FDA, VA Give Exoskeleton Chance to Walk the Walk

A company outside Boston creates a device that would let quadriplegics get out of their wheelchairs and start new lives. Will health plans cover this?

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Taking a walk is one of life’s simpler pleasures. But walking is also an everyday activity that we largely take for granted. A spinal cord injury that would suddenly rob us of our ability to walk is hard to imagine.

But it happens to thousands of Americans every year. According to the National Spinal Cord Injury Statistical Center in Birmingham, Ala., about 12,500 Americans suffer a spinal cord injury each year and about a quarter of a million people in the country are living with the aftermath. Those statistics are for spinal cord injuries of all sorts. If the injury is in the cervical region, the result is either incomplete or complete quadriplegia. If the injury is lower down in the thoracic, lumbar or sacral regions, various levels or paraplegia—paralysis of the legs and lower body—may occur. About 40% of spinal cord injuries involve paraplegia with about half being complete and half being incomplete. The center estimates that the health care costs and living expenses during the first year after the injury are, on average, more than $500,000 and more than $65,000 each year after.

Regardless of the severity, a spinal cord injury often is a devastating injury at many levels—physical, emotional, medical, social, financial. Beyond the numerous associated medical conditions, these patients have a life that is severely hampered because of physical limitations. And the change is sudden—a very stark before-and-after contrast.

Historically, persons with paralysis have had only a few limited options for activities of daily living. The basic design of the wheelchair developed by John Dawson in England in the late 18th century remained virtually unchanged until electric motors and various other electronic adaptations were added.

VA is buying

Early versions of exoskeletons—wearable robotic suits that help people move—date back to the ’70s. But it was only recently that the technology became truly usable because of breakthroughs in computational power and battery technology. New exoskeleton devices have been developed by a number of companies. These amazing machines can translate the user’s body movements to activate motors, which, in turn, move the lower limbs through pre-programmed, coordinated gait patterns.

Only one version, developed by Rewalk Robotics in suburban Boston, has obtained FDA approval for home use. Late last year, the Veterans Administration announced that it would pay for ReWalk’s devices. The company’s stock price jumped up with that news. By some counts, 42,000 veterans have lost the use of their legs and as many as half of them might benefit from a ReWalk device. Although the VA needs to work through a number of operational issues such as ramping up their evaluation and training programs at the 24 VA centers that specialize in spinal cord injuries, it is conceivable that within a relatively short time we will start to see many people wearing exoskeletons in our communities.

The ReWalk exoskeleton allows the user with paralysis to perform a variety of maneuvers such as standing, sitting, and, yes, walking. People use the device to get up and down stairs, although FDA approval does not currently include an indication for stair use. The components of the ReWalk include a wristband remote con-
trol communicator, bilateral articulating legs consisting of thigh and calf components, pelvic band, straps and padding, ankle/foot bed, and backpack containing the main and auxiliary batteries. Motors in the exoskeleton control movements at the hip and knee joints. The ankle joints are assisted with a non-motorized exoskeleton mechanical and spring-assisted device integral to the ReWalk.

ReWalks need to be custom fitted to the user according to pelvic width, thigh length and shank length. Additionally, crutches attached to the user’s arms—or, alternatively, a walker—are needed to maintain balance. Candidates for the device should have hands and shoulders capable of supporting the crutches or a walker, healthy bone density, ability to stand using a device such as a standing frame, general good health, height between 5’3” and 6’2” and weight of 220 pounds or less.

To initiate use on the remote control communicator the user first sets the desired maneuver or “mode,” then he or she must initiate the desired motion by shifting the center of mass in various directions. The available modes include rising from a seated position, moving from standing to a seated position, walking and returning to a seated position. So, for example, to stand, the person sets the remote control communicator to the “standing mode.” A five-second pause is programmed into the cycle to permit time for proper crutch placement. During this time the user must also shift his or her center of mass forward to a position above the feet. The imbedded sensors ensure proper position and the device can then raise the user into a standing position. Numerous sensors ensure that the exoskeleton is in the proper position and will not initiate any motion unless proper positioning is present.

Walking involves combining body position, trunk posture, weight shifting, and proper placement of the arms and crutches or walker. The device won’t go into walk mode until sensors determine proper positioning and offloading of weight from the initiating leg. The next step is initiated once the initial leg has completed its swing motion and the user shifts the body weight onto this leg. This in turn allows the motors to initiate the same sequence on the contralateral leg if the user shifts the body to the proper position. The cycle is then repeated.

Ceasing the weight shift causes the device to cease to move the user forward.

The device has built-in hardware and software safety and emergency features. It has automatic testing features that will disable the system if any of the components are not functioning or communicating properly. It also has redundant controls and limits to prevent excessive joint flexion or extension.

Ready to use

Numerous studies have been done to ensure safety and efficacy, including studies on the cardiovascular system, energy expenditure, heart rate, and oxygen use. The research showed that metabolic demands—how much physical work the user must use—are well within acceptable levels. Those results helped build a case that ReWalk was ready for people to use and not some sci-fi project. Studies also demonstrated a training effect that created a more efficient use of energy (and speed) after the user became more adept at using the device.

The ReWalk device could revolutionize the care and treatment of spinal cord injuries and paraplegia no matter what the cause. Priced at between $80,000 and $100,000, it will be an expensive item for the VA system and some health plans. The current models are designed specifically for people with spinal cord injuries. But ReWalk may be modified for use by people with walking and other movement problems, regardless of the cause: stroke, cerebral palsy, spina bifida, traumatic brain injury, Guillain Barre syndrome (subject to FDA approval, of course).

ReWalk again demonstrates the speed at which miracles are occurring in Tomorrow’s Medicine.