

Two-year results from the CLASP IID randomized trial: the first head-to-head TEER trial in patients with degenerative MR

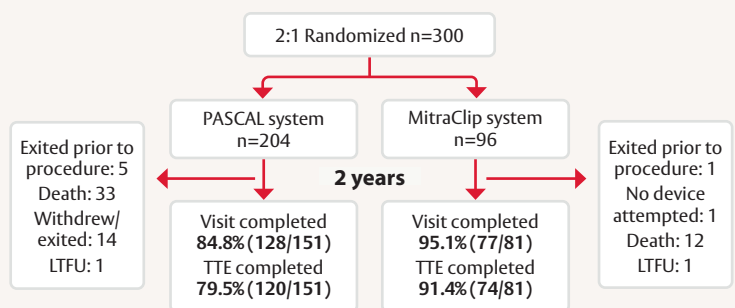
At 2-Years the PASCAL system demonstrates sustained safety and effectiveness for prohibitive surgical risk DMR patients:

- ✓ Favorable survival
- ✓ Significant and sustained MR reduction
- ✓ Significant and consistent improvements in functional status and quality-of-life

Study design

The **CLASP IID trial** is the first prospective, multicenter, multinational, randomized controlled pivotal trial comparing two contemporary TEER therapies in **prohibitive-surgical-risk** patients with **significant symptomatic 3+ or 4+ DMR**¹.

- 54 sites in U.S., Canada, Europe
- Most users were new to the PASCAL system, all were experienced with MitraClip
- Independent Echocardiographic Core Laboratory, Central Screening Committee, Clinical Events Committee and Data Safety Monitoring Board

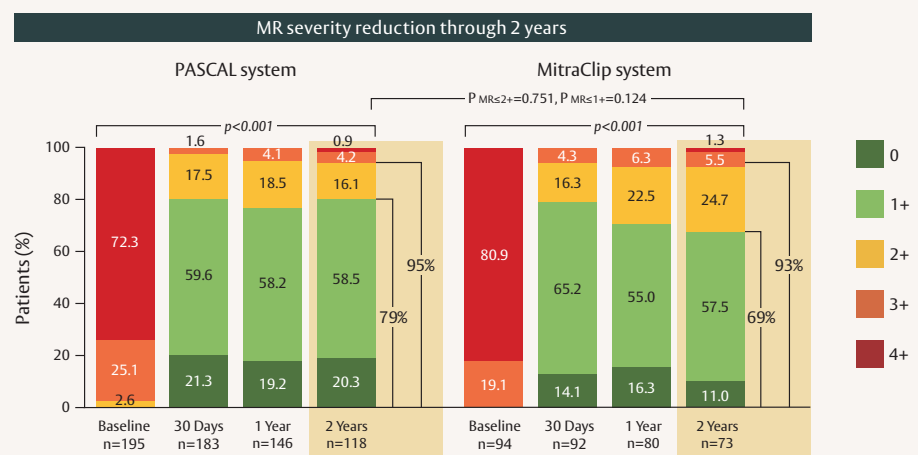


PASCAL system is safe and effective with proven clinical results

The CLASP IID trial met its primary safety and effectiveness endpoints with the PASCAL system demonstrating low 30-day MAE rate and significant MR reduction at 6 months¹. At one year, the PASCAL system demonstrated high survival, significant and sustained MR reduction and improvements in functional and quality-of-life outcomes¹. Here we report the 2 years outcomes of the CLASP IID trial.

Significant and sustained MR reduction at 2 years

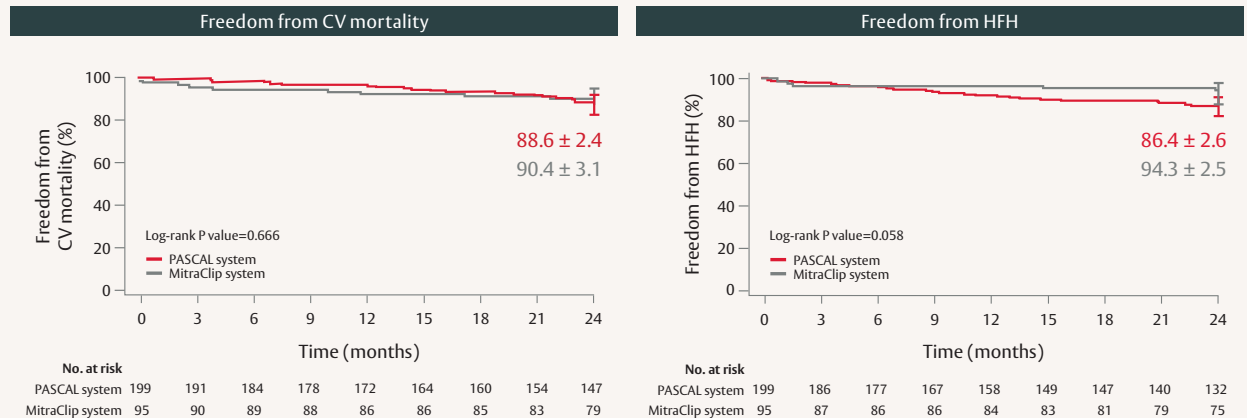
79%
of patients showed sustained MR 0/1+ at 2 years with the PASCAL system



Graph shows unpaired analysis. MR severity assessed by TTE.

MR: mitral regurgitation, TEER: transcatheter edge-to-edge, DMR: degenerative mitral regurgitation, USA: United States of America, LTFU: lost to follow up, TTE: transthoracic echocardiography, MAE: major adverse events.

High freedom from cardiovascular mortality and heart failure hospitalization at 2 years

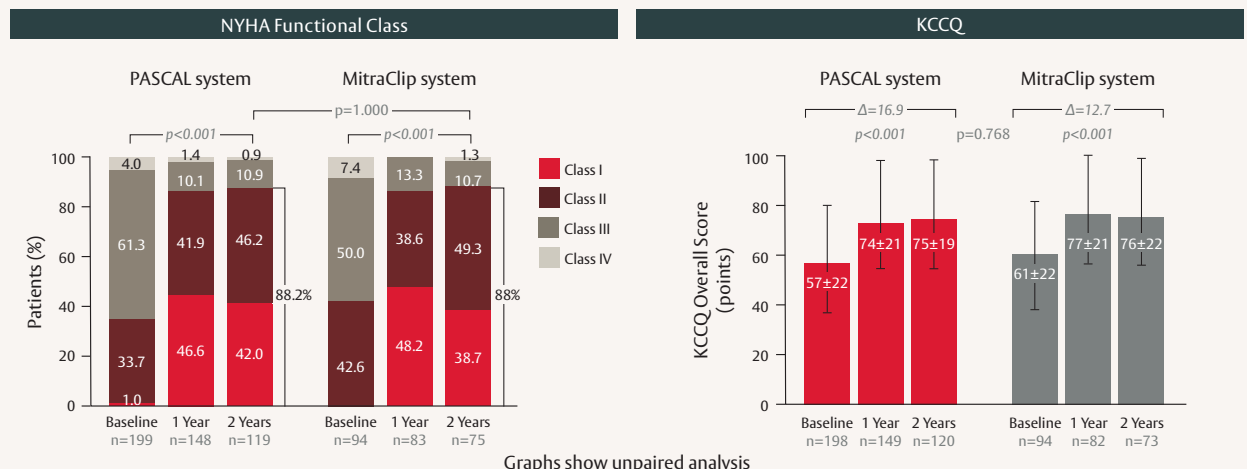


Graphs show Kaplan-Meier analysis time to first event (KM estimate ± SE) and error bars represent 95% CI.

89% freedom from CV mortality at 2 years with the PASCAL system²

86% freedom from HFH at 2 years with the PASCAL system²

Significant and sustained improvements in functional capacity and quality of life at 2 years



88% of patients achieved NYHA Class I/II at 2 years with the PASCAL system²

17 POINT KCCQ improvement from baseline to 2 years with the PASCAL system²

Two-year results from the CLASP IID randomized trial confirm the sustained safety and effectiveness of the PASCAL system in treating a broad population of DMR patients

CV: cardiovascular; HFH: heart failure hospitalization, NYHA: New York Heart Association, KCCQ: Kansas City Cardiomyopathy Questionnaire.

For details on statistical analyses please see reference 2.

References:

1. Zahr F, et al. One-year Outcomes from the CLASP IID Randomized Trial for Degenerative Mitral Regurgitation. *JACC Cardiovasc Interv.* 2023;16(23):2803-2816.
2. Zahr F, et al. CLASP IID Randomized Trial and Registry: Two-Year Outcomes of Transcatheter Edge-to-Edge Repair for Degenerative Mitral Regurgitation. Presented at: TCT Annual Congress; 2024 Oct 30; Washington, DC.

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