Minimally Invasive Soft Robotic Prototypes Provide Variable Occlusion in a Simplified Aortic Flow Model

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BACKGROUND

- Non-compressible torso hemorrhages (NCTH) have high mortality and morbidity rates[1] (**Fig. 1A**).
- Clinically-available emergency aortic occlusion devices such as the REBOA save lives, but often at the cost of life-threatening complications such as vessel injury, tissue ischemia, and reperfusion injury[2] (**Fig. 1B**).
- Variably-occlusive prototypes like pREBOA show promise in preventing such complications but are burdened by limited control[3] (**Fig. 1C**).

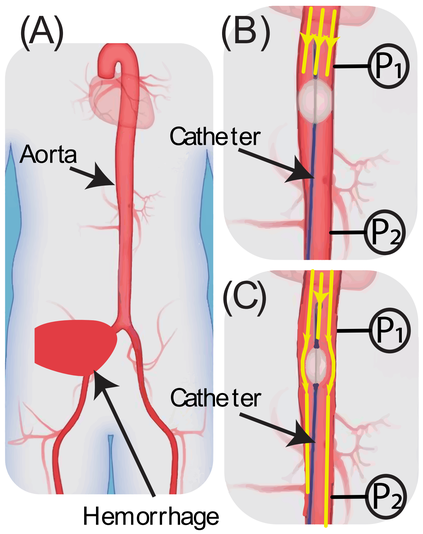

Fig. 1. (A) NCTH, (B) REBOA, (C) pREBOA

OBJECTIVES

(1) Design, (2) fabricate, and (3) characterize the variable occlusive performance of a soft-robotic, minimally-invasive intravascular aortic occlusion device.

APPROACH

Laminate material layers can be precision cut, stacked, and heat fused to make complex mm-scale structures (**Fig. 2**).

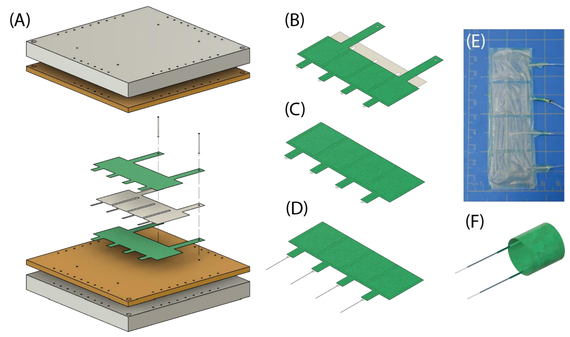

Fig. 2. Fabrication process of occlusive balloon

This process is used to create multiple components of the proposed device, including the occlusive balloon and endothelial bracing mechanism (**Fig. 3**).

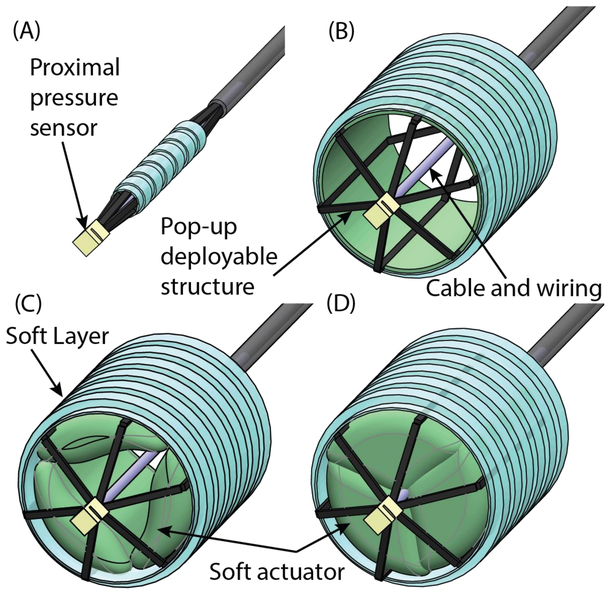

Fig. 3. Proposed device and functionality. (A) Ready-to-deploy compact device, delivered in a small catheter. (B-D) Deployment and subsequent actuation of the occlusive balloons from partial to full occlusion.

RESULTS

Initial testing of occlusive balloons in an in-vitro setup yielded promising results, with designs such as the "phased tetracuspid" displaying a high degree of linearity between inflation pressure and aortic pressure (**Fig. 4**).

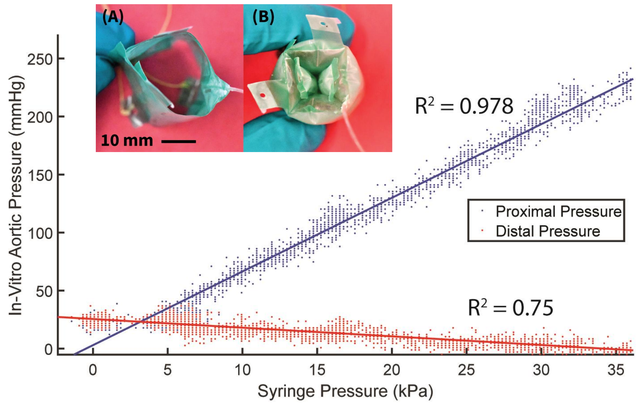

Fig. 4. Correlation between inflation pressure of occlusive balloon (pictured in (A) inflated and (B) deflated states) and in-vitro aortic pressure.

This testing was conducted without an accompanying stabilization mechanism, which complicated deployment of the balloons in the presence of fluid flow. This necessitated the development of a rigid bracing mechanism fabricated using principles of MEMS (**Fig. 5**).

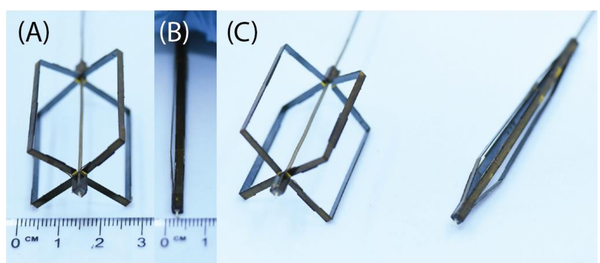

Fig. 5. Bracing mechanism. (A) Deployed bracing mechanism, (B) Undeployed bracing mechanism, and (C) Side-by-side view of deployed and undeployed mechanisms.

SUMMARY

- **The soft-robotic occlusive device demonstrates variable-occlusion in an aorta-model system (Fig. 6).**
- The current device can be inserted via a 5 mm access port and expand to a diameter of 30 mm.

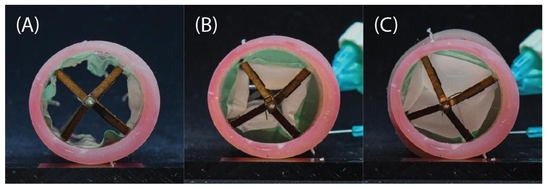

Fig. 6. Integrated device deployed inside 27-mm ID silicone tube with (A) Deflated balloons, (B) Partially-inflated balloons, and (C) Fully inflated balloons.

FUTURE DEVELOPMENT

Future steps involve further device testing, simulation, integration into a closed-loop feedback system, and *ex-vivo* and *in-vivo* testing.

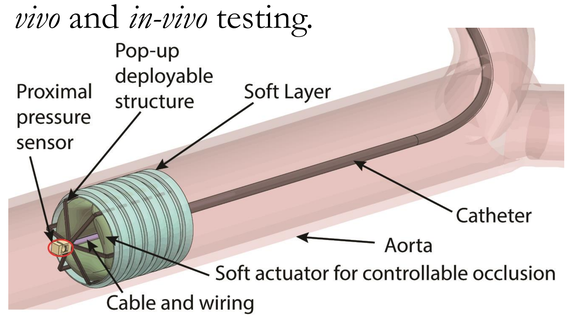

Fig. 7. Proposed device in endovascular environment

CITATIONS

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[2] Levin, S, et al. *J Vasc. Surg.* **(2021)**; 74(2):467-476
[3] Heindl, S, et al. *Cureus.* **(2020);** 12(7): e8999

ACKNOWLEDGEMENTS

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