

The PASCAL platform, the therapy to successfully treat TR

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Addressing Tricuspid Valve Challenges

Dense chordae



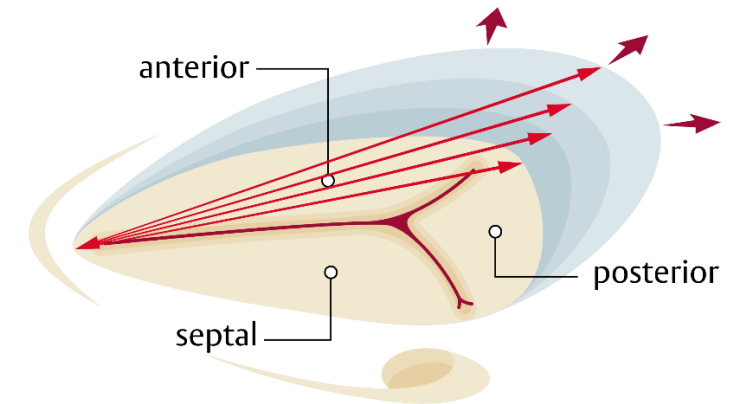
- High variability of chordae: quantity, density, and location^{1,2}
- Thin and fragile chordae¹

Thin, variable leaflets



- Thin, translucent, and more delicate leaflets^{1,2}
- Usually 3 leaflets, but variable or with deep clefts and folds^{2,3}

Large annulus



- Tricuspid valve has the largest annulus⁴
- 90% of TR is functional TR (FTR), presenting with annular dilatation⁵

PASCAL Ace implant system

Atraumatic clasp design

Designed to enable recapturing the fragile tricuspid leaflet multiple times without clinically significant damage

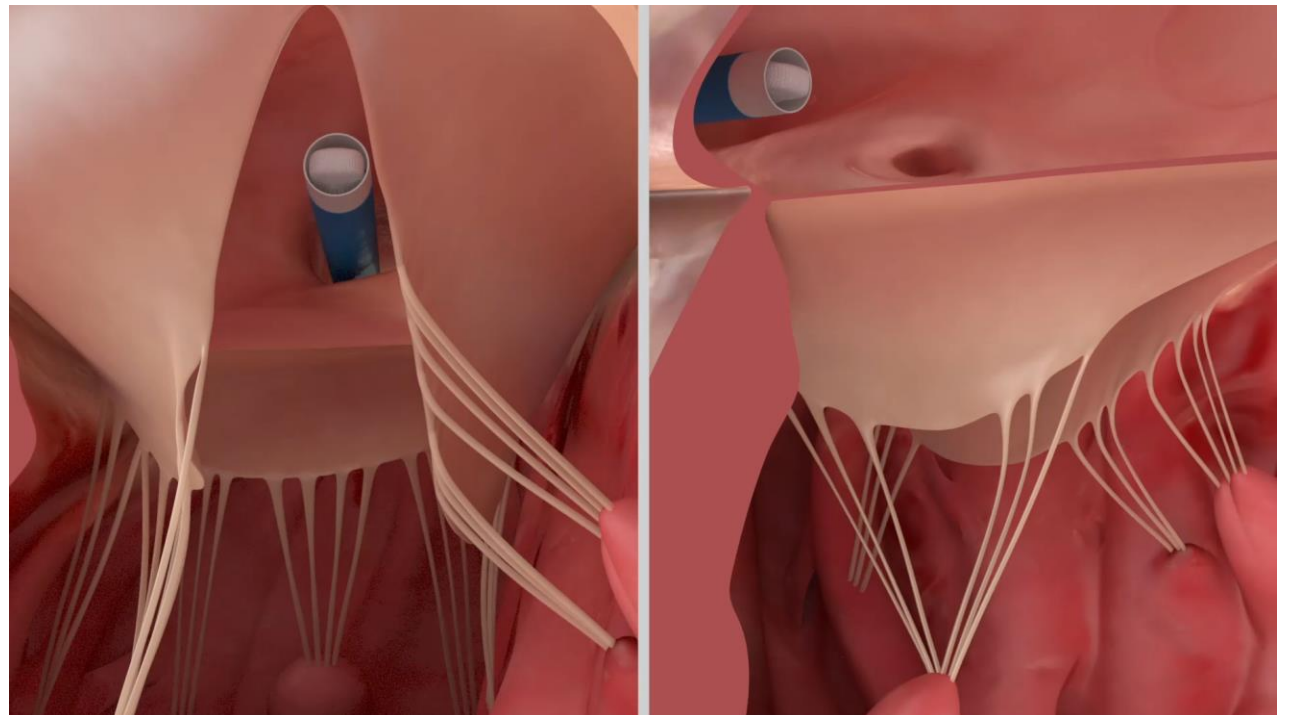
Independent, multiple grasping

Supports gentle interaction and capture of leaflets in difficult pathologies

Implant elongation

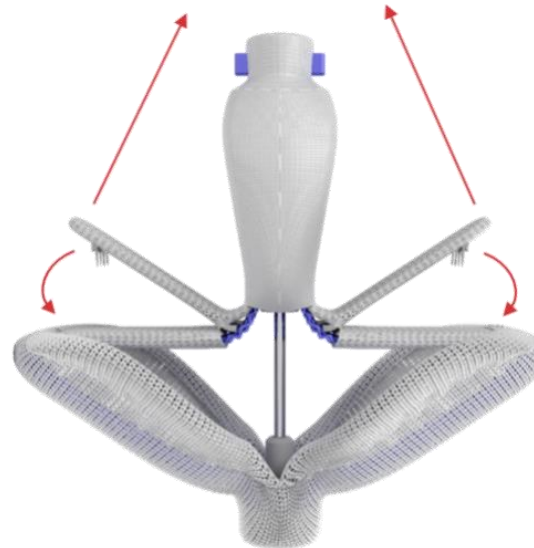
Facilitates safe repositioning within dense chordae and subvalvular apparatus

Tricuspid valve repair with PASCAL Ace implant system

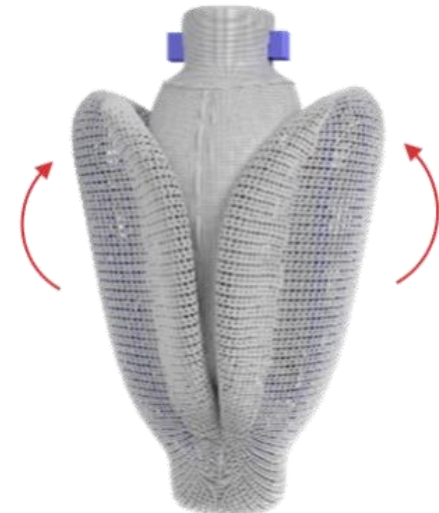


Optimized Subvalvular Maneuvering Passive closure mechanism gentle with leaflets

Elongation & Nitinol Design



Closed Clasps applying a passive constant force

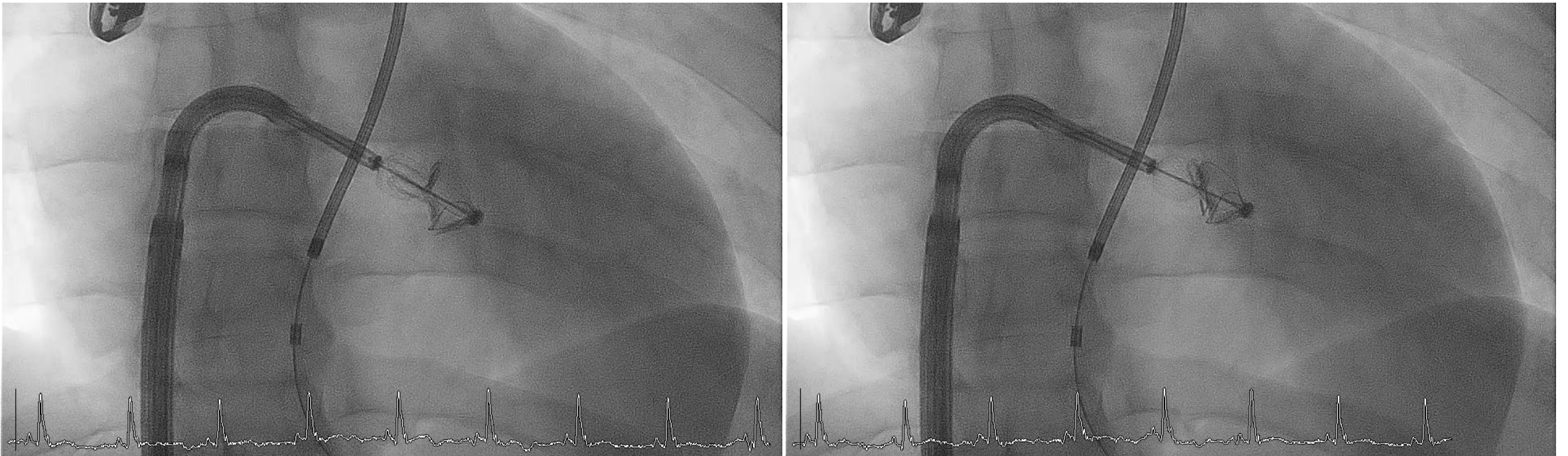


Passive constant force allows paddles close with no lock

Optimized Subvalvular Maneuvering

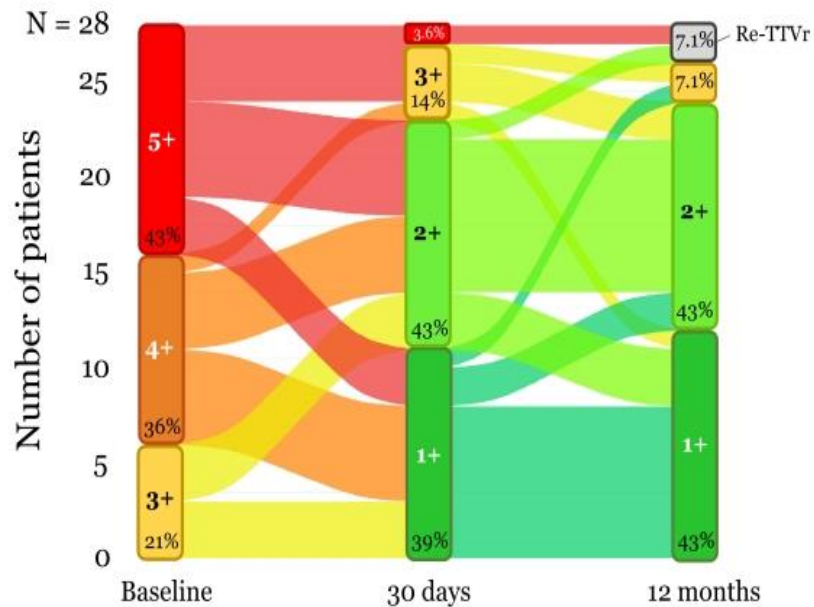
Safety and Flexibility

Elongation & Nitinol Design



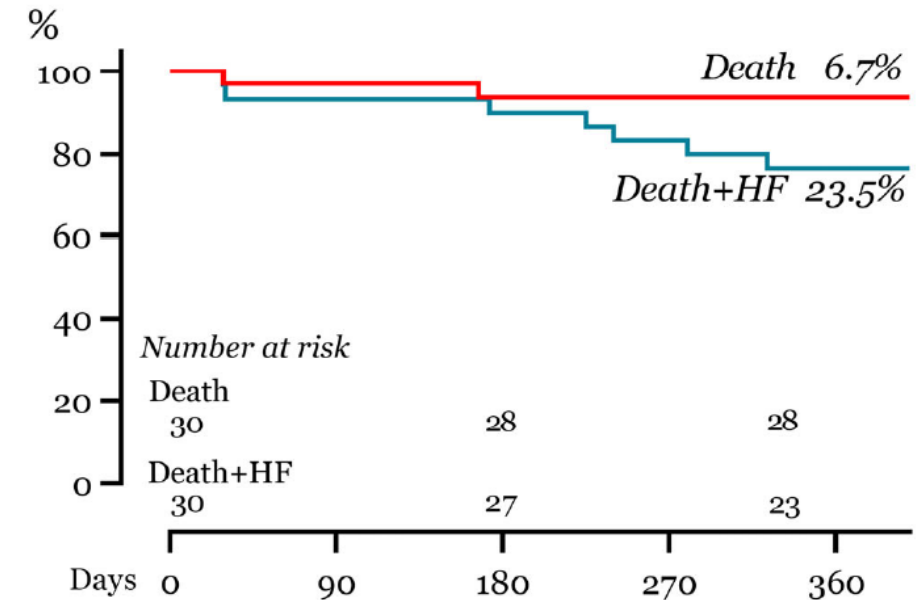
PASCAL for TR Compassionate Use 1-year Outcomes in first clinical experience (n=30)

TR Severity



Durable TR reduction with 86% TR 1+/2+ @1y

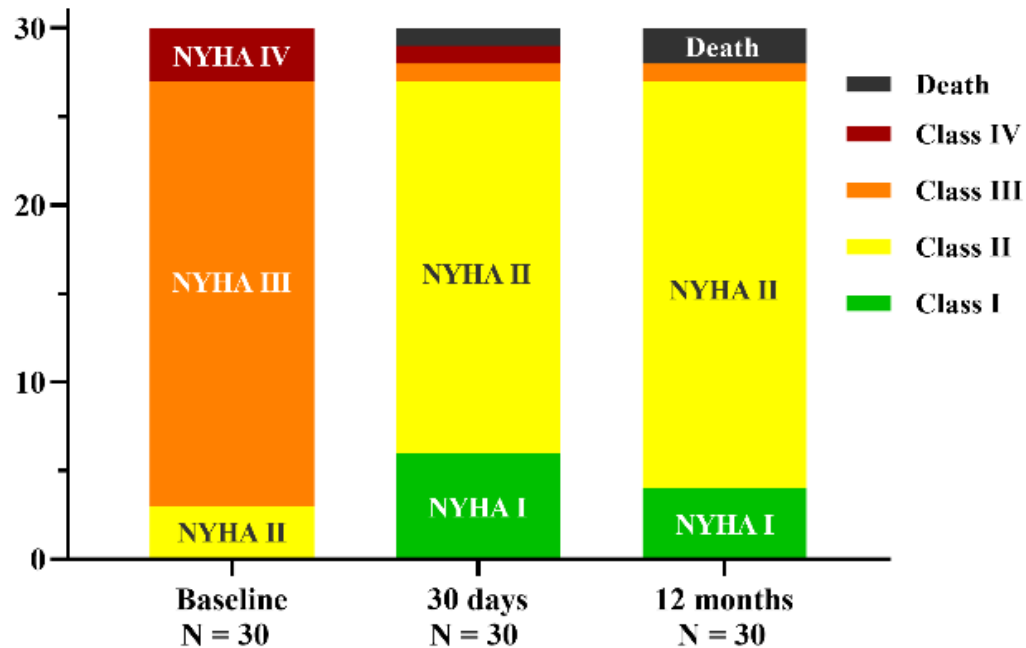
Survival



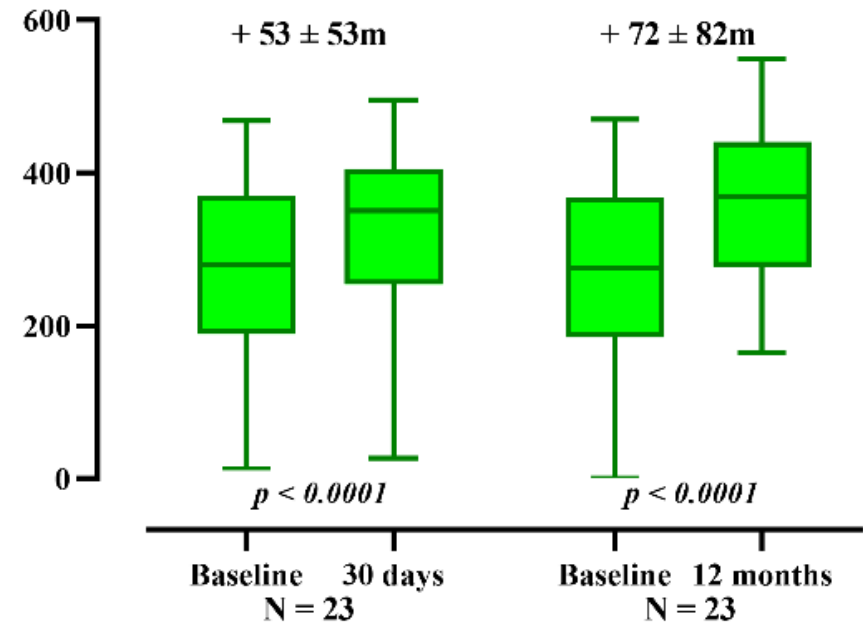
93.3% of patients alive at 12 months

PASCAL Repair System for TR Compassionate Use 1-year Outcomes

NYHA



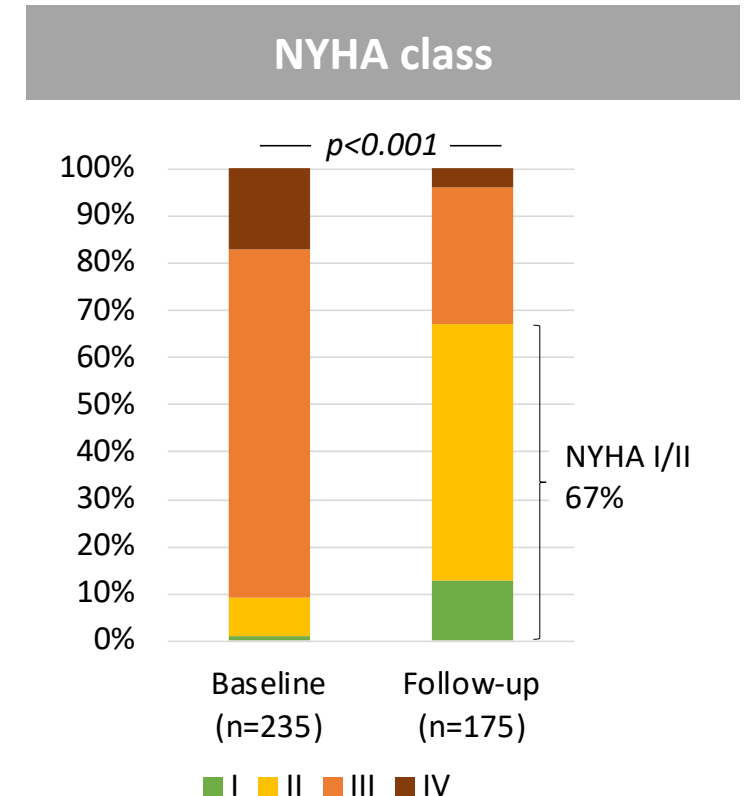
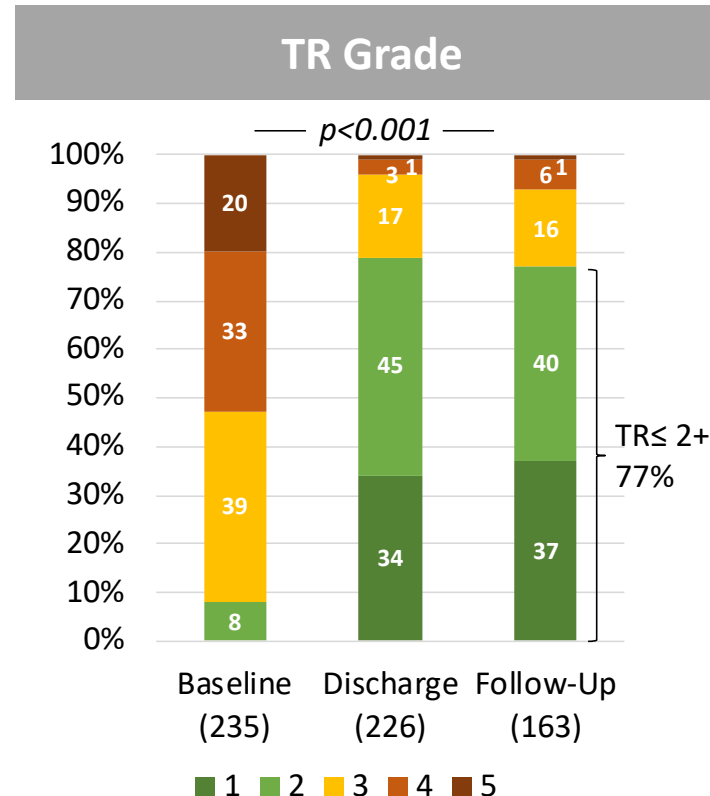
Six-minute walk distance, m



PASCAL Platform: Multicentre Experience for TR 8 tertiary centers in Germany and Switzerland (235 pts); up to 1-Year Outcomes

Procedural outcome, %

Technical success	98
Number of devices, n	1.7 ± 0.6
Procedure time, min	107 ± 52
Concomitant mitral TEER	7
SLDA (n=4)	2
Access complication (n=2)	1
Other adverse event	0



CLASP TR (n=34), 30-day FU just published

TABLE 6 CEC-Adjudicated MAEs (N = 34)	
Cardiovascular mortality	0
Myocardial infarction	0
Stroke	0
Renal complications requiring dialysis or renal replacement therapy	0
New need for renal replacement therapy	0
Severe bleeding*	2 (5.9)
GI bleed	2 (5.9)
Access site bleed	0
Reintervention related to implant	0
Major access site and vascular complications requiring intervention	0
Composite MAE rate	2 (5.9)
Other clinical safety events	
All-cause mortality	0
Heart failure rehospitalization	0
SLDA rate	1 (2.9)
<p>Values are n or n (%). *Severe bleeding is major, extensive, life-threatening or fatal bleeding, as defined by the Mitral Valve Academic Research Consortium.</p> <p>CEC = clinical events committee; SLDA = single-leaflet device attachment; other abbreviations as in Table 3.</p>	

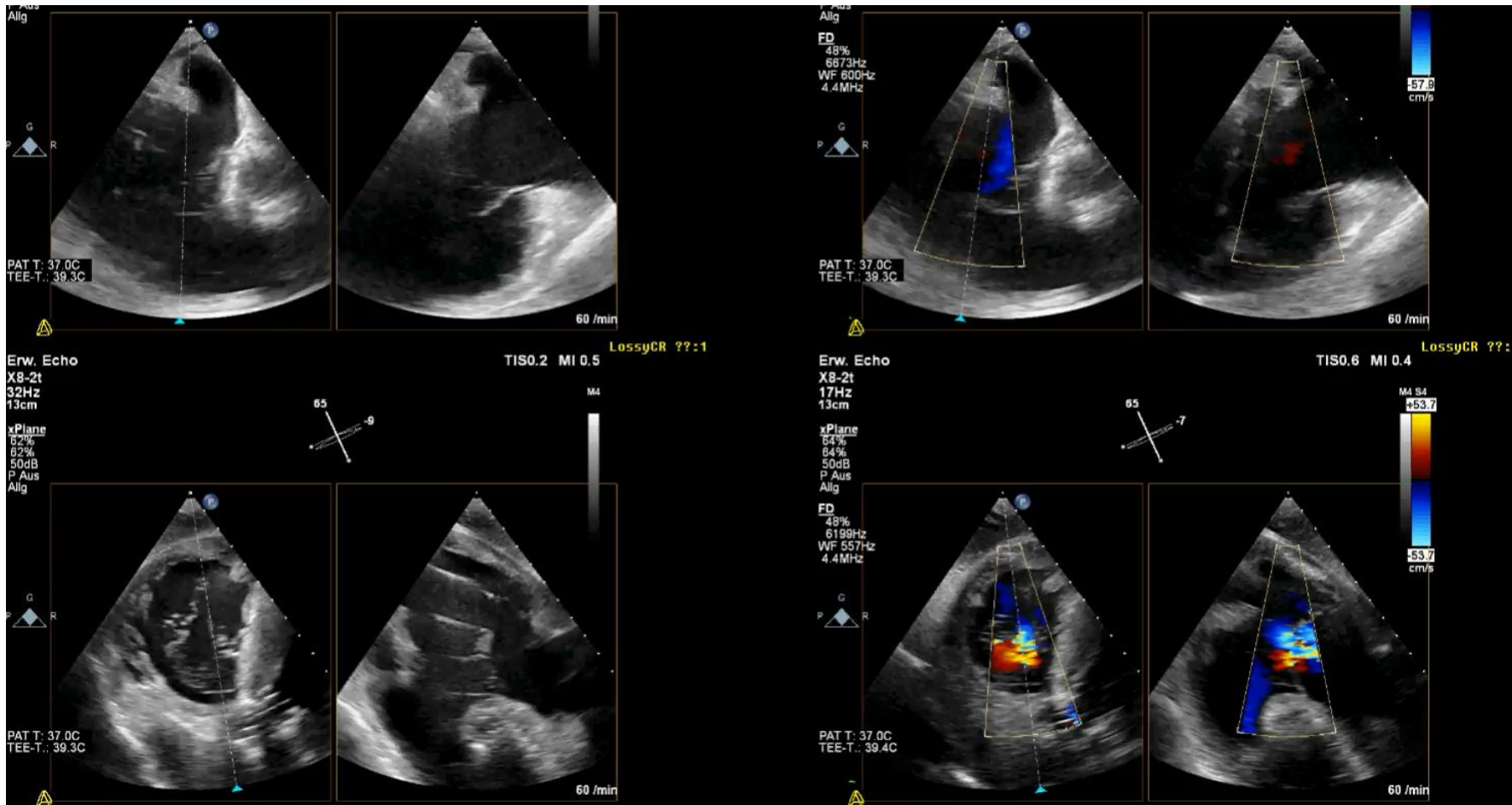
ORIGINAL INVESTIGATIONS

Feasibility Study of the Transcatheter Valve Repair System for Severe Tricuspid Regurgitation



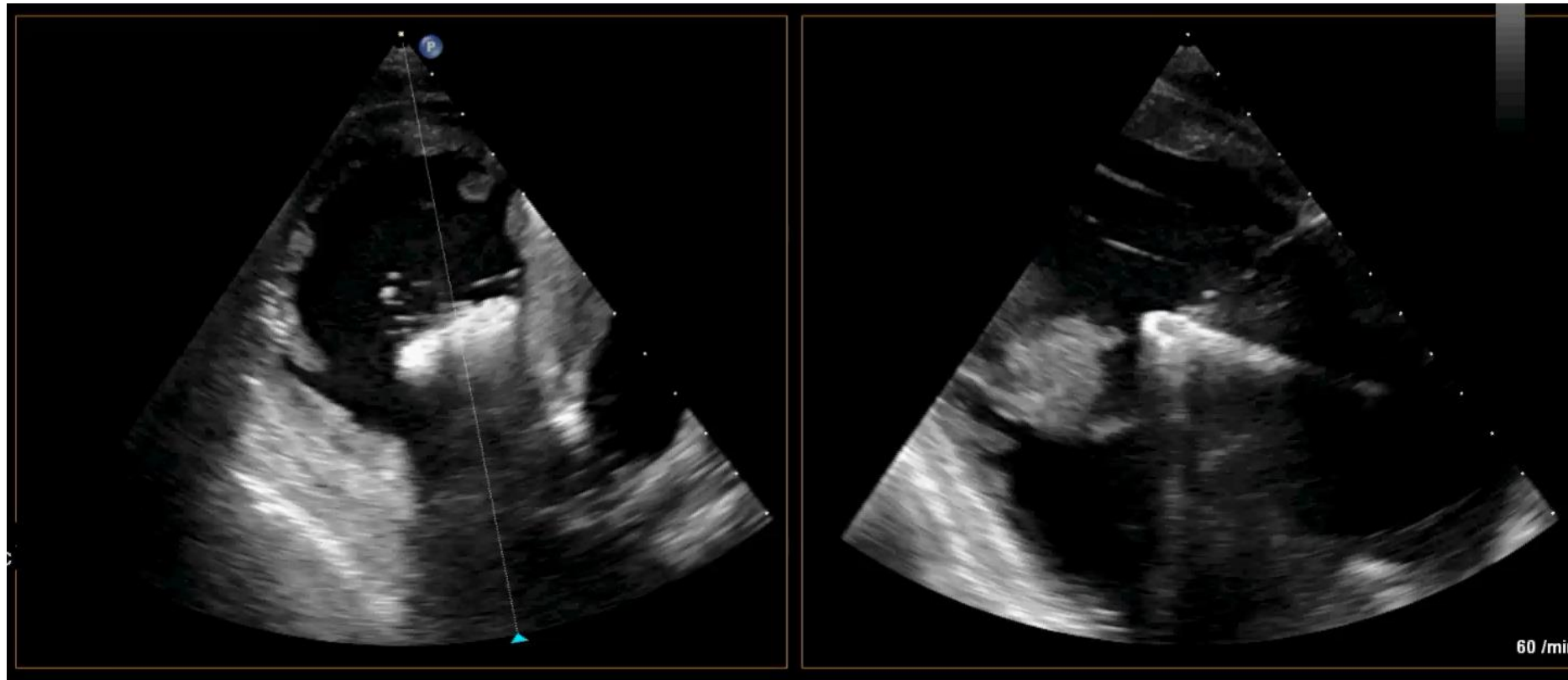
Susheel Kodali, MD,^a Rebecca T. Hahn, MD,^{a,b} Mackram F. Eleid, MD,^c Robert Kipperman, MD,^a Robert Smith, MD,^a D. Scott Lim, MD,^f William A. Gray, MD,^g Akhil Narang, MD,^h Sorin V. Pislaru, MD,ⁱ Konstantinos Koulogiannis, MD,^g Paul Grayburn, MD,^g Dale Fowler, MD,^j Katie Hawthorne, MD,^g Abdellaziz Dahou, MD,^h Shekhar H. Deo, MBBS, PhD,^j Prashanthi Vandrangi, PhD,^j Florian Deuschl, MD,^j Michael J. Mack, MD,^g Martin B. Leon, MD,^g Ted Feldman, MD,^j Charles J. Davidson, MD,^h on behalf of the CLASP TR EFS Investigators

TEER with PASCAL Ace in an 78yo male patient with severe, secondary TR (grade 3/5)



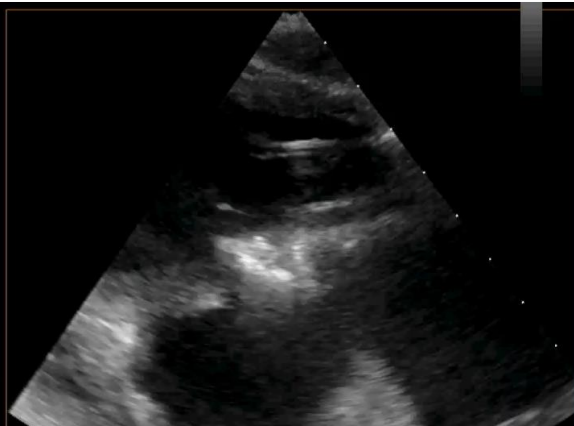
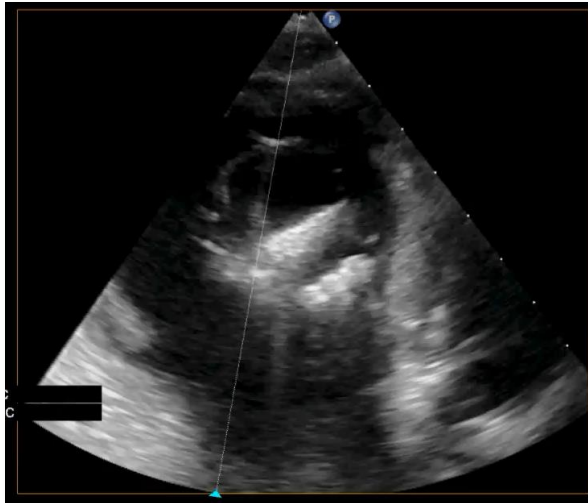
- **Atrial TR**
- **Moderate annular dilation**
- **Coaptation deficit centrally and in anteroseptal commissure**

TEER with PASCAL Ace - 1st device in anteroseptal commissure

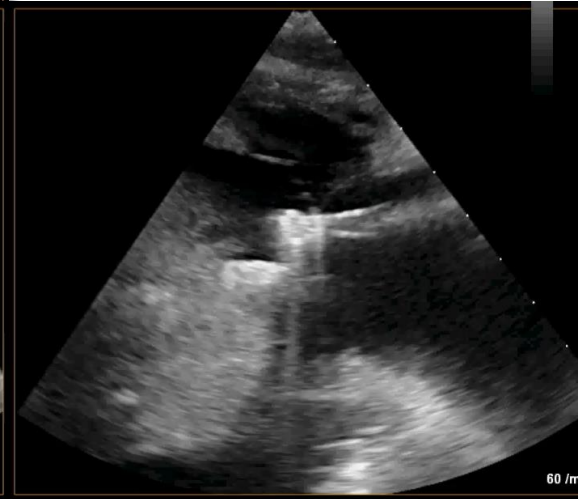
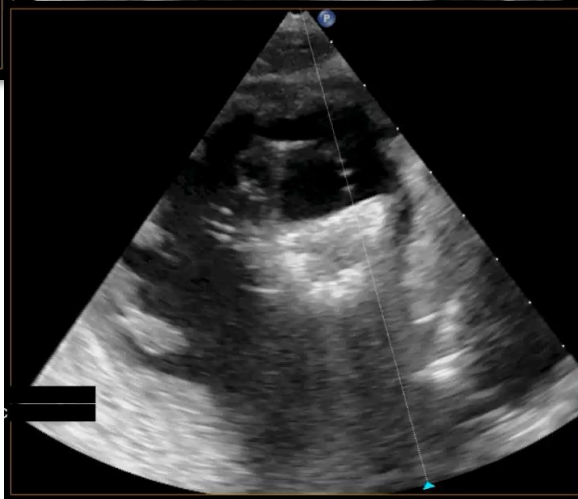


- Atrial TR
- Moderate annular dilation
- Coaptation deficit centrally and in anteroseptal commissure

TEER with PASCAL Ace - 2nd device in anteroseptal commissure



- Independent grasping of anterior tricuspid leaflet (note lowering of anterior clasp)

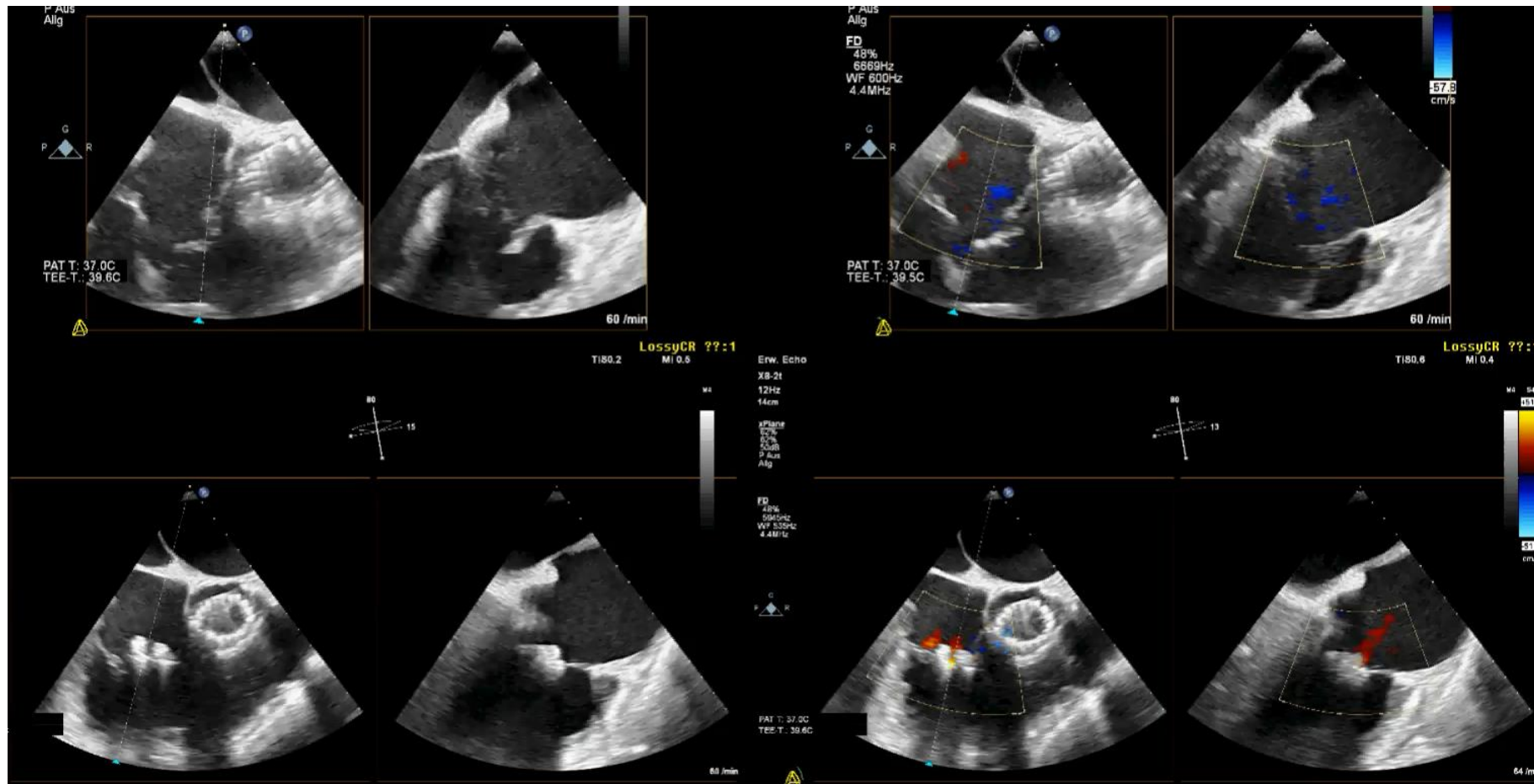


- Septal orientation and independent grasping of septal leaflet
- Device closure

EuroValve

October 28- 29 2021
HOTEL LIÈGE CONGRÈS, BELGIUM

TEER with PASCAL Ace - pre versus post



- Both devices implanted in anteroseptal comm. with optimal leaflet insertion
- Central device implanted using independent grasping
- Residual TR “trace”

Conclusions

- **The PASCAL repair system has shown**
 - high technical success rate (86% of patients with TR $\leq 2+$ sustained at 1 year)
 - stable clinical benefit
 - high safety (CLASP TR with 30 day mortality)
- **Patients selection can still be challenging (leaflet quality, morphology, gap size, annulus size)**
- **CLAPSP II TR is 1:1 randomizing PASCAL vs OMT (only US/Canada)**

Thank you

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