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Endovascular Papillary Muscle Approximation: A Novel Approach for Heart Failure Treatment

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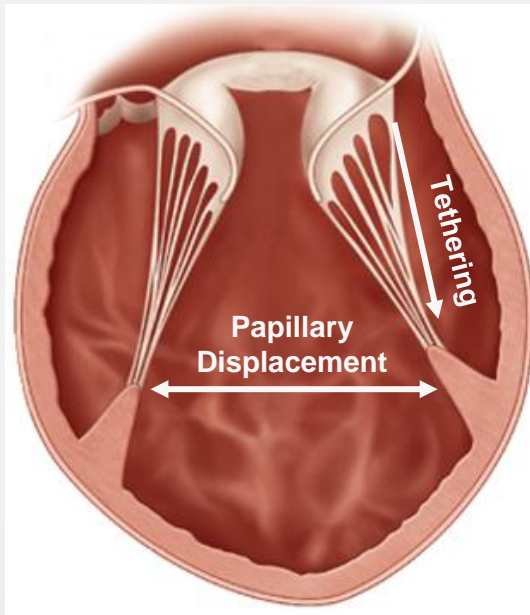


Disclosures

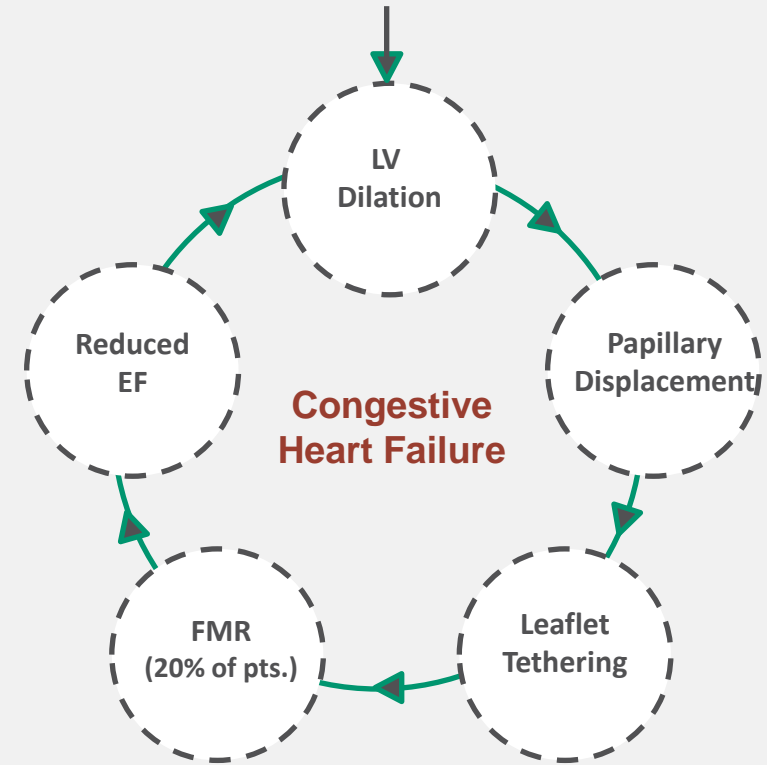
Physician name	Company	Relationship
Horst Sievert	Abbott, Ablative Solutions, Adona Medical, Akura Medical, Ancora Heart, Append Medical, Axon, Bavaria Medizin Technologie GmbH, BioRefine, Bioventrix, Boston Scientific, Cardiac Dimensions, Cardiac Success, Cardimed, Cardionovum, Contego, Coramaze, Croivalve, CSL Behring LLC, CVRx, Dinova, Endobar, Endologix, Endomatic, Esperion Therapeutics, Inc., Hangzhou Nuomao Medtech, Holistick Medical, Intershunt, Intervene, K2, Laminar, Lifetech, Magenta, Maquet Getinge Group, Metavention, Mitralix, Mokita, Myotec, Neurotronic, Novelrad, NXT Biomedical, Occlutech, Recor, Renal Guard, Shifamed, Terumo, Trisol, TruLeaf, Vascular Dynamics, Vectorious Medtech, Venus, Venock, Vivasure Medical, Vvital Biomed, Whiteswell, Xenter	Study honoraria to institution, travel expenses, consulting fees to institution

Background

Geometric dislocation of the papillary muscles is part of a vicious circle in heart failure patients



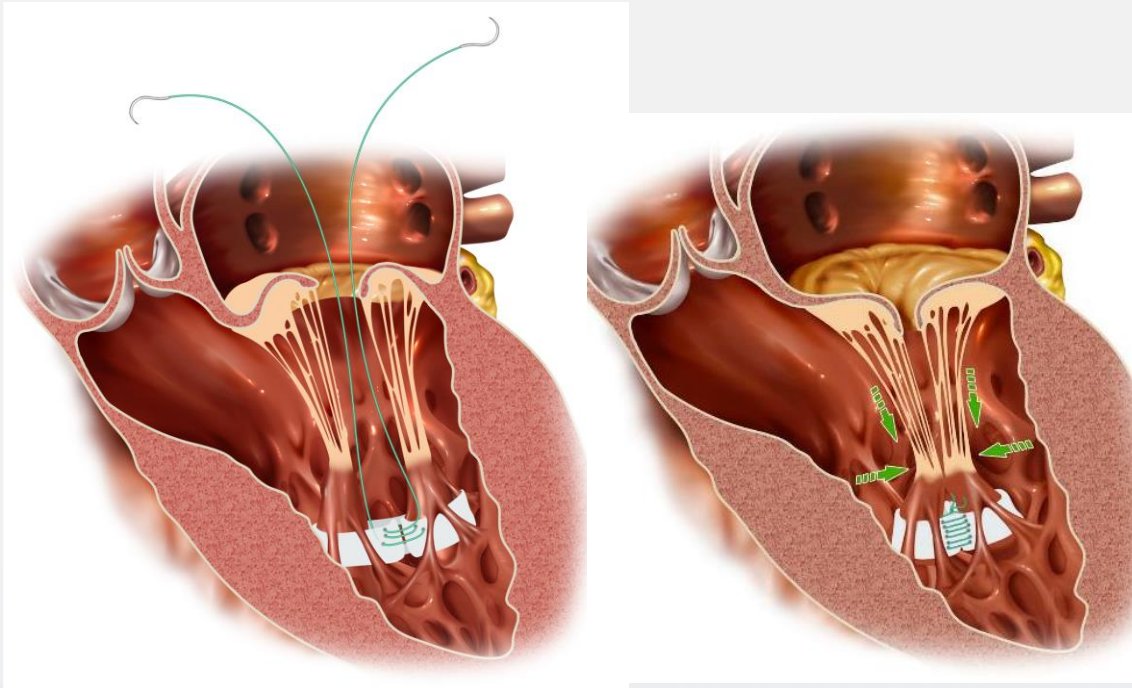
Dilated LV



It has not been targeted yet by a catheter based procedure

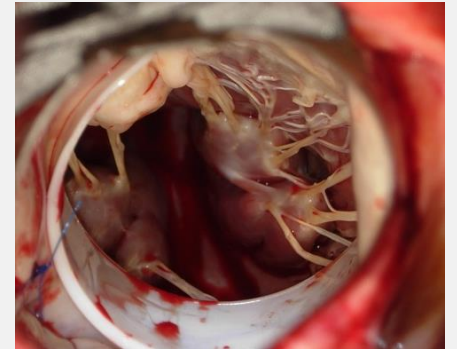
Surgical Papillary Muscle Sling Procedure

- Placement of a Gore-Tex tube around the papillary muscles
- The goal is to reshape the ventricle in order to improve LV function
- Typically, the Sling Procedure is combined with ring annuloplasty to treat mitral regurgitation

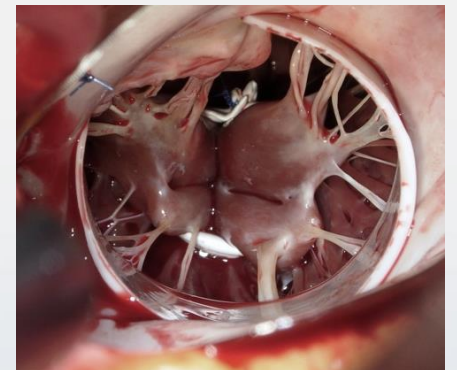


Surgical sling approximating papillary muscles

Papillary muscles surgeons' view



Vascular graft forms the surgical sling

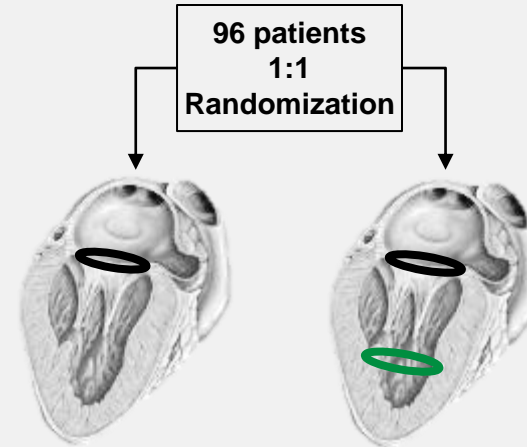


Surgical Sling Procedure Improves LV Function



Papillary Muscle Approximation Versus Restrictive Annuloplasty Alone for Severe Ischemic Mitral Regurgitation

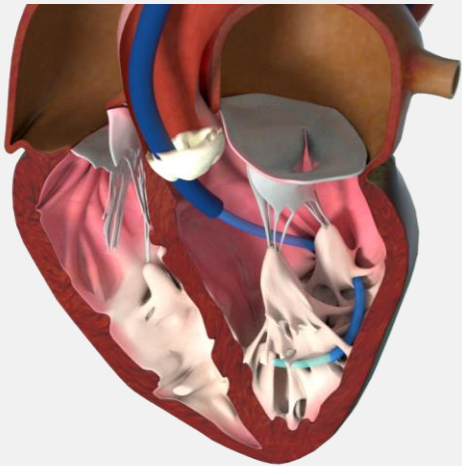
Francesco Nappi, MD,^{a,b} Mario Lusini, MD, PhD,^a Cristiano Spadaccio, MD, PhD,^{a,c} Antonio Nenna, MD,^a Elvio Covino, MD,^a Christophe Acar, MD, PhD,^d Massimo Chello, MD^a



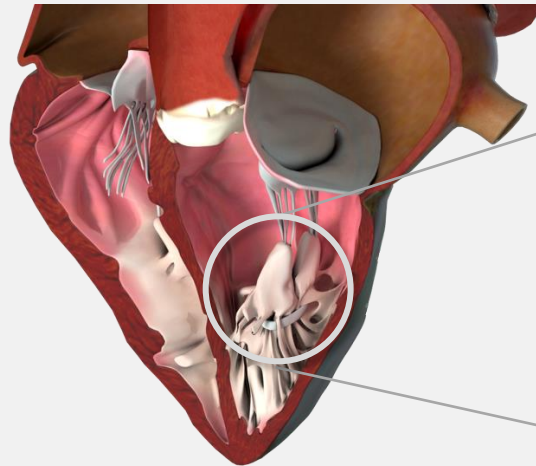
- **Randomized** study with 5 years follow-up
- LV function improvement:
 - ✓ EF improvement
 - ✓ LV size reduction
 - ✓ Tenting reduction

5 years follow-up	MVA Mitral Valve Annuloplasty	MVA + Sling	Clinical Benefit
MR grade 3-4	19(55.9%)	10(27.0%)	2X less MR recurrence
EF improvement %	3.2	9.1	2.8X EF improvement
ΔLVEDD, mm	-0.8	-6.2	7X reduction
PASP, mmHg	-3.4	-7	2X reduction
Mitral tenting area, mm ²	+12	-98	Tenting reduction

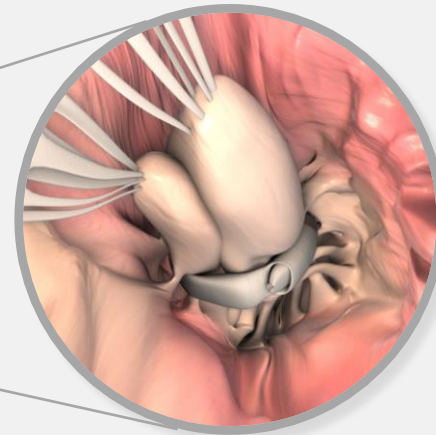
The Vsling™ Concept



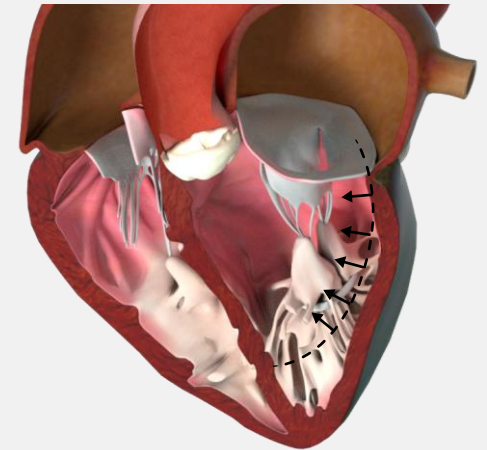
Transfemoral access, profile equivalent to a 14F sheath



An anchorless, adjustable sling is placed around the papillary muscles



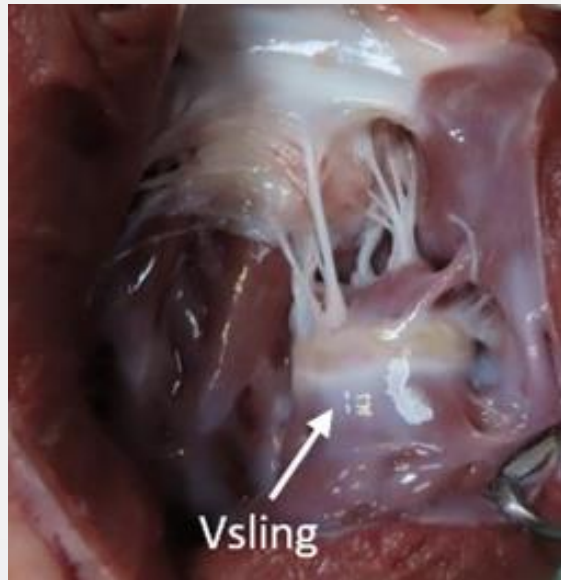
The sling can be adjusted, repositioned, or removed until the final deployment



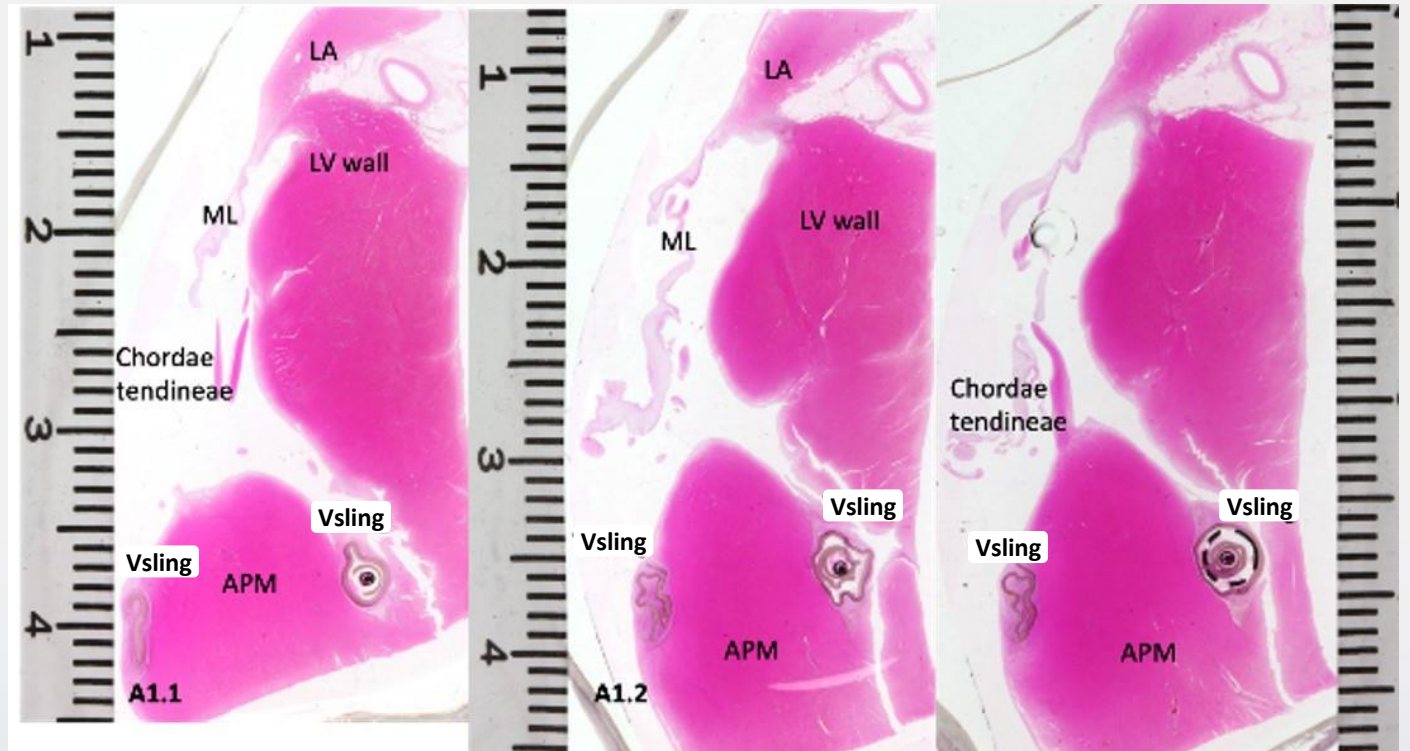
This leads to reshaping of the ventricle which reduces wall stress, enhances contractility and initiates therapeutic remodeling

Chronic Animal Trials

- Transcatheter approach in all animals
- Chronic animal study included histological evaluation of 6 animals at 90 days
- The histological findings were within the expected range, indicating safety of the device



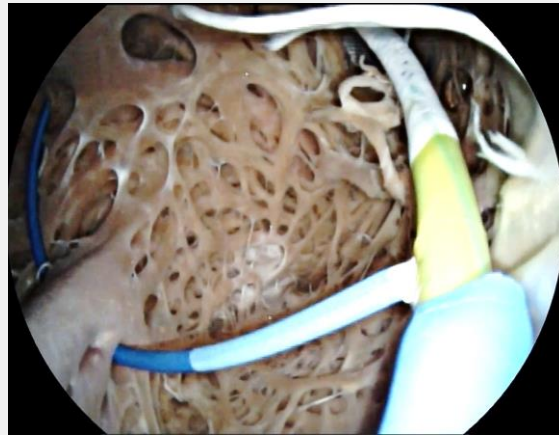
Full tissue ingrowth
at 90 days post-Vsling™
implantation



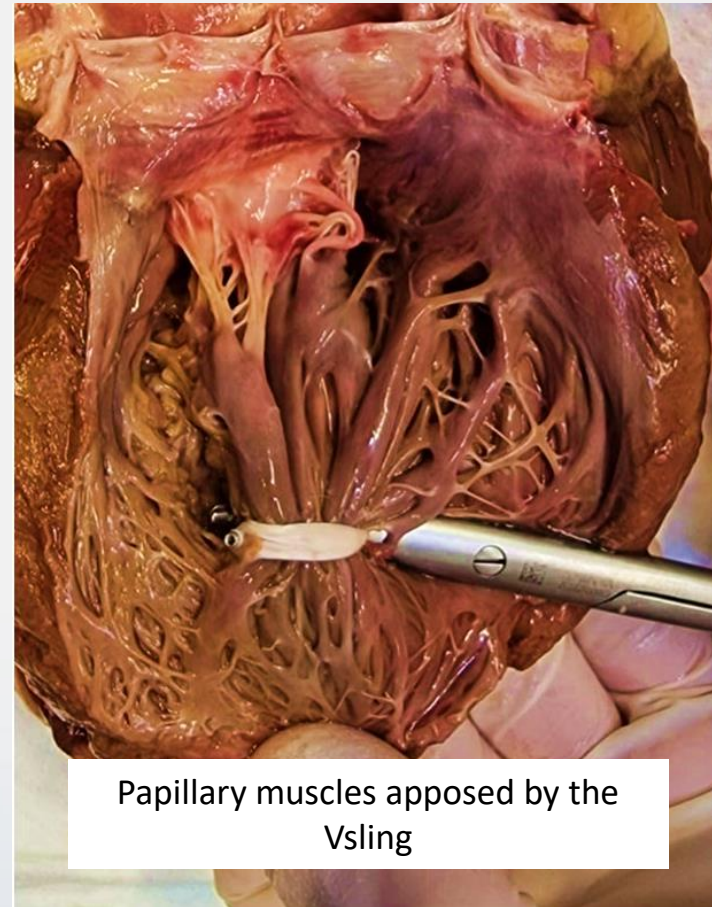
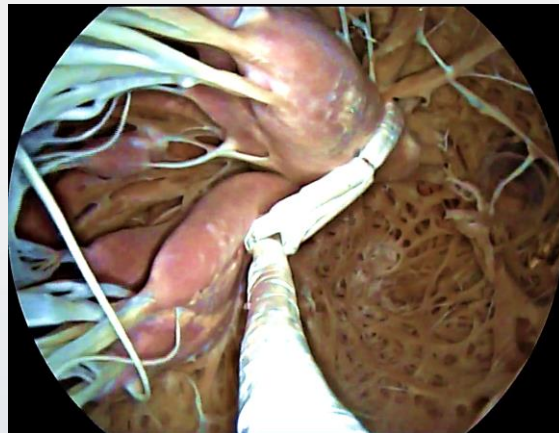
Human Cadavers - Transfemoral Procedures

Feasibility of transcatheter procedures was evaluated in full-torso cadavers

Encircling around
papillary muscles
and through
trabeculations



Implant size
adjustment
prior to
detachment



Papillary muscles apposed by the
Vsling

The Vsling is indicated for HFrEF with Dilated LV

Key Inclusion Criteria

- Ejection Fraction $\geq 20\%$ and $\leq 40\%$
- FMR grade $\leq 2+$ (\leq mild FMR)
- NYHA class II-IVa
- LV End Diastolic Diameter (LVEDD) ≥ 55 mm
- Cardiomyopathy of ischemic or non-ischemic origins

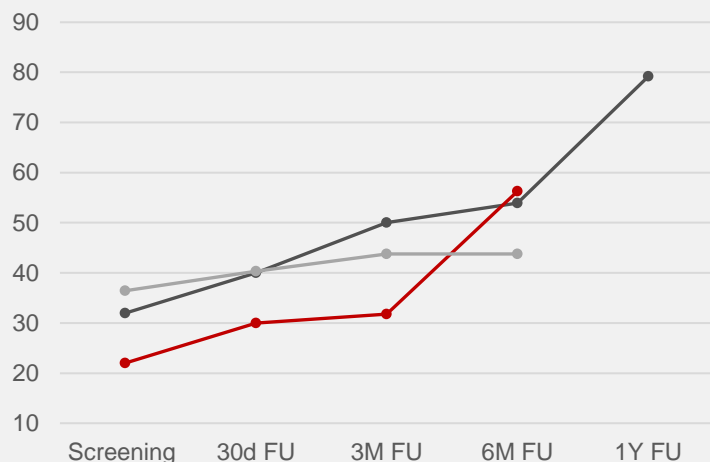
Key Exclusion Criteria

- Prior mitral valve replacement
- Any evidence of structural mitral lesions
- Severe Aortic stenosis
- Severe Tricuspid regurgitation

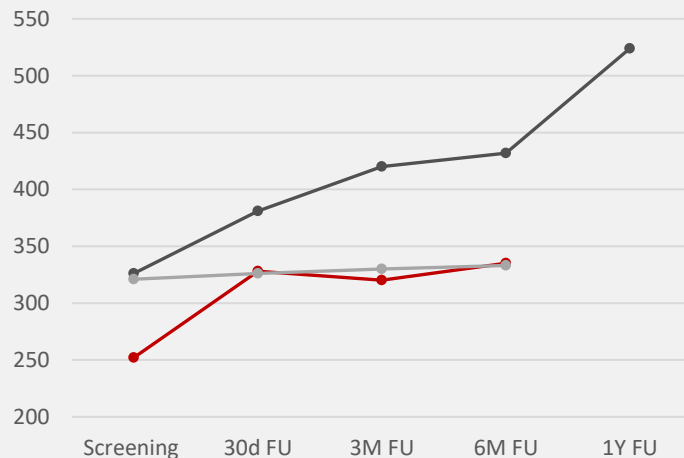
Patients Implanted with the Vsling Device

Patients treated in Georgia with gen 2

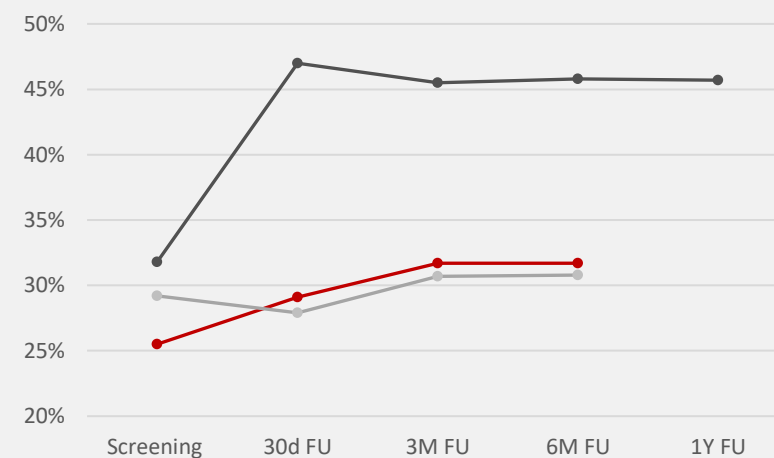
KCCQ [points] Cardiomyopathy questionnaire



6MWT [meters] Six minutes walk test



EF%- Ejection Fraction [%]



- Gen 2 procedures duration ranged between 70 to 130 minutes
- Improvement in QOL and 6MWT maintained throughout follow-up
- Improvement in EF and Global Longitudinal Strain maintained throughout follow-up
- No HF hospitalizations throughout the follow-up period

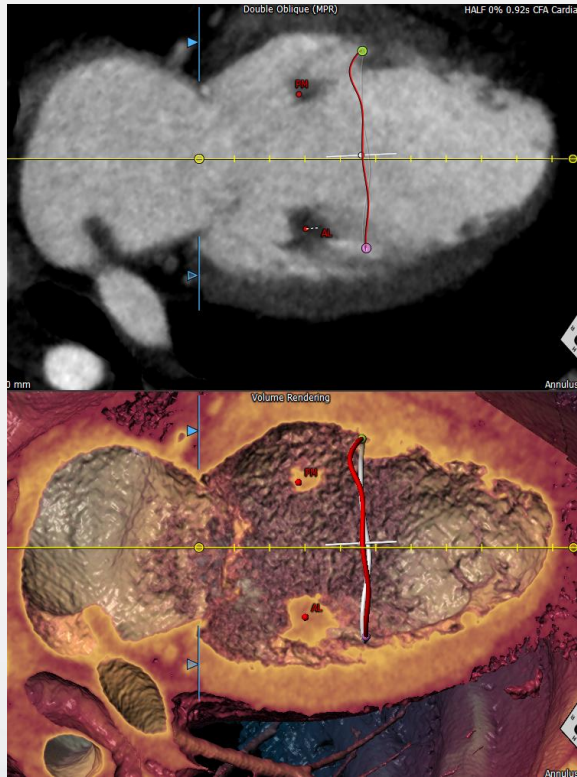
—●— Patient 08-009
—●— Patient 08-011
—●— Patient 08-013

Case Example

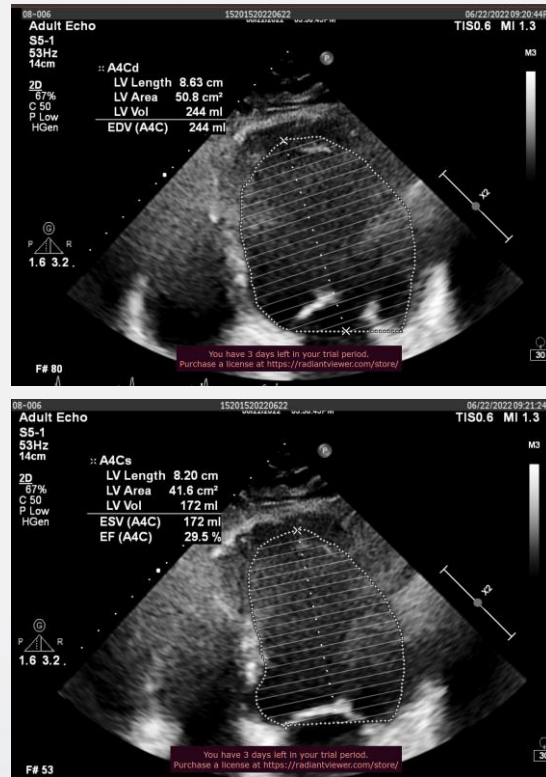
- 57 year old male
- Dilated ischemic cardiomyopathy
- NYHA class III
- 1 HF related hospitalization in past year
- EF 29%
- MR 1+

Patient-Specific Procedure Planning

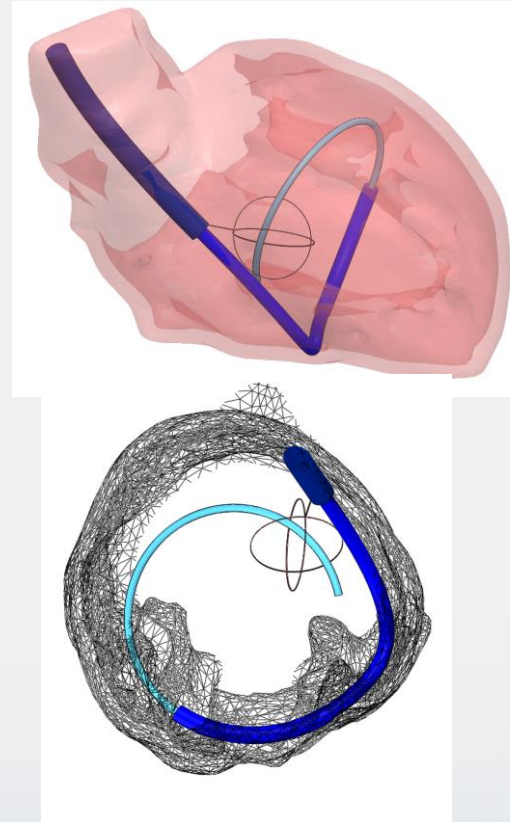
CT Assessment



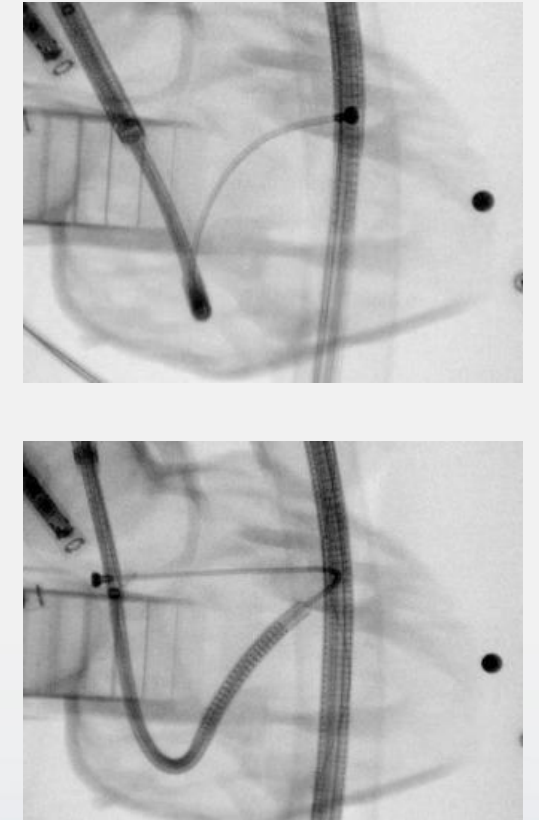
Echo Measurements



Virtual Planning

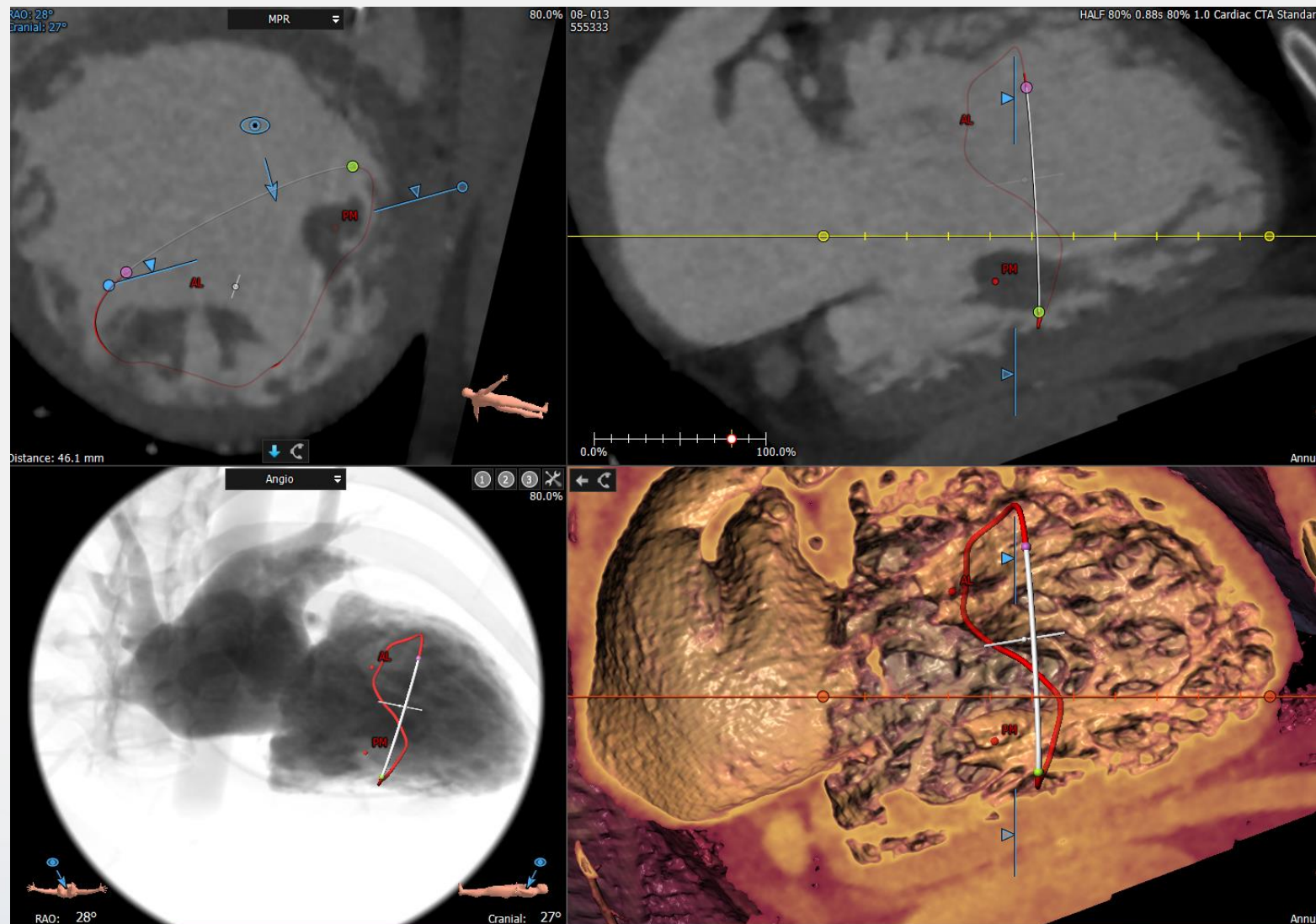


3D Model Procedures

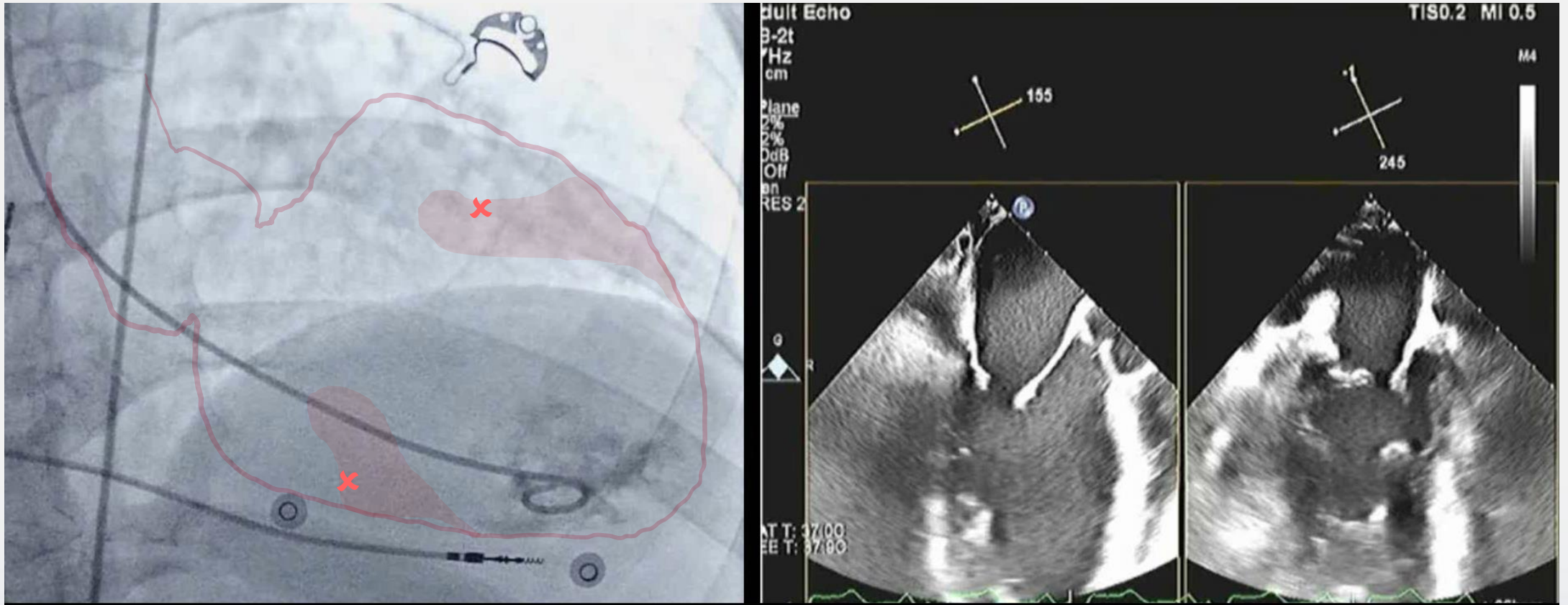


Procedure Planning

- Defining encircling paths
- Verifying implant size range

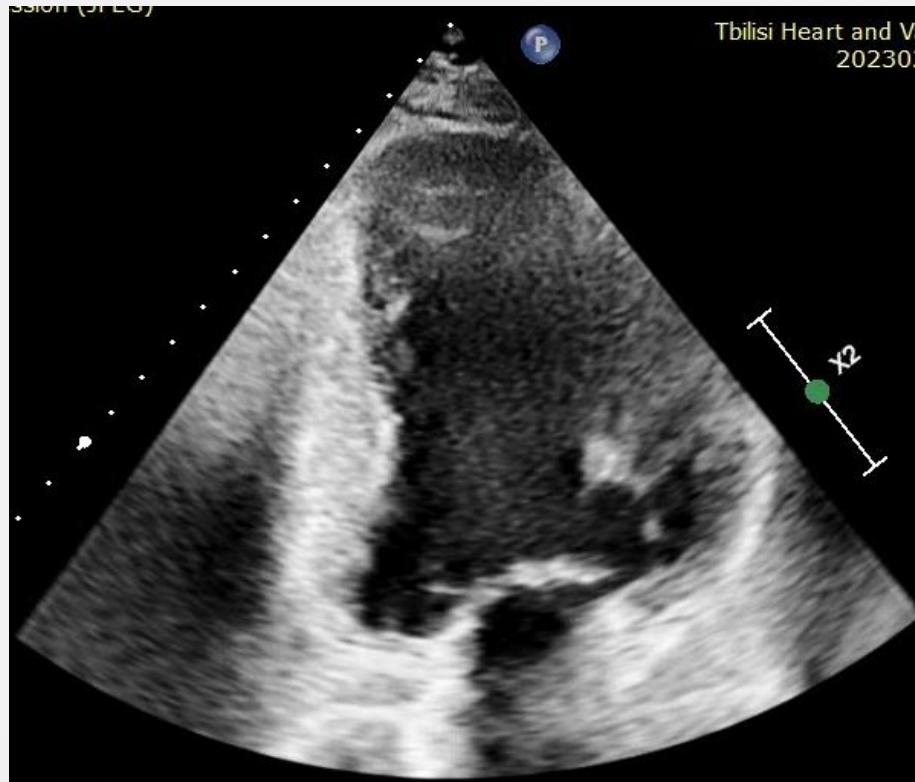


Procedure

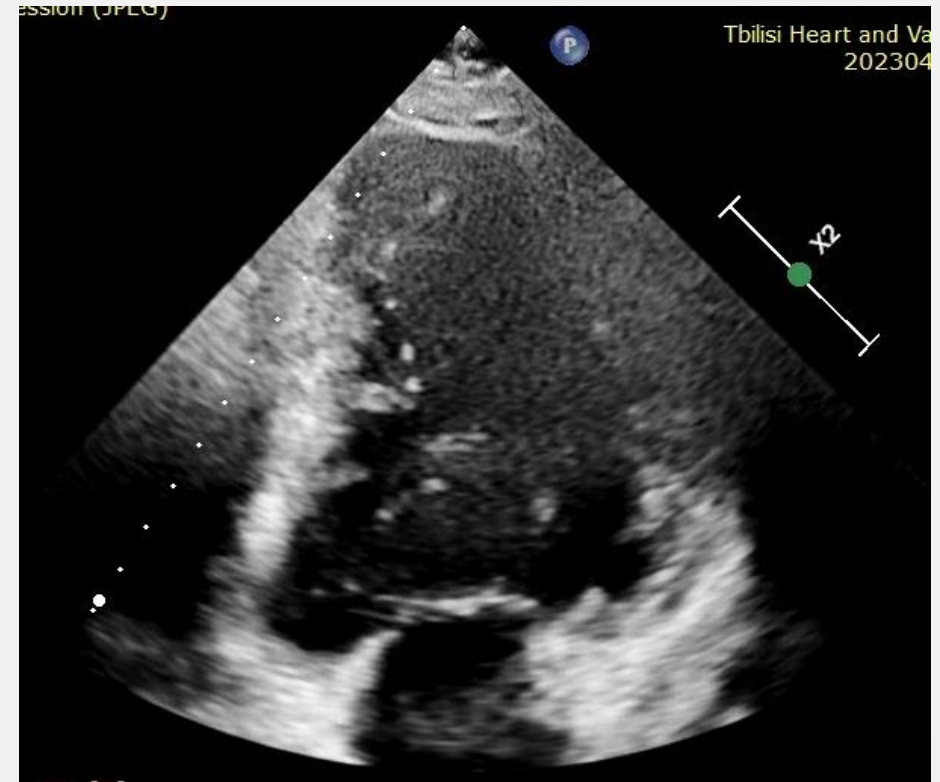


Echo Follow-up

Pre-procedure



30 days post-procedure

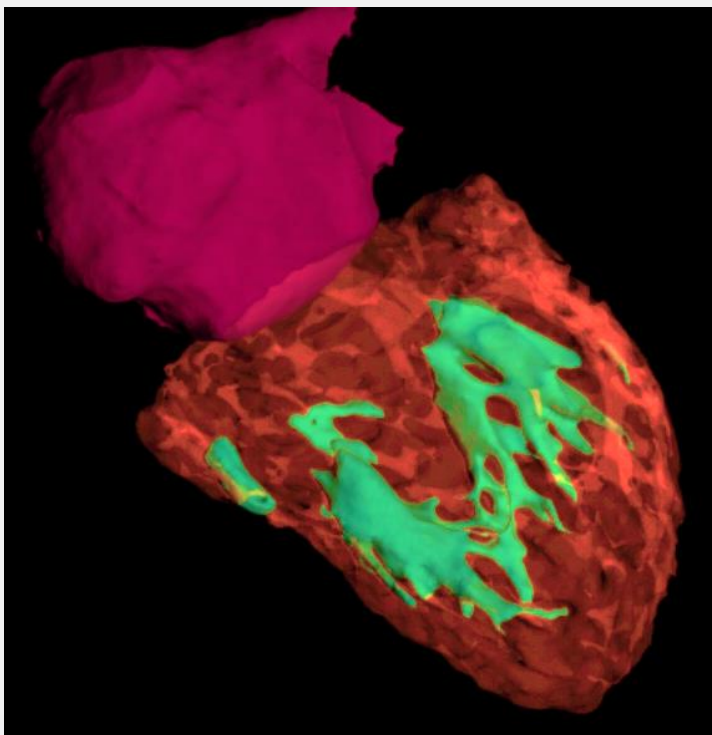


LV reshaping with the Vsling implant

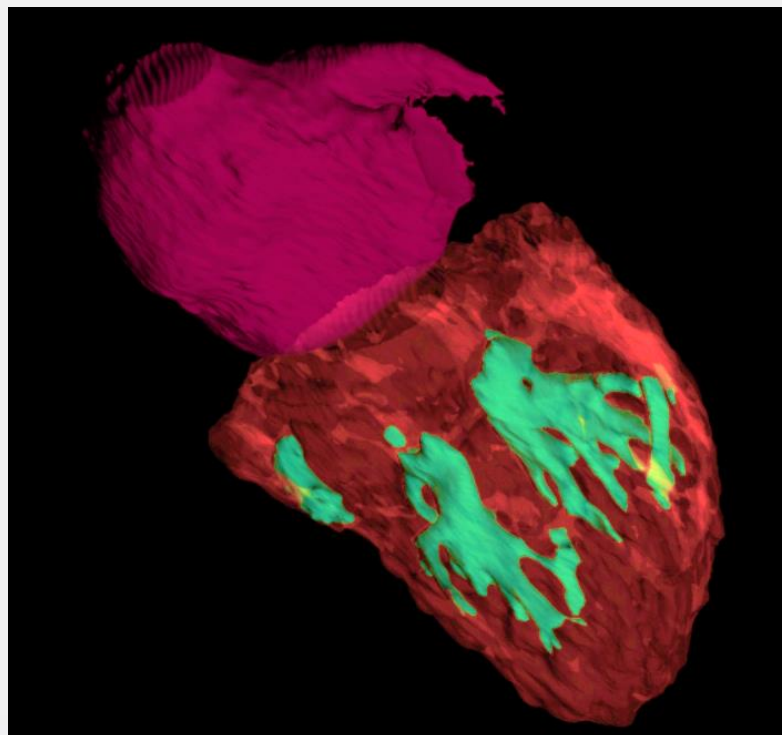
Maintained papillary muscle approximation

CT Follow-up

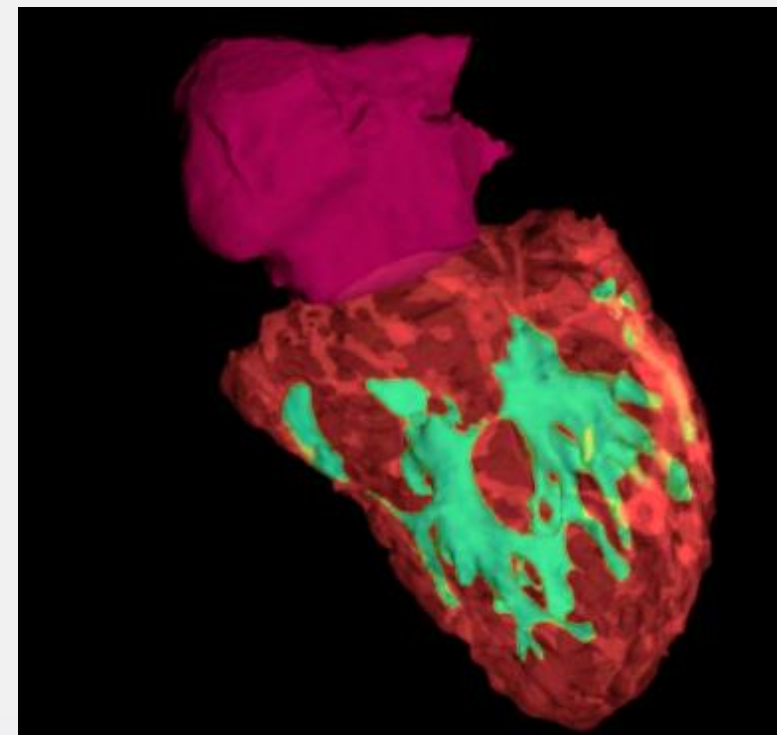
Pre-procedure



Post-procedure 10 days



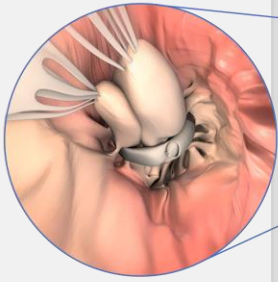
Post-procedure 6 months



CT segmentation by LARALAB heart.ai platform

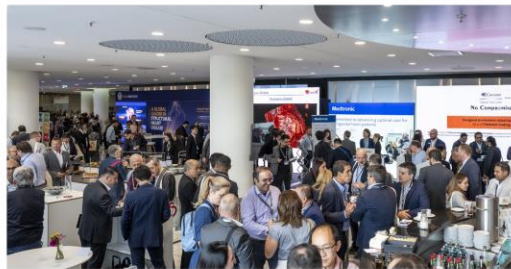
Visible Initiation of tissue ingrowth in 6 months follow-up

Summary & Conclusion



- The Sling procedure is a surgical technique to approximate the papillary muscles to treat heart failure
 - proven to be effective in HFrEF patients
- The transcatheter Vsling procedure is feasible
- It resulted in
 - symptomatic improvement (QoL, 6 MWTD)
 - improvement of the EF
- The procedure does not block future interventions
- This may become a treatment option for HFrEF patients
- The FIH is on-going

Thank you for your time!



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