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RESEARCH REPORT

CLINICAL EVALUATION OF FUNCTIONAL ELECTRICAL STIMULATION EFFECTIVENESS OF ANTAGONISTIC MUSCLE GROUPS AT WRIST AND ANKLE IN PATIENTS AFTER ISCHEMIC STROKE IN LONG TERM FOLLOW UP

OCENA KLINICZNA SKUTECZNOŚCI FUNKCJONALNEJ STYMULACJI ELEKTRYCZNEJ MIĘŚNI ANTAGONISTYCZNYCH STAWU NADGARSTKA I SKOKOWEGO U CHORYCH PO UDARZE NIEDOKRWIENNYM W OBSERWACJI DŁUGOTERMINOWEJ

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ABSTRACT

Introduction

So far, no detailed evaluation of the results of neuromuscular therapy with functional electrical stimulation combined with kinesiotherapy in long-term observation with clinical methods assessing the scale of post-stroke deficits, muscle strength and the severity of the spasticity symptom on the more paresis side has been performed.

Aim

The aim of this study was to compare results of neuromuscular functional electrical stimulation algorithm (NMFES) associated with a uniform system of kinesiotherapy based mainly on proprioceptive neuromuscular facilitation (PNF) procedures versus the same system of applied kinesiotherapy alone in home-based treatment of ischemic stroke patients in two months follow up.

Material and methods

The same set of clinical studies has been applied to a group of 25 healthy volunteers once as well as three times (T0- at hospital ward up to 7 days after an incident, T1- after 21 days of treatment at a hospital ward, T2-after 62 days of home-based treatment) to the 50 patients after ischemic stroke divided into two groups, 25 subjects each (NMFES+K and K groups). Evaluation of treatment effects in two groups of patients was performed with NIHSS scale, Lovett's scale and Ashworth's scale.

Results

After 60 days of applied treatment, only patients of the NMFES+K group represented a statistically significant decrease of NIHSS scale score, indicating the retirement of stroke symptoms. The symptom of increased muscle tension evaluated in the Ashwort's scale in patients of the NMFES+K group significantly decreased but not in patients of K group. The muscle force of extensor muscles of upper and lower extremities significantly increased only in patients of the NMFES+K group. In general, patients from both groups did not present significant abnormalities in sensory perception within dermatomes C5-C7 and L5-S1 on the more paretic side.

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Conclusions
The proposed personalized, safe and controlled in use a NMFES electrostimulation algorithm gives better, and long-lasting functional effects than previously used as a standard, making it a targeted treatment method. In patients after an ischemic stroke, this treatment reduces post-stroke deficits, increases muscle strength, and reduces the severity of the spasticity symptom on the more paralyzed side.

Keywords: ischemic stroke, rehabilitation, functional neuromuscular stimulation, proprioceptive neuromuscular facilitation, clinical evaluation

STRESZCZENIE
Wstęp
Dotychczas nie dokonywano szczegółowej oceny wyników leczenia terapią nerwowo-mięśniowej funkcjonalnej stymulacji elektrycznej skojarzonej z kinezyterapią w obserwacji długoterminowej metodami klinicznymi, oceniających skalę deficytów poudarowych, siłę mięśni oraz nasilenie objawu spastyczności po stronie bardziej niedowładnej.

Cel
Celem pracy było porównanie wyników skuteczności algorytmu funkcjonalnej elektrostymulacji nerwowo-mięśniowej (NMFES) połączonego z jednolitym systemem kinezyterapii opartym głównie na terapii PNF, z tym samym systemem stosowanej samej kinezyterapii w leczeniu chorych po udarach niedokrwiennych mózgu w warunkach domowych w obserwacji dwumiesięcznej.

Materiał i metody
Ten sam zestaw badań klinicznych przeprowadzono na grupie 25 zdrowych ochotników jednorazowo i trzykrotnie (T0-na oddziale szpitalnym do 7 dni po incydencie, T1- po 21 dniach leczenia na oddziale szpitalnym, T2-po 62 dniach leczenia w domu) u 50 chorych po udarze niedokrwiennym, podzielonych na dwie grupy po 25 osób każda (grupy NMFES+K i K). Ocenę efektów leczenia w dwóch grupach pacjentów przeprowadzono za pomocą skali NIHSS, skali Lovett oraz skali Ashworth.

Wyniki
Po 60 dniach stosowanego leczenia, tylko pacjenci z grupy NMFES+K wykazywali statystycznie istotny spadek wyniku w skali NIHSS wskazujący na ustąpienie objawów udaru mózgu. Objaw wzmożonego napięcia mięśniowego oceniany w skali Ashworta u pacjentów z grupy NMFES+K istotnie zmniejszył się, ale nie u pacjentów z grupy K. Siła mięśni prostowników kończyn górnych i dolnych istotnie wzrosła jedynie u pacjentów z grupy NMFES+K. Ogólniepacjenci z obu grup nie wykazywali istotnych nieprawidłowości w percepcji czucia powierzchniowego w obrębie dermatomów C5-C7 i L5-S1 po stronie bardziej niedowładnej.

Wnioski
Zaproponowany spersonalizowany, bezpieczny i kontrolowany w użyciu algorytm elektrostymulacji NMFES daje lepsze i długotrwałe efekty funkcjonalne niż dotychczas stosowany jako standard, co czyni go celowaną metodą leczenia. U pacjentów po udarze niedokrwiennym, terapia ta zmniejsza deficyty poudarowe, zwiększa siłę mięśni oraz zmniejsza nasilenie objawów spastyczności po stronie bardziej niedowładnej.

Słowa kluczowe: udar niedokrwienny, rehabilitacja, funkcjonalna stymulacja nerwowo-mięśniowa, proprioceptywne ułatwianie nerwowo-mięśniowe, ocena kliniczna

Introduction

The strategy of treatment the patients after an ischemic stroke includes specific therapeutic procedures of kinesiotherapy and physical therapy as well as pharmacological treatment (Adams *et al.* 2003, Berge *et al.* 2021). The modifications depend mainly on the onset and severity of the pathological symptoms and the contraindications or indications for pharmacological treatment, e.g., thrombolytic, antiplatelet or anticoagulant treatment. Rehabilitation is mainly targeted to decrease a spasticity symptom and increase the activity of paretic muscles (Duncan *et al.* 2005). The emergence of new treatment and rehabilitation methods in stroke patients is promising in the development of neurological rehabilitation. Most treatments are not yet widely accepted and are still under clinical trials.

The kinesiotherapeutic procedures performed by physiotherapists in patients after ischemic stroke are based mainly on the PNF method, i.e., "proprioceptive neuromuscular facilitation" (Adler *et al.* 2014, Hindle *et al.* 2012). The remaining procedures are individualized, depending on the psychophysical state of the patient, but they mainly include passive, strengthening, and active muscles exercises on the paretic side, exercises to reduce the spasticity symptom (PIR – post-isometric relaxation), and other exercises to stimulate proprioceptors. During the 10-days stay at the hospital ward, upright positioning is carried out with teaching to sit down, teaching to change positions and global movements of the body performed during everyday life (e.g., changing positions in bed, changing from a wheelchair to a chair). Another element of rehabilitation procedures is teaching to walk (locomotion), including walking with handrails and walking with the use of orthopaedic equipment (walking frame, quadruped). Other conducted exercises are breathing and balance, in which the eyesight, hearing, touch, balance, speech and deep feeling receptors are exercised (Coleman *et al.* 2017).

Physical therapy treatments applied to patients after ischemic stroke include mainly "warming therapy" and electrostimulation of paretic muscles to improve the actions of motor units' activity undergoing the pathological changes of neurogenic type. Modalities of electrotherapy include most commonly functional electrical stimulation (FES), and neuromuscular functional electrical stimulations (NFES), and their variable effectiveness with various combinations of stimuli algorithms have been proven (Knutson *et al.* 2015).

Electrotherapy is sometimes enriched with neuromuscular functional electrical stimulation of the muscles acting antagonistically at the wrist and the ankle joints described by Lisiński *et al.* (2008). Similarly, to the studies of Kraft *et al.* (1992), who used a combination of PNF and functional electrical stimulation (FES) in stroke patients, a significant improvement in the function of weak muscles of the symptomatic extremities was found, both upper and lower. Until now, however, studies in this area were performed in relation to a small group of patients after ischemic stroke (N = 24) in short-term observation (after 20 days). The question arises, will these positive effects of kinesiotherapy (PNF mainly) associated with NMFES electrotherapy of antagonistic muscles acting at the wrist and the ankle "survive" in a longer observation period in ischemic stroke patients?

Aim

The aim of this study is to compare results of neuromuscular functional electrical stimulation algorithm (NMFES) associated with a uniform system of kinesiotherapy based mainly on PNF procedures versus the same system of the applied kinesiotherapy alone in home-based treatment of ischemic stroke patients in two months follow up. The evaluation of treatment effects in two groups of patients will be performed with clinical studies.

Subjects and methods

Subjects and study design

The same set of clinical studies has been applied to a group of 25 healthy volunteers once, as well as three times (T0-at hospital ward up to 7 days after incident, T1-after 21 days of treatment at hospital ward, T2-after 62 days of home-based treatment) to the 50 patients after ischemic stroke divided into two groups, 25 subjects each. Patients of the first group gave their written consent to receive both kinesiotherapy (based on PNF mainly) associated with NMFES electrotherapy of antagonistic muscles acting at the wrist and the ankle (NMFES+K group), patients of the second group were obligated to receive a similar set of only kinesiotherapeutic procedures under the supervision of a physiotherapist and agreed to this status. Patients of the second group could not receive electrotherapy because of the contraindications, which among others, included cardiovascular complications. Both patients of two groups and healthy volunteers did not differ with demographic and anthropometric characteristics; the patients of both groups were treated with the same duration (Table1). Data received in a healthy group of subjects was used as a control for comparison with patients.

The criteria for patient's enrollment in the studies were the age from 40 to 70 years, clinically proven ischemic stroke with MRI evidence immediately after an ischemic event in the acute phase of a stroke. Then, the patients were monitored in the subacute phase of stroke (days 8–10) and after the end of early post-stroke rehabilitation for 4–6 weeks in the chronic phase of ischemic stroke.

Both the NMFES + K group and the K group patients showed similar symptoms of ischemia in the fronto-parietal (45%) or subcortical (55%) areas in the MRI studies. The ischemia area in the cross-section (coronal) was on average 276 mm^2 ± 65mm^2 in the K group and 297mm^2 ± 82mm^2 in the NMFES+K group.

Criteria for excluding patients from the research were epilepsy episodes and other consequences of direct craniocerebral or spine injuries, severe cardiovascular disorders, pregnancy, implants that were ferromagnetic, electronic implants such as a pacemaker or a cochlear implant.

For the performance of non-invasive examinations and electrotherapy treatments, the consent of the Bioethics Committee of the Medical University of Karol Marcinkowski in Poznań was obtained (Resolution 1279/18).

Clinical evaluation

The NIHSS scales (Brott *et al.* 1989, Young *et. al.* 2005), the muscle strength rating scale according to Lovett (Lovett and Martin 1916, Cuthbert and Goodheart 2007), and the scale of assessments of muscle tension according to Ashworth (Brott *et al.* 1989, Bohannon and Smith 1987) were used for evaluation of the neurological status of patients by three rehabilitation physicians. The sensory

Table 1. Characteristics of the studied subjects.

Study group Variable	Healthy volunteers (control) N = 25 13♀, 12♂		PatientsNMFES+K group N = 25 12♀, 13♂		Patients K group N = 25 14♀, 11♂	
	Mean ± SD	Min-Max	Mean ± SD	Min-Max	Mean ± SD	Min-Max
Age	42.1 ± 3.7	30–52	60 ± 5.1	44–69	61 ± 3.7	58–68
Height (cm)	164.3 ± 5.3	158–181	164.1 ± 5.1	157–176	166.3 ± 4.1	163–178
Weight (kg)	70.4 ± 5.1	54–82	71.2 ± 4.1	52–87	73.0 ± 5.1	51–89
Observation time T0-T2 (days)	NA	NA	61 ± 2	51–70	62 ± 3	53–71

perception was assessed according to the dermatomal scheme using the tactile method with von Frey's filaments (Semmes-Weinstein monofilaments) (Haloua *et al.* 2017, Lisiński and Huber 2017).

The National Institute of Health Stroke Scale (NIHHS) unambiguously defines criteria that significantly correlate with the severity of a stroke, mainly in the monitoring of damage in the anterior cerebral vascularization area and has a large prognostic value in terms of mortality. Value 0 – indicates no deviation from the neurological status, and a value greater than 20 indicates significant neurological deviation and indicates an increased risk of mortality.

Six grades Lovett's scale defines the muscle force, where 0 reflects no muscle voluntary contraction, and 5 expresses full ability to perform an active movement with a heavy load.

Five-grade Ashworth's scale is used to assess the increased muscle tone (clinically the spasticity symptom). The test consists of performing the passive movement when performing 0 means no increased muscle tone and 4 the extremity immobilized in flexion or extension.

Sensory perception examinations with calibrated silicon von Frey's monofilaments included three-touch trials at areas of dermatomal innervation (C4-S1). If a subject reported the touch sensation applied to the skin twice, it was assumed as a positive test result. Perception evoked by pressure with the filament of 0.30 mm in diameter corresponded to normal perception, with 0.12 mm to hyperesthesia and with 0.55 mm to analgesia.

Treatment with NMFES

A personal, mobile, four-channel stimulator (NeuroTrac® Sports XL, Verity Medical Ltd., UK) was used for electrostimulation of antagonistic muscle groups acting at the wrist and the ankle (Figure 1).

The stimulating device was equipped with an algorithm of parameters of electrical stimuli individually adjusted for a patient from the NMFES+K group, based on surface electromyography (sEMG)recordings and electroneurography(ENG) testes performed in T0. The description of the analysis and interpretation of the sEMG and ENG test results is provided in other papers (Lisiński *et al.* 2008, Huber *et al.* 2013, Lisiński and Huber, 2017).

The principles of NMFES stimulation of muscles acting antagonistically on the wrist (extensors carpi muscles group versus flexor carpi muscles group) and the ankle (tibialis anterior muscle versus calf muscles) during applied electrotherapy sessions are described in the paper of Lisiński *et al.* (2008).

The device has the option to read out from memory data on the frequency and regularity of the patient's stimulation, which is valuable information for treatment verification (Table 2).

The therapist could also set parameters, save, and secure the setting to prevent unplanned changes performed by participants. This had a significant impact on patient's behavior, who, while being under control, more carefully followed the stimulation regime. Two pairs of self-adhesive surface electrodes (AxelgaardUltrastim Wire Neurostimulation Electrodes with MultiStick Gel, 5 cm × 5 cm, Axelgaard Manufacturing Co. Ltd., Denmark) were placed over the skin of muscles to perform the electrostimulations in alternative mode. The anode was placed on a muscle belly while the cathode on the distal tendon of a muscle.

The stimulation algorithm included the duration of one stimulation session (at least twice a day) for 14–22 minutes (18 minutes on average), depending on the severity of the changes in nerve impulses transmission within motor fibers of lower extremity nerves (peroneal and tibial) determined in ENG tests, and the results of the sEMG frequency parameter recorded during the maximal muscles contraction attempt (34–68 Hz, 47.3 Hz on average; Table 2). The frequency of bipolar rectangular electric pulses applied

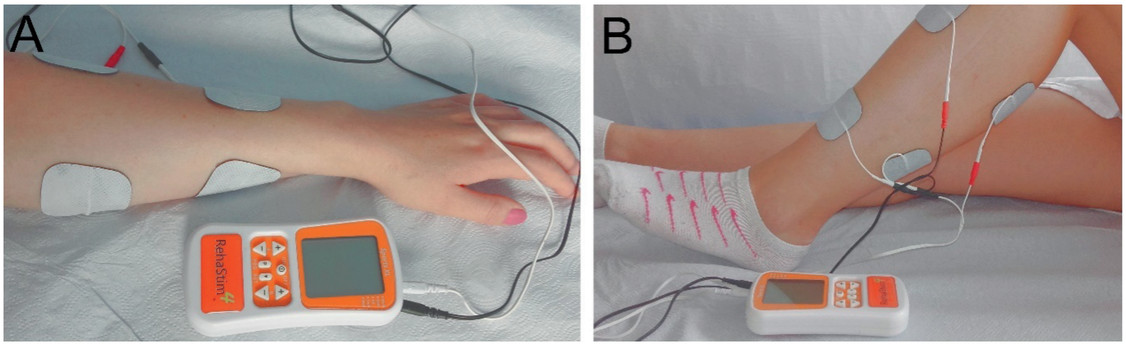

Figure 1. Placement of electrodes stimulating the muscles acting antagonistically on the wrist (A, extensors carpi muscles group versus flexor carpi muscles group) and the ankle (B, tibialis anterior muscle versus calf muscles) during applied electrotherapy sessions in ischemic stroke patients of the NMFES+K group.

Table 2. Summary of applied NMFES parameters.

Study group Variable	Patients ofNMFES+K group, N = 25 12♀, 13♂	
	Mean ± SD	Min-Max
Expected stimulation (hours)	20.3 ± 1.5	18–24
Detected stimulation (hours)	19.7 ± 1.7	15–22
Train stimulation frequency (Hz)	47.3 ± 3.2	34–68
Single stimulus duration (ms)	14.7 ± 3.1	12.2–17.1
Train duration (sec)	4.0 ± 1.2	3–6
Intervalbetweentrains (sec)	4.1 ± 1.5	2–5
Session duration (mins)	18.9 ± 1.7	14–22
Applied stimulus strength (mA) Upper extremity muscles -flexors -extensors	26.3 ± 3.2 27.1 ± 3.1	28–34 22–32
Applied stimulus strength (mA) Lower extremity muscles -flexors -extensors	25.7 ± 3.0 28.1 ± 3.5	22–35 24–31

in series also depended on the frequency of sEMG recorded recruitment of muscle motor units during attempts of three maximal contractions. Short bursts (pulses) of electrical stimuli to optimize stimulation in terms of charge required to reach threshold and selectivity of stimulated motor units was introduced as a novel electrostimulation procedure.

The single stimulus duration was calculated from the repetitive measurements of susccessive single muscle motor action potentials in sEMG recordings (14.7 ± 3.1 ms on average, range from 12.2 to 17.1ms). In general, patients with moderate neurogenic changes received stimuli with duration from 12 ms to 14 ms, and those with severe neurogenic changes a duration of 15 ms to 17 ms. Patients who represented severe neurogenic changes received stimulations with frequencies from 34–68 Hz (47.3 ± 3.2 Hz on average).

The sessions were performed five times a week for not less than 2 months. Intervals of 2–5 s between pulse series were 4.1 ± 1.5 s on average. All participants were instructed to increase the stimulus strength (Table 2, bottom) and reach its maximal value when the toe's visible movement was observed without intrusive pain.

Treatment with kinesiotherapy

Rehabilitation treatments conducted by physiotherapists were mainly based on the PNF method. The therapist applied patterns of flexion, abduction, and external rotation as well as extension, abduction and internal rotation for the paralyzed upper and lower extremities. Other kinesiotherapy treatments were individualized depending on the psychophysical state of the patient but mainly included passive, supportive and active exercises on the side of paresis, exercises reducing the spasticity symptom (PIR – post-isometric relaxation treatments), stretching exercises – stimulating proprioreceptors.

During the 10-days stay in the neurological rehabilitation ward, upright positioning was carried out with teaching to sit down, teaching to change positions, and global movements performed during everyday life (e.g., changing position in bed, changing from a wheelchair to a chair). Another element of the rehabilitation procedures was learning to walk (locomotion), including walking with handrails and walking with orthopedic equipment (walking frame, quadruped). Physiotherapy treatments included mainly "warming therapy"; no electrotherapy treatments other than those described in the study were performed. All patients of both groups (NMFES+K and K groups) received the same sets of procedures with the same intensity.

Data analysis

Statistica software, version 13.1 (StatSoft, Poland), was used for calculations. Descriptive statistics included mean and median values, standard deviations (SD), and minimum (min) and maximum (max) values for measurable variables. Minimum, maximum, and median values were used for the description of ordinal scale variables. The normality distribution and homogeneity of variances were conducted mostly with Shapiro-Wilk tests and with Leven's tests in some cases. In 25 patients with ischemic stroke, the median values of parameters from clinical studies were compared using Student's t-test and Mann-Whitney test; in some cases, ANOVA was used. It was assumed that a comparison of values at $p \leq 0.05$ determined significantly statistical differences.

RESULTS

None of the participants reported side effects nor pain during the treatment sessions, and none of them reported persistent pain after the therapy had finished. Data in Table 2 convince that most of the patients maintained the therapy regime because detected stimulation time (19.7 ± 1.7 hours on average) what almost equal to the expected stimulation time (20.3 ± 1.5 hours on average) when it was read-out from the memory of the personal stimulating device.

Results of clinical evaluation at three stages of observation before and after applied treatment in both groups of patients are shown in Figure 2, while the principles are presented in Table 3.

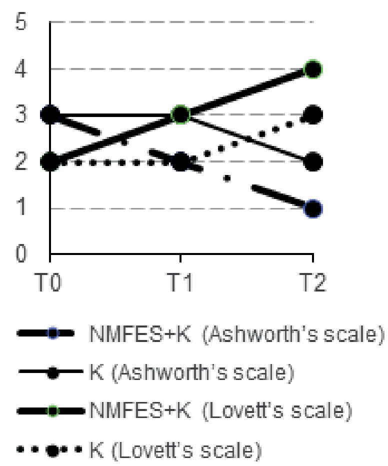

Figure 2. Summary of clinical results recorded in two groups of patients at three stages of observation.

Table 3. Comparison of results from clinical studies recorded in two groups of patients and healthy subjects. Results refer to measurements performed in patients on the paretic side identified in preliminary clinical examinations. When comparing the results of the Ashworth's and Lovett's scale tests, they were cumulatively averaged for the examination of the extensor and flexor muscles of the upper and lower extremities.

Test or parameter	Healthy volunteers N = 25	T0 Acute phase (up to 7 days after incident)		T1 Subacute phase (after 21 days of treatment)		T2 (after 62 days of home-based treatment)		p Patients T0 vs. T2 Before--After	p Healthy vs. PatientsT0 Before	P Healthy vs. Patients T2 After
		Group NMFES+K patients N = 25	Group K patients N = 25	Group NMFES+K patients N = 25	Group K patients N = 25	Group NMFES+K patients N = 25	Group K patients N = 25			
NIHSS scale (0–28)	0	7	7	6	6	4	5	NMFES+K p = 0.03 K p = 0.05	NMFES+K p = 0.008 K p = 0.008	NMFES+K p = 0.04 K p = 0.03
Ashworth's scale (+4–1) -upper extensors -upper flexors	1 1	1 3	1 3	1 2	1 3	1 1	1 2	NMFES+K p = 0.04 K p = 0.05	NMFES+K p = 0.03 K p = 0.03	NMFES+K NS K p = 0.05
-lower extensors -lower flexors	1 1	1 3	1 3	1 2	1 3	1 1	1 3	NMFES+K p = 0.04 K NS	NMFES+K p = 0.03 K p = 0.03	NMFES+K NS K p = 0.03
Lovett'sscale (0–5) -upper extensors -upper flexors	5 5	3 2	3 2	4 3	3 2	4 4	3 3	NMFES+K p = 0.04 K p = 0.05	NMFES+K p = 0.02 K p = 0.02	NMFES+K p = 0.05 K p = 0.04
-lower extensors -lower flexors	5 5	3 3	4 3	3 4	4 3	4 4	4 3	NMFES+K p = 0.03 K NS	NMFES+K p = 0.03 K p = 0.04	NMFES+K p = 0.05 K p = 0.04
Perception FvF (1-normal, 0-hypoaesthesia) C5-C7 L5-S1	1 1	0 1	0 1	1 1	0 1	1 1	1 1	NMFES + K p = 0.03 K p = 0.05	NMFES + K NS K NS	NMFES + K NS K NS

Abbreviations: NS-not significant

Following applied treatment, patients of the NMFES+K group represented a statistically significant decrease of the NIHSS scale score, indicating the retirement of stroke symptoms that was not observed in patients from the group K. However, patients of both groups in T2 still differed in a health status from healthy subjects.

The symptom of increased muscle tension evaluated in the Ashwort's scale in both patients of the NMFES+K and K groups was manifested more in examined muscle flexors than extensors of upper and lower extremities similarly at 3. Applied treatment provided a gradual but significant decrease of the scale index, which could be observed in the patients of the NMFES+K group both in T0 and T1 observation but not in the patients of the K group. In fact, the muscle tension of patients from the NMFES+K group was comparable to the results of the healthy subjects. A similar tendency but related to the muscle force increase of extensor muscles of upper and lower extremities could be observed in patients of the NMFES+K group at p = 0.04. The patients of group K after two months of treatment still differed significantly from healthy subjects taking into account results of the Lovett's scale measurements.

Patients from both groups did not present abnormalities in sensory perception within dermatomes of lower extremities on the paretic side; deficiencies were observed in dermatomes C5-C7 which were observed to be retired in T2.

Discussion and conclusions

Results of similar studies described in this paper have never been presented before. So far, no detailed evaluation of the results of treatment with combined NMFES and PNF therapy in long-term follow-up after 60 days has been performed with the use of a set of clinical evaluation methods selected for the project, assessing the scale of post-stroke deficits, muscle strength and the severity of the spasticity symptom on the more paretic side.

The presented research results indicate a better therapeutic effect with the combined PNF kinesiotherapy and neuromuscular functional electrostimulation than with the use of only PNF kinesiotherapy in patients after an ischemic stroke. Based on the results of this study and Lisiński *et al.* (2008), it can be concluded that the proposed personalized, safe, and controlled use NMFES electrostimulation algorithm gives better, and long-lasting functional effects than previously used as a standard, making it a targeted treatment method. In patients after ischemic strokes, this treatment reduces post-stroke deficits, increases muscle strength, and reduces the severity of the spasticity symptom on the more paralyzed side.

From the application point of view, the research will make it possible to track the effectiveness of treatment, especially with the method of functional muscle electrostimulation on the basis of biofeedback in patients after ischemic strokes; from the cognitive point of view, they will provide knowledge about the phenomena of functional reorganization of the neural centers of the spinal cord and the phenomenon of neuroplasticity at the supraspinal level.

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