



# Hemostatic Agents/Devices



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Disclosure: Co-founder and CEO, Innovative Trauma Care

# Civilian Hemorrhage Problem

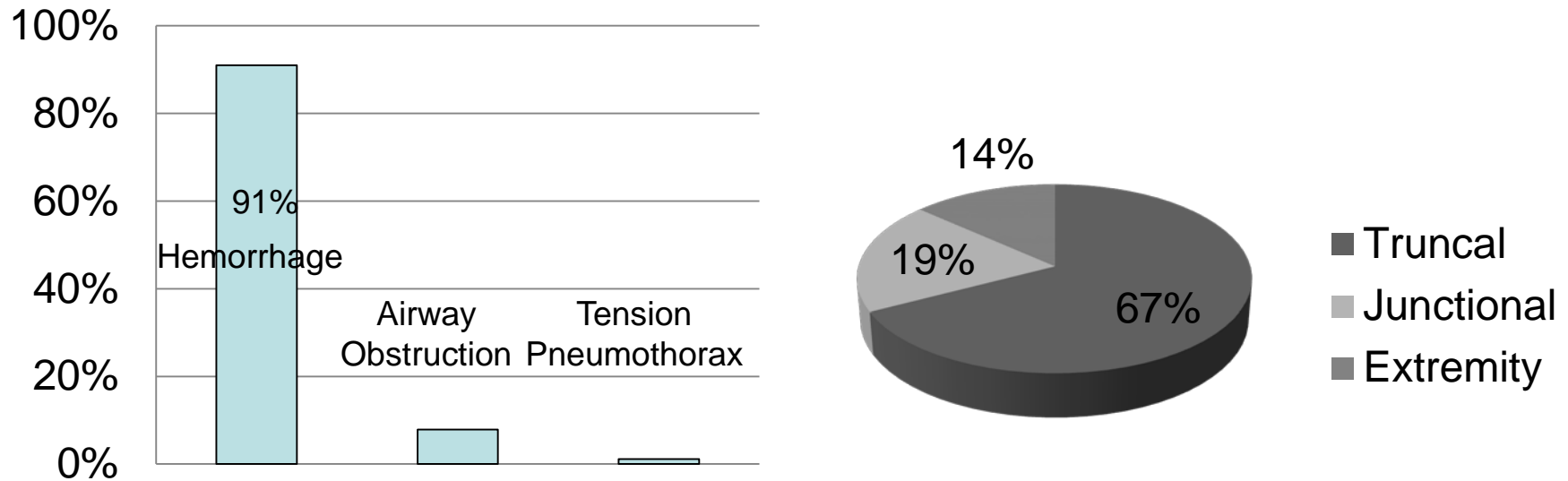
- Hemorrhage is a leading cause of preventable death
  - Up to 40% of civilian trauma deaths due to uncontrolled hemorrhage\*
  - 25-30% of trauma patients are coagulopathic by the time they reach the trauma room
- Current research indicates stopping hemorrhage early is critical to good outcomes
  - Reduces occurrence of coagulopathy
  - Reduces downstream complications and cost
  - Improved survival rates if hemorrhage is controlled prior to onset of shock

Sauaia et al. 1994 Arch Surg; Kauvar et al. 2006 J. of Trauma; Jansen et al. 2009 BMJ

# Military Hemorrhage PROBLEM:

A new USAISR study finds that nearly 25% of the 4,596 combat deaths in Iraq and Afghanistan between 2001 - 2011 were "potentially survivable"

- 87% of the deaths occur prior to reaching a medical facility
- 91% of potentially survivable deaths were due to uncontrolled blood loss



"Hemorrhage control, both control of torso hemorrhage and junctional hemorrhage are top research priorities," Butler told members of the Defense Health Board on June 25, 2012.

\*Eastridge et al. J Trauma Acute Care Surg. 2012; 73 (S431-S437)

# Scalp Lacerations

**“Fatal Hemorrhage From Simple Lacerations of the Scalp”**, . R. Hamilton, J. P. Sunter, and P. N. Cooper, Forensic Science, Medicine, and Pathology

- Frequent occurrence
- Even “trivial” lacerations of blood-rich areas such as the scalp may bleed profusely and persistently
- Seven cases in which hemorrhage from simple scalp lacerations was considered to be the principle cause of death



# Hartford Consensus Statement

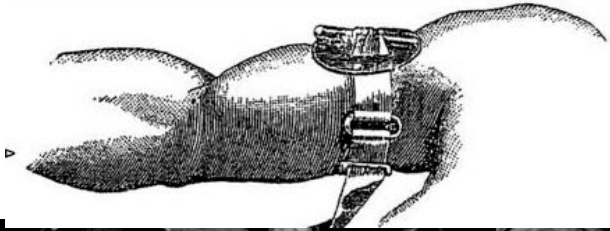
Joint committee to Create a National Policy to Enhance Survivability from Mass Casualty Shooting Events

## THREAT

1. Threat suppression
2. **Hemorrhage control**
3. Rapid Extrication to safety
4. Assessment by medical providers
5. Transport to definitive care



# Current Hemorrhage Control Technology:



The same “technology” has been used for thousands of years

- Direct pressure
- Tourniquets
- Gauze for packing wounds



New Technology Breakthroughs:

- Hemostatic Agents
- Tranexamic Acid
- Junctional Tourniquets
- Abdominal Tourniquets
- iTClamp



# Hemostatic Agents

- Combat Gauze (QuickClot)
  - Absorbs water and concentrates clotting factors
  - Wide deployment with U.S. Military
- Celox
  - Chitosan granule-impregnated z-fold gauze
  - Adhesive-like action attracts RBCs to form tight adherent clots
  - Deployed with UK military
- Both CG and Celox recommend by TCCC
- Limited by requirement for 3-5 minutes direct pressure



# Tourniquets



- Demonstrated effectiveness in the prehospital military for extremity trauma – saved lives
- Recommended by TCCC to be placed 2-3 inches above injury
  - Application of 2<sup>nd</sup> tourniquet just above the original if a distal pulse remains



**C**ombat **A**pplication **T**ourniquet

Risk and Augustine 2012 JEMS; Kragh et al. 2012 J. of Am. J. of Surgery

# Tourniquets

- Most tourniquets were Combat Application Tourniquets (71/79, 90%)
- Most limbs (83%, 54/65) had palpable distal pulses present
- 79 tourniquets, injuries were venous in 83% and arterial in 17%
- In total = 14 arterial injuries (only 5 had effective arterial tourniquets applied)
- Medics were generally surprised at how tight a tourniquet must be to stop arterial flow

“Forward Assessment of 79 Prehospital Battlefield Tourniquets Used in the Current War”, King D. van der Wilden G. Kragh J. Blackbourne L, JSOM, 33 – 38

# Junction Specific Tourniquets



## Combat Ready Clamp (CRoC):

- only use in the groin/axilla
- extremely painful
- 1 document successful case study



## Junctional Emergency Treatment Tool (JETT):

- simultaneous occlusion of blood flow to both lower limbs



## SAM Junctional Tourniquet:

- only use in the groin/axilla

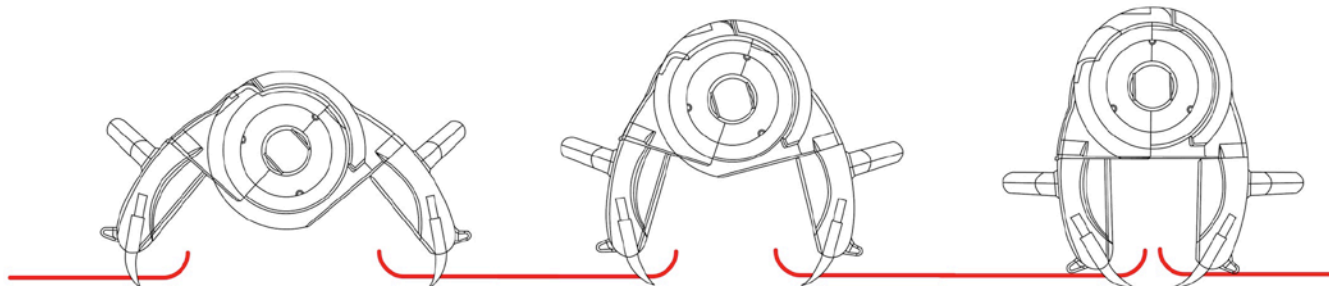
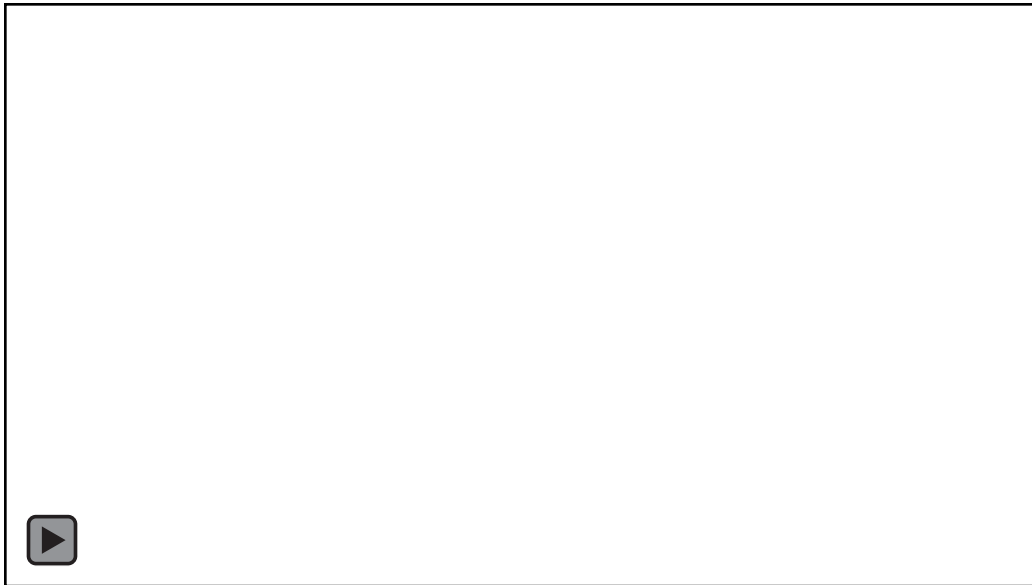


## Abdominal Aortic Tourniquet:

- compresses aorta
- FDA-approved

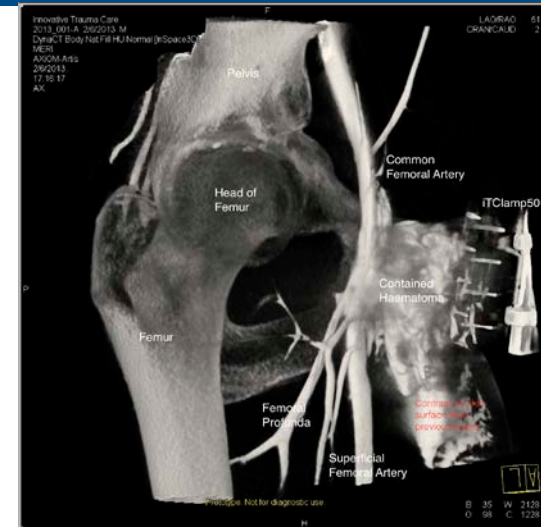
# iTClamp

A fluid tight seal at the skin results in a high pressure, contained hematoma. Stasis of flow causes a stable clot to temporize until surgical repair. Distal flow is preserved if the artery is not transected.



# iTClamp – Pre Clinical Studies

- 100% effective in pre-clinical swine study
  - Lethal femoral artery injury model
  - No tissue damage
  - Filips et al. 2013 Prehospital Emergency Care
- Pre-clinical cadaver study
  - Effective and safe across multiple compressible zones (junctional areas, scalp, extremities)
  - Distal flow maintained
  - Not effected by patient movement
  - Mottet et al. *in press* J. of Trauma
- Additional studies
  - Can be effectively applied over clothing
  - Requires minimal training



# Human Use Case Studies

**\*All reported uses have been 100% successful**



39-year-old male drug addict presented with severe venous bleeding from the femoral vein in the groin due to multiple injections (IV abuse)



64 year old man near Olive Branch, Mississippi was trimming tree limbs when his chainsaw got caught in his shirtsleeve and came down on his left upper arm, leaving a 7 inch long, 1 inch deep wound that was bleeding uncontrollably. Patient did not require blood transfusion and was release 8 hours later.

# Summary



- **Uncontrolled hemorrhage is a significant problem**
- **Hemostatic Devices:**
  - **Junction Specific Devices**
    - Junctional injuries above the inguinal ligament
  - **Tourniquets**
    - Amputation, Mangled Extremities
  - **Hemostatic Agents**
    - Cavity Wounds
  - **iTClamp 50**
    - Compressible Bleeding – scalp, neck, axilla, groin, extremities
    - Fast, Light (1 oz), Effective (< 5 seconds) – tactical, uses, mass casualty
    - Intuitive (minimal training)