

The first head-to-head trial in TEER for patients with degenerative MR

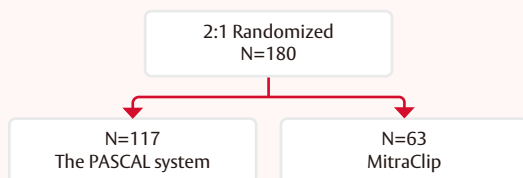


PASCAL Ace implant

PASCAL implant

Study design

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



Primary Endpoints:

- Composite MAEs* at 30-days
- MR ≤ 2+ at 6 months

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

CLASP IID is the first **rigorous, randomised controlled trial** to directly compare the safety and effectiveness of two contemporary TEER therapies.



43 sites in 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 a low composite MAE rate and significant and sustained MR reduction at 6 months.

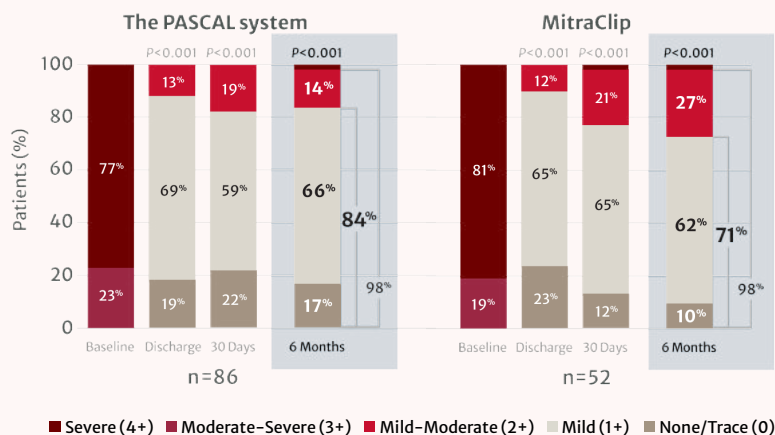
	The PASCAL system (n=117)	MitraClip (n=63)
Composite MAEs* at 30 days	3.4%	4.8%
MR ≤ 2+ at 6 months	96.5%	96.8%

Significant MR reduction

Echocardiographic Core Laboratory assessment at 6 months

84%

MR 0/1+ at 6 months with the PASCAL system

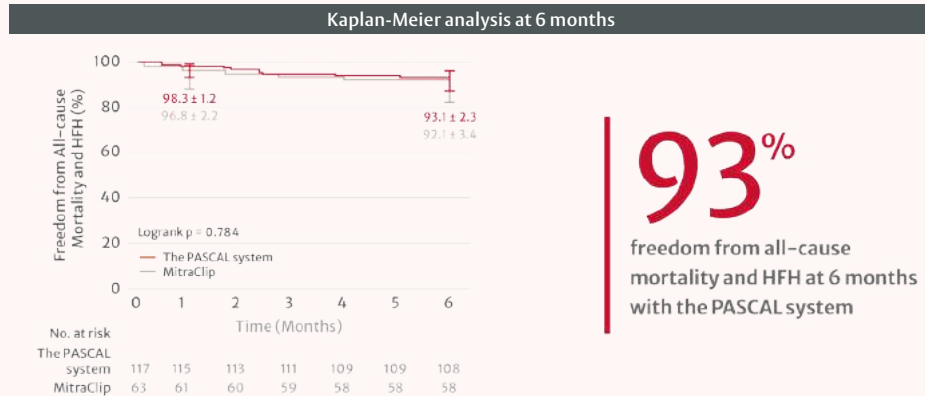


*Composite MAEs include cardiovascular mortality, stroke, myocardial infarction, new need for renal replacement therapy, severe bleeding, and non-elective mitral valve re-intervention (either percutaneous or surgical).

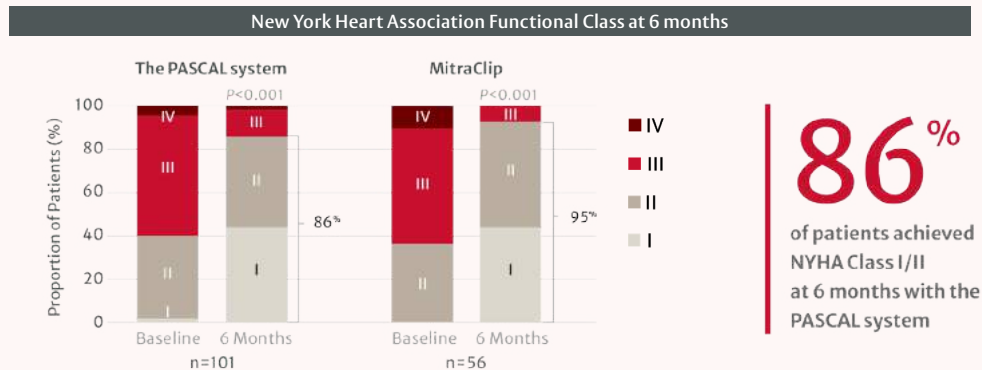


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High freedom from all-cause mortality and HF hospitalisation



Significant improvements in functional capacity and quality of life outcomes



Conclusion

- ✓ The CLASP IID trial, the first randomised controlled trial to directly compare two contemporary TEER therapies, further establishes the safety and effectiveness of TEER for prohibitive risk DMR patients.
- ✓ The CLASP IID trial met its primary endpoint establishing non-inferiority of the PASCAL system compared to the MitraClip system regarding safety and effectiveness.
 - Low composite MAE rate of 3.4% at 30 days
 - Significant and sustained MR reduction with 98% of patients achieving MR $\leq 2+$ at 6 months
- ✓ In early experience, the PASCAL system delivered outstanding outcomes: low complication rates and robust MR reduction, accompanied by high survival and significant improvements in functional capacity and quality of life at 6 months.
- ✓ The PASCAL system delivered sustained MR $\leq 1+$ durability with 84% of patients at MR $\leq 1+$ at 6 months.

Reference

1. Results from the CLASP IID randomized, controlled pivotal trial for degenerative mitral regurgitation in prohibitive surgical risk patients. NCT03706833

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