The 21st Century Approach to Mitral Regurgitation: Transcatheter Mitral Valve Repair

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Disclosures

• Travel reimbursement from Abbott Vascular, Edwards Lifesciences, Medtronic Inc and St Jude Medical
Prevalence of Mitral Valve Disease

Prevalence of Mitral Valve Disease

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age 18-64 (N = 6,287)</th>
<th>Age 65-74 (N = 3,579)</th>
<th>Age &gt; 75 (N = 1,745)</th>
<th>Frequency adjusted to 2000 US adult population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitral Regurgitation (n = 449)</td>
<td>36 (0.58%)</td>
<td>250 (6.4%)</td>
<td>163 (9.3%)</td>
<td>1.7% 95% CI [1.5-1.9]</td>
</tr>
<tr>
<td>Mitral Stenosis (n = 15)</td>
<td>4 (0.06%)</td>
<td>7 (0.2%)</td>
<td>4 (0.2%)</td>
<td>0.1% 95% CI [0.02-0.2]</td>
</tr>
</tbody>
</table>

Mechanism of Mitral Regurgitation

• **Organic**: Valve components are abnormal
  – Prolapse
  – Ruptured chordae/flail leaflet
  – Rheumatic disease
  – Congenital abnormality
  – Endocarditis

• **Functional**: valve components are normal
  – LV dilation and remodeling leads to …
    • Annular enlargement
    • Papillary muscle displacement
Chronic Severe MR: Indications for Surgery

• **Class I**
  – Symptomatic (NYHA II-IV) in the absence of LV dysfunction (e.g. LVEF > 30%) and/or ESDd > 55mm)
  – Asymptomatic with LVEF 30-60% and/or ESDd > 40mm

• **Class IIa**
  – Asymptomatic with preserved LV function (e.g. LVEF > 60% and ESDd ≤ 40mm) +/- the presence of new onset AF or pulmonary hypertension
  – Symptomatic (NYHA III-IV) with evidence of LV dysfunction in setting of organic mitral disease

• **Class IIb**
  – Symptomatic (NYHA II-IV) despite optimal therapy with evidence of LV dysfunction in the setting of functional mitral regurgitation

Surgery is Underutilized in Symptomatic Patients

Surgery is Underutilized in Symptomatic Patients

Surgery is Underutilized in Symptomatic Patients

Surgery is Underutilized in Asymptomatic Patients

Need for Alternative Therapies

- Evolving technologies are all based upon surgical techniques
  - Edge-to-Edge Repair (Alfieri technique)
  - Annuloplasty
    - Indirect
    - Direct
  - Chordal Replacement
  - Percutaneous Mitral Valve Implant
Edge-to-Edge Repair: Alfieri Technique

• Described in 1992
  – Suture part of anterior and posterior leaflet edges together
  – Usually applied to A2-P2 central segment

• Usually used in conjunction with mitral annuloplasty
Edge-to-Edge Repair

• Pathophysiologic effects of Edge-to-Edge repair
  – Facilitates proper leaflet coaptation
  – Creates tissue bridge
  – Restrains LV wall

• Can lead to decrease in mitral valve area so should be avoided in patients with . . .
  – Rheumatic MR
  – Severe annular calcification with thickened leaflets
  – Ring size less than 30 mm
The MitraClip System performs percutaneous mitral valve repair by creating a vertical line of coaptation, forming a double-orifice valve.

- Beating heart procedure—no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimize MR reduction
- Designed to preserve surgical options
- Femoral venous access
- Limited hospital length of stay
The MitraClip System
Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald D. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engoron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*
EVEREST II Study Design

• Design:
  – RCT comparing mitraclip vs. surgery in a 2:1 randomization fashion

• Primary Efficacy Endpoint
  – Composite of freedom from death, from mitral valve surgery and from grade 3+ or 4+ MR at 12 months

• Primary Safety Endpoint
  – Rate of major adverse events at 30 days
    • Includes death, MI, reoperation for failed MV repair, CT surgery for complications, stroke, renal failure, wound infection, mechanical ventilation > 48 hrs, GI complication requiring surgery, new-onset AF, septicemia or transfusion of > 2U PRBC
EVEREST II Study Design

• Inclusion Criteria
  – 3+ or 4+ chronic MR AND
    • Symptomatic with EF > 25% and LVSDd < 55mm
    OR
    • Asymptomatic with . . .
      – EF 25%-60% or
      – LVSDd > 40 mm AND
      – Atrial Fibrillation or
      – PASP > 50 at rest or > 60 with exercise

• Exclusion Criteria
  – Anatomical criteria making percutaneous closure untenable
  – Recent MI
  – Prior mitral valve surgery or valvuloplasty
  – Not candidate for surgery
# EVEREST II: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MitraClip (N=184)</th>
<th>Surgery (N=95)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>67.3 ± 12.8</td>
<td>65.7 ± 12.9</td>
<td>0.32</td>
</tr>
<tr>
<td>Male sex</td>
<td>115 (62%)</td>
<td>63 (66%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Prior CHF</td>
<td>167 (91%)</td>
<td>74 (78%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Prior MI</td>
<td>40 (22%)</td>
<td>20 (21%)</td>
<td>0.99</td>
</tr>
<tr>
<td>AF</td>
<td>59 (34%)</td>
<td>35 (39%)</td>
<td>0.42</td>
</tr>
<tr>
<td>Diabetes</td>
<td>14 (8%)</td>
<td>10 (11%)</td>
<td>0.50</td>
</tr>
<tr>
<td>COPD</td>
<td>27 (15%)</td>
<td>14 (15%)</td>
<td>0.99</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>38 (21%)</td>
<td>18 (19%)</td>
<td>0.87</td>
</tr>
<tr>
<td>Characteristic</td>
<td>MitraClip (N=184)</td>
<td>Surgery (N=95)</td>
<td>p-value</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------</td>
<td>----------------</td>
<td>---------</td>
</tr>
<tr>
<td>LVEF</td>
<td>60.0 ± 10.1</td>
<td>60.6 ± 11.0</td>
<td>0.65</td>
</tr>
<tr>
<td>NYHA Class</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>17 (9%)</td>
<td>19 (20%)</td>
<td>0.16</td>
</tr>
<tr>
<td>II</td>
<td>73 (40%)</td>
<td>21 (33%)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>82 (45%)</td>
<td>41 (43%)</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>12 (7%)</td>
<td>4 (4%)</td>
<td></td>
</tr>
<tr>
<td>Severity of MR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2+</td>
<td>8 (4%)</td>
<td>7 (7%)</td>
<td>0.38</td>
</tr>
<tr>
<td>3+</td>
<td>130 (71%)</td>
<td>67 (71%)</td>
<td></td>
</tr>
<tr>
<td>4+</td>
<td>46 (25%)</td>
<td>21 (22%)</td>
<td></td>
</tr>
<tr>
<td>Cause of MR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional</td>
<td>49 (26%)</td>
<td>26 (27%)</td>
<td>0.81</td>
</tr>
<tr>
<td>Degenerative</td>
<td>135 (74%)</td>
<td>69 (73%)</td>
<td></td>
</tr>
</tbody>
</table>
# EVEREST II: Efficacy Results

<table>
<thead>
<tr>
<th>Event</th>
<th>MitraClip</th>
<th>Surgery</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Composite Efficacy Endpoint</strong></td>
<td>100 (55%)</td>
<td>65 (73%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Death</td>
<td>11 (6%)</td>
<td>5 (6%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Surgery for MV dysfunction</td>
<td>37 (20%)</td>
<td>2 (2%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Grade 3+ or 4+ MR</td>
<td>38 (21%)</td>
<td>18 (20%)</td>
<td>1.00</td>
</tr>
</tbody>
</table>
## EVEREST II: Safety Results

<table>
<thead>
<tr>
<th>Event</th>
<th>MitraClip</th>
<th>Surgery</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Major Adverse Event</td>
<td>27 (15%)</td>
<td>45 (48%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td></td>
<td><strong>- Excluding transfusion</strong></td>
<td>9 (5%)</td>
<td>9 (10%)</td>
</tr>
<tr>
<td>Transfusion ≥ 2U PRBC</td>
<td>24 (13%)</td>
<td>42 (45%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Urgent CT surgery</td>
<td>4 (2%)</td>
<td>4 (4%)</td>
<td>0.57</td>
</tr>
<tr>
<td>Renal failure</td>
<td>1 (&lt; 1%)</td>
<td>0</td>
<td>1.00</td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (1%)</td>
<td>2 (2%)</td>
<td>0.89</td>
</tr>
<tr>
<td>Mechanical ventilation ≥ 48 hrs</td>
<td>0 (0%)</td>
<td>4 (4%)</td>
<td>0.02</td>
</tr>
</tbody>
</table>
### EVEREST II: Secondary Endpoints

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MitraClip (N=184)</th>
<th>Surgery (N=95)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in LVEF</td>
<td>-2.8 ± 7.2 *</td>
<td>-6.8 ± 10.1 *</td>
<td>0.005</td>
</tr>
<tr>
<td>Change in EDV</td>
<td>-25.3 ± 28.3 *</td>
<td>-40.2 ± 35.9 *</td>
<td>0.004</td>
</tr>
<tr>
<td>Change in QOL score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 mo. (physical)</td>
<td>4.4 ± 9.8 *</td>
<td>4.4 ± 10.4 *</td>
<td>0.98</td>
</tr>
<tr>
<td>12 mo. (mental)</td>
<td>5.7 ± 9.6 *</td>
<td>3.8 ± 10.3 *</td>
<td>0.24</td>
</tr>
<tr>
<td>Severity of MR</td>
<td></td>
<td></td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>0-1+</td>
<td>66 (43%)</td>
<td>52 (76%)</td>
<td></td>
</tr>
<tr>
<td>2+</td>
<td>59 (39%)</td>
<td>14 (20%)</td>
<td></td>
</tr>
<tr>
<td>3+</td>
<td>21 (14%)</td>
<td>3 (4%)</td>
<td></td>
</tr>
<tr>
<td>4+</td>
<td>7 (5%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

* - p value < 0.01 from baseline
# EVEREST II: Subgroup Analyses

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Percutaneous Repair</th>
<th>Surgery</th>
<th>Difference between Percutaneous Repair and Surgery (%)</th>
<th>P Value for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>100/181 (55)</td>
<td>65/89 (73)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>63/114 (55)</td>
<td>43/59 (73)</td>
<td></td>
<td>0.97</td>
</tr>
<tr>
<td>Female</td>
<td>37/67 (55)</td>
<td>22/30 (73)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td>0.009</td>
</tr>
<tr>
<td>≥70 yr</td>
<td>52/86 (60)</td>
<td>23/38 (61)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70 yr</td>
<td>48/95 (51)</td>
<td>42/51 (82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MR</td>
<td></td>
<td></td>
<td></td>
<td>0.02</td>
</tr>
<tr>
<td>Functional</td>
<td>26/48 (54)</td>
<td>12/24 (50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degenerative</td>
<td>74/133 (56)</td>
<td>53/65 (82)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVEF</td>
<td></td>
<td></td>
<td></td>
<td>0.06</td>
</tr>
<tr>
<td>&lt;60%</td>
<td>35/68 (51)</td>
<td>15/28 (54)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥60%</td>
<td>64/111 (58)</td>
<td>50/61 (82)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: The chart illustrates the difference in outcomes between Percutaneous Repair and Surgery, with the P values indicating statistical significance.
EVEREST II RCT: Summary

• Surgery was found to be superior to MitraClip in terms of primary efficacy endpoint
  – Driven by need for MV surgery in MitraClip group

• MitraClip was found to be superior to Surgery in terms of primary safety endpoint
  – Driven entirely by need for transfusions with surgery

• MitraClip patients did experience durable improvements
  – Quality of Life measurements
  – LV ejection fraction
  – LVEDV and dimensions
  – Severity of MR
Acute and 12-Month Results With Catheter-Based Mitral Valve Leaflet Repair

The EVEREST II (Endovascular Valve Edge-to-Edge Repair) High Risk Study

Patrick L. Whitlow, MD,* Ted Feldman, MD,† Wes R. Pedersen, MD,‡ D. Scott Lim, MD,§ Robert Kipperman, MD,∥ Richard Smalling, MD, PhD,¶ Tanvir Bajwa, MD,# Howard C. Herrmann, MD,** John Lasala, MD, PhD,†† James T. Maddux, MD,‡‡ Murat Tuzcu, MD,* Samir Kapadia, MD,* Alfredo Trento, MD, §§ Robert J. Siegel, MD, §§ Elyse Foster, MD,||| Donald Glower, MD,¶¶ Laura Mauri, MD,## Saibal Kar, MD, §§ on behalf of the EVEREST II Investigators
EVEREST II High Risk Registry

- **Study Design**: Multicenter, single arm study

- **Key Inclusion Criteria**
  - Symptomatic 3+ or 4+ MR
  - Predicted surgical risk $\geq 12\%$ by STS score or surgeon evaluation

- **Comparator Group**
  - Retrospectively matched group of patients treated with maximum medical therapy
## EVEREST II HRR: Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MitraClip (N=78)</th>
<th>Medical Rx (N=38)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>76.7 ± 9.8</td>
<td>77.2 ± 13.0</td>
<td>0.85</td>
</tr>
<tr>
<td>Male sex</td>
<td>62%</td>
<td>50%</td>
<td>0.84</td>
</tr>
<tr>
<td>Prior CHF</td>
<td>100%</td>
<td>83.3%</td>
<td>0.0007</td>
</tr>
<tr>
<td>COPD</td>
<td>34.6%</td>
<td>33.3%</td>
<td>0.95</td>
</tr>
<tr>
<td>NYHA Class III or IV</td>
<td>89.7%</td>
<td>83.9%</td>
<td>0.20</td>
</tr>
<tr>
<td>LVEF</td>
<td>54.4 ± 13.7</td>
<td>55.2 ± 18.1</td>
<td>0.82</td>
</tr>
<tr>
<td>MR Etiology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Functional</td>
<td>59.0</td>
<td>63.9</td>
<td>0.49</td>
</tr>
<tr>
<td>Degenerative</td>
<td>41.0</td>
<td>36.1</td>
<td></td>
</tr>
<tr>
<td>STS Score</td>
<td>14.2 ± 8.2</td>
<td>14.9 ± 8.5</td>
<td>0.68</td>
</tr>
</tbody>
</table>
EVEREST II HRR: Mortality

Graph showing freedom from mortality over time with high risk study and concurrent comparator group. The graph indicates a significant difference in mortality rates between the two groups at 12 months, with a p-value of 0.047. The number of patients at risk at each follow-up visit is also shown in the table below:

<table>
<thead>
<tr>
<th>Follow-up Visit</th>
<th>Pre Procedure</th>
<th>30 Day</th>
<th>6 Month</th>
<th>12 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>At Risk (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRS</td>
<td>78</td>
<td>72</td>
<td>66</td>
<td>54</td>
</tr>
<tr>
<td>CCG</td>
<td>36</td>
<td>34</td>
<td>27</td>
<td>22</td>
</tr>
</tbody>
</table>
## EVEREST II HRR: Other Outcomes

<table>
<thead>
<tr>
<th>Outcome at 12 months</th>
<th>MitraClip</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death 30 days</td>
<td>6/78 (7.7%)</td>
<td>N/A</td>
</tr>
<tr>
<td>Death 12 months</td>
<td>19/78 (24.4%)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>2/78 (2.6%)</td>
<td>N/A</td>
</tr>
<tr>
<td>NYHA Class I/II</td>
<td>40/54 (74.1%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>NYHA Class III/IV</td>
<td>14/54 (25.9%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>MR grade ≤ 2+</td>
<td>42/54 (77.8%)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Quality of Life (n=47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>31.6 (BL) → 36.5 (12 mo)</td>
<td>0.01</td>
</tr>
<tr>
<td>Mental</td>
<td>44.2 (BL) → 49.2 (12 mo)</td>
<td>0.06</td>
</tr>
</tbody>
</table>
EVEREST II High Risk Registry: Summary

• Patients with moderate to severe MR at high risk for MV surgery could be successfully treated with MitraClip
  – Procedural mortality rate at 30 days less than predicted for surgery and similar to comparator control group
  – Durable improvements in NYHA functional class, decrease in severity in MR and improvement in LV volumes

• Limitations
  – Comparator group recruited retrospectively
  – Limited number of patients
  – Heterogeneous group with regards to determination of “high risk”
Current Status of the MitraClip

• October 24, 2013: FDA approved the MitraClip for the following commercial indication:
  
  “The MitraClip is intended to treat patients with significant symptomatic degenerative mitral regurgitation with MR ≥ 3+ who have too high a risk for surgery”

• COAPT trial to evaluate the role of MitraClip in treating functional MR is ongoing
COAPT Trial

• **Design:** Prospective, multicenter, RCT

• **Objective:**
  – examine safety and efficacy of MitraClip device used in addition to standard care for *functional* MR and CHF compared to standard care alone

• **Primary Endpoints**
  – *Efficacy:* recurrent HF hospitalizations at 12 months
  – *Safety:* composite of mortality, stroke, LVAD, heart transplant or worsening kidney function at 12 months
Case History: BC

- 89 y/o female, known severe mitral regurgitation
- **Chief Complaint**: increasing fatigue, dyspnea on exertion, weakness
- **Hx**: HTN, CKD, Hx Breast Cancer 2003 s/p lumpectomy, squamous cell 2007, right nephrectomy 1970, severe MR, osteoporosis
- **STS score MV Repair** – 5%
- **STS score MV Replacement** – 8.3%
- Surgical evaluation with Dr Borkon: High surgical risk
BC: TEE

• CONCLUSIONS

1. Normal left ventricular systolic function, with an estimated ejection fraction of 60%.

2. Diffusely myxomatous mitral valve with bileaflet prolapse. Moderate to severe mitral regurgitation. There is more prominent prolapse involving P1 and P2 scallops. Regurgitant volume is 26 cm$^3$. Regurgitant fraction is 50%.
Lossy compression - not intended for diagnosis
BC Pre-procedure TEE
Crossing the Septum
Clip in LV

Lossy compression - not intended for diagnosis
Clip in LV

Lossy compression - not intended for diagnosis
Failed Grasp

Lossy compression - not intended for diagnosis
Successful Grasp

Lossy compression - not intended for diagnosis
Successful Grasp

Lossy compression - not intended for diagnosis
3D Imaging
Residual MR
Advancing 2nd Clip

Lossy compression - not intended for diagnosis
2nd Grasp
2nd Grasp

Lossy compression - not intended for diagnosis
Mitral Valve Gradient
3D imaging – 2 clips
Final Result

Lossy compression - not intended for diagnosis

FINAL CLIP 2
Home the Next Day!
Evolving Technologies for Mitral Valve Disease

• Based on Surgical Techniques
  – Annuloplasty
    • Direct
    • Indirect
  – Chordal Replacement
  – Mitral Valve Replacement
Annuloplasty: Surgical Theory

• Principles
  – All valves with significant chronic MR have some degree of annular dilation
  – Re-establishing physiologic configuration of mitral annulus will improve leaflet coaptation

• Percutaneous Approaches
  – *Indirect*: Implant device within coronary sinus with aim of “pushing” posterior annulus anteriorly
  – *Direct*: Device reshapes and cinches mitral annulus directly without involving coronary sinus
Indirect Percutaneous Mitral Annuloplasty

The Carillon XE Device
The Carillon XE Device

• AMADEUS Trial ¹
• First-In-Man Trial
• 48 patients with . . .
  – Symptomatic moderate-severe functional MR
  – EF < 40%
• Results
  – 20-30% reduction in MR
  – Improvement in HF symptoms
  – Low rates of adverse events

• TITAN Trial ²
• Phase II single arm study
• 53 patients with . . .
  – At least moderate (2+) functional MR
  – NYHA Class II-IV
  – EF < 40%
• Of the 53 patients,
  – 36 had successful implant
  – 17 had device recaptured

Indirect Mitral Valve Annuloplasty: Limitations

- Coronary compression
- Anatomical limitations of the relationship of the coronary sinus to the mitral annulus
- Variability in coronary sinus anatomy
- May preclude future CRT
Direct Percutaneous Mitral Annuloplasty: Mechanical Cinching Approach

• ** Principle**
  - Sutures implanted onto/near annulus and used to directly cinch the posterior annulus

• ** Devices**
  - Mitralign
  - Accucinch

• ** Limitations**
  - Only cinches posterior annulus
Direct Percutaneous Mitral Annuloplasty: Energy-Mediated Cinching Approach

**Principle**
- Heat energy is applied to annulus causing scarring and shrinking

**Devices**
- QuantumCor
- ReCor

**Limitations**
- Imprecise scarring can lead to MS or residual MR
- Possible damage to neighboring structures, e.g., leaflets, aortic valve, coronary sinus or circumflex artery
Surgical Chordal Replacement

- Initially used as adjuncts in surgical treatment for anterior or posterior leaflet prolapse

- Sometimes used on either/both anterior and posterior leaflets with limited leaflet resection...
  - Preserve tissue
  - Increase leaflet coaptation surface area
  - Replace thickened rheumatic chords

- Long-term durability of aggressive chordal replacement has not been established
Chordal Reconstruction: Percutaneous Techniques

• **Principles**
  - Synthetic chord is implanted and anchored between LV myocardium and leaflet via transapical puncture
  - Mainly for degenerative MR
Chordal Reconstruction: Percutaneous Technology

• **Current Status of Devices**
  
  – *NeoChord*: received CE mark in early 2013; TACT registry enrolling in Europe
  
  – *MitraFlex*: pre-clinical stages
  
  – *Babic*: pre-clinical stages

• **Limitations**
  
  – Requires precise adjustment of chordal length
  
  – May pre-dispose to LV thrombus
Transcatheter Mitral Valve Replacement

- Currently in various stages of testing
  - CardiAQ
  - Endovalve-Herrmann
  - Lutter

- Involves variety of approaches
  - Trans-septal
  - Trans-apical
  - Mini-thoractomy

- Challenges
  - Risk of paravalvular leaks
  - Possible LVOT obstruction
Finding the Right Patient
Who Might Benefit from TMVR?

• Patients with:
  – Moderate to severe mitral regurgitation
  – Symptoms
  – Appropriate anatomy
  – At high or prohibitive risk for surgery

• Agreement from the Heart Team that the patient is likely to benefit
The Importance of the Heart Team
Who Might Not be a Candidate for TMVR?

• Patients with:
  – Mixed valve disease
  – Complex CAD that would benefit from surgery
  – Inappropriate anatomy
  – Life expectancy limited by other medical problems

• Patients who are not interested in undergoing a major cardiovascular procedure
Conclusions

- Evolving percutaneous technologies to treat MR are derived from surgical techniques
- Most devices remain in development, however Mitraclip has gained FDA approval for treatment of patients with degenerative MR who are not candidates for surgery
- Challenges of mitral valve anatomy may make developing a one-size-fits-all strategy difficult
Thank You