Expecting exoskeletons for more than spinal cord injury

Exoskeletons that can help the paralysed to walk are available now. But they might also help patients with stroke damage, cerebral palsy, multiple sclerosis, or Parkinson's disease. So when might they be ready to take home? Adrian Burton investigates.

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It's hard to imagine how someone with a spinal cord injury who has lost the ability to walk must feel when, assisted by an exoskeleton—a robotic suit that supports their weight and helps moves their limbs for them—they are returned some of their former mobility. Advances in this field have been spectacular. The bulky, body-enveloping suits of just a few years ago (akin to the cargo-lifting exoskeletons worn by characters in films such as *Alien* and *Avatar*) are being replaced by more lightweight, more agile, more usable, more human designs: those commercially available today are far more sleek than the heavy exoskeleton showcased at the 2014 FIFA World Cup. But now imagine an even more discrete system that provides powered postural assistance to patients with, say, multiple sclerosis. Imagine a robotic arm orthosis that cancels out tremors in people with Parkinson's disease, or a small wearable machine that helps retrain the brain to coordinate movement. Imagine a hardly noticeable soft suit of straps and thin cables providing powered gait correction to stroke survivors or children with cerebral palsy. All these things and more are being developed and could soon be part of our rehabilitation and home care arsenal. The battle to bring new exoskeletons out of the cupboard is on.

And developers can smell success. At the World Congress of the American Orthotic and Prosthetic Association (Las Vegas, NV, USA, September, 2017), the talk was of a market worth perhaps US$1.8 billion by 2025—now just 7 years away—and of over 100 000 robotic exoskeletons sold and in use by then. However, obstacles to bringing out a new generation of exoskeletons for use by patients with neurological conditions other than spinal cord injury still exist. Designs need to be perfected, especially if they are to move out from the controlled confines of the rehabilitation unit and into patients' homes. In addition, evidence needs to be gathered to confirm their benefits, licensing approvals granted, and so on. So, when might we see these devices available?

"Designs for spinal cord injury for rehabilitation and home and community use, and a soft suit for stroke rehabilitation, are ready and do not need further development", explains Larry Jasinski, CEO of ReWalk Robotics (Marlborough, MA, USA). "[But those] for multiple sclerosis, Parkinson's disease, a home or community version of a [stroke assistance device], and products to assist the elderly are at concept stages and require refinement, testing, and further studies. Most of these require 2-4 years of funding and development, but are based on existing technical concepts that can be built upon."

"As a field, we have made good progress on the engineering front", says Ashish Deshpande, Associate Professor of Mechanical Engineering at the University of Texas at Austin (Austin, TX, USA), whose group is perfecting an exoskeleton for use in the rehabilitation of patients with stroke and brain injury. "Designs are becoming more compact, devices are becoming safer and more comfortable, and algorithms are being developed to allow for subject-specific assistance. There is still some way to go, however, in terms of lowering the weight and attaining seamless interaction with the user."

Benny Lo and his team at Imperial College London (London, UK), who are working on an arm-worn exoskeleton to correct tremors in patients with Parkinson's disease, also need time to perfect their potentially quality of life-changing device. "We have a working prototype, but it still requires much more development in terms of optimising the design, reducing the weight, extending battery life, etc, before we can start subject or clinical studies", he explains.

"We started working on developing exosuit [ie, soft suit] technology in 2012, initially with the goal of helping healthy people walk with less effort and, in 2014, began exploring the possibility of adapting the technology for patients with post-stroke difficulties", explains Conor Walsh, head of the Harvard Biodesign Laboratory (Harvard University, Boston, MA, USA). "Post-stroke gait is characterised by asymmetric and inefficient walking, and we felt that an exosuit could help restore the function of the impaired limb." The suit is attached to the wearer's legs via straps. Light-weight cables connected at the ankle joint and operated by motors, pulleys, and batteries worn around the waist help to support patient movement. "We have shown that the exosuit can supplement the paretic limb's residual ability to generate forward propulsion and ground clearance during walking, and that may help a person to train to achieve a more normal walking behaviour after stroke", says Walsh. "Delivering small amounts of active assistance through this lightweight and non-restrictive interface could have a positive effect on the mobility of people with physical impairments." It is hoped that a productised version will begin trials later this year.

But are such trials really necessary? Can we not simply see that an exoskeleton works and go straight

For a **patient experience of being able to stand and walk again** see https://www.youtube.com/watch?v=HAWT5CeoH9g

For an **example of a commercially-available exoskeleton for patients with spinal cord injuries** see https://www.youtube.com/watch?v=AYVZped_Qh4

For the **exoskeleton showcased at the 2014 World Cup** see https://www.youtube.com/watch?v=inCvbDLfXBo

For more on the **use of exoskeletons for children with cerebral palsy** see https://directorsblog.nih.gov/2017/09/05/robotic-exoskeleton-could-be-right-step-forward-for-kids-with-cerebral-palsy/

For more about **ReWalk Robotics research** see http://rewalk.com/

For the **exoskeleton being developed at University of Texas at Austin** see https://www.youtube.com/watch?v=9EF1hmdt83c

For the **exoskeleton being developed at Imperial College London** see https://spectrum.ieee.org/the-human-os/biomedical/devices/exoskeleton-could-quell-the-tremors-of-parkinsons-disease-patients-at-crucial-moments

For the **exoskeleton being developed at Harvard University** see https://wyss.harvard.edu/technology/soft-exosuit/

Will exoskeletons for patients with neurological disorders be a common sight?

For more on the **use of exoskeletons for people with spinal cord injury** see *Medical Devices: Evidence and Research* 2016; **9:** 455–66

For more on **FDA approvals and risk-benefit decisions** see *JAMA* 2017; **317:** 693–94

For the **approval of medical devices in the EU** see https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en#current_legislation

For the **approval of medical devices in the UK** see https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-medical-technologies-guidance

For more on the **difficulties of insurers covering the costs for exoskeletons** see http://www.modernhealthcare.com/article/20161126/MAGAZINE/311269982/why-cant-devicemakers-and-insurers-get-along

For the **exoskeleton developed at Vanderbilt University** see https://news.vanderbilt.edu/2016/03/10/fda-approves-vanderbilt-designed-indego-exoskeleton-for-clinical-and-personal-use/

into production? Not really, explains Jasinski: "For exoskeletons not already on the market [in the USA], clinical trials [are] required by the [US Food and Drug Administration (FDA)], primarily to demonstrate their safety." Lo too highlights the need to conduct trials, first in healthy individuals and then, if ethical approval is given, with an initially limited number of patients. "If the outcome is promising and funding allows, we will then carry out an extensive clinical trial involving hundreds of patients. As our main research focus is on developing technologies for improving patient care, clinical trials are essential steps for us to demonstrate the potential benefits of our technologies to patients' health", he explains. However, "the lengthy ethics approval process, difficulties in patient recruitment, and clinical uptake are major obstacles we face."

Deshpande also affirms that, while exoskeletons have the potential to assist with rehabilitation therapy, more work is needed to determine the most effective ways of using them. "Does the advantage lie in allowing more repetitions of movements, or do these devices have the potential to bring about a fundamental change in how we deliver therapy? Maybe they will also help in assessing progress or lack thereof. To address these challenges we are collaborating with clinicians and researchers from the fields of biomechanics and neuroscience. We are also carrying out experiments with healthy subjects and the affected population to show that these devices can positively affect a patient's ability to learn a new motor task. We have begun a pilot test with stroke patients to examine the efficacy of one of our devices in delivering therapy. More elaborate clinical trials are currently being planned."

In fact, while exoskeletons have been demonstrated as beneficial to people with spinal cord injuries, the same remains to be demonstrated for patients with movement disorders, explains Patrizio Sale (Assistant Professor in the Department of Physical and Rehabilitation Medicine, General Hospital of the University of Padua, Padua, Italy). "Until now, only preliminary data have been collected for [wearable devices] in, for example, Parkinson's disease. Some 70% of patients with advanced disease fall at least once a year, and two-thirds suffer recurring falls, mostly during walking. But studies on such patients have mostly focused on responses while standing. Owing to the progressive nature of Parkinson's disease, understanding the long-term benefits of exoskeleton-based assistance is important." However, he remains upbeat. "[As devices become available] we need to conduct clinical trials in heterogeneous samples of patients to assess the benefits in terms of mobility and satisfaction with them, and to show improvement in performances over time in full autonomy at home for all activities of daily living."

Trials are also important because exoskeletons are expensive (anywhere from about US$19 500 for a soft-suit exoskeleton to US$40 000 and upwards for powered, hard exoskeletons), and without such evidence, social health-care systems and insurers may not want to take on the costs of unproven technology. "Further studies to establish these technologies as standards of care with larger bodies of evidence will be needed to gain [positive] reimbursement coverage decisions", says Jasinski. But even if the FDA, European agencies, or other regulatory bodies were to approve them—necessary and often long processes required before any device could be marketed—this may not necessarily translate into automatic coverage by insurers or into their provision by national health-care systems. At the very least, this would require cost-effectiveness studies.

"Our hope and expectation is that exoskeletons will provide health benefits, in addition to improved mobility and social inclusion", says Michael Goldfarb, Professor of Mechanical Engineering at Vanderbilt University (Nashville, TN, USA), whose group has developed a commercially available exoskeleton for people with spinal cord injury. "It's difficult to put a price on quality of life, but our hope is that the health benefits provide an economic case—measurable reduction in medication or hospitalisation associated with secondary health effects—that either fully or largely offset the cost. Studies are underway to characterise the health benefits, and the potential impact on health-care costs."

Currently, some US manufactures have teams dedicated to helping patients gain reimbursement. However, "the industry is building the case regarding what insurance companies should cover, and we are starting to see movement in this direction", says Walsh. "And as the technology continues to be refined and optimised and, as the market grows, there will be opportunities for cost reduction."

Are we at the beginning of a revolution in which exoskeletons could change the lives of patients with multiple sclerosis, cerebral palsy, stroke damage, movement disorders, or other neurological problems? Might these devices one day become a common sight? The next few years will tell.

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