Prosthetic Pacing Device for Unilateral Facial Paralysis

Prosthetic Pacing Device for Unilateral Facial Paralysis

V. Rantanen[1], A. Vehkaoja[1], J. Verho[1], P. Veselý[2], J. Lylykangas[3], M. Ilves[3], E. Mäkelä[4,5], M. Rautiainen[4], V. Surakka[3] and J. Lekkala[1]

[1] Department of Automation Science and Engineering, Tampere University of Technology, Tampere, Finland
[2] International Clinical Research Center, St. Anne's University Hospital Brno, Brno, Czech Republic
[3] Research Group for Emotions, Sociality, and Computing, School of Information Sciences, University of Tampere, Tampere, Finland.
[4] Department of Otorhinolaryngology, School of Medicine, University of Tampere, Tampere, Finland.
[5] Department of Clinical Neurophysiology, Medical Imaging Centre, Pirkanmaa Hospital District, Tampere, Finland.

Abstract—**Facial pacing ultimately aims at improving the quality of life of people suffering from unilateral facial paralysis. A device to study facial pacing is presented. It is able to measure electromyography signals from the healthy side of the face and simultaneously activate the corresponding muscles on the paralyzed side with electrical stimulation. Tests with healthy participants are ongoing and clinical studies are to be started soon. Four measurement and four stimulation channels of the device enable studying different electrode configurations and stimulation patterns for recognizing and reanimating symmetrical facial expressions in the future. Preliminary testing with ten healthy volunteers showed average partial activation threshold of 2.50 mA (± 0.47 mA) and 3.00 mA (± 0.67 mA) for *orbicularis oculi* and *orbicularis oris* muscles, respectively, and full eye closure threshold of 4.45 mA (± 0.69 mA).**

Keywords— **Electrical stimulation, facial pacing, facial paralysis.**

I. Introduction

Activation of muscles results from electric signals originated from the brain and transmitted by the nervous system to the muscles. Unilateral facial paralysis is a condition that causes the activations of facial muscles to become limited on one side of the face. A common reason for this is that the facial nerve fails to properly conduct the electric signals to the muscles. The lack of conductivity may be partial or total, and the underlying nerve damage may heal or be permanent. Facial paralysis causes problems with daily functions such as blinking, smiling, and eating. The patients may also suffer from concerns related to their appearance and feel being unable to fully express themselves. [1, 2]

The goal of this study is to introduce a research prototype for prosthetic, transcutaneous facial pacing. The pacing includes the electrical measurement and detection of facial muscle activations from the healthy side and the use of this information for electric stimulation of the muscles on the other side to produce symmetrical expressions. Principle of facial pacing is illustrated in Fig. 1.

The presented prototype is a device that integrates measurement, processing, and stimulation hardware into one table-top unit. The programmable device allows carrying out the required processing in real-time to study facial pacing for the reanimation for unilateral facial paralysis. While the real-time processing is not yet fully implemented, the performance and patient safety characteristics of the developed device are presented along with the preliminary results from facial muscle stimulation tests with human subjects.

II. Related work

The main focus in the development of prosthetic, transcutaneous pacing technologies for unilateral facial paralysis has been in reanimating the eye blink. This appears to be a result of two reasons. Firstly, blinking is required for the eye to stay moist and healthy despite the paralysis. Secondly, natural blinking is a simple movement that can be considered to have only two states and in most cases eyes are held closed for a fixed duration. Additionally, the transitions between these states do not show a lot of variation between repetitions. On the contrary, other facial muscle activations are more complex. They vary in the dynamics, duration, and intensity of the activations.

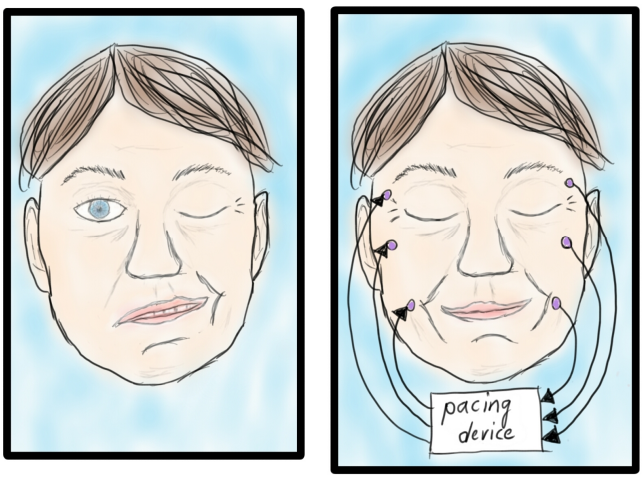

Fig 1. Principle of facial pacing for unilateral facial paralysis.

One way to detect the blinks is to use electromyography (EMG) measurements [3–7]. An infrared-based measurement has also been suggested as an alternative that overcomes problems the electrical measurement might have, such as cross-talk of the stimulation signal to the measurement channels [8]. The electric stimulation patterns commonly used for *orbicularis oculi* muscle to produce blinks are simple trains of square wave pulses [3, 9]. Stimulation patterns to produce natural blinks have also been verified by measuring the eyelid movements with gyroscopes [10]. The current state of the art focuses on detecting and stimulating normal blinking with fixed blink duration. Special cases such as the corneal reflex that would require more complex processing to determine its duration have not been studied. Further, there does not appear to be reports on transcutaneous stimulation to produce natural activations of other facial muscles than *orbicularis oculi*.

The stimulus waveforms can be chosen from a multitude of options, but it has been concluded that having several options only complicates the decision making and does not appear to provide advantage over having a fixed waveform with adjustable parameters [11]. Using balanced biphasic waveforms is recommended to avoid the adverse effects on the skin that monophasic ones may have [11–13]. The waveform of the stimulation most likely does not have an effect on the comfort of the stimulation as has been observed for larger muscles such as quadriceps [14].

Two common configurations for an electrical stimulator are constant voltage and constant current. The former delivers the chosen voltage waveform to the target and the current is dependent on the impedance of the target. The latter delivers the chosen current waveform, and adjusts the voltage to achieve it with the connected load impedance. Constant current configuration is more suitable for stimulation as the charge of the waveform is dependent on the current, and the amount of charge delivered to the muscle is the main factor causing its contraction [12]. Thus, more controlled stimulation results can be obtained by using constant current configuration.

The basic principle of activating muscles with electric stimulation is that the nerve is activated rather than the muscle [15]. Most earlier studies deal with situations where the facial nerve only has a lesion, and muscle activation can be induced via the nerve. The muscle can also be completely denervated, which is why the activation of muscles requires significantly more charge to be delivered to them [15, 16].

The pacing system needs to process measured signals in real time to translate the facial activity of the healthy sides to stimulation signals for activating the paralyzed one. The delay between the activations of the healthy and the paralyzed side should be minimized in order for the facial expression to be observed as synchronous. Human visual system operates discontinuously and periodically analyses visual stimuli [17]. Visual stimuli with discontinuities shorter than 25 ms were left undetected in a study with 10 participants [17]. The maximum delay in facial activity between the sides can be even longer and still be perceived as synchronous [18, 19]. Most people won't notice a delay of less than 33 ms between the movements of the two sides of the face when observing an eye blink, and longer delays stay unnoticed when the movement is eyebrow lift, lip depression or smile [18, 19].

Some studies have used a separate device connected to a PC for the pacing [3, 20]. Such configuration may have difficult-to-predict delays caused by the operating system and communication between the device and the computer. Other studies have reported the use of real-time processing with field-programmable gate arrays (FPGAs) and application specific integrated circuits (ASICs) to implement the pacing [21]. Such components have also been used in dedicated stimulator devices [22]. Modern microcontrollers and digital signal processors are capable for the low-latency processing tasks, and the selection of the hardware should be based on fulfilling the computational requirements. Work towards implantable pacing devices for reanimating eye blinks is also ongoing [23–25], and the work can be expected to continue to include other important facial movements.

III. Requirements for Electrical Safety

Medical device directive 93/42/EEC of European Commission defines essential requirements for devices used in the treatment of patients in EU [26]. Other regions of the world have similar regulations defined by respective authorities. In addition to actual medical devices, prototype devices under clinical investigation must fulfil the requirements.

The standards define a large amount of rules related to, for example, mechanical, thermal, ergonomic, and material safety, but the most important safety aspect that applies to electrical stimulators is the electrical safety. The related standard followed in European Union and in most other parts of the world is *IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Third edition)*, published by International Electrotechnical Commission in 2005.

IEC 60601-2-10 is a particular standard giving *Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*. Its main requirements for the operation of an electrical stimulator are the following:

- Stimulation current can be adjusted in small enough steps. The maximum allowed step size is 1 mA or 1 V

and the amplitude of the smallest stimulus available must be less than or equal to 2 % of the maximum.
- If the maximum output amplitude of a stimulator is greater than 10 mA or 10 V, its initial output amplitude after power-on, must be at zero level.
- The stimulator must notify its user if the output amplitude is greater 10 mA or 10 V, or if the energy of the stimulus pulse is greater than 10 mJ (to a 1 kΩ load.)
- The energy of a single stimulus pulse must not exceed 300 mJ when injected to a load of 500 Ω.
- The maximum stimulus current is 50 mA for frequencies up to 400 Hz and 100 mA for higher frequencies.

The listed items do not fully describe the electrical requirements but can be considered to include the most important safety aspects regarding stimulators and facial pacing devices.

IV. Device description

The pacing system includes the actual device that measures facial EMG signals, processes them in real time, and produces stimulation signals. A PC is used to adjust the stimulation parameters and to store the measurement data. The device and the PC communicate wirelessly through Wi-Fi connection. Fig. 2 shows a block diagram of the pacing system and Fig. 3 an image of the device.

A. Hardware

The device includes four EMG measurement amplifiers and four electrical muscle stimulator amplifiers. MyRIO device from National Instruments is used to provide the embedded functionality and communication capabilities for the device.

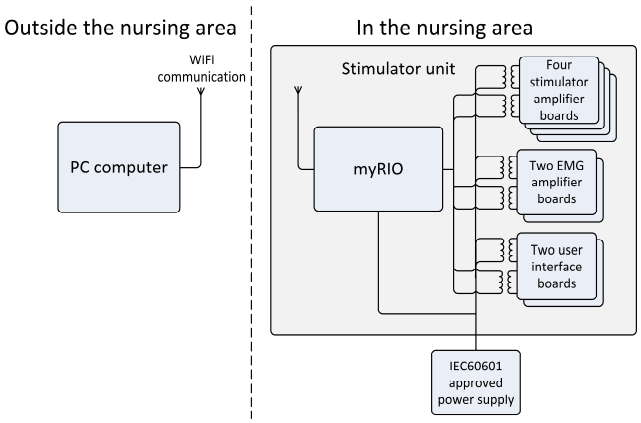

Fig 2. Block diagram of the stimulation system.

EMG measurement amplifiers

The EMG amplifiers have a nominal gain of 700, and the high-pass and low-pass cut-off frequencies are currently set to 0.55 Hz and 200 Hz.

The amplifiers are isolated. Each pair of channels has a common isolation. The measurement amplifiers are also protected against the output voltage of the stimulators. In order to recover quickly after stimulator-caused overloads, they also have an option for locking the internal filters during stimulation pulses.

12-bit analogue-to-digital converter of myRIO is used to sample the amplified EMG signals. The sampling rate of the EMG signals is adjustable up to at least 10 kHz per channel depending on other processing that is carried out in myRIO. High sampling rate is an advantage when trying to minimize the detection delay of muscle activations based on EMG.

Stimulator amplifiers

The stimulator amplifiers have a nominal maximum output current of ±48 mA that is achieved with varying load impedances by adjusting the output voltage up to ±100 V.

Each stimulation amplifier is isolated separately, which gives more freedom to their simultaneous use. Whenever an amplifier is not outputting a current, it is disconnected using a solid state relay in order to keep the leakage currents and noise at minimum level.

The digital-to-analogue converter of myRIO has a resolution of 12-bits, which is enough for converting the digital stimulus waveforms to analogue signals which are then fed to the stimulation amplifiers.

Fig 3. The pacing device. The unit of the scale is cm.

The pacing device is currently controlled mainly from the PC through graphical user interface but the device has also push-buttons for adjusting the amplitude of the stimulation signal and for triggering the stimulation burst. The device includes LEDs that inform the user when the stimulator current amplitude has been adjusted to more than 10 mA and when any of the channels is outputting the stimulus.

As written in chapter II the particular standard IEC60601-2-10 sets the current and energy limits for stimulators. In order to remain within limits also in single fault cases, the device has several safety features implemented in hardware. These are output current limitation, lead-off detection, and pulse duration monitoring. All input and output connections of the device also have 8 kV ESD protections.

The output current is limited in normal operation to ±48 mA, but in case of an error in the operation of myRIO that would result in much higher stimulator current; the current is limited to ±65 mA by the amplifier. The lead-off detector follows the output voltage of the amplifier that increases when the impedance of the stimulation target increases. In case the stimulation electrode contact is poor or the electrode is completely detached and the output voltage rises to ±115 V the stimulation amplifier is shut down. The delay of the shutdown depends on the stimulation current and is approximately 120 µs with high current values and increases to few hundred micro seconds when the current is low or the electrode is not completely detached.

Temperature monitoring and over temperature cut-off circuitry are also implemented. Additionally, an error signal is sent to myRIO by the amplifier if any of the safety features are triggered. The wall adapter is AFM60US24 manufactured by XP Power and has IEC60601 approval.

B. Software

The software of the pacing system consists of the user interface and software on the computer, and the software on the National Instruments (NI) myRIO embedded system. Both parts of the software are implemented with National Instruments' LabVIEW.

The software architecture is a state machine whose states provide the necessary functionality. The main states of the program are initialization and stimulation. The former includes routines for initial configuration and to wait for user input before making the stimulation and measurement possible. The latter includes parallel loops that communicate with each other to carry out the tasks required for the stimulation, measurement, and data logging on the computer.

PC-software and graphical user interface

The current software implementation requires the stimulation signal parameters to be manually set, and the stimulation to be manually triggered. In the future, the device will

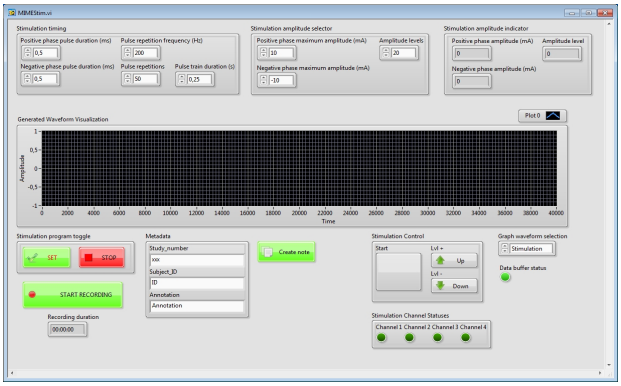

Fig. 4. The graphical user interface of the system.

be used to automatically determine the parameters and start the stimulation. In that case, most of the processing will be transferred to myRIO, and computer will only be used to set the limits within which the myRIO can alter the parameters for safe use. Currently, the stimulation parameters are adjusted through graphical user interface (GUI) that runs on the PC computer. The GUI is shown in Fig. 4.

Embedded Software

The embedded software of the pacing device resides completely on the FPGA circuit of myRIO. The FPGA provides good real-time signal processing performance for detecting the facial muscle activations and using them to determine and trigger the stimulation signals for facial pacing. Stimulation and measurement are performed in separate loops to minimize any risk of software error in the stimulation and to allow higher sampling rate to produce the stimulation signal than is necessary for EMG measurement.

C. Stimulation signal

Stimulation amplifiers and the generation of the stimulation signals are designed to be able to produce any type of stimulus waveforms. Based on the conclusions of [11], the user interface software is currently designed to produce trains of predetermined square wave pulse waveforms.

Following parameters of the stimulation signal can be adjusted: positive phase duration, negative phase duration, pulse repetition frequency, pulse train duration, amplitude of the positive phase, and amplitude of the negative phase. Currently balanced stimulus waveform is not forced, even if it is recommended to avoid electrochemical reactions in long-term use.

D. Electrodes

Commercial stimulation electrodes made from carbonized rubber are currently used with the device. The stimula-

tion electrodes are shaped to proper size for the muscle to be stimulated. Too large electrode area makes focusing the stimulation current to correct muscle difficult, and too small area increases the current density at the skin-electrode interface increasing the risk for electric skin irritation or even burns. IEC 60601-2-10 says that the risks must be properly managed when the current density exceeds 2 mA/cm^2. Electrode connectors were selected so that measurement and stimulation cables and electrodes cannot be accidentally confused. This is a common requirement for any electrical device.

E. Results of safety test and performance tests

Correct operation of all safety features of the pacing system was verified and electromagnetic compatibility test was performed to confirm that the RF emissions of the device stay within allowed limits. The most critical characteristics, such as leakage and auxiliary currents and correct operation of the safety features were verified also by an external testing laboratory before the device received an approval to be used in a clinical study.

The performance of the EMG and stimulation amplifiers was also tested. The noise level of the EMG measurements is approximately 1.7 μA_{rms} when 50 Hz powerline interference is not considered. The common-mode rejection ratio was measured to be 70 dB at 50 Hz and its harmonics.

The gain and bandwidth of the EMG amplifiers corresponded with the specified values. The bandwidth of the stimulation amplifiers was measured to be approximately 30 kHz at full ±48 mA current. The bandwidth increases to 60 kHz when the current is decreased to ±12 mA. With high current values the bandwidth is limited by the slew rate of the current generators, which was measured to be at least 3.5 mA/µs. The noise level of the stimulation amplifiers was measured to be 40 μA_{rms}. The switching delay of the solid-state relays of the stimulation amplifiers when turning them on is approximately 800 µs. The device itself therefore does not prevent activating the disabled side of the face with a delay less than 33 ms compared to the healthy one. Delay caused by the detection of muscle activation from EMG signals and the time the muscle takes to activate when stimulated can be expected to be much longer.

V. Preliminary Testing with Healthy Voluteers

Preliminary experiments were performed with ten healthy volunteer subjects. The study was accepted by the ethical committee of Pirkanmaa Hospital Disctrict (R15067). Informed consent was obtained from all individual participants included in the study.

Average age of the subjects was 43.6 years (33–63 yrs.) and three of them were female. The purpose of the experiments was to gain knowledge about stimulation current amplitudes required to activate the facial muscles: *orbicularis oculi* (to produce eye blink) and *orbicularis oris* (important for drinking and eating).

Stimulation electrodes were attached based on [27] on one side of the participants' face for stimulating one muscle at a time. Biphasic square wave pulses and the following stimulation waveform parameters were used: positive and negative phase duration 0.4 ms and pulse repetition frequency 250 Hz. Pulse train duration was 0.08 s for *orbicularis oculi* and 1.00 s for *orbicularis oris*. The amplitude was increased in 0.5 mA steps until a visible movement was observed by two experimenters to determine the movement threshold. Further, in the case of *orbicularis oculi*, the amplitude was increased until an eye closure (i.e. blink) was evoked. The results are presented in Fig. 5.

The required currents for *orbicularis oculi* were significantly smaller than what was found in [9] for people that had an acute facial palsy (movement threshold 4.0 mA ± 1.4 mA and blink threshold 7.2 mA ± 2.7 mA). This may be caused by the higher pulse repetition frequency in the presented study (250 Hz vs. 100-150 Hz in [9]). The electrode placement was also different: in the presented study electrodes were on the muscle but in [9] the electrodes were on top of the facial nerve branches of the muscle.

VI. Conclusions

A short description of a device intended for studying possibilities of facial pacing was presented. The pacing aims at regaining facial functions, such as eye blink and smiling, of people suffering from unilateral facial paralysis.

Next phase of the research is to carry out more experiments with a larger number of healthy volunteers and later with patients suffering from long-lasting unilateral facial paralysis or paresis. Future research questions include:

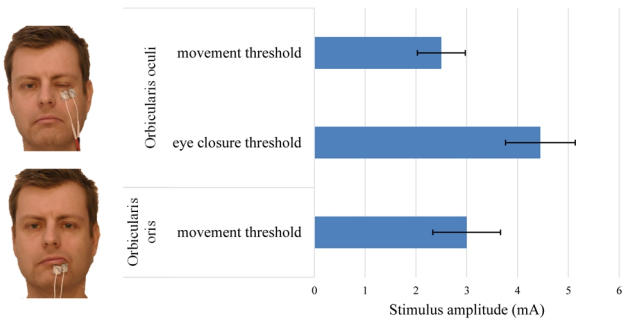

Fig. 5. The average amplitude thresholds (± standard deviation) for activating the facial muscles.

1. Comparing the required stimulation parameters between healthy and paralyzed subjects. Finding out how the duration of the paralysis affects the required stimuli.
2. Optimal positioning of the electrodes for each muscle, especially for permanently paralyzed patients with whom neural stimulation is not possible.
3. Differences between muscles in respect to responsiveness to stimuli.
4. Possibilities to target the stimulation current to certain muscle by using an electrode array instead of bipolar electrodes.

Acknowledgment

This research was funded by the Academy of Finland: decision numbers 278529, 276567, and 278312 and Competitive Funding to Strengthen University Research Profiles.

References

1. Rumsey N, Clarke A, White P, Wyn-Williams M, Garlick W (2004) Altered body image: appearance-related concerns of people with visible disfigurement. J Adv Nurs 48(5):443–453
2. Coulson SE, O'dwyer NJ, Adams RD, Croxson GR (2004) Expression of emotion and quality of life after facial nerve paralysis. Otol Neurotol 25(6):1014–1019 DOI 10.1097/00129492-200411000-00026
3. Frigerio A, Cavallari P (2012) A closed-loop stimulation system supplemented with motoneurone dynamic sensitivity replicates natural eye blinks. Otolaryngol Head Neck Surg 146(2):230–233 DOI 10.1177/0194599811427255
4. Sarasola Sanz A, Frigeni M, Cavallari P, Frigerio A, Pedrocchi A, Ferrante S (2013) Design of a Contralaterally Triggered Neuroprosthesis for the Paralyzed Eyelid: Surface EMG Mapping of the Orbicularis Oculi Muscle for Real-time Eye Blink Detection. Proceedings of the 18th IFESS Conference, San Sebastian, Spain, 2013, pp 49–52
5. Frigerio A, Brenna S, Cavallari P (2013) Surface electromyography recording of spontaneous eyeblinks: applications in neuroprosthetics. Otolaryngol Head Neck Surg 2013 148(2):209–214. DOI 10.1177/0194599812469352
6. Frigerio A, Cavallari P, Frigeni M, Pedrocchi A, Sarasola A, Ferrante S (2014) Surface electromyographic mapping of the orbicularis oculi muscle for real-time blink detection. JAMA Facial Plast Surg 16(5):335–342 DOI 10.1001/jamafacial.2014.283
7. Yi X, Jia J, Deng S et al. (2013) A Blink Restoration System With Contralateral EMG Triggered Stimulation and Real-Time Artifact Blanking, in Biomedical Circuits and Systems, IEEE Transactions on , 7(2):140–148 DOI: 10.1109/TBCAS.2013.2255051
8. Frigerio A, Hadlock TA, Murray EH, Heaton JT (2014) Infrared-based blink-detecting glasses for facial pacing: toward a bionic blink, JAMA Facial Plast Surg 16(3):211–218 DOI 10.1001/jamafacial.2014.1
9. Frigerio A, Heaton JT, Cavallari P, Knox C, Hohman MH, Hadlock TA (2015) Electrical Stimulation of Eye Blink in Individuals with Acute Facial Palsy: Progress toward a Bionic Blink. Plast Reconstr Surg 136(4):515e–523e DOI 10.1097/PRS.0000000000001639
10. Marcelli E, Cavallari P, Frigerio A, Colletti G, Biglioli F, Fanti R, Plicchi G, Cercenelli L (2013) A new gyro-based method for quantifying eyelid motion. Int J Artif Organs 36(3):195–202 DOI 10.5301/ijao.5000178
11. Kantor G, Alon G, Ho HS (1994) The effects of selected stimulus waveforms on pulse and phase characteristics at sensory and motor thresholds. Phys Ther 74(10):951–962.
12. Reed B (1997) The Physiology of Neuromuscular Electrical Stimulation. Pediatr Phys Ther 9:96–102
13. Johnson MI (2002) Transcutaneous Electrical Nerve Stimulation. In: Kitchen, S (ed.) 2002, Electrotherapy: Evidence Based Practice. 11 edn, Churchill Livingstone (Elsevier Health Sciences), London
14. Delitto A, Rose SJ. (1986) Comparative comfort of three waveforms used in electrically eliciting quadriceps femoris muscle contractions Phys Ther 66(11):1704–1707
15. Peckham PH, Knutson JS (2005) Functional electrical stimulation for neuromuscular applications. Annu Rev Biomed Eng 7:327–360
16. Shafshak TS (2006) The treatment of facial palsy from the point of view of physical and rehabilitation medicine. Eura Medicophys 42(1):41–47
17. Rodriguez MR, Mendez E (1998) Quantal processing of visual information in the brain. Neuroscience 84(3):641–644 DOI 10.1016/S0306-4522(97)00679-9
18. Kim SW, Heller ES, Hohman MH, Hadlock TA, Heaton JT (2013) Detection and perceptual impact of side-to-side facial movement asymmetry. JAMA Facial Plast Surg 15(6):411–416 DOI 10.1001/jamafacial.2013.1227
19. Hohman MH, Kim SW, Heller ES, Frigerio A, Heaton JT, Hadlock TA (2014) Determining the threshold for asymmetry detection in facial expressions. Laryngoscope 124(4):860–865. DOI 10.1002/lary.24331
20. Sachs NA, Chang EL, Weiland JD (2006) Contralateral EMG-triggered electrical stimulation of the eyelid. 11th Annual Conference of the International Functional Electrical Stimulation Society, Zao, Japan, 2006, pp 286–288
21. Chen K, Chen T-C, Cockerham K, Liu W (2009) Closed-loop eyelid reanimation system with real-time blink detection and electrochemical stimulation for facial nerve paralysis. IEEE International Symposium on Circuits and Systems (ISCAS),Taipei, Taiwan, 2009, pp 549–552 DOI 10.1109/ISCAS.2009.5117807
22. Meza-Cuevas MA, Gummenscheimer A, Schroeder D, and Krautschneider, WH (2012) Portable Neuromuscular Electrical Stimulator. ICT.OPEN, Rotterdam, Netherlands, 2012, 4 pages
23. Cao J, Lu B, Li L, Tong K, Wang W (2008) Implanted FNS system in closed-circle may become a way for the restoration of eye blinking and closing function for facial paralysis patient. Med Hypotheses 70(5):1068–1069 DOI 10.1016/j.mehy.2007.11.008
24. Cao J, Li L, Tong K, Lu B, Chu C, Li H, Yang B, Wang W (2009) FNS therapy for the functional restoration of the paralysed eyelid. J Plast Reconstr Aesthet Surg 62(12):e622–624 DOI 10.1016/j.bjps.2008.10.018
25. McDonnall D, Askin R, Smith C, Guillory KS (2013) Verification and validation of an electrode array for a blink prosthesis for facial paralysis patients. 6th International IEEE/EMBS Conference on Neural Engineering (NER), San Diego, CA, USA, 2013, pp 1167–1170 DOI 10.1109/NER.2013.6696146
26. Council directive 93/42/EEC (1993) Official Journal of the European Communities 12/07/1993:1-43
27. Fridlund, AJ, Cacioppo, JT (1986) Guidelines for human electromyographic research. Psychophysiology, 23(5):567–589

Author: Ville Rantanen
Institute: Tampere University of Technology
Street: Korkeakoulunkatu 3
City: Tampere
Country: Finland
Email: ville.rantanen@tut.fi

The authors declare that they have no conflict of interest.