

Treatment of Obstructive Sleep Apnea with Unilateral Hypoglossal Nerve Stimulation

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Treatment of obstructive sleep apnea (OSA) is particularly challenging in patients who do not tolerate continuous positive airway pressure (CPAP) therapy. Electrical stimulation of the hypoglossal nerve (HGN) is a potential therapy in these individuals, as such stimulation causes activation of the tongue musculature with resultant tongue protrusion and increased pharyngeal airway area. This case-study describes the implantation of a Hypoglossal Nerve Stimulation (HGNS) System and clinical outcomes in one patient.

A 59 year old woman diagnosed with OSA (apnea-hypopnea index, AHI 40.3 events/hr; BMI 33.5 kg/m²) who failed CPAP therapy was enrolled in a feasibility clinical study and implanted with a HGNS System. Surgical implantation of the system required placement of: a cuff electrode on the right HGN; two subcutaneous respiratory sensing leads bilaterally along the costal margin; and an implantable neurostimulator subcutaneously in the right infraclavicular region. Intra-operative fluoroscopic images of the upper airway in the sagittal plane showed anterior movement of the tongue and increased anteroposterior airway dimensions with HGNS (Figure 1).

Following implantation and a healing period of 36 days, a sleep study was performed to determine therapeutically appropriate HGNS settings (pulse width, frequency and current). Stimulation current was increased to a level that optimized inspiratory flow and/or did not cause arousal from sleep. The patient was sent home with the device programmed to deliver nightly HGNS synchronous with inspiration. At 6 months post-implant a sleep study with HGNS was performed. Relative to the pre-implant sleep study, the AHI, arousal index, (Ari), and oxygen desaturation index (ODI) were reduced and daytime symptoms (Epworth Sleepiness Score, ESS) improved (Table 1). The patient reported some minor tongue abrasion in the early treatment period but no severe adverse events have been reported. The patient continues to receive nightly HGNS TherapyTM having used her device for 180 of the last 187 days for an average of 7.5 hours per night.

Awake nasoendoscopy was also performed in this patient to visualise the pharyngeal region(s) during stimulation. Mueller maneuver suggested that the velopharyngeal region was the primary site of narrowing. Stimulation markedly increased cross-sectional area (CSA) in both the oro- and velopharyngeal regions (Figure 2). This suggests that HGNS and anterior genioglossus movement is capable of increasing not only oropharyngeal CSA, as would be expected, but also velopharyngeal CSA, most likely through mechanical coupling of the tongue and soft palate.

This case-study demonstrates the feasibility of long-term HGNS TherapyTM for treating OSA.

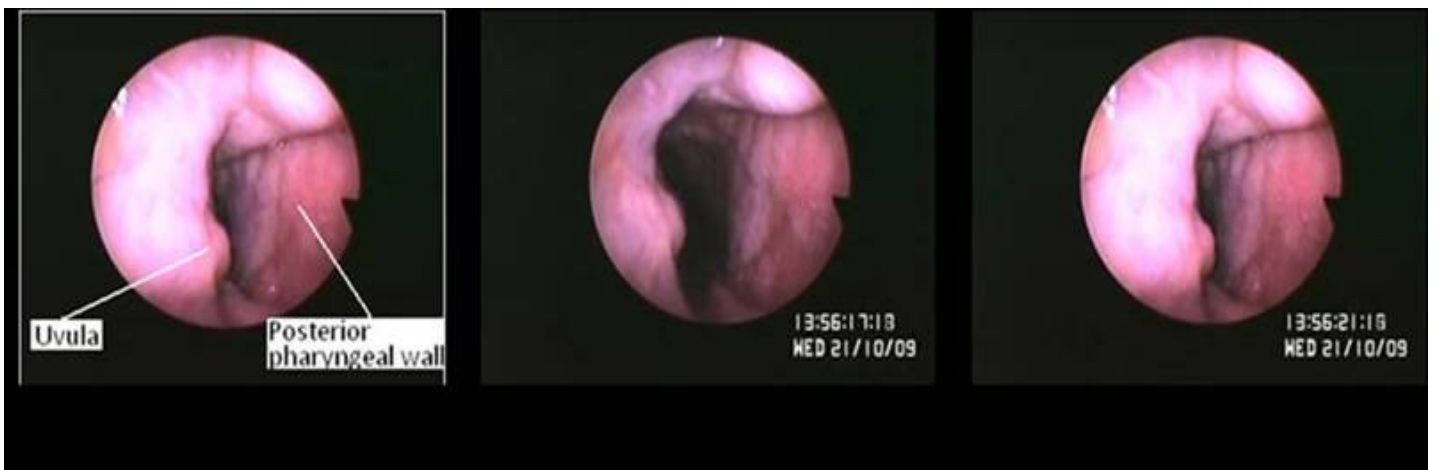
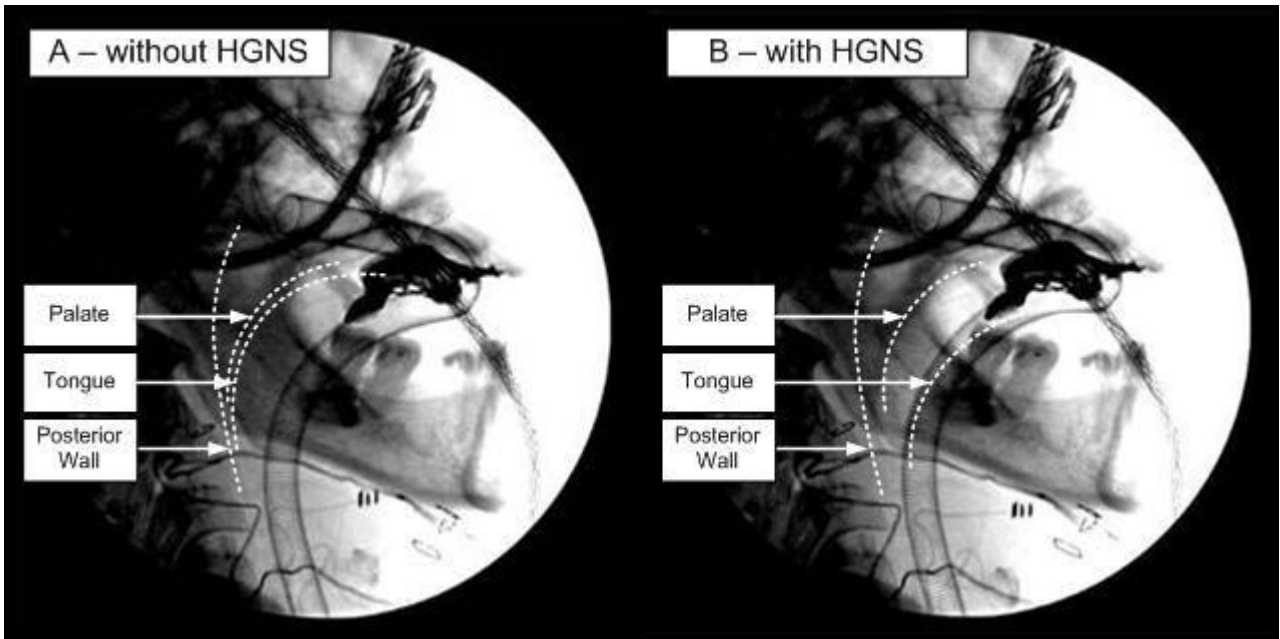


Table 1. Polysomnographic data at baseline and 6 months post-implant.

	Baseline	6 Months
AHI (events/hr)	40.3	15.2
Arl (events/hr)	36.1	10.1
ODI 4% ((events/hr)	19.3	6.4
ESS	9	6