



A Feasibility Study to Assess Safety and Effectiveness of the
JenaValve Transfemoral TAVR System in the Treatment of
Patients With Severe Aortic Regurgitation (AR)

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Speaker's name: Prof. med. Stephan Baldus

I do not have any potential conflict of interest

I have the following potential conflicts of interest to report:

lecture fees /proctoring honoraria from JenaValve

- Prevalence: 1-2% of adults >65 years¹ old.
- Treatment in severe AR: SAVR
- Current TAVI limitations:
 - Valve securement
 - Limited clinical evidence
- 30-day mortality (transfemoral TAVI): 12.6%²

¹Nkomo VT, Gardin GM, Skelton TN, et al. *Lancet*. 2006;368:1005-11.

²Rawasia WF, Khan MS, Usman MS et al. *Catheter Cardiovasc Interv*. 2019;93:345–353.



Nitinol Support Frame

- Self-expanding

Porcine Pericardial tissue

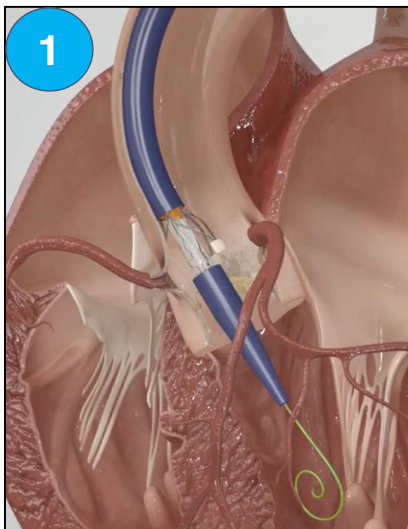
- Supra-annular prosthesis

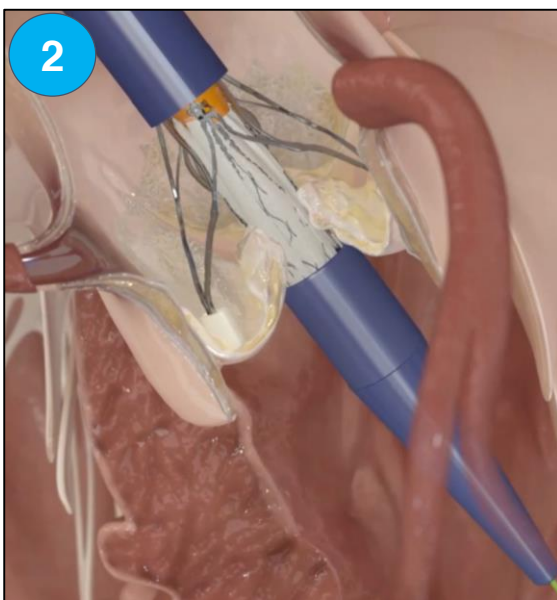
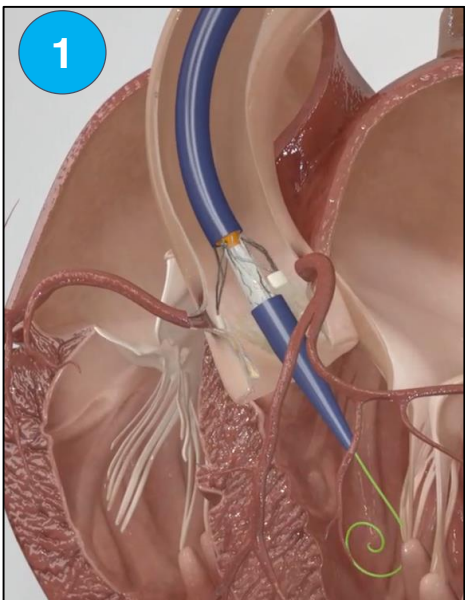
Locators

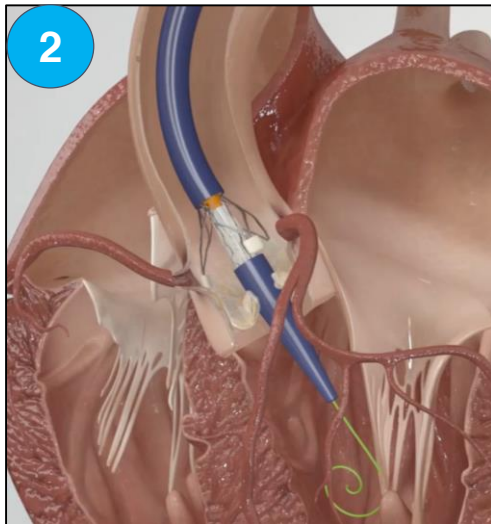
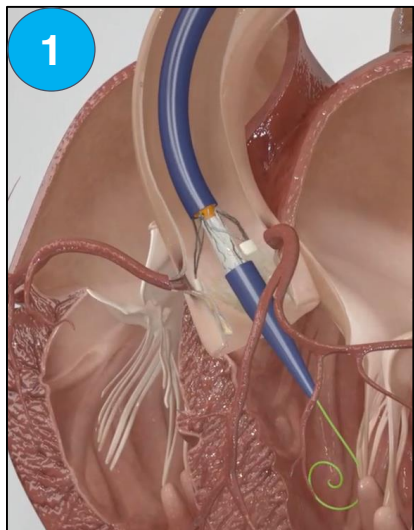
- Aligns valve & sets depth with native anatomy
- Native leaflets are “clipped” during deployment

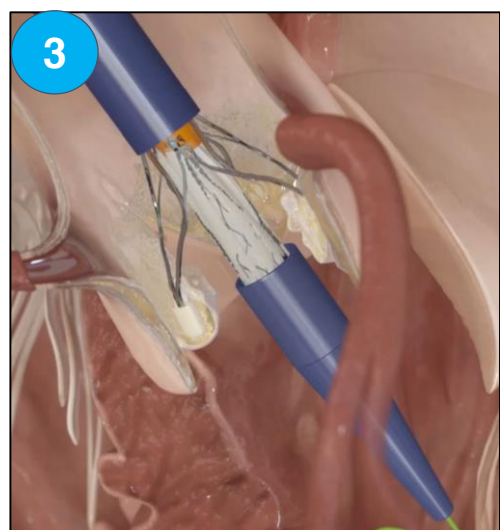
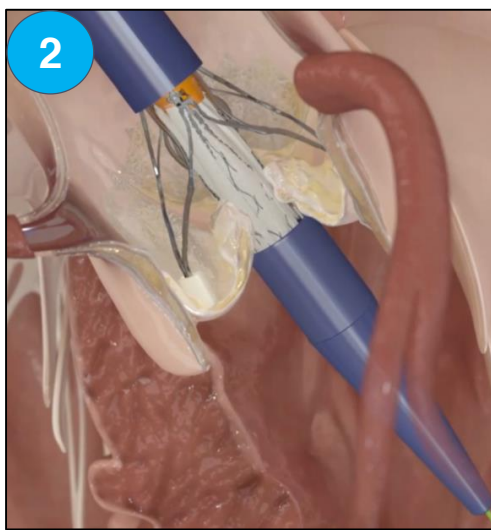
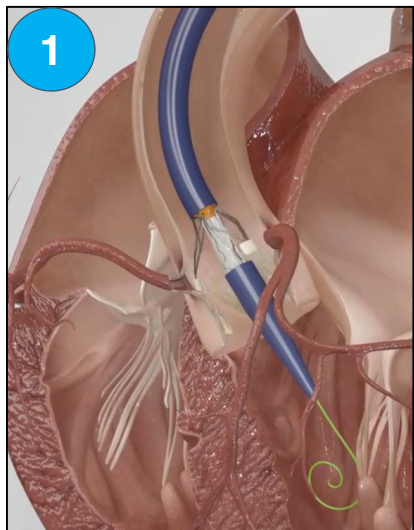
Sealing Ring

- 24 diamond-shaped cells for securement and sealing
- Minimal protrusion into LVOT







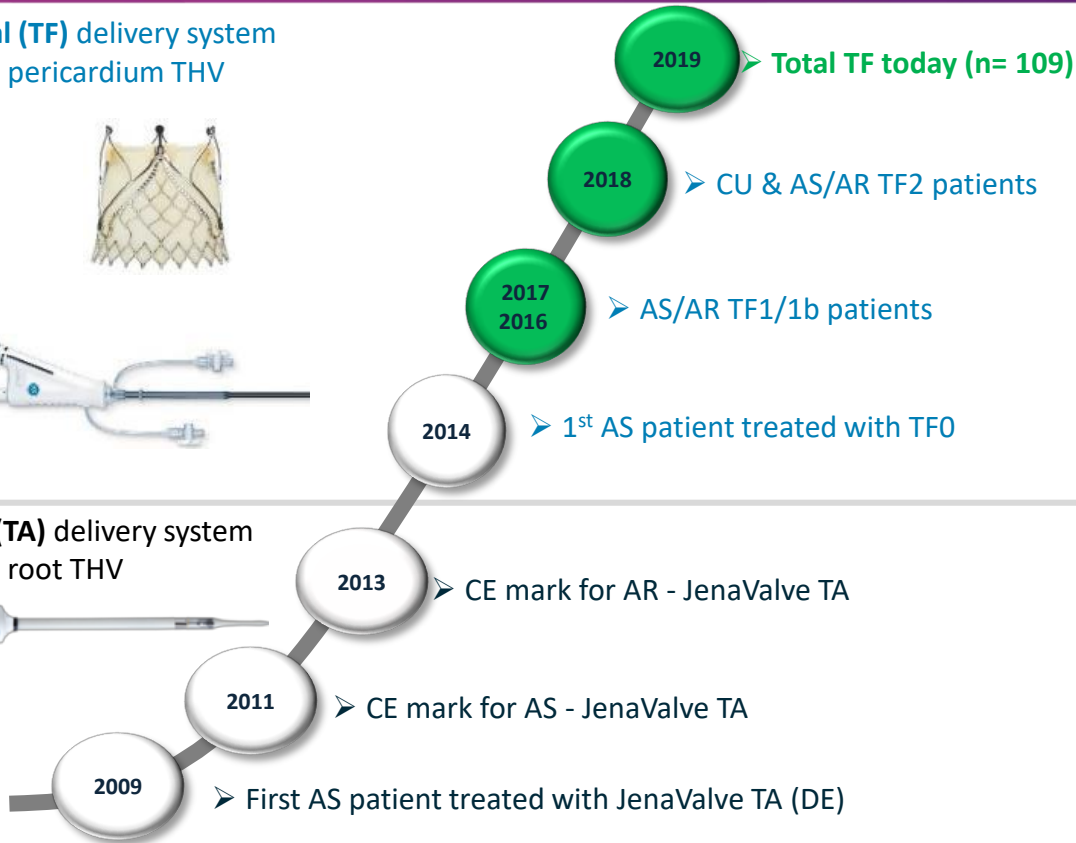
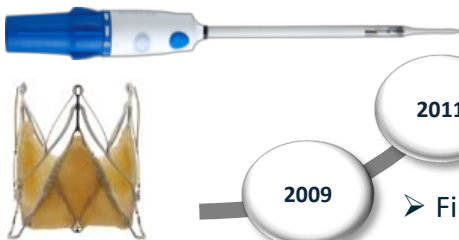


JenaValve Pericardial THV

Transfemoral (TF) delivery system
with porcine pericardium THV



Transapical (TA) delivery system
with porcine root THV



JenaValve AR Global Clinical Program Characteristics



EU Study Program

US Study Program

Extreme and High Surgical Risk

Prospective, Multicenter, Single Arm

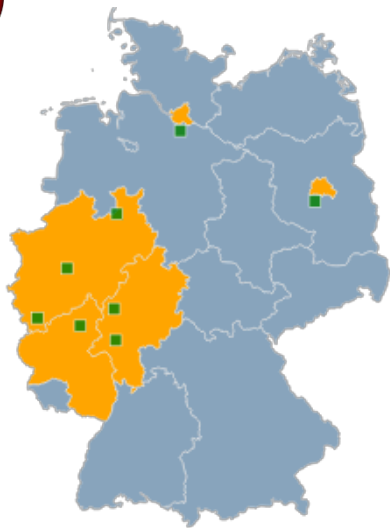
Primary Endpoint: All Cause Mortality at 30 days

Additional Evaluations: VARC-2, Hemodynamics, NYHA, 6-MWT, KCCQ

Total Patients: up to 60

Total Patients: up to 40

Global AR Clinical Program Sites



Cologne

Berlin

Bad Oeynhausen

Bad Nauheim

Hamburg

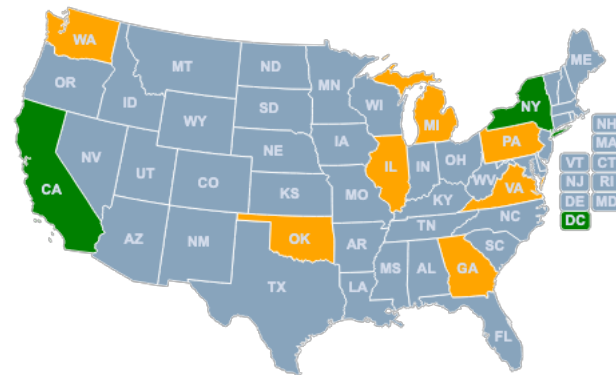
Dortmund

Bonn

Frankfurt



Erasmus Medical Center



Cedars Sinai

Columbia University

MedStar WHC

Emory University

Oklahoma Heart

Univ. of Washington

Prairie Heart

Pinnacle Health

Carilion Med Center

Univ. of Michigan

Study Design	Prospective, multi-center, single-arm safety and performance trial
Patients/sites	Up to 60 patients at up to 12 centers in Germany and The Netherlands
Operations	independent ECHO core lab
Key inclusion criteria	<ul style="list-style-type: none">• Severe aortic regurgitation• STS Score of $\geq 8\%$ or heart team agreement the patient is high-risk for SAVR
Primary endpoint	All-cause mortality at 30 days post-treatment
Secondary endpoints	Safety: VARC-2 definitions Performance: Valve function and hemodynamics, NYHA Class, 6MWT, KCCQ
Success endpoints	Technical, procedure and device success per VARC-2 definitions

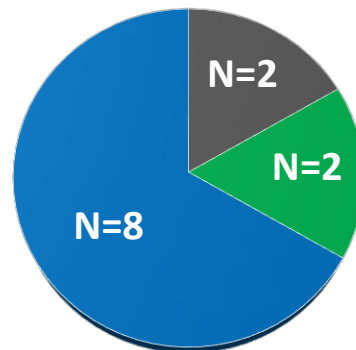
12 patients enrolled at 7 centers

University Hospital Cologne Cologne, Germany Stephan Baldus	5
Heart Center Bonn, University Hospital Bonn, Germany Heart Center, University Hospital Halle, Germany Hendrik Treede	2
German Heart Center Berlin DHZ Berlin, Germany Jörg Kempfert	2
Kerckhoff Heart Center Bad Nauheim, Germany Won-Keun Kim	1
Heart and Diabetes Center Bad Oeynhausen, Germany Tanja Rudolph and Sabine Bleiziffer	1
Erasmus Medical Center Rotterdam, The Netherlands Nicolas Van Mieghem	1

	% (n=12)
Age (years, mean \pm SD)	75 \pm 7.2
Female, %	67 (8)
NYHA Class III/IV (n [%])	67 (8)
STS Score (% , mean \pm SD)	3.5 \pm 2.1
Frailty, %	33 (4)
Pulmonary Hypertension, %	25 (3)
Porcelain Aorta, %	8 (1)
Aortic annulus diameter (mm, mean \pm SD)	25 \pm 2.3
AVA (cm ² , mean \pm SD)	2.6 \pm 0.4
LVEF (% , mean \pm SD)	53 \pm 8.5
Atrial Fibrillation, %	42 (5)
Mitral regurgitation, %	83 (10)
Prior PCI, %	17 (2)

THV Size Implanted

- Size 23 (16.7%)
- Size 25 (16.7%)
- Size 27 (66.7%)



Post-dilatation performed, %

% (n=12)

0.0 (0)

JVT sheath in to sheath out (mins, mean \pm SD)

22 \pm 9

Access open to access close (mins, mean \pm SD)

71 \pm 20

	% (n=12)
Technical success per VARC-2, %	92 (11)

Conversion to surgery, %	8.3 (1)
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Safety

Myocardial infarction*	
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Major vascular complication*	8.3 (1)
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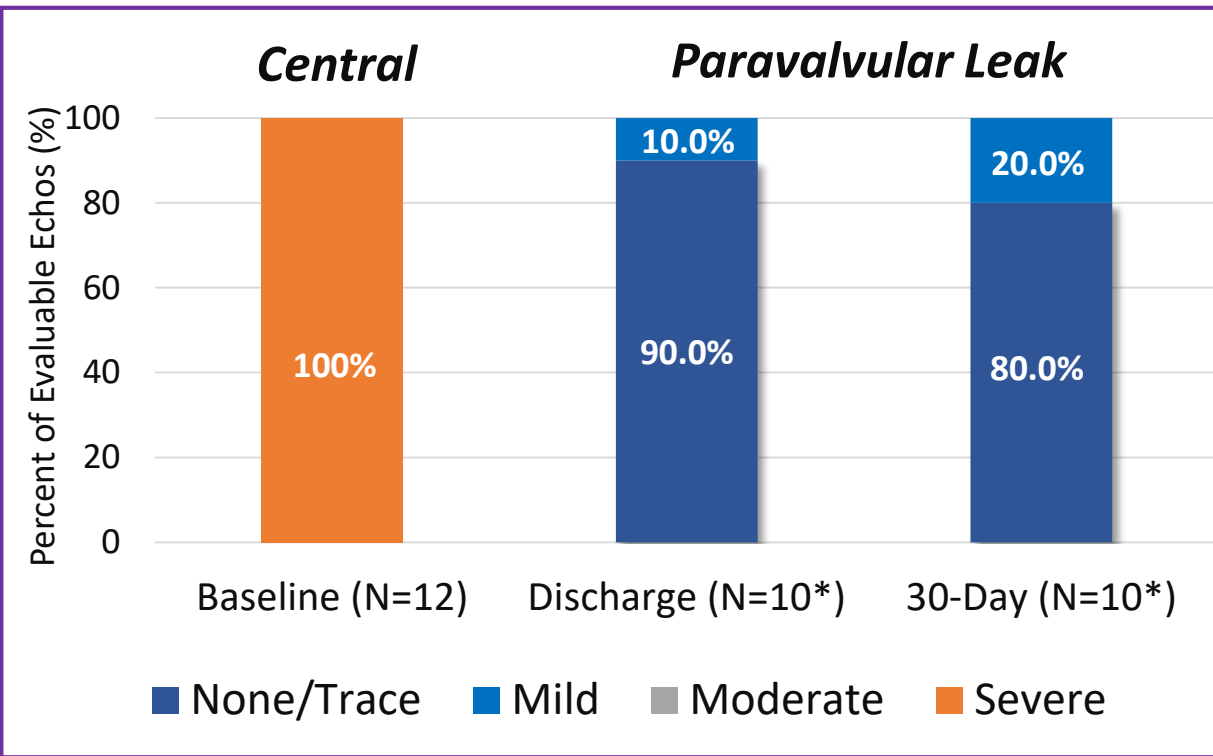
All stroke	0.0
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New permanent pacemaker	8.3 (1)
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Number of patients with ≥ 1 VARC-2 event	25.0 (3)
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*Procedure abandoned after sheath insertion

Aortic Regurgitation & Hemodynamics at 30 Days

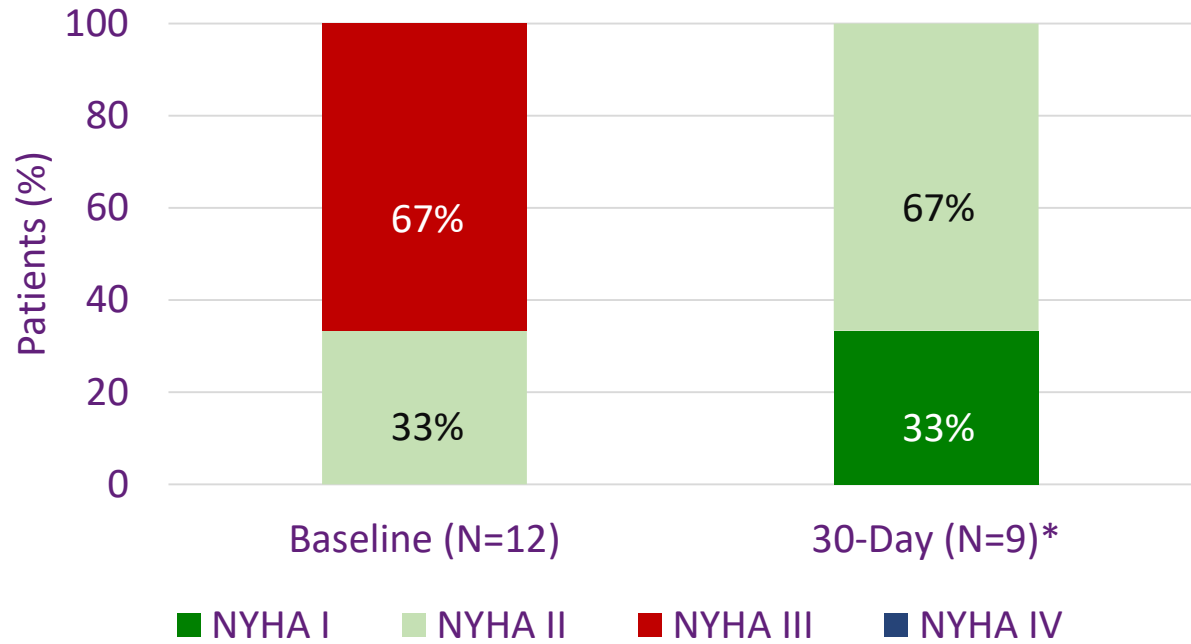


	Mean ± SD [N]
Mean Gradient (mmHg)	4.3 ± 1.7 [10]
EOA (cm ²)	2.4 ± 0.5 [5]
LVEF (%)	49.3 ± 9.6 [9]

30 day mortality: 0%

*Excludes one Pt. converted to SAVR and one patient without follow-up

NYHA Class



*Excludes one Pt. converted to SAVR and two patients without follow-up

In the first CE-mark study dedicated to transfemoral treatment for aortic regurgitation, the JenaValve THV demonstrated:

- No mortality at 30 days
- No paravalvular leak greater than mild at 30 days
- Favorable hemodynamics
- Clinical improvement

Thank you!