44 Cases of Peripheral Facial Paralysis Treated by the SXDZ-100 Nerve and Muscle Stimulator*

YANG Jin-sheng 杨金生, CUI Cheng-bin 崔承斌, GAO Xin-yan 高昕妍, ZHU Bing 朱兵 & RONG Pei-jing 容培晶

Institute of Acu-Moxibustion, China Academy of Chinese Medical Sciences, Beijing 100700, China

Objective: To observe the clinical effects of the Hua Tuo Manual Acupuncture Therapeutic Stimulator for peripheral facial paralysis. Methods: 87 patients with peripheral facial paralysis were divided randomly into the SXDZ-100 Nerve and Muscle Stimulator treatment group (44 cases) and the G6805 Electric Stimulator control group (43 cases). The acupoints selected for both the two groups were local points as well as distal points as Hegu (LI 4), Waiguan (TE 5), Sanyinjiao (SP 6), Taichong (LR 3). Effectiveness was compared between the two groups. Results: Both groups had a total effective rate of 100%. But the cure rate was 90.9% in the treatment group, and 73.0% in the control group, indicating a significant difference (P<0.05). No side effects were found in either of the two groups. Conclusion: The SXDZ-100 stimulator is more effective than the G6805 electroacupuncture stimulator for treatment of peripheral facial paralysis.

Key words: Manual Acupuncture Therapeutic Stimulator; peripheral facial paralysis

Electroacupuncture has been the commonly used treatment for peripheral facial paralysis in clinical settings. The SXDZ-100 Nerve and Muscle Stimulator is a newly devised apparatus which can imitate manual acupuncture through a built-in chip with condensed signals from acupuncture experts. Hereby, the authors compared the effects of G6805 electroacupuncture stimulator with SXDZ-100 in peripheral facial paralysis patients enrolled from November of 2007 to May of 2008.

GENERAL DATA
All 87 cases of peripheral facial paralysis were outpatients from the Acu-Moxibustion Hospital, China Academy of Chinese Medical Sciences. They were randomly divided into a treatment group (44 cases) and a control group (43 cases) according to the order of visiting. The detailed data were shown in Table 1.

Table 1. General Data of the Two Groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Gender (n)</th>
<th>Age (year)</th>
<th>Disease course (day)</th>
<th>Location (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>male</td>
<td>female</td>
<td></td>
<td>Inferior FS</td>
</tr>
<tr>
<td>Treatment</td>
<td>44</td>
<td>25</td>
<td>19</td>
<td>12-76</td>
<td>1-180</td>
</tr>
<tr>
<td>Control</td>
<td>43</td>
<td>27</td>
<td>16</td>
<td>14-75</td>
<td>1-150</td>
</tr>
</tbody>
</table>

Notes: FS = Foramen Stylomastoideum

The general data as age, gender, disease course and location were analyzed by χ² test. There was no significant difference between the two groups (P>0.05), indicating that the data were comparable.

METHODS
For the treatment group
The acupoints used were ipsilateral Yangbai (GB 14), Sibai (ST 2), Dicang (ST 4), Yingxiang (LI 20),
Jiachengjiang (Extra), Quanliao (SI 18), Xiaguan (ST 7), Jiache (ST 6), Qianzheng (Extra), Yifeng (TE 17) and Waiguan (TE 5); contralateral Hegu (LI 4); and bilateral Sanyinjiao (SP 6) and Taichong (LR 3). The reinforcing and reducing waves were chosen via the panel of SXDZ-100 Nerve and Muscle Stimulator. The positive electrode was connected to Yifeng (TE 17), and the negative electrode was connected to Qianzheng (Extra). The intensity was regulated according to the patient’s pain threshold, and with mild stimulation for the deficiency syndrome, strong stimulation for the excess syndrome. The mild stimulation with light wave pulse could induce formication with slight twitching of the muscles, whereas the strong stimulation with apparent wave pulse could induce heavy twitching of the muscles. The treatment was given once a day, 25 minutes each time, 10 sessions constituted one therapeutic course with a 3-day interval between courses. The patient received 3 courses of treatment at most.

For the Control group

The same acupoints were selected as that in the treatment group. The dense-sparse wave was chosen from the panel of G6805 electroacupuncture stimulator. The negative and positive electrodes connected and the stimulation intensity decided, the treatment given was the same as that in the treatment group.

Criteria for Diagnosis

According to the criteria set in *Clinical Diagnosis and Treatment Standards for Common Diseases*: 1) indefinite in age of onset; 2) facial mimetic muscle paralysis on the affected side; 3) exclusion of the peripheral facial nerve injury caused by the lesions of otology and cerebellopontine angle; 4) with the syndromes of pain in mastoidia, auditory perceptual disorders, dysgeusia in the front 2/3 of the tongue, etc.

Criteria for Inclusion

1) The patients were in accordance with the diagnostic criteria as mentioned above; 2) the age range was from 10–80 years; 3) those patients with central facial paralysis, acute inflammatory multiple dem-yelinizing neuropathy, skull base diseases, space-occupying lesions, parotitis, parotid neoplasms, suppurative lymphadenitis, and complications of otitis media were excluded; 4) those who signed the informed consent.

Criteria for Exclusion

1) Those with cardiac pacemakers for whom electroacupuncture is forbidden; 2) those with severe disorders in the heart, brain, liver, kidneys, endocrine and hematopoietic systems; 3) those aged under 10 years or over 80 years; 4) alcohol and/or drug abuse, with depression or other mental disorders; 5) those who could not finish the treatment course or did not cooperate well.

Criteria for Therapeutic Effects

The therapeutic effects of facial paralysis were evaluated according to the 40-score method established by the Japanese Neurology Committee. The patients were asked to frown, lightly closing their eyes, heavily closing their eyes, close the affected-side eyes, move their nose, inflate their cheeks, show the teeth, whistle, etc. and were scored in 3 grades. The score 4 was given for no difference found between the two sides of the face; the score 2 for hypomotility found on the affected side; and the score 0 for inability to move the affected side. The evaluations were done before treatment and 3 courses after treatment with the following formula: The relief rate = ((score after treatment − score before treatment) / (40 − score before treatment)) ×100%.

Cured: The relief rate was 100%. Markedly relieved: The relief rate was 60%–90%. Improved: The relief rate was 25%–59%. Failed: The relief rate was 0–24%.

Statistical Analysis

The χ² test was adopted by using SPSS 12.0 statistical software.

RESULTS

1. Comparison of the clinical effects between the two groups (see Table 2).
Table 2. Therapeutic Effects in the Two Groups

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Cured</th>
<th>Markedly Improved</th>
<th>Improved</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>44</td>
<td>40 (90.9%)</td>
<td>3 (6.8%)</td>
<td>1 (2.3%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Control</td>
<td>43</td>
<td>31 (73.0%)</td>
<td>5 (10.8%)</td>
<td>7 (16.2%)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

As shown in Table 3, the cure rate was higher in the treatment group (90.9%) than that of the control group (73.0%) by Chi-square test ($\chi^2=8.65, P<0.05$).

2. For a comparison of the cure rates in the different treatment courses between the two groups (see Table 3).

Table 3. The Cure Rates in Different Courses

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>1st course</th>
<th>2nd course</th>
<th>3rd course</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>40</td>
<td>11(27.5%)</td>
<td>22(55.0%)</td>
<td>7(17.5%)</td>
</tr>
<tr>
<td>Control</td>
<td>27</td>
<td>5(18.5%)</td>
<td>12(44.5%)</td>
<td>10(37.0%)</td>
</tr>
</tbody>
</table>

As shown in Table 3, the cured rates in the 1st and 2nd courses were higher in the treatment group.

Side Effects
No side effects as acupuncture syncope, difficult withdrawal of the needles, hematoma and reaction of vital signs were found in both the two groups.

DISCUSSION
The effects of acupuncture can be improved by different manipulations performed and by the collected and practiced experience. Langevin’s group has used a novel in vivo ultrasound (US)-based technique to quantify tissue displacement with varying amounts of rotation, downward and upward movement performed by a computer-controlled acupuncture needling instrument. The results revealed that increasing the amount of rotation had a significant linear effect on tissue displacement during downward and upward needle motion, as well as on rebound tissue displacement after downward needle movement.\(^3\) HU Yin-e et al thought that acupuncture belongs to a physical stimulation and the effect varies to different stimulus intensities.\(^4\) The previous study indicated that different acupuncture manipulations could be expressed in the dorsal horn of spinal cord neurons which could be recorded by electrophysiological methods. The acupuncture information was decoded and transferred to chips that biological signals cloned and recoded before output. The SXDZ-100 Nerve and Muscle Stimulator is a patented product researched and developed by the Suzhou Medical Appliance Factory and the Institute of Acupuncture and Moxibustion of China Academy of Chinese Medical Sciences. This innovative product has a chip integrated 6 simplex manipulations as well as 6 duplex manipulations from acupuncture expertise. The output biological electric signals were performed on the human body via electric stimulator after amplification.\(^5\)

The present clinic study showed that curative rates were better in the SXDZ-100 group than in the G6805 group under the same improved rate, indicating the SXDZ-100 was a more effective approach for peripheral facial paralysis than conventional electroacupuncture stimulators. The authors observed the curative rate in the 1st and 2nd course is more than that of 3rd course in both groups but no statistical difference was found between the two groups which might be because of the number of patients accepted. Otherwise no side effects were found in both groups.

Traditional acupuncture manipulation is important in clinic therapy whereas a more complicated operation is an obstacle for different practitioners. Moreover, commonly used electroacupuncture stimulators are not an ideal choice which can quickly adapt to the same current and waveform and its effects may decrease in the procession of treatment. The SXDZ-100 provides a new option in acupuncture treatment in that it mimics manual manipulation as standard acupuncture expertise and easy to handle, therefore deserves increased use in clinic settings.

REFERENCE
1. Tao TZ. Criteria of Diagnosis and Treatment for
Clinically Commonly-seen Diseases (Chin). Beijing: Combined Beijing Medical University and China Union Medical University Press 1995; 98.
