Effects of functional electrical stimulation-cycling on shoulder pain and subluxation in patients with acute–subacute stroke: a pilot study
Ozgur Z. Karaahmet\textsuperscript{a}, Eda Gurcay\textsuperscript{b}, Zeynep K. Unal\textsuperscript{a}, Damla Cankurtaran\textsuperscript{a} and Aytul Cakci\textsuperscript{a}

Introduction
Stroke was reported as the second most common cause of death and the third most common cause of reduced disability-adjusted life years worldwide (Lozano \textit{et al.}, 2012). The most common and destructive result of this disability is the functional impairment of the upper extremity. As a result of this functional disability, shoulder pain and subluxation occur more frequently in hemiplegic patients. Shoulder pain may develop in \textasciitilde 16–72\% of patients. In patients with involuntary movement in the affected extremities, this rate can be up to 80\% (Walsh, 2001; Karaahmet \textit{et al.}, 2014). The etiology of hemiplegic shoulder pain is multifactorial, such as shoulder subluxation, spasticity in the pectoralis major and subscapularis, adhesive capsulitis, bursitis, tendinitis, and shoulder-hand syndrome (Chuang \textit{et al.}, 2017). Despite the use of multiple treatment regimens, neuromuscular electrical stimulation and transcutaneous electrical nerve stimulation are two most common approaches to reduce pain in clinical practice (Price and Pandyan, 2001). Glenohumeral subluxation is seen in 15–81\% of patients, and the most important reason is the deterioration of the shoulder biomechanics. In a recent systematic review and meta-analysis, it has been shown that functional electrical stimulation (FES) can be used to prevent or reduce shoulder subluxation in the post-stroke early period (Gu and Ran, 2016).

FES-cycling is a relatively new technology, and in recent years, cycling exercise has been combined with FES, a technique used to provide voluntary muscle contraction during a functional task. Low-level electrical current is applied either to the nerve controlling the muscles or directly to the motor end-plate of the muscle system. This facilitates the reorganisation of neuromuscular activity and enhances neuronal excitability of the sensorimotor cortex. The method has been reported as safe and feasible (Golaszewski \textit{et al.}, 2004; Chae \textit{et al.}, 2008; Francis \textit{et al.}, 2009; Alon \textit{et al.}, 2011; Bauer \textit{et al.}, 2015). Very few studies have been conducted on the effect of FES-cycling on hemiplegic patients’ motor and gait improvement (Ferrante \textit{et al.}, 2008; Ambrosini \textit{et al.}, 2011). Our study is the first randomized-controlled study using the FES-cycling to examine shoulder subluxation, and to compare it with traditional rehabilitation therapy in patients with acute–subacute stroke. Therefore, the
aims of the present study were primarily to evaluate the effects of the FES-cycling ergometry training to reduce shoulder pain and to prevent subuxation, and secondarily to evaluate the improvement of upper extremity motor functions in patients with stroke.

**Participants and methods**

**Participants**

This study was designed and performed as a prospective, randomized, controlled clinical trial. Patients with stroke referred to the Physical Medicine and Rehabilitation Clinic were enrolled in this study. Participants were totally volunteers and were informed about the nature of the study. All procedures were in consistency with the Helsinki Declarations of 1975. The study was confirmed by the hospital local ethical committee.

Patients between the ages of 18 and 80 years, who had a first stroke and were subsequently hospitalized and rehabilitated for 4 weeks were included in this study. Patients who provided limited cooperation and had sensory aphasia, recurrent stroke or bilateral hemiplegia, vasomotor instability (coagulation disorder), lower motor neuron disorder, limitation/instability/dislocation of the shoulder joints, severe spasticity (Modified Ashworth scale > 3), pressure ulcer/skin loss at stimulation point, and uncontrolled epilepsy were excluded from the study. Demographic and clinical characteristics of patients were recorded. Patients were divided into two groups and were randomized by sealed envelope method; the first group included the patients receiving standard rehabilitation treatment plus FES-cycling and the second group (control group) included patients receiving only standard rehabilitation therapy.

**Intervention**

Both groups were trained with a standard rehabilitation program, five times a week lasting 30 min each, totally 20 sessions, accompanied by a specialist physiotherapist. This program consisted of range of motion, stretching, and strengthening exercises.

Patients in FES-cycling group were seated on a chair in front of a motorized cycle-ergometer (MOTOmed; Reck GmbH, Betzenweiler, Germany) during the treatment. A current-controlled eight-channel stimulator (RehaStim; Hasomed GmbH, Magdeburg, Germany) was used, and surface electrodes were applied in a bipolar configuration on the anterior and the posterior deltoid, biceps, and triceps muscles of the affected upper extremity. Rectangular biphasic pulses with a pulse width of 300 μs and a stimulation frequency of 20 Hz were adopted. For participants treated with FES, stimulus intensity was placed on each muscle at a tolerated value producing visible muscle contractions. All sessions consisted of a 5-min warm-up of passive cycling, a 15-min training of FES-cycling, and a 5-min cool-down of passive cycling. Patients were required not to participate voluntarily to the arm pedaling but to keep concentrating on the exercise. When passive cycling was carried out, arms of the patients were moved only by the motor of the ergometer, ensuring a constant speed of 20 rpm during the training session.

**Outcome measurements**

Analyses of shoulder subluxation were carried out by radiography. The vertical component of the glenohumeral alignment was determined by measuring the vertical distance between the point on the acromion and the central point of the humeral head (Fig. 1). We accepted more than 9.5-mm acromiolumeral distance (AHD) as an indicator of shoulder subluxation (Hall et al., 1995).

Shoulder pain was determined when a patient reported pain at the shoulder of the hemiplegic side at rest or during passive range of motion. The intensity of the pain in the hemiplegic shoulder was rated by the numeric rating scale (NRS), with values between 0 and 10 (Kim et al., 2014).

The motor recovery of patients was assessed clinically with Brunnstrom scale (Brunnstrom, 1970). The Brunnstrom scale evaluates motor recovery of patients with stroke and includes six stages from ‘1, flaccid, no voluntary movement’ to ‘VI, isolated joint movement’. The patients with stages less than 3 were included.

The motor functionality of the upper extremity was analyzed using the Fugl-Meyer Motor Assessment test (FMA) (Fugl-Meyer et al., 1975) and Frenchay arm test (FAT) (Wade, 1992). FMA is one of the most commonly used quantitative measures of motor impairment. Each item of the FMA is graded on a three-point ordinal scale (0 = cannot perform, 1 = performs partially, and 2 = performs fully), and the items measure motor performance, sensory function, balance, range of motion, and joint pain. The upper extremity motor function portion of the FMA is used in this study (maximum score is 66). FAT is a simple measurement of arm function. It takes less than 3 min to complete and consists of five tasks. The patient receives one point for each successfully completed task.

Functional status was assessed by the functional independence measure (FIM) (Keith et al., 1987; Küçükdeveci et al., 2001). The FIM scale assesses physical and cognitive disability. Items are scored on the level of assistance needed for an individual to perform daily living activities. The scale includes 18 items. Each item is scored from 1 to 7 according to the level of independence: 1 represents total dependence and 7 indicates complete independence. Possible scores range from 18 to 126.

**Statistical analyses**

Data were analyzed using the commercial IBM SPSS for Windows version 20 (IBM Corp., Armonk, New York, USA). Summary of the characteristics variables were performed using descriptive analysis; the values of mean ± SD and median (minimum–maximum) were
presented for quantitative variables. Yates’ $\chi^2$ and Fisher exact tests were used to assess the qualitative differences within groups. Alternatively, numeric variables were detected using Student $t$-test and the Mann-Whitney $U$-test. A $P$ value less than 0.05 was considered indicative of statistical significance.

## Results

A total of 30 patients were recruited in the study, and 21 patients who were able to complete 20 sessions of training were analyzed. Twelve patients performed FES-cycling ergometry training and nine performed standard rehabilitation therapy. No adverse effects were reported during the sessions.

The two groups were homogeneous in terms of demographic and clinical findings ($P > 0.05$) (Table 1). Intragroup comparisons showed improvements for AHD, FMA, and FIM in both groups after treatment (Table 2). In intergroup comparisons, only the severity of pain, measured with the NRS, decreased more in the FES-cycling group than the control group ($P = 0.037$). When correlation analyses between subluxation and demographic and clinical findings were applied, only positive correlation between subluxation and pain was obtained ($P = 0.022, r = 0.498$).

## Discussion

In the current prospective randomized-controlled pilot study, we primarily evaluated the effects of the FES-cycling ergometry training on shoulder pain and subluxation, and secondarily evaluated the improvement of upper extremity motor functions in patients with acute–subacute stroke. Our results showed that shoulder pain decreased more in favor of the FES-cycling group compared with the standard rehabilitation program.

Since the 1990s, FES has been increasingly used in poststroke gait rehabilitation, given some evidence of its effectiveness in improving motor and walking ability. A safe and economical tendency for FES-based gait training is the use of FES synchronized to the cycling movement, which allows the lower extremity muscles to

---

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

<table>
<thead>
<tr>
<th>Variables</th>
<th>FES-cycling group ($n = 12$)</th>
<th>Control group ($n = 9$)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean ± SD) (years)</td>
<td>56 ± 17.5</td>
<td>58 ± 15.4</td>
<td>0.643</td>
</tr>
<tr>
<td>Sex (female/male) [n (%)]</td>
<td>6 (50)/6 (50)</td>
<td>2 (22)/7 (78)</td>
<td>0.367</td>
</tr>
<tr>
<td>Time since stroke (mean ± SD) (days)</td>
<td>46.8 ± 10.3</td>
<td>35.2 ± 35.7</td>
<td>0.166</td>
</tr>
<tr>
<td>Type of stroke (ischemic/hemorrhagic)</td>
<td>10 (83)/2 (17)</td>
<td>8 (89)/1 (11)</td>
<td>0.612</td>
</tr>
<tr>
<td>[n (%)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side of paresis (right/left)</td>
<td>5 (41)/7 (59)</td>
<td>6 (67)/3 (33)</td>
<td>0.387</td>
</tr>
<tr>
<td>[n (%)]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder pain (+ /−) [n (%)]</td>
<td>4/8</td>
<td>3/6</td>
<td>0.676</td>
</tr>
<tr>
<td>Shoulder subluxation (+ /−) [n (%)]</td>
<td>3/9</td>
<td>1/8</td>
<td>0.414</td>
</tr>
<tr>
<td>NRS (0–10) (mean ± SD)</td>
<td>1.6 ± 2.6</td>
<td>2 ± 3</td>
<td>0.832</td>
</tr>
<tr>
<td>AHD (mean ± SD) (cm)</td>
<td>1 ± 0.2</td>
<td>0.9 ± 0.7</td>
<td>0.641</td>
</tr>
<tr>
<td>Brunnstrom (median) (minimum–maximum)</td>
<td>2 (1–2)</td>
<td>2 (1–3)</td>
<td>0.059</td>
</tr>
<tr>
<td>FMA (0–66) (mean ± SD)</td>
<td>8.8 ± 11.4</td>
<td>8.7 ± 5.1</td>
<td>0.506</td>
</tr>
<tr>
<td>FAT (0–5) (mean ± SD)</td>
<td>0</td>
<td>0.1 ± 0.3</td>
<td>0.208</td>
</tr>
<tr>
<td>FIM (8–126) (mean ± SD)</td>
<td>74.7 ± 12.7</td>
<td>74.6 ± 12.4</td>
<td>0.915</td>
</tr>
</tbody>
</table>

AHD, acromiohumeral distance; FAT, Frenchay arm test; FES, functional electrical stimulation; FIM, functional independence measurement; FMA, Fugl-Meyer assessment; NRS, numeric rating scale.
move into coordinated motion, approximating the cyclic movements of locomotion (Ambrosini et al., 2011).

Motorized cycling ergometer is a particularly useful treatment for severely disabled patients with stroke because automatic pedaling facilitates phasic, coordinated muscle activity with continuous use of the hemiside extremitas (Hancock et al., 2012). In addition, FES exercise can increase the strength and prevent atrophy of paralyzed muscles by using stimulation patterns that induce recurrent contractions in selected muscle groups (Sheffler and Chaic, 2007). In a variety of studies, afferent stimulation elements are associated with beneficial changes in brain activity, including recurrence, functional target activity, and FES. Clinical evidence suggests that FES-mediated therapy reduces motor impairment in people with hemiparesis (Ambrosini et al., 2011). In a previous study (Lee et al., 2012), FES could be an alternative strategy to increase muscle performance in severely disabled patients (Santos et al., 2006; Kesar et al., 2010). However, no previous study investigated the efficacy of FES-cycling-assisted ergometer training on hemiplegic upper extremity in patients with acute–subacute stroke, including evaluation of the patient’s functional ability. Only a small scale, nonrandomized controlled study was conducted in China to reduce spasm of upper limbs in hemiplegic patients (Zhu et al., 2006). To our best knowledge, this is the first randomized-controlled study performed with the FES-cycling and traditional treatment on hemiparetic upper extremity in patients with acute–subacute stroke.

There are contradicting reports in the literature on the relationship between shoulder subluxation and pain. Although many studies have demonstrated a positive correlation between shoulder subluxation and pain, others have revealed no such correlation (Karabulut et al., 2014). We found positive correlation between subluxation and pain. Although the NRS was further decreased after treatment in favor of FES-cycling group, there was no significance in subluxation, presumably owing to the small sample size.

The shortcomings of this study were including relatively a small number of participants, which could be insufficient to observe the effects of FES training, and that the duration of the 4-week therapeutic intervention could not be enough to accurately demonstrate the additional effects of the FES training compared with the standard treatment.

**Conclusion**

This study demonstrated that FES-cycling was superior to standard rehabilitation therapy for shoulder pain relief in patients with acute–subacute stroke. Although AHD did not reflect any significant improvement, fewer patients in the FES-cycling group developed subluxation. Therefore, combining FES-cycling ergometry training with a standard rehabilitation program alleviates shoulder pain and may prevent development of shoulder subluxation over time.

**Acknowledgements**

**Conflicts of interest**

There are no conflicts of interest.

**References**


### Table 2: Intragroup comparisons of pretreatment and post-treatment values

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pretreatment</th>
<th>Post-treatment</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>FES-cycling group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS (0–10) (mean±SD)</td>
<td>1.6±0.2</td>
<td>0.8±0.1</td>
<td>0.005*</td>
</tr>
<tr>
<td>AHD (mean±SD) (cm)</td>
<td>1.2±0.3</td>
<td>0.8±0.1</td>
<td>0.016*</td>
</tr>
<tr>
<td>Brunnstrom [median]</td>
<td>2 (1–5)</td>
<td>0 (1–3)</td>
<td>0.014</td>
</tr>
<tr>
<td>(minimum–maximum)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA (0–68) (mean±SD)</td>
<td>8.8±11.4</td>
<td>6.8±10.1</td>
<td>0.003*</td>
</tr>
<tr>
<td>FAT (0–5) (mean±SD)</td>
<td>0.5±1</td>
<td>0.3±0.2</td>
<td>0.109</td>
</tr>
<tr>
<td>FIM (8–126) (mean±SD)</td>
<td>74.7±12.7</td>
<td>74.8±12.6</td>
<td>0.003*</td>
</tr>
<tr>
<td>Control group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS (0–10) (mean±SD)</td>
<td>2±3</td>
<td>1±2</td>
<td>0.084</td>
</tr>
<tr>
<td>AHD (mean±SD) (cm)</td>
<td>1.4±0.3</td>
<td>0.7±0.1</td>
<td>0.011*</td>
</tr>
<tr>
<td>Brunnstrom [median]</td>
<td>4 (1–5)</td>
<td>3 (1–5)</td>
<td>0.034</td>
</tr>
<tr>
<td>(minimum–maximum)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA (0–68) (mean±SD)</td>
<td>8.7±5.1</td>
<td>7.3±4.5</td>
<td>0.020*</td>
</tr>
<tr>
<td>FAT (0–5) (mean±SD)</td>
<td>1.8±1.0</td>
<td>0.7±1.0</td>
<td>0.043*</td>
</tr>
<tr>
<td>FIM (8–126) (mean±SD)</td>
<td>74.8±12.4</td>
<td>74.8±12.6</td>
<td>0.008*</td>
</tr>
</tbody>
</table>

AHD, acromiohumeral distance; FAT, Frenchay arm test; FES, functional electrical stimulation; FIM, functional independence measurement; FMA, Fugl-Meyer assessment; NRS, numeric rating scale.

*P<0.05, statistically significant.

### Table 3: Comparison of changes in pretreatment and post-treatment values between groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>FES-cycling group</th>
<th>Control group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS (0–10) (mean±SD)</td>
<td>−1.4±2.2</td>
<td>0.7±1.2</td>
<td>0.015*</td>
</tr>
<tr>
<td>AHD (mean±SD) (cm)</td>
<td>0.2±0.2</td>
<td>0.4±0.3</td>
<td>0.315</td>
</tr>
<tr>
<td>Brunnstrom [median]</td>
<td>1 (2–3)</td>
<td>−1 (2–3)</td>
<td>0.119</td>
</tr>
<tr>
<td>(minimum–maximum)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FMA (0–68) (mean±SD)</td>
<td>9.5±8.3</td>
<td>12.3±19.2</td>
<td>0.582</td>
</tr>
<tr>
<td>FAT (0–5) (mean±SD)</td>
<td>0.5±1</td>
<td>1.7±1.9</td>
<td>0.950</td>
</tr>
<tr>
<td>FIM (8–126) (mean±SD)</td>
<td>−3.5±5.1</td>
<td>−1.2±5.5</td>
<td>0.187</td>
</tr>
</tbody>
</table>

AHD, acromiohumeral distance; FAT, Frenchay arm test; FIM, functional independence measurement; FES, functional electrical stimulation; FMA, Fugl-Meyer assessment; NRS, numeric rating scale.

*P<0.05, statistically significant.
Effects of FES-cycling on shoulder pain Karaahmet et al.

Copyright © 2018 Wolters Kluwer Health, Inc. Unauthorized reproduction of this article is prohibited.