

# Successful removal and reimplant of vagal nerve stimulator device after 10 years

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### Abstract

The number of implanted vagal nerve stimulators is growing and the need for removal or revision of the devices will become even more frequent. A significant concern about Vagus Nerve Stimulation (VNS) therapy is the presence of the spiral stimulating electrodes, wrapped around the nerve, once treatment is considered ineffective or is no longer desired. Our purpose is to demonstrate the feasibility of complete removal and replacement of the vagal nerve stimulator electrodes using microsurgical technique even after a long period, without damaging the nerve. We attempted removal and replacement of spiral stimulating electrodes from a patient who received a 10-year long VNS therapy for drug-resistant epilepsy. Our results indicate that the spiral electrodes may be safely removed from the vagus nerve, even after several years. The reversibility of lead implantation may enhance the attractiveness of VNS therapy. Furthermore, with a correct microsurgical technique, it is possible to respect the normal anatomy and functionality of vagal nerve and to reimplant a new VNS system with all its components, maintaining the same therapeutic efficacy after many years.

### Key Words

Electrical stimulation, epilepsy, epilepsy surgery, pharmaco-resistant epilepsy, vagus nerve stimulation

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*Ann Indian Acad Neurol 2012;15:128-9*

### Introduction

The first vagal nerve stimulator was implanted in 1988 and actually Vagus Nerve Stimulation (VNS) is a viable therapeutic option for medically intractable epilepsy when elective epilepsy surgery is not appropriate.<sup>[1-3]</sup>

VNS therapy is increasingly used for refractory epilepsy control in most epilepsy surgery centers and it is considered a key tool in the armamentarium of epilepsy clinicians. Therefore, an increasing need for the removal and/or the replacement of the device in the near future is possible. Implantation of device and electrodes is a relatively simple procedure and has been previously described.<sup>[1-5]</sup> Attachment of the electrodes to the vagus nerve involves the placement of two platinum spiral electrodes and an additional silicone spiral tether around the left vagus nerve.<sup>[4,5]</sup>

Although the generator device may be easily removed, there are concerns about whether removal of the electrodes would cause injury to the vagus nerve, as there is typically fibrosis of the areas surrounding the electrodes and their leads. Commonly used option is to cut off the distal leads leaving the electrodes around the vagus nerve.<sup>[6-8]</sup> However, there are situations in which complete removal of the electrodes is especially desirable. In case of breakage or infection of the leads or abnormalities of the nerve-electrode interface, new stimulating electrodes and leads must be implanted.<sup>[9-11]</sup> We report a case of successful VNS removal and reimplant after 10 years.

### Case Report

A 47-year-old man was implanted with VNS device in 1998 in another institution. He had pharmaco-resistant epileptic encephalopathy and did not qualify for elective epilepsy surgery. He was submitted to two replacements of the pulse generator in 2002 (in an other institution) and finally in 2008 in our center. Few months after the second pulse generator replacement, the patient developed a serious problem in the healing of surgical scar that caused a breakage of the leads of the electrode. Because of the optimal seizure control resulted from VNS treatment, with more than 50% decrease in frequency and number of seizures, we decided to replace VNS with a new system. Therefore, he was submitted to complete removal of the VNS system (pulse generator, leads and electrodes) and to

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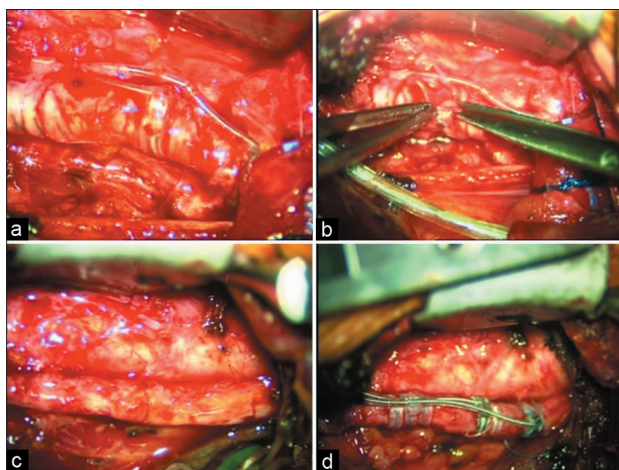


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10.4103/0972-2327.94997



**Figure 1:** The images show the microsurgical pattern of elicoidal electrode removal and reimplant around vagal nerve. (a) Old electrodes enveloped in fibrotic tissue, (b) piecemeal removal of electrodes and silicon spiral tether, (c) vagus nerve anatomical preservation, (d) new electrode implantation

an *ex novo* implant procedure [Figure 1]. The removal of the helical electrode was performed with the aid of an operating microscope; dense scar and fibrosis that linked electrodes to left vagal nerve were peeled out by microscissor and the electrodes and the silicone spiral tether were cut and piecemeal removed [Figure 1a and b]. The lack of gross changes of the vagus nerve observed after electrode removal was impressive [Figure 1c]. When new VNS electrodes were placed cranial to the site of the removed electrodes [Figure 1d], an excellent nerve–electrode interface was achieved, with impedances comparable to those achieved during implantation in naive subjects.

## Discussion

The increased use of vagal nerve stimulation for control of intractable epilepsy will necessitate the occasional removal or replacement of the vagal nerve electrode. In literature, only a few papers have reported about this condition, and to our knowledge, this is the first case of a complete removal and replacement of VNS after 10 years.<sup>[6-8]</sup> In accordance with the method described by MacDonald and W. T. Couldwell, we prefer to use microsurgical straight scissors rather than tenotomy scissors to remove the electrode and we remove the anchoring loops and the electrodes sequentially in a caudal-to-cranial direction.<sup>[6]</sup>

The present case demonstrates that VNS electrodes may be safely removed even after a very prolonged period (10 years) of implantation with preservation of vagus nerve anatomical and functional integrity. The feasibility of electrode and lead removal may increase the appeal of VNS therapy since it appears to be a reversible procedure and does not necessarily result in retained electrodes and leads. Also, in our case,

the impedances were comparable to those achieved during implantation in naive subjects, as described by Espinosa *et al.*<sup>[7]</sup>

These observations suggest that very little changes occur in the vagus nerve as a result of long-term stimulation and are consistent with reports on long-term safety and a normal post-mortem histologic examination of a chronically stimulated human vagus nerve.<sup>[7]</sup>

## Conclusion

Our case confirms that electrode and lead removal and reimplant are technically feasible without obvious adverse effects on the vagus nerve even after a very prolonged period of implantation, with an optimal anatomical and functional preservation of vagus nerve.

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**How to cite this article:** Giulioni M, Martinoni M, Naldi I, Bisulli F, Pozzati E, Tinuper P. Successful removal and reimplant of vagal nerve stimulator device after 10 years. *Ann Indian Acad Neurol* 2012;15:128-9.

**Received:** 04-10-10, **Revised:** ???, **Accepted:** 05-11-10

**Source of Support:** Nil, **Conflict of Interest:** Nil