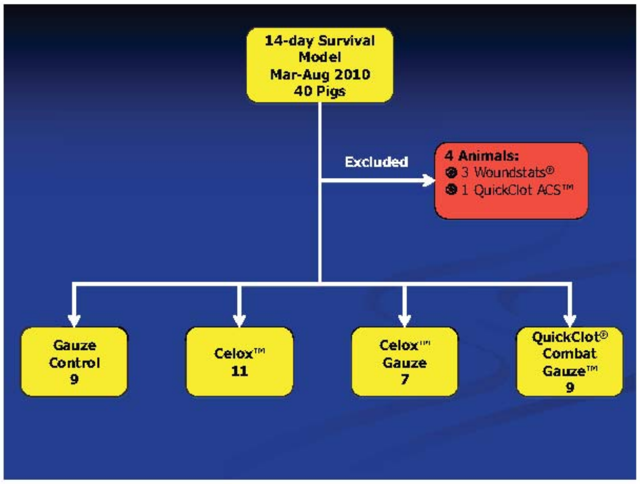

Treatment & "Damage Control"
Hemostatic packing for 15 min

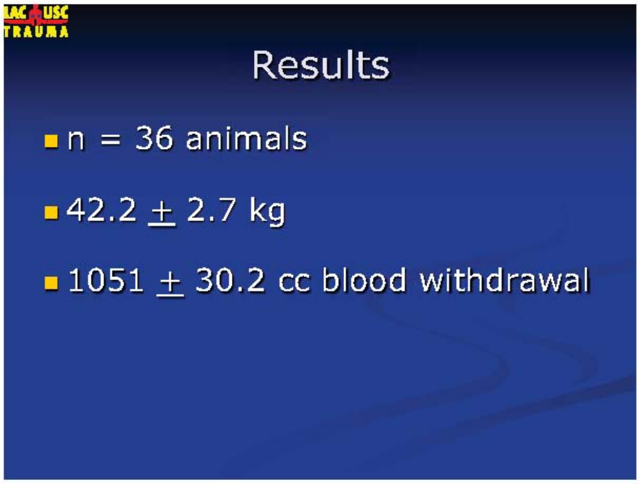

Treatment & "Damage Control"
Hemostatic packing for 15 min
Removal, Repacking & closure

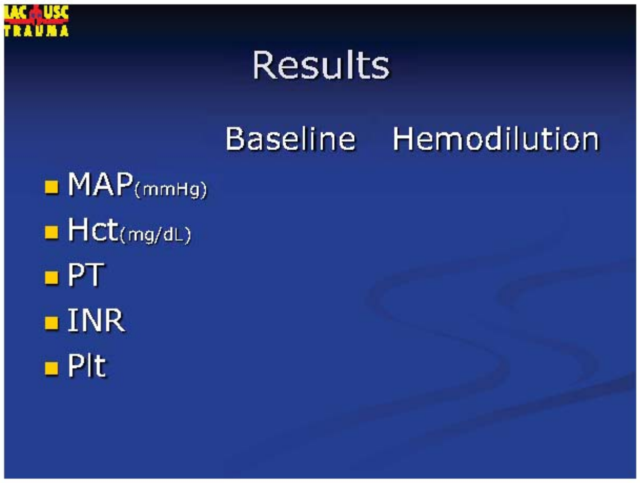

Treatment & "Damage Control"
Hemostatic packing for 15 min
Removal, Repacking & closure
Takeback at 48 hr

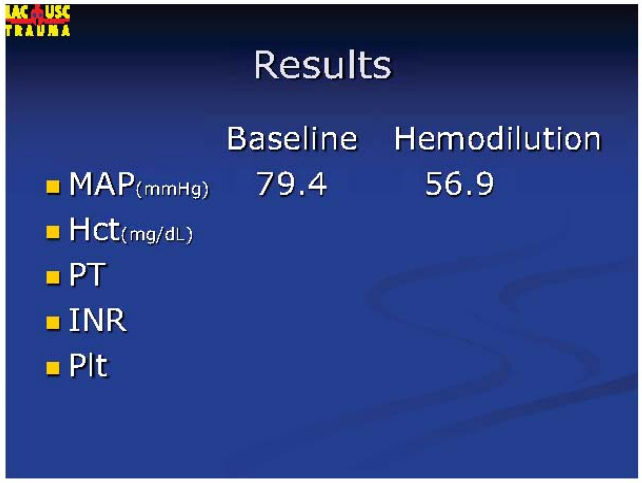

LAC USC TRAUMA
Treatment & "Damage Control"
Hemostatic packing for 15 min
Removal, Repacking & closure
Takeback at 48 hr
Definitive hemostasis and closure

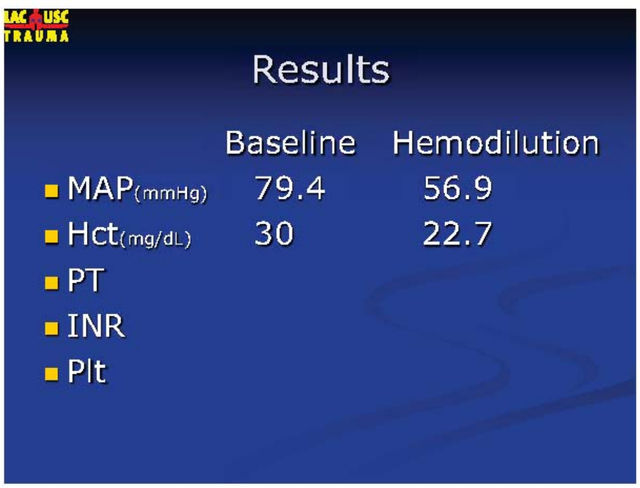

LAC USC TRAUMA
12 day Observation
Recovery following re-closure
Observation for 12 days
Necropsy at day 14

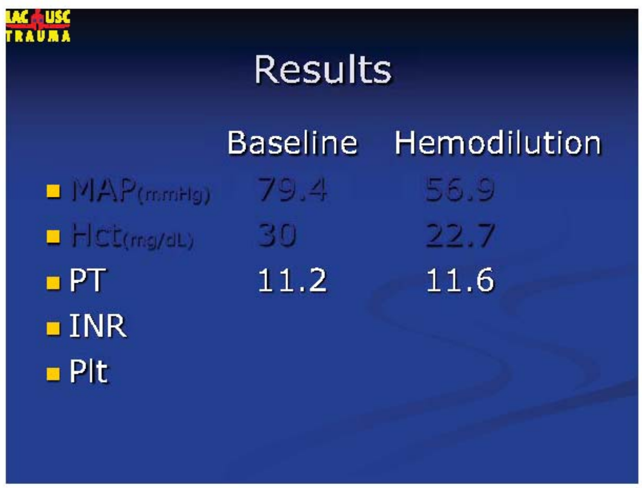

14-day Survival Model
Mar-Aug 2010
40 Pigs
Excluded
4 Animals:
3 Woundstats®
1 QuickClot ACS™
Gauze Control 9
Celox™ 11
Celox™ Gauze 7
QuickClot® Combat Gauze™ 9

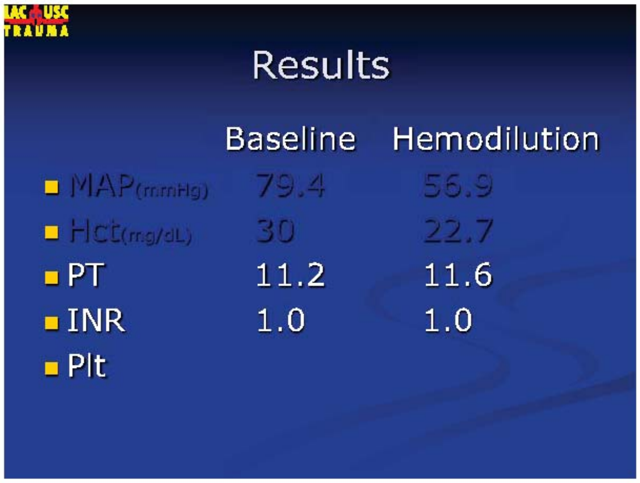

LAC USC TRAUMA
Results
n = 36 animals
42.2 ± 2.7 kg
1051 ± 30.2 cc blood withdrawal

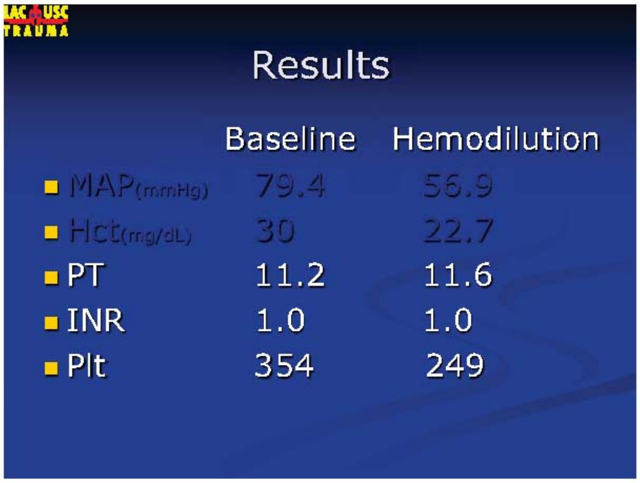

Results
Baseline Hemodilution
MAP(mmHg)
Hct(mg/dL)
PT
INR
Plt

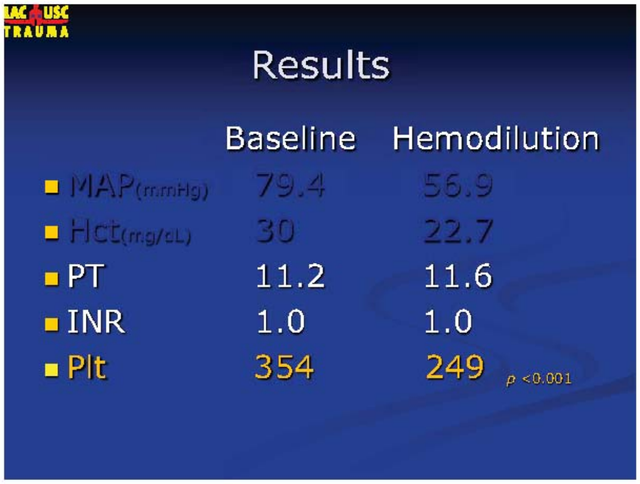

Results
Baseline Hemodilution
MAP(mmHg) 79.4 56.9
Hct(mg/dL)
PT
INR
Plt

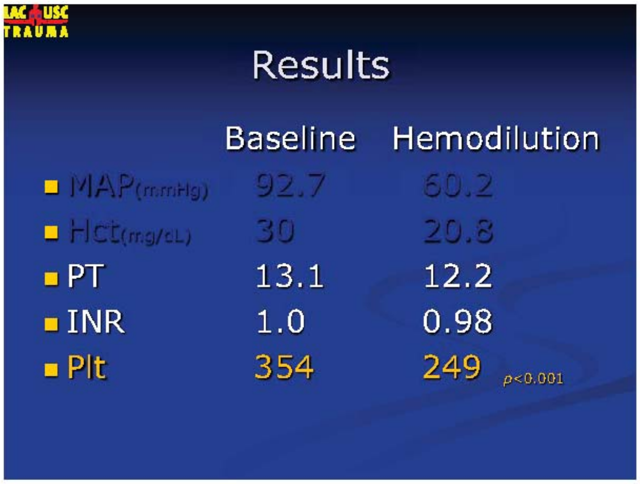

Results
Baseline Hemodilution
MAP(mmHg) 79.4 56.9
Hct(mg/dL) 30 22.7
PT
INR
Plt

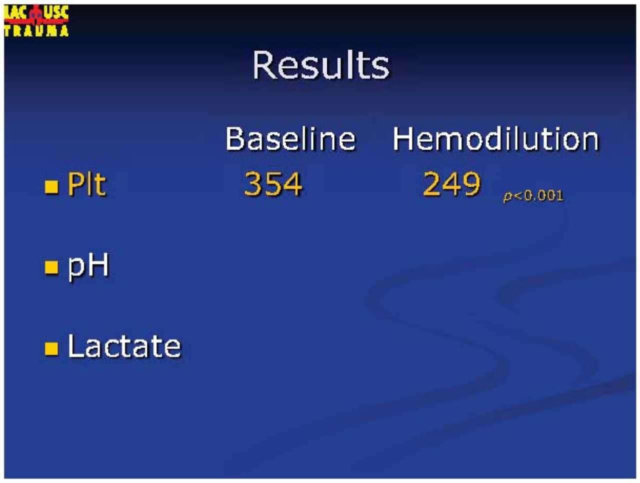

Results
Baseline Hemodilution
MAP(mmHg) 79.4 56.9
Hct(mg/dL) 30 22.7
PT 11.2 11.6
INR
Plt

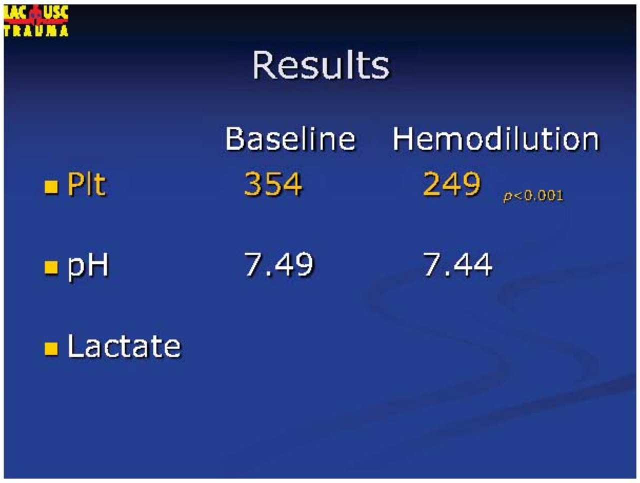

Results
Baseline Hemodilution
MAP(mmHg) 79.4 56.9
Hct(mg/dL) 30 22.7
PT 11.2 11.6
INR 1.0 1.0
Plt

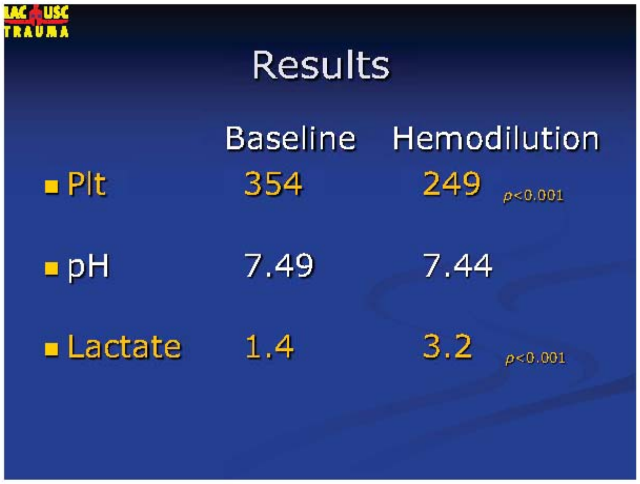

Results
Baseline Hemodilution
MAP(mmHg) 79.4 56.9
Hct(mg/dL) 30 22.7
PT 11.2 11.6
INR 1.0 1.0
Plt 354 249

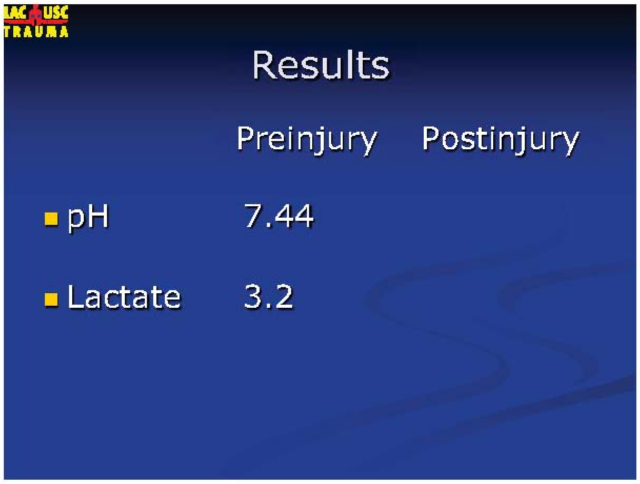

Results
Baseline Hemodilution
MAP(mmHg) 79.4 56.9
Hct(mg/dL) 30 22.7
PT 11.2 11.6
INR 1.0 1.0
Plt 354 249 p <0.001

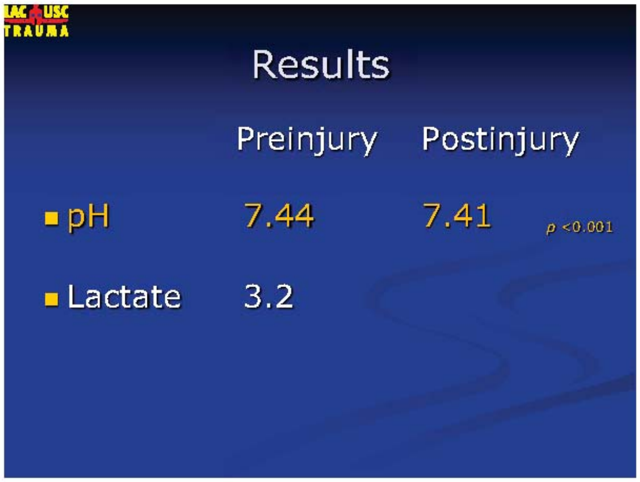

Results
Baseline Hemodilution
MAP(mmHg) 92.7 60.2
Hct(mg/dL) 30 20.8
PT 13.1 12.2
INR 1.0 0.98
Plt 354 249 p<0.001

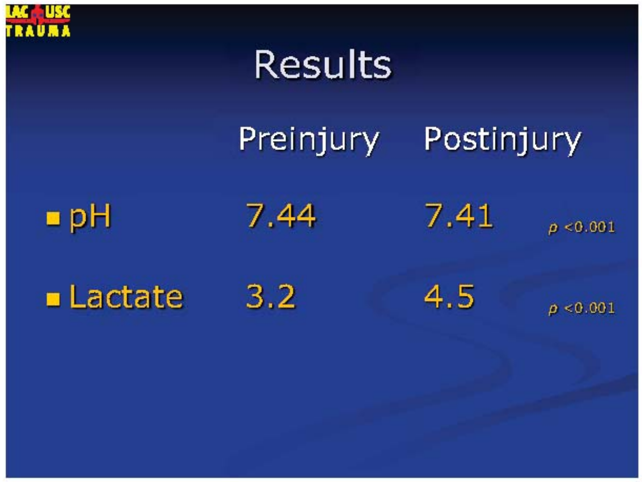

LAC USC TRAUMA
Results
Baseline
Hemodilution
Plt
354
249
p<0.001
pH
Lactate

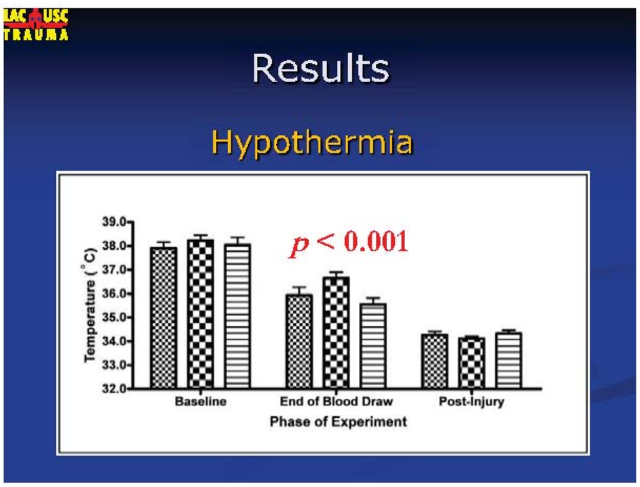

LAC USC TRAUMA
Results
Baseline
Hemodilution
Plt
354
249
p<0.001
pH
7.49
7.44
Lactate


LAC USC TRAUMA
Results
Baseline
Hemodilution
Plt
354
249
p<0.001
pH
7.49
7.44
Lactate
1.4
3.2
p<0.001

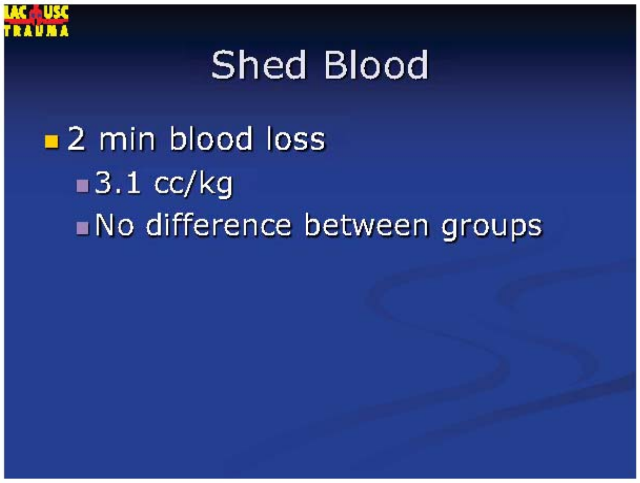

LAC USC TRAUMA
Results
Preinjury
Postinjury
pH
7.44
Lactate
3.2

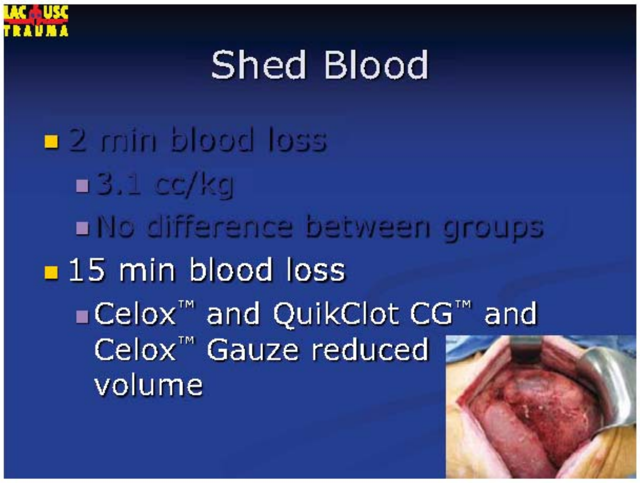

LAC USC TRAUMA
Results
Preinjury
Postinjury
pH
7.44
7.41
p <0.001
Lactate
3.2

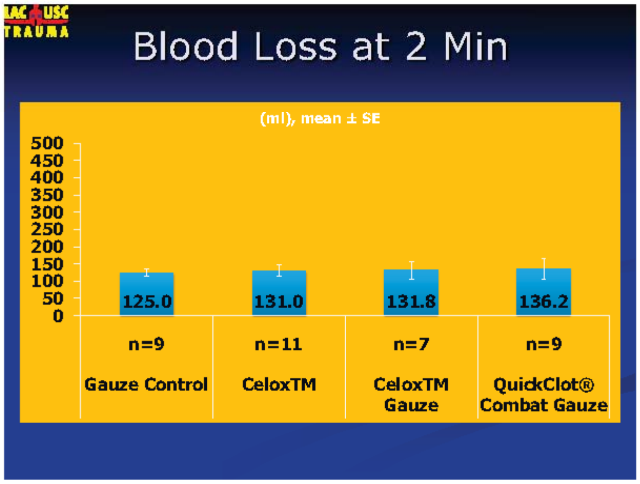

LAC USC TRAUMA
Results
Preinjury
Postinjury
pH
7.44
7.41
p <0.001
Lactate
3.2
4.5
p <0.001

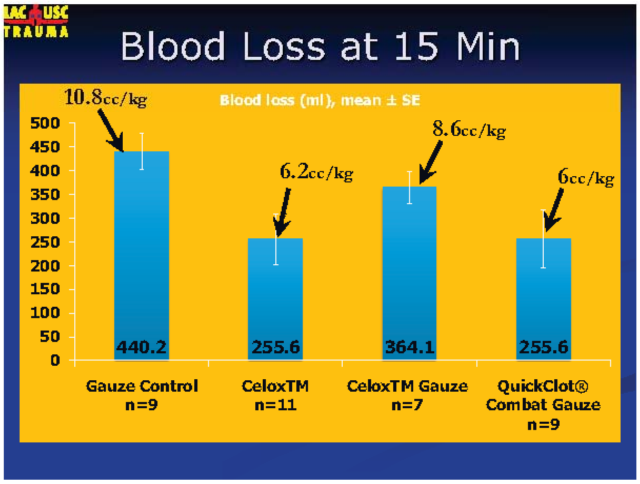

LAC USC TRAUMA
Results
Hypothermia
p < 0.001
Temperature (°C)
39.0
38.0
37.0
36.0
35.0
34.0
33.0
32.0
Baseline
End of Blood Draw
Post-Injury
Phase of Experiment

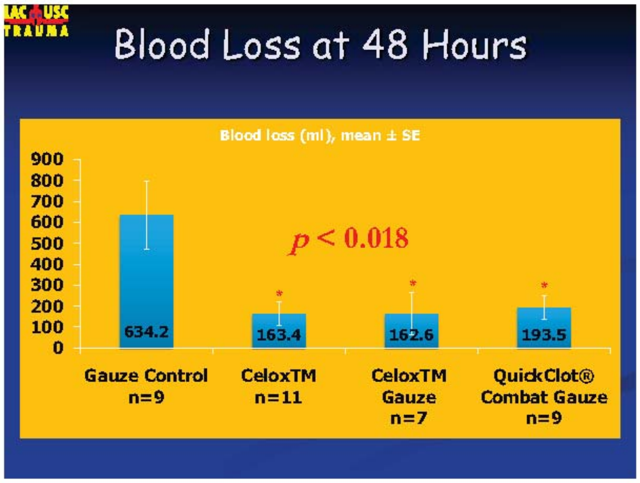

LAC USC TRAUMA
Shed Blood


LAC USC TRAUMA
Shed Blood
2 min blood loss
3.1 cc/kg
No difference between groups

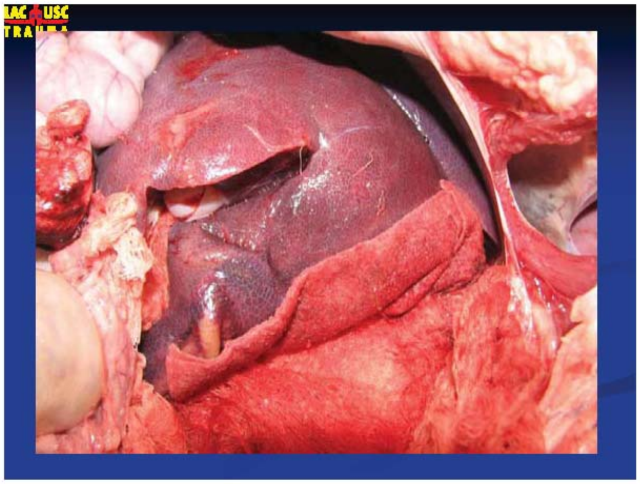

LAC USC TRAUMA
Shed Blood
2 min blood loss
3.1 cc/kg
No difference between groups
15 min blood loss
Celox™ and QuikClot CG™ and Celox™ Gauze reduced volume

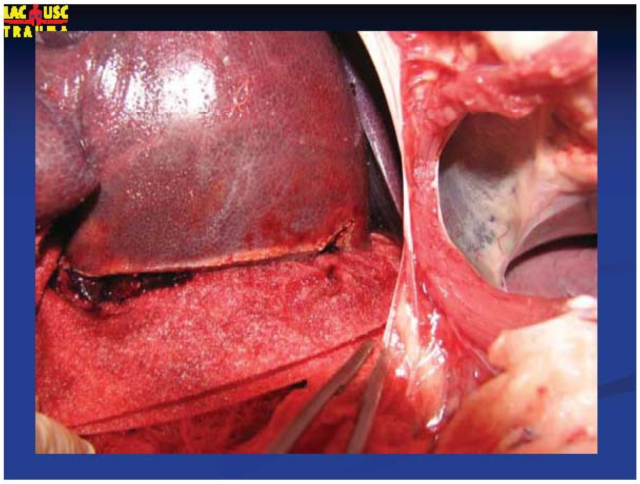

LAC USC TRAUMA
Blood Loss at 2 Min
(ml), mean ± SE
500
450
400
350
300
250
200
150
100
50
0
125.0
131.0
131.8
136.2
n=9
n=11
n=7
n=9
Gauze Control
CeloxTM
CeloxTM Gauze
QuickClot® Combat Gauze

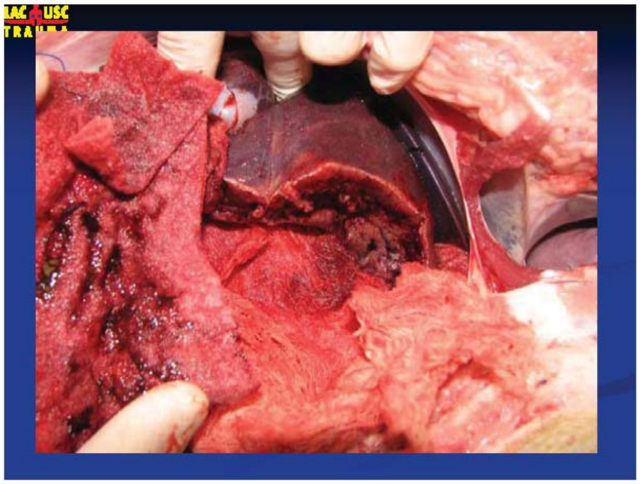

LAC USC TRAUMA
Blood Loss at 15 Min
Blood loss (ml), mean ± SE
10.8cc/kg
6.2cc/kg
8.6cc/kg
6cc/kg
500
450
400
350
300
250
200
150
100
50
0
440.2
255.6
364.1
255.6
Gauze Control n=9
CeloxTM n=11
CeloxTM Gauze n=7
QuickClot® Combat Gauze n=9

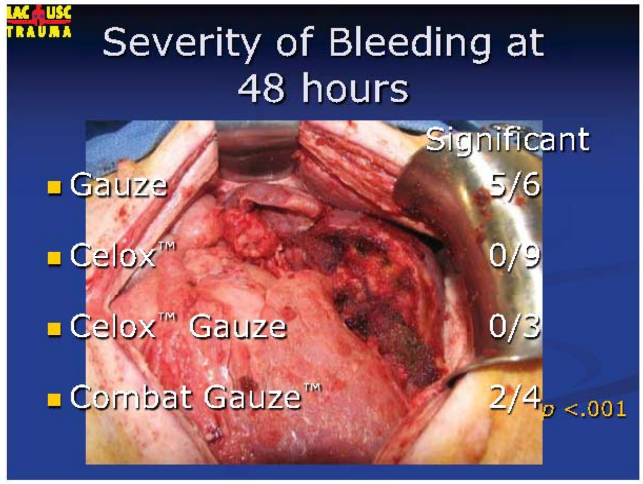

Blood Loss at 48 Hours
Blood loss (ml), mean ± SE
900
800
700
600
500
400
300
200
100
0
p < 0.018
634.2
163.4
162.6
193.5
Gauze Control n=9
CeloxTM n=11
CeloxTM Gauze n=7
QuickClot® Combat Gauze n=9


Severity of Bleeding at 48 hours

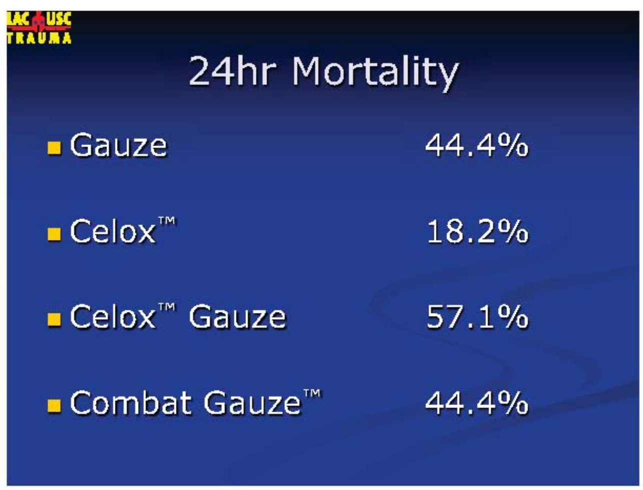


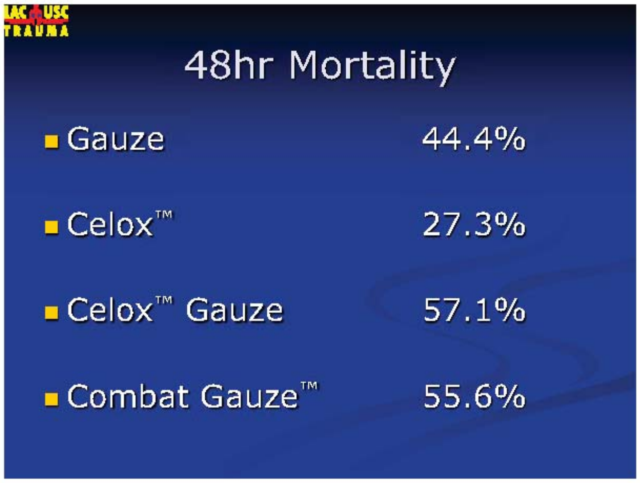




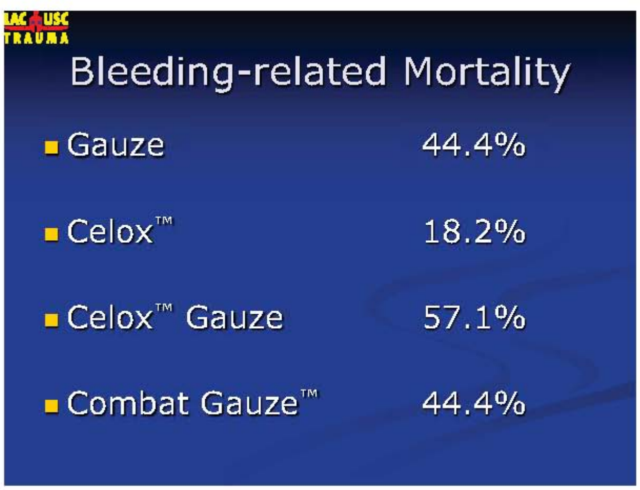

Severity of Bleeding at 48 hours
Significant
Gauze 5/6
Celox™ 0/9
Celox™ Gauze 0/3
Combat Gauze™ 2/4
p <.001


On-table Mortality
Gauze 22.2%
Celox™ 0%
Celox™ Gauze 28.6%
Combat Gauze™ 22.2%


24hr Mortality
Gauze 44.4%
Celox™ 18.2%
Celox™ Gauze 57.1%
Combat Gauze™ 44.4%

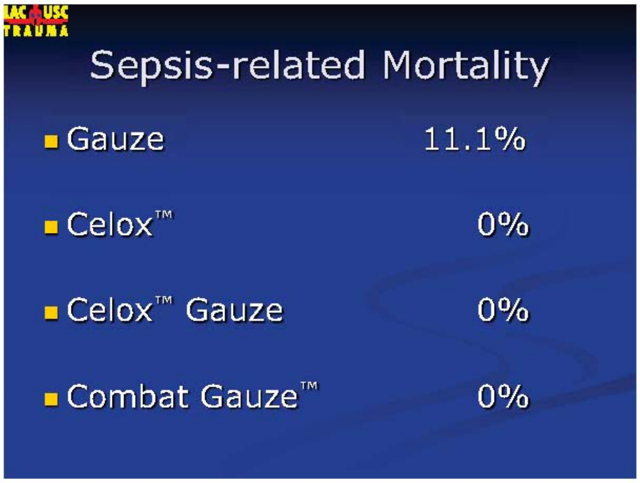

48hr Mortality
Gauze 44.4%
Celox™ 27.3%
Celox™ Gauze 57.1%
Combat Gauze™ 55.6%

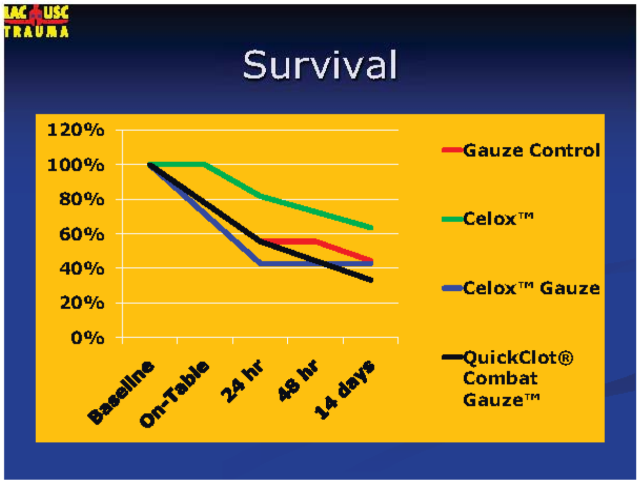

2 week Mortality
Gauze 55.6%
Celox™ 36.4%
Celox™ Gauze 57.1%
Combat Gauze™ 66.7%

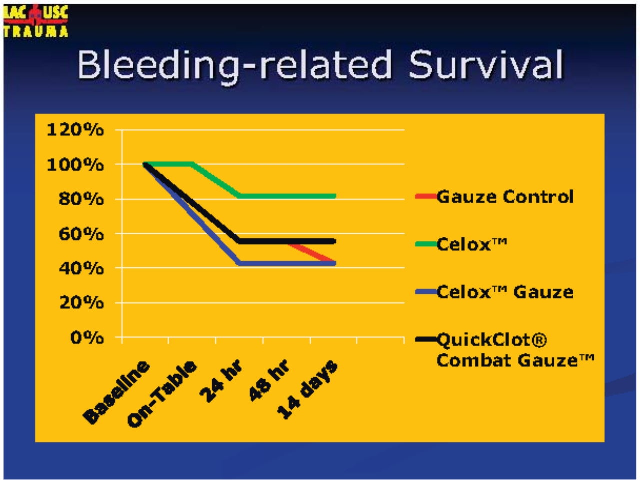

Bleeding-related Mortality
Gauze 44.4%
Celox™ 18.2%
Celox™ Gauze 57.1%
Combat Gauze™ 44.4%

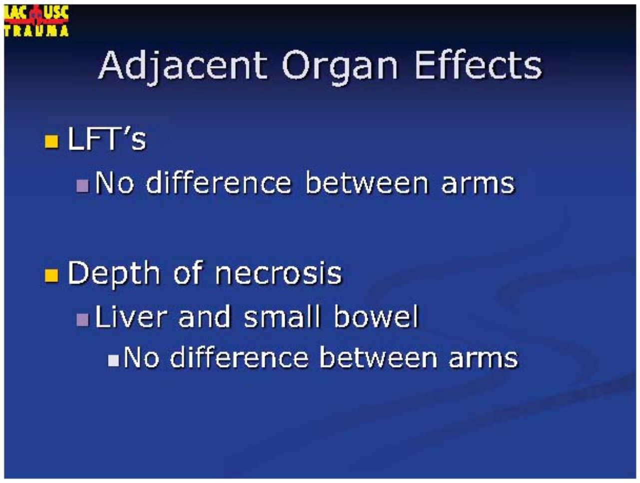

SBO-related Mortality
Gauze 11.1%
Celox™ 18.2%
Celox™ Gauze 0%
Combat Gauze™ 22.2%

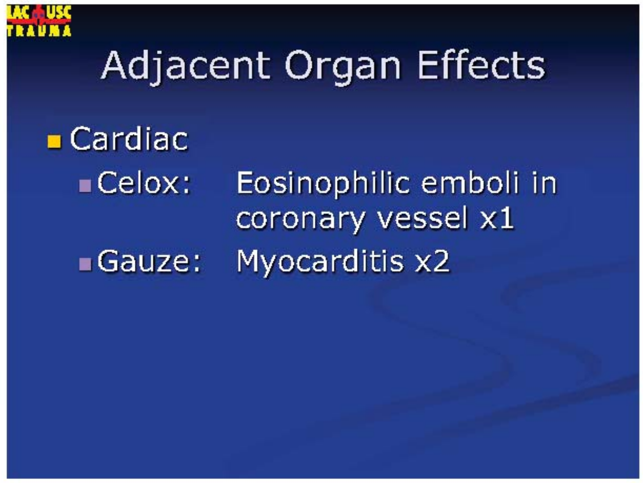

LAC USC TRAUMA
SBO-related Mortality

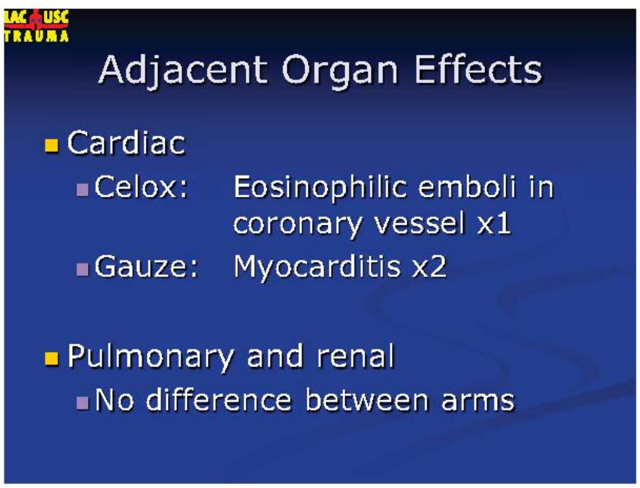

LAC USC TRAUMA
Sepsis-related Mortality
Gauze 11.1%
Celox™ 0%
Celox™ Gauze 0%
Combat Gauze™ 0%

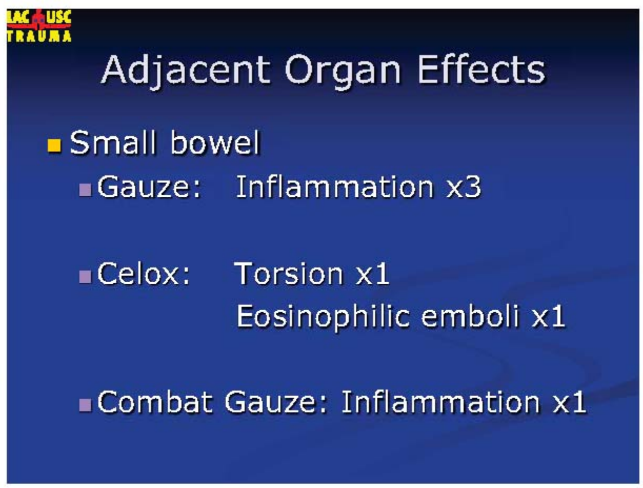

LAC USC TRAUMA
Survival
120%
100%
80%
60%
40%
20%
0%
Baseline
On-Table
24 hr
48 hr
14 days
Gauze Control
Celox™
Celox™ Gauze
QuickClot® Combat Gauze™

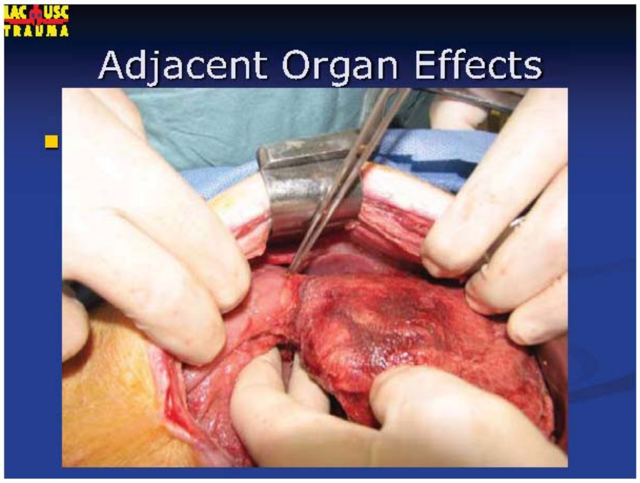

LAC USC TRAUMA
Bleeding-related Survival
120%
100%
80%
60%
40%
20%
0%
Baseline
On-Table
24 hr
48 hr
14 days
Gauze Control
Celox™
Celox™ Gauze
QuickClot® Combat Gauze™


Adjacent Organ Effects
LFT's
No difference between arms
Depth of necrosis
Liver and small bowel
No difference between arms

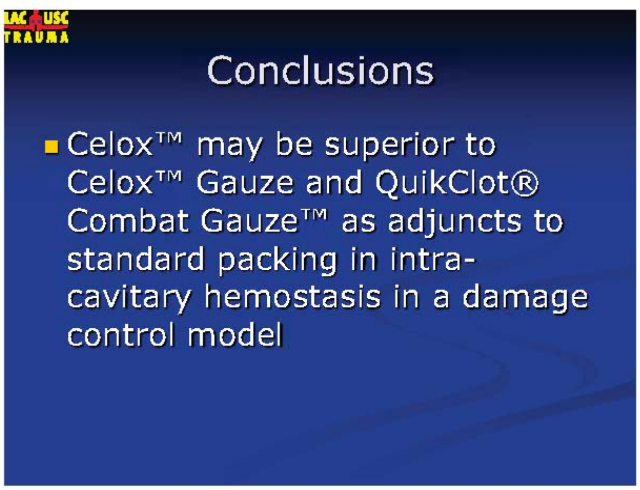

Adjacent Organ Effects
Cardiac
Celox: Eosinophilic emboli in coronary vessel x1
Gauze: Myocarditis x2

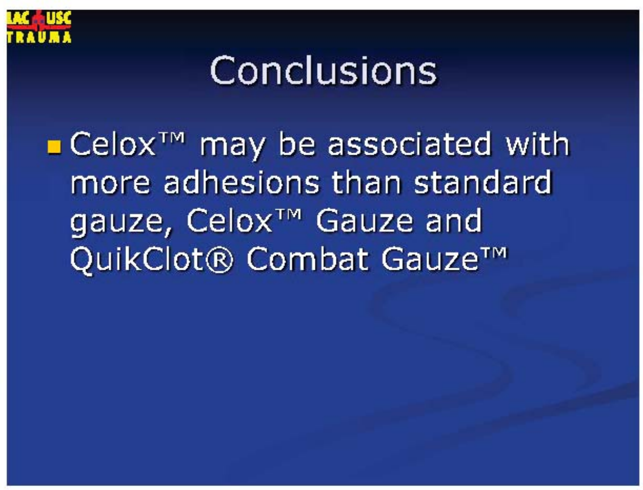

Adjacent Organ Effects
Cardiac
Celox: Eosinophilic emboli in coronary vessel x1
Gauze: Myocarditis x2
Pulmonary and renal
No difference between arms


Adjacent Organ Effects
Small bowel
Gauze: Inflammation x3
Celox: Torsion x1
Eosinophilic emboli x1
Combat Gauze: Inflammation x1


LAC USC TRAUMA
Adjacent Organ Effects


LAC USC TRAUMA
Small bowel adhesions


LAC USC TRAUMA
Conclusions
Celox™ may be superior to Celox™ Gauze and QuikClot® Combat Gauze™ as adjuncts to standard packing in intra-cavitary hemostasis in a damage control model


LAC USC TRAUMA
Conclusions
Celox™ may be associated with more adhesions than standard gauze, Celox™ Gauze and QuikClot® Combat Gauze™

Affect of Altitude on Extremity Compartment Syndrome (ECS)

United States Air Force School of Aerospace Medicine (USAFSAM)/FEEH

Dr. John Kalns

INTRODUCTION: ECS is believed to be exacerbated by hypobaric conditions during AE evacuation but scientific evidence supporting this claim does not exist. METHODS: ECS was initiated in the pig by placement of a balloon catheter between the tibia and the tibialis anterior muscle of the hind limb. Inter-Compartmental Pressure (ICP) greater than Mean Arterial Pressure was maintained for 5 or 6 hours and then reduced and pigs monitored for 8 hours. In some cases pigs were exposed to hypobaric conditions equivalent to 7,000 feet elevation after injury. RESULTS: After injury ICP's increased for 2 hours and then stabilized at an elevated value associated with ECS. Five hour injury (n=10) produced ICP's that meet compartment syndrome criteria, MAP-ICP< 45 mm-Hg, 30% of the time whereas 6h injury (n=10) produced ECS criteria 100% of the time. This finding suggests that there is a critical threshold for ECS. Histological assessment of muscle demonstrated edema, necrosis and extensive neutrophilic infiltrate in limbs with elevated post-injury ICP's. Immunohistochemistry showed the presence of the redox stress product 3-nitrotyrosine in severely injured muscle. Myoglobin in plasma was elevated 10- fold in pigs that experienced increased ICPs. Altitude exposure after injury has no effect on ICP or muscle pathology. Inflammatory cytokines are elevated however. Conclusion: We have shown that ECS with features similar to those observed in AE patients can be produced in the pig. Future studies will examine the impact of hemorrhage/resuscitation and pharmacologic agents on ECS in the AE environment.

U.S. AIR FORCE

Affect of Altitude on Extremity Compartment Syndrome (ECS)

John Kalns, Ph.D. (contractor)
USAFSAM/FEEH

Every Airman a Force Multiplier
August 2010 AFMS Research Symposium

Objectives

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- Develop a clinically relevant model of ECS
- Determine if altitude exposure:
  - Increases incidence of ECS.
  - Increases severity of injury.
- Teaching objectives:
  - Definitions of compartment syndrome.
  - Observations made in an animal model.
  - Pathological features.
  - Effect of altitude exposure on compartment syndrome.

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What is ECS?

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- Pressure within the fascia-limited compartments of a limb increases to a point that microcirculation and tissue perfusion is compromised.
- Secondary to physical trauma such as bone fracture or crush injury, tourniquet or muscle overexertion.
- Theory: Positive feedback cycle where inflammation drives edema and hypoxia which causes more inflammation.
- End state: Prolonged hypoxia leading to myonecrosis, nerve damage and long term disability.

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Definition of ECS (teaching objective)

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- Difference in pressure between Mean Arterial Blood Pressure (MAP) and Pressure Measured in the Compartment (ICP) falls below 45mm Hg.
- Stated mathematically: ICP-MAP < 45 mm Hg.
- References
  - Use of ICP: McQueen MM, Court-Brown CM. Compartment monitoring in tibial fractures. The pressure threshold for decompression. *J Bone Joint Surg Br.* 1996; 78:99-104.
  - ECS during current deployments: Ritenour AE, Dorlac WC, Fang F, et al. Complications after fasciotomy revision and delayed compartment release in combat patients. *J Trauma.* 2008; 64(Suppl):S153-161.

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Animal Model of ECS

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- Anesthetic GKX (guaifenesin 0.05 g/ml, ketamine 0.01 g/ml and xylazine 0.01 g/ml) administered at a rate of 2.5 ml/kg/hr through the venous line installed in the ear.
- Balloon Injury made by placing an angioplasty balloon between the tibia and tibialis anterior muscle.
- 4-6h of balloon injury (pressure 20mm greater than MAP) followed by 8h observation at altitude or ground then euthanasia.
- MAP is measured by a pressure transducer placed in the carotid artery.
- ICP is measured by placing a TwinStar pressure transducer into the muscle compartment.

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Balloon Model

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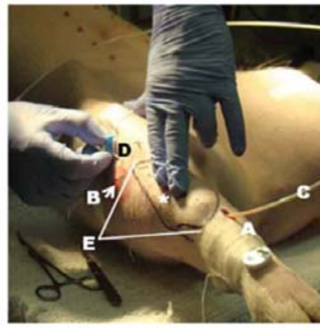

Positioning of angioplasty balloon and pressure transducer. A blunt plastic trocar is inserted at A and carefully pushed between the tibia and the overlying anterior muscle compartment to exit at B. An angioplasty balloon is then attached to the trocar and drawn into position beneath the central portion of the muscle compartment. Saline to inflate the balloon is supplied through C. The pressure transducer is positioned via a catheter inserted at D such that the recording tip of the transducer is located near the center of the tibialis anterior muscle approximately 1 cm below the skin surface (indicated by asterisk). E indicates the location of the anterior muscle compartment, outlined on the skin to aid in positioning instruments.

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Data and Biosamples

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- MAP and ICP pressures
- Systemic O2 saturation
- Blood myoglobin levels (evidence of muscle destruction)
- Muscle pathology and immunohistochemistry of sections.

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Schedule for Samples

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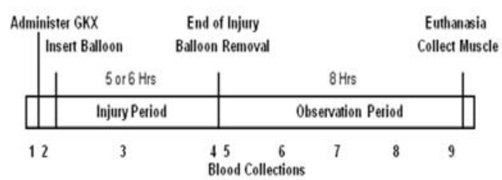

8

Results, ICP at Ground

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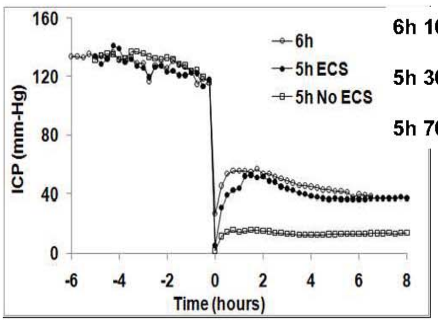

6h 100% ECS (n=8)

5h 30% ECS (n=3)

5h 70% No ECS (n=7)

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Results, ICP-MAP at Ground

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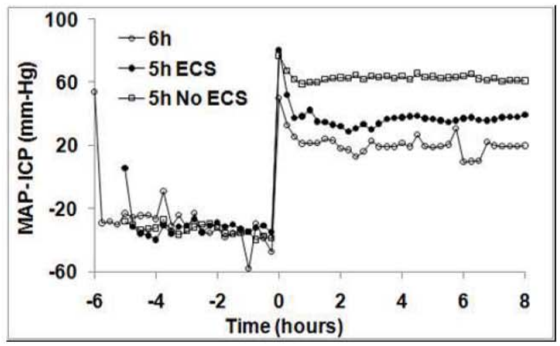

10

Results, Histopathology at Ground

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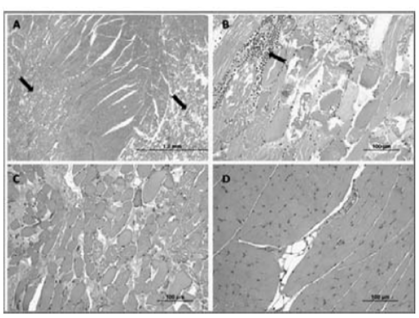

Histopathology of muscle injured for 6h and collected 8h after. Panel A, muscle showing areas of severe injury (arrows) separated by uninjured tissue (center). Panel B, neutrophilic infiltrate in a severely injured region of muscle. Panel C, Significant muscle degeneration as shown by hyalinization in fiber cross sections. Panel D, uninjured control muscle.

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Results, Histopathology Summary at Ground

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Category	5h	SD	6h	SD	P
Muscle Degeneration	0.77	0.61	2.1	0.70	<0.001
Muescle Necrosis	0.17	0.24	0.333	0.35	0.231
Edema	0.33	0.31	1.10	0.75	0.012
Hemorrhage	0.07	0.21	0.67	0.44	0.002
Mineralization	0.20	0.28	0.17	0.18	0.754
Thrombi	0.07	0.14	0.53	0.53	0.021
Neutrophilic infiltrate	0.33	0.35	0.88	0.50	0.011

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Myoglobin at Ground

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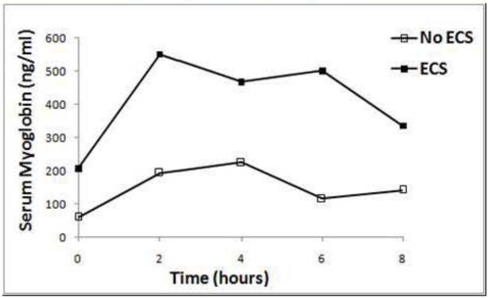

N=3 for ECS and No ECS groups. Samples after balloon release. Values of all prior to balloon release <100 ng/ml

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Results at Ground Summary

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- All or nothing response to injury. ECS pressures are not much different between 5 or 6h injury.
- Incidence of ECS following 5h only 30% versus 100% following 6h injury.
- Histopathology shows increased neutrophils, degeneration, edema. Multi-focal showing a mixture of affected muscle bundles next to ones that are minimally affected.
- Myoglobin in blood supports greater extent of necrosis in ECS limbs compared to non-ECS limbs.
- Immunohistochmistry for iNOS and 3-nitrotyrosine do not show significant differences between ECS control.

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Comparison of ICP Altitude vs. Ground

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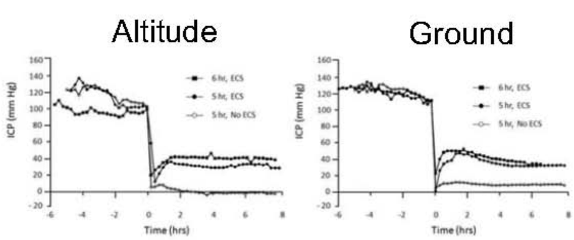

Is the difference statistically significant?

15

There are some differences in ICP

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	Ground	Altitude	p-value
Time to Peak (h)	1.650 (0.285)	2.575 (2.202)	0.222
Peak ICP (mm-Hg)	57.8 (11.5)	32.6 (14.6)	0.004
AUC ICP (mm-Hg*h)	94.2 (23.5)	49.6 (25.2)	0.009

- Altitude has significantly lower peak ICP and lower AUC ICP.
- Suggests that muscle exposure to high pressure is reduced.

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But altitude makes no difference in incidence

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- 5h Injury, Altitude, 4/16 ECS (25%) versus 3/10 ECS (30%) at Ground.
- Diagnosis is made on the basis of pressure determination. What about the transducer?
  - Q: Does it measure the same at altitude as on ground? A: YES. Part of another report.
  - Q: What about MAP and other systemic effects contributing to ECS? A: MAP-ICP is actually less at altitude meaning that altitude should have little effect if pressure is all that is important.

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Altitude vs. Ground: Signaling

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	Normobaric (n=10)	Hypobaric (n=22)	p-value
FGF	0.175 (0.164)	0.202 (0.156)	N.S.
IGF-1	0.232 (0.028)	0.979 (0.301)	0.001
TNF-alpha	0.377 (0.173)	0.601 (0.091)	0.003
IL-6	0.788 (0.628)	2.966 (0.231)	0.001
Il-1 beta	0.385 (0.048)	0.363 (0.021)	N.S.
IGF-BP4	3.621 (0.359)	4.022 (0.308)	0.004
IGF-BP5	1.644 (0.158)	01.648 (0.287)	N.S.
BMP-4	1.817 (0.705)	2.612 (1.442)	0.039
NO2-Tyrosine	169.7 (16.6)	194.3 (10.5)	0.001
TGF-B2	0.188 (0.159)	0.109 (0.169)	N.S.
NO2/NO3	91.1 (53.5)	73.5 (15.1)	N.S.

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Signals Interpreted: Inflammation

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- Inflammation INCREASED in altitude exposed muscle both injured and control.
  - Increased Il-6 and TNF, early mediators in control and injured tissue.
    - No difference in TNF expression between ECS limbs (altitude vs. ground).
  - Increased redox product nitrotyrosine at altitude.
  - Early inflammation proceeds more rapidly at altitude or response is more robust. Can't tell.
  - We don't know if muscle is expressing or immune cells.

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Signal Interpretation: Wound repair

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- Wound repair INCREASED in altitude exposed muscle.
  - IGF-1, IGF-BP4, BMP-4 all increased at altitude both in control and injured muscle.
  - BMP-4 is significantly increased in ECS muscle compared to uninjured.
  - Earlier response or altered response? Can't say.

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Histopathology: No difference

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- No difference attributable to altitude exposure.
- Difference between ECS and non-ECS at altitude the same as ground.

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Conclusions

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- Threshold injury model for ECS established.
- ECS CAUSES increased incidence of degeneration, necrosis, edema, neutrophil infiltration and myoglobin release.
- ECS CAUSES diffuse multi-focal injury.
- Altitude DOES NOT INCREASE incidence of ECS or severity of pathology.
- Altitude INCREASEs expression of inflammation and wound healing signals in uninjured and injured tissue.

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Unanswered Questions

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- Does altitude set up muscle for more severe injury later? Easy enough to test with longer trial.
- Is hypobaric hypoxia the same as normobaric hypoxia? Easy to test.
- What early events trigger ECS? How can ECS be prevented? What signaling pathways are invoked?
  - Continuous proteomic and metabalomic profiling enabled by the TwinStar device makes this possible.
- Pigs have a relatively uniform genetic background.
  - Single Nucleotide Polymorphism (SNP) analysis may provide understanding of critical pathways and better means of mitigating risk by rapid identification of ‘at risk’ genotype.

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Acknowledgements

Every Airman a Force Multiplier

- Dr. Rick Odland, TwinStar- Model development, discussion of possible altitude effects and use of the TwinStar catheter.
- Dr. Tom Walters, USAISR- Useful discussion of the model and the state of the art.
- LtCol Steve Fecurra (CCATT)- Brought ECS at altitude to the attention of USAFSAM.
- Col Robert Michaelson (USAFSAM)- Discussion of gas effects at altitude.
- Maj Julio Lairet (MEDCOM AISR)- Discussion of ECS and AE transport.
- Col Glenn Hover (USAFSAM)- Support of the ECS program.
- Dr. Roger Vanderbeek (711th XP)- Support and understanding of the ECS program.
- The Hyperion crew who did the work: Jonathan Baskin, Jennifer Barrett, Adrienne Santos.

24

Bacterial Growth at Altitude

United States Air Force School of Aerospace Medicine (USAFSAM)/Center for Sustainment of Trauma and Readiness (CSTARS); Cincinnati, OH

Capt Ryan Earnest

OBJECTIVES: Bacterial growth is a known risk factor for tissue loss and complications in contaminated musculoskeletal wounds. Current care for these casualties includes strategic aeromedical evacuation. The effect of altitude on bacterial growth in contaminated complex wounds is unknown. We hypothesized that exposure to hypobaric hypoxia alters bacterial growth in contaminated complex musculoskeletal wounds. METHODS: We adapted a previously characterized caprine model. Under anesthesia, complex musculoskeletal wounds were created and inoculated with bioluminescent Pseudomonas aeruginosa. At 20 hours post surgery and inoculation, goats (n=5) underwent simulated aeromedical evacuation for seven hours at 8800 feet in a hypobaric chamber. Controls (n=5) were transported without flight simulation. Bacteria were quantified using photon counting at preflight (20 hours post surgery), post flight (7 hours from preflight and 27 hours post-surgery), and necropsy (24 hours from preflight and 44 hours post surgery). Results are expressed as Relative Luminescent Units (RLU) normalized to each goat's pre-flight baseline value. Statistical analysis was performed with Mann-U-Whitney test with $p<0.05$ deemed significant. RESULTS: There were no deaths in either group. Each group demonstrated increasing RLU values over time (Figure 1). Goats undergoing simulated aeromedical evacuation demonstrated increased mean RLU values as compared to control animals at the post flight and necropsy time points. CONCLUSION: In the current study, simulated aeromedical evacuation resulted in increased bacterial luminescence in a contaminated complex wound. These findings are important because they suggest that hypobaric hypoxia during aeromedical evacuation may accelerate bacterial growth in contaminated wounds.

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SUPPLEMENTAL OXYGEN DECREASES WOUND BACTERIAL GROWTH AFTER SIMULATED AEROMEDICAL EVACUATION IN GOATS

Capt Ryan E. Earnest, Dennis I. Sonnier, Amy T. Makley, Eric M. Campion, Stephanie R. Bailey, Joseph Wenke, Alex B. Lentsch, Timothy A. Pritts, Jay A. Johannigman, Col Warren C. Dorlac

Aeromedical Evacuation

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- Moderate altitude change occurs during commercial and military flight
  - AE cabin profiles can range from 4000 – 8800ft
  - Hypobaric environment
- Ambient barometric pressure at a cabin altitude of 8,000 ft = 563mm Hg.
  - Decrease to 89 percent hemoglobin saturation

Aeromedical Evacuation

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- Altitude exposure may lead to:
  - Hypoxia – O_2 saturation decreasing to <90%
    - Commercial air crew members have documented saturation ranges from 80% - 93%
  - Symptoms similar to acute mountain sickness
    - Even after 3 hours in commercial flight conditions

Basnyat B, Murdoch DR. High-altitude illness. Lancet 2003; 361:1967-74.
Muhm JM, Rock PB, McMullin DL, et al. Effect of aircraft-cabin altitude on passenger discomfort. N Engl J Med 2007; 357:18-27.

Aeromedical Evacuation

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- Combat casualties in the AE transport system have <u>not</u> routinely received:
  - pulse oximetry evaluation
  - supplemental O_2 for non-ventilated patients

Aeromedical Evacuation

Every Airman a Force Multiplier

- Wound oxygen tension may be vital for wound healing
  - Decreased incidence of surgical site infections
  - Oxygen: essential for eliminating pathogens and stimulating phagocytosis

Kuhne HH, Ullmann U, Kuhne FW. New aspects on the pathophysiology of wound infection and wound healing--the problem of lowered oxygen pressure in the tissue. Infection 1985; 13:52-6.
Ives CL, Harrison DK, Stansby GS. Tissue oxygen saturation, measured by near-infrared spectroscopy, and its relationship to surgical-site infections. Br J Surg 2007; 94:87-91.

Musculoskeletal Injury

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- Involves severe bone and soft tissue injury
  - Complex wounds
  - Difficult to treat
  - Complications include wound ischemia, infection, non-healing, and tissue loss

Musculoskeletal Injury

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- Common diagnosis in patients undergoing AE
  - Over 50% of all combat wounds
  - Up to 24% of all evacuated patients
- Hypobaric/Hypoxic AE environment and its effects on complex wounds are not well understood

Cohen SP, Brown C, Kurihara C, PlunkettA, Nguyen C, Strassels SA. Diagnoses and factors associated with medical evacuation and return to duty for service members participating in Operation Iraqi Freedom or Operation Enduring Freedom: a prospective cohort study. Lancet.; 375:301-9.

Hypothesis

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1. Exposure to hypobaric hypoxia alters bacterial growth in complex musculoskeletal wounds
2. This effect could be attenuated with the administration of supplemental oxygen

Model

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- Adapted an established caprine complex musculoskeletal wound model
  - US Army Institute of Surgical Research
    - Joseph Wenke, PhD
  - Castrated male goats
    - Consistency of musculoskeletal composition

Complex Musculoskeletal Injury

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Complex Musculoskeletal Injury

Every Airman a Force Multiplier


Complex Musculoskeletal Injury

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Wound Model

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- Inoculation with bioluminescent Pseudomonas aeruginosa
- Dressed with wet to dry dressing and a self adhering bandage
- Arterial line and nasal cannula placed intraoperatively

Simulated Aeromedical Evacuation

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- Three Groups
  - AE
  - AE with supplemental Oxygen (AE O_2)
  - Ground Control
- 21 hours after surgery subjects in flight group underwent simulated AE
  - 8800 ft for 7 hours
  - Arterial PaO_2, oxygen saturation, and wound oxygen tension monitored throughout the flight
- Ground controls were transported to the chamber, but did not undergo flight

Photon Camera Imaging

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- Photon camera images used to quantify wound bioluminescent bacteria post-injury
  - 20 hours (preflight)
  - 28 hours (postflight)
  - 44 hours (necropsy)

Aeromedical Evacuation Timeline

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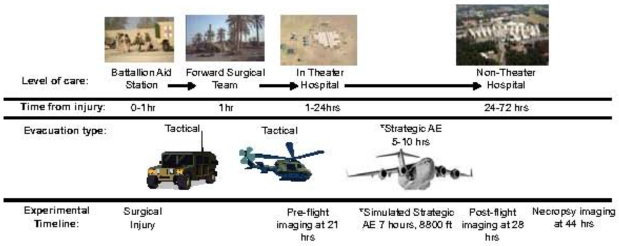

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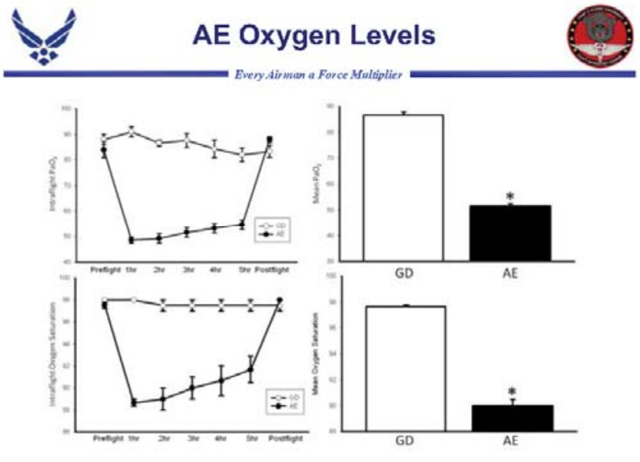
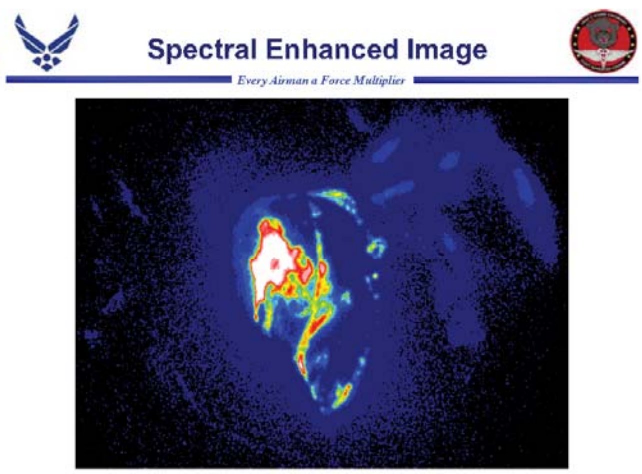
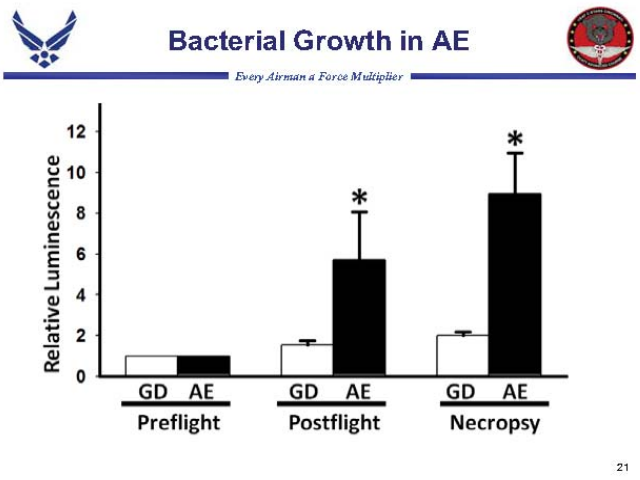
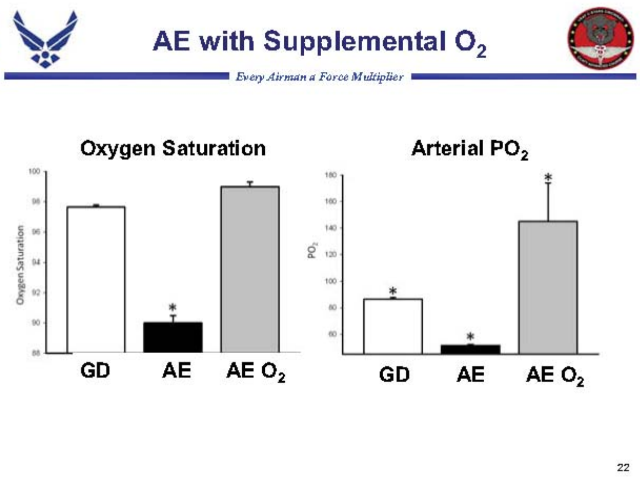

AE Oxygen Levels
Every Airman a Force Multiplier
Preflight 1hr 2hr 3hr 4hr 5hr Postflight
GD
AE
*

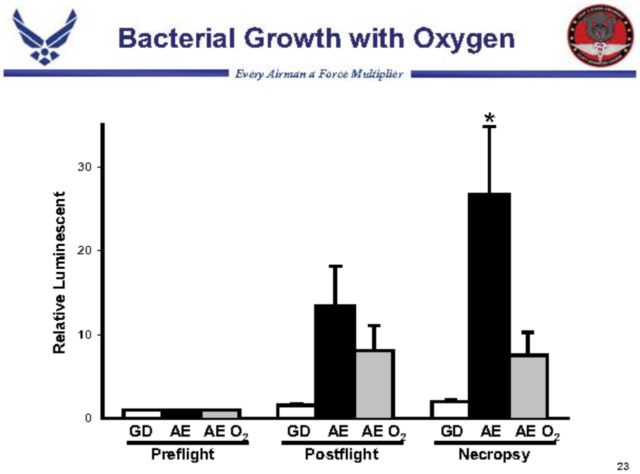

Bright-field Image
Every Airman a Force Multiplier

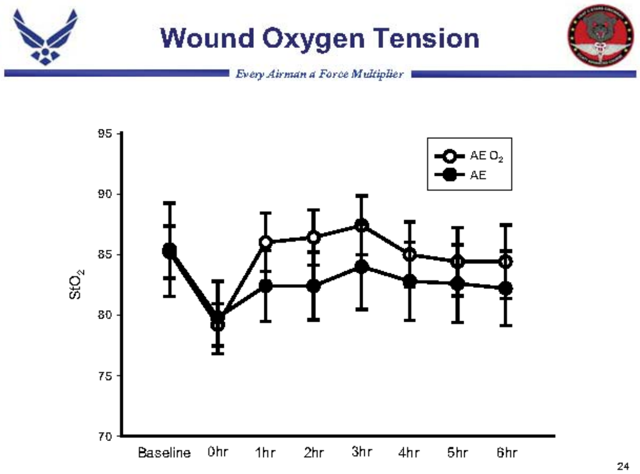

Photon Image
Every Airman a Force Multiplier


Spectral Enhanced Image
Every Airman a Force Multiplier


Bacterial Growth in AE
Every Airman a Force Multiplier
Relative Luminescence
12
10
8
6
4
2
0
*
*
GD AE
Preflight
GD AE
Postflight
GD AE
Necropsy
21


AE with Supplemental O2
Every Airman a Force Multiplier
Oxygen Saturation
Arterial PO2
GD
AE
AE O2
GD
AE
AE O2
22


Bacterial Growth with Oxygen
Every Airman a Force Multiplier
Relative Luminescent
30
20
10
0
*
GD AE AE O2
Preflight
GD AE AE O2
Postflight
GD AE AE O2
Necropsy
23


Wound Oxygen Tension
Every Airman a Force Multiplier
AE O2
AE
StO2
95
90
85
80
75
70
Baseline
0hr
1hr
2hr
3hr
4hr
5hr
6hr
24

Conclusions

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- Demonstrated feasible AE model for investigation of musculoskeletal wounds
- Mild altitude exposure of AE results in mild hypoxia
- Hypobaric hypoxia increased bacterial luminescence in a complex wound
- Increased bacterial growth may be abrogated with addition of supplemental oxygen

Active Investigation

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- What is the role of wound therapy on bacterial growth during AE?
- What is the role of hypoxia vs. the hypobaric environment?
- How much oxygen is needed?

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Acknowledgements

Every Airman a Force Multiplier

- Supported by USAF award FA7014-09-2-0005
- Combat Casualty Care Research Program, USAMRMC
- USAF/711th HPW
- WPAFB Surgical Research Program
- University of Cincinnati Department of Surgery
  Division of Research Residents and Support Personnel
  Cincinnati, OH

Technical Evaluation of Enroute Care Mechanical Ventilation

United States Air Force School of Aerospace Medicine (USAFSAM)/Center for Sustainment of Trauma and Readiness (CSTARS); Cincinnati, OH

SMSgt Dario Rodriguez, Jr.

INTRODUCTION: Mechanical ventilation in far forward military operations requires a device that is consistent, light weight and easy to use. We evaluated the SAVe (simplified automated ventilator) in a laboratory setting to determine performance characteristics. **METHODS**: Three SAVe resuscitators were tested. Each was attached to a test lung with volume, pressure, and flow measured with a pneumotachometer. Compliance and resistance of the test lung were varied to simulate varying patient conditions. Oxygen was entrained at the inlet and FIO2 was measured with a fast response oxygen analyzer at the airway. All measurements were made at sea level, 4000, 8000, 12,000, and 18,000 feet. Battery life was measured twice with each device by operating it to exhaustion. **RESULTS**: Delivered tidal volume and inspiratory time varied when changing lung model conditions as well as between devices within the same lung model condition at sea level and at altitude. The largest reduction in tidal volume was at the lowest compliance. Measured FIO2 was comparable to reported FIO2 although it decreased with simulated spontaneous breathing through the device. **CONCLUSIONS**: The SAVe resuscitator is a limited function device. Tidal volume delivery is inconsistent with decreased lung compliance and/or increased resistance. The set respiratory rate and tidal volume are not guaranteed under these conditions. During spontaneous breathing, room air is supplied to the patient. The SAVe could potentially be used for ventilatory support of carefully selected military casualties to replace manual ventilation, but caregivers must be aware of the limitations.

Technical Evaluation of Enroute Care Mechanical Ventilation

Integrity - Service - Excellence

The Center for Sustainment of Trauma and Readiness Skills/Institute of Military Medicine University of Cincinnati

SMSgt Dario Rodriquez Jr. BS RRT
Thomas C. Blakeman BA RRT
Col Warren Dorlac MD
Col Jay A. Johannigman MD
Richard D. Branson MSc RRT

Overview

- Evaluation of SAVe (Simplified Automated Ventilator)
  - Study objective
  - Device characteristics
  - Evaluation methods
  - Results
- Mechanical Ventilation in a Hot Zone
  - Study objective
  - Implication of MV in a CBRN environment
  - Study design
  - Results
- Evaluation of Aeromedical Transport Ventilators
  - Study objective
  - Device characteristics
  - Study design
  - Results

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SAVe Study Objective

- Assess performance characteristics of the SAVe
  - Determine accuracy of delivered tidal volumes at variable lung impedance
  - Evaluate operational impact of variable lung impedance
  - Evaluate use with supplemental oxygen
  - Identify operational characteristics when exposed to hypobaric environment

Integrity - Service - Excellence

Light, Lean, Go Anywhere

- Lightweight
- Small
- Battery powered
- Single limb circuit

Integrity - Service - Excellence

SAVe Model 600

- 3.1 lbs
- 6.25” X 6.75” X 2.5”
- Battery powered
- Single limb circuit
- One set of vent parameters
  - Tidal Volume of 600 ml
  - Respiratory Rate of 10 bpm
  - Flow Rate of 16 lpm
- No PEEP

Integrity - Service - Excellence

Study Methods

- Three SAVe devices were attached to a TTL (Michigan Instruments) via manufacturer supplied single limb circuit
- A pneumotachograph (Hans Rudolph) was placed between the vent circuit and test lung for measurement of pressure, volume, and flow and the data was recorded to a PC
- Ability of device to maintain set rate and tidal volume was tested using four simulated patient scenarios at sea level and simulated altitudes of 4K, 8K, 12K and 18K ft

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Study Methods Continued

- Fours scenarios simulated normal lungs, chronic lung disease, acute and severe respiratory distress syndrome
- Oxygen was set at 1, 3, and 6 lpm at the inlet of the SAVe and the delivered FIO_2 was measured using a fast response oxygen analyzer (Oxygraf)
- Testing was done with a passive model and a spontaneously breathing model
- The flow of oxygen was also set at 20 and 25 lpm to determine effects on ventilator performance

Integrity - Service - Excellence

Impact of Compliance

- Delivered tidal volume, inspiratory time, and respiratory rate varied when changing lung model conditions as well as between devices within the same condition

	SAVe #1	SAVe #2	SAVe #3	Insp. Time Range	Respiratory Rate
Compliance 1.0	694 ± 2.5	647 ± 3.0	646 ± 11.2	2.0 – 2.4	9 - 10
Compliance 0.8	667 ± 1.3	645 ± 4.2	622 ± 8.1	2.1 - 2.4	10
Compliance 0.2	508 ± 1.9	573 ± 3.1	538 ± 13.9	1.8 – 2.2	10 - 11
Compliance 0.1	250 ± 2.1	276 ± 2.7	280 ± 1.9	1.1 – 1.2	17 - 18

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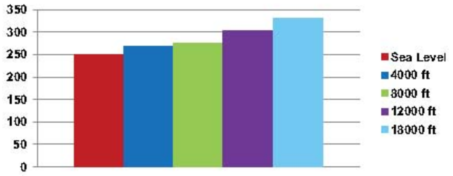
Effects of Altitude

- Delivered tidal volumes at compliances of 1.0 and 0.8 ml/cmH_2O were comparable to tidal volumes at sea level
- At compliances of 0.2 and 0.1 ml/cmH_2O the delivered tidal volumes increased stepwise from sea level through each test altitude



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Evaluation with Supplemental Oxygen

- Delivered FIO_2 varied widely throughout the breath cycle at each oxygen setting
- Although variable during the breath, mean FIO_2 was within 5% of the reported FIO_2
- Although the operator manual cautions against using flow rates in excess of 6 lpm, we evaluated ventilator operation using higher flow rates to test the effect on performance. At an oxygen flow rate of 20 lpm the SAVe experienced periodic breath stacking and additional volume was added to the test lung between breath cycles. At 25 lpm, the SAVe failed to cycle but volume from the oxygen flow was added to the test lung

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Mechanical Ventilation in a Hot Zone

- Implication of mechanical ventilation in a CBRN (chemical, biological, radiologic, nuclear) exposed environment
- Evaluate effects of the addition of a CBRN filter to a mechanical ventilator
  - Determine performance characteristics of four portable ventilators affixed with a CBRN filter
  - Evaluate the anti-asphyxiation properties of the selected ventilators
  - Determine ability to filter all of a patients inspired gas

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Study Methods

- Evaluate four transport ventilators used around the world for disaster management
- Each device was attached to a TTL (Michigan Instruments) via manufacturer supplied single limb circuit
- A pneumotachograph (Hans Rudolph) was placed between the vent circuit and test lung for measurement of pressure, volume, and flow and the data was recorded to a PC
- Lung compliance was set at 0.02 L/cmH_2O and resistance was set at 5 cm H_20/L/s

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Study Methods Continued

- Ventilator settings were: A/C mode, respiratory rate 35 bpm, tidal volume 450 ml, PEEP 10 cm H_2O, inspiratory time 0.8 seconds, and FIO_2 0.21
- Ability of the ventilator to assure all gas delivered to the patient passes through the CBRN filter was assessed by connecting the ventilator to a model simulating spontaneous breathing
- We simulated a device failure by turning each test ventilator off and having the driving ventilator deliver a breath, simulating a patient breathing through the test ventilator's anti-asphyxiation valve

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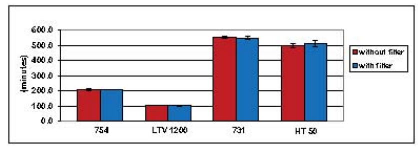
Battery Test Results

- Range of battery duration varied widely across all ventilator models (99.8 – 562.6 minutes)
- There was no significant difference in battery duration with any of the individual ventilators tested while operating with and without the CBRN filter attached



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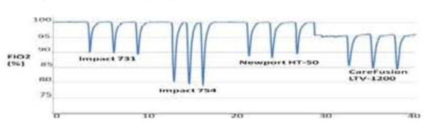
Air Entrainment Results

- Flow demand testing demonstrated that if inspiratory demand exceeds the set ventilator flow, gas would be drawn through the anti-asphyxiation valve
- FIO_2 decreased as room air was drawn in via the anti-asphyxiation valve – in a contaminated environment this would expose the patient to the contaminant
- Decrease in FIO2 was 10% – 20% due to air entrainment through the anti-asphyxiation valve



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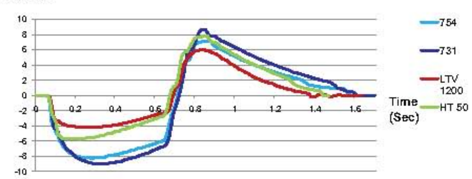
Effects on Patient Triggering

- Triggering evaluation suggested that work of breathing under this condition differed among ventilators
- Impact 731 generated the greatest pressure change from base line suggesting the highest work of breathing (only device allowing entire gas source to patient to pass through filter)
- CareFusion LTV 1200 demonstrated the least peak negative pressure



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Comments

- CBRN filter is a potentially important addition to a portable ventilator in providing clean air in the event of intentional or accidental environmental contamination
- Our study showed that the use of a CBRN filter does not decrease battery duration of the 4 portable ventilators
- The longer the filter is used in a contaminated environment the possibility exists that battery duration may be affected
- Even though patients can entrain gas through the anti-asphyxiation valve in the event of inadequate inspiratory flow or device failure, the benefit of the CBRN filter may be lost due to the entrainment of contaminated room air
- The Impact 731 was the only ventilator tested that directs all entrained room air through the filter

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Aeromedical Transport Ventilators

- Aeromedical transport ventilators must have the ability to ventilate patients with decreased lung compliance that accompanies acute lung injury and acute respiratory distress syndrome
- Adequate battery life is required to power the ventilators when alternating current is not available
- Work of breathing required to trigger the ventilator during spontaneous breathing is dependent on device's ability to respond to inspiratory effort
- Accuracy of tidal volume delivery at various altitudes is crucial for the safe management of critically ill patients during air transport

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Device Description

Impact 731

Impact 754

LTV 1000

	Dimensions (LxWxH)	Weight (lbs)	Breath type (VCV/PCV)	Piston or Turbine	Inspired/expired Vt monitoring	Battery type (internal)	Altitude Compensation
Impact 731	12.5x8x4.5	9.7	Yes	Piston	Inspired Only	Lithium ion	Yes
Impact 754	11.5x8.9x4.5	12.8	VCV Only	Piston	Inspired Only	Lead-acid	Yes
Pulmonetics LTV 1000	12x10x3	13.4	Yes	Turbine	Yes	Lead-acid	No

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Study Methods

- Evaluate Impact 731, Impact 754, and Pulmonetics LTV 1000 to assess battery life, triggering, and performance
- Each ventilator was attached to a dual chamber test lung (Michigan Instruments) with a pneumotachometer (Hans Rudoldph) placed in line
- Data generated for each evaluation was recorded to a PC for further analysis
- Battery life was tested using the following settings to approximate the mean settings on day 1 of the ARDSnet trial (other than FIO_2): Respiratory rate 35, tidal volume 450 ml, PEEP 10, FIO_2 0.21
- Each ventilator was operated until the battery was completely discharged

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Study Methods Continued

- Triggering was evaluated by placing a lift bar between the test lung chambers, with a ventilator driving one side of the test lung simulating aggressive patient triggering
  - The test ventilator was attached to the other side, set at PSV 10 cm H_2O (if available), and data recorded to assess trigger responsiveness
- Sensitivity was set to the most sensitive value that did not cause auto-triggering
- Evaluation of tidal volume delivery was performed at sea level and simulated altitudes of 8,000 and 15,000 feet, at a set tidal volume of 500 ml

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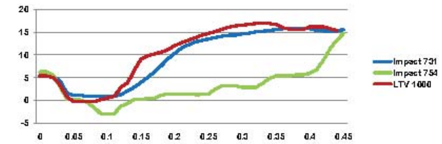
Battery and Triggering Results

- Battery testing was done a minimum of two times per device
- Durations for the LTV 1000, Impact 754, and Impact 731 were 101.7, 205.6, and 553.7 minutes respectively
- Ability to respond to an aggressive inspiratory effort varied widely between devices
- The LTV 1000 produced the shortest inspiratory delay time, Impact 731 produced smallest peak negative pressure from baseline and Impact 754 was least responsive during this test



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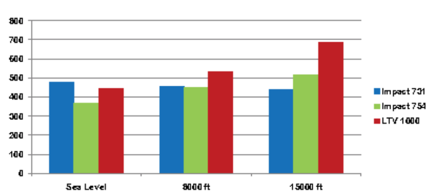
Effects of Altitude

- Delivered tidal volume varied among devices at sea level and at altitude
- Most tidal volumes were within ASTM standards



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Results

- Impact 731 provided a substantially longer battery life than the other ventilators
- Impact 731 and LTV 1000 had comparable triggering response while the Impact 754 required more negative pressure to trigger a breath
- Since the 754 does not have PSV mode, the triggering evaluation was done in A/C mode with an inspiratory time of 0.3 seconds, to maximize the flow delivered during the evaluation

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Results Continued

- A possible reason for the poor triggering response during an aggressive effort with the 754 is the maximum inspiratory flow rate is 60 lpm, where the 731 and LTV 1000 is 100 lpm
- Impact 731 and 754 compensated for changes in altitude where the LTV 1000 did not
- Caregivers must understand the performance and limitations of portable ventilators to ensure patient safety during transport

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THANK YOU

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Joint Medical Distance Support and Evacuation (JMDSE), Joint Capability

United States Joint Forces Command (USJFCOM)-J02M

CDR Greg Cook

The United States Joint Forces Command (USJFCOM) is conducting the Joint Medical Distance Support and Evacuation (JMDSE), Joint Capability Technology Demonstration (JCTD) to enable precise logistical delivery of critical, mission specific medical equipment and supplies to include telemedicine, digital patient encounter documentation, and transmission capabilities for medical first responders. These enhanced capabilities will be air-dropped by Joint Precision Airdrop Systems (JPADS) from manned and/or Unmanned Aerial Systems (UAS) to augment and extend in-place combat casualty care within forward Army, Marine Corps and Special Operations ground forces, Air Force Para-rescuers, and Navy ships/submarines with limited organic medical support. Within these combatant organizations, medics or corpsmen will be provided an on-demand capability to capture and transmit digital physiological monitoring data (i.e. blood pressure, pulse, temperature, respirations, ECG, ECO2, SP02, ventilator treatment, data elements common to the Tactical Combat Casualty Care and Field Medical Cards), and digital voice recordings of patient encounters to enable immediate telementoring and to facilitate accurate, complete point-of-injury data within permanent medical records. A set of ruggedized equipment and a lightweight digitally enabled physiological monitoring system are being integrated with military radios and soldier headset voice data capture technologies, and will be packaged for just-in-time air delivery via JPADS. A series of three 2010-11 Operational Demonstrations involving with land, air and maritime forces will be used to determine the utility of JMDSE capabilities. We discuss the technologies employed, the operational scenarios and results of the first series of exercises.


Joint Medical Distance Support & Evacuation
JOINT MEDICAL DISTANCE SUPPORT & EVACUATION (JMDSE)
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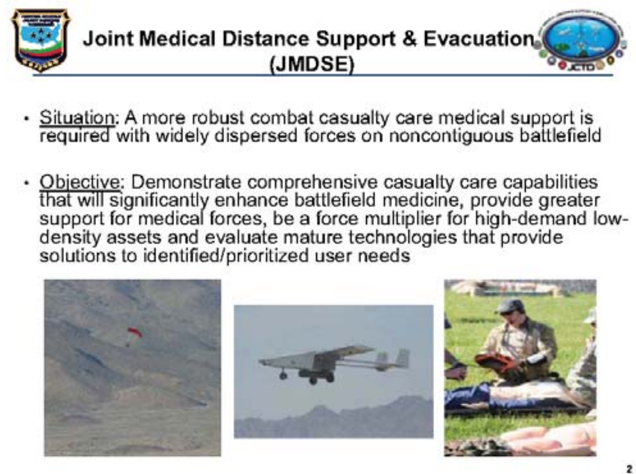
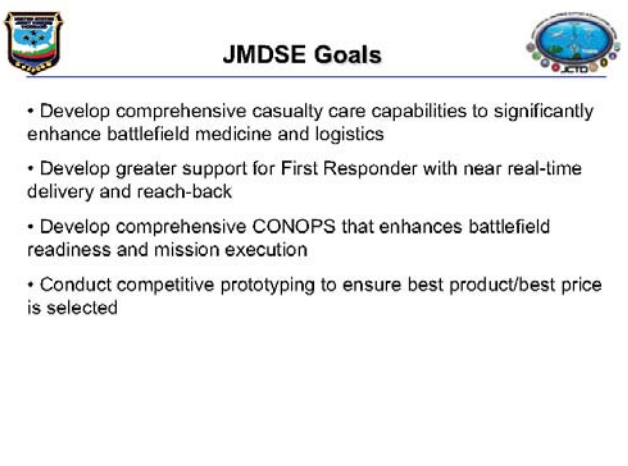
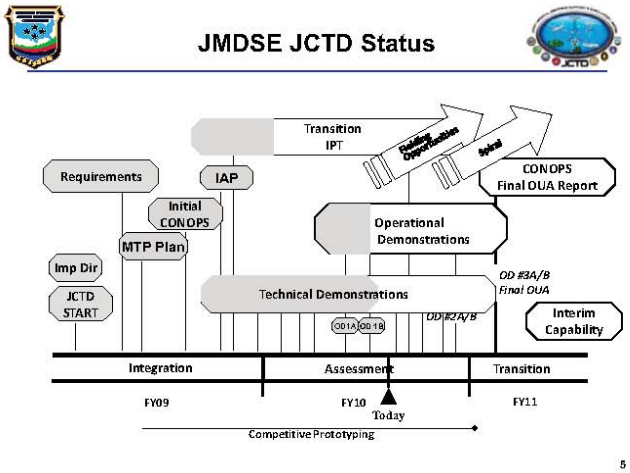
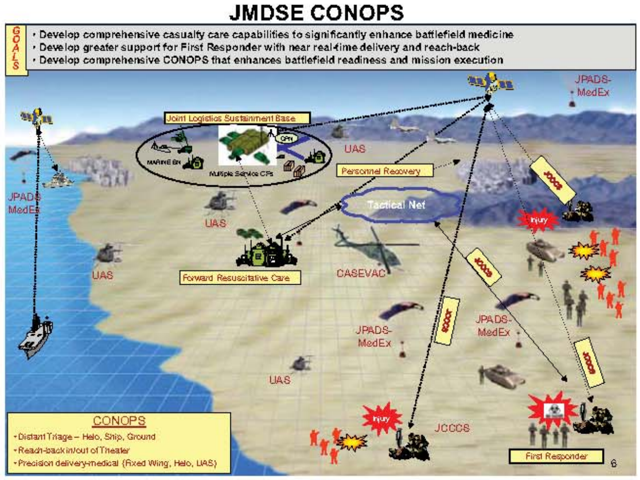
1


Joint Medical Distance Support & Evacuation (JMDSE)
• Situation: A more robust combat casualty care medical support is required with widely dispersed forces on noncontiguous battlefield
• Objective: Demonstrate comprehensive casualty care capabilities that will significantly enhance battlefield medicine, provide greater support for medical forces, be a force multiplier for high-demand low-density assets and evaluate mature technologies that provide solutions to identified/prioritized user needs
2

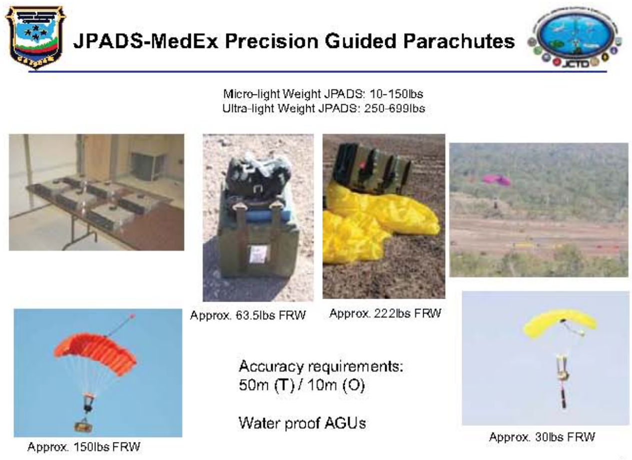

JMDSE Goals
• Develop comprehensive casualty care capabilities to significantly enhance battlefield medicine and logistics
• Develop greater support for First Responder with near real-time delivery and reach-back
• Develop comprehensive CONOPS that enhances battlefield readiness and mission execution
• Conduct competitive prototyping to ensure best product/best price is selected
3

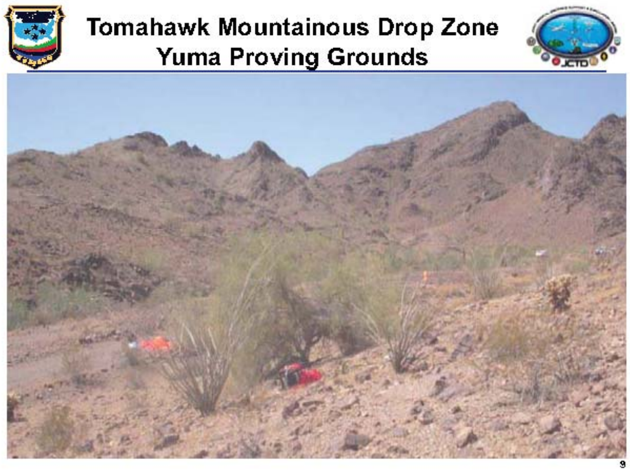

JMDSE Management
• COCOM/User Sponsor
– U.S. Joint Forces Command
• DDR&E(RFD) Oversight Executive
– Mr. Greg Reid
• Operational Manager
– USJFCOM Office of the Command Surgeon (J02M) – CDR Greg Cook
• Technical Manager
– Natick Soldier, Research, Development and Engineering Center (USA/NSRDEC) – Mr. Richard Benney
– Telemedicine and Advanced Technology Research Center (USA/TATRC) – Dr. Gary Gilbert
• Transition Manager Sponsors
– Marine Corps Systems Command – JPADS-Med/ULW – Mr. Bill Barnebee
– Defense Health Information Systems (DHIMS) – IM/IT – COL Barrow
– Defense Threat Reduction Agency (DTRA) – BioWarfare/JPADS-MedEx Integration
• Lead Service – N/A
• Other Participants
– Air Force – AF/SGR, ACC; DTRA, SOCOM, PACOM, Fleet Forces Command, USA/ARDEC
4

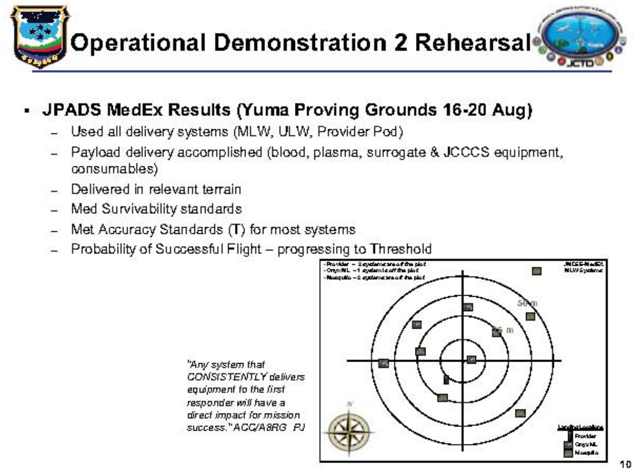

JMDSE JCTD Status
Transition IPT
Spiral
CONOPS Final OUA Report
Requirements
IAP
Initial CONOPS
MTP Plan
Operational Demonstrations
Imp Dir
JCTD START
Technical Demonstrations
OD #3A/B Final OUA
OD1A
OD1B
OD #2A/B
Interim Capability
Integration
Assessment
Transition
FY09
FY10
Today
FY11
Competitive Prototyping
5

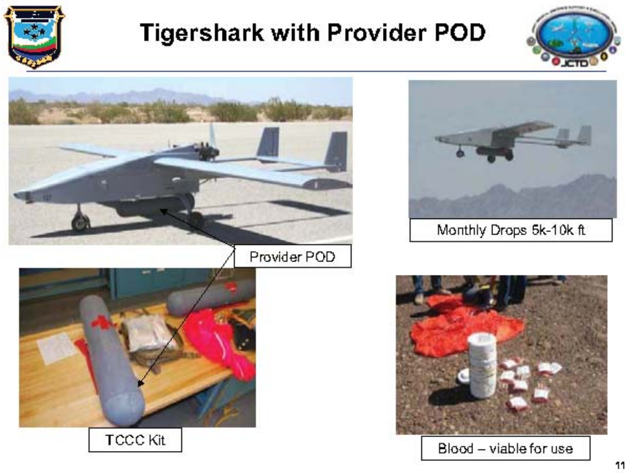

JMDSE CONOPS
GOALS
• Develop comprehensive casualty care capabilities to significantly enhance battlefield medicine
• Develop greater support for First Responder with near real-time delivery and reach-back
• Develop comprehensive CONOPS that enhances battlefield readiness and mission execution
JPADS-MedEx
Joint Logistics Sustainment Base
Multiple Service CPs
UAS
Personnel Recovery
Tactical Net
Injury
Forward Resuscitative Care
CASEVAC
JCCCS
First Responder
CONOPS
• Distant Triage – Helo, Ship, Ground
• Reach-back in/out of Theater
• Precision delivery-medical (Fixed Wing, Helo, UAS)
6

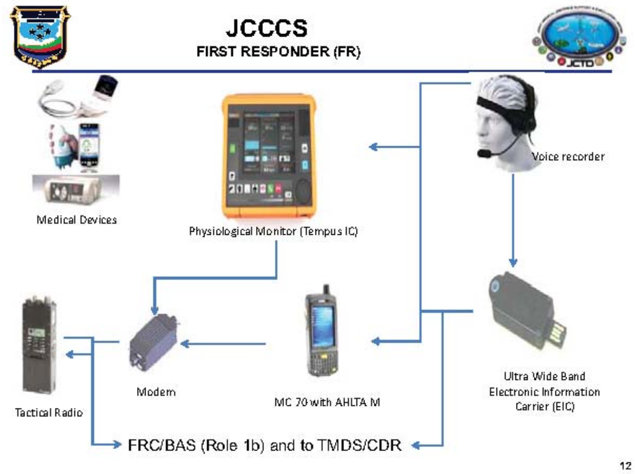

JMDSE Technology
Joint Precision Airdrop System Medical Express (JPADS-MedEx)
• Ultra Light Weight (ULW: 250-700 lbs) small medical bundles or equipment delivery
• Micro Light Weight (MLW: 10-150 lbs) robot/sensor/psyop delivery
• Integrate in Manned USAF/USMC Platforms: HH-60, CH-53, C-130, C-17, V-22
• Integrate MLW in Unmanned Aerial Systems: TIGERSHARK, MAVERICK, etc.
– Develop CONOPS and TTPs for future technical solution
– Collaborate with Marine Corps Warfighting Lab (MCWL) and other organizations to deliver JCCCS
– Observe other organizations proof-of-concept utilizing a UAS to extract critically injured, but stabilized personnel from denied/remote areas to a more accessible area
– Demonstrate quick reaction response to biological attack scenarios
Joint Combat Casualty Care System (JCCCS)
- Combat Casualty Care System (CCCS) – integrated medical support systems
- Telemedicine System
• Remote casualty care on land, in air and at sea
• Extended and enhanced medical support at the point of injury
• Automated Monitoring virtually connecting point of injury to higher medical echelon of care.
• Audio, data, and voice communications between First Responder (point of injury) and higher Health Service Support Capabilities (HSSC)
• Remote monitoring, recording and transmission of vitals; dispense fluids/medicines as needed/ directed by higher HSSC
• Quick reaction incident response to biological attack
7


JPADS-MedEx Precision Guided Parachutes
Micro-light Weight JPADS: 10-150lbs
Ultra-light Weight JPADS: 250-699lbs
Approx. 63.5lbs FRW
Approx. 222lbs FRW
Approx. 150lbs FRW
Accuracy requirements:
50m (T) / 10m (O)
Water proof AGUs
Approx. 30lbs FRW
8

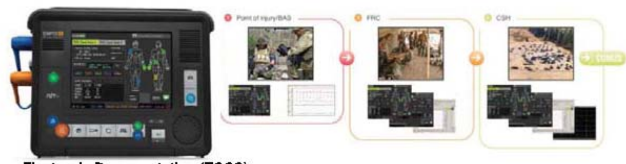

Tomahawk Mountainous Drop Zone
Yuma Proving Grounds
9


Operational Demonstration 2 Rehearsal
JPADS MedEx Results (Yuma Proving Grounds 16-20 Aug)
Used all delivery systems (MLW, ULW, Provider Pod)
Payload delivery accomplished (blood, plasma, surrogate & JCCCS equipment, consumables)
Delivered in relevant terrain
Med Survivability standards
Met Accuracy Standards (T) for most systems
Probability of Successful Flight – progressing to Threshold
"Any system that CONSISTENTLY delivers equipment to the first responder will have a direct impact for mission success." ACC/A8RG PJ
10


Tigershark with Provider POD
Monthly Drops 5k-10k ft
Provider POD
TCCC Kit
Blood – viable for use
11


JCCCS
FIRST RESPONDER (FR)
Medical Devices
Physiological Monitor (Tempus IC)
Voice recorder
Tactical Radio
Modem
MC 70 with AHLTA M
Ultra Wide Band Electronic Information Carrier (EIC)
FRC/BAS (Role 1b) and to TMDS/CDR
12

Documentation of Care, Sharing, Integration



Electronic Documentation (TCCC)

Ultrasound

13

Operational Demonstration 1B Phase II

- **JCCCS Results (Fort Detrick, MD 03-05 May)**
  - Used all JMDSE 1A care/monitoring systems
  - Evaluated CONOPS, systems & telemedicine capabilities for operational utility
    - Voice recording
    - Physiological monitoring
    - Physiological data storage
    - Data transmission to FRC using surrogate networks
  - Users reported utility for all systems (mission dependent, conditional based on future functional tests, varied usefulness at FR echelon)
  - Systems progressing toward threshold measures of performance

"I believe once the system is fully developed it will significantly enhance the first responders capabilities and the survivability of wounded/ injured personnel at the incident site." ACC/ASRG PJ

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OD1 After Action

ACC Pararescue Jumpers

"Any system that CONSISTENTLY delivers equipment to the first responder will have a direct impact for mission success."

"I believe once the system is fully developed it will significantly enhance the first responders capabilities and the survivability of wounded/ injured personnel at the incident site."

"MicroFly was the only system we had extensive time with. I strongly agree that the system will increase mission success in situations were the on-hand medical supplies do not meet the need."

"Systems were not followed during jumps. However, previous training showed that combo drops with guided systems will be a huge benefit for this mission set."

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JMDSE Event Calendar

Date	Event	Location
8-9 Sept	OD2B Rehearsal	AFMESA, Ft Detrick
10 Sept	OD2 Final Planning Conference	AFMESA, Ft Detrick
13-17 Sept	OD2A Execution	YPG, Yuma AZ
4-7 Oct	OD2B Execution	AFMESA, Ft Detrick
11 Nov	SUBLANT Test	Bahamas
5-15 Apr	Balikatan 11	Republic of Philippines
9-13 May	OD3	YPG

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Summary

- **Management**
  - Technical Managers, Operational Manager and Transition Manager are meeting on a regular basis
  - TELCONs every 2 weeks for feedback and information dissemination
  - CONOPS, Transition and Operational Demonstration Planning ongoing
  - DOTMLPF Findings & Recommendations
- **Technology/Capabilities/Metrics**
  - Technologies for JPADS-Med and JCCCS integration & testing
  - Capabilities and Metrics have been established and continue to be monitored
- **Milestones**
  - OD1B Completed – 19 – 23 Apr/3 - 7 May 2010
  - Monthly tech tests – ongoing
  - OD2 – 13 – 17 Sep/4 - 7 Oct 2010

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Questions/Discussion

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Operational Demonstration 2A
13-17 Sept at Yuma Proving Grounds

- **JPADS MedEx Objectives**
  - High Altitude JCCCS equipment drops (ULW, MLW)
  - Drop Blood in new design insulated container
  - Drop liquid and frozen plasma
  - Drop live vaccines, test assays, and BioChem sensors for DTRA
  - Drop in Mountainous area
  - Improve accuracy (focus on MLW, Provider; T-80% CEP, 50m)
  - Improve Probability of Successful Flight (T-92%)
  - Improve Packing, Rigging, Loading, GPS Retransmission Kit training.
  - Demonstrate a UAS extraction of a field test using Tigershark
  - Conduct combo drops with guided systems (PJ) (ULW-Microfly system)

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Operational Demonstration 2B
4-7 Oct at Fort Detrick, MD

- **JCCCS Objectives**
  - Evaluate capability using ground force, biological event and follow-on PJ scenario.
  - Advance the voice recording capabilities
  - Demonstrate TCCC card implementation (EIC/Tempus IC)
  - Improve User training
  - Demonstrate data transmission (voice reports, images, physiological data, snapshot waveforms over tactical radios)
  - Integrate portable data storage device into patient monitors
  - Evaluate FRC reachback capability
  - Create patient encounter report at FRC (text, images, snapshot waveforms)

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Capabilities/Metrics – JPADS-Med ULW/MLW

	JPADS-Med ULW (250-700 lbs)		JPADS-Med MLW (10-150 lbs)	
Capability	Baseline/Threshold	Objective	Baseline/Threshold	Objective
Altitude/Standoff	25,000 MSL with 8km offset	25,000 MSL with 30km offset	5,000-25,000 ft MSL, 8km offset at 25,000 ft MSL	25,000 MSL with 30km offset
Accuracy GPU (full weight class range)	150m CEP	50m CEP	50 m	10m CEP
Maritime Configuration	None	Rotation and Water Resistance	None	Rotation and Water Resistance
System Connectivity	Load mission planning data through hardwire	Load mission planning data wirelessly	Load mission planning data through hardwire	Load mission planning data wirelessly
Platform	C-130, C-17, V-22, CH-53, CH-46	C-7A Caribou, C-23B Sherpa, C-27A, DC-3, CASA 212 and Unmanned Aerial System (i.e. K-Max, A160)	C-130, C-17, V-22, CH-53, CH-46, TIGERSHARK, MAVERICK UAS	Same threshold
Canopy	Existing USMC inventory, MMPS MP 360, TP 400, MC-5	Existing USMC inventory, HG380	Parafoil and drogue	Same as threshold
Survivability	85% at 17 kts ground wind	85% at 25 kts ground wind	85% at 17 kts ground wind	85% at 25 kts ground wind
Guidance	Global Positioning System, Selective Availability/Anti Spoofing Module (SAASM) compliant	Global Positioning System, Selective Availability/Anti Spoofing Module (SAASM) compliant	Global Positioning System	Global Positioning System, Selective Availability/Anti Spoofing Module (SAASM) compliant
Reuse	15 times	30 times	15 times	30 times
Shock	4-7G opening shock, 15/18fps vertical drop	TBD by Service	4-7G opening shock, 15/18fps vertical drop	Same as threshold
Packing and Rigging Time	2 hours by trained operators	Same as threshold	2 hours by trained operators	Same as threshold
Interoperability	Fully compatible with Precision Airdrop System (PADS) software	Same as threshold	Fully compatible with Precision Airdrop System (PADS) software	Same as threshold

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Capabilities/Metrics – JCCCS

Capability	Baseline/Threshold	Objective
System Connectivity	Comms and stations hardwired to litter	Wireless connectivity
Shock resistance	4-7G opening shock, 15/18fps vertical drop	Same as threshold
Power	System battery pack - 3-6 hours	Same as threshold and plug into unit hotel power
Platform delivery	JPADS deliverable kits	Same as threshold and pack up kits, maritime configurations
Configuration	Litter interfaced system, FRC/BAS system, shipboard system	Fully integrated into threshold systems
Bandwidth	Scaleable down to 9.6KB	Same as threshold
Interoperability	Interoperable with existing tactical radios, i.e. SINGARS, INMARSAT	Same as threshold and JTRS Waveforms, MILSATCOM, & other Service systems

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Field Intravenous Fluid Reconstitution (FIVR)

Air Combat Command (ACC)/SGR, Langley AFB, Hampton, VA

LtCol Steven Stern

The objective of the FIVR project is to develop a Food and Drug Administration (FDA) approved device consisting of integrated medical components capable of producing packaged intravenous fluids for use by medical personnel in field locations. FIVR shall be capable of being employed at forward resuscitative care (or higher) deployed medical treatment facilities to provide initial resuscitative and surgical medical care to stabilize patients for evacuation to a higher level of care.

The FIVR device shall produce FDA approved IV solutions to include normal saline, half normal saline, dextrose 5% with normal saline, and lactated ringers at deployed locations for immediate use or storage. A pre-filter shall condition potable water to Environmental Protection Agency (EPA) quality where the FIVR device shall have the capability to condition the incoming water temperature; a function to sterilize the water suitable for injection; and an automated methodology to fill chemical pre-loaded bags to produce packaged intravenous solutions.

A FIVR device will culminate with FDA approval and will enhance capability reducing the medical logistical footprint and lift requirements. This operational outcome will facilitate essential care in theater and enhance care during contingencies. This capability is needed to decrease the risk of not having sufficient intravenous fluids available at deployed locations and reduce the logistical footprint (lift, storage, and waste) associated with the current operations requirement.

Headquarters Air Combat Command

Field Intravenous Fluid Reconstitution (FIVR)

Lt Col Steve Stern
Air Combat Command
Medical Modernization Division
25 August 2010

UNCLASSIFIED

Overview

- Our Mission
- Modernization Process
- FIVR Operational Capability

2

Bottom Line Up Front

- We support the warfighter and the deployed ground medic
- Supported missions include: force on force, humanitarian, disaster relief
- Team with Ground Manpower And Equipment Force Packaging Agency
- Deployed ground medic (end user) is our customer
- Identify capability gaps, define requirements and seek out solutions and advocate for deployed ground medic needs
- Transition solutions from a concept to a warfighter capability
- Provide world class expeditionary ground medical capabilities
- We are ACC/SG lead for Combat Air Force & AFMS Strategic Planning
- We are ACC/SG lead for Line & AFMS Program Objective Memorandum (POMs) R&D efforts
- Our partnerships include services, research labs, other DoD agencies

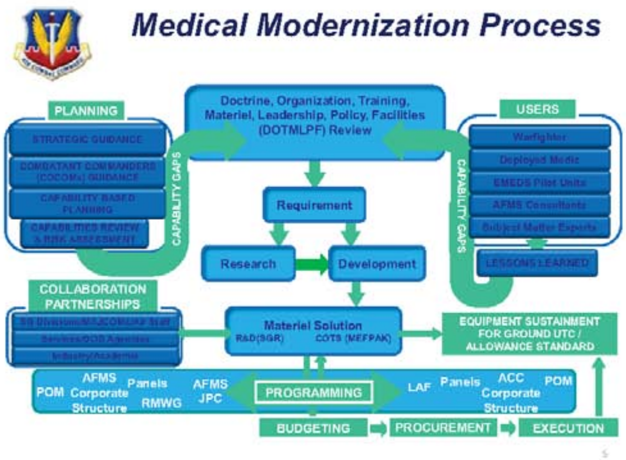
3

ACC Medical Modernization Planning Mission

- Support the warfighter and deployed ground medics by providing world class ground medical capabilities
- Harness leading edge technology to provide the link between current needs and future capabilities

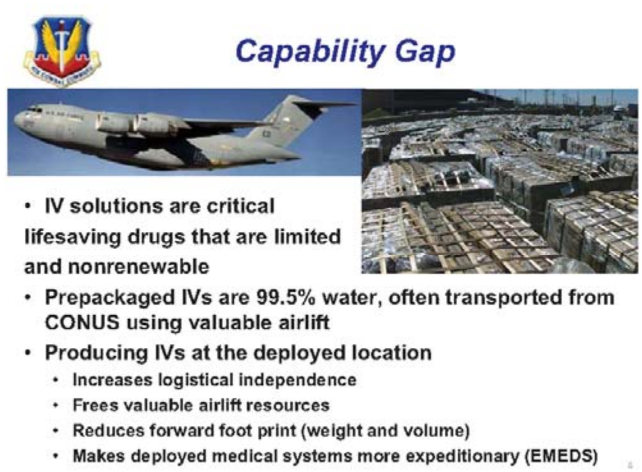
Objective: Transition Medical Solutions To The Warfighter

4


Medical Modernization Process
Doctrine, Organization, Training, Materiel, Leadership, Policy, Facilities (DOTMLPF) Review
PLANNING
STRATEGIC GUIDANCE
COMBATANT COMMANDERS (COCOMs) GUIDANCE
CAPABILITY BASED PLANNING
CAPABILITIES REVIEW & RISK ASSESSMENT
CAPABILITY GAPS
USERS
Warfighter
Deployed Medic
EMEDS Pilot Units
AFMS Consultants
Subject Matter Experts
LESSONS LEARNED
CAPABILITY GAPS
Requirement
Research
Development
COLLABORATION PARTNERSHIPS
Materiel Solution
R&D(SGR)
COTS (MEFPAK)
EQUIPMENT SUSTAINMENT FOR GROUND UTC / ALLOWANCE STANDARD
POM
AFMS Corporate Structure
Panels
RMWG
AFMS JPC
PROGRAMMING
LAF
Panels
ACC Corporate Structure
POM
BUDGETING
PROCUREMENT
EXECUTION


Overview
• Purpose: Discuss the operational capabilities of the FIVR device.
• Objective: Provide a summary of current integrated system design of the FIVR project.
• Funding: PE 64617
• LAF PE for RDT/E & OT/E
• Transition Warfighter Material Capability


History of Field IV Systems Lessons Learned
• Resuscitative Fluids Production and Reconstitution System (REFLUPS)
• Sterile Water For Injection device
• Lessons learned: Heat sterilization, automation, shelf life, and FDA approval


Capability Gap
• IV solutions are critical lifesaving drugs that are limited and nonrenewable
• Prepackaged IVs are 99.5% water, often transported from CONUS using valuable airlift
• Producing IVs at the deployed location
• Increases logistical independence
• Frees valuable airlift resources
• Reduces forward foot print (weight and volume)
• Makes deployed medical systems more expeditionary (EMEDS)

Required Capability

- To generate sterile water for topical use and intravenous (IV) fluids used in treatment of critical casualties
  - Used in forward resuscitative and field hospitalization facilities
  - Enhances expeditionary capability of medical first responders & initial/intermediate deployed medical treatment facilities
- Joint Future Capabilities: Focused Logistics & Protection
- Force on Force; WMD Threat; Humanitarian Assistance; and Civil-Military Operations
- AF CONOPS: Agile Combat Support (ACS)

Key Performance Parameters

CCJO Key Characteristics	Para #	KPP	Development Threshold	Development Objective	Rationale/ Analytical References
Expeditionary	6.1.2.1	Meets U.S. safety and efficacy standards	FDA approved with restrictions	FDA approved	DOD mandated standard of quality for medical materiel
Expeditionary	6.1.2.2	Produce IV fluids in the field	Pretreated source water complying with EPA standards derived from, STANAG 2136 water	Using any water source	Available water sources in the field environment

Force Protection/Survivability and Net Ready KPPs are Not Applicable

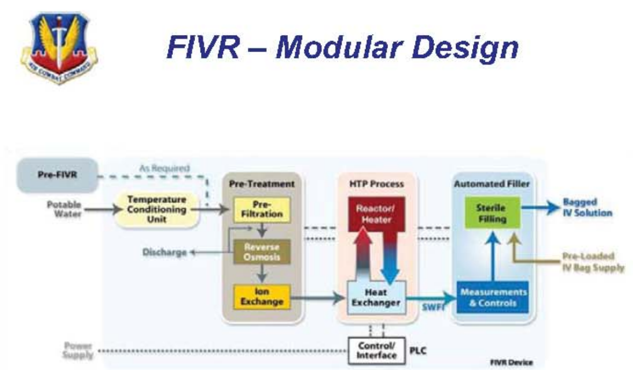
Key System Attributes

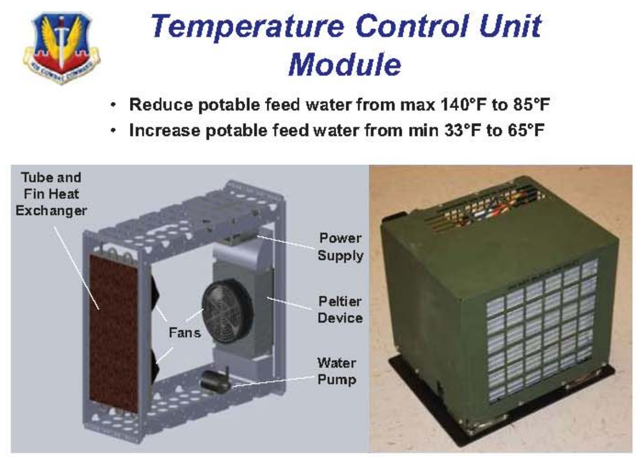
Description	Threshold Requirement	Objective Requirement
Produce FDA approved IV fluids in deployed locations	Same	Same
Source water temperature	33-140 Degrees F	Same
Source water quality	EPA quality from STANAG 2136	EPA quality from any source
Fluid production rate	10 L/hr	20 L/hr
Produce (IV) fluids	4 IV solutions	4 IV solutions
IV fluid shelf life	>30 days	>6 months
Pre-loaded bags shelf life	>12 months	>18 months
Modal weight	<120 lbs	<50 lbs
System size/volume	<20 cu ft	<6 cu ft
System power consumption	<6.0 kW	<2.0 kW
Waste effluent production rate	<20% of product	<5% of product
Product storage temperature	59-86 Degrees F	45-110 Degrees F

Intended Use
Make IV Solutions in the Field


Artist's Rendering

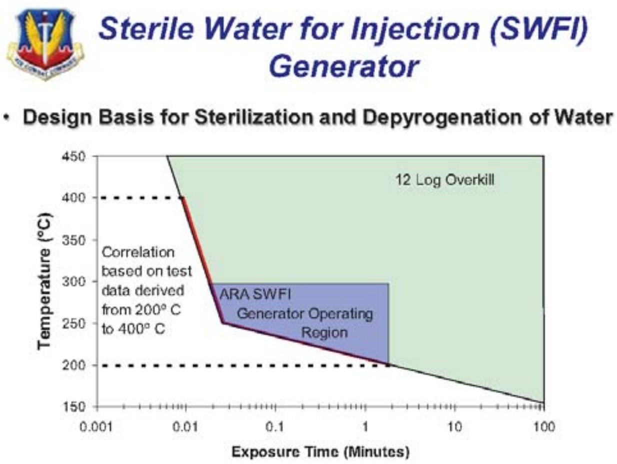
Provide FDA approved IV solutions in support of the full spectrum of deployed scenarios including wartime operations, deterrence and contingency operations, peacetime engagement, crisis response and humanitarian relief operations by trained military personnel.


FIVR – Modular Design
Pre-FIVR
As Required
Potable Water
Temperature Conditioning Unit
Pre-Treatment
Pre-Filtration
Reverse Osmosis
Ion Exchange
Discharge
HTP Process
Reactor/ Heater
Heat Exchanger
SWFI
Automated Filler
Sterile Filling
Measurements & Controls
Bagged IV Solution
Pre-Loaded IV Bag Supply
Power Supply
Control/ Interface
PLC
FIVR Device


Temperature Control Unit Module
• Reduce potable feed water from max 140°F to 85°F
• Increase potable feed water from min 33°F to 65°F
Tube and Fin Heat Exchanger
Power Supply
Peltier Device
Fans
Water Pump


FIVR Water Preconditioner "Pre-FIVR"
• The Pre-conditioned component takes potable water and conditions it to Environmental Protection Agency (EPA) National Primary Drinking Water Standards
• The U.S. Army Center for Health Promotion and Preventive Medicine conducted a worldwide analysis of water quality based on water test data to identify likely contaminants to potable water
• US Army TARDEC, Water Treatment and Handling Team designed the test parameters, test plan, and oversaw the tests.
• Commercial Off the Shelf (COTS) Reverse Osmosis Systems potable water challenge testing by the National Sanitation Foundation (NSF) International
• Gives a dual purpose Use for EMEDS


Sterile Water for Injection (SWFI) Generator
• Filtration (carbon filter/RO/IE Resin)
• Heat sterilization (hydrothermal)
• Quality Control
ALARM


Sterile Water for Injection (SWFI) Generator
Design Basis for Sterilization and Depyrogenation of Water
12 Log Overkill
Correlation based on test data derived from 200° C to 400° C
ARA SWFI Generator Operating Region
Temperature (°C)
Exposure Time (Minutes)
450
400
350
300
250
200
150
0.001
0.01
0.1
1
10
100

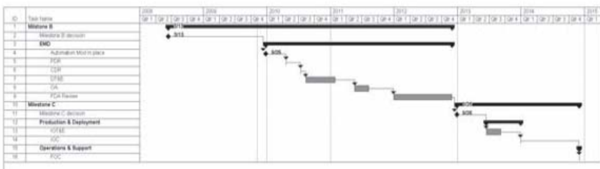

Components For Automation
Artist's Rendering
Aseptic Fill
Bar Code Reader
Hot Stamp Printer
PDC
ASEPTIC FILLING SYSTEMS


Bag Design
FDA compliance
Material Selection & Testing
Device Design Selection & Testing
Material Compatibility
Extractable / Leachable Investigation
Printing Compliance / Leaching Ink
MVTR & OTR / Influences Shelf Life
cGMP Commercial Manufacturability
Drug Loading / Equipment Investigation
Leak Analysis / Barrier Integrity / Migration & Ingress
Design with Push Port
Filled IV bag contains new lot number, expiration date, User ID


IV Bags Preloaded With USP Powder
Half Saline
Normal Saline
D5NS
Lactated Ringers
12 D5NS Bags Compared :
2.34 lbs
33 lbs
228 cu in
1632 cu in
Pilot Toxicity Testing – NMRC
Extended Shelf life

Road Ahead

- Final Configuration
- Food And Drug Administration Approval Strategy
- Test and Evaluation



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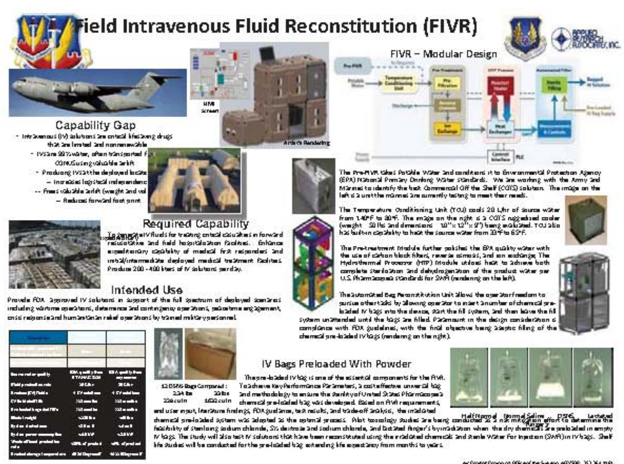
Gap + Requirement = Solution

- We want your input regardless of your rank, title or position
- Our job is to improve your ability to get things done, easier and faster
- Goal is to improve your deployment capabilities
- To do our job better we need help from your input
- Does not matter if need is a device or the need for a better way of doing things



A comparison of proximal tibia, proximal humerus and distal femur infusion rates under high pressure using the EZ-IO Intraosseous device on an adult swine model

59th Medical Wing (MDW)

Maj Julio Lairet

OBJECTIVES: Compare the intraosseous flow rates of the proximal tibia, distal femur and the proximal humerus using high pressure (>300 mmHg) in an adult swine model. METHODS: A 25mm EZ-IO needle was inserted into the proximal tibia bilaterally of eleven swine, and a 45mm needle was inserted into the distal femur and proximal humerus bilaterally. Intravascular volume was removed until the mean arterial pressure was decreased to 25% from baseline. Infusion of normal saline was carried out at each site for a period of 10 minutes with a pressure bag at highest achievable pressure (> 300 mmHg). At the end of 10 minutes infusion rates were calculated. Following euthanasia the bone IO insertion sites were harvested by the veterinary pathologist for histopathologic examination. Statistical analysis was performed using ANOVA. RESULTS: The mean infusion pressure for the tibia was 580 mmHg, 553 mmHg for the femur and 499 mmHg for the humerus. Comparing the infusion rates of the humerus (213 mL/min) to the tibia (138 mL/min) revealed a $p<0.001$. When comparing the humerus (213 mL/min) to the femur (138 mL/min); $p< 0.001$. Comparison between the tibia (103 mL/min) and the femur (138 mL/min) did not reveal statistical significance $p<0.138$. Histopathologic examination revealed minimal to mild subperiosteal and/or periosteal hemorrhage adjacent to where the intraosseous needle was inserted.

Conclusion: The rate of infusion was greater via the humerus route compared to the tibia and the femur. Additional studies are needed to further evaluate high pressure infusions (>300 mmHg) using intraosseous devices.

Develop America's Medical Airmen Today ... for Tomorrow

A comparison of proximal tibia, proximal humerus and distal femur infusion rates under high pressure (>300 mmHg) using the EZ-IO Intraosseous device on an adult swine (Sus scrofa) model

Maj Julio Lairet
Director Enroute Care Research Center

The opinions or assertions contained in this herein are the private views of the author and are not to be construed as official or as reflecting the views of the United States Air Force or the Department of Defense

Providing Great Care...Building Warrior Medics

Investigators

Develop America's Medical Airmen Today ... for Tomorrow

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- V. Bebarta [1]
- K. Lairet [2]
- R. Kaprowicz [1]
- C. Lawler [1]
- R. Pitotti [1]
- J. Cowart [1]
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Background

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- Acute hemorrhage is the leading cause of battlefield deaths in modern warfare.
- Intravenous access is the cornerstone of resuscitation.

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Background

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- Performing venous cut-downs or obtaining central venous access through the placement of an introducer into the subclavian or femoral veins can be time consuming, require surgical expertise, and is especially challenging when caring for multiple casualties due to a lack of personnel.

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Background

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- In the resuscitation phase, fluids and blood products need to be given rapidly, however the optimal method for pressure infusion through the EZ-IO® device is unknown.
- Currently, infusion rates through an IO in the adult patient are limited to that which can be generated through a pressure bag inflated to 300 mmHg.

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Background

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- A previous study comparing the infusion rates between the Belmont FMS 2000 rapid infusion device (RID) and pressure bag assisted flow through the EZ-IO® revealed statistically significant higher infusion rates when the pressure was >300 mmHg.

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Background

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- The femur has been used as an alternative site for placement of IO in pediatric patients.
- This site has not been validated for high volume resuscitation in the adult patient.

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Purpose

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- We compared the flow rates of the proximal tibia, distal femur and the proximal humerus using high pressure (>300 mmHg) through an intraosseous infusion needle on the adult *Sus scrofa* swine model.

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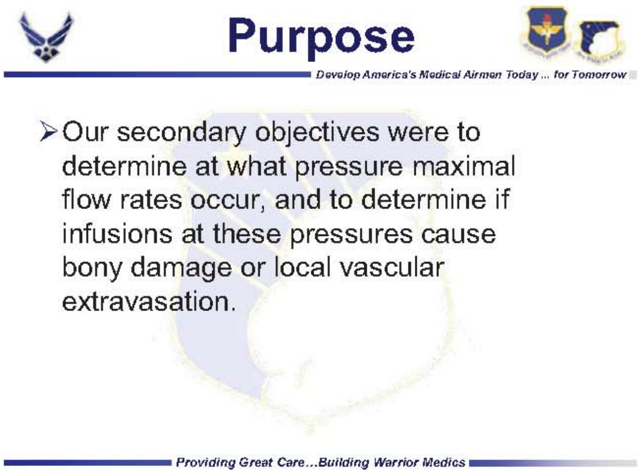
Purpose
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➢Our secondary objectives were to determine at what pressure maximal flow rates occur, and to determine if infusions at these pressures cause bony damage or local vascular extravasation.
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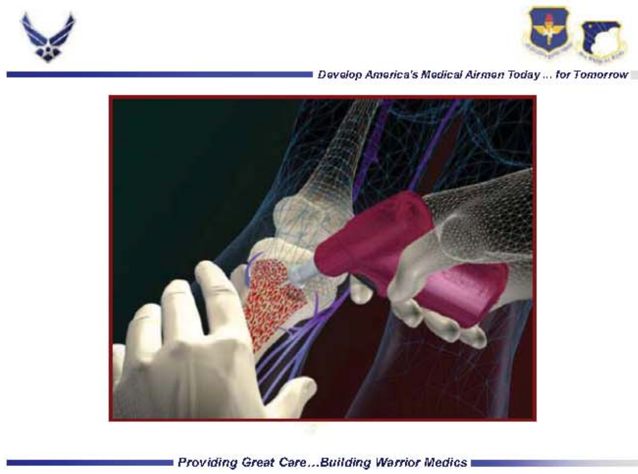
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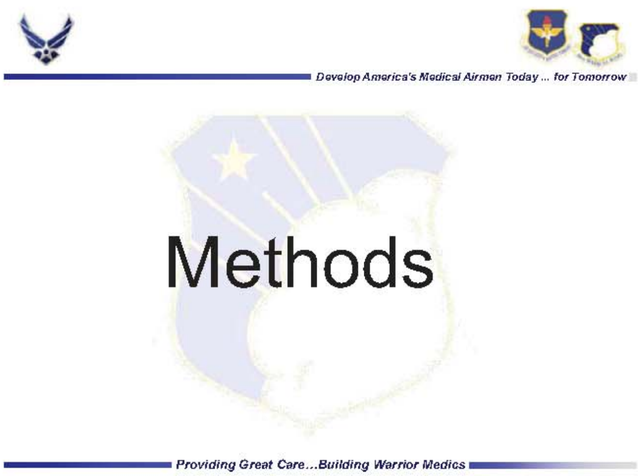
Develop America's Medical Airmen Today ... for Tomorrow
Methods
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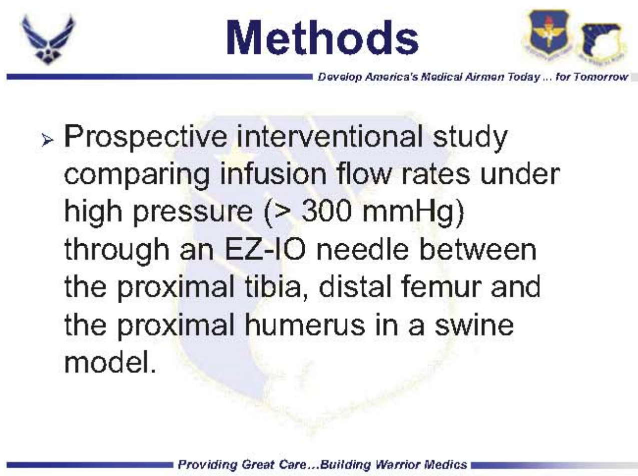
Methods
Develop America's Medical Airmen Today ... for Tomorrow
➢ Prospective interventional study comparing infusion flow rates under high pressure (> 300 mmHg) through an EZ-IO needle between the proximal tibia, distal femur and the proximal humerus in a swine model.
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EZ-IO Placement

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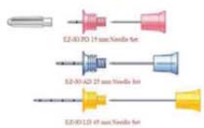
- A 25mm was placed in the proximal tibia bilaterally, and a 45mm needle was placed in the distal femur and proximal humeri bilaterally of eleven swine.



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EZ-IO Placement

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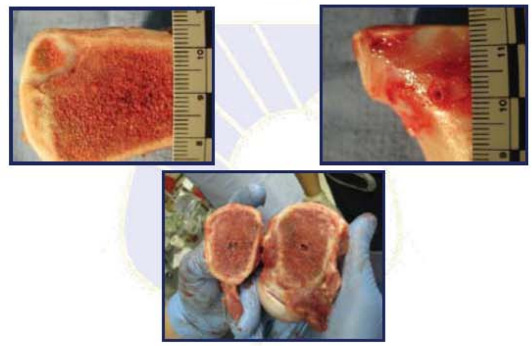

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EZ-IO Placement

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- Placement confirmed by
  - Bone marrow aspiration
  - Ease to normal saline flush
  - Direct visualization by contrast injection under fluoroscopy

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EZ-IO Placement

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Pressure Bag Infusion

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- Cuff inflated to 600 mmHg
- Pressure was monitored
- Pressure bag was pumped as necessary to maintain the highest possible pressure

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Pressure Measurement

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- Pressure measured at the infusion site with an Ashcroft General Purpose Digital Gauge at 15 sec intervals for 10 minutes

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Infusion Rate

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- At the end of the infusion:
  - volume of NS administered and flow rates were calculated

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Post Infusion

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- IV Contrast Infused to evaluate for extravasation post infusion.

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Pathology

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- Following euthanasia the bone IO insertion sites were harvested by the veterinary pathologist, fixed in 10% neutral buffered formalin, and decalcified in EDF decalcifying solution.
- The tissues were routinely processed for histopathologic examination.

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Statistical Analysis

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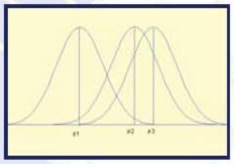
- ANOVA comparison of all three arms.



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RESULTS

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Results

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- The average weight of the swine was 71 Kg (range 64-84 Kg).
- Successful placement of the IO needle was confirmed in all the sites.

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Comparison of flow rates

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Site	Rate of infusion (mL/min)	Ave. Maximum pressure (mmHg)
Humerus	213 mL/min (SD 53.2 mL/min)	499 mmHg (SD 59.2)
Femur	138 mL/min (SD 65.3 mL/min)	553 mmHg (SD 61.7)
Tibia	103 mL/min (SD 48.1 mL/min)	580 mmHg (SD 54.7)

p<0.001

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Comparison of flow rates

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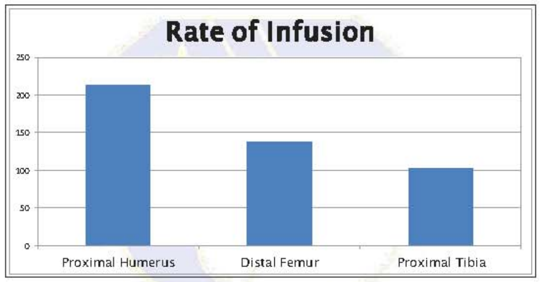

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Post Hoc analysis Turkey HSD

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- Comparison of flow rates:
  - Humerus (213 mL/min) versus the tibia (103 mL/min) and the femur (138 mL/min) revealed statistical significance with p<0.001
  - Tibia (103 mL/min) versus femur (138 mL/min) did not reveal statistical significance with p<0.138

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Comparison of Mean IO infusion pressure

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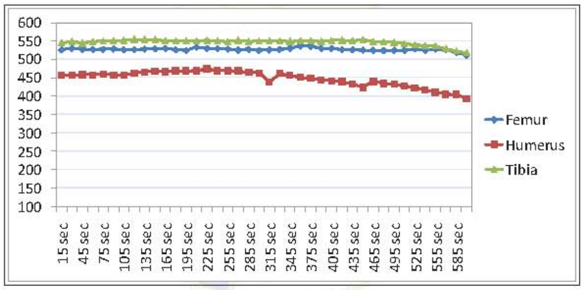

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Extravasation of Contrast

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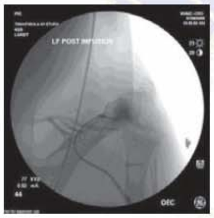
- We did not detect contrast extravasation post infusion.

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Histopathologic Examination

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- Revealed minimal to mild subperiosteal and/or periosteal hemorrhage adjacent to where the intraosseous needle was inserted, with minimal to mild hemorrhage within the marrow space, and variable amounts of subperiosteal and scattered bone debris.
- These findings are consistent with intraosseous device placement and we considered them clinically insignificant.

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Histopathologic Examination

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- The IO device needle extended through the compact cortical bone on all samples and terminated within the medullary cavity or in cancellous bone.
- Fracture of the bone, misplacement, and posterior bone cortex disruption were not found.

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Limitations

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1. The primary limitation is the use of an animal model.
2. The infusion period in this study was limited to ten minutes.
3. This study did not evaluate histopathology of the lung tissue for the potential risk of fat or bony emboli.
4. The data established in this study only pertain to the IO device and insertion sites. This data may not translate to other IO devices, insertion sites.

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Conclusion

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- The rate of infusion was greater via the humerus route compared to the tibia and the femur.
- In this model the humerus appears to be superior site to the tibia and femur for resuscitation with crystalloids.

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Conclusion

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- We found that the swine bone tolerated pressures > 300 mmHg without clinical histopathologic damage.
- Additional studies are needed to further evaluate high pressure (>300 mmHg) infusions using intraosseous devices.

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Way Ahead

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- Blood
- Evaluation for pulmonary fat embolism
- Plasma

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Questions?

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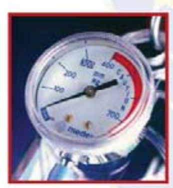

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Inflammation Following Hemorrhage and AE

United States Air Force School of Aerospace Medicine (USAFSAM)/Center for Sustainment of Trauma and Readiness (CSTARS); Cincinnati, OH

Tim Pritts, MD, PhD

OBJECTIVES: Hemorrhage is the leading cause of potentially preventable mortality in current military conflicts and is associated with acute inflammation. Improved resuscitation strategies are necessary for optimal outcomes, but the effect of hypobaric hypoxia on the inflammatory response to hemorrhage and resuscitation is unknown. We hypothesized that exposure to hypobaric hypoxia may alter the acute inflammatory response. METHODS: Mice underwent femoral artery cannulation and hemorrhage using a pressure-clamp model, then resuscitation with Lactated Ringer's solution (LR) or a 1:1 ratio of fresh packed red cells and plasma from donor animals (1:1). At 1 and 24 hours following resuscitation, mice underwent simulated shock in mice. These findings suggest that the current practice of aeromedical evacuation following injury, including rapid transport to higher echelons of care, may not negatively impact the inflammatory response following hemorrhage.

Inflammation Following Hemorrhage and Aeromedical Evacuation

Amy T. Makley MD, Michael D. Goodman MD, Eric Campion MD, Dennis Sonnier MD, Lou Ann W. Friend RVT, Rebecca Schuster, Stephanie Bailey, Warren C. Dorlac MD, Jay A. Johannigman MD, Alex B. Lentsch PhD, Timothy A. Pritts MD, PhD

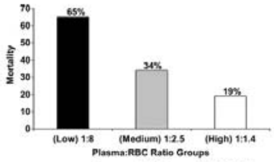
Department of Surgery, University of Cincinnati

Hemorrhagic Shock

- Leading cause of potentially preventable mortality following traumatic injury
- Global ischemia-reperfusion injury
- Dysfunctional systemic inflammatory response
  - Infection, multi-system organ failure

Resuscitation

Potential opportunity
- Attenuate inappropriate inflammation
- Reduce organ injury
- Improve survival
- Affect late complications



Borgman et al, *J Trauma*, 2007: 805-813

Aeromedical Evacuation

- Rapid transport of critically ill patients
- Patients may be exposed to hypobaric hypoxia
- Even mild hypobaric hypoxia may alter the response to injury

Hypobaric Hypoxia

- Moderate altitude change occurs during commercial and military flight
- Altitude exposure may lead to:
  - Hypoxia – oxygen saturation levels to <90%
  - Symptoms similar to acute mountain sickness
    - Even after 3 hours in commercial flight conditions
  - Effects of continued altitude exposure may be mediated by inflammation

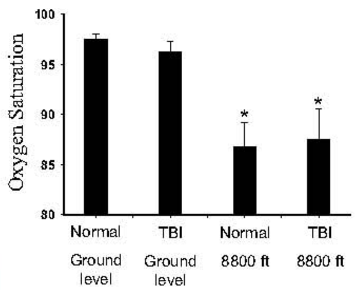
University of Cincinnati

AE and Inflammatory Response

- Hypobaric hypoxia could represent a "second hit"
  - Timing of post-injury AE could impart physiologic stressors that adversely influence outcome
- Few studies exist that:
  - Characterize the inflammatory response to AE
  - Address the impact of AE on injury patterns
  - Guide optimization of the immunological status to minimize the physiologic impact of flight

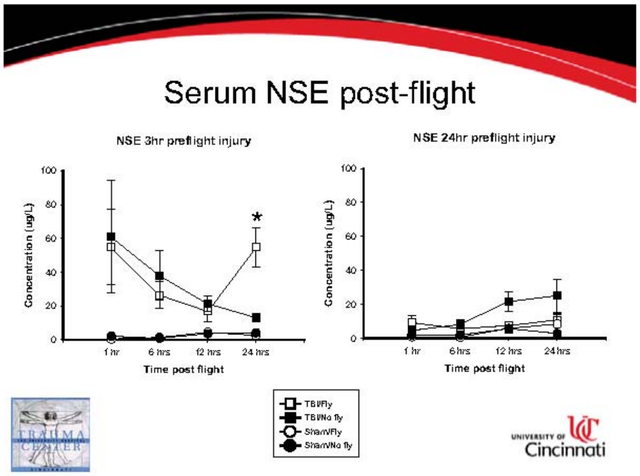
University of Cincinnati

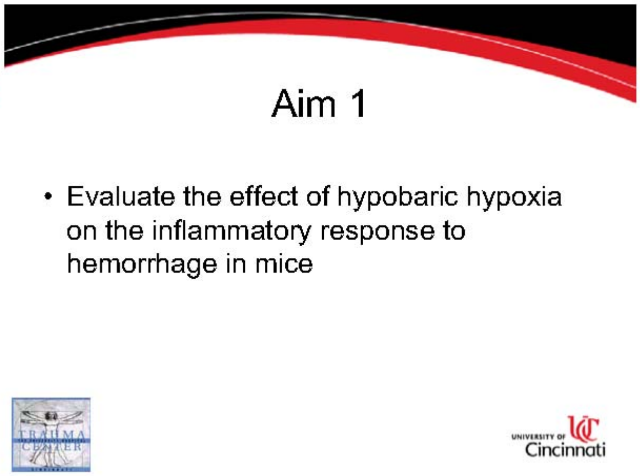
Effect of Altitude: Hypoxia

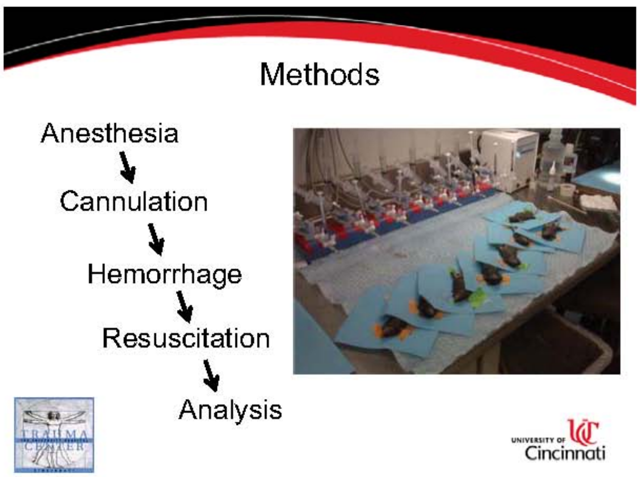


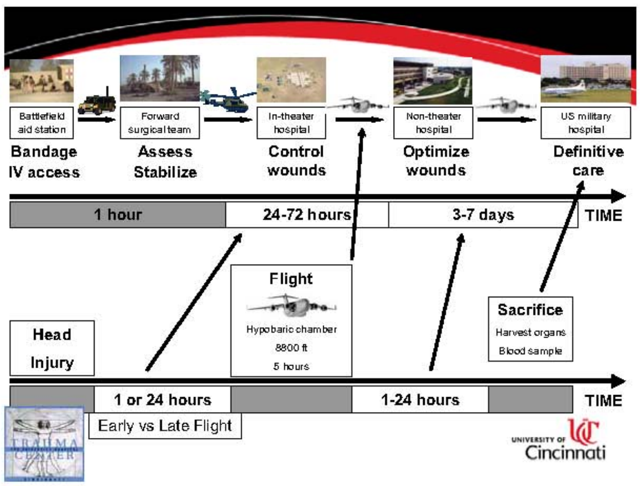
University of Cincinnati

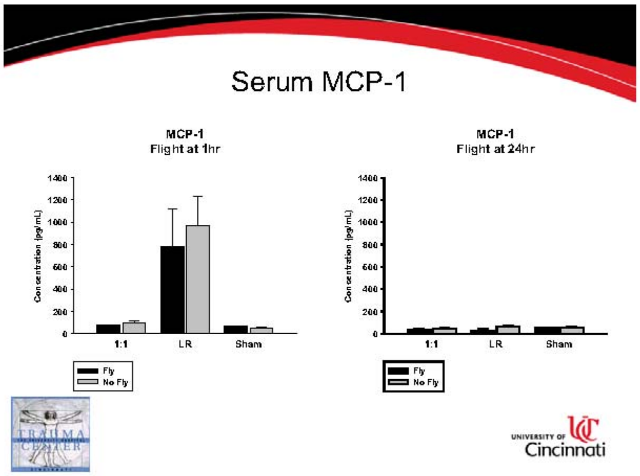
Effects of Altitude: Hypoxia

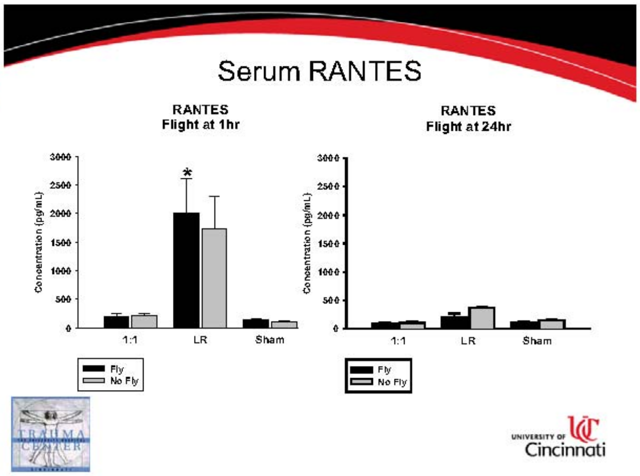

Serum NSE post-flight
NSE 3hr preflight injury
NSE 24hr preflight injury
Concentration (ug/L)
Time post flight
1 hr
6 hrs
12 hrs
24 hrs
TBI/Fly
TBI/No fly
Sham/Fly
Sham/No fly
UNIVERSITY OF Cincinnati

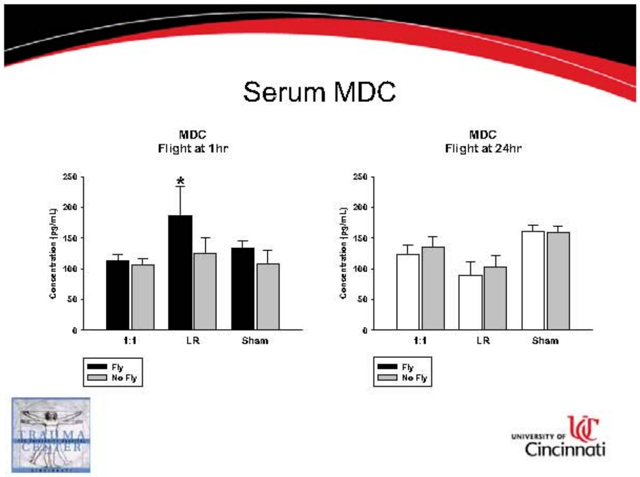

Aim 1
• Evaluate the effect of hypobaric hypoxia on the inflammatory response to hemorrhage in mice
UNIVERSITY OF Cincinnati

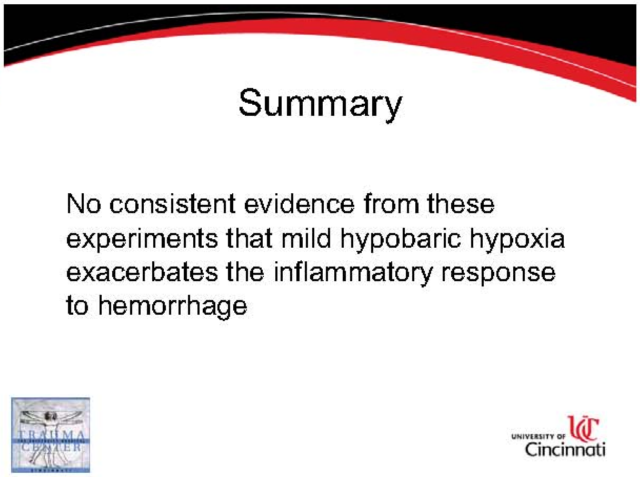

Methods
Anesthesia
Cannulation
Hemorrhage
Resuscitation
Analysis
UNIVERSITY OF Cincinnati


Battlefield aid station
Forward surgical team
In-theater hospital
Non-theater hospital
US military hospital
Bandage IV access
Assess Stabilize
Control wounds
Optimize wounds
Definitive care
1 hour
24-72 hours
3-7 days
TIME
Flight
Hypobaric chamber
8800 ft
5 hours
Sacrifice
Harvest organs
Blood sample
Head Injury
1 or 24 hours
1-24 hours
TIME
Early vs Late Flight
UNIVERSITY OF Cincinnati


Serum MCP-1
MCP-1
Flight at 1hr
MCP-1
Flight at 24hr
Concentration (pg/mL)
1:1
LR
Sham
Fly
No Fly
UNIVERSITY OF Cincinnati


Serum RANTES
RANTES
Flight at 1hr
RANTES
Flight at 24hr
Concentration (pg/mL)
1:1
LR
Sham
Fly
No Fly
UNIVERSITY OF Cincinnati


Serum MDC
MDC
Flight at 1hr
MDC
Flight at 24hr
Concentration (pg/mL)
1:1
LR
Sham
Fly
No Fly
UNIVERSITY OF Cincinnati


Summary
No consistent evidence from these experiments that mild hypobaric hypoxia exacerbates the inflammatory response to hemorrhage
UNIVERSITY OF Cincinnati

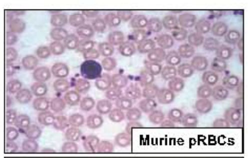
Aim 2

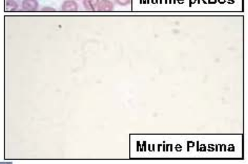
- Evaluate the effect of blood component transfusion on the inflammatory response to hemorrhagic shock in mice

Background

- "Standard of care" is crystalloid first, then pRBCs, then other products as needed
- Whole blood likely best, but not widely available
- How does a 1:1 ratio of plasma:pRBCs influence systemic inflammation?

Methods


Murine pRBCs


Murine Plasma

Anticoagulant

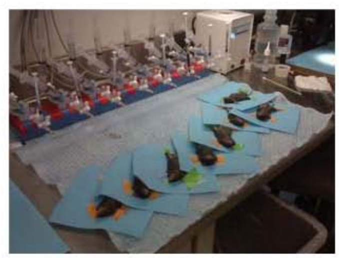
CP2D (Citrate Phosphate Double Dextrose)
- Glucose 257.6 mmol/L
- Citrate-citric acid 105.0 mmol/L
- Sodium phosphate 18.5 mmol/L
- pH 5.7

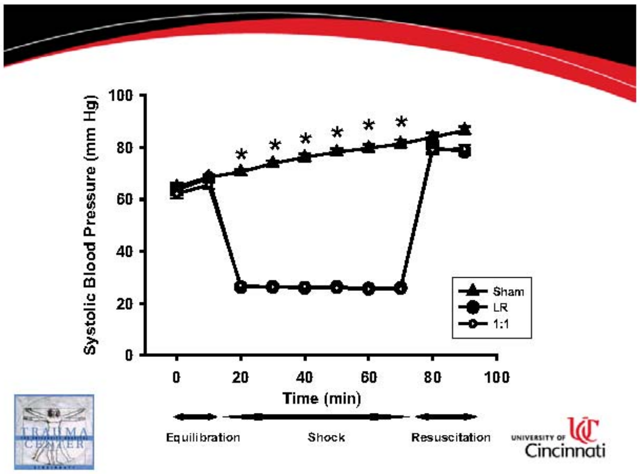
RBC additive solution

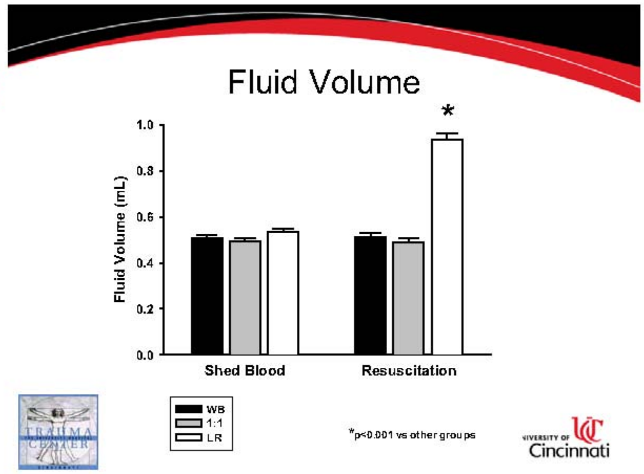
AS-3 (Nutricel)
- Glucose 55.5 mmol/L
- Sodium chloride 70.1 mmol/L
- Sodium phosphate 20 mmol/L
- Citric acid 12 mmol/L
- Adenine 2.2 mmol/L
- pH 5.8

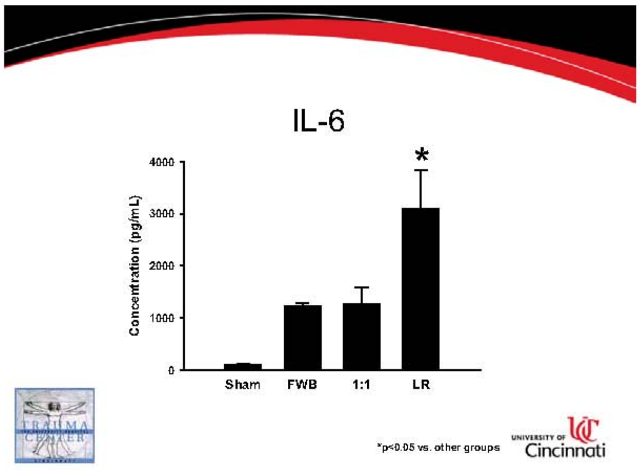
Methods

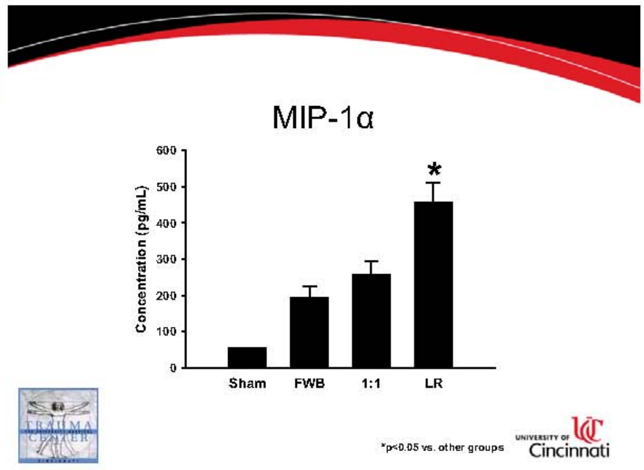
Anesthesia → Cannulation → Hemorrhage → Resuscitation → Analysis

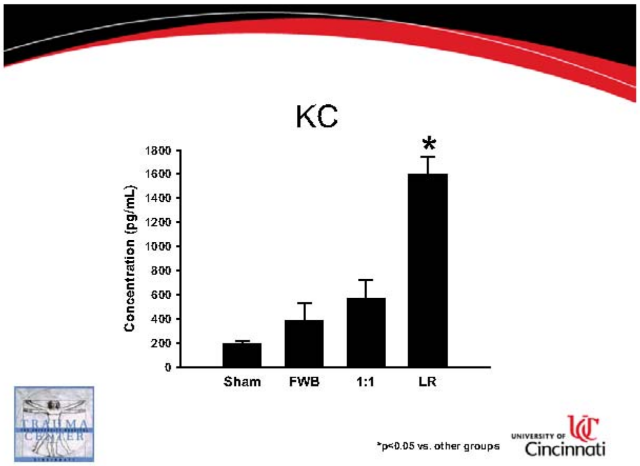


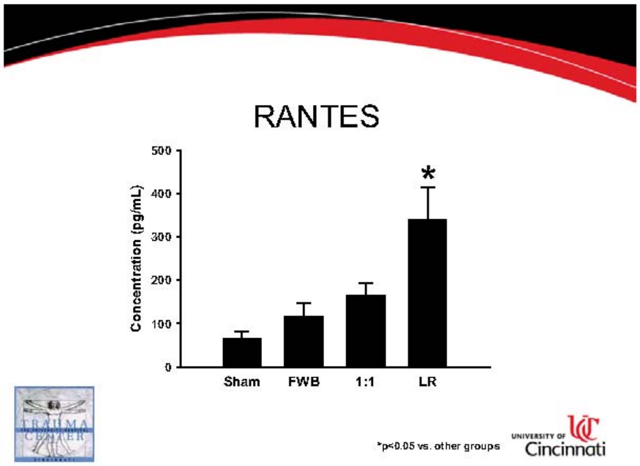

Systolic Blood Pressure (mm Hg)
100
80
60
40
20
0
0
20
40
60
80
100
Time (min)
Sham
LR
1:1
Equilibration
Shock
Resuscitation
UNIVERSITY OF Cincinnati

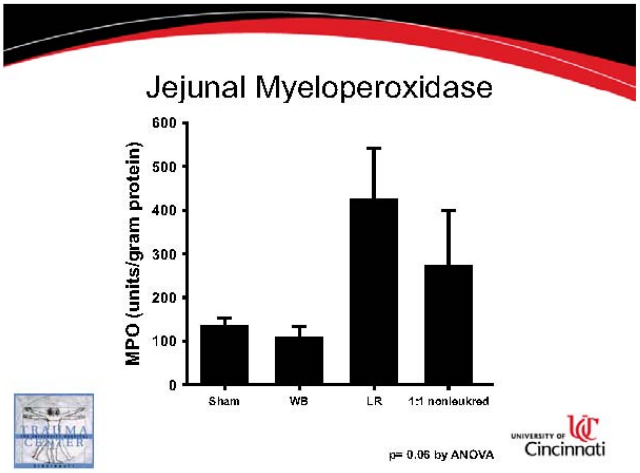

Fluid Volume
Fluid Volume (mL)
1.0
0.8
0.6
0.4
0.2
0.0
Shed Blood
Resuscitation
WB
1:1
LR
*p<0.001 vs other groups
Cincinnati

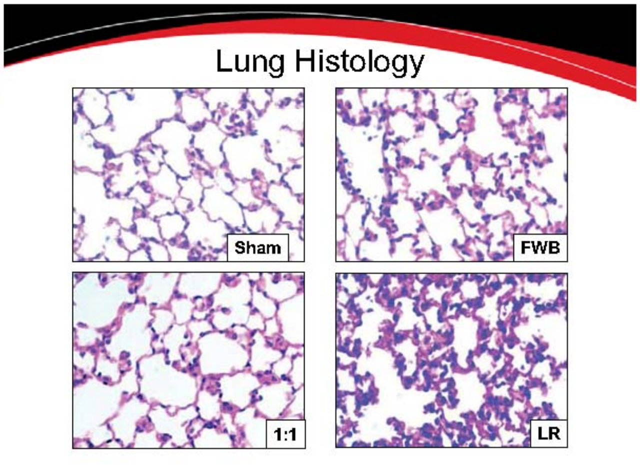

IL-6
Concentration (pg/mL)
4000
3000
2000
1000
0
Sham
FWB
1:1
LR
*p<0.05 vs. other groups
UNIVERSITY OF Cincinnati


MIP-1α
Concentration (pg/mL)
600
500
400
300
200
100
0
Sham
FWB
1:1
LR
*p<0.05 vs. other groups
UNIVERSITY OF Cincinnati


KC
1800
1600
1400
1200
1000
800
600
400
200
0
Concentration (pg/mL)
*
Sham
FWB
1:1
LR
*p<0.05 vs. other groups
UNIVERSITY OF Cincinnati


RANTES
500
400
300
200
100
0
Concentration (pg/mL)
*
Sham
FWB
1:1
LR
*p<0.05 vs. other groups
UNIVERSITY OF Cincinnati


Jejunal Myeloperoxidase
600
500
400
300
200
100
0
MPO (units/gram protein)
Sham
WB
LR
1:1 nonleukred
p= 0.06 by ANOVA
UNIVERSITY OF Cincinnati


Lung Histology
Sham
FWB
1:1
LR

Summary

- Conventional crystalloid administration, FWB, and 1:1 each achieve goal resuscitation parameters
- Resuscitation with warm FWB
  - Requires less fluid volume
  - Decreases systemic inflammation
  - Reduces pulmonary capillary leak
  - Attenuates lung injury
- 1:1 ratio of plasma to pRBCs very similar to whole blood

Aim 3

- Evaluate the effects of varied ratios of blood and FFP (“damage control resuscitation”) on the inflammatory response to hemorrhage in mice

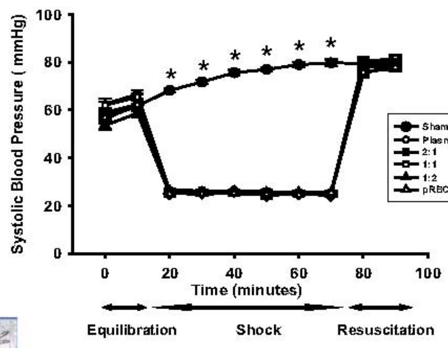
Background

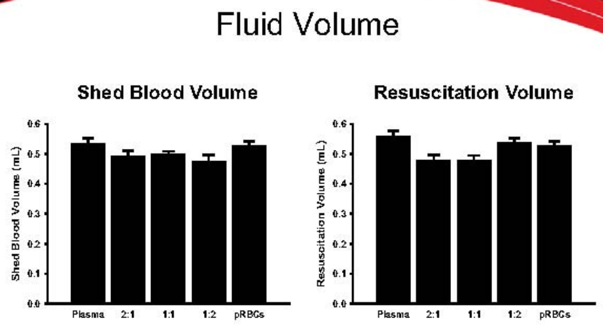
	Ratio of Products	Mortality
Borgman, 2007	1:1.4 plasma:pRBCs	↓
Gunter, 2007	2:3 plasma:pRBCs	↓
Sperry, 2008	1:1.5 plasma:pRBCs	↓
Schreiber, 2009	1:1 plasma:pRBCs	↓
Holcomb, 2009	1:2 plasma:pRBCs	↓

- Retrospective reviews
  - Association between high ratios of plasma:pRBCs and survival
  - Potential confounder of survival bias

Hypothesis

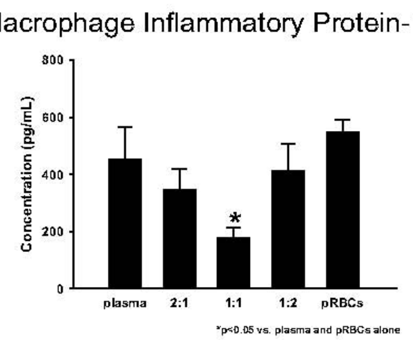
Transfusion of a high ratio of plasma:pRBCs would decrease the systemic inflammatory response following hemorrhagic shock

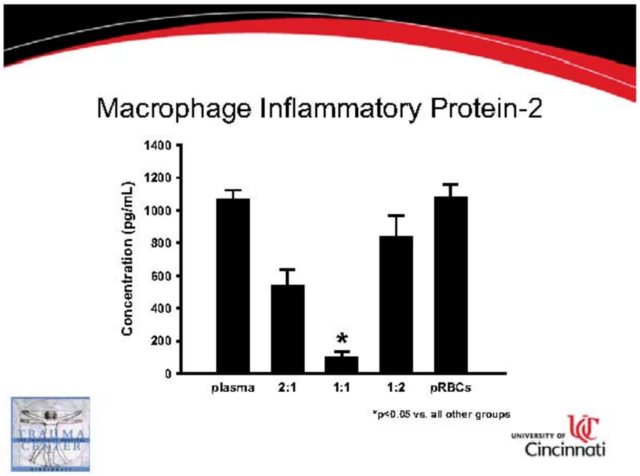


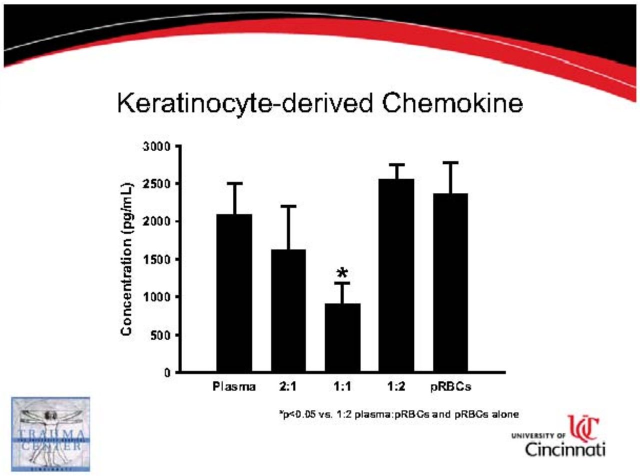


Resuscitation Strategy	pH	Base Excess	HCO_3^- (mmol/L)	Lactate (mmol/L)	Hb (grams)
Plasma	7.48±0.02*	1.2±1.5	24.6±1.4	1.84±0.27	9.83±0.33**
2:1 plasma:pRBCs	7.29±0.02	1.5±0.6	28.2±0.7	0.78±0.06	11.22±0.73
1:1 plasma:pRBCs	7.35±0.02	-0.2±1.2	23.2±1.2	1.62±0.68	10.28±0.92**
1:2 plasma:pRBCs	7.33±0.04	0.8±1.1	24.8±1.3	1.33±0.26	13.20±0.60
pRBCs	7.29±0.01	-1.0±0.4	26.1±0.5	2.06±0.69	13.08±0.58

*p<0.05 vs. all other groups;
**p<0.05 vs. pRBCs and 1:2 plasma:pRBCs




Macrophage Inflammatory Protein-2
Concentration (pg/mL)
1400
1200
1000
800
600
400
200
0
*
plasma
2:1
1:1
1:2
pRBCs
*p<0.05 vs. all other groups
UNIVERSITY OF Cincinnati


Keratinocyte-derived Chemokine
Concentration (pg/mL)
3000
2500
2000
1500
1000
500
0
*
Plasma
2:1
1:1
1:2
pRBCs
*p<0.05 vs. 1:2 plasma:pRBCs and pRBCs alone
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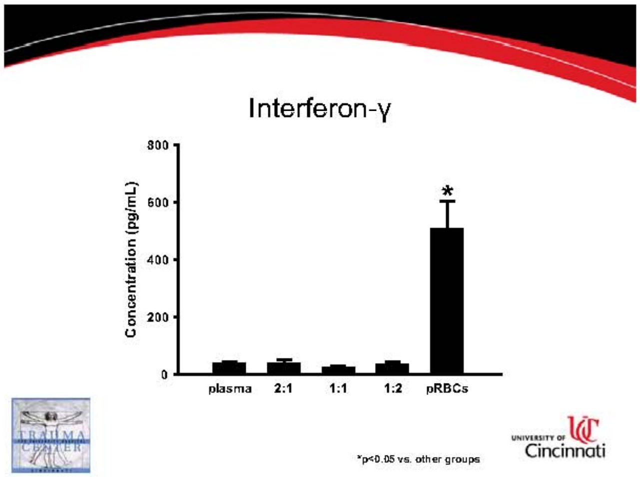
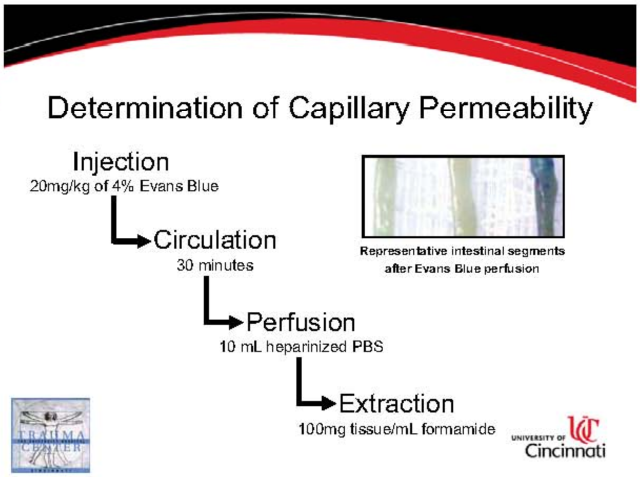
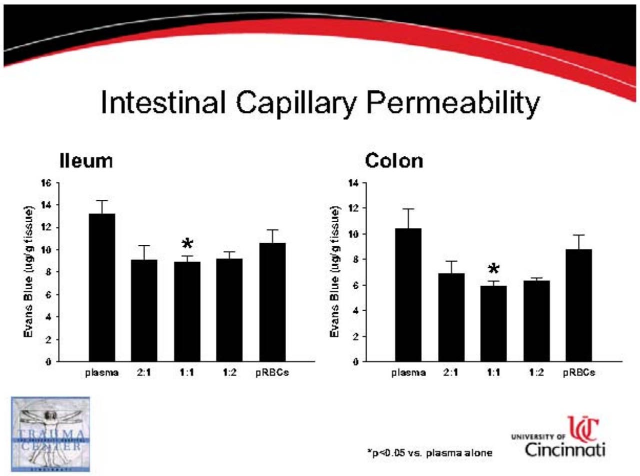
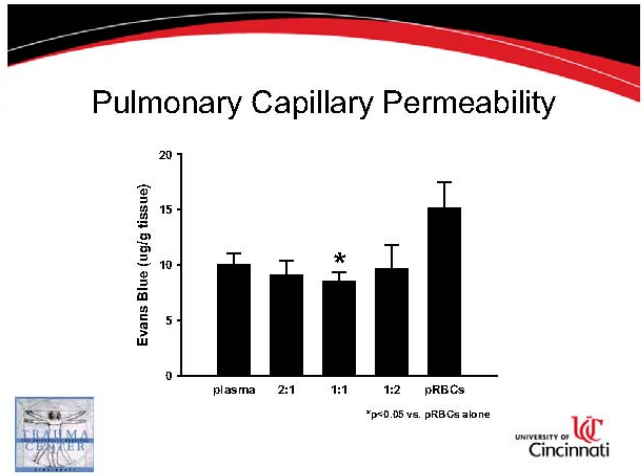
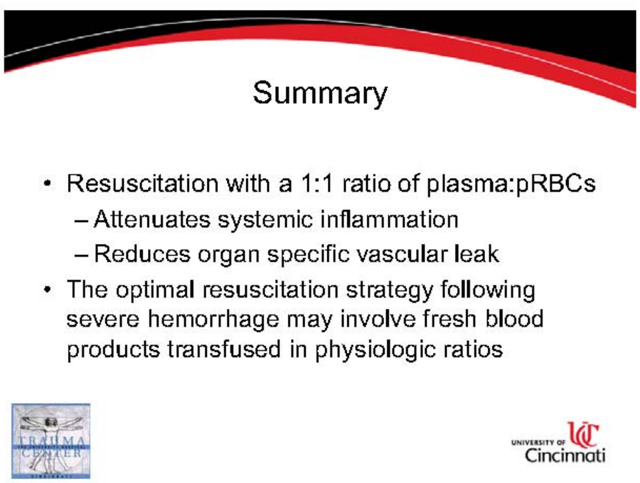
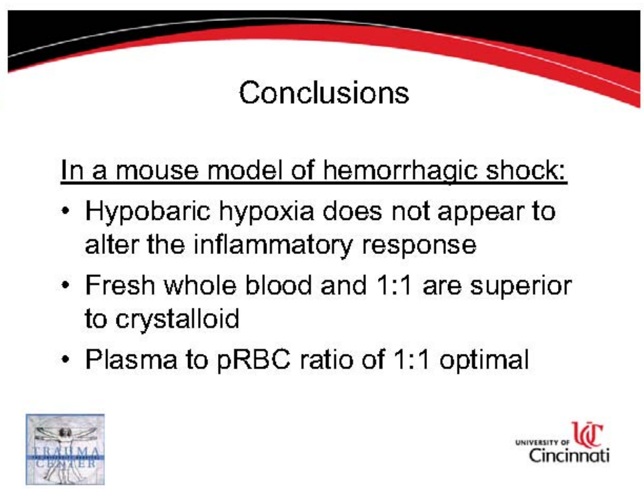

Interferon-γ
Concentration (pg/mL)
800
600
400
200
0
*
plasma
2:1
1:1
1:2
pRBCs
*p<0.05 vs. other groups
UNIVERSITY OF Cincinnati

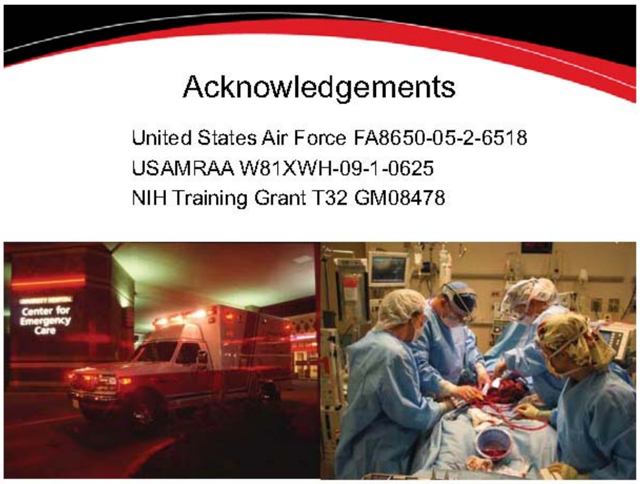

Determination of Capillary Permeability
Injection
20mg/kg of 4% Evans Blue
Circulation
30 minutes
Perfusion
10 mL heparinized PBS
Extraction
100mg tissue/mL formamide
Representative intestinal segments
after Evans Blue perfusion
UNIVERSITY OF Cincinnati


Intestinal Capillary Permeability
Ileum
Colon
Evans Blue (ug/g tissue)
plasma
2:1
1:1
1:2
pRBCs
*
*p<0.05 vs. plasma alone
University of Cincinnati


Pulmonary Capillary Permeability
Evans Blue (ug/g tissue)
plasma
2:1
1:1
1:2
pRBCs
*
*p<0.05 vs. pRBCs alone
University of Cincinnati


Summary
• Resuscitation with a 1:1 ratio of plasma:pRBCs
– Attenuates systemic inflammation
– Reduces organ specific vascular leak
• The optimal resuscitation strategy following severe hemorrhage may involve fresh blood products transfused in physiologic ratios
University of Cincinnati


Conclusions
In a mouse model of hemorrhagic shock:
• Hypobaric hypoxia does not appear to alter the inflammatory response
• Fresh whole blood and 1:1 are superior to crystalloid
• Plasma to pRBC ratio of 1:1 optimal
University of Cincinnati


Acknowledgements
United States Air Force FA8650-05-2-6518
USAMRAA W81XWH-09-1-0625
NIH Training Grant T32 GM08478
Center for Emergency Care

MAF Aircrew Fatigue Countermeasures Survey

United States Air Force School of Aerospace Medicine (USAFSAM)

Col/Dr. Jane Karen Klingenberger

No Go Pills (hypnotics) have been available to aircrews for several years for use in operational settings; however, to date there has been no assessment of their efficacy. Are Mobility Air Force (MAF) aircrews effectively utilizing pharmaceuticals that enhance sleep (hypnotics) to count the effects of "jet lag" and other operational disruptors including circadian rhythm?

Currently there are three hypnotics that are ground tested and approved for all MAF aircrews. The presentation will be a review and discussion based on a new aircrew survey and the results of a convenience sample of respondents assessing the self reported frequency and effectiveness of "No Go" medication use.

Preliminary data suggests that 40%-50% of MAF aircrews are using "No Go" medication while TDY or on overseas missions with a statistically significant difference in the length of sleep.

Headquarters U.S. Air Force

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Preliminary Survey Results: Fatigue Countermeasures Use in Mobility Air Forces

Colonel Karen Klingenberger, MD, MPH
Air National Guard Readiness Center
Deputy Air Surgeon
25 Aug 2010

Year of the Air Force Family

1

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Overview

- Background
- Methods
- Study Design
- Results
- Discussion
- Strengths/Weaknesses
- Implications

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Background

- Sleep is a basic but precious commodity
  - Elusive during sustained global operations
- Aircrew cannot be trained to become less physiologically fatigue
- Restorative sleep is required to recover from severe physiological fatigue

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Background

- Mitigation of fatigue is complex
- Occupational risk interventions
  - Engineering controls
    - Billeting
  - Administrative Controls
    - Policies
    - Education
    - Scheduling
      - AMMO/FAST

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But, When Administrative Controls Aren't Enough…

Year of the Air Force Family

Background

- Personal protection/intervention
  - Sleep hygiene
  - Napping/Inflight napping
  - Hypnotics or "no go" medication

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Background

- 2001 USAF policy changed
- 2003 AMC authorized hypnotics/"no go"
- Three approved medications
  - Restoril (temazepam)
  - Ambien (zolpidem)
  - Sonata (zaleplon)

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Background

- Characterize use of "no go" medications
  - Commissioned through USAFSAM by AMC/SG, Maj Gen Robb
  - Target population Air Mobility Command
  - Expanded for all Mobility Air Forces

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Methods

- Literature Search
- Survey Development →Iterative Process
  - Expert Input
    - Dr. Nancy Wesensten (WRAIR)
  - Operational Input
    - Pilots
    - Flight Surgeons
  - Pilot Testing
    - Oklahoma Air National Guard

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Methods

- Survey Deployment
  - Anonymous survey offered at FlyAwake.org
  - Dates
    - 1 April to 30 April 2010
  - Initially deployed through an FCIF
  - E-mail reminder
    - Cosigned letter
      - MG Bash AMC (Operations) and MG Robb AMC (Surgeon General)
    - 15 April 2010

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Methods - Study Design

- Structure
  - 66 questions
    - 62 questions
      - Qualitative
      - Quantitative
        - Likert scales1 to 7
    - 4 comment questions
  - Four sections
    - Demographics
    - Sleep patterns at homestation
    - Sleep patterns while TDY or overseas
    - General questions

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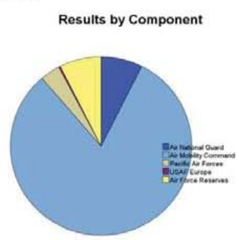
Results

Demographics

- Cummulative Responses
  - Estimatedover 10,000 in MAF
  - 1037 responses/10%
- Components
  - Air Mobility Command (AMC)
    - 843 responses/81.3%
  - Air Force Reserves (ARC)
    - 77 responses/7.4%
  - Air National Guard (ANG)
    - 77 responses/7.4%
  - Pacific Air Force (PACAF)
    - 37 responses/3.6 %
  - USAF Europe (USAFE)
    - 3 responses/.3%



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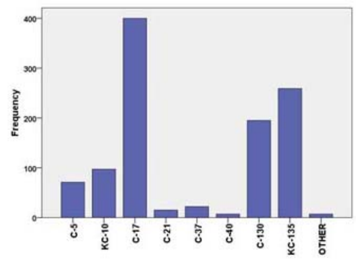
Results

Demographics – Crew Positon

- Rank
  - Officer – 733/70.7%
  - Enlisted –304/29.3%
- Age
  - Median – 31 years
  - Range – 40 years
    - Ages 19 to 59
- Years in service
  - 73% < 15 years
- Flying Hours
  - 50% > 2000 hours
- Crew Position
  - Pilots 63.9 %
  - Load Master 14,3 %
  - Flight Engineers 6.6 %
  - Boom Operators 5.5 %
  - Navigators 3 %
  - Others 7%
- Aircraft



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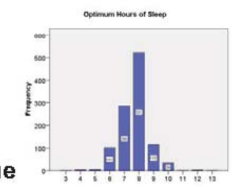
Results

- Amount of sleep to feel fully rested
  - 7.71 hours
- Sleep at homestation
  - 7.07 hours
- Sleep TDY/Overseas
  - 6.55
- 83.5% not ready to fly due
  - 1% of the time or greater



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Results

- 86.9% tested one or more approved "no go"
  - 47.3% tested all three
  - 22.0% tested only Ambien
    - Another 17.6% tested a combination of Ambien/Sonata or Ambien/Restoril
- 13.0% Had not tested any approved "no go"
- No go use by 43.3% MAF aircrews surveyed

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Analysis

- Descriptive frequency analysis
  - Optimum number of hours to be fully rested
- Comparison of Means
  - Quantity of sleep (homestation/TDY)
  - Quality of sleep at (homestation/TDY)
    - Likert scale from 1 to 7
  - Alertness (homestation/TDY)
    - Likert scale from 1 to 7

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Analysis

- Statistical Analysis
  - Independent t-tests
    - Never taking medication versus taking “no go”
  - Paired t-tests of sample means
    - Group taking “no go” medication → before and after

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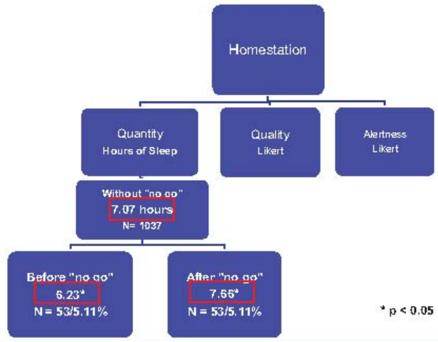
Results
Mean Quantity



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Results
Operational Alertness

- Perception of operational alertness
  - Likert: 1 no more alert→7 much more alert
- Outcome after "no go" Medication
  - TDY/Overseas Missions
    - 4.72 mean baseline of all responders (N = 1073)
      - 4.86 → do not take "no go" medication
        - N = 600
      - 4.55 → do take "no go" medication
        - N = 473
    - Responders who do take "no go"
      - Report alertness of 5.32 after "no go"

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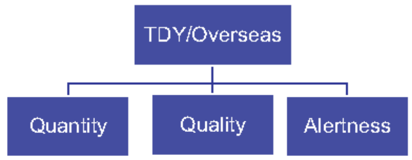
Results
Means



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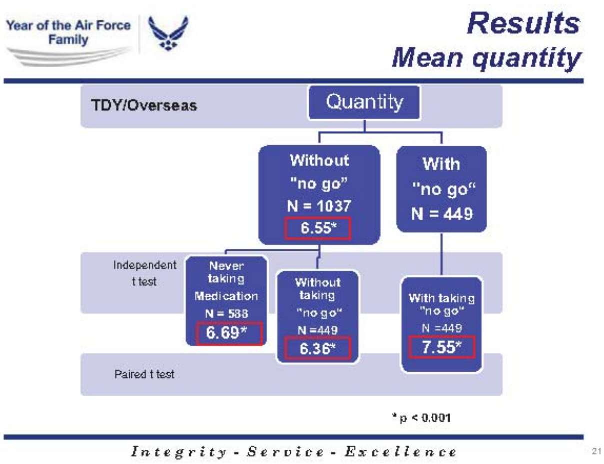
Year of the Air Force Family
Results
Mean quantity
TDY/Overseas
Quantity
Without "no go" N = 1037 6.55*
With "no go" N = 449
Independent t test
Never taking Medication N = 588 6.69*
Without taking "no go" N =449 6.36*
With taking "no go" N =449 7.55*
Paired t test
* p < 0.001
Integrity - Service - Excellence
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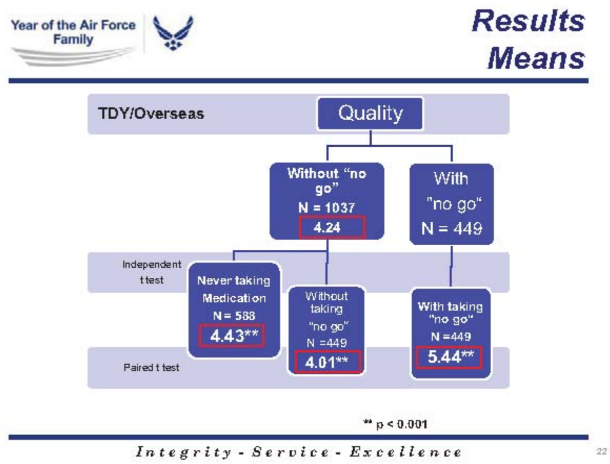
Year of the Air Force Family
Results
Means
TDY/Overseas
Quality
Without "no go" N = 1037 4.24
With "no go" N = 449
Independent t test
Never taking Medication N = 588 4.43**
Without taking "no go" N =449 4.01**
With taking "no go" N =449 5.44**
Paired t test
** p < 0.001
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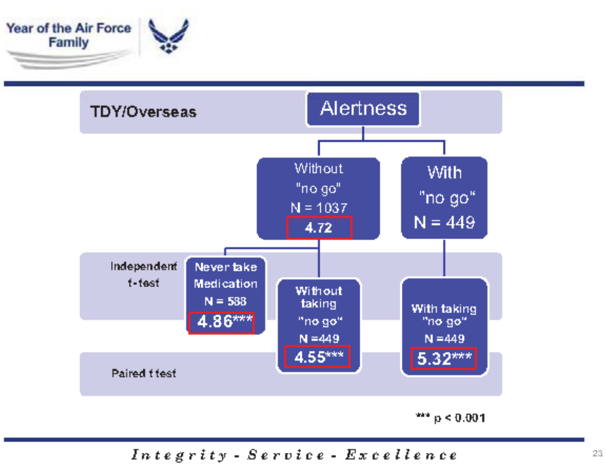
Year of the Air Force Family
TDY/Overseas
Alertness
Without "no go" N = 1037 4.72
With "no go" N = 449
Independent t-test
Never take Medication N = 588 4.86***
Without taking "no go" N =449 4.55***
With taking "no go" N =449 5.32***
Paired t test
*** p < 0.001
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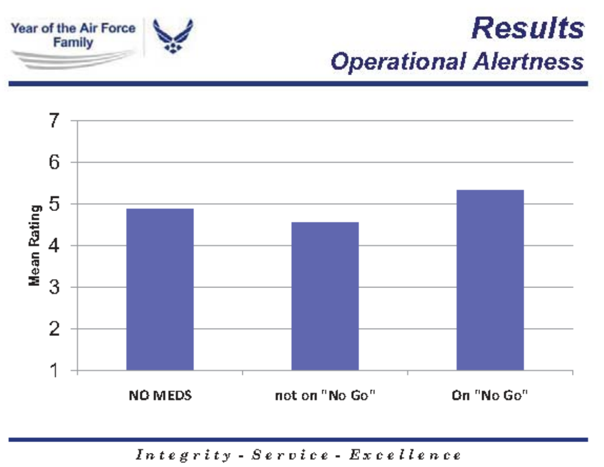
Year of the Air Force Family
Results
Operational Alertness
Mean Rating
7
6
5
4
3
2
1
NO MEDS
not on "No Go"
On "No Go"
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Year of the Air Force Family

Results
Means

Mean Values				
	Homestation		TDY/Overseas Missions	
	Without "no go" (N=1037)	With "no go" (N=53)	Without "no go" (N=1037)	With "no go" (N= 449)
Quantity (Hours)	7.07	7.66	6.55	7.55
Quality (Likert 1-7)	5.27	5.79	4.24	5.44
Alertness (Likert 1-7)	5.52	5.77	4.70	5.31

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Year of the Air Force Family

Discussion

- Statistically and clinically significant
- Operational significance
  - "No go" use primarily in theater/TDY
  - No go use by 43.3% MAF aircrews surveyed
    - Overall self-report
      - Improved quantity of sleep
      - Improved quality of sleep
      - Improved operational alertness
  - Aircrews report lack of consistent education about "No Go"

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Year of the Air Force Family

Strengths/Weaknesses

- Strengths
  - N > 1000
  - Comprehensive survey
    - Napping
    - comments
- Weaknesses
  - Low response rate
    - Generalize to total MAF population?
  - Small Δ → statistical significance

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Year of the Air Force Family

Implications of Research

- Operational impact
  - 83.5% not ready to fly due to lack of sleep
    - 1% or greater of the time
- "No go" effective fatigue countermeasure
- Flight surgeons key to mitigation
  - Be the expert and advocate
  - Inform policy and operational decisions
  - Ensure aircrews ….
    - Educated
    - Access
    - Ground tested

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