

# Examining the Biomechanical and Biological Effects of IMPEDE-FX Embolization Plugs



Baqir Kedwai, BHSc, Zachary Zottola, BS, Joshua Geiger, MD, Daniel Lehane, BA, Sam Najjar, Michael Stoner, MD, Doran S. Mix, MD University of Rochester Medical Center, Division of Vascular Surgery, Department of Surgery, Rochester, NY.

## INTRODUCTION

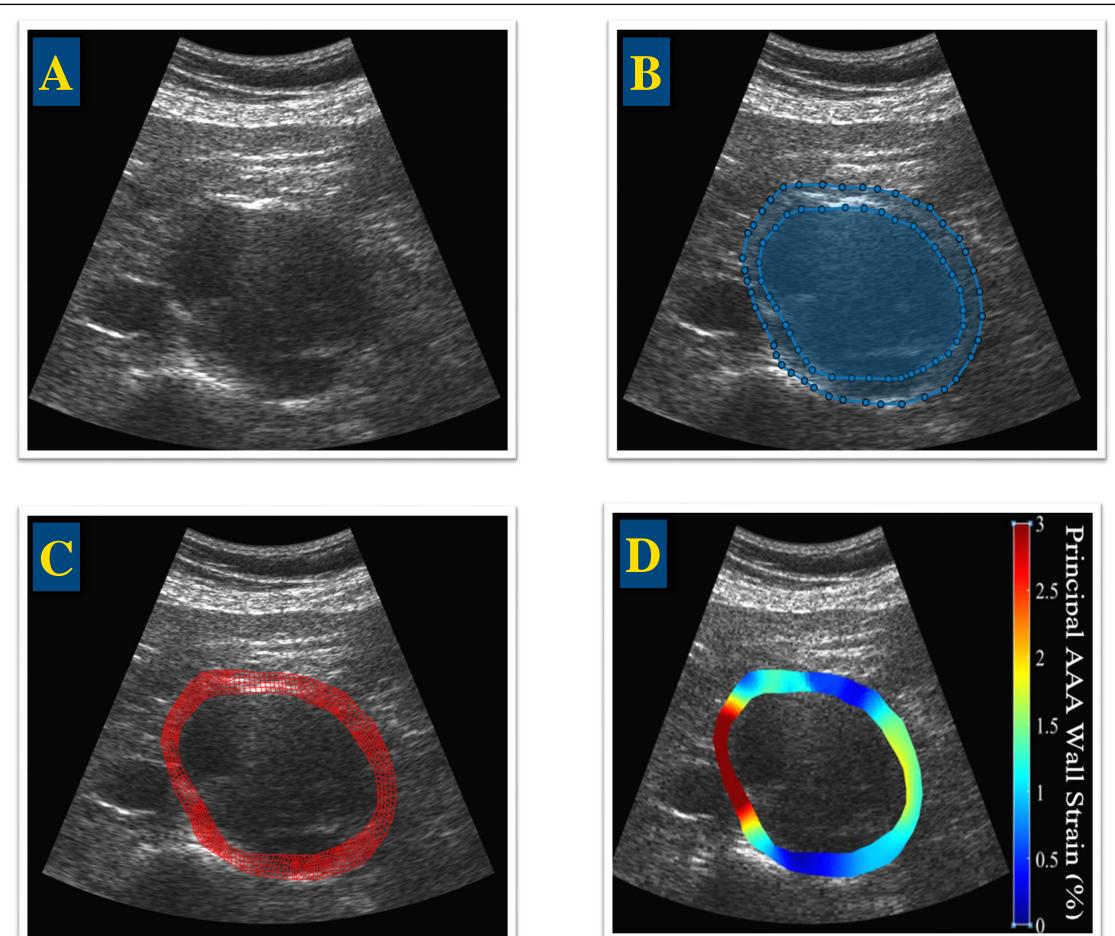
The IMPEDE-FX plug is a self-expanding shape memory polymer that promotes clot formation and collagen production

Ultrasound elastography (USE) can measure pressurenormalized aortic principal wall strain ( $\overline{\epsilon_{\rho+}}$ /PP, %/mmHg)

**Aim 1**: Measure the effect of IMPEDE-FX on  $\overline{\varepsilon_{\rho+}}$ /PP via USE

Aim 2: Evaluate device-tissue interactions in explanted plugs

## **METHODS**



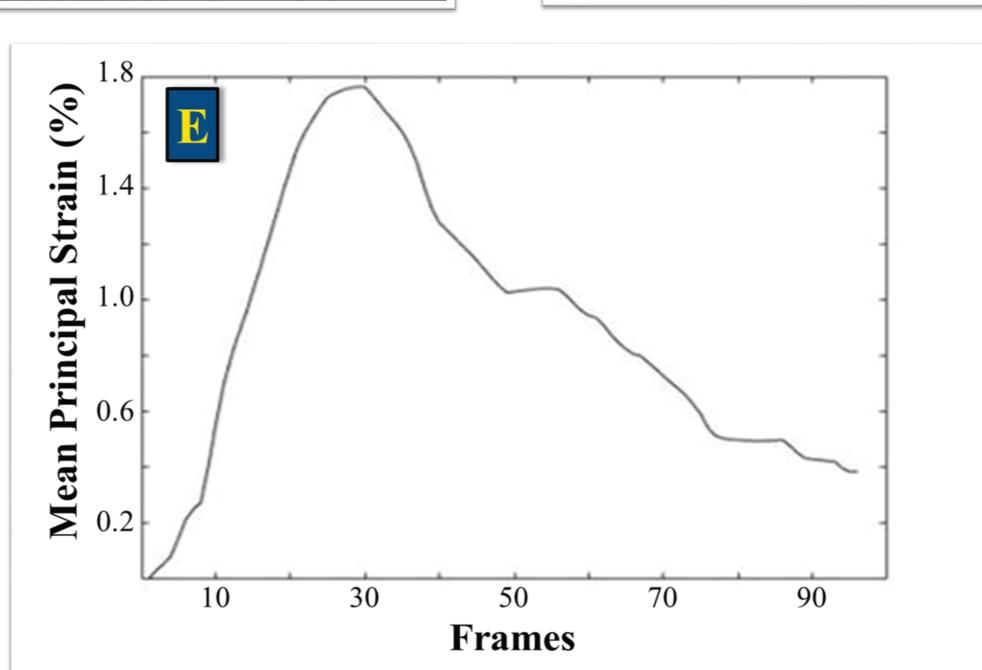


Figure 1. A) B-mode ultrasound image; B) Region of interest defined; C) Finite element mesh overlay; D) Parametric color map; E) Graph of mean principal strain per frame.

#### **METHODS**

3.4 cm endograft deployed into 3D-printed axisymmetric AAA model and connected to hemodynamic flow circuit

IMPEDE-FX plugs deployed in two conditions:

- Stepwise to 100% (16 plugs) then 150% (24 plugs)
- Immediate to 250% (40 plugs)

Axial ultrasound imaging at 5, 10 & 15 mins for each volume

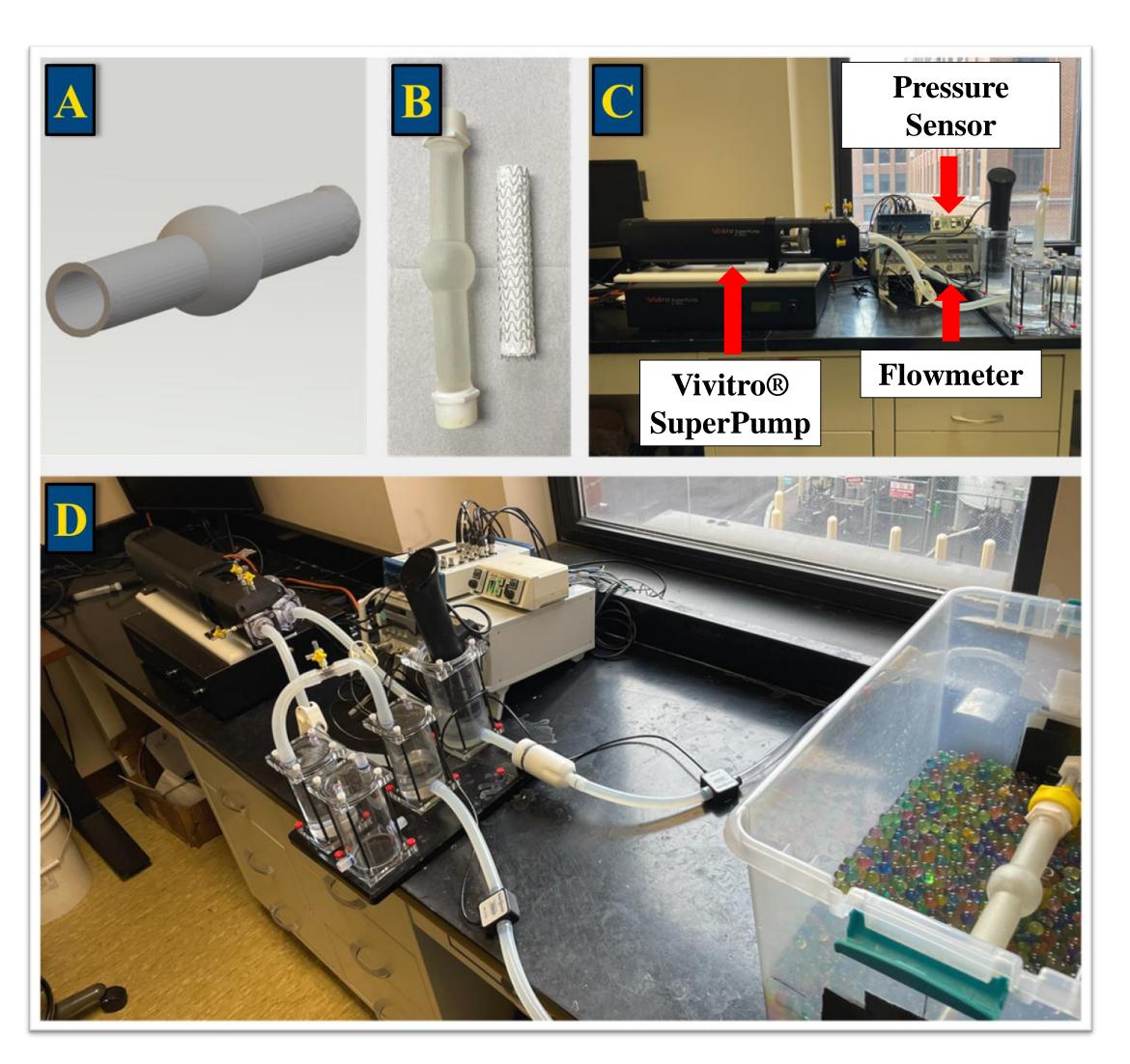


Figure 2. A) Stl. file of idealized AAA model; B) 3D-printed model; C) Flow circuit; D) Model attached to flow circuit.

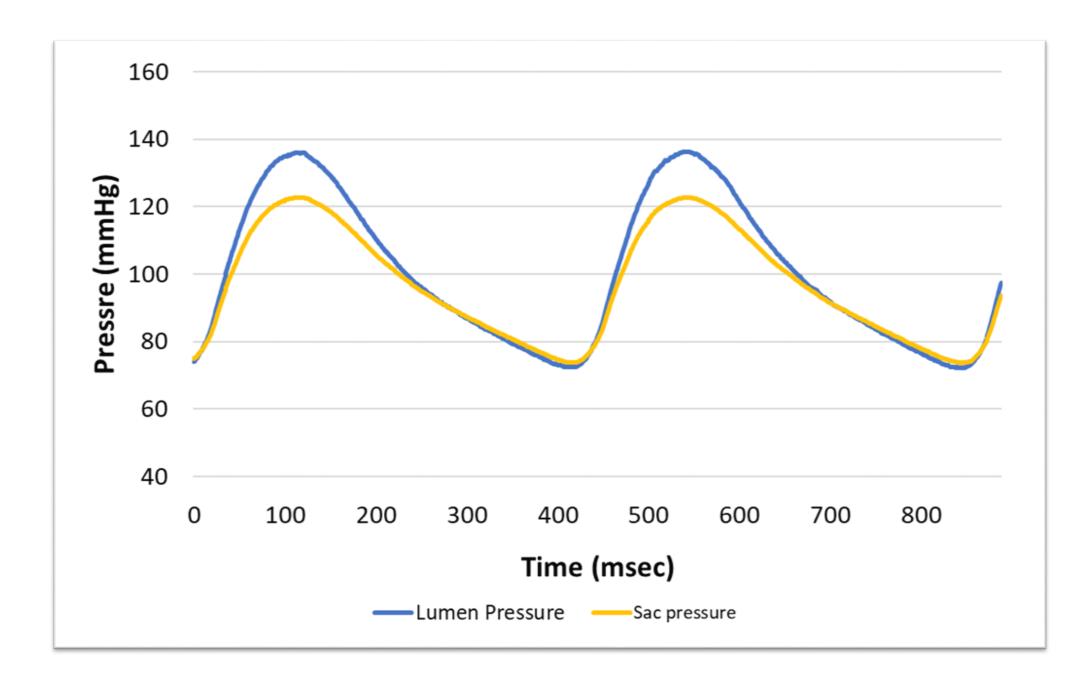
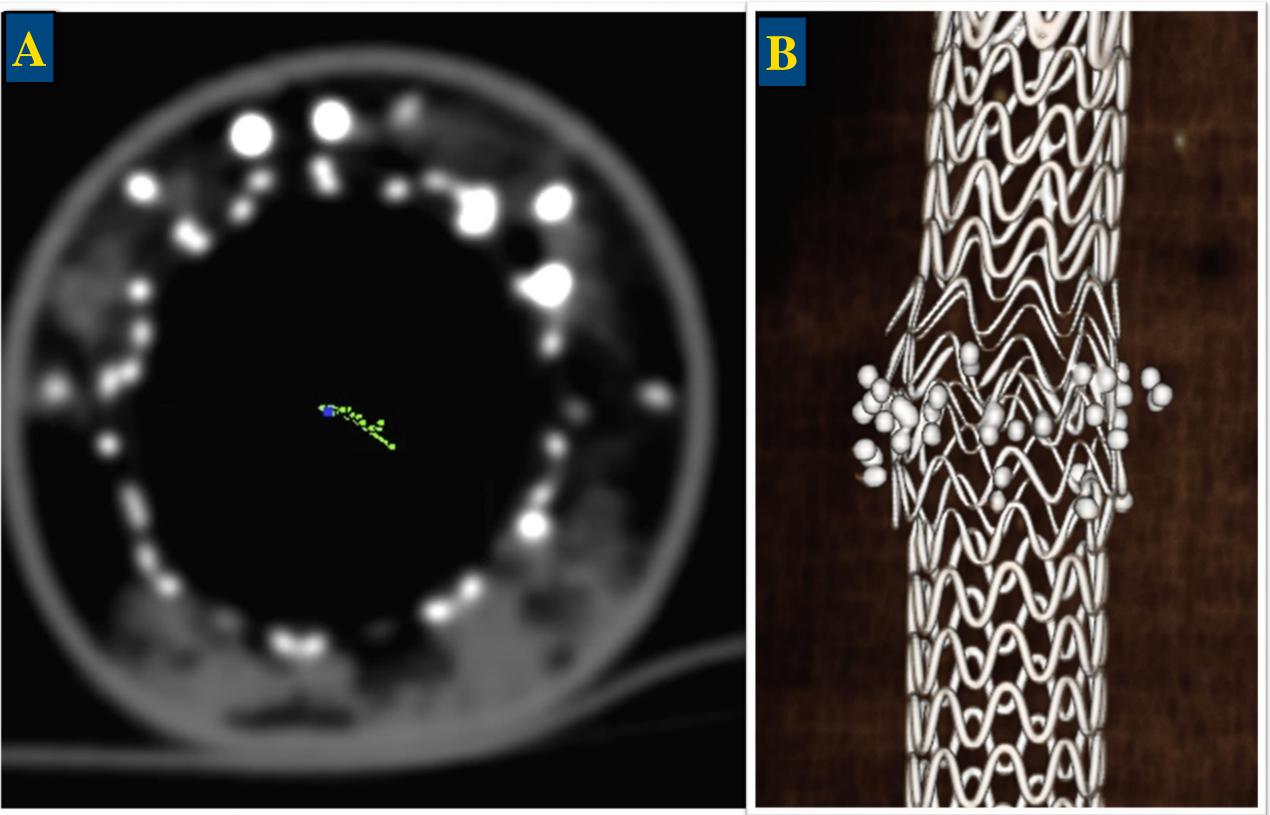


Figure 3. Pressure tracings over time.

#### RESULTS



Packing Volume
100%
150%
10 20 30
Time (mins)

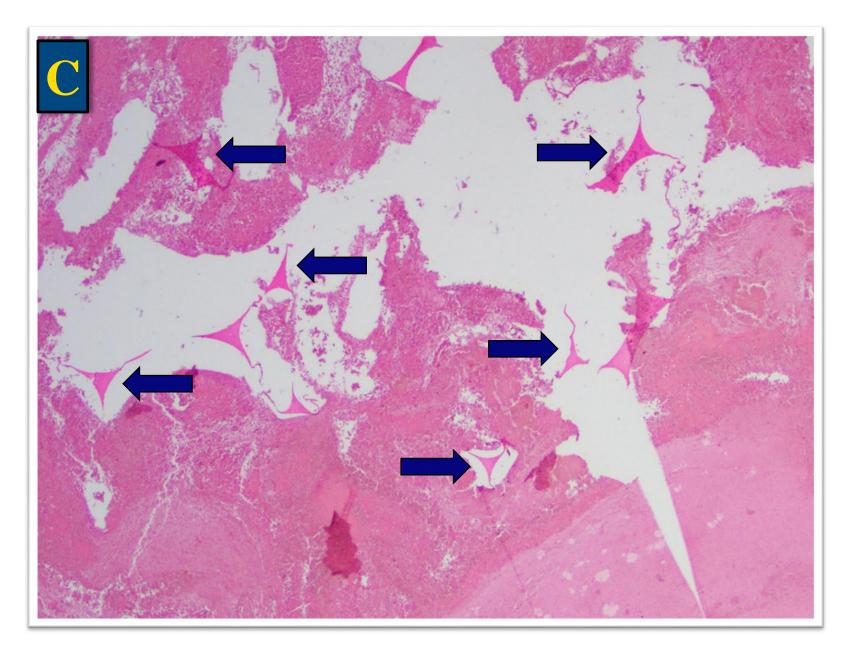
**Figure 4. A)** Axial CT and **B)** 3D reconstruction of endograft-model construct after plug deployment.

**Figure 5.** Relative change in  $\overline{\varepsilon_{\rho+}}/PP$  over time after plug deployment.

# CASE STUDY: EXPLANTED IMPEDE-FX PLUGS







**Figure 6. A)** Explanted graft; **B)** Extracted clot; **C)** H&E stain of polyurethane plug material and thrombus.

# CONCLUSIONS

Higher packing volumes and rates of the IMPEDE-FX Plug are associated with reduced  $\overline{\varepsilon_{\rho+}}$ /PP in idealized aneurysm models

No evidence of device-tissue integration on preliminary H&E stain analysis

Future directions

- Study the effects of a wider range of packing volumes and deployment rates on  $\overline{\varepsilon_{\rho+}}/PP$
- Conduct micro-CT and comprehensive histopathologic testing to examine the host response of aneurysms to explanted plugs