ADDITION OF AN INTRAFASCICULAR ELECTRODE AT THE SITE OF APPLICATION OF A MULTIPOLAR NERVE CUFF ENHANCES THE OPPORTUNITY FOR SELECTIVE FASCICULAR ACTIVATION

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Abstract- Multipolar nerve cuffs are being developed to apply to peripheral trunk nerves in an effort to limit the number of implanted components of an FES system, while at the same time allowing specific fascicles within the cuffed nerve to be independently activated. Because the electrode contact sites of a multipolar circumferential fitted cuff are positioned only at the surface of the cuffed nerve, it is difficult to activate fascicules that are located deep within the nerve. This situation might be improved if one or more additional electrode contacts were provided within the core of the nerve. An obvious choice for such a contact is to use an intrafascicular electrode (IFE) such as those described by Horch and his colleagues. In our present study we inserted a single IFE into a trunk nerve that subserves the forelimb muscles in an adult anesthetize pig. An 18 pole multichannel nerve cuff was then applied to the nerve at the same site. We stimulated different combinations of the cuff contact sites with and without the IFE while monitoring the evoked EMGs from an array of innervated forearm and shoulder muscles to assess the ability to activate different fascicles independently. The results have shown that the use of the IFE in combination with the normal cuff contacts can afford modest improvements in the degree of selective muscle activation that is possible.

Keywords - FES, multipolar nerve cuffs, intrafascicular electrodes, selective nerve activation.

I. INTRODUCTION

Nerve cuff electrodes provide an attractive means to activate muscles in motor neuroprostheses that employ functional electrical stimulation techniques. In contrast to epimesial or intramuscular electrodes, the nerve cuff can be placed proximally on the limb to isolate it from the direct mechanical disturbances that could come during contraction of the activated muscles. A second advantage is that the intimacy of the cuff contacts with the underlying nerve permits the use of low currents (ca. 1 ma) to be effective in activating the muscles. To minimize the amount of surgery required to install electrodes that can access all of the requisite muscles for a given function such as hand grasp restoration, efforts are underway to utilize multipolar cuffs such as is shown in Fig.1. With such a cuff, the individual contact sites can be used in combinations to selectively activate discrete fascicles within the trunk nerve. For a hand grasp application, finger extension would be achieved using a multipolar cuff applied to the radial nerve, while flexion of the fingers would mainly be activated by a another multipolar cuff applied to the median nerve. Demonstrations of the

effectiveness of multipolar cuffs have been performed using the sciatic nerve in cats (Grill and Mortimer 1996) and using the optic nerve in man (Veraart et. al. 1998). There are no reports to our knowledge regarding their use when applied to the forearm nerves in man. In lieu of that we are using an animal model consisting of the pig forelimb to assess the ability of novel multipolar cuff designs to achieve selective fascicular activation. It is difficult to activate fascicles that are located in the interior of the trunk nerve without at the same time activating those nearer to the surface. Conceptually, the situation might be improved if one or more electrode contact sites were installed in the center of the trunk nerve, and the objective of the present studies is to determine the extent to which that concept is valid. To assess the activation of the various muscle nerves, we simultaneously monitored the individual EMG signals evoked among 9 separate muscles. This paradigm is similar to one that we have employed in prior studies (e.g. Riso et. al. 2000).

II. METHODOLOGY

A. Animal Preparation

Acute experiments were performed on 4 adult farm pigs (approx. wt. 60 kg.) using Isofluran (Abbot) anesthesia. With the animal in the supine position an exposure was prepared through the auxilla to access the bracial plexus nerves. The division of the plexus that more distally would give rise to the radial nerve was identified using visual examination and electrical stimulation and then mobilized for a distance of 20 mm. An intra-fascicular electrode (IFE) was installed in the center of the nerve by attachment to a fine needle and then a multipolar nerve cuff was installed around the nerve at that same location. The skin over the extensor compartment of the forearm was removed to expose the underlying muscles so that pairs of fine wire electrodes could be installed for bipolar recording of evoked EMG activity. The monitored forearm muscles included: six superficial muscles that abductor or extend the toes (M1,M2,M3,M4,M5,M6), and the wrist extensor carpi radialis (M7). In addition to these forearm muscles, the nerve at the cuffed location innervates muscles of the shoulder, and we placed similar EMG electrodes percutaneously into the shoulder muscles in anterior, lateral and posterior locations to monitor the EMGs evoked by contractions of those muscles (M7,M8,M9). All EMG signals were bandpass filtered (50 Hz - 1kHz), sampled at 2kHz and stored on disk.

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B. Nerve Cuff and Intrafascicular Electrode

The nerve stimulation cuff (Fig 1) [3] contained 18 contacts that are arranged into 6 sets of longitudinal tripoles providing six separate channels around the circumference of the nerve $(0^{\circ}, 60^{\circ}, 120^{\circ}, 180^{\circ}, 240^{\circ} \text{ and } 300^{\circ})$. Within the cuff, the outer electrode contacts from each tripole are connected to each other and used as anodes verses the center contact which is connected as cathode. The tripole electrode contacts had 3mm longitudinal separation. The IFE consisted of a single 25um dia. platinum-iridium wire with teflon strand of insulation (A-M Systems, Inc., Carlsberg, WA). A small window (1mm long) was made in the insulation to form a single electrode 'contact' site. When the IFE was used during the stimulation tests, it was connected as an anode while a pair of outer cuff contacts then served as stimulus cathodes. Stimulus pulses were constant current bi-phasic, balanced charge, but the charge recovery phase was reduced in amplitude relative to the primary phase (ratio 1 to 10).



Fig.1 Depicting combined use of a self coiling 18 pole nerve cuff and a fine wire intrafasicular electrode. The cuff is fabricated from silicone sheeting. Electrode contacts consist of platinum on a polyimide substrate.

C. Data Collection and Experimental Protocol

The objective of the present investigation was to determine if the use of the IFE in conjunction with the cuff contacts would yield different patterns of nerve activation than could be obtained using only the six channels of the multipolar cuff alone. Therefore, we first determined the recruitment characteristics for each channel of the cuff under the usual tripole cuff configuration, and then we repeated the testing using the IFE in conjunction with each channel of the cuff. All of the stimulation was performed using cathodic primary phase pulses having repetition frequency of 25 Hz. Each test trial consisted of an identical staircase of pulse width changes having a series of steps that increased and then decreased in pulse duration from 20 to 350 microsecs. Twelve pulses were presented at each staircase level so that a given step level lasted approx. 0.5 s before the pulse width was changed. The muscle contractions were isometric with the foot clamped at a fixed position (30 degree flexed from the fully extended position).

Such recruitment characteristics were performed for each cuff 'channel' at increasing amplitudes of current, beginning at threshold levels (usually >0.2ma) and progressing to about 1.5ma (rarely to 2.0ma). The upper current level that was tested depended on the response. Usually, the selectivity would ultimately diminish when the stimulus current became too high, because the greater stimulus spread increased the likelihood of activating fascicles lying deeper within the nerve.

III. RESULTS

The evoked muscle activity for one of the animals is shown in Fig 2 as an example of the degree of selectivity that is typically obtained using the 6 different cuff channels without any use of the IFE. For each channel the pattern varies depending on the level of the stimulus current. In each case illustrated in the figure the data generated by the current that provided the best selectivity for that channel is presented. This selection is subjective and is based on the premise that the most useful cuff channels must provide as much muscle selectivity as possible while at the same time providing a graded recruitment characteristic for the activated muscles. In these studies we also strove to avoid having two channels produce similar activation results since more choices might be useful for patterning a good hand grasp in our final application. However, it should be considered that seemingly redundant channels might still be useful, because it is possible that different motor units are being activated in each case and this could be useful for cyclic rotation of the work load in muscles to forestall fatigue.

As shown in the figure, 0° produces isolated M8 and M9 shoulder activation. 60° produces only weak M8 and M9 activity. 120° shows strong M2 and M3 toe activation. 180° has M2, M3, M5 and M6 strong at the onset compared to M1 and M4 which become more substantial only at higher PW. 240° represents an ideal channel in that it is purely activating the wrist extensor muscle. 300° is similar to 240° but requires higher PW and is less responsive.



Fig 2 - Showing typical activation profiles of the extensor muscles and shoulder muscles activated using the 6 different tripolar contact sets in the nerve cuff in the conventional way.



Fig 3 - Showing additional activation profiles that become available when the IFE is utilized in conjunction with the cuff channels as indicated (0, 60, 240 and 300°). 120 and 180° channels not shown because they didn't yield patterns different from those obtained without employing the IFE.

In Fig. 3 we present the situation that was obtained when the IFE was substituted as the anodal contact during tripolar stimulation. We obtained modestly unique results compared to the six previous patterns that are shown in Fig.2. 0° IFE now activates M1, 2, 3, 4, 5 and 6 with M1 and 4 weakest. 60° IFE is a bit different from 0° IFE in that M2 predominates and M1 and 6 are absent. 240° IFE shows M2, 3, 4, 5 are uniform relative to each other while M6 is strongest. This should be contrasted with 120° for which M2 and 6 are strongest. Finally, 300° IFE gives a result similar to 240° IFE, but the response from M6 is reduced.

Adjustment of the stimulus amplitude is useful to obtain good recruitment as illustrated with another animal in Fig 4. Here we used only the normal cuff tripole configuration, because it was adequate to achieve isolated activation of the wrist muscle Extensor Carpi Radialis. At 1.8ma, modulation of the PW over the region from about 80us, to 250us, yielded smooth recruitment curves as indicated by the recorded EMG and by the extension torque that was generated about the "wrist joint". The control strategy that would be employed when using this muscle for FES would be to use the lower current amplitude (1.8ma) when low torque was desired and to use the higher current (2.0ma) when higher torque was needed. Note that the use of the higher current results in somewhat greater "spill over" to the toe extensor muscles.



Fig 4 - Results from two individual recruitment trials are superimposed. Stimulus current increased from 1.8ma to 2.0ma. The resulting Ext. Carpi Rad. EMGs are superimposed whereas the EMGs from the toe and shoulder muscles are shown offset for visibility. Calibration of all EMG is the same. The stimulus PW was changed stepwise from 20 - 250us every 0.5s as shown in the staircase.

However, since this spill over is modest it probably wouldn't be bothersome,. It should be noted here, also, that we usually didn't need to use currents as high as 2 ma, and that this case (which is a different animal from the one whose data are reported in Figs. 2 and 3), represents the upper range of current requirements in our experience thus far with the present design cuffs.

IV. DISCUSSION

The use of multipolar nerve cuffs presents some attractive advantages for FES. If a single cuff can be installed proximally on the limb and control several muscles independently, the amount of surgery required to implant electrodes would be reduced. A problem with the use of epimesial and intramuscular electrodes stems from mechanical coupling between the neural interface and the evoked muscle contractions. Any disturbance of the electrical coupling of the electrode contacts with the motor nerve fibers can alter the recruitment behavior. This problem might be reduced if the neural interface can be located proximal to the muscles. Chronic studies are needed, however, for each planned installation site to determine the extent to which contractions of the proximal musculature might also effect the nerve cuff installations. Another advantage of the nerve cuff approach in general is that reasonably small currents are needed on the order of 1 ma. Coupled with electrode contacts that have a few kOhms impedance, this requires that the stimulator need have only a few volts compliance which can help to reduce its size and power consumption.

Our results indicate that in most instances, activation of one set of tripole contacts produces an activation pattern that is different from that which is evoked by the nearest neighboring set of tripoles. This suggests that better selectivity of muscle activation might be achieved if a higher density of tripole channels was available within the cuff. Perhaps double the present density would be an appropriate next development. 'Fitting' more contacts sites around the cuff inner wall presents no problem, but the additional leads wires needed to access those contacts would be a major impediment unless suitable multiplexing (switching) circuitry is developed. Of course, the desirability of more 'channels' is dependent on the application and how much specificity is needed, but it should be remembered that the topography of peripheral nerves is variable among individuals, and a greater number of stimulation sites to choose among within the cuff post implantation could help compensate for these uncontrolled differences.

In each of the four animal preparations that were tested, we were able to obtain at least 2 or 3 additional muscle activation 'profiles' by employing the intrafascicular electrode. Depending on the particular FES application, those additional possibilities might be very important for the functionality of the FES system. Although absolute specificity for each of the 9 muscles monitored in this study was never achieved, we feel that we are making progress in that direction. The residual problem is of the same nature as the 'spill over' referred to in the literature with the use of epimesial and intramuscular electrodes.

A drawback of the use of an IFE is that there is a potential to damage the nerve at the time of installation. In succeeding work, we plan to add additional IFE sites into the same nerve, but we also plan to study the effects of applying 'steering currents' with and without IFEs. It is possible that the use of steering currents alone may accomplish all the selectivity that might be needed for a hand grasp neuroprosthetic system and that would obviate the need for the inclusion of one or more IFEs.

V. CONCLUSION

Results thus far have shown that the inclusion of a single supplementary electrode site inside a large diameter (ca. 5-6mm) trunk nerve that is to be activated using a multipolar nerve stimulation cuff adds additional variety to the different patterns of nerve fascicles that can be driven with that cuff. Additional development of the strategy of using IFEs in combination with multipolar cuffs seems warranted.

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