

Herz-Focus
KARDIOLOGISCHE SOMMERAKADEMIE: HERZINSUFFIZIENZ
Eltville, 29.6.16

Kardiale strukturelle Interventionen: Shunts, paravalvuläre Leckagen, Ventrikelreduktion

Horst Sievert, Laura Vaskelyte,
Ilona Hofmann, Bojan Jovanovic,
Predrag Matic, Markus Reinartz, Kolja Sievert
CardioVascular Center Frankfurt - CVC,
Frankfurt, Germany

Shunts

- Vorhofseptumdefekt
- VSD (angeboren, nach Myokardinfarkt)
- Duktus Botalli
- AV- Shunts
-
- Was offen ist, wird zugemacht

HERZ+FOCUS

KARDIOLOGISCHE SOMMERAKADEMIE:
HERZINSUFFIZIENZ

INTERAKTIV

29.06.²⁰¹⁶



Neue nicht-medikamentöse Therapieoptionen bei Herzinsuffizienz

DECEMBER 2-3, 2016 | PARIS, FRANCE

D-HF 2016 – DEVICE THERAPIES FOR HEART FAILURE



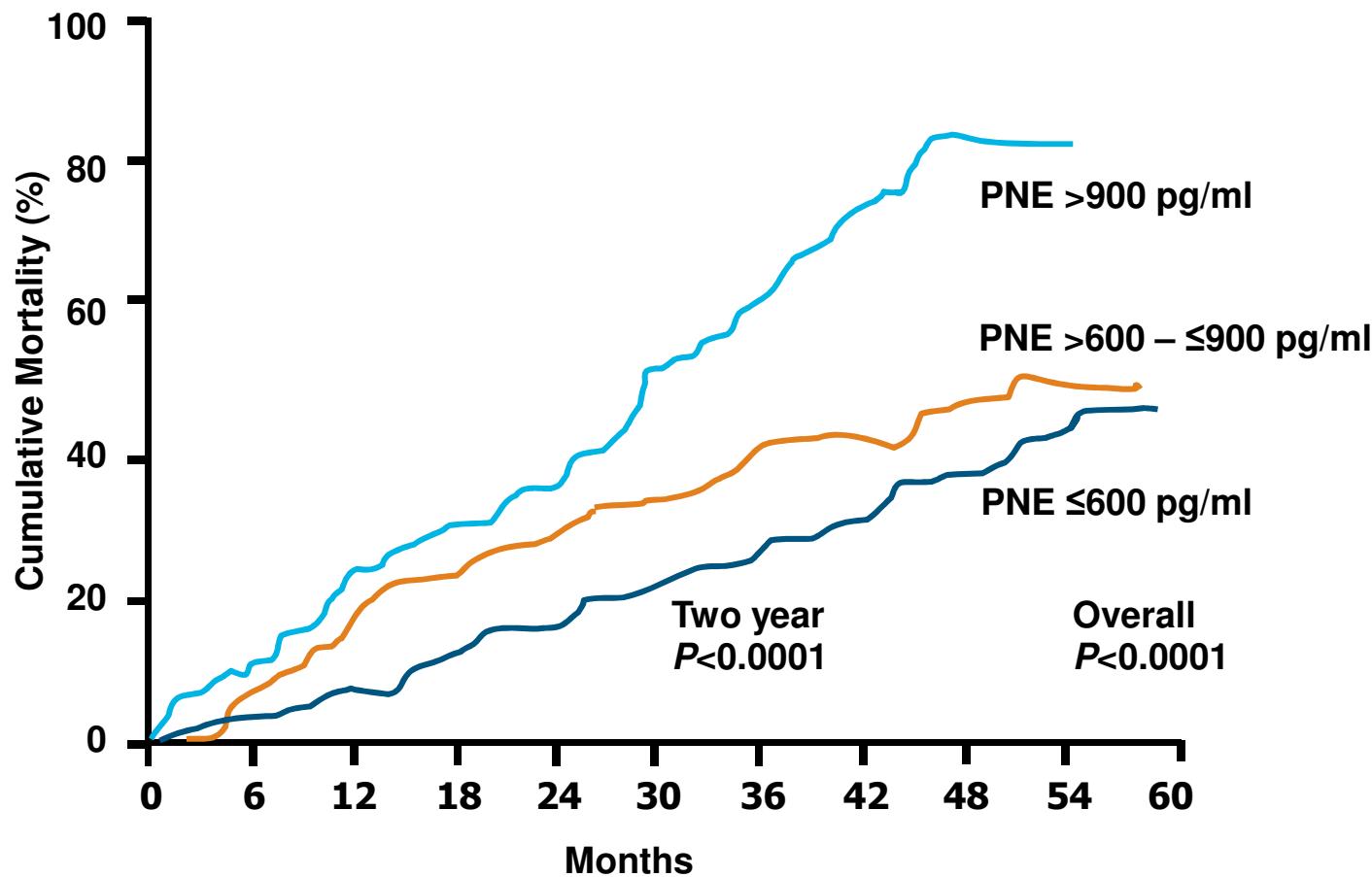
FOCUS



www.csi-congress.org/d-hf

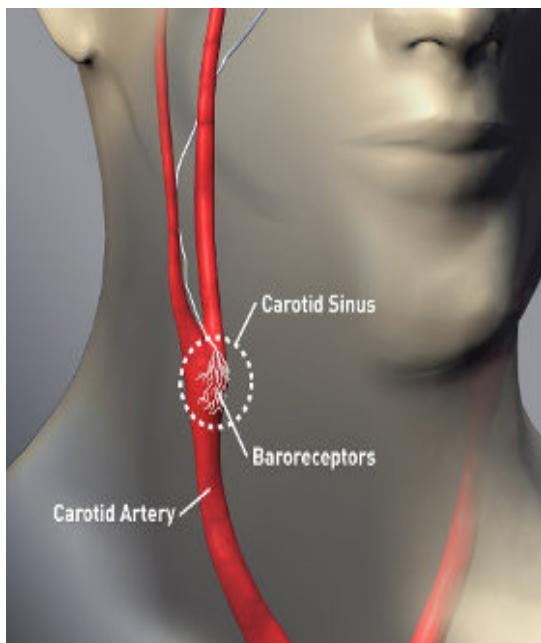
- Barorezeptorstimulation
- Verfahren zur Behandlung von LV Aneurysmen
 - Parachute
 - Revivent
- Klappeninterventionen
- Anlage eines interatrialen Shunts
- Andere Verfahren in der Erprobung

Bei Patienten mit Herzinsuffizienz ist der Sympathikus aktiviert
Das Plasma-Noradrenalin korreliert mit der Mortalität

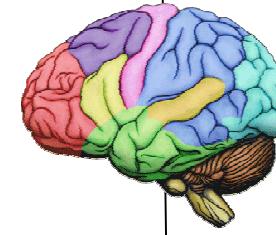


Francis GS, et al. *Circulation*. 1993;87:VI40-VI48.

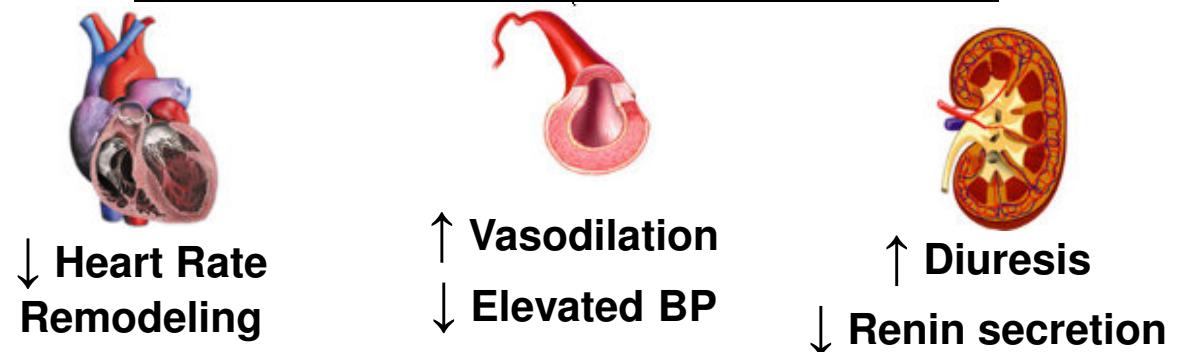
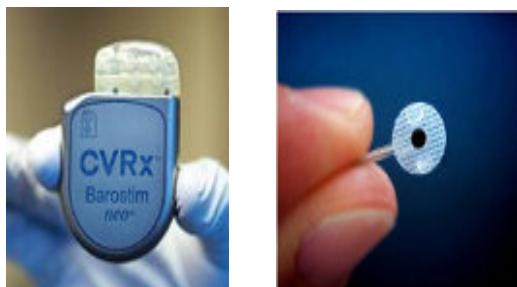
Baroreflex Activation: Mechanism of Therapy in CHF



Carotid Baroreceptor Stimulation Afferent Signaling



Inhibits **Sympathetic Activity**
Enhances **Parasympathetic Activity**



Electrode, implanted at the carotid bulb

First Generation Lead (Bilateral)



Rheos

New Generation Lead
(Unilateral)



neo

Pulse Generator

First Generation



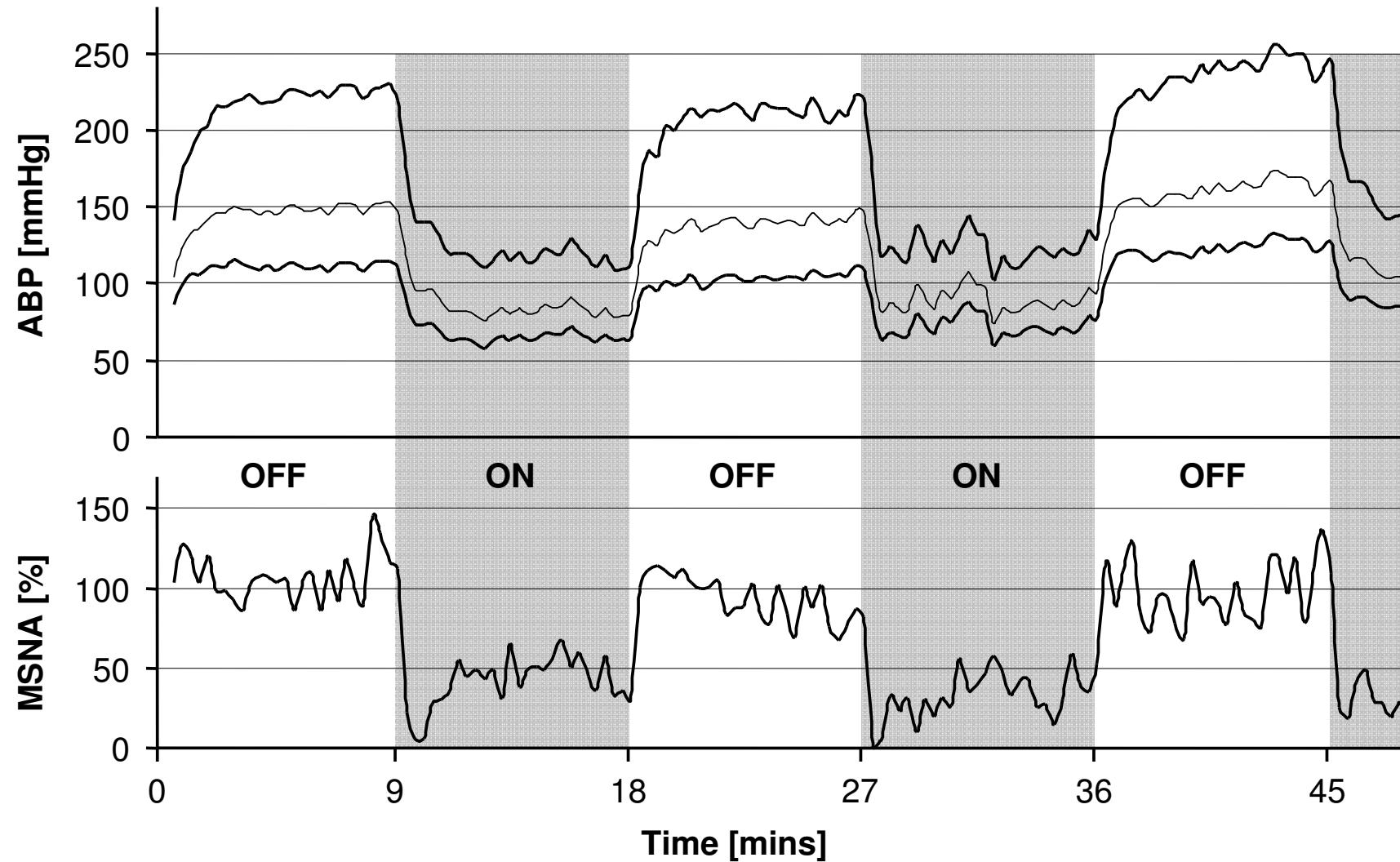
Rheos

New Generation

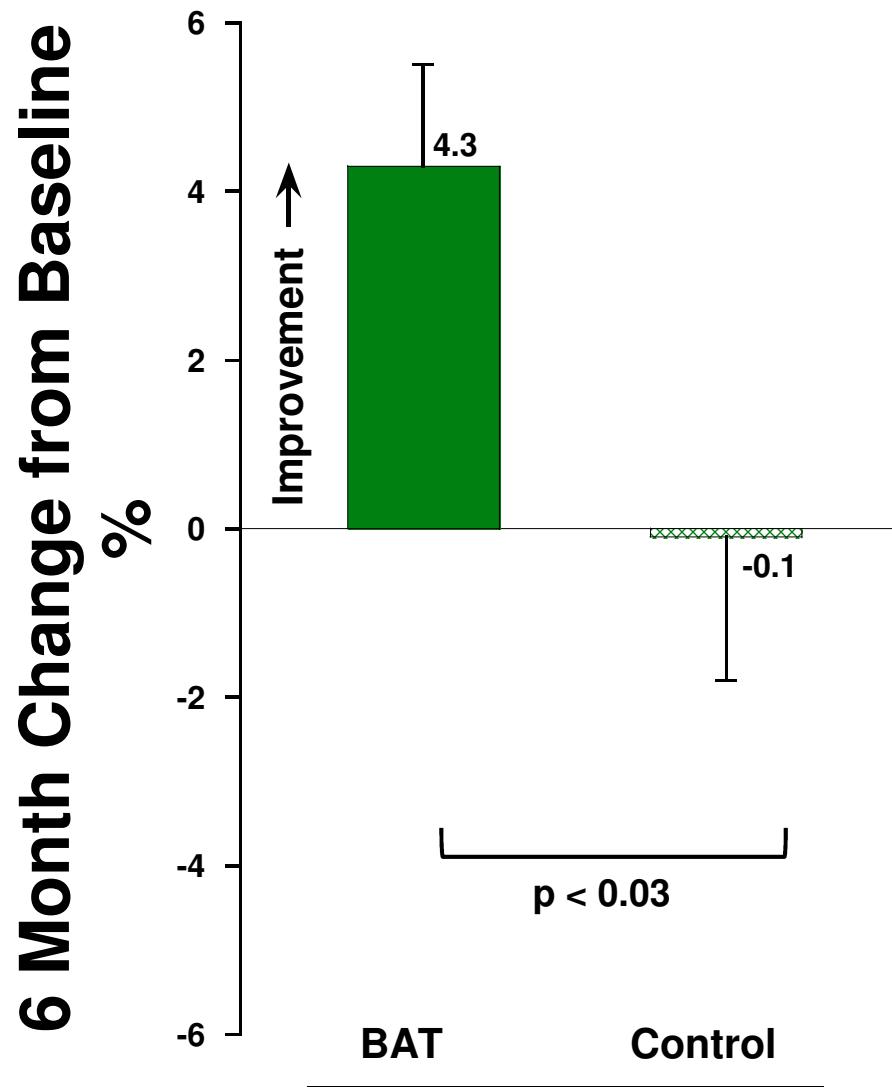


neo

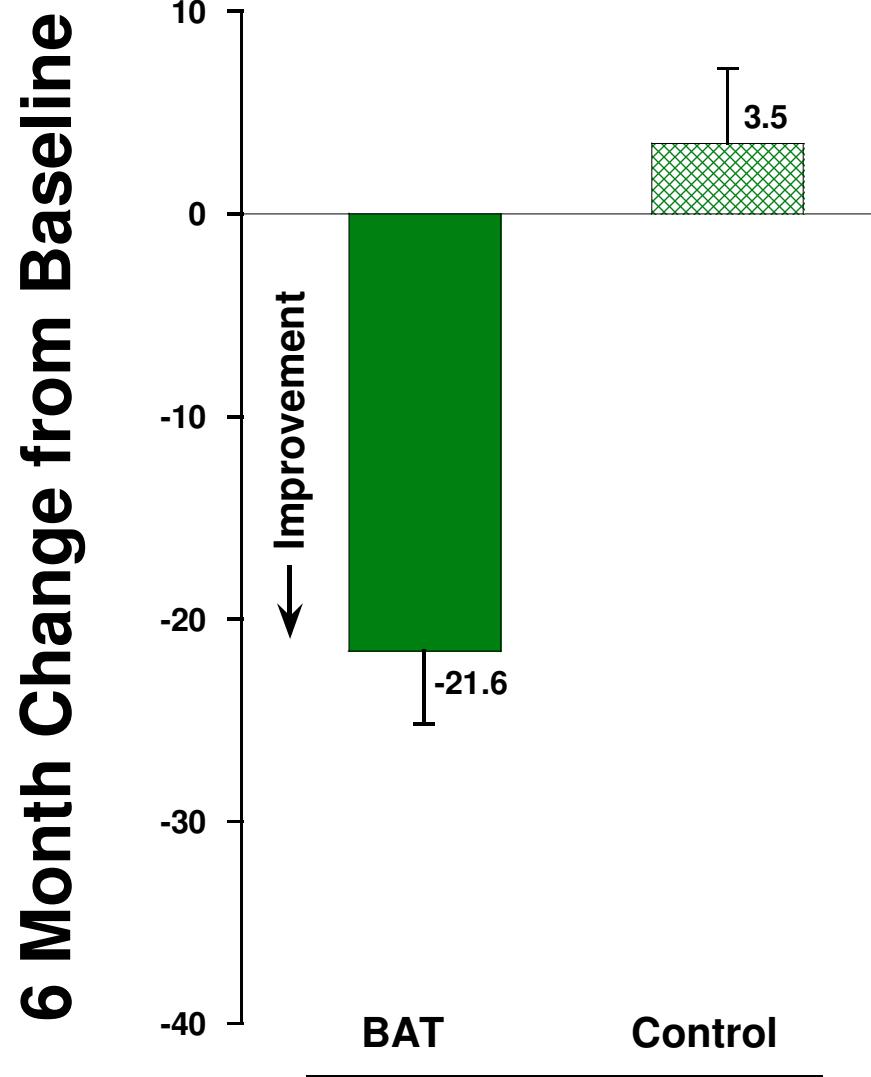
BP and Acute Muscle Sympathetic Nerve Activity After 3 Months of Therapy

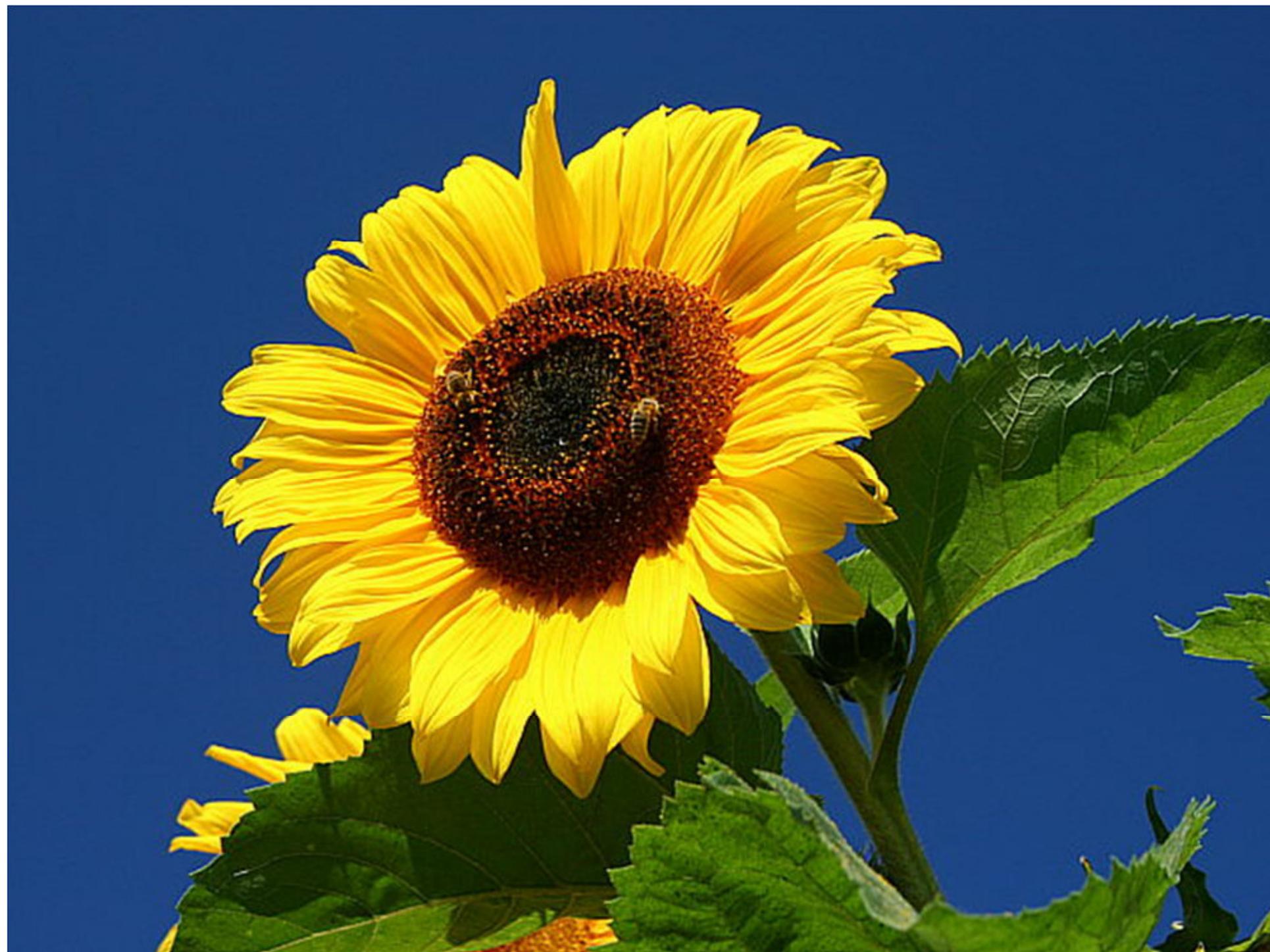


LV Ejection Fraction



MLWHF QoL Score

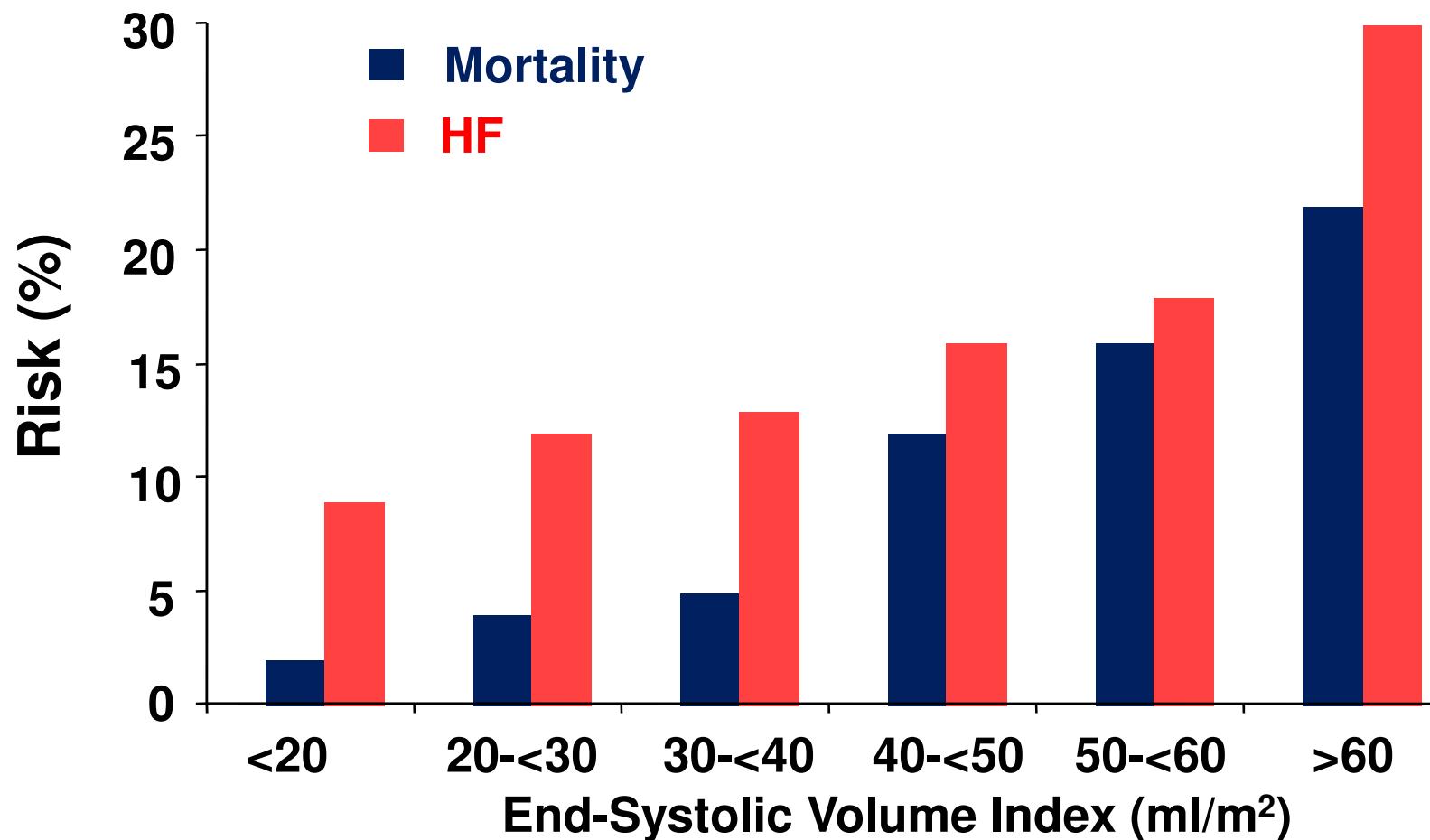




- Barorezeptorstimulation
- Verfahren zur Behandlung von LV Aneurysmen
 - Parachute
 - Revivent
- Klappeninterventionen
- Anlage eines interatrialen Shunts
- Andere Verfahren in der Erprobung

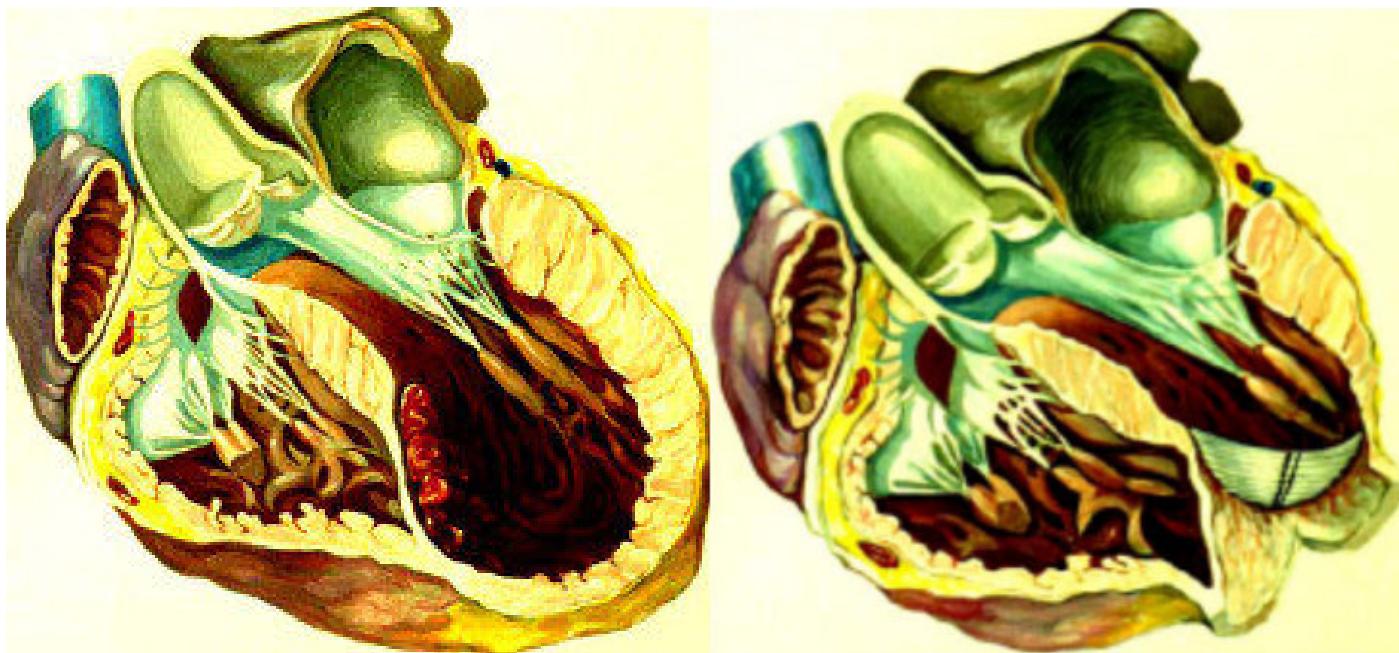
Endsystolic LV Volume predicts mortality

GUSTO-I study: 1 yr FU



Dor Procedure

Aneurysm Resection



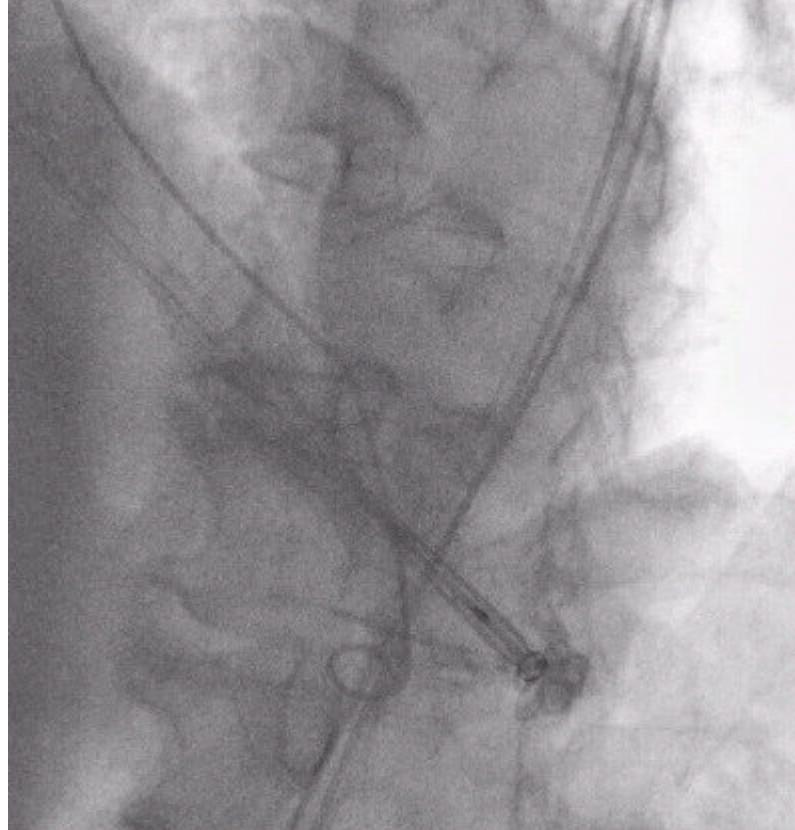
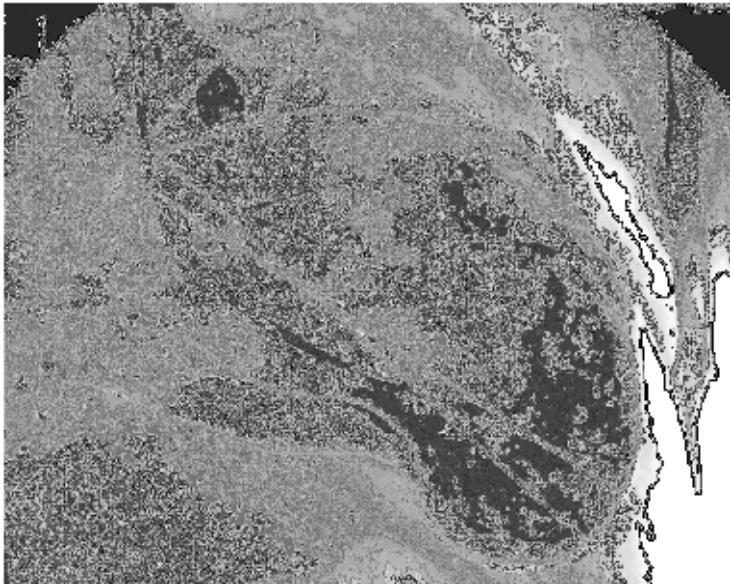
- Reduces the LV size and LV wall stress
- Improves contractility of remote myocardium

The Parachute (or VPD implant) mimics the Dor procedure

- Ventricular implant
 - Nitinol struts
 - ePTFE membrane
 - Polymer foot
 - 8 sizes

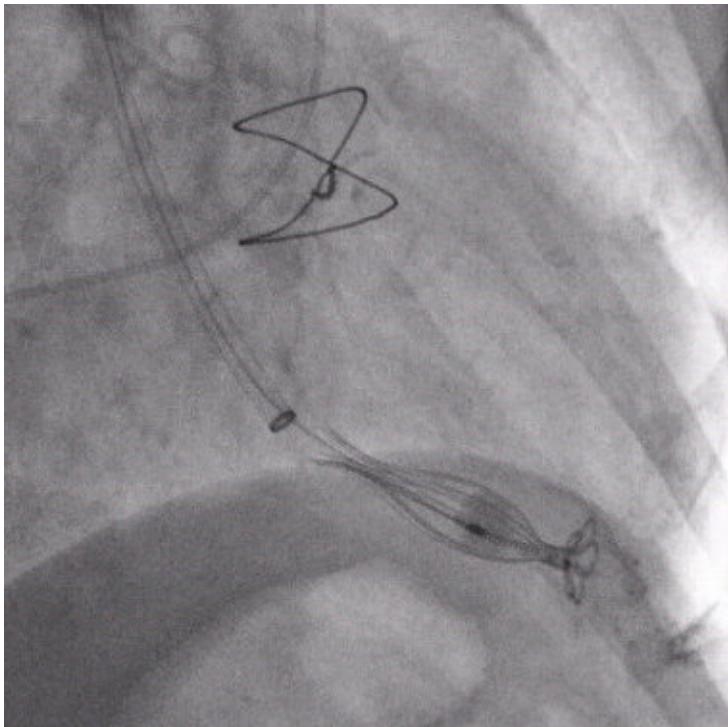


Device Implantation

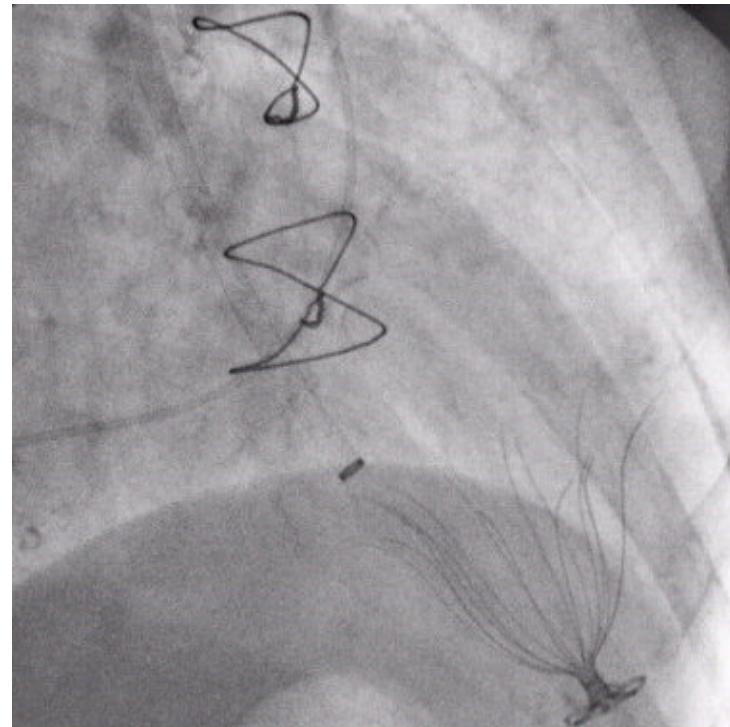


- 70 y.o. male
 - AMI in 1998, CABG in 1999
- Left ventricular aneurysm,
EF 38%
- On Aspirin, Carvedilol,
Ramipril, Nitro, Lasix
- NYHA III

Device Implantation

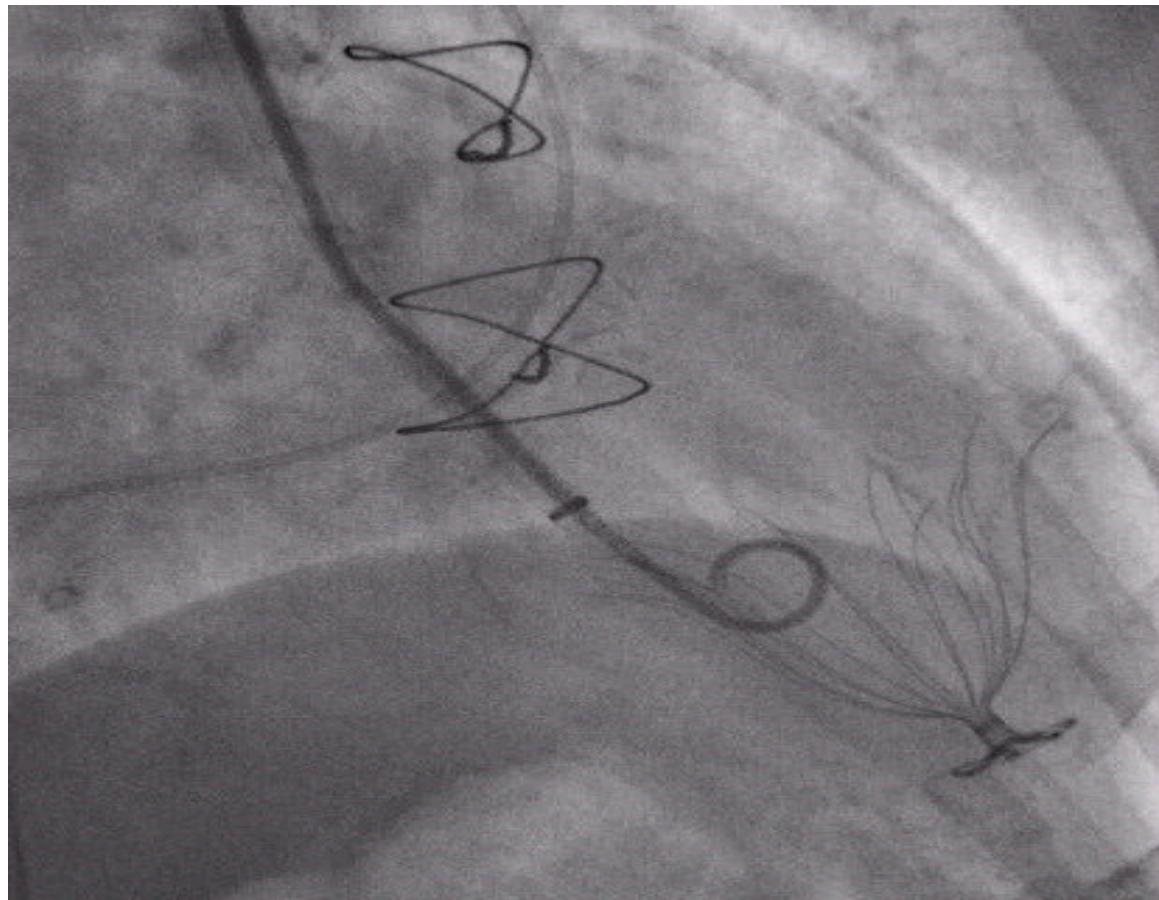


BALLOON INFLATION TO
EXPAND DEVICE



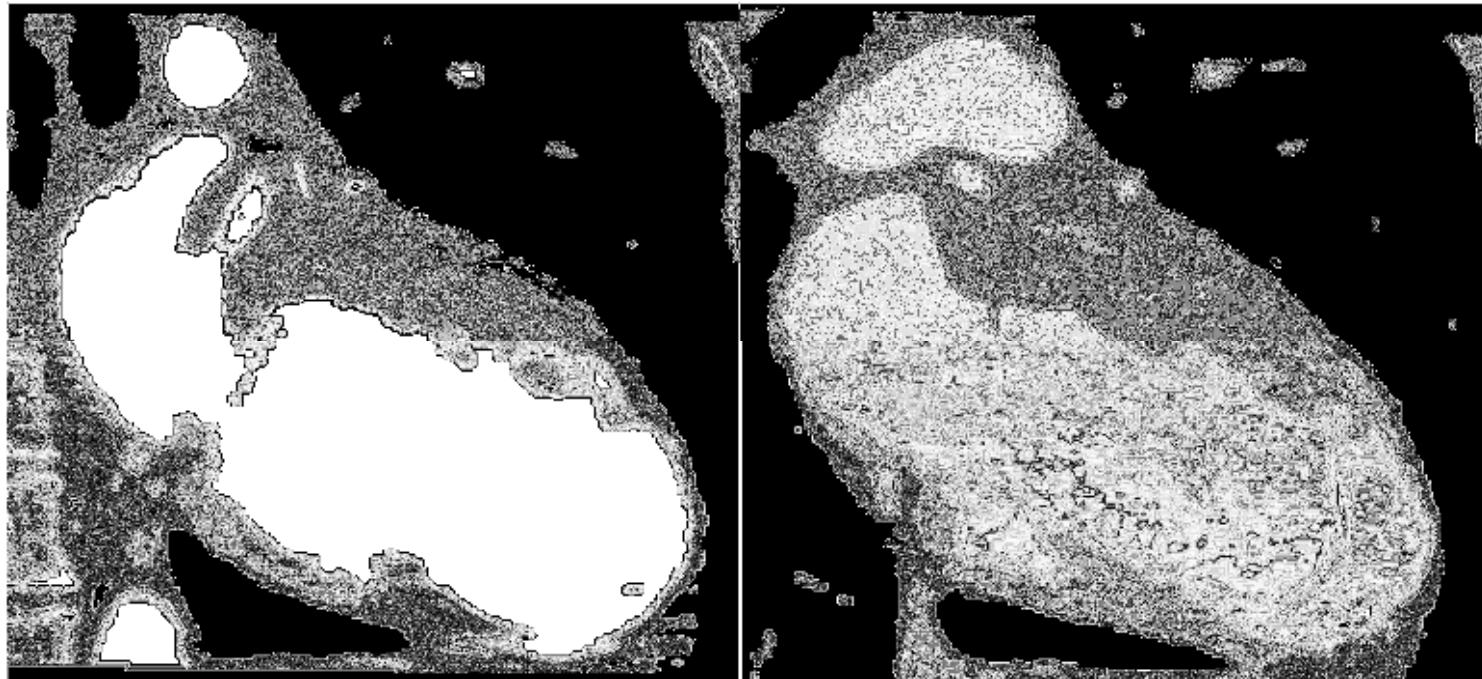
FULL DEPLOYMENT

Device Implantation



FINAL ANGIO

CT Scan



before

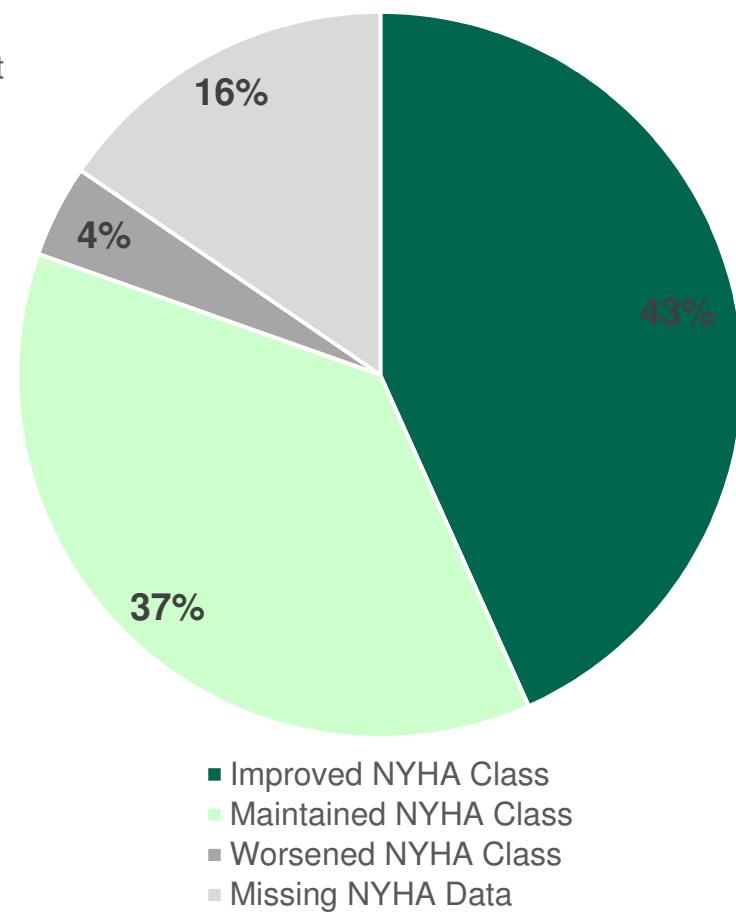
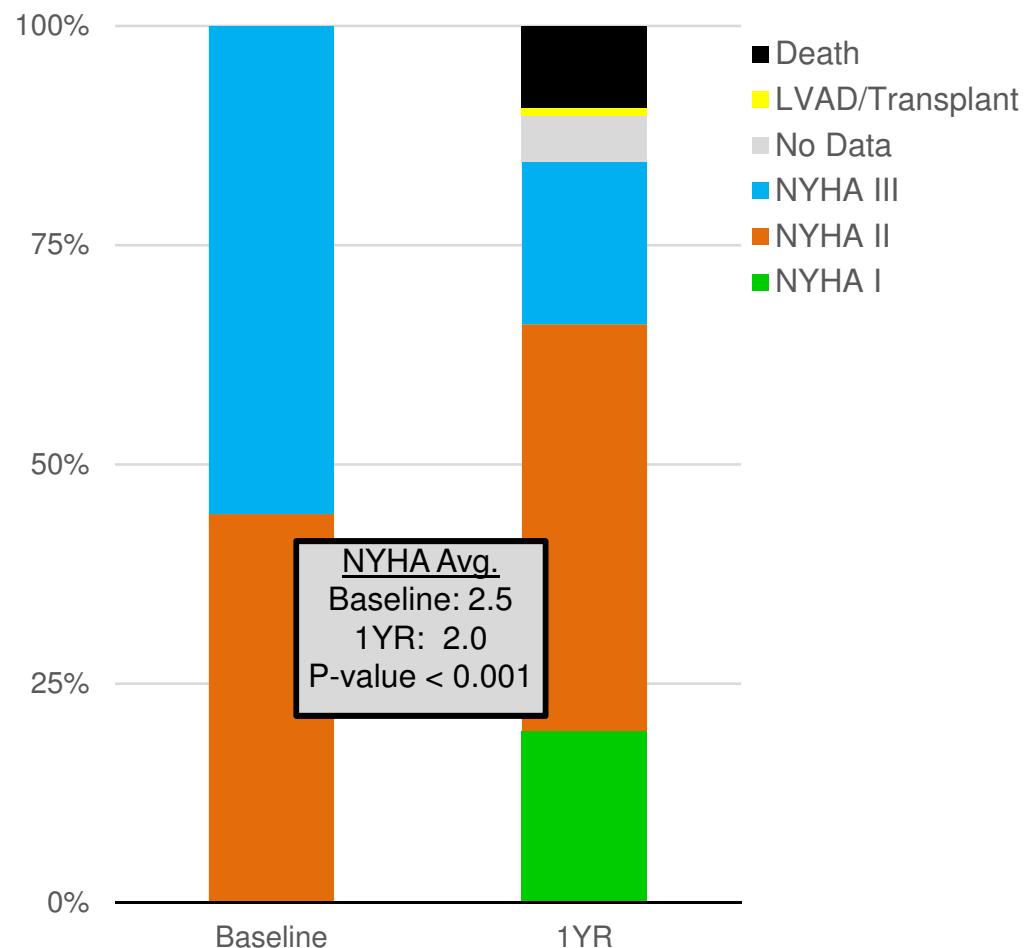
6 months

Hemodynamics

	N	Baseline	12 Months	Difference	p-value
Vitals					
Heart Rate, bpm	83	69.0 ± 13.7	69.1 ± 10.7	0.2 ± 13.7	NS
Blood Pressure					
Systolic, mmHg	82	120.5 ± 16.3	118.3 ± 13.8	-2.3 ± 16.7	NS
Diastolic, mmHg	82	72.5 ± 10.1	71.9 ± 9.5	-0.6 ± 12.1	NS
LV Volume					
ESVi, ml/m ²	64	84.0 ± 24.2	70.5 ± 24.5	-13.5 ± 22.8	<.0001
EDVi, ml/m ²	64	117.3 ± 26.3	99.1 ± 27.3	-18.2 ± 27.0	<.0001
Systolic Function					
Ejection Fraction, %	64	29.2 ± 7.9	31.0 ± 7.6	1.8 ± 8.6	0.1
Fractional Shortening, %	57	18.6 ± 9.7	20.1 ± 8.5	1.4 ± 10.7	0.3
Contractility Index (Ees), mmHg-m ² /ml	63	1.4 ± 0.5	1.7 ± 0.6	0.3 ± 0.6	<.001
Stroke Work / EDVi, mmHg	63	27.7 ± 9.7	29.8 ± 7.8	2.1 ± 10.5	0.1
Diastolic Function					
LAVi, ml/m ²	50	42.5 ± 15.8	38.3 ± 11.2	-4.2 ± 15.1	0.05

Parachute: NYHA Assessment, N=97

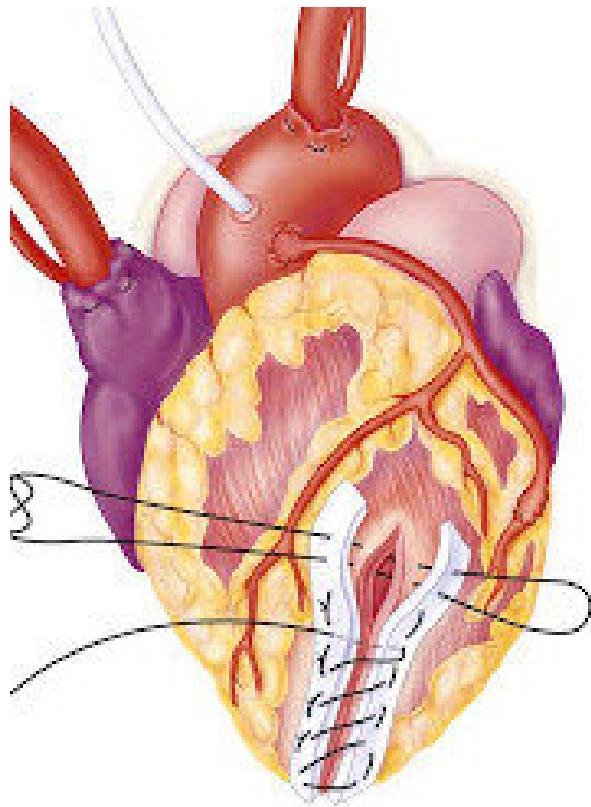
80% of Patients Improved or Maintained at 1Y



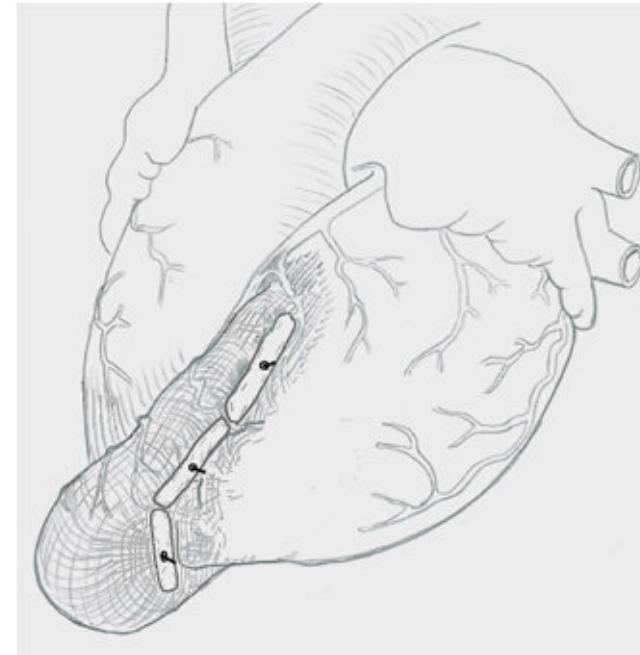


- Barorezeptorstimulation
- Verfahren zur Behandlung von LV Aneurysmen
 - Parachute
 - Revivent
- Klappeninterventionen
- Anlage eines interatrialen Shunts
- Andere Verfahren in der Erprobung

Predicate: Surgical Ventricular Reconstruction



Open Surgical Repair

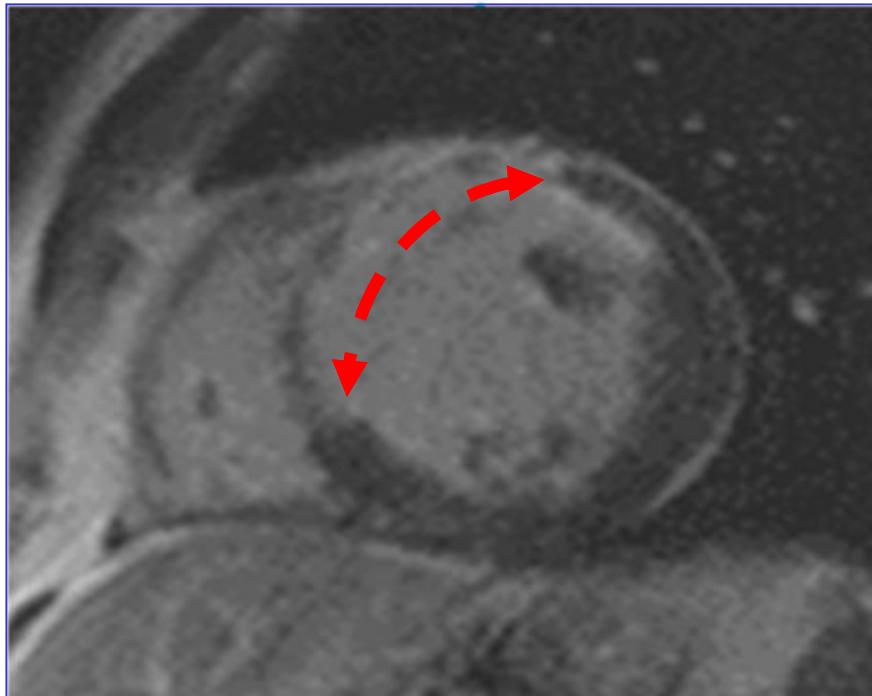


**Bioventrix
Revivent TC**
**Closed chest, off pump,
no ventriculotomy**

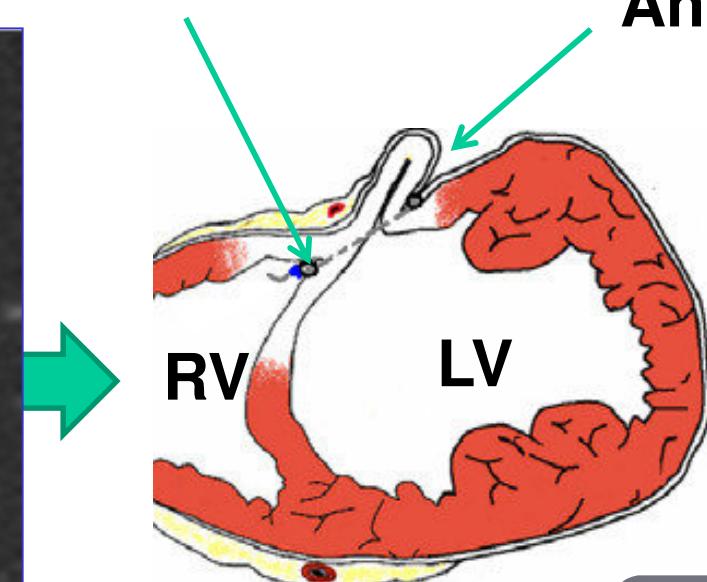
Revivent Mechanism of Action

Volume Reduction by Exclusion of Scarred Myocardium

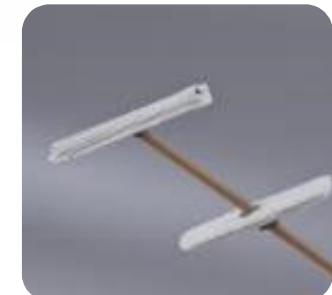
Region of LV Scar



Internal
Anchor

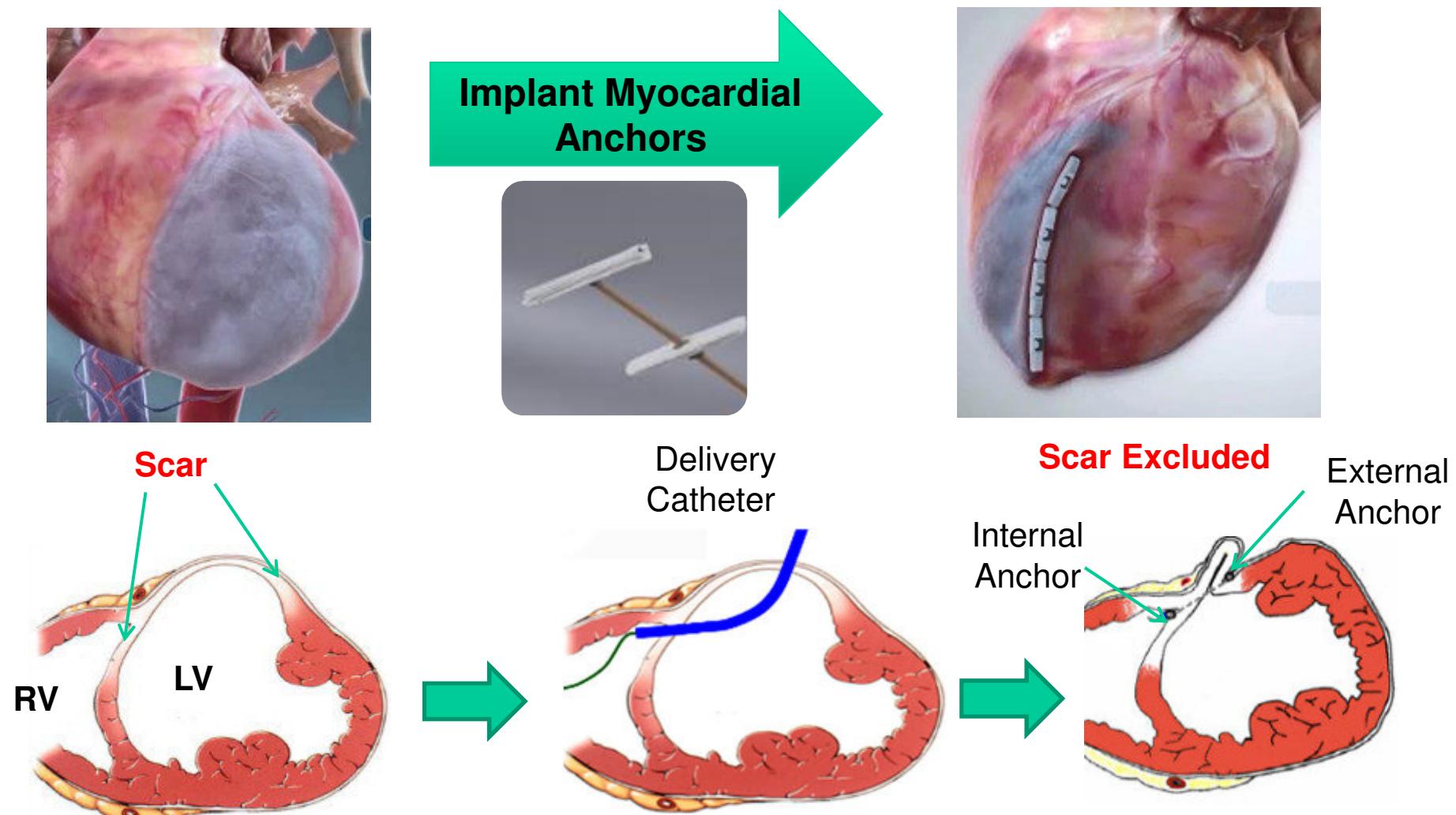


External
Anchor

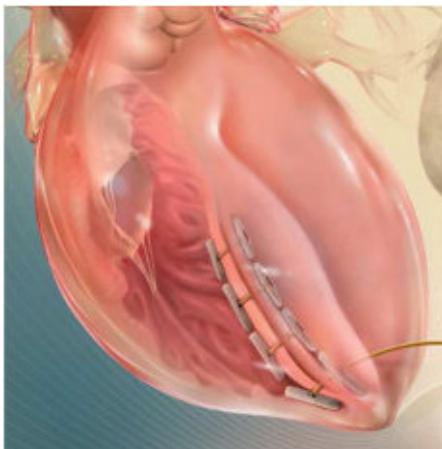


Anchor Pair
with Tether

Revivent Principles of Operation: Scar Exclusion = Volume and Wall Tension Reduction



Vorteile gegenüber der konventionellen OP



- Minimal invasiv
- Keine Thorakotomie
- Am schlagenden Herzen
- Keine Ventrikulotomie
- Ohne HLM
- Aorta wird nicht abgeklemmt

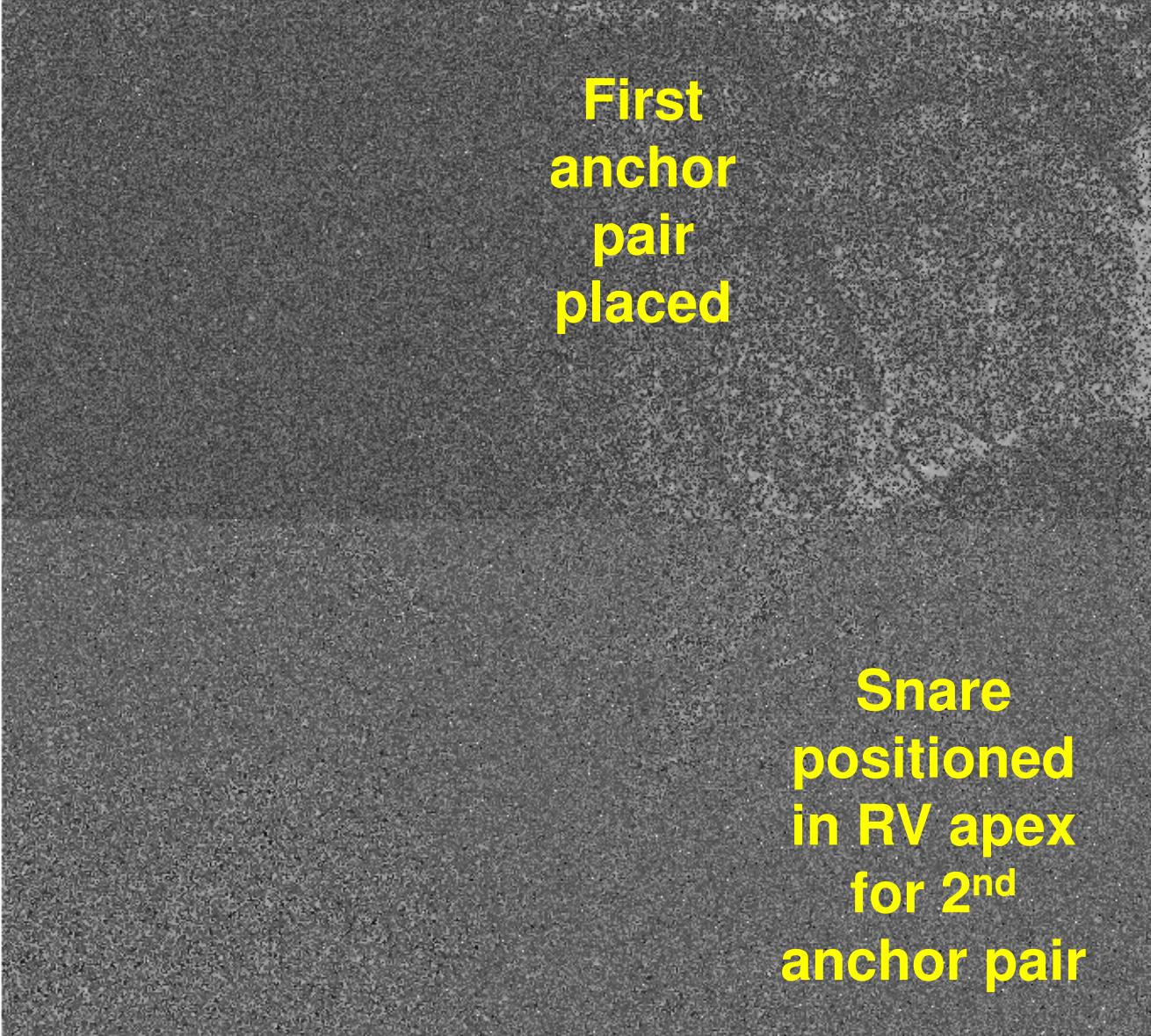


Revivent TC -Transcatheter LV Volume Reduction



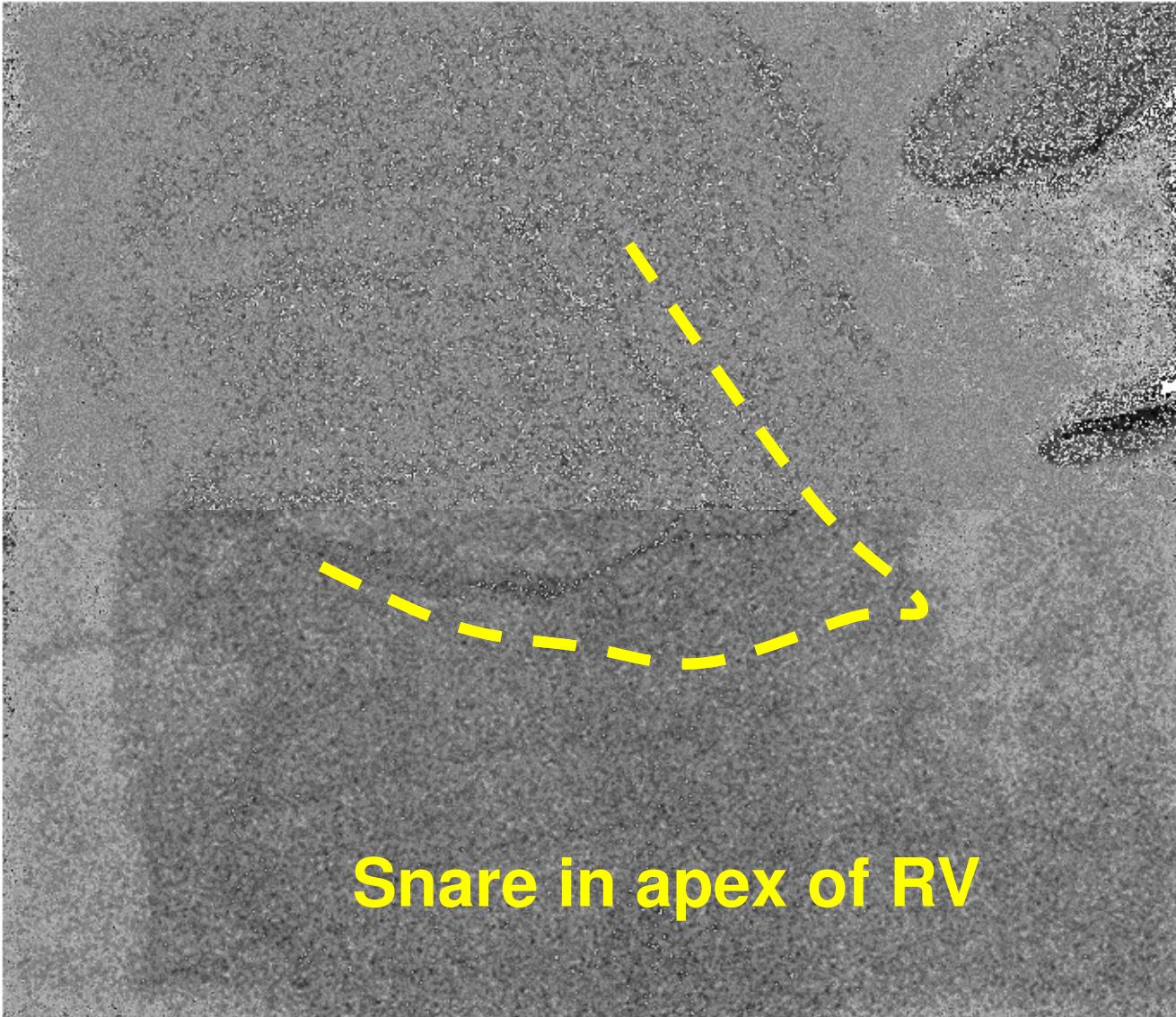
**Curved Needle from
LV free wall through
septum**

**Snare loop capturing
needle in RV**

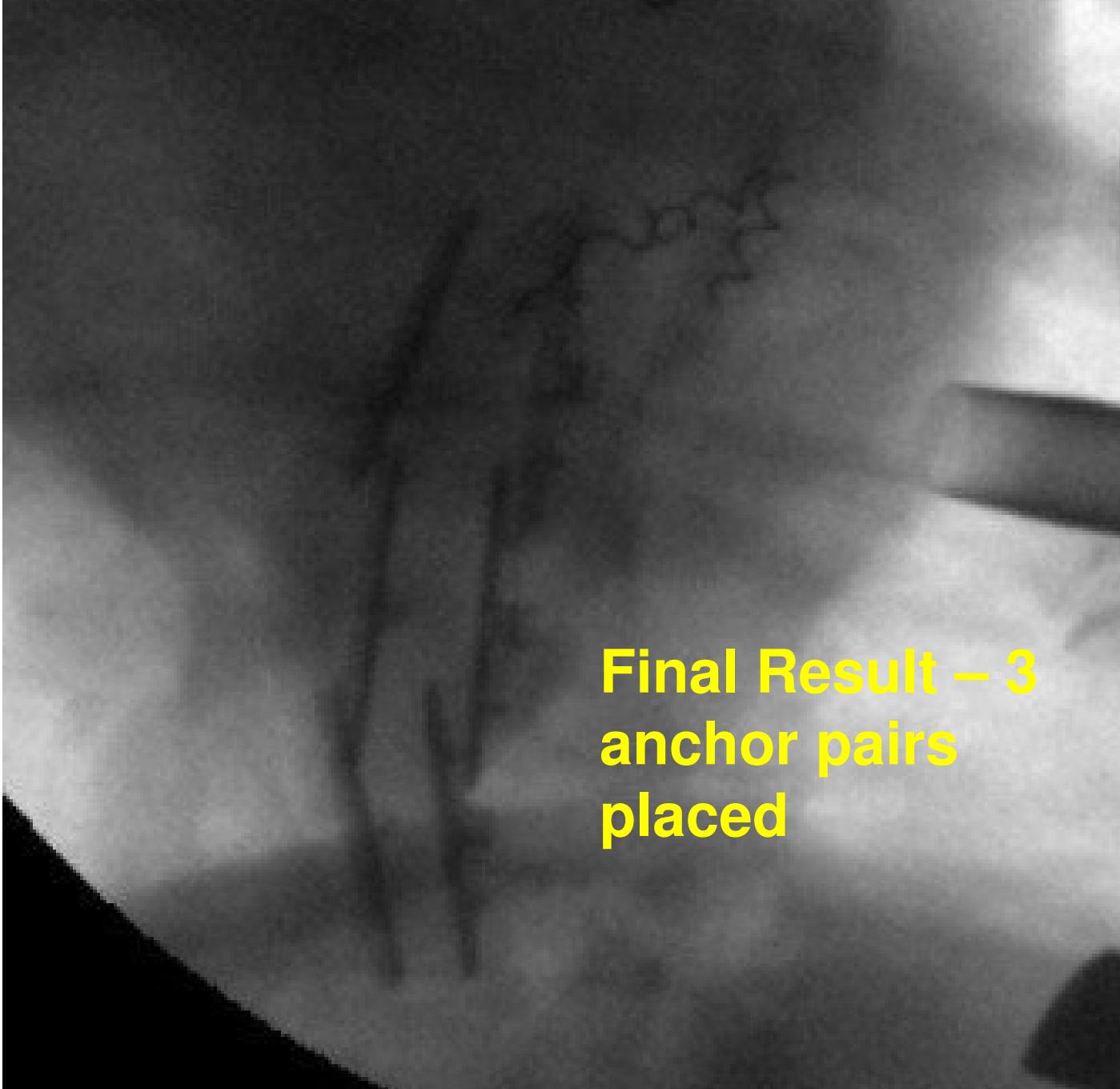


First
anchor
pair
placed

Snare
positioned
in RV apex
for 2nd
anchor pair



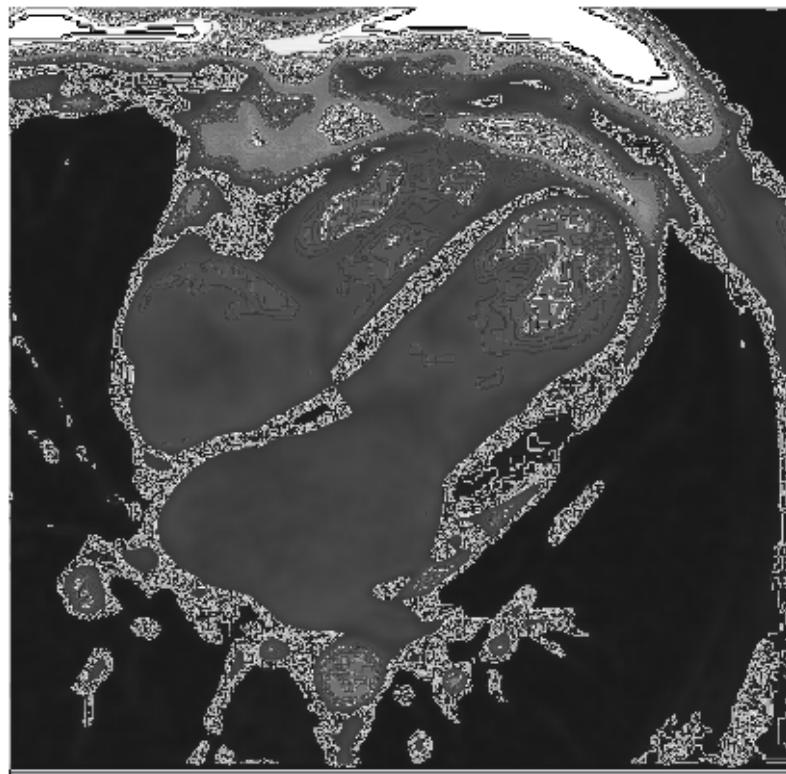
Snare in apex of RV



**Final Result – 3
anchor pairs
placed**

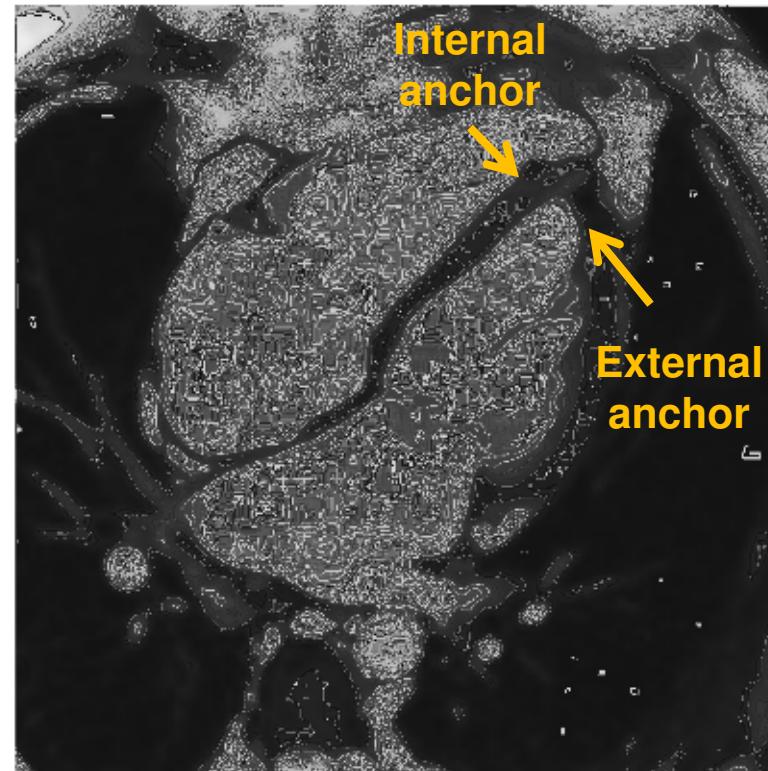
Typical Result: More physiological LV size and geometry

Baseline



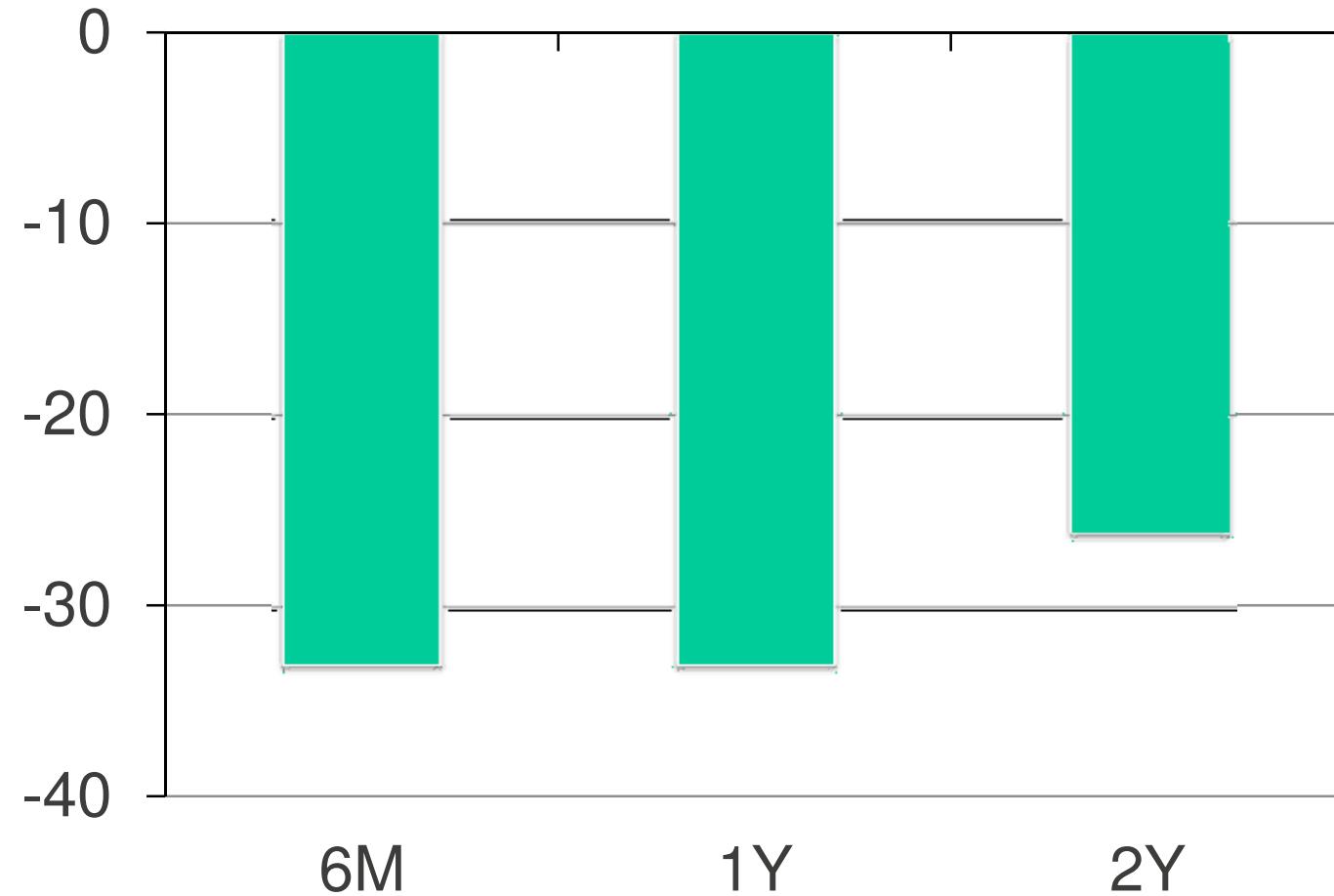
$\text{LVESVI} = 127 \text{ ml/m}^2$ End-Systole

6 months Post Revivent procedure

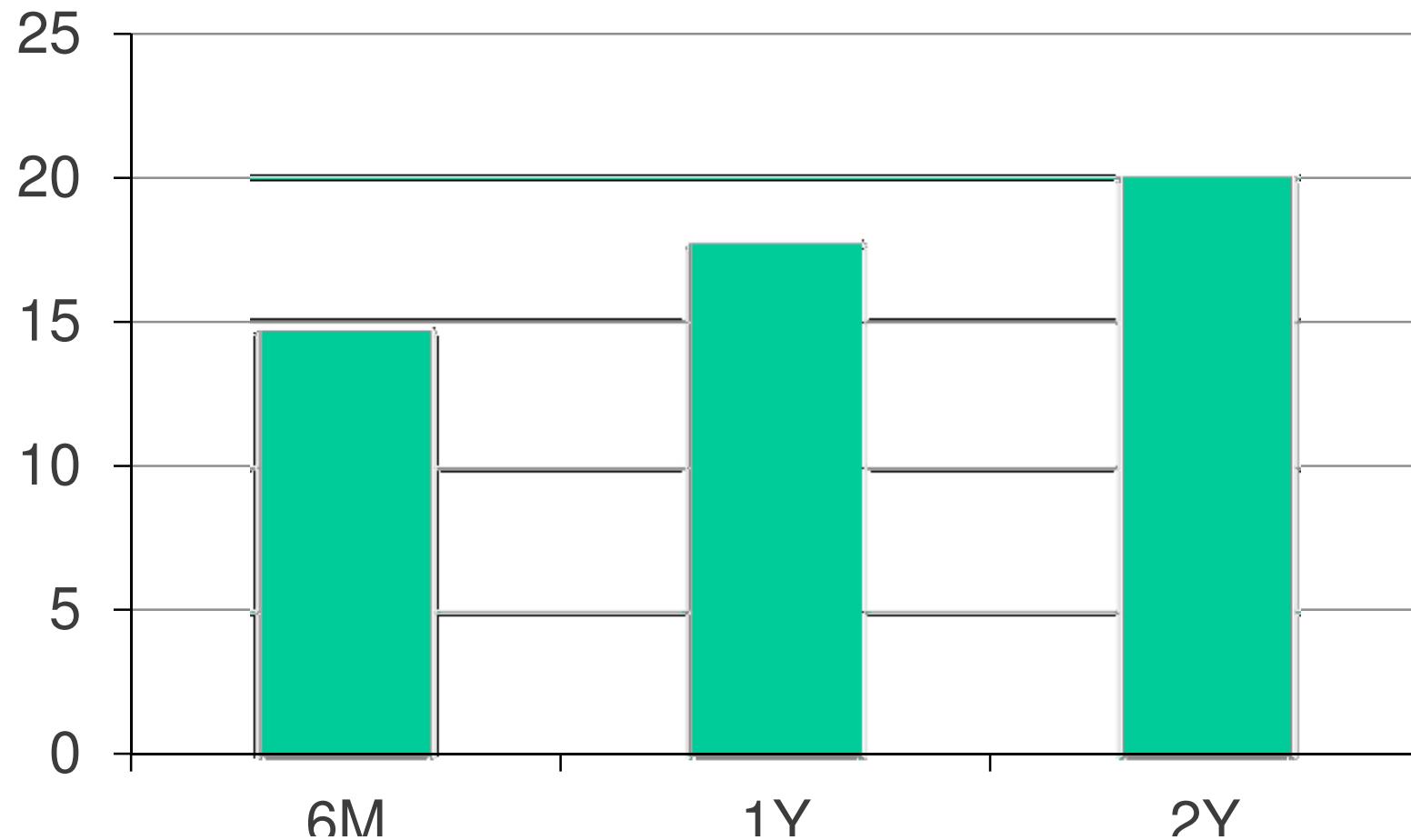


$\text{LVESVI} = 69 \text{ ml/m}^2$

Full 2-Y Data: LVESVI [mL/m²]

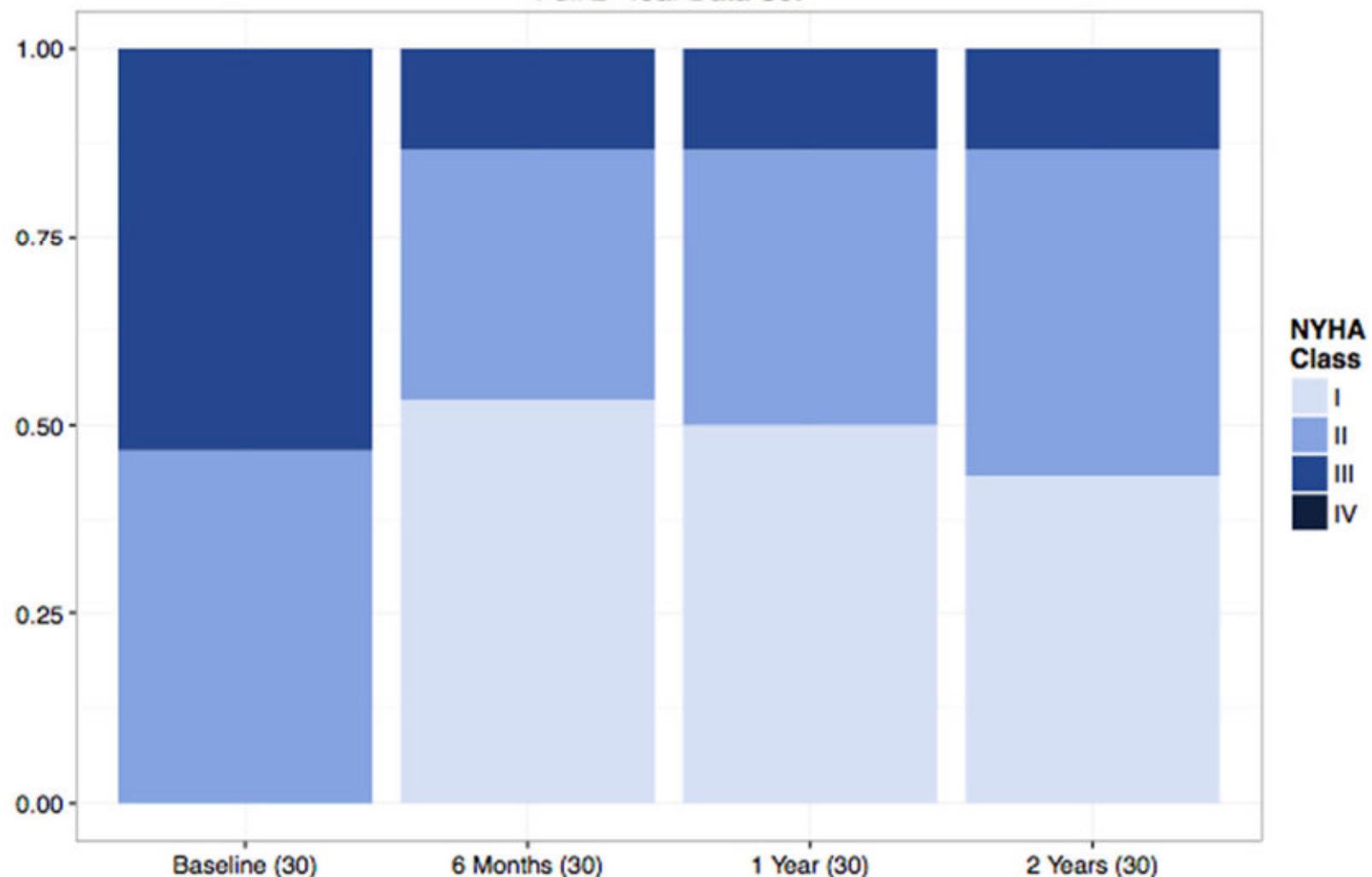


Full 2-Y Data: EF [%]



New York Heart Association Class (NYHA)

Full 2-Year Data Set

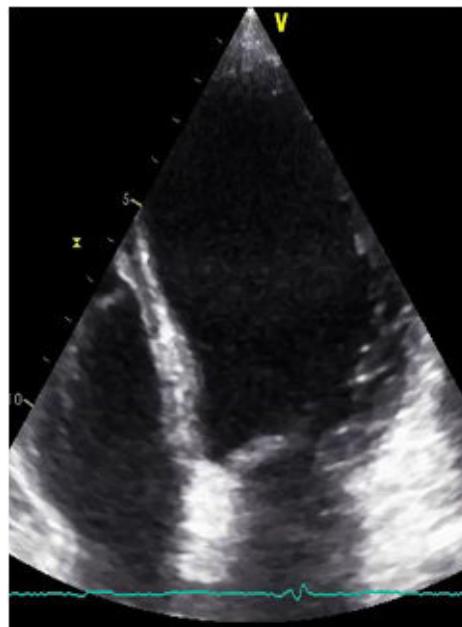


Paired two-samples t-test

Data current as of March 2016

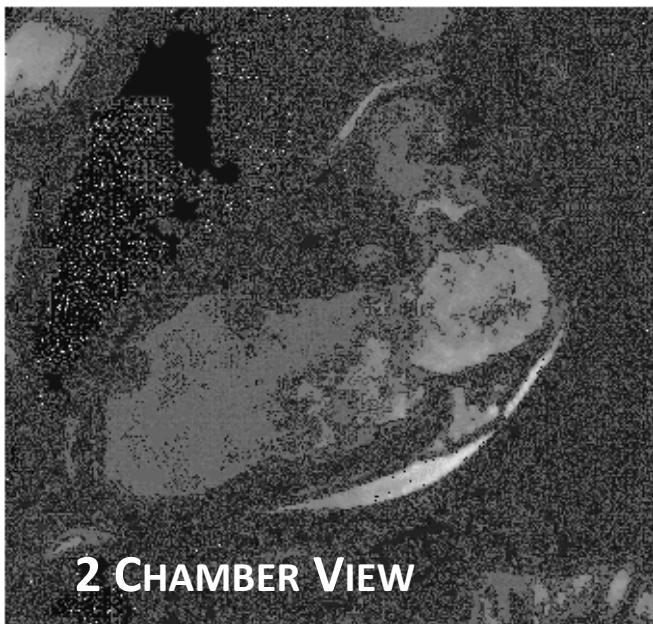
Welche Patienten profitieren?

APPROPRIATE SCAR IN THE ANTERIOR SEPTUM, ANT. WALL, & APEX



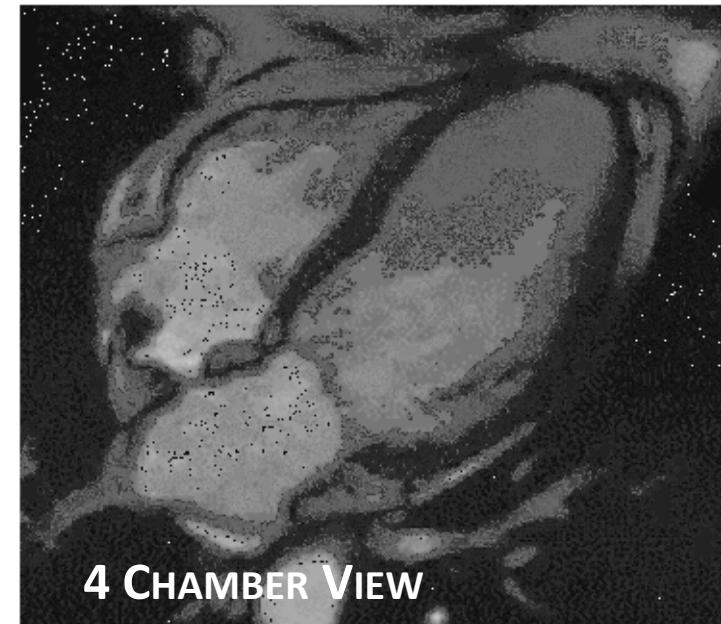
TTE VIDEO

4 CHAMBER VIEW



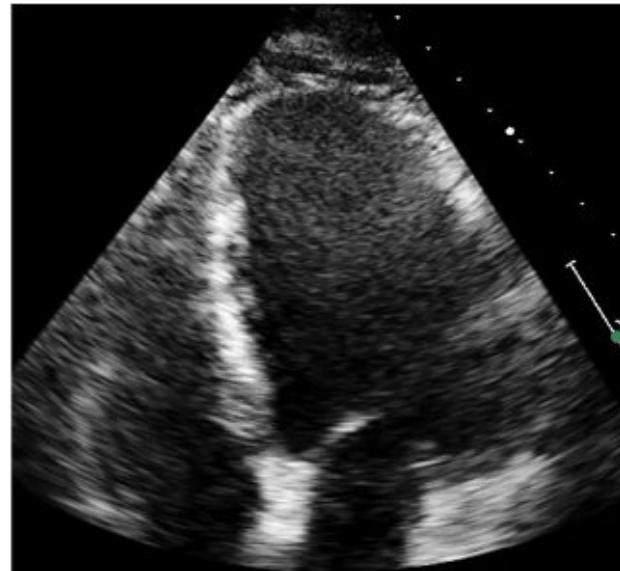
2 CHAMBER VIEW

**MRI
VIDEO
(GADOLINIUM
ENHANCED)**



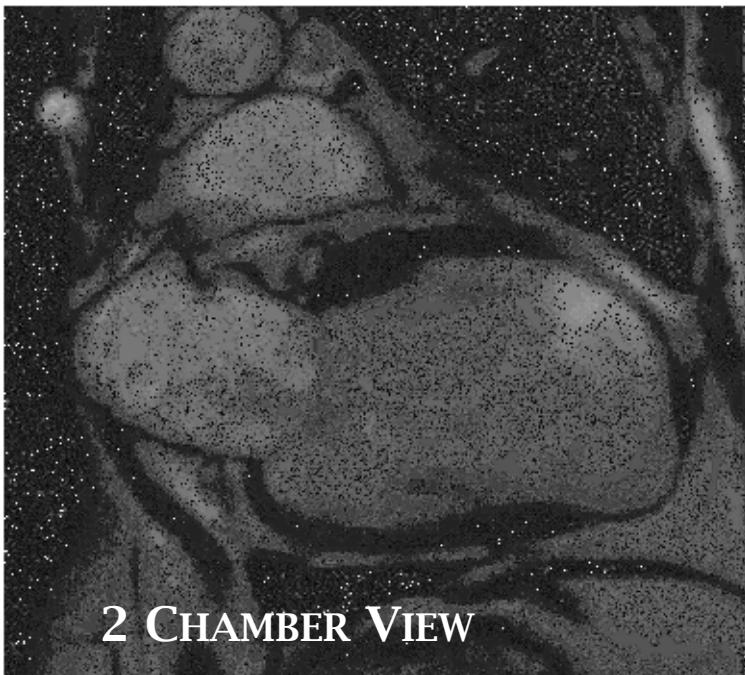
4 CHAMBER VIEW

APPROPRIATE ANTEROSEPTAL SCAR WITH CORRECT SIZE

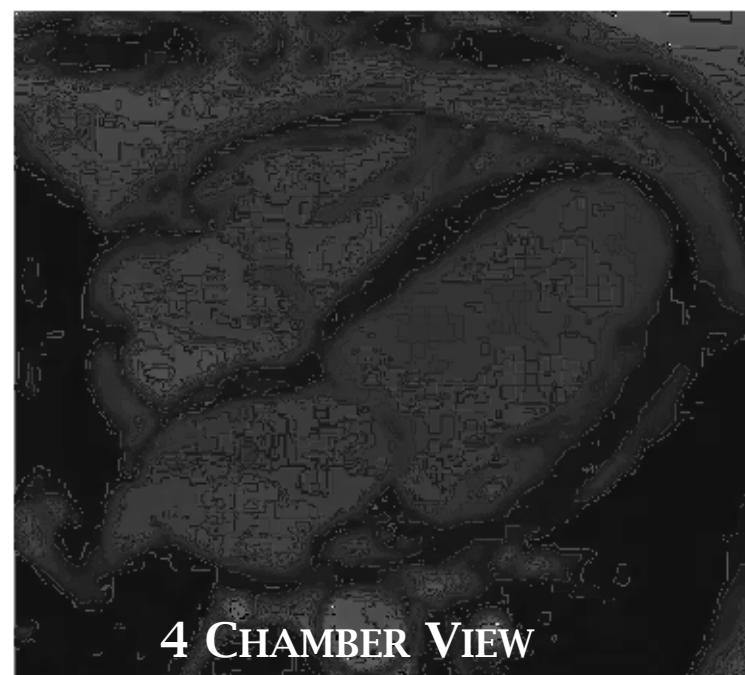


TTE
4 CHAMBER VIEW

MRI (GADOLINIUM ENHANCED)

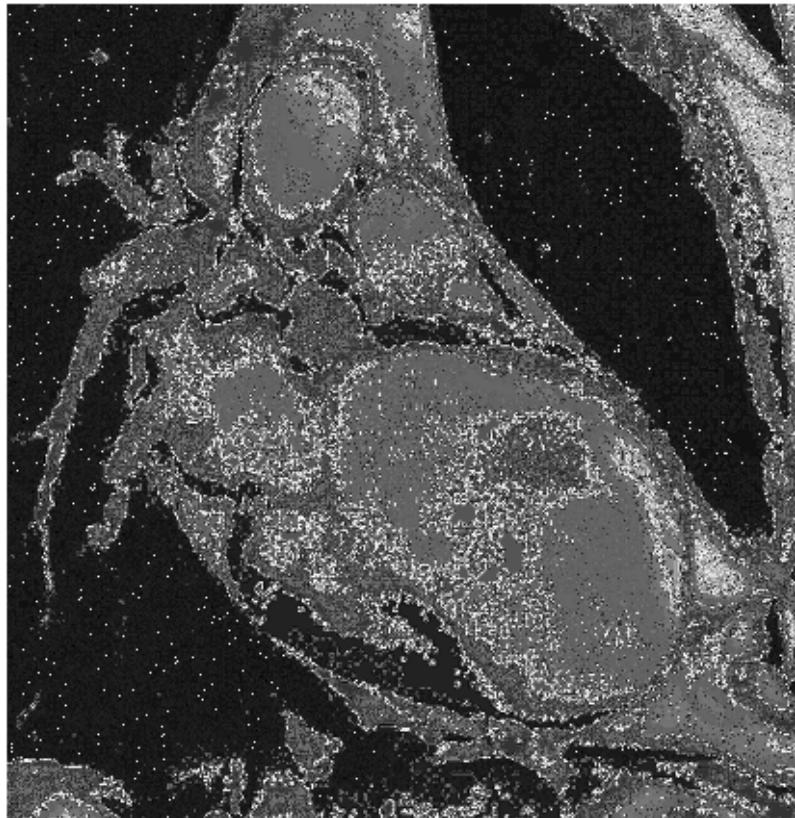


2 CHAMBER VIEW

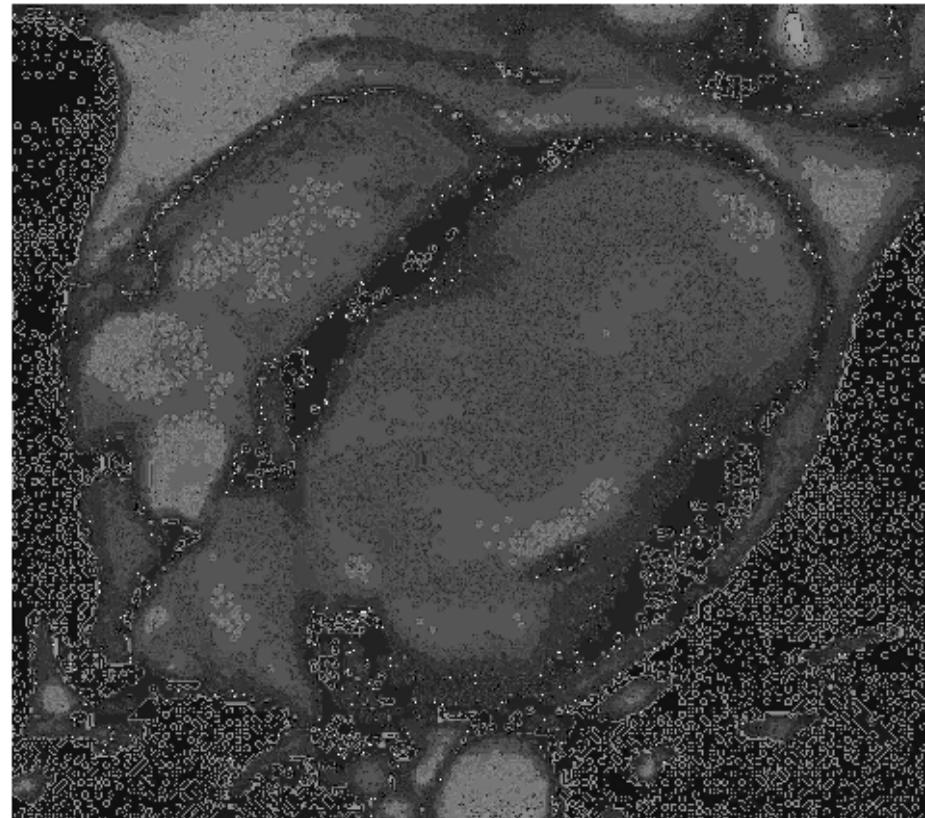


4 CHAMBER VIEW

DYSKINETIC MYOCARDIUM WITH ANTEROSEPTAL SCAR



2 CHAMBER VIEW

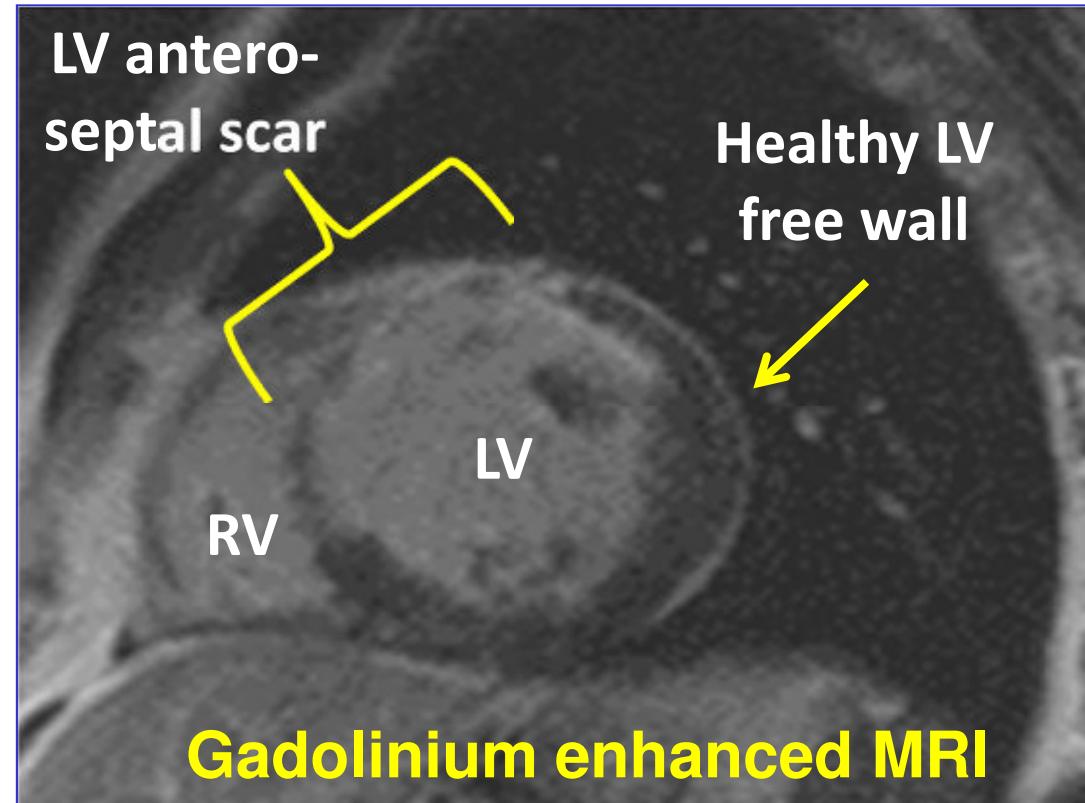


4 CHAMBER VIEW

MRI (GADOLINIUM ENHANCED)

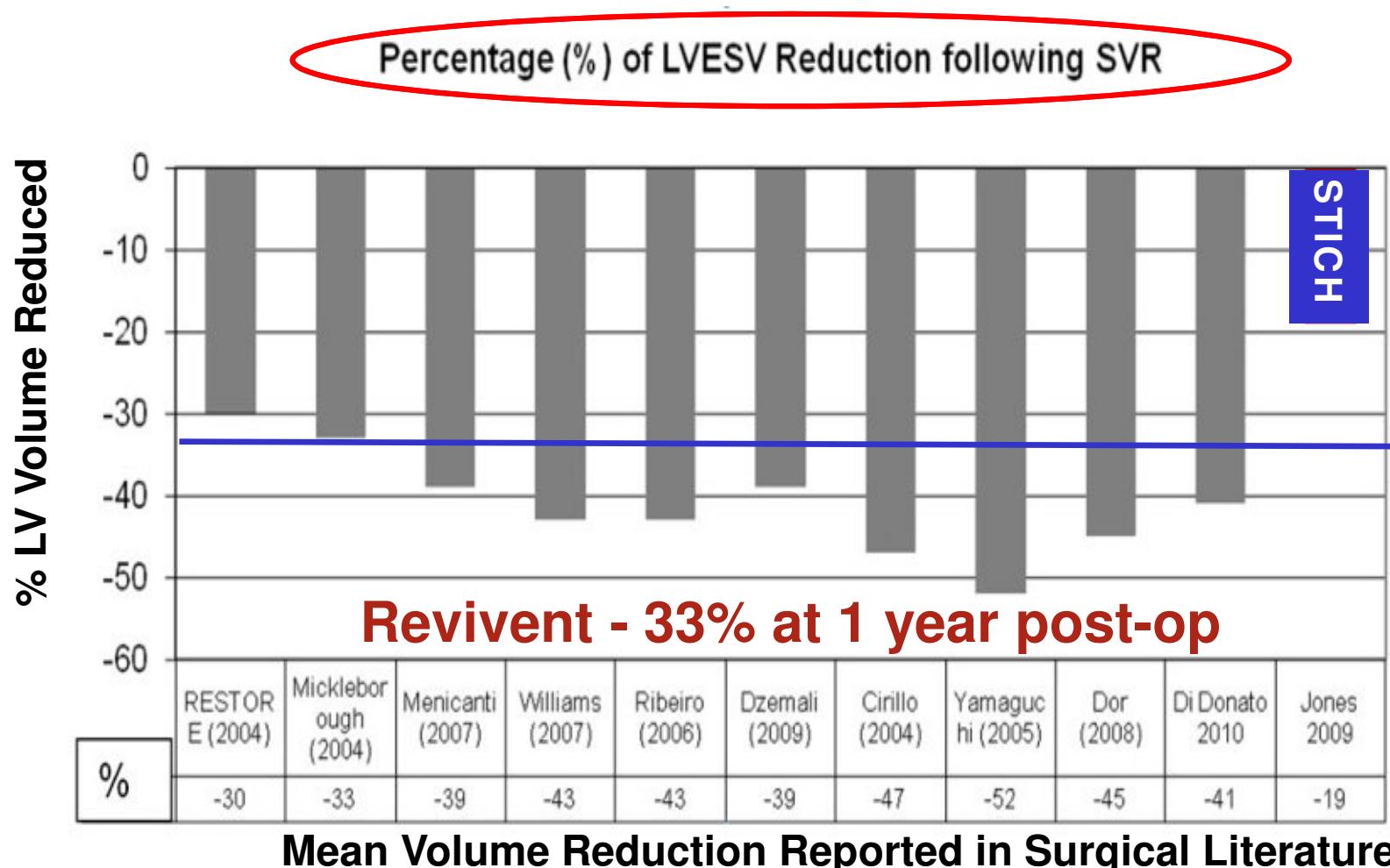
Einschlusskriterien

- Z.n. VWI
- LV vergrößert
- Umschriebene Narbe anterior oder antero-septal
- EF \leq 35%
- LVESVI > 60 ml
- NYHA II-IV



Revivent Compared to Surgery & the STICH Trial

Surgical LV Volume Reduction Trials Summary



- Barorezeptorstimulation
- Verfahren zur Behandlung von LV Aneurysmen
 - Parachute
 - Revivent
- Klappeninterventionen
- Anlage eines interatrialen Shunts
- Andere Verfahren in der Erprobung

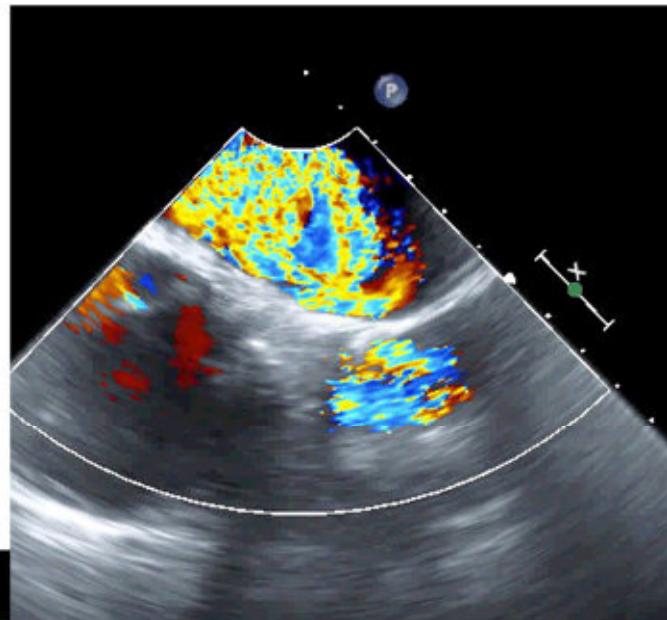
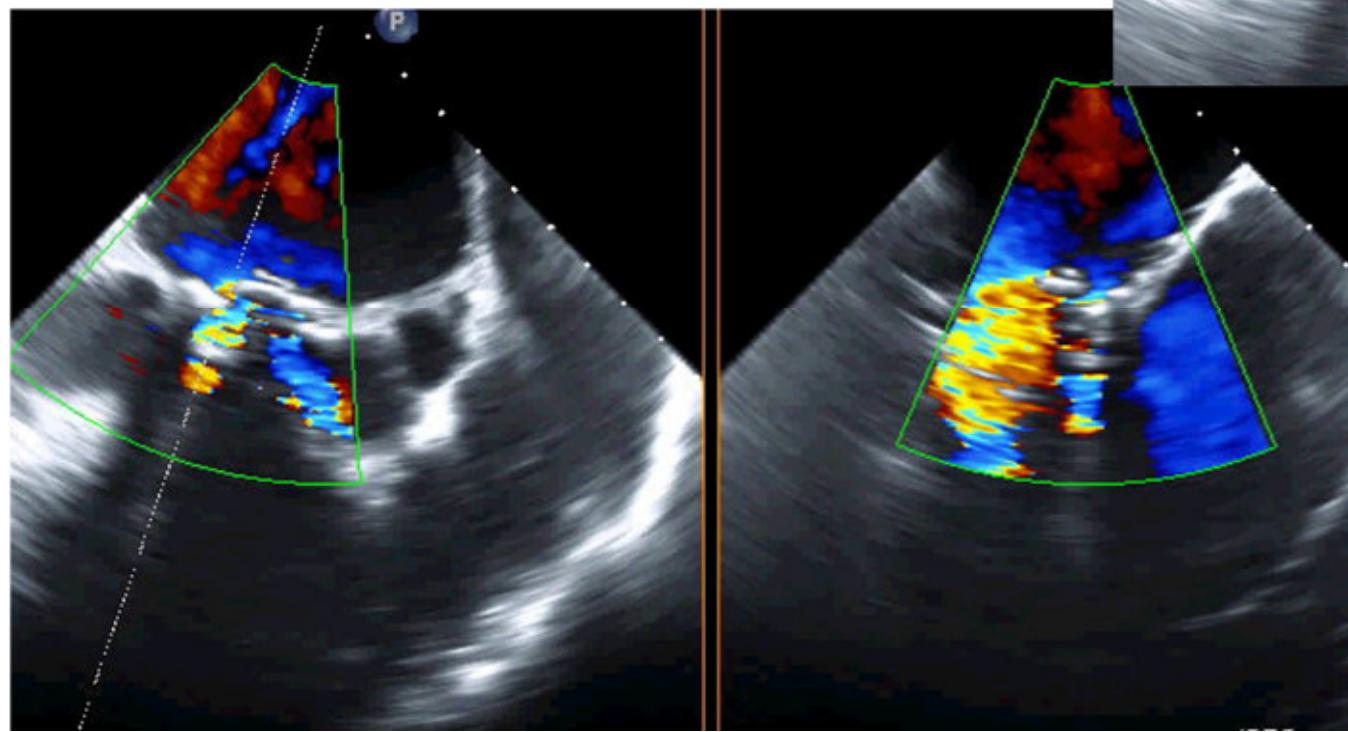
Klappeninterventionen bei Herzinsuffizienz

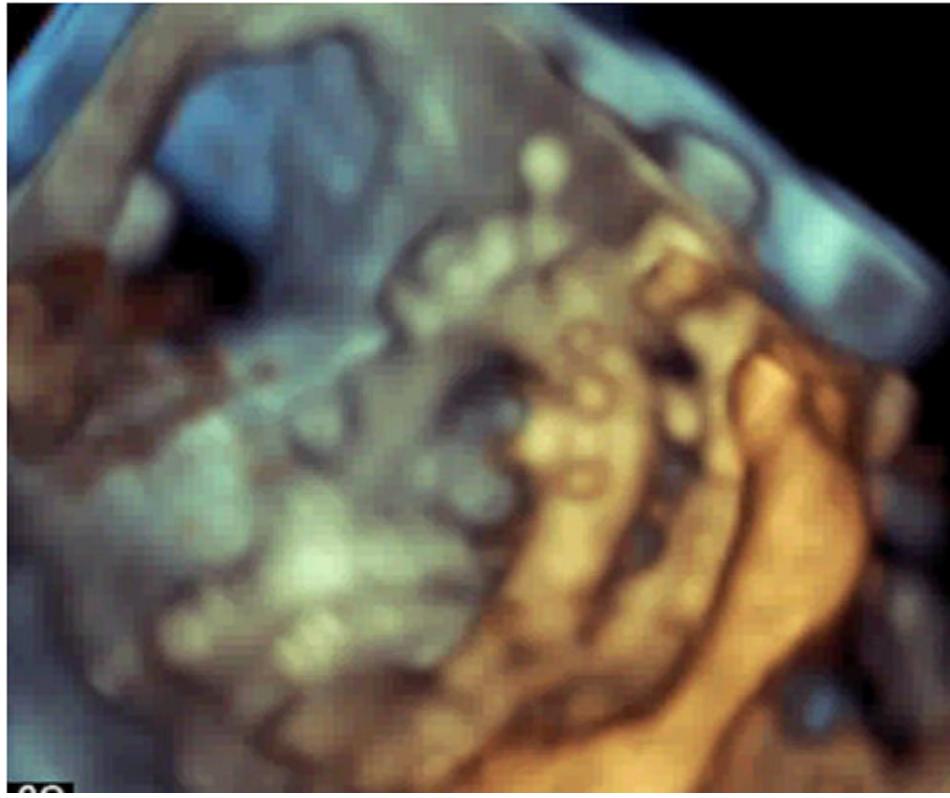
- TAVI
- MitraClip
- Katheteranuloplastik der Mitralklappe
- Mitralklappen-Implantation
- Pulmonalklappen-Implantation
- Katheteranuloplastik der Trikuspidalklappe
- Klappenimplantation in die VCI
- Katheterverschluß paravalvulärer Lecks

S.W., m, 40 J

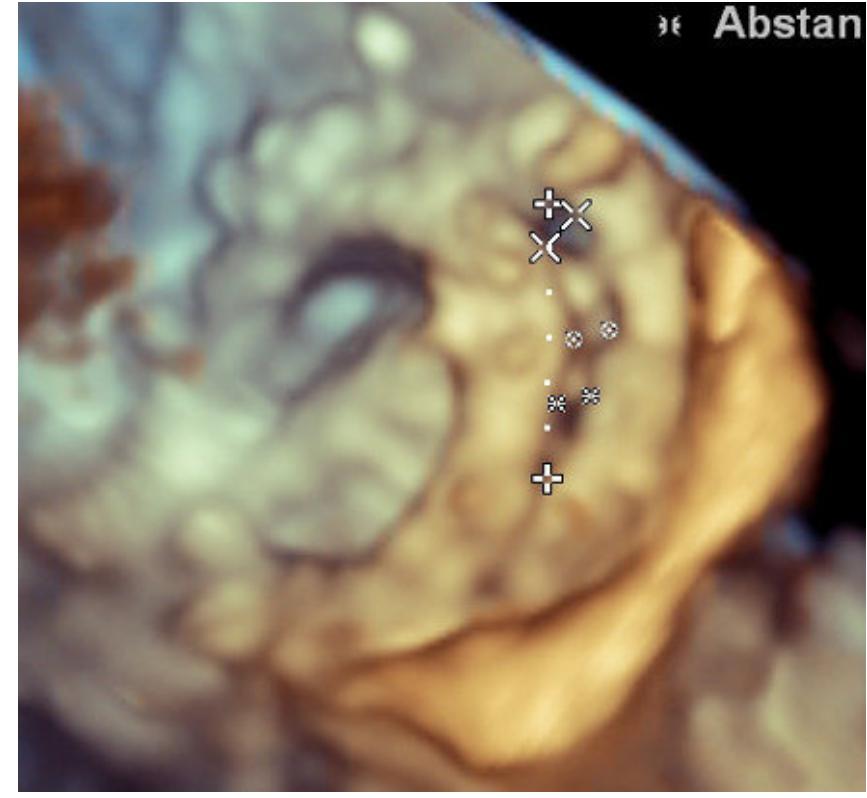
- Mitralklappenersatz wegen Endokarditis 1988 und 1989
- 2012 Mitralklappenersatz wegen paravalvulärem Leck und Endokarditis (ON-X 27/29mm)
- Hämolyse
 - Hb 9 g/l
- Schwere Herzinsuffizienz
 - TTE: LV ↑, EF 45%, PA 60mmHg
- Embolischer Insult Jan 2012

Severe MR with reflux into the pulmonary veins due to two leaks (at 1-4 o'clock and 6 o'clock)



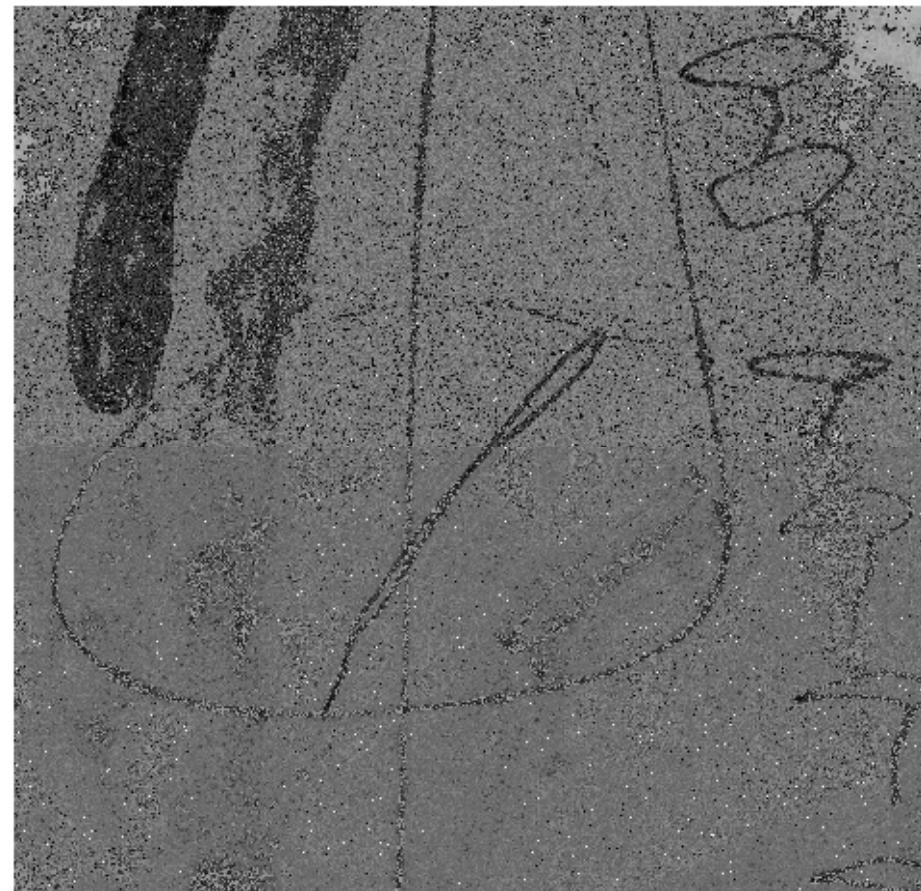


Leak between
1 and 4 o'clock

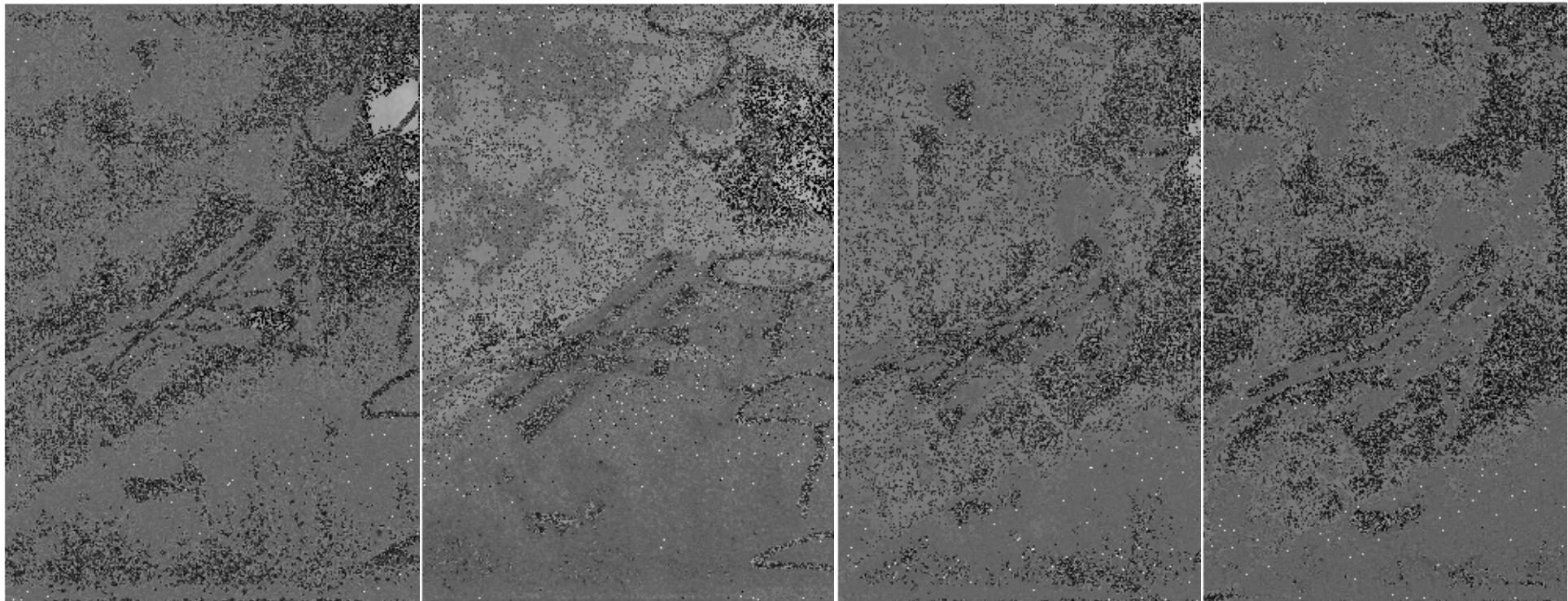


18x3mm

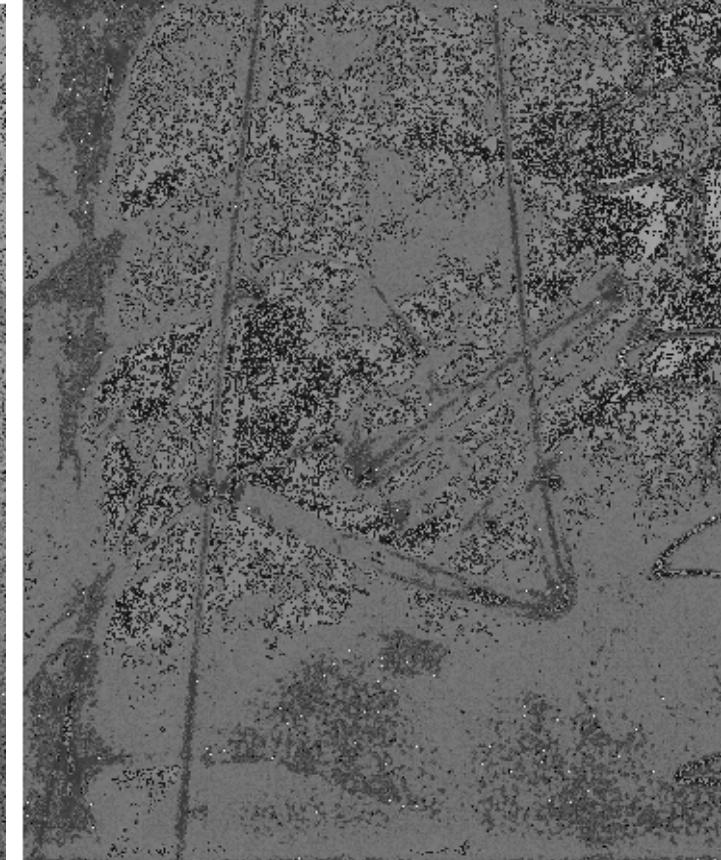
6.2.2013



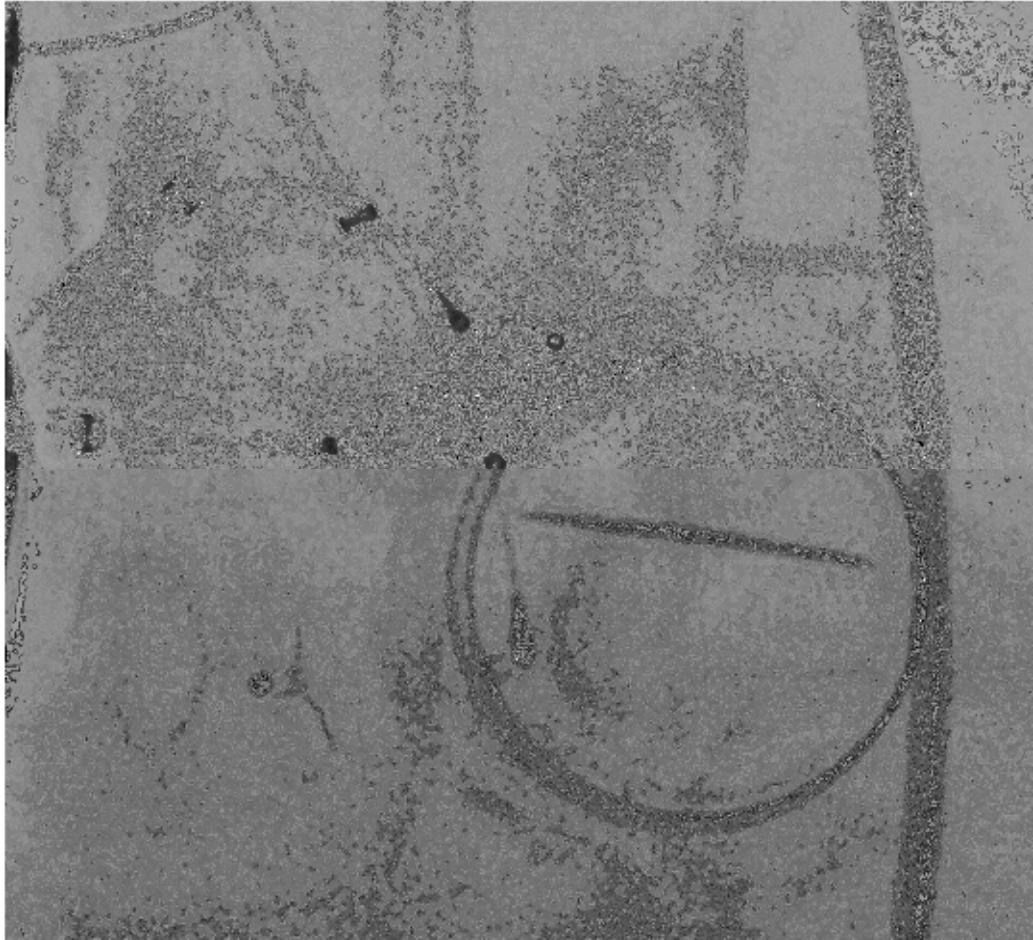
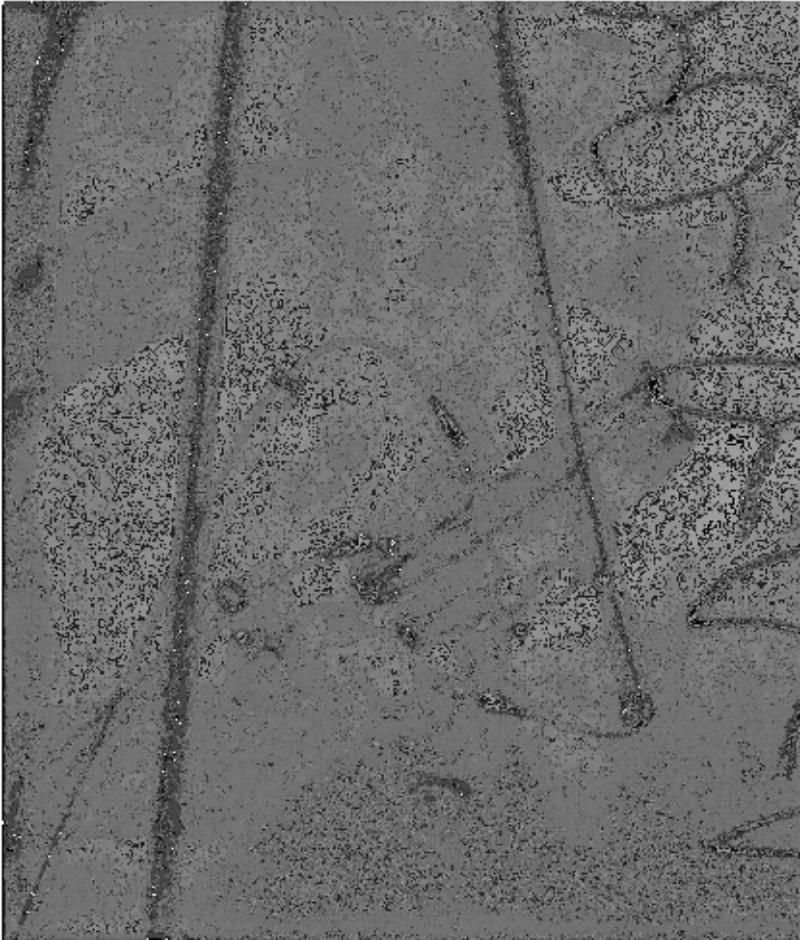
- Retrograde crossing of the leak
- Wire snared in the LA via transseptal sheath



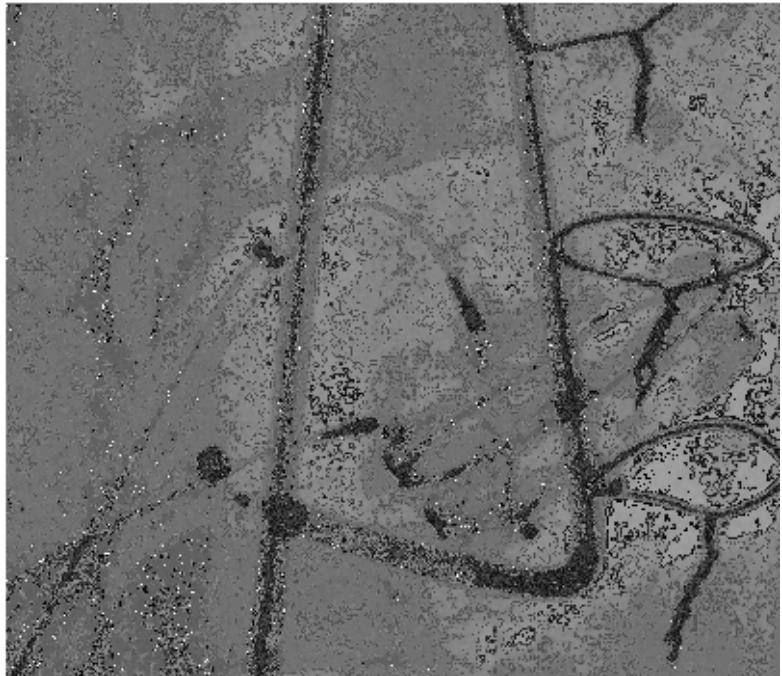
- Two transvenous 6 F Cook Shuttle sheaths
- Two AVP-II 10mm



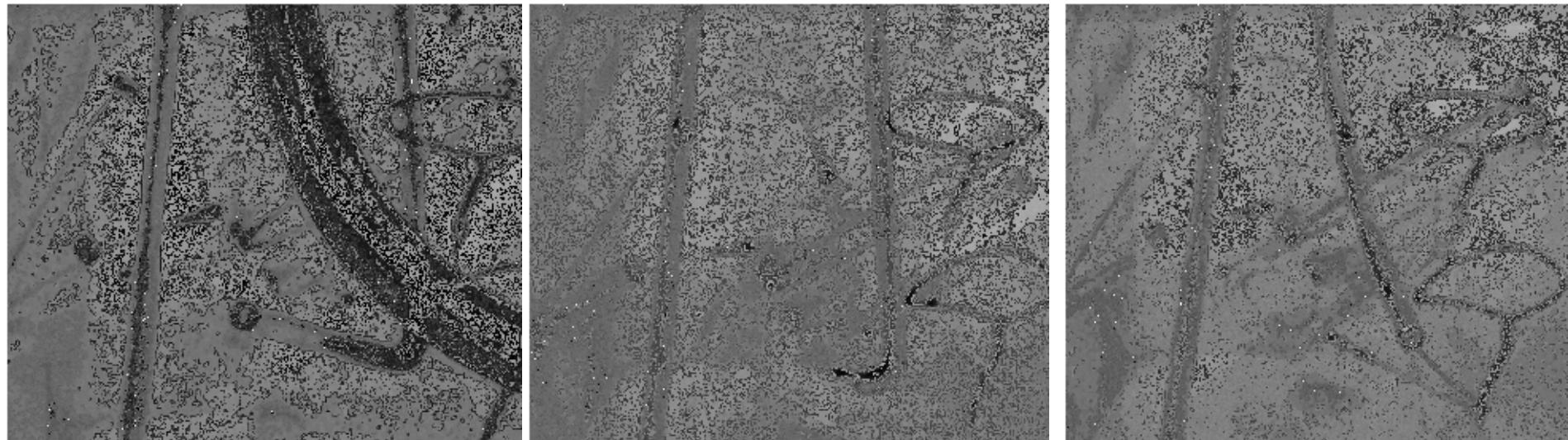
- Two AVP-II 10mm still attached
- Retrograde crossing side by side to the implanted devices
- AVP-II 12 mm



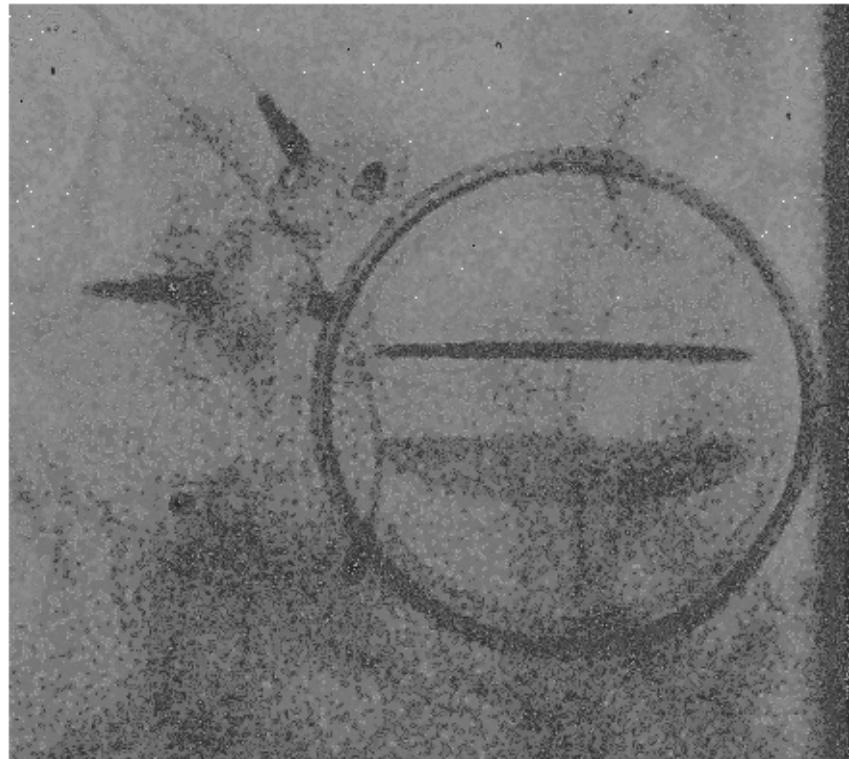
- Final check before release
-



- AVP-II 12 mm recaptured
- → both leaflets are moving



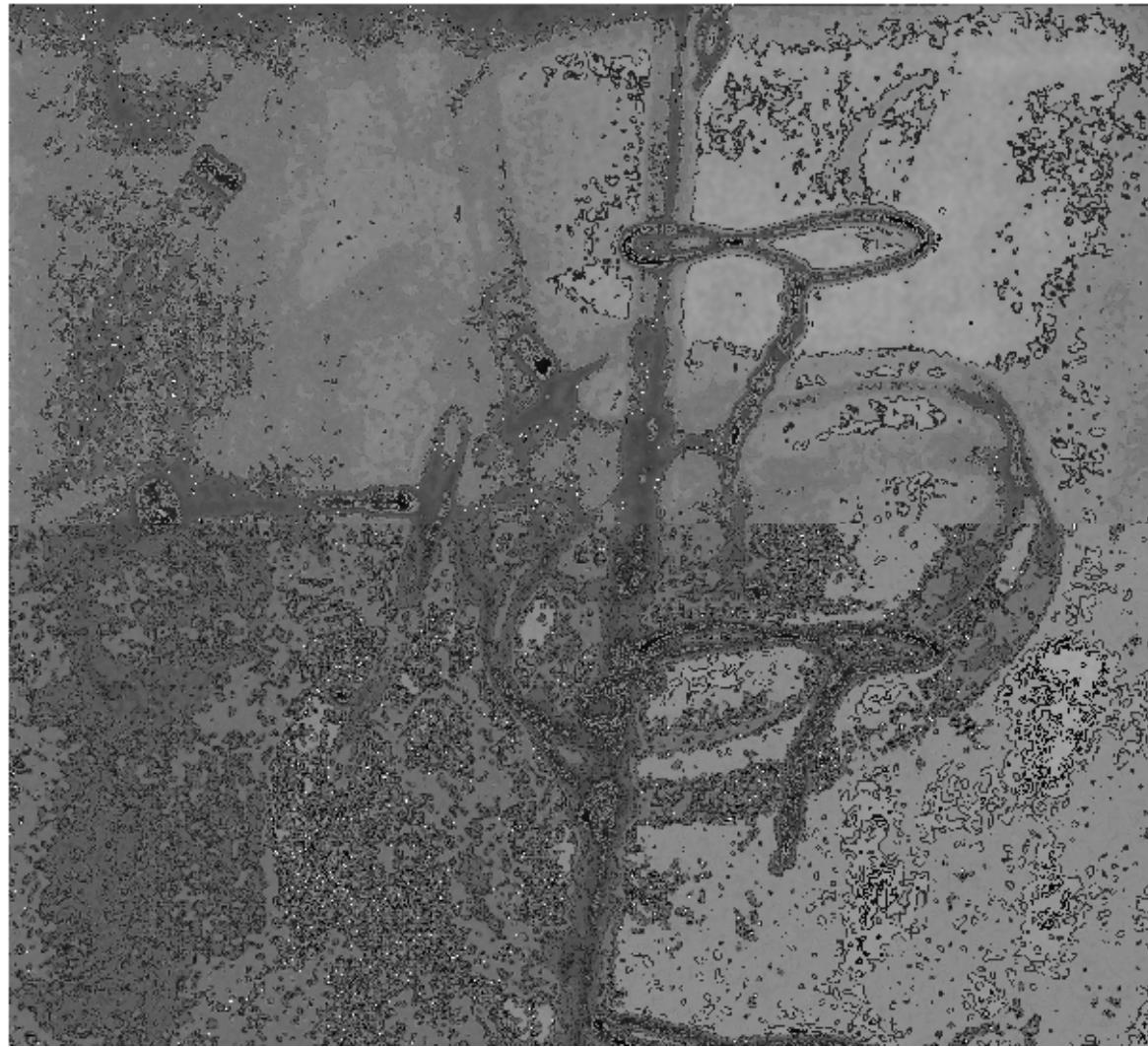
- AVP-II 12 mm exchanged for an 8mm



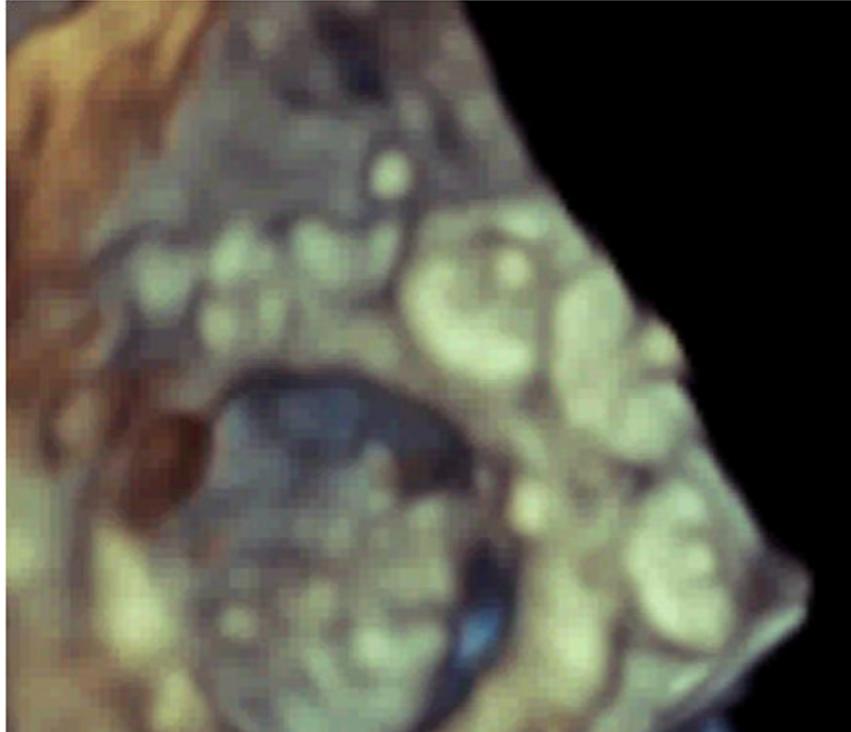
- Final check before release
-



- The transarterial plug is released
- Release of the 1st transvenous plug
- Leaflets are mobile



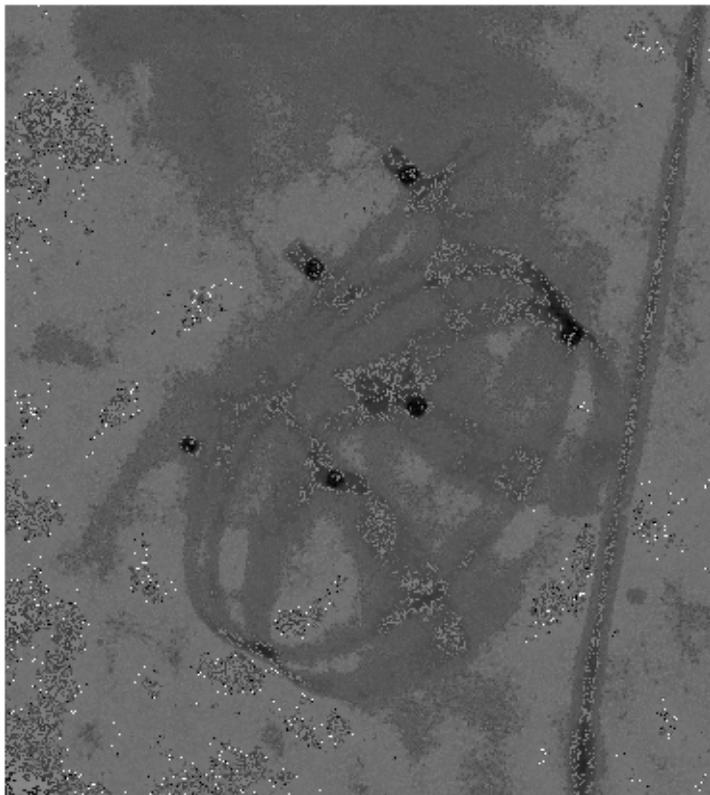
- Release of the 2nd transvenous plug



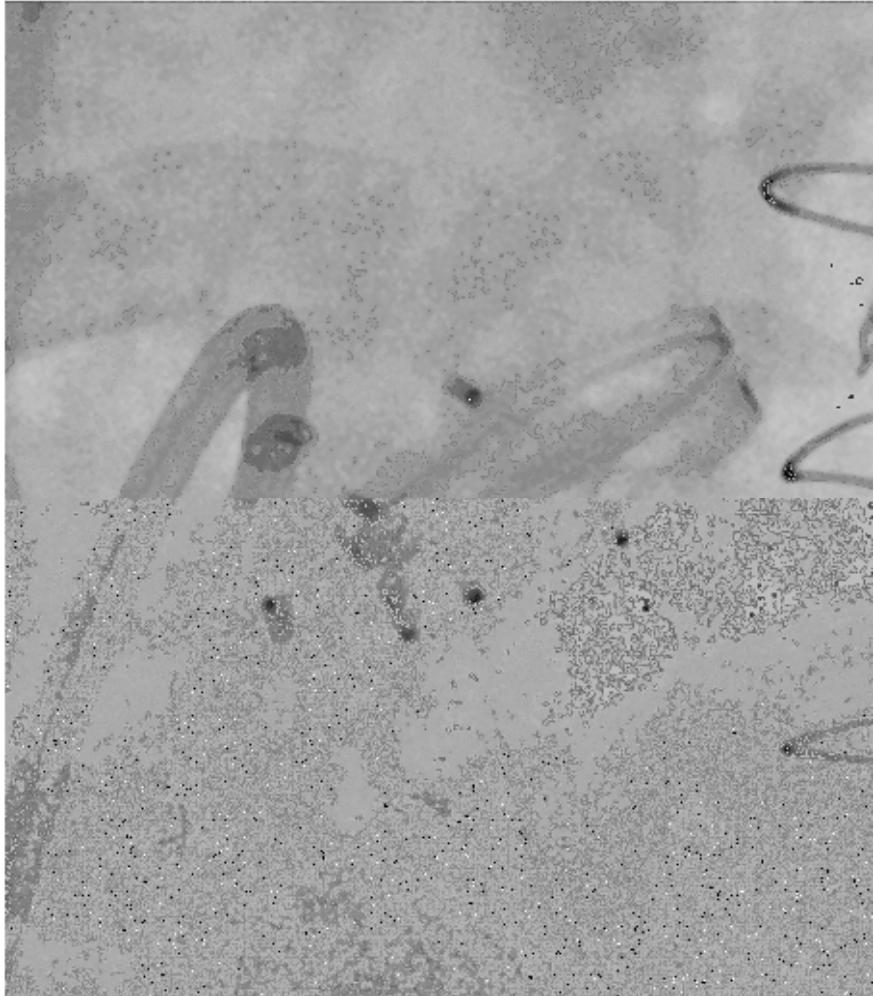
- Leaflets are mobile

28.6.13

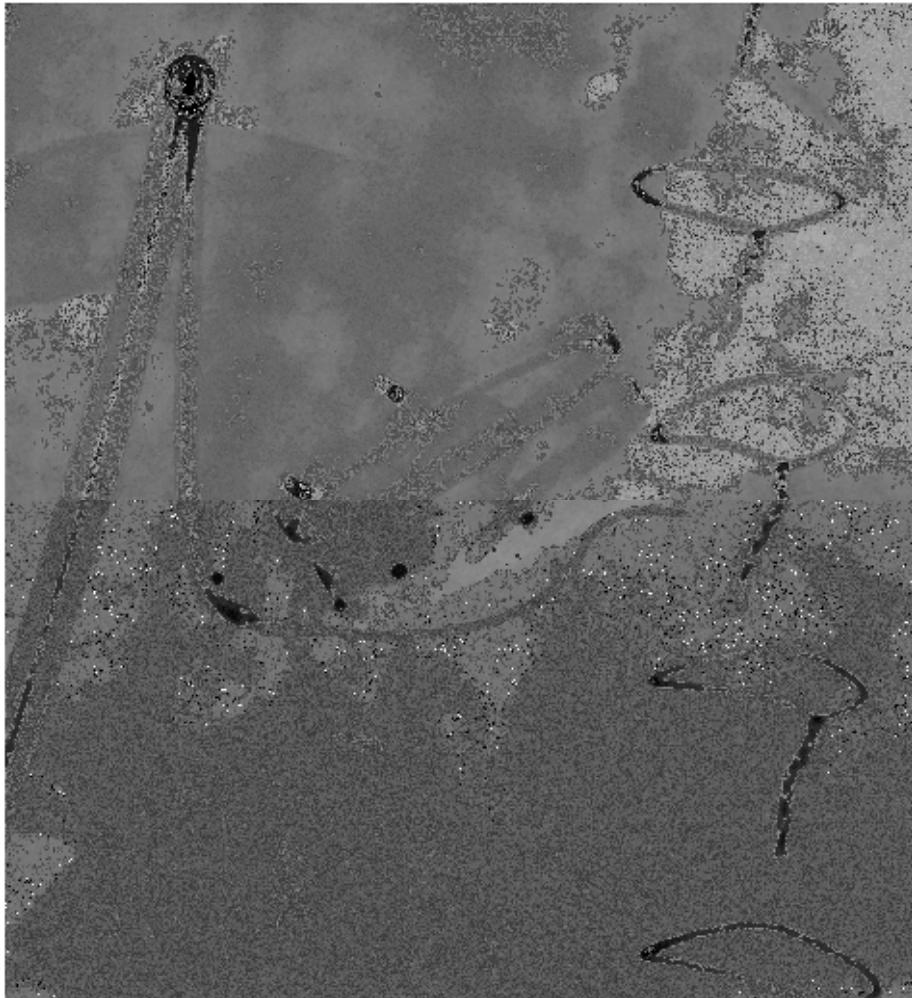
4 months later



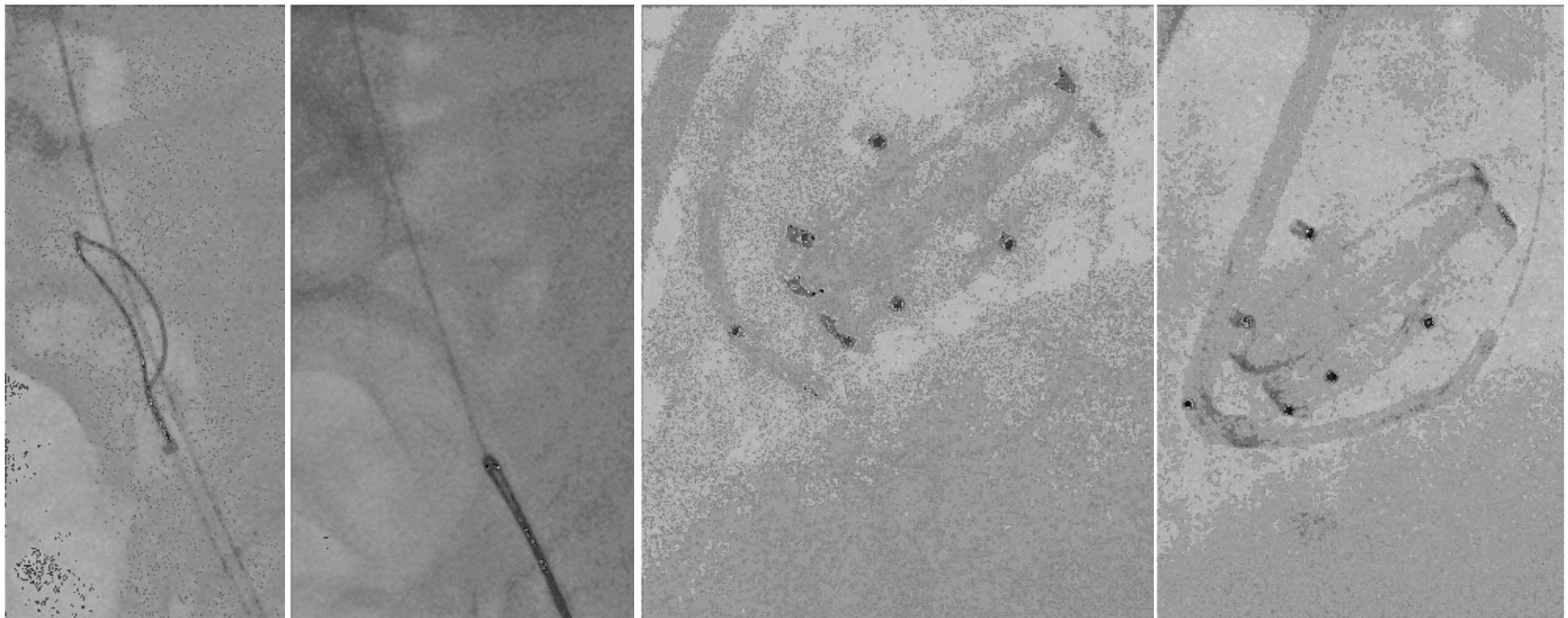
- Occluder position unchanged
- Residual MR due to the 2nd leak



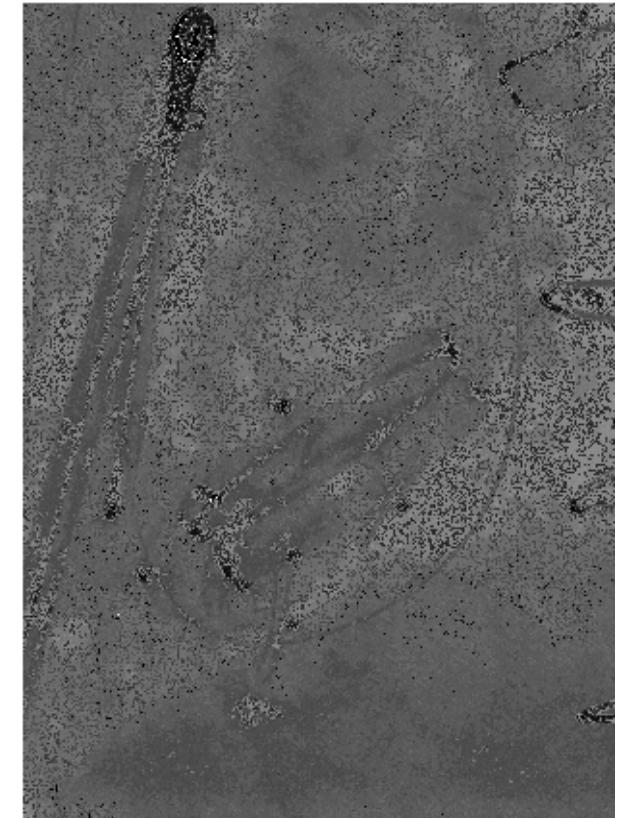
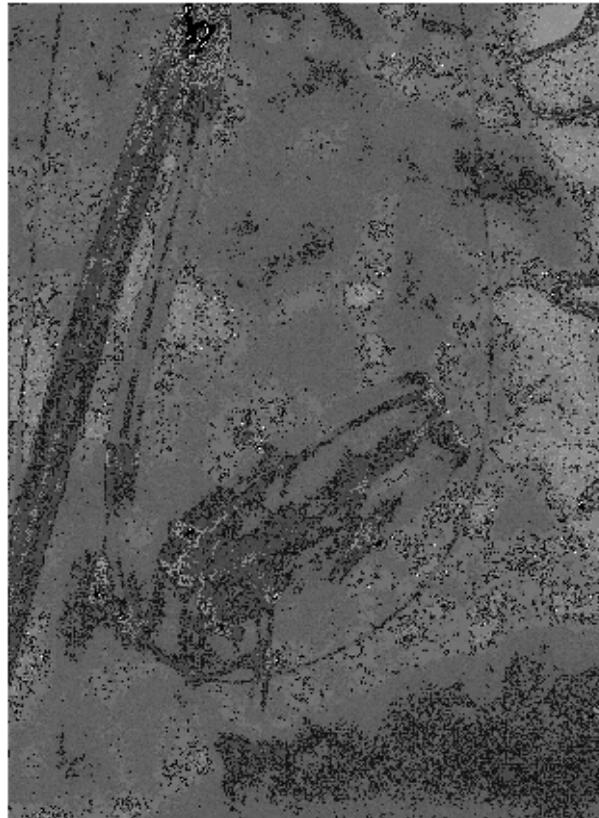
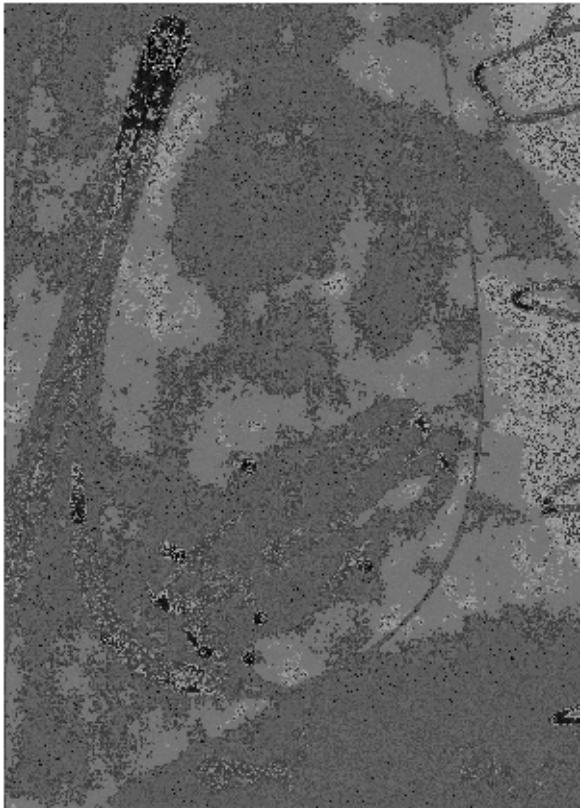
- Transseptal Agilis sheath
 - 5F FR4
 - Hydrophilic wire
-
- Transseptal puncture was difficult
 - Puncture site too close to the valve



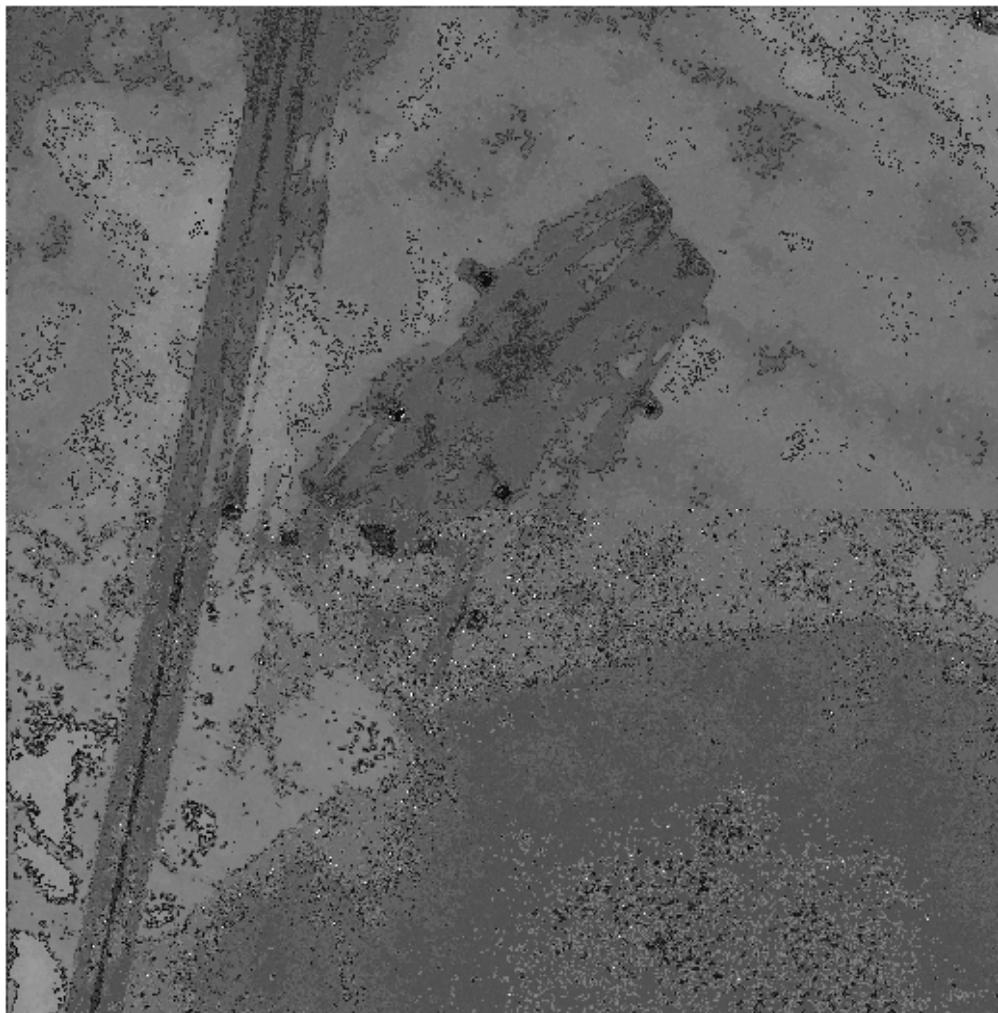
- catheters / sheaths could not cross



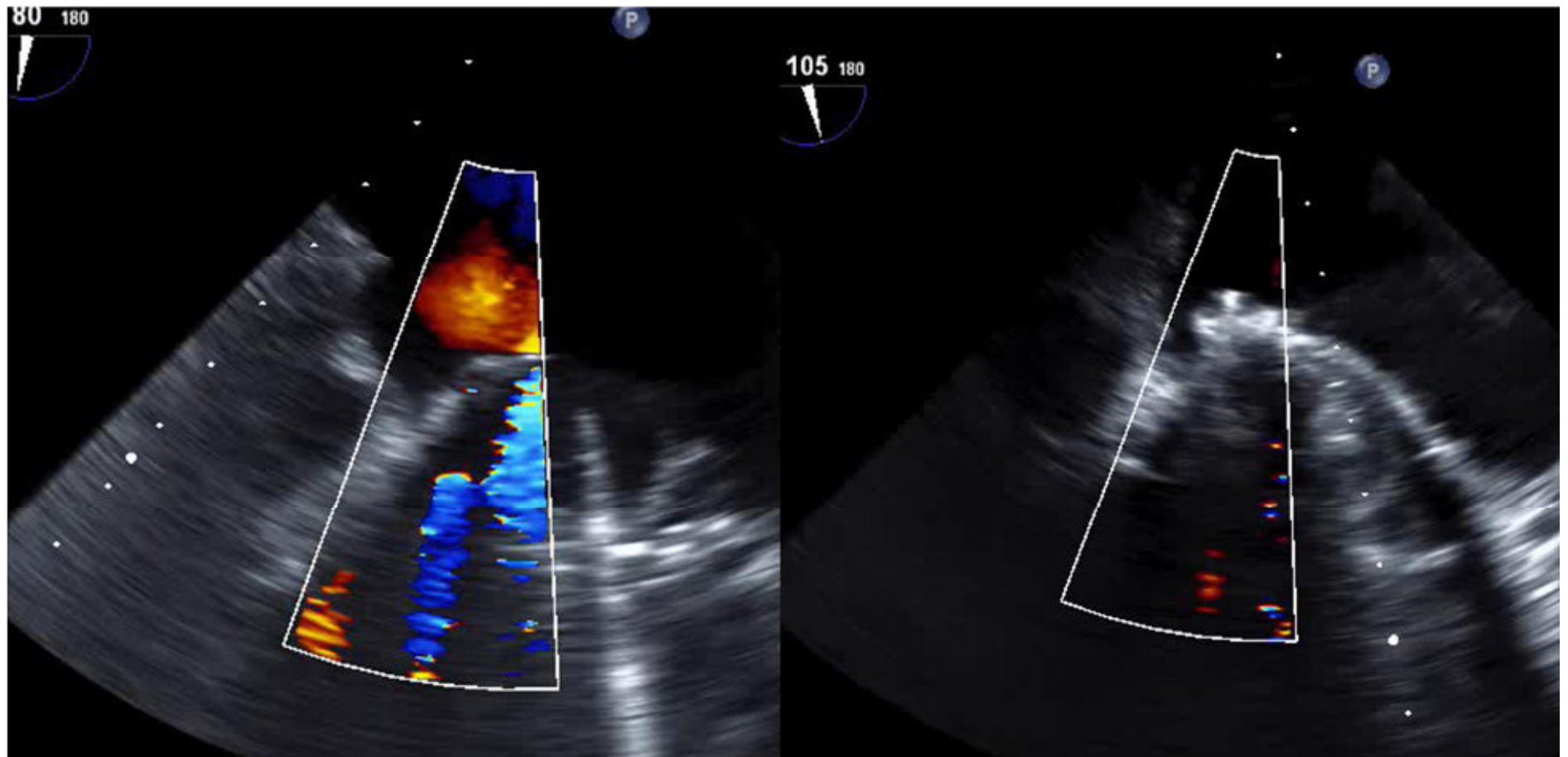
- Arteriovenous loop
- 8F Guiding catheter with 5F diagnostic catheter inside



- AVP-II 10mm through 8F guiding catheter
- Arteriovenous loop in place side by side with the occluder



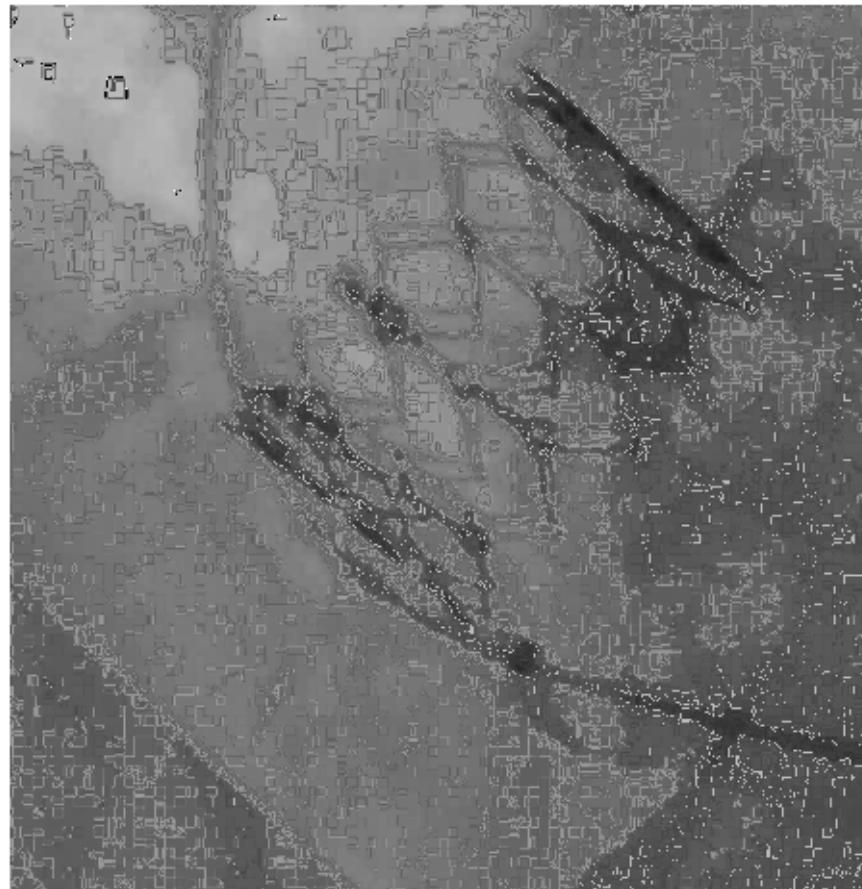
- ... release



before

after

Paravalvuläres Leck nach TAVI





Primel

- Barorezeptorstimulation
- Verfahren zur Behandlung von LV Aneurysmen
 - Parachute
 - Revivent
- Klappeninterventionen
- Anlage eines interatrialen Shunts
- Andere Verfahren in der Erprobung

Ein Vorhofseptumdefekt ...

- führt zu einem Links-Rechts-Shunt
- dieser führt zu
 - Volumenüberlastung des rechten Herzens
 - Pulmonaler Hypertonie
 - Rechtsherzinsuffizienz
 - Alles nicht gut bei Patienten mit Herzinsuffizienz
 - aber es gibt vielleicht Ausnahmen

Wann könnte ein ASD bei Patienten mit Herzinsuffizienz von Vorteil sein?

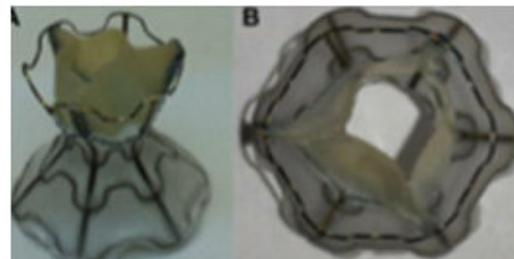
- Wenn der ASD klein ist
 - ... dann führt er nicht zu einem PA-Druck ↑
 - ... aber er könnte zu einer Abnahme des LA-Drucks führen
- Die Arbeitsbelastung wird vom kranken linken Ventrikel auf den gesunden rechten Ventrikel verlagert
- Dieses Prinzip könnte besonders bei der diastolischen Herzinsuffizienz wirksam sein

Wie ist die Idee entstanden?

- Lutembacher Syndrom
 - Patienten mit Mitralstenose und ASD haben weniger Symptome als Patienten ohne ASD
- Eine Ballonseptostomie bessert die Symptome bei Mitralstenose
- Auch bei anderen Formen der Linksherzinsuffizienz führt eine Septostomie zu einer Besserung der Symptome
- Fallberichte über Linksherzdekompensation nach ASD-Verschluss bei Patienten mit eingeschränkter LV Funktion
- Fallberichte über den Einsatz von fenestrierten ASD-Okkludern bei Patienten mit Linksherzinsuffizienz

Wie kann man einen ASD erzeugen?

- Ballondilatation
 - Stent
 - IASD System
-
- V-Wave
 - Mit Perikardklappe



IASD Device System Study

- patients with **preserved** LV function -

- Main inclusion criteria

- >40 yrs
- NYHA III-IV
- EF > 45%
- LVEDP > 15mmHg



- Main exclusion criteria

- PAP > 60mmHg
- Significant coronary or valvular disease

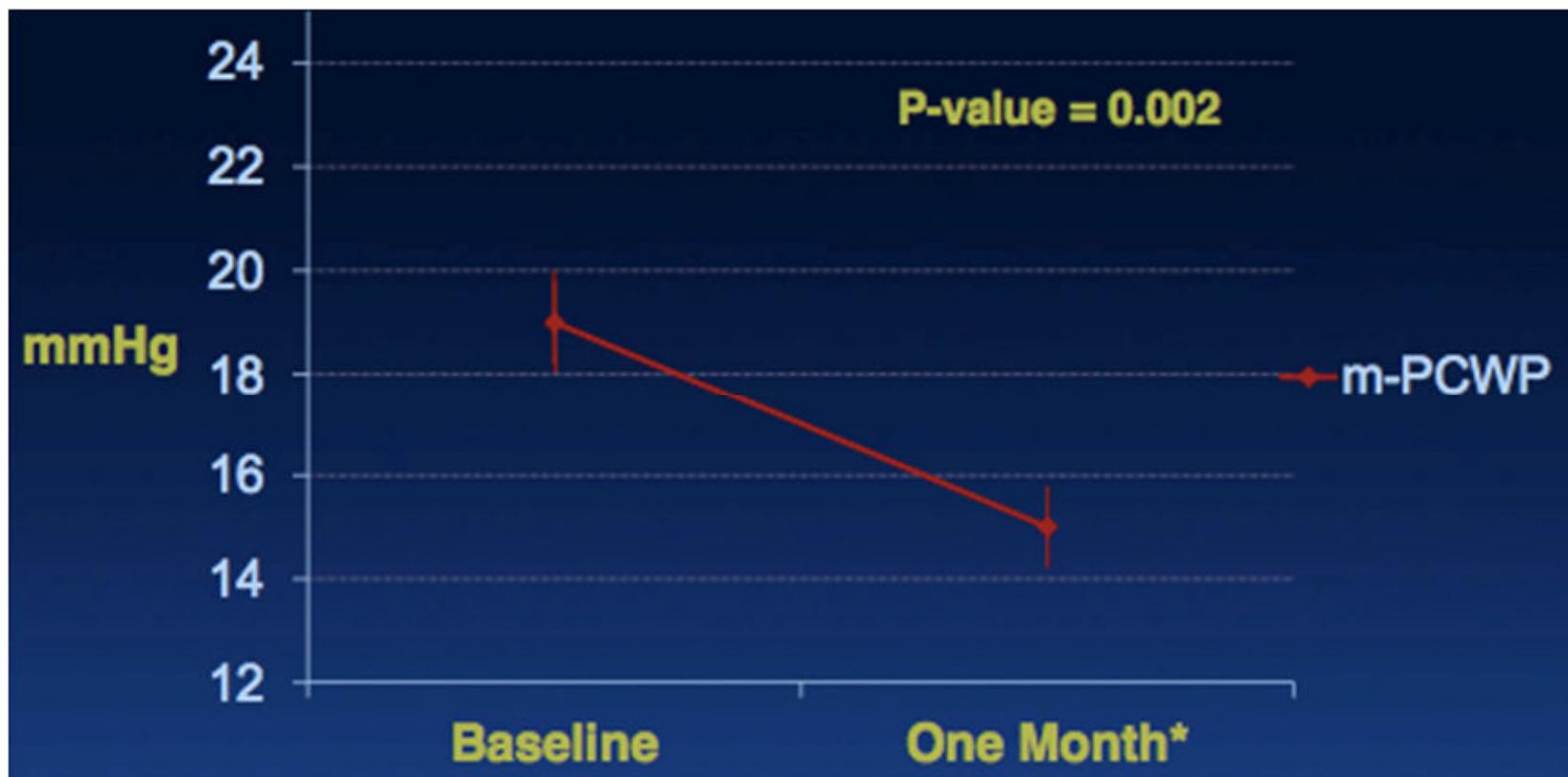
IASD Device System Study

- patients with preserved LV function -

- Baseline characteristics (n=11)
 - Female gender 55%
 - Age 70 ± 11.9
 - Coronary artery disease 36%
 - Hypertension 91%
 - Diabetes 45%
 - Atrial fibrillation 36%
 - EF $57 \pm 9\%$
 - PCPW $18 \pm 4.9 \text{ mmHg}$
 - PAP syst $45 \pm 12 \text{ mmHg}$

IASD Device System Study

- patients with preserved LV function -



No significant changes for RA and PA pressures

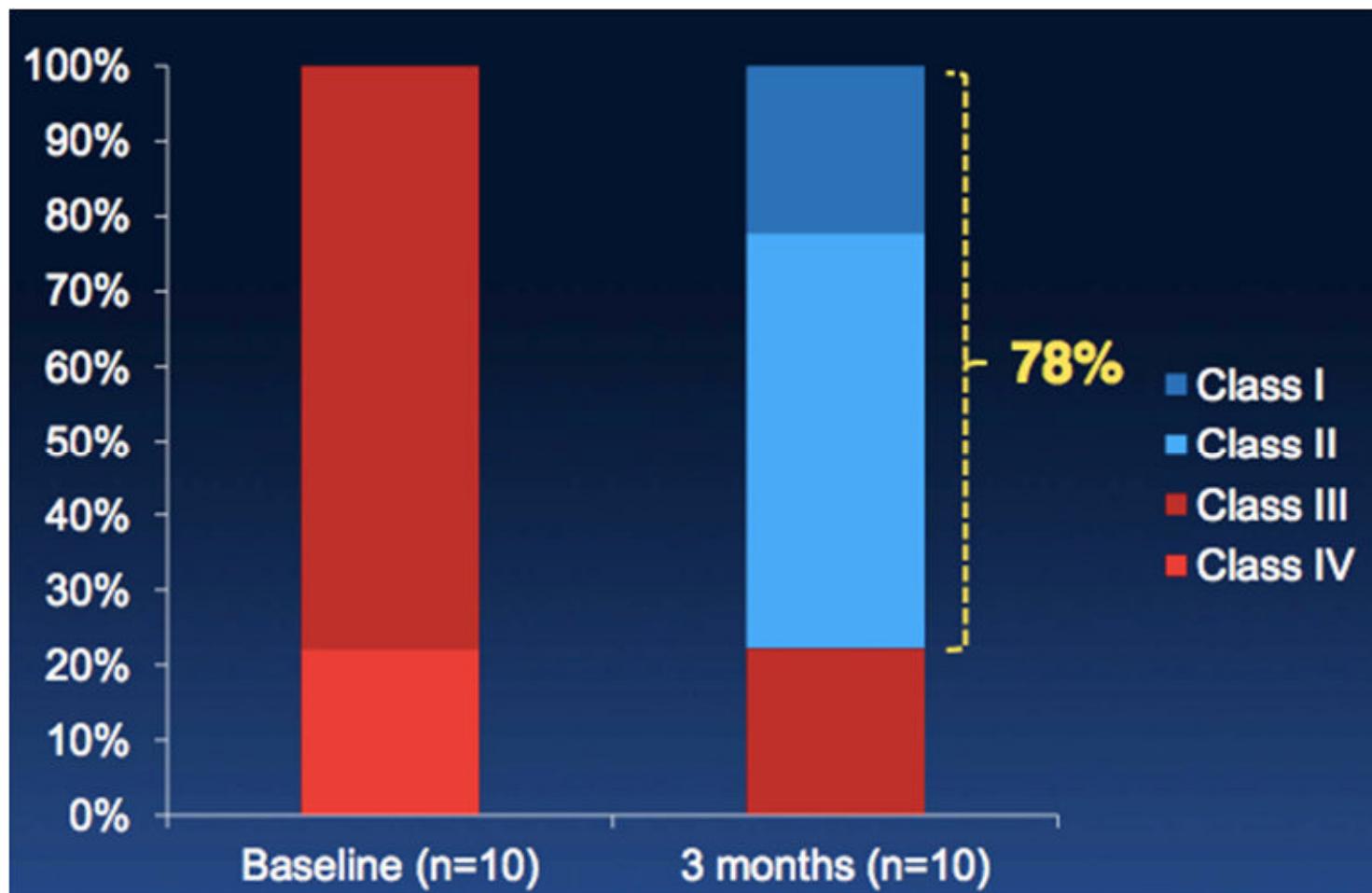
IASD Device System Study

- patients with preserved LV function -

	Baseline	3 mo	P
NYHA	3.2	2.1	0.0008
MLWHF Score	48	29	0.073
6 MWD (m)	330	350	0.2
NT-pro BNP	211	168	0.071

IASD Device System Study

- patients with preserved LV function -



Bei Patienten mit
eingeschränkter LV
Funktion?

V-Wave clinical trial

- patients with **reduced EF** -

- Main inclusion criteria
 - EF 15-40%
 - NYHA III (-IV)
 - Normal RV function
- Main exclusion criteria
 - Severe pulmonary hypertension
 - PAP < 55 mmHg



V-Wave clinical trial

- patients with reduced EF -

- Baseline characteristics (n=6)

- Age	66 ± 7 yrs
- Gender male:	5
- Hypertension	5
- Diabetes	5
- NYHA III	6
- Atrial fibrillation	4
- CKD	5
- COPD	3
- Previous MI	5
- NT-proBNP	3839 ± 3640

V-Wave clinical trial

- patients with reduced EF -

- Baseline echo characteristics (n=6)

- EF

- $29 \pm 8 \%$

- LV EDD

- $65 \pm 11 \text{ mm}$

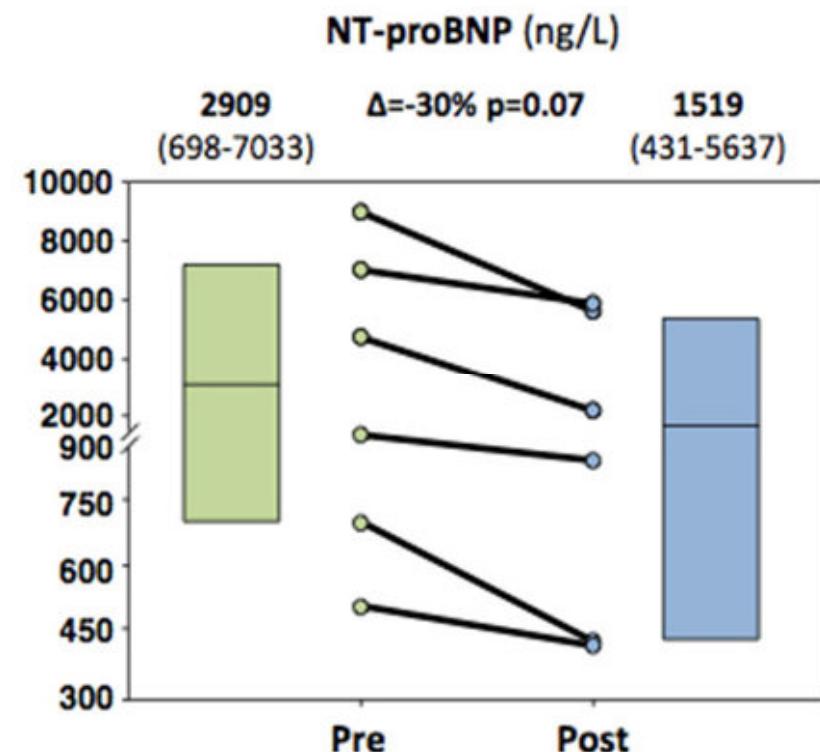
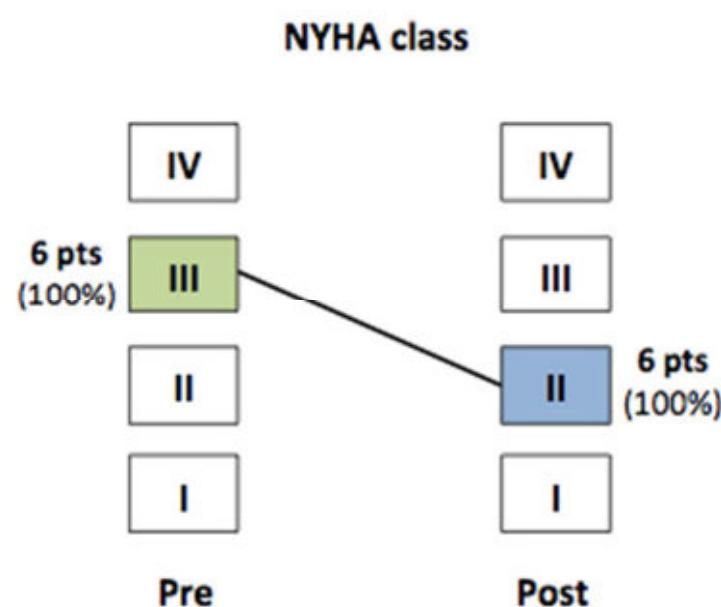
- PAP

- $40.3 \pm 13.4 \text{ mmHg}$

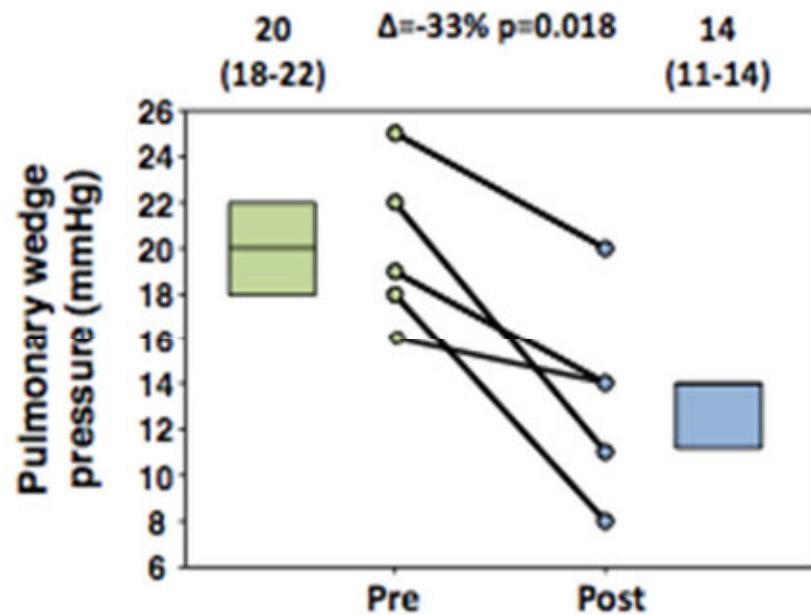
- CO

- $4.5 \pm 1 \text{ l/min}$

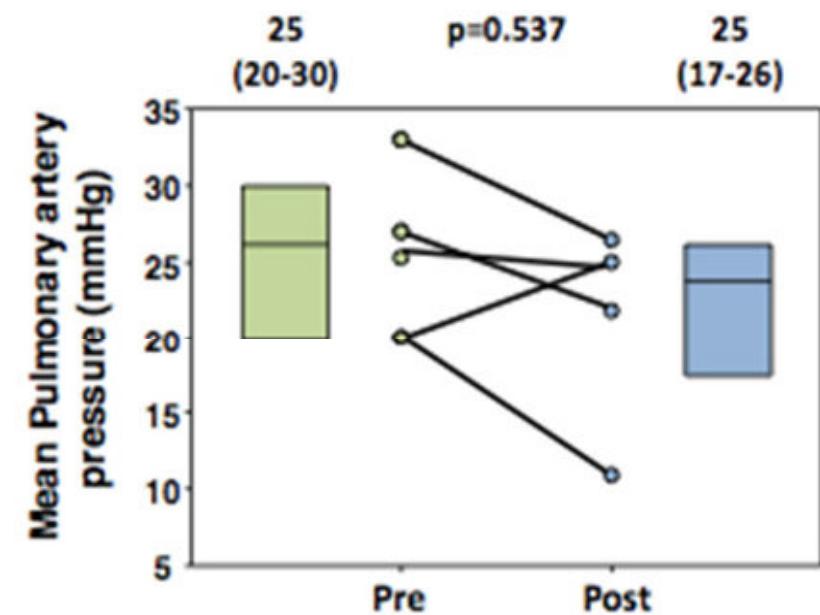
Initial results with V-Walve FU 6 months



Initial results with V-Walve FU 6 months



Decrease of PWP



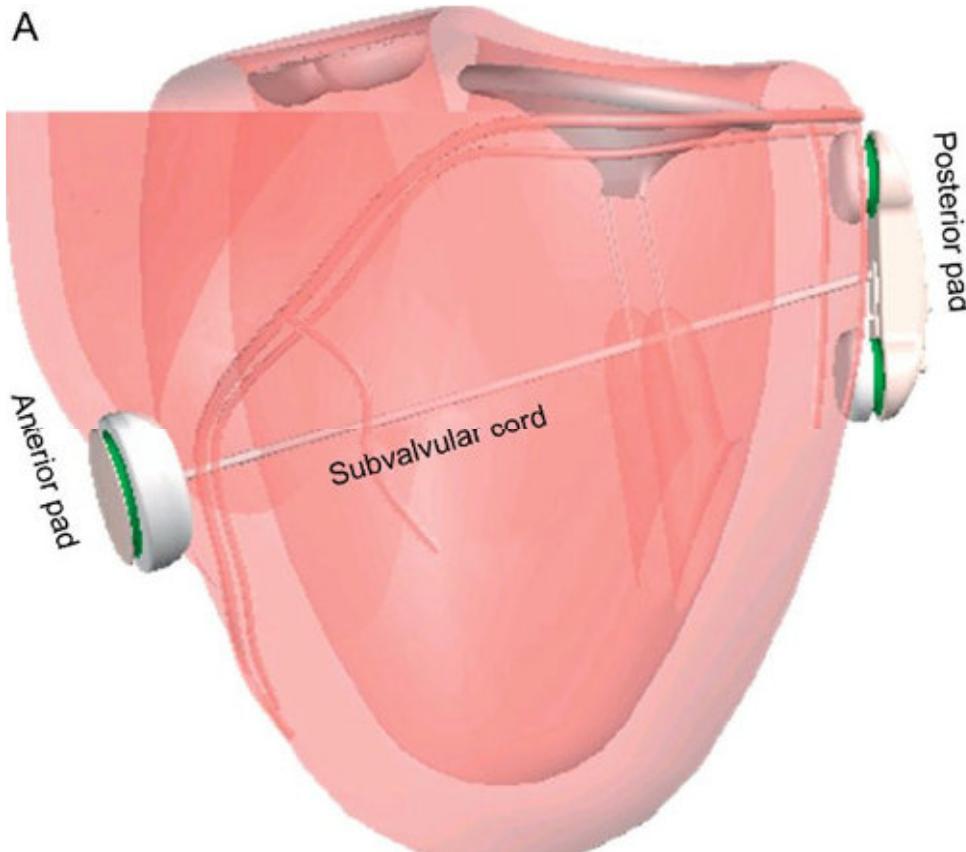
No increase
in PA pressure

- Barorezeptorstimulation
- Verfahren zur Behandlung von LV Aneurysmen
 - Parachute
 - Revivent
- Klappeninterventionen
- Anlage eines interatrialen Shunts
- Andere Verfahren in der Erprobung



ns-flare.de

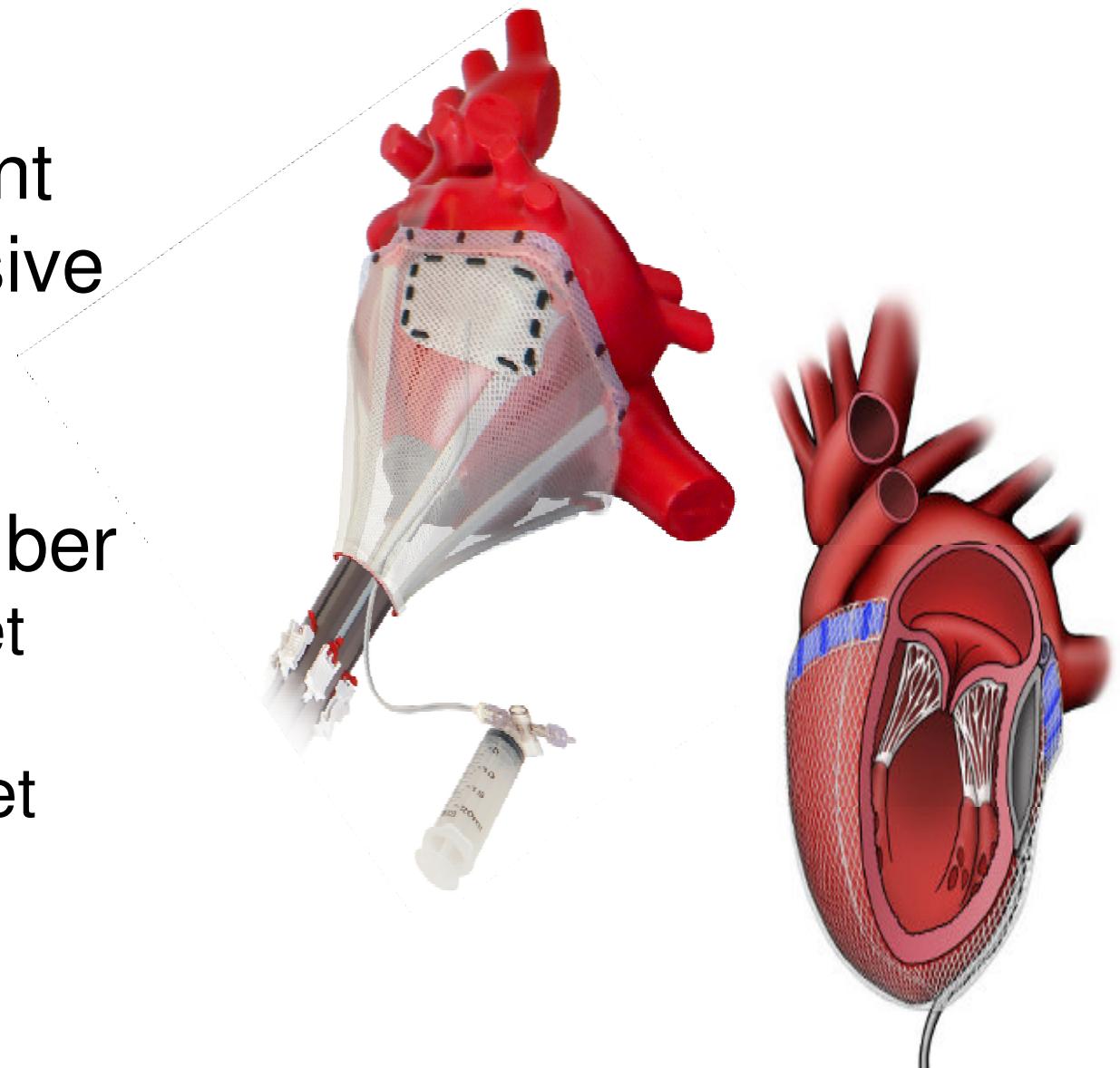
Coapsys



- Kompression des linken Ventrikels führt zu einer "remodeling"
- Besserung der Herzinsuffizienz
- Randomisierte Studie positiv
- Projekt gestoppt in der Zeit der Bankenkrise

Mardil - VenTouch

- Passive restraint
- Minimally invasive thoracotomy delivery
- Inflatable chamber
 - Reduces leaflet tethering
 - Improves leaflet coaptation
 - Reduces MR



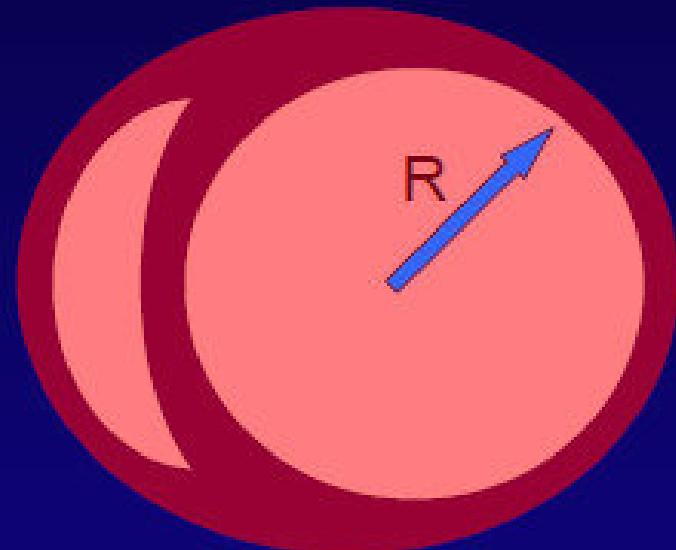
Symphony device

- Implantable synchronized pump
- Implant in pacemaker pocket
- One graft to subclavian
- Works with ECG to decrease afterload and increase cardiac output
- Device output 3.0L/min



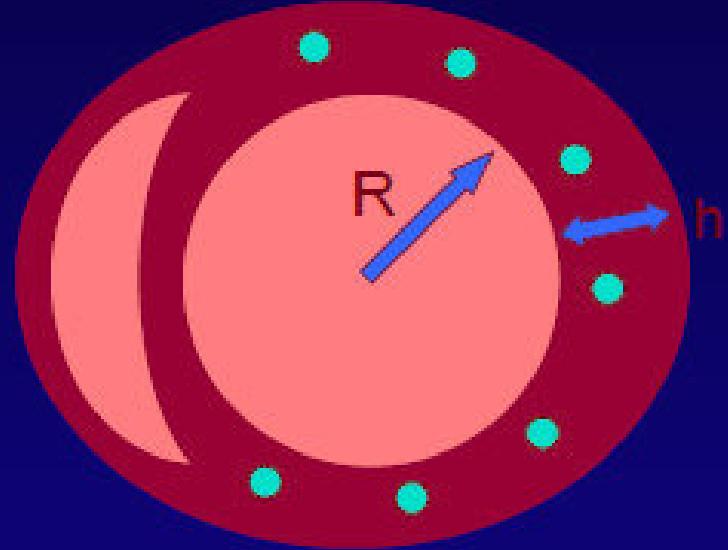
LV Restoration & Laplace's Law

The mechanism of the Algisyl-LVR Device



Dilated

$$\sigma = \frac{P \times R}{2h}$$



Modified (LVR)

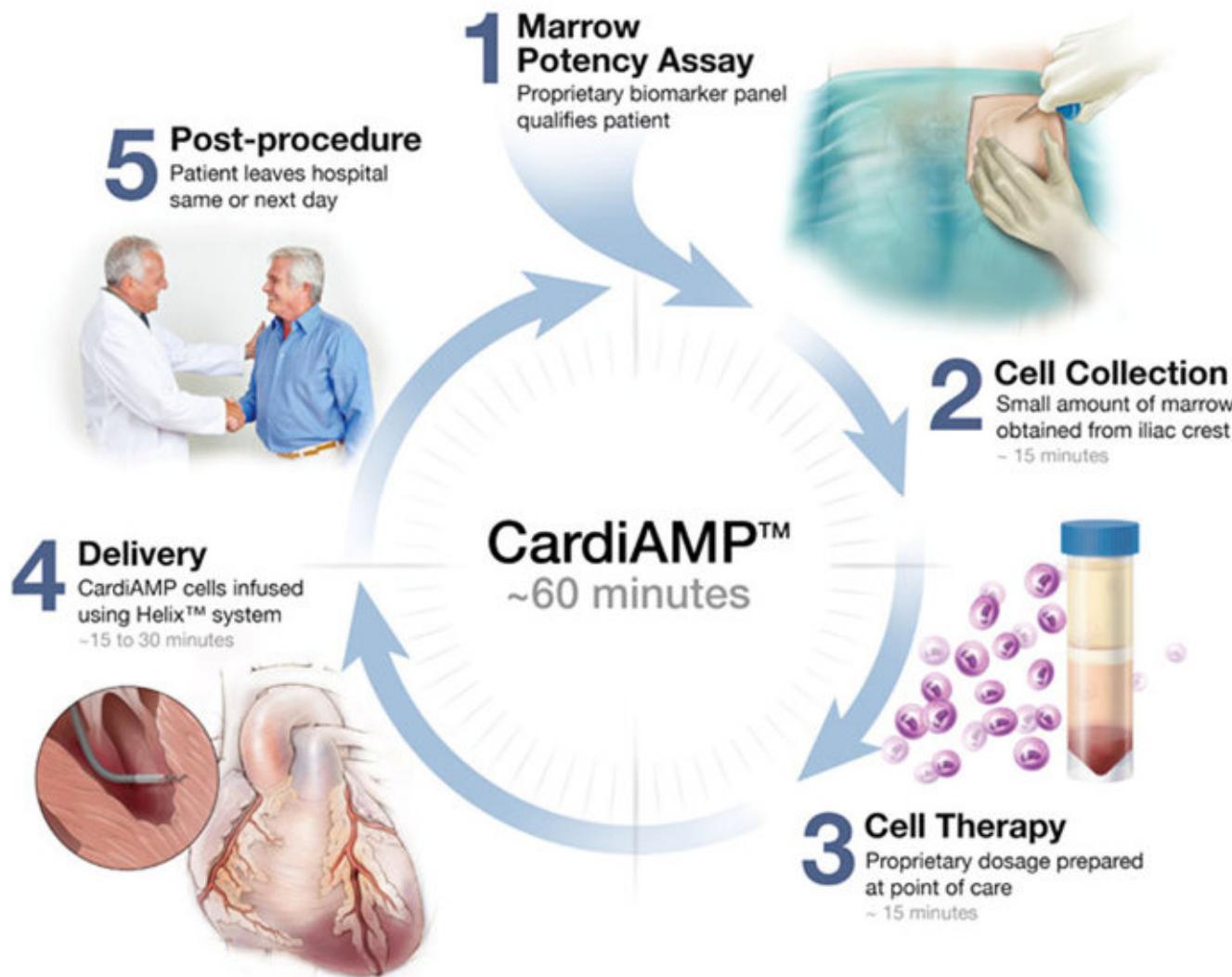
$$\sigma = \frac{P \times R}{2h}$$

↑ LV Thickness(h) and ↓ LV Radius (R) produce:

↓ LV wall tension or stress (σ) and ↓ LV pressure (P)

BioCardia

- Stem cell delivery - CardiAMP



Weitere Verfahren in der Erprobung

- Phrenic nerve stimulation
- Renal denervation
- Vagus stimulation
- Carotid body modulation
- Pulmonary banding
-

Vielen Dank für Ihre Zeit!