ROBOTIC MEANS OF REHABILITATION OF MOTOR ACTIVITY OF PATIENTS IN THE POST-STROKE PERIOD

Zemlyakov IY[2], Zhdanov DS[1,2] ✉, Bureev AS[1,2], Golobokova EV[1,2], Kostelei YaV[1,2,3]

[1] National Research Tomsk State University, Tomsk, Russia

[2] Federal Research and Clinical Centre for Medical Rehabilitation and Balneology of the Federal Medical Biological Agency of Russia, Moscow, Russia

[3] Tomsk State University of Control Systems and Radioelectronics, Tomsk, Russia

Stroke prevalence is one of the most acute problems in the medical and social aspects of society: strokes are the second most common in the mortality statistics of the population. In the Russian Federation, stroke occurs annually in almost 500,000 people and is the first among the causes of death from neurological diseases and the second most common cause of death after heart disease. The most common consequences of stroke are motor disorders of varying severity, manifested as changes in muscle tone, paresis and paralysis, and impaired walking function. This paper is an overview of the current state of robotic rehabilitation devices used for post-stroke limb paresis and of expected trends of their development. The existing variants of their construction, conditions of kinesiotherapy sessions for obtaining the greatest effect are considered. The authors are of the opinion that the nearest prospect for the development of high-tech devices of this type is not only complex stationary universal complexes for clinics, but also simple mobile specialized simulators with remote medical control for outpatient use.

Keywords: medical robotics, devices for rehabilitation, stroke, exoskeleton, biofeedback, functional electrical stimulation

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✉ **Correspondence should be addressed:** Dmitry S. Zhdanov
Novosobornaya ploshchad', 1, k. 103, Tomsk, 63450, Russia; D_S_Zhdanov@mail.ru

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РОБОТОТЕХНИЧЕСКИЕ СРЕДСТВА РЕАБИЛИТАЦИИ ДВИГАТЕЛЬНОЙ АКТИВНОСТИ ПАЦИЕНТОВ В ПОСТИНСУЛЬТНОМ ПЕРИОДЕ

И. Ю. Земляков[2], Д. С. Жданов[1,2] ✉, А. Ш. Буреев[1,2], Е. В. Голобокова[1,2], Я. В. Костелей[1,2,3]

[1] Национальный исследовательский Томский государственный университет, Томск, Россия

[2] Федеральный научно-клинический центр медицинской реабилитации и курортологии Федерального медико-биологического агентства, Москва, Россия

[3] Томский государственный университет систем управления и радиоэлектроники, Томск, Россия

Проблема распространенности инсультов одна из самых острых в медицинской и социальной составляющей жизни общества — инсульты занимают второе место по распространенности в статистике смертности населения. В Российской Федерации инсульт наблюдается ежегодно почти у 500 000 человек и является первым среди причин смерти от неврологических заболеваний и вторым по частоте в структуре смертности после заболеваний сердца. Наиболее частые последствия инсульта — двигательные нарушения различной степени выраженности, проявляющиеся в виде изменения мышечного тонуса, парезов и параличей, нарушений функции ходьбы. В обзоре представлены результаты анализа текущего состояния и возможных направлений развития роботизированных реабилитационных устройств, используемых при постинсультных парезах конечностей. Рассмотрены существующие варианты их построения, условия проведения кинезиотерапевтических сеансов для получения наибольшего эффекта. Ближайшую перспективу развития высокотехнологических устройств данного типа авторы видят в создании не только сложных стационарных универсальных комплексов для клиник, но и простых мобильных специализированных тренажеров с удаленным врачебным контролем для амбулаторного использования.

Ключевые слова: медицинская робототехника, устройства для реабилитации, инсульт, экзоскелет, биологическая обратная связь, функциональная электростимуляция

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✉ **Для корреспонденции:** Дмитрий Сергеевич Жданов
Площадь Новособорная, д. 1, каб. 103, г. Томск, 63450, Россия; D_S_Zhdanov@mail.ru

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Medical robotics is a complex and very specific field that lies at the intersection of several high-tech areas of science and technology. According to D. Engelberger, titled "The Father of Robotics," "hospitals are the perfect place and the perfect environment for robots to be used" [1]. Nevertheless, robotic systems will not be able to completely replace humans in the near future — so far they can only perform routine and repetitive actions [2, 3].

Robotic devices (RDs) in medicine were first used in 1985 to precisely guide needle movement in brain tissue biopsies using a PUMA 560 arm [2]. In the future, the development of positioning surgical systems has become the main focus of medical robotics. However, remotely controlled manipulators cannot be called robotic devices in the full sense, although they have proven themselves in microsurgery [4].

With the development of microelectronics and general robotics, the implementation of RDs in medicine has expanded significantly [5]. Their implementation in laboratory diagnostics [5], surgery [6], psychiatry and psychology [7], dentistry [8] and other areas has become possible. At the same time, the early introduction of service RDs in hospitals to serve patients with low mobility is of high relevance. By performing routine tasks, they significantly reduce the workload of nurses [9].

There is another area of healthcare where RDs may be in high demand. Globally, about 17 million people suffer from strokes each year, losing some or all of their motor function. Survival rates have trended upward in recent years and will reach 70 million by 2030, placing a significant burden on national health and social care systems [10]. RDs for rehabilitation of this category of patients are designed to solve the problem of restoring the functioning of the affected limbs.

The purpose of the review was to conduct a technical analysis of the existing robotic systems for motor rehabilitation of patients in the post-stroke period, and to describe the expected trends of robotics development. Materials were searched in the National Library of Medicine, Scopus, eLIBRARY, Google Patents, and a number of other scientific and patent-oriented databases.

Trends in the development of rehabilitation RDs

Restoration of motor functions of stroke patients is currently possible with the help of external robotic devices (exoskeletons) and electromechanical devices that conduct forced training of the limb in accordance with the methods of kinesotherapy. Electromechanical RDs were first used at the turn of the 1980-90s [11, 12]. By utilizing the feedback sensors of the RD design during exercises, an attempt was made to ensure that the exoskeleton interacted with the human in the atraumatic and most complete manner possible. Thus, the positive effect of exoskeleton use in neurorehabilitation was first described in 1998 [13]. The authors showed the absence of side effects, good tolerance of the prescribed procedures and a significant effect of manipulations with the injured limb on the process of recovery of motor centers of the cerebral cortex.

Over the next 20 years, the number of publications devoted to poststroke neurorehabilitation with the use of RD grew rapidly. In the Russian-language literature, the issue of neurorehabilitation with the use of RD up to 2018 is reflected in the analytical review [14]. The use of RDs in the domestic clinical practice of neurorehabilitation of that period can be estimated by counting the number of cited articles by Russian authors: only 5 out of 71 articles were cited. Another national review mentions more than 240 models of RDs for restorative care [15]. The authors came across findings saying that to fix in memory a motor act it is necessary to perform the exercise at least 400 times. However, in the absence of an RD, it is difficult to do this without errors.

The authors of one review point to the ever-increasing cost of rehabilitation courses for stroke patients in the recovery and residual periods, as well as the high cost of appropriate equipment [16]. This is related to the process of development and implementation of RDs with the possibility of individual adaptation, including the use of artificial intelligence elements. High cost of such products determines a small number of manufactured products given the significant labor input and expenses to obtain appropriate certificates [17]. The second development trend is that more and more mobile compact devices designed for individual continuous use are appearing on the market [18]. Compared to stationary rehabilitation simulators, they are more demanding in terms of materials used, workmanship and energy consumption, which also affects the cost of production. The market for rehabilitation devices is expected to grow by a third to reach $16.6 billion annually over the five years from 2020 to 2025. At the same time, it should be taken into account that the high-tech devices in question are currently available to less than 50% of those who need it [16].

The high burden on the staff of rehabilitation departments, the significant cost of equipment and the scarce number of specialized clinical centers make it necessary to limit the duration of the rehabilitation therapy cycle to a few weeks. The way out of this situation may be the growth of production and expansion of the range of rehabilitation RDs for home use, which are relatively inexpensive due to their narrow specialization and therefore simplified design. It will make it possible to organize a continuous rehabilitation process under periodic medical supervision and achieve positive results in less time. Unfortunately, the domestic segment of the market for personalized rehabilitation RDs is in its infancy and thus is not broad enough [16].

Neurorehabilitation devices

RDs for neurorehabilitation can be qualified as service robots in the subcategory "robots for patient rehabilitation" [19]. Some experts proposed subdividing them into two subclasses: robots designed to train lost motor function after stroke (therapeutic devices) and robots designed to compensate for lost skills (assistive devices) [20]. The relevance of using both types of RD is explained by the fact that they organically complement each other at different stages of rehabilitation. The workload on medical personnel is reduced due to the saving of time for face-to-face control of the correctness of exercise performance, and there is an economic effect expressed in an increase in the number of supervised patients even though there is a minor increase in the workload on one physician.

Devices designed for neurorehabilitation of limbs and their parts can be divided into three types [21–23]:

1) static orthopedic devices whose primary function is that of limb support. They do not have any actuators. These are various types of splints, lumbars, braces and fixators [24];

2) dynamic orthoses that preserve the mobility of the limb. They can be passive, supportive, or active, with mechanical actuators that train a specific joint [25];

3) robotic exoskeletons that replicate the mechanical properties of the limb and, as a result, better match its anatomy. Despite their cumbersome feel and high cost, these solutions are the most suitable for the tasks of neurorehabilitation and functional prosthetics in conditions of free movement.

Let us consider the latter option as the most universal solution, although so far exoskeletons for medical use have not been identified as a separate category in the domestic system of standards [26]. Exoskeletons involve safe, collaborative work with the patient to enable use and improve residual motor function. Consequently, actuation and control systems must provide a minimum of two modes of operation: position-controlled mode and force-controlled mode. In position-controlled mode, the RD moves along predetermined spatial and temporal trajectories defined by its settings. The force-controlled mode relies on the use of the patient's muscular effort to generate a full range of motion in the RD: this mode is suitable for minor muscle paresis. Position control can be added as an additional loop to correct the correctness of the exercise.

The reduction in rehabilitation time using exoskeletons in kinesiotherapy was first shown in paper [21]. At the same time, no significant differences in the effectiveness of exercises with exoskeletons with and without adaptive control were found [22]. The authors even lean in favor of RDs without adaptive capabilities because of their lower cost, higher reliability, and ease of use and maintenance.

The period of the start of rehabilitation measures and the parameters for robot-assisted gate training (RAGT) depend on many factors [23]. It has been found that the best results can be obtained in the acute period of the disease, with a session lasting 30 minutes, three times a week for four weeks. Six clinical parameters were used to assess the condition, including the Fugl-Meyer Sensomotor Function Assessment Scale, the Berg Balance and Balance Impairment Assessment Scale, the Torso Movement Control and Impairment Assessment Scale, the modified Barthel Index for assessing independence in basic activities of daily living, and the modified Ashworth Muscle Spasticity Scale. This statement was confirmed by the results of electromyogram (EMG) studies of a group of 36 patients. The difference of EMG parameters (frequency of peaks, its duration and area) between the control and experimental groups was reliable [27].

Exoskeletons of the upper limbs are more complex in relation to RDs of the same type for the lower limbs. This is due to the fact that the simple movements of the large joints are supplemented by rotations of the hand, as well as grasping or pinching movements of the fingers [28, 29]. However, robotic devices known to date able to perform finger movements, do not take into account the movement of the wrist, so the devices either hold it stationary, or allow it to make movements only in one plane: to bend and unfold. Functional multifacetedness of the simulation of human hand and finger movements implies a high complexity of the task of controlling the RD, including the use of artificial intelligence elements and methods of detecting the patient's movement intentions, including registration of extensometric and electrophysiological signals of paretic muscles [30].

Devices for restoration of upper limb function

There is still no unified coordinated, functionally and physiologically grounded concept of neurorehabilitation measures of arm and hand mobility using robotic devices despite a sufficient number of RD models focused on restoring upper extremity function [31]. This is caused by the ambiguity of existing approaches to neurorehabilitation of stroke patients and the diversity of clinical conditions, which often have no clear distinctions and are combined [31]. As a result of the described situation, there are now available RDs designed to restore hand function based on EMG with brain-computer interface (BCI) and somatosensory RDs with functional electrical stimulation (BCI-FES) [32].

The rehabilitation process using EMG can be based on the principles described below. No significant difference in the effectiveness of the described methods has been found yet [33]:

1) stimulation of the muscles of the paretic limb with electrostimulator signals that correspond to physiological norms and are stored in an appropriate database: the electromyogram is used to monitor the effects;

2) use of the "mirror" principle, whereby an amplified signal is applied to the paretic limb, which is recorded on the healthy limb when the patient attempts to perform identical movements;

3) use of EMG in a biofeedback circuit (biofeedback), when electromyograms are presented to the patient in the "mirror" mode when the patient attempts to make identical movements with the paretic and healthy hand.

RDs using BCI implement different approaches based on recording electroencephalograms (EEG) of motor cortical areas. The main problem of such RDs is the ambiguity of interpretation of the recorded signal. An algorithm based on the analysis of spatial and temporal characteristics of the EEG in several frequency ranges of the total bandwidth of an electroencephalogram signal appears to be relatively simple and specialized even though it requires substantial computational power [34]. A more universal and faster algorithm for minimizing the energy of the signal of the recognized image, allows to obtain approximate solutions, which in some cases turn out to be more effective [35]. The PSD (power spectral domain) algorithm is based on measuring the power spectral density of a signal consisting of a large number of sinusoids generated by independent sources, as observed in many noise-like signals [36]. The general disadvantages of RDs with neurointerfaces include the current impossibility to isolate weak activation signals of small muscles of the hand and forearm that control individual fingers.

Somatosensory RDs are based on the creation of a biofeedback loop between completed sets of movements and sensations received from the visual, auditory or tactile systems of the body [37]. Audio-visual biofeedback combined with virtual or augmented reality technologies, where patients performed exercises with somatosensory immersion effects, proved to be the most effective. Feedback sensors installed to capture movements record force, speed of movement, or position in space of the arm, hand, and/or fingers. Subsequent studies have proven that multisensory stimulation and mechanical feedback to aid in rehabilitation training significantly shorten the rehabilitation process and have long-lasting effects [38].

An effective means of restoring mobility is BCI-FES, in which stimulating pulses induce muscle activity in parallel with forced movements of the entire limb or some part of it. Thus, through reciprocal relations in the motor centers of the cortex, a stable connection between the external stimulus and the corresponding movement is formed. The effectiveness of the method has been shown to restore mobility of both lower [39, 40], and upper limbs regardless of age and gender [41, 42]. At the same time, the greatest effect was demonstrated in the acute phase of stroke. Being slightly inferior in efficiency to somatosensory RDs, rehabilitation simulators of this type can be simpler, cheaper and more compact due to their narrow specialization aimed at training a limited number of movements.

Devices for restoration of lower limb function

Many authors have noted a significant reduction in neurorehabilitation time in patients with lower limb paresis when using robotic exoskeletons, as well as a more effective recovery of their functioning [43–46]. Recently, flexible lower limb exoskeletons have begun to proliferate, effectively addressing some of the problems of traditional rigid exoskeletons by providing better simulation of the biomechanics of normal walking, increased stiffness at the joints, lighter weight and a relatively compact control system [43].

According to the findings, the attention of lower limb exoskeleton developers over the past decades has focused on three main areas: materials, manufacturing technology and controls [44]. No fundamental improvements have been made to the mechanical part of the design. Biologically neutral lightweight titanium-based alloys and carbon fiber composite plastics have expectedly come to the fore. This makes it possible to significantly simplify the production technology, replacing stamping under the press by modeling the product in a lightweight mold with heating and subsequent solidifying during polymerization of binding resins. Thus, the manufacturing of the basis for the mechanical part of exoskeletons became feasible to small companies. Also, it became possible to customize exoskeleton parts during the production stage. Control of exoskeleton mechanics is developing rapidly, power consumption becoming much lower and elements are becoming more compact — all this due to the emergence on the market of microcontrollers comparable in performance to desktop computers of the early 2000s, as well as miniaturized stepper motors with high torque.

The introduction of BOS to enhance exoskeleton control capabilities appears to be a positive development. One direction is the development of adaptive control based on motion intention recognition using acceleration sensors and percutaneous EMG sensors [45]. In this case, as the authors rightly point out, the main obstacles become the multiplicity of inconsistent scales and assessments of motor activity in post-stroke patients; this makes it difficult to objectively assess the effectiveness of interventions, the lack of adequate mathematical models linking EMG activity of motor nerves with the corresponding leg movement, especially when walking up and down the stairs, as well as the very nature of EMG signals with impaired muscle coordination after stroke, which requires the use of multilayer neural network models for their recognition. Addressing these challenges will allow for partial automation of the rehabilitation process, primarily in terms of modifying the exoskeleton's effect on gait as progress is made in motor skill recovery. The authors rightly note that the introduction of exoskeletons with adaptive control will not only reduce the burden on the rehabilitation physician by taking over the solution of routine tasks, but will also give a significant economic effect due to the increase in the number of patients per one physician.

At the same time, even the use of simplified robotic actuators that implement the motion of only the hip and knee joints during training already has a positive effect on the restoration of walking biomechanics. When analyzing the results of the effect of such a scheme on the recovery of motor functions, we found a general improvement in motor movements, a decrease in extensor muscle tone and an increase in the duration of the support phase in the step cycle; at the same time, the step cycle itself was reduced from five parts to three. The authors concluded that robotic training with active actuators for the hip and knee joints indirectly promotes changes in kinematic parameters in the ankle joint by bringing pattern parameters closer to some average movement pattern [46].

CONCLUSION

Analyzing the works describing the effect of RDs on functional recovery of limbs of post-stroke patients, one cannot but agree with the position stated in one of the works: most sources describe only ideas, at best preliminary design and testing of prototypes, rather than evaluation of devices already in production or ready for mass production [47]. In addition, despite the social significance and importance of the introduction of medical RDs, so far the bulk of proposals in the domestic market is represented by foreign inventions. It should be noted that their high cost and complexity of service maintenance amid sanctions imposed on Russia require a speedy solution of the problems of development and serial production of domestic devices of similar purpose.

The main conclusion of the presented review is that in order to maintain the continuity of the rehabilitation process and really improve the quality of life of patients, it is necessary to develop not only highly effective robotic complexes available for large clinics and rehabilitation centers, but also relatively simple, inexpensive and readily available RDs for home use. This will make the rehabilitation process truly continuous. An example of this could be relatively simple and inexpensive specialized BCI-FES-type RDs for post-stroke patients, the fabrication and sale of which, in our opinion, would not require large investments.

The use of medical service robots for patients with limited mobility at home is still difficult due to the high cost and the need to create an extensive network of service centers. However, the use of such voice-activated RDs in clinical settings is more than justified, as it can reduce the workload of nurses and automate such routine procedures as dispensing medications or monitoring patients' temperature and blood pressure in the morning.

If we analyze the state and immediate prospects for the development of rehabilitation RDs, we should expect their development in two complementary directions.

On the one hand, the emergence of an increasing number of models of universal stationary complexes, oriented for operation in clinical settings and large rehabilitation centers. Initially, each such complex should have a library of profiles of "standard" training sessions of the general plan with the possibility of expansion and supplementation with new combinations of exercises. A prerequisite for such systems should be the use of multi-loop biofeedback, providing individual adaptation to the capabilities of each patient with elements of self-learning. The individual patient profiles developed during the training sessions should be stored in a digital library and used for follow-up visits. At the same time, the distribution of such profiles is hardly advisable due to their high individuality.

On the other hand, to ensure the continuity of the rehabilitation process, we should expect to see the development of a market for relatively inexpensive specialized, possibly mobile, devices for home use. The cost of such RDs can be reduced in case of their functional specialization, use of simplified technologies and unification of the mechanical part and electromechanical equipment, as well as if we keep the set of exercise profiles at a reasonable minimum. But even in this case, the use of at least one biofeedback, allowing to organize adaptation and self-learning of the RDs, should be considered as a necessary condition. Providing these products with the means of objective control (surface EMG, accelerometry) of motor activity of the affected limbs together with the data transmission channel to a remote server will provide the most complete conditions for full rehabilitation measures.

In conclusion, the authors would like to note that the introduction of robotics in medicine is bound to increase the efficiency of diagnostic, therapeutic, and rehabilitative procedures and improve the long-term survival rate of patients. Widespread robotization of healthcare can create conditions for a fairly rapid transition of medicine to a completely different level of diagnosis and treatment, which was recently considered fantastic.

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