Mitral Loop Cerclage (MLC) as a Variant form of 'Mitral Cerclage Annuloplasty' that adds a device (CSTV) for preventing potential complications : A preclinicial study with mature devices

June-Hong Kim, MD. Si-Chan Sung, Min-Ku Chon, Sang-hyun Lee, Soo-Yong Lee, Hyng-Gon Je, Ki-Seok Choo, Jong-Min Hwang, Jeong-Su Kim, Yong-Hyun Park, Jun-Oh Kim, Kook-Jin Chun

Pusan National University Yangsan Hospital

PNUH 양산부산대학교병원 PUSAN NATIONAL UNIVERSITY YANGSAN HOSPITAL

Disclosure of ‘Conflict of Interest’

- Founder and stock holder : Tau-PNU Medical of Pusan National University

- Intellectual Properties of ‘Mitral Cerclage ’ and “Mitral Loop Cerclage’

Mitral Cerclage Annuloplsty (MCA)

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PRE-CLINICAL RESEARCH

Mitral Cerclage Annuloplasty, A Novel Transcatheter Treatment for Secondary Mitral Valve Regurgitation

Initial Results in Swine

June-Hong Kim, MD,*† Ozgur Kocaturk, MSc,* Cengizhan Ozturk, PhD, MD,*‡
Anthony Z. Faranesh, PhD,* Merdim Sonmez, MSc,*‡ Smita Sampath, PhD,* Christina E. Saikus, BS,*
Ann H. Kim, BS,* Venkatesh K. Raman, MD,* J. Andrew Derbyshire, PhD,* William H. Schenke, BS,*
Victor J. Wright, BS,* Colin Berry, PhD, MD,* Elliot R. McVeigh, PhD,* Robert J. Lederman, MD*

Bethesda, Maryland; Busan, Korea; and Istanbul, Turkey

Kim JH et al. JACC 2009

Innovation is Alive in 2013

Leaflet Solutions

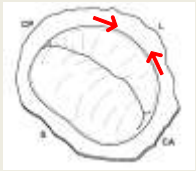
- Evalve/Abbott MitraClip
- Neochord
- Cardiosolutions, Middle Peak Medical

Leaflet Clip

Direct Annular Shape Change

- Mitralign
- Valtech (Cardioband)
- Guided Delivery Systems

Annular Reshaping



Coronary Sinus Annuloplasty

- Carillon
- Mitral Valve Cerclage

Coronary Sinus Reshaping

Mitral Valve Replacement

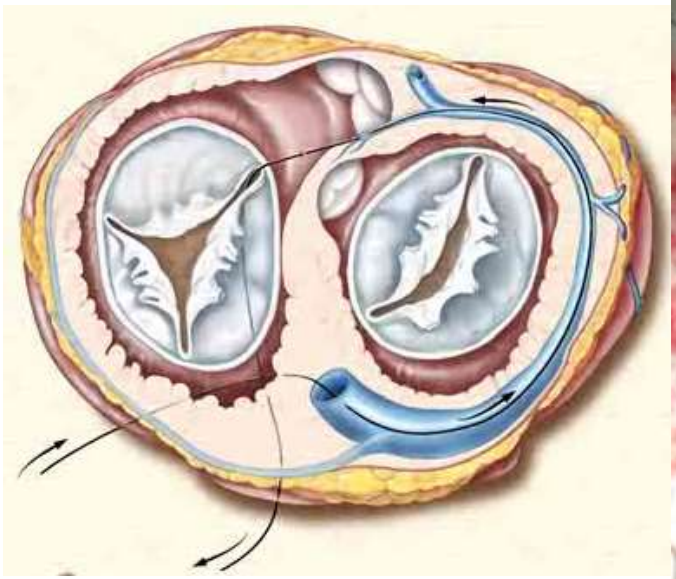
- Endovalve
- CardiAQ
- Tiara
- M-Valve

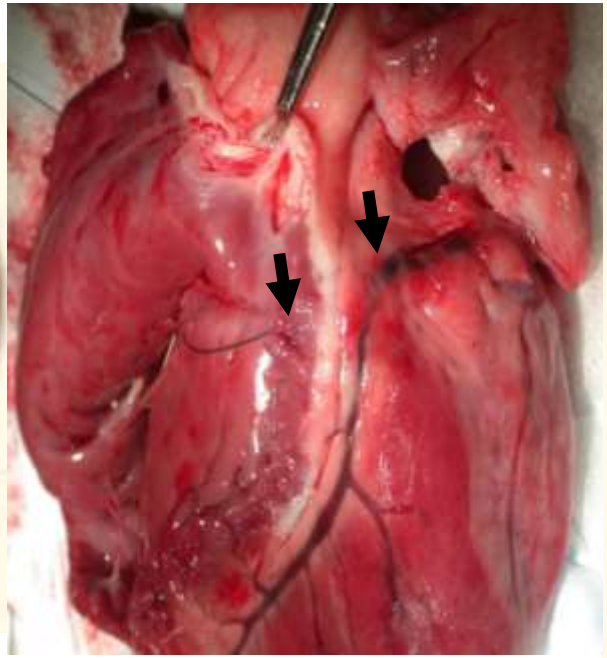
MV Replacement

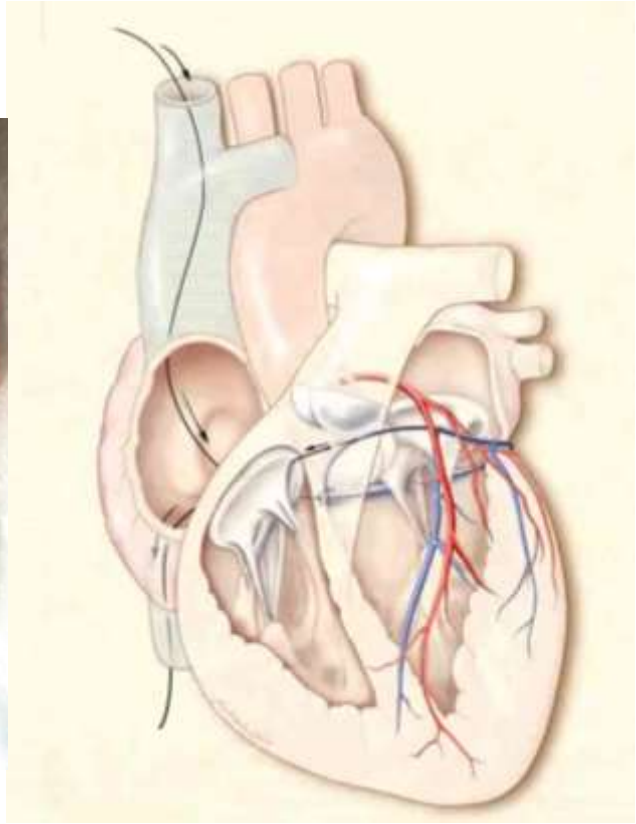
TCT 2013 Jason Rodgers

The unique design of mitral cerclage annuloplsty

Specially designed in order to deliver
circumferential tension around MV annulus

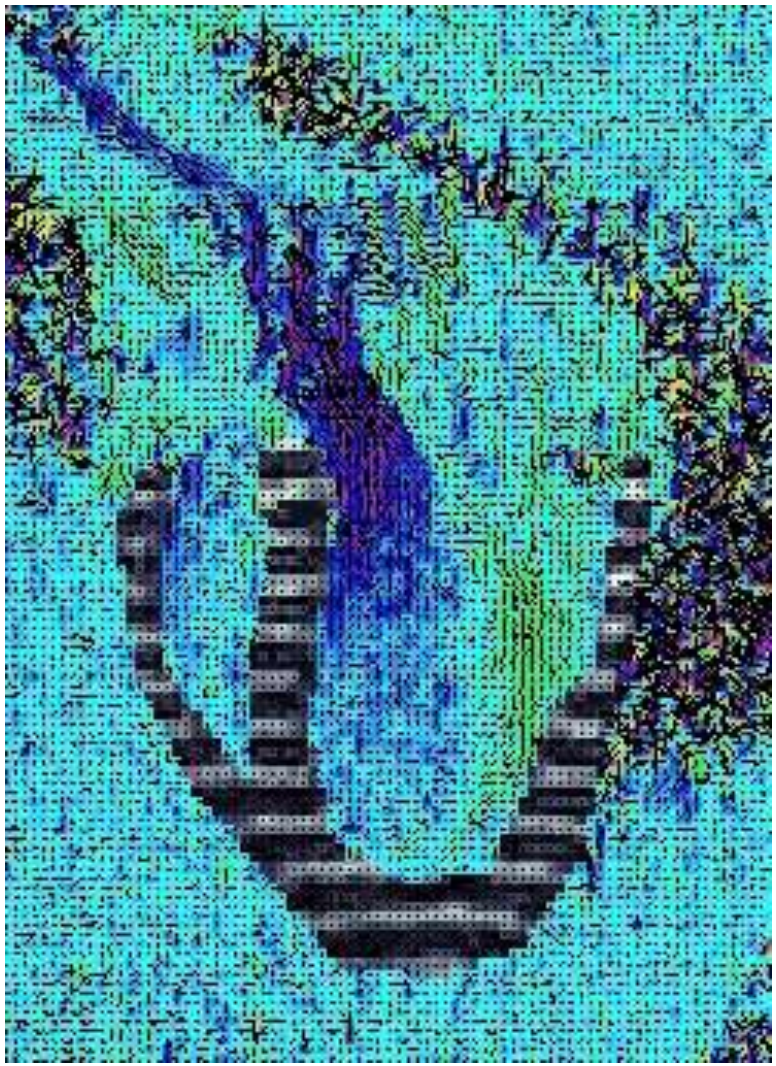


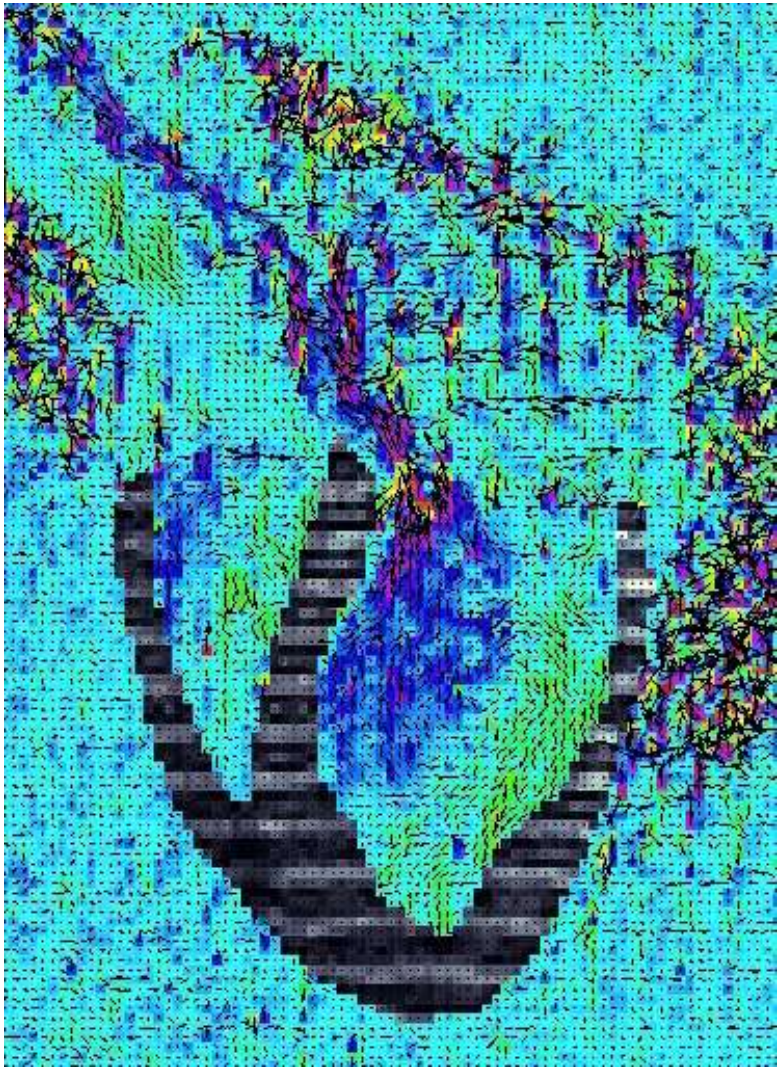




⇓⇓ **Septal traversal**

Excellent efficacy of Mitral Cerclage in reducing Mitral Regurgitation (in swine hearts)

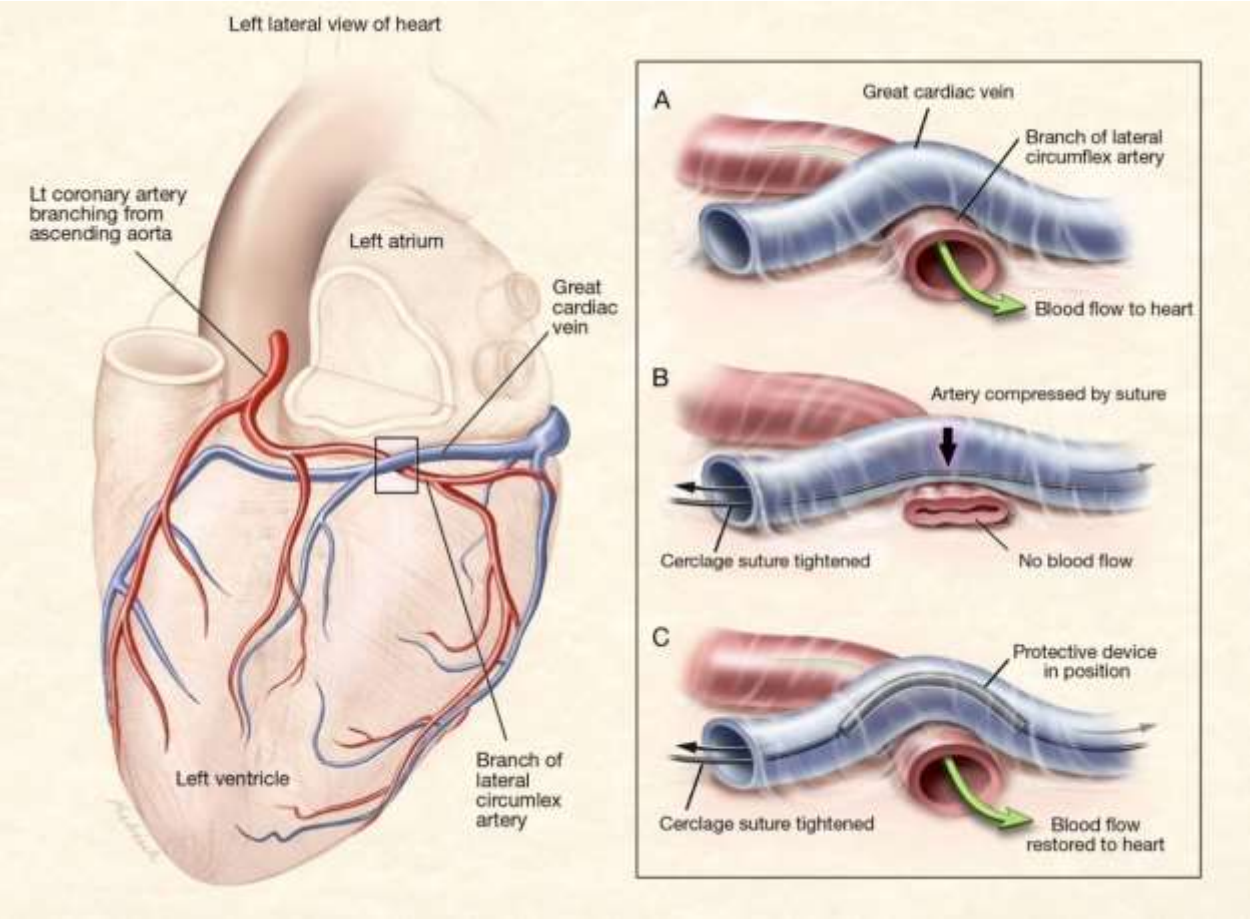




Kim JH et al. JACC 2009:54

Another feature of Mitral Cerclage

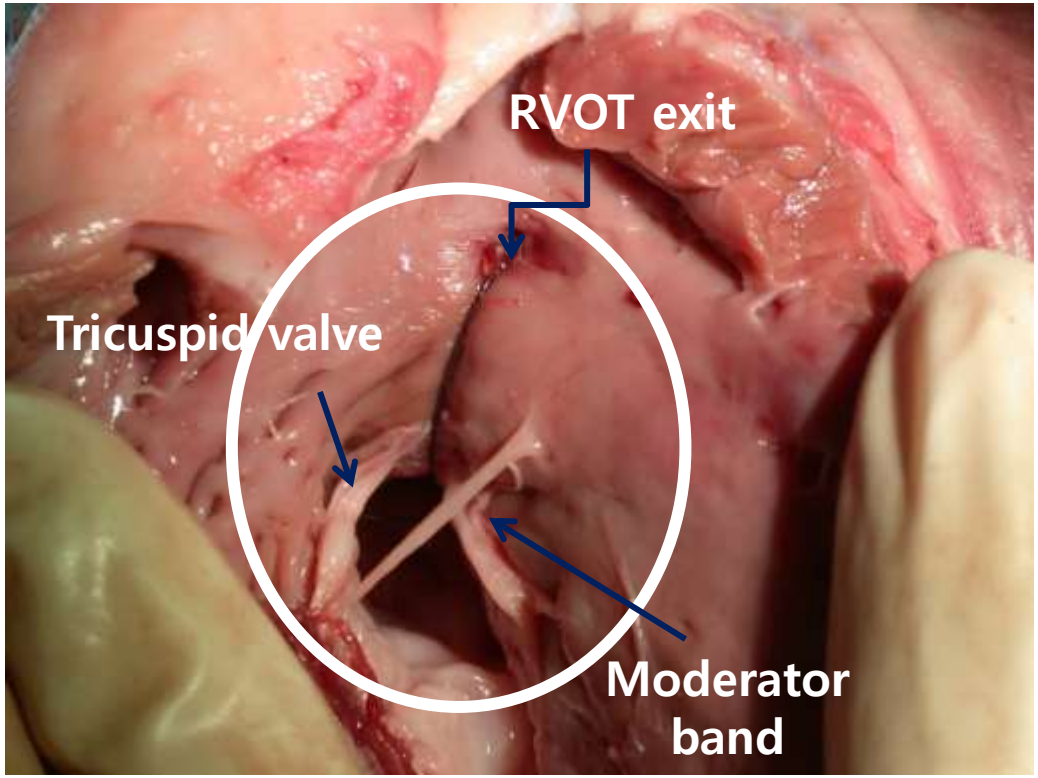
Mitral Cerclage can avoid pinching of underlying LCx artery by a simple rigid arched structure



Kim JH et al. JACC 2009:54

What are remained of miral cerclage for human translation ?

Safety issues #1 : Erosion and its consequent TV damage

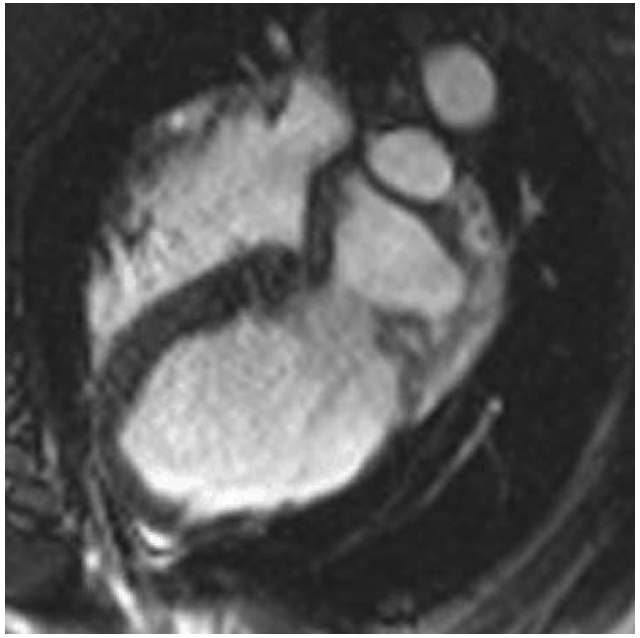


Subvalvular structure : vulnerable to erosive destruction by cerclage suture (nylon)

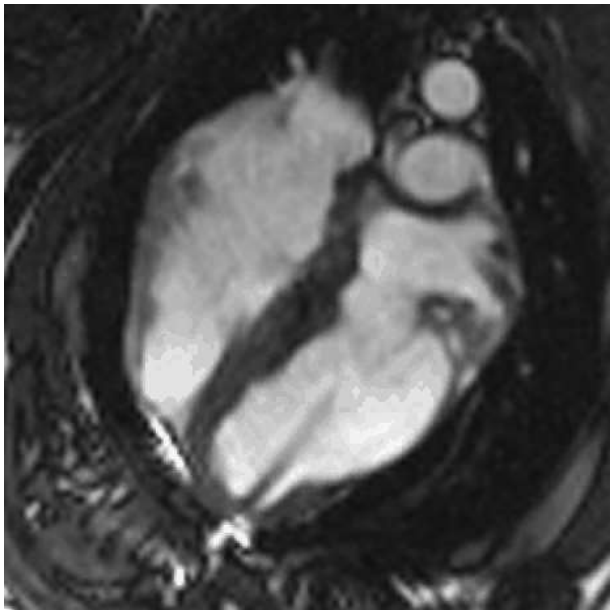
What are remained of mitral cerclage for human translation?

Safety issues #1 : Erosion and its consequent TV damage

MR regurgitant fraction 43%
in a pig



Cerclage abolish MR
Immediate post-procedure

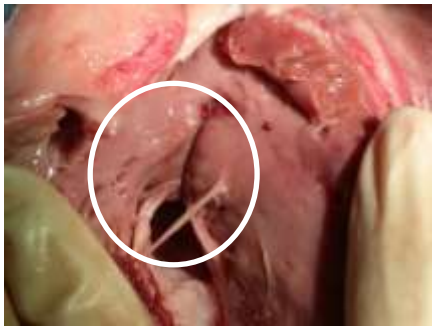


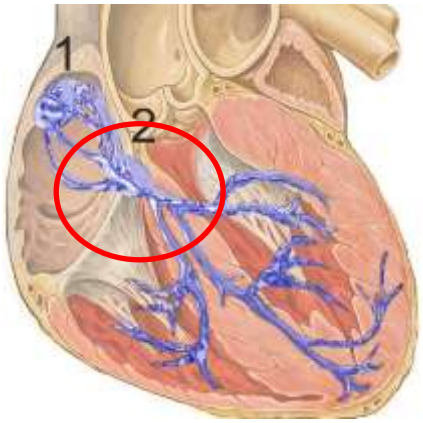
3wk FU. Persistent no MR
But severe TR due to valve destruction

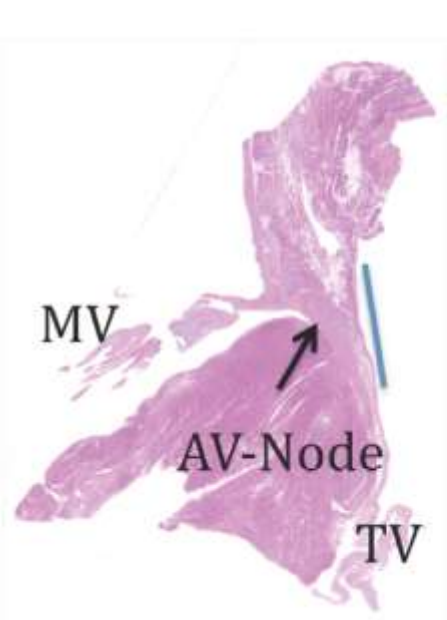
Unpublished data

What are remained of mitral cerclage for human translation?

Safety issues #2 : Potential risk of Conduction Block
: RV and RA part of cerclage path is too close to conduction system







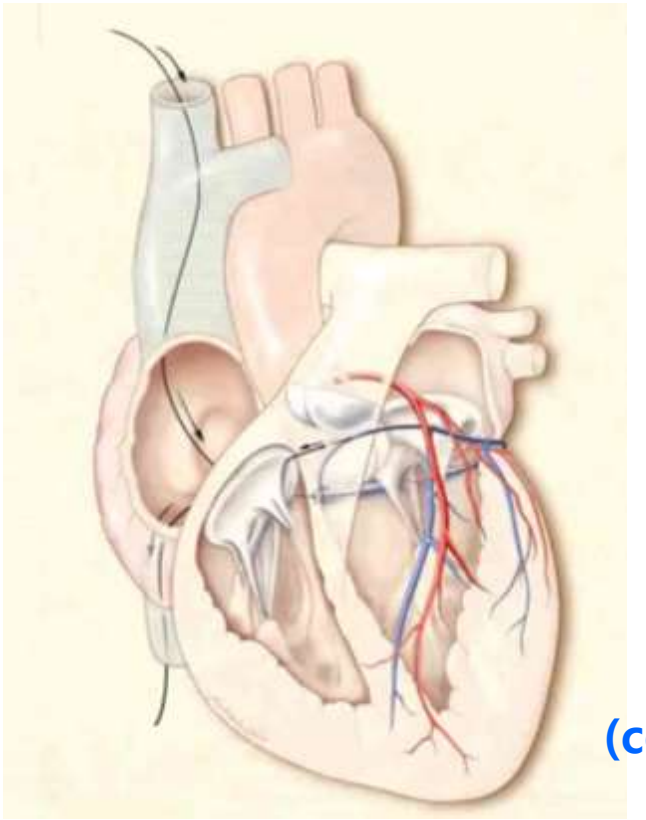
Human Cadaver Cercalge Pathologic Report
By Dr. Renu Virmani

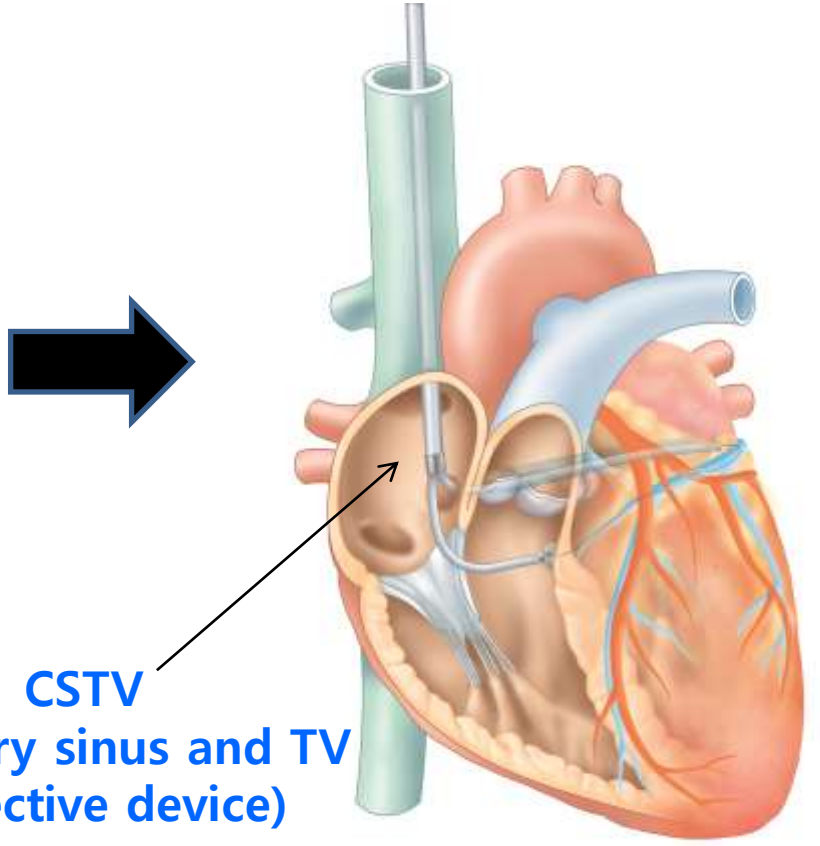
Unpublished data

How to solve these saferty issue of mitral cerclage?

- Erosion, conduction block risk (+)
- Procedural feasibiliby : relatively low

- No safety issue
- High Technical feasibiliby



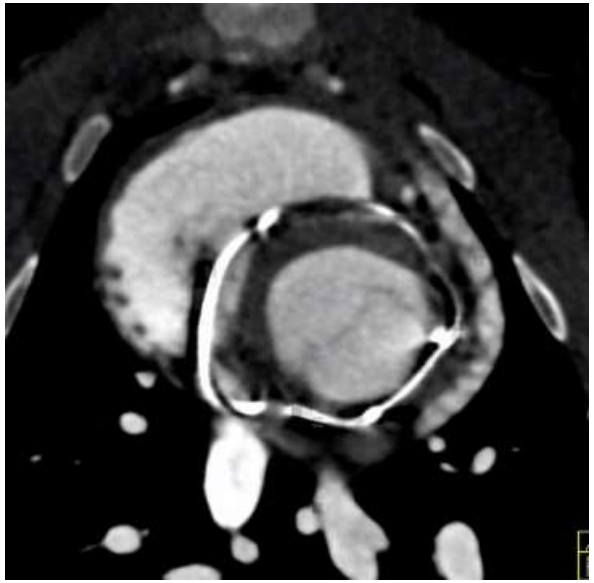


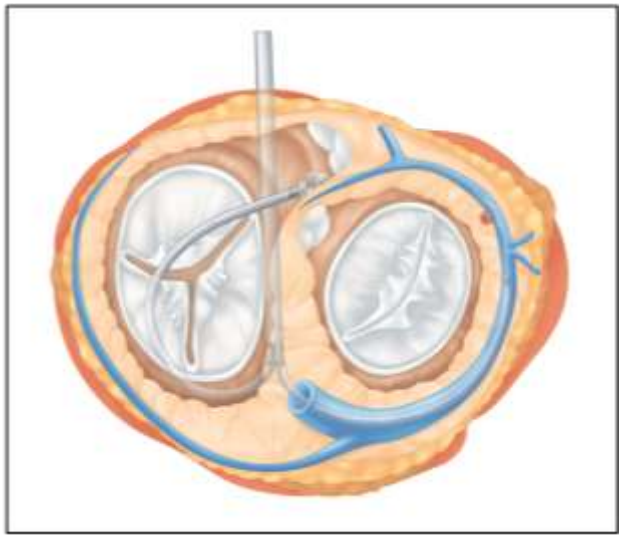
CSTV
(coronary sinus and TV protective device)

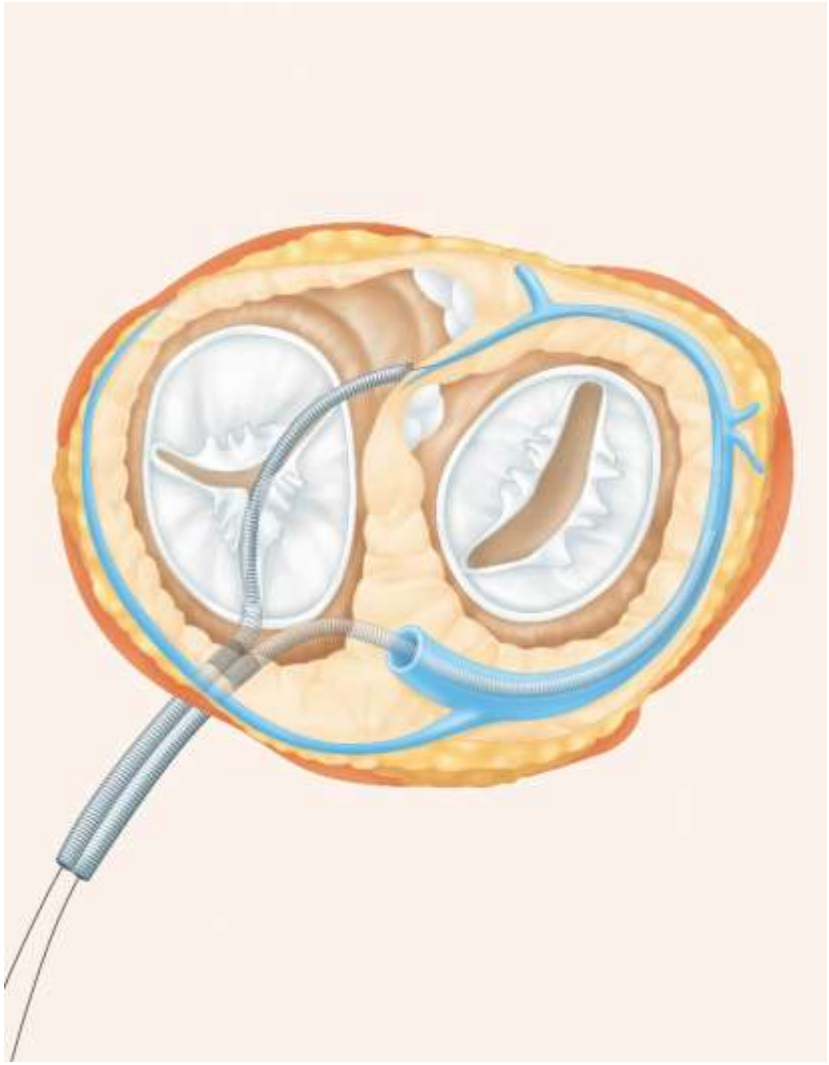
Mitral Cerclage + a bifid appliance = Mitral Loop Cerclage

The function of CSTV (1)

Arch formation during tension : TV & conduction system protection







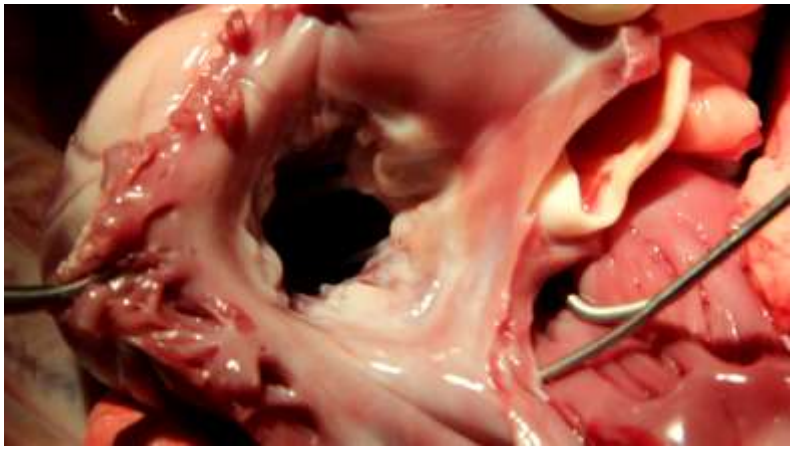
The function of CSTV (2)

Interactive adjustment during procedure

Effective reducing ability of Septal lateral demension !

SL distance reduction
19.6 → 10.9 cm (by 44%)

MV from LV side

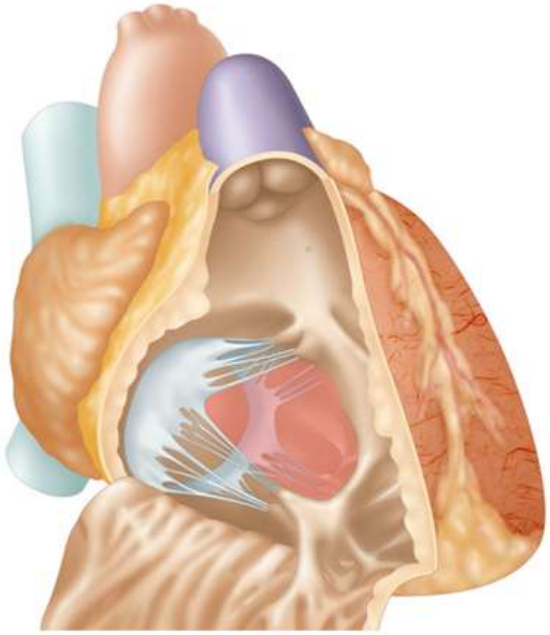


MV from LA side

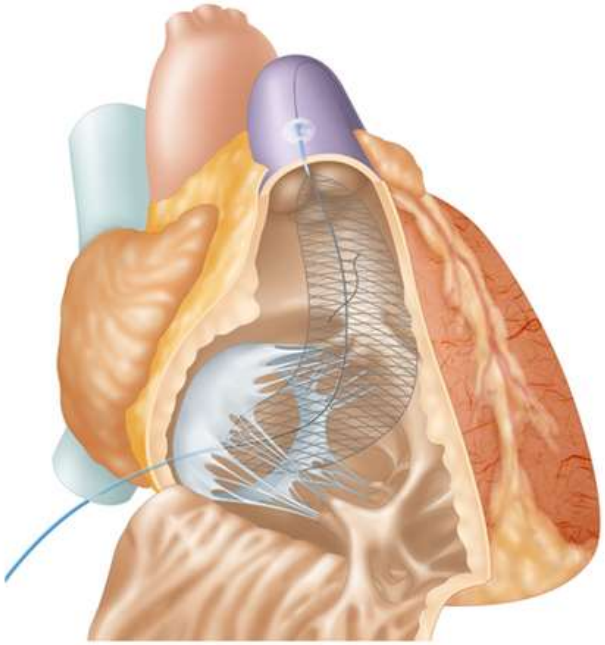
Mitral Loop Cerclage

Procedure overview

The concept of the 'Safe Zone' for safe procedure

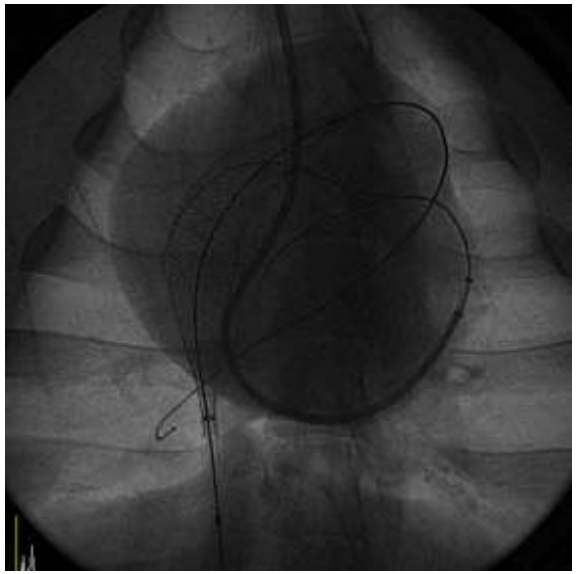


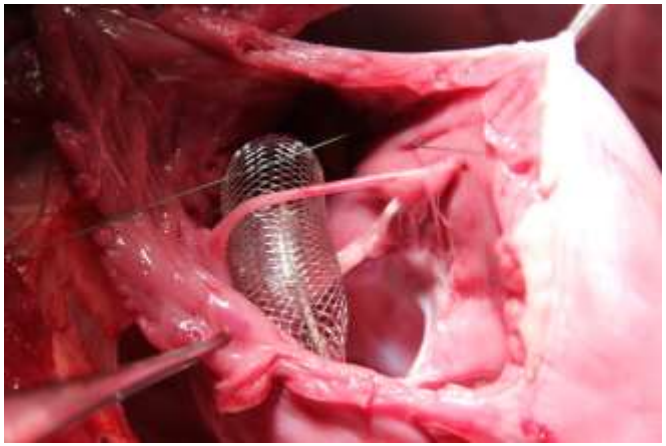
'Safe zone' in red



Mesh

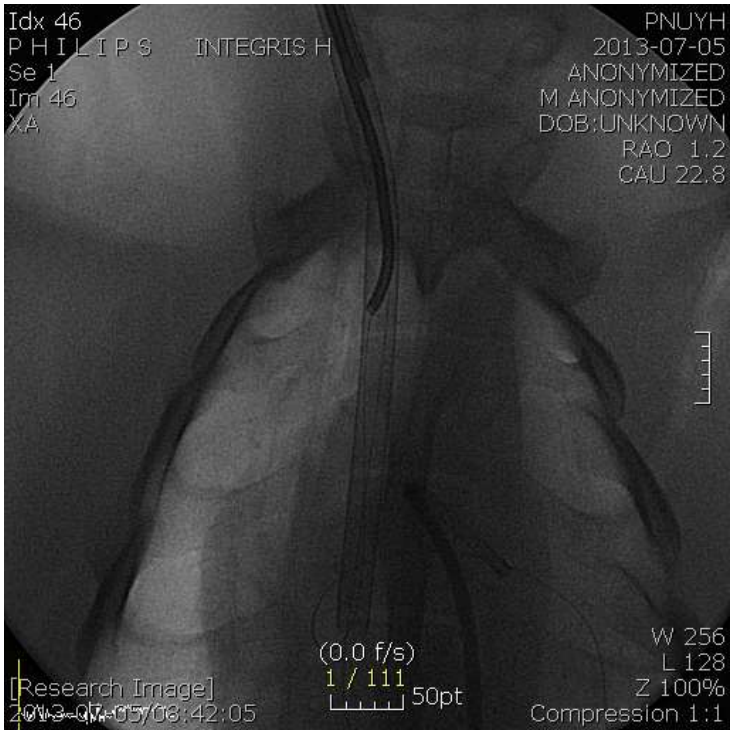
- Blocking member
- Approach from IVC



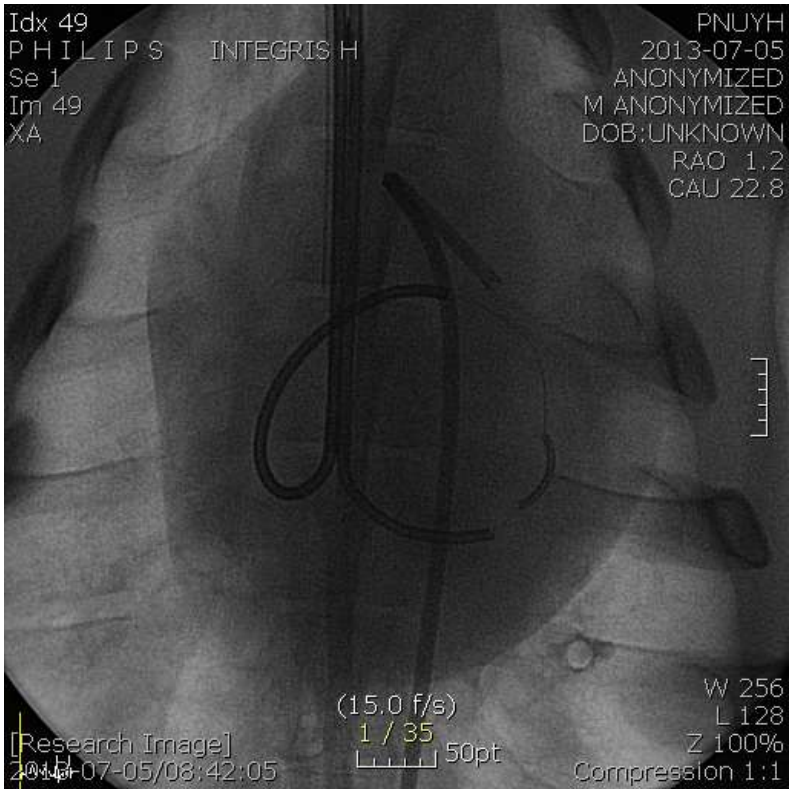


Delivery of CSTV

Easy and Simple procedure !!



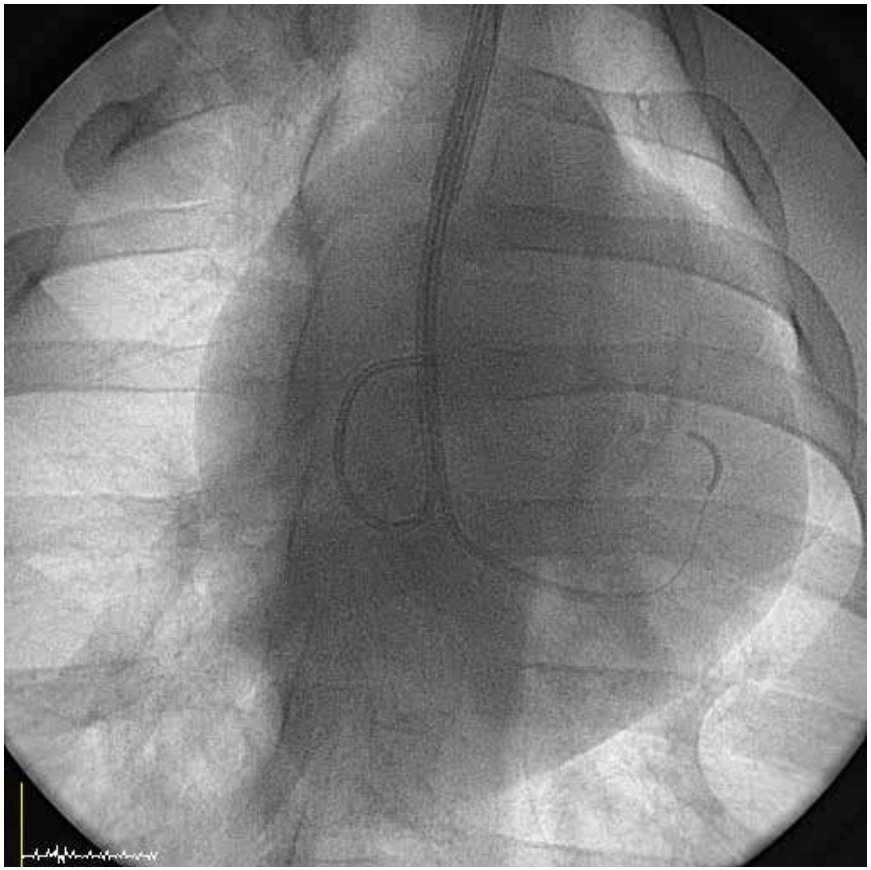
CSTV delivery though cerclage suture



Tensioning though MC with CSTV

Retrieval of devices

Easy and Simple !!



survival animal experiements (n=9)

Healthy hearts model

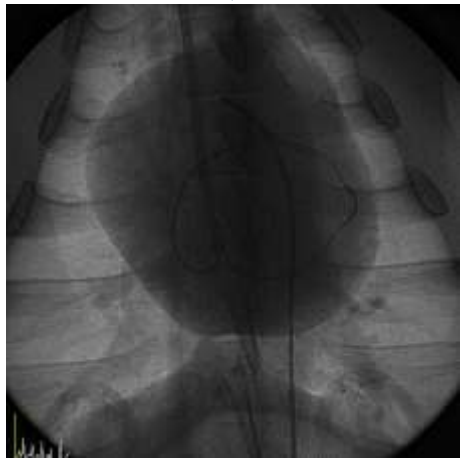
- Short term (2 weeks, n=4) with *immature devices*
- Midterm (6 weeks, n=5) with *mature device* for FIM

  - No safety issue & excellent proof of concept with immature devices
  - Mature devices for First-In Man study

  - **Procedural success rate (100%, 154 $\pm 45\ min$)**

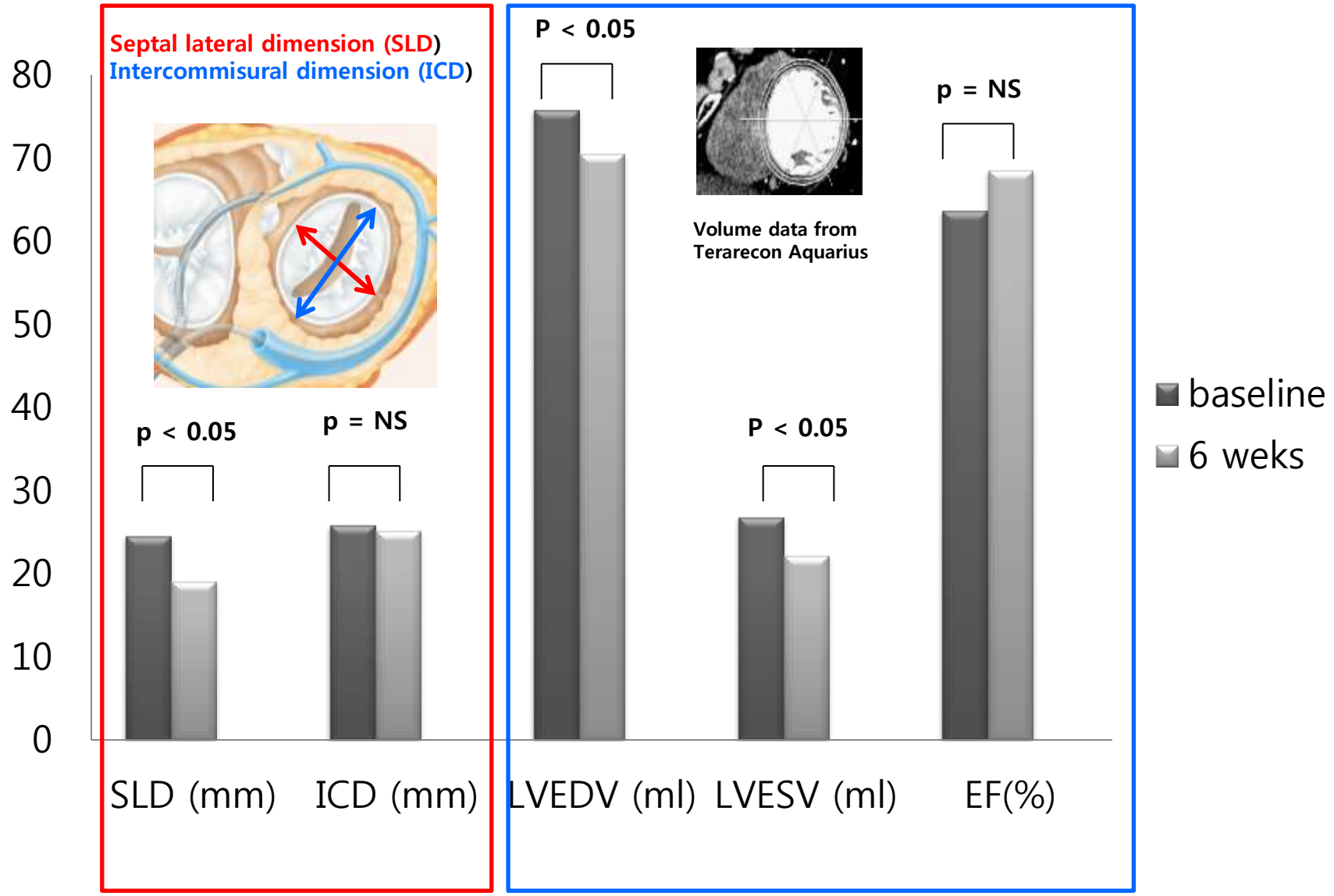
A representative case
6 wks FU CAG and Cardiac CT image

Post-procedure



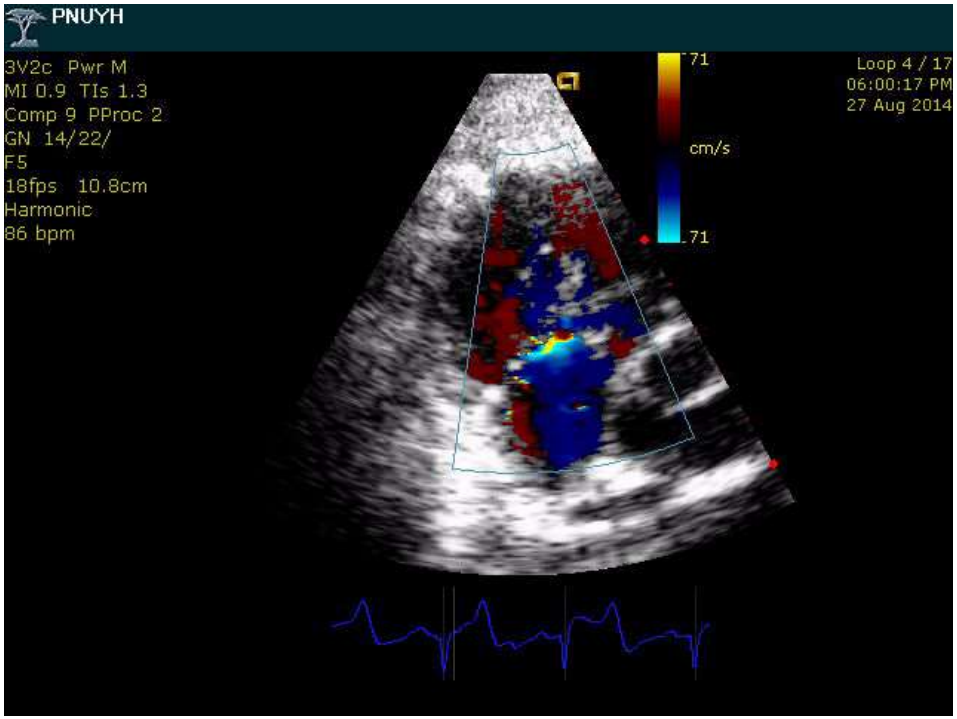
6weeks F/U

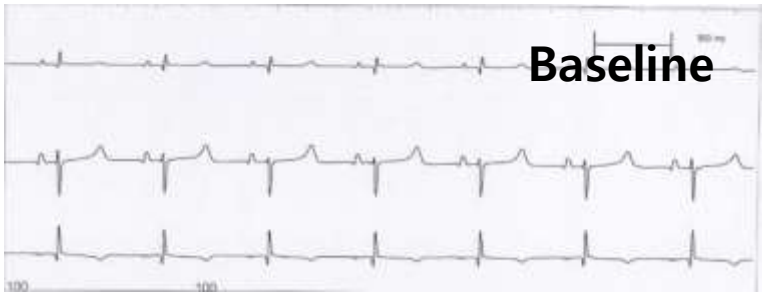
6 weeks FU cardiac CT data (n=5)

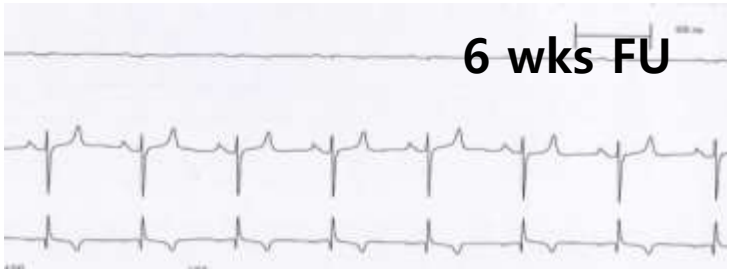


Tricuspid regurgitation, Conduction block (6wks follow-up result)

Mild Tricuspid Regurgitation, No conduction abnormality

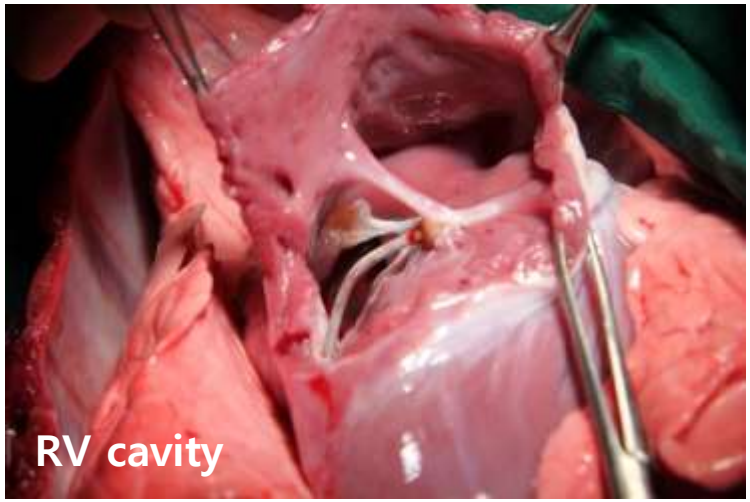


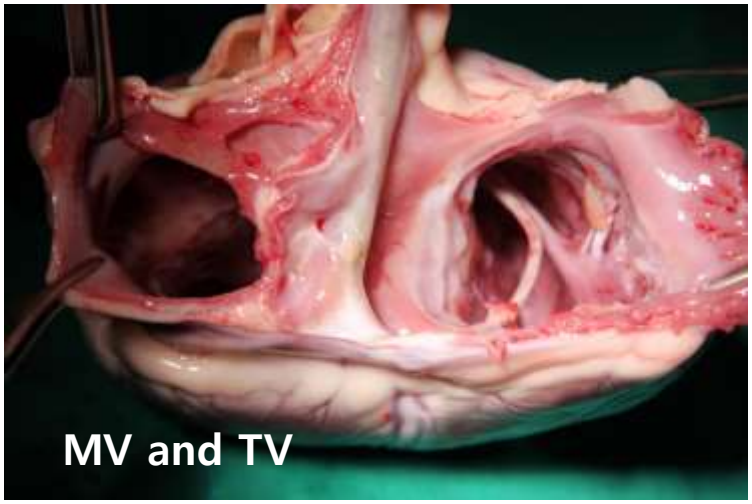


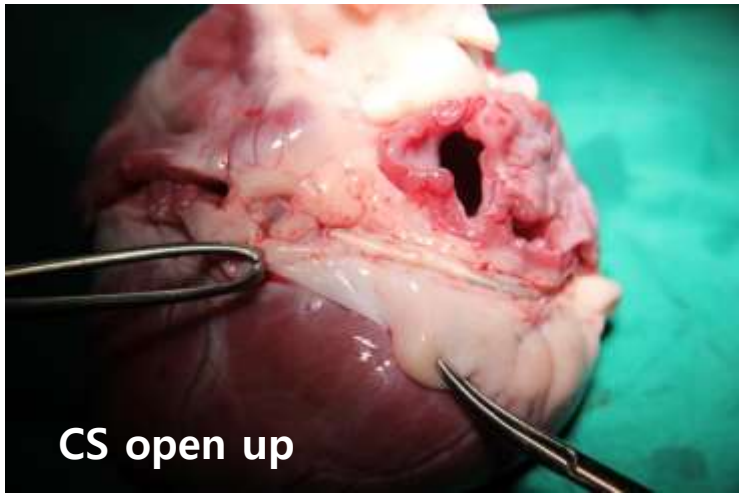


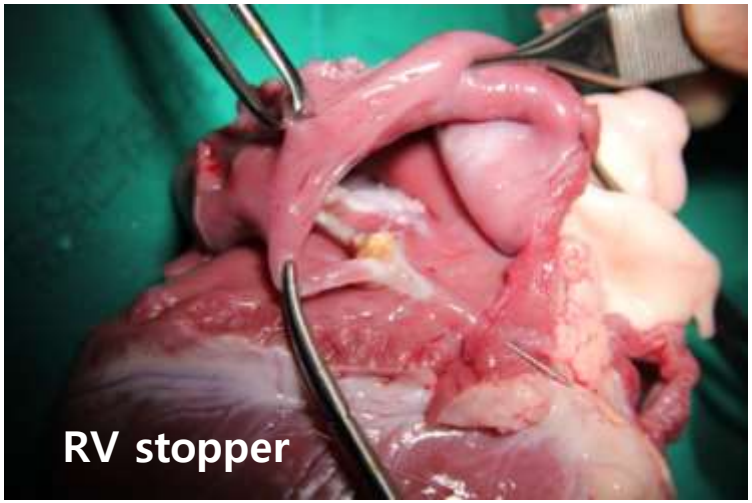
Tissue erosion (6wks follow-up result)

No evidence of Tissue erosion









Pathologic report

Excellent biocompatibility of the implanted device without any significant inflammatory reaction or erosion.

Safety of Mitral Loop Cerclage

Complications in survival experiements (n=9)
1. Transient ST change with apical ballooning suggestive of LV dysfx (n=1, 11.1%)
2. Mild dissection of great cardiac vein (n=3, 33.3%)
3. Minimal temporary dye staining in basal septum (n=1, 11.1%)
4. Mild pericardial effusion (n=1, 11.1%)

Potential Mode of complications

Serious
1. Infection
2. Cardiac tamponade)
3. Myocardial erosion
4. Conduction block
5. Tricuspid malfunction
6. Coronary artery pinching

Non serious
1. Coronary sinus dissection & coronary vein thrombosis
2. Pericardial effusion
3. Transient ECG change during procedure : VPCs, transient ST change
4. Access site hematoma
5. Intramyocardial hematoma

Tension release appeared to be possible at 6wks follow-up

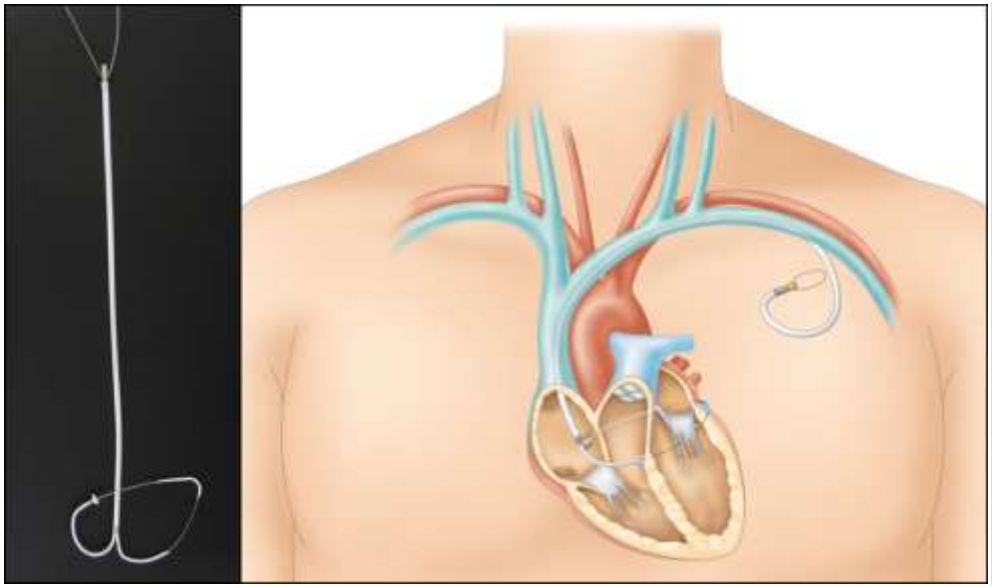
Under tension

After tension release

Mitral Loop Cerclage

Two types of MLC

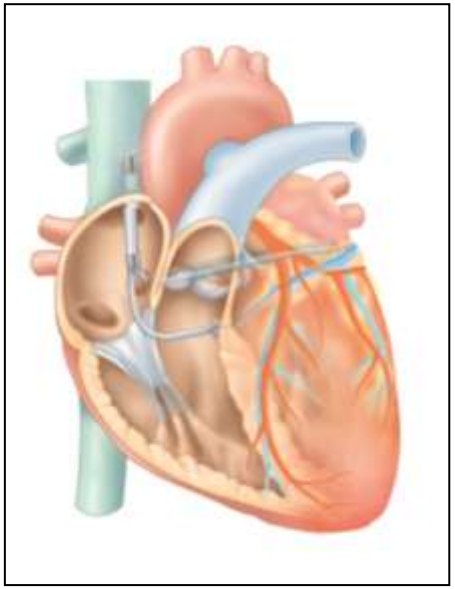
Pacemaker type



Ready for FIM

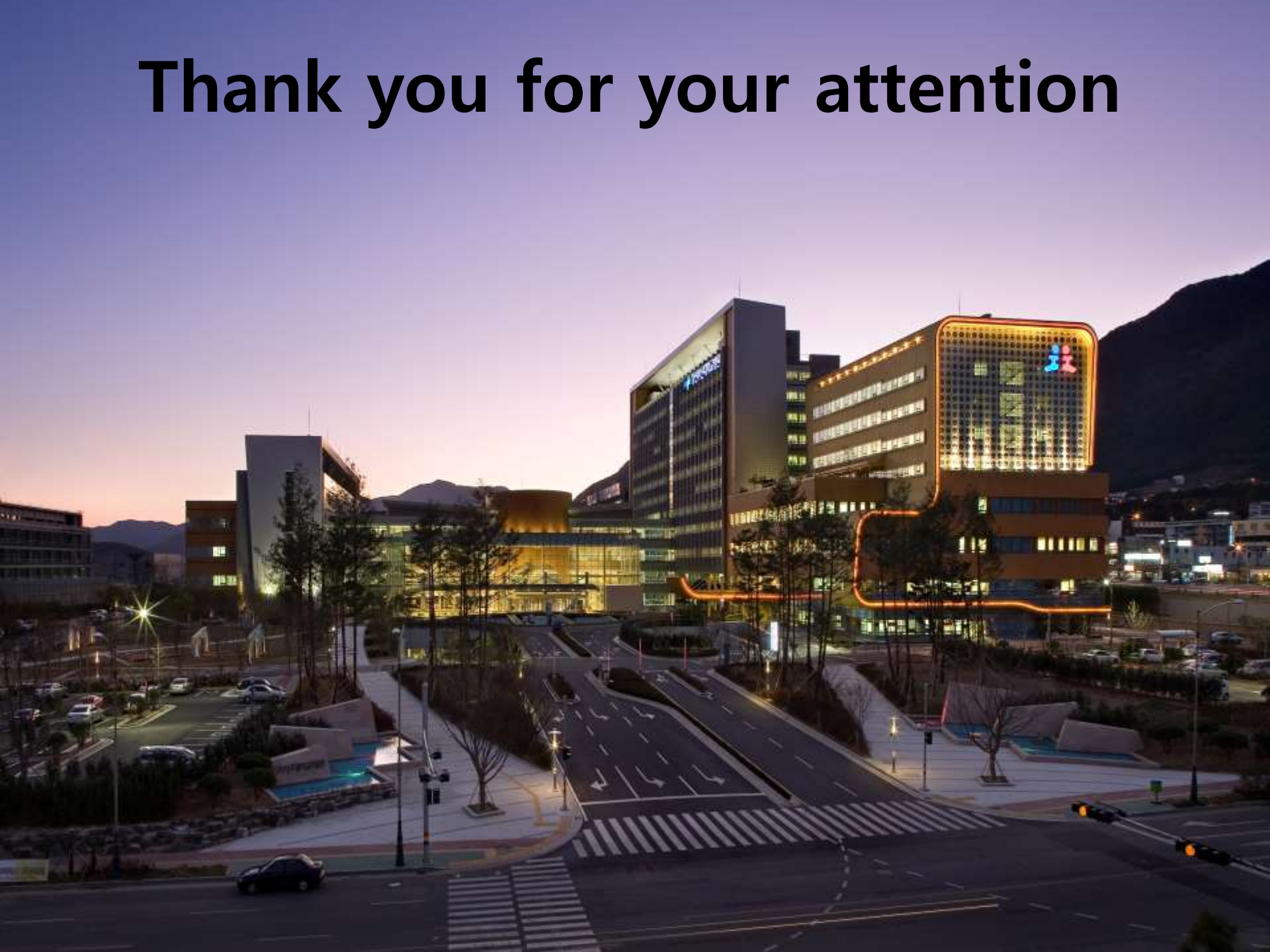
pending approval of KFDA

Intravascular type



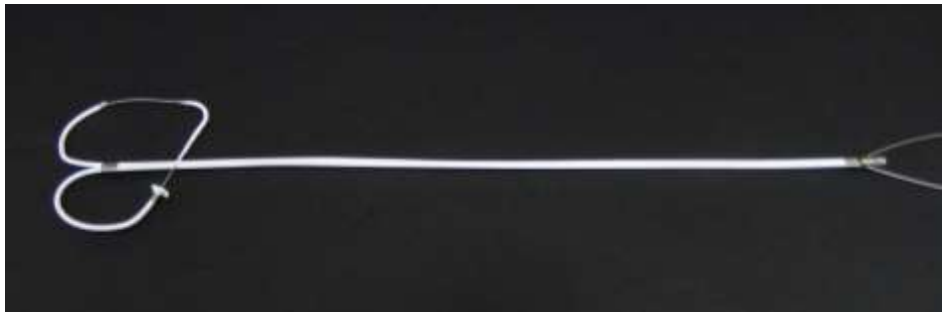
Under development

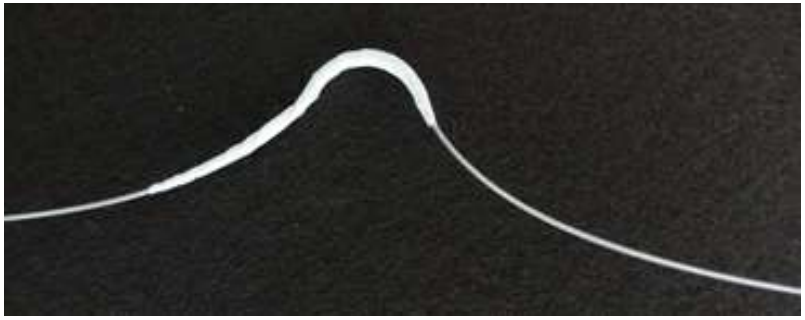
Thank you for your attention



Mitral Loop Cerclage

Two main Implantable parts





CSTV with cerclage rope

① Coronary sinus and TV protective device
② **ePTFE coating**
③ Tension stoper (SUS)
④ Two Polyurethane tube (5Fr in size)

cerclage rope

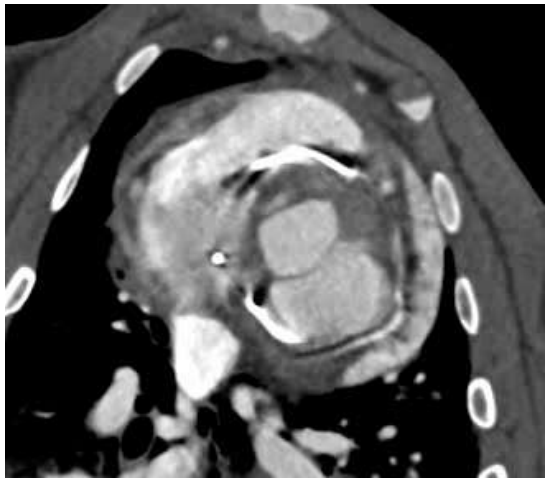
① **Nylon coated**
② fine stainless rope : **radiopaque**
③ Coronary artery protective part in a single unit
④ 0.6 mm in thickness

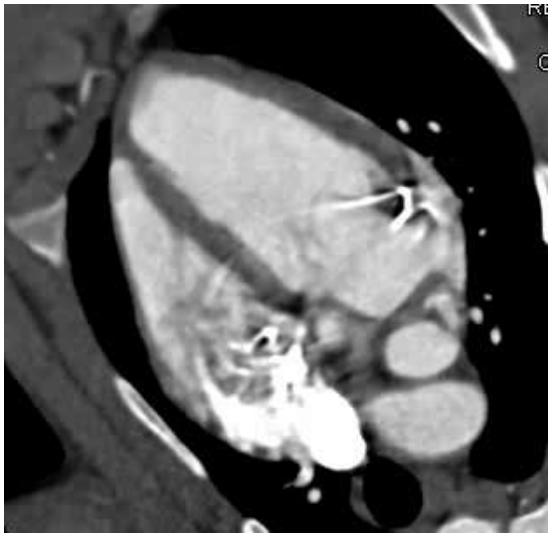
+ procedural devices : commercially available products

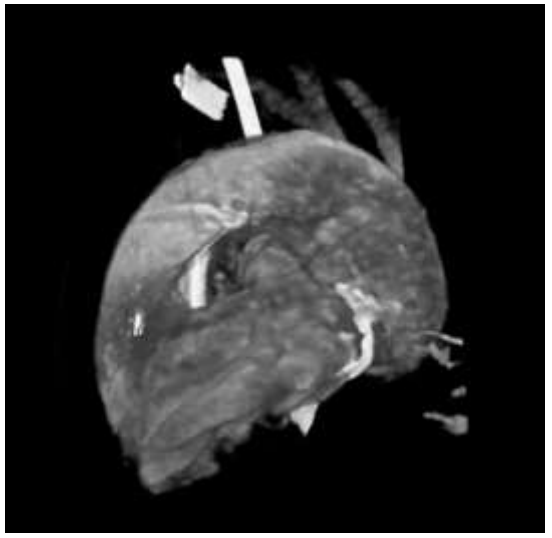
A representative case
2 wks FU Cardiac CT image

Post-procedure

2 wks FU



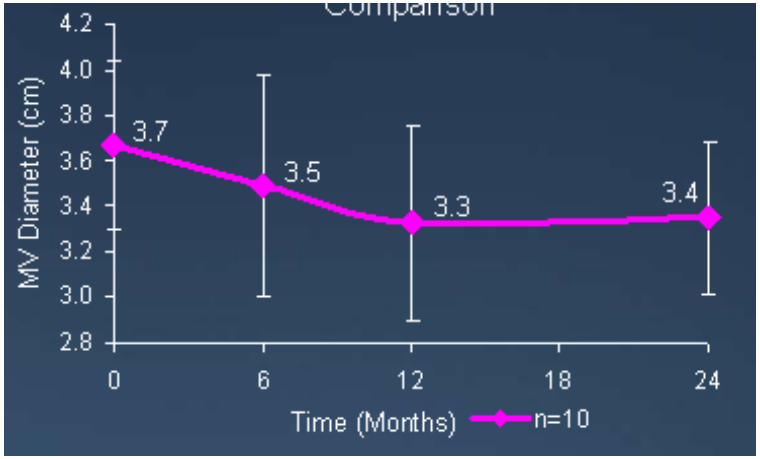




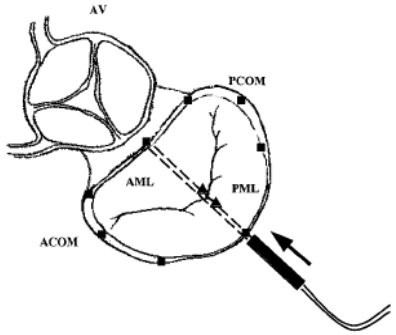
TCT 2013, June-Hong Kim et al.

Insufficient Shortening of SL annular dimension (≈10%)

Monarc



Viacor



Actually we need '20%' reduction of SLD

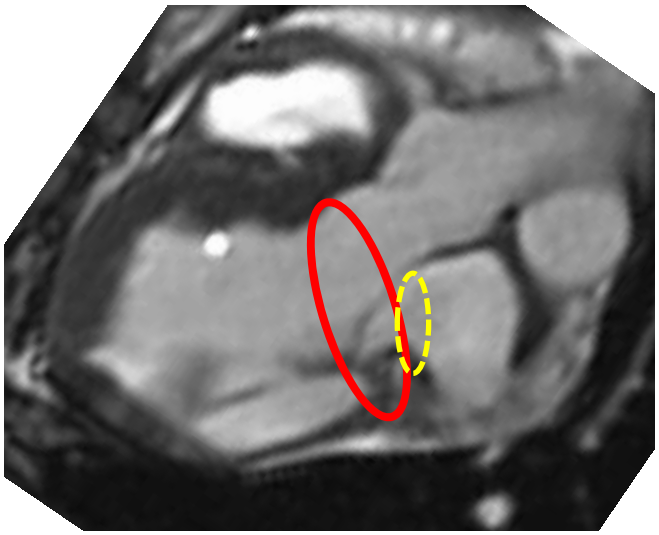
The Journal of Thoracic and Cardiovascular Surgery • Volume 123, Number 5 881

What's more of Mitral Cerlcage ?

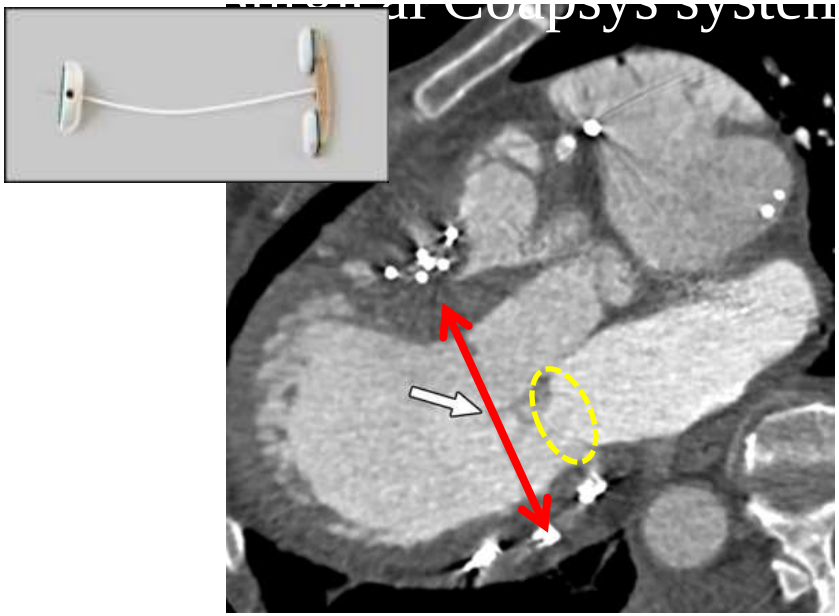
2. "LV basal squeezing" in Functional MR in Heart failure : more beneficial?

Surgical Coapsys : Survival Benefit & MACE reduction by 67% at 2yr compared with standard MV repair (p=0.019)

Mitral cerclage



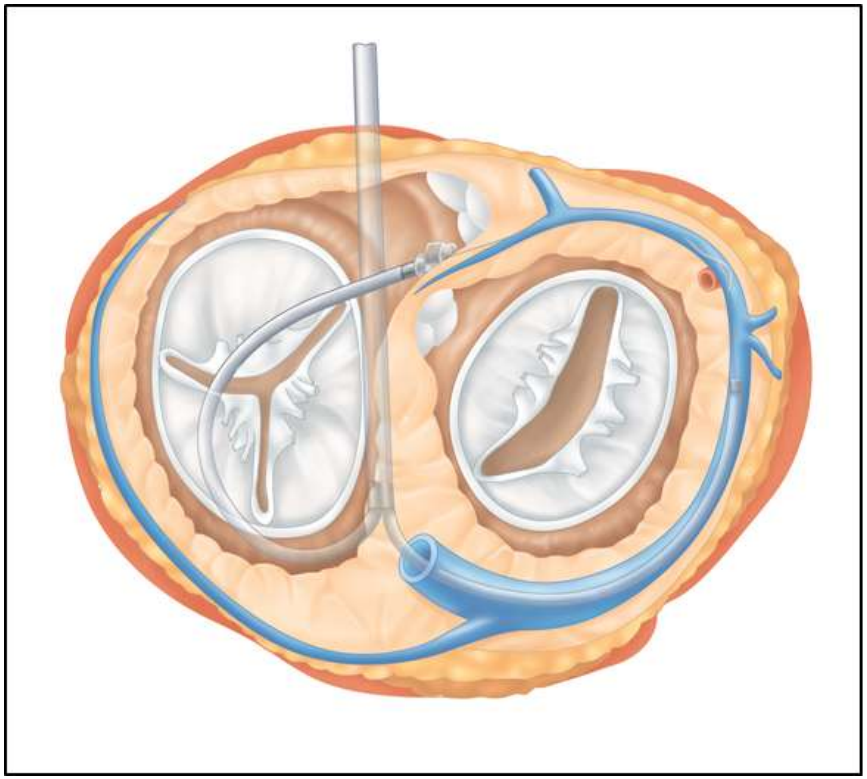
'Surgical Coapsis'



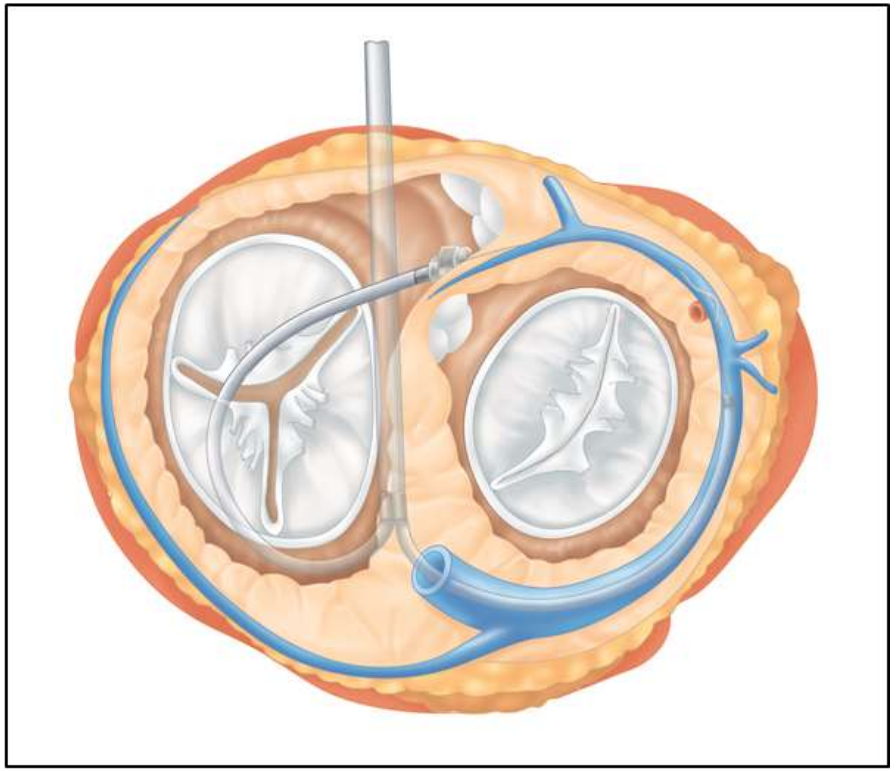
RCT : Coapsys MV repair in *"Functional"* MR RESTORE-MV study (n=165)

Grossi et al. JACC 2010. 56;1984-93

승모판 루프 써클라지
(Mitral Loop Cerclage)



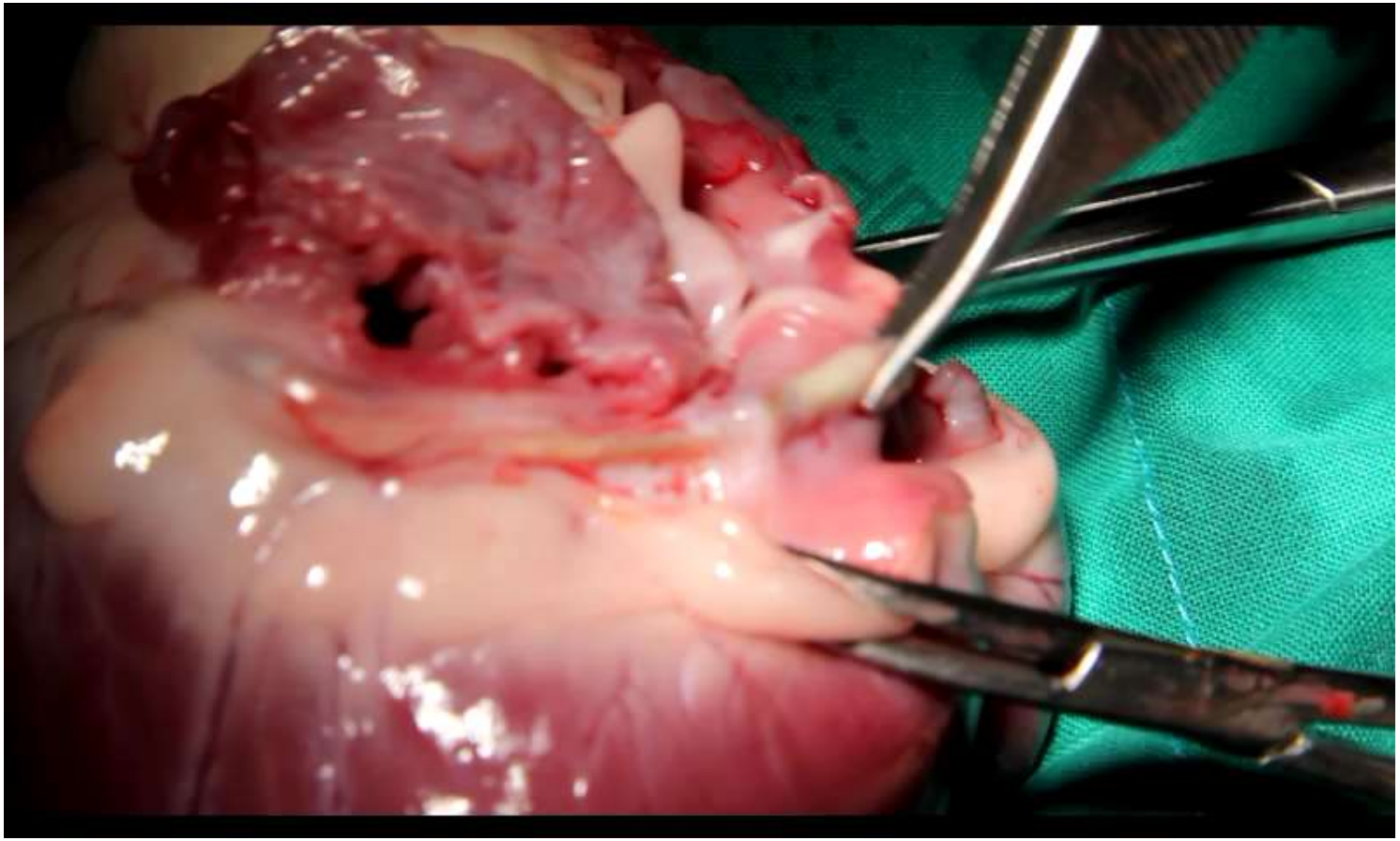
Tension (-)



Tension (+)

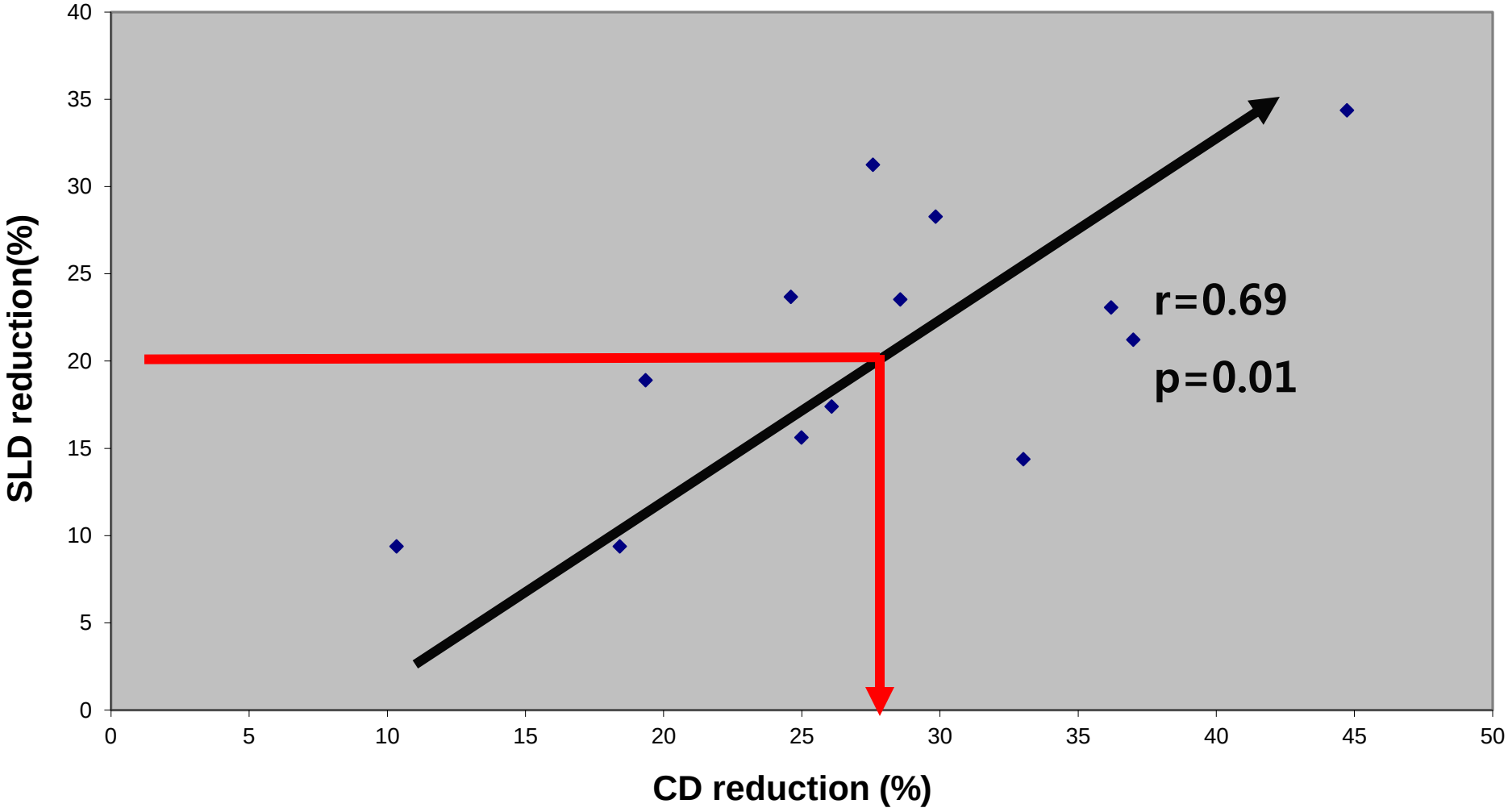
Stability of coronary protective device (6wks follow-up result)

Fixed coronary protective device



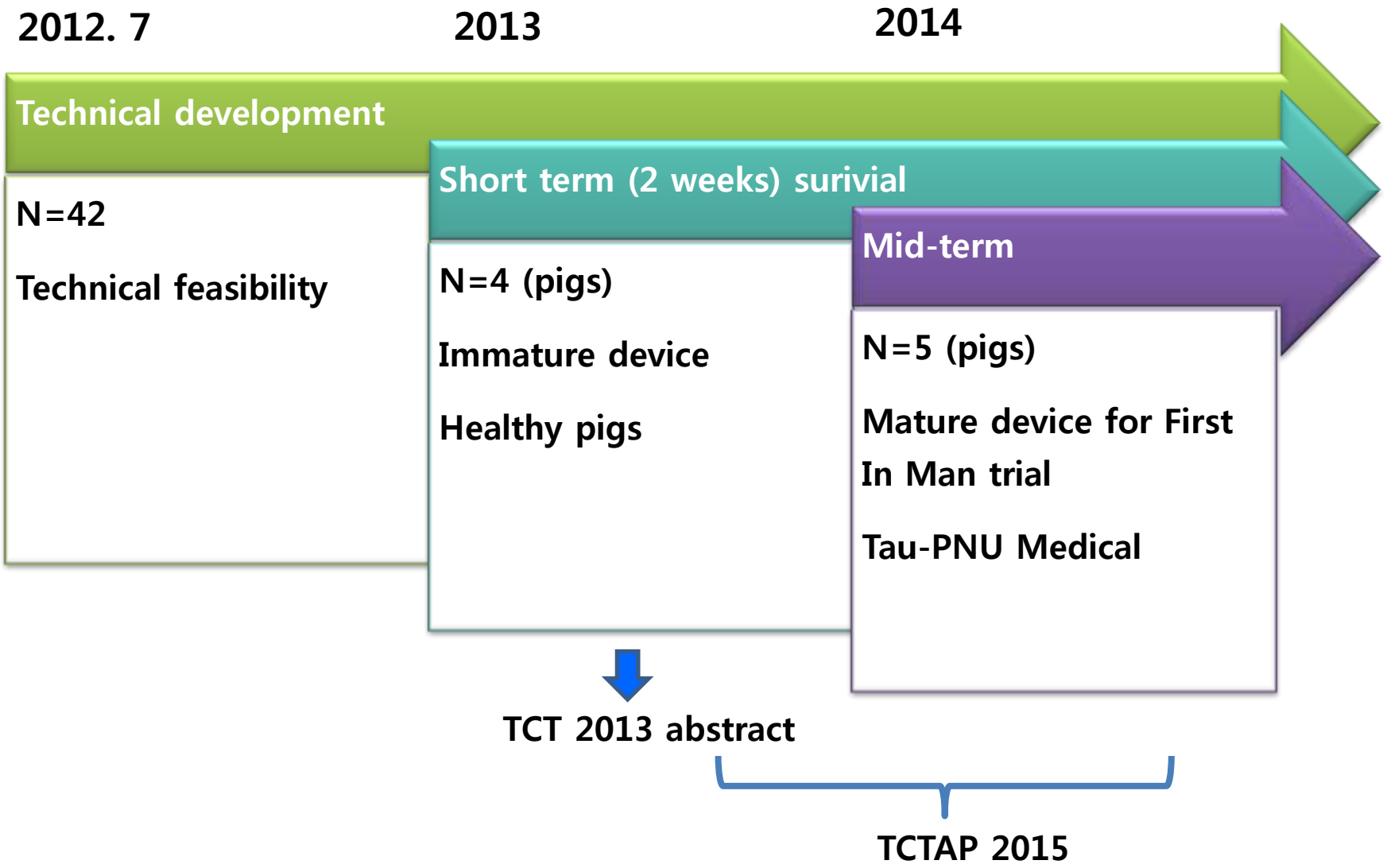
Septal Lateral Dimension

SLD reduction accoding to CD reduction



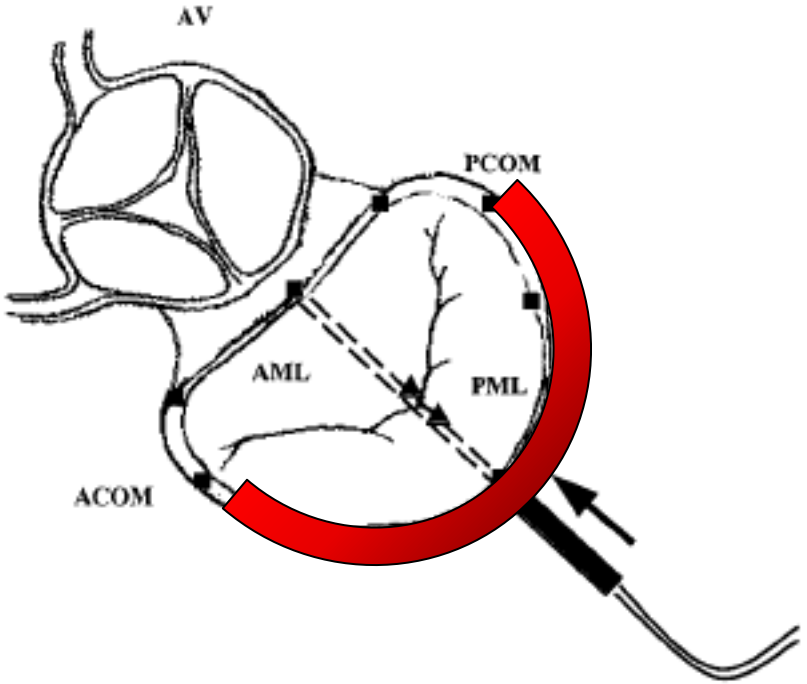
Kim JH et al. JACC 2009:54

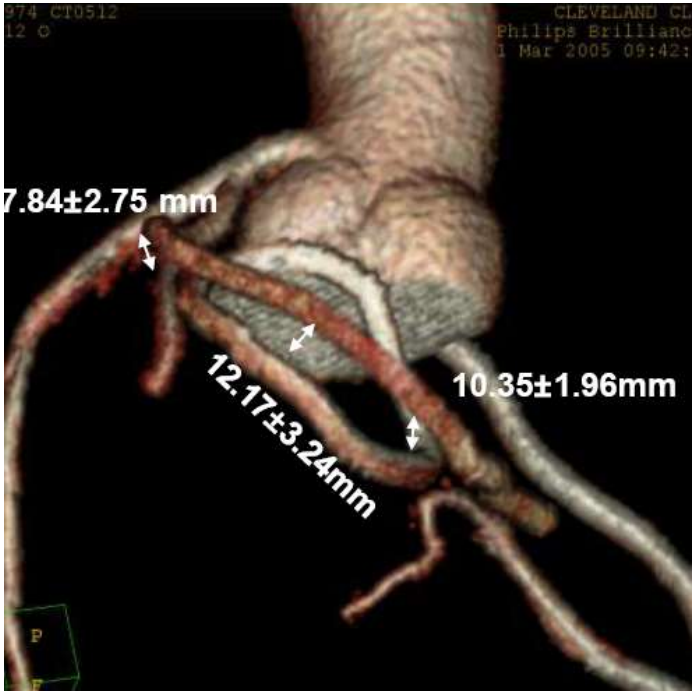
The development of Mitral Loop Cerclage



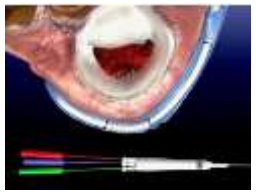
Limitations of ‘Coronary sinus’ approach

Sino-annular discordance+ partial ring tension ?

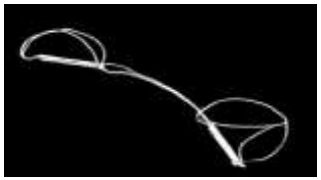




Monarc



Viacor

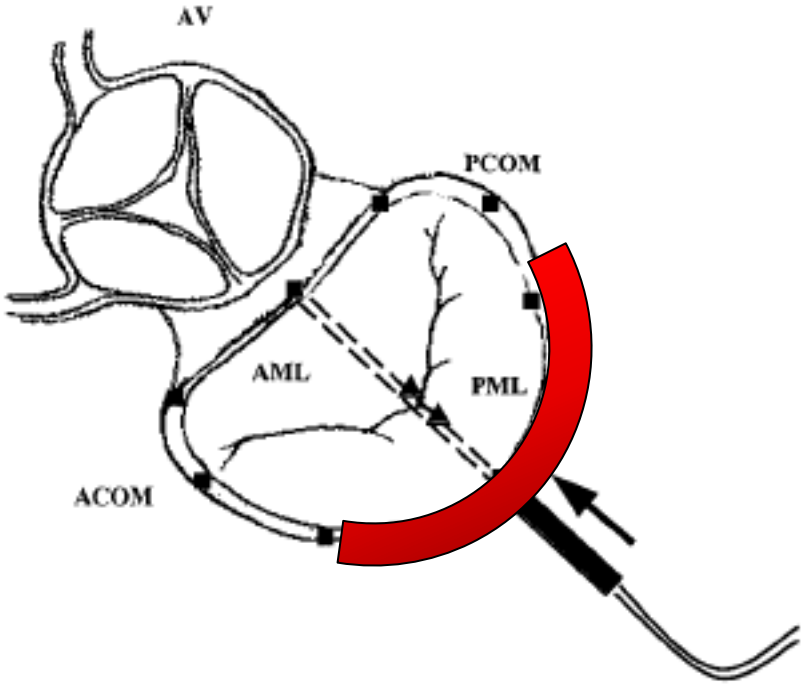


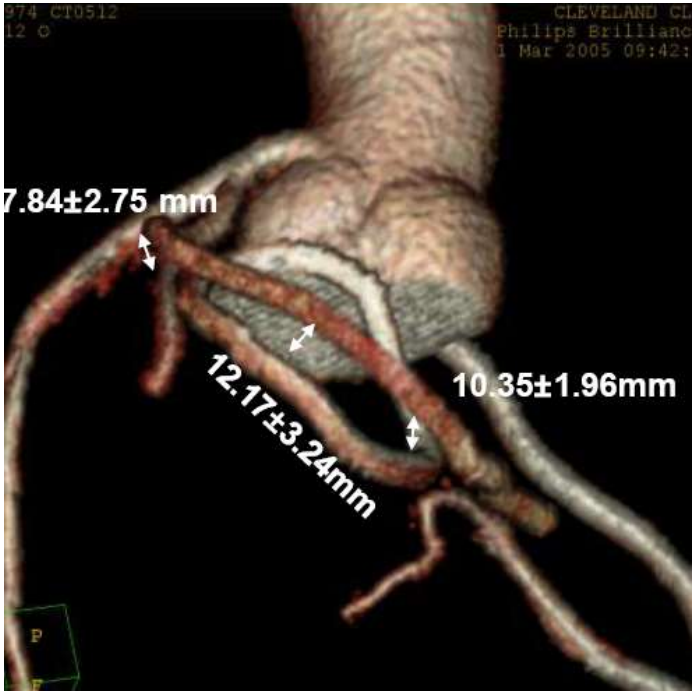
Carillon

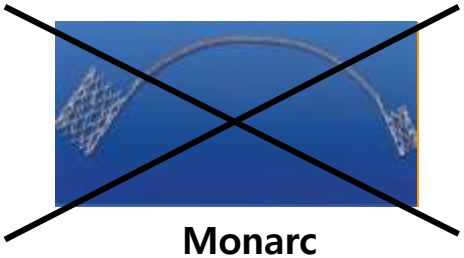
Limitations of 'Coronary sinus' approach

Sino-annular discordance+ partial ring tension ?

=> Lesser efficacy

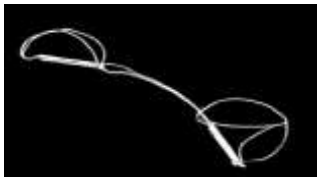






Monarc

Viacor



Carillon

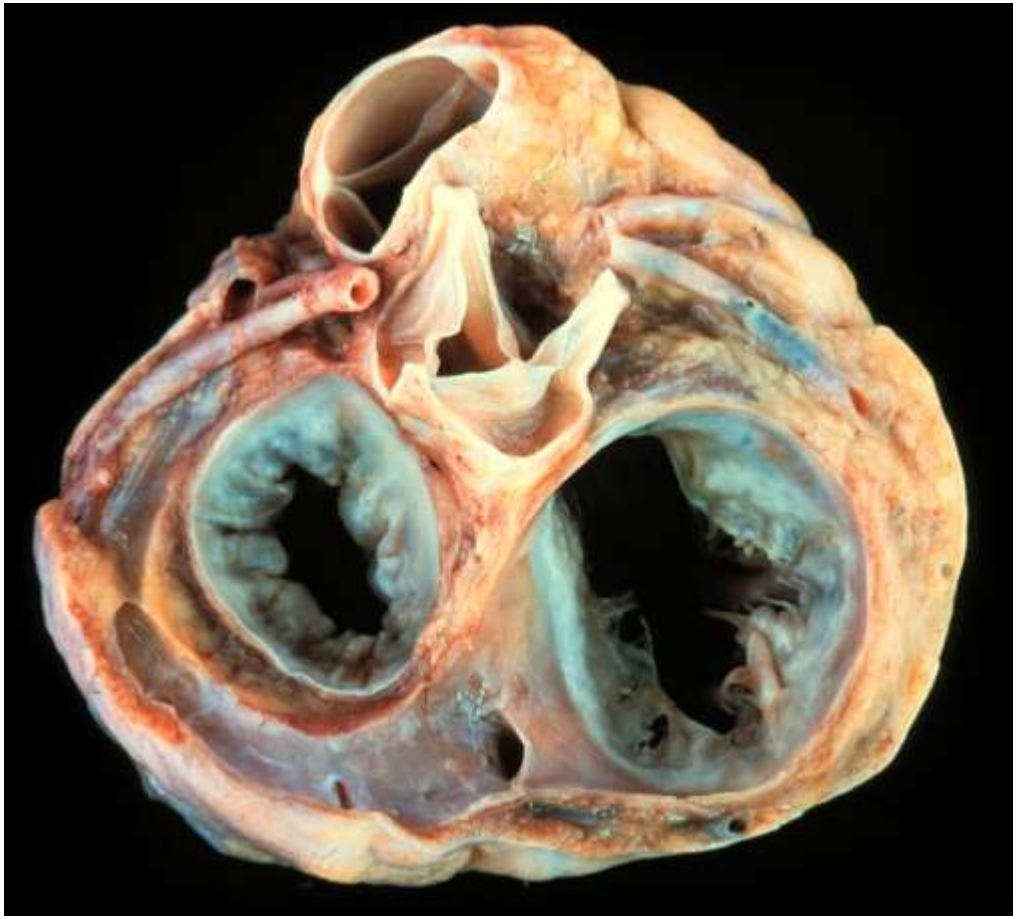
Coronary sinus approach

Simple & Easy !

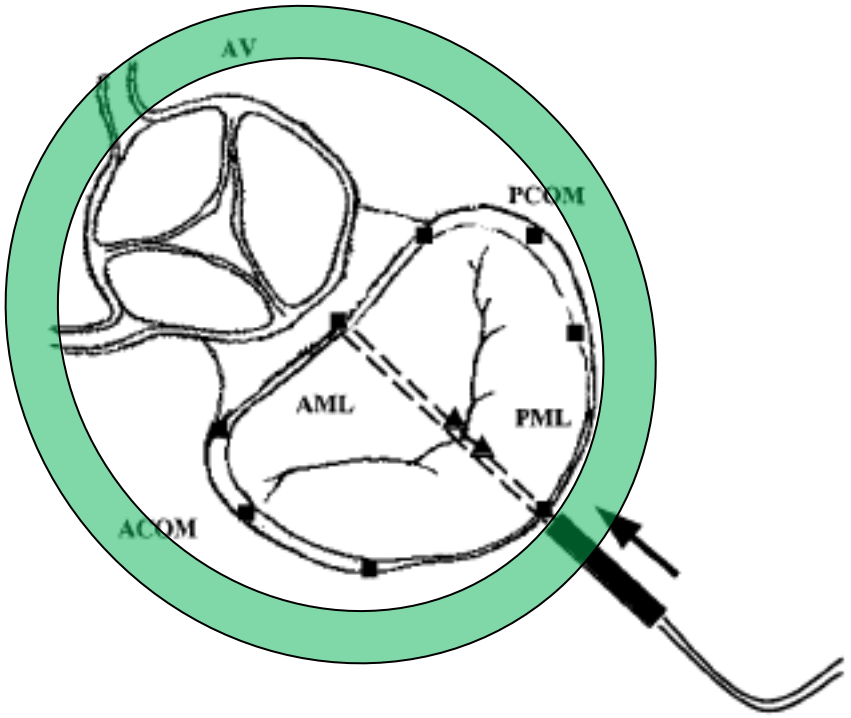
Takes advantage
of proximity of CS
to the mitral annulus

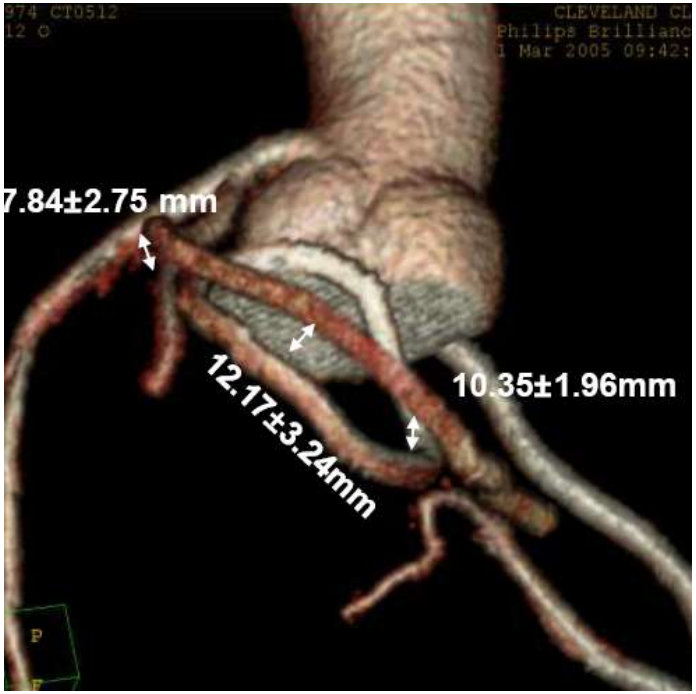
Easy access to CS

CS approach doesn't need
Sophisticated imaging guidance



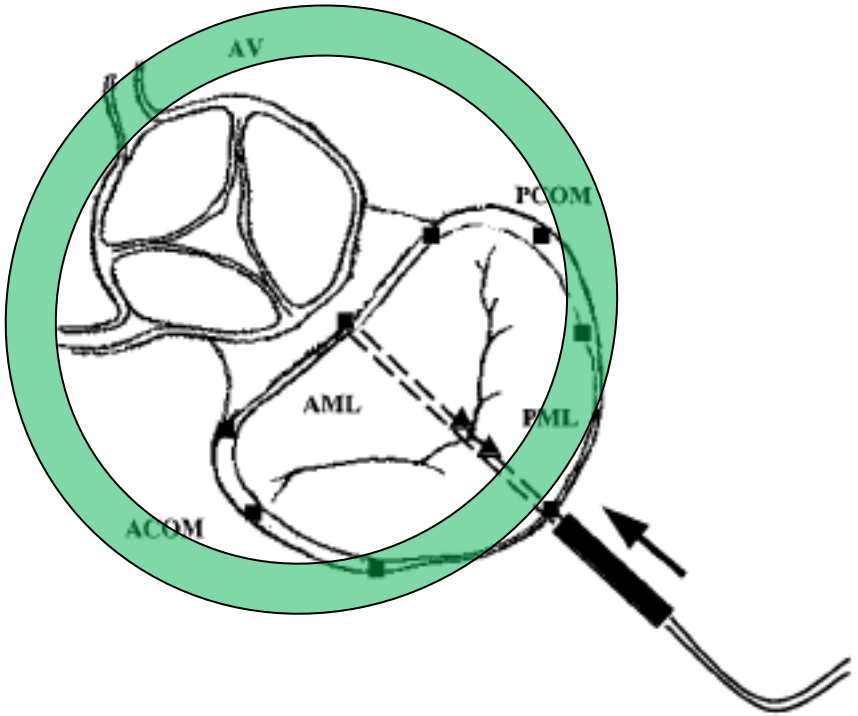
Sino-annular discordance + circumferrential tension….yes! It really works!

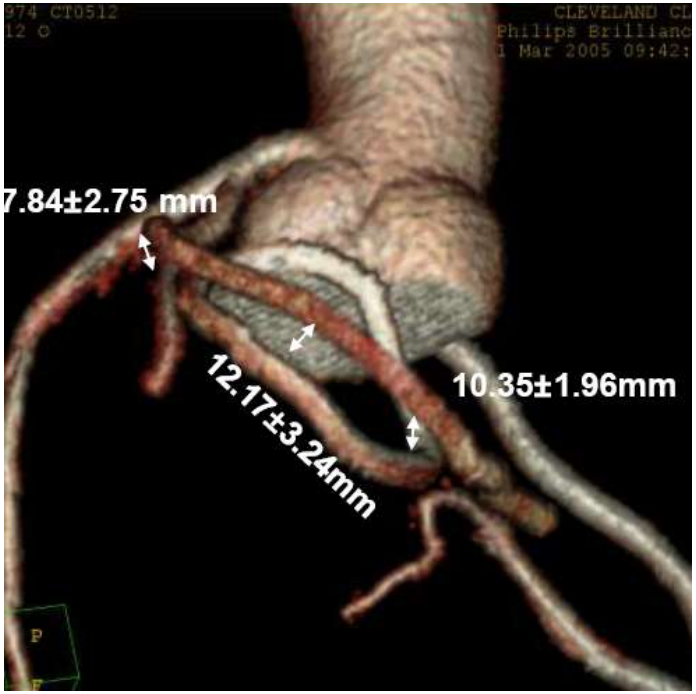




Mitral cerclage deilivers circumferrential tension around MV annulus

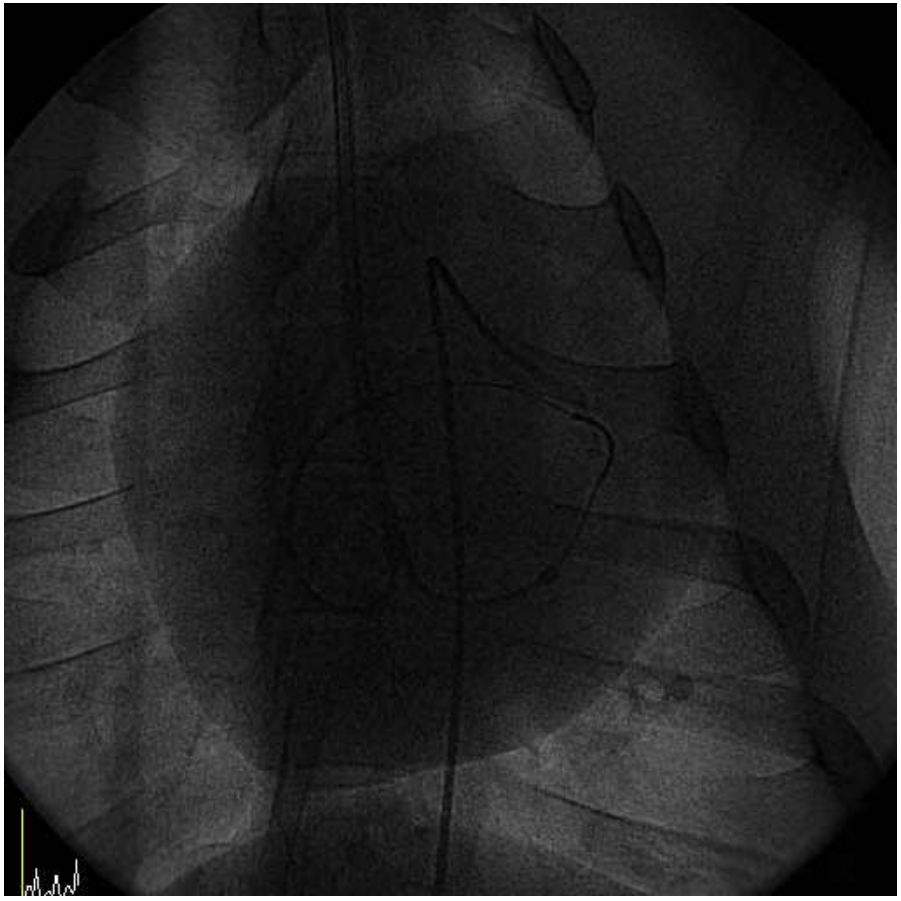
Sino-annular discordance + circumferrential tension….yes! It really works!



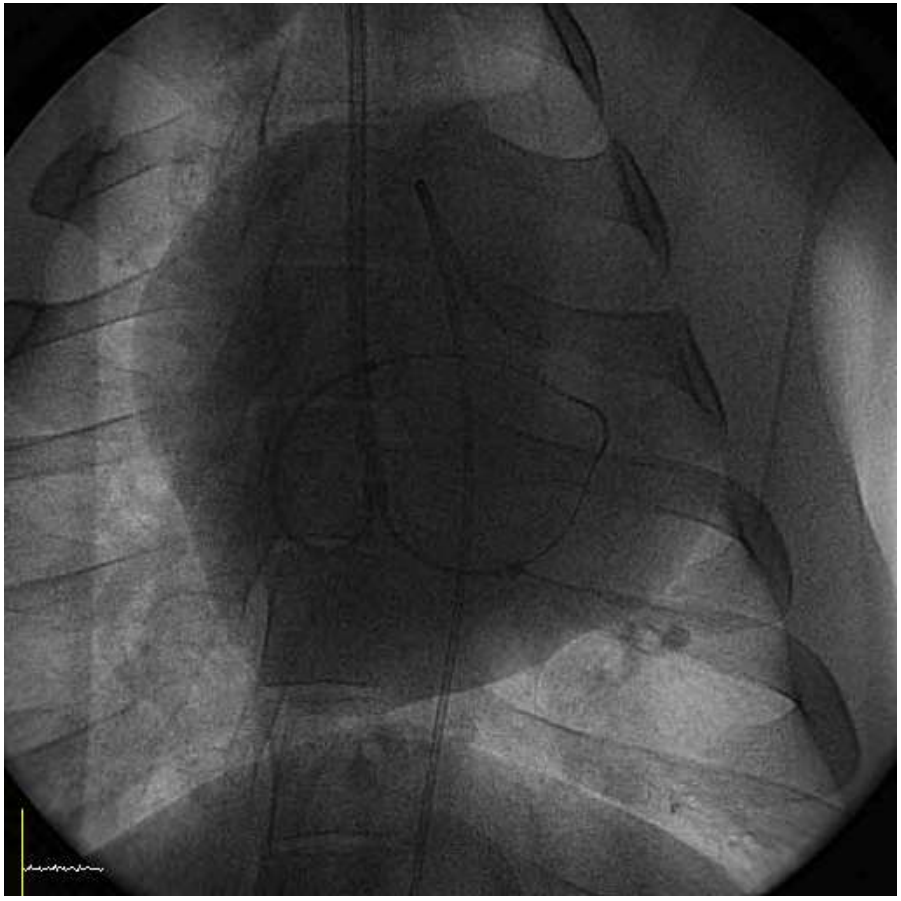


Mitral cerclage deilivers circumferrential tension around MV annulus

Tension release appeared to be possible at 6wks follow-up



Under Tension



Tension release