



EASE Trial - Exhale Airway Stents for Emphysema

- Purpose:* Evaluate safety & efficacy of Airway Bypass
- Population:* Homogeneous emphysema subjects
RV/TLC > 0.65
- Design:* Randomized (2 treated : 1 control),
double blind
- Control:* Bronchoscopy sham
- Size:* Bayesian Model
Adaptive stop at 315 subjects
- Follow-up:* Day 1; Months 1, 3, 6 and 12;
Years 2-5 (Treatment Group Only)

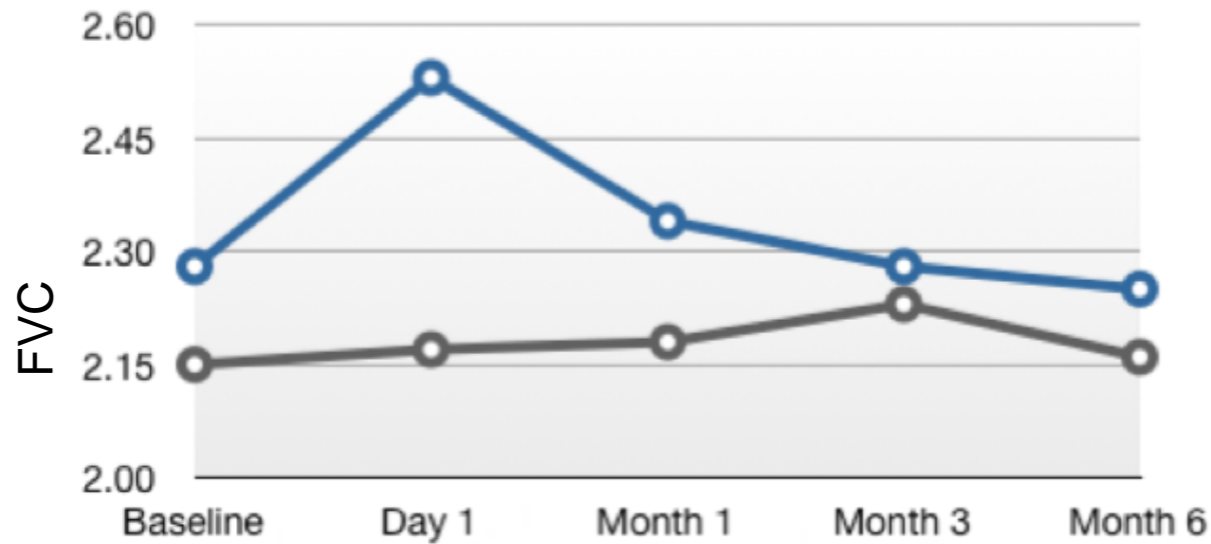


6 Month Primary Safety Endpoint

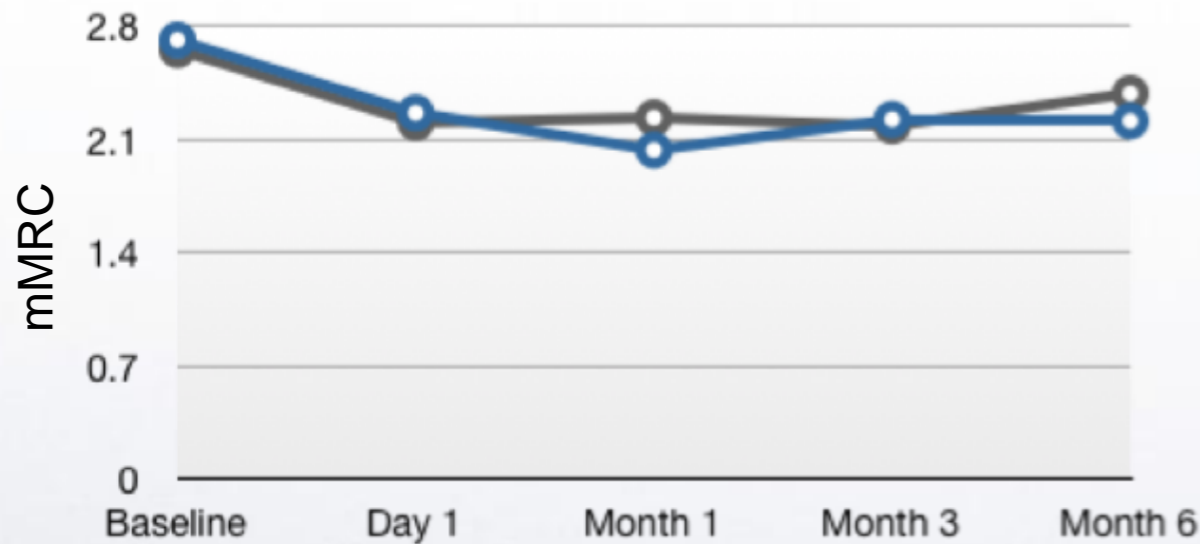
Composite Endpoints Rate	AIRWAY BYPASS (n = 208)	CONTROL (n = 107)
Hierarchical Total	15.9% (33 subjects)	12.1% (13 subjects)
Respiratory failure with (mechanical ventilation \geq 24 hr)	1.9% (4)	0
Pneumothorax with tube drainage > 7 days	1% (2)	0
Major Hemoptysis (\geq 200mL)	0.5% (1)	0
Pulmonary infection or COPD (hospitalized >7 days)	10.6% (22)	8.4% (9)
Death (\leq30 days & respiratory)	1.9% (4)	3.7% (4)



Primary Endpoint Components



For Airway Bypass, FVC increases day 1
Returns to baseline by Month 3
Control unchanged



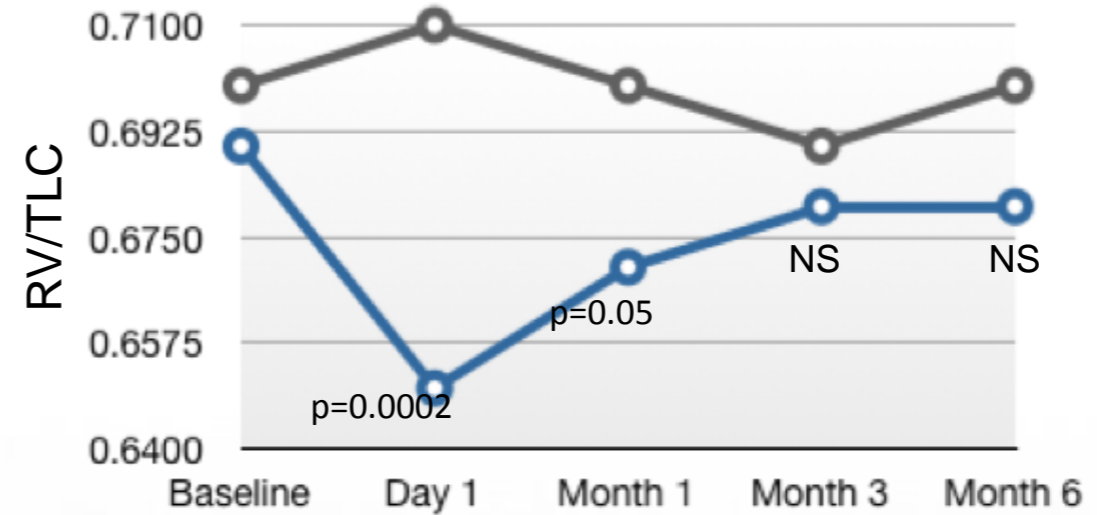
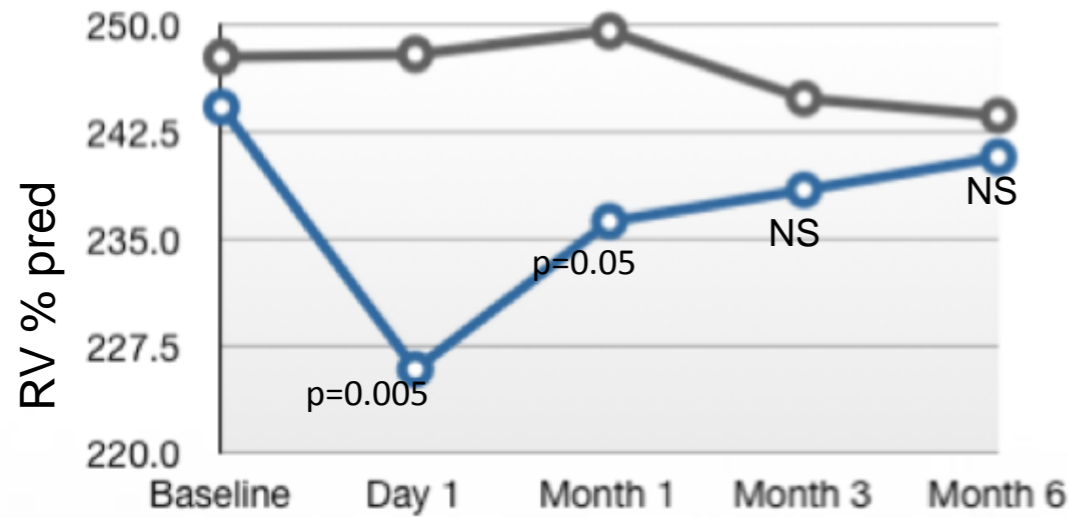
mMRC decreases in both groups after baseline
No differences between groups

Responder Rate

AB	16.4	13.4	11.8	14
SC	5.2	11.3	11.6	11

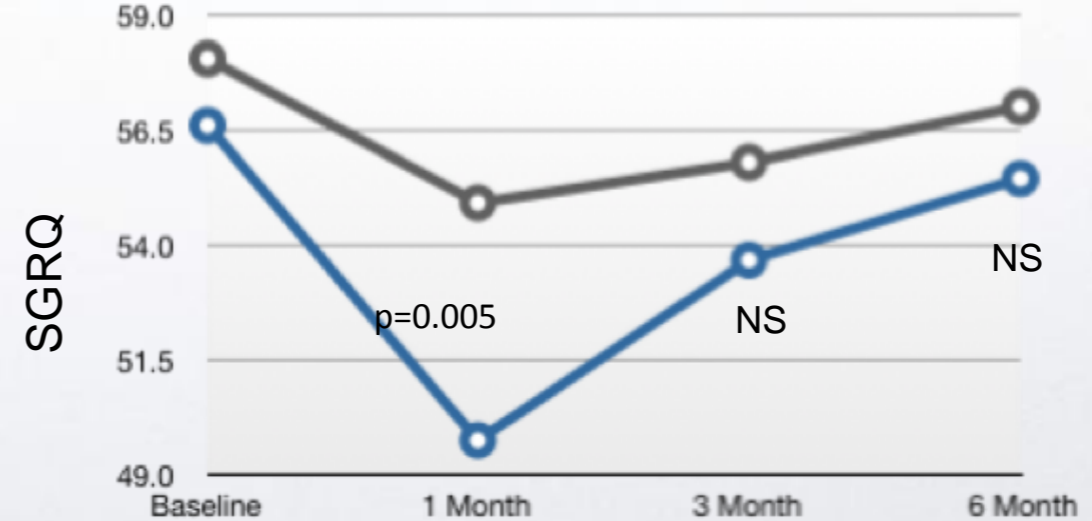
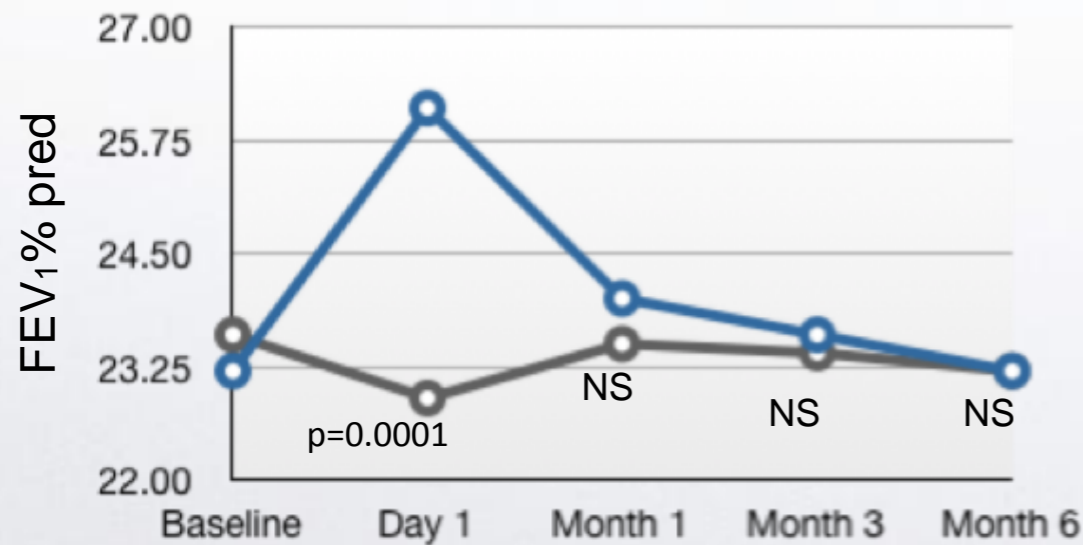


Secondary Endpoint Components



○ AB Mean

○ SC Mean





Airway Bypass Conclusions

- “Proof of principle”
 - ↓ of hyperinflation
 - ↑ in lung function & patient centered outcomes
- Good Safety Profile:
- Benefit declines over time
 - Stent occlusion main reason for decline
 - Factors to improve durability being investigated