Let doctors judge effectiveness, urges medical laser designer, *PAGE 186*

A CAHNERS PUBLICATION

JUNE 12, 1995

design news

AMERICA'S BEST READ DESIGN ENGINEERING MAGAZINE

MODERN MEDICAL MIRACLES

Electrodes, lasers, materials target paraplegia and other ailments

PAGE 69

▶ Adhesives make disposables possible, p. 91

▶ Pneumatics breathe new life into medical design, p. 97

Muscle stimulator lets PARAPLEGICS walk

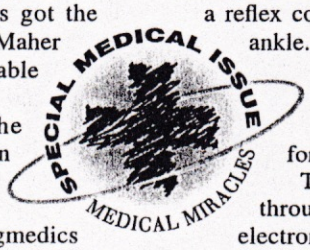
Parastep system offers the wheelchair-bound a new life

Julie Anne Schofield, Associate Editor

Although a paraplegic, Patrick Maher is an experienced and active walker. In fact, he can walk a mile without sitting down. This April, he was the first to walk using the power of his voice.

Maher spoke commands such as "stand up" and "right foot" into a microphone attached to a neuromuscular stimulator. The stimulator sent electricity to electrodes attached to his legs to produce a walking action while Maher gripped a walker for balance and support.

Although the system sometimes got the words "right" and "left" confused, Maher pronounced the prototype manageable and a success.



Everyday miracles. Though the voice-controlled stimulator is still an experimental device, its underlying technology is proven. It's the basis for the Parastep® system from Sigmedics Inc., Northfield, IL. Approved by the U.S. Food and Drug Administration last spring, Parastep encompasses an open-loop system that electrically stimulates groups of muscles across the hips and knees. The resulting contractions let users rise from a sitting position, take right and left steps, and return from standing to sitting.

Designed by Daniel Graupe, a professor of electrical engineering, computer science, and bioengineering at the University of Illinois at Chicago, and Dr. Kohn of Chicago's Humana-Michael Reese Hospital, the Parastep system won't replace a wheelchair. But, for patients in otherwise good health, it can permit short periods of standing and walking.

The Parastep system typifies functional electrical stimulation (FES)—applying electricity to the body to produce a specific outcome. One common example: a cardiac pacemaker, which uses electricity to initiate and control heart muscle contractions.

Normally, leg movement originates in the motor areas of the brain. Spinal-cord injuries disrupt the neural pathway between the brain and the muscles. With Parastep, a viable muscle—even though atrophied—can still be activated and controlled via electrical stimulation applied below the level of the spinal-cord injury.

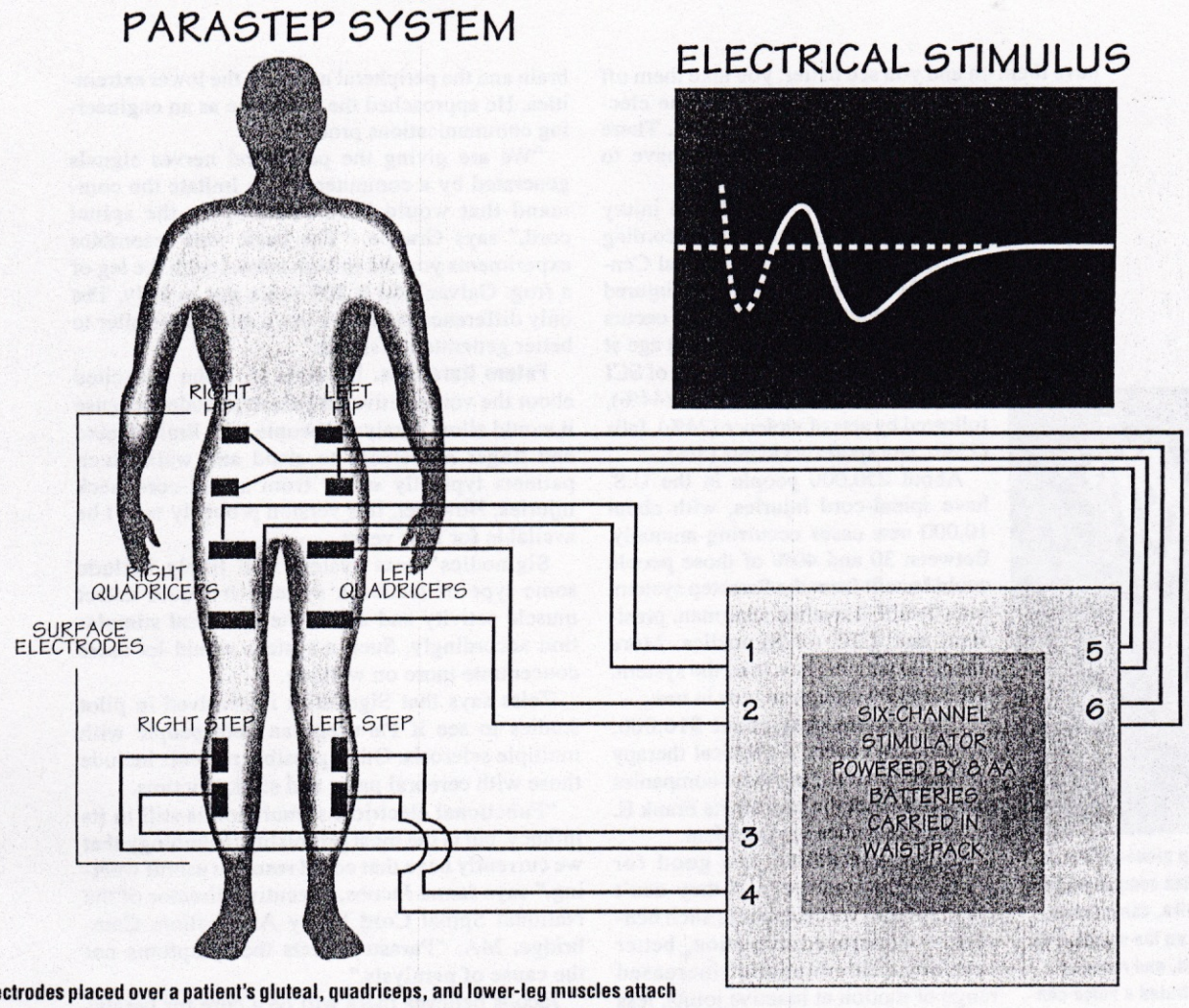
How it works. The system works by generating sequences of electrical pulses. These pulses pass to target peripheral nerves through reusable skin electrodes placed over the buttocks muscles, quadriceps, and below the knee.

Stimulating the quads causes a contraction that extends the knees, enabling the user to stand. Stimulating the sensory nerves in the lower legs initiates a reflex contraction to flex the hip, knee, and ankle. This lifts the foot off the floor as though the person had stepped on a tack. The stimulator then applies a pulse to the quads to extend the knee for another step.

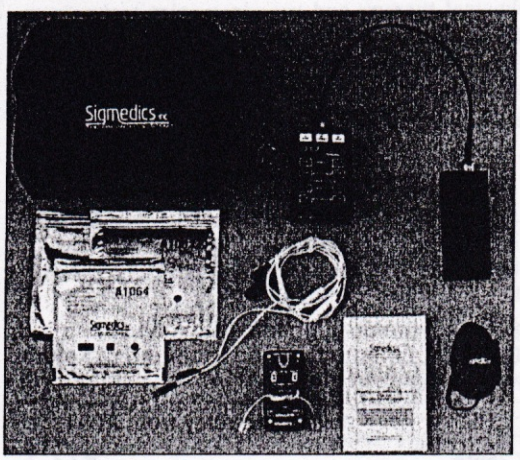
The user controls the stimulation through switches on the handgrips of an electronically modified walker or through a keypad on the stimulator unit. Switches permit standing and sitting, taking right steps, taking left steps, and increasing and decreasing the electrical current.

Electrical impulses come from a stimulator unit about the size of a Walkman attached to the user's waist. A power pack with eight rechargeable 1.2V AA batteries also sits in the waistpack. Output current ranges between 0 and 300 milliamperes.

An 8-bit, 4-MHz Hitachi microprocessor with on-chip memory controls the timing of the pulses. Programming depends on each patient's response to stimulation. Although walking appears to be a simple matter of putting one foot in front of the other, it's actually a complex process involving dif-



Skin electrodes placed over a patient's gluteal, quadriceps, and lower-leg muscles attach via cables to a microprocessor-controlled electrostimulator unit. Electrical impulses cause the muscles to contract, enabling the patient to stand and take steps.



In addition to the electronically adapted walker, the Parastep system includes surface electrodes, power and electrode cables, an electrostimulator, battery pack with recharger, and tester.

ferent muscles that must be precisely coordinated. Graupe addressed this problem by developing software for the processor that controls the timing of muscle stimulation.

No breeze to use. Using the Parastep system is intensive and requires strong commitment and discipline. To use the system, patients must balance themselves while standing, lower themselves from a walker to a wheelchair, and be in good cardiovascular shape.

Moreover, walking on legs that are completely paralyzed is complicated by lack of sensory feedback. "It's like walking on air," says Graupe. If the spinal cord is totally severed, patients have no sensation or motor ability. They use the walker for support, but 95% of body weight should be borne by the leg muscles—an act of faith for someone with no lower-body sensation.

Both Graupe and Kohn stress that Parastep is no cure. "It's like glasses," explains Graupe, "you

have them on and you see better, you take them off and you don't. Here, if you disconnect the electricity, the patient collapses like a noodle. There shouldn't be any false hopes. Patients have to relearn how to stand and walk."

Young men and wheelchairs. Spinal-cord injury (SCI) most frequently strikes young men. According to the National Spinal Cord Injury Statistical Center, Birmingham, AL, 82% of spinal-cord injured people are males. The highest rate of injury occurs between ages 16 to 30, and the most frequent age at injury is 19. The center says the leading cause of SCI involves motor-vehicle accidents (44%), followed by acts of violence (24%), falls (22%), and sports accidents (8%).

Parastep pioneer Patrick Maher has completed one-mile walks, can balance himself on the walker with one hand, and recently demonstrated a voice-controlled prototype developed by Dr. Daniel Graupe and Dr. Kate H. Kohn.

About 250,000 people in the U.S. have spinal-cord injuries, with about 10,000 new cases occurring annually. Between 30 and 40% of those people could benefit from the Parastep system, says Paul F. Lavallee, chairman, president, and CEO of Sigmedics. More than 300 patients have tried the system. About 200 systems are now in use.

The system costs about $16,000, which also covers 32 physical therapy training sessions. Insurance companies generally foot the bill, reports Frank E. Zeiss, Sigmedics vice president.

Stand and deliver. It's good for patients to stand, even if they can't walk. Being vertical leads to such benefits as improved circulation, better cardiovascular function, increased range of motion at inactive joints, less skin breakdown due to pressure sores, stronger bones, increased muscle bulk, and improved morale.

Parastep users can empty a dishwasher, drink from a water fountain, operate a copying machine, get books from a bookcase, enter and exit narrow passageways, and make presentations while standing. Says Graupe, "It means so much tears come to their eyes, especially if they've been in a wheelchair for 5 to 10 years."

Graupe's FES research started in 1970; patients using his system took their first steps in December 1981 at an FES research clinic established with Kohn at Michael Reese Hospital. His goal: to create a system that patients could control and use independently.

In December 1988, Graupe rounded up some venture capital groups to set up Sigmedics. He gave the company the patents on the condition that it manufacture his system for sale. FDA approval took $5.5 million and about four years.

Graupe considers the spinal-cord lesion an interruption of the communications channel between the brain and the peripheral nerves at the lower extremities. He approached the challenge as an engineering communications problem.

"We are giving the peripheral nerves signals generated by a computer which imitate the command that would have come down the spinal cord," says Graupe. "The basic idea resembles experiments you did in high school with the leg of a frog. Galvani did it 200 years ago in Italy. The only difference is that we use a microcontroller to better generate the signal."

Future iterations. Dr. Kate H. Kohn is excited about the voice-activated Parastep model because it would allow paralyzed people with limited hand and finger movement to stand and walk. Such patients typically suffer from spinal-cord neck injuries. However, this version probably won't be available for four years.

Sigmedics' next system will likely include some type of feedback system. It would detect muscle activity and adjust the electrical stimulation accordingly. Such a system would let users concentrate more on walking.

Zeiss says that Sigmedics is involved in pilot studies to see if Parastep can help people with multiple sclerosis. Other possible patients include those with cerebral palsy and stroke victims.

"Functional electrical stimulation is still in its infancy, but is the most promising technology that we currently have that could result in useful walking," says Janna Jacobs, executive director of the National Spinal Cord Injury Association, Cambridge, MA. "Parastep treats the symptoms not the cause of paralysis."

Jacobs believes there will be a cure for paralysis someday. She predicts that it will involve a combination of surgeries, drug treatments, and physical therapy and not electronics technology. But, until medical science unravels the mysteries of spinal-cord regeneration, systems such as the Parastep will continue to help paralyzed people regain lost ground. dn

For more information

For more information on the products involved in the design of the Parastep system, circle the appropriate numbers below on the Reader Service card.

8-bit microcontroller from Hitachi
Circle **712**
Analog/digital converter from Analog Devices **Circle** **713**
High-voltage solid-state relay from AT&T
Circle **714**

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