





POWER FORWARD

New exoskeleton makes walking possible for some people with SCI.

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or some people with spinal cord injury (SCI), powered exoskeletons promise a great leap forward in mobility and a range of related physiological and psychological benefits. But designing a device that is compact and lightweight enough to promote independence, yet still affordable enough for widespread use, has proven to be a challenge.

A new device produced by a team of engineers at Vanderbilt University in Nashville in collaboration with clinical personnel at Shepherd Center in Atlanta, may be a breakthrough in the field. The Vanderbilt exoskeleton weighs just 27 pounds and can snap apart to fit into a backpack. Unique among such devices, the exoskeleton is designed to allow a person with paraplegia to carry the device to a public place on the back of a wheelchair, assemble it, put it on, take a walk and return to a wheelchair without assistance.

The Vanderbilt exoskeleton is the first of its kind to incorporate functional electrical stimulation, or FES, in which small electrical pulses are applied to paralyzed muscles. Research shows FES can enhance muscle strengthening and neuromuscular re-education. Now on the verge of commercialization, the device may also become the most affordable exoskeleton on the market. The FDA has already approved two other exoskeletons for clinical use. Meanwhile, trials of the Vanderbilt device at Shepherd Center have revealed some potential advantages of this exoskeleton.

A COLLABORATIVE EFFORT

The Vanderbilt team has been consulting with Shepherd clinicians on the device's design. "I know as an engineer that if you try to do this without involving people with deep clinical expertise, it's going to fail," says device inventor Michael Goldfarb, Ph.D., head of Vanderbilt's Center for Intelligent Mechatronics.

Shepherd Center physical therapist Clare Hartigan, MPT, and her colleagues helped the Vanderbilt team understand the impact of an exoskeleton on people with paraplegia, including issues with skin care, blood pressure, spasticity and functional progression.

"This device has real functional possibilities in the home or office environment," Hartigan says. "I believe it has great promise as a gait training device, especially the FES component. Incorporating FES into gait is a huge advantage."

A FOUR-HOUR WALK

Exoskeletons may never replace wheelchairs, Hartigan says, because chairs are so fast, safe, reliable and cost-effective. But the most common orthoses – leg braces and the FES-enabled Parastep system – used by people with paraplegia to aid mobility put most of the wearer's weight on the shoulders. That design causes fatigue and risks a debilitating shoulder injury. So, these devices tend to go unused, Hartigan says. Exoskeletons carry the wearer's weight, which makes walking much easier. Former Shepherd Center patient Michael Gore, a T10 complete paraplegic who has been testing the device for the researchers, has used the device for as long as four hours at a time.

The Vanderbilt exoskeleton can be used by any person with the tricep and grip strength to use a stability aid, Dr. Goldfarb

notes. That profile includes some people with SCI as high as the lower cervical cord. The wearer controls the device by leaning his body forward, backward or to the side. Dr. Goldfarb compares it to a "legged Segway." It has been tested on steps, curbs and slopes up to five degrees.

Dr. Goldfarb's team is now testing the FES function, which activates the patient's musculature while working in tandem with the exoskeleton's motors. "We use as much of the subject's muscle as possible and fill out the rest with the exoskeleton," Dr. Goldfarb explains. "We want the control system to fuse with the musculature in a seamless way so the motors don't fight the muscles."

By connecting the device to a laptop, the team can estimate the user's contribution to the walking motion. For example, FES to Gore's muscles contributes about 35 percent of the torque and power of his walk in the exoskeleton. The FES operation does not noticeably affect the device's operation, except the user's power contribution can extend its battery life. Dr. Goldfarb anticipates that a future version of the exoskeleton will use implanted, wireless electrodes to administer FES.



A STEP BEYOND

The Vanderbilt team has finalized a licensing agreement for commercial sale of the device by Parker Hannifin Corp., a Cleveland-based maker of motion and control technologies ranging from aircraft wheels to pneumatic valves. The Vanderbilt device will be a relatively late entrant to a rapidly growing field of powered exoskeletons.

Two exoskeletons have received FDA approval for clinical use – Ekso Bionics' Ekso and Argo Medical's ReWalk. Shepherd is the only clinic to have tested both of these and the Vanderbilt device, and Gore is the only subject to have used all three, Hartigan says. Based on exoskeleton testing at Shepherd Center, Hartigan, Gore and Shepherd Center Medical Director Donald Peck Leslie, M.D., note some distinct advantages of the Vanderbilt device, which Parker Hannifin aims to submit to the FDA for approval in late 2013.

One issue is the degree to which the devices promote independence. The Ekso and the ReWalk, for example, each weigh about 45 pounds and require the wearer to use a backpack. Because of their weight, size and design, both of these devices also require a second person to transport and set up the device before it is worn. The Vanderbilt device, by contrast, is designed to be transported, assembled, donned and doffed independently.

Another is the devices' therapeutic value. The ReWalk's double-crutch based gait mechanism does not allow the reciprocal arm swing of normal gait, Hartigan says. "A device that uses an upper- and lower-extremity reciprocal gait pattern may be more intuitive to learn. For patients with SCI, a device that replicates 'normal' gait may potentially be more effective as a therapeutic tool."

Cost is another issue. An article in *Fast Company* magazine earlier this year priced the Ekso at \$130,000, though the company says it is aiming to produce a personal Ekso to retail for \$50,000 to \$75,000 in 2014.¹ Reports have indicated the ReWalk will cost \$85,000 or more. Parker Hannifin

Principal Engineer Ryan J. Farris says, "The price point for the [Vanderbilt] device will be significantly lower than the published costs for either the ReWalk or the Ekso system." The company's manufacturing experience and infrastructure should help keep the price low, Dr. Goldfarb adds.

For Gore, the Vanderbilt exoskeleton has been "the closest I've been to walking since my injury." Of all the devices, he felt it was the easiest to learn and provided the greatest sense of control. Wearing it helps to relieve pain and provides exercise at the same time, he notes. And for people with paraplegia who battle depression, Gore says, "Being able to stand up in the house or in public makes you feel a lot better emotionally."

People who are interested in participating as research subjects in the Vanderbilt exoskeleton trial at Shepherd Center should complete the intake form available at www.shepherd.org/research. 

1 "Ekso's Exoskeletons Let People Walk. Will Anyone Actually Wear One?" *Fast Company*, March 19, 2012. Accessed at www.fastcompany.com/magazine/164/ekso-bionics.

Testing, testing...

There is a dearth of published data about the effectiveness of powered exoskeletons – in part, because some have not been developed in academic settings, says Vanderbilt University's Michael Goldfarb, Ph.D., inventor of the Vanderbilt exoskeleton.

As part of a five-year research and development project funded by the National Institutes of Health, the Vanderbilt engineering team is collaborating with Shepherd Center clinicians to test and evaluate the device. Based on data gathered in July 2012, the team plans to publish this fall the first journal paper employing standard metrics for functional efficacy and exertion. The metrics include the Six-Minute Walk Test, Ten-Meter Walk Test, and the Timed Up and Go Test. These three functional gait assessments have already been performed with research participant Michael Gore walking with long leg braces on and then repeated with Gore walking with the Vanderbilt exoskeleton. Shepherd Center researchers expect to continue this testing with additional research participants.

Meanwhile, Dr. Goldfarb indicated in July that the numbers were looking good during trials with Gore, who was using the exoskeleton to walk through Shepherd Center.

