



Right Heart Remodelling after Transcatheter Tricuspid Valve Intervention with the DUO™ System

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2025



Potential conflicts of interest

Speaker's name: Nadira Hamid

☒ I have the following potential conflicts of interest to declare:

Received consulting fees from Abbott Structural, 4C Medical Technologies, Inc., Alleviant Medical, Inc., AMX, Edwards Lifesciences, Philips, Valcare Med Ltd., Vdyne, W. L. Gore & Associates, Inc, Johnson & Johnson, Laza Medical, CroiValve

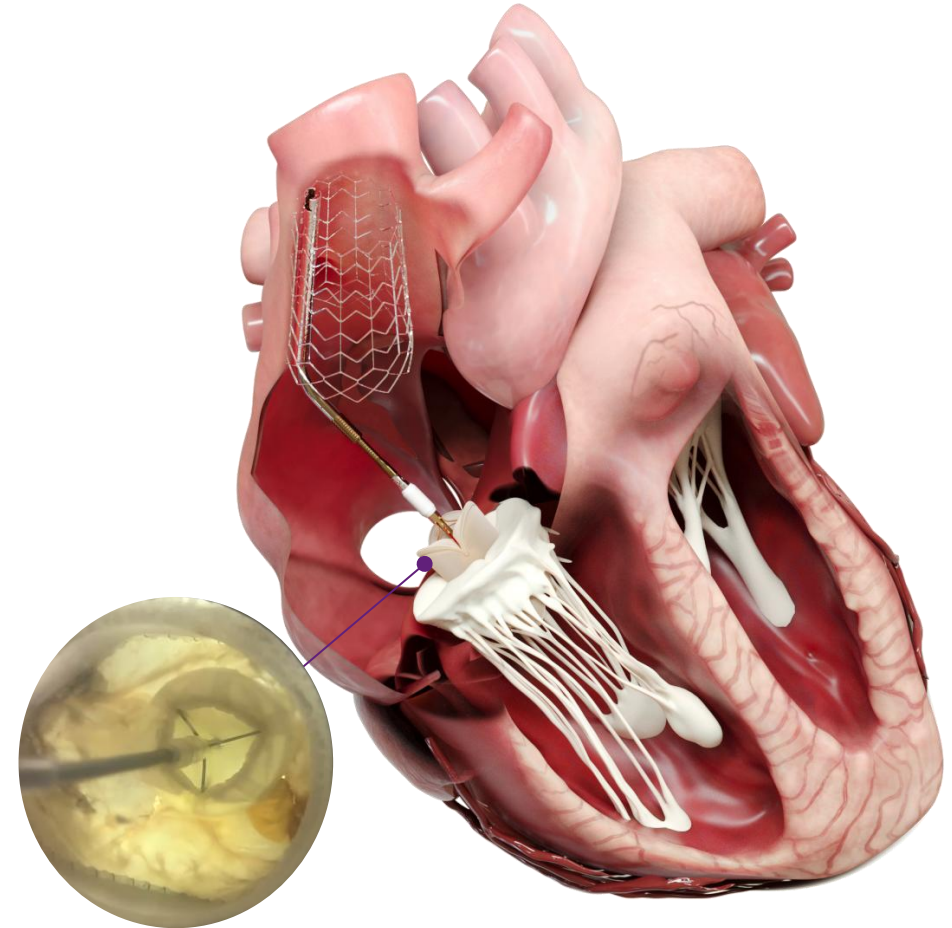
DUO™ Coaptation Valve System

Coaptation Valve

- Pericardial skirt "balloons" to fill the regurgitant orifice and adapts to heterogeneous valve morphologies, commissures and complex leak profiles
- Internal prosthetic valve to support diastolic flow
- Works in tandem with native valve

Anchor System

- Suspension arm holds coaptation valve across the tricuspid valve without annular contact
 - Fully adjustable during the procedure to optimize position
 - Proximal delivery system is locked, disconnected and removed
- Stent anchors the suspension arm in the SVC



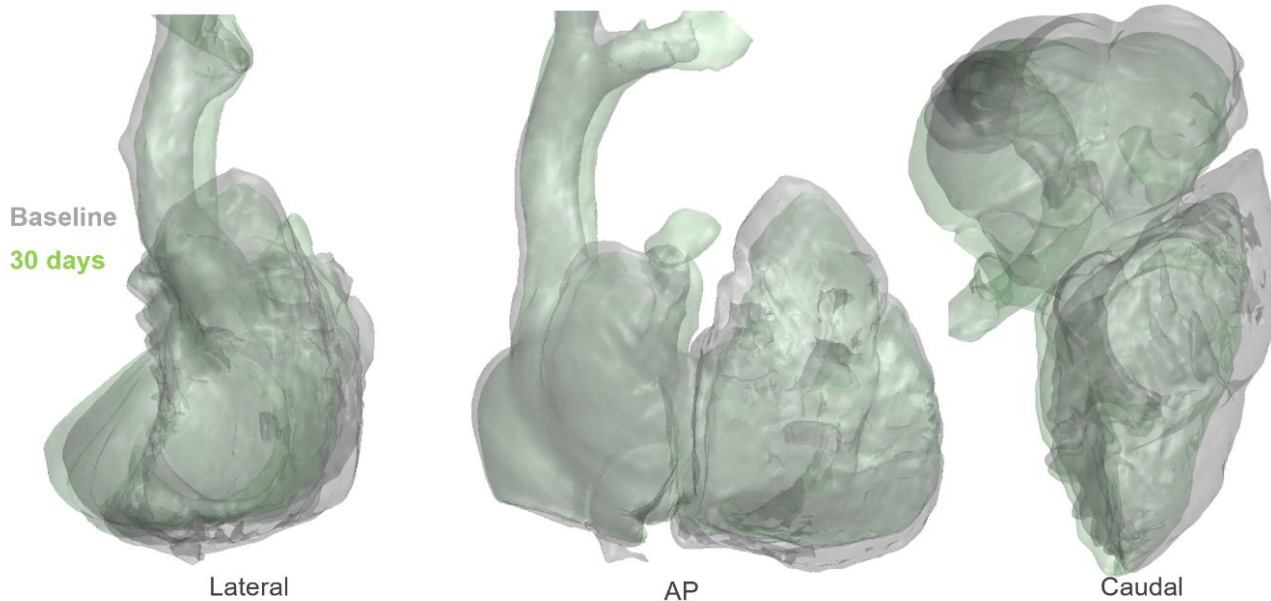
TANDEM I First in Human Study

- **Design:** Prospective, non-randomized, multicentre study
- **Objective:** Demonstrate safety and effectiveness of the DUO Coaptation Valve System in patients with severe symptomatic TR
- **Investigators:** Professors Adam Witkowski, Wojciech Wojakowski, Dariusz Jagielak, Zenon Huczek
- **Trial Oversight:** Echo core lab, Clinical events committee, NCT05296148

Patient Demographics	N = 11
Age (years)	78 (71-84)
Female	91%
NYHA Class III or IV	91%
HFH in prior 12 months	45%
Massive/Torrential TR	82%
LVEF (%)	49 (43-56)
Annular Diameter (mm)	52 (43-69)
Atrial Fibrillation	100%
Previous Left-Sided Valve Intervention	27%
RVEDD Mid (mm)	45
RVEDD Mid Index (mm/m ²)	27

DUO Preserves Native Anatomy

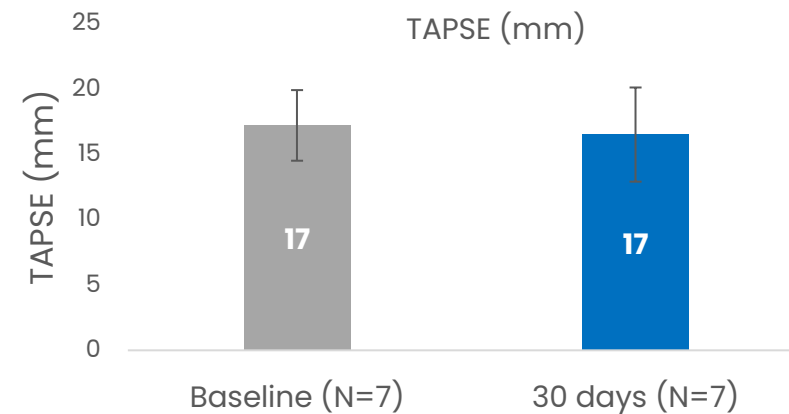
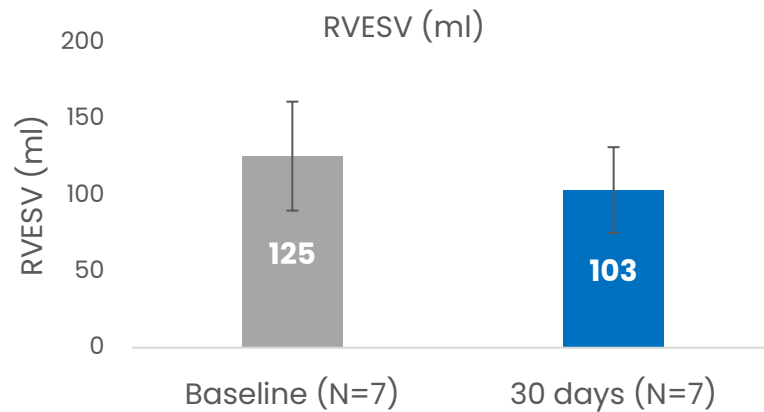
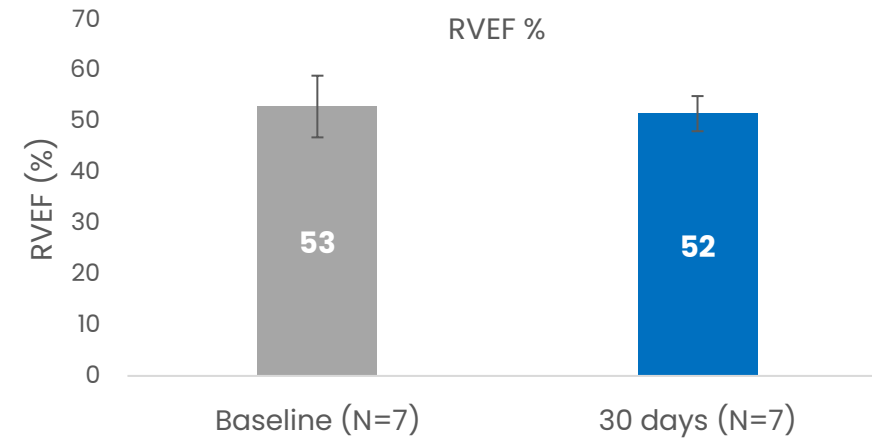
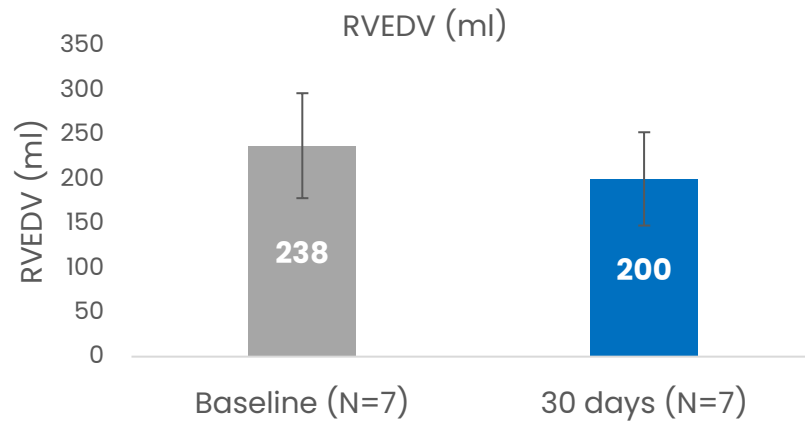
Positive RV and RA Remodelling: 30 Day CT



- Baseline and 30-day CT
- Positive reverse ventricular remodelling seen through reduction in right heart volume and size while maintaining RV function
- Stable coaptation valve position not impacted by changes to the free wall

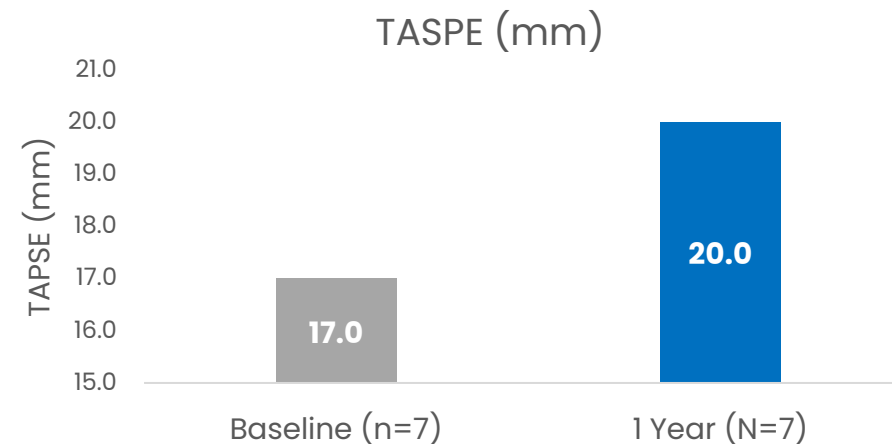
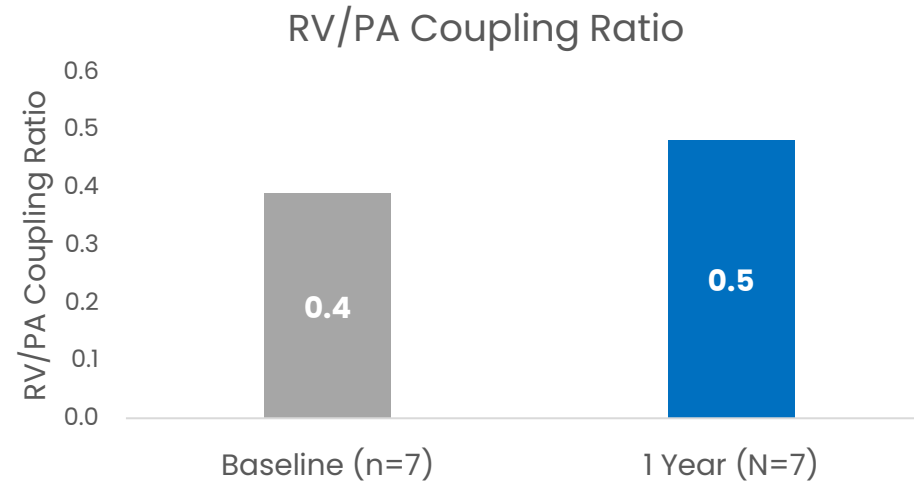
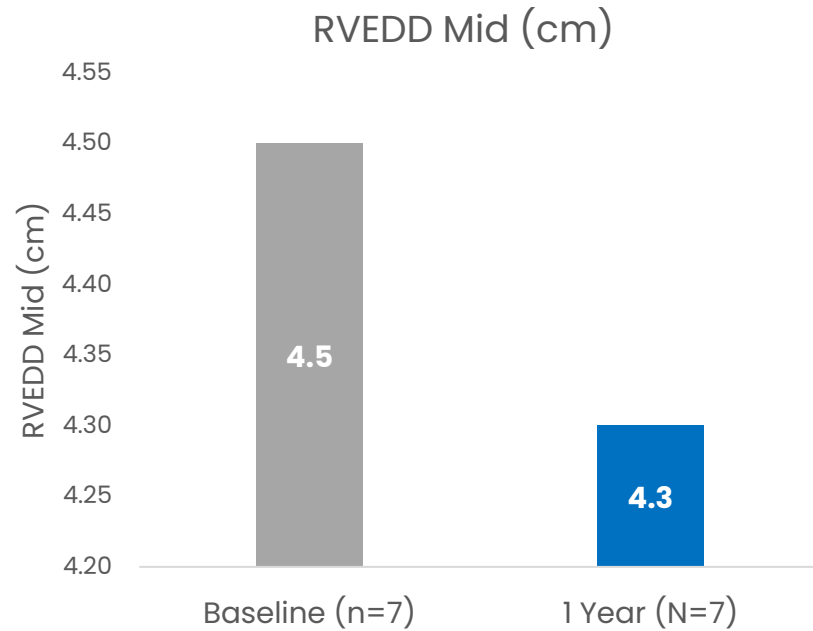
Positive RV Remodeling & Preserved RV Function

30 Days (CT & Echo)



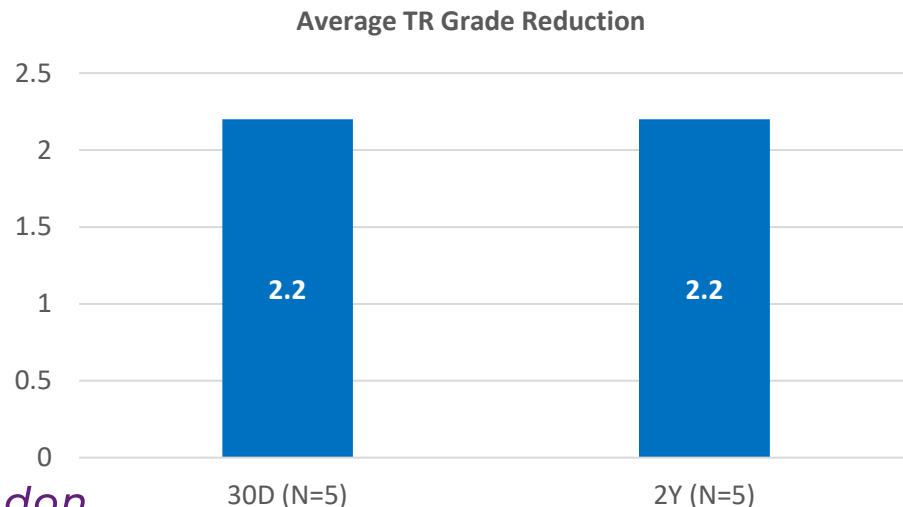
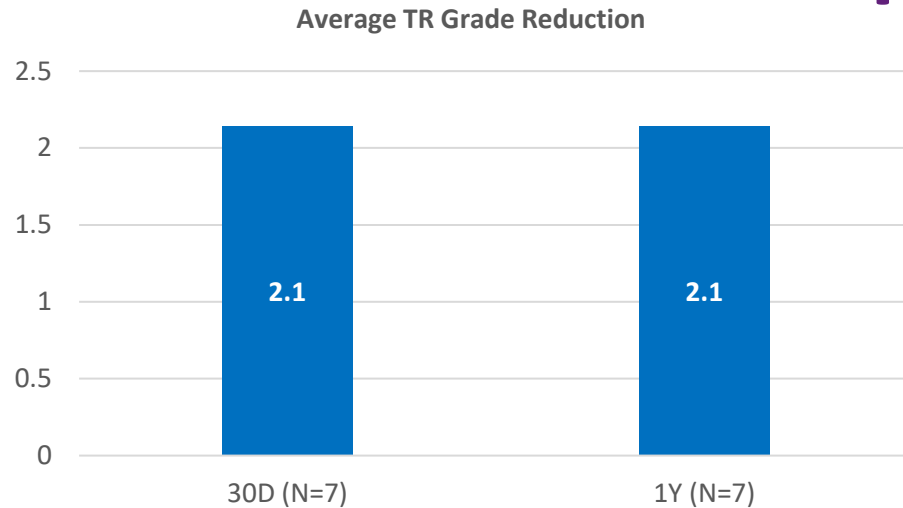
Positive RV Remodeling & Preserved RV Function

1 Year (Echo)



Sustained TR Reduction

Up to 2 Years



- N=11 patients enrolled in TANDEM I FIH Study
- 2/11 acute interventions
- Residual TR follow up data on 7 patients
 - 55% Torrential TR
 - TR Reduction in all patients (ranging from 1 to 4 grades)
- **TR Reduction of 2.2 grades sustained throughout 2 year FU**

Conclusions

- **Designed to treat a broad patient population**
 - Independent of annular diameter and coaptation gap size
 - Standard echo imaging, enabling a scalable procedure
- **Excellent clinical outcomes**
 - Sustained TR reduction translating to QoL improvements
 - No adverse events relating to contact with critical structures: e.g. conduction disturbances
- **Supports right heart reverse remodelling while maintaining RV function**
 - Reduction in RV volumes seen at 30 days and 1 year follow up
 - Preservation of native anatomy maintains RV function

Ongoing Clinical Investigations

- Sustained TR reduction and clinical outcomes past 2 years in TANDEM I FIH
- Actively enrolling TANDEM II EFS in leading US and EU centers
- Optimized stent design implemented in TANDEM II with positive outcomes and no SAEs
- Larger, more conformable DUO Adapt coaptation valve being implemented in TANDEM II to treat even larger, more complex leak profiles



SAEs (TANDEM II, n= 6)	30D
Reintervention	0
Death	0
Disabling stroke	0
Myocardial infarction	0
Major access site and vascular complications	0
Severe bleeding	0
Renal failure requiring dialysis	0
Major cardiac structural complications	0
New PPM	0



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