Get Ready for Percutaneous Mitral Valve Approaches

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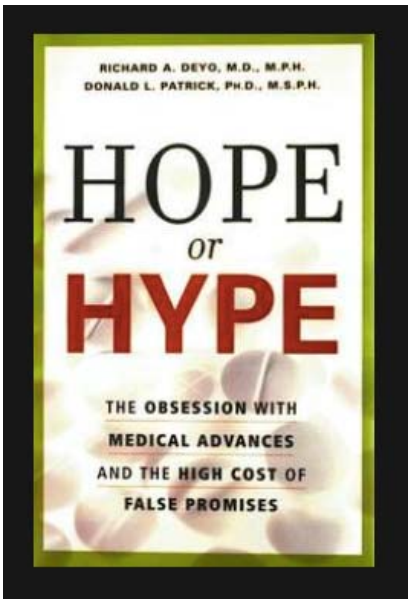


HOPE – Unmet Need: There are patients with severe MR who need something done and are too high risk for surgery

HYPE – Wall Street Mentality: There are not millions of these patients, and we are not yet sure who benefits and who does not

Four Transcatheter Approaches

- Edge-to-edge clip (Alfieri-type) repair (MitraClip FDA approved)
- Annuloplasty
- Chordal replacement
- Mitral valve replacement (TMVR)

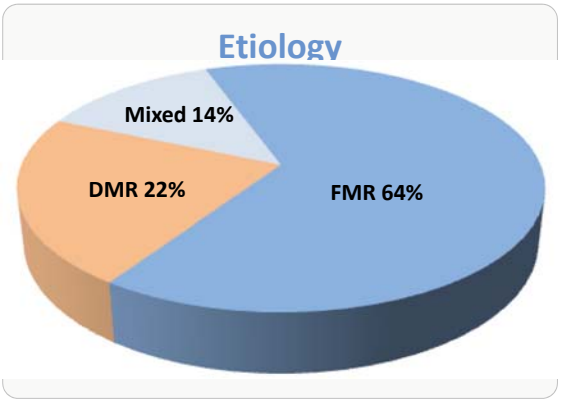
Transcatheter Mitral Valve Repair

MitraClip® System

MitraClip Worldwide Experience

>52,000 Patients

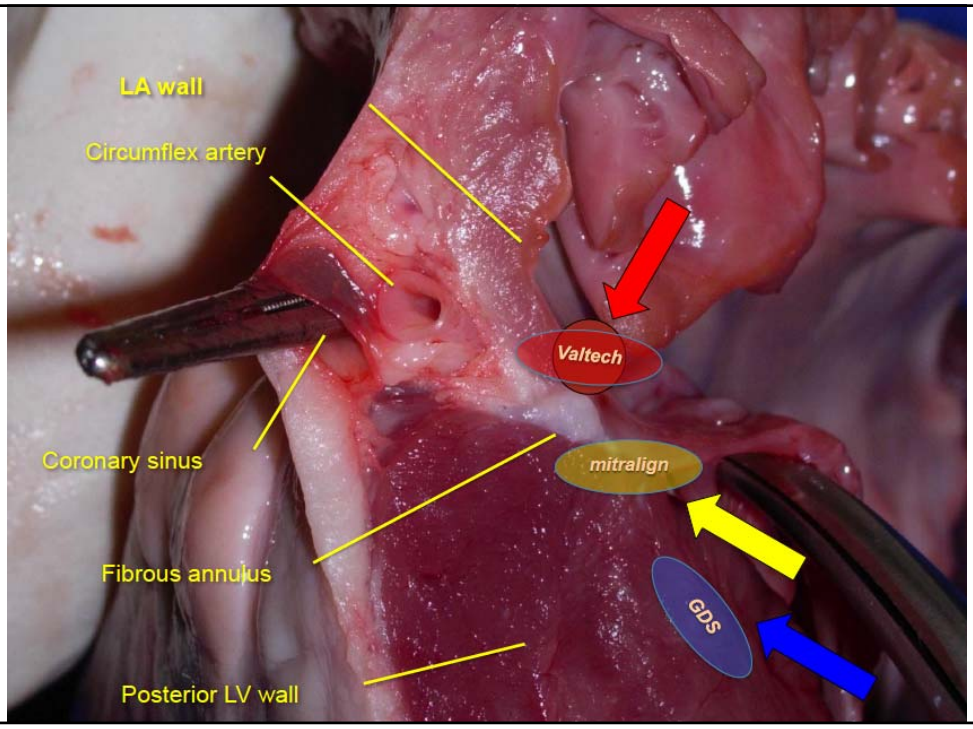
Implant Rate: 97%



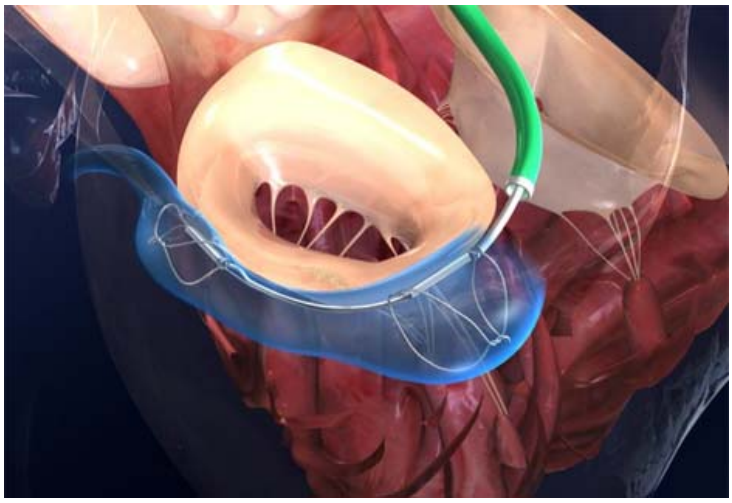
MitraClip is Good but there are Issues

- Failure to eliminate MR
  - Is moderate (2+) good enough?
  - Residual severe (3-4+) in 5-10% of patients
- Late recurrence of MR
  - Reduces option for surgical repair
- Mitral stenosis
  - MPG < 5 mmHg in cath lab can be worse when patient is ambulatory

Transcatheter Annuloplasty



Carillon Device



Carillon Pivotal FDA IDE Trial

- 400 patient trial in 50 sites in US, Canada, Europe and Australia
- Blinded, sham-controlled
- 2:1 randomization
- Co-Primary Efficacy Endpoints
  - 1st Primary endpoint: Hierarchical Endpoint
    - Death, Heart Failure, 6 minute walk-test at 12 months
  - 2nd Co-Primary Efficacy Endpoint
    - Reduction in Regurgitant Volume at 12 months in treatment group compared to control group

Transcatheter Mitral Annuloplasty in Chronic Functional Mitral Regurgitation

6-Month Results With the Cardioband Percutaneous Mitral Repair System

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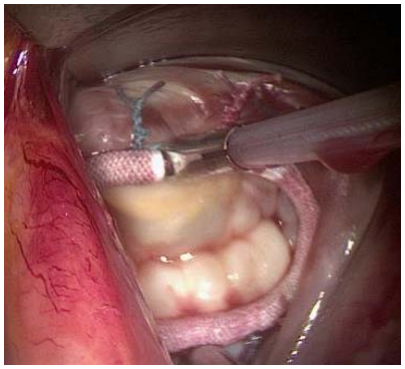
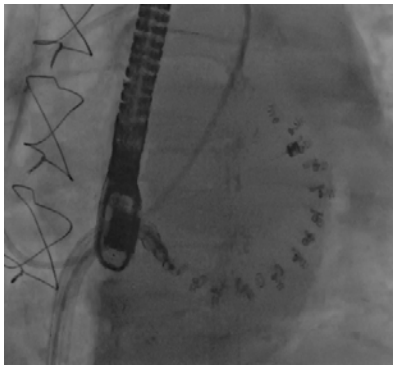
Cardioband is a Transfemoral Adjustable Ring

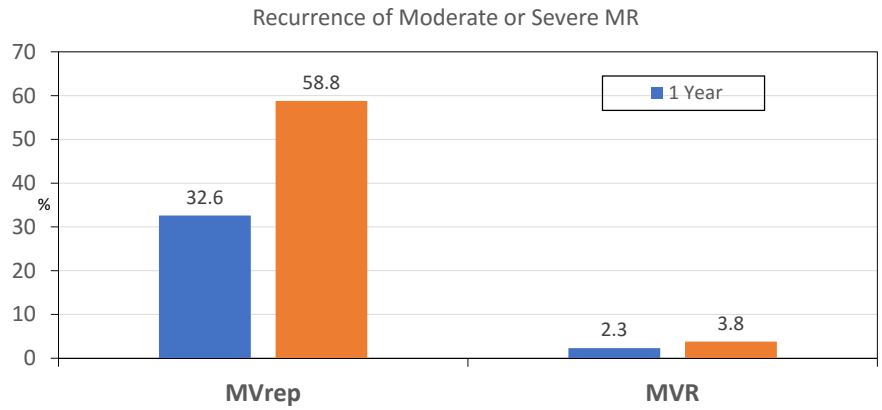
Surgery



Cardioband

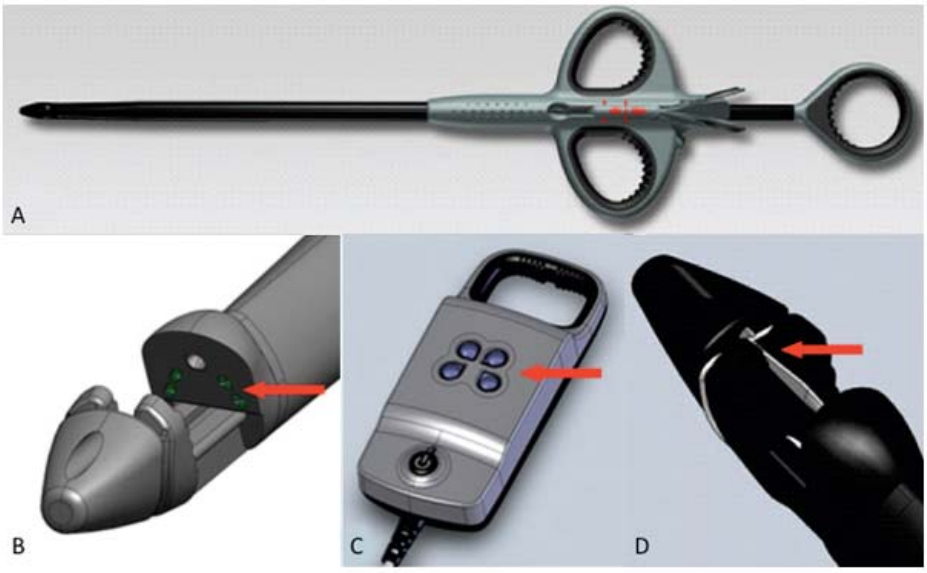


Caveat: MR Recurrence after Complete Ring Annuloplasty in CTSN Severe MR Trial



Secondary (functional) MR is a Disease of the LV; not the mitral annulus!

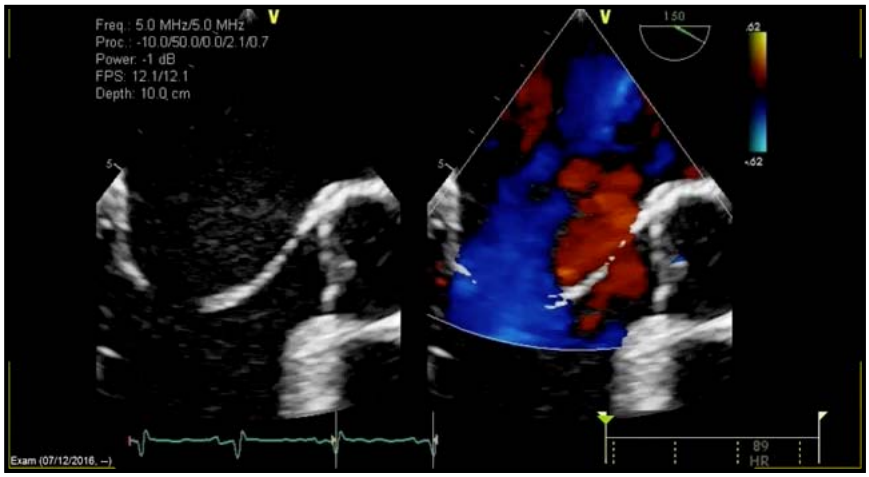
Chord Replacement



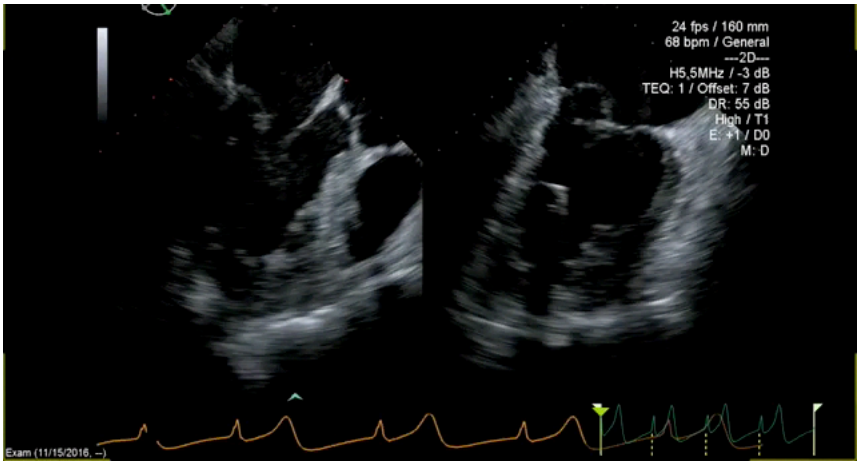
NeoChord Pivotal Trial

- 440 randomized pts, plus roll-in patients
- 20 sites
- Co-PIs – David Adams/Michael Borger
- Primary effectiveness endpoint – freedom from mod/sev MR at 1 year and freedom from mitral valve replacement or reintervention
- Primary safety endpoint – freedom from death, stroke, MAE (MVARC def) at 30 days

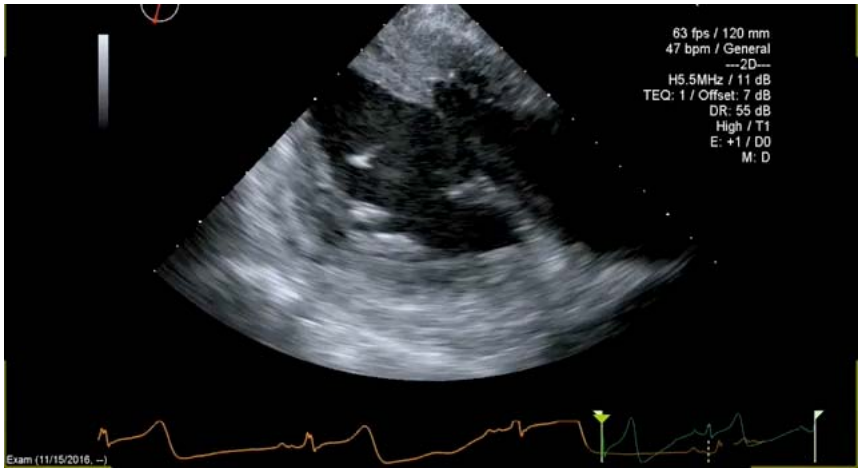
Severe MR



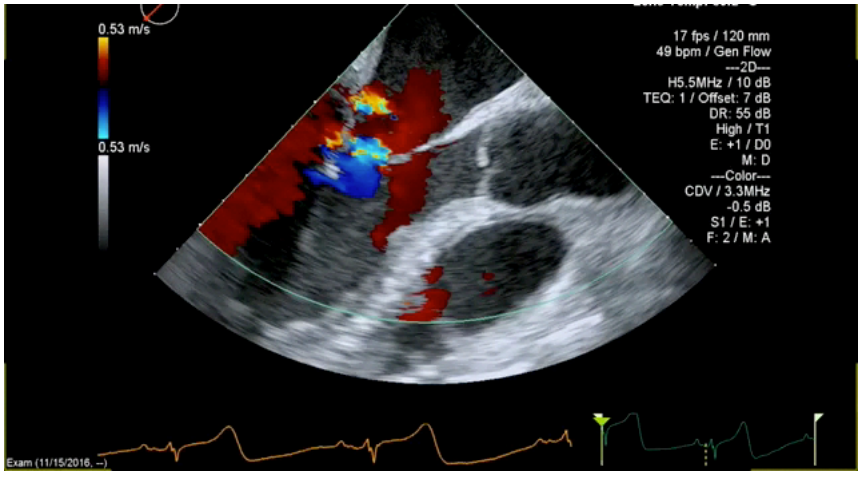
NeoChord Device - Grasp



Neochords Attached



Final Result



Chord Replacement: Caveats

- Still a thoracotomy; needs to become transfemoral, transseptal
- Benefit of off-pump not clear in CABG trials
- MVR often done minimally invasively now
- Early European results show late recurrence of MR (learning curve?)

Transcatheter Mitral Valve Replacement (TMVR)

- In light of CTSN trials, TMVR offers potentially lower risk option for valve replacement
- Technically more challenging than TAVR
  - Mitral annulus geometry
  - Larger orifice area
- Multiple devices under development
  - Transapical easier; EFS nearly done, pivotal startup
  - Transfemoral already starting

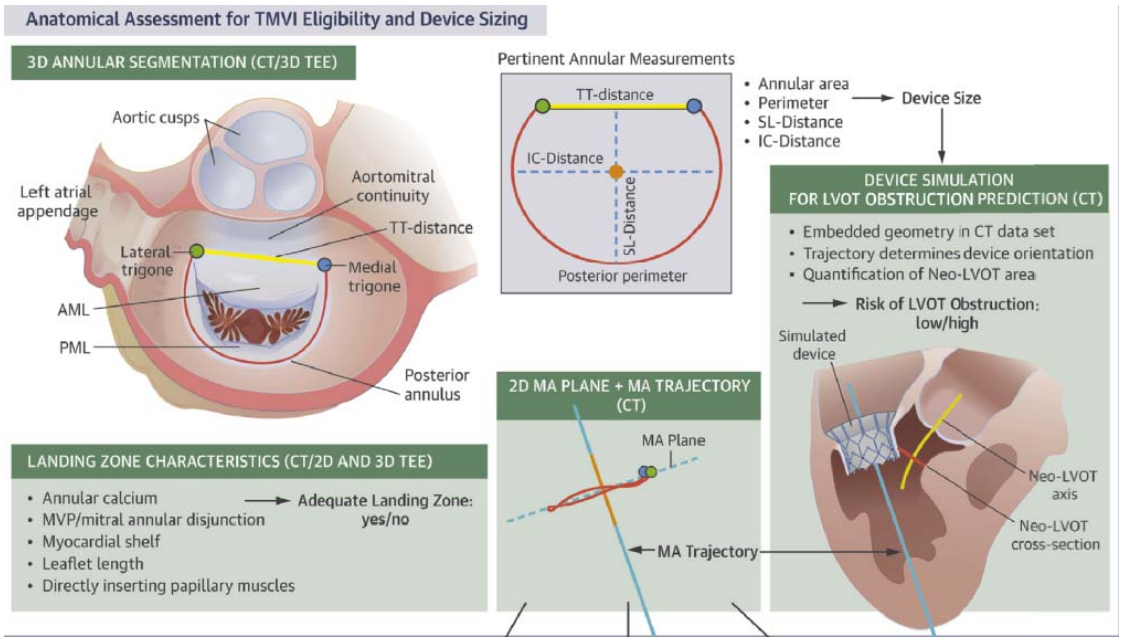
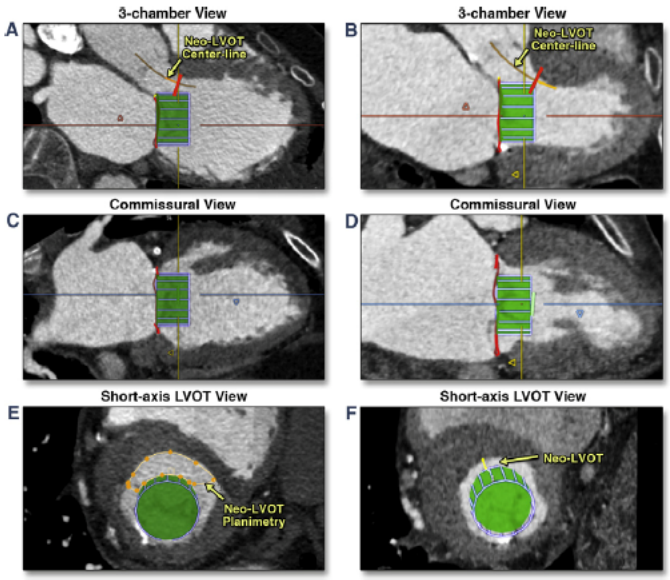
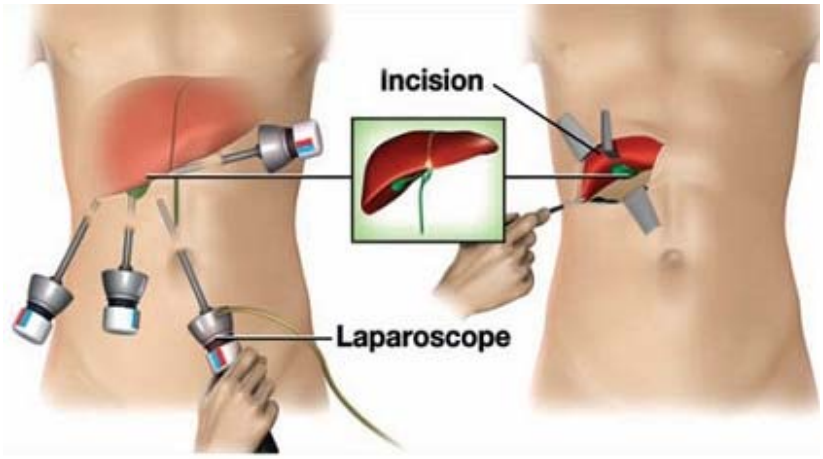


FIGURE 10 Prediction of Neo-LVOT Dimensions



Less invasive always wins!



Laparoscopic Cholecystectomy Open Cholecystectomy

TMVR Devices in Human Trials

Tendyne

Twelve

CardiaQ

Cephea

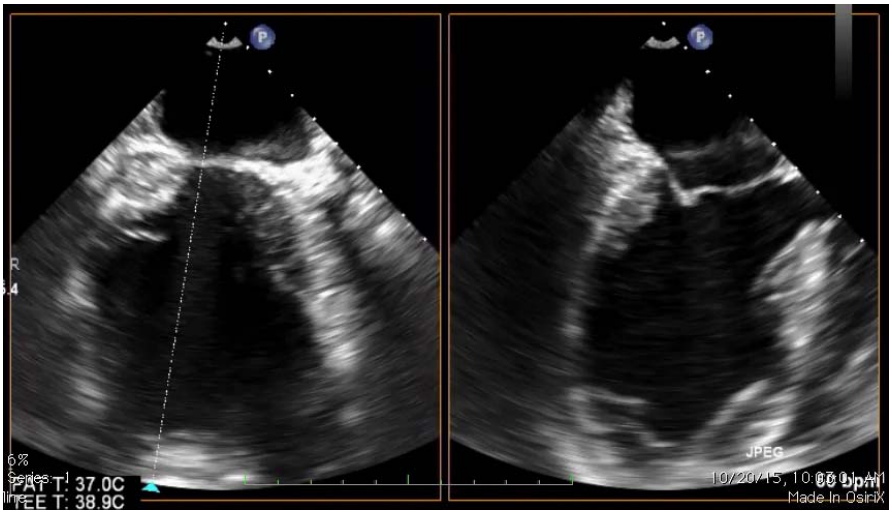
Neovasc Tiara

MValve

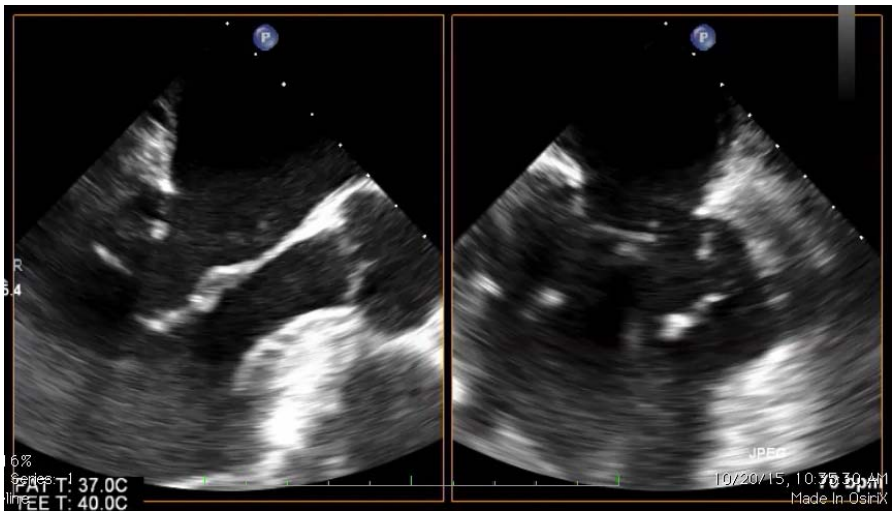
Different Designs for the Same Thing

Over time, TMVR devices will get smaller and better!

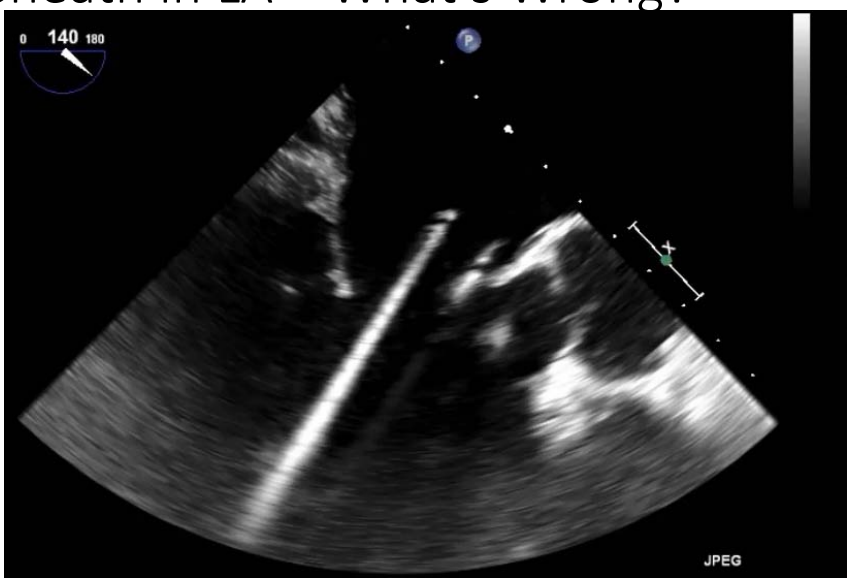
Finger at LV Apex



Wire in LUPV – Balloon to LA

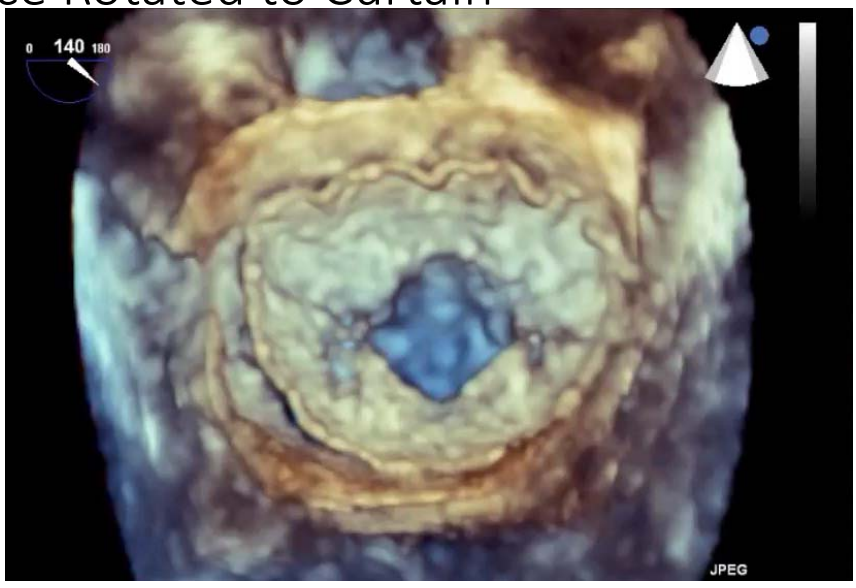


32F Sheath in LA – What's Wrong?

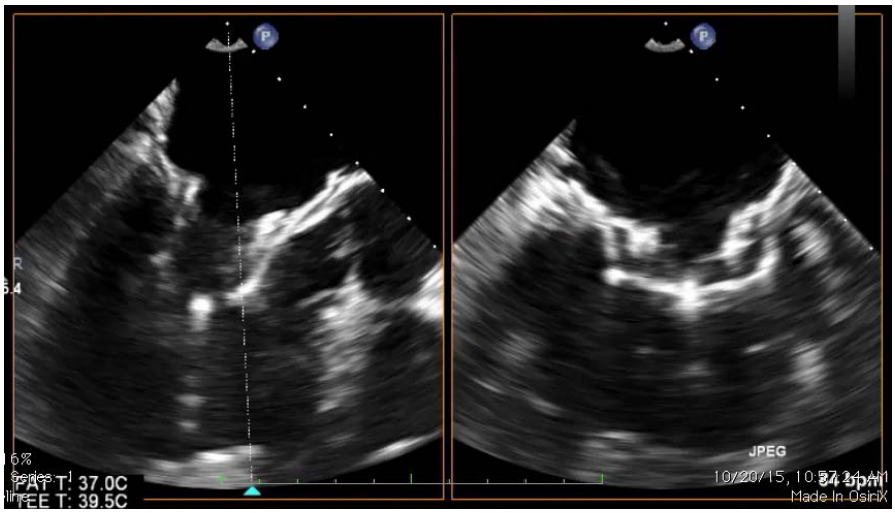


Device Extruding from Sheath

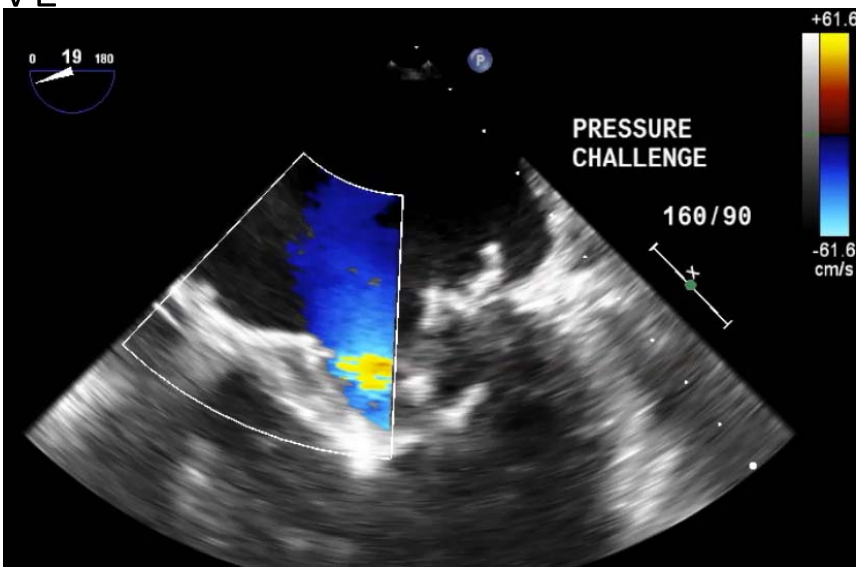
Device Rotated to Curtain

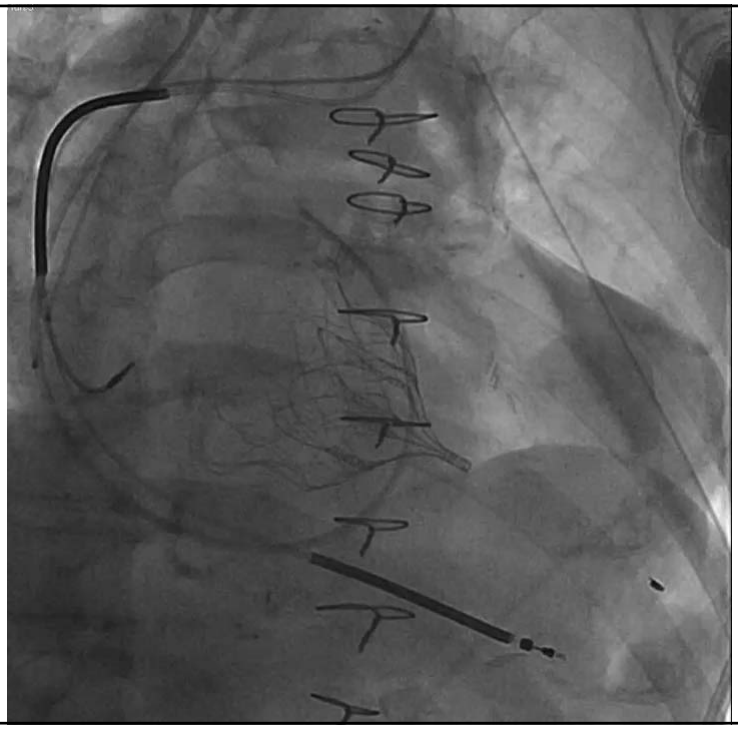


Device Seated



No PVL





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Transcatheter Mitral Valve Replacement for Patients With Symptomatic Mitral Regurgitation

A Global Feasibility Trial

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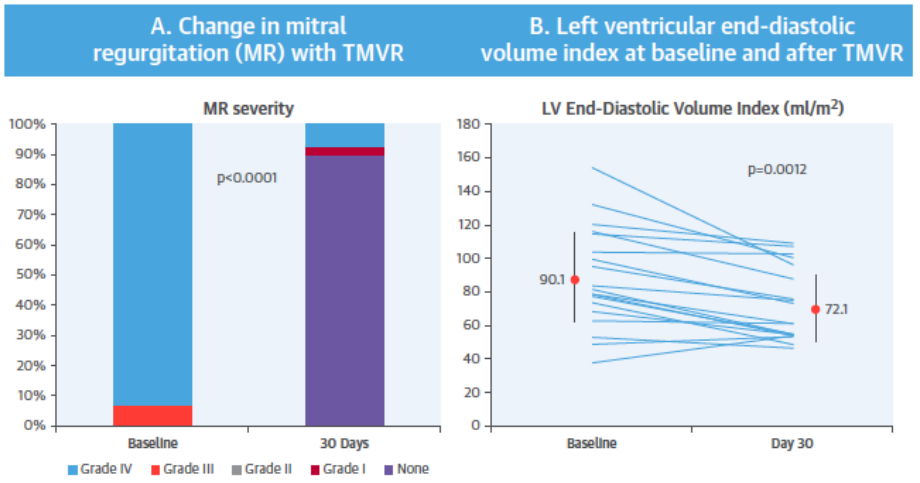
O/30 cardiovascular deaths at 30 days
1/3 (3.3%) noncardiovascular death (Hosp acq pneumonia)
0/30 strokes
0/30 acute MIs

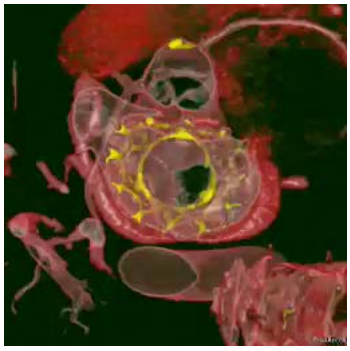
Tendyne 30-Day Results

CENTRAL ILLUSTRATION Change in Mitral Regurgitation and LV Volumes After TMVR

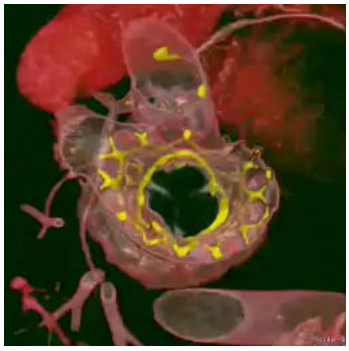


Device Thrombosis

One month post TMVR
INR 1.1
Mean gradient 10 mmHg



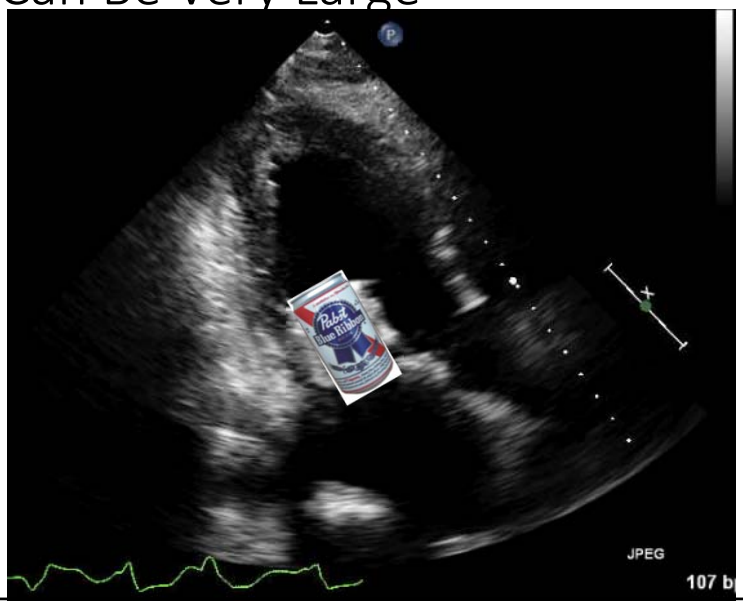
Three months post TMVR
INR 4.0
Mean gradient 2 mmHg



TMVR Devices

- Multiple device designs resemble surgical bioprosthetic valves
- Differences in leaflet tissue
  - Porcine vs bovine pericardium
- Differences in anchoring
  - Apical tether, annular fixation, leaflet clips, other
- First-in-human trials underway in Europe, Asia, United States

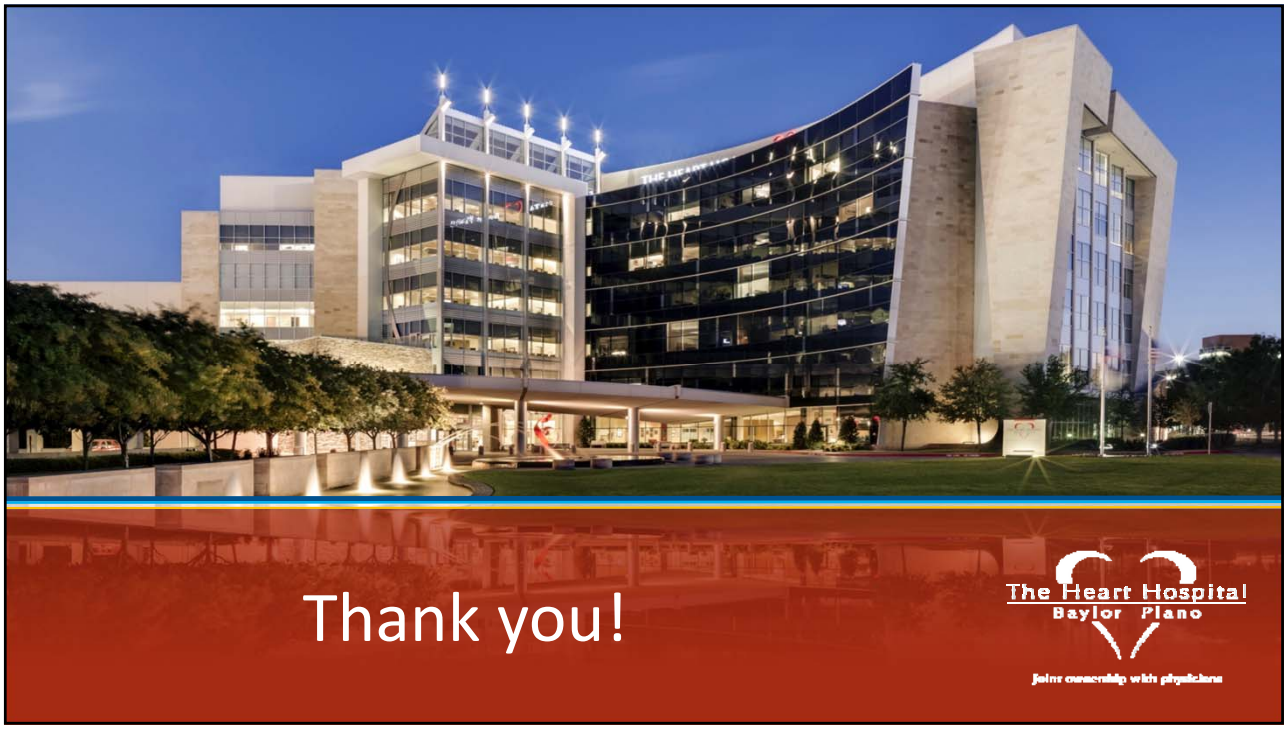
Profile Can Be Very Large



Challenges

- Mitral anatomy/function complex
- Mitral annular calcium
- Large device profiles
- Delivery systems large, mostly transapical
- LVOT obstruction / SAM
- Anchoring
- Paravalvular MR / hemolysis
- Device thrombosis
- Device-specific imaging needs

Multidisciplinary Mitral Valve Clinic



Thank you!

The Heart Hospital
Baylor Plano
Joint ownership with physicians