Novel Surgical Approaches to Treatment of Mitral Regurgitation

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Disclosures

- none
• The mitral valve is complex

• Proper mitral valve function is determined at multiple levels

• Effective repair often utilizes a combination of techniques
Implications for catheter approaches

- Complex anatomy
  - Not circular
  - Not 2D
- Sizing
- Fixation
- Sealing
- Annular-LV chordal interaction
- Adjacent structures (Cx, CS, AVB)
- LVOT obstruction
- Durability
Etiology of Regurgitation

Type I: Normal leaflet motion
Type II: Increased leaflet motion
Type IIIa: Restricted leaflet motion
Type IIIb: Restricted leaflet motion
Type I
Normal Leaflet Motion

- Annular dilatation
- Annuloplasty restores normal anatomic shape
Type II
Excess leaflet motion

- Prolapse secondary to elongation or rupture
- Strategy determined by amount of leaflet tissue
  - Excess
    - Leaflet displacement
    - Targeted resection
    - Sliding plasty
  - Minimal
    - Chordal transfer
    - Neochords
Type II
Excess leaflet motion
(triangular resection)
Type II
Excess leaflet motion

- Prolapse secondary to elongation or rupture

- Strategy determined by amount of leaflet tissue
  - Excess
    - Leaflet displacement
    - Targeted resection
    - Sliding plasty
  - Minimal
    - Chordal transfer
    - Neochords
    - Triangular resection (more tissue)
Type III
Restricted Leaflet Motion

- IIIA- Restricted opening
  - Commisural Fusion
    - Comissurotomy

- Leaflet Retraction
  - Leaflet augmentation

- Chordal Retraction
  - Chordal Fenestration
Type III
Restricted Leaflet Motion

- IIIA- Restricted opening
  - Commisural Fusion
    - Comissurotomy
  - Leaflet Retraction
    - Leaflet augmentation
  - Chordal Retraction
    - Chordal Fenestration
Type III
Restricted Leaflet Motion

- IIIB - Restricted closing
  - Leaflet tethering
  - Downsized annuloplasty
    - Rigid ring
Repair often requires combination of techniques

- PL prolapse from ruptured chord, AL prolapse from chordal elongation.

- Severe myxomatous degeneration and annular dilatation

- Repair with quadrangular resection of the PL, sliding leaflet plasty, and neochords to posterior and anterior leaflets

- 38-mm Carpentier-Edwards Physio
There are a number of TMV-Repair and TMV-Replacement devices currently in development, each with unique approaches and features.

- **Leaflet Repair**: Valve leaflets are secured together creating two new smaller valves.
- **Annular Repair**: Shape and dimension of the annulus or LV are modified.
- **Chordae Repair**: Artificial chordae are attached between leaflet and LV.
- **Valve Replacement**: A new valve is delivered inside the native valve.
The COAPT Trial
Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation

A parallel-controlled, open-label, multicenter trial in 614 patients with heart failure and moderate-to-severe (3+) or severe (4+) secondary MR who remained symptomatic despite maximally-tolerated GDMT

Randomize 1:1*

MitraClip + GDMT
N=302

GDMT alone
N=312

*Stratified by cardiomyopathy etiology (ischemic vs. non-ischemic) and site

Key Inclusion Criteria

1. Ischemic or non-ischemic cardiomyopathy with LVEF 20%-50% and LVESD ≤70 mm
2. Moderate-to-severe (3+) or severe (4+) secondary MR confirmed by an independent echo core laboratory prior to enrollment (US ASE criteria)
3. NYHA functional class II-IVa (ambulatory) despite a stable maximally-tolerated GDMT regimen and CRT (if appropriate) per societal guidelines
4. Pt has had at least one HF hospitalization within 12 months and/or a BNP ≥300 pg/ml* or a NT-proBNP ≥1500 pg/ml*
5. Not appropriate for mitral valve surgery by local heart team assessment
6. IC believes secondary MR can be successfully treated by the MitraClip

Adjusted by a 4% reduction in the BNP or NT-proBNP cutoff for every increase of 1 kg/m² in BMI >20 kg/m²
All-cause Mortality

HR [95% CI] = 0.62 [0.46-0.82]  
P<0.001

NNT (24 mo) = 5.9 [95% CI 3.9, 11.7]

No. at Risk:
MitraClip + GDMT  302  286  269  253  236  191  178  161  124
GDMT alone        312  294  271  245  219  176  145  121  88

Time After Randomization (Months)

Stone GW et al. NEJM 2018: on-line
Annuloplasty Devices (Direct and indirect)

**Indirect**

**Direct**
Coronary Sinus Annuloplasty

Problems:

- coronary sinus often too atrial
- circumflex artery compression
92% of patients with MR ≤2+ at One Year

- 31% MR 2
- 86% MR ≤2+
- 86% MR ≤2+
- 92% MR ≤2+

Pre (N=20)
1 M (N=30)
6 M (N=20)
1 Y (N=20)
Transcatheter Annuloplasty

Valtech Cardioband
- transseptal access
- anchor screws
- Adjustable
- CE mark
- US clinical trial beginning
- Results of MR

<table>
<thead>
<tr>
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<th>Baseline N=31</th>
<th>Discharge N=29</th>
<th>1 month N=28</th>
<th>6 months N=22</th>
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<tr>
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<td>3-4+</td>
<td>2+</td>
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<td>P&lt;0.001 vs baseline</td>
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Expert Rev Med Devices, 2017
Cradioband

**NYHA Class**
P < 0.01

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<th>NYHA Class</th>
<th>Baseline</th>
<th>12 months</th>
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<td>I</td>
<td>39</td>
<td>19</td>
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<td>II</td>
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<td>III</td>
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63% NYHA I/I

**MLHFQ Score**
P < 0.01

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<td>N = 15</td>
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Septo-lateral Displacement [mm]

Baseline: 37 ± 4 mm
Discharge: 26 ± 4 mm

p < 0.01
Millipede
Chordal Repair

Neochord

Harpoon
Neochord 1 yr Results

Eur J Cardiothor Surg, 2018
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<td>Valve Name</td>
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<td>CardiAQ</td>
<td>Tendyne</td>
<td>Intrepid</td>
<td>HighLife</td>
<td>Caisson</td>
<td>Sapien M3</td>
<td>Cephea</td>
<td>Cardio Valve</td>
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<td>Device Image</td>
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<td><img src="image8.png" alt="Cephea" /></td>
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<tr>
<td>Access</td>
<td>TA</td>
<td>TA/TF</td>
<td>TA</td>
<td>TA</td>
<td>TA (valve) and TF (ring)</td>
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- Different approaches to fixation
- Anatomic challenges (LVOT obstruction)
1. **Conformable Outer Stent** engages the annulus providing fixation & sealing while isolating the inner stent from the dynamic anatomy

2. **Circular Inner Stent** houses a 27 mm tricuspid bovine pericardium valve

3. **Flexible Brim** aids imaging during delivery & subsequent healing

   One implant platform regardless of delivery approach:

   trans-apical or trans-septal
Fixation and Sealing

Cork effect produced by variable stiffness along the height of the Outer Stent
Radial interference, small cleats, frictional elements & tissue ingrowth
Leveraging but not relying upon the native leaflets
Tendyne Mitral Valve
Mitral regurgitation is often multifactorial.

Competent repair requires a thorough understanding of the underlying pathophysiology and the ability to utilize multiple repair strategies.

Successful catheter-based strategies will likely apply multiple repair techniques.
Thank You