

Cardiovate Develops First Bioabsorbable Vascular Graft

For patients who suffer from <u>peripheral vascular disease</u> (PVD), there's a promising option being developed in San Antonio that could help improve blood flow, and ultimately, prevent amputations. <u>Cardiovate</u> is a biomedical technology startup company that got its start in the labs at <u>The University of</u> <u>Texas at San Antonio</u> (UTSA). Best known for its innovative blood vessel graft technology, Cardiovate recently received \$150,000 from the <u>University of Texas Horizon Fund</u> to help commercialize its technology that was initially developed through UTSA and the <u>UT Health Science Center</u>.

Cardiovate has an issued patent and technology license agreement with both institutions, which allows the company the access required to continue its research and product development initiatives on its medical device. Their bioabsorbable vascular graft can help treat vascular diseases by repairing and replacing existing blood vessels.

UTSA alumna Jordan Kaufmann, UTSA Research Vice President and biomedical engineering professor Mauli Agrawal, and Steven Bailey, division chief for cardiology in the UT Health Science Center's School of Medicine, founded Cardiovate in 2012. Kaufmann developed the graft as part of her doctoral research with the support of faculty advisers Agrawal and Bailey, who now serve on the Cardiovate board of directors.

"Cardiovate's disruptive technology will improve outcomes for patients who suffer from vascular diseases such as peripheral artery disease," stated UT System Innovation and Strategic Investment Associate Vice Chancellor Julie Goonewardene, who also is managing director of the UT Horizon Fund. "The UT Horizon Fund continues to support the company's efforts to move its life-saving medical device from the laboratory to the bedside."

Cardiovate CEO <u>Mark Stanford</u> was hired in 2014 and has been busy continuing the development of Cardiovate's patented vascular graft technology in the last 12 months, with a grant from the Small Business Innovation Research (SBIR), recent funding from <u>Targeted Technology Fund</u>, and the recently announced UT Horizon funding.

Standeford is experienced in the medical device industry, having successfully developed and commercialized more than 35 new devices that have generated billions of dollars in incremental revenue. Before joining Cardiovate, Standeford held key positions at <u>Acelity</u> and <u>Hill-Rom</u>.

Vascular Grafts Improve Patient Outcomes

Vascular grafts are most often called in for patients suffering from peripheral vascular disease. PVD is a progressive disease that restricts blood flow to certain parts of the body. In extreme cases, it can block blood flow completely. Cardiovate is focused on the treatment of the most severe cases, which require bypass surgery.

Bypass grafting is one of several surgical techniques used to treat peripheral vascular diseases. Other treatments may include angioplasty and/or stenting, atherectomy, or cryoplasty.

Surgery for bypass grafting redirects blood flow around the blockage in the blood vessel, thus creating an alternate blood flow path with a graft that bypasses the blocked or damaged vessel. The graft may come from a healthy section of the patient's own vein, or a synthetic polyester material.

While some patients have to rely on synthetic graft material because they do not have enough healthy tissue to provide their own graft, synthetics also introduce the possibility of blood clotting if the body doesn't react well to the artificial graft.

Cardiovate's vascular graft is, thus, a significant advancement over the commonly used synthetic graft. "Our technology provides the immediate benefits of a vascular bypass graft to restore blood flow, which existing products do as well," Standeford said. "We go well beyond that by allowing our device to be a tissue scaffold as well.

"This scaffold will allow the body to generate new blood vessel tissue which, in turn, will provide a clear pathway for blood flow, outlasting existing synthetic bypass graft patency results. These better long term results will reduce the overall cost of repeat treatments," Standeford explained. Standeford told the Rivard Report how Cardiovate is first focusing on developing its medical device for use in repairing the blood vessels in the legs.

"When a patient needs a bypass graft you typically use the patient's own vascular tissue to create that bypass," Standeford said. "Only about half (of the patients) are good candidates, the other half don't have enough healthy vascular tissue so they'll need a synthetic bypass graft (for the blood vessel). "Common side effects include clots forming at the graft site when using synthetic grafts. You can't keep bypassing the same area, so when clots happen in the leg, that can result in an amputation," Standeford added.

The technology part of this biotech advance is the scaffold that provides support for the body's cells to migrate into the scaffold and develop a brand new blood vessel. The scaffold structure, over time, is bioabsorbed by the body.

"Current synthetic materials don't work well in the long term, as they oftentimes become clogged just like the original blood vessel they replaced," Standeford said. "There's nothing currently on the market like our bioabsorable bypass graft that also (acts as) a tissue scaffold for helping patients grow a new blood vessel."

The funding is promising for a biotech company like Cardiovate that's just getting started. "It's so hard to get investors in early because of the long horizon for product development for a biotech application," Standeford said.

Cardiovate currently operates from its main business office in San Antonio as well as its lab, which is located at the University of Iowa (UI) BioVentures Center in the UI Research Park. The company is currently discussing plans to relocate the research lab back to San Antonio, where it all started in 2012. Cardiovate currently holds the patent for its new medical device, but has not yet filed it with the FDA for approval. Cardiovate will soon begin a 12-month long-term study on the use of vascular grafts versus native tissue in a large animal study.

"Once we use this in leg blood vessels and help save people's legs from amputation, we'll focus on adapting the medical device for cardiac use," Standeford said. "There should be no need to change surgical technique, we just need to make the device sizing is appropriate for use in the larger vessels in cardiac surgery."

The use of bioabsorbable material is growing in cardiac and other medical applications – from sutures to orthopedic surgery. Cardiovate's bioabsorbable vascular graft reflects this trend in biotech advances.

"This increased usage will help create the foundation of clinical knowledge around the use of bioabsorbables, which in turn, supports our intended use of it for vascular repair," Standeford said. "Ultimately, we want to improve long-term patient outcomes and help reduce the overall cost of care while reducing risks to the patient."

For patients facing possible amputation, bioabsorbable vascular grafts provide a promising alternative. "Developing a product that has so much promise to help patients with a terrible progressive condition is inspiring on its own, and the fact that there is a significant undermet need in this area makes for a great business opportunity," Standeford said.

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