A case of transcatheter edge-to-edge mitral valve repair

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Potential conflicts of interest

Speaker's name: Didier Tchétché

☐ I have the following potential conflicts of interest to report:
Consultant fees from Edwards LifeSciences

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Patient Presentation

History

- 81-year-old man
- Worsening dyspnea
- NYHA III

Laboratory Results

- Hb: 14.5 g/dL
- Creatinine: 176 mmol/L (eGFR 33 ml/min/1.73m^2)
- NT-proBNP: 4500 pg/mL
- CRP: 11 mg/L

Past Medical History

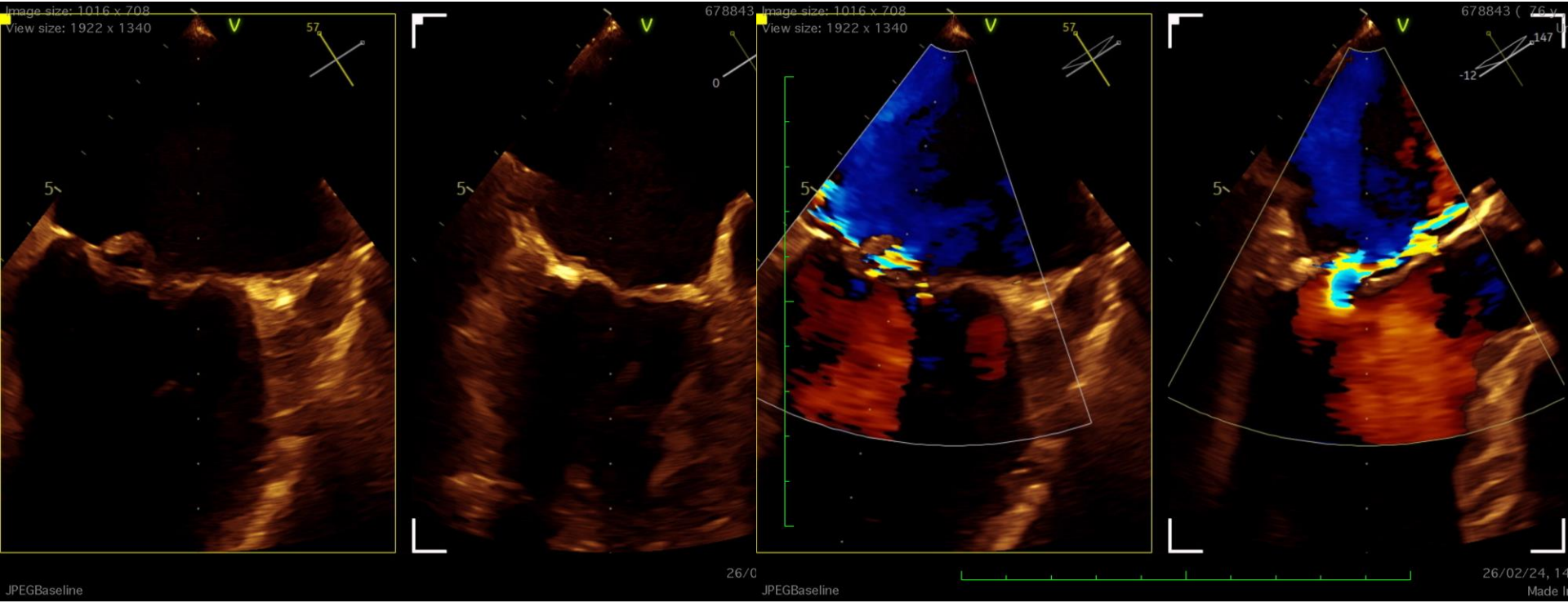
- Former smoking
- Paroxysmal atrial fibrillation, COPD
- 2020: pulmonary embolism
- 2023: colon carcinoma

Baseline Transthoracic Echo

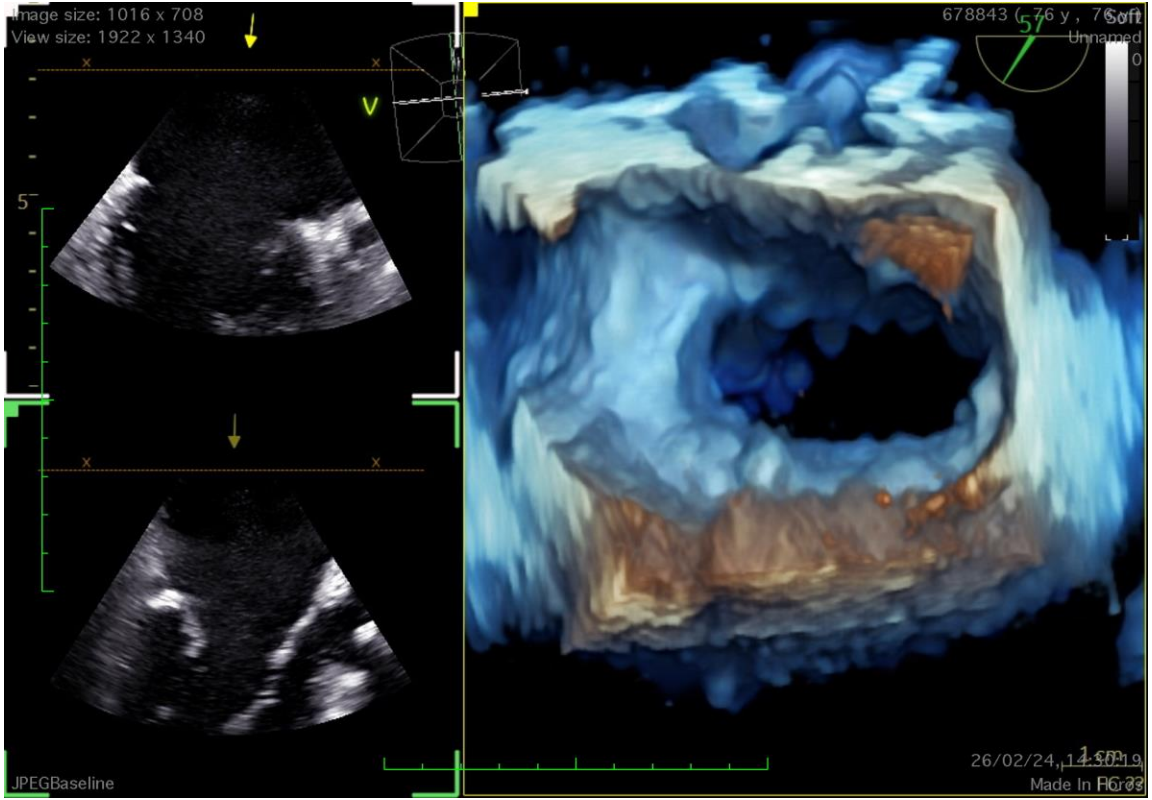
- Severe primary MR (EROA: 0.75 cm^2, RV 85 ml)
- LVEF: 55 %
- RV: moderate dilatation and normal function
- Moderate TR
- sPAP 61 mmHg

NYHA: New York Heart Association; COPD: Chronic obstructive pulmonary disease; Hb: hemoglobin; eGFR: estimated glomerular filtration rate; NT-proBNP: N-terminal pro–B-type natriuretic peptide; CRP: C-reactive protein; MR: mitral regurgitation; EROA: effective regurgitant orifice area; LVEF: left ventricular ejection fraction; RV: right ventricle; TR: tricuspid regurgitation; sPAP: systolic pulmonary artery pressure.

Baseline Transoesophageal echo



Baseline Transoesophageal echo



Baseline Transoesophageal echo: summary

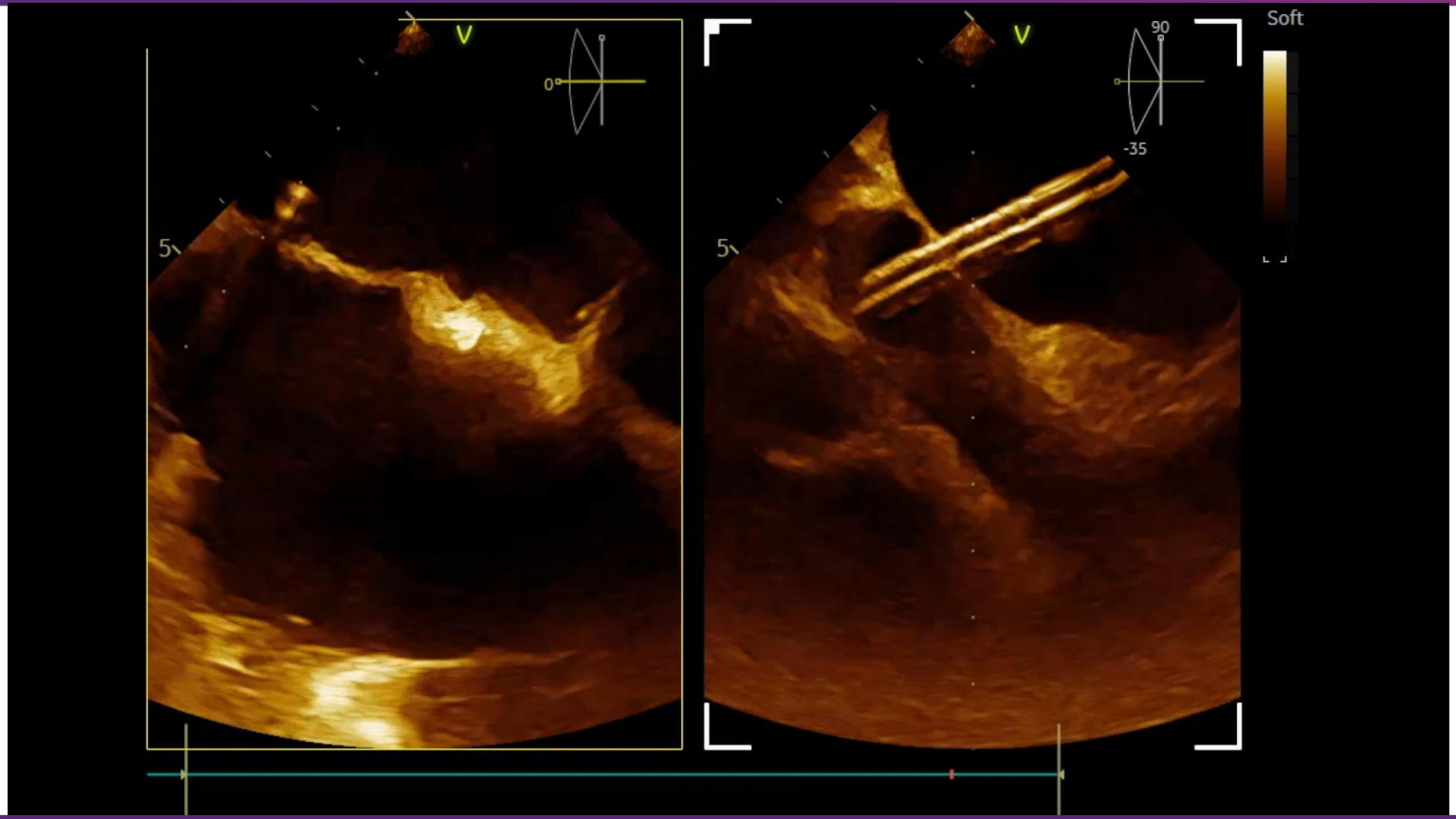
- **Severe MR** (EROA: 0.78 cm^2, RV 05 ml)
- **Primary etiology:** partial P2-P3 prolapse due to chordal rupture

The Strategy

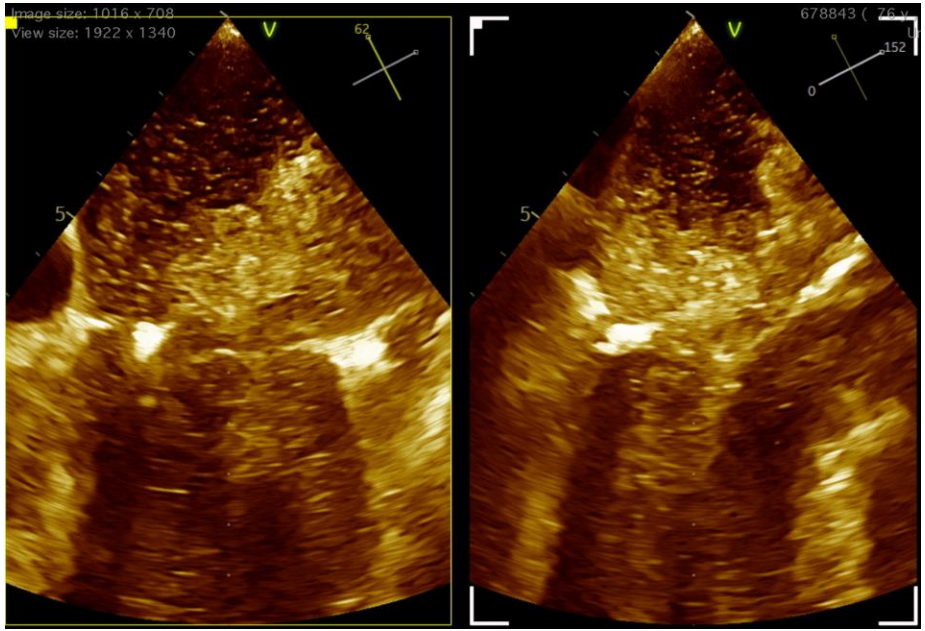
Favourable anatomy for TEER: central position, no calcification, MG 3 mmHg, normal leaflets mobility, posterior leaflet 9 mm, flail width 11 mm, flail gap 10 mm

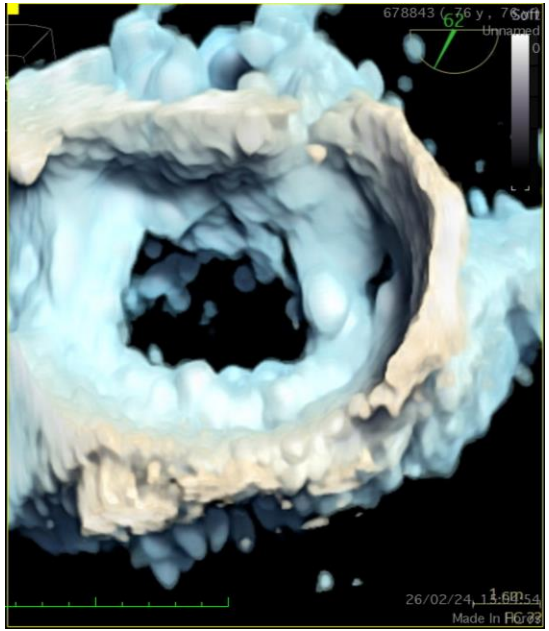
MR: mitral regurgitation; EROA: effective regurgitant orifice area; RV: right ventricle; TEER: transcatheter edge to edge repair; MG: mean gradient.

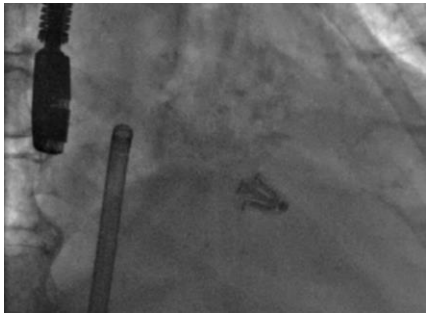
Transeptal puncture: 4.5 cm

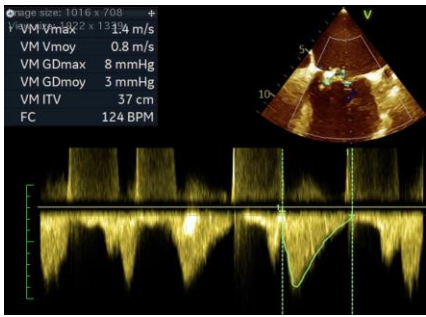


Implantation of the 1st PASCAL Ace implant in A3-P3 position

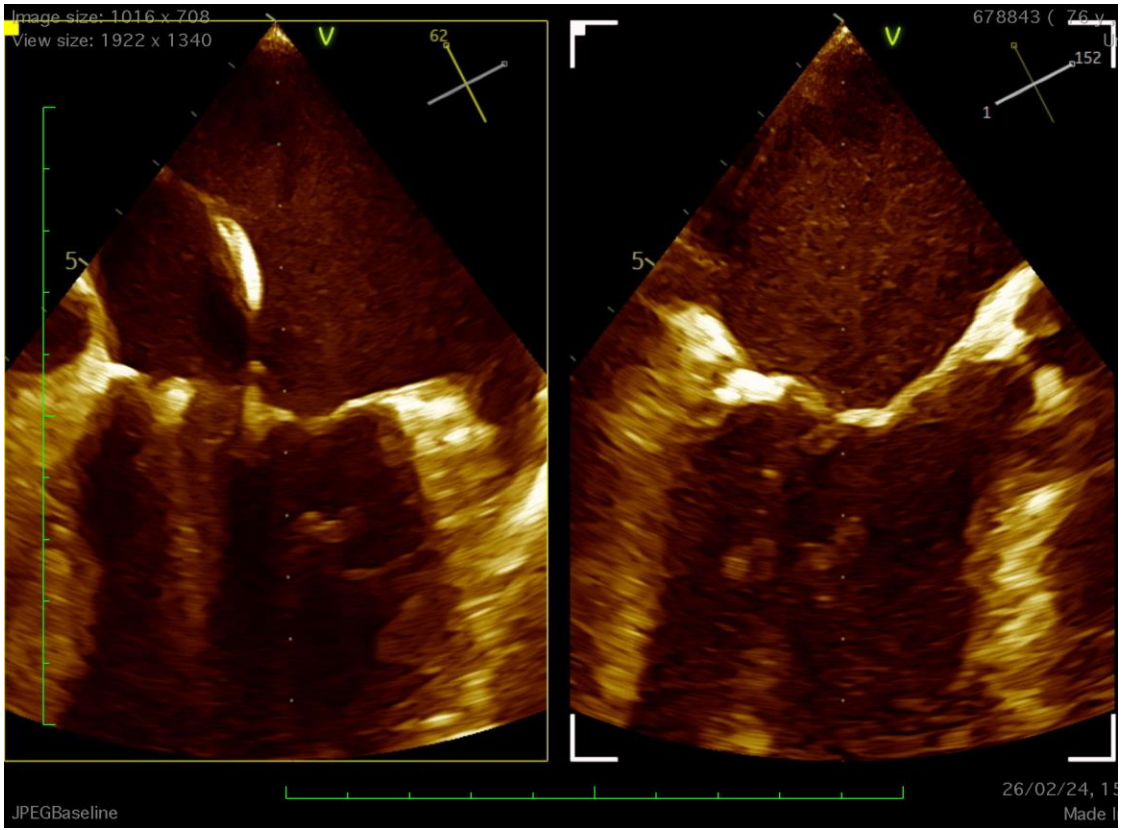


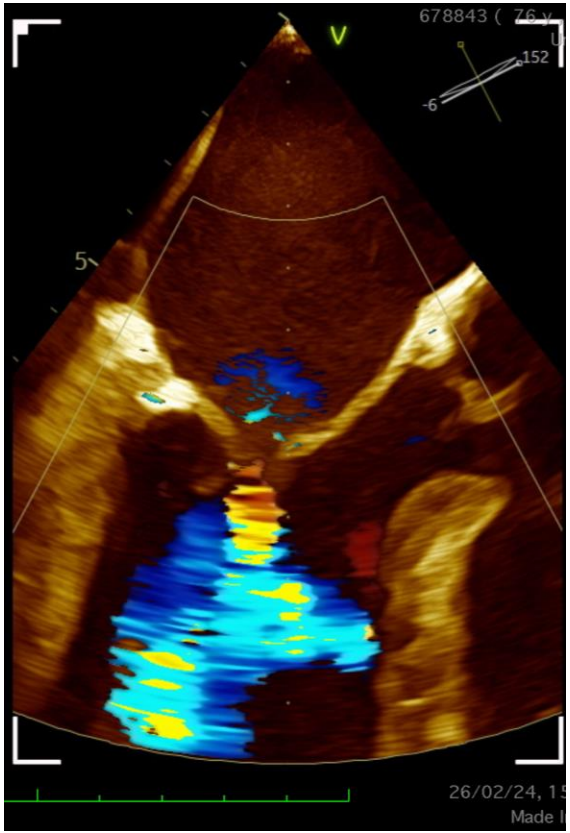




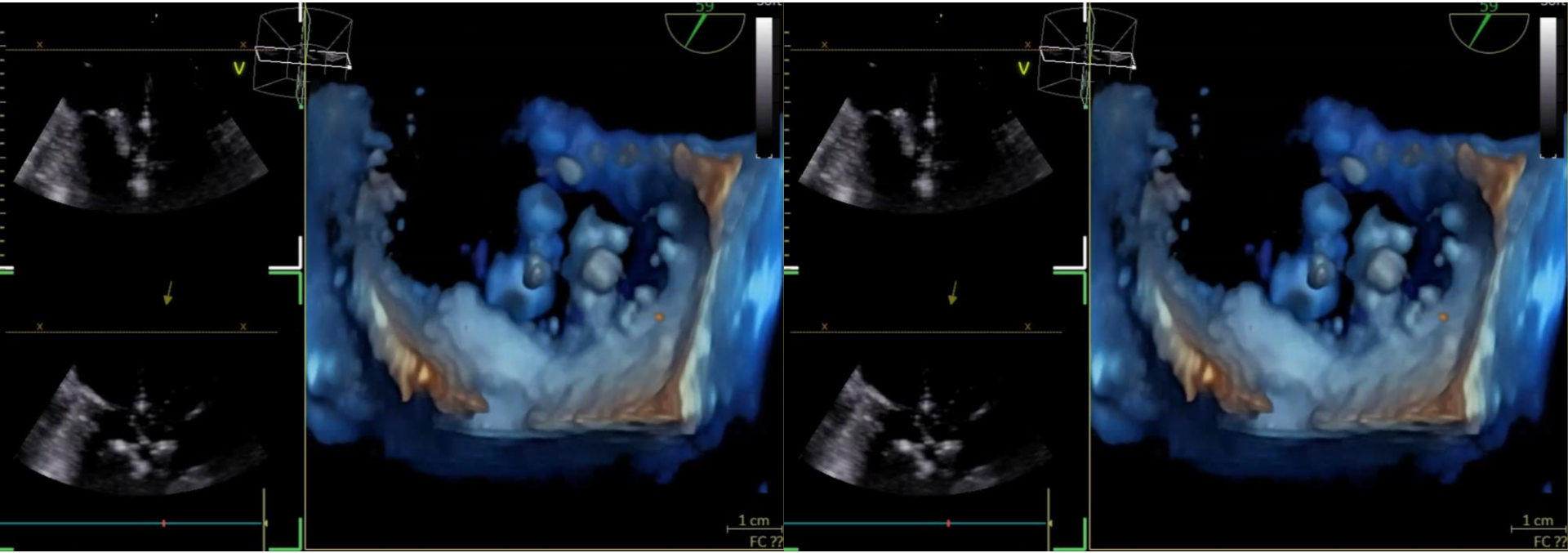


Implantation of the 2nd PASCAL Ace implant lateral to the 1st one





Lateral repositioning of the 2nd PASCAL Ace implant (2 captures)



Discharge transthoracic echocardiography

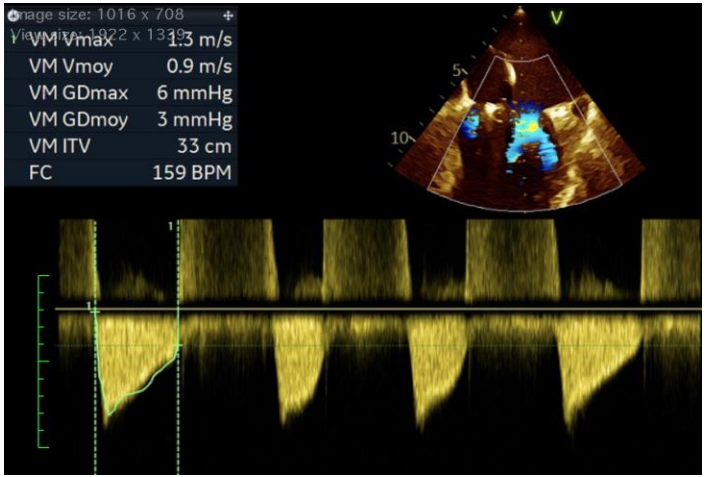
Mild MR, no MS (MG 3 mmHg)

LVEF: 65 %

RV normal function and dimension

Trivial TR

sPAP 35 mmHg



MR: mitral regurgitation; MS: mitral stenosis; MG: mean gradient LVEF: left ventricular ejection fraction; RV: right ventricle; TR: tricuspid regurgitation; sPAP: systolic pulmonary artery pressure.

Conclusion

- MR reduced to mild with 2 PASCAL Ace implants after a total of 3 leaflet capture attempts

The PASCAL Precision system is designed to allow staged leaflet capture and optimization of implant placement

What do we know about the effect of multiple Leaflet capture attempts on leaflet integrity?

Thank you

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Atraumatic clasp and closure: simulation-, evidence-, and case-based discussion

C. Besler

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Potential conflicts of interest

Speaker's name: C. Besler

I have the following potential conflicts of interest to report:

- Speaker honoraria: Edwards Lifesciences

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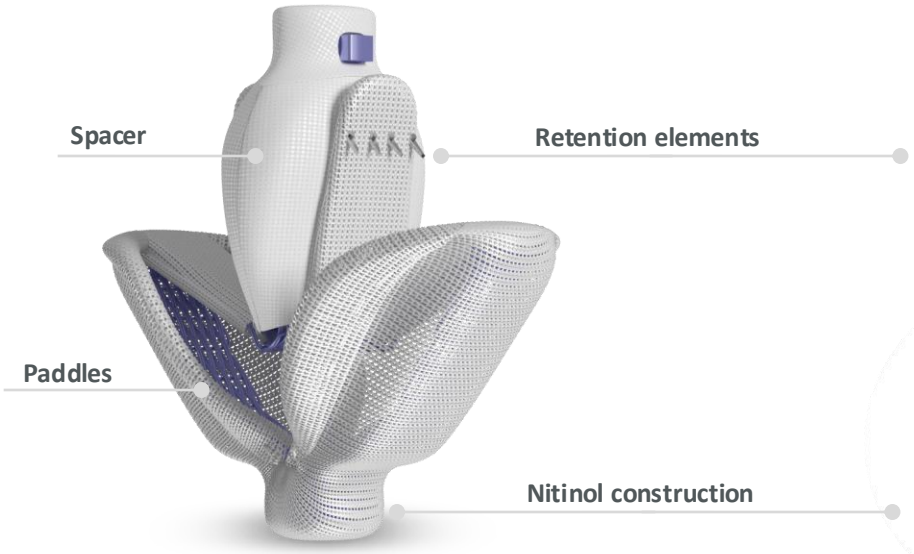
Edwards PASCAL Precision Transcatheter Valve Repair System

*Atraumatic clasp and closure help you preserve leaflet integrity**



A single row of retention elements to clasp, reclasp, and preserve leaflets

Close the implant to conform to native anatomy and flex during cardiac cycle

* Performance and simulation data on file. Images are not actual size.

Background & aim of the study

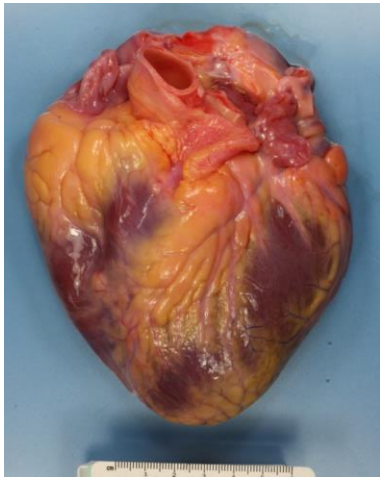
Background:
The **effect of multiple clasp attempts** on leaflet integrity is unknown and there is **no available standard** to assess clinically relevant injury to the leaflets.

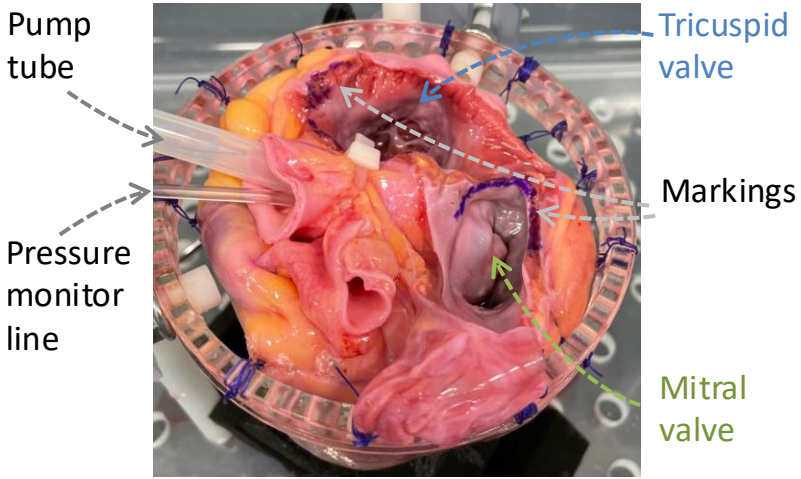
Aim:
Edwards Lifesciences partnered with CV Path Institute* to **evaluate the impact of multiple clasping and closing attempts on** mitral and tricuspid valve **leaflet integrity**.

*CV Path Institute is an independent not-for-profit organization with a research team consists of cardiologists, pathologists, scientists, and other highly skilled technical staff who have a deep understanding of cardiovascular pathology (www.cvpath.org)

Experimental set-up

Using heart cadaver models (n=9) to replicate the in vivo anatomy and leaflet tissue properties of both mitral and tricuspid valves





Opening of atria to expose mitral and tricuspid valves

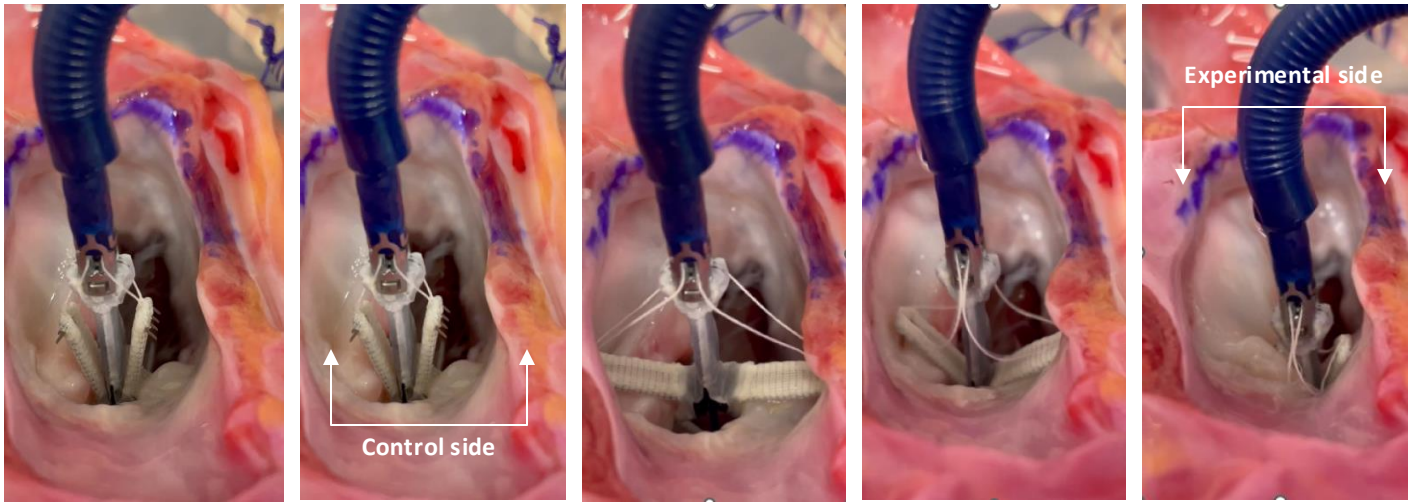
Marking of the **experimental side**

Pump to generate **forward flow** in the ventricle & prevent folded leaflet capture

Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute.

Experimental set-up

The mitral and tricuspid valves on each heart model were partitioned into a control and an experimental side*



Leaflet capture

Implant closure

Leaflet capture & closures

n=15
on experimental side

n=2
on control side

* For the mitral valve, both anterior and posterior leaflets were evaluated; for the tricuspid valve, anterior and septal leaflets were evaluated. Tests were performed using either the PASCAL implant (n=5 for mitral valve, n=3 for the tricuspid valve) or the PASCAL Ace implant (n=4 for mitral valve, n=6 for the tricuspid valve)

Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute.

Experimental set-up

Leaflet damage scores ≥ 4 were defined by the CV Path Institute to be clinically relevant injuries †

PASCAL and PASCAL Ace implants

n=5 for MV
n=3 for TV

n=4 for MV
n=6 for TV

Leaflet damage scoring system developed by CV Path Institute*

I. Leaflet damage score	II. Grade of surface roughening extent
Score 0 = No discernable damage	Grade 0 = No roughening
Score 1 = Small (≤1 mm in size) surface defects	Grade 1= minimal irregularity of the valve
Score 2 = 1-5 mm in size	Grade 2 = imprints of the device visible of the surface of the valve
Score 3 = 2-5 mm in size	Grade 3 = deep imprint of the device easily visible
Score 4 = 2-5 mm in size	Grade 4 = surface tears visible
Score 5 = > 5mm in size	

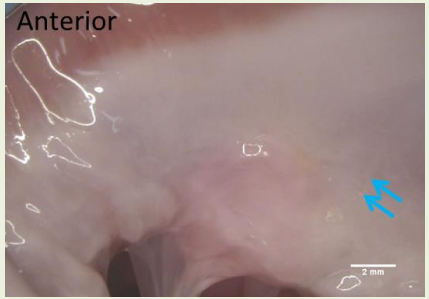
† Leaflet damage scores greater than or equal to four were defined to be clinically relevant injuries because these conditions might induce adverse effects on the degree of regurgitation.
*CV Path Institute is an independent not-for-profit organization with a research team consists of cardiologists, pathologists, scientists, and other highly skilled technical staff who have a deep understanding of cardiovascular pathology (www.cvpath.org).
Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute.

MV: mitral valve; TV: tricuspid valve.

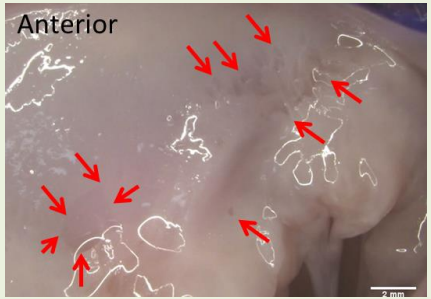
Small surface imprints and damages (<5mm) only on the atrial side of the leaflet

*Representative gross images of excised leaflets obtained by digital photography immediately after completion of leaflet captures**

MITRAL VALVE

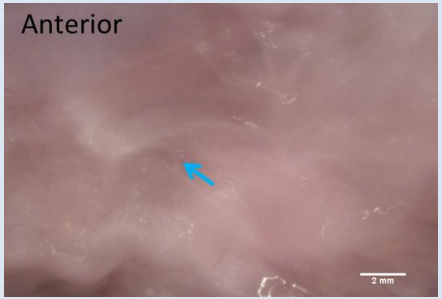


Control side
(n=2 leaflet captures)



Experimental side
(n=15 leaflet captures)

TRICUSPID VALVE



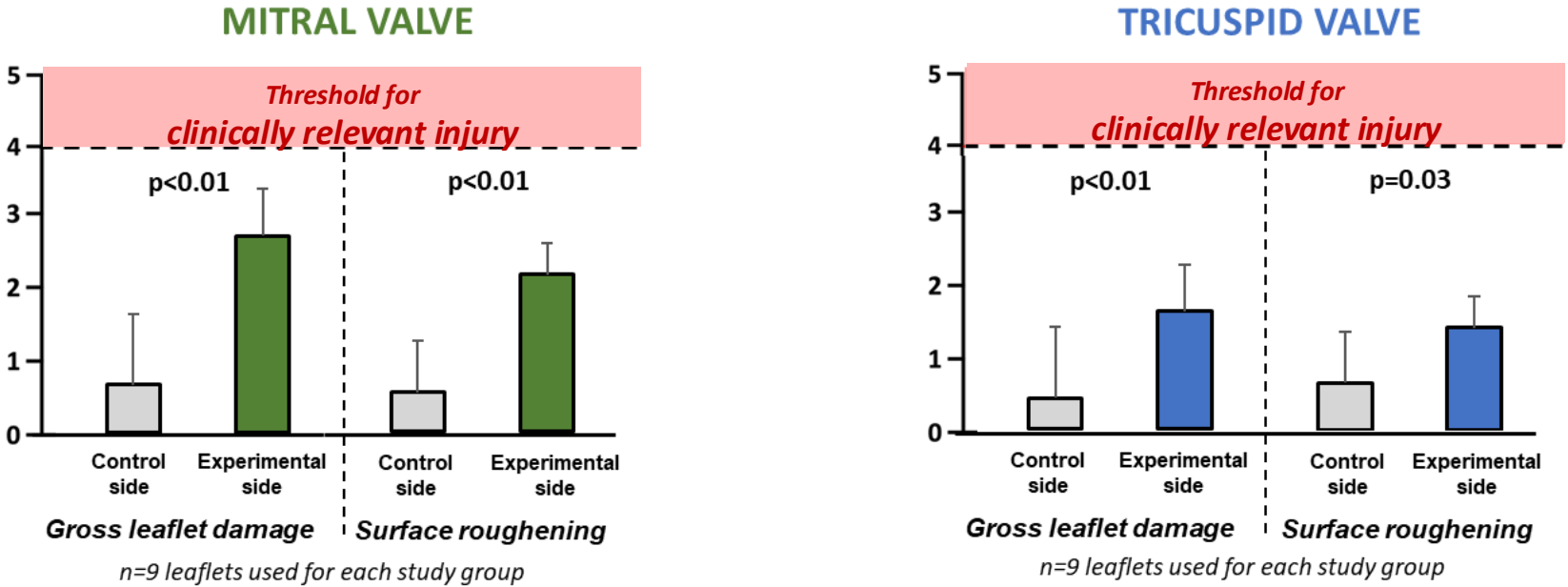
Control side
(n=2 leaflet captures)

Experimental side
(n=15 leaflet captures)

* For the mitral valve, both anterior and posterior leaflets were evaluated; for the tricuspid valve, anterior and septal leaflets were evaluated. Tests were performed using either the PASCAL implant (n=5 for mitral valve, n=3 for the tricuspid valve) or the PASCAL Ace implant (n=4 for mitral valve, n=6 for the tricuspid valve)
Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute.

No clinically relevant injury for either the mitral or tricuspid valve

Leaflet damage was assessed on excised leaflets under the dissection microscope using either the PASCAL or the PASCAL Ace implants[1]*



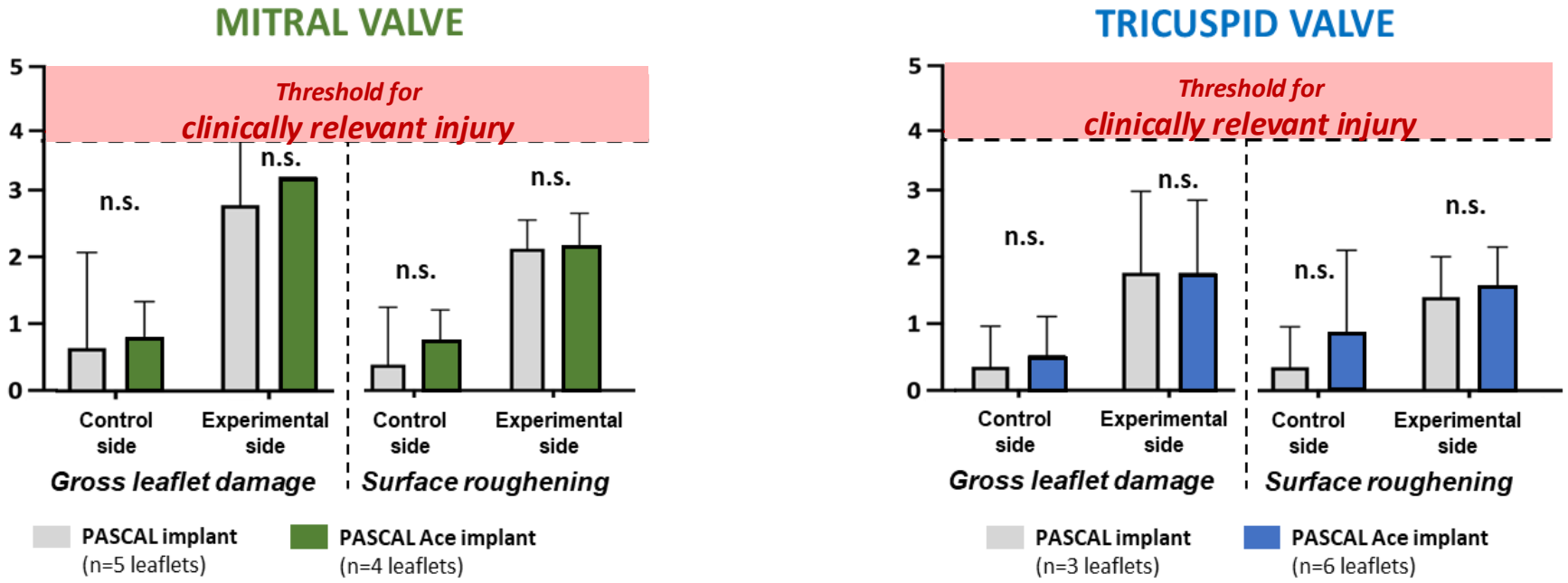
P-values were obtained using Wilcoxon rank-sum test to compare data

[1]Tests were performed using either the PASCAL implant (n=5 for mitral valve, n=3 for the tricuspid valve) or the PASCAL Ace implant (n=4 for mitral valve, n=6 for the tricuspid valve)

*Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute. Observers were 3 internal, 1 external.

No clinically relevant injury with either the PASCAL or the PASCAL Ace implants

*Leaflet damage was assessed on excised leaflets under the dissection microscope**



P-values were obtained using Wilcoxon rank-sum test to compare data

*Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute. Observers were 3 internal, 1 external.

Limitations and conclusion

Limitations

- Lack of dynamic motion and accurate physiological pressures may **underestimate** the extent of the leaflet injury that may occur *in vivo*
- Tissue fragility due to post-mortem autolysis may **exaggerate** the leaflet tissue damage

This *in vitro* study showed:

- **Small** surface imprints and damages (<5mm) only on the **atrial side** of the leaflet
- For either the mitral or tricuspid valve
- With either the PASCAL implant or the PASCAL Ace implants

This *in vitro* study showed no clinically relevant leaflet injury, even under extreme experimental conditions*

*Extreme experimental conditions consisted of n=15 leaflet capture and device closed attempts
Performance, design and simulation data on file; Experiments and analysis performed by CV Path Institute.

Thank you

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Atraumatic clasp and closure: simulation-, evidence-, and case-based discussion

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Zurich, Switzerland

Potential conflicts of interest

Speaker's name: M. Taramasso

I have the following potential conflicts of interest to report:
Honoraria or consultation fees: Edwards Lifesciences, Abbott, Medtronic, Boston Scientific, Shenqi Medical, CoreMedic, CardioValve, PiCardia, MEDIRA, Simulands, ReCross, VentriMend, H-D Imaging

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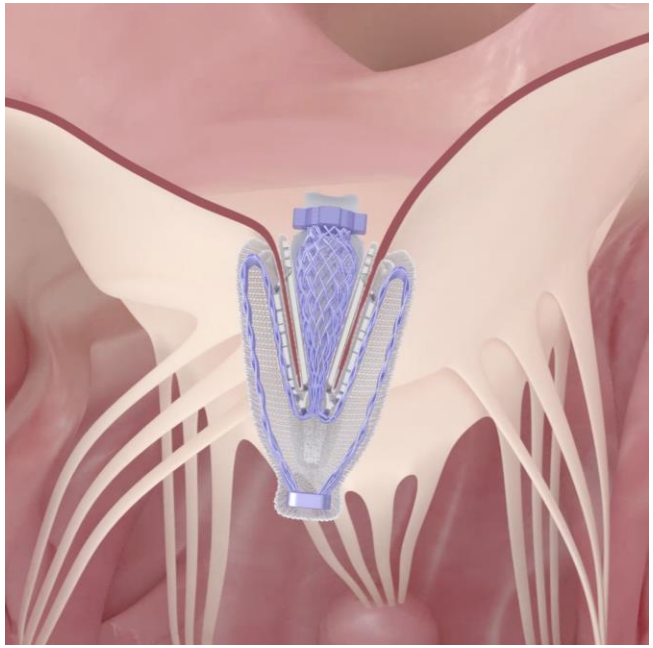
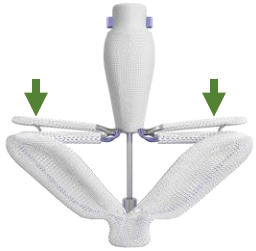
Nitinol Construction: spring-like closure and dynamic implant flexing*

Closes the PASCAL and PASCAL Ace implants to conform to native anatomy and flex during the cardiac cycle



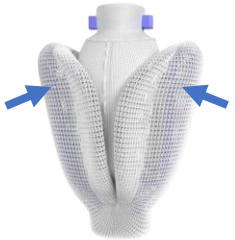
✓ **Nitinol Clasps**

Constant passive force to engage inner paddle and maintain leaflet capture



✓ **Nitinol Paddles**

Constant passive force towards the spacer to naturally close the implant



*Design data on file

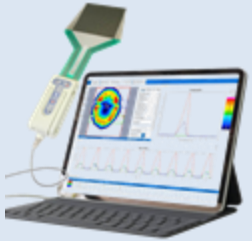
Study aim, material and methods

Aim of the study

Edwards Lifesciences has developed an *in vitro* platform **to evaluate** clasp and paddle **force distribution on the leaflets** for PASCAL and PASCAL Ace implants[1]

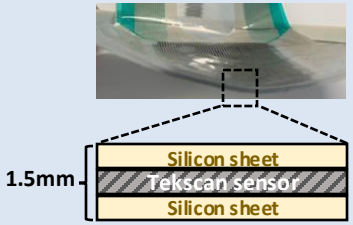
Recording of force measurements

- Tekscan I-Scan System
- Flexible force and pressure mapping sensor (Tekscan sensor 5027)



Simulation of valve anatomy

- 1.5 mm thick[2] simulated leaflet
- 3D-printed gasket as a simplified annulus

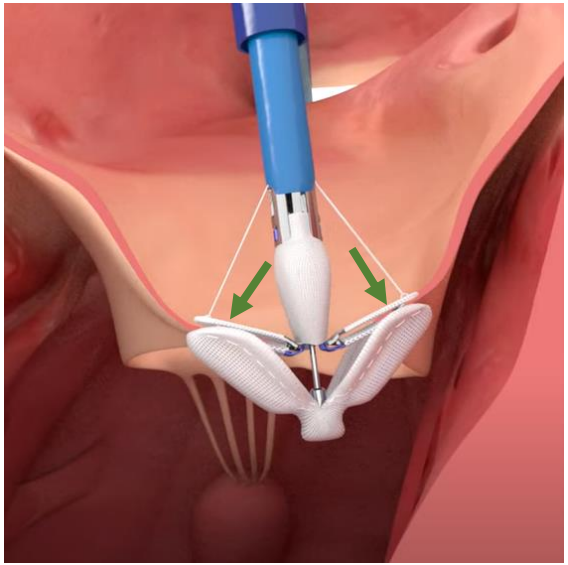


[1]Test performed using the PASCAL Precision system with PASCAL (n=3) or PASCAL Ace (n=3) implants; each device was tested 5 times with insertion of the simulated leaflet of 70-80% for a total of 15 measurements per implant type. Performance, design and simulation data on file; experiments and analysis performed by Edwards Lifesciences

[2]Crawford M.H., Roldan C.A., Quantitative assessment of valve thickness in normal subjects by transesophageal echocardiography. Am J Cardiol. 2001 Jun 15;87(12):1419-23.

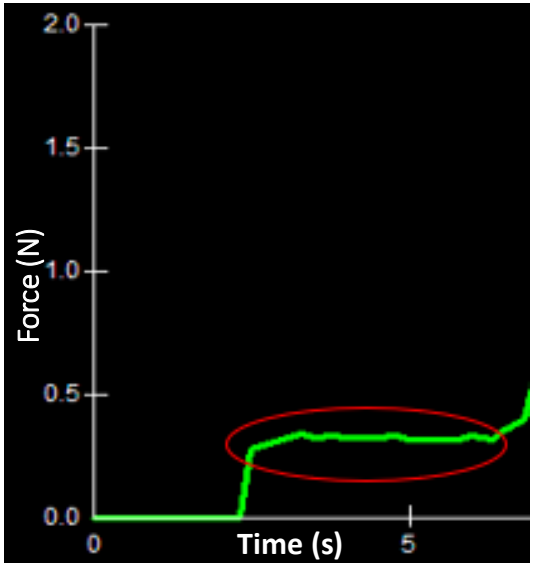
Results: clasp force at leaflet-captured configuration

Exerted by the clasp when it secures the leaflet in leaflet-captured configuration



Clasp force
at leaflet-captured configuration

Representative video showing the leaflet-captured configuration with the PASCAL Ace implant



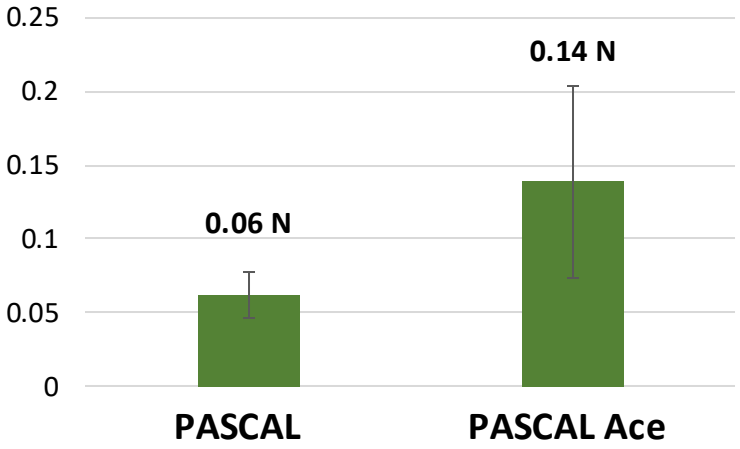
Example of a force over time curve for the PASCAL Ace implant (n=1)

Test performed using the PASCAL Precision system with PASCAL (n=3) or PASCAL Ace (n=3) implants; each device was tested 5 times with insertion of the simulated leaflet of 70-80% for a total of 15 measurements per implant type. Performance, design and simulation data on file; experiments and analysis performed by Edwards Lifesciences

Results: clasp force at leaflet-captured configuration

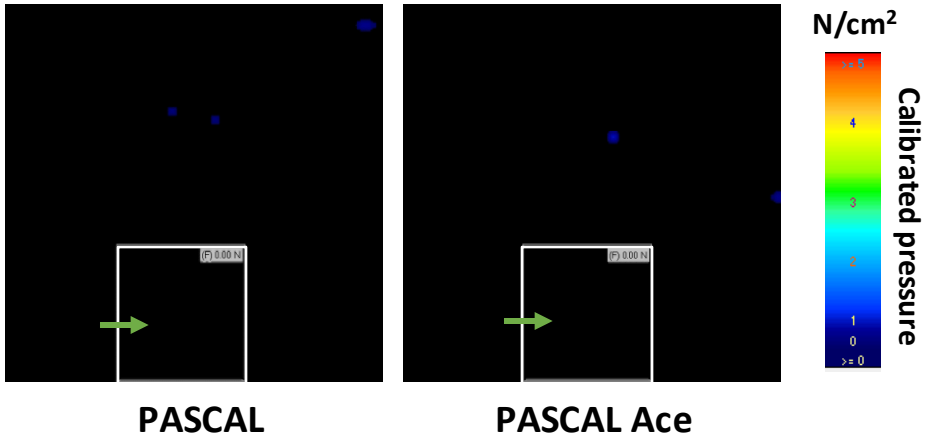
Average peak clasp force

(n=15 measurements/implant type*)



Pressure mapping

(representative videos of clasp force distribution)

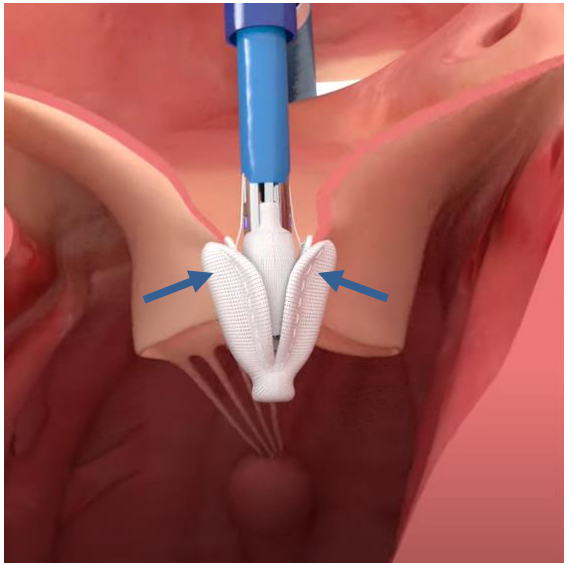


The observed constant clasp force on the simulated leaflet may be beneficial for intraprocedural staged leaflet capture and optimization

*Test performed using the PASCAL Precision system with PASCAL (n=3) or PASCAL Ace (n=3) implants; each device was tested 5 times with insertion of the simulated leaflet of 70-80% for a total of 15 measurements per implant type. Performance, design and simulation data on file; experiments and analysis performed by Edwards Lifesciences

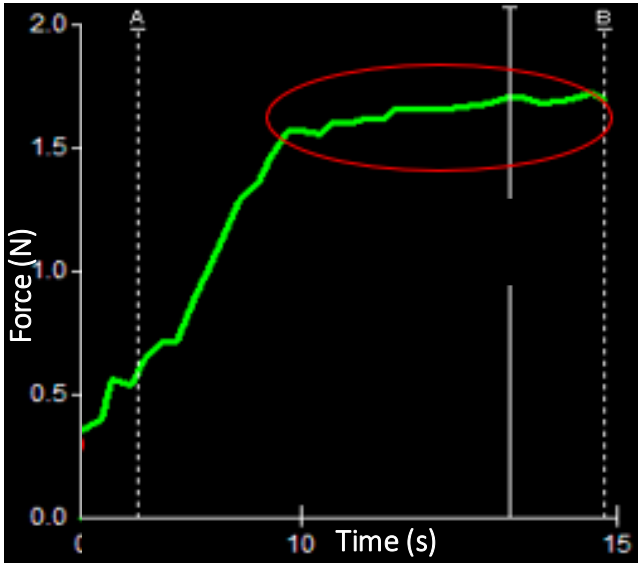
Results: paddle force during implant closing

Exerted by the paddles when the implant is closing



Paddle force
during implant closing

Representative video showing the closing of the PASCAL Ace implant



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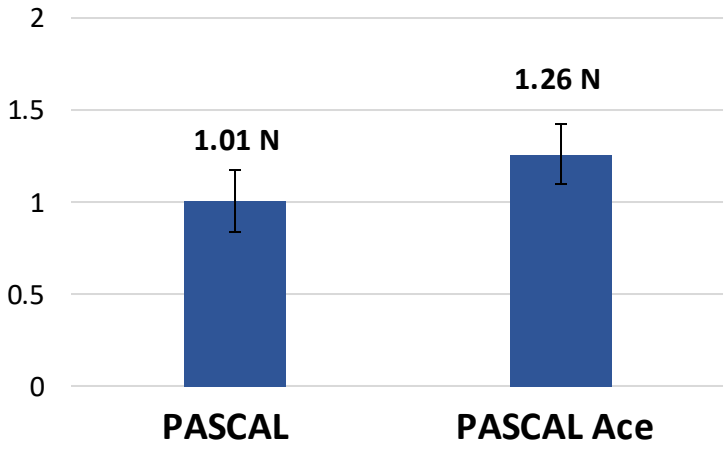
Results: paddle force during implant closing

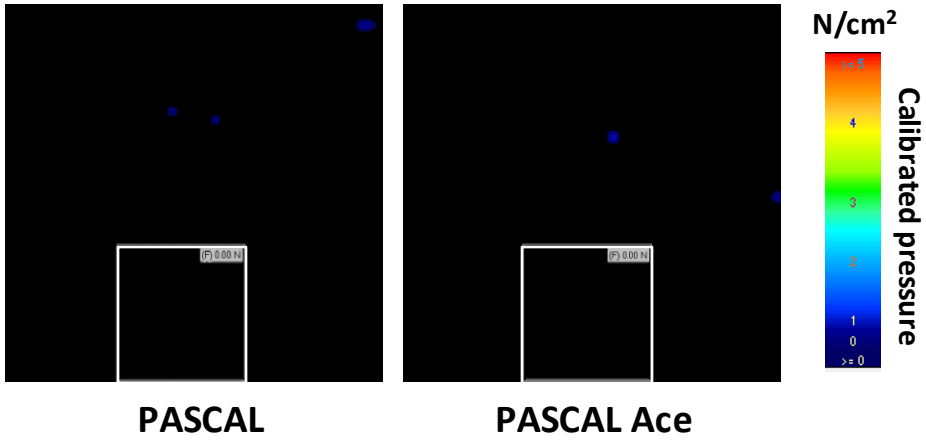
Average peak paddle force

(n=15 measurements/implant type*)



Pressure mapping

(representative videos of paddle force distribution)



The closing force is evenly distributed across the paddles and the retention elements without any large area of pressure concentrations on the simulated leaflets

*Test performed using the PASCAL Precision system with PASCAL (n=3) or PASCAL Ace (n=3) implants; each device was tested 5 times with insertion of the simulated leaflet of 70-80% for a total of 15 measurements per implant type. Performance, design and simulation data on file; experiments and analysis performed by Edwards Lifesciences

Limitations and conclusion

Limitations

- **No available standard** to assess the impact of implant force distribution on the leaflets
- The simulated leaflet is **a simplification** of the valvular anatomy, therefore **force** exerted by the clasps and paddles on the leaflets **might have been underestimated.**

Atraumatic clasp & closure help you preserve leaflet integrity[1]

- A single row of retention elements to clasp, reclasp, and **preserve leaflets**
- A nitinol construction closes the implant to **conform to native anatomy** and flex during the cardiac cycle

Safe optimization of leaflet capture[1] may result in further regurgitation reduction[2]

1. Performance, design and simulation data on file and marketing evaluation. Experiments and analysis performed by CVPath Institute. 2. Hausleiter J, et al. EuroIntervention. 2023 Jan 23;18(12):957-976.

Thank you

Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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