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# Functional Electrical Stimulation for home use in patients after stroke

## Funkcionalna električna stimulacija za kućnu upotrebu kod bolesnika nakon moždanog udara

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**Abstract.** ***Aim:*** The aim of this pragmatic observational study was to identify for which purposes Functional electrical stimulation (FES) has been prescribed in University Rehabilitation Institute of Republic of Slovenia – Soča (URI-Soča) for long term treatment at home and whether prescribing practice has been changed over time in the last 10 years. ***Methods:*** A pragmatic cohort retrospective study included 373 stroke patients that performed inpatient rehabilitation at the Department for rehabilitation of patients after stroke URI-Soča between January 2010 and December 2019, and used FES at home after discharge. ***Results:*** FES was most often prescribed to patients with mild disability and severely affected upper extremity after stroke. Half of the patients used FES on the paretic upper extremity, 46.9% on the hemiparetic upper and lower extremity and only minority (2.9%) on the affected lower extremity alone. The upper limb stimulation predominated almost in the whole observational period. 22.3% of the patients used FES for more than 1 year, on average 3.5 years. A combination of FES and botulinum toxin therapies was used as a spasticity treatment of affected upper extremity in almost one third of patients (29.8%). In a group that used FES for more than one year, botulinum toxin therapies were statistically significantly more frequent (P<0.001). ***Conclusions:*** Almost one-third of patients included in this study got FES for home use to manage spasticity. More than a half of those who used FES at home for years used combination of botulinum toxin and FES therapies which suggests they felt effectiveness of combined treatment approach.

**Keywords:** Botulinum Toxins, Type A; electric stimulation; stroke rehabilitation; home environment

**Sažetak.** ***Cilj:*** Cilj ove pragmatične opservacijske studije bio je utvrditi u koje se svrhe upotrebljava funkcionalna električna stimulacija (FES) u *Univerzitetnom institutu* za rehabilitaciju Republike Slovenije u Soči (URI-Soča) nakon moždanog udara za dugotrajno liječenje kod kuće i je li se praksa propisivanja mijenjala tijekom vremena u posljednjih deset godina. ***Metode:*** U pragmatičnu kohortnu retrospektivnu studiju bila su uključena 373 bolesnika s moždanim udarom koji su provodili stacionarnu rehabilitaciju na Odjelu za rehabilitaciju bolesnika nakon moždanog udara u URI-Soča između siječnja 2010. i prosinca 2019., a koristili su FES kod kuće nakon otpusta. ***Rezultati:*** FES je bio najčešće propisivan bolesnicima s lakšim oštećenjem i teškom parezom gornjeg ekstremiteta nakon moždanog udara. Polovina bolesnika koristila je FES na paretičnom gornjem ekstremitetu, 46,9 % na hemiparetičnom gornjem i donjem ekstremitetu i manjina (2,9 %) samo na paretičnom donjem ekstremitetu. Stimulacija gornjih udova prevladavala je gotovo u cijelom razdoblju promatranja. 22,3 % pacijenata koristilo je FES dulje od jedne godine, u prosjeku 3,5 godine. Kombinacija FES-a i terapije botulinskim toksinom korištena je za liječenje spasticiteta zahvaćenog gornjeg ekstremiteta kod gotovo jedne trećine bolesnika (29,8 %). U skupini koja je koristila FES dulje od godinu dana, terapije botulinskim toksinom bile su statistički značajno češće (P < 0,001). ***Zaključci:*** Gotovo jedna trećina pacijenata u našoj studiji primila je FES za kućnu upotrebu za liječenje spastičnosti. Više od polovine onih koji su godinama koristili FES kod kuće, koristilo je kombinaciju botulinskog toksina i FES terapije, što sugerira da su osjetili učinkovitost kombiniranog pristupa liječenju.

**Ključne riječi:** botulinski toksin, tip A; električna stimulacija; rehabilitacija nakon moždanog udara; kućno okruženje

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## INTRODUCTION

Stroke survivors can suffer several long-lasting neurological deficits, among them hemiparesis is presented in three-quarters of patients[1]. Variability in recovery is substantial across patients and usually occurs slowest in those with less successful outcomes[2]. In general, the best outcomes are associated with the greatest return toward the normal state of brain functional organization. Brain plasticity after stroke refers to changes in interhemispheric lateralization, activity of association cortices linked to injured zones, and organization of cortical representational maps[3, 4]. Research evidence indicates that not only central nervous system (CNS) structure and function can change in response to injury, but also that changes are activity dependent[3]. Higher-intensity training and greater task demands produce a better functional outcome[5]. Critical principles of motor learning required for CNS activity-dependent plasticity include close-to normal movements, muscle activation driving practice of movement, focused attention, repetition of desired movements, and training specificity[3]. Modern restorative approaches involving repetitive practice are emerging. Functional electrical stimulation (FES) fits in these approaches though the method was used before the latest findings of neuroscience[6, 7]. It is a technique that uses low-energy electrical pulses to artificially generate body movements in individuals who have been paralyzed due to injury to CNS[8, 9]. FES uses both somatosensory inputs and passive or active assisted movements as means to improve motor performances. Possible peripheral mechanisms of FES include a training effect resulting in improved fitness and strength of the remaining motor units, improvement of flexibility and range of motion of affected limbs resulting in voluntary efforts becoming more effective, and reduced spasticity in the affected muscles[10].

Longer-lasting changes in corticospinal excitability can be induced after approximately 40 h of FES therapy. This are the reasons why we believe that the continuation of FES therapy over a long period of time in the home environment is appropriate.

Meta-analyses of randomised-controlled studies supported the conclusion that FES appears to moderately improve activity compared with no intervention or conventional training[11-13]. In stroke rehabilitation guidelines FES is highly recommended to reduce motor impairment and improve function of wrist and forearm muscles and gait function in selected patients[14, 15]. According to this, FES application early after stroke has been proved to improve mobility and ability in activities of daily living[16], which is also the case in the subacute rehabilitation treatments. Literature also describes possible effects of FES on spasticity and concurring muscle changes after stroke, however, these effects are less well established[17] and are therefore not part of clinical practice recommendations.

Reduction of chronic hemiplegic impairment after stroke is generally difficult[11]. The basis of a brain plasticity approach to rehabilitation also includes intensive treatment provided over longer period of time than that of the usual rehabilitation programs. Because FES has been proofed to be safe and useful therapy in home environment[18-20], it also fits in the prolonged treatment strategy after stroke. FES has been used in clinical practice of stroke rehabilitation in University Rehabilitation Institute of Republic of Slovenia – Soča (URI-Soča) for more than 40 years. Furthermore, patients have been entitled to a single-channel functional electrical stimulator for home use at the expense of national health insurance. The aim of this pragmatic observational study was to identify for which purposes FES has been prescribed for long term treatment at home and whether prescribing practice has been changed over time in the last 10 years.

## PARTICIPANTS AND METHODS

This is a 10-year, pragmatic retrospective cohort study conducted at the Department for rehabilitation of patients after stroke in University Rehabilitation Institute of Republic of Slovenia – Soča (URI-Soča). The study included stroke patients admitted to an inpatient interdisciplinary rehabilitation program between January 2010

and December 2019. The local Medical Ethics Committee URI-Soča approved the study (No. 035-1/2021-1/2-1). Because it was not possible to obtain written informed consent from all patients as some of them no longer attended the rehabilitation clinic, URI-Soča approved using of recorded data.

The following data were collected: age, sex, type of stroke, side of impairment after stroke, scores of Functional Independence Measure (FIM) at discharge[21], Brunnstrom stage of stroke recovery for upper extremity[22] at discharge, side of electrical stimulation and botulinum toxin treatments (BoNT) of affected upper extremity. Patients were divided into two groups regarding to the Brunnstrom stage of upper limb recovery. First group included patients of Brunnstrom stage 1-3, with more severe upper limb paresis that do not perform more than synergy movement patterns and muscle tone progresses from flaccidity to increased levels of spasticity. Second group included patients of Brunnstrom stage 4-6 where spasticity continues to be less pronounced and muscle coordination begins to improve. The severity of disability after stroke was graded upon FIM: mild disability (FIM > 80), moderate disability (FIM 40-80), sever disability (FIM < 40)[23]. The duration of FES use was determined according to the prescriptions of spare parts for FES devices (electrodes, electrode cables, etc.), whereby the date of the last prescription was taken as the end of use of FES. National health insurance covers the prescription of spare parts for FES device every 3 months.

The criteria for prescription of a single channel FES device for home use at URI-Soča derived from years of clinical experiences on this field taking into account the general contraindications for electrical stimulation (patient's cardiovascular capability (NYHA Class > II)[24], intact skin, adequate joint range of motion, no severe lesion of peripheral nerves, well preserved muscle contractility, patient's ability to communicate and cooperate in the rehabilitation program, motivation for FES, absence of an implanted electrical device, no malignancy in the area of treatment). The aims of prolonged electrical stimulation were facilitation of voluntary movements, muscle strengthening, moderation of spasticity and maintaining range of motion, and FES during gait[25].

We performed a thorough education of the patient or his/her caretaker how to operate the FES device (including electrode positioning and defining stimulation intensity) during inpatient rehabilitation program. Patients were given a written protocol for daily home electrical stimulation. At least a 30-min of FES program session everyday was recommended combined with individually specific exercises for the affected limb. FES targets on the hemiparetic side were the wrist and finger extensors, medial portion of deltoid, triceps brachii, quadriceps, tibialis anterior muscle and peroneal nerve. For statistical analysis, the stimulation sites were combined into three groups 1) FES of the paretic upper limb, 2) FES of the paretic upper and lower limbs and 3) FES of the paretic lower limb.

In years 2010 to 2019 commercially available single channel FES devices that could be prescribed at the expense of national health insurance in Slovenia were FEPA-10 (Furlan & Co. d.o.o., Ljubljana, Slovenia) and HEMIFES (Institute Joseph Stefan, Ljubljana, Slovenia). The values of the stimulation threshold in these devices range between 15 and 60 V. The saturation value depends on the size of the muscles stimulated. Frequencies of about 30 Hz were most often applied and short duration of stimuli was preferably used (0.1 ms to 0.3 ms).

### Statistics

Statistical analysis was carried out using SPSS Statistics, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The summary statistics for each variable were presented as mean, standard deviation and range, or as counts with percentages as appropriate. Patients were divided into two groups according to the duration of FES use, a group that used FES for up to 1 year and the one that used FES for more than 1 year. Between groups comparison was obtained through chi-squared test for categorial variables. A P-value < 0.05 was considered as statistically significant.

## RESULTS

In 10 years, we prescribed the single channel FES devices for home use to 373 patients who underwent inpatient rehabilitation program after stroke in URI-Soča. On average patients were 57

**Table 1.** Demographic and clinical characteristics of patients

| Characteristics | | N | % |
|---|---|---|---|
| Men | | 251 | 67.3 |
| Women | | 122 | 32.7 |
| Type of stroke | Ishaemic | 266 | 71.3 |
| | Haemorraghic | 107 | 28.7 |
| Side of paresis | Left | 189 | 50.7 |
| | Right | 181 | 48.5 |
| | Bilateral | 3 | 0.8 |
| Brunnström stage | 1 | 25 | 6.7 |
| | 2 | 197 | 52.8 |
| | 3 | 52 | 13.9 |
| | 4 | 51 | 13.7 |
| | 5 | 42 | 11.3 |
| | 6 | 6 | 1.6 |
| Site of ES | Upper extremity | 186 | 50.1 |
| | Upper and lower extremity | 175 | 46.9 |
| | Lower extremity | 11 | 2.9 |
| BoNT | | 111 | 29.8 |

Legend: ES, electrical stimulation; BoNT, botulinum toxin therapy.

**Table 2.** The severity of disability and Brunnstrom stage of upper limb recovery

| Disability Graded upon FIM* | Brunnstrom stage 1-3 | Brunnstrom stage 4-6 | P[1] |
|---|---|---|---|
| FIM < 40 | 4 (1.19%) | | |
| FIM 40-80 | 68 (20.35%) | 7 (2.1%) | 0.000 |
| FIM > 80 | 173 (51.8%) | 85 (25.4%) | |

Legend: FIM, Functional Independence Measure; *Missing data 36 (9,6%); [1]chi-sqared test.

**Table 3.** Duration of FES use at home according to Botulinum toxin therapy

| BoNT | FES ≤ 1 year | FES > 1 year | P[1] |
|---|---|---|---|
| No | 226 (77.9%) | 36 (43.4%) | 0.000 |
| Yes | 64 (22.1%) | 47 (56.6%) | |

Legend: BoNT, Botulinum toxin therapy; [1]chi-sqared test.

years old (range 18-81, SD 12.41 years), with average total FIM 93 (range 36-122, SD 17.81) at discharge from inpatient rehabilitation. Other demographic and clinical characteristics of the patients are shown in Table 1. An average of 37 electrical stimulators were prescribed per year (SD 14.1, range 22-65) (Figure 1). The demographic and clinical characteristics of the patients are shown in Table 1.

There is a statistically significant difference in the prescription of FES between the observed groups (chi-squared test, P=0.000) (Table 2). FES is prescribed most frequently (in 51.8% of cases) in patients with mild poststroke disability with severely impaired upper extremity (FIM > 80, Brunnstrom stages 1-3) (Table 2). Half of the patients (50.1%) used FES on the paretic upper extremity, 175 patients (46.9%) combined on the hemiparetic upper and lower limb and only minority (2.9%) on the affected lower extremity alone. The upper limb stimulation predominates almost in the whole observational period, while the combination of the upper and lower limb stimulation prevailed in years 2011, 2014 and 2017 (Figure 2). Two hundred and ninety patients (77.7%) used FES for at least one year after the prescription and 83 (22.3%) for more than 1 year, on average 3.5 years (SD 1.94; range 2 to 9 years). A combination of FES and BoNT was used as a spasticity treatment of affected upper extremity in almost one third of patients (29.8%). Forty-seven (42.3%) out of them used the combined therapies (BoNT and FES) for more than 1 year, on average 3.9 years (SD 2.06; range 2 to 9 years). In the group that used FES for more than one

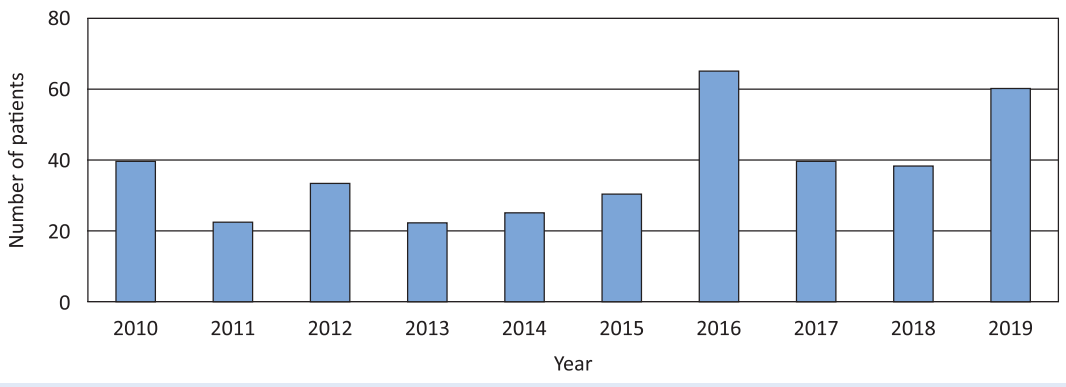


**Figure 1.** Number of patients with FES devices for home use in years 2010 to 2019.

year, BoNT was statistically significantly more frequent (chi-squared test, P=0.000) (Table 3).

## DISCUSSION

In this pragmatic study, we explored the role of FES for home use in a large cohort of patients with stroke. The retrospective review of medical documentation showed that a relatively constant number of FES devices for home use were prescribed in the 10 years period. On average, 37 stimulators were prescribed per year. Given that an average of 264 stroke in-patients were treated each year in the institution[26], FES device for long term use was prescribed in 13% of them annually. The targets of long-term FES at home use in stroke survivors in URI- Soča remained more or less the same in the last 10 years. Though prescription criteria were initially based merely on clinical experiences, the scientific evidence of their suitability is growing[9]. The majority of the patients got the FES device with the aim to improve muscle strength of wrist and finger extensors and ankle dorsiflexors on the hemiparetic side. Most of these patients used FES therapy at home for less than one year. On average, they had better motor functions and higher FIM scores. Though early RCTs reported a statistically significant advantage in the use of FES for improving muscle strength in stroke patients vs. other available interventions[27], feasibility of FES is not merely muscle strengthening. FES uses both somatosensory inputs and passive movements as means to improve motor performances[9, 28, 29].

Neuroimaging studies demonstrated that passive movements result changes in functional brain activations that resemble the ones elicited by active movements[30, 31] and somatosensory inputs lead to changes in the cortical excitability[32]. Furthermore, studies of cortical and subcortical correlates of FES of wrist extensor and flexor muscles in healthy subjects by fMRI revealed an activation pattern of an extensive neural network comprising the contralateral primary motor cortex, primary somatosensory cortex and premotor cortex, ipsilateral cerebellum, bilateral secondary somatosensory cortex, the supplementary motor area and anterior cingulate cortex[28]. However, longer-lasting changes in corticospinal excitability can be induced after approximately 40 h of FES therapy[9]. This are the reasons why we believe that the continuation of FES therapy over a long period of time in the home environment is appropriate. Similarly, Hara et al. found that the EMG-controlled FES home-based therapy effectively improved wrist, finger extension and shoulder flexion and made hemiparetic patients to increase the chance to regain use of the hemiparetic arm in ADL[20].

Almost one-third of patients included in our study got FES for home use to manage spasticity, especially those with severely affected upper extremities. It seems that they found FES therapy effective, for a quarter of them actually liked using FES for years. The effectiveness of FES as a clinical treatment of spasticity is still an open question. It is unclear whether to stimulate a spastic muscle or its antagonists and whether electrical stimulation can actually worsen spasticity[33], although some studies indicated a

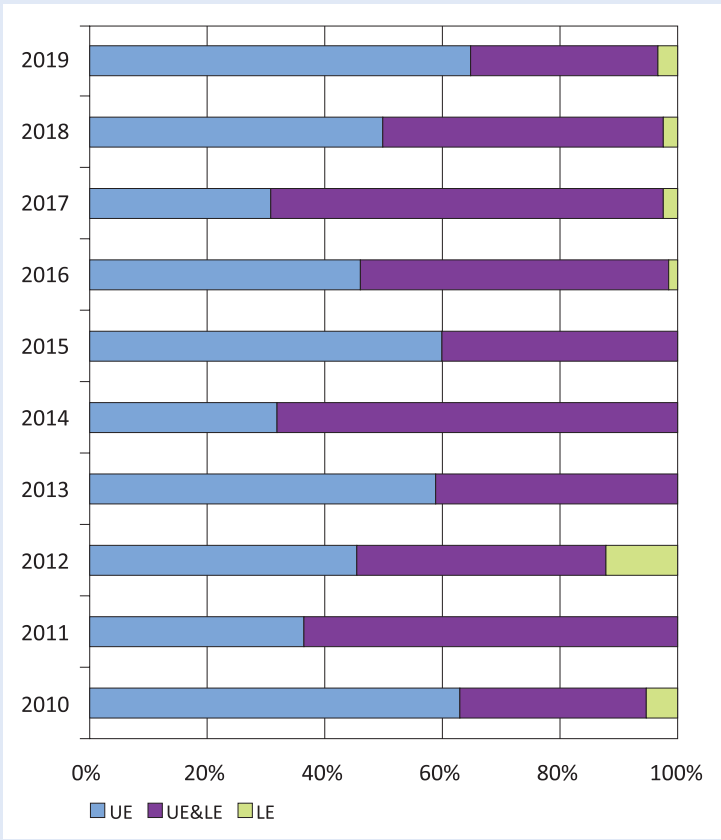


**Figure 2.** Stimulation site proportions in years 2010 to 2019
Legend: UE, upper extremity; UE&LE, upper and lower extremity; LE, lower extremity.

decrease in spasticity after treatment with FES[2]. In our clinical practice we use FES of the antagonists to strengthen the remaining motor units and increase their endurance, maintain range of motion of affected limbs and reduce spasticity[34, 35]. It is worth mentioning that excessive spasticity might complicate successful FES and is an exclusion criterion for home use.

Nowadays chemodenervation using BoNT is highly recommended to reduce focal or segmental and symptomatically distressing spasticity after stroke[14]. However, the combination of the FES and BoNT therapies has not yet been well established[36] and we lack agreement on the most effective approach. Paralytic effect of BoNT starts earlier when the toxin uptake is increased with electrical stimulation, when electrical stimulation is applied to the injected muscles during the BoNT uptake process in a single electrical stimulation session performed on the same day of BoNT injection[37, 38]. BoNT in combination with FES in the setting of stimulation of spastic muscle antagonist and longer stimulation protocols addresses both the positive and negative components of upper motor neuron system (UMNS) simultaneously and could possibly lead to increased functional gains relative to either of them alone[33, 38, 39]. Among our patient almost a quarter was treated combining BoNT and FES. More than a half of those used FES at home for years, which suggests they felt effectiveness of combined treatment. We hypothesized that FES is an effective form of adjuvant therapy, as it facilitates muscle re-education, including antagonist strengthening and agonist lengthening.

This pragmatic study enlightened the long-term FES therapy at home, especially regarding ambiguity of clinical trials findings on FES spasticity treatment. We are well aware of many limitations of the study. Most importantly, the retrospective nature of the study limited the availability of the clinical data. In addition, we had no influence on the follow-up referrals of patients, though URI-Soča was the only rehabilitation center in the country that prescribes FES. To monitor the effects of long-term FES therapy in the future systematic follow up protocols are needed or long-term FES therapy should become a part of telerehabilitation programs.

Though the indication for FES as a therapy for spasticity in stroke patients is not clear, our clinical experiences show that long-term FES offers an effective management of spasticity, especially in combination with BoNT.

## CONCLUSIONS

FES has been used for many years in URI-Soča clinical practice and remains one of the most modern therapeutic procedures in stroke rehabilitation according to new evidence on the mechanisms and its efficacy that has been available in recent years. FES is also simple and safe therapy for long-term home use. Though the indication for FES as a therapy for spasticity in stroke patients is not clear, our clinical experiences show that long-term FES offers an effective management of spasticity, especially in combination with BoNT.

**Conflicts of interest:** Authors declare no conflicts of interest.

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