First-in-Human Transcatheter Mitral Valve Implantation: Lessons learnt

Lars Søndergaard
Olaf Franzen
Nikolaj Ihlemann
Huan Loh
Brent Ratz
Arshad Quadri

Rigshospitalet, Copenhagen, Denmark
CardiAQ ValveTechnologies, Inc., USA

Transcatheter Mitral Valve Implantation
Challenges

- Access
  - Transapical
  - Transatrial
  - Transseptal

Transcatheter Mitral Valve Implantation
Challenges

- Access
- Large delivery system
  - Large annulus size

Transcatheter Mitral Valve Implantation
Challenges

- Access
- Large delivery system
- Frame
  - Dynamic environment
    - fracture <-> erosion/compression

Transcatheter Mitral Valve Implantation
Challenges

- Access
- Large delivery system
- Frame
- Valve tissue
  - High transvalvular gradient

Transcatheter Mitral Valve Implantation
Challenges

- Access
- Large delivery system
- Frame
- Valve tissue
- Annulus
  - Saddle shaped
  - Large range in size

Transcatheter Mitral Valve Implantation
Challenges

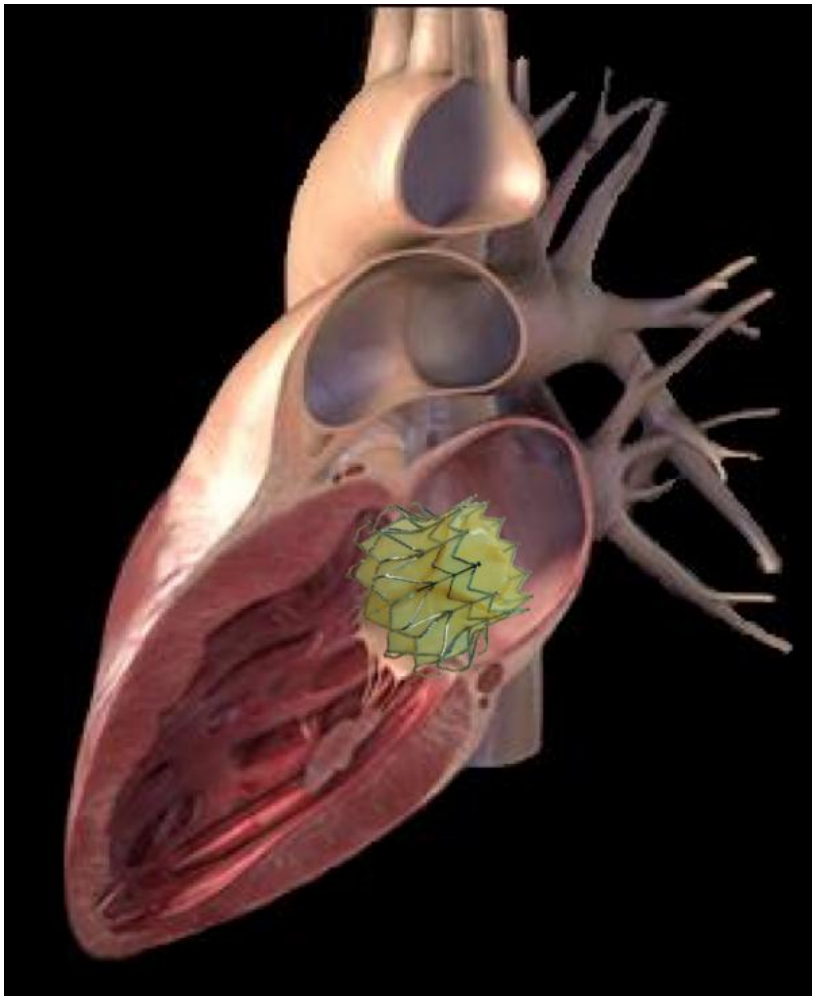
- Access
- Large delivery system
- Frame
- Valve tissue
- Annulus
- Anchoring
  - No calcium -> radial force may cause compression
    - LVOT, coronary sinus, LCX

Transcatheter Mitral Valve Implantation
Challenges

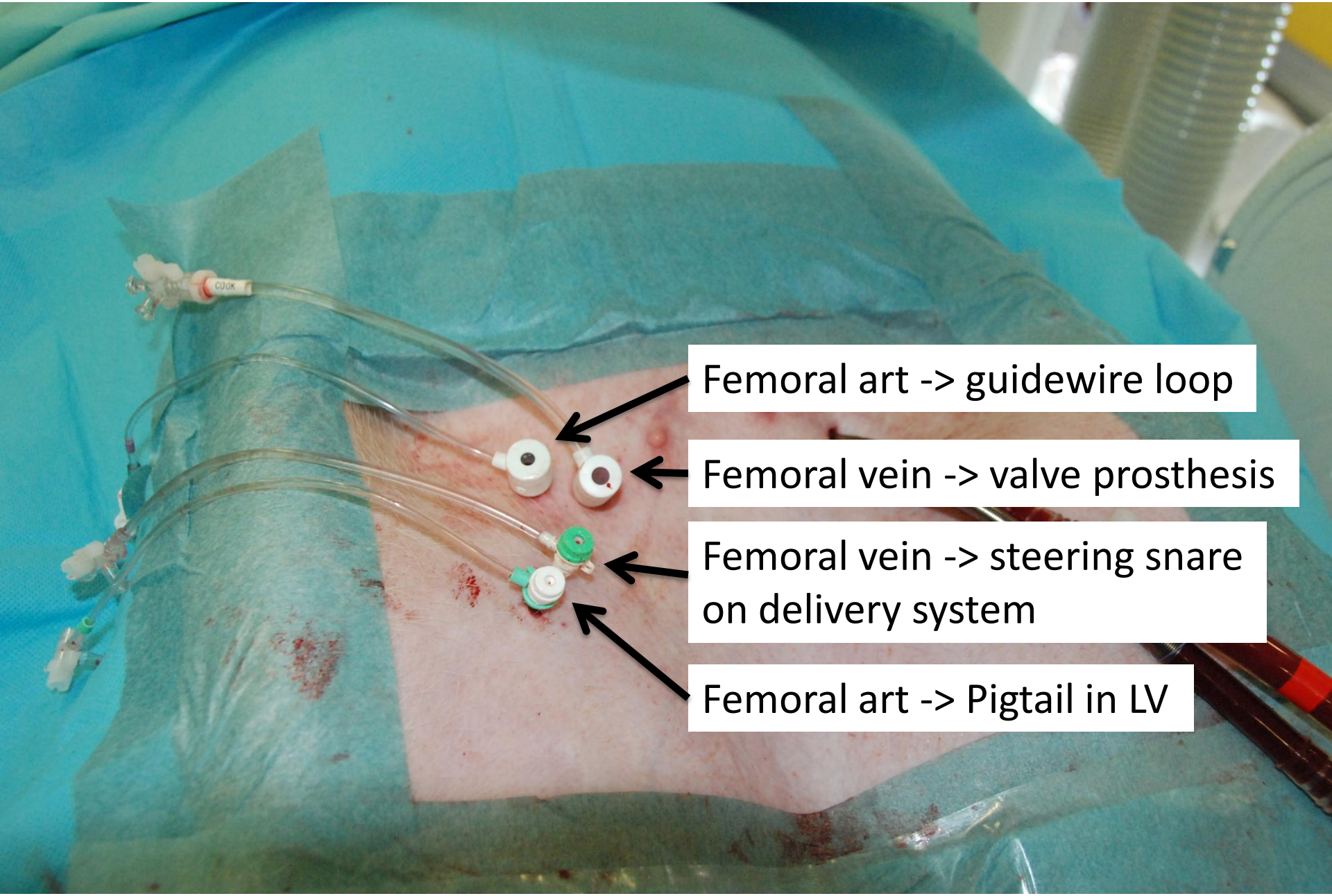
- Access
- Large delivery system
- Frame
- Valve tissue
- Annulus
- Anchoring
- Submitral apparatus
  - Should be preserved in functional MR

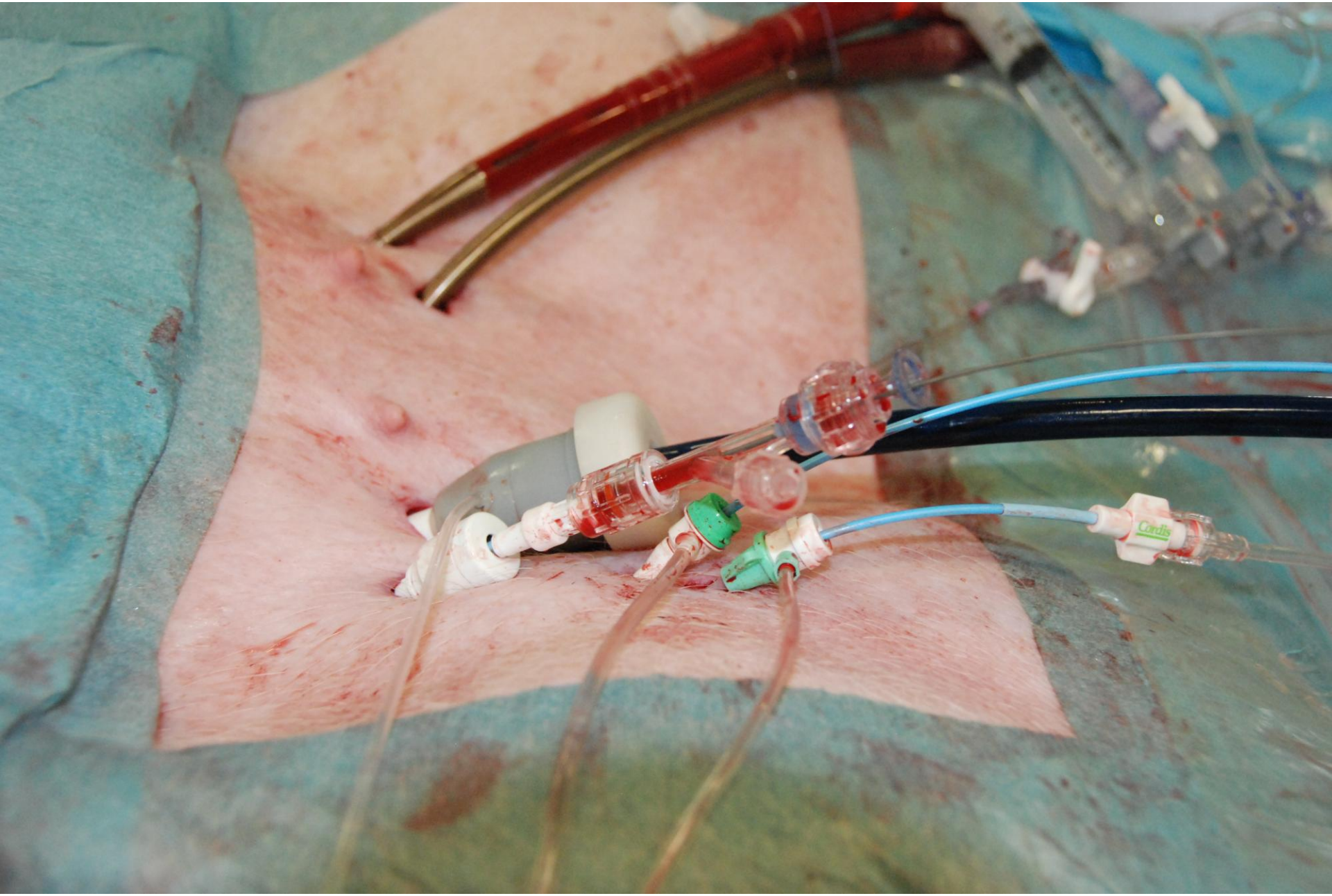
TMVI with CardiAQ™

- Transcatheter access
  - Antegrade approach
  - Transveneous, transseptal
  - Multi-stage controlled deployment
- Pericardial tissue valve
  - Tri-leaflet design
- Nitinol frame
  - Self-expanding, bi-level design
  - 2x12 opposing anchors
  - Unique “foreshortening” design for annular attachment
  - Preserves sub-valvular apparatus



Animal studies

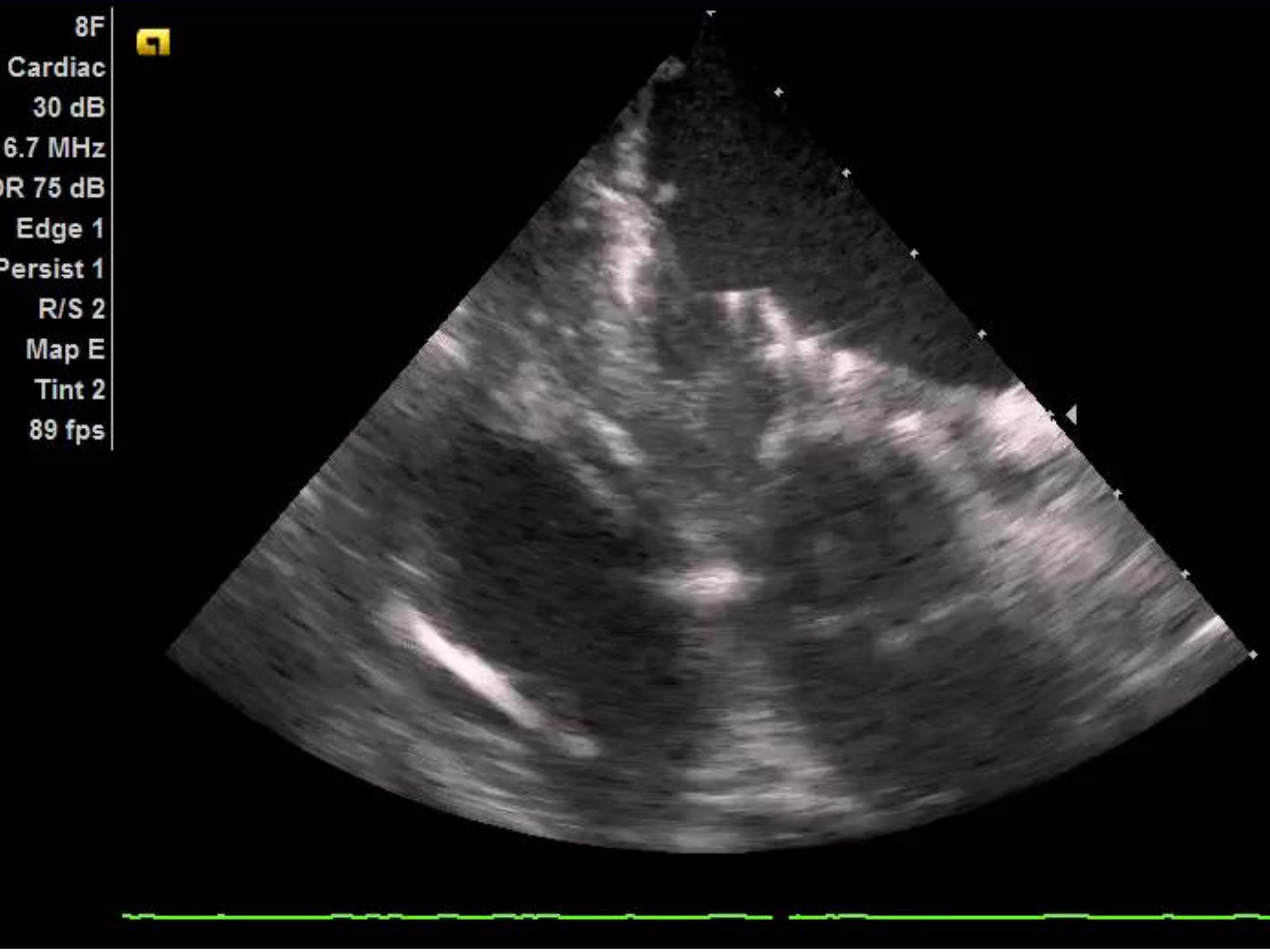

Femoral art -> guidewire loop
Femoral vein -> valve prosthesis
Femoral vein -> steering snare on delivery system
Femoral art -> Pigtail in LV


Cordis

Animal studies

Summary

- Venous access
- Antegrade and transseptal approach
- Cph manoeuvre
- Steering with snare and guide wire
- No compression of adjacent structures
- Preserved mitral apparatus

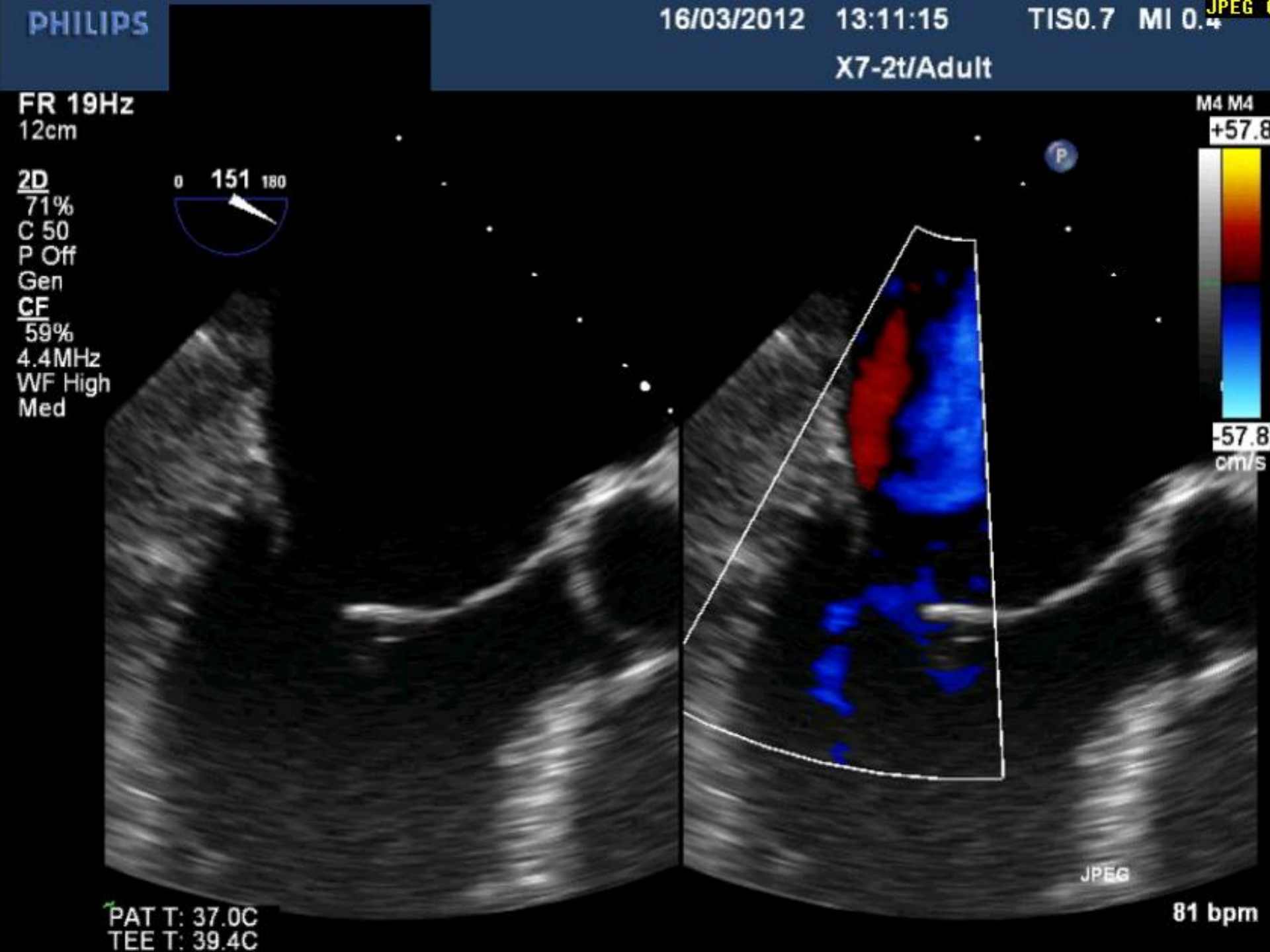

8F
Cardiac
30 dB
6.7 MHz
R 75 dB
Edge 1
Persist 1
R/S 2
Map E
Tint 2
89 fps

FIH TMVI

- 86 years old male, frail
- Hypertension
- Ischaemic heart disease (CABG & PCI)
- Severe MR
- NYHA-class IV despite optimal treatment
- LVEF 45%

Heart Team Decision

- Not eligible for mitral valve surgery due to extreme risk
- Not eligible for MitraClip due to large coarptation gap and restrictive PML

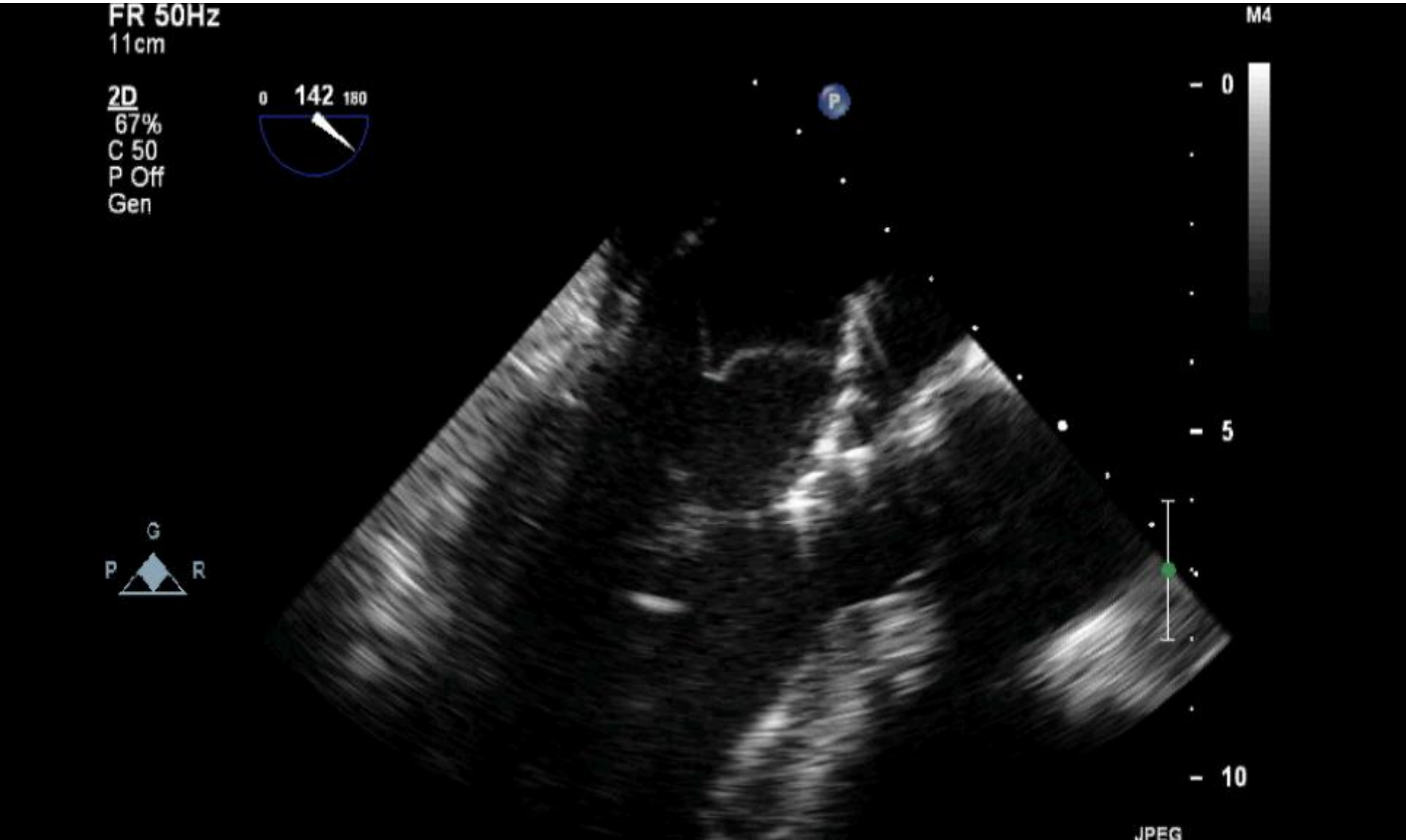

PHILIPS
16/03/2012 13:11:15 TIS0.7 MI 0.4
X7-2t/Adult
FR 19Hz
12cm
2D
71%
C 50
P Off
Gen
CF
59%
4.4MHz
WF High
Med
0 151 180
M4 M4
+57.8
-57.8
cm/s
JPEG
PAT T: 37.0C
TEE T: 39.4C
81 bpm

Heart Team Decision

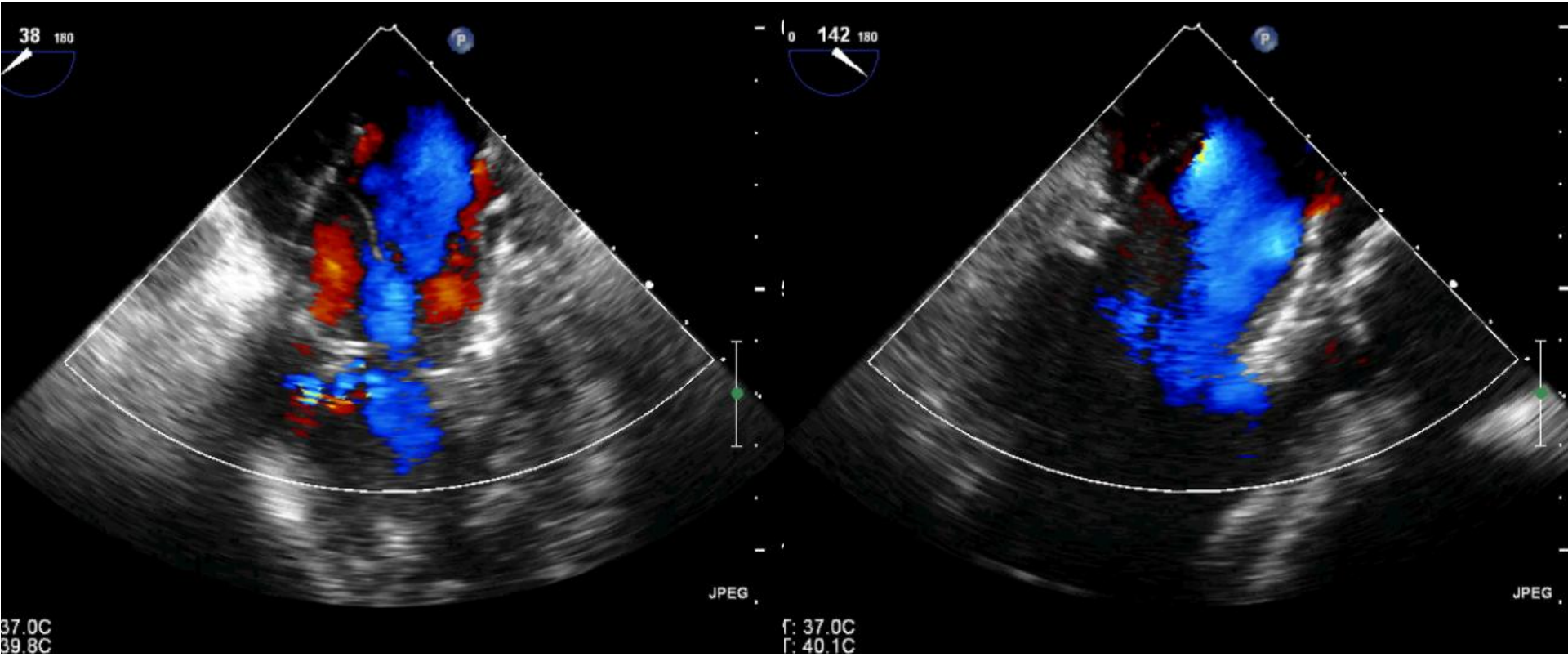
- Not eligible for mitral valve surgery due to extreme risk
- Not eligible for MitraClip due to large coarptation gap and restrictive PML
- TMVI?
- Approval from EC & DMA
  - Compassionate use
- Extended informed consent from patient

Copenhagen June 12th 2012

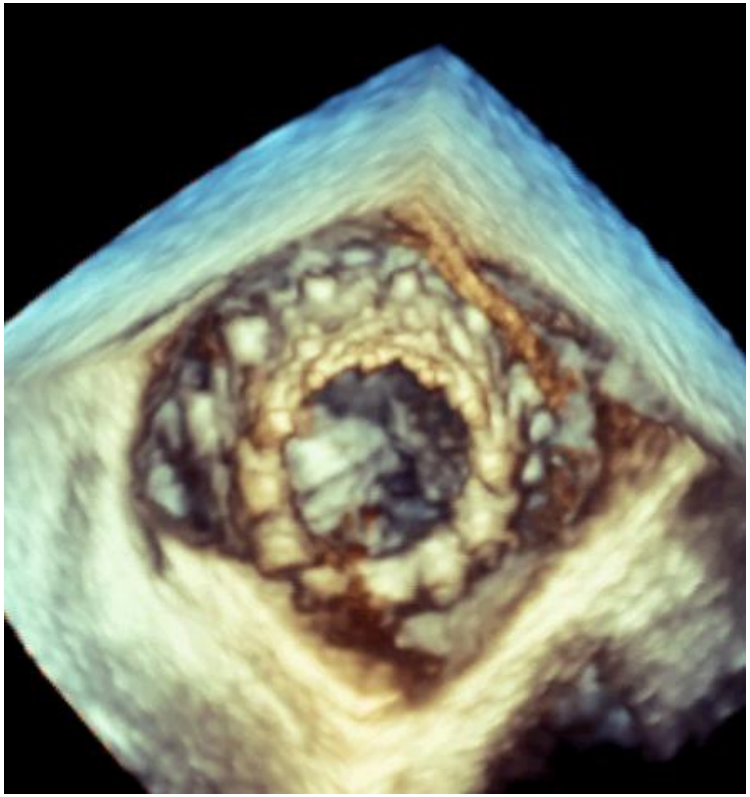
Deployed valve

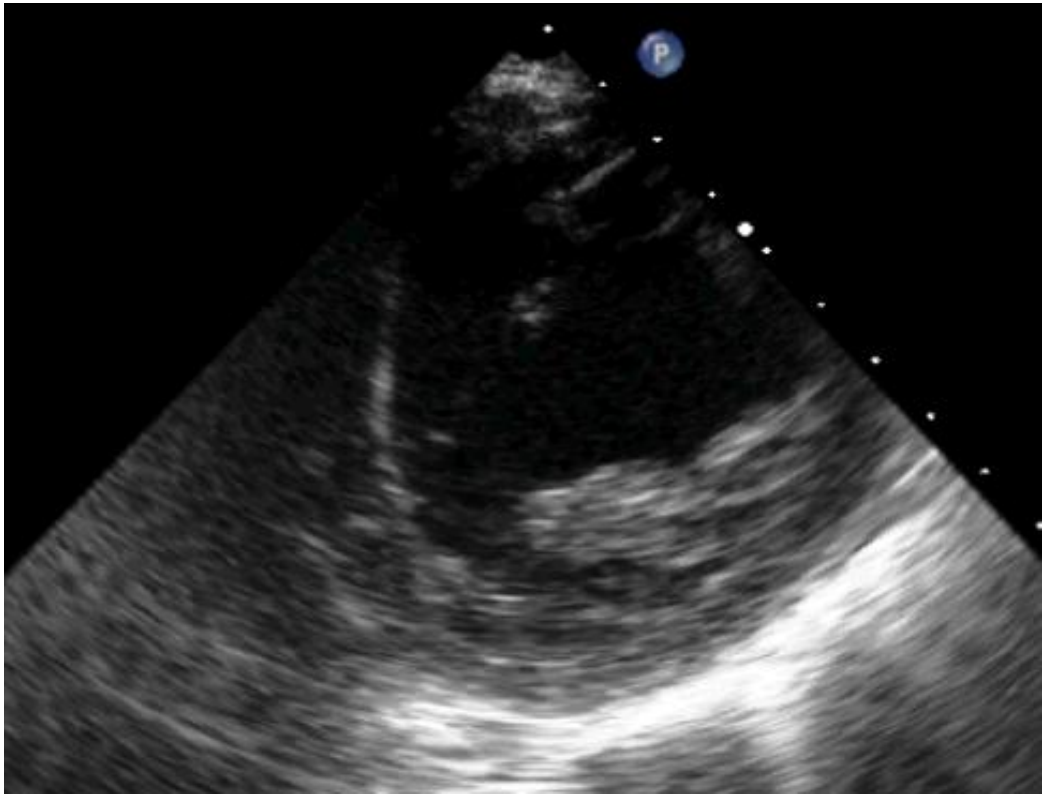


Valve after deployment



Echocardiography

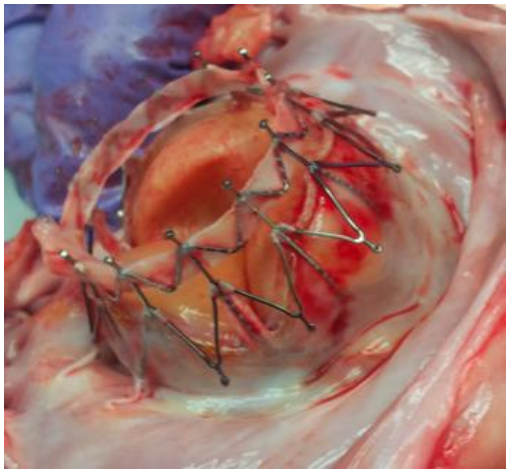




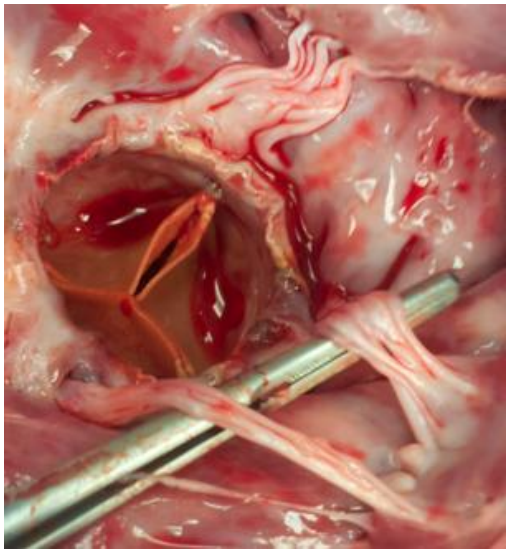
Gen 2 Chronic Animal – 97 days

- Elective term demonstrated:
  - No thrombus formation
  - Open LVOT
  - MR <1+
  - No implant migration
  - In-growth showed good healing
  - Good hemodynamics performance
  - Healthy growth (92 kg → 112 kg)

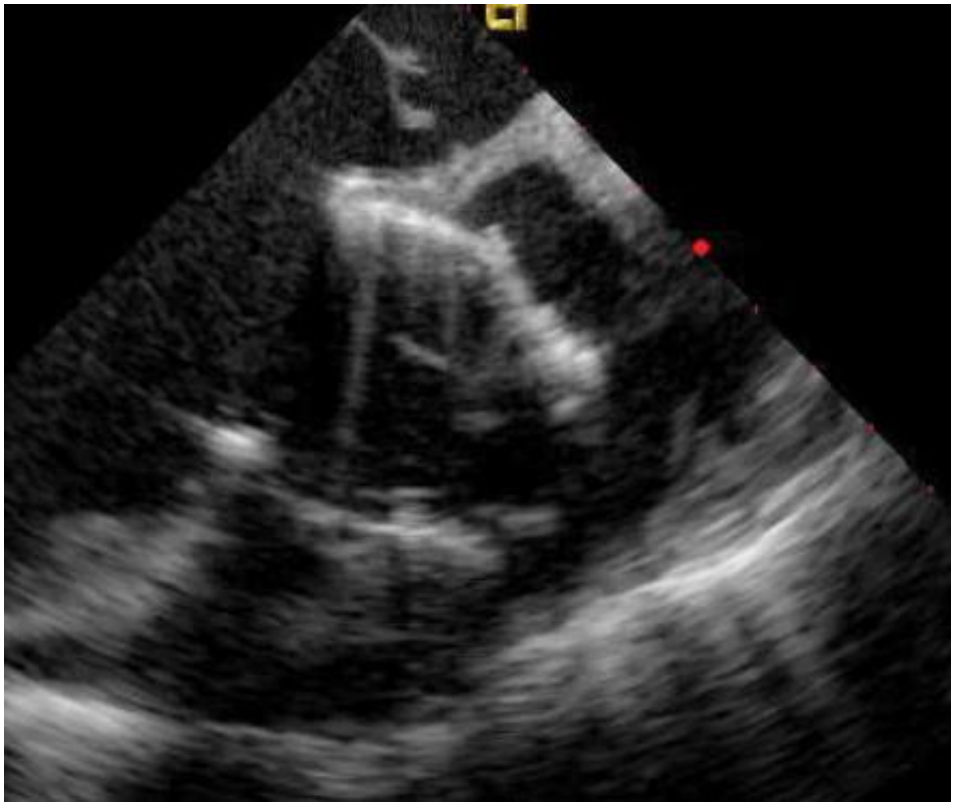
Left Atrial View

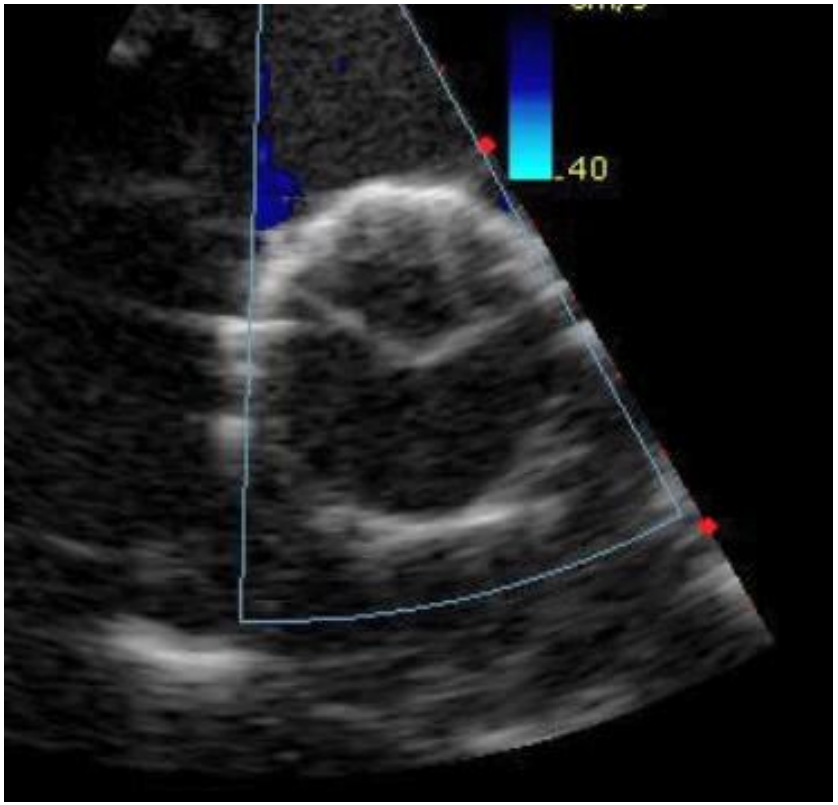


Left Ventricular View



Gen 2 Chronic Animal – 3 mo





Conclusions

- Challenging anatomy
- CardiAQ's 2012 FIH demonstrated that percutaneous, transseptal TMVI is feasible
- Finishing pre-requirements to take Gen 2 into human feasibility during latter part of 2013, with a formal clinical trial expected in 2014
- Several other concepts under development

Copenhagen FIH Team