

Rehabilitation robots and the continuum of care

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The use of robotic devices for physical rehabilitation therapy is growing as the underlying technologies become more advanced and cost-effective. This trend is set to continue, opening new avenues for the adoption of rehabilitation robotics in our everyday lives. In this whitepaper we outline design and development considerations as well as key technologies for rehabilitation robotics, particularly wearable exoskeletons.

Global demand for physical rehabilitation therapy is rising. It's driven by many factors, from the frailty and neurological disorders associated with ageing to improved survival rates for strokes and better potential outcomes for spinal cord injury patients. With a growing world population, and increased life expectancy in many countries, the need for greater provision of physical rehabilitation therapy is here to stay.

This heightened demand places a huge burden on healthcare providers, especially when resources are already stretched. Therapeutic exercise can be a complex and time-consuming process. For instance, the UK's National Institute for Health and Care Excellence (NICE) recommends that stroke patients undergo 45 minutes of each rehabilitation therapy they're prescribed five days per week.

A growing market

Clinical settings are making increased use of advanced robotic solutions to aid physical rehabilitation. Integral robotic rehabilitation systems can ease physical demands placed on physiotherapists and support longer duration treatment sessions for the benefit of patients. They can also gather more consistent and precise data about an individual patient's progression, informing and aiding the path to recovery.

Various market reports indicate that demand for physical rehabilitation robots will surge over the next five years. A study by Wintergreen Research Inc. anticipates that the market for exoskeletons and wearable robots alone will grow from its 2018 value of \$130million to reach \$5.2billion by 2025¹.

It's likely that robotic rehabilitation solutions for use at-home will be a major driver of growth in this space. Traditional rehabilitation treatment models are evolving, with more treatment delivered in the home environment. Studies have demonstrated similar or better outcomes for telerehabilitation compared to

traditional therapy provided in clinic settings². As robotic solutions become cheaper and more accessible, their use in at-home treatment is likely to grow.

These changes mirror the movement towards increased at-home treatment across the wider healthcare ecosystem. See our paper on improving dialysis in the home for patients with chronic kidney disease here www.sagentia.com/insight/improving-dialysis-in-the-home.



The rehabilitation robotics spectrum

Devices that help people rediscover movements can be relatively simple in nature. Robotic ball therapy has been shown to deliver significant improvements in grip strength and unilateral dexterity for moderately affected stroke patients³.

However, as indicated by the Wintergreen study mentioned above, the more complex wearable exoskeleton robots are gaining a lot of attention. Offering a blend of rehabilitative and everyday assistive support, this is robotic therapy at its most advanced. The potential of these devices to improve physical mobility, fitness and quality of life for people with spinal cord injury or illness-related mobility problems is ground-breaking and truly lifechanging.

At the extreme end of mechatronics, exoskeleton robots demand a fusion of mechanical, electrical and control engineering expertise. Their production and operation draws on a vast array of technologies and materials as well as sophisticated use of data. Over the past decade, the industry has evolved to the point where actuation can be achieved within a smaller, more efficient footprint. Battery packs are more compact, lighter and longer lasting. Materials are also stronger, more pliant and lighter. Moreover, control systems and feedback monitoring can be coupled with machine learning for next generation smarter devices.

Advances in technology

Sensors

As sensor technology becomes more sophisticated, robot functionality is taken to a higher level. For example, the robotic company Cyberdyne uses electromyographic (EMG) sensors to read nerve signals from users' limbs and control exoskeleton motions. This solution is unique in that it provides instant sensorimotor feedback to signals sent from the brain. Exoskeletons complete movements for patients where this signal may have deteriorated, or where the muscles are too weak to carry out the motion desired.

Re-mapping nerve signals to physical motion in this way is key to neurorehabilitation. The limitation is that it is only viable for patients with some level of nervous signal in their limbs. However, EMG sensors can also be used in exoskeletons that augment the strength of healthy users. An instinctive control interface means normal muscle contraction can activate the motion. Cyberdyne has its own range of products for labour support aimed at healthcare workers who need to lift or move patients.

Force sensors, gyroscopes and accelerometers are also frequently used for feedback control, user input and data capture. These sensors are simple in nature, but with advanced signal processing, complex systems can be created. An example of this can be found in the Bimeo by Kinestica. Its system comprises three inertial measurement units (IMUs), each consisting of an accelerometer, gyroscope and magnetometer. By processing the raw outputs of individual sensors, the system can determine the orientation of each IMU, calculate joint angles, then establish the exact hand position of the user in three-dimensional space. The fundamental simplicity of this system underpins a cost-effective, commercialized rehabilitation device with proven benefits.

Actuators

Actuators generate the physical motion and support that exoskeletons bring to users. Interestingly, each exoskeleton currently on the commercial market draws on different functional drivers for actuator design and selection.

The burly appearance of the exoskeleton designed by Rex Bionics is a result of the ten actuators it carries onboard, which enable it to be freestanding and self-balancing. The exoskeleton fully supports its user and removes the need for crutches (normally used for balancing), leaving the arms free for upper-body exercises and daily activities.

This contrasts with the ethos behind the design of Phoenix by SuitX, a lower body exoskeleton which only uses two actuators at the hips. Its lightweight design is facilitated by clever use of electronically controlled tension settings at the knees which tighten when the wearer is standing and swing freely when they're walking. The Phoenix is so lightweight and adjustable that wheelchair users can put it on without assistance. This represents a step towards bringing robotic exoskeleton technology to the home for assistive everyday use improving users' independence and social integration.

A further example of design intent related to actuators can be found in the Hank exoskeleton by Gogoa. This model makes use of six actuators to achieve precise control at each joint for controlled and targeted rehabilitation exercises. The level of assistance can evolve with the patient throughout the process of gait recovery. A similar ethos can be seen in the design of eksoNR (by Ekso Bionics).

Materials

Advancements in materials are also facilitating product innovation. The robotic knee braces designed by Roam Robotics make use of high-strength fabrics to create actuators powered by compressed air. This lowers the weight of the product and is significantly more cost-effective than use of traditional actuators.

Data analytics

The field of rehabilitation robotics also benefits from developments in data management and analysis. Hocoma has embraced the power of data-driven rehabilitation with its digital network (hoconet) which combines patient monitoring across products for better clinical integration. Hocoma's product range covers early, middle and later stage gait recovery as well as arm and hand function recovery. With its unique, integral, clinician-centred approach, Hocoma helps healthcare professionals assess patient progress objectively for better management of rehabilitation.

The development and integration of new technologies into the field of rehabilitation robotics is happening at pace. Nevertheless, as with any medical application, devices need to undergo risk classification, rigorous testing and market approval.



Physical work for rehabilitation clinicians

Use of rehabilitative exoskeleton robots today

In a medical context, the FDA and other regulatory bodies have approved several models of wearable exoskeleton for rehabilitation and walking assistance. Rehabilitation centres increasingly use these devices to improve the physical therapy experience and reduce the need for clinicians to repeat strenuous and repetitive tasks in awkward positions.

For patients, wearable exoskeleton devices can fast-track the rehabilitation process by allowing them to hold weight-bearing positions at an earlier stage in their recovery. It's also easier to extend the duration of therapy in line with patient progress when therapists don't have to perform a physical role. What's more, patient motivation can be greatly improved with the immediate in-session feedback provided by a robotic device.

Some devices have been approved for use in the home under the supervision of a trained person. In the near future, we can expect to see increased use in home settings, perhaps with a therapist supervising or initiating sessions via video link. This could significantly improve the intensity and effectiveness of therapy that patients receive, without subjecting them to long and frequent visits to a clinic. In the post Covid-19 world, we anticipate that this will be a prime area of opportunity for robotic medical device companies.

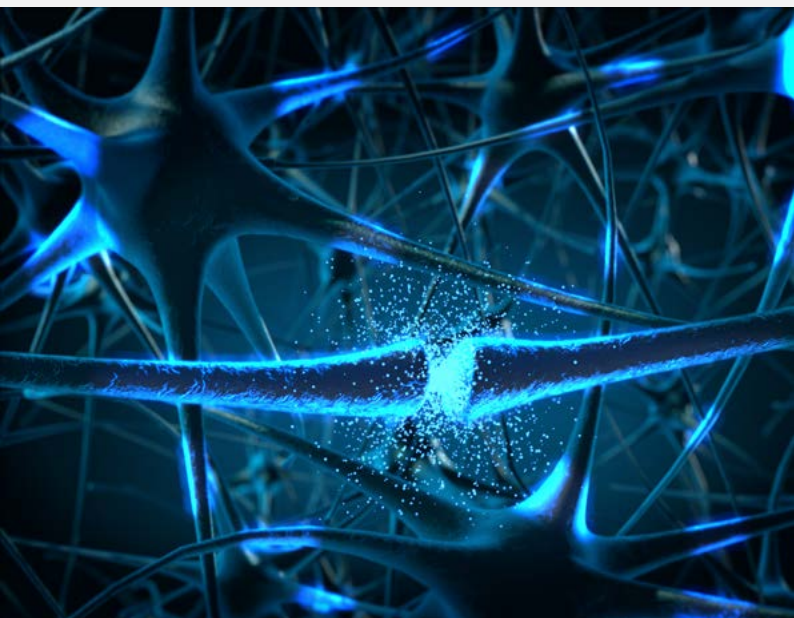
Over time, greater use of robotic exoskeletons for rehabilitative and assistive purposes will help accelerate and fine-tune innovation based on real needs. A growing pool of user feedback will provide robust insights to inform the future development of safe, viable and effective products.

From rehabilitation to long-term assistance

Studies have shown that recovery from conditions involving the central nervous system is aided by neuroplasticity⁴ where the brain 'reorganizes' itself to compensate for injury or disease. For this reason, many new rehabilitation techniques incorporate neurorehabilitation and neurobiological treatment with physical therapy⁵.

Robotic exoskeletons can help bridge the gap between neurological and physical rehabilitation. As people regain mobility, synaptic connections between the central nervous system and the muscles are re-established. Sensors detect signals from the brain and use actuators to enable or complete the motion that a damaged nervous system cannot. By performing these exercises, the nervous system is moulded to effectively 'connect' with the locomotive system through an interactive bio-feedback loop.

Nevertheless, even an optimal exploitation of neuroplasticity won't necessarily result in full functional recovery⁶. So wearable systems are needed to both support physical therapy and to compensate for persisting sensorimotor deficits. With advanced actuation, sensing and control, these systems are becoming more robust and capable of performing daily activities, in the home as well as at the clinic. In the future, it is likely that wearable devices will have the ability to continuously adapt and reduce support until recovery plateaus, from which point they can compensate for chronic impairments⁷. Advances in AI and machine learning will play a pivotal role here.



Looking ahead

The development and production of wearable exoskeleton robots for rehabilitative and assistive therapy is expensive. However, the cost / benefit equation is improving as the underlying technologies evolve and components become cheaper, smaller and lighter. Coupled with greater acceptance and demand for such devices, this is unlocking new potential for product development.

Certain critical success factors are universal, whether you're developing a simple robotic ball or a more complex exoskeleton solution. As with any medical device, it's important to be aware of relevant regulatory requirements for products in target geographical markets. Considering this at the front end of the design process is vital, as early stage decisions can have a significant bearing on a device's suitability for clinical use.

A user-centered design approach is also essential. If the device is intended for a clinical setting, you need to consider whether patients will be able to use it with limited supervision. If it's oriented towards use in the home, think about whether patients with impaired mobility will be able to use the equipment independently, safely and effectively.

For a more detailed overview of design considerations, download our whitepaper [Searching for Balance](http://www.sagentia.com/insight/searching-for-balance-the-science-in-design-thinking) [www.sagentia.com/insight/searching-for-balance-the-science-in-design-thinking]. It has some useful pointers on how to satisfy the three pillars of Design Thinking: user need, technical feasibility and commercial viability.

Long-term use of robotic exoskeleton devices to aid the mobility of people with permanent physical impairment is likely to gain momentum in the coming years. There are still many barriers that make routine use of personal exoskeletons for everyday life difficult. Some of these are related to the technology itself, but others are linked to use environments and acceptance of the devices in the wider world.

For instance, historically, it has been difficult for users of wearable exoskeletons to obtain insurance. The insurance is a multi faceted issue due to the expensive technology, extensive usage risk assessments to negotiate and the great variation of user circumstance and ability. However, things are starting to change. An important milestone was achieved in 2019, when US health insurance provider Cigna announced that it would consider insuring individuals using the devices on a case-by-case basis⁸.

Final thoughts

Rehabilitative robotics is an exciting field with much potential, particularly in the exoskeleton space. However, the complexity and sophistication of device design and development requires a vast range of skills and technologies. Multiple elements – from moving parts to software design – are subject to stringent medical regulatory requirements. Balancing the various considerations while ensuring costs don't spiral beyond the point of commercial viability is no mean feat.

At Sagentia, we help clients deliver innovative devices across the patient care continuum. We understand the stringent requirements of this highly regulated environment and hold ISO13485 accreditation for medical device development. Our deep technical understanding in bring products to market and step changes in enabling technology, ensures we deliver real-world relevance to our insights and recommendations.

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