FALSE HOPES, REAL PROMISE
THE CHALLENGE TO RESTORE PARALYZED LIMBS
Helping Paraplegics Walk: Looking Beyond the Media Blitz

BY HOWARD JAY CHIZECK

It happens at least 20 times a day, 8,000 times a year: someone in the United States, usually young and healthy, suffers a spinal-cord injury and becomes partially paralyzed. When the injured patients ask their physicians, “Will I ever walk again?” the answer is usually “no.” Some have to be told that they will never again feed themselves or brush their hair. The number of Americans with spinal-cord injuries that cause some form of paralysis is estimated to be between 175,000 and 500,000. Such injuries are almost surely permanent. The spinal cord simply does not heal itself, and to the victims, these injuries are a crushing blow. Their independence, their source of livelihood, and often their self-image have been suddenly and permanently damaged. The lifestyles of their families must change as well.

Historically, there have always been those who offered hope and “cures” for spinal-cord injuries—using devices chemical, mechanical, electrical, and spiritual. Testimonials of cures abound, primarily because the terms “paraplegia” and “quadriplegia” loosely describe a number of different conditions. People who are described as paralyzed may have partial control of their limbs; the spinal-cord nerves feeding those limbs may not have been completely destroyed. In some of these cases, physical therapy may restore the use of the injured limbs. In other cases, patients improve on their own.

In the last two decades, researchers have begun to stimulate paralyzed limbs electrically in an effort to restore function to paralyzed muscles. At least 12 research centers worldwide are investigating ways to apply, control, and coordinate such electrical stimulation, which is called functional neuromuscular stimulation (FNS). The results so far are promising; these experimental techniques have enabled a small, carefully selected group of paraplegic patients to walk hundreds of meters in the laboratory, using walkers for support. Some of these patients have walked tens of meters with crutches, which afford a greater measure of independence. An even smaller number have climbed up and down stairs equipped with hand railings.

In other labs, a small number of quadriplegics, paralyzed from the neck and shoulders down, have attained enough control of their paralyzed hands and forearms to accomplish simple but important tasks, such as feeding themselves, combing their hair, and brushing their teeth. These achievements could mean the difference between total dependence on other people and some sense of self-sufficiency.

For both quadriplegics and paraplegics, devices that can restore function in paralyzed limbs promise a new and exciting measure of independence. However, these devices are still experimental. A long list of difficult technical problems remains to be solved before such devices can leave the laboratory for

Electronic devices have enabled a few paralyzed people to walk and use their hands. But contrary to reports in the popular press, these devices are years away from commercial use.
widespread use. Unfortunately, that is not the message that has been broadcast to the public through recent articles and television shows.

Articles such as “Someday I Will Walk Again” in Reader's Digest and “First Steps,” a prime-time, made-for-TV movie on CBS, have exaggerated accounts of the capabilities and availability of FNS devices. Such accounts may have raised false hopes in many patients with spinal-cord injuries and their families. Investigators fear that these overblown media accounts will not only disappoint patients but impede future work in the field.

The truth is that no commercial FNS devices are now available that provide paraplegics with the ability to walk, or that enable quadriplegics to have hand and forearm control. Furthermore, such devices are not expected to be widely available in the near future.

The only commercial FNS devices now available are those that help correct relatively minor gait problems, such as lifting and dropping the foot at the right moment. Problems with foot drop usually occur when a patient is recovering from a stroke and only the lower leg remains paralyzed. The patient therefore has difficulty controlling the movement of that foot.

Having said all this, I must note that current progress in this field is very encouraging. While major advances are not on the immediate horizon, the future of FNS devices is bright.

Approximating Nature—Crudely

Before considering how these artificial devices work, we must first understand how the original equipment works. In all vertebrate animals, motion is accomplished when muscles contract. The muscles are turned on electrically by signals carried by nerves, which form the wiring of the motor-control system. Some nerves run from the spinal cord to the muscles, carrying signals that trigger movement. Most of these signals originate in the brain. Other nerves carry sensory information from the muscles, joints, and skin to the spinal cord and ultimately to the brain.

Sometimes the sensory information received at the spinal cord is enough to trigger the nerves that control movement. For instance, if you step on a piece of glass, the resulting sensation of pain triggers the nerves to command your foot to lift. This is called a reflex action because the information does not need to reach the brain to elicit a response.

When the spinal cord is injured, motor-control signals from the brain to the muscles may be disconnected. As a result, the patient becomes unable to move certain muscles voluntarily. The higher the injury in the spinal cord, the more muscles will be paralyzed. While lower-level injury may result in paralysis of the legs, injury to the upper parts of the spinal cord may mean paralysis of the legs, trunk, and arms.

If the spinal cord is injured, the pathway for feeding sensory information to the brain may also be disconnected. As a result, the patient will have impaired (or no) sensation from the areas connected by nerves to the spinal cord below the injury level. However, reflexes will still exist.

The hope is to develop "neural prosthetic" devices that can at least partially replace the function of the injured spinal cord. The problem, however, is much more difficult than simply restoring signal transmission. Researchers must find some way of approximating the extraordinarily complex system for human motor control.

In this system, each single motor nerve cell (motor neuron) activates hundreds or thousands of muscle fibers. Fibers are the cells in muscles that, when activated by an electrical signal, essentially convert chemical energy that the body derives from food into contractive force. Each muscle fiber receives its stimulus from only one motor neuron. A motor neuron and all of its associated muscle fibers are together called a motor unit.
For movements such as walking or grasping an object with one hand, the central nervous system coordinates all the sensory information coming in with motor commands going out to the many muscles involved in producing the desired movement. In a sense, the human nervous system is an extremely complicated parallel processor, receiving, coordinating, and transmitting an enormous number of signals simultaneously.

At this stage, researchers are not even attempting to reproduce this natural motor-control system in its full complexity. Instead, they are concentrating on developing substitute systems that can achieve rudimentary motor control over paralyzed limbs.

Benjamin Franklin and the Leyden Jar

The use of electrical stimulation for medical purposes has a long and somewhat dubious history. As early as 46 A.D., the Roman physician Scribonius Largus prescribed the use of the torpedo fish, an electric ray fish, to treat headaches and gout. The torpedo fish was to be placed over the painful spot, where it would deliver a numbing electrical shock.

Then, in the 1740s, when scientists first learned to produce electricity and store it (in a Leyden jar), electrical cures were reported for paralysis, kidney stones, epilepsy, and heart pain, as well as other ailments. Among the early practitioners of electrical stimulation was Benjamin Franklin, who used an electrostatic generator with Leyden-jar storage to treat patients suffering from convulsions, reportedly with good results.

The first use of electrical stimulation to contract muscles is commonly attributed to Luigi Galvani in 1791. Galvani produced the contractions by conducting electricity from a metal rod through the nerve and muscle of a frog’s leg to another metal rod. Alessandro Volta verified Galvani’s experimental results and corrected his idea that the source of electricity was the animal rather than the metal rods.

The modern use of electrical stimulation to activate paralyzed muscles is at least 25 years old. In 1960, Adrian Kantrowitz enabled a paraplegic to stand for several minutes by stimulating the muscles in his legs. The current, when switched on, created an electric field between a “ground” electrode and the active electrodes attached to the patient’s skin. The electric field stimulated certain nerves in the patient’s posterior that in turn caused muscles in the

Today electrodes almost as fine as human hair (magnified, top) carry the electrical signals that stimulate paralyzed limbs. The Teflon-coated electrodes are inserted with a hypodermic needle into the muscles that control movement. When these muscles are stimulated in sequence, the patient can stand or walk.

Center: Sensors taped to the legs send information on the changing angles of the joints to a portable stimulator/computer (bottom), which then sends the signals for the next move.
body to contract. The contraction straightened the patient's knees, allowing him to support his own weight.

More recently, researchers have also developed techniques to deliver electrical stimulation through electrodes implanted in the target muscle, or surgically implanted around or on top of the actual nerves. In 1970, researchers at the Rancho Los Amigos Hospital in California, and another group in Ljubljana, Yugoslavia, were the first to report standing and some forward motion in paraplegics. The Yugoslavian group used surface electrodes for stimulation, and has since enabled 17 patients to stand and 3 patients to walk using a walker or crutches.

In 1973, a paraplegic at the University of Virginia at Charlottesville walked approximately 40 feet using a walker for support. Stimulation was provided by a system of implanted electrodes. In 1983, Dr. Herwig Thoma of the University of Vienna also used implanted electrodes to enable two patients to stand and walk up to 100 meters with crutches. Several other laboratories, including the Pritzkler Institute in Chicago, are working on FNS standing and walking systems as well.

Researchers working on these systems face a number of technological problems. For instance, while surface electrodes are the easiest to install since they remain outside the body, they are not very selective in the muscles they activate. That's because they must send their signals through the skin and fatty tissue, so they end up activating a number of different muscles and nerves. Furthermore, most surface electrodes must be replaced daily.

Intramuscular electrodes, which contain insulated stainless steel wires inserted through the skin into the muscle with de-insulated tips, are far more selective and reliable. They usually stimulate only the particular muscle (and nerves) into which they have been inserted. However, even though intramuscular electrodes do not require surgery, they are difficult to install. Electrodes surgically implanted around or on top of specific nerves may turn out to be the best for long-term use. However, because they are installed through surgery, they are not the modus operandi for the temporary and often changing demands of research.

The size of the electrodes and the materials they consist of present further technological limitations. Smaller electrodes made of materials more like human tissue must be developed before large numbers
Devices that electrically stimulate paralyzed limbs promise a new measure of independence. Left: A paraplegic is able to stand and maintain his balance with the help of a neuro-muscular-stimulation device developed at Case Western Reserve University and the Cleveland VA Medical Center. Researchers there have also devised a system of stimulation that enables quadriplegics—paralyzed from the neck down—to pick up a coffee cup (bottom).

of electrodes can be implanted inside the body. Even more constraining is scientists' lack of in-depth knowledge about the basic biomechanical workings of the human body. We simply don’t yet know how to coordinate the transmission of signals to and from a large number of electrodes simultaneously. No more than 50 electrodes are now being used even in the most sophisticated experimental systems. The body's natural system of motor control, in contrast, employs thousands of simultaneous signals to regulate movement. Thus, today’s artificial motor signals can command only large groups of motor units instead of individual units.

Stimulating Muscles by Trial and Error

All existing neural prostheses work in similar ways. First, the patient generates commands either by making a physical movement or by turning a switch off or on. In some experimental systems, quadriplegics move their shoulder in a certain way and a transducer mounted on the shoulder translates that movement into an electrical signal. This signal then prompts muscles in the hand to contract in a certain way. If the person pulls his shoulder back, for instance, his finger and thumb open and extend. In this way, a sequence of different shoulder movements can enable a quadriplegic to grasp and pick up a coffee cup.

In most experimental systems for paraplegics, the patient generates binary (on-off) signals using simple hand switches. The signals are sent to an electronic "stimulator," which uses this information to generate one electrical signal for each electrode. The electrodes carry these signals into the body, where they stimulate specific muscles. These muscles might control the way a particular joint should move, or how quickly the patient's foot should be lifted off the floor. When all these muscles are stimulated in the proper sequence, acts such as walking or grasping an object—which so many of us take for granted—can be achieved.

Researchers now use painstaking trial and error to determine the correct sequence of complicated movements needed for walking. These movements, which are different for every patient, can also be determined mathematically from knowledge of the biomechanical system. However, this approach is again constrained by our limited knowledge of the body's biomechanics. Once scientists establish the Continued on page 62
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movement sequence, they must determine the series of electrical stimuli needed to produce that movement and store it in the computer, to be refined as the patient learns to make the desired movement.

In most of these systems, the electrical stimulator is driven by a nonportable minicomputer, but work is progressing on more portable units. One of the stimulators used for walking at Case Western Reserve can be mounted on the patient’s belt. The battery-powered device has a sophisticated microprocessor programmed with a stimulation sequence custom-made for each patient.

This year some researchers have enabled paraplegics to walk much longer distances than ever before using more sophisticated control sequences. Under the direction of Byron Marsolais and colleagues at Case Western Reserve University, two patients at the Cleveland Veterans Administration Medical Center have been able to repeatedly move more than 400 feet using a rolling walker. One of these patients walked more than 700 feet. Using a stimulation sequence designed by Rudi Kobetic, this patient can also repeatedly ascend and descend stairs using hand railings.

In all these experimental systems, some method of support is needed to sustain the patients’ weight and help them maintain their balance while they attempt to walk. The additional support can be provided by support harnesses, parallel bars, four-post walkers, rolling walkers, and crutches.

Fine-Tuning the Controls

A complicated sequence of signals must also be devised to restore function in the paralyzed hand muscles of quadriplegic patients. Hunter Peckham, Michael Keith, and colleagues at Case Western Reserve have developed a system that relies on subtle shoulder movements to direct basic grasping movements in the hand. More than 10 patients have learned to use this system for such tasks as eating, typing (with a mechanical aid for pushing the keys), writing, drinking from rigid cups, and holding cigarettes.

At present, most neural prostheses for paraplegics rely on “open-loop control.” The devices stimulate muscles based only on patients’ commands and information previously stored in the computer. The controlling computer does not use measurements of movement to determine the stimulation signals.

In another, more sophisticated strategy, sensors taped or strapped onto the patient’s limbs measure each limb’s position and movements, and the computer uses this information to direct the stimulation of different muscles as needed. My colleagues and I at Case Western Reserve have developed such a system of “closed-loop control” in which four sensors measure the changing angle of the knees and ankles as our patients are standing. We have found that the system helps patients maintain their balance and perform other tasks without having to worry about whether their legs are about to buckle.

Jerold Petrofsky at Wright State University has also reported using closed-loop control strategies for walking as well as for standing—work that has been well-publicized in the popular media. The publicity surrounding his work has been a source of controversy among other researchers (see “The Nan Davis Story: A Trail of False Hopes,” page 60).

A system of closed-loop control does offer enormous potential for helping patients walk. Externally mounted sensors could be used to provide feedback from muscle movements as they happen and to time the next cycle of movements. For instance, information indicating that the right foot has reached the ground and is supporting weight might be used to initiate the next step with the left foot. Sensors may also eventually be used to measure and modify quantities of motion, such as the degree of force applied when the foot contacts the floor.
Several labs are also developing sensors to help quadriplegics regulate their hand motions when attempting to grasp a fork or coffee cup. However, no one has yet developed an effective closed-loop control system for accomplishing either walking or grasping an object. The problem is once again technological: external sensors are difficult to calibrate and to attach to a fixed position. These drawbacks could be dangerous if the error produces a misstep when the patient isn’t ready to move. In addition, many patients find such visible electronic gadgetry unsightly. Developing suitable sensors is a major technical challenge in producing effective FNS systems for both paraplegics and quadriplegics.

**Who Will Use Them and Who Will Pay?**

Perfecting the devices now being studied in research laboratories for commercial use will take years. Today technicians must regularly adjust the neural prostheses used for walking. The devices also require a marathon-like effort from patients, since their muscles are easily fatigued from the constant artificial stimulation.

Most of the technological problems with neural prostheses will eventually be overcome. By the time they are, I hope we will have answered an often-neglected question: who will use these devices? This question really has two parts. Which patients, if given the choice, will use the systems, and which patients will be given the choice?

Despite the existence of walking aids such as long leg braces, most individuals who are paralyzed in both legs choose to use wheelchairs as their primary vehicle for mobility. This is simply because the physical effort associated with using braces does not justify the amount of increased access they afford.

Similarly, paraplegics will probably use FNS systems only if they are relatively easy to wear and take care of, and if they do not make excessive demands on patients' energy and time. How these prostheses look is also important; many paraplegics don’t wish to wear a device that attracts unwanted attention.

Most importantly, neural prostheses must provide paraplegics with capabilities they don’t now have. Such systems must provide them with the ability not only to walk reasonable distances but also to overcome barriers such as stairs. Devices that help paraplegics stand must allow them to do so while engaged in significant, mind-consuming tasks. If the new devices don’t provide these added capabilities, it is unlikely that most paraplegics will abandon their wheelchairs.

Quadriplegics’ acceptance of devices that help them use their hands may be a very different story. The ability to manipulate objects could mean the difference between dependence on nursing care and the ability to take control of many basic needs. There is also a strong financial reason for developing easy-to-use neural prostheses for quadriplegics. By replacing some of the nursing care quadriplegics require, such devices could save millions of dollars in health-care costs. These devices may even enable some quadriplegics to regain useful employment.

Although it is impossible to estimate accurately the cost of these devices, they will probably be at least as expensive as an automobile. Even so, given the strong financial incentives, public and private health-insurance companies will probably cover such devices, making them affordable to most quadriplegics.

The balance of costs and benefits may be less compelling for devices that aid paraplegics. Insurance companies might argue that paraplegics can already get around with wheelchairs, and many have jobs. The intangible improvements to individuals’ quality of life are not always the overriding concern of health-care insurers. And with the growing push to contain medical costs, policymakers may decide that public health-care programs such as Medicaid and Medicare cannot afford to pay for these devices. Thus, when they finally become commercially available, not all paraplegics who need them may be able to afford them.

The future of efforts to restore muscle function to disabled individuals through the use of electrical stimulation is promising. However, multidisciplinary teams of scientists, engineers, and health-care professionals will have to work long and hard to solve difficult technical problems before these devices become widely available. This research should not be pressured by premature and exaggerated accounts of success in the popular press, which may raise false hopes among patients and damage the credibility of investigators in the field.

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