

Finalist Abstracts

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A non-invasive, wearable telehealth device to detect thrombosis and monitor vascular access health of arteriovenous fistulas and grafts in hemodialysis patients.

A patent vascular access is crucial for successfully performing hemodialysis. Patients with kidney failure undergoing dialysis treatment have heightened risks of acute arteriovenous fistula (AVF) and graft (AVG) clotting (thrombosis) exposing them to significant morbidity, mortality and financial burdens. In most cases, hemodialysis vascular access clotting resulting in a nonfunctional AVG/AVF happens in the nonhealthcare setting and is usually not detected until the patient is seen at the next hemodialysis appointment. This results in a lost window of opportunity for early recognition and timely intervention to salvage the hemodialysis access. Studies have demonstrated poor access outcomes in patients who undergo delayed thrombectomy (clot removal) after access clotting and better outcomes in those undergoing early salvage. Currently, there are no wearable devices available to detect hemodialysis vascular access clotting in real time to expedite time to intervention. Our wearable device aims to identify hemodialysis access clotting in real time and will help increase patient awareness and reduce complications associated with hemodialysis vascular access clotting. The device uses a small sensor to monitor the patient's vascular access in real time and sends the acquired data to a local microcontroller for signal processing. A machine learning algorithm then classifies the input data to identify hemodialysis vascular access clotting and automatically alerts the patient and their health care team. This non-invasive device will expedite time to intervention, cut financial costs, morbidity and mortality associated with AVF/AVG clotting related complications and ultimately improve delivery of care.

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Development of an Automated Multimodal Sensor to Improve Patient Outcomes in Hemodialysis

The proposed innovation provides for an integrated, automated means of monitoring of important physiological parameters during hemodialysis, including blood volume status (absolute and relative), vascular access function (flow rate and circulation) and ultrafiltration rate. In the current ESRD care environment in the United States, minimizing workflow and usability burden is of paramount importance in driving technology adoption. Specially designed flow probe sensors are integrally mounted to a hemodialysis machine, and seamlessly couple with the patient's blood tubing set when it is attached for treatment. All actions needed to perform measurements are timed and fully automated by the hemodialysis machine, eliminating the need for user intervention and associated user-based error.

By taking this approach, measurements which previously require trained users, standalone equipment and/or significant workflow disruption can be performed easily and more frequently. This is especially impactful in care settings such as in-home or in-center self-care hemodialysis, where patients take on greater ownership of their therapy. By eliminating dependence on external factors, the technology is highly applicable in these settings, giving the patient expanded empowerment and increased participation in their care. Data obtained is not only valuable to guide patient care (e.g. guiding ultrafiltration rate or goal, referrals for preventative vascular access procedures) but can also be a powerful tool to drive patient engagement and autonomy. Curating and delivering this data via smartphone app to a patient can be used to provide direct feedback and encourage 'nudges' in lifestyle activities (e.g. fluid intake regulation, care of their vascular access). Application of data science and advanced analytics to large pools of such data, anonymized and coupled with symptoms/outcome information can be used to develop smart algorithms for real-time, closed loop treatment control.

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Fluo Medical Fistula Monitoring Device

In the United States, over 700,000 people have end stage renal disease and many depend on hemodialysis for survival. Hemodialysis requires a specific venous access; in a majority of patients, an arteriovenous fistula is the access of choice. These fistulas are surgically created but then need to “mature” before they can be used for dialysis. This takes on average 100 days. Even worse, up to 60% of newly placed arteriovenous fistulas fail to mature altogether.

These challenges extend the overall time spent utilizing problematic temporary hemodialysis catheters. Fortunately, we have procedures to address the most common problems encountered with arteriovenous fistulas, but we lack a reliable, objective way to follow the course of arteriovenous fistula maturation and make early informed treatment decisions. Existing solutions lack the feasibility to make numerous assessments over time, are too costly and often require active connection to a hemodialysis machine.

The vision for our solution is a wearable, real-time monitor of arteriovenous fistula attributes that identifies failing or properly maturing arteriovenous fistulas. Patients will benefit from real-time arteriovenous fistula data immediately postoperatively without requiring significant time, skills of a healthcare professional, or concurrent connection to a hemodialysis machine. When early arteriovenous fistula maturation failures are identified, providers will be notified in order to evaluate if early interventions are necessary.

The device will be compatible with current and future hemodialysis systems. It will engage patients and providers with actionable data to help reduce fistula maturation failure, associated catheter costs and hospital readmissions. The goal is to utilize new arteriovenous fistulas as early as possible. The immediate market will be closed hospital systems who would directly benefit from cost savings with decreases in overall catheter use time.

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Digitally-delivered behavior change program to help patients delay dialysis

Chronic Kidney Disease (CKD) is an irreversible disease. Kidney function deteriorates over time to end stage renal disease (ESRD) that requires renal replacement therapies (RRT). During the time it takes to progress from initial diagnosis to ESRD, a lot of efforts can be taken to try to preserve kidney function as much as possible.

RenalTracker believes that the effects of these efforts have not been maximized. RenalTracker is a cost-effective, patient-centered, digital therapeutic that aims for the best-possible individual prognosis for each CKD patient and delay RRT in ESRD patients. This is achieved by using data analytics to maximize the effects of CKD self-management programs, modify the individual risks contributing to loss of kidney function, reverse or slow disease progression for as long as possible, maintain patients' quality of life and reduce socioeconomic costs. It works through extensive data analytics to enhance the educational effects for each patient and reduce the barriers that prevent the adoption of positive lifestyle- and therapy-associated behavior patterns.

RenalTracker delivers new or existing CKD self-management programs via digital platforms and uses behavior change elements to help patients modify progression risks. It takes each patient's individual barriers for the adoption of risk-reducing lifestyle changes into account and uses patient feedback and data analytics to optimize each patient's outcome.

RenalTracker is under continuous development and builds on an intensive discovery journey that helped shape today's product. The company started in 2016 and created digital kidney guidebooks, helping more than 6,800 patients. We took Renaltracker a long way since - our most recent product iteration includes a web dashboard that has helped an additional number of 859 patients. As we continue to scale, we are continuing to listen to patients and develop Renaltracker into the best digital therapeutic that helps improve CKD outcomes.

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Utilizing Optical Interrogation Methods for Early Diagnosis of Peritonitis in Peritoneal Dialysis Patients

In the United States, over 26,500 patients use peritoneal dialysis (PD) each year and are at risk for developing peritonitis, an infection of the peritoneum that causes scarring and thus prevents the peritoneum from serving as an efficient exchange membrane during PD. Patients then have to switch from the gentler and more convenient method of PD to hemodialysis (HD). While PD utilizes an at-home setup, HD requires multiple visits to dialysis centers, which is both inconvenient and expensive -- healthcare, dialysis center, and hospitalization costs sum to over double that of PD. The current standard of care for detecting peritonitis involves the patient first self-reporting their symptoms and then sending in their dialysis waste for a white blood cell (WBC) test and bacterial culture, which can take up to 8 days. Untreated infection puts the patient at risk for developing peritonitis, inflammation of the peritoneum, and other possible complications.

Our team aims to design a way to detect peritonitis before patient awareness for those who are using PD in order to treat the infection earlier. This will reduce acute hospitalization costs and prevent scarring of the peritoneum, therefore improving PD longevity. Our solution, the OpticLine, seamlessly integrates within the current PD setup, connecting in series with the drain lines used. The OpticLine will use spectrophotometry to analyze the optical density (OD) of WBCs in the dialysis waste fluid as a way to gauge for infection.

Using our works-like spectrophotometer prototype, we measured various WBC concentrations in Dulbecco's phosphate-buffered saline (DPBS). Our results from our works-like spectrophotometer prototype experiment indicate that we detect a significant difference in optical density between our two WBC concentrations of interest: 10 WBC/mm³ (normal) and 1000 WBC/mm³ (infected) (p-value = 1.47E-07).

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Nitric Oxide-Eluting, Disposable Hemodialysis Catheter Insert to Prevent Infection and Thrombosis

Despite substantial efforts by the nephrology community to reduce utilization of dialysis catheters, the majority of ESRD patients in the USA initiate hemodialysis (HD) with a tunneled dialysis catheter (TDC) with approximately one-quarter of them remaining catheter-dependent thereafter. TDCs are associated with decreased patient survival as well as multiple complications, such as central venous stenosis, infection and thrombosis. The yearly cost of hemodialysis for patients using a TDC is approximately \$20,000 greater as compared to dialyzing through an AVF. There are two major pathologic entities that lead to TDC dysfunction and associated complications: infection and platelet activation leading to thrombosis. Nitric oxide (NO) is an endogenously formed gaseous molecule that is well known to play a key role in preventing infection and thrombosis. The very short half-life of NO is a major advantage because only a relatively low steady-state level of NO present at the inner and outer surfaces of the TDC is required to achieve the desired antimicrobial and antithrombotic effects. Further, there is no risk of systemic effects when using NO release materials/devices that emit NO at rates that are near physiological levels. This KidneyX: Redesign Dialysis Phase I proposal aims to develop an innovative NO releasing TDC insert device. The disposable NO release insert will be replaced at each dialysis session (every 2-3 days). The proposed project is designed to meet two specific KidneyX goals: 1) to improve quality of life for dialysis dependent patients by minimizing burden on the family and care partner(s) and improving their ability to work, travel, and engage in recreational activities; and 2) to improved renal replacement therapy access. These goals will be achieved by a decreasing the rate of infections, thrombosis, fibrin sheath formation, and central vein stenosis, which will, in turn, reduce hospitalizations, morbidity, and mortality associated with TDC use.

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Smart Sensor-enhanced Needle Guide Reduces Pain and Cost in Clinic: Major Enabler of Home Hemodialysis

Over 460,000 Americans undergo hemodialysis today. Currently a technician sticks two sharp, large bore needles into an AV fistula, guided only by palpation. Vessel damage from this technique often requires costly repair operations and contributes to patient morbidity and mortality. Ultimately, with no accessible vessel, the patient dies. JEM's breakthrough approach can put an end to this 50 year old technique.

The JEM™ is a sensor-enhanced, fenestrated titanium cylindrical needle guide that is implanted in the subcutaneous tissue. It safely directs a blunt needle through an opening in the skin to an underlying fistula, reducing pain from large bore needles. By assuring needle penetration of the vessel at the same spot each time, the JEM limits damage to the surrounding fistula wall. Substantial cost savings will result simply by reducing frequent repair and replacement operations.

A biosensor on the JEM cylinder with an audio-visual alarm will reduce risks of back wall perforation and needle dislodgement with subsequent risk of severe patient hemorrhage. Other sensors will detect early fistula failure and contribute by gathering data during dialysis that will customize dialysis for each patient. In addition to needle placement benefit, the sensors also measure blood flow, allowing nephrologists to identify increased stenosis risk.

The JEM, by facilitating painless, safe cannulation will accelerate transition to home dialysis. The safety alert detecting needle dislodgement enables a paradigm improvement in dialysis, allowing patients to safely dialyze at home, at night, freeing the patient three days/ week to pursue other activities.

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Atomically Precise Membranes (APM) for High-Flux and Selective Removal of Blood Toxins

We propose a solution to the problem of replicating kidney functions by creating chemically synthesized, atomically precise membranes that can be as thin as a single-molecule that mimic the highly permeable and selective membrane channels present in human cells. The current dialysis process relies on polymeric membrane dialyzers whose permeabilities cannot compete with human kidneys that filter 70 liters of plasma on a daily basis. Our membranes are created in a radically different way by assembling designed, chemically synthesized channel molecules into two-dimensional dense arrays. The ultimately thin barriers offer an exceptional permeability that will greatly reduce the dialyzer unit size enabling the development of portable/wearable dialysis devices. We will synthesize these channels using unique "Molecular Lego" approach that our group has developed over the last 15 years. The general chemical structure of our "Lego bricks" resembles natural amino acids but contains an additional pair of amine and carboxyl groups ("buttons" and "holes") to hold two "bricks" tightly by forming a pair of peptide bonds. This interlocking mechanism allows us to construct protein-like macromolecules with programmable shapes and functionalities by assembling diverse building blocks step-wise. We will use this technology to develop membranes containing rigid "Molecular Lego" channels with atomically precise pore sizes, leading to sharp molecular weight cut-offs that can prevent any albumin loss. We can also tune the hydrophobicity/hydrophilicity of the membrane surfaces and inner walls independently to suppress the fouling of the membranes and promote the removal of protein-bound uremic toxins. Our ultimate goal is to create a compact multi-stage membrane system that can replicate the function of the proximal tubule to selectively recover small nutrients, salts and water from the filtrate, reformulate, and return to the blood while excluding toxins. This will open the door for renal replacement therapy to personalized/precise medicine beyond simple dialysis.

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Displacer-enhanced hemodialysis: improving the intradialytic removal of protein-bound uremic toxins using binding competitors

Hemodialysis is a life-sustaining treatment for the almost half a million patients who have lost their kidney function and are currently receiving chronic hemodialysis in the United States. Hemodialysis can remove uremic toxins (deleterious substances that accumulate in the body as kidney function declines). One class of toxins, however, is notoriously difficult to remove by hemodialysis: protein-bound uremic toxins. This is because, in the patient's blood, these toxins are bound to a protein called albumin. Albumin itself is too large to be removed with conventional hemodialysis, and since it clings to these toxins, they cannot be effectively removed. Research suggests that these toxins negatively affect our patients' health, and yet no practical progress has been made in recent decades to more effectively remove these toxins from the blood.

We have developed a concept called "displacer-enhanced dialysis": during the dialysis treatment, a displacer substance is infused into the dialysis machine's blood tubing upstream of the artificial kidney. This displacer binds to the same binding sites on albumin as the toxins. Thus, it quite effectively competes with the toxins for their albumin binding, displaces them from the albumin molecule, and, once they are free, they can then be easily removed in the artificial kidney. All of this happens outside of the patient's body.

In laboratory experiments, we have seen up to a 3-fold increase in the removal rate of these toxins. Recently, a study in human dialysis patients has confirmed this effect. But the displacers used so far for these proof-of-concept studies are not suitable for long-term use in patients.

The goals of this KidneyX proposal are: 1. To advance our search for an ideal displacer (or a combination of displacers) that can be used routinely in chronic hemodialysis, and 2. To study the effects of longer-term use of such displacers.

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Drug-Eluting Electrospun Hemodialysis Graft

An arteriovenous graft (AVG) for hemodialysis is a tube that connects an artery to a vein. It allows recurrent needle placement to remove and return blood during dialysis. The use of an AVG is associated with a high risk for failure due to uncontrolled cell growth at the connection of the graft to the vein (known as neointimal hyperplasia), blood clotting and bacterial infection. By one year, the majority of grafts will be lost or require an intervention. The need for recurrent graft maintenance and salvage procedures poses a burden on the patients and their families and results in added financial expenditure to the health care system. The search for an alternative graft with improved outcomes has been the 'holy grail' of dialysis access surgery. We have a synthetic electrospun graft that we believe will demonstrate benefits over currently available grafts. Our graft has the trusted structural safety and reliability of the current synthetic grafts with the added benefit of early puncture (cannulation) and allows cell ingrowth and epithelialization, mimicking a native vessel, with the added protection that these cells provide against thrombosis and infection. It thus may compete with newer biologic grafts.

We have the technology to incorporate drugs that reduce neointimal hyperplasia into the electrospun fibers and localize this attachment to a certain segment (venous edge) and layers of choice (inner layer, mid layer). Drug-eluting medical devices have shown promise in reducing neointimal hyperplasia. The production of this graft is standardized and cost of production can be contained. The goal of this Phase I proposal is to conduct early benchtop studies in which we plan to characterize the drug release profile with different incorporated doses and produce prototypes demonstrating different spatial localization of the target drug, which we hope to later test in animal models.

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Development of a Dialysate- and Cell-Free Renal Replacement Technology

Current clinical approaches to treat patients with end stage renal disease (ESRD) include hemodialysis, peritoneal dialysis, and renal transplantation. Our project was motivated by the following considerations. It would be desirable to develop a renal replacement technology (standalone, wearable or implantable format) that for the first time did not require the use of an external dialysate solution to drive the passive flux of ions and water across a semipermeable membrane. Secondly, it would be very advantageous to have the capability of adjusting the transport of ions and water under feedback/sensor control to prevent the changes in blood chemistry that result from alterations in dietary food and fluid intake. Thirdly, a dialysate- and cell-free technology that could potentially function continuously either in an external or implantable format would more closely mimic the native kidney. Here we describe the initial design and operation of a novel technology that has ultrafiltration and ion/water transport capabilities. The device couples for the first time new multiple wafer electrodeionization technology with pressure driven ultrafiltration, nanofiltration and reverse osmosis modules specifically developed for this project. Importantly, the device does not utilize external water/dialysate or living cells. The technologic advances and approaches employed in this proposal can be potentially utilized in the future in various configurations that include standalone, wearable and implantable renal replacement devices to treat patients with compromised kidney function. The technology we describe represents a significant advance in the field of renal replacement therapy ever since hemodialysis was first developed as a therapeutic modality over 70 years ago.

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The Ambulatory Kidney to Improve Vitality (AKTIV)

Kidney disease affects over 30 million adults in the US, is the 9th leading cause of death, and remains a devastating medical, social, and economic problem for patients, families, and society worldwide. With the rapid increase of obesity, diabetes, and hypertension, the number of ESRD patients is likely to increase for decades. The only treatments available for ESRD patients are dialysis or kidney transplant. For those on dialysis, deaths occur primarily from complications associated with kidney failure, comorbidities, and dialysis treatment, including cardiovascular disease and infections. Risks of complications from infections, blood clots, and vascular access failure remain exceedingly high. Current dialysis technology requires most patients travel to a dialysis center and spend 4-6 hours tethered to large dialysis machines, 3 times/week for the rest of their lives. Patients are unable to live full and productive lives due to the physical toll dialysis takes and the excessive amount of treatment time required.

Dialysis as a life-sustaining therapy for irreversible kidney failure was pioneered at the University of Washington; over 50 years later, there have been few patient-transformational technical innovations. The UW Center for Dialysis Innovation (CDI) is reinventing dialysis by applying new ideas, 21st century technologies, and exceptional science. We envision hemodialysis therapy that is accessible, complication-free, and more effectively emulates healthy kidney function with dramatically improved outcomes and quality of life for patients.

The CDI will transform dialysis using state-of-the-art biomaterials and engineering technologies. Our high-powered, multidisciplinary team is developing revolutionary dialysis technologies, focused on developing the AKTIV (Ambulatory Kidney to Improve Vitality): a wearable, miniaturized dialysis system that is low-cost, water-efficient, requires minimal anticoagulation, offers complication-free blood access, and is patient-friendly. The AKTIV will provide sustained life, and higher quality, more productive lives for patients worldwide, allowing almost unlimited mobility, dramatically reduce pharmaceutical burden, and reduce dietary restrictions.

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An Air Removal System For a Wearable Renal Therapy Device

This is a project to develop an automatic air removal system that can be used safely in a wearable renal therapy device with minimal user intervention.

All existing dialysis systems require a method of preventing air bubbles introduced in the dialysis process from being returned into the patient's blood circulation. Most existing systems use a drip chamber with a level detector where the blood exits from the bottom and the air rises to the top. The equipment operator observes the drip chamber level and makes level adjustments when required. These systems must always be maintained in a vertical orientation in order to function safely.

Wearable systems as per their portable nature may not always be in the vertical orientation. Because of the difficulty involved in removing air from a system that may be in different orientations, the air removal devices on some wearable systems that have been proposed are minimal or nonexistent.

This system uses an air removal filter of the design used in cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) systems. These filters also must be in the vertical orientation in order to remove air that accumulates in the chamber, however, they will continue to remove air from the blood path even when they are not in that vertical orientation.

This system ensures that the air accumulated in the chamber is removed only at times when the filter is in the vertical orientation and will prompt the user if that orientation has not been maintained in a recent period of time. This system can also determine and signal the patient with an alarm if the hydrophobic isolation filter element has been wetted and thus has reduced the accuracy of the integrated return blood pressure monitor.

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Intracorporeal Hemodialysis System

We will develop a hemodialysis system (iHemo) that will allow patients to receive the benefits of frequent and prolonged hemodialysis with the operational simplicity of peritoneal dialysis. The iHemo achieves hemodialysis simplification and risk reduction by implanting a compact hemodialyzer (HemoCartridge) to create permanent internal vascular connections, which will eliminate needle-based vascular access. The iHemo will improve dialysis patient outcomes and their quality of life by eliminating risk of accidental blood disconnect and encouraging frequent and prolonged hemodialysis treatments, especially within the home setting.

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Building New Kidneys

Kidney transplantation provides the best clinical outcomes for patients with kidney disease with better survival and quality of life compared to dialysis. Unfortunately, there is a severe shortage of donor kidneys for transplantation. Using multiple patented technologies, Miromatrix is working to bioengineer new kidney grafts that consist of human cells grown in pig extracellular matrix (ECM) scaffolds. Perfusion decellularization removes the native cells from pig kidneys while leaving behind a transplantable scaffold that provides the framework needed to grow a new kidney graft. This matrix is completely free of cells and is therefore well-tolerated in humans, as demonstrated by two commercial products developed through decellularization of pig livers, MIROMESH® (soft tissue reinforcement) and MIRODERM® (advanced wound care), that have been implanted into thousands of patients. Perfusion recellularization is used to grow human cellular tissues within pig ECM scaffolds, creating functional tissue. Miromatrix' perfusion software drives cells to regenerate kidney structures, including blood vessels and nephrons, in laboratory bioreactors. As an initial step, Miromatrix has developed a process to revascularize kidney grafts with consistent performance in vivo. Revascularized kidney grafts have shown sustained vascular patency on follow-up angiographies in chronic pig transplantation models without evidence of blood clotting. This strategy provides the blood vessels required for future implantation of grafts with kidney cells to restore kidney function. To that end, we developed a method to deliver kidney epithelial cells, collected from donor pig kidneys, to the nephrons and collecting system of decellularized kidney scaffolds. These cells repopulate the pig matrix, grow, and regenerate tubule structures, indicating great potential for functional regeneration. The approach to kidney cell isolation, seeding, and co-culture recellularization is being optimized first using pig kidneys, and will then be translated using discarded human kidneys for eventual human kidney bioengineering.

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