

Self-Propelling Hemorrhage Control Powder With Thrombin And Tranexamic Acid Achieves Hemostasis In Upper Gastrointestinal Bleeding

Youjie Zhang, ME

Graduate Student

Joint Biomedical Engineering Department

Medical College of Wisconsin

Marquette University

Versiti Blood Research Institute

youzhang@mcw.edu

Disclosures:

**Dr. Christian Kastrup and Dr. James R. Baylis
are cofounders, shareholders and of CoMotion Drug Delivery Systems,
which is working to commercialize the self- propelling powder technology, CounterFlow.**

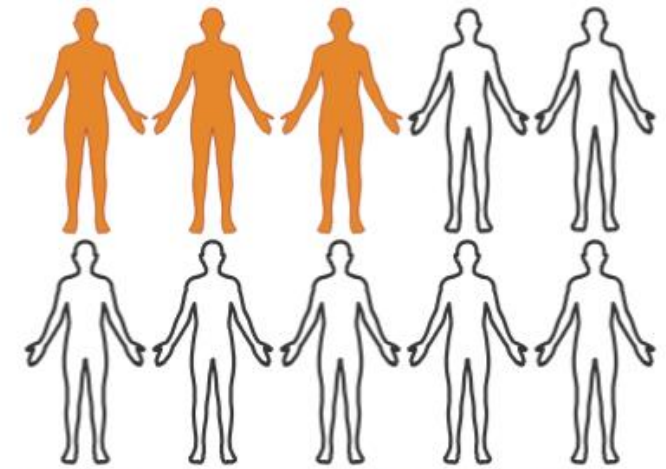
**Dr. Arefi, S.M.A, Dr. Dana Grecov, Dr. Christian Kastrup and Youjie Zhang
are named inventors on a patent application related to the powder spray device
and are involved in its commercialization.**

Bleeding... It's A Problem.



Acute Gastrointestinal Illness (AGI) Is A Major Burden In Military Populations.

- AGI has than one million cases annually and an estimated cost of \$847 million in Military population
- Upper gastrointestinal bleeding (UGIB) accounts for 75% of acute GI bleeding and remains a medical emergency with significant mortality.



**Death rate of UGIB
can be as high as 30%.**

What Is Upper Gastrointestinal Bleeding (UGIB)?

- **Upper gastrointestinal bleeding** is bleeding from the esophagus, stomach and etc
 - Forrest Ia: active spurting bleeding
 - Forrest Ib: active oozing bleeding



Forrest Ia Bleeding



Forrest Ib Bleeding

- A **rebleeding event** means bleeding recurs after initial hemostasis or clinical stabilization.
 - Rebleeding rate is up to 30%

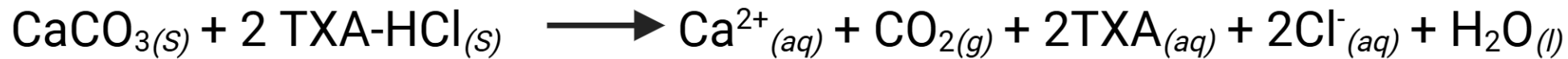
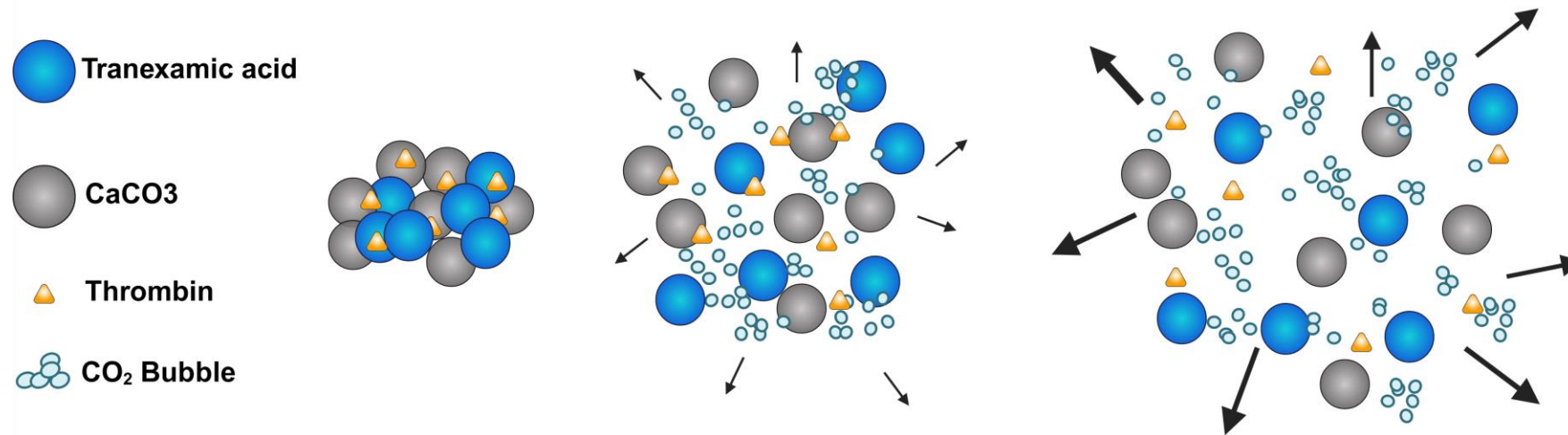
The Effectiveness Of Current Treatment Options For Severe UGIB Is Limited.



- **Traditional treatment:**
 - Injection of epinephrine
 - Thermal coagulation
 - Mechanical device
- **Limitations:**
 - Obscured visualization
 - Difficult to reach lesions

- **Newer treatment:**
 - Topical hemostatic powders and gels
- **Limitations:**
 - easily be washed away

Self-propelling Hemorrhage Control (SPHC) Powder Uses Self-propelling Carbonate Particles To Deliver Thrombin And Tranexamic Acid.



⋮

Tranexamic acid (TXA)

TXA is an antifibrinolytic drug, a “clot stabilizer”

CounterFlow™ TNT-G **Bleeding**



SPHC (CounterFlow) Safely Delivers Tranexamic Acid and Thrombin.

Gauze Delivers:

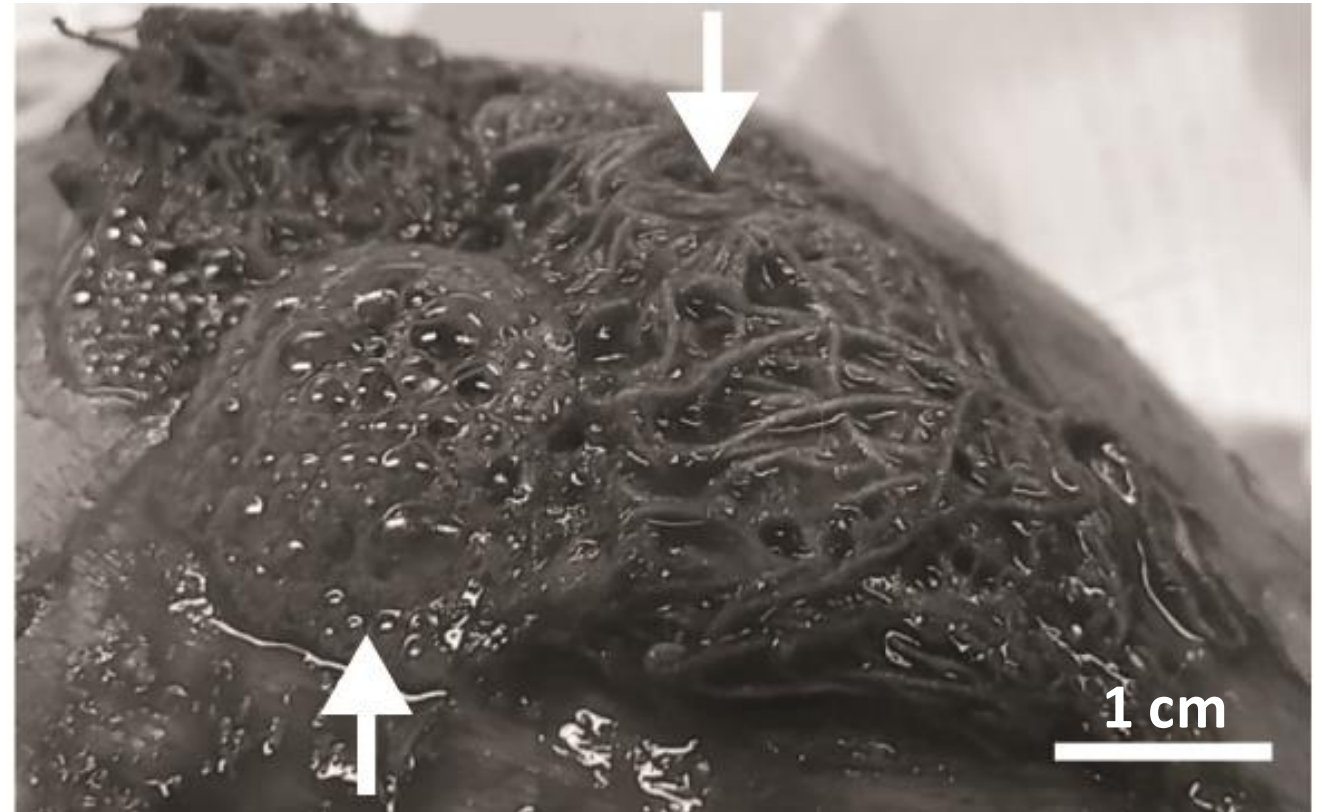
- Systemic TXA
- Ca^{2+}
- Pressure from CO_2
- Thrombin

CounterFlow Components are Safe:

CaCO_3 and CO_2

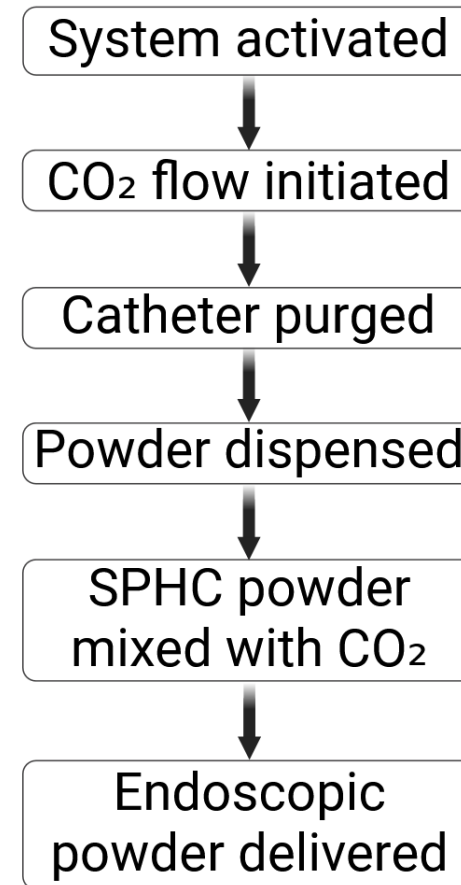
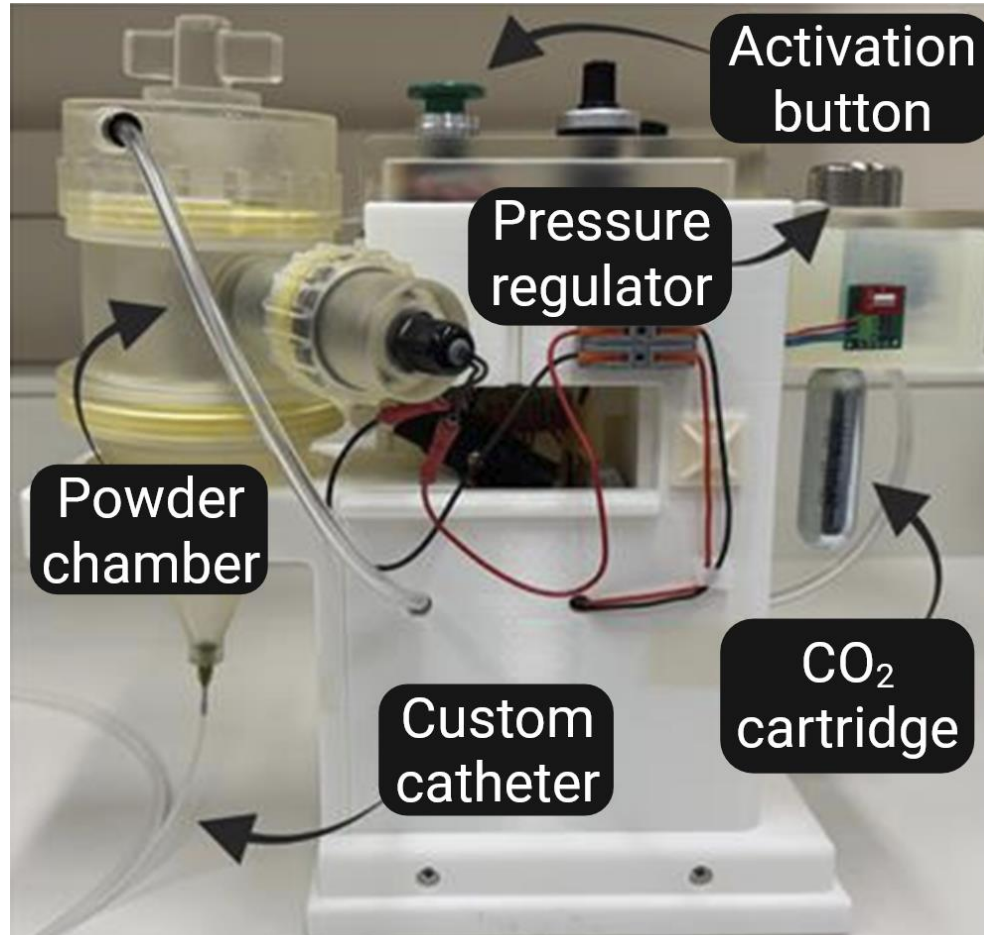
- Bioabsorbable and soluble in blood, wounds and vessels

CounterFlow Gauze in a swine model

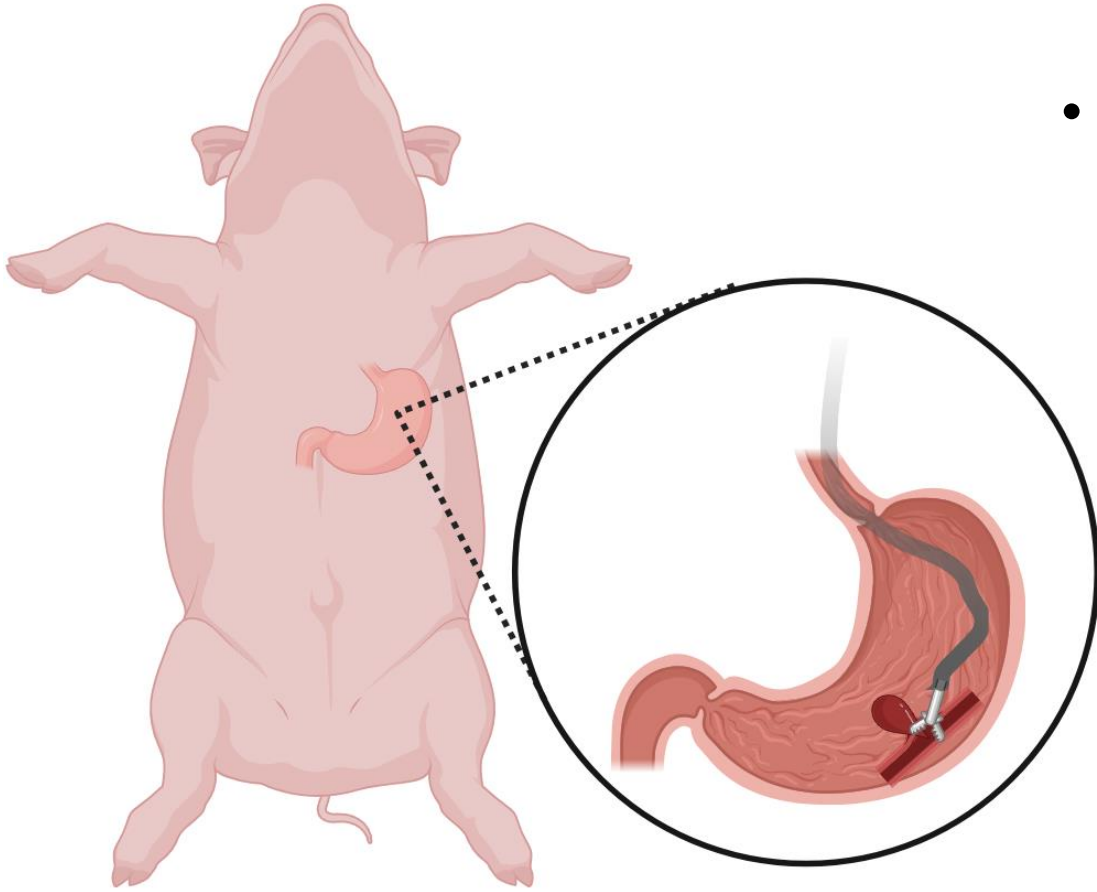


Bubbles escaping wound

SPHC Can Be Efficiently Delivered By The Pilot Device.

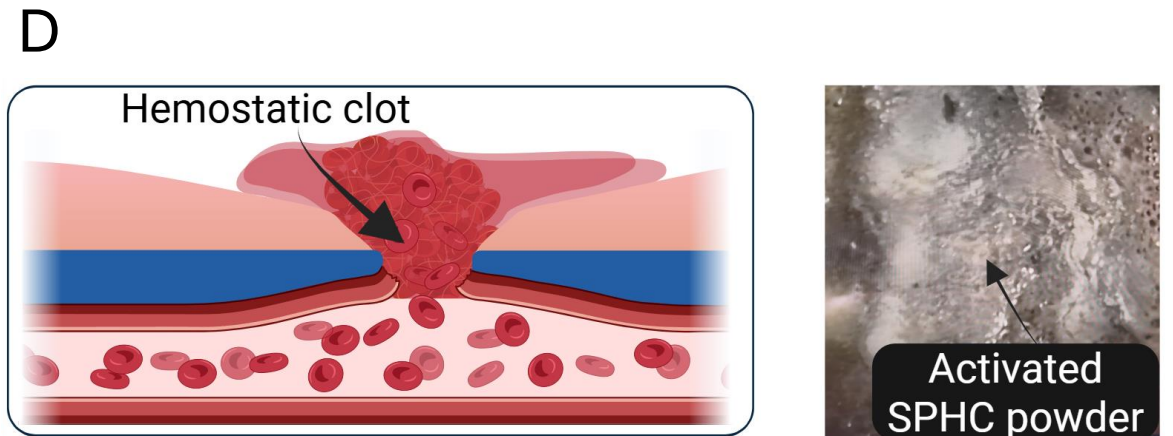
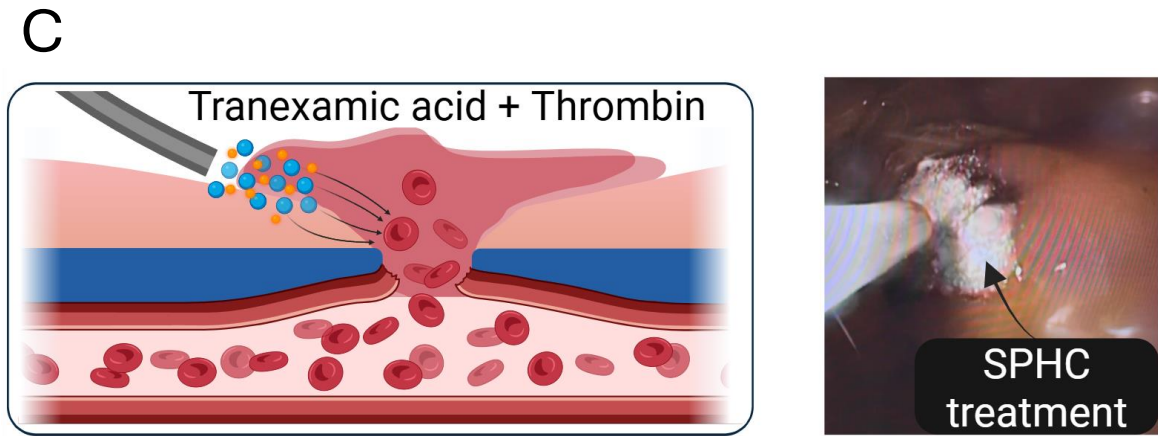
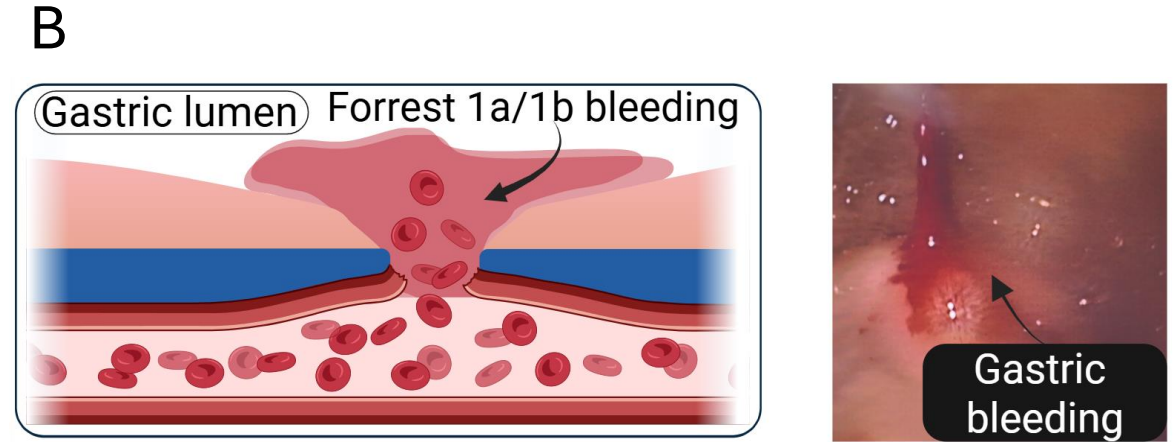
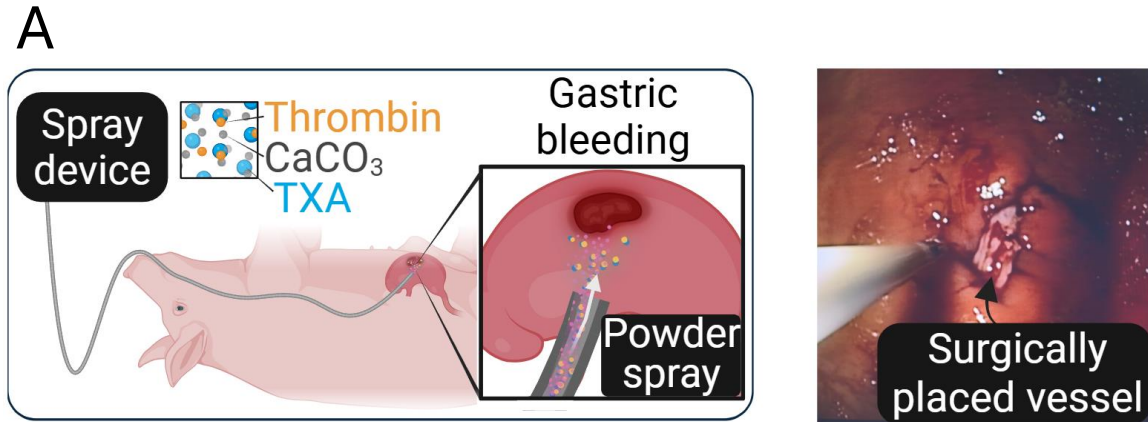


Swine Model of Forrest 1a/1b UGIB



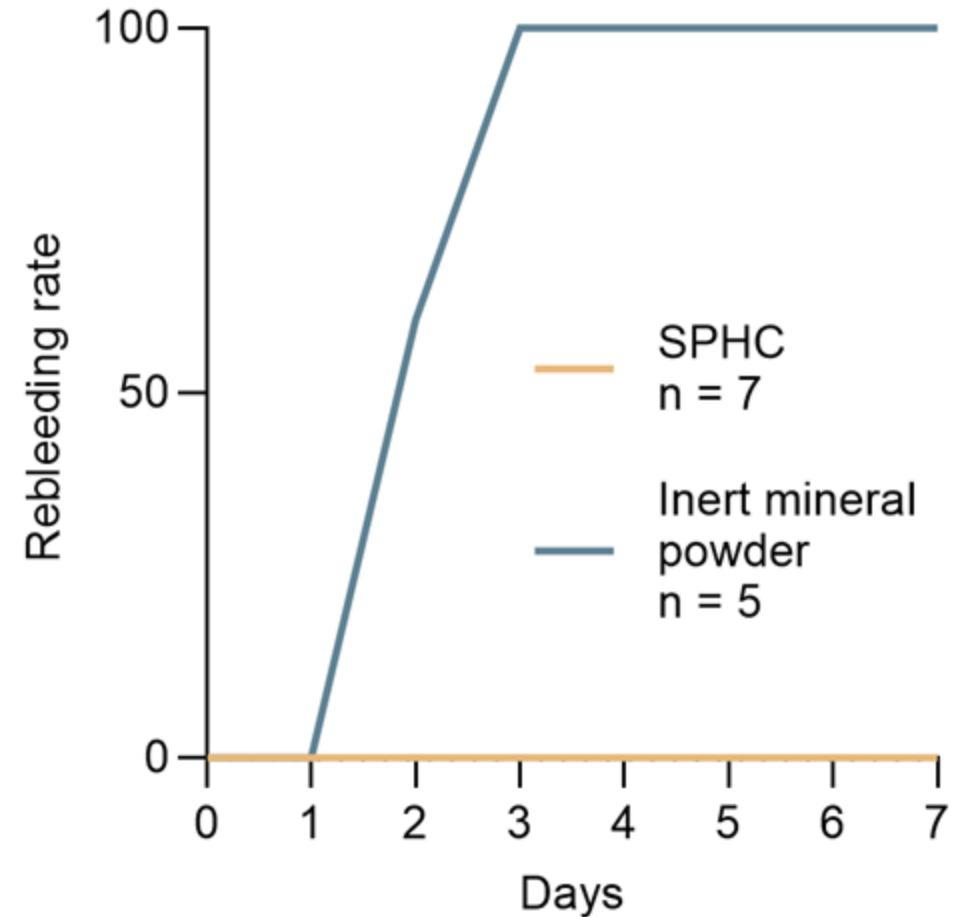
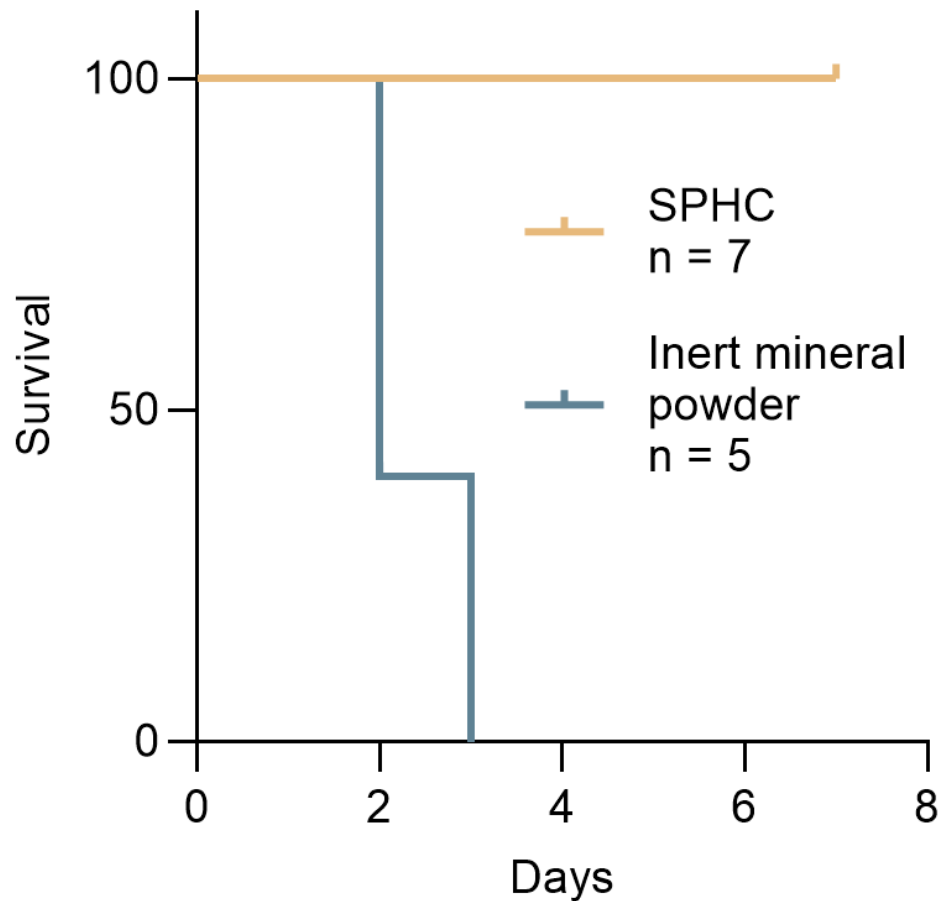
- **A reliable Forrest 1a/1b UGIB model in swine**
 - Isolate gastroepiploic artery
 - Create an incision on the stomach
 - Fold the isolated artery into the stomach
 - Create a blood vessel that can be used to create the active bleeding

SPHC Powder Halts Severe Upper Gastrointestinal Bleeding.

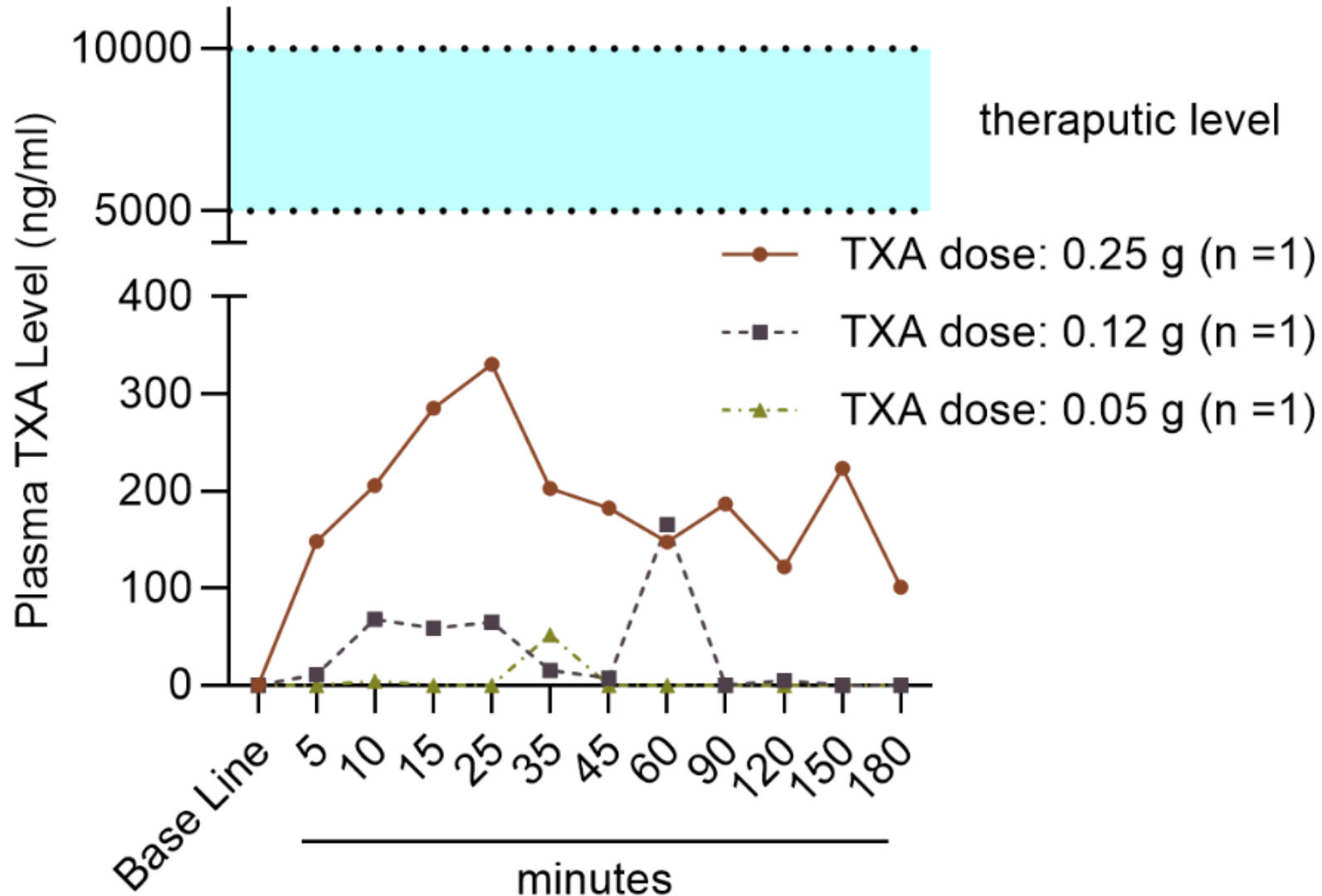


- There is no difference in mean time to hemostasis for different treatment :
 - SPHC: 2.8 min
 - Inert mineral powder: 2.5 min

SPHC Shows No Rebleeding And High Survival Rate.



Systemic TXA is Minimal After Upper GI Treatment.



Conclusion

- **Endoscopic SPHC effectively controlled UGIB.**
- **SPHC prevented rebleeding for up to 7 days.**
- **Local SPHC application resulted in detectable systemic TXA exposure.**

Collaborators:

- **Andrew Beckett** (Canadian Armed Forces)
 - **Nathan White** (U. Washington)
- **Andrew Cap, Patrick Ketter, Julie Rizzo, Kathy Ryan** (USAISR)
 - **Joao Rezende-Neto** (U. Toronto)
- **Hugh Semple, Catherine Tenn** (Defense Research and Development Canada)
 - **Dana Grecov** (UBC)

Acknowledgments:

- **Versiti Blood Research Institute**
 - **Halen Turner, MD**
 - **Monica Seadler, MD**
 - **Sarah Fisher, MD**
 - **Jeffrey Anderson, MD, FACS**
 - **Mitch Dyer, MD**
 - **Chad Skaer**
- **University of British Columbia**
 - **Dr. Massimo Cau**
 - **Dr. Nabil Ali-Mohamad**
- **University of Washington**
 - **Xu Wang, MD**
 - **Dr. Kristyn Ringgold**
- **University of Toronto**
 - **Dr. Kanwal Singh**
 - **Dr. Aron Shoara**
 - **CoMotion**
 - **Dr. James Baylis**



National
Defence

Défense
nationale



Questions