PASCAL System for the treatment of mitral regurgitation

Body of evidence

Clinical evidence for the use of the PASCAL system for the treatment of mitral regurgitation

Edwards

PASCAL System body of evidence: Mitral regurgitation

Consistent favourable safety and sustained MR reduction with the PASCAL system[1–3]

2,000+ patients targeted in studies[1–4]

4 studies and **1** registry*

9+ years of study†

MR severity evaluated by independent ECL

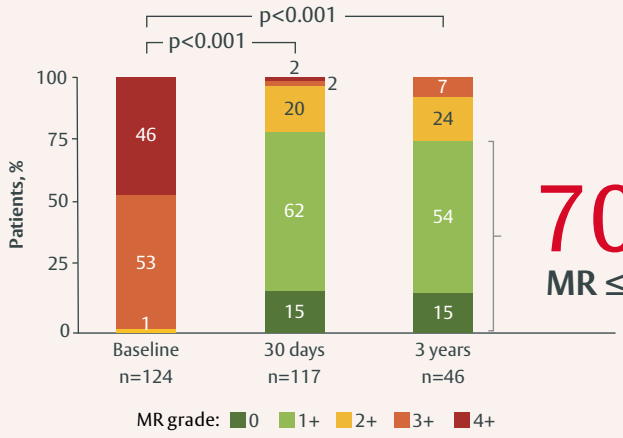
Prespecified adverse events adjudicated by CEC

THE CLASP STUDY

Prospective, multicentre, single-arm study[1]

124 patients | **3** years†

Favourable and durable outcomes at 3 years in patients with clinically significant, symptomatic FMR or DMR.[1]



70% MR ≤1+

71% in FMR patients

67% in DMR patients

75% freedom from all-cause mortality

73% freedom from HFH

89% NYHA class I/II

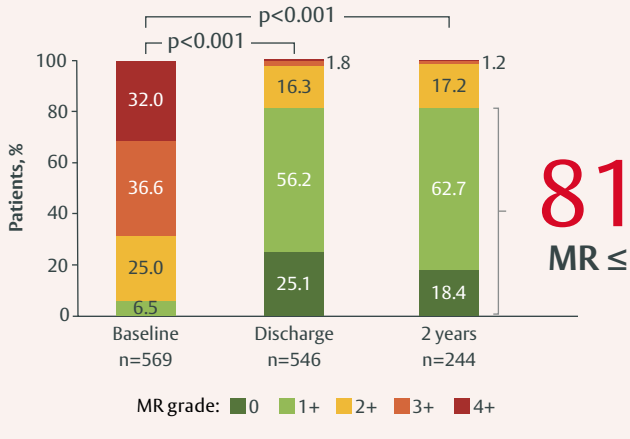
Figure shows unpaired analysis. Adapted from Spargias K *et al.* 2023. For details on statistical analyses, please see reference 1.

THE MiCLASP STUDY

Prospective, multicentre, single-arm, post-market clinical follow-up study[2]

600 patients† | **2** years†

Confirmed safety and significant, sustained effectiveness at 2 years in patients with significant, symptomatic MR in a post-market setting.[2]



81% MR ≤1+

83% in FMR patients

76% in DMR patients

88% freedom from CV mortality

74% freedom from HFH

74% NYHA class I/II

+13 pts KCCQ-OS

Figure shows unpaired analysis. Adapted from Geisler T. 2024. For details on statistical analyses, please see reference 2.

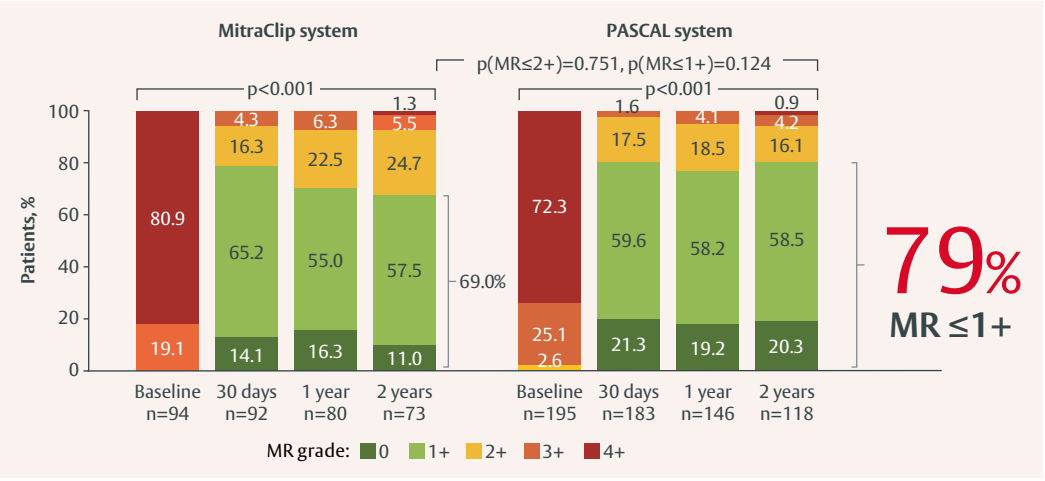
THE CLASP IID TRIAL

Prospective, multicentre, randomised controlled pivotal trial[3]

204 patients treated with the PASCAL system†

2 years†

Confirmed safety and significant, sustained effectiveness at 2 years in patients with significant, symptomatic DMR.[3]



79% MR ≤1+

89% freedom from CV mortality

86% freedom from HFH

88% NYHA class I/II

+17 pts KCCQ-OS

with the PASCAL system

Figure shows unpaired analysis. Adapted from Zahr F. 2024. For details on statistical analyses, please see reference 3.

THE CLASP IID REGISTRY

Prospective, multicentre, single-arm study[3]

98 patients†

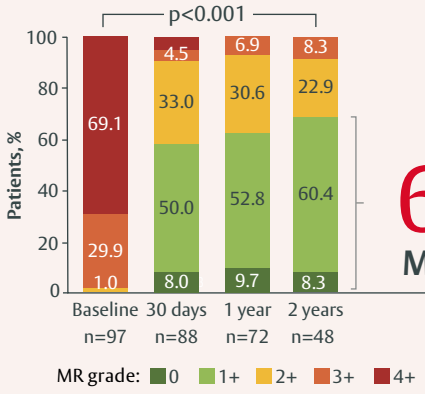
2 years†

Significant and sustained MR reduction at 2 years in patients with significant, symptomatic DMR and complex mitral valve anatomy.[3]

Baseline anatomical complexity distribution

- **37.2%** ≥2 independent significant jets
- **15.0%** Bileaflet/multi-scallop prolapse involvement
- **13.3%** Mitral valve orifice area <4.0 cm²
- **10.6%** Flail width >15 mm and/or flail gap >10 mm
- **9.7%** Significant jet in the commissural area
- **14.2%** Other[a]

[a]Please refer to reference 3 for details.



69% MR ≤1+

84% freedom from CV mortality

85% freedom from HFH

84% NYHA class I/II

+12 pts KCCQ-OS

MR figure shows unpaired analysis. Figures adapted from Zahr F. 2024. For details on statistical analyses, please see reference 3.

THE CLASP IIF TRIAL

Prospective, multicentre, randomised controlled pivotal trial[4]

First head-to-head randomised controlled trial to evaluate the safety and effectiveness of M-TEER with the PASCAL system compared with the MitraClip system in patients with FMR on guideline-directed medical therapy.[4]

Primary endpoints: Safety: Composite of major adverse events at 30 days

Effectiveness: Time from randomisation date to first HFH or death, through 5-year follow-up

*CLASP, CLASP IID trial, CLASP IID registry, CLASP IIF and MiCLASP. Note: CLASP IIF currently in progress.

†Based on reported follow-up.

Edwards PASCAL Precision System

Accurate, intuitive control
Advanced catheter and handle design facilitates smooth navigation and implant deployment*

Versatile implant configuration
Adapt to specific procedural and anatomical needs

Atraumatic clasp and closure
Enhance leaflet capture with atraumatic reclasp capabilities

Predictable release
Deploy the implant with procedural confidence†

*Design data on file and marketing evaluation.
†Performance and design data on file.

Learn more about the PASCAL system at Edwards.com/gb/PASCAL

For details on statistical analyses, please see references 1–3.

Abbreviations

CEC:	clinical events committee
CV:	cardiovascular
DMR:	degenerative mitral regurgitation
ECL:	echocardiography core lab
FMR:	functional mitral regurgitation
HFH:	heart failure hospitalisation
KCCQ-OS:	Kansas City Cardiomyopathy Questionnaire overall summary score
M-TEER:	mitral transcatheter edge-to-edge repair
MR:	mitral regurgitation
NYHA:	New York Heart Association

References

1. Spargias K, Lim DS, Makkar R *et al.* Three-year outcomes for transcatheter repair in patients with mitral regurgitation from the CLASP study. *Catheter Cardiovasc Interv*. 2023; **102:** 145–54.
2. Geisler T. Two-year outcomes of mitral transcatheter edge-to-edge repair from the MiCLASP study. PCR London Valves, 24–26 November 2024, London, UK.
3. Zahr F. CLASP IID randomized trial and registry: Two-year outcomes of transcatheter edge-to-edge repair for degenerative mitral regurgitation. TCT 2024, 27–30 October 2024, Washington, DC, USA.
4. ClinicalTrials.gov. Edwards PASCAL CLASP IID/IIF pivotal clinical trial (CLASP IID/IIF). Available at: https://clinicaltrials.gov/study/NCT03706833 [Accessed 3 January 2025].

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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