



**Stop Bleeding. Save Lives.**

# **Celox Gauze**

**The most effective haemostatic gauze**

## **Competitor Comparison**

2016



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# Background

Hemorrhage is still the most common cause of death in the military due to high prevalence of penetrating injury.

Civilian trauma also results in high levels of death from Hemorrhage.

Increasing adoption of haemostats in military and civilian emergency services continues.



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# **Celox Gauze is the most effective hemostatic gauze, with published results in real world use:**

- Proven in air ambulance and military use
- Celox meets the criteria for an ideal hemostat
- Competitor gauze products have no human published data
- 100 % success in femoral artery trials



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# Supporting Data



# Field experience with a Chitosan-based hemostatic dressing

- E.C.T.H. TAN, C.P. Bleeker (Royal Netherlands Army)
- Comparison of novel dressings with hemostatic properties to control heavy bleeding in non-compressible areas
- Discusses findings from using Celox Gauze to control trauma in the War in Afghanistan and also civilian casualties

**MCI MEDICAL CORPS** Report from MCI 3. /4-2011  
INTERNATIONAL FORUM

**CELOX**

E. C. T. H. TAN, C. P. BLEEKER (NETHERLANDS)  
**Field experience with a chitosan-based haemostatic dressing**

Uncontrolled hemorrhage is the leading cause of death among combat casualties and is the second major cause of death in civilian trauma patients. Major improvements have been made in the development of novel dressings with haemostatic properties to control heavy bleeding in non-compressible areas. We describe the use of chitosan gauze (Celox Gauze<sup>®</sup>), a chitosan-based haemostatic agent for the control of massive traumatic bleeding in 7 patients.

**Introduction**

Bleeding remains a leading cause of death in trauma patients, both in civilian and military settings. Military experience in Vietnam, Iraq and Afghanistan has led to the introduction of the Combat Application Dressing (CAT<sup>®</sup>) in areas where bleeding from the extremities and haemostatic dressings for severe bleeding from extremities, head, neck and torso. Meanwhile, several NATO countries have equipped their troops with haemostatic dressings and included the use of dilute penicillin, such as the TCCC (Tactical Combat Casualty Care) guidelines of November 2006 and the IATLS (International Advanced Trauma Life Support) guidelines. Since 2006 the Royal Netherlands Army have used HaemCar<sup>®</sup> as their haemostatic dressing in the field based on IATLS 2006 12<sup>o</sup> (57). Many compressive arterial studies 1-8 and case series 9-12 have been written on the use of haemostatic dressings.

Chitosan gauze is a new haemostatic based on the polycationic chitosan. It is derived from chitin, a complex carbohydrate which occurs in the exoskeleton of crustaceans such as shrimps. Among other factors that promote the reaction with the blood, chitosan contains small positively charged particles. These particles, extracted from shrimp, cross react with red blood cells and form a solid clot, regardless of the natural clotting mechanism of the body. In addition, chitosan absorbs water, one of the main components of blood, allowing the natural clotting factor to become more concentrated, promoting activation of the body's clotting mechanism. The function of chitosan is not affected by essential factors such as body temperature (hypothermia or heat) and works in heparinized patients and patients using aspirin. Chitosan causes no

*Fig. 1. Lifeline 2's mobile medical team in action during an operation.*

# Field experience with a Chitosan-based hemostatic dressing

- Describes the use of Celox Gauze for control of massive traumatic bleeding in 7 patients

**Table 1: Patients**

	Sex	Age (yr)	Ethnicity	Accident	Cause	Location	Successful
1	M	40	Caucasian	Car collision	Soft tissue bleeding	Upper leg	Yes
2	F	20	Caucasian	Cycle collision with car	Neck wound	Lateral side of neck	Yes
3	F	47	Caucasian	Fall from height	Fractured skull base.	Ears and nose	No
4	M	26	Pashtun	IED blast fragments	Arterial bleeding from the groin	Left groin	Yes
5	M	25	Pashtun	Gunshot wound	Muscular bleed	Buttock	Yes
6	M	23	Hazara	Rock crushing pelvis	Pelvic girdle . fracture, venous	pelvis	Yes
7	M	76	Pashtun	Sharp amputation	Muscular bleed	Thigh stump	Yes

## Celox Gauze used for control of traumatic bleeding in a series of seven patients.

- Successfully stopped bleeding where pressure dressings / gauze/ emergency bandages failed.
- No re-bleeding in transfer.
- No leakage throughout monitored period – up to 24 hours.

Reference: Tan ECTH, Bleeker CP, MCI Forum 3/4-2011.



## Example case: Gunshot wounds

- Multiple gunshot wounds to arm, leg, buttocks.
- Persistent bleeding from buttock wound.
- Not controlled by plain gauze.
- Packed with Celox Gauze.
- Bleeding stopped.
- Removed after 24 hours, with no further bleeding.



Bleeding gunshot wound in thigh.



## Example case: IED Blast

- Multiple blast injuries.
- Tear wound, left groin, arterial bleed.
- Emergency bandage applied in field, leaked.
- Celox gauze applied, bleeding stopped.
- Transferred to Operating Room, cleaned, treated.



Groin wound from shrapnel injury treated by Celox gauze.

## Example case: Road traffic accident

- High energy trauma to cyclist hit by car.
- Venous bleeding, left side of neck.
- Normal pressure bandage did not help.
- Celox gauze stopped bleeding.
- Transport to hospital and care in hospital with no leakage.



Lifeline crew in action



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# Fulfils the criteria for an ideal hemostatic dressing.

Authors conclusion.

Also: “a safe and useful tool in stopping or controlling external blood loss in our series of patients”.



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# NAMRU / ONR study



**NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO  
TECHNICAL REPORT # TR-2012-22**

**COMPARISON OF NOVEL HEMOSTATIC GAUZES TO QUIKCLOT  
COMBAT GAUZE IN A STANDARDIZED SWINE MODEL OF  
UNCONTROLLED HEMORRHAGE**

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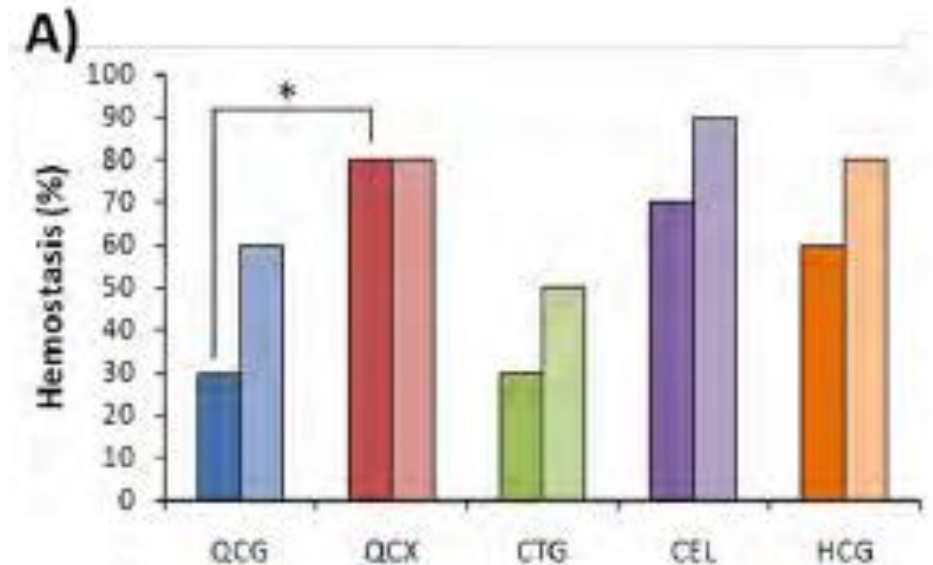
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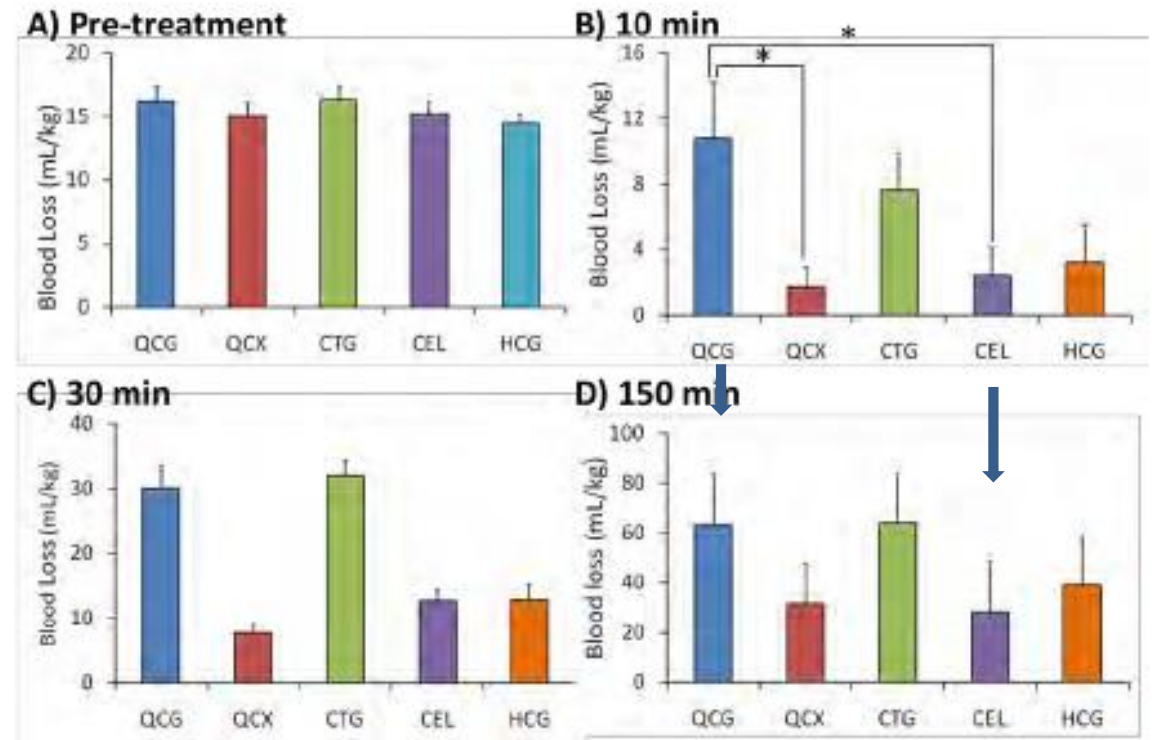
## Results: Hemostasis

- Celox Gauze: 70 % at 3 minutes and 90 % at end of study.
- Clearly outperforming Combat Gauze throughout.
- Outperforms Chitogauze throughout.
- Celox Gauze is #1 at study end with 90% Hemostasis.



## Results: Celox had Lowest Blood Loss

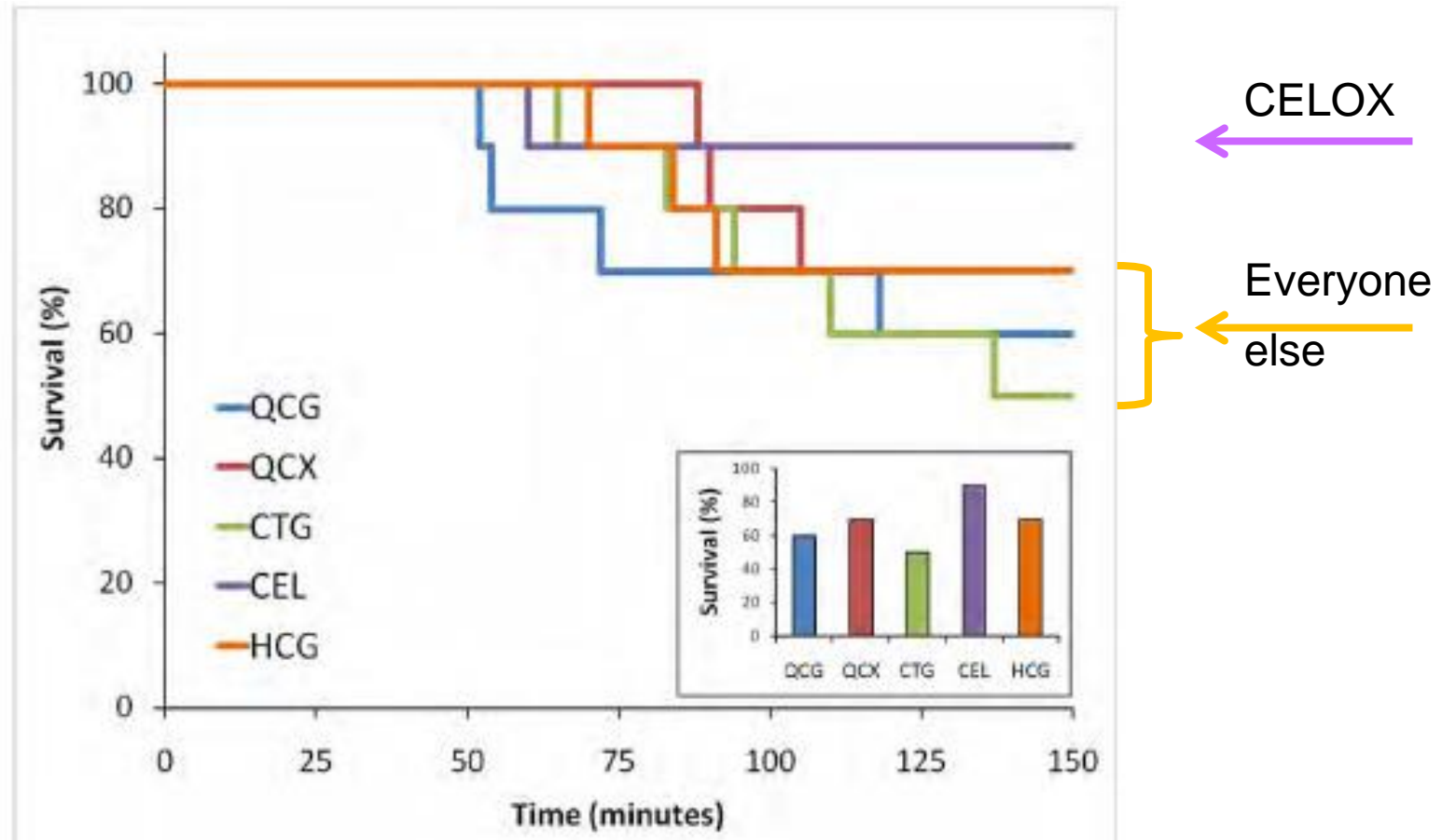
- Celox lowest blood loss overall
- 1,200 ml less than Combat Gauze, 400 ml less than Chitogauze (in a 36 kg animal).
- Significantly better than CG at 10 minutes (but so is CGXL).



**Celox lowest blood loss overall.**



## Results: Survival



**Celox is the clear winner: 90 % observed survival - matching the 90 % hemostasis.**



# Enhanced Dressing

## Management of External Hemorrhage in Tactical Combat Casualty Care: Chitosan-Based Hemostatic Gauze Dressings

*TCCC Guidelines – Change 13-05*

*Brad L. Bennett, PhD, NREMT-P; Lanny F. Littlejohn, MD; Bijan S. Kheirabadi, PhD; Frank K. Butler, MD; Russ S. Kotwal, MD; Michael A. Dubick, PhD; Jeffrey A. Bailey, MD*

- Inconsistencies with Combat Gauze poor efficacy in coagulopathy.
- 38% of all combat casualties are coagulopathic there is a need for an enhanced haemostatic dressing.
- Successful outcomes using CELOX in civilian hospital based case reports and pre-hospital battlefield reports.
- In specific US Spec operation forces UK Mod and 8 other NATO militaries and numerous US elite tactical federal, state, city and county LE teams.



# Conclusion

- 1) Celox Gauze is the most effective haemostatic gauze, with published results in real world use.
- 2) Celox successfully stops bleeding from arterial injuries, gunshot wounds, road traffic injuries, blast injuries, crush injury.
- 3) Celox Granules are proven to work on hypothermic casualties (shock) as well as anti-coagulated blood.

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# Celox Gauze compared to Combat Gauze





# Celox Gauze v Quikclot Gauze (Combat Gauze)

## Combat Gauze Features

- 12 foot gauze;
- Kaolin impregnated;
- Combat Gauze is the CoTCCC product of choice.
- X-ray strip;
- Vacuum pack.
- 5 year shelf life

## Celox Advantages

- 90% survival in DoD (compared to 60 % for Combat Gauze).
- Celox is effective on hypothermic blood.
- Celox works mechanically independent of the bloods intrinsic clotting mechanism
- Celox swells to fill wound.

## Combat Gauze disadvantages

- Kaolin is an inorganic material
- Works by activating the intrinsic clotting mechanism of the blood.
- Will not function with a compromised clotting mechanism as a result of severe trauma injuries

## Celox Features

- Celox has been allergy tested and is non-allergenic
- No proteins in Celox.
- Celox has an excellent safety record – including use of bulk granules.
- Residual granules are absorbed in the body.
- Celox is approved by CoTCCC.



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# US CoTCCC

## - Formal announcement of Celox Approval-

Management of External Hemorrhage in Tactical Combat Casualty Care: Chitosan-based Hemostatic Gauze Dressings

TCCC Guidelines Change 13-05

16 April 2014

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# Celox compared to Chitogauze Pro



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# Celox Gauze v Chitogauze Pro

## Chitogauze Features

- Chitosan impregnated Gauze
- 12 foot gauze;
- Residuals metabolized.
- Antibacterial properties in the dressing.;
- X-ray strip;
- 4 (5?) year shelf life

## What Chitogauze say

- Chitogauze has no loose particles that could cause embolism;
- Chitogauze is stronger antimicrobial
- Chitogauze is more flexible.
- Chitogauze has an X-ray strip and Celox does not.

## Celox Advantages

- 90 % survival in DoD (compared to 70 %).
- Celox 5' allows significantly faster packing.
- Celox 10' treats larger wound.
- More Chitosan on Celox (3x)
- Celox expands on wetting.

## Handling Chitogauze objections

- The Celox particles are on the surface for maximum effect. Celox has an excellent safety record – including use of bulk granules.
- Both products are chitosan-based. Local antibacterial properties are restricted to *in the dressing* and have no clinical relevance.
- The thicker Celox allows faster packing.
- Celox gauze has a high tensile strength and stays together when removing it from a wound.