

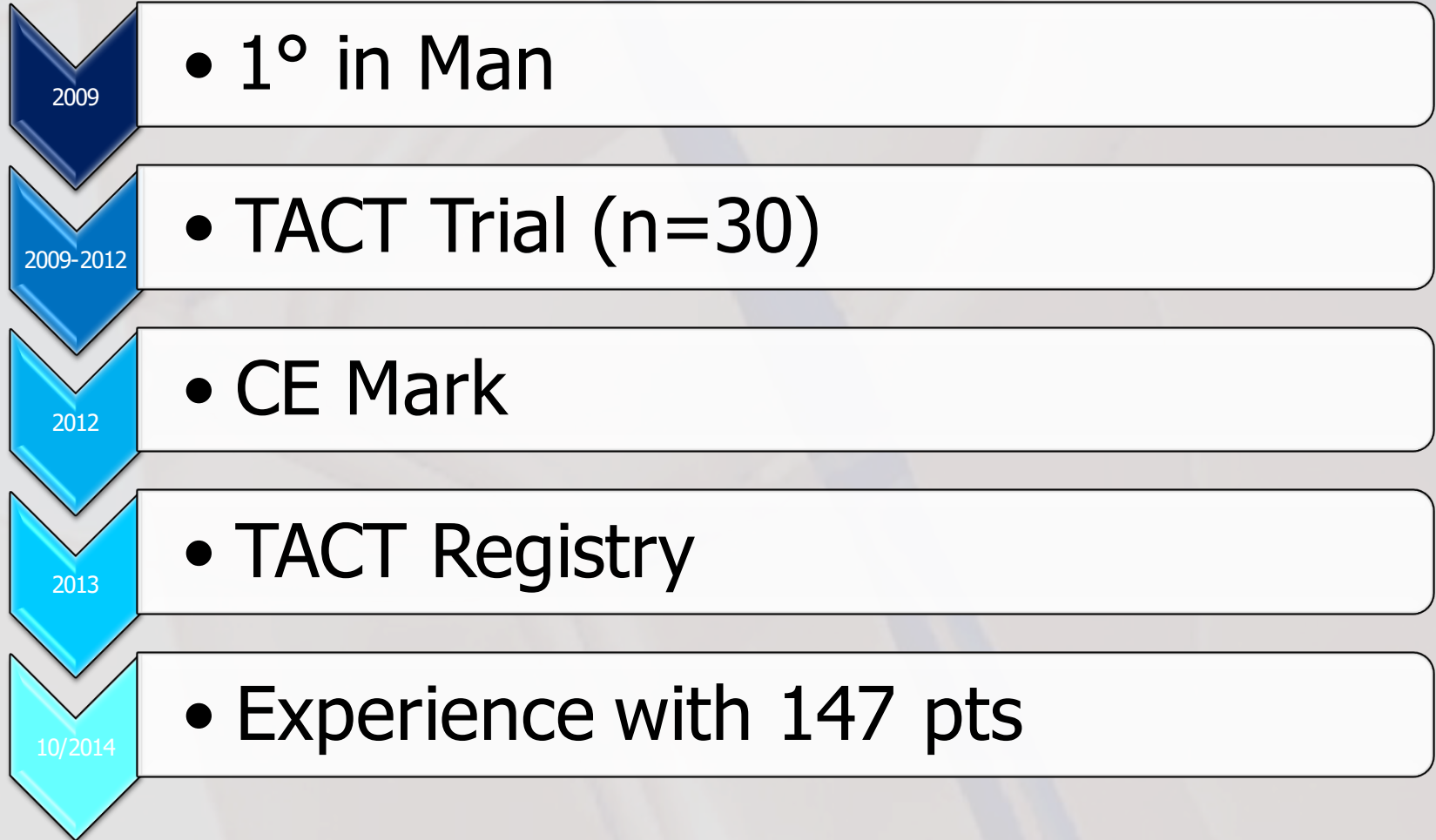
Francesco Alamanni MD

NEOCHORD

NeoChord is a medical device which allows a less-invasive mitral valve repair to be performed on a beating heart through a 2- to 3-inch incision between the ribs in patients with severe mitral valve regurgitation (“MR”).



TIMELINE



Current activity: 360+ cases

- **ITALY 155** (Torino, Milano, Brescia, Padova, Reggio Emilia, Bologna, Rapallo, Roma, Palermo, Bari,)
- **LITHUANIA 75** (Vilnius)
- **GERMANY 51** (Frankfurt, Leipzig, Trier, Goettingen, Duisburg, Munich, Hamburg, Dresden, Cologne)
- **TURKEY 27** (Ankara, Antalya, Istanbul area)
- **FRANCE 17** (Bordeaux, Lyon)
- **FINLAND 9** (Helsinki, Turku)

- **OTHER COUNTRIES: LATVIA, POLAND, BELGIUM, SWITZERLAND, CANADA, NETHERLANDS, AUSTRIA (1-8 cases each)**

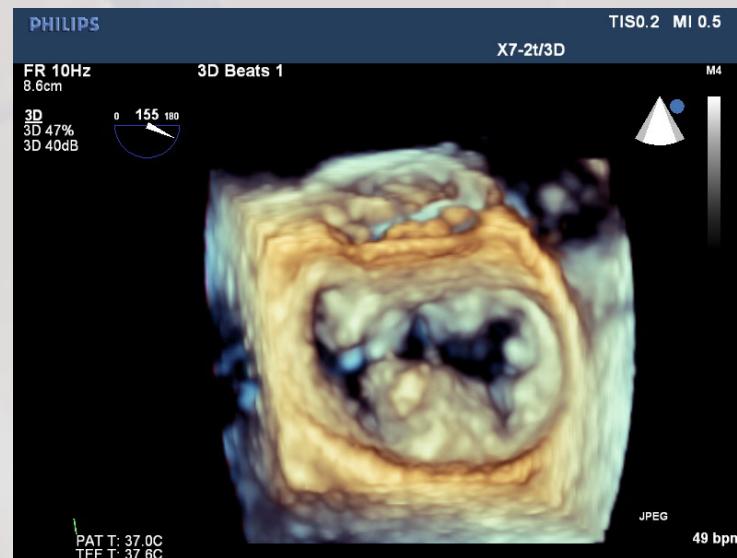
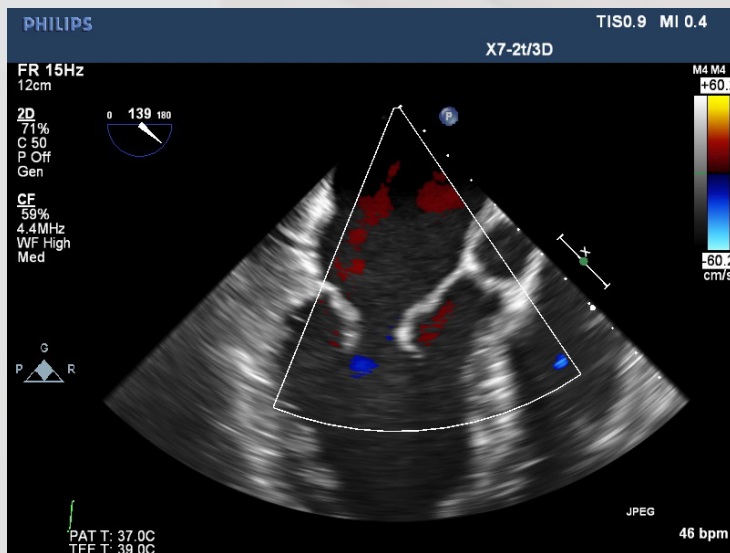
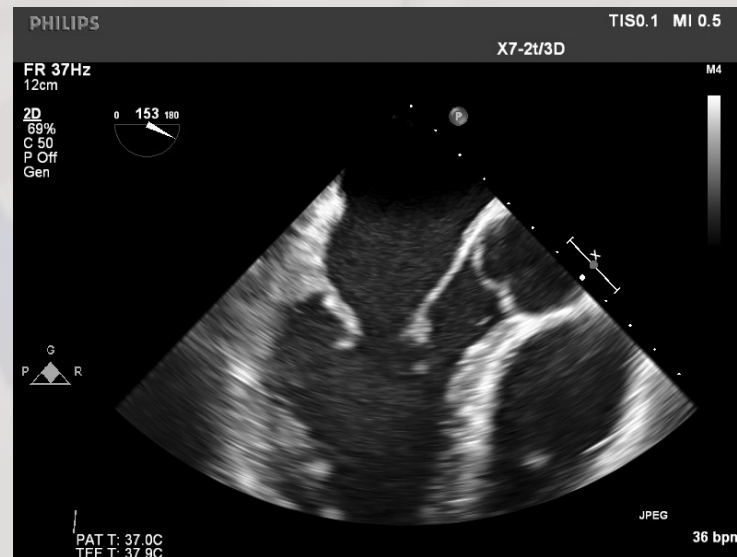
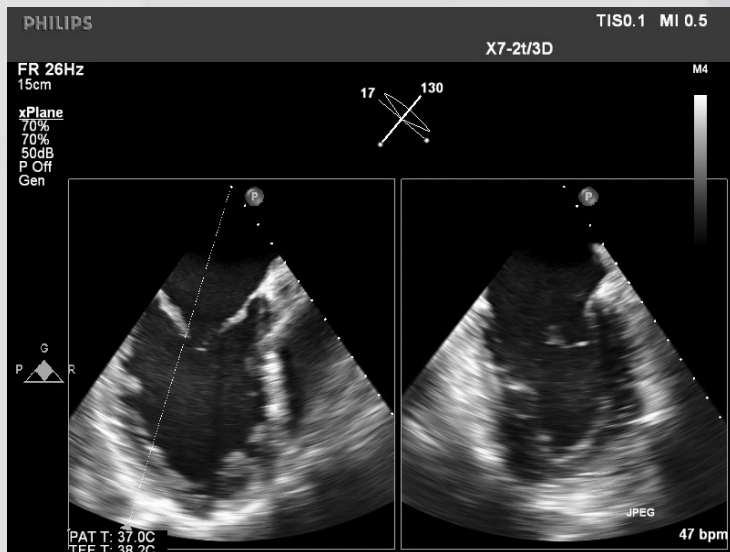
The NeoChord DS1000 System is CE Marked and approved for sale in Europe.

Attention: In the United States, the NeoChord device is not available for commercial use

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**

Ideal Candidate

Actually we operated 21 patients: low or moderate risk patient with severe degenerative MR, mostly with prolapse centered around the P2 scallop and good leaflet Coaptation Potential (absolute annular dimensions not important).

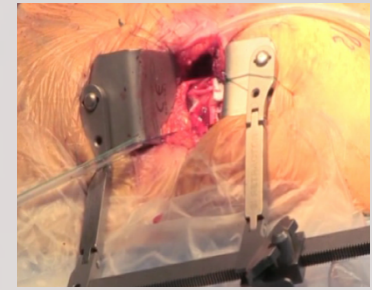
Surgical Procedure



❖ **Left minithoracotomy**

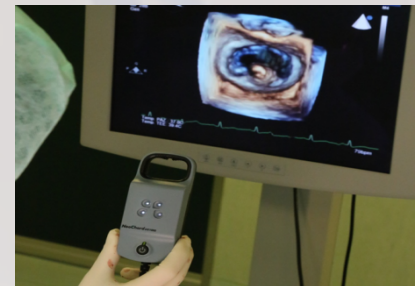
❖ **Exposition of the apex by pulling out the pericardium**

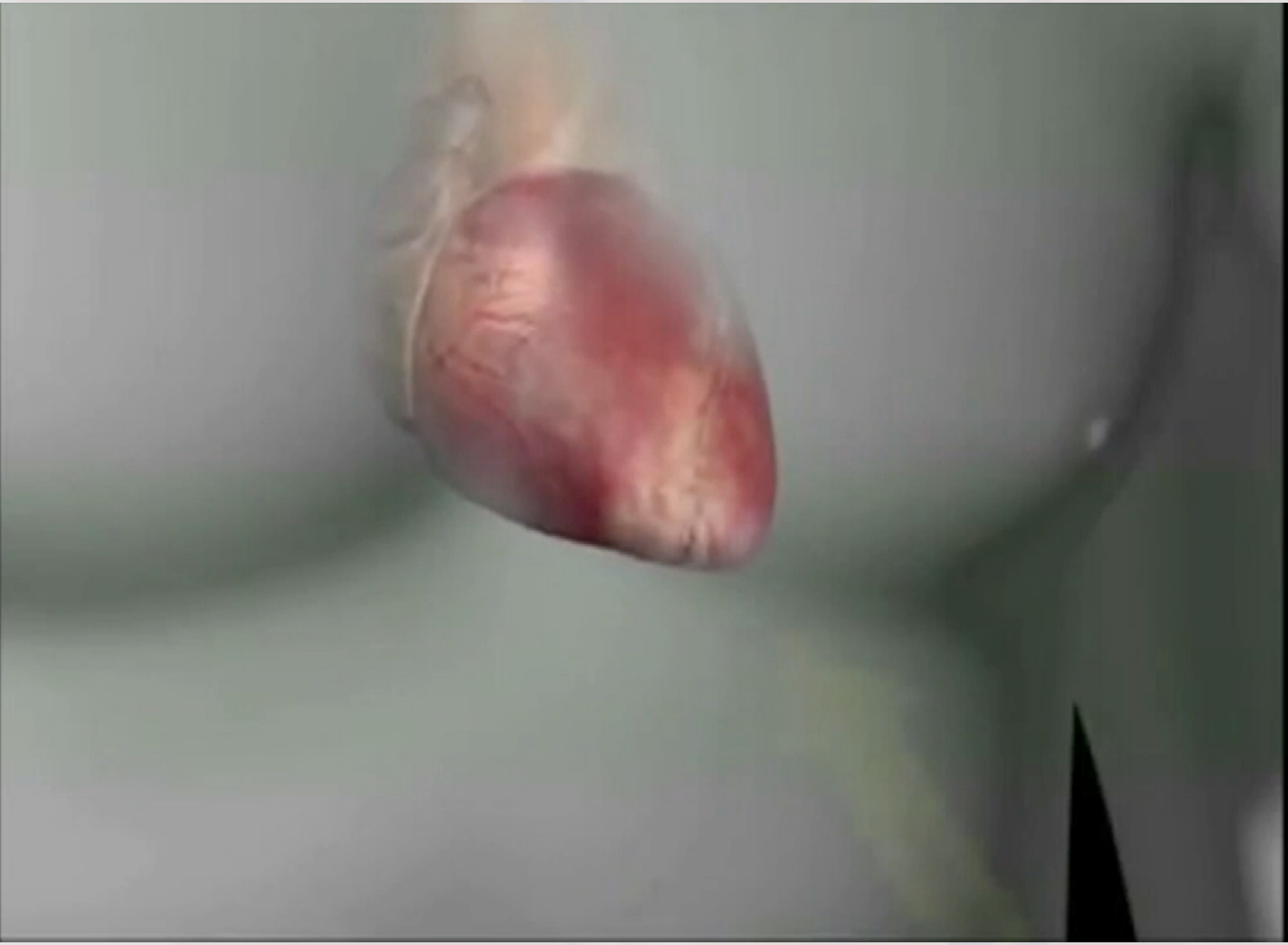
❖ **Plastic bag to collect blood**



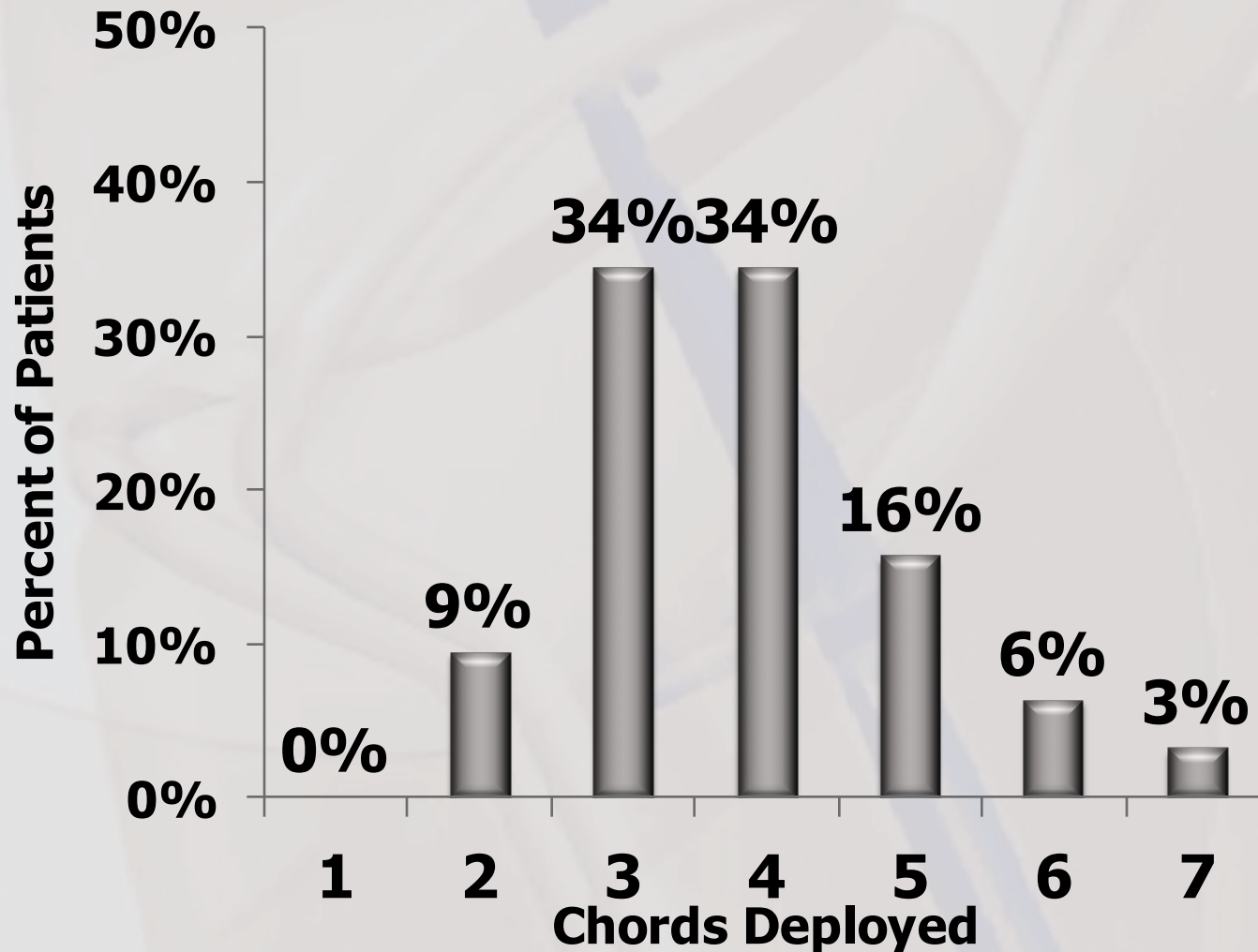
❖ **Double purse string with pledgets 1-2 cm lateral – posterior (smaller than for TAVI)**

❖ **IMAGING and COLLABORATION**

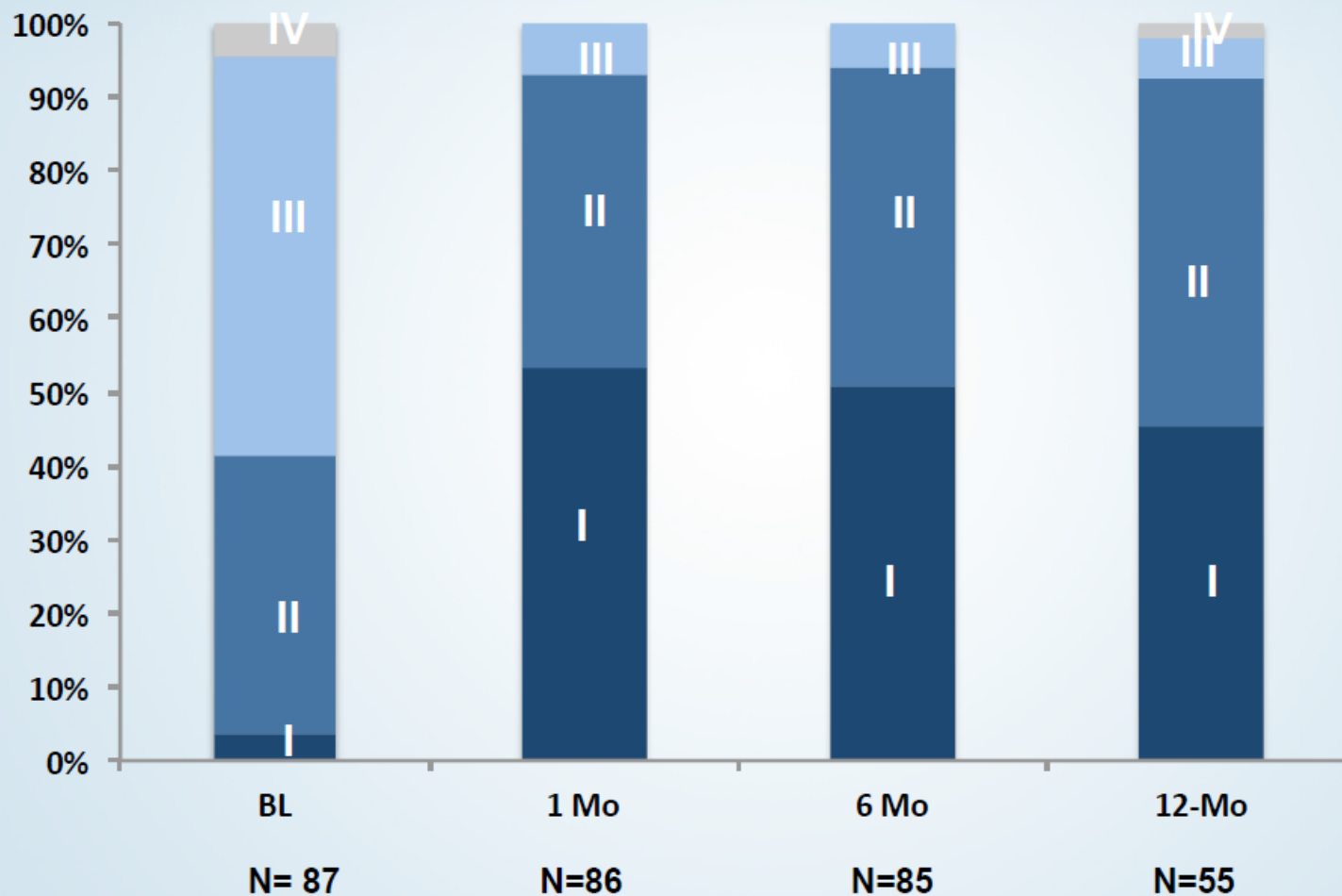




NeoChords per Patient



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



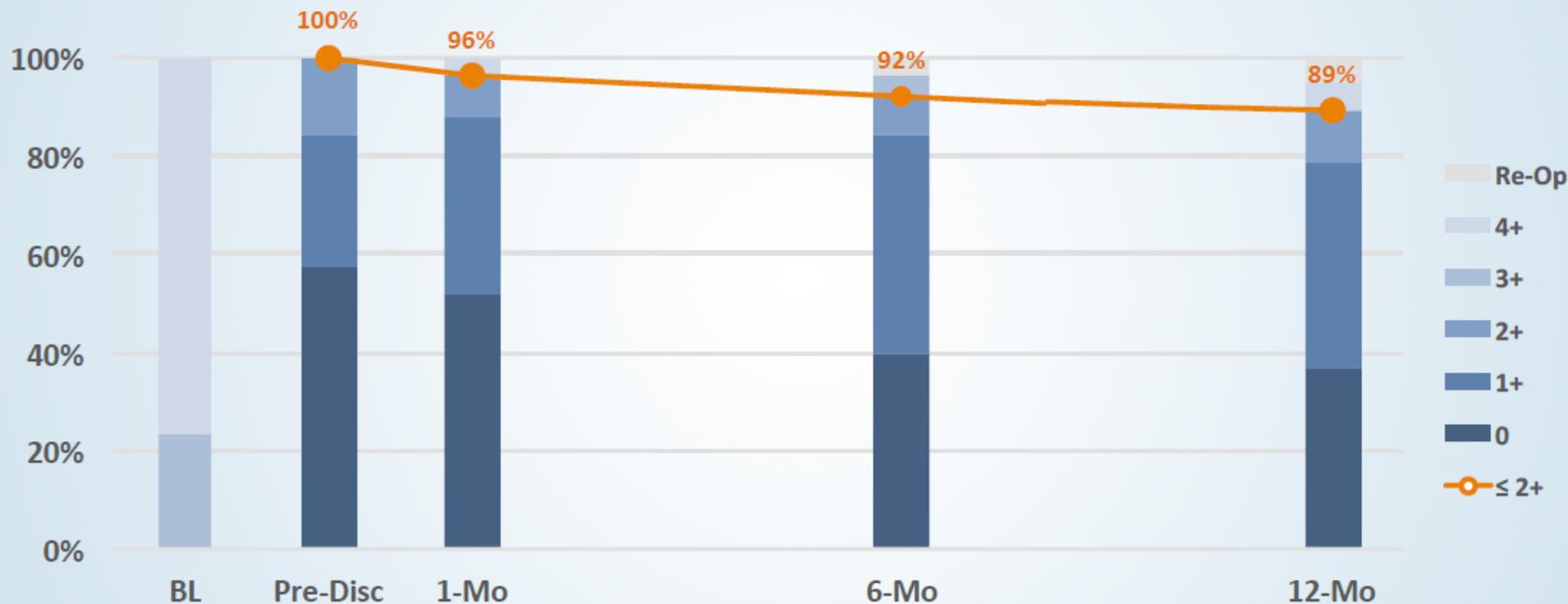
**Date set as of 1-Jul-15

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Efficacy at 1 Year

Type "A" & "B" Registry Patients

N = 25 at 6 Months, N = 19 at 12 Months



- Type A&B patients removing first 2 patients at each site

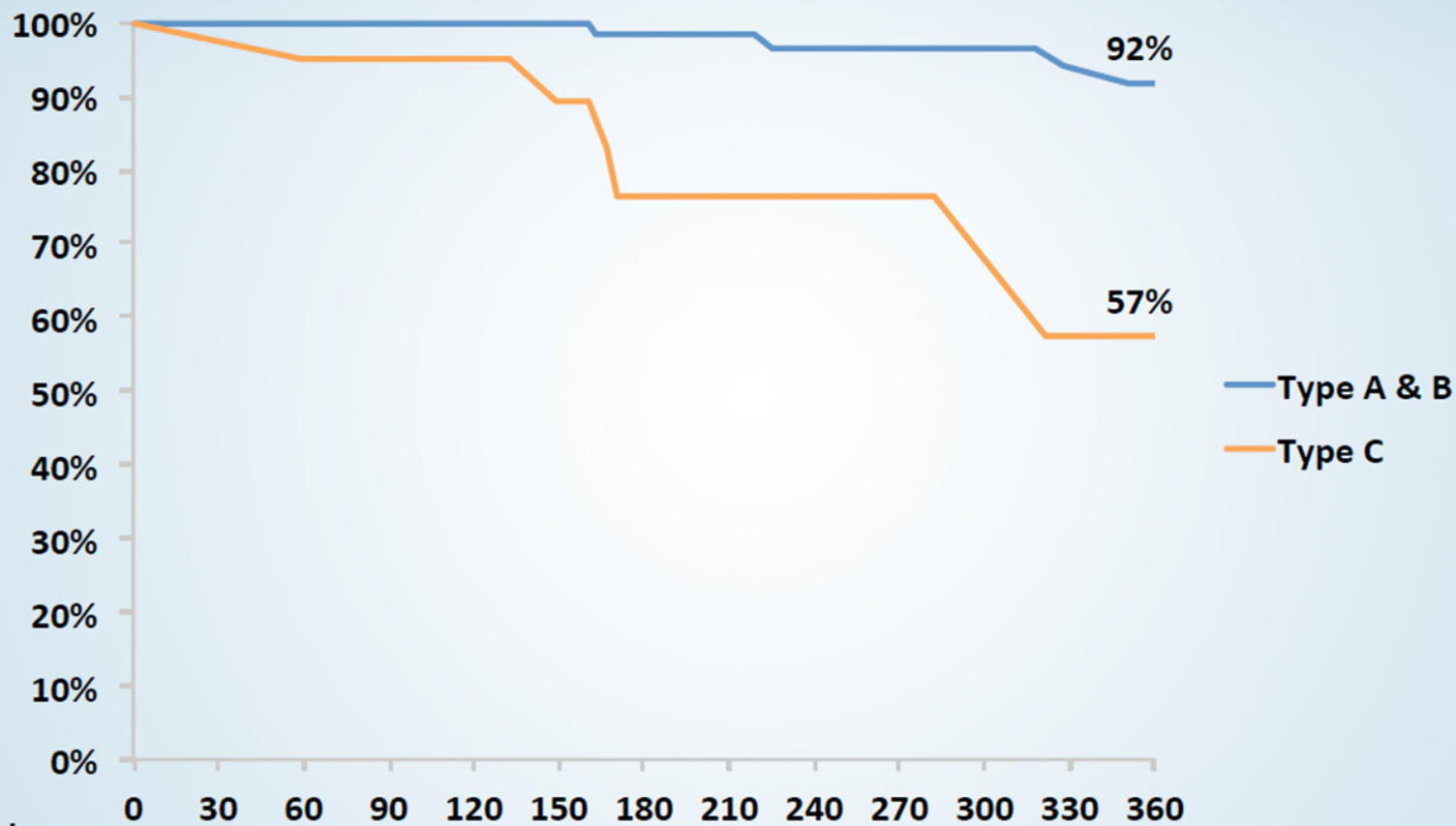
*Registry: Core Lab Assessment

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Type A & B vs. Type C – DURABILITY (30 days to 1 Year)



At Risk:

Type A & B:	68	68	57	38
Type C:	20	20	11	3

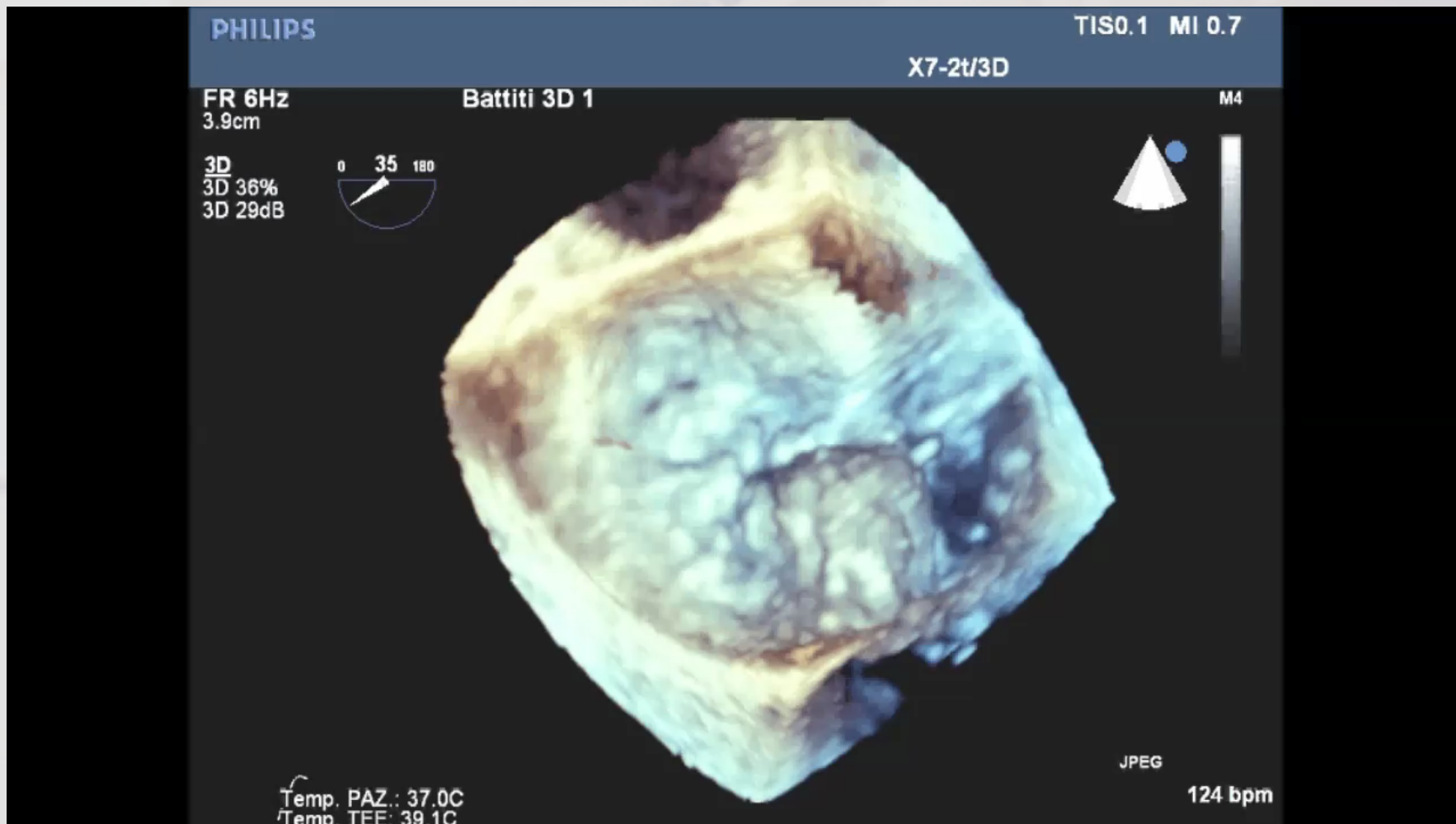
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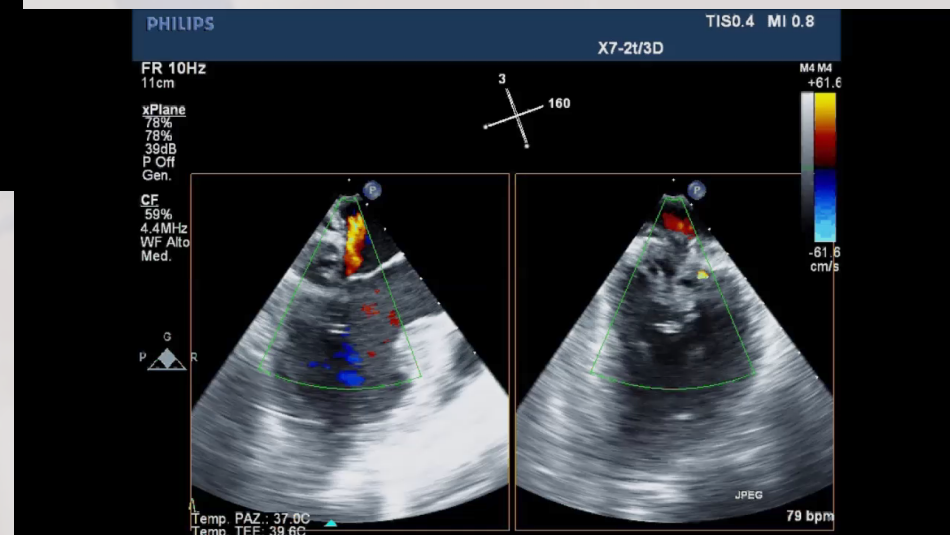
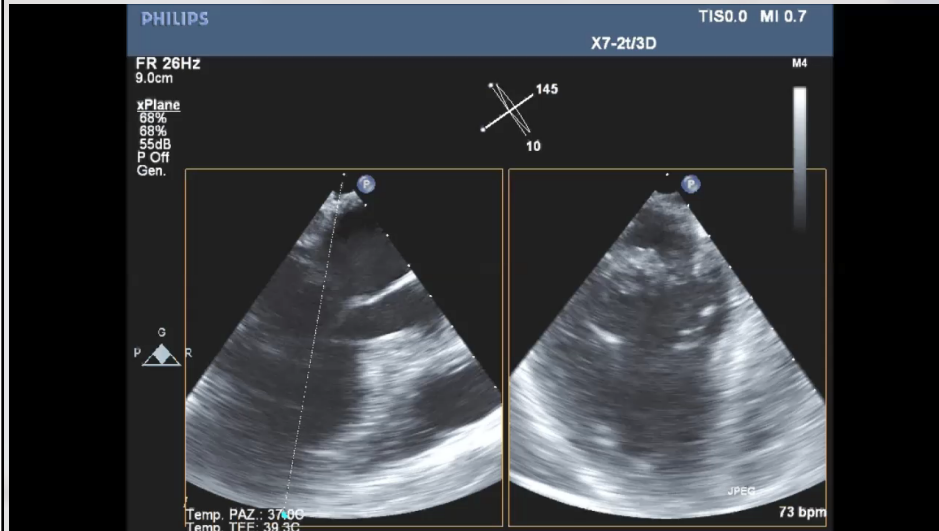
Reasons for Recurrency of MR

- **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**

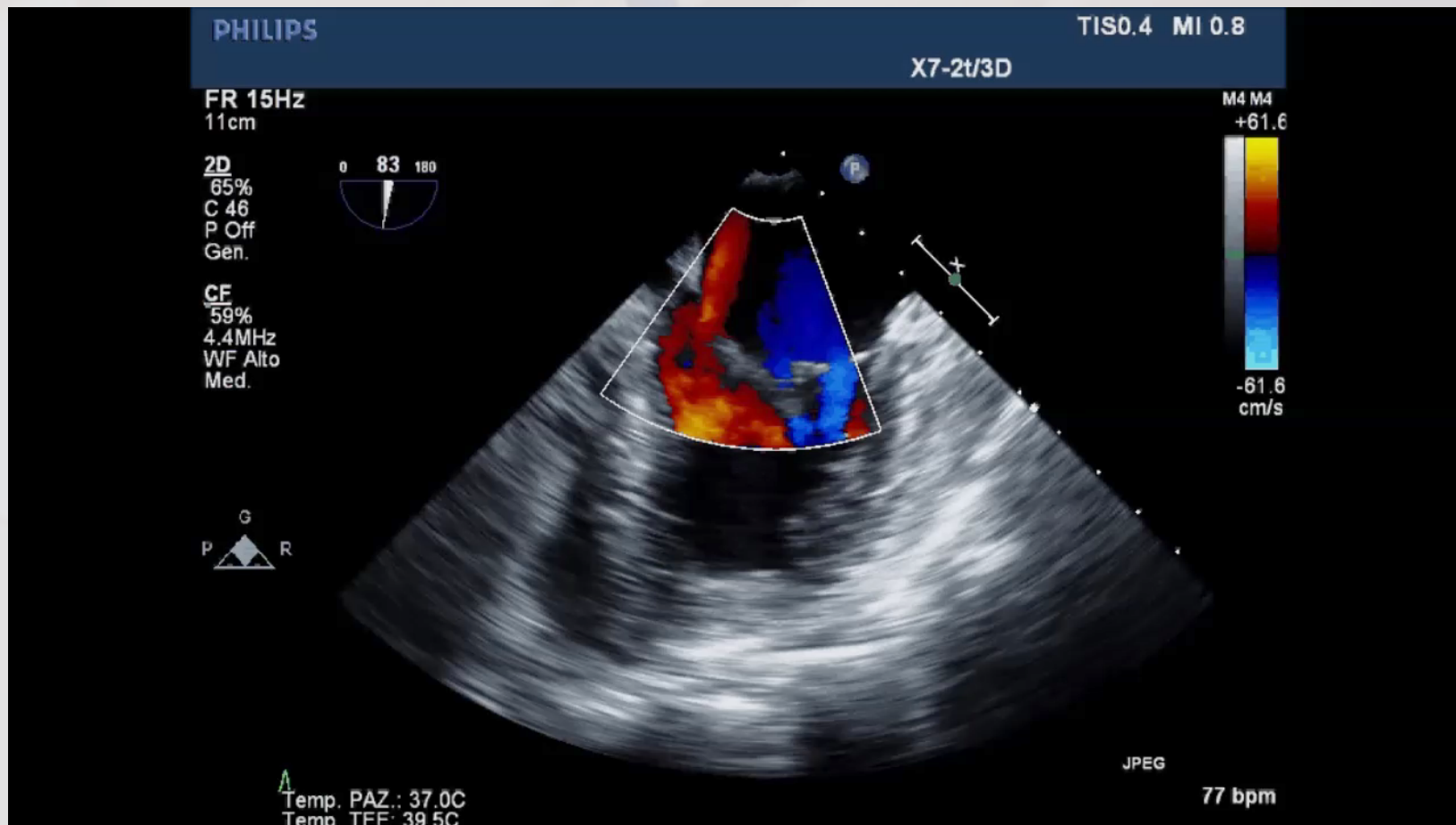
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Conclusion

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

With continuous technical refinement, the NeoChord procedure is reaching (in Type A pts) and is approaching (in Type B pts) the results of open surgery. (?)

The excellent safety profile and improving results makes it an attractive option also for Type C pts in whom a standard surgical procedure is undesirable

Limits

This technique allows to solve the problem of chordal elongation or rupture but is applied following the guidelines drawn up for open surgery, where we can reshape the individual components of the mitral valve (ring, leaflets, chordal and papillary muscles)

The goal

Adaptability of the guidelines to the new procedures.

What to do? how to do?

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Grazie