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**Title:** Analysis of arousability of upper airway stimulation in obstructive sleep apnea

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**Body:** Background: Previous studies showed that electrical stimulation of the hypoglossal nerve (N XII) can improve obstructive sleep apnea (OSA). In this study we looked to the effect on the different arousals indices in both responders and non-responders. Methods: Upper Airway Stimulation (Inspire Medical Systems, Inc) systems were implanted in moderate-to-severe OSA patients who failed, or were intolerant of CPAP. The system is intended to reduce sleep apnea by stimulating the N XII to advance the tongue-base. AHI (events/hr), Micro Arousal Index (MAI, events/hr), total number of arousals and respiratory arousals were collected using lab-based PSG in 7 patients including comparison of responders (n=4) vs. non-responders (n=3) at baseline (pre-implant) and 6-M post-implant.

Polysomnographic results

	Baseline (pre implant)	6 Months after implantation
Responders (N=4)		
AHI (/h sleep)	32±15	11±7**
MAI (/h sleep)	34±12	9±3*
Total number of arousals	170±55	55±16*
Total number of respiratory arousals	64±31	8±8*
Non-Responders (N=3)		
AHI (/h sleep)	35±14	53±14
MAI (/h sleep)	34±6	38±13

Total number of arousals	200±51	201±81
Total number of respiratory arousals	102±53	125±95

\*  $p < 0.05$ , \*\* AHI reduction of 50% and  $< 20$

All arousal indices decreased statistically significantly in responders and there was no stimulation disturbance seen in the non-responder group. Conclusion: Upper Airway Stimulation to treat OSA has a clear therapy efficacy at 6-M post-implant in a selected group of moderate-to-severe OSA subjects and that there is no arousal effect of the stimulation itself. It confirms the non-arousal effect of N XII stimulation as shown in our earlier pilot study (Arch Otolaryngol Head Neck Surg 2001;127:1216-23).