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Enhancing TAVI Robot Flexibility Using Semi-Extensible Materials

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INTRODUCTION

Global demographic aging poses a major challenge to healthcare systems, intensified by the significant increase in medical needs specific to the elderly population. To address these increasing demands and minimize risks associated with medical vascular interventions, such as aortic valve stenosis pathology [1], prioritizing less invasive approaches has become imperative. In this context, Transcatheter Aortic Valve Implantation (TAVI) has emerged as a significant advancement, offering a less invasive alternative to traditional cardiac surgery [2]. To optimize the precision and efficiency of this procedure, the use of a growing robot [3] stands out as an innovative approach. Its ability to deploy from the inside ensures flexibility tailored to the unique morphology of each patient, thus reducing the risks of tissue perforation. Inspired by the work of Li et al. [4], a cadaveric clinical test was undertaken, implementing an 8 mm diameter growing robot made from silicone-coated Ripstop Nylon and pressurized with an iodine solution (Fig.1). The results of these trials revealed difficulties in navigating through narrow anatomical areas such as stenosis. Consequently, a study on the compliance of growing robots was undertaken, exploring the use of various materials with different properties.

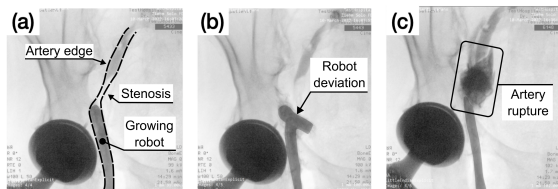


Fig. 1 Deployment of an 8mm growing robot made of Ripstop Nylon fabric in the right femoral artery with a stenosis (a) resulted in the deviation of the robot (b) and ultimately the tear of the artery (c).

MATERIALS AND METHODS

The study was conducted using a system (Fig.2) comprising a saline solution reservoir for an 8 mm growing robot, an internal pressure sensor, an air removal device, and two distinct pressurization systems: continuous and pulsatile. Continuous pressurization creates a

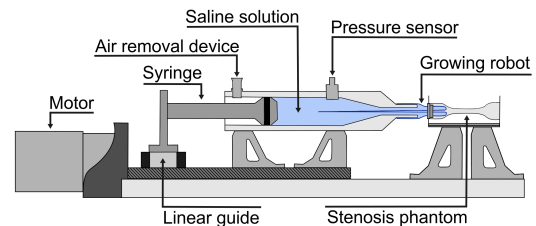


Fig. 2 Experimental platform equipped with a pressurization system designed to execute the eversion of a robot through a rigid phantom simulating a stenosis.

stable environment, allowing the robot to operate under a constant load. In contrast, pulsatile pressurization, characterized by sinusoidal pulses with a maximum frequency of 10 Hz, was integrated specifically to reduce friction at the robot's head by breaking static friction points. For material selection, a targeted approach was taken to highlight different modulus of elasticity (E). Polytetrafluoroethylene-PTFE (Zeus) was chosen for its low friction to reduce internal robot friction. Silicone-coated Ripstop Nylon fabric (Extremtextil), preformed with Sil-Poxy adhesive (SmoothOn) [4], provides a flexible and robust combination. Lastly, Thermoplastic Polyurethane-TPU (Chamfr) was selected for its semi-extensible properties, enabling it to stretch under force.

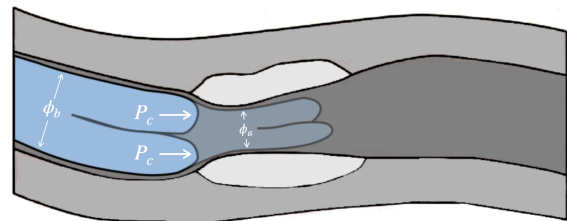


Fig. 3 Deployment of the growing robot, under a crossing pressure P_c , to pass through a stenosis with a reduced diameter ϕ_a , starting from an initial diameter ϕ_b .

The first phase of this study, conducted in a free environment, aims to characterize the critical pressure thresholds. This includes the minimum pressure required to initiate the eversion process (P_e) and the maximum pressure at which the robot reaches its point of rupture or undergoes irreversible deformation (P_r). The second phase, performed in a constrained environment simulating

rigid stenosis of 6 mm to 4 mm (Fig.2), focuses on the behavior of materials during their traversal (Fig.3). It incorporates a crossing pressure measurement just before entering the stenosis (P_c).

RESULTS

The initial findings (Table.I) reveal that TPU stands out for its ability to evert with the lowest initial eversion pressure ($P_e = 3.0\text{kPa}$). Additionally, although PTFE has a higher rupture pressure ($P_r = 300.0\text{kPa}$), the P_e/P_r ratio for TPU (0.02) is significantly lower than that of PTFE (0.33). Therefore, TPU demonstrates a greater safety margin before reaching its rupture limit ($P_r = 150.0\text{kPa}$) compared to PTFE.

| Material | E [MPa] | P_e [kPa]* | P_r [kPa]* | P_e / P_r |
|----------|-----------|--------------|--------------|-------------|
| PTFE | 0.5 - 1.0 | 100 | 300 | 0.33 |
| Fabric | 1 - 6 | 7 | 80 | 0.08 |
| TPU | 10 - 100 | 3 | 150 | 0.02 |

* : Average value based on 10 tests

TABLE I . Pressure Characteristic Comparison

While traversing a stenosis, both the fabric and the PTFE encountered difficulties when the diameter reached 6 mm. The fabric reached a maximum crossing pressure of $P_c = 80.0\text{kPa}$, ultimately reaching its rupture pressure, resulting in an explosion that tore the artery (Fig.1). Similarly, the PTFE reached a maximum crossing pressure of $P_c = 300.0\text{kPa}$, corresponding to its rupture pressure, causing permanent deformation and preventing further passage through the stenosis. Despite several attempts to reduce friction through pulsatile pressurization, no significant improvement was observed.

On the other hand, the TPU has demonstrated the ability to traverse stenoses with low pressures and without permanent material deformation (Fig.4). Its various passages through stenoses of varying diameters revealed a correlation between the degree of stenosis narrowing and the observed pressure levels (Table.II). As the severity of stenoses increases, the resistance to passage also increases, requiring higher crossing pressures. It reached a maximum crossing pressure of $P_c = 94.0\text{kPa}$ for a maximum stenosis diameter of 4 mm. Furthermore, continuous pressure was sufficient for TPU to navigate through the stenosis, making pulsatile pressure unnecessary.

| Stenosis diameter [mm] | P_c [kPa]* |
|------------------------|--------------|
| 6 | 18.4 |
| 5 | 50.8 |
| 4 | 94.0 |

* : Average value based on 5 tests

TABLE II - TPU pressure across stenosis diameters

When comparing the pressures commonly applied during the deployment of stents for the treatment of femoral stenoses (see Table III), the lowest recorded nominal pressure (NP), established at 912 kPa (here, the rated burst pressure (RBP) is excluded to prevent any risk of perforation) can be regarded as the maximum tolerated limit. Consequently, the TPU exhibits a maximum crossing pressure ($P_c = 94.0\text{ kPa}$), almost 10x lower than the maximum tolerated pressure.

| Stent System | NP [kPa] | RBP [kPa] |
|---------------------------|----------|-----------|
| Medtronic RESOLUTE ONYX | 1216 | 1824 |
| Boston Scientific PROMUS | 912 | 1621 |
| Boston Scientific SYNERGY | 1117 | 1620 |

TABLE III - Deployment pressures of stent systems

DISCUSSION

Although air pressurization offers great flexibility to growing robots due to air compressibility, its use is limited in clinical applications such as endovascular where the use of a fluid is imperative. However, fluid-based pressurization presents major drawbacks due to its higher density and non-compressibility, thereby reducing the robot's flexibility. According to this study, the use of semi-elastic materials such as TPU allows for better adaptation to clinical requirements by combining elasticity and resistance. Ongoing and future work involves designing a preformed TPU-based growing robot with full automation of its deployment. Additionally, research will be conducted to simulate this type of behaviour and material in the context of endovascular surgery [5].

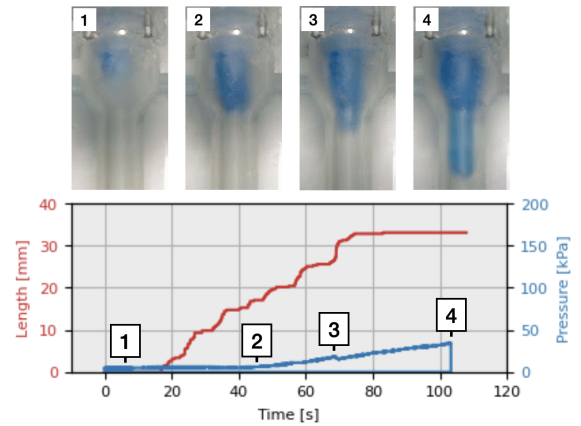


Fig. 4 Deployment of the TPU through a 6 mm diameter stenosis, characterized by its pressure profile including: initiation of eversion (1) at 3.4kPa, the start of passage at the stenosis entrance (2) at 7.4kPa, passage through the stenosis (3) at 17.5kPa, and complete deployment of the robot (4) at 33.6kPa.

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