



## Advancements in Pulmonary Vein Thrombosis Treatment: Bench-scale Efficacy of a Developed Three-Disc Self-Expanding Braided Pulmonary Clot Retrieval Device

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### ABSTRACT

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Rare, pulmonary vein thrombosis is a potentially life-threatening condition that most often arises as a complication of malignancy, post-lung surgery, or atrial fibrillation and may also be present in the idiopathic setting. PVT poses significant risks of pulmonary infarction, pulmonary edema, right ventricular failure, and peripheral embolisms going on to cause stroke, limb ischemia, and renal infarction. Traditional techniques of clot removal, which are used majorly in older and larger thrombi, involve multiple attempts at aspiration and pose a risk of significant loss of blood along with procedural complications. Here, this research paper proposes a new, self-expanding three-disc braided pulmonary clot retrieval device to overcome the drawbacks of current treatment modalities. The device possesses architectural and mechanical properties enabling a maximally retrievable clot by a minimally invasive endovascular approach to reduce the complications and bring the procedure closer to safety and efficacy. It ensures easy clot removal from the vessel as it has less risks than conventional methods. This deployment is with a procedure involving a relatively small entry point, minimizing invasive trauma to the patient, such that clot extraction can be efficiently completed with minimal blood loss and further trauma. This clot retrieval device was proven by in-vitro testing to be suitable and to perform well with bench-scale evaluation. Such a result gives great promise toward enhancing patient outcome in the management of pulmonary thromboembolism brought about by this innovative approach. However, further pre-clinical trials are warranted to validate these findings and place this device as a superior alternative to clot retrieval at present.

### KEYWORDS:

Pulmonary vein thrombosis (PVT), Clot retrieval device, minimally invasive endovascular procedure, Pulmonary thromboembolism and In-vitro efficacy testing.

### INTRODUCTION

Pulmonary vein thrombosis is one of the rare and lethal diseases that mostly presents as a complication after malignancy, lung surgery, or atrial fibrillation and sometimes as an idiopathic disease. PVT normally has a high predisposition to severe complications such as

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pulmonary infarction, pulmonary edema, right ventricular failure, and peripheral embolisms which risk leading to stroke, limb ischemia, or renal infarction.[1]The standard treatment for pulmonary thromboembolism is clot evacuation to restore normal blood flow. The traditional methods of clot removal, although originally effective in many patients, inadequately remove the older and larger clots and frequently require multiple attempts, with increased risks of major bleeding and procedural complications.[2] These problems emphasize an ever-greater need for more sophisticated, effective solutions in the treatment of thromboembolic diseases[3]. Even with the advancement in minimally invasive technologies, current techniques for clot removal remain inadequate, especially in the management of complex

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thrombi. This is so because of incomplete retrieval of older and larger clots that often require multiple procedures with a likelihood of causing more harm to the patient [4]. Beyond this, conventional devices are short on mechanical properties that would make it possible to negotiate the complex anatomy of the pulmonary vasculature without suffering damage to the vessel walls. Thus, there exists an urgent and great need for an alternative device which can safely and effectively remove clots while minimizing procedural risks and improving patient safety.[5]

A novel self-expanding, braided, three-disc braided pulmonary clot retrieval device will be developed and validated in the proposed research. Such an innovative device that complements the existing shortcomings of traditional aspiration techniques will be designed to optimize clot retrieval in a minimally invasive approach[6]. The study proposes that the mechanical properties of the device will be evaluated in terms of its in-vitro efficacy testing and whether it has the capability to enhance patient outcomes by reducing complications associated with clot removal techniques available in the current science[7].

This study will answer three important questions: Is the self-expanding three-disc braided pulmonary clot retrieval device capable of retrieving older, larger clots in pulmonary vessels in which conventional aspiration methods often fail? Does the unique braided nitinol design of the device facilitate superior navigation through the complex pulmonary vasculature compared with current methods? Third, will the device lower procedural risks, such as blood loss, vessel damage, and complications after the procedure, when compared to traditional clot removal procedures?

The background for this study lies in the current deficiencies associated with clot removal therapies. In the scientific community, the self-expanding three-disc braided pulmonary clot retrieval device is considered to be one of the greatest innovations available for the treatment of thromboembolism [8]. The woven nitinol is the material for this device, allowing it to have flexibility with retained structural integrity and conformity to vessel walls so as to best match the pulmonary vasculature anatomy. The ability of the shape memory characteristic of nitinol enables the opening of the device to its intended diameter on deployment, thus ensuring optimum contact with the vessel wall for patency maintenance to ensure no post-procedure complication from vessel compression or re-occlusion.

Three disc self-expandable pulmonary clot retrieval device is vary on the human anatomy or their vessel and depend on the diagnosis of the patient. These devices are inserted via a catheter, typically through the femoral or jugular vein, and advanced to the site of the clot in the pulmonary arteries. Once the clot is trapped, it can be removed entirely or aspirated through the catheter, depending on the device

design. The device may either fragment the clot for easier aspiration or directly remove it in one piece.

### **Vessel Injury and Complications:**

**Vascular damage:** The process of inserting and manipulating the catheter can result in vessel injury, such as perforation, dissection, or hematoma at the insertion site or within the vasculature. There is a risk that fragments of the clot may be dislodged during the procedure, potentially traveling to other parts of the body, such as the brain, kidneys, or limbs, and causing new embolic events.

### **Incomplete Clot Removal:**

The mechanical device may not be able to remove the entire clot, particularly for organized or fibrotic clots, which are harder to fragment or remove completely. Residual clot may lead to incomplete resolution of the PE or require additional interventions. Some large or complex clots may require multiple passes or a combination of mechanical and thrombolytic therapies to achieve complete resolution.

### **Procedure Complexity and Operator Skill:**

The technical complexity of the procedure requires highly trained operators to ensure effective clot trapping and retrieval. Incorrect positioning of the device or improper clot manipulation could lead to complications, such as vessel injury, incomplete clot removal, or embolization. Advanced imaging techniques (e.g., fluoroscopy, CT angiography, ultrasound) are necessary to guide the catheter to the correct location, which increases the procedural complexity.

### **Limited Effectiveness for Chronic Clots:**

Chronic or organized clots (those that have been present for a longer period and have become more fibrotic) may be less amenable to removal with mechanical clot trapping devices. In such cases, the clots may require alternative treatments, such as surgical embolectomy or thrombolysis.

### **Risk of Reperfusion Injury:**

After successful clot removal, there is a potential risk of reperfusion injury, where the sudden return of oxygenated blood to previously ischemic lung tissue causes inflammation and tissue damage. This can lead to complications such as pulmonary edema or lung injury.

### **Not Suitable for All Patients:**

Some patients may not be ideal candidates for mechanical clot trapping due to factors such as small or tortuous pulmonary arteries, which make catheter navigation difficult or impossible. Patients with contraindications to anticoagulation or those at high risk for catheter-related complications (e.g., active bleeding disorders or severe obesity) may not be suitable for this procedure.

### **Time-Consuming and Invasive:**

While still less invasive than surgical options, the clot trapping procedure can take a significant amount of time,

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especially in complex cases with large or difficult-to-reach clots. This may delay treatment compared to more immediate pharmacological options.

### **Potential for Post-Procedure Complications:**

After the procedure, patients require close monitoring for potential complications such as bleeding, vessel dissection, or the development of new embolic events. They may also require intensive care to manage the effects of reperfusion injury or hypoxemia.

Unlike other aspiration techniques that most often fail to bring out the older and larger clots due to a propensity for multiple attempts at procedures, which are associated with potential risks of blood loss, self-expanding devices allow easy, complete removal of clots in one attempt at the procedure[4], [9]. The three-disc design enhances the efficiency of clot capture, which then helps to reliably restore blood flow without repeated interventions. The minimally invasive deployment process of the device reduces further trauma and better recovery rates accelerate quicker recovery periods with possible savings in healthcare due to reduced hospital stay and other intervention procedures.

The three-disc self-expanding braided pulmonary clot retrieval device offers specific advantages over conventional methods, particularly with regard to the ability to pass complex vascular pathways without inflicting damage on vessel walls[4], [6]. This significantly decreases the likelihood of complications like vessel injury and pulmonary infarction as well as embolism post-procedure[9]. The mechanical and structural properties of the device, including its nitinol structure, enhance its performance in restoring blood flow and removing clots especially in such emergencies as stroke and myocardial infarction and renal infarction.

Another approach the device holds to reduce patient discomfort and procedural trauma is through minimally invasive deployment techniques [10]. Moreover, its catheter-based delivery system allows for exact removal of clots in minimized risks attributed to traditional approaches—mostly invasive. This research work therefore describes about the self-expanding clot retrieval device that would treat thromboembolic conditions, which in the long run yield better patient outcomes compared to the conventional approach.

## **MATERIALS AND METHODS**

In the design of our three-disc self-expanding braided pulmonary clot retrieval device, we minimized the material usage but provided maximum strength and longevity of structure. This innovative braided configuration with special welding improves the performance of the device,

reducing risks of thrombosis, ischemic stroke, pulmonary embolization, and long-term heart diseases.

### **Braiding Development Process:**

This braiding technique in developing the pulmonary retrieval device is synthesized by proper braiding with a commercial braiding machine. Nitinol wires are woven with steady strands at different angles of fixing, ranging from 120° to 145° and the speed of this process is maintained in the range of 30 RPM to 35 RPM. The fer height is kept between 200mm to 202mm as these optimized values are contributed toward achieving an optimal structural integrity and flexibility in the device. This set of parameters has to be considered so that the device undergoes through pulmonary vasculature while keeping its shape and functionality. The device size will be between 6mm to 25mm in diameter and 59mm to 75mm in length. It is compatible with 9 Fr to 12 Fr catheters. For simulation in vitro deployment purposes, a device with 6mm diameter and 59mm length was chosen, as the dimensions of this site generally match the typical pulmonary veins observed in pre-clinical as well as clinical studies.

### **Shape Setting Technique to Maximize Functionality:**

Braided pulmonary retrieval device implies a very critical process that is involved in the optimization of shape setting. The diameters which range from 12mm to 25mm are attached to a mandrel where the correct dimensions are set to the different pulmonary vessels. Their setting takes place by using heat treatment where the temperature range between 450°C to 550°C occurs. This process fixes the mechanical properties of nitinol, which lets the device retain its intended form post-deployment and allows it to support the pulmonary vessels effectively. The shape-setting technology aids in improving the conformability of the retrieval device to the vascular contours along with long-term performance and reliability.

### **Mounting of Pulmonary Retrieval Device over the Inner Lumen:**

Mounting the braided pulmonary retrieval device over the inner lumen of the delivery catheter is critical in the assembly of the catheter. The mounting ensures the device placed inside the vasculature does so in a proper and precise manner during the procedure. Good mounting gives stability and efficiency to the device, enabling ease of deployment without harming the vessel walls surrounding it and smooth retrieval.

### **Jacketing the retrieval device using laser welding:**

The braided pulmonary retrieval device assembles through laser welding at the proximal end for securing the jacket. Given pre-weld preparation to ensure good assembly and cleanliness, precise parameters will be observed in laser

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welding: wavelength within the range of 0.21mm to 0.55mm, power settings at 220-240V, pulse durations within the ranges of 0.7ms to 1.00ms, and frequency settings within the ranges of 1.0Hz to 50Hz. This would ensure that strong welds are achieved, contributing further to the strength and overall durability of the device.

### Microscopic Inspection and Final Assembly:

After braiding and assembly, the braided pulmonary retrieval device underwent microscopic observation using a stereo optical microscope. A great deal of attention was paid in observing the pattern as well as the angle of the braid for the precision of the structural integrity of the device. It is afterwards inspected, sealed in an aluminum pouch and pre-cleaned. This will then be transferred to the delivery system for loading and stands at the final step of the development process; hence it is ready for testing and further validation.

The three disc braided clot retrieval device mounted into the delivery system has been depicted in the figures 01 & 02 respectively.

### Pre-cleaning:

Before using it, a clot retrieval device should be cleaned by immersion in 70% to 80% isopropyl alcohol and 20% to 30% distilled water solution to ensure proper agitation for dissolution of surface contaminant residues. Then it should undergo a soak phase for penetration and removal of deeper residues. After cleaning, it is rinsed with purified water and then dried through a nitrogen stream to prevent residue from building up. Then, the described procedure ends with meticulous optical inspection as the last check if in fact the device observes high standards of cleanliness for safety and proper operation.



Figure 01 Three-Disc Braided Clot Retrieval Device



Figure 02 Three-Disc Braided Clot Retrieval Device mounted into a delivery system

### The Delivery System:

#### Loading of braided pulmonary retrieval device into catheter for optimal deployment:

The preparation and assembly of a braided pulmonary retrieval device involves a series of steps to ensure the safe and effective deployment of the device. This process begins with the careful preparation of the catheter with mounted retrieval clot over inner lumen, which serves as the delivery mechanism for the retrieval device. The first step in preparing

the catheter involves removing any protective covers to expose the catheter's surface.

The second step in preparing the mounted retrieval device over inner lumen involves removing any protective covers to expose the catheter's surface. This ensures that the catheter is clean and free of debris, minimizing the risk of contamination during the assembly process. Any residual debris or contaminants must be removed to maintain the sterility and integrity of the inner lumen with retrieval device.

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Once the catheter is prepared, the retrieval device (mounted retrieval device over inner lumen) is carefully positioned onto the distal end of the catheter, aligning it with the deployment mechanism. The retrieval device must be handled with care to avoid damage to its structure, which could compromise its performance during deployment. The retrieval device is securely placed and properly aligned into the catheter. To affix the retrieval device inside the catheter, a crimp the retrieval device by manually and employed to compress the retrieval device into the catheter. This process requires finesse to achieve a secure fit while preserving the structural integrity of the retrieval. Special attention must be paid to avoid exerting excessive force, which could deform or damage the device during crimping.

Once the retrieval device is securely loaded into the catheter, the assembly undergoes a thorough inspection to confirm proper alignment and integrity. Visual examination and tactile inspection are performed to ensure that the retrieval device is securely attached and positioned correctly for deployment.

At the proximal end of the catheter, a handle (Pusher Tube) is engaged to control the deployment process. This handle provides the physician with the ability to manipulate the catheter and precisely deploy the retrieval device at the target location within the patient's vasculature. The handle allows for smooth and controlled movement of the catheter; enables to retrieve the clot from vessel by retrieval device with minimal trauma to the surrounding tissues.

The flexibility and tractability of our retrieval device system facilitate precise delivery to the target thrombosis region, even in challenging anatomies. This ease of deployment enhances procedural success rates and minimizes the risk of complications associated with improper retrieve device placement. Proper loading and handling of the retrieval device and catheter assembly are essential to ensure the successful delivery and deployment of the braided pulmonary retrieval device.

The delivery system comprises several components, including the outer sheath, outer sheath flush port, guide wire flush port, handle, catheter, haemostatic valve, and soft tip. Each component plays a crucial role in facilitating the delivery and deployment of the peripheral stent.

### **Delivery System Components:**

**Retrieval Device:** The Pulmonary braided retrieval device comes in sizeable variations in four sizes-6-10 mm, 11-14

mm, 15-18 mm and 19-25 mm for the different vessel sizes. The retrieval device comprises interwoven metal meshes that form a flexible arrangement. In-vitro testing is done to determine trackability, flexibility, and radial force in a simulated vascular model to ensure proper course and vessel support during interventional procedures.

**Pusher Tube (Handle):** This handle is used in complex peripheral interventions, interventional cardiology, and vascular surgery in a size range from 4 to 5 Fr. The handle features an ergonomic design, providing better control and maneuverability. When under test in an in-vitro setup, the handle allows for precise navigation through the simulated vascular pathway, improving the results of the procedure and trackability.

**Catheter:** It allows for a controlled advancement and careful positioning of the retrieval device. It is available in 9Fr to 12Fr sizes, made to track through vasculature, in-vitro testing using it to make trackability and performance in tough environments put on the test.

**Inner Lumen:** An inner lumen will be provided to assist in the support of the retrieval device's navigation through the procedure inside the catheter. It is designed for vessels of diameter 1.43 mm to 3.43 mm; thus, these diameters of blood vessels can deploy and retract devices without any interference while conducting procedures.

**Soft Tip:** The soft tip, which is available in sizes from 2.1 mm to 5.1 mm, provides flexibility along with reduced trauma to the vessel while advancing to maximize retrieval tool navigational ability. In-vitro testing has shown that this end of the retrieval tool continues to have smooth navigation of vascular models without causing major trauma to allow safe and precise deployment.

**Haemostatic Valve:** The haemostatic valve, with size 9Fr to 12Fr, is used in testing to limit access to the vascular model, restricting just controlled entry while preserving haemostasis. The fluid leakage is controlled when catheters and delivery systems are being introduced or withdrawn and provides a stable environment as required for proper assessment. A complete assembly of a Three-Disc Braided Clot Retrieval implant with its delivery system has been depicted in the figure 03.

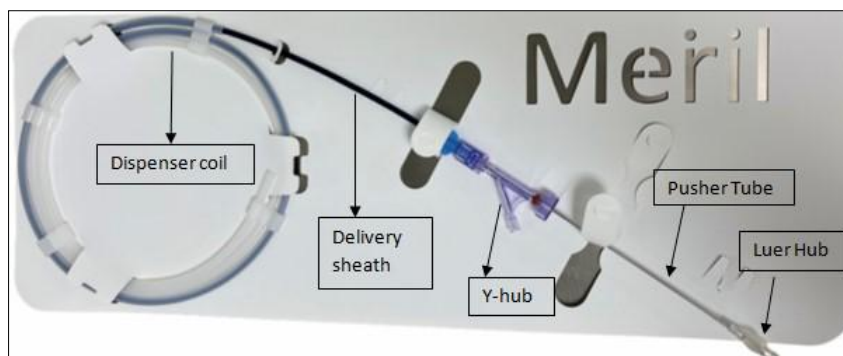


Figure 03 A complete assembly of a ‘Three-Disc Braided Clot Retrieval Device with its delivery system’

**RESULTS AND DISCUSSION**

**\*Trackability Test Evaluation of the Three-Disc Self-Expanding Braided Pulmonary Clot Retrieval Device:**

Trackability test of the braided pulmonary retrieval device system must be conducted as a parameter check in order to access the capability of the system for precise navigation along different complex vascular pathways. Trackability is considered an important parameter wherein proper deployment and positioning of devices are mandatory during interventional procedures, mainly in peripheral vascular interventions and interventional cardiology and vascular surgery.

**Experimental Setup:**

It was conducted in the laboratory by using vascular phantoms designed for simulating human vascular anatomy and physiology. These silicon-rubber phantoms (shown in the figure 04 mimics the mechanical properties of blood vessels. Along a standard route, one braided pulmonary retrieval device was introduced into the model with the help of catheter, and the performance was tested adapting it to various pathways- straight segments, bends, and narrow regions.

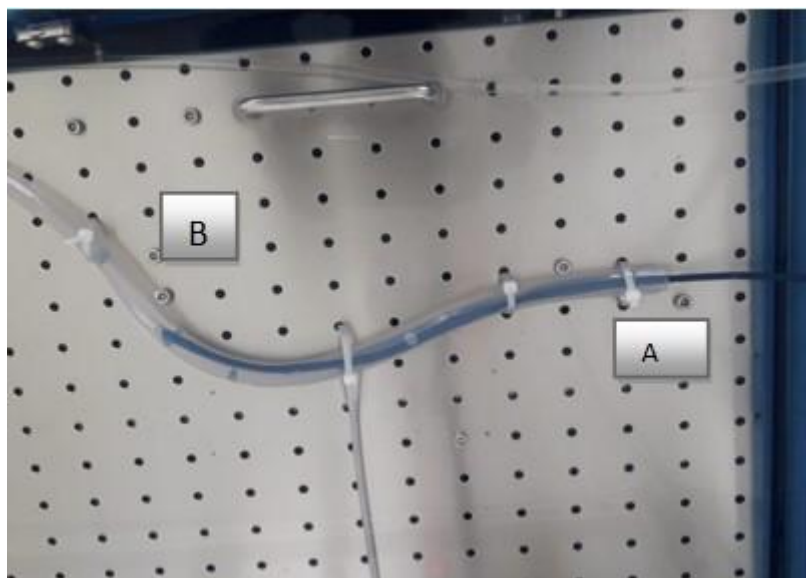


Figure 04. Simulated silicon-rubber pulmonary vascular phantom

Table 01 Summarizes the parameters used in the trackability test.

Sr. No.	Paramters	Range
1	Guide wire	0.035”
2	Insertion rate	30-40 cm/min
3	Fluid Test Medium	Purified Water
4	Temperature	37°C
5	Sheath	3.67 – 4.0 MM OD

**Trackability Test Results:**

In vitro experiments were performed by advancing the distal end of the braided pulmonary clot retrieval device, held by

the guide wire fixed at its proximal end, from point "A" to point "B". The forces recorded at different points were used to analyze the advancements of the device along the

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simulated vascular pathway.

Calculated the average force applied in maneuvering the device and evaluated the trackability of the system at large. These provided invaluable information about the performance of the navigated device and its possible clinical applications.

Number	Direction	Near Max (N)	Near Avg (N)	Standard Value (N)
1	Push	1.58	0.90	3.00
2	Push	1.57	0.90	3.00
3	Push	1.58	0.90	3.00

The average force required to propel the device was 0.90 N across all conditions and far less than the benchmark of 3 N. These results indicate that the braided pulmonary retrieval device system has high tractability, passes smoothly through a simulated vascular environment, and does not require high forces.

### \*Evaluating the In-Vitro efficacy of a Three-Disc Self-Expanding Braided Pulmonary Clot Retrieval Device:

We tested the process of the in-vitro deployment and retrieval of the nitinol-based, self-expanding braided pulmonary retrieval device to determine whether it is effective and precise in terms of removing clot material. This process was conducted inside a pulmonary simulation test model, (step by step in-vitro process has been illustrated in the figure 05). The deployment of the retrieval device followed standard procedural steps that allowed for proper, controlled, and accurate placement in the simulated environment.

### Deployment Process:

The retrieval device was advanced successfully to the region of thrombosis along the simulated vascular pathway. Once the device had reached the desired location, it was noted that the distal marker band was ahead of the distal end of the dilated segment, thus providing adequate coverage over the clot. The proximal marker band aligned with the thrombosis- this would be a sign of proper placement. The delivery system has a reciprocating mechanism that allows gradual forward movement and resultant engagement of the device with the clot.

Positioning was ensured at the first deployment so the device was overlying the clot area entirely. If only partially deployed, and not in contact with the vessel walls, repositioning was allowed. This level of flexibility allowed proximal or distal control readings to be made if appropriate,

Table 02 presents the push force parameters and the results of the trackability test.

Push Force Parameters:

- Push Speed: 50 mm/sec
- Push Distance: 250 mm
- Device Size: 06 × 59 mm

before proceeding to optimize the placement of the device prior to restarting the retrieval procedure. After the successful deployment and clot capture, the device was fully released, and the clot was aspirated out of the simulated vessel.

Summary of results for the deployment procedure: Figure 04 showing the different stages of deployment that occur during initial partial and final retrieval states:

- (A) Initial Stent Deployment
- (B) Partial Stent Deployment
- (C) Captured Clot
- (D) Retrieved Clot

### Performance Testing:

Effective deployment by the braided pulmonary retrieval device in the simulated pulmonary environment confirmed the in-vitro test. Since the device could encompass and retrieve the clot within the silicon tube of 5.5 mm in diameter, it managed to position very precisely. Significant repositioning capabilities ensured retrieval devices could target the right area without damaging the vessel walls surrounding the area meant for targeting.

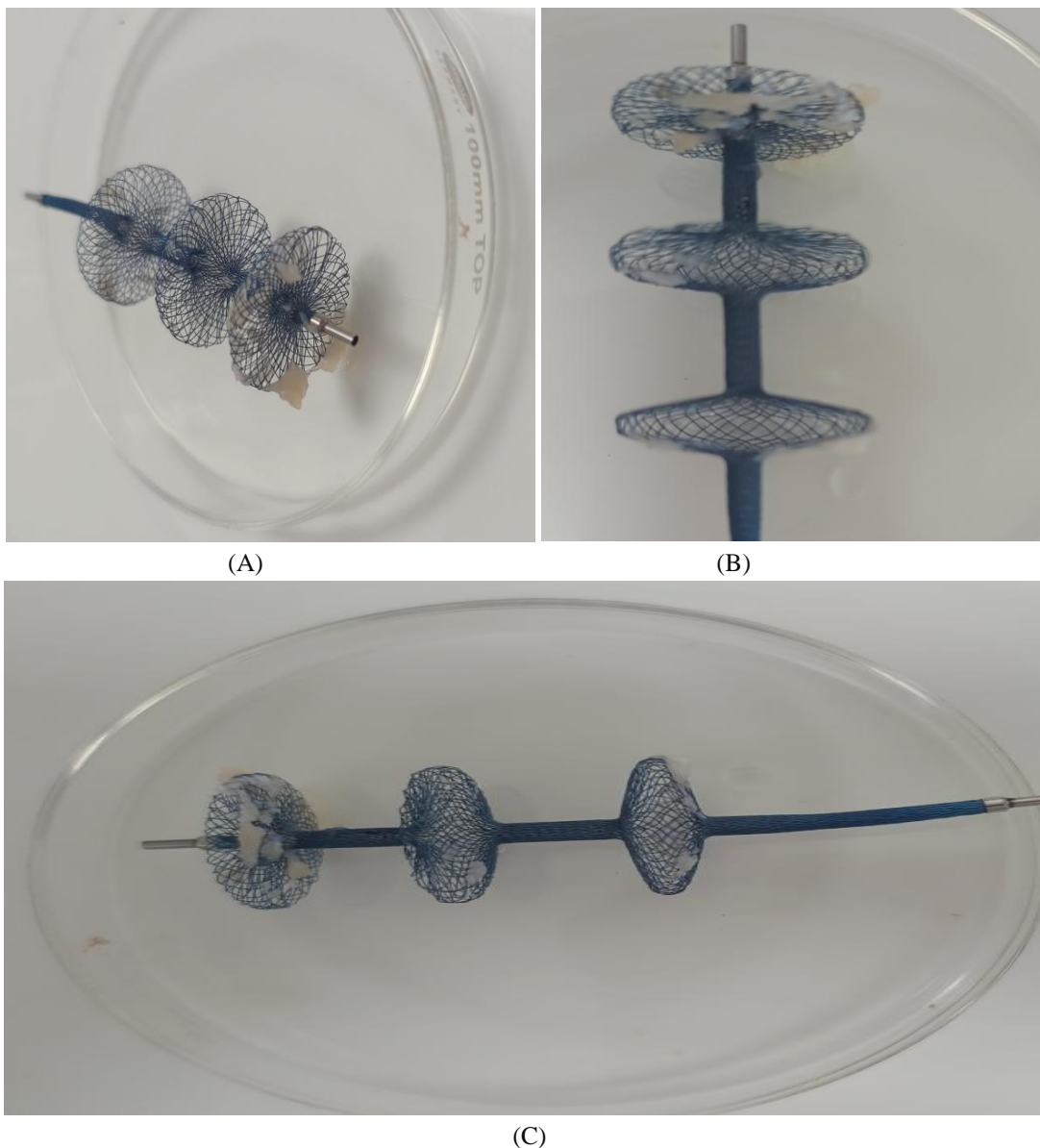
If there were any remaining thrombus pieces in the device at the time of the first removal, the deployment could be redone to allow for multiple attempts at removal of residual clot material. This ability to restart the deployment, ensured clot removal would be more effective, minimizing the chance of retained thrombus material.

### In-vitro test of tissue:

"In in-vitro tests, it was observed that smaller pore sizes in the material facilitate greater tissue collection, whereas larger pore sizes contain less tissue.

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Sr. No.	Pore Size	No. Of Particle	mm <sup>2</sup>
1.	Big	4-5	2
2.	Medium	8-10	1
3.	Small	15-20	0.97



**Figure 05 Tissue were trapped in the device**

The device comprises three discs, each characterized by distinct porosities and angular orientations. These discs are specifically engineered to capture tissue particles in varying quantities. Among the three, the third disc demonstrated the highest efficiency in capturing tissue particles, ensuring comprehensive collection and optimal functionality.

**Procedure Summary:**

**Preparation:** Sterilized equipment, and the system was unlocked so that deployment could proceed.

**Device Development:** Pusher tube was advanced step by step with retraction of the sheath. Controlled step advancement provided higher accuracy in deployment.

**Clot Retrieval:** The device was advanced via the vessel until the clot was caught and fully retrieved.



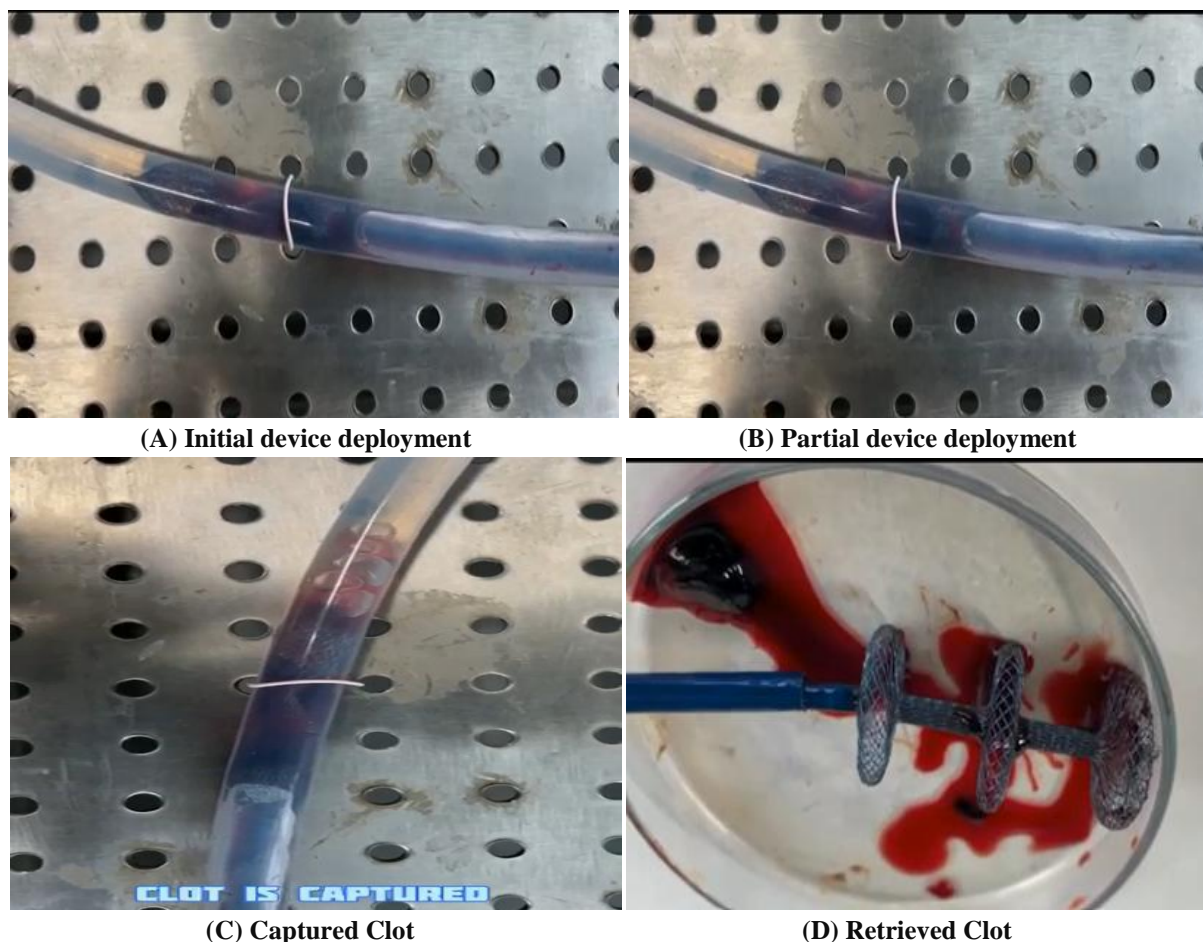


Figure 6 Overall setup of an in-vitro pulmonary simulation model for retrieval of clot and remove by pulmonary retrieval device system

## CONCLUSION

Bench-scale testing of the three-disc self-expanding braided pulmonary clot retrieval device system has gone well, with promising results that speak about its potential effectiveness in the treatment of ischemic stroke and pulmonary embolism. It demonstrated exact placement, controlled delivery within simulated vascular environments, and successfully navigated challenging vascular anatomy. The different positive outcomes from trackability and push ability tests further elucidate that the device has been able to handle difficult vessels, as well as thrombosis, in a safe fashion with minimal risks for device migration.

The successful reproduction of in vitro test conditions to natural clinical scenarios indicates that the retrieval device used here may safely and effectively be employed within a clinical environment, thus improving procedural outcomes and safeguarding patients. These results indicate that the system has immense potential to address the unmet needs in thrombosis treatment, hence enhancing patient care.

These encouraging findings warrant and pave the way for a planned pre-clinical study to observe inflammatory responses and circulation dynamics; these results will, in turn, provide impetus for further advancement into a clinical trial. Results

of this preclinical study will be published in a subsequent paper.

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