In-Vitro Assessment: "A Study on the Performance of a Developed Four-Loop Snare System in Retrieving Inferior Vena Cava Filters"

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Abstract

Inferior Vena Cava (IVC) filters are the medical device that serves a crucial role in preventing pulmonary embolism by capturing blood clots within the body. Inserted via catheters, these devices are essential for patients unable to utilize conventional anticoagulant therapies, often seen in conditions like Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE), especially post-surgery or during periods of immobility. When the risk of clots subsides, minimally invasive retrieval procedures become viable. In this study, we introduce the innovative 'Four-Loop Snare System' for interventional applications. The snare devices are basically meant to retrieve the foreign materials like catheters, guide-wires and IVC filters. In the present research study, the focus of 'Four-Loop Snare System' is for retrieving IVC filters. Unlike conventional three-loop snares, our Four-Loop Snare design offers tailoring to tackle the issues related to filter tilt and migration. By adding an extra loop to the conventional snare device, we significantly improved its grasping ability, effectively increasing the cross-sectional area. This specialized snare is developed for capturing, holding, and retrieving IVC filters, exhibiting superior efficacy over traditional counterparts. Its flexible structure allows precise navigation within blood vessels. By manipulating the snare loop, healthcare professionals can securely encircle and retrieve objects, ensuring safe removal without invasive surgery. Our in-vitro study substantiates the enhanced efficiency and safety of this novel 'Four-Loop Snare System, highlighting its potential in advancing minimally invasive medical procedures.

Keywords:

IVC Filters, Pulmonary Embolism Prevention, Blood Clot Capture, Anticoagulant Therapies, Minimally Invasive Retrieval, Interventional Procedures, Four-Loop Snare System, Cross-Sectional Area and In-Vitro Study.

1. Introduction

An inferior vena cava (IVC) filter is a medical device that can stop blood clots from going up into the lungs. The inferior vena cava is a large vein in the middle of your body. Inferior vena cava (IVC) filters serve as critical medical devices for patients at risk of thrombo-embolic diseases, particularly when anticoagulation is temporarily contraindicated or for individuals undergoing high-risk procedures such as bariatric or spine surgery. Over the years, the use of these optional IVC filters has surged due to their potential lifesaving benefits. However, the increased usage has also brought to light the challenges associated with their retrieval.

Retrieval of IVC filters is imperative once their filtration function is no longer required or when complications arise, such as severe tilt or migration beyond the IVC. Although standard retrieval techniques have shown high technical success rates and minimal complications, certain situations, such as filter migration or tilt, demand more advanced and innovative approaches.

In this context, our study introduces a novel and improved ‘Four-Loop Snare System’ designed to overcome the limitations of traditional single or three-loop snare devices. We introduce an innovative approach that integrates strategically positioned additional loop around the filter tip. This configuration increases the cross-sectional area, thereby significantly improving the ability to grasp IVC filters effectively. These loops are created using a specially designed straight-shaped catheter with a 15-degree angle curve, facilitating its maneuverability within veins and arteries. By engaging guide-wires with a snare and subsequently pulling them into a large sheath, our technique effectively stabilizes the filter tip, allowing smooth retrieval into the sheath.

The necessity for such innovative techniques arises from the complications associated with indwelling IVC filters, which mandate their removal in specific scenarios. Complications such as filter tilt leading to potential endothelialization and trapped emboli within the filter pose significant challenges during retrieval procedures. Several advanced techniques have been developed to address these challenges, including the Recovery Cone over the wire method, tip-deflecting wires, curved sheath balloon displacement techniques, and dissection techniques using forceps or laser. However, the success of these methods is contingent upon the position, tilt, and dwelling time of the filter.

In this study, we present the results of our advanced ‘Four-Loop Snare System’ specifically engineered to address the challenges posed by filter tilt and migration. This technique boasts enhanced grasping capability, achieved by incorporating an additional loop within the existing snare devices, thereby increasing the cross-sectional area. Our method is tailored to significantly improve the success rate of IVC filter retrieval, providing a practical solution in cases where conventional methods prove ineffective. The subsequent in-vitro investigation conducted in this study will offer a detailed analysis of the effectiveness and versatility of our innovative approach across a range of pre-clinical and clinical scenarios.

2. Materials and Method

The effectiveness of this ‘Four-Loop Snare System’ is intricately intertwined with the intricacies of the device's construction method and design architecture, particularly in relation to snare loop flexibility, migration resistance, and accuracy. Braided loops, notable for their remarkable radial expansive force and enduring flexibility, plays a pivotal role in this scenario. Their distinctive attribute lies in allowing free movement of wires at their contact points. This inherent flexibility enables the snare loop to adeptly adapt and conform during the dynamic muscle contractions occurring within the complex anatomical landscapes of coronary and peripheral vascular systems. This interplay between design, materials, and physiological context underscores the importance of understanding and optimizing these factors in the development of aforementioned ‘Four-Loop Snare System’ for medical interventions.

The snare loop manufacturing process involves several key stages, including Braiding, Shape setting, Chemical passivation, Laser welding and Pre-cleaning.

2.1 Developing a Novel 'Four-Loop Snare Device'.

2.1.1 "Four-Loop Snare Device's Braiding Process: Precision and Methodology in Nitinol-Platinum Wire Weaving"

For preparing the braided loop, the process commences with preparation preceding the weaving of nitinol-platinum wires. Nitinol, stands out for its extraordinary shape memory effect and superb elasticity. When exposed to a suitable stimulus like heat, it possesses the remarkable ability to recall a predetermined shape and revert to it. This unique characteristic has led to the preference of nitinol alloy, in combination with platinum alloy (for fluoroscopic properties), over the traditional use of stainless steel in the manufacturing of aforementioned 'Four-Loop Snare. Nitinol not only demonstrates shape memory effect and super-elasticity but also boasts biocompatibility and corrosion resistancy. In contrast, stainless steel lacks these distinctive properties, making nitinol a superior choice for various applications. Initially, it was imperative to cleanse both the mould and wires thoroughly, employing a lint-free cloth to eliminate any traces of dust or particles. This ensured a clean surface for the subsequent procedure. The desired number of wires, cut to equal lengths, was then threaded through designated holes in the mould, aligning with the required length for braiding.

To secure the wires during braiding, multiple wires were passed through the mould holes as shown in the **figure.01**. With the initial setup complete, the braiding process began. By manually twisting the mould, the wires twisted, forming a secure braid as shown in the **figure.02**. Upon completion of the manual braiding, the loose ends of the braided wires were securely fastened with the copper wire to prevent any unwinding or deformation. Throughout this process, stability was maintained to ensure uniformity in the weave.

The length of the braided wire was then measured and trimmed according to the desired specifications. This manual braiding technique, executed with precision and care, resulted in the successful creation of braided loops perfectly tailored to the specific requirements of the mould." The resulting 'Four-Loop Snare System' has been depicted in the **figure.03**.

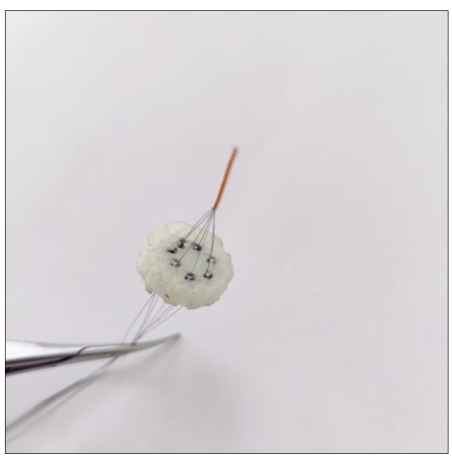

Figure.01: Multiple wires are fed into the mould to create a tightly woven braid, ensuring a secure configuration.

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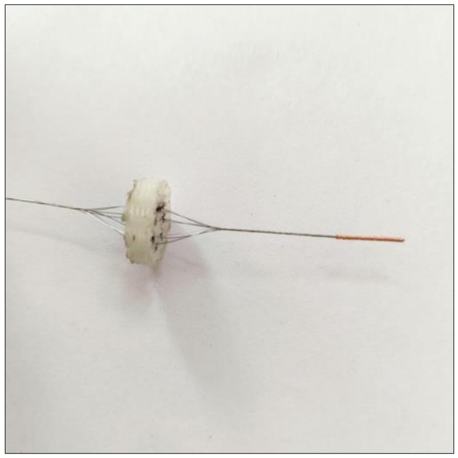

Figure.02: A secure braid is achieved by manually twisting the mold, ensuring precise formation and structural integrity.

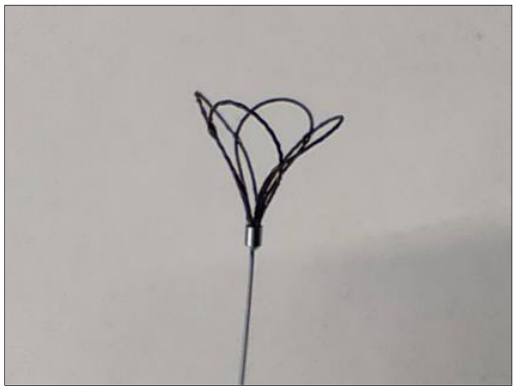

Figure.03: A Four-Loop Snare Device crafted through the manual braiding of nitinol-platinum wires.

2.1.2 "Primary Shape setting of the Four-loop Snare Device"

The process of shaping the Four-loop Snare device, known as the primary shape setting, involved a manipulation of the braided snare loop made of nitinol-platinum. This manipulation was accomplished by securely immobilizing the snare loop onto a copper wire wound around it, within a shape-setting machine designed to mimic the intended final shape.

A customized heat treatment, ranging from 495 to 550 degrees Celsius, was applied to initiate the shape-setting transformation. This heat treatment method, applicable to both the shape memory and super-elastic variants of nitinol and platinum, played a crucial role in precisely establishing the desired shapes. This controlled thermal process was instrumental in enabling the snare loop to consistently exhibit the specified shape memory or super-elastic characteristics, making it highly suitable for its intended application.

2.1.3 "Optimizing Corrosion Resistance: Nitric Acid Treatment and Protective Layer Formation"

The process included rigorous chemical cleaning and precisely controlled oxidizing treatment. The specialized chemical passivation equipment, specifically the "2-MLH" model from (*Remi Electrotechnik in Maharashtra, India)*, was employed. Nitric acid (HNO3), a potent oxidizing agent, was used to treat the snare loop.

Nitric acid interacted with the surface of the Snare Loop, resulting in significant improvements. Firstly, it eliminated impurities such as free iron and nickel, which could potentially cause corrosion and biocompatibility issues during intervention. The cleaning process involved treating the material with nitric acid, followed by extensive rinsing using distilled water and Isopropyl Alcohol. Subsequently, the item was dried using a sterile cloth at room temperature. Secondly this process bolstered the snare loop's structural integrity, ensuring optimal performance and durability within the body.

This comprehensive passivation process not only guaranteed the snare loop's effectiveness but also promoted patient well-being while minimizing potential complications. The formation of the clean surface was confirmed by the change in the snare loop's color, transitioning from metallic violet-blue to silver.

2.1.4 "Laser Welding Process for Precise Braided Four-Loop Snare Fusion"

The laser welding equipment setup was a critical step in this process. Specific laser parameters were configured based on factors such as the snare loop's material composition and the desired weld quality. These parameters included power level, pulse duration, beam diameter, and scanning speed, all of which were fine-tuned for optimal results.

After chemical passivation, laser welding process was carried out in which, jacket along with the delivery wire was welded with the aforementioned retrieval device. In the core welding process, the laser beam was focused on the designated joint area where the segments of the braided Snare Loop needed to be seamlessly united. The concentrated energy from the laser beam caused the targeted material to melt at the joint, creating a confined molten pool. As the laser beam moved across the joint, the molten material solidified progressively. This gradual solidification resulted in the formation of a robust weld, effectively fusing the snare loop segments together. The outcome was a durable and reliable joint that met the high standards required for the Four-loop Snare device.

2.1.5 "Essential Welding Cleaning: Removing Contaminants from the Snare Loop"

The pre-cleaning process for the Four-loop Snare device involves the essential step of removing body fluids and other contaminants from it. This pre-cleaning was carried out using Spray Isopropyl Alcohol (IPA). A specific mixture comprising 70% IPA and 30% water was prepared, which was then applied to the snare loop along with the delivery wire. The snare loop and delivery wire were either sprayed or soaked with this IPA-water mixture. This pre-cleaning procedure ensures the removal of body fluids and contaminants, preparing the snare loop for subsequent manufacturing processes.

2.2 The Delivery System for a Novel 'Four-Loop Snare Device"

2.1.1 The delivery system accompanied by its component parts:

The "Four-Loop Snare System" employs an efficient push-pull mechanism to ensure precise retrieval. The delivery system, comprises a 3.2, 6, and 7 Fr delivery catheter *(manufactured by Shanghai Eco Precision, Zhangjiang, China),* a Torque Device *(manufactured by Qosina Corp., USA),* a Delivery wire (*KT Medicals, Taiwan),* and an Insert Tube *(Radhamadhav Inc, India).* These components collaborate to achieve accurate and controlled positioning of the braided Four-Loop Snare.

During the procedure, the delivery wire bonds with the snare loop, enabling a controlled and smooth pushing force for accurate delivery of the braided snare loop to the intended location, to ensure effective targeting. To enhance visibility and precision, the system incorporates platinum radio-opaque marker rings on the non-braided tube and inner tube at three strategic points, denoting the proximal, distal, and retrieval locations. These markers serve as reliable radiographic guidance, enabling healthcare professionals to closely monitor the snare loop's placement within the Endovascular system. These markers substantially improve snare loop visibility during fluoroscopy procedures, ensuring precise alignment and placement.

2.1.2 The loading of 'Four-Loop Snare Device' into the Delivery System:

Retrieving an inferior vena cava (IVC) filter from the vascular system involves a process to ensure the safety and accuracy of the procedure. To initiate this process, a set of essential tools including a snare loop, delivery wire, insert tube, and catheter are gathered and inspected to guarantee they are in proper working condition. Before insertion, it is critical to confirm that the snare loop is of the correct size and in a ready-to-use state.

The procedure begins with the careful insertion of the insert tube and delivery wire as shown in the **figure.04.** The distal end of the delivery wire is securely fastened to the proximal end of the insert tube. The snare loop is then affixed onto the proximal end of the insert tube, ensuring a firm and stable attachment. With precision, the snare loop is gently slid into the insert tube, guaranteeing a secure fit to prevent any potential dislodgment during the procedure.

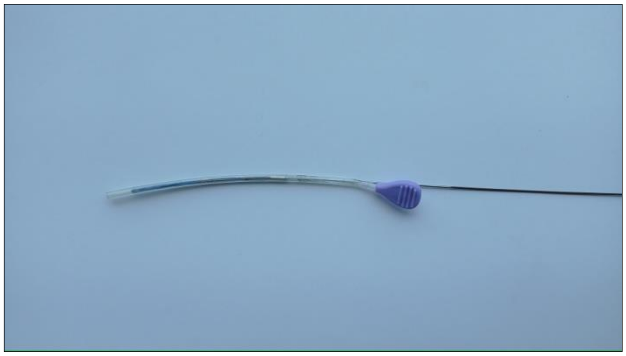

Figure.04 Insertion of the snare loop into the insert tube for subsequent loading step

Following this, the loaded tube, containing the snare loop, is delicately inserted into the catheter as shown in the **figure.05.** The proximal end of the loaded tube is inserted to the catheter's hub distal end. To navigate the snare loop into the specific position within the body where the IVC filter is located, the medical professional holds the catheter steadily. With slow, controlled movements, the delivery wire is gently pushed inside the catheter. Doctors also utilize the sheath before or after deploying the snare device to navigate the vascular system effectively. This technique enables them to securely capture and withdraw the filter, reducing the likelihood of complications and ensuring the patient's safety.

Figure.05 Demonstration for the partial insertion of the snare loop into the catheter

The medical professional closely monitors the progress to ensure the wire reaches the catheter's proximal end and effectively surrounds the IVC filter. **Figure 06** illustrates the image of a delivery system with a retrieval device emerging from it.

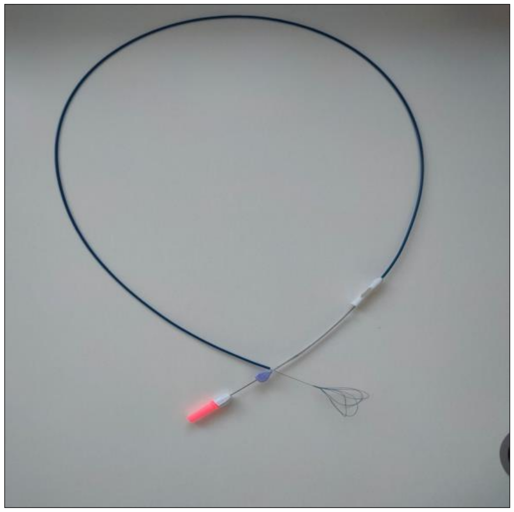

Figure.06 Delivery system with a retrieval device emerging from it

After confirming the correct positioning of the snare loop around the IVC filter, it is securely fastened to prevent any unintended movement, ensuring the successful retrieval of the filter. To complete the procedure, all components are systematically removed from the patient, leaving the snare loop securely in place, encapsulating the IVC filter for retrieval.

2.1.3 The Access for Delivery System:

The choice of access points for retrieving the IVC filter depends on factors such as the type of filter, its placement, and the patient's vascular anatomy. Typically used access points include the femoral vein, jugular vein, or internal jugular vein, depending on the orientation of the IVC filter. The retrieval procedure begins by introducing the aforementioned delivery system assembly through one of these access sites. Subsequently, the established pull-push delivery mechanism is utilized for the retrieval of the filter.

3. Result and Discussion

In the rigorous evaluation of the newly developed snare loop designed for retrieving IVC filters, a highly advanced in-vitro vascular simulation model was utilized, replicating the intricate conditions within the human body. This sophisticated model was having, features of a synthetic IVC vessel with a precisely inserted IVC filter. The snare loop, a pivotal component of this evaluation, was expertly positioned around the IVC filter within the synthetic vessel as shown in the **figure.07**. Careful measures were taken to tighten the loop effectively, ensuring the successful retrieval of the filter without causing any damage.

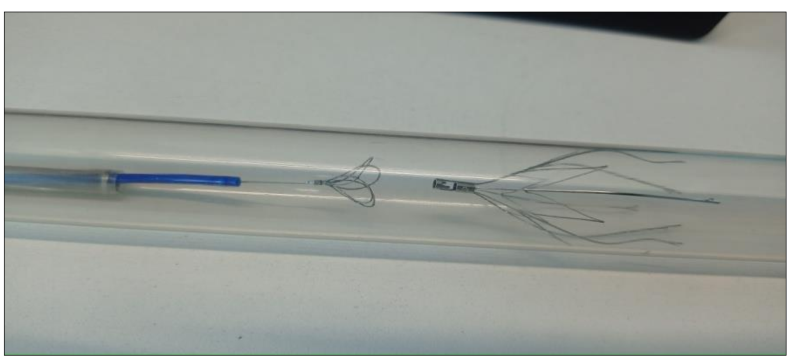

Figure.07 Positioning the snare loop around the filter

The evaluation process followed a series of systematic steps. Initially, the synthetic vessel was filled with heparinized saline, mimicking the physiological environment of a human blood vessel. Subsequently, the IVC filter was strategically placed within the vessel, simulating real-world scenarios. The snare loop, a key element of this assessment, was then inserted around the filter and tightened with precision to facilitate retrieval. The success of this procedure was gauged by the snare loop's ability to safely extract the filter without inflicting any harm upon the synthetic vessel. To accomplish this, the snare loop was first prepared for an attempt to capture the IVC filter, as depicted in **Figure.08.** Moreover, the time required for this retrieval process was diligently recorded, providing crucial insights into the efficiency of the snare loop.

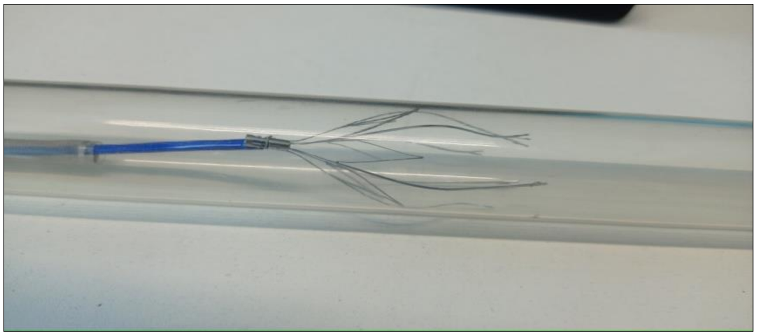

Figure.08 The snare loop being ready for capturing the IVC filter

The outcomes of this comprehensive in-vitro simulation were highly promising. The snare loop demonstrated an impressive success rate in retrieving IVC filters, as illustrated in **Figure.09 and Figure.10.** This highlights its effectiveness in safely and efficiently extracting the filters. Notably, the snare loop demonstrated compatibility with a diverse range of IVC filter types, underscoring its versatility and applicability for interventional radiologists dealing with varied patient cases. These findings were derived through a standard and widely accepted in-vitro testing method, making the results comparable to similar evaluations of other IVC filter retrieval devices in the medical field.

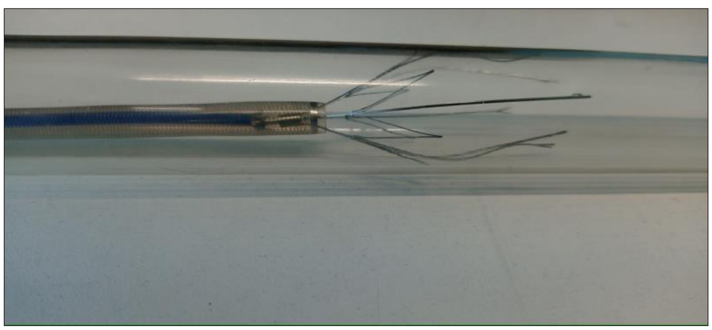

Figure.09 Safely extracting the IVC filter through the snare loop

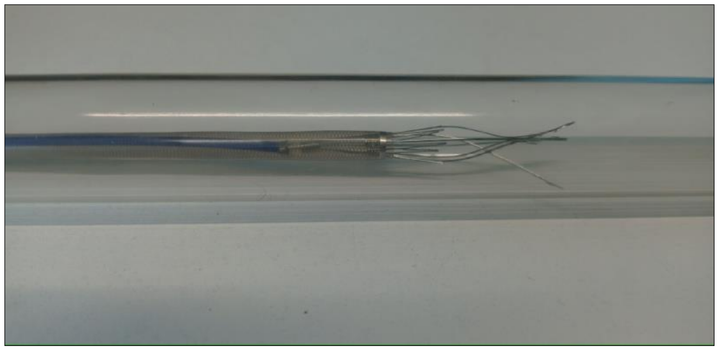

Figure.10 Efficiently retrieving IVC filter from the synthetic vessel into the delivery catheter using the 'Four-Loop Snare System'

Although the results are promising, the study acknowledges the need for further validation in real-world situations. Therefore, this current research, with its in-vitro assessment, can serve as a foundation for future pre-clinical and clinical evaluations.

4. Conclusion

Our study advocates for the use of the "Four-Loop Snare System" in IVC filter retrieval, emphasizing its minimal risk of complications and high success rate. When a single loop fails, additional loops stabilize the filter, allowing for safe retrieval without sharp instruments or dissection, preventing direct injury to the IVC. Irregularities observed in the IVC during the procedure healed naturally over time, aligning with previous findings. This technique offers flexibility as the procedure can be abandoned without risking entanglement. Despite concerns about increased traction force, filter fractures have not been reported with this approach. The "Four-Loop Snare System" enhances control and traction, ensuring better alignment of the filter tip and improving retrieval outcomes. Utilizing larger sheaths accommodates multiple loops, optimizing the procedure's effectiveness. Our research suggests that employing additional loops can augment retrieval success, making the "Four-Loop Snare System" a valuable advancement in challenging IVC filter retrievals.

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