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Attachment of leads to RF-BION® microstimulators

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Abstract

The RF-BION (RFB) is a Radio-Frequency (RF) microstimulator powered and controlled by an AC magnetic field which is intended to be used for electrical stimulation applications. It is housed in a cylindrical ceramic case with the stimulating and indifferent electrodes on opposite ends. Due to its small size (16.7 mm, 2.4 mm) and cylindrical shape, it can be easily injected with insertion tools next to a muscle motor-point or close to a nerve to deliver stimulation. For some clinical applications, however, intramuscular lead electrodes or cuff electrodes may be better suited at the stimulation site. To combine the advantages of RFB devices and electrode leads, a leaded RFB has been developed. The leaded RFB is a standard RFB whose simulating end has been modified to allow connection of a variety of electrodes with leads. The leaded RFB has been successfully implanted in an animal for a chronic experiment where it was attached (1) to a Peterson Intramuscular electrode and (2) to a modified Peterson electrode with the distal 3.2 cm of length exposed.

1. INTRODUCTION

The RF BION device (RFB) is a fully implantable and injectable microstimulator designed to deliver pulses for therapeutic or functional electrical stimulation. It is powered and controlled by an AC magnetic field generated by an external coil. The receiving antenna and the electronic circuit of the RFB are enclosed in a cylindrical ceramic case. The stimulating and indifferent electrodes are located at either end of the case. By virtue of its small size (16.7 mm x 2.4 mm) and its wireless communication system, the RFB can be implanted in a minimally invasive manner, which represents an important advantage over other implantable systems. Besides being used directly as a stimulating device, the RFB can also be attached to a lead for those applications where it is desirable to do so. For example, in an application such as diaphragm pacing [1], the Peterson Intramuscular [2] lead electrode which can be anchored into the thin diaphragm muscle motor-points is better suited. Another example is given by applications which require selective stimulation of a nerve or specific fibers within a nerve. In such cases, cuff or button electrodes are better suited. For combining the advantages of lead electrodes with those of the RFB technology, a leaded RFB has been developed. This new device allows the attachment of different types of lead electrodes, making it suitable for a wide range of applications.

We describe here how the leaded RFB is constructed, and how the key design requirements were met. Surgical crimp tools were developed for attaching the electrode lead to the leaded RFB in a sterile field. Finally, the first animal case was reported where leaded RFB were implanted in a sterile surgical field and crimped to Peterson electrodes.

2. METHODS

2.1. The leaded RFB

The leaded RFB includes a standard RFB device whose stimulating end has been modified to allow an insulated connection of a pigtail lead (Fig. 1, joint 1). The 8 cm pigtail is connected at its distal end to a crimped tube (joint 2). The other end of the crimped tube (joint 3) is designed to be attached to an electrode lead. Insulation of the entire splice is insured by a silicone sleeve which is placed over it and backfilled with silicone.

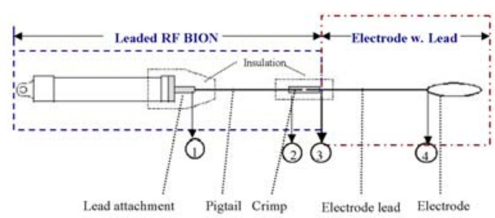

Fig 1: (Top) Diagram of Leaded RFB connected to Electrode with a lead. (Bottom) Leaded RFB.

2.2. Requirements for the leaded RFB

The leaded RFB needed to fulfil some of the same requirements as the standard RFB: hermeticity, strength and bio-compatibility. Moreover, it needed to be designed in a way to avoid galvanic and corrosion problems and had therefore to meet additional requirements. For animal use, the additional requirements included:

- It needed to maintain electrochemical stability for at least a 3-month period.
- The resistance of the pigtail lead including the crimp and the lead attachment needed to be kept at a minimum to have maximum compliance voltage available.
- Insulation and dielectric strength needed to be kept high to prevent any leakage.
- The new joints at either end of the pigtail lead needed to be sufficiently strong (i.e. able to withstand 1.5 N of axial force).
- To insure that the device can withstand fatigue it might encounter while implanted, it had to withstand 750,000 bending cycles without being damaged.

2.3. Requirements for crimp tools

Surgical crimp tools had to be developed to splice the electrode lead to the leaded RFB in a sterile field (see Fig 2). These tools include: (1) a crimp tool for connecting the electrode lead to the crimp; (2) Rubber tipped forceps for handling the different parts without damaging them; (3) Carbide-insert scissors for cleanly trimming the electrode lead before crimping; (4) Sterile silicone for insulating the crimp joint; and (5) a syringe with a blunt-tipped needle for dispensing the silicone into the crimp sleeve.

Requirements for these tools included:

- They must be sterilizable.
- They must enable a single surgeon to perform the crimping in a sterile field.
- The crimp tool has to provide reliable crimps.

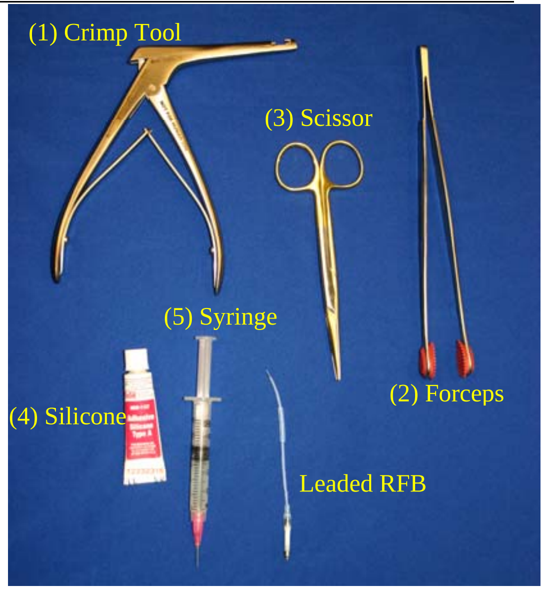

Fig 2: The surgical tools. Also shown is the leaded RFB with the silicone sleeve over the pigtail lead which is required for insulating the joint after attaching the electrode lead.

3. RESULTS

3.1. Tests of the leaded RFB

Four lead attachments with crimp tubes at both ends were cyclically bent for 1,500,000 cycles. Another group of 5 leaded RFB cases with electrode lead attachment and pigtail lead underwent a pull test and broke at >1.5 N. All 5 leaded RFB cases passed a 3 point bend test with a force greater than 4 N.

3.2. Tests of the Crimp

The crimp tool was used to prepare 10 samples, each consisting of two leads and three crimp tubes. The samples could withstand an axial force of more than 1.5 N, and had reliable low resistance connection.

3.3. Preliminary validation with the first implantation

Preliminary validation of the leaded RFB and the surgical tools was provided recently. Four leaded RFBs, each attached to a single Peterson lead electrode, were implanted for the first time in a female cat in a study designed to treat overactive bladder and urinary retention in spinal cord injured subjects. Two Peterson Intramuscular electrodes were placed in the anal and urethral sphincters using a 16 gauge needle introducer. Two other Peterson electrodes with 3.2 cm of exposed length were sutured on the bladder wall. The four leads were then tunnelled to the mid-back. The proximal end of the electrode leads were cleanly trimmed with the carbide-insert scissors and inserted into the crimp tube of the leaded RFB. Connection was performed in a sterile field using crimp tool (Fig. 3).

Fig 3: Crimping the Peterson Intramusclar electrode to the leaded RFB during surgery.

Then, the silicone sleeve, which sits on the pigtail lead, was slid over the crimp so that it covered all of the exposed areas at the crimp joint. Sterile silicone glue was injected inside the sleeve using the syringe (Fig 4).

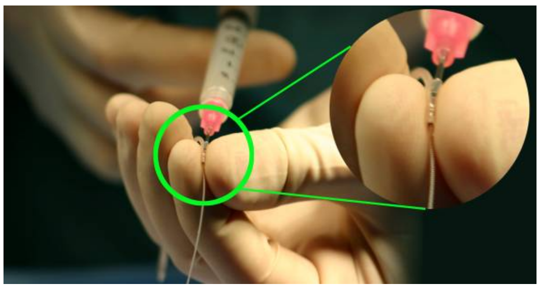

Fig 4: Backfilling of the silicone sleeve with silicone glue for insulating the crimp.

The silicone glue cured for at least one hour while the incision was being closed (Fig. 5a). The entire crimping procedure was quick (3 minutes) and effective. Functionality of the leaded devices was tested using the external coil to activate the RFBs. All four devices were able to stimulate the target tissues.

Fig 5 (a) Insulated splice (performed during the surgery). (b) Insulated splice with spot ties (will be performed in future surgeries)

4. DISCUSSION AND CONCLUSIONS

The leaded RFB and the surgical crimp tools have been tested mechanically, electrically and have been used satisfactorily in an animal study. The device and the crimp tools provided reliable splices. Four devices were successfully implanted and crimped to Peterson electrodes in a sterile field using the surgical crimp tools. The connection was easily performed and was effective.

There is a concern about the stability of the splice, as the silicone takes up to 24 hours to fully cure. To address this potential issue, it is planned to add spot ties at each end of the sleeve (Fig 5b) to prevent the sleeve from moving.

Additional animal studies using the leaded RFB attached to different electrode leads are planned to commence in the coming months. Currently, the leaded RFB is being qualified for human use.

References

[1] DiMarco AF, Onders RP, Kowalski KE et al. Phrenic Nerve Pacing in a Tetraplegic Patient via Intramuscular Diaphragm Electrodes. *AJRCCM*, Vol. 166, 1604-06, 2002.

[2] Peterson DK. Nochomovitz M, DiMarco AF, and Mortimer JT. Intramuscular Electrical Activation of the Phrenic Nerve *IEEE Trans. BME*, Vol. BME-33, No3, 342-51, 1986.

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