PRELIMINARY RESULTS OF THERAPEUTIC ELECTRICAL STIMULATION UTILIZING EPIMYSIAL ELECTRODES

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ABSTRACT

This report describes a clinical program in which electrical stimulation via surgically placed electrodes is combined with routine surgical intervention and physical therapy. The electrodes are surgically fixed to the epimysium and the leads directed subcutaneously to exit the skin at a common site. The clinical rational for placement of electrodes and the stimulation protocol are presented and responses to stimulation in the first three implant patients described. Preliminary results indicate that functional muscle contractions of the deep hip muscles can be obtained with epimysial electrodes. Stimulation with surface electrodes alone has not produced a useful muscle response. These results have immediate application to short-term therapeutic intervention for patients with upper motor neuron disorders. Encouragement is also provided for future clinical use of implanted stimulation systems.

INTRODUCTION

Therapeutic electrical stimulation (TES) has proven to be a highly useful modality for the treatment of patients with upper motor neuron paresis such as commonly occurs after stroke, head trauma or spinal injury. TES is utilized not only to help retard or prevent muscle atrophy until such time as voluntary recovery occurs, but to facilitate the amount and rate of motor recovery. Additional benefits of stimulation have been reported including diminution in spasticity, the prevention or correction of contractures, prevention of osteoporosis and cardiovascular conditioning.

Common to all the above applications is the necessity of obtaining a satisfactory muscle contraction. Electrical stimulation has commonly been applied via skin electrodes. Such electrodes are easily applied and have the additional advantage of being noninvasive. There are, nevertheless, inherent limitations in the use of transcutaneous electrodes. Although stimulation of certain lower extremity muscle groups such as the quadriceps can usually be obtained, it is often not possible to obtain an adequate contraction in muscles that are deep beneath the surface. In patients with intact sensation pain may be a limiting factor. For example, the gluteus medius, gluteus maximus and adductor magnus muscles are covered by a thick layer of adipose tissue and it is not often possible to get a good muscle response with skin electrodes.

Another problem that frequently occurs is related to the morphology of the muscle. For example, the large subcutaneous surface area of the quadriceps makes this muscle ideal for surface stimulation. The long narrow shape of the hamstring muscles however, makes it difficult to obtain

a satisfactory contraction. Moreover, the innervation of the hamstrings is on the deep surface of the muscle making it less accessible than the motor point region of the quadriceps.

The above examples serve to illustrate inherent limitations in the application of TES to the lower extremities using skin electrodes. We believed there was a need to develop other types of electrodes to extend the benefits of TES to the key muscle groups not accessible via surface electrodes. Epimysial electrodes placed on the surface of the muscle have been successfully utilized to stimulate muscle (1). This is a preliminary report of our experience with epimysial electrodes for TES of the gluteus medius, gluteus maximus and adductor magnus muscles.

METHODS

Electrodes consisted of a 10 mm diameter, circular titanium disc mounted on medical grade silastic to provide insulation and enable fixation to the epimysium. Electrode leads were made of medical grade stainless steel wire (33 AWG in diameter).

The following procedure was employed to determine the optimum site for electrode placement. An electrical probe of the same diameter as the electrode was placed over the estimated motor point in surgery. Electrical pulses were applied to this probe and the probe moved over the surface of the muscle until the optimal response was obtained.

The wire leads were passed through the skin on the medial thigh and were separated from one another by approximately 1 cm. The leads were attached to a connector for attachment to a commercially available stimulator. The stimulation program was begun two weeks after electrode implantation utilizing a compensated monophasic pulse of 300 usec duration. The stimulation time was progressed to approximately two hours per day. A 1:3 on/off duty cycle was used until the muscle could sustain a functional contractions for 30 minutes and, then, the off time was decreased. Hip abduction and extension moments were measured post-operatively to enable quantification of voluntary strength and to compare the response of epimysial and skin electrodes.

RESULTS

Three patients (with stroke or head trauma) were studied. All three had electrodes placed on the gluteus medius for hip stability; one had electrodes placed on the external surface of the gluteus maximus and two on the posterior surface of the adductor magnus for hip extension.

Electrodes were placed over the posterior edge of the gluteus medius just above the sciatic notch. At this location the muscle and/or fascia overlying the superior gluteal nerve is thin. A strong response of the gluteus medius was obtained in surgery.

The results of stimulation for the first three patients are depicted in Figures 1 and 2. Both the response to electrical stimulation and voluntary movement improved over the course of treatment. The maximum tolerable level of stimulation with skin electrodes produced a minimal contraction in comparison to activation utilizing the epimysial electrodes.

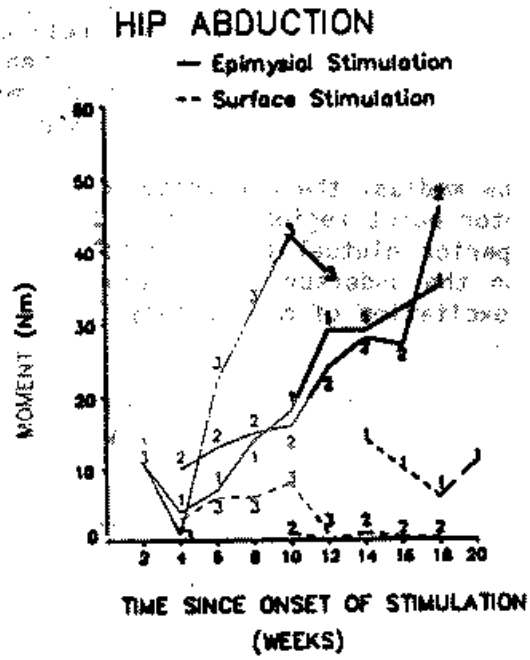

Fig. 1. Electrically stimulated hip abduction moment. Patients 1,2 and 3.

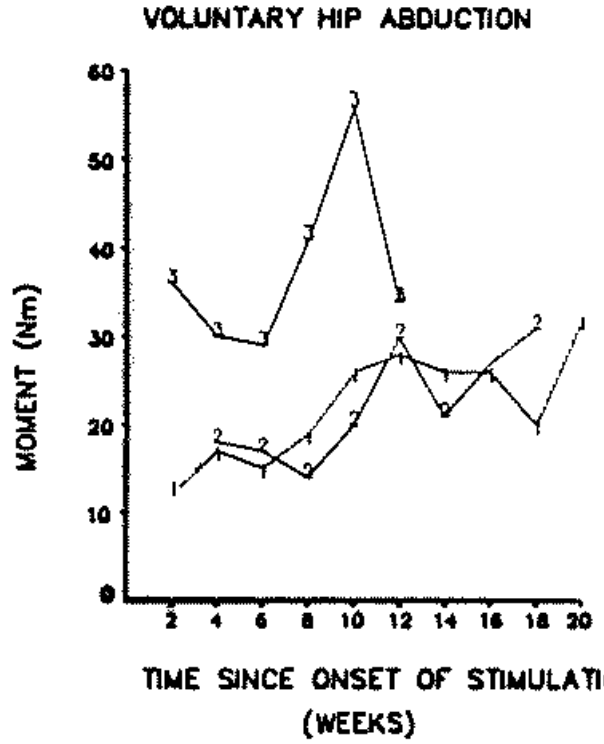

Fig. 2. Maximum voluntary hip abduction moment. Patients 1,2 and 3.

In each instance stimulation of the gluteus medius resulted in activation in the tensor fascia femoris indicating activation of the superior gluteal nerve. In one patient this resulted in undesirable excessive hip flexion during the stance phase. Phenol injection of the superior gluteal nerve in the interval between the medius and the tensor fascia femoris was performed to eliminate this unwanted response.

Unlike the gluteus medius, the electrodes on the gluteus maximus were not placed in the motor point region which is on the interior surface of the muscle. The superior gluteal nerve (which innervates the gluteus maximus) arborizes on the undersurface of the muscle. Stimulation in surgery resulted in excitation of muscle only in the immediate vicinity of the electrode.

Hip extension, like hip abduction, increased throughout the duration of the stimulation program. The stimulation characteristics (threshold, maximum tolerated amplitude, amplitude above threshold, impedence) are listed in Table 1. Of particular note, there was a wide variation of the threshold to stimulation. This is closely correlated with whether or not there were visible motor nerve endings on the surface of the muscle and underneath the electrode at the site of implantation.

TABLE I

STIMULATION CHARACTERISTICS OF EPIMYSIAL ELECTRODES

	Gluteus Medius N=3	Gluteus Maximus N=1	Adductor Magnus N=2
Threshold (ma)	9-33 6-19 1-8	10-39	1-3 1-2
Maximum Amplitude Tolerated (ma)	30-48 8-13	25-41	30-54 20-43 11-15
Amplitude Above Threshold (ma)	7-13 23-30 1-12	6-22	19-41 9-14
Impedance (ohms)	350-480 240-480 210-410	230-350	350-440 370-480

DISCUSSION

Percutaneous fine wire electrodes have been previously utilized to electrically stimulate muscle (2). This research has demonstrated that passage of fine wires through the skin can be tolerated for long time intervals without significant clinical problems. Our preliminary results suggest percutaneous passage of small diameter lead wires connected to epimysial electrodes can also be well tolerated.

Visible contraction of the entire muscle at surgery was not achieved unless the electrode was placed on the motor point region at the site of motor innervation. Stimulation of the gluteus maximus muscle on the external surface, within tolerable levels of stimulation, resulted in contraction of muscle only in the immediate vicinity of the electrode. Placement of an array of multiple epimysial electrodes could be expected to achieve a stronger response. We chose to place epimysial electrodes on the external surface of the gluteus maximus because it is more technically difficult to place epimysial electrodes on the under surface of the muscle.

The superior gluteal nerve does not divide until it passes underneath the inferior surface of the gluteus medius. We were able to activate the entire population of nerve fibers, innervating this muscle by placing epimysial electrodes in the motor point region directly over the posterior edge of the external surface of the gluteus medius directly opposite the nerve. In this region the gluteus medius is thin. The maximal force output that could be tolerated by the patient appeared to be limited by discomfort. We presently plan to compare the force output in surgery in the anesthetized patient with the amount of force that can be achieved in therapy. It is noteworthy that all of our patients had at least some, although impaired, sensation in the lower limb. Further experience is necessary to determine the relationship between stimulation parameters and pain in patients with implanted epimysial electrodes.

A visible contraction of the adductor magnus was achieved by placing the epimysial electrode over a motor point region at the site of observed motor nerve entry. The adductor magnus is innervated by multiple nerve branches which may divide at a considerable distance from the muscle. Therefore, the motor point region of the adductor magnus is quite large and a single epimysial electrode could not be expected to activate the entire muscle. Again, an array of multiple epimysial electrodes may be necessary for the adductor magnus in order to achieve activation of all motor units within the muscle.

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