University of Pittsburgh

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Featured Inventors: Antonio D'Amore, PhD; Vinay Badhwar, MD; William Wagner, PhD

The Self Generating Heart Valve

A micro-mechanically designed, permanent, living, human heart valve replacement.

Value Proposition

For patients affected by heart valve diseases who require a full valve replacement, the OneValve technology provides a novel heart valve prosthesis which unlike the commercially available mechanical and bioprosthetic heart valves is non-thrombogenic, durable, and capable of reducing the risk of calcification and endocarditis. This product functions in all 4 valves positions therefore it has the flexibility to address the entire $4.9 billion market for heart valve replacement.

Market Opportunity

Over 83k life-saving prosthetic valve operations were performed in the US in 2014 with a cost of $164k/procedure. The global valve market is expected to surpass $ 4.9 billion in 2017. There are two types of prosthetic heart valve for replacement: mechanical and bioprosthetic. Mechanical valves are durable. However, these valves require anticoagulant therapy because of an increased risk of thrombosis. Bioprosthetic valves do not require anticoagulant therapy. However, bioprostheses have drawbacks such as limited durability due to calcification. Our prototype, a FDA class III device introduces potential savings of $ 2.9 billion/year.

Competitive Landscape

The heart valve technology landscape is characterized by a small group of large companies controlling > 90% of the global market and by a number of start-up or university spin-off companies still at product development or "first in man" stage. Key players include: Medtronic, Boston Scientific, St Jude Medical, Edwards LifeSciences, Cryolife/On-X and Xeltis. Due its main features (e.g. reduced risk of thrombosis, endocarditis and calcification), *OneValve* technology has a significant competitive advantage. However, due to barriers to entry, *OneValve's* path to market will involve partnership with major valve manufacturing companies.

IP Landscape

-PCT/US2016/019837, (WO 2016/138416 A1, 09/2016);
-PCT/US2016/019849, (WO 2016/138423 A1, 09/2016);

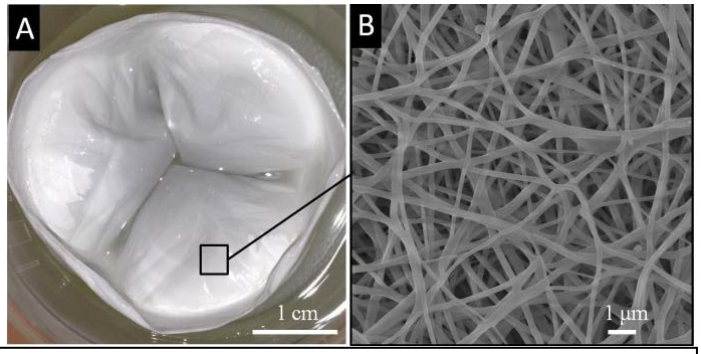

Figure 1. A) OneValve: polyurethane fibrous, stentless tri-leaflet valve mimicking native valve anatomy, mechanics and micro-structure. **B)** Scanning Electron Microscopy: polyurethane micro-fibers in OneValve device fully recapitulating native heart valve morphology

Technology

OneValve introduces a novel polymer processing technique which enables to fabricate micro-fibers based, fully assembled tri-leaflet valve with desired shape and size. The key mechanism of action for this technology is based on the notion of endogenous tissue growth, a process where the medical device material is gradually replaced by functional tissue produced by the patient own cells that have been recruited *in situ*. The formation of functional tissue not only impacts on the calcification mechanism but also, by allowing for the formation of endothelial cells layer on the device surface, reduces the device thrombogenicity.

Stage of Development

Our data on polycarbonate urethane-urea (PCUU) showed good motility, cellular infiltration, limited to no calcification and thrombus formation at 16 weeks on a single pulmonary valve leaflet ovine model. In addition, *in vitro* and in *silico studies* provide evidence of our capacity to fully control valve mechanics and micro-structure. The next step to further de-risk this technology is confirming the positive outcomes (e.g. valve function, lack of thrombus formation and calcification) of the previous single leaflet animal study conducting a second *in vivo* study which utilizes our tri-leaflet valve technology.

Funding

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FEATURED INVENTORS:

Antonio D'Amore, PhD

- Researcher associate with experience (10 years) at senior level, focus on Tissue Engineering, Biomaterials and Biomechanics;
- Departments of Bioengineering and Surgery, McGowan Institute for Regenerative Medicine, University of Pittsburgh;
- RiMED Foundation fellow;

Education

-PhD in biomechanics and tissue engineering. University of Pittsburgh and University of Palermo.

-MSc Biomedical Engineering, Imperial College London

-MSc Mechanical Engineering, University of Palermo

Publications

1. **D'Amore**, et al. Bi-layred polyurethane-extracellular matrix cardiac patch improves ischemic ventricular wall remodeling in a rat model. Biomaterials 2016 (107), 1–14, *IF 8.415*.

2. **D'Amore**, et al. Large strain stimulation enhances extracellular matrix production and stiffness in an elastomeric scaffold model. Journal of the Mechanical Behavior of Biomedical Materials 2016 (62), 619–635, *IF 3.47*.

3. **D'Amore**, et al. From single fiber geometry to macro-mechanics: A structural finite-element model for elastomeric fibrous biomaterials. Journal of the Mechanical Behavior of Biomedical Materials 2014, 39, 146–161, *IF 3.47*.

4. **D'Amore**, et al. Characterization of the Complete Fiber Network Topology of Planar Fibrous Tissues and Scaffolds. Biomaterials 2010; 31:(20) 5345-5354, *IF 8.415*.

William R. Wagner, PhD

- Director of the McGowan Institute for Regenerative Medicine
- Professor of Surgery, Bioengineering and Chemical Engineering at the University of Pittsburgh
- Scientific Director of the NSF Engineering Research Center on "Revolutionizing Metallic Biomaterials"
- Chief Science Officer for the Armed Forces Institute of Regenerative Medicine
- Editor-in-Chief, *Acta Biomaterialia*
- Chairman for the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Americas region
- Fellow of the American Institute for Medical and Biological Engineering (AIMBE)
- Fellow of the Biomedical Engineering Society, the International Union of Societies for Biomaterials Science and Engineering, TERMIS, and the American Heart Association

Education

- BS Chemical Engineering, Johns Hopkins University
- PhD Chemical Engineering, University of Texas

Publications

1. Ye SH, Hong Y, Sakaguchi H, Shankarraman V, Luketich SK, D'Amore A, **Wagner WR**: Non-thrombogenic, biodegradable elastomeric polyurethanes with variable sulfobetaine content. *ACS Appl Mater Interfaces* 6:22796-806 (2014).
2. Hobson CM, Amoroso NJ, Amini R, Ungchusri E, Hong Y, D'Amore A, Sacks MS, **Wagner WR**: Fabrication of elastomeric scaffolds with curvilinear fibrous structures for heart valve leaflet engineering. *J Biomed Mater Res A* 103:3101-6 (2015).
3. Yoshizumi T, Zhu Y, Jiang H, D'Amore A, Sakaguchi H, Tchao J, Tobita K, **Wagner WR**: Timing effect of intramyocardial hydrogel injection for positively impacting left ventricular remodeling after myocardial infarction. *Biomaterials* 83:182-93 (2016).
4. D'Amore A, Yoshizumi T, Luketich S, Wolf M, Gu X, Cammarata M, Hoff R, Badylak S, **Wagner WR**: Bi-layered polyurethane – Extracellular matrix cardiac patch improves ischemic ventricular wall remodeling in a rat model. Biomaterials 107:1-14, (2016).

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