



New medical technology: Cybernic treatment as a functional regenerative treatment

CYBERDYNE, Inc. develops products and services based on cybernic technologies in the fields of medicine, welfare, personal care, business and labour support. CYBERDYNE, Inc. was founded in 2004 by Yoshiyuki Sankai, of the University of Tsukuba in Ibaraki Prefecture, Japan, who established cybernics, a field that is defined as the fusion of humans, robots and information systems. Under the philosophy that technology exists for humans and society, the company promotes social innovation with innovative cybernic systems. One of its novel products, the world's first cyborg-type robot, HAL®, can be controlled by intention-based bioelectrical signals generated by neural activity to regenerate, improve, support and expand the wearer's physical, brain and nerve functions.

The cyborg-type robot HAL is a cybernic system developed for the purpose of regenerating and improving patients' brain-neuro-physical functions. HAL is equipped with the cybernic treatment control system and includes the following: cybernic voluntary control, which is a function based on bioelectrical signals derived from a person's brain and nervous system that reflect an intended movement; cybernic autonomous control, which is a function based on processing by artificial intelligence; cybernic impedance control, which is a function that adjusts to the wearer's individual characteristics; and a cybernic hybrid control system that combines all three functions.

The world's first robotic treatment device, medical HAL, was demonstrated in a good clinical practice-adherent clinical trial¹ led by Takashi Nakajima of the National Hospital Organization, Niigata National Hospital in Japan. The trial was conducted in ten facilities to target slow, progressive, rare neuromuscular diseases: spinal muscular atrophy, spinobulbar muscular atrophy, amyotrophic lateral sclerosis, Charcot-Marie-Tooth disease, distal myopathy, inclusion body myositis, congenital myopathy and muscular dystrophy. The world's first robotic treatment to be paid for using public health insurance began in Japan in September 2016. In Germany, clinical evaluations targeting spinal cord injuries were conducted using results from research led by Thomas Schildhauer. Public worker's compensation insurance in Germany has been covering the treatment for people with spinal cord injuries since August 2013.

In the treatment using HAL, clear differences in the active areas of the brain were observed before and after treatment. Cybernic treatment can be

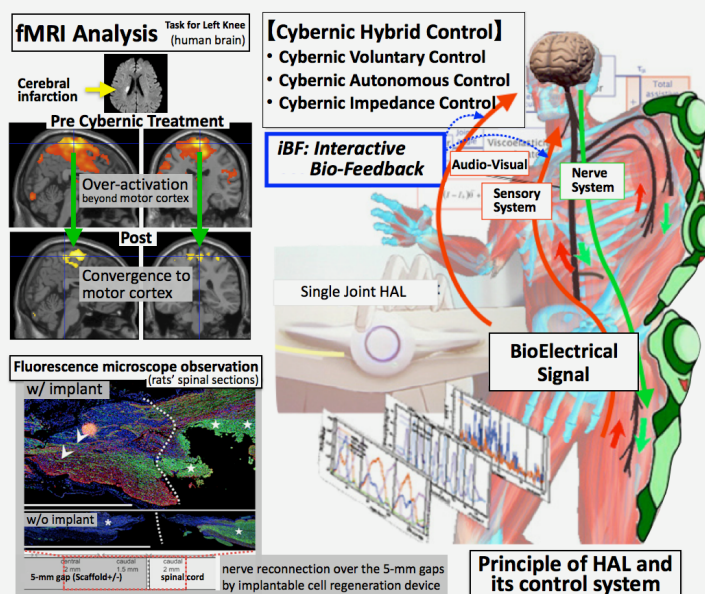


Figure 1. The principle of HAL. Clear differences in the active areas of (top left) the brain of a person with cerebral infarction and (bottom left) spinal sections of the implant and control rats.

categorized as a functional regenerative treatment and has been made possible only by HAL's ability to simultaneously realize informational and physical interactions between the human and HAL to functionally integrate humans and robots. HAL's presence between the patient's brain and his or her nervous and musculoskeletal systems allows the establishment of interactive biofeedback (iBF). The iBF adjusts or strengthens the synaptic connections between the brain, nervous system and musculoskeletal system, and promotes neuroplasticity to restructure the connectome, which is the network of neural connections in the human brain.

Medical technology developed using cybernics is known as medical cybernics. New treatment methods that include combinations of HAL and regenerative medicine, HAL and implanted devices, and HAL and pharmaceuticals are being developed.

The combination of HAL and regenerative medicine, which we call cybernic treatment with stem cells, will combine cutting-edge medical technologies. For example, when used to treat people with a spinal cord injury the physical repairation effects of regenerative medicine and the functional regeneration effects of HAL are expected to be more effective in combination than if each treatment were to be used alone. Such promising regenerative medicine includes, but is not limited to, autologous bone marrow-derived mesenchymal stem cells (in research led by Osamu Honmou), Muse cells (in research led by Mari Dezawa) and surgically transplanted autologous stem cells.

The combination of HAL and pharmaceuticals is called cybernic treatment with drugs. Botox injections were administered to patients who experience severe contractures because of stroke or encephalomyelitis. The use of HAL when the botox injection was providing relief from the contractures resulted in the reestablishment and improvement of the patients' voluntary movements (in collaborative research with Ryuji Kaji).

To study cybernic treatment with devices, which combines HAL and implanted devices, basic science research on nerve connectivity was conducted on rats that had 5 mm of their spinal cords removed. By implanting a three-dimensional scaffold structure made of nanofibre hydrogel and a honeycomb-structured collagen sponge, the nerves were successfully reconnected covering this 5 mm gap (Figure 1, ref. 2). We are planning to use HAL in the next

step to confirm the effects of this combination.

HAL can extract faint information from the brain and nervous system that reflects the intent of the wearer, process the input and output, and monitor the state of the patient's nervous and musculoskeletal systems. In other words, HAL is able to cover both the treatment and evaluation aspects of medicine and has the potential to take over medicine for patients with brain, nerve and muscle diseases. Through the next generation of medical technology, such as HAL's combination with regenerative medicine, implanted devices and pharmaceuticals, and through the development of cybernic treatment as the future of medicine, energetic physicians, researchers and business entrepreneurs are creating markets in the medical field and starting a new era of medical innovation.

REFERENCES

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