Gait rehabilitation in patients with spastic hemiparesis: new opportunities

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Gait disturbances are a common consequence of stroke. New technologies, such as exoskeletons (ESs), may aid recovery, but their effectiveness has not yet been proven enough.

Objective: *to evaluate the effectiveness of medical ESs and spasticity treatment for gait rehabilitation in patients with spastic hemiparesis due to acute stroke.*

Patients and methods. *The study included 42 patients with spasticity and gait disturbances who has had a stroke 1.5–4 years ago. Clinical assessment included: Tardieu scale (TS), Modified Ashworth scale (MAS), Rankin Scale, Visual Analogue Scale (VAS); 10 Meter Walk Test (10MWT) and Berg balance scale (BBT), Rivermead Mobility Index (RMI). The patients were divided into two representative groups (22 and 20 participants). Patients of the 1st group were training in the ES ExoAtlet for 10 days (original method and method of differentiation of efforts were used), the 2nd group was assigned to physical therapy for the same period. Then all patients received an injection of 300–400 U of botulinum neurotoxin (BNT) under ultrasound control into the spastic muscles of the lower limb. The examination was carried out at three control points (CPs): 1st day (1st), 12th day (2nd), and 33rd day (3rd).*

Results and discussion. *Comparison of both groups on the 2nd CT showed significantly (p<0.05) better results in the 1st group: 10MWT (0.43 and 0.47 m/s), BBT (42 and 44.5), muscles of the back of the thigh – hamstrings assessed by TS (132° and 137.5°). Gait speed apparently increased due to balance training, correction of postural-phobic disorders, stretching of spastic muscles, and suppression of the stretch reflex. At the 2nd CPs, injections of incobotulinum toxin (Xeomin®) were performed. On the 3rd CP, significantly (p<0.05) better results were obtained in the 1st group according to tests: 10MWT (0.49 and 0.56 m/s), BBT (46 and 49), TS (144° and 155°). Comparison of group differences between the 1st and 3rd CPs showed an absolute increase in test results (p<0.01): 10MWT (0.07 and 0.12 m/s), BBT (3.5 and 8.5), TS (14.5° and 22°). Improvement in gait indicators on the third CP demonstrates the potentiating effect of BONT injections and ES exercises.*

Conclusion. *ES ExoAtlet use is a promising technique for restoring gait: the combined use of an exoskeleton and BONT gives a pronounced potentiating effect.*

Keywords: *gait disturbances; spasticity; post-stroke rehabilitation; exorehabilitation; exoskeleton ExoAtlet; botulinum neurotoxin; incobotulinum toxin (Xeomin®).*

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Disability caused by brain injuries of various etiologies in the vast majority of cases accompanies movement disorders. According to various estimates, walking disorders affect from 460 thousand to 1.5 million out of the 12 million disabled people living in the Russian Federation [1]. Long-term neurological deficits mainly persist in the consequences of stroke and brain injury, which are most often characterized by the formation of spastic hemiparesis. At the same time, the rehabilitation approach underlying the International Classification of Functioning, Disability and Health (ICF, 2001) allows us to consider the problems of patients considering only their syndromes, regardless of the etiology of brain damage [2].

The features of the sanogenesis of central nervous system injuries associated with the processes of neuroplasticity lead to the formation of compensatory functional systems in the early recovery period, which further complicate restoring the movements to their former capability. One of them is a pathological stereotype of walking, the direct causes of which are muscle weakness and a violation of proprioception, leading to violations of the body schema and postural stability, the development of spasticity and postural anxiety-phobic disorder [3, 4].

The popular statement that «walking is trained only in walking» allows you to encourage the patient to practice using walkers, rollators and bars, which, unfortunately, does not allow you to re-form the correct image of walking with the correction of pathological stereotypes and syndromes [4–7]. Physical therapy specialists do not have the physical ability to simultaneously control the position of the pelvis, back, hip, lower leg and foot to restore the physiological pattern of walking, so physical therapy classes often restore the ability to move, but through the formation and consolidation of pathological stereotypes – as the only possible option at this stage of sanogenesis and rehabilitation. Currently, there is a limited number of methods that can create a permanent correction system that functions directly during walking and has a neuromodulating effect – this is the correction of muscle tone in the treatment of spasticity, taping and the use of functional electrical stimulation.

Treatment of spasticity with botulinum neurotoxin (BoNT) is currently the most obvious and accessible method, which has become a full-fledged medical technology over the past 3–4 years. It includes original methods: manual muscle spasticity testing, comprehensive assessment of spasticity and paresis on the Tardieu scale (TS), targeted administration of BoNT using ultrasound (US) and electromyographic navigation [8–10]. At the same time, botulinum therapy, pushing the framework of the «rehabilitation window», opens up opportunities for further rehabilitation, but cannot replace it [11].

The duration of adaptation, the physical and financial costs of patient management, the lack of staff and the limitations of the time of hospitalization determine the growing need for the development of new effective means and methods of rehabilitation [12]. One of these opportunities is the development and creation of robotic systems. In the last decade, locomotor assisting robots (exoskeletons – ES) have been increasingly used to restore walking, based on the method of external reconstruction of walking with extensive possibilities for modeling patient movements in real time [13–18]. Currently, the practice of using two types of ES designed to restore the function of the lower extremities both stationary and mobile is being developed in neurorehabilitation.

The most well-known among stationary systems is Lokomat (Hocoma AG, Switzerland). Walking in this ES is performed on a moving surface with fixed lower limbs in accordance with the physiological movements of the hip, knee and ankle joints, with the unloading of body weight and limited or complete absence of movement of the center of body mass. This does not allow complex coordinated activity of the muscles of the trunk, pelvic girdle and extremities, which limits the restoration of their interaction, does not sufficiently affect proprioception, and this, in turn, complicates the restoration of balance, muscle control, balance and body schema. The patient is completely dependent on the exoconstruction during the training process, which does not leave him the opportunity to overcome the difficulties of walking, restore self-confidence and increase motivation. In the stationary system, there are no visual and spatial changes while walking, which limits the semantic significance of training, which is especially important for rehabilitation, i.e. there is no basic biological meaning of walking «to reach the goal».

The mobile ES is fixed on the patient, equipped with its own processor, which processes the signals from the sensors and generates control signals to the drives of the ES. In contrast to stationary systems, mobile ES has fundamental design and user advantages [19]. One example of such devices is the original ExoAtlet ES of domestic production (ExoAtlet LLC, Russia), which is currently being introduced into rehabilitation practice in the Russian Federation and is intended for social readaptation and medical rehabilitation of patients with walking disorders [16, 17, 20, 21].

The aim of the study was to evaluate the effectiveness of using medical exoskeletons and the treatment of spasticity to restore walking for patients with the consequences of acute brain damage in the form of spastic hemiparesis.

The patients and the methods used. The effect of the new rehabilitation equipment on the recovery of walking for patients with hemiparesis and its combined use with the treatment of spasticity with BoNT drugs was studied. We used: mobile type ES of domestic production (ExoAtlet); therapeutic exercises to restore walking (exercise therapy); BoNT (incobotulotoxin – Xeomin ®).

The inclusion and exclusion criteria were determined in accordance with the study objectives and the ExoAtlet ES instructions. Also, at the stage of selecting patients, the results of clinical trials and the accumulated experience with ExoAtlet equipment, reflected in scientific and methodological publications, were taken into account [13–15, 22–25]. The reason for inclusion in the study was the presence of the consequences of stroke with the development of hemiparesis and impaired walking. The exclusion criteria were: the presence of joint contractures; the difference in the length of the legs >2 cm; intolerance or contraindications to physical exertion, including verticalization; severe osteoporosis; <24 points on the Short Mental Status Assessment Scale; paresis in the leg <2 points on the five-point muscle strength assessment scale of the Medical Research Council (MRCS); paresis in the arm <3 points on the MRCS; spasticity in the arm >2 points on the Modified Ashworth Scale (MAS).

The study included 42 patients [35 men (83%) and 7 women (17%)] at the age of 47 to 75 years (average age – 61.2±8.6 years), who had a stroke from 1.5 years to 4 years ago (average period after stroke – 2.8±1.1 years) and had spastic hemiparesis and walking disorders.

The study was an open controlled study with the selection of the main (n=22) and control (n=20) groups by simple randomization and direct analysis. Patients of the main group received classes in the ES, the control group-classes in therapeutic gymnastics with walking training (physical therapy). At the end of the 10-day training course, patients of both groups were treated for spasticity with BoNT injection.

The examination was carried out according to three Checkpoint studies (ChpS): the 1st ChpS (day 1) – initial examination and the beginning of the course of treatment and rehabilitation; the 2nd ChpS (12±2 days) – evaluation of the effectiveness of the 10-day course of training (the main group – in ExoAtlet, the control group-physical therapy) and the introduction of 300 to 400 units of incobotulotoxin under ultrasound navigation into the spastic muscles of the leg (the dosage was determined individually after a manual muscle test); 3rd ChpS scan (33±2 days) – final assessments of the complex application of the rehabilitation method (ES or physical therapy) and botulinum therapy and evaluation of the effectiveness of the treatment of spasticity (23±2 days after the introduction of BoNT).

To assess the patient's condition and the effectiveness of rehabilitation measures on ChpS, the following scales were used: MRCS, MAS, TS; 10-Meter Walk Test (10MWT) and the Rivermead mobility index (RMI) – to assess walking and mobility; Berg Balance Scale (BBS) – to assess balance and balance; Modified Rankin scale (mRS) – to assess activity and participation [26–33]. A visual analog scale (VAS) was used to assess the patient's satisfaction with the treatment results.

It should be noted that the design of the study did not allow the physical therapy specialists to take advantage of the effect of the introduction of BoNT (BoNT was introduced only after the methods of physical influence – classes in ES or physical therapy). This construction of the study was necessary for the correct assessment of the effect of physical therapies on spasticity.

During the 10-day training course, in accordance with the ExoAtlet operating manual, training modes (step-by-step, continuous, by effort) and the following techniques were used: 1) training walking; 2) rhythmic continuous walking; 3) walking with tension in the mode of effort; 4) alternating walking. Taking into account the characteristics of patients (hemiparesis), the software «differentiation by effort» was used for the first time, taking into account the asymmetry of movement and strength of the limbs. This allowed us to choose a combination of modes, offer and test an original method for training patients with hemiparesis.

The introduction of BoNT on the 2nd ChpS was carried out within the framework of the developed technology for the treatment of spasticity, which includes diagnostics, treatment methodology and evaluation of its effectiveness [8, 9]. The data analysis included the assessment of MAS and TS only hamstrings, the muscles of the posterior surface of the thigh, responsible for shortening the step with an increase in tone in them and the most indicative for assessing the effect of ES on spasticity.

The hypothesis of study for the possible recovery of walking when using the ExoAtlet mobile ES was the following: conducting a two-week course (10 classes) for 1 hour a day in conditions of real movement on a flat surface with transferring the body center of gravity and a double step of the specified characteristics will re – induce static and statokinetic reflexes, through the mechanisms of intero-and proprioception, launch the mechanisms of restoring the image of the body schema and maintaining balance, destroy the pathological stereotype of walking and activate the «lumbar locomotor center» [34–37]. Mechanical action on muscle contractures and rhythmic long-term resistance to the stretch reflex (stretch reflex) will increase the threshold of triggering muscle spindles and intrafusal fibers, which will reduce the manifestations of spasticity and increase the step length of the paretic limb. The subsequent use of botulinum therapy will lead to a mutual potentiation of the effect by reducing the activity of small α-motor neurons by blocking the release of acetylcholine, which will create conditions for the consolidation and development of the rehabilitation effect.

The data was recorded in the individual registration card of the patient. The formation of an electronic database, statistical analysis and charting were carried out using the application software packages MS Office 2010 and Statistica for Windows 8.0 (StatSoft Inc., USA). The following methods were used: determination of numerical characteristics of variables and indicators in the dynamics of changes in the values of variables, estimation of the normal distribution by the Shapiro–Wilk test, Wilcoxon T-test (Wilcoxon Matched Pairs Test), Mann–Whitney U–Test (Mann–Whitney U-Test), correlation coefficient r-Spearman.

The study protocol was approved by the local ethics committee of the Military Medical Academy. The subjects were informed about the objectives of the study and signed an informed consent.

The results. Patients in the main and control groups were similar in terms of gender, age, disease duration and baseline values of the estimated parameters ($p<0.05$). As part of the confirmation of the working hypothesis, the following areas of analysis of the obtained data were formed:

1) evaluation of the effectiveness of the use of medical ES in the main group of patients in comparison with the control group (Table. 1);

2) evaluation of the combined effect of ES and botulinum therapy (Tables 2, 3);

3) assessment of the overall dynamics of the recovery process in the comparison groups (Table 4).

Table 1. Indicators of muscle tone, muscle strength, gait function and functional independence before (1st ChpS) and after (2nd ChpS) rehabilitation course in both groups, Me [25th; 75th percentile]

Assessment scales	Main group		Control group	
	1st ChpS (n=22)	2nd ChpS (n=22)	2nd ChpS (n=20)	2nd ChpS (n=20)
BBT, points	41,0 [37,0; 46,0]#	44,5 [39,0; 50,0]#	40,0 [36,5; 46,0]*	42,0 [37,5; 48,5]*
10MWT, м/s	0,4 [0,35; 0,46]#	0,47 [0,43; 0,53]#	0,39 [0,34; 0,46]*	0,43 [0,40; 0,50]*
MAS, points	2,5 [2,0; 3,0]#	2,0 [1,5; 2,0]#	2,0 [2,0; 3,0]	2,0 [2,0; 3,0]
TS, degrees	229,5 [226,0; 233,0]#	237,5 [234,0; 241,0]#	228,0 [224,5; 233,0]	232,0 [230,0; 239,5]
MRCS, points	3,5 [3,0; 4,0]	4,0 [3,0; 4,0]	3,5 [3,0; 4,0]	4,0 [3,0; 4,0]
RMI, points	11,0 [9,0; 12,0]#	12,0 [10,0; 12,0]#	11,0 [9,0; 13,0]*	11,5 [10,0; 13,0]*
mRS, points	3,0 [2,0; 4,0]	3,0 [2,0; 3,0]	3,0 [2,0; 3,0]	3,0 [2,0; 3,0]
VAS, points	1,0 [1,0; 1,0]#	4,0 [4,0; 6,0]#	1,0 [1,0; 1,0]*	3,0 [2,0; 3,5]*

Note. Pairwise comparison before and after rehabilitation in the control and main groups; * – $p<0.05$, # – $p<0.001$; the Wilcoxon T-test is 0.00 in all pairwise measurements.

As can be seen from Table 1, there are several blocks for assessing vital activity and the degree of influence of ES and exercise therapy on them:

– walking and balance (10MWT, BBT) [27, 33];
– spasticity and muscle contractures (MAS, TS) [9, 31];
– muscle strength indicators (MRCS) [32];
– general rehabilitation assessment (mRS, RMI) [28, 30];
– assessment of the patient's activities (VAS) [29].

The main areas for which significant improvements were noted were the indicators of balance, walking and spasticity. At the same time, if balance and walking had positive trends in both groups ($r=+0.65$) and were confirmed by a broader RMI score ($r=+0.77$), spasticity indicators were characterized by greater variability in response to the use of ES. This was especially noticeable for MAS, where indicators had minimal changes in the control group. The severity of spasticity was the main factor affecting balance and walking ($r=-0.82$ and $r=-0.51$, respectively). The use of hardware rehabilitation had a positive effect on the stretching of the muscles in the posterior thigh surface (hamstrings), which was demonstrated by a significant ($p<0.001$) dynamics by MAS in response to the use of ES. The absence of such an effect in the control group indicated that the usual course of physical therapy was not sufficient to affect the muscle contracture.

The TS score also allowed us to study the reaction of hamstrings in case of provoking the stretch reflex [9]. Changes in the scale indicators, obviously, demonstrated a return inhibition of the reflex and an increase in the threshold of irritation if provoked during classes in the apparatus. It was assumed that the use of BoNT on the 2nd ChpS would strengthen these trends.

The improvement of balance and balance had more stable and pronounced trends in the main group (Me=44.5; $p<0.001$) compared to the control group (Me=42.0; $p<0.05$).

In addition, there was a positive trend in the 10MWT and RMI tests, as well as in the VAS indicators, which directly corresponded to changes in the real capabilities of the patient and affected the assessment of the rehabilitation methods used (Me=4 and Me=3, respectively; $p<0.001$).

The low significance and dynamics of changes in mRS in both groups were due to the fact that the study solved only one of the rehabilitation problems – the restoration of walking, which did not affect other aspects of human activity included in the mRS assessment [30]. There were no significant differences in the severity of paresis according to MRCS [32]. The assessment of the dynamics of changes on the studied scales is presented in Table 2.

Table 2. Comparison of the absolute increases in the indices of the assessment scales on the 2nd ChpS and 3rd ChpS in both groups, Me [25th; 75th percentile]

Assessment scales	Δ indicators between 1st *and 2nd ChpS*		Δ indicators between 1st *and 3rd ChpS*	
	Main group (n=22)	Control group (n=20)	Main group (n=22)	Control group (n=20)
BBT, points	3,0 [3,0; 3,0]	2,0 [2,0; 3,0]*	8,5 [6,5; 10,0]	3,5 [3,0; 5,0]#
10MWT, м/s	0,06 [0,05; 0,07]	0,04 [0,03; 0,05]#	0,12 [0,12; 0,19]	0,07 [0,05; 0,14]#
MAS, points	0,5 [0,0; 1,0]	0,0 [0,0; 0,5]*	1,0 [1,0; 1,0]	0,5 [0,0; 0,1]#
TS, degrees	7,0 [6,0; 8,0]	4,0 [3,0; 5,0]#	22,0 [17,0; 26,0]	14,5 [11,0; 17,5]#
MRCS, points	0,0 [0,0; 0,0]	0,0 [0,0; 1,0]	1,0 [0,0; 1,0]	1,0 [0,0; 1,0]
RMI, points	1,0 [1,0; 2,0]	1,0 [0,0; 1,0]*	1,0 [1,0; 2,0]	1,0 [1,0; 2,0]*
mRS, points	0,0 [0,0; 0,0]	0,0 [0,0; 1,0]	0,0 [0,0; 0,0]	0,0 [0,0; 0,0]
ВАШ, points	3,0 [3,0; 5,0]	2,0 [1,0; 2,5]#	7,0 [6,0; 8,0]	4,0 [3,5; 5,0]#

Note. The significance of differences between the main and control groups on the 2nd and 3rd ChpS: * – $p<0.05$; # – $p<0.01$; the Wilcoxon T-test is 0.00 in all pairwise measurements.

Table 3. Comparison of rating scales results after injection of BoNT i n the 3rd ChpS and the initial data of the general group, Me [25th; 75th percentile]

Scales	Initial data of the base group (n=42)	Reference groups		Comparison of the groups studied	
		Main group (n=22)	Control group (n=20)	U-criteria of Mann-Whitney	P (the importance level)
BBT, points	40,0 [37,0; 46,0]	49,5 [40,5; 54,0]	46,0 [39,0; 51,0]	162,0	<0,05
10MWT, м/s	0,40 [0,35; 0,48]	0,56 [0,53; 0,60]	0,49 [0,44; 0,56]	124,5	<0,01
RMI, points	11,0 [9,0; 12,0]	12,5 [11,0; 14,0]	12.0 [11,0; 13,0]	187,0	0,1
MAS, points	2,5 [2,0; 3,0]	1,0 [1,0; 1,5]	1,5 [1,0; 2,0]	161,0	0,1
TS, degrees	228,5 [228,0; 233,0]	255,0 [250,0; 260,0]	244,0 [238,5; 249,5]	88,0	<0,001
MRCS, points	3,5 [3,0; 4,0]	4,0 [3,0; 4,0]	4,0 [3,0; 4,0]	201,0	0,82
mRS, points	3,0 [2,0; 4,0]	3,0 [2,0; 3,0}	3,0 [2,0; 3,0]	204,0	0,69
VAS, points	1,0 [1,0;1,0]	8,0 [7,0; 9,0]	5,0 [4,5; 6,0]	23,0	<0,001

Table 4. Comparative assessment of the dynamics (between 1st and 3rd ChpSs) of the recovery process in the study groups

Assessment scale	Average absolute increase		Absolute advance coefficient	Absolute advance %
	main group (n=22)	control group (n=20)		
BBT, points	3,091	2,500	1,236	23,6
10MWT, м/s	0,060	0,039	1,818	81,8
RMI, points	1,182	0,650	1,538	56,8
MAS, points	0,591	0,275	2,149	114,9
TS, degrees	6,773	4,100	1,652	65,2
VAS, points	3,682	2,400	2,534	153,4
Average	2,839	1,863	1,655	65,5

Analysis of the degree of positive dynamics of the evaluation scales on the 2nd ChpS (see Table. 2) confirms the trends noted in the intergroup analysis of indicators (see Table 1). The main areas that can be affected by walking in the apparatus, namely, a decrease in the severity of muscle contractures in hamstrings (by 0.5 vs 0.0; $p<0.05$), a decrease in the reflex muscle reactivity of hamstrings (by 7 vs 4; $p<0.001$) and balance training during movement (by 3 vs 2; $p<0.05$), were realized through a pronounced increase in 10MWT (by 0.06 vs 0.04; $p<0.001$). 0.001) and reflected in the increase in RMI (by 1 vs 0; $p<0.05$).

The analysis of changes on the *3rd ChpS* was the result in both groups, both for the treatment of spasticity with the introduction of BoNT, and for the rehabilitation methods used. All indicators on the *3rd ChpS*, with the exception of the MRCS and mRS scores, showed a pronounced prevalence of positive dynamics in the main group. The dynamics of the indicators of balance, walking, and spasticity in the main group with high significance ($p<0.01$ and $p<0.001$) showed almost twice the increase in the indicators of these scales in the control group and relative to the initial data: respectively, BBT-8.5 vs 3.5 and 3.0 points; MAS – 1.0 vs 0.5 and 0.5 points; TS-22.0° vs 14.5° and 7.0°. The main indicator demonstrating the achievement of the patient's rehabilitation goal which was the increase in speed and confidence in walking 10MWT, the increase of which also showed a twofold excess compared to the control group and the initial data (0.12 vs 0.06 and 0.07 m/s, respectively). This was also reflected in the VAS indicators, which demonstrated the patient's satisfaction with the treatment (7 vs 4 and 3 points, respectively; $p<0.001$).

To demonstrate the changes in the absolute values of the evaluation scales between the initial and final data of patients of both groups, an analysis of the effectiveness of BoNT administration was performed; its results are presented in Table. 3.The data of the general group (n=42) are presented as the initial indicators.

When analyzing the data presented in Table 3, the indicators of 10MWT (0.56 m/s) and TS of hamstrings (255°) deserve special attention. Normal indicators of a healthy person are a comfortable walking speed of 0.59 m / s and TS indicators for hamstrings of 260–270°.

The dynamics of the recovery process were evaluated by calculating the coefficients of absolute advance on the scales and its average value (see Table 4). The evaluation scales, that did not show significant differences in the dynamics, were not taken into account.

The analysis of the presented calculations showed the severity of changes per unit of time in the intergroup analysis (see Table 4). With this method, the integral severity of the effect of the use of ES on the six presented scales was 65.5%. At the same time, it should be taken into account that in this case it was impossible to take into account the potential effects of complex rehabilitation and ES.

Discussion. The results of pilot studies of the use of ExoAtlet ES for patients with injuries and diseases of the central nervous system revealed its effectiveness in a number of indicators [6, 38]. The main attention of research is focused on the study of the effectiveness of robotic systems in the rehabilitation for patients with paraparesis due to spinal cord injuries of various etiologies (autoimmune, traumatic, vascular) [5–7, 13, 14, 20, 22].

When dealing with asymmetric neurological deficits (hemiparesis), there is always a question of the adequacy of the efforts generated by robot-assisted systems. At the same time, the results of studies devoted to the restoration of movement for patients who have suffered brain damage, as a rule, do not have a sufficient number of observations and are ambiguous in the choice of assessment methods [12, 16, 21, 23, 24]. So, for example, in the work of E.V. Pismennaya et al. [39] a full assessment of biomechanics was also carried out after a course of training in ExoAtlet ES for patients with the consequences of ONMC. There was an improvement in all the main characteristics of the step and an increase in the speed of movement, while the study was performed on five patients, spasticity was not evaluated, and the question of the correctness of the use of clinical and rehabilitation scales remained unresolved.

Design by A. Picelli et al. [40] is based on the study of the effect of ES on the spasticity of the lower leg muscles that cause equinovarus deformity of the foot. The study was conducted against the background of already conducted treatment of BoNT spasticity. Both in the control group and in the main group, it was shown that training in ES did not affect the already achieved effects of BoNT, but improved the indicators of walking speed. D. Erbil et al. [41] used a similar work design, but the emphasis was on assessing balance and mobility indicators. We compared the groups of patients who underwent stroke, after treatment of BoNT spasticity, as well as those who received physical therapy and ES classes. Improved balance and walking and reduced spasticity were shown in both groups, with significant prevalence of balance and mobility indicators in the ES group. The design of both of these studies excludes the possibility of assessing the direct impact of ES on spasticity. The muscles selected for the analysis are not indicative, since the main obvious effect of ES has on the mechanics of movement in the knee and hip joints, which was clearly shown in their work on changing the biomechanics of walking by E. V. Pismennaya et al. [39]. The construction of our work, on the contrary, makes it possible to assess the isolated effect of ES on walking performance and spasticity, while the group of muscles of the posterior thigh surface was chosen as the study group. The subsequent use of BoNT gave consolidation of the effects and developed the trends identified during training in ES.

In general, the results of the study confirmed the formulated working hypothesis. The observed decrease in the severity of spasticity (demonstrated by the MAS and TS data) combined with the use of ExoAtlet and BoNT ES can be explained by mechanical stretching of muscle contractures and an increase in triggering the threshold of the stretch reflex. Traditionally, one of the important indicators of neurological deficits is the degree of paresis severity according to MRCS [32]. The lack of dynamics of this indicator is quite understandable, since the restoration of muscle strength is possible only through independent training and cannot be achieved by hardware techniques. The walking score (10MWT) and mobility score (RMI) are actually integral indicators which demonstrate the end result and the expansion of life opportunities for a particular patient. The positive dynamics of 10MWT was based on both an increase in the step length achieved by reducing spasticity and contracture, and an improvement in balance and related effects. A similar situation was with RMI. The less pronounced dynamics (compared to 10MWT) is quite understandable, since its calculation includes parameters that could not be trained with the help of ES classes (lifting objects from the floor, taking a bath, etc.) [28, 33]. Obviously, in this case, 10MWT was the most indicative test with high environmental friendliness in terms of assessing the recovery of walking and assessing the impact of the use of ES on the restoration of real life activity.

Special attention should be paid to the results that demonstrate an improvement in balance and correlate with an increase in walking speed. According to the literature, the use of stationary ES (such as Lokomat) does not demonstrate such results [16–18, 39, 42, 43]. These achievements, apparently, are connected with the capabilities of mobile ES, which include ExoAtlet, namely, with real movement in space with full weight transfer of the body and the work of the muscles of the back and pelvic girdle. The «effort differentiation» mode used for the first time allowed correcting the asymmetry of neurological deficits, improving the dynamics of recovery of walking speed and confidence in patients with the consequences of brain damage. The statistically significant improvement in balance and balance revealed by us in the course of the study against the background of ExoAtlet ES and BoNT injections, compared with the control group, is probably due to the compensation of several links in the pathogenesis of walking disorders:

– balance training in the process of real movement;
– activation of the intero-and proprioreceptor apparatus of joints and tendons in the process of real movement;
– a positive request to segmental systems for the formation of a balanced walk;
– psychoemotional training to overcome postural-phobic disorder;
– training of static and statokinetic reflexes.

The methods used and the results achieved characterize an increase in the ability to move (speed, stability), but cannot show changes in the quality of walking. To assess the quality of walking and its compliance with physiological biomechanics, it is necessary to conduct research in a full-fledged laboratory of walking and video analysis of movement (gate analysis).

Conclusion. Therefore, it should be noted that it looks promising to use ES in the complex rehabilitation of patients suffering from consequences of brain damage, which allows to increase the efficiency of restoring the speed and confidence of walking through the mechanisms of restoring balance, reducing the severity of muscle contractures and destroying the pathological stereotype of walking in the conditions of real movement model implementation. The combined use of ES with incobotulotoxin (Xeomin) showed a mutual potentiation of the effects, and BoNT in a total dosage of 300 to 400 Units, in turn, demonstrated the effectiveness and safety in the treatment of spasticity of the muscles of the lower extremities. The developed scheme of complex application of exorehabilitation and botulinum therapy for restoring walking has shown its effectiveness and is appropriate for use for patients with the consequences of brain damage, accompanied by hemiparesis and movement disorders. Its use allows us to expect an increase in the walking speed from 0.4 to 0.56 m/s, bringing these characteristics of the patient closer to the indicators of the normal speed of comfortable walking. The use of ES cannot reduce the specific period of rehabilitation and the period of hospitalization, but, having a higher efficiency and the possibility of achieving a positive result, it allows to count on reducing the overall duration of rehabilitation and the number of hospitalizations.

To study the mechanisms of the restorative effects of ES, to clarify the degree of influence of the proposed methods in patients with different etiologies of brain damage, further studies are required.

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