PREDICTIVE FACTORS FOR QUADRICEPS RECONDITIONING VIA ELECTRICAL STIMULATION

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INTRODUCTION

Electrical stimulation of muscles paralyzed by spinal cord injury shows promise to be a valuable therapeutic adjunct to traditional rehabilitation therapies. Yet, no one has demonstrated a satisfactory way to predict the outcome of programs that recondition paralyzed muscle by surface electrical stimulation; or for that matter, what constitutes an optimal reconditioning protocol. A lack of reliable predictive criteria can result in unrealistic hopes (or alternatively prejudices) by the patient, therapist or physician. Also, any use of electrical stimulation for functional purposes (such as walking or standing) requires that the appropriate muscles first be reconditioned. Knowing what factors are important for reconditioning, and how best to achieve reconditioning, thus can serve as guidelines for selection for functional electrical orthoses.

Over the past three years, we have been studying the application of electrostimulation to a diverse group of male veterans who have paraplegia or quadriplegia. Our goals have been to develop a set of measures that could predict how well a particular patient might respond to a 1 to 2 month period of electrically induced quadriceps exercise and to measure what therapeutic benefits the patient might achieve by such exercise. To date, 31 patients have undergone at least 3 to 8 weeks of twice-daily electrically induced exercise of the quadriceps. We have measured many physiological and psychological parameters in these individuals before, during and after attempting thigh muscle reconditioning.

We have been investigating how such factors as time since injury, level of injury, extent of spasticity, residual voluntary muscle force, residual muscle mass, age, psychological status, and days of reconditioning might relate to the ultimate force and fatigability achieved in a muscle undergoing reconditioning. In this paper, we concentrate on time since injury and baseline measures of stimulated torque as predictors. A trend in our data suggests that a factor like time since injury might be crucial in determining the extent of reconditioning. These trends might well indicate limits for selecting appropriate patients in which surface electrical muscle stimulation has a high **probability of being effective.**

METHODS

Measurement of Torque

All subjects received medical permission to participate in the study and gave informed consent to an institutionally approved protocol. Response to electrical stimulation of muscle was determined immediately after assessing spasticity, while the subject was positioned on a gurney. The pendulum drop test of Wartenburg as refined by Bajd and Bowman (1) was used in our study to measure spasticity. The subject was placed supine on a gurney with both legs free to swing at the knee without obstruction. The short and long term effects of electrical stimulation on spasticity are being reported elsewhere (2).

During the first test session, we determined sensory and motor threshold currents, and a torque recruitment curve for each leg. Current levels of 20 to 160 mA were applied in ascending order (20 mA per step, with 3 or 4 stimuli given at each level). We placed 2" by 4" carbon rubber electrodes with affixed water soaked sponge pads on the midline of the thigh over the quadriceps, with the indifferent electrode centered 3cm above the patella, and the active electrode 10 cm above the indifferent. The reference stimulus was a charge balanced pulse train of 100 mA amplitude, 20 Hz frequency and 400 µsec pulse width, with these parameters continually being monitored with a battery operated oscilloscope. If an individual had any response to this preliminary test, we then fixed the stimulus amplitude at 100 mA and alternately stimulated each leg for 2.5 seconds over a 20 minute test period. During this time the legs were secured at 60° flexion in force transducers (Sensotek) at the ankle. We measured the isometric peak torque produced and monitored the decline of this torque in each leg. The torque that a muscle was able to produce after 20 min of cyclic exercise was termed the "end torque", and it represented one measure of the fatigability of the muscle. We determined three other relative measures of fatigue: the duration of stimulation when the torque declined to 50% and 20% of peak, and the percentage of peak torque remaining after 20 min of stimulation.

All data were then entered into a spreadsheet program (Jazz™) on Apple Macintosh Plus Computers for analysis and plotting (via Jazz™ and Cricket Graph). Peak torque and end torque values for each subject and each leg were plotted as a function of the number of days of stimulation (not calendar days), beginning with the 3 baseline measures and continuing in 2 week increments. Three evaluations were performed after weeks 4 and 8, one after weeks 2 and 6, for those subjects still continuing under the reconditioning protocol. A few subjects had additional evaluations at weeks 3, 5 and 7.

Reconditioning Protocol

All subjects underwent twice daily 20 minute exercise sessions, which were at least 4 hours apart, 6 days a week. Stimulus amplitudes were set at 100 to 120 mA. Compliance was guaranteed since these sessions were almost always initiated by the therapist, unless the subject was on a rare one or two day pass away from the hospital. In the latter case, the amount and timing of exercise were logged by the subject in a diary. The subjects were either **sitting in their wheelchairs or laying supine in bed with knees elevated; their lower legs were unrestrained during exercise and moved against gravity.**

RESULTS

The 31 subjects were almost equally divided into those within their first year post injury (n=15) and those at greater than one year post injury (n=16). All subjects received at least 2 and generally 3 baseline evaluations, all done at least a day apart. All participated in at least two weeks of the reconditioning protocol. Twenty four (11 < 1 year post, 13 >1 year post) received at least 4 weeks of stimulation. Ten of these continued for another 4 weeks, and received 1 to 3 evaluations at the end of week 8.

Restrengthening as a Function of Time

Figure 1 illustrates representative results from two subjects, both with complete T6 injuries, with one at <3 months post injury (Figure 1A, B) and the other at 8.8 years post (Figure1C, D). The filled circles track the peak torque produced during each 20 minute test session, while the open circles indicate the torque remaining at the end of the 20 minutes of exercise. The subject whose data are plotted in Figure 1A, B had the best response (i.e., the maximum increase in peak torque) to our reconditioning protocol. He showed some variability in the peak torque produced during the baseline evaluations, as did most of our subjects (see references 3, 4). This subject had slight increases in peak and end torque for the first 3 weeks. At the end of week 4, the peak torque produced increased by a factor of 2 or more; a similar doubling was also seen between week 6 and 8. The peak torque seen in either leg was at a maximum during the first 8 week evaluation, then showed a successive decline during the remaining two 8 week evaluations. The end torque profiles were very similar to those of the peak torque profiles for this subject.

The other subject whose results are plotted in Figure 1 showed little or no strength increase in either leg, as measured by peak torque changes, even after 8 weeks of exercise; but did exhibit measurable increases in end torque. Note that the peak force seen in either leg steadily declined across the 3 baseline evaluations and in one leg across the 8 week evaluations.

Both subjects exhibited a marked increase in the ratio of end to peak torque at week 2 that persisted throughout the reconditioning protocol (Figure 1E).

In the 7 subjects who received less than 4 weeks of exercise, 10 legs yielded peak torques at the 2 week evaluation that were almost identical to the maximum each achieved in any of their respective baselines. Three legs produced measurably less peak torque at week two when compared to the maximum baseline peak, and one of these was substantially less by a factor of 4 (from 48 N-m during the first baseline to 12 N-m at week 2). Of the 14 legs, only one (from a C6?7 incomplete, 7 months post) exhibited any appreciable strength gain; its peak stimulated torque was doubled from <30 to slightly >60 N-m at week 2.

Comparing Baseline, 4 and 8 Week Evaluations

Peak and end torques produced during the 4 and 8 week evaluation sessions were compared to those seen during the baseline evaluations in three different ways: 1) values obtained during the first evaluations at week 4 and 8 were compared to the values obtained during the first baseline (since many laboratories only make one initial measurement); 2) average values obtained during the three (or 2 or 1) evaluations at week 4 and 8 were compared to average baseline values (thus somewhat smoothing out test-to-test variability); and 3) maximum values obtained during any one of the three 4 or 8 week evaluations were compared to the maximum observed during the baseline tests (thus looking for the relative size of any change).

After 4 weeks of exercise, 15 of the 46 legs tested at 4 weeks had peak torques during the first 4 week evaluation that were more than (n=10) or less than (n=5) 5 N-m over that of the first baseline. Ten legs had averaged 4 week peak torques that were 5 N-m above that of the averaged baseline peak torques, two legs had a 4 week average that was 5 N-m below that of the average baseline (Figure 2B, E). Nine of these 10 legs were of individuals with less than one year post injury (Figure 2E). Fifteen legs exhibited maximum week 4 peak torques that were 5 N-m greater than (n=9) or less than (n=6) the maximum seen in any baseline evaluation (Figure 2D, F). With but one exception, the 9 legs exhibiting increases of 5 N-m or more in the maximum peak torque were again from subjects within one year post injury (Figure 2F). In contrast, all six 6 legs exhibiting reductions at 4 weeks in the maximum peak torque of 5 N-m or more were greater than1 year post injury (Figure 2F). However, baseline peak torques were not even weakly related to years post injury (regression coefficient <0.05). In fact, only 6 of the 22 legs with maximum base torques above 10 N-m were from individuals with <1 yr post (Figure 3A,B).

Taking all legs together, the averaged week 4 peak torques were more strongly related (R value = 0.79) to the averaged baseline values (Figure 2A), than the values obtained from the first 4 week evaluation were to those of the first baseline evaluation (R=0.62). The slopes of the regression lines respectively comparing averages (Figure 2A) or maximums (Figure 2C) at 4 weeks to baseline averages or maximums were both nearly unity, indicating that across the entire population that we worked with, little change in average or maximum peak torque occurred with 4 weeks of exercise.

In contrast, average end torques at 4 weeks were almost 2.4 times that of the averaged baseline end torques, with a regression coefficient of 0.90 (Figure 2G). This indicates a significant enhancement in endurance. Another way to show this increase is presented in Figure 2H, where the percentage ratio of end to peak torque for all baseline and 4 week evaluations is plotted as a function of time since injury. Note that almost all of the open squares (from the 3 four week evaluations) lie above the small closed squares that plot baseline values. When the averaged

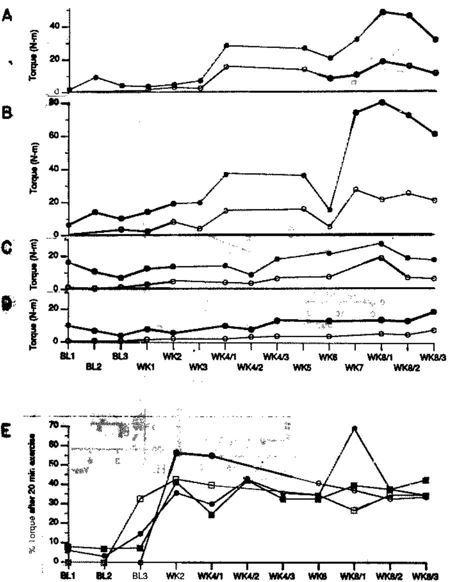

Figure 1: (A-D) Time series for two subjects. Peak torque generated (filled circles) during each 20 minute test period and torque remaining at the end of each test period (open circles). A and B represent the left and right legs respectively of one subject, C and D the same for the other subject. (E) Percent of generated peak torque remaining at the end of the test period, same two subjects. Filled symbols represent the first subject, open symbols the other subject. Circles represent the left leg and squares represent the right leg, both subjects.

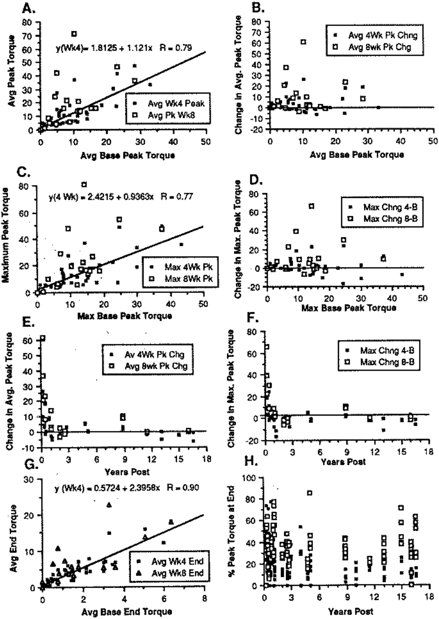

Figure 2: Comparison of average and maximum peak and end torques and changes in these torques per leg, brought about by our reconditioning protocol. The small filled squares represent 4 week evaluations; the larger open squares (or triangles in 2G) represent 8 week evaluations.

end torques from the 4 evaluations were compared to average baseline end torque values, all but four legs showed an increase; and these four legs remained essentially unchanged. Five of the 6 legs exhibiting average end torque changes of greater than 5 N-m were from subjects within one year post injury. As a further measure of fatigability, we **determined the time when the torque declined to 50% of peak torque.** t too was almost universally elevated, further **indicating increased endurance.**

After 8 weeks of exercise, 9 of the 20 legs tested had peak torques during the first 8 week evaluation that were more than 5 N-m over that of the first baseline. Negative changes in peak torque between the first baseline and first 8 week evaluation were seen in only 2 legs, and these reductions were slight (<1.5 N-m). Eight of the 9 plus an additional leg had averaged 8 week peak torques that were 5 N-m above that of the averaged baseline peak torques (Figure 2B), as were their 8 week maximum peak torques above maximum baseline peak torque (Figure 2D). Seven of these 9 legs were of individuals with one year post injury or less (Figure 2F). Only one leg exhibited a maximum **week 8 peak torque that was 5 N-m less than the maximum seen in any baseline evaluation.**

The average end torque measured at 8 weeks exceeded the averaged baseline end torque by 5 N-m in both legs of four subjects (3 <1 yr post, 1 @ 8.8 yrs post).

Predictive Factors

We next determined whether a knowledge of time post injury or of the average or maximum baseline torques could be used to predict the extent of restrengthening. An inspection of Figures 2B, D, E, F reveals certain trends. Legs with baseline peak torques below 4 N-m (average) or 7N-m (maximum) showed no increase in peak torque at 4 weeks or at 8 weeks (c.f., Figure 2B, D). Also, but for one subject, the only appreciable increases in average or maximum peak torque at weeks 4 and 8 occurred if the individual being stimulated was within one year post injury (Figure 2E, F).

Also because of the statistical relationship between the magnitudes of base torques and the torques seen at 4 weeks (Figures 2A,C), at first glance it would appear that the legs that were stronger at baseline would have undergone more reconditioning by week 4 than weaker muscles. But, the strongest muscle at baseline (those producing over 10 N-m of force) often were from individuals with greater than 1 year post injury (Figure 3A,B); and this group **underwent little or no strength increase.**

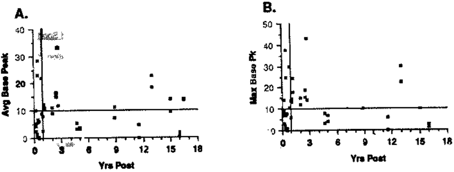

FIGURE 3: Average and maximum baseline peak torques versus years post-injury for those subjects with at least four weeks of exercise.

DISCUSSION

Our findings point out some very important factors that need to be considered when electrical stimulation of paralyzed muscle is proposed. First and foremost, early reconditioning may be essential. And, secondly, muscles may weaken past a point where it is no longer viable for them to be reconditioned.

Many groups have used surface stimulation to restrengthen muscles paralyzed by spinal cord injury. Some use reconditioning protocols similar to ours, where the legs are exercised against gravity (5, 6, 7). Others use closed loop controllers to adjust stimulus amplitudes so that an appropriate fixed weight can be lifted (8 - 12). Still others use stimulators with ramping amplitude onset and offset and limit switches to provide eccentric/concentric **exercise (9, 10). Each method has produced restrengthening in a limited number of individuals, and these individu-**

als form the bases of publications about the particular method. But, a careful analysis of published graphs and discussions with the various principals of the different laboratories involved, reveal that not all patients undergo reconditioning and that failures to restrengthen generally go unreported because they are not going to be used in subsequent functional studies.

We have no doubt that there are more effective ways to recondition than to exercise against gravity. And perhaps twice-daily stimulation sessions are too much, or more than eight weeks of exercise are needed. But, it is clear that our protocol did enhance endurance, even after as little as two weeks of exercise. Perhaps a viable step would be to adopt the concentric/eccentric exercise scheme proposed by Glaser (9, 10) on our next dozen patients to see if a more physiological form of exercise enhances reconditioning and changes the predictive criteria.

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