HIC Business Summary

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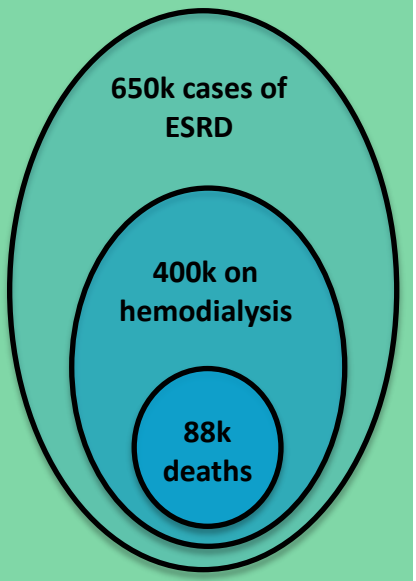
Ruying Chen

Sabrina Kamran

Marleny Santos



$34 billion net costs covered by Medicare

AV fistulas is gold standard; not ideal for older population

⬇

42% hemodialysis patients get AV grafts; alternative to AV fistulas when they fail

⬇

50% clot within first year; 75% within year 2

⬇

5 year survival rate is 35%

THE CONCEPT

Z-ion+ grafts are intended for the 400,000 patients that are on hemodialysis every year. Z-ion+ graft coatings are long-lasting and durable and can prevent clots over 5 years. Z-ion+ technologies' initial market entry will target current medical device companies in the AV graft market by licensing our technology. Given Z-ion+ coatings' unique ability to be versatile in use, our subsequent market entry will bring Z-ion+ technologies to other vascular medical device companies. We believe that the development of Z-ion+ coatings will improve the quality of life of hemodialysis patients while reducing financial burden associated with vascular access failure in our country.

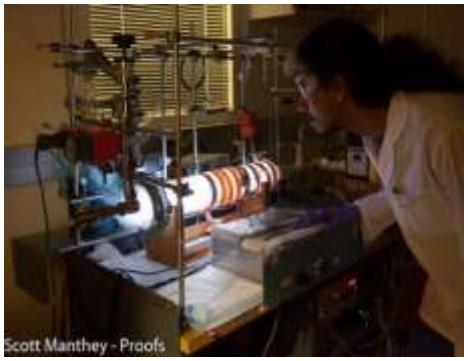
THE PROBLEM

Kidney disease is the 9th leading cause of death in the United States. According to the United States Renal Data System (USRDS) Report of 2013, approximately 1900 people per million have ESRD, and Gilbertson et al. report that these numbers are predicted to rise to over 700,000 of the total US population by the year 2015. The main therapies for ESRD are dialysis and kidney transplantation, costing Medicare $29 billion dollars annually. Vascular access (VA) is needed for hemodialysis (HD) treatment, and it is reported that nearly 20% of all hospitalizations in the HD population is due to VA dysfunction, costing Medicare approximately $1 billion per annum.

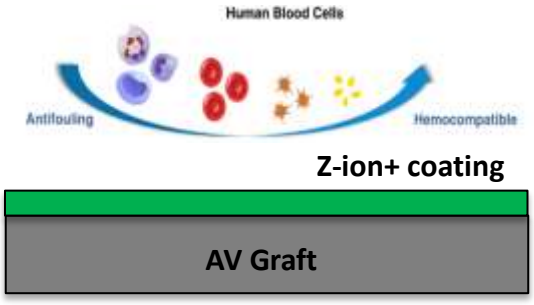
Arteriovenous (AV) grafts are the most commonly used type of vascular access in the U.S.. The current vascular grafts available in the market are associated with complications such as failure to mature, infection, stenosis, and thrombosis; resulting in access dysfunction. Nearly 20% of all hospitalizations in the hemodialysis population are due to access dysfunctions; costing Medicare approximately $1 billion dollars per year. **(1)**. AV grafts have patency rates around 50% in their first year and 33% six months later **(2).** The risk ratio for thrombosis in AV grafts is of 1.06 **(3).** These failures lead to higher mortalities, morbidities, and overall financial costs associated with graft dysfunction maintenance and repair. Among the many possible solutions to this problem, Z-ion+ can solve one: decrease failure through non-fouling coating for AV grafts.

THE SOLUTION

The solution to this issue of clotting in vascular grafts is non-fouling zwitterionic coatings prepared by gas plasma treatment technology. Glow discharge plasma treatment has been used in the past to create non-fouling surface coatings by the deposition of monomers such as tetraglyme, ethylene glycol and 2-hydroxyethyl methacrylate (HEMA). Furthermore, these coatings can be readily applied to various surfaces of varying geometries.



For successful plasma polymerization, it is important that the monomer of interest be easily volatilized into a gaseous state. Zwitterionic polymer hydrogels in mice have shown to resist foreign-body reaction due to their ability to resist nonspecific protein adsorption. However, zwitterionic polymer precursors, such as carboxybetaine methacrylate (CBMA) and sulfobetaine methacrylate (SBMA) are solids with very high melting points which would not make them ideal candidates for glow-discharge plasma treatment to coat surfaces.



Z-ion+ coatings are prepared by a patent pending technology that results in the preparation of quasi-zwitterionic surfaces via glow-discharge plasma treatment. This is achieved by the simultaneous and controlled introduction of a positively charged and a negatively charged monomer within the gas plasma chamber. These monomers crosslink and deposit on the surface via the glow-discharge gas plasma process to form a quasi-zwitterionic surface coating that have positive and negative charge throughout the surface similar to a zwitterionic polymer.

"Blood compatibility is a big issue with vascular grafts and needs to be addressed." –Jonathan Himmelfarb, MD

Advantages of gas plasma technology

Can be applied to any surface with different geometries

Forms strong covalent bonds with the surface

Crosslinks desired monomers on the surface and makes them durable

Advantages of zwitterionic polymers

Naturally occurring in the body, eg: amino acids

Resistant to nonspecific accumulation of proteins and microorganisms

Have shown to be non-fouling in a mice animal model

Go-To-Market Strategy

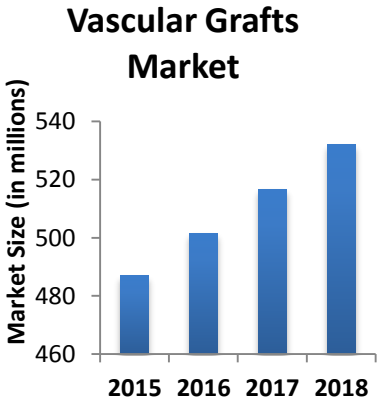
License Z-ion+ coating technology to medical device companies

Phase I
Leading AV graft companies

Phase II
Other vascular device companies

These Z-ion+ coatings can be applied to any vascular graft, providing a non-stick surface that inhibits blood proteins from sticking, thus preventing blood clots in the long run. Moreover, this invention would lead to a new generation of non-fouling surfaces that would resist nonspecific protein adsorption. We have seen promising results from lab bench experiments so far and are in process of optimizing these coatings so that they can be ready for animal experiments.

The Market



In 2013, the Institute of Health, the U.S. Renal Data System, and the National Institute of Diabetes valued the global Medical Device Coating Market at roughly $6.1 billion dollars, with an expected growth to $9 billion by 2019 and a compounded annual growth rate of 7.3%. The AV graft industry has shifted towards focusing on durability since many clots are usually preceded by a structural defect. While much of the market is focused on trying to develop structurally sound grafts, there is still a need to improve on anti-fouling clots since this is the ultimate last step before the patients needs to have their graft manually declotted. We realize that AV grafts for hemodialysis patients is only a segment of the entire medical device coating market, and we are therefore considering expansion into other types such as cardiovascular grafts.

The Competition

	Z-ion+ Technologies	PROPATEN	BARD PERIPHERAL VASCULAR
Anti-fouling	+++	+	+
Coating Durability	+++	+	+
Inexpensive	+++	+	+

Our main competitors, GORE-TEX and Bard, hold 60% of the market share. Although both have focused on making anti-clotting surfaces for AV grafts, a large part of their focus is on easy to insert and anti-kink tubing. Both companies have built on upon standard polytetrofluorethylene technology and in acquiring innovations from other coating companies, such as GORE-PROPATEN with CARMEDA's BioActive Surface.

Other competitors include Merit Medical, FLIXENE, and Nicast which all provide variants of PTFE coatings. While these PTFE coatings are common, patients are still experiencing AV graft clotting and hence failure.

The Customers

Although the end users of the superior offering Z-ion+ provides are hemodialysis patients, the actual buyers would very unlikely be them. We are considering our target customer, the buyers, as dialysis centers, hospitals and clinics who hold the grafts in their inventory. In line with the Health Care reimbursement and payment structure, we will need to be approved by Insurance companies and programs such as Medicare and Medicaid. Finally, we must have certain relationship with established medical device manufacturers who can provide the basic graft to which we will apply Z-ion+ coating. The alternative to manufacturing and distributing grafts with Z-ion+ technology is to license the patent pending technology to other manufacturers.

The Costs

The cost saving potential for health providers and reimbursement agencies of using Z-ion+ coated grafts over any other graft in the market is on average $4,614 dollars per patient. Although this may not seem as a worthwhile amount, the population who will potentially need an AV graft is approximately 605,900 people; leading to an average saving of $2.8 billion dollars. Considering current graft patency rates, after two years, most patients will need a procedure such as thrombectomy or graft replacement. Using the Coverage, Coding and Reimbursement Overview from Medicare, Medicaid, and Commercial Insurances, we have calculated the opportunity cost of continuing to use the currently available coated grafts. Current vascular grafts range in price from $1,675 to $2,674 per unit; but are not the cost driving portion of the equation. The cost per patient with a failed graft ranges from $11,055 to $19,471 dollars, from which up to $9,416 could be due to only maintenance and repair, not considering having to replace the graft.

Traction

Startup Weekend Health Innovation Award Grand Prize, $500

HIC Prototype funding

UW Science and Technology Showcase Grand Prize, $1000

Judged by Seattle Professionals and Entrepreneurs

UW NSF I-Corps Sites Grant, $2500

Customer Validation Funding awarded through UW CoMotion

Tentative Timeline

THE Z-ION+ TEAM

Executive Team

Marvin Mecwan, UW Bioengineering student
Marvin is a PhD student in Bioengineering at the University of Washington, a Technology Entrepreneurship student at the UW Foster School of Business, and founder of the Z-ion+ Technologies in the laboratory of Dr. Buddy Ratner. Prior to graduate school, Marvin was the Scientific Product Manager of BioDLogics, LLC. His interests lie in biomaterials

Ruying Chen, UW Bioengineering candidate
Ruying is a PhD candidate in Bioengineering at the University of Washington, and a Technology Entrepreneurship student at the UW Foster School of Business. Her research focuses on gene delivery using biomaterial implants. Her experience with tissue engineering and animal models have contributed to the testing and optimization of Z-ion+ Technologies.

Sabrina Kamran, UW Pharmacology candidate
Sabrina is a PhD student in the Department of Pharmacology, a Molecular Medicine Certificate student in the UW Department of Molecular Medicine and Mechanism of Disease, and a Technology and Entrepreneurship Certificate Student at the UW Foster School of Business. Her role as the President of the Science, Engineering and Business Association (SEBA) at UW has been crucial in developing the marketing and business strategy for Z-ion+ technologies.

Marleny Santos, UW MBA candidate
Marleny is an MBA candidate at the UW Foster School of Business. She holds a Medical Degree, which has provided insight into the healthcare field as a provider, and experience as an entrepreneur, which has helped develop Z-ion+'s business and financial strategy.

Advisory Board

Buddy Ratner, PhD
Buddy Ratner is the Michael L. & Myrna Darland Endowed Chair in Technology Commercialization, as well as professor of bioengineering and chemical engineering. His research interests include the synthesis and characterization of polymeric biomaterials, plasma deposition of thin films and surface analysis. He has started several start-up companies during his time at the University of Washington and has been a crucial advisor and mentor to the development of Z-ion+ technologies

Emer Dooley, MBA, PhD
Emer Dooley is a faculty member at the University of Washington. She specializes in technology strategy, entrepreneurship and venture capital and has taught in both the Business School and the Department of Computer Science and Engineering. She works with the Buerk Center for Entrepreneurship, where her primary goal is to involve students in all aspects of company creation, technology commercialization and investment. She has increasingly become involved in working with students on using business thinking to help solve problems in the medical field.

Jonathan Himmelfarb, MD
Jonathan Himmelfarb is the Joseph W. Eschbach Endowed Chair in Kidney Research, a professor of Medicine and the Director of the Kidney Research Institute. His research interests include dialysis vascular access and biomarkers of cardiovascular risk in kidney disease and his clinical interests involve clinical and translational kidney research. . He has increasingly become involved in collaborating with professors and students to come up with practical solutions to chronic kidney disease issues.

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