OneValve: The Self Generating Heart Valve

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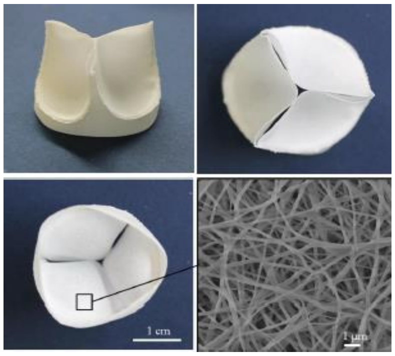
Over 110,000 heart valve replacements are performed for heart valve disease annually in the United States, with the global market surpassing $5 billion this year (2018). Two main classes of prosthetic valves currently service this market: mechanical and bioprosthetic. Mechanical valves, while durable, are prone to blood clots and require expensive and risky lifelong anticoagulation. Bioprosthetic valves do not require anticoagulation, yet they have limited durability requiring costly and dangerous re-interventions. *OneValve* technology provides a novel, innovative heart valve prosthesis that is non-thrombogenic, durable, and capable of resisting calcification and endocarditis. *OneValve* heart valves can be used for all 4 valve positions and have distinct advantages that will disrupt both the mechanical and bioprosthetic heart valve markets.

Technology Description

OneValve introduces a novel biopolymer processing technique which enables fabrication of a micro-fiber based, fully assembled heart valve with desired shape, size, and mechanics. Polycarbonate urethane-urea (PCUU) is used in our novel processing method to fabricate both stented and non-stented valve prothesis for all valve positions. 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's own cells recruited in situ. The formation of functional tissue reduces calcification, but also allows for the formation of an endothelial cell layer on the device surface, reducing thrombogenicity.

Advantages

- Non-thrombogenic degradable polyurethane valve does NOT require anti-coagulation (unlike current mechanical valves)
- Polymeric valve capable of tissue regeneration resists degeneration/calcification (unlike current bioprosthetic valves)
- Stentless or stented design configurations make surgical implantation easy
- Elastomeric valves suitable for minimally invasive/transcatheter implantation
- Regenerative properties will allow for somatic growth, ideal for pediatric/young adult applications to avoid multiple re-operations



Applications

- Platform for construction of stentless and stented biomimetic polymeric heart valve prosthetics for all four native valve position
- Orthopedic, Vascular, Gastrointestinal, Tracheal, Muscle/Fascial applications exist for the polymer processing technique for market expansion

Stage of Development

OneValve PCUU material demonstrated good leaflet motility, no thrombus formation, cellular infiltration, and no calcification at 16 weeks in an ovine single pulmonary leaflet replacement study. *In Vitro* studies demonstrate control of microstructure and valve mechanics. An *in vivo* study recently demonstrated good acute (12 hour) function via echocardiography, no thrombosis, and structural integrity of a fully developed stented pulmonary valve in the porcine model. Planning is underway for chronic studies of the full valve device to characterize function, material degradation, and cell infiltration.

IP Status

6 patent applications cover polymer processing methods, valve deployment, chordae/suture products (US 16/071,243, US 15/553,811, US 15/553,799, PCT/US2018/017795, PCT/US2048/022863, PCT/US2018/019358, US provisional 62/663,721, as well as Canadian, European, and Japanese patent applications

Funding/Key Publications

NIH #HL069368 ($5M), RiMED Foundation ($1M), McGowan Foundation ($1M), Pitt CTSI ($50k), Coulter Translational Partners ($100k)

- **D'Amore**, Luketich, Raffa, Olia, Menallo, Mazzola, D'Accardi, Grunberg, Gu, Pilato, Kameneva, Badhwar, **Wagner**. Heart valve scaffold fabrication: bioinspired control of macro-scale morphology, mechanics and micro- structure. Biomaterials 2018, 150, 25-37.
- **Coyan**, **D'Amore**, Matsumura, Pedersen, Luketich, Shanov, Katz, David, **Wagner**, Badhwar. In Vivo Functional Assessment of a Novel Degradable Metal and Elastomeric Scaffold-Based Tissue Engineered Heart Valve. Journal of Thoracic and Cardiovascular Surgery, in press 9/2018.

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