

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

## Authors:

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## 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 Cardiovascular Inc.) was sutured to a custom, 3D printed valve holder along two (150°) or three (120°) posts on the distal end. The annulus ring was sealed with a 3D printed cap. Hydrodynamic testing of the valves mounted in mitral and tricuspid positions were performed using a pulse duplicator system (Vivitro Labs, Canada) using 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, input S35 waveform comprising of a 35% systolic-65% diastolic configuration (Vivitest, Vivitro Labs), with a stroke volume of 50 mL for tricuspid (Noordegraaf et al, 2019) and 71.4 mL for mitral conditions respectively.

## Results:

Valve performance results in the tricuspid position showed a root mean square volumetric flow rate ( $Q_{RMS}$ ) of 135 mL/s, a transvalvular pressure gradient ( $\Delta P$ ) of 3.97 mmHg, an effective orifice area (EOA) of 1.30 cm<sup>2</sup>, and a regurgitation factor (RF) of 7.70%. In the mitral position, the results showed a  $Q_{RMS}$  of 180 mL/s, a  $\Delta P$  of 8.27 mmHg, an EOA of 1.08 cm<sup>2</sup>, and an RF of 8.34%.

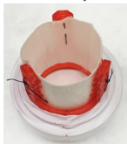

Valve Type	$Q_{RMS}$ (mL/s)	$\Delta P$ (mmHg)	EOA (cm <sup>2</sup> )	RF (%)
Tricuspid 	135	3.97	1.30	7.70
Mitral 	180	8.27	1.08	8.34

Figure 1: Tricuspid and mitral pressure and flow comparisons.

## Conclusions:

Preliminary data of cylindrical PSIS valves in both tricuspid and mitral positions show clinically acceptable hydrodynamics metrics of valve performance. Additional testing will help to establish statistical significances or lack thereof between the two valve groups.

**Reference(s):** Vonk Noordegraaf A, et al: Eur Respir J. 2019 Jan 24;53(1):1801900.

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