6IXS

VASCULAR SOLUTIONS

INTRODUCING LONG LASTING SYNTHETIC BLOOD VESSELS THAT SEAMLESSLY INTEGRATE INTO YOUR BODY

6ixS Vascular Solutions utilizes a breakthrough material to make lifesaving, long-lasting, off-the-shell and low cost synthetic blood vessel replacements that simultaneously provide solutions to narrowing, clotting and infection by optimizing healing. We aim to transform synthetic vascular grafts for patients with end stage renal disease (ESRD).

DEFINING THE PROBLEM

The kidney's ability to remove waste from the bloodstream makes it one of the five vital organs. Chronic kidney disease is the progressive loss of kidney function and can be separated into five stages depending on the kidney's functionality. The fifth and final stage is called end stage renal disease and occurs when the kidney is nearly nonfunctional. Without a functioning kidney, patients will be required to begin dialysis which is a process that removes waste from the blood. This avoids the need for a kidney transplant.

There are **Three Main Methods** of creating dialysis access for ERSD:

Method #1: Catheter

Catheters are often used for temporary vascular access while another more permanent method is being created. The catheter is placed by inserting a tube into a vein near the neck through the skin. This is the easiest method of vascular access, and it requires the least preparation time. However, it is the most prone to infection due to the nature of the open interface between your body and the atmosphere. Catheters are normally removed once other blood accesses become functional.

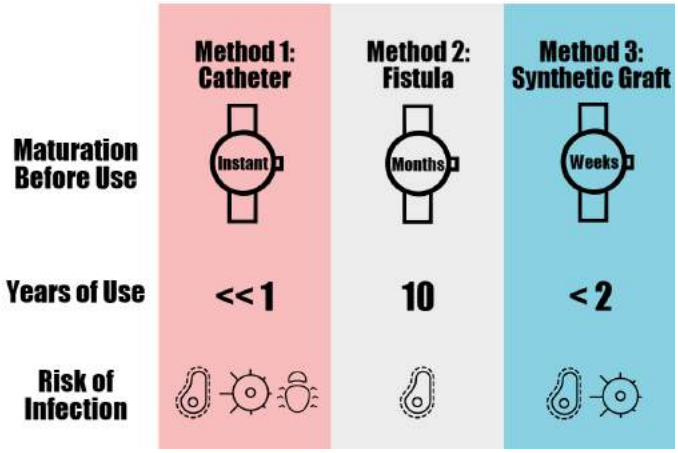
Method #2: Fistula – Using the Patient's Native Vessel

The current standard is creating a fistula by connecting an artery with a vein in the arm. Before use, a fistula requires months to mature and grow stronger in order to withstand increased blood flow. Until the fistula fully matures, a catheter must be inserted for dialysis. Longer maturation periods translates to more catheter use and higher risks of infection. Healthy fistulas are durable but they are not always a viable option. If the fistula is too weak after maturation, it will be unable to create vascular access. As a result, not all patients are able to use a fistula.

Method #3: Synthetic Vessels

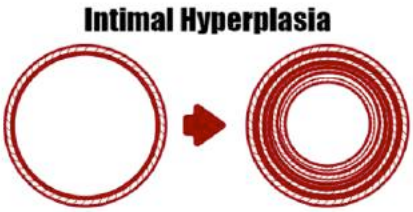
The alternative approach is using synthetic grafts. Instead of a direct connection between the artery and vein, a synthetic graft is inserted in the middle and connects the two. Grafts have a quicker maturation period compared to fistulas. However, the products that are currently on the market have a success rate of about 50% for the first year and 35% for the second year.

Summary of Today's Technologies



There are **Three Main Complications in Synthetic Vessels**:

1. **Intimal Hyperplasia:** thickening of the vessels and constriction of blood flow
2. **Thrombosis:** coagulation or clotting of blood
3. **Infection:** introducing foreign disease-inducing agents into the body



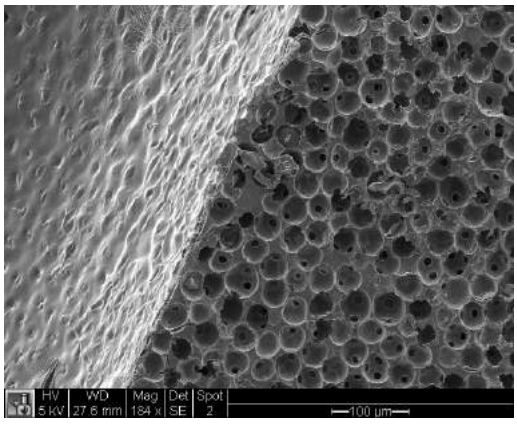
The primary cause for graft failure is narrowing at the place where the graft connects to the vein, also known as intimal hyperplasia. Low mechanical compliance is a major cause of narrowing. The mechanical compliance of current graft materials are already low. The scar layer that encapsulates the current graft after implantation makes it even less compliant. When narrowing proceeds to certain extent, the blood flow in the graft becomes very low, and blood clotting of the whole graft follows. If the risk of these complications can be reduced to a level closer to fistula, the market share of vascular grafts is expected to increase significantly.

Other Applications

Although the synthetic graft industry is currently focused on development for use in dialysis, **another major application is use in cardiovascular disease (CVD)**. The deadliest type of cardiovascular disease is coronary artery disease, which oftentimes requires the creation of a new blood flow pathway called a bypass. Current synthetic grafts tend to have dramatically increased failure rates in bypasses due to small diameters. This is because the effects of thrombosis and intimal hyperplasia become much more pronounced at small diameters and cause graft failure. With innovations in the design and use of vascular grafts, it is foreseeable that their use could easily be extended into the field of CVD and be used to save millions of lives.

OUR SOLUTION

To address the problems described above, our company, 6ixS Vascular Solutions, is developing a synthetic graft utilizing a **precisely engineered micro-porous structure that is optimized for blood vessels ingrowth**. For the graft material, we are using polyurethane which is biologically stable and elastic to match the mechanical compliance of native blood vessels.



In order to create a successful synthetic graft, we must meet the following targets:

1. **Reduce Intimal Hyperplasia (IH)**. In order to reduce intimal hyperplasia, our graft will match the mechanical compliance seen in native vessels and minimize flow disturbances. The porous structure of our graft attracts large amount of macrophages (immune cells) from the body. These immune cells will attract the healthy endothelial cells (lining of blood vessels), which are known to suppress IH. Even if IH does developed, our material can still respond to the high pressure by expanding, thus neutralizing the effect of IH.

2. **Reduce thrombosis**. Healthy endothelial cells are the best clot-resisting material ever exists. Since our vascular graft can attract endothelial cells from our body, it is expected to significantly improve the coverage of endothelial cells in the graft. If complete coverage of endothelial cells on the blood contacting surface is achieved (complete healing), our vascular graft is expected to have similar clot-resistance to the native blood vessels.

3. **Reduce infection**. Our material reduces the chance of infection by attracting large amounts of macrophages. It has been tested that the porous material decreases bacteria colony in vascular grafts by 1000 fold.

With our solutions to the major complications, it is expected that our synthetic graft will have significantly higher success rates than current synthetic grafts.

Demo:
The objective of our booth will be to highlight the current issues with synthetic grafts, present how our unique solution can combat these major issues, and offer a competitive market strategy. Our visuals will include a poster that efficiently covers the major aspects of both the science and business. We will also build a large scale model of our synthetic graft to emphasize our unique solution. Lastly, we will display a video comparing our synthetic graft with a competitor's graft and show how well our grafts expand under pressure, quantitatively characterized by mechanical compliance.

COMPETITIVE STRATEGY

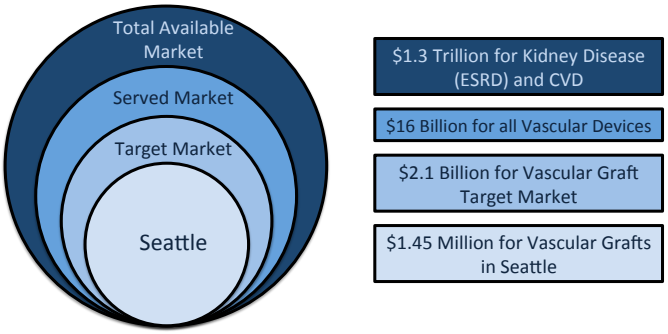
	HIGH SUCCESS RATE	TIME TO MATURATION	LOW PRICE	HIGH COMPLIANCE	
GORE	✗	✓	✓	✗	
Artegraft	✗	✓	✗	✗	
CYTOGRAFT Tissue Engineering	✓	✗	✗	✗	
6IXS VASCULAR SOLUTIONS	✓	✓	✓	✓	

Gore-Tex®, the largest producers of synthetic grafts, is our major competitor. Research on their grafts shows poor success rates and poor compliance. Cytograft and other tissue engineered grafts utilize one's own cells which have high success rates. However, the time to culture cells for a graft require is long and it comes with a high cost. Our 6ixS synthetic grafts provide an affordable option with quick vascular access. Also, by allowing one's own cells to integrate into our graft, it will maximize compliance and success rates.

There is also ongoing research that focuses on developing grafts with coatings of chemicals that are meant to aid in reducing clotting and hyperplasia. However, these solutions are mostly temporary as they the coatings will eventually be exhausted or eroded and lose function.

Our 6ixS synthetic grafts provide an affordable option that allows for quick vascular access. In addition to this, by allowing one's own cells to integrate into our graft, it will maximize compliance and success rates.

GO TO MARKET STRATEGY



Our main customer base consists of doctors and patients. While doctors and patients do not directly buy the grafts, they do have a say in which devices get brought into the hospitals. Typically, doctors and patients tell the supply chain managers which grafts they would like to buy, and supply chain managers buy hospital supplies through Group Purchasing Organizations (GPOs).

The best way to market our graft would be through publications in medical journals, presentations at conferences, and relationships with influential doctors such as Dr. Ted Kohler or Dr. Jonathan Himmelfarb. Dr. Jonathan Himmelfarb, director of the Center for Dialysis Innovation (CDI) and President of the American Society of Nephrology, is already a sponsor of our device, and is extremely influential in the vascular access community.

According to interviews with several doctors, the **one characteristic of a vascular graft that would get their attention right away would be a high success rate**, especially if its performance is comparative with the native vessel.

FDA Approval

It typically takes at least 5 years for medical devices to go through the FDA approval process, either through the 510(k) or the premarket approval (PMA) process.

Typically, vascular grafts are registered as **Class II** devices, which are *substantially equivalent* to an existing device and require a 510(k) route to FDA approval.

However, due to the novel design of our technology, it is possible that the FDA will consider it a **Class III** device. In this case, it would be subject to the lengthier PMA process. In both cases, 6 months of animal trials are required; the main difference between the two routes is that the PMA route requires 12-18 months of clinical trials, while the 510(k) route requires only 6 months.

TRACTION

This product is being developed at the request of Dr. Jonathan Himmelfarb, President of the American Society of Nephrology and Director of the Kidney Research Institute. It is the first project funded by the new UW Center for Dialysis Innovation.

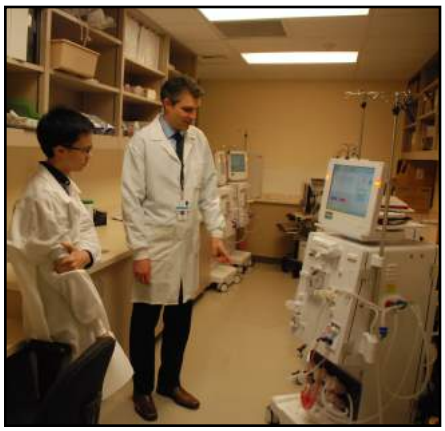
We have been working **UW CoMotion** to advance commercialization and marketing of our process.

Our innovative device has been registered under a **2016 Provisional Patent**. The **underlying 6S porous biomaterials technology** is registered under a **2003 Patent** under our advisor within the Bioengineering Department, Dr. Buddy Ratner, with the University of Washington; it is now being used by Helionics in a line of STAR® Biomaterials devices that focus on intraocular devices. Mike Connolly within UW CoMotion, has been helping us develop our commercialization timeline and facilitate the patenting and FDA approval process.

We have received **Funding** from the following grants and organizations:

2016 Health Innovation Challenge Prototype - $2,200
2016 NSF Innovation Corps - $2,500
2015 Center for Dialysis Innovation (CDI)

We have **Established Connections** with leading academic and medical researchers in the area that lends support for the device and underlying technology.



The underlying 6S technology of our pro-healing material has been thoroughly investigated in a multitude of high-impact **Publications** such as PNAS. This underlying technology has already been successfully implemented in glaucoma intraocular devices in human trials.

We have performed **Interviews** 11 dialysis patients and 9 doctors & nurses, including Dr. Ted Kohler, UW Professor of Surgery, who as previously mentioned has experience with animal and clinical trials of vascular grafts.

FINANCIALS

Our financial projections reflect the need for FDA approval, as described above. Therefore, the first five years of our projections show revenue from grants and other funding (UW's Center for Dialysis Innovation, CoMotion, SBIR and NIH grants). In year six, we project modest sales based on the relationships and demand created during the FDA approval process.

As described above, it is likely that our vascular graft will have to go through the more lengthy and expensive PMI process for FDA approval. We expect costs for this to range from $200,000 to $350,000 spread out over years 2-4. This will be funded by SBIR grants as well as ongoing funding from the Center for Dialysis Innovation. Expenses will be kept to

a minimum by renting lab space in the Department of Bioengineering at the University of Washington.

We expect to be approved for sale by year 6 and will begin generating revenue based on the following assumptions:

- We estimate the market for synthetic grafts used for ESRD patients to be 45,000 units per year, which is 40% of the entire market and includes those for whom fistula is not an option. By year 6, we believe we will have the traction to capture 90% of the local market as well as some of the larger national market for a total units sold of 2000 and $1.4 Million in revenue.
- The current reimbursement rate by Medicare for arteriovenous access with a non-autogenous graft is $705. Using a conservative estimate that only patients covered by Medicare will choose this procedure, we expect to use the existing code with revenue of $705 per graft, before applying for our own code and reimbursement rate due to the expected improved patient outcomes.*

**Commonly Used Permanent Vascular Access Codes. Fistula First Breakthrough Initiative, Sept. 2011.*

Our expenses are based on the following assumptions:

- Our major expenditures in years 1-5 will be R&D, FDA approval, Selling & Distribution (establishing connections), Salaries and General & Administrative.
- COGS will enter in year 6 when our vascular grafts are on the market. The production cost of one of our vascular grafts is $50.80, which includes $50 of material and $0.80 of direct labor. Labor is inexpensive because the grafts can be made in bulk by two technicians at the rate of 400 per day. Grafts are shelf stable indefinitely. This also allows us to be ready to handle demand in excess of our predictions. Gross margins are $654.20 per graft.
- Royalties and licensing agreements with the University of Washington will enter sometime between years 3 and 5, depending on traction and negotiations and we are working with CoMotion to further plan for these expenses.

Financial Estimate Summary

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total Revenue	$229,700	$500,000	$500,000	$1,250,000	$1,250,000	$2,660,000
Total Expenses	$137,000	$272,000	$400,000	$848,000	$798,000	$942,500
Net	$92,700	$22,800	$100,000	$402,000	$452,000	$1,717,500

MANAGEMENT TEAM

Le- Chief Technology Officer (CTO)
Le is a PhD student from Professor Buddy Ratner's lab , with a BS in Polymer Science and Engineering from Beijing University of Chemical Technology and an MS in Chemical Engineering from Oregon State University. He is funded by the Center for Dialysis Innovation to develop the SixS Vascular Graft. Le leads and coordinates all aspects of research in this project.

Nicholas - Chief Financial Officer (CFO)
Nicholas is a fourth year chemical engineering student at the University of Washington (UW). He analyzes the compliance of the vascular graft and the native vessel using 3D ultrasound and manages the finances of 6ixS Vascular Solutions.

Isaac - Chief Operating Officer (COO)
Isaac is a senior in the Chemical Engineering Department at UW. He is developing a standard method for molding and producing vascular grafts from the 6S material, as well as a method to reduce exposure of freshly produced grafts to air, via a plastic coating.

Jason - Chief Design Officer (CDO)
Jason is a senior in the Chemical Engineering department at the University of Washington. His work with 6ixS involves optimizing the polymer graft material and scaling up production. He has internship experience working with software for chemical industries. He enjoys working in the biotech field and aspires to explore more ways to improve daily living.

Melissa – Chief Executive Officer (CEO)
Melissa is a fifth year chemical engineering student at UW. She is developing a gelatin coating that serves as a biodegradable barrier while the graft becomes fully adapted into the body. She is a UW Boeing *F.I.R.S.T.* and Boeing Emerging Leaders in Engineering Scholar. She has over three years of research experience at UW,

Ellyce - Marketing Strategy
Ellyce is a second year Evening MBA student at the UW Foster School of Business focused on Marketing and Finance. Her marketing experience spans over a decade and she has worked with start-ups, the Fortune 500, and mid-size companies in a variety of industries. She was also a part of vHAB, a team that made it to the finals in the 2015 Business Plan Competition.

Anna- Business Strategy
Anna is an MBA student in the UW's Foster School of Business, focusing on Strategy and Organizational Design. As an Independent Business Strategy Consultant, Anna works with small and early stage businesses in a variety of industries on mission and strategy to maximize profits & expand market share.

Advisors and Sponsors

Daniel Schwartz - UW Chemical Engineering
Professor Schwartz is a Joint Faculty of Maetiral Science Engineering and Chemical Engineering at UW. He is also the director of Clean Energy Institute. Dan is currently leading a group of graduate and undergraduate students in the department of Chemical Engineering as part of the special design program.

Buddy Ratner - UW Bioengineering
Professor Ratner is a Joint Faculty of Bioengineering and Chemical Engineering at UW. He is the advisor for 6ixS Vascular Solution. His lab conducts research that supplements 6ixS Vascular Solution's product. He has commercialized a lot of biomedical products.

Dr. Jonathan Himmelfarb - UW Medicine
Dr. Himmelfarb is the councilor of American Society of Nephrology. He is also the director of Kidney Research Institute. He initiated this project.

Mike Connolly - UW CoMotion
Mike is a UW CoMotion Entrepreneur in Residence serving as advisor for the 6ixS team on the patenting, commercialization, and FDA approval processes.With over 25 years of medical technology experience, Mike has an MBA from Stanford, M.S. from MIT and B.S. from the Naval Academy.