Mitral Loop Cerclage
a catheter-based treatment of functional mitral regurgitation (CSTV)

June-Hong Kim, MD, PhD
Professor, Director of Cardiology
Pusan National University Yangsan Hospital
Yangsan, South Korea

junehongk@gmail.com
Disclosure of ‘Conflict of Interest’

• Equity: Tau-PNU Medical Co. of Pusan National University

• Intellectual Property of ‘Mitral Cerclage ’ and ‘Mitral Loop Cerclage’ that are assigned to NIH, or Tau-PNU or Pusan National University.

• Collaborator with NHLBI Division of Intramural Research (Z01-HL006040)
Transcatheter MV repair

Leaflet correction + annuloplasty

Leaflet correction

Direct annuloplasty

Indirect annuloplasty

Mitraclip

Cardioband

Carillon

Cerclage
CS approach: limitations and solutions

1: hemi-circumferrential compression: insufficient
   - Solution: circumferential compression

2: Coronary artery entrapment
   - Solution: coronary protection

3: Coronary sinus far from annulus
   - Solution: “Apical tilt” of plane
Pre-clinical ‘mitral cerclage’

Kim JH, Lederman RJ, JACC 2009;54:638
Basal LV squeezing: Is it OK for sick heart?

Preserved contractility & reduced LV wall tension

Kim JH, Lederman RJ et al. JACC 2009;54:638

2.2 ± 1.3
2.6 ± 1.5 (mmHg/ml)
n=11
p < 0.01

Tension (-) Tension (+)

Computational heart modeling with real human data, under review
What is Mitral Loop Cerclage?

- Circumferential tension around MV anulus by LV basal squeezing

- Reinforce of safety issues
  - improving technical feasibility

Mitral Cerclage + a bifid appliance = Mitral Loop Cerclage

CSTV (coronary sinus and TV protective device)

Kim JH et al. JACC 2009; 54:638-51
Kim JH et al. Eurointervention 2016; 8;11(14)
How to function?

(1) TV & conduction protection

(2) Interactive tension adjustment

(3) Easy re-adjustment of tension when it is needed

Arch formation during tension

Septal lateral dimension

Tensioning through a tip of CSTV loop

Kim JH et al. Eurointervention 2016; 8;11(14)
The first case of Mitral Loop Cerclage FIM in PNUYH, Korea (July 10th 2015)

Inclusion: NYHA class III or IV dyspnea due to severe functional MR in spite of optimal medical TX at least for 3 months
mitral loop cerclage procedure

Pressurized coronary venogram to approach SV

Target-capture device in RVOT to snare guidewire

Deliver cerclage rope in single union with coronary protection

Deliver CSTV along with cerclage rope

Interactive tension adjustment

Subcutaneous tension lock is adjustable

EuroPCR 2018

JCR 2019
FIM result of Mitral Loop Cerclage (n=5)

(1) Regurgitant Volume (RV, mL)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV</td>
<td>54.8</td>
<td>18.5</td>
</tr>
</tbody>
</table>

(2) Reverse remodeling

- LVESV: 39% ↓
- LA vol: 34% ↓

(3) Electrical remodeling (n=2)

AF reverted to NSR in all cases of chr AF


USA cerclage human trial in 2018
- NIH-Transmural IDE
- Intra-cardiac locking

2nd Clinical trial in Korea Underway
- Inclusion criteria
- Function MR with Chr AF

AFRICA study: AF Reversion to sinus In Cerclage Annuloplasty
A Representative Case:
74F, NICM, NYHA IV dyspnea despite aggressive medical therapy for 1yr

- ERO 0.34 cm$^2$
- RV 63 ml
- Atrial fibrillation

- ERO 0.14 cm$^2$
- RV 25 ml
- Normal sinus R

- ERO 0.10 cm$^2$
- RV 23 ml
- Normal sinus R

- Mild MR
- Normal sinus R
Extension of Mitral Loop Cerclage to treat TR

Mitral Loop Cerclage + Septal leaflet extension on CSTV

Cerclage TR Block
Cerclage T-leaflet for severe TR
Functional TR model

*Isolated porcine heart model with mechanical pumping system
Cerclage TR Block: Animal study

Septal leaflet extension on CSTV

Functional TR

Torrential TR: valve destruction
One device treats two valves at once

Mitral Loop Cerclage (MLC) + Septal leaflet extension on MLC platform

Functional MR being treated with cerclage tension

One procedure with one device for treating both MR/TR at once

Functional TR being treated with cerclage T-leaflet

‘BUY 1 GET 2’ Procedure
Summary

- Mitral Loop Cerclage has shown significant reduction of functional MR & reverse remodeling of LV/LA

- Septal leaflet extension on Mitral Loop Cerclage may have potential to treat both MR/TR simultaneously
Mitral cerclage: safety issues

**TV damage**

**Conduction block**

Porcine Heart

Human Cadaver Heart