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JOHN A. GRUNER, Ph. D.^b ROGER M. GLASER, Ph. D.^c STEVEN D. FEINBERG, M.D. STEVEN R. COLLINS, M.S. NOEL S. NUSSBAUM, Ph. D.

Department of Physiology Wright State University School of Medicine Dayton, Ohio 45435

Rehabilitation Institute of Ohio Miami Valley Hospital Dayton, Ohio 45409

Physiology Research Laboratory Veterans Administration Medical Center Dayton, Ohio 45428

A System for Evaluation and Exercise-Conditioning of Paralyzed Leg Muscles^a

ABSTRACT

The purpose of this project was to develop instrumentation and protocols in which electrical stimulation is used to induce exercise in paralyzed quadriceps muscles strength and endurance evaluation and conditioning. A computer-controlled electrical stimulation system, using surface electrodes, automatically regulates the bouts of leg extension exercise. Load weights attached just above the ankles can be progressively increased over a number of training sessions in such a manner that a measure of the fitness of the legs can be obtained. With three exercise sessions per week for 9 weeks, the strength and endurance of the quadriceps muscles of two paraplegic and four quadriplegic subjects were gradually and safely increased. During exercise at a \overline{X} load weight of 5.4 kg, \overline{X} heart rate did not rise above rest, whereas systolic blood pressure increased about 20 mm Hg, and skin temperature above the active muscles increased about 1.75°C. Such exercise conditioning appears to be safe and may provide important health benefits, including improved fitness of the muscles and bones, better circulation in the paralyzed limbs, and enhanced self-image. Conditioned electrically stimulated paralyzed leg muscles may be used for locomotion in conjunction with special vehicles. DOI

INTRODUCTION

To improve fitness and locomotive capability of individuals with paralyzed legs, a wheelchair-like vehicle which can be propelled by electrically stimulated knee-extensor muscle contractions has been constructed and successfully tested (1, 2). Safe and effective use of such a vehicle will, however, require certain minimal performance capabilities of the paralyzed legs. Therefore, the strength and endurance of the muscles to be stimulated must be evaluated and, if necessary, conditioned by exercise prior to prescription of a leg propelled vehicle (LPV).

After a prolonged period (months to years) of disuse, a paralyzed endurance-type muscle tends to atrophy and undergo histochemical changes, a process in which twitch duration shortens and fatigability increases when the muscle is electrically stimulated (3-5). Previous studies have shown that strength and/or endurance can be increased in paralyzed muscles by electrical stimulation exercise programs (6– 10). This suggests that exercise protocols which are used to improve strength and endurance via voluntary exercise may be adapted for conditioning paralyzed muscles via electrical stimulation. Unfortunately, there are few studies in the literature describing instrumentation or procedures for conditioning paralyzed muscles in humans via electrical stimulation.

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^b Present affiliation: Department of Neurosurgery, New York University Medical Center, 550 First Ave., New York, N.Y. 10016.

^c Please address all correspondence to: Dr. Roger M. Glaser, Department of Physiology, Wright State University School of Medicine, Dayton, Ohio 45435 (Phone: 513-873-2742).

Recent studies in our laboratories have shown that sufficient leg strength can be obtained by electrical stimulation of paralyzed muscles to operate an LPV (11,12). It has also been observed that strength and endurance of electrically stimulated paralyzed muscles can be increased in paraplegic and quadriplegic subjects at a rather rapid rate when using progressive loading exercise protocols. However, since the bones of paralyzed limbs are usually osteoporotic (especially where spasticity is low) and may not be restored at the same rate as muscle, care must be taken during electrical stimulation to avoid excessive stresses which might lead to bone or joint injury.

To facilitate evaluation and exercise conditioning of paralyzed leg muscles in a clinical laboratory setting, a stationary LPV simulator would be desirable. Furthermore, safe and effective exercise protocols need to be established to minimize the risk of injuries to the paralyzed limbs. Therefore, the purpose of this project was to develop and evaluate an ergometer-type device and protocols which could be used in conjunction with functional electrical stimulation (FES) for paralyzed muscle evaluation and conditioning.

METHODS

Subjects

Paraplegic (N=2) and guadriplegic (N=4) subjects with essentially no voluntary movement of their lower limbs and an absence of lower motor neuron involvement were chosen for this study. They were screened by a physician for cardiopulmonary and musculoskeletal conditions which would contraindicate participation. All subjects were informed orally and in writing as to the nature and extent of testing, as well as to the possible risks and the precautions taken. Understanding was expressed by the signing of consent forms. Screening and testing procedures were approved by the human subjects research committees of Wright State University and Miami Valley Hospital.

Leg Conditioning System—LPV Simulator

Figure 1 illustrates a paraplegic test subject during leg exercise using the leg conditioning system. This device is composed of three basic sections: (i) the framework, consisting of the ramp and backboard against which the wheelchair is positioned; (ii) the





"drive" system, which in this case consists of weights attached above the ankles via a cable and pulley system (Fig. 2) to simulate the type of repetitive limb movement required for operating the LPV; and (iii) the electronic instrumentation consisting of the computer, the electrical stimulator, and feedback sensors. During exercise sessions the electrocardiogram, leg-position, and stimulus voltages are recorded on a Grass 7P polygraph, whereas the stimulus parameters, leg-extension values, heart rate (as monitored by a GEDCO CT-2 cardiotachometer) and skin-surface temperature (as monitored by a YSI Telethermometer) over the active muscles are printed out on an Epson MX-100 printer with each extension-relaxation cycle. After every four contraction cycles, arterial blood pressure is determined by auscultation using a sphygmomanometer and stethoscope. A stimulation shut-off switch is held in the subject's hand for safety.

During operation of this system, a computer pro-

FIGURE 2

Schematic diagram of leg conditioning system /LPV simulator. Subject is seated in wheelchair with legs attached just above the ankles to cable-and-weight system. Computer-controlled stimulus isolation unit provides stimulus to the appropriate muscle group through surface electrodes. Heart rate, skin temperature, and leg position are monitored by the computer. The polygraph records EKG, leg position, and stimulus amplitude. A force transducer is placed in series with a cable attached to the leg to measure isometric leg strength or endurance periodically. Leg conditioning system: LPV simulator in operation with a paraplegic subject.

gram monitors leg position and controls stimulation to the muscles. Leg position during dynamic exercise is determined by potentiometers driven by the weightlifting cable attached to the ankle. Signals from these feedback sensors, after being converted to digital values by analog-to-digital converters, are monitored by the computer to form a closed-loop control system (cf 13-16). Errors in desired limb position are used to calculate subsequent stimulus amplitudes to achieve tracking. A schematic diagram of the computer system is given in Figure 2.

With leg extension exercise, the computer gradually increases the stimulus amplitude until the leg extends from its resting position to the maximum desired position (PMAX), and then gradually decreases the stimulation until the leg returns to resting position. However, a trial run is first performed in which the stimulus threshold for contraction is determined for each leg. Then, during continuous (cyclic) operation, the rate of increase of stimulus amplitude above threshold is adjusted on each repetition so that PMAX will be reached in 7 sec. The stimulus amplitude will then gradually decrease, allowing the leg to return to resting position. Although supra-threshold stimulation and muscle contractions occur for 14-sec periods, leg movement actually occurs when the contractile tension exceeds the load, typically during the middle 7 sec of these periods. (Figure 3 illustrates the relationship between electrical stimulation amplitude and leg position during cyclic contractions of the quadriceps muscles.) At all times, the computer checks to determine whether special conditions (including operator or subject commands) have occurred indicating that stimulation should be discontinued. For example, if the stimulus current is at maximum and the leg fails to extend more than 20 deg from rest, the muscles are considered to be fatigued and stimulation of that leg is terminated.

Electrical stimulation system—An Apple II Plus computer interfaced with A/D and D/A converters (Analog Devices ADC 0808 and ADC 7524) with 8-bit resolution provides voltage-control signals to an electrically isolated, battery powered stimulator. The stimulator delivers constant-current pulses of 200 microseconds duration to two cathodal surface electrodes (3M Company) each located over a selected motor point of the quadriceps muscle group. Stimulation of the motor points is sequential (17) (180 deg out of phase) at a frequency of 30 Hz. An anodal (common) electrode is placed just proximal to the patella of each leg.

Figure 4 provides a functional block diagram of the electrical stimulator. The circuitry employs CMOS digital logic and single supply operational amplifiers which operate from a small 9-volt battery. An external d.c.-to-d.c. converter powered by 6-volt gel cells provides the high voltage (+200 volts) output. The stimu-



FIGURE 3

Recording of two extension-relaxation cycles for the right and left legs during exercise with a 2-kg load weight.

lator consists of three basic sections: pulse generation, control, and high-voltage output. For pulse generation, a clock whose output is set at 120 Hz is used. This clock feeds into a divide-by-four counter which provides sequential 30-Hz pulses. Outputs 0 and 2 are used for the right leg stimulator channel, whereas outputs 1 and 3 are used for the left leg stimulator



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channel. (Because of the similarity in circuitry for these channels, only the right leg channel is illustrated.)

To generate pulses of the desired width, the output of the clock is also fed into a monostable multivibrator. By ANDing the multivibrator output with the counter output pairs, two 180 deg out-of-phase 30-Hz pulses of 200 microsecond duration are generated. The amplitude of each stimulator channel output is controlled by the computer via 0-5 volt D/A signals with 256-unit resolution. These control signals are fed to opto-isolators which electrically isolate the stimulator from the computer and all other electrical equipment. They are then fed by buffer amplifiers through analog switches whose switching rates are controlled by the outputs of the AND gates. Outputs from the analog switches pass through buffer amplifiers, high voltage protection diodes and current-limiting resistors (150 milliampere max) to drive the high voltage switching transistors. The collector of each output transistor is connected to an active cathodal electrode which is placed over a selected motor point of the quadriceps, whereas the common anodal electrode, which is placed just proximal to the patella, is connected to the positive terminal of the high voltage supply. Thus, computer controlled activation of the analog switches causes the high voltage switching transistors to conduct, which completes the circuit between the high voltage supply and electrodes, resulting in curent flow through the skin and underlying tissues. Note that the stimulator "ground" must be kept isolated from the subject and from all other electrical circuitry to prevent potentially hazard-



ous electrical shocks. At the established pulse width, using 30 cm² electrodes, the maximal transcutaneous current density is 5 milliampere/cm² and average current density is only 30 microampere/cm². No electrode burns have been encountered with this system.

Leg Conditioning Program Protocol

In designing a conditioning program for the legs in preparation for using the LPV, both strength and endurance development were taken into consideration. Thus, an individually paced progressive-intensity conditioning program using the leg conditioning system was developed. This program provides training through exercise at a high number of weight lifting repetitions plus gradual incremental increases in load. The program consists of sessions approximately 1.5 hours in duration three times per week.

Figure 5 illustrates the load weight progression protocol used for both evaluation and conditioning of electrically stimulated paralyzed quadriceps muscles. Each session consists of two "strength conditioning" trials during which the subjects attempt to lift a load weight 20 times with each leg through a preset range of motion (typically 70 deg). The two trials are separated by a 10-minute rest period. Successful completion of both trials on two consecutive sessions at a given test weight qualifies a subject to advance to the nexthigher test weight (0.5 kg greater) on the next session. Following the second trial of each session, an "aerobic conditioning" exercise routine is undertaken in which the load weight is decreased to no greater than 50 percent of that in the previous exercise. Aerobic conditioning consists of more-rapid (1 per 3 sec) alternating contractions of both legs within the prescribed range of motion for 10 minutes or until the legs fatigue.

The maximal load weight which we anticipate using will be 18 kg. This value was selected on the basis of both practical and safety considerations. Since the LPV would require about 1.5-2.0 kg of force to operate, the 18-kg conditioning limit will most likely provide adequate reserve for operating the LPV under various locomotive conditions. Furthermore, exceeding this limit increases unnecessarily the risk of injury to subjects. Using the described protocol, approximately 24 weeks of exercise is required to achieve the maximal load weight if all sessions are successfully completed. When the 18-kg limit is achieved by subjects, the conditioning program protocol will be modified by keeping this load weight constant and increasing the number of lift repetitions. That should gradually increase endurance capabilities of these muscles.



FIGURE 5

Diagram of protocol which was designed to increase the strength and endurance of paralyzed quadriceps muscle in a safe, progressive manner.

RESULTS

During the first few electrical stimulation exercise sessions, 4 of the 6 subjects (Fig. 6, subjects b, c, d, and f.) demonstrated spastic, jerky contractions, and/or flexor-withdrawal and crossed extensor reflex activity. With subsequent conditioning sessions, however, the contractions became smoother and more coordinated.

Figure 6 provides individual subject information and their right leg load weight progression data for as many as 30 exercise sessions. Left leg load weight progression data are similar, although not identical. The exact starting load weight was determined during pre-testing examination sessions. Individuals with greater initial strength and endurance capabilities of the stimulated muscles (a,b,e,f) progressed regularly with only an occasional extra session at a given load weight. In contrast, subjects c and d, with their much lower strength and endurance capabilities, remained at the starting load weight for 10 and 14 exercise sessions, respectively. By the time of this report, subject c increased 6 increments in load weight, whereas d increased 2 increments. Subject c was the only participant to have the load weight reduced (sessions 16 and 17) because of an inability to complete an exercise trial at a previously accomplished load weight. This subject then went on to successfully complete sessions at the next 5 load weight increments.

Mean heart rate and arterial blood pressure responses elicited during maximal strength-conditioning exercise of the last exercise session completed (20 contractions of each leg in 10 min at a $\overline{X} \pm SD$ load weight of 5.4 \pm 2.9 kg) are illustrated in figures 7 and 8, respectively. Since the results for the two 10-min exercise trials were essentially the same, the mean values for these trials are presented. With the onset of exercise, there was a drop in heart rate of 10 BPM, whereas systolic and diastolic blood pressure rose approximately 20 mm Hg and 5 mm Hg respectively. Throughout the remainder of the exercise, heart rate and arterial blood pressure remained relatively constant.

Mean skin temperatures over the right quadriceps muscle group during the two successive 10-min strength conditioning exercise trials is illustrated in Figure 9. Skin temperature increased approximately 1.75 deg C over this 30-min period. Skin temperature increased throughout the first 10-min exercise trial, and continued to increase during the 10-min rest period. During the second 10-min exercise trial, however, skin temperature remained essentially constant.

DISCUSSION

The particular individually-paced exercise protocol used in this study permits both evaluation and conditioning of electrically stimulated paralyzed quadriceps muscles. Because of its progressive nature over numerous exercise sessions, the risks of injury to the paralyzed limbs appears to be greatly diminished. This may not be true with exercise protocols which incorporate maximal contractions during each of the exercise sessions. Thus, with the present protocol, information concerning maximal strength and endurance can only be obtained during exercise sessions that cannot be successfully completed-which may take several weeks to ascertain. Although we currently have no objective data on bone density, we feel that gradual progressions in load weights will permit more even gains in muscle and bone strength. We therefore suggest caution to anyone considering the use of electrical stimulation exercise protocols aimed at rapid development of muscle strength.

Another potential benefit of using this progressive protocol is that it permits a period of orientation at light loads which seems essential for smooth, coordinated muscle contractions. During the first several exercise sessions, a decline in spastic, reflexive activ-

Individual Subject - Load Weight Progression (Right leg)



FIGURE 6

Individual subject load weight progression data for the right leg. The conditioning protocol in Figure 5 was followed.

ity during electrical stimulation was observed in most of the subjects tested. This gives the appearance that some form of "learning" is taking place—possibly at the spinal-cord level. Passive stretching exercises prior to active exercise sessions may also contribute to improved performance.

To evaluate risk encountered by subjects during electrical stimulation exercise sessions, heart rate, blood pressure, and the skin temperature above the active muscles were monitored. With electrical stimulation induced exercise in paraplegic and quadriplegic subjects, heart rate does not appear to provide an index of exercise stress as commonly used for ablebodied subjects during voluntary exercise. The lack of increase in heart rate when going from rest to exercise may be due to loss of afferent pathways from receptors in the periphery, and lack of vagal inhibition and sympathetic stimulation of the heart. In contrast, arterial blood pressure in spinal-cord-injured subjects does respond to the exercise stress by increases in both systolic and diastolic values. This response may be due to intact spinal reflexes which result in splanchnic vasoconstrictions, and increases in cardiac output via increases in stroke volume. Similar patterns of heart rate and blood pressure responses have been reported for bicycle ergometry and isometric leg exercises using electrical stimulation of paralyzed muscles (11,12). The level of injury may, however, influence the magnitude of these cardiovascular responses.

We consider it essential to evaluate blood pressure responses to this type of exercise to minimize risk to the subjects. The importance of this became clear when one of our prospective subjects (C-8 quadriplegic) experienced greatly elevated arterial blood pressure (in excess of 175 mm Hg systolic) on two separate attempts to exercise via electrical stimulation. This was considered hazardous, and the individual was excluded from participation in this study.

Because of the loss of sympathetic pathways to the lower extremities in many spinal-cord-injured patients, which could diminish central control of arterioles and sweat glands in the affected limbs, thermoregulation during exercise could present a potential problem. Our measurements of a 1.75 deg C increase



FIGURE 7

Mean heart-rate response during the two strength-conditioning trials of the last exercise session completed.



FIGURE 8

Mean arterial blood pressure responses during the two strength-conditioning trials of the last exercise session completed.

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FIGURE 9

Mean skin temperature over the right quadriceps muscle group during two successive 10-min strength-conditioning trials of the last exercise session completed.

in skin temperature above the active muscles indicates that these muscles are not being over-heated at the particular exercise intensities used. The leveling off of these temperatures during trial II suggests that steadystate thermoregulation was achieved. It is apparent, however, that muscle temperature is influenced by the exercise intensity and duration, the clothing worn, and the environmental conditions. Therefore, **muscle temperature monitoring** is advisable to avoid hazardous thermal stresses.

Unexpected effects of the electrical stimulation conditioning programs were observed in two subjects. Subject e is an incomplete G-7 quadraplegic who was capable of weak voluntary contractions of the quadriceps when beginning the program. After several weeks of exercise, however, he reported that these voluntary movements were getting stronger, and that he had better leg functions. Thus, electrically induced conditioning programs, which permit strong contractions, may promote training effects in muscles beyond those achieved with low levels of voluntary exercise. In another unexpected situation, subject f who had been diagnosed as a C-6 quadraplegic with complete motor paralysis (absence of E.M.G. activity when attempting to move voluntarily and some sensory sparing) demonstrated the ability to assist leg extensions voluntarily, and to control the rate of leg lowering during periods of weak electrically stimulated contractions. Thus, this subject may actually be incomplete, and motorneurons to the quadriceps may be facilitated by supraspinal pathways during electrical stimulation which permits this voluntary aspect of movement. (These effects were not observed in the other four subjects.)

From the data obtained thus far, we conclude that the instrumentation described and the fitness evaluation/exercise conditioning protocol used are effective and safe. No adverse effects of the electrical stimulation exercise to the limbs have been observed and the intermittant progressive intensity exercise permits adaptation to the stress and continuous monitoring of physiological responses. The heart rate, blood pressure, and skin temperature data presented suggest that physiological responses to this type of exercise are not excessive for most individuals, under the enviGRUNER et al.: LEG MUSCLE CONDITIONING

ronmental conditions and exercise intensities employed. Potential benefits of this form of exercise include improvement in: muscle strength and endurance; bone strength; circulation; cardiopulmonary fitness; and locomotive capability using a legpropelled vehicle. More research, however, is necessary to substantiate and quantify benefits ■

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