Effect of muscle strengthening on peripheral facial palsy: A randomized controlled trial

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ABSTRACT. Objective: To evaluate the effect of muscle strengthening intervention in peripheral facial palsy (PFP). Methods: A randomized controlled trial was conducted at five hospitals. Fifty-one subjects with PFP who showed a response of less than 20% on electroneurography (ENoG) were enrolled. Subjects in a muscle-strengthening-intervention group (MS Group) underwent a selective muscle contraction intervention (SMCI). Subjects in another group not receiving muscle strengthening intervention (Non-MS Group). Both groups underwent three interventions: Prohibition of maximum effort movements, Stretching of the affected facial muscles, and Mirror biofeedback therapy. The outcomes were measured by the Sunnybrook Facial Grading System (FGS) at 6 months after onset (primary endpoint) and at 12 months after onset (secondary endpoint). The subjects in the MS Group and Non-MS Group were further divided into subgroups showing ENoG responses of 10% or less and ENoG responses of over 10%, as a sub-analysis. Results: No significant differences between the MS Group and Non-MS Group at either the primary endpoint or secondary endpoint. Among the subjects in the treatment group with an ENoG response of over 10% at the primary endpoint, the FGS Composite Score and FGS Voluntary Movement score were both significantly higher in the MS Group than in Non-MS Group. Although the MS Group had a significantly lower FGS Resting Symmetry Score, there was no significant difference between the two groups in the FGS Synkinesis Score. Conclusions: SMCI improved paralysis in subjects exhibiting an ENoG response of over 10% within the 6 months from onset without any deterioration of synkinesis.

Key words: peripheral facial palsy, muscle strengthening, synkinesis, selective muscle contraction intervention

The sequelae of peripheral facial paralysis (PFP) include various disorders such as prolonged paralysis, synkinesis, tinnitus, and dizziness. The purpose of rehabilitation for PFP patients is generally to improve paralysis and prevent and reduce synkinesis, the most frequently observed indication. Earlier studies on rehabilitation interventions for PFP, however, have tended to emphasize only the reduction of synkinesis. As a consequence, the recovery of the strength of the mimetic muscles has been insufficient in a number of cases with advanced paralysis. Barbara M et al. observed early improvement in PFP in patients who obtained increases in muscle strength using the proprioceptive neuromuscular facilitation method during the early stages after onset. Their study, however, terminated before the PFP extended into the later stages, which precluded any investigation of the synkinesis that later appears in PFP patients. It remains inconclusive whether muscle strengthening positively affects synkinesis reduction and muscle strength recovery. Kayamori et al., for example, report that muscle strengthening worsens synkinesis and should be accordingly avoided. On the other hand, in the review of rehabilitation for PFP by Diels, HJ et al., small, symmetrical
movements limiting excursion at the stage of flaccid paralysis were performed. Then, proper instruction through neuromuscular retraining was provided as soon as synkinesis appears. As a result, significant reduction in synkinesis was observed. Even when these reports are compared, whether muscle strengthening positively affects synkinesis reduction and muscle strength recovery remains inconclusive). Therefore, we hypothesized that selective muscle contraction (muscle strength intervention) affects improvement in paralysis of PFP without worsening synkinesis as compared with no muscle strength intervention. Thus, we investigated the effect of muscle strengthening intervention in moderate-to-severe Bell’s palsy and Ramsey Hunt syndrome by conducting a cluster randomized controlled trial, in this study.

Methods

Experimental design

This study was a single-blind cluster randomized controlled trial. It was expected to be difficult to blind the therapist, and bias could potentially occur if the same therapist was to intervene with both groups. For these reasons, we chose a cluster randomized trial design to reduce the between-group treatment bias.

The study was undertaken at 5 hospitals in Japan between April 2011 and September 2013. A total of 51 patients were enrolled, 39 with a diagnosis of Bell’s palsy and 12 with a diagnosis of Ramsay Hunt syndrome. The institutional review board of the Ethics Committee of Research at Toyohashi Municipal Hospital approved this study (Number 28, 2011). All of the patients gave us their written informed consent before the start of the trial.

The inclusion criteria were as follows: age 13 to 70 years, unilateral PFP (Bell’s palsy, Ramsay Hunt syndrome), electroneurography (ENoG) response of less than 20% within 7 to 14 days from onset, a House-Brackmann scale assessment ranging from grade V to VI.

The exclusion criteria were as follows: trauma, tumor, age of under 12 years or over 70 years, bilateral paralysis, mental illness, long-term hospitalization for treatment of other diseases.

All of the patients were started on steroid therapy immediately, from their first hospital visit.

Randomization

This prospective randomized control study used a randomized cluster design. Five research hospitals were randomly assigned to either the group with muscle strengthening intervention (MS Group) or the group without muscle strengthening intervention (Non-MS Group). Each target hospital was assigned PFP patients in number treated in the year leading up to March 2011, after the hospitals were stratified into four groups to prevent bias in the numbers of patients treated (above or below median). Independent researchers used the RAND function MS Excel (Microsoft Corporation, Seattle, WA) to randomize the hospitals. Each stratum was force-randomized to two arms.

Intervention

Rehabilitation program

Each of the five hospitals was assigned two patient groups in order to conduct the evaluations and guidance according to the protocol of an outpatient prospective study. The protocols of the two interventions were provided to the investigators in written manuals to ensure a standardized approach. Teaching contents were taught once a month using different instruction brochures. The MS Group underwent the muscle strengthening intervention. Initially the muscles were strengthened through small movements of muscles close to the midline such as the orbicularis oculi, corrugator supercilium, and orbicularis oris. Next, when improvement of the facial muscles was recognized, the intervention was switched to the selective muscle contraction intervention (SMCI) in order to strengthen individual muscles. The subjects were instructed to contract their facial muscles only on the paralyzed side, and not to contract any other muscles. The subjects in the Non-MS Group, meanwhile, performed eye-opening exercises to prevent oral-ocular synkinesis. These subjects were instructed not to move their eyebrows during the eye-opening exercise, and to perform the exercise continuously. The subjects in both groups underwent three other ordinary treatments: 1) prohibition of maximum effort movements and electrical stimulation, 2) stretching of the affected facial muscles when muscle tone appeared, 3) mirror biofeedback therapy to reduce the synkineatic movement when synkinesis appeared (Table 1). Both of the patient protocols were designed to take 30 minutes to complete, and the subjects in both groups were encouraged to perform them for at least 30 minutes a day at home. All three of these interventions were commenced within 2 months from the onset of PFP.

Measurements

The Sunnybrook Facial Grading System (FGS), a widely used method to assess the effects of medical interventions on facial function after PFP, was used to perform assessments at 6 months and 12 months after onset. FGS is a regionally weighted system based on an evaluation of facial symmetry at rest (Resting Symmetry Score), voluntary facial movements (Voluntary Movement Score), and synkinesis (Synkinesis Score). Each of the scores is evaluated on a point scale to generate a Composite Score on a continuous scale (0 to 100). The composite score is calculated as \[ 1 \times \text{Voluntary Movement Score} + 5 \times \text{Resting Symmetry Score} + 1 \times \text{Synkinesis Score} \]. The interventions were also recorded on video by the prescribed method. Trained physi-
dose administered at 1 week after onset (prednisolone about 120 to 200 mg per day), based on the
into three dose levels, namely, small (prednisolone 30 mg
dropped out of the study. Steroid therapy was classified
Statistical analysis

14) The initial ster-
oid therapy was also investigated by dosage.

Statistical analysis

13) The estimated sample size was 26 patients
be expected
from that study suggested that 17.6-point difference could
out to compare similar outcome measurements. The data
sample size calculations were performed using G* Power software referring back to a previous study13) carried
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Sample size

The sample size calculations were performed using G* Power software referring back to a previous study13) carried
out to compare similar outcome measurements. The data
from that study suggested that 17.6-point difference could be expected13). The estimated sample size was 26 patients
per group, with a significance level of 5% and a power of
80% under bilateral hypothesis.

Results

A flow diagram for this study is shown in Fig. 1. Fifty-one patients were enrolled in the study over the period
from April, 2011 to September, 2012, when the offer to ac-
cept more subjects into the study expired. Five hospitals
were randomized to the MS Group (2 hospitals, 31 partici-
pants) and Non-MS Group (3 hospitals, 20 participants).
Fourteen participants were excluded because of loss to
follow-up (n=12), a lack of reported data (n=1), and hospi-
tal entry for other disease (n=1). After excluding the drop-
outs, the 6-month analysis included 5 facilities and 37 sub-
jects (MS Group, 2 facilities, 19 participants; Non-MS Group,
3 facilities, 18 subjects). The 12-month analysis included 5
facilities and 31 participants (MS Group, 2 facilities, 15
participants; Non-MS Group, 3 facilities, 16 participants).
In the HB scale assessment at the time of onset, 3 and 16
patients in the MS Group and 8 and 10 patients in the Non-
MS Groups were assessed as grade V and grade VI, respec-
tively, and there was no significant difference between the
assessment rates by the X^2 test. The interventions were
started in all hospitals within at least two months from the
onset of PFP.

The baseline characteristics of the groups are summa-
rized in Table 2. The clinical characteristics of the two
groups were comparable. When the treatment groups were
divided into subjects showing ENoG responses of 10% or
less versus ENoG responses of over 10%, the only signifi-
cantly different baseline characteristic to appear was the
steroid therapy dose in the subjects showing an ENoG re-
response of over 10%.

As shown in Table 3, there were no significant differ-
ences between the MS Group and Non-MS Group in the Composite Score, Resting Symmetry Score, Voluntary
Movement Score, or Synkinesis Score at the primary end-
point. When comparing only the subjects showing ENoG
responses of 10% or less, there were no significant differ-

| Intervention | MS Group | Non-MS Group |
|--------------|----------|--------------|
| Selective muscle contraction intervention (SMCI) in order to strengthen individual muscles. | Eye-opening exercises to prevent oral-ocular synkinesis. |
| Ordinary treatment | Prohibition of maximum effort movements and electrical stimulation. | Stretching of the affected facial muscles when muscle tone appeared. |
| | Mirror biofeedback therapy to reduce the synketic movement when synkinesis appeared. |

Abbreviations: MS Group, The muscle strengthening intervention group; Non-MS Group, The group without muscle strengthening intervention.

Both protocols were designed to take 30 minutes to complete.
Both protocols were encouraged to perform at least 30 minutes a day at home.
Figure 1. Flow diagram of enrollment, randomization, and loss to follow-up in this study.
Abbreviations: MS intervention, muscle strengthening intervention group; Non-MS intervention, group without muscle strengthening intervention.

Table 2. Baseline characteristics of patients

| Subjects                        | Total | ENoG 10% or less (6 month) | ENoG over 10% (6 month) |
|---------------------------------|-------|-----------------------------|-------------------------|
|                                 | MS    | Non-MS                      | MS                       |
|                                 | n=19  | n=18                         | n=14                     |
|                                 |       |                             | n=11                     |
| **Sex, n (%)**                  |       |                             |                          |
| Female                          | 11 (61) | 7 (39)                       | 7 (50)                   |
| Male                            | 8 (42)  | 11 (58)                      | 7 (64)                   |
| **Age, Mean±SD**                | 46±13 | 49±16                        | 46±13                    |
| **Diagnosis, n (%)**            |       |                             |                          |
| Bell’s palsy                    | 15 (54) | 13 (46)                      | 11 (61)                  |
| Ramsay Hunt syndrome            | 4 (44)  | 5 (56)                       | 3 (43)                   |
| **HB grade, n (%)**             |       |                             |                          |
| V                               | 3 (27)  | 8 (73)                       | 2 (33)                   |
| VI                              | 16 (62) | 10 (38)                      | 12 (63)                  |
| **ENoG, Mean±SD**               | 7.0±5.8 | 11.1±9.3                     | 4.0±2.8                  |
| **Decompression, n (%)**        |       |                             |                          |
| Yes                             | 6 (75)  | 2 (25)                       | 6 (75)                   |
| No                              | 13 (45) | 16 (55)                      | 8 (47)                   |
| **Steroid therapy**             |       |                             |                          |
| High                            | 12 (67) | 6 (33)                       | 8 (57)                   |
| Medium                          | 2 (25)  | 6 (75)                       | 1 (20)                   |
| Small                           | 2 (25)  | 6 (75)                       | 2 (67)                   |
| **Note. Values are shown as n (%) and mean±S.D.**
Abbreviations: SD, standard deviation; MS, muscle strengthening intervention group; Non-MS, group without muscle strengthening intervention; HB, House-Brackmann’s facial grading system; ENoG, electroneurography; Decompression, facial nerve decompression.
*: p<0.05, P values significant at a level of significance P=0.05;
Steroid therapy was classified into a small dose (prednisolone 30 mg per day), medium dose (prednisolone 60 mg per day), or high dose (prednisolone approximately 120 to 200 mg per day) based on the dose of 1 week after onset.
EFFECT MUSCLE STRENGTHENING ON PFP

Fig. 2. Composite Score, Resting Symmetry Score, Voluntary Movement Score and Synkinesis Score at 6 months or 12 months in the ENoG ʽ10% group. P values correspond to the results of two-way analysis of variance analysis. The error bar plots the standard deviation in both group. Abbreviations: ENoG, electro-neurography; MS, muscle strengthening intervention group; Non-MS, group without muscle strengthening intervention.

ences between the MS Group and Non-MS Group in the Composite Score, Resting Symmetry Score, Voluntary Movement Score, or Synkinesis Score (Fig. 2).

When comparing only the patients showing ENoG responses of over 10%, the Composite Score and Voluntary Movement Score were significantly higher in the MS Group than in the Non-MS Group at the primary endpoint, respectively (main effect: p = 0.026, p = 0.031). The MS Group also showed a significantly lower Resting Symmetry Score (main effect: p = 0.024), though no significant difference was found between the groups in the Synkinesis Score (main effect: p = 0.802). No significant differences were found between the MS Group and Non-MS Group in any of the scores at the secondary endpoint (Fig. 3).

Discussion

The physical therapies for PFP often include relaxation, massage, and stretching using small, slowly executed movements to reduce synkinesis and hypertonus. Our group also prescribes eye-opening exercises, avoidance of gross muscle strengthening, biofeedback therapy using surface electromyograms and mirrors, and the prohibition of electrical stimulation therapy. We have yet to determine, however, whether muscle strengthening intervention has a negative effect on synkinesis after PFP.

In this study we compared patients with moderate-to-severe PFP within 2 months after onset in two groups (MS group and Non-MS group).

We instructed the subjects in the MS Group to perform exercises to promote muscle recovery of the orbicularis muscle and interglialis muscle, that is, the midline facial muscles. Later, when the subjects’ voluntary movement improved, we instructed them to focus on the strengthening of the frontalis muscle, orbicularis oculi, corrugator muscle, zygomaticus major, zygomaticus minor, and risorius individually while suppressing the healthy side by hand (SMCI). No instruction on strengthening was provided to the subjects in the Non-MS Group.

No significant difference in the FGS score was found
between the two treatment groups, and muscle strengthening was not found to worsen the synkinesis score. Similar results were obtained in the groups showing an ENoG response of less than 10%, that is, in the patients with severe axonotmesis, and the strengthening of individual muscles was thought to have little influence on the synkinesis score under that condition. In the analysis of the subjects showing an ENoG response of over 10%, the Composite Score at 6 months and Voluntary Movement Score were significantly higher in the MS Group than in the Non-MS Group. The Resting Symmetry Score was significantly lower in the MS Group, whereas the Synkinesis Score showed no significant

Table 3. Composite Score, Resting Symmetry Score, Voluntary Movement Score, Synkinesis Score at 6 months and 12 months.

| FGS                      | 6 month       |                 | P       | 12 month       |                 | P       |
|--------------------------|---------------|-----------------|---------|---------------|-----------------|---------|
|                          | MS            | Non-MS          |         | MS            | Non-MS          |         |
| Composite Score          | 65.8±26.0     | 55.7±19.1       | 0.187   | 79.5±17.0     | 71.4±15.4       | 0.180   |
| Resting Symmetry Score   | 6.8±5.1       | 8.3±4.5         | 0.353   | 5.3±5.2       | 8.1±4.8         | 0.129   |
| Voluntary Movement Score | 75.6±23.0     | 66.4±18.0       | 0.189   | 89.1±14.1     | 82.8±13.8       | 0.216   |
| Synkinesis Score         | 3.0±2.4       | 2.4±2.4         | 0.488   | 4.3±2.9       | 3.2±2.8         | 0.303   |

Note. Values are mean ± SD.
Abbreviations: FGS, Sunnybrook Facial Grading System; MS, The muscle strengthening intervention group; Non-MS, The group without muscle strengthening intervention.

Figure 3. Composite Score, Resting Symmetry Score, Voluntary Movement Score and Synkinesis Score at 6 months or 12 months in the ENoG > 10% group. P values correspond to the results of two-way analysis of variance analysis. The error bar plots the standard deviation of both group. Abbreviations: ENoG, electro-neurography; MS, muscle strengthening intervention group; Non-MS, group without muscle strengthening intervention.
difference between the both groups.

These results suggested that the strengthening of individual muscles may help to improve paralysis without worsening synkinesis in subjects with less axonal degeneration who showed an ENoG response of over 10%.

**Study limitations**

There are several points to consider in the interpretation of our study results. First, our study was limited by the small sample size and a 39% drop-out rate. The higher-than-expected dropout rate pushed the final sample size (n=37) significantly below the size estimated before the study (n=52). Second, the video clips of the patients in this study were evaluated by a single physical therapist. As a consequence, we were unable to investigate how interobserver variability in the scoring of the FGS may have affected our results. Third, different medical interventions are performed for the research at the participating institutions, and there are differences in therapeutic policies between the institutions and the influence of guidance skill. Fourth, the steroid dose administered to subjects showing ENoG responses greater than 10% differed significantly between institutions. Lastly, the present study was not designed to collect FGS at onset, which may not be a true comparison of both intervention groups at the early 6 months. Further study on these points will be necessary, as well.

**Conclusion**

We examined the effects of individual strength reinforcement interventions on PFP by randomly deploying different programs at multiple institutions, as well as by FGS. Among the subjects showing an ENoG of higher than 10% at 6 months, the Composite Score and Voluntary Movement Score assessed by the Sunnybrook method were significantly lower in the former than in the latter, and the Symmetry Score was significantly lower in the former than in the group without intervention, the Resting Symmetry Score was significantly lower in the former than in the latter, and the Synkinesis Score showed no significant difference.

Compared to coarse exercise, the controlled muscular strengthening intervention focused on individual muscles may be useful for improving voluntary movements without degrading synkinesis in patients showing an ENoG response of over 10% in association with Bell’s palsy and Ramsey Hunt syndrome. In the future we will need to conduct controlled studies using drug therapy.

**Conflict of Interest:** There were no conflicts of interest in this study.

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