





# The Effect of Functional Electrical Stimulation on Stroke Recovery: A Randomized Controlled Trial

## Fonksiyonel Elektrik Stimülasyonunun İnme İyileşmesi Üzerindeki Etkisi: Randomize Kontrollü Çalışma

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Geliş Tarihi/Received: 31.01.2018

Kabul Tarihi/Accepted: 04.05.2018

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**ABSTRACT Objective:** To investigate the effect of upper extremity functional electrical stimulation (FES) on functional recovery in stroke patients. **Material and Methods:** The study was a randomized-controlled prospective trial, and approved by the local ethics committee. Stroke patients met criteria and accepted to be in study were randomly allocated to routine physiotherapy (control group) or routine physiotherapy + FES (FES group). Primary [Fugl-Meyer and Modified Ashworth Scale (MAS)] and secondary measures [range of motion, Motor Activity Log-28 (MAL-28), Jebsen-Taylor test, handgrip strength, Short Form-36] were assessed before treatment (t0), at the second week of therapy (t1) and after treatment (t2). **Results:** Seventeen patients were included in the study (control n: 8, FES n: 9). There were no significant differences between the groups for all outcomes at t0, t1 and t2 assessments. Significantly better results were detected in terms of elbow flexor muscles MAS score (p:0.014), upper extremity Fugl-Meyer score (p:0.011), grip strength (p:0.015) and MAL-28 score (p:0.012) within the FES group. The upper extremity Fugl-Meyer score of the control group was found to be significantly higher at repeated measures within the group (p:0.012). **Conclusion:** Upper extremity FES can be preferred as an additional method in upper limb rehabilitation to improve spasticity, motor functions, handgrip strength and level of independence in performing activities of daily living in stroke patients.

**Keywords:** Functional electrical stimulation; stroke; spasticity

**ÖZET Amaç:** Üst ekstremitte fonksiyonel elektrik stimülasyonunun (FES) inmeli hastalarda fonksiyonel iyileşme üzerine etkisini araştırmak. **Gereç ve Yöntemler:** Randomize-kontrollü prospektif çalışmamız için etik kurul onayı alındı. Kriterleri karşılayan ve çalışmaya katılmak için onam veren inmeli hastalar rutin fizyoterapi (kontrol grubu) ve rutin fizyoterapi+FES (FES grubu) olarak 2 gruba randomize edildi. Hastalar tedavi öncesinde (t0), tedavinin ikinci haftasında (t1) ve tedavi bitiminde (t2) primer [Fugl-Meyer ve Modifiye Ashworth skalası (MAS)] ve sekonder ölçütler [eklem hareket açıklığı, Motor Aktivite İzlemi-28 (MAI-28), Jebsen-Taylor testi, el kavrama gücü, Kısa form-36] ile değerlendirildi. **Bulgular:** Çalışmaya 17 hasta dahil edildi (8 kontrol, 9 FES grubu). Her iki grup arasında t0, t1 ve t2 ölçümlerinde tüm ölçütlerde istatistiksel anlamlı fark gözlenmedi. FES tedavisi alan grupta tekrarlayan ölçümlerde dirsek fleksör spastisitesi (p:0.014), üst ekstremitte Fugl-Meyer skoru (p:0.011), kavrama gücü (p:0.015) ve MAI-28 skorlarında (p:0.012) istatistiksel anlamlı iyileşme saptandı. Kontrol grubunda üst ekstremitte Fugl-Meyer skorunda istatistiksel anlamlı düzelme tespit edildi (p:0.011). **Sonuç:** Üst ekstremitte FES, inmeli hastalarda spastisite, motor fonksiyon, el kavrama gücü ve günlük yaşam aktivitelerinde iyileşme için standart fizyoterapiye ilave bir teknik olarak tercih edilebilir.

**Anahtar Kelimeler:** Fonksiyonel elektrik stimülasyonu; inme; spastisite

Stroke is a global health-care problem that leads to both physical and cognitive impairment.<sup>1-3</sup> Reduced upper limb function is common after stroke and 23-43% of patients have insufficient functional improvement in the upper extremity, although 4-5% of patients return to completely normal functioning.<sup>4</sup> Motor impairment in the upper extremity

lasting for a long time can result in patients becoming functionally dependent on others for activities of daily living (ADL).

Conventional rehabilitation, neurophysiological treatment methods, functional electrical stimulation (FES), electromyographic biofeedback and orthoses are used in the rehabilitation of the upper extremity in stroke patients. FES is the stimulation of muscles with impaired neurological control or motor function using a low-voltage electrical current through a superficial electrode. The aim of FES is to create functional and useful movements.

Randomized controlled trials exploring the effects of FES on upper extremity function in stroke patients have been published with conflicting results.<sup>5-12</sup> The aim of this study was to investigate the effect of FES on range of motion (ROM), muscle tone, motor function, grip strength, ADL and quality of life in stroke patients.

## MATERIAL AND METHODS

### SUBJECTS

In this randomized, controlled, prospective study, an evaluation was made of stroke patients who were admitted to the Department of Physical

Medicine and Rehabilitation. The inclusion criteria were as follows: a first experience of hemiplegia or hemiparesis associated with stroke, stroke duration of >3 months and <3 years, use of any oral medications at stable dosage to reduce spasticity for at least one month before the first assessment, and agreement to continue with the same dose until the final assessment, Brunnstrom stage of 2, 3, 4 or 5 in the upper extremity and hand, having sitting balance, and aged >18 years. The exclusion criteria are shown in Table 1. A total of 29 patients who met the criteria were randomly separated using a computer program into 2 groups as the control group and the FES group (Figure 1). Informed consent was obtained from all participants. Approval for the study was granted by the Local Ethics Committee. This study was conducted in accordance with the Helsinki Declaration 2008 principles.

### FES DEVICE-BIONESS H200

H-200™ (Bioness, Inc, Santa Clarita, Calif) consists of an orthosis to support the hand and wrist, a control unit to send an electrical current to the fingers and superficial electrodes that provide transmission of electrical stimulation to the muscles.

**TABLE 1:** Exclusion criteria.

1	MAS 4 spasticity in a hand or upper extremity muscle
2	Contracture that causes restriction in elbow, wrist and fingers
3	Movement disorders such as ataxia, dystonia, dyskinesia
4	Concomitant lower motor neuron or peripheral nerve injury in upper extremity
5	Significant co-morbidities that may interfere with rehabilitation such as severe heart disease, uncontrolled hypertension
6	Unconsciousness and dementia
7	Active infection
8	Wound (in practice area)
9	Tumor in the ipsilateral extremity
10	History of convulsions
11	Active complex regional pain syndrome
12	Pregnancy or puerperium or lactation
13	Aphasia that may cause understanding and comprehension disorder
14	Unable to approve informed consent
15	Stroke that may cause bilateral involvement
16	Involvement of brain stem
17	Neurolysis for spasticity within the last three months
18	Electrical stimulation to upper extremity previously.

MAS: Modified Ashworth Scale.

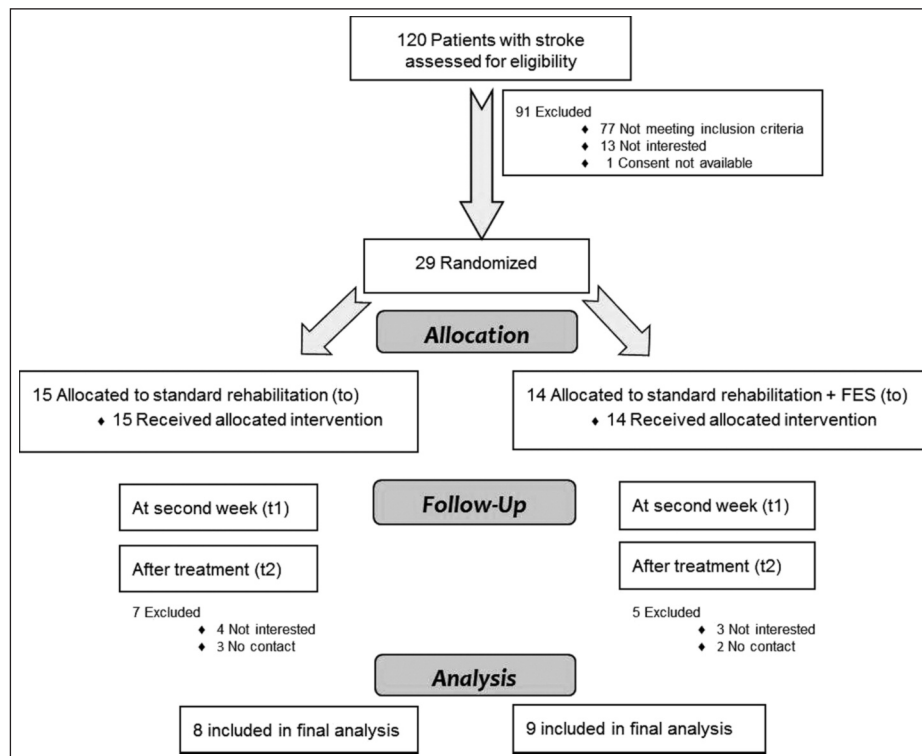


FIGURE 1: Flow of participants throughout the trial.

After the physiotherapist determined an effective contraction, the appropriate orthotic type and electrode regions for the patient were decided. Then the electrodes were fixed to the orthosis to be located in five different muscle regions of the extensor digitorum, extensor pollicis brevis/longus, thenar muscles, flexor digitorum superficialis and flexor pollicis longus.

During the treatment, if extension of the fingers was required, the appropriate program (open exercises) was selected from the control unit and then stimulations were sent to the extensor digitorum, extensor pollicis brevis/longus muscles. Complete extension of the fingers, which is one of the most difficult movements for stroke patients, was thus performed. If rough grip with finger flexion was required, the grip function (grip exercises) was selected from the control unit and then stimulations were sent to the flexor digitorum superficialis and flexor pollicis longus muscles.

## THERAPY

Stroke patients hospitalized in the Department of Physical Medicine and Rehabilitation were evalu-

ated by a physiatrist and an appropriate treatment through a neurological rehabilitation program is planned and administered regularly during the stay in the hospital. A standard rehabilitation schedule was applied to patients in the control group for 5 days a week over a period of 8 weeks. The rehabilitation program included ROM, stretching of the muscles, strengthening exercises of both upper and lower extremity applied according to Bobath technique, rough and fine grip, sitting, standing, loading, walking and balance training, water-based exercise training (aquatic exercises applied with the help of physiotherapist to increase standing and walking balance and strength and to improve walking quality), and exercises for ADL. In addition to the above-mentioned routine therapies, FES training with Bioness H200 device (NESS, Ranana-Israel, 2010) was administered to the patients in the FES group by an occupational therapist 5 days a week for 8 weeks. For the patients to become accustomed to the device and electrical current, the FES therapy was administered for 15 minutes, twice a day in the first week of therapy, and thereafter for 45 minutes, twice a day.

## ASSESSMENT

Patients in both groups were evaluated by same examiner before treatment (t0), at the second week of treatment (t1) and after treatment (t2). The shoulder passive ROM for both sides was measured with a goniometer. The upper extremity and hand-wrist motor function levels were determined using the the Fugl-Meyer scale.<sup>13</sup> The tonus of shoulder, elbow, wrist and hand muscles was assessed with the Modified Ashworth Scale (MAS).<sup>14</sup> Motor Activity Log-28 (MAL-28) was performed to determine the usage of affected extremities in ADL.<sup>15</sup> The Jebsen-Taylor hand function test was used to evaluate hand and upper extremity functions.<sup>16</sup> 3 sub-tests of the Jebsen-Taylor test including simulated feeding, lifting a large light object and lifting large heavy objects were applied. Handgrip strength was measured with a Jamar dynamometer (Sammons Preston, Chicago-USA, 1999). Quality of life was assessed with the Short Form-36 (SF-36).

## DATA ANALYSIS

SPSS for Windows (version 15.0) software was used for statistical analysis. The numerical data were assessed by non-parametric tests because of the small number of patients and the data did not conform to normal distribution. The Chi-square test was used to determine whether there was a significant difference in demographic, clinical and etiological features between the groups for nominal variables. A value of  $p < 0.05$  was accepted as statistically significant in the assessment of the results. The comparison of repeated measures within groups was performed with the Friedman test. Paired comparisons for groups that were significant according to the Friedman test were compared using the Wilcoxon test with a value of  $p < 0.017$  considered to be significant with Bonferroni correction. The Mann-Whitney U test was used to compare differences between two groups.

## RESULTS

The mean age of the patients was  $52.6 \pm 16.5$  years for the control group and  $52.3 \pm 16.5$  years for the FES group. The mean disease duration was  $306.2 \pm 219.5$  days for the control patients and

$429.1 \pm 346.3$  days for the FES patients. The demographic and clinical characteristics (age, gender, disease duration, type of stroke and hemiplegic side) of all the patients are shown in Table 2. There were no statistically significant differences between the groups in respect of these features.

There were no statistically significant differences between the measurements of the two groups (control vs. FES) for all assessed parameters including ROM, MAS, upper extremity Fugl-Meyer assessment, the Jebsen-Taylor hand function test, MAL-28 and SF-36 ( $p > 0.05$ ).

The mean MAS score of elbow flexor muscles in the t2 assessment was found to be significantly lower than that of the t0 in the FES group ( $p:0.014$ ), but there was no significant difference in the control group ( $p > 0.017$ ) (Table 3).

In the FES group, there was a significant increase between the t2 and t0 assessments ( $p:0.011$ ) in the mean Fugl-Meyer upper extremity total scores. There was a significant increase between the t2-t0 ( $p:0.012$ ) and t2-t1 assessments ( $p:0.012$ ) in the mean Fugl-Meyer upper extremity total scores in the control group (Table 3).

The mean grip strength of the t2 assessment was significantly higher than t0 in the FES group

**TABLE 2:** Demographic and clinical features of the patients.

	Control Group	FES Group	p
Age (years)	52.6±16.5	52.3±16.5	0.962
Gender, n (%)			0.627
Female	3 (37.5%)	3 (33.3%)	
Male	5 (62.5%)	6 (66.7%)	
Disease duration (days)	306.2±219.5	429.1±346.3	0.229
Stroke type, n (%)			0.576
Hemorrhagic	2 (25%)	1 (11.1%)	
Ishemic	6 (75%)	8 (88.9%)	
The affected side, n (%)			0.581
Right	3 (37.5%)	4 (44.4%)	
Left	5 (62.5%)	5 (58.8%)	
Brunnstrom stage			
Upper extremity	3.3±0.7	3.2±1.2	0.616
Hand	3.1±0.9	3.3±1.2	0.724

FES: Functional electrical stimulation

Data are expressed as mean ± standart deviation for continuous variables, number (percentage) for categorical variables.

**TABLE 3:** Comparison of outcomes between control and FES group.

	Control Group	FES Group
<b>Fugl-Meyer upper extremity score</b>		
t0	22±8.9	23.6±12.4
t1	22±8.9	23.7±12.4
t2	27.3±9.1 <sup>a,b</sup>	27.6±15.3 <sup>a</sup>
<b>Fugl-Meyer hand score</b>		
t0	4.6±3.8	6.3±4.8
t1	4.6±3.8	6.4±4.7
t2	6.3±4.3	8.7±6.9
<b>Elbow flexor muscle spasticity (MAS)</b>		
t0	1±0.9	1.3±0.8
t1	0.7±0.7	1.2±0.8
t2	0.5±0.7	0.6±0.7 <sup>a</sup>
<b>MAL-28 score</b>		
t0	3.7±3.1	3.7±2.7
t1	3.8±3.1	3.7±2.7
t2	6.1±4.2	7.6±6.1 <sup>a,b</sup>
<b>Jebsen-Taylor (Simulated feeding)</b>		
t0	95.1±38.6	86.7±45.7
t1	94.7±38.8	81.3±47.2
t2	82.6±42.0	73.1±47.7
<b>Jebsen-Taylor (Lifting large light object)</b>		
t0	109.3±30.2	101.1±37.4
t1	109.5±29.6	101.0±37.7
t2	109.0±31.0	95.3±38.8
<b>Jebsen-Taylor (Lifting large heavy object)</b>		
t0	111.2±24.7	103.3±33.0
t1	111.1±25.1	103.0±33.7
t2	110.8±25.9	102.1±35.5
<b>Grip strength (kilograms)</b>		
t0	3.5±3.2	4.8±5.3
t1	3.9±3.1	5.4±5
t2	4.7±4	6.1±5.7 <sup>a</sup>

Data are expressed as mean ± SD. MAS: Modified Ashworth Scale, MAL-28: Motor Activity Log-28, FES: functional electrical stimulation, t0: before the treatment measurement, t1: second week of the treatment measurement, t2: end of the treatment measurement <sup>a</sup>: significant difference between t2 and t0 within group <sup>b</sup>: significant difference between t2 and t1 within group

( $p:0.015$ ). An increase was determined at the end of the treatment assessments in the control group but not of a statistically significant level ( $p>0.017$ ) (Table 3).

The t2 assessment was found to be statistically significant compared to t0 and t1 for the MAL-28 scores in the FES group ( $p:0.012$ ). There was also an increase of mean MAL-28 scores in the t2 as-

essment compared to both the t0 and t1 assessments in the control group but this increase was not statistically significant ( $p>0.017$ ) (Table 3).

There were no statistically significant differences between repeated measures within the groups for shoulder ROM, spasticity of all upper extremity and hand muscles except elbow flexor muscles, Fugl-Meyer wrist-hand, Jebsen-Taylor test score and SF-36 scores ( $p>0.017$ ).

## DISCUSSION

The results of this study showed statistically significant differences in terms of spasticity in the elbow flexor muscles, upper extremity motor function, grip strength and independence level in ADL in the FES group after 8 weeks of therapy. After the standard rehabilitation program alone, only upper extremity motor function level (Fugl-Meyer) increased. On the other hand, there was no statistically significant difference between control and FES group in all outcomes.

The upper extremity is affected more than the lower extremity after a stroke and upper extremity motor recovery is weaker than that of the lower extremity. In surviving hemiplegic patients, the functional usage rate of the upper extremity is 50% while the independent walking rate is 82%.<sup>17</sup> In severe hemiplegic patients, an improvement in hand functions occurs in only 15% of patients who have survived.<sup>17</sup> The use of FES as described in this study may improve the chances of recovery of upper-extremity functions.

FES is a low-frequency electrical stimulation modality that has a functional purpose to improve activity. Previous studies have shown the effectiveness of FES on parameters such as ROM, spasticity and hand functions.<sup>18-23</sup> However, there are also studies claiming that FES is no more effective than standard rehabilitation programs.<sup>24,25</sup>

In a controlled study, Ring et al. investigated the effects of upper extremity neuroprosthesis on elbow and wrist active ROM in stroke patients and found a statistically significant increase in the treatment group compared to the control group.<sup>19</sup> In another study, no difference was observed in shoulder



passive ROM between the groups of patients with acute or chronic stroke.<sup>23</sup> In the current study, after eight weeks of treatment, no difference was found both in comparisons within the groups and between the groups in respect of flexion, abduction, external and internal rotation measurements of the shoulders.

Hendricks et al. determined a statistically significant decrease in spasticity of the elbow flexor muscles with the use of FES.<sup>21</sup> A greater improvement in the muscle tonus of patients with greater Fugl-Meyer scores was also observed. The limitations of that study were a lack of randomization and the absence of a control group. In the current study, end-of-treatment values of elbow flexor muscle spasticity were lower than the baseline assessments in the FES group and this reduction was found to be statistically significant. Furthermore, there were also reductions in the spasticity of the shoulder flexor-abductor, wrist flexor muscles and triceps between the groups and between repeated measures, although these improvements were not statistically significant. Despite the frequent use of the muscle tonus scale in stroke patients, MAS is a subjective method. Therefore, any potential difference between the two groups may be not detected.

Wang et al. investigated the effects of FES on upper extremity Fugl-Meyer scores in acute or chronic stroke patients and an improvement was determined at the end of the 6<sup>th</sup> week which continued until the 12<sup>th</sup> week in patients with short disease duration.<sup>23</sup> In the current study, disease duration could not be evaluated because of the small number of patients, and no statistically significant difference was found between the groups. However, end of treatment assessment values were significantly higher than those of the baseline assessments in both groups.

The effect of neuroprosthesis on grip strength was investigated in 29 chronic stroke patients by Alon et al.<sup>22</sup> Assessments were performed while patients were wearing the neuroprosthesis and a significant grip strength increase was reported. Ring et al. also showed that patients capable of active movement in the wrist and fingers completed the

tasks of lifting heavy and light objects in the Jebsen-Taylor test in a statistically shorter time while wearing the neuroprosthesis.<sup>19</sup> In the current study, dynamometer assessments were performed at the end of treatment in the FES group when the device was not worn. Grip strength measurement was significantly higher than the baseline assessment in the FES group although the neuroprosthesis was not worn. In addition, scores of simulated feeding, lifting large light and heavy objects were not significantly improved in both group. This may have been due to an 8-week FES therapy period being insufficient for stroke patients with a slow recovery rate. Use of the device for housework can be recommended to patients, as a statistically significant improvement in grip strength and Jebsen-Taylor test have been determined when the neuroprosthesis was worn in other studies.<sup>19,22</sup>

In this study, when the groups were compared according to the MAL-28 scores, the difference between the groups was not statistically significant. However, the values of the end-of-treatment assessments in the FES group were significantly higher than those of the baseline assessments. The use of the neuroprosthesis seems to provide a partial improvement in the level of independence for ADL as there was no statistically significant improvement in the MAL-28 scores of the control group.

The limitations of this study are that the size of the study sample was small because of the width of the inclusion and exclusion criteria, there was a lack of personnel experienced in the use of FES, the treatment program was intensive at 45 minutes twice a day for 8 weeks, the long-term effectiveness of the treatment was unknown because the assessments were only performed at the end of treatment, and there were no data of measurements when the device was worn.

Although the small number of patients is the most important reason for there being no statistically significant difference related to ROM, muscle tonus, motor level, hand functions, grip strength, level of independence in ADL and quality of life, another significant reason seems to be that advanced functional rehabilitation was ap-

plied to both groups for at least 4 hours a day for 8 weeks. However, the difference may not have been evident because patients with poor prognosis indicators, such as incontinence, were included in the FES group. In future studies, the streaming of patients according to poor prognosis indicators such as age, severity of the lesion and incontinence may help to identify the difference more clearly.

## CONCLUSION

It can be concluded that upper extremity FES can be used as an additional method for the rehabilitation of stroke patients to improve spasticity, motor functions, handgrip strength and level of independence in performing ADL. It can be helpful during the recovery period and patients with hand impairments can use this in their daily lives.

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