Coagulation Profiles of a Mesoporous Bioactive Glass Hemostat Using Human and Porcine Plasma: Pivotal Preclinical Study Designs

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Introduction

Hemostatic agents have advanced significantly since the Gulf and Afghan wars, yet challenges remain in terms of long-term adsorption, chronic infection risk, and in vivo non-invasive traceability. **Mesoporous bioactive glass (MBG)** is a highly porous silica-based biomaterial possessing an ordered network of **2–50 nm pores**, an exceptionally **high specific surface area (200–800 m^2/g)**, and interconnected pore channels that rapidly absorb blood and plasma. The combination of high porosity, large surface area, and bioactive ion exchange likely accelerates clot formation while the material remains absorbable, making MBG an attractive next-generation topical hemostatic agent. MBG containing Tantalum (Ta-MBG) is anti-microbial, anti-fungal, and potentially radiopaque. Both are hemostatic in murine tail-bleed models. Here, we assessed the ability of Ta-MBG/MBG to accelerate clotting and lysis; to verify its radiopacity; and to describe a pivotal swine coagulopathic bleeding model for Ta-MBG efficacy

Objectives

1. To evaluate the ability of Ta-MBG/MBG to accelerate clotting and lysis in human and porcine plasma
2. To verify that Ta-MBG is radiopaque
3. To discuss the pivotal porcine dilutional coagulopathy liver injury model for Ta-MBG efficacy

Materials and Methods

Human and Porcine citrated plasmas, and human and porcine recombinant tPAs were obtained from Innovative Research, Novi, MI. Ta-MBG and MBG were synthesized by sol-gel methods at MS&T and characterized by BET for surface area, pore size and volume and by SEM-EDS for size shape and elemental composition. Radiopacity measurements were performed using a GE Lunar iDXA™ dual-energy X-ray absorptiometry (DEXA) platform and by a Gendex 765 DC dental x-ray set to 65 kVp. Clotting was assessed with citrated human and porcine plasma. Hemostatic agents MBG, Ta-MBG, Kaolin, Celox™ or ACT glass beads were incubated at 0.5 mg/ml for 15min @ RT then centrifuged. Supernatants were supplemented with 1 µg/ml human or 9 µg/ml porcine tPA then 200 µl added in quadruplicate to 96 well plates containing 10 µl of 0.2 M mM $CaCl_2$ and the A 405 nm (porcine) or A 380 nm (human) recorded at 37°C for 90 minutes on a Molecular Devices reader. Onset time, Vmax, time to Vmax, lysis rate, lysis time and clot density were analyzed from the A 405 vs time curves using SoftMax^{R}Pro software. Graphical representations of the dilutional coagulopathy porcine liver laceration model were created using BioRender software.

Conclusions

These results represent verification that **Ta-MBG:**

1. Accelerates clotting of both human and porcine plasma without impairing fibrinolysis and superior to a cleared topical hemostat.
2. Is radiopaque and can be detected intraorally by clinical x-ray and *in vitro* using standard DEXA instrumentation
3. May be a significant advance in battlefield, surgical, and ambulatory hemostasis management pending the pivotal dilutional coagulopathic porcine liver laceration model scheduled to begin in Q4 2026

Data/Results

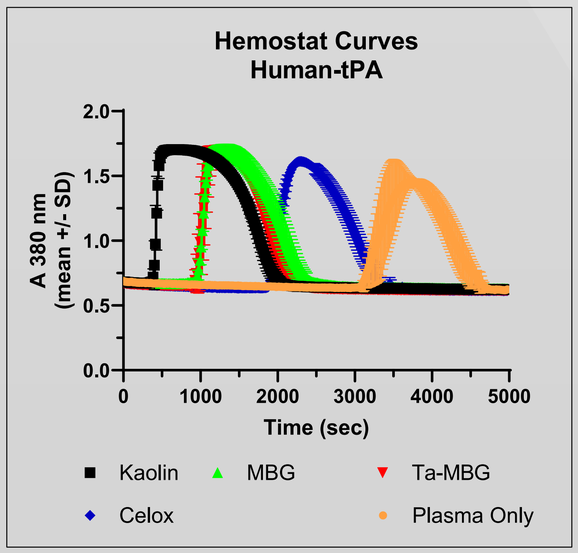

Figure 1. Human Kinetic Clotting and Lysis Curves: Kaolin control (black boxes) had fastest clotting. MBG (green) and Ta-MBG (red) had similar clotting and lysis curves. Celox, Glass and Plasma clotted after 2000 seconds. 380 nM was chosen to reduce hemolysis evident in the human plasma samples

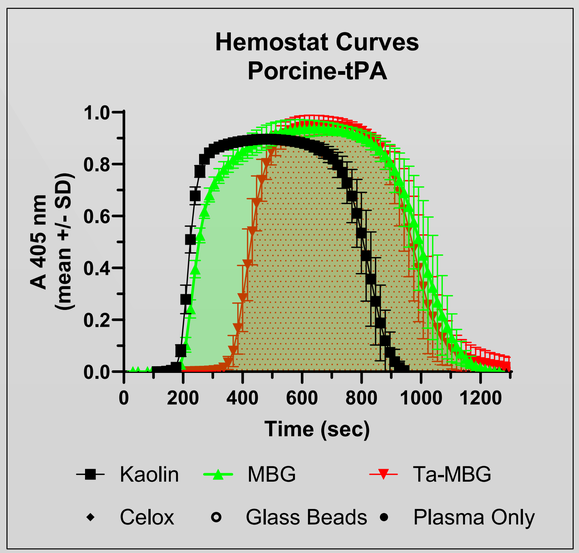

Figure 2. Porcine Kinetic Clotting and Lysis Curves. Kaolin Control (black boxes) and MBG (green triangles) had similar clotting kinetics. Ta-MBG (red triangles) had a slower inset time but similar lysis rates at MBG. Celox, Glass and Plasma alone did not clot

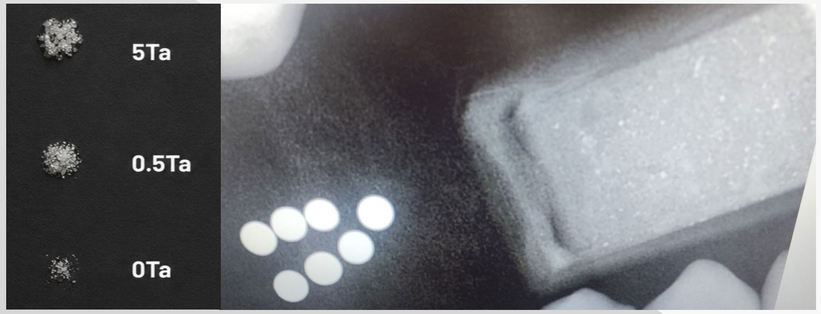

Figure 3 (Above). Radiopacity of Ta-MBG (Left: DEXA of 0, 0.5 and 5 mol Ta-MBG) Right (Intraoral Xray of 5%Ta-MBG powder with Pb shots as reference

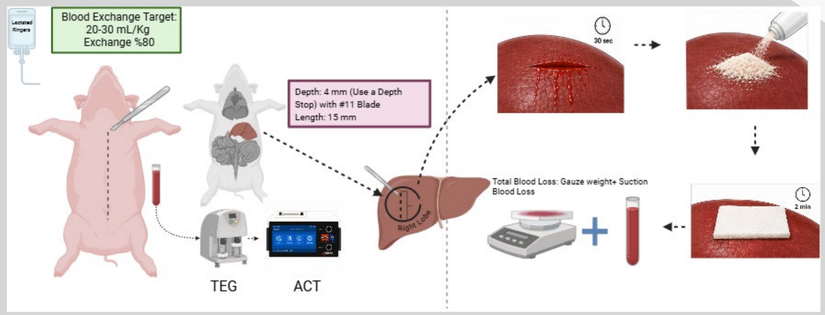

Fig 4. (Above) Porcine Liver Laceration Dilutional Coagulopathy Model

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