Eastern Association for the Surgery of Trauma

28th Annual Scientific Assembly

Sunrise Session 1
The Bleeding Stops Here! New Advances in Early Hemorrhage Control

January 14, 2015
Disney's Contemporary Resort
Lake Buena Vista, Florida

From Baghdad to Boston: Immediate Hemorrhage Control in the Mangled or Amputated Extremity

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Disclaimers

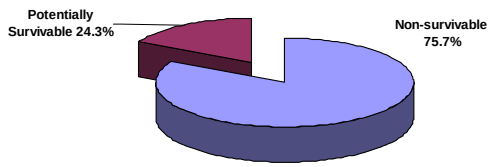
The opinions or assertions contained herein are the private views of the author.

No material or financial conflicts of interest in any product or device

The age of the IED

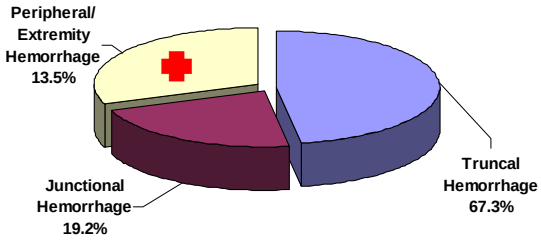
Potentially Survivable Deaths on the Modern Battlefield

(October 2001-June 2011, n = 3040 pre-MTF deaths)



Eastridge BJ, Mabry RL, et al. **Death on the battlefield (2001-2011): implications for the future of combat casualty care.** J Trauma Acute Care Surg. 2012 Dec;73(6 Suppl 5):S431-7.

Breakout of Potentially Survivable Hemorrhagic Deaths: n = 976



Eastridge BJ, Mabry RL, et al. **Death on the battlefield (2001-2011): implications for the future of combat casualty care.** J Trauma Acute Care Surg. 2012 Dec;73(6 Suppl 5):S431-7.

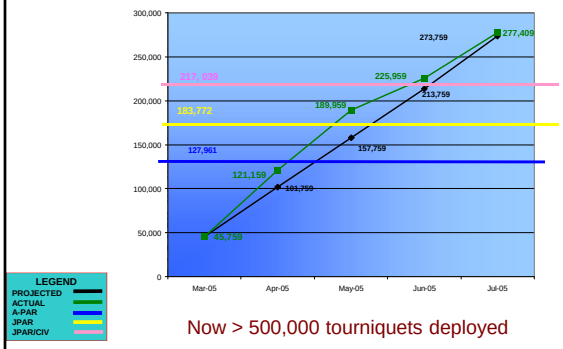
Early modern experience

- Tourniquets somewhat underutilized
  - 59% (98/165) of casualties with traumatic amputation or major extremity vascular injury did NOT have tourniquets.
  - 57% of deaths may have been prevented with earlier tourniquet use.

Beekley AC, Sebesta JA, et al. **Prehospital tourniquet use in Operation Iraqi Freedom: effect on hemorrhage control and outcomes.** J Trauma. 2008 Feb;64(2 Suppl):S28-37; discussion S37.

UNCLASSIFIED

SWA TOURNIQUET PRODUCTION / FIELDING



Now > 500,000 tourniquets deployed

UNCLASSIFIED

Anatomy of a C-A-T

The Combat Application Tourniquet (C-A-T) is a small and lightweight one-handed tourniquet that can completely occlude arterial blood flow in an extremity.

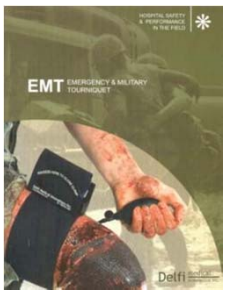
Combat Application Tourniquet (CAT-1)

One of top 10 Army inventions in 2005.

SOF Tactical Tourniquet

British Tourniquet

Pneumatic tourniquets



Great for evacuation platforms and treatment facilities

> "The fate of the wounded lays with those who apply the first dressing."
> - Col. Nicholas Senn, 1844-1908

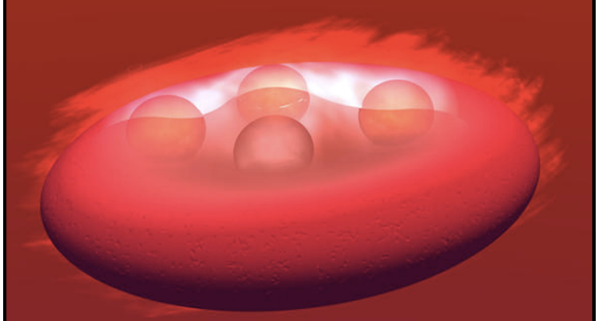
- Tactical Combat Casualty Care (TC3)
  - Circulation
  - Breathing
  - Airway

http://www.naemt.org/education/TCCC

Doctrine

- Care Under Fire
  - Last update June 2014
  - Committee on Tactical Combat Casualty Care
- Tourniquet is first choice for severe/life-threatening bleeding
- Apply second tourniquet above first if necessary (side by side)
- Reassess in Tactical Field Care phase

Hemorrhagic Shock



"That rude unhinging of the machinery of life"
- Samuel Gross, MD

Early Tourniquet Use is better

- "Tourniquet use when shock was absent was strongly associated with saved lives, and prehospital use was also strongly associated with lifesaving."
- "No limbs were lost due to tourniquet use."

Kragh JF Jr, Walters TJ, et al. **Survival with emergency tourniquet use to stop bleeding in major limb trauma.** Ann Surg. 2009 Jan;249(1):1-7.

Tourniquet Application

- Apply without delay when indicated.
- Apply the tourniquet without removing the uniform – make sure it is clearly proximal to the bleeding site.
- Tighten until bleeding is controlled.
- May need a second tourniquet applied just above the first to control bleeding.
- Don't put a tourniquet directly over the knee or elbow.
- Don't put a tourniquet directly over a holster or a cargo pocket that contains bulky items.

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

Mortality from Isolated Civilian Penetrating Extremity Injury

W.C. Dorlac, MD, M.E. DeBakey, J.B. Holcomb, MD, S.P. Fagan, MD, K.L. Kwong, MD, G.R. Dorlac, MD, M.A. Schreiber, MD, D.E. Persse, MD, F.A. Moore, MD, and K.L. Mattox, MD

Background: Although studies have ascertained that ten percent of soldiers killed in battle bleed to death from extremity wounds, little data exists on exsanguination and mortality from extremity injuries in civilian trauma. This study ex-

Results: Fourteen patients meeting inclusion criteria were identified from over 75,000 trauma emergency center (EC) visits. Average age was 31 years and 93% were males. Gunshot wounds accounted for 50% of the injuries. The ex-

units of packed red blood cells. All patients died, 93% succumbing within 12 hours.

Conclusion: Although rare, death from isolated extremity injuries does occur in the civilian population. The major-

"57% of patients had bleeding from a site that anatomically might have been amenable to tourniquet control."

trauma center or underwent cardiopulmonary resuscitation (CPR) or emergency center thoracotomy (ECT).

tially resuscitated (eight with ECT and one with CPR). Those undergoing operative repair received an average of 26 ± 14

Keywords: trauma exsanguination extremity EMS, extremity injury tourniquet emergency thoracotomy

J Trauma. 2005;59:217–222.

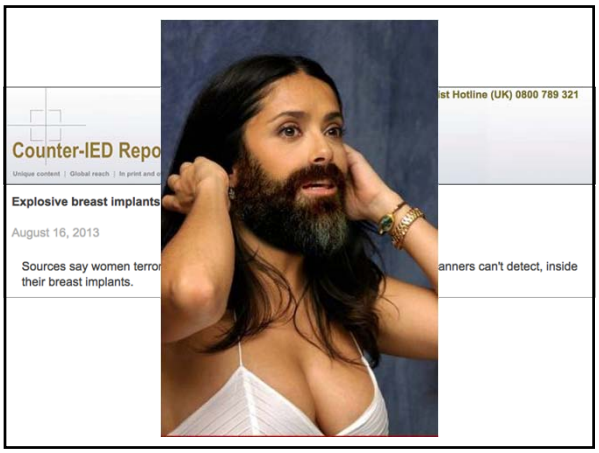
A GLOBAL THREAT

From January to November 2011, outside of Iraq and Afghanistan:

- 6,832 IED events globally, averaging 621 per month
- 12,286 casualties
- 111 countries
- Of those totals, 490 events and 28 casualties were in the United States

Frankenbombers are 'new kind of terrorism': Al Qaeda hopes to surgically implant bombs into thugs

BY JAMES GORDON MEEK / DAILY NEWS WASHINGTON BUREAU / Monday, December 6, 2010, 4:00 AM


ist Hotline (UK) 0800 789 321
Counter-IED Repo
Explosive breast implants
August 16, 2013
Sources say women terror
anners can't detect, inside
their breast implants.


Civilian Events


boston

Boston Marathon Bombing AAR

3 killed, 273 injuried

44 leg injuries

16 amputations

Number of pre-hospital tourniquets: 44
Number improvised tourniquets: 43
Hemostatic dressings: 0

slide courtesy of LTC David King

Changing civilian practice

Changing civilian practice

THE WALL STREET JOURNAL.

Tourniquets Gain New Respect
Recent Tragedies Prompt Rethinking of Ancient Technique

By DEVLIN BARRETT

Oct. 22, 2013 7:47 p.m. ET

The school shooting in Newtown, Conn., and the Boston Marathon bombing are prompting medical experts to change their thinking about the long-disdained technique of using tourniquets to save lives.

Wisconsin Rapids, Wis., policeman Drew Borchardt applies a tourniquet to fellow patrol officer Brian Fischer during a training session. *Associated Press*

Rapidly improvised tourniquets were widely used after the Boston Marathon bombing attack in April. *MetroWest Daily News/Associated Press*

Drawing on lessons from those attacks and battlefields in Afghanistan and Iraq, emergency-medicine doctors are recommending that rescue personnel carry tourniquets and be prepared to use them in mass-casualty events.

A tourniquet is a bandage or other device applied tightly to restrict blood flow and prevent a victim with an arm or leg wound from bleeding to death. For decades, many first-aid classes and doctors have taught that tourniquets were too dangerous to use, because prolonged loss of blood circulation can lead to loss of a limb.

Now, a group of surgeons is challenging that view, advocating tourniquet training not just for police officers but for teachers and others who work in public places.

"It's kind of a radical change in thinking, because for years we have been teaching that tourniquets should be the absolute last resort," said Peter Pons, associate medical director for the National Association of Emergency Medical Technicians. In recent months, he has begun teaching tourniquet use to police officers in Denver, where he lives.

Studies have shown that tourniquets distributed to soldiers in the Iraq and Afghanistan wars helped save lives, Dr. Pons said. And researchers haven't found instances in which improper tourniquet use cost a soldier's limb, he added.

The risk of limb loss may have been overstated because it can take two hours or more for a tourniquet to damage a limb beyond repair, and it is unusual in the U.S. for someone suffering a life-threatening injury to take more than two hours to reach professional medical help, according to Dr. Pons and others.

The tourniquet's benefit, by contrast, comes in the initial minutes before medical personnel arrive. Shooting or bombing victims can bleed to death in five minutes.

Several doctors noted that the response at the Boston Marathon—where bystanders immediately used T-shirts and whatever else they had to make improvised tourniquets—shows that, in some ways, common sense among the public is ahead of current medical practice.

Lenworth Jacobs, a Connecticut doctor, said tourniquets wouldn't have prevented the deaths of children in last December's shootings in Newtown, because so many of the wounds were to vital organs. But tourniquets, he argued, would save lives in other cases, including the recent terror attack at a mall in Nairobi, Kenya.

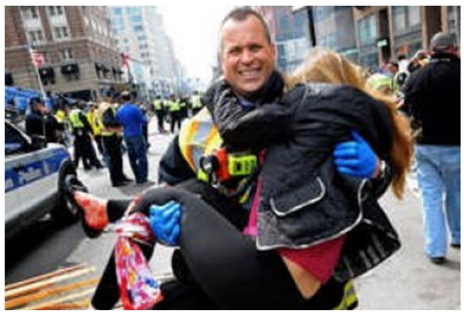
After the Newtown shooting, Dr. Jacobs was among the medical experts asked by the American College of Surgeons and the Federal Bureau of Investigation to draft recommendations for the best way to respond to such events. Those recommendations, called the Hartford Consensus, included a call for wider use of tourniquets.

Some experts remain cautious about tourniquets. Jeffrey Pellegrino, a member of the American Red Cross Scientific Advisory Council, said in a statement that "the majority of bleeding incidents can be stopped by applying direct pressure to the wound. Because of the risk to the limb, lay responders who have been trained should only use a tourniquet as a last resort in cases where help is delayed, when bleeding cannot be controlled by direct pressure, or if applying direct pressure is not possible."

Alexander Eastman, a trauma surgeon who is a member of the Dallas Police Department's SWAT team, said tourniquets should be carried on first responders' uniforms. In his own job on a SWAT team, he often carries a pack with military-style tourniquets he can distribute to officers or victims.

Bryan Anderson treated with 3 tourniquets

Effective Tourniquet?



almost always ineffective, or even harmful

Preventable battlefield death from inadequate, improvised tourniquet

67% of improvised battlefield tourniquets were ineffective.

Kragh JF Jr, et al: Practical Use of Emergency Tourniquets … *J Trauma.* 64:S38-50, 2008.

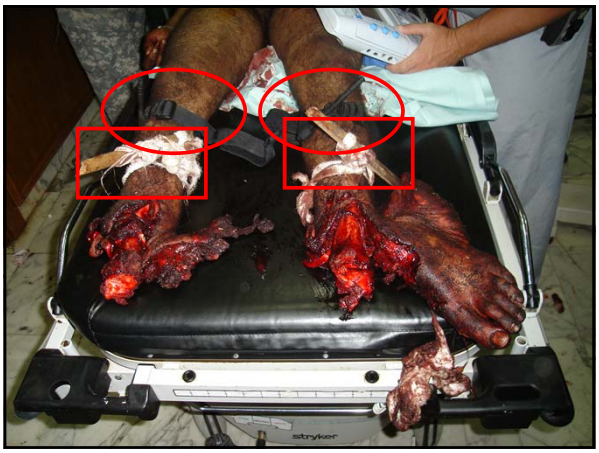
Tourniquet Mistakes to Avoid!

- Not using one when you should
- Using a tourniquet for minimal bleeding
- Putting it on too proximally
- Not taking it off when indicated
- Taking it off when the casualty is in shock or has only a short transport time to the hospital
- Not making it tight enough – the tourniquet should eliminate the distal pulse
- Not using a second tourniquet if needed
- Waiting too long to put the tourniquet on
- Periodically loosening the tourniquet to allow blood flow to the injured extremity

**** These lessons learned have been written in blood. ****

Tourniquet Pitfalls

Too tight... Too loose…



Training

- Tactical Combat Casualty Care
  - 1st line providers
  - PHTLS Chapter 16
  - Comes with an equipment list
  - Trains medics and non-medical personnel
  - C,B,A instead of ABC's
- Joint Forces Combat Trauma Management Course
  - Surgical teams
  - Multidisciplinary
  - Translate current lessons learned
    - Decrease learning curve

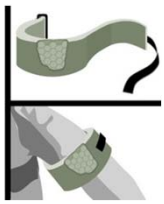
Live Tissue Training…

Why Carry Your Tourniquet When You Can Wear It?

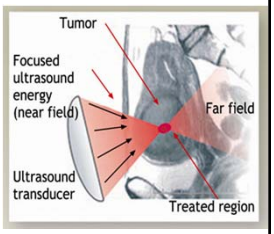
Uniform Integrated Tourniquet System

Deep Bleeder Acoustic Coagulation Program (DBAC)

1. Diagnose & self-adjust



2. Intervene



Challenges…

Summary

The implementation of improved extremity tourniquet devices and guidelines has been a success story for Army medicine and research.

Providing medics with treatment options for junctional and truncal/incompressible hemorrhage are current research challenges (e.g. pre-hospital rFVIIa, lyophilized plasma?)

Real changes to practice need to be data driven.

Advances in Hemorrhage Control

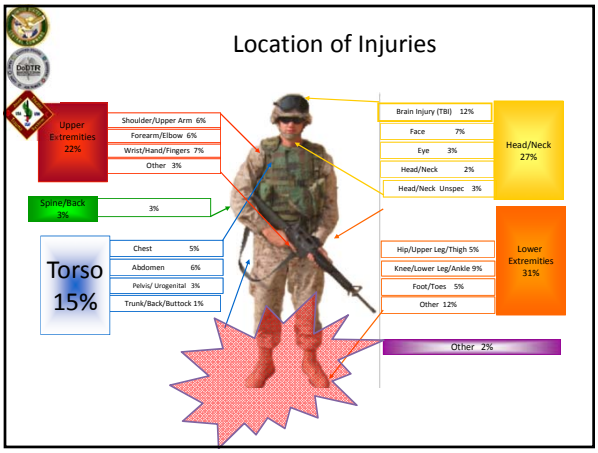
Advanced Topical Hemostatics
Junctional Hemorrhage Control

Stacy A Shackelford, MD, FACS

Disclaimer: The views expressed here are my own and do not reflect official policy of the DoD, Air Force, or Air Force Research Lab.

I have no commercial interests in any product discussed.

Location of Injuries

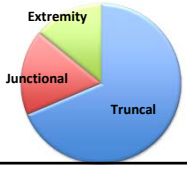


Potentially Survivable Prehospital deaths

- Civilian
  - 54 % hemorrhage
  - 28% neurotrauma
  - 10% hemorrhage + neurotrauma
  - 6% asphyxia
  - 1% asphyxia + neurotrauma
    - *Davis et al, J Trauma Acute Care Surg, 2014*
- Military
  - 91% hemorrhage
  - 8% Airway obstruction
  - 1% Tension pneumothorax
    - *Eastridge et al, J Trauma Acute care Surg, 2012*

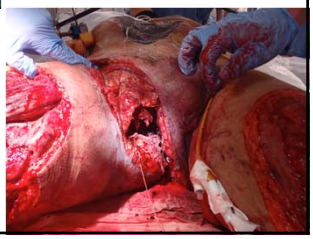
Junctional Hemorrhage Deaths

- Civilian
  - Incidence of death from junctional hemorrhage not reported
- Military
  - **Potentially survivable hemorrhagic deaths**
    - 19% prehospital deaths from junctional hemorrhage
    - 21% in-hospital deaths from junctional hemorrhage
      - Eastridge et al., 2011, 2012



Advanced Hemostatic Dressings

External Hemorrhage control



The Gauze Dressing

Products currently sanctioned by US military CoTCCC

Categories of hemostatic dressings

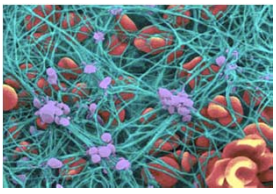
- Factor concentrators
  - Quickclot granules
- Procoagulants
  - Activate clotting cascade
    - Combat gauze
    - Rapid Deployment Hemostat
  - Provide clotting factors (fibrinogen, thrombin)
    - Dry fibrin seal
    - Fibrin Adhesive STat dressing
    - Salmon thrombin fibronogen
- Mucoadhesives (chitosan based-cross-link cellular blood components)
  - Hemecon bandage
  - ChitoGauze
  - Celox gauze

Ideal characteristics

- Stops arterial bleeding (2-3 min manual compression)
- Stops coagulopathic bleeding
- No side effects or excessive heat
- Safe for medics
- Causes no pain
- Ready and easy to use
- Little training requirement
- Lightweight and durable
- Long shelf life
- Effective at extreme temperatures
- FDA approved
- Biodegradable/Bioabsorbable
- Low cost
- Internal use indication
- Safety evidence
- X-ray detectable

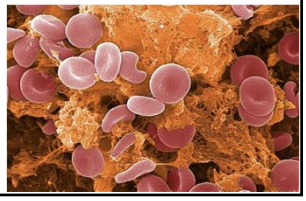
Off Label Use

Next Generation Products?



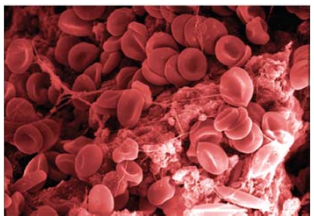
Biomaterials and Bioengineering

Dressing-coagulation system interface

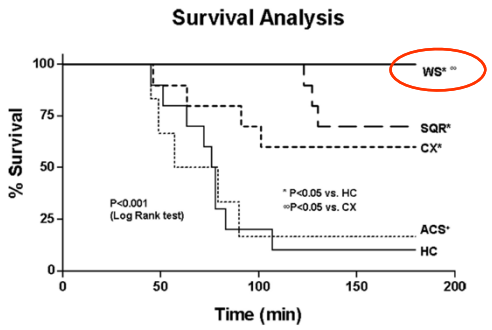


WoundStat

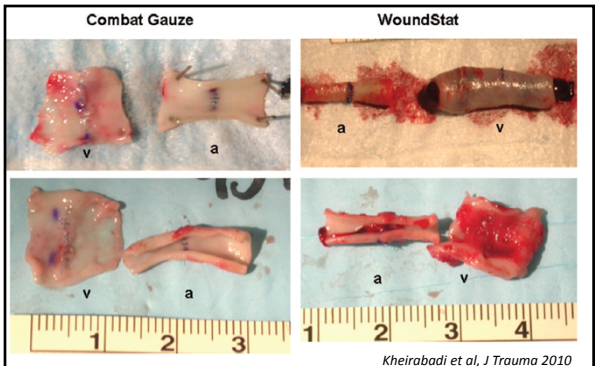
- Developed by VCU
- Smectite granules
- Dual mechanisms
  - mechanical
  - clot potentiation



Ward et al, J Trauma 2007



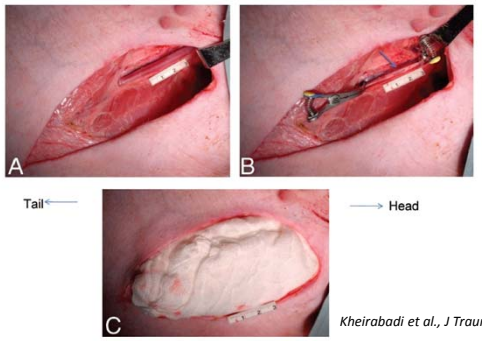
Kheirabadi et al., J Trauma 2009



Kheirabadi et al, J Trauma 2010

Must Balance Expedience with Safety!

Standardized Hemorrhage Model



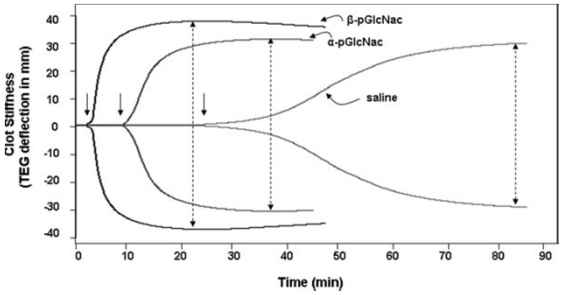
Kheirabadi et al., J Trauma 2011

Rapid Deployment Hemostat (RDH) Bandage

The Rapid Deployment Hemostat Bandage (RDH) was jointly developed by Marine Polymer Technologies and the Office of Naval Research. The active ingredient is derived from a single-cell, saltwater algae.

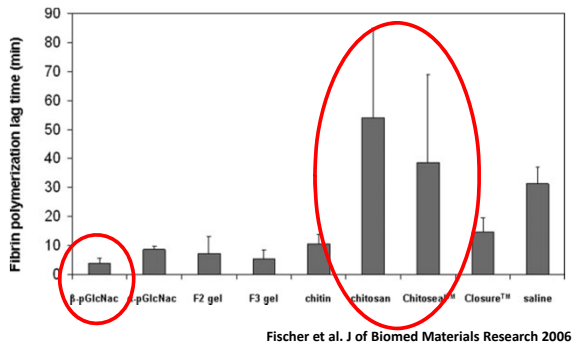
looking to nature for answers
nanofiber poly-N-acetyl glucosamine

Comparison of Glucosamine Based Materials



Fischer et al. J of Biomed Mat Res 2006 DOI 10.1002/jbm.a.30877

Time to initial thrombin generation by TEG



Fischer et al. J of Biomed Materials Research 2006

Thirty Consecutive Uses of a Hemostatic Bandage at a US Army Combat Support Hospital and Forward Surgical Team in Operation Iraqi Freedom

The Journal of **TRAUMA®** *Injury, Infection, and Critical Care* • Volume 71, Number 6, December 2011

David R. King, MD, MAJ, MC, USAR

- Modified RDH bandage
- Used in OR in a forward facility
- Variety of locations and injuries

- Hemostasis in 16 of 19 cases
  - including 7 cases after Combat Gauze failed

"Active" Dressings

- Contain clotting factors or precursors
- Advanced biomaterials
- Work in cold, coagulopathic patient

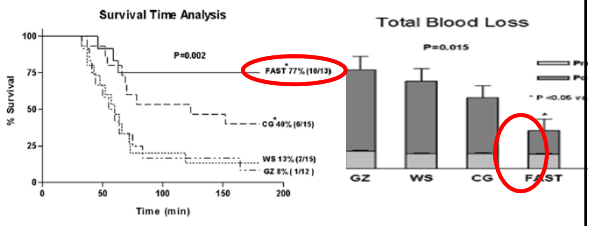
FAST Dressing

- aka “Plasma Protein Dressing”
- Human fibrinogen, thrombin, factor XIII, albumin
  - freeze dried
  - bound to single layer **absorbable** backing
- Activated on contact with tissue or blood

Kheirabadi et al., J Trauma, 2010;69:1062

Clot-Inducing Minerals Versus Plasma Protein Dressing for Topical Treatment of External Bleeding in the Presence of Coagulopathy

Bijan Shams Kheirabadi, PhD, James E. Mace, MD, Irasema B. Terrazas, MS, Chriselda G. Fedyk, MS, Krystal K. Valdez, BS, Martin J. MacPhee, PhD, Dawson Beall, MS, J. Scot Estep, DVM, Michael A. Dubick, PhD, and Lorne H. Blackbourne, MD



Kheirabadi et al., J Trauma, 2010;69:1062

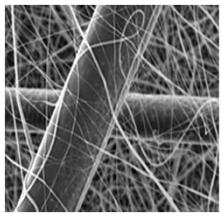
Fibrin Patch (TachoSil)

Human fibrinogen and thrombin
Absorbable equine collagen matrix

Baxter International Inc.

Salmon Thrombin-Fibrinogen

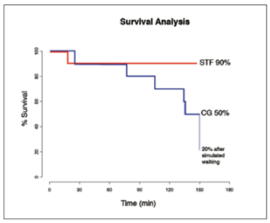
- Lyophilized STF
- Dissolvable dextran nanofiber matrix
- Contact with blood
  - matrix dissolves
  - STF released
  - clot formation



Virg Commonwealth Univ and USUHS

Salmon Thrombin-Fibrinogen

Coagulopathic swine model, Combat guaze control



Measure	CG	STF	*p* Value
Survival rate, injury to 2.5 hours (%)	5 (50%)	9 (90%)	0.14*
Final survival after simulated walking (%)	2 (20%)	9 (90%)	0.005*
Survival time (min)	119.7 ± 14.9	145.6 ± 14.2	0.05**

Notes: *Data were analyzed using exact test.
**Data were analyzed using ANOVA.

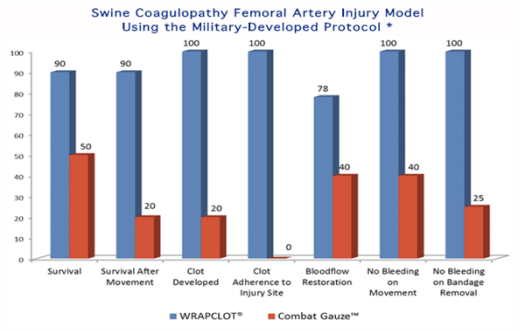
Floyd et al, JSOM 2012

FASTCLOT(R) Family

- SURGICLOT(R)
  - intraoperative
- WRAPCLOT(R)
  - trauma

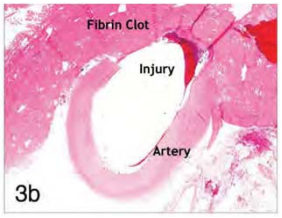
St. Teresa Medical Inc., St. Paul, Minnesota

Trauma Model - WRAPCLOT



Journal of Special Operations Medicine Volume 12, Edition 2/Summer 2012

Clot Formation



Combat Gauze WRAPCLOT

Floyd et al., J Spec Oper Med, Summer 2012

Junctional Hemorrhage: back to low tech

- With preventable deaths from extremity hemorrhage greatly reduced by tourniquet use, junctional hemorrhage has surpassed extremity hemorrhage as the leading cause of death from external hemorrhage.
  - Eastridge, J Trauma, 2012

AAJT

SAM

CRoC

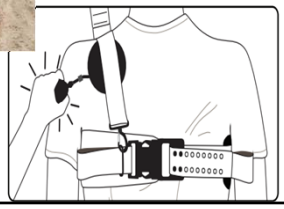
JETT

Combat Ready Clamp (CRoC)

Abdominal Aortic and Junctional Tourniquet (AAJT)

Junctional Emergency Tourniquet Tool (JETT)

SAM Junctional Tourniquet



Junctional Tourniquets

- Will only work if used
- Alternative is exsanguination in the field
- Require dedicated training

XStat (RevMedX, Wilsonville, OR)

iTClamp™

Innovative Trauma Care, Inc

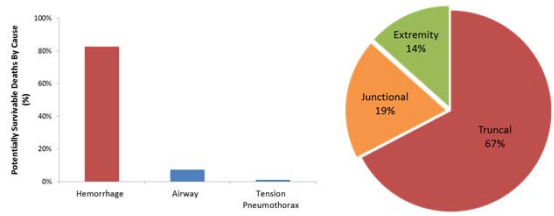
Mottet et al., J Trauma Acute Care Surg 2014

Prehospital Truncal Hemorrhage Control

David R King, MD, FACS
LTC, US Army Joint Special Operations Command
Massachusetts General Hospital & Harvard Medical School
Division of Trauma, Emergency Surgery, and Surgical Critical Care

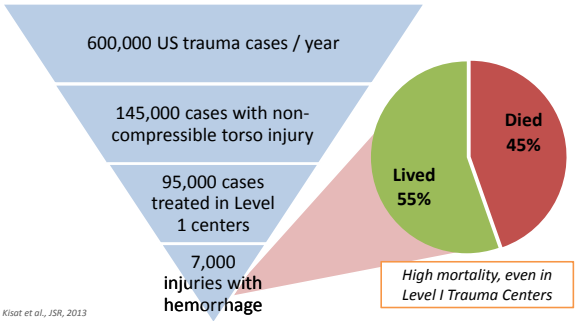
The Problem

Non-compressible hemorrhage is the leading cause of potentially survivable death on the battlefield



*"During [Operation Enduring Freedom and Operation Iraqi Freedom], there was **no effective means to control or temporize truncal sources of hemorrhage in the battlefield**. This signifies a clear and persistent gap in medical treatment capability."*
Eastridge *et al.*, J. Trauma 73 (6), 2012

Epidemiology of Non-Compressible Torso Hemorrhage



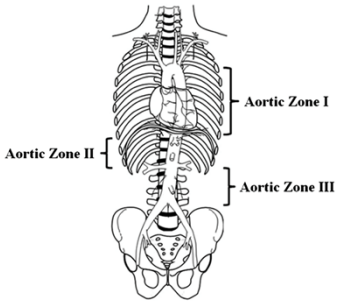
High mortality, even in Level I Trauma Centers

Kisat et al., JSR, 2013

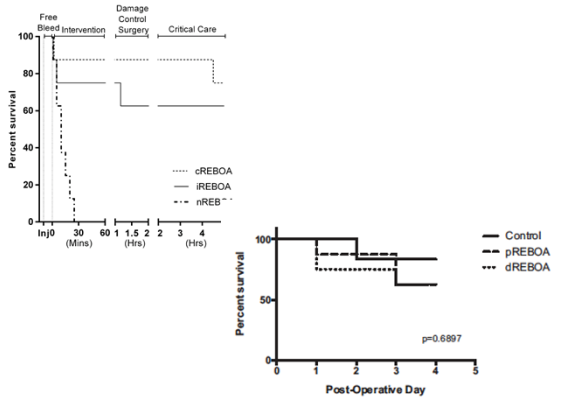
Traumatic intra-abdominal hemorrhage control:
Has current technology tipped the balance toward a role for prehospital intervention?

Muzzafer Chaudery, MRCS, James Clark, MRCS, Mark H. Wilson, FRCS, Duncan Bew, FRCS, Guang-Zhong Yang, PhD, *and* Ara Darzi, FRS, *London, United Kingdom*

REBOA



Reference	Findings
Hughes Surgery, 1954	First described use "intraortic balloon catheter tamponade"
Low et al. Ann Emerg Med 1986	Clinical series of use in 23 patients 2/15 trauma patients survived; overall survival: 26%
Martinelli *et al.* J. Trauma 2010	Clinical series of 13 pelvic hemorrhage patients 12/13 became transferrable; Survival = 46%
Brenner et al. J. Trauma 2013	Clinical series of use in six cases No hemorrhage-related mortality; No REBOA complications
London Air Ambulance Press Release	Conducted pre-hospital REBOA

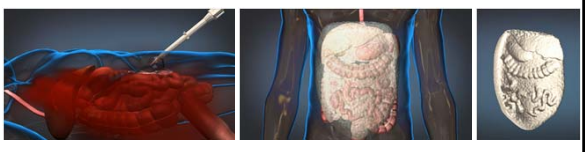


Nonoperative management of hemodynamically unstable abdominal trauma patients with angioembolization and resuscitative endovascular balloon occlusion of the aorta

Takayuki Ogura, MD, Alan T. Lefor, MD, MPH, Minoru Nakano, MD, PhD, Yoshimitsu Izawa, MD, *and* **Hideo Morita, MD,** *Gunma, Japan*

- Unstable patients underwent REBOA
- Then take to the *CT scanner !!!!!!!*
- Followed by IR for angioembo
- 6 of 7 survived
- Like all clinical REBOA, no control
- No informed/waiver of consent!

Self-Expanding Foam Treatment



- Two part liquid reacts *in situ* to generate a solid, conformal device
- Device delivered using standard, laparoscopic tools & techniques
- Provides intra-abdominal compression
- Removal at surgery (3 hrs)

Self-expanding foam improves survival following a lethal, exsanguinating iliac artery injury

Adam Rago, MS, Michael J. Duggan, DVM, John Marini, John Beagle, George Velmahos, MD, PhD, Marc A. De Moya, MD, Upma Sharma, PhD, John Hwabejire, MD, *and* David Richard King, MD, *Boston, Massachusetts*

Self-expanding foam for prehospital treatment of severe intra-abdominal hemorrhage: Dose finding study

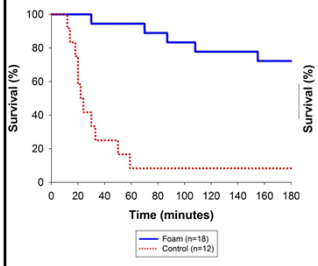
Miroslav P. Peev, MD, Adam Rago, PhD, MS, John O. Hwabejire, MD, Michael J. Duggan, DVM, John Beagle, BS, John Marini, BS, Greg Zugates, BS, Rany Busold, PhD, Toby Freyman, PhD, George S. Velmahos, MD, PhD, Marc A. Demoya, MD, Daniel Dante Yeh, MD, Peter J. Fagenholz, MD, Upma Sharma, PhD, *and* David Richard King, MD, *Boston, Massachusetts*

Self-expanding foam for prehospital treatment of intra-abdominal hemorrhage: 28-day survival and safety

Rago, Adam P. MS; Duggan, Michael J. DVM; Beagle, John; Peev, Miroslav P. MD; Marini, John; Hwabejire, John O. MD; Hannett, Patricia; Zugates, Greg PhD; Busold, Rany; Helmick, Marc; Velmahos, George MD, PhD; Demoya, Marc A. MD; Yeh, Daniel Dante MD; Fagenholz, Peter J. MD; Sharma, Upma PhD; King, David R. MD

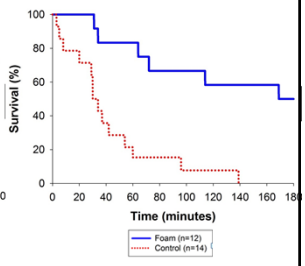
Efficacy In Lethal Injury Models

Lethal Grade V Liver Injury



Duggan et al., J Surg Res 2012; Peev et al, J Trauma 2014

Lethal Iliac Artery Transection



Duggan et al., J Surg Res 2014; Rago et al, J Trauma 2014

Overview of Animal Testing

Formulation selection

Swine
16 formulations evaluated

n = 58

Lethal liver injury

Swine
Venous bleeding
3 Hours

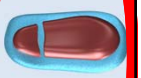
n = 431

Lethal iliac injury

Swine
Arterial bleeding
3 Hours

n = 39

Non-lethal spleen injury



Swine
Survival study
28 & 90 days

n = 27

Self-Expanding Foam for Severe Abdominal Hemorrhage: A Multi-Center Dose Translation Study in Recently Deceased Humans

Presented at the 28th Assembly of the Eastern Association for the Surgery of Trauma, Orlando, FL

TOMORROW, 9:20am

~~Non-Compressible~~ Compressible

Hemorrhage

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REBOA v FOAM

REBOA	FOAM
requires femoral access	requires peritoneal access
total occlusion	partial occlusion
safe to 1 hr	safe to 3 hrs
risk of paraplegia	risk of bowel injury
risk of bowel injury	
requires removal	requires removal
OFF-LABEL USE	NEEDS FDA APPROVAL

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