The Use of the RF BION® Microstimulator to Relieve Pain Due to Shoulder Subluxation in Chronic Hemiplegic Stroke Patient – A Case Report

Misawa A 1, Shimada Y 2, Matsunaga T 2, Aizawa T 1, Hatakeyama K 2, Chida S 2, Sato M 2, Davis R 3, Zilberman Y 3, Cosendai G 3, Ripley AM 3

1 Akita University School of Medicine Department of Orthopedic Surgery, Akita, Japan
2 Akita University Hospital Rehabilitation Division, Akita, Japan
3 Alfred Mann Foundation, Santa Clarita, CA, USA

Email: amisawa@med.akita-u.ac.jp

Abstract

The aim of this study is to evaluate the ability to relieve pain by implanting and stimulating RF BION® microstimulators (Alfred Mann Foundation, Santa Clarita, CA, USA) in a chronic stroke hemiplegic subject. Shoulder subluxation is among the most commonly cited causes of shoulder pain in hemiplegia. The subject was implanted with an RF-BION® device at both the axillary nerve and the motor point of the middle deltoid muscle. Two weeks after implantation, the subject commenced electrical stimulation of the posterior and middle deltoid muscles, which has continued for over 3 months. After 3 months of stimulation, the patient’s pain was reduced from 100 to 0 (as measured using the VAS Pain scale).

1 Introduction

Loss of upper motor control due to stroke results primarily in limb paralysis and secondarily in disuse atrophy of the affected muscles and shoulder joint. This atrophy may result in complications such as joint pain and skin breakdown, which are even more troubling to the patient than the loss of motor function. Shoulder subluxation has been observed in 17 to 81% of hemiplegic patients [4]. Muscle paresis around the shoulder joint decreases its stability and results in shoulder subluxation, which is among the most commonly cited causes of shoulder pain in hemiplegia [7]. It is difficult to treat these conditions even though traditional rehabilitation technique and medicine are tried. Currently, there are several devices that electrically stimulate these paralyzed muscles [4, 5], and we have tried to prevent muscles atrophy with a surface electrode and/or a percutaneous one [7]. Both types of electrodes have merit, but have not yet been used in daily-life effectively [6].

The RF BION® device is a completely implanted electrode/stimulator that has been developed in the United States in recent years [1, 3]. A glass-cased version of the BION device is being used by Dupont et al. [3] in clinical trials as a therapeutic electrical stimulator to treat conditions of disuse atrophy: shoulder subluxation and knee osteoarthritis. In this study, we are evaluating the ability to relieve shoulder pain by implanting ceramic-case versions of the RF BION microstimulators in patients’ paralyzed shoulder muscles.

2 Methods

(a) Subject

To date, a single patient has been enrolled in the study. The patient is a 66 year-old man, five years post-stroke with left hemiplegia.

(b) Outcome Measures

We are evaluating the effectiveness of the device by measuring pain (using the visual analog scale [VAS]), range of motion (ROM) at the shoulder, strength of the deltoid muscle (as measured by handheld dynamometer), degree of shoulder subluxation (using both radiological and clinical evaluations), and muscle atrophy (via a measurement of the upper arm girth). We are evaluating the safety of the device by examining the implant site and monitoring stimulation thresholds.

Before implanting the RF BION devices, we performed these tests at baseline. Following commencement of stimulation, follow-up evaluations were performed at 1-, 2-, 3-, 4-, and 6-weeks, and 3 months.
BION microstimulator implantation was performed in the sterile operating room at the Akita University Hospital (Akita, Japan), using aseptic technique and local anesthesia (1% Mepivacaine) at the site of insertion. We implanted two BION devices for the deltoid muscle: one was near the axillary nerve and it stimulated the posterior portion of the deltoid muscle, and partially the middle deltoid; the second one was close to the motor point of the middle deltoid muscle (Figure 1).

Two weeks after implantation, electrical stimulation was started.

(d) Stimulation levels

Stimulation was performed at a frequency of 20 Hz, a pulse width of 0.2 ms, and constant current was adjusted to give maximum contraction force. The 20-second stimulation cycle included a 3 second ramp up, 7 second burst on and 10 seconds off. The protocol of this study is to receive stimulation of the deltoid muscles daily for 6 months. In the beginning, the patient received stimulation for 10 minutes, 5 times each day, and then gradually increased the amount of stimulation until reaching a maximum of 1 hour, 3 times a day by week 4.

3 Results

There were no adverse events for the patient during the implantation, stimulation or follow-up. The stimulation contracts the target muscle, as anticipated. The shoulder subluxation is corrected when stimulation is on, but it returns to baseline levels when stimulation is off. The stimulation thresholds have been stable during these 3 months.

- Pain: Before stimulation, the VAS pain score was 100. Two to 3 months after, the pain was relieved to a level of 0 (Figure 2).

- ROM: There has been no significant difference in range of motion between baseline and after 3 months of stimulation.

- Strength of deltoid muscle: The strength of the deltoid muscle has increased between baseline and 3 months post-stimulation. The anterior, middle and posterior portions of the muscle increased from 8 to 17N, 1 to 27N, and 1 to 24N, respectively.

- Shoulder Subluxation: There was no significant change on the shoulder joint following 3 months of stimulation. Using fluoroscopy, we confirmed that the humerus head was replaced into the joint while the patient received stimulation (Figure 3).

- Muscle atrophy: At baseline, there was a 2.5 cm difference in upper arm girth between the two arms. After one week of stimulation, the affected arm had increased 2 cm in girth. After 3 months of stimulation, the difference in upper arm girth between the two arms was remained at 0.5 cm.
Clinical evaluation of the tissue around shoulder: Before and after implanting the BION devices, there was no redness, tenderness or swelling around the shoulder area including the deltoid muscle.

4 Discussion and Conclusions

Shoulder pain following a hemiplegic stroke is common, persistent and distressing to patients. There is little evidence supporting any substantial forms of pain treatment for shoulder subluxation, thus emphasizing the importance of this presented treatment, which has given such pain relief.

There have been a few studies that evaluated shoulder function before and after 6 weeks of stimulation, but we could not find any long-term study over 3 months [2]. Those studies used three kinds of electrodes (surface, intramuscular, and completely implantable electrodes) and also three kinds of target muscles (posterior, middle deltoid and supraspinatus). We chose to activate the deltoid muscle only as because the supraspinatus muscle is part of the rotator cuff and there is a probability of causing or aggravating a “rotator cuff tear,” which is the one of causes of shoulder pain. Also there is consideration that stimulation of the supraspinatus results in inconsistent joint reduction in the subluxed hemiplegic shoulder and provides less joint reduction than the deltoid muscles [7].

It is difficult to compare these results with the other studies because there are none that used the same target muscle and same term to study the effect of stimulation. At 3 months post-stimulation, our patient has relief of pain and keeps good muscle contraction. These results suggest a feasibility of using RFB devices implanted both next to nerve and next to muscle motor point to elicit a contraction and relief of pain.

We are still conducting this study and plan to enroll a total of 5 patients in this study. This therapy is not a cure for stroke, but it may help patients to regain some use of their arm function by avoiding pain when they move it.

References


Acknowledgements

All equipments and technology were provided by Alfred Mann Foundation for Scientific Research. We thank for Gerry Loeb and David Yu for their assistance in designing the study.