

First UK Genio Nyxoah bilateral hypoglossal nerve stimulator implant for obstructive sleep apnoea

BY RYAN CHEONG

Obstructive sleep apnoea remains a very challenging condition to treat, but more options are becoming available.

An estimated eight million adults in the UK suffer from obstructive sleep apnoea (OSA) and experience symptoms of troublesome snoring, daytime sleepiness and witnessed choking and gasping for breath during sleep in addition to the range of serious negative health consequences, including significantly elevated risks of fatal strokes and heart attacks [1]. The pathophysiology of OSA is multifactorial and results in the narrowing and obstruction of the upper airway during sleep.

The usual first-line medical management for obstructive sleep apnoea in addition to lifestyle optimisation is in the form of continuous positive airway pressure (CPAP). CPAP works by delivering pressurised air into the nose and throat and acts as a pneumatic splint to reduce the frequency and severity of upper airway obstruction during sleep. However, the primary challenge with CPAP is that one in three patients find it difficult to tolerate, with a published patient non-compliance rate of 34.1% [2].

I performed the first UK Genio Nyxoah bilateral hypoglossal nerve stimulator implants in December 2024 at the Royal National ENT Hospital, University College

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Figure 1: Schematic of Genio Nyxoah bilateral hypoglossal nerve implant components.

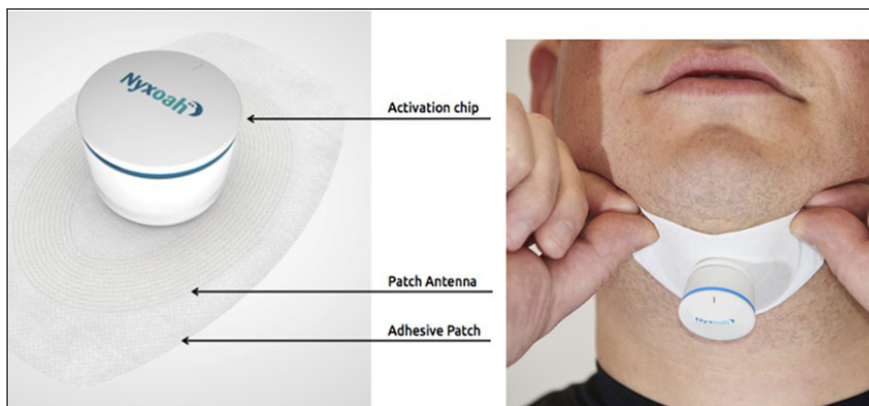


Figure 2: Genio Nyxoah picture of external activation chip and adhesive patch.

London Hospitals, for OSA patients who were unable to tolerate CPAP. The implants have successfully been activated in February 2025 without any complications and patients have reported significant improvements in their quality of sleep and daytime sleepiness.

The Genio Nyxoah bilateral hypoglossal nerve stimulator implant consists of a surgically implantable stimulator, an activation chip connected to a disposable patch and a charging unit for the activation chip, as demonstrated in Figure 1. The external activation chip is applied over the surgically implanted stimulator with the disposable patch every night prior to sleep and removed when the patient

wakes up, as shown in Figure 2. It works by delivering an electrical pulse to both the right and left hypoglossal nerves that approximate the patient's respiratory cycle to move the tongue forward and unblock the upper airway during sleep. It is activated and patient controlled by a proprietary smartphone application.

It differs from the Inspire unilateral hypoglossal nerve implant in certain ways:

1. CE mark approval has been in place since 2019 for the treatment of complete concentric collapse of the palate, which makes up 37% of patients with obstructive sleep apnoea [3].
2. Full body MRI compatibility to 3 Tesla.

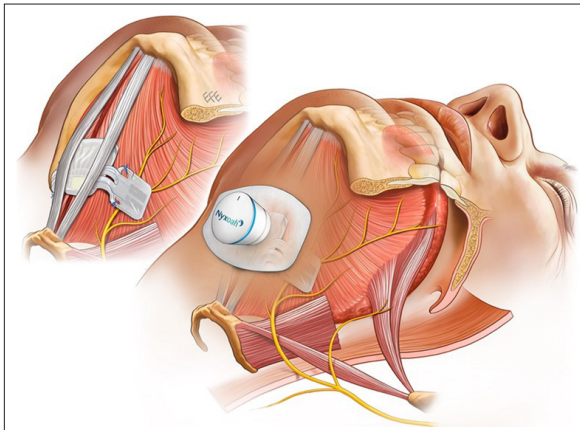


Figure 3: Pictorial diagram of the Genio Nyxoah implant overlying the genioglossus muscles and hypoglossal nerves bilaterally.

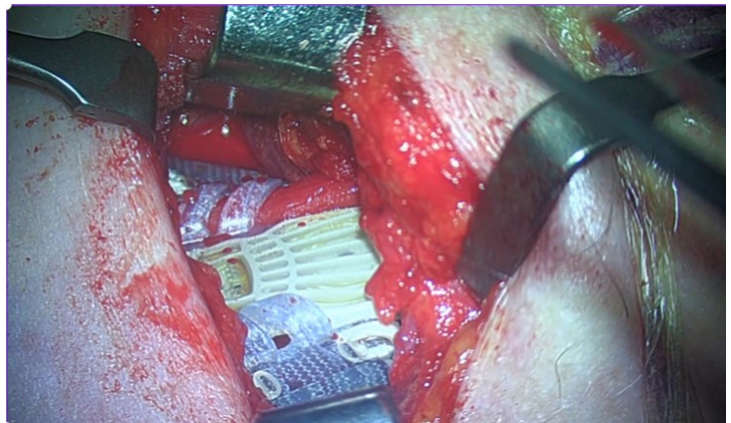


Figure 4: Intraoperative clinical photograph of the first UK Genio Nyxoah implant secured in position overlying the genioglossus muscles and hypoglossal nerves bilaterally.

3. Single incision submental surgical procedure with no risk of pneumothorax.
4. External power source without the need for a further surgical procedure every 10 years.
5. No implanted neck lead, reducing the risk of lead-associated complications.

The surgical procedure involves a submental incision to expose the mylohyoid muscle, followed by dissection to reach the genioglossus muscle and the bilateral branches of the hypoglossal nerve. The implant is then secured in this location, as shown in the diagram (Figure 3) and intraoperative photograph (Figure 4).

The eligibility criteria for the Genio Nyxoah bilateral hypoglossal nerve stimulator implant include:

1. Moderate to severe obstructive sleep apnoea, Apnoea Hypopnoea Index (AHI) 15–65.
2. CPAP non-adherence (intolerance, failure or refusal must be documented).
3. Body Mass Index (BMI) ≤ 35 kg/m².
4. Percentage of central sleep apnoea $\leq 25\%$.
5. Other sleep disorders excluded or treated (e.g. insomnia, restless legs syndrome, periodic limb movements of sleep).

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The Genio Nyxoah DREAM multicentre pivotal trial with 115 enrolled patients reported achieving all its primary efficacy endpoints, including an AHI responder rate of 63.5% ($p=0.002$), Oxygen Desaturation Index (ODI) responder rate of 71.3% ($p<0.001$) and median 12-month AHI reduction of 70.8% with a serious adverse events rate of 8.7% including dysphagia and device dislocation [4].

Prior to the commencement of neurostimulation therapy for OSA patients, it is important to consider developing the capabilities of a robust sleep surgery unit. This includes diagnostic capabilities, such as level 1 polysomnogram sleep studies, and anaesthetic skillset for drug-induced sleep endoscopy (DISE). A sleep multidisciplinary team with close working relationships with respiratory and sleep physicians is also essential. Additionally, the unit should have the surgical skills for other forms of reconstructive and ablative sleep surgery procedures for patients who do not meet the eligibility criteria for a hypoglossal nerve stimulator implant. Having previously successfully completed the first female Inspire unilateral hypoglossal nerve stimulator implant in the UK for OSA in June 2024, my team and I were able to seamlessly integrate both the Inspire and Genio Nyxoah hypoglossal nerve implants to offer the full spectrum of personalised non-CPAP treatment options to our OSA patients.

References

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