Options For “No Option” Patients: Focus On Less Invasive Ventricular Enhancement (LIVE) [Revivent™]

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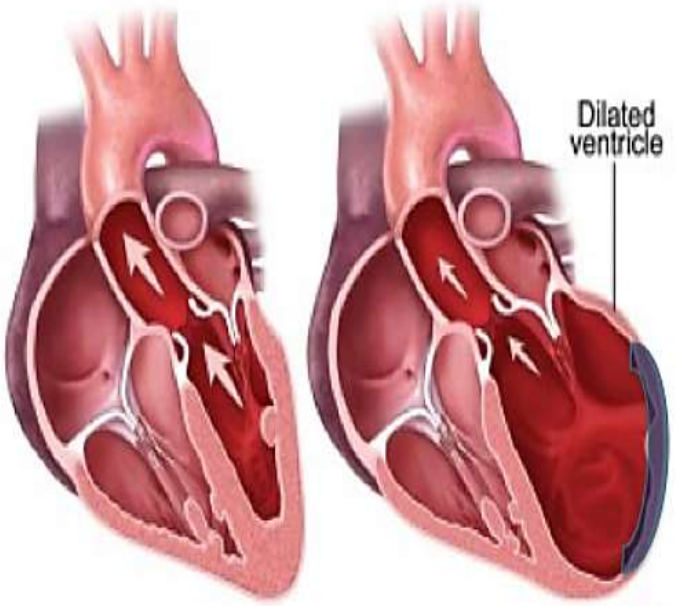
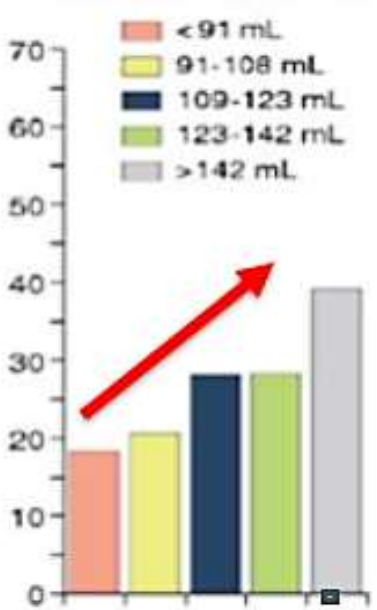
Background

Normal heart vs. Ischemic Cardiomyopathy

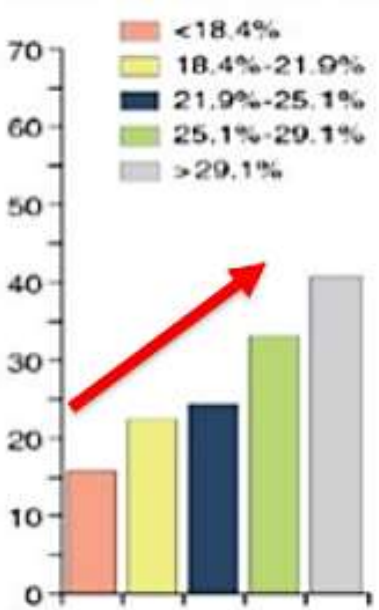


End-Diastolic Volume



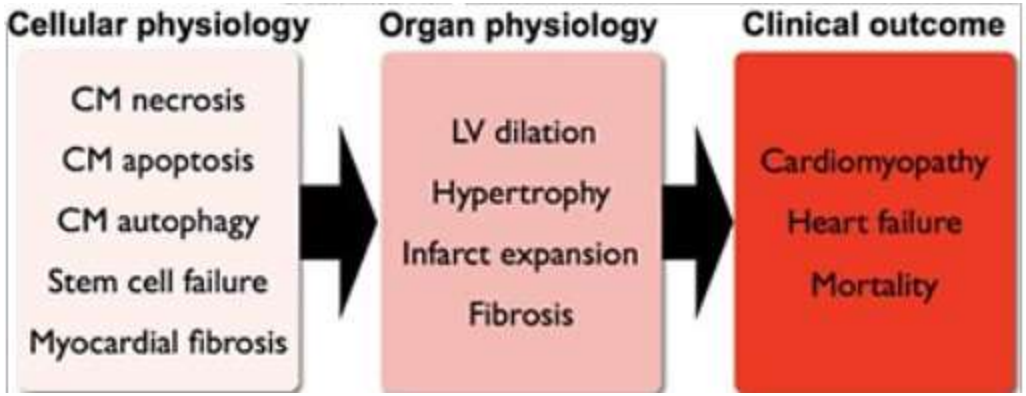
Death or Hosp for HF
P-Trend < 0.0001

In-Segment Length



Death or Hosp for HF
P-Trend < 0.0001

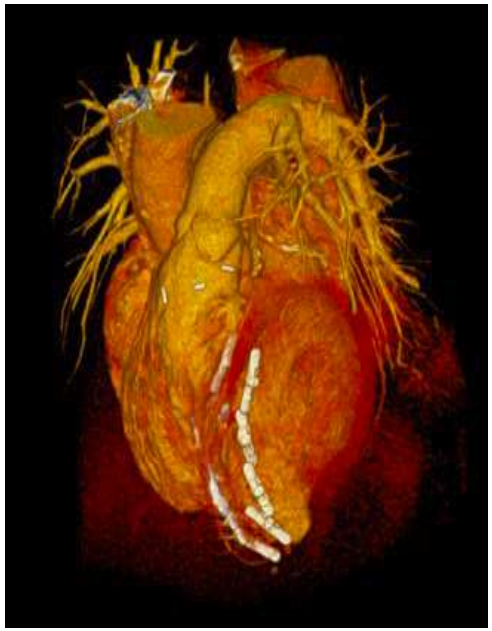
Myocardial Infarction



LV Cavity Restoration Procedures

LV volume reduction surgery:

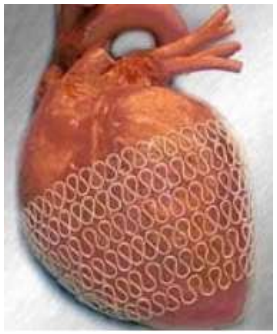
- Open excision (Cooley, Batista
- Patch for geometric preservation(Dor)
- Aneurysmorraphy
- Surgical LV reduction ± CABG (STICH)



Revivient, Bioventrix

Remodelling constraint (surgery):

CorCap device, Acorn
(Acorn trial)

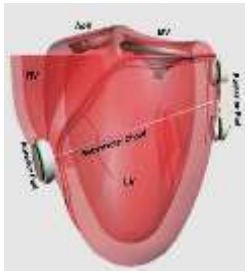


HeartNet, Paracor Medical
(HeartNet trial)

VenTouch,
(Mardil Medical)

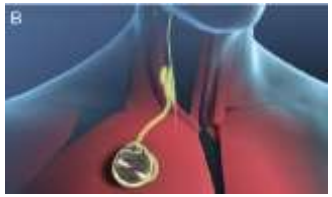
Parachute (Cardiokinetix)

LV reshaping implant& reduction of MR (surgery):



iCoapsys, Myocor Inc,
(RESTOR-MV trial)

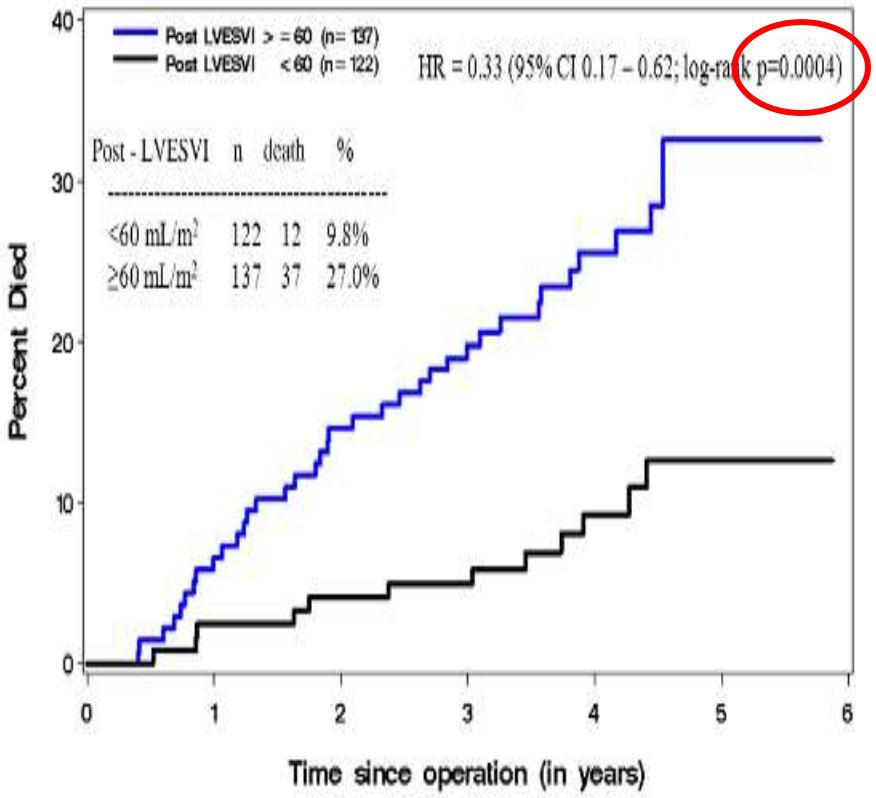
Modulation of autonomic verve system – ↓ LV remodelling

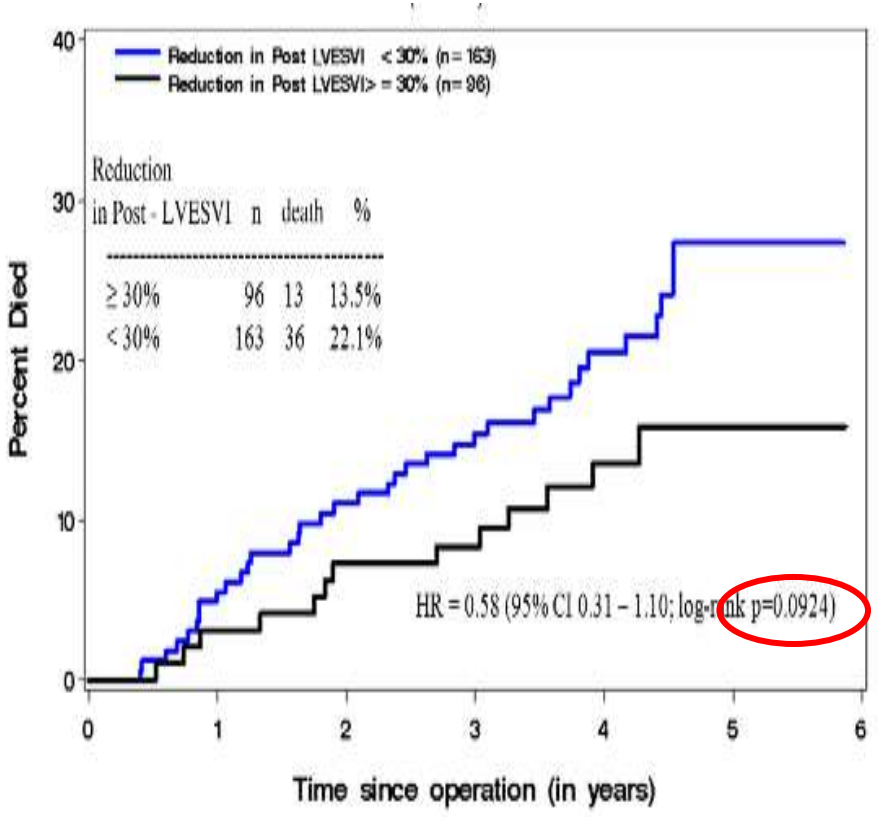


Vagal nerve stimulation (NECTAR-HF trial)

Background

Lessons from STICH Trial





Cumulative risk of death: CABG plus SVR in 259 pts & post-op LVESVI < or ≥ 60 mL/m²

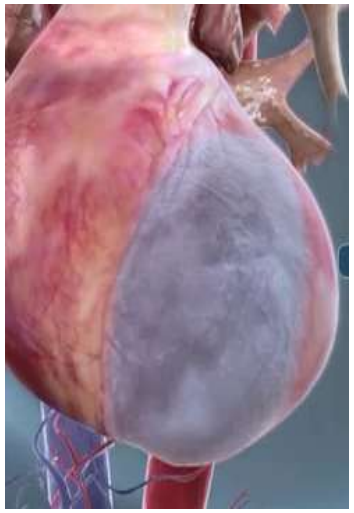
Cumulative risk of death: CABG + SVR & reduction in post-op LVESVI < or ≥ 30% of baseline LVESVI

***SVR=surgical ventricular restoration**

Michler R, et al. J Thorac Cardiovasc Surg. 2013; 146(5): doi:10.1016

Less Invasive Ventricular Enhancement (LIVE)
Revivent™ - Technology Characteristics

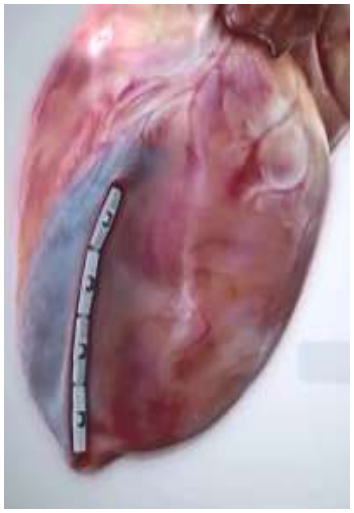
Scar Exclusion = Volume & Wall Tension Reduction



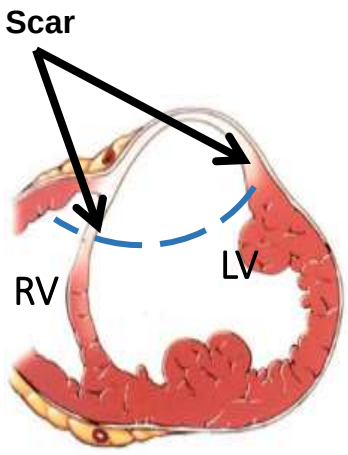
Ischemic cardiomyopathy due to post-MI scarring

Implant Myocardial Anchors

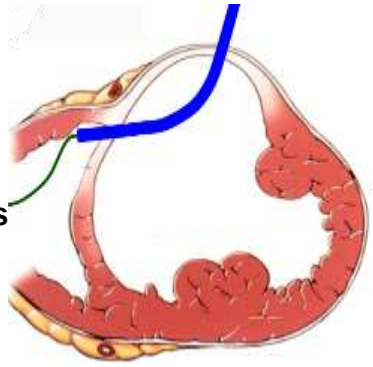
Myocardial anchors & tethers

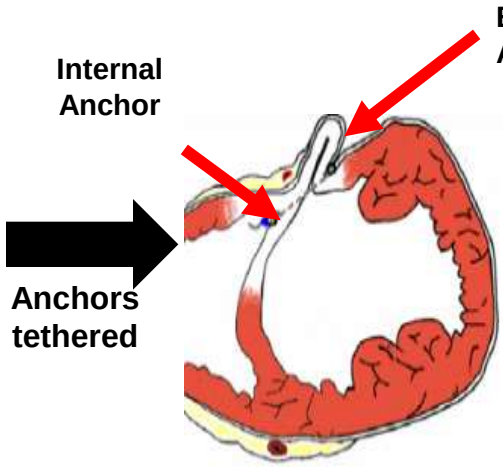


Scar excluded, LV wall tension decreased & function improved



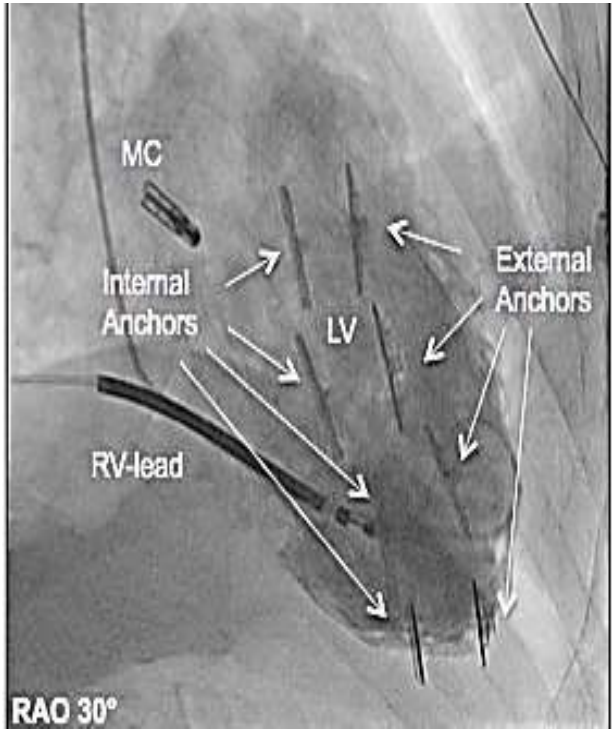
Tethers across the scar





Anchors tethered

Less Invasive Ventricular Enhancement (LIVE)
Revivent™ : Myocardial Anchoring System



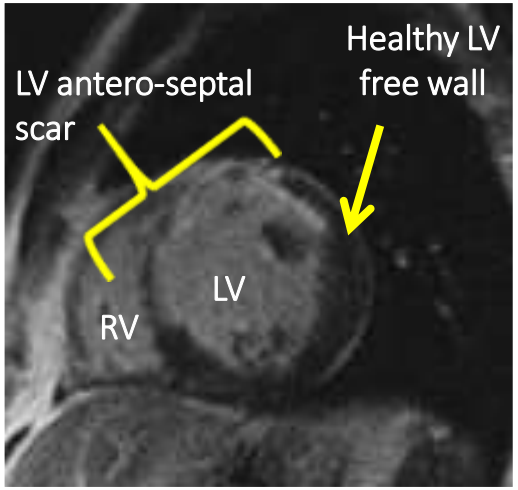
- Restore LV size, volume, shape & efficiency
- Rapid, consistent deployment
- Reduced surgical risk (no sternotomy, no CPB)
- Significant improvement in clinical outcomes

Less Invasive Ventricular Enhancement (LIVE)
Revivent™

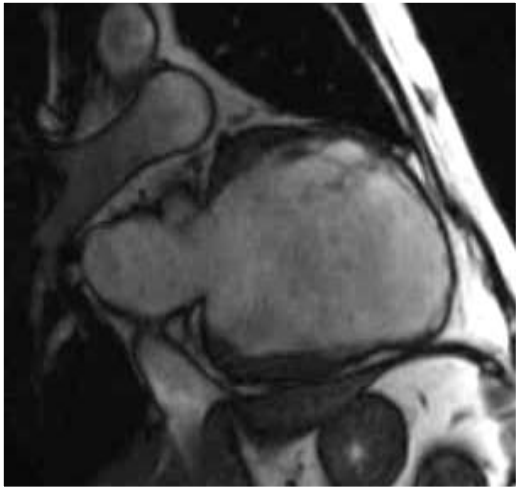
Myocardial Anchoring System – Combined Transthoracic / Endovascular Delivery (Hybrid Approach)

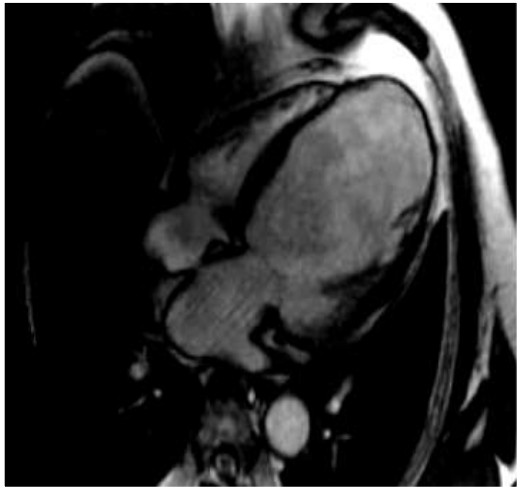
Inclusion Criteria
Dilated left ventricle post MI
Anteroseptal or anterior scar
Akinetic or dyskinetic segment of LV
LVEF ≤ 40%
LVESVI > 60 ml/m2
NYHA FC II-IV

Exclusion Criteria
LV thrombus (AC first)
Previous CABG



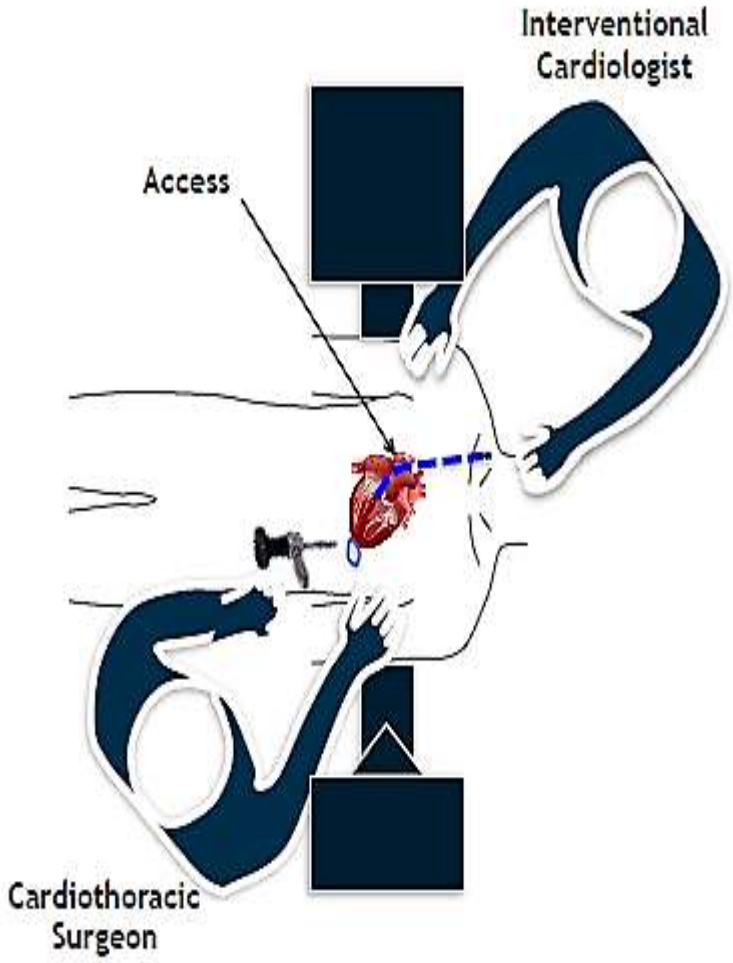
LVEDV I 195.6 ml/m^2
LVESV I 161.1 ml/m^2
SV 61.4 ml; EF 18%





Less Invasive Ventricular Enhancement (LIVE) Revivent™

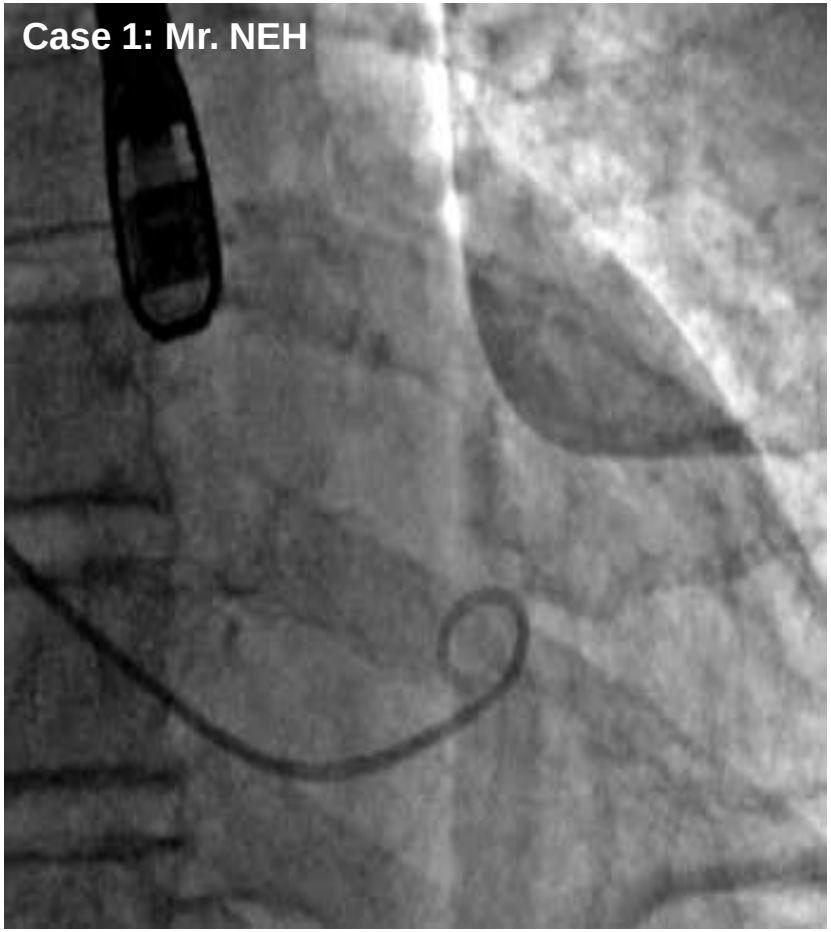
Transcatheter Approach .....

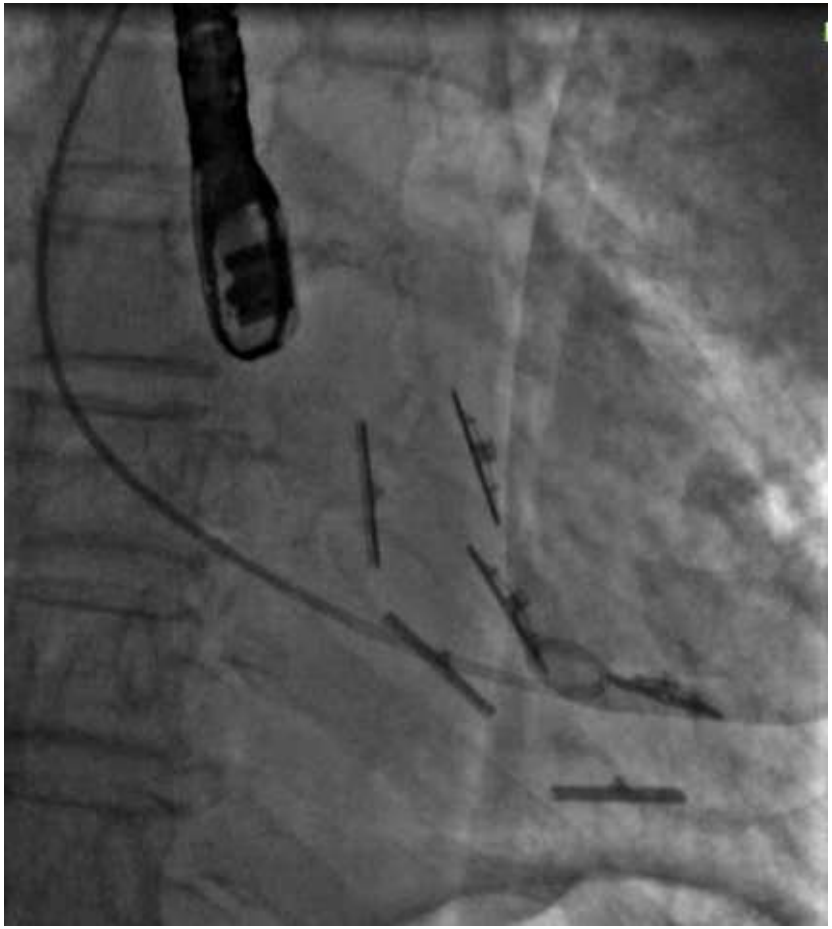


Numerous significant benefits .....

Adjustable scar exclusion tailored to patient
No left ventriculotomy
No sternotomy
No extracorporeal circulation
No aortic cross-clamping
No ischemic arrest
CE Mark and U.S. Pivotal IDE approved

Pre & Post Revivent™ LV Angiography

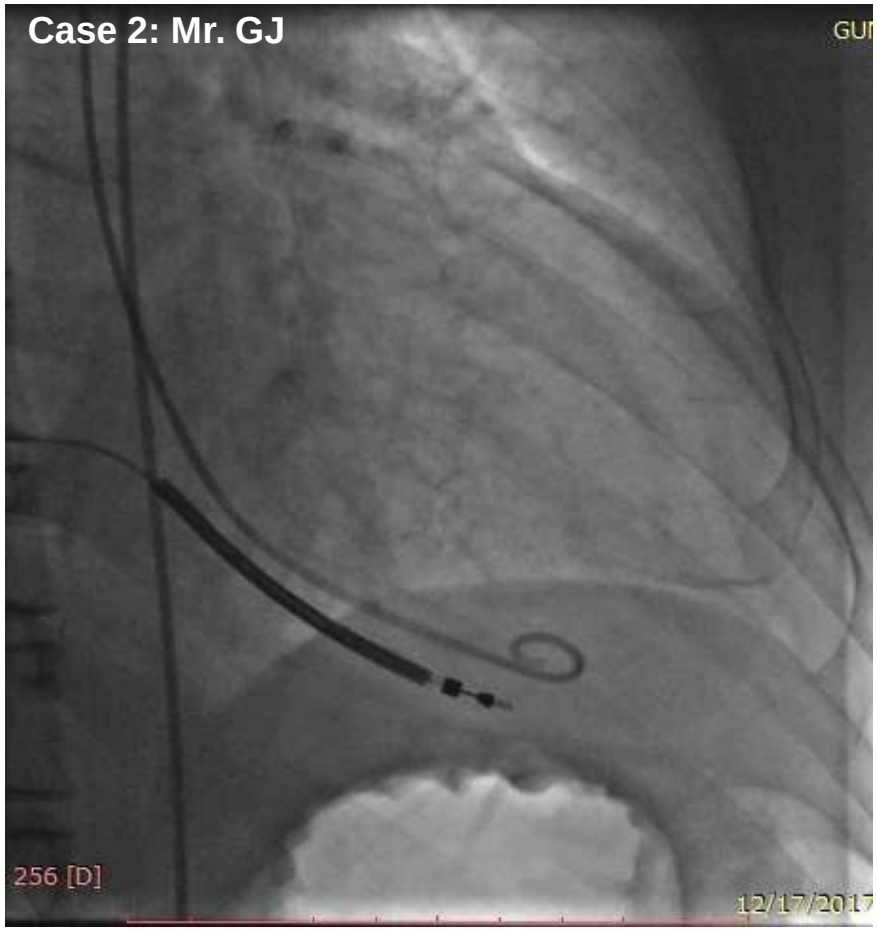


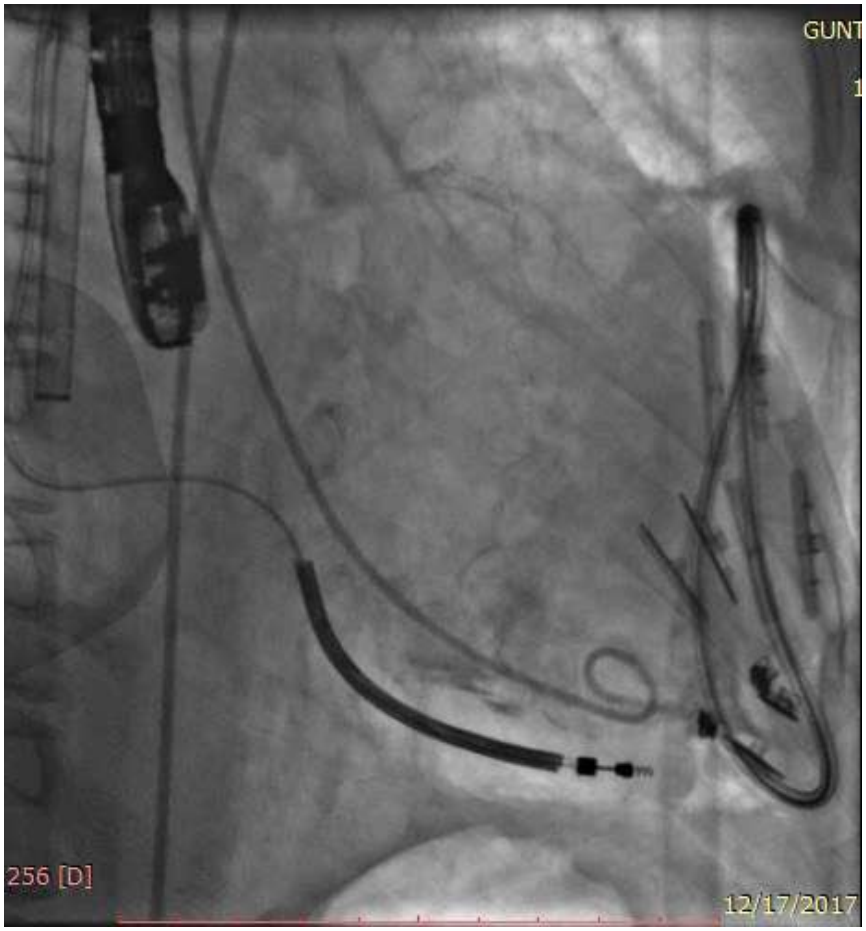


NYHA III
Massive scar involving septum, anterior, anterolateral, apical regions. Dyskinetic apex.
EF 26%

EF 56%, ∆ LVESVI 35%

Pre & Post Revivent™ LV Angiography

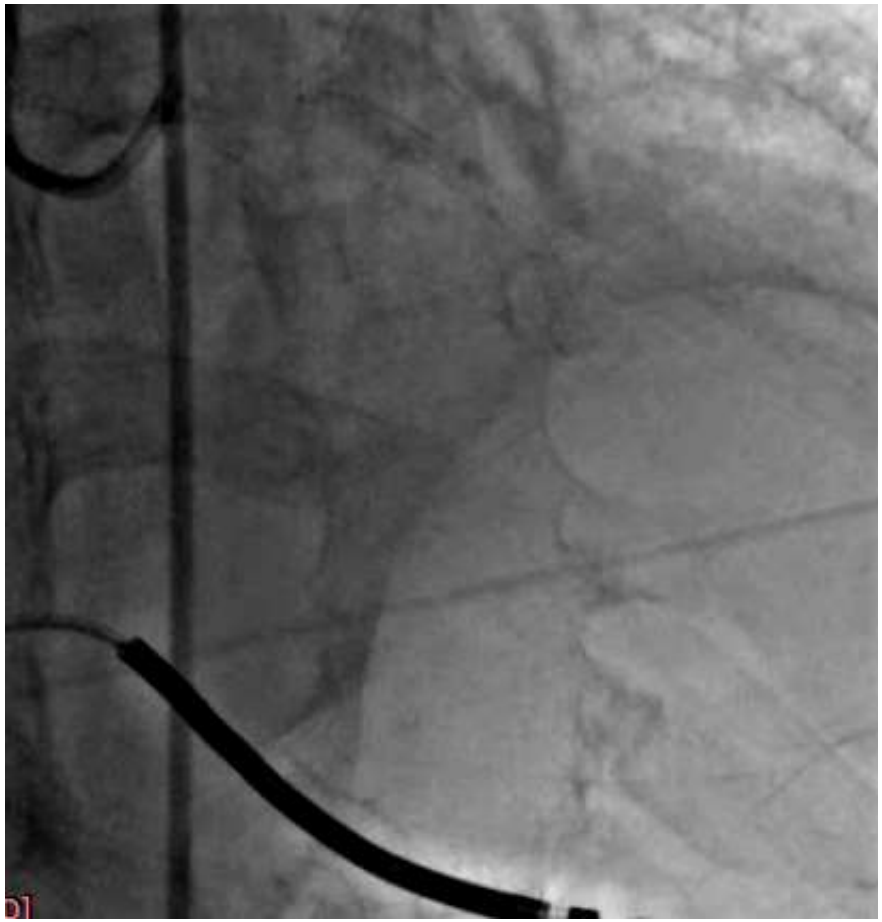




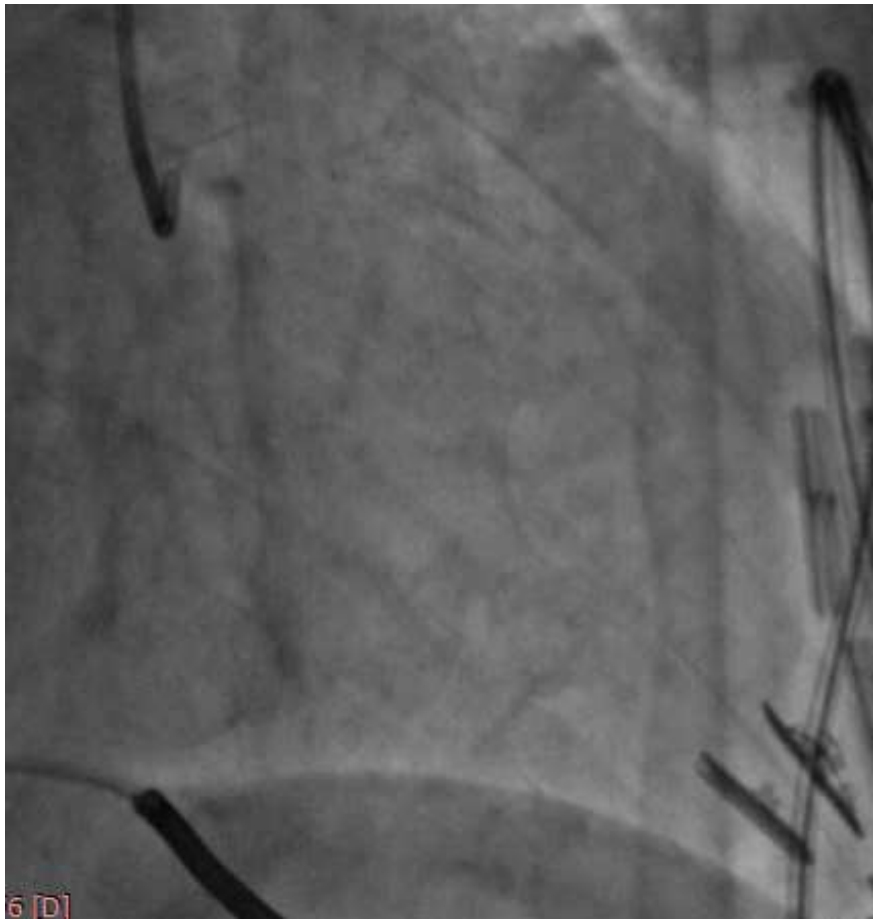
NYHA III
Massive scar involving septum, anterior, anteriolateral, apical regions.
EDVI 149 ml/m^2, ESVI 103 ml/m^2

EDVI 91 ml/m^2, ESVI 66 ml/m^2, Δ LVESVI 36%

Pre & Post Revivent™ Coronary Angiography

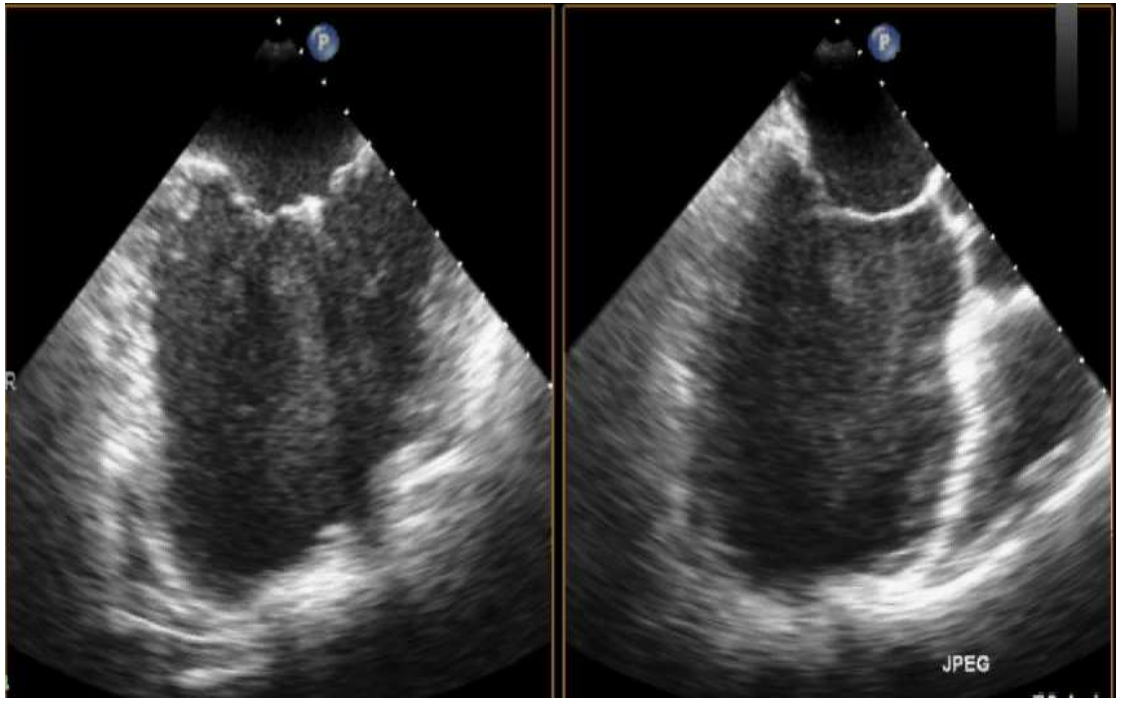


Before



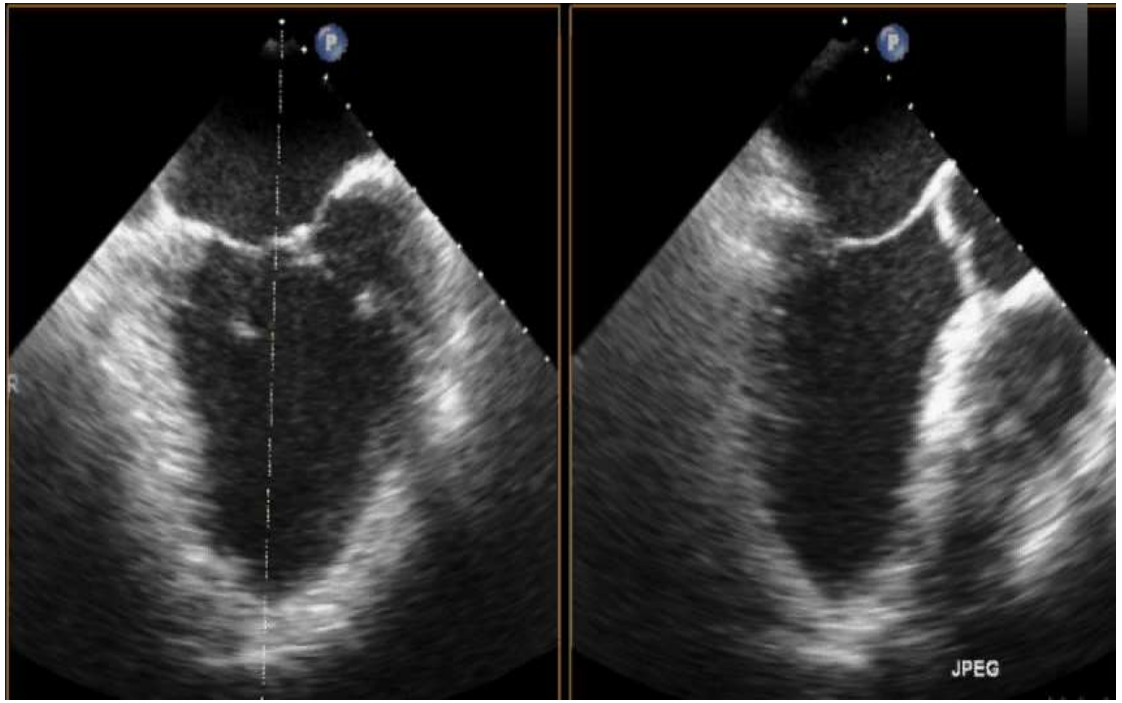
After Revivent™ :
No flow compromise

Baseline



After Revivent™

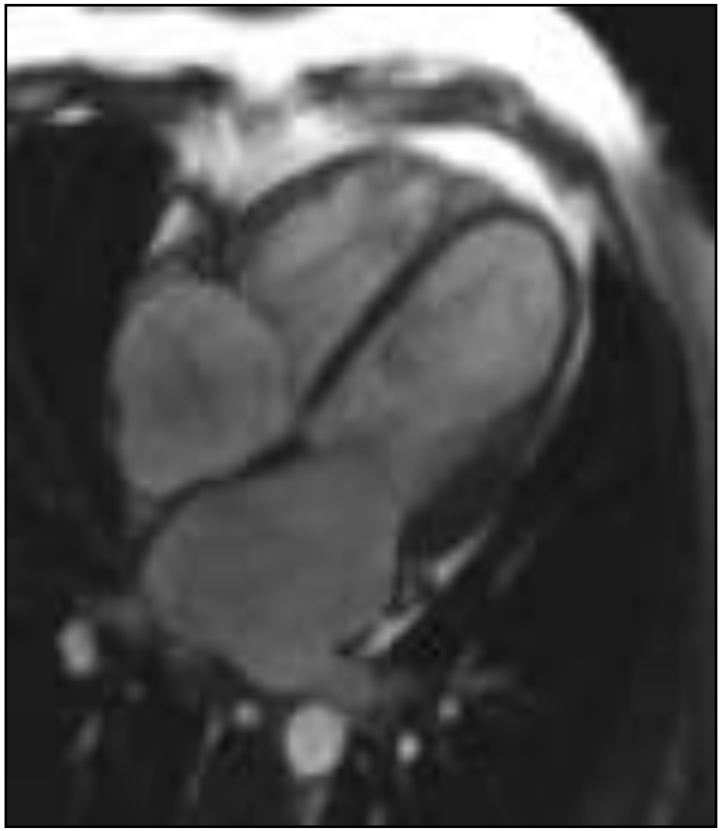
Note: smaller LV with enhanced contractility, better shaped apex, absence of SEC



Pre & Post Revivent Cardiac MRI - 12 Months

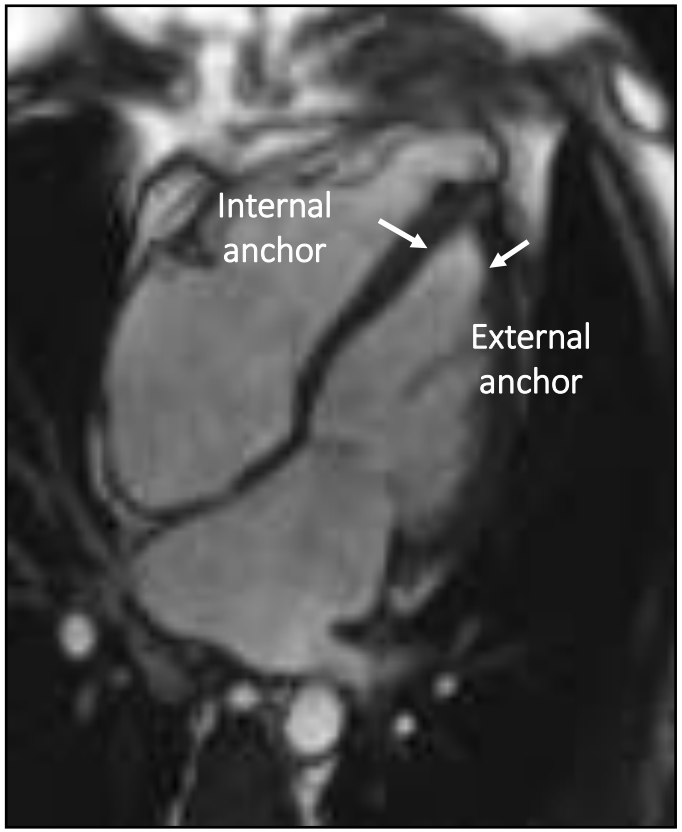
More Physiological LV Size & Geometry

Baseline



LVESVI = 127 ml/m^2

6 Months Post Revivent Procedure



LVESVI = 69 ml/m^2

Current Clinical Data

Two clinical studies in EU using identical myocardial anchors in the similar patient population (89 patients)

- **52** cases in EU using **sternotomy approach (EC)**
- **37** cases in EU using **mini thoracotomy less invasive hybrid approach (TC)**

Postmarket data collection / Procedure Simplification Initiative (PSI):

- **57** cases in EU using **mini thoracotomy less invasive hybrid approach (PSI)**

Data current as of December 18, 2017

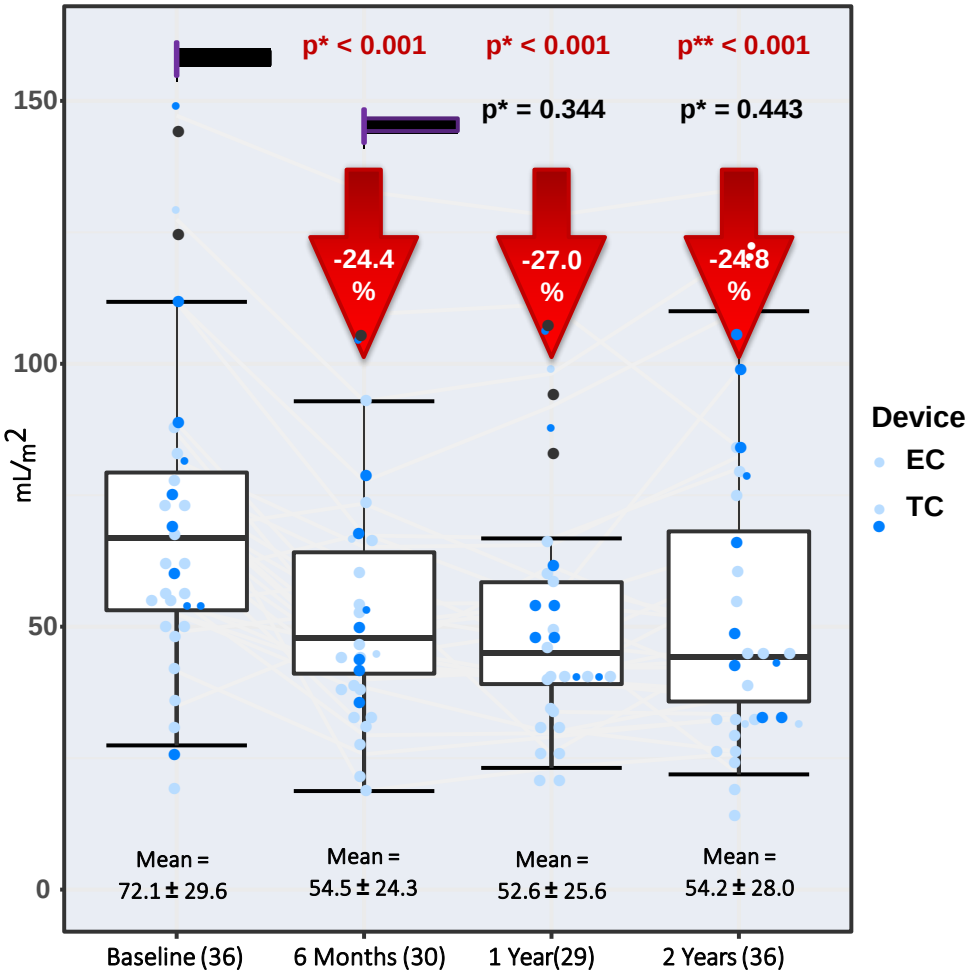
Baseline Data: EC & TC

	EC	TC	P value
N	52	37	
Age [years]	57.9 ± 10.3	62.3 ± 9.2	0.107
Gender [m / f]	43 / 9	29 / 8	0.813
BMI [kg / m²]	29.0 ± 5.7	28.5 ± 5.8	0.608
Diabetes [%]	19.2	19.4	1.000
Hypertension [%]	63.5	69.4	0.650
Hyperlipidemia [%]	69.2	66.7	0.820
Previous CVA [%]	13.5	8.3	0.517
Neuro deficit [%]	12.5	33.3	0.422
NYHA II [%]	44.2	41.7	1.000
Prior PCI [%]	67.3	86.1	0.050
Previous PM [%]	2.9	5.6	1.000
Prior ICD [%]	15.4	58.3	< 0.001

Data current as of November 2017

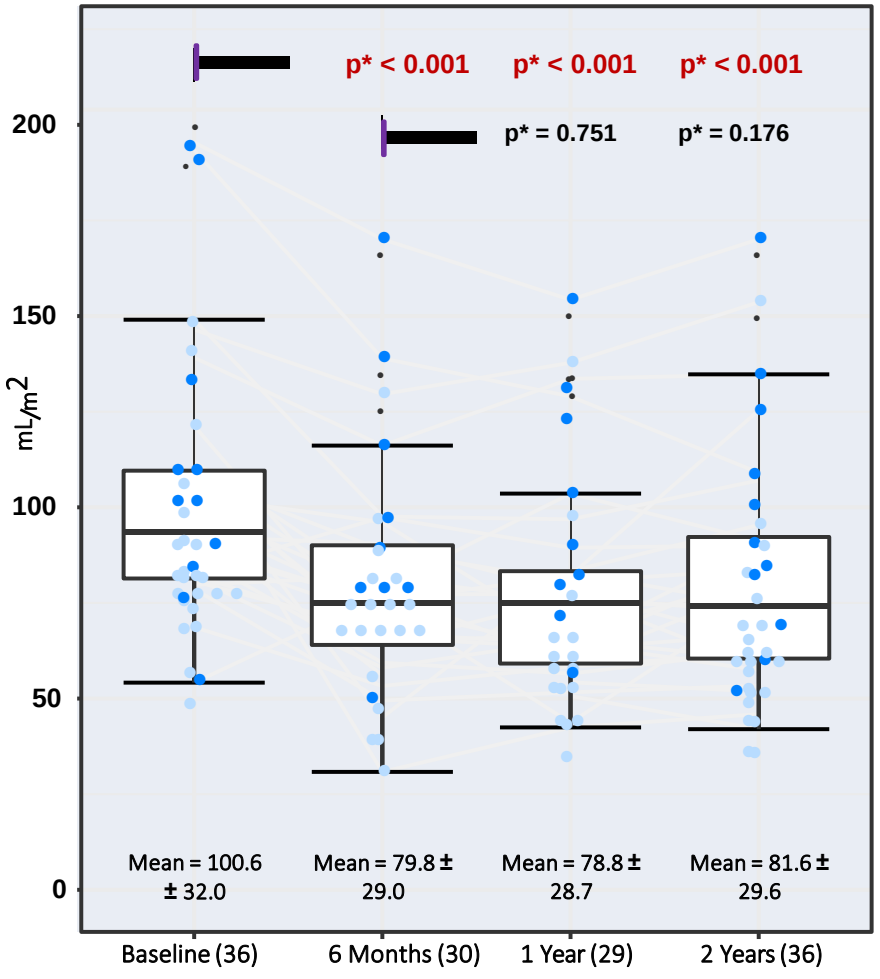
Left Ventricular Volume Index :
Echo Data (Cases With 2–Year Follow–Up)

LVESVI



*Student's t–Test, **Wilcoxon–Signed–Rank Test

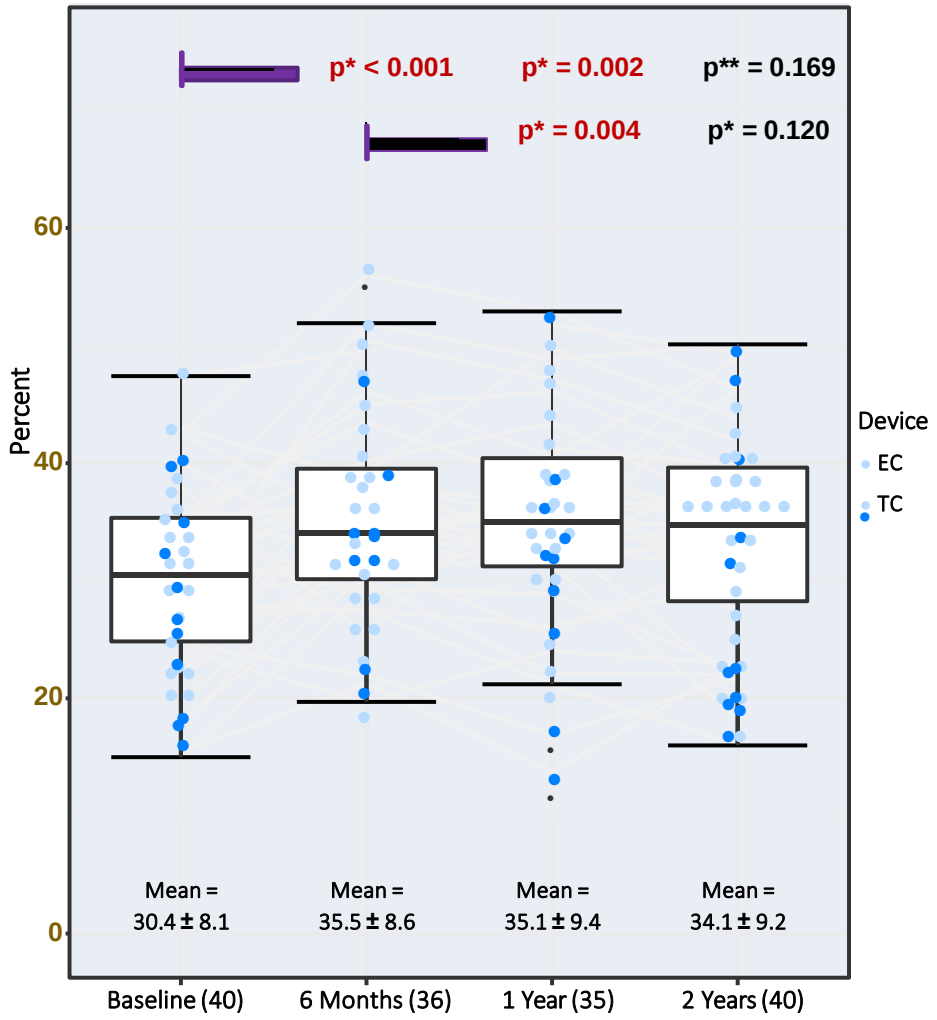
LVEDVI



*Student's t–Test, **Wilcoxon–Signed–Rank Test

Left Ventricular Ejection Fraction & NYHA Class:
Echo & Clinical Data (Cases With 2–Year Follow–Up)

LV EF



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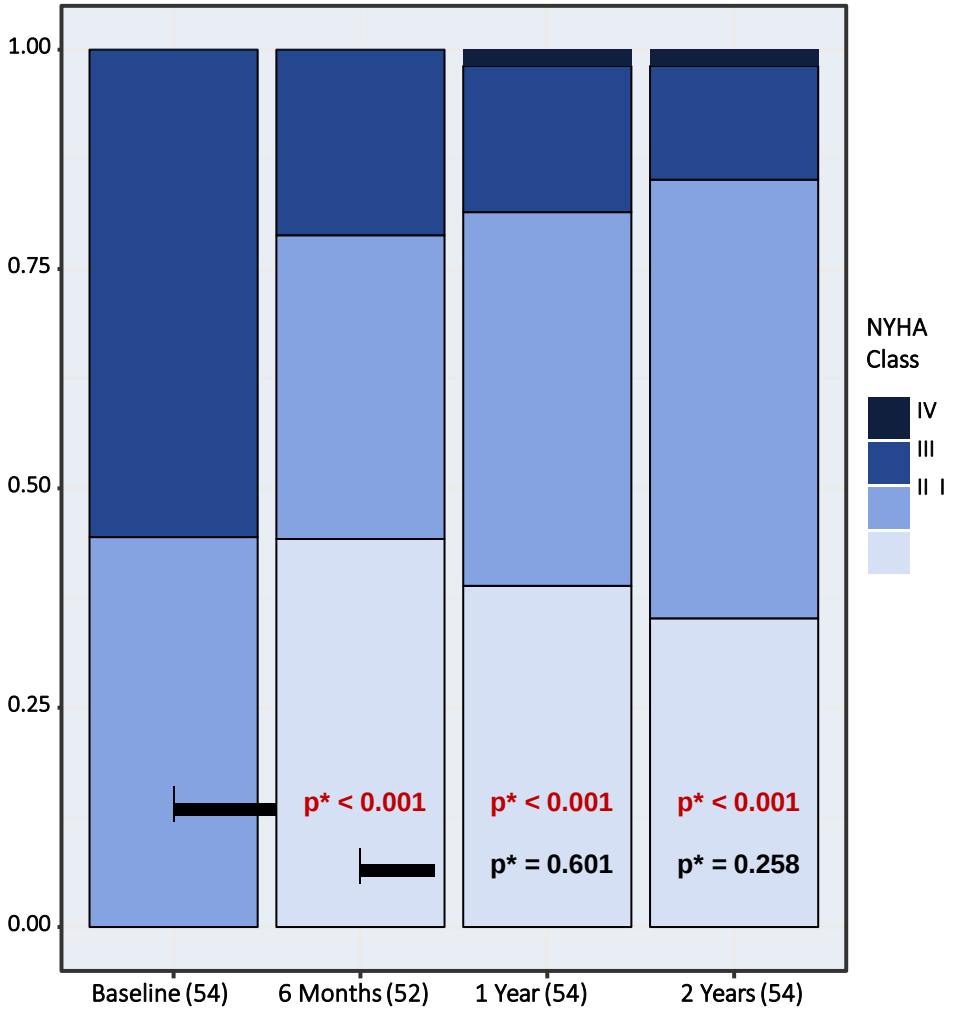
NYHA Class

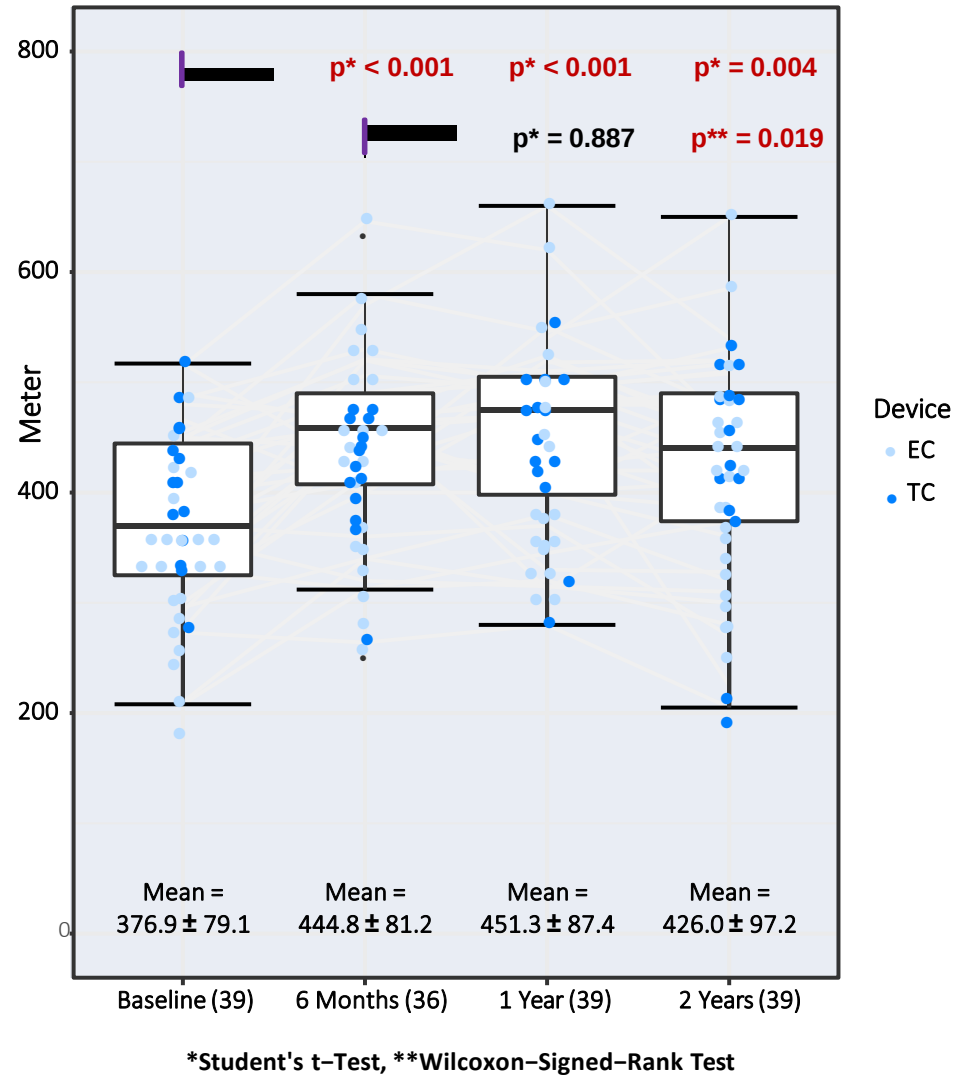


* Chi–Squared Test – Data current as of November 2017

Six Minute Walk Test (SMWT) & Minnesota Living with Heart Failure Questionnaire (MLHFQ)

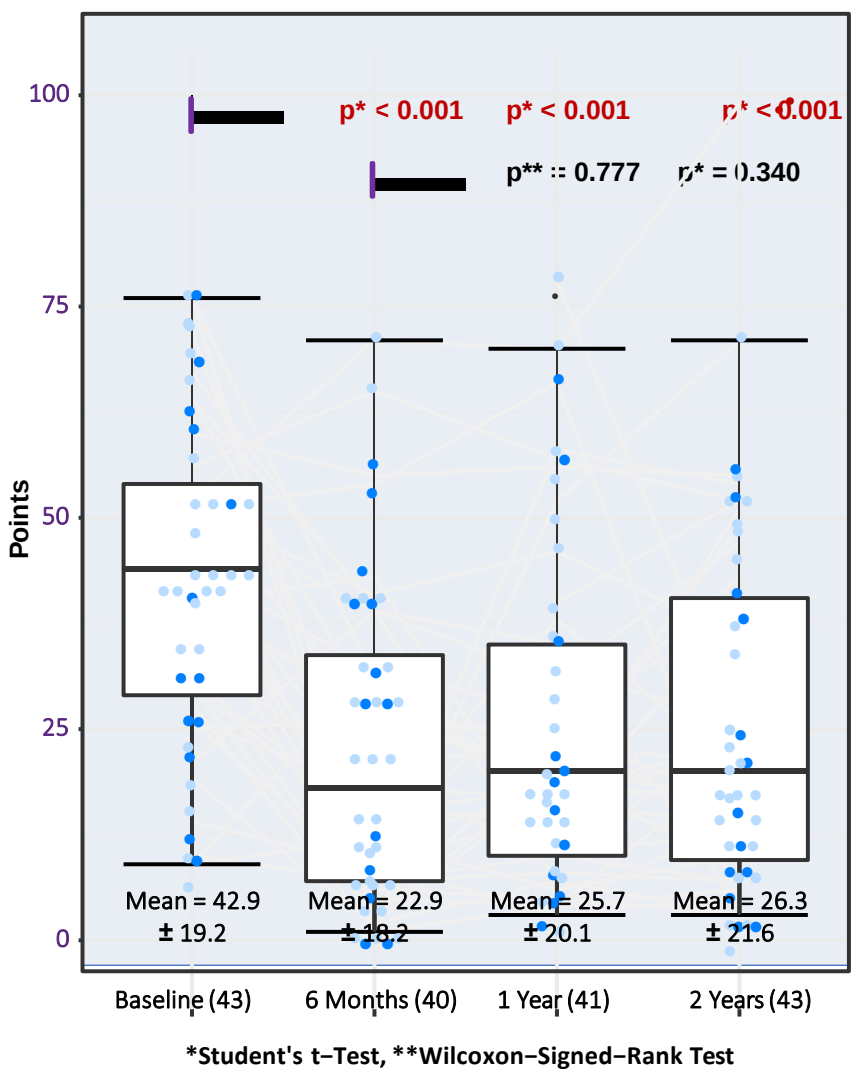
Cases With 2–Year Follow–Up

SMWT



*Student's t–Test, **Wilcoxon–Signed–Rank Test

MLHFQ



*Student's t–Test, **Wilcoxon–Signed–Rank Test

Procedure Simplification Initiative (PSI):
Post Market Data Collection

Patient Demographics

Total Number of Patients	57
Successful Procedures	54/57 (94.7 %)
Age [years]	58.2 ± 10.2
Height [cm]	170.0 ± 8.7
Weight [kg]	77.8 ± 16.6
BSA [m2]	1.91 ± 0.24
Gender [% male]	75.0
Preop ICD / PM [%]	35.8

Operative Data

Total Number of Patients	54
Skin-to-Skin Time [hh:mm]	3:23 ± 1:21
Total Anchors	2.7 ± 1.0
Internal Anchors	1.5 ± 0.7
External Anchors	1.2 ± 0.8
Fluoroscopy Time [mm:ss]	49:06 ± 26:26
Dosage [mGy/cm^2]	2065 ± 1973

Data current as of December 18, 2017

PSI Pre- / Post-Op Data

N=54	Pre-op	Post-op	P
LVEF [%]	28.6 ± 7.8	36.8 ± 8.6	< 0.001
LVESVI [mL/m²]	67.9 ± 24.8	39.6 ± 8.4	< 0.001
LVEDVI [mL/m²]	95.5 ± 30.6	59.0 ± 2.1	< 0.001

(Paired t-Test)

Volumes data taken from intraoperative echocardiography.
Data current as of December 18, 2017

Comparison EC & TC / PSI

	EC & TC (86)	PSI (54)
EF [Change in %]	+ 16.7	+ 34.1
LVESVI [Change in %]	- 24.4	- 42.5
LVEDVI [Change in %]	- 20.7	- 37.9
Stay On ICU [Median in Days]	4	1
Hospital Stay [Median in Days]	23	7

Volume data taken from echo (EC and TC 3 months, PSI postoperative)

Complications

Total Number of Patients	54
In-Hospital Mortality	5 (9.3 %)
Tricuspid Valve Injury RV	6 (11.5 %)
Perforation	9 (17.3 %)
Anchor Pulled Through / VSD	3 (5.7 %)

Data current as of December 4, 2017

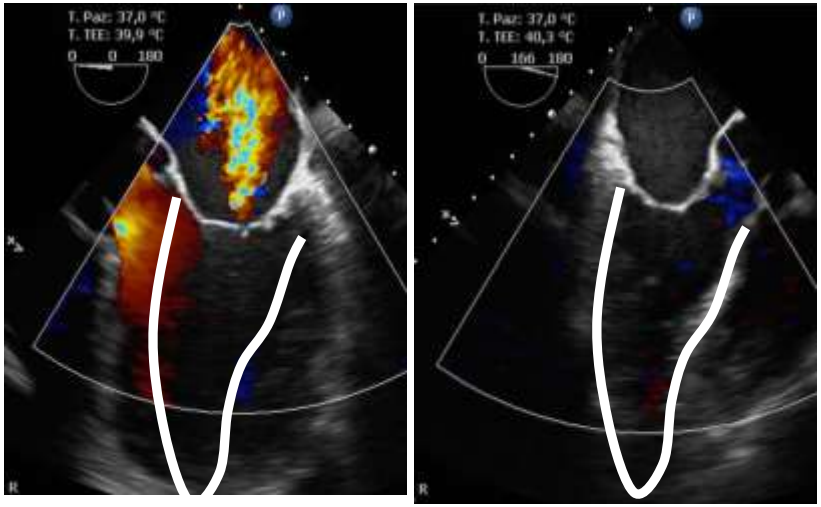
Impact on Mitral Regurgitation

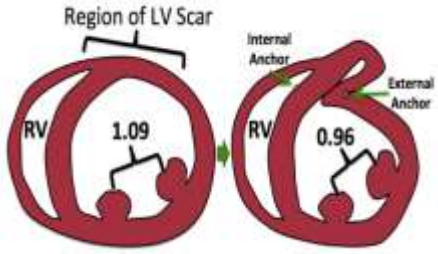
MV ≥ 2 n = 12	Pre-Op	Post-Op	*p* [Paired t-Test]
MR [Grade]	2.2 ± 0.5	1.3 ± 0.8	**0.008**
Annulus Diameter [mm]	42.1 ± 7.9	42.6 ± 7.6	0.820
Coaptation Depth [mm]	9.97 ± 3.49	9.36 ± 2.62	0.031
Tenting Area [mm²]	2.54 ± 1.01	2.58 ± 0.85	0.148
Tenting Volume [mm³]	5.76 ± 3.24	6.23 ± 3.00	0.547

CoreLab Data, November 2017

Patient Results 6 Months Post Procedure Show Improved Blood Flow

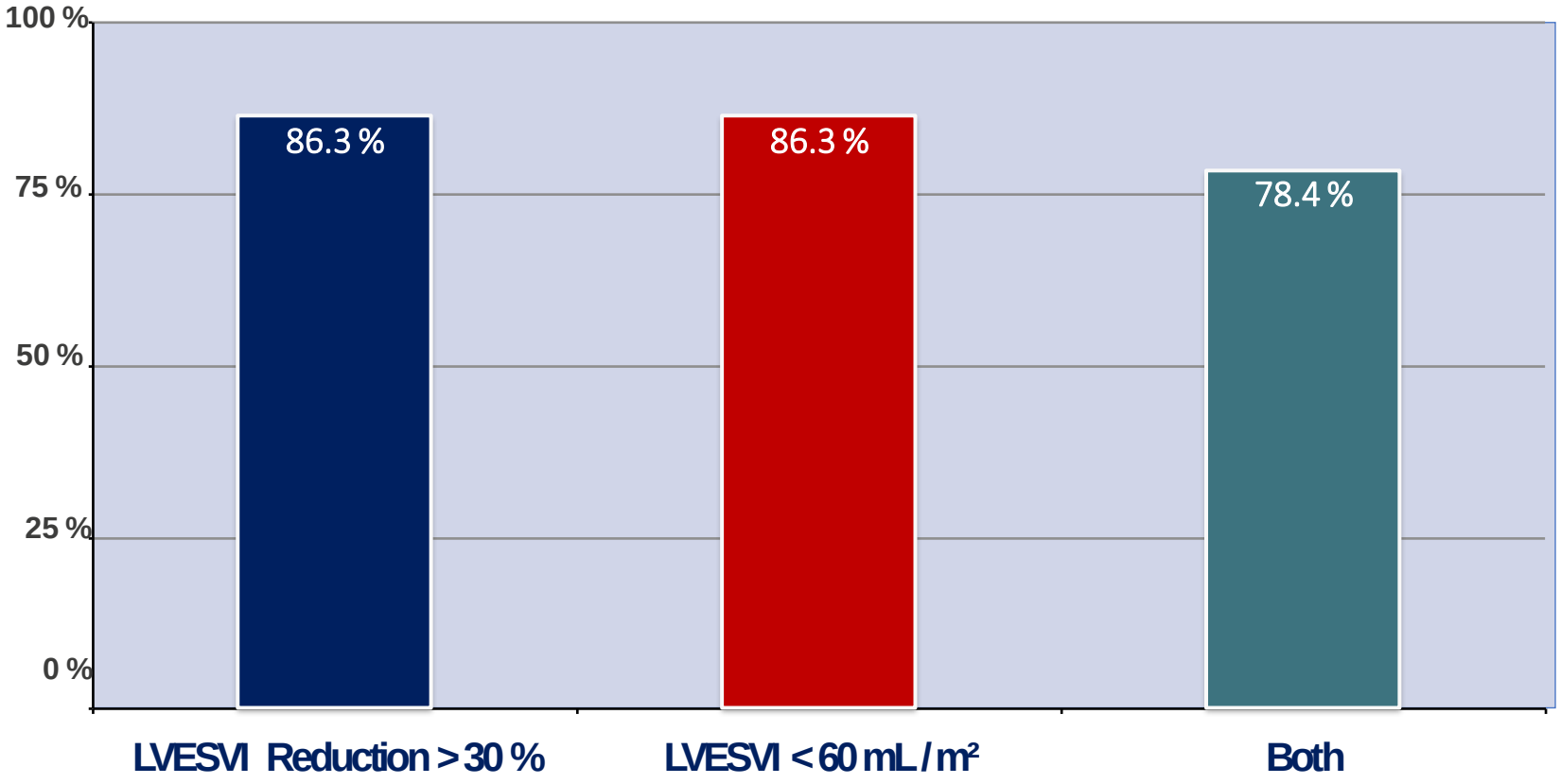
Baseline 6 month follow up





Change in papillary muscles geometry possibly influencing functional MR?

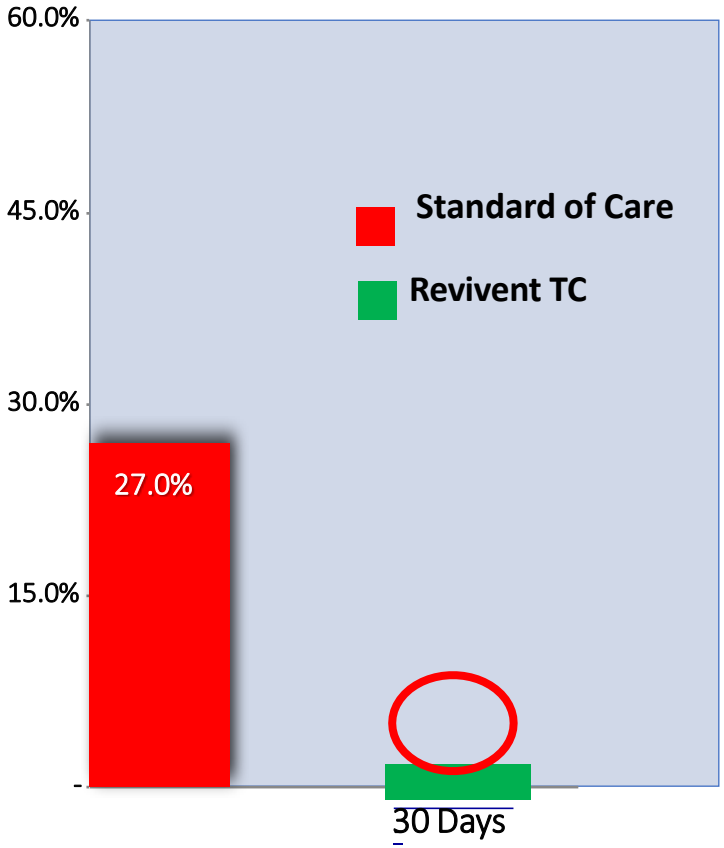
Postoperative PSI Results Better Than STICH Cut-Offs

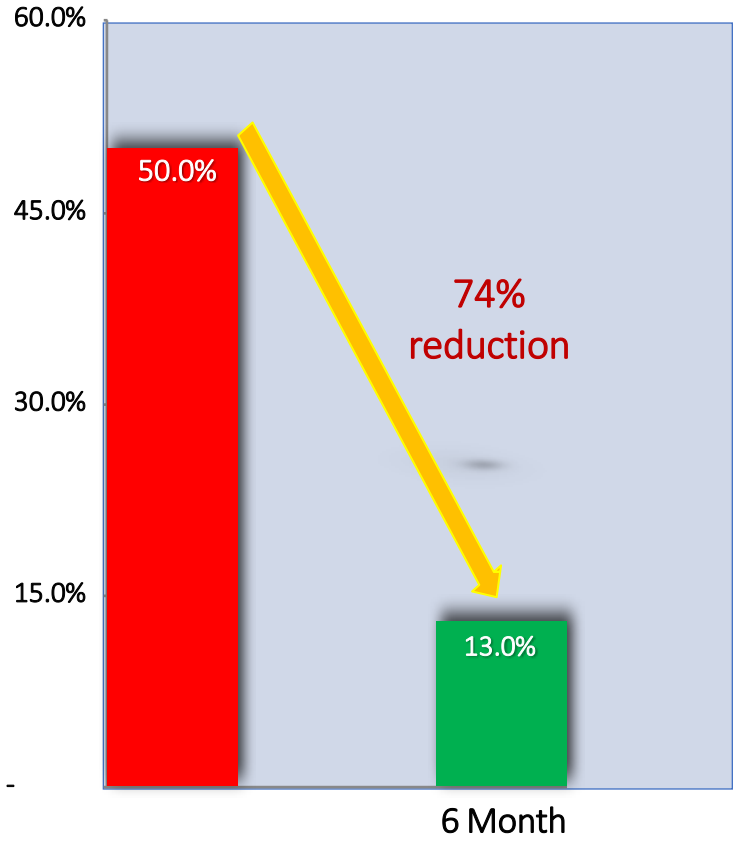


Data current as of November 22, 2017

Revivent Dramatic Reduction In Readmission Rates

Readmission Rate: Current Standard of Care vs. Revivent TC





Revivent's dramatic reduction in readmission rates has the potential to deliver significant cost savings to a healthcare system that currently spends >$30B annually treating HF in the U.S. alone

Source: Aghababian RV. Rev Cardiovasc Med 2002; 3:S3; Jong P et al. Arch Intern Med 2002; 162:1689 Jencks and Williams. NEJM 2009; 360:1418

Final Conclusions

- The Revivent system significantly:
  - **reduces** LVESVi and LVEDVi,
  - **improve** LV ejection fraction,
  - **improve** NYHA class, 6 minute walk test and QoL.
- With the Revivent TC system this can be done as minimally invasive hybrid procedure. In experienced centers the procedure showed a reasonable short learning curve
- These results remain stable for 2 years.
- The real clinical benefit needs to be confirmed by larger studies

Thank You