Repair of Mitral Valve Prolapse with a Novel Leaflet Plication Clip in an Animal Model

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Disclosures

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Background

- Mitral regurgitation (MR) is the 2nd most common valve-related indication for cardiac surgery
- Degenerative MV disease is the predominant pathology:
  - Chordae tendineae elongation/rupture
  - Excessive/redundant leaflet tissue

Leaflet prolapse $\rightarrow$ Malcoaptation $\rightarrow$ MR

Adapted from Cohn LH, ed. Cardiac Surgery in the Adult. 2008. McGraw-Hill
Mitral Valve Repair

Segmental leaflet resection

Leaflet plication “foldoplasty”

- Mitral valve repair outcomes: 12.6% composite adverse events rate
- Many high-risk patients are deemed non-operative candidates
- **Emergence of minimally-invasive & beating-heart repair techniques**

Beating-Heart Mitral Valve Repair

- Numerous devices in development
  - Indirect annuloplasty via coronary sinus
  - Artificial chordae implantation
  - *Edge-to-edge leaflet repair*

**MitraClip**
(Abbott Vascular)

- No devices achieve isolated *leaflet plication*

Adapted from Chiam PTL, Ruiz CE. Percutaneous Transcatheter Mitral Valve Repair: A classification of the technology. JACC: Cardiovascular interventions. 2011; 2(1) 1-13.

Leaflet Plication Clip

- Folded nitinol wire
  - 0.44mm diameter
  - Central loop (*)
  - Sharpened arms (△)
- Opened state for leaflet grasping
- Closed, resting state for leaflet plication
- Deployment device for open-heart implantation/testing
Implantation & Mechanism of Action
Study Aim & Design

• Assess short-term performance of the leaflet plication clip for MVP repair in an animal model

• Open-heart clip implantation

• Echocardiographic assessment
Methods

- Yorkshire female swine (N=7, weight = 60-73kg)
- Surgery:
  - Left thoracotomy (4
th intercostal space)
  - 2D/3D epicardial echo (baseline)
  - Cardiopulmonary bypass #1
  - Open-heart chordae cutting via left atriotomy → MR creation
  - 2D/3D epicardial echo (off bypass)
  - Cardiopulmonary bypass #2
  - Open-heart Leaflet plication clip application
  - Direct/epicardial echo off CPB (2hr post)
  - Euthanasia & explant
Echocardiographic Analysis

- **MR Grade:**
  - 2D color Doppler imaging
  - 0-4 scale: None (0), Trivial (1), Mild (2), Moderate (3), Severe (4)

- **Vena contract area**

- **Coaptation height (CH)**

- **Posterior mitral leaflet mobility ($\Delta \theta$)**
  - ($\Delta \theta$) = $\theta_d - \theta_s$
  - $\theta_d$ = diastolic posterior leaflet angle
  - $\theta_s$ = systolic posterior leaflet angle
Results

• All animals survived the surgical procedure
• 2-4 primary and secondary chordae were cut in each animal to create MVP/MR
• Successful clip implantation in all cases without significant leaflet trauma
• No evidence of thrombosis on/around clip
• No evidence of clip embolism
• 2 cases of slight clip movement
  – tangling with underlying 2° chordae
  – shifting to oblique position
MR Grade (2D color Doppler)

Baseline

Post-Chordae cutting – P2 flail

Post-Clip placement
Median MR grade: Trivial (1+) $\rightarrow$ Moderate-severe (3.5) $\rightarrow$ Mild (2+)
Vena Contract Area

Mean VCA: 0.08cm\(^2\) → 0.21cm\(^2\) → 0.16cm\(^2\)
Coaptation Height & Leaflet Mobility

**Coaptation Height**

**Posterior Leaflet Mobility**

**Leaflet Mobility, Δθ (°)**

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<tr>
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<th>Pre-MR</th>
<th>Post-MR</th>
<th>Clip</th>
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<tbody>
<tr>
<td>Leaflet Mobility</td>
<td>40.0</td>
<td>45.0</td>
<td>50.0</td>
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**NS**
Conclusions & Future Work

• The leaflet plication clip reduces **MR grade** in the setting of MVP in an acute animal model by solely plicating the prolapsed segment
• **Coaptation height** is restored to baseline
• **Leaflet mobility** is not hindered by the clip

• Adjunctive repair techniques (annuloplasty)
• Minimally-invasive development
  – “Mini-mitral” & Robotic techniques
  – Image-guided beating-heart approaches
Thank You