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Advancing Vascular Care: Development of Steerable Microcatheter with Detachable Tip for Liquid Embolization of Vascular Aneurysm: In-vitro Analysis

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Abstract

Ongoing advancements in vascular intervention are fueled by the pursuit of improved patient outcomes and procedural efficiency. This study presents a newly developed steerable microcatheter tailored for the delivery and retrieval of liquid embolic agents in vascular procedures, specifically targeting the obstruction of blood flow to aneurysms. Key to this research is the incorporation of a biocompatible and embolization tip that can be detached from the steerable microcatheter body using thermoplastic sleeves. This research distinguishes itself by utilizing medical-grade and cost-effective materials, thereby ensuring precise and efficient operation of the technology. In-vitro experiments validate the accuracy and effectiveness of the detachable steerable microcatheter, guaranteeing targeted delivery of embolic agents to the intended vascular site aneurysms. Upon deployment, the tip seamlessly integrates with the liquid embolic fluid, thereby optimizing embolization outcomes.

Keywords: Vascular Intervention, Steerable Microcatheter, Liquid Embolic Agents, Procedural Efficiency & Embolization Outcomes

Introduction

In recent years, vascular interventions have undergone remarkable advancements driven by the imperative to enhance patient outcomes and procedural efficiency. A development in this realm involves the utilization of steerable microcatheter for delivering embolic agents, particularly in treating vascular pathologies such as aneurysms. Embolization, the deliberate occlusion of blood vessels, has become integral in managing various vascular conditions. Despite the vital role played by traditional microcatheters in facilitating embolization procedures, limitations persist, particularly regarding precision and adaptability to anatomical complexities

Traditional microcatheters are constrained by a narrow range of sizes, limiting their ability to balance flexibility and structural integrity. These limitations are especially pronounced when navigating small, tortuous, or complex vascular pathways. Anatomical challenges, such as sharp bends, abrupt directional changes, and branching structures in delicate areas like the cerebral vasculature, demand exceptional precision and control. Traditional microcatheters often lack adequate steerability, frequently slipping or failing to maintain trajectory, resulting in procedural delays, increased risk of complications like vessel perforation, and reduced effectiveness in complex interventions.

Steerable detachable microcatheters address these limitations through advanced features. Distal-tip deflection enables precise navigation through tortuous vascular pathways, while advanced materials provide an ideal balance between flexibility for maneuverability and strength to withstand vascular forces. Additionally, precise rotational control allows operators to guide the catheter tip accurately into the desired branches, improving procedural outcomes and reducing risks. The detachable microcatheter for liquid embolization is designed with a distal outer diameter of 1.5Fr and a proximal outer diameter of 2.7Fr, ensuring compatibility with the access system, such as guide catheters or sheaths. Its standard length of 165 cm accommodates diverse anatomical access requirements and lesion locations. The catheter offers versatility with tip shapes, including straight, angled, and pre-shaped configurations, for effective navigation of tortuous vessels. Detachable tip lengths are available in 1.5 cm, 3 cm, and 5 cm, providing precision for different clinical applications. Additionally, the microcatheter is compatible with guidewires smaller than 0.010 inches, enhancing maneuverability and control during procedures.

The use of **thermoplastic sleeves** allows the tip to be detached and repositioned as needed. This feature ensures the **targeted delivery of embolic agents**, reducing the risk of embolization in non-target areas. Additionally, it facilitates retrieval after deployment, minimizing the risk of residual catheter material.

To address these challenges, our research presents an approach: a detachable tip steerable microcatheter tailored for precise embolic agent delivery. This technology aims to overcome existing limitations and redefine procedural efficacy standards in vascular interventions. At the heart of this advancement lies the incorporation of a biocompatible and embolization tip, detachable from the microcatheter body via advanced thermoplastic sleeves. This detachable feature not only enhances maneuverability within the vasculature but also enables precise placement and retrieval of the microcatheter, thereby augmenting procedural outcomes.

The introduction of a detachable tip steerable microcatheter heralds a paradigm shift in vascular intervention. Unlike conventional micro catheters constrained by fixed configurations, this novel technology offers unprecedented flexibility and adaptability. By integrating a detachable tip, steerable microcatheter facilitates precise and targeted delivery of embolic agents to desired vascular sites, optimizing therapeutic outcomes. Moreover, the use of medical grade biocompatible and embolization materials underscores commitment to patient safety and long-term efficacy. Through ongoing research, detachable tip steerable micro catheters hold significant promise in revolutionizing the management of vascular pathologies such as aneurysm.

Materials and Method

Importance of Material Selection for Microcatheters:

The selection of appropriate materials is a critical aspect in the design and development of microcatheters, as it directly influences their performance and compatibility within medical settings.

Commonly Used Polymers

Microcatheters, integral to various interventional procedures, are typically crafted from medical-grade outer materials, with polymers emerging as primary candidates. These polymers can be Pellethane, Grillamide, Vestamide, Silicone, Polyester, Polystyrene, Nylons, Polyether Ether Ketone (PEEK), HDPE, LDPE, TPU, PSU, EVA, PVDF or Tecoflex. These materials are frequently employed due to their exceptional properties as the upper layer of the microcatheter. They offer a harmonious blend of flexibility, durability, radio-density, and biocompatibility, all of which are imperative for their successful application in medical contexts. The catheter's surface should be visually smooth and devoid of impurities, meeting inspection standards under 2.5 times magnification with normal or corrected vision.

Composition and Layering:

The catheter comprises multiple layers and materials, which can be PTFE (Polytetrafluoroethylene), ePTFE (expanded PTFE), ETFE (Ethylene Tetrafluoroethylene), FEP (Fluorinated Ethylene Propylene). PTFE, known for its non-stick properties and biocompatibility, has been utilized for its exceptional lubricity and biocompatibility. In microcatheters, PTFE, ePTFE, and FEP reduce friction between the microcatheter and guidewire or internal catheter lumen, facilitating smooth navigation through the vasculature. These layers must be firmly combined without defects such as delamination, shrinkage, or damage to ensure optimal performance and durability.

Advanced Materials in Medical Device Design:

Titanium, Nickel-Titanium Wire, 304V Stainless Steel, and other advanced materials play crucial roles in microcatheter design.

Nickel-Titanium Wire

- Known for its shape memory and superelasticity properties.
- Comprising approximately 50% nickel and 50% titanium.
- Exhibits phase transition behavior, superelasticity, and shape memory effect (SME).
- Utilized in diverse applications, enabling substantial deformation with rapid restoration.

304V Stainless Steel

- Renowned for its mechanical strength, biocompatibility, and resistance to corrosion.
- Crucial in devices such as microcatheters.

Stainless Steel and Nickel-Titanium Braided Ends:

- Provide reinforcement and flexibility, enhancing the catheter's functionality during procedures.

Radiopaque Markers

Incorporation of radiopaque markers made from either platinum-iridium, Stainless Steel, Tungsten, or Gold Electroplated Stainless Steel at the catheter head enhances utility. These markers:

- Serve as visible indicators under medical imaging.
- Aid in precise positioning and navigation during procedures, improving patient outcomes.

Exploring Polymers in Microcatheter Construction:

PEBAX Polymers

- Polyether block amide (PEBAX) polymers are crucial for minimally invasive medical procedures.
- Offer a unique combination of flexibility, durability, and biocompatibility.
- Suitable for medical devices due to these properties.

Considerations for Polymer Grades

- Mechanical strength, flexibility, and radiopacity are crucial for performance.
- Tecoflex grades (78A, 68A, 95A, 98A, 65D, 78D, 82D) and PEBAX grades (7233, 6333, 5533, 3533, 2533) represents a spectrum of properties tailored to specific microcatheter design requirements.

- Higher durometer grades for increased stiffness and pushability.
- Lower durometer grades for greater flexibility and maneuverability.

Compatibility with Other Materials

Existing microcatheters face issues like rigid fixed-length designs, insufficient flexibility, ineffective coatings, and limited maneuverability in tortuous anatomies, which increase procedural risks and delays. Their stiff materials, designed for pushability, compromise flexibility, making it difficult to navigate sharp turns or narrow vessels without risking vessel trauma. Additionally, lack of effective friction-reducing coatings complicates advancement and increases complications. Steerable microcatheters solve these challenges by incorporating softer, flexible materials for improved navigation, flexibility in length, and precise control. Advanced coatings minimize friction, enabling smoother navigation through complex anatomies. These innovations enhance pushability, trackability, and safety, ensuring precise and efficient treatment delivery.

Interaction with coatings and reinforcements impacts performance and biocompatibility.

The Detachable Section: The microcatheter tip's design emphasizes compatibility with biological tissues, aiming to minimize adverse reactions or tissue damage upon contact. This feature is crucial for ensuring patient safety and reducing the risk of complications during procedures involving delicate vascular structures. The catheter features a detachable section at its tip, available in lengths of 15mm, 25mm, and 45mm. This section is designed to detach with a specified release force ranging between lowest ranges, providing flexibility in procedural requirements. Furthermore, the microcatheter is engineered to withstand pressure up to 250psi, ensuring robustness and durability during clinical use. Moreover, the potential biodegradability of the tip introduces an innovative approach to medical device design. If the tip can degrade over time, it could obviate the need for additional removal procedures, streamlining patient care and potentially reducing healthcare costs.

Microcatheter Functionality: The Role of Detachable Sleeves and Manufacturing Processes:

The detachable sleeve serves as an additional component that attaches to the microcatheter shaft, fulfilling multiple functions in clinical practice:

Operational Control: By providing a gripping surface, the sleeve facilitates easier manipulation of the microcatheter by the operator. This capability is essential for precise navigation within the body's vascular system.

Tip Control: The sleeve may incorporate mechanisms to control the separation or deployment of the microcatheter's tip. This feature enables the operator to release devices or substances at specific anatomical locations, enhancing procedural precision.

During the manufacturing process of microcatheters, a polymer material is melted to facilitate the application of a heat-shrink tube. This outer layer material is selected to recover post-procedure and act as insulation.

Initially, depending on the grade of polymer utilized, the material is heated to its melting point, rendering it malleable and facilitating shaping to the required dimensions for the microcatheter.

Subsequently, after sufficient melting, the material is encased with a heat-shrink tube, chosen to snugly fit over the microcatheter's outer layer. Upon exposure to heat, the heat-shrink tube contracts, ensuring a tight seal.

The detachable sleeve mechanism plays a pivotal role in engaging the microcatheter tip to the body securely. This mechanism must balance durability to withstand the conditions within the vascular system with the ability to detach when necessary. Achieving this balance ensures both the safety and efficacy of the microcatheter during procedures, as it enables precise control over engagement and disengagement while minimizing the risk of complications.

Steerable Microcatheter

Pull Wire: A flexible wire within the catheter that can be manipulated by pulling or pushing, primarily controlling the distal end of the catheter's movement.

Marker Ring: Positioned at the distal end, this ring, connected to the pull wire, serves as a visual guide for precise navigation within the body during procedures.

Assembly Security: The marker ring, PTFE liner, and outer Pebax control are securely joined to create a unified catheter shaft. Techniques such as adhesive bonding, heat bonding, or mechanical interlocking are employed to ensure component stability during usage.

Roller/Push Mechanism: Located at the proximal end, the slider roller regulates the pull wire's movement. Actuating the slider roller, for instance, moving the slider forward or backward changes the tension on the control wire within the catheter shaft, causing the tip to deflect in the corresponding direction, thereby controlling the marker ring's function at the distal end & allowing for precise navigation around vascular curves and obstacles

The hub of the Microcatheter

The microcatheter hub is constructed from either polyamide, Polypropylene, Acrylonitrile Butadiene Styrene (ABS), Polyethylene (PE), Polyvinyl Chloride (PVC), Polyether Ether Ketone (PEEK) or nylon, a versatile thermoplastic material renowned for its robustness, resistance to chemicals, and ability to maintain dimensional stability. Its widespread application in medical devices is attributed to its durability and biocompatibility, ensuring reliable performance during clinical procedures. This entire hub is compatible with DMSO in medical devices.

The strain relief component of the microcatheter is crafted from either thermoplastic polyurethane (TPU) with a hardness rating of 42A, Silicone Rubber, Thermoplastic Elastomers (TPE), Polyurethane (PU), Polyvinyl Chloride (PVC), Polyethylene (PE), Polypropylene or Vestamide renowned for its flexibility and resilience, boasts exceptional mechanical properties, including high tensile strength, resistance to abrasion, and elasticity. Its frequent use in medical devices is attributed to its capability to provide cushioning and safeguard against strain or bending. All of this Strain relief is compatible with DMSO in medical devices.

To secure the hub and strain relief at the proximal end of the microcatheter, UV (Ultraviolet) rays are employed alongside a UV-curable adhesive or bonding agent. These adhesives are specially formulated materials designed to undergo polymerization and solidification upon exposure to UV light, ensuring robust and reliable fixation.

Hydrophilic Coating

The distal portion of the microcatheter undergoes cleaning and preparation to enhance the adhesion of the hydrophilic coating material. Application of the hydrophilic coating to the designated area employs techniques such as dip coating, spray coating, or brush coating, with precise control over thickness and coverage. Subsequent curing or drying processes solidify the hydrophilic coating, ensuring robust adhesion to the device surface.

Casing

Serving as the housing or enclosure for components like the Roller/push button, the casing is an integral part of the catheter assembly. It offers protection and structural support to internal components while potentially providing a comfortable grip for the user. The Figures 01 (Roller Mechanism) and 02 (Push Button) illustrate the complete structure of the developed detachable tip steerable microcatheter.

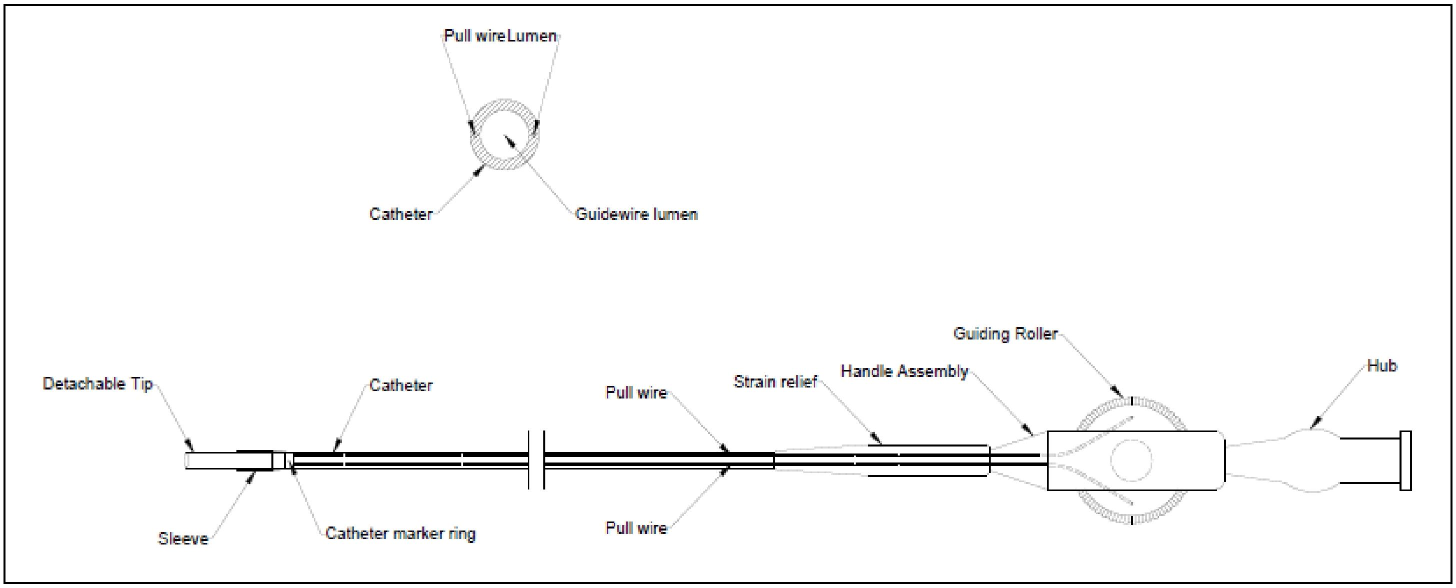


Figure 1: Roller Mechanism

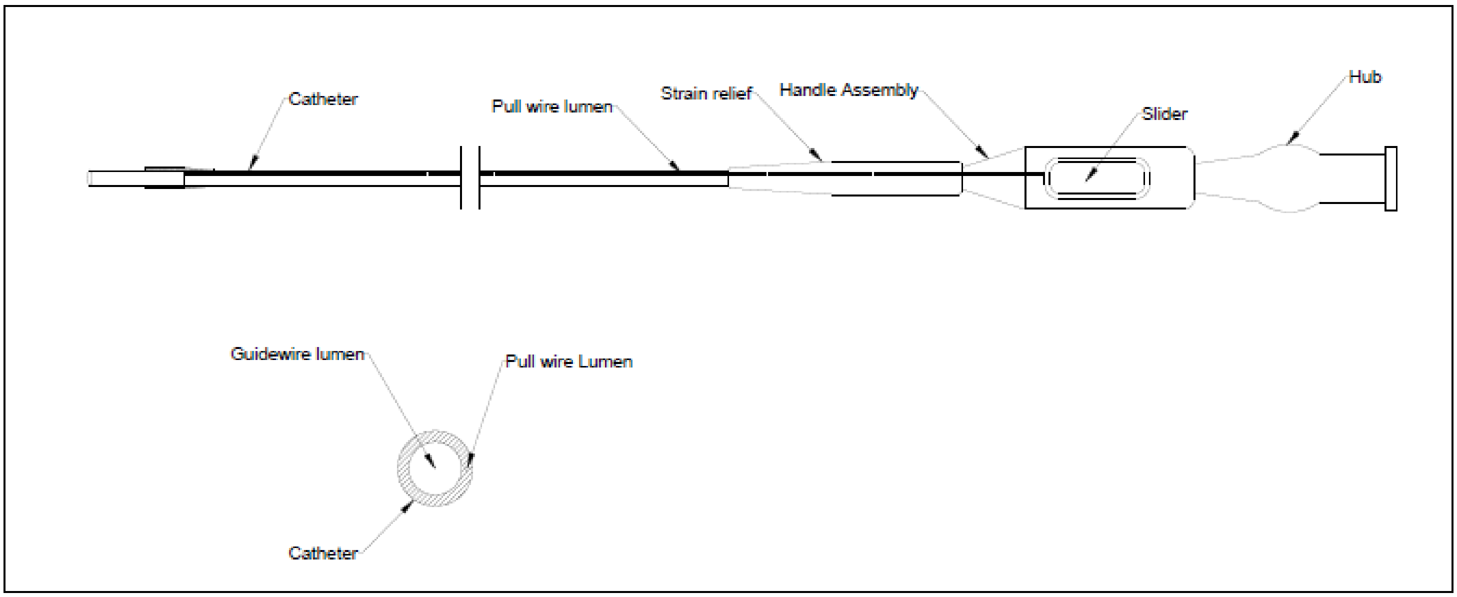


Figure 2: Push Button Mechanism

Results and Discussion

Delivery of Embolic Agents

The primary function of the microcatheter lies in delivering embolic agents to specific vascular sites, facilitating targeted treatments such as occluding blood flow to tumors or arteriovenous malformations. The mechanism for retracting the tip from the microcatheter body introduces an essential aspect of usability. By operating at a predetermined retraction force, this mechanism enhances control and consistency during removal procedures. This feature not only reduces the risk of damage or complications but also improves the overall user experience, contributing to the device's effectiveness and safety profile.

In-Vitro Test Simulation Analysis

In this study, we conducted an in-vitro simulation study as shown in the figure.03 (A), (B), (C), (D), (E) to assess the control and operation of the aforementioned

Microcatheter within a vascular environment. The detailed procedures and preparations involved in this simulation aimed to replicate real-world clinical scenarios and evaluate the functionality and efficacy of the Microcatheter in delivering embolic agents to specific vascular sites.

The Detachable Microcatheter was executed with careful attention to maintaining sterility. This precaution is essential to prevent contamination, which could adversely affect the validity of the experimental results. Subsequently, flushing the guide catheter with embolization liquid was performed to prepare the catheter for insertion and ensure its proper functionality during the procedure. This preparatory step is crucial for optimizing the performance of the Microcatheter in delivering embolic agents.

The simulation further involved submerging the model in a water bath set to 37°C to simulate body temperature, replicating physiological conditions within the vasculature. This step aimed to mimic the environment encountered during actual procedures, ensuring that the experimental setup closely resembled clinical practice.

Inserting the guide wire into the designated location followed by passing the microcatheter over the guide wire and positioning its tip past the distal edge of the aneurysm were critical steps in the simulation. Achieving precise positioning of the microcatheter tip is paramount for effective treatment outcomes, as it ensures accurate delivery of embolic agents to the target site.

After positioning the microcatheter, gentle retraction was employed to reduce slack and ensure optimal placement within the aneurysm. This maneuver enhances the stability of the microcatheter during the delivery of embolic agents, minimizing the risk of unintended displacement or migration.

Passing dimethyl sulfoxide (DMSO) through the microcatheter, potentially facilitated by shaking the embolization liquid for 15 minutes, aimed to ensure the proper distribution of the embolic agent within the vascular model. Subsequent verification of liquid surpassing the Detachable Microcatheter confirmed successful delivery to the target area.

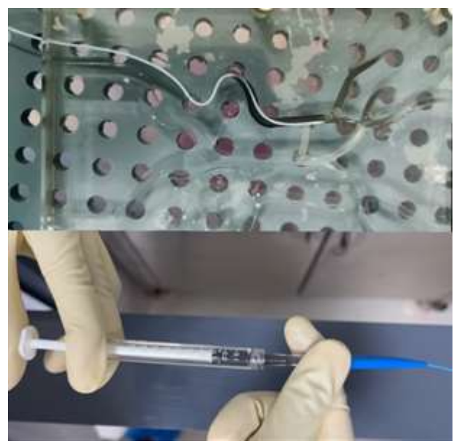
Finally, removing the catheter from the neurovascular model allowed for the assessment of liquid consistency, ensuring that it solidified as intended. The retention of the microcatheter tip inside the model served as an indicator of successful embolic agent delivery, validating the efficacy of the Microcatheter in the simulated vascular environment.

A : During introduction of microcatheter into the vessel

B: During injection of embolization liquid

C: Filling of syringe with embolization liquid

D: Microcatheter reached at the target location



E: Injection of embolization liquid during procedure

Figure 3: Steps in the Microcatheter-Assisted Embolization Procedure

Overall, the results of this in-vitro simulation study demonstrated the feasibility and effectiveness of controlling and operating the Microcatheter within a vascular setting. These findings provide valuable insights into the device's performance and usability, paving the way for further clinical evaluation and potential advancements in interventional medicine.

Conclusion

In conclusion, the development and evaluation of the novel steerable microcatheter presented in this study represent a significant advancement in vascular intervention techniques. Designed specifically for the precise delivery and retrieval of liquid embolic agents to target aneurysms, this microcatheter introduces key innovations, notably the incorporation of a biocompatible and embolization tip detachable from the microcatheter body using thermoplastic sleeves. By leveraging medical-grade and cost-effective materials, this technology ensures precise and efficient operation, promising improved patient outcomes and procedural efficiency. The validation of the microcatheter's efficacy through in-vitro experiments underscores its potential for clinical application. Simulation procedures, mirroring real-world clinical scenarios, demonstrated the microcatheter's functionality and efficacy in delivering embolic agents with precision and reliability. From maintaining sterility during microcatheter retrieval to confirming successful embolic agent delivery within the model, each step of the simulation contributed to our understanding of the microcatheter's performance in a vascular environment. Overall, these findings affirm the feasibility and effectiveness of the novel steerable microcatheter in addressing aneurysm obstruction and facilitating targeted treatments in vascular interventions. The retractable tip mechanism, coupled with precise control during deployment and removal procedures, enhances usability and safety, laying the groundwork for further clinical evaluation and potential advancements in interventional medicine.

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