RF BION microstimulator implantation technique for shoulder subluxation

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Abstract

There are many papers reporting results from stimulating muscle groups for shoulder subluxation using surface and percutaneous electrodes. These electrodes have both advantages and disadvantages with respect to using them on a daily basis; thus, electrodes without external wires would be ideal. We have now experienced using the completely implantable RF-BION® microstimulators (Alfred Mann Foundation, Santa Clarita, CA, USA) for a chronic stroke hemiplegic subject who has shoulder subluxation and resulting pain. The subject was implanted with an RF BION device at both the axillary nerve and at the motor-point of the middle deltoid muscle. We are describing the RF BION microstimulator implantation technique and the target points for stimulating the shoulder nerves and muscle motor-points for reduction of pain.

1 Introduction

Advances in electronics have made it possible to restore paralyzed muscles by functional electrical stimulation (FES). One principal difference among the various approaches to restoration of paralyzed muscles is the use of surface versus internal electrodes for stimulation. The surface electrode is convenient for treatment but it is difficult to stimulate deep areas and the muscle response changes each time it is placed on the skin [7]. In addition, the patients often feel pain due to the activation of the sensory fibers. The percutaneous electrode, which is already an approved, advanced medical treatment in Japan, can stimulate muscles selectively and in deep areas easily [9]. Also, the response is stable and we can control the stimulation parameters with external devices. This electrode, however, goes through the skin so it has problems of cosmetics, infection, breakage and movement.

The completely implanted electrode and stimulator may prove to be better since it should have a smaller risk of infection and one does not need to deal with sterilization of the percutaneous wire implant area.

Over the past 5-10 years, we have heard about the RF BION device (RFB), which is a completely implanted electrode/stimulator that has been developed in the United States [1,3,4,6]. Recently, we began collaborating with the Alfred Mann Foundation (AMF) to use the RFB for this project.

There are many reports that stimulated muscle groups for shoulder subluxation [2,6,7,8,10]. Our first project for human therapy is to relieve the chronic intractable pain from shoulder subluxation following stroke by implanting the ceramic-cased RFBs (provided by AMF) in middle and posterior deltoid muscles. The glass-cased RFB (Alfred Mann Institute, University of Southern California, Los Angeles, CA) has been used for shoulder subluxation in clinical trials for muscle building and restoration of paralyzed muscle and pain relief [6].

The purpose of this presentation is to introduce the technique for implanting the ceramic-cased RFB in shoulder muscles.

2 Methods

The subject was a 66 year-old man, five years post-stroke. Before implantation, we confirmed that the subject’s deltoid muscle responded to surface stimulation. The muscles chosen to reduce shoulder subluxation pain were the middle and posterior deltoid muscles.

3 Results

(a) Implantation

The target muscle was on the left side so the subject was placed on his right side during implantation. RFB implantation was performed
in the sterile operating room at Akita University Hospital (Akita, Japan), using aseptic technique and local anesthesia (1% Mepivacaine) at the site of insertion. A 5 mm skin incision was made. A probe electrode was attached to an external battery-operated stimulator. The probe was inserted into the tissue to locate the appropriate stimulation site for the RFB. A 10 cm plastic venous introducer (dilator and sheath) was used to insert the RFB. The introducer was passed down over the probe electrode; stimulation was repeated to confirm the nerve’s response. The probe electrode was withdrawn, the dilator was removed from the sheath, and the RFB was slid down to the tip of the sheath, cathode-end first, using an ejection tool. Small holes had been machined 10-15 mm from the tip of the sheath to allow electrical contact of the RFB anode with the tissue using saline, which was injected into the sheath. The RF-coil was placed over the shoulder and the device was tested by observing the muscle contraction. Stimulation parameters at levels necessary to achieve threshold and a strong contraction were recorded. If the muscle responses were strong and effective, then the RFB was gently ejected into the tissue by holding the ejection tool against the RFB and sliding the sheath up over the device. Retesting of the RFB was then done.

The first RFB was implanted on the axillary nerve posterior-lateral to the humerus, 5-6 cm beneath the acromion. The stimulation of the axillary nerve provided adequate contraction of the deltoid muscles, without any adverse “spill-over” effect [Figure 1]. The first RFB stimulated the posterior portion and partially stimulated the middle deltoid muscle. A second RFB was implanted at the motor-point of the middle deltoid muscle. The point for implantation was laterally, 4-5 cm down from acromion [Figure 2]. This microstimulator also provided adequate stimulation to have an effective muscle contraction.

Following implantation of the devices, X-rays were obtained from the anterior-posterior view, without electrical stimulation, to confirm and document the position of the devices [Figure 3].

Figure 1: Proving the good point for the axillary nerve.

Figure 2: Axillary nerve and the motor point of middle deltoid muscle.

Figure 3: AP view at shoulder joint after implantation.

(b) Recovery

Following the surgical procedure, the subject waited for 2 weeks to allow the wound to heal
prior to starting supra-threshold stimulation. For the first week after implantation, the subject wore a sling to minimize movement of the shoulder. Brief threshold testing was done at one week post-implantation to insure that the RFBs were working properly. At that time, we confirmed that the devices were properly activating the muscle.

4 Discussion and Conclusions

The RFB is a micro-miniature, single channel stimulator that can be injected into muscles with local anesthesia. The convenience of using RFBs has proven to be an important advantage for therapeutic electrical stimulation of atrophied muscles [6].

In this study, the implantation caused little pain during procedure and no significant swelling after procedure. The implantation time is approximately 20 minutes per device. Our patient has been satisfied with absence of complications and easily self-administered therapy.

Acros et al. reported on the ceramic-cased Bion devices implanted by open surgical dissection in rats [1]. Davis et al. developed the minimally invasive technique to insert and retrieve the RFB safely near hypoglossal nerves in sheep [3] and in humans for obstructive sleep apnea [4]. They concluded that the surgical technique to safely insert a microstimulator, such as the RFB, adjacent to nerves for FES, requires a rounded and small diameter stimulation probe electrode, as well as plastic introducers with tapered dilators that do not have sharp edges. According to our experience in this time, their procedure to insert the RFB is easy and safe for clinical use. They also reported the question regarding removal of the RFB. Prior to implantation, a suture is attached to the small eyelet on the anodal end, allowing the RFB to be withdrawn. The RFB can be retrieved up to 6 days post-operatively, without a cut-down [5].

Histological damage due to implantation could be a major problem. Histological evaluation in other studies using RFBs showed scar but no evidence of necrosis or other inflammatory reactions with regard to implantation of the Bion [1,4,6].

We conclude that a minimally invasive implantation and retrieval technique for placing the ceramic-cased RF BION microstimulator is now available, and our initial experience using it suggests that it allows an easy and safe detection of a satisfactory target point(s) for stimulating shoulder muscles.

References


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