

Core-Lab Adjudicated Contemporary Clinical Outcomes at 1 Year with MitraClip™ (NTR/XTR) System from Global EXPAND Study

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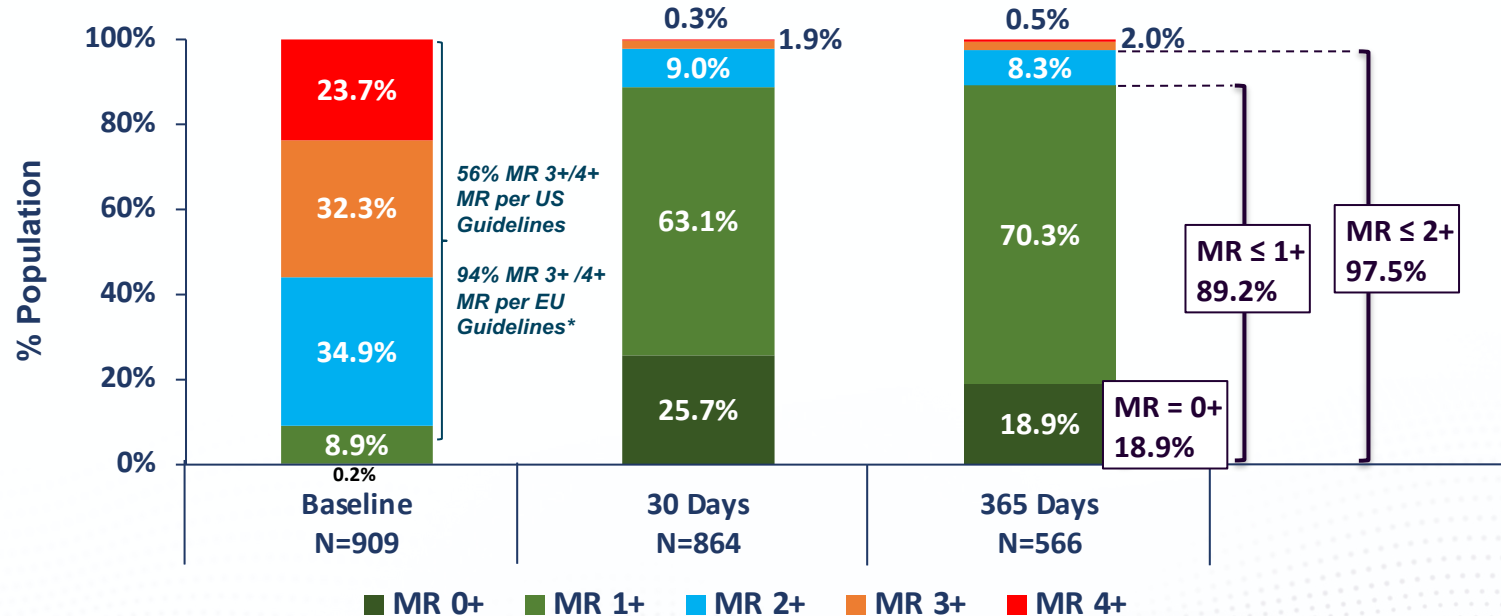
EXPAND Study Design

- **DESIGN:** Prospective, multi-center, international, single-arm study that enrolled 1041 subjects at 57 centers in United States and Europe.
- **KEY OUTCOME MEASURES:**
 - MR Severity, Procedural Outcomes, Major Adverse Events (MAE)
 - Survival and Heart Failure Hospitalization
 - Quality of Life (KCCQ score) and Functional Assessments (NYHA class)
- **DATA ADJUDICATION:**
 - Echo core laboratory (ECL): MR Etiology, MR Severity*, detailed baseline mitral valve anatomic characterization, LV dimensional measures
 - Clinical Events Committee (CEC): Major adverse events (all-cause mortality, MI, Stroke, Non-elective CV surgery related to device related complications)
 - Independent Physician Committee: Single leaflet device attachment (SLDA) and leaflet injury events

*MR severity assessed per ASE Guidelines** consistent with prior MitraClip trials (e.g. EVEREST II, REALISM, COAPT etc.)

**Zoghbi et al. J Am Soc Echoc 2003;16:777-802, 2017;30:303-371, 2019;32:431-475

ECL Adjudicated MR Severity



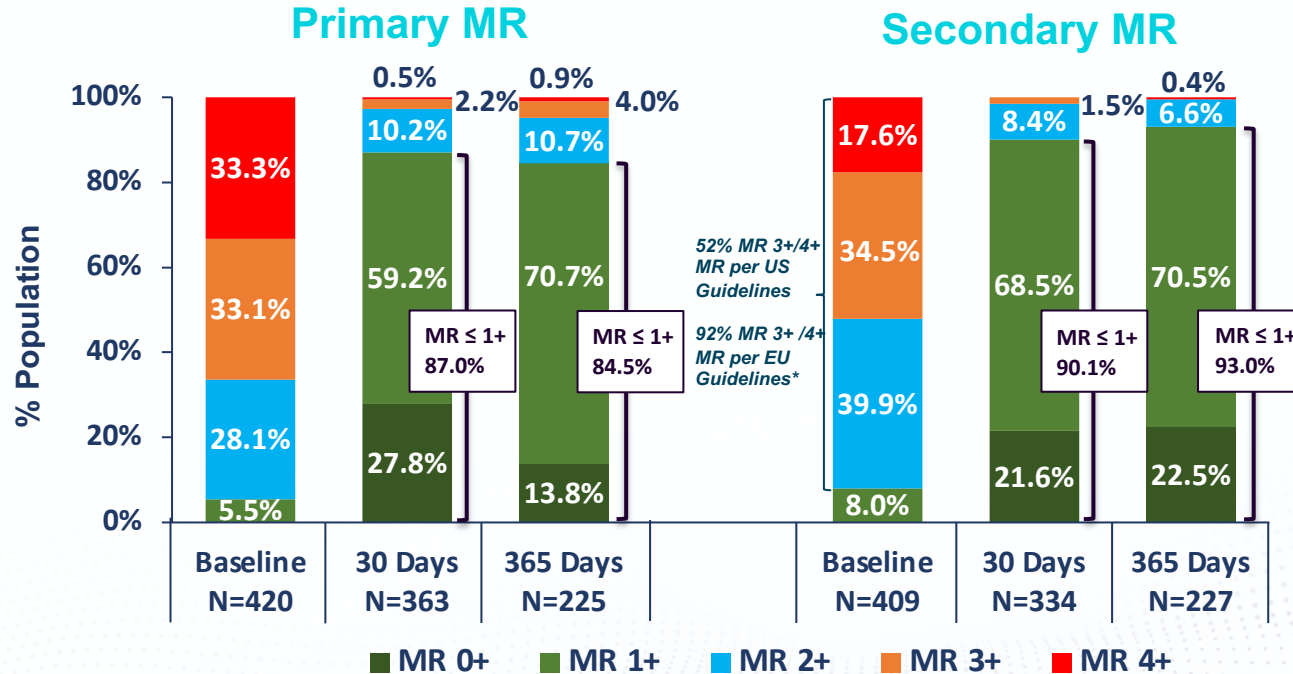
- Significant MR Reduction from baseline through 1 year was maintained; Trace MR was achieved in 18.9%, MR ≤ 1+ was achieved in 89.2% and MR ≤ 2+ was achieved in 97.3% at 1 year follow up.

*von Bardeleben et al. ESC 2019

CRF

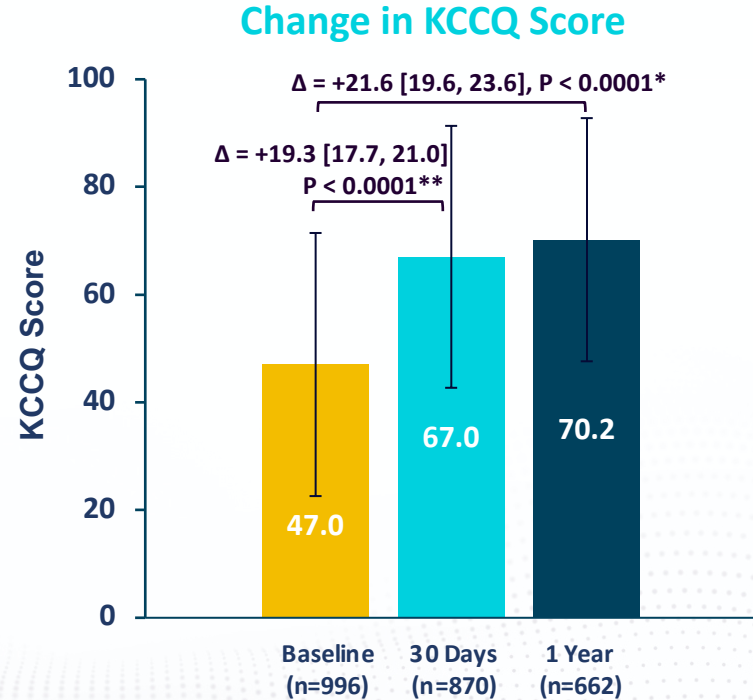
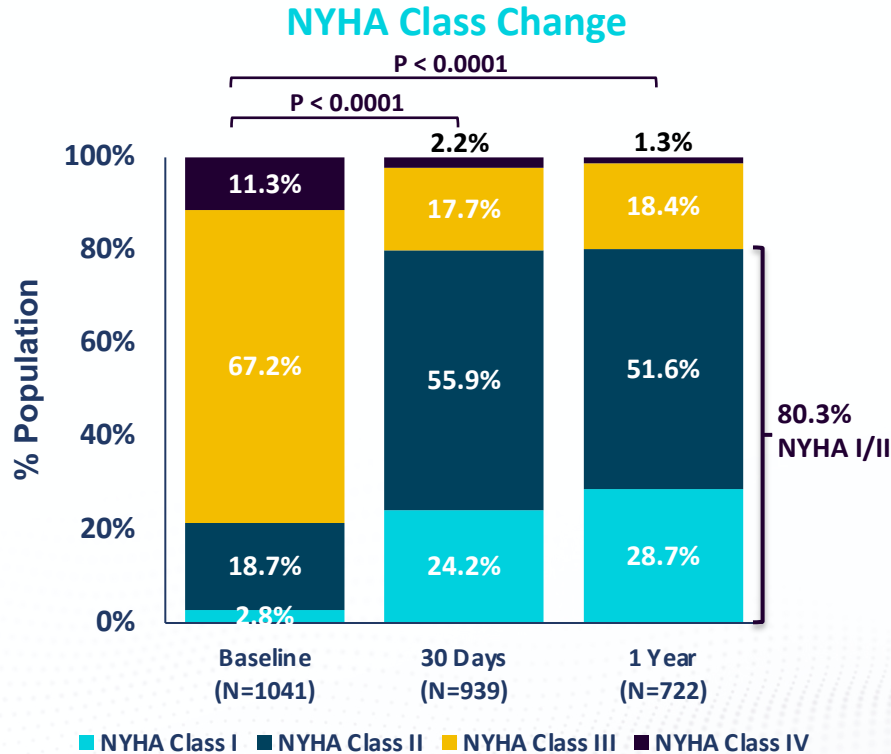
TCT CONNECT

ECL Adjudicated MR Severity by Etiology



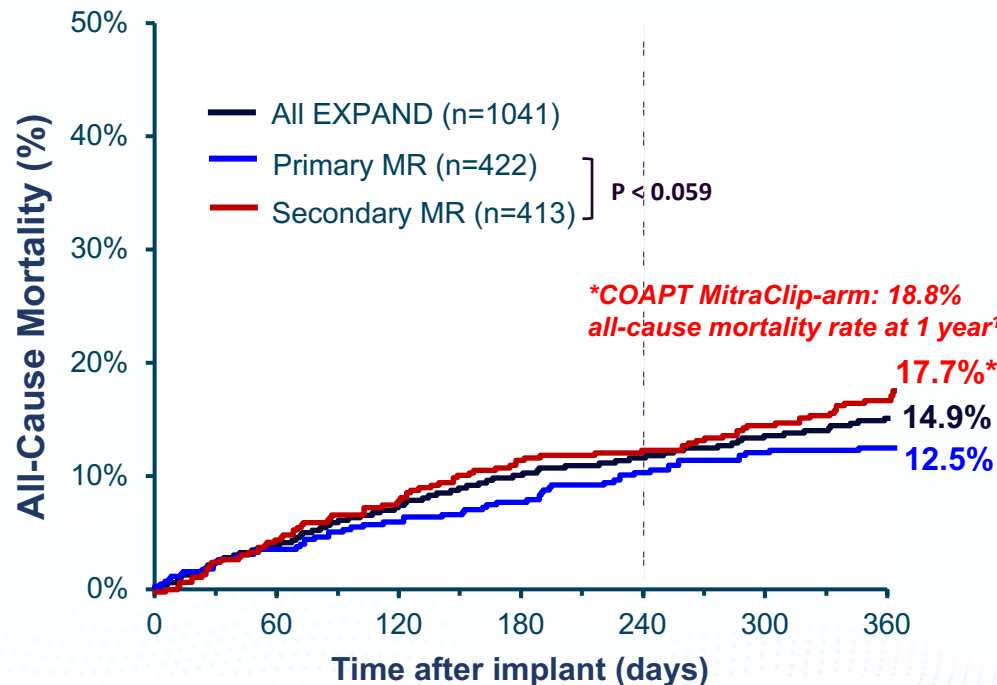
- At 1 Year MR Reduction to ≤ mild maintained in 84.5% and 93% subjects in Primary and Secondary MR respectively.

Functional and Quality of Life Improvement



*Pairwise comparison between Baseline and 1 Year (n=648);
Baseline and 30 day (n=853); 95% CI shown in brackets

1 Year Mortality and Adverse Events



at Risk:

All EXPAND	1041	1002	890	583
Primary MR	422	406	376	256
Secondary MR	413	399	341	212

Adverse Events	All EXPAND n=1041	PMR n=422	SMR n=413
All-cause Mortality	14.9% (147)	12.5% (51)	17.7% (68)
MI	1.2% (12)	0.7% (3)	1.5% (6)
Stroke	1.7% (18)	2.4% (10)	1.2% (5)
SLDA**	1.7% (18)	2.4% (10)	1.9% (8)
Leaflet Injury**	0.4% (4)	0.5% (2)	0.5% (2)
MV Stenosis	0.5% (5)	0.7% (3)	0.5% (2)
MV Reintervention	1.9% (20)	2.1% (9)	1.5% (6)

**Single leaflet device attachment (SLDA) and leaflet injury adjudicated by an independent physician committee based on procedural and follow up images, clinical and surgical reports

¹Stone et al. NEJM;379:2307-2318

Conclusions

- This study represents the first contemporary report of 1 year outcomes associated in patients with both primary and secondary MR treated with the third generation MitraClip™ NTR and XTR Systems.
- Results indicate that MR $\leq 1+$ is being achieved more often with the third generation MitraClip™ (compared to prior generations) which is maintained at 1 year.
- Significant reduction in MR was associated with sustained improvements in quality of life and heart failure symptoms at 1 year.
- Introduction of additional clip size, XTR and improvements in the delivery system resulted in greater reduction in MR without an increase in adverse events.