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Improvement of Gait & Muscle Strength with Functional Electrical Stimulation in Sub-acute & Chronic Stroke Patients

S. K. Sabut, C. Sikdar, R. Kumar, and M. Mahadevappa, *Member, IEEE, EMBS*

Abstract - **The main objective of this work was to evaluate and compare the effects of Functional Electrical Stimulation (FES) therapy in the walking ability and muscle strength studied by electromyography (EMG) analysis between subacute and chronic stroke patients. Eighteen consecutive hemiplegic patients suffering from foot drop were assigned either to subacute or chronic group. Patients of both groups' were treated according to conventional rehabilitation program combined with FES therapy for 12 weeks. At post-treatment, subacute subjects showed a mean increase in walking speed of 29.4% and chronic subjects of 17.1% and the physiological cost index (PCI), with a reduction of 73.1% in subacute subjects and 46.5 % in chronic subjects. Improvement was also found in cadence, step length, and mean-absolute-value (MAV) and root-mean-square (RMS) of EMG signal of tibialis anterior (TA) muscle in both groups, but subacute subjects improved better compared with chronic subjects. Thus we suggested that an early intervention of FES therapy combined with conventional rehabilitation program (CRP) could significantly improve the gait and muscle strength in stroke survivors.**

I. INTRODUCTION

STROKE results an impairment of the sensory-motor systems. Motor weakness, poor motor control, and spasticity result in an altered gait pattern [1]. Rehabilitation of gait after stroke is one of the key issues for all patients as soon as their medical condition is stabilized. Foot drop following stroke prevents the patient from effectively swinging the leg when walking, causing an abnormal gait [2]. Although most motor and functional recovery occurs in the first 3 months after stroke, evidence for effect of therapeutic exercise programs have been found with chronic stroke in motor control, strength, mobility and balance [3-5].

Despite undergoing rehabilitation, many people are left with a walking deficit after stroke [6]. In a most recent study, Sabut et al., reported that the Functional Electrical Stimulation (FES) therapy combined with conventional therapy treatment more effectively improves the walking ability and enhances the motor recovery when compared with conventional therapy alone in chronic stroke patients [7]. A study reported that functional strength training of lower extremities improves physical performance more than traditional training in subacute stroke [8]. FES has been used to replace lost descending control and restore a variety of movements, including walking [9]. The use of FES therapy, of the common peroneal nerve during the swing phase of gait cycle may have advantages over passive orthosis for facilitating motor relearning [10]. In 1961, Liberson and his colleague reported the first clinical application of FES for restoration of drop-foot [11]. FES used in chronic subjects has been shown to improve mobility, and reduce spasticity [12]. Walking speed was enhanced and the PCI improved with stroke survivors treated with the Odstock dropped foot stimulator, for an average of 4.5 months. Studies in literature have shown that FES has a positive orthotic effect on walking ability of subjects after stroke [13]. Studies have suggested that peroneal nerve FES during walking improves gait and physiological cost index (PCI) in patients with chronic stage [12, 14-15] and during the acute stage of recovery [16]. There has been no study on the combined effect of FES with the conventional therapy in subacute and chronic stages of stroke patients. The purpose of the present study was to evaluate the effect of FES therapy along with conventional rehabilitation program (CRP) will improve better in gait, and muscle recovery than the chronic stroke patients.

S. K. Sabut is with School of Electronics Engineering, KIIT University, Bhubaneswar, India (e-mail: sukanta207@gmail.com).

C. Sikdar is with National Institute for the Orthopaedically Handicapped, Kolkata, India. (e-mail: sikdarchhanda@yahoo.com).

R. Kumar is with National Institute for the Orthopaedically Handicapped, Kolkata, India. (e-mail: director@nioh.in).

M. Mahadevappa is with the School of Medical Science & Technology, Indian Institute of Technology, Kharagpur, India (corresponding author phone: +91-3222-282300; fax: +91-3222-282221; e-mail: mmaha2@smst.iitkgp.ernet.in).

II. MATERIALS AND METHODS

A. Subjects

Eighteen stroke patients having foot drop with dorsiflexion and eversion weakness participated in this study. Fourteen subjects were male and four were female and ages ranged from 40 to 65 years; the mean age was 50.5 ± 4.3 in the subacute group and 47.2 ± 7.8 in the chronic group. The subjects were assigned either to a subacute group (<6 months post stroke) or to a chronic group (>6 months post stroke). The inclusion criteria for the study were: 1) foot drop due to stroke, 2) first hemiplegia of at least 3 months in duration as a result of a stroke with a stable neurology, 3) no medical contraindication to walking or to electric stimulation, and 4) ability to walk at least 10 meters without assistance.

B. Intervention

The study was approved by Institute Ethical committee and the subjects were signed the informed consent. Subjects received the electrical stimulation to the peroneal nerve while walking for 15-30 minutes per day along with CRP including 60 minutes each of physiotherapy and occupational therapy, given once per day, 5 days per week for 12 weeks. The exercise program was designed to improve strength, balance and to encourage more use of the affected extremity.

C. Walking with FES System

Electrical stimulation was applied using a modified portable neuromuscular stimulator (EMS, Johari Digital Healthcare Ltd. India). Stimulation was applied with surface electrodes placed over the common peroneal nerve and motor point of the anterior tibialis (TA) muscle to elicit dorsiflexion and eversion of the foot and achieves a toe clearance while walking. FES was delivered in a bi-phasic rectangular pulse with 0.3ms pulses at 40 Hz with intensity of 20 to 40 mA to produce desired movement at the ankle. The stimulation of the affected leg was triggered with the swing phase of the gait cycle using a heel switch.

D. Conventional rehabilitation Programme

Conventional rehabilitation therapy consisted of the following strategies: 1) strategies to joint mobilization and range of motion exercises; 2) exercises to improve strength; 3) strategies to manage spasticity; 4) exercises for increase range of motion, compensatory strategy; 5) strategies to improve balance, and mobility.

III. OUTCOME MEASURES

The following outcome measures were used to evaluate the progression of the patient's rehabilitation under different therapeutic approaches: 1) walking ability measured by gait parameters; 2) the effort of walking measured by PCI; 3) EMG analysis of TA muscle for muscle power.

A. Gait parameters

The 10-m walk was timed using a stopwatch, measuring tape and the steps were counted. Our basic outcome measurement gait variables were walking speed, cadence, and step length. Patients were instructed to walk at their comfortable speeds on a walkway. Changes in gait variables and effort of walking measured by PCI were assessed both by a six-minute walk test (6MWT).

B. Physiological Cost Index (PCI) of walking

The PCI is a measure of the energy cost of walking. Heart rate was measured using a Casio heart-rate monitor, and gait speed and distance were measured using a standard stopwatch and measuring tapes. The PCI is a gait efficiency measure and is expressed in heart beats per meter travelled. It is calculated as follows:

$$PCI = [HR(w) - HR(r)] / S$$

Where: HR (w) = Heart Rate Walking (heart beats/minute); HR(r) = Heart Rate Resting (heart beats/minute); S = Speed of Walking (meters/minute).

C. Recording of EMG signal

Surface electromyography (EMG) signals from the TA muscle of the affected leg were recorded using a multichannel data acquisition system (PowerLab system, AD Instruments, Castle Hill, NSW, Australia) with subjects were seated in a chair with the knee flexed at 90 degrees and ankle at neutral position. A pair of surface electrodes was placed over the TA muscle of the affected leg of the subject. The EMG was recorded for 10 seconds by encouraging the maximum voluntary contractions (MVCs) of ankle dorsiflexors. Data analysis was performed off-line using MATLAB with the Signal Processing toolbox (The MathWorks Inc., Natick, MA, USA). The signal was full wave rectified using an absolute function to produce a linear envelope. The EMG signals were analyzed for temporal parameters such as mean-absolute-value (MAV) and maximum root-mean-square (RMS max) for a window length of 10 seconds. A customized software program was used to determine the MAV and RMSmax of the TA, muscles for finding clinical benefits with FES therapy.

D. Data analysis

Baseline measurements were compared with those obtained at 3 months after treatment. The paired t-test was used to estimate whether the treatment with FES therapy significantly improves the patients walking abilities and motor recovery at post-treatment within each group and independent test between the groups. The percentage change between baseline and post- treatment data was calculated as ((pre-treatment minus post-treatment)/pre-treatment))* 100. The significance level α was set at 0.05 for all tests.

IV. RESULTS

A. Gait Parameters

After treated with FES based rehabilitation program both the groups significantly increased the walking velocity, cadence, stride length, and step length are described in table 1. The mean walking speed in the subacute subjects significantly improved from 0.34 ± 0.17 m/s to 0.44 ± 0.18 m/s ($p<0.05$) of 29.4%; whereas the chronic subjects improved from 0.39 ± 0.17 m/s to 0.47± 0.21 m/s ($p<0.05$) of 17.1% at the end of the trial. Similarly improvements were also measured in cadence with subacute subjects improved from by 17.6% and the chronic group improved by 13.3% respectively. A low PCI indicates an energy-efficient gait. The table 2 shows a clinically relevant energy efficient gait treated with FES based program. The subacute subjects showed a significant reduction of PCI by 73.1% and the chronic subject showed an insignificant reduction of PCI by 46.5 %, which indicates better and energy-efficient gait with an early intervention of electrical stimulation.

B. Electromyographic Analysis

Table 2 shows the measured temporal parameters the MAV and RMSmax values of TA EMG signal before treatment in both groups. The measured temporal parameters of TA EMG signals were improved significantly in both groups. The change in MAV value was 29.1% in the subacute group and 16.8% ($p<0.05$) in the chronic group at pre- and post-treatment assessment. Similarly the RMS value also has shown significant improvement.

Table 1: Measured gait parameters between the groups

Groups	Speed (m/s)	Cadence (steps/min)	PCI (beats/mtr)
Subacute (*n* = 8)			
Pre-test	0.34±0.17	67±18.2	1.04±0.5
Post-test	0.44±0.18	78.8±14.7	0.28±0.17
Mean diff.	0.1	11.8	0.76
% change	29.4*	17.6*	73.1*
Chronic (*n* = 12)			
Pre-test	0.39±0.17	74.2±24.2	1.2±0.22
Post-test	0.47±0.21	84.1±20.6	0.64±0.1
Mean diff.	0.08	13.3	0.56
% change	17.1*	13.3*	46.5*

Note. Values are mean ± SD.
Abbreviation: PCI, physiological cost index.
**p* < .05; Paired *t*-test.

Table 2: Measured temporal parameters within each group

Groups	MAV (mV)	RMS (mV)
Subacute (*n* = 8)		
Pre-test	0.023±0.004	0.08±0.03
Post-test	0.029±0.003	0.11±0.05
% change	26.1*	37.5*
Chronic (*n* = 12)		
Pre-test	0.025±0.004	0.12±0.08
Post-test	0.03±0.003	0.15±0.01
% change	20*	25.1*

Note. Values are mean ± SD.
Abbreviation: MAV, mean-absolute-value; RMS, root-mean-square;
**p* < .05; Paired *t*-test.

A. *Comparison between groups*

The subjects demonstrated significant improvements within each group in walking parameters, physiological cost index, and muscle strength at post-test. However comparison between the groups at post-treatment results showed non-significant difference in walking speed, cadence (p>0.05) and a significant difference was seen in PCI measurement.

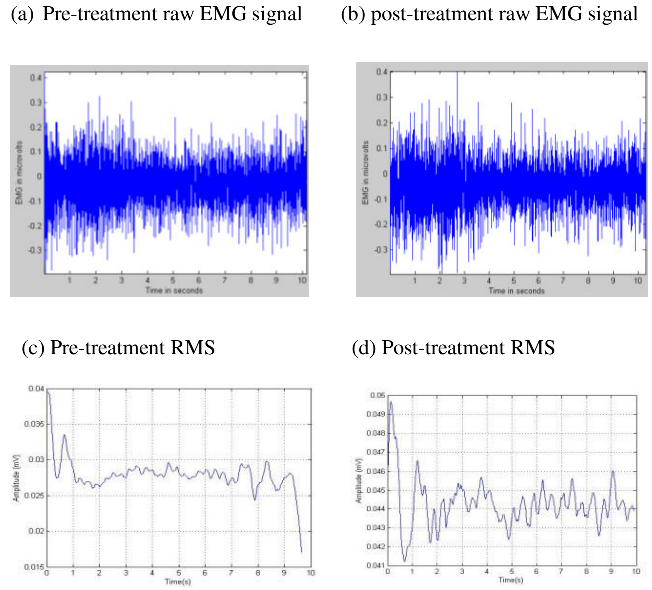

Fig.2. An example of synthesized RMS of sEMG of tibialis anterior from a single subject.

V. DISCUSSION

The purpose of this study was to investigate and compare the effects of FES therapy on recovery walking ability, and muscle strength between subacute and chronic stroke subjects. The 12-week supervised clinics-based rehabilitation program associated with FES therapy resulted in better improvement in subacute subjects compared to chronic stroke subjects. Gains were observed in walking parameters, and strength of TA muscle. The differences between the subacute and chronic groups suggest that the FES based rehabilitation program promoted the recovery and functional gains with an early intervention after stroke.

A significant improvement was measured in walking velocity both in the subacute (29.4%) and the chronic (17.1%) subjects. In a similar study, Yan et al reported that 15 sessions of simple FES, given 30 minutes per session along with standard rehabilitation 5 days a week, improved motor recovery and functional mobility in acute stroke subjects, more than placebo stimulation and standard rehabilitation, or standard rehabilitation only [16].

It was observed that while the stimulator was being used, the immediate effect of FES acted as an orthosis, bringing the ankle into greater dorsiflexion during swing phase, thus the walking was easier, faster, and effortless. Subjects also had shown improvement in gait, effort of walking and muscle strength. To assess effects on more distal outcomes such as disability and quality of life, a large, multisite trial is needed. The limitations of this study design were the absence of a control group. Hence more research is warranted to determine the effect of FES based rehabilitation program in subacute stroke patients.

VI. Conclusion

The results of this study showed that the combined effect of FES therapy and conventional rehabilitation program improved better in terms of walking ability, energy efficient gait and muscle strength of treated tibialis anterior muscle with subacute than the chronic stroke subjects. The subjects could walk more quickly with less effort by using a FES device while walking. We concluded that an early intervention of FES therapy along with CRP significantly improves the gait and muscle strength in the process of stroke recovery. Therefore, we suggest that the FES may be used as a standard therapeutic protocol with conventional techniques for treatment of spasticity foot drop in early recovery stage in the physical rehabilitation practices.

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References

[1] I.A. De. Quervain, S.R. Simon, S. Leurgans, W.S. Pease, and D. McAllister, "Gait pattern in the early recovery period after stroke," *J Bone Joint Surg AM,* vol. 78, no. 10, pp. 506-1514, 1996.

[2] J.H. Burridge, D.E. Wood, P.N. Taylor, and D.L. McLellan, "Indices to describe different muscle activation patterns, identified during treadmill walking, in people with spastic drop-foot," *Med Eng Phys,* vol. 23, no. 6, pp. 427-434, 2001.

[3] J.H. Liepert, H. Bauder, H.R. Wolfgang, W.H. Milner, E. Taub, and C. Weiller, "Treatment-induced cortical reorganization after stroke in humans," *Stroke, vol.* 31, pp. 1210-1216, 2000.

[4] L.F. Teixeira-Salmela, S. Nadeau, I. Mcbride, and S.J. Olney, "Effects of muscle strengthening and physical conditioning training on temporal, kinematic and kinetic variables during gait in chronic stroke survivors," *J Rehabil Med*, vo.l. 33, no. 2, pp. 53-60, 2001.

[5] C. Winstein, E.R. Gardner, D.R. McNeal, P.S. Barto, and D.E. Nicholson, "Standing balance training: effect on balance and locomotion in hemiparetic adults," *Arch Phys Med Rehabil, vol.* 70, no. 10, pp. 755-762, 1989.

[6] P.W. Duncan, L.B. Goldstein, D. Matchar, G.W. Divine, and J. Feussner, "Measurement of motor recovery after stroke: outcome assessment and sample size requirements," *Stroke,* vol. 23, no. 8, pp. 1084-1089, 1992.

[7] S.K. Sabut, C. Sikdar, R. Mondal, R. Kumar, and M. Mahadevappa, "Restoration of gait and motor recovery by functional electrical stimulation therapy in persons with stroke," *Disabil Rehabil, vol.* 32, no. 19, pp. 1594-603, 2010.

[8] M. Bale, and L.I. Strand, "Does functional strength training of the leg in subacute stroke improve physical performance? A pilot randomized controlled trial," *Clin Rehabil*, vol. 22, pp. 911-921, 2008.

[9] V. Gritsenko, and A. Prochazka, "A functional electric stimulation assisted exercise therapy system for hemiplegic hand function," *Arch Phys Med Rehabil, vol.* **85, no.** 6, pp. 881-885, 2004.

[10] R.G. Lee, and P.V. Donkelaar, "Mechanisms underlying functional recovery following stroke," *Can J Neurol Sci,* vol. 22, no. 4, pp. 257-263, 1995.

[11] W.H. Lieberson, D. Scot, and M. Dow, "Functional electrotherapy: stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients," *Arch Phys Med Rehabil, vol.* 42, pp. 101-105, 1961.

[12] J.H. Burridge, P.N. Taylor, S.A. Hagan, D.E. Wood, and I.D. Swain, "The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients," *Clin Rehabil, vol.* 11, no. 3, pp. 201-210, 1997.

[13] P.N. Taylor, J.H. Burridge, A.L. Dunkerley, D.E. Wood, J.A. Norton, C. Singleton, and I.D. Swain, "Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking," *Arch Phys Med Rehabil,* vol. 80, pp. 1577-1583, 1999.

[14] Y. Laufer, M. Hausdorff, and H. Ring, "Effects of a foot drop neuroprosthesis on functional abilities, social participation, and gait velocity," *Am J Phys Med Rehabil, vol.* 88, pp. 14-20, 2009.

[15] T. Yan, C. Hui-Chan, and L. Li, "Functional electrical stimulation improves motor recovery of the lower extremity and walking ability of subjects with first acute stroke: a randomized placebo-controlled trial," *Stroke,* vol. 36, no. 1, pp. 80-85, 2005.

[16] K. Dunning, K. Black, A. Harrison, K. McBride, and S. Israel, "Neuroprosthesis Peroneal Functional Electrical Stimulation in the Acute Inpatient Rehabilitation Setting: A Case Series," *Phys Ther, vol.* 89, no. 5, pp. 499-506, 2009.