# New Technology for Stroke Rehabilitation

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## Abstract

A study was conducted using the "Spinal neuroprosthesis neurostimulation device" specs 26.60.13-004-65248030-2021, which is designed to stimulate the dorsal roots of the cervical and lumbar spinal branches by rhythmic electrical stimulation during defined phases of the step cycle.

The aim of the study was to evaluate the safety and efficacy of a neuroprosthesis to regulate motor functions in patients with the consequences of an acute cerebrovascular accident.

Group 1 (main group): Patients who underwent transcutaneous electrical spinal cord stimulation with a neuroprosthesis and standard rehabilitation (therapeutic exercises, massage, physiotherapy). Group 2 (control): Patients who underwent electrical stimulation with a neuroprosthesis without current and standard rehabilitation. Primary efficacy point: improvement in walking performance in the 10-metre walk test and the 6-minute walk test.

Secondary efficacy points: Improvement in performance tests on various scales: Fugl-Meyer, the Medical Research Council Scale for Muscle Strength , quantitative muscle strength assessment, Berg Balance Scale, Functional Independence Scale, modified Ashworth Scale and analysis of spatio-temporal and kinematic parameters assessed by laboratory methods, video recording of muscle activity.

The rehabilitation course consisted of 12 daily procedures, each lasting 40-60 minutes and performed on a treadmill for 20 minutes. Tests were performed 1-2 days before the start of the rehabilitation course and the day after the rehabilitation course ended.

The results of a clinical study showed that the use of a neuroprosthesis leads to a significant improvement in muscle strength, the ability to maintain balance, a decrease in spasticity and an increase in functional independence.

**Keywords:** motor rehabilitation, stroke, electrical stimulation, spinal cord, walking

## Introduction

According to the WHO, 15 million people worldwide are diagnosed with stroke each year, of which about 6 million die and 5 million remain disabled[1,2]. The incidence of ischemic stroke is high. In Russia there are more than 500 thousand new cases annually. The severity of neurological disorders is a serious medical and social problem and requires the search for new methods of rehabilitation. About one third of patients suffering from the consequences of stroke become disabled because there is no effective rehabilitation. Movement disorders after stroke are the main cause of disability in patients. In 80-90% of cases, motor pathology manifests itself in the form of a hemiparesis syndrome (i.e. restricted mobility of the right or left limbs) with varying severity and type of expression[1-3]. Improving motor functions, especially gait in a post-stroke patient, is an urgent task. The epidural spinal cord stimulation method (in which electrodes are placed directly on the dura mater) has been shown to be effective in the rehabilitation of patients with movement disorders after spinal cord injury4-8. The TSCS method allows superficial transcutaneous stimulation of the spinal cord without surgery. Studies have shown that TSCS induces involuntary step movements in healthy subjects and in spinal patients[9-12]. The mechanism of action of percutaneous electrical nerve field stimulation (PENFS) aims to activate the spinal circuits below the lesion through sensory proprioceptive and skin afferents of the posterior roots of the spinal cord. This has been confirmed both by theoretical studies based on the properties of current propagation in an electrically inhomogeneous brain tissue environment and cell membrane biophysics, and by electrophysiological studies[13-19]. These

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sensory afferents transmit excitatory postsynaptic potentials to spinal motor neurons via mono- and polysynaptic connections, and the stimulating electrodes should be placed at the site most likely to recruit the dorsal roots innervating the muscles of the legs (or arms)[20-22]. To correct walking and stimulate the leg muscles, the electrodes should be placed at the level of the T11-L1 vertebrae[23].

TSCS improves motor activity in patients with spinal cord lesions[1,2], including patients after spinal cord injury more than four years ago with motor deficit to complete paralysis, despite ongoing intensive rehabilitation[3,4]. After several months of PENFS combined with motor training, patients with incomplete spinal cord injury regained voluntary control over previously paralysed muscles, started walking or cycling during spinal cord stimulation.

In the present study, we used percutaneous superficial TSCS, non-invasive method of activating the same nerve structures at the level of the spinal stenosis[19,20]. The advantage of TSCS is a gentle effect on the patient and a lower number of contraindications.

Purpose of the study: To evaluate the efficacy and safety of a spinal neuroprosthesis to regulate motor functions in patients with the consequences of an acute cerebrovascular accident (ACVA).

## Materials & Methods

The spinal neuroprosthesis (hereafter referred to as neuroprosthesis) provides for the activation of the movement networks of the spine as well as the motor pools of the flexors and extensors during the swing or support phase. The neuroprosthesis consists of a multi-channel stimulator to stimulate the spinal cord, an electrode matrix placed on the skin above the patient's spine, and leg motion sensors (Fig. 1A). The stimulation is controlled by an external computer via a wireless network.

The goal of motor rehabilitation with a neuroprosthesis is to improve movement abilities and increase mobility in the lower limbs, and increase strength in the limbs.

The stimulation mediated by the neuroprosthesis consists of continuous and rhythmic stimulation. Continuous stimulation of the lumbar thickening of the spinal cord occurs at the level of the T11-T12 vertebrae to facilitate leg movements. In addition, continuous stimulation of the cervical spinal cord (cervical thickening) is performed at the level of the C5-C6 vertebrae to increase the activity of the hands and increase the excitability of the descending pathways. Against the background of continuous stimulation, rhythmic stimulation of the roots of the spinal cord at the level of the T11 and L1 vertebrae is performed to realize a certain phase of movement synchronized with the rhythmic movements of the intact lower extremities. The stimulation mode depends on the stepping phase. In the stance phase the extensor muscles are activated, in the swing phase the flexor muscles. To activate the flexor muscles during the pushing and transfer phase, the roots of the upper segments of the lumbar extension of the spinal cord (T11) are rhythmically stimulated. In the stance phase, the roots of the lower segments of the lumbar thickening (L1) are stimulated to activate the extensor muscles of the legs. To regulate the movements of the right leg, the roots of the spinal cord on the right side are stimulated, to regulate the movements of the left leg - the roots on the left side. This technique was tested on healthy subjects and showed an effective change in walking kinematics[13, 14].

The present study included men and women aged 18 to 70 years who were hospitalised for rehabilitation and had suffered a stroke verified by magnetic resonance imaging or computed tomography, with a time period from the time of stroke of 1 month to 1 year and clinical manifestations of stroke in the form of movement disorders such as hemiparesis. Recovery of walking and paretic arm function was assessed using tests and scales. The study was conducted in two groups: the main group consisted of patients receiving motor rehabilitation with a neuroprosthesis (TSCS+), and in the control group, patients receiving motor rehabilitation with a neuroprosthesis (TSCS-) with sham stimulation. All patients additionally received standard rehabilitation, a course of 12 procedures.

*Figure 1. A - Model of a neuroprosthesis. B - Neuroprosthesis on the patient during the manipulation treatment.*

All patients with hemiparesis underwent treadmill training with body weight support and gait training on the floor (Fig. 1B). After 12 weeks of training, the patients with mild to moderate stroke showed an improvement in walking symmetry and an increase in walking speed. All patients

In addition to training with and without neurostimulation, all patients received massage, therapeutic exercises, and physiotherapy.

Treadmill speed (m/c), asymmetry between right and left leg stride lengths, and distance covered in 10 min were recorded during each treadmill exercise session. The data were recorded in individual registration cards (IRCs). The responses of the gastrocnemius muscle, tibialis anterior muscle, vastus lateralis muscle and biceps femoris muscle on both sides were recorded. The Neostim-5 stimulator (Cosima) was used to elicit motor responses. The cathode was placed between the spinous processes of the L1 and L2 vertebrae, and the anodes were attached to the crests of the pelvic bones. Unipolar pulses with a frequency of 0.3 Hz were used.

Statistical analysis of neurological testing results

The frequencies and distributions of the discrete traits were compared using the $\chi 2$-test. Pairwise comparisons were made for a number of methods using the Wilcoxon test and the Mann-Whitney rank test. The group effect and the treatment effect - values at the first and second visit and at the last visit - were calculated using the factors mixed ANOVA, visit (1 or 2/15) and groups (1-main /2-control). In addition, multivariate analysis of variance was performed in some cases, followed by multiple comparisons and other factor sets, for example the hemiparesis side. Individual items represented by ordinal scales were compared using rank criteria. Correlations between subscales at baseline and endline, and correlations between scales and the parameters of age, weight and height were calculated using Pearson's and Spearman's coefficients. Statistical decisions were made at the 5% significance level, although trends towards significance were also taken into account due to the large individual data dispersion and small sample sizes. Data analysis was carried out using the SPSS Inc. software package.

## Results

The study included 22 patients with hemiparesis (2-3-4 points) after an ACVA. Patients were able to stand independently and walk at least 10m on the floor (with a cane or walker if necessary). There were no significant differences between the groups in terms of age, gender, side of hemiparesis, type of stroke, time period after stroke, use of technical rehabilitation equipment (TRE) (Table 1).

*Table 1. The effect of rehabilitation with a neuroprosthesis on gait parameters in the 6-minute walk test.*

| Group | N | Sex M/F | Age -yrs | Type of ACVA (clot/ICH*) | Period after ACVA (mos) | Number of patients with TRE |
|---|---|---|---|---|---|---|
| 1 | 10 | 8/2 | 56,4±9,0 | 9/1 | 7,1±3,0 | 3 |
| 2 | 10 | 7/3 | 52,9±10,8 | 8/2 | 6,9±3,5 | 2 |

*Ischaemic stroke/Intracerebral hemorrhage

At the beginning of the study, the distances covered did not differ significantly between the groups. Patients in the main group walked 236.8±70.7 m, patients in the control group - 248.4±87.8 m. After the rehabilitation course, the distance walked increased in both groups and was 293.4±90.1 m and 266.3± 71.3 m in the main and control groups, respectively. In the main group, the distance increase was 56.6±11.9 m, in the control group 17.9±11.9 m. In the main group, the distance increase was significantly different from zero (p<0.001), in the control group the change was insignificant. There is a high probability (p=0.948) that the changes in distance travelled differ between the groups.

A 44 m increase in distance travelled in the 6-minute walk test is the minimum clinically significant difference (MCID) in patients who had a stroke 2-6 months ago. Among patients in the main group, the increase in distance is ~30 show value greater than the MCID.

After the course, the patients in the main group recorded a significant increase in biceps and quadriceps femoris strength on the paretic side of 0.4 points (p=0.032). The patients in the control group showed an increase in the strength of the iliacus muscle on the healthy side by 0.2 points (p=0.048) and an increase in the strength of the foot muscle by 0.3 points (p=0.012).

After the course, the main group registered an increase in motor functions by 3.4 points with a tendency to a significant difference from zero (p=0.102). The cumulative FIM score in the main group changed from 117.9±2.141 to 120.7±2.481 and in the control group from 118.6±2.141 to 120.2±2.481. The change in total score correlated significantly with hemiparesis side (ρ=0.654, p=040).

After the course of rehabilitation, RRS scores decreased by 0.9 points in the main group and were significantly different from zero (p<0.001), and in the control group - by 0.4 points and were different from zero at the trend level (p=0.095).

The increase in walking speed after rehabilitation was reflected in the step structure (Fig. 2A). In the main group, on the paretic and intact side, the total phase of support decreased by ~3%, the period of double support decreased by ~10%, and the period of single support increased by ~5% (Fig. 2B-D). The transfer period in the first group increased by ~5% on both sides (Fig. 2E). These changes in step structure indirectly reflect an increase in vertical stability and coordination in the patients of the main group. In the control group, the total support phase on the intact side decreased by ~3% (Fig. 2B), the single support on the paretic side increased by the same amount (Fig. 3D), and the transfer phase on the intact side increased (Fig. 2E). Significant differences between the groups were seen in all characteristics of the phases of the step (Fig. 2B-E).

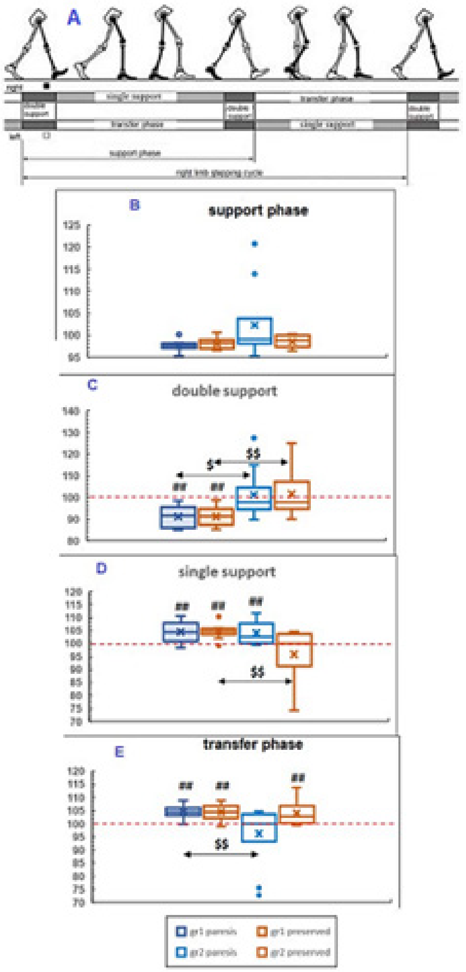


*Figure 2. Changes in the structure of the step cycle after the rehabilitation course compared to the parameters before the course (%).*

The increase in the amplitude of the tibialis anterior muscle responses on the paretic side was 10% and differed significantly from the change in activity of this muscle on the paretic side in the control group. Muscle activity on the healthy side also increased significantly after the course, but the increase in activity was significantly less in this group than on the paretic side.

The use of the neuroprosthesis also led to a significant change in gait pattern and showed an improvement in stability and coordination when walking. These changes were not present in the control group. The range of motion of the ankle joint during walking increased significantly after the course in the main group.

Thus, rehabilitation with a neuroprosthesis (TSCS) has a positive effect on the function of walking by increasing not only speed but also stability and coordination and facilitating walking on uneven surfaces.

There was a significant trend towards an increase in the EMG activity of TA in the paretic limb of the patients in the main group during a 10-metre walk at a comfortable speed (119±27%, p=0.055). The EMG activity of GM in the healthy limb of the patients in the control group also increased significantly during a 10-m walk, both were at a comfortable speed (116±18%, p<0.01) . There is a very reliable trend that the TA-GM coactivation index of a healthy limb increased more in the main group compared to the control group when walking at a comfortable speed (119±41% versus 91±45%, p = 0.054). This fact apparently indicates an increase in ankle stiffness after rehabilitation with a neuroprosthesis (Fig. 3).

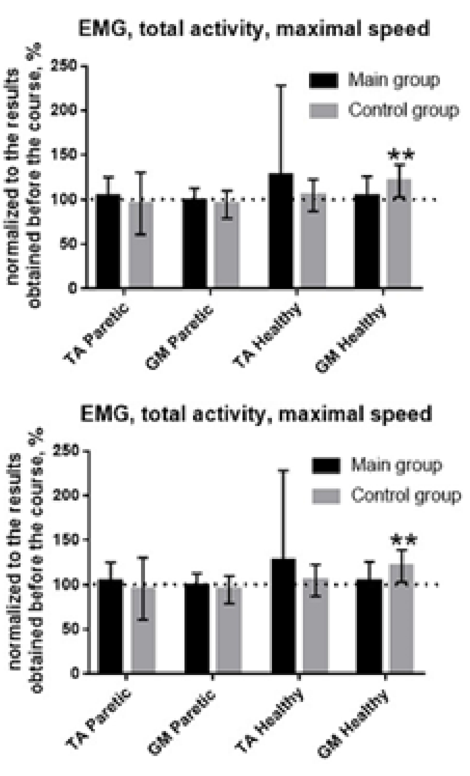


*Figure 3. Changes in total EMG for TA and GM of the paretic and healthy limbs of patients in the control and main groups. A - 10-metre walk at comfortable speed, B - 10-metre walk at maximum speed.*

Analysis of the total EMG recorded during the 10-metre test while walking at a comfortable speed revealed a highly significant trend towards an increase in the activity of TA in the paretic limb of the patients in the main group.

In the patients of the main group, there was a significant increase in the amplitude of the muscle responses on the side of the paretic limb in the vastus lateralis muscle by 172% (*T=5, p=0.021), as well as a significant increase in the amplitude on the side of the healthy limb in the biceps femoris muscle by 527% (**T=8, p=0.046), and on the side of the paretic limb by 784%. An increase in the excitability of the locomotor networks on the paretic limb side was observed in four out of ten patients. The motor responses after the course appeared at a higher current intensity compared to the threshold values of the current before the rehabilitation course.

## Discussion

The amplitude of muscle responses in the patients of the main group increased in all muscles of the paretic and intact limbs compared to the patients of the control group, with the exception of the tibialis anterior muscle (Fig. 4). There were no significant differences between the main group and the control group.

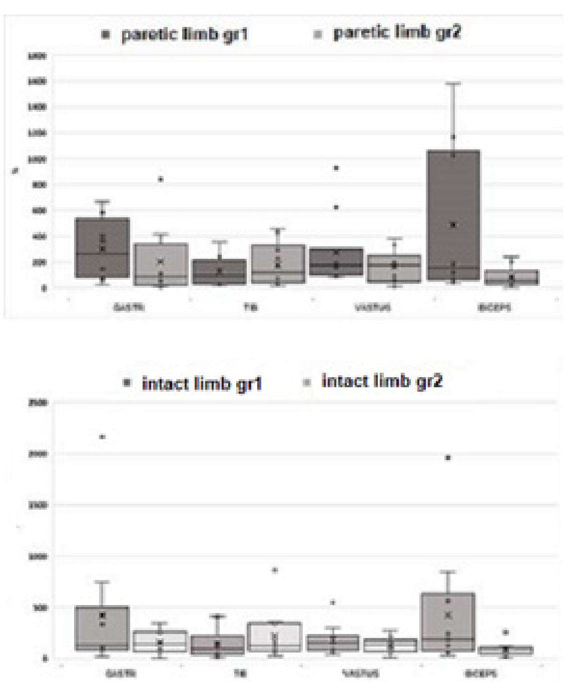


*Figure 4. The maximum values of the increase in muscle responses after the rehabilitation course for 10 patients from the main group (gr1) and 10 patients from the control group (gr2) for the paretic and intact limb.*

In the main group, after the rehabilitation course, there was an increase in the amplitude of the muscle responses of the lower leg and foot flexors of the paretic and healthy limbs (biceps femoris muscle, gastrocnemius muscle) and a significant increase in the amplitude of the muscle responses of the vastus lateralis muscle. However, in the control group there was a tendency for the amplitude of the responses of the lower leg and foot extensor muscles (vastus lateralis and tibialis anterior muscles) to increase. The following conclusions can be drawn from the data obtained.

The primary point of efficacy, according to the results of both tests, was reached at the level of minimal clinically important differences (MCID) in the main group and was not reached in the control group, indicating the effectiveness of the use of a spinal neuroprosthesis in the rehabilitation of patients with the consequences of an acute cerebrovascular accident.

According to the results of all tests and physiological examinations, with one exception, significant improvements in indicators were obtained in the main group, and in one test there was a significant improvement at the trend level. In the control group, four tests, including the tests of the primary efficacy point, showed no improvement in performance. This fact also points to the advantages of using a neuroprosthesis in rehabilitation compared to conventional rehabilitation methods.

After the course of rehabilitation, significant differences were found between the main and control groups in the results of physiological studies of walking (gait kinematics), muscle activity, and excitability of the lumbar thickening of the spinal cord, suggesting that the use of a neuroprosthesis causes reorganization of the locomotor networks of the spinal cord and underlies the advantages of the use of neuroprostheses in rehabilitation over traditional rehabilitation methods.

The results of kinematic studies and the analysis of EMG activity of leg muscles indicate the effectiveness of the stimulation effect in regulating the stepping movements of the paretic limbs. An important fact is the increase in the range of motion in the ankle joint in the patients of the main group (this was not the case in the patients of the control group). This means that during stimulation the trailing of the foot is canceled and the foot is involved in the work.

## Conclusions

Spinal neuroprosthesis is an effective means of restoring walking stereotype and increasing walking speed in patients with hemiparesis in the early and late recovery period after stroke. When using a neuroprosthesis in rehabilitation, a two-week course is sufficient to achieve minimal clinically significant changes.

Author contributions

T.Moshonkina - author of the idea

E.Zharova - patient search, assessment of the dynamic status of patients

S.Ananiev - Conducting the research

N.Shandybina - research implementation

E.Vershinina - statistical data processing

V.ALyakhovetskii - evaluation of walking kinematics

A.Grishin - evaluation of data

Yu.P.Gerasimenko - author and inventor of the COSIMA neuroprosthesis.

Conflict of interest statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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