First-in-Human Robotic-assisted TAVR for the Treatment of Severe Aortic Valve Stenosis

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Disclosure of Relevant Financial Relationships

I, Yan Wang DO NOT have any financial relationships to disclose.

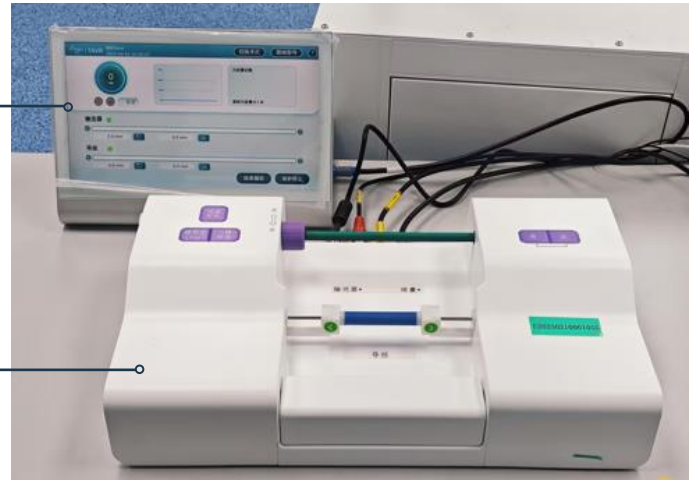
Background

- TAVR procedures, especially those with self-expanding valves, require high team coordination, advanced technical skills, and collaborative expertise.
- This feasibility study aimed to preliminarily assess the safety and efficacy of the robotic-assisted TAVR system.
- The first-in-man robotic-assisted TAVR procedure was successfully completed in Xiamen on June 8, 2025.

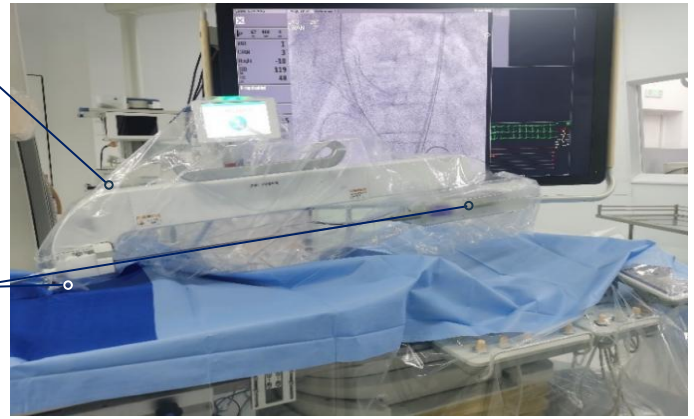
Master operating system

Execution System

System Introduction



Master Operating System

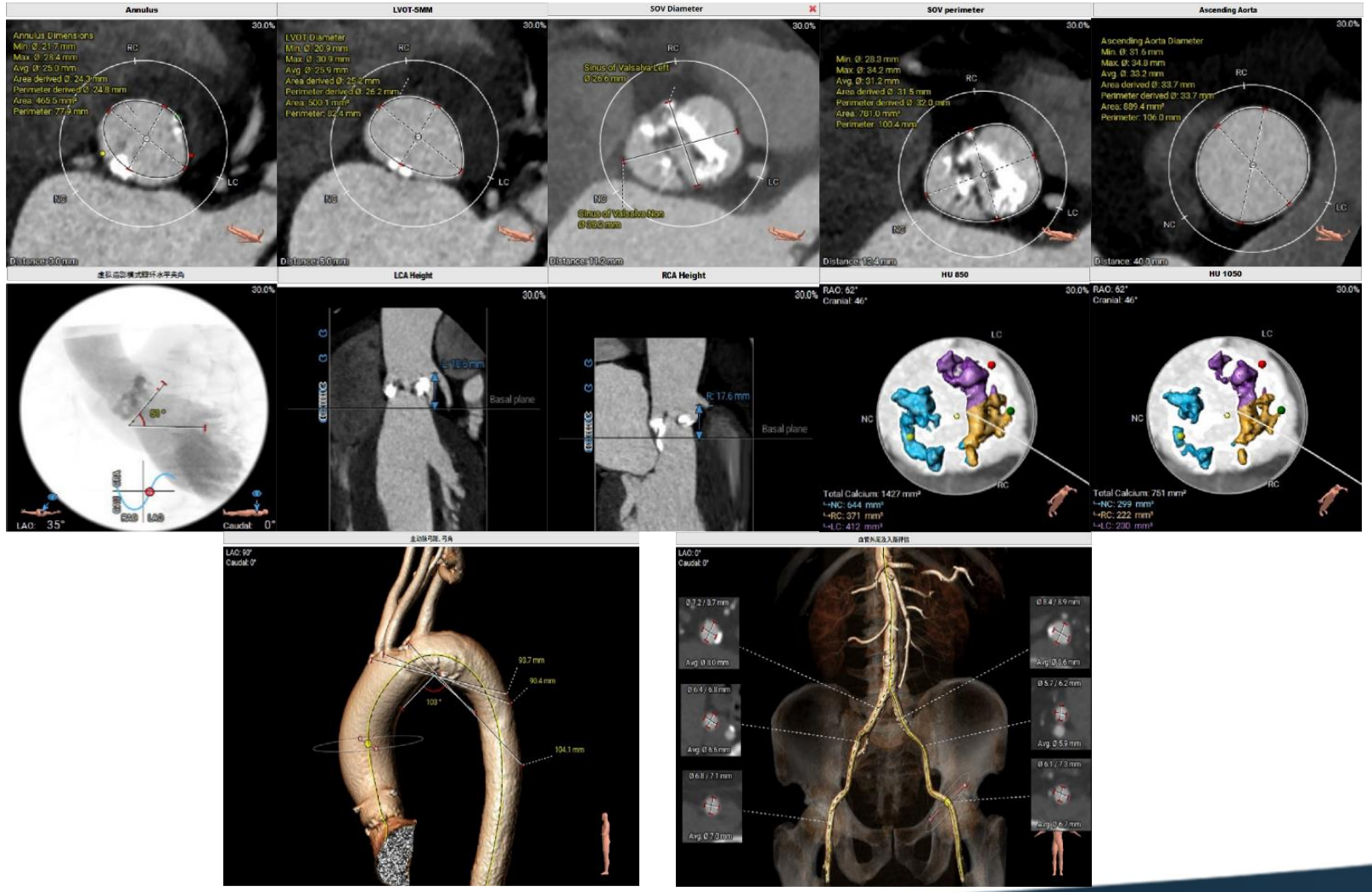


Execution System

- Remote control enables radiation protection
- Efficient installation and switching
- Highly sensitive force feedback
- High-precision grasping and manipulation
- Simultaneous control of multiple instruments

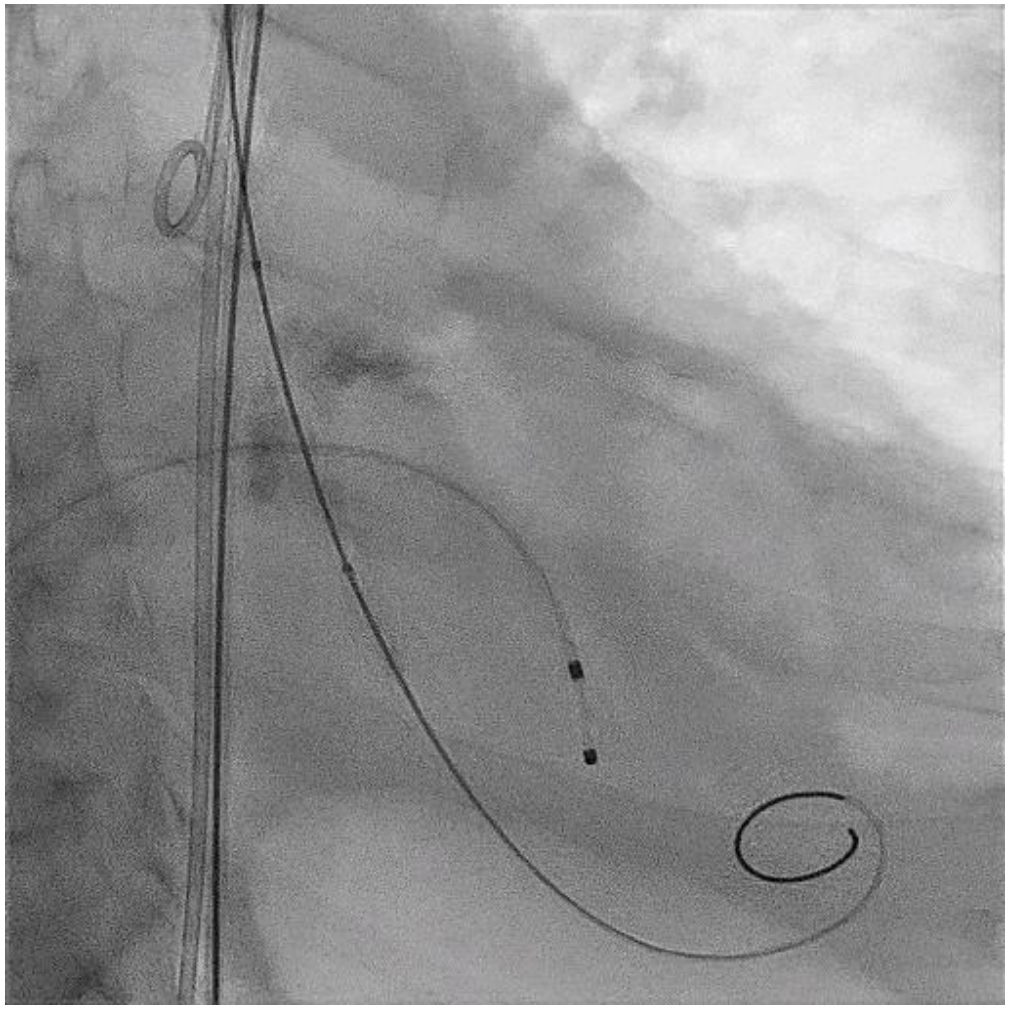
Robotic-assisted TAVR Case

- 70-year-old male
- Recurrent exertional dyspnea
- Dx: Severe AS with moderate-to-severe AR
- Aortic CTA：BAV, severe calcification, leaflet thickening and adhesion



Robotic-assisted TAVR

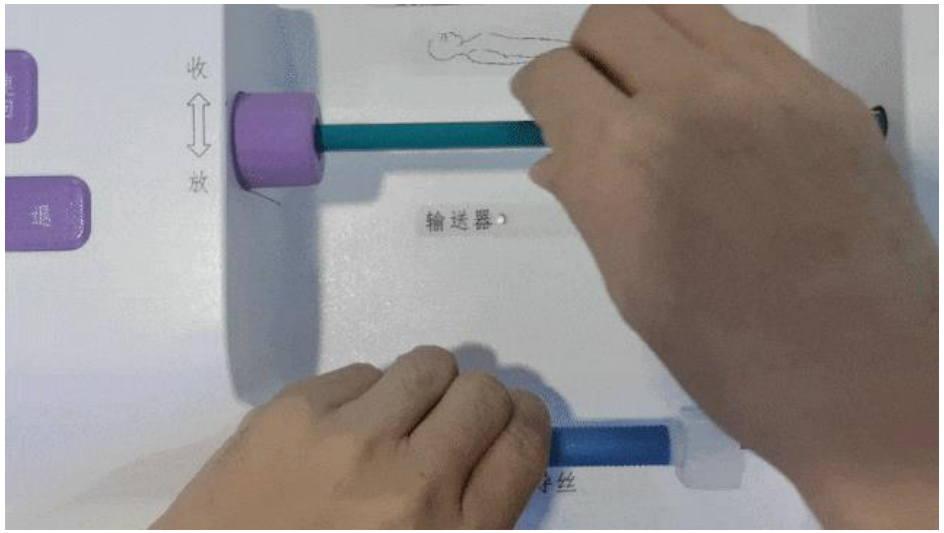
- Preparation
- Predilation with PEIJIA 18X40mm balloon
- PEIJIA TaurusElite® delivered via robotic system
- Robotic control performed after predilation

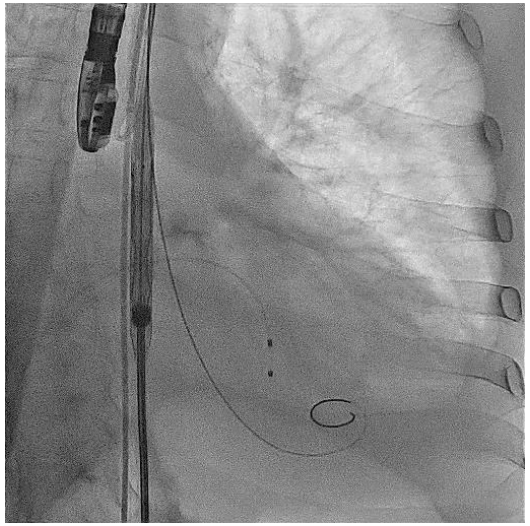


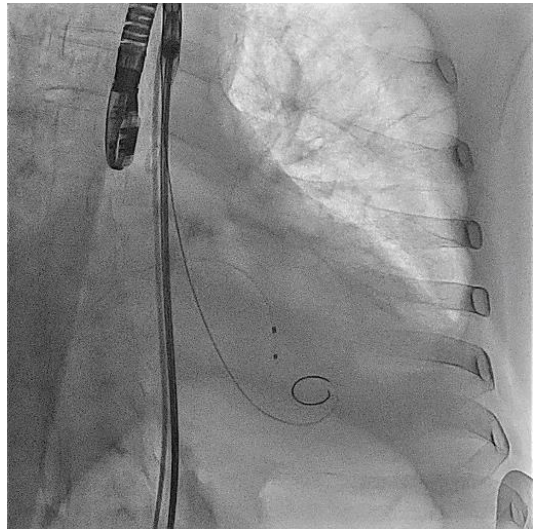
Robotic-assisted TAVR

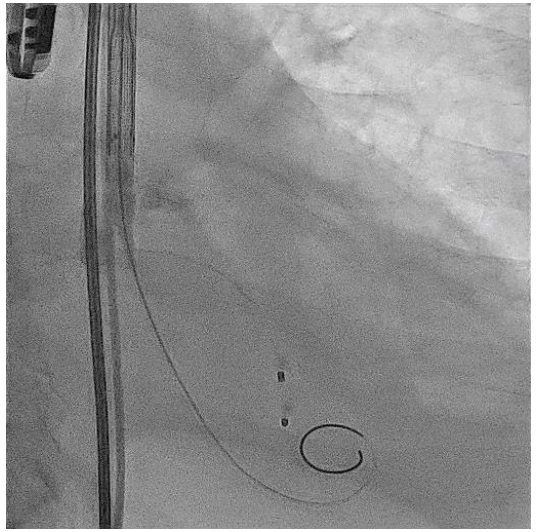
Procedural Steps

- The robotic arm advances the valve delivery system toward the aortic root.
- The delivery system passes through the arch.
- The valve is accurately positoned at virtual annulus plane of the aorta.





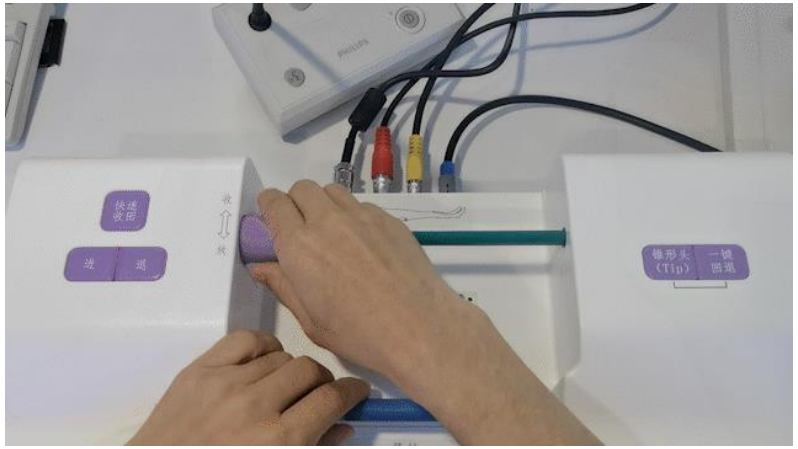


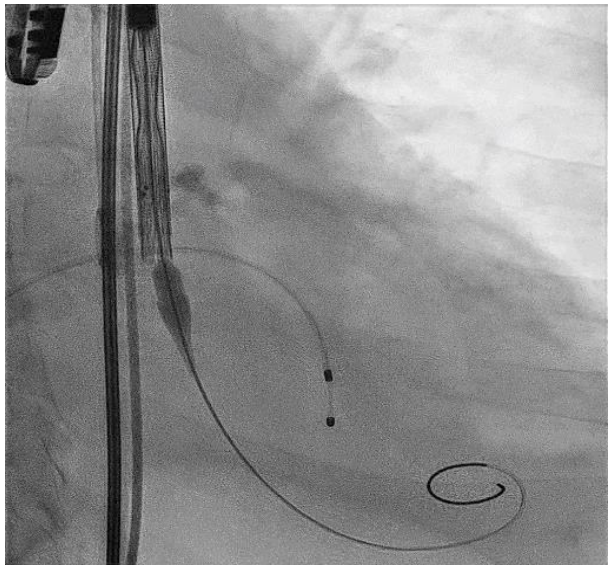


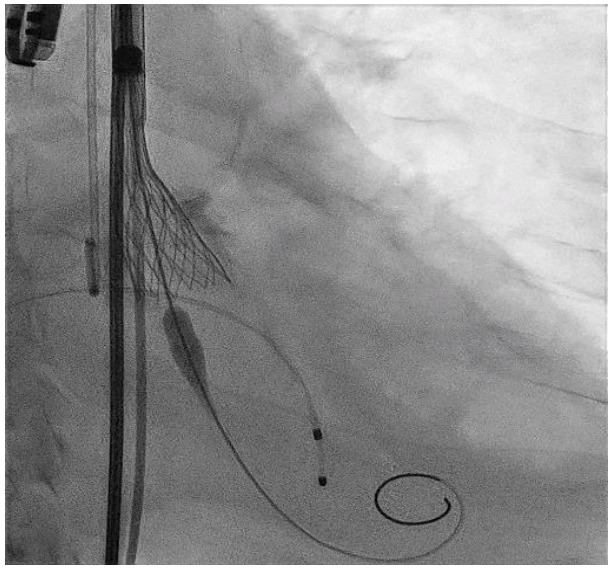
Robotic-assisted TAVR

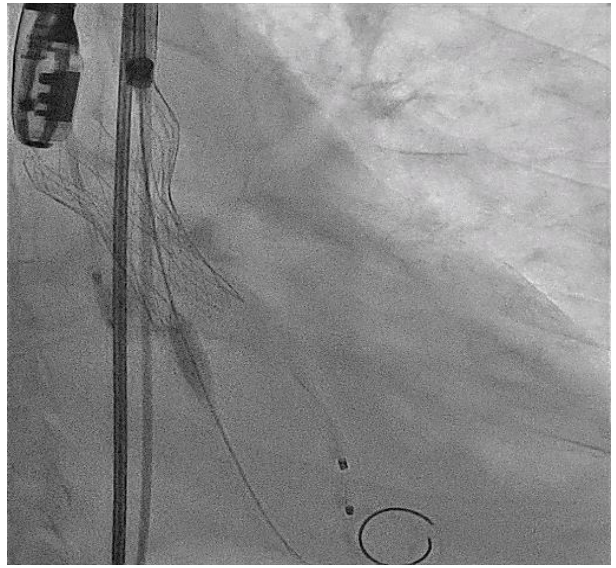
Procedural Steps

- Release of the aortic valve
- Retraction of delivery catheter system
- Coronary angiography
- Post-dilation



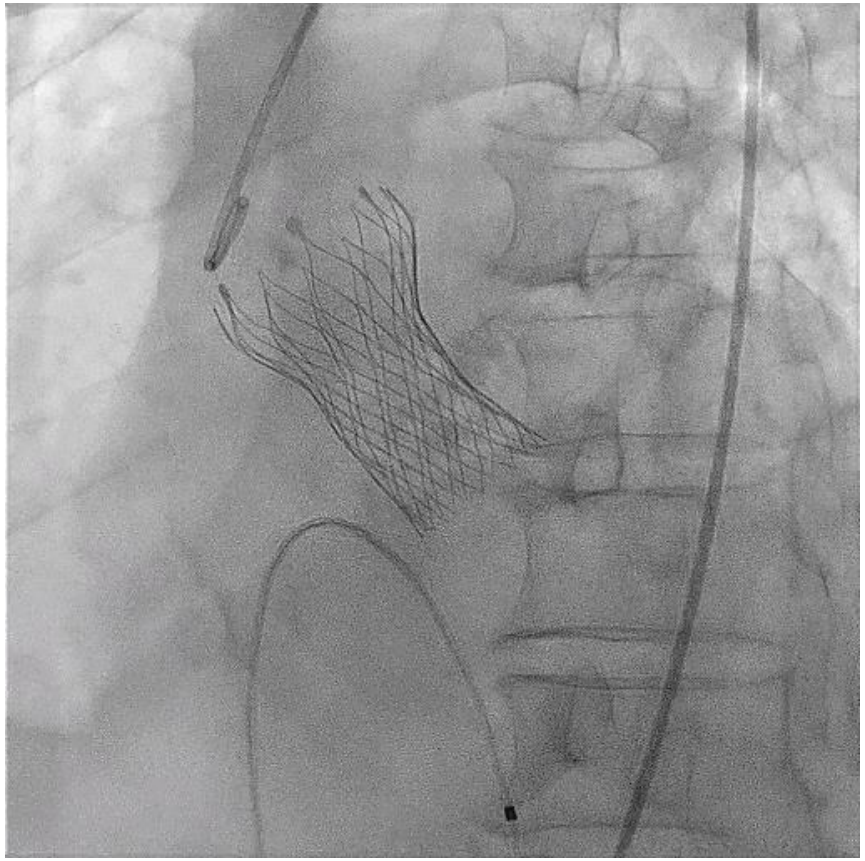






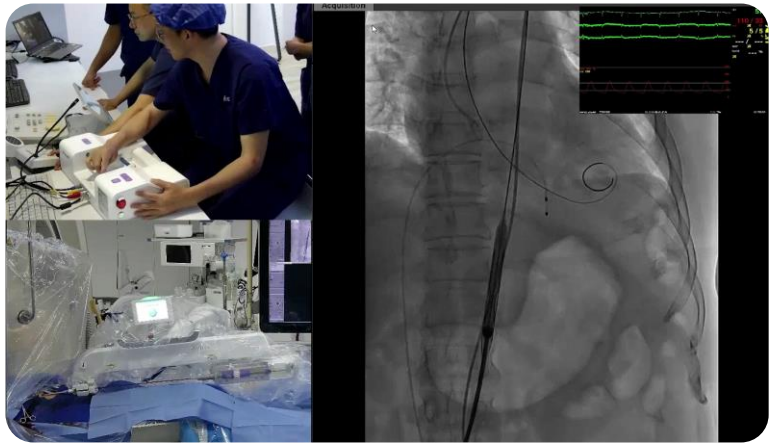
Robotic-assisted TAVR

Results

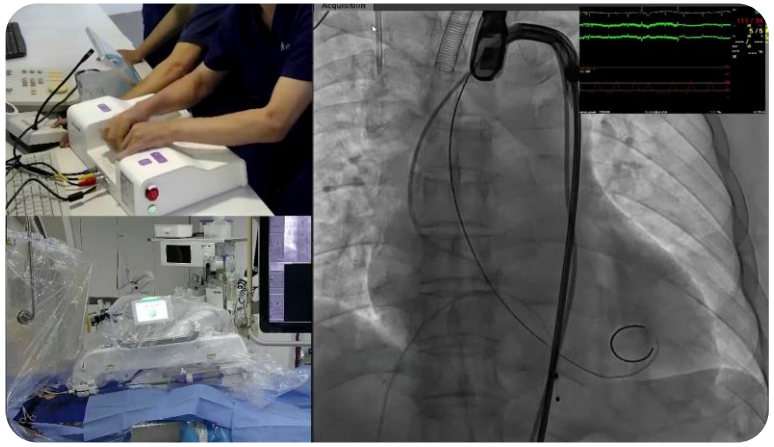


1. The world's first entirely robot-assisted TAVR case, performed on a severely calcified bicuspid aortic valve anatomy.
2. Remote, stable and precise robotic control throughout the procedure
3. Only one operator required in the catheterization lab - for real-time angiography and angle adjustments
4. High efficiency: 24 minutes from insertion to removal. Procedure time can be further reduced with trained and proficient users.

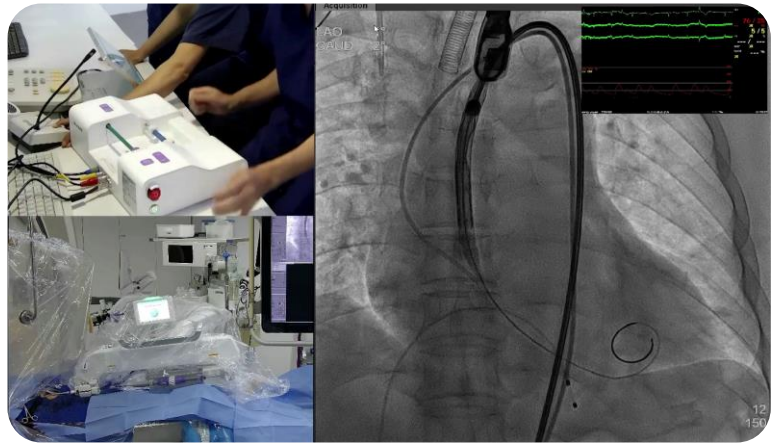
Robotic-assisted TAVR



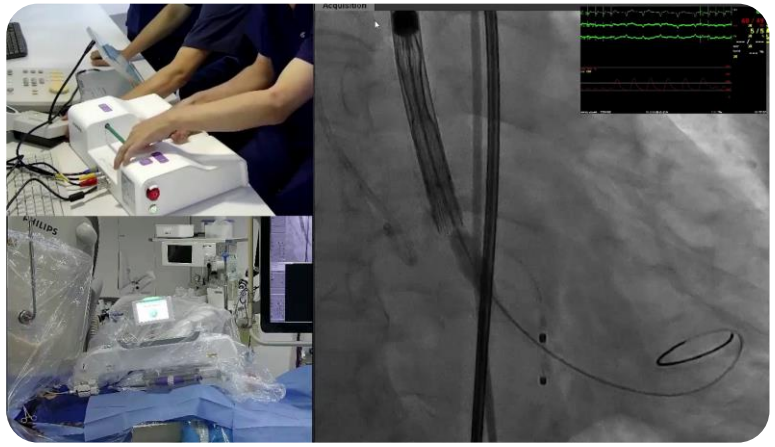
Descending Aorta Advancement



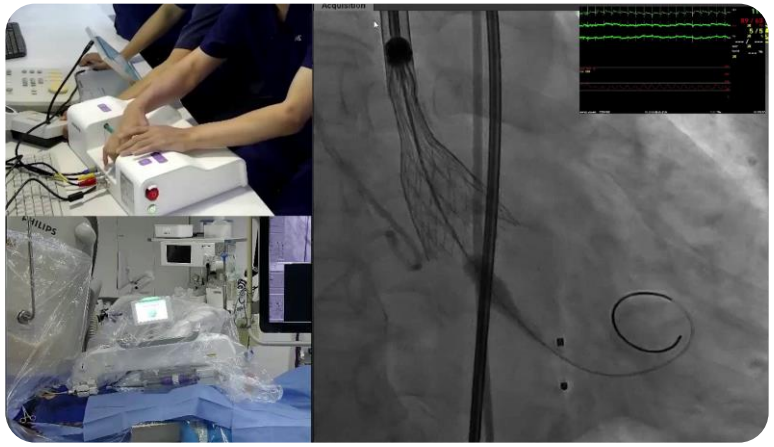
Arch Crossing



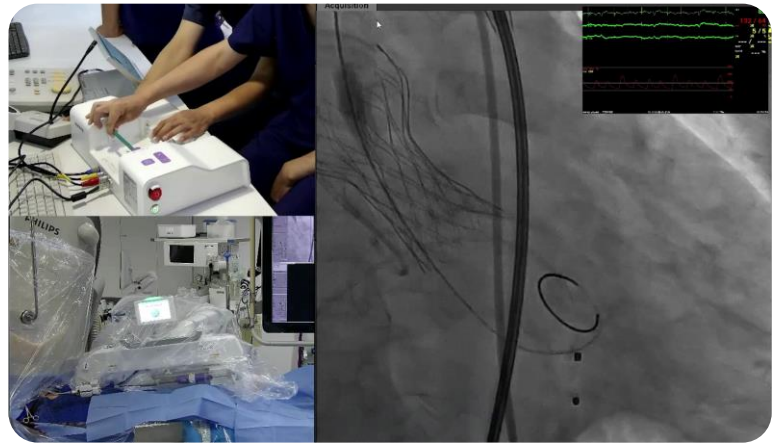
Valve Crossing



Valve Deployment



Valve Release



Delivery System Withdrawal

Robotic-assisted TAVR Feasibility Trial Overview

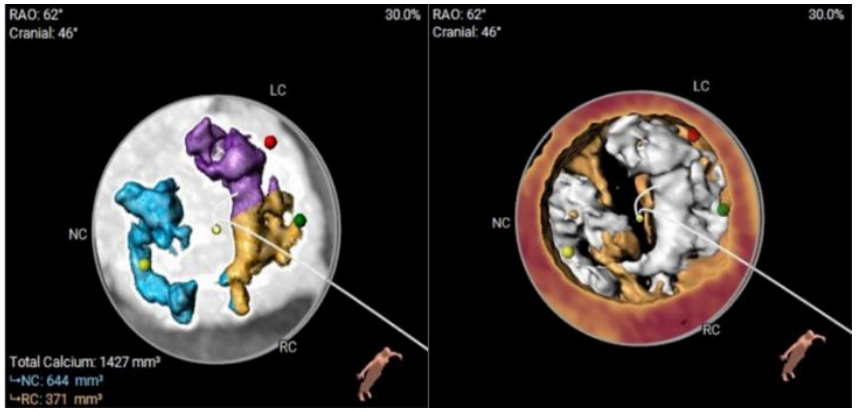
In this early feasibility trial, 5 robotic-assisted TAVR procedures were performed.

Success rate: 100%, no deaths, surgical interventions, or strokes reported

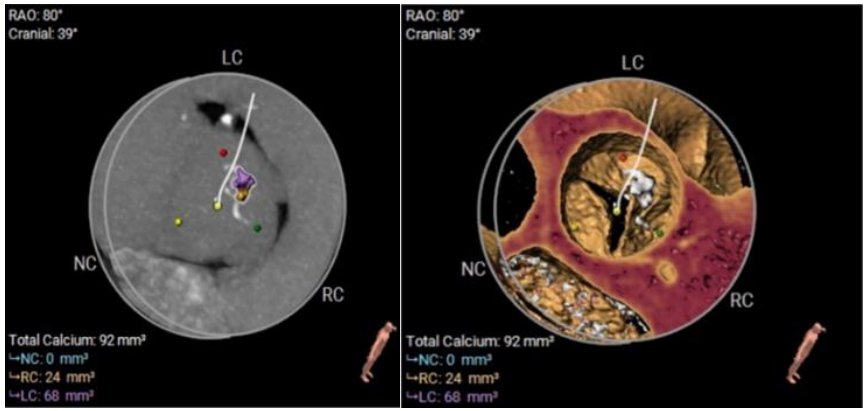
No.	Age	Gender	Diagnosis	Date of TAVR	THV type	Duration of procedure	Dose of radiation exposure*	Post-operative pressure gradient	PVL
Case1#	70	Male	AS + AR	2025/04/02	Taurus 26mm	24 min	0.15 mSv	3 mmHg	Mild
Case2#	70	Male	AS + AR	2025/04/29	Taurus 29mm	11 min	0.11 mSv	3 mmHg	No
Case3#	69	Female	AS + AR	2025/05/29	Taurus 23mm	13 min	0.22 mSv	1 mmHg	No
Case4#	69	Male	AS	2025/06/16	Taurus 29mm	14 min	0.43 mSv	1 mmHg	Mild
Case5#	84	Male	AS	2025/07/08	Taurus 26mm	14 min	0.047mSv	4 mmHg	Trivial

* The effective dose of radiation exposure for the primary operator during the procedure.

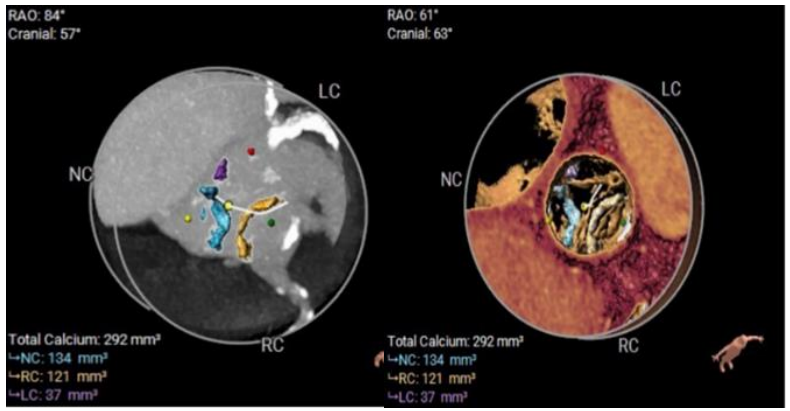
Anatomic characteristics of the five cases



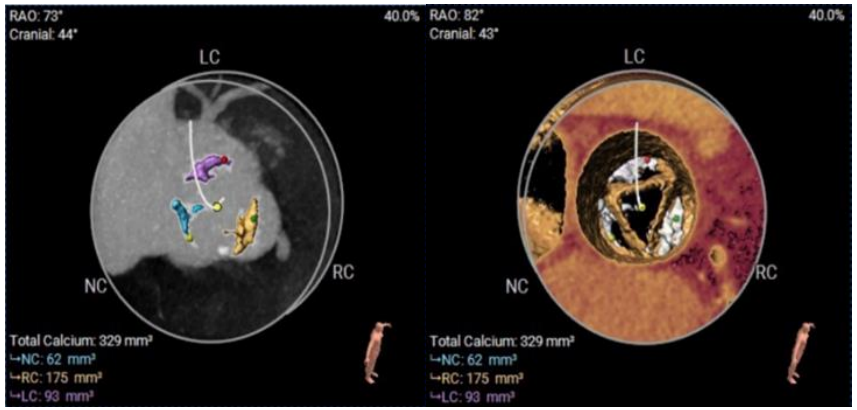
Case1#
Severe Calcified Type 0 BAV



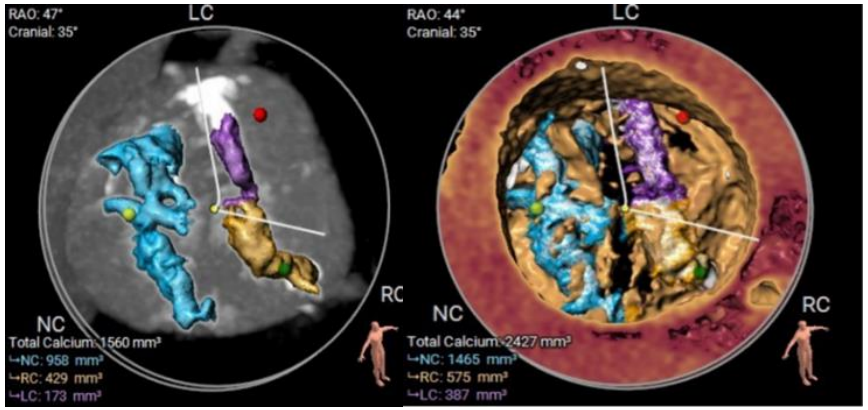
Case2#
Mild Calcified Type 1 BAV



Case3#
Mild Calcified TAV



Case4#
Moderate Calcified TAV

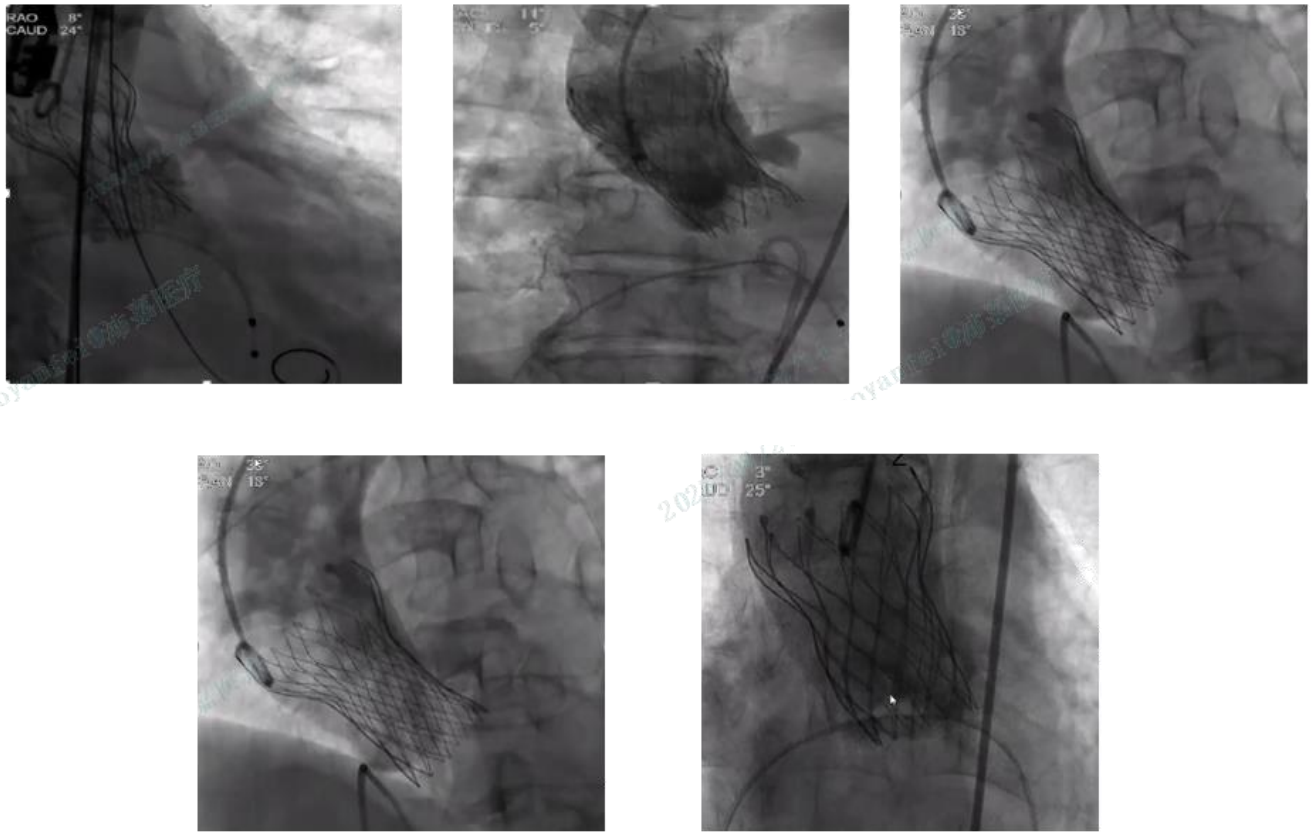


Case5#
Severe Calcified Type 1 BAV

Procedural Outcomes

OUTCOME	TAVR（n=5）
Technical Success	5(100%)
Conversion to Manual or Surgical Manipulation, n (%)	0
Valve-in-Valve	0
Aortic Root Injury	0
Major Bleeding	0

* Definition derived from VARC-3.



Outcomes at 30-Day

OUTCOME	TAVR（n=5）
All Cause Mortality	0
MACCE	0
Major/Life Threatening Bleeding	0
Major Vascular Complication	0
NYHA class,n(%) I II III IV	 2（40） 3（60） 0 0

OUTCOME	TAVR（n=5）
LVEF（%）	62±9
AVA（cm^2）	1.53±0.27
Vmax（m/s）	2.43±0.67
Pmax（mmHg）	24.5±13.5
Pmean（mmHg）	12.5±6.5
Surgery/Intervention Related to the Device	0

Conclusion

1.The first-in-human entirely robot-assisted TAVR procedure yielded highly encouraging outcomes.

2.The robotic system’s secure manipulation of the ultra-stiff guidewire demonstrated superior stability and precision compared to manual operation.

3.Simultaneous control of the TAVR delivery system and guidewire by a single operator enhanced procedural control, optimized clinical outcomes, and reduced heart team staffing requirements.

4.These findings provide a pivotal basis for the initiation of a subsequent randomized controlled trial (RCT).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