Outcomes in Mitraclip for Degenerative Mitral Regurgitation

HerzGefässZentrum Zürich
KLINIK IM PARK

HIRSLANDEN
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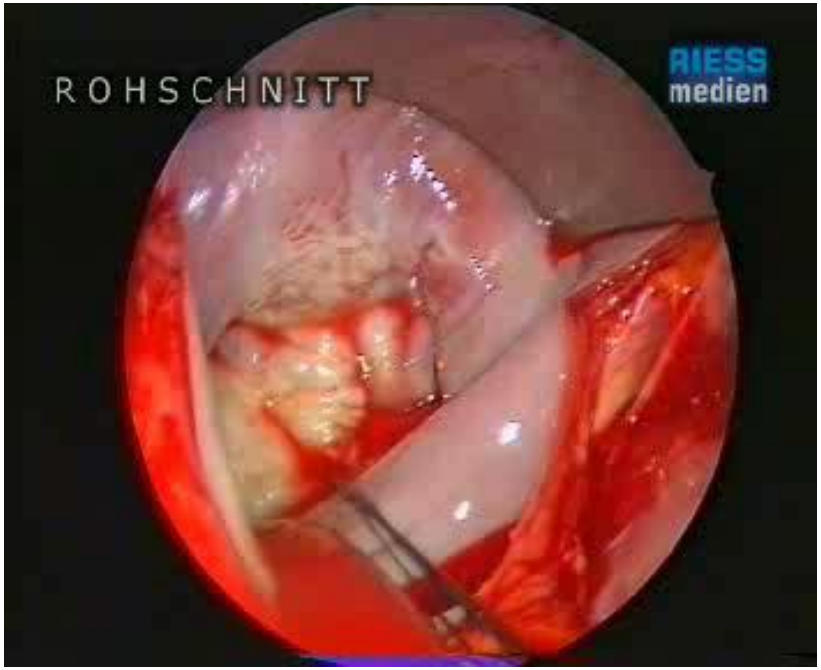
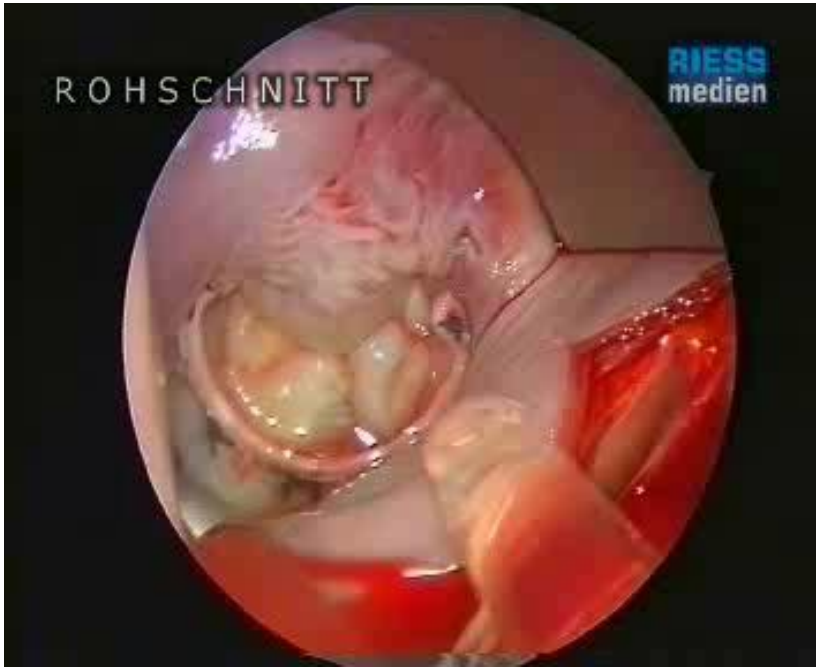
Dr. Olaf Walter Franzen

Mitral valve repair



pre



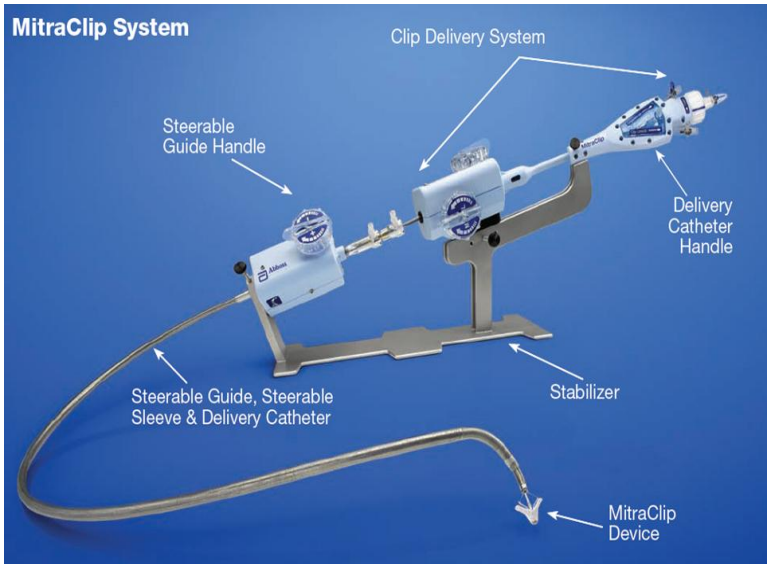
post

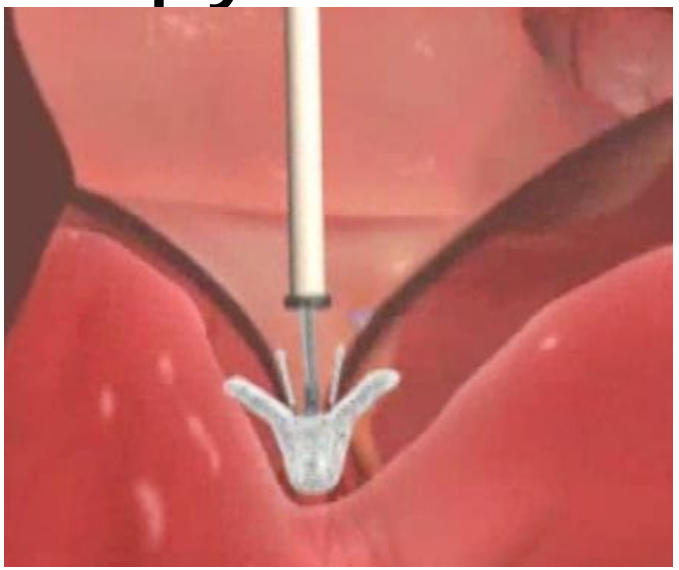
Courtesy PD Dr. Boehm

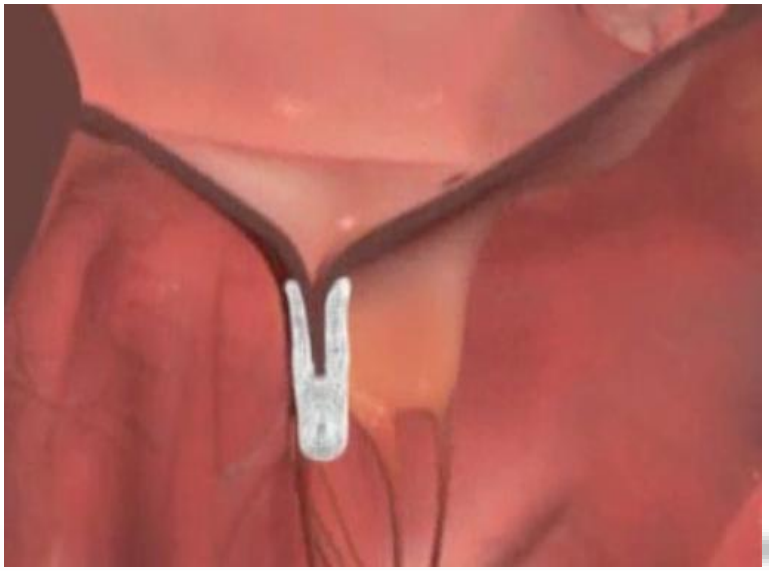
Mitral Valve Surgery

Publication	MR	Surgery		5 Years MI < 3/4
Flameng et al, Circ 2003 Herzzentrum Leuven	Degen. MR	Reconstruction	n = 242	83%
Mihaljevic et al , JACC 2007 Cleveland Clinics	Isch MR	Anuloplasty	n = 290	80%
Maisano et al, EuroIntervent 2006 Univ. Mailand	Degen. and funct MR	edge-to-edge without Ring	n = 28	86%

MitraClip Therapy





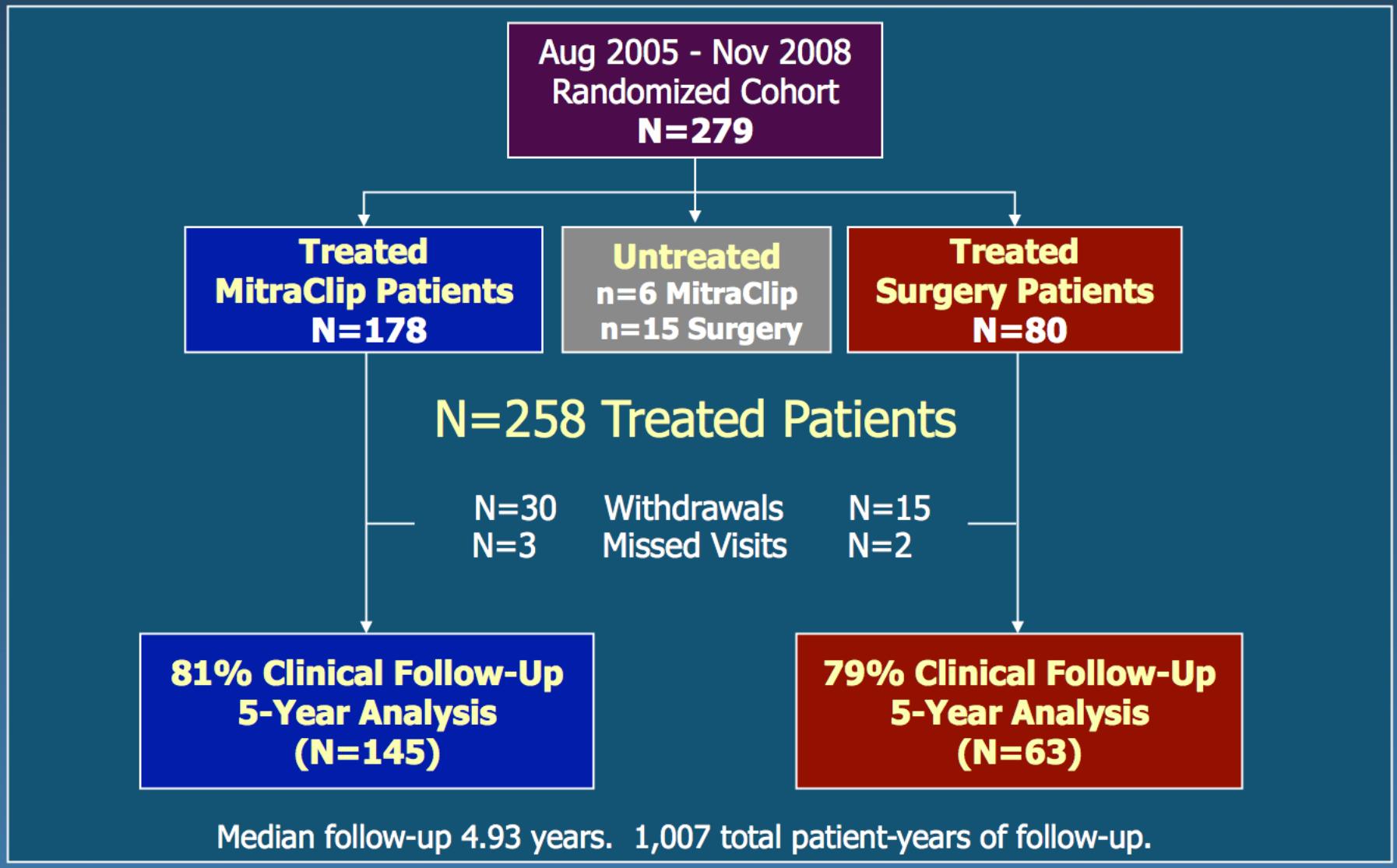


EVEREST II


The NEW ENGLAND JOURNAL of MEDICINE
Percutaneous Repair or Surgery for Mitral Regurgitation
Ted Feldman, M.D., Elyse Foster, M.D., Don Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., M.Sc., for the EVEREST II Investigators*
www.nejm.org

Clinical Follow-Up

EVEREST II RCT



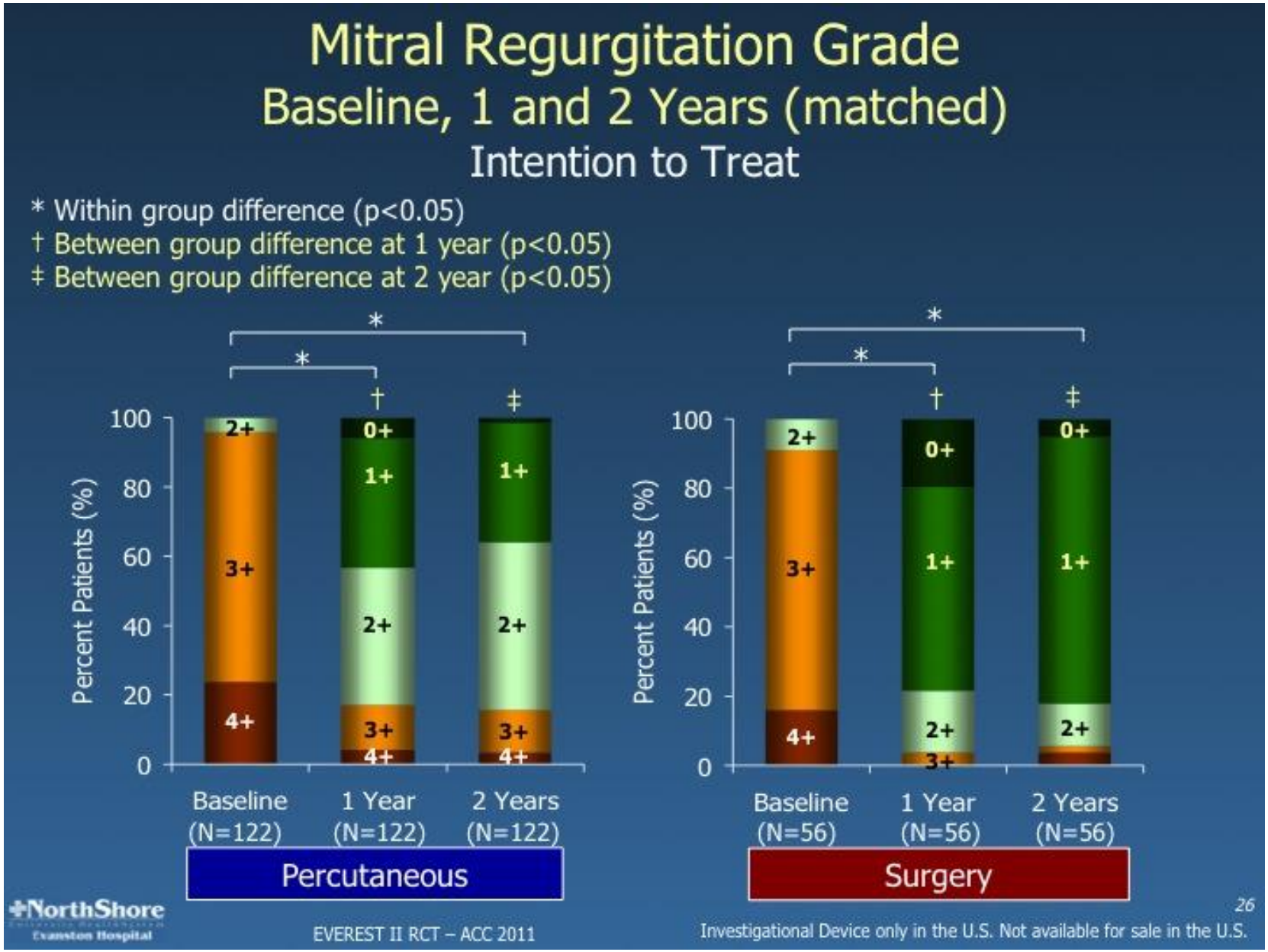
NorthShore
University HealthSystem
Evanston Hospital

Baseline Characteristics

EVEREST II RCT

Characteristic	MitraClip N = 184	Surgery N = 95	p-value
Age (mean), years	67	66	ns
Male	63%	66%	ns
History of CHF	91%	78%	0.005
NYHA Functional Class III/IV	51%	47%	ns
Functional MR Etiology	26%	27%	ns
Coronary Artery Disease	47%	46%	ns
Prior Myocardial Infarction	22%	21%	ns
Previous Cardiovascular Surgery	22%	19%	ns
Atrial Fibrillation	34%	39%	ns
COPD (with or without home O_2)	15%	15%	ns
Moderate to Severe Renal Disease	3%	2%	ns
Diabetes	8%	11%	ns
LV Ejection Fraction (mean), %	60	61	ns
LV End Systolic Dimension (mean), cm	3.7	3.5	ns

EVEREST II


Mitral Regurgitation Grade
Baseline, 1 and 2 Years (matched)
Intention to Treat
* Within group difference (p<0.05)
† Between group difference at 1 year (p<0.05)
‡ Between group difference at 2 year (p<0.05)
Percent Patients (%)
100
80
60
40
20
0
2+
3+
4+
0+
1+
2+
3+
4+
1+
2+
3+
4+
Baseline (N=122)
1 Year (N=122)
2 Years (N=122)
Percutaneous
Baseline (N=56)
1 Year (N=56)
2 Years (N=56)
Surgery
NorthShore
Evanston Hospital
EVEREST II RCT – ACC 2011
Investigational Device only in the U.S. Not available for sale in the U.S.
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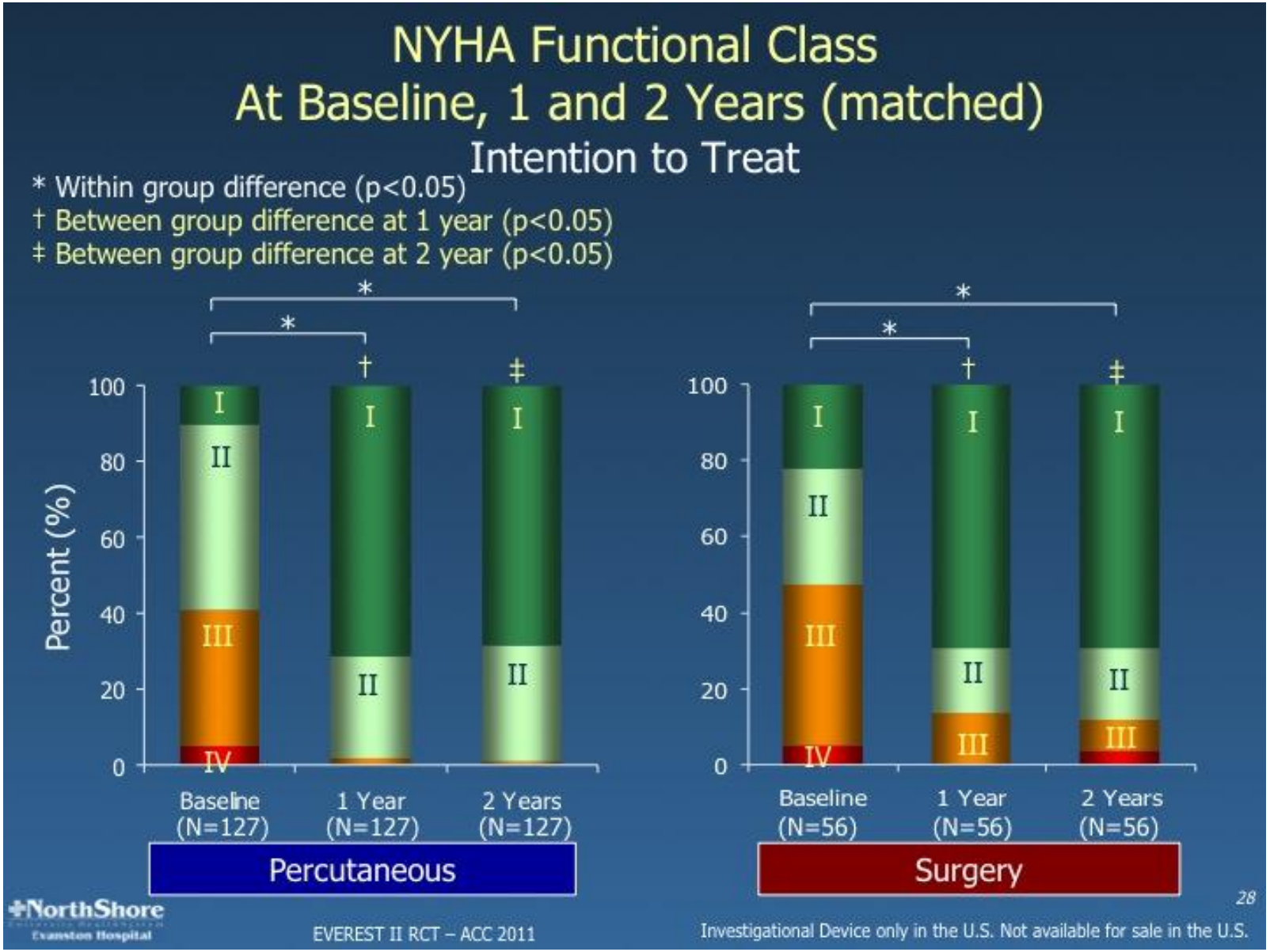
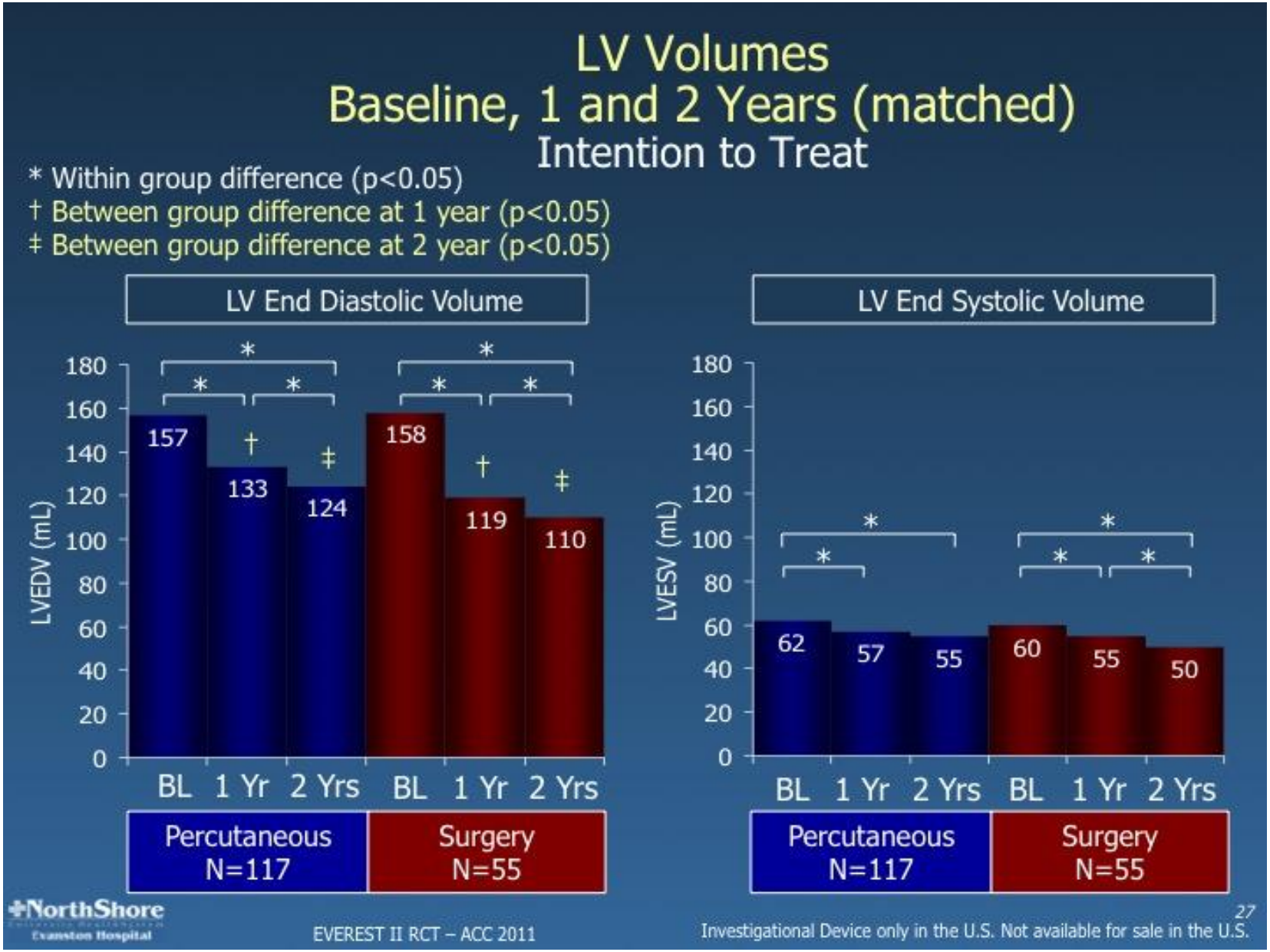
EVEREST II


NYHA Functional Class
At Baseline, 1 and 2 Years (matched)
Intention to Treat
* Within group difference (p<0.05)
† Between group difference at 1 year (p<0.05)
‡ Between group difference at 2 year (p<0.05)
Percent (%)
100
80
60
40
20
0
I
II
III
IV
Baseline (N=127)
1 Year (N=127)
2 Years (N=127)
Percutaneous
Baseline (N=56)
1 Year (N=56)
2 Years (N=56)
Surgery
NorthShore
Evanston Hospital
EVEREST II RCT – ACC 2011
28
Investigational Device only in the U.S. Not available for sale in the U.S.

EVEREST II


LV Volumes
Baseline, 1 and 2 Years (matched)
Intention to Treat
* Within group difference (p<0.05)
† Between group difference at 1 year (p<0.05)
‡ Between group difference at 2 year (p<0.05)
LV End Diastolic Volume
LVEDV (mL)
180
160
140
120
100
80
60
40
20
0
157
133
124
158
119
110
BL 1 Yr 2 Yrs BL 1 Yr 2 Yrs
Percutaneous N=117
Surgery N=55
LV End Systolic Volume
LVESV (mL)
62
57
55
60
55
50
BL 1 Yr 2 Yrs BL 1 Yr 2 Yrs
Percutaneous N=117
Surgery N=55
NorthShore
Evanston Hospital
EVEREST II RCT – ACC 2011
27
Investigational Device only in the U.S. Not available for sale in the U.S.

Many unexperienced Centers in the EVEREST trial

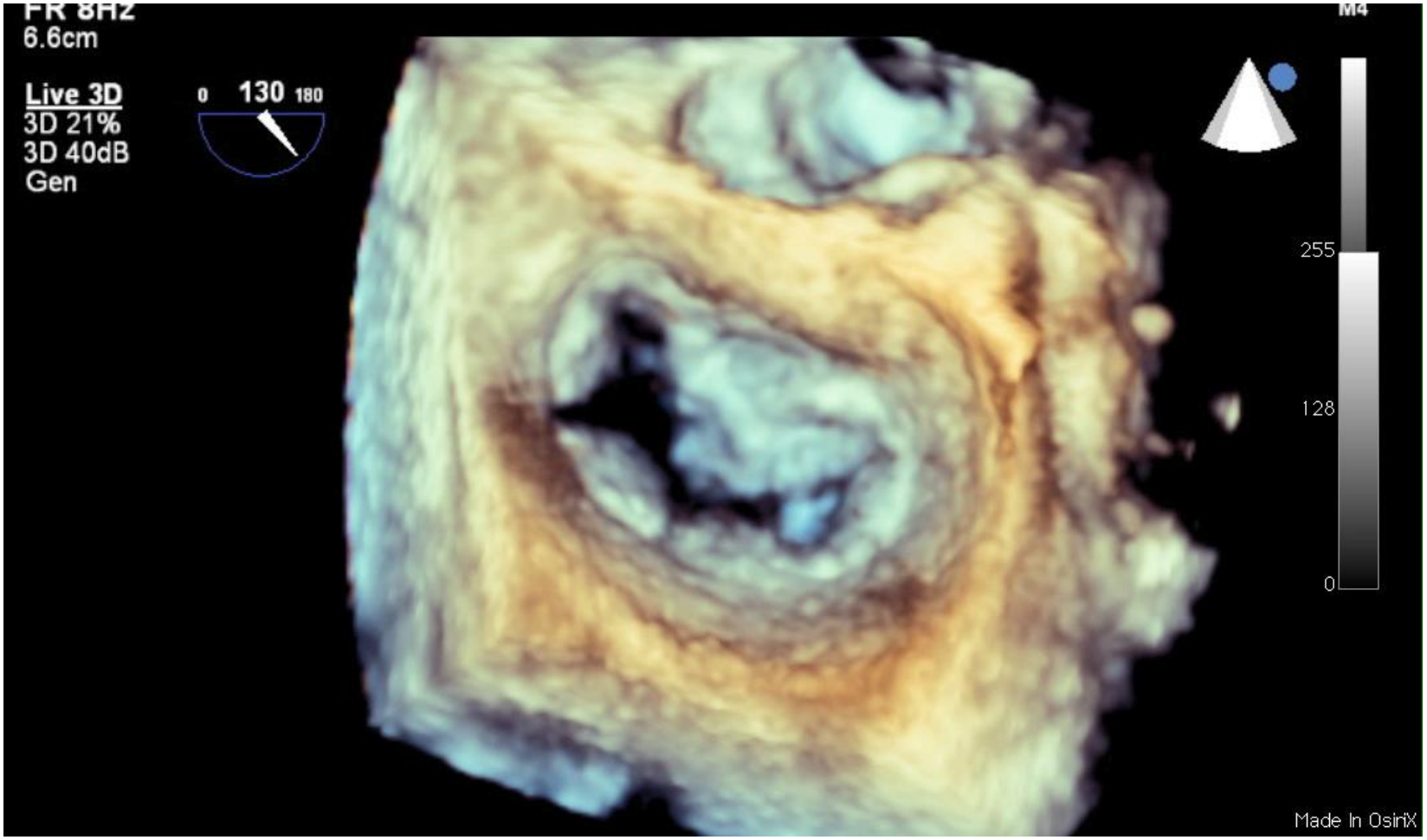
- A. Good result expected (curative treatment expected)

- B. Most likely reasonable result expected with expected clinical benefit (possibly curative)

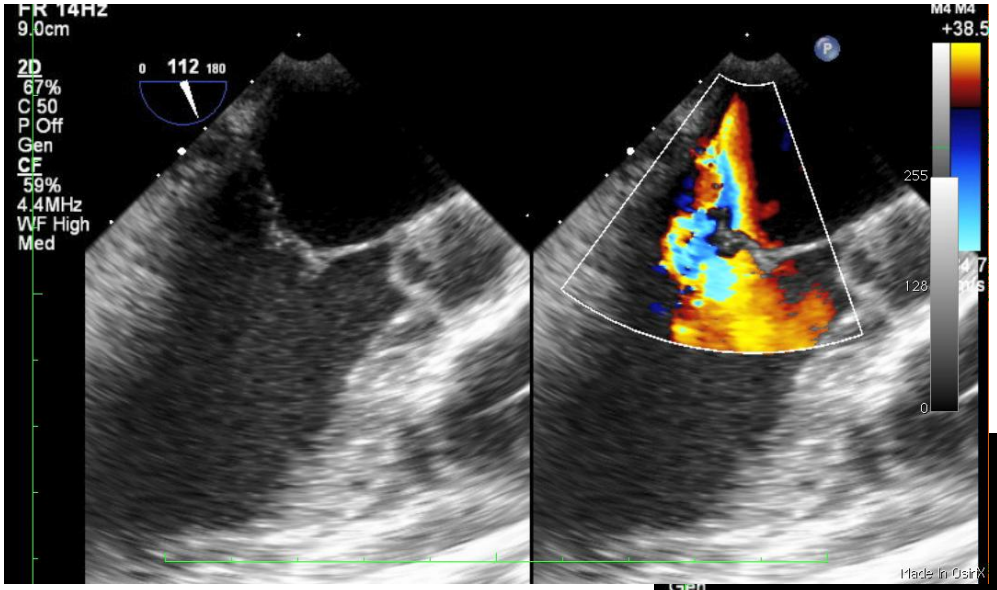
- C. Certain reduction expected with uncertain clinical benefit and durablilty (expected
- D. Unsuitble valve


2cm
75
165
45/min

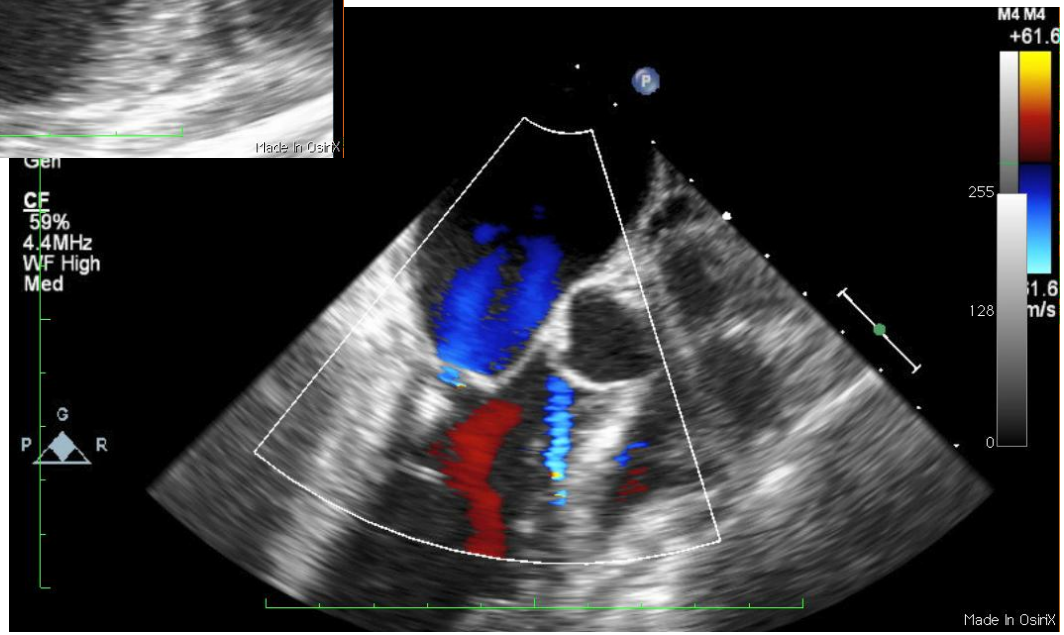
Non-central pathology

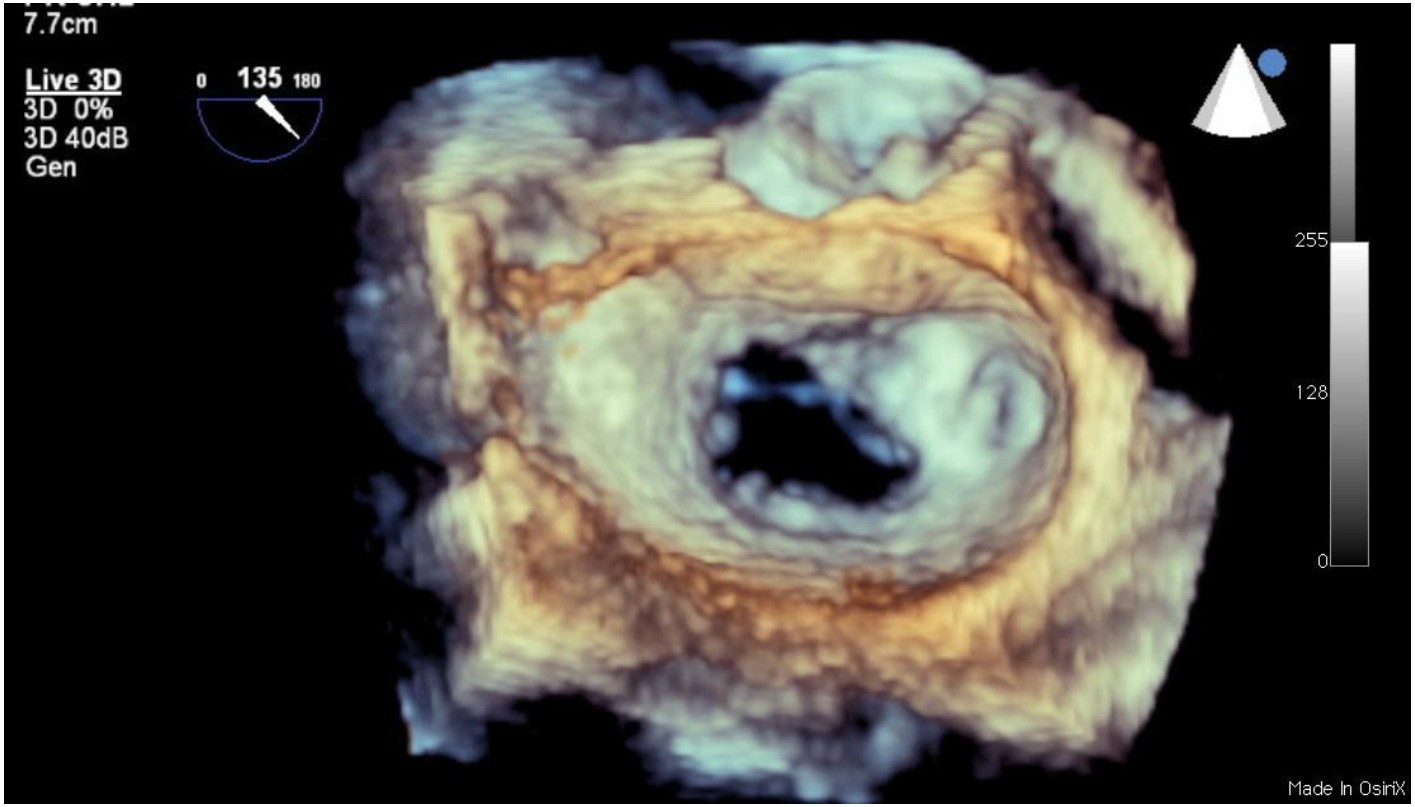


Before

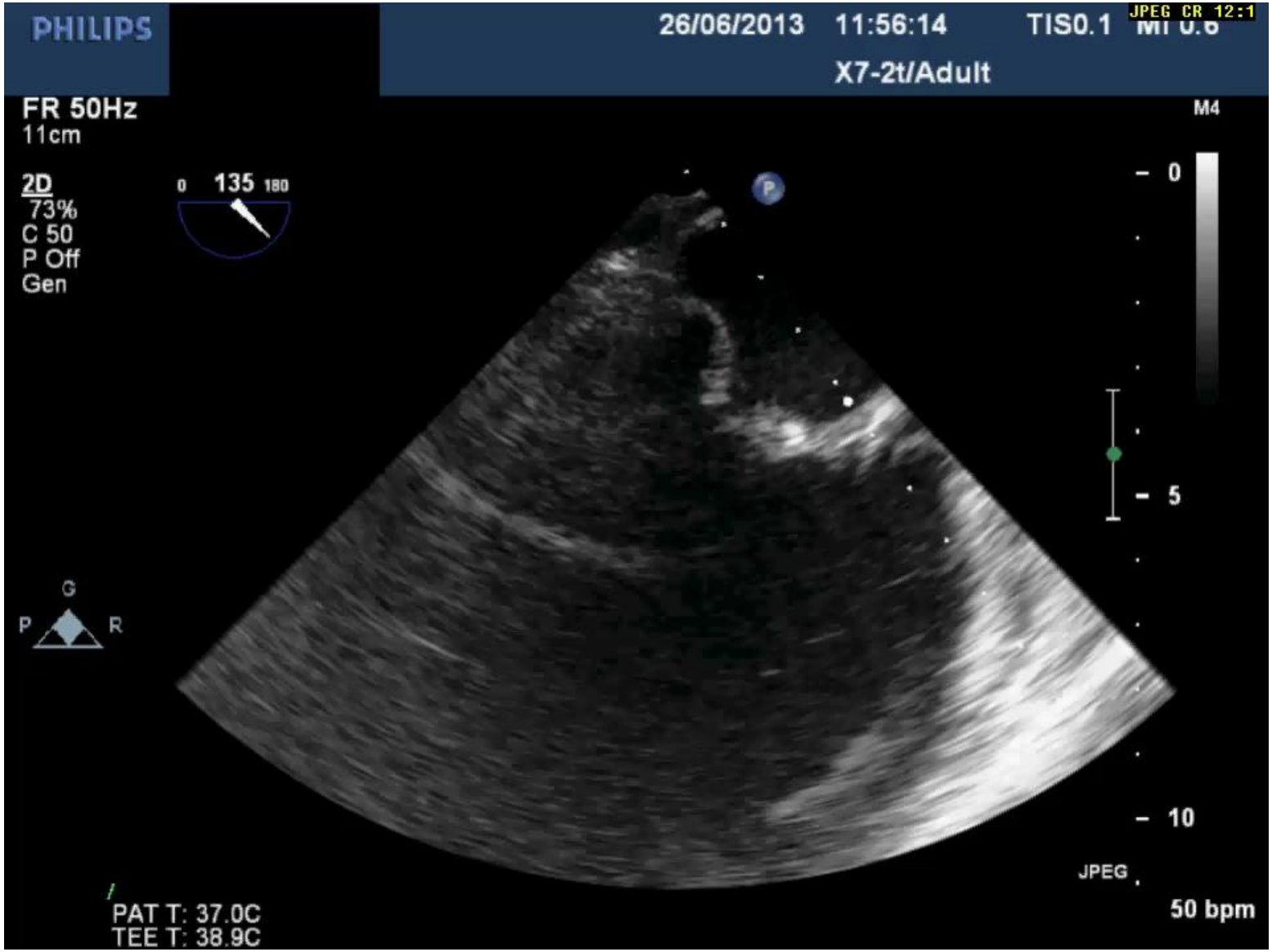


After




7.7cm
Live 3D
3D 0%
3D 40dB
Gen
0
135
180
255
128
0
Made In OsiriX

Flail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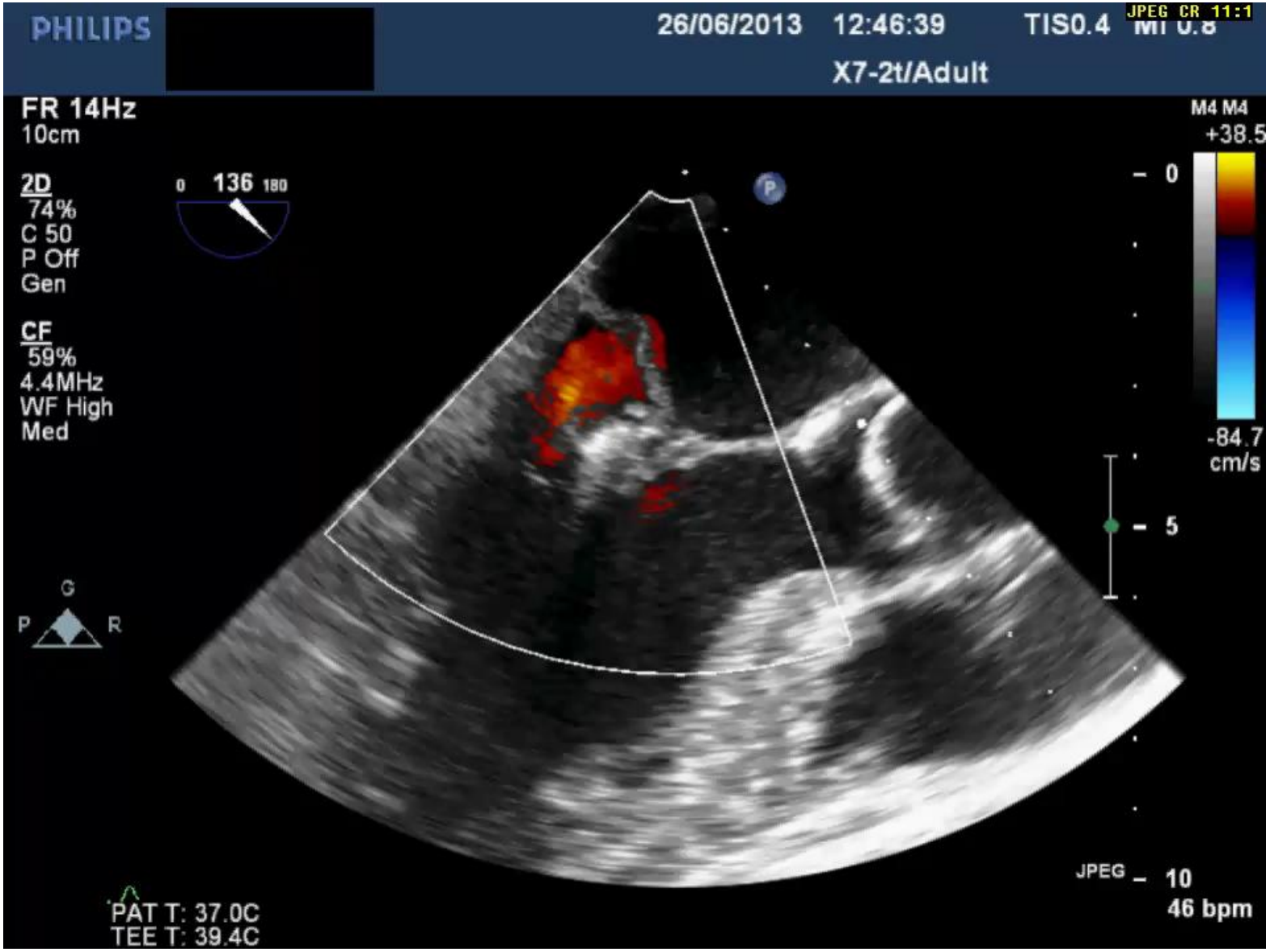
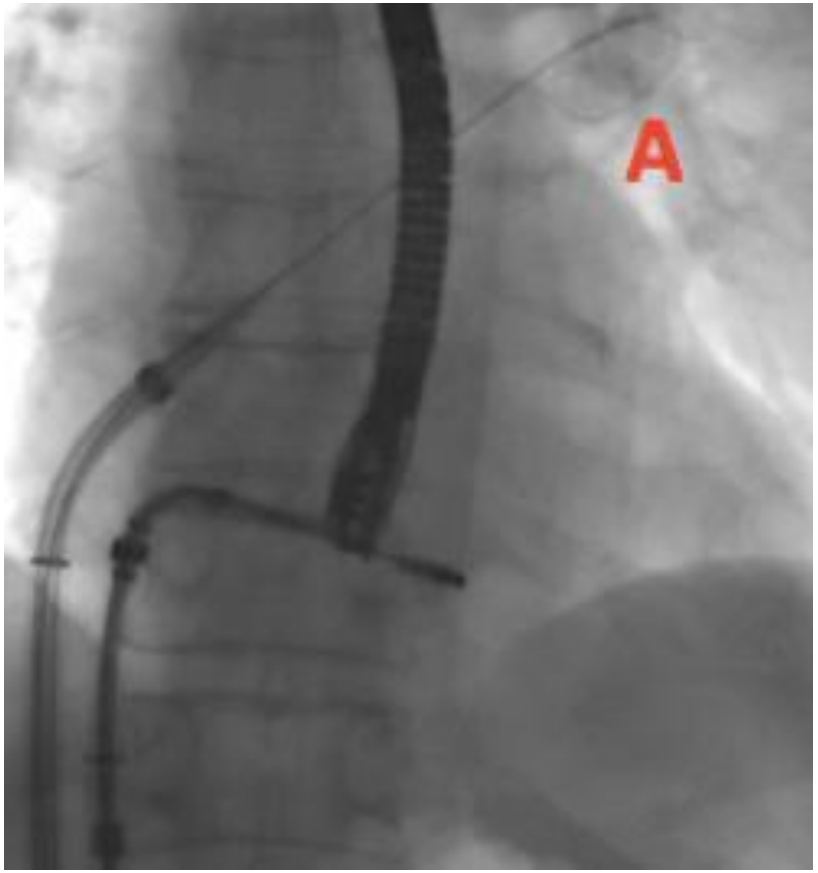
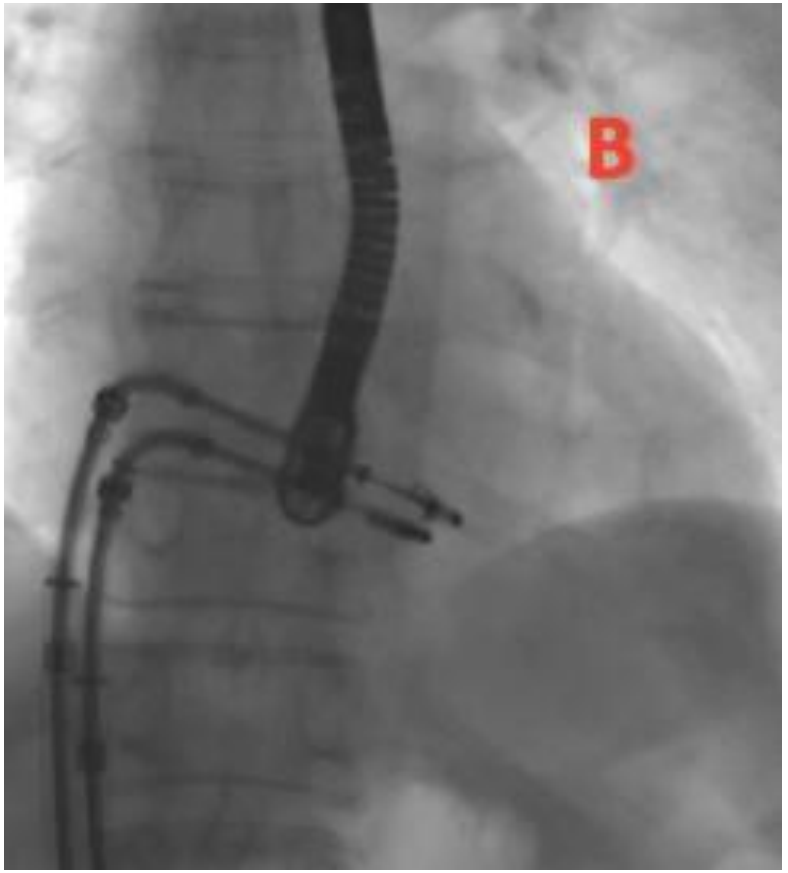
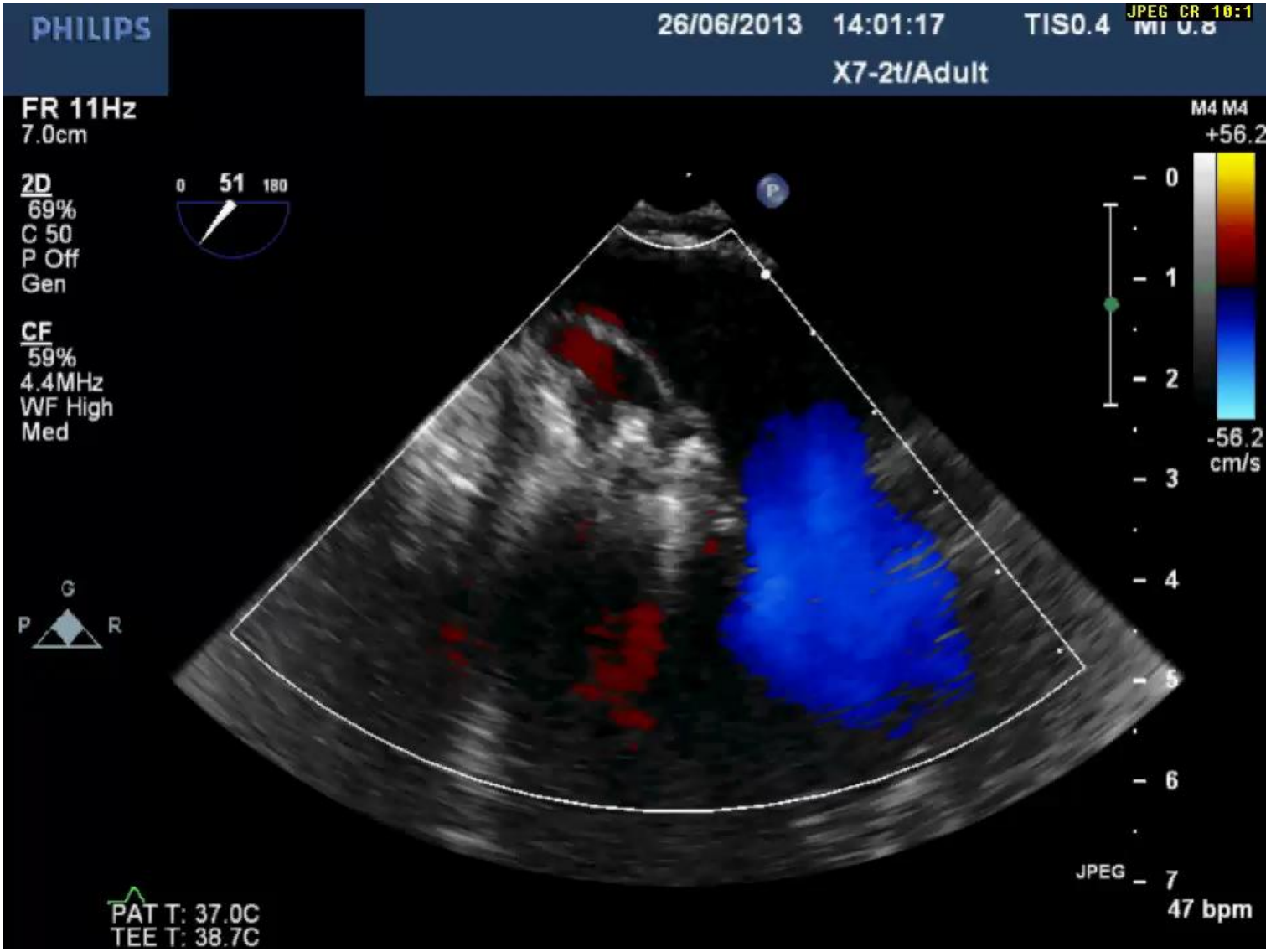
26/06/2013 11:56:14 TIS0.1
JPEG CR 12:1
X7-2t/Adult
FR 50Hz
11cm
2D
73%
C 50
P Off
Gen
0 135 180
M4
0
5
10
G
P
R
JPEG
PAT T: 37.0C
TEE T: 38.9C
50 bpm


PHILIPS
26/06/2013 12:46:39 TIS0.4
JPEG CR 11:1
X7-2t/Adult
FR 14Hz
10cm
2D
74%
C 50
P Off
Gen
CF
59%
4.4MHz
WF High
Med
0 136 180
M4 M4
+38.5
-84.7
cm/s
0
5
10
G
P
R
JPEG
46 bpm
PAT T: 37.0C
TEE T: 39.4C


A


B


PHILIPS
26/06/2013 14:01:17 TIS0.4
JPEG CR 10:1
X7-2t/Adult
FR 11Hz
7.0cm
2D
69%
C 50
P Off
Gen
CF
59%
4.4MHz
WF High
Med
0 51 180
M4 M4
+56.2
-56.2
cm/s
0
1
2
3
4
5
6
7
G
P
R
JPEG
47 bpm
PAT T: 37.0C
TEE T: 38.7C

Clinical outcomes through 12 months in patients with degenerative mitral regurgitation treated with the MitraClip® device in the ACCESS-EUrope Phase I trial[†]

Hermann Reichenspurner[a,*], Wolfgang Schillinger[b], Stephan Baldus[c], Jörg Hausleiter[d], Christian Butter[e], Ulrich Schäefer[f], Giovanni Pedrazzini[g], Francesco Maisano[h], on behalf of the ACCESS-EU Phase I Investigators

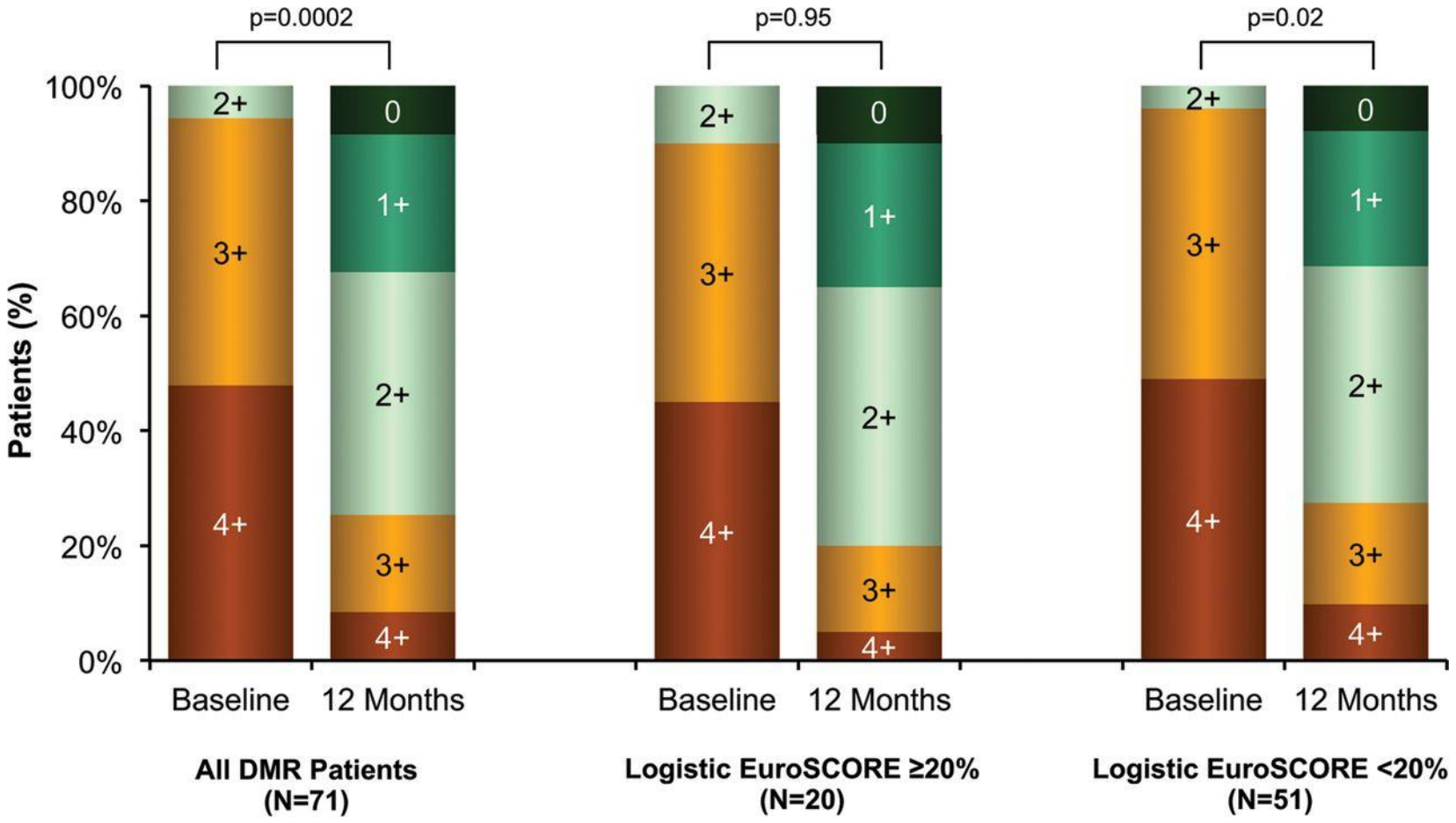
Patient Population

Characteristic[a]	DMR patients (*N* = 117)
Age (years)	
Mean ± SD (*N*)	75.6 ± 12.1 (117)
Patients over 75 years of age	61.5% (72/117)
Gender	
Female	50.4% (59/117)
Male	49.6% (58/117)

Major Findings

- 94,5 % success rate
- *56,6 % (60/1006) of pts had MR* ≤1+ at discharge
- 84/107 had a Euroscore < 20 8,6 ± 5,1
  - 30 day mortality in this group : 4,8 %
  - 12 month mortality in this : 14,3 %

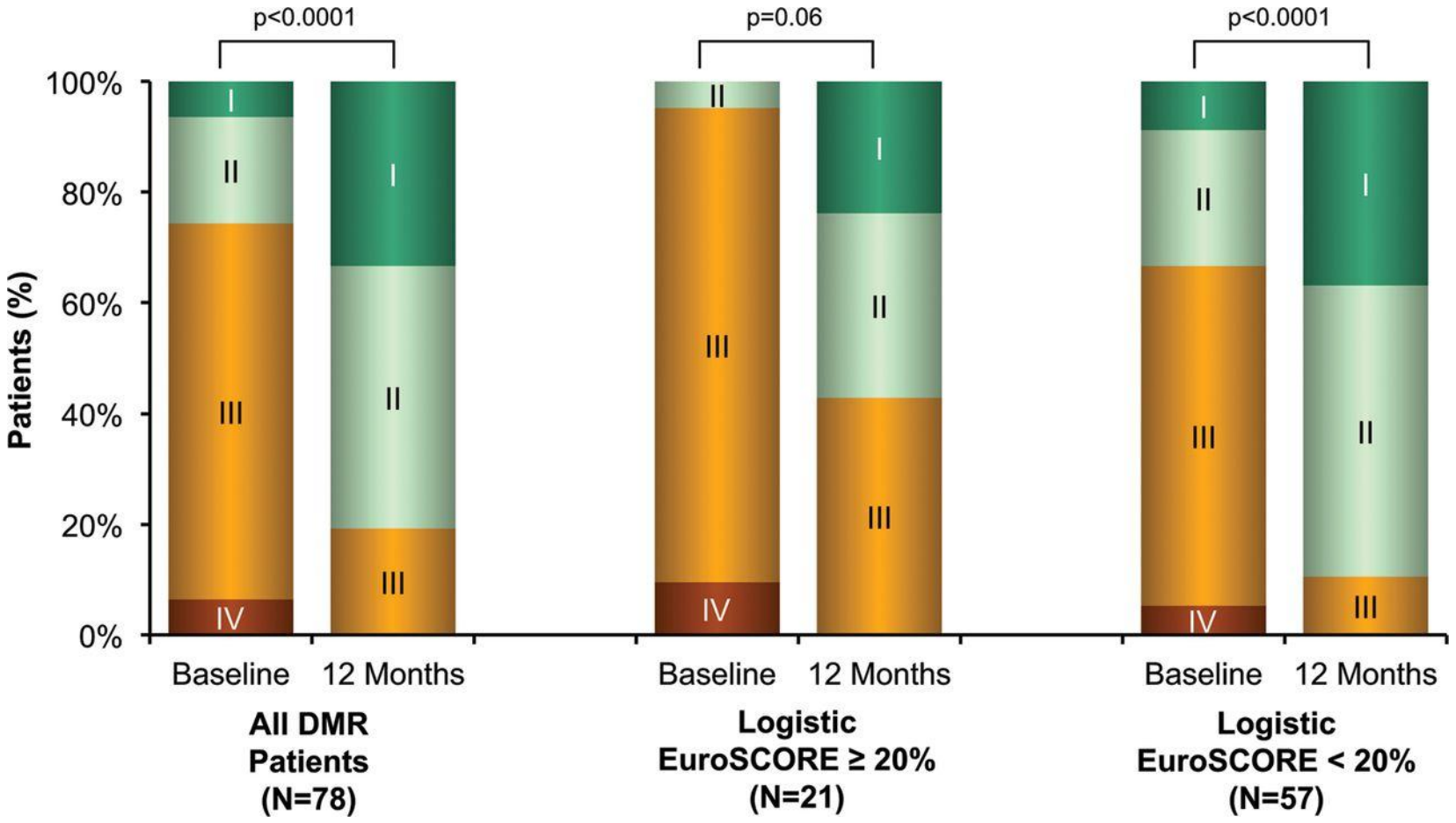
Mitral regurgitation at baseline and 12 months (paired data).



Reichenspurner H et al. Eur J Cardiothorac Surg 2013;44:e280-e288

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

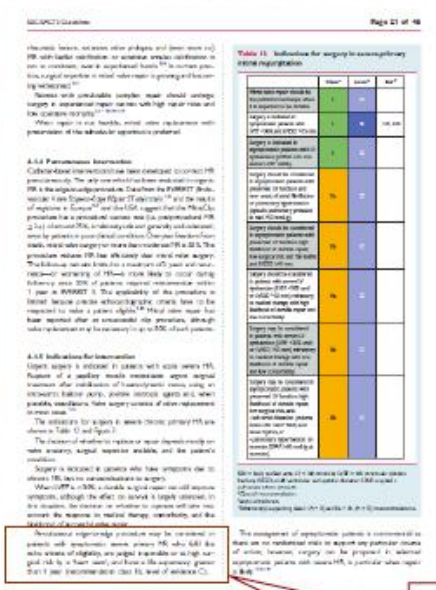
New York Heart Association Functional Class at baseline and 12 months (paired data).



Reichenspurner H et al. Eur J Cardiothorac Surg 2013;44:e280-e288

EUROPEAN JOURNAL OF CARDIO-THORACIC SURGERY

Percutaneous edge-to-edge repair in ESC/EACTS 2012 Guidelines on the management of valvular heart disease



Indication for primary MR

"Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary MR who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a 'heart team', and have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C)."

page 21

Source: http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/valvular-heart-disease.asp

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109
European Journal of Cardio-Thoracic Surgery 2012 - doi:10.1093/ejcts/ezs455

www.escardio.org/guidelines

EACTS

EUROPEAN SOCIETY OF CARDIOLOGY®

Conclusions

- Mitraclip is mostly used in an elderly patient population with dMR
- Most of the patients In ACCESS I have a relatively low risk for surgery as measured by EUROSCORE
- MR reduction is reported to be better than in EVEREST II
- Mortality is lower than expected by EUROSCORE
- Its time to predict good results and lower the treshold for treatment in this group