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Functional Electrical Stimulation of the Peroneal Nerve for Hemiplegia

Long-Term Clinical Follow-up*

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In 1968, a project was initiated by Vert Mooney at Rancho Los Amigos Medical Center to develop a surgically implantable neuroelectrical stimulator that could be used to correct footdrop in hemiplegics by stimulation of the peroneal nerve. This early work led to a system called the neuromuscular assist (NMA)[4]. The apparatus was composed of three main parts: (1) an external stimulator and antenna that generated and transmitted a radio-frequency signal through the skin, (2) a heel switch transmitter that triggered the stimulator, and (3) a surgically implanted receiver and bipolar cuff electrode that received the signal from the stimulator and converted it to a series of electrical pulses applied to the motor branches of the peroneal nerve.

The equipment, criteria for selection of patients, and surgical technique were described in detail in an earlier report[4], as were the preliminary clinical results in sixteen consecutive patients who were operated on between 1971 and 1974. Because there have been no long-term reports in the literature of the results of direct electrical stimulation of peripheral nerves to restore skeletal muscle function, we decided to carry out a long-term follow-up evaluation of these patients.

Results

In this report the case numbers of the patients are the same as in our earlier report[4], which provided detailed information on the clinical status of the patients before surgery. At the time of the previous report, the results in two patients (Cases 9 and 11) were classified as a failure and their implants had been removed. In addition, there were four subsequent failures that required implant removal, bringing the number of removals to six. There were several reasons for removal in some patients. These reasons included inconvenience and difficulty in operating the equipment (Cases 11 and 13), evidence of progressive nerve damage (Cases 9 and 12), late infection (Cases 9, 12, and 15), and electrical malfunction of the implant (Case 7).

Ten patients had a successful clinical result. Two (Cases 4 and 5) used the neuromuscular assist for an average of sixteen months, until they died from causes unrelated to the implantation. One patient (Case 10) had a successful outcome for thirty-six months, until acute polyneuritis of unknown etiology resulted in complete paraplegia, preventing further use of the implant. The other seven patients (Cases 1, 2, 3, 6, 8, 14, and 16) continued to use the unit for an average of 11.6 years (range, 10.1 to 12.3 years).

In 1984, the seven living patients who had a successful result were tested in the Pathokinesiology Laboratory. Four (Cases 2, 3, 6, and 16) had recovered volitional dorsiflexion during swing phase, had less than 10 degrees of footdrop, and no longer required the assist for walking. Two patients (Cases 3 and 14) had 20 degrees of footdrop or more and continued to use the implant for all walking activities. The remaining patient (Case 1) had stopped routine use of the assist one year before the last evaluation (11.3 years after implantation) because he had regained active dorsiflexion during swing phase. However, after he discontinued use of the assist, spasticity of the triceps surae increased. When tested 12.3 years after implantation, he no longer had adequate dorsiflexion with stimulation and there was a 20-degree equinus deformity. When the posterior tibial nerve was blocked, the patient was able to dorsiflex the ankle to the neutral position voluntarily, and lengthening of the Achilles tendon was being planned.

Discussion

Seroma formation about the implant appeared to be the precipitating cause of late infection in three patients and led to nerve damage in two of them. Inflammation along the lead-wire was often noted in patients with little subcutaneous tissue, particularly during the first several months after implantation. When the knee was temporarily splinted in extension, the inflammatory response subsided. Knee motion may have triggered the inflammation and formation of the seroma, which increased susceptibility to secondary bacterial contamination. More extensible leads and greater compliance of the lead-wire and electrode should reduce the risk of this complication substantially, since in patients who have a cardiac pacemaker and phrenic-nerve stimulator with a lead-wire that does not cross a major joint, seroma formation and late infection do not appear to be problems[1,2].

Two of the patients who had an infected seroma subsequently required increased amplitudes of stimulation for

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an adequate dorsiflexion response, which is indicative of nerve injury. At the time of removal of the implant, extensive epineural fibrosis was found. The nerve was adherent to surrounding scar tissue and not freely movable.

An interesting observation in the group of patients who underwent prolonged stimulation was that some recovered dorsiflexion during swing phase and ultimately no longer required stimulation for walking. Long-term stimulation may have facilitated functional motor recovery.

In our patients, it was difficult to establish a balanced response so that the foot dorsiflexed to the neutral position without excessive varus or valgus displacement. At surgery, balance was achieved by placement of the single electrode around selected motor branches of the peroneal nerve[4]. However, other muscles (soleus, gastrocnemius, tibialis posterior, and long toe flexors) that are not innervated by the peroneal nerve are active in the hemiplegic patient and exert a varus force on the foot during gait[3]. Consequently, even though a balanced dorsiflexion response was obtained at surgery, four patients later required revision surgery to correct foot imbalance. A dual-electrode system would eliminate this complication. Thus, one electrode placed around the motor branches to the tibialis anterior and extensor hallucis longus (foot invertors) and the other around the nerves innervating the common toe-extensor and peroneal muscles (foot evertors) would enable the varus and valgus position of the foot to be precisely balanced after surgery by independent adjustment of the amplitude of stimulation at each electrode.

So-called gadget intolerance of the external portion of the assist unit was a universal complaint and was a primary reason for failure in two patients. The intolerance had its roots in either repeated failures of the external apparatus, requiring many returns to the clinic for repair, or the difficulty that the hemiplegic patients had in operating the equipment with only one normal arm.

Because of difficulty in achieving a balanced dorsiflexion response and gadget intolerance, the neuromuscular assist program was discontinued in 1975. However, recent advances in microprocessor technology and the development of long-lived implanted batteries (with a life expectancy of more than five years) now make it feasible to develop a stimulator with a surgically implanted power source, similar to the cardiac pacemaker. We are therefore proceeding to develop totally implanted multichannel systems that are capable not only of correcting footdrop but also of restoring or improving walking for patients with more extensive central paralysis affecting the entire lower limb.

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