Cardioband Clinical Results

Sept. 2016

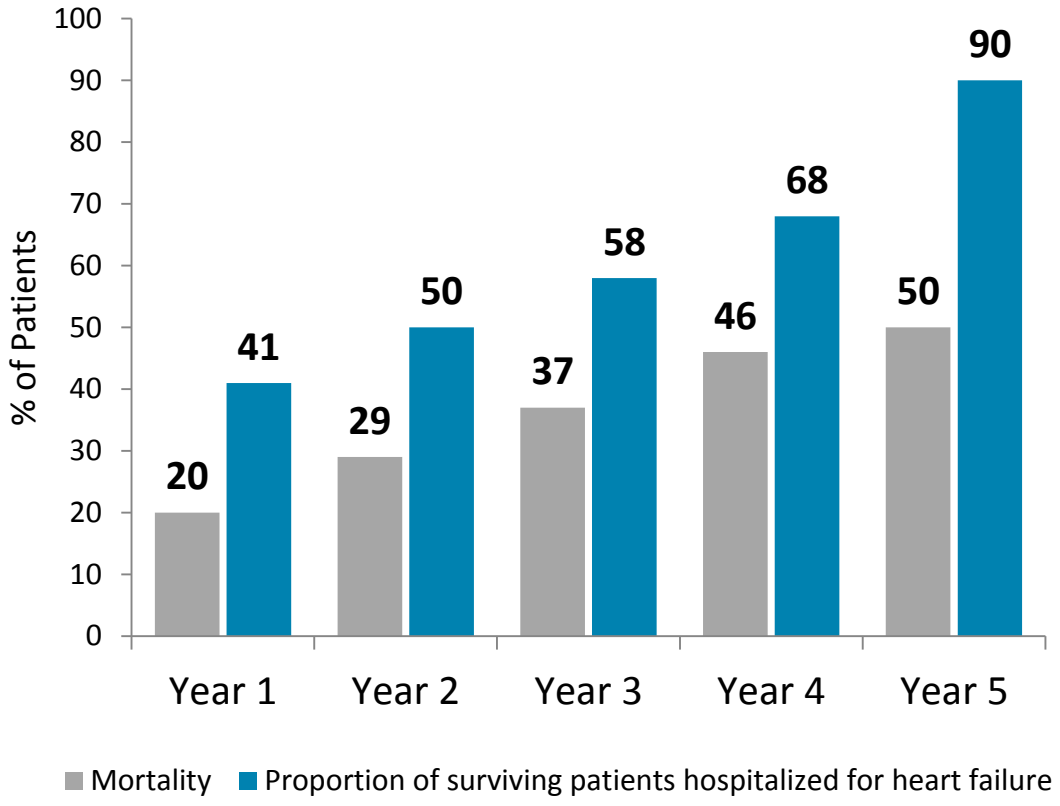


Medically Managed Patients with Severe MR Have Poor Outcomes

20%
One year mortality rate

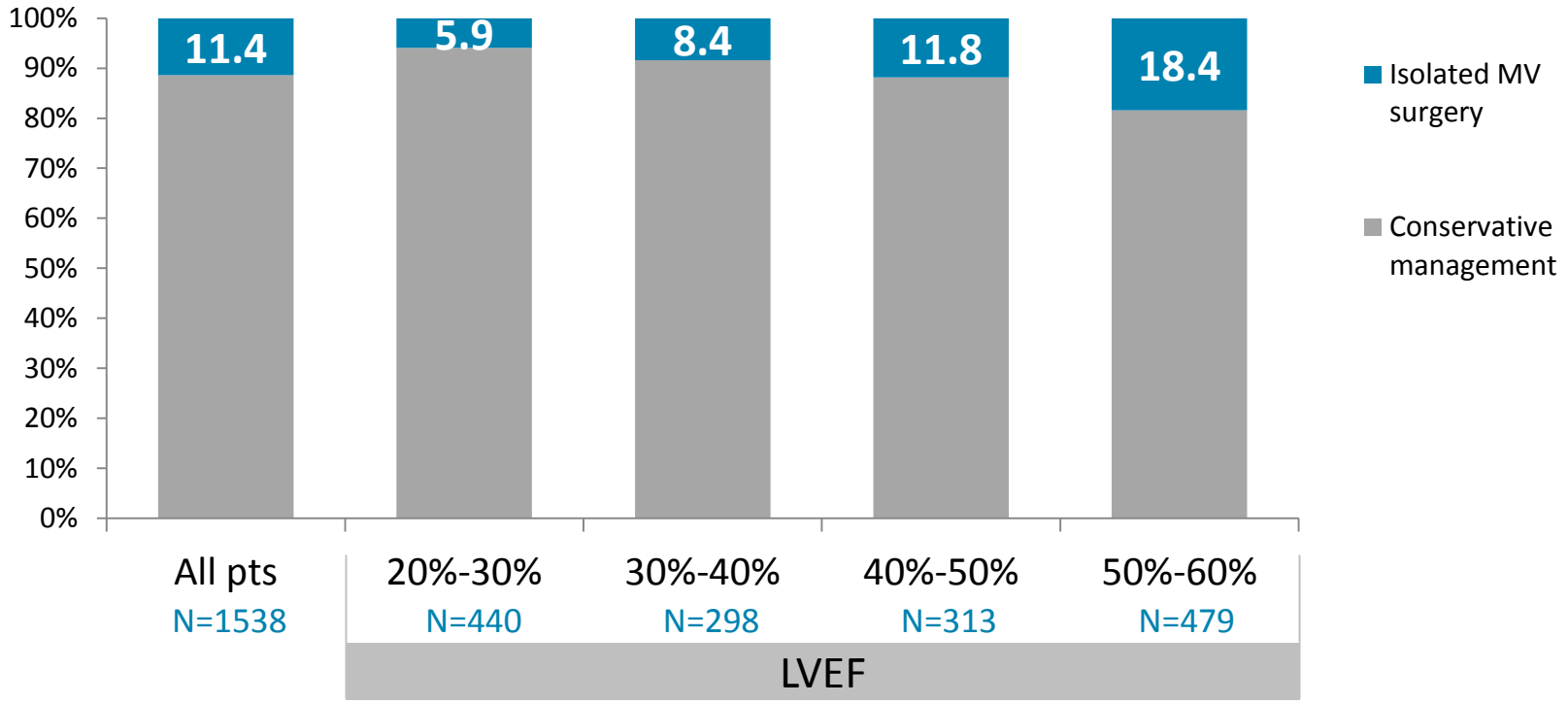
50%
Five year mortality rate

Very high
rate of heart failure hospitalization



*Sachin S. Goel, JACC Volume 63, Issue 2, January 2014

Most Patients with Isolated FMR are Conservatively Managed Today*



***Duke Databank:** 1,538 pts with echocardiographic 3+ to 4+ FMR and LVEF ≥20% between 2000 and 2010 not undergoing CABG

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* Curtesy of Dr. Michael Mack

Cardioband Percutaneous Direct Mitral Annuloplasty

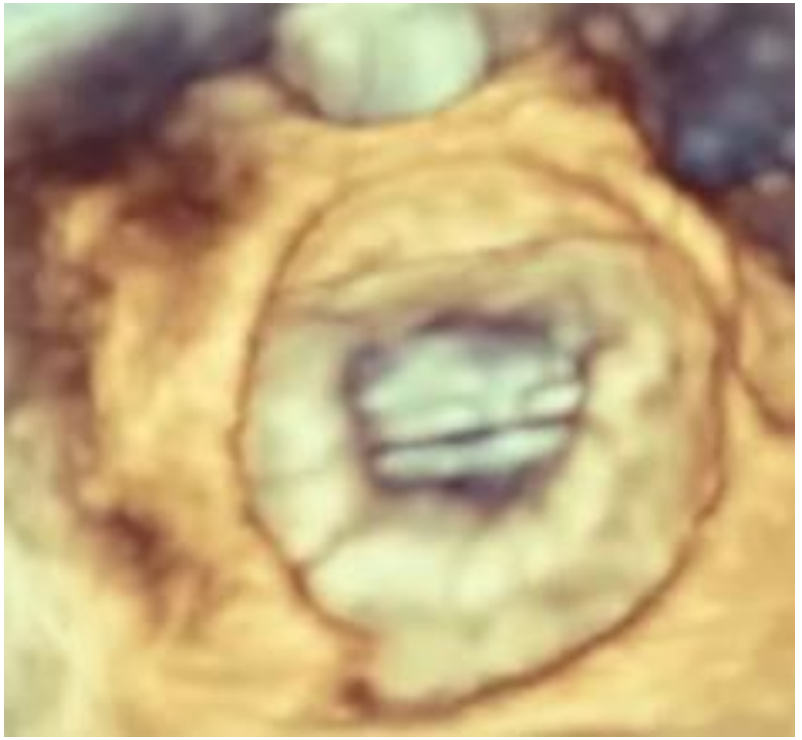
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Guess: Which is Cardioband?

Surgery

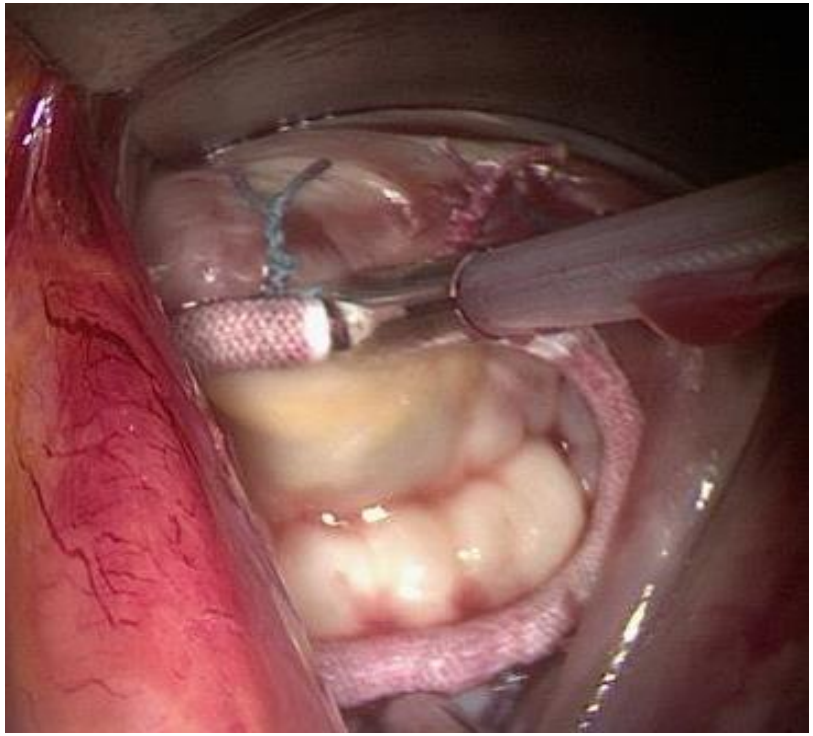


Cardioband

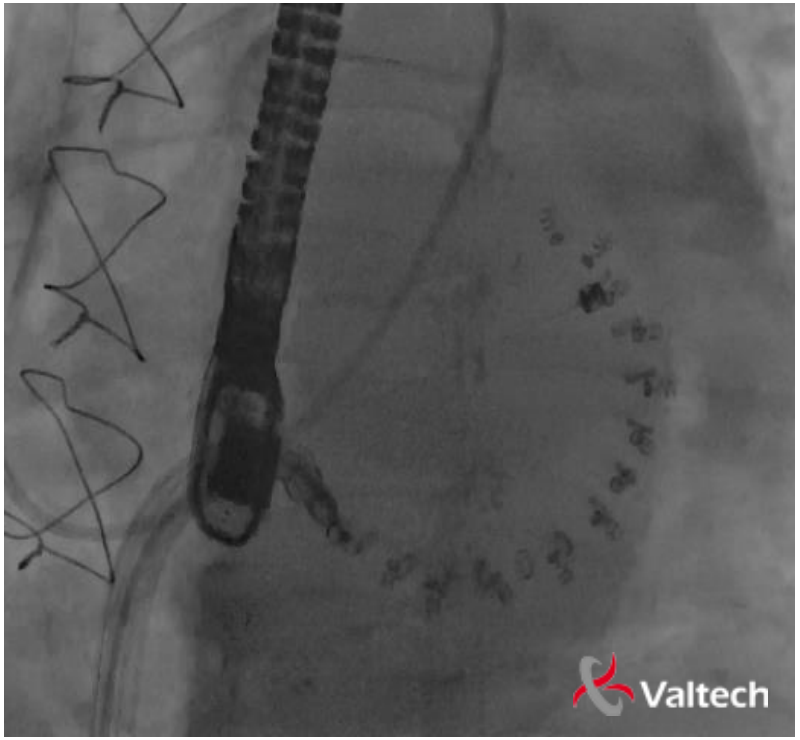


But Cardioband is Performed Tranfemorally

Surgery



Cardioband

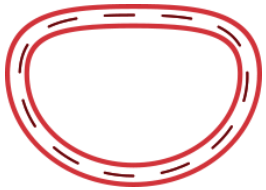


Cardioband: Key benefits



Transfemoral venous access (transseptal)

best for safety



Supraannular fixation

like in surgery



Significant Reduction of Annular dimensions

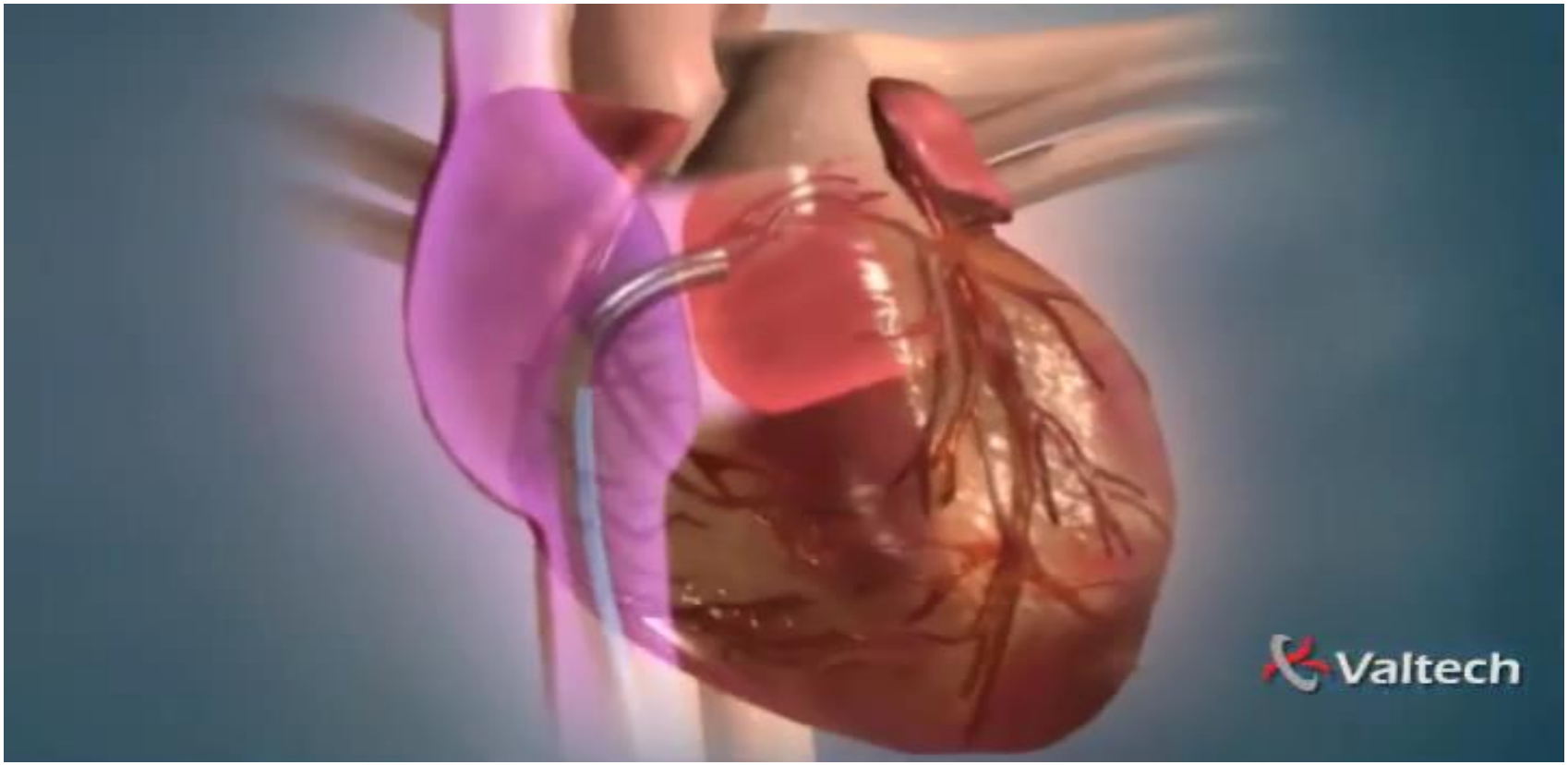
up to size 28 surgical ring



Keeps future options open

by preserving the native anatomy

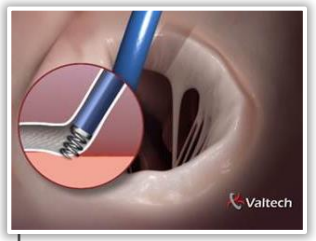
Watch How Cardioband Works





Cardioband procedure: Major Steps









Pre-Procedure Planning

1 **Transseptal Puncture**

2 **System Insertion**

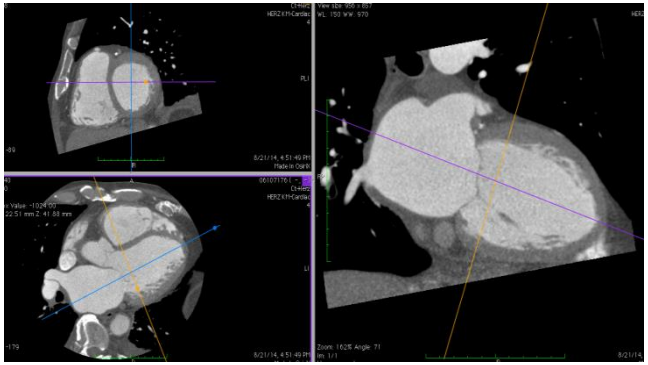
3 **Implant Deployment**

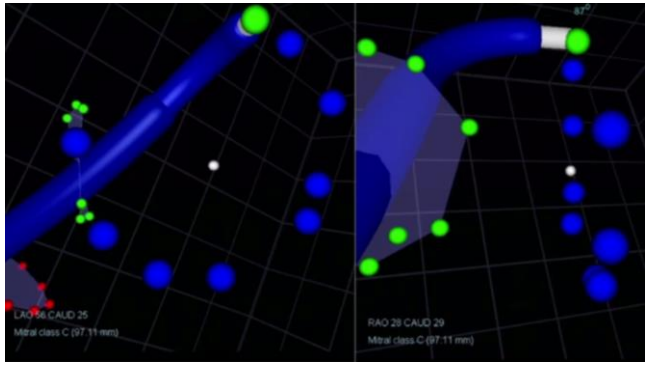
4 **Implant Size Adjustment**

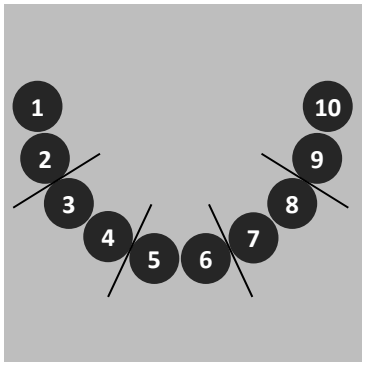
Pre-procedure CT for Automatic Planning

CT Analysis provides

- Sizing of the Annulus
- Transseptal Puncture location
- Expected Fluoroscopy Projections
- 3D preview of system position

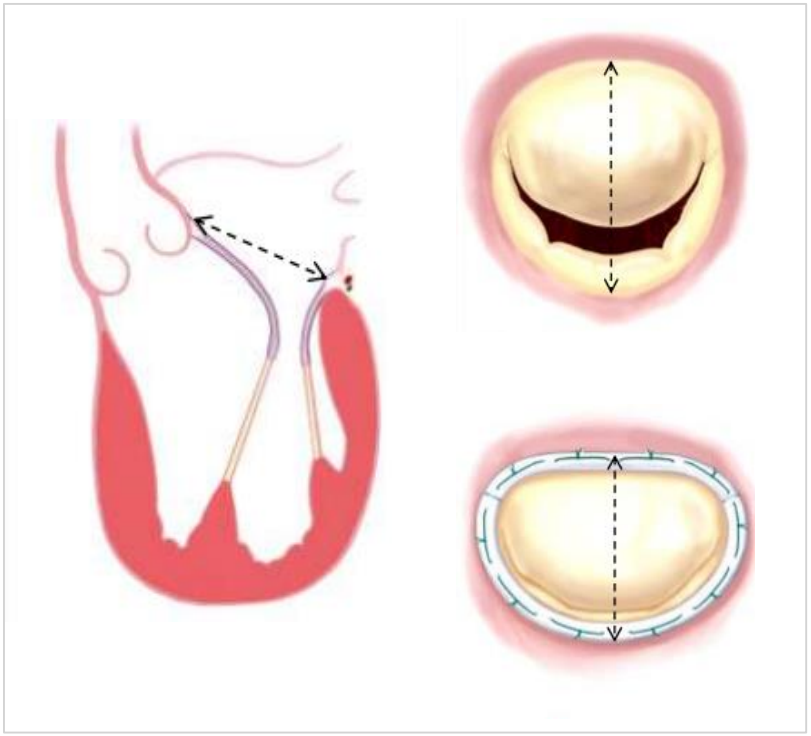






Reduction of Septo Lateral (A-P) Diameter by Cinching

Reduction in A-P

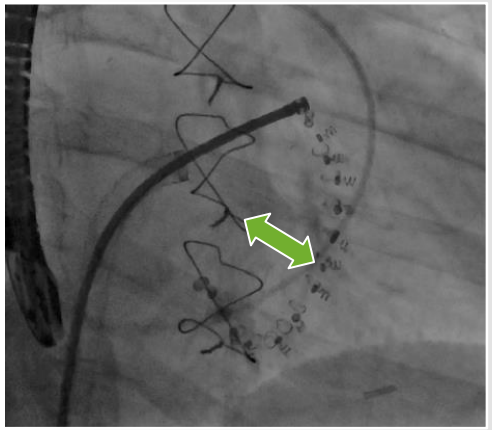


Cincing performed on Cadaveric Heart (TVT 2012)

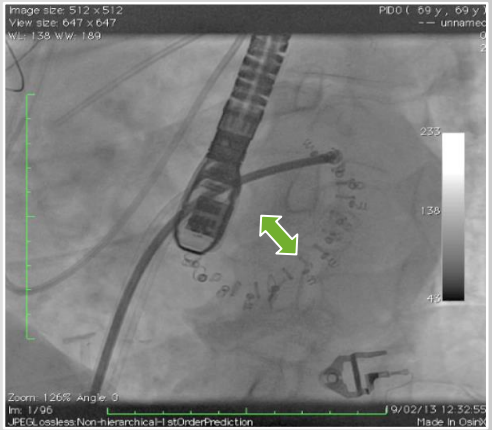


Intra Procedure Reduction of Septo Lateral (A-P) Diameter by Cinching

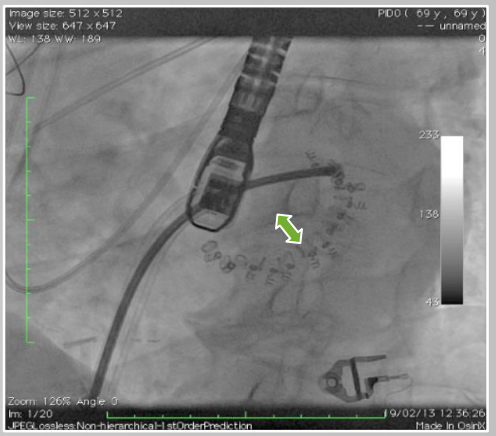
Annular Cinching by 10%



Annular Cinching by 20%

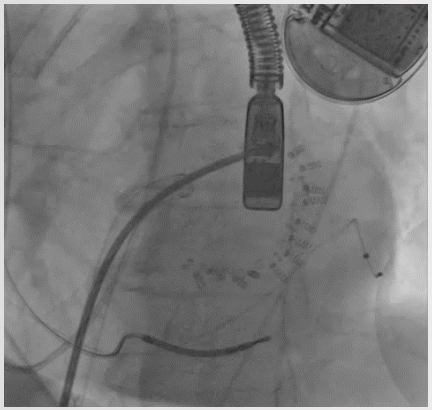


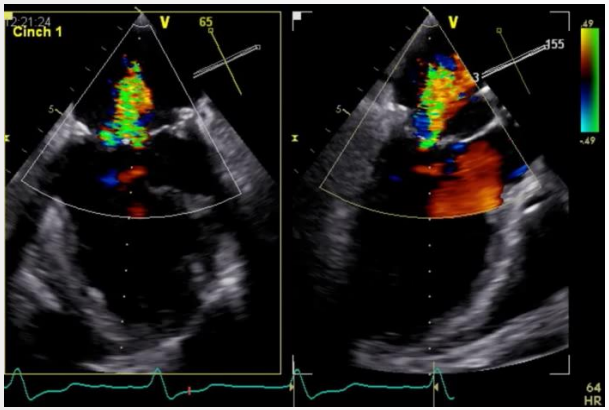
Annular Cinching by 40%



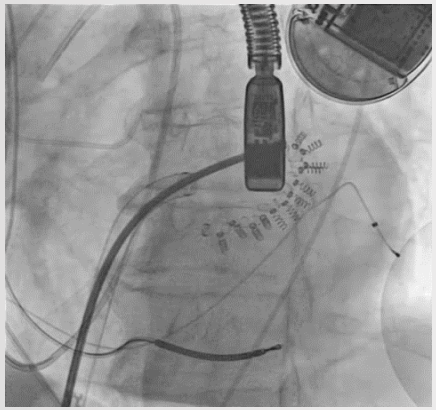
And Reduction of MR

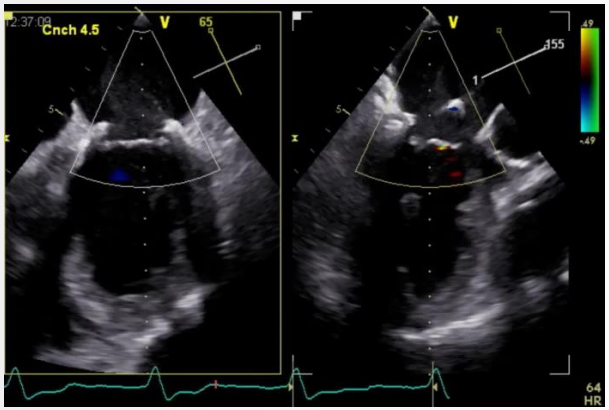
Baseline



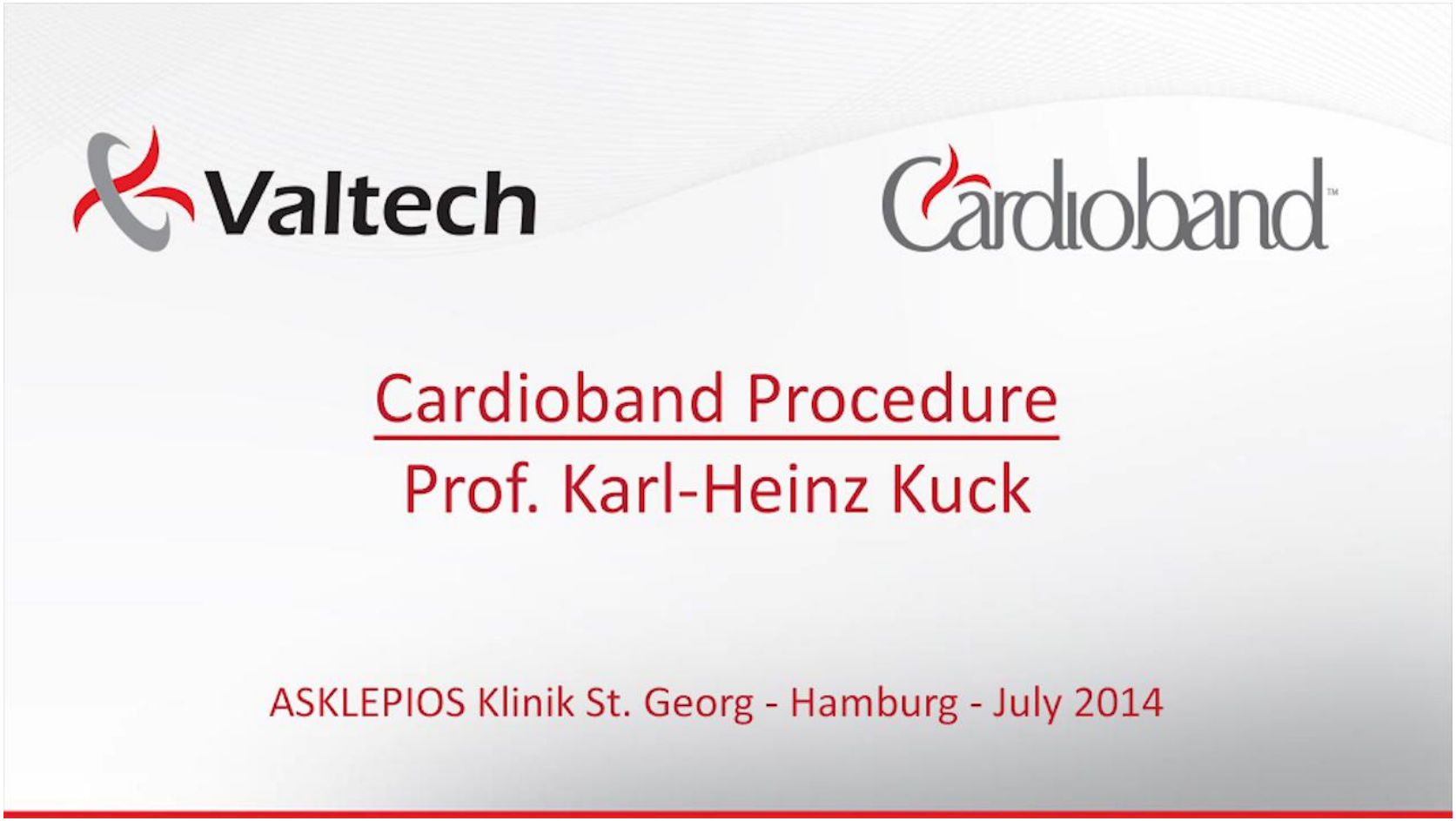


Final size Post Adjustment





And In Real life…



Update from European trial - 50 patients results

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The Study

A single arm, multi-center, prospective study with intra-subject comparisons to evaluate the performance and safety of the Cardioband for repair of functional mitral regurgitation.



Participating Sites



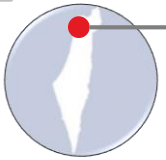
Zurich University Hospital **(2)**



Bichat Hospital **(12)**



HSR, Milan **(10)**



Rambam Health Care Campus **(1)**

Asklepios Klinik, St. Georg **(8)**



Medizinische Klinik Universitätsklinikum Bonn **(14)**



Heart Center University of Köln **(3)**





All Sites Implant Guided By Product Specialist Only.
Six More Sites Are Trained And Awaiting First Patient

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Study Demographics (N=50)

Variable	No. (%) or Mean
Age (years)	71 ± 8
Gender	Male 39 Female 11
Euroscore II (%)	7.5
Baseline NYHA Class of III or IV (%)	82
Ischemic **Non Ischemic**	31 19
LVEDD (mm) Avg (min-max)	61 ± 6
EF (%) Avg (min-max)	33 ± 11
Prev CABG **COPD** **Moderate to Severe Renal Failure** **Severe Pulmonary Hypertension** **Afib**	16 (32%) 11 (22%) 38 (76%) 12(24%) 39 (78%)

Reported Major Safety Events at 30 Days

30 Day Events*	Patients Experiencing Event, # (%) All Patients N=50
Death	2 (4%)
Hemorrhagic Stroke**	1 (2%)
Need for elective Mitral Operation**	1 (2%)
Ischemic attack	1 (2%)
Major Bleeding Complications	1 (2%)
Renal Failure	2 (4%)
Myocardial Infarction	0 (0%)
Respiratory Failure	0 (0%)
Cardiac Tamponade	1 (2%)

* VARC Guidelines (European Heart Journal, 2012, 33:2403-2414)
** Part of the Death case
One additional death case per ITT - compassionate

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Primary EndPoints

Safety	Performance
• Overall rate of Major Serious Adverse Events (SAEs) and Serious Adverse Device Effects (SADE) until hospital discharge and at post-operative 30 days. • Major SAEs: Death, myocardial infarction, cardiac tamponade, device related cardiac surgery, stroke	• Technical success rate of the implantation of the Cardioband • Technical feasibility of Cardioband adjustment • Cardioband ability to reduce mitral valve regurgitation (MR) Intra-procedure, at hospital discharge and at 30 days.

*Events will be defined according to VARC II guidelines

Secondary EndPoints

Safety	Performance
• Overall rate of Major Serious Adverse Events (SAEs) and Serious Adverse Device Effects (SADE) until 24 months	• MR Severity at 6, 12 and 24 months • Change in 6 MWT in 6, 12 and 24 months • Change in quality of life (MLWHFQ) at 6, 12 and 24 months

Major Inclusions



Inclusions

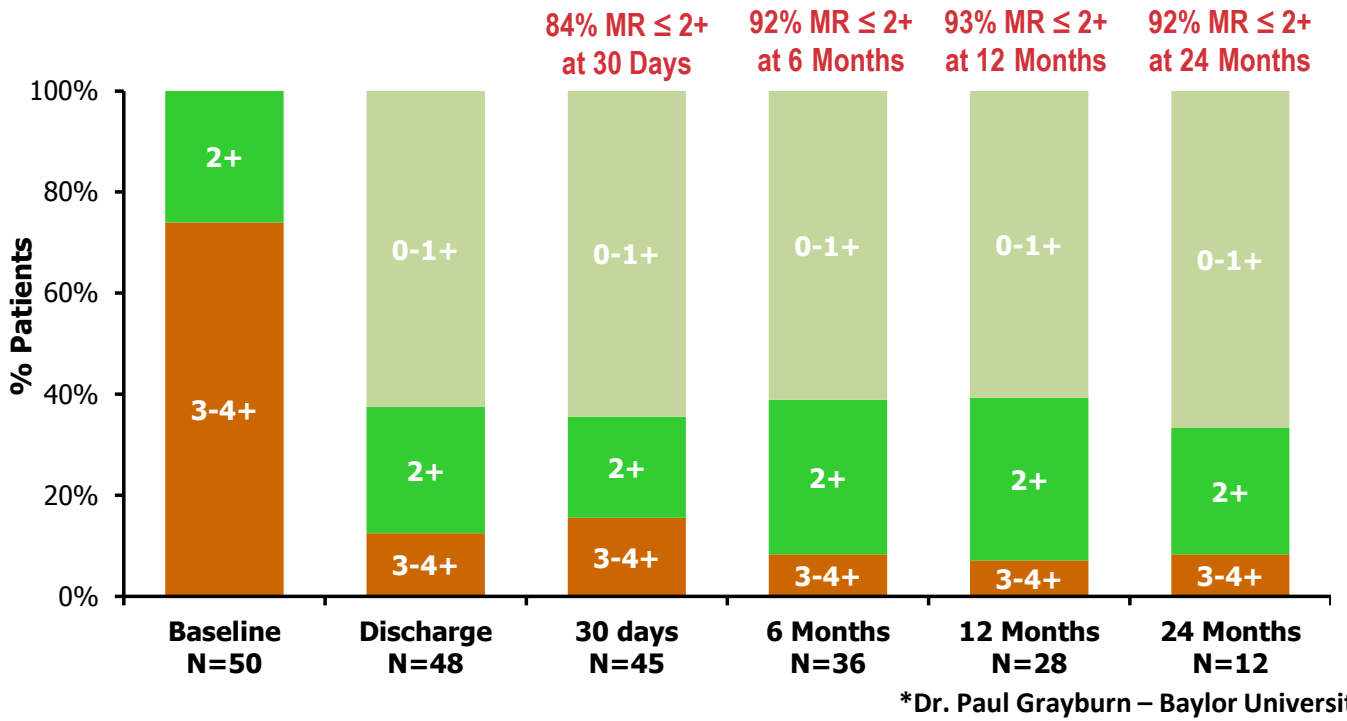
- Age > 18 years
- Symptomatic patients (NYHA Class II-IV) despite optimal medical therapy , including CRT if indicated
- LVEF ≥ 25%, LVEDD ≤ 70mm
- Moderate to severe functional MR
- Subject is high risk to undergo MV surgery
  (as assessed by a cardiac surgeon and a cardiologist, at the site and according to ESC/EACTS guidelines on the management of valvular heart disease)

Major Exclusions



- Untreated clinically significant CAD requiring revascularization
- Pulmonary hypertension >70mmHg at rest
- Renal insufficiency requiring dialysis
- Right-sided congestive heart failure with echocardiographic evidence of severe right ventricular dysfunction and severe tricuspid regurgitation
- Heavily calcified annulus or leaflets
- Any recent cardiovascular intervention
- CVA or TIA within 6 months or severe carotid stenosis (>70% by Ultra sound)
- Mitral valve anatomy which may preclude proper device treatment

92% patients with MR≤2+ At 24 Months By Core Lab*

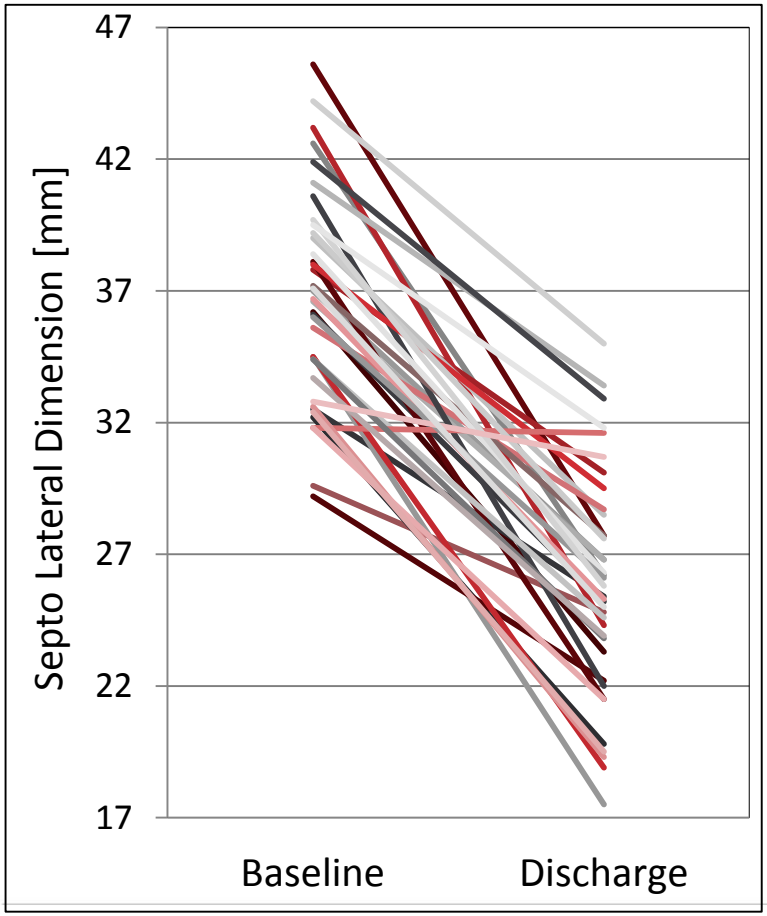


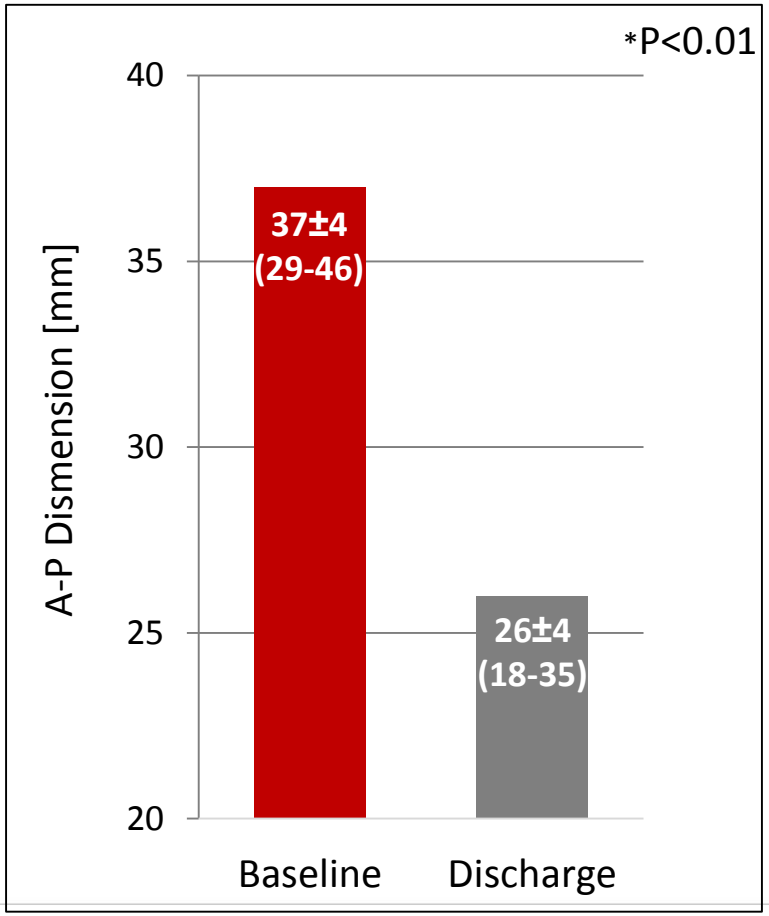
*Dr. Paul Grayburn – Baylor University

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Annular Reconstruction by Significant Reduction in Septo Lateral (A-P) Dimension

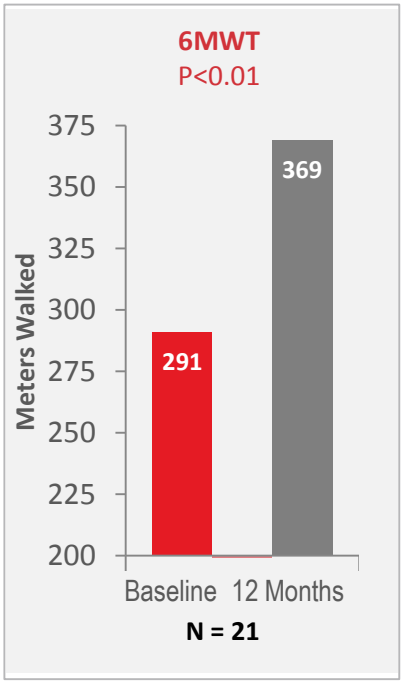
30% average reduction in A-P (N=39)

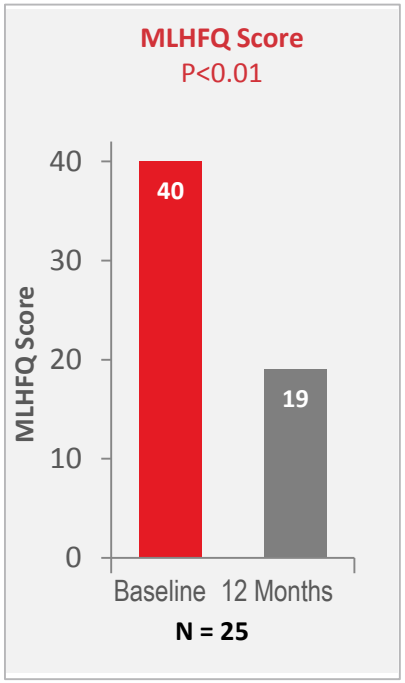


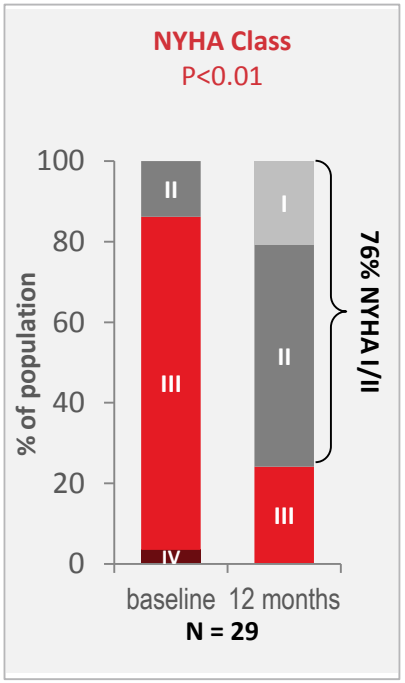


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Functional Improvement at 12 Months

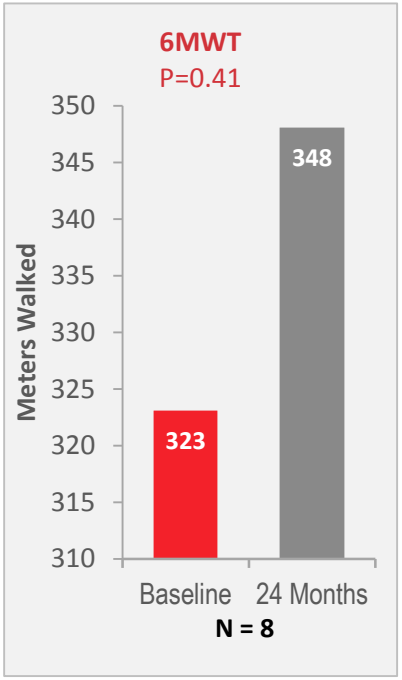


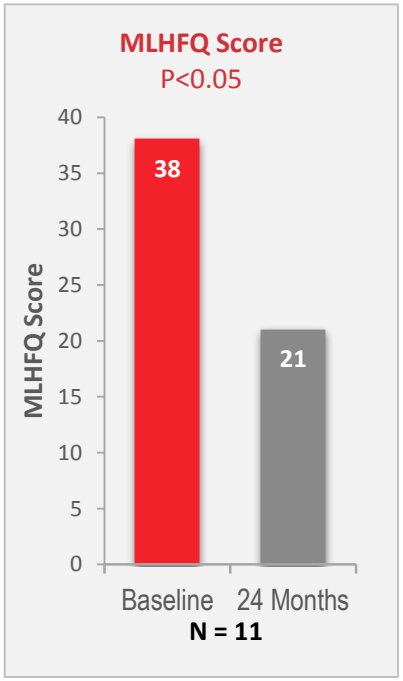


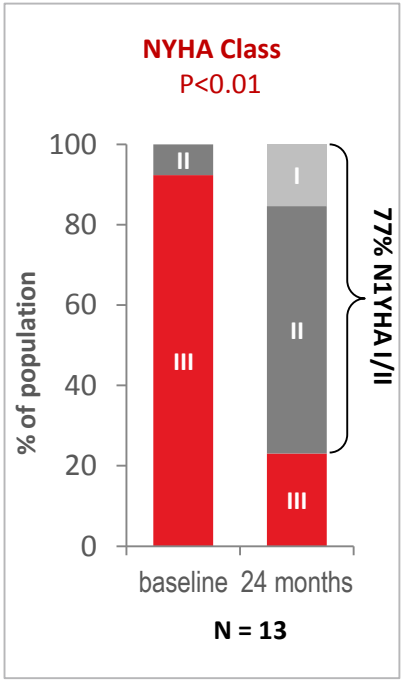


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Functional Improvement at 24 Months







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Summary

- Transcatheter surgical annuloplasty is feasible.
- Safety profile similar to equivilant transcatheter procedures.
- Significant and consistent reduction in SL dimension
- Significant and consistent reduction in MR
- **Options remain open for future interventions**



Cardioband - Delivering Surgical Annuloplasty Through A Catheter