



A tipping point for PASCAL platform - experience in practice

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Potential conflicts of interest

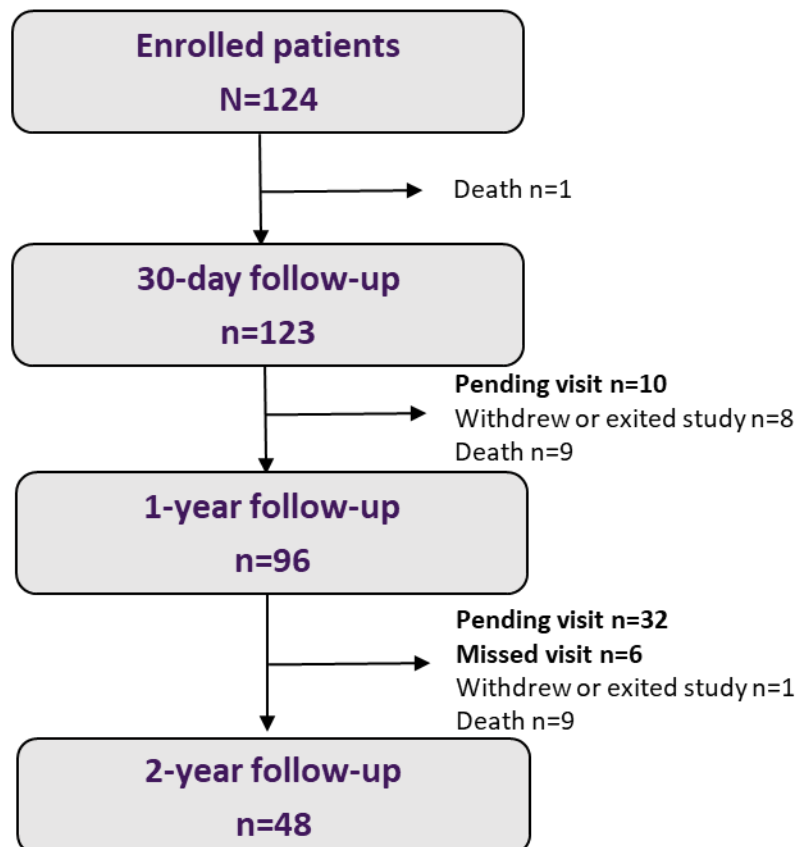
Speaker's name: Jörg Hausleiter, Munich, Germany

☐ I have the following potential conflicts of interest to report:

Speaker honoraria and institutional research support from Edwards Lifesciences

Advisory board activities for Edwards Lifesciences

Study enrollment



Baseline characteristics

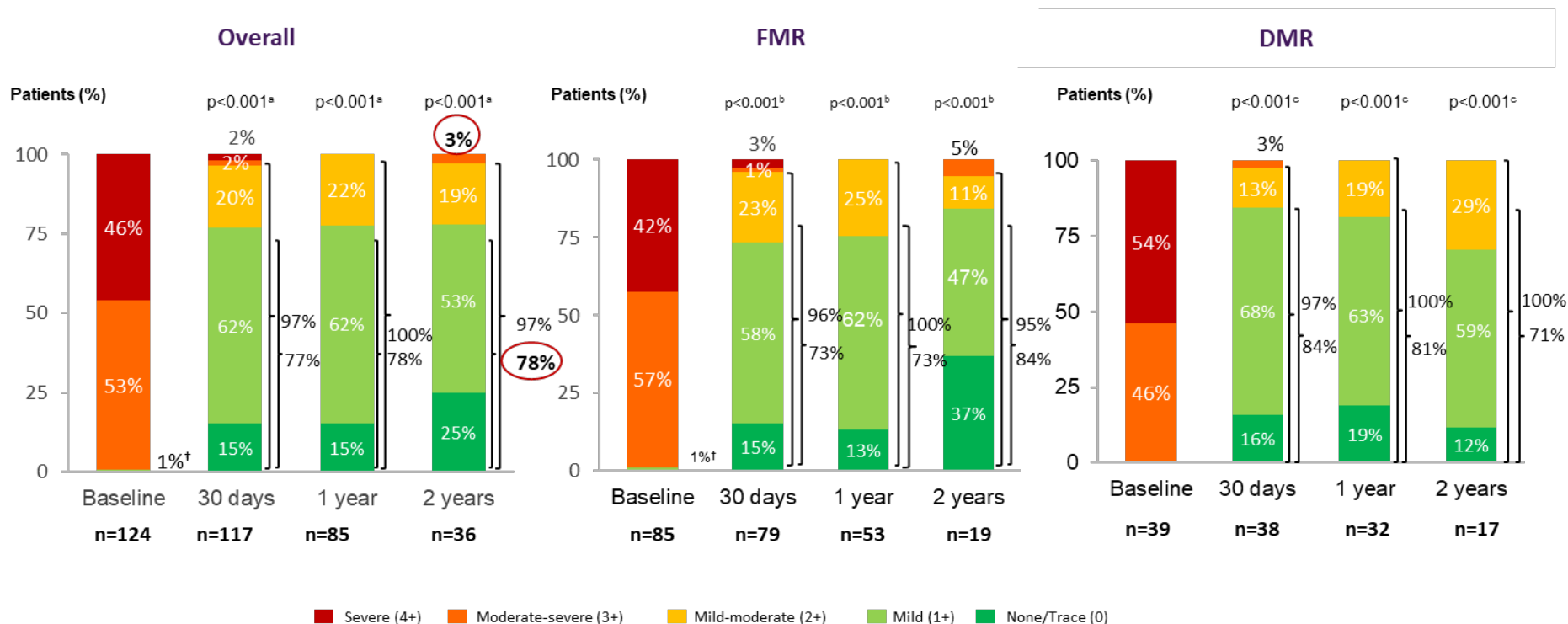
	N=124 % or Mean \pm SD
Age, years	75 \pm 11
Male	56%
NYHA functional class III-IVa	60%
Etiology	
Functional	69%
Degenerative	31%
MR severity $\geq 3+$ by TTE or TEE	100%
PISA EROA, cm ²	0.38 \pm 0.15
Regurgitant volume, ml	57 \pm 20
Vena contracta width, A-P, mm	6.3 \pm 1.4

<https://clinicaltrials.gov; NCT03170349>

Szerlip M, et al. 2-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study. JACC Cardiovasc Interv. 2021;14(14):1538-1548

Sustained MR Reduction, Low MR Recurrence

78% MR $\leq 1+$ sustained at 2 years by core lab¹



¹Cardiovascular Core Lab at Morristown Medical Center, Morristown, NJ, USA. Graphs show unpaired data. p-value calculated from paired analysis using Wilcoxon signed rank test. *baseline vs. 30 days (n=117; MR $\leq 1+$ =77%; MR $\leq 2+$ =97%), 1 year (n=85; MR $\leq 1+$ =78%; MR $\leq 2+$ =100%), and 2 years (n=36; MR $\leq 1+$ =78%; MR $\leq 2+$ =97%), *baseline vs. 30 days (n=79; MR $\leq 1+$ =73%; MR $\leq 2+$ =96%), 1 year (n=53; MR $\leq 1+$ =75%; MR $\leq 2+$ =100%), and 2 years (n=19; MR $\leq 1+$ =84%; MR $\leq 2+$ =95%), *baseline vs. 30 days (n=38; MR $\leq 1+$ =84%; MR $\leq 2+$ =97%), 1 year (n=32; MR $\leq 1+$ =81%; MR $\leq 2+$ =100%), and 2 years (n=17; MR $\leq 1+$ =71%; MR $\leq 2+$ =100%). †One patient had MR 1+ by TTE although 3+ by TEE. DMR: degenerative mitral regurgitation, FMR: functional mitral regurgitation. Szerlip M, et al. 2-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study. JACC Cardiovasc Interv. 2021;14(14):1538-1548.

PASCAL Platform Experience in 4900+ Commercially Treated MR Patients

- Retrospective analysis of acute results in 4900+ consecutive PASCAL repair system repair procedures in MR patients post CE mark approval
- Analyses were performed by Edwards Lifesciences, and do not include Echo Core Lab analysis or Clinical Events Committee assessment. Data are collected by Edwards Clinical Specialists supporting 100% of procedures.

Etiologies treated (n=4,604)

Total MR Patients

FMR: 49%

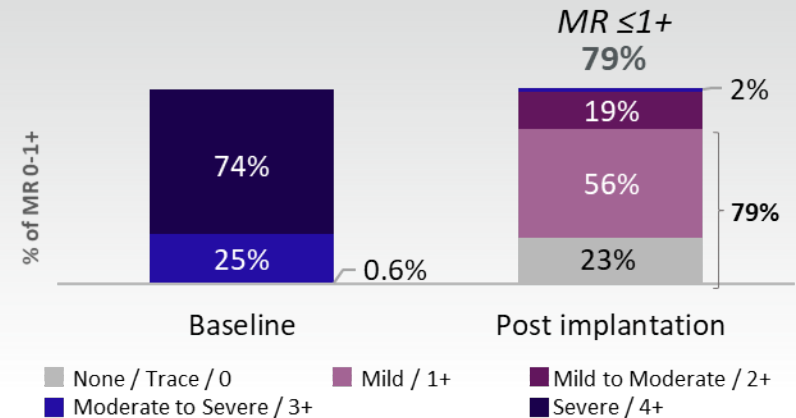
DMR: 28%

Mixed: 22%

Safety

- 99.9% freedom from intraprocedural death or shift to surgery
- 98.7 % freedom from Serious Adverse Events¹

Acute Efficacy² (n=4,744)



¹Serious Adverse Events defined as Intraprocedural complications as per implantor / echo physician feedback to onsite Edwards Clinical Specialist who supported the case. 100% of cases reported were supported. Total 4926: 1.3% SLDA and Other SAEs

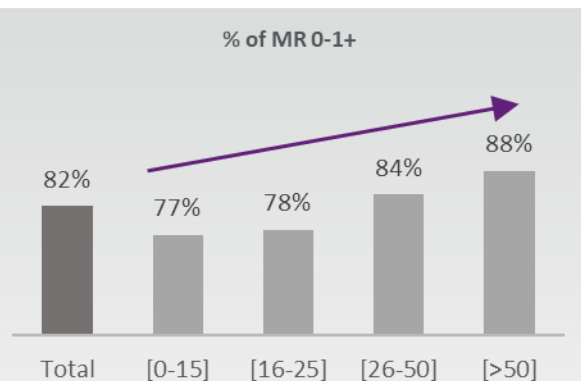
²Residual regurgitation as per implantor / echo physician acute assessment and reported by onsite clinical specialist, in non-aborted procedures.

Note: Partial data sets available on first N=4926; data being analysed up to N=4744; Etiology information available N=4604

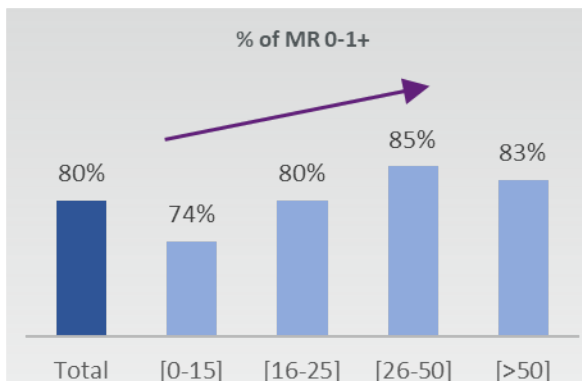
Edwards Lifesciences internal data on file.

High Rates of MR 0-1+ Can Be Achieved After a Short Learning Curve

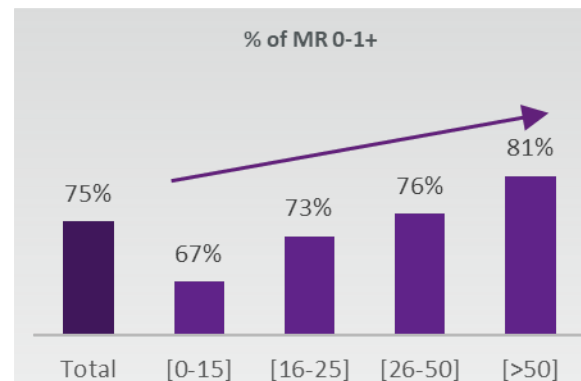
FMR (N=2213; non-aborted)



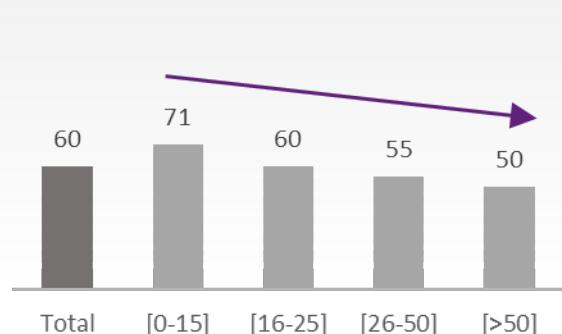
DMR (N=1254; non-aborted)



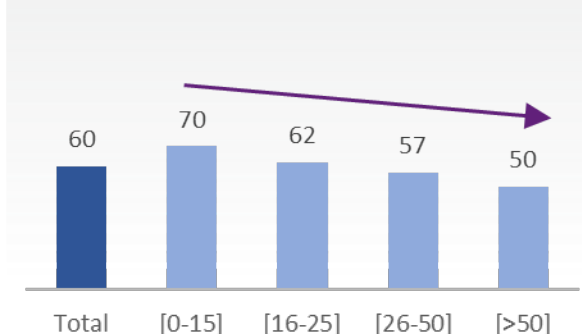
Mixed (N=973; non-aborted)



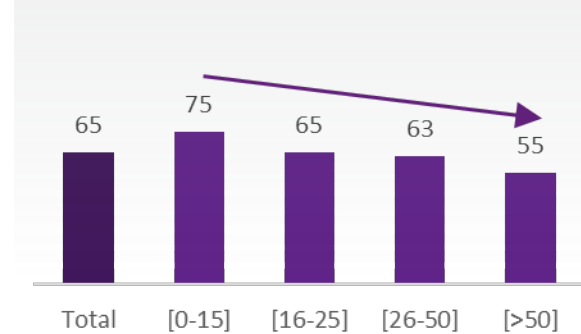
Median procedure time (min)



Median procedure time (min)



Median procedure time (min)

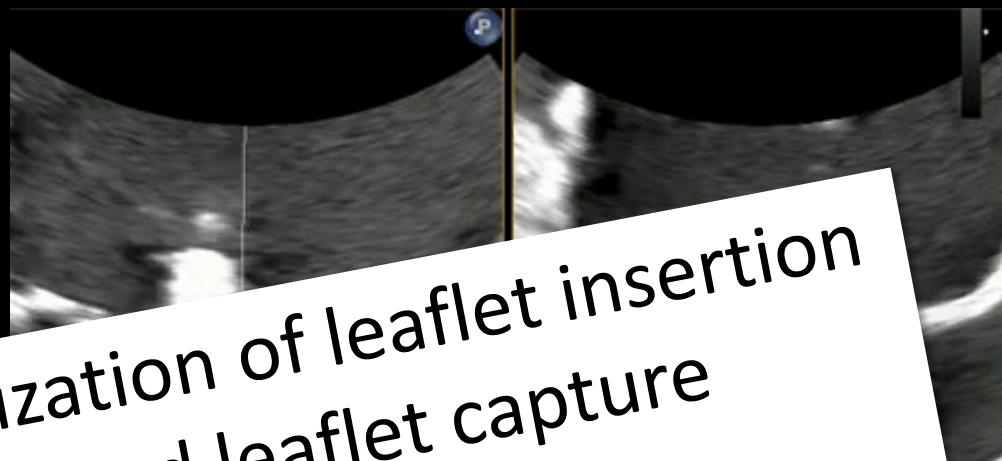
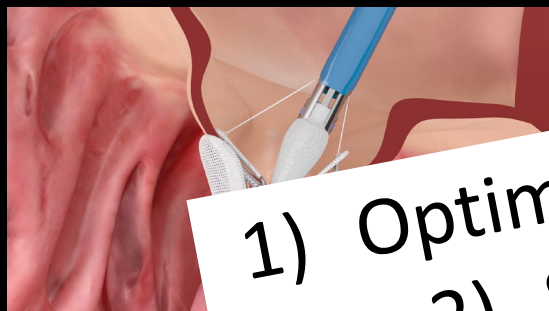


Note: Analysis done on residual MR and procedural time data when available for the first N=4744 non-aborted cases with etiology information available, a total of 4440 cases. Residual regurgitation as per implanter/echo physician acute assessment and reported by onsite clinical specialist. DMR: degenerative mitral regurgitation, FMR: functional mitral regurgitation.

Edwards Lifesciences internal data on file.

Improving MR Reduction

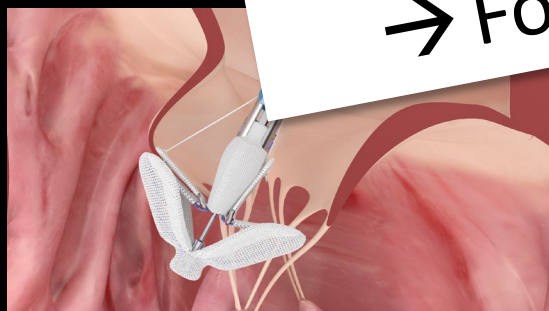
Leaflet capture
optimization



- 1) Optimization of leaflet insertion
- 2) Staged leaflet capture

→ For obtaining MR1+ results!

Staged le

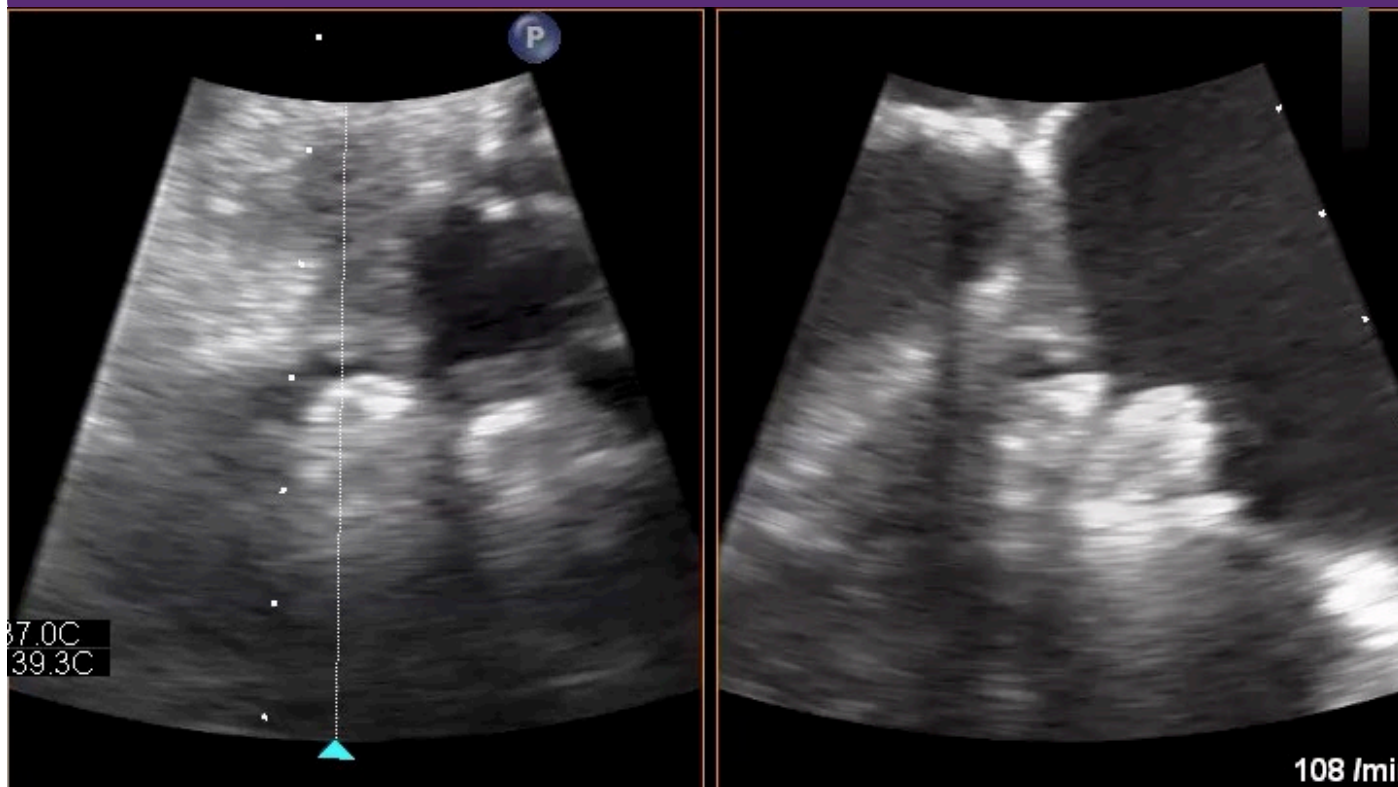


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PASCAL Transcatheter Valve Repair System

Flexible Nitinol Device For Distributing Leaflet Pulling Forces

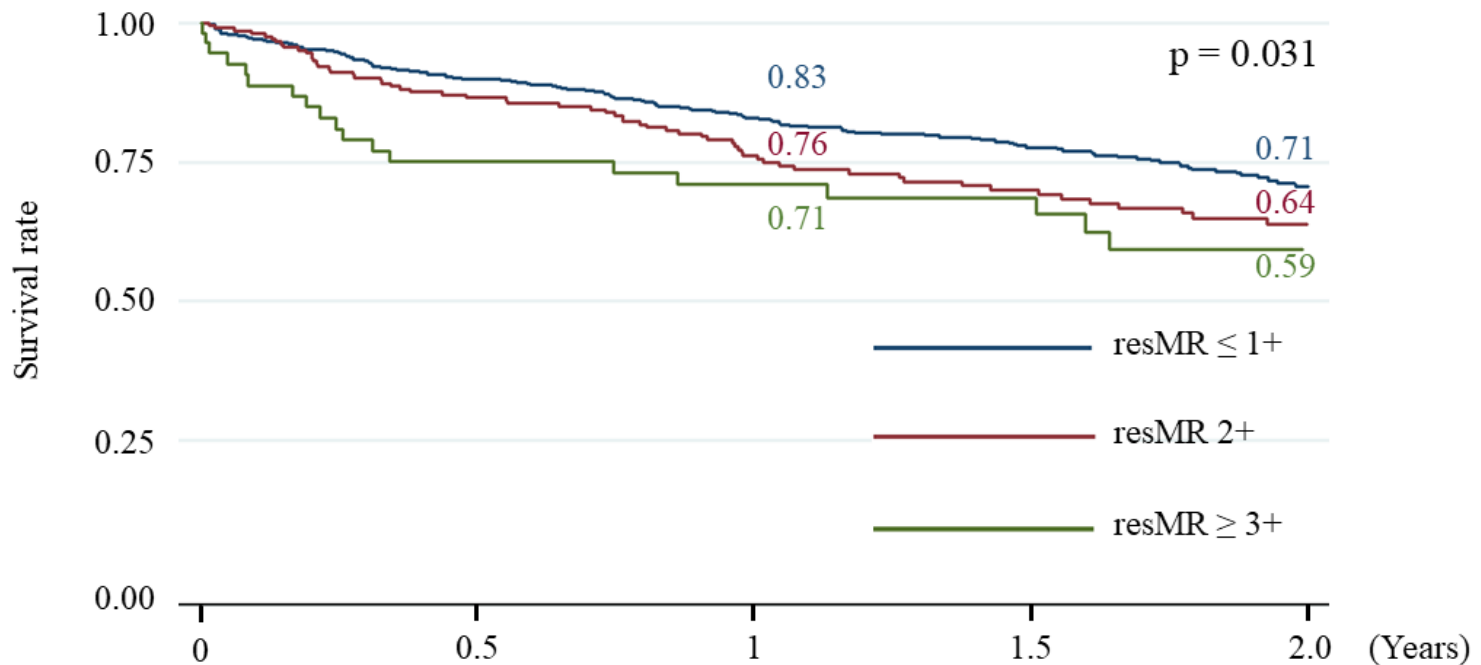
Atraumatic Device Flexibility



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Is the degree of MR reduction of relevance?

Mortality in the EuroSMR registry



Number at risk

resMR \leq 1+	546	455	374	280	205
resMR 2+	207	167	131	90	60
resMR \geq 3+	56	38	34	23	16

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Conclusions

The PASCAL repair system is a differentiated therapy for MR patients

- **In the CLASP study at 2 years follow up¹:**
 - Robust and durable MR reduction
 - Positive LV remodelling
 - High survival rates and reduced annualised heart failure hospitalization rates
- **In real world experience of 4900+ cases acute results**
 - 84% MR 0-1+ reported after 25 cases and sustained with more case experience in both FMR and DMR patients
 - Procedure time \leq 62 minutes after 15 cases in both FMR and DMR patients

The randomized CLASP IID/IIF pivotal clinical trial is ongoing (NCT03706833)

CLASP IID / IIF



The Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial (CLASP IID/IIF)

Prospective, multicenter, randomized, controlled pivotal trial

Purpose:

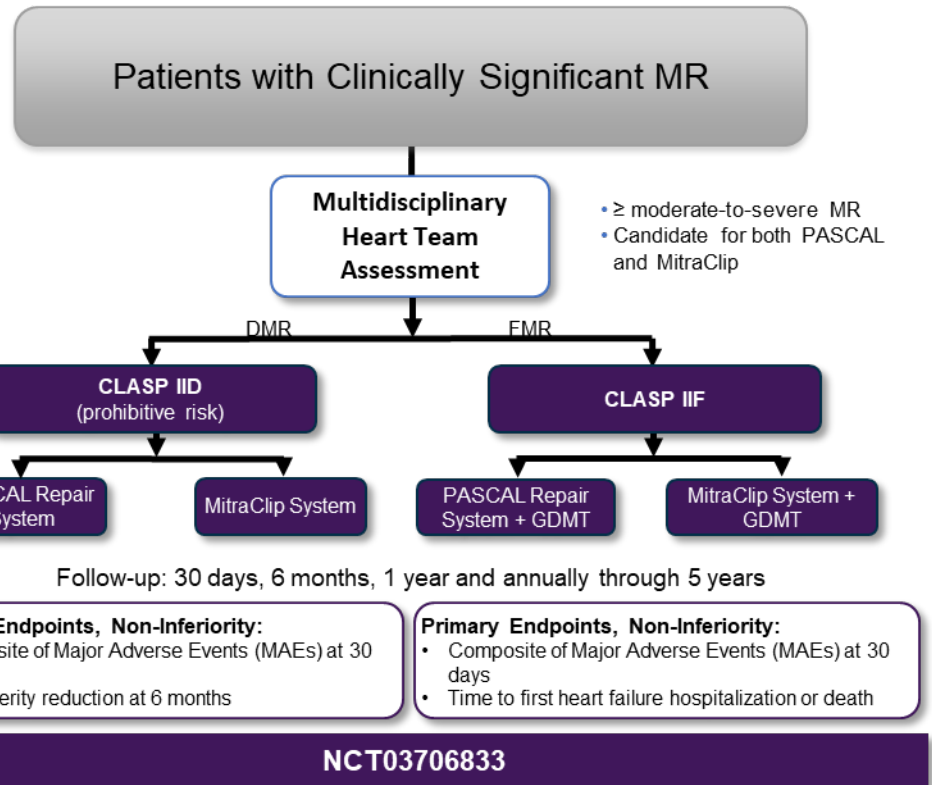
Establish the safety and effectiveness of the PASCAL Repair System compared to the MitraClip System in patients with degenerative and functional mitral regurgitation (MR)

IID Principal Investigators:

- Scott Lim, MD
- Robert Smith, MD
- Linda Gillam, MD
- Jörg Hausleiter, MD

IIF Principal Investigators:

- Brian K. Whisenant, MD
- Vinod Thourani, MD
- Paul Grayburn, MD
- Ralph Stephan von Bardeleben, MD



<https://clinicaltrials.gov; NCT03706833>

Thank You

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