

University of Pittsburgh

ID: 3518

Featured Inventors: Yadong Wang

InSitu A new vessel, made inside you

Value Proposition

We provide an innovative synthetic vascular graft to solve the thrombosis and infection problems of clinically available products for peripheral artery bypass. Our target customers are surgeons, who perform vascular bypass procedures. They need us because our product, unlike prevailing synthetic vascular grafts, provides low thrombogenicity and minimal rejection by transforming into functional arteries composed of host tissue. We provide value through helping healthcare providers and payers save money as well as helping surgeons provide treatment with better outcomes on patients.

Market Opportunity

Current prosthetic vascular grafts used in peripheral bypass procedures can provide instant relief for severe vascular disease but suffer from high rates of foreign material rejection. InSitu's pioneering graft utilizes patients' natural regeneration capability to remodel the implanted synthetic tube into a native vessel without incurring any additional costs. Our product will be reimbursable under current DRG and CPT codes covering peripheral bypass procedures. Based on conservative estimates, InSitu will generate \$14M in firstyear revenue, and will have a \$130M annual revenue 5 years after market entry.

Competitive Landscape

The vascular graft market is split between the few major industries that have been key players for decades and the few smaller existing companies that are in their start up stage. Due to the unique qualities of the InSitu graft, there is no other comparable graft that is currently on the market. However, these companies identified as competitors offer synthetic vascular grafts that have been utilized for quite some time and have proven to be the best alternative to autologous. These synthetic grafts tend to have complications such as infection due to it being a foreign material once placed in the body. With the InSitu graft that we are offering, we can provide a substitute that promotes natural vascular tissue formation as the synthetic component of the graft slowly degrades within the body. The implementation of this can potentially increase primary and secondary patency in comparison to synthetic vascular grafts.

IP Landscape

Biodegradable Vascular Grafts (US non-provisional patent application 2014/0309726)

Methods of Electrospinning and Compositions Made Therefrom (US non-provisional patent application 2015/0322202) Resorbable Vascular Grafts with Clinically Relevant

Dimensions and Handling (PCT application PCT/US2016/037790)

Rapid Transformation

Image: State of the sta

Technology

The major causes of synthetic graft failure can be traced back to the prolonged presence of foreign materials. Based on this, a vascular graft fully composed of biodegradable synthetic polymers is a promising solution. Dr. Yadong Wang invented the core technology of InSitu vascular graft enabling fast tissue regeneration as well as providing compliance for vessel activity through rapid degradation and elasticity of the materials. This innovative medical device is structured as a soft, fast-degrading inner core reinforced by a stiffer, slow-degrading thin sheath. After implantation, the core begins to resorb rapidly into the body. As the synthetic scaffold is broken down into non-toxic biomolecules, originally existing in the human body, infiltrating cells build up a new vessel in its place. The stiff sheath eases surgical implantation and provides fallback structural support during the regeneration process.

Stage of Development

Previous studies have implanted the InSitu grafts in the rat infrarenal abdominal aorta. The graft had largely degraded and transformed into a new vessel with an imperfect but evident arterial architecture at one year. Engineering efforts since then have adapted the graft design and fabrication process for large animal implants. The remaining gap for our technology is large animal studies. Validation of graft patency, durability, neoartery tissue formation, and time course of transformation using a large animal model like sheep, would provide us valuable information to evaluate the grafts translational potential.

Funding

The majority of funding for killer experiment R&D and researcher salaries will come from Coulter TPII funding. Deficiencies in funding and funding for clinical trials in the latter stage of development will be filled by equity capital from venture capitalists and ANGEL investors. We are seeking additional funding sources to support General and Administrative (G&A) costs. Other potential sources include foundation grants, SBIR/STTR grants, NIH translation grants, Federal and State grants, Coulter grants, economic development organizations, and corporate partner investors.

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FEATURED INVENTORS:

Yadong Wang

Yadong Wang, PhD is the founder of InSitu and inventor of the specified polymer used in the vascular grafts product. He is the William Kepler Whiteford Professor of Bioengineering at University of Pittsburgh and a world-known expert in the field of biomaterial, regenerative medicine, and drug delivery. Dr. Wang trained at Stanford and MIT, has published in Nature, Science, and PNAS and holds numerous patents.

Education

M.S. of Chemistry, Kansas State University, 1995

Ph.D. of Chemistry, Stanford University, 1999

Postdoctoral of Biomedical Engineering, Massachusetts Institute of Technology, 2002

Publications

- Wang Y, Ameer GA, Sheppard BJ, and Langer R. A Tough Biodegradable Elastomer. <u>Nat.</u> *Biotechnol.*, 20: 602-606, 2002.
- Wu W, Allen R, and Wang Y. Fast degrading elastomer enables rapid remodeling of a cell-free synthetic graft into a neo-artery. <u>Nat. Med.</u>18, 1148– 1153, 2012. (Featured in Editors' Choice in Science Translational Medicine and Nature Medicine Podcast.)
- Allen RA, Wu W, Yao M, Dutta D, Duan X, Bachman TN, Champion HC, Stolz DB, Robertson AM, Kim K, Isenberg JS, and Wang Y. Nerve regeneration and elastin formation within poly(glycerol sebacate)-based synthetic arterial grafts one-year post-implantation in a rat model. <u>Biomaterials.</u> 35(1):165-73, 2014.
- Jeffries E, Allen R, Gao J, Pesce M, and Wang Y. Highly Elastic and Suturable Electrospun Poly(Glycerol Sebacate) Fibrous Scaffolds. <u>Acta</u> <u>Biomater</u>. 18:30-9, 2015.

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