Title: Hydrodynamic Assessment of a Small Intestinal Submucosa Tubular Aortic Valve

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Objective:

For young children with critical valve defects, and for older patients who are contra-indicated for receiving mechanical and bioprosthetic valves, treatment options are extremely limited. The purpose of this study was to determine whether tubular porcine small intestinal submucosa (PSIS) bio-scaffold valves can facilitate robust aortic valvular hydrodynamic function and serves as a potential treatment option for the aforementioned patient sub-sets.

Methods:

A 26-mm PSIS tubular valve (CorMatrix Cardiovascular Inc., Roswell, GA) was sutured to a custom, 3-D printed valve holder along its ring and its three posts on the distal end (120^o separation distance; Fig. 1A). Hydrodynamic testing was performed using a pulse duplicator system (Vivitro Labs Inc., Victoria, BC, Canada) filled with 0.9% saline solution, with the PSIS valve mounted in the aortic position. A flow probe was affixed between the aortic and ventricular chamber and pressure transducers were inserted in the atrial, ventricular, and aortic locations (AMpack, Vivitro Labs). Tests utilized a stroke volume of 71.4 mL, heart rate of 70 BPM, and input flow waveform comprising of a 35% systolic-65% diastolic configuration (S35 Waveform, Vivitest software, Vivitro Laboratories).

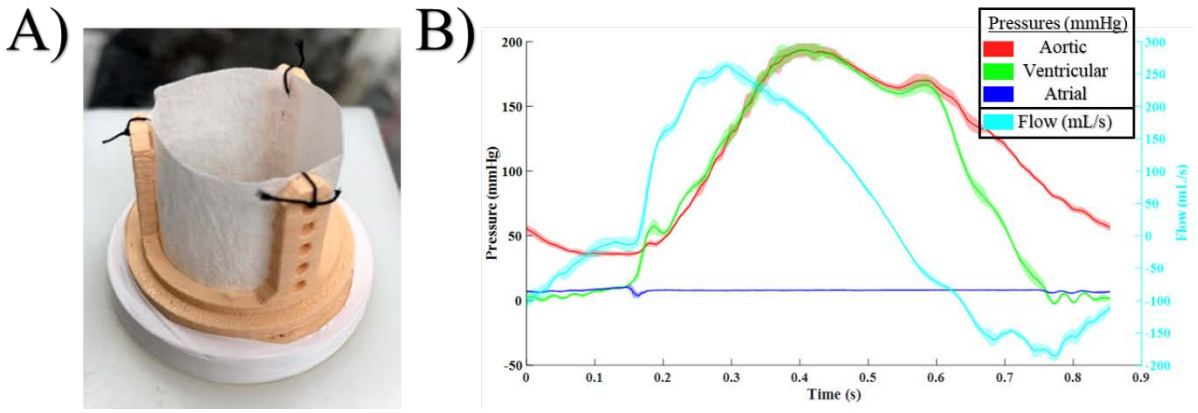

Figure 1: A) Tubular PSIS valve sutured on ring with three posts at 120 degrees apart. B) Pressure and flow waveforms averaged over 10 cardiac cycles.

Results:

Tests revealed a root mean square volumetric flow rate (Q_{RMS}) of 182 mL/s, an effective orifice area (EOA) of 0.73 cm^2, transvalvular pressure gradient of 27.64 mmHg and a regurgitation factor (RF) of 9%. While the pressure gradient was higher than bioprosthetic valves previously tested in our laboratory under similar conditions, ~15.9 mmHg, it was substantially less than clinical critical aortic valve stenosis (>40 mmHg; *Lancellotti P, Seisyou K., J. Echocardiog, 12, pp12-16, 2014*).

Conclusions:

The tubular PSIS aortic valve may facilitate robust hydrodynamic valve function and could also serve as a scaffold for *de novo* valvular tissue growth by the host after implantation.

Title: Hydrodynamic Assessment of a Small Intestinal Submucosa Tubular Mitral Valve

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Objective:

For young children with critical valve defects, and for older patients who are contra-indicated for receiving mechanical and bioprosthetic valves, treatment options are extremely limited. The purpose of this study was to determine whether tubular porcine small intestinal submucosa (PSIS) bio-scaffold valves can facilitate robust mitral valvular hydrodynamic function and serves as a potential treatment option for the aforementioned patient sub-sets.

Methods:

A 26-mm PSIS tubular valve (CorMatrix Cardiovascular Inc., Roswell, GA) was sutured to a custom, 3-D printed valve holder along its ring and its two posts on the distal end (150^{o} separation distance; Fig. 1A). Hydrodynamic testing was performed using a pulse duplicator system (Vivitro Labs Inc., Victoria, BC, Canada) filled with 0.9% saline solution, with the PSIS valve mounted in the mitral position. A flow probe was affixed between the atrial and ventricular chamber and pressure transducers were inserted in the atrial, ventricular, and aortic locations (AMpack, Vivitro Labs). Tests utilized a stroke volume of 71.8 mL, heart rate of 70 BPM, and input flow waveform comprising of a 35% systolic-65% diastolic configuration (S35 Waveform, Vivitest software, Vivitro Laboratories).

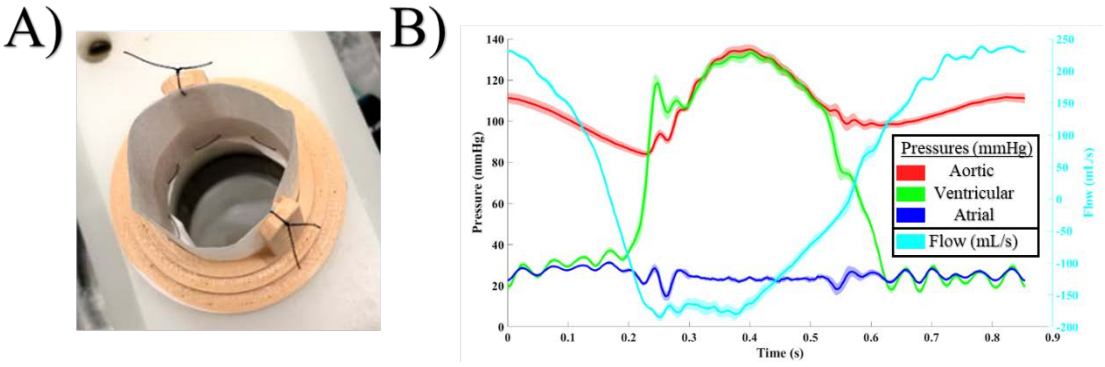

Figure 1: A) Tubular PSIS valve sutured on ring with two posts at 150 degrees apart. B) Pressure and flow waveforms averaged over 10 cardiac cycles.

Results:

Tests revealed a root mean square volumetric flow rate (Q_{RMS}) of 139 mL/s, an effective orifice area (EOA) of 1.18 cm^2, transvalvular pressure of 6.88 mmHg and a regurgitation factor (RF) of 16%. While the RF was higher than bioprosthetic valves (RF ~ 6.5%; unpublished observation performed under similar conditions in our laboratory), it was nonetheless considerably less compared to clinically categorized mild mitral valve RF of < 30% (*Zoghbi W, et al, J. American Society of Echocardiography, 16(7), pp.777-802, 2003*).

Conclusions:

The tubular PSIS mitral valve appears to facilitate robust hydrodynamic valve function and may concomitantly serve as a scaffold for *de novo* valvular tissue growth by the host after implantation.