

Title: Tricuspid versus Mitral Performance of Cylindrical Porcine Small Intestinal Submucosa Valves

Authors:

Chia-Pei Denise Hsu¹, Asad Mirza¹, Robert Matheny², Sharan Ramaswamy¹

¹Department of Biomedical Engineering, Florida International University, Miami, FL 33174

²CorMatrix Cardiovascular Inc., Roswell, GA 30076

Objective:

Treatment options are extremely limited for children and older patients who are contra-indicated for receiving mechanical or bioprosthetic valves. The purpose of this study is to determine whether cylindrical porcine small intestinal submucosa (PSIS) bio-scaffold valves can facilitate robust valvular function in the mitral after having undergone recent clinical experience in the tricuspid location.

Methods:

A 26-mm PSIS cylindrical valve (CorMatrix) was sutured to a 3D printed valve holder along three posts at 120 degrees apart on the distal end. The annulus ring was sealed with a 3D printed cap. Hydrodynamic testing of valves mounted in mitral and tricuspid positions were performed using a pulse duplicator system (Vivitro) with 0.9% saline solution. A flow probe was affixed between atrium and ventricular chambers, and pressure transducers were inserted in the atrial, ventricular, and aortic locations. Tests utilized heart rate of 70 BPM, an input waveform comprising of a 35% systolic-65% diastolic configuration (Vivitest), and a stroke volume of 50 mL for tricuspid and 71.4 mL for mitral conditions.

Results:

Valve performance in the tricuspid position showed root mean square volumetric flow rate (Q_{RMS}) of 72.75 mL/s, transvalvular pressure gradient (ΔP) of 2.47 mmHg, effective orifice area (EOA) of 1.11 cm², and regurgitation factor (RF) of 6.84%. In the mitral position, the results showed Q_{RMS} of 101.75 mL/s, ΔP of 0.395 mmHg, EOA of 2.48 cm², and RF of 13.75%.

TRICUSPID				
Valve Type (Normal)	Regurgitation Factor (%) (< 30)	ΔP (mmHg) (< 5)	Q_{RMS} (mL/s) (< 225)	EOA (cm ²) (> 1)
*PSIS (N=4)	6.84 ± 0.62	2.47 ± 0.92	72.75 ± 1.05	1.11 ± 0.24
Mechanical	4.91	1.89	74.7	1.05
Bioprosthetic	8.73	0.8	72.76	1.57

MITRAL				
Valve Type (Normal)	Regurgitation Factor (%) (< 30)	ΔP (mmHg) (< 10)	Q_{RMS} (mL/s) (< 712)	EOA (cm ²) (> 1)
*PSIS (N=4)	13.75 ± 0.71	0.395 ± 0.13	101.75 ± 0.44	2.48 ± 0.35
Mechanical	3.71	2.08	101.42	1.36
Bioprosthetic	10.41	1.88	103.37	1.46

*Mean ± SEM

Figure 1: Tricuspid and mitral flow and pressure comparisons

Conclusions:

Data show clinically acceptable hydrodynamic performance of PSIS valves with comparable pressure gradient, flow rate, and EOA to clinically available mechanical and bioprosthetic valves. The PSIS valve from CorMatrix shows a greater EOA and smaller pressure drop, but a larger regurgitation in the mitral compared to tricuspid conditions. Hence transitioning the PSIS valve from its current tricuspid applications to the mitral appears feasible, with a minor concern in regurgitation, though not clinically remarkable.