Abstract

Implantable microstimulators have been tested in a variety of clinical applications. To implant these devices, an insertion probe, aided by stimulation, is used to locate the target site. The microstimulator, held by an introducer tool, is directed through a small (5 mm) skin opening into the tissues and is positioned close to a nerve/motor-point. The tool is used to deposit the microstimulator after testing the nerve’s threshold and maximal responses. With the introducer withdrawn, the microstimulator’s effectiveness is retested. If the responses are not adequate, the device cannot be easily retrieved.

The AMF ceramic-cased RF BION ® microstimulator (2.5mm x 16mm) has an eyelet on its anodal end with an absorbable suture attached. This allows the easy removal of the device during surgery (to reposition the devices) and post-operatively (until the device has become sufficiently encapsulated by tissue).

Three patients (obstructive sleep apnea: 2; post-stroke shoulder subluxation pain: 1) have been implanted with 2 microstimulators each. In the 3 implantation surgeries, a total of 9 insertions of RFBs with 3 retrievals were performed intra-operatively. In the 2 OSA patients, 3 of 4 microstimulators were easily removed 6 days post-operatively by re-opening the wound and pulling the attached suture. No difficulties or complications occurred in these explants.

1 Introduction

Clinical success and economics require that a minimal number of microstimulators be accurately implanted adjacent to nerve/motor-point targets for FES. With these demands, a retrieval microstimulator that can be removed without the patient or the device being damaged in the process, and that can be re-inserted for optimal placement represents an advance.

The ceramic-cased RF BION® microstimulator (RFB; Alfred Mann Foundation, Santa Clarita, CA) has an eyelet on its anodal end which allows an absorbable monofilament 4’0’’ suture to be attached to it. This feature facilitates the easy, minimally invasive removal of RFB devices both during surgery (to reposition the devices) and post-operatively (until the device has become sufficiently encapsulated by tissue).

In these situations the RFB device is retrieved by locating the suture, which is gently pulled until the RFB is removed from the wound.

Acute and chronic retrieval studies have been performed using the RFB devices in both animals (sheep) and in 3 humans.

Two initial reports of the animal study were presented at IFESS in 2002-3 [1][2]. The results of the one patient with post-stroke shoulder subluxation pain implanted with 2 RFB devices in the Deltoid muscle are being submitted for presentation at this IFESS Meeting [3][4].

2 Methods

Nine sheep were used to develop the insertion and retrieval techniques for the RF BION® Microstimulator. The target sites were the left and right Hypoglossal Nerves (HGN) using an anterior and posterior approach for a total of 4 RFBs implanted per sheep. These techniques were then applied to the human studies to treat obstructive sleep apnea and pain associated with shoulder subluxation [1-4].

2.1 Intra-operative Retrieval

During the implantation procedure, if the device implant location was not optimal for stimulation effect, the device was retrieved by pulling on the suture and was then re-implanted.
2.2 Post-Operative Retrieval

Post-operatively (up to 6 days post-implant), the device was removed by opening the wound, locating the suture, and pulling on the suture until the device had exited the skin.

3 Results

3.1 Pre-clinical Experience

In a series of 7 sheep there were 28 sites where an RFB was implanted; 5 sites needed to have a retrieval and reinsertion. One site needed 3 retrievals and a total of 4 insertions. A total of 7 device-retrievals were done in 5 of the 28 sites.

In a separate series of 2 sheep, 3 RFBs were retrieved post-operatively. One RFB was retrieved successfully by pulling on the suture at 6 days post-operatively. The other two RFBs were removed at 14 and 21 days post-operatively. Encapsulation prohibited retrieval of these devices by pulling on the suture and therefore, a cut down was needed. All incisions healed without edema, erythema or bleeding. Both sheep are still in study as of April 2004. One sheep has 3 remaining implanted RFBs and the other has 1 remaining implanted RFB.

3.2 Clinical Experience

Two clinical trials are currently being conducted using the RFBs: (1) to evaluate the effect of stimulation of the HGN to treat obstructive sleep apnea; and (2) to evaluate whether stimulation of the deltid nerve (axillary nerve) and motor-point can reduce pain associated with shoulder subluxation in patients post-stroke. In these studies, retrieval of RFBs has been successfully performed by pulling on the suture both intra-operatively and up to 6 days post-operatively.

3.2.1 Obstructive Sleep Apnea (OSA): 2 Patients

OSA Patient #001 had one insertion for each of the 2 RFB implantations, one adjacent to the left HGN and one adjacent to the right HGN. No intra-operative retrievals were done.

Because of inadequate therapeutic results, these 2 RFBs were removed 6 days post-operatively by opening the wound, pulling on the attached suture and withdrawing the microstimulator. No difficulty or complications were reported.

OSA Patient #002 had the left RFB inserted adjacent to the HGN on the second attempt, so one retrieval was necessary. The right RFB was inserted only once, close to the HGN. Because the right RFB did not elicit an appropriate muscular response in testing later that day, this 2nd device was removed 6 days post-operatively by opening the wound, pulling on the attached suture and withdrawing the microstimulator. No difficulty or complications were reported.

3.2.2 Pain Associated with Shoulder Subluxation (SS): 1 Patient

SS Patient #001 had one RFB inserted 3 times close to the Left Axillary Nerve; retrieval was done twice. A second RFB was inserted once adjacent to the Mid Deltoid Motor-point; retrieval was not necessary.

![Figure 1: Anterior Neck. RFB device is retrieved by gently pulling on the suture.](image1)

![Figure 2: Left Shoulder. RFB device is retrieved by gently pulling on the suture.](image2)
Both RF BION® Microstimulators have been functioning effectively on a daily basis for 3+ months. Preliminary results show a constant relief of shoulder pain in this patient to date [3].

4 Discussion and Conclusions

In many implantable electrical stimulation therapies, the norm has been to have a ‘Trial’ period of stimulation for 4-7 days to indicate a probable successful therapy. If success is indicated, then a full electronic system can be implanted; if the therapy is unsuccessful, then the lead and electrodes can be removed, e.g. spinal cord stimulation. These criteria can be realized by using the AMF RF BION® Microstimulators in the first 6 days to evaluate their effectiveness. If they are not effective, preliminary data suggest they can be removed safely under sterile conditions for up to at least 6 days.

References


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