A Novel Approach for Aortic Valve Bicuspidization: Integrating Computational and Ex-vivo Simulation Concepts of Free-edge Leaflet Length in a modified Schäfer's procedure.

Objective: Bicuspidization repair of the congenitally diseased aortic valve has been shown to be a promising, durable technique. However, the optimal gross morphology of this repair has yet to be defined. This study introduces a novel repair technique that combines simulation concepts and free-edge leaflet length (FEL), utilizing a modified Schäfer's procedure, to investigate the impact of FEL variation and valve function in bicuspidization repair techniques.
Methods: Model bicuspid valves were generated with varying FEL via fluid-structure interactions (FSI) in a single patient-specific model geometry (1.1 to 1.8 times the diameter, Figure 1). Based on results (Figure 2,3), three representative models (1.2D, 1.57D, 1.8D) were replicated in explanted porcine aortic roots (n=3), using bovine pericardium to adjust leaflets to desired FEL, valves were compared to a previously validated bicuspid control model, all within the same root. Valves were tested on a validated ex-vivo univentricular system under physiological conditions (Figure 4). Outcomes included transvalvular gradient, regurgitation fraction, and orifice area. Linear mixed effects model and pairwise comparisons to analyze outcomes across FEL were employed.
Results: FSI simulations established a clear correlation between FEL and stenosis, with FEL less than 1.3 times the diameter resulting in significant stenosis (>10mm Hg). Ex-vivo analyses similarly showed significant decrease in aortic regurgitation, an increase of aortic orifice, and a reduction in stenosis in the 1.57D repair model ($p<0.01$) compared to the baseline as well as both the 1.2D and 1.8D repair models. Pairwise revealed 1.57D was associated with lower gradient not only when compared to the control and 1.2D but also to 1.8D ($p<0.01$). In contrast to simulated results, 1.8D exhibited more stenosis ($p<0.01$) increased regurgitation ($p=0.013$) compared to the 1.57D model, and smaller orifice area than both 1.2D ($p=0.04$) and 1.57D ($p<0.01$) models.
Conclusions: Achieving an optimal FEL is imperative to avoid stenosis in aortic valve bicuspidization repair. However, excessive FEL extension can result in unfavorable outcomes, such as stenosis and regurgitation. Future investigations are warranted to determine the ideal FEL range, assess the outcomes of extended FEL, evaluate the long-term durability of these repairs, and consider the influence of various anatomic variations on the repair process.

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Figure 1: Pressure gradients and flow rates in systole compared across multiple cases. Figure 2: Flows in mid systole. The cases with free edge rest lengths of 1.1d and 1.2d show obvious stenosis, reduced orifice area, and narrowed jets of forward flow. The case with free edge rest length 1.4d has considerably less restriction; the cases with 1.57d and 1.8d have no apparent stenosis or restriction to forward flow. Figure 3: Stenosis decreased with increasing Free Edge Length. Figure 4: Validated univentricular system utilized for ex-vivo analysis.

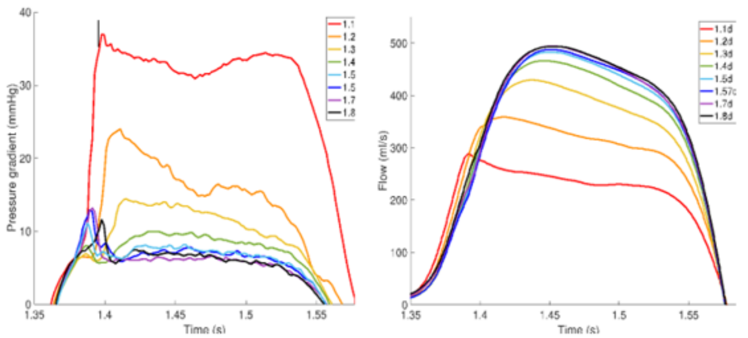

Figure 1

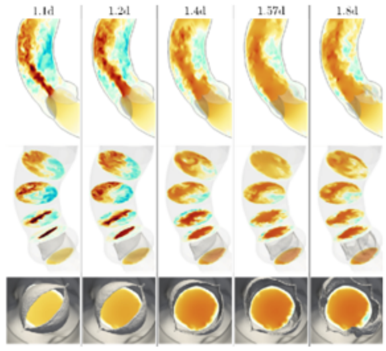

Figure 2

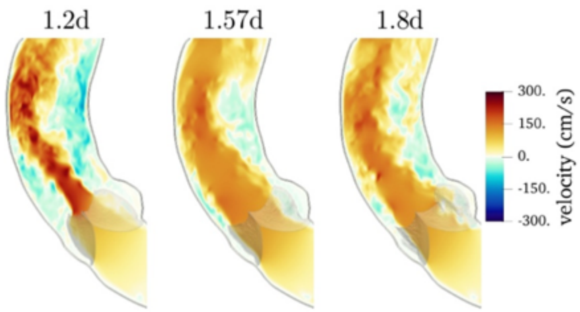

Figure 3

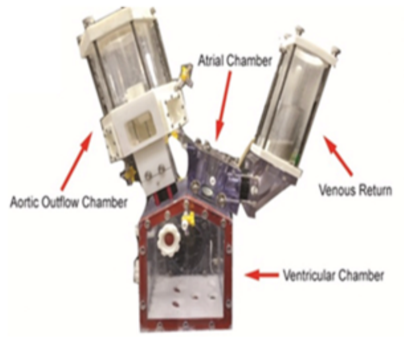

Figure 4