European Archives of Oto-Rhino-Laryngology (2019) 276:3153–3158
https://doi.org/10.1007/s00405-019-05594-3

LARYNGOLOGY

Exploring stimulation patterns for electrical stimulation of the larynx using surface electrodes

Marlies Feiner[1] · C. Gerstenberger[1] · W. Mayr[2] · D. Hortobagyi[1] · M. Gugatschka[1]

Received: 8 March 2019 / Accepted: 2 August 2019 / Published online: 14 August 2019

Abstract

Purpose Functional electrical stimulation (FES) is considered an upcoming treatment modality for a number of laryngeal diseases. However, sound data are scarce when it comes to surface FES to treat voice disorders. Aim of the present study was to identify and differentiate suitable surface FES patterns to activate internal laryngeal muscles.

Methods Non-invasive FES was performed in a cohort of 17 elderly woman. Our user-customized electrical stimulation setup allowed us to deliver ten different stimulation patterns (rectangular and sawtooth shaped) with variation of frequency and amplitude. Stimulation outcome, i.e., vocal fold (VF) reaction, was continuously verified by transnasal endoscopy.

Results Responses to FES using ten different stimulation patterns varied inter-individually. None of the stimulation parameter sets could elicit a VF reaction in all participants.

Conclusion Based on our findings we conclude that individual fitting is necessary when defining surface stimulation parameters. To overcome limitations of previous studies, devices with freely programmable patterns are required as shown here. Endoscopic control of VF reaction is absolutely essential to ensure effectiveness of the delivered patterns.

Keywords Laryngeal functional electrical stimulation · Transcutaneous electrical stimulation · Voice rehabilitation · Presbyphonia · Dysphonia

Introduction

Functional electrical stimulation (FES) of laryngeal muscles is not new in the realm of laryngology and dates back to the 1960s [1]. The basic principle of FES is to stimulate a nerve with electric pulses to elicit a muscular reaction. FES in the field of laryngology aims to target the nerves supplying the laryngeal muscles, i.e., the recurrent laryngeal nerve (RLN) or the superior laryngeal nerve (SLN). The majority of works in the field deals with unilateral vocal fold paralysis (UVFP) [2, 3], some, like Ptok and Strack, suggesting that patients with a combined therapy (electrical surface stimulation plus voice training) delivered better results than voice therapy alone [4]. The same authors had concluded in an earlier paper on UVFP in 2005, that electrical stimulation proved no significant effects when compared to voice training alone [5]. Notably, only indirect parameters, maximum phonation time and vocal fold (VF) irregularity, were obtained as outcome variables as well as when setting up the stimulation parameters. Other authors explored the effects of transcutaneous FES on VF vibration irregularity [6], muscle tension dysphonia [7], or on healthy speakers' voices [8]. Also, in the field of swallowing disorders several studies were performed. Some of these also mentioned effects on VF movement [9–12]. In some studies though, effects of surface FES have not been visually verified [5, 8].

Furthermore, many of the published studies had only preliminary character and later publications on subsequent controlled clinical studies have been pursued so far. As a consequence, surface FES of the laryngeal muscles has not found wider acceptance and application in the therapeutic community and is often considered only as a concomitant therapy without verified effects. The lack of sound data may be due to limitations in the currently available stimulation devices for application in the neck region. Many of them are primarily designed for treatment of swallowing disorders and have limited spectrum of FES patterns, which may not

✉ Marlies Feiner
marlies.feiner@klinikum-graz.at

[1] Division of Phoniatrics, Medical University Graz, Auenbruggerplatz 26, 8036 Graz, Austria

[2] Center for Medical Physics and Biomedical Engineering, Medical University of Vienna, Graz, Austria

be sufficient for voice-related applications. It may also be due to safety reasons, as application at the neck region can lead to considerable discomfort and critical risks, e.g., co-stimulation of vagal nerve branches.

In the present study we sought to identify and differentiate suitable FES patterns in a controlled clinical setting to elicit VF reactions in a cohort of elderly women. By administering electrical stimulation in a clinical setup with computer-controlled generation of stimuli we were able to test novel pulse shapes, durations, frequencies and amplitudes. Permanent endoscopic visual control during all stimulation procedures allowed us to follow the movement responses in the glottal area.

Methods

Study design, participants, and data collection

This pilot study sought to create a basic understanding for a later trial dealing with presbyphonia. Between June 2017 and April 2018, we enrolled 20 German-speaking women, target age between 55 and 75 years, with subjective voice complaints for longer than 3 months. We included only participants who were in good general health. All volunteers with a prior history of tracheostomy or a neurological disease were excluded. No participant had a VF movement disorder as proven with laryngostroboscopy. All study procedures were approved by the ethics committee of the Medical University of Graz. Written informed consent was obtained from all individuals ahead of participation.

Test procedure

Prior to the test session a speech–language pathologist explained the study procedure to each participant and answered arising questions. Participants were instructed to give notice in case of perceiving any kind of discomfort, as a request for immediate stop of stimulation. The FES test sessions were paused whenever the participant asked for and limited to a maximum duration of 1 hour. Special care was taken to ensure a relaxed and comfortable sitting position throughout the testing period.

Stimuli were delivered using a pair of conductive rubber electrodes, 40 × 28 mm in size (Schwa-Medico Ltd., Gießen, Germany), placed bilaterally alongside the upper posterior margin of the thyroid cartilage (Fig. 1), with moistened sponge pads providing a low-resistance electrode–skin junction.

The electrodes were positioned and kept in place during the tests manually by a member of the research team. A computer-controlled electrical stimulation device (STMISOLA System, BIOPAC Systems, Inc., Goleta, CA, USA) was used

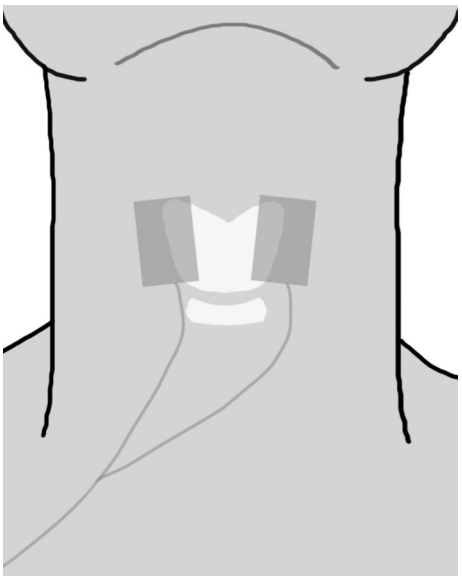

Fig. 1 Positioning of the electrodes

to deliver single pulses and trains of stimuli. This system can provide freely programmable pulse forms, in our study rectangular and sawtooth-shaped monophasic or biphasic pulses, with phase-durations down to a minimum of 0.01 ms delivered at freely adjustable frequencies. Current intensity can be set within a range from 0 to 100 mA. The endoscopic laryngeal video and applied electrical stimulation patterns were simultaneously recorded (PowerLab, Labchart, ADInstruments, New Zealand) throughout the session. Glottal reactions to FES could thereby be monitored in real time during the session as well as analyzed in detail afterwards.

Instruments and variables

Our extensive test protocol included ten FES patterns which were examined for their ability to elicit VF reactions (see Table 1). The protocol comprised both short rectangular (1 ms per phase) and longer sawtooth-shaped (10–500 ms per phase) charge-balanced biphasic pulses. The pulse forms used in this study are outlined in Fig. 2.

These were applied as single stimuli or as pulse trains with different frequencies (see Table 1). To familiarize participants with FES and to limit the examination time of transnasal flexible endoscopy, sensory thresholds for perception of current and maximum tolerable current intensities were determined using single stimuli in a quick procedure prior to the test session without endoscopy. Following this, FES was started using the ten stimulation parameter settings. Intensity of current was stepwise increased in increments of 1 mA up to the initially determined tolerable maximum or stopped at subjective discomfort. Reactions

Table 1 Evaluated parameter settings with distribution of positive reactions and current intensities

Stimulation parameter settings				Positive VF reactions		Current intensity at positive reaction (mA)		
Setting number	Pulse shape	Pulse duration (ms)	Frequency (Hz)	%	*n* (*N*)	*M*	SD	Range
PS 1	Rect	1	1	50	6 (12)	13	4	7–18
PS 2	Rect	1	50	33	4 (12)	12	5	6–17
PS 3	Rect	1	80	19	3 (16)	9	2	7–11
PS 4	Saw	10	1	29	5 (17)	10	4	6–16
PS 5	Saw	10	50	41	7 (17)	8	3	4–12
PS 6	Saw	50	1	46	6 (13)	7	2	3–9
PS 7	Saw	50	10	59	10 (17)	7	2	4–11
PS 8	Saw	100	1	13	2 (16)	9	3	7–11
PS 9	Saw	250	1	18	3 (17)	9	1	8–10
PS 10	Saw	500	1	29	5 (17)	8	4	3–12

VF vocal fold, *M* mean, *SD* standard deviation, *PS* parameter setting, *rect* rectangle pulse shape, *saw* sawtooth pulse shape

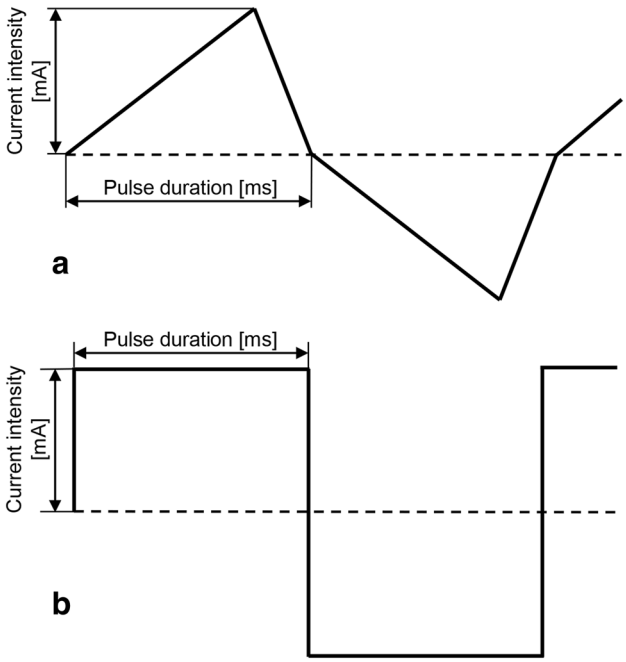

Fig. 2 Rectangular (**a**) and sawtooth- (**b**) shaped biphasic pulses

to FES in each stimulation setting were considered positive, when a clear visually observable VF twitch was seen by the examining otolaryngologist. Responses of the ventricular folds, swallowing and laryngeal descent by an activation of the pre-laryngeal muscles were not considered as positive reaction. Based on the observed glottal reaction, current intensity was increased to maximum individually accepted levels before switching to the next stimulation parameter setting.

Results

Participants

In all, we included 17 participants in this study. Three participants had to be excluded due to discomfort during the procedures. All participants were female, between 60 and 74 years old, with a mean age of 66 years (SD 4) and reported subjective voice complaint noticed for longer than 3 months before entry in the study.

Stimulation parameter settings

We evaluated ten FES parameter settings for their efficacy to elicit a VF twitch. Although some of them could induce positive reactions in more participants than others, none of the settings were effective for all participants. The comparison of positive reactions to different stimulation patterns demonstrated that none of the settings were clearly advantageous compared to the others. The most effective of the ten tested parameter settings could elicit VF twitches in ten out of 17 participants. A detailed overview of the results is provided in Table 1.

In one participant neither rectangular nor sawtooth-shaped pulses induced a visible VF reaction. Intensity levels for evoking positive VF reactions varied within the parameter settings and also intra-individually. During the familiarization procedure participants reported at which intensity level they perceived the current (sensory threshold) for the six single stimuli parameter settings. We compared these sensory thresholds with the current intensities required for a positive VF reaction for stimulation with the same parameter settings (shown in Table 1). Participants reported a sensation of current at intensities on average 38% (SD 18) below the

current intensities necessary for an endoscopically visible positive VF reaction.

Discussion

FES is considered an upcoming treatment modality for a variety of laryngeal diseases such as VF paralysis, spasmodic dysphonia or presbyphonia [13–15]. However, when it comes to surface FES there is a lack of sound data. In addition to the factors mentioned in the introduction, this is also due to the complex neuroanatomy and electrophysiology of the human larynx that is still not fully understood to date [16]. This pilot study served as a first step to investigate the possibility of eliciting VF reactions through surface FES with various stimulation parameter settings comparing their ability to elicit VF twitches. However, taking into account previous trials [2, 7] and the feasibility character of this study, our sample size of 17 patients needs to be considered at the upper range of available studies. A strength of this trial was the use of a freely programmable stimulation device, enabling us to investigate and evaluate a wide range of different stimulation patterns. Commercially available stimulation devices used in previous studies allow only the application of limited stimulation patterns [8, 17].

Many studies in the field of 'FES and voice' used the VitalStim® device with the equal called setting (Chattanooga Group, Chattanooga, TN, USA) [8, 11, 17–19]. This setting consists of rectangular shaped biphasic pulses with a duration of 0.3 ms per phase applied with 80 Hz. Parameter setting three in this study is based on similar rectangular shaped pulses applied also with 80 Hz, but with a longer pulse duration of 1 ms. The applied current intensities in the studies using VitalStim® are comparable to setting number three in our study with a mean of 9 mA. Interestingly, we found this specific pattern to be less effective in our study if compared to rectangular shaped pulses at lower frequencies or most sawtooth-shaped pulses. The shorter pulse durations of 0.1 ms per phase of the rectangular shaped pulses applied with 100 Hz by Seifpanahi et al. [20] and their higher applied current intensities can to some extent, be compared to our tested parameter setting three with 1 ms, as it is known that shortening of the pulse width in the subrheobase range can be effectively compensated by increase of amplitude and leads to comparable motor unit recruitment. Ptok and Strack used another device with so-called exponential currents with a considerable longer pulse duration of 240 ms [4]. Comparison to parameter setting number nine in our protocol (sawtooth shaped pulses with 250 ms pulse duration, frequency of 1 Hz) is only possible, if 240 ms pulse duration was also indicated per phase. Also, comparison of the used current intensities is not possible, since they were not reported in their study. As a matter of fact, the most effective of our evaluated stimulation patterns (parameter setting number seven, sawtooth pulse shape, 50 ms pulse duration, 10 Hz) was not reported in any studies on FES and voice up to now. This points out again the advantage of using a device with customizable parameter settings for finding an optimized parameter set for each individual.

It has been reported before, that voice changes but also sensory perception of FES vary individually [8]. We can clearly confirm this and must add that not in all individuals of our cohort VF responses could be elicited with surface FES within a tolerated intensity range, which points out again the necessity for visual validation. Discomfort during FES is correlated with current intensity, so higher intensities may result in higher levels of discomfort. On the contrary, current intensity must be high enough to elicit contraction of the targeted muscles. Besides staying within the individually tolerated intensity ranges, other strategies for reducing discomfort were adopted in our test protocol. Longer pulse durations allow the same charge at lower impulse intensity. Sawtooth pulse shapes with their slow rising of the intensity of each single impulse allow the pain fibres in the skin and nerve and the healthy muscle fibres directly below the electrode to accommodate.

Another major challenge is the deep location of the target nerve. The applied stimuli pass a number of anatomical structures namely the platysma, the omohyoid, sternohyoid, and thyrohyoid muscles [21] and may elicit undesired co-contractions. To minimize the side effects of co-contractions, individual positioning of the electrodes and suitable stimulation parameter setting are key factors. So far, there is no standard surface electrode setup for general application in sight, previous studies used different strategies with various electrode numbers, sizes and positions [4, 17, 20]. A study by Humbert et al. [17] tested ten different electrode placements in a remarkably high number of volunteers ($n=27$) with minimal changes of VF movement in only two positions. LaGorio et al. [18] aimed to stimulate the SLN with one pair of electrodes while targeting the cricothyroid muscles with another pair in a combined approach. Their smaller sample of seven participants with VF bowing showed significant improvement of maximum phonation time after 15 voice therapy sessions paired with concurrent FES. Notably, this is the only study so far which addresses aged voice issues.

In a sample of 32 healthy participants Seifpanahi et al. placed the electrodes at the thyrohyoid membrane above the internal branch of the superior laryngeal nerve (iSLN) entrance to the larynx and one passive electrode at the dorsal neck and described a significant adduction of the VF as measured by the angle at the anterior commissure [20]. They reported significant changes of F_0 in a previous trial [22] which is in contrast to other studies [8, 17]. They explained their positive findings by a selective stimulation

of the iSLN. However, taking into account the size of the stimulation electrode, the anatomy and course of the SLN seem questionable, if a selective stimulation of the iSLN is technically feasible. Taken in consideration the relative uncertainty of surface application of FES due to anatomical variations (low larynx position, short neck, pronounced subcutaneous fat tissue, etc.) we chose an electrode design and location to target a broader anatomical area. The feasibility of our approach was confirmed by visual endoscopic control. The use of two electrodes instead of three or four was regarded favorable for a planned later self-administered home training study.

Specific consideration needs to be taken into account when it comes to seniors. Humbert et al. suggested to not generalize their results to populations over 60 years, as muscle denervation might lead to diminished VF movement elicited through FES [17]. Age-related partial laryngeal denervation and alterations of the neuro-muscular end plate are very likely [23], which might demand for long pulse durations. In the extreme case of iatrogenic UVFP (with a high rate of synkinetic reinnervation) exponential currents with a pulse duration as long as 240 ms were applied to selectively stimulate a potentially denervated muscle [4] due to the reduced accommodation ability. To verify this assumption, we included a set of longer sawtooth pulse durations in our test protocol. Interestingly, these did not reveal better results compared to the shorter ones.

Conclusion

Our study examined a wide range of electrical stimulation patterns applied via surface electrodes under permanent visual control in a cohort of elderly women. We could not identify one ideal parameter setting that elicited VF reactions in each subject, thus individual fitting is necessary when it comes to clinical trials. When using surface FES in a therapeutic manner, a device with customizable parameter settings is mandatory.

Funding This work was supported by the Austrian Research Promotion Agency (Österreichische Forschungsförderungsgesellschaft), fund no. 848458.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the ethics committee of the Medical University of Graz and with the 1964 Helsinki Declaration and its later amendments.

References

1. Böhme G (1965) Die Effektivität der Elektrotherapie bei laryngealen Erkrankungen im strobsokopischen Bild. Z Laryngol Rhinol Otol 44:481–488
2. Garcia Perez A, Hernández López X, Valadez Jiménez VM et al (2014) Synchronous electrical stimulation of laryngeal muscles: an alternative for enhancing recovery of unilateral recurrent laryngeal nerve paralysis. J Voice 28:524.e1–524.e7. https://doi.org/10.1016/j.jvoice.2014.01.004
3. Zealear DL, Dedo HH (1977) Control of paralyzed axial muscles by electrical stimulation. Trans Sect Otolaryngol Am Acad Ophthalmol Otolaryngol 84:310
4. Ptok M, Strack D (2008) Electrical stimulation-supported voice exercises are superior to voice exercise therapy alone in patients with unilateral recurrent laryngeal nerve paresis: results from a prospective, randomized clinical trial. Muscle Nerve 38:1005–1011. https://doi.org/10.1002/mus.21063
5. Ptok M, Strack D (2005) Voice exercise therapy versus electrostimulation therapy in patients with unilateral vocal fold paralysis. HNO 53:1092–1097. https://doi.org/10.1007/s00106-004-1216-8
6. Ptok M, Strack D (2009) Therapeutic effects of electrical stimulation therapy on vocal fold vibration irregularity. HNO 57:1157–1162. https://doi.org/10.1007/s00106-008-1828-5
7. Gorham-Rowan M, Morris R (2016) Exploring the effect of laryngeal neuromuscular electrical stimulation on voice. J Laryngol Otol 130:1022–1032. https://doi.org/10.1017/S0022215116009038
8. Fowler LP, Gorham-Rowan M, Hapner ER (2011) An exploratory study of voice change associated with healthy speakers after transcutaneous electrical stimulation to laryngeal muscles. J Voice 25:54–61. https://doi.org/10.1016/j.jvoice.2009.07.006
9. Ludlow CL, Humbert I, Saxon K et al (2007) Effects of surface electrical stimulation both at rest and during swallowing in chronic pharyngeal Dysphagia. Dysphagia 22:1–10. https://doi.org/10.1007/s00455-006-9029-4
10. Carnaby-Mann GD, Crary MA (2007) Examining the evidence on neuromuscular electrical stimulation for swallowing: a meta-analysis. Arch Otolaryngol Head Neck Surg 133:564–571. https://doi.org/10.1001/archotol.133.6.564
11. Humbert IA, Poletto CJ, Saxon KG et al (2006) The effect of surface electrical stimulation on hyolaryngeal movement in normal individuals at rest and during swallowing. J Appl Physiol 101:1657–1663. https://doi.org/10.1152/japplphysiol.00348.2006
12. Miller S, Jungheim M, Kühn D, Ptok M (2013) Electrical stimulation in treatment of pharyngolaryngeal dysfunctions. Folia Phoniatr Logop 65:154–168. https://doi.org/10.1159/000355562
13. Pitman MJ (2014) Treatment of spasmodic dysphonia with a neuromodulating electrical implant. Laryngoscope 124:2537–2543. https://doi.org/10.1002/lary.24749
14. Mueller AH, Hagen R, Foerster G et al (2016) Laryngeal pacing via an implantable stimulator for the rehabilitation of subjects suffering from bilateral vocal fold paralysis: a prospective first-in-human study. Laryngoscope 126:1810–1816. https://doi.org/10.1002/lary.25792
15. Karbiener M, Jarvis JC, Perkins JD et al (2016) Reversing age related changes of the laryngeal muscles by chronic electrostimulation of the recurrent laryngeal nerve. PLoS ONE 11:e0167367. https://doi.org/10.1371/journal.pone.0167367
16. Martin-Oviedo C, Maranillo E, Lowy-Benoliel A et al (2011) Functional role of human laryngeal nerve connections. Laryngoscope 121:2338–2343. https://doi.org/10.1002/lary.22340

17. Humbert IA, Poletto CJ, Saxon KG et al (2008) The effect of surface electrical stimulation on vocal fold position. Laryngoscope 118:14–19. https://doi.org/10.1097/MLG.0b013e318155a47d
18. Lagorio LA, Carnaby-Mann GD, Crary MA (2010) Treatment of vocal fold bowing using neuromuscular electrical stimulation. Arch Otolaryngol Head Neck Surg 136:398–403. https://doi.org/10.1001/archoto.2010.33
19. Law T, Lee KY-S, Wong RWM et al (2017) Effects of electrical stimulation on vocal functions in patients with nasopharyngeal carcinoma. Laryngoscope 127:1119–1124. https://doi.org/10.1002/lary.26243
20. Seifpanahi S, Izadi F, Jamshidi A-A, Shirmohammadi N (2017) Effects of transcutaneous electrical stimulation on vocal folds adduction. Eur Arch Oto-rhino-laryngol 274:3423–3428. https://doi.org/10.1007/s00405-017-4619-3
21. Ludlow CL (2010) Electrical neuromuscular stimulation in dysphagia: current status. Curr Opin Otolaryngol Head Neck Surg 18:159–164. https://doi.org/10.1097/MOO.0b013e3283395dec
22. Seifpanahi S, Izadi F, Jamshidi A-A et al (2016) Role of the internal superior laryngeal nerve in the motor responses of vocal cords and the related voice acoustic changes. Iran J Med Sci 41:374–381
23. Takeda N, Thomas GR, Ludlow CL (2000) Aging effects on motor units in the human thyroarytenoid muscle. Laryngoscope 110:1018–1025. https://doi.org/10.1097/00005537-200006000-00025