Transcatheter Aortic Valve Replacement with Ken-Valve in Aortic Regurgitation (Jenscare Scientific): One Year Outcomes And Challenging Cases

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

NATURE OF FINANCIAL RELATIONSHIP	INELIGIBLE COMPANY
Grant/Research Support	Edwards Lifesciences, Shockwave, Abbott Vascular, Corysm
Consultant Fees/Honoraria	Medtronic, Edwards Lifesciences, Abbott Vascular, Boston Scientific, Jenscare
Individual Stock(s)/Stock Options	Total Flow Medical Shockwave Kardium Huihe Vesalius
Other	Eligibility Committee Board Member (TRINITY Trial)

All relevant financial relationships have been mitigated.

Faculty disclosure information can be found on the app

Innovative Design of Ken-Valve TAVR Device for AR

Precise deployment & stable anchoring

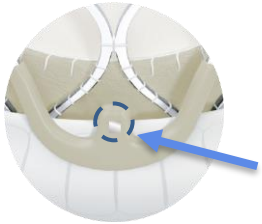
Integrated clamps & radial force

- Stronger leaflet clamping for stable anchoring
- Enhanced radial force to reduce valve migration
- Minimal oversizing required

Soft PTFE skirt to prevent PVL and to reduce conduction defect

Supra-annulus leaflet design for optimal EORA

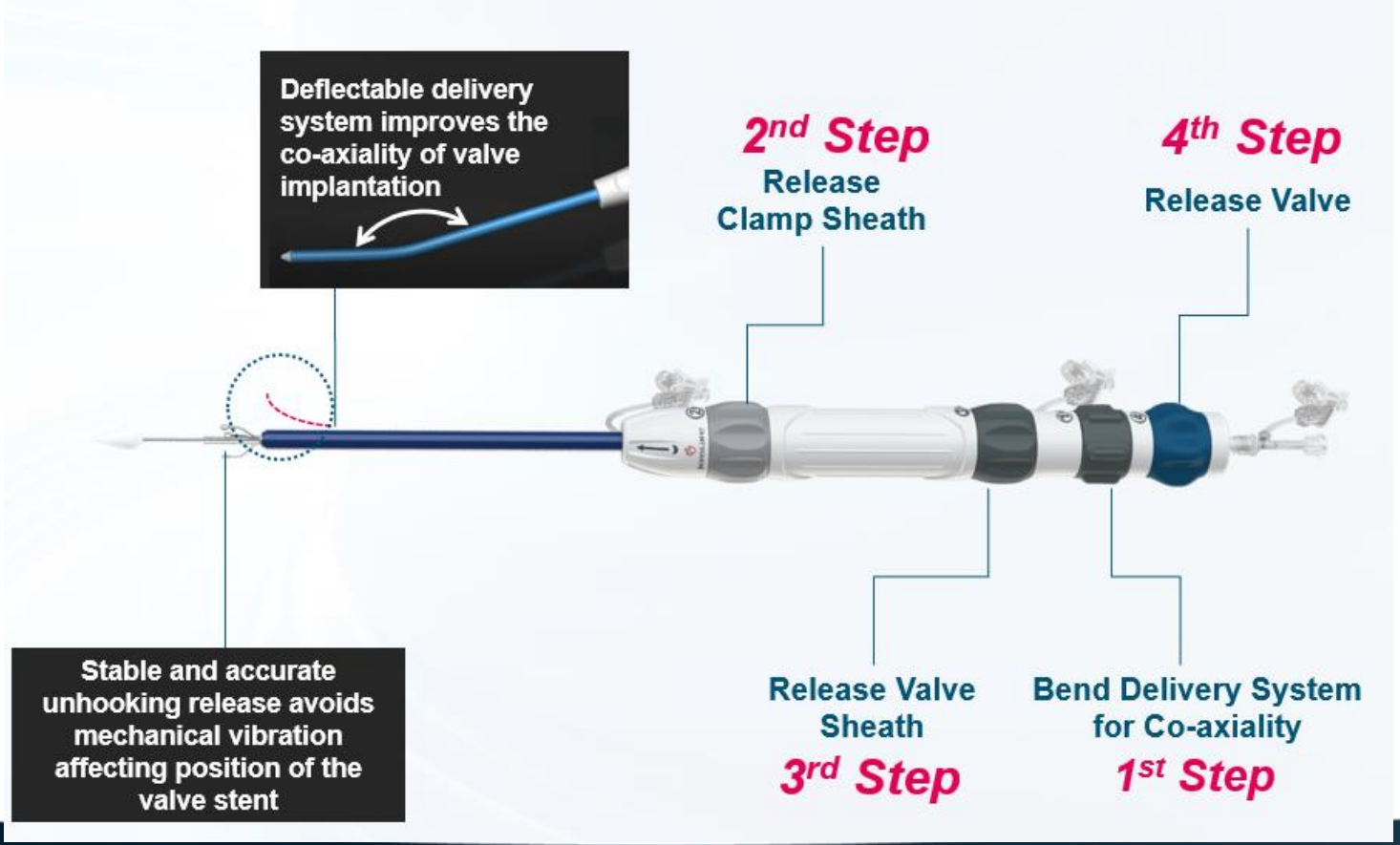
Clamps wrapped by bovine pericardium to minimize tissue injury



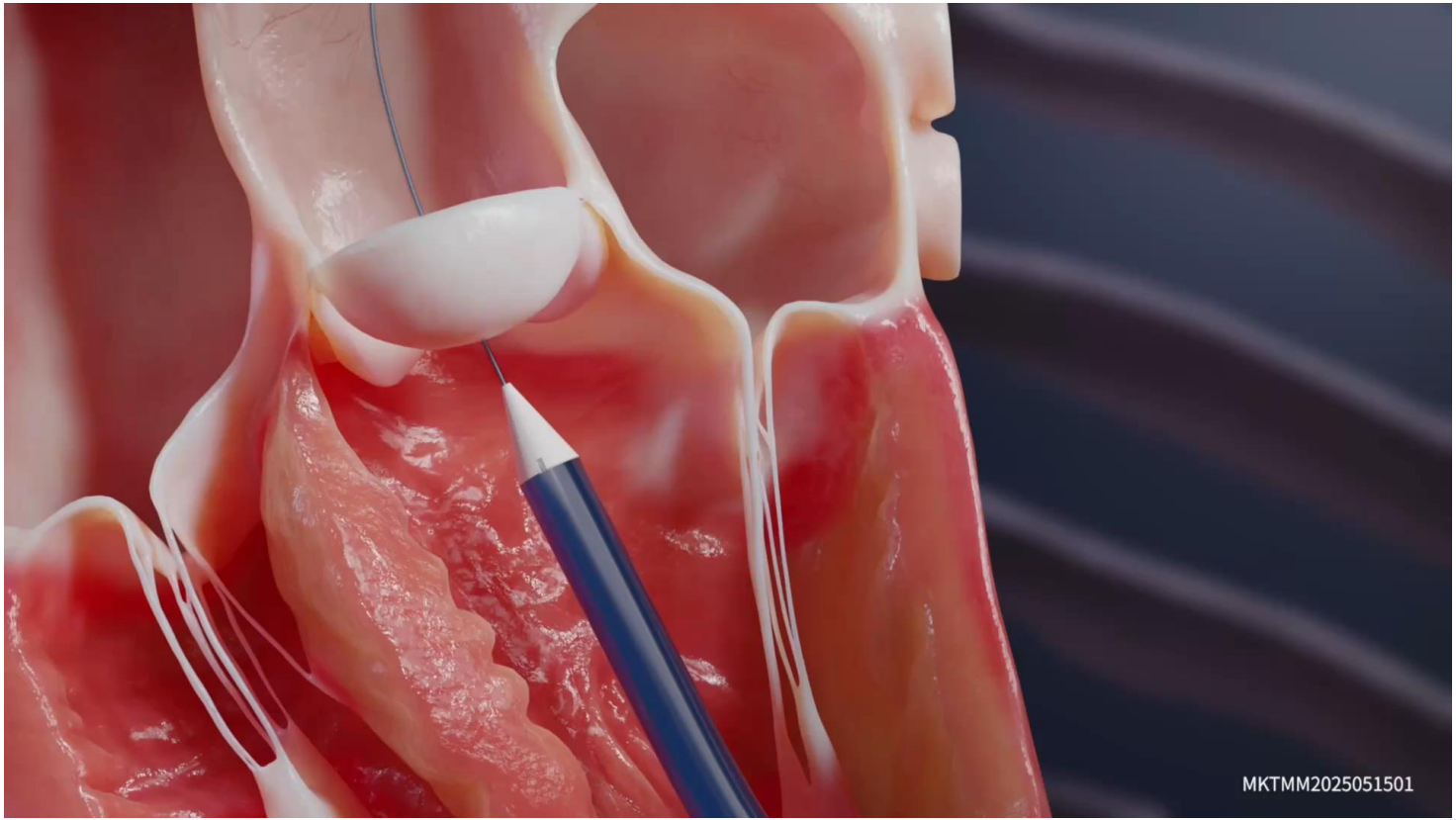
Anchor marker ensures precise positioning

Short stent frame for future coronary access

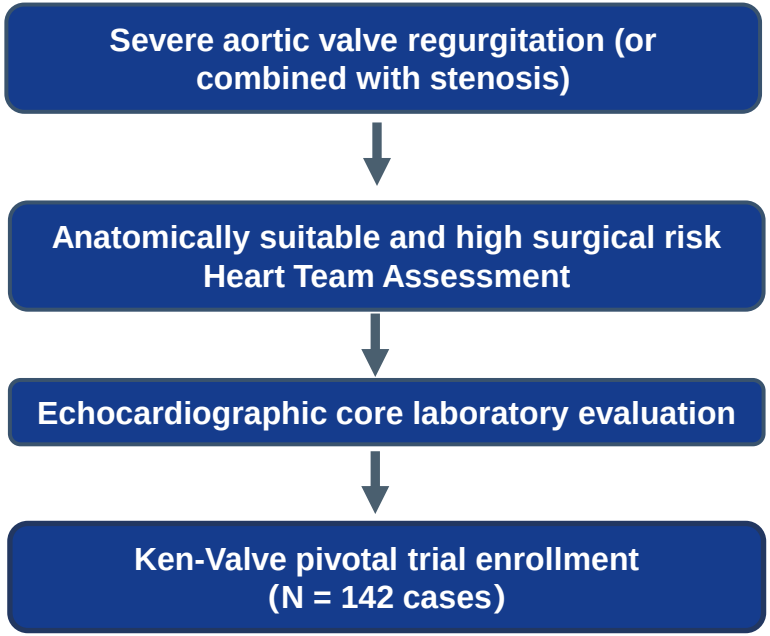
Ken-Valve TAVR Delivery System



Ken-Valve TAVR Procedure



Ken Valve Pivotal Trial



Outcome Measure **：** ***MVARC criteria***

- Study Design

- **Prospective**
- **Single Arm**
- **Multi-center Study in China** (15 enrolling sites)

- Objective

To evaluate the safety and efficacy of the Ken-Valve TAVR System in treating symptomatic **AR** (or combined with stenosis) patients with high surgical risk.

- Endpoint

All cause mortality, heart function, quality of life, device success rate at 12 months, and MACE event at 30 days.

- Follow up： Discharge, 30d, 6m, 12m

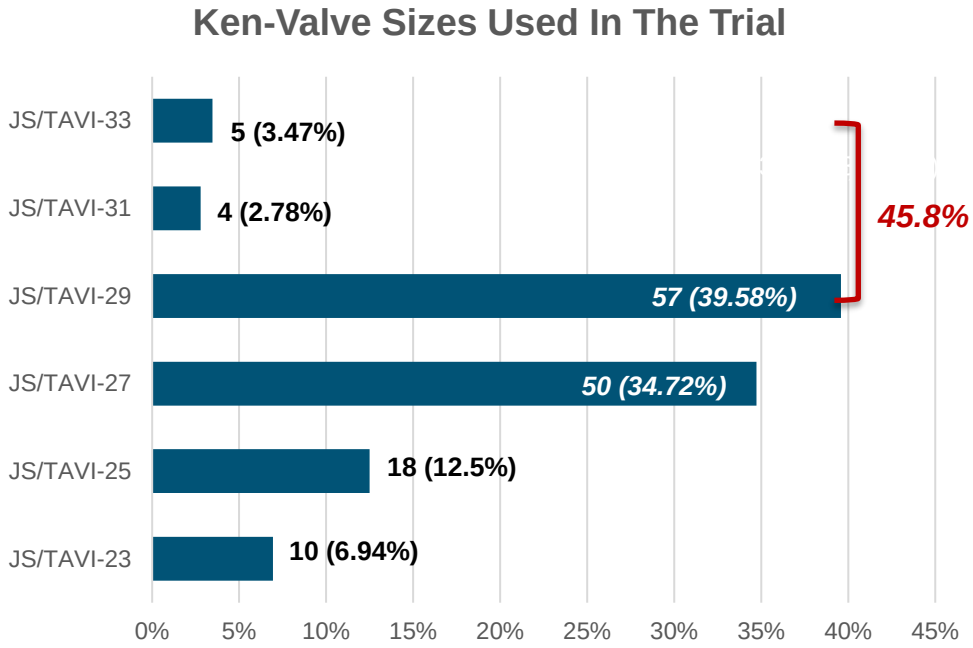
■ ***Coordinating Investigator***

The First Affiliated Hospital of Naval Medical University | Prof. XU Zhiyun
West China Hospital, Sichuan University | Prof. GUO Yingqiang

Baseline Characteristics

Clinical Characteristics (n=142)			
Age — yr	70.3 ± 5.5	COPD	40.1% (57/142)
Male Gender	63.68% (90/142)	Peripheral vascular disease	48.6% (69/142)
BMI — kg/m2	23.1 ± 3.3	Prior surgical history	51.4% (73/142)
Moderate to severe frailty	62% (88/142)	NYHA class	
Diabetes	11.3% (16/142)	I	0
Hypertension history	71.8% (102/142)	II	0.7% (1/142)
Coronary artery disease	43% (61/142)	III	47.9% (68/142)
Previous stroke or TIA	21.8% (31/142)	IV	51.4% (73/142)
Atrial fibrillation	11.3% (16/142)	STS score	5.9 ± 3

Distribution of Ken-Valve Sizes Used



✓ ***46%*** *of enrollments utilized valve sizes* ***> 29mm***

- *Two patients used two Ken-Valves, one used a 27mm and a 29mm valve; the other one used two 27mm valves.*

Baseline Characteristics and Procedural Outcomes

Echocardiographic Data （N=142)	
Severity of aortic regurgitation	
severe, grade 3+	100%
Severity of aortic stenosis	
mild, grade 1+	9.2%
moderate, grade 2+	2.1%
severe, grade 3+	12%
Effective regurgitant orifice area (cm2)	0.5 ± 0.3
Vena contra width (cm)	0.8 ± 0.2
Stroke volume (ml)	77 ± 35
Left ventricular end-systolic dimension (cm)	45 ± 11
Left ventricular end-diastolic dimension (cm0	62 ± 10
Average transvalvular gradient (mmHg)	33 ± 18
Peak transvalvular velocity (m/s)	3.6 ± 1.1
Left ventricular ejection fraction mean (%)	54 ± 13

Procedural Outcomes （N=142）	
Procedural time (mins)	121 ± 63
Device time (mins)	9 ± 9
Procedural Success	96.5%**
Device Success	97.2%*
Conversion to surgery	1.4% (2/142)
Acute renal dysfunction	0.7% (1/142)
Needed for CPB	0.7% (1/142)
In-hospital or 30-day mortality	2.1%(3/142)

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** Device Success: 4 patients needed a second valve or open heart surgery due to misposition of the Ken-Valve.*

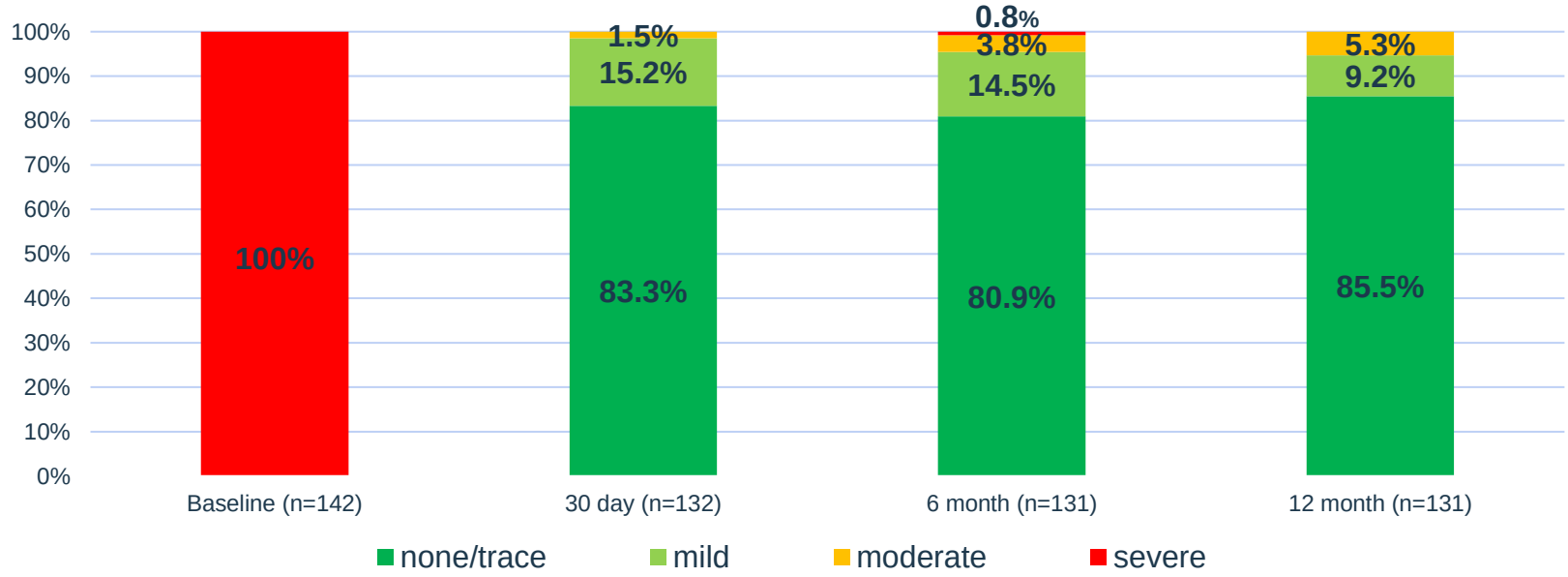
Major Adverse Events at 1 Year

All-cause mortality	5.6% (8/142)
Permanent pacemaker implantation rate	14.1% (20/142)
III degree AV block	8.5% (12/142)
Other types of arrhythmias	5.6% (8/142)
Major bleeding	4.2% (6/142)
Stroke	2.1% (3/142)
Reintervention	0.7% (1/142)
Coronary artery obstruction	0
Thrombosis	0
Cardiac tamponade	0

- *The overall composite MAE rate at 1-year is 23.24%.*
- *Among the 8 all-cause mortality events, 3 of them were deemed "possibility related" with the device, and 4 of them were deemed "possibility related" with the procedure by the CEC.*

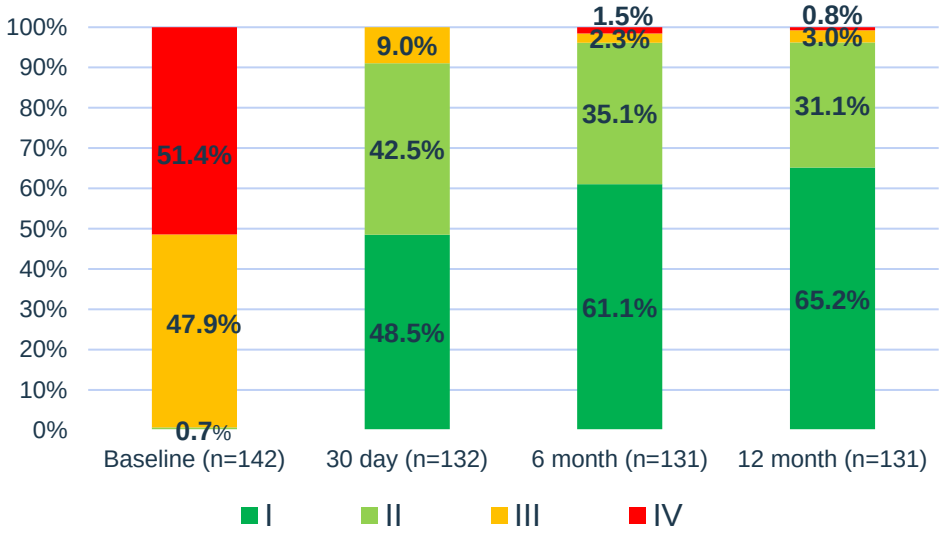
Significant AR Reduction at 1 Year

94.7% of the patients had mild or less AR or PVL at 12 months (P < 0.001)



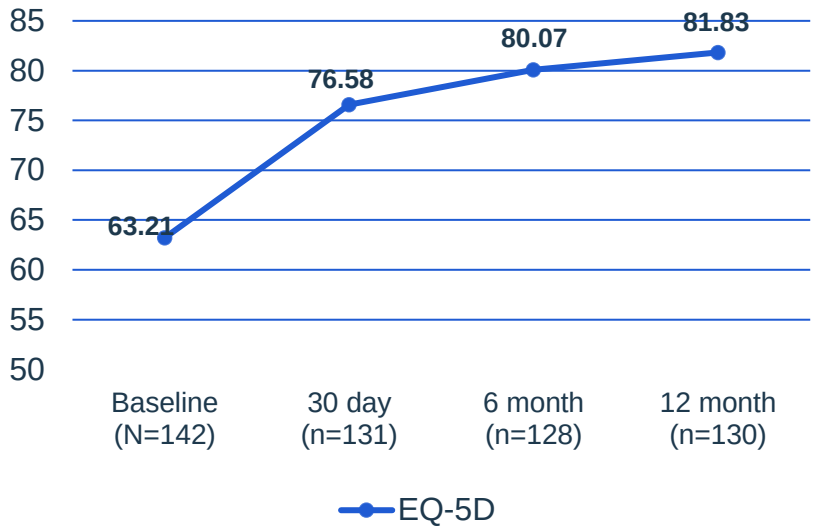
Cardiac Function and Quality of Life at 1 Year

NYHA Classification



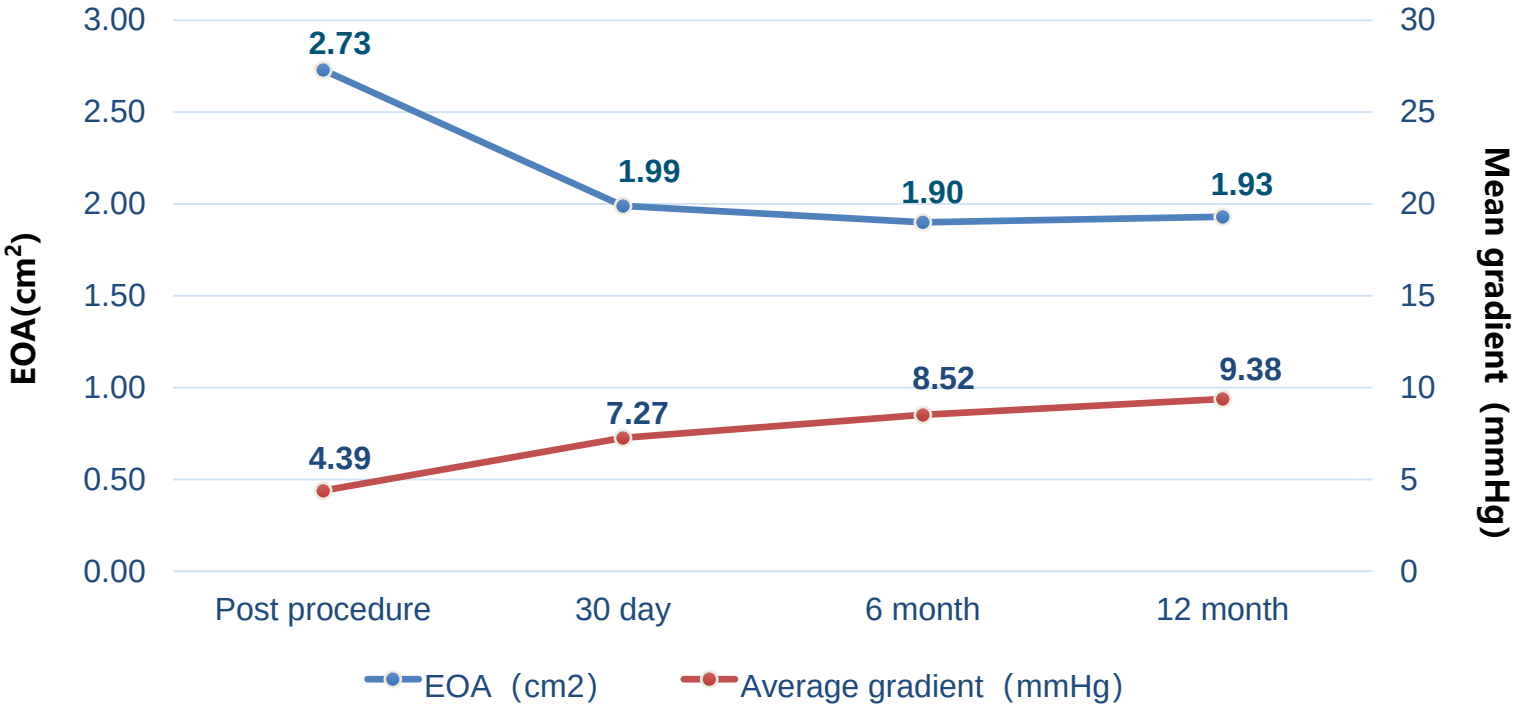
96% of the patient in NYHA Class I/II at 12 months *(P<0.001)*

EQ-5D



Significant improvement in QoL at 12 months *(P<0.001)*

EOA and Mean Transvalvular Gradient at 1 year



Case I

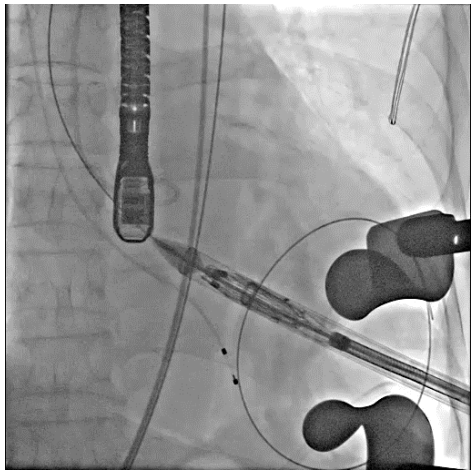
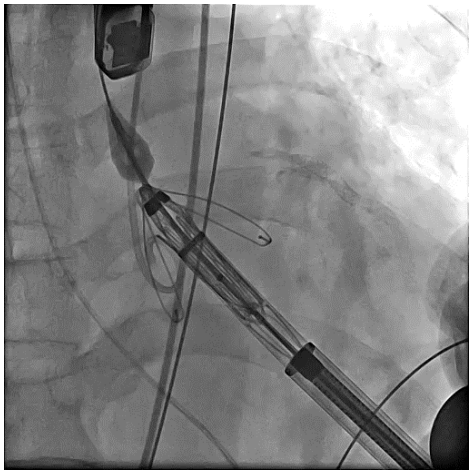
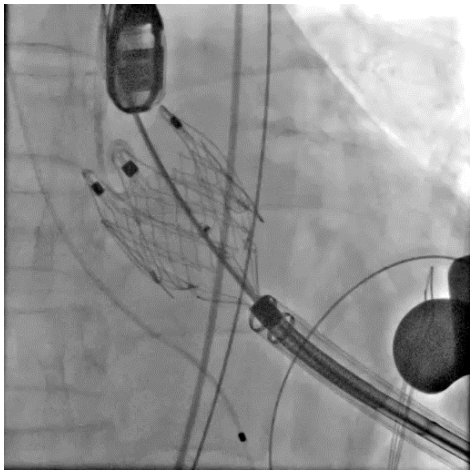
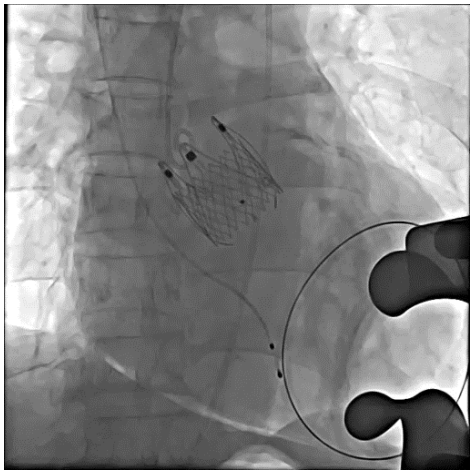
- 67 y/o Male in NYHA Class III, diabetes, post PCI
- Enlarged left ventricle with LVEF - 28%, PASP=50mmHg
- Severe aortic valve regurgitation (4+), no mitral or tricuspid valve disease

Case I

Key challenges of the case:

1. Severely dilated annulus and STJ (mean annular diameter - 30.5mm and 47.4mm)
2. Poor LVEF - 28%.

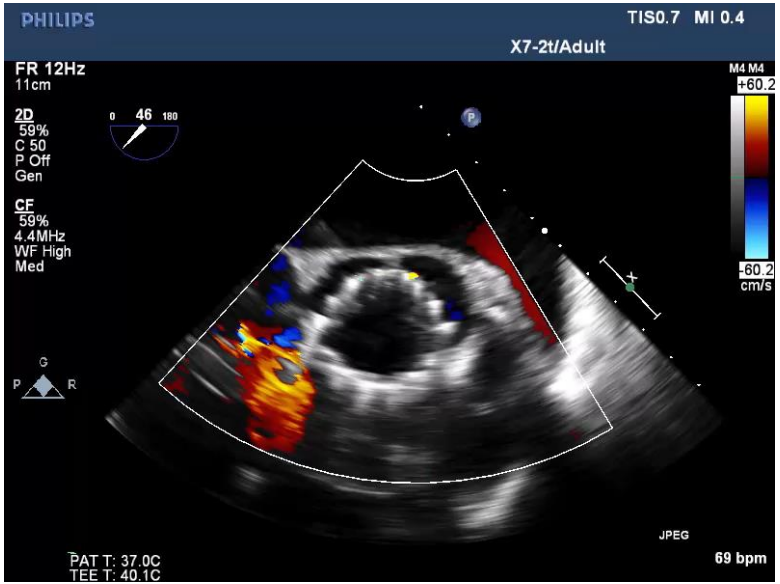
Case 1

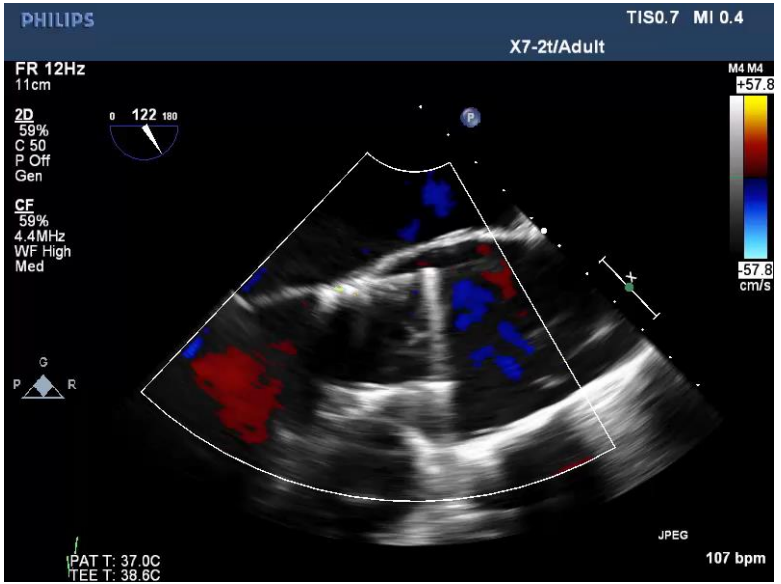





Procedural steps:

1. Advancement of the delivery system over a guidewire, flexion of the delivery system to achieve co-axiality
2. Deployment of the three clamps into aortic sinus
3. Valve deployment
4. Stable valve position with trivial PVL

1 year follow up



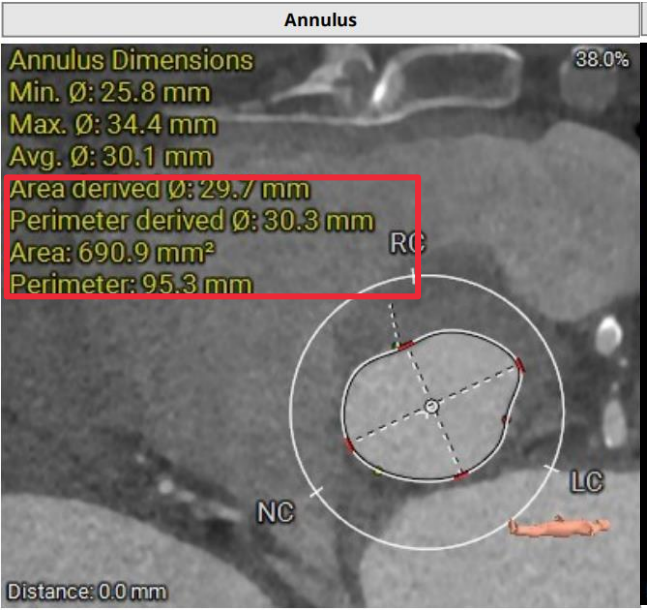


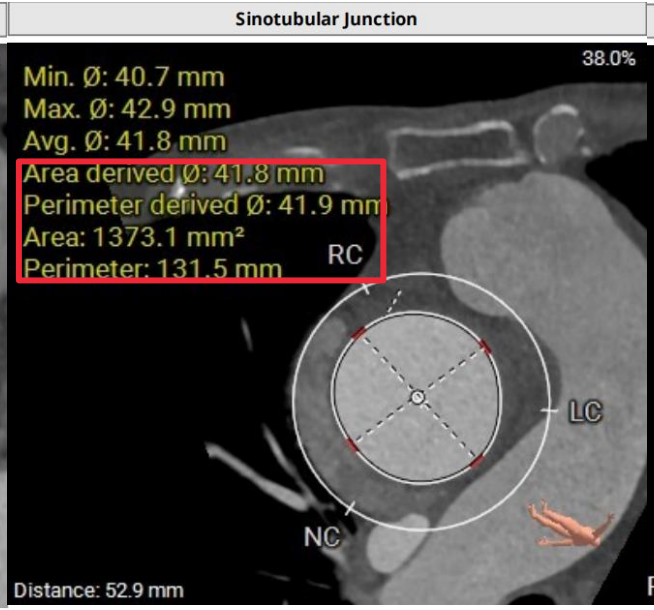
1. NYHA I/II
2. Well functioning Ken-Valve with excellent hemodynamics and no PVL
3. LVEF improvement from 28% to 51%
4. LV remodeling from 229/166ml to 111/54ml

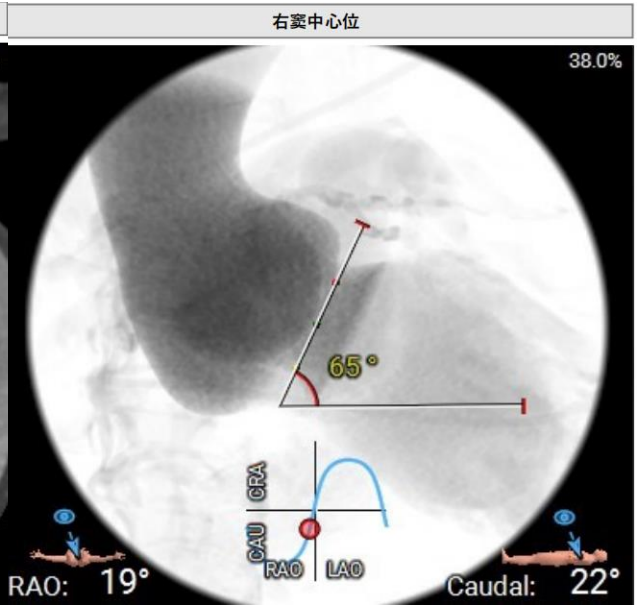
Case II

- 80 y/o male in NYHA Class III
- Hx of hypertension, pneumonia, post and prostate and esophagus cancer surgery and radiotherapy
- Enlarged left ventricle and left atrium, LVEF=44%
- Severe aortic valve regurgitation (4+), mild to moderate mitral regurgitation

Case II







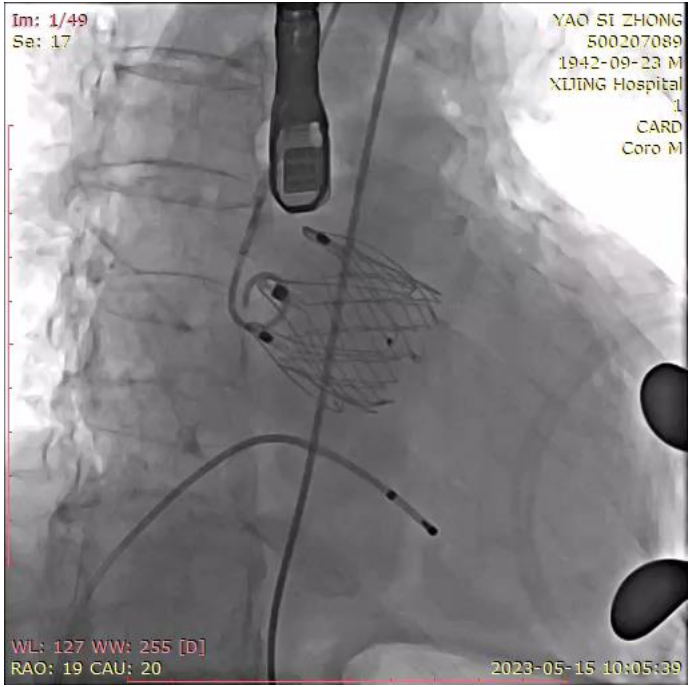
Key challenges of the case:

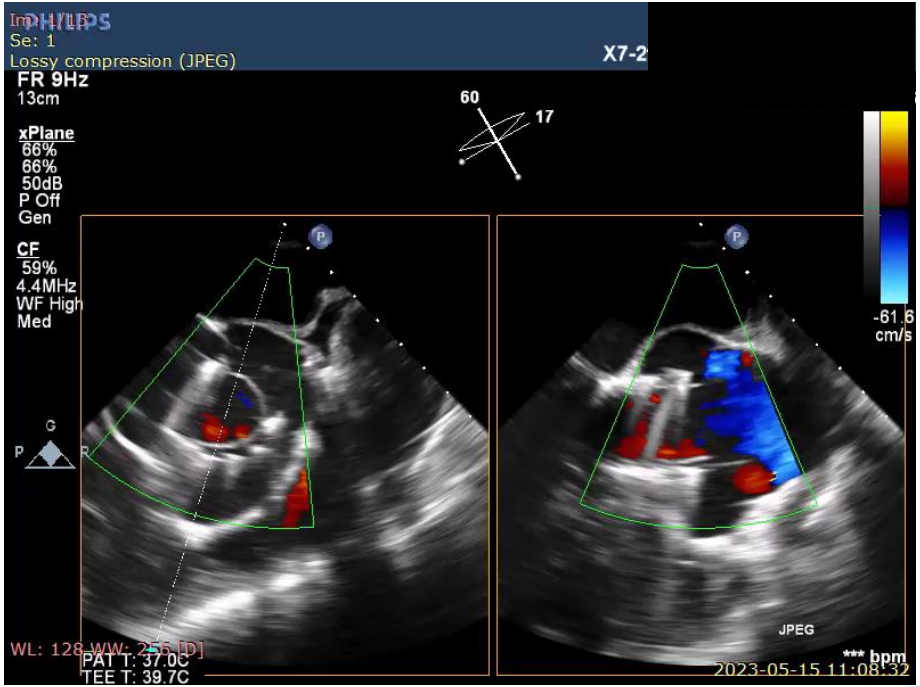
1. Dilated aortic annulus and STJ (mean diameter - 30.3mm and 41.9mm)
2. Horizontal heart, co-axiality could be difficult to achieve

Case II

Follow-up at 1 month:

1. Well functioning well valve with no PVL
2. Clinical improvement in NYHA class and QoL





Conclusions

- **Ken-Valve TAVR system is an innovative device, designed specifically to treat aortic regurgitation (AR) or predominantly AR mixed with AS**

- **Device advantages:**
  - ✓ Integrated clamping + radial force anchoring mechanism, provide reliable anchoring
  - ✓ PVL mitigating valve stent design
  - ✓ Multiple and large valve size options to accommodate various anatomy
  - ✓ Deflectable delivery system allows better co-axiality and alignment

Conclusions

- Ken-Valve Pivotal Trial demonstrated good procedural safety and effectiveness
- Excellent device performance with large EOA, low transvalvular gradient with minimal PVL
- Significant clinical improvement in NYHA class and QoL with low rate of adverse events
- Encouraging treatment option for high-risk patient with severe AR and mixed AR

THANK YOU

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