Surgical Technique to insert and retrieve BIONs® (microstimulators) safely near deep Nerves for Functional Electrical Stimulation.

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Abstract
The first generation BIONs® have a glass encased microstimulator with an external tantalum capacitor electrode and have been injected through a 12-gauge (OD: 2.8 mm) needle. This second generation of BION® devices are encased in a ceramic cylinder, approximately 10 times stronger than the glass case, with platinum-iridium electrodes. Over a period of 7 months, a surgical technique has been developed to insert this BION® through a 5 mm incision, using a stimulating electrode probe to find the deep nerves, followed by a tailored plastic introducer (dilator + sheath) used to insert and test the BION’s® position before depositing it adjacent to the nerve. The BION® can be retrieved up to the next 8-10 days by reopening the small wound and withdrawing a subcutaneous placed suture attached to the BION’S® proximal end. The BION® can then be reinserted. Beginning in June 2001, 10 sheep had a total of 34 BIONs implanted adjacent to the hypoglossal nerves in the lower jaw. All BION® units implanted and stimulated have continued to produce visible movement of the tongue as view through an endoscope, except one that functioned at the time of implant.

1. Introduction
The BION® system is a wireless network of up to 255 single-channel microstimulators controlled and powered by an RF link from a central controller. Each stimulator is encased by a ceramic cylinder capped with a cathode and an anode of platinum-iridium. The BION® is 15.6 mm long and 2.3 mm in diameter. Each stimulator produces asymmetric biphasic capacitively-coupled constant-current pulses. Pulse width (0 to 500 µsec), pulse amplitude (0 to 40 mA) and pulse frequency (0 to 800pps per BION®, with 3,472 pps shared among all active BION® microstimulators) are controlled digitally and powered by the controller via a 2 MHz AC magnetic link. [1].

A] BION® Injection Technique.
In 2001, Dupont et al. [2] reported the use of the glass-cased BIONs® (2 mm x 16 mm) injected with a 12-gauge needle (OD: 2.8 mm) into shoulder muscles of 5 post-stroke patients, to reduce subluxation and improve muscle strength. They also reported on 3 patients with osteo-arthritis of the knees, who were undergoing quadriceps muscle stimulation following the injection of BIONs®. Pre-clinical testing using this technique had been reported by this group [3].

B] BION® Implantation using Open Surgical Dissection.
In 2001, Arcos et al. [1] reported on the ceramic-cased BIONs® implanted by open surgical dissection in rats for periods of up to 5 months. Results show benign tissue reactions resulting in identical encapsulation around BIONs® and controls. Stimulation threshold levels did
not change significantly over time.

2. Method and Results

Beginning June 2001, each of 2 sheep under general anesthesia, had a BION® unit implanted bilaterally adjacent to the hypoglossal nerves in the lower jaw using a posterior approach. A 5 mm skin incision was made 2 cm anterior to the carotid vessels. A probe electrode (OD: 0.76 mm; Tip: 0.71 mm rounded; Fig. 1B), attached to an external battery operated stimulator, was directed medially, upwards and anteriorly to find the hypoglossal nerve. This was shown by stimulation and observing tongue contractions via an endoscope. A 10 cm plastic Venous Introducer (outer sheath + inner dilator; Medamicus, Inc., Plymouth, MN) was used to insert the BION®; the sheath’s OD: 2.96 mm and ID: 2.44 mm. The Introducer was passed down over the probe electrode; stimulation was repeated to confirm the nerve’s response (Fig. 1C). The probe electrode was withdrawn; the sheath was released from the dilator and slide down to the tip. The dilator was removed. Small holes had been machined 10-15 mm from the tip to allow electrical contact of the BION® anode with the tissue. Saline was injected down the sheath. The BION® was slide down the sheath, cathode-end first. The R.F. coil was held over the jaw to activate the BION® to stimulate the hypoglossal nerve, causing tongue contractions. The BION® was then gently deposited from the sheath, by holding the dilator against the BION® and sliding the sheath up over the BION® (Fig. 1D). Retesting of the BION® was then done.

The question arose regarding removal of the BION®, and for repositioning after it had been released from the sheath. It was decided to weld a small eyelet on to the anodal end so a suture could be attached allowing the BION® to be withdrawn. After testing successive sheep for BION® + eyelet + suture implantations and removals; it was possible to retrieve the BION® the same day of implantation, and at 3rd and 6th day post-implant. However, when tried on the 21st day, the BION® was non-retrievable due to encapsulation; a cut down was required to remove it. Because of the window of opportunity to remove the BION® extending probably to 8-12 days, a decision was made to use only absorbable mono-filament 5 ‘O’ suture, the end of which is sutured to the subcutaneous tissue, and the 5 mm wound is closed.

Eight sheep were implanted with the BION® + eyelet + suture attachments. Each sheep also had 2 BIONs® inserted adjacent to each of the hypoglossal nerves, 2 introduced by the posterior and 2 by anterior approaches.

All 34 BION® units implanted have continued to produce visible movement of the tongue as viewed with an endoscope except one that functioned at the time of implant.

Histology and Threshold Tables are in preparation.

3. Summary and Conclusions

The surgical technique to safely insert a microstimulator, such as the BION®, adjacent to deep nerves for FES, does require rounded and small diameter stimulation probe electrodes, as well as plastic Introducers with tapered dilators that do not have sharp edges. The ability to retrieve deeply placed BIONs®, immediately or during the next 8-10 days,
without a cut-down or reinserting another BION®, is an important patient safety factor and good economics.

BION® is the Trade Mark of the Injectable Microstimulator of the Advanced Bionics Corporation, Valencia, CA.

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**References**

