An Intramuscular Bipolar MES Electrode for Implantable Systems

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Abstract

A fully-implanted intramuscular bipolar myoelectric signal (MES) recording electrode has been developed for use with functional electrical stimulation (FES) and other implantable systems. Epimysial-based MES electrodes, which are sutured onto the surface of a muscle, are currently used in our FES systems. While these work well, the epimysial recording electrodes may be difficult to implant if the target muscle is small or deep. Epimysial electrodes also require surgical incisions to expose the target muscles, and their implantation can be time-consuming if many electrodes are being implanted.

The intramuscular stimulating electrode (IM-STIM) that we use is able to access small and/or deeper muscles of the hand and forearm while minimizing incision size and implantation time. The IM-STIM electrode has been shown to have excellent tissue response characteristics and long-term durability. The IM-STIM design has been modified to create an intramuscular bipolar MES electrode (IM-MES) that provides similar benefits. Mechanical analyses and in vivo studies have been performed to demonstrate the suitability of the IM-MES electrode for clinical use.

1 Introduction

Myoelectric signal (MES) recording electrodes are often used in functional electrical stimulation (FES) systems as sources of control signals. We currently use epimysial-based MES electrodes in our stimulation systems [1] (Figure 1). These electrodes are sutured to the surface of a muscle. The epimysial recording electrodes, like epimysial electrodes for stimulation, may be difficult to implant if the target muscle is small or deep. Epimysial electrodes also require surgical incisions to expose the target muscles, and their implantation can be time-consuming if many electrodes are being implanted.

Figure 1. Epimysial MES electrode.

The development of an intramuscular stimulating electrode (IM-STIM) has achieved the goals of being able to access small muscles (e.g., intrinsic hand muscles) and deeper muscles of the forearm while minimizing incision size and implantation time [2]. The IM-STIM electrode (Figure 2) consists of a pair of helically coiled insulated cables placed in Silastic tubing. At one end, the electrode is terminated with a standard connector. At the stimulating end, the insulation is removed from both cables and the wire is wrapped around the outside of the silicone tubing to form the stimulating surface. The electrode is stabilized in the muscle tissue by a polypropylene anchor. The IM-STIM electrode has been shown to have excellent tissue response characteristics and long-term durability.

Figure 2. IM-STIM electrode.

Just as the development of the intramuscular stimulating electrode provided advantages over the epimysial stimulating electrodes, it is anticipated that modifying the IM-STIM design to create an intramuscular bipolar MES electrode (IM-MES) would provide similar benefits (smaller incisions, decreased implantation time, access to smaller and deeper muscles).

2 Methods

2.1 Design Changes

Lead
The lead will be the same configuration as that used with the stimulating electrodes and the epimysial MES electrode. Two separate conductors made of Teflon-coated, 7-strand type 316L stainless steel wire are helically wound in tandem and placed inside silicone tubing

Connector
Either an industry-standard bipolar IS-1 connector or the CWRU Y-branch connector can be used.

Anchor
The anchor will be the same as the IM-STIM electrode; a 6-barb polypropylene anchor with a central polypropylene core that is heated to melt into the coils and lock the anchor into the lead.

Recording surface
On the recording end of the electrode, one of the two conductors is deinsulated where it exits the tube and is then wrapped around the outside of the tubing (Figure 3) for 4 mm. It then is inserted back into the tubing. The second conductor is fed back inside the tubing to a small hole in the tubing 10 mm from the end. It then exits the tubing, is deinsulated, then is wrapped around the tubing for 4 mm and inserted back into the tubing. The insertion holes in the tubing are sealed with silicon adhesive.

Figure 3. IM-MES electrode.

Insertion Tool
The IM-STIM insertion tools were modified to accommodate the larger IS-1 connector or Y-branch connector. A commercially-available peelable sheath is now used.

2.2 Mechanical Testing

The section of the tip where the 2nd conductor is bent and fed back into the tubing was an area of concern from a mechanical standpoint. The bent area may have too high a strain (causing cracks or deformations), while the straight section may have a fatigue failure after many bends. The 7-strand type-316 stainless steel wire from an electrode was analyzed both mechanically and optically.

2.3 Animal Testing

A nerve cuff electrode was placed on the peroneal nerve of an anesthetized cat. An IM-MES electrode was placed in the tibialis anterior muscle, and an epimysial MES electrode was sutured to the surface of the muscle (Figure 4). A comparison was made of the signals recorded by the two electrode types when the nerve cuff electrode was stimulated and when a 200 Hz sinusoidal signal was injected across the electrodes.

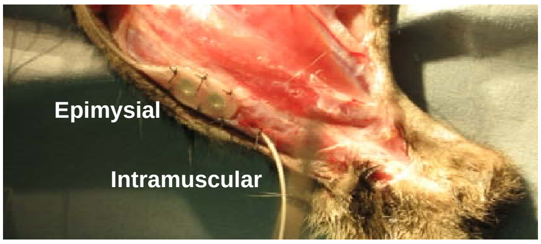

Figure 4. Epimysial and IM-MES electrodes in cat muscle.

3 Results

3.1 Electrode Fabrication

The IM-STIM electrode fabrication protocols were successfully modified to incorporate the design changes for the IM-MES electrode.

3.2 Mechanical Testing

Fatigue tests on the 7-strand type-316 stainless steel wire indicate that, at a bending radius that the electrode tip is likely to encounter, the wire can survive millions of cycles without having a fatigue failure.

Scanning electron microscope (SEM) views of the sharp bend in the tip show no cracks or deformations (Figure 5) that would result from excessive strain.

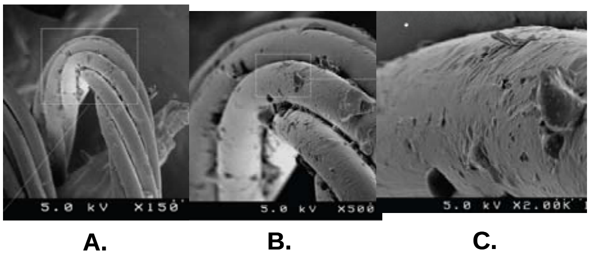

Figure 5. SEM of bend in IM-MES electrode tip. 'B.' is an enlargement of the box in 'A.'. 'C.' is an enlargement of the box in 'B.'.

3.3 Animal Testing

The epimysial MES and IM-MES electrodes recorded similar M-wave response signals when the nerve was stimulated by the nerve cuff electrode (Figure 6).

The two electrodes also had nearly identical responses to an injected 200 Hz signal (Figure 7).

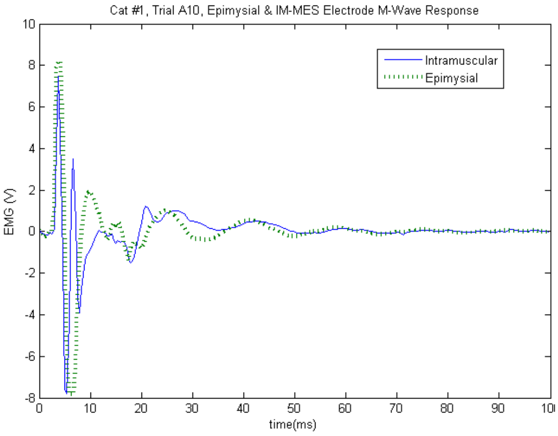

Figure 6. M-wave response of IM and epimysial MES electrodes from nerve cuff stimulation.

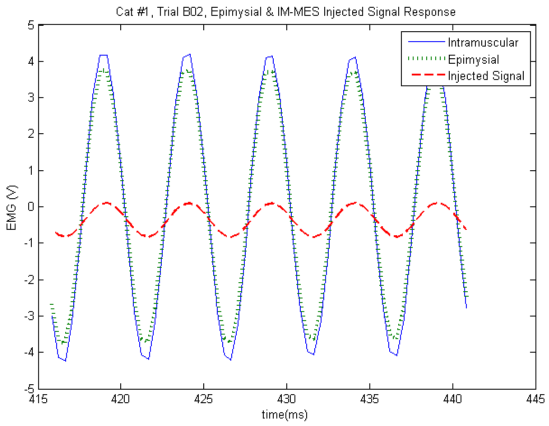

Figure 7. Recordings from epimysial & IM-MES electrodes during injected 200 Hz sinusoidal signal

4 Discussion and Conclusions

The intramuscular stimulating electrode (IM-STIM) was easily modified into an intramuscular MES recording electrode (IM-MES). The manufacturing changes do not induce any excessive mechanical strains, thus the IM-MES electrode should have a longevity similar to the IM-STIM electrode. The changes to the insertion tool do not alter the complexity or accuracy of the insertion method.

The IM-MES electrodes record signals that are equivalent to those recorded with epimysial MES electrodes. Since the design changes do not involve changes in the materials used by existing electrodes, do not decrease the expected longevity of the electrode, and functions equivalently to existing MES electrodes, the IM-MES electrode is an acceptable alternative to the epimysial MES electrode for use in human applications.

References

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