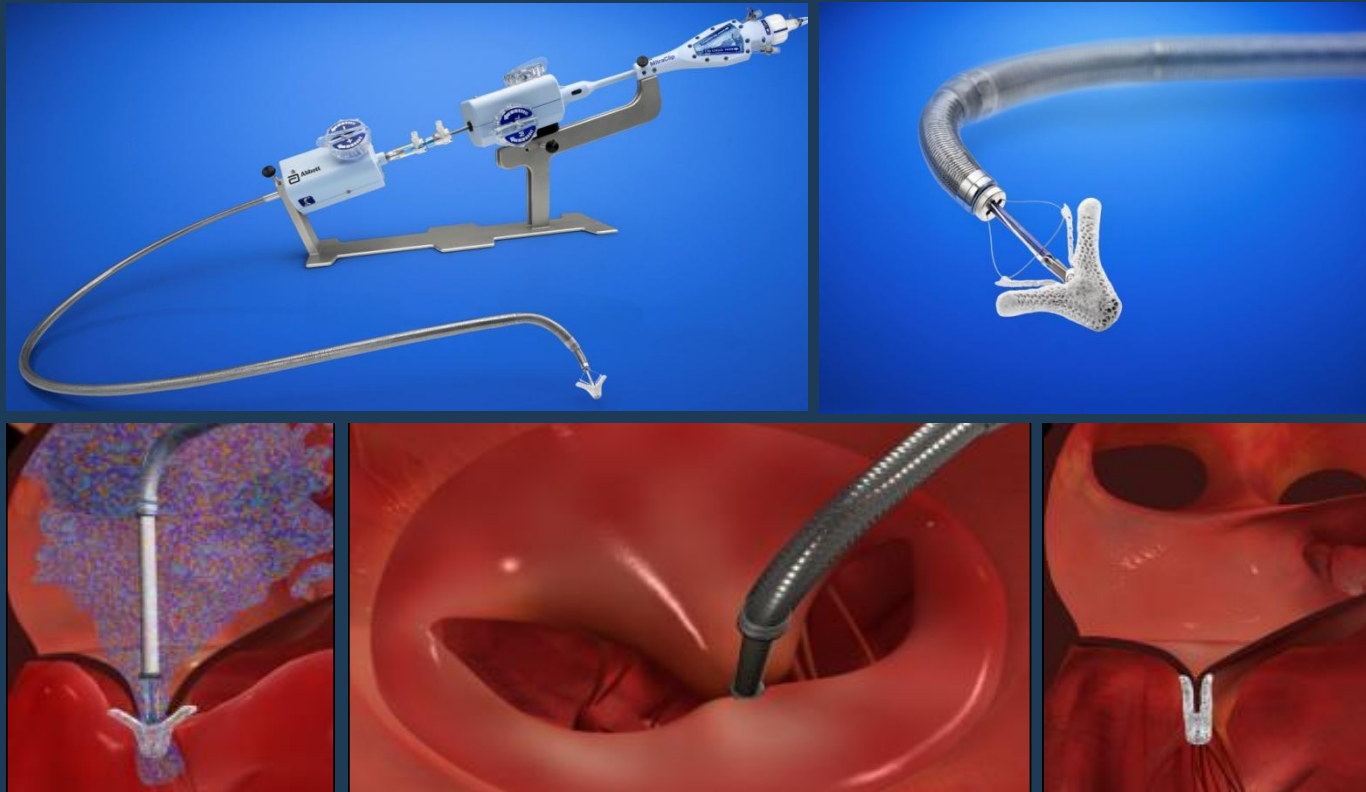


# ACCESS-EUROPE Phase I

## A Post Market Study of the MitraClip System for the Treatment of Significant Mitral Regurgitation in Europe: Analysis of Outcomes at 1 Year

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on behalf of the ACCESS EU investigators



# Baseline Demographics and Co-Morbidities

Demographics and Co-morbidities	EVEREST II RCT Device Patients N=178	EVEREST II High Surgical Risk Cohort N=211	ACCESS EU – MitraClip Patients N=567
Age (mean $\pm$ SD), years	67 $\pm$ 13	76 $\pm$ 10	74 $\pm$ 10
Logistic EuroSCORE, (%)			
Mean $\pm$ SD	NA	NA	23 $\pm$ 18
Logistic EuroSCORE $\geq$ 20%, (%)	NA	NA	45
STS Mortality Risk, (%)			
Mean $\pm$ SD	5 $\pm$ 4	12 $\pm$ 8	NA
STS Mortality Risk $\geq$ 12%, (%)	6	48	NA
Male Gender, (%)	64	61	64
Coronary Artery Disease, (%)	47	81	63
Previous Cardiovascular Surgery, (%)	23	58	37
Myocardial Infarction, (%)	22	49	32
Cerebrovascular Disease, (%)	8	21	13
Moderate to Severe Renal Failure, (%)	3	31	42
Atrial Fibrillation, (%)	33	64	68
NYHA Functional Class III or IV, (%)	50	86	85

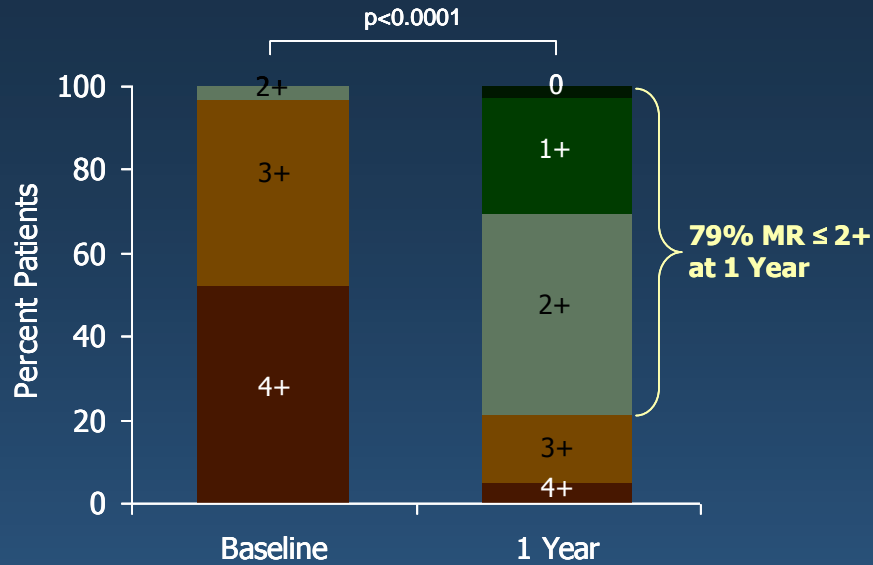
# Site Reported Safety Events At 30 Days

1-Year Events*	All Patients N=567	Logistic EuroSCORE $\geq 20\%$ N=253	Logistic EuroSCORE $< 20\%$ N=314	p-value
Death	19 (3.4%)	11 (4.3%)	8 (2.5%)	ns
Stroke	4 (0.7%)	3 (1.2%)	1 (0.3%)	ns
Myocardial Infarction	4 (0.7%)	2 (0.8%)	2 (0.6%)	ns
Renal Failure	27 (4.8%)	16 (6.3%)	11 (3.5%)	ns
Respiratory Failure	4 (0.7%)	3 (1.2%)	1 (0.3%)	ns
Need for Resuscitation	10 (1.8%)	7 (2.8%)	3 (1.0%)	ns
Cardiac Tamponade	6 (1.1%)	3 (1.2%)	3 (1.0%)	ns
Bleeding Complications	22 (3.9%)	12 (4.7%)	10 (3.2%)	ns

\* As reported by the sites

# Efficacy Results

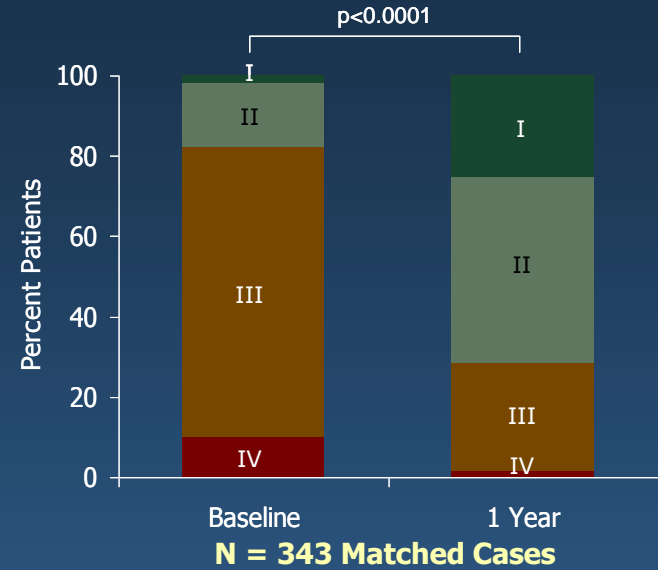
## Mitral Regurgitation Grade\*



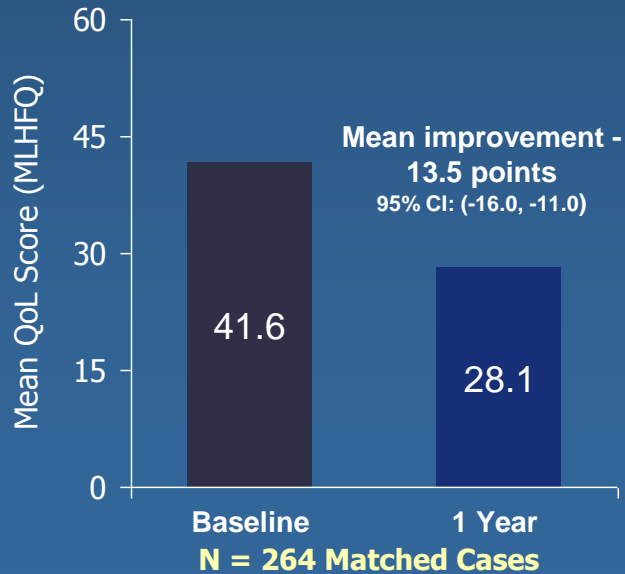
\*As assessed by the sites

**N = 327 Matched Cases**

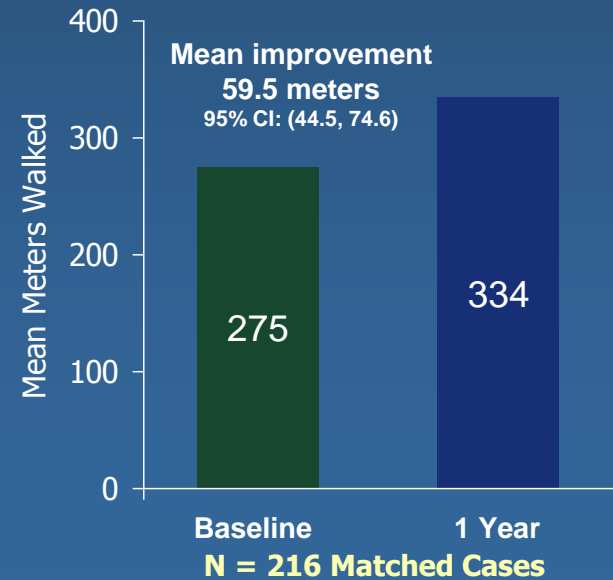
## NYHA Functional Class



## MLHFQ



## 6MWT



# Conclusion

- The MitraClip procedure provides significant clinical benefits to patients with severe MR in a real world setting consistent with results in controlled clinical trials.
- The MitraClip therapy therefore provides a treatment option for a patient population with an important unmet clinical need.