Facial muscle reanimation by transcutaneous electrical stimulation for peripheral facial nerve palsy

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Abstract— **Reanimation of paralyzed facial muscles by electrical stimulation has been studied extensively in animal models, but human studies in this field are largely lacking. Twenty-four subjects with a peripheral facial nerve palsy with a mean duration of ten years were enrolled. We studied activations of four facial muscles with electrical stimulation using surface electrodes. In subjects whose voluntary movement was severely impaired or completely absent, the electrical stimulation produced a movement that was greater in amplitude compared with the voluntary effort in 10 out of 18 subjects in the frontalis muscle, in 5 out of 14 subjects in the zygomaticus major muscle, and in 3 out of 9 subjects in the orbicularis oris muscle. The electrical stimulation produced a stronger blink in 8 subjects out of 22 compared with their spontaneous blinks. The stimulation could produce a better movement even in cases where the muscles were clinically completely paretic, sometimes also in palsies that were several years old, provided that the muscle was not totally denervated. Restoring the function of paralyzed facial muscles by electrical stimulation has potential as a therapeutic option in cases where the muscle is clinically paretic but has reinnervation.**

Index Terms— **facial paralysis, functional electrical stimulation, prosthetics**

I. Introduction

FACIAL nerve palsy is a condition that has important medical and social consequences for the affected individual. Deficit in blinking and eye-closure is the most important medical concern as it predisposes the cornea to drying and abrasion. Weakness in facial muscles is also associated with oral incompetence that causes drooling and difficulties in eating and drinking. The loss of symmetric facial expression complicates the communication of emotions and can affect quality of life [1]. The most common form of facial nerve palsy is Bell's palsy, with an incidence of around 25 out of 100 000 individuals per year [2], and accounts for more than a half of all facial nerve palsies [3]. The outcome of Bell's palsy is usually good. However, 10% to 30% of patients are left with residual weakness, asymmetry, or otherwise impaired function [3], [4]. Other etiologies, such as traumas, tumors, or infections, have variable and often less favorable prognoses.

Current options for the restoration of facial symmetry and function comprise physical therapy, botulinum toxin injections, and surgical interventions. Although various types of physical therapies have been proposed, the evidence on their benefits is somewhat contradictory [5], [6]. Botulinum toxin injections can be used to alleviate synkinesias and spasms and to improve symmetry by weakening the healthy side [7]. Surgical interventions aim to assist eye-closure, to improve rest symmetry, or to restore the movements of the paralyzed side of the face. The interventions aiming to restore the dynamic function of the paralyzed face include cross-facial nerve grafts [8], masseter to facial nerve transfers [9], and temporalis muscle [10] and free microneurovascular muscle transfers [11]. While these interventions can be very helpful in the restoration of facial symmetry and function, these techniques are demanding and not suitable for all patients. Thus, other treatment options to reanimate the paralyzed face are needed.

The principle of the reanimation of paralyzed facial and laryngeal muscles with electrical stimulation has been studied since the 1970's in several experimental models. During these experiments, investigators measured the activity of the intact muscles of the contralateral side and, using this information,

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stimulated the paralyzed side. The technique is referred to in the literature as electronic pacing. Electronic pacing has been studied for the activation of denervated or reinnervated facial and laryngeal muscles in different animal models [12], [13], [14], [15]. In a rabbit model, electrical stimulation with implanted electrodes has been shown to be feasible even over the longer term, i.e., months [16]. More recently, electronic pacing has been studied in an experimental nerve lesion to produce an eye blink in rabbits [17] and in the facial muscles of rats [18]. Despite several animal studies, studies on humans have so far been scarce. Eliciting an eye blink with electrical stimulation has been studied to some extent [19], [20]. Moreover, the principle of facial pacing on humans has been demonstrated on the frontalis muscle that was temporarily paralyzed with local anesthetics [21]. However, human studies on the reanimation of paralyzed facial muscles other than orbicularis oculi are currently largely lacking.

In the present study, our goal was to study the feasibility of electrical stimulation with surface electrodes for the reanimation of different facial muscles in subjects with a peripheral facial nerve palsy. The frontalis, zygomaticus major, orbicularis oris, and orbicularis oculi muscles were stimulated in an attempt to produce forehead wrinkle, smile, lip pucker, and eye blink, respectively.

II. Methods

A. Subjects

Twenty-four patients (10 men, 14 women), aged 23 to 71 years (M = 51, SD = 13), presenting with a peripheral facial nerve palsy were recruited to the study after a patient database search or during outpatient visits to the Department of Otorhinolaryngology, Tampere University Hospital, Finland (n=14, subjects 1 to 14, or Tampere group) and the Department of Plastic Surgery, Helsinki University Hospital, Finland (n=10, subjects 15 to 24, or Helsinki group). The duration of the palsy ranged from 4 months to 59 years (M = 10, Mdn = 3 years). The most common single cause of the paresis was Bell’s palsy (10 subjects), followed by a vestibular nerve schwannoma (four subjects) (Appendix I).

The study was approved by the Ethics Committee of Pirkanmaa Hospital District. The participants volunteered and signed a written consent form concerning the participation and a separate consent form for the use of the video and photographic material.

B. Assessment of the palsy

The severity of the palsy was individually assessed with the Sunnybrook facial grading system (SFGS) [22] that was scored offline by three investigators from a video recording, and with a nerve conduction study (NCS) and electromyography (EMG). SFGS is a composite score that evaluates the rest symmetry, symmetry of the movements, and synkinesias, ranging from zero (total paralysis) to one hundred (normal facial function). The SFGS score ranged from 11 to 78 (M = 37, SD = 19). The mean SFGS score was 45 (SD = 20) in the Tampere group and 27 (SD = 11) in the Helsinki group. A Mann-Whitney test showed that the scores of the Helsinki group were statistically significantly lower than the scores of the Tampere group ($U = 29.0$, $p < 0.05$).

The NCS and EMG data were obtained from 21 subjects. Three subjects declined the examination. Numeric data for the bilateral NCS of the facial nerve were available from 16 subjects. The compound muscle action potential amplitude registered from the nasalis muscle ranged between 0.0 and 1.8 mV (M = 0.8, SD = 0.6) for the paralyzed side and from 0.9 to 2.3 mV (M = 1.7, SD = 0.5) for the unaffected side. EMG data were available for the frontalis and orbicularis oris muscles from all 21 subjects and for the orbicularis oculi muscle from 20 subjects. Five subjects had signs of ongoing reinnervation in at least one muscle. Four subjects had a finding of total denervation of at least one muscle. The severity of the neurogenic damage in the EMG data correlated positively to the degree of the paresis assessed with SFGS in the frontalis muscle ($r_s = 0.701$, $p < 0.001$). The correlation was not, however, significant between the needle EMG finding and the degree of the paresis in the orbicularis oris muscle ($r_s = -0.307$, $p > 0.05$) nor in the orbicularis oculi muscle ($r_s = -0.063$, $p > 0.05$).

C. Equipment

The stimulator used in the experiment was developed and manufactured at the Faculty of Biomedical Sciences and Engineering, Tampere University of Technology [23]. The stimulation parameters that produced the best facial muscle activations in healthy individuals in a preliminary pilot testing were chosen for the experiment. A one-second-long train of bipolar rectangular pulses with a phase duration of 0.4 ms and a frequency of 250 Hz were used for the stimulation of the frontalis, zygomaticus major, and orbicularis oris muscles. The same stimulation parameters were used for the stimulation of the orbicularis oculi muscle except for the length of the stimulation train, which was set at 0.08 seconds. Five trains of stimuli were delivered with an approximately one-second inter-train interval. Commercial adhesive pre-gelled electrodes (Quirumed®, GMDASZ Manufacturing Co., Ltd., Shenzhen, China) were used for the stimulation. The surface area of the electrodes was manually trimmed to approximately 1.5 cm2. The skin was prepared with an alcohol swab before the adhesion of the electrodes.

D. Procedure

The frontalis, orbicularis oculi, zygomaticus major, and orbicularis oris muscles were stimulated one at a time. The stimulation sites were chosen according to previously described guidelines for EMG measurements [24]. The stimulation was started at the current amplitude level of 0.5 mA and the current amplitude was raised at 0.5 mA steps. For the frontalis, zygomaticus major, and orbicularis oris muscles, the stimulation was continued until the subject asked to stop or when an amplitude limit of 10 mA was reached (patients 1 to 14 from the department of otorhinolaryngology, Tampere University Hospital, Tampere group). For subjects 15 to 24 from the department of plastic surgery, Helsinki, Finland (Helsinki group) who had a more severe palsy, had undergone more surgical interventions, and were expected to have a higher excitation threshold, there was no preset upper limit for the stimulation current. Instead, the stimulation was continued until the subject asked to stop. The stimulation was also stopped if the safety settings of the device prevented the stimulation from continuing. In the case of the orbicularis oculi muscle, the stimulation was continued until a complete eye-closure was observed by two investigators during the online analysis, or until the subject asked to stop.

After the movement threshold was reached (i.e., some movement was observed by two investigators in the area of the stimulation during the online analysis), the subject was asked to give a pain rating on a scale of 1 to 9 (grade 1 meaning no pain and grade 9 meaning severe pain) after each set of five stimulus trains.

The order of the stimulation sites was counterbalanced so that the first stimulated muscle was either the frontalis muscle followed by the orbicularis oculi, zygomaticus major, and orbicularis oris muscles, the zygomaticus major muscle followed by the orbicularis oris, frontalis, and orbicularis oculi muscles, or the orbicularis oris followed by the frontalis, orbicularis oculi, and zygomaticus major muscles.

The stimulations were recorded with a Panasonic V750 digital video camera with 50 frames per second.

E. Analysis

Two investigators independently performed an offline visual analysis of the video recordings in order to evaluate the electric current amplitude level at which a movement of the target muscle was produced (movement threshold), and the current amplitude level at which the maximal movement was achieved. In case of a discrepancy between the two estimations, the videos were reanalyzed together by the two investigators to reach a consensus. Possible activations of other muscles alongside the target muscle were also noted. The effect of the stimulation was evaluated and compared with the maximal voluntary activations of the corresponding function of the frontalis, zygomaticus major, and orbicularis oris muscles. In the case of eye blink, the stimulated blink was compared with the most complete spontaneous eye blink of the paralyzed side.

A cross-tabulation analysis and a chi-square test of independence were used to evaluate the relationship between the needle EMG findings and the stimulated activations in the frontalis, orbicularis oris, and orbicularis oculi muscles. The stimulated activations were categorized into two classes: no movement and some movement. A Mann-Whitney test was then used to compare the differences in the movement threshold for the different muscles between the Tampere and Helsinki groups.

III. Results

Results of the stimulations by subject are presented in Tables I, II, III, and IV. Those subjects who had the most severe paresis of the frontalis, zygomaticus major, and orbicularis oris muscles (SFGS subscore 1 or 2 for the corresponding function) and whose eye blink was defective are discussed in more detail below.

The stimulation produced a better (larger in amplitude) movement in 6 out of the 12 subjects with no voluntary movement (SFGS subscore 1) and in 4 out of the 6 subjects with a minor voluntary movement (SFGS subscore 2) of the frontalis muscle. The results of the stimulations for all subjects are presented in Table I. Examples of the stimulated movements compared with the voluntary movement are presented in Figure 1 and Video 1.

Table I
Results of the stimulation of the frontalis muscle.

Subject number	SFGS subscore for forehead wrinkle	Better movement with stimulation?	Stimulation current at the maximal amplitude of movement
1	2	Yes	6.0 mA
2	5	Yes	4.5 mA
3	4	Yes	6.5 mA
4	4	No	5.0 mA
5	2	Yes	9.0 mA
6	5	No	10.0 mA
7	1	Yes	6.5 mA
8	2	No	7.5 mA
9	1	No (no movement)	
10	3	Yes	6.0 mA
11	2	No	5.5 mA
12	2	Yes	7.0 mA
13	1	Yes	4.5 mA
14	2	Yes	8.0 mA
15	1	Yes	11.5 mA
16	1	Yes	13.5 mA
17	1	No (no movement)	
18	1	No (no movement)	
19	1	No (no movement)	
20	3	No	6.5 mA
21	1	No (no movement)	
22	1	Yes	8.5 mA
23	1	Yes	6.0 mA
24	1	No (no movement)	

Fig. 1. Voluntary activation of the frontalis muscle compared with the stimulated activation at a current amplitude of 3.5 mA.

The electrical stimulation produced a better movement in 3 out of the 7 subjects with no voluntary movement and in 2 out of the 7 subjects with a minor voluntary movement of the zygomaticus major muscle. The results of the stimulations for all subjects are presented in Table II. Examples of the stimulated movements compared with the voluntary movement are presented in Figure 2 and Video 2.

Table II
Results of the stimulation of the zygomaticus major muscle.

Subject number	SFGS subscore for open mouth smile	Better movement with stimulation?	Stimulation current at the maximal

			amplitude of movement
1	2	No	10.0 mA
2	4	No	6.0 mA
3	4	No	8.0 mA
4	3	Yes	8.5 mA
5	3	Yes	9.0 mA
6	4	Yes	10.0 mA
7	1	Yes	8.0 mA
8	2	No (no movement)	
9	2	No (no movement)	
10	2	Yes	10.0 mA
11	4	No	7.5 mA
12	2	No	10.0 mA
13	2	No	6.0 mA
14	3	No	7.5 mA
15	3	No (no movement)	
16	1	Yes	28.0 mA
17	1	No (no movement)	
18	1	No (no movement)	
19	1	Yes	5.5 mA
20	3	No	13.0 mA
21	1	No (no movement)	
22	2	Yes	34.0 mA
23	3	No	19.0 mA
24	1	No (no movement)	

Fig. 2. Voluntary activation of the zygomaticus major muscle (closed-mouth and open-mouth smile) compared with the stimulated activation at a current amplitude of 9.0 mA.

The electrical stimulation produced a better movement in 1 out of 3 subjects with no voluntary movement and in 2 out of 6 subjects with a minor voluntary movement of the orbicularis oris muscle. The results of the stimulations for all subjects are presented in Table III. Examples of the stimulated movements compared with the voluntary movement are presented in Figure 3 and Video 3.

TABLE III

RESULTS OF THE STIMULATION OF THE ORBICULARIS ORIS MUSCLE.

Subject number	SFGS subscore for lip pucker	Better movement with stimulation?	Stimulation current at the maximal amplitude of movement
1	3	No	10.0 mA
2	3	No	5.0 mA
3	3	No	6.5 mA
4	4	Yes	9.0 mA
5	3	No	9.0 mA
6	3	No (no movement)	
7	1	Yes	7.0 mA
8	2	No	4.0 mA
9	3	No (no movement)	
10	2	No	10.0 mA
11	5	No	6.0 mA
12	3	Yes	9.0 mA
13	2	No	8.0 mA
14	4	No	9.0 mA
15	3	No	18.5 mA
16	1	No (no movement)	
17	4	No (no movement)	
18	4	No	15.5 mA
19	2	No (no movement)	
20	4	No	8.5 mA
21	3	No (no movement)	
22	2	Yes	22.0 mA
23	2	Yes	37.0 mA
24	1	No (no movement)	

Fig. 3. Voluntary activation of the orbicularis oris muscle compared with stimulated activation at a current amplitude of 19 mA.

The spontaneous blink on the paralyzed side was defective in varying degrees in all but one subject. The stimulation produced a better blink in 4 out of 13 subjects whose spontaneous blink covered a maximum of half of the pupil and in 4 out of 9 subjects whose spontaneous blink covered more than half of the pupil, which can be interpreted as resulting in a complete eye blink [25]. The results for all subjects are presented in Table IV. An example of a spontaneous blink compared with a stimulated blink is presented in Figure 4 and Video 4.

TABLE IV

RESULTS OF THE STIMULATION OF THE ORBICULARIS OCULI MUSCLE.

Subject number	SFGS subscore for eye closure	Best spontaneous blink	Better movement with stimulation?	Stimulation current at the maximal amplitude of movement
1	4	almost complete	no	6.0 mA
2	5	almost complete	yes	4.5 mA
3	4	almost complete	no	6.5 mA
4	4	almost complete	no	5.0 mA
5	4	almost complete	not analyzable	
6	3	Half	not analyzable	
7	4	almost complete	yes	6.5 mA
8	3	less than half	no	7.5 mA
9	2	less than half	no (no movement)	
10	4	less than half	yes	6.0 mA
11	5	complete	no	5.5 mA

12	3	almost complete	yes	7.0 mA
13	3	almost complete	no	4.5 mA
14	4	almost complete	yes	8.0 mA
15	2	twitch	yes	11.5 mA
16	3	twitch	yes	13.5 mA
17	3	twitch	no (no movement)	
18	2	twitch	no (no movement)	
19	3	less than half	no (no movement)	
20	2	twitch	no	6,5 mA
21	3	twitch	no (no movement)	
22	3	Half	yes	8.5 mA
23	3	less than half	no	6.0 mA
24	3	Half	no (no movement)	

Fig. 4. A spontaneous blink compared with a stimulated blink at a current amplitude of 6.5 mA.

In all cases where a movement could be produced, the subject's spontaneous or reflex blink was involved in, and thus facilitated the movement. Two subjects were left out of the analysis, one due to video recording failure and the other due to squeezing of the eyes during the stimulation, making the visual analysis of the stimulation-induced blinks impossible.

The movement thresholds (Table V), defined as the lowest electric current amplitude that produced a visible activation of the target muscle as evaluated in the offline video analysis, were significantly higher for the subjects from the Helsinki group compared with the subjects from the Tampere group.

TABLE V
MEAN ELECTRIC CURRENT AMPLITUDES AT THE MOVEMENT THRESHOLD.

	Mean amplitude (mA) ± SD to movement		
Stimulated muscle	Tampere group	Helsinki group	Mann-Whitney test
Frontalis	2.4 ± 0.5 (n = 13)	5.2 ± 2.2 (n = 5)	U = 2.0, p < 0.01
Zygomaticus major	5.6 ± 1.6 (n = 11)	9.9 ± 1.9 (n = 4)	U = 0.0, p < 0.01
Orbicularis oris	3.1 ± 1.0 (n = 12)	6.8 ± 3.0 (n = 6)	U = 6.0, p < 0.05
Orbicularis oculi	2.3 ± 0.9 (n = 12)	4.7 ± 2.2 (n = 5)	U = 9.5, p < 0.05

Depending on the stimulated muscle, the stimulation spread in varying degrees to other muscles, most commonly to adjacent muscles. The spreading of the stimulation was the most evident during the stimulation of the zygomaticus major muscle. The muscles typically activated at the same time were the zygomaticus minor, levator anguli oris, and orbicularis oculi muscles. In two subjects with no visible or only a minor voluntary movement of the zygomaticus major muscle, however, the stimulation did not spread significantly to other muscles, producing a rather natural movement (Video 2). Also, during the stimulation of the frontalis and orbicularis oris muscles, the stimulation often activated other muscles; typically, the orbicularis oculi muscle was activated during the stimulation of the frontalis muscle, and the mentalis and depressor labii inferioris muscles were activated during the stimulation of the orbicularis oris muscle, and sometimes more distant muscles.

The cross-tabulation results between the EMG finding and the stimulated activation in the frontalis muscle are shown in Table VI. A chi-square test of independence was performed to study the relationship between the EMG finding and the stimulated activation in the frontalis muscle. The relationship between these was significant (X^2 (4, 21) = 13.65, p < 0.01). In cases of complete denervation, the stimulation did not produce any visible movement, whereas when the degree of denervation was moderate, slight, or the EMG finding was normal the stimulation produced a movement (Table VI).

TABLE VI
CROSS-TABULATION RESULTS BETWEEN THE EMG FINDINGS AND THE STIMULATED ACTIVATIONS OF THE FRONTALIS MUSCLE.

		Stimulation result for the frontalis muscle		
		no movement	movement	total
EMG findings	complete denervation	3 60.0%	0 0.0%	3 14.3%
	severe denervation	2 40.0%	4 2.0%	6 28.6%
	moderate denervation	0 0.0%	9 56.3%	9 42.9%
	slight denervation	0 0.0%	2 12.5%	2 9.5%
	normal	0 0.0%	1 6.3%	1 4.8%
	total	5 100.0%	16 100.0%	21 100.0%

The cross-tabulation results between the EMG finding and the stimulated activation in the orbicularis oris muscle are shown in Table VII. The chi-square test showed that the relationship between the EMG finding and the stimulated activation in the orbicularis oris muscle was significant (X^2 (3, 21) = 11.966, p < 0.01). Again, if the denervation was total, the stimulation did not elicit any visible movement (Table VII). In cases where the denervation was severe, and in most of the cases the denervation was moderate, the stimulation elicited visible movement, whereas in three of the four cases where the denervation was slight, no visible movement occurred. Two of the three subjects had a beard, which probably altered the electrode contact.

The cross-tabulation results between the EMG finding and the stimulated activation in the orbicularis oculi muscle are shown in Table VIII. The chi-square test showed no significant relationship between the EMG finding and the stimulated activation in the orbicularis oculi muscle (X^2 (4, 18) = 4.661, p > 0.05). However, the frequencies in Table VIII suggest that the stimulation was more likely to be successful in those cases where the degree of denervation was slight.

TABLE VII
CROSS-TABULATION RESULTS BETWEEN THE EMG FINDINGS AND THE STIMULATED ACTIVATIONS OF THE ORBICULARIS ORIS MUSCLE.

		Stimulation result for the orbicularis oris muscle		
		no movement	movement	total
EMG findings	complete denervation	1 20.0%	0 0.0%	1 4.8%
	severe denervation	0 0.0%	7 43.8%	7 33.3%
	moderate denervation	1 20.0%	8 50.0%	9 42.9%
	slight denervation	3 60.0%	1 6.3%	4 19.0%
	normal	0 0.0%	0 0.0%	0 0.0%
	total	5 100.0%	16 100.0%	21 100.0%

TABLE VIII
CROSS-TABULATION RESULTS BETWEEN THE EMG FINDINGS AND THE STIMULATED ACTIVATIONS OF THE ORBICULARIS OCULI MUSCLE.

		Stimulation result for the orbicularis oculi muscle		
		no movement	movement	**total**
EMG findings	complete denervation	1 25.0%	0 0.0%	1 5.6%
	severe denervation	1 25.0%	3 21.4%	4 22.2%
	moderate denervation	2 50.0%	7 50.0%	9 50.0%
	slight denervation	0 0.0%	3 21.4%	3 16.7%
	normal	0 0.0%	1 7.1%	1 5.6%
	total	4 100.0%	14 100.0%	18 100.0%

The mean electric current amplitudes for the last full set of five stimulation trains before the subject asked to stop the stimulation or the device's safety settings stopped delivering stimuli are presented in Table IX. In one subject, the stimulation was stopped by the safety settings of the device during the stimulation of the frontalis muscle at the current amplitude level of 9.0 mA. In two subjects the stimulation was stopped by the safety settings during the stimulation of the zygomaticus major muscle at the current amplitude levels of 8.0 mA and 28.5 mA, and in two subjects the stimulation was stopped during the stimulation of the orbicularis oris muscle at the current amplitude levels of 5.0 mA and 48.0 mA, the latter being the maximal output of the device. For the orbicularis oculi muscle, for which the stimulation was discontinued if eye-closure was observed during the online analysis, the maximal electric current amplitude levels at the end of the stimulation were 5.7 mA SD ±1.4 mA for the Tampere group and 9.3 mA SD ±6.1 mA for the Helsinki group.

TABLE IX
MEAN MAXIMAL ELECTRIC CURRENT AMPLITUDES.

	Stimulated muscle	Mean maximal electric current amplitude (mA) ± SD
Tampere group	Frontalis	7.6 ± 1.9
	Zygomaticus major	8.6 ± 1.5
	Orbicularis oris	8.6 ± 1.8
Helsinki group	Frontalis	8.8 ± 4.8
	Zygomaticus major	16.7 ± 10.2
	Orbicularis oris	14.3 ± 13.5

In subjects for whom the stimulation produced at least some movement, the mean pain rating at the level of the maximal movement was 5.5 (SD ± 2.5, range 1 to 9) for the frontalis muscle, 5.8 (SD ± 2.9, range 1 to 9) for the zygomaticus major muscle, 5.3 (SD ± 2.6, range 2 to 9) for the orbicularis oris muscle, and 4.3 (SD ± 2.6, range 1 to 9) for the orbicularis oculi muscle. In the case of the orbicularis oculi muscle, the two abovementioned subjects and one subject whose stimulus-induced blink could not be distinguished from the reflex blinking, resulting in no pain rating, were not included.

IV. DISCUSSION

A considerable number of individuals who are affected by a peripheral facial nerve palsy are left with residual symptoms that have consequences in their everyday life. Several of our subjects had undergone more or less extensive surgical interventions to restore facial symmetry and function. While many of them had benefited from the surgery, they still had unresolved issues, such as a defective eye blink and drooping forehead. The subjects who had not had operative treatments and had achieved a nearly normal resting symmetry through spontaneous recovery, still reported problems caused by the defective function of the facial muscles that were either medically or socially disabling, such as problems with eye health and the inability to smile.

To the best of our knowledge, our study is the first one that has investigated the restoration of the function of facial muscles other than orbicularis oculi by electrical stimulation in persons with a facial nerve palsy. Frigerio et al. [20] have recently reported that transcutaneous electrical stimulation produced a complete eye closure in 55% of participants with acute facial nerve palsy when the zygomatic facial nerve branch was stimulated. In the present study, we focused on subjects who had passed the acute phase, many having a paresis with a duration of several years. In our study, the success rate in producing a stronger stimulated blink compared with the individual's spontaneous blink was 36%. Regarding the other stimulated muscles, in cases where the function of the muscle was severely defective, the electrical stimulation produced a better movement than the voluntary activation in 56% of cases for the frontalis muscle, in 36% for the zygomaticus major muscle, and in 33% for the orbicularis oris muscle.

Our subjects presented palsies of variable durations and different causes, and therefore the generalization of the results by etiology is difficult since the number of subjects with a given cause was relatively small. We have shown, however, that activating facial muscles by electrical stimulation is possible in palsies with different causes and also in older palsies.

The subjects in the Helsinki group required significantly higher stimulation currents in order to initiate a movement in the target muscle. Many of these subjects had a paralysis as a consequence of different neoplasias and supposedly more severe initial axonal damage, and hence poorer outcome than those with an idiopathic palsy. These subjects had also had more surgical interventions that cause scar formation, which may have affected the conductive characteristics of the tissues. There was quite a lot of variation in the tolerated electric current amplitudes. Also, the reported pain ratings at the electric current amplitude level that produced the maximal movement, as evaluated in the offline video analysis, varied from not painful at all to very painful, underlining the very high inter-individual variability for the acceptability of the electrical stimulation. Considering these things, reanimating facial muscles by electrical stimulation would not be a one-size-fits-all kind of treatment, but rather a tailor-made solution with individually adjusted stimulation parameters and sites and number of electrodes.

Another limitation of our study is the visual analysis of the facial movements that is susceptible to subjective bias that we tried to minimize by using two evaluators. Currently, no method that could be considered as a gold standard to objectively analyze the stimulated facial movements exists, and we consider the analysis procedure we used was adequate for the objectives of our study.

Stimulation of the zygomaticus major muscle proved to be particularly challenging. The stimulation often spread to adjacent muscles, creating an unnatural appearance in respect to smiling. Spreading of the stimulation also occurred while stimulating other muscles; however, in these cases the activation of other muscles rarely produced expressions that would be considered disturbing or disfiguring. The difficulties in the electrical stimulation of the zygomaticus major muscle may result from spreading of the stimulus via facial nerve branches and from the greater distance between the electrode and the muscle due to adipose tissue. Whether experimenting with stimulation electrode locations as opposed to using predetermined locations would yield better results is worth further study.

The stimulator we used in this experiment had four stimulator channels, four channels for the EMG measurements, and freely adjustable stimulation waveform, thus providing flexible potential for future studies on facial pacing. In addition to defining appropriate stimulation parameters, facial pacing requires a reliable EMG or other muscle activation measurement method from the healthy side of the face [26]. The signal analysis and stimulation signal generation should be fast enough to produce a movement that is perceived as natural [27]. With the prospect of a wearable prosthesis, cosmetically acceptable electrodes should be developed.

In summary, the preliminary results presented in this study are promising regarding the reanimation of paralyzed facial muscles with electrical stimulation. Traditionally, it has been believed that in a late recovered facial palsy the muscle function can no longer be regained after two or three years, and that a clinically spastic or nonfunctional muscle is scarred, shortened, or atrophied. Therefore, targeted reinnervation attempts with nerve transpositions or nerve grafts are usually performed at one-year post palsy at the latest. Our study shows that muscles that have been clinically dormant for more than 10 years can function with targeted stimulation, if a subclinical innervation exists.

V. Conclusion

Electrical stimulation has the potential for restoring the function of facial muscles even in facial nerve palsies that are several years old and where the muscle has no clinical functionality, provided the muscle is not completely denervated. Further studies are indicated to establish the efficacy, tolerability, and safety of the electrical stimulation, especially in a long-term use.

References

[1] S. E. Coulson, N.J. O'Dwyer, R. D. Adams, G. R. Croxson, "Expression of emotion and quality of life after facial nerve paralysis," *Otol Neurotol*, vol. 25, no. 6., pp. 1014-1019, 2004. doi: 10.1097/00129492-200411000-00026.

[2] S. K. Katusic, C. M. Beard, W.C. Wiederholt, E. J. Bergstralh, L. T. Kurland "Incidence, clinical features, and prognosis in Bell's palsy Rochester, Minnesota, 1968-1982," *Ann Neurol*, vol. 20, no. 5, pp. 622-627, 1986.doi: 10.1002/ana.410200511.

[3] E. Peitersen, "Bell's palsy: the spontaneous course of 2,500 peripheral facial nerve palsies of different etiologies," *Acta Otolaryngol*, vol. 122, no. 7, pp. 4-30, 2002. doi: 10.1080/000164802760370736.

[4] P.P. Devriese, T. Schumacher, A. Scheide, R.H. de Jongh, J. M. Houtkooper, "Incidence, prognosis and recovery of Bell's palsy. A survey of about 1000 patients (1974-1983)," *Clin Otolaryngol Allied Sci*, vol. 15, no. 1, pp. 15-27, 1990. doi: 10.1111/j.1365-2273.1990.tb00427.x.

[5] L. M. Pereira, K. Obara, J.M. Dias, M. O. Menacho, E. L. Lavado, J. R. Cardoso, "Facial exercise therapy for facial palsy: systematic review and meta-analysis," *Clin Rehabil*, vol. 25, no. 7, pp. 649-658, 2011. doi: 10.1177/0269215510395634.

[6] L. J. Teixeira, J. S. Valbusa, G. F. Prado, "Physical therapy for Bell's palsy (idiopathic facial paralysis)," *Cochrane Database Syst Rev*, no. 3, CD006283, 2018. doi: 10.1002/14651858.CD006283.pub3.

[7] O. B. Mehdizadeh, J. Diels, W. M. Whit, "Botulinum toxin in the treatment of facial paralysis," *Facial Plast Surg Clin N Am*, vol. 24, no. 1, pp. 11-20, 2016. doi: 10.1016/j.fsc.2015.09.008.

[8] E. I. Lee, K. A. Hurvitz, G. R. Evans, G. A. Wirth, "Cross-facial nerve graft: past and present," *J Plast Reconstr Aesthet Surg*, vol. 61, no. 3, pp. 250-256, 2008. doi: 10.1016/j.bjps.2007.05.016.

[9] W. Wang, C. Yang, Q. Li, W. Li, X. Yang, Y. X. Zhang, "Masseter-to-facial nerve transfer: a highly effective technique for facial reanimation after acoustic neuroma resection," *Ann Plast Surg*, vol. 1, pp. s63-s69, 2014. doi: 10.1097/SAP.0000000000000246.

[10] M. L. Cheney, M. J. McKenna, C. A. Megerian, R. G. Ojemann, "Early temporalis muscle transposition for the management of facial paralysis," *Laryngoscope*, vol. 105, no. 9, pp. 993-1000, 1995. doi: 10.1288/00005537-199509000-00021.

[11] T. M. Ylä-Kotola, M. S. Kauhanen, S. L. Asko-Seljavaara, "Facial reanimation by transplantation of a microneurovascular muscle: long-term follow-up," *Scand J Plast Reconstr Surg Hand Surg*, vol. 38, no. 5, pp. 272-276, 2004. doi: 10.1080/02844310410029138.

[12] D. L. Zealear, H. H. Dedo, "Control of paralysed axial muscles by electrical stimulation," *Acta Otolaryngol*, vol. 83, no. 1-6, pp. 514-527, 1977. doi: 10.3109/00016487709128880.

[13] M. Broniatowski, L. A. Ilyes, G. B. Jacobs, D. I. Rosenthal, A. J. Maniglia, H. M. Tucker, Y. Nosé, "Dynamic rehabilitation of the paralyzed face: I. Electronic control of reinnervated muscles from intact facial musculature in the rabbit," *Otolaryngol Head Neck Surg*, vol. 97, no 5, pp. 441-445, 1987. doi: 10.1177/019459988709700502.

[14] M. Broniatowski, L. A. Ilyes, G. Jacobs, Y. Nosé, H. M. Tucker HM, "Dynamic rehabilitation of the paralyzed face II. Electronic control of the reinnervated facial musculature from the contralateral side in the rabbit," *Otolaryngol Head Neck Surg*, vol. 101, no. 3, pp. 309-313, 1989. doi: 10.1177/019459988910100303.

[15] M. Broniatowski, S. Grundfest-Broniatowski, C. R. Davies, G. B. Jacobs, H. M. Tucker, Y. Nosé Y, "Dynamic rehabilitation of the paralyzed face: III: Balanced coupling of oral and ocular musculature from the intact side in the canine," *Otolaryngol Head Neck Surg*, vol. 105, no. 5, pp. 727-733, 1991. doi: 10.1177/019459989110500516.

[16] D. N. Tobey, D. Sutton, "Contralaterally elicited electrical stimulation of paralyzed facial muscles," *Otolaryngology*, vol. 86, no. 5, pp. 812-818, 1978. doi: 10.1177/019459987808600528.

[17] X. Yi, J. Jia, S. Deng, S. G. Shen, Q. Xie, G. Wang, "A blink restoration system with contralateral EMG triggered stimulation and real-time artifact blanking," *IEEE Trans Biomed Circuits Syst*, vol. 7, no. 2, pp. 140-148, 2013. doi: 10.1109/TBCAS.2013.2255051.

[18] M. A. Attiah, J. de Vries, A. G. Richardson, T. H. Lucas, "A rodent model of dynamic facial reanimation using functional electrical stimulation," *Front Neurosci*, 11:193, 2017. doi: 10.3389/fnins.2017.00193.

[19] A. Frigerio, P. Cavallari, "A closed-loop stimulation system supplemented with motoneurone dynamic sensitivity replicates natural eye blinks," *Otolaryngol Head Neck Surg*, vol. 146, no. 2, pp. 230-233, 2012. doi: 10.1177/0194599811427255.

[20] A. Frigerio, J. T. Heaton, P. Cavallari P, C. Knox, M. H. Hohman, T. A. Hadlock, "Electrical stimulation of eye blink in individuals with acute facial palsy: Progress toward a bionic blink," *Plast Reconstr Surg*, vol. 136, no. 4, pp. 515e-523e, 2015. doi: 10.1097/PRS.0000000000001639.

[21] M. Kurita, A. Takushima, Y. Muraoka, T. Shiraishi, K. Harii, "Feasibility of bionic reanimation of a paralyzed face: a preliminary study of functional electrical stimulation of a paralyzed facial muscle controlled with the electromyography of the contralateral healthy hemiface," *Plast Reconstr Surg*, vol. 126, no. 2, pp. 81e-83e, 2010. doi: 10.1097/PRS.0b013e3181df6ff3.

[22] B. G. Ross, G. Fradet, J. M. Nedzelski, "Development of a sensitive clinical facial grading system," *Otolaryngol Head Neck Surg*, vol. 114, no. 3, pp. 380-386, 1996. doi: 10.1016/S0194-59989670206-1.

[23] V. Rantanen, A. Vehkaoja, J. Verho, P. Veselý, J. Lylykangas, M. Ilves, E. Mäkelä, M. Rautiainen, V. Surakka, and J. Lekkala, "Prosthetic pacing device for unilateral facial paralysis," in *Proc. MEDICON*, Springer, Cham, 2016, pp. 647–652. doi: 10.1007/978-3-319-32703-7_126.

[24] A. J. Fridlund and J. T. Cacioppo, "Guidelines for human electromyographic research," *Psychophysiology*, vol. 23, no. 5, pp. 567–589, 1986. doi: 10.1111/psyp.1986.23.issue-5.

[25] M. B. Abelson, F. J. Holly, "A Tentative Mechanism for Inferior Punctate Keratopathy," *Am J Ophthalmol*, vol. 83, no. 6, pp. 866-869, 1977. doi: 10.1016/0002-9394(77)90916-3.

[26] V. Rantanen, M. Ilves, A. Vehkaoja, A. Kontunen, J. Lylykangas, E. Mäkelä, M. Rautiainen, V. Surakka, J. Lekkala, "A survey on the feasibility of surface EMG in facial pacing," in *Proc. EMBC*, IEEE, 2016, pp. 1688–1691. doi: 10.1109/EMBC.2016.7591040.

[27] S. W. Kim, E. S. Heller, M. H. Hohman, T. A. Hadlock, J. T. Heaton, "Detection and perceptual impact of side-to-side facial movement asymmetry," *JAMA Facial Plast Surg*, vol. 15, no. 6, pp. 411-416, 2013. doi: 10.1001/jamafacial.2013.1227.