

Clinical Case: Transcatheter tricuspid valve repair

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National PI for the SCOUT Trial

Disclosures

- ◆ Core Lab Director for multiple tricuspid device trials for which I receive no direct compensation:
 - SCOUT Trial
 - Triluminate Trial
 - Tri-Repair Trial
- ◆ Speaker: Abbott Structural, GE, Philips, Boston Scientific
- ◆ Consultant: Gore&Associates, NaviGATE, Abbott Structural, GE, Philips

Trialign Transcatheter Repair: Technology Overview

- Based on Surgical Predicate (Posterior Annuloplasty)
- Small footprint
- Ability to customize location and plication distance in tricuspid annulus
- Front line therapy leaves a significant amount of native anatomy undisturbed
- ◆ Customizable for # of pledgets implanted

Wire Placement



Pledget Delivery

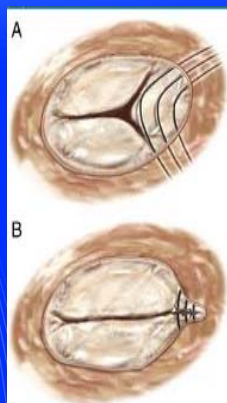


Plication & Lock

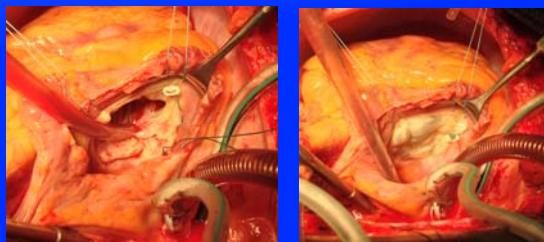


Surgical Bicuspidization (Kay Procedure)

Classic Kay
Procedure



Modified Kay



- **Caveats:**
- Running sutures to prevent dehiscence
- Distance from APC to SPC is often >4cm
- Maximum pledget span is 2.8cm

Clinical Case

- ◆ 64 y.o female with Past Medical History:
 - HTN, hyperlipidemia, NIDDM (HA1c 6.4 on 12/18/15), asthma, COPD (not on oxygen or intubated for), RHD s/p s/p mitral commissurotomy 1981 and re-op mechanical MVR in 2001 (#25 St. Jude valve) with UGIB 2013 in setting of supra-therapeutic INR, A- fib and CVA 2006 (no residual deficits), chronic diastolic CHF (EF 70%)
- ◆ Chief Complaint:
 - Worsening shortness of breath that resolves with rest and is associated with chest tightness when walking >2 blocks with worsening fatigue and "low energy".
 - Recent cardiac catheterization: normal coronary arteries
 - Echocardiogram: normal St. Jude MVR, aortic valve sclerosis, 4+ tricuspid regurgitation with dilated but normally functioning right ventricle.
- ◆ Presents now for Transcatheter Tricuspid Valve Repair

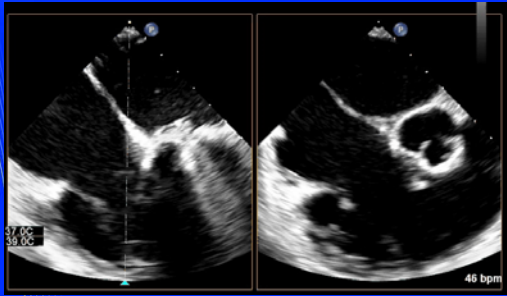
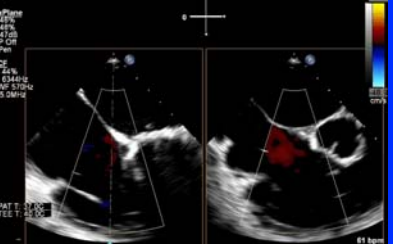
Baseline Parameters

- | | |
|--|---|
| <ul style="list-style-type: none"> ◆ Medications <ul style="list-style-type: none"> • Carvedilol 3.125 mg PO BID • Furosemide 80 mg PO QD • Spironolactone 25 mg PO QD • Advair Diskus 500 mcg-50 mcg BID • Coumadin 3 mg PO QD • MetFORMIN 500 mg PO BID • Pravastatin 40 mg PO QD | <ul style="list-style-type: none"> ◆ Baseline Clinical Evaluation <ul style="list-style-type: none"> ◆ MLWHF (QoL Questionnaire) = 50 ◆ 6MWT = 228.6 meters |
|--|---|

Baseline Echo


- ◆ Posterior sub-annular trabeculation
- ◆ Septal leaflet tethering
- ◆ TR Jet elliptical

Key Patient Data	
LVEF	69%
Forward Stroke Volume	43.6 cc
RVEF	60%
RA Volume	86.4 cc
TR Grade	Severe
Regurgitant Volume	75 cc
EROA	0.77 cm ²
TAPSE	1.3 cm
Tenting Distance	0.76 cm
TR PISA Radius	0.98 cm
PAPs	34 mmHg
TV end-diastolic Diameter	4.14 cm

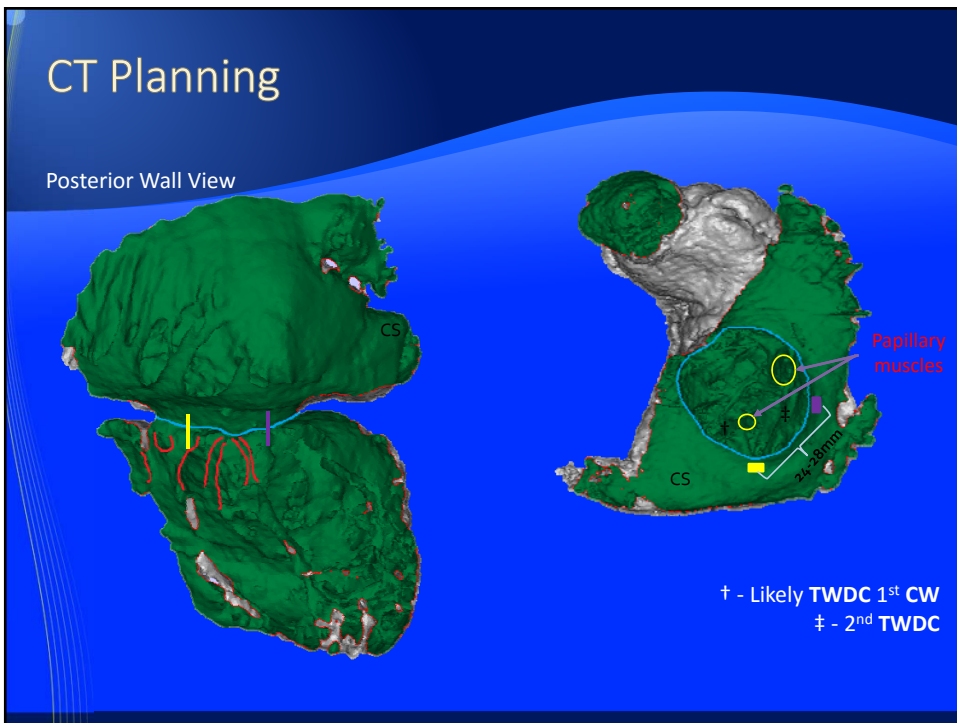
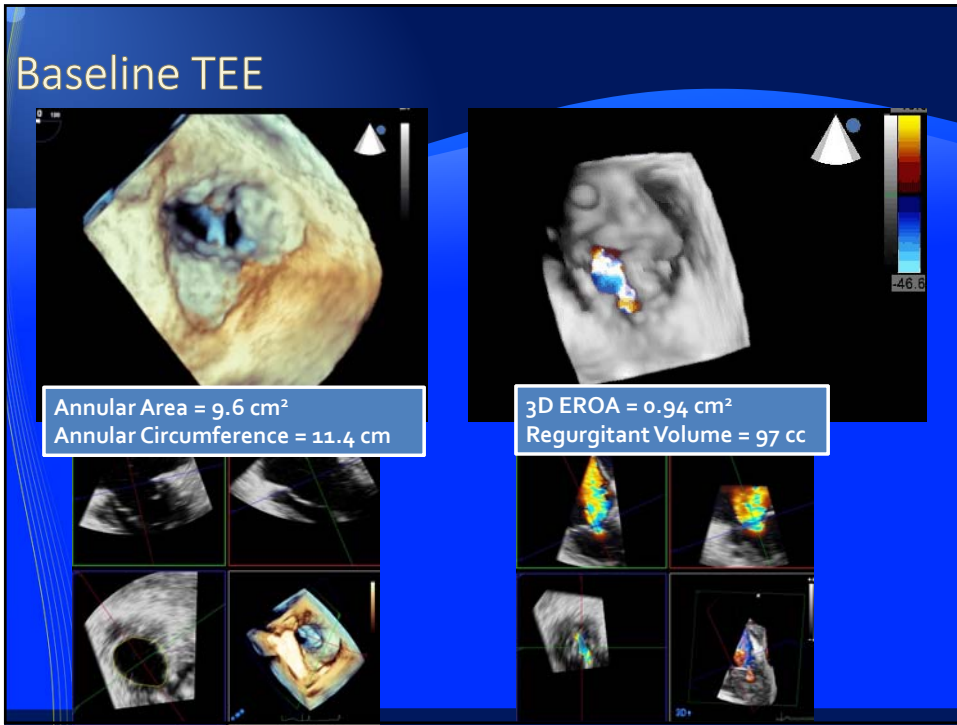



Intra-procedural Quantitation: Baseline

3D EROA



Parameter	
Tricuspid Annular Area	9.6 cm ²
Tricuspid Valve Area	6.04 cm ²
Tricuspid EROA	0.94 cm ²
Tricuspid Regurgitant Volume	97 cc
Forward Stroke Volume	43.6 cc



CT Planning

Pectinate muscle may resemble CW on Echo

Place CW behind or just beside muscular ridge (Red)

Trabeculae may increase depth at AP location.

Posterior-Septal Implant Location

Anterior-Posterior Implant Location

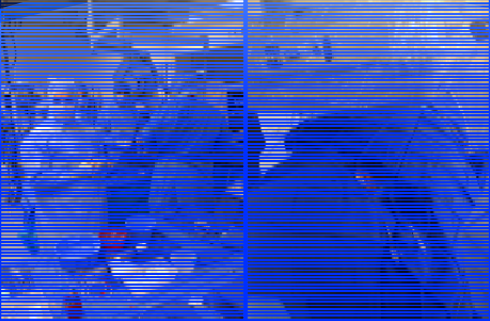

Confidential

Trialign: PERCUTANEOUS TRICUSPID VALVE ANNULOPLASTY SYSTEM (PTVAS)



Bicuspidization of the TV with the Mitralign System

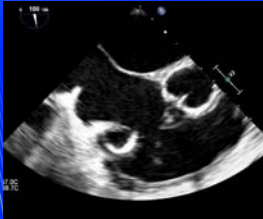
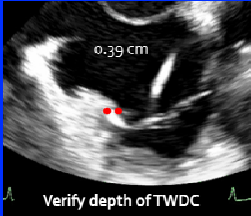

Procedural Steps

- **Right Internal Jugular Access**
- **Two 14F Sheaths**
- Position wire delivery to deliver 1st pledget (anchor)
- Repeat wire delivery steps to deliver 2nd pledget (anchor)
- Cinch pledgets together to obliterate the posterior leaflet and deliver lock on atrial side





1st Tricuspid Wire Delivery Catheter

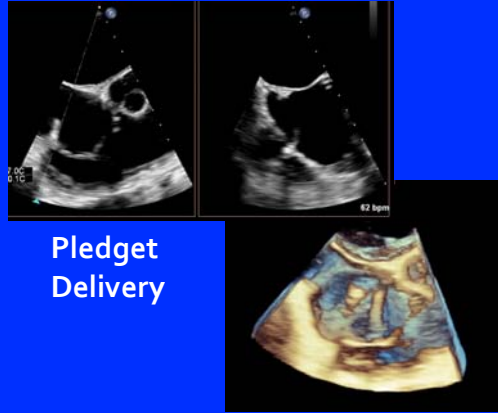
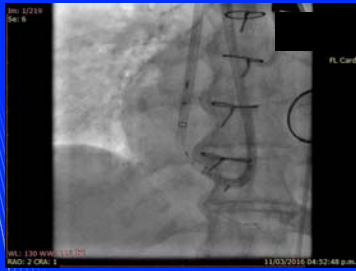




Verify position/depth



- Tricuspid Wire Delivery Catheter shaft in the correct position in the TV orifice with tip pointed toward the outside

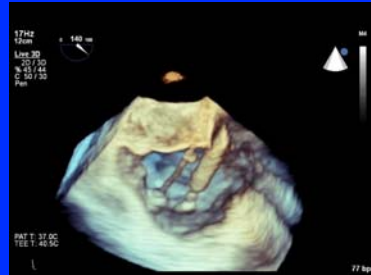
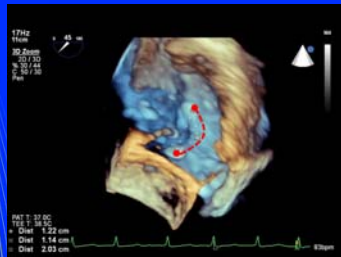
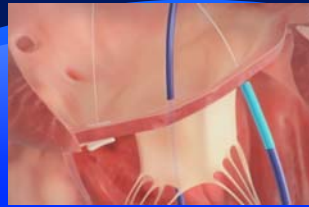
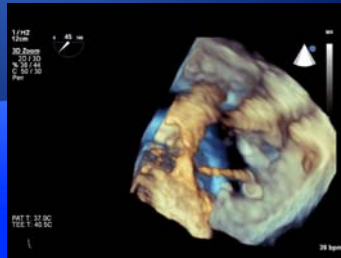
Pledget Delivery



Pledget Delivery

Pledget Delivery Catheter (PDC) Annulus Crossing

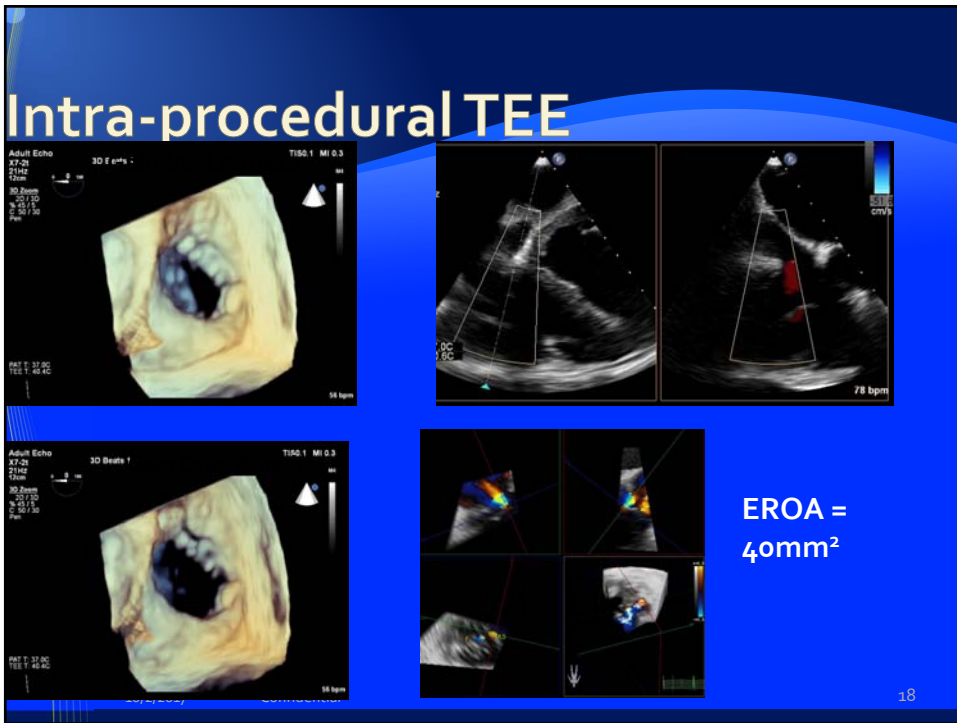
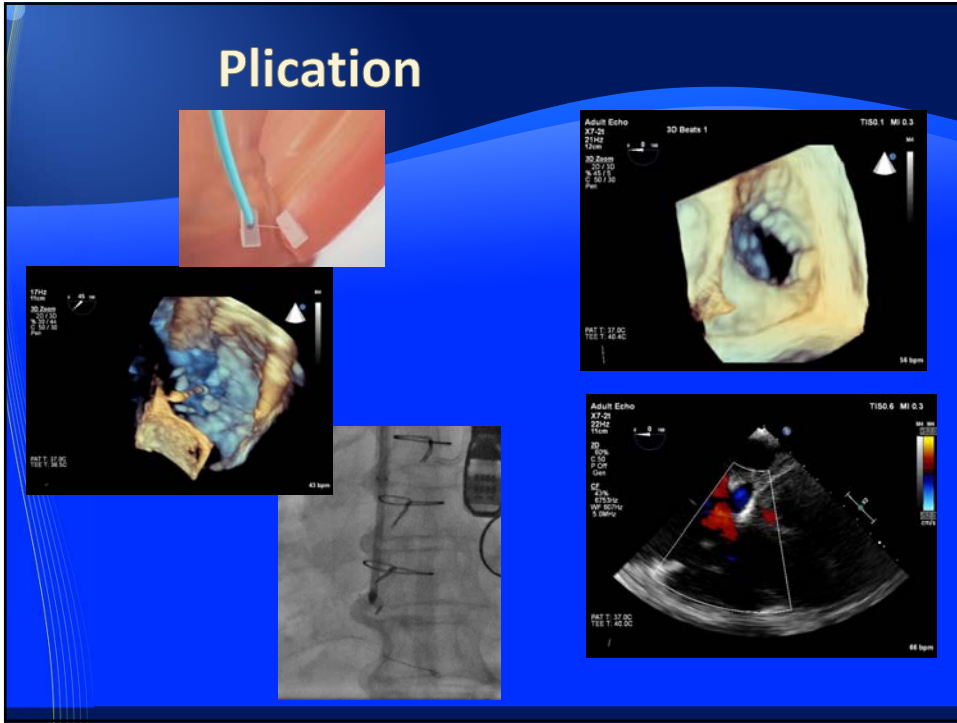
2nd Tricuspid Wire Delivery Catheter



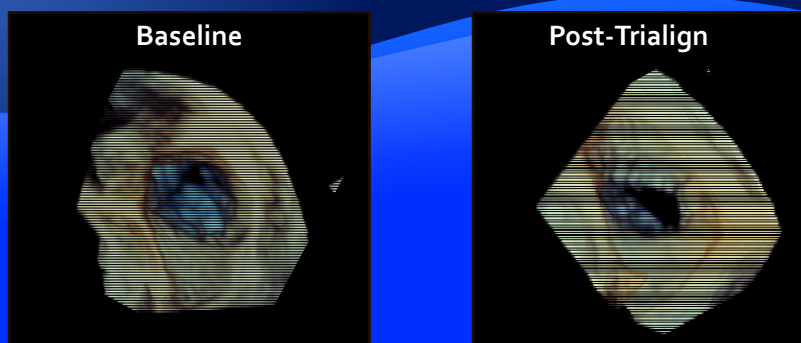
Distance = 2.36 cm
(Ideal = 2.4-2.8 cm)

Second Pledget Delivery

Plication



Final Initial Trialalign 3D



Parameter	Baseline	Post-Trialalign	Reduction
Tricuspid Annular Area	13.9 cm ²	7.6 cm ²	56%
Tricuspid Valve Area	9.5 cm ²	6.5 cm ²	31%
Tricuspid EROA	0.99 cm ²	0.43 cm ²	45%
Tricuspid Regurgitant Volume	84 cc	40 cc	52%
Forward Stroke Volume	78 cc	77 cc	0%
PASP (mmHg)	58	58	0%

30 day Results

Baseline		30 Day	
LVEF	69%	LVEF	63%
Forward Stroke Volume	44 cc	Forward Stroke Volume	67cc
RVEF	60%	RVEF	55%
RA Volume	86 cc	RA Volume	76 cc
TR Grade	Severe	TR Grade	Mod-Severe
Regurgitant Volume	75 cc	Regurgitant Volume	39 cc
EROA	0.77 cm ²	EROA	0.40 cm ²
TAPSE	1.3 cm	TAPSE	1.5 cm
Tenting Distance	0.76 cm	Tenting Distance	0.51 cm
TR PISA Radius	0.98 cm	TR PISA Radius	0.54 cm
TV Annular Area	9.6 cm ²	TV Annular Area	8.6 cm ²

30 day Parameters

Medications

- ◆ Carvedilol 3.125 mg PO BID
- ◆ Furosemide 40 mg PO QD (↓ by 40 mg)
- ◆ Spironolactone 25 mg PO QD
- ◆ Advair Diskus 500 mcg-50 mcg BID
- ◆ Coumadin 3 mg PO QD
- ◆ MetFORMIN 500 mg PO BID
- ◆ Pravastatin 40 mg PO QD

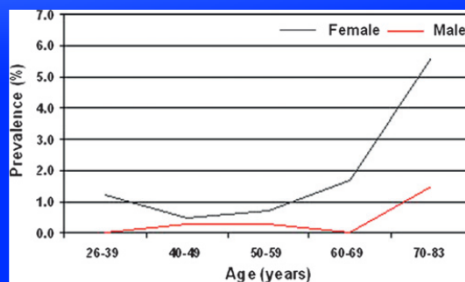
Clinical Evaluation

- ◆ **MLWHF (QoL Questionnaire) = 5 (↓ by 45 points)**
- ◆ **6MWT = 338 meters (↑ by 110 meters)**

3 month follow-up :
6MWT increased by
another 50 meters

CHALLENGE: TR is a Progressive Disease

- Echocardiographic data from the Framingham Heart Study suggest overall prevalence of \geq moderate TR = 0.8%, and increases with age.
- Overall prevalence of significant TR was 4.3 times greater in females than males.
- ~30-40% of patients presenting with Mitral Regurgitation have Tricuspid Regurgitation



Singh JP, Evans JC, Levy D. Prevalence and clinical determinants of mitral, tricuspid, and aortic regurgitation (the Framingham Study). Am J Cardiol 1999;83:897

SCOUT I subject reaches 1-year time-point

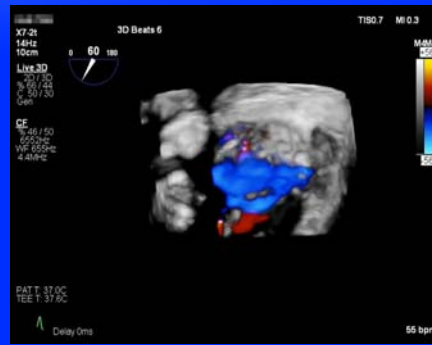
3D ECHO post baseline procedure

TR 1 year post procedure



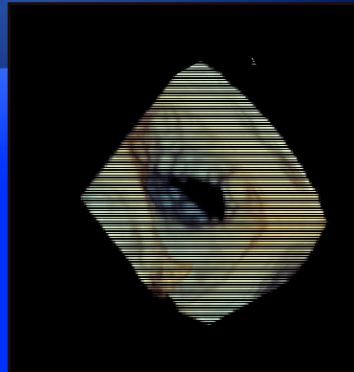
Original pledgets

Bicuspidized tricuspid valve:
Original pledget pair intact



Severe TR

Initial Pledgets Intact: Progression of Annular Dilatation

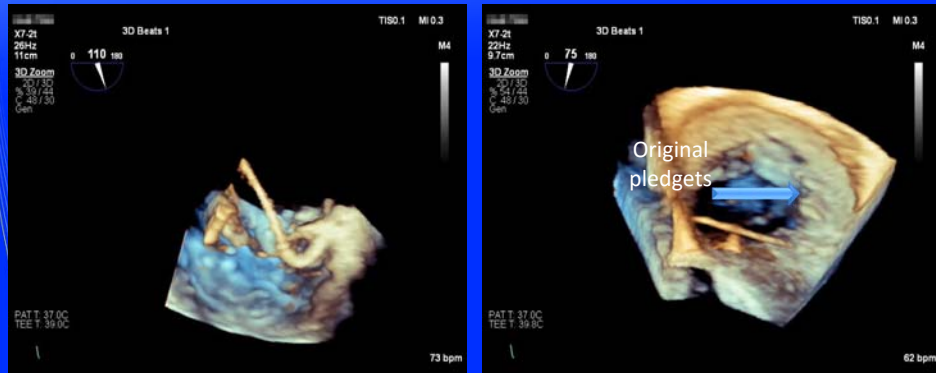


Initial Trialign



Initial Trialign

Positioning Wire Delivery



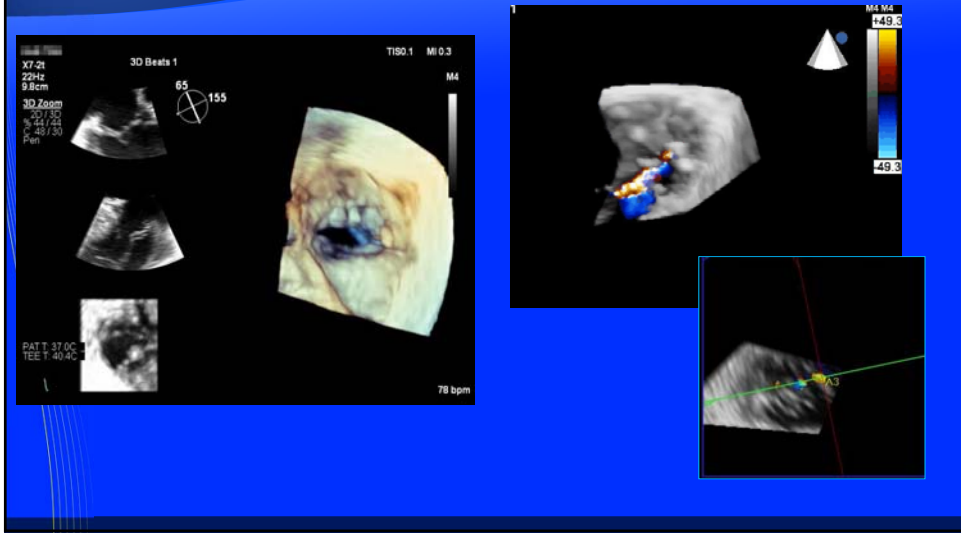
Plication

Pre

Post



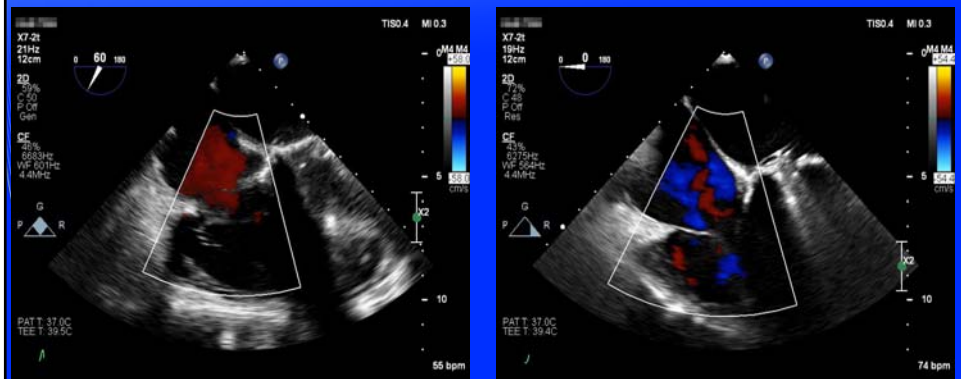
3D view of Plicated Implants and valve



Color Doppler Comparison

Baseline

Post Procedure



Mild/Moderate TR

Conclusion

- Large, unmet need for a minimally invasive tricuspid valve repair procedure
- Trialign offers a small footprint that leaves all options open post-procedure
- SCOUT I is the first reported, multi-center, independently adjudicated, clinical data on transcatheter tricuspid repair with:
 - Demonstrated high procedural success rate
 - Robust safety signal with no 30d mortality
 - Significant improvement in patient symptoms and QOL through 6 months
- Retreatment is possible