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A reusable, self-adhesive electrode for intraoperative stimulation in the lower limbs

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Abstract—A suction-based stimulating electrode was designed and fabricated to allow intraoperative testing of lower-limb muscles during routinely scheduled surgical procedures. The suction device can adhere to a small exposure of muscle surface with reproducible contact forces and can maintain its geometric relationship to the underlying tissue for sufficient time to grade the resulting muscle contraction before removal and repositioning. When operated with a 10-cc syringe, the device can generate between 0 and 23 N of contact force; correlation between measured contact forces and those analytically predicted was 0.989. Preliminary animal testing indicates that the reusable device maintains its position over the nerve entry point even during vigorous active contractions of the stimulated muscle. Thus, it may be a valuable useful tool for locating the optimal site for a permanent electrode for functional electrical stimulation (FES) applications, as well as an ideal means of providing accurate and repeatable stimulation in various locations.

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INTRODUCTION

Epimysial electrodes for functional electrical stimulation (FES), consisting of platinum disks with Dacron-reinforced elastomer skirts, which are sutured directly to the surface of the muscle at the nerve entry point, are safe and effective methods of activating the paralyzed nervous system (1,2). With these electrodes having been implanted in more than 200 patients to date, experience with surgical placement of these electrodes in the upper limb and clinical success in a hand grasp neuroprostheses for individuals with mid- to low-level tetraplegia is well documented (3–6).

The success of the epimysial configuration in upper-limb applications of implantable FES systems makes it the logical choice for lower-limb applications as well. Although there have been isolated attempts to implant epimysial electrodes into the muscles of the lower limb (7–12), further study is needed to determine the performance of the electrodes on these muscles. The relative strength and selectivity of the stimulated contractions, as well as the optimal location of epimysial electrodes in the

quadriceps, gluteal, and paraspinal muscles, and efficient surgical approaches to implantation and lead routing, are all important aspects under consideration when developing an implementation strategy for a surgically implanted neuroprosthesis. Electrode positioning directly affects the ability to generate sufficient extension about the trunk, hip, and knee, and optimization is therefore critical for FES applications that are intended to provide standing and walking functions.

To locate an optimal electrode position, surgeons currently probe the exposed muscle intraoperatively with an epimysial electrode; permanent electrode placement is based on observation and palpation of the induced contraction. However, if the probing electrode is applied with more force in one area than another, the resulting contractions may not accurately indicate the more suitable position for a permanent electrode. In addition, the probing electrode cannot be held reliably by hand at one precise location during a contraction. The position of the moving motor nerve relative to the stationary hand-held electrode or probe changes as the muscle contracts, resulting in a degradation of the stimulated response.

As the response degrades and the muscle relaxes, the motor point often resumes its original position relative to the stimulating probe held lightly on the muscle surface, causing another vigorous contraction and initiating the excitation-relaxation cycle all over again. This "limit cycling" behavior is commonly observed during intraoperative mapping with hand-held probes and makes the evaluation of the stimulated response and identification of the best site for suturing an epimysial electrode difficult for the surgeon. Finally, qualitative results are not sufficient for discerning small differences in stimulated response. More quantitative assessments of joint moment generated with stimulation during surgery will require a repeatable method for temporarily securing an electrode to the muscle. Therefore, the goal of this study was to design a tool to facilitate mapping and intraoperative testing of epimysial electrodes to optimize final electrode placement, and to help characterize quantitatively the stimulated response of paralyzed muscle to epimysial electrodes in the lower limbs.

METHODS

The design process was initiated by defining a set of functional requirements and technical specifications for a reusable epimysial mapping probe capable of maintaining its position relative to the motor point of a surgically exposed muscle with a small but constant contact force. The final device must accurately simulate the behavior of a standard sutured epimysial electrode. However, it must also be easily removed and reapplied to the muscle surface at various locations for response mapping during routine surgical procedures.

The device must also contact the surface with repeatable force and maintain its position relative to the underlying tissue for several seconds of testing, regardless of the plane on which it is applied; such features will facilitate quantitative comparison of muscle recruitment properties for various stimulating locations. Additionally, the narrow, deep muscle exposures created during lower-limb surgeries necessitate a small device (no dimension greater than 2 cm) that is very simple to operate.

For these requirements to be met, a suction-type electrode was designed and fabricated. Suction-based EMG/EKG recording electrodes have been in common use for many years. While the mechanism of attaching the electrode to the tissue in both cases relies on imposing a pressure gradient, an innovative approach to the suction electrode was required to produce a new electrode that (1) is suitable for use intraoperatively and can be sterilized and reused in a surgical field; (2) is appropriate for stimulating exposed neural tissue, rather than recording surface biopotentials; (3) can be easily removed and rapidly reapplied during intraoperative localization of the motor point during mapping procedures; (4) is small enough for use in a surgical site; and (5) exactly duplicates the materials and recruitment properties of the implanted neural prosthesis. No existing EMG or EKG electrode meets these constraints.

The stimulating surface and lead wire are exactly those used in the standard epimysial electrode employed in the hand-grasp neuroprosthesis known commercially as the Freehand System (NeuroControl Corporation, Valley View, OH), thereby accurately simulating the behavior of the same electrodes in a lower-limb neuroprosthesis. The force with which the device contacts the muscle tissue depends on the difference between air pressures inside and outside the suction chamber. Atmospheric pressure outside the chamber is constant in every direction, and pressure inside the chamber can be controlled by connecting it to a closed system of volume, such as a syringe. The suction chamber can be kept relatively small, as it need not be significantly larger than the platinum stimulating disk and chamber-wall thickness. In

addition, it should be easily sterilized and manufactured entirely from biocompatible and implantable elastomers.

A two-piece injection mold was fashioned from brass, and the device was made from silicone rubber (MDX-4-4210 Medical Grade Elastomer, Dow Corning, Midland, MI). About 10 inches of rubber tubing (0.030″ ID, 0.065″ OD, Silastic, Dow Corning) was used to connect the air reservoir of the suction chamber to a syringe via a three-way stopcock. The platinum stimulating disk and lead was obtained from the Technical Development Laboratory of the Cleveland FES Center and is the same type currently being used in implanted epimysial electrodes for both upper- and lower-limb applications. The external dimensions of the device are shown in **Figure 1**. The prototype measured 0.219 in. (0.556 cm) in height with an outer diameter of 0.75 in. (1.90 cm).

As volume in the closed system is increased by drawing back the syringe plunger, a vacuum is created within the device. Tissue pressure pushes the tissue into the suction chamber and atmospheric pressure pushes the top surface of the device inward; together these two effects bring the muscle and stimulating electrode into contact. After the device is sealed from the syringe by the stopcock, the surgeon is free to use both hands while the electrode remains applied with constant force. The stopcock is opened either to the syringe or to outside air to release the device for repositioning.

Several size constraints were considered during fabrication while attempting to keep the device as small as possible. For example, an adequate surface area within the walls was necessary to convert pressures to the required force ($F = P \times A$). The thickness of the walls and top surface also contributes to the overall size of the device, but a minimum thickness was maintained to provide a sufficient seal and rigidity. Finally, the air tube was kept a minimum distance from the tissue surface to prevent excess blood and debris from blocking the air flow through the air holes and/or tube.

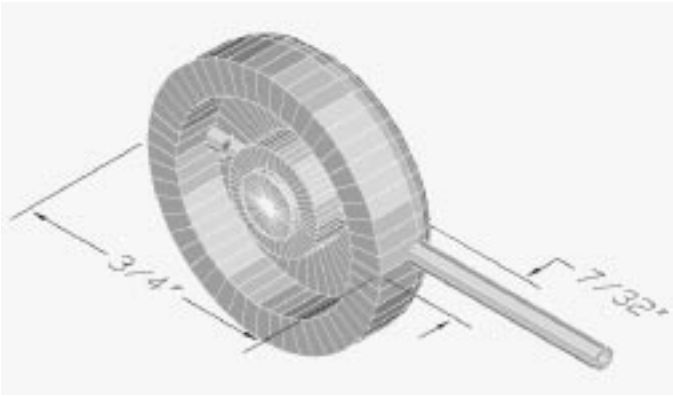

Figure 1.
Representation of prototype suction-based intraoperative mapping electrode showing vacuum chamber, relief for stimulating platinum disk, suction tube, and device dimensions (1.90-cm outer diameter and 0.219-cm height).

In an initial test of the electrode, it adhered to a smooth dry surface for more than one hour. Because this time far exceeded the design requirements, the contact force generated by the device at various levels of air evacuation was rigorously tested. Adhesion forces were predicted from the geometry and deformation of the suction chamber with the use of **Equations 1** and **2** below:

$$P_{\text{chamber}} = (V_{\text{chamber}} \times P_{\text{atm}})/(V_{\text{chamber}} + V_{\text{syringe}}) \quad [1]$$

$$F_{\text{adhesion}} = (P_{\text{atm}} - P_{\text{chamber}}) \times A_{\text{chamber}} \quad [2]$$

An electrode housing with no electrode or lead was fabricated and attached to a calibrated spring ($k = 305.7$ N•m), which was in turn attached to the mandrill of a motorized high-precision milling machine. A polished steel plate was attached to the base of the machine, and the electrode was adhered to the plate via vacuum pressure that was created with various levels of syringe evacuation. The spring was then stretched at a constant rate of 6.70 in./min by the position control of the milling machine. When the force in the spring exceeded the electrode adhesion force, the suction device lost contact with the baseplate, the motor was turned off, and linear displacement was recorded. With the use of the spring constant and the distance that the spring stretched, adhesion forces for each syringe evacuation were calculated. A schematic diagram of the testing apparatus is shown in **Figure 2**.

RESULTS

Figure 3 illustrates the predicted and experimentally derived adhesion forces for the prototype device. Although the measured values were consistently lower than those predicted analytically, the shapes of both relationships were nearly identical. Experimentally measured values followed the same relationship to syringe evacuation as the predicted values, with a correlation of 0.989. Limited in-vivo testing has also been performed in several anesthetized dogs, and preliminary qualitative results

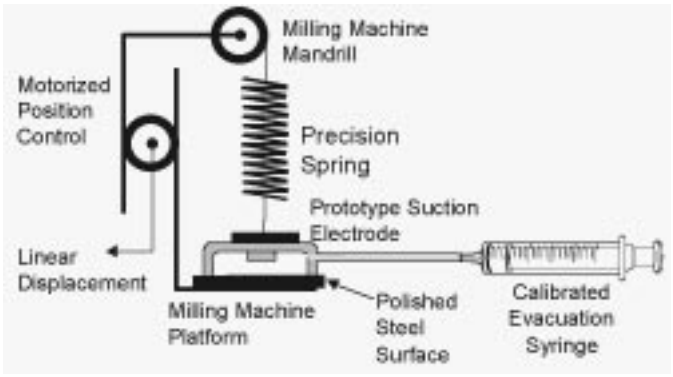

Figure 2.
Experimental setup to calibrate adhesion force as a function of syringe evacuation for prototype suction electrode (not to scale).

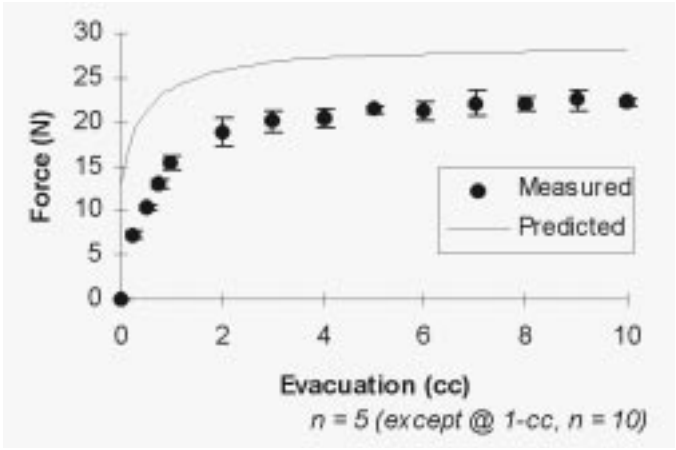

Figure 3.
Predicted and experimentally derived values of normal adhesion force as a function of syringe evacuation. Measured values were highly repeatable as evidenced by small standard deviations and were well correlated with predictions ($r^2 = 0.989$)

indicate both excellent electrode-tissue contact and adequate adhesion force with minimal syringe evacuation (low applied pressures to minimize occlusion of underlying blood vessels). **Figure 4** depicts a typical result from the in-vivo tests and shows the suction mapping electrode in place on the motor point prior to stimulation (**Figure 4a**) and during an active contraction elicited with electrical stimulation (**Figure 4b**). As shown in these illustrations, the device maintained its position relative to the nerve entry point even during active contraction and movement of the muscle. Evident in **Figure 4** is a translation and counterclockwise rotation of the suction electrode as it moves with the underlying muscle tissue.

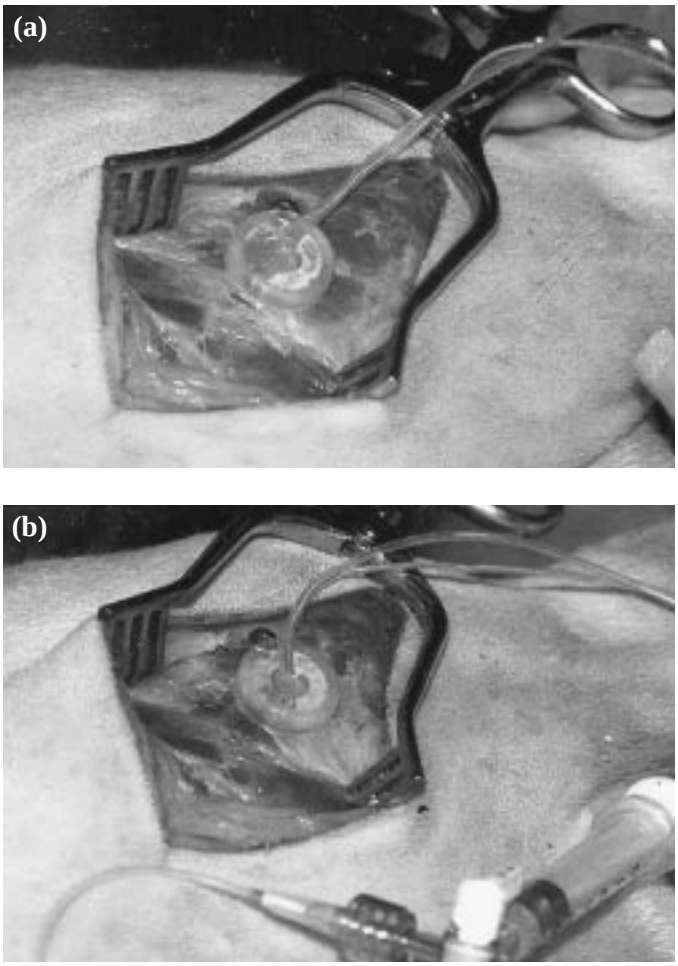

Figure 4.
Example of in-vivo testing on an anesthetized dog showing (a) suction mapping electrode held in place without stimulation and (b) same electrode during an active contraction elicited by electrical stimulation. Translation and rotation of electrode with underlying muscle are clearly evident while firm and consistent contact is maintained.

Stimulated contractions elicited with the electrode were consistent and stable over time, exhibiting none of the limit-cycling behavior or variations with applied pressure frequently observed with hand-held probes.

DISCUSSION

The results indicate high potential for the suction-type epimysial electrode as an intraoperative testing device. The narrow range of adhesion forces at a given level of syringe evacuation is evidence of the repeatability of the device, while the large overall range and

predictability of forces will provide the surgeon with improved probing capabilities. In-vivo testing has shown that the device can maintain its relationship to the underlying tissue even on strongly contracting muscle, further suggesting that it might be useful during the collection of quantitative muscle/tendon forces data during surgery or animal experiments. By virtue of its size and shape, the device cannot be forced underneath the muscle surface, thereby keeping responses consistent with those that would be obtained with a standard epimysial electrode. The large forces shown in **Figure 3** indicate that the current suction chamber far exceeds that necessary to keep the device in place and a smaller suction chamber may be adequate. A device with slightly thinner walls and a smaller functional surface area is currently being fabricated for testing. **Figure 3** represents a calibration curve depicting the adhesion forces as a function of syringe evacuation, and maximal values on the curve should not be misconstrued as recommended operating points for the suction electrode. The operating range of the device should be kept below 5 N to minimize ischemic or mechanical damage to the underlying tissue.

Care should be taken when applying any suction-based device to delicate neurovascular structures. Pressures as low as 3 mm/Hg can exceed certain capillary pressures and compromise the microcirculation of the tissue underlying a suction electrode. Therefore, this device should only be used with the minimal syringe evacuation to maintain the electrode in place, and higher evacuations (leading to increased pressures) should be avoided. Future modifications to the design should be considered that would prevent potentially dangerous pressures from being developed, such as a pressure-limiting diaphragm or other valving mechanism to limit applied pressure.

Even without advanced design features to limit the applied pressure, the suction-based electrode may be safe and suitable for intraoperative use if syringe evacuations are restricted to less than 0.5 cc (adhesion forces less than 5 N). Since the electrode will only be applied for a matter of seconds as stimulation is applied to elicit and grade a contraction, the resulting pressures in this range are within physiologically tolerable limits for short-duration applications. The design is not recommended for chronic application. Rather, the electrodes should be applied just long enough to test an electrode location at the minimal evacuation volumes necessary to maintain its relationship to the underlying tissue.

In addition, any trauma that may be caused by the mapping electrode would be inconsequential when compared to the manipulation, dissection, incisions, and suturing required during the surgical procedure to install the neuroprosthesis itself. In fact, the new tool may prevent unnecessary trauma to the nerve and muscle tissue as the motor point mapping process is improved by eliminating the frequent removal and relocation of improperly positioned electrodes. Relative to other procedures, the intraoperative mapping is the least traumatic aspect of the entire implant process—with or without a suction electrode.

Although the pressures exerted by the device may not exactly match those experienced by electrodes after implantation, the electrode should reduce two sources of variability during the implant surgery. First, the pressure applied by a surgeon using a hand-held probe can vary considerably from trial to trial. A suction-based mapping electrode can exert repeatable adhesion forces even at low evacuation volumes so that stimulated responses from different electrode positions can be more readily compared and the optimal location determined. Second, surgeons experience difficulty moving hand-held probes with the contracting muscle and alter the relationship of the stimulating surface to the underlying neural structures. The suction-based electrode can move with the contracting tissue and maintain its geometric relationship to the nerve and muscle. Removing these sources of variability could be more valuable in the short term than accurately simulating the pressures applied in situ. Further research should be directed to determining the shear stresses and pressures to which implanted epimysial electrodes are subjected in order to improve their design and further refine the intraoperative mapping process.

CONCLUSION

A suction-type stimulating electrode was designed and fabricated to allow intraoperative testing of lower-limb muscles during routinely scheduled surgical procedures. The suction device can adhere to a small exposure of muscle surface with reproducible contact forces, and maintain its relationship to the underlying tissue for several minutes. When operated with a 10-cc syringe, the device can generate between 0 and 23 N of contact force. The experimental behavior of the device was consistent with predictions, as the correlation between measured contact forces and those analytically derived was very high (0.989). Preliminary animal testing indicates that the reusable device maintains its position over the nerve entry point even during vigorous active contractions of the stimulated muscle.

The suction electrode described in this paper solves many of the problems encountered during motor point mapping with hand-held probes and provides a means of quantitative muscle force evaluation. The device has potential to simplify the procedure of localizing areas of maximal stimulated responses, minimize variation with applied pressure, free the surgeon's hands from maintaining a hand-held probe, and elicit consistent responses during movement with stimulated contractions. Its true value and usefulness during the surgical installation of lower-limb neuroprostheses remains to be determined in human volunteers.

Future development should focus on quantifying the effects of the acute application of the suction mapping electrode on the vascular and neural structures beneath it. In addition, a better understanding of the forces, pressures, and stresses imposed upon epimysial electrodes after they are implanted and all incisions are closed and healed would help direct the redesign of implantation tools such as the suction mapping electrode, implant procedures, and the electrodes used in lower-limb neuroprostheses themselves.

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