ORIGINAL ARTICLE
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Bilateral hypoglossal nerve stimulation for treatment of adult obstructive sleep apnoea

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A new method of hypoglossal nerve stimulation to treat sleep apnoea does so bilaterally *via* an implanted neurostimulator activated externally. Its simplicity and relative non-invasiveness have not compromised its effectiveness relative to older methods. http://bit.ly/2lDCeif

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ABSTRACT

Background and aim: Hypoglossal nerve stimulation (HNS) decreases obstructive sleep apnoea (OSA) severity *via* genioglossus muscle activation and decreased upper airway collapsibility. This study assessed the safety and effectiveness at 6 months post-implantation of a novel device delivering bilateral HNS *via* a small implanted electrode activated by a unit worn externally, to treat OSA: the Genio™ system.

Methods: This prospective, open-label, non-randomised, single-arm treatment study was conducted at eight centres in three countries (Australia, France and the UK). Primary outcomes were incidence of device-related serious adverse events and change in the apnoea–hypopnoea index (AHI). The secondary outcome was the change in the 4% oxygen desaturation index (ODI). Additional outcomes included measures of sleepiness, quality of life, snoring and device use. This trial was registered with ClinicalTrials.gov, number NCT03048604.
Results: 22 out of 27 implanted participants (63% male, aged 55.9±12.0 years, body mass index (BMI) 27.4 ±3.0 kg·m^{-2}) completed the protocol. At 6 months BMI was unchanged (p=0.85); AHI decreased from 23.7 ±12.2 to 12.9±10.1 events·h^{-1}, a mean change of 10.8 events·h^{-1} (p<0.001); and ODI decreased from 19.1±11.2 to 9.8±6.9 events·h^{-1}, a mean change of 9.3 events·h^{-1} (p<0.001). Daytime sleepiness (Epworth Sleepiness Scale; p=0.01) and sleep-related quality of life (Functional Outcomes of Sleep Questionnaire-10; p=0.02) both improved significantly. The number of bed partners reporting loud, very intense snoring, or leaving the bedroom due to participant snoring decreased from 96% to 35%. 91% of participants reported device use >5 days per week, and 77% reported use for >5 h per night. No device-related serious adverse events occurred during the 6-month post-implantation period.
Conclusions: Bilateral HNS using the Genio™ system reduces OSA severity and improves quality of life without device-related complications. The results are comparable with previously published HNS systems despite minimal implanted components and a simple stimulation algorithm.