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Zero-Gravity Robotic-Assisted Locomotion Simulator in Rehabilitation: a Prospective Randomized Clinical Study of 30 Spinal Trauma Sequelae Patients

Polina V. Tkachenko*, Vadim D. Daminov

National Medical and Surgical Center named after N.I. Pirogov, Moscow, Russian Federation

ABSTRACT

INTRODUCTION. According to the WHO, between 250,000 and 500,000 people are affected every year with spinal cord injury (SCI) around the world. The number of disabled people as a result of spinal cord injury in Russia is estimated to be over 250,000 and is increasing due to injury rate growth and survival rate improvement of patients in the acute and long-term periods of traumatic spinal cord injury (TSCI).

AIM. To justify the efficacious and safe use of a zero-gravity robotic simulator for a locomotor therapy in the complex rehabilitation of patients with SCI and compare this therapeutic approach with conventional motor rehabilitation programs using other robotic mechanotherapy techniques.

MATERIAL AND METHODS. Neurological and functional disorders were analyzed in 30 patients with SCI on the basis of clinical examination and electromyography (EMG) findings. All the patients were classified into an intervention group and a control group by a sequential randomization. The rehabilitation programs for the intervention and control groups were alike, except for robotic mechanotherapy.

RESULTS. A significant positive dynamic change in motor functions according to the ASIA Impairment scale was noted in the intervention group, in which 2 patients moved up to a higher level. The EMG data showed a significant difference between the groups in favor of the intervention one. A significant difference in postural function improvement was found between the intervention and control groups in a seated position. The rehabilitation of patients from the intervention group engaged the axial muscles, promoting an increase in strength and better control of the trunk muscles. A significant spasticity decrease and changes in the functional status of the patients were observed in both groups. The patients' ability to perform normal daily activities was registered to improve.

CONCLUSION. The study demonstrated that robotic musculoskeletal training in zero-gravity conditions is safe and effective in complex rehabilitation of patients with SCI and improves motor skills, self-care and postural function. A significant correlation was found between neurological and functional changes, indicative of a restorative concept of the new therapeutic modality. Further studies with increased capacity are reasonable.

KEYWORDS: weightlessness, robotic-assisted device, electrical stimulation, rehabilitation, spinal cord injury

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***For correspondence:** Polina V. Tkachenko, e-mail: tkachenk1o@rambler.ru

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Безопорный роботизированный локомоторный симулятор в реабилитации: проспективное рандомизированное клиническое исследование 30 пациентов с последствиями травмы позвоночника

Ткаченко П.В*., Даминов В.Д.

Национальный медико-хирургический центр им. Н. И. Пирогова, Москва, Россия

РЕЗЮМЕ

ВВЕДЕНИЕ. По данным ВОЗ, от 250 000 до 500 000 человек в год страдают от травматического повреждения спинного мозга во всем мире. Число инвалидов в результате травмы спинного мозга (ТСМ) в России, по оценкам, составляет более 250 000 человек и увеличивается в связи с ростом травматизма и улучшением выживаемости пациентов в остром и отдаленном периодах травматического повреждения спинного мозга

ЦЕЛЬ. Обосновать эффективное и безопасное использование роботизированного тренажера невесомости для локомоторной терапии в комплексной реабилитации пациентов с ТСМ и сравнить данный терапевтический подход с традиционными программами двигательной реабилитации с использованием других методов роботизированной механотерапии**.**

МАТЕРИАЛ И МЕТОДЫ. Неврологические и функциональные нарушения были проанализированы у 30 пациентов с ТСМ на основании результатов клинического обследования и электромиографии (ЭМГ). Все пациенты были разделены на рабочую и контрольную группу путем последовательной рандомизации. Программы реабилитации для рабочей и контрольной групп были одинаковыми, за исключением роботизированной механотерапии.

РЕЗУЛЬТАТЫ. В рабочей группе были отмечены значительные положительные динамические изменения двигательных функций по шкале нарушений ASIA, в которой 2 пациента перешли на более высокий уровень. Данные ЭМГ показали значительную разницу между группами в пользу интервенционной. Была обнаружена значительная разница в улучшении постуральной функции между рабочей и контрольной группами в положении сидя. Реабилитация пациентов из рабочей группы задействовала осевые мышцы, способствуя увеличению силы и лучшему контролю мышц туловища. В обеих группах наблюдалось значительное снижение спастичности и изменения функционального статуса пациентов. Было зарегистрировано улучшение способности пациентов выполнять нормальную повседневную деятельность.

ЗАКЛЮЧЕНИЕ. Исследование продемонстрировало, что роботизированная тренировка опорно-двигательного аппарата в условиях невесомости безопасна и эффективна в комплексной реабилитации пациентов с ТСМ и улучшает двигательные навыки, самообслуживание и постуральную функцию. Была обнаружена значительная корреляция между неврологическими и функциональными изменениями, что свидетельствует о восстановительной концепции нового терапевтического метода. Дальнейшие исследования с увеличенной производительностью являются разумными.

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***Для корреспонденции:** Ткаченко Полина Владимировна, e-mail: tkachenk1o@rambler.ru

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INTRODUCTION

According to the WHO, every year, around the world, between 250,000 and 500,000 people suffer spinal cord injury all over the world [1]. There are more than 250,000 people in Russia with disabilities due to spinal cord injury (SCI), and their number is growing as the incidence of injury and survival rates in the acute and long-term periods of traumatic spinal cord injury are increasing (TSCI). Spinal cord injury is accompanied by the impairment of many body functions. The basic disabling factor is the loss of ability to maintain an upright posture and walk, leading to malfunctions of respiratory organs, blood circulation, urination, and gastrointestinal tract [2]. Being in a wheelchair for too long creates conditions for multiple complications arising from the forced position, hypodynamia and positional compression. In this regard, the restoration of the upright posture and locomotion is an important driver for that category of the affected.

The rehabilitation techniques available for the patients with persistent motor function disorders may be targeted to substitute or to restore the functions. The restorative concept of rehabilitation prescribes treatment that integrates segments below the affection level into functioning and selects devices that help incorporate these segments into the motor activity [3, 4]. The most commonly used therapy is gait training with partial bodyweight support, for example, using robotic medical devices like Lokomat [4, 5]. However, the cost of such devices is quite high and involves the use of sophisticated technical equipment [6]. Besides, early verticalization, which does not always furnish a positive outcome even if high-tech approaches are employed, can be a problem of robotic-assisted locomotor therapy. On the contrary, it promotes a spasticity increment, physical exertion, and additional traumatization of patent's tissues [7, 8]. At the same time, the early start of rehabilitation actions considerably improves the prognosis for functional recovery, including locomotion [9, 10].

It is believed that a high rehabilitation potential of the patients after TSCI is fully realized if the principles of consecutive kinesigenesis are met, when the difficulty of patient's locomotor tasks gradually levels off.

A zero-gravity robotic simulator for locomotion therapy allows sanogenesis mechanisms to be exploited to a greater extent, which will mitigate the effect of the disabling factors and enhance overall rehabilitation efficacy and motor recovery, in particular. For this, technical solutions are used that vary in body weight compensation method, development of active or passive motions in paretic extremities, and bio-feedbacks used for movement control and management. The zero-gravity principle is used in elastic and rigid suspension systems like a RedCord or Exart kinesiotherapy device under dry floatation or even aqueous environment [11]. We tested the effect of an Exart kinesiotherapy device when applied to patients with severe TSCI in our Medical Rehabilitation Clinic in Pirogov National Medical and Surgical Center.

In view of the aforesaid, the present study is aimed to justify the efficacy and safety of the zero-gravity robotic-assisted locomotion simulator when used for locomotor therapy of patients with traumatic spinal cord injury as compared with conventional programs of motor rehabilitation and locomotor training including the use of other robotic locomotor therapy modalities.

AIM

To justify the efficacious and safe use of a zero-gravity robotic simulator for a locomotor therapy in the complex rehabilitation of patients with SCI and compare this therapeutic approach with conventional motor rehabilitation programs using other robotic mechanotherapy techniques.

MATERIAL AND METHODS

Participants

We conducted a randomized clinical trial between September and December 2020. A total of 30 patients with traumatic spinal cord injury (TSCI) were included in the study. The randomization was based on continuous sampling of total population of TSCI patients, who came to the Rehabilitation Clinic for treatment within the specified period of time. All the admitted patients were submitted to the registry. Each patient, if met the inclusion criteria, was assigned a sequence number from 1 to 30: odd-numbered patients were assigned to the intervention group, while the even-numbered to the control group. Informed consent was obtained from all the patients, who agreed to participate in the study.

Inclusion criteria

This study was approved by the Local Ethics Committee of the Pirogov National Medical and Surgical Center (protocol № 15, 19.08.2020) and performed in accordance with the World Medical Association Declaration of Helsinki on Medical Research Involving Human Subjects and its 2013 amendments.

The patient sample was derived by the inclusion criteria: injury age of 3 months and older; injury at the levels of cervical spine, thoracic spine and thoracolumbar spine; severity of conduction disorder by the ASIA score: A, B, C and D; severity of paraparesis from 0 to 6 by the 6-point score.

All the patients included in the study were classified into two groups:

1. Intervention group (n=15), who underwent locomotor therapy on a zero-gravity robotic-assisted simulator (10 sessions);

2. Control group (n=15), who received locomotor therapy on a robotic, partial bodyweight-support simulator (10 sessions).

In addition to the robot-assisted locomotion therapies, the patients from both groups received the same range of conventional rehabilitation measures: two motor therapy modalities such as therapeutic exercises and mechanotherapy; three physical therapy modalities such as transcutaneous electrical spinal cord stimulation (TESCS), muscle electromyostimulation of lower limbs, and massage. Each modality had 10 sessions. When necessary, patients received psychological exercises.

Robot-assisted locomotion training procedure

The training procedure on the zero-gravity robotic-assisted locomotion simulator involved two steps.

The first step was preparatory. Its objectives were to make a patient ready for exercise load and for capabilities to work on voluntary movements. The swim and walk settings were used. The objectives of the second (basic) step were to develop active and passive voluntary movements, work out compound motor actions in zero-gravity conditions, and work out rhythmic movements. The active voluntary movements were evoked directly by muscle work, while the passive voluntary movements were produced by muscle contraction in the other body segment and were induced by the force of inertia.

The development of passive voluntary movements was through the swim settings applying an "aid mode". The "aid mode" was enabled for lumbar, femoral and talocrural regions; leg-swinging exercises were being practiced (Fig. 1).

Fig. 1. *Exart zero-gravity robotic-assisted locomotor training with synchronized multimodal electrostimulation*

Transcutaneous electrical spinal cord stimulation (TESCS) procedure

Starting from the first exercise, transcutaneous electrical spinal cord stimulation (TESCS) was enabled concurrently with zero-gravity robotic-assisted mechanotherapy. The electrodes of the first and second channels were placed as follows: the active ones were placed on the presumed lumbar enlargement zone at the level of the acantha of the Th12 vertebra over the right and left paravertebral lines, while the passive ones were placed in the projection of iliac crests. The third and fourth channels were used for stimulation of the quadriceps femoris: two passive and two active electrodes were used because of a large area of the muscle. That said, the active electrodes were placed on motor points of lateral and medial vastus muscles and on rectus femoris. The passive electrodes were put on the upper third of the thigh. A channel splitter was used to connect the two electrodes.

Here, we used modulated, unipolar, single pulses of 0.1–0.5 ms in length with a modulation frequency of 10 kHz and a current amplitude of 200–250 mA; the pulse repetition frequency corresponds to the movement frequency of the simulator actuators. The TESCS procedure lasted 30 min.

Measurements

The safety and efficacy of the approach under study were evaluated using a complex clinical and instrumental examination. On the first and last days of the rehabilitation course, the patients from both groups underwent the following clinical monitoring: the spinal cord conductivity (sensory and motor divisions) was analyzed by the ASIA scale (American Spinal Cord Injury Association) [12]; self-care and mobility were assessed by the VFM scale (Valutazione Funzionale Mielolesi) for patients with spinal cord injury (SCI); interference surface electromyography (sEMG) of the rectus femoris muscle for objectivization of neurologic examination; muscle tone was measured by the Ashworth Scale; and postural functions (weight distribution in percentage while sitting on the platform for 10 sec with the eyes closed) were evaluated on a Tyromotion's TYMO force plate. The 50/50 distribution between the right and left sides is a norm, and an increment in the difference between the sides is the severity of postural dysfunction.

The electromyographic assessment of the peripheral neuromuscular apparatus employed a Neuro-MVP-micro 4-channel electroneuromyograph (Neurosoft Company, Russia). The interference surface electromyography of the rectus femoris muscle was recorded on both sides. The electrodes were placed in the middle between anterior iliac spine and superior kneecap; the distance between the central lines of the electrodes was 20 mm. The sEMG of muscles was recorded twice for each measurement (with relaxed muscles and maximum voluntary muscle tension) and the best result was used for analysis.

Statistical analysis

Statistical analysis was performed using LibreOffice Calc ver. 5.2 software and data manipulation language R ver. 4.0.2 (2020-Jun-22) in RStudio ver. 1.3.1093. The spreadsheet was used for data accumulation and pre-processing. A script was written by the R language for automated processing of the prepared data arrays [13]. Statistical criteria and group distribution metrics of variables were selected using the common guidelines [14].

The normality of distribution was evaluated by the Shapiro-Wilk test. The data were presented as the median of the first and third quartiles of minima and maxima for each of the observable variables (median [LQ; UQ] (min-max)). The diagrams were built by the ggplot2 package (ver. 3.3.2). The VisAnalyser ver. 1.0.0.0 software was utilized for graphical representation of frequency response envelopes

after Fourier transform. The Wilcoxon test for paired samples was employed to evaluate significant changes in precourse and postcourse measures. The Mann-Whitney test and Fisher exact test were used to evaluate significant changes in measures between the groups. The measured side and observation point (precourse and postcourse, respectively) acted as factor variables. The analysis of correlations between neurological and functional changes (the ASIA and VFM scales in our case) used the Spearman's rank correlation coefficient. The differences were considered significant at $p<0.05$.

RESULTS AND DISCUSSION

This study included 30 patients allocated into two groups with 15 subjects in each. No significant differences in sex (p=0.45), age (p=0.75), injury age (p=0.25) and severity of presentations (p=0.93) were found between the intervention and control groups (Table 1).

Table 1. *Patient demographics*

Characteristic	Intervention group (n=15)	Control (n=15)
Age	28 (24–32)	32 (23–39)
Male	11 (73.3%)	8 (53.3%)
Injury age, months	20 (13–37)	22 (18–61)
ASIA scale:		
A	5	4
B	1	1
C	8	8
D	1	2

The study showed that the zero-gravity simulator was safe in use: no complications or adverse effects were discovered; the hemodynamics were stable throughout the course, with no deviations detected. A recovery of a sacral pressure ulcer was observed in one patient from the intervention group: Stage 2 ulcer on admission and Stage 1 ulcer upon the course completion.

The changes in ASIA motor scores of the lower extremities were observed among both groups: from 0 [0–14.5] (0–25) and a total precourse score of 101 to 2 [0–14.5] (0–29) and a total postcourse score of 119 ($p<0.05$) in the intervention group, and from 0 [0–1.5] (0–35) and a total precourse score of 84 to 0 [0–2.5] (0–35) and a total postcourse score of 86 (p=0.112) in the control. The positive outcome was considered to be a change in the motor function of the lower extremities by one score at a minimum, and the negative outcome was considered to be no change (Table 2).

Table 2. *Distribution of patients with changes in ASIA motor scores of the lower extremities*

	Positive outcomes	Negative outcomes	*Row totals*
Intervention group	5	10	15
Control	1	14	15
Column totals	6	24	30 (in total)

Two patients from the intervention group were observed to move up to a higher category by the ASIA scale. In the first case, a 32-year-old patient (TSCI at the level of Th4, ASIA A, injury aged 23 months) was documented to improve tactile sensibility by 3 scores, deep sensibility by 2 scores and motor behavior by 2 scores – one score each for plantar flexors of toes on both sides. Besides, sensibility control appeared upon deep pressing on the anal sphincter region. Upon the course completion, the patient was categorized as C.

In the second case, a 22-year old patient (TSCI at the level of Th12-L1, ASIA C, injury aged 11 months) was documented to improve tactile sensibility by 5 scores, deep sensibility by 4 scores and motor behavior by 7 scores – one score each at different levels on both sides. Upon the course completion, the patient was categorized as D.

A significant change that did not result in the group change by the ASIA scale among the intervention group was also an appearance of voluntary contraction of the anal sphincter in one control patient. No similar cases were documented in the control group.

A rise in the VFM scale estimates following the rehabilitation course (p=0.001) was noted among both groups by evaluating the dynamics of functional changes, indicative of an improvement in the functional status in either therapeutic course. No significant differences were revealed between the groups by assessing the dynamics by the Mann-Whitney test (p=0.386) (Table 3).

The analysis of sEMG results evaluated only the changes in sEMG signal data from the rectus femoris muscle on both sides. The total was 25 in the intervention group and 7 in the control. No significant differences were found between the groups through the evaluation of the dynamics of the sEMG signal by the Mann-Whitney test (p=0.038) (Table 3).

Table 3. *Dynamics of functional changes*

Measure	Intervention group (n=15)	Control (n=15)
VFM scale:		
Before therapy	219 [191.5–242.5] (125–264)	196 [186.5–236.5] (148–252)
Post-therapy	235 [200–248.5] (125–271)*	213 [190.5–240.5] (152–258)*
sEMG signal (rectus femoris muscle)	1 [0–3] (0-6) †	0 [0–0.5] (0–2)
Ashworth scale:		
Before therapy	1.5 [1–2] (0.5–3)	2.0 [1–2] (1–3)
Post-therapy	1.0 [1–1.5] (0–2)*†	1.0 [1–2.5] (0–5)
Postural functions:		
Before therapy	3.0 [1.5–6.5] (0–14)	2.0 [1.5–3] (1–5)
Post-therapy	1.0 [0.5–2.5] (0–7)*†	1.0 [1–2.5] (0–5)

Note: *The data are presented as the median [Q1–Q3] (min-max); * Significance of differences before and post-treatment; † Significance of differences as compared to the control*

The following basic types of changes were identified in the study:

1. Type II changes: an increase in amplitude over a 10–20-Hz low-frequency range. Type II changes are an increase in the spastic-tonic component of the EMG signal, with such a signal being recorded for patient's voluntary intents;

2. Type III changes: an increase in amplitude over a 20–50-Hz midrange (Fig. 2);

3. Type IV changes: an increase in amplitude over a 50–100-Hz high-frequency range.

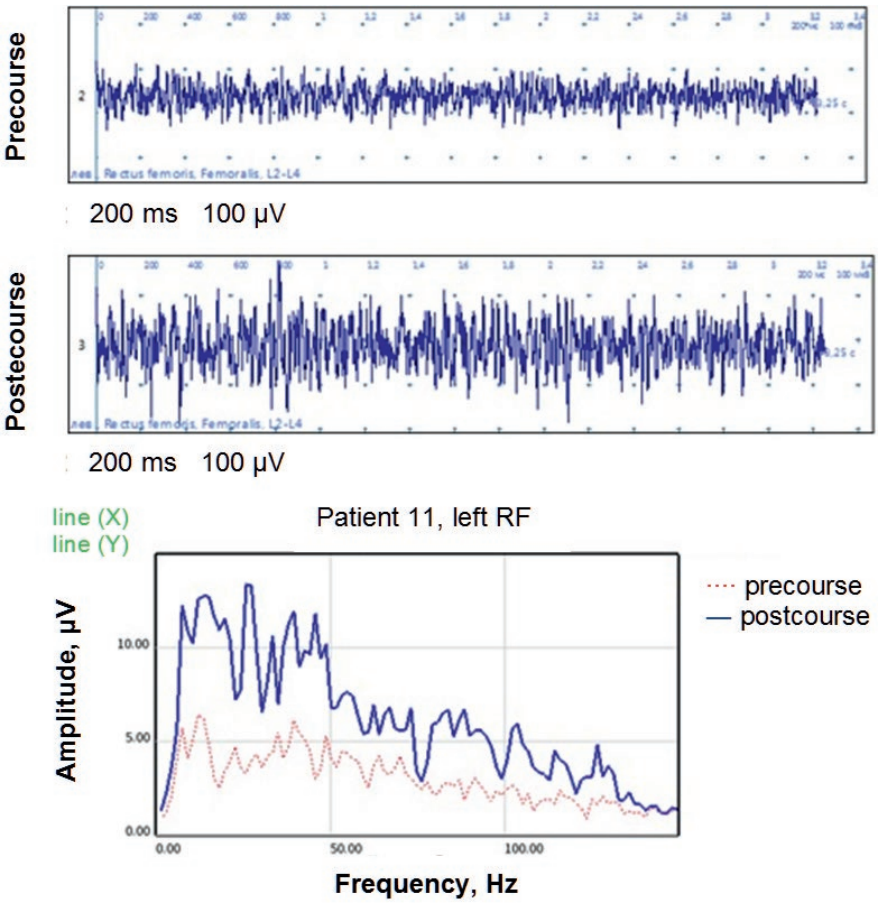

Fig. 2. *Type III changes: native curves of increased amplitude over a 20–50-Hz midrange*

A total of 9 patients from the intervention group and 5 patients from the control were found to have changes in the dynamics of the EMG signal in one muscle under test. While, when compared with the ASIA scale, positive changes were discernible in 5 patients from the intervention group and in 1 patient from the control group. This is indicative of a higher sensitivity of the sEMG method towards detecting changes in voluntary muscle control.

A decrease in spasticity by the modified Ashworth scale was noted in both groups post-therapy, though differences were significant only in the intervention group ($p<0.01$).

Evaluation of the dynamics revealed no significant differences between the groups (p=0.181) (Table 3).

The postural stability was examined in a seated position to evaluate the ability to maintain equilibrium. The data are presented as a difference taken from the modulus between the 50% normal value and the measured value. For example, ABS (50–49)=1 or ABS(50–53)=3, as it does not matter for functional assessment where imbalance is shifting, only the degree of imbalance matters. Significant differences were noted in the intervention group (p<0.01). To evaluate the results between the groups, the difference between precourse and postcourse values in each group was factored in; significant differences were detected between the intervention group and the control (p=0.03) (Table 3).

The analysis of correlations between neurological and functional changes took into account ASIA sensibility and motor total scores as the neurological dynamics, as well as changes in sensibility and motor function at the level of S4–S5 segments. A significant positive correlation between neurological and functional changes was detected for patients from the intervention group (r = 0.735, p = 0.001), and it was however insignificant for the control group (r = -0.18442, p = 0.511) (Fig. 3), which may be suggestive of a restorative concept of the new therapeutic modality.

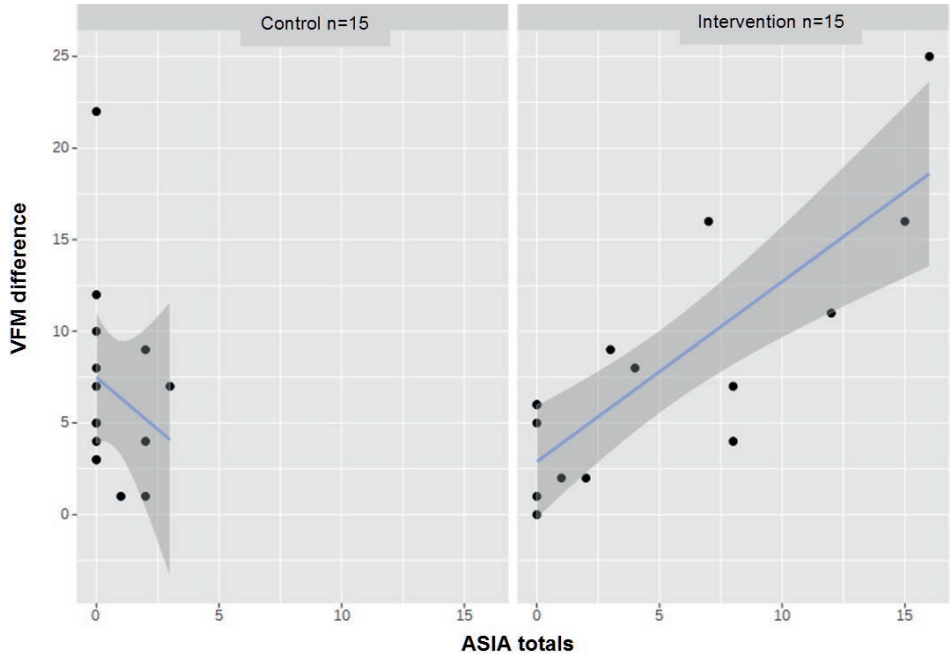

Fig. 3. *A scatter plot of neurological and functional measures*

The zero-gravity principle has been used in the rehabilitation practice for many years and studied extensively since the 60-ies of the last century to accomplish space flight programs and explore physiological parameters in weightlessness conditions on long-term stay of astronauts in orbit. An abrupt decline in tonic muscle system control has been established to occur under microgravity, which may promote a decrease in the competitive effect of different locomotor centers on the lower motor neuron, facilitating the task to restore the cortical motor control [15]. The zero-gravity condition lightens the weight of body segments, thereby ensuring the voluntary muscular activity at a muscle strength of 3 scores and less. Besides, zero-gravity therapeutic techniques favor a reduction in pain and spasms and prevent dynamic stereotype from distortion as usually observed when the function of paretic muscles is compensated by overlying unaffected body segments. Weightlessness (microgravity) in suspension abates the mechanical load and reaction of the body support, with the range of motions being preserved at the same time [15].

No differences in the frequency of clinical responses to therapy were found between the intervention and control groups upon completion of this study, corroborating that the zero-gravity approach is effective in rehabilitation practice. However, positive trends of changes in the motor division by the ASIA scale were observed, and two patients from the intervention group moved up to a higher ASIA level. The analysis of sEMG data showed significant differences between the groups in favor of the intervention group and demonstrated a better sensitivity of the approach towards motor function changes.

At present, using sEMG quantitative data proves to be impossible for the evaluation of rehabilitation dynamics. The changes in the frequency range prove to be more stable for different measurements, which may be indicative of more motor units being involved in muscle contraction and of a change in muscle contraction control level [16]. The studies [17-19] use various techniques to render sEMG data into ordinal scales, which are recognized by the researchers themselves to be not simple-to-use and unsuitable for screening in the general medical practice. The specialists in Russia also use data translation into the ordinal data; four types of sEMG signal response and change rate have been proposed for use: Type I, no changes; Type II, a change in oscillation amplitude; Type III, a change in amplitude and frequency; Type IV, a change in EMG type [20]. Based on the data reported, here we propose an ordinal scale of changes in the amplitude-frequency spectrum following Fourier transform (Table 4). The transformation is performed in an automatic mode using the electromyographic equipment specified above.

Table 4. *Ordinal scale of changes in amplitude-frequency spectrum of EMG after Fourier transform*

Type	EMG signal change	Assessment (scores)
Type I	no significant changes	0
Type II	enhanced amplitude in low-frequency range (10–20 Hz)	1
Type III	enhanced amplitude in midrange (20–50 Hz)	2
Type IV	enhanced amplitude in high-frequency range (50–100 Hz)	3

The sEMG signal amplitude was considered as enhanced if it more than doubled or by more than 5 μV in absolute amount for the selected frequency. The approach proposed herein for sEMG data assessment does not claim to be complete and precise, and we pursued the aim to try to create a practical basis for alternative assessment. The sEMG assessment may have additional value both in predicting the functional outcome and in evaluating the therapeutic effectiveness.

The present study also found a more pronounced improvement in postural function in the sitting position in the intervention group, which may indicate an increase in strength and better control of the trunk muscles. Besides, a significant correlation between neurological and functional changes was detected in the intervention group. This may suggest a restorative concept of the new therapeutic approach. However, further research with a power increment is needed. The present study has a limitation – a small sample – which also necessitates further research.

Some studies evaluated the dynamics of neurological changes in patients post-TSCI, depending on timeframes post-injury [21-24]. All the studies quoted give fairly similar results in terms of timing and speed of recovery. The analysis of these data demonstrates that major changes in the condition of the patients with SCI occur between three months and one year, while the changes in those patients with more than 12 months from the date of injury are insignificant. Here, we obtained positive outcomes in patients with a trauma aged more than 12 months, which may indicate that rehabilitation actions are required irrespective of injury age.

CONCLUSION

Thus, the findings from this study suggest that sophisticated robotic-assisted devices emulating not only walking, but also phylogenetically older locomotor patterns have prospects for use not only as a substitutive, but also as a restorative concept of rehabilitation. In that case, apart from substitution for the lost postural and motor functions, which benefit has been proved, the restoration is possible in orthopaedic and neurological statuses. This can manifest itself in an increased range of movement in the joints of the lower limbs to physiological limits, a higher organization of myoelectrical activity below the affection level and formation of voluntary movements and voluntarily triggered locomotor muscle synergies. The consequence is that an erect posture and primitive locomotion of the patients with severe TSCI can be restored.

ADDITIONAL INFORMATION

Information about the authors:
Polina V. Tkachenko, Cand. Sci. (Med.), Head of the Medical Rehabilitation Department for patients with impaired peripheral nervous system and musculoskeletal system, National Medical and Surgical Center named after N.I. Pirogov, Russia.
E-mail: p.nikitchenko@gmail.com, ORCID ID: http://orcid.org/0000-0003-1672-9405
Vadim D. Daminov, Dr. Sci. (Med.), Chief of Medical Rehabilitation Clinic, National Medical and Surgical Center named after N.I. Pirogov, Russia.
E-mail: daminov07@mail.ru, ORCID ID: http://orcid.org/0000-0001-7141-6052

Authors' contribution:
All authors confirm their authorship according to the ICMJE criteria (all authors contributed significantly to the conception, study design and preparation of the article, read and approved the final version before publication).
Special contribution:
Polina V. Tkachenko – review of the publications, development of the study design, selection and examination of patients, data processing, analysis and interpretation, statistical data processing, writing the text of the manuscript, checking critical content.
Vadim D. Daminov – scientific revision of the text of the manuscript, approval of the manuscript for publication.

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The authors declare no obvious or potential conflict of interest associated with publication of this article.

Ethics Approval:
The authors state that all the procedures used in this paper comply with the ethical standards of the institutions that carried out the study and comply with the Helsinki Declaration as revised in 2013. This study was approved in Local ethical committee of the National Medical and Surgical Center named after N.I. Pirogov, Protocol № 15, 19.08.2020.
Consent for Publication:
Consent of patients (their representatives) to the processing and publication of non-personalized data was obtained.

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