ECRONICON OPEN ACCESS

EC NEUROLOGY
Research Article

Effects of a Therapy Based on a Functional Electrical Stimulation of Bimanual Activation Combined with the Training of Electromyographic Biofeedback on the Motor Function of the Upper Limb in Subjects with Stroke

Sebastián Eduardo Alarcón Arancibia[1]*, Barbara Sánchez O[1], Hachi Manzur V[2] and Julio Torres E[1]

[1]*Kinesiologist, Service of Physical Medicine and Rehabilitation, Clínica Dávila, Recoleta, Chile*

[2]*Hospital Clínico Universidad Católica, Santiago, Chile*

***Corresponding Author:** Sebastián Eduardo Alarcón Arancibia, Kinesiologist, Master degree in Neurorehabilitation, Service of Physical Medicine and Rehabilitation, Clínica Dávila, Recoleta, Chile.

Received: December 14, 2020; **Published:** January 30, 2021

Abstract

Introduction: Stroke is the leading cause of death and disability in Chile. More than 85% of patients suffer from hemiplegia and more than 69% functional motor disability of the upper extremities. This alteration generates an impact on the use of the upper limb, affecting the various activities of people's daily lives. There are no studies that combine electromyographic biofeedback therapy and bimanual activation with functional electrical stimulation in subjects with stroke. Therefore, there is interest in determining the effect of a training protocol based on Functional Electrical Stimulation (FES) with bimanual activation and biofeedback therapy on the function of the upper limb.

Methodology: 15 subjects with stroke between 40 and 85 years recruited in the outpatients neurorehabilitation program of Clínica Dávila, randomized in an experimental group and in two control groups of 5 subjects. In each session the experimental group will train fifteen minutes of bimanual activation with functional electrostimulation and then a ten-minute biofeedback training program, while the control 1 and control 2 group trained under the same conditions but with placebo FES and placebo BF-EMG respectively.

Results: There were significant changes in the experimental group after the intervention.

Conclusion: This study suggests the electrical stimulation works and biofeedback as a tool for the rehabilitation of the upper limb in subjects with stroke.

Keywords: *Stroke; Neurofeedback; Rehabilitation*

Introduction

Our country has experienced a great change in its age composition in recent years, positioning itself as one of the oldest countries in Latin America. This, in turn, has brought changes in the health situation of Chileans, where cerebrovascular accident (CVA) is the main cause of death, with 9,004 deaths in 2013, which corresponds to one person per hour. It is estimated that there are 24,964 new cases annually (69 cases each day) [1].

More than 85% of stroke patients suffer from hemiplegia, and more than 69% of them experience a functional motor disability of the upper limbs [2]. In addition, it is the first specific cause of healthy years of life lost due to disability in those over 74 years of age. For all the above, stroke is a critical Public Health problem [1].

According to the latest AUGE clinical guideline for ischemic cerebrovascular accident, in the Chilean population, 14% of patients with severe paresis, with little or no active movement upon admission, experienced a complete recovery, while 30% achieved a partial recovery. This deficit generates an impact on the use of the upper limb for reaching, grasping, manipulating, environmental exploration, balance, thus affecting the various activities of daily life [1]. Despite all interventions, functional motor disability often appears in the upper limbs rather than the lower limbs. One of the reasons may be the high frequency with which the middle cerebral artery (MCA) or its derivatives are affected in stroke, whose territory includes cortical areas corresponding to the motor functions of the upper extremities (75% of the extension of the affected territory by the ACV). Lang., *et al*. noted that upper extremity motor disability significantly affects stroke patients' performance of activities of daily living, such as eating, wearing clothes, or washing their face [2,3]. These functions of the upper extremities have been emphasized as an important element in humans [4]. From this perspective, this disease is a generator of important and diverse sequelae both in the motor and cognitive fields, which significantly interfere with the quality of life of those who present it. There are a variety of therapeutic interventions for upper limb motor recovery, ranging from neurodevelopmental techniques, bimanual training, movement restriction therapy, strength training, mirror therapy, mental practice, biofeedback, virtual reality technology and movement therapy. assisted by robotic devices (Table 1) [1].

Multiple previous studies have been conducted using different techniques in combination. Hyun Seok [3] compared two groups of subacute stroke sequelae subjects. The experimental group received restrictive therapy combined with visual biofeedback. The latter consisted of a device that projected different games on the screen connected to a dynamometer and a pinch meter, without using EMG. The control group only received visual biofeedback therapy. No significant differences were found between both groups in all the variables evaluated; Purdue Pegboard test, JAMAR grip strength test, Wolf test for motor function, EFM-ES, motor index, Korean version of the modified Barthel index. To date, there are no studies that combine electromyographic biofeedback therapy with FES in subjects with subacute cerebrovascular accident sequelae.

Biofeedback

In this technique, biological signals are presented to the user through a visual stimulus. The use of visual biofeedback is recommended to improve functions and motor performance of the upper limb in sequelae of stroke [5-7], but the dose of biofeedback has not yet been an investigated parameter [8]. In a meta-analysis, Moreland and Thomson found a small increase in upper limb functionality using biofeedback compared to conventional therapy [8].

For this study, the EMGOne device was used, which is a Chilean device based on low-cost electromyographic biofeedback (BF-EMG), which allows the detection of muscle activity, amplifies it and displays it as feedback through a visualized video game. on a tablet. This favors proprioception [9] and motivation [7], improves motor learning, attention [5] and functions of both the upper [1,3,8] and lower [10-12] limbs with more results. effective in less time [13-16], although it is possible to find compensatory movement strategies [17].

Functional electrostimulation (FES): It is a muscle stimulation technique by means of electrical current applied by a system of superficial electrodes that induce an immediate muscular contraction of the skeletal muscles to achieve functional movements [18]. It increases active movement after stroke and has better evidence in the subacute stage [19-21]. It reduces spasticity and improves activation, range, and functionality in a hemiparetic wrist [22]. However, more research is needed to reach conclusive results [23]. For this study, TrainFes was used, an FES device created by the Chilean company TrainFes®, which provides different treatment modalities. In this study, a positional recording of the healthy limb will be carried out which, when detecting the wrist extension movement, will trigger the same move-

ment in the paretic limb through direct stimulation of the involved muscles. The waveform is square symmetric biphasic, with control per current and compensated. The intensity ranges from 0 - 130 mA, with steps of 1 mA, a frequency: 1 - 60 Hz and a pulse width: 20 - 400 uS per phase. All these specifications guarantee safety for tissues with compensated waves, which implies that the sum of charges (Q) applied is 0, so it must have 2 polarities, and the sum of the charges of the positive phase and those of the negative phase must be equal so that they are cancelled. This allows there to be no net accumulation of charge in the tissues; otherwise, the net accumulated charges generate chemical effects on the tissues. In addition, TrainFES® has international standards, complying with ISO13485 and IEC606001.

Functional electrostimulation is being widely applied with good evidence, but we believe that it can be complemented with other types of therapies. It is important to be able to carry out this study since currently there are no studies that combine conventional therapy, functional electrical stimulation and electromyographic biofeedback and in subjects with sequelae of cerebrovascular accident. In addition to this, and the impact that the function of the upper limb has on the quality of life of the subjects, there is an interest in determining the effect of a training protocol based on conventional therapy, functional electrical stimulation (FES). with bimanual activation and biofeedback therapy in upper limb function.

Hypothesis

The association of the training protocol with conventional therapy, functional electrical stimulation, and electromyographic biofeedback produces favorable results in the activation and opening function of the paretic hand in patients with subacute cerebrovascular accident.

Objective of the Study

To demonstrate the efficacy of an intervention protocol of conventional therapy, functional electrostimulation and biofeedback in subjects with subacute cerebrovascular accident in the functionality of the paretic upper limb.

Methodology

Design

The procedures of this quantitative, longitudinal, randomized controlled experimental type research. respected the ethical standards consistent with the Declaration of Helsinki (1975), updated in 2008. This study and its informed consent were approved by the ethics committee of the northern metropolitan health service and of the Dávila Clinic, where the investigation was carried out.

Sample

According to studies that used biofeedback and functional electrical stimulation, a minimum of 30 subjects are needed [2,3]. Considering that it is a pilot study, 15 subjects were measured between March to October 2019.

Inclusion criteria: Cooperative subjects aged between 40 and 85 years with subacute supratentorial ischemic stroke, between 7 days and 6 months of evolution, with sequelae of hemiparesis of the upper limb, with M3 activation in the manual muscle test for all muscle groups of the hand, with 0 and 1+ on the modified Ashworth scale and that they maintain a seated position.

Exclusion criteria: Were visual disorders, sensorimotor of the undamaged upper limb, previous cerebrovascular accident, musculoskeletal alterations, surgeries or functional impotence due to pain VAS 8/10 that do not allow mobilization of the paretic hand.

Randomization

The randomization was through a fish tank in three groups: Experimental, Control 1 and Control 2, in which finally 5 subjects were assigned to each group (Figure 1).

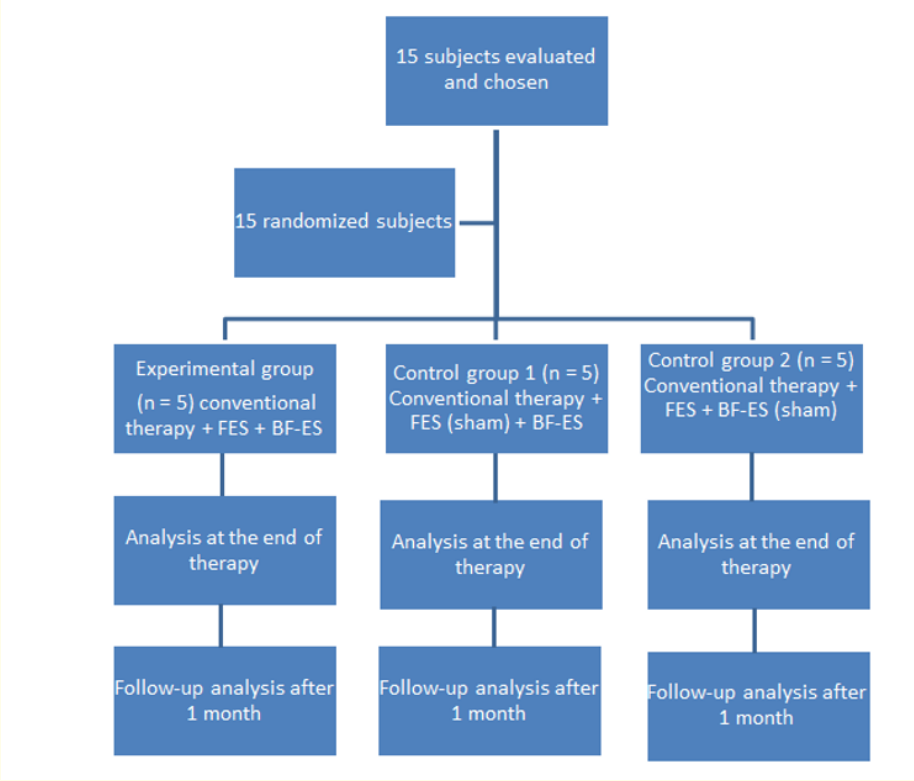

Figure 1: *Research flow chart.*

Blinding

This study is double blind. The evaluator was blind at the beginning, at the end of the second and fourth weeks, and after one month of follow-up, he will be blind for the following measurements in the most affected upper limb; manual muscle test (TMM) together with the modified Ashworth scale for the wrist flexor extensors and the Fugl-Meyer scale [25] for the upper limb (EFM-ES). The subjects were also blind. Data analysis was also performed by a blinded statistician at the end of therapy and at the end of follow-up. Only the therapist who applied the therapy was not blind.

Intervention

It lasted four weeks, three times a week. Each subject was seated in a chair with a back, with a table in front and the arms in a position of fifteen degrees of shoulder, ninety degrees of elbow flexion and zero degrees of wrist. In each session, the experimental group trained in the first place 30 minutes of conventional therapy that consisted of 75% of the time in neuromuscular activation, two exercises per muscle group, firstly without resistance and secondly, moderate resistance. For each exercise there were fifty repetitions. The muscle groups to be trained were: flexion and extension of the wrist and fingers and pronosupination. The other 20% of the therapy was sustained flexibilization of twenty seconds for each muscle group; flexors, extensors, pronators, supinators. Finally, 5% of the therapy, in practice, protopathic and epicritic sensory stimulation was performed with four elements: a brush, a ball with plastic tips, a sponge and a vibrator all over the forearm, wrist and fingers, with a dosage of 20 repetitions for each element.

Then, they trained fifteen minutes of bimanual activation with functional electrostimulation, where each subject performed twenty repetitions of bimanual wrist extension within one minute, holding two cones with a ring in the middle which they had to keep in that position throughout the extensor movement and with one-minute rest in rest position without activation. Finally, they underwent a 10-minute EMGONE biofeedback training program, which consisted of overcoming obstacles that were at the bottom of the tablet screen at a speed of 0.5 in the application, normal gravity of 1.0x in the configuration, with obstacles that appear every five seconds, and with a size of 50 cm.

As for the control groups, control group 1 trained under the same conditions but functional electrostimulation was placebo with a suboptimal intensity, while control group 2 also received the same treatment as the experimental group but the administration of placebo electromyographic biofeedback with a submaximal precalibration (Figure 2).

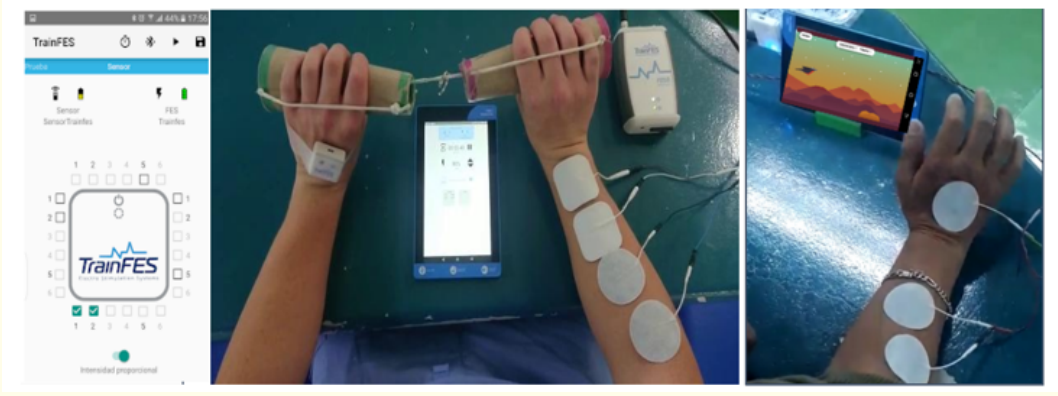

Figure 2: *Therapy based on the use of a functional bimanual electrostimulator with electromyographic biofeedback.*

Results

Statistics

The Willcoxon test was used to compare the results between the groups and the values before and after treatment for all subjects. The results were expressed as medians with the minimum and maximum value. The level of statistical significance $p < 0.05$ was considered for the comparison of the variables before and after treatment and between the three study groups (Table 1).

Fugl-Meyer test

In the experimental group, there is a median difference of 13 points, and in the two control groups there were no significant changes for this test.

In total, eleven subjects increased their score on the scale; all subjects from the experimental group (100%), four subjects from control group 2 (80%) and only one from control group 1 (20%) (Figure 3).

There were only two outliers, one for control group 1 and one for control group 2.

	Exp	Min-max	Control 1	Min-max	Control 2	Min-max
Fugl-Meyer						
Before	32	14-58	64	55-66	60	40-63
Then	51	32-66	64	12-66	65	51-66
Difference	13	8-27	-1	-6-11	6	-1-11
P value	*(p = 0,04)		(p = 0,7)		(p = 0,078)	
Sensitivity						
Before	7	10-12	9	3-4	10	8-12
Then	10	9-12	12	10-12	12	11-12
Difference	2	0-6	3	2-6	2	0-3
P value	(p = 0,1)		*(p = 0,04)		(p = 0,06)	
Rank						
Before	15	15-24	24	21-24	24	21-24
Then	24	15-24	24	24-24	24	21-24
Difference	7	0-9	0	0-3	0	-3-3
P-value	(p = 0,1)		(p = 0,3)		(p = 1)	
Pain						
Before	13	10-23	19	15-23	19	15-23
Then	20	15-24	23	20-24	24	20-24
Difference	3	1-13	4	-3-9	5	0-6
P value	*(p = 0,043)		(p = 0,138)		*(p = 0,066)	
TMM FM						
Before	3	3-5	4	3-5	3	3-4
Then	4	3-5	5	4-5	5	4-5
Difference	1	0-1	0	0-2	1	1-2
P value	*(p = 0,046)		(p = 0,180)		*(p = 0,034)	
TMM EM						
Before	3	3-4	4	3-4	3	3-4
Then	4	4-5	5	4-5	5	4-5
Difference	1	0-1	1	0-2	1	1-2
P value	*(p = 0,046)		(p = 0,102)		*(p = 0,034)	
Ash FM						
Before	0	0-1	0	0-1	0	0-1
Then	0	0-0	0	0-0	0	0-0
Difference	0	-1-0	0	-1-0	0	-1-0
P value	(p = 0,157)		(p = 0,317)		(p = 0,317)	

<Ash EM						
Before	0	0-1	0	0-1	0	0-1
Then	0	0-0	0	0-0	0	0-0
Difference	0	-1-0	0	-1-0	0	-1-0
P value	(p = 0,317)		(p = 0,317)		(p = 0,317)	

Table 1: *Analysis of intergroup results.*

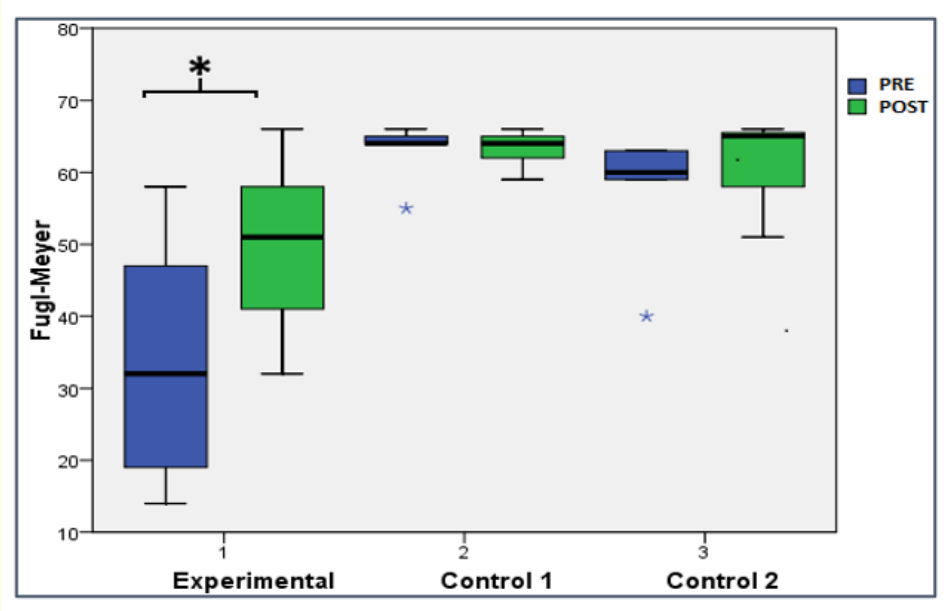

Figure 3: *Comparison of the changes for the Fugl-Meyer test of the paretic upper limb in the different groups before and after the intervention.*

TMM

For the group of wrist extensors, only the statistically significant changes were for the experimental group and the control group 2. As for the control group 1, there were no significant changes. This same phenomenon occurred for the wrist flexor groups (Figure 4). There were only two outliers, one for the experimental group and one for the control group 1.

Ashworth

There were no significant changes for tone in any of the muscle groups. All subjects completed the research protocol with Ashworth 0 in all muscle groups.

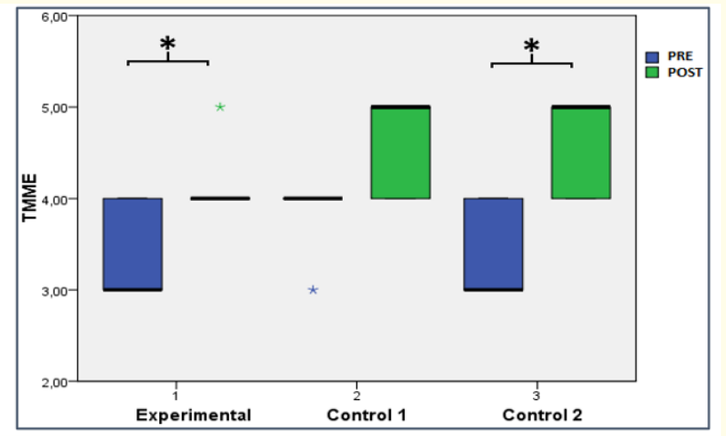

Figure 4: *Comparison of changes in the manual muscle test for the paretic upper limb wrist extensors in the different groups before and after the intervention.*

Discussion

Stroke can cause significant impairment of the function of the upper extremities that affects the performance of activities of daily living (ADL). Functional electrical stimulation (FES) is related to day-to-day functionality. This research only analyzes the motor results, but the impact it has on ABVD remains to be analyzed.

John Eraifej, 2017 analyzes the impact of the FES on activities of daily living (ABVD). He reaches conclusive results regarding FES and ABVD improvement as long as FES therapy is started after 2 months and not at one year (27). Considering the above, it would be interesting to be able to include scales that target changes at the ABVD level in the future, because although motor scales can demonstrate changes, they do not have a real impact if they are not functional in the daily life of patients. Other scales to use to complement this study may be the ARAT scale, used by Agnes Sturma 2018 (28)

Various rehabilitation technologies have been developed to promote recovery of upper limb motor function after stroke, including robotic devices, virtual reality, and functional electrical stimulation (FES) systems, but there are no interventional studies in the literature that combine FES therapy with Biofeedback.

Intense training and repetition are believed to be key in upper limb recovery after stroke (French et al., 2009, 2010). And this protocol according to its intervention is of intense and repetitive treatment like other studies. (29)

Considering the point of the intervention, it is worth comparing the training time allocated in this protocol for the upper limb, which is 55 minutes, compared to the therapy time that some centers actually allocate, in order to know if it is feasible to implement this therapy. Studies such as those of Christine Smith, 2019 use up to eight therapy sessions using the FES system each lasting one hour, for a period of up to 6 weeks, a dosage very similar to this research.

This time is very different from what physiotherapists use for rehabilitation in their daily lives. (30) For example, in a recent article, Jong et al. (2017) studied 46 stroke patients with poor arm function at three rehabilitation centers in the Netherlands for 8 weeks, and found that physical and occupational therapists spent an average of 4 to 7 minutes on arm treatment per session , which as a total duration was 30 minutes. (31) In this case, it could be discussed how little time is spent on recovering the arm, and how difficult it could be if a physiotherapist wanted to use this protocol in their therapies. (32)

Although repetition is key in motor learning, this study could have used more variability of exercises with different elements and activities for hand function, such as Christine Smith, 2019 who uses different activities (30)

Regarding the results, there are factors that could have affected such as calibration, electrode placement, and muscle response. In clinical practice, if some physiotherapists wanted to use these therapies, they should take into account that the devices and their programming are operator dependent, directly affecting the task and the subject's performance. (33). On the other hand, the non-significant difference between the two control groups is attributed to a ceiling effect because the median of the initial value for all the tests was very high. One way to avoid this with future studies is to use a pre-test system for the homogeneity of the groups at the time of starting the intervention

As limitations, first is the programming of the operator dependent on each device. In addition, there is still little adherence by physiotherapists to new devices and technology. The use of these devices is not for any patient who has suffered a cerebrovascular accident, since they must be cognitively able to understand and follow simple commands, have adequate vision that allows them to see the screen.

Novak and Von Der Heyde, 2013 say that practice, repetition, and structured training programs with appropriate electromyographic biofeedback facilitate the establishment of correct motor patterns (28). The fact of the need for the use of these two devices as combination therapy is debatable, but based on the results of this pilot study and the literature, it is that whether the use of these devices together or in isolation can be suggested.

Conclusion

The combination of the three interventions suggests having a greater impact on hand function in patients with subacute stroke sequelae.

Even so, there were no changes in sensitivity, so only the suggestion of changes in function of the upper limb can be correlated with changes at the motor level.

It is necessary to incorporate new technological elements in rehabilitation, which favor the updating of this and are affordable, low-cost and that thus the subjects can train longer, together with creating better treatment protocols and thus enhance the function of the hand by the importance it has in daily activities.

The non-significant difference of the two control groups is attributed to a ceiling effect because the median of the initial value for all the tests was very high. One way to avoid this with future studies is to also use different scales such as the ARAT scale.

The analysis of the data is still missing in the follow-up of the subjects that are currently being investigated. Due to this, together with the low sample size, and the lack of greater homogeneity of the sample, it is only possible to suggest that the application of functional electrical stimulation and biofeedback together can be a good complement to conventional therapy, but more research is needed in this area.

Bibliography

1. Guía Clínica AUGE. "Accidente cerebrovascular isquémico en personas de 15 años y más". *Serie Guías Clínicas MINSAL* (2013).
2. Ju-Hong Kim. "The effects of training using EMG biofeedback on stroke patients upper extremity functions". *The Journal of Physical Therapy Science* 29 (2017): 1085-1088.
3. Hyun Seok MD., *et al.* "Can Short-Term Constraint-Induced Movement Therapy Combined With Visual Biofeedback Training Improve Hemiplegic Upper Limb Function of Subacute Stroke Patients?". *Annals of Rehabilitation Medicine* 40.6 (2016): 998-1009.
4. Kim HH., *et al.* "Intervenciones para promover la recuperación de la extremidad superior en pacientes con accidente cerebrovascular: una revisión sistemática". *Journal of Korean Society of Occupational Therapy* (2012): 129-145.
5. Pietrosimone Brian., *et al.* "Clinical Strategies for Addressing Muscle Weakness Following Knee Injury". *Clinics in Sports Medicine* 34.2 (2015): 285-300.
6. Urra O., *et al.* "The impact of visual feedback on the motor control of the upper-limb". *IEEE Engineering in Medicine and Biology Society* (2015): 3945-3948.
7. Rehabilitation of Upper Extremity Nerve Injuries Using Surface EMG Biofeedback: Protocols for Clinical Application.
8. Nelson Lonnie a. "The Role of Biofeedback in Stroke Rehabilitation: Past and Future Directions". *Topics in Stroke Rehabilitation* 14.4 (2007): 59-66.

9. Giggins Oonagh M., *et al.* "Biofeedback in Rehabilitation". *Journal of Neuro Engineering and Rehabilitation* 10.1 (2013): 60.

10. Jonsdottir J., *et al.* "Concepts of motor learning applied to a rehabilitation protocol using biofeedback to improve gait in a chronic stroke patient: an A-B system study with multiple gait analyses". *Neurorehabilitation and Neural Repair* 21 (2007): 190-194.

11. Johanna Jonsdottir., *et al.* "Task-Oriented Biofeedback to Improve Gait in Individuals With Chronic Stroke: Motor Learning Approach". *Neurorehabilitation and Neural Repair* 24.5 (2010): 478-485.

12. Rosalyn Stanton., *et al.* "Biofeedback improves performance in lower limb activities more than usual therapy in people following stroke: a systematic review". *Journal of Physiotherapy* 63.1 (2017): 11-16.

13. Oonagh M., *et al.* "Persson and Brian Caulfield Biofeedback in rehabilitation". *Journal of Neuro Engineering and Rehabilitation* (2013).

14. Akkaya N., *et al.* "Efficacy of electromyographic biofeedback and electrical stimulation following arthroscopic partial meniscectomy: a randomized controlled trial". *Clinical Rehabilitation* 26.3 (2012): 224-236.

15. Vanessa Draper. "Electromyographic Biofeedback and Recovery of Quadriceps Femoris Muscle Function Following Anterior Cruciate Ligament Reconstruction". *Physical Therapy* 70.1 (1990): 11-17.

16. Nelson LA. "The Role of Biofeedback in Stroke Rehabilitation: Past and Future Directions". *Topics in Stroke Rehabilitation* 14.4 (2007): 59-66.

17. Taub R., *et al.* "A placebo-controlled trial of constraint-induced movement therapy for upper extremity after stroke". *Stroke* 37.4 (2006): 1045-1049.

18. Axel Forman. "Recovery of supraspinal control of leg movement in a chronic complete flaccid paraplegic man after continuous low-frequency pelvic nerve stimulation and FES-assisted training (2017).

19. Howlett O. "Using functional electrical stimulation with stroke survivors: A survey of Victorian occupational therapists and physiotherapists". *Australian Occupational Therapy Journal* 65.4 (2018): 306-313.

20. Jonsdottir J., *et al.* "Arm rehabilitation in post stroke subjects: A randomized controlled trial on the efficacy of myoelectrically driven FES applied in a task-oriented approach". *PLoS One* 12.12 (2017): e0188642.

21. Cuesta-Gómez., *et al.* "The Use of Functional Electrical Stimulation on the Upper Limb and Interscapular Muscles of Patients with Stroke for the Improvement of Reaching Movements: A Feasibility Study". *Frontiers in Neurology* 8 (2017): 186.

22. Nakipoğlu Yuzer GF., *et al.* "A Randomized Controlled Study: Effectiveness of Functional Electrical Stimulation on Wrist and Finger Flexor Spasticity in Hemiplegia". *Journal of Stroke and Cerebrovascular Diseases* 26.7 (2017): 1467-1471.

23. Eraifej J., *et al.* "Effectiveness of upper limb functional electrical stimulation after stroke for the improvement of activities of daily living and motor function: a systematic review and meta-analysis". *Systematic Reviews* 6.1 (2017): 40.

24. Schuster-Amft C., *et al.* "Effect of a four-week virtual reality-based training versus conventional therapy on upper limb motor function after stroke: A multicenter parallel group randomized trial". *PLoS ONE* 13.10 (2018): e0204455.

25. Amano S., *et al.* "Reliability of remote evaluation for the Fugl-Meyer assessment and the action research arm test in hemiparetic patients after stroke". *List of issues Topics in Stroke Rehabilitation* 25.6 (2018): 432-437.

26. Bernhardt Julie., *et al.* "Agreed definitions and a shared vision for new standards in stroke recovery research: The Stroke Recovery and Rehabilitation Roundtable taskforce". *International Journal of Stroke* 12.5 (2017): 444-450.

Volume 13 Issue 2 February 2021