SmartReactors

ADVANCEMENTS IN DIALYSIS TECHNOLOGIES:

THE ROLE OF CAMOUFLAGE™ COATING FOR DIALYSIS DEVICES

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1 Introduction

1.1 Kidney Failure: Chronic and Acute

Kidney failure occurs when the kidneys are no longer able to adequately filter blood and maintain homeostasis of fluids, electrolytes, and waste products. This can manifest in two primary forms: chronic kidney failure, also known as end-stage renal disease (ESRD), and acute kidney injury (AKI).

ESRD results from the progressive loss of kidney function over months or years, commonly due to underlying conditions such as diabetes mellitus, hypertension, glomerulonephritis, or polycystic kidney disease. These chronic conditions lead to irreversible damage and scarring of the renal tissue, eventually requiring renal replacement therapy. In contrast, AKI is a sudden decline in kidney function, often triggered by events such as severe infections, drug toxicity, major surgery, or reduced blood flow to the kidneys. AKI is often reversible, some cases require short-term dialysis to stabilize fluid, electrolyte, and waste levels. If kidney function does not recover, AKI can progress to chronic kidney disease.

Globally, chronic kidney disease is a major public health issue, affecting an estimated 850 million people, with millions progressing to ESRD annually. In the United States alone, over 800,000 people are living with ESRD, the majority requiring long-term dialysis. Although kidney transplantation is the most effective and definitive form of renal replacement, the scarcity of donor organs limits access; more than 90,000 patients are on the transplant waiting list in the U.S., with far fewer transplants performed each year.

Given the high burden of both acute and chronic kidney failure and the limited availability of transplantation, dialysis remains a cornerstone of renal replacement therapy. Whether used temporarily in AKI or long-term in ESRD, dialysis plays a critical role in maintaining metabolic stability and improving survival.

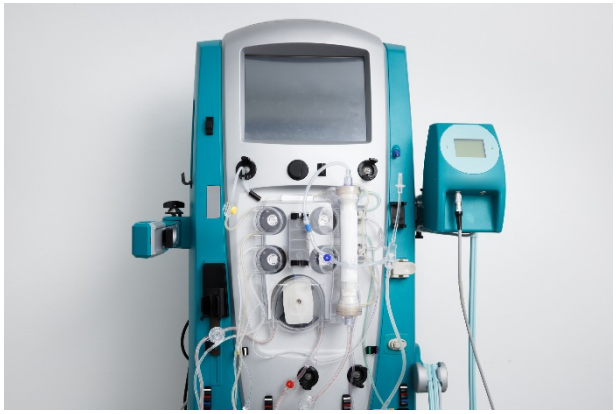

Fig 1 Hemodialysis machine

1.2 Treatment: Hemodialysis

Dialysis is a medical treatment used to replace the filtering functions of the kidneys in patients with kidney failure. There are two main types of dialysis: hemodialysis and peritoneal dialysis. Hemodialysis involves circulating the patient's blood through an external machine to remove waste products and excess fluid, while peritoneal dialysis uses the lining of the abdominal cavity as a natural filter. Although both methods serve the same purpose, this article focuses exclusively on hemodialysis, which is the most used modality worldwide and is central to both acute and long-term management of kidney failure.

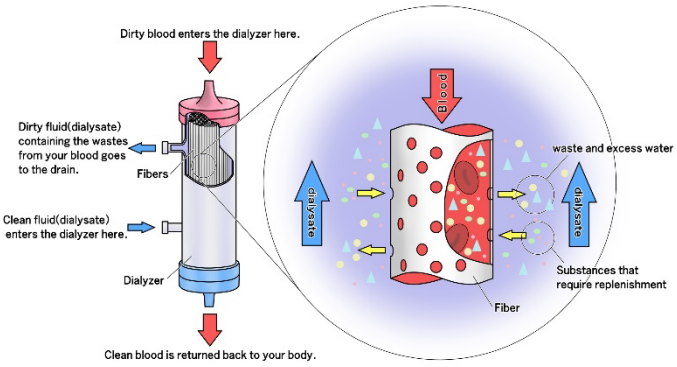

Fig 2 Diagram of Hemodialyzer Function

The procedure involves circulating the patient's blood through an external device called a dialyzer, which serves as an artificial kidney. Inside the dialyzer, blood flows along one side of a semi-permeable membrane, while a specially formulated solution called dialysate flows on the other. Through diffusion and ultrafiltration, solutes and fluid pass from the blood into the dialysate, which is then discarded. A hemodialysis machine manages this process by regulating blood flow, dialysate composition, temperature, and pressure. Vascular access is required to enable extracorporeal blood flow; this can be achieved through an arteriovenous (AV) fistula, synthetic graft, or central venous catheter. While AV fistulas and grafts are preferred for long-term use in ESRD patients, central venous catheters are often used for acute dialysis due to their immediate availability.

A typical chronic hemodialysis session lasts three to five hours and is performed three times per week. In acute cases, the frequency and duration of dialysis are tailored to the patient's rapidly changing clinical needs. Acute hemodialysis may be performed daily or in shorter, more frequent sessions, depending on the severity of the condition and response to therapy. In both acute and chronic kidney failure, hemodialysis serves as a vital intervention. While it does not restore kidney function, it enables survival and stabilizes the internal environment until kidney recovery or transplantation becomes possible.

2 Dialysis Technology: Current Limitations

Although hemodialysis technology has advanced significantly, critical challenges remain with both dialyzers and vascular access devices, particularly related to thrombosis, inflammation, and biocompatibility.

2.1 Dialyzer Limitations

The dialyzer, often referred to as the artificial kidney, is a core component of the hemodialysis system. It contains thousands of hollow fibers made from synthetic polymers such as polysulfone or polyethersulfone, which serve as the semipermeable membranes for the removal of toxins and excess fluid from the blood. Despite advances in membrane technology, dialyzers face significant limitations related to their blood-contacting surfaces, which trigger adverse biological responses.

One of the primary challenges is thrombosis. Contact between blood and the artificial membrane surface activates platelets and the coagulation cascade, resulting in clot formation within the dialyzer. To prevent clotting, patients require systemic anticoagulation, typically with heparin, which carries its own risks including bleeding complications. Additionally, clot formation can impair dialyzer performance and necessitate premature replacement, increasing treatment costs and waste.

Beyond thrombosis, dialyzer membranes can induce inflammatory responses due to pro-inflammatory protein adsorption and activation of the complement system. This inflammation contributes to chronic complications such as anemia, cardiovascular disease and dialysis-related amyloidosis, reducing patient quality of life and survival. Repeated exposure to surfaces with low biocompatibility can exacerbate these systemic effects.

2.2 Vascular Access Limitations

Vascular access is the critical lifeline for hemodialysis, providing the route through which blood is withdrawn and returned during treatment. The two most common access types when native arteriovenous fistulas are not feasible are arteriovenous grafts and central venous catheters. Both have significant limitations related to thrombosis, infection, and inflammation, which contribute to morbidity, hospitalization, and increased healthcare costs.

Arteriovenous grafts are synthetic conduits, usually made of expanded polytetrafluoroethylene (ePTFE), surgically implanted to connect an artery to a vein. While AV grafts offer quicker maturation for use compared to fistulas, they are prone to thrombosis due to blood-material interactions and turbulent flow. Repeated clotting leads to frequent interventions such as thrombectomy or graft replacement. Furthermore, graft surfaces can provoke chronic inflammatory responses and neointimal hyperplasia, causing stenosis and eventual failure.

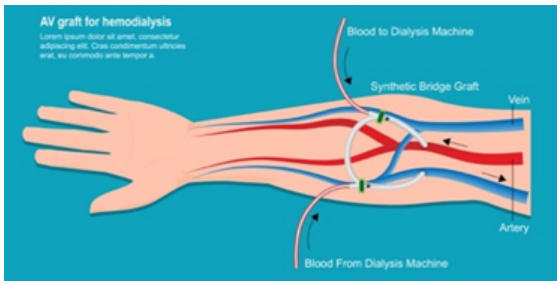

Fig 3 AV graft

Central venous catheters, typically inserted into large veins like the internal jugular or subclavian, provide immediate access but carry high risks of infection and thrombosis. Catheter-related bloodstream infections (CRBSIs) are a leading cause of morbidity and mortality in dialysis patients. The synthetic catheter surfaces also induce platelet adhesion and activate coagulation cascades, necessitating anticoagulant locks or systemic anticoagulation, which have their own risks.

3 Camouflage™ Coating Technology

Camouflage™ coating technology, developed by Smart Reactors, is an advanced surface treatment designed to significantly enhance the performance and safety of blood-contacting medical devices used in hemodialysis. This technology directly addresses critical challenges such as hemocompatibility, thrombosis, and inflammation, common factors that limit the durability and efficacy of dialyzers, AV grafts, and central venous catheters.

3.1 How Camouflage™ Works

Camouflage™ functions by concealing the artificial device surfaces from direct interaction with 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.

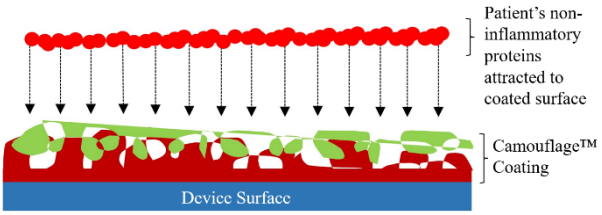

Fig 4 Camouflage™ coating technology

3.2 Key Properties of Camouflage™

Hemocompatibility: Camouflage™ is engineered to be highly hemocompatible, allowing it to interact harmoniously with blood components. By selectively adsorbing non-inflammatory proteins, the coating prevents the nonspecific protein adsorption that typically

triggers platelet activation and coagulation pathways. This interface reduces the initiation of the coagulation cascade, thereby lowering the risk of thrombosis while maintaining stable blood flow conditions at the device interface.

Thrombosis Reduction: The coating's ability to reduce platelet adhesion and activation is critical in preventing thrombus formation on blood-contacting surfaces. Thrombosis within dialyzers, AV grafts, and central venous catheters can lead to device failure, treatment interruptions, and increased patient morbidity. Camouflage™ diminishes these risks by providing a surface that reduces the early steps of clot formation. This reduction in thrombogenicity also has the potential to lower dependence on systemic anticoagulation therapies, which carry inherent bleeding risks.

Anti-Inflammatory Effects: Chronic inflammation is a major contributor to complications in dialysis patients, often resulting from repeated exposure to surfaces with low biocompatibility. Camouflage™ minimizes immune activation by masking the device surface from leukocytes and other inflammatory cells.

Ultra-Thin Coating: A critical advantage of Camouflage™ is its nanoscale ultra-thin profile. This minimal thickness ensures that essential device functions, such as solute and fluid exchange in dialyzers, are not compromised. The coating maintains the permeability and filtration efficiency of dialysis membranes, preserving the device's therapeutic performance. Similarly, when applied to AV grafts and central venous catheters, the coating does not interfere with mechanical properties or blood flow dynamics, making it suitable for long-term use.

3.3 Implications for Dialysis Devices

Applied to dialyzers, Camouflage™ can reduce clot formation within the extracorporeal circuit, decreasing treatment complications and extending dialyzer lifespan, which is particularly relevant for reuse protocols. For vascular access devices such as AV grafts and central venous catheters, the coating's thrombosis and inflammation mitigating properties may reduce device failure rates, lower infection risk, and decrease the frequency of interventions required to maintain patency. Collectively, these improvements could translate to enhanced patient safety, fewer hospitalizations, and overall better quality of life for individuals dependent on long-term hemodialysis.

4 Camouflage™ Pre-Clinical Data

Smart Reactors has performed detailed biocompatibility evaluations of Camouflage™ to compare its performance to alternative, commercially available coatings used for blood-contacting medical devices.

4.1 Hemocompatibility

Camouflage™ coating passivates the surface while reducing platelet activation and inhibiting the coagulation cascade. Evidence of minimal progression towards thrombus formation (clot), with red blood cells remaining in suspension (Fig 5 & 6).

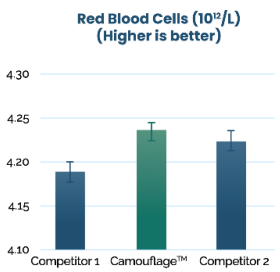

Fig 5 Red Blood Cells

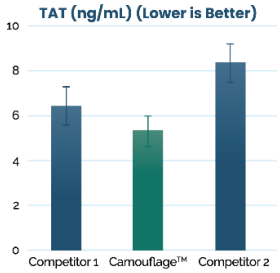

Fig 6 TAT

4.2 Anti-Inflammatory Effects

Camouflage™ coating minimizes the interaction with white blood cells and reduces the inflammatory response. Data demonstrates white blood cells exhibiting minimal adhesion to the surface, with elastase activity remaining at low levels with suppressed inflammatory response (Fig 7 & 8).

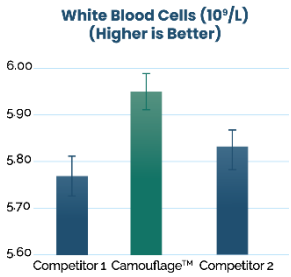

Fig 7 White Blood Cells

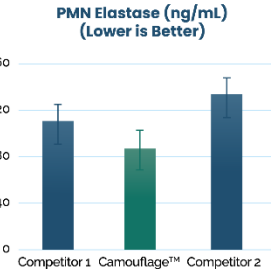

Fig 8 PMN Elastase

5 Conclusion

Kidney failure, both acute and chronic, poses a growing global health burden. While AKI may require short-term dialysis and can sometimes be reversed, chronic kidney failure often leads to ESRD where long-term dialysis is necessary. Due to limited availability of kidney transplants, many patients depend on hemodialysis to maintain metabolic stability. However, the blood-contacting surfaces of dialyzers, AV grafts, and central venous catheters can cause serious complications such as thrombosis, inflammation, and device failure.

Camouflage™ coating technology offers a promising solution to these challenges by introducing a hemocompatible, ultra-thin surface layer that actively suppresses thrombus formation and inflammatory responses without compromising device function. Its bioengineered design reduces the need for systemic anticoagulation, lowers infection risk, and enhances the durability of critical dialysis components. By addressing the biological limitations that undermine current dialysis technologies, Camouflage™ has the potential to improve treatment reliability, reduce complications, and enhance quality of life for patients undergoing long-term dialysis.