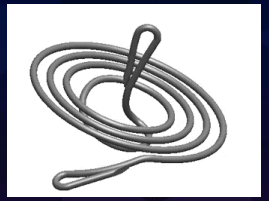


Mitralix Tricuspid Insufficiency Repair

MATTERS Study: FIM Transcatheter Tricuspid Valve Repair by the Mistral Device

Haim Danenberg, MD

Hadassah Hebrew University Medical Center

Jerusalem, Israel

Hadassah Medical Center

Haim Danenberg, MD

I have relevant financial relationships

Clinical Proctor: Medtronic, V wave

Research Grant: Abbott

Speaker: Edwards

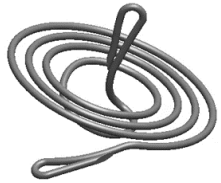
Consultant: Cardiosert , Capricon , Mitralix, 3D-Simbionix

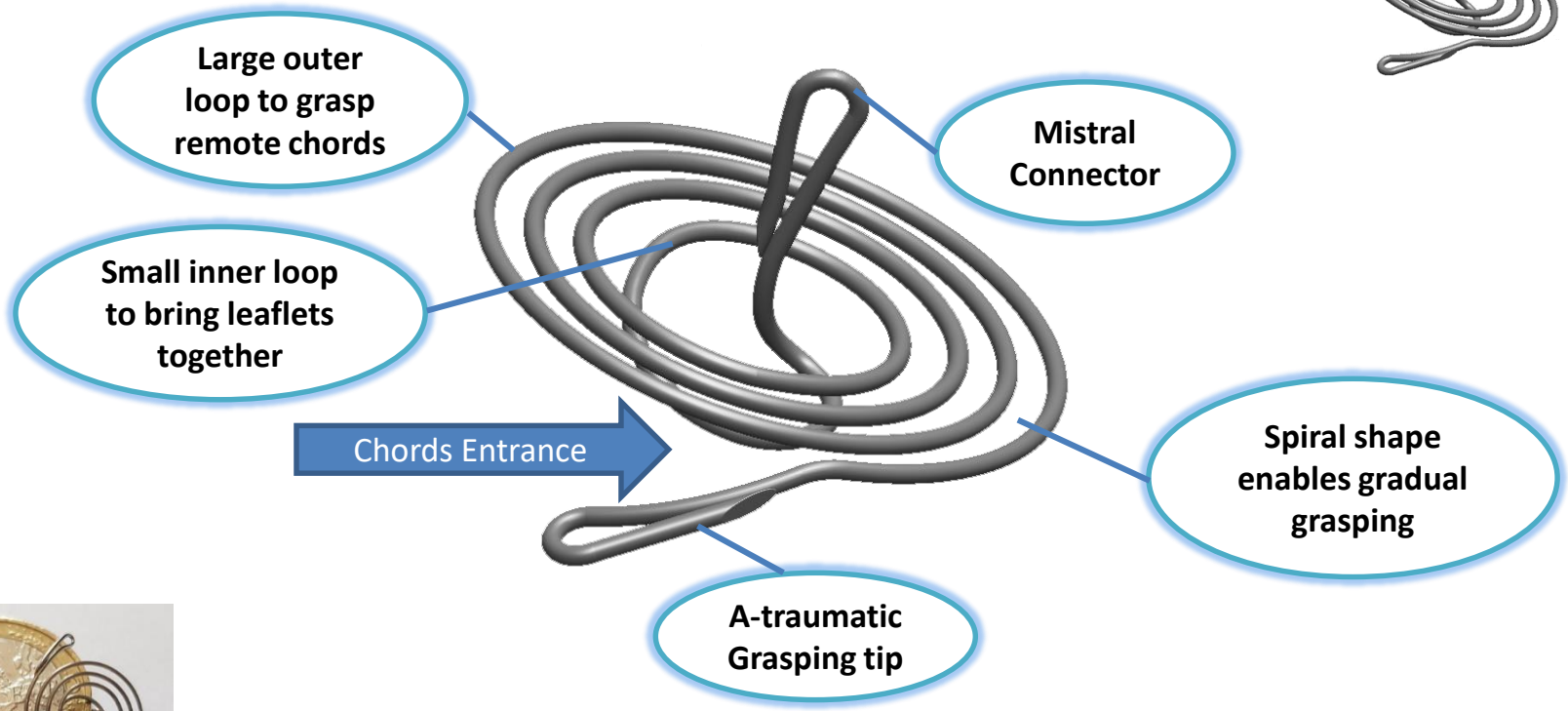
Board Member: VVT, OmniSense

Background

- Mistral [Mitralix Ltd., Israel] is a catheter-based treatment for tricuspid (TR) and mitral (MR) regurgitation
- Spiral shaped implant and an 8.5F delivery system
- The device improves leaflets coaptation by gently grasping chords from two or three leaflets
- This is a report of the ongoing FIM trial

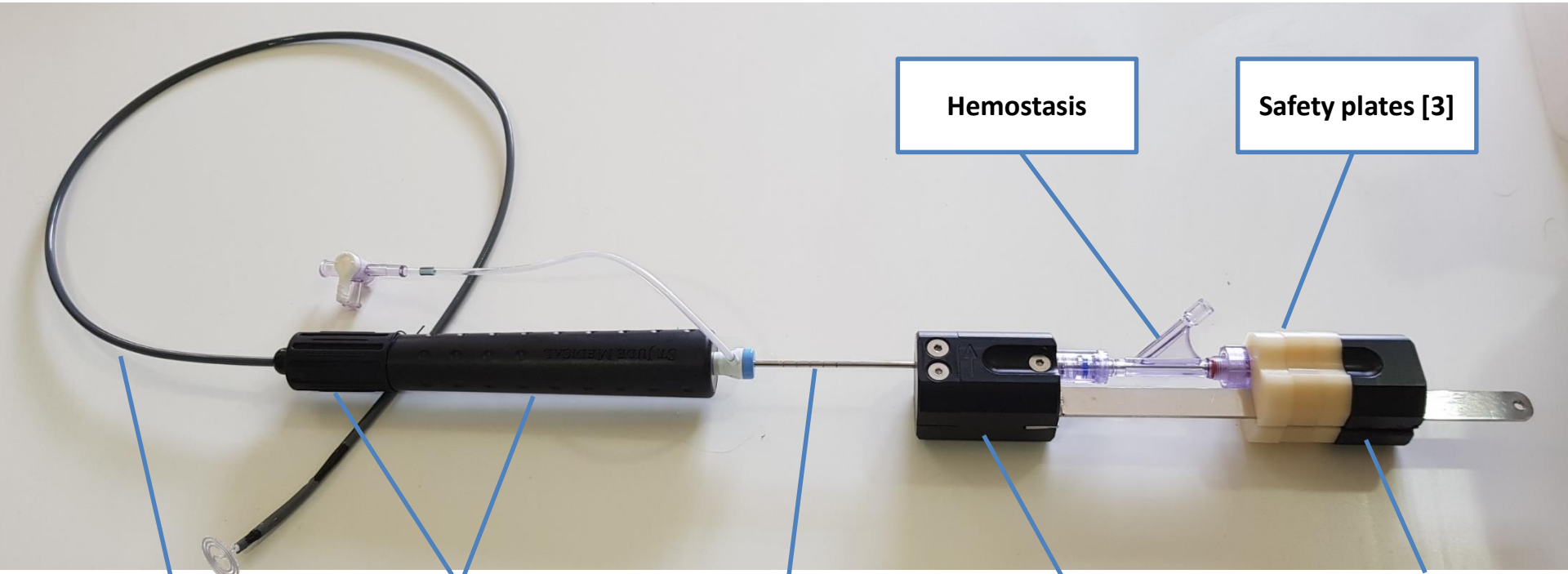
Mistral – Mitral and Tricuspid Repair Device



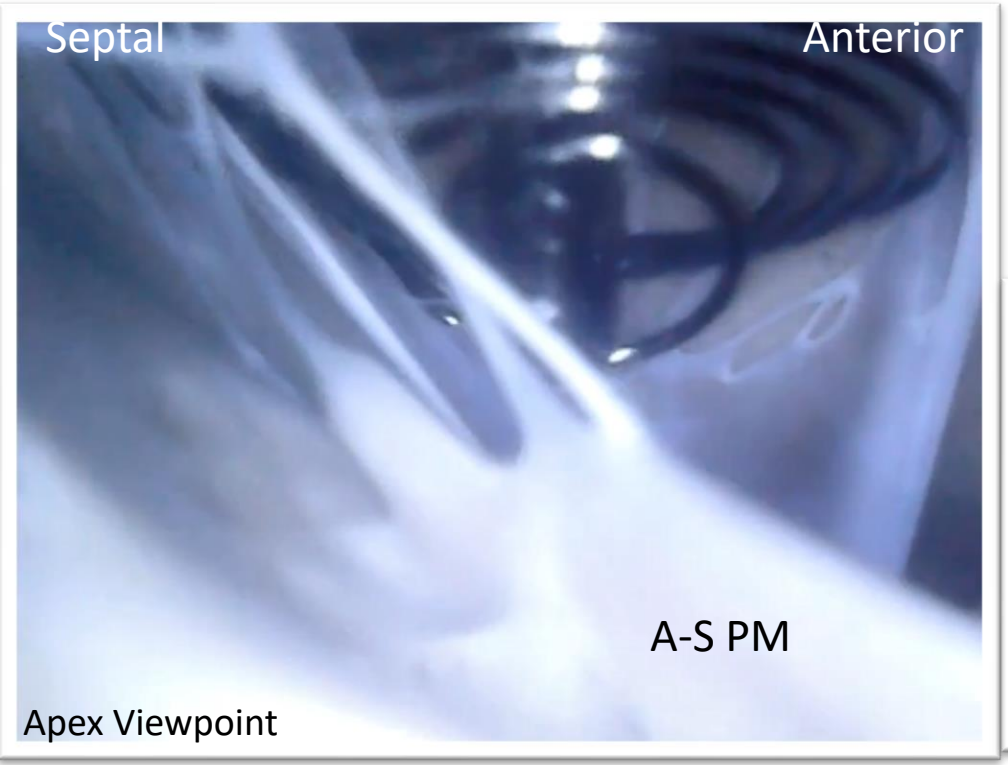


Made of single part, biocompatible Nitinol, 0.4mm wire diameter.

MDS - Mistral Delivery System

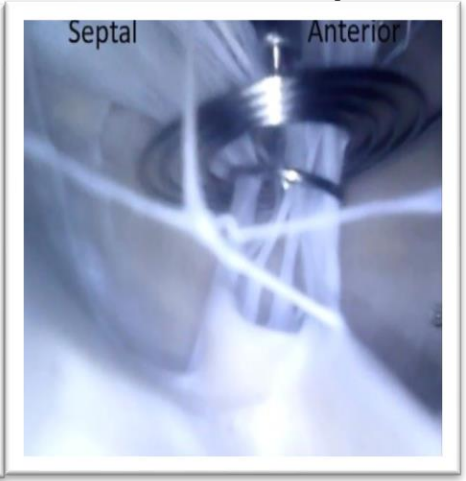


Mistral – Mode of Action 40sec



Cadaver Heart - Tricuspid Valve

Flower bouquet



Chordal bouquet

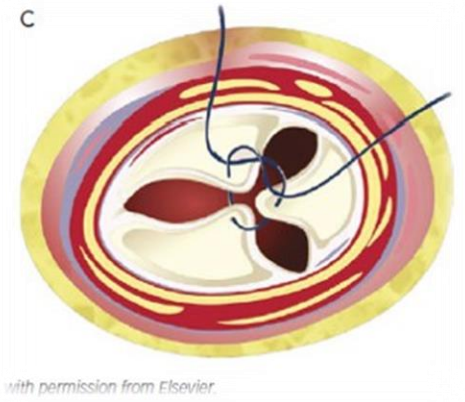
You can watch online: https://youtu.be/qcQ8Wm8YiNQ

SAP Grasp Method

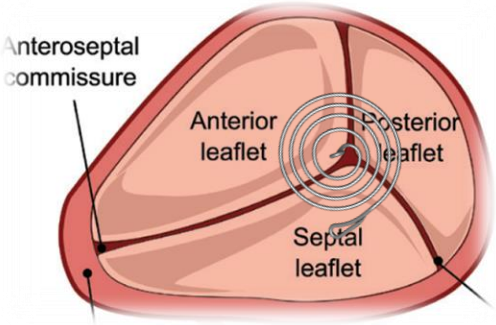
(**S**eptal-**A**nterior-**P**osterior)

Clover repair

Source: Rodes-Cabau, 2016 [2]

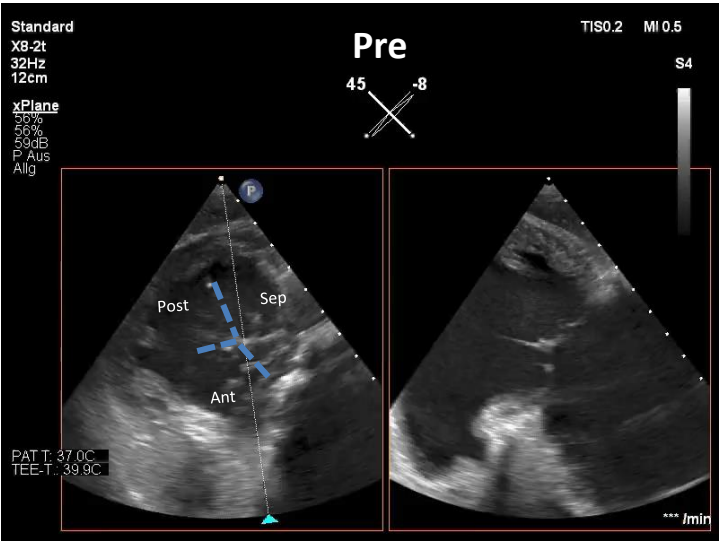


Mistral SAP



SAP Method – Single Implant

Run 33 Pre procedure SAX Baseline

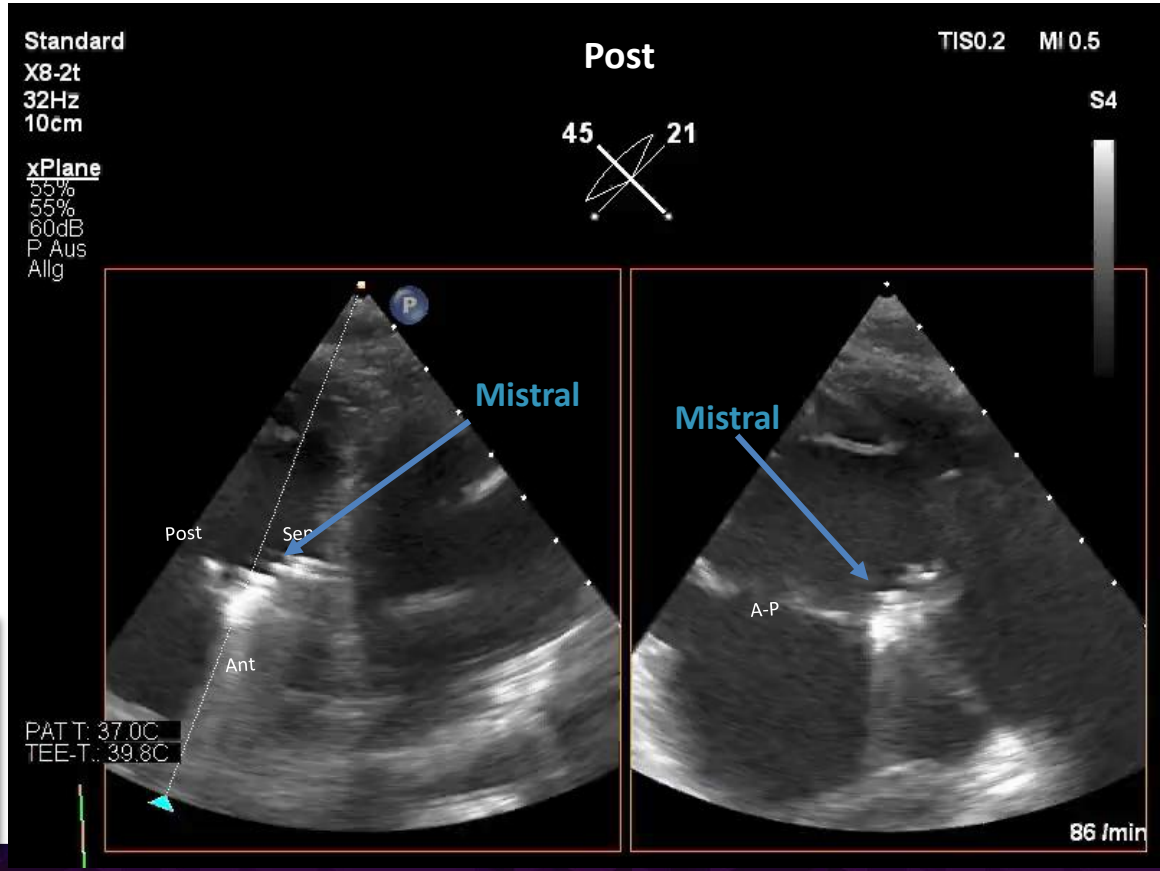


(Septal-Anterior-Posterior)

Central Septal chordae and A-P PM chordae (from both Posterior and Anterior leaflets) were grasped – SAP (Single Implant)

MN901: Pre Vs. Post Implantation

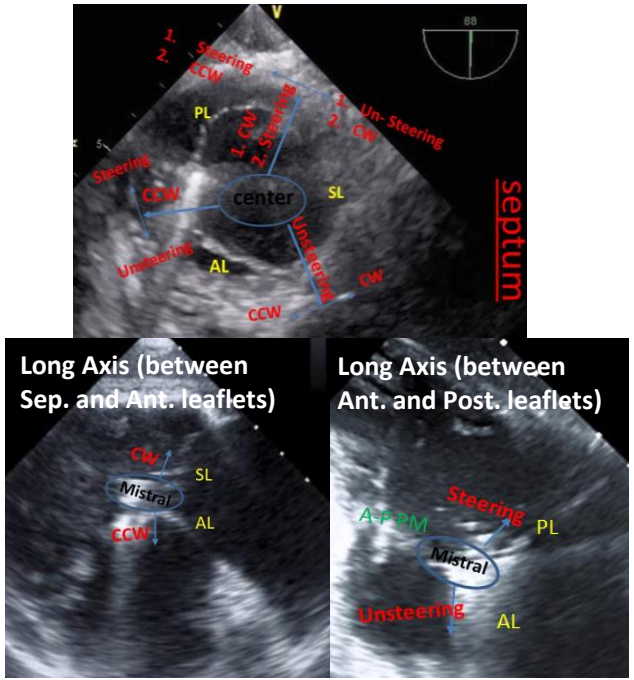
Run 117 Post Procedure

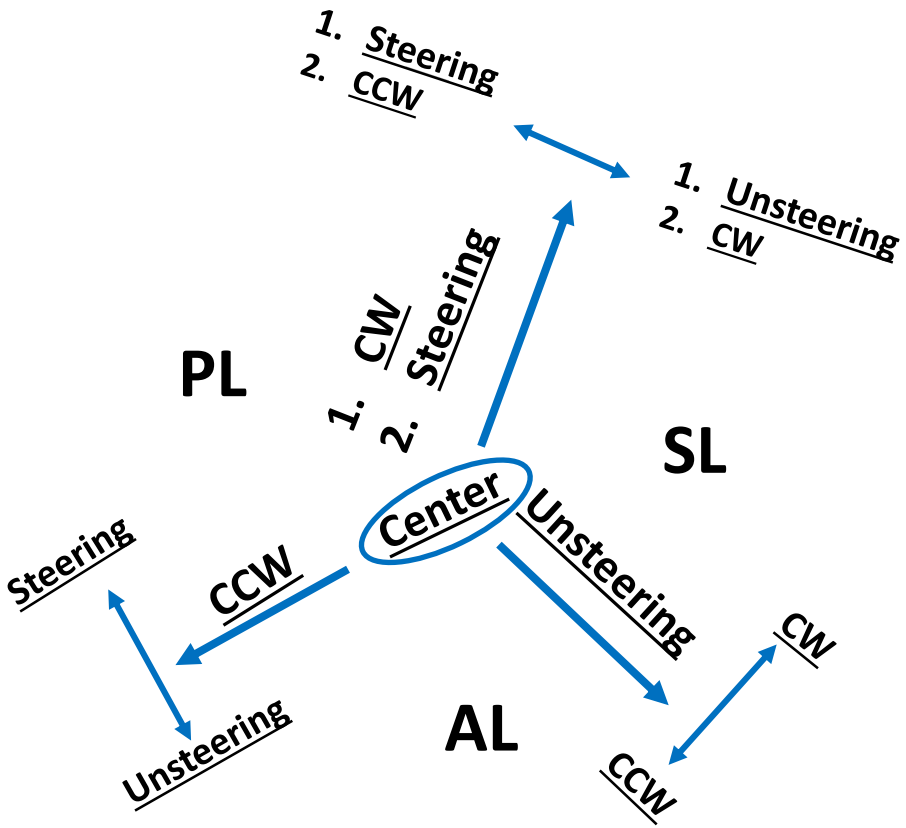


Mistral Release in Fluoroscopy

https://youtu.be/y8iwOyTvNXQ

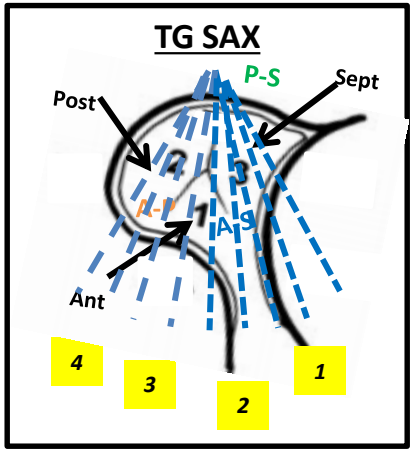
Mistral Movement Direction Map

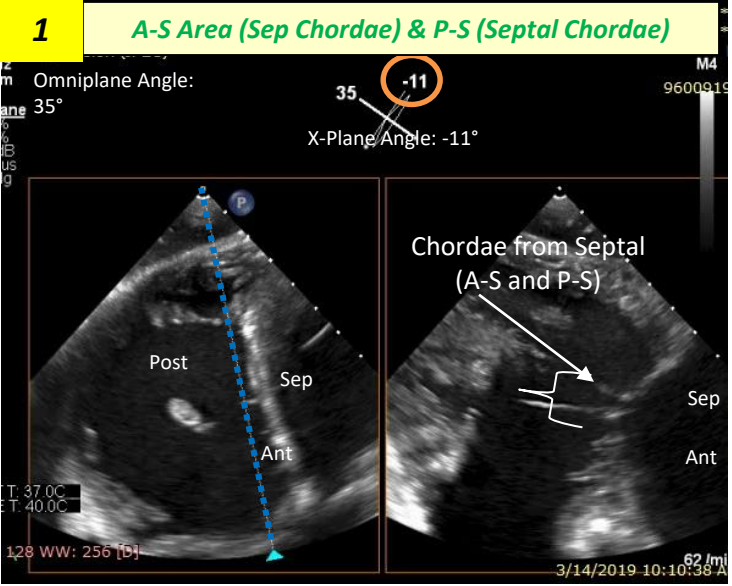


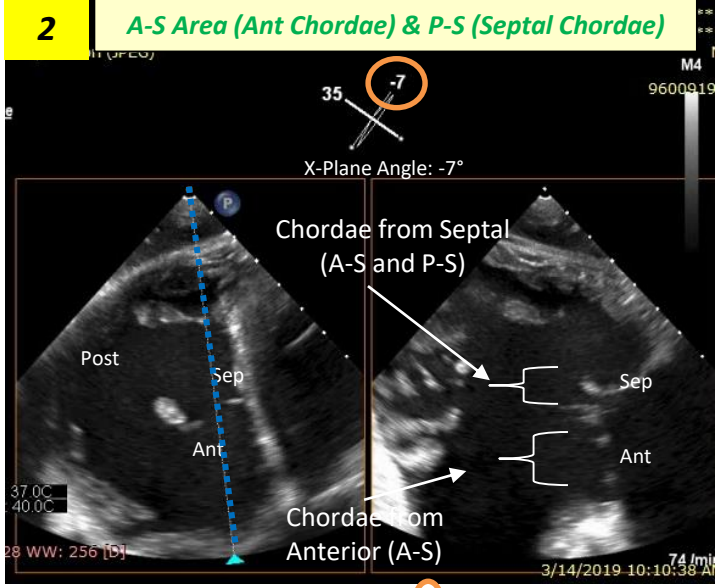


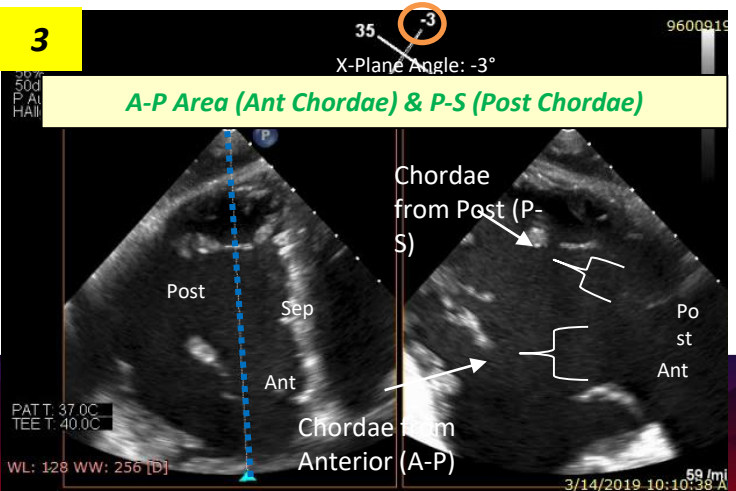
Scan Tricuspid TG (SAX and X-Plane) views-

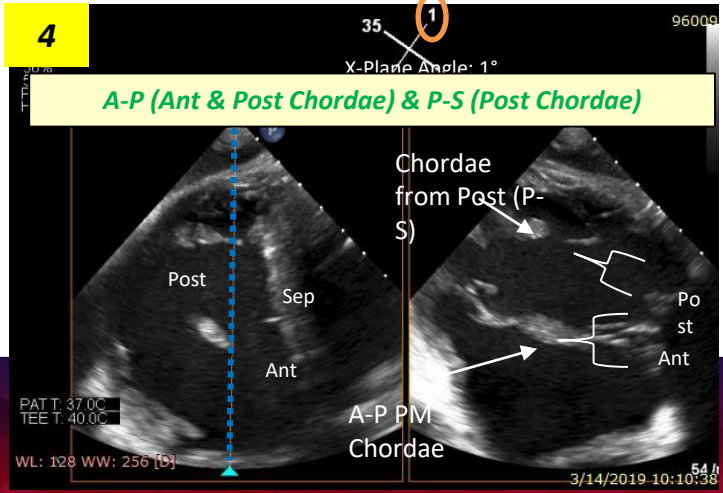
Patient selection (and Procedure) Main Views

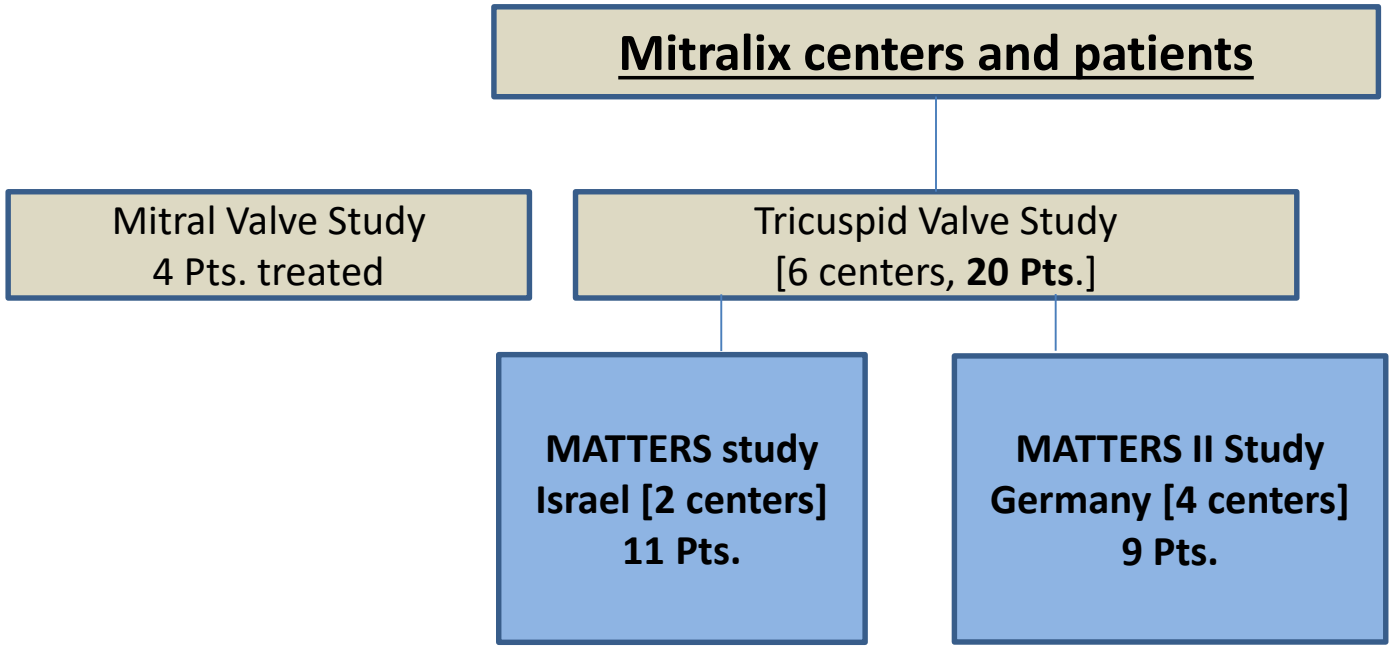











Mitralix centers and patients
Mitral Valve Study
4 Pts. treated
Tricuspid Valve Study
[6 centers, **20 Pts**.]
MATTERS study
Israel [2 centers]
11 Pts.
MATTERS II Study
Germany [4 centers]
9 Pts.

Clinical Data: TR Cases (1/2)

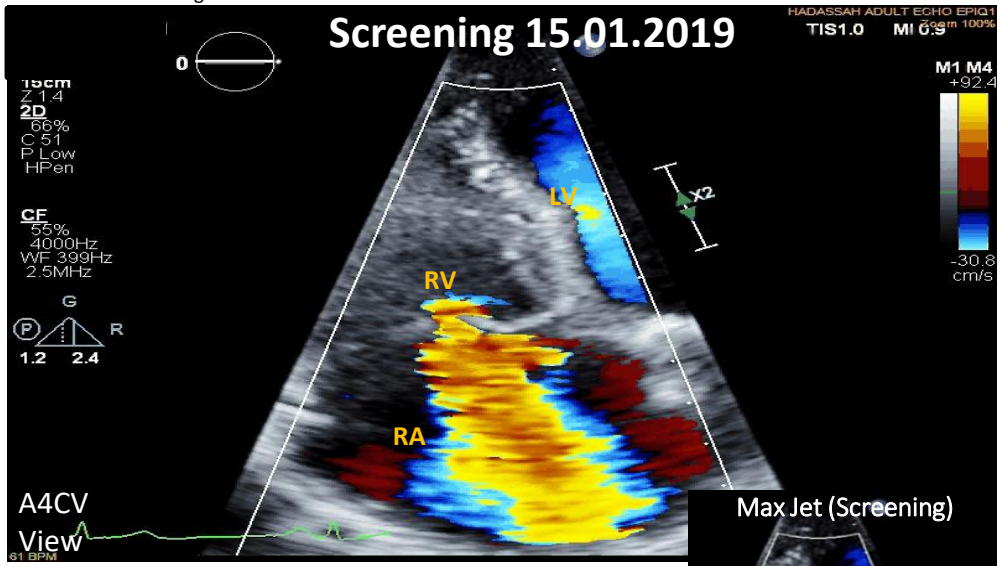
#	Patient (Age)	Follow up month (date)	Location	# Devices	Performance	Safety	Efficacy
1	AL301 (89)	12 (1/16)	Hamburg	2	Success	✔	Unchanged
2	CV302 (76)	12 (4/16)	Frankfurt	1	Success	✔	Unchanged
3	CV303 (85)	12 (5/17)	Frankfurt	1	Success	✔	Unchanged
4	CV304 (78)	12 (5/17)	Frankfurt	1	Success	✔	Significant improvement
5	HD701 (71)	- (8/17)	Jerusalem	1	Removed	✔	N/A
6	HD702 (59)	12 (4/18)	Jerusalem	1	Success	✔	Excellent
7	HD703 (80)	12 (7/18)	Jerusalem	1	Success	✔	Improved
8	HD704 (73)	12 (10/18)	Jerusalem	1	Success	✔	Excellent
9	HD705 (78)	12 (10/18)	Jerusalem	1	Removed	✔	N/A
10	HD706 (78)	12 (1/19)	Jerusalem	1	Success	✔	Excellent

Clinical Data: TR Cases (2/2)

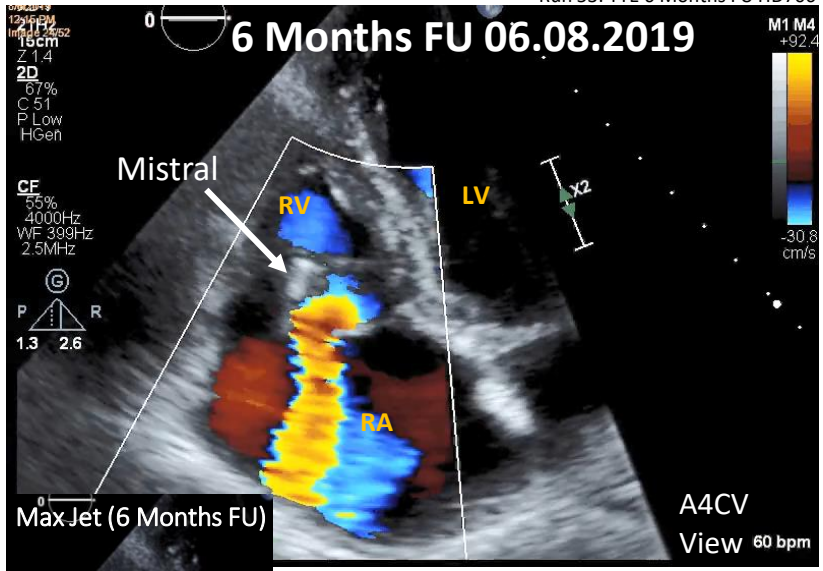
#	Patient (Age)	Follow up month (date)	Location	# Devices	Performance	Safety	Efficacy
11	MN901 (73)	6 (4/19)	Munich	1	Success	✔	Excellent
12	MN902 (84)	- (1/19)	Munich	0	Not Implanted	✔	N/A
13	SH707 (83)	6 (6/19)	Sheba	1	Success	✔	Improved
14	SH708 (82)	3(8/19)	Sheba	2	Success	✔	Excellent
15	SH709 (65)	3 (10/19)	Sheba	1	Success	✔	Unchanged
16	CV905 (76)	1 (11/19)	Frankfurt	1	Success	✔	Excellent
17	HD710(77)	1(1/20)	Jerusalem	2	Success	✔	Improved
18	HD711(69)	1 (1/20)	Jerusalem	1	Success	✔	Excellent
19	CV906(82)	1 (1/20)	Frankfurt	2	Success	✔	Excellent
20	CV907(83)	1 (1/20)	Frankfurt	2	Success	✔	Improved

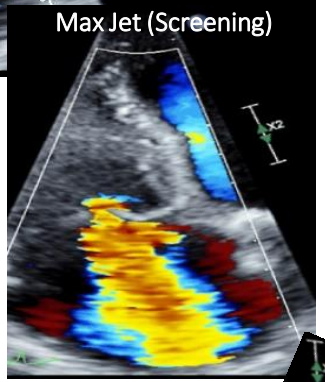
(HD706) Screening Vs. 6M FU – Mitralix Ltd. Mistral Device in Tricuspid

Run 58: TTE Screening HD706



Run 53: TTE 6 Months FU HD706





TR
- **VC Width** [cm]: **0.95** [Severe]
- **EROA** (by PISA) [cm²]: **0.52** [Severe]
- **Rvol** (by PISA) [ml/beat]: **45** [Severe]

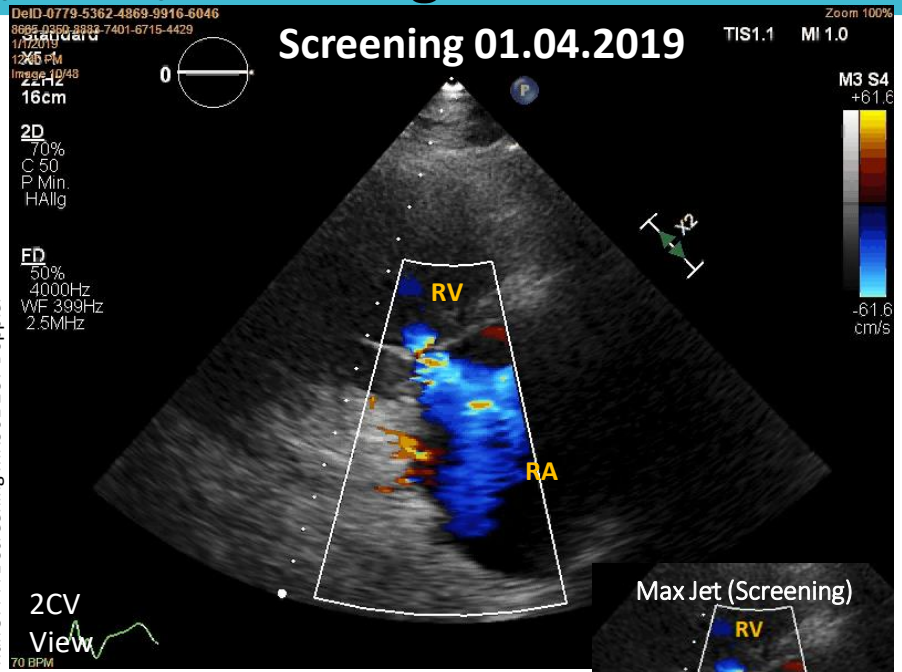
RV
- **RV FAC** [%]: **36.7** [Normal]

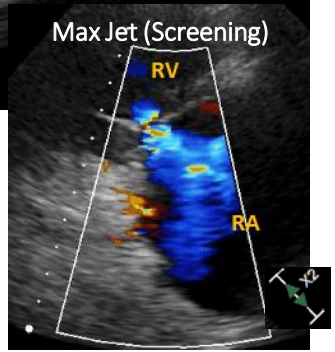
QOL
- **6MWT** [m]: **400**
- **KCCQ**: **54.69**
- **NYHA class:** **III**

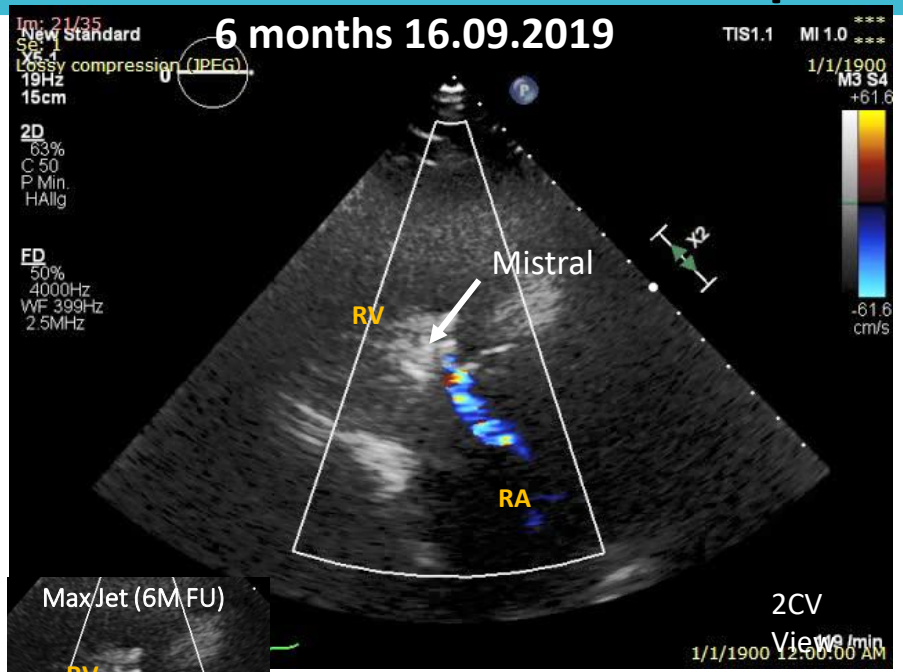
% Improvement:

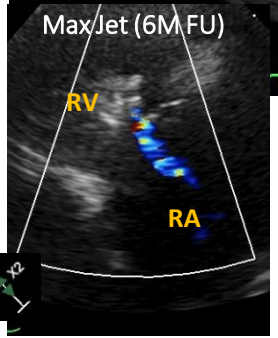
- **VC Width** [cm]: **0.47** [Moderate] — **102%**
- **EROA** (by PISA) [cm²]: **0.17** [Mild] — **67%**
- **Rvol** (by PISA) [ml/beat]: **13** [Mild] — **71%**
- **RV FAC** [%]: **41** [Normal] — **12%**
- **6MWT** [m]: **458** — **14.5%**
- **KCCQ**: **94.44** — **73%**
- **NYHA class:** **I**

(MN901) Screening Vs. 6M FU – Mitralix Ltd. Mistral Device in Tricuspid









TR

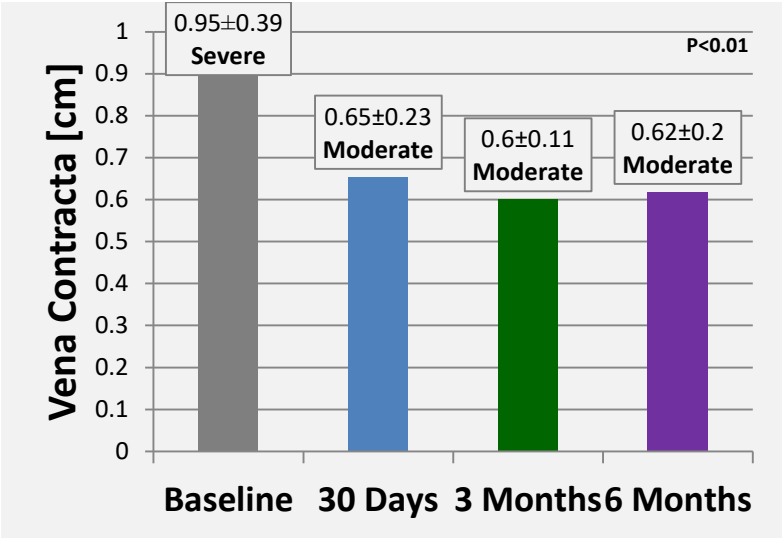
- **TR Grade:** **3 out of 5**
- **VC Width** [cm]: **0.82** [Severe]
- **PISA Radius** [cm]: **0.68** [Moderate]
- **EROA** (by PISA) [cm²]: **0.32** [Moderate]
- **Rvol** (by PISA) [ml/beat]: **28** [Mild]

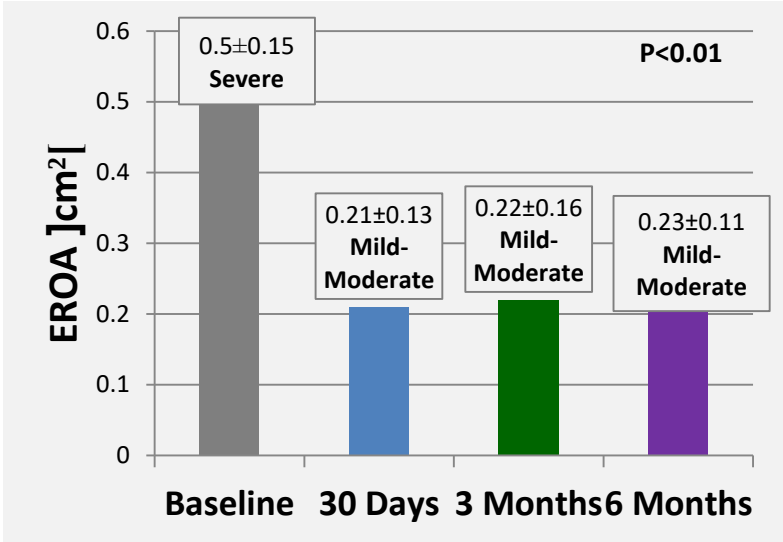
QOL

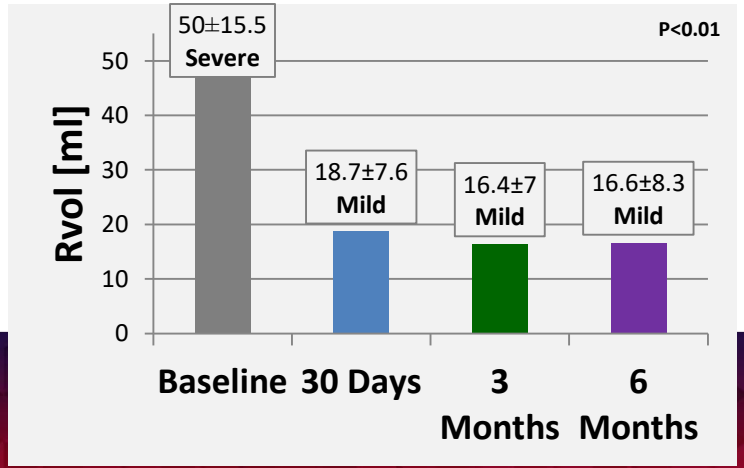
- **6MWT** [m]: **75**
- **KCCQ**: **36.46**
- **NYHA class:** **III**

	% Improvement:
TR Grade: **1 out of 5**	
VC Width [cm]: **0.48** [Moderate]	**41%**
PISA Radius [cm]: **0.40** [Mild]	**41%**
EROA (by PISA) [cm²]: **0.13** [Mild]	**59%**
Rvol (by PISA) [ml/beat]: **10** [Mild]	**64%**
6MWT [m]: **237**	**216%** [Δ=162m]
KCCQ: **81.77**	**124%**
NYHA class: **II**	

TR Grade Parameters

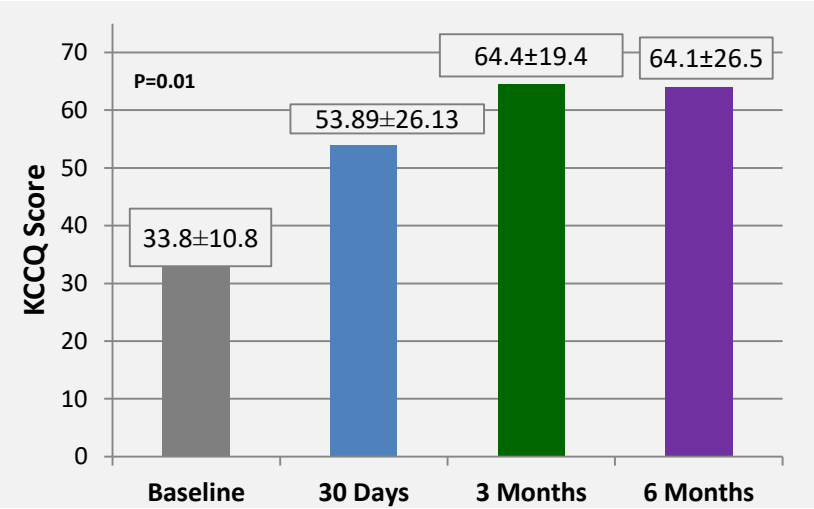


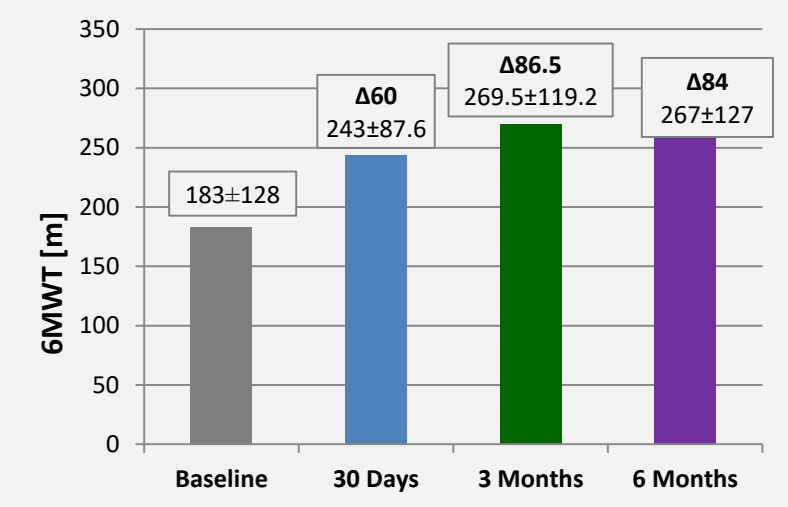




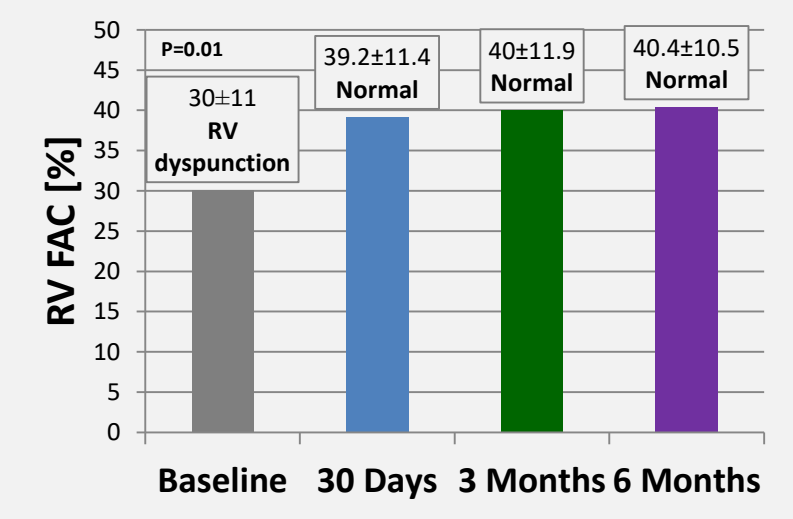
Note: Baseline n=14, 30 Days n=10, 3 months n=6, 6 months n=5

QOL





RV function



Note: Baseline n=14, 30 Days n=10, 3 months n=6, 6 months n=5

Mitralix Highlights

Safety profile @ 1 Year	• No Death • No bleeding • No perforation
Recovery	• Discharge 1-2 days post procedure
Quality of Life (QOL)	• Clear QOL improvement within following day.
MR & TR parameters improvement	• Six-month data indicate a durable repair • Color doppler, VC, Rvol, EROA, etc.
Heart functioning	• Clear improvement of right ventricle contraction.

Thanks!

END