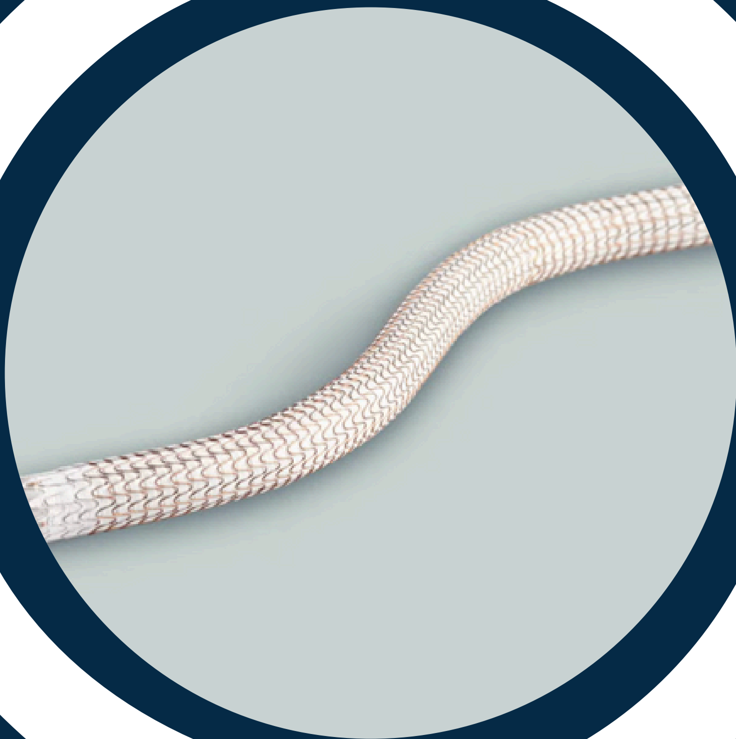
SmartReactors

ENHANCING VASCULAR GRAFTS WITH CAMOUFLAGE™ COATING



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Abstract

Optimizing the performance of vascular grafts remains a persistent clinical challenge for patients undergoing vascular surgery and reconstruction particularly due to complications such as thrombosis, poor endothelization and chronic inflammation, all of which significantly compromise long-term patency and clinical outcomes. Despite substantial progress in biomaterial development and improved mechanical properties, conventional grafts often fail to replicate hemocompatibility and effectively support endothelilization necessary for sustained success. Smart Reactors Camouflage™ coating technology represents an innovative surface treatment engineered for a wide -range of blood-contacting medical devices. Engineered to minimize the initiation of the clotting cascade, Camouflage™ demonstrates excellent hemocompatibility and promotes rapid endotheliziation, essential for graft longevity.

This paper outlines the clinical and biological imperatives for advancing vascular graft performance, examines the pathophysiological barriers of current graft designs, and highlights the clinical validation of Camouflage™ in improving hemocompatibility and endothelization. By uniting biocompatibility with advanced surface engineering, Camouflage™ represents a transformative approach for vascular graft surgery and reconstruction.

1. Introduction

1.1 Contextualizing Vascular Grafts Materials

Vascular protheses (grafts) are critical blood-contacting devices, constructed from a range of biological and synthetic materials and are widely utilized to replace or bypass damaged or occluded blood vessels across various vascular surgical interventions (Fig. 1). Traditionally constructed from synthetic polymers, such as expanded polytetrafluoroethylene (ePTFE) and polyethylene terephthalate (PET), these conduits are designed to replicate the mechanical durability of native vessels while maintaining long-term patency. However, despite advances in material science, synthetic grafts particularly in small-diameter applications (≤4mm) are hindered by poor endothelization, high thrombogenicity, intimal hyperplasia and increased susceptibility to infection [1]. Autologous grafts, the gold standard in Coronary Artery Bypass Grafting (CABG), are harvested from the patient's own vasculature and exhibit superior biocompatibility and physiological integration. However, their clinical performance is often limited by variable patency rates. Biological grafts including allografts and xenografts present a biologically active alternative and retain extracellular matrix (ECM) indicators conducive to remodelling. However, their use is hindered by increased immunogenicity and the risk of pathogen transmission. Tissue-engineered vascular grafts (TEVGs) are designed to imitate the characteristics of blood vessels while facilitating host-mediated remodelling and regeneration. Despite their promise, TEVGs remain predominantly in the experimental phase.

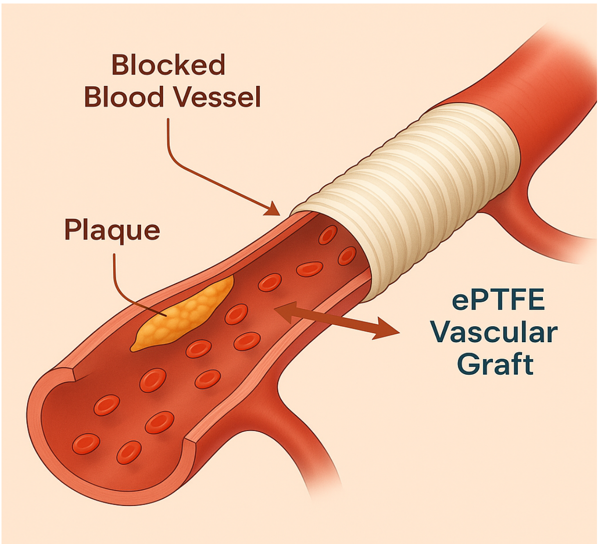

Fig 1: ePFTE place in blood vessel to replace the occluded vessel.

1.2 Clinical Applications of Vascular Grafts in Surgical Practice

Clinical applications of vascular grafts encompass the management of advanced atherosclerotic disease, aneurysms, traumatic vascular injury and the establishment of vascular access in patients with end-stage renal disease [2]. Atherosclerotic disease which is characterized by the accumulation of lipid-laden plaques with the arterial intima, leads to progressive luminal narrowing and impaired hemodynamics. This pathophysiological process underlies peripheral artery disease (PAD), where reduced perfusion to the lower extremities results in ischemic symptoms. In such cases, revascularization procedures, such as femoral-popliteal bypass procedures, are employed to circumvent the occluded arterial segments and restore distal blood flow. CABG, the most prevalent clinical application of vascular grafts, is performed to restore myocardial perfusion by anastomosing autologous or synthetic grafts distal to atherosclerotic lesions. This procedure often utilizes common vascular grafts including the saphenous vein graft (SVG), harvested from the patient's leg and internal mammary artery (IMA) for long-term patency and resistance to atherosclerosis (Fig. 2).

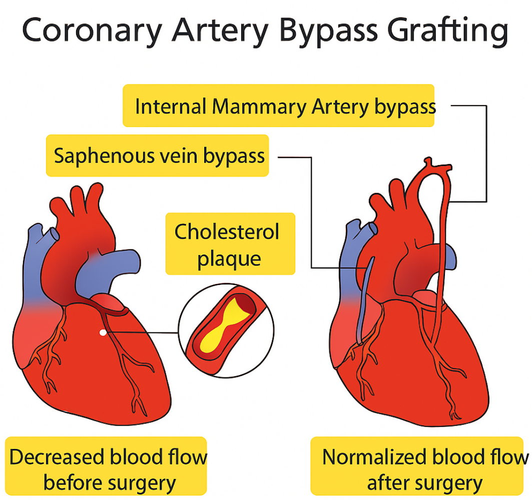

Fig 2: CABG before and after surgery

Vascular grafts also play a critical role in the surgical treatment of aneurysmal disease, often being used in conjunction with stents to reinforce the affected vessel. In both abdominal or thoracic aortic aneurysms, endovascular graft repair (EVAR/TEVAR) involves the intraluminal deployment of a synthetic graft to exclude the aneurysmal sac from systemic circulation, thereby preventing rupture and maintaining continuity throughout the graft lumen (Fig. 3).

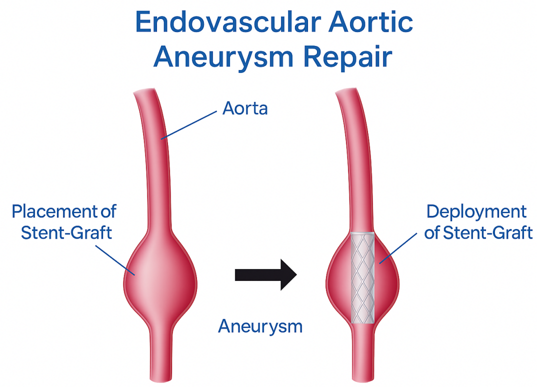

Fig 3: Stent-graft creating a new passage for blood flow

In the context of end-stage renal disease, when native arteriovenous (AV) fistulas are not feasible due to unsuitable vasculature or previous access site failure, vascular grafts are frequently utilized to establish long-term hemodialysis access. AV grafts are typically constructed by subcutaneously anastomosing a synthetic conduit between an artery and a vein, most commonly in the upper extremity. This configuration provides a reliable site for repeated cannulation, enabling effective extracorporeal blood flow during dialysis (Fig. 4).

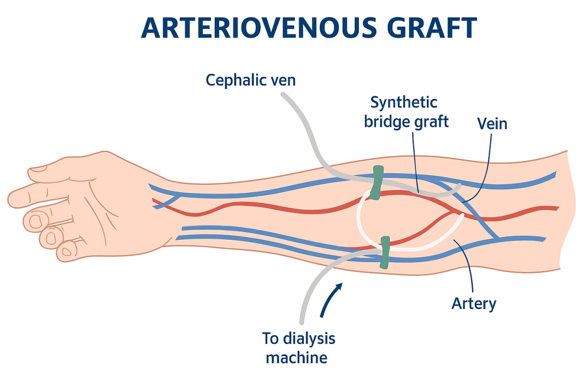

Fig 4: Arteriovenous graft in haemodialysis care

1.3 Hemodynamic Considerations in Vascular Graft Design

The success of vascular grafts critically depends on optimizing hemodynamic parameters to ensure adequate tissue perfusion while minimizing complications such as thrombosis, intimal hyperplasia and overall graft failure. Hemodynamics in grafts is governed primarily by pressure-driven blood flow and the interaction of blood within the graft wall, which affects both mechanical and biological responses.

1.3.1 Flow Resistance and Geometry

For steady, laminar flow of blood similar to Newtonian fluid, the velocity profile within a cylindrical vessel is parabolic in shape, with maximum velocity at the center and zero at the walls due to the no-slip condition. In this case, the flow resistance in a vessel with inner radius r and length L is given by Poiseuille's law: where μ is the viscosity of blood.

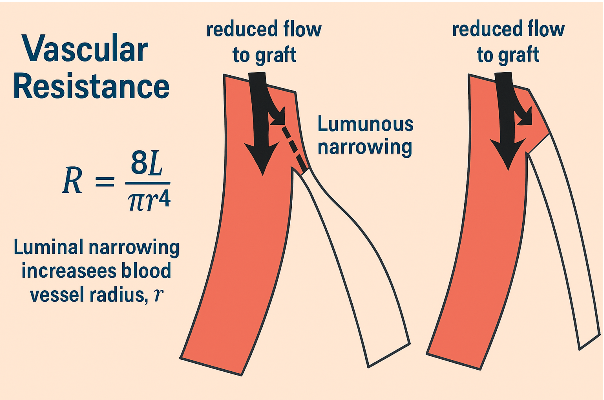

Fig 5: Effects of changes to graft resistance as a result of graft narrowing (left). Diffuse narrowing can similarly increase resistance and attenuate flow (right).

Thus, grafts with smaller diameters or longer lengths exhibit significantly higher flow resistance which can reduce distal perfusion and promote graft failure [3]. Additionally, bifurcations within or distal to the graft alter flow disruption, potentially diverting blood away from the target tissues.

1.3.2 Wall Shear Stress

Wall Shear Stress (WSS), which refers to the tangential frictional force exerted by blood flow on the endothelial surface is a crucial mechanobiological stimulus. Physiological WSS maintains endothelial health, while oscillatory WSS induces pro-inflammatory and pro-thrombotic endothelial phenotypes, promoting platelet activation and intimal hyperplasia. Regions of low WSS have been correlated with graft stenosis and eventual graft failure. Low WSS promotes endothelial dysfunction and can lead to the formation of atherosclerotic plaques, which are critical in the development of graft occlusion. Therefore, maintaining favorable WSS profiles is essential in vascular graft design.

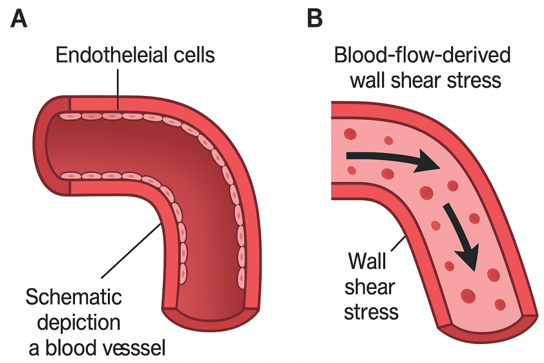

Fig 6: Image of blood vessel lined with endothelial cells (A) and blood-fluid derived wall shear stress (B).

1.3.3 Biological Responses

Altered hemodynamics including changes in blood flow patterns, shear stress and turbulence can activate mechanotransduction pathways that influence cell behavior. These alterations trigger intracellular signaling cascades such as the p38 MAPK pathway, which plays a central role in regulating cellular responses to mechanical stress. These biological responses contribute to processes such as inflammation and cell proliferation. These biological responses can lead to unfavorable outcomes such as graft stenosis and eventual graft failure.

1.3.4 Mechanical Compliance and Elasticity

Mechanical compliance and elasticity of the graft material must be carefully matched to those of the native vessel to prevent compliance mismatch. This mismatch can induce abnormal flow dynamics and localized mechanical stress at anastomotic sites, accelerating graft failure over time. Mechanical stress at anastomotic sites can accelerate endothelial injury promoting thrombosis and intimal hyperplasia. Synthetic materials such as e PTFE often necessitate surface coatings to enhance their biocompatibility and enhance their mechanical properties.

2. Emerging Market Trends

The global vascular graft market is projected to experience steady growth, driven by the rising prevalence of cardiovascular diseases, an ageing global population, and ongoing advancements in surgical and biomaterial technologies [5]. Recent trends indicate a growing preference for biologically engineered grafts and minimally invasive surgical techniques. Biologically derived vascular grafts are gaining clinical traction due to their structural similarity to native tissue, which enhances biocompatibility and reduces the incidence of complications such as thrombosis and infection over extended periods. Currently, the adoption of endovascular grafting has expanded due to its association with reduced postoperative morbidity, shorter hospital stays, and faster patient recovery compared to traditional open surgical procedures. Together, these developments signal a paradigm shift in vascular graft design and implementation, emphasizing long-term safety, functionality, and patient-centred outcomes.

2.1 Current Industry Leaders: Benchmarking Vascular Graft Technologies in the Market

The vascular graft market is currently dominated by synthetic grafts composed of ePTFE and PET, with major manufacturers including W.L Gore & Associates, Invamed, Getinge AB, Terumo and Bard Peripheral Vascular. Dacron and ePTFE grafts lack the bioactive surface properties required to prevent thrombus formation or modulate the immune response, often resulting in early graft failure due to thrombosis, intimal hyperplasia, or infection. While modifications such as heparin-based coatings have been introduced to improve vascular graft performance, these enhancements offer limited efficacy over long-term implantation as they rely on agents that diminish in activity over time due to degradation and surface fouling.

As such, there is growing interest in vascular grafts that integrate biocompatible surface technologies to address the limitations of traditional materials, with a focus on promoting endothelial integration and minimizing thrombosis related issues.

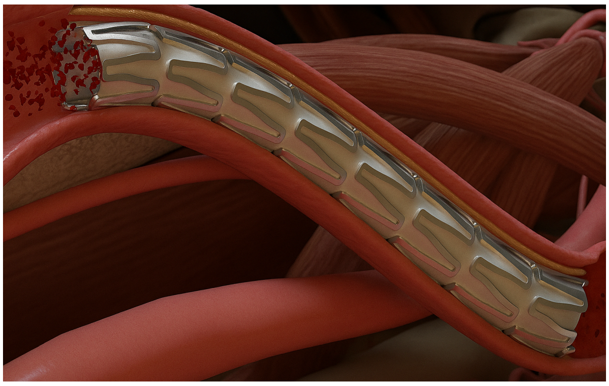

Fig 7: Endovascular Stent Graft inserted into vessel. Self-expanding nitinol stent material with expanded ePTFE graft.

2.2 Strategic Considerations for R&D Teams in Early-Phase Vascular Design

In the early stages of vascular graft development, R&D teams must strategically prioritize material selection, surface engineering, and biological responsiveness to optimize long-term clinical performance. Material biocompatibility and mechanical compliance must align with native vascular tissue to minimize blood flow disruption. Surface properties should be engineered not only for hemocompatibility, by minimizing platelet activation, promoting endothelialization and integration. Early incorporation of these design considerations is critical for improving graft patency, reducing postoperative complications, and ensuring overall translational success.

3. Surface Engineering of Vascular Grafts: The Role of Camouflage™ Coating

Surface engineering plays a critical role in optimizing vascular graft performance by directly influencing the grafts interaction with blood. Smart Reactors Camouflage™ coating technology is an advanced surface modification designed to enhance the performance and safety of blood-contacting devices used in vascular graft. This technology directly addresses critical challenges such as poor hemocompatibility, thrombus formation and inflammation, common factors that limit the durability and efficacy of vascular grafts. This surface modification design facilitates seamless integration of vascular grafts, significantly improving long-term graft patency and biocompatibility.

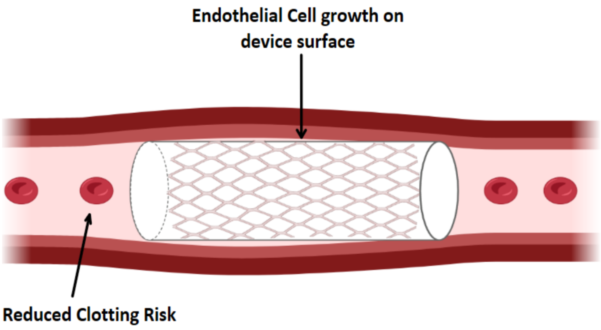

Fig 8: Smart Reactors Camouflage™ Coating on stent-graft indicating reduced clotting risk and promoting endothelial cell growth.

3.1 Camouflage™ Mechanism of Action

Camouflage™ coating technology effectively conceals the surface of the device preventing direct interaction with the surrounding circulating blood. It achieves this by attracting non-inflammatory proteins from the patients' blood to the coated surface. This advanced interface regulates blood-material interactions, minimizing the biological responses that lead to clot formation, immune activation, and vascular injury. By providing a smooth, non-thrombogenic surface, Camouflage™ minimizes platelet adhesion and activation while promoting the proliferation and integration of endothelial cells.

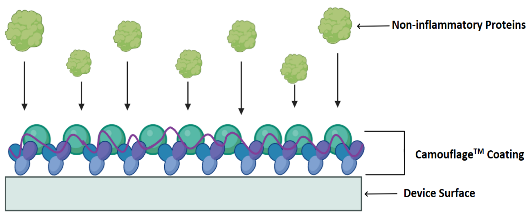

Fig 9: Camouflage™ Coating Technology Mechanism of Action

3.2 Optimizing Thromboresistance in Vascular Graft Materials

Synthetic vascular grafts are often limited by complications such as thrombosis. Camouflage™ addresses this challenge by minimizing platelet activation, a key precursor to thrombosis. By maintaining a non-thrombogenic interface and supporting stable blood flow, Camouflage™ significantly reduces the risk of thrombotic events and enhances long-term graft patency.

3.3 Enhancing Endothelization for Improved Graft Functionality

Camouflage™ coating promotes the rapid attachment and proliferation of endothelial cells, ensuring faster integration of the device with the vascular system. This accelerated healing process reduces exposure time to circulating blood, decreasing the reliance on long-term antiplatelet therapy and improving overall device safety.

3.4 Anti-Inflammatory Modulation for Graft Integration and Host Compatibility

Chronic inflammation is a key contributor to vascular graft complications, often resulting from prolonged exposure to surfaces with low biocompatibility. Camouflage™ minimizes immune activation by concealing the device surface from leukocytes and other inflammatory cells thereby creating a more favorable environment for graft integration. This anti-inflammatory effect enhances vascular stability, promotes smoother integration and prevents chronic inflammation.

4. Preclinical Validation of Camouflage™

A series of assessments were conducted to evaluate the key performance indicators of Camouflage™ coating. including hemocompatibility, endothelization and inflammatory response. Smart Reactors benchmarked its performance against alternative commercially available coatings for blood-contacting devices.

4.1 Hemocompatibility

The reduced thrombin-antithrombin (TAT) levels observed with Smart Reactors Camouflage™ coating in comparison to Phosphorylcholine (PC) and Albumin, demonstrate its superior efficacy to minimize clot formation (Fig. 10). Camouflage™ coating passivates the surface effectively reducing platelet activation and inhibiting the coagulation cascade. As a result, minimal thrombus formation is observed, with red blood cells remaining in suspension (Fig. 11).

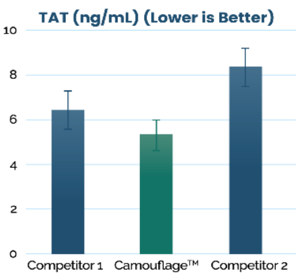

Fig 10: TAT levels

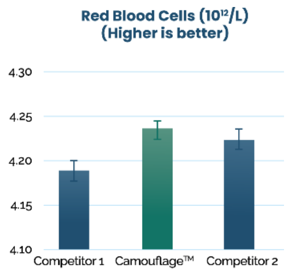

Fig 11: Red Blood Cell Levels

4.2 Endothelialization

Camouflage™ coating applied to a nitinol surface significantly enhanced endothelial cell proliferation when compared to uncoated stents, thereby reducing the duration of device exposure to circulating blood. After a 29-hour incubation period, human umbilical vein endothelial cells (HUVECs) exhibited significantly higher uptake on Camouflage-coated nitinol surfaces than on uncoated counterparts (Fig. 12), indicating improved cellular compatibility and highlighting accelerated endothelialization.

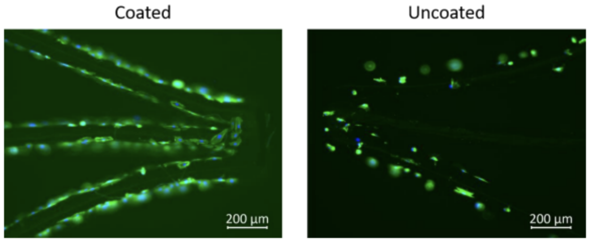

Fig 12: Endothelial cell adhesion following a 29-hour dynamic incubation period

4.3 Anti-Inflammatory Effects

Camouflage™ exhibits minimal white blood cell (WBC) adhesion, effectively preserving overall WBC levels. In contrast, coatings such as PC and Albumin result in a significant reduction in WBC levels due to excessive cell attachment (Fig. 13) Reduced levels of PMN elastase observed with Camouflage™ indicate a lower risk of triggering inflammatory responses compared to coatings such as PC and Albumin (Fig. 14).

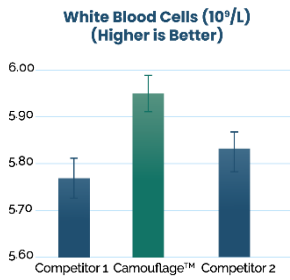

Fig 13: White Blood Cell Levels

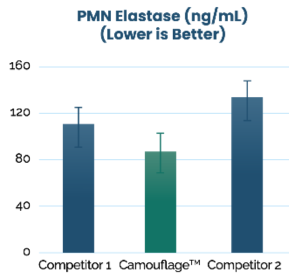

Fig 14: PMN Elastase Levels

5. Animal Model Evaluation

This preclinical study was conducted to assess the safety and endothelialization performance of Camouflage™ -coated nitinol stents compared to uncoated control stents using a rabbit carotid artery model. Rabbits were chosen for their anatomically suitable vessel size and widespread acceptance in vascular implant research. This model offers translational relevance for early-phase assessment of vascular implant devices in-vivo.

Gross inspection of the stented vessel segments revealed clear differences in tissue coverage between Camouflage™ -coated and uncoated stents at the acute time point. At 24 hours, the coated stent exhibited early tissue deposition along the struts indicating a more rapid healing response. In contrast, the uncoated stent remained largely bare, with minimal visible surface coverage. Notably, no thrombus formation was observed on either device (Fig. 15).

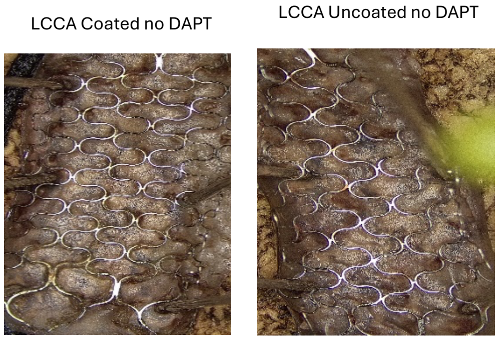

Fig 15: Gross Inspection of Stents Explanted 24 Hours Post-Implantation

By 14 days, all stents—coated and uncoated, with or without Dual Antiplatelet therapy (DAPT) exhibited clear endothelialization, with no thrombus formation or abnormalities. Notably, stents implanted under DAPT conditions demonstrated slightly greater endothelial coverage than non-DAPT, regardless of coating (Fig .16 &17).

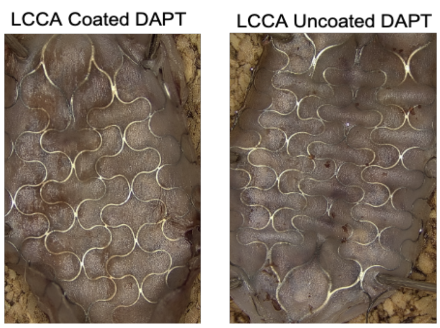

Fig 16: Gross Inspection of Stents Explanted 14 days Post-Implantation (with DAPT)

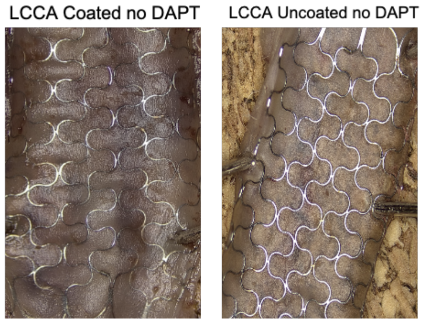

Fig 17: Gross Inspection of Stents Explanted 14 days Post-Implantation (with no DAPT)

At 90 days, both coated and uncoated implants exhibited complete endothelial coverage (Fig. 18). However, Camouflage™ -coated stent demonstrated a thinner endothelial layer compared to the uncoated control, suggesting a reduced propensity for neointimal hyperplasia and favorable long-term healing response.

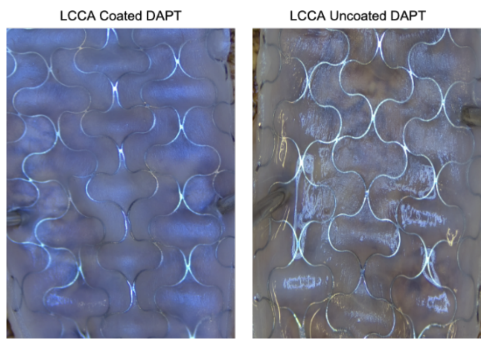

Fig 18: Gross Inspection of Stents Explanted 90 days post-implantation

6. Future Perspectives: Toward Advanced and Adaptive Vascular Grafts

The future of vascular grafts largely hinges on the refinement and advancement of currently available technologies. Camouflage™ is progressively evolving to coat a diverse range of blood-contacting medical devices. Smart Reactors is actively partnering with leading medical device manufacturers and academic institutions to optimize the coatings' performance and validate its clinical benefits. Through sustained collaboration and scientific innovation, Camouflage™ is driving the development of a next-generation biocompatible coating that enhances device integration, minimizes the risk of thrombosis and accelerates the healing process. These ongoing efforts hold the potential to significantly improve the efficacy and safety of vascular surgery and reconstruction. This shift toward surface modified grafts will lead to enhanced clinical outcomes, reduced complications and improved patient prognosis over the long-term.

7. Conclusion

Optimizing vascular grafts through innovative technologies like Smart Reactors Camouflage™ represents a significant advancement in the field of vascular surgery and reconstruction. This coating enhances hemocompatibility, promotes endothelialization and reduces an inflammatory response, addressing the critical limitations of traditional graft materials. Moving forward, the integration of this advanced technology will be crucial in overcoming challenges such as graft failure, thrombosis and chronic inflammation, thereby paving the way for mor effective, durable and personalized vascular treatments in the future.

8. References

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