Female-Focused Hydrogel-Coated Balloon Therapy for Peripheral Artery Disease

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Background

Peripheral artery disease (PAD) affects more than 200–230 million people worldwide and 8–12 million individuals in the United States[1,2]. It is marked by progressive narrowing of lower-extremity arteries, leading to claudication and, in advanced cases, limb-threatening ischemia[1]. PAD remains substantially underdiagnosed and undertreated, with many patients not identified until later stages and a large proportion failing to receive guideline-directed medical therapy (GDMT)[1,3]. Significant sex-based disparities in diagnosis, management, and outcomes further contribute to inequities in care[2,3]. For patients with symptomatic femoropopliteal disease, drug-coated balloons (DCBs) are an established therapy that restore blood flow and reduce restenosis[4]. Current DCB platforms deliver a fixed drug load, limiting opportunities for patient-specific dose optimization[4].

Objective

This study explores the feasibility of a drug-agnostic hydrogel coating that permits on-demand, controlled drug dosing compatible with existing commercial balloons. The goals are to demonstrate that our hydrogel-based balloon coating system can offer custom drug dosing while (1) withstanding physiological pressure and flow rates and (2) retaining the antiproliferative drug at the vessel wall.

Methods

Balloon Manufacturing

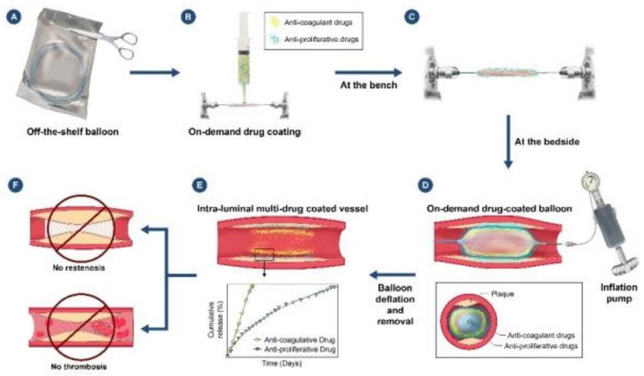

Figure 1: Workflow of creating hydrogel coated balloon

Mock Circulatory Loop (MCL) Testing

To test the balloon under physiologic pulsatile flow, we used an MCL with BP and flow rate controlled at 140/80 mmHg and 100 mL/min. The deployment site was arranged in parallel with the main circulation to mimic the SFA.

Drug Elution Testing

To test the ability of the coating to retain the drug, we sampled the fluid downstream of the deployed balloon in both the MCL and static setting and quantified the amount of enoxaparin with a dye-based Azure A assay.

Results

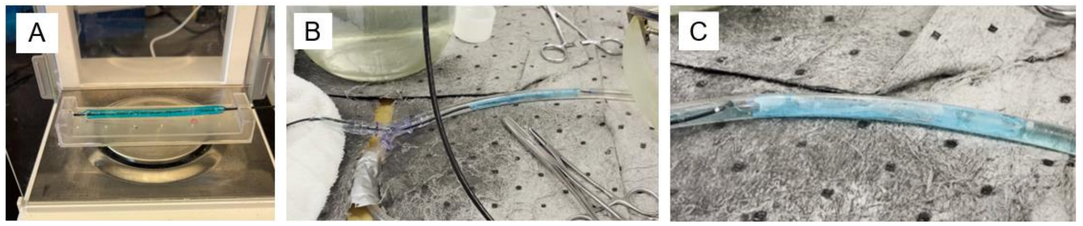

Figure 2: (A) Freshly coated balloon (B) Balloon being deployed with a guide wire (C) Balloon being removed from vessel leaving hydrogel in place

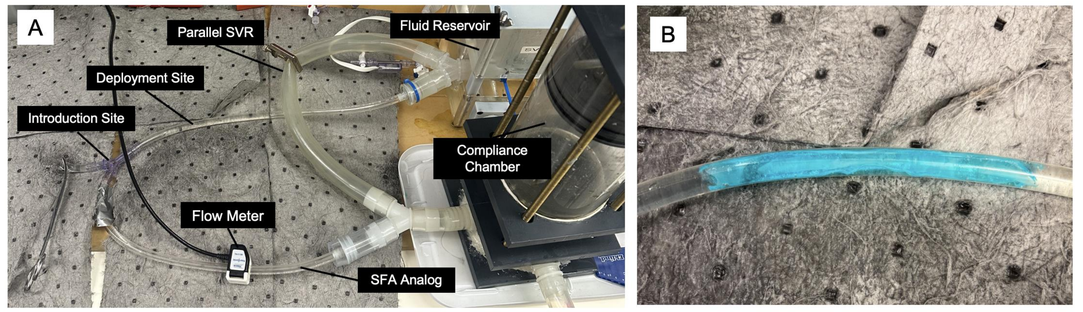

Figure 3: (A) Mock circulatory loop setup with deployment site in parallel with main circulation (B) Hydrogel post-deployment with dye added for visualization.

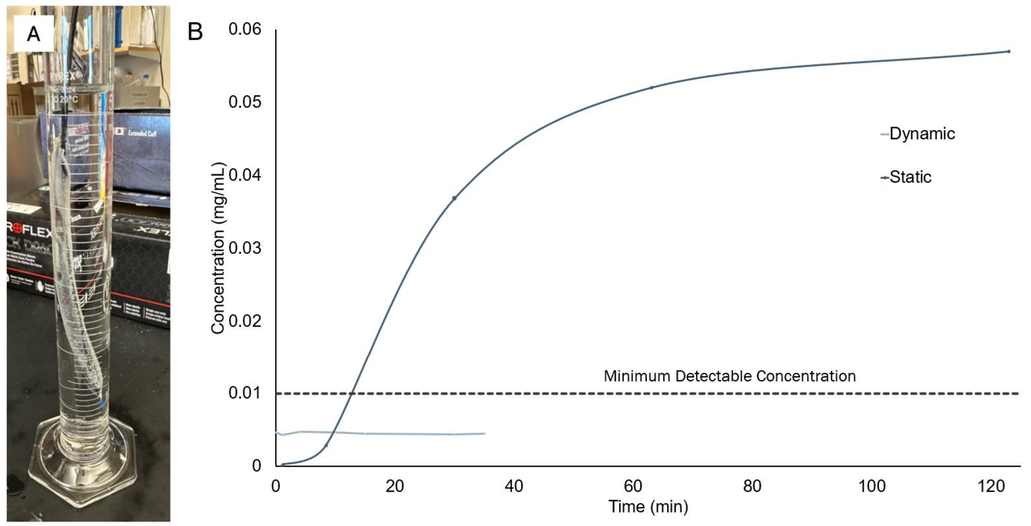

Figure 4: (A) Hydrogel-coated balloon containing 10 mg of enoxaparin submerged in 50 mL of 40% glycerol (B) Detectable concentration of eluted enoxaparin graphed over time in both the MCL and in a static setting.

Discussion

- A smooth uniform coating is deployable using a guide wire without loosening from the balloon (Fig. 2).
- MCL was able to reproduce physiologic flow of 100 mL/min flow and 140/80 mmHg of pressure.
- MCL testing demonstrates that a uniform coating is can withstand physiologic blood pressures for at least >30 min (Fig. 3).
- In a static setting, enoxaparin eluted from the hydrogel and plateaued within 2 hrs at 0.057 mg/mL in 50 mL of diluent, corresponding to ~25% of initial enoxaparin in the coating (Fig. 4).
- Dynamic elution studies were below the minimum detectable concentration (Fig. 4).

Future Work

- We will incorporate both male and female porcine SFAs into our model for more accurate material properties (hydrophilicity and compliance).
- While enoxaparin offers localized anticoagulation, our next goal is to evaluate hydrogel retention of paclitaxel, the standard antiproliferative drug used in vascular interventions.
- To improve analytical accuracy, we plan to replace dye-based assays with HPLC, enabling precise quantification of individual drug species and degradation products.
- Combine multiple drug combinations in the hydrogel and deploy in MCL.

Acknowledgments

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References

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