ORIGINAL REPORT

EFFECTS OF A FUNCTIONAL ELECTRICAL STIMULATION-ASSISTED LEG-CYCLING WHEELCHAIR ON REDUCING SPASTICITY OF PATIENTS AFTER STROKE

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Objective: To determine whether short-term propulsion of a functional electrical stimulation-assisted leg-cycling wheelchair (FES-LW) in patients with stroke can reduce spasticity of the affected leg and whether FES has additional effects on reducing spasticity.

Design: Within-subject comparison.

Subjects: A total of 17 patients after stroke were recruited from the university hospital.

Methods: Subjects propelled 2 leg-cycling wheelchairs (the FES-LW and the LW) and a manual wheelchair along an oval pathway. The Modified Ashworth Scale (MAS), H reflex/maximal M response (H/M ratio) and relaxation index were used to evaluate the immediate effects on leg spasticity. The changes in MAS, H/M and relaxation index were used to evaluate the effect of FES in comparing 2 leg-cycling wheelchairs.

Results: The MAS and H/M ratio were significantly decreased and the relaxation index significantly increased by FES-LW and LW usage. For subjects with higher muscle tone, significant lowering of the changes in MAS, H/M ratio and higher relaxation index were found for FES-LW usage compared with LW usage.

Conclusion: Leg spasticity is reduced after short-term propulsion of the FES-LW and LW. The application of FES has an additional effect on reducing spasticity in subjects with higher muscle tone.

Key words: spasticity, functional electrical stimulation, leg-cycling, wheelchair, stroke.

INTRODUCTION

Of those patients who survive the acute phase after stroke, more than half have limited ambulatory ability because of muscle weakness or strong synergies and spasticity of the paretic leg (1, 2). Most of these patients use manual wheelchairs (MW) to improve their mobility and prevent falls during activities of daily living. However, the increase in muscle tone following stroke often impedes them from operating a MW very well. They often experience performance difficulties such as deviating from the desired direction towards the affected side, straying off the edge of a ramp, and other dangers arising from unilateral limb propulsion (3, 4). The asymmetrical propulsion pattern forces a patient’s trunk to lean towards the affected side. The unbalanced posture may increase abnormal muscle tone on the affected side and adversely affect long-term recovery (5, 6). These issues might be a good reason to discourage patients from self-propulsion of wheelchairs after stroke, particularly soon after stroke onset.

There are, however, some innovative leg-propelled wheelchairs, which were developed specifically for patients after stroke (7–9). Makino et al. (7) proposed a wheelchair with 2 pedals propelled by both legs. Tsai et al. (8, 9) proposed 2 types of leg-propelled wheelchairs, both propelled by the unaffected leg. The above studies have demonstrated that leg exercise provides higher physiological efficiency than arm exercise with respect to wheelchair propulsion. However, the effect of leg propulsion on the muscle tone of the affected leg has not been investigated.

Many therapeutic approaches, such as physical exercise and electrophysiological treatments, have been utilized to decrease spasticity (10–14). Physical exercise, such as cycling motion, is a useful therapeutic approach to reduce spasticity. In patients with multiple sclerosis, muscle tone was significantly decreased after leg cycling movements (10, 11). Although these 2 studies had positive results regarding reduced spasticity after leg cycling movements, the results were not specifically related to patients after stroke. Other studies have reported that repetitive passive movement of spastic muscle can increase the range of motion and reduce the stiffness of hypertonic joints of patients after stroke (12, 13). The above mentioned studies suggest that cyclic leg movement may be a possible therapeutic modality to reduce spasticity in patients with stroke. Clinical applications utilizing electrical stimulation have been widely adopted for the treatment of spasticity. Some authors have presented studies specifically to assess the effect of electrical stimulation on spasticity (14–18). In addition, some studies have reported a
modification of spasticity from functional electrical stimulation (FES) for accomplishment of functional activities (19, 20). The above mentioned studies found positive effects of electrical stimulation in persons with spinal cord injuries (SCI) and stroke. Therefore, combining cycling motion with FES for the affected leg may be a useful approach to reduce spasticity.

We propose a new assistive device, a functional electrical stimulation assisted leg-cycling wheelchair (FES-LW), which allows patients after stroke to move assisted by FES applied to the affected leg (21). Although the FES-LW provides more mobility for patients after stroke, the neuromuscular effects on the affected leg after propelling the FES-LW are not clear. The aim of this study was to determine whether short-term propulsion of the FES-LW in patients after stroke can immediately reduce the spasticity of the affected leg and whether FES applied to the affected leg during cycling has additional effects to those of cycling without FES.

METHODS

Subjects
A total of 17 patients after stroke (12 men and 5 women) with a mean age of 56.4 (standard deviation (SD) 7.3, range 45–72) years were recruited from the university hospital. Inclusion criteria included the following: (i) patients with hemiplegia; (ii) hypertonia in the affected leg, Modified Ashworth Scale (MAS) score ≥ 1+; and (iii) sufficient cognitive function to realize testing instructions and understand the potential risks of this study. Exclusion criteria included (i) visuo-spatial impairment; (ii) diagnosis of heart failure, arrhythmia, or angina; and (iii) orthopaedic or neurological diseases impairing wheelchair propulsion. For all subjects, the time after lesion detection was 5.1 (SD 2.2) weeks. Eight subjects had right-side hemiplegia and the other 9 had left-side hemiplegia. Eight subjects had cerebral haemorrhage and the others cerebral ischaemia. The characteristics of subjects who participated in this study are shown in Table I. The purpose and procedures of the clinical evaluation were fully explained to all subjects, their informed consent obtained, and the study was approved by the ethics committee of the National Cheng Kung University Hospital.

Wheelchairs
The FES-LW combines a leg-cycling wheelchair (LW) with an FES controller (Fig. 1a). This is a cycling system equipped with ankle-foot orthoses (AFOs) attached to the wheelchair. The AFOs were utilized to prevent accidental disengagement of the subject’s leg and abduction of the affected hip joint. The hinge joint of each AFO (Fig. 1b) allows ankle dorsi- and plantar-flexion during cycling motion. The LW is steered via a lever attached to the castor on the unaffected side. Two LWs were fitted with the lever on either side to suit left- or right-side hemiplegia. The FES controller detected the current position of the affected leg through an angular encoder (MES-30-360P; Microtech Laboratory Inc, Kanagawa, Japan) attached to the shaft of the cycling system. The 0 degree position was defined as the proximal point of the crank when the crank is parallel to the ground. The FES controller stimulates the quadriceps and hamstring when the affected leg sweeps through the range from 50° to 180° and 200° to 290°, respectively. The stimulation parameters included rectangular, biphasic waveforms with sequential 20 Hz frequency and pulse duration 300 ns. Subjects propel the LW using the unaffected leg and affected leg alternately. When FES was applied to the affected leg during propelling, it was expressed as the FES-LW.

A commercial MW (KM-8520; Karma Medical Products Co., Ltd, Chia-Yi, Taiwan) was defined as the control group. The MW propelled by the unaffected arm and leg was compared in this study. The rear tyres of each wheelchair were changed to 24 × 13/8-inch solid rubber tyres, and the weight of each wheelchair was equalized.

Procedures
Before the trial, subjects practised under the supervision of a physiotherapist with each wheelchair for 1 h a day, every other day for a period of 2 weeks. The stimulation intensity of the FES-LW was adjusted by the therapist on an individual basis to elicit muscle contraction without introducing pain. The simulation intensities applied to the subjects’ quadriceps and hamstring were in the range 40–58 mA and 42–64 mA, respectively. For the testing trial, subjects were instructed to propel each wheelchair along an oval-shaped pathway for 100 m at a comfortable speed (Fig. 2). After turning round, subjects propelled the wheelchair anticlockwise on the same pathway for another 100 m. Subjects completed 3 test trials separated by at least one day of rest during the span of 10 days.

Table I. Characteristics of participants (n = 17)

<table>
<thead>
<tr>
<th>Variables</th>
<th>n</th>
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<tbody>
<tr>
<td>Gender, men/women, n</td>
<td>12/5</td>
</tr>
<tr>
<td>Age, years, mean (SD)</td>
<td>56.4 (7.3)</td>
</tr>
<tr>
<td>Time after stroke, weeks, mean (SD)</td>
<td>5.1 (2.2)</td>
</tr>
<tr>
<td>Side of stroke, right/left, n</td>
<td>8/9</td>
</tr>
<tr>
<td>Pathology, ischaemia/haemorrhage, n</td>
<td>9/8</td>
</tr>
<tr>
<td>MAS, 0/1/1+/2/3/4</td>
<td>0/0/3/5/6/3</td>
</tr>
<tr>
<td>Brunnstrom stage, I/II/III/IV/V/VI</td>
<td>0/5/8/3/1/0</td>
</tr>
</tbody>
</table>

SD: standard deviation; MAS: Modified Ashworth Scale.
Subsequently, the amplitude of the small M response (10% activity. The peak-to-peak amplitude of the H reflex was divided by H reflex without significant background electromyography (EMG) of nerve stimulation. We recorded and filtered 3–5 trials of reliable concurrent with the H reflex was monitored to maintain the consistency intensity of the stimulation current was adjusted to locate the maxi-
mum during all test trials.

H reflex measurement. The subjects sit with the affected knee straight and the affected ankle in a neutral position to measure the H reflex of the soleus. The H reflex and M response were elicited using a single rectangular 1-ms electrical pulse from an electrical stimulator (Model S88; Grass Technologies, Astro-Med, Inc., West Warwick, RI, USA). An adhesive anode was placed over the patella of the affected leg, and a bar cathode was fixed over the posterior tibial nerve of the popliteal fossa. We attached 2 20-mm silver-silver chloride electrodes along the soleus 2–3 cm below the heads of the gastrocnemius muscle and one electrode above the lateral malleolus. The electrodes were connected to an amplifier (Model 7P511; Grass Technologies) and the amplifier was connected to a digital oscilloscope for real-time display. The intensity of the stimulation current was adjusted to locate the maximal peak-to-peak amplitudes of the non-rectified M response (M<sub>max</sub>). Subsequently, the amplitude of the small M response (<span class="MathJax_Span" role="presentation" class="MathJax_SPAN" data-service="MathJax" data-mathml="10 \pm 3\% M_{\text{max}}."><span class="MathJax_Span" role="presentation" class="MathJax_SPAN" data-service="MathJax" data-mathml="10 \pm 3\% M_{\text{max}}."><span class="MathJax_Span" role="presentation" class="MathJax_SPAN" data-service="MathJax" data-mathml="10 \pm 3\% M_{\text{max}}.">
</span></span></span>) concurrent with the H reflex was monitored to maintain the consistency of nerve stimulation. We recorded and filtered 3–5 trials of reliable H reflex without significant background electromyography (EMG) activity. The peak-to-peak amplitude of the H reflex was divided by the M<sub>max</sub> and expressed as the H/M ratio.

Pendulum test. The subjects sit and their affected leg is lifted to achieve maximum possible knee extension and then released. The leg was allowed to drop freely until it stopped. Knee angle was recorded with an electrogoniometer (S700 Joint Angle ShapeSensor; MeasureIn Inc., Fredericton, NB, Canada) attached to the knee joint. The output of the electrogoniometer was sampled and recorded using an analogue-to-digital converter (USB-6008; National Instruments, Austin, TX, USA). A total of 2–4 reliable drop trials are filtered and analysed. The angle at the start of the leg drop was the onset angle and the end of the oscillation was the resting angle. The relaxation index (RI) is expressed as the ratio between the (first flexion angle–onset angle) and the (resting angle–onset angle).

DATA ANALYSIS

MAS, H/M ratio, and the RI, were compared pre- and post-test to determine the immediate effects on muscle tone for each wheelchair. The changes in MAS (MAS<sub>c</sub>), changes in H/M (H/M<sub>c</sub>) and changes in RI (RI<sub>c</sub>) were compared between the FES-LW and the LW to examine the effects of FES on reducing spasticity. The MAS<sub>c</sub> was calculated as post-test data minus pre-test data. The H/M<sub>c</sub> and RI<sub>c</sub> were obtained by subtracting pre-test data from post-test data and dividing by pre-test data. The Wilcoxon signed-rank test was used for ordinal data and the paired t-test was used for continuous data comparison. Analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 12 (SPSS, Chicago, IL, USA). A p-value < 0.05 was considered statistically significant.

RESULTS

Immediate effects on spasticity

MAS was significantly decreased after operating the FES-LW (p = 0.005) and the LW (p = 0.008), but not the MW (p = 0.083, Table II). The H/M ratio was significantly decreased after operating the FES-LW (p < 0.001) and the LW (p < 0.001), but not the MW (p = 0.148). RI was significantly increased after operating the FES-LW (p < 0.001) and the LW p < 0.001), but not the MW (p = 0.699). Collectively, MAS, H/M ratio, and RI indicated significant and substantial reductions in spasticity after operating the FES-LW and the LW.

Effects of FES during leg cycling

The results of MAS<sub>c</sub> revealed no significant difference (p = 0.102; Table III) between the FES-LW and the LW. H/M<sub>c</sub> of the FES-LW was lower than that of the LW and RI<sub>c</sub> of the FES-LW were higher than that of the LW. No significant difference (p = 0.139 in H/M<sub>c</sub> and p = 0.055 in RI<sub>c</sub>) were found between the 2 chairs. Subsequently, we divided subjects into 2 groups as follows: (A) lower muscle tone group (n = 8; MAS 1+ and 2) and (B) higher muscle tone group (n = 9; MAS 3 and 4). For the lower muscle tone group, there were no significant differences in MAS<sub>c</sub>, H/M<sub>c</sub> and RI<sub>c</sub> between the FES-LW and the LW. For the higher muscle tone group, the results of MAS<sub>c</sub> was significantly lower (p = 0.046; Table III) in the FES-LW compared with the LW. The H/M<sub>c</sub> of the FES-LW was significantly lower (p = 0.030) and RI<sub>c</sub> of the FES-LW

<table>
<thead>
<tr>
<th>FES-LW</th>
<th>LW</th>
<th>MW</th>
</tr>
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<tbody>
<tr>
<td>Pre-test</td>
<td>0/0/3/5/6/3</td>
<td>0/1/3/6/7/0</td>
</tr>
<tr>
<td>Post-test</td>
<td>0.055*</td>
<td>0.008*</td>
</tr>
<tr>
<td>H/M ratio, mean (SD)</td>
<td>0.67 (0.21)</td>
<td>0.66 (0.21)</td>
</tr>
<tr>
<td>Post-test</td>
<td>0.54 (0.19)</td>
<td>0.56 (0.18)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>RI, mean (SD)</td>
<td>1.06 (0.24)</td>
<td>1.02 (0.24)</td>
</tr>
<tr>
<td>Post-test</td>
<td>1.25 (0.22)</td>
<td>1.13 (0.22)</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.001*</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
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*Significant difference between pre- and post-test, p < 0.05.

was significantly higher ($p < 0.001$) than those of the LW. The results revealed that operating the FES-LW has an additional effect on reducing spasticity compared with the LW, but only in subjects with higher muscle tone.

**DISCUSSION**

The FES-LW was designed to apply FES to the affected leg during cycling in order to increase mobility for patients after stroke. In our previous study, the clinical performance of the FES-LW was evaluated and compared with that of a MW. The results demonstrated that patients after stroke would benefit from using the FES-LW because of significantly higher speed and physiological efficiency and better manoeuvrability (21). The current study focused on the neuromuscular effects of different wheelchair operation modes. We used the MAS, H/M ratio, and RI to evaluate the immediate effects on spasticity for patients after stroke during the FES-LW, the LW, and the MW. In comparing pre- and post-test data, we found that the MAS, H/M ratio and RI were significantly affected in the FES-LW and the LW but not in the MW. The results indicated that short-term propulsion of leg-cycling wheelchairs (both with and without FES) results in immediate reduction in leg spasticity. Moreover, for subjects with higher muscle tone, H/Mc was significantly lower and Rlc was significantly higher in the FES-LW than the LW. The results show that FES has additional effects on reducing spasticity.

In the present study, no significant difference was found in MAS, H/M ratio and RI in the MW, even though 3 subjects showed increased MAS after using the MW. From observation, subjects tended to push the hand-rim using the unaffected hand and step on the ground using the unaffected foot to operate the MW. This asymmetrical propulsion pattern forces the user’s trunk to lean towards the affected side, resulting in an unbalanced posture. In addition, they swing their trunk forwards and backwards in an effort to maximize wheelchair propulsion, thus producing a dynamically unstable posture during use of the MW. The imbalance and unstable trunk posture are believed to induce immediate increases in abnormal muscle tone (5–6). In comparison, no increased spasticity was found in the FES-LW and the LW. The symmetrical bilateral leg cycling pattern associated with the 2 LWs allows subjects to maintain a balanced trunk posture, but can also prevent induction of abnormal muscle tone.

The significant reduction in MAS, H/M ratio and increase in RI found in the FES-LW and LW revealed that the spasticity of the affected leg was immediately and significantly decreased after short-term propulsion. When subjects propel LWs with a cycling motion, the knee joint performs a reciprocal flexion/extension movement. Repeated passive knee movements were studied by Nuyens et al. (22). They reported that passive knee movements induced a decrease in spastic hypertonia in patients after stroke through a combination of reflexive and mechanical factors. The ankle joint also performs dorsi- and plantar-flexion movement during cycling because of the AFO with hinge joint. Yeh et al. (13) concluded that cyclic muscle stretches successfully reduced MAS grade and reduction in elastic and viscous properties of ankle joint dorsiflexion. Previous studies reported that the soleus H reflex of normal subjects was significantly decreased after an acute bout of leg cycling (23). Similar results were also found in patients with multiple sclerosis for unloaded cycling (11). Rosche et al. (10) reported that a motorized exercise-cycle was used to treat spasticity in subjects who suffered predominantly from multiple sclerosis. They concluded that there was a slight significant decrease in F-wave amplitude after treatment. These referenced studies prove that leg cycling is a rhythmic movement that may change the properties of spastic muscle and soft tissue and also the neuronal excitation of the affected leg. Cycling therefore has positive anti-spastic effects.

There are very few studies into the clinical performance of patients after stroke who perform leg cycling with muscle contractions aided by electrical stimulation. Janssen et al. (24) conducted a study of the effects on affected leg cycling with electrical stimulation in patients with chronic stroke. They found that a short bout of leg cycling can improve their functional performance, but the electrical stimulation has no additional effects on these patients. In the present study, we found that FES-LW and the LW provides a positive effect on reducing spasticity immediately after test, but no significant difference was found between leg cycling with or without FES. However, when subjects were divided into higher and lower muscle tone groups, significant lowering of MASc, H/Mc and higher Rlc were found in the FES-LW compared with the LW for the higher muscle tone group. That means when the FES was applied to the quadriceps and hamstrings of the affected leg during cycling, spasticity was reduced in the knee and also in the ankle for subjects with higher muscle tone. The possible mechanism could be that the electrical stimulation may lead to generalized desensitization of the spinal pathway, reducing the spasticity of spasm muscles (17, 25). Electrical stimulation is reported to affect the nerve fibres to the muscles, but could also travel to higher brain centres, potentially stimulating reorganization of neuromuscular activity (25).

A limiting factor of FES is the uncomfortable and painful sensations experienced when the intensity increases enough.
to elicit functional movement. This is the case specifically in patients with residual perception, such as incomplete SCI or stroke. In the present study, low stimulation intensities were applied to the subjects to avoid pain. The stimulation intensity was adjusted to elicit muscle contraction without introducing pain. Only a limited number of nerves could be stimulated, therefore reducing the effect of FES. This may be the reason that the effect of FES on reducing spasticity was observed only in the higher muscle tone group.

In conclusion, the FES-LW was designed to provide increased mobility for patients with stroke and also to give them the opportunity to propel a wheelchair themselves. To the best of our knowledge, this is the first study to combine FES with leg cycling in a wheelchair to reduce spasticity. We conclude that short-term propulsion of the FES-LW and LW is a useful therapeutic approach to reduce spasticity in stroke patients. Furthermore, the application of FES to the affected leg during cycling had an additional effect on reducing spasticity in the group with higher muscle tone.

ACKNOWLEDGEMENTS

The authors thank the patients and hospital staff who participated in this project. This research was supported by grant NSC 94-2614-B-006-002 from the National Science Council, Taiwan.

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