Self-Expanding Cannula with Small Incision for Mechanical Circulatory Support

UNIVERSITY of MARYLAND SCHOOL OF MEDICINE

Alaya Chubb, Jason Costa, Chris Guerra, Rishika Jadhav, Trixy Tran, Alena Zheng(BIOE386)

Advisors: *Dr. Dong Han, UMD SOM & Dr. Kimberly Stroka, UMD BIOE*

UNIVERSITY OF MARYLAND 1856

A. JAMES CLARK SCHOOL OF ENGINEERING

Background

Current State of Problem

Mechanical circulatory support (**MCS**) is vital to manage **heart and lung diseases**, the leading causes of death in the United States.

- Heart failure ⇒ 6.2 million
- Lung disease ⇒ 1 in 6 annual deaths

Unfortunately, MCS system deployment is highly invasive and convoluted.

- **Complications**: Bleeding from the heart, corporeal trauma, delayed incision site healing, postponed resuscitation, and require skilled surgeons

Design Requirements

Dynamic Diameter: 15-32 Fr	Support Flow Rate: 3-6 L/min	Pressure Drop < 20 mmHg

Our Solution

Our solution is to develop a novel **cannulation device** that is inserted at a minimal diameter and utilizes a peripheral dilation balloon for rapid deployment.

- **Goals**: Improve access to timely life-saving care, patient recovery, cannula site healing, and quality of life post-operation

Methods

Balloon Design

1. Internal tubing perforation - awl tool
   - Crosshair perforations 1 cm apart
2. Securing balloon to tubing
   - Hot glue, gorilla glue, shrink wrap (most successful)
3. Securing tubing to 30 mL syringe
4. Internal tubing close at one end
5. Aluminum stent & external tubing
   - Expand with balloon and retain shape post-expansion

Coated Stent Design

1. Stitch cannulation tip and external tube to opposite side of stent
2. Coat stent in ChronoSil AL (10% w/v in tetrahydrofuran)
   - Dip 3 times from the tip to 3 cm of the external tube
3. Once dried insert guide wire into the cannulation apparatus
4. Insert guidewire into introducer sheath

Calculations for Balloon Design

Table 1. **Poiseuille's Law Calculations**

Case	1	2	3	4
Viscosity (mPa*s)	3	4	3	4
Radius (mm)	5	5	5	5
Length (cm)	40	40	40	40
Pressure Drop (mmHg)	1.8336	2.445	3.667	4.89
Flow Rate (L/min)	3	3	6	6

- Viscosity of blood in large vessels follows Poiseuille's Law
- Vessel of interest: femoral artery
- Constant radius/length once deployed
- Avg. adult rate of blood flow: 5 L/min
- ΔP > 20 mmHg ⇒ reduced cardiac output and increased afterload
- Less blood pumped ⇒ more force req.

Table 2. **Free-Body Analysis**

$\sigma = \frac{F}{A} \qquad E = \frac{\sigma}{\varepsilon} \qquad \varepsilon = \frac{L - L_0}{L_0}$

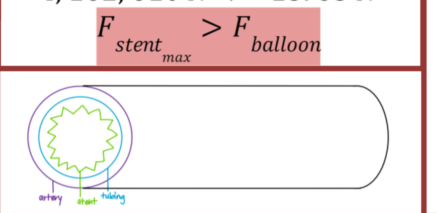
Givens	E_{stent} (GPa)	E_{tubing} (MPa)	E_{artery} (kPa)	d_{min} (mm)	d_{max} (mm)	d_{artery} (mm)
	53-76	500	262.8	5	10	8

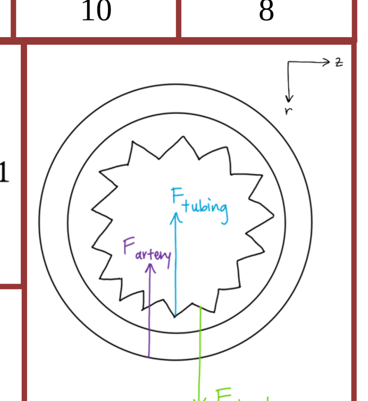
$$\varepsilon = \frac{10mm - 5mm}{5mm} = 1 \Rightarrow E = \sigma$$
$$E_{stent} = \sigma_{stent}$$
$$53 \times 10^9\ Pa = \frac{F}{A_{stent}}$$
$$A_{stent} = \frac{\pi}{4} d_{max}^2 = \frac{\pi}{4}(0.01m)^2$$
$$A_{stent} = 7.85 \times 10^{-5}\ m^2$$
$$F_{stent_{max}} = 4,162,610\ N$$

$$E_{artery} = \frac{F}{A_{artery}}$$
$$262.8 \times 10^3\ Pa = \frac{F}{\frac{\pi}{4}(0.008)^2\ m^2}$$
$$F_{artery} = 13.21\ N$$

$$E_{tubing} = \frac{F}{A_{tubing}}$$
$$500 \times 10^6\ Pa = \frac{F}{\frac{\pi}{4}(7.85 \times 10^{-5})^2\ m^2}$$
$$F_{tubing} = 2.42\ N$$

$$F_{stent_{max}} > F_{tubing} + F_{artery}$$
$$F_{balloon} = F_{tubing} + F_{artery}$$
$$4,162,610 > 2.42 + 13.21$$
$$4,162,610\ N > 15.63\ N$$
$$F_{stent_{max}} > F_{balloon}$$





Design Process

Initial Schematics / *CAD Rendering*

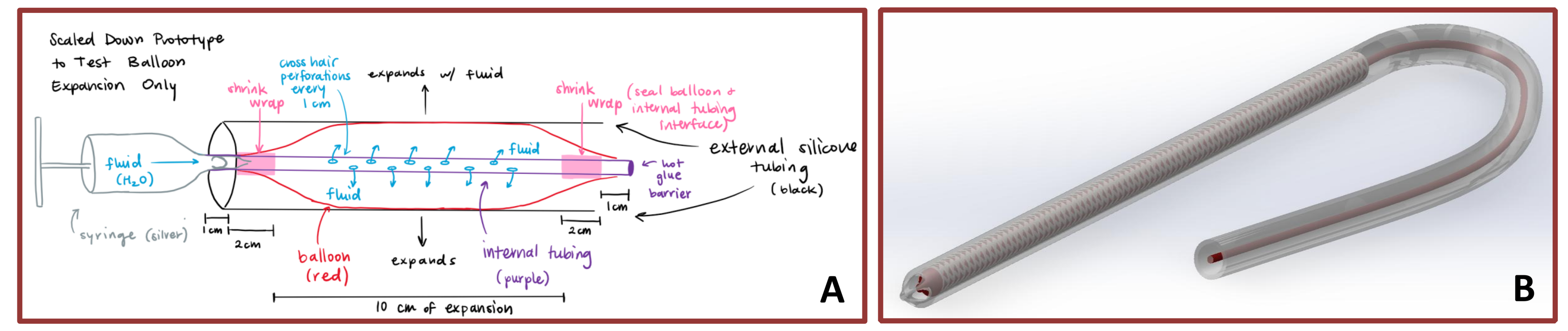


Figure 1. **Initial drawn schematic (A) and CAD rendering (B) of balloon design.** Peripheral dilatation balloon expands stent inside cannulation tube. After expansion, balloon is removed and stent maintains external tube's diameter.

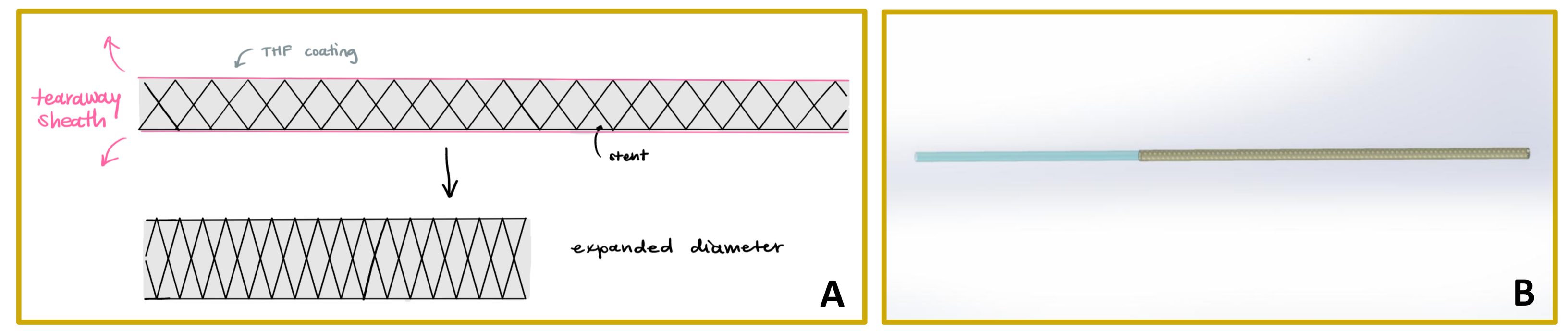
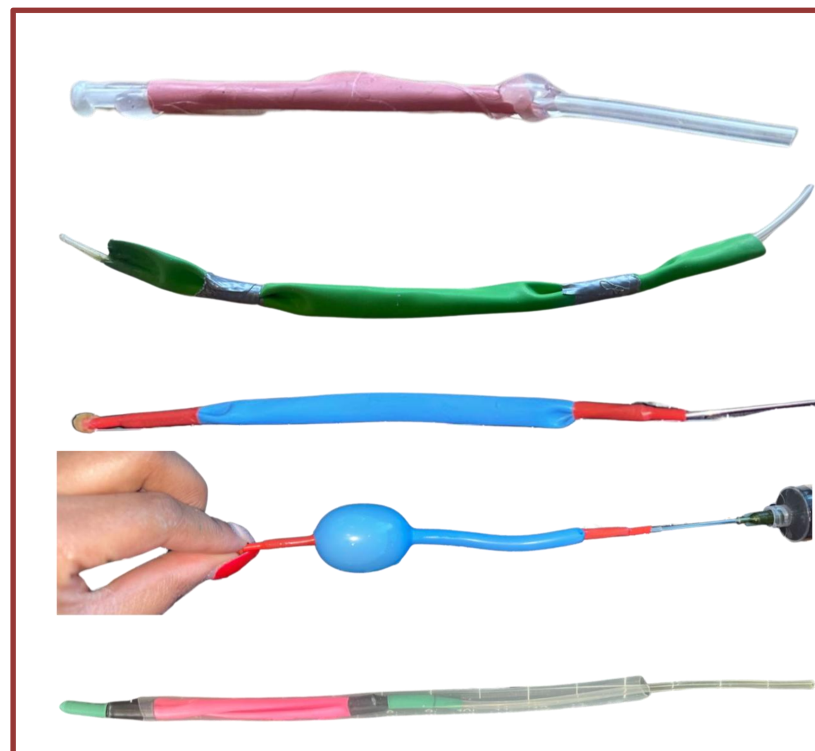


Figure 2. **Initial drawn schematic (A) and CAD rendering (B) of coated stent design.** Coated stent is attached to additional tubing. Non-expanding region of tube does not enter the body. The cannulation device is deployed using introducer sheath, which is removed after insertion into body and allows stent to expand upon its removal.

Prototyping Process



Iteration I: Utilized gorilla and hot glue to create dilatation balloon. Significant leakage occurred.

Iteration VI: Minimal leakage occurred. Did not it in external tube.

Iteration XII: Utilized shrink wrap. Moderate leakage, adequate expansion, but it did not fit in the external tube.

Iteration XIII: Used two shrinks wrap at each end of the balloon. Fit into external tube, but inflation in tube resulted in leakage.

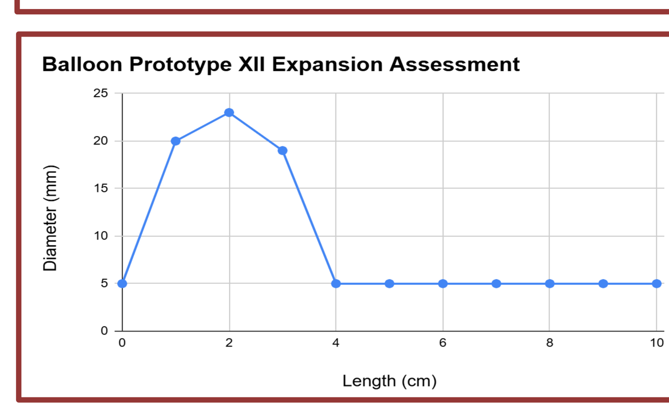


Figure 3. **Balloon Prototype XII Expansion Assessment.** Demonstrates inconsistent expansion of the balloon once inflated.

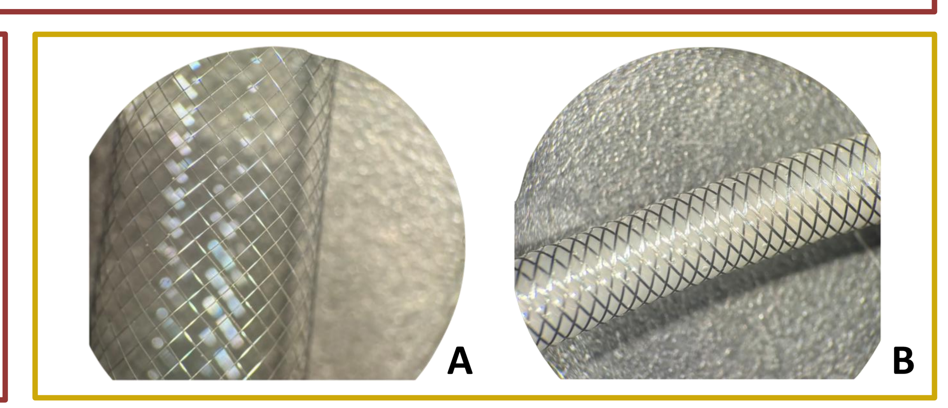
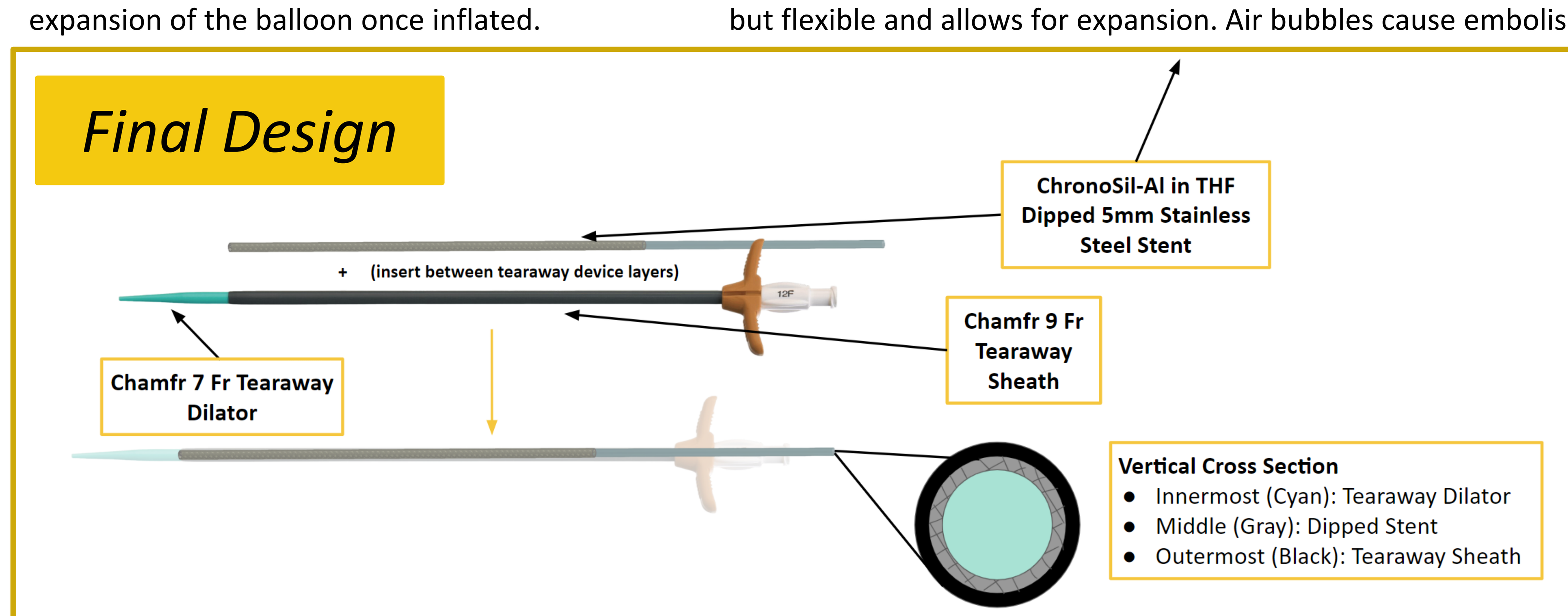


Figure 4. **Stainless steel braid before (A) and after (B) dipping.** Stainless steel was dipped into tetrahydrofuran. Coating is thick but flexible and allows for expansion. Air bubbles cause embolism.

Final Design



Results and Conclusions

Summary of Balloon & Coated Stent Designs

	Balloon Cannula Design	Coated Stent Cannula Design
Materials	Latex balloon, silicone tubing, shrink wrap, hot glue	Coated stent, tear-away inducer, silicone tube
Methods	Fasten latex balloon to internal balloon tubing, insert into external cannulation tube along with stent	Attach coated stent to tube and coat the stent, then insert cannulation tube into inducer
Function	Uses balloon to expand tube, then allow stent to maintain diameter when balloon is removed	Insert inducer into patient and then tear away inducer

Testing Setbacks

- Leakage at ballon-internal tubing interface
- Dilation balloon size incompatibility with external tubing
- Unsuccessful expansion of external tubing

- Coating process resulted in uneven coating and poor adhesion
- Air bubbles formation can cause embolism (sudden obstruction)

Bioethical Implications

Positive	Negative
Medical Personnel: Increased access to emergency care, decreased need for surgeon to perform cannulation due to user-friendly & timely deployment	• Embolism caused by leakage or air bubbles ⇒ heat sealing at interfaces • Restenosis caused by collapsed stent ⇒ ensuring sufficient radial force of stent
Patients: Reduced trauma, enhanced healing due to minimal invasiveness	• Challenges maintaining pressure ⇒ bubble detection via real time flow monitoring

Future Work

Sew ECMO tube attachment to cannula entrance → **Refine dip-coating to mitigate air bubbles** → **Repeat with 10 mm max diameter nitinol stent**

Deploy in representative artificial artery

Deploy in femoral artery tissue samples

Verify compliance with design criteria

References

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