



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.**

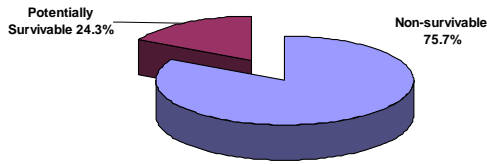
**No material or financial conflicts of interest
in any product or device**

The age of the IED



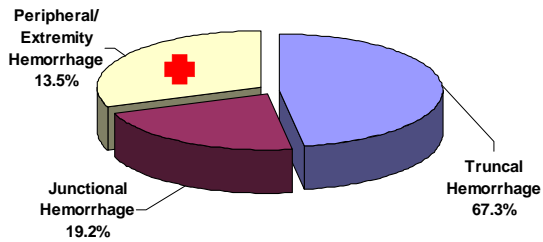
Potentially Survivable Deaths on the Modern Battlefield

(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

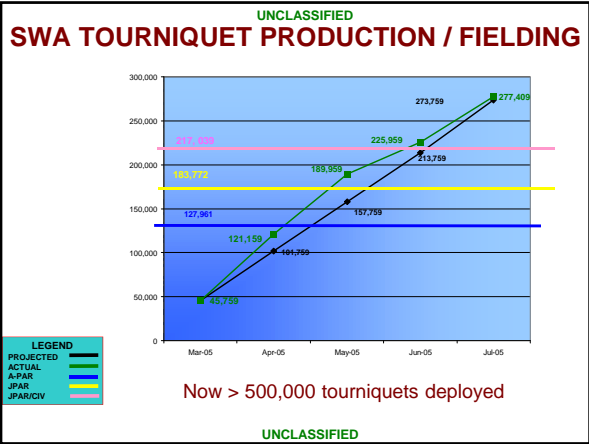


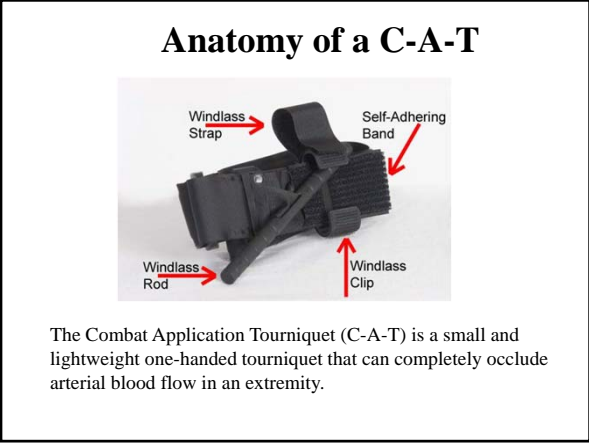
Eastridge BJ, Mabry RL, et al. **Death on the battlefield (2001-2011): implications for the future of combat casualty care.** J Trauma Acute Care Surg. 2012 Dec;73(6 Suppl 5):S431-7.

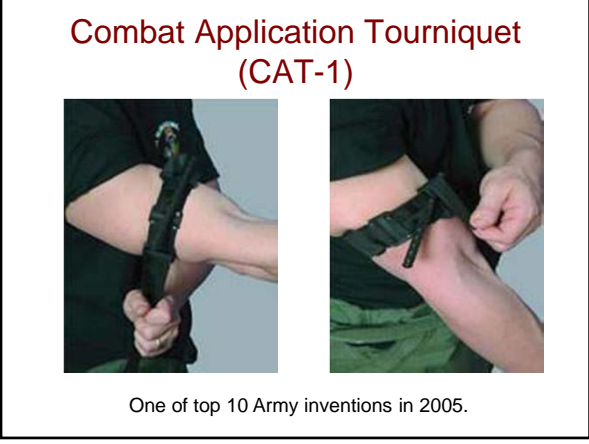
Early modern experience

- 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.







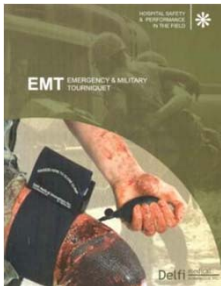


SOF Tactical Tourniquet



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~~
- ~~Circulation~~



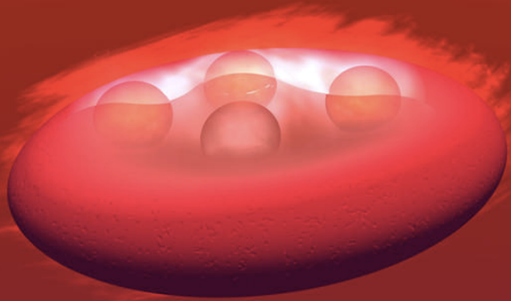
<http://www.naemt.org/education/TCCC>

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.**

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 17 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).

initially 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.

COUNTERIMPROVISED EXPLOSIVE DEVICE
STRATEGIC PLAN
JIEDDO
ATTACK THE NETWORK | DEFEAT THE DEVICE | TRAIN THE FORCE
2012-2016



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

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Counter-IED Report
Unique content | Global reach | In print and online

Explosive breast implants
August 16, 2013

Sources say women terrorists can't detect, inside their breast implants.

ist Hotline (UK) 0800 789 321



Civilian Events









Boston Marathon Bombing AAR

3 killed, 273 injured

44 leg injuries

16 amputations

Number of pre-hospital tourniquets: 44

Number improvised tourniquets: 43

Hemostatic dressings: 0

slide courtesy of LTC David King







THE WALL STREET JOURNAL.

Tourniquets Gain New Respect Recent Tragedies Prompt Rethinking of Ancient Technique

By DEVLIN BARRETT

The school shooting in Newtown, Conn., and the Boston Marathon bombing are prompting medical experts to change their thinking about the long-discounted 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. Associated Press/Associated Press

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

A tourniquet is a bandage or other device applied tightly to restrict blood flow and prevent a victim who is bleeding from losing too much blood. For obvious, but often overlooked, reasons, heavy first-aid courses do not always teach that tourniquets are the long-proven, simple, and practical principle of blood circulation can last to loss of a limb.

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

In a kind of medical change in thinking, because for years we have been teaching that tourniquets should be the absolute last resort, said Peter Fries, 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. Fries said. And researchers have found instances in which emergency medicine doctors have used a tourniquet, and it remained in the U.S. by someone suffering a life-threatening injury to take more than two hours to reach professional medical help, according to Dr. Fries and others.

The tourniquet's benefit, by contrast, comes in the vital minutes before medical personnel arrive. "Blood can't be pumped to the limb, so it's not going to be there," he said.

Several doctors noted that the response after 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.

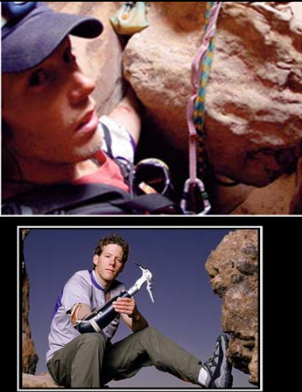
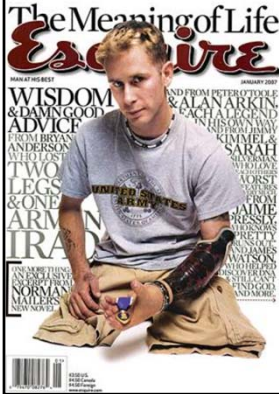
Dr. Jacobus, a Connecticut doctor, said tourniquets wouldn't have prevented the deaths of children in last December's shootings in Newtown, because so many of the wounds were to vital organs. But tourniquets, he argued, would have been useful in other cases, including the recent school attack in Florida.

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

Some experts remain cautious about tourniquets, however. Dr. Fries, a member of the American Heart Association's Scientific Advisory Council, said in a statement that "the benefits of tourniquets have not been fully established and that the use of tourniquets carries the risk of the limb, by responders who have been trained should only use a tourniquet as a last resort in cases where limbs are at risk, when bleeding cannot be controlled by direct pressure, or if applying direct pressure is not possible."

Dr. Fries' team, said tourniquets should be carried on first-responder vehicles. It is less clear on a SWAT team, he often carries a pack with military-style tourniquets he can distribute to officers in cities.

Bryan Anderson treated with 3 tourniquets



Aron Ralston
Forget Chuck Norris, this guy has real bravery!

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

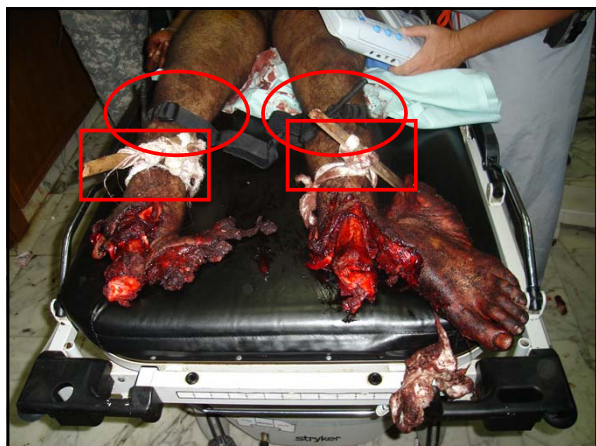
*** These lessons learned have been written in blood. ***

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



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

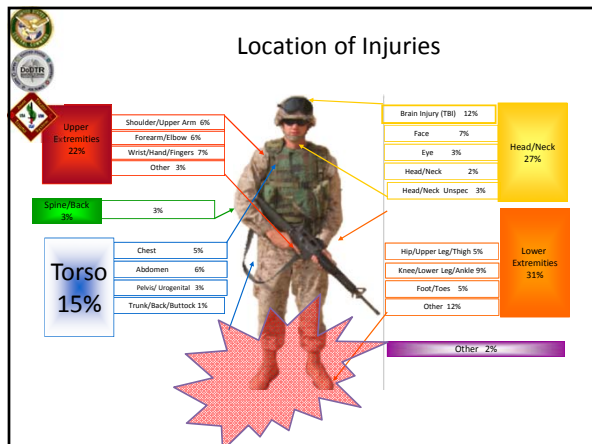
Advanced Topical Hemostatics

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.



Potentially Survivable Prehospital deaths

- Civilian
 - 54 % hemorrhage
 - 28% neurotrauma
 - 10% hemorrhage + neurotrauma
 - 6% asphyxia
 - 1% asphyxia + neurotrauma

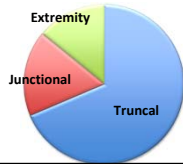
– Davis et al, J Trauma Acute Care Surg, 2014
- Military
 - 91% hemorrhage
 - 8% Airway obstruction
 - 1% Tension pneumothorax

– 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

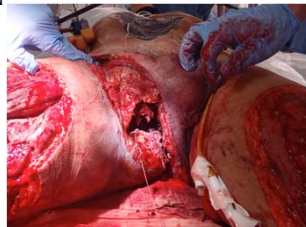
– Eastridge et al., 2011, 2012





Advanced Hemostatic Dressings

External Hemorrhage control



The Gauze Dressing



Products currently sanctioned by US military CoTCCC



Categories of hemostatic dressings

- Factor concentrators
 - Quikclot 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

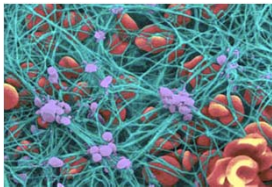
Ideal characteristics

- 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

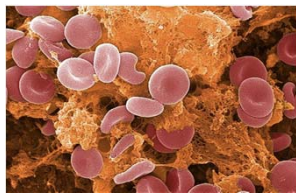



Next Generation Products?



Biomaterials and Bioengineering

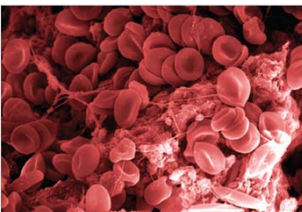
Dressing-coagulation system interface



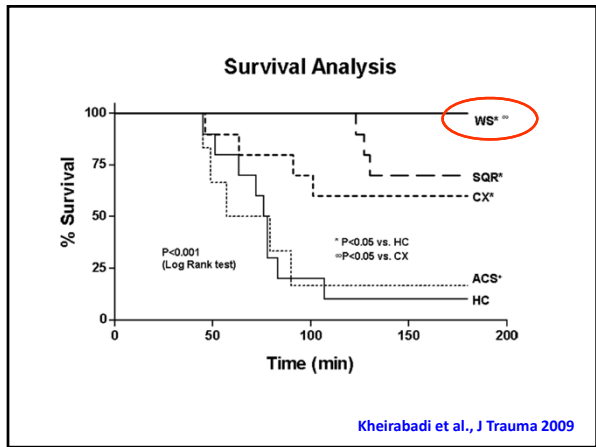


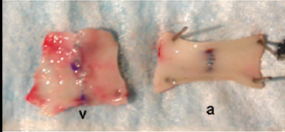

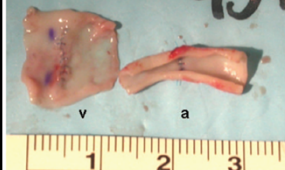
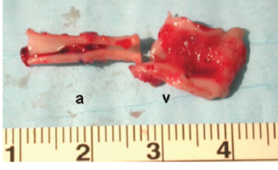
WoundStat

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



Ward et al, J Trauma 2007

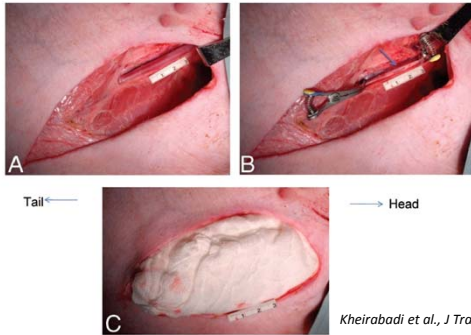


Combat Gauze	WoundStat
	
	

Kheirabadi et al, J Trauma 2010

Must Balance Expedience with Safety!

Standardized Hemorrhage Model



Rapid Deployment Hemostat (RDH) Bandage

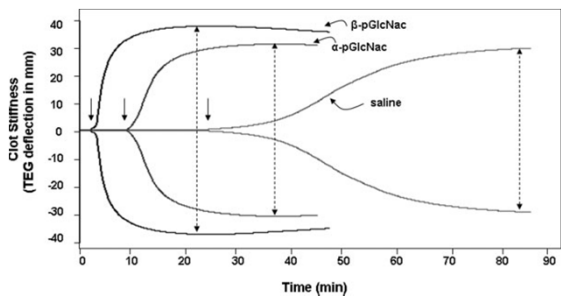


The Rapid Deployment Hemostat Bandage (RDH) was jointly developed by Marine Polymer Technologies and the Office of Naval Research. The active ingredient is derived from a single-cell, saltwater algae.



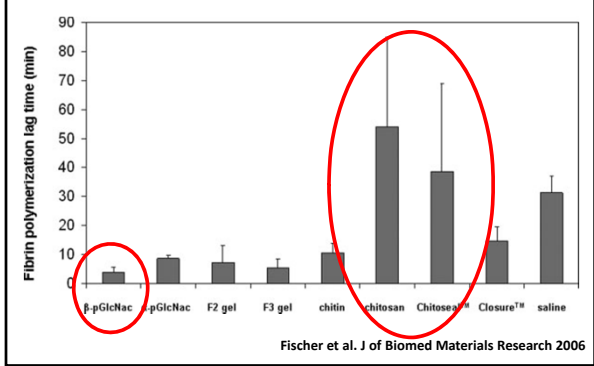
looking to nature for answers
nanofiber poly-N-acetyl glucosamine

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



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

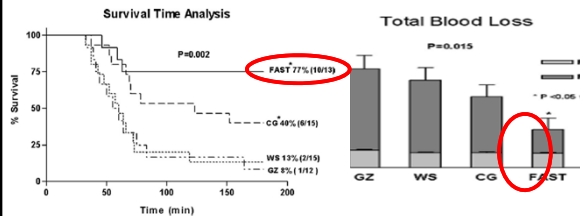
FAST Dressing

- 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)

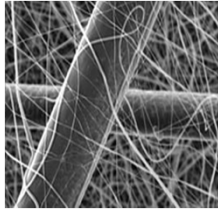


Human fibrinogen and thrombin
Absorbable equine collagen matrix

Baxter International Inc.

Salmon Thrombin-Fibrinogen

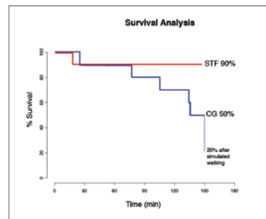
- Lyophilized STF
- Dissolvable dextran nanofiber matrix
- Contact with blood
 - matrix dissolves
 - STF released
 - clot formation



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

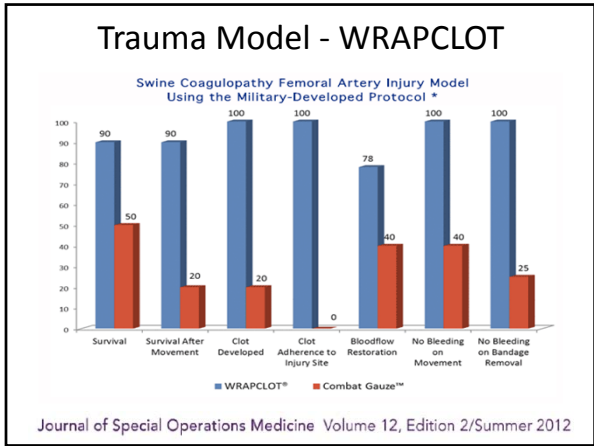
FASTCLOT^(R) Family

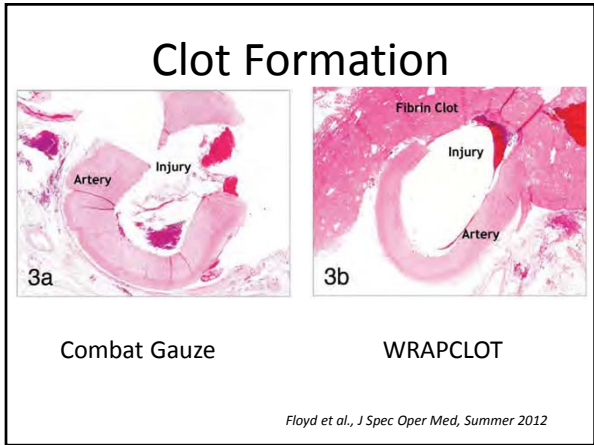
Dextran carrier that contain Thrombin and Fibrinogen



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

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







- 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)



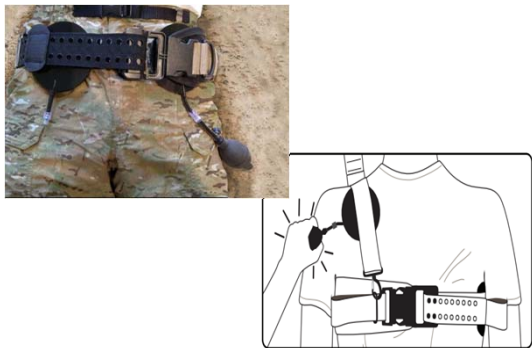
Abdominal Aortic and Junctional Tourniquet (AAJT)



Junctional Emergency Tourniquet Tool (JETT)



SAM Junctional Tourniquet



Junctional Tourniquets

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

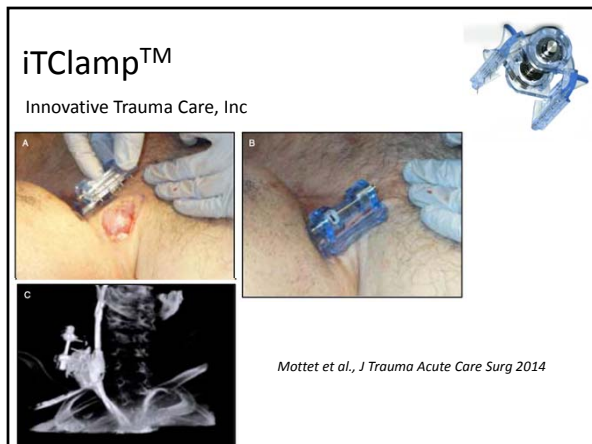




XStat (RevMedX, Wilsonville, OR)

iTClamp™

Innovative Trauma Care, Inc



Mattet et al., J Trauma Acute Care Surg 2014

Self-Expanding Foam for Pre-Surgical Treatment of Noncompressible Abdominal Hemorrhage

LTC David R King, MD, FACS, USAR
 Massachusetts General Hospital & Harvard Medical School
 Division of Trauma, Emergency Surgery, and Surgical Critical Care



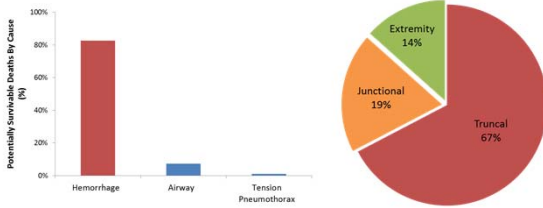
DATE

Arsenal Medical - Proprietary

1

The Problem

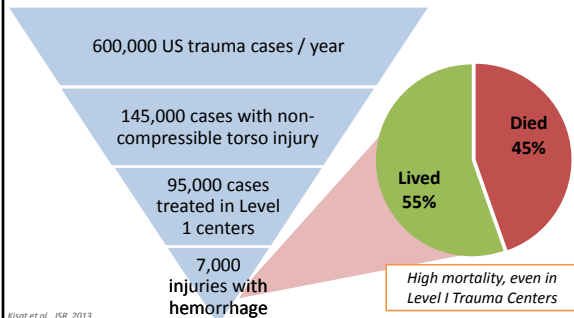
Non-compressible hemorrhage is the leading cause of potentially survivable death on the battlefield



"During [Operation Enduring Freedom and Operation Iraqi Freedom], there was no effective means to control or temporize junctional or 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

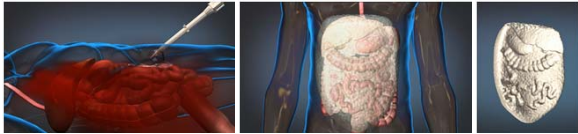


Kisot et al., JSR, 2013

Arsenal Medical - Proprietary

3

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 (1 hr)

Arsenal Medical - Proprietary 4



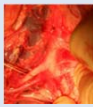

Self-Expanding Foam *In vivo*



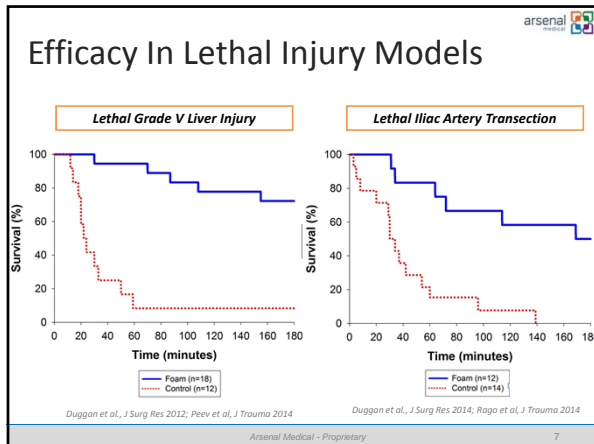
Extensive Pre-Clinical Testing Demonstrates Product Performance

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Overview of Animal Testing

<p>Formulation selection</p>  <p>Swine 16 formulations evaluated</p> <p>n = 58</p>	<p>Lethal liver injury</p>  <p>Swine Venous bleeding 3 Hours</p> <p>n = 431</p>	<p>Lethal iliac injury</p>  <p>Swine Arterial bleeding 3 Hours</p> <p>n = 39</p>	<p>Non-lethal spleen injury</p>  <p>Swine Survival study 28 & 90 days</p> <p>n = 27</p>
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Results: Swine Safety Study

- ☑ Methods: 28-day and 90-day study following simulated foam use vs. low grade splenic injury
- ☑ Results:
 - ☑ Identified maximum tolerable foam dose (150mL)
 - ☑ Enteric repair required in all animals (one complication)
 - ☑ All remaining animals survived to 28 or 90 days without clinical complications; no evidence of compartment syndrome
 - ☑ Foam treatment did not increase abdominal adhesions
 - ☑ Foam remnant particles well tolerated

Rago et al., J Trauma 2014
Rago et al., J Trauma, In Press

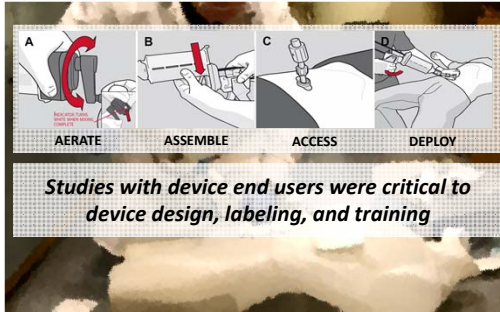
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Delivery Device

Study Condition	1HR Survival (%)	3HR Survival (%)	Hem. Rate (g/kg/min)
Operational temperature: 10°C (n=6)	100%	83%	0.36 ± 0.06
Operational temperature: 50°C (n=6)	100%	67%	0.54 ± 0.26
Accelerated shelf-life (n=6)	100%	83%	0.49 ± 0.25
Control (n=14)	7%	7%	3.1 ± 1.2

Rago et al., J Trauma, In Press 9

Human Factors/Usability Testing



Pre-Clinical Simulated Human Testing

- ▣ Findings in animals must be translated to human device use
- ▣ Requirements for self-expanding foam:
 - ▣ Comparable tissue biomechanics
 - ▣ Variations in cavity size to account for natural patient variability
 - ▣ Representative internal organ anatomy



Recently Deceased Study (RDS) in Humans

Objective	Confirm appropriate human dose in recently deceased subjects
Study Population	Subjects within three hours of death <i>Minimize any post-mortem changes in tissue compliance</i>
Sites	Massachusetts General Hospital University of Texas Health Science Center – Houston Oregon Health and Science University
Outcome	Foam performance as compared to swine results

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Study Procedure

Instrumentation

- Instrument to record Intraabdominal pressure (IAP)
- Access abdomen per IFU
- Simulate bleed: Add 1500mL fluid

Foam Delivery

- Deploy foam using representative, prototype delivery system

Outcome Evaluation

- Record IAP by minute
- Assess foam contact with abdominal organs
- Characterize foam samples *in vitro*

Study outcomes are compared to pre-clinical data as a surrogate for foam performance

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Summary

- ☑ Self-expanding foam may be the first pre-surgical treatment for noncompressible abdominal hemorrhage
- ☑ Safety and efficacy demonstrated in hundreds of swine studies
- ☑ Deployment in recently deceased subjects represents a new model for translational research

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