Implantation techniques and experience with percutaneous intramuscular electrodes in the lower extremities

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Abstract—Innervated paralyzed muscles have been implanted with temporary percutaneous intramuscular electrodes in order to allow selective stimulation of as many muscles as necessary to achieve a cosmetically acceptable and energy-efficient gait in paraplegic subjects. Fine wire electrodes were implanted under sterile conditions at the motor points (MP) of hip extensors, flexors, abductors and adductors; knee extensors; and ankle plantar- and dorsi-flexors. Electrodes were routed to the MP's from one of four skin sites on the legs where the wires emerged. Employed were both a direct approach from the skin site to the MP and an indirect approach which involved one or more subcutaneous passages of the electrode wire from the MP to the skin site. Muscles were stimulated approximately 12 hours per week in daily electrical exercise and gait training. Electrodes were removed when they exhibited one of two types of failure: breakage, as determined by high impedance, or loss of adequate function as a result of electrode movement. Of 1025 electrodes implanted in 6 subjects over a period of 38 months, 35 percent failed within the first 4 months; more than 75 percent of those early failures resulted from electrode movement. Complete withdrawal of those electrodes was usually possible. The probability of electrode failure decreased exponentially during the first 4 months and reached less than 4 percent per month for electrodes implanted for longer than 6 months. These procedures have allowed multiple revisions toward a more functional neuro-orthotic system.

INTRODUCTION

Neuro-orthotic systems have enabled selected paraplegic individuals to walk using functional electrical stimulation with surface electrodes (1,6,12,15), with percutaneous intramuscular electrodes (9), with nerve cuff electrodes (2), and with epineural electrodes (17). Some of these subjects have been able to walk with reciprocal gait (7,10,12), and others with a swing-through gait (2,17) using either a walker or crutches.

The problem with surface stimulation has been the difficulty of achieving selective stimulation of muscles, particularly of the hip flexors (16). (An alternative is to achieve hip flexion through stimulation of afferent nerves in the area of the popliteal fossa, producing a flexion reflex (8).) Reliability is also a problem with surface electrodes because small differences in electrode placement create large differences in response, and habituation of the reflex can occur.

Another approach is the use of either epineural or nerve cuff electrodes which have been implanted only for providing foot dorsiflexion (18) and hip and knee extension (2,4). Subjects using such electrodes for hip and knee control were able to use the system for a swing-through gait. Since no hip flexion was provided, they had to lift their bodies during each swing phase, requiring large energy expenditure. In effect, this system provided an electronic equivalent of long-leg braces, and a level of function that had already proved too energy-demanding for most subjects with injuries above the T-11 level (19). These systems have the potential of providing the needed hip control, but the problem has been to provide the necessary number of channels and the proper coordination of those channels.

In order to allow selective stimulation of as many muscles as are necessary to provide patients with a gait which is cosmetically acceptable and energy efficient; we have implanted subjects with temporary percutaneous intramuscular electrodes. Since 1970, similar electrodes have been used in upper limb functional neuromuscular stim-
ulation by Dr. P. H. Peckham and the senior author; and more recently by Dr. Peckham and Dr. Michael Keith. Their results will be reported separately.

This paper describes the techniques of implantation in an ongoing research program which has already enabled paraplegic individuals to achieve the functional movements necessary for standing, level walking, and ascending and descending stairs (5).

METHODS

Paraplegic subjects with upper-motor-neuron deficits with a level of injury between T-4 and T-11 and with no significant peripheral nerve damage were considered for this study. They were each given a physical examination and tested for availability of muscles capable of contraction with electrical stimulation. Testing was done with a 26-gauge probe needle to minimize the trauma to muscle tissue. Subjects selected were implanted with percutaneous intramuscular wire electrodes (3,9) placed in 19-gauge needles for implantation.

The electrodes were made from 76-micrometer, 10-strand, stainless steel Teflon-coated wire; each strand was 25 micrometers in diameter. About 35 mm of the wire was deinsulated at one end, and the bared wire was wound over a .15 mm mandril. The final 5 mm of the deinsulated portion was fashioned into a hook to anchor the electrode in the muscle (Figure 1). The implanted electrodes delivered cathodic constant-current, biphasic, balanced-charge, capacitively-coupled (to the electronics) pulses with amplitude of 20 mA and pulse width up to 150 μsec at frequencies up to 50 Hz. The anodic reference surface electrode was carbon with disposable dry gel (3M).

Cadaver dissections were done to check the distribution of peripheral nerves to the desired muscles and to assess their access from the designated points of insertion. Two sites of insertion were chosen bilaterally. One was on the medial aspect of the thigh, approximately halfway between the hip and the knee to access the hip extensors, flexors, adductors, and abductors and the knee flexors and extensors. The second point was chosen on the medial calf just below the knee, for access to the ankle plantar- and dorsi-flexors.

A sterile procedure was used for implantation. The probe needles, electrodes, and all wire connections to the stimulator were gas-sterilized with ethylene oxide.

An anterior approach was used for the quadriceps, sartorius, gracilis, tensor fasciae latae, and posterior portion of adductor magnus. The subject was placed in a supine position and a disposable surgical scrub sponge impregnated with Betadine soap was used to scrub from just below the knees to the iliac crests, bilaterally. The legs were supported on a leg support and draped with multiple sterile towels following coating with Betadine solution.

Figure 1
Electrode tip. Note insulation on part of coiled section and the anchoring hook with 10 strands of wire. Scale is in centimeters.
The prone position was used for implantation of the gluteals, hamstrings, tibialis anterior, peroneals, soleus, and gastrocnemius. Pillows were placed under the abdomen and the patient placed prone on top of them. The prep was from the ankles to the thoraco lumbar junction. Implantation sessions were limited to 2 hours in the supine position or 3 hours in the prone position.

A motor point (MP) for the desired muscle was found by stimulation with a 26-gauge needle probe. The probe was left in place until a percutaneous intramuscular wire electrode produced the same response.

Two methods were used for the implantation:

The first technique was a direct approach used where the MP was sufficiently close to the designated implant site. The minimum depth of the MP was determined first by withdrawing the active probe until it no longer produced the desired muscle contraction. The insertion trajectory was then approximated by laying the 19-gauge needle, containing the wire electrode, on top of the skin in the appropriate direction of the probe and the distance from the point of insertion to the MP noted on the needle shank. A point at least 5 mm from any other wire entry at the electrode site was chosen and the needle with an electrode in place was inserted through the skin, rapidly so as to minimize the reflex activity. Assessment was made of the path from the MP to the needle entry point from two perpendicular directions. Then the 19-gauge needle containing the electrode was advanced toward the MP. Single pulses of stimulation were sent to the probe and to the electrode in the needle; the needle was advanced until its response matched that of the probe.

Throughout the advancement of the needle, care was taken to avoid major blood vessels. Pressure was placed over the electrode tip and the 19-gauge needle was withdrawn. If the response to stimulation produced by the electrode was good, with the desired motor function coming on rapidly without hesitation or undesirable reflex activity, probing was begun for the next MP. Otherwise that electrode was withdrawn. There was no problem in removing the entire electrode and that generally remained true for up to approximately 6 weeks postimplantation. If the attempt for the chosen muscle was unsuccessful after nine tries, it was abandoned until another session.

The second technique was an indirect approach to MP’s that were a long distance from the implant site. Probing with the 26-gauge needle was done as before. Then a 9-inch 19-gauge needle containing the electrode was placed from any convenient site to the MP and tested as before (Figure 2A:a,b,c). When the desired muscle response was obtained, the 19-gauge needle was withdrawn (Figure 2A:d). A 12-inch 19-gauge stainless steel needle with a stylet without a hub was then inserted alongside the emerging electrode, with care not to catch or disrupt the electrode (Figure 2B:a). This needle was passed subcutaneously toward the electrode site on the leg. A .15 mm stainless steel wire with a 1 cm hook at the end was threaded free-end-first through the 19-gauge needle (Figure 2B:b). The end of the hook was caught in the end of the needle, leaving a loop protruding. The free end of the electrode was threaded through the loop to 3 mm beyond the end and the wire was pulled, causing the loop with the electrode to be pulled through (Figure 2B:d,e).

Advancement of the needle had to be coordinated with reduction in the size of the electrode loop. It was best to place tension on the electrode by advancing it about 3 cm beyond the tip of the 19-gauge needle and then to pull both needle and pretensioned electrode through. Thus, the electrode loop popped through the hole in the skin and became subcutaneous. Then pressure was placed over the site of the loop and the 19-gauge needle was withdrawn, with all tension released from the electrode. This procedure could
be repeated as many times as necessary until finally the electrode wire emerged at the desired skin site. Electrodes placed with this technique could be removed by methods similar to those used for other electrodes.

Following implantation, the electrode sites were dressed with dry sterile gauze until oozing stopped after a period which ranged from 1 day to slightly over a week. When the sites were dry, the only dressing was a Tegaderm (3M) patch which was impervious to bacteria and fluid but allowed water vapor to escape. Sites were cleansed daily with 70 percent isopropyl alcohol. If there were positive cultures, sites were also washed daily with Betadine solution. If an electrode site appeared irritated, triple antibiotic ointment was applied to the site daily. Sites were checked weekly.

Once the initial implantation reaction was over, at approximately 1 week, the electrodes were soldered to small connectors and the muscle was exercised on a regular basis. Muscles were electrically exercised for 1 hour daily with repetition of the walking cycle once each second while the subject was lying down. Further, three times each week there were 2 hours of stimulation during testing and walking practice.

All electrodes were tested for impedance changes. Our in vitro testing indicated that an ohmic component of impedance over 2 kilohms meant that the electrode was broken and as a result there was the possibility of tissue damage due to increased charge density (13). Those electrodes were not used and were removed as soon as possible. Electrodes were also removed if stimulation produced undesirable or inadequate response. (Electrodes that were immediately withdrawn during implantation procedures were not included in the removed-electrode population that was analyzed.)

Removed electrodes were tagged with identification numbers and implant history. They were kept in distilled water until they could be examined with scanning electron microscopy. Data on 1025 electrodes were tabulated and analyzed using the life table and survival functions programs of the BMDP Statistical Software package (Department of Biomathematics, University of California).
RESULTS

Although useful muscle forces were achieved in all muscles attempted, for some, multiple implantations separated by periods of electrical exercise were needed. Hamstrings were especially hard to implant effectively.

Removed electrodes had an encapsulation plug, much like a hair follicle, around them at the point of entry into the skin. The encapsulation appeared to extend deeply along the electrode, especially if it had been implanted for longer than 6 weeks. Electrodes were difficult to remove after 6 weeks or more; and these often broke on removal. Electrodes which failed in the first 3 to 6 weeks after implantation were most likely to have moved away from the nerve; these showed a normal impedance measurement but failed to produce the desired muscle response. The remaining electrodes generated repeatable and useful muscle forces. When mechanical failure occurred they showed a high impedance, and were no longer used.

Preliminary electron microscopy data of removed electrodes indicate the presence of some inclusions and manufacturing irregularities in some of the failed electrodes. Failure was distributed as follows: 50 percent in the insulated portion of the electrode, 25 percent in the deinsulated portion, and 25 percent at the junction of the insulated and deinsulated portions (11). Corrosion had occurred in some electrodes.

The probability of failure of electrodes dropped exponentially in the first 4 months, and linearly thereafter; after 6 months the probability of failure was approximately 4 percent per month (Figure 3). Thirty-five percent of electrodes failed within the first 4 months. Thirty-eight percent of 1025 electrodes implanted over a 38-month period continued to function 1 year after implantation. Twenty-two percent survived for 2 years (Figure 4).

Only five electrodes were removed for reaction that gave reason to suspect infection. On seven occasions, subjects with positive cultures of staph aureus were treated with Keflex for 10 days, all with good results. Two subjects developed a generalized cellulitis of one leg which responded to antibiotic treatment. No specific electrode involvement could be found on clinical examination. Both recovered completely with antibiotic treatment. One subject developed a superficial fungus infection in the electrode site on one leg which responded well to antifungal treatment.

DISCUSSION

This technique has allowed implantation of more than 1000 electrodes in 10 subjects, 6 of whom are currently active, in order to develop and refine a neuro-orthotic system without the need for repeated major surgery. The major problem has been change of electrode function due either to movement or breakage. It seemed that most movement occurred within the first 6 weeks after implantation. There did not appear to be much difference in failure rate if the electrodes were used immediately after implantation or not.

Figure 3
Probability of electrode failure as a function of time since implantation.
We assumed that most movement occurred due to the large motions required for transfers and range, yet we did not feel that it was reasonable to curtail these motions for several weeks postimplantation.

Electrode breakage appeared related to the design and placement of electrodes. A large number of failures occurred at the insulated-deinsulated boundary where a change in geometry would lend itself to stress concentrations. Electrodes that passed through many fascial planes that moved with respect to each other were subject to significant stresses. Electron microscopic studies have revealed that some failures are due to wire manufacturing defects; attempts are being made to improve quality control at the level of manufacture. A new wire configuration is currently being tested which should minimize mechanical stresses.

Another major problem was the inability to precisely characterize electrode placement, resulting in much time consumed by implantation procedures. The advantage of the indirect approach was that motor points could be found with greater precision, and inadequate electrodes could be removed easily after only the initial step, saving the subject much implantation trauma. In early work, a separate electrode site was chosen for the foot muscles because it was too difficult to place the needles from the medial thigh site with the direct approach. Development of the indirect approach made the distant insertion possible; however, the leg site was so well tolerated that we chose to keep it.

Ultrasound was investigated as a potential aid but was found to be of no help. We have begun to employ fluoroscopy, but danger from X-ray exposure to both subject and operator will limit its usefulness.

Once the total muscle needs of our neuro-orthotic system are determined and an implantable stimulator (14) is available, the temporary system can be replaced by a permanent system using either epimysial or nerve-cuff electrodes or a combination. In the meantime, the current system provides great flexibility since the number of stimulation channels can be 32 or more; and it can include all innervated paralyzed muscles. In addition, this procedure produces minimal damage to the subject’s body, allowing multiple revisions toward a more functional neuro-orthotic system.

DEDICATION

This paper is dedicated to the memory of Miles McLendon whose careful work, patience, and caring contributed immeasurably toward development of an electronic orthotic system for improving the quality of life of paralyzed people.
APPENDIX:
IMPLANTATION OF
INDIVIDUAL MUSCLES

Knee Extensors: An attempt was made to implant electrodes in the quadriceps without producing reflex response or recruitment of other muscles. An electrode was implanted near the emergence of the femoral nerve from the pelvis to recruit all four heads of the quadriceps. First, the femoral artery was palpated on the line connecting the pubic tubercle to the anterior superior iliac spine (ASIS). Probing was done lateral to this point and an electrode inserted directly from the medial thigh. The individual heads of the quadriceps excluding the rectus femoris were also implanted.

Vastus lateralis’ MP was generally found at the point where the line dividing the proximal 1/4 from the distal 3/4 of the distance between the ASIS and the patella met the line dividing the medial 3/4 from the lateral 1/4 of the thigh. Vastus intermedius’ MP was found slightly medial and distal to the MP of vastus lateralis. The MP of vastus medialis was found about midway between the ASIS and the patella along the line dividing the medial 1/4 from the lateral 3/4 of the thigh. A more proximal placement of the vastus medialis electrode tended to recruit also the sartorius.

Hip Flexors: Four muscles were implanted for hip flexion: the sartorius, tensor fasciae latae, gracilis, and iliopsoas. The sartorius responded best to probing at the level of the pubis approximately on the line dividing the medial 1/4 and the lateral 3/4 of the thigh. Weaker function was present distally. The tensor fasciae latae was found at the same level on the line dividing the medial 3/4 and lateral 1/4 of the thigh. We found that stimulation of the tensor fasciae latae at a location immediately lateral to the anterior iliac crest produced only internal rotation of the thigh. The gracilis’ MP was found at the medial 1/4 of the thigh about 3 cm distal to the pubis. Once the response was obtained with the probe, it was best to stimulate through the probe during insertion of the electrode to provide better definition and visibility of the muscle. In two subjects, the iliopsoas was implanted from above and medial to the iliac crest. The subject was positioned on his opposite side to displace the abdominal contents from the pelvic wall. A precurved needle was inserted against the iliac wing to minimize the hazard of intestinal damage. An acceptable response from iliopsoas was usually obtained after inserting the electrode about 15 cm from the iliac crest against the pelvic wall.

Ankle Plantar- and Dorsi-Flexors: Plantar- and dorsi-flexion were produced by implantation of electrodes at a site on the medial calf just distal to the knee joint. The tibialis anterior and peroneus longus were implanted to produce balanced dorsiflexion with the MP accessed about 2 cm distal to the head of the fibula. Initially the electrode was passed directly through the interosseous membrane. However, passing through the membrane appeared to cause unreasonably early electrode failure. Later, with the patient prone instead of supine, the electrode was inserted about 2 cm proximal and medial to the fibular head and directed inferiorly and laterally to lie in proper relation to the peroneal nerve. It was then run inferiorly and medially to the leg site, creating a “V” shaped path designed to provide stress relief (Figures 2A,2B). The subject was placed prone to allow access to the popliteal fossa for implantation of the soleus. The best response was obtained at about the level of the tibial tubercle about 3 cm deep. A more distal probing recruited the tibialis posterior which produced undesirable inversion of the foot. The medial or lateral gastrocnemius was recruited best at a location medial or lateral 1/4 at the level of the knee’s rotational axis.

Hip Extensors and Adductors: Three muscles were implanted for hip extension: the posterior portion of the adductor magnus, the distal part of gluteus maximus, and the semimembranosus or biceps femoris. The posterior adductor was the easiest of the three to implant. The subject was lying on his back with his leg abducted and knee flexed. The point of best response was slightly proximal and deep to the site of the gracilis. The insertion was done directly from the medial thigh site.

For the gluteus maximus, the subject was lying prone. The best response was at a point medial to a line from the posterior superior spine to the ischial tuberosity just below the top of the trochanter. The electrodes were implanted next to the probe and then advanced by the indirect technique to the medial thigh site, by routing them laterally around the hip joint. The MP of gluteus medius was found lateral to the line from the posterior superior spine to the ischial tuberosity at the top of the trochanter. The electrode was advanced similarly.

The semimembranosus was found at the medial 1/4 of the thigh about 9 cm distal to the pubis. The biceps femoris was best lateral to the midline at the junction of the distal and proximal halves of the thigh. Sciatic nerve stimulation often accompanied hamstring recruitment; and had to be avoided.
REFERENCES