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In-Vitro Assessment of Developed Peripheral Fibered Embolization Coil Deployment: A Key to Obstruct Blood Flow in Peripheral Arterial and Venous Vessel

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ABSTRACT

The present research study introduces a developed peripheral fibered embolization coil tailored for peripheral arterial and venous vessel embolization interventions. Crafted with platinum tungsten material and integrated with strategically positioned nylon fibers, this coil aims to bolster thrombogenicity and occlusion efficacy. Its primary objective is to achieve optimal vessel occlusion, particularly in cases involving aneurysms or aberrant blood flow. Through in-vitro assessment, the coil's deployment via catheter, along with its performance and efficacy, is scrutinized, prioritizing effective blood flow obstruction while mitigating adverse effects or complications. This scientific research propels interventional radiology forward by presenting an embolization coil poised to elevate patient outcomes and amplify the safety and efficacy of peripheral vessel embolization procedures. Moreover, it delves into the developmental trajectory and pivotal considerations underlying the coil's design and testing, furnishing invaluable insights for future research endeavors and clinical implementations within the realm of interventional radiology.

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KEYWORDS:

Peripheral embolization coil, Platinum tungsten material, Vessel occlusion efficacy, Interventional radiology and Thrombogenicity.

INTRODUCTION

Peripheral arterial and venous vessel embolization procedures are vital interventions for managing various vascular conditions such as aneurysms and abnormal blood flow. These procedures employ embolic agents to obstruct or reduce blood flow within targeted vessels, thus preventing complications and promoting therapeutic outcomes. Coil embolization has emerged as a widely accepted method due to its effectiveness, versatility, and minimal invasiveness. Recently, there has been an escalating demand for advanced embolization coils capable of achieving more precise and durable vessel occlusion, particularly in peripheral arteries and veins.To meet this demand, researchers and medical device manufacturers have been exploring innovative designs and materials to enhance coil performance and efficacy. One promising development is the introduction of peripheral fibered embolization coils, incorporating nylon fibers strategically placed to improve thrombogenicity and occlusion efficacy.

Different coil shapes play a crucial role in optimizing embolization outcomes across various artery anatomies. Each shape is purposefully designed to address specific vessel requirements, ensuring effective occlusion while minimizing the risk of recanalization.

In our previous work, we developed a novel neurovascular embolization coil to treat brain aneurysms. Currently, we are focusing on peripheral fibered embolization coils designed to occlude vessels in peripheral segments. We have developed three types of coils for this purpose helical, twister, and diamond-shaped each available in various sizes. This article presents our latest advancements and an in-vitro evaluation of these new coil designs.

Helical Shape: Offers advantages in maintaining consistent occlusion along the vessel's path, especially in arteries with relatively straight geometries.

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Twister Shape: Tailored to fill irregularly shaped arteries effectively, making it suitable for embolizing vessels with complex anatomies.

Diamond Shape: Maximizes flow disruption to prevent recanalization, particularly suitable for arteries where comprehensive occlusion is critical.

Increasing the fiber density in Peripheral Fibered Embolization Coils significantly enhances their efficacy by promoting faster occlusion and improved thrombogenicity. Our approach involves augmenting fiber quantity within the coil, achieved by inserting fibers between coil pitches at reduced distances. This strategy results in better occlusion, providing a novel avenue for enhancing peripheral embolization coil performance.

The primary objective of this study is to describe the development and in-vitro assessment of a peripheral fibered embolization coil designed specifically for peripheral arterial and venous vessel embolization procedures. Constructed using platinum tungsten material for excellent visibility under fluoroscopy and MRI, the coil incorporates nylon fibers between coil pitches to enhance thrombogenicity and promote rapid clot formation.

In-vitro testing involves assessing deployment characteristics, performance, and efficacy in obstructing blood flow within simulated peripheral vascular models. Emphasis is placed on evaluating complete and durable vessel occlusion without adverse effects such as migration or coil compaction. These results offer valuable insights into the coil's safety profile and effectiveness in achieving therapeutic outcomes.

MATERIALS AND METHODS

The development and fabrication process of the peripheral fibered embolization coil involved several steps carried out under sterile conditions and in compliance with ISO 13485 guidelines.

Cutting and Secondary Coiling Process:

The initial phase of the coil fabrication procedure involved acquiring highly biocompatible, radiopaque material, commonly utilized in medical applications for its exceptional properties. Precision cutting tools were employed to slice the coil to the precise length required, ensuring unparalleled uniformity and accuracy in dimensions.

Following the cutting process, the coil underwent a secondary coiling procedure, wherein it was carefully wound around a mandrel to achieve the desired shape and diameter of the embolization coil. This secondary coiling step is crucial in determining the final characteristics and performance of the embolization device, as it dictates aspects such as flexibility, conformability, and overall efficacy in medical interventions. During the secondary coiling process, expert craftsmanship was employed to wind the coil around the mandrel, ensuring optimal alignment and distribution of the material to achieve the desired structural integrity and performance. Each coil was intricately shaped to meet specific medical requirements, taking into account factors such as vessel morphology, vessel anatomy, deployment techniques, and compatibility with imaging modalities for precise placement and monitoring during procedures.

Attention to detail and adherence to stringent quality standards were paramount throughout the cutting and secondary coiling stages, guaranteeing that each embolization coil produced exhibited consistent and reliable performance characteristics. This approach not only ensures the safety and efficacy of the final product but also underscores the commitment to delivering innovative solutions in the field of interventional medicine.

Heat Treatment Process:

The secondary wound coils underwent a heat treatment process aimed at enhancing their structural integrity and mechanical functionality to meet the stringent requirements for successful deployment and effective occlusion within the vessels. This heat treatment procedure entailed subjecting the coils to carefully controlled temperatures ranging from 550°C to 650°C for about 30 minutes strategically designed to induce favorable alterations in their molecular structure. Through this approach, the coils were transformed, optimizing their performance characteristics and ensuring they were suitably prepared for their intended medical application.

Welding Process:

The coil tip undergoes a welding process, joining it with a secondary shaped coil at the device's distal end. This welding procedure ensures a firm attachment without compromising the integrity of the coil structure. Specifically crafted with a round and smooth surface, the coil tip aims to safeguard the artery wall during deployment, thereby reducing the potential for vascular injury.

Fiber Insertion Process:

The fiber insertion process for the development of embolization coil is a critical step in enhancing the efficacy and stability of the coils for peripheral vessel embolization procedures. The process involves several key steps to ensure the proper integration of nylon fibers into the coil structure.

First, the platinum tungsten coil was prepared for fiber insertion. This process included cleaning the coil to remove any debris or contaminants that could interfere with the insertion process. The coil was then positioned for fiber insertion using a specialized tool for holding it. Fiber insertion was typically carried out using specialized tools such as forceps and micro scissors. Next, the nylon fibers were carefully inserted between the coil pitches.

This task demanded precision and attention to ensure the secure integration of fibers into the coil structure. It required precise work under a microscope. Forceps were employed to

securely hold the fibers in place, while micro scissors were utilized to trim them to the appropriate length. The placement of nylon fibers within the coil was strategic, aimed at enhancing thrombogenicity and occlusion efficacy. This entailed positioning the fibers at specific intervals or concentrations to optimize their effectiveness in obstructing blood flow.

Throughout the fiber insertion process, quality control measures were implemented to ensure the integrity of the coils. This included inspecting the coils under magnification to verify the proper placement of the fibers and to check for any defects or irregularities. Once the fiber insertion process was completed, the embolization coils shown in the figure 01, 02 & 03 were ready for in-vitro testing to evaluate their performance and efficacy. This testing typically involved deploying the coils via catheter into a simulated vascular environment and assessing their ability to obstruct blood flow effectively without causing adverse effects or complications.

In our investigation of embolization coils for peripheral artery deployment, we evaluated three distinct shapes: helical, twister, and diamond. Each coil shape offers a

unique range of lengths and diameters, catering to different clinical needs.

The helical coil, ranging from 3.0 to 20 cm in length and 2 to 20 mm in diameter, offers versatility ideal for robust occlusion in large or complex vascular regions. It is well-suited for embolization procedures across a broad spectrum, accommodating applications in both small and large vessels. The twister coil, with lengths from 2.0 to 14.5 cm and diameters from 3.2 to 10.5 mm, strikes a balance between flexibility and occlusive power, making it particularly effective for medium-sized vessels. Its design ensures precise placement and reliable occlusion, crucial in peripheral arteries such as the femoral and popliteal vessels. Lastly, the diamond coil, ranging from 2.3 to 8.0 cm in length and 3 to 6 mm in diameter, is tailored for smaller vessels and targeted embolization needs. Its compact size allows navigation through narrow pathways, facilitating effective blockage in vessels like the tibial and brachial arteries. Combining multiple coils of varying sizes can enhance occlusion outcomes, addressing specific anatomical challenges in peripheral vascular interventions.

All these coils maintain their dimensions post-deployment, whether using primary coil diameters of 0.018″ or 0.035″, ensuring predictable performance. This variety in coil design and sizing allows for tailored treatment approaches, optimizing patient outcomes in peripheral artery interventions.

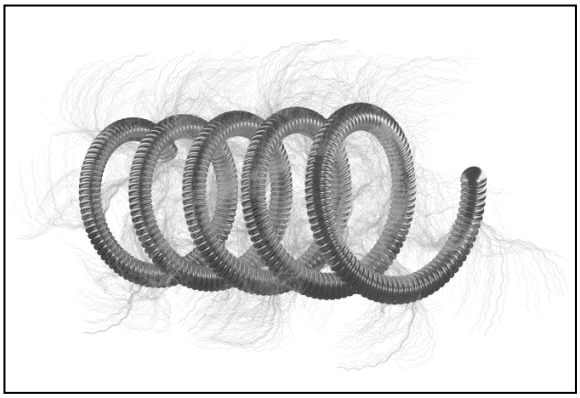


Figure 01 Helical shape peripheral fibered embolization coil

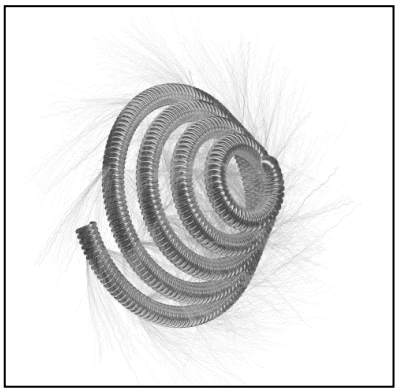


Figure 02. Twister shape peripheral fibered embolization coil

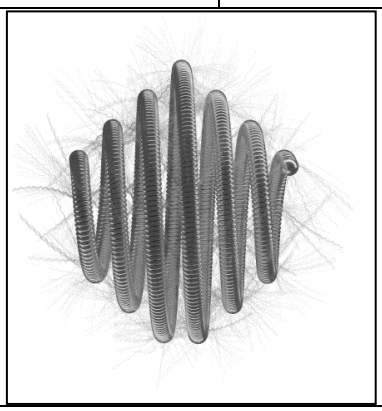


Figure 03 Diamond shape peripheral fibered embolization coil

Delivery System Preparation & Coil Loading Process

The successful deployment of coil-based medical devices relies heavily on the preparation and loading process of the delivery system. The whole delivery system assembly is depicted in the figure 04. The compatibility of delivery catheters varies depending on the primary coil diameter. For the 0.018″ coil, a 2.8 or 3.0 Fr micro-catheter is appropriate, while for the 0.035″ coil, a 5.0 Fr catheter is recommended. Correspondingly, guide wire compatibility is contingent on coil diameter, with 0.018″ and 0.035″ guidewires for the respective coils. Our delivery system operates through a pushable mechanism. This intricate procedure involves several essential components, each playing a crucial role in ensuring the efficacy and safety of the device. Let's delve into the detailed breakdown of these components and their functions.

1. Loading Tube:

At the heart of the delivery system lies the loading tube (length ranging from 200-210 mm, an outer diameter of 0.6-1.3 mm, and an inner diameter of 0.63-0.9 mm). This cylindrical structure serves as the vessel through which the coil is loaded. The loading tube provides a secure and controlled environment for the coil, ensuring its integrity during handling and deployment.

2. Hub:

Connected to the loading tube at its proximal end, the hub (length ranging from 25-35 mm, a distal end outer diameter of 4.1-4.9 mm and an inner diameter of 1.0-1.1 mm, and a proximal end outer diameter of 6.1-6.9 mm and an inner diameter of 4.1-4.5 mm) serves multiple essential purposes for the delivery process. Primarily, it facilitates flushing by providing a connection point for syringes or other flushing devices. Additionally, the hub functions as a stable anchor, securely holding the loading tube during the deployment procedure, thus minimizing the risk of inadvertent movements that could compromise the procedure's success.

3. Protective Tube:

During transportation and storage, protecting the delicate loading tube from potential damage is paramount. The protective tube (length ranging from 195-205 mm, an outer diameter of 5.7-5.8 mm, and an inner diameter of 4.4-4.5 mm) serves this purpose by enveloping the loading tube, shielding it from external forces and environmental factors. This protective measure ensures that the loading tube arrives at its destination unharmed, ready for the crucial deployment process.

4. Protective Wire:

To further fortify the security of the coil within the loading tube, a protective wire (length ranging from 230-240 mm and an outer diameter of 0.55-0.65 mm) is employed. This wire is strategically positioned at both ends of the loading tube, effectively securing the coil in place during shipping and storage. By preventing any unintended movements or disruptions, the protective wire safeguards the coil's integrity, guaranteeing its readiness for deployment when needed.

5. Stylet:

The final component of the delivery system is the stylet (length ranging from 250-260 mm and an outer diameter of 0.55-0.65 mm), an indispensable tool for the loading and deployment process. Supplied alongside the coil, the stylet plays a pivotal role in guiding the coil out of the loading tube and into the delivery catheter. With precision and control, the stylet ensures smooth and accurate advancement of the coil, facilitating its seamless integration into the targeted area.

The preparation and loading process of coil delivery systems demand attention to detail and the coordinated effort of various components. From the protective measures of the loading tube and protective wire to the functionality of the hub and the precision of the stylet, each element contributes to the overall effectiveness and safety of the procedure. By understanding the roles and significance of these components, healthcare professionals can ensure the successful deployment of coil-based medical devices, ultimately benefiting patient outcomes.

The process of preparing a delivery system and loading a coil for medical procedures is a critical aspect of ensuring the efficacy and safety of the intervention. It involves steps to safeguard the integrity of the coil while facilitating its smooth deployment into the target area within the patient's body.

To commence the preparation, a cylindrical hollow tube is carefully selected to accommodate the coil. This tube is chosen for its robustness to prevent any damage to the coil during transportation and storage, while also ensuring the seamless deployment of the coil from the tube to the catheter during the procedure. Selecting a tube with adequate mechanical strength is imperative to safeguard the coil effectively.

The loading tube is then connected to a hub at its proximal end. The bonding between the loading tube and the hub is of paramount importance to guarantee safe operation. A selection of the hub is indispensable, as it serves as the connection point for various purposes, including flushing and other procedural requirements. The proper bonding between the loading tube and the hub ensures the stability and reliability of the delivery system.

Moreover, a protective tube is chosen to envelop the loading tube, further safeguarding it from potential damages during transportation and storage. This protective measure ensures that the loading tube remains securely housed within the protective tube, preserving its integrity until the procedure commences.

Additionally, a protective wire is employed to prevent premature deployment of the coil from the loading tube during shipping/transportation. This wire acts as an additional layer of security, ensuring that the coil remains safely contained until the intended deployment.

In the loading process, the coil is loaded into the loading tube, either manually or with the assistance of specialized tools such as stylets and forceps. This step requires precision and care to ensure that the coil is properly positioned within the loading tube, ready for deployment during the procedure.

Overall, the delivery system preparation and coil loading process demand attention to detail and adherence to strict protocols to guarantee the safety and efficacy of the medical intervention. By following these steps diligently, healthcare professionals can ensure optimal outcomes for patients undergoing coil-based procedures.

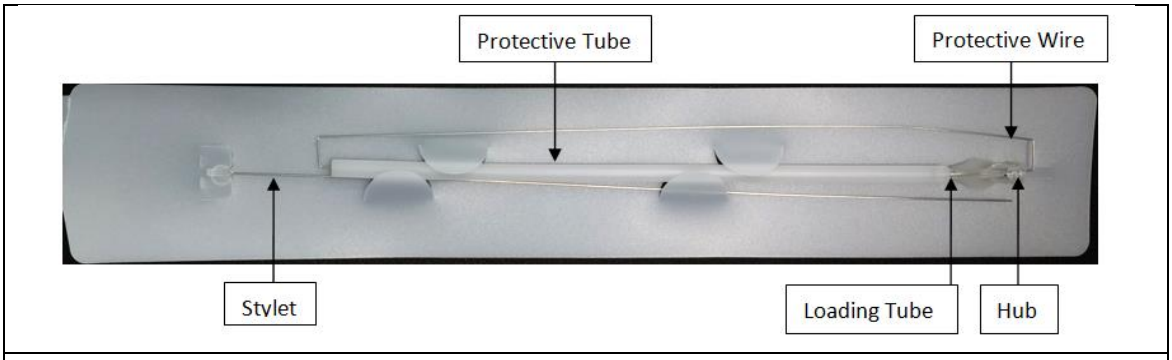


Figure.04 The Delivery System Assembly size matrix

Primary Packaging and Sterilization Process

The initial step in the primary packaging process for the Fibered Embolization Coil entailed the assembly of the coil within a maintained clean room environment, where laminar airflow ensured the highest standards of cleanliness. Within that controlled setting, skilled technicians delicately positioned each component of the coil with precision and care, adhering to strict quality assurance protocols.

Following the assembly process, the coil was carefully nestled into a specialized tray designed to securely hold its intricate structure. From there, it was gently enveloped within a TYVEK pouch, a material chosen for its exceptional barrier properties that safeguarded the coil from environmental contaminants and maintained its sterility.

The sealing of these pouches was a critical step in the packaging process, performed with exacting precision using a sealing machine calibrated to maintain a controlled temperature. This ensured the integrity of the seal, preventing any potential compromise to the sterility of the enclosed coil. Once sealed, each pouch underwent a visual inspection, where highly trained quality control personnel scrutinized every inch for any signs of defects or damage. Any anomalies were promptly addressed to maintain the highest standards of product quality and safety.

As a final touch, product information labels were applied to each pouch, providing essential details regarding the contents and usage instructions. This ensured that healthcare professionals had access to crucial information when utilizing the Fibered Embolization Coil in medical procedures.

Following the comprehensive packaging process, the sealed pouches were transferred to the sterilization section, where they underwent a rigorous sterilization procedure to ensure the complete eradication of any potentially harmful microorganisms.

Within the sterilization chamber, the pouches were strategically arranged to facilitate maximum penetration of the sterilizing agent and efficient removal during subsequent aeration processes. Chemical process indicators were affixed to each pouch to monitor the sterilization cycle, providing an additional layer of assurance regarding the efficacy of the process.

Furthermore, to guarantee the effectiveness of the sterilization process, biological indicators and process challenge devices were included in each sterilization load. These measures ensured that every Peripheral Fibered Embolization Coil underwent thorough sterilization, meeting the stringent standards outlined in ISO 11135:2007.

The entire sterilization process was controlled through the utilization of a programmable logic controller (PLC) operated sterilizer, allowing for precise adjustment of temperature and aeration time parameters. Additionally, the process underwent regular re-validation procedures to ensure ongoing compliance with industry standards and regulations, further underscoring the commitment to product quality and safety.

RESULTS AND DISCUSSION

Our in-vitro deployment simulation model, designed to replicate the conditions of the popliteal artery with a 5 mm diameter, formed the foundation for evaluating the successful deployment of our product, particularly the 0.018″ coil measuring 6X140 mm. This simulation method plays a crucial role in predicting in-vivo implantation outcomes, ensuring the efficacy and safety of our peripheral fibered embolization coil for clinical application.

The deployment procedure for the pushable type fibered embolization coil commenced with the careful extraction of the loading tube assembly from the tray to ensure precise handling. Subsequently, the protective wire and tube were removed from the assembly, and the loading tube was

securely inserted into the base of the angiographic catheter hub equipped with a luer lock connector. Following this, the embolization coil was pushed into the angiographic catheter using the provided stylet, and after insertion, both the stylet and loading tube were removed. The coil was then advanced to the catheter's tip with an appropriately sized guidewire for precise positioning before deployment, which was facilitated either through saline/contrast flush or the push technique.

The deployment and delivery process of the fibered embolization coil play critical roles in ensuring its efficacy in peripheral vessel embolization procedures. In this study,

we conducted in-vitro tests to evaluate the performance and efficacy of the coil deployment process, aiming to predict its ability to obstruct blood flow effectively without adverse effects or complications.

To cater to diverse anatomical variations and encountered diseases in peripheral vessel embolization procedures, we introduced three different shapes of embolization coils: helical, twister, and diamond. These shapes were selected to accommodate various vessel geometries and ensure optimal coil positioning for effective occlusion.

Constructed with platinum tungsten material, the coils offer high radiopacity and excellent biocompatibility, ensuring clear visualization under fluoroscopy during deployment and minimizing the risk of adverse reactions or inflammatory responses in patients.

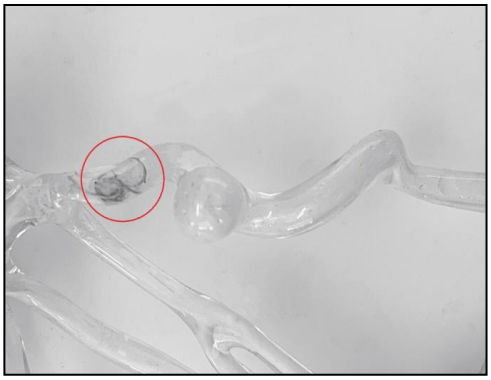
During the deployment process, attention is paid to the coil's positioning to ensure proper placement and maximum contact with the vessel wall. Once positioned, the coil is deployed gradually to allow it to expand and conform to the vessel's shape, achieving effective occlusion.

In our in-vitro tests, we assessed key parameters including the ease of coil delivery through the catheter, its ability to conform to the vessel's shape, stability post-deployment, and its capacity to achieve complete occlusion without migration or displacement.

Our results indicated that the fibered embolization coils effectively obstructed blood flow in simulated vessels, with minimal risk of migration or displacement. The strategic placement of nylon fibers between coil pitches enhanced thrombogenicity and occlusion efficacy, further improving performance.

Overall, our findings suggest that fibered embolization coils offer a promising solution for peripheral vessel embolization procedures, providing effective occlusion while minimizing complications. The successful deployment process of the peripheral fibered embolization coil is depicted in Figure 05.

(A)



(B)

Figure 05 (A) & (B) Successful deployment of peripheral fibered embolization coil in simulated peripheral vascular model for in-vivo implantation prediction

CONCLUSION

In conclusion, this research article presents the development and in-vitro testing of a peripheral fibered embolization coil with the aim of enhancing the efficacy and safety of peripheral arterial and venous vessel embolization procedures. By integrating platinum tungsten material and strategically placed nylon fibers, the coil exhibits improved radiopacity, thrombogenicity and occlusion efficacy. Through comprehensive in-vitro testing, the deployment of the coils via catheter and their performance in obstructing blood flow were evaluated, with a focus on achieving effective vessel occlusion while minimizing adverse effects or complications. The findings suggest that the developed coil holds promise for addressing conditions such as aneurysms and abnormal blood flow in peripheral arteries and veins. This research contributes significantly to the advancement of interventional radiology techniques, offering a new generation of embolization coils tailored to enhance patient outcomes. Additionally, the development process and key considerations discussed provide valuable insights for future research and pre-clinical or clinical applications. Overall, this study underscores the importance of innovation in medical device design and testing to meet the evolving needs of patients and clinicians in managing peripheral vessel abnormalities. Further research is also underway to explore the use of these coils in various in-vivo applications. We will continue to document our progress in upcoming articles.

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