



Recent Clinical Evidence

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Innere Medizin III - Kardiologie und Angiologie



Potential conflicts of interest

Speaker's name: Tobias Geisler

I have the following potential conflicts of interest to report:

Boston Scientific: Research grants

Edwards Lifesciences: Research grants, honoraria

Medtronic: Honoraria

Expert opinion disclaimer

- Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

The CLASP IID Randomized Trial

Edwards PASCAL TrAnScatheter Valve RePair System Pivotal Clinical Trial

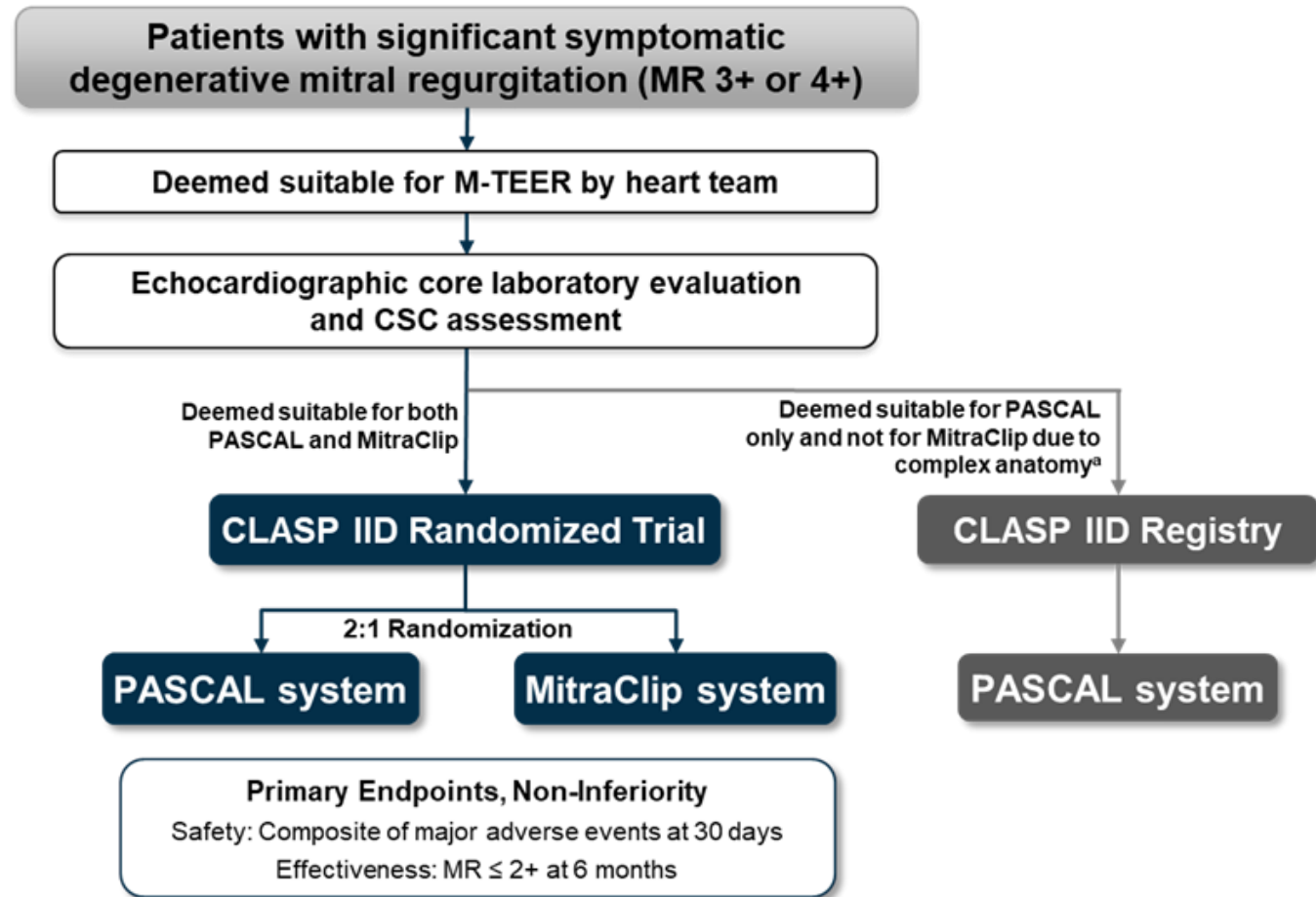
Prospective, multicenter, multinational, randomized, controlled pivotal trial

Purpose:

Evaluate the safety and effectiveness of the PASCAL transcatheter valve repair system compared to the MitraClip system in significant symptomatic DMR patients at prohibitive risk for surgery

IID Trial Oversight:

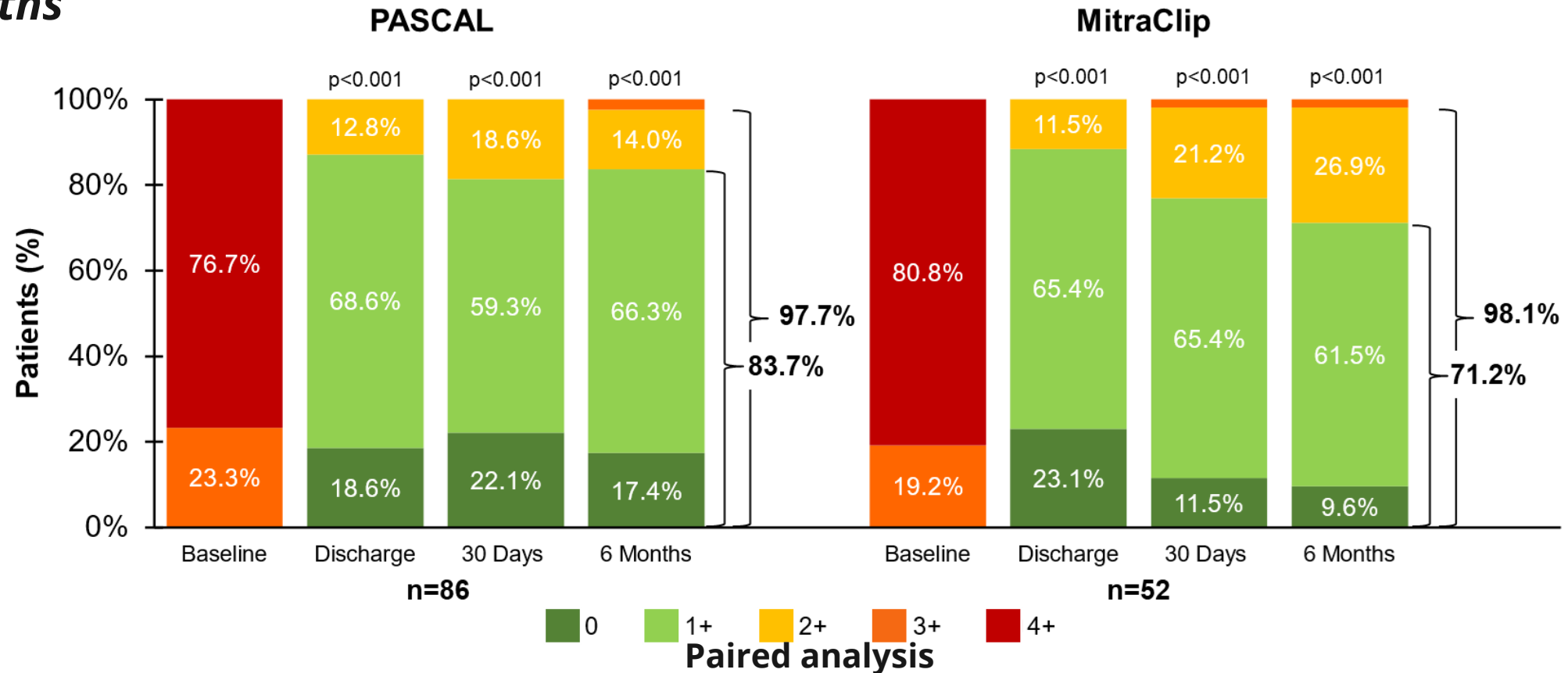
- Central Screening Committee (CSC)
- Echocardiographic Core Laboratory
- Clinical Events Committee (CEC)
- Data Safety Monitoring Board



^aBased on the anatomical considerations in the special patient populations section of the current MitraClip Instructions for Use (IFU). MR: Mitral regurgitation; DMR: Degenerative mitral regurgitation; M-TEER: Mitral valve transcatheter edge-to-edge repair. Lim D.S. et al., Randomized Comparison of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation in Prohibitive Surgical Risk Patients. JACC Cardiovasc Interv. 2022 Dec 26;15(24):2523-2536.

MR Reduction by Core Lab¹

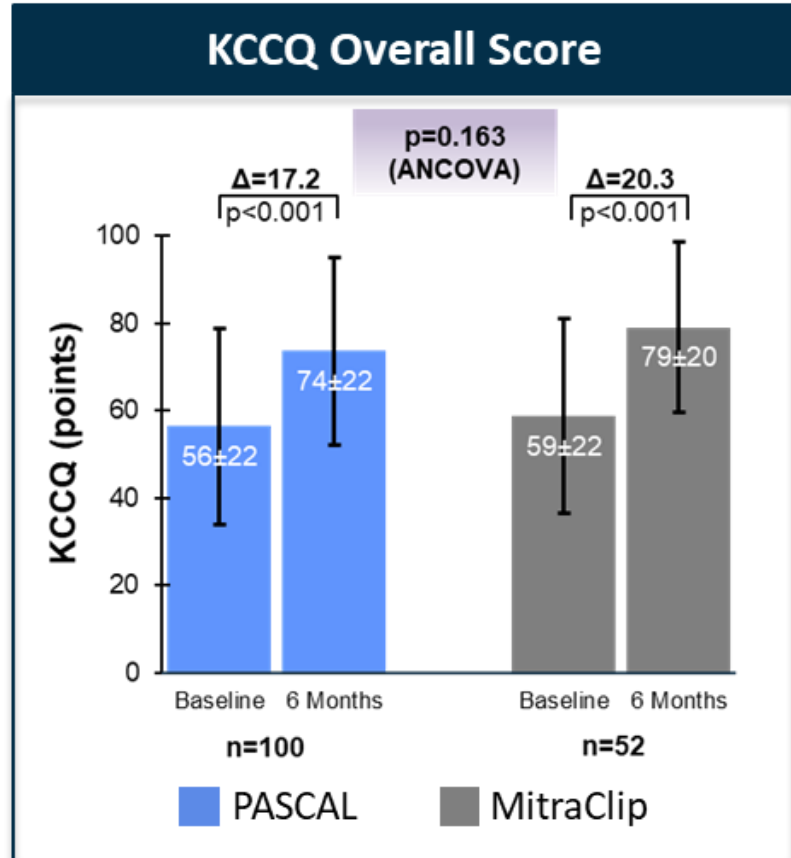
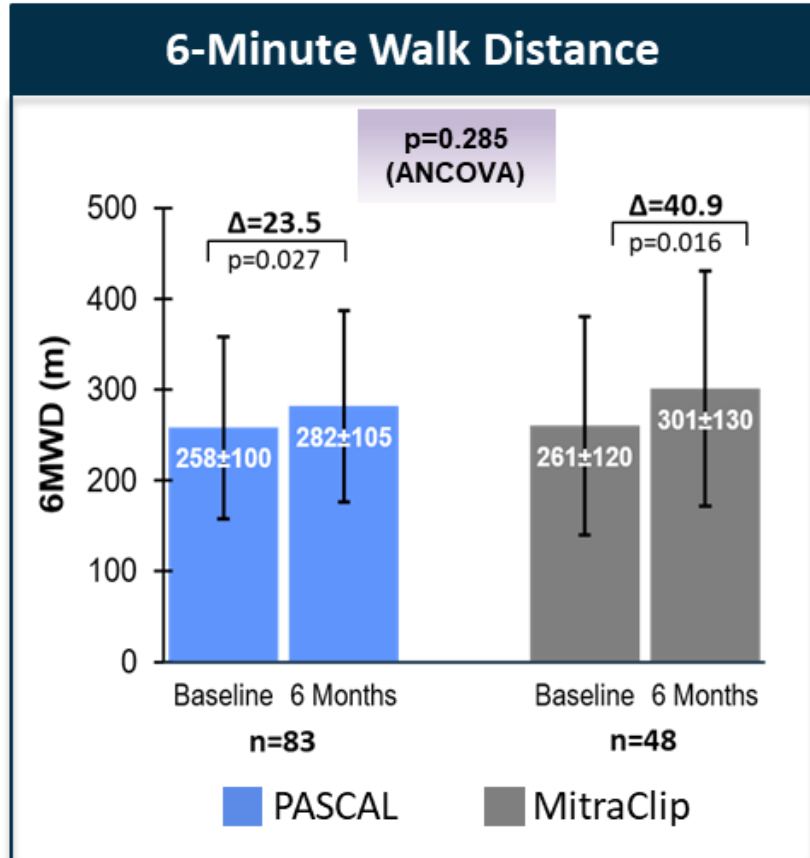
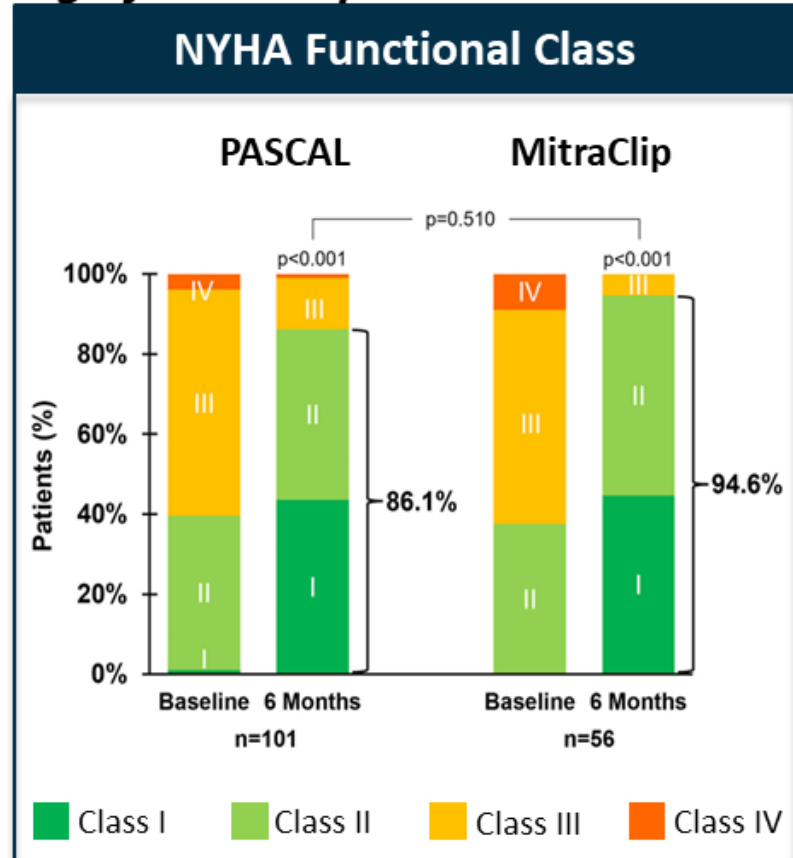
Significant MR reduction with the PASCAL repair system: 97.7% with MR $\leq 2+$ at 6 months



Primary effectiveness endpoint met proving non-inferiority of PASCAL in MR reduction. Graph shows paired analysis and p values relative to baseline were calculated using the Wilcoxon signed rank test. ¹Echocardiographic core lab: Atlantic Health System Morristown Medical Center, Morristown, NJ, USA. MR severity assessed by transthoracic echocardiography (TTE). Adopted from Lim D.S. et al., Randomized Comparison of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation in Prohibitive Surgical Risk Patients. JACC Cardiovasc Interv. 2022 Dec 26;15(24):2523-2536.

Functional and Quality of Life Outcomes

Significant improvements at 6 months



NYHA functional class graph shows paired analysis; p values for intragroup comparison were calculated using the Wilcoxon signed rank test and p value for intergroup comparison was calculated using the Wilcoxon rank sum test. 6MWD and KCCQ graphs show paired analysis (mean \pm SD); p values for intragroup comparisons were calculated using Student's t-test and p values for intergroup comparisons were calculated using the analysis of covariance (ANCOVA) model adjusted for baseline values and planned treatment as covariates. NYHA, New York Heart Association; 6MWD: 6-minute walk distance; KCCQ, Kansas City Cardiomyopathy Questionnaire; Lim D.S. et al., Randomized Comparison of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation in Prohibitive Surgical Risk Patients. JACC Cardiovasc Interv. 2022 Dec 26;15(24):2523-2536.



Universitätsmedizin Essen
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Klinik für Kardiologie und Angiologie



New PASCAL Precision Repair System:

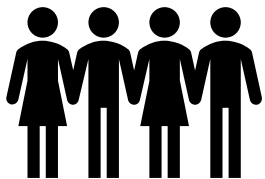
Preliminary data, single center, Essen





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Demographics and Procedural Details

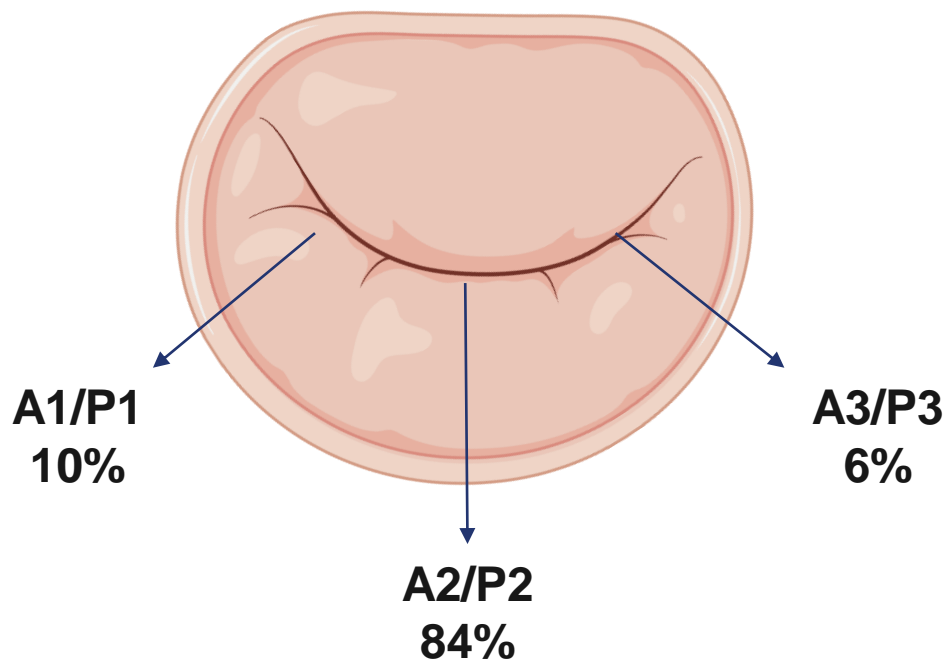


- **n = 49**
- **Mean age: 76±11 yrs**
- **30-day mortality: 0%**

49% : 51%

FMR	DMR	Mixed
37%	22%	41%

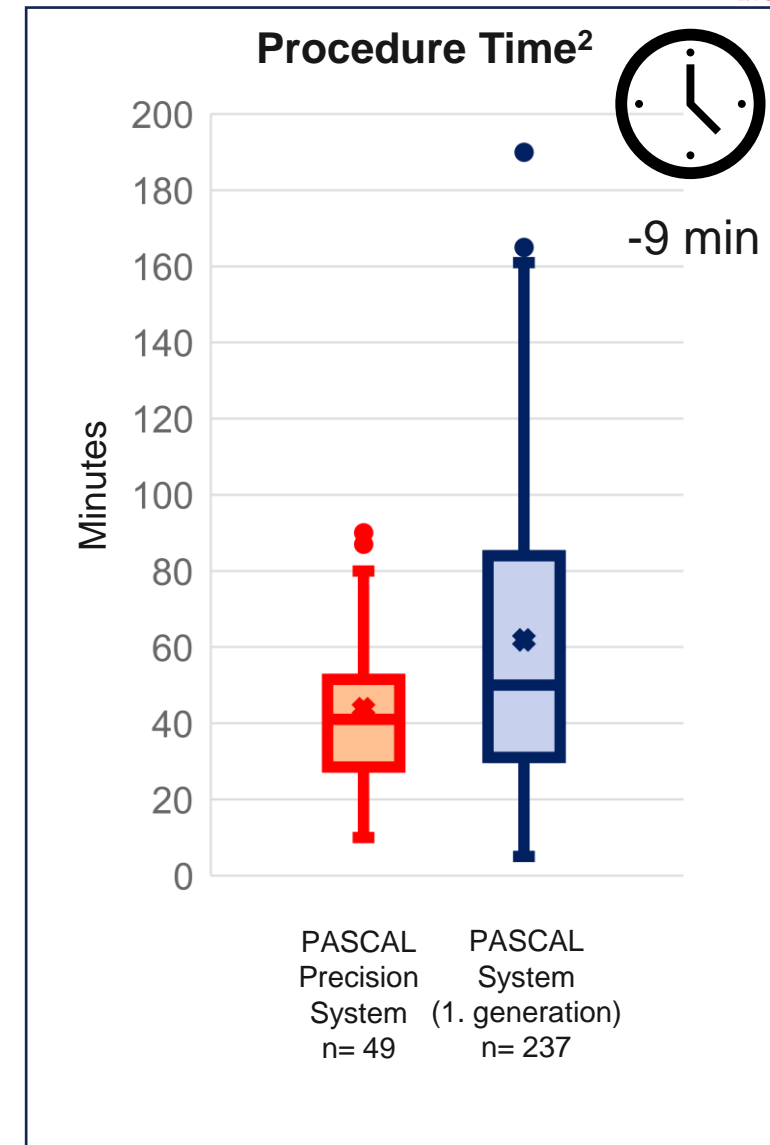
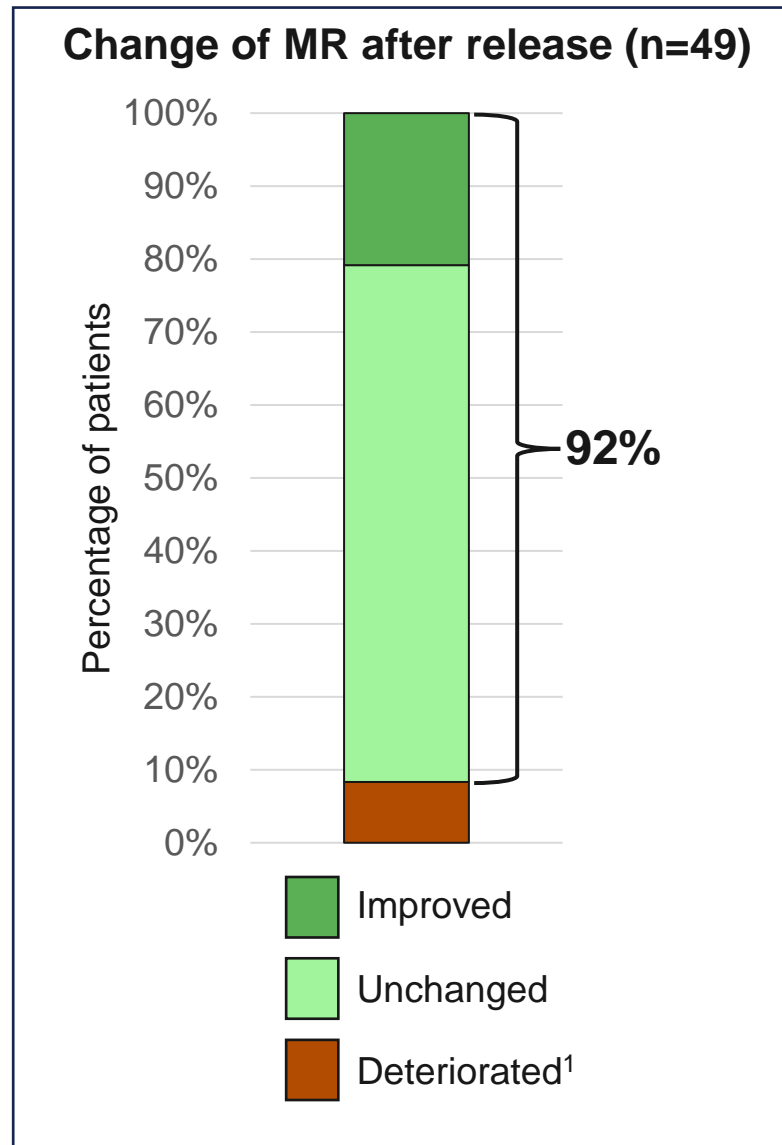
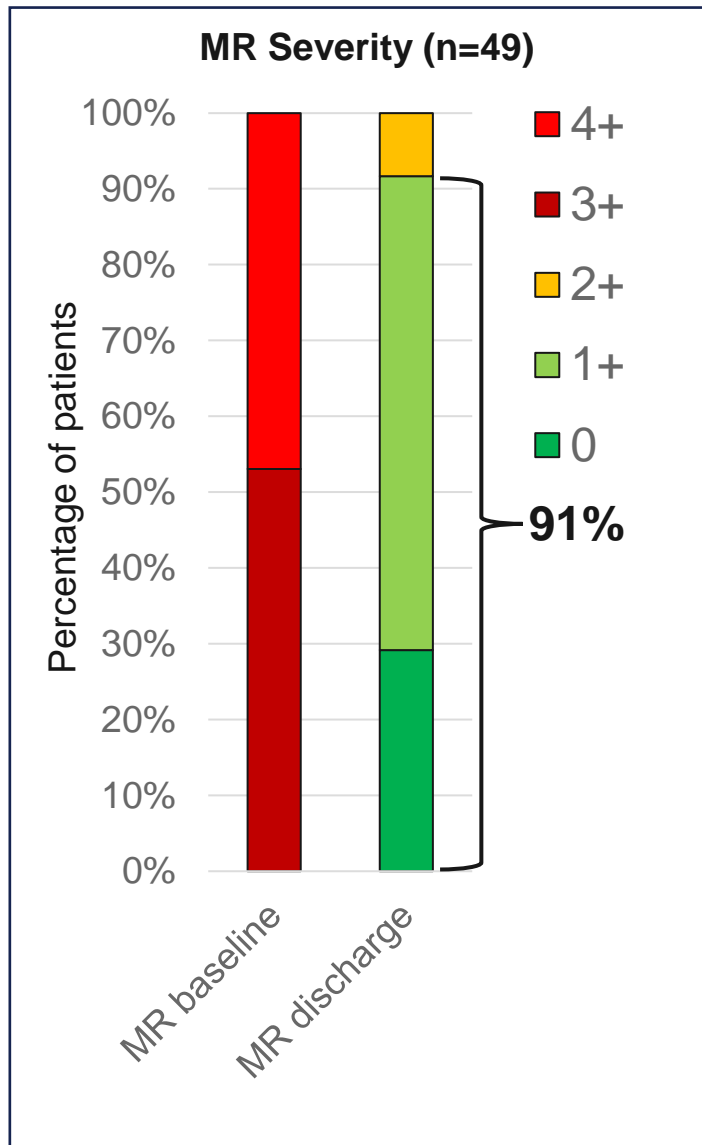
ESC/EACTS complexity ¹		
IDEAL	CHALLENGING	COMPLEX
37 %	33%	31%



1 Implant = 80%
2 Implants = 20%

PASCAL	PASCAL Ace	PASCAL & PASCAL Ace
45%	51%	4%

1 st Implant	2 nd Implant
Grasping Attempts*	Grasping Attempts*
3 (1; 17)	2 (1; 4)
Independent Grasping	Independent Grasping
55%	6%
Leaflet Optimization	Leaflet Optimization
63%	8%



Thank You!

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