

# TRANSCATHETER MITRAL VALVE IMPLANTATION FOR SEVERE MITRAL REGURGITATION:

## THE TENDYNE GLOBAL FEASIBILITY TRIAL 1 YEAR OUTCOMES

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On behalf of the Tendyne GFS Investigators

# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

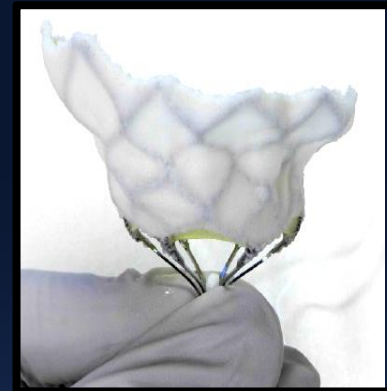
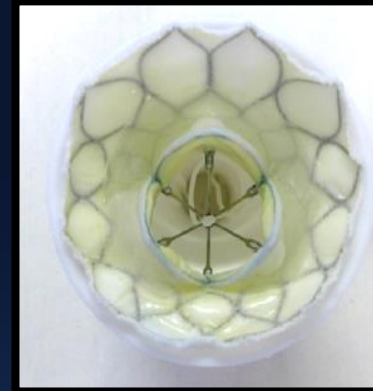
## Company

- |                                  |   |
|----------------------------------|---|
| • Grant/Research Support         | • Tendyne, Medtronic                                  |
| • Consulting Fees/Honoraria      | • Medtronic, Abbott, Boston Scientific, 4Tech, Cephea |
| • Major Stock Shareholder/Equity | • N/A   |
| • Royalty Income                 | • N/A   |
| • Ownership/Founder              | • N/A   |
| • Intellectual Property Rights   | • N/A   |
| • Other                          | • N/A   |

# Tendyne Transcatheter Mitral Valve

## Tendyne Device

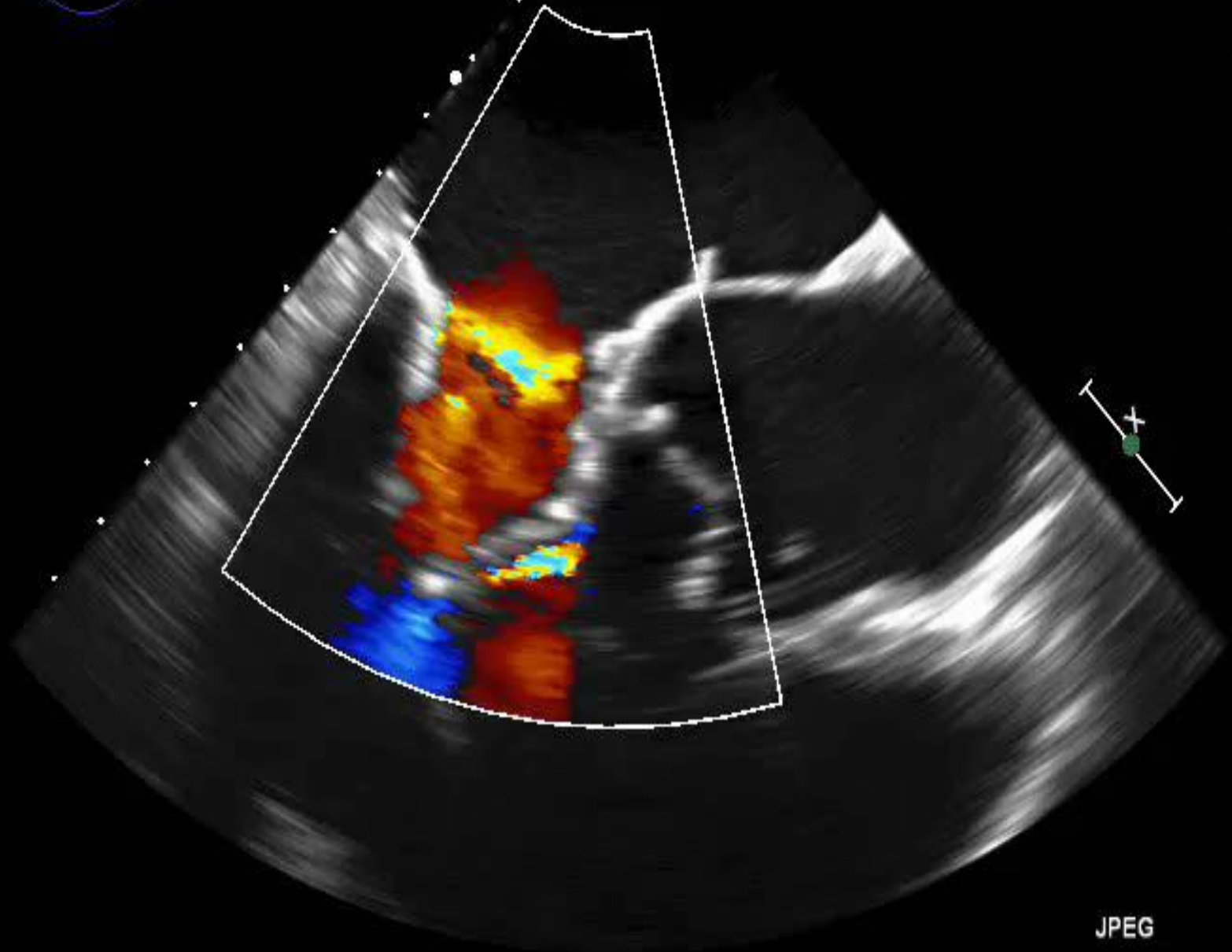
- Tri-leaflet porcine pericardial valve
- Self-expanding nitinol double frame
  - D-shaped outer frame, anterior cuff
- Large valve size matrix
  - Single inner valve size
  - Multiple outer frame sizes
- Transapical access, valve tethered to apex
  - Adjustable tension provides valve stability
- Apical Pad assists in access closure
- Valve fully retrievable and repositionable



2D  
66%  
C 50  
P Off  
Gen



CF  
59%  
4.4MHz  
WF High  
Med



JPEG

Image size: 800 x 600

View size: 445 x 709

WL: 127 WW: 255

X7-2t

6Hz

6.9cm

3D Zoom

2D / 3D

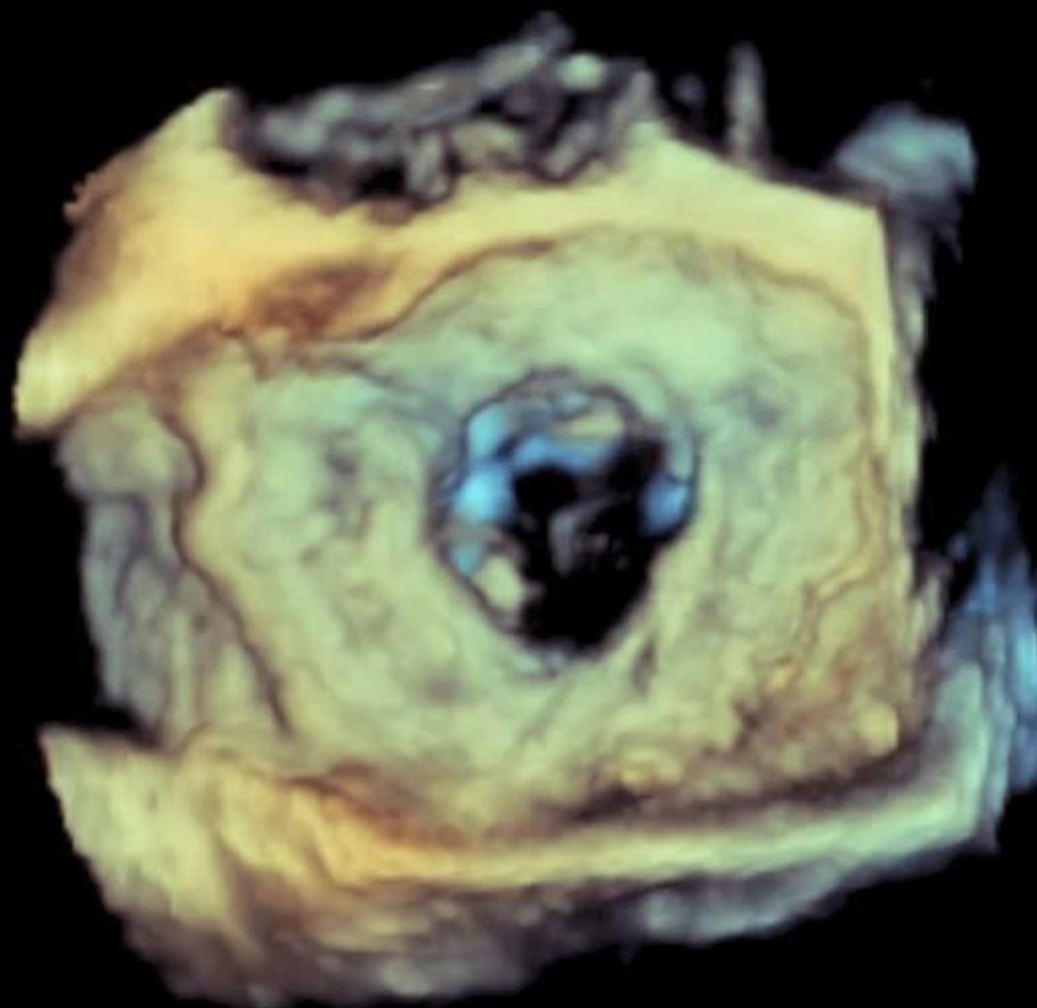
% 54 / 0

C 50 / 30

HGen



3D Beats 1



0297165 ( 82 y , 82 y )

TISE.2 M4 0.0

20150429.094913

M4



PAT T: 37.0C

TEE T: 39.5C

Zoom: 118% Angle: 0

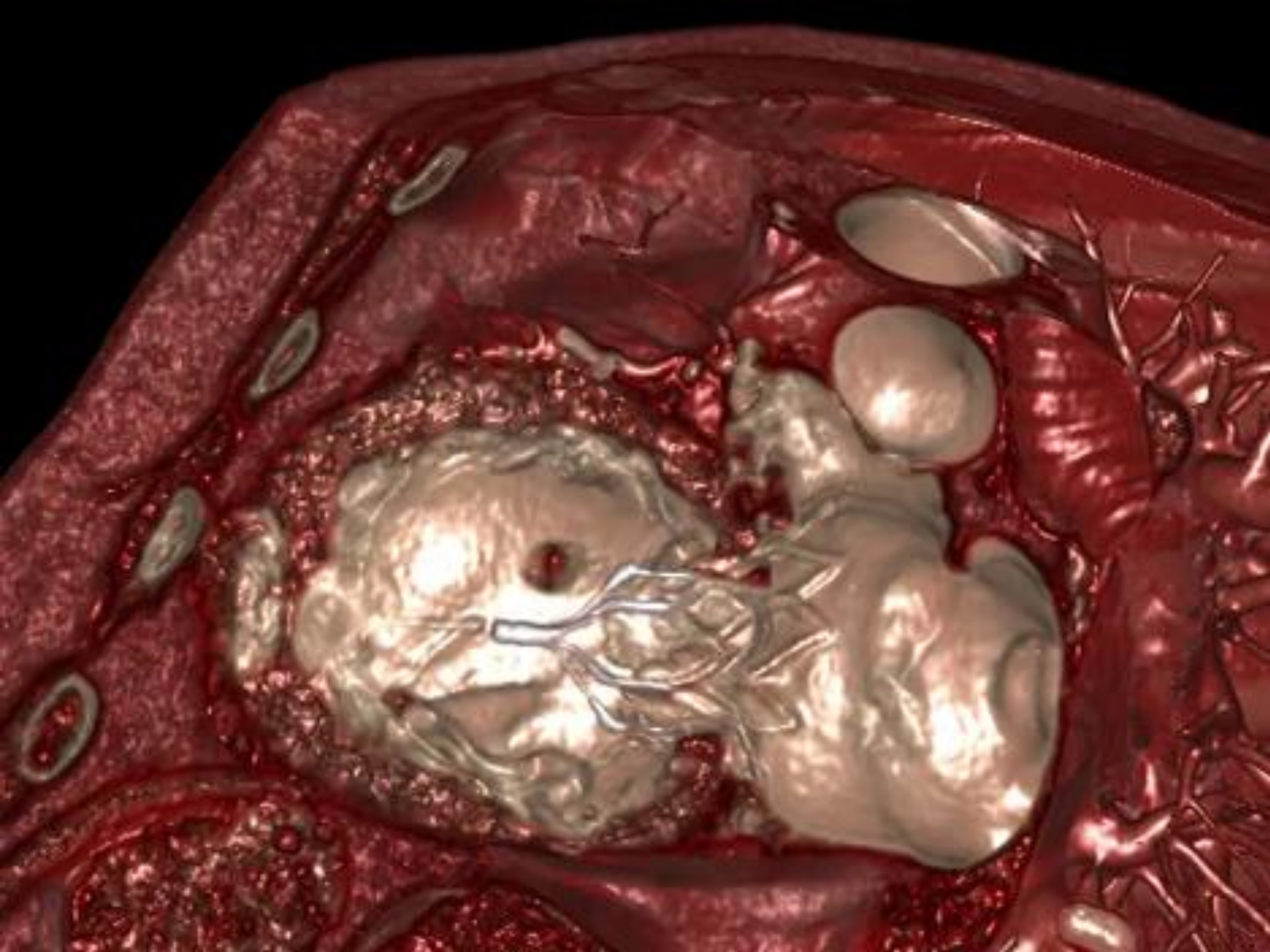
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JPEGBaseline

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Made In OsiriX

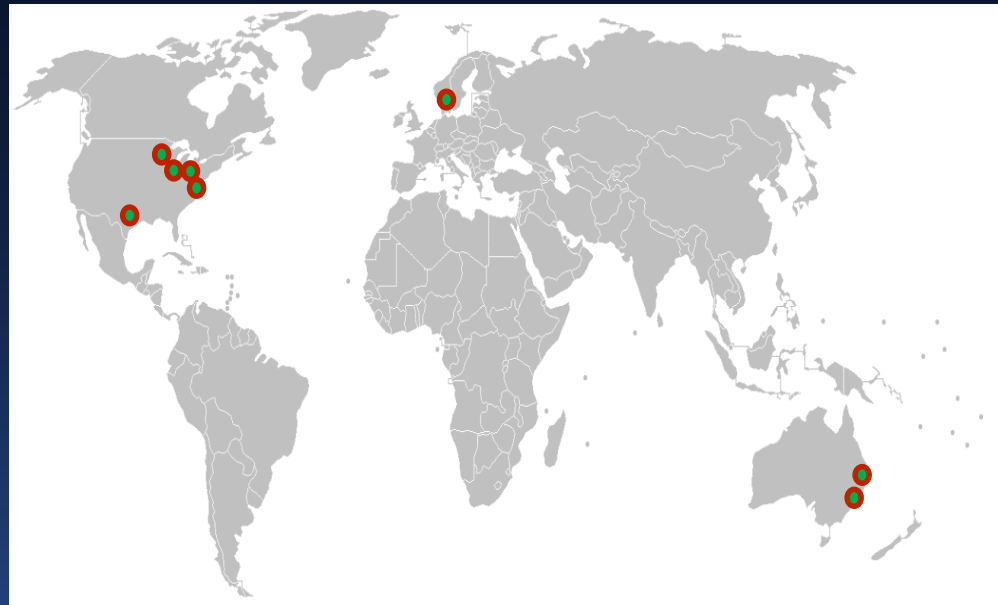




# Tendyne TMVR GFS Investigators

## Global Feasibility Study (n=30)

- St Vincent's Hospital, Sydney
- Abbott Northwestern, Minneapolis
- Prince Charles Hosp, Brisbane
- Baylor Heart and Vascular, Dallas
- Oslo University Hospital, Oslo
- Evanston Hospital, Chicago
- Cleveland Clinic, Cleveland
- Medstar Hospital, Washington DC



November 2014 – March 2016

# Tendyne Global Feasibility Study

## Objective

Evaluate the safety, performance and usability of the Tendyne Mitral Valve System

## Key Outcome Measures

1. Mitral regurgitation\*
2. LV function and dimensions by echocardiogram
3. Device function by echocardiogram
4. Major Adverse Events\*\*
5. NYHA Classification
6. 6 Minute Hall Walk Test
7. Quality of Life (KCCQ)

\* Echo Core Laboratory: Beth Israel Deaconness MC

\*\* Clinical Events Committee



# Tendyne Global Feasibility Study

## Inclusion criteria:

1. Severe mitral valve regurgitation of primary or secondary etiology
2. NYHA functional class II, III or ambulatory IV
3. Age  $\geq 18$  yrs, able to provide informed consent
4. Poor candidate for cardiac surgery as determined by the Heart team (including Cardiologist and Cardiac Surgeon)

## Exclusion criteria:

1. Severe mitral annular or valvular calcification/stenosis, vegetation or mass
2. Largest annular dimension  $>45$ mm, LVEDD  $>70$ mm
3. LVEF  $<30\%$ , severe TR/RV dysfunction/pulmonary HT
4. Prior aortic or mitral valve surgery
5. Small neo-LVOT (echo, CT modeling, 3D printing)

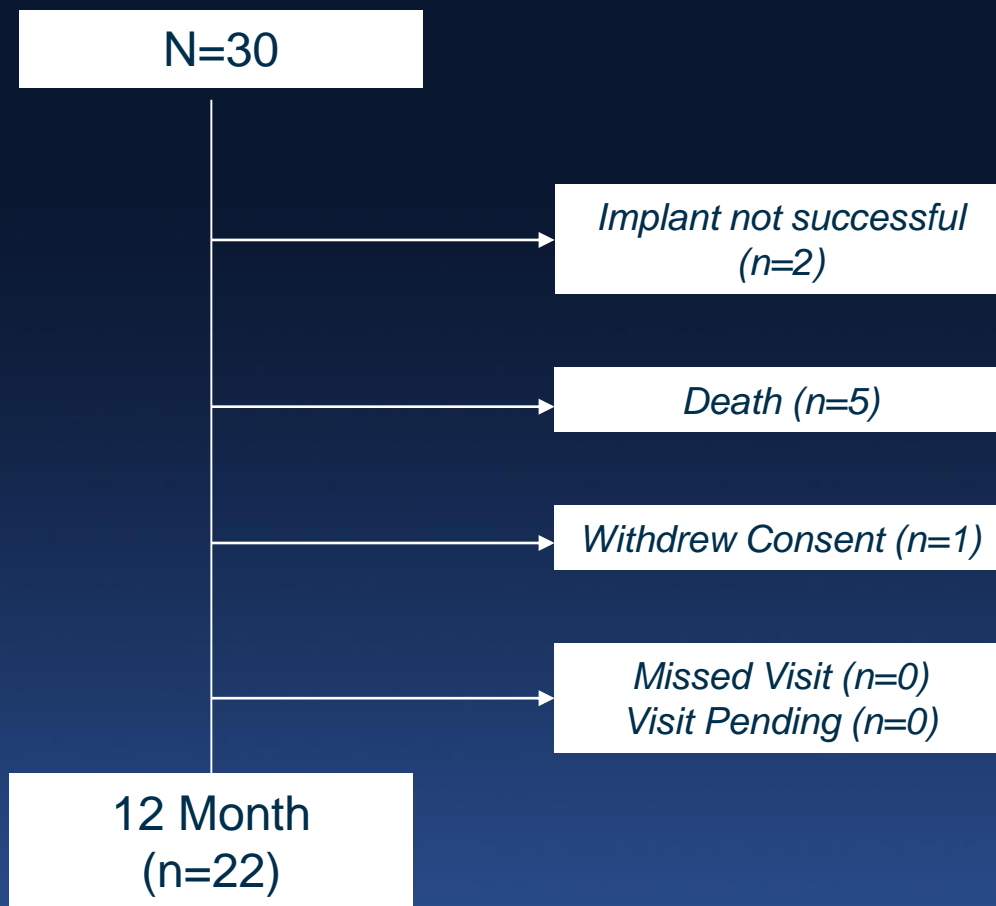
# Tendyne GFS: Demographics (n=30)

Age at Baseline	
Mean $\pm$ SD	75.6 $\pm$ 9.2 years
Range	55.1-91.4 years
Gender	
Male	25 (83.3%)
Female	5 (16.7%)
NYHA Functional Class	
II	14 (46.7%)
III	16 (53.3%)
IV	0 (0%)
STS Score (range)	7.3 $\pm$ 5.7 (2-16 )

# Tendyne GFS: Patient Overview (n=30)

<b>Baseline Mitral Valve pathology</b>	
Primary MR	3/30 (10%)
Secondary MR	24/30 (80%)
Mixed pathology	3/30 (10%)
<b>Baseline LV function</b>	<b>N=29</b>
LVEF <30%	3/29 (10.3%)
LVEF 30-50%	14/29 (48.3%)
LVEF >50%	12/29 (41.4%)
<b>Baseline MR severity</b>	
Grade 3+	2/29 (6.9%)
Grade 4+	27/29 (93.1%)

# GFS: Subject follow-up as of 23 May 2017



# Kaplan-Meier survival curve (n=30)



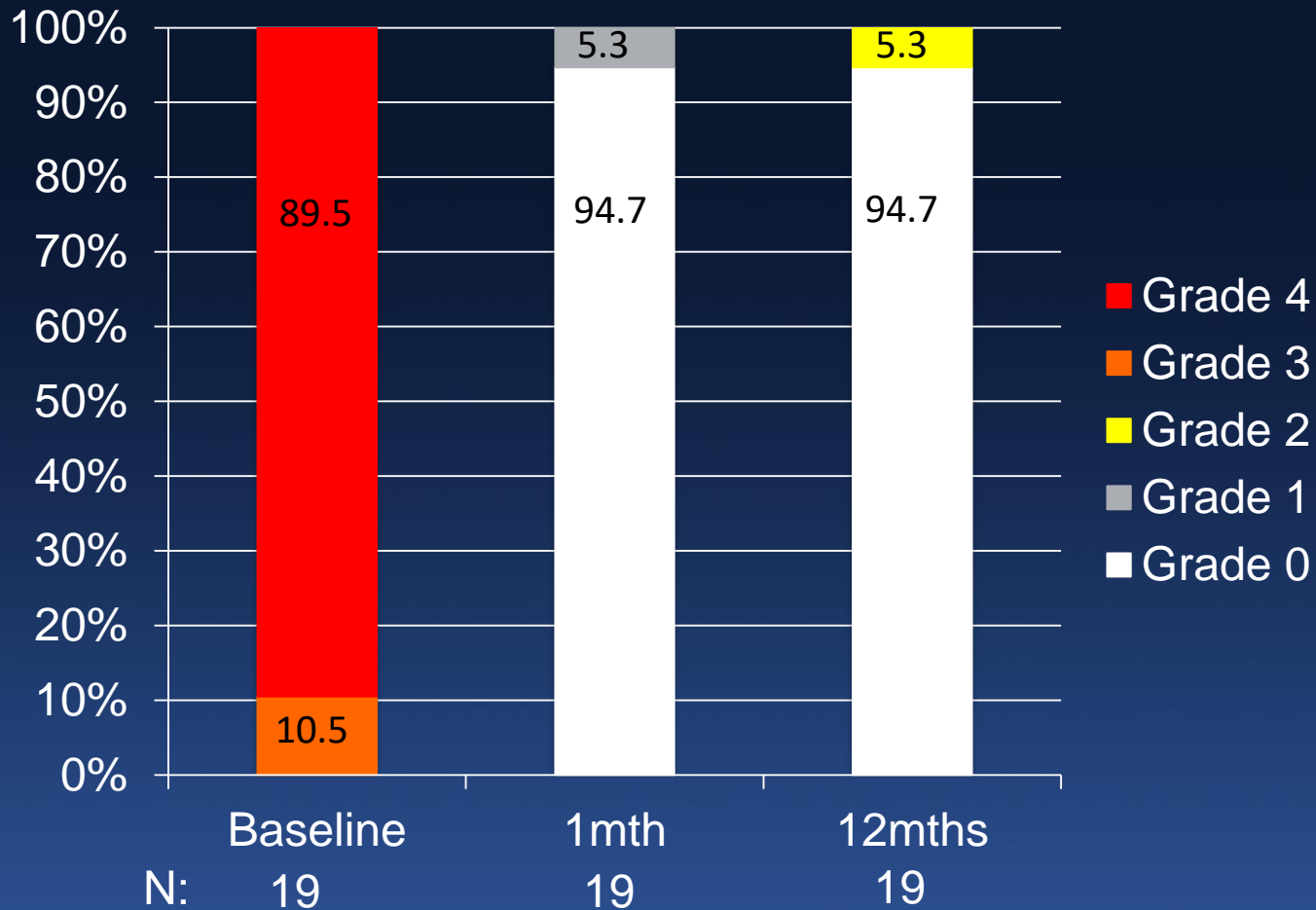


# Tendyne TMVR: 1yr outcomes

<b>Outcome</b>	<b>N=30</b>
Death (all cause)	5 (16.7%)
Cardiac	4 (13.3%)
Non-cardiac	1 (3.3%)
CVA/TIA	0 (0%)
<b>Re-hospitalisation</b>	
Heart failure	3 (10.0%)
MV surgery	0 (0%)
<b>Valve performance (n=28)</b>	
Malposition/PVL/hemolysis	1 (3.6%)
Leaflet thrombosis	1 (3.6%)

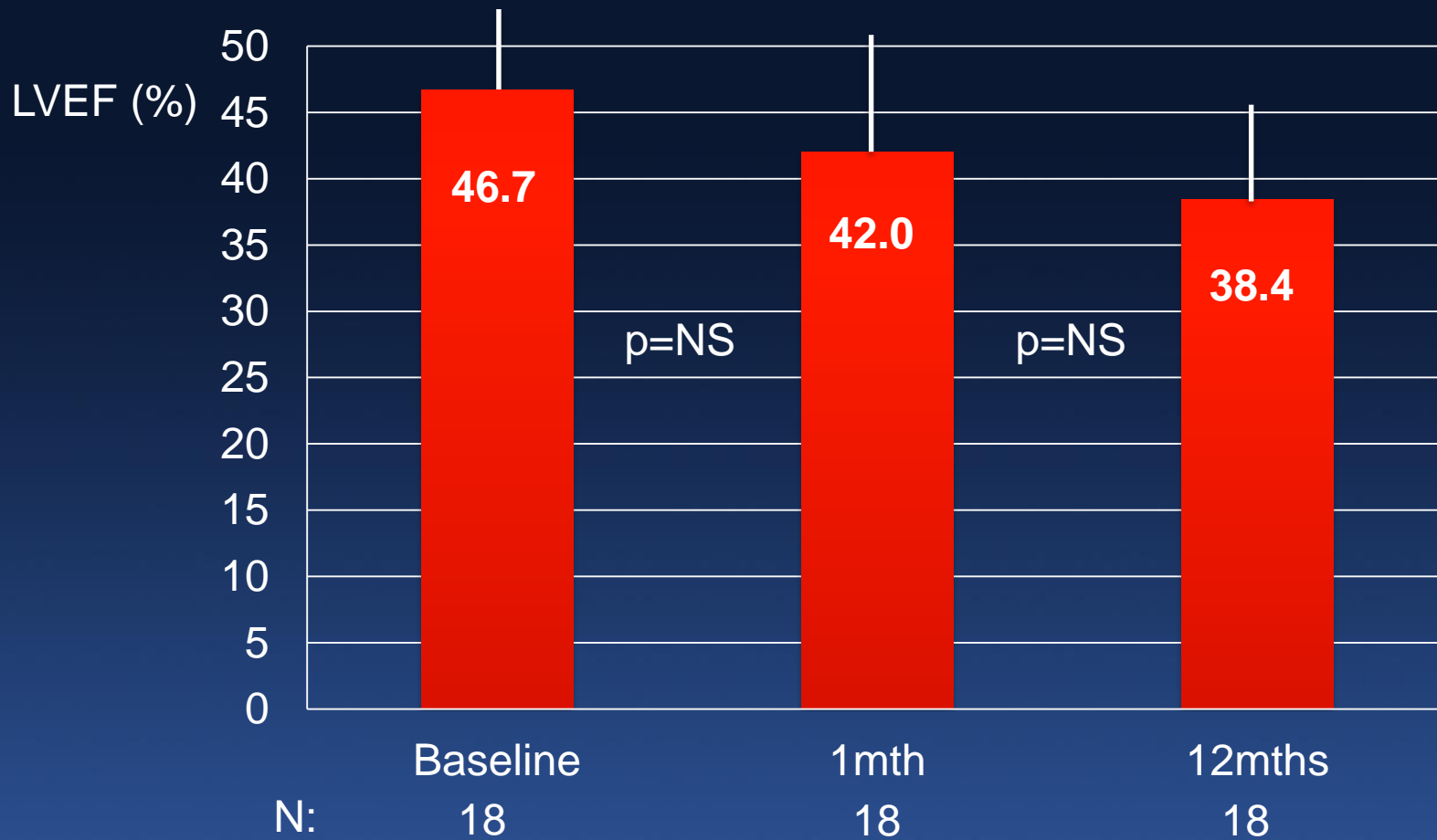
# MR severity 1 year post-TMVR

Paired data



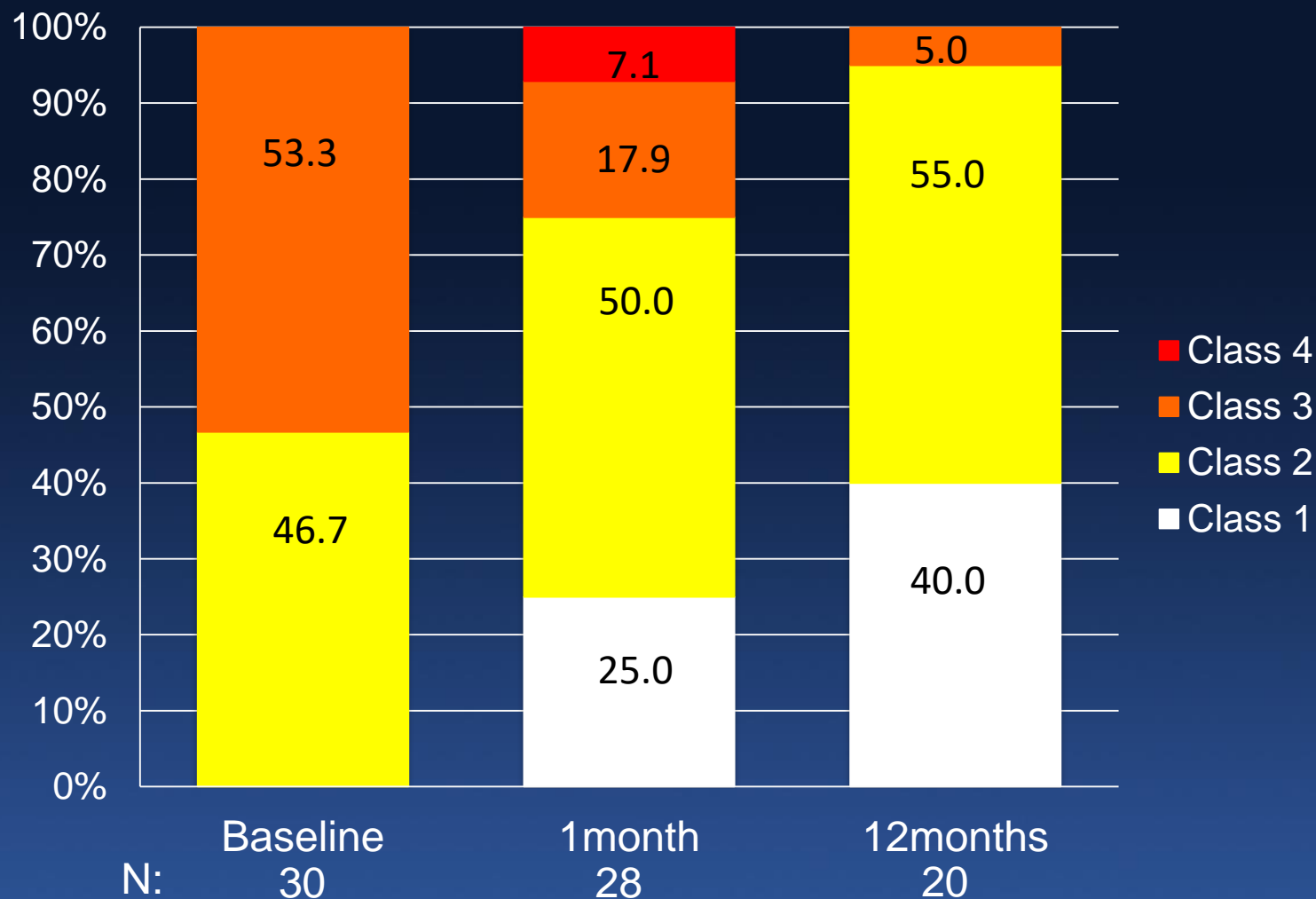
# LVEF post-TMVR

Paired analysis



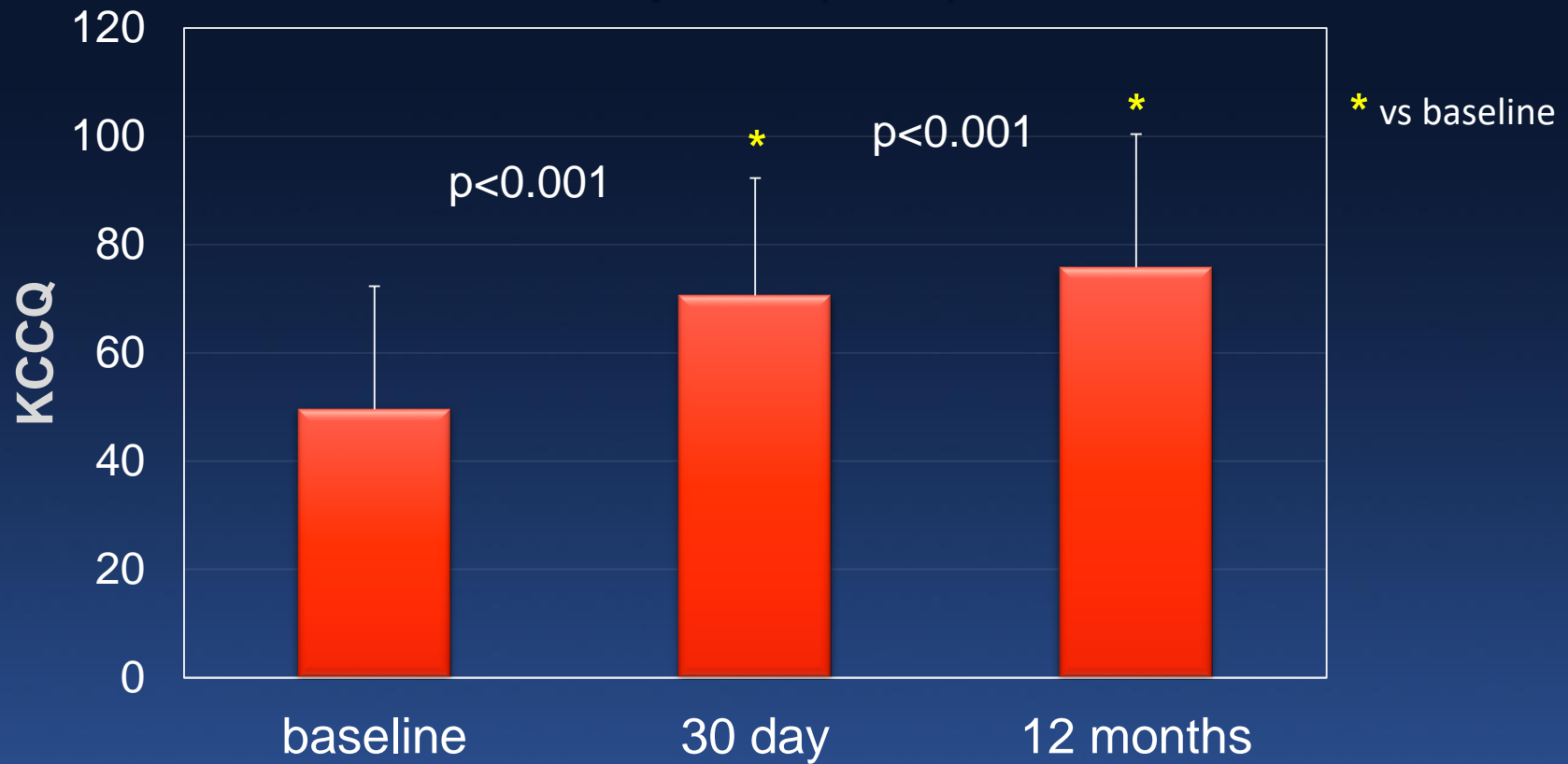
# Functional capacity post-TMVR (n=30)

## NYHA Class



# Quality of Life: KCCQ

KCCQ in subjects with complete data at three timepoints (n=22)





# Tendyne TMVR: Conclusions (n=30)

Safe and effective procedure:

- Retrievable, repositionable device
- Predictable deployment, well tolerated
- No procedural deaths or strokes

Encouraging mid-term clinical and echo results:

- Low one year mortality (16.7%)
- Durable relief of MR (no MR in 95%)
- Low need for hospitalisation for heart failure (10%)
- Substantial improvements in NYHA class, QOL

CE Mark Study / Expanded Global Feasibility Study enrolling