

NEOCHORD

Una tecnica nuova che si affaccia all'impiego clinico. Come è il device, come funziona

Prof Francesco Alamanni



TIMELINE

2009

- 1° in Man

2009-2012

- TACT Trial (n=30)

2012

- CE Mark

2013

- TACT Registry

10/2014

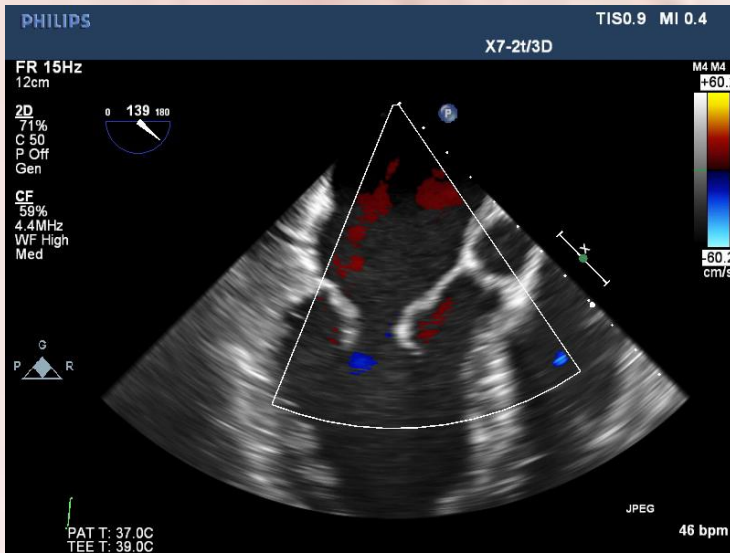
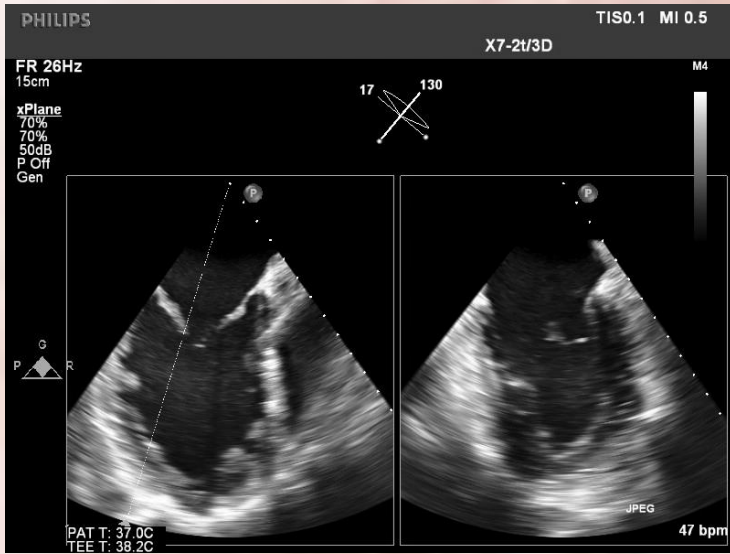
- Experience with 147 pts



NeoChord DS1000 Device



Preoperative Screening (TEE)



Patient Stratification (Anatomical)

Type A “Ideal” Patient:

- Central P2 prolapse
- >8mm predicted coaptation length with repair

Type B “Adequate” Patient:

- Less than 8 mm coaptation length
- Prolapse extending to portions of P1 or P3

Type C “Challenging” Patient:

- Prolapse involving commissures or anterior leaflet
- LV dilatation with tethering of leaflets
- Central regurgitant jet component
- Calcified leaflet segments

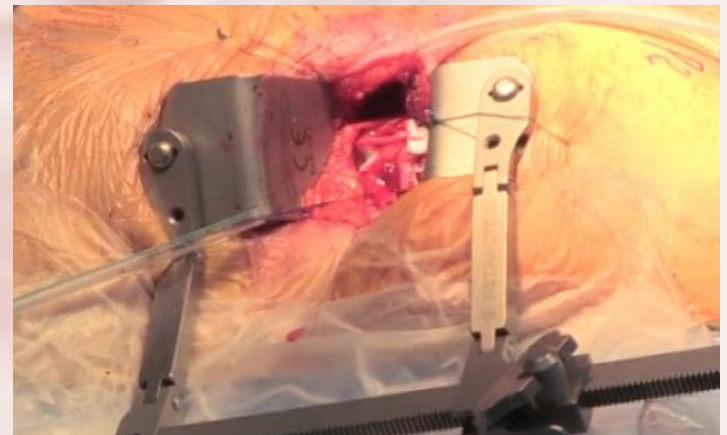


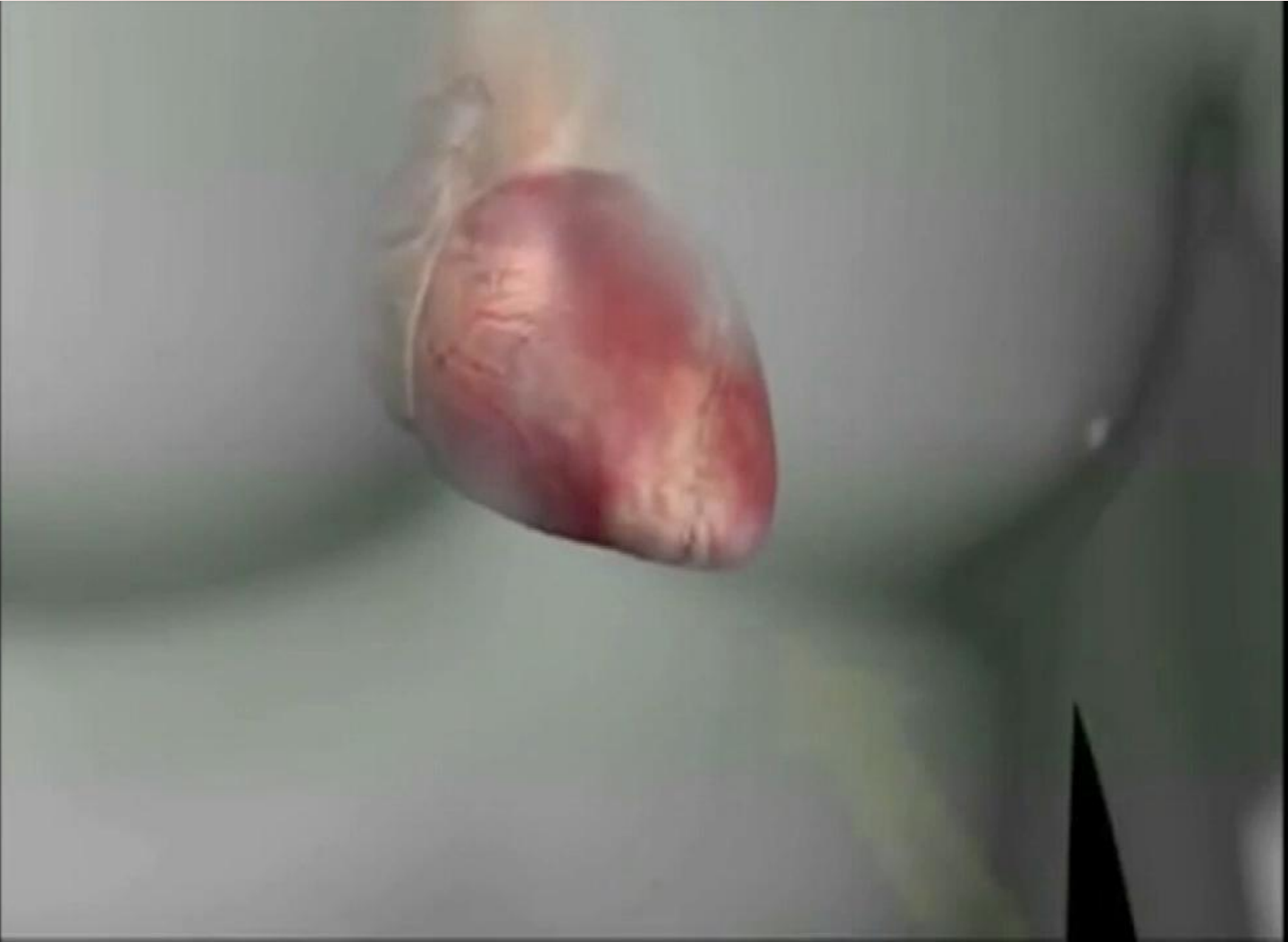
The ideal candidate is a low or moderate risk patient with severe degenerative MR, with prolapse centered around the P2 scallop and good leaflet Coaptation Potential (absolute annular dimensions not important).



Surgical Procedure

- Left minithoracotomy
- Plastic bag to collect blood
- Exposition of the apex by pulling out the pericardium
- Double purse string with pledgets
 - 1-2 cm lateral - posterior
 - Smaller than for TAVI
- **IMAGING and COLLABORATION**





TACT Trial Overview

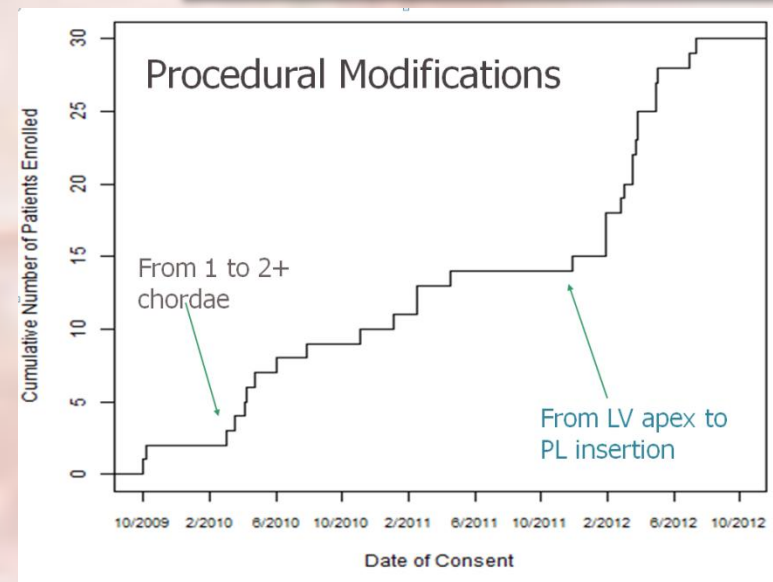
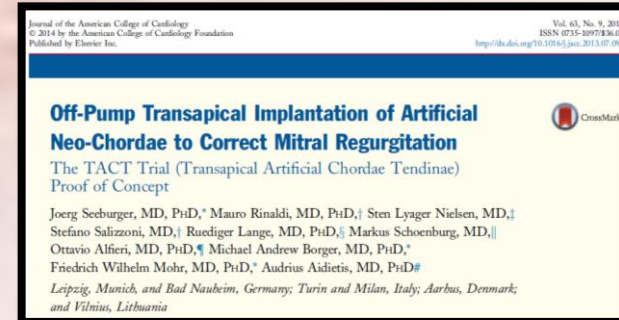
- Multi-Center, Prospective, Single Arm Study
- **30 patients** in Europe
- 1, 6, 12 and 24 month follow-up

Key Inclusion Criteria

- Severe MR \geq Grade 3+
- Isolated posterior prolapse
- Indicated for surgical MV repair

Key Exclusion Criteria

- Functional or ischemic MR
- Severe LV dysfunction: LVEDD >6.5 cm
- Anterior or bi-leaflet prolapse
- Permanent AF



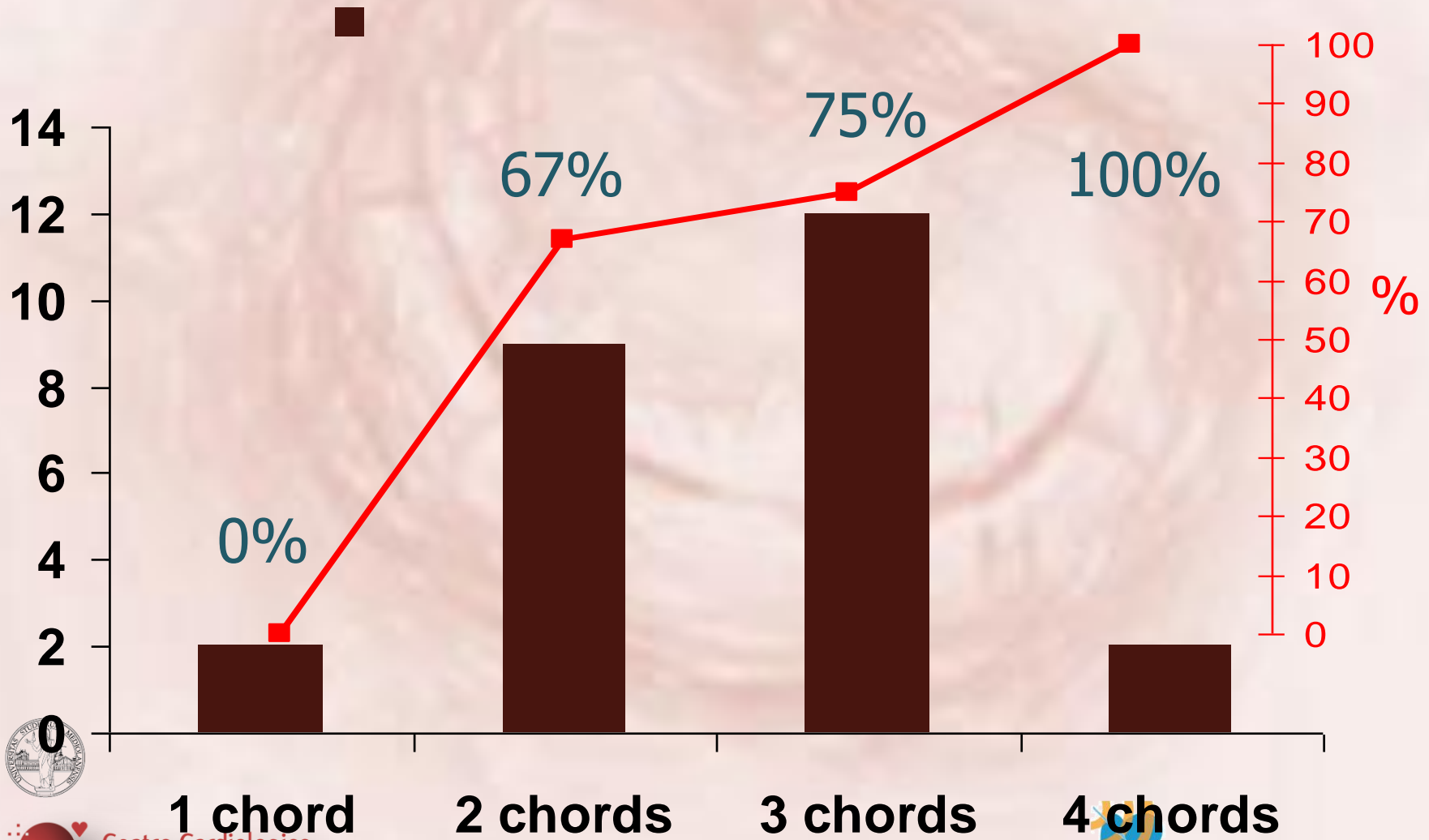
TACT Trial MAEs at 30 days

	Total N=30	Patients 1-15	Patients 16-30
Description of MAE	N(%)	N(%)	N(%)
Death	1 (3.3)	1 (6.7)	0
Reoperation for failed repair	6 (20.0)	5 (33.3)	1 (6.7)
Transfusion of >2 units blood	5 (16.7)	4 (26.7)	1 (6.7)
Procedural ventilation >48 hrs	1 (3.3)	1 (6.7)	0
Stroke	1 (3.3)	1 (6.7)	0
MI	0	0	0
Non-elective surgery	0	0	0
Renal failure	0	0	0
Deep wound infection	0	0	0
New onset of permanent AF	0	0	0
Septicemia	0	0	0
Any MAE*	8 (26.7)	7 (46.7)	1 (6.7)

* Patients can have more than one event; therefore, the total does not equal the sum of the events



30 Day Results Per # of Chordae



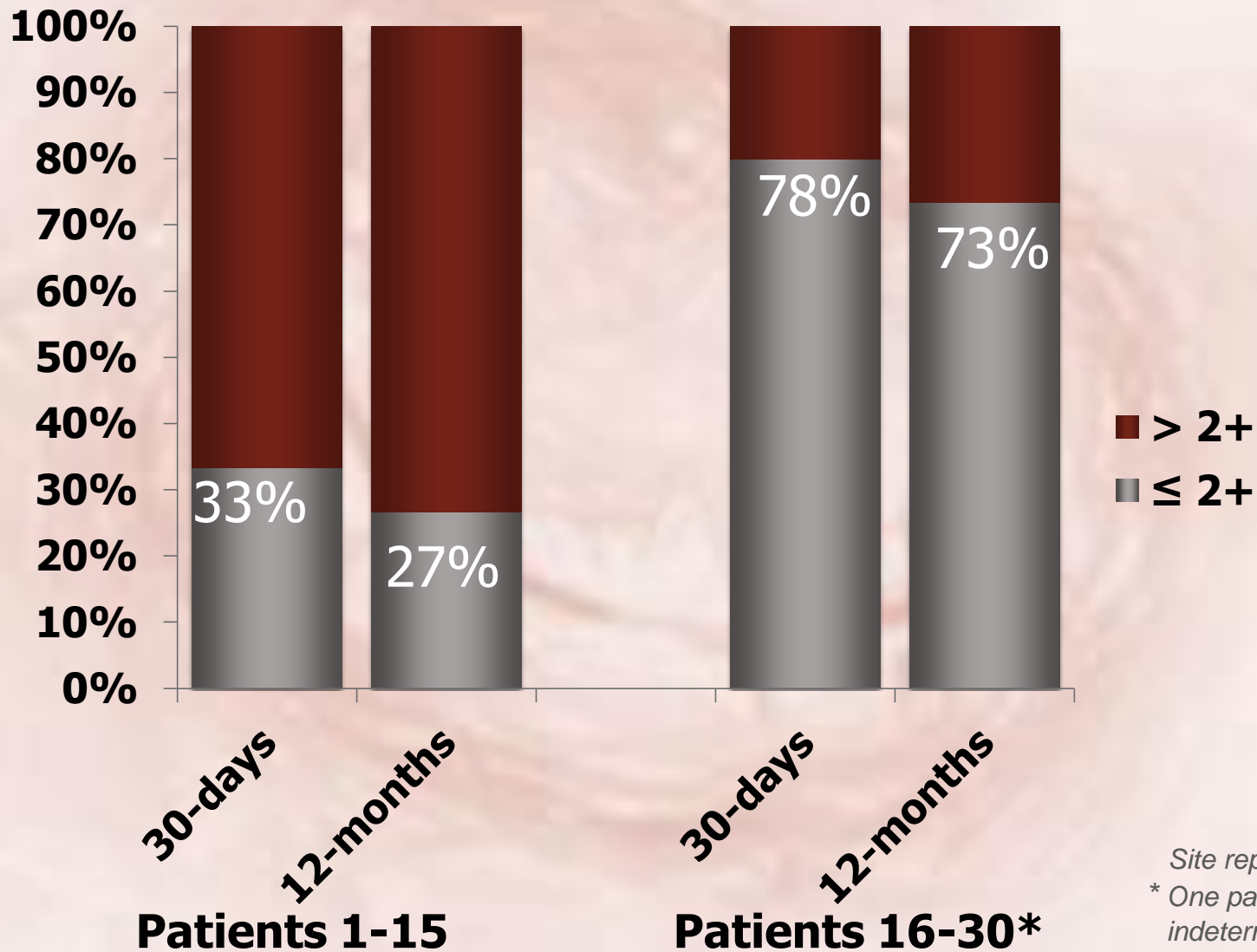
1 chord

2 chords

3 chords

4 chords

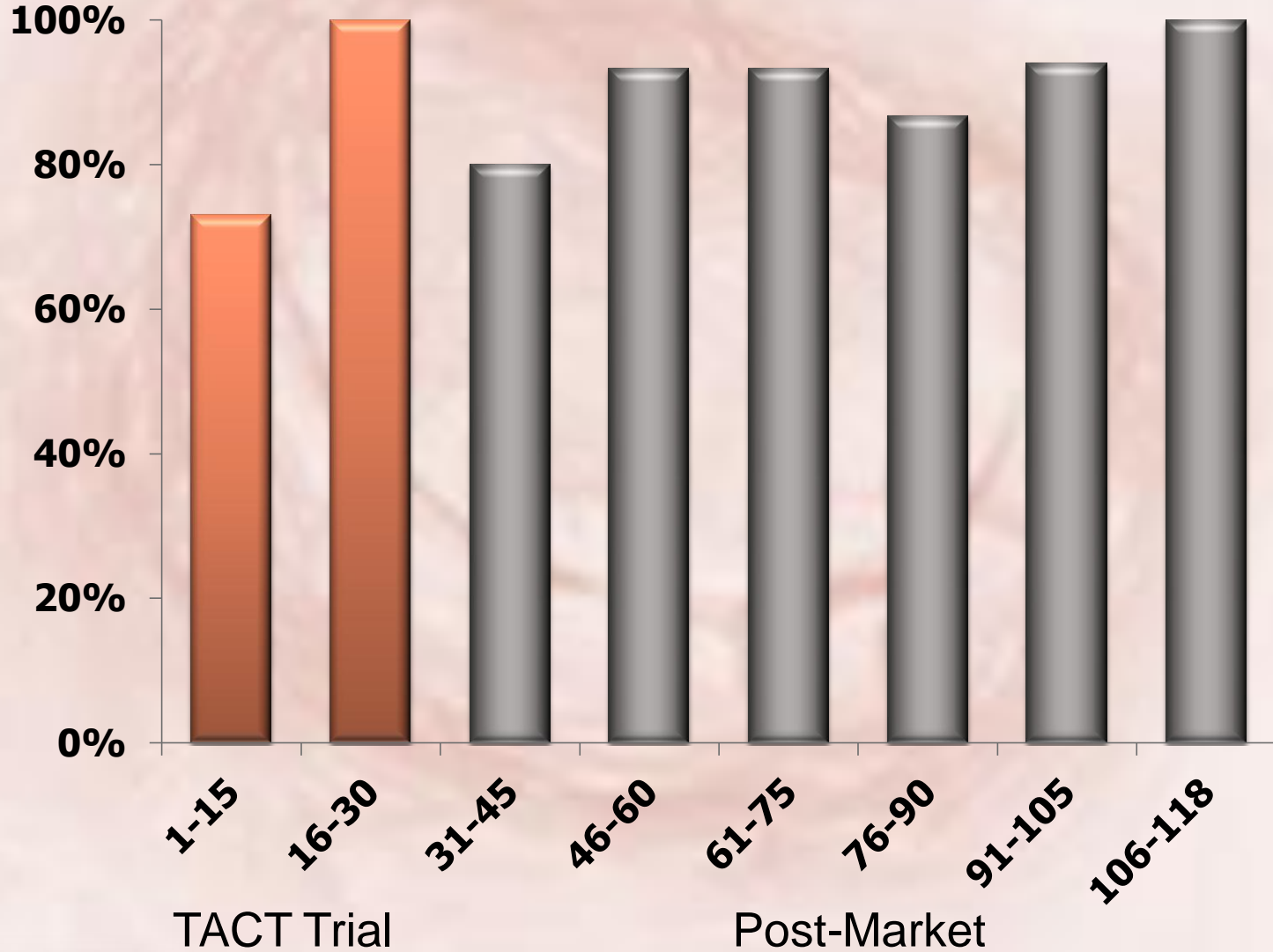
Results Stable Through 12 Months



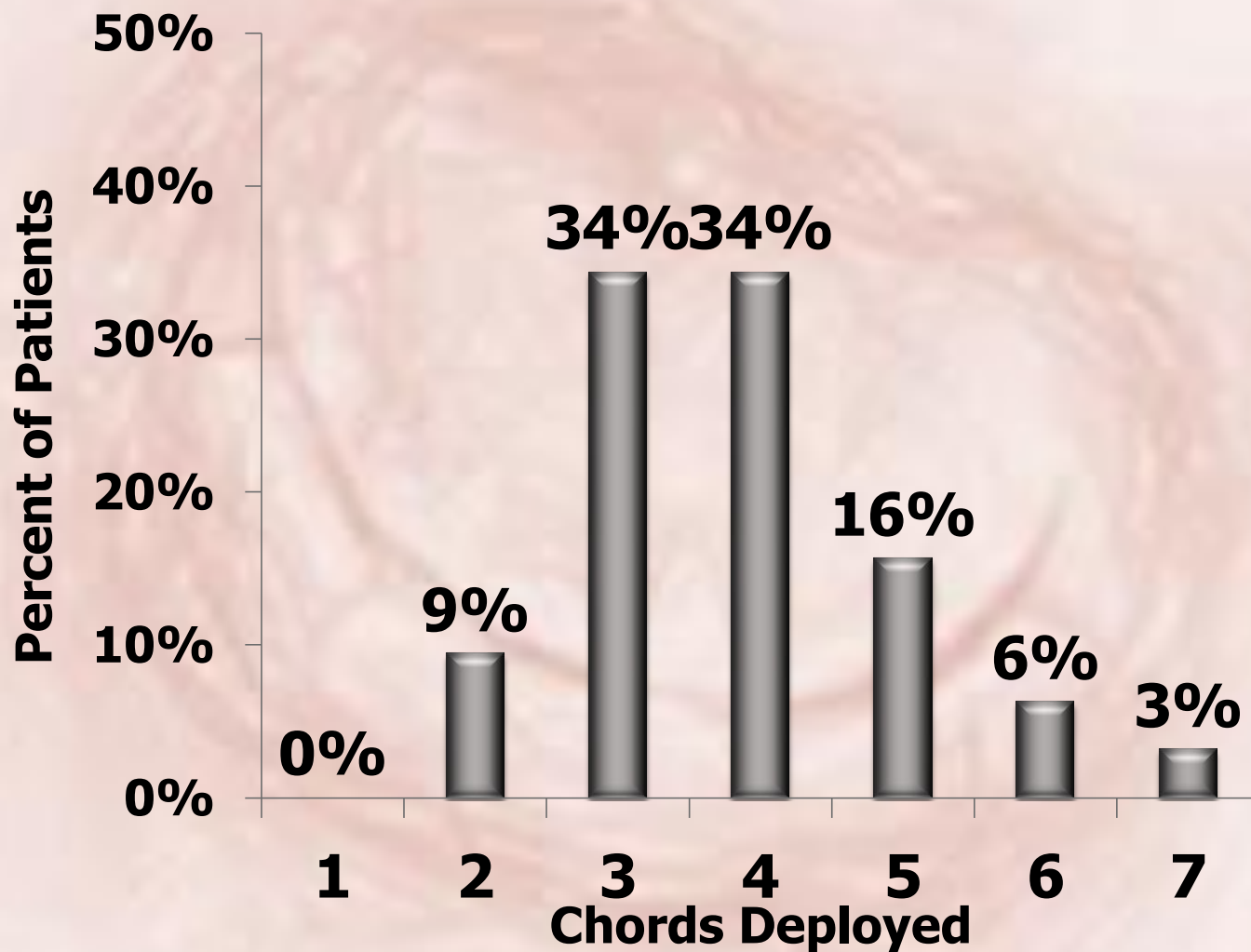
Site reported echo
* One patient with an indeterminate echo at 30 days is not included

Acute Procedure Success (All Pts)

93% Acute Procedure Success* in the Post-Market Setting

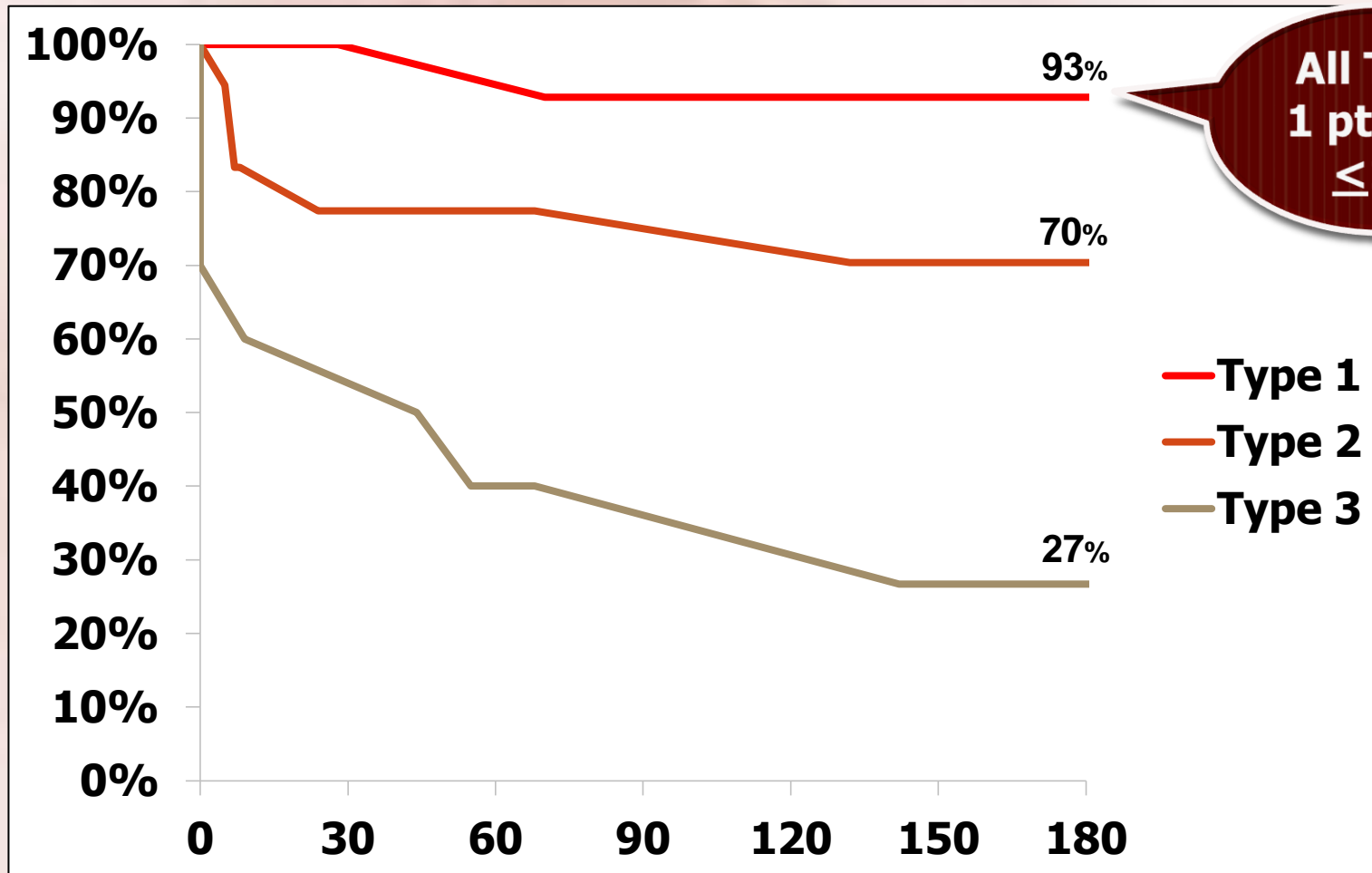


NeoChords per Patient



- Average skin-skin time: 131 ± 31 minutes (min 75, max 220)
- Average time to place chords: 36 ± 22 minutes (min 13, max 121)

Freedom From MR >2 By Pt Type



Reasons for Recurrency of MR

- NeoChord Dehiscence
 - Historically main concern
 - Greatly reduced since multiple Neochords and postero-lateral entry site
 - Now in about 25% of recurrences
- NeoChord elongation (50% of recurrences)
 - Reverse remodeling?
 - LV Apical fixation issue?
- Anterior Leaflet flail (25%)
 - Interference between NeoChords and native chordae



Conclusion

Procedure with a "limited" learning curve

High risk patients are prone to be treated

Early results are encouraging especially if anatomical criteria predict a correct coaptation height following the repair

