Progress Toward a Percutaneously Adjustable Mitral Ring: Micardia

Maurice Buchbinder, MD
Foundation for Cardiovascular Medicine
La Jolla, CA
Disclosure

Speaker’s name: Maurice Buchbinder, MD

☑ I have the following potential conflicts of interest to report: Micardia Inc

☑ Consulting
☑ Stockholder of a healthcare company
☑ Scientific Advisory/Board Member
☐ I do not have any potential conflict of interest
Ischemic MR

• Following Mitral valve repair with annuloplasty surgery recurrent (>2+) MR is seen in 10-30% of patients (McGee; J. Thorac Cardiovasc Surg 2004;128:916-24)

• Recurrent MR appears within the first year following surgery with increasing incidence over time. (McGee; J. Thorac Cardiovasc Surg 2004;128:916-24)

• Unlike in degenerative disease or non ischemic dilated cardiomyopathy, IMR is associated with asymmetric deformation of the mitral annulus (Kwan; Circulation. 2003;107:1135.)
Current technology does not cope well with such ischemic changes

- Residual > 2+ post-op MR (6-10%)
- 6 month, recurrence (15%-25%)
- 3 Years, recurrence (30% to 50%)

Edwards Physio
Medtronic Duran
SJM Tailor
ATS Simulus

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The MiCardia Dynamic Ring: enCor™

- Without activation this NITINOL device functions as a “standard” annuloplasty ring
- However with its Pre-attached electrodes it can be ACTIVATED using RF energy making the ring Adjustable or Dynamic
- Available in sizes from 28 through 36 mm

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Intra-Operative Re-shaping

- Following surgical implantation Once the electrodes are connected to a proprietary MiCardia RF generator.

- The NITINOL ring can be activated to reshape the ring and treat residual MR.

- Echocardiography usually confirms the need and effectiveness of activation during and post re-shaping.

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Dynamic Ring - Activation

- Although reshaping or ring activation can be done intra-operatively at the time of implantation.
- Reshaping can be done at a later date (months after implantation) upon recurrence of MR using minimally invasive/ percutaneous techniques.

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Dynaplasty™: enCor™

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Extensive Pre-clinical experience (has shown reliable activation)

- Consistent A-P distance shortening by 0.5-3.0mm
- Inter-Commissural distance contracted by 1.0-3.5mm
- No heat damage to the surrounding tissue

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Postero-Medial commissure activation

Courtesy Dr. Alex Marmureanu
Human Experience : DYANA study

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Clinical Experience: European DYANA Study (Endpoints)

- **Primary Efficacy**
  - Procedural success with <2+ MR or <1+ with activation

- **Primary Safety**
  - Comparison of early and late adverse events to literature references

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# 30 Human Implants Completed

<table>
<thead>
<tr>
<th>Site</th>
<th>Implants</th>
<th>Activations</th>
</tr>
</thead>
<tbody>
<tr>
<td>University Hospital of Homburg</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Leipzig University Heart Center</td>
<td>11</td>
<td>1</td>
</tr>
<tr>
<td>Sana Herzchirurgie, Stuttgart</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>University Hospital, Kiel</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>7</strong></td>
</tr>
</tbody>
</table>

No adverse effects due to intra-operative activation noted

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Clinical Experience

Activated Patients

Red lines are individual patient data

3.1 ± 0.7

Black line is the average

0.3 ± 0.3

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### Intra-Operative activation

#### Intermediate follow up

<table>
<thead>
<tr>
<th>Time</th>
<th>0</th>
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<th>2</th>
<th>3</th>
<th>4</th>
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</thead>
<tbody>
<tr>
<td>0.14</td>
<td>0.13</td>
<td>0.42</td>
<td>0.53</td>
<td>3.17</td>
<td>3</td>
</tr>
</tbody>
</table>

- **30 Patients**
- **7 Activations (20%)**
- **No MACE > 1 Month**

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TTE 2D pre-procedure
Bi-leaflet Prolapse

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TTE 4-chamber Pre-procedure

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TTE 4-chamber post ring implant prior to activation

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TTE 2-chamber post ring implant prior to activation
RF connecting cable in place
TEE 3-chamber Post-activation
6-Month F/U, TTE 4-chamber

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Clinical Experience

- 3 Cardiac related SAE’s in 3 patients (None were device related)
  - 1 pt unstable angina pectoris day 74 post op
    - Required hospitalization.
  - 1 pt heart block day 12 post op
    - Pacemaker implantation
  - 1 pt Bypass spasm -> Hemodynamic instability → Multi organ failure
    - Patient expired on day 2 post op
    - Annuloplasty ring + coronary bypass x2
Ultimate Valve Repair Modality: late activation
**enCor**

**LATE activation: Sub Q device platform**

- From a two lead system, the device has evolved into a Single lead unit with atrial exit of the lead upon implantation and pacemaker like Subcutaneous “pocket“ implantation.
- This allows Simple percutaneous access for outpatient activation when needed.

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Pre clinical Percutaneous Reshaping: Sub-Q Device Platform @140 days

• Full activation within 60 seconds
Pre clinical Percutaneous Reshaping: Sub-Q Device Platform @140 days

- No infection
- No dehiscence
- Full activation @ 140 days, despite 100% in-growth

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Trans-Catheter Device Platform

- Steerable Delivery Catheter
- Ring “Snaps Together” after delivery
- Built in Anchors for Fixation
- Delayed Activation with “Wireless” Percutaneous Catheter

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Percutaneous Trans-Catheter Device Platform

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Conclusions

- From this early clinical experience the MiCardia Dynamic Annuloplasty Ring appears to be a promising device for surgical treatment of Mitral regurgitation.

- The Intra-operative adjustable feature may be an extremely valuable tool for optimization of surgical results.

- Further minimally invasive adjustments in ring geometry in the follow up phase could be a compelling advantage for its use.

- Early experience with a percutaneous Trans-catheter dynamic ring implantation system appears encouraging.

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