



Novel Percutaneous Aortic Heart Valve and Delivery System

Contact

Pedro "Peter" Hernández
Director, Technology Management
and Commercialization
Florida International University
11200 SW 8th St., MARC 440
Miami, FL 33199
Tel: 305-348-0008
Fax: 305-348-0081
E-mail: pedro.hernandez7@fiu.edu

Inventors

- Richard Schoepfoerster, Ph.D.
- Thomas Claiborne, M.S.

Field

- Cardiology
- Medical Device

Technology

Revolutionary percutaneous heart valve (PHV) products:

- A more durable artificial aortic valve with the beneficial properties of a natural tissue valve
- A catheter delivery system which can be used with any percutaneous valve

Key Benefits and Features

- Superior to mechanical and tissue valves
- Less stressful on patient health
- Payer friendly
- Allows physicians more time for patients

Stage of Development

Prototype developed and validated

Status

Seeking development and commercialization partners

Patent Applications Filed

PCT and US on properties of the heart valve and delivery system

Two products have been developed at FIU which are significant improvements over both open heart surgery, and other percutaneous Heart Valve (PHV) technologies. One product is a percutaneous artificial valve which has the beneficial properties of a natural tissue valve, while lacking the negative properties of a mechanical valve. The other is a catheter delivery system which can be used with any percutaneous valve.

Product and Technology

According to the American Heart Association's 2006 Heart and Stroke Statistical Update, valvular heart disease is responsible for nearly 20,000 deaths each year in the United States and is a contributing factor in about 42,000 deaths, with a majority of these cases involving disorders of the aortic valve (63 percent). Unfortunately, many of these deaths could have been prevented had there been a viable alternative to open heart surgery.

Developers of percutaneous approaches to heart valve replacement are solving some of the current problems of open heart surgery, but have yet to address others. Therefore we set out to develop innovative products which address the challenges of other percutaneous procedures. Our research led us to two products.

1) A catheter deliverable artificial trileaflet heart valve prosthesis or percutaneous heart valve (PHV): Our PHV is comprised of two main elements; (a) an artificial polymer-based composite leaflet material; and (b) a self-expanding metal alloy stent or support/fixation structure.

Our prototype currently utilizes a super-biostable polymer and a commercially available polyester mesh; however other polymers can be utilized. The stent is composed of super-elastic Nitinol wire, which has excellent biocompatibility and mechanical properties. Testing has indicated that our prototype is equally or more effective than our competitors.

2) A catheter-based percutaneous heart valve delivery system: This PHV delivery system is designed to complement any self-expandable PHV. It is comprised of a PHV crimping/loading tool, a catheter designed to facilitate PHV deployment, and a control hand piece that allows remote PHV deployment and catheter tip deflection or steering. Key features in our design are the crimping tool and the steering feature. There are no commercially available equivalents for the system at present.

We have designed both products to be compatible with other products. Currently we are performing further bench testing, and are looking to enter animal trials.

Market Potential

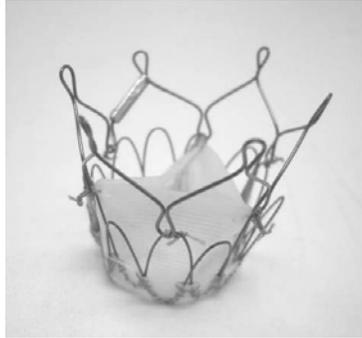
Leading PHVs are presently in clinical trials. It is predicted that percutaneous procedures will grow significantly within the next five years, and that the total market for valve procedures will grow as well. In 2004 the U.S. artificial aorta valve market was estimated to be about \$280 million a year. Edwards Lifesciences predicts this number to grow to \$800 million by 2014. However, one company in specifically in PHV space, has already been purchased for \$700 million in 2009, prior to FDA approval of their technology. Indicating that growth predictions are greater than previously anticipated.

Summary

When compared open heart surgery using both tissue and mechanical valves, the percutaneous approach has a shorter recovery time and hospital stay, does not require anti-coagulant drugs, and is less than ¼ of the cost (\$25k vs. \$120k). The successful implementation of PHV technology is expected to supplant open chest valve replacement as the gold standard.

Our percutaneous valve is very competitive as it 1) uses an artificial base valve, which can last more than 10 years and 2) does not require ballooning dilation, rapid pacing of the heart nor anti-coagulant drugs, when compared to competitors and state of the art procedures.

Percutaneous Heart Valve (PHV)



PHV Delivery System

