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# Performance Evaluation of a Peripheral Covered Stent Graft System Using In-Vitro Channel Study

Kothwala Dr. Deveshkumar, Lad Hirenkumar, *Patel Tanvi
Meril Medical Innovations Private Limited, Bilakhia House, Survey No.879, Muktanand Marg, Chala, Vapi, Dist-Valsad, Gujarat, 396191, India.

**Abstract:**
The Peripheral covered stent graft system is self-expanding device has a mesh like structure made with e-PTFE material, which surrounds a flexible Nitinol stent frame. It combines a Nitinol stent framework with an expanded poly-tetra-flouro-ethylene (e-PTFE) covering and radiopaque Tantalum markers for enhanced visibility and deployment precision. The covered stent of this device helps reduce the risk of complications, such as re-stenosis and the formation of atherosclerotic plaques. Peripheral artery disease (PAD) is a common condition where the blood vessels in the legs get narrow or blocked. This can cause serious problems like poor blood flow, tissue damage, loss of limbs, or even death. While treatments like medications, angioplasty, and surgery work for many patients, some complex or hard-to-treat blockages need the use of Peripheral covered stent graft system. It is used to restore blood flow, stop more blockages, and sustained support for conditions like peripheral artery disease (PAD), aneurysms, and complicated blood vessel problems. This research article presents an in-vitro simulation test methodology aimed at evaluating the performance, safety, and efficiency of this device. The in-vitro channel study replicated physiological environments to evaluate the device's performance prior to Pre-clinical & clinical application. In-vitro channel study was developed to mimic the anatomical and hemodynamic environment of peripheral arteries. Artificial fatty deposits were created using polyurethane, and a saline-based blood analog was used to simulate physiological flow. The device was deployed under controlled conditions, and its performance was evaluated across multiple parameters, including deployment success, interaction with the vessel wall, self-expansion efficiency, and restoration of blood flow. The in-vitro simulation validated the mechanical integrity, vascular apposition, and overall efficacy of the Peripheral Covered Stent Graft System in re-establishing vascular patency. While the results are promising, the absence of biological interaction highlights the need for further preclinical studies and chronic implantation evaluations to confirm long-term safety and effectiveness. These findings support the device's readiness for clinical trials and its potential as a valuable intervention for treating PAD.

**Keywords:**
Vascular stent graft, Endovascular Intervention, Aneurysm Treatment Device Peripheral artery disease (PAD), In-Vitro Channel, Fatty deposits, Self-expansion and Pre-clinical Device Testing

## Introduction:

Peripheral Covered Stent Graft System is a flexible, self-expanding vascular prosthesis comprised of expanded poly-tetra-fluoro-ethylene (e-PTFE) encapsulating a Nitinol stent framework, except the flared stent graft ends with the four radiopaque Tantalum markers.

One of the main causes of serious health problems worldwide is Peripheral Artery Disease (PAD), especially in older adults PAD happens when the blood vessels that supply blood to the legs become narrowed or blocked due to fat build up. This reduces blood flow and can lead to symptoms like pain, trouble in walking, or even losing a limb. The Peripheral Covered Stent Graft System is a medical device designed to help restore blood flow, reduces re-stenosis, navigate tortuous arteries in these blocked arteries and improve patient safety. It combines a stent (a tube to support the artery) and a graft (a covering to seal the artery) to ensure blood can flow properly again (Liu, 2023).

  

Before using this device in patients, it is very important to test it in a controlled condition to make sure it works safely and effectively. In-vitro simulations, which are laboratory tests, allow doctors and scientists to test the device under safe conditions before using it on people. This article describes how these tests are done. The Peripheral Covered Stent Graft System helps open blocked arteries, especially in areas like the femoral, iliac, and popliteal arteries (Crawford, 2005). By using this system, blood flow can be restored, and problems like blood vessels getting blocked again (re-stenosis) can be reduced. The device specifically designed to address the challenges that occur from torturous passage and having difficulty in getting diagnostic and therapeutic agents precisely inside the vessels.

Demonstrated the efficacy and adaptability of self-expanding stents in vascular procedures, reinforcing their potential for use in peripheral artery disease (Fitzgerald et al, 2021.), laid the groundwork for covered stents in treating peripheral arterial aneurysms, highlighting procedural success and positive midterm follow-up outcomes. Before using the device in patients, it needs to be tested using in-vitro simulation methods to evaluate its performance under controlled conditions.

**Literature Review:**

Peripheral Artery Disease (PAD) remains one of the major contributors to global morbidity and mortality, particularly among the aging population In PAD, the blood vessels supplying the legs become narrowed or blocked due to the accumulation of fatty deposits, restricting blood flow and leading to severe complications such as pain, difficulty walking, and even limb amputation. The Peripheral Covered Stent Graft System was developed for the treatment of vascular obstructions to restore blood flow and improve clinical outcomes. (Liu, 2023). It combines a stent for structural support with a graft to seal the artery, offering an effective solution for managing complex vascular lesions, especially in the iliac, femoral, and popliteal arteries (Crawford, 2005).

Before this system can be used in Pre-clinical & clinical practice, it is essential to evaluate its performance in a controlled laboratory environment. In-vitro simulation tests provide an effective method for assessing the functionality of the device without the immediate risk to patients. These tests simulate real-world conditions, allowing researchers to observe how the device performs under varying scenarios and ensuring its safety and efficacy prior to clinical use. According to (Liu, 2023),
such tests are crucial in enhancing the predictive accuracy of pre-clinical studies and enabling more informed decisions regarding device development and clinical application. In-vitro models for stent graft systems are designed to replicate anatomically accurate conditions, including vessel geometry and blood flow dynamics. These simulations, using blood-mimicking fluids like saline, are invaluable for investigating device behaviour in various scenarios, such as different clot types, vessel sizes, and flow rates (Perrira, 2022).Through this method, researchers can study the interaction between the stent graft and the artery, ensuring the system performs well in challenging situations.

The importance of fluid dynamics in vascular interventions has been widely studied, as it plays a pivotal role in the effectiveness of devices such as stent grafts. According to (Perrira, 2022), fluid dynamics modelling helps predict how the device will behave in actual patients and provides crucial insights into the potential risks and benefits of its clinical application. By simulating blood flow, researchers can evaluate how well the Peripheral Covered Stent Graft System restores vascular patency, reduces blood leakage, and prevents re-stenosis. Studies by (Fitzgerald, 2021), highlight the importance of self-expanding stent designs, which have been shown to offer better engagement with the arterial wall and improve device stability after deployment. The Peripheral Covered Stent Graft System builds upon these advancements by combining self-expanding properties with the sealing capability of a covered graft, providing an innovative approach to managing PAD (Crawford, 2005).

  

In-vitro testing ensures that the device meets the required performance standards for long-term use, without compromising the safety of the patient. Recent advances in in-vitro models have emphasized the importance of predicting device performance in complex scenarios before Pre-clinical & clinical application. A study by (Liu, 2023), demonstrated how in-vitro simulations of vascular devices could predict the success of interventions and minimize the need for early animal testing. This approach reduces both the ethical concerns and the financial costs associated with preclinical studies while ensuring that the device will be effective in real-world applications.

The device incorporates a self-expanding stent combined with a covered graft to enhance arterial support and reduce the risk of re-stenosis. In-vitro model studies play a critical role in evaluating device performance, ensuring its effectiveness, and minimizing the reliance on animal testing.

**Material Method:**
The in-vitro simulation channel study of a vascular system was designed to copies the conditions of the Peripheral arteries where the stent graft is deployed. The test setup included:

- ✧ **Fatty Deposits replica:** Artificial fatty tissue created with Polyurethane, Resemble the consistency and structure of natural fat deposits.
- ✧ **Fluid dynamics:** Used saline solution with viscosity similar to blood flow.
- ✧ **Device deployment:** The Peripheral Covered Stent Graft System, designed as a self-expanding stent with a mesh structure and biocompatible covering, was deployed into the channel study where artificial Fatty Deposits was formed, and once in position, It was expanded to treat the fatty deposits. The entire system was than self-expansion, preventing leakage and re-narrowing.

**Key Device Specifications:**
- ✧ **Material:** Expanded polytetrafluoroethylene (e-PTFE) covering a Nitinol stent framework.
- ✧ **Radiopaque Markers:** Four Tantalum markers at the flared stent graft ends.
- ✧ **Device Design:** Flexible, self-expanding stent with a 2 mm uncovered portion at each end.
- ✧ **Delivery Wire:** Pre-mounted on an 8-10F delivery system, compatible with a 0.035” guidewire.
- ✧ **Delivery system usable length:** 800-1000 mm.

The in-vitro simulation study for the Peripheral covered stent graft system involves duplicating conditions of human vascular system to evaluate the device's performance. Here's a structured approach to conducting this simulation:

**Setup of the Simulation Environment**
- ◆ **Material:** The simulation channel was typically made up of silicone materials to mimic the compliance and functional characteristics of human blood vessels.
- ◆ **Geometry:** The In-Vitro Channel Study was designed with precise anatomical dimensions, incorporating bifurcations and tortuous pathways to replicate real-life conditions as shown in Figure 1.

  

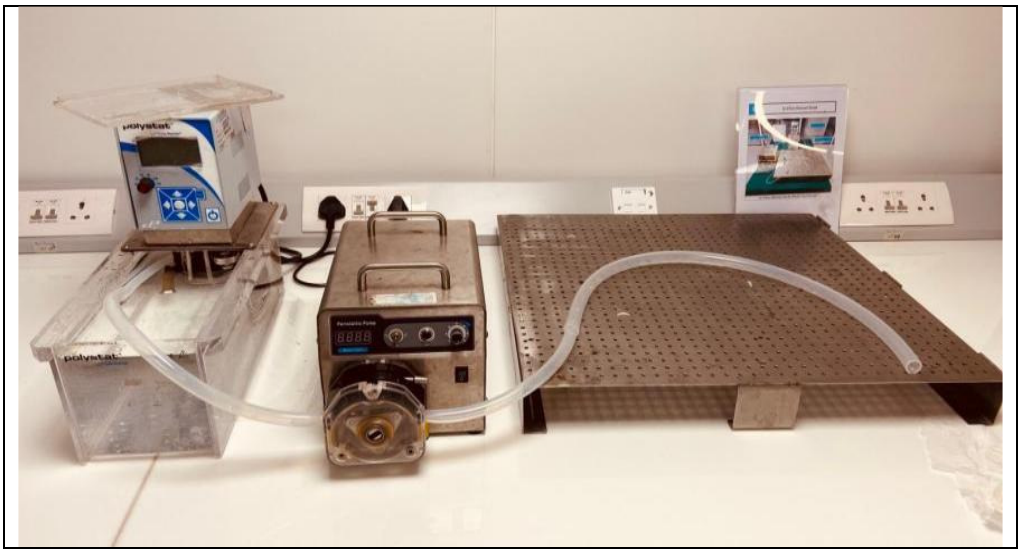

**Figure 1: In-Vitro Channel Study Set-Up**

**Preparation of the Fatty Deposits**

- **Fatty Deposits Composition:** Artificial fatty deposits (created with Polyurethane) were fabricated to replicate human plaques. These deposits vary in composition to assess the device's performance under controlled condition.
- **Fatty Deposits Placement:** The fatty deposit was placed in a target location within the Channel, typically where a blockage would occur in a patient with Peripheral Artery Disease as shown in figure 2.

**Flow Simulation**

- **Blood-Mimicking Fluid:** A blood analog with fluid similar viscosity and flow characteristics was circulated through the Simulation Channel. This helps in assessing how the device performs in conditions mimicking in vivo blood flow.
- **Flow Rate:** The flow rate was controlled to match physiological conditions of the Peripheral arteries.

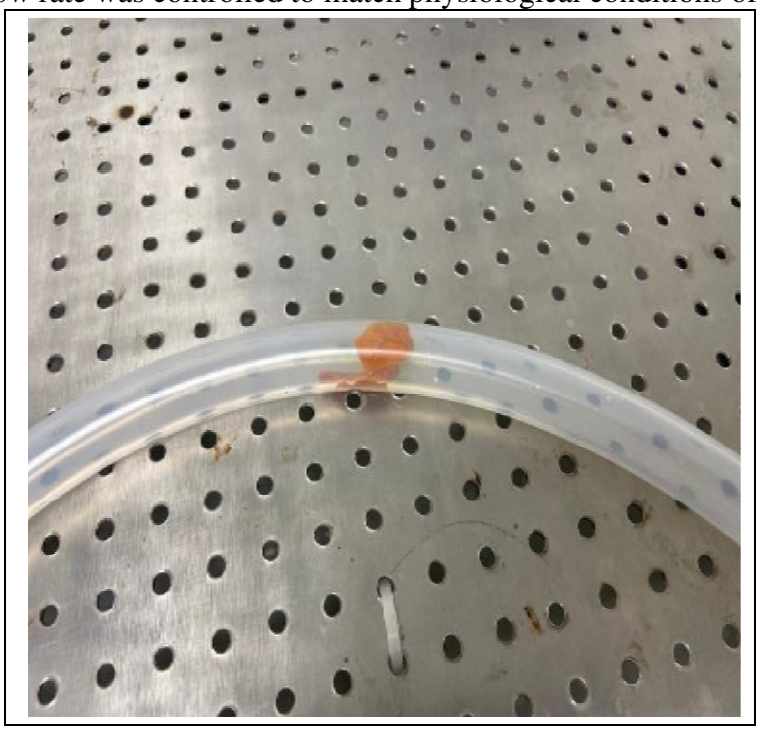

**Figure 2: Fatty Deposits Placement**

**Introduction of the Device**

  

**a. Device Deployment Preparation:**

- **Device Preparation:** Retrieve the Peripheral System from its sterile packaging and secure the hemostasis valve by rotating it in a clockwise direction. Flush the stent graft lumen with sterile saline by using a small volume syringe. Attach the syringe to the Luer port at the back of the Stent Graft System and flush the Stent Graft System until saline leaks from the distal tip of the delivery system. Attach the syringe to the Luer port on the Hemostasis valve, open 1- way stopcock (in line with Hemostasis valve) and flush the Stent Graft System until saline leaks from the distal end of the Stent Graft System. Close the stopcock when flushing is complete and remove the syringe from the Luer port as shown in figure 3.

**Figure 3: Flushing the stent graft lumen with saline**

**b. Accessing the In-Vitro Channel:**

The guidewire was inserted into the target location. The Peripheral Graft Stent System was then advanced over the guidewire until the radiopaque marker on the delivery system reached the desired position. The system was carefully navigated through the tortuous pathways of the in-vitro channel, simulating its behavior within human vasculature.

**c. Position:** The delivery system was accurately positioned at the location of the fatty deposits in the study channel.The delivery system was withdrawn, with the graft stent remaining in place and ready for deployment.

**d. Device Introduction:**

- **Loading the Device:** Connected the hemostatis valve with Guidewire. The Peripheral covered stent graft system, which is typically stent self-expansion designed to reduce the blockage of peripheral artery, was loaded into the Guidewire.
- **Advancement Through the Guidewire:**

The Rotating Hemostatic Valve (RHV) was released, and the introducer sheath was carefully advanced along the guidewire until it was securely positioned. Subsequently, the hemostasis valve was tightened to establish a controlled and secure seal, ensuring system stability during the procedure. The device was advanced through the Guidewire system by pushing it forward using a delivery wire. As it moves through the Delivery system, it remains constrained in its collapsed form to allow smooth passage.

- **Navigation through the Vasculature:** The operator ensured that the device does not encounter any undue friction or obstacles while navigating the tortuous pathways of the Study Channel, using slight adjustments in the delivery system to steer through difficult bends or curves.

**e. Deployment at the Fatty Deposits Site:**

- **Reaching the Occlusion:** Once the device tip is positioned at the site of the fatty deposits as shown in figure 4, the operator slowly advances the delivery system while maintaining the position of the

  

Peripheral Covered Stent Graft System.This action enables the stent to self-expand, progressively deploying within the vessel.

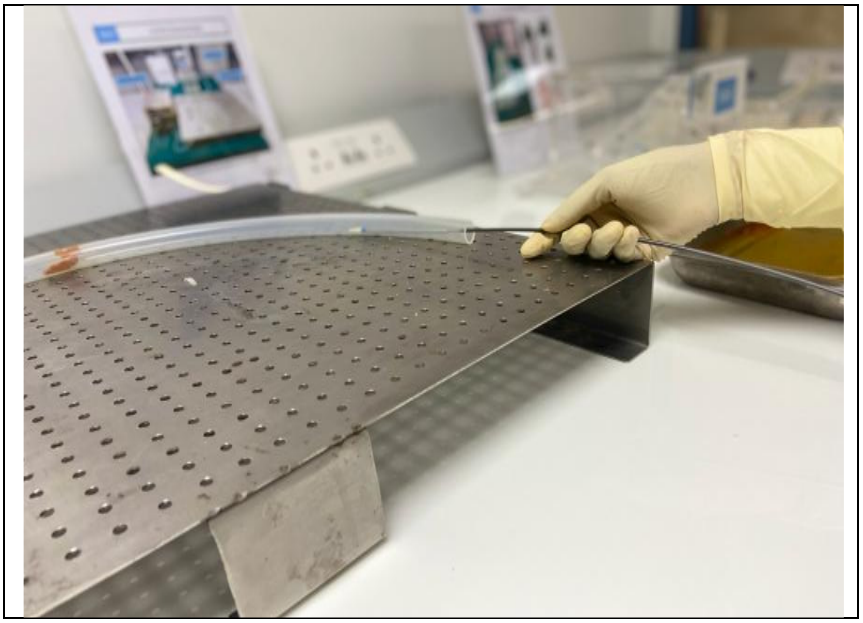

**Figure 4: Insert the Delivery system to the target location**

- **Engagement of the Fatty Deposits:** As the Peripheral covered stent graft system was expanded, it deployed its mesh-like structure at the site where fatty deposits have caused the narrowing or blockage.

**Device Activation**

- **Stent Self- Expansion:** After the Peripheral covered stent graft system was fully deployed, the stent Inserted expands to its intended size, pressing against the vessel walls as shown in Figure 5.

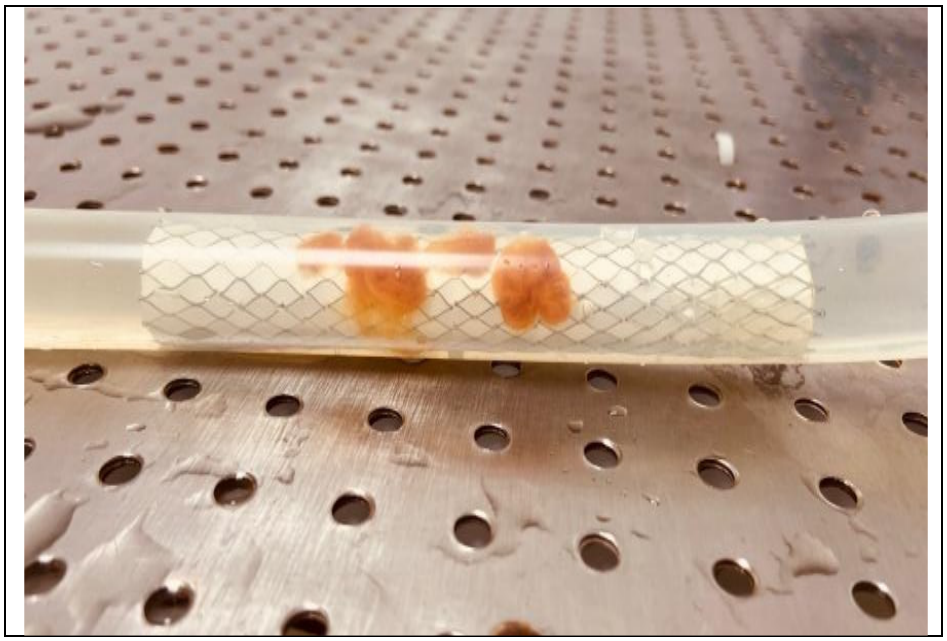

**Figure 5: Self-expanded Stent**

**Challenges during stent expansion**

  

- **Resistance from Tortuous Pathways:** When the device was inserted, the in vitro channel contained bends and branches. The operator skillfully navigated these regions without causing expansion of the stent.

**Flow Assessment after stent expansion**

- **Flow Restoration Check**: Once the stent was expanded, fluid flow through the In-Vitro Channel was restored. The fluid flow in the study channel was then assessed to ensure it mimicked successful reperfusion, similar to what would be observed in a human patient following stent expansion.

**Evaluation of Performance**

- **Success of Self-Expansion**: The success of self-expansion was evaluated by determining whether the device was able to achieve full expansion in a single pass.
- **Embolic Fragmentation**: Assessed if any distal embolization or plaque fragmentation occurred during the Stent Placement process. This is critical as it can lead to secondary strokes in patients.
- **Vessel Wall Interaction**: evaluation of the in-vitro channel was conducted to identify any damage caused by excessive force or friction from the device. This assessment ensured the device's safe navigation while minimizing potential vascular injury.

**Repeat with Different Conditions**

- Tested the device under various conditions:
- Different vessel geometries (straight vs. tortuous pathways).
- Different occlusion locations (proximal vs. distal arteries).

This in-vitro test helps to validate the Peripheral covered stent graft system's performance before Extending to Pre-clinical & clinical trials or further regulatory evaluation.

**Results:**

The results of these tests collectively evaluated the performance, safety, and reliability of Peripheral covered stent graft system. Study revealed Device Deployment, Retrieval durability, Vessel wall integrity safety and first-pass success that demonstrate it can significant improve clinical outcomes for patients suffering from Peripheral artery disease (PDA). The peripheral covered stent grafts has shown ease in deployment on fatty deposits and restore the blood flow in the blocked artery after the procedure. These test are essential in validating the functionality and safety of peripheral covered stent graft system. They ensure that the device can perform under various conditions without causing harm to patients.

**Table: 1 Test Parameters and Observations**

| Sr. No. | Test Parameter | Observation |
|---|---|---|
| 01 | Device Deployment Testing | The device deployed smoothly without resistance or malfunction. |
| 02 | Retrieval Testing | The device remained structurally intact and fully functional throughout the deployment cycles. |
| 03 | Vessel Wall Integrity | The synthetic In-Vitro Channel Study showed no signs of mechanical damage, suggesting that the device applies safe forces during navigation. |
| 05 | Stent- Expansion | The device was able to self-expansion in one pass. |

**Discussion:**

  

During deployment of the Peripheral Covered Stent Graft System benefits from its unique, self-expanding structure, that allows for smooth expansion and contraction within the vessel? The radiopaque marker at equal distance on device enhances the visibility during the procedure. The e-PTFE (expanded polytetrafluoroethylene) material provides a smooth, biocompatible surface with exceptional sealing properties, forming a secure barrier between the blood flow and the vessel wall, thereby mitigating the risk of endoleaks and reducing risk factor. The Nitinol stent framework is characterized by superior flexibility and mechanical strength, allowing the stent to adapt to tortuous vascular anatomies, ensuring the sustained patency of the vessel over time.

Additionally, the covered stent enhances the device's effectiveness and safety by providing optimal coverage and support. The inclusion of four Tantalum markers at the flared ends of the stent graft significantly enhances radiopacity. The Nitinol core wire with a hydrophilic PTFE coating further reduces friction, facilitating easier deployment.
Although the in-vitro simulation demonstrated the stent graft's ability to engage the vessel wall and preserve vascular integrity, the lack of physiological and biological factors in the testing environment limits the extrapolation of these findings to in-vivo settings, thereby necessitating further preclinical and clinical validation to confirm long-term performance and clinical efficacy.

**Conclusion:**

The Peripheral Covered Stent Graft System effectively addresses several significant challenges associated with Peripheral Arterial Disease (PAD). A key benefit of the Peripheral Covered Stent Graft System is its ability to provide effective and reliable support, ensuring successful deployment in a single attempt. Because prompt and through fatty deposit removal is necessary to prevent blockage of peripheral arteries and lower the risk of additional problems, this is very important in real-world use, where quick and effective results are needed for the best patient outcomes. Because a high first-pass success rate minimizes the duration of PAD treatment. It helps maintain the function of peripheral arteries, which is directly linked to improved patient outcomes. The in-vitro simulation methodology used in this study effectively validated the efficacy and safety of the peripheral covered stent graft system to restoring blood flow by addressing fatty deposits in the arteries. By simulating real-world clinical conditions, the study offered a thorough insight into the device's performance in terms of deployment and self-expansion. This in-vitro testing an essential step in the preclinical validation process that helps to identify any potential issues and optimize device performance before advancing to clinical trials. The in-vitro study supports the device's preparedness for pre-clinical & clinical trials by demonstrating the fulfilment of essential performance criteria, including mechanical integrity, effective vascular engagement and conformability, maintenance of optimal hemodynamic conditions (adequate blood flow), durability under cyclic stress, and a reduced risk of complications such as thrombosis and re-stenosis. The findings of this study indicate that the device has the potential to become a crucial tool in managing PAD, potentially decreasing patient morbidity and mortality by providing a safer and more efficient method for restoring blood flow in peripheral arteries.

**Future work**:
**Preclinical Animal Studies:**
To better understand how the Peripheral Covered Stent Graft System works inside the body, animal testing is an important next step. These in-vivo animal studies help to shows that how the body react with these device over time

**Chronic Implantation Studies:**
Long-term studies are essential to evaluate the sustained performance of the Peripheral Covered Stent Graft System. These studies assess the device's durability over time, ensuring it maintains its structural integrity and minimizes the risk of complications, such as re-stenosis.

  

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