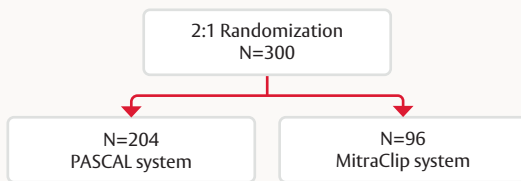


# The first head-to-head trial in TEER for patients with degenerative mitral regurgitation (DMR)

The PASCAL system demonstrated non-inferiority vs the MitraClip system in safety and effectiveness at 1 year

## Study design

Patients who are symptomatic, have 3+ or 4+ degenerative mitral regurgitation (DMR) and are deemed prohibitive risk for surgery.



### Primary Endpoints:

- Composite major adverse events (MAE)\* at 30 days
- MR ≤ 2+ at 6 months

Powered for non-inferiority of the PASCAL system to the MitraClip system

## Study aim

The CLASP IID trial is the first head-to-head randomized controlled trial to directly compare the safety and effectiveness of two contemporary transcatheter edge-to-edge repair (TEER) therapies.



54 sites in the U.S., Canada, Europe



Most users were new to the PASCAL system, all were experienced with MitraClip



Study oversight included independent Echocardiographic Core Laboratory, Central Screening Committee, Clinical Events Committee and Data Safety Monitoring Board

## 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 months.

	PASCAL system	MitraClip system
Composite MAE* at 30 days	4.6% (9/195)	5.4% (5/93)
MR ≤ 2+ at 6 months	97.9% (186/190)	95.7% (88/92)

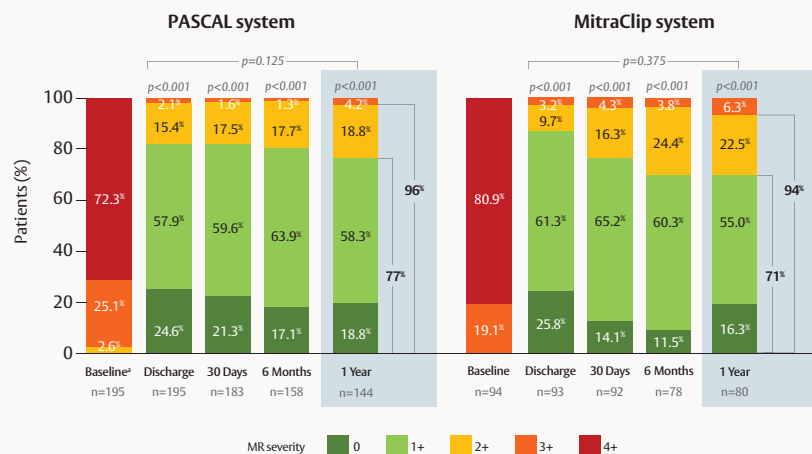
\*Composite MAE rate includes cardiovascular mortality, stroke, myocardial infarction, new need for renal replacement therapy, severe bleeding, and non-elective mitral valve reintervention (either percutaneous or surgical).

## Significant and sustained MR reduction at 1 year

MR severity through 1 year

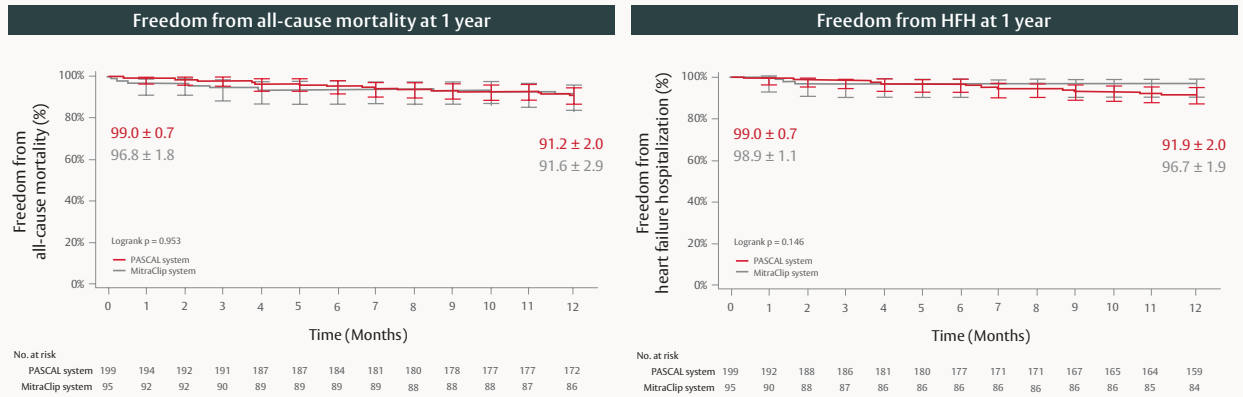
77%

of patients experienced significant reduction to MR ≤ 1+ with the PASCAL system<sup>1</sup>



Echocardiographic Core Lab: Atlantic Health System Morristown Medical Center, Morristown, NJ, USA. TTE: Transthoracic echocardiography, TEE: Transesophageal echocardiography. Graph shows unpaired analysis. P values relative to baseline were calculated using the Wilcoxon signed rank test and P values between discharge and 1 year for MR ≤ 2+ were calculated using the exact McNemar's test. <sup>1</sup>TEE was used for baseline qualification of 5 patients.

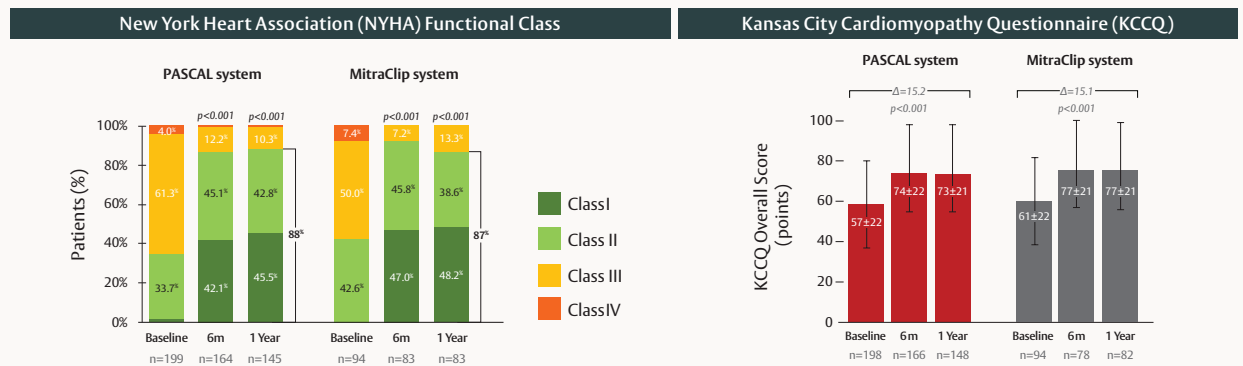
## High survival and low heart failure hospitalization (HFH) rate at 1 year



**91%** freedom from all-cause mortality at 1 year with the PASCAL system<sup>1</sup>

**92%** freedom from HFH at 1 year with the PASCAL system<sup>1</sup>

## Significant sustained improvements in functional capacity and quality of life at 1 year



**88%** of patients achieved NYHA Class I/II at 1 year with the PASCAL system<sup>1</sup>

**15** point improvement on KCCQ from baseline to 1 year with the PASCAL system<sup>1</sup>

### Conclusion

- ✓ One-year results from the CLASP IID randomized trial confirm the safety and performance of mitral valve transcatheter edge-to-edge repair with the PASCAL system for prohibitive surgical risk DMR patients. At one year, the PASCAL system demonstrated:
- High survival and low heart failure hospitalization rate
  - Significant and sustained MR reduction
  - Meaningful and sustained improvements in functional and quality-of-life outcomes

### Reference

1. Zahr F, Smith RL, Gillam LD, et al. One-year Outcomes from the CLASP IID Randomized Trial for Degenerative Mitral Regurgitation. *J Am Coll Cardiol Intv* 2023; Oct 26; [Epub Ahead of Print]; DOI: <https://doi.org/10.1016/j.jcin.2023.10.002>

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