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Title: Long-term response of upper airway stimulation in obstructive sleep apnea

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Body: Background: Previous studies identified patient selection criteria for therapy success in Upper Airway Stimulation (Inspire Medical Systems, USA) for treatment of moderate-to-severe OSA in patients intolerant to continuous positive airway pressure. The current study reported therapy response at 12-months post-implant in subjects who met selection criteria. Methods: Among 34 implanted subjects, 18 met criteria for responder and 16 did not. AHI (Level 1 monitoring) were measured at 12 months. All patients were monitored for device-related adverse events and patients met selection criteria were examined for therapy response during over-night PSG. Results: There were no device malfunctions or un-anticipated device-related adverse events from 6-12 months. Among patients who met selection criteria and for which data are available, the AHI reduction was maintained at 12-month. Improvement for ESS and FOSQ were also observed in these subjects from baseline to 6-month, 10.7 ± 5.4 to 7.5 ± 4.1 (p=0.03), and 88.8 ± 22.1 to 104.6 ± 13.7 (p=0.01) for ESS and FOSQ, respectively. AHI remained unchanged at 12-month for patients that did not meet selection criteria.

AHI	Baseline	6-Mon	12-Mon
Responders (N=18)	33.9±6.2	17.0±18.5*	11.0±10.8*
Non-responders (N=16)	50.4±17.4	51.3±27.6	46.2±25.6

* indicated significant changes from baseline (p<0.01)

Conclusion: The current study has demonstrated that Upper Airway Stimulation to treat OSA has a sustained therapy efficacy at 12-month post-implant in a selected group of moderate-to-severe OSA

subjects.