THE EFFECT OF TRANSCRANIAL STIMULATION ON THE MECHANICAL EFFICIENCY OF PERSONS WITH CEREBRAL PALSY

DISSERTATION

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By

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The problem of this study concerns the reduction of spasticity in physically handicapped persons with CP. The hypotheses tested were: that there would be no significant difference between the mechanical efficiency (ME) of persons with spastic CP following application of the TENS Unit and following application of the placebo unit; that there would be no significant difference between the ME of males with spastic CP, following application of the TENS Unit or the placebo unit, and the ME of females with spastic CP, following application of the TENS Unit or the placebo unit; and that there would be no significant interaction between the treatment factor and the gender category.

Mechanical efficiency (ME) was used to study the effectiveness of the TENS Unit. The data were analyzed using a two factor analysis of covariance.

A mechanically braked ergometer was used to test each subject on a graded exercise test. Expired respiratory gases were collected and analyzed by a Metabolic Measurement Cart (MMC). Subjects were
treated with a working TENS Unit on a placebo unit provided by Pain Suppression Labs, Inc.

Subjects were assigned randomly to one of the stimulators by random drawing. Stimulation was applied transcranially, and an exercise test was given twenty minutes to one hour following stimulation. The second test was conducted forty-eight hours after the first session to allow time for any changes caused by the stimulator to return to baseline. The difference in ME between the pretest and the posttest was calculated and the data were subjected to an analysis of covariance. The resultant F statistic was 17.43, which has a significance of 0.0003. The results indicate that the TENS Unit does significantly reduce spasticity in persons with spastic type CP.
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CHAPTER I

INTRODUCTION

The introduction of new therapeutic modalities and the application of existing therapeutic modalities for treating spasticity as a result of cerebral palsy (CP) raise questions about the objective effects of the modalities. This question is complicated by the problems of assessing the effectiveness of the treatment modality for CP: the evaluator may be biased by his/her desire to see the treatment be effective; the patient may be motivated to improve because of the attention he/she is receiving, i.e., the Hawthorne Effect; and other variables may affect the subject during the course of a long study. Controlled observations of physiological phenomena are one solution to the problem of obtaining objective data about the effectiveness of treatment modalities for CP.

Although no objective data exist establishing the therapeutic effectiveness of the Transcutaneous Electrical Nerve Stimulator (TENS), the manufacturer, Pain Suppression Labs Inc., has stated that the TENS
Unit is effective in reducing spasticity in persons with CP (2). Treatment by the TENS Unit has been reported to enhance physical therapy (3, 4, 6).

A study which would provide objective data about the efficacy of the TENS Unit would be beneficial in providing an assessment of a unit which parents may ask school systems to address in individual educational plans (IEP's). It would also expand the knowledge base about CP and provide information which would be incorporated into Special Education coursework at the post-secondary level. Teacher trainers would be able to present information to students taking Special Education courses about the manifestation and treatment of CP and their relationship to instruction of persons with CP. The study would also provide content material for college coursework in areas such as adaptive physical education, rehabilitation, occupational therapy and physical therapy.

Statement of the Problem

The problem of this study concerns the reduction of spasticity in physically handicapped persons diagnosed as having CP.
Purpose of the Study

The purpose of this study is to assess the efficacy of the Transcutaneous Electrical Nerve Stimulator (TENS) designed and marketed by Pain Suppression Labs Inc. as a modality for reducing spasticity in persons with CP.

Hypotheses

To carry out the purpose of this study, the following hypotheses were tested:

1. There is no significant difference between the mechanical efficiency (ME) of persons with spastic CP, ages ten to thirty-five years, following application of the TENS Unit and the mechanical efficiency (ME) of persons with spastic CP, ages ten to thirty-five years, following application of the placebo unit.

2. There is no significant difference between the mechanical efficiency (ME) of males with spastic CP, ages ten to thirty-five years, following application of the TENS Unit or the placebo unit, and the mechanical efficiency (ME) of females with spastic CP, ages ten to thirty-five years, following application of the TENS Unit or the placebo unit.

3. There is no significant interaction between the treatment factor (application of the TENS Unit and the placebo unit) and the sex category factor (male and female).
Significance of the Study

Although direct brain stimulation has been previously used for treating spasticity (1, 5), these studies reported variable results ranging from a high rate of success to less favorable success. Some of the problems associated with the surgical implantation of an electrode on the surface of the brain included: expense of the procedure; high risk of infection; variable output of voltage; and subjectively determined results. The problems associated with direct brain stimulation are not associated with the use of the TENS Unit (2). Because the technique is noninvasive, the discomfort and risk of infection common to invasive procedures are not present. The stimulation effect of the TENS Unit, however, is comparable to surgically implanted units because the device uses electrodes analogous to the standard EEG electrodes. Recent studies using the TENS Unit (2, 3) indicate that transcranial electrical nerve stimulation reduces hyperreflexia and produces alterations in neurotransmitters (i.e., serum cortesol; adreno cortico tropic hormone; serum tryptophan; serum serotonin; serum gamma alpha butyric acid). Changes in these neurotransmitters directly affect hypertonicity to the extent that there is an increase or decrease in
motor rigidity associated with fluctuations in the levels of certain neurotransmitters.

This study evaluates whether the Transcutaneous Nerve Stimulator (TENS) has an objective, quantifiable effect on muscle spasticity. The techniques explored in this study provide a technically and economically feasible method of screening potential users of the TENS Unit to determine the unit’s probable effectiveness before an individual spends a substantial amount to purchase the device. The information gained expands understanding of the effects of long term deconditioning by providing new tools with which to test populations previously untetable. This study is significant in that it:

1. Provides objective assessment of a therapeutic modality.

2. Provides a means of assessing patient suitability for the modality.

3. Provides content material for college coursework in areas of adaptive physical education, rehabilitation, occupational therapy and physical therapy.

4. Increases the knowledge base in cerebral palsy.

5. Provides the information to teach people techniques for working with individuals with cerebral palsy.
Definition of Terms

Definitions for the purpose of this study are as follows:

1. **Cerebral Palsy (CP).**—Cerebral palsy is a nonprogressive motor impairment existing from the perinatal period. The most common form is muscle spasticity, which includes muscle hyperactivity, innervational overload, or hyperreflexia. It is a chronic, nonepisodic condition.

2. **Mechanical Efficiency (ME).**—Mechanical efficiency is the ratio of the work performed to the energy consumed in performing an operation.

3. **Spasticity.**—Spasticity is a chronic pathological condition involving exaggerated tendon reflexes and muscular spasms.

Limitations

These limitations are recognized for this study:

1. The age range of the subjects necessary to conform to previous studies and to evaluate overall physiologic response may have diluted the subject pool at each age and may have obscured age specific effects.

2. This study attempted to assess the response of one subgroup of persons with CP, those with the spastic type.
3. Direct biochemical assays will not be available to confirm responses in this group of subjects; however, biochemical studies are in progress at other laboratories.

4. The mechanisms of long term deconditioning and how they may affect responses to stimulation are not adequately understood.

5. Subjects were volunteers who were affected with CP. Since the criterion measure was based on a physiologic response, it would not have been influenced by cognitive or emotional factors which could differentiate between volunteers and non-volunteers.

6. The conclusions drawn are applicable only to persons with spastic CP.

7. This was an exploratory study designed only to determine whether the phenomena of beneficial physiologic responses to the TENS Unit existed. This study did not attempt to measure the subjects' optimal responses to stimulation or the optimal schedule of stimulation that would benefit the subject.

Summary

The problem of applying existing therapeutic modalities and introducing new therapeutic modalities for treating spasticity in individuals with CP lies in the absence of objective observation of the treatments
and, thus, the absence of an objective assessment of the treatments' effectiveness. This problem has been associated with testing the effectiveness of the Transcutaneous Electrical Nerve Stimulator (TENS), a device claimed to reduce spasticity in persons with CP.

It is asserted that controlled observations of physiologic phenomena would solve the problem of obtaining objective data regarding the effectiveness of treatment modalities for spasticity in CP.

The problem of this study concerns the improvement of neuromuscular function in the physically handicapped diagnosed as having CP. To achieve the purpose of this study the following hypotheses were tested. First, it was hypothesized that there would be no significant difference between the mechanical efficiency (ME) of persons with spastic CP, ages ten to thirty-five years, following application of the TENS Unit and the ME of persons with CP, ages ten to thirty-five years following application of the placebo unit. Secondly, it was hypothesized that there would be no significant difference between the ME of males with spastic CP, ages ten to thirty-five years, following application of the TENS Unit or the placebo unit, and the ME of females with spastic CP, ages ten to thirty-five years, following application of the TENS Unit or the placebo
unit. Finally, it was hypothesized that there would be no significant interaction between the treatment factor (application of the TENS Unit and the placebo unit) and the sex category (male and female).

The information gained in this study expands the understanding of the effects of long term deconditioning by providing new methods by which to test previously untestable populations. The study's primary significance is that it provides objective assessment of a therapeutic modality, i.e. the TENS Unit. The study's secondary significance is that it increases the knowledge base in cerebral palsy and provides content material for college coursework in areas of adaptive physical education, rehabilitation, occupational therapy and physical therapy.

The study's limitations included restriction of the age range of the subjects and restriction of the sample to individuals with spastic CP. Furthermore, chemical analysis of blood samples from the group was not carried out in order to confirm responses to the TENS Unit. Also, long term deconditioning is not clearly explained in the literature on CP or on any disabled group. Therefore, the effects of deconditioning could not be accounted for in this study.
Chapter II includes a review of related literature. Chapter III describes the methods and procedures used in the data collection and data analysis. Chapter IV contains the obtained descriptive and inferential statistics and a discussion of the results. Chapter V presents a summary of the study, the conclusions, and recommendations for further research.
CHAPTER BIBLIOGRAPHY


CHAPTER II

SYNTHESIS OF RELATED LITERATURE

Introduction

This chapter presents a review of the related literature as it relates to the current study. The literature cited is grouped into the following categories: Cerebral Palsy and Functional Capacity; Direct Brain Stimulation and Associated Problems; Research Using the TENS Unit; Methods of Spasticity Reduction; Evaluation of Spasticity Using Mechanical Efficiency; Cerebral Palsy and Education; and Summary.

Cerebral Palsy and Functional Capacity

Most authorities (1, p. 152; 25, p. 86; 26, p. 444) indicate that cerebral palsy (CP) is a nonprogressive motor impairment existing from the perinatal period. The most common form is muscle spasticity, which is described as muscle hyperactivity, innervational overload, or hyperreflexia. Furthermore, authorities indicate that CP is not an episodic condition. The disease is continuously present; that is, it is not a condition that attacks the individual at different
times. About 90 per cent of those individuals with CP have the spastic type (26). Other forms of CP are: Ataxia, Dystonia, Ballismis, and mixed types.

It has been reported in studies (1, p. 154; 4, 6, 16, 17, 25, 26) conducted on individuals with CP that spasticity affects the individual's ability to function through several mechanisms. Usually, the person will have a reduction of aerobic capacity of from 10 per cent to more than 50 per cent of the norm.

A study supporting these assertions was conducted by Lundberg (17). The results indicated a decrease in heart rate (HR) in individuals with CP. The research was a longitudinal study of HR during submaximal work in fourteen persons with CP ranging in age from fourteen to twenty-seven years. Using a bicycle ergometer, work tests were conducted once a month for two years for all subjects, and for three years for eleven of the subjects. A study by Knutsson (16) on muscle activation patterns was conducted on adults affected with spastic hemiparesis, paraparesis, and CP. Limb movements were recorded and surface EMG's were taken from different leg muscles and compared for each individual patient to the normal movement of the control group, i.e., healthy volunteers. The results indicated a decreased capacity to accelerate motion secondary to antagonist restraints
for the handicapped group.

Another study indicated that rehabilitation programs for handicapped individuals achieve little effectiveness. Bar-or’s (4) study to determine the physiological effects of a sports rehabilitation program involved a sample of thirty-four spastic CP and post-poliomyelitic adolescents and young adults ranging in age from fifteen to twenty-two years. For a period of one year, the handicapped individuals participated in a conditioning program twice a week. When compared to a control group of non-exercised individuals with CP, the exercised group showed no significant changes attributable to the conditioning program.

In a study examining the effects of physical training of individuals with CP, ages seven to twenty-five years, Berg (6) reported that individuals with motor control handicaps experienced strain in performing the activities of daily living. Furthermore, training effects in persons with CP were sometimes not found immediately. Berg also reported that, after three and one half months of summer vacation during which training was interrupted, the maximal oxygen uptake of the group in training was significantly reduced.
Direct Brain Stimulation and Associated Problems

Direct brain stimulation has been previously explored as a treatment modality for spasticity (9, 20, pp. 334-335). The earlier studies reported variable results: some reported a high rate of success while others were less favorable in their reports. The successful findings included: reduced muscle rigidity; improved speech; reduced athitocity; and improved function in activities of daily living (9). These areas of improved function were not affected by other treatment modalities.

There were a number of methodological problems with the earlier use of cerebral stimulation. First the technique required surgically implanting an electrode on the brain's surface. This procedure had all of the problems associated with invasive procedures: it was traumatic; it was expensive; it carried a high risk of infection; it required extensive medical follow up; and it was unacceptable to many individuals. In addition, the equipment, subject to service problems, was not easily accessible. The voltage output of the equipment was overly variable; improvement was often decided subjectively. Also, the procedures did not lend themselves to controlled studies, and follow up was frequently inconsistent (20, pp. 336-340). Although the
technique did not gain widespread acceptance, these studies did indicate that cortical stimulation was a promising treatment modality.

Research Using the TENS Unit

A treatment modality which would affect the typical CP patient would necessarily result in a reduction of the spasticity. It would, therefore, also result in an increase in the individual mechanical efficiency (ME).

Pain Suppression Labs Inc. of Elmswood Park, New Jersey, has a Transcutaneous Electrical Nerve Stimulator (TENS Unit) which they claim temporarily reduced spasticity in persons with CP (10). The unit has been in use for over ten years as an effective treatment for severe headaches (19, 24). The unit has also been used to treat dental and maxillofacial problems such as temporo-mandibular joint dysfunction (27). There are no reports of adverse effects resulting from the application of the Pain Suppression Lab's TENS Unit.

The TENS Unit uses electrodes analogous to standard EEG electrodes which are applied to the scalp (10). Therefore, it is a transcranial stimulator. Compared to a standard EEG unit, however, the TENS Unit employs a carrier frequency that carries the stimulating frequency deeper into the brain.
The TENS Unit has been applied to some individuals with spastic CP (19, 24). A concomitant subjective decrease in spasticity and improvement in function has been noted. Improvement has occurred approximately twenty minutes after the treatment and has lasted several hours (10).

The initial impression of a decrease in spasticity with an increase in function was followed up by Malden and Charash (18). They evaluated a group of children with spastic CP on their own motor scale which involved some subjective estimation of function. Their subjects were aged two months to fifteen years and beyond. Their design involved evaluating the subjects before and after the application of the TENS Unit. They found a two-fold improvement in motor function post-treatment with the unit. They concluded that the improvement in motor function was due to the inhibition of primitive pathological reflexes. These findings could also be described as a reduction in hyperreflexia.

Pain Suppression Labs Inc. has provided additional preliminary information which does provide some insight into possible mechanisms by which their stimulator might reduce spasticity. According to Dauron (10), one ongoing project revealed several alterations in neurotransmitters following transcranial stimulation.
The serum cortesol level was increased while the adreno
cortico tropic hormone (ACTH) was decreased. The serum
tryptophan level was also decreased while the serum
serotonin level and the serum gamma alpha butyric acid
(GABA) levels were increased.

Models of Spasticity Reduction

Messing (21) reported that a decrease in serotonin
level was associated with an increase in motor rigidity,
or in other terms, an increase in hypertonicity. There
was also an increase in the startle response, i.e.,
hyperreflexia, and an increase in response to noxious
stimuli; this also parallels the hyperreflexia of the CP
patient. The researchers hypothesized that serotonin is
involved with many behavioral regulatory mechanisms such
as body temperature. There was a large amount of
variability in individual responses to serotonin.

Tryptophan is a precursor of serotonin (22,
describe GABA as an inhibitory amine. It is a central
nervous system agent that inhibits the neuronal
transmission of impulses. It is synthesized in the
central nervous system. Only trace amounts are found in
the peripheral nervous system. Its action is thought to
be limited to the central nervous system because it does
not readily cross the brain-blood barrier; however, all
levels of neurons are sensitive to it. GABA is the most abundant neurotransmitter. It is found in concentrations of from ten times to 100 times the concentration of other neurotransmitter substances. Its rate of clearance is also on the order of magnitude of ten to 100 times the rate of other neurotransmitters. The primary action of the GABA is to inhibit synaptic transmission of impulses (28). Other corticosteroids cause a decrease in sensitivity to neuronal signals. ACTH is hormone which is produced when cortisol levels are low. It triggers the release of more cortisone. The serum ACTH levels are low when the serum cortisol levels are high.

Evaluation of Spasticity Using Mechanical Efficiency

The next major question is how can the clinical effectiveness of the transcranial stimulator be evaluated? Perhaps the most promising technique is through examining its effects on mechanical efficiency.

Mechanical efficiency (ME) has been expressed in a number of ways. Bar-or (3, p. 7) described ME as the ratio between the mechanical work performed and the chemical energy consumed. Work is defined in physical terms as occurring when a force causes a body to move along the line of force (6, pp. 82-85). Body, in this sense, is described as the object upon which the force
is acting. Perhaps the key to this definition is that movement must occur.

Mechanical efficiency (ME) has been expressed mathematically. Devries (11, pp. 432-433) describes several types of ME. Gross efficiency is defined as:

\[ ME = \frac{W}{E} \]

where \( W \) is work performed, and where \( E \) is energy consumed in performing the task. Devries also described net efficiency as:

\[ ME = \frac{W}{E} - e \]

where \( W \) and \( E \) are work performed and energy consumed. \( e \) is the amount of energy consumed at rest. Delta efficiency was defined as:

\[ ME = W/E \triangleq E \]

where \( \triangleq \) represents change.

Another equation represents the conversion of the units to those commonly found in exercise labs:

\[ ME = \frac{W \ (Kg \times M/Min)}{V O_2 \times (2 \times 75 \ Kgm \times ML)} \]

The expression \((2 \times 75 \ Kgm \times ML)\) is a conversion factor to express energy in calories.

Both Shepard (23) and Astrand and Rodahl (2) use the expression:

\[ ME = \frac{W \times 100}{E - e} \]
Bar-Or (3) has also used the following expression:

\[ ME = \text{Mechanical Power Output} \]

\[ (\text{Metabolic rate exercise}) - (\text{Metabolic rate rest}) \]

This expression corresponds to Devries (11, p. 433) expression for net ME. Any of these expressions are sensitive indices of changes in the amount of energy one must exert to achieve a given amount of work.

Any reduction in spasticity results in less energy being needed to perform a given amount of work. To understand how this works one must consider the mode of action of the skeletal muscles. Henneman (14, pp. 773-776) states that the most closely related muscles are the direct agonists such as biceps–triceps dyad. When one muscle is stimulated and contracts (the agonist), the opposing muscle (the antagonist) must lengthen. The antagonist regulates the action of the agonist by exerting a breaking action in counter force by contracting to a limited degree and relaxing in stages rather than all at once. Gardiner (12, pp. 155-158) has referred to the agonist as the prime mover. The antagonist has been described as modifying the action of the prime mover by varying the rate and degree of relaxation. Basmajian (5), however, states that the agonist usually relaxes completely during movements.
Cerebral Palsy and Education

Knowledge about cerebral palsy and the mechanisms by which it limits people is important to the educator because one half of all physically handicapped children have CP (8, PP. 180-182). The tendency for children with CP to have multiple handicapping conditions complicates the assessment procedure and the development of educational programs for them. Frequently sensory abilities are also affected (13, p. 354).

An individual's basic movement skills provide the framework for that person's development (15, pp. 378-380). Therefore, physiological impairments may have dramatic effects on all areas of development. Specific educational recommendations are usually expressed in terms of the medical model of disease and treatment. These recommendations are usually expressed in terms of physical goals and behavior modification (8, pp. 180-182).

Summary

The research on cerebral palsy and functional capacity indicates that spasticity profoundly affects an individual's ability to function through several mechanisms. Some of the problems observed include: a decrease in HR in persons with CP (17); decreased
capacity in muscle activation (16); lack of significant changes attributable to conditioning programs (4); and significantly reduced maximal oxygen uptake for CP disabled individuals (6).

Studies in direct brain stimulation (9, 20, pp. 336-340) indicate that cortical stimulation is a promising treatment modality for spasticity. There have been, however, several methodological problems associated with the use of cerebral stimulation. McLellan (20, p. 336-340) emphasizes that the lack of controlled studies and inconsistent followup are major barriers to overcoming the problems of investigating the therapeutic effects of direct brain stimulation.

Investigations using the Transcutaneous Electrical Nerve Stimulator (TENS), a device manufactured by Pain Suppression Labs Inc., have indicated that the TENS Unit reduces spasticity in persons with CP (9). Additional research indicates: an increase in motor function post-treatment with the TENS Unit (18); a decrease in spasticity and improvement in function following application of the TENS Unit (19, 24); and alterations in neurotransmitters associated with hypertonicity after application of the TENS Unit (10).
Models of spasticity reduction based on changes in neurotransmitters have been researched (21, 22, pp. 214-215; 28, pp. 1558-1563). The value of studies on the fluctuation of neurotransmitter levels (i.e., serotonin, tryptophan, GABA, and ACTH) lies in the implications regarding the reduction of spasticity in CP patients by the inhibitory effects of specific neurotransmitters.

The validity of utilizing mechanical efficiency (ME) as a means by which to study the clinical effectiveness of the TENS Unit is established by the presentation of the mathematical derivations of ME (2, 3, pp. 82-85; 7, 11, p. 443; 23) and explanations about spasticity reduction and corresponding reductions in energy requirements (5, 12, pp. 155-158; 14, pp. 773-776).

It is important for educators to remain aware of the instructional implications of handicapping conditions which confound the presence of cerebral palsy in children. The data in the literature indicate that one half of all physically handicapped children have cerebral palsy. The medical model of diagnosis and treatment has been the usual procedure employed in making educational recommendations and developing educational programs for children with cerebral palsy (8).
CHAPTER BIBLIOGRAPHY


CHAPTER III

PROCEDURE FOR THE STUDY

Introduction

The purpose of this study is to assess the efficacy of the Transcutaneous Electrical Nerve Stimulator (TENS) designed and marketed by Pain Suppression Labs Inc. as a modality for improving neuromuscular function in persons with CP.

This chapter presents the methodology used in the study. The information in the chapter is presented under five headings: Sample; Instrumentation; Protocol; Research Design; and Summary.

Sample

Subjects for this study were thirty six adults and children with established diagnoses of spastic type cerebral palsy (CP). Thirty subjects completed the study both test sessions and were included in the data analysis. The mean age of the subjects completing the study was twenty-three years with a range of ten to thirty-five years. There were thirteen males and seventeen females in the group. Seventeen of the
subjects were participants in CP sports programs in the Dallas-Fort Worth area. Six subjects did not complete the study. Three of these were unable to maintain the pedaling motion on the ergometer. The other three did not return for the second session.

**Instrumentation**

Each subject was asked to perform a graded exercise test on a bicycle ergometer. The ergometer used was a Tunturi mechanically braked ergometer which displayed the pedaling speed in revolutions per minute (rpm) and the resistance to pedaling in Newtons (N). Expired respiratory gases were collected and analyzed by a Beckman Metabolic Measurement Cart (MMC). The MMC measured the volume of air expired, the amount of CO₂ produced, and the amount of O₂ used. The respiratory exchange quotient (RQ) was calculated.

Subjects were treated with one of two stimulators provided by Pain Suppression Labs, Inc. One unit was a working stimulator and the other was a placebo unit. The personnel associated with the data collection were not advised about which unit was the placebo until the data collection had been completed, i.e. the study was double blinded.
Protocol

Each subject was asked to give informed consent. Informed consent was also asked from the parents of subjects under the age of eighteen years. Those giving informed consent were screened to ascertain that they were in the American College of Sports Medicine (ACSM) low risk category regarding the potential for developing cardiovascular complications during or following maximal exercise. The subjects were also given a resting twelve lead electrocardiogram.

Subjects were assigned to one of the stimulators (TENS or Placebo) by random drawing. Each subject also drew slips of paper to determine whether the stimulator would be applied just prior to their first exercise test session or prior to their second exercise test session. The slips were replaced prior to each subject's drawing to insure that the drawing was random. This procedure was recommended by the researcher's dissertation committee. The basis of the recommendation was the necessity to counterbalance any improvement effect due to practice (i.e., the pedaling motion). Stimulation was applied transcranially, just above the subject's ears for ten minutes. The subject was tested twenty minutes to one hour following the stimulation. The second exercise session was conducted forty-eight hours
after the first to allow time for any changes caused by the stimulator to return to a baseline.

During the graded exercise test, the workload was started at 0 N and increased every two minutes until: the subject reached a RQ of 1.0; the subject was unable to continue; the ACSM discontinuation criteria were met; or until the subject requested that the test be stopped. The workload was increased by two to five N every two minutes, based on the subject's: heart rate response; blood pressure response; and ability to maintain pedal velocity. The heart rate was measured by an EKG utilizing lead V5 every minute. Expired gases were also measured every minute. Blood pressure was recorded every two minutes. The frequency of measurement was decreased to every thirty seconds as the RQ approached 1.0 or as the subject appeared to be laboring to maintain the workload.

The workload in watts (w) was calculated from the resistance and pedal velocity utilizing the formula:

\[ W = \frac{N \times R \times x}{30} \]

where \( W \) = workload in watts, \( N \) = resistance in Newtons and \( R \) = pedal velocity in RPM. ME was calculated utilizing the formula:

\[ ME = \frac{W}{E} \]
Where \( ME = \) mechanical efficiency, \( W = \) workload in watts, and \( E = \) energy consumes in liters of \( O_2 \).

Research Design

A two factor analysis of covariance was used to test the hypotheses. The change in \( ME \) from the first test to the second test was the dependent variable. The covariate was the initial oxygen uptake. The subjects were grouped by the unit (TENS or placebo) they drew and they were blocked by gender to form a two factor design. The pretest was defined as any exercise test performed without having utilized the stimulator for at least 48 hours. The post test was defined as any exercise test performed within one hour of using the stimulator.

The data were entered into a computer data file utilizing keyboard entry. The statistical analysis was performed on the Digital Equipment Corporation (DEC) VAX computer utilizing the BMDP statistical program. The routine used was the BMDP 2v program for analysis of variance and covariance including repeated measures. The statistical procedures employed included the following:

1. Calculation of the means and standard deviations for the covariate and the dependent variable.
2. Utilization of a two factor analysis of covariance to test the hypotheses.

Summary

This study assesses the efficacy of the TENS Unit as a modality for improving neuromuscular function in persons with CP. The statistics procedures employed in the study include:

1. Calculation of the mean and standard deviation for the covariate and the dependent variable.

2. A two factor analysis of covariance.

A Tunturi mechanically braked ergometer was used to enable each subject to perform a graded exercise test. Expired respiratory gases were collected and analyzed by a Beckman Metabolic Measurement Cart (MMC). Subjects were treated with a working TENS Unit and a placebo unit provided by Pain Suppression Labs, Inc.

Screening tests for the purpose of ascertaining whether subjects had a potential for developing cardiovascular complications during or following exercise were used.

Subjects were assigned randomly to one of the stimulators by random drawing prior to the first exercise session. Stimulation was applied transcranially, and an exercise test was given twenty minutes to one hour following stimulation. The second
exercise test session was conducted forty-eight hours after the first session to allow time for any changes caused by the stimulator to return to baseline.
CHAPTER IV

RESULTS AND DISCUSSION OF RESULTS

Introduction

It was hypothesized that no difference in mechanical efficiency (ME) would be found in persons when treated with the Pain Suppression Lab's TENS Unit and when treated with the placebo unit. It was also hypothesized that there would be no difference between males and females in their change in ME following use of the stimulator, and that there would be no change in the ME which could be attributed to the interaction of gender (sex) and the unit (TENS or placebo) used.

The primary test of the hypothesis was a two factor analysis of covariance. The analysis of covariance was chosen because it was not possible to obtain an adequate population which was homogeneous on factors such as: age, severity of involvement, body surface area, and participation in aerobic activities, i.e., many of the CF sports. By using the initial, or nonstimulator influenced oxygen uptake as the covariate, the entry level variance was controlled.
The information presented in this chapter is organized beneath two headings: descriptive statistics, and analysis of covariance. The data were arranged to include all tests performed without stimulation as exercise pretest. All tests performed with stimulation were called exercise posttest.

Descriptive Statistics

The raw data of each of the thirty subjects completing two tests, were used to calculate the performance measures. The data were entered into a Vax computer by keyboard entry. The data were subjected to a two factor analysis of covariance using the BMDP 2V program for analysis of variance and covariance. Means and standard deviations were obtained for the data. These data are presented in Table I.

There were thirty subjects completing the study. Thirteen were males and seventeen were females. Six additional subjects were either unable to pedal the ergometer or withdrew from the study. Of those subjects completing the study, eleven drew the placebo unit and nineteen drew the TENS Unit.

The mean exercise pretest oxygen uptake for the males who drew the placebo unit was 1.58 liters and the mean oxygen uptake on the exercise pretest for females
who drew the placebo unit was 1.21 liters. The mean oxygen uptake on the exercise pretest for males who drew the TENS Unit was also 1.58 liters. The mean exercise pretest oxygen uptake for females who drew the TENS Unit was 1.12 liters.

**TABLE I**

**MEANS AND STANDARD DEVIATIONS OF THE VARIABLES**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Range</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>10-35</td>
<td>23.00</td>
<td>07.40</td>
</tr>
<tr>
<td>WL</td>
<td>6.00-156.6</td>
<td>39.90</td>
<td>56.30</td>
</tr>
<tr>
<td>( V_021 )</td>
<td>0.54-002.2</td>
<td>01.34</td>
<td>00.45</td>
</tr>
<tr>
<td>Me 1</td>
<td>5.20-077.5</td>
<td>51.50</td>
<td>19.40</td>
</tr>
<tr>
<td>WL 2</td>
<td>6.30-197.9</td>
<td>84.80</td>
<td>42.00</td>
</tr>
<tr>
<td>( V_022 )</td>
<td>0.65-002.5</td>
<td>01.51</td>
<td>00.52</td>
</tr>
<tr>
<td>Me 2</td>
<td>7.60-099.5</td>
<td>55.10</td>
<td>19.50</td>
</tr>
<tr>
<td>Ch Me</td>
<td>-18.10-027.0</td>
<td>03.40</td>
<td>10.60</td>
</tr>
<tr>
<td>Rec 1</td>
<td>02.00-008.0</td>
<td>05.10</td>
<td>01.40</td>
</tr>
<tr>
<td>Rec 2</td>
<td>02.00-009.0</td>
<td>05.10</td>
<td>01.80</td>
</tr>
</tbody>
</table>

\( WL \) = prestimulation workload in watts  
\( V_021 \) = prestimulation oxygen uptake in liters/minute  
Me 1 = prestimulation mechanical efficiency  
WL 2 = poststimulation workload in watts  
\( V_022 \) = poststimulation uptake in liters  
Me 2 = poststimulation mechanical efficiency  
Ch Me = change in mechanical efficiency  
Rec 1 = prestimulation recovery time in minutes  
Rec 2 = poststimulation recovery time in minutes  

See Appendix for further details.

**Analysis of Covariance**

The data were subjected to a two factor analysis of covariance by the BMDP 2V computer program. The grouping variables were the sex of the subject (sex)
and the unit which the subject drew (unit). The dependent variable was the change in ME from exercise pretest to exercise posttest. Table II presents: the cell means and standard deviations for the covariate; the oxygen uptake (VO2) on exercise pretest; and the change in ME from exercise pretest to exercise posttest. A visual review of the data indicates that there is no difference between the subjects who drew the placebo unit, and those who drew the TENS Unit on their entry level oxygen uptake. There were some small differences between the males and females who drew each unit. The mean exercise pretest oxygen uptake for the males who drew the placebo unit was 1.58 liters and the mean oxygen uptake on the exercise pretest for females who drew the placebo unit was 1.21 liters. The mean oxygen uptake on the exercise pretest for males who drew the TENS Unit was also 1.58 liters.

The mean exercise pretest oxygen uptake for females who drew the TENS Unit was 1.12 liters. One would expect that the males would have a larger VO2 because males generally have a larger body surface area (BSA) and the oxygen uptake is closely related to the BSA (8).
<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo Males</th>
<th>Placebo Females</th>
<th>TENS Males</th>
<th>TENS Females</th>
</tr>
</thead>
<tbody>
<tr>
<td>VO2 X</td>
<td>1.58</td>
<td>1.21</td>
<td>1.58</td>
<td>1.12</td>
</tr>
<tr>
<td>VO2 sd</td>
<td>.71</td>
<td>.37</td>
<td>.43</td>
<td>.29</td>
</tr>
<tr>
<td>Me X</td>
<td>-2.46</td>
<td>-7.47</td>
<td>8.34</td>
<td>6.95</td>
</tr>
<tr>
<td>Me sd</td>
<td>8.29</td>
<td>8.10</td>
<td>7.47</td>
<td>8.85</td>
</tr>
<tr>
<td>Adjusted Cell Means</td>
<td>-1.96</td>
<td>-7.75</td>
<td>8.86</td>
<td>6.48</td>
</tr>
</tbody>
</table>

VO2 X = the mean oxygen uptake on the exercise pretest
VO2 sd = the standard deviation for the oxygen uptake on the exercise pretest
Me X = the mean change in mechanical efficiency between the exercise pretest and the exercise posttest
Me sd = the standard deviation of the change in mechanical efficiency between the exercise pretest and the exercise posttest
Me = change in mechanical efficiency between the exercise pretest and the exercise posttest

The mean change in ME between the exercise pretest and the exercise posttest for males who drew the placebo unit was -2.46, while the mean change in ME for females who drew the placebo unit was -7.47. The mean change in ME between the exercise pretest and the exercise posttest for males who drew the TENS Unit was 8.34, and the mean change in ME for the females who drew the TENS Unit was 8.95. The adjusted cell means for the change
in ME between the exercise pretest and the exercise posttest were: -1.96 for males drawing the placebo unit; -7.75 for females drawing the placebo unit; 8.86 for males drawing the tens unit; and 8.48 for females drawing the TENS Unit. While there is a difference between the males and females on the change in ME for the TENS Unit, the direction and magnitude of the change was influenced by unit much more than by sex. The adjusted cell means for the change in ME are of similar magnitude and direction.

The observations are confirmed by the F statistic presented in Table III. The F statistic for the unit factor is 17.43, which is significant at the .0003 level. The F statistics for the sex factor and for the sex factor by the unit factor interaction were less than 1.0. These F statistics were significant at the .40 to .50 level. Therefore only the F statistic for the unit factor was significant at the .05 level.
### TABLE III

**ANALYSIS OF COVARIANCE**

<table>
<thead>
<tr>
<th>Source</th>
<th>Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit</td>
<td>1207.44</td>
<td>1</td>
<td>1207.44</td>
<td>17.43</td>
<td>.0003</td>
</tr>
<tr>
<td>Sex</td>
<td>0049.95</td>
<td>1</td>
<td>0049.95</td>
<td>00.72</td>
<td>.40</td>
</tr>
<tr>
<td>U x S</td>
<td>0048.11</td>
<td>1</td>
<td>0048.11</td>
<td>00.69</td>
<td>.41</td>
</tr>
<tr>
<td>VO2</td>
<td>0026.05</td>
<td>1</td>
<td>0020.05</td>
<td>00.29</td>
<td>.59</td>
</tr>
<tr>
<td>error</td>
<td>0017.31</td>
<td>25</td>
<td>0069.26</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Unit** = treatment unit (TENS or Placebo)

**Sex** = male or female

**U x S** = the unit by sex interaction

**VO2** = the exercise pretest oxygen uptake

**Discussion of Results**

The first hypothesis, stated in the null form, was that there would be no significant difference between the ME of persons with spastic CP, ages ten to thirty-five years, following application of the TENS Unit and the ME of persons with spastic CP, ages ten to thirty-five years following application of the placebo unit. The F statistic obtained was significant at the .0003 level which greatly exceeds the customary .05 level of significance. Therefore the null hypothesis is rejected.

The alternate hypothesis, that the TENS Unit does reduce spasticity in persons with spastic type CP, is
accepted. These results were predicted by the changes in the blood neurotransmitter levels following stimulation with the unit (7). In that study the GABA, cortisol, and serotonin levels increased noticeably starting twenty minutes following use of the stimulator. The cortisol and the GABA exhibit an inhibitory effect which would be likely to inhibit the spasticity by reducing the hyperreflexia and the hypertonicity (12). The increase in serotonin level would be expected to also result in a decrease in the hypertonicity, thereby reducing the spasticity.

GABA is found in medications used to treat spasticity (6). The two most common approaches used are to include GABA as the primary active ingredient in the medication or to modify the body's metabolic cycles for GABA in order to increase the amount available to the nervous system. It is considered to reduce spasticity by acting at multiple binding sites in the nervous system. This reduces the space available for substances that facilitate the transmission of the impulses maintaining the hypertonicity and the hyperreflexia.

The serum serotonin level is more difficult to evaluate. Serotonin is produced in the central nervous system and in the intestines (13, pp. 212-15). Since
most of the circulating serotonin comes from the intestines, several questions arise:

1. Does the serotonin in the blood cross the blood-brain barrier?

2. Does the circulating serotonin level reflect the central nervous system action of the serotonin?

The results of this study suggest that the increased serotonin levels found following use of the stimulator in previous studies (7) are indicative of the central nervous system action of the serotonin.

The results of this study are similar to those of Cooper (5). He also found that cerebral stimulation does reduce spasticity in persons with CP. There were also major differences between this study and Cooper's study. He used direct brain stimulation from surgically implanted electrodes to achieve the spasticity reduction while this study used the application of surface electrodes. Since any invasive procedure increases the chances of detrimental effects to the completion of the study (i.e., risk to the subject; cost of conducting the study; time necessary to evaluate results; compliance; and the numbers of subjects withdrawing from the study), one would have to demonstrate that the invasive procedure was able to result in a substantially larger improvement in
function. It is unlikely that such an improvement could be shown because the researcher would need to demonstrate that any improvements were due to the stimulation alone. Cooper (5) stated that they assessed improvement after about six months to allow for complete recovery from the surgery. That time interval is sufficiently long to raise questions about how other intervening variables could affect the results.

Although there are technical problems in comparing the MEs measured during this study to those measured by previous studies (1,2,3,9,10), all of the studies found that persons with CP do have impaired MEs and that the MEs reported were able to be modified with different types of intervention. The MEs reported by Bar-Or, Berg, Lundberg, and Knuttson (1,2,3,9,10) were measured with a substantial amount of time between measurements, and they were measured while the subjects were participants in an exercise training program. The MEs measured during this study were determined with a minimal amount of time between exercise testing sessions. This procedure reduces the opportunity for other uncontrolled variables to intervene. There are also problems in comparing the populations used in studies cited because of population variables such as:
1. Differences in ethnic groups' capacity for exercise.

2. The lack of an objective international scale to classify the functional capacities of persons with CP that is generally included in clinical studies (see Appendix).

3. The probability that persons from European countries would have more experience with the techniques used such as bicycling.

These studies reported that the improvements due to exercise programs were substantial, but they required a longer than predicted training period, and the improvements deteriorated rapidly with any interruption of the training schedule. They also reported high drop-out rates.

This study found that the ME of persons treated with the placebo unit was depressed forty-eight hours following the initial exercise period. Since the ME would be expected to be stable, this finding indicates that persons with spastic type CP experience some unexpected muscle trauma with exercise. One could hypothesize that the impairment is due to hypoxia since even a moderate muscle contraction will result in a marked decrease in bloodflow through the muscle (8, pp. 146-151).
The spastic muscle may not have the circulatory reserves to meet the increased metabolic needs of the active muscle, resulting in hypoxic damage. Such a mechanism would explain why persons with CP required longer training times to demonstrate a training effect, and why the effect was not maintained as long as it would be in an unimpaired person. The TENS Unit appears to have the potential to permit the person with spastic CP to participate in an exercise training program or rehabilitation program and to obtain the improvements that would be predicted based on the specific program.

The potential changes in bloodflow may help explain another phenomenon observed during the study. Many of the subjects demonstrated one or more of the following changes on their exercise EKGs:

1. Premature atrial contractions.
2. ST segment elevation.
3. ST segment depression.

These changes were evaluated by a cardiologist (4) who stated that they did not appear to be indicative of cardiac disease, but, they did appear to be associated with an autonomic nervous system abnormality, or a circulation pattern disturbance. These changes were generally not found on the resting EKG tracings. This
phenomenon has not been previously reported in persons with CP. These changes are noteworthy because they were found in twenty-nine out of thirty exercise pretests and in twenty-seven out of thirty post-tests. Since this phenomenon was not anticipated, and had not been previously described, methodology to permit a more comprehensive assessment of the phenomenon was not included. Since the decrease in ME was only found in groups using the placebo unit, the action of the TENS Unit prevented the apparent muscle damage which resulted in the loss of efficiency. One effect of reducing spasticity would be to increase muscle blood flow. This would increase the tissue oxygenation. The effect would be difficult to assay with the techniques used for this study since measurements were taken twenty minutes to one hour following use of the stimulator. This is not enough time to assure that the individual has reestablished a circulatory equilibrium.

The results of this study also support the findings of Malden and Charash (11) who found that there were substantial improvements in function when the TENS Unit was combined with physical therapy. The results of this study indicate that the improvements that Malden and Charash (11) found may have been due to two factors: The first factor would be the direct
reduction in spasticity experienced by the subject; and the second factor would relate to the phenomenon of the reduced ME experienced for a period of time following exercise. When the TENS Unit is used, the subjects did not have to overcome the unctional defect caused by the decrease in ME. The major implication of this finding is that the full benefits of any treatment program can only be realized when they are carried out with some form of spasticity reduction.

The second hypothesis, stated in the null form, was that there would be no significant difference in change of the ME from the exercise pretest and the exercise posttest between males and females. This hypothesis was tested by the F statistic for the sex factor. The F ratio obtained was 0.72, which has a significance of 0.40. Since the significance did not reach the customary 0.05 level, the hypothesis is retained. The previously cited studies which measured ME in persons with CP (1, 2, 3, 9, 10) did not report any sex differences. The results of this study are, therefore, consistent with the other studies cited.

The third hypothesis, stated in the null form, stated that there would be no significant interaction between sex (male or female) and unit (TENS or placebo). This hypothesis was tested by the F
statistic for the unit factor by sex factor interaction. The F ratio obtained was 0.59, which yielded a significance of 0.41. Since the significance did not reach the 0.05 criterion, the hypothesis was not rejected. This finding does indicate that males and females with spastic CP can achieve a substantial reduction in spasticity after using the unit. There are no other data to compare this finding with since most of the work on neurotransmitters does not discuss sex differences in transmitter levels or in the organism's response to the transmitters.

Summary

This was an exploratory study to determine whether treatment with a transcutaneous cranial electric nerve stimulator would reduce spasticity in persons with spastic type CP. Thirty adults and children with spastic type CP were given graded exercise tests before and after stimulation with the TENS Unit and a placebo unit. The difference in ME between the exercise pretest and the exercise posttest was calculated and the data were subjected to an analysis of covariance. The resultant F statistic was 17.43, which has a significance of 0.0003. Neither the sex factor nor the interaction of the sex factor and the unit factor resulted in F statistics that was 0.05 or less. The
results indicate that the TENS Unit does significantly reduce spasticity in persons with spastic type CP. The results of this study are consistent with the data demonstrating that the unit does alter the neurotransmitter levels, and that these alterations reduce the level of spasticity. The results are also consistent with other studies which demonstrated functional improvement following use of the TENS Unit.

The data also indicated that there are cardiovascular changes associated with spasticity or with CP which have not been described previously.
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4. Blomqvist, C., personal communication via meeting, located at University of Texas Health Science Center, Dallas, Texas, July 15, 1986.


CHAPTER V

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Introduction

This study was concerned with determining whether the TENS unit manufactured by Pain Suppression Labs, Inc., does reduce spasticity in persons with spastic cerebral palsy. The sequence of steps through which the problem was approached included measuring the mechanical efficiency of persons with spastic type CP at their maximal aerobic capacity on a graded exercise test before and after stimulation with the TENS unit applied transcranially. The difference between the prestimulation exercise ME and the poststimulation exercise ME.

The general research design was a two factor analysis of covariance, grouping on unit and blocking on sex to test the hypotheses. The specific statistical procedures employed included calculation of the means and standard deviations of the dependent variable for each cell in the design.
During June to August, 1986, thirty six volunteers with spastic type CP were given graded exercise tests with and without transcranial stimulation by the TENS unit. The ME at the maximal aerobic capacity was calculated for each test.

Summary of Findings

This was an exploratory study to determine whether treatment with a transcutaneous cranial electric nerve stimulator would reduce spasticity in persons with spastic type CP. Thirty adults and children with spastic type CP were given graded exercise tests before and after stimulation with the TENS Unit and a placebo unit. The difference in ME between the exercise pretest and the exercise posttest was calculated and the data were subjected to an analysis of covariance. The resultant F statistic was 17.43, which has a significance of 0.0003. Neither the sex factor nor the interaction of the sex factor and the unit factor resulted in F statistics that were 0.05 or less. The results indicate that the TENS Unit does significantly reduce spasticity in persons with spastic type CP. The results of this study are consistent with the data demonstrating that the unit does alter the neurotransmitter levels, and that these alterations reduce the level of spasticity. The results are also
consistent with other studies which demonstrated functional improvement following use of the TENS Unit.

The data also indicated that there are cardiovascular changes associated with spasticity or with CP which have not been described previously.

The results of the tests indicated that spasticity is significantly reduced by the application of the TENS Unit.

Conclusions

Based on the results of this study, the following conclusions were reached:

1. The TENS unit manufactured by Pain Suppression Labs, Inc. does have an objectively verifiable effect of reducing spasticity in persons with spastic type cerebral palsy.

2. The individual's gender does not have a significant effect on the ME.

3. Sex does not interact with the effect of the unit in its reduction of spasticity.

Recommendations for Further Research

The present study was an exploratory one to answer the question about whether the unit objectively reduces spasticity in persons with spastic type CP. Since that
question has been answered, many more questions about the use of the unit present themselves, such as:

1. How long does the effect last?
2. Is there a cumulative effect for treatments over several days?
3. Does it affect other aspects of the condition such as perceptual problems?
4. What are the long-term effects of the treatments?
5. What is the optimal treatment schedule?

The following statements list the research recommendations:

1. Utilizing methodology similar to or different from this study, test a group of subjects daily, for five days following one application of the stimulator. The purpose of the procedure would be to quantify the duration of the improvement in ME following use of the stimulator.

2. Utilizing methodology similar to this study, test the subjects after varying stimulation patterns such as once and twice daily for one, three, five, seven, and ten days of stimulation. The purpose of the procedure would be to objectively verify whether there are any cumulative effects of stimulation over a short period of time. Longer periods of stimulation would
permit more variables to intervene, possibly confounding the results.

3. Repeat the above studies utilizing additional treatment schedules such as: treatments every other day; treatments three times a day; and treatments four times a day. The purpose of this procedure would be to determine the optimal treatment schedule to employ with the unit.

4. Utilizing methodology similar to this study, perform a study combining the optimal treatment schedule derived above with a course of physical therapy, occupational therapy, or speech therapy. This would be to determine whether the effects of the unit would enhance the other treatment modality. It would also provide the information to permit developing treatment plans that would maximize the individual's potential with the unit.

5. Utilizing educational assessment instrumentation appropriate to the population being studied, assess the rate of learning in a group of tasks over a four week period with and without employing the stimulator. The purpose of this study would be to determine whether the improved physical functioning associated with the reduced spasticity would have a parallel improvement in academic classroom functioning.
6. Utilizing methodology similar to this study, test groups of persons with other impairments experiencing spasticity such as: those with multiple sclerosis; head injury; or post-cerebral vascular accident. The purpose of this procedure would be to determine whether other impairments were also subject to possible amelioration through the use of the unit.

7. Utilizing measures of autonomic nervous system (ANS) function such as: heart rate variability; heart rate; blood pressure; blood flow; and temperature responses to challenges with and without stimulation. ANS challenges include cold pressor tests and tilt tests. The purpose of this procedure would be to assess the ANS involvement in CP and to verify whether it is ameliorated by use of the unit.
APPENDIX

Age Factors and Recovery Times for
Control and Experimental Group

The mean age of the subjects in the experimental group was 21.6 years and the mean age of persons in the control group was 23.0 years. This difference is within acceptable tolerances to indicate that the groups did not differ substantially in age. A correlational matrix was generated. The matrix did not indicate strong relationships between age and other variables.

The mean exercise pretest recovery times for the control group was 6.1 minutes and the mean recovery time for the control group was 5.3 minutes. The mean exercise posttest recovery time for the control group was 4.5 minutes and the mean exercise posttest recovery time for the control group was 5.1 minutes.

The recovery times were not substantially changed in the control group, but they were reduced noticeably in the experimental group. The magnitude of this change is small but indicative of an improvement related to the treatment. These figures are not compensated for changes in exercise duration or workload achieved. There was a mean change of -6.3 watts in the control
group and a mean change of 19.6 watts in the experimental group. These changes parallel the changes in ME described above, and indicate that the control group decrease in recovery time may be understated because of the time needed to recover from the higher exercise loads.
Sports Classifications for Persons with Cerebral Palsy

Class I  Severe involvement in all four limbs.

Class II Severe to moderate quadriplegic, normally able to propel wheelchair with legs or if able, propels wheelchair very slowly with arms.

Class III Moderate quadriplegic, fair functional strength and moderate control problems in upper extremities and torso.

Class IV Lower limbs have moderate to severe involvement.

Class V Good functional strength and minimal control problems in upper extremities.

Class VI Moderate to severe quadriplegic.

Class VII Moderate to minimal hemiplegic.

Class VIII Minimally affected hemiplegic.

There is an international rating scale used to categorize participants in CP sports. The scale (1, p. 162) is being utilized with increasing frequency, but it is not utilized in many clinical settings. The rating scale is presented above. The subjects participating in the study were classified using this scale. The results for the control groups were:

Sports Class VIII = two participants.
Sports Class VII = four participants.
Sports Class VI = four participants.
Sports Class IV = one participant.
The results for the experimental group were:

Sports Class VII = seven participants.
Sports Class VI  = nine participants.
Sports Class V   = two participants.
Sports Class II  = one participant.
APPENDIX BIBLIOGRAPHY

BIBLIOGRAPHY

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**Personal Communication**

Blomqvist, G., personal communication via meeting, located at University of Texas Health Science Center, Dallas, Texas, July 15, 1986.