GTX Medical
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Offering hope for spinal cord injury patients

GTX Medical is developing innovative neuromodulation therapies to reverse paralysis and improve functional recovery in individuals living with spinal cord injury.

More than 1,000 people suffer a life-altering event daily that leads to a spinal cord injury (SCI) and subsequent loss or reduction in sensory, motor and autonomic functions. With no cure available—only physical therapy to help individuals learn to live with their disability—the consequences of SCI are devastating for those affected.

GTX is a global medical device company that is striving to grant new hope for recovery from SCI. Established in 2014 as a spin-out from EPFL in Lausanne, Switzerland, GTX is developing neuromodulation therapies to restore mobility and motor function, improve autonomic functions and accelerate the gains enabled by rehabilitation therapy.

"We are the first company in the world to provide medical devices that have the potential to reverse paralysis in people with a spinal cord injury," said Jan Öhrström, Chairman of the Board at GTX. "Our goal is for each patient to regain as much function as possible, and that can vary depending on the injury suffered, for instance, enabling a person to feed themselves or walk again without assistance."

GTX believes its innovative device-based therapies could also reduce healthcare costs, as the improvements in functional recovery could enable people with SCI to become more independent.

The company is currently progressing two different neuromodulation approaches for spinal cord stimulation (Fig. 1). Its non-invasive transcutaneous LIFT device to restore upper limb movement and hand function is expected to reach the market by 2022, while the implantable Go-2 system to restore locomotion in the lower limbs will be submitted for approval in 2024.

Improving grasp and arm movement

For individuals with paralysis in the upper limbs, an improvement in neuromuscular function directly translates into significant gains in terms of quality of life. For example, regaining the ability to hold a fork could enable individuals to feed themselves independently, likewise improved motor skills may provide the individual with the ability to manage a keyboard or tablet.

GTX is developing the transcutaneous LIFT device for non-invasive electrical spinal cord stimulation (NESS) therapy to enable restoration of motor control and function in the upper limbs after SCI. The LIFT device for NESS is designed to re-establish communication between spared neural networks and the brain by means of a stimulation approach through the skin that uses patented waveforms.

Wearable gel electrodes are attached to the skin on the back of the patient's neck (cervical spine) and controlled via a hand-held stimulator programmed with a tablet. The LIFT device has adjustable settings for current, frequency, waveform and duration of stimulation, and is designed for use in a rehabilitation clinic or at home.

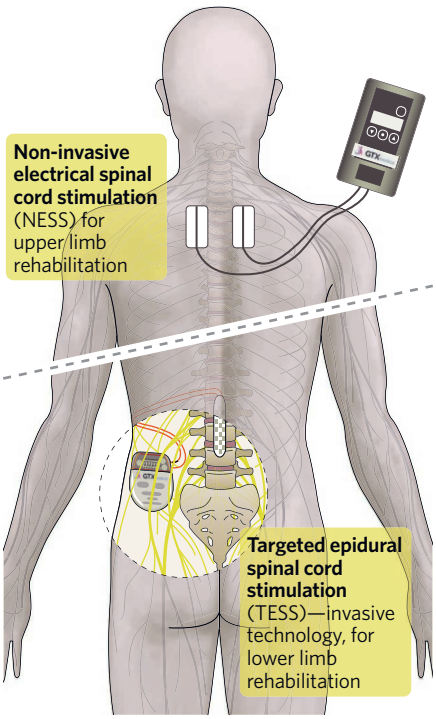

Fig. 1 | GTX's two neuromodulation therapies to reverse paralysis. LIFT device delivers non-invasive electrical spinal cord stimulation (NESS) for upper limb rehabilitation. Go-2 device delivers targeted epidural spinal cord stimulation (TESS) for lower limb rehabilitation.

The scientific basis for development of the LIFT system is predicated upon research studies performed on animal and human subjects with SCI demonstrating that residual (spared) sensory and motor pathways were critical in mediating the voluntary movements that are possible when NESS therapy is paired with task-based training by the individual[1].

A pivotal study is due to launch in Q4 2020, seeking market approval in the USA by 2022.

Restoring leg motor functions

GTX is also progressing a breakthrough implantable neuromodulation therapy that delivers targeted epidural spinal cord stimulation (TESS) for lower limb rehabilitation. The device-based therapy comprises a set of implanted and wearable components, called Go-2, combined with intensive rehabilitation.

The therapy aims to restore motor function in the legs by re-engaging neural circuitry in the spinal cord below the site of injury. This ground-breaking approach is based on research by Grégoire Courtine, CSO at GTX and Professor of Neuroscience and Neurotechnology at the EPFL in Lausanne, which showed that people with long-term paralysis due to SCI were able to stand and walk again after 5 months of TESS combined with intensive rehabilitation[2,3].

"TESS also has the potential to improve functioning of the autonomic nervous system," said Courtine. "Some patients in studies to date have reported important improvements in other comorbidities of SCI, such as bowel and bladder function and blood pressure."

GTX's Go-2 components include an implantable pulse generator and 16-electrode lead, which are configured to stimulate different aspects of limb motion. These are controlled by a wearable device that stores libraries of activities, such as walking, standing, sit-to-stand transition and bicycling, which are tailored for the patient. Rehabilitation physicians and therapists can use a tablet to fine-tune these for the patient, adjusting elements such as the timing, duration and direction of joint movement such as a hip flexion or knee extension.

A first-in-human study of the complete Go-2 system is due to start in early 2021 in the EU with market approval being sought in 2024. In June 2020, the company has been granted breakthrough device designation from the U.S. Food and Drug Administration for its implantable Go-2 system. A feasibility study in the USA is planned for the second half of 2021.

"This is just the beginning—our understanding of the scientific mechanisms underlying TESS is opening additional avenues to develop neurostimulation treatments that target other neurological functions and even other types of patients," said Courtine.

1. Smith, A.C., Rozwod, M., Tefertiller, C. et al. *Academy of Neurologic Physical Therapy* 1 May 2020 http://neuropt.org/docs/default-source/sci-sig/current-state-of-the-research/scisig_tscs_summary_2020.pdf (2020).
2. Wagner, F.B., Mignardot, J., Le Goff-Mignardot, C.G. et al. *Nature* **563**, 65–71 (2018).
3. Formento, E., Minassian, K., Wagner, F. et al. *Nat. Neurosci.* **21**, 1728–1741 (2018).

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