Let's Implant a LVAD

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PROFILE-LEVEL	Official Shorthand	General time frame for support
INTERMACS LEVEL 1	"Crash and burn"	Hours
INTERMACS LEVEL 2	"Sliding fast"	Days to week
INTERMACS LEVEL 3	Stable but Dependent	Weeks
INTERMACS LEVEL 4	"Frequent flyer"	Weeks to few months, if baseline restored
INTERMACS LEVEL 5	"Housebound"	Weeks to months
INTERMACS LEVEL 6	"Walking wounded"	Months, if nutrition and activity maintained
INTERMACS LEVEL 7	Advanced Class III	

Treatment

- Long-term LVAD

- Conventional surgery
- HTx waiting list
- *Mitraclip??*
- *Cardioband??*

INTERMACS level 4 to 7

- **Mitral valve surgery**
- **Revascularization (STICH TRIAL)**
- **Ventricular septal reshaping**
- **Unconventional surgery**

(Mitraclip, Cardioband, Bioventrix)

MITRA-FR Study

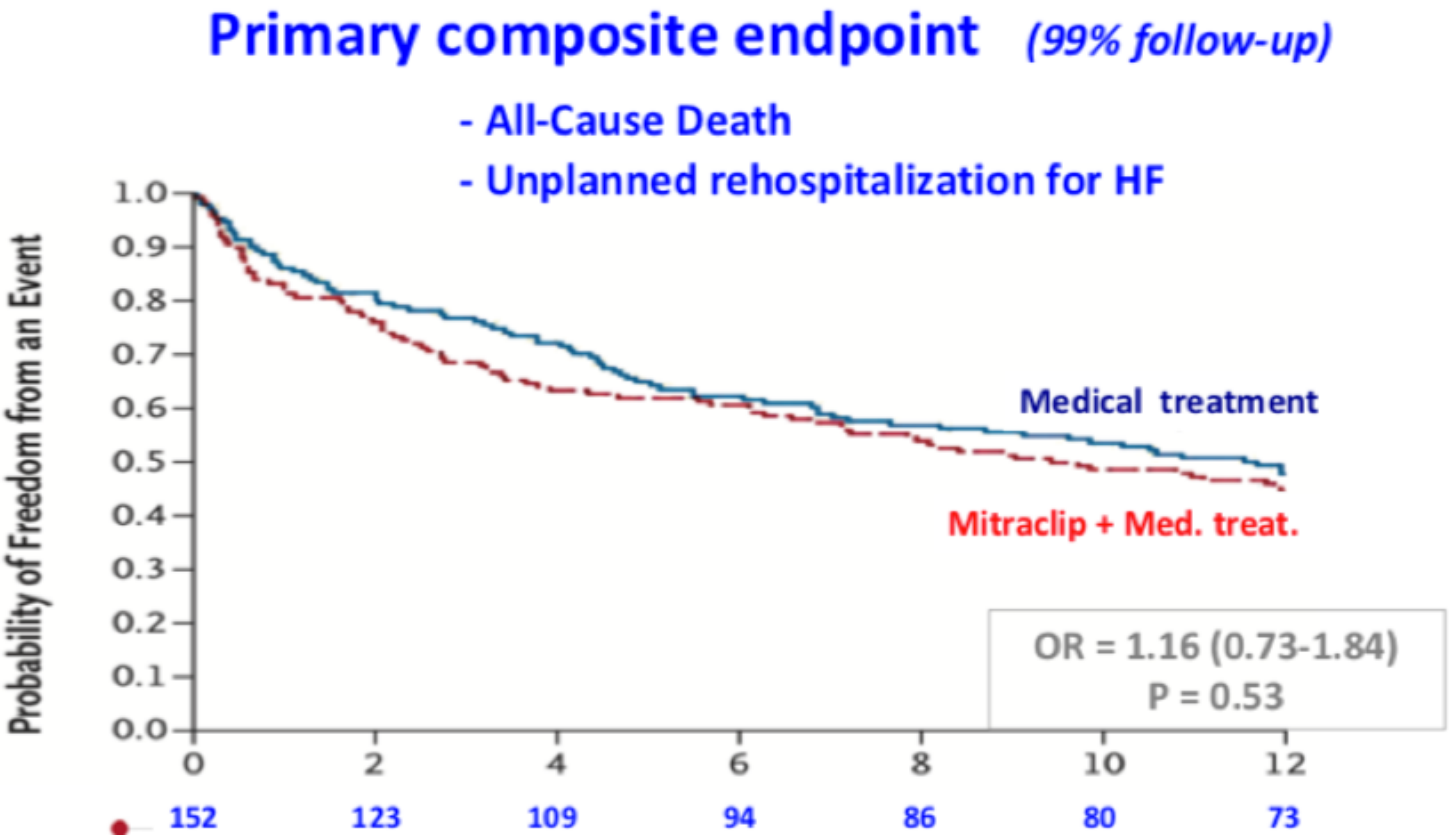
Objective → to evaluate the clinical efficacy of percutaneous mitral valve repair in addition to medical treatment in patients with heart failure and severe functional/secondary mitral regurgitation versus medical treatment alone.

Primary Endpoint "Composite" → All-Cause Deaths or Unplanned rehospitalization for Heart failure at 12 months

2 Groups

- 144 pt: **MitraClip + Optimal Medical therapy**
- 144 pt: **Optimal Medical therapy**

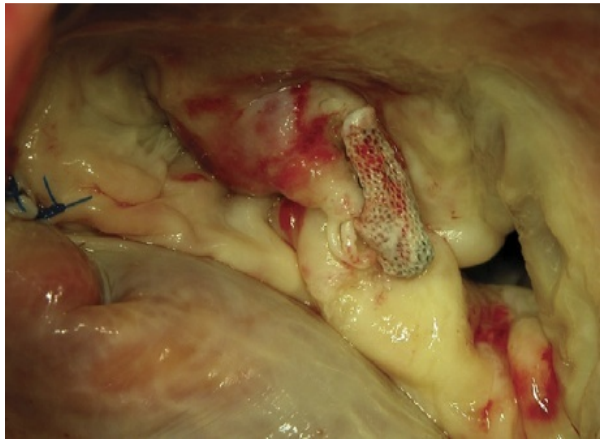
MITRA-FR Study

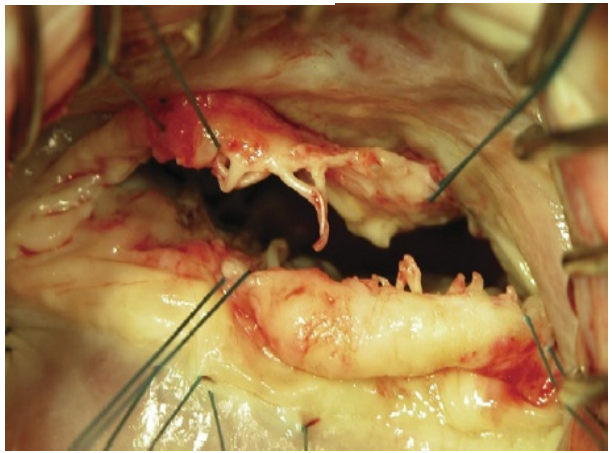


Complex Surgical Valve Repair After Failed Percutaneous Mitral Intervention Using the MitraClip Device

Stephan Geidel, MD, Jörg Ostermeyer, MD,
Michael Lass, MD, and Michael Schmoeckel, MD

Ann Thorac Surg 2010;90:277–9





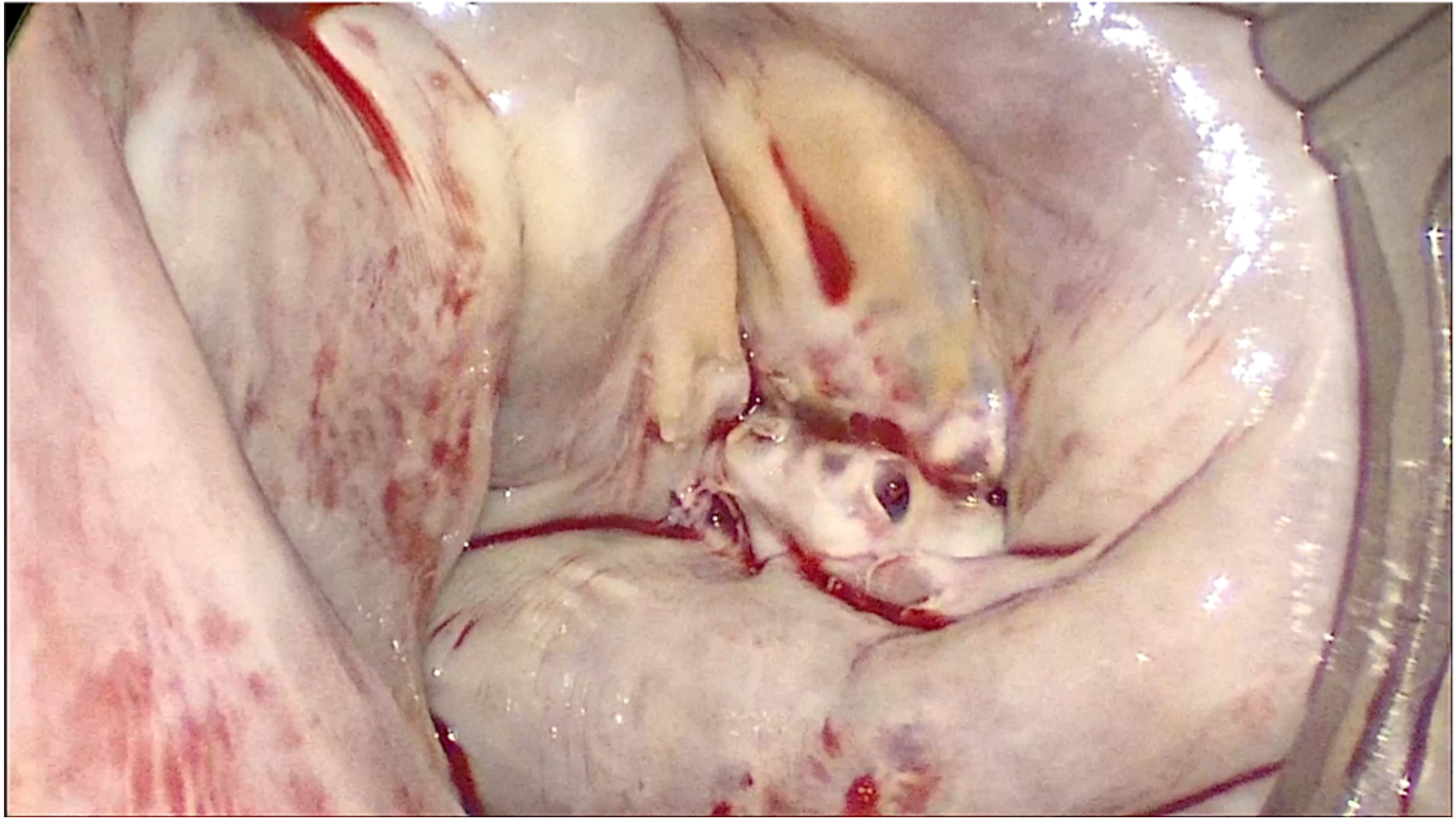
procedure. It is outlined that the conditions for surgery can be severely deteriorated, thereby reducing the chance for successful surgical repair after preceding mitral intervention.

Clinical Case

- Woman, 70 y
- Severe functional MR (Carpentier type I and IIIB)
- Permanent AF in Dilatative Cardiomiopathy (FE 35%)
- Episodes of Pulmonary Edema, TVS
- ICD/CRT implantation
- 06/2017 RHC: CVP 2, PAP 23/10/13, W 7, CI 1.58

→ MitraClip procedure with 3 clips

- MR reduced (moderate)
- Worsening conditions. FE 20% , increased PAPS, UTIC on inotropes



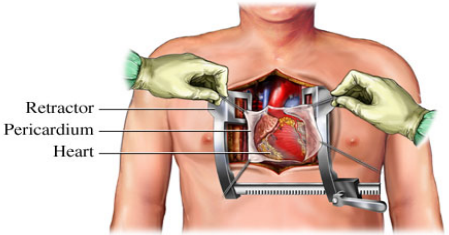
MitraClip

- **Pale** copy nof the Alfieri stich
- MR 2 is …a success…!!!???
- **Turbolences** (no PISA possible), stenosis? (2 clips …)
- Anatomical exclusions
- Mitral Valve **repair after clip**?

NOT a resonable option for functional MR in operable patients

Minimally invasive mitral valve surgery

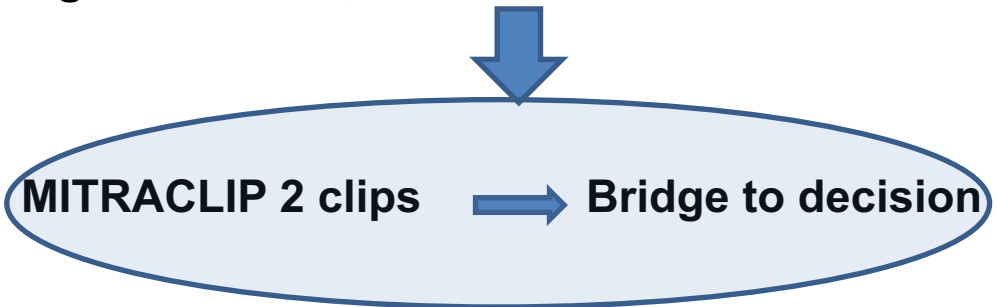
Evolution of Minimally Invasive Surgical Approaches



…from a wide open view to a total 3D video assistance…

Clinical case

- Sex: Female, Age: 54, Etiology: Post Ischemich Cadiomyopathy
- **INTERMACS Level: 4**
- **Episodes of pulmonary edema**
- **RHC (September 2017): CVP 9, sPAP 68, mPAP 45, dPAP 34, W 29, IC 1,65 PVR 6,6, TPG 16**
- **Post-NO: CVP 5, sPAP 55, mPAP 34, dPAP 20, W14, IC 1,77, PVR 4,5**
- **Echocardiogram EF 25%, MR 4+**



PRO Mitraclip

Pulmonary edema

High Wedge pressure

No Inotropic dependent

Severe MR, good echo parameters

Costs

Less invasive

PRO LVAD

Intermacs 4 ?

Severe pulmonary hypertension

Bridge to Candidacy

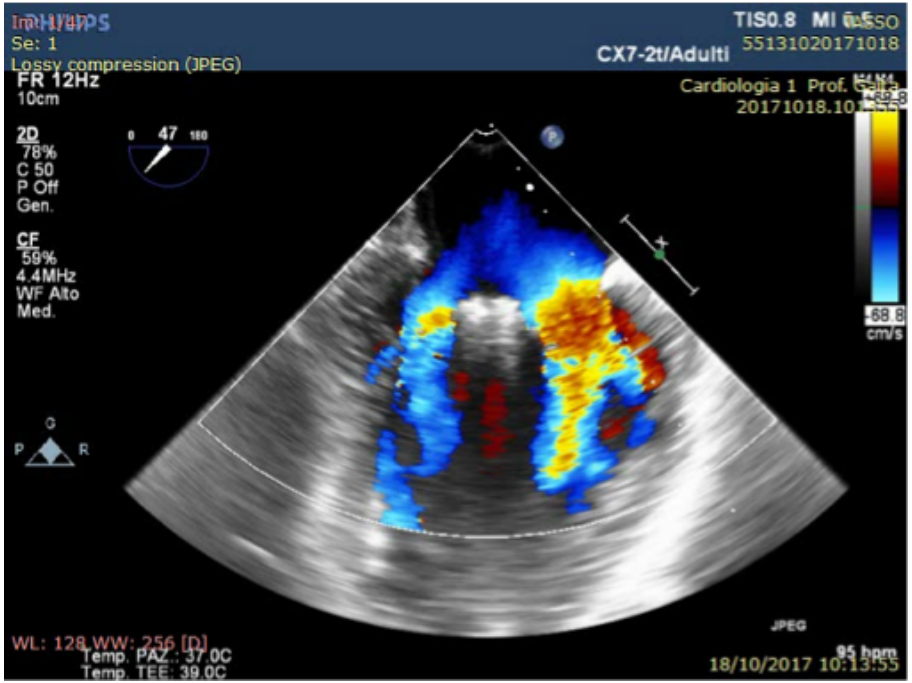
After 7 months…

- April 2018 new hospitalization for heart failure**, INTERMACS level 3**
- RHC: CVP 7, sPAP 70, mPAP 47, dPAP 29, W 34, IC 1,85, CO 3,3, PVR 4,29, TPG 13
- Ecochardiogram: EF 19%, RM 3+, Area 2,3 cmq, GM 6 mmhg, sPAP 81 mmHg

LVAD Bridge to candidacy + Mitraclip removal

Mitral valve stenosis after Mitraclip implantation

1 or 2 clips makes the difference!!



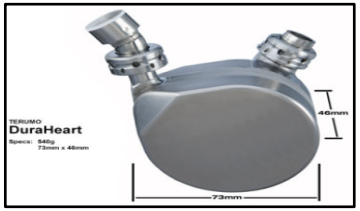
Largest to smallest
...in ten years...

4° Generation

100 grams

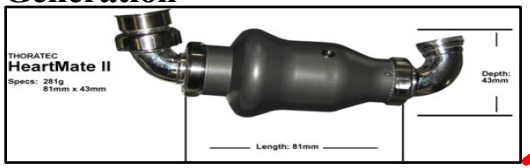
92 grams

3° Generation

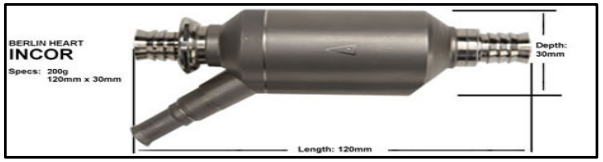


500 grams

2° Generation



300 grams



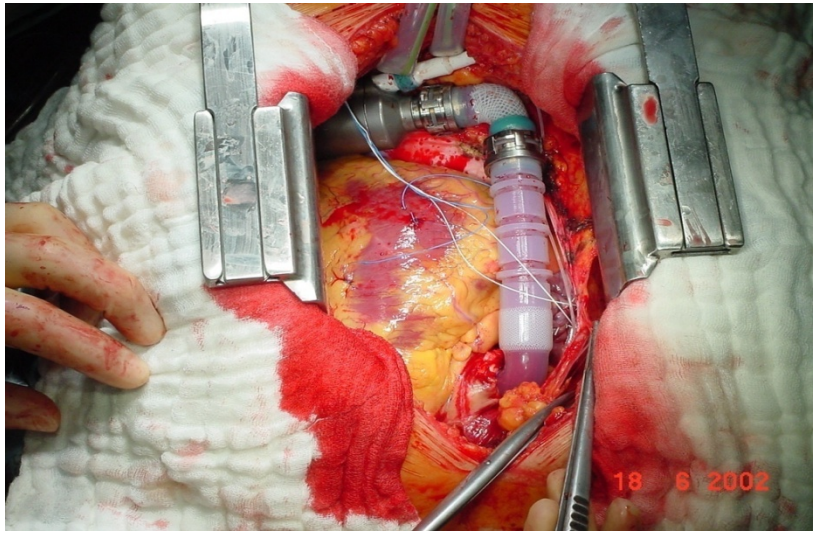
100 grams

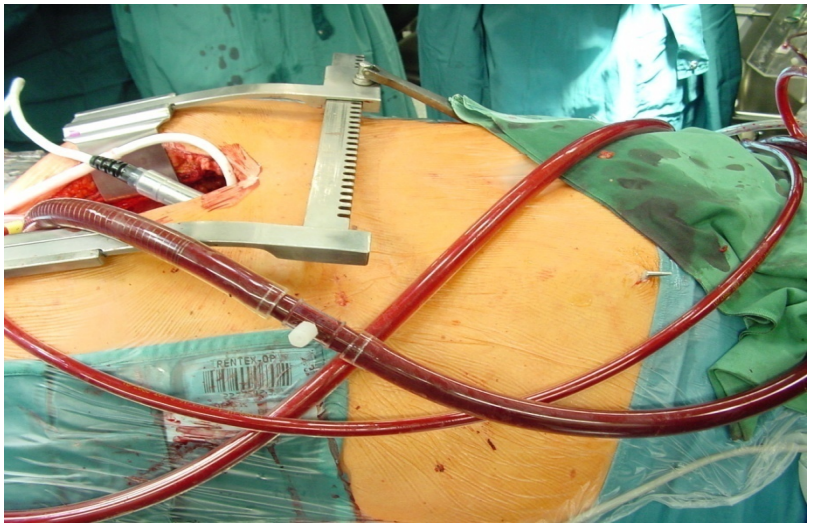
1° Generation

750 grams

1000 grams

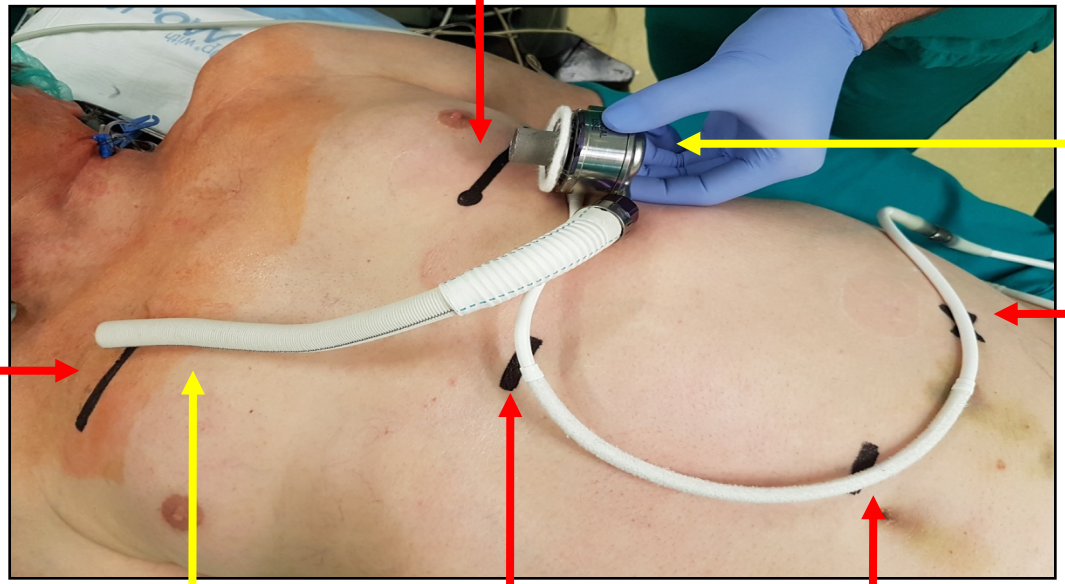
Ten years ago……Implantation





Minimally invasive LVAD implantation

Minitoracotomia antero-laterale sx (V-VI spazio intercostale)



Device

Exit-site

Minitoracotomia anteriore dx (II spazio intercostale)

Condotto di outflow

1° tunnellizzazione driveline

2° tunnellizzazione driveline

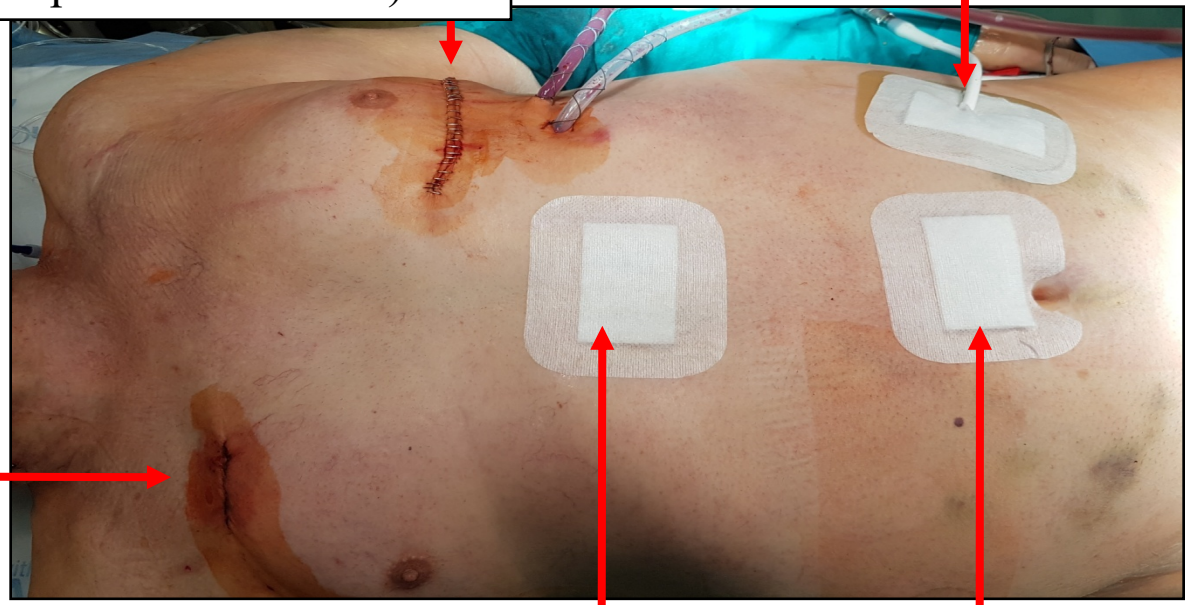
Minimally invasive LVAD implantation

Mitraclip removal

Minimally invasive LVAD implantation

Minitoracotomia antero-laterale sx (V-VI spazio intercostale)

Exit-site



Minitoracotomia anteriore dx (II spazio intercostale)

1° tunnellizzazione driveline

2° tunnellizzazione driveline

MITRACLIP before LVAD therapy ?

Systematic underestimation of mitral stenosis due to

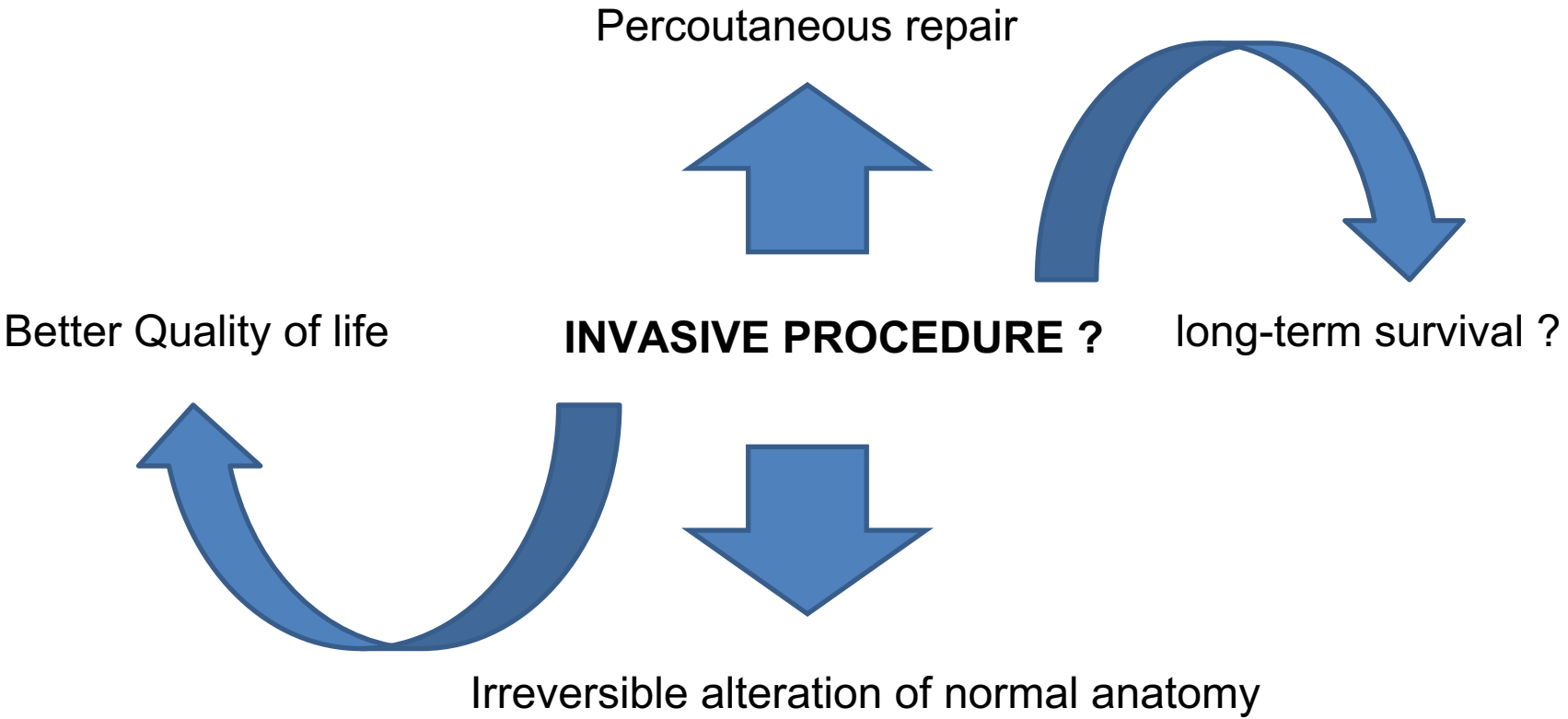
- **low CI**
- **high EDLVP**
- **double orifice (no PISA)**
- **conglutination of cordae (subvalvular stenosis)**

Need for clip removal? Residual moderate mitral regurgitation (mitral leaflets damage during removal)

Reduced LV unloading

Reversibility of pulmonary hypertension in BTC strategy?

MITRACLIP


Percoutaneous repair
Better Quality of life
INVASIVE PROCEDURE ?
long-term survival ?
Irreversible alteration of normal anatomy

Can we safely and effectively treat less sick non-inotrope dependent patients?

NYHA Class III		Class IIIB	Class IV (Ambulatory)		Class IV (On Inotropes)		
INTERMACS Profiles	7	6	5	4	3	2	1
Percent of current implants in INTERMACS[1]	1.0%	1.4%	3.0%	14.6%	29.9%	36.4%	14.3%
		FDA Approval: Class IIIB/IV					
CURRENTLY NOT APPROVED		LIMITED ADOPTION			GROWING ACCEPTANCE		

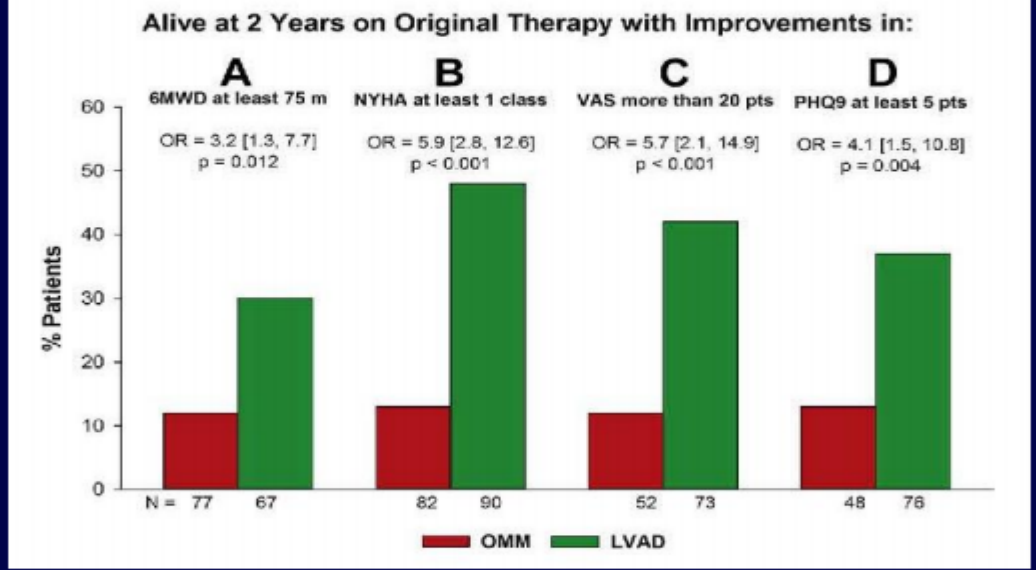
Prospective, nonrandomized, observational, multicenter clinical trial N= 200

ROADMAP Non-inotrope dependent

[1]Kirklin et al J Heart Lung Transplant 2014; 33:555-64

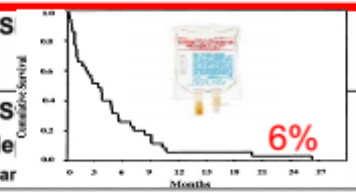
Improved 6MWT, NYHA, QOL and Depression in LVAD Patients

FIGURE 5 Primary and Secondary Composite Endpoints



INTERMACS: 7 clinical scenarios based hemodynamic and functional capacity at the time of LVAD implant

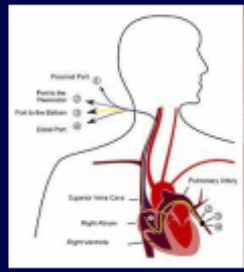
ADULT PROFILES	Current CMS - DT Functional Indication	IV INO*	Official Shorthand	NYHA CLASS Assumed	Modifier option
INTERMACS LEVEL 1	Met	X	"Crash and burn"	IV	TCS A
INTERMACS LEVEL 2	Met	X	"S	IV	TCS A
INTERMACS LEVEL 3	Met	X	"S de Car	IV	TCA if hosp FF if home A
INTERMACS LEVEL 4	+ Peak $VO_2 \leq 12$		Resting symptoms on oral therapy at home	AMB IV	FF A
INTERMACS LEVEL 5	+ Peak $VO_2 \leq 12$		"Housebound", Comfortable at rest, symptoms with minimum activity ADL	AMB IV	FF A
INTERMACS LEVEL 6			"Walking wounded"-ADL possible but meaningful activity limited	IIIB	FF A
INTERMACS LEVEL 7			Advanced Class III	III	A only



* Intravenous inotropic therapy only approved for refractory Class IV symptoms

Too sick?

?



Too well

Objective

TAKE HOME MESSAGES

- Mitraclip application should be performed in higher intermacs patients
- One clip …… no more
- Mitral stenosis is regularly underestimated
- Mitraclip as bridge to VAD ……. There is a price to pay!
- Mitral disruption due to clip removal can compromise the unloading of the left ventricle and the reversibility of pulmonary hypertension in a bridge to transplant strategy