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Developing a Neurovascular Embolization Coil with Delivery System to Treat Brain Aneurysms

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Abstract

Aneurysms, characterized by weakened areas in arterial walls, pose a significant risk of life-threatening hemorrhage and permanent brain damage upon rupture. In this research, we present a novel neurovascular embolization coil assembly comprising an embolization coil and a delivery system, aimed at addressing the challenges associated with embolism trauma. The neurovascular embolization coil system features a delivery configuration that enables precise deployment of the embolization coil. Additionally, it incorporates a secondary coil system consisting of predefined shapes and patterns, which are derived by customizing a primary coil made of a super-elastic shape memory material. The proposed delivery system offers notable advantages, including cost-effectiveness and safety. It facilitates easy detachment of the coil implant through a threading mechanism, reducing procedural complications and enhancing patient safety. To validate the performance of the developed delivery system, an in-vitro implantation study was conducted using a simulated neurovascular model under normal conditions. The study successfully demonstrated the efficient deployment of the embolization coil using the developed delivery system.

Keywords: Aneurysms · Neurovascular embolization coil system · Simulated model

Introduction

The treatment of intracranial aneurysms has significantly evolved over the years, with the development of endovascular techniques providing less invasive alternatives to surgical interventions [1]. One such technique is the use of neurovascular embolization coil Systems, which are specifically designed for the endovascular embolization of intracranial aneurysms [2]. These systems utilize coils as super durable embolic agents that can effectively occlude the aneurysm and prevent the risk of rupture [3]. Intracranial aneurysms are characterized by a swelling or ballooning inside a blood artery of the neurons. They can occur in various neurovascular regions, such as the anterior and posterior neurovasculature [4]. Examples of aneurysms in the anterior neurovasculature include those in the Internal Carotid Artery (ICA), Superior Hypophysial Artery (SHA), Ophthalmic Artery (OA), and Anterior Choroidal (AC) [5]. Aneurysms in the posterior neurovasculature may involve the Anterior Inferior Cerebellar Artery (AICA), Posterior Inferior Cerebellar Artery (PICA), and Superior Cerebellar Artery (SCA), among others [6]. The coiling technique using neurovascular embolization coils involves the placement of these coils within the aneurysm to achieve occlusion of the aneurysm sac and reduce the risk of bleeding [7]. This minimally invasive procedure is performed endovascularly by inserting a steerable catheter into the patient's circulatory system and directing it to the cerebrum [8]. The coils deployed inside the aneurysm assist in physically slowing or stopping blood flow, promoting the development of a clot and the release of thrombogenic factors [9]. The deployment of neurovascular embolization coils plays a crucial role in the coiling process. However, there are potential challenges associated with coil deployment, including the risk of aneurysm rupture and inadequate framing and filling of the coils. Improper coil deployment can lead to aneurysm formation at the treatment site, highlighting the need for improved coil designs and delivery systems [10,11]. This research article aims to explore a new neurovascular embolization coil and delivery system that overcomes the limitations of conventional assemblies. By addressing the drawbacks associated with coil deployment, it is expected that this new system will enhance the efficacy and safety of endovascular coiling treatments for intracranial aneurysms. The subsequent sections will provide a comprehensive analysis of the novel coil system, including its design, deployment mechanism, and potential benefits in the treatment of intracranial aneurysms.

Materials and Methods

The objective of the neurovascular embolization coil system is to facilitate the neurovascular embolization of cerebral aneurysms, as well as other neurovascular disorders, such as Arteriovenous Malformations (AVMs) and Arteriovenous Fistulas (AVFs). For the development of the neurovascular coils, a platinum-tungsten alloy (92% platinum, 8% tungsten) is utilized. The neurovascular embolization coil employed in the present research study is a composite coil consisting of a primary coil and a secondary coil with a complex and helical shape. The complex and helical shape coils are visually represented in Figures 1 and 2, respectively. The secondary coil is generated by reshaping the primary coil using a predetermined mandrel. To ensure proper attachment of the delivery wire to the coil implant, a connecting member is employed. The Neurovascular embolization coil system demonstrates exceptional flexibility, stretch-ability, and foldability. It exhibits the ability to transform into a rigid iron ring when maximally constricted, and into a simple string-like structure when maximally extended. For the implantation procedure, the coil is loaded into an introducer sheath. The implant, along with the delivery system, is manually connected to the delivery wire and compressed within the introducer sheath.

Figure 1. Complex configuration of a neurovascular embolization coil.

Figure 2. Helical configuration of a neurovascular embolization coil.

In this research study, the implantation procedure involves the use of a readily available 1.26 Fr (0.0165 inch inner diameter) micro-catheter. The Neurovascular embolization coil delivery system consists of several essential components, including the Delivery wire, Introducer sheath, Connecting member, Neurovascular embolization coil, and Neurovascular embolization coil tip.

Delivery wire

The delivery wire, as depicted in Figure 3, is an integral component of the system. It possesses a diameter ranging from 0.09 mm at the distal end to 0.40 mm at the proximal end, with a total length of 1900 mm. Constructed from a Polytetrafluoroethylene (PTFE) coated nitinol material, the delivery wire plays a crucial role in facilitating the connection between various system components. It specifically assists in coupling the connecting member of the delivery system, enabling the transportation of the Neurovascular embolization coil to the targeted aneurysm site.

Introducer sheath

The introducer sheath, depicted in Figure 3, is a key component of the system. It is designed with an Outer Diameter (OD) of 0.70 mm, an Inner Diameter (ID) of 0.50 mm, and a length of 1200 mm. The sheath is composed of ML21/PTFE material, chosen for its desirable properties. The main function of the introducer sheath is to facilitate the loading of the Neurovascular embolization coil onto the delivery wire. Additionally, during the deployment procedure, it assists in advancing the delivery wire into the microcatheter, ensuring smooth and controlled placement of the embolization coil at the intended location.

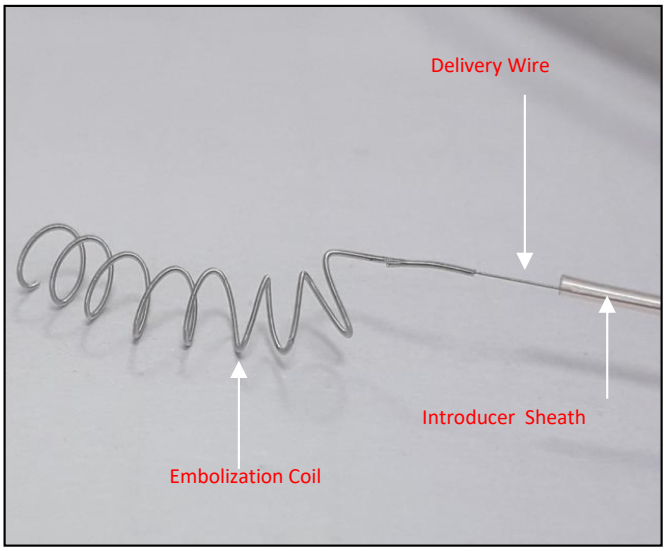

Figure 3. Demonstration of delivery wire, introducer sheath and embolization coil.

Connecting member

The illustrated component in Figure 4, known as the connecting member, is made from platinum (92%)-tungsten 8%) alloy. It has specific measurements of 0.3175 mm (outer diameter), 0.2175 mm (inner diameter), and 5 mm (length). This connecting member serves the purpose of mechanically securing a neurovascular embolization coil within the introducer sheath and functions as the detachment mechanism.

Figure 4. Connecting member

Neurovascular embolization coil

The illustrated neurovascular embolization coil in Figure 5 possesses dimensions of 0.0125mm (inner diameter), 0.3175mm (outer diameter), and a length of 1000mm. Its primary purpose is to safeguard against the rupture of intracranial aneurysms by obstructing blood flow into the aneurysm.

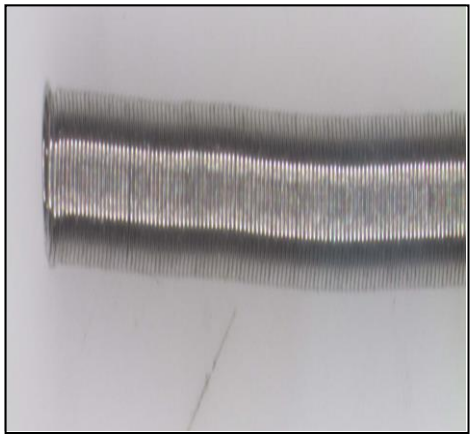

Figure 5. Neurovascular embolization coil.

Neuro coil tip

The depicted neuro coil tip in Figure 6 is composed of a platinum (90%) - iridium (10%) alloy and is employed for the prevention of aneurysm rupture.

Figure 6. Neuro coil tip.

The complete delivery system assembly, depicted in Figure 7, is designed to facilitate the safe deployment of the neurovascular embolization coil. The delivery wire is connected to the connecting member through laser welding, utilizing specific parameters such as power (240V), pulse width (0.5 ms), and spot diameter (0.2 mm). Once connected, the delivery wire is inserted into the introducer sheath and advanced until the connecting member exits the distal end of the sheath. The connecting member and delivery wire are manually attached to the neurovascular embolization coil through a threading

mechanism shown in Figure 8. To simplify the loading process, micro-forceps are used to hold the connecting member while the delivery wire is pulled towards the proximal end. Visual inspection is conducted to verify the correct positioning of the connecting member, and the compatibility between the delivery mechanism and the introducer sheath is assessed. Finally, the delivery system is securely placed within a dispenser coil and sealed in a tyvek pouch.

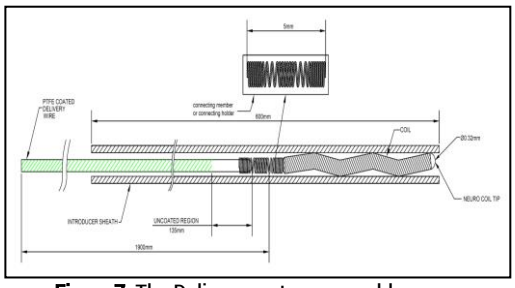

Figure 7. The Delivery system assembly.

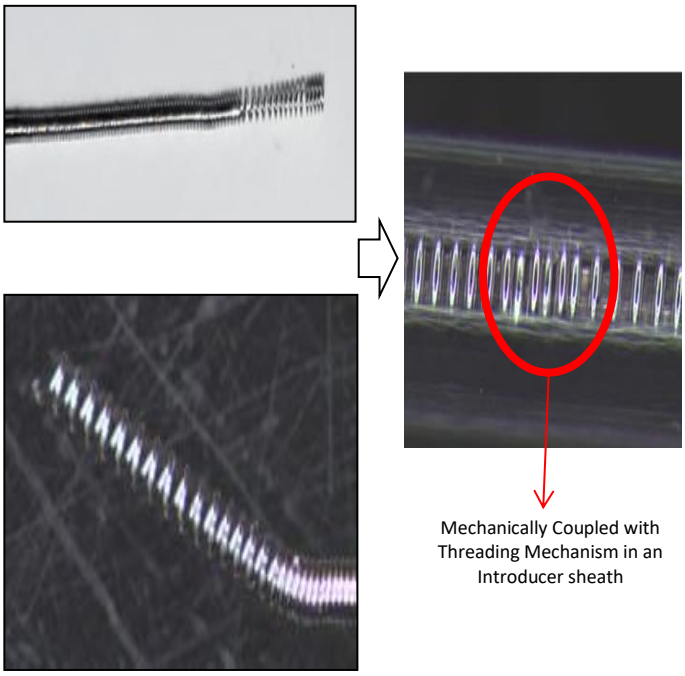

Figure 8. Threading mechanism.

During surgical procedures involving the deployment of the coil, a microcatheter is inserted into the femoral artery near the groin and guided to the aneurysm site within the cerebrum. To facilitate this process, the delivery system is extracted from its packaging box, and the dispenser coil is removed from the tyvek pouch. The loaded system is then extracted from the dispenser coil, as demonstrated in Figure 9.

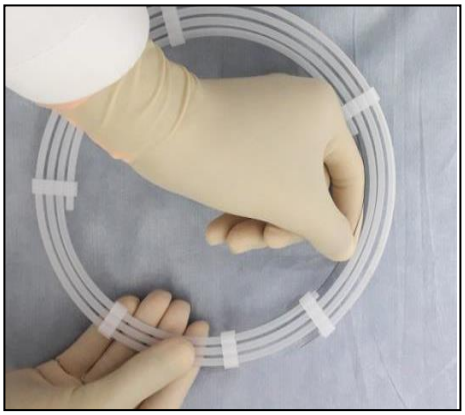

Figure 9. Removal of a loaded system from the dispenser coil.

Once the introducer sheath is properly inserted into the hub of the microcatheter, the Rotating Hemostatic Valve (RHV) illustrated in Figure 10 is loosened and moved forward. The distal end of the introducer sheath is partially inserted into the RHV, which is connected to the microcatheter. The RHV is then securely tightened, and it is checked whether any fluid leaks from the proximal end of the introducer sheath.

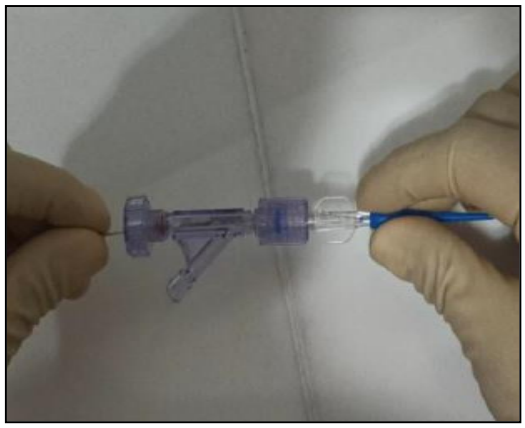

Figure 10. Rotating Haemostatic Valve (RHV).

The Neurovascular embolization coil system is progressed into the micro-catheter by pushing the delivery wire until the tip of the wire aligns with the tip of the micro-catheter. Subsequently, the coil is meticulously positioned at the intended target site, as demonstrated in Figure 11.

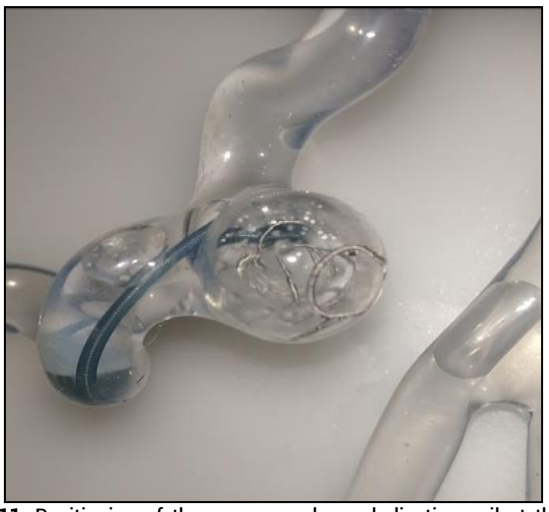

Figure 11. Positioning of the neurovascular embolization coil at the desired site.

After the Neurovascular embolization coil system has been fully advanced to the desired location, a torque device is positioned at the proximal end of the delivery wire. The torque device is then cautiously rotated clockwise, which typically takes 5-7 seconds for the coil to detach. If detachment is not felt or observed under fluoroscopy, the torque device is continuously rotated until detachment is confirmed. The delivery wire is slowly pulled back to ensure the coil remains in place without any movement. Fluoroscopic monitoring is used to verify the successful detachment of the coil. Once coil detachment is confirmed, the delivery wire is gradually withdrawn from the micro-catheter. This process ensures that the coil implant is effectively loaded at the target site using the aforementioned delivery system.

Result and Discussion

The *in vitro* implantation of a neurovascular embolization coil in a simulated neurovascular model shown in the Figure 12 yielded promising results. The simulated neurovascular model was carefully chosen for its ability to replicate conditions found within the human body (*in vivo*). In this research study, a secondary coil with a complex and helical shape was utilized. The primary coil was formed by developing the secondary coil around a predetermined mandrel, and a connecting member was employed to join the delivery wire and the coil implant together. During the implantation process, the neurovascular embolization coil was placed inside the lumen of an introducer sheath in a linear position, after which it was axially stretched. Upon deployment, the coil regained its complex and helical shape, returning to its original structure. This unique combination of shapes ensured that the

embolization coil adequately filled the aneurysm, facilitating its deployment at the intended site. The delivery wire used in the procedure featured a tapered configuration and a polymeric coating. These design elements provided the delivery system with enhanced flexibility and lubricity, enabling smooth movement through the tortuous vasculature. Consequently, the delivery friction and retraction friction experienced were significantly reduced compared to conventional wires. The results of the study highlighted the simplicity and efficiency of the neurovascular embolization coil. The setup time required for its use was minimal, making it a convenient option for clinicians. Notably, the coil's retractable nature allowed for precise adjustments, ensuring optimal placement and occlusion. Furthermore, the coil's self-expanding properties, attributed to the super-elastic shape memory material used in its construction, facilitated its transformation from the delivery configuration to the deployed configuration upon implantation at the target site. During deployment, the coil tip plays a crucial role in preventing lumen rupture, particularly in compromised arteries or aneurysm walls. Additionally, the loading process of the embolization coil into the delivery system proved to be advantageous, simplifying the overall procedure and reducing the risk of implant damage. Overall, the results of the *in vitro* implantation of the neurovascular embolization coil in the simulated neurovascular model demonstrated its effectiveness and potential for improving neurovascular interventions. The findings support its use as a viable option for achieving appropriate aneurysm filling, while also emphasizing its user-friendly features and potential to minimize complications associated with implantation procedures.

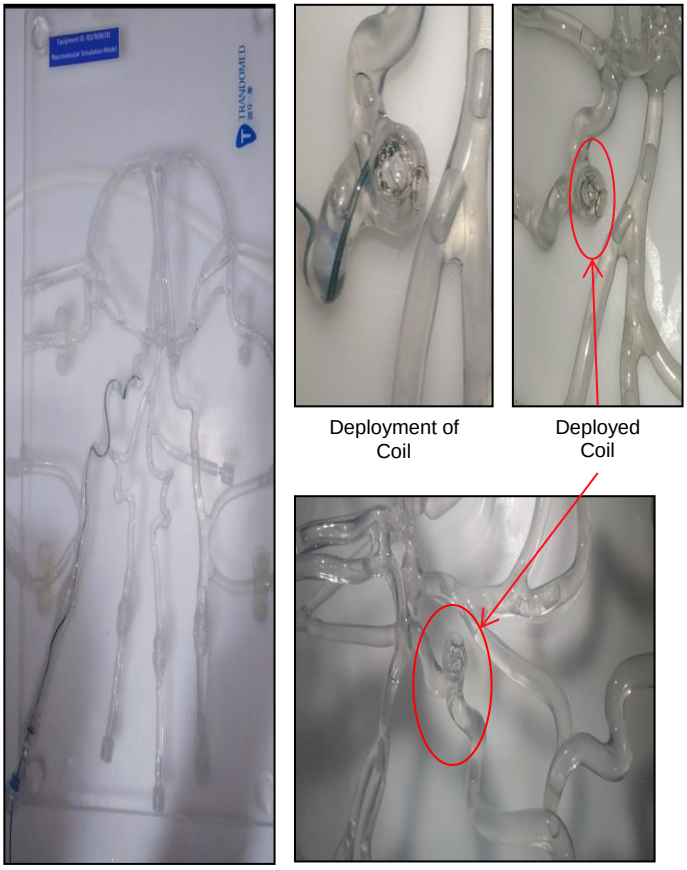

Figure 12. Coil deployment in neurovascular simulation model.

Conclusion

In conclusion, the research study confirms the effectiveness and benefits of the threading mechanism in delivering the neurovascular embolization coil implant. The mechanism allows for quick detachment in a clock wise direction, making it cost-effective and superior to other coils on the market. The delivery system used in the study successfully implanted the coil in the neurovascular simulation model, demonstrating its safety and relevance. The findings of this study offer valuable insights for future pre-clinical investigations into treating neuro-vasculature disorders like AVM and AVF. Implementing the threading mechanism and delivery system discussed in this research can potentially enhance treatment approaches and improve patient outcomes. Further studies and clinical trials are needed to validate and expand upon these findings, aiming to provide more effective treatment options for patients with neuro-vasculature disorders.

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