

# Efficacy of Two Novel Hemostatic Agents (XStat and Hydrogel) in a Coagulopathic Model of Severe Hemorrhage

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## Rationale

- Exsanguination: #1 cause of preventable battlefield death¹
  - 20% are junctional wounds not amenable to tourniquet<sup>1</sup>
- TCCC has approved 3 hemostatic products
  - Combat Gauze, ChitoGauze, and Celox Rapid Gauze
- Newer products with novel mechanisms of action include XStat (rapidly expanding sponges) and Hydrogel (hydrophilic polymer)
- However, no previous studies have contrasted XStat and Hydrogel with traditional products in Survival, Blood Loss, Hemostasis, and Rebleeding in a swine model of severe hemorrhagic shock<sup>2</sup>

# Methods

## Subjects

• 35 Female swine (sus scofa), 35-45kg

## Groups / Hemostatic Agents (Randomly Assigned)

Combat Gauze® (n=8)

Hydrophilic Polymer Gel Forms a

Bio-Adhesive Plug

**XStat®** (n=7)

Rapidly Expanding Sponges Impregnated with

Chitosan Injected into Wound

Combat Gauze® (n=8)



Embedded w/ Kaolin (white clay)
Activates Factors XI & XII

ChitoGauze<sup>™</sup> (n=5)



Embedded w/ Chitosan (polysaccharide from shellfish)
Crosslinks RBCs

Celox Rapid<sup>TM</sup> (n=7)



# Methods

#### Procedures

### 1. Surgical Preparation

- Cannulations:
- Carotid Artery (Vital Sign Monitoring)
- External Jugular (Fluid Replacement)
- Right Femoral Artery (Blood Removal)
- Left Femoral Artery Exposure

#### 2. Induction of Coagulopathy<sup>3</sup>

- Replace 50% of subject blood with colloid
- Lower core temp to 33°C (+/- 0.5°C)
- 10 min stabilization

#### 3. Kheirabadi Femoral Artery Hemorrhage Model<sup>4,5</sup>

- 6mm arterial punch, left femoral artery
- 45 sec free bleed

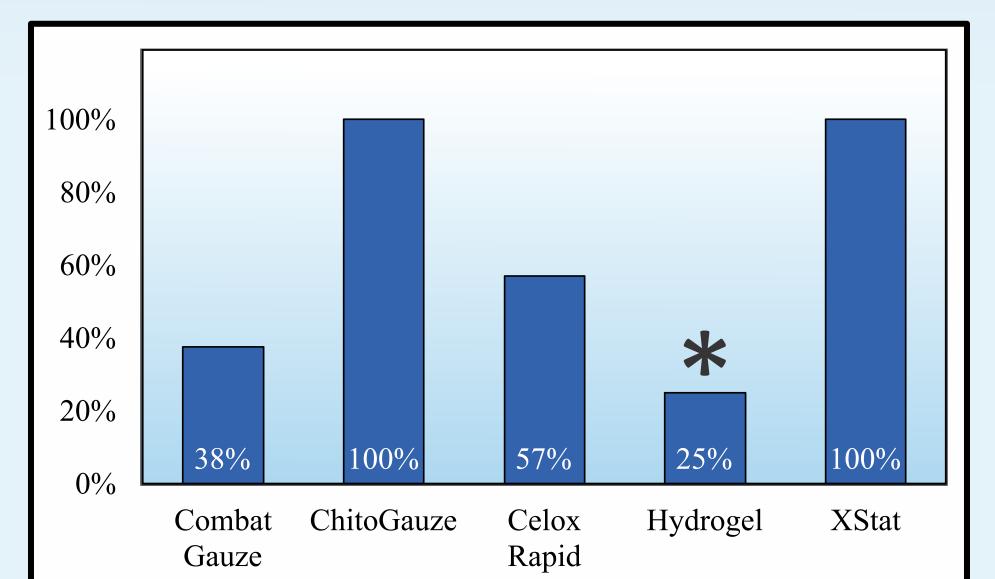
#### 4. Treatment

- Application of agent with 3 minutes of pressure
- 5. Observation for 2.5 hours

# Hypotheses

- No statistically significant difference between groups in:
- Survival (H1) (Fisher's Exact Test)
- Blood loss (H2) (Kruskal-Wallis; Mann-Whitney)
- Primary Hemostasis (H3) (Fisher's Exact Test)
- Rebleed (H4) (Fisher's Exact Test)
- Each at the p < .05 statistical significance threshold

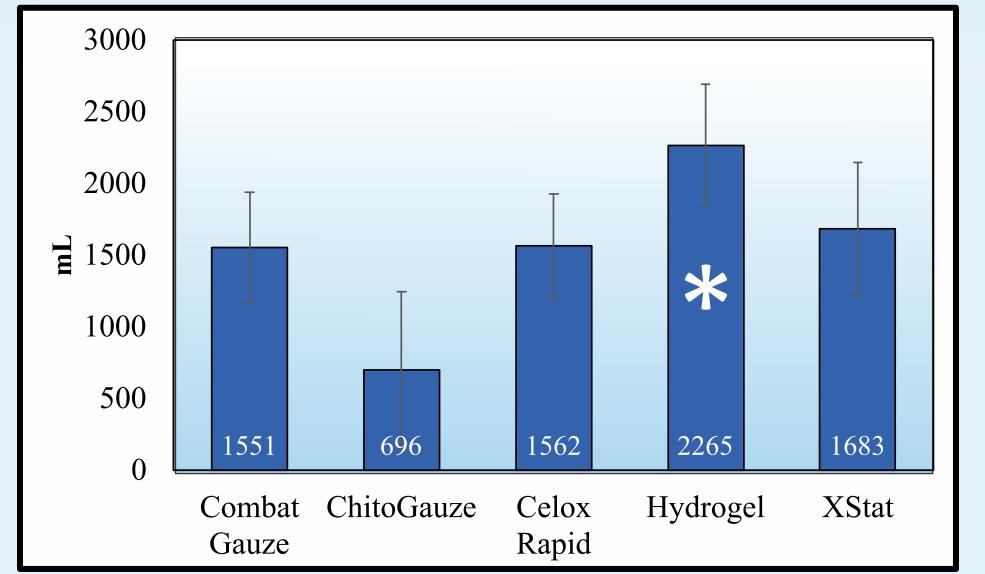
# Results



\*p < .02 vs ChitoGauze and XStat

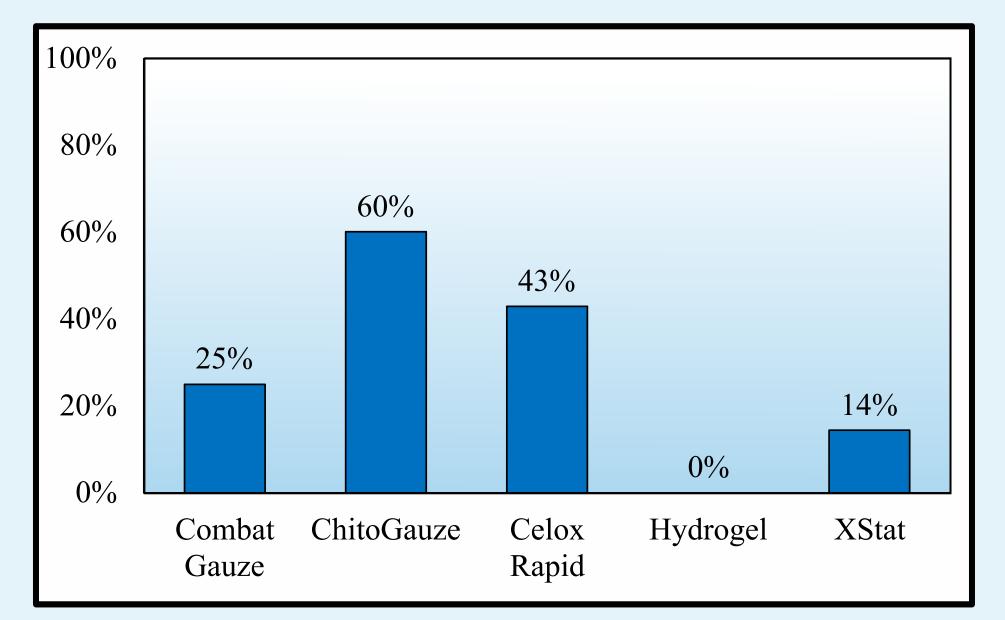
H1: Survival

### **H2: Post Treatement Blood Loss**



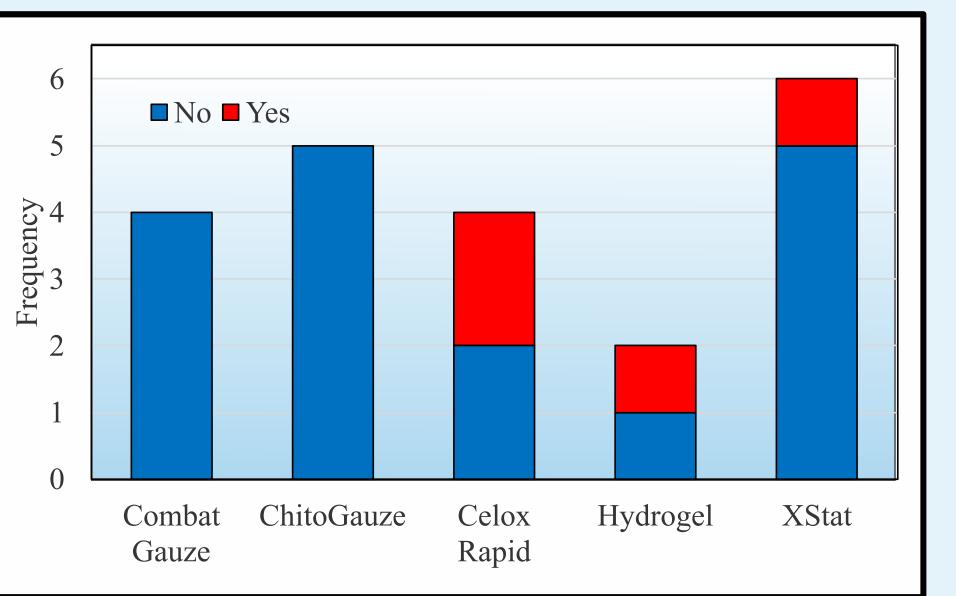
\*p < .04 vs ChitoGauze

## H3: Primary Hemostasis



p = .07; Hydrogel vs ChitoGauze

## H4: Rebleed



p = .21

# Disclaimer: The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Defense or the United States Government.

Research data derived from a Naval Medical Center Portsmouth IRB/IACUC approved protocol.

# Discussion

## *Implications*

- Xstat → Can Save Lives in Combat
  - 100% Survival
  - Intermediate Blood Loss, Hemostasis, Rebleed
- HydroGel → Will Not Save Lives in Combat
- 25% Survival
- High Blood Loss, Rebleed; 0% Hemostasis

## Limitations

- Modest Sample Size
- One swine groin coagulopathy model
  - May not generalize to
  - Other wound locations / severity
  - Irregular wounds
- Laboratory setting only

# **Future Research**

- Replication!
  - Larger sample sizes
  - Other wound models
- Contrast with other modalities (e.g. junctional tourniquet)
- Testing in combat / simulated combat settings

## Conclusion

XStat has the potential to save lives on the battlefield, while Hydrogel does not appear to be an effective hemostatic agent for severe hemorrhagic coagulopathy

# Bibliography

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