Effects of Single Noninvasive Spinal Cord Stimulation in Patients with Post-Stroke Motor Disorders

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Abstract—Post-stroke gait disorders are often characterized by abnormal kinematic and kinetic patterns, deviations in spatiotemporal features, altered muscle activation, and increased power requirements while walking. The investigation is aimed at determining the possibility of using transcutaneous spinal cord stimulation (TSCS) to influence the kinematics of walking in stroke patients with hemiparesis in the early and late recovery periods (1−12 months) after stroke. Continuous and phasic stimulation was used during motor training on a treadmill. For stimulation of spinal neuroprosthesis including a multichannel stimulator for TSCS (Cosyma, Russia) with sensors for determining the phases of walking was used. The biomechanical study of the walking function was carried out with the Steadys system (Neurosoft, Russia). The study involved 15 patients (ages from 33 to 79 years). We analyzed the parameters of stepping movements when walking on the floor without stimulation before and after training on a treadmill using TSCS. A comparative analysis of the kinematics of walking before and after training showed an increase in walking speed, the length of the step cycle, and an increase in the range of movements in the hip, knee, and ankle joints, in 40% patients the height of the paretic foot lift increased by 1−2 cm. The results show that the training with the use of TSCS can be considered as a rehabilitation method for correcting walking after a stroke.

Keywords: stroke, hemiparesis, spinal cord, stimulation, kinematics of walking
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INTRODUCTION

The frequency of ischemic stroke in Russia is more than 500 000 new cases annually. The severity of neurological disorders caused by it is a serious medical and social problem and requires searching for new methods of neurorehabilitation of patients. Movement disorders of varying degrees and nature are the most common symptom of brain damage, both in the acute and chronic stages of the disease and are the leading factor in the disability of such patients. Post-stroke gait disorders are often characterized by abnormal kinematic and kinetic patterns, abnormalities in intra- and interlimb coordination, altered muscle activation, and increased energy expenditure during walking [1].

For the rehabilitation of motor functions after a stroke, along with the use of pharmaceuticals, physio-therapeutic methods of treatment are actively used, such as thermal effects on spastic muscles, magneto-therapy, electrical stimulation of certain muscle groups, and transcranial magnetic stimulation. In recent years, special attention has been paid to search-ing for new methods of rehabilitation treatment that would reduce the severity of neurological disorders and improve the quality of life of patients. One such method is transcutaneous spinal cord stimulation (TSCS). Due to the use of a specially shaped electrical impulse, such stimulation is able to painlessly affect the structures of the spinal cord using noninvasive stimulation. The main advantage of this technique is the possibility of implementing stimulating effects with skin electrodes, in contrast to epidural electrical stimulation, which is performed using electrodes applied to the dura mater of the spinal cord, which requires surgical intervention. In several clinics, TSCS is used as an independent or auxiliary therapy for a wide variety of diseases and in most cases, it is well combined with other methods of physiotherapy and medications. It has been shown that TSCS allows one to initiate involuntary stepping movements in healthy subjects and in spinal patients [2−6]. After the use of electrical stimulation of the spinal cord in combina-tion with locomotor training for 7 months there was a restoration of body weight support and the appearance

of voluntary leg movements in patients with a complete loss of motor functions due to trauma to the cervical spinal cord [7]. TSCS caused normalization of motor functions and coordination of movements in children with cerebral palsy [8]. Of particular interest is the possibility of targeted activation of certain neural structures of the spinal cord with the help of TSCS, taking into account the phases of the step cycle [9, 10].

Hemiparesis, as a weakening of muscle tone, diagnosed in patients who have suffered a hemispheric cerebral stroke, occurs due to a violation of impulses from the motor cortex to the spinal cord, which leads to delayed initiation and termination of muscle action and prevents sufficiently fast movements. The mechanism of action of TSCS is due to the activation of afferent fibers of the dorsal roots [11, 12], which affect neural networks and motor pools. It is assumed that such stimulation in combination with locomotor training promotes synaptic reorganization in the neural networks of the spinal cord and enhances motor responses due to the mechanisms of neuroplasticity of the central nervous system and remodeling of cerebral and spinal neuronal ensembles. The start of these processes can be activated by direct stimulation of the affected centers of the primary motor cortex or neural networks of the spinal cord [13].

Objective—To investigate the effect of single sessions of TSCS on walking in patients with hemiparesis as a result of cerebral stroke.

MATERIALS AND METHODS

The study included 15 patients (4 women and 11 men) with hemiparesis resulting from ischemic hemispheric stroke. The mean age of the patients was 59 ± 14.3 (from 33 to 79) years, the time after acute cerebrovascular accident was 5 ± 4.0 (from 1 to 12) months, 9 patients had damage to the right hemisphere of the brain, 6, to the left. All patients were diagnosed with various concomitant diseases: 2 patients had hypertension (HT) of the 2nd degree, 12 had HT of the 3rd degree, and 2 had type 2 diabetes mellitus. Also, among the diseases, chronic forms of cystitis, hepatitis, and pancreatitis were detected in isolated cases. All patients had muscle strength of 4 points of the paretic lower limb according to the scale of the Medical Research Council (MRC).

Study design. The study is experimental, controlled, and non-randomized.

Inclusion criteria: Patients with hemiparesis in the early to late recovery periods (1−12 months), initial emerging ischemic hemispheric stroke; age up to 80 years old; functional readiness for verticalization; adequate response for a test with orthostasis; the ability to hold a vertical stand for 1 min; walking without foreign auxiliary items; clear consciousness with a level of wakefulness sufficient to assimilate and follow instructions during research and training; the absence

of cognitive impairments that prevent the understanding of the tasks set by the researcher; lack of sensorimotor aphasia; the presence of tone in the muscles of the lower limb above 2 points according to the modified Ashfort spasticity scale; absence of decompensated somatic pathology, ischemic ECG changes, and heart failure (grade II and above according to Killip); the absence of diseases of the central and peripheral nervous system, in addition to a stroke, accompanied by a neurological deficit (consequences of injuries, tumors, polyneuropathy, etc.); and absence of orthopedic pathology (articular deformities and contractures, pronounced pain syndrome, limb amputations, etc.).

Exclusion criteria: Inadequate response of the cardiovascular system during training; fear of walking on a treadmill; refusal of the patient to carry out therapeutic measures; and negative dynamics of neurological and/or somatic status.

Terms of conduct. The study was carried out in the period from 2020 to 2021, in the laboratory of clinical biomechanics of the Federal Research Clinical Center, Federal Medical-Biological Agency of Russia (FMBA) (Moscow).

Study of the biomechanics of walking. A biomechanical study of the walking function was performed using the Steadys system (Neurosoft, Russia). To do this, Neurosens inertial sensors were fixed on the sacrum, the outer surface of the middle third of the thigh, the outer ankle, and the instep of the foot on both sides (Fig. 1). A total of seven sensors were used. Each sensor contains two registration channels using electromyography (EMG). The sensors on the thigh were used to record the EMG signal from the rectus femoris muscle and the total activity of the biceps and semitendinosus muscles, and the sensors on the lower leg were used to record the EMG of the anterior tibial muscle and the total activity of the external and internal heads of the triceps muscle of the leg. Medico disposable electrodes installed using SENIAN recommendations [14] were used for registration.

The position of the patient standing upright with straightened hips and knees was taken as neutral (calibration position). Next, biomechanical parameters were recorded during walking. The patient walked at his own pace for a distance of 10 m, each time turning around at the end and continuing to move again. Steps with unsteady parameters (acceleration and deceleration) were automatically discarded by the software. On average, registration was completed when 30 step cycles or more were reached. The software, based on the verified algorithm for determining step cycles (SCs), determined the SC for each leg and, in accordance with them, calculated other parameters of the SC.

The biomechanical parameters of walking were analyzed. Time parameters: the periods of the stance phase and the swing phase of the limb were measured

Fig. 1. Placement of recording electrodes, neuroprosthesis, and Stedys sensors on a patient while walking on a treadmill.

in % of the SC: support period (SP), single support period (SSP), total double support period (TDSP), the parameter of the beginning of the SC of the other leg (the beginning of the second double support (SDS)), and step frequency (SF). Spatial Parameters: foot height (FH), walking speed (WS), and step cycle length (SCL). Kinematic parameters were recorded for the hip, knee, and ankle joints in the sagittal plane (flexion-extension) with the construction of a goniogram for the SC with subsequent automatic determination of the following parameters: for the hip joint (HJ), the total amplitude of HJ flexion-extension (HJF), phase of HJ maximum flexion (HJMF), and phase of HJ maximum extension (HJME). For the knee joint (KJ), the total amplitude of KJ flexion-extension (KJF), the phase of KJ maximum extension (KJME), and the phase of KJ maximum flexion (KJMF). For the ankle joint (AJ), we analyzed the AJ flexion-extension amplitude (AJF) developed during the SC.

The profile of muscle bioelectrical activity (EMG) was analyzed in the SC. For statistical comparison, we took the maximum developed amplitude in μV for the anterior tibialis (*TA*), gastrocnemius lateralis (*GL*),

Table 1. Set sequence

No.	Set
1	Walking on the floor without stimulation (control)
2	Walking on a treadmill without stimulation
3	Walking on a treadmill, continuous transcutaneous electrical spinal cord stimulation (TSCS) at the level of T11−T12 vertebrae, frequency 30 Hz
4	Walking on a treadmill, stimulation of the roots in the region of the T12 vertebrae during the stance phase of the healthy leg (activation of the flexors of the paretic leg), frequency 40 Hz
5	Walking on a treadmill, stimulation of the roots in the region of the vertebrae L1 during the swing phase of the healthy leg (activation of the extensors of the paretic leg), frequency 20 Hz
6	Walking on a treadmill, combination of stimulation 4 and 5
7	Walking on a treadmill, combination of stimulation 3 and 6
8	Walking on the floor without stimulation (control)

quadriceps femoris (*QF*), and biceps femoris (*BF*) muscles.

All parameters were determined while walking on the floor without external influence before and after TSCS during training on a treadmill (Fig. 1).

Technique of TSCS. A spinal neuroprosthesis was used for TSCS (Cosyma, Russia), including a six-channel stimulator and a detection system, sensors to determine the phases of walking, namely, the transfer or support of the leg on which the sensor is installed. The basis of the sensors is an electronic gyroscope combined with an accelerometer. The algorithm for processing gyroscope and accelerometer signals and detecting walking phases is described in [15]. Such a neuroprosthesis provides simultaneous or sequential continuous TSCS at the level of the T11−T12 vertebrae with the stimulating electrode located along the midline of the spinal cord and stimulation of the spinal cord roots at the level of the T11 and L1 vertebrae from the affected side when the electrodes are placed 1−3 cm laterally from the midline.

The stimulation frequency at the level of T11−T12 vertebrae was 30 Hz, at the level of the roots of the spinal cord in the region of the T12 vertebra, 40 Hz, and in the region of the roots below the L2 vertebra, 20 Hz. The pulse shape is bipolar, filled with a frequency of 5 kHz. The stimulation intensity was selected individually, for each stimulation level separately, immediately after the start of walking on the treadmill, increasing the stimulation intensity by 1 mA. The intensity of the current should have caused parasthesia or be 5−10% less than the intensity that causes parasthesia, but when performing stepping movements, TSCS should not have caused unpleasant or painful sensations. When walking on a treadmill, several series of TSCS were sequentially performed, providing targeted stimulation of the neural structures of the motor system of the spinal cord. The study with each patient included a certain sequence of sets (Table 1). Each of the TSCS series lasted 1−2 min, with a break of 2−

5 min. Patients were instructed to walk at a pace that was comfortable for them. The speed of the treadmill belt was selected individually; the average belt speed was 0.3 ± 0.02 m/s. We compared the parameters of walking on a flat surface (on the floor) without stimulation before and after stimulation. Asymmetry was calculated as the difference between the parameter values in the healthy and paretic leg for the same condition.

Data analysis. Statistical analysis of variations with the calculation of the arithmetic mean ± standard error, was carried out in Microsoft Excel. The significance of differences in indicators was determined using paired *t*-Student's criterion, the differences were considered significant at $p < 0.05$.

RESULTS

Walking speed is the most common parameter characterizing gait. In persons with post-stroke gait disturbance, the speed varies from about 0.18 to 1.03 m/s, while in healthy adults it averages 1.4 m/s [16]. In these studies, the walking speed of patients on a flat surface without TSCS before a rehabilitation session varied in the range of 0.28−0.89 m/s, averaging 0.57 ± 0.05 m/s. After the rehabilitation session, the rate increased in 10 out of 15 patients (Fig. 2a), and varied in the range of 0.29−0.91 m/s, on average, 0.6 ± 0.05 m/s.

After training, when walking on the floor, the length of the step cycle increased in 10 patients (Fig. 2b), from 80.8 to 84.5 cm on average (Table 2). The increase in walking speed is probably due to an increase in the length of the SC, the correlation coefficient is 0.90 before and 0.87 after the application of TSCS, and changes in SF and WS correlated with each other, the coefficient is 0.76. The SF changed more differently, an increase in SCL was observed in eight patients, a decrease in four, and in three patients the SCL did not change. The correlation between SCL
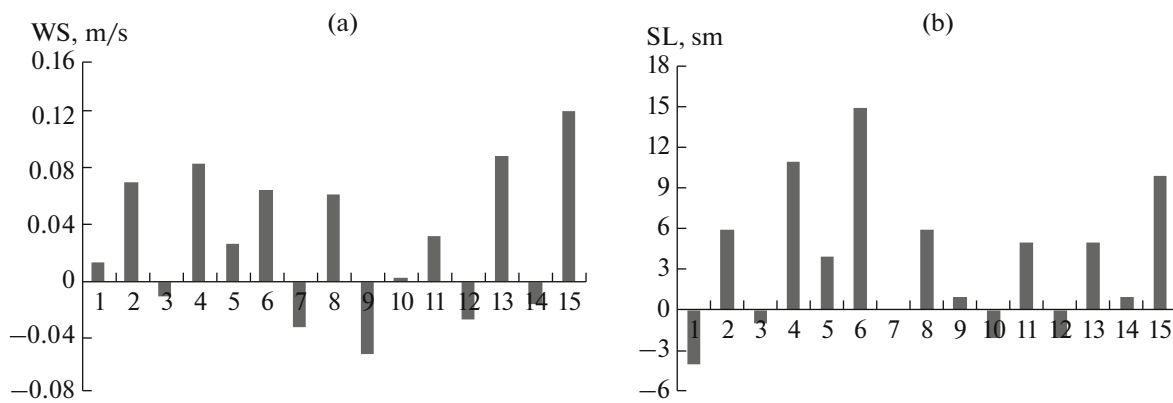
Fig. 2. Changes in walking speed (a) and the length of the step cycle (b) after training on a treadmill using transcutaneous electrical spinal cord stimulation (TSCS). The abscissa shows the patient number, n = 15. On the *y*-axis, the difference between the parameter value after training and before training.
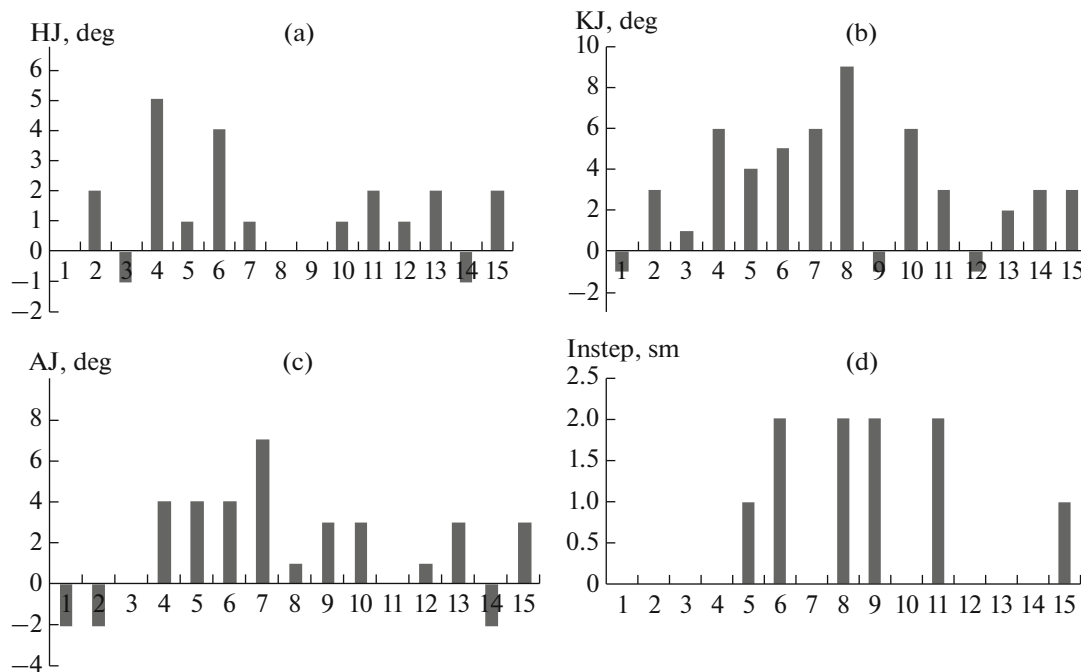

Fig. 3. Changes in the amplitude of the joint angles and the foot lift on the paretic side after training on a treadmill with the use of transcutaneous electrical spinal cord stimulation (TSCS). (a) Hip joint (b) knee-joint, (c) ankle joint, (d) SH. For other designations, see Fig. 2.

and SF was 0.56 before and 0.62 after training, with a 0.7 correlation between changes in SCL and SF.

It can be seen (Fig. 3) that in a significant number of patients (9−12) there was an increase in the amplitude of the articular angles when walking on the floor after training on a treadmill using TSCS. Thus, the angle in the hip joint on the paretic side increased on average in the group from 23.6° ± 1.94° to 24.9° ± 2.02°, in the knee joint from 42.2° ± 3.56° to 45.4° ± 3.2°, in the ankle joint, from 24.1° ± 2.03° to 25.9° ± 1.86° (Table 2). On the healthy side, a significant increase in the angle was observed only in the AJ. An increase in the range of motion did not always lead to an increase in the foot lift, which was observed in six patients, but a decrease in the foot lift was not observed in any patient. In addition, the time of maximum extension of the hip joint (HJME) within the duration of the step cycle also slightly increased (Table 2). When walking on the floor, the parameters characterizing the phases of walking, SP, SSP, TDSP, and SDS did not change significantly, this concerns the duration of the phases themselves and the difference between the values of the paretic and healthy legs.

Table 2. Biomechanical parameters of walking before and after transcutaneous electrical spinal cord stimulation (TSCS)

Group	Parameter	Before	After
Temporary	SP, %	66.1 ± 0.93 71.8 ± 1.53	66.4 ± 1.13 71.9 ± 1.60
	SP asymmetry, %	6.43 ± 1.64	6.51 ± 1.64
	SSP, %	28.40 ± 1.42 33.80 ± 1.06	28.13 ± 1.46 33.67 ± 1.14
	SSP asymmetry, %	6.33 ± 1.68	6.41 ± 1.64
	TDSP, %	37.87 ± 1.65 38.03 ± 0.11	38.46 ± 1.89 38.25 ± 1.84
	TDSP asymmetry, %	0.4 ± 1.52	0.30 ± 0.06
	SDS, %	45.70 ± 1.63 53.30 ± 2.07	45.30 ± 1.50 54.40 ± 1.46
	Asymmetry of SDS, %	9.44 ± 2.91	9.56 ± 2.81
	SC, steps/min	42.1 ± 0.88	42.5 ± 1.98
Spatial	SCL, cm	80.90 ± 5.85	84.50 ± 5.99*
	WS, m/s	0.57 ± 0.05	0.60 ± 0.05*
	FH, cm	10.40 ± 0.71 12.47 ± 0.81	11.07 ± 0.78* 12.47 ± 0.77
Kinematic	HJF, °	23.60 ± 1.94 30.93 ± 1.75	24.87 ± 2.02* 31.20 ± 1.65
	HJME, %	51.67 ± 0.01 58.67 ± 1.69	52.60 ± 0.19* 56.80 ± 1.79*
	HJMF, %	89.67 ± 1.55 90.62 ± 1.10	88.50 ± 1.54 89.31 ± 0.78
	KJF, °	42.20 ± 3.55 52.40 ± 2.02	45.40 ± 3.20* 54.13 ± 2.03
	KJME, %	65.21 ± 8.47 71.27 ± 8.49	68.21 ± 8.49 71.87 ± 8.19
	KJMF, %	72.14 ± 0.97 77.60 ± 1.96	72.71 ± 0.88 77.07 ± 2.03
	AJF, °	24.13 ± 2.03 25.13 ± 1.48	25.93 ± 1.85* 26.53 ± 1.76*

The upper row of numbers in the columns is a paretic leg, the lower row is a healthy one. *—significant differences with the value before stimulation. For an explanation of the abbreviations, see the Methodology section.

Table 3. Maximum envelope amplitude of electromyography (EMG) (μuV)

Muscle	*BF*		*QF*		*TA*		*GL*	
Leg	H*	P	H*	P	H*	P	H	P
Before	82 ± 46.6	64 ± 35.3	55 ± 17.9	47 ± 30.4	130 ± 44.3	95 ± 54.7	95 ± 55.7	71 ± 42.0
After	59 ± 28.3	63 ± 55.0	44 ± 15.0	46 ± 30.4	122 ± 45.5	96 ± 69.4	85 ± 61.3	75 ± 59.2

BF—biceps femoris, *QF*—quadriceps femoris, *TA*—tibialis anterior, *GL*—gastrocnemius lateralis muscles. H—healthy leg. P—paretic leg. *—significant differences between the values before and after training with the use of transcutaneous electrical spinal cord stimulation (TCSC), $p < 0.05$.

The EMG amplitudes significantly decreased in three muscles of the healthy limb, while the changes were insignificant on the affected side (Table 3). This effect was observed in 75% of cases.

DISCUSSION

In the present study, non-invasive electrical spinal cord stimulation was used for the first time to regulate stepping movements in post-stroke patients. The results of the study show that after a single training session on a treadmill with the use of TSCS, walking parameters change. First of all, it concerns an increase in the speed of walking on the floor without stimulation. This parameter correlates with the length of the stride cycle, both before and after stimulation. The correlation between SCL and SF was less, but the correlation between changes in SCL and SF (0.7) and between changes in SL and SF (0.76) suggests that the increase in SC was due to both SCL and SF. The change in SCL, in turn, is associated with an increase in the range of motion in the joints, mainly in the hip joint. In [17], in identifying the most important clinical variables that determine gait speed in individuals with stroke, it was shown that lower limb motor function, balance, and hip flexion strength were significantly associated with comfortable and maximum gait speed with a correlation coefficient from 0.5 to 0.88. According to our data the correlation coefficient between the increase in the angle in the hip joint and the increase in the SF was quite high and amounted to 0.71 for a healthy leg and 0.77 for a paretic leg. In addition, after training, the asymmetry or difference between the phases of maximum hip extension of the healthy and paretic legs decreased, but this was not found for other joints (Table 2). Previously, domestic researchers [18] found that with an increase in step length, the interlink angles in the hip, knee, and ankle joints increase, which is especially characteristic of extension amplitudes in the ankle joint. According to our data, the relationship between changes in SF and changes in the range of motion in the KJ and HJ was less pronounced, the correlation did not exceed 0.4, however, a significant increase in the range of motion in the AJ for the paretic leg and in the HJ for both limbs was found. Another important spatiotemporal parameter of walking is the FH. The foot lift depends on the movement in different joints, it is known that even in the case of normal walking, the nature of the gait varies greatly from person to person. Some people put the most effort in the ankle joint while walking, while others put more stress on the knee joint [19]. The amplitude of the angle in the SC on the paretic side increased in 12 patients, while on the healthy side, in 9 patients, in the HJ, in 10 patients, both on the paretic and healthy sides. More pronounced changes in amplitude in all joints led to an increase in SH of the paretic leg by 1−2 cm in 6 patients. SH increase was shown previously in healthy subjects with TSCS, while

the increase in the amplitude of the angle in the HJ was maximum [20]. According to our data, the increase in the instep is related to the contribution of HJF and SC. This is confirmed by the high correlation between the SH values and the amplitude of the angle in the SC. It was the largest of all joints and was 0.8 before training and 0.86 after training, the correlation with HJ and HJ slightly decreased after training and was 0.49 for HJ and 0.58 for HJ. The height of the lift of the healthy leg varied in different patients in different directions, therefore, on average for the group, this parameter for the healthy leg did not change, thus, the asymmetry between the foot lift of both limbs decreased. Since the SC has only one degree of freedom as an indicator of the pathological process, a decrease [21], we consider the increase in speed associated with the length of the SL to be a positive change obtained as a result of training with the use of TSCS.

A well-known method of gait correction is functional electrical muscle stimulation (FEMS). Comparative analysis of changes in the parameters of stepping movements during FEMS and during TSCS showed that the use of FEMS daily for 16 weeks together with botulinum toxin increased the speed by 0.09 m/s, in the control group (without botulinum toxin), by 0.04 m/s after 16 weeks of training [22]. SH increase in the paretic limb in 6 patients, in the absence of a decrease in the rest, is an important positive indicator of gait change in patients with hemiparesis. Results similar in mean values are shown with FEMS in patients with multiple sclerosis and stroke. Foot clearance during the swing phase increased by 5.26 mm after 4 weeks of daily training [23]. Thus, it can be concluded that a single application of TSCS is quite effective in the regulation of stepping movements in post-stroke patients, comparable to multiple application of FEMS.

We consider more pronounced changes in the parameters of the paretic limb as positive changes due to the effect mainly on the neural networks of the paretic side. Taking into account the increase in the range of motion in the articular angles of the healthy leg, although less pronounced, we can talk about the effect of training on gait in general. The need to maintain the relative symmetry of the functions of the right and left sides of the body leads to the fact that the healthy side of the body or limb, having a greater functional reserve than the diseased one, seeks to reduce the asymmetry by bringing the pattern of its movements closer to the kinematics of the affected limb. This is also manifested in a decrease in the EMG amplitude on the healthy side, which reflects a decrease in the load on a healthy limb and a change in the regulatory mechanisms of coordination of movements.

CONCLUSIONS

Non-invasive TSCS is a safe and painless method of influencing the structures of the spinal cord; all patients were tolerant to such stimulation and did not experience negative aspects during its implementation. The effectiveness of spinal cord stimulation was manifested in an increase in walking speed, an increase in the range of motion in the joints of the paretic leg, and a decrease in the asymmetry of individual parameters of both limbs, which facilitated interlimb coordination. After stimulation, 40% of patients showed a decrease in foot drag in the paretic limb due to an increase in the elevation of the limb above the support.

A more detailed analysis of various algorithms of multisegmental phase-dependent stimulation on gait parameters is a task for future research.

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ETHICAL STANDARDS

All studies were carried out in accordance with the principles of biomedical ethics formulated in the Declaration of Helsinki of 1964 and its subsequent updates, and approved by the Bioethical Committee of the Federal Scientific Clinical Center of the Federal Medical and Biological Agency of Russia (Moscow).

INFORMED CONSENT

Each participant in the study provided a voluntary written informed consent signed by him after explaining to him the potential risks and benefits, as well as the nature of the upcoming study.

CONFLICT OF INTEREST

The authors declare the absence of an obvious and potential conflict of interest related to the publication of this article.

CONTRIBUTION OF AUTHORS

D.V. Skvortsov—conducting clinical trials, analyzing the data obtained. I.N. Bogacheva—analysis and discussion of data, review of publications on the topic of the article. N.A. Shcherbakov—review of publications on the topic of the article, data analysis, preparation of the manuscript. A.A. Grishin, S.N. Kaurkin—conducting clinical trials, analyzing the data obtained. T.R. Moshonkin—research design development, data analysis. Yu.P. Gerasimenko—development of study design, discussion of the results.

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