Three-Dimensional Intracardiac Echocardiography Guidance for Preclinical Transseptal Implantation of the SATURN Transcatheter Mitral Valve Replacement System

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	Boston Scientific
Consultant Fees/Honoraria	4C Medical, InnovHeart, Philips

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

SATURN TMVR

The Saturn TMVR Bioprosthesis has a multicomponent design. The design includes:

- an annular structure, intended to be positioned behind the native mitral leaflets, to reshape and stabilize the MV annulus
- a central valve, intended to be expanded inside the mitral orifice
- a set of connecting arms, solid with the central valve, to provide mechanical continuity between the valve and the annular structure

annular structure

+

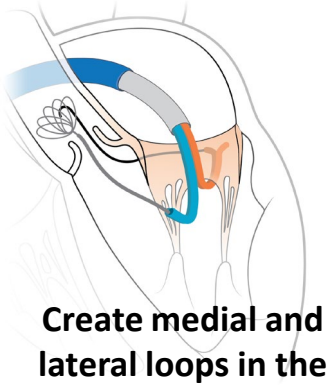
central valve

connecting arms

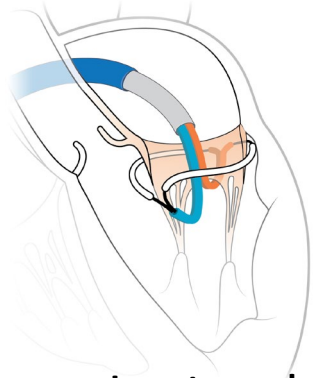
=

Saturn TMVR

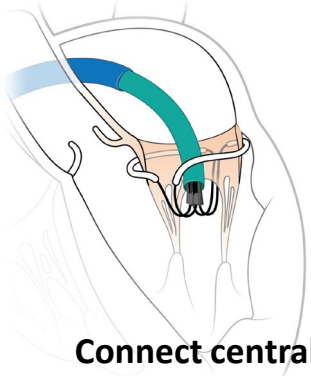
SATURN TS TMVR Procedural Steps



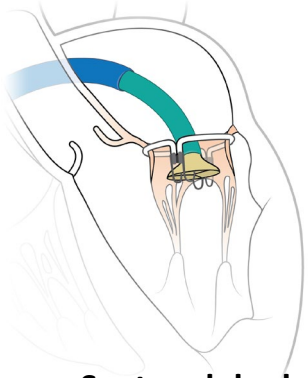
Create medial and lateral loops in the subannular groove of the mitral annulus



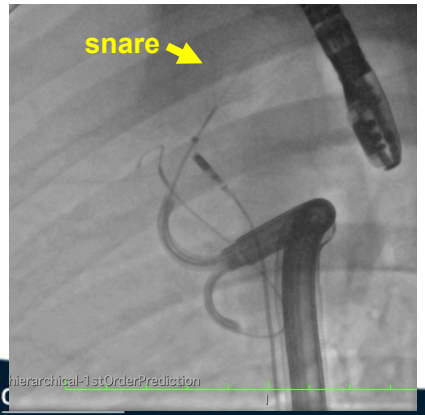
Insert annular segments (pink arrows)

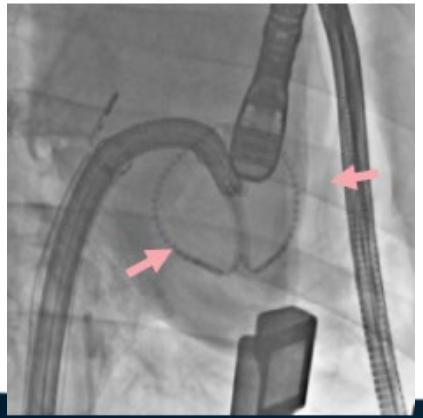


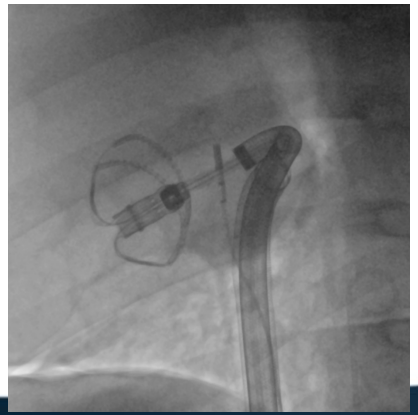
Connect central valve to subannular structure



Seat and deploy

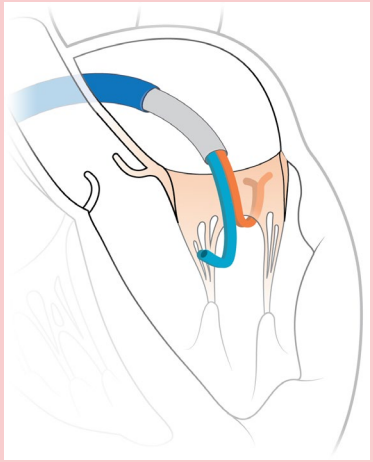
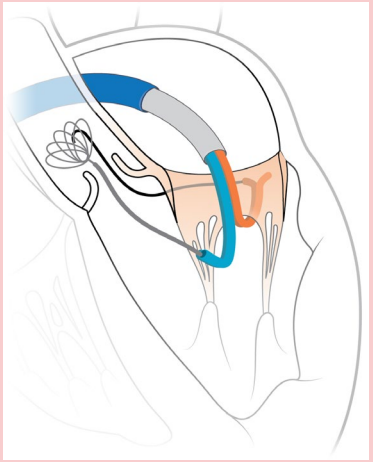
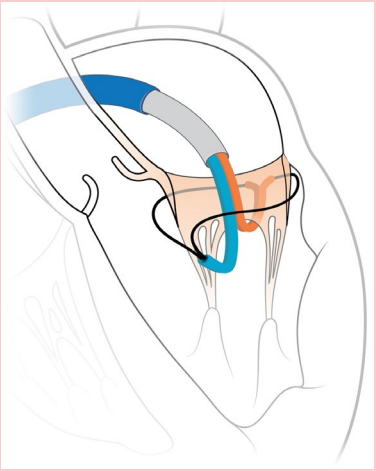






TVT

Subannular Structure

1. Position guidewire delivery system (GWDS) at A2 and P2 for placement of medial and lateral loops	2. Creation of 1st Loop (medial) embracing the mitral chordae in the subannular groove	3. Creation of 2nd Loop (lateral) embracing the mitral chordae in the subannular groove
		

Aim	**To evaluate whether 3D ICE can reliably visualize embracement of the mitral chordae to form the subannular structure for SATURN TS TMVR**
Study Population	**14 Yorkshire pigs**
Methods	• **3D ICE imaging (Verisight Pro, Philips) used to guide creation of the subannular structure.** • **Necropsy performed after valve delivery to evaluate capture of mitral chordae and implant position**

VeriSight Pro 3D ICE catheter features

Outer diameter
9 F

Working length
90 cm

Cable length
4 ft

Minimum sheath size
10 F

Catheter tip
2 cm with softer[1] design

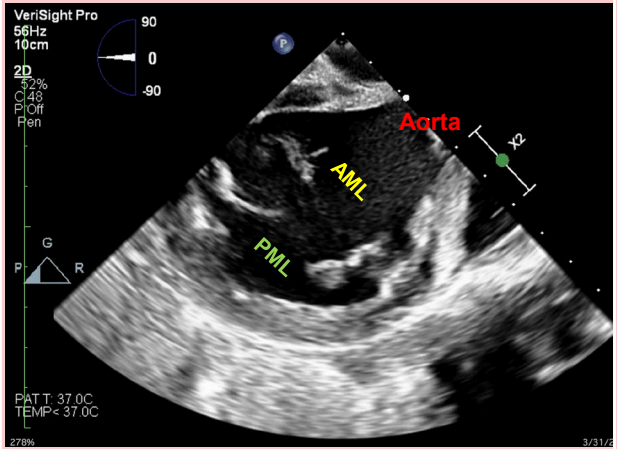
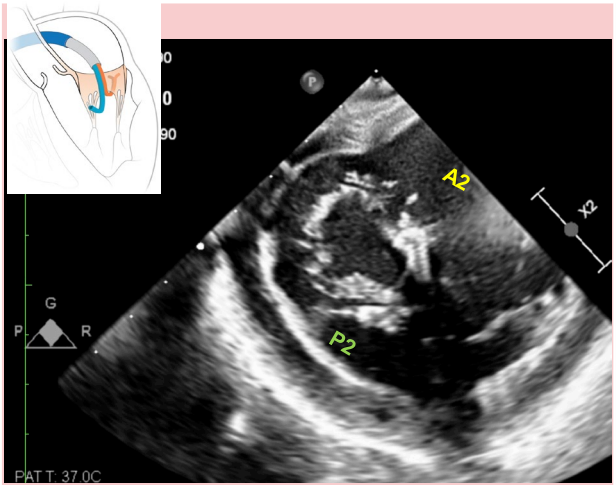
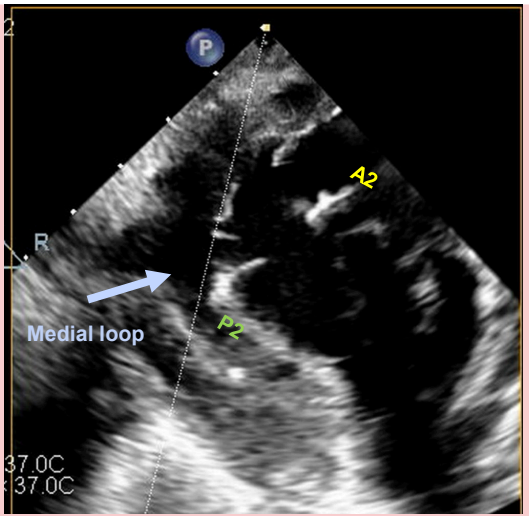
xMatrix 840 elements
90x90 Field of View
4-10 MHz

Clutch
Maintains deflections

Steering wheels
4-way steering for A/P and L/R

[1]VeriSight handling claims validated by clinician feedback collected from a bench study, with a sample size of 16 physicians and 16 technicians, totaling 32 clinicians. Clinicians also provided feedback based on images taken by VeriSight Pro in a porcine model. Data on file (D000259724).

Creation of Subannular Structure using 3D ICE Guidance

Mitral Valve Leaflets (ventricular view) by 3D ICE	GWDS positioned at A2 and P2	Wire entry at P2 to create medial loop
		

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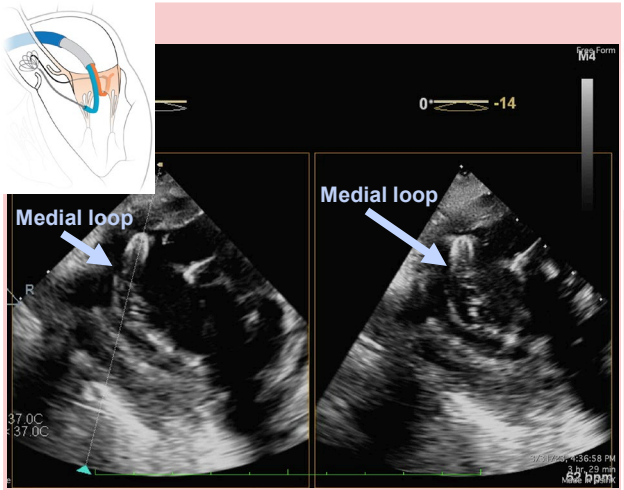
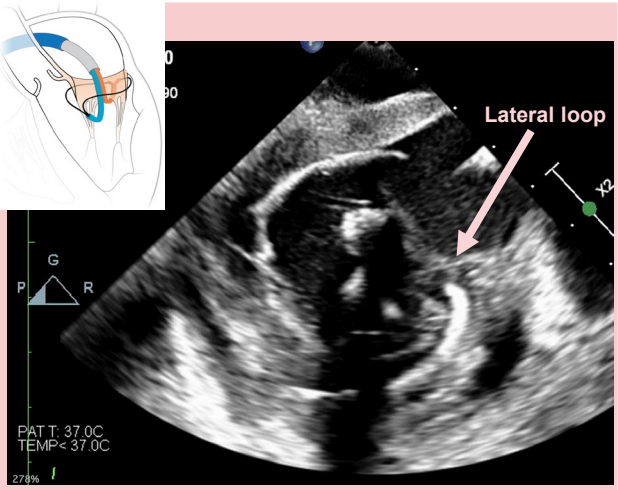
Creation of Subannular Structure using 3D ICE Guidance

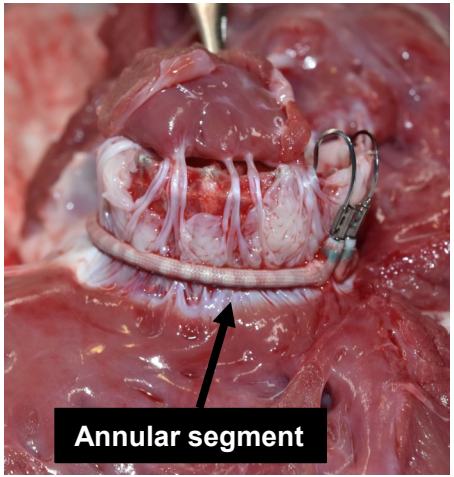
Medial Loop complete Wire exit at A2	Exit of Lateral Loop at A2	Completed subannular loops

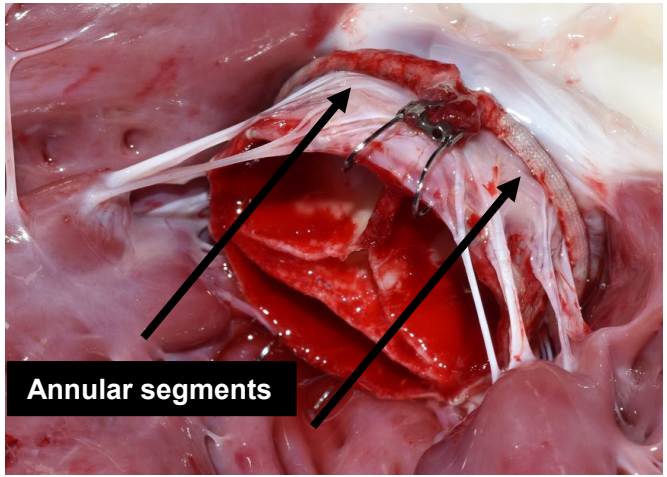




Procedural Success

- The mitral valve and subvalvular apparatus were successfully imaged in all animals.
- Necropsy demonstrated **complete capture of mitral chordae** and correct valve position in all animals.





Summary

- 3D ICE is a novel tool that is advantageous for visualization of anatomic structures and interventional tools that are not aligned in a single imaging plane.

- The electronic steering of the 3D ICE catheter facilitated guidewire visualization traversing the subannular grove.

- This study demonstrates successful utilization of 3D ICE guidance for transseptal SATURN TMVR.