



Latest Advances in LAAO

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REQUIRED

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Advisory Board, Consultant, Speaker's Bureau

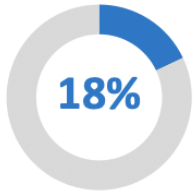
Phillips, Abbott Structural Heart, Boston Scientific

LAAO Projections



50K

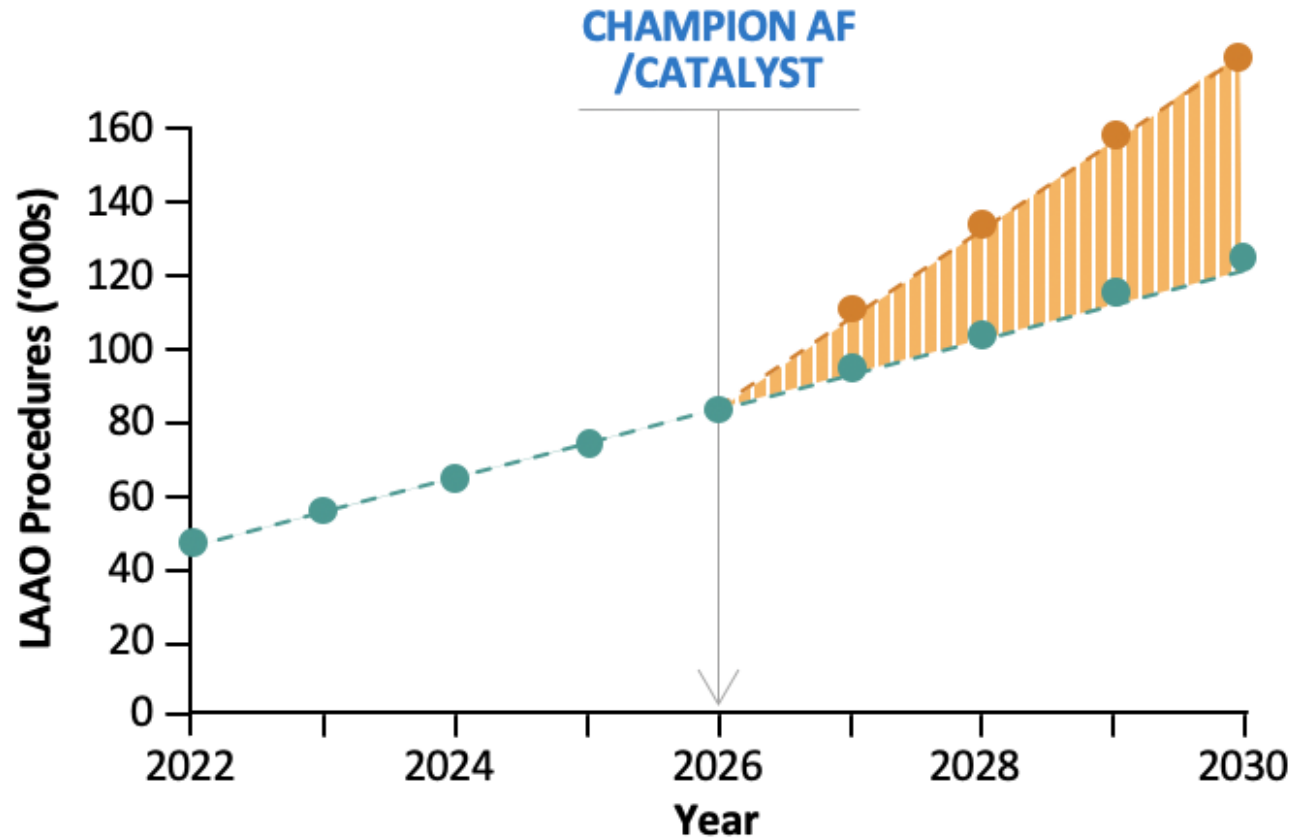
US LAAO endocardial procedures were conducted in 2022¹



18%

Market growth will accelerate at a CAGR of 18% (2021 – 2030)¹

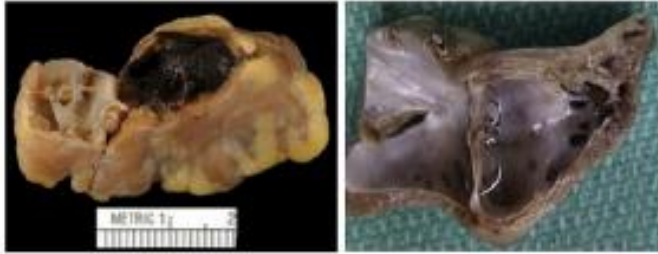
US LAAO procedure volumes predicted to increase yearly¹



LAAO Landscape + Future Goals

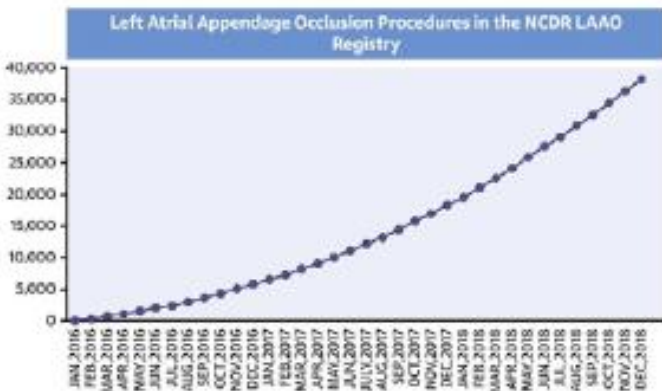
Evolution of LAAO

Concept
↓
Pivotal Trials
↓
Approval & adoption



5 Year Outcomes in PROTECT AF and PREVAIL		HR	P Value
Efficacy		0.82	0.30
All stroke or SE		0.96	0.90
Ischemic stroke or SE		1.70	0.08
Hemorrhagic stroke		0.20	0.0022
Ischemic stroke or SE >7 days		1.40	0.30
CV/unexplained death		0.59	0.03
All-cause death		0.73	0.04
Major bleed, all		0.91	0.60
Major bleeding, non procedure-related		0.48	0.0003

Favors LAAO ← → Favors Warfarin



Can we do it safer?

- Less exchanges
- One TSPx
- One device deployed

Can we do it faster?

- One device deployed
- One sheath used
- Minimalistic approach
- Less resources

Can we do it better?

- Complete seal
- No DRT

Operator Education
Operator Experience
Imaging Innovation
Tracking Outcomes
Device Innovation

Operator Education - Experience

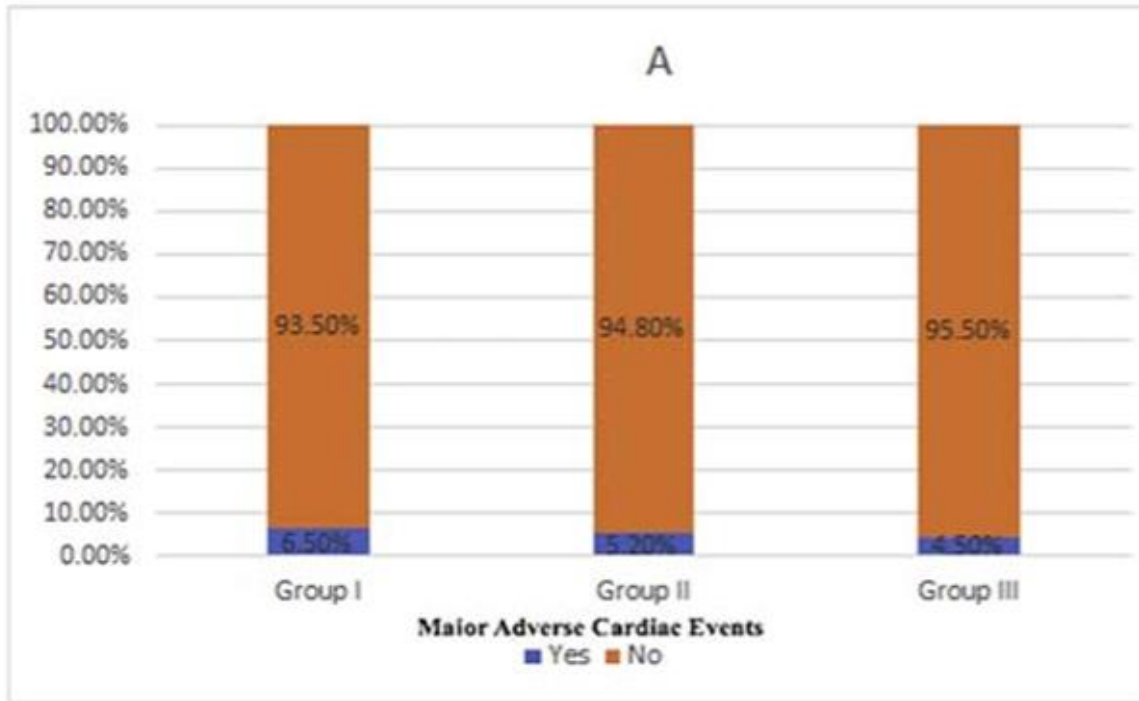
- **Concept, simple:**



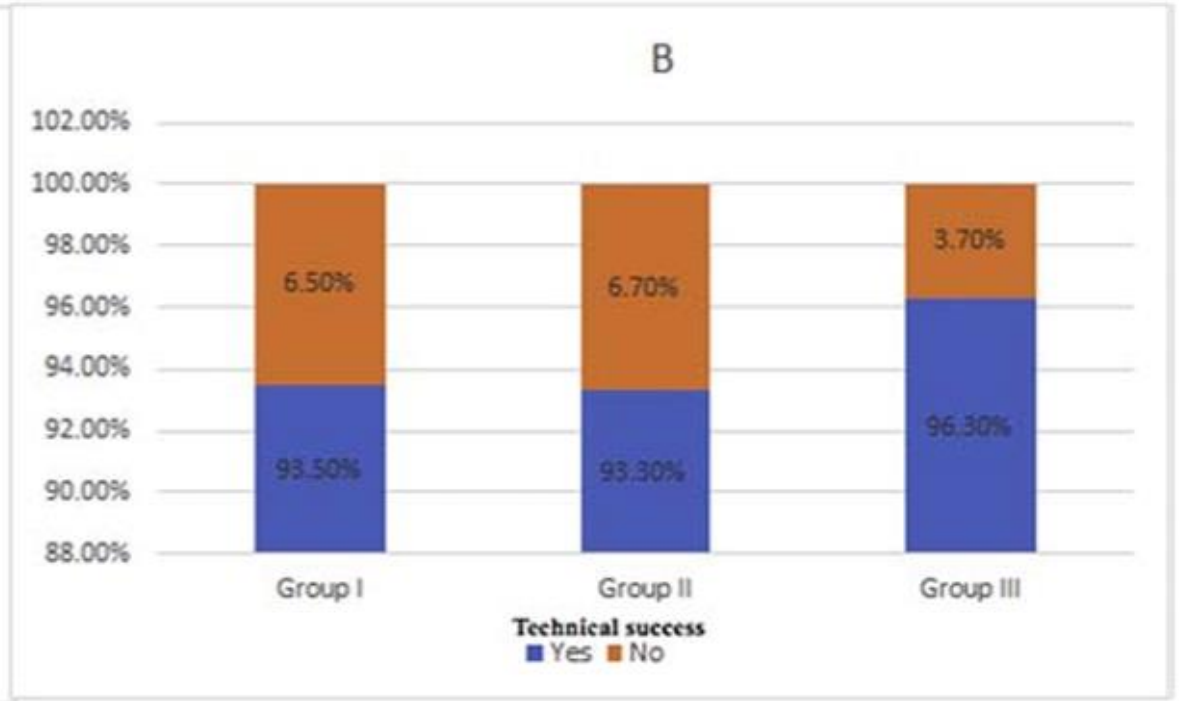
- **Not a procedure with symptomatic benefit:**
 - Safe
 - Reproducible
 - Should not increase risk of harm

Operator Education - Experience

MACE



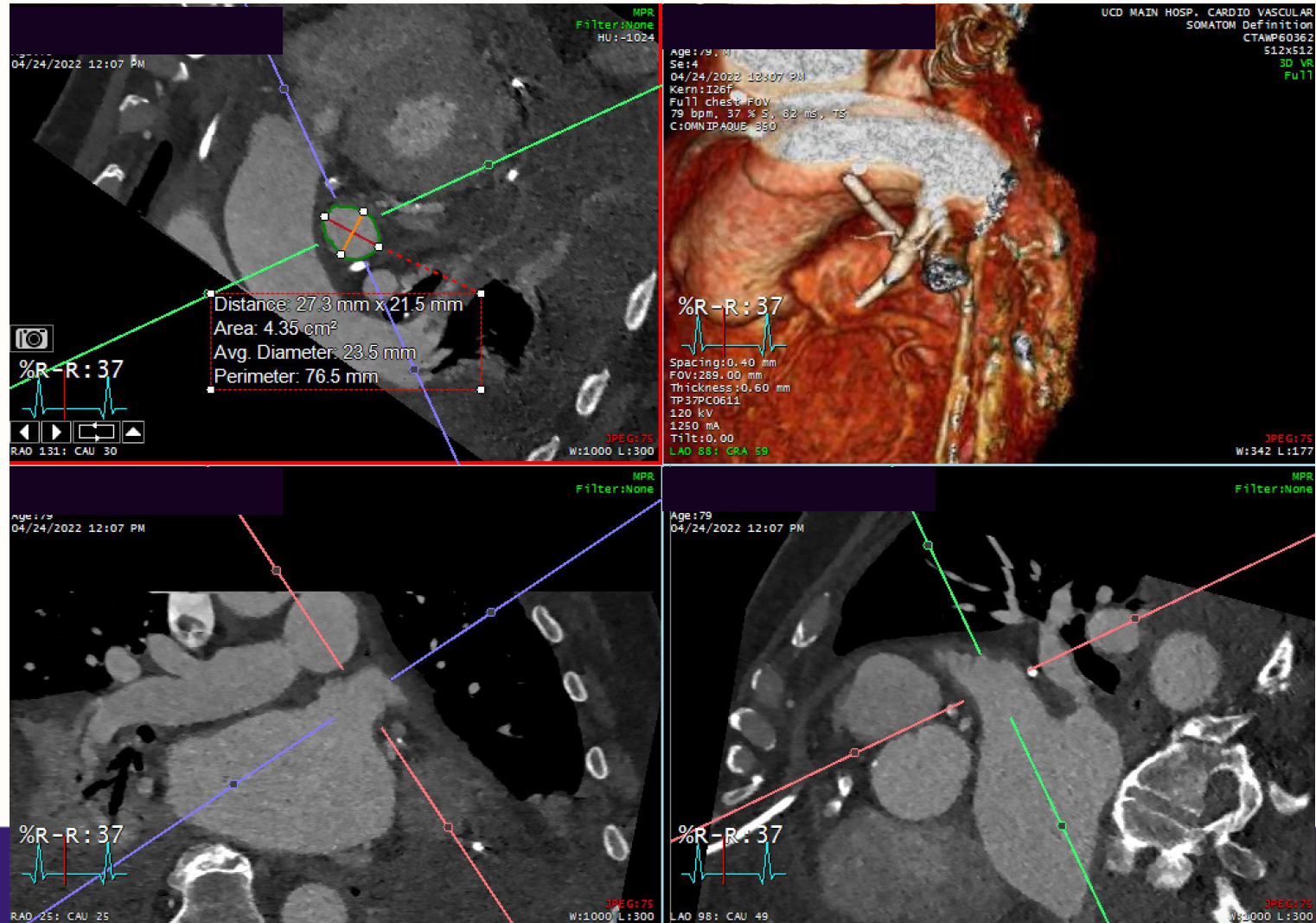
TECHNICAL SUCCESS



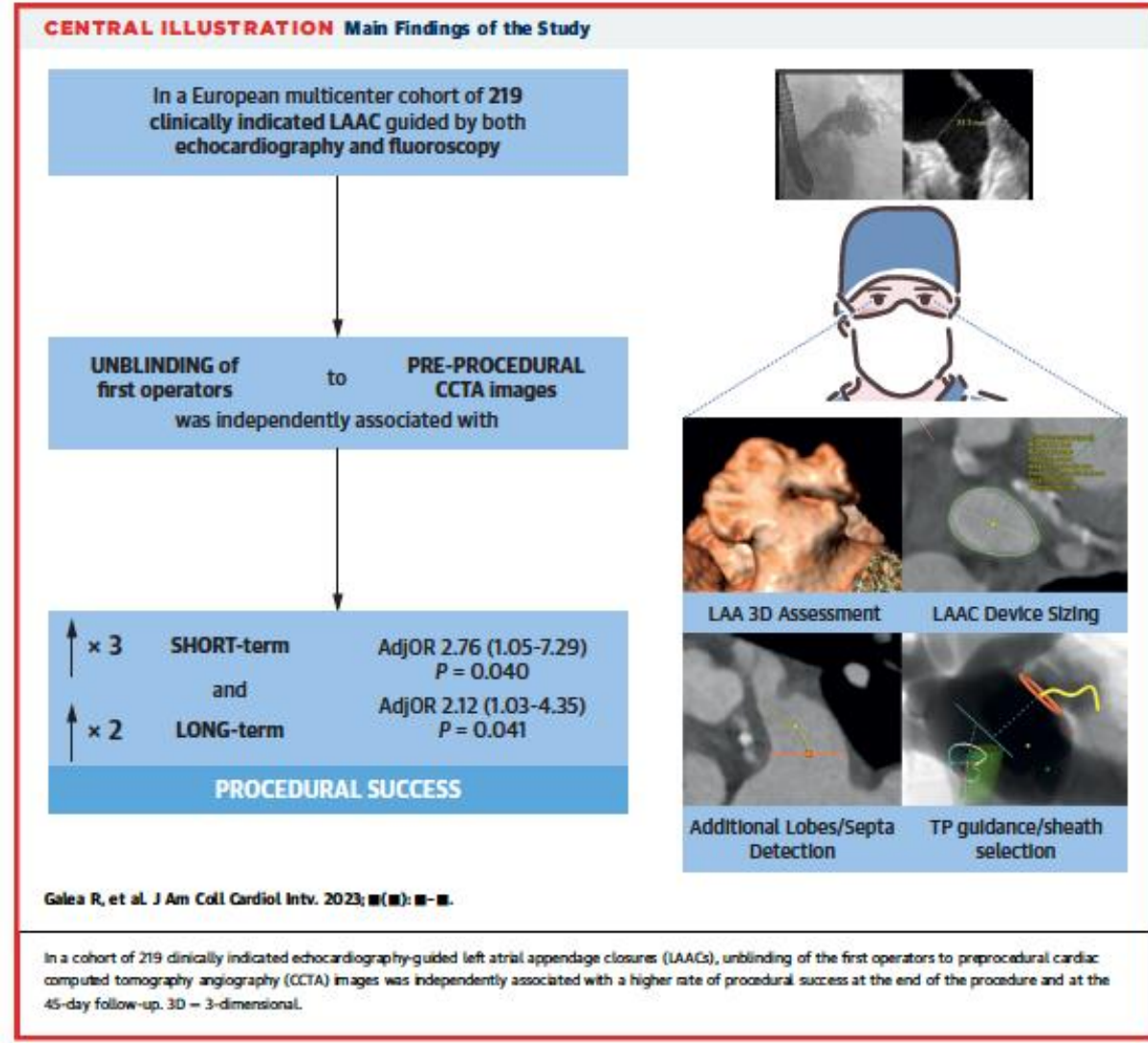
Group 1: < 40, Group 2: 41-80, Group 3: > 80

Innovation in Imaging: Pre-procedure CT Planning

- LAA dimensions
- Morphology (lobes, pectinates, etc)
- Trajectory
- Sheath type
- TSPx location



Innovation in Imaging: Pre-procedure CT Planning



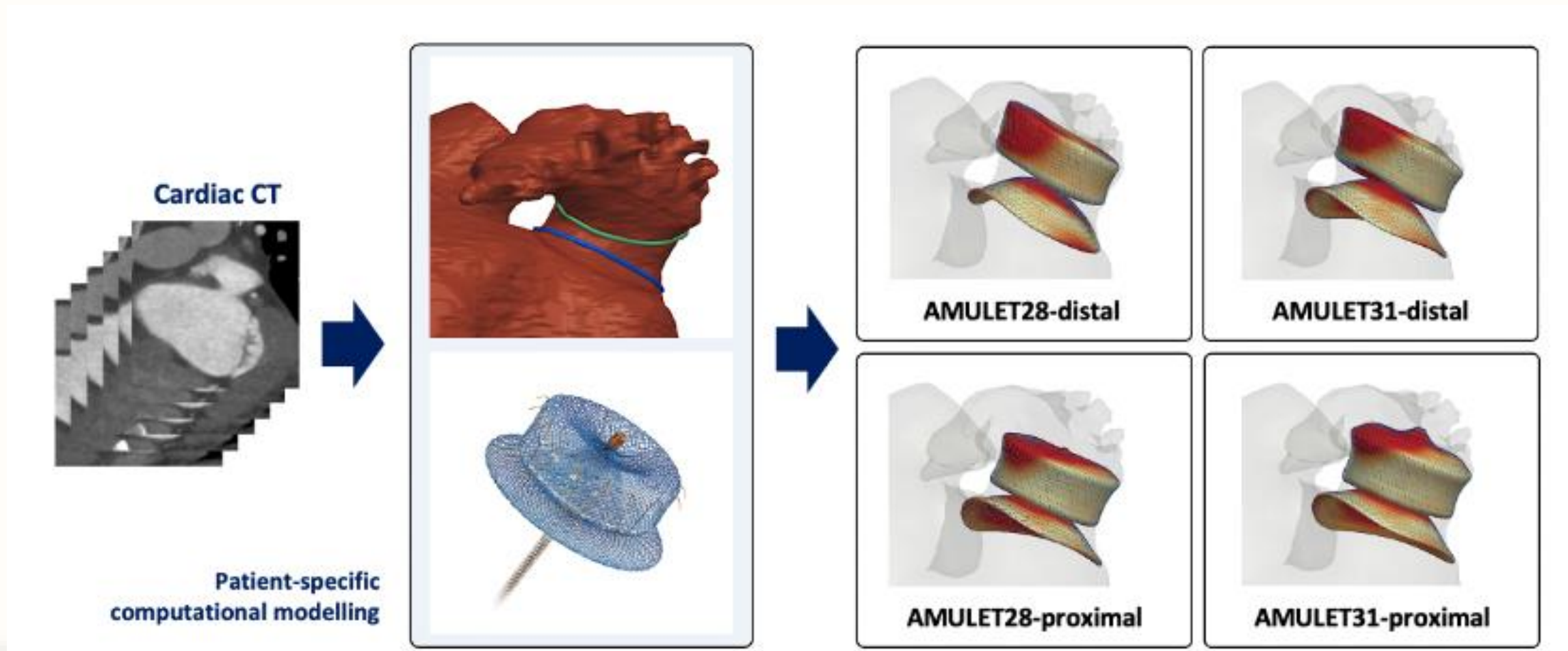
Innovative re-procedure CT Planning

The image displays a composite of the WATCHMAN TruPlan CT Imaging Software interface. Key components include:

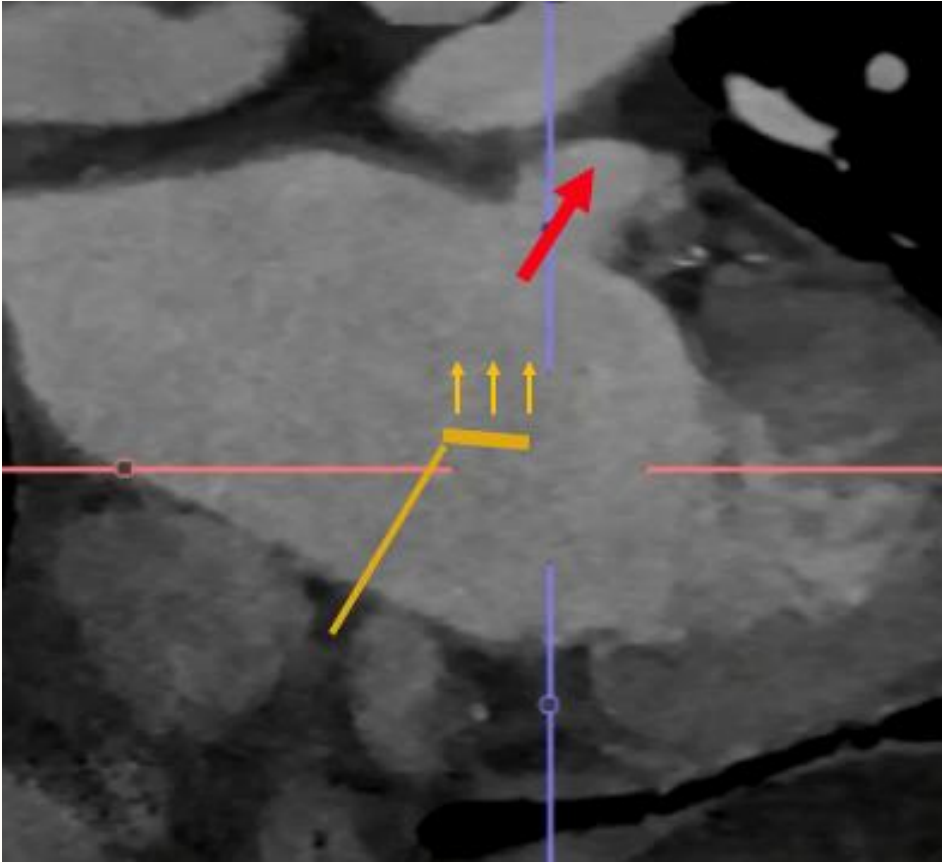
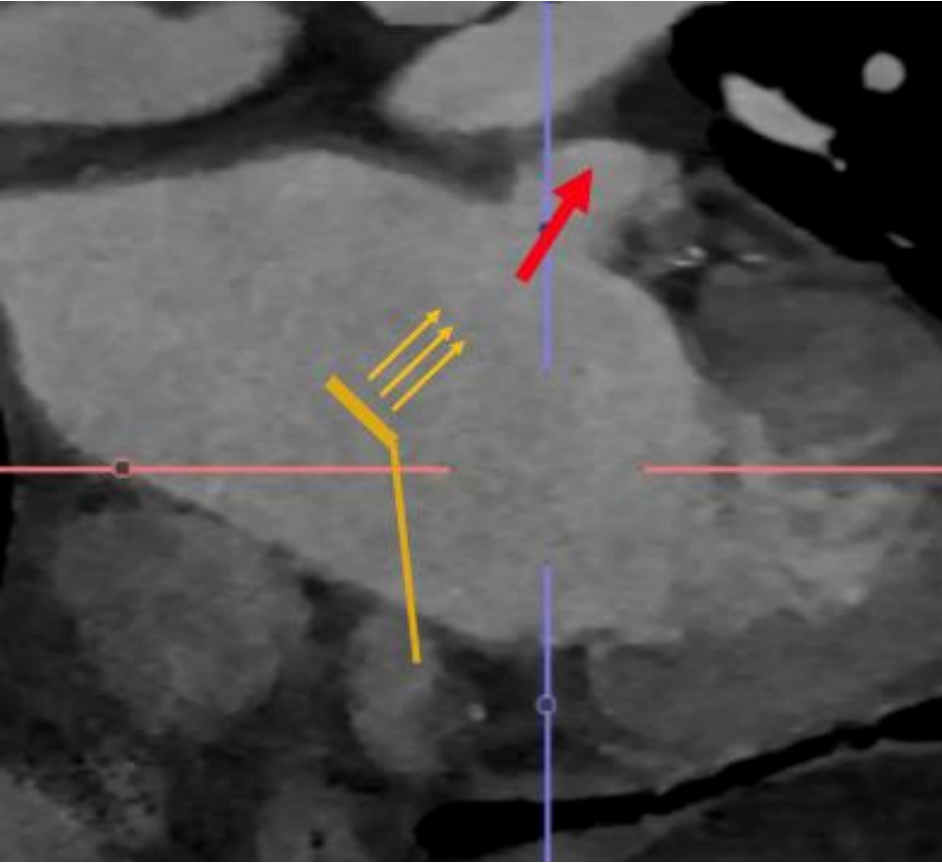
- Software Interface:** Multiple overlapping windows showing the software's layout. The top navigation bar includes tabs for LAA, FLUORO, TEE, ICE, THROMBUS, FOLLOW-UP, and MPR. The main area displays various CT scan views (axial, sagittal) with overlaid LAA measurements and device placement guides.
- Planning Report Details:** A central report window titled "WATCHMAN TruPlan CT Imaging Software" containing:
 - PLANNING REPORT DETAILS:** Creation Date: 2/16/2023 1:04 PM, CT Scan Date: Physician: hspj04, Patient: WCS-CT-TRAINING-04.
 - PATIENT INFORMATION:** Patient: WCS-CT-TRAINING-04, Age: [redacted], Gender: [redacted].
 - LAA INFORMATION:** A table with columns for measurement type and value.

Measurement	Value
Max Diameter	35.5 mm
Min Diameter	21.9 mm
Avg Diameter	27.4 mm
Area	396.2 mm ²
Perimeter	113.2 mm
Depth	18.0 mm
 - WATCHMAN FLX™ Left Atrial Appendage Closure Device Sizing Chart:** A chart showing device sizes (25mm, 30mm, 35mm) corresponding to LAA diameters. A red bar indicates the selected size is 35mm.
 - PERIL THRESHOLDING:** A section for setting measurement thresholds.
 - COMMENTS:** A field for user notes.
- 3D Models:** A separate window showing 3D anatomical models of the Left Atrial Appendage (LAA) and the WATCHMAN FLX™ device, with labels for "Endocardial" and "LSP/LAA Intacardiac Ridge".
- CT Scans:** Multiple axial CT slices showing the LAA and the device's position relative to the heart anatomy.

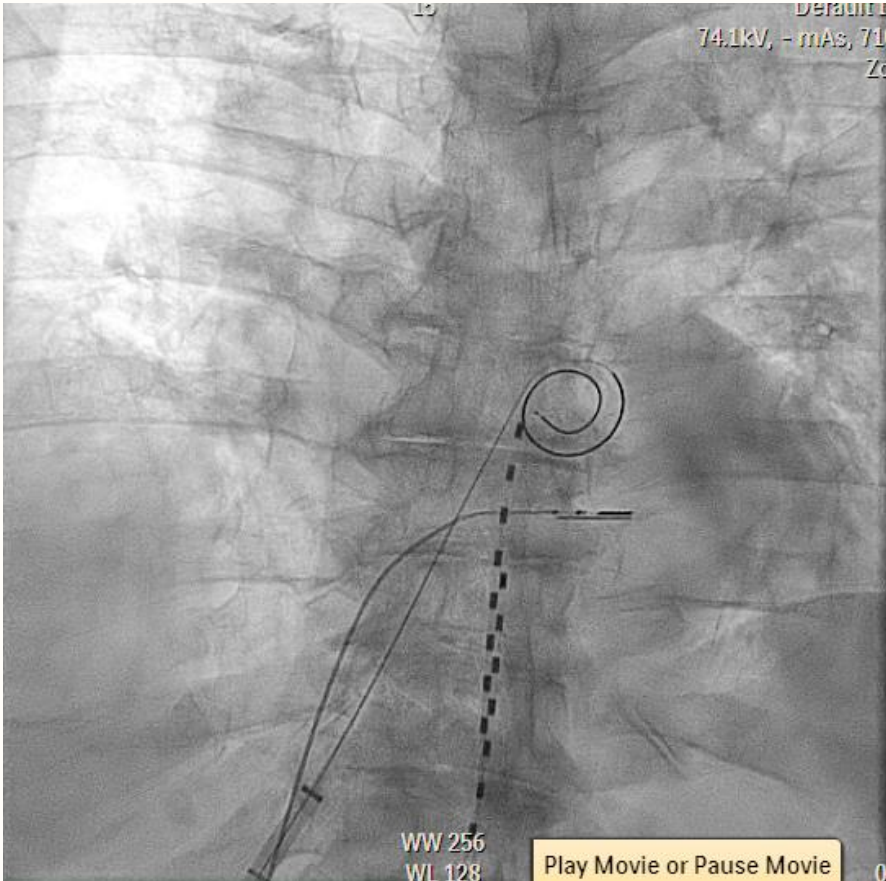
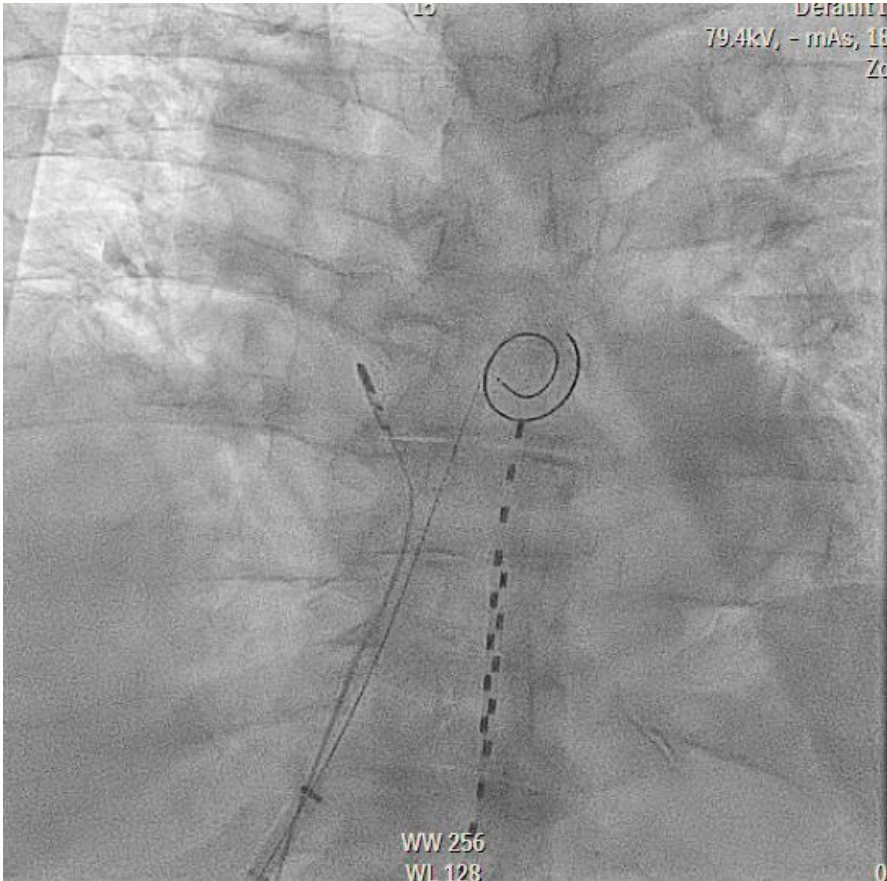
Innovation in Imaging: Pre-procedure CT Planning



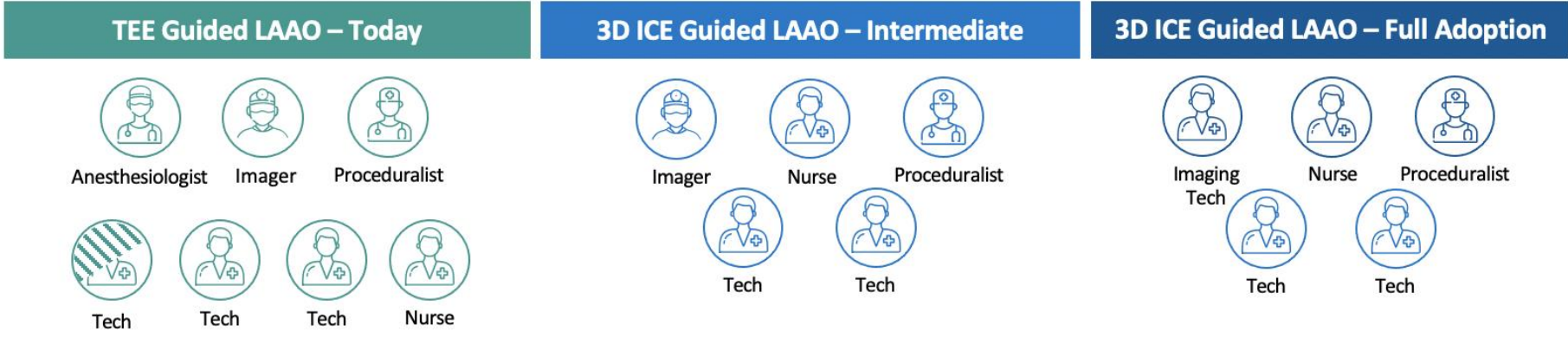
3D ICE - LAAO



3D ICE - LAAO



CT screening and ICE may possibly relieve growing bottleneck



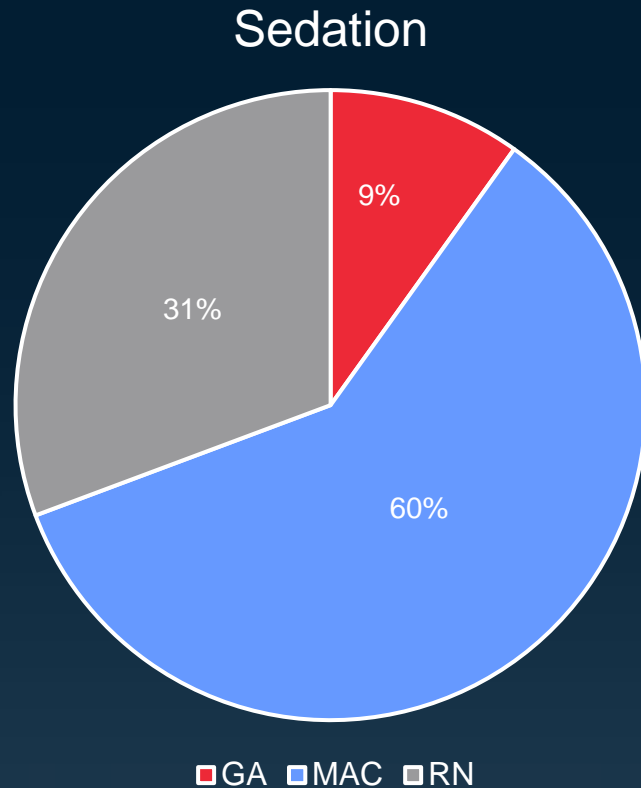
	TEE Guided LAAO – Today	3D ICE Guided LAAO – Intermediate	3D ICE Guided LAAO – Full Adoption
Physician #	3	2	1
Staffing	3-4 Staff	3 Staff	4 Staff
Scheduling	Challenging / Further Out	Moderate	Easy / Prompt
Procedure Day	Higher Risk of Delays	Medium Risk of Delays	Low Risk of Delays
Total Room Time	113 mins (published avg)	80 min (published avg)	80 min (published avg)
Same Day Discharge	More limitations	Less Limitations	Less Limitations

3D intracardiac echocardiography (3D-ICE) guided transcatheter left atrial closure (LAAC): Results from a single center registry

*Tai H. Pham¹, Carter W. English¹, Edris Aman¹, Kwame Atsina¹,
Benjamin Stripe¹, Jason H. Rogers¹, Gagan D. Singh¹*

¹University of California, Davis Division of Cardiovascular Medicine

Results



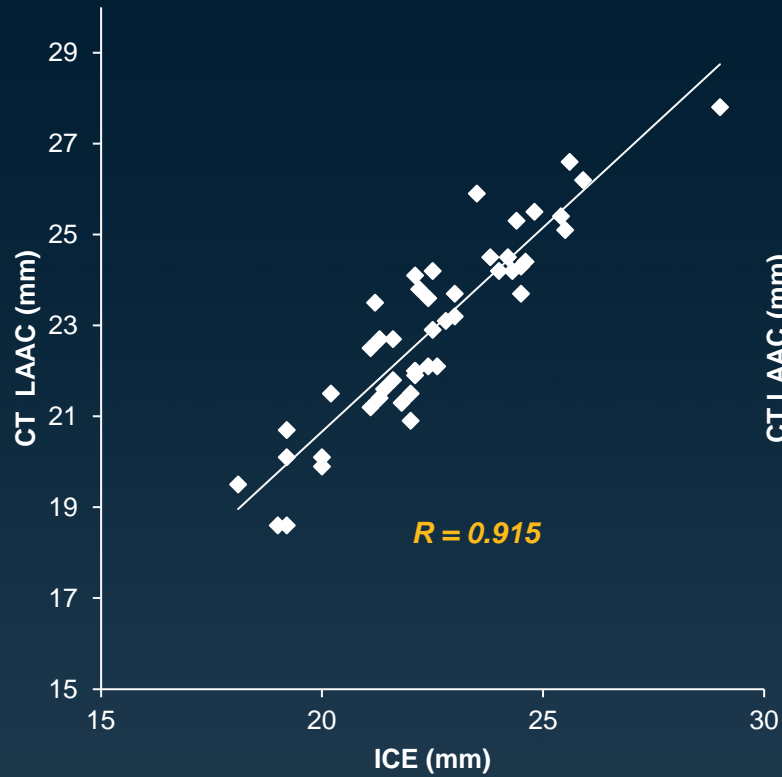
Procedural	N = 57
Time ICE to cross (min)	2:30 ± 1:56
Adjunctive PTA (n)	4 (7.0)
Fluoro time (min)	20.0 ± 5.9
Procedural time (min)	62.5 ± 12.1
Average hospital stay (days)	1.7 ± 0.5
Technical success (%) *	100
Procedural success (%) ^	100

* Technical Success: no TEE conversion, closure with PDL < 5mm

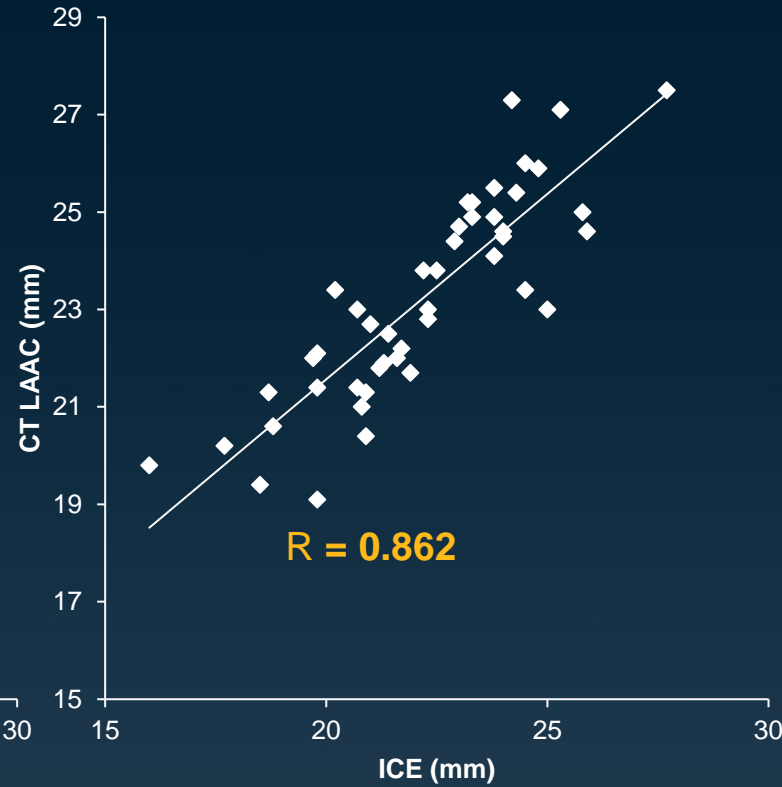
^ Procedural Success: device success and no in-hospital device or procedural related issues

CT LAAC vs ICE – Post-deployment

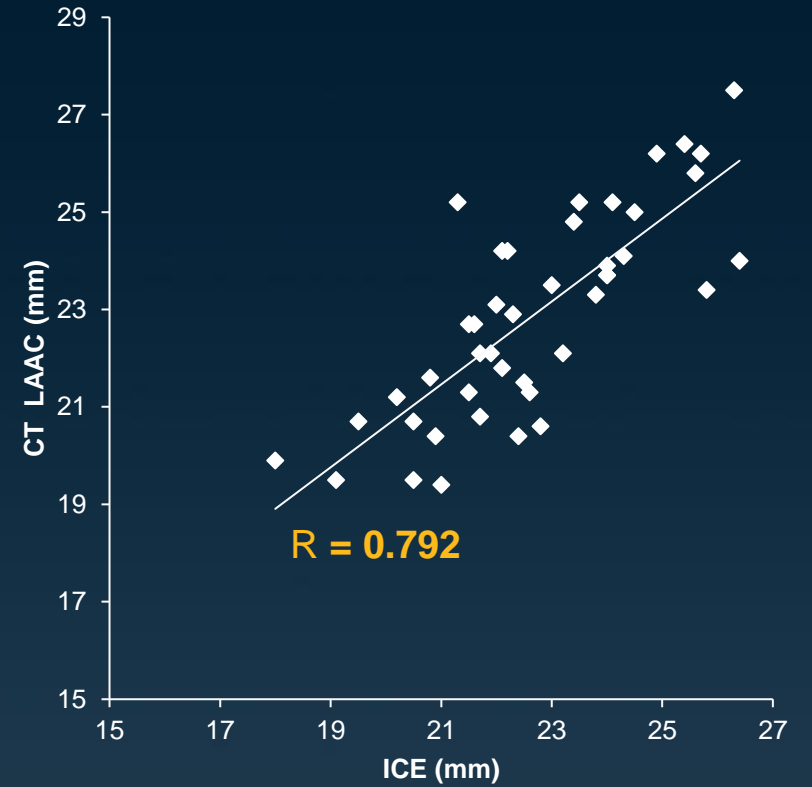
Device Diameter Ao View



Device Diameter MV View

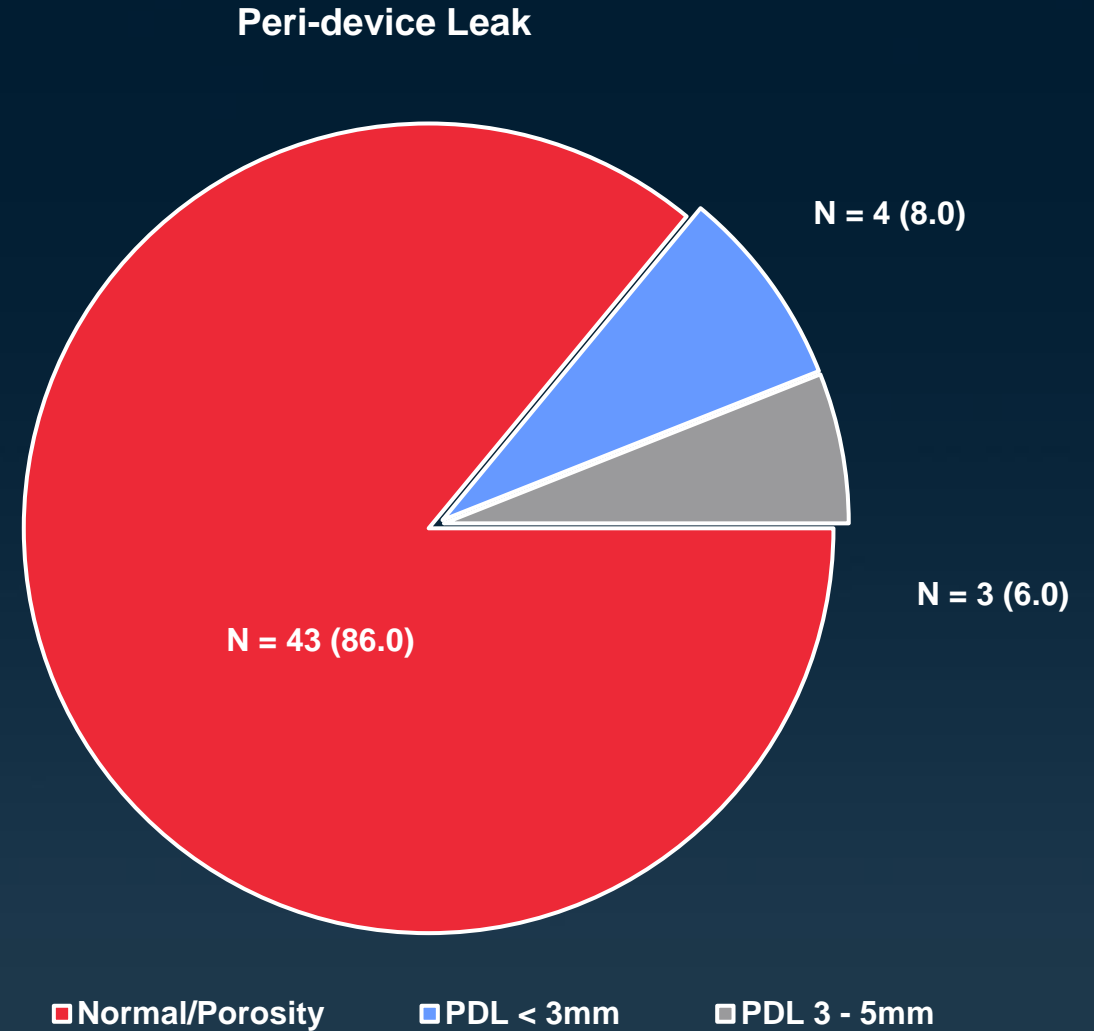


Device Diameter PV View



Follow Up

- One patient passed post-discharge from unrelated causes, one suffered spontaneous RP bleed during follow up period
- Incidence of PDL > 3mm was 6%. No PDL > 5mm
- No DRT on follow up imaging and all patients were able to discontinue anticoagulation
- No MACE, device embolization, or pericardial effusion



Device Innovation

WATCHMAN FLX™ Pro

LEFT ATRIAL APPENDAGE CLOSURE DEVICE



Featuring
HEMOCOAT™
Technology

Design Goals:

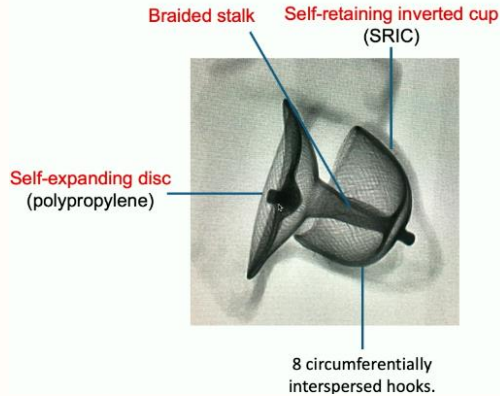
Reduce Device
Related Thrombus

Post-Approval
Monotherapy Study

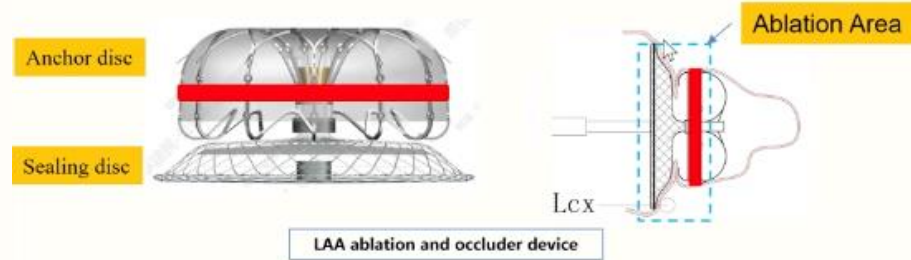
Reduce
Untreatable LAAs

Improve Seal
Performance

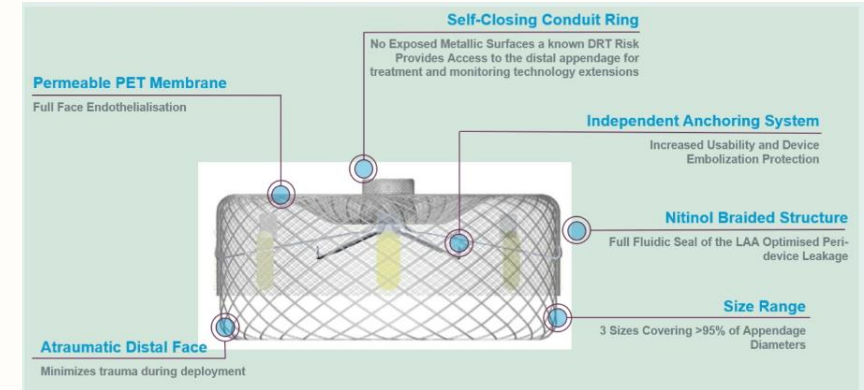
Device Innovation - 2023



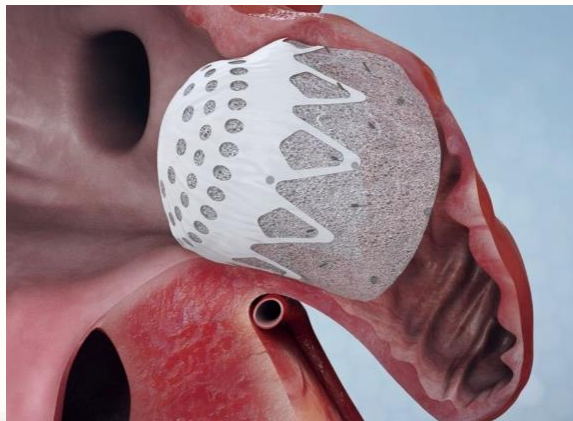
OMEGA



E-SealLA



Zenith



Conformal

Type I
without disc
(plug shape)



Type II
with proximal
disc

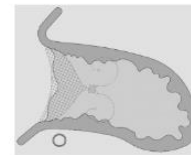


Cormos

IDEA: Red wine stopper



DESIGN: The thick plug



PRODUCT: The Leftear® LAA Occluder



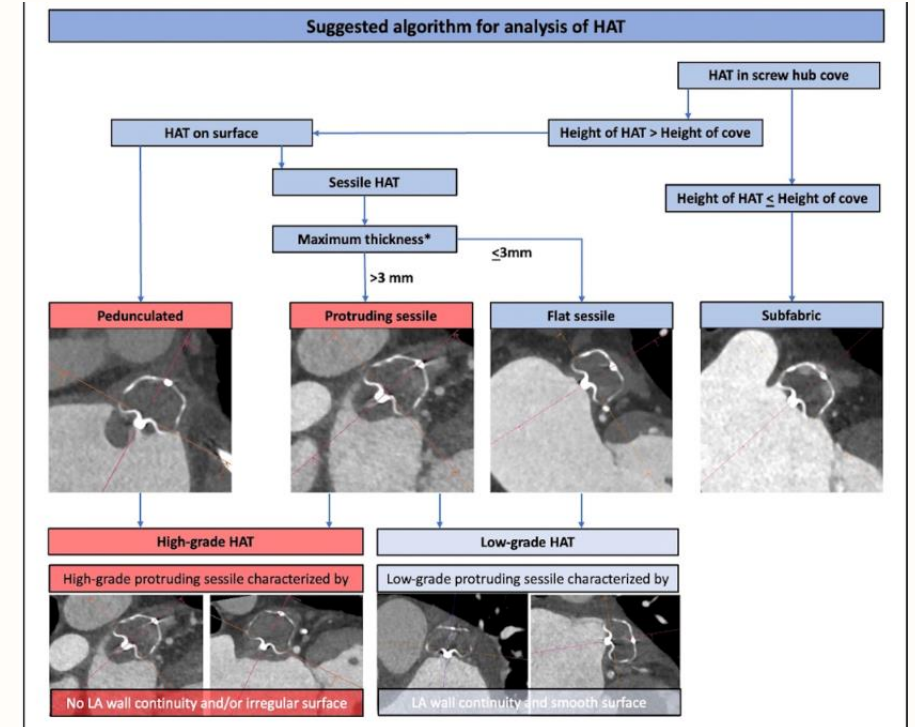
The fixed disc looks like an umbrella, with a 1-mm barb on each of the eight frames for withdrawal and re-position.

The sealing disc is an isosceles trapezoid-shaped three-dimensional network structure.

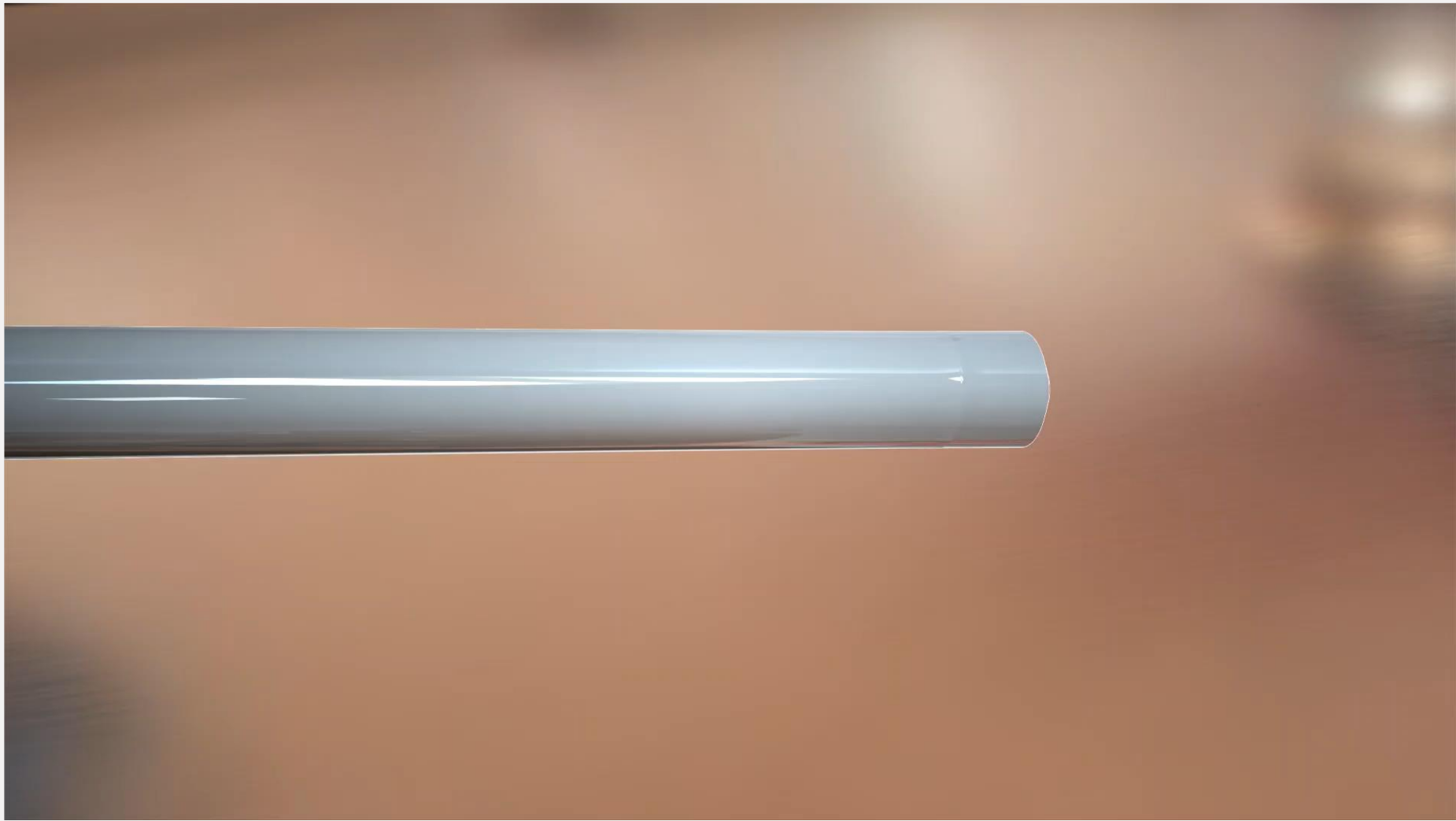
Leftear

Device Innovation

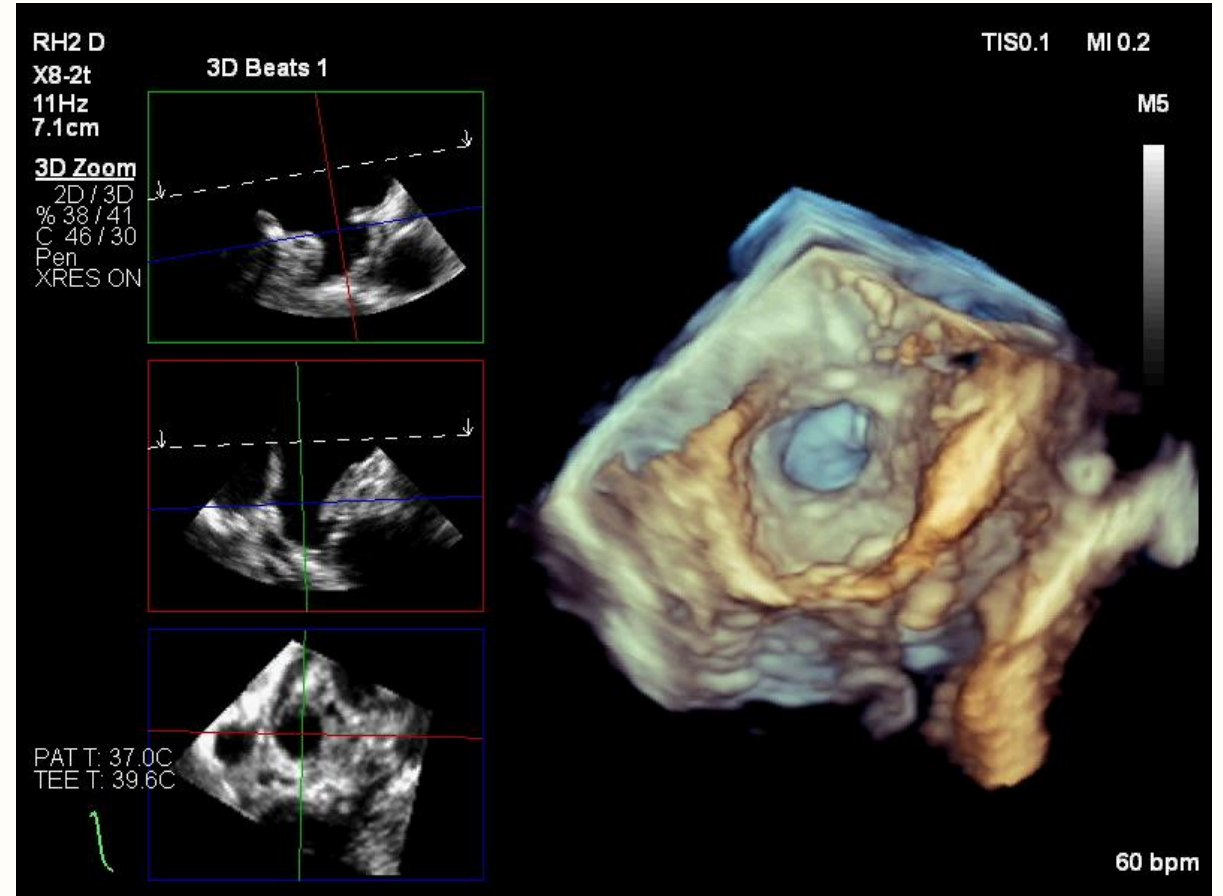
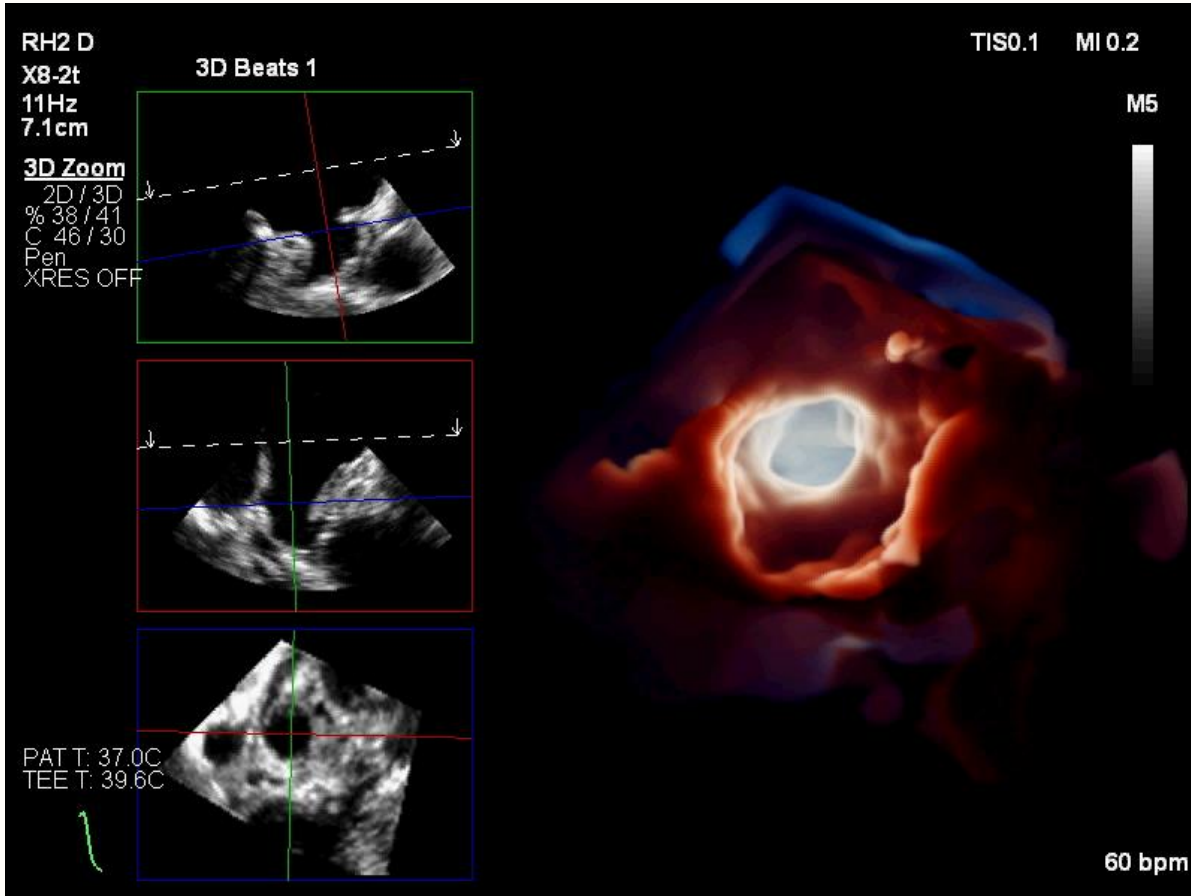
- Current generation devices: “all forms of plugs”
- Varying PDL rates. Implications of PDL still debated
- Clinical significance of low risk vs high risk DRT/HAT



Device Innovation – Left Atrial Appendage Exclusion (LAAX)

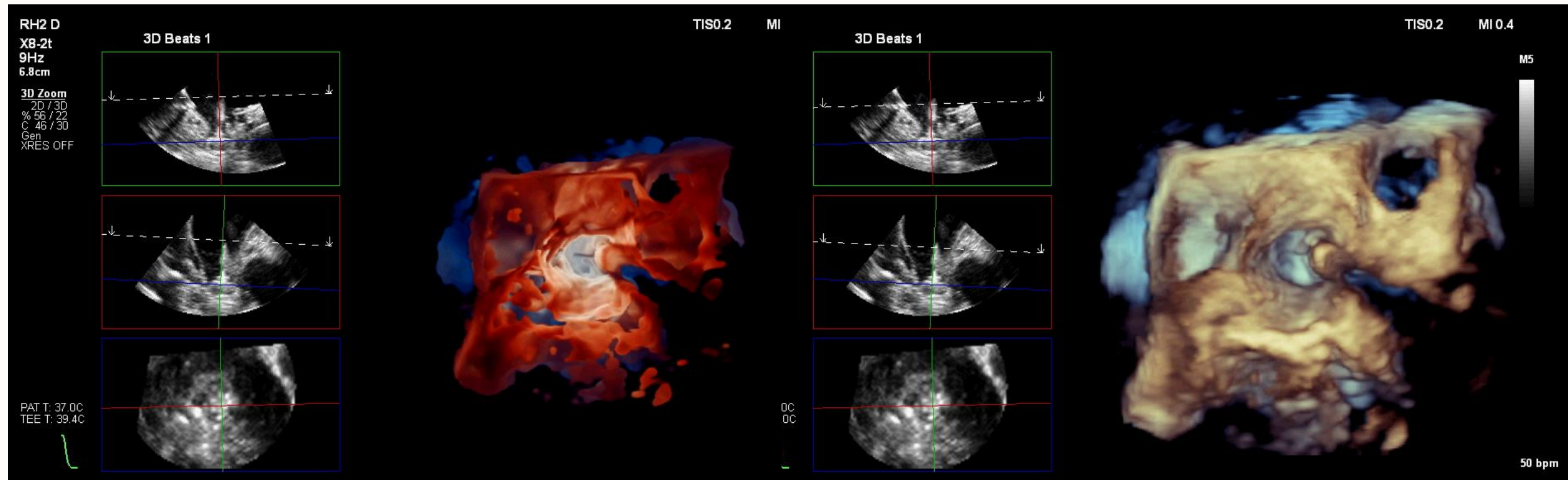


LAA Pre-Procedure



Courtesy of Hahn R, Vahl T, Sommer R, Columbia University

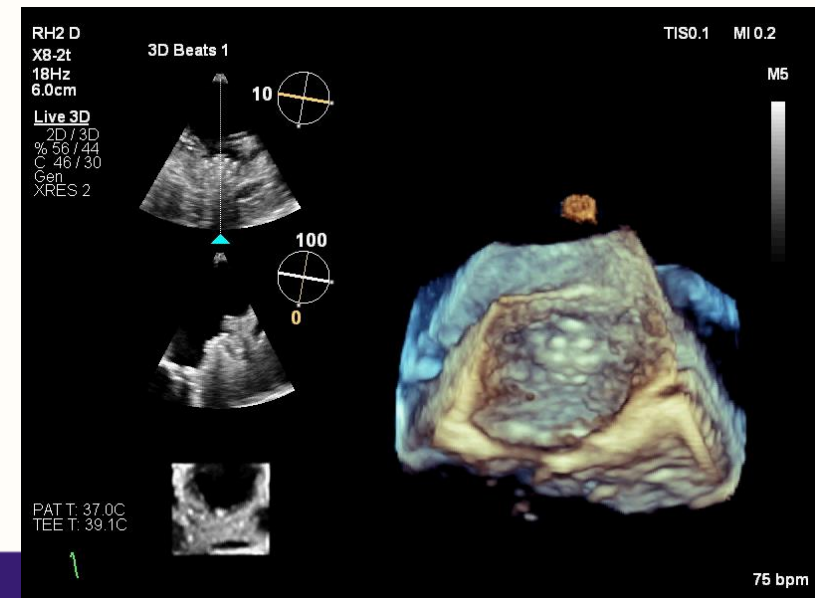
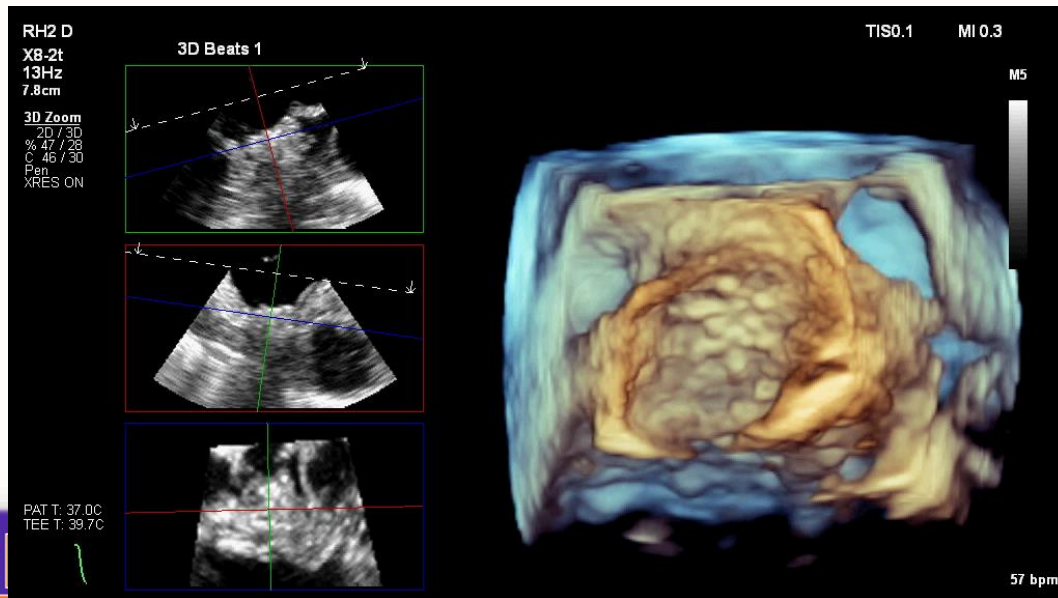
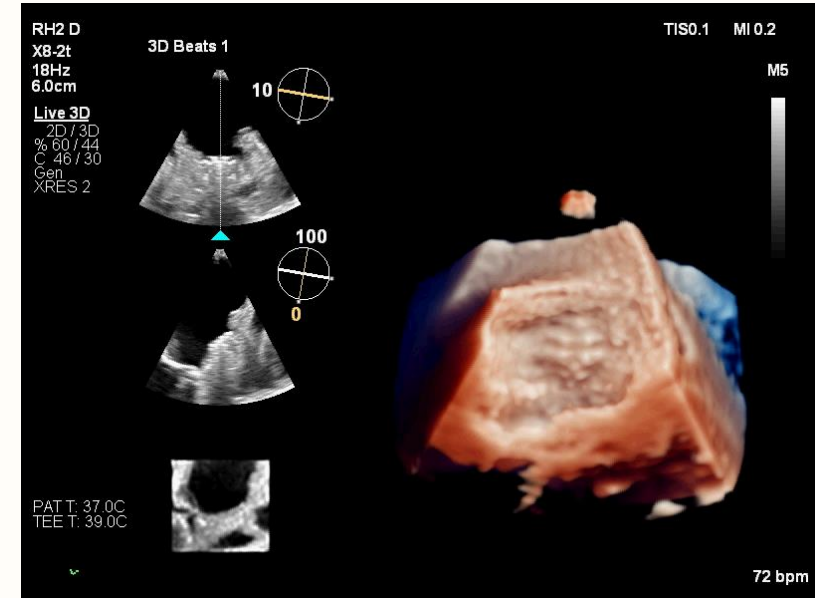
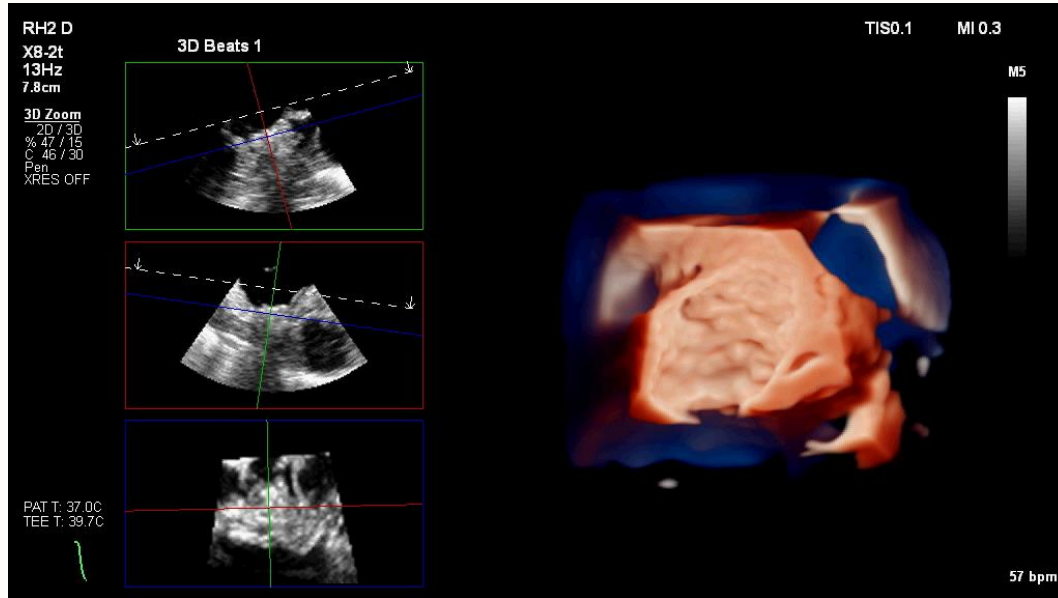
Rotational Closure



Courtesy of Hahn R, Vahl T, Sommer R, Columbia University

Immediate Post-Procedure

45 day Follow-Up



Courtesy of Hahn R, Vahl T, Sommer R, Columbia University

Final Thoughts – LAAO Innovation Landscape

- **Devices innovation – somewhat stagnant**
 - Exception: Laminar. LAAO -> LAAX
- **Increasing use of CT for pre- and post- LAAO**
- **Increasing use of 3D ICE**
- **Collectively, increasing...**
 - Increasing reproducibility, safety, same day discharge programs
 - Decreasing PDLs, DRTs
- **Important to prepare for increase in eligible patients**