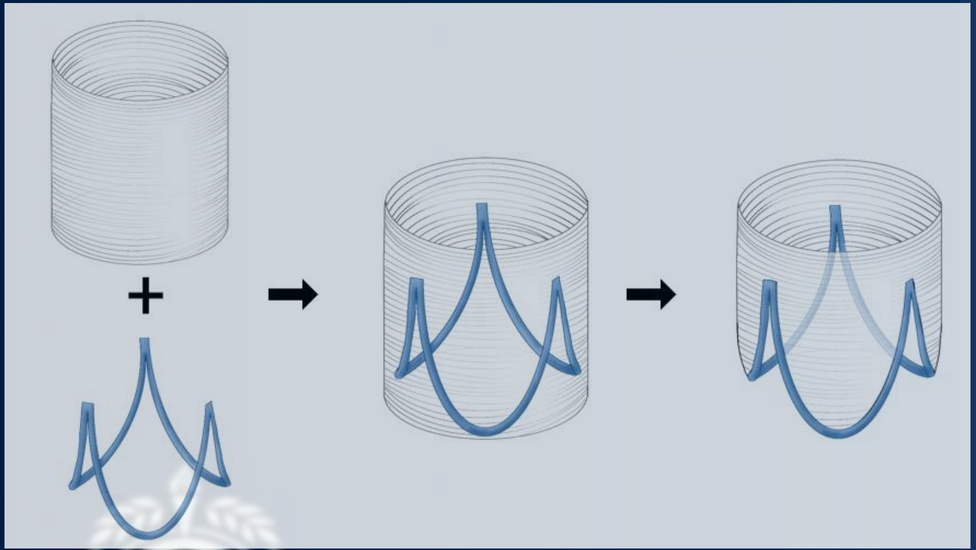
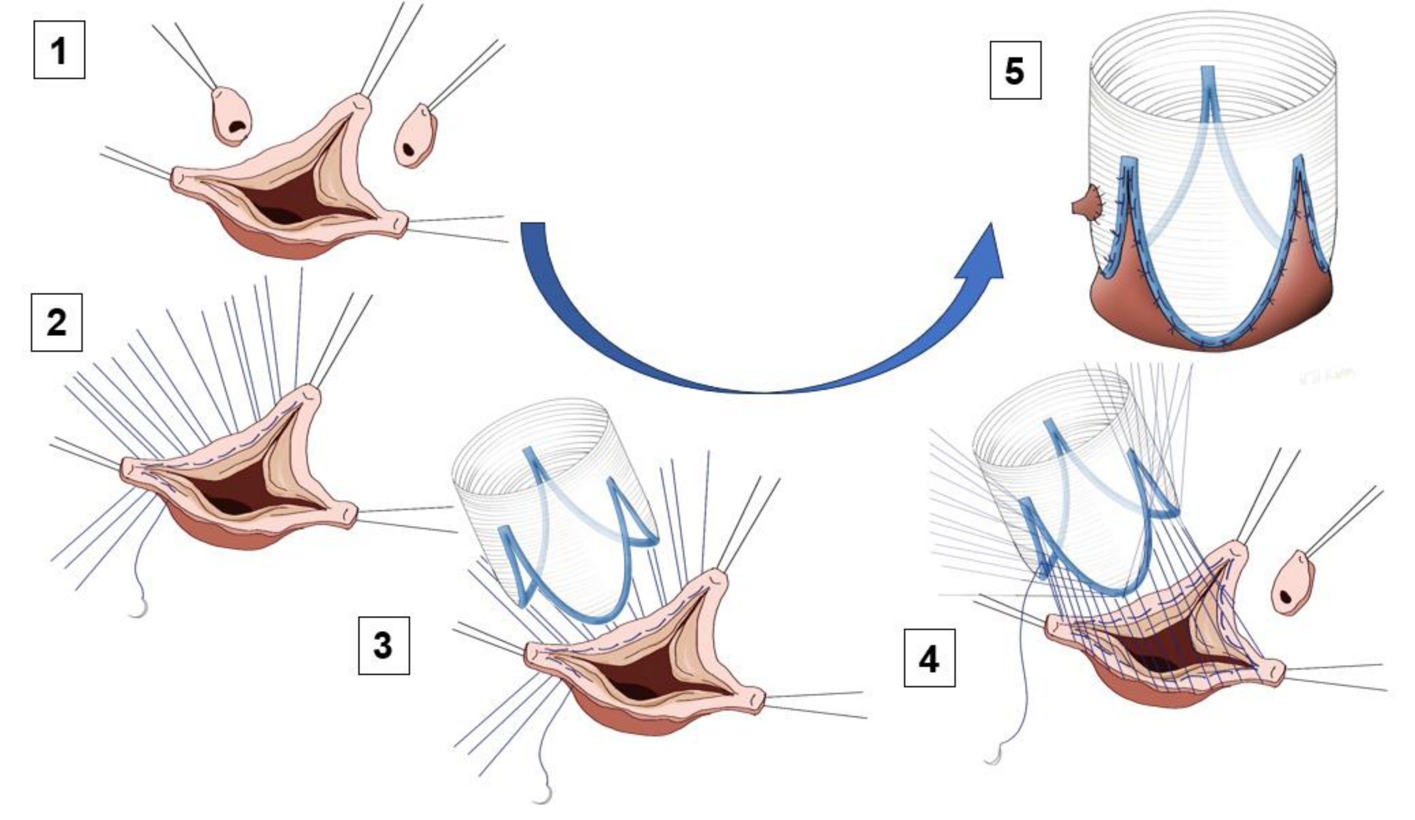
A Novel 3-D Reinforced Graft for VSARR: Hemodynamic Comparison with Conventional VSARRs Using Ex-Vivo Heart Simulator

Novel Reinforced Graft for VSARR



- VSARR is an effective technique to treat aortic root aneurysm or AR in cases with pliable cusps.
- However, it remains underutilized due to procedural complexity and difficulty in standardization.
- We developed a novel device consisting of (1) a rigid 3-D coronet-shaped aortic annular skeleton assembled with (2) a woven polyester graft

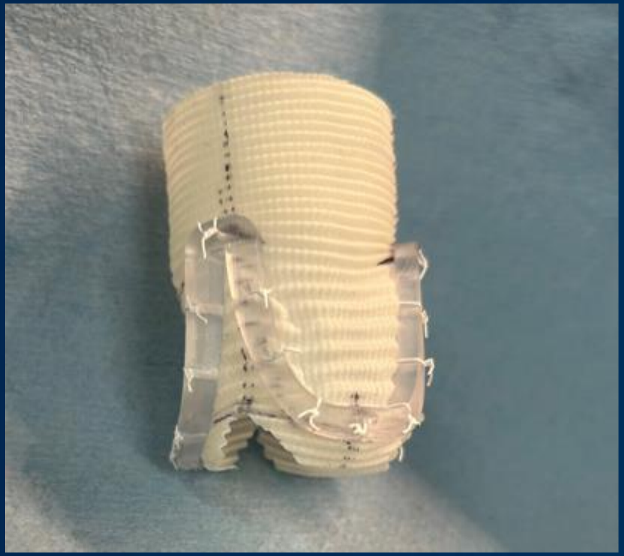
Device Concept and Procedural Flow

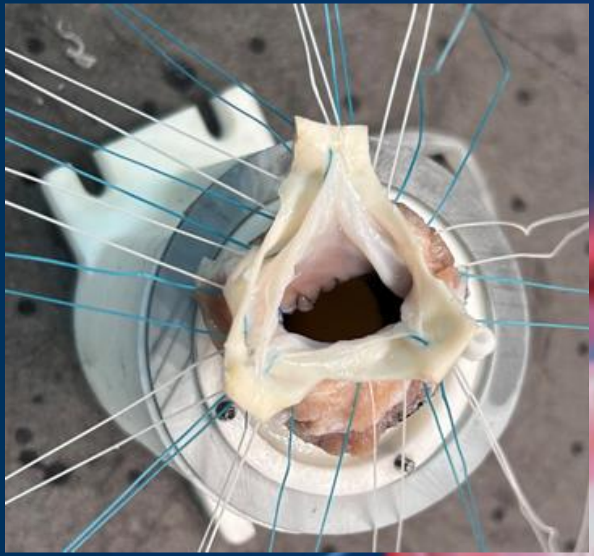


- This reinforced 3D frame is designed to attach to the basal ring of the root by a single-layer hemostatic line to obviate the need for basal layer stitches typically required in conventional root reimplantation.
- Without the basal layer stitch, the rigidity of the 3D ring is supposed to hold the basal ring preventing annular dilatation.

The Application of the Novel Device


3-D printed
coronet-shaped rigid ring


Final device:
assembled ringed graft


Anchoring stitches on
the trimmed aortic root


Completed VSARR
using the device

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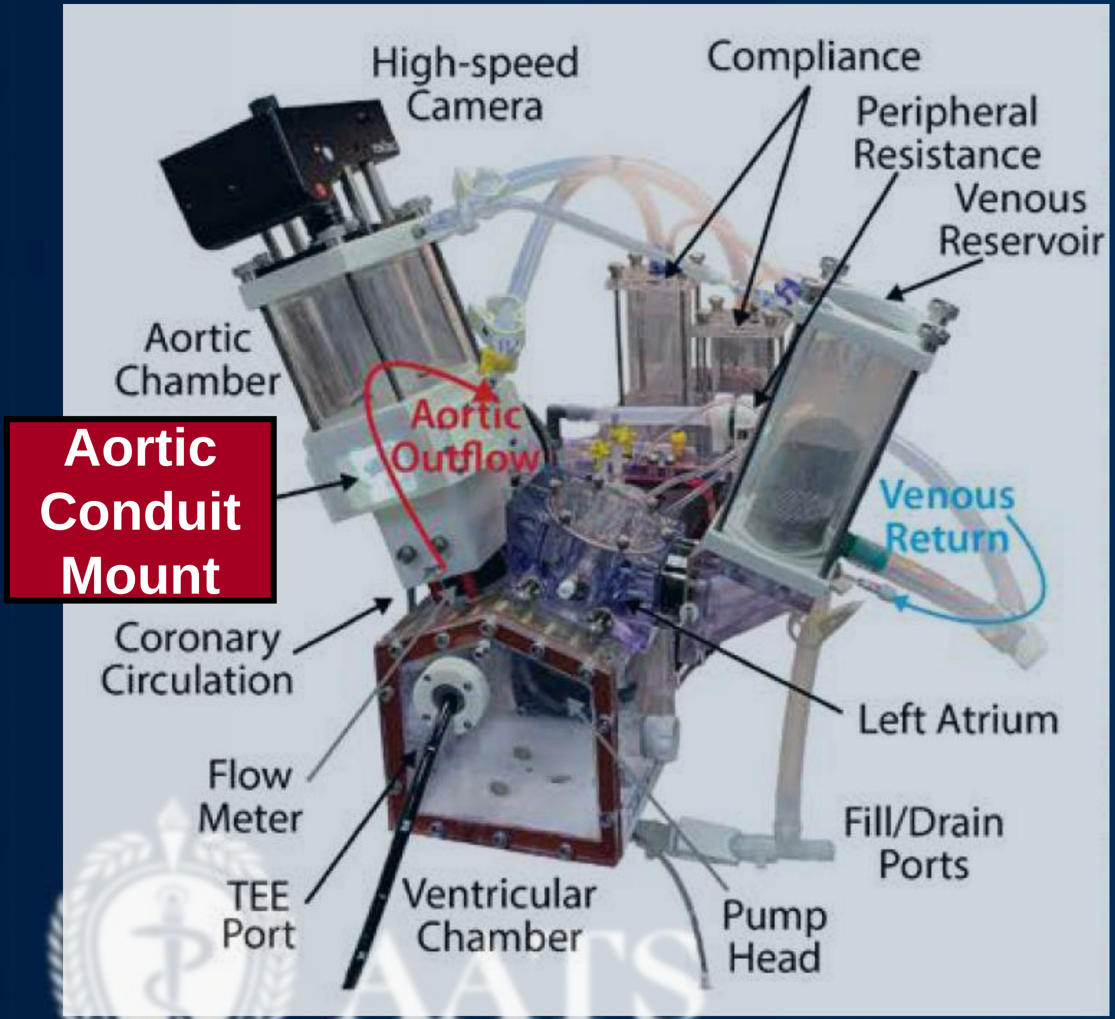
3-D Printed Ex-Vivo Left Heart Simulator



The system is comprised of a set of modular 3-D–printed chambers mounted to a pulsatile linear pump with several more adjuncts enclosed

(venous reservoir, a leakless disc valve in the mitral position, a series of compliance chambers, flow meters, a heat exchanger and a peripheral resistance valve).

The hemodynamic settings of the system are controlled by adjustments in compliance and resistance

(heart rate=70 beats/min; effective stroke volume=80mL/beat; cardiac output= 5.6L/min; systolic duration=50%; target mean blood pressure=100mmHg)

Direct measurement of hemodynamic parameters

Study Design and Endpoints

- **Primary Endpoint: Aortic regurgitation fraction** *(the most clinically relevant variable)*

- Final 5 samples in each group were determined *(**Total 15 samples** for comparisons)*

  Non-inferiority design assuming: mean AR fraction of 4.0%, standard deviation of 1.5%, threshold for a difference of 3%; Power=80%, Alpha=0.05 → ≥ 4 samples in each group are requires

- Using 5 porcine aortic roots, the novel (**Novel**), reimplantation (**David**) and remodeling (**Yacoub**) techniques were implemented in each of the 5 roots in randomized orders (28mm-straight graft for all) to set the baseline conditions identical.

- *Secondary Endpoints:*

  Trans-aortic mean pressure gradient, effective orifice area, trans-aortic energy losses (forward, closing, regurgitant and total) and procedural times

Baseline Characteristics

	Novel	David	Yacoub	P value
Anatomic parameters, mm				
Annular diameter	25.2±1.5	25.2±1.5	25.2±1.5	1.00
Commissural height	23.6±2.3	23.6±2.3	23.6±2.3	1.00
Geometric height, left cusp	25.8±8.6	25.8±8.6	25.8±8.6	1.00
Geometric height, right cusp	24.6±9.0	24.6±9.0	24.6±9.0	1.00
Geometric height, non-coronary cusp	25.2±8.7	25.2±8.7	25.2±8.7	1.00
Free-edge length, left cusp	37.0±10.4	37.0±10.4	37.0±10.4	1.00
Free-edge length, right cusp	38.8±10.5	38.8±10.5	38.8±10.5	1.00
Free-edge length, non-coronary cusp	38.0±10.0	38.0±10.0	38.0±10.0	1.00
Hemodynamic parameters				
Hear rate, bpm	70	70	70	1.00
Mean arterial pressure, mmHg	100.5±0.3	100.3±0.3	99.6±0.3	0.10
Systolic blood pressure, mmHg	124.2±0.9	124.4±1.0	124.3±1.6	0.97
Diastolic blood pressure, mmHg	78.7±0.7	79.6±0.8	78.5±1.4	0.20
Pump stroke volume, mL	109.9±0.1	109.9±0.1	111.94±4.5	0.39
Effective stroke volume, mL	81.5±1.4	78.9±1.8	80.49±3.6	0.28
Cardiac output, L/min	5.7±0.1	5.5±0.1	5.63±0.3	0.28

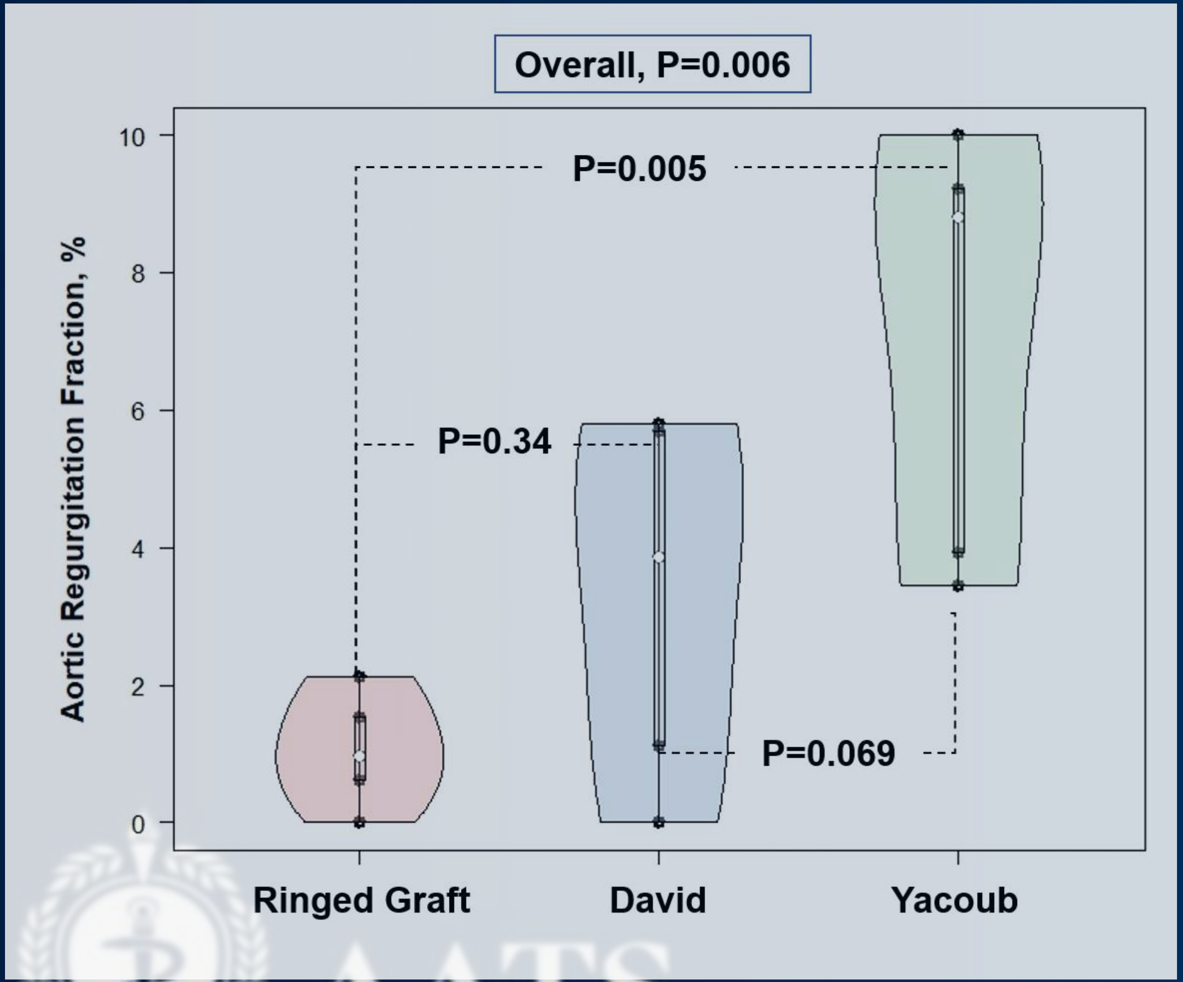
Results Summary

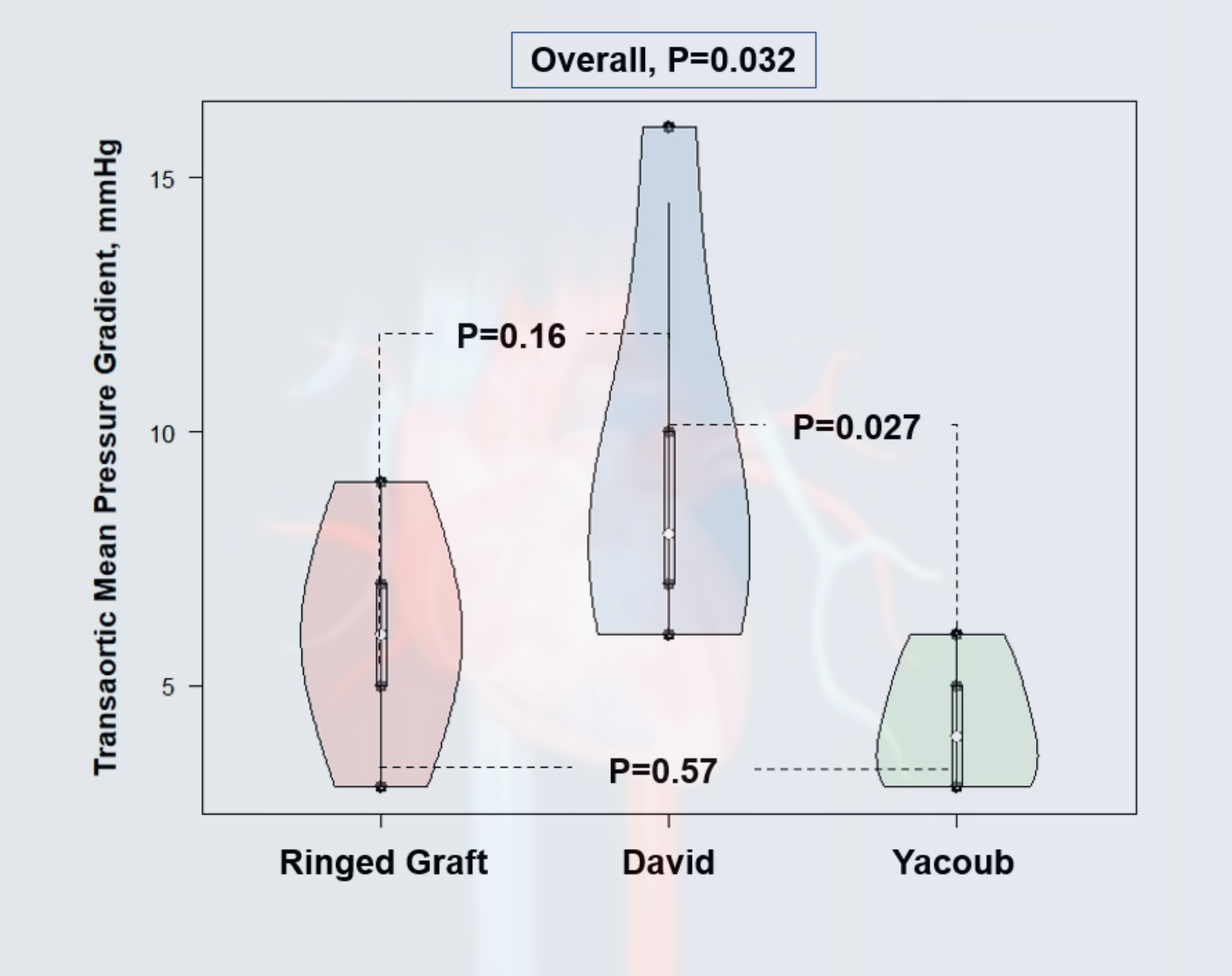
Primary Endpoint

	Novel	David	Yacoub	P value			
				Overall	Novel vs. David	Novel vs. Yacoub	David vs. Yacoub
Aortic regurgitation volume, mL	0.6±0.5	2.6±2.1	6.0±3.3	**0.009**	0.37	**0.007**	0.086
Aortic regurgitation fraction, %	**1.6±0.8**	**3.6±2.2**	**7.1±3.1**	**0.006**	0.34	**0.005**	0.069
Effective orifice area, cm^2	2.0±0.8	1.4±0.2	1.7±0.4	0.22	0.20	0.72	0.56
Trans-AV mean pressure gradient, mmHg	6.0±2.2	9.4±4.0	4.2±1.3	**0.032**	0.16	0.57	0.028
Trans-aortic energy loss, mJ							
Forward energy loss	118.0±88.5	259.2±97.9	65.0±22.9	**0.005**	**0.034**	0.54	0.005
Closing energy loss	8.0±7.0	11.3±4.2	20.8±8.1	**0.026**	0.72	**0.025**	0.100
Regurgitation energy loss	5.0±6.8	20.4±26.7	62.3±42.2	**0.024**	0.69	**0.023**	0.98
Total energy loss	127.2±93.5	283.9±89.9	190.0±127.3	0.099	0.085	0.62	0.36
Procedural time, min	23.2±6.2	37.8±8.5	15.2±2.3	**<0.001**	**0.008**	0.15	**<0.001**

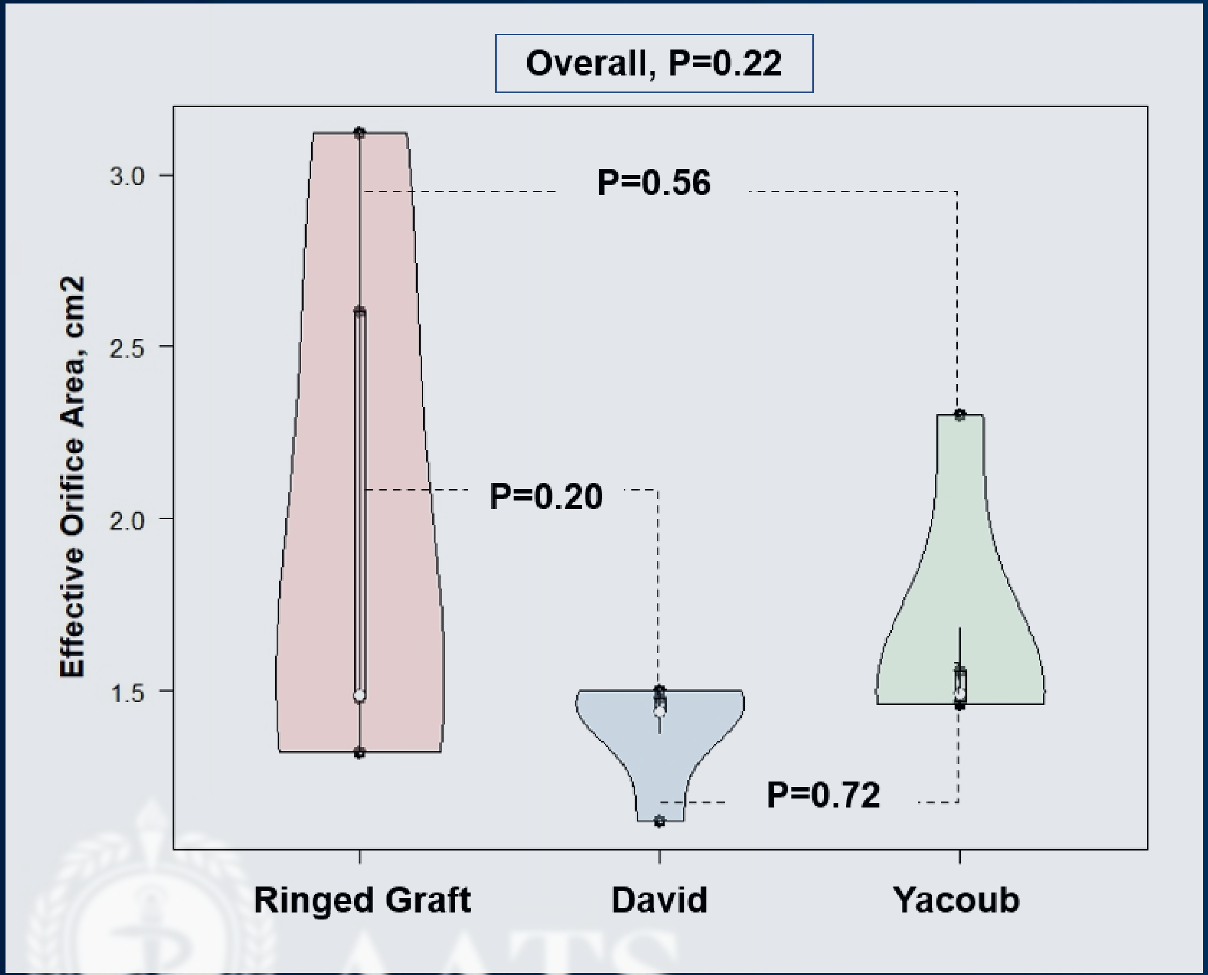
Fixed effect ANOVA for overall comparisons; Tukey honestly significant difference method for post-hoc comparisons

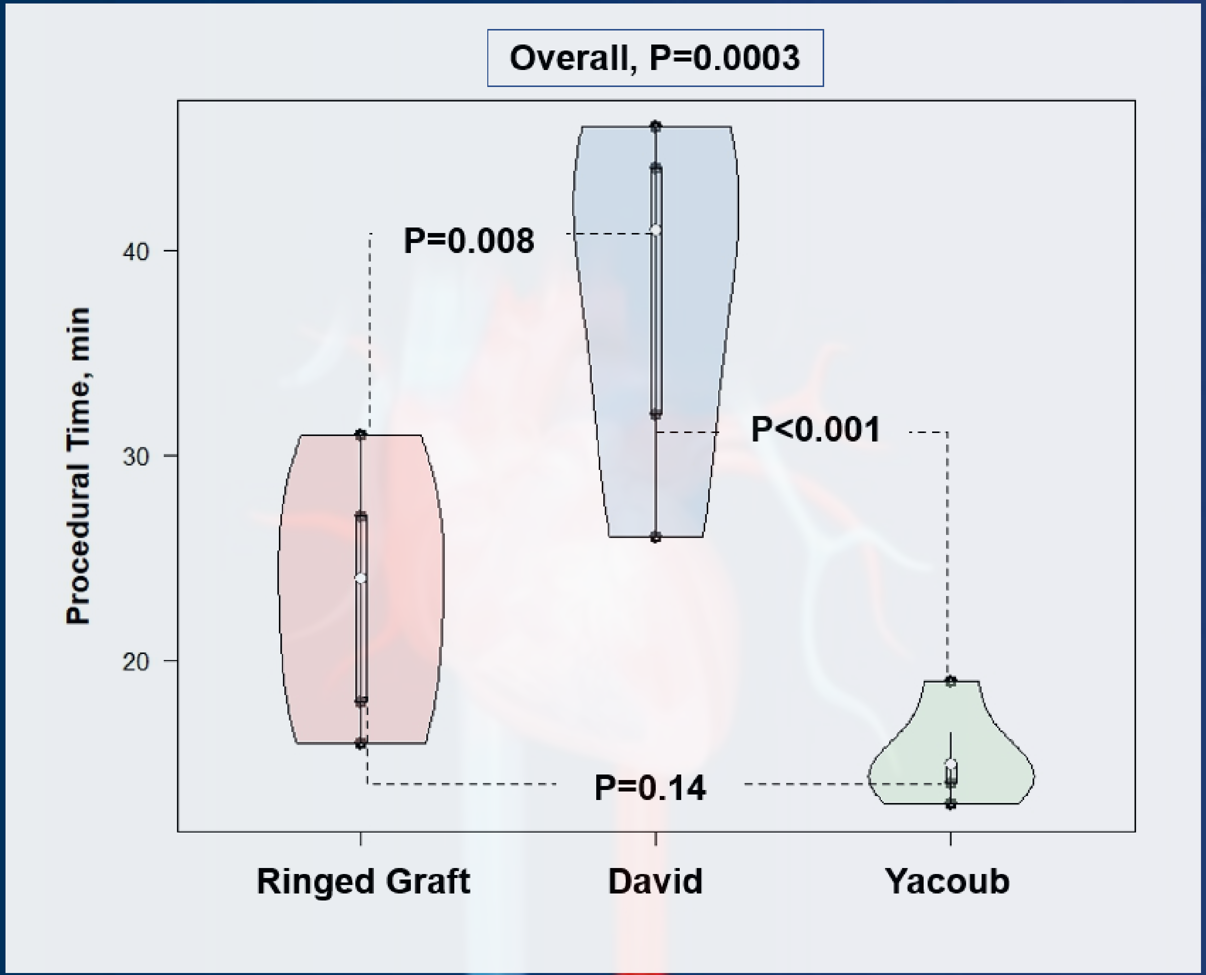
Aortic Regurgitation Fraction and Trans-aortic Mean Gradient



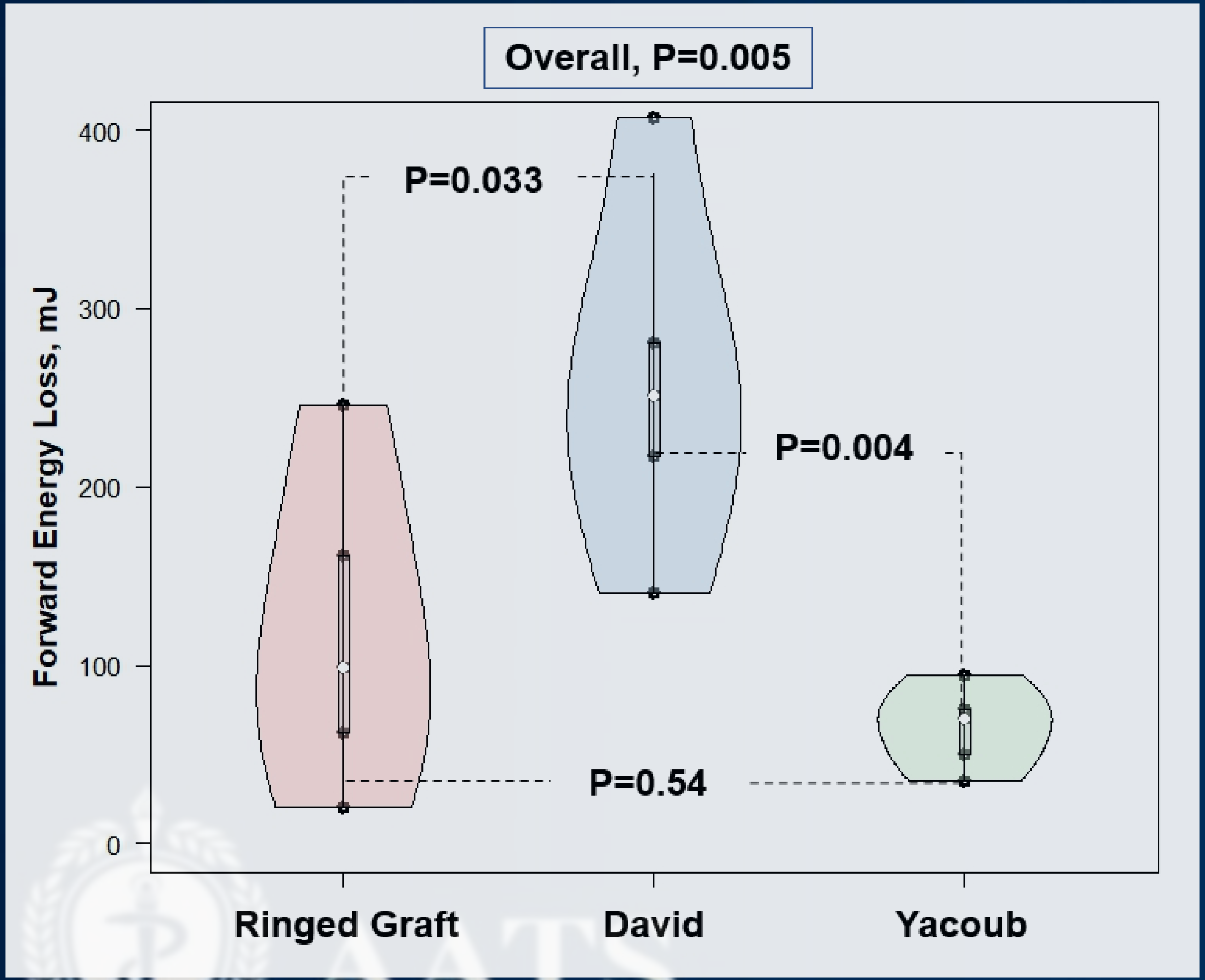


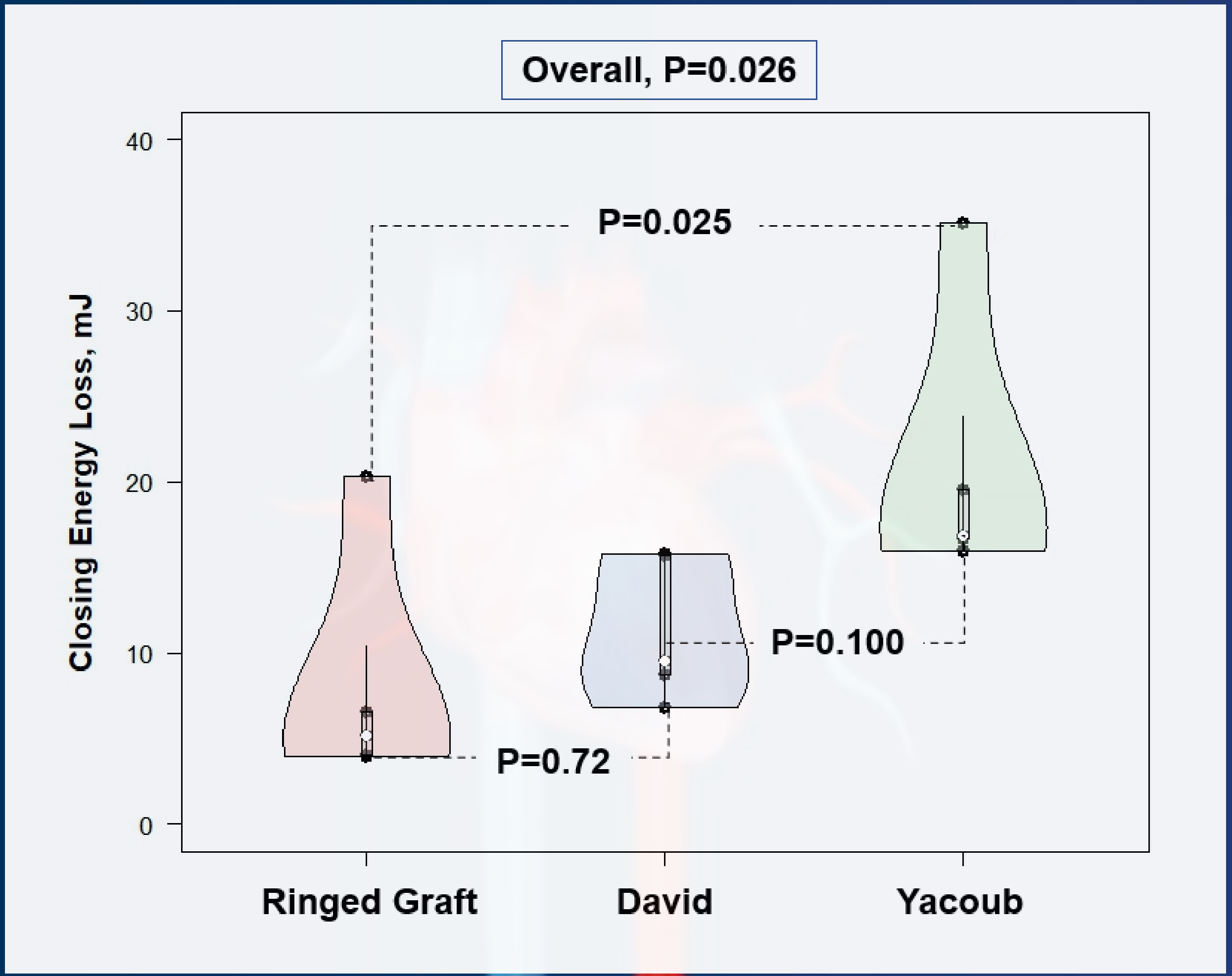
Effective Orifice Areas and Procedural Times



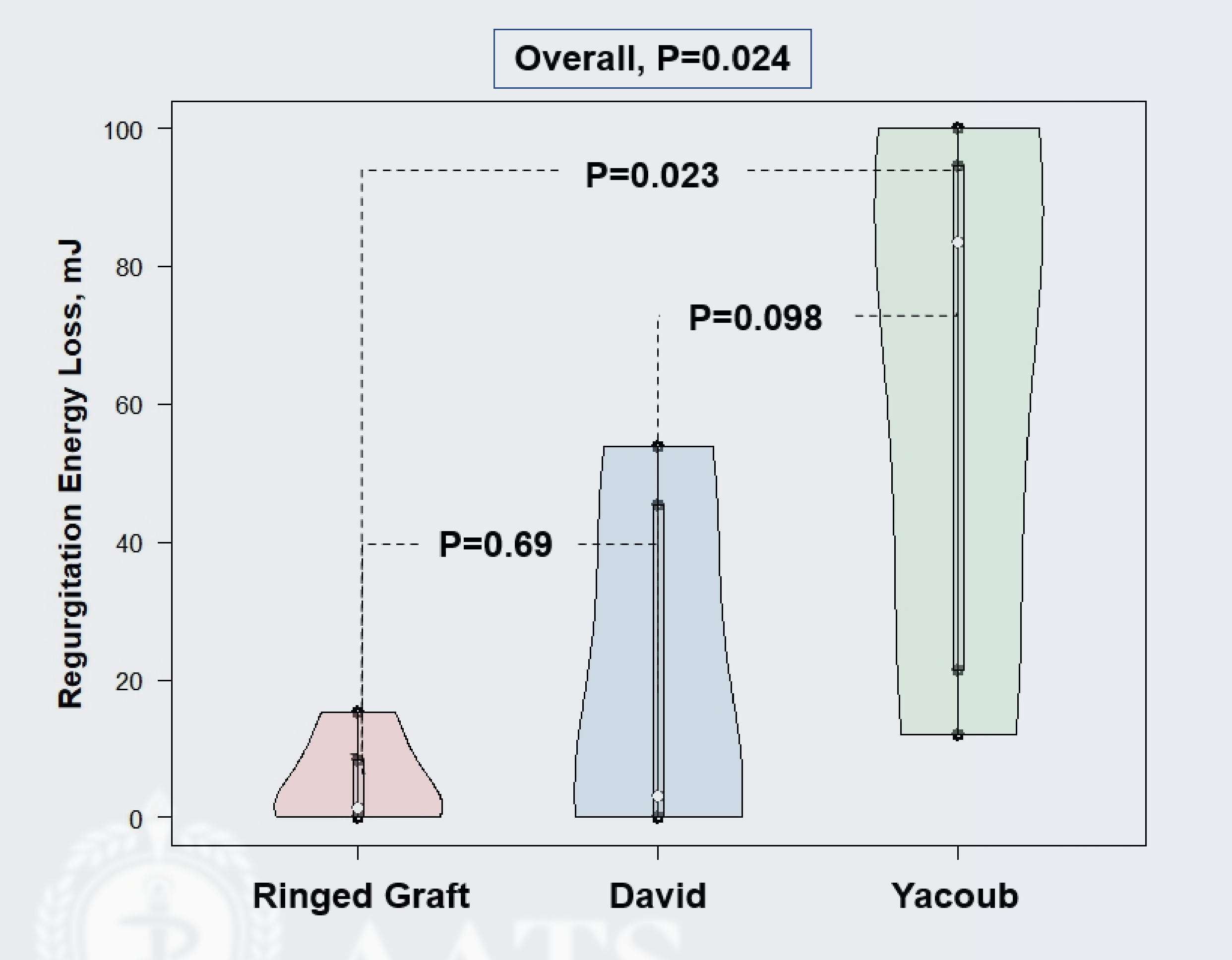


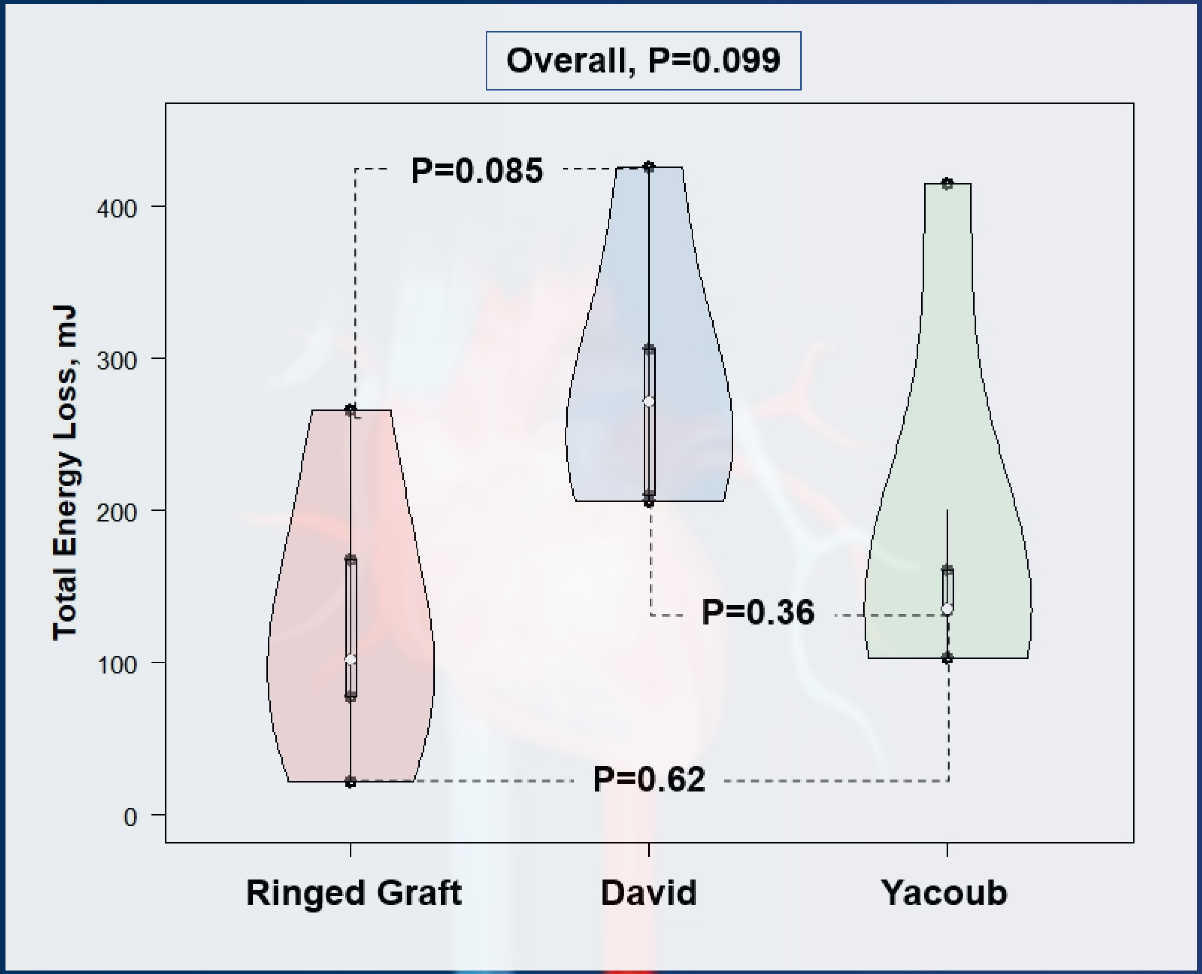
Forward and Closing Energy Losses





Regurgitation and Total Energy Losses





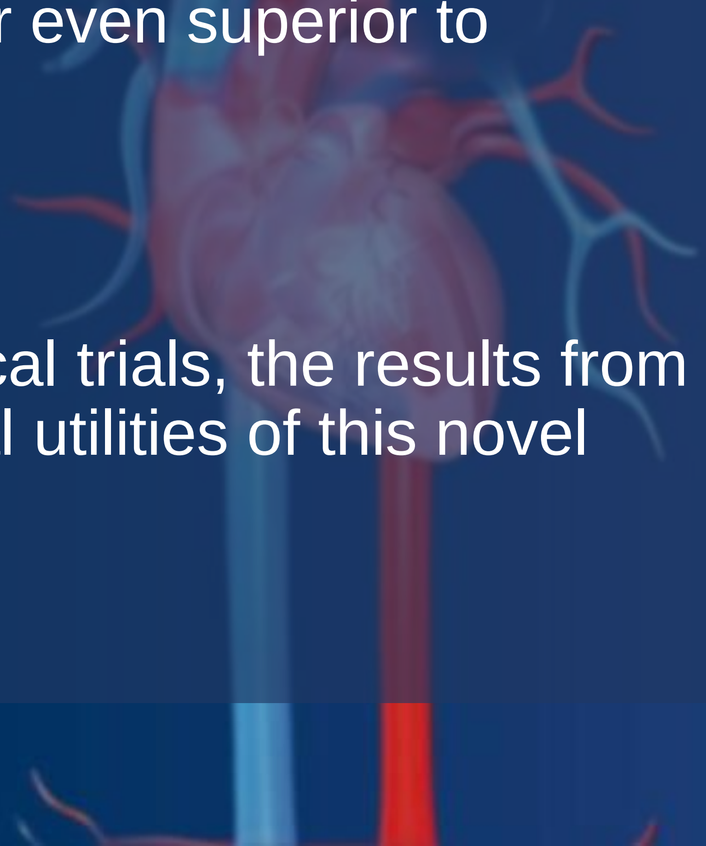
Conclusions

- Summary of Findings

  The VSARR performed using the novel 3D-reinforced graft showed short procedural time and favorable hemodynamic profiles (low AR fraction and pressure gradient) that are non-inferior or even superior to conventional VSARR techniques.

- Perspectives:

  Pending further in-vivo experiments and clinical trials, the results from the present research suggest potential clinical utilities of this novel VSARR.



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